Technology Assessment

Technology Assessment Program

Negative Pressure Wound Therapy Devices

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Negative Pressure Wound Therapy Devices

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ECRI Institute

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This report is based on research conducted by the ECRI Institute under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10063). The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. No statement in this article should be construed as an official position of the Agency for Healthcare Research and Quality or of the U.S. Department of Health and Human Services.

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None of the investigators has any affiliations or financial involvement related to the material presented in this report.

Peer Reviewers

We wish to acknowledge individuals listed below for their review of this report. This report has been reviewed in draft form by individuals chosen for their expertise and diverse perspectives. The purpose of the review was to provide candid, objective, and critical comments for consideration by the EPC in preparation of the final report. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers.

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Negative Pressure Wound Therapy Devices:

List of devices names*

ActiV.A.C.® Therapy Unit
Engenex® Advanced NPWT System
Exusdex® wound drainage pump
EZCARE Negative Pressure Wound Therapy
InfoV.A.C.® Therapy Unit
Invia Liberty Wound Therapy
Invia Vario 18 c/i Wound Therapy
Mini V.A.C.®
NPD 1000 Negative Pressure Wound Therapy System
Prodigy™ NPWT System (PMS-800 and PMS-800V)
PRO-I™
PRO-II™
PRO-III™
RENASYS™ EZ Negative Pressure Wound Therapy
SVEDMAN™ and SVED™ Wound Treatment Systems
V.A.C.® ATS™
V.A.C.® Freedom™
V.A.C.® Instill Device
V.A.C.® Therapy Unit
V.A.C.® (Vacuum Assisted Closure™)
V1STA Negative Pressure Wound Therapy
Venturi™ Negative Pressure Wound Therapy

* These devices have U.S. Food and Drug Administration 510(k) clearance for marketing in the United States.

November 12, 2009

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Executive Summary

The Center for Medicare Management at the Centers for Medicare and Medicaid Services (CMS) requested this report from The Technology Assessment Program (TAP) at the Agency for Healthcare Research and Quality (AHRQ). AHRQ assigned this report to the following Evidence-based Practice Center: ECRI Institute EPC (Contract Number: 290-2007-10063).

Section 154 (c) (3) of the Medicare Improvements for Patient and Providers Act (MIPPA) of 2008 calls for the Secretary of Health and Human Services to perform an evaluation of the Healthcare Common Procedure Coding System (HCPCS) coding decisions for Negative Pressure Wound Therapy (NPWT) devices. Specifically, the evaluation of existing HCPCS codes for NPWT should:

- ensure accurate reporting and billing for items and services under such codes; and
- use an existing process for the consideration of coding changes and consider all relevant studies and information furnished pursuant to such processes.

The HCPCS Level II coding system is a comprehensive, standardized system that classifies similar products that are medical in nature into categories for the purpose of efficient claims processing. Products are classified based on similarities in function and whether the products exhibit significant therapeutic distinctions from other products. Currently, all NPWT devices are classified into the same HCPCS codes. The Healthcare Common Procedures Coding System (HCPCS) code E2402 applies to the pump (NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE) and HCPCS code A6550 applies to the dressing sets (WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES). HCPCS code A7000 applies to the canister that goes with the pump.

Negative pressure wound therapy (NPWT) applies a localized vacuum to draw the edges of the wound together while providing a moist environment conducive to rapid wound healing. The development of negative pressure techniques for wound healing is based on two theories: (1) the removal of excess interstitial fluid decreases edema and concentrations of inhibitory factors, and increases local blood flow; and (2) stretching and deformation of the tissue by the negative pressure is believed to disturb the extracellular matrix and introduce biochemical responses that promote wound healing.

NPWT systems include a vacuum pump, drainage tubing, and a dressing set. The pump may be stationary or portable, may rely on AC or battery power, allows for regulation of the suction strength, has alarms to indicate loss of suction, and has a replaceable collection canister. The dressing sets may contain either foam or gauze dressing to be placed in the wound and an adhesive film drape for sealing the wound. The drainage tubes come in a variety of configurations depending on the dressings used or wound being treated. NPWT Systems currently available in the U.S. are listed in Table 1.

Table 1. Negative Pressure Wound Therapy Devices Marketed in the U.S.

Manufacturer	Trade or Brand Names of Negative Pressure Wound Therapy Devices
Blue Sky Medical Group 6965 El Camino Real, Suite 105-602 La Costa, CA 92009 (Blue Sky Medical Group is now owned by Smith & Nephew, Inc.)	V1STA Negative Wound Therapy (portable unit) EZCARE Negative Wound Therapy (stationary unit)
Boehringer Wound Systems, LLC P.O. Box 910 Norristown, PA 19404	Engenex® Advanced NPWT System (Boehringer Laboratory Suction Pump System) ConvaTec (Skillman, NJ) markets and distributes the Engenex® NPWT system
Innovative Therapies Inc. 10948 Beaver Dam Rd, Suite C Hunt Valley, MD 21030	SVEDMAN™ and SVED™ Wound Treatment Systems
Kalypto Medical 6393 Oakgreen Ave. Hastings, MN 55033 (Iasis Medical, Inc.)	NPD 1000 Negative Pressure Wound Therapy System (no manufacturer information currently available from a Web site)
KCI, USA Inc. (Kinetic Concepts, Inc.) 8023 Vantage Dr. San Antonio, TX 78230	InfoV.A.C.® Therapy Unit (stationary unit) ActiV.A.C.® Therapy Unit (portable unit) V.A.C.® Freedom™ V.A.C.® ATS™ V.A.C.® Instill System (delivery of topical solutions)
Medela AG Medical Equipment Laettichstrasse 4b 6341 Baar Switzerland; Medela Healthcare Medela, Inc. 1101 Corporate Drive McHenry, IL 60050	Invia Liberty Wound Therapy (portable) Invia Vario 18 c/i Wound Therapy (stationary, mobile with battery)
MediTop BV Vlasakker 22 3417 XT Montfoort The Netherlands; The Medical Company P.O. Box 2116 3800 CC Amersfoort The Netherlands	Exusdex® wound drainage pump
Premco Medical Systems, Inc. 699 Main Street New Rochelle, NY 10801 USA	Prodigy™ NPWT System (PMS-800 and PMS-800V)
Prospera 2831 Bledsoe Street Fort Worth, TX 76107 (Prospera Technologies LLC owns the Prospera NPWT systems and brand)	PRO-I™ (stationary and portable) PRO-II™ (portable) PRO-III™(stationary and portable)

Manufacturer	Trade or Brand Names of Negative Pressure Wound Therapy Devices
Smith & Nephew, Inc. 970 Lake Carillon Drive, Suite 110 St. Petersburg, FL 33716	V1STA Negative Pressure Wound Therapy (portable unit) EZCARE Negative Pressure Wound Therapy (stationary unit) RENASYS™ EZ Negative Pressure Wound Therapy
Talley Group Ltd. Premier Way Abbey Park Romsey, Hants SO 51 9 DQ England; U.S. Talley Medical 4740 Ladestone Dr. Williamston, MI 48895	Venturi™ Negative Pressure Wound Therapy (portable or stationary)

Methods of the Review

The Centers for Medicare and Medicaid Services (CMS) have partnered with the Agency for Healthcare Research and Quality (AHRQ) to commission a review of NPWT devices as required by the MIPPA legislation. AHRQ contracted with one of its Evidence-based Practice Centers (EPCs), the ECRI Institute EPC, to perform the review. The purpose of this review is to provide information to CMS to consider along with other inputs in evaluating HCPCS coding for NPWT devices. CMS will use this review in its assessment of whether existing HCPCS codes adequately reflect the range of NPWT devices on the market today.

The process of systematic review as practiced by the EPC Program follows specific prescribed steps:

1. The investigators start with formulated "key" questions. These questions test hypotheses and are structured using the "PICO" framework: patients, intervention of interest, comparator, and outcomes. EPC are encouraged to focus on outcomes that are relevant and important to patients (patient-oriented outcomes). The framework is depicted visually in the "analytic framework" that the EPC program uses to show the relationship between the key questions and the outcomes used to address these questions. (See, for example, Figure 1.)
2. Inclusion and exclusion criteria for studies to be used in the review are determined based on the specific questions to be addressed. Criteria may vary for each question in the review.
3. Next, an objective and comprehensive search of the medical literature and "gray literature," (i.e., reports, monographs and studies produced by government agencies, educational facilities and corporations that do not appear in the peer-reviewed literature) is conducted. The reference lists of included studies are examined for any studies not identified by electronic searches.
4. Studies are compared to the inclusion criteria developed prior to examining the evidence, and those included in the review are then critically appraised, noting features of the design and conduct of the studies that create potential for bias. Bias, in this context, is a study feature that could impact whether the treatment being studied is responsible for the outcomes observed. Studies with a low potential for bias are typically described as being of "high quality," whereas those with high potential for bias are described as being of "low" or "poor" quality, and those of moderate quality as having intermediate potential for bias. The degree to which a study protects against bias is referred to as "internal validity." Following this appraisal, data are extracted from the included studies and analyzed or summarized as appropriate.

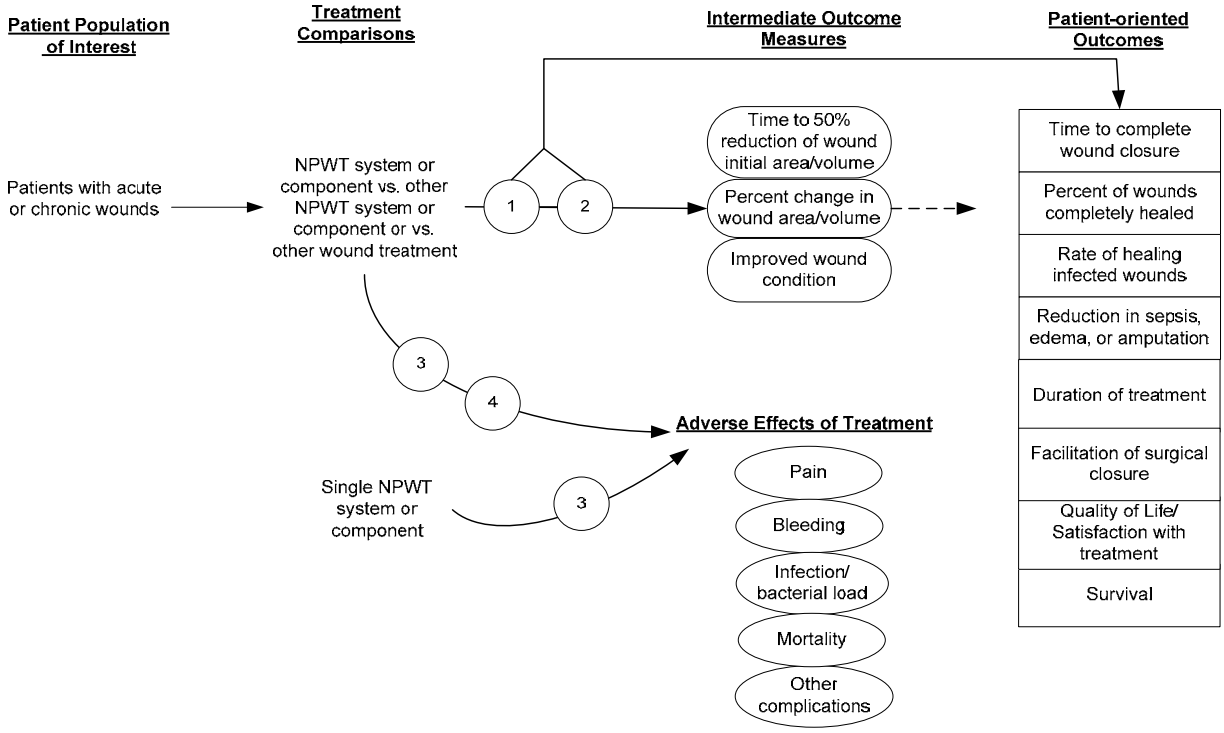
After receiving the work assignment for this review in December, 2008, we developed the following Key Questions:

1. *Does any single NPWT system have a significant therapeutic distinction in terms of wound healing outcomes compared to any other NPWT system for the treatment of acute or chronic wounds?*

2. *Does any component of a NPWT system have a significant therapeutic distinction in terms of wound healing outcomes compared to any other similar component of a NPWT system for the treatment of acute or chronic wounds?*
3. *What are the reported occurrences of pain, bleeding, infection, other complications, and mortality for NPWT systems?*
4. *Do patients being treated with one NPWT system have a significant therapeutic distinction in terms of less pain, bleeding, infection, other complications, or mortality than other NPWT systems?*

For the purpose of addressing these Key Questions, we considered any NPWT system or component commercially marketed within the past 20 years. In-house developed, noncommercial devices (what might be considered "home-made" negative pressure devices) were excluded. In addressing the questions, we sought the specific outcomes depicted in the analytic framework in Figure 1. According to guidance provided by the U.S. Food and Drug Administration (FDA), we considered improved wound healing and improved wound care to be the most important clinical outcomes associated with the use of a wound-treatment device. The most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete healing (partial healing for facilitation of surgical wound closure). Improvements in wound care can potentially reduce the occurrence of conditions such as infection that can interfere with proper wound healing. Thus, measuring the impact of NPWT on the occurrence or healing of infections, as well as its impact on the incidence of sepsis, edema, or amputation is important. In addition to these outcomes, we consider other outcomes important to patients, such as quality of life, satisfaction with treatment, duration of treatment, and survival, in keeping with the methods guidance for the EPC Program.

Figure 1. Analytic Framework



Note:

- In keeping with guidance provided by the FDA, in this report we considered improved wound healing and improved wound care to be the most important clinical outcomes. The most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete healing (particularly when NPWT is used to prepare a wound for surgical closure). Please note: process indicators such as improved compliance, convenience and personal preference (and patient oriented outcomes such as quality of life or satisfaction with treatment) are considered by CMS to be significant distinctions only to the extent that they result in demonstrably improved clinical outcomes.
- Improved wound condition as presented in the Analytic Framework is defined as a reduction in wound exudate and infectious materials; the promotion of granulation tissue formation and perfusion; an improvement in graft appearance; a reduction in odor; and a greater rate of epithelialization.

Inclusion and exclusion criteria were then developed to specify the types of studies appropriate for addressing each of these Key Questions. These criteria are explained in detail in the Methods section of this report, but are briefly described here. To address the key questions that consider whether one NPWT system or its components has a significant therapeutic distinction compared to another NPWT system or its components, we included any controlled study that used a NPWT system for the treatment of chronic or acute wounds. (Components of a NPWT system include the pump, the tubing, the dressing kits, and the services provided as part of the NPWT system.) Questions 1, 2 and 4 require comparative studies of different NPWT systems or components. For Key Question 2, studies were required that compared different dressing sets, tubing, or pumps while maintaining identical components for the other parts of an NPWT system. In other words, both groups in the study would need to be receiving NPWT.

In keeping with the methods of the EPC Program, we planned to perform “adjusted indirect comparisons” if no studies directly comparing NPWT systems or components were

available.(1,2) Appropriate indirect comparisons can only be performed when randomized controlled trials (RCTs) have compared the interventions of interest to a third, common comparator. In adjusted indirect comparisons, the comparison of the intervention of interest (i.e., different NPWT systems) is adjusted by the results of their direct comparison with a common control group (e.g., standard wound therapy).(3) The validity of an adjusted indirect comparison depends on the internal validity and similarity of the included trials. Thus, to be considered for inclusion in an indirect comparison, studies would be similar in terms of quality, similar for factors related to applicability (population, interventions, and settings), and similar in measurement of outcomes including the incidence of adverse events.(3-6) The use of nonrandomized studies for indirect comparisons is not considered scientifically valid because of the many confounding variables that cannot be accounted for in such comparisons.(7) Even when RCTs are available for indirect comparisons, the conclusions must be framed cautiously because of the difficulty in assuring that the trial features are truly similar enough.

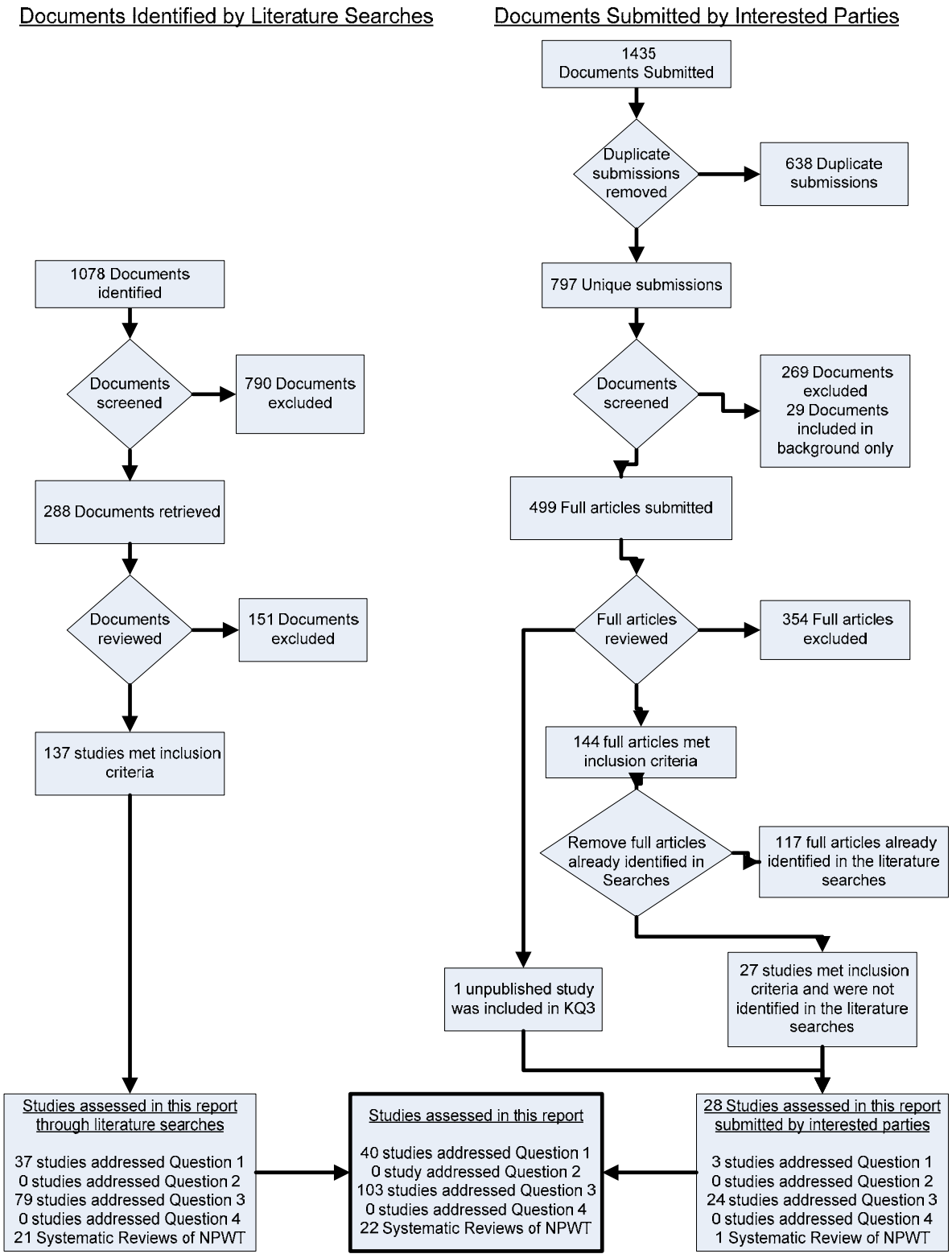
To address Key Question 3 regarding reported occurrences of adverse events for NPWT, we included case series and uncontrolled trials.

Searches were undertaken of 13 electronic bibliographic databases from 1950 to the present for published primary clinical studies and any secondary publications. To supplement the electronic searches, we manually reviewed the reference lists of studies meeting inclusion criteria. In addition, we searched for ongoing clinical trials using ClinicalTrials.gov and Controlledtrials.com. In the interest of being certain that our searches identified all relevant studies, we invited manufacturers, professional organizations, the FDA and the Centers for Medicare & Medicaid Services (CMS) to submit the following:

- A current product label (requested of industry stakeholders only)
- Published randomized controlled trials, observational studies, or other compelling clinical evidence examining the use of NPWT devices to impact relevant clinical outcomes
- Unpublished randomized controlled trials, observational studies, or other compelling clinical evidence examining the use of NPWT devices to impact relevant clinical outcomes.

The materials received were then assessed against the a priori inclusion criteria for each Key Question. Over 1,400 individual items were submitted by interested stakeholders for possible inclusion in the report. All items were reviewed for their relevance to the key questions. None of the submissions were studies directly comparing different NPWT devices or systems. We identified one additional systematic review(8), three comparison studies evaluating NPWT vs. a comparator treatment(9-11), and 23 uncontrolled case series(12-34) that met the inclusion criteria for consideration but which had not been identified by our electronic searches. In addition, we included one unpublished case series submitted by Smith and Nephew(35) giving us a total of 24 additional case series included in this report. Figure 2 is an attrition diagram that provides a visualization of the disposition of materials as they were evaluated for possible inclusion in the report.

Figure 2. Disposition of Documents Identified by Internal Searches and Outside Submissions



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

The most common reasons for exclusion of submitted materials were

- personal statements of support for specific NPWT systems that did not include data relevant to this review
- animal studies
- studies not relevant to negative pressure wound therapy
- narrative reviews
- poster presentations
- case studies (fewer than five patients)
- publications that duplicated an already included study

A listing of individual stakeholders with included and excluded submissions including reasons for exclusion are provided in Appendix D.

Next, an assessment of the potential for bias of the included studies was performed using a quality assessment instrument developed by ECRI Institute for comparative studies and the Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool(36) for systematic reviews of the literature.

Evidence for Negative Pressure Wound Therapy

Key Question 1: Does any single NPWT system have a significant therapeutic distinction in terms of wound healing outcomes compared to any other NPWT system for the treatment of acute or chronic wounds?

No studies directly comparing one NPWT system to another NPWT system that addressed this Key Question were identified by our searches or in the materials submitted by interested parties. We did identify one recently completed trial listed on ClinicalTrials.gov which appears to compare two different systems, but the investigators did not wish to share any information about the trial prior to publication.

Based on our pre-determined methodology, evidence for indirect comparisons was to be obtained from RCTs of commercially available NPWT systems versus a common comparator. Of 40 studies comparing a NPWT system to another wound care therapy, all were studies of the Kinetics Concepts Inc. (KCI) VAC® system, and only nine were RCTs. Therefore no indirect comparisons with other NPWT systems were possible. Despite the fact that we could not use the studies to answer the Key Question, we assessed the studies for risk of bias and extracted data on treatment procedures, patient characteristics, and study outcomes. We have provided tables with this information in Appendix C for the interested reader, and briefly discuss these studies here.

Our quality assessment of the 40 comparison studies indicated that the majority had significant potential for bias. None of the studies received a high-quality rating; seven (18%) were rated moderate, and 33 (82%) were rated low. Typical study limitations included lack of concealment of treatment allocation, lack of blinding of patients and assessors, failure to report patient characteristics, and small study populations. As explained below, these studies comparing NPWT systems to standard wound care did not meet the study design and conduct requirements needed for use in an indirect comparison analysis.

Blinding patients, treating physicians, and outcome assessors to treatment increases the internal validity of studies. In a situation where patients are being treated by NPWT systems, blinding the patient and the physician providing care is probably not feasible. To prevail over these limitations, van den Boogaard et al.(37) recommend overcoming all other potential shortcomings, i.e., wound assessors should be blinded to treatment, patient groups must be comparable, group allocation should be concealed, and full follow-up of a sufficient proportion of all included patients should be performed.

A majority of the studies did not overcome these deficiencies. None of the studies reported that the physicians were blinded to treatment assignment, and only five (12%) of the studies reported blinding of outcome assessors. In only 7% of studies was there concealment of allocation to treatment, one of the most crucial elements of any RCT, with failure to do so typically resulting in selection bias.(38,39)

Only 14 (35%) studies had similar populations, and 30% of the studies did not have similar follow-up times. Over 75% of the studies either reported a potential conflict of interest in terms of funding (k = 9) or made no report of their funding source (k = 22). Lastly, over 50% of the studies had a study size of fewer than 50 patients; 85% of the studies included fewer than 75 patients.

Key Question 2: Does any component of a NPWT system have a significant therapeutic distinction in terms of wound healing outcomes compared to any other similar component of a NPWT system for the treatment of acute or chronic wounds?

No studies directly comparing one NPWT component to another NPWT component (with both groups receiving negative pressure treatment) that addressed this Key Question were identified by our searches or in the materials submitted by interested parties.

Key Question 3: What are the reported occurrences of pain, bleeding, infection, other complications, and mortality for NPWT systems?

Adverse events were reported in 37 of 40 studies comparing NPWT to other treatments. Of the 37 studies reporting events, seven (19%) studies described NPWT as a safe treatment. Fewer complications were reported in the NPWT-treated patients than in those receiving other wound therapies in 19 (51%) studies(9-11,40-55) and similar complications were reported in 8 (22%) studies.(56-63) Adverse events reported in 103 case series included pain (k = 12), bleeding (k = 7), infection/bacterial colonization (k = 15), mortality (k = 4), and other complications (k = 18).

Key Question 4: Do patients being treated with one NPWT system have a significant therapeutic distinction in terms of less pain, bleeding, infection, other complications, or mortality than other NPWT systems?

No studies comparing one NPWT system to another NPWT system were identified by our searches, and none were submitted by interested parties. Consequently, we were not able to answer this Key Question. Adverse events described in the studies comparing NPWT to some other form of wound care and in case series are described under Key Question 3.

Conclusion

Based on our defined search strategies and submissions from interested parties, no studies directly comparing one NPWT system to another NPWT system were identified that addressed

Key Questions 1, 2 or 4. Thus, we were not able to identify a significant therapeutic distinction of one NPWT system or component over another through the use of head-to-head comparisons. A recently completed study listed on ClinicalTrials.gov (NCT00583141; NCT00590369) may address this question, but the investigators did not wish to disclose any details of the study design prior to publication. In the absence of head-to-head comparison studies, we examined comparison studies of NPWT systems or components versus a common comparator in hopes of assessing the relative efficacy and/or safety of different NPWT systems using adjusted indirect comparisons. Our review of 40 comparison studies found that all of the controlled trials involved the evaluation of one NPWT device, the V.A.C.® manufactured by KCI. Furthermore, to be considered for inclusion in an indirect comparison, studies must be RCTs and must provide sufficient information to determine their comparability in terms of patient characteristics, patient exclusion/inclusion criteria, methodology, outcome definitions, outcome measures, and application of the comparison treatment. Only nine of the KCI VAC® comparison studies were RCTs and none of these RCTs met the requirements necessary for the indirect comparison option had there been studies of more than one NPWT system. Consequently, at this time the available evidence cannot be used to determine a significant therapeutic distinction of a NPWT system.

Our searches did not identify any studies comparing one NPWT system component to another NPWT system component that addressed Key Question 2. This question was designed to examine studies that compared different dressing sets, tubing, or pumps while maintaining identical components for the other parts of an NPWT system. In particular, we were looking for studies that evaluated gauze versus foam dressing sets in various wound types.

While we were able to capture the severity of harms reported by case series and comparison studies evaluating NPWT to comparator treatments, due to the lack of studies comparing one NPWT system to another NPWT system, we were unable to determine the severity of adverse events for one NPWT system compared to another.

We identified a total of 22 other systematic reviews, all published between 2000 and 2008, that covered NPWT devices. These reviews included studies reporting data on NPWT for patients with a broad range of wound types and focused on comparison to other wound treatments (gauze, bolster dressings, wound gels, alginates, and other topical therapies). The systematic reviews of NPWT reveal several important points about the current state of the evidence on this technology. First, all of the systematic reviews noted the lack of high-quality clinical evidence supporting the advantages of NPWT compared to other wound treatments. The lack of high-quality NPWT evidence resulted in many systematic reviewers relying on low-quality retrospective studies to judge the efficacy of this technology. Second, no studies directly comparing different NPWT systems or components (such as foam vs. gauze dressings) were identified by any of the reviewers.

In their systematic review of clinical studies of NPWT, Peinemann et al.(64) sought to identify unpublished completed or discontinued RCTs to gain a broader knowledge of the NPWT evidence. The authors were concerned that previous systematic review conclusions on efficacy and safety based on published data alone may no longer hold after consideration of unpublished data. The authors invited two NPWT device manufacturers KCI. (V.A.C.®) and BlueSky Medical Group Inc. (Versatile 1 Wound Vacuum System) and authors of conference abstracts to provide information on study status and publication status of sponsored trials. Responses were received from 10 of 17 (59%) authors and both manufacturers. BlueSky Medical Group Inc., however, had not sponsored relevant RCTs and only provided case reports. The authors

determined that of 28 RCTs, 13 had been completed, six had been discontinued, six were ongoing, and the status of three could not be determined. Nine trials were unpublished, and no results were provided by the investigators. Peinemann et al. concluded that the “lack of access to unpublished study results data raises doubts about the completeness of the evidence base on NPWT.”(64)

Clinical research on NPWT capable of indicating if any one NPWT system or component provides a significant therapeutic distinction requires study design and conduct that will minimize the possibilities for bias. Important study design features that were not typically reported such as concealment of allocation, reporting of randomization methods, use of power analysis to ensure adequate study size, blinding wound assessors, and reporting of complete wound healing data will improve the internal validity and the informativeness of the studies.

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Abbreviations and Acronyms

ABI	Ankle brachial index
AF	Atrial fibrillation
AMWT	Advanced moist wound therapy
AS	Aortic stenosis
BMI	Body mass index
CA	Can’t answer
CABG	Coronary artery bypass surgery
CAD	Coronary artery disease
CAS	Carotid artery stenosis
CC	Cubic centimeter
CHF	Congestive heart failure
CD	Coronary disease
CDI	Closed drainage and irrigation
CDT	Closed drainage technique
CHD	Coronary heart disease
CHF	Congestive heart failure
CI	Confidence interval
CKD	Chronic kidney disease
CLD	Chronic lung disease
CM	Centimeter
CNP	Continuous negative pressure
COPD	Chronic obstructive pulmonary disorder
CRF	Chronic renal failure
D	Day(s)
DED	De-epidermalized dermis
DFU	Diabetic foot ulcer
DM	Diabetes mellitus
DSWI	Deep sternal wound infection
EQ-5D	EuroQol 5 Dimensions Index
ESRD	End stage renal disease
ESRF	End stage renal failure
F	Female
F/U	Follow-up
gm/dl	Grams per deciliter
HF	Heart failure
HP	Healthpoint System
ICG	Indocyanine Green
IDDM	Insulin dependent diabetes mellitus
IHD	Ischaemic heart disease
IQR	Interquartile range

ISS	Injury Severity Score
L	Length
LOS	Length of hospital stay
LVEF	Left ventricular ejection fraction
M	Male
mg/l	Milligram per liter
MI	Myocardial infarction
ml	Milliliter
mmHg	Millimeters of mercury
MRI	Magnetic resonance imaging
MW	Moist to wet
NA	Not applicable
NIDDM	Non insulin dependent diabetes mellitus
NPIT	Negative pressure instillation therapy
NPWT	Negative pressure wound therapy
NR	Not reported
NS	Not significant
OR	Operating room
PA	Peripheral arteriopathy
PAD	Peripheral arterial disease
PAOD	Peripheral artery occlusive disease
PM	Post-sternotomy mediastinitis
PPI	Present pain intensity
PU	Polyurethane
PVA	Polyvinyl alcohol
PVD	Peripheral vascular disease
QOL	Quality of life
RCT	Randomized controlled trial
RD	Renal disease
RF	Renal failure
ROCF	Reticulated open cell foam
RR	Risk ratio
SF-36	Short Form 36
SF-MPQ	Short Form-McGill Pain Questionnaire
SIGN	Scottish Intercollegiate Guideline Network
SOC	Standard of care
SOM	Post-sternotomy osteomyelitis
SR	Systematic review
SSD	Silver sulphadiazine crème
SSI	Surgical site infection
STSG	Split thickness skin graft
SWT	Standard wound therapy
TNP	Topical negative pressure

TPN	Total parenteral nutrition
um	Micrometer
VAC	Vacuum-assisted closure
VAS	Visual analogue scale
W	Width
WDS	Wounds
WM	Wet to moist
WMD	Weighted mean differences

Background

The Center for Medicare Management at the Centers for Medicare and Medicaid Services (CMS) requested this report from The Technology Assessment Program (TAP) at the Agency for Healthcare Research and Quality (AHRQ). AHRQ assigned this report to the following Evidence-based Practice Center: ECRI Institute EPC (Contract Number: 290-2007-10063).

Section 154 (c) (3) of the Medicare Improvements for Patient and Providers Act (MIPPA) of 2008 calls for the Secretary of Health and Human Services to perform an evaluation of the Healthcare Common Procedure Coding System (HCPCS) coding decisions for Negative Pressure Wound Therapy (NPWT) devices. Specifically the evaluation of existing HCPCS codes for NPWT should:

- ensure accurate reporting and billing for items and services under such codes; and
- use an existing process for the consideration of coding changes and consider all relevant studies and information furnished pursuant to such processes.

The HCPCS Level II coding system is a comprehensive, standardized system that classifies similar products that are medical in nature into categories for the purpose of efficient claims processing. Products are classified based on similarities in function and whether the products exhibit significant therapeutic distinctions from other products. Currently, all NPWT devices are classified into the same HCPCS codes. The Healthcare Common Procedures Coding System (HCPCS) code E2402 applies to the pump (NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE) and HCPCS code A6550 applies to the dressing sets (WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES). HCPCS code A7000 applies to the canister that goes with the pump.

Chronic and Acute Wounds

This report specifically examined the use of NPWT for the treatment of the following wound types: diabetic foot ulcers, pressure ulcers, vascular ulcers (includes venous ulcers and arterial ulcers), burn wounds, surgical wounds (especially infected sternal wounds) and trauma-induced wounds. More than 2.8 million patients in the United States suffer from chronic wounds.(1) The prevalence of chronic ulcers has been estimated to be 120 per 100,000 patients between the ages of 45 and 64 years; prevalence increases to more than 800 per 100,000 patients over age 75.(1)

Chronic wounds have not completed the process of healing in the expected time frame, usually within 30 days, or have proceeded through the healing phase without establishing the expected functional result.(2) These wounds usually do not close without interventions, and are sometimes resistant to healing interventions. Diabetic foot ulcers, pressure ulcers or “bed sores,” vascular ulcers, and complications of surgically created sternal wounds commonly become chronic wounds because their etiologies impede healing and they persist without proper medical care. For the purposes of this review, we consider chronic wounds to be those wounds present for more than 30 days and acute wounds to be those present for less than 30 days. Diabetic foot ulcers, pressure ulcers, venous leg ulcers, and infected sternal wounds are the chronic wounds most often treated with NPWT. Surgical wounds, burn wounds and trauma wounds are the most common acute wounds treated with NPWT.

Diabetic Foot Ulcers

Patients with diabetes often develop foot ulcers due to atherosclerosis that impedes blood flow to the extremities and peripheral neuropathy that prevents the sensation of discomfort associated with mechanical stress on or injury to the feet. Each of these complications of diabetes increases the probability of ulcer formation on pressure-bearing areas of the feet. Neuropathy is present in 60% to 70% of patients with diabetic foot ulcers, with 15% to 20% of patients having a combination of neuropathy and vascular problems.(3) Patients with diabetic neuropathy are often not aware of repeated mechanical trauma, and ulcers commonly form under the foot. An estimated 16 million Americans are known to have diabetes.(4) Among patients with diabetes, 15% develop a foot ulcer, and 12-24% of individuals with a foot ulcer require amputation.

Diabetic foot ulcers may be classified using the Wagner Classification System.(5) This system is based mainly on wound depth and consists of six wound grades. Grade 0 foot ulcers have intact skin with bony deformities or dry keratinized skin that increases the potential for ulceration, grade 1 involves ulceration of the dermis, grade 2 has ulceration involving tendons and joints, grade 3 extends to the bone and causes osteomyelitis, grade 4 shows localized gangrene, and grade 5 has gangrene involving a major portion of the foot.(6) Improved foot care will often help in healing foot ulcers caused by diabetic neuropathy, but ischemic foot ulcers are often difficult to heal unless the underlying vascular problems are corrected.(3,7)

The major health consequences of diabetic foot ulcers are wound infections, osteomyelitis, and subsequent amputation. Individuals with severe diabetic foot ulcers may be at risk of dying due to large vessel arteriosclerotic disease involving the coronary or renal arteries.(3,4) The management of diabetic foot ulcers requires appropriate therapeutic footwear, a wound dressing that provides a moist environment, debridement when necessary, antibiotic therapy if osteomyelitis or cellulitis is present, and evaluation and correction of peripheral arterial insufficiency.(4)

Pressure Ulcers

Pressure ulcers, also called “decubitus ulcers,” “bed sores,” or “pressure sores” are defined as lesions caused by unrelieved pressure or shear resulting in damage of underlying tissue.(8) These wounds often occur over bony prominences. Prolonged pressure causes ischemia, which leads to tissue necrosis that typically first occurs in the tissue closest to the bone. Ischemic cell death produces inflammation that results in blood clotting, platelet aggregation, immune complex formation, and the accumulation of inflammatory cells. Patients who are chair or bedridden are at increased risk for developing pressure ulcers. The following factors further increase their risk of pressure ulcer development: advanced age, impaired ability to reposition themselves, friction, decreased sensory perception, impaired nutrition, and excessive exposure to moisture (i.e., incontinence, excessive perspiration, wound drainage).(9) The exact incidence and prevalence of pressure ulcers is unclear. Reports of pressure ulcer incidence vary widely, from 0.4% to 38% in acute care, from 2.2% to 24% in long-term care, and from 0% to 17% in home care.(10)

Pressure ulcers are classified in stages according to the degree of tissue damage. Stage 1 pressure ulcers are distinguished by non-blanchable redness of intact skin, stage 2 by superficial skin loss (partial-thickness skin loss of the epidermis and dermis), stage 3 by subcutaneous tissue loss (full-thickness skin loss penetrating through the epidermis and dermis into the subcutaneous tissue), and stage 4 by tissue loss that extends into the underlying muscle, tendon, or bone.(9) The health consequences of pressure ulcers include local infection, sepsis, osteomyelitis, and

pain.(11) Local infection of pressure wounds is common and is usually controlled by debridement and antibiotics. Osteomyelitis is a risk in pressure ulcer patients because these ulcers develop over bony prominences.

In addition to the four stages described above, the National Pressure Ulcer Advisory Panel (NPUAP) also lists “Suspected Deep Tissue Injury” and “Unstageable” as pressure ulcer stages.(12,13) The Suspected Deep Tissue Injury stage is described as “purple or maroon localized areas of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.” This new stage recognizes that some pressure ulcers begin with deep tissue damage and work their way to the surface rather than starting at the surface and working their way down. The designation “unstageable” is recommended when the base of an ulcer is covered by slough and/or eschar. However, since these new pressure ulcer stages and definitions were published in 2007, earlier clinical publications will refer only to stages 1 through 4.

Treatment of pressure ulcers centers on the following interventions: management of tissue load (i.e., pressure, friction, shearing), nutritional support, ulcer care, and management of bacterial colonization and infection.(9) Standard care for pressure ulcers depends on the ulcer stage and usually includes pressure relief and skin protection to prevent progression of the ulcer to advanced stages, debridement of necrotic tissue in stage 3 and 4 ulcers, wound cleansing, and dressings that promote a moist wound environment.

Venous Leg Ulcers

Vascular leg ulcers are the result of chronic venous insufficiency (venous leg ulcers, 80% to 95% of vascular ulcers), or arterial insufficiency (arterial leg ulcers, 5% to 10%). Between 10% and 35% of the U.S. population has some type of venous disease, and lower extremity skin ulcers are reported in 1% to 22% of individuals over age 60. The underlying problem in venous leg ulcers is venous hypertension in the deep and superficial venous system caused by incompetent valves and the incomplete removal of blood from the venous system. The disorder may be due to a previous blood clot that destroys the valves, a comorbid medical problem (arterial disease), or a hereditary absence of the valves in the venous system. The venous hypertension dilates capillaries, increases capillary filtration causing edema followed by destruction of subcutaneous tissues and the formation of an ulcer. Due to poor blood flow in the area of the ulcer, wounds caused by venous insufficiency are hard to heal and often recur.(14)

Venous leg ulcers, if left untreated, may remain for years and lead to depression, anxiety, reduced activity, and a reduction in the patient’s quality of life.(15,16) Pain may be experienced by as many as 80% of venous leg ulcer patients.(17) Edema of the leg is frequently associated with venous leg ulcers. The edema may be the result of the venous insufficiency, inflammation, compromised lymphatic system associated with the wound, or of systemic disorders such as heart failure.(18) Contact dermatitis is also common in venous leg ulcer patients, and allergic reactions to wound dressings, topical ointments, and bandage material may hinder wound healing.

Treatment of venous leg ulcers involves cleaning and protecting the wound, facilitating the healing process, and providing hemodynamic support to control the underlying disorder responsible for the ulcer.(14) Wound cleaning can be performed with sterile or nonsterile water or saline and gauze compresses to remove loose slough and eschar from the wound. When

necessary, debridement can be performed with application of enzymes or sharp debridement procedures (forceps, scissors, lasers) before applying the dressing and compression bandages. Hemodynamic support is provided by compression bandages that counter the venous hypertension responsible for ulcer development. Compression bandages are a vital part of treating venous leg ulcers. Therapeutic compression stockings with compression of 30 to 40 mmHg will counteract the capillary pressure in the tissues. Restoring blood flow through the skin reduces edema, increases oxygen and carbon dioxide exchange, and increases nutrient flow into the tissues. Compression may be applied using a single-component (a stocking or single type of bandage) or a multi-component system using several layers of material. A systematic review from 2009 examined the evidence for compression treatment of venous leg ulcers. According to the authors venous ulcers heal more rapidly with compression than without and multi-component systems achieve better healing outcomes than single-component compression.(19)

Surgical Wounds

Most surgically created sternal wounds heal without complications. However, in some cases wound healing is delayed due to the presence of infection or wound dehiscence (partial or complete separation of the wound).(20) Most chest wound infections arise from complications of cardiac surgery through a sternotomy incision.(21) Sternal wound infections are associated with an extremely high mortality rate if recognized late or treated improperly.(22) Complications associated with sternotomy occur in about 2% to 5% of closures. Approximately 1.2% of patients undergoing sternotomy will develop deep sternal wound infections. Patients with sternal wound infections can develop mediastinitis (deep chest infection), with potential exposure of bypass grafts and rupture of the ventricle, contributing to an approximately 20% overall reported mortality.(20)

There are a variety of classification methods used to differentiate between acute and chronic, superficial or deep, and infected or non-infected sternal wounds. The Centers for Disease Control and Prevention (CDC) defines a deep surgical site infection (SSI) as one that occurs within 30 days after the operation, appears to be related to the operation, involves the deep soft tissues of the incision, and at least one of the following: 1) purulent drainage from the deep incision but not from the organ/space component of the surgical site; 2) deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following symptoms: fever, localized pain or tenderness, unless site is culture negative; 3) an abscess or other evidence of infection involving the deep incision is found on direct observation, histopathologic, or radiological examination; and 4) diagnosis of a deep SSI by a surgeon or attending physician.(21)

Treatment of sternal wound infections usually involves aggressive surgical debridement, sternal wound drainage, management of infection, closed irrigation, periodic open packing of the wound, and delayed closure of the sternal defect.(23) Advances in plastic and reconstructive surgery have shown the importance of bringing well-vascularized tissue into the wound following debridement.(21) Debridement creates a void (a deficit or defect), which if not filled, can be a space for fluid and bacteria to accumulate. Vascularized tissue fills the space, delivers antibiotics, and heals the wound by forming connections to surrounding tissues through multiple small blood vessel connections.

Burns

Severe burns can cause significant morbidity and mortality because the resulting wounds are at a high risk of becoming seriously infected. Infection remains the leading cause of death among patients who are hospitalized for burns. Second-degree (partial thickness) and third-degree (full thickness) burns, because they destroy the epidermis and part or all of the underlying dermis, have only limited ability to heal. The risk of burn wound infection increases with the extent of the burn due to breakdown of the skin's natural barrier to pathogen invasion and generalized immune suppression. Burn wounds may be classified as wound cellulitis (in which the infection involves the unburned skin at the margin of the burn) or as an invasive wound infection (characterized by microbial invasion of viable tissue beneath the burn wound eschar). Recommendations typically call for debridement of nonviable tissue in the wound, followed by the application of silver sulfadiazine cream every 12 hours. Wounds that are colonized more heavily or those that deteriorate are often treated with mafenide acetate (Sulfamylon®). The topical creams are removed daily, and the wound is cleaned with a surgical detergent.(24)

Trauma Wounds

Soft-tissue injuries due to high energy trauma (caused by motor vehicle accidents, industrial injuries, falls, and gunshot wounds) can be difficult to treat. NPWT is being used to treat many of these wounds with the hope of reducing infection and promoting healing sufficient to allow skin grafting or flap closure.(25-27)

Phases of Normal Wound Healing

Skin wounds heal in three distinct phases: the hemostatic or inflammation phase, the proliferative phase, and the maturation or remodeling phase.(7,28-30) The inflammatory phase begins with tissue damage that often results in the release of blood and the formation of a fibrin clot. Platelets release cytokines and growth factors that attract inflammatory cells (neutrophils, eosinophils, and monocytes) and initiate the inflammatory response. The inflammatory phase also initiates cellular and vascular responses that clear dead tissue, bacteria, and foreign material from the wound. Vasodilation and increased capillary permeability around the wound allow serum proteins and leukocytes to infiltrate the area and begin the healing process. Macrophages appear within 48 hours and aggressively remove dead tissue and bacteria. Activated macrophages secrete cytokines that attract fibroblasts to the wound. The clot forms a temporary shield over the wound and also provides a structure through which inflammatory cells, fibroblasts, and vascular endothelial cells move to form granulation tissue. The inflammatory phase lasts about 2-5 days.(30,31)

Fibroblasts appear in the wound within two to three days and mark the beginning of the fibroblast proliferation phase. This phase may last up to 3 weeks. Fibroblasts produce and extrude collagen, which then forms into fibers that provide tensile strength to the wound. Fibroblasts also secrete a variety of growth factors that guide the formation of the new extracellular matrix. New blood vessels advance into the wound along with the fibroblasts to satisfy the metabolic needs of collagen formation. The new blood vessels, collagen, and proteoglycan ground substance form the granulation tissue. Granulation tissue fills a deep wound during the early phases of the healing process and is composed of rapidly dividing fibroblasts, new collagen fibers produced by those fibroblasts, and new capillaries that supply oxygen and nutrients to the new tissue. Its formation is a key part of wound healing. Myofibroblasts within the granulation tissue contract, pull the wound edges together, and reduce the size of the wound.

Reepithelialization occurs during the fibroblast proliferative phase as epithelial cells proliferate and migrate over the granulation tissue. The new epithelial cells provide a barrier to bacteria and prevent fluid loss. In wounds with a large surface, epithelialization is enhanced by a moist environment. Dry wounds with a large dry eschar (commonly referred to as a scab) impede epithelial cell migration.

By three weeks after injury, collagen synthesis and degradation are in homeostasis, and wound remodeling begins. Maturation of the wound takes place with increasing levels of type I collagen, compared to type III collagen, and thickening of the collagen fibers. The new tissue formed in the wound progressively increases in tensile strength. This process may continue for up to two years.(30,31)

Negative Pressure Wound Therapy

Principles of NPWT

In his book on vacuum therapy, published in 2006, Willy(32) lists five mechanisms by which the application of negative pressure to a wound may aid in the healing process: 1) wound retraction, 2) stimulation of granulation tissue formation, 3) continuous wound cleansing after adequate primary surgical debridement, 4) continuous removal of exudate, and 5) reduction of interstitial edema. Wound retraction under negative pressure brings the edges of the wound closer together while also putting mechanical stress on the tissue. The externally applied stress is thought to create microdeformations in individual cells that induces the production of cellular messengers responsible for increasing matrix synthesis and cell proliferation within the wound.(33-35) Increased rates of granulation tissue formation have been noted in studies using NPWT.(33,35,36) Continuous wound cleansing may reduce the bacterial burden present in a wound(33) as well as remove substances that inhibit wound healing. However, some studies have noted no change or an increase in the bacterial burden during the use of NPWT that did not affect the healing process.(37,38) Interstitial fluid (exudate) that accumulates in a wound may mechanically compress local capillaries and restrict blood flow into the wound. Removal of exudate from a wound may reduce tissue edema and promote blood flow back into the wound area.(33,39,40)

Manufacturers of NPWT devices use different wound dressings. The two most commonly used dressings are foam and moistened cotton gauze. The manufacturer of Vacuum Assisted Closure (V.A.C.®), Kinetic Concepts, Inc. (KCI) uses open-celled reticulated foam dressing to evenly distribute the negative pressure across the wound bed. The foam is covered with a transparent film that prevents bacteria from reaching the wound and also seals the wounds to maintain the vacuum. Foams containing silver or other antibiotics are available from some manufacturers. Other NPWT systems may use moistened gauze instead of foam. Nonadherent gauze is placed next to the wound bed and then the moistened gauze is used to fill the wound. Antimicrobial gauze may also be used. Once applied, the gauze is also covered by a transparent adhesive film dressing. Manufacturers recommend initially changing the dressing at 48 hours then two to three times per week as indicated.

Once the dressing is applied, an evacuation tube runs from the wound through the dressing, drawing excess exudates away from the wound and into a canister attached at the other end. The canister is attached to a vacuum pump that provides either continuous or intermittent negative pressure, adjusted for the type of wound. Pressure is applied in the range of -5 to -125 mmHg (adjustable to higher pressures, depending on the particular device used).(41)

Negative Pressure Wound Therapy Devices

This technology is primarily intended for chronic wounds that have been resistant to other forms of wound care, and for minimizing scarring on acute wounds by promoting healing through granulation tissue formation and re-epithelialization ("secondary intention").(42) Therefore, it may be used as either a primary or secondary line of treatment, depending on the type of wound.

Contraindications of NPWT

Contraindications to NPWT for chronic wounds include, but may not be limited to:

- Exposed vital organs (treatment may proceed after the organ has been covered by vicryl absorbable mesh)
- Inadequately debrided wounds; granulation tissue that will not form over necrotic tissue
- Untreated osteomyelitis or sepsis within the vicinity of the wound
- Presence of untreated coagulopathy
- Necrotic tissue with eschar
- Malignancy in the wound (negative pressure therapy may lead to cellular proliferation)
- Allergy to any component required for the procedure

NPWT should be used cautiously when there is active bleeding, when the patient is on anticoagulants, when there is difficult wound hemostasis, or when placing the dressing in proximity to blood vessels.

Negative Pressure Wound Therapy Systems

NPWT systems include a vacuum pump, drainage tubing, and a dressing set. The pump may be stationary or portable, rely on AC or battery power, allows for regulation of the suction strength, has alarms to indicate loss of suction, and has a replaceable collection canister. The dressing sets may contain either foam or gauze dressing to be placed in the wound and an adhesive film drape for sealing the wound. The drainage tubes come in a variety of configurations depending on the dressings used or wound being treated.

The Healthcare Common Procedures Coding System (HCPCS) code E2402 applies to the pump (NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE) and HCPCS code A6550 applies to the dressing sets (WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES). HCPCS code A7000 applies to the canister that goes with the pump.

NPWT systems are considered Class II devices by the U.S. Food and Drug Administration (FDA) and fall into one of two FDA Product Codes. Devices under product code "JCX" are described as "apparatus, suction, ward use, portable, ac-powered" and under product code "BTA" as "pump, portable, aspiration (manual or powered)." Devices that are not NPWT systems are included under product codes JCX and BTA. Both codes are under regulation number 878.4780 which describes powered suction pumps:

> A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's

airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter.

Redon bottles (high-vacuum drainage bottles) were one of the early vacuum sources used for wound drainage and vacuum therapy.(32) Initially the suction strength is approximately 900 mmHg but declines as the canister is filled. The Redon set comes with a bottle and drainage tubing but no dressing set. The Redon bottle is not included in HCPCS code E2402 because it is not an electric pump. Vacuum drainage bottles are covered under HCPCS code A7043 (VACUUM DRAINAGE BOTTLE AND TUBING FOR USE WITH IMPLANTED CATHETER). The Redon set received FDA 510(k) clearance for marketing in July 2000 as "a non-powered, single patient, portable suction apparatus that consists of a manually operated plastic disposable evacuation system intended to provide vacuum for suction drainage of surgical wounds."

Vacuum therapy for wounds was developed in the 1980s and became commercially available in the 1990s.(32) Table 2 lists NPWT systems that have U.S. Food and Drug Administration 510(k) clearance for marketing in the United States. The table contains specific indications and contraindications according to 1) information in the 510(k) clearance summary and 2) company Web sites and labeling information. Table 3 lists specific product information by manufacturer.

Table 2. Negative Pressure Wound Therapy Systems: Indications and Contraindications

Product Name	Manufacturer	U.S. Food and Drug Administration Indications for Use (510k database)	Indications Presented on Company Web site	Contraindications Presented on Company Web site
V1STA Negative Wound Therapy (portable unit)	Blue Sky Medical Group / now owned by Smith & Nephew, Inc.	The BlueSky VISTA™ Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing (K061367 / Aug 2006)	V1STA and EZCARE are indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing. V1STA and EZCARE are appropriate for use on the following wounds: • Pressure ulcers • Diabetic/neuropathic ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Explored fistulae • Skin flaps and grafts	• Untreated Osteomyelitis. Negative Pressure can be used to treat wounds with osteomyelitis in conjunction with appropriate antibiotic therapy and adequate debridement. • Presence of Necrotic Tissue with Eschar. Ideally non-viable tissue should be removed from the wound bed to maximize results. • Exposed organs or blood vessels • Malignancy in the wound bed with the exception of palliative care where negative pressure has been ordered to relieve pain and manage excessive drainage. • Unexplored fistulae
EZCARE Negative Wound Therapy (stationary unit)	Blue Sky Medical Group / now owned by Smith & Nephew, Inc.	The Versatile 1 EZCare™ Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing (K061919 / Feb 2007)		

Product Name	Manufacturer	U.S. Food and Drug Administration Indications for Use (510k database)	Indications Presented on Company Web site	Contraindications Presented on Company Web site
Engenex® Advanced NPWT System	Boehringer Wound Systems Marketed and distributed by ConvaTec	The Boehringer Laboratories Suction Pump System is intended for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudate, irrigation fluids, body fluids and infectious materials (K061788 / Jul 2006)	The Engenex Advanced Negative Pressure Wound Therapy System is intended for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudate, irrigation fluids, body fluids, and infectious materials.	Do not use the Engenex Advanced Negative Pressure Wound Therapy System for application to wounds where there is evidence of • Exposed arteries or veins in wound • Fistula – unexplored • Fistula - non enteric • Osteomyelitis, untreated • Malignancy in the wound • Necrotic tissue with eschar Emergency Airway Aspiration Pleural, mediastinal or chest tube drainage. These applications require a device that provides specific low suction levels and an underwater seal. Surgical Suction Do not apply the Engenex Wound Dressings directly to exposed blood vessels, organs, or nerves.
SVEDMAN™ Wound Treatment System	Innovative Therapies Inc.	The ANTLIA II™ Suction Pump System is indicated for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials (K070904 / Apr 2007)	The SVEDMAN™ Wound Treatment System is indicated for patients who would benefit from vacuum-assisted drainage with delivery of topical wound treatment solutions and suspensions over the wound bed. Types of wounds for which the SVEDMAN® Wound Treatment System has been indicated include chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.	The SVEDMAN™ Wound Treatment System is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulae, or necrotic tissue with eschar present. Do not place the Svamp® Dressing over exposed blood vessels or organs. The Svamp® Dressings are also contraindicated for hydrogen peroxide and solutions which are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity.
SVED™ Wound Treatment System	Innovative Therapies Inc.			

Product Name	Manufacturer	U.S. Food and Drug Administration Indications for Use (510k database)	Indications Presented on Company Web site	Contraindications Presented on Company Web site
NPD 1000 Negative Pressure Wound Therapy System	Kalypto Medical	NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing (K080275 / Oct 2008)	Not available	Not available
InfoV.A.C.® Therapy Unit (stationary unit)	KCI, USA Inc.	The V.A.C.® Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The V.A.C. GranuFoam® Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types. (InfoV.A.C.® Therapy Unit: K063740 / Jun 2007) (ActiV.A.C.® Therapy Unit: K063692 / Jun 2007) (V.A.C.® Therapy System: K062227 / Oct 2006)	*From the V.A.C.® Therapy Safety Information Brochure:* The V.A.C.® Therapy System is an integrated wound management system for use in acute, extended and home care setting. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The V.A.C. GranuFoam® Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types.	*From the V.A.C.® Therapy Safety Information Brochure:* Do not place foam dressings of the V.A.C.® Therapy System directly in contact with exposed blood vessels, anastomotic sites, organs, or nerves. NOTE: Refer to Warnings section for additional information concerning Bleeding. V.A.C. ® Therapy is contraindicated for patients with: • Malignancy in the wound • Untreated osteomyelitis NOTE: Refer to Warnings section for Osteomyelitis information. • Non-enteric and unexplored fistulae • Necrotic tissue with eschar present NOTE: After debridement of necrotic tissue and complete removal of eschar, V.A.C.® Therapy may be used. • Sensitivity to silver (V.A.C.® GranuFoam® Silver Dressing only).
ActiV.A.C.® Therapy	KCI, USA Inc.			
V.A.C.® Therapy Unit	KCI, USA Inc.			

Product Name	Manufacturer	U.S. Food and Drug Administration Indications for Use (510k database)	Indications Presented on Company Web site	Contraindications Presented on Company Web site
mini V.A.C.®, V.A.C.® Freedom™, V.A.C.® ATS™	KCI, USA Inc.	The V.A.C.® family of devices with wound site feedback control are negative pressure devices used to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/ or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. Feedback control is achieved by measuring the level of negative pressure at the wound site. (K032310 / Oct 2003)	*From brochure:* Chronic, diabetic or pressure ulcers; acute, traumatic or dehisced wounds; flaps and grafts; partial-thickness burns	*From brochure:* Contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistula, or necrotic tissue with eschar present. Do not place V.A.C.® dressing over exposed blood vessels or organs. KCI dressing systems are also contraindicated for use with hydrogen peroxide and solutions that are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity.
V.A.C.® (Vacuum Assisted Closure™)	KCI, USA Inc.	The V.A.C.® System is a powered suction pump system that is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound* healing, including patients who wound benefit from vacuum-assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or alternating suction pressures. * The V.A.C.® is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, pressure ulcers, flaps, and grafts. (K021500 / Dec 2002)	See above	See above

Product Name	Manufacturer	U.S. Food and Drug Administration Indications for Use (510k database)	Indications Presented on Company Web site	Contraindications Presented on Company Web site
V.A.C.® Instill Device (delivery of topical solutions)	KCI, USA Inc.	The V.A.C. Instill® device is indicated for patients who would benefit from vacuum-assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed. The V.A.C.® is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, diabetic ulcers, pressure ulcers, flaps, and grafts. (K021501 / Dec 2002)	The V.A.C.® Instill System is indicated for patients who could benefit from V.A.C.® Instill Therapy coupled with controlled delivery and drainage of topical wound treatment solutions and suspensions over the wound bed. This includes patients who would benefit from removal of infectious material or fluids from wounds under the influence of continuous negative pressure. *From brochure:* Chronic, diabetic or pressure ulcers; acute, traumatic or dehisced wounds; flaps and grafts; partial-thickness burns	*From brochure:* Contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistula, or necrotic tissue with eschar present. Do not place V.A.C.® dressing over exposed blood vessels or organs. KCI dressing systems are also contraindicated for use with hydrogen peroxide and solutions that are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity.

Product Name	Manufacturer	U.S. Food and Drug Administration Indications for Use (510k database)	Indications Presented on Company Web site	Contraindications Presented on Company Web site
Invia Liberty Wound Therapy (portable)	Medela Healthcare, Medela, Inc.	The Medela® INVIA Wound Therapy is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. (K080357 / Jul 2008)	The Invia Vario 18 AC/DC c/i is intended to be used to create localized topical negative pressure when used with a wound sealing kit based on the publications and teachings of Mark Chariker, MD and Katherine Jeter, EdD, ET to promote wound healing and drainage of fluids and infected materials from the wound into a disposable or reusable canister. The types of wounds indicated are: • Diabetic/Neuropathic ulcers • Pressure ulcers • Chronic and acute wounds • Dehisced wounds	Contraindicated for patients with: • Malignancy of the wound • Untreated osteomyelitis • Non-enteric and unexplored fistula • Necrotic tissue with eschar present Do not place Invia® Healing System dressing over exposed blood vessels or organs.
Invia Vario 18 c/i Wound Therapy (stationary, mobile with battery)	Medela Healthcare, Medela, Inc.	The Medela Invia Vario 18 c/i Suction Pump is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. The device is also indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids (including vomit) or infectious materials from a patient's airway or respiratory support system, either during surgery or at the patient's bedside. (K0614345 / Jun 2006)		
Exusdex® wound drainage pump	MediTop BV / The Medical Company	The Exusdex® Wound Drainage Device is a compact, portable device indicated for patients who would benefit from the application of negative pressure to the area of a wound, for the aspiration and removal of surgical fluids, irrigation fluids, tissue (including bone), gases, bodily fluids or infectious materials either during surgery or at the patient's bedside particularly as the device may promote wound healing. (K082311 / Oct 2008)	The company Web site does not provide this information	The company Web site does not provide this information

Product Name	Manufacturer	U.S. Food and Drug Administration Indications for Use (510k database)	Indications Presented on Company Web site	Contraindications Presented on Company Web site
Prodigy™ NPWT System (PMS-800 and PMS-800V)	Premco Medical Systems, Inc.	The Prodigy™ 800V NPWT System is indicated for use in patients that would benefit from a suction device particularly as the device may promote wound healing or for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from a patient's airway or respiratory support system either during surgery or at the patient's bedside. (K082415 / Nov 2008)	The company Web site does not provide this information	The company Web site does not provide this information
PRO-I™ (stationary)	Prospera	The NovaSpine Powered Suction Pump PRO-I is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from a patient's airway or respiratory support system either during surgery or at the patient's bedside. (K062456 / Oct 2006) *The PRO-I has the same configuration and construction as the SIMEX suction pumps which have a separate 510(k) clearance also granted to NovaSpine LLC.*	The Prospera PRO Negative Pressure Wound Therapy pumps are indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing.	When used for wound healing, the PRO-I and PRO-II are contraindicated in the presence of: • Necrotic Tissue • Unexplored or non-enteric fistulae • Untreated osteomyelitis • Wounds containing malignant tissue • Exposed arteries, veins, or organs
PRO-II™ (portable)	Prospera			

Product Name	Manufacturer	U.S. Food and Drug Administration Indications for Use (510k database)	Indications Presented on Company Web site	Contraindications Presented on Company Web site
RENASYS™ EZ	Smith and Nephew	The Renasys EZ is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. (K082426 / Sept 2008)		

Product Name	Manufacturer	U.S. Food and Drug Administration Indications for Use (510k database)	Indications Presented on Company Web site	Contraindications Presented on Company Web site
Venturi™ Negative Pressure Wound Therapy	Talley Group Ltd.	Use of the Venturi TM Negative Pressure Wound Therapy system is indicated for use for patients with acute or chronic wounds that may be benefited by the application of negative pressure therapy and the potential wound healing effects of removal of fluids including wound exudates, irrigation fluids, body fluids, and infectious materials. Venturi is intended for use in acute care settings only. The Venturi™ Negative Pressure Wound Therapy system is contraindicated in the presence of: • Necrotic tissue • Untreated osteomyelitis • Fistula • Wounds with malignant tissue • Exposed vasculature • Exposed nerves • Exposed anastomotic site • Exposed bone or tendons • Wounds with difficult hemostasis (K080897/July 2008)	This information is not presented on the company Web site.	This information is not presented on the company Web site.

Table 3. Negative Pressure Wound Therapy Device Product Description (information obtained from manufacturer Web sites)

Product Name	Manufacturer	Pump	Drains	Dressing Set
V1STA Negative Wound Therapy (portable unit)	Blue Sky Medical Group / now Smith & Nephew, Inc.	**Maximum vacuum:** 200 mmHg **Weight:** 1.9kg **Battery operation:** Up to 12 hours **Battery type:** Nickel Metal-Hydride **Charging:** ~4 hours **Alarms:** Low vacuum Low battery High vacuum/release **Mode of Operation:** Constant and Intermittent	Drains for small, medium, large, X-large, and fistula wounds. Drains come in flat, channel, and round. These drains are placed inside the wounds with one end leaving the wound from under the transparent film. The drain must be secured to maintain a seal.	**Non-adherent gauze:** placed on the wound bed **Antimicrobial gauze:** fills the wound space, impregnated with 0.2% polyhexamethylene biguanide **Transparent film:** covers the entire wound and 2 inches of the periwound skin Uses the Chariker-Jeter Technique Dressing is changed after 48 hrs and 2-3 times per week thereafter A **Foam Dressing Kit** received FDA 510(k) clearance in November 2008. The foam is made of polyurethane.
EZCARE Negative Wound Therapy (stationary unit)	Blue Sky Medical Group / now Smith & Nephew, Inc.	**Maximum vacuum:** 200 mmHg **Weight:** 3.3kg **Battery operation:** ~40 hours **Battery type:** Lithium Ion **Charging:** 3 hours to 80% charge **Alarms:** Low vacuum Low battery **Mode of Operation:** Constant and Intermittent		

Product Name	Manufacturer	Pump	Drains	Dressing Set
Engenex® Advanced NPWT System	Boehringer Wound Systems	The therapy unit includes a case that encloses a diaphragm pump, a regulation control circuit and a rechargeable battery. The pump applies controlled suction adjustable by the user in the range of 30 mmHg to 75 mmHg. The pump operates in continuous and intermittent modes. It incorporates a proprietary detection system to monitor and display the condition of the wound dressing and the collection system. Compliance monitoring on all models allows clinicians to track the progress of therapy at the site of the wound.	The **Tube Attachment Device (TAD)** consists of tubing joined to a moisture vapor-permeable adhesive film. The Tube Attachment Device includes a controlled filter vent. The vent works in combination with the flow detection system of the pump to provide information on system performance. The TAD is applied over the wound cover to provide the suction source for negative pressure wound therapy. TADs are provided sterile. On small wounds, the T.A.D. may be used in place of the wound cover to cover and seal the wound.	The wound dressing incorporates the unique **Bio-Dome™** technology to promote healing. The wound dressing is comprised of non-woven polyester layers joined by a silicone elastomer. This material is arranged in three layers and comprises the packing portion of the dressing, which effectively fills the wound while permitting efficient fluid transport of exudates. **Bio-Dome Easy Release:** These dressings provide a smooth contact surface that may be used in all wound types and should result in less patient discomfort during dressing changes. The Bio-Dome™ Easy Release dressing is available in small, medium, large and extra large varieties. The **Wound Cover** is a thin film dressing that serves to cover and seal wounds. It consists of polyurethane film coated on one side with a hypoallergenic, pressure sensitive acrylate adhesive. The **Engenex® Tunnel Dressing** is recommended for use in wounds with tunnels or sinus tracts. The tunnel dressing is comprised of non-woven polyester layers, and are provided sterile. Tunnel dressings are tapered for ease of insertion. Tunnel dressings are used to maintain a flow passage for therapy administration until the distal portion of the tunnel has closed. Two sizes are available: small and large.

Product Name	Manufacturer	Pump	Drains	Dressing Set
SVEDMAN™ Wound Treatment System	Innovative Therapies, Inc.	The SVEDMAN™ Wound Treatment System device is enclosed in an aluminum case to help prevent damage from drops and impacts. **Light Weight** – The therapy unit weighs only 5.5 lbs (2,495 g) and can be easily carried and transported. **Long-life Pump** – Diaphragm-type pump with brushless motor increases life expectancy of the unit and minimizes maintenance requirement. **PowerGuard** – An internal battery provides approximately 12 hours of operation from a single full-charge. **TherapyGuard** - Automated alarms for leak/low pressure and full canister. Alarms provide both a visual and audible indication. Alarms will self-reset once a problem is corrected or can be manually reset by turning the therapy unit OFF and ON.	**SpeedConnect™ Tubing Set** and irrigation tubing.	The Svedman® and Sved® Wound Treatment Systems are offered with our proprietary and patent pending **Svamp® Foam Dressing**. Also comes with an occlusive drape.
SVED™ Wound Treatment System	Innovative Therapies, Inc.	**Light Weight** – The therapy unit weighs only 1.9 lbs. (862 g) and can be easily carried and transported. Other features same as above.		
NPD 1000 Negative Pressure Wound Therapy System	Kalypto Medical	The manufacturer does not currently have a Web site that provides product information		

Product Name	Manufacturer	Pump	Drains	Dressing Set
InfoV.A.C.® Therapy Unit (stationary unit)	**KCI, USA Inc.** (the following 5 systems are listed by KCI as currently available)	The InfoV.A.C.® Therapy System includes new features, like SensaT.R.A.C.® Technology, including Seal Check™, Therapy History Reports and Digital Wound. Imaging • 5.9 lbs. • 6 hour average battery life • Negative Pressure: -25 mmHg through -200 mmHg SensaT.R.A.C.® Technology helps monitor and maintain target pressure. Audible and visual alarms for enhanced patient safety. Alarm differentiation for easier troubleshooting. Seal Check™ to help locate and resolve leaks. Digital Wound Imaging - Upload wound images from your digital camera. Helps calculate wound area and volume.	**SensaT.R.A.C.® Pad** - designed with patient comfort in mind. Thinner, more flexible pad material for easy application over body contours. Designed with enhanced fluid dynamics to help reduce tubing blocks and associated alarms. Low profile design is discreet under clothing. A hole is cut in the Tegaderm Dressing and the T.R.A.C. pad seals over the hole. **TRAC tubing** - patented T.R.A.C.® (Therapeutic Regulated Accurate Care) technology monitors and maintains target pressure. T.R.A.C. allows for Smart Alarms to help ensure patient safety.	**V.A.C. GranuFoam® Dressing** is a black, polyurethane foam dressing: Assists granulation tissue formation in wounds. Open pore nature (400-600 microns) provides equal distribution of negative pressure at the wound site. Hydrophobic, open pore structure helps facilitate exudate removal. Available dedicated dressings for specific wound applications. This dressing is cut to size and placed in the wound. **V.A.C. GranuFoam® Silver®:** Micro-bonded metallic silver is uniformly distributed throughout the dressing, providing continuous delivery of silver even after sizing. **V.A.C. Vers-Foam®** dressing is a versatile, micro-porous, polyvinyl alcohol dressing that is used with the V.A.C.® System to help promote healing for many traumatic and chronic wounds. Non-adherent material helps promote graft take. High tensile strength makes it easy to place and remove from tunnels and undermining. Increased density for restricted in-growth of granulation tissue for a more comfortable dressing change. Helps protect delicate underlying structures in wounds, such as tendon and bone. Pre-moistened with sterile water. **3M™Tegaderm™Dressing:** Designed exclusively for use with V.A.C.® Therapy. Provides a moist wound healing environment.
ActiV.A.C.® Therapy	**KCI, USA Inc.** (the following 5 systems are listed by KCI as currently available)	Portable system 2.4 lbs. 14 hour average battery life 300 ml canister 25-200 mmHg Continuous and Intermittent		
V.A.C.® ATS™	**KCI, USA Inc.** (the following 5 systems are listed by KCI as currently available)	ATS = Advanced Therapy System, designed for higher acuity wounds for patients in acute care and long-term care facilities. 12.3 lbs. (5.6 kg) **Canister Volume:** 500 ml or 1,000 ml **Battery Life:** Approximately 4 hours Audible and visual alarms 50-200 mmHg Continuous and Intermittent		

Product Name	Manufacturer	Pump	Drains	Dressing Set
V.A.C.® Freedom™	**KCI, USA Inc.** (the following 5 systems are listed by KCI as currently available)	Portable system 3.20 lbs 300 ml canister **Battery Life:** Approximately 12 hours Audible and visual alarms 50-200 mmHg Continuous and Intermittent		Barrier to outside contaminants. Applied over the wound and foam dressing.
V.A.C.® Instill System®	**KCI, USA Inc.** (the following 5 systems are listed by KCI as currently available)	Designed for delivery of topical solutions as well as negative pressure therapy. 14.5 lbs **Battery Life:** 4 hrs Optional Large 1,000 ml canister 50-200 mmHg **Mode of Operation:** Instillation, Continuous and Intermittent		
Invia Liberty Wound Therapy (portable)	Medela Healthcare, Medela, Inc.	2.2 lbs	Wound drain: 100% silicone drain is easy to cut and flexible allowing simple placement in the wound.	**Antimicrobial Kerlix™ gauze:** Fluff into the wound bed to provide a preventative barrier reducing risk of infection. **Non-adherent wound contact layer:** This layer of protection placed directly on the wound bed is designed to cause less trauma to new tissue and minimize patient discomfort during dressing changes. **Transparent dressing:** Waterproof film designed to protect the integrity of the wound; easy to cut and customizable to each unique size.
Invia Vario 18 c/i Wound Therapy (stationary, mobile with battery)	Medela Healthcare, Medela, Inc.	c/i = constant / intermittent		
Exusdex® wound drainage pump	MediTop BV	The company Web site does not provide this information.	The company Web site does not provide this information.	Uses Kerlix / Kerlix AMD gauze. The Web site does not provide any further product information.

Product Name	Manufacturer	Pump	Drains	Dressing Set
Prodigy™ NPWT System (PMS-800 and PMS-800V)	Premco Medical Systems, Inc.	Our PMS-800 and PMS-800V *(Variable)* differ significantly from other devices of its kind in that they are controlled by a microprocessor with fully operational touch screen interface.	The company Web site does not provide this information.	The company Web site does not provide this information.
PRO-I™ (stationary)	Prospera	Developed for hospital and in-home use. 0-200 mmHg 4 hrs operation on battery Continuous and Intermittent 6.16 lbs. 800 ml canister **Variable Pressure Therapy (VPT):** Pressure levels and time settings for high and low pressures are completely customizable. Recommended pressures of between 40 and 80 mmHg	Variety of drain sizes and shapes.	**Non-contact layer:** Reduce the risk of gauze adherence over vital structures such as bone, tendon, ligament, cartilage, muscle and vessels. (Optional step) Custom cut-to-fit the wound bed. **AMD™ gauze:** Reduces the microbial population and absorbs exudate. Impregnated with Polyhexamethylene Biguanide. Offers 48-72 hours microbial control. “Moisten” gauze for drier wounds. Use dry gauze for highly exuding wounds. Wrap or “sandwich” the drain between the gauze. Place into wound until level or below skin surface. **Transparency:** Secures the components below. Protects wound from environment. Allows moisture vapor transfer rate. Uses the Chariker-Jeter technique
PRO-II™ (portable)	Prospera	Contoured design for patient comfort. Virtually silent operation. Discreet, disposable canister. Over 24-hour battery run-time. Also uses Variable Pressure Therapy. 250 ml canister		

Product Name	Manufacturer	Pump	Drains	Dressing Set
RENASYS™ EZ	Smith and Nephew, Inc.	Intuitive design and quick-click connectors to help reduce the risk of medical errors User-friendly analog pressure control (40-200 mm Hg) Simple on/off toggle switch Multiple safety alarms with patient lock-out feature Lightweight (7.4 lbs/3.3 kg) Up to 40-hour battery life after charging to 80% capacity in 3 hours IV pole and bed mount 800 cc canisters	Variety of drain sizes and shapes.	**RENASYS™-F Foam Dressing Kit** • Hydrophobic, open-pore foam for exudate removal • Integral groove • Available in a variety of sizes to fit a range of wound types **RENASYS™-G Gauze Dressing Kit** • Ideal for explored fistulae, circumferential and tunneling wounds • Fits most wound sizes and types • Simplified for quick and easy use in the O.R. • Enhances patient comfort upon application and removal Dressing kits are also described above for the EZCARE and VISTA
Venturi™ Negative Pressure Wound Therapy	Talley Group Ltd.	The Web sites provides very few details about the pump.	The Web sites provides very few details about the drains.	Range of wound sealing kits – no specifics presented on the company Web site. Demonstration used gauze dressing with the drain tube placed within the wound.

Complementary or Competing Products

There are several requirements for proper and rapid healing of an open wound. First, either the edges of the wound must be allowed to seal back together (healing by “primary intention”), or granulation tissue must form to fill the wound bed (healing by “secondary intention”). Second, the wound must remain moist because new epidermal cells will only travel across moist surfaces. Third, bacterial infection must be prevented by not allowing contamination to reach the wound. Fourth, any fluids should be removed from the wound site and while appropriate moisture is maintained. Finally, contributing factors to wound occurrence should be eliminated, or minimized, if elimination is not possible. Bedridden patients may need special support surfaces, protein-calorie malnutrition and vitamin deficiencies should be corrected, inadequate blood flow to the site of the wound should be corrected if possible, and drugs know to impede wound healing should be adjusted.(28)

Standard Treatments

Standard treatment for established wounds incorporates common principles that apply to the management of all wound types. These include removal of necrotic tissue through debridement (achieved through sharp debridement using forceps and scissors, autolytic debridement by endogenous enzymes present in the wound, or application of exogenous enzymes in commercially available wound care products) and moisture balance through the selection of the proper wound dressing.(28)

For most chronic and acute wounds, saline-moistened cotton gauze (wet-to-moist) has been the standard treatment and most commonly used dressing. Gauze dressings are moderately absorptive, easily available, and inexpensive. Saline-moistened gauze dressings can maintain a moist wound environment provided they are kept continuously moist until the dressing is removed. Therefore, wet-to-moist gauze dressings require close maintenance and added nursing time. The removal of a wet-to-moist dressing that has been allowed to dry may reinjure the wound by removing granulation tissue and lead to delayed wound healing. The removal of dried gauze dressings also causes considerable pain, impedes healing, and increases the risk of infection. While gauze dressings are much less expensive per dressing than modern synthetic dressings, the increase in labor costs and ancillary supplies such as gloves and biohazardous waste disposal increase the total cost of care. The drawbacks to the use of saline-moistened gauze dressings have been reviewed elsewhere.(43)

Synthetic Wound Dressings

Dressings are selected based on the characteristics of the wound at any given point during the healing process.(28) Wounds which produce exudate will need an absorptive dressing (hydrocolloid, foam, alginate, hydrofiber) and dry wounds will need a dressing that provides hydration (hydrogel). The type of dressing used will change as the wound goes through the phases of wound healing. Synthetic wound dressings inhibit the loss of water vapor from the wound, thereby creating a moist environment. Moist wound environments promote epithelialization and healing. In addition to creating a moist wound environment, ideal synthetic dressings perform the following functions: remove excess exudates and toxic components; allow gaseous exchange; provide thermal insulation; and protect against secondary infection. A wide variety of synthetic wound dressings are available.(44-46) Some of the unique features of each are described below. Often, these dressings are used in conjunction with silver or other topical agents intended to limit infection and speed healing.

Negative Pressure Wound Therapy Devices

The following dressings may be used on chronic or acute wounds depending on the nature of the wound.

- Hydrocolloid dressings are composed of adhesive, absorbent, and elastomeric components. Carboxymethylcellulose is the most common absorptive ingredient. They are permeable to moisture vapor, but not to water. In addition, they facilitate autolytic debridement, are self-adhesive, mold well, provide light-to-moderate exudate absorption, and can be left in place for several days, minimizing skin trauma and healing disruption. They are intended for use on light-to-moderately exuding, acute or chronic partial- or full-thickness wounds, but are not intended for use on infected wounds. Upon sustained contact with wound fluid, the hydrocolloid forms a gel.
- Foam dressings vary widely in composition and construction. They consist of a polymer, often polyurethane, with small, open cells that are able to hold fluids. Some varieties of foam dressings have a waterproof film covering the top surface and may or may not have an adhesive coating on the wound contact side or border. Foams are permeable to water and gas, and are able to absorb light to heavy exudate. This type of dressing is frequently used under compression stockings in patients with venous leg ulcers.
- Film dressings consist of a single thin transparent sheet of polyurethane coated on one side with an adhesive. The sheet is permeable to gases and water vapor but impermeable to wound fluids. Film dressings retain moisture, are impermeable to bacteria and other contaminants, allow wound observation, and do not require a secondary dressing. The adhesive is inactivated by moisture and therefore will not stick to the moist wound bed or to moist skin. Excessive fluid buildup may break the adhesive seal and allow leakage. Film dressings are intended for superficial wounds with little exudate and are commonly used as a secondary dressing to attach a primary absorbent dressing. The dressing may remain in place for up to seven days if excessive fluid does not accumulate. Film dressings are generally hard to apply due to self-sticking and must be placed at least 1 to 2 cm beyond the wound edges. Film dressings have been used extensively to treat split-thickness graft donor sites.
- Alginate dressings are made from calcium or calcium-sodium salts of natural polysaccharides derived from brown seaweed. When the alginate material comes into contact with sodium-rich wound exudates, an ion exchange takes place and produces a hydrophilic gel. This hydrophilic gel is capable of absorbing up to 20 times its weight and does not adhere to the wound. This dressing sometimes emits a foul odor, but can remain in place for about seven days if enough exudate is present to prevent drying. This category of dressing is best suited for moist, moderate to heavy exuding wounds. Alginate dressings require a secondary dressing, such as a film dressing, to hold them in place and to prevent the alginate from drying out.
- Hydrofiber dressing is composed of sodium carboxymethylcellulose fibers.(47) The fibers maintain a moist wound environment by absorbing large amounts of exudate and forming a gel. This dressing is not intended for lightly exuding wounds. A secondary dressing is required.
- Hydrogel sheets are three-dimensional networks of cross-linked hydrophilic polymers. Their high water content provides moisture to the wound, but these dressings can absorb small to large amounts of fluid, depending on their composition. These dressings are

cooling and soothing, reduce pain, rehydrate dry wound beds, and are easy to apply and remove. Depending on wound exudate levels, hydrogels may require more frequent dressing changes, every one to three days, compared to other synthetic dressings. Hydrogel sheets can be used on most wound types but may not be effective on heavily exuding wounds. Amorphous hydrogels are similar in composition to hydrogel sheets but lack the cross-linking. The gel may also contain additional ingredients such as collagens, alginate, or complex carbohydrates. Amorphous hydrogels can donate moisture to a dry wound with eschar and facilitate autolytic debridement in necrotic wounds. A second dressing may be used to retain the gel in shallow wounds.

- Collagen-based dressings contain purified collagen derived from bovine, porcine, equine, or avian sources. The type and concentration of collagen varies depending on the actual dressing. Rather than just providining structural support within a wound, collegan is now believed to play a critical role in all aspescts of wound healing. When a wound is first formed platelets aggregate around exposed collagen. The platelets release a variety of growth factors and cytokines that attract inflammatory cells (macrophages, neutrophils, eosinophils) to the wound. The inflammatory cells degrade collagen and other protein debris in the wound and at the same time produce factors that attract and stimulate fibroblast activity. Fibroblasts secrete matrix metalloproteinase (MMP) along with collagen and produce factors that attract additional fibroblasts as well as epithelial cells and vascular endothelial cells into the wound. These cells then produce the granulation tissue that forms the extracellular matrix. The MMPs are responsible for degrading non-viable collagen while the new matrix is forming. However, in chronic wounds fibroblasts may produce too much MMPs and too little of the factors that inhibit MMPs. When this occurs the MMPs may be destroying new viable collagen as well and preventing proper wound healing. Collagen-based dressings are believed to aid wound healing by stimulating fibroblast production, have a hydrophilic property that enhances fibroblast movement, and inhibition and deactivation of MMPs.(29)

Antimicrobial Wound Dressings

Infected wounds are defined as having a bacterial population size of 10^5 colony forming units per gram of tissue. Most wounds are either “contaminated” or “colonized” by bacteria which are not necessarily associated with tissue invasion. The concept of “critical colonization” has been introduced in recent years to convey that bacterial growth may play a role in delayed healing of wounds in the absence of the traditional criteria for infection. Approaches to reducing the volume or “density” of bacteria in a noninfected wound include use of gentle wound irrigation with normal saline and use of occlusive dressings, or application of topical antibiotics or antiseptics designed to remain in contact with the wound surface.(28,48) Chronic wound infections generally have multiple bacterial contaminants with *Staphylococcus aureus* the most common.(49)

Bacteria within an infected wound are embedded in a protective polysaccharide biofilm produced by the bacteria. The biofilm allows for the exchange of water and nutrients and impedes the entry of antibiotics. The biofilm may be responsible for increased resistance to the actions of antibiotics as well as to natural host defenses. Thus the biofilm makes wound bacteria hard to eradicate. Bacterial colonization may obstruct wound healing by impairing white cell function, increasing tissue hypoxia, reducing the number and proliferation of fibroblasts through the production of endotoxins, and prolongation of the inflammatory phase of wound healing.

Negative Pressure Wound Therapy Devices

Infected wounds are diagnosed clinically through the following signs and symptoms: increased pain and exudate, foul odor, an excessive inflammatory response in the wound bed coupled with an unhealthy appearance to the granulation tissue. Wound debridement is a critical means of reducing bacterial burden while also removing bacterial toxins and the wound debris that is a source of nutrients to the bacteria. Appropriate systemic antibiotic therapy is also recommended for infected wounds when bacteremia, septicemia, progressive cellulitis, or intractable osteomyelitis are present.(28,49-53)

Silver has been used for several centuries to treat wounds. Silver's antibacterial and antifungal properties have been used in the treatment of burn wounds, venous leg ulcers, diabetic foot ulcers, and other types of chronic wounds. Today, several brands of wound dressings incorporate silver into advanced synthetic wound dressing materials. As the dressing material accumulates fluid, silver ions are released from the dressing into the wound environment. Free silver cations are responsible for silver's antimicrobial action by blocking cellular respiration and disrupting bacterial cell membranes. Silver ions bind to tissue proteins causing lethal changes to cell structures. Silver ions also bind and denature bacterial RNA and DNA. Silver nitrate solutions were first used to treat burn wounds in the late 1960s followed by the use of silver sulfadiazine cream.(50,54)

The following is a partial list of wound dressings that contain silver or other antimicrobial agents:

- Coloplast Corporation manufactures Contreet® Foam Adhesive/Non-Adhesive and Contreet® Hydrocolloid Dressing containing silver.
- Hollister Incorporated manufactures Restore Foam Dressing Silver, Restore Contact Layer Silver, and Restore Calcium Alginate Dressing Silver.
- Johnson & Johnson, Inc. manufactures Actisorb®, a line of silver-containing dressings.
- Kendall manufactures Kerlix™ AMD™ gauze that contains polyhexamethylene biguanide.(55)
- Smith & Nephew, Inc manufactures Acticoat™ Moisture Control Dressing containing nanocrystalline silver.

Skin Grafts and Skin Substitutes

Skin grafts are utilized in the treatment of venous leg ulcers(56), diabetic foot ulcers, and burn wounds.(57) Skin grafts are believed to assist wound healing by providing dermal collagen, growth factors, and biological occlusion and protection of the wound.(57,58) Skin grafts are usually taken from a portion of intact skin of the same individual (autograft), but may be obtained by human skin donors (allograft). Skin grafts may be used in later stages of wound healing after the wound has established sufficient granulation tissue to support the graft.

A variety of skin substititues and alternatives have been developed to treat chronic wounds.(59,60) Autologous tissue grafting is an invasive and painful procedure, and often the extent of damaged skin is too large to be covered by autologous tissue graft alone. Bioengineered skin substitutes are designed to replace the damaged epithelial and dermal layers of skin with a biological replacement that enhances wound healing. Many of the conditions and biological factors needed in the healing process may be provided by the substitute skin products.

Negative Pressure Wound Therapy Devices

Skin substitutes allow re-epithelialization to occur while permitting gas and fluid exchange, and provide mechanical coverage and protection from bacterial influx. Most biosynthetic skin substitutes are used temporarily as a specialized dressing to replace skin function until the skin repairs spontaneously or until skin replacement is possible with autograft. A small number, however, are designed to permanently incorporate into the debrided wound (e.g., by generating neodermis). Skin substitutes may be acellular or cellular. Acellular products only contain the matrix composed of collagen, hyaluronic acid, and fibronectin. The construction of the matrix allows easy access by host cells during the healing process. Cellular products contain cells such as fibroblasts and keratinocytes within a collagen or polyglactin matrix. The cells may be allogeneic or autologous.

The biological materials used to form these skin substitutes vary by product. The following is a brief description of some of the products currently available to treat burns and other skin wounds:

- AlloDerm® (LifeCell Corporation, Branchburg, NJ, USA) – acellular, de-epithelialized cadaver dermis
- Apligraf® (Organogenesis, Inc., Canton, MA, USA) – neonatal keratinocytes and collagen seeded with neonatal fibroblasts
- Biobrane® (UDL Laboratories, Inc., Rockford, IL, USA) – silicone, nylon mesh, and collagen
- Dermagraft® (Advanced BioHealing, Inc., Westport, CT, USA) – polyglycolic acid or polyglactin-910 seeded with neonatal fibroblasts
- Epicel® (Genzyme Biosurgery, Cambridge, MA) – autologous cultured keratinocytes
- GraftJacket® (Wright Medical Technology, Inc., Arlington, TN, USA) – freeze-dried acellular human dermal matrix
- Integra® Dermal Regeneration Template (Integra LifeSciences Holding Corp., South Plainsboro, NJ, USA) – silicone, collagen, and glycosaminoglycan
- Oasis® (Healthpoint Ltd., Fort Worth, TX, USA) – derived from porcine small intestinal submucosa
- OrCel® (Forticell Bioscience, Inc., New York, NY, USA) - normal human allogeneic skin cells (epidermal keratinocytes and dermal fibroblasts) are cultured in two separate layers into a Type I bovine collagen sponge
- Promogran® (Systagenix Wound Management, London, UK; formerly marketed by the professional wound care business of Ethicon Inc, a Johnson & Johnson company) – bovine collagen and oxidized regenerated cellulose
- Suprathel® (Polymedics Innovations GMbH, Denkendorf, Germany)—lacto-capromer, polylactic acid

Methods

The Center for Medicare Management of the Centers for Medicare and Medicaid Services (CMS) requested this report from The Technology Assessment Program (TAP) at the Agency for Healthcare Research and Quality (AHRQ). AHRQ assigned this report to the following Evidence-based Practice Center: ECRI Institute EPC (Contract Number: 290-2007-10063).The purpose of this review is to provide information to CMS for consideration in HCPCS coding decisions. The review will facilitate CMS' evaluation of HCPCS coding for NPWT devices by providing CMS with relevant studies and information for consideration of coding changes, as required by the MIPPA legislation. CMS will use this review in its assessment of whether existing HCPCS codes adequately represent the technology and comparative benefits of NPWT devices.

The EPC Program of AHRQ contracts with organizations to perform scientific reviews of a variety of topics. The ECRI Institute EPC is one of four EPCs with a focus on assessments for CMS.

The process of systematic review as practiced by the EPC Program follows specific prescribed steps:

1. The investigators start with formulated "key" questions. These questions test hypotheses and are structured using the "PICO" framework: patients, intervention of interest, comparator, and outcomes. EPC are encouraged to focus on outcomes that are relevant and important to patients (patient-oriented outcomes). The framework is depicted visually in the "analytic framework" that the EPC program uses to show the relationship between the key questions and the outcomes used to address these questions. (See Figure 3.)
2. Inclusion and exclusion criteria for studies to be used in the review are determined based on the specific questions to be addressed. Criteria may vary for each question in the review.
3. Next, an objective and comprehensive search of the medical literature and "gray literature," (i.e., reports, monographs and studies produced by government agencies, educational facilities and corporations that do not appear in the peer-reviewed literature) is conducted. The reference lists of included studies are examined for any studies not identified by electronic searches.
4. Studies are compared to the inclusion criteria developed prior to examining the evidence, and those included in the review are then critically appraised, noting features of the design and conduct of the studies that create potential for bias. Bias, in this context, is a study feature that could impact whether the treatment being studied is responsible for the outcomes observed. Studies with a low potential for bias are typically described as being of "high quality," whereas those with high potential for bias are described as being of "low" or "poor" quality, and those of moderate quality as having intermediate potential for bias. The degree to which a study protects against bias is referred to as "internal validity." Following this appraisal, data are extracted from the included studies and analyzed or summarized as appropriate.

The following is a detailed explanation of the methods followed in this review.

Key Questions

1. After receiving the work assignment for this review in December, 2008, we developed the following Key Questions *Does any single NPWT system have a significant therapeutic distinction in terms of wound healing outcomes compared to any other NPWT system for the treatment of acute or chronic wounds?*
2. *Does any component of a NPWT system have a significant therapeutic distinction in terms of wound healing outcomes compared to any other similar component of a NPWT system for the treatment of acute or chronic wounds?*
3. *What are the reported occurrences of pain, bleeding, infection, other complications, and mortality for NPWT systems?*
4. *Do patients being treated with one NPWT system have a significant therapeutic distinction in terms of less pain, bleeding, infection, other complications, or mortality than other NPWT systems?*

For the purpose of addressing these Key Questions we will use the following definitions:

- Any NPWT system or component commercially marketed within the past 20 years will be considered in this report. Restricting inclusion to currently commercially available NPWT systems would eliminate research performed with devices that have been discontinued as new models replaced them. In-house developed/produced/created/built devices (what might be considered "home-made" negative pressure devices) were excluded.
- Components of a NPWT system include the pump, the tubing, the dressing kits, and the services (education, clinical care, special treatment protocols, staff intervention, clinical support, etc.) provided as part of the NPWT system.
- Acute wounds: present for $\leq$30 days
- Chronic wounds: present for >30 days

This report also provides an overview of the clinical research evaluating NPWT systems. However, this report does not address whether NPWT systems provide a better wound care alternative compared to non-NPWT wound care therapies.

Analytic Framework

The analytic framework below (Figure 3) graphically depicts the events that individuals with chronic or acute wounds experience as they are treated with negative pressure wound therapy. This figure portrays the pathway of events that patients experience, starting from when they are first identified (the far left of the figure), to the treatments they receive, and to patient-oriented outcomes. As such, patients in the population of interest are identified and "enter" the pathway at the left of the figure. Each of the questions is represented in the framework by a circled number.

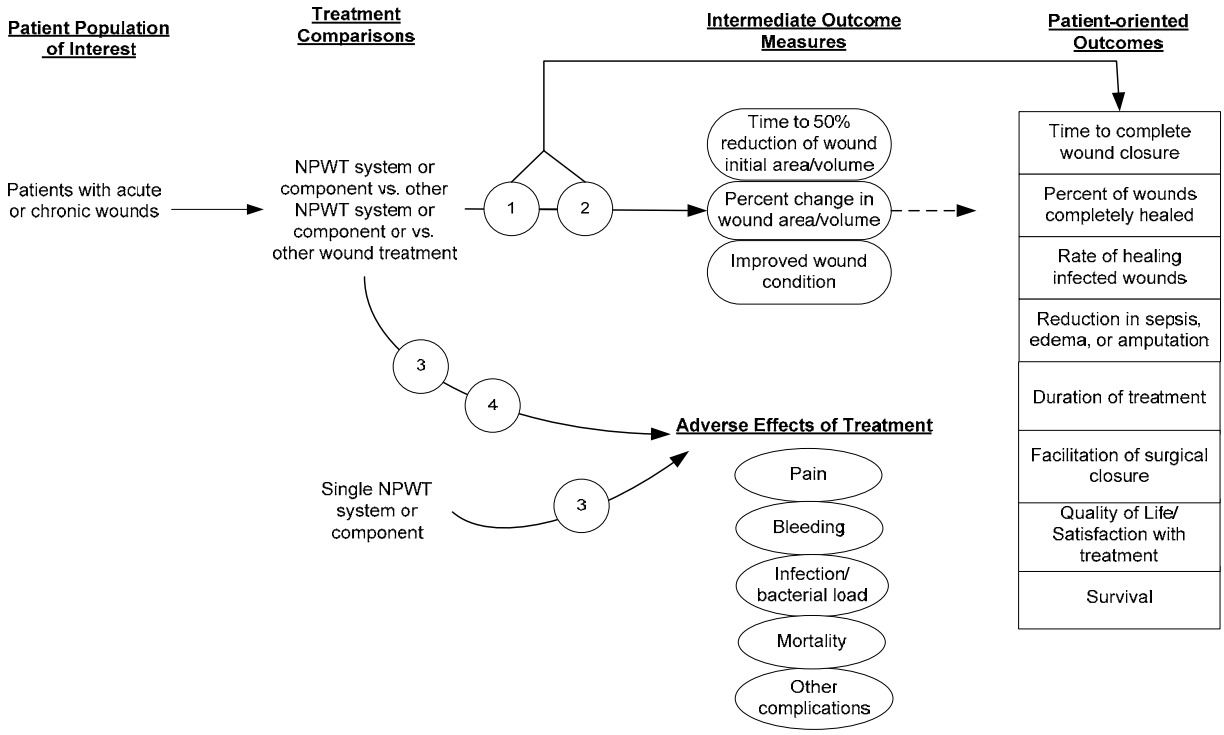
According to a guidance document prepared by the FDA in 2006, clinical outcomes associated with the use of a wound-treatment product or device can be broadly grouped into two

categories—improved wound healing and improved wound care.(61) A number of outcomes or endpoints fall into these two categories. The most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete wound healing. The FDA defines complete wound healing as skin closure without drainage or dressing requirements.(61) Facilitation of surgical wound closure by partial healing is also a clinically important measure of improved wound healing.

Improvements in wound care can potentially reduce the occurrence of conditions, such as infection, that can interfere with proper wound healing.(61) Thus, measuring the impact of NPWT on the occurrence or healing of infections, as well as its impact on the incidence of other problems, such as sepsis, edema, or amputation, is important. We consider all of these outcomes in our evaluation of the evidence and the claim of significant therapeutic distinction. In addition to these outcomes, we consider other outcomes important to patients, such as quality of life, satisfaction with treatment, duration of treatment, and survival. (Note: process indicators such as improved compliance, convenience and personal preference (and patient-oriented outcomes such as quality of life or satisfaction with treatment) are considered by CMS to be significant distinctions only to the extent that they result in demonstrably improved clinical outcomes.)

In some cases, wound healing technologies are not expected to result in complete wound closure. Rather, the treatment may be intended to advance the wound to a stage where healing is possible. We consider these goals to represent intermediate treatment outcomes. If the overall treatment strategy is successful, the benefit of these intermediate treatment outcomes will be reflected in improved rates of complete healing. Intermediate outcome states are represented by the following outcomes: time to 50% reduction of wound volume, percent change in wound volume, and improved wound condition. Outcome assessment should also include measurement of adverse events that result from the treatment or natural history of the disorder. We consider adverse events in Key Questions 3 and 4. The adverse events include: pain, bleeding, infection/bacterial load, mortality, and other complications.

Figure 3. Analytic Framework



Note:

- In keeping with guidance provided by the FDA, in this report we considered improved wound healing and improved wound care to be the most important clinical outcomes. The most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete healing (particularly when NPWT is used to prepare the wound for surgical closure). Please note: process indicators such as improved compliance, convenience and personal preference (and patient oriented outcomes such as quality of life or satisfaction with treatment) are considered by CMS to be significant distinctions only to the extent that they result in demonstrably improved clinical outcomes.
- Improved wound condition as presented in the Analytic Framework is defined as a reduction in wound exudate andinfectious materials; the promotion of granulation tissue formation and perfusion; an improvement in graft appearance; a reduction in odor; and a greater rate of epithelialization.

Inclusion Criteria

We used the following criteria to determine which studies identified by our searches and submitted by invited manufacturers and professional organizations would be included in our analysis. These criteria were developed prior to any review of the clinical literature or materials sent by interested parties. Inclusion and exclusion criteria were developed to specify the types of studies appropriate for addressing each of the Key Questions.

Population

1. *Results for patients with different wound etiologies (diabetic ulcers, pressure wounds, vascular ulcers, surgical wounds, trauma wounds, etc.) must be reported separately.*
   Time to heal and the frequency and characteristics of adverse events can be expected to vary depending on the underlying cause of the wounds.

2. *Study must have enrolled human subjects.*
   Studies of animals are outside the scope of this assessment. Evidence-based reports, for the purpose of policy or clinical decision making, rarely rely on non-clinical evidence (studies using animals, cell culture, cadavers, etc.) to address the effectiveness of treatments. While animal studies may lead to important discoveries that ultimately prove valuable in human applications, experts have cautioned that fewer than a third of highly-cited animal studies translate into human RCTs showing the same results of treatment.(62) Animal studies also seldom use study design procedures such as randomization, concealment of allocation, and blinding of outcome assessment that would limit the potential forbias.(63) Publication bias, the preferential publication of studies with positive results, may be especially common with animal studies.(64) In addition, positive results in animal studies may not translate well to the clinical setting. Investigators can control the severity of the wound in animals to a greater extent than in human studies. Animal subjects are likely to be younger and healthier than humans with wounds. Animals in such studies may not have co-morbid health conditions or exposure to concurrent medical interventions, in contrast to human subjects with wounds. An additional problem with animal studies of wound healing is determining which of the human wound etiologies (pressure ulcers, diabetic foot ulcers, venous leg ulcers, burns, sternal wound infections, or trauma-induced wounds) the animal model represents..

Intervention

3. *Study must evaluate the efficacy and/or safety of a NPWT system or components of an NPWT system commercially marketed within the past 20 years.*
   In-house developed/produced/created/built devices (what might be considered “home-made” negative pressure devices) are outside the scope of this assessment.

Study Design

4. *Studies must have included five or more patients per treatment group.*
   The results of smaller studies and especially case reports are often not applicable to the general population.

5. *For Key Question 1, 2, and 4, study must have been a controlled study comparing one NPWT system or components of a system to another NPWT system or components.*
   Randomization to a NPWT system group was not required. For Key Question 2, studies were required that compared different dressing sets, tubing, or pumps while maintaining identical components for the other parts of an NPWT system. In other words, both groups in the study would need to be receiving NPWT. For Key Question 3, no control group was required, because the focus of the question was simply to identify adverse events rather than compare rates across systems or components. However, because of the potential for bias in case series studies, no analyses were performed using adverse event data from these studies.

6. *If a study employed a cross-over design, data from the second half of the study were excluded*. Because there may be a lingering treatment effect from the first treatment applied, we exclude data from the second half of cross-over trials. Studies that did not report data from the two different periods separately were excluded.

Outcomes

7. *The reliability and validity of all instruments measuring relevant outcomes such as quality of life or pain must have been addressed in the published literature.*
   However, if a study did not use a validated instrument, then the entire study was not necessarily excluded for all outcomes—only its data from instruments in which the psychometric properties were not reported in the published literature were excluded.
8. *Study must have reported on at least one of the outcomes of interest for one or more of the Key Questions.*
9. *For all outcomes, we only considered time points for which at least 50% of the enrolled participants contributed data.*

Publication Type

10. *Study must have been published in English.*
    Moher et al. have demonstrated that exclusion of non-English language studies from meta-analyses has little impact on the conclusions drawn.(65) Juni et al. found that non-English studies typically were of lower methodological quality and that excluding them had little effect on effect size estimates in the majority of meta-analyses they examined.(66) Although we recognize that in some situations exclusion of non-English studies could lead to bias, we believe that the few instances in which this may occur do not justify the time and cost typically necessary for translation of studies to identify those of acceptable quality for inclusion in our reviews.
11. *Study was reported as a full-length article. Abstracts were only considered if they contained new or previously unreported data from a published full article.*
    Published abstracts and letters alone do not include sufficient details about experimental methods to permit verification and evaluation of study design.(67,68) We only included data from an abstract if it reported additional outcomes from a study and patient group that had been reported in a full-length article that met all inclusion criteria.(69) For this report, publication also includes non-confidential transmission of a study report to ECRI Institute or non-confidential information on a study with sufficient detail to permit an evaluation of the study.
12. *When several sequential reports from the same study center were available, we included outcome data from only the largest, most recent or most complete report. However, we used relevant data from earlier and smaller reports if the report presented pertinent data not presented in the larger, more recent report.*
    This criterion prevents double-counting of patients.

Table 13 in Appendix A lists the reasons for exclusion for all excluded studies and retrieved documents.

Search Strategy

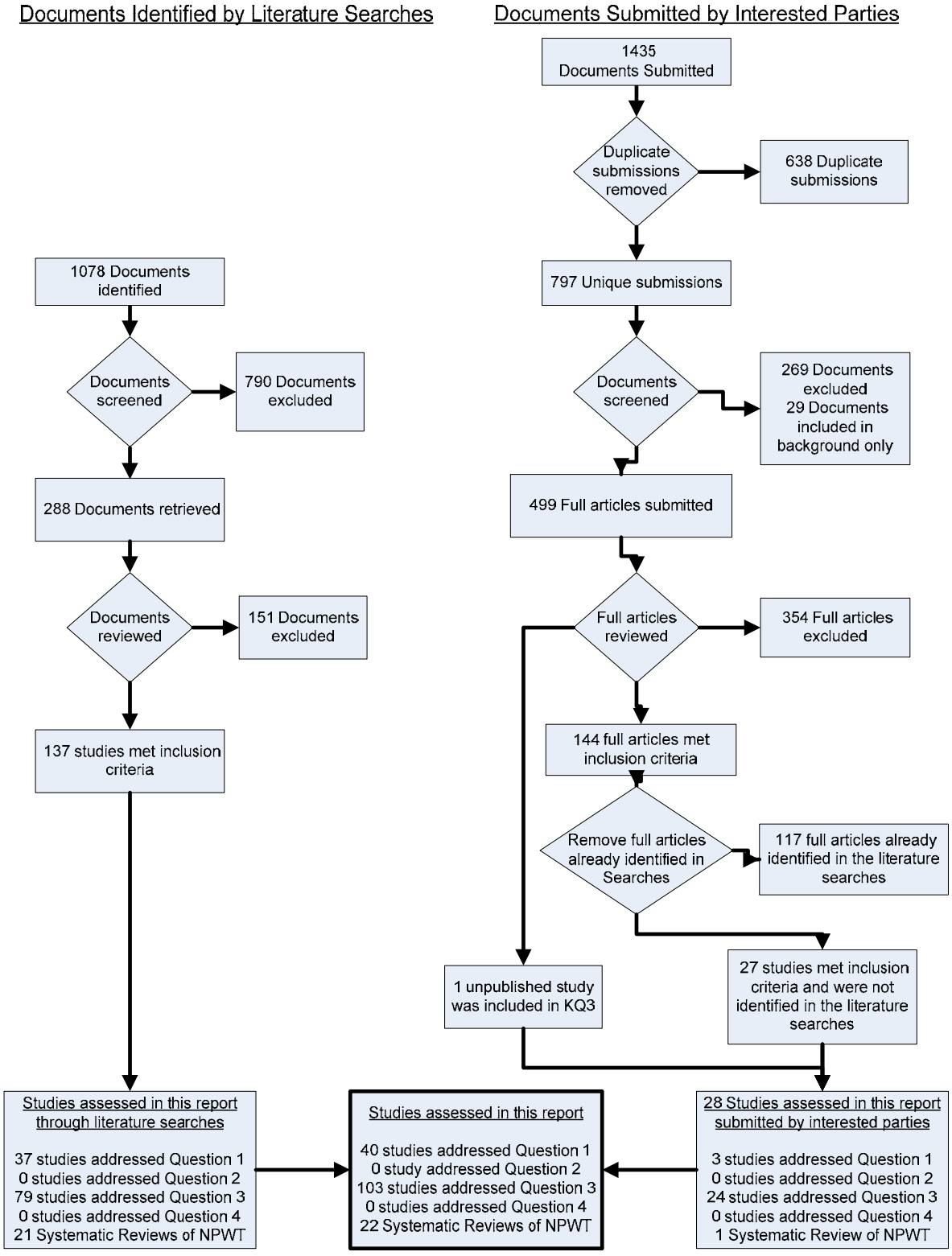
To identify relevant information on the benefits and harms of NPWT systems, we employed the following search strategies:

- Systematic search of 13 external and internal electronic databases, including CINAHL, EMBASE, and MEDLINE from 1950 (MEDLINE)/1980 (EMBASE)/1982 (CINAHL) to the present for fully published primary clinical studies. A detailed search strategy is presented in Appendix A. Articles were retrieved for further review if they 1) evaluated the efficacy and/or harms of an NPWT system or components of a system; 2) reported outcomes for human patients; and 3) were published in English. Excluded from further consideration were animal studies, cell culture studies, and studies that focused on the mechanisms of NPWT. Also excluded were editorials, letters, comments, and meeting/poster abstracts. We only considered abstracts if they contained new or previously unreported data from a published full article. See Appendix A for a full explanation of our electronic database search.
- Systematic search of the following databases unlimited by date for secondary publications (e.g., systematic reviews, Health Technology Assessments): The Cochrane Database of Systematic Reviews (Cochrane Reviews), Database of Abstracts of Reviews of Effects (DARE), and Health Technology Assessment and Database (HTA).
- Search for additional published and unpublished studies, which included the following steps:
    - Manual search of bibliographies listed in fully published studies
    - Search and written inquiry to regulatory agencies, including the U.S. Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS)
    - Search of http://clinicaltrials.gov and http://www.controlled trials.com for ongoing clinical trials
- In the interest of being certain that our searches identified all relevant studies, we invited manufacturers and professional organizations to submit the following (see Appendix A for a list of all organizations contacted):
    - A current product label (requested of industry stakeholders only)
    - Published randomized controlled trials, observational studies, or other compelling clinical evidence that uses NPWT devices to impact relevant clinical outcomes
    - Unpublished randomized controlled trials, observational studies, or other compelling clinical evidence that examined the use of NPWT devices to impact relevant clinical outcomes.

The materials received were then assessed against the a priori inclusion criteria for each Key Question. Over 1,400 individual items were submitted by interested stakeholders for possible inclusion in the report. All items were reviewed for their relevance to the key questions. None of the submissions were studies directly comparing different NPWT devices or systems. We identified one additional systematic review,(70) two comparison studies evaluating NPWT vs.

a comparator treatment,(71,72) and 23 uncontrolled case series(73-95) that met the inclusion criteria for consideration but which had not been identified by our searches. In addition, we included one unpublished case series submitted by Smith and Nephew(96) giving us a total of 24 additional case series included in this report. Figure 4 is an attrition diagram that provides a visualization of the disposition of materials as they were evaluated for possible inclusion in the report.

Figure 4. Disposition of Documents Identified by Internal Searches and Outside Submissions



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

The most common reasons for exclusion of submitted materials were

- personal statements of support for specific NPWT systems that did not include data relevant to this review
- animal studies
- studies not relevant to negative pressure wound therapy
- narrative reviews
- poster presentations
- case studies (fewer than five patients)
- publications that duplicated an already included study

A listing of individual stakeholders with included and excluded submissions including reasons for exclusion are provided in Appendix D.

Study Quality Assessment

After determining which of the publications identified in our searches and materials submitted by interested parties met the inclusion criteria for this report, we assessed the potential for bias in these studies. The potential for bias in each study was assessed using a quality assessment instrument developed by ECRI Institute for comparative studies.

A poorly designed study may contain biases with the potential to artificially alter how effective a technology appears to be. In this sense, a bias is an error introduced into sampling or testing. In well-constructed studies, biases are minimized by design and conduct, and changes in outcomes and differences in outcomes between groups are definitively attributed to the treatment of interest. For these reasons, high-quality studies are ones in which study design and conduct eliminate or greatly reduce the potential for bias. The degree to which a study protects against bias is referred to as "internal validity." Evaluating study quality is a means of assessing the risk that bias, whether systematic or nonsystematic, has obscured the true treatment effect of the interventions under study and lowered the study's internal validity. Assessing study quality is therefore an essential part of making judgments about the overall strength of a body of evidence that addresses a key question.

To aid in assessing the quality of each of the studies included in this report, we used the quality assessment instruments developed by ECRI Institute for comparative studies as shown in Appendix B. Studies that did not meet the inclusion criteria were not assessed for quality. The ECRI Institute instrument examines different factors of study design that have the potential to reduce the validity of the conclusions that can be drawn from a study. In brief, the tool was designed so that a study attribute that, in theory, protects a study from bias receives a "Yes" response. If the study clearly does not contain that attribute it receives a "No" response. If poor reporting precludes assigning a "Yes" or "No" response for an attribute, then "NR" is recorded (NR = not reported).

To estimate the quality of an individual study, we computed a normalized score so that a perfect study received a score of 10, a study for which the answers to all items was "No" received a score of 0, and a study for which the answers to all questions was "NR" was 5.0. We then classified the overall quality of the evidence base by taking the median quality score. Quality

scores were converted to categories as shown in Table 4 below. Studies with a low potential for bias are typically described as being of "high quality," whereas those with high potential for bias are described as being of "low" or "poor" quality, and those of moderate quality as having intermediate potential for bias.

Table 4. Study Quality Categories by Overall Quality of Evidence Base

	Low	Moderate	High
Median Overall Quality Score of the evidence base	≤6.0	>6.0 but <8.5	≥8.5

Data Synthesis

The most appropriate study to address Key Questions 1, 2, and 4 is one that would directly compare the efficacy and/or safety of one NPWT system or components of a system to another NPWT system or its components. If the evidence base included two or more studies comparing one NPWT system to another, and when 75% or more of the available study data for an outcome could have been used in this analysis, we would have attempted to reach a quantitative conclusion using a random-effects meta-analysis and calculated a summary effect size estimate. Meta-analysis is a statistical technique that can be used to maximize the information obtained from the available evidence. Sometimes, individual studies are too small to determine even the direction of a possible effect. Using well-developed techniques, meta-analysis involves an efficient pooling of the data to possibly enable an evidence-based conclusion. Studies are not weighted equally, but instead larger studies tend to be weighted more heavily due to the increased precision of effect size estimates. An effect size is a measure of the size of a relationship between two treatments and is usually expressed as the difference between treatment results or as the ratio of treatment results. In a random-effects meta-analysis the study weights are determined not only by within-study variation, but also by between-study variation (which is also referred to as heterogeneity).(97)

If applicable, heterogeneity would have been assessed using the I^2 statistic, with an I^2 greater than or equal to 50% as evidence of substantial heterogeneity among study results.(97,98) Substantial heterogeneity among studies may have indicated that the studies being pooled are measuring different treatment effects. If at least five studies were used in a meta-analysis, we would have performed a meta-regression in an attempt to explain the heterogeneity using the permutation test p-value as described by Higgins and Thompson.(99) The following variables would have been used in a meta-regression: size of wound, duration of wound, patient comorbidities, use of ancillary treatments, and intensity of treatment. We would have attempted to obtain a quantitative summary effect estimate from an evidence base with unexplained heterogeneity. Individual studies may have undue influence in a meta-analysis and may be the sole reason a summary effect size is significant. Therefore, we would have tested homogeneous meta-analyses for robustness and the influence of single studies by the removal and replacement of each separate study, and by performing cumulative meta-analysis by publication date.

In the event that a quantitative conclusion were not possible, we would have entered all available data into a random effects meta-analysis to determine the robustness of a qualitative (i.e., direction of effect) conclusion. We would have performed the same sensitivity analyses as described above (removal of individual studies and performing cumulative meta-analysis). The data would have been considered robust if the summary effect size remained statistically

significant and the direction of the effect size did not change (go from positive to negative or negative to positive) during the analysis.

In keeping with the methods of the EPC Program, we would have performed "adjusted indirect comparisons" if no studies directly comparing NPWT systems or components of a system were available.(100,101) In adjusted indirect comparisons, the comparison of the intervention of interest (i.e., different NPWT systems) would have been adjusted by the results of their direct comparison with a common control group (e.g., standard wound therapy).(102) The validity of an adjusted indirect comparison depends on the internal validity and similarity of the included trials. Thus, to be considered for inclusion in an indirect comparison, studies would have been similar in terms of quality, similar for factors related to applicability (population, interventions, and settings), and similar in measurement of outcomes including the incidence of adverse events.(102-105)

Evidence for indirect comparisons would have been obtained from randomized controlled trials (RCTs) of NPWT systems versus a common comparator. Evidence from non-randomized studies would not have been considered because indirect analyses are only recommended when RCTs are available. Non-randomized controlled trials may lead to biased estimates of treatment effects due to differences in baseline characteristics between groups within different studies. Even when patient characteristics are similar, other aspects of non-randomized controlled trials may vary, such as use of ancillary treatments, other aspects of patient care, or application of the actual intervention.(102) Even when RCTs are available for indirect comparisons, the conclusions must be framed cautiously because of the difficulty in assuring that the trial features are truly similar enough.

The validity of an adjusted indirect comparison depends on the internal validity and similarity of the included trials.(102) Thus, to be considered for inclusion in an indirect comparison, studies would have provided sufficient information to determine their comparability in terms of patient characteristics, patient exclusion/inclusion criteria, methodological quality, outcome definitions, outcome measures, and methods used in the comparison condition. Patients in studies on NPWT would have been similar in terms of age, comorbidities, use of ancillary treatments, type of wound, and severity of wound. The comparator condition would have been similar in terms of products (e.g., dressings), dosage, frequency of administration, and method of application. The studies considered in an indirect comparison would also have been similar with regard to important methodological criteria, such as concealment of allocation, proper randomization, blinding, follow-up times, and completion rates. In an attempt to locate appropriate studies to include in an indirect comparison, we abstracted and catalogued all relevant data from full-length controlled trials on NPWT systems. These data are reported in Appendix C.

Results

Key Question 1: Does any single NPWT system have a significant therapeutic distinction in terms of wound healing outcomes compared to any other NPWT system for the treatment of acute or chronic wounds?

Based on our defined search strategies (see Appendix A) and submissions from interested parties (Appendix D), no studies comparing one NPWT system to another NPWT system were identified that addressed this Key Question.

Quantitative Synthesis of the Evidence Base

Due to the lack of studies that directly compared the efficacy and safety of one NPWT system to another NPWT system, we were unable to perform a quantitative synthesis to determine whether one system has any significant therapeutic distinction over another.

Qualitative Synthesis of the Evidence Base

For the same reasons listed above for quantitative synthesis, no qualitative synthesis was possible.

Was an indirect comparison possible?

Based on our pre-determined methodology, evidence for indirect comparisons was to be obtained from RCTs of commercially available NPWT systems versus a common comparator. Of 40 studies comparing a NPWT system to another wound care therapy, all were studies of the Kinetics Concepts Inc. (KCI) V.A.C.® system and only nine were RCTs. Therefore no indirect comparisons with other NPWT systems were possible.

In order to determine whether we could form evidence-based conclusions using methods of indirect comparison, we tabled important information from studies that compared NPWT to other wound therapies. Our systematic search of the literature, together with the submissions provided by manufacturers, identified 40 controlled studies comparing NPWT to other wound treatments. The material submitted by manufacturers contained two comparison studies involving NPWT systems that were not identified in our searches.(71,72) During the review process of the report, we also identified one additional comparison study of interest.(106) None of the submitted materials contained unpublished comparison studies with sufficient information to be included in this report. All of the identified studies evaluated the V.A.C.® Therapy system (KCI) in comparison to other wound therapies. Thus, we were unable to perform any indirect comparisons.

Despite the fact that we could not use the studies to answer the Key Question, we assessed the comparison studies for risk of bias and extracted data on treatment procedures, patient characteristics, wound types, comparator treatments, and study outcomes. We have provided tables with this information in Appendix C for the interested reader, and briefly discuss these studies here. The overall quality of the evidence base of 40 studies was considered low (significant potential for bias) based on a median quality score of 4.32 (see Study Quality Assessment in Methods Section). None of the studies received a high-quality rating; seven (18%) were rated moderate, and 33 (82%) were rated low. Typical study limitations included lack of concealment of treatment allocation, lack of blinding patients and assessors, lack of reporting patient characteristics, and small study populations.

Blinding patients, treating physicians and outcome assessors to treatment increases the internal validity of intervention studies. In a situation where patients are being treated by NPWT systems, blinding the patient and the physician providing care is not feasible. To prevail over these limitations, van den Boogaard et al.(107) recommend overcoming all other potential shortcomings, i.e., wound assessors should be blinded to treatment, patient groups must be comparable, group allocation should be concealed, and full follow-up of a sufficient portion of all included patients should be performed.

None of the studies that we assessed reported that the physicians were blinded to treatment assignment, and only five (12%) of the studies reported blinding of outcome assessors. In only 7% of studies was there concealment of allocation to treatment. Only 14 (35%) studies had similar populations (i.e., wound size, wound severity and comorbidities), and 30% of the studies did not have similar follow-up times. Over 75% of the studies either reported a potential conflict of interest in terms of funding (k = 9) or made no report of their funding source (k =22). Lastly, over 50% of the studies had a study size of fewer than 50 patients, in 85% of the studies there were fewer than 75 patients. Assessments of all included comparison studies can be found in Appendix B.

The seven moderate quality studies evaluated the use of the V.A.C.® system in the treatment of diabetic foot ulcers,(108,109) pressure ulcers,(110) chronic leg ulcers,(111) and wounds with mixed etiologies.(112-114) Two studies evaluated the use of the V.A.C.® system to secure split-thickness skin grafts.(112,115) Comparators included bolster dressings,(112) standard of care,(113) the Healthpoint System of topical gel products,(110) and advanced moist wound therapy (i.e., hydrogels, hydrocolloids, or alginates).(108,109,111,114) Primary endpoints included measures of wound reduction or time to complete wound healing.

Four studies concluded that the V.A.C.® system provided additional benefit when compared to other interventional treatments.(108,110,113,115) Vuerstaek et al.(115) evaluated 60 patients with chronic leg ulcers (venous, atherosclerotic, or mixed etiologies) randomized to treatment by V.A.C.® or alginate/hydrocolloids. Time to complete healing was significantly reduced in the V.A.C.® group: 29 days (95% CI: 25.5 to 32.5) versus 45 days (95% CI: 36.2 to 53.8). Results for secondary outcomes included a greater relapse at one-year followup (52% of all healed V.A.C.® ulcers relapsed compared with 42% in the control group). Both groups reported significant increases in quality of life and similar decreases in pain.

One moderate-quality study of 342 diabetic foot wounds,(108) reported a mean change in wound size in favor of the V.A.C.® system (-4.32 cm^2 versus -2.53 cm^2, p = 0.021), as well as a higher proportion of V.A.C.®-treated wounds achieving complete closure (43% vs. 28.9%). Data, however, were only reported for day 28 during the “active treatment phase,” whereas both three and nine month follow-up assessments were completed for patients achieving ulcer closure. This study reported the highest attrition rate (over 30%) of any controlled study; 40 patients (13% V.A.C.® due to adverse events).

Ford et al. reported increased rates of pressure ulcer wound healing, superiority in decreasing inflammation at the wound site, and increased number of capillaries (suggesting the promotion of formation of granulation tissue) for the V.A.C.® system compared to the Healthpoint System (HP).(110) The HP system includes three gel products: Accuzyme (papain-urea debridement ointment), Iodosorb (0.9% cadexomer iodine) and Panafil (papain-urea, chlorophyllin, and copper ointment). However, in this interim report of the six-week study, complete wound healing

was reported for only four wounds: two (10%) with V.A.C.® and two (13%) with the HP products. In a similar length study, Joseph et al.(113) studied 24 patients with 36 chronic non-healing wounds (79% pressure ulcers). Average initial wound volume was larger for V.A.C.® wounds (38 cubic centimeters (cc) vs 24 cc), however, a significant reduction in wound volume was still demonstrated (78% vs 30% control). A significantly greater reduction in wound depth (66% vs. 20% control; p = 0.00001) and width was reported; however, improvement in width, depth, and volume did not extrapolate to wound length (p = 0.38).

Three studies concluded a comparable benefit in comparisons of the V.A.C.® to control treatments.(109,112,114) Moisidis et al.(112) enrolled 22 patients (used as their own controls) with wounds clinically ready for skin graft. At two weeks, a quantitative assessment by a clinician blinded to treatment reported no significant difference in degree of epithelialization. A greater degree of epithelialization was reported in six cases (30%), the same degree in nine cases (45%), and less epithelialization in five cases (25%) of V.A.C.® versus control-treated wounds.

Armstrong et al.(109) reported results of a post hoc analysis of their 16-week study of 164 diabetic foot amputation wounds. Results for this evaluation of the impact of wound chronicity indicated no significant difference for proportion of acute (<30 days, 75% of study patients) and chronic (>30 days, 25% of the study population) wounds achieving complete wound closure (acute $p = 0.072$, chronic $p = 0.320$) between NPWT and control groups. However, the authors found improved time to complete healing with NPWT compared to control treatments for both acute and chronic wounds.

Braakenburg et al.(114) evaluated 65 patients with chronic and acute wounds. Similar results were reported for overall change in wound area ($0.1 cm^2$/day), time to satisfactory healing (median 16 days (V.A.C.® vs. 20 days [control]) and overall change in the amount of granulation.

For further information on comparison studies evaluating V.AC.® to other treatments for acute and chronic wounds, please see Appendix C.

Key Question 2: Does any component of a NPWT system have a significant therapeutic distinction compared to any other similar component of a NPWT system for the treatment of acute or chronic wounds?

Our searches did not identify any studies comparing one NPWT system component to another NPWT system component (with both groups receiving negative pressure treatment) that addressed this Key Question. No published on unpublished studies of this design were submitted by interested parties. This question was designed to examine studies that compared different dressing sets, tubing, or pumps while maintaining identical components for the other parts of an NPWT system.

We did identify one study that compared the V.A.C.® Therapy system (KCI) to an alternative form of negative pressure using vacuum bottles while using the same foam dressing set. This study is briefly described here.(116) In this study, Wild et al.randomized ten patients with Grade III and Grade IV pressure ulcers to the V.A.C.® Therapy system (KCI) or the Redon drain/vacuum group (P.J. Dahlhausen & Co. GmbH, Cologne, Germany). All patients were treated with the same GranuFoam®(KCI) dressings. V.A.C.®-treated wounds received negative pressure (-125 mmHg) therapy by a computerized controlled therapy unit. A typical maximum treatment pressure for the NPWT devices currently cleared for marketing in the U.S. is -200 mmHg. Wounds in the control group received uncontrolled negative pressure (-900 mmHg) by a non-powered Redon vacuum bottle.

Primary endpoints for the study included absolute and relative proportion of the wound area consisting of granulation tissue, fibrin deposits and necrosis. Results indicated that V.A.C.® was more effective than the Redon vacuum bottles in terms of change in surface granulation tissue (increase of 54% versus decrease of 7.1%, control; $p = 0.001$), presence of necrotic tissue (0.3% versus >10%, control), and change in fibrin tissue (decrease of 27% versus increase of 21.8%, control; $p = 0.035$).The study was terminated at day nine due to the large disparity in outcomes between treatment groups, and the added care needed for the Redon group. The authors concluded that the non-powered vacuum bottle approach to applying negative pressure to a pressure ulcer was not appropriate.

Key Question 3: What are the reported occurrences of pain, bleeding, infection, other complications, and mortality for NPWT systems?

Adverse events were reported in 37 of 40 (92%) studies comparing NPWT to other treatments. Of the 37 studies reporting events, seven (19%) studies described NPWT as a safe treatment. Fewer complications were reported in the NPWT-treated patients than in those receiving other wound therapies in 19 (51%) studies(1,23,71,72,106,108,110,113,114,117-126) and similar complications were reported in 8 (22%) studies.(109,127-133) Most commonly reported adverse events included pain (k = 8), bleeding (k = 6), infection (k = 13), mortality (k = 10), and other complications (k = 17). Reports were similar for bleeding, infection, amputation, and other complications (i.e, fistulae). However, fewer secondary amputations (7 versus 17) were reported in NPWT groups (all studies reported using V.A.C.® system). Reports of adverse events for comparison studies can be found in the tables that follow.

Reports of adverse events described in systematic reviews can be found in Table 42 in Appendix C.

Table 5. Reports of Pain in Comparison Studies of NPWT Devices

Reference	Wound Type	Treatment	Number of Patient Reports (n)
Bickels et al.(134)	Soft tissue defects	V.A.C.®	No patients experienced substantial pain
	Soft tissue defects	SOC	No patients experienced substantial pain
Braakenburg et al.(114)	Acute and chronic	V.A.C.®	2 patients discontinued treatment due to pain during dressing change
	Acute and chronic	Conventional	NR
Denzinger et al.(135)	Complex inguinal	V.A.C.®	Not specifically quantified, however patients reported more pain with dressing change in V.A.C.® group
	Complex inguinal	SOC	Less pain reported than V.A.C.® group
Genecov et al.(131)	STSG	V.A.C.®	No difference in pain
	STSG	Control	No difference in pain
McCallon et al.(120)	DFU	V.A.C.®	Due to initial foam collapse and/or with foam removal; Number of patients NR
	DFU	Saline-moistened gauze	NR
Moues et al.(136)	Full-thickness	V.A.C.®	1 patient discontinued treatment due to ischaemic pain with increased tissue necrosis
	Full-thickness	Standard moist gauze	NR
Ozturk et al.(117)	Fournier's gangrene	V.A.C.®	Patients reported less pain when measured by Visual Analogue Scale (0-10, with higher numbers indicating more pain) Mean V.A.S. score: 2.4
	Fournier's gangrene	SOC	Mean V.A.S. score: 6.8
Vuerstaek et al.(115)	Chronic leg ulcers	V.A.C.®	3 complaints of pain reported as adverse events; mean pain scores decreased over time
	Chronic leg ulcers	Control	1 complaint of pain reported as adverse event; mean pain scores decreased over time

DFU Diabetic foot ulcer
NR Not reported
SOC Standard of care
STSG Split thickness skin graft
V.A.S. Visual analogue scale for pain

Table 6. Reports of Bleeding in Comparison Studies of NPWT Devices

Reference	Wound Type	Treatment	Number of Patients Reports (n)
McCallon et al.(120)	DFU	V.A.C.®	Granulation tissue growth into pores of the foam frequently resulted in minor capillary disruption upon V.A.C.® foam dressing removal.
	DFU	SOC	NR
Simek et al.(123)	Deep sternal	V.A.C.®	Intractable: 2.9%
	Deep sternal	Conventional	Intractable: 3.6%
Segers et al.(122)	PM	V.A.C.®	4
	PM	Closed drainage	4
Fuchs et al.(23)	Deep sternal	V.A.C.®	NR
	Deep sternal	Conventional	2 deaths due to bleeding
Bickels et al.(134)	Soft tissue	V.A.C.®	No patients had excessive bleeding
	Soft tissue	SOC	No patients had excessive bleeding
Vuerstaek et al.(115)	Chronic leg	V.A.C.®	0
	Chronic leg	Conventional (hyrocolloids, alginates)	2

NR Not reported

Table 7. Reports of Infection in Comparison Studies of NPWT Devices

Reference	Wound Type	Treatment	Number of Patient Reports (n)
Armstrong et al.(109)	Diabetic foot amputation	V.A.C.®	NR
	Diabetic foot amputation	SWT	2
Blume et al.(108)	DFU	V.A.C.®	Wound infection: 4 Cellulitis: 4 Osteomyelitis: 1 Staphylococcus: 1 Infected skin ulcer: 1
	DFU	AMWT	Wound infection: 1 Cellulitis: 1 Infected skin ulcer: 2
Ford et al.(110)	Pressure ulcer	V.A.C.®	Osteomyelitis confirmed in 13 wounds (treatment not confirmed)
	Pressure ulcer	Healthpoint System	Osteomyelitis confirmed in 13 wounds (treatment not confirmed)
Joseph et al.(113)	Pressure ulcer	V.A.C.®	Osteomyelitis - 1
	Pressure ulcer	Saline wet-to-moist	Osteomyelitis – 2 Wound infection - 6
Labler et al.(71)	Soft tissue	V.A.C.®	Infections resulting in non-union: 2 Infections: 1
	Soft tissue	Epigard® dressing	Infections resulting in non-union: 2
Moues et al.(136)	Full-thickness	V.A.C.®	4
	Full-thickness	Standard moist gauze	1
Rinker et al.(121)	Open tibia fracture	V.A.C.®	6% infectious complications
	Open tibia fracture	SOC	18% infectious complications
Song et al.(124)	Surgical	V.A.C.®	Mediastinitis - 1
	Surgical	SOC	Recurrent mediastinitis - 1
Segers et al.(122)	PM	V.A.C.®	Mortality caused by surgical site infection: 4 (13.8%)
	PM	Closed drainage	Mortality caused by surgical site infection: 7 (20.6%
Stannard et al.(125)	Hematoma	V.A.C.®	NR
	Hematoma	Pressure dressing	1 - late infection at site of hematoma
	Fracture	V.A.C.®	3
	Fracture	Post-operative dressing	3

Reference	Wound Type	Treatment	Number of Patient Reports (n)
Timmers et al.(106)	Post-traumatic osteomyelitis	NPIT	Recurrence of osteomyelitis – 3 (10%)
	Post-traumatic osteomyelitis	SOC	Recurrence of osteomyelitis – 55 (58.5%)
Vuerstaek et al.(115)	Chronic leg	V.A.C.®	0
	Chronic leg	Conventional (hyrocolloids, alginates)	1
Yang et al.(72)	Fasciotomy	V.A.C.®	None
	Fasciotomy	Saline wet-to-moist	Wound Infection – 1

AMWT Advanced moist wound therapy
DFU Diabetic foot ulcer
NPIT Negative pressure instillation therapy
NR Not reported
PM Post-sternotomy mediastinitis
SOC Standard of care
SWT Standard wound therapy

Table 8. Reports of Mortality in Comparison Studies of NPWT Devices

Reference	Wound Type	Treatment	Number of Patient Reports (n)
Blume et al.(108)	DFU	V.A.C.®	3
	DFU	AMWT	3
Braakenburg et al.(114)	Chronic and acute	V.A.C.®	3
	Chronic and acute	Hydrocolloid dressings, alginate, acetic acid or Eusol (sodium hypochlorite)	5
Catarino et al.(137)	Post-sternotomy mediastinitis	V.A.C.®	Due to pneumonia 5 months postoperative: 1
	Post-sternotomy mediastinitis	Closed drainage and irrigation	0
Doss et al.(128)	Post-sternotomy osteomyelitis	V.A.C.®	Hospital mortality: 1
	Post-sternotomy osteomyelitis	SOC	Hospital mortality: 1
Fuchs et al.(23)	Deep sternal	V.A.C.®	Death due to vacuum-related perforation: 1
	Deep sternal	Conventional	Death due to bleeding: 2 Death due to septic shock: 2
Huang et al.(127)	Limb	V.A.C.®	1
	Limb	SOC	1
Immer et al.(130)	Deep sternal wound infection	V.A.C.®	Multiorgan failure: 1
	Deep sternal wound infection	V.A.C.® plus excision plus musculocutaneous flap	NR
	Deep sternal wound infection	Excision plus musculocutaneous flap	Multiorgan failure: 1 Uncontrollable septicemia: 1
Segers et al.(122)	PM	V.A.C.®	9
	PM	Closed drainage	9
Song et al.(124)	Surgical	V.A.C.®	Death from aspiration pneumonia: 2 Death from multisystem organ failure: 1
	Surgical	SOC	Death from aspiration pneumonia: 1
Vuerstaek et al.(115)	Chronic leg	V.A.C.®	4
	Chronic leg	Conventional (hydrocolloids, alginates)	2

AMWT Advanced moist wound therapy
DFU Diabetic foot ulcer
NR Not reported
SOC Standard of care

Table 9. Reports of Other Complications in Comparison Studies of NPWT Devices

Reference	Wound Type	Treatment	Number of Patient Reports (n)
Armstrong et al.(109)	Diabetic foot amputation	V.A.C.®	Serious complication: 1
	Diabetic foot amputation	SWT	NR
Blume et al.(108)	DFU	V.A.C.®	Secondary amputations: 7 Edema: 5
	DFU	AMWT	Secondary amputations: 17 Edema: 7
Braakenburg et al.(114)	Acute and chronic	V.A.C.®	Early dismissal: 2 Refusal to cooperate: 1
	Acute and chronic	Conventional	Amputation: 1 Early dismissal: 6
Domkowski et al.(129)	Post-sternotomy mediastinitis	V.A.C.®	Multisystem organ failure: 2 Overwhelming sepsis: 2
	Post-sternotomy mediastinitis	Standard of care	NR
Huang et al.(127)	Limb	V.A.C.®	Above-knee amputation: 1 Below-knee amputation: 1
	Limb	SOC	Above-knee amputation: 2
Joseph et al.(113)	Pressure ulcer	V.A.C.®	Calcaneal fracture: 2 Amputation: 2
	Pressure ulcer	Saline wet-to-moist	Fistulae: 2
Labler et al.(71)	Soft tissue	V.A.C.®	Amputation:1
	Soft tissue	Epigard® dressing	Amputation: 2 (1 patient died 2 days later due to cardiovascular instability) Non-union without infection: 1
Moisidis et al.(112)	Clinically ready for skin graft	V.A.C.®	Difficulty in maintaining pressure: 3
	Clinically ready for skin graft	Bolster dressing	NR

Reference	Wound Type	Treatment	Number of Patient Reports (n)
Moues et al.(136)	Full thickness	V.A.C.®	Erosion of adjacent tissue due to increased local pressure: 1 Maceration/eczema: 2 Sudden increase in body temperature: 1 Postoperative complications after surgical closure: 32% Most notable postoperative complications: Abscess: 2 Fistula: 1 Total skin graft failure: 1
	Full thickness	Standard moist gauze	Allergic reaction to Furacine®: 2 Wound surface area increase: 3 Postoperative complications after surgical closure: 43% Most serious postoperative complications: Abscess: 1 Fistula: 1 Skin graft failure of 40%: 1
Rinker et al.(121)	Open tibia fracture	V.A.C.®	Overall complication rate: 35% Flap related complications: 12% Amputation: 1 (6%)
	Open tibia fracture	SOC	Overall complication rate: 53% Flap related complications: 21% Amputation: 2 (5%)
Schwein et al.(126)	Pressure Ulcer	V.A.C.®	Hospitalization for a wound-related problem: 3 (5%)
	Pressure Ulcer	Any other wound care modality	Hospitalization for a wound-related problem: 310 (14%)
Shilt et al.(138)	Traumatic	V.A.C.®	Patients requiring home nursing after discharge: 4
	Traumatic	Standard of care	NR
Siegel et al.(119)	Radiation-associated	V.A.C.®	Amputation:1 Mild discomfort: 3 Skin rash: 2 Itching: 3
	Radiation-associated	SOC	Above-knee amputation: 3 Hip disarticulation: 1
Simek et al.(123)	Deep sternal	V.A.C.®	Fistula: 14.7%
	Deep sternal	Conventional	Fistula: 10.7%

Reference	Wound Type	Treatment	Number of Patient Reports (n)
Sjogren et al.(139)	Post-sternotomy mediastinitis	V.A.C.®	Recurrent sternal fistulae: 4 (6.6%)
	Post-sternotomy mediastinitis	Conventional	Recurrent sternal fistulae: 2 (5%)
Song et al.(124)	Surgical	V.A.C.®	Chronically draining wound: 1
	Surgical	SOC	Chronically draining wound: 1 Omental flap losses: 2 Intestinal evisceration: 1 Hernia: 1
Stannard et al.(125)	Hematoma	V.A.C.®	NR
	Hematoma	Pressure dressing	NR
	Fracture	V.A.C.®	Delayed wound breakdown: 1
	Fracture	Post-operative dressing	Delayed wound breakdown: 1

AMWT Advanced moist wound therapy
DFU Diabetic foot ulcer
SOC Standard of care
SWT Standard wound therapy

For additional information on adverse events we identified 103 case series (studies with no control group) of NPWT. 24 of these studies had not been identified in our literature searches. Studies included chronic wounds (k = 48), acute wounds (k = 35) or mixed wounds (e.g., chronic and acute) (k = 20). We prepared four tables that summarize the data reported in these studies: patient characteristics, treatment details, outcomes reported, and adverse events (see Appendix C). The tables are organized by year (the most recent is first) and then by author, alphabetically. Ninety-five studies specified using the vacuum-assisted closure device manufactured by KCI.

The adverse events reported in these studies include pain (k = 12);(78,88,91,140-148) bleeding (k = 7);(79,142,147,149-152) infection or bacterial colonization (k = 15);(37,77,85,86,96,148-150,153-159) mortality (k = 4);(149-151,153) and other complications (k = 18).(95)

Table 10 lists the 18 studies that mentioned other complications, such as fistulae and skin blisters. Case series may report adverse events inconsistently. Some case series report all adverse events, while others report events the authors consider “serious.” If a study does not report a particular adverse event it still may have occurred unless the publication specifically states that the specific adverse event did not occur. Based on the inconsistencies of reporting for case series, we have not pooled the results to determine a rate of adverse event occurrence.

Table 10. Other Complications Reported in Case Studies

Reference	Other Complications
Chen et al. 2008(160)	Right ventricular rupture while a patient was being treated with vacuum-assisted closure dressing. The patient coughed excessively during early postoperative period, possibly resulting in sternal shear force being applied directly over the right ventricular wall[1]
Ha et al. 2008(140)	Dryness, sloughy wounds, and excoriation as reasons for discontinuing the use of the vacuum-assisted closure therapy[1]
Wondberg et al. 2008(161)	Fistulae, fascial edge necroses, skin blister, prolapses of small bowel between fascia and foam[1]
Baharestani et al. 2007(162)	Development of an enterocutaneous fistula during vacuum-assisted closure therapy[1]
Bendewald et al. 2007(82)	Significant skin irritation from the negative pressure wound therapy dressing material[1]
McCord et al. 2007(142)	Dermatitis or skin maceration from adhesive dressing[1]
Rao et al. 2007(163)	Intestinal fistulation during vacuum-assisted closure therapy[1]
Morgan et al. 2006(164)	Flap failure in a patient treated with vacuum-assisted closure therapy[1]. The system was set at 125 mmHg; authors stated that this pressure was probably too high for a flap
Butter et al. 2005(144)	Failure of wound closure after use of vacuum-assisted closure therapy and recurrent pilonidal sinuses
Caniano et al. 2005(165)	Retained sponge and device malfunction[1]
Heller et al. 2005(87)	Low-output small bowel enterocutaneous fistula[1]
Perez et al. 2007(95)	High-output enterocutaneous fistula[1]
Stone et al. 2004(90)	Abdominal abscesses and enterocutaneous fistula[1]
Gustafsson et al. 2003(146)	Minor air leakage requiring complementary draping[1]
Suliburk et al. 2003(166)	Vacuum assisted closure therapy[1] was discontinued as a result of fistulae that developed or as a result of poor fascia
Armstrong et al. 2002(85)	Periwound maceration, periwound cellulitis, and deep space infection[1]
De Lange et al. 2000(167)	Retention development, some developed septicemia, fistulae, local necrosis, chest wall dehiscence possibly caused by local air leakage[1].
Argenta and Morykwas 1997(148)	Fistula development when a foam dressing was placed directly over compromised intestine in a debilitated patient who had eviscerated[1].

[1] Device manufactured by KCI

Key Question 4: Do patients being treated with one NPWT system have a significant therapeutic distinction in terms of less pain, bleeding, infection, other complications, or mortality than other NPWT systems?

Our searches, as well as material provided by interested parties, did not identify any studies comparing one NPWT system to another NPWT system. Consequently, we were not able to answer this Key Question and we were not able to determine the severity of adverse events for one NPWT system compared to another.

Stakeholder Submissions

ECRI Institute invited NPWT device manufacturers and other interested stakeholders (i.e., wound care-related organizations) to submit relevant clinical materials for consideration in the report (Table 14). Specifically, we requested the submission of published or unpublished randomized controlled trials, observational studies or other compelling evidence that examined the use of NPWT devices or systems to impact relevant clinical outcomes. We were also interested in the submission of materials regarding any ongoing clinical trials.

We initially identified the following relevant clinical materials from the submissions that had not been identified in our searches: one systematic review,(70) two comparison studies,(71,72) and 23 single arm studies(73-95) for inclusion in this report. In addition, we included one unpublished case series submitted by Smith and Nephew(96) giving us a total of 24 additional case series included in this report.

During the review process of the report, we received nine submissions for possible inclusion in the report. Of these additional submissions, we included one nonrandomized comparison study(106) in this report. Counting this additional submission, three comparison studies which were previously not identified by ECRI were included in the report. For more information on submissions by individual stakeholders, please see Appendix D.

Previous Systematic Reviews

We identified a total of 22 systematic reviews, all published between 2000 and 2008, that covered Negative Pressure Wound Therapy (NPWT) devices. These reviews included studies reporting data on NPWT for patients with a broad range of wound types. The reviews also included information from studies assessing the comparative effectiveness of NPWT with other wound treatments. A majority of the studies included what were regarded as traditional treatment comparators or "standard of care." In addition, all of the reviews included additional interventions such as gel products, bolster dressings, hydrocolloids, and other topical treatments. All of the studies reported using the V.A.C.® system (KCI). None of the reviews included studies that compared one NPWT system to another. For more information about the conclusions drawn from these reviews, see Table 11.

The two earliest reviews (published in 2003) will not be discussed here.(168,169) The evidence base for ten of the 20 reviews published since 2004 focused strictly on comparison studies. The remaining reviews also included retrospective studies, case studies, and cost-effectiveness analyses, and one review included animal studies.(170) Further information about the reviews and individual studies included can be found in Table 39 and Table 40 in Appendix C, respectively.

Quality of the Systematic Reviews

We assessed the quality of each review using the Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool.(171) AMSTAR consists of 11 items used to assess whether or not a systematic review includes important elements, such as a comprehensive literature search, assessment of study quality, appropriate methods to combine study findings and assessment of publication bias. To rate the quality of the review, we have applied a rating of "High" if the review received at least 8 "yes" responses, and a rating of "Low" if the review received 8 or more "no" responses. Studies with mixed responses between these ranges were assigned a rating of "Moderate." Based on these criteria, we found that 12 of the 20 included reviews were of moderate quality. The remaining reviews were graded as high (3) or low (5). All of the high-quality reviews performed duplicate study selection, assessed the likelihood of publication bias, and indicated conflict of interest; three items typically omitted by other reviews. None of the low-quality reviews assessed the quality of included studies and only half performed a comprehensive literature search. Complete details of our quality assessment can be found in Table 41.

Findings of the Systematic Reviews

High Quality Reviews

None of the high-quality reviews concluded that NPWT provided additional benefit when compared to other interventional treatments.(172-174) The first high-quality review focused solely on treatment of burn wounds, and included only one small trial.(172) Twenty patients (serving as their own controls) were randomized to either a 48-hour treatment of topical negative pressure (TNP), a term used by the authors for NPWT, or silver sulphadiazine (SSD). Significant differences in favor of NPWT were reported at day 3 and day 5, however, no difference was reported at day 14. Shortcomings reported by study authors included absence of reporting clinically relevant outcomes and a limited description of randomization methods and allocation concealment.

The second high-quality review, included 17 comparison studies (ten RCTs) evaluating various wound types and reported a benefit to patients treated with NPWT for surrogate outcomes of wound healing.(173) Significant advantages in favor of NPWT were reported in four of seven studies reporting wound closure as well as a significantly faster rate of wound healing reported in one large RCT. Despite these favorable results, the authors concluded that the overall evidence was insufficient to clearly prove an additional clinical benefit of NPWT.

The remaining high-quality review included seven RCTs and concluded no significant benefit was shown in the treatment of chronic wounds with NPWT when compared to moistened gauze dressings or other topical agents. Small study populations, unclear allocation methods, and lack of blinding of outcome assessors were all indicated as methodological flaws in the NPWT literature.(174)

Moderate Quality Reviews

Five of twelve (42%) moderate-quality reviews concluded that NPWT was more effective than the control treatments.(175-178) One of these reviews focused only on patients with post-sternotomy mediastinitis (PM).(175) Two nonrandomized comparison studies included in this review evaluated overall survival and quality of life (QOL) as primary outcomes. The Health Survey Questionnaire given to patients in one study resulted in a significant difference in the QOL in favor of V.A.C.® therapy over sternum removal.(130) One study of 102 patients demonstrated overall survival in the V.A.C.® group as significantly higher than in the conventional treatment; 97% versus 84% (6 months), 93% versus 82% (one year) and 83% versus 59% (five years).(139) A larger retrospective study by the same authors(179) comparing 46 PM coronary artery bypass patients treated with V.A.C.® therapy to 4,781 coronary artery bypass patients without mediastinitis. Results from this trial, however, demonstrated V.A.C.® treated patients faring as well as the non-infected cohort with no significant differences found in early or late survival between the groups. Lastly, one review evaluated use of NPWT in the management of diabetic foot ulcers. Results from four RCTs indicated that NPWT was more effective than comparator treatments. The quality of the evidence was weak however and patient selection was limited to patients with sufficient blood supply which "*distorts the perceived clinical benefits of the therapy*."(70)

Two reviews concurred that NPWT appeared to be more effective than topical treatments in the management of skin grafts and soft tissue flaps.(176,177) Three studies,(124,131,132) covered in both reviews, reported that use of NPWT resulted in fewer tissue flaps per patient,(124,132) and improved reepithelialization.(132) Another review described the evidence as "tentative" for NPWT being as good as other therapies for some wounds. The authors reviewed a variety of studies of NPWT used for pressure ulcers, post-traumatic wounds, diabetic foot ulcers, venous and arterial leg ulcers, and mixed wound types and included 14 RCTs in their evaluation. Although NPWT appeared to be at least as effective as other wound treatments, the interpretation was "hampered by the diversity of the study designs and the methodological weaknesses in the studies."(178)

The remaining seven reviews reported either a comparable benefit or no benefit in comparison to control treatments.(25,107,180-184) A comparable benefit was seen for acute lower limb trauma and burn wounds in one review.(25) Positive outcomes for 34 patients with fasciotomy after tibial compartment syndrome included a statistically significant shorter time to closure compared to standard dressing. Patients with burn wounds benefited by NPWT treatment with less graft

loss and shorter hospital stay. Based on evidence from six comparison and several case series, the authors concluded that the effectiveness of NPWT was comparable to the standard dressing and wound coverage methods.

Mixed results were obtained by one reviewer focusing on treatment of pressure ulcer wounds with the Healthpoint System of topical wound treatments.(107) Two of five RCTs, only including patients with pressure ulcers, found no significant differences in wound healing. The remaining three studies, examining wounds with mixed etiologies, found a decrease of wound treatment time in favor of V.A.C.®. Study authors, however, caution the interpretation of these findings due to the lack of a subgroup analysis which is an essential component to studying effects of different interventions in patients with wounds of mixed etiology.

No benefit to treatment was seen by the remaining moderate-quality reviews. The largest review, published in 2007, assessed over 700 patients treated with six treatment methods. Based on the "newly available evidence" authors indicated that no clear statement about the clinical efficacy and safety of NPWT could be made.(180) Two reviews evaluated treatments for various wound types. One concluded no worthwhile evidence supported the use of NPWT,(183) while the other stated that the more credible evidence suggested no benefit from V.A.C.® therapy when compared to standard of care and OpSite dressings.(181)

A review of six RCTs based their recommendation on one highly rated RCT due to the poor quality ratings of the five other studies.(184) Patients with acute, surgical wounds from partial foot amputations were randomized to NPWT or standard care. In addition, some underwent surgical closure. The authors concluded that no statistically significant difference existed between NPWT and standard care in the rate of complete wound closure (patients had complete wound closure but did not undergo surgical wound closure).

Six RCTs qualified for inclusion in the final review; five of the included studies examined fewer than 25 patients.(182) No significant advantage was seen for NPWT on primary endpoints (i.e., complete healing) while varying results were found for secondary endpoints (i.e., QOL).

Table 11. Summary of Conclusions

Reference	Title	Authors' Conclusions	Study Quality Rating
Gregor et al. 2008(173)	*Negative Pressure Wound Therapy: A Vacuum of Evidence?*	Overall evidence was insufficient to clearly prove an additional clinical benefit of NPWT.	High-Quality Review
Ubbink et al. 2008(174)	*Topical negative pressure for treating chronic wounds*	No significant benefit was shown in the treatment of chronic wounds with NPWT when compared to moistened-gauze dressings or other topical agents.	High-Quality Review
Wasiak and Cleland 2007(172)	*Topical negative pressure (TNP) for partial thickness burns*	There is a paucity of high-quality RCTs on for partial-thickness burn injury, with insufficient sample size and adequate power to detect differences, if there are any, between NPWT and conventional burn wound therapy dressings.	High-Quality Review
Noble-Bell and Forbes 2008(70)	*A systematic review of the effectiveness of negative pressure wound therapy in the management of diabetes foot ulcers*	Although evidence from four RCTs indicated that NPWT is more effective than comparator treatments, study quality was weak to moderate.	Moderate-Quality Review
Schimmer et al. 2008(175)	*Management of post-sternotomy mediastinitis: experience and results of different therapy modalities*	Based on retrospective studies alone (no prospective randomized trials have been published), benefits to treatment of post-sternotomy mediastinitis with VAC included less treatment failure, shorter postoperative stay, lower rates of recurring infection, improved QOL, and an increase in overall survival. Prospective randomized controlled trials are needed.	Moderate-Quality Review
Ubbink et al. 2008(183)	*A systematic review of topical negative pressure therapy for acute and chronic wounds*	There is no worthwhile evidence to support the use of NPWT in the treatment of various wounds.	Moderate-Quality Review
van den Boogaard et al. 2008(107)	*The effectiveness of topical negative pressure in the treatment of pressure ulcers: a literature review*	Topical negative pressure wound therapy has not proven to be more effective than various control interventions.	Moderate-Quality Review

Reference	Title	Authors' Conclusions	Study Quality Rating
Vikatmaa et al. 2008(178)	*Negative Pressure Wound Therapy: a Systematic Review on Effectiveness and Safety*	NPWT appears to be a safe alternative treatment. There is tentative evidence that NPWT is at least as good as or better than current local treatment for wounds. However, there is a shortage of reliable research data on the effectiveness of NPWT	Moderate-Quality Review
Costa et al. 2005 (modified 2007)(181)	*Vacuum-assisted wound closure therapy (V.A.C.®)*	There is insufficient evidence to recommend the routine use of VAC therapy.	Moderate-Quality Review
Kanakaris et al. 2007(25)	*The efficacy of negative pressure wound therapy in the management of lower extremity trauma: Review of clinical evidence*	Based on evidence from a limited number of controlled trials, authors recommend the use of NPWT in the acute phase of blunt, penetrating and thermal trauma of the extremities.	Moderate-Quality Review
Vlayen et al. 2007(180)	*Vacuumgeassisteer de Wondbehandleing: e en Rapid Assessment*	The newly available evidence did not allow the authors to make a clear statement about the clinical efficacy and safety of NPWT.	Moderate-Quality Review
Ontario Health Technology Advisory Committee 2006(184)	*Negative Pressure Wound Therapy: Update*	Based on the evidence to date, the clinical effectiveness of NPWT to heal wounds is unclear.	Moderate-Quality Review
Pham et al. 2006(176)	*The safety and efficacy of topical negative pressure in non-healing wounds: a systematic review*	There is a paucity of high-quality RCTs of topical negative pressure for wound management with sufficient sample size and adequate power to detect any differences between topical negative pressure and standard dressings.	Moderate-Quality Review
Gray & Pierce 2004(177)	*Is Negative Pressure Wound Therapy Effective for the Management of Chronic Wounds?*	Based on two small studies, NPWT may be superior to saline-moistened gauze in the treatment of chronic wounds. Insufficient evidence exists to determine whether NPWT is superior to advanced dressings in promoting healing of pressure ulcers and diabetic foot ulcers. In addition, based on three quasi-experimental studies, superiority of NPWT was determined in the treatment of soft-tissue flaps and skin grafts when compared to topical antimicrobial agents and gauze.	Moderate-Quality Review

Reference	Title	Authors' Conclusions	Study Quality Rating
Samson et al. 2004(182)	*Wound-Healing Technologies: Low-level Laser and Vacuum-assisted Closure*	VAC trials did not find a significant advantage for intervention on primary endpoint, complete healing, and did not consistently find significant differences on secondary endpoints. Evidence was limited by poor study quality.	Moderate-Quality Review
Contractor et al. 2008(185)	*Negative Pressure Wound Therapy With Reticulated Open Cell Foam in Children: An Overview*	The evaluation of single case studies and retrospective reviews revealed V.A.C.® as a safe alternative to traditional methods in treating axial, chronic extremity wounds and complex lawnmower injuries. Additional benefits included a reduction in infection rates in tibial shaft fractures and spinal fusions. Randomized prospective studies are needed to make recommendations for the safe and efficacious clinical practice.	Low-Quality Review
Schintler and Prandl 2008(170)	*Vacuum-assisted closure – what is evidence based?*	The investigators concluded that vacuum therapy, when used by experienced surgeons, is an excellent option to support wound healing. Although this therapy appears effective, its superiority to conventional techniques has not been demonstrated. Further prospective randomized blinded studies are needed.	Low-Quality Review
Raja and Berg 2007(186)	*Should vacuum-assisted closure therapy be routinely used for management of deep sternal wound infection after cardiac surgery?*	Current evidence is weak to support the routine use of V.A.C.® for management of deep sternal wound infection after cardiac surgery.	Low-Quality Review
Mendonca et al. 2006(187)	*Negative-pressure wound therapy: a snapshot of the evidence*	Due to the mixed results in the few RCTs examined, the authors cannot confirm a clear clinical effectiveness of TNP.	Low-Quality Review
Gupta and Cho 2004(188)	*A Literature Review of Negative Pressure Wound Therapy*	Based on 61 retrospective studies and 3 prospective studies, the authors conclude that the clinical outcomes demonstrate significance in all of the comparative studies with overall outcome data supporting its effectiveness.	Low-Quality Review

Meta-Analysis

In only one of the reviews did the authors perform a meta-analysis using wound-healing data from patients treated with NPWT.(173) In this review, an analysis of four RCTs and two nonrandomized controlled trials (non-RCTs) for change in wound size indicated results favoring NPWT (standardized mean difference (SMD): RCTs, -0.57; 95% CI, -0.94 to -0.20; non-RCTs: SMD, -1.30; 95% CI, -2.07 to -0.54). Reasons given in the Cochrane review by Ubbink et al. for not performing meta-analysis included the diverse endpoints and comparator treatments in the trials.(174) Furthermore, these authors criticize the use of data from subgroup analyses and of the incorporation of non-quantitative comments (e.g., "some patients experienced pain") in other reviews of NPWT.

Adverse Events

Finally, the authors were in overall agreement that NPWT is a safe alternative treatment. Reported complications included infection, hematoma, fistulae, failure to heal, osteomyelitis and pain. Although serious harms from treatment with NPWT including mortality and re-amputation have been reported, they are rare. For a complete listing of reported adverse events related to NPWT and comparator treatments, please see Table 42.

Overview of the Systematic Reviews

The systematic reviews of NPWT reveal several important points about this technology. First, all of the systematic reviews noted the lack of high-quality clinical evidence supporting the advantages of NPWT compared to other wound treatments. The lack of high-quality NPWT evidence resulted in many systematic reviewers relying on low-quality retrospective studies to judge the efficacy of this technology. Second, the other systematic reviews found no studies directly comparing different NPWT devices or components have been published. Direct comparison studies are especially important in determining which dressing approach (foam or gauze) may provide the best potential for wound healing. Third, other systematic reviews concluded that NPWT must be evaluated according to wound type. Wound healing varies according to the type of wound being treated and NPWT benefits described for one wound type cannot be transferred to other wound types. Most wound types have too little high-quality NPWT evidence to judge if NPWT is better than standard care for specific wounds. Studies comparing foam to gauze are needed for each wound type before decisions can be made about which systems or components offer significant therapeutic distinctions.

Peinemann et al.(189) have examined the potential for publications bias within the NPWT clinical literature. Publications bias is the tendency to publish only positive results and not to publish results that suggest no difference in measured outcomes. If publication bias were to exist within the NPWT literature, any conclusions based on this literature would be inaccurate. The authors completed literature searches for RCTs comparing NPWT with other wound therapies and examined congress proceedings and online trial registers for clues to unpublished RCTs. Manufacturers of NPWT devices (Kinetic Concepts Inc. and BlueSky Medical Group Inc.) and authors of conference abstracts were contacted and asked to provide study information. Responses were received from 10 of 17 (59%) authors and both manufacturers. Trials were considered nonrandomized if concealment of allocation to treatment groups was classified as "inadequate." An RCT was classified as "unpublished" if no full-text paper on final study results (completed trials) or interim results (discontinued trials) was available. A total of 28 RCTs referring to at least 2755 planned or analyzed patients met the inclusion criteria. Thirteeen RCTs

had been completed, six had been discontinued, six were ongoing, and three RCTs had an unclear status. Full-text publications were available on only 30% of the patients from 19 completed or discontinued RCTs. Of the 14 conference abstracts that reported on findings from these 19 RCTs, six abstracts were later published as full-text articles. Peienemann et al. speculated that "some of these RCTs remained unpublished because they were of poor quality or produced negative results," concluded that the "lack of access to unpublished study results data raises doubts about the completeness of the evidence base on NPWT."(189)

Ongoing Clinical Trials

To locate recently conducted and ongoing clinical trials of negative pressure wound therapy, we searched two databases: http://clinicaltrials.gov and http://www.controlled-trials.com. Our searches identified 27 clinical trials with the following status: completed (5), recruiting outside of the U.S. (8); not yet open (4); and ongoing but not recruiting (2). See Table 12 for additional information regarding these trials.

ECRI Institute contacted the sponsors of two trials comparing NPWT devices (NCT00583141; NCT00590369); however, we were unable to obtain any further study information at this time.

Table 12. Clinical Trials

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
NCT00583141[a]	The Cleveland Clinic in collaboration with Smith & Nephew, Inc.	Treatment, randomized, open label, factorial assignment – Versatile One (EZCare) versus KCI VAC negative pressure/vacuum systems	Investigate whether differences can be found in selected outcomes related to wound care, using Versatile One (EZCare) versus KCI VAC negative pressure/vacuum systems.	July 2005	August 2008	50 adults, ages 18 years and older	KQ1
NCT00590369[a]	The Cleveland Clinic in collaboration with Smith & Nephew, Inc.	Treatment, randomized, open label, factorial assignment – Versatile One (EZCare) versus KCI VAC negative pressure/vacuum systems	Investigate whether differences can be found in selected outcomes related to wound care, using Versatile One (EZCare) versus KCI VAC negative pressure/vacuum systems.	July 2005	August 2008	50 adults, ages 18 years and older	KQ1
NCT00754156[d]	University of Kentucky	Treatment, non-randomized, open label, parallel assignment, safety/efficacy study – ABRA Abdominal Closure System plus V.A.C. vs. V.A.C. Therapy alone	Compare the efficacy of utilization of the Canica ABRA system combined with the KCI VAC system for closure of open abdomen, versus the utilization of the KCI VAC system alone.	September 2008	July 2010	30 adults, ages 18 years and older	KQ1

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
NCT00834314	University Hospital Manheim in collaboration with DFG (German Research Foundation), KCI International and Medela Healthcare	Treatment, randomized, open label, active control, parallel assignment, safety/efficacy study – Vacuum-Pack-technique for temporary abdominal closure vs. negative pressure wound therapy for temporary abdominal closure with V.A.C.® Abdominal Dressing System)	Determine whether two vacuum-wound-dressing techniques (the so called "abdominal dressing" versus "vacuum-pack technique") are equally effective in the treatment of open abdomen.	March 2009	June 2010	20 adults, ages 18 years and older	KQ2
NCT00876551	Hannover Medical School, Hannover, Germany	Treatment, non-randomized, open label, uncontrolled, single group assignment, safety/efficacy study – treatment will include a polyurethane foam (KCI) and CNP -125 mmHg using KCI V.A.C.®	Determine the short and long term outcome of endoscopic vacuum assisted closure of intrathoracic postsurgical leaks.	January 2008	December 2012	30 adults ages 18 years and older	KQ3
NCT00847730	KCI USA, Inc.	Supportive care, open label, single group assignment – V.A.C.® GranuFoam®™	Evaluate the ease of use of the V.A.C.® GranuFoam® ™ Bridge dressing on diabetic foot ulcers receiving VAC Negative Pressure Therapy.	February 2009	March 2009	75 adults, ages 18 years and older	KQ3
ISRCTN69032034	University of York, York, UK, in collaboration with the Medical Research Council	RCT – Participants will be randomized to receive NPWT therapy or the comparator treatment (spun hydrocolloid, alginate or foam dressings).	Determine if topical negative pressure therapy is a clinically and cost-effective treatment for grade III/IV pressure ulcers	July 1, 2008	August 31, 2009	50	KQ3

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
NCT00582179[c]	University of Alabama at Birmingham	Treatment, randomized, open label, parallel assignment, efficacy study – patients will be treated with a pressure dressing and observation or with a Vacuum-Assisted Closure device (VAC)	Evaluate the use of a negative pressure vacuum device in treating draining hematomas following traumatic injury.	September 2001	December 2008	100 adults, ages 19 years and older	KQ3
NCT00829621	University of Missouri-Columbia in collaboration with Medtronic	Treatment, randomized, open label, active control, parallel assignment – IVAC suction 75 mmHg vs. 125 mmHg	Determine whether or not the negative pressure associated with an IVAC is sufficient to remove BMP-2 from a surgical wound.	December 2008	December 2010	20 adults, ages 18 years and older	KQ3
NCT00582998[e]	University of Alabama at Birmingham in collaboration with KCI USA, Inc.	Treatment, randomized, open label, parallel assignment, efficacy study – Standard post-operative wound dressing vs. Vacuum-Assisted Closure (VAC) device	Evaluate the use of a negative pressure vacuum device in treating soft tissue injuries and the surgical incision following open reduction and internal fixation of calcaneus, tibial plateau, and pilon fractures.	June 2001	November 2008	189 adults, ages 19 years and older	KQ3
NCT00432965[b]	KCI USA, Inc.	Treatment, randomized, open label, active control, parallel assignment, safety/efficacy study – Optimized moist wound therapy including physicians use of alginates, hydrogels, hydrocolloids, collagens, etc. vs. VAC therapy	Determine if topical negative pressure therapy delivered by the V.A.C.® device is clinically efficacious and cost effective in the treatment of diabetic foot ulcers.	May 2002	Not provided	338 adults, ages 18 years and older	KQ3

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
NCT00654641	West Virginia University in collaboration with CAMC Health System	Prevention, randomized, open label, active control, parallel assignment, efficacy study – Negative Pressure wound closure for 72 hours post-operatively vs. Suture closure of subcutaneous tissue and skin stapling and sterile bandage placement	Assess whether applying a source of vacuum (suction) to wounds following Cesarean delivery can reduce the risk of wound complications.	September 2007	November 2010	220 women, ages 18 years and older	KQ3
NCT00582361[e]	University of Alabama at Birmingham in collaboration with KCI USA, Inc.	Treatment, randomized, open label, parallel assignment, efficacy study – patients will have a standard dressing applied following initial treatment of their open fracture or will have a Vacuum-Assisted Closure (VAC) device applied following initial treatment of their open fracture	Evaluate the use of a negative pressure vacuum device in treating traumatic wounds sustained as a result of an open fracture that requires surgery.	June 2001	March 2008	63 adults, ages 19 years and older	KQ3
NCT00773981	Hvidovre University Hospital in collaboration with Braun Aesculap	Treatment, randomized, open label, parallel assignment, safety/efficacy study – patients treated with a catheter with daily rinsing for a minimum of 7 days or Endoluminal vacuum therapy	Investigate the effects of transrectal vacuum treatment on the healing of anastomotic leakage after rectum resection.	October 2008	October 2011	60 adults, ages 18 years and older	KQ3

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
NCT00789659[d]	University of Mississippi Medical Center in collaboration with the Orthopaedic Trauma Association	Prevention, randomized, open label, parallel assignment – postoperative wounds will be dressed with a negative pressure (V.A.C.) dressing or a completely occlusive dressing that is attached to a device that allows a constant negative pressure of 125 mmHg to be generated	Assess the efficacy of VAC therapy on morbidly obese orthopedic trauma patients, specifically those with pelvic ring, acetabular or proximal femur fractures that would require surgery.	January 2009	December 2009	60 adults, ages 18 to 64 years	KQ3
NCT00724750[b]	University of Chicago	Treatment, randomized, open label, parallel assignment, efficacy study – Gauze suction (G-SUC) Negative Pressure Wound Therapy vs. Vacuum-Assisted Closure Device (VAC) Negative Pressure Wound Therapy	1) Compare the effectiveness of G-SUC and standard VAC therapy with regards to change in wound size over 1-2 weeks and number of patients who are able to clear infection by 4 days. 2) Compare the failure of each method of therapy by documenting the number of dressing that cannot be maintained because of fluid or suction. 3) Measure and compare the cost of the two wound treatments	July 2006	December 2008	120 adults, ages 18 years and older	Studies comparing NPWT to a comparator treatment

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
NCT00691821[d]	St. Joseph's Healthcare in collaboration with Ontario Ministry of Health and Long term Care, St. Michael's Hospital, Toronto, Women's College Hospital, Hamilton-Niagara-Haldimand-Brant Community Care Access Centre, Toronto Central Community Care Access Centre	Treatment, randomized, open label, active control, parallel assignment, safety/efficacy study – Participants will receive standard dressings changes as needed. Different dressing types (e.g., silver, simple gauze, hydrogel, foam, creams, gels) will be used dependent on the type of the wound (e.g., dry, wet, and intermediate) vs. Negative Pressure Wound Therapy (Vacuum-Assisted Closure System [V.A.C.® Therapy™])	Assess the difference in the percent reduction in wound surface area, without surgery, of chronic pressure ulcers of the pelvic region for Negative Pressure Wound Therapy (NPWT) at 12 weeks compared to standard dressing. Efficacy, cost-effectiveness, safety and quality of life will also be evaluated for standard wound dressing versus NPWT.	July 2008	March 2011	184 adults, ages 18 years and older	Studies comparing NPWT to a comparator treatment
NCT00243620	Maastricht University Medical Center in collaboration with KCI medical B.V.	Treatment, randomized, open label, active control, parallel assignment, efficacy study – VAC vs. standard wound care according to the SIGN guideline and a multiple-layer compression bandage until complete healing. Four basic types of commercially available wound dressings will be used in this study including hydrogels, alginates, hydrocolloids, and films. The choice of dressing most depended on the ulcer type, the amount of exudate and the physician's preference.	Measure the efficacy of vacuum-assisted closure versus modern wound dressings in the treatment of chronic leg ulcers. Primary focus will be on time-to-complete-healing.	May 2001	May 2004	60 adults up to 85 years of age	Studies comparing NPWT to a comparator treatment

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
NCT00121537	The University of Texas Health Science Center at San Antonio	Treatment, randomized, open label, active control, single group assignment – Vacuum-assisted closure versus standard wet to dry dressing	Measure the efficacy of vacuum-assisted closure versus standard wet to dry dressing in treating lower leg fasciotomy. Primary focus will be on rate of wound healing.	July 2005	Not provided	30 adults, ages 18 years and older	Studies comparing NPWT to a comparator treatment
NCT00635479	University of Missouri-Columbia	Treatment, randomized, open label, parallel assignment, efficacy study – Vacuum-Assisted Closure (VAC) device for surgical incision vs. Gauze dressing for surgical incision	Examine the efficacy and cost effectiveness of the VAC device in comparison to traditional gauze wound dressing in pelvic fractures and acetabular fractures. Specific focus will be on potential reductions in the incidence of post-operative surgical wound drainage, infections, and hospital stay.	March 2008	December 2008	50 adults, ages 18 years and older	Studies comparing NPWT to a comparator treatment
NCT00224796[b]	KCI USA, Inc.	Treatment, randomized, open label, active control, parallel assignment, safety/efficacy study – Vacuum-Assisted Closure (V.A.C.®) Therapy vs. moist wound therapy	Compare the effectiveness of Vacuum Assisted Closure (V.A.C.®) Therapy to moist wound therapy of amputation wounds of the diabetic foot.	May 2002	October 2005	146 adults, ages 18 years and older	Studies comparing NPWT to a comparator treatment

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
NCT00234559	KCI USA, Inc.	Treatment, randomized, open label, active control, parallel assignment – vacuum-assisted closure (VAC®) therapy compared to moist wound therapy	Determine: 1) If vacuum-assisted closure therapy results in altered proteomic expression of angiogenic markers compared to moist wound therapy. 2) If vacuum-assisted closure therapy results in increased angiogenesis compared to moist wound therapy.	September 2005	Not provided	20 adults, ages 18 years and older	Studies comparing NPWT to a comparator treatment
NCT00548314	Association of Dutch Burn Centres	Treatment, randomized, open label, parallel assignment, efficacy study – dermal substitute Matriderm, split skin graft and VAC therapy vs. dermal substitute Matriderm, and split skin graft vs. split skin graft and VAC therapy vs. split skin graft	Determine whether a treatment of full thickness wounds by the dermal substitute Matriderm, split skin graft and VAC treatment will improve scar quality. Additional areas of focus include: increase on the take of graft, improvement of scar assessment scale, scar color/pigmentation and time to complete healing.	October 2007	Not provided	72 adults, ages 18 years and older	Studies comparing NPWT to a comparator treatment

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
NCT00605189	KCI USA, Inc.	Basic science, randomized, open label, parallel assignment – Powered Suction Pump (VAC Freedom) continuous suction vs. Powered Suction Pump continuous suction vs. Moist Wound Therapy (Allevyn, Tielle, SoloSite, Curagel) Foam Dressings, Hydrogel Impregnated Gauze, Hydrogel Sheet Dressings	Examine how cellular energies and oxygenation levels are related to various wound treatment therapies in patients with diabetic foot ulcers.	July 2007	August 2008	39 adults with Type II diabetes and chronic diabetic foot ulcers	Studies comparing NPWT to a comparator treatment
NCT00494793	Malmö University Hospital in collaboration with Gävle Hospital, Falu Hospital, Kinetic Concepts, Inc., and The Swedish Research Council	Treatment, open label, uncontrolled, single group assignment, efficacy study – vacuum-assisted wound closure (VAWC) and mesh mediated fascial traction for closure of open abdomens	Prospectively evaluate a combination of vacuum-assisted wound closure and mesh mediated fascial traction for closure of open abdomens.	February 2006	February 2012	10 adult open abdomen patients	Studies comparing NPWT to a comparator treatment
ISRCTN67751142[b]	Department of Health, London, UK, in collaboration with Hillingdon Hospital NHS Trust	RCT - compression pump and suction therapy versus standard 4-layer bandages	Determine if the use of compression pump and V.A.C. suction therapy provide better management for venous ulcers than standard 4-layer bandages	February 2005	March 2007	NR	Studies comparing NPWT to a comparator treatment

Clinicaltrials.gov Identifier or Other Identifier	Sponsor	Study Design	Purpose	Start Date	Expected Completion Date	Estimated Enrollment	Relevance to Key Questions
ISRCTN86386707[b]	VU University Medical Center; funded by NOW-Biopartner First Stage Grant	RCT - 5 day prior wound bed preparation with Vacuum-Assisted Closure therapy (VAC) vs. 5 day prior wound bed preparation with VAC followed by application of Tiscover	Determine if ulcers treated with Tiscover (cultured, autologous skin) will significantly decrease in size resulting in most cases in full healing, compared to the control group (VAC), which is not treated with Tiscover	October 2005	October 2007	100	Studies comparing NPWT to a comparator treatment

[a] Device comparison
[b] Completed
[c] Suspended
[d] Not yet open
[e] Ongoing, but not recruiting

Discussion and Conclusions

Based on our defined search strategies and the materials provided by interested parties, no studies directly comparing one NPWT system to another NPWT system were identified that addressed Key Question 1, 2, or 4. Thus, we were not able to identify a significant therapeutic distinction of one NPWT system or component over another through the use of head-to-head comparisons.

In the absence of head-to-head comparison studies, we searched the clinical literature to identify comparison studies of NPWT systems versus a common comparator. We attempted to assess the relative efficacy and/or safety of different NPWT systems using adjusted indirect comparisons. Our review of 40 comparison studies found that all of the controlled trials involved the evaluation of one NPWT device, the V.A.C.® manufactured by KCI. Furthermore, to be considered for inclusion in an indirect comparison, studies must be RCTs and must provide sufficient information to determine their comparability in terms of patient characteristics, patient exclusion/inclusion criteria, methodology, outcome definitions, outcome measures, and application of the comparison treatment. Only nine of the KCI VAC® comparison studies were RCTs and none of these RCTs met the requirements necessary for the indirect comparison option had there been studies of more than one NPWT system.Consequently, at this time the available evidence cannot be used to determine a significant therapeutic distinction of a NPWT system.

None of the 40 comparison studies met the design and conduct requirements to be considered high quality, only seven studies could be considered moderate quality, and the majority of studies (82%) were rated low quality. A low quality study rating calls into question the internal validity of study results and reduces our confidence in the relationship between the interventions and the outcomes. Our conclusions about study quality are also in agreement with the systematic reviews examined in this report. These reviews indicated that the majority of evidence on NPWT was of poor quality.

In their systematic review of clinical studies of NPWT, Peinemann et al.(189) sought to identify unpublished completed or discontinued RCTs to gain a broader knowledge of the NPWT evidence. The authors were concerned that previous systematic review conclusions on efficacy and safety based on published data alone may no longer hold after consideration of unpublished data. The authors invited two NPWT device manufacturers Kinetic Concepts Inc. (V.A.C.®) and BlueSky Medical Group Inc.(BSM)(Versatile 1 Wound Vacuum System) and authors of conference abstracts to provide information on study status and publication status of sponsored trials. Responses were received from 10 of 17 (59%) authors and both manufacturers. BSM, however did not sponsor relevant RCTs and only provided information on case reports. Peienemann et al. concluded that the “lack of access to unpublished study results data raises doubts about the completeness of the evidence base on NPWT.”(189)

Our searches did not identify any studies comparing one NPWT system component to another NPWT system component that addressed Key Question 2. No studies of this design were submitted by interested parties. This question was designed to examine studies that compared different dressing sets, tubing, or pumps while maintaining identical components for the other parts of an NPWT system. In particular we were looking for studies that evaluated gauze versus foam dressing sets in various wound types. This would help determine which dressing approach may provide the best potential for wound healing in a variety of wound care situations. The clinical trials now in development or nearing completion examine many different wound types

(see Table 12) but do not address the merits of gauze versus foam within NPWT systems. The recently completed studies from the Cleveland Clinic (NCT00583141; NCT00590369) may address this question but the details of the study design are presently unavailable. The investigators did not wish to disclose any details of the study design prior to publication.

We did identify one high-quality study(116) that compared an electrical pump to a Redon set as vacuum sources while using the same foam dressing set. The findings of this study indicate that the vacuum bottle approach to applying negative pressure to a pressure ulcer is not appropriate. However this study does not directly address any of the questions posed in this report.

Our assessment of adverse events in the evidence base used to address Key Question 3 indicates that the most commonly reported adverse events associated with NPWT are pain, bleeding, and infection. While reports were similar for complications such as bleeding or infection, fewer reports of serious harms (i.e., secondary amputations, graft failure) have been reported when using NPWT compared to patients treated by comparator treatments. Of the 37 studies reporting events, seven (19%) studies described NPWT as a safe treatment. Fewer complications were reported in the NPWT-treated patients than in those receiving other wound therapies in 19 (51%) studies and similar complications were reported in 8 (22%) studies. Due to the lack of studies comparing one NPWT system to another NPWT system, we were unable to determine the severity of adverse events for one NPWT system compared to another (Key Question 4).

Clinical research on NPWT capable of indicating if any one NPWT system or component provides a significant therapeutic distinction requires study design and conduct that will minimize the possibilities for bias. Important study design features that were not typically reported such as concealment of allocation, reporting of randomization methods, use of power analysis to ensure adequate study size, blinding patients and especially wound assessors, and reporting of complete wound healing data will insure the internal validity of study results. None of the studies included in the present review reported that the physicians were blinded to treatment assignment, and only 12% of the studies reported blinding of outcome assessors. In only 7% of studies was there concealment of allocation to treatment, one of the most crucial elements of any randomized controlled trial with failure typically resulting in selection bias.(183,190) Selection bias refers to the presence of systematic differences between the treatment group and the control group at the onset of a study. If the patient groups differ substantially in any way, this may contribute to systematic differences in outcomes that are unrelated to the intervention of interest. The most effective way of guarding against selection bias is to randomly assign patients to treatment groups and fully concealing the treatment allocation process during the randomization.

Findings from one wound type cannot be transferred to another so determining if any one NPWT system or component provides a significant therapeutic distinction relies on numerous high quality studies of several different wound types. In conclusion, the strongest evidence of efficacy will come from properly designed and conducted randomized controlled trials that have been replicated by independent research units.

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Appendix A: Methods of Identifying the Literature

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date Limits	Platform/Provider
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	1982 through January 19, 2009	OVID
ClinicalTrials.gov	Searched December 24, 2008	www.clinicaltrials.gov
Cochrane Central Register of Controlled Trials (CENTRAL)	Through 2009, Issue 1	www.thecochranelibrary.com
Cochrane Database of Systematic Reviews (Cochrane Reviews)	Through 2009, Issue 1	www.thecochranelibrary.com
Current Controlled Trials	Searched February 24, 2009	http://www.controlled-trials.com/mrct/
Database of Abstracts of Reviews of Effects (DARE)	Through 2009, Issue 1	www.thecochranelibrary.com
EMBASE (Excerpta Medica)	1980 through March 23, 2009	OVID
FDA MAUDE Database	1999 – February 28, 2009	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
Health Technology Assessment Database (HTA)	Through 2009, Issue 1	www.thecochranelibrary.com
Healthcare Standards	Searched January 30, 2009	ECRI Institute
MEDLINE	1950 through March 23, 2009	OVID
PreMEDLINE	Searched January 7, 2009	www.pubmed.gov
U.K. National Health System Economic Evaluation Database (NHS EED)	Through 2009, Issue 1	www.thecochranelibrary.com
U.S. Centers for Medicare & Medicaid (CMS) Web site	Searched December 24, 2008	www.cms.gov www.coverageandpayment.com
U.S. National Guideline Clearinghouse™ (NGC)	Searched January 30, 2009	www.ngc.gov

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

Search Strategies

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across Embase, Medline, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), EMTREE, PsycINFO and Keywords

Conventions:

OVID

$	=	truncation character (wildcard)
exp	=	"explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)
.de.	=	limit controlled vocabulary heading
.fs.	=	floating subheading
.hw.	=	limit to heading word
.md.	=	type of methodology (PsycINFO)
.mp.	=	combined search fields (default if no fields are specified)
.pt.	=	publication type
.ti.	=	limit to title
.tw.	=	limit to title and abstract fields

PubMed

[mh]	=	MeSH heading
[majr]	=	MeSH heading designated as major topic
[pt]	=	publication type
[sb]	=	Subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
[sh]	=	MeSH subheading (qualifiers used in conjunction with MeSH headings)
[tiab]	=	keyword in title or abstract
[tw]	=	text word

Topic-specific Search Terms

Concept	Controlled Vocabulary	Keywords
Negative pressure wound therapy	Vacuum assisted closure Vacuum Negative pressure wound therapy (CINAHL heading only)	NPWT Negative pressure Negative-pressure Subatmospheric Sub-atmospheric VAC V.A.C. VACT V.A.C.T. Vacuum assisted Vacuum-assisted
Specific Devices		Active AC Exsudex Ezcare system Invia Liberty Mini VAC Model 2006 npd 1000 Prospera Svedman treatment unit VAC freedom Venturi negative pressure Versatile 1 Vista portable Wound therapy pump
Specific Manufacturers		Blue Sky BlueSky Iasis Innovative Therapies Kalypto KCI Kinetic Concepts Medela Prospera Superior Healthcare Talley Medical

Concept	Controlled Vocabulary	Keywords
Wounds	Diabetic foot Exp injury/ Exp plastic surgery/ Exp reconstructive surgical procedures/ Exp skin ulcer/ Exp skin ulcers/ Surgical flaps Exp wounds and injuries/ Wound$ Exp wound healing/	Amputate$ Bed sore$ Burn$ Decubitus Deglov$ Dehisc$ Diabetic sore$ Diabetic ulcer$ Electric$ injur$ flap Frostbit$ Pressure sore$ Pressure ulcer$

EMBASE/MEDLINE
Human, English Language

Set Number	Concept	Search Statement
1	NPWT	Vacuum assisted closure.de. or vacuum.de. or (negative-pressure or negative pressure or NPWT or vacuum assisted or vacuum-assisted or VAC or VACT or subatmospheric or sub-atmospheric)
2	Specific devices	Active ac or Exsudex or Ezcare system or Invia or liberty or Mini VAC or Model 2006 or npd 1000 or prospera or Svedman treatment unit or VAC freedom or Venturi negative pressure or Versatile 1 or Vista portable or Wound therapy pump
3	Specific manufacturers	(Blue Sky or BlueSky or Iasis or Innovative Therapies or Kalypto or KCI or Kinetic Concepts or Medela or Prospera or Superior healthcare or Talley Medical).dm,ti,ab.
4	Combine sets	or/1-3
5	Wounds & wound healing	Exp wounds and injuries/ or exp injury/ or exp wound healing/ or wound$.hw. or exp reconstructive surgical procedures/ or exp plastic surgery/ or su.fs.
6	Specific wounds	Surgical flaps.de. or Exp skin ulcers/ or exp skin ulcer/ or decubitus or ((bed or pressure or diabet$) adj (sore$ or ulcer$)) or bedsore$ or diabetic foot.de.
7		Amputat$ or Burn$ or Deglov$ or Electric$ injur$ or Frostbit$ or Wound$ or flap or dehisc$
8	Combine sets	or/5-7
9	Combine sets	4 and 8
10	Limit by publication type	9 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.)
11	Limit by study type	10 and ((cross-over studies or crossover procedure or crossover design or exp controlled study/ or exp clinical trial/ or exp comparative study/ or cohort analysis or intermethod comparison or parallel design or control group or prospective study or retrospective study or case control study or major clinical study).de. or (ISRTCN or "0400 empirical study" or "0430 followup study" or "0450 longitudinal study" or "0451 prospective study" or "0600 field study" or prospect$).tw.)
12	Eliminate overlap	Remove duplicates from 11

PubMed
English language, In process/publisher

Set Number	Concept	Search Statement
1	NPWT	"negative-pressure" OR "negative pressure" OR NPWT OR "vacuum assisted" OR "vacuum-assisted" OR VAC OR "V.A.C." OR VACT OR "V.A.C.T." OR subatmospheric OR "sub-atmospheric"
2	Specific devices	"Active ac" OR Exsudex OR "Ezcare system" OR Invia OR liberty OR "Mini V.A.C." OR "mini-V.A.C." OR "Model 2006" OR "npd 1000" OR prospera OR "Svedman treatment unit" OR "VAC freedom" OR "Venturi negative pressure" OR "Versatile 1" OR "Vista portable" OR "Wound therapy pump"
3	Specific manufacturers	"Blue Sky" OR BlueSky OR Iasis OR "Innovative Therapies" OR Kalypto OR KCI OR "Kinetic Concepts" OR Medela OR Prospera OR "Superior healthcare" OR "Talley Medical"
4	Combine sets	or/1-3
5	Wound healing	Wound* OR injury OR injuries OR heal OR healed OR healing
6		((bed OR pressure OR diabetic) AND (sore* OR ulcer*)) OR bedsore* OR "diabetic foot"
7		Amputat$ OR Deglov$ or Electric$ OR fracture* OR Frostbit$ or burn$ OR flap OR dehisc$ OR surgical
8	Combine sets	#5 OR #6 OR #7

Total Identified	Total Downloaded	Total Retrieved	Total Included
1,078	**382**	**288**	**137**

Table 13. Excluded Documents

Reference	Reason for Exclusion
Agosti et al. 2007(191)	Case study
Apelqvist et al. 2008(192)	Cost analysis
Armstrong and Nguyen 2000(193)	Not a NPWT device
Armstrong et al. 2004(194)*	Possibly a homemade device
Armstrong et al. 2005(195)	Duplicate study(109)
Armstrong et al. 2006(196)	Conference presentation
Augustin 2006(197)	Conference abstract
Aust et al. 2008(198)	No relevant outcomes
Baharestani et al. 2008(199)	No relevant outcomes
Barker et al. 2000(200)	Not a commercially available device
Barnes and Miller 2007(201)	Conference abstract
Barringer et al. 2004(202)	Not a clinical study
Bee et al. 2008(203)	Subpopulation received both treatments
Bernstein et al. 2008(204)	Conference abstract
Bischoff et al. 2003(205)	Homemade device
Blackett and Bohnenkamp 2006(206)	Conference presentation
Bovill et al. 2008(207)	Narrative
Brin et al. 2006(208)	Case report
Bruenner et al. 2006(209)	Conference abstract
Bui et al. 2006(210)	Homemade device
Burbage 2008(211)	Conference presentation
Burdette-Taylor 2003(212)	Case reports
Buttenschoen et al. 2001(213)	Homemade device
Campbell 2004(214)	Case report
Centers for Medicare & Medicaid Services 2009(215)	HCPCS and CPT coding information
Centers for Medicare & Medicaid Services 2009(216)	HCPCS and CPT coding information
Centers for Medicare & Medicaid Services 2009(217)	DMEPOS fee schedule
Chavarria-Aguilar et al. 2004(218)	Homemade device
Cipolla et al. 2005(219)	Does not address key question
Corvino and Stokes 2008(220)	Case report
Davis 2006(221)	Case report
Dedmond et al. 2006(222)	Duplicate study(27)

Reference	Reason for Exclusion
De Leon et al. 2006(223)	Conference presentation
Doxford 2007(224)	Narrative
Edwards 2006(225)	Conference abstract
Eginton et al. 2003(226)	Fewer than 5 patients per study arm
Eifert et al. 2007(227)	Patients received dual therapies
Excerpt from Teot et al. 2008(228)	Duplicate study(229)
Farren et al. 2007(230)	Case study
Fife et al. 2008(231)	No relevant outcomes
Foo et al. 2008(232)	Case report
Francu 2008(233)	Conference abstract
Frykberg et al. 2006(234)	Guideline
Girolami et al. 2007(235)	Case reports
Gupta et Cho 2004(236)	Duplicate study(188)
Harris 2007(237)	Case study
Harris 2008(238)	Case report
Heinsler et al. 2006(239)	Conference presentation
Hill et al. 2007(240)	Case reports
Howell-Taylor et al. 2008(241)	Case reports
Hunter et al. 2007(242)	Narrative
Ingari et Powell 2007(26)	Narrative
Institute for Clinical Systems Improvement 2008(243)	Health Care Protocol
IQWiG 2006(244)	Duplicate study(173)
IQWiG 2007(245)	Narrative
Jeschke et al. 2004(246)	Dual therapy
Jones et al. 2005(247)	Healthy volunteers
Karoo et al. 2008(248)	Case report
Kendall et al. 2008(249)	Conference presentation
Keyser 2008(250)	Conference presentation
Kim et Hong 2007(251)	Homemade device
Kollrack and Mollenhoff 2008(252)	Conference abstract
Krasner D. 2002(253)	Does not address key question
Kring et al. 2008(254)	Case reports
Kwansink et al. 2005(255)	Does not address key question
Lambert et al. 2005(256)	Narrative

Reference	Reason for Exclusion
Lang et al. 1999(159)*	Possibly a homemade device
Lavery et al. 2008(257)	Duplicate study(257)
Li et al. 2007(258)	Not a NPWT study
Lianos et al. 2006(259)	Homemade device
Lopez et al. 2005(260)	Homemade device
Lubke et al. 2008(261)	Conference abstract
Luckraz et al. 2003(262)	Patients received dual therapies
Manahan and Shermak 2006(263)	Does not address key question
Martinsek et al. 2007(264)	Case report
Matzi et al. 2006(265)	Conference abstract
McCord et al. 2007(266)	Conference presentation
McGinnis and Lisco 2007(267)	Case report
McLane et al. 2006(268)	Case report
Medeiros et al. 2004(269)	Not a NPWT study
Mees et al. 2008(270)	Homemade device
Mendez-Eastman S. 2005(271)	Does not address key question
Miller and Brown 2003(272)	Case report
Miller and Brown 2003(273)	Case report
Miller and Brown 2003(274)	Case report
Miller and Brown 2004(275)	Case report
Miller and McDaniel 2004(276)	Case reports
Miller and McDaniel 2005(277)	Case report
Miller and McDaniel 2005(278)	Case report
Miller and McDaniel 2005(279)	Case report
Miller and McDaniel 2006(280)	Case reports
Miller et al. 2002(281)	Study arms both received V.A.C.®
Miller et al. 2004(282)	Study arms both received V.A.C.®
Miller et al. 2005(283)	Case report
Mody et al. 2008(284)	Homemade device
Moues et al. 2004(38)	Duplicate study(136)
Moues et al. 2005(285)	Duplicate study(38)
Nelson 2007(286)	Narrative
NHS Quality Improvement Scotland 2003(287)	Narrative
Niehuser 2008(288)	Case report
No author 2008(289)	Conference abstract

Reference	Reason for Exclusion
No author 2008(290)	Conference abstract
Noridian 2008(291)	HCPCS coding information
O'Keefe and Gutta 2008(292)	Conference abstract
Olejnik et al. 2008(293)	Homemade device
Oomen et al. 2007(294)	Focus on reconstructive surgery
Parker et al. 2007(295)	Not a NPWT study
Parrett et al. 2006(296)	Narrative
Pattison et al. 2006(297)	Case report
Peinemann et al. 2008(298)	Methodology paper
Powell and Bruch 2007(299)	Case report
Price et al. 2006(300)	Conference abstract
Pu 2008(301)	Narrative
Rajzer et al. 2006(302)	Conference abstract
Reddy et al. 2008(303)	Focus too broad for inclusion as Previous Systematic Review
Registered Nurses Association of Ontario 2005(304)	Guideline
Registered Nurses Association of Ontario 2007(305)	Guideline
Sachithanandan et al. 2008(306)	No relevant outcomes
Schimmer 2007(307)	Does not address key question
Schlatterer et al. 2008(308)	Narrative
Schuster et al. 2006(309)	Focus on acellular dermal matrix
Segers et al. 2006(310)	Uses KCI foam dressing only
Segers et al. 2006(311)	Does not address key question
Sibbald et al. 2003(312)	Narrative review
Shalom et al. 2008(313)	Homemade device
Simek 2006(314)	Conference abstract
Smith 2004(315)	Reanalysis of already published data
Sposato et al. 2001(316)	Not describing a clinical study
Stojkovic et al. 2008(317)	Protocol
Strecker et al. 2007(318)*	Possibly a homemade device
Stremitzer et al. 2006(319)	Conference abstract
Suess et al. 2006(320)	Narrative
Tamir et al. 2006(321)	Conference abstract
Tamir et al. 2007(322)	Does not address key question

Reference	Reason for Exclusion
Tanna et al. 2009(323)	Case report
Teot et al. 2006(229)*	Possibly a homemade device
Teot et al. 2007(324)	Conference presentation
Teot et al. 2007(325)	Duplicate report(324)
Timmers et al. 2005(326)	Healthy volunteers/No relevant outcomes
Timms 2007(327)	Case report
TriCenturion 2004(328)	Coverage information/pumps
TriCenturion 2006(329)	Review of HCPCS E2402
TriCenturion 2007(330)	Coverage information/pumps
TriCenturion 2007(331)	Review of HCPCS E2402
TriCenturion 2008(332)	Review of HCPCS E2402
Wainstein et al. 2008(333)	Does not address key question
Webb 2008(334)	Conference presentation
Webb 2008(335)	Conference presentation
Wild et al. 2004(336)	Non-English
Witkowski 2008(337)	Conference abstract
World Union of Wound Healing Societies 2008(338)	Consensus document

* Study authors did not reply to our request for information

Note: Table 13 has been corrected to reflect the 151 documents excluded at the "article level" (i.e., based on full document, whether a published study, meeting abstract or conference presentation, or other retrieved document) during the review of materials identified in internal electronic and manual searches.

Table 14. Summary of Stakeholder Solicitations and Responses

Name	Type of Contact	Responses Received (Y/N)
Boehringer Laboratories, Inc./ConvaTec Inc. markets and distributes all Boehringer Laboratory NPWT systems	Manufacturer	Y
Innovative Therapies, Inc.	Manufacturer	N
Kinetic Concepts, Inc. (KCI)	Manufacturer	Y
Medela Healthcare/Medela, Inc.	Manufacturer	Y
Premco Medical Systems, Inc.	Manufacturer	N
Prospera Technologies	Manufacturer	Y
Smith & Nephew	Manufacturer	Y
Superior Health Care Concepts d/b/a National Wound Care	Manufacturer	N
Talley Medical, USA	Manufacturer	Y
MediTop BV	Vendor Identified by AHRQ	N
Kalypto Medical	Vendor Identified by AHRQ	N
Advanced Medical Technology Association (AdvaMed)	Professional Organization	N
American Academy of Dermatology	Professional Organization	N
American Association of Diabetes Educators	Professional Organization	N
American Burn Association	Professional Organization	N
American College of Surgeons	Professional Organization	N
American Diabetes Association	Professional Organization	N
American Professional Wound Care Association	Professional Organization	N
American Society of Plastic Surgeons	Professional Organization	N
Association for the Advancement of Wound Care	Professional Organization	Y
Biotechnology Industry Organization (BIO)	Professional Organization	N
Medical Device Manufacturers Association	Professional Organization	N
National Pressure Ulcer Advisory Panel (NPUAP)	Professional Organization	N
Wound Care Institute	Professional Organization	N
Wound Healing Society	Professional Organization	N
Wound Ostomy and Continence Nurses Society	Professional Organization	Y
CMS	Other	Y
FDA	Other	N
K. Kowalske, M.D. *(upon AHRQ's request)*	Other	N

Table 14a. Total Stakeholder Solicitations and Responses

Type of Contact	Total Number Contacted by ECRI Institute	Total Number of Responses
Manufacturers	9	6
Additional vendors identified by AHRQ	2	0
Professional Organizations	15	2
Other: CMS & FDA	2	1
K. Kowalske, M.D.	1	0
Totals	29	9

Notes:

1. Initial contact was made on 12/30/08 via e-mail and hard mail. Follow-up e-mails were sent on 01/29/09.
2. A submission was received from the American Physical Therapy Association; however, this organization was not on the list of those we contacted directly. This response was NOT included in the table above.
3. A submission was received from Alliance of Wound Care Stakeholders/Coalition of Wound Care Manufacturers (Nusgart Consulting); however, this organization was not on the list of those we contacted directly. This response was NOT included in the table above.
4. This table does not reflect other unsolicited responses received.

Appendix B: Quality of Literature

ECRI Institute Study Quality Assessment Instrument

The following instrument was used to evaluate the quality of the included studies. Because it was the most consistently reported outcome, wound area reduction was the outcome for which quality was assessed.

The final quality score was calculated: Yes = 1 point; No = -1 point; NR = 0 point; the raw score was then converted to a 0 to 10 scale by adding the number of questions, dividing by double the number of questions, and then multiplying by ten. Controlled trials with a score of less than 6 as Low quality, greater than 6.0 up to 8.5 as Moderate quality, and greater than 8.5 as High quality.

Quality Assessment Instrument for Controlled Trials

1) Were patients randomly assigned to the study's groups?
2) Did the study use appropriate randomization methods?
3) Was there concealment of group allocation?
4) For non-randomized trials, did the study employ any other methods to enhance group comparability?
5) Was the process of assigning patients to groups made independently from physician and patient preference?
6) Did patients in different study groups have similar levels of performance on the outcome of interest at the time they were assigned to groups?
7) Were the study groups comparable for all other important factors at the time they were assigned to groups?
8) Did the study enroll all suitable patients or consecutive suitable patients within a time period?
9) Was the comparison of interest prospectively planned?
10) If patients received ancillary treatment(s), was there a ≤5% difference between groups in the proportion of patients receiving each specific ancillary treatment?
11) Were the two groups treated concurrently?
12) Was compliance with treatment ≥85% in both of the study's groups?
13) Were patients blinded to the treatment they received?
14) Was the healthcare provider blinded to the groups to which the patients were assigned?
15) Were those who assessed the patient's outcomes blinded to the group to which the patients were assigned?
16) Was the integrity of blinding of patients, physicians or outcome raters tested and found to be preserved?
17) Was the outcome measure of interest objective and was it objectively measured?
18) Was a standard instrument used to measure the outcome?

19) Was there ≤15% difference in the length of follow-up for the two groups?

20) Did ≥85% of the patients complete the study?

21) Was there a ≤15% difference in completion rates in the study's groups?

22) Was the funding for this study derived from a source that would not benefit financially from results in a particular direction?

Table 15. Answers to Quality Assessment of Controlled Studies Comparing NPWT to Comparative Treatments†

Studies	Year	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Timmers et al.(106)	2009	N	N	N	N	N	NR	Y	Y	N	Y	N	NR
Blume et al.(108)	2008	Y	Y	Y	Y	Y	Y	Y	NR	Y	Y	Y	Y
Gabriel et al.(339)	2008	N	N	N	N	N	N	Y	N	N	Y	N	NR
Korber et al.(340)	2008	N	N	N	N	N	N	N	N	N	Y	N	NR
Ozturk et al.(117)	2008	N	N	N	N	NR	NR	NR	Y	Y	Y	Y	Y
Rinker et al.(121)	2008	N	N	N	N	N	NR	Y	Y	N	Y	NR	NR
Simek et al.(123)	2008	N	N	N	N	N	Y	Y	NR	N	Y	N	NR
Armstrong et al.(109)	2007	Y	NR	Y	Y	Y	Y	Y	NR	Y	Y	Y	NR
Denzinger et al.(135)	2007	N	N	N	N	N	Y	Y	NR	N	Y	N	NR
Lavery et al.(341)	2007	N	N	N	Y	N	N	N	NR	N	Y	N	NR
Moues et al.(136)	2007	Y	Y	NR	Y	Y	N	N	NR	Y	N	Y	NR
Siegel et al.(119)	2007	N	N	N	N	N	N	N	N	N	Y	N	NR
Braakenburg et al.(114)	2006	Y	Y	NR	Y	Y	Y	Y	Y	Y	NR	Y	Y
Huang et al.(127)	2006	N	N	N	N	NR	Y	Y	N	N	Y	NR	NR
Stannard et al.(125)	2006	Y	Y	NR	Y	Y	N	N	N	N	Y	Y	NR
Vuerstaek et al.(115)	2006	Y	Y	Y	Y	Y	Y	Y	NR	Y	Y	Y	NR
Yang et al.(72)	2006	N	N	N	N	N	NR	NR	Y	N	Y	N	NR
Bickels et al.(134)	2005	N	N	N	N	N	NR	NR	Y	N	Y	N	NR
Fuchs et al.(23)	2005	N	N	N	N	N	NR	Y	Y	N	Y	N	NR
Immer et al.(130)	2005	N	N	N	N	N	N	N	N	N	Y	NR	NR
Schwien et al.(126)	2005	N	N	N	N	N	NR	NR	NR	NR	NR	NR	NR
Segers et al.(122)	2005	N	N	N	N	N	N	N	N	Y	N	NR	N
Sjogren et al.(139)	2005	N	N	N	N	N	Y	N	Y	N	Y	NR	NR

Studies	Year	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Vidrine et al.(342)	2005	N	N	N	N	N	Y	N	Y	Y	Y	Y	NR
Kamolz et al.(343)	2004	N	N	N	N	N	N	Y	Y	Y	Y	Y	NR
Labler et al.(71)	2004	N	N	N	N	N	NR	NR	N	N	Y	N	NR
Moisidis et al.(112)	2004	Y	NR	NR	Y	Y	Y	Y	N	Y	Y	Y	Y
Page et al.(1)	2004	N	N	N	N	N	Y	Y	N	N	NR	NR	NR
Stone et al.(133)	2004	N	N	N	N	N	Y	Y	N	N	Y	NR	Y
Shilt et al.(138)	2004	N	N	N	N	NR	NR	NR	Y	N	Y	N	NR
Domkowski et al.(129)	2003	N	N	N	N	N	NR	NR	NR	N	NR	NR	NR
Song et al.(124)	2003	N	N	N	N	N	Y	Y	Y	N	Y	NR	NR
Wanner et al.(118)	2003	N	N	N	N	N	NR	N	Y	NR	Y	Y	NR
Doss et al.(128)	2002	N	N	N	N	N	NR	Y	N	N	Y	NR	NR
Ford et al.(110)	2002	Y	Y	NR	Y	Y	NR	NR	NR	Y	Y	Y	NR
Scherer et al.(132)	2002	N	N	N	N	N	N	N	Y	N	Y	NR	NR
Catarino et al.(137)	2000	N	N	N	N	N	NR	N	Y	N	Y	NR	N
Joseph et al.(113)	2000	Y	Y	N	Y	Y	N	NR	NR	Y	NR	Y	NR
McCallon et al.(120)	2000	N	N	N	Y	Y	NR	NR	NR	Y	Y	Y	NR
Genecov et al.(131)	1998	N	N	N	N	N	Y	Y	NR	Y	Y	Y	Y
Percent of "Y" Responses		**22**	**17**	**7**	**27**	**25**	**35**	**45**	**37**	**35**	**82**	**37**	**15**

† Based on "change in wound area/volume" as the reference outcome

Table 15a. Answers to Quality Assessment of Controlled Studies Comparing NPWT to Comparative Treatments†

Studies	Year	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Overall Score
Timmers et al.(106)	2009	N	N	NR	N	Y	Y	NR	Y	Y	Y	4.54
Blume et al.(108)	2008	N	N	N	N	N	Y	Y	N	Y	N	6.59*
Gabriel et al.(339)	2008	N	N	N	N	Y	Y	Y	Y	Y	N	3.41*
Korber et al.(340)	2008	N	N	N	N	NR	NR	Y	Y	Y	NR	2.72**
Ozturk et al.(117)	2008	N	N	N	N	N	N	Y	Y	Y	NR	4.54**
Rinker et al.(121)	2008	N	N	N	N	Y	Y	NR	Y	Y	Y	4.54
Simek et al.(123)	2008	N	N	N	N	Y	Y	Y	Y	Y	NR	4.09**
Armstrong et al.(109)	2007	N	N	Y	N	Y	Y	Y	Y	Y	N	7.95*
Denzinger et al.(135)	2007	N	NR	NR	N	NR	NR	Y	Y	Y	Y	4.50
Lavery et al.(341)	2007	N	NR	NR	N	NR	NR	Y	NR	NR	N	3.18*
Moues et al.(136)	2007	N	N	N	N	Y	Y	Y	Y	Y	N	5.68*
Siegel et al.(119)	2007	N	NR	NR	N	NR	NR	NR	Y	Y	NR	2.95**
Braakenburg et al.(114)	2006	N	N	N	N	Y	Y	Y	N	N	N	6.4*
Huang et al.(127)	2006	N	NR	NR	N	NR	NR	NR	NR	NR	NR	3.86**
Stannard et al.(125)	2006	N	N	N	N	Y	Y	Y	Y	Y	N	5.45*
Vuerstaek et al.(115)	2006	N	N	N	N	Y	Y	Y	N	Y	NR	7.04**
Yang et al.(72)	2006	N	N	N	N	NR	NR	NR	Y	Y	NR	3.41**
Bickels et al.(134)	2005	N	N	N	N	NR	NR	NR	Y	Y	Y	3.63
Fuchs et al.(23)	2005	N	N	N	N	Y	Y	Y	Y	Y	NR	4.32**
Immer et al.(130)	2005	N	N	N	N	Y	Y	N	Y	Y	NR	2.95**
Schwien et al.(126)	2005	N	NR	NR	N	NR	NR	NR	NR	NR	N	3.18*
Segers et al.(122)	2005	N	N	N	N	Y	Y	Y	N	N	NR	2.27**
Sjogren et al.(139)	2005	N	N	N	N	Y	Y	N	Y	Y	Y	4.09

Studies	Year	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Overall Score
Vidrine et al.(342)	2005	N	N	N	N	Y	Y	Y	Y	Y	NR	5.0**
Kamolz et al.(343)	2004	N	N	NR	NR	Y	Y	Y	Y	Y	NR	5.45**
Labler et al.(71)	2004	N	N	NR	N	Y	Y	N	Y	Y	NR	3.41**
Moisidis et al.(112)	2004	N	N	Y	N	N	N	Y	Y	Y	NR	6.59**
Page et al.(1,112)	2004	NR	NR	NR	N	NR	NR	N	Y	Y	NR	3.86**
Stone et al.(133)	2004	N	N	N	N	Y	NR	NR	Y	Y	NR	4.09**
Shilt et al.(138)	2004	N	N	NR	N	N	Y	Y	Y	Y	Y	4.32
Domkowski et al.(139)	2003	N	N	N	N	Y	Y	NR	NR	NR	NR	3.18**
Song et al.(124)	2003	N	N	N	N	Y	Y	Y	Y	Y	Y	5.00
Wanner et al.(118)	2003	N	NR	N	N	Y	Y	Y	Y	Y	NR	4.77**
Doss et al.(128)	2002	N	N	N	N	N	NR	NR	NR	NR	NR	2.72**
Ford et al.(110)	2002	N	NR	Y	NR	Y	Y	Y	Y	NR	N	7.27*
Scherer et al.(132)	2002	N	N	N	N	Y	NR	Y	Y	Y	NR	3.63**
Catarino et al.(137)	2000	N	N	N	N	Y	Y	Y	Y	Y	NR	4.09**
Joseph et al.(113)	2000	N	N	Y	N	Y	Y	Y	Y	Y	NR	6.6**
McCallon et al.(120)	2000	N	N	NR	N	Y	Y	Y	Y	Y	N	5.68*
Genecov et al.(131)	1998	N	N	Y	N	Y	Y	Y	N	Y	Y	5.45
Percent of "Y" Responses		**0**	**0**	**12**	**0**	**65**	**65**	**65**	**77**	**82**	**20**	
Median Score												**4.32**

† Based on "change in wound area/volume" as the reference outcome

* Fully or partially funded by KCI

** Conflict of interest not reported

Table 15b. Answers to Quality Assessment of a Controlled Study Comparing NPWT to a Redon Bottle†

Studies	Year	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Wild et al.(116)	2008	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NR

Table 15c. Answers to Quality Assessment of a Controlled Study Comparing NPWT to a Redon Bottle†

Studies	Year	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Overall Score
Wild et al.(116)	2008	N	NR	Y	N	Y	Y	Y	Y	Y	Y	8.64

† Based on “change in wound area/volume” as the reference outcome

Appendix C: Evidence Tables

Key Question 1

Table 16. Comparison Trials of NPWT Devices Used to Treat Chronic Wounds

Reference	Wound Type	Comparator	Number of Patients Enrolled	Quality Score*
Blume et al. 2008(108)	Diabetic Foot Ulcer	Advanced Moist Wound Therapy (AMWT)	342	Moderate
Armstrong et al. 2007(109)	Diabetic Foot Ulcer	Standard wound therapy (SWT)	162	Moderate
Lavery et al. 2007(341)	Diabetic Foot Ulcer	Wet-to-moist	1,721	Low
McCallon et al. 2000(120)	Diabetic Foot Ulcer	Saline-moistened gauze	10	Low
Schwien et al. 2005(126)	Pressure Ulcer	Any other wound care modality	2,348	Low
Wanner et al. 2003(118)	Pressure Ulcer	Gauze soaked with Ringer's solution	22	Low
Ford et al. 2002(110)	Pressure Ulcer	Healthpoint System (HP)	28	Moderate
Joseph et al. 2000(113)	Pressure Ulcer	Saline wet-to-moist	24	Moderate
Denzinger et al. 2007(135)	Complex Inguinal	Saline moistened gauze	16	Low
Moues et al. 2007(136)	Full-thickness	Standard moistened gauze	54	Low
Siegel et al. 2007(119)	Radiation-associated	Standard of care	41	Low
Braakenburg et al. 2006(114)	Chronic and acute	Hydrocolloid dressings, alginates, acetic acid or Eusol (sodium hypochlorite)	65	Moderate
Bickels et al. 2005(134)	Soft tissue defects	Standard of care	38	Low
Page et al. 2004(1)	Open foot	Standard of care	47	Low

* ECRI Institute study quality assessment instrument

Diabetic Foot Ulcers: The quality of the studies of diabetic foot ulcers was moderate (2 studies) and low (2 studies). Methodological study flaws included lack of appropriate randomization, high attrition and funding from a potentially biased source. Of the four studies, only one study indicated an appropriate randomization method. This study, however, reported the highest attrition rate of over 30% of the patient population.(108) One low-quality study,(120) reported "flip of a coin" followed by an alternate allocation as a randomization method. Finally, all of the studies were funded by one manufacturer which increases the potential for bias in reporting of results.

All four studies evaluated V.A.C.® (KCI, USA Inc.) a powered suction pump system, for the treatment of diabetic foot ulcers; one study evaluated diabetic foot amputation wounds. (Table 23). Comparator treatment for two studies was moistened gauze.(120,341) Two other studies assessed advanced moist wound therapy (hydrogels, hydrocolloids and alginates).(108,109) Patients averaged 58 years of age; average duration of ulcers was over 200 days. Complete patient and wound characteristics are presented in Table 24.

V.A.C.® foam dressings were changed every 48 hours as per the manufacturer's recommendations in three studies(108,109,120) and control treatments were closely monitored with two studies adhering to standardized guidelines.(108,109) Wound measurements were assessed as frequently as every dressing change or up to 10 times in one 112-day study.(108) Treatment related characteristics are presented in Table 25.

Individual study results for four diabetic foot ulcer studies are presented in Table 26. Outcome reporting varied across studies but each study reported some measure of ulcer size reduction or time to complete wound healing. Small sample size (n = 10) precluded the determination of any statistically significant benefit in one low-quality study.(120) A 28.4% average decrease (V.A.C.®) and 9.5% average increase (control) was reported, however, one V.A.C.® (20%) wound increased in size and healed by "secondary intention." Satisfactory healing was achieved in an average of 22.8 (±17.4) days for V.A.C.® and 42.8 (±32.5) days for control.

One moderate-quality study of 342 diabetic foot wounds;(108) reported a mean change in wound size in favor of NPWT (-4.32 cm^2 versus -2.53 cm^2, p = 0.021) as well as a higher proportion of V.A.C.®-treated patients achieving complete wound closure (43% vs. 28.9%). Data, however, were reported for day 28 during the "active treatment phase" although both 3 and 9 month follow-up assessments were completed for patients achieving ulcer closure. In addition, 40 patients (13% V.A.C.®) discontinued treatment due to adverse events (Table 6).

Armstrong et al.(109) reported results of a secondary analysis of a 16-week study of 164 diabetic foot amputation wounds. Results for this evaluation of wound chronicity indicated no significant difference for proportion of acute and chronic patients achieving complete wound closure or time to complete closure. In addition, there was no significant difference in the proportion of acute or chronic wounds that achieved complete closure between NPWT and SWT groups (acute *P = 0.072*, chronic *P = 0.320*). Lastly, a low-quality study by Lavery et al.(341) reported wounds healed at 12 and 20 week assessments with results favoring NPWT over standard of care (39.5% vs. 23.9%, week 12; 46.3% vs. 32.8%, week 20).

Pressure Ulcers: Quality of the four pressure ulcer studies was moderate(110,113) and low.(118,126) Of the four studies, three included small study populations ranging in size from 22 to 28 patients. One of two RCTs did not report randomization methods.(118) One study indicated

that outcome assessors were blinded to treatment.(113) Studies did not indicate concealment of group allocation, and underreported patient characteristics which increases the likelihood that study patients were not comparable at baseline. All four studies either reported funding by one manufacturer or failed to report a conflict of interest.

Three studies strictly included only pressure ulcer wounds while one study involved patients with other types of wounds.(113) Comparator treatments included traditional and non-traditional treatments. Primary outcomes varied across studies and ranged from wound healing outcomes (i.e., change in wound volume) to quality of life issues (i.e., rates of hospitalization and emergent care). Two studies reported time to satisfactory wound healing(110,118) while one study stated "complete wound closure was not a realistic end point since wounds were of variable sizes and anatomic locations."(113)

Three studies showed a favorable effect in the group that received NPWT, however this was only significant in one study.(113) Results for one moderate-quality study included increased rates of wound healing, superiority in decreasing inflammation at the wound site, and increased number of capillaries (suggesting the promotion of formation of granulation tissue) compared to HealthPoint System.(110) In this 6 week study, complete healing was reported for only 4 wounds; 2 (10%; V.A.C.®) and 2 (13% HP).

A similar length study(113) evaluated 24 patients with 36 chronic non-healing wounds (79% pressure ulcers). Average initial wound volume was larger for V.A.C.® wounds (38 cubic centimeters (cc) vs 24 cc) however a significant reduction in wound volume was still demonstrated (78% vs 30% control). A significantly greater reduction in wound depth (66% vs. 20% control; $p < 0.00001$) and width was reported however improvement did not extrapolate to wound length.

One low-quality study evaluated 2348 patients (60 V.A.C.®) identified from a search of 1.94 million start-of-care assessments.(126) The purpose of this study was to determine whether NPWT was associated with positive quality outcomes. Instances of hospitalization for wound problems (5% versus 14%, control) and instances of emergent care for wound problems were lower (0% versus 8% control) for V.A.C.®. Ulcer size, treatment duration and treatment comparators were not indicated by study authors.

Wanner et al.(118) evaluated pressure ulcers of 22 paraplegics or tetraplegic patients. Authors concluded that gauze soaked with Ringer's solution was equally effective as NPWT in "time needed to form granulation tissue" (27 days vs. 28 days control).

Miscellaneous Chronic Wounds: Six studies included chronic wounds from miscellaneous diagnoses. Five of the studies were rated of low quality(112,119,134-136) and one was rated moderate.(114) Descriptions of study designs may be found in Table 19.Comparator treatments for five of the six trials were standard of care. Control treatment for the sixth study was "modern dressings" which includes hydrocolloid dressings, alginates, acetic acid or Eusol (sodium hypochlorite).(114) Table 20 and Table 21 list additional patient and treatment-related characteristics.

Three of the six studies reported a comparable benefit to time to satisfactory healing in comparison to control treatments.(1,114,136) One moderate-quality study, Braakenburg et al.(114), evaluated 65 patients with chronic and acute wounds. Similar results were reported for overall change in wound area (0.1 cm^2/day), time to satisfactory healing (median 16 [V.A.C.®]

vs. 20 [control]) and overall change in the amount of granulation. Two patients discontinued V.A.C.® due to pain during dressing changes; one patient refused to cooperate (V.A.C.®); one amputation and 6 early dismissals were reported for the control group.

Moues et al.(136) reported similar "time to surgical readinesses" for 54 patients treated with V.A.C.® or SOC. Two V.A.C.® patients discontinued treatment due to sepsis of unknown origin. Two control patients registered wound surface area increase. Postoperative complications were high, reported in 32% of V.A.C.® and 43% of control groups (Table 5). Page et al.(1) reported no difference in "time to closure" and "wound cavity filling" for 47 patients with open foot wounds (Table 22).

Three remaining studies concluded that NPWT was more effective for time to wound closure than the control treatments.(119,134,135) Denzinger et al.(135) studied treatment of 16 complex inguinal wounds; 6 wounds treated with V.A.C.®. Median duration until complete wound closure was significantly shorter for V.A.C.® treated (38.9 days versus 69.8 days, control).

In one study of 41 patients with radiation-associated wounds, a significant improvement was reported for success of wound closure with the need for soft tissue transposition, hospital stay and length of overall treatment.(119) Mean change in wound area for V.A.C.® was reported at -329 cm^3; however, the authors failed to report data for the control group. Amputations were reported in both both groups (V.A.C.® [1] and control [3]).

Bickels et al.(134) studied 62 patients with soft tissue defects. V.A.C.® patients had significantly greater rates of primary wound closure with or without skin graft; and significantly shorter hospital stays than non-V.A.C.® patients. Authors failed to report baseline wound size for controls; three control patients required lower extremity amputation.

Acute Wounds

The evidence base for comparison trials of NPWT used to treat acute wounds includes 16 low-quality studies (Table 17).

Table 17. Comparison Trials of NPWT Used to Treat Acute Wounds

Reference	Wound Type	Comparator	Number of Patients Enrolled	Quality Score*
Timmers et al. 2009(106)	Post-traumatic osteomyelitis	SOC	124	Low
Simek et al. 2008(123)	Deep sternal	Conventional	62	Low
Yang et al. 2006(72)	Fasciotomy	SOC	68	Low
Stannard et al. 2006(125)	Study1: hematoma	Study 1: Pressure dressing	Study 1: 44	Low
	Study 2: fracture	Study 2: Post-operative dressing	Study 2: 44	Low
Fuchs et al. 2005(23)	Deep sternal	Conventional	68	Low
Immer et al. 2005(130)	Deep sternal wound infection	Sternal excision and primary musculocutaneous flap	55	Low

Reference	Wound Type	Comparator	Number of Patients Enrolled	Quality Score*
Segers et al. 2005(122)	Post-sternotomy mediastinitis (PM)	Closed drainage	63	Low
Sjogren et al. 2005(139)	PM	Conventional	101	Low
Domkowski et al. 2003(129)	PM	SOC	102	Low
Song et al. 2003(124)	Surgical	Standard of care (SOC)	35	Low
Doss et al. 2002(128)	Post-sternotomy osteomyelitis	SOC	42	Low
Catarino et al. 2000(137)	PM	Closed drainage and irrigation	17	Low
Shilt et al. 2004(138)	Traumatic	SOC	31	Low
Kamolz et al. 2003(343)	Burn	Silver sulphadiazine	7	Low
Gabriel et al. 2008(339)	Infected	SOC	30	Low
Ozturk et al. 2008(117)	Fournier's gangrene	SOC	10	Low
Rinker et al. 2008(121)	Open tibia fracture	SOC	55	Low
Huang et al. 2006(127)	Limb	SOC	24	Low
Labler et al. 2004(71)	Soft tissue	Epigard® dressing	23	Low

* ECRI Institute study quality assessment instrument

Surgical Wounds: The evidence base for studies evaluating NPWT treatment of sternal wounds (Table 31) included one randomized controlled trial and one retrospective review. Stannard et al.(125) evaluated two small study populations: (1) trauma patients with hematomas and (2) patients with high-risk fractures. Results for both studies included a significant difference in mean days to drainage favoring V.A.C.® (hematoma study: 1.6 days (d) versus 3.1; fracture study: 1.8 d versus 4.8). A higher infection rate for non-NPWT patients was reported in the hematoma study, while similar rates of infection and complications were reported in the fracture study.

The retrospective review by Song et al.(124) reported no significant differences for average days between debridement and definitive closure of the sternal wound (6 ±1.3 d versus 8 ±2.9 d, control). Results for all studies evaluating acute wounds can be found in Table 34.

Surgical Site Infections (SSI): Eight low-quality studies evaluated V.A.C.® for the treatment of surgical site infections (SSI). Interventions included conventional treatments (2 studies), closed drainage (3 studies), and standard of care (2 studies). Some studies reported similar results for wound healing(23,128,137,139), while two reported significant benefit(123) or modest benefit to NPWT.(122)

In a study of 62 patients with sternal wound infections, Simek et al.(123) reported significant findings for failure rate (5.8% versus 39.2%, control) and 1-year mortality (14.7% versus 39.2%, control) in favor of V.A.C.®.

In a similar-sized study, Fuchs et al.(23) retrospectively evaluated 68 patients and reported similar time to primary or secondary wound healing (21 days (IQR: 15 to 26d) versus 28 days (IQR: 18 to 54d), control). A total of 5 deaths occurred in this study; one death from vacuum-related perforation.

Segers et al.(122) evaluated 63 post-sternotomy (PM) patients treated by V.A.C.® or closed drainage technique (CDT). Duration of therapy (22.8 days versus 16.5, NS) and mean SSI hospital stay (46.1 versus 35.7) were longer with V.A.C.®. A high morbidity rate was reported (29%) with 9 deaths reported in each patient group. Mortality caused by SSI was lower for V.A.C.® (4 [13.8%]) versus control (7 [20.6%]). See Table 8 for a further description of acute study complications.

Sjogren et al.(139) examined 101 PM patients treated by V.A.C.® or conventional treatment which included open dressings, closed irrigation, pectoral muscle flaps, or omentum flaps. 61 patients underwent V.A.C.® as a single-line therapy followed by sternal rewiring. Results were similar for treatment duration, length of stay, and rate of infection, however, overall survival was significantly better in the V.A.C.® (97% versus 84% [6 months], 93% versus 82% [1 year], and 83% versus 59% [5 years]).

Standard of care was evaluated as a comparator treatment for two studies evaluating treatment of SSI. In a study of 102 PM patients, Domkowski et al.(129) reported four deaths overall (2 from multisystem organ failure and 2 from overwhelming sepsis). Doss et al.(128) reported similar results for reduction in wound size (4.63 cm^2/day versus 3.2 cm^2, control) and mortality (1 in each group) in a study of 42 PM patients.

A smaller study of 17 PM patients(137) reported similar time to wound closure (11 d median versus 13 d) although a significantly higher treatment failure for patients treated with closed

drainage and irrigation (0 versus 5, control). See Table 32 and Table 33 for additional information on patient and treatment characteristics, respectively.

Lastly, Immer et al.(130)assessed 55 patients with deep sternal wound infections (DSWI) after cardiac surgery. Study population was divided into three groups: (1) NPWT (2) NPWT plus secondary sternal excision and musculocutaneous flap and (3) sternal excision and primary musculocutaneous flap. Survival was significantly better in Group 1 (NPWT only) who also scored significantly higher on a quality-of-life assessment, SF-36, for aspects of physical function, general health and vitality.

Traumatic Wounds: In 2004, Shilt et al.(138) examined 31 pediatric patients for treatment of lawnmower injuries. Length of hospital stay was longer in V.A.C.® treated (16.8 versus 10.2, control). Similar results were reported when a questionnaire (Vosburgh et al.), was administered to evaluate post-treatment functional outcomes (23.0 versus 22.6, control).

Standard of care was compared to V.A.C.® in one low-quality study.(72) Yang et al. compared 68 patients with fasciotomy wounds for traumatic compartment syndrome. Results indicated a significant reduction in overall time to definitive wound closure by either delayed primary closure with sutures or STSG for V.A.C.®-treated (6.7 days versus 16.1 days, $p = 0.0001$).

Timmers et al.(106) recently assessed treatment of 124 post-traumatic osteomyelitis patients by negative pressure instillation therapy (NPIT) versus SOC. The median duration of the first hospital stay did not differ (36 days (V.A.C.®) vs. 27.3 days), however due to the high number of recurrences of osteomyelitis (58.5%) and subsequent rehospitalizations, the cumulative duration of hospital stay was significantly higher in the control group (73 days versus 36 days (V.A.C.®) ($p < 0.0001$).

Burn Wounds: One low-quality study examined treatment of burn wounds for 7 patients (used as their own controls).(343) Wounds with more intense injury received V.A.C.® while the other less injured hand received silver sulphadiazine (SSD) crème. Results indicate a greater reduction of edema formation within the V.A.C.® treated hand.

Miscellaneous Acute Wounds: Traditional treatments were compared to V.A.C.® in five low-quality studies examining miscellaneous acute wound.(71,117,121,127,339) Results were similar for two(117,127) while three studies found benefit from V.A.C.® treatment.(71,121,339)

A subgroup of 55 sub-acute patients underwent a free muscle flap for treatment of a Gustilo grade IIIB or IIIC tibia fracture(121) (overall n = 105). Time to bony union was significantly less for V.A.C.® treated (4.9 months versus 7.2 months). Length of hospital stay was similar (20.8 ±10.5 versus 20.2 ±8.5, control).

Gabriel et al.(339) evaluated 30 patients with infected trunk and extremity wounds treated with NPWT with instillation. NPWT patients (n = 15) experienced significantly fewer days to wound closure (13.20 ±6.75 versus 29.6 ±6.54, control) and significantly shorter days to patient discharge (14.67±9.18 versus 39.2 ±12.07, control). 100% of wounds were healed with NPWT with instillation versus 66.7% of the traditional group.

In 2004, Labler et al.(71) compared 23 patients with severe open fractures treated by V.A.C.® or Epigard® dressing. Wounds were “healed uneventfully” for 11 of 13 (85%) V.A.C.® versus five of ten (50%) control wounds. Rate of infection was higher for Epigard® treated (6 of 11 (55%) versus 2 of 13 (15%), V.A.C.®).

In a small study (n = 10) of patients with Fournier's gangrene, similar results were shown for "time to satisfactory healing" (9 days vs 10d (control); and "hospital stay"(14 days vs 13 days (control).(117) Pain assessment measured by the visual analog scale (VAS) indicated less pain in V.A.C.® group (2.4 and 6.8, control). Patients scored need for analgesics, number of times per day mobile, and number of additional dressing changes per day.

Results for hospital stay and wound volume were similar in a study of 24 patients with limb wounds.(127) Mean days for hospital stay (32.1d vs. 34.3) and reduction in dimension (47% vs. 41% control) and reduction in volume (49% vs. 39% (control)) were all similar for V.A.C.® and control groups. Adverse events resulting in discontinuation of treatment included 1 death and 2 amputations in V.A.C.® (25% of group). One death and two amputations were reported in SOC group as well.

Skin Graft: The evidence base for comparison trials of NPWT devices used to secure skin grafts includes two moderate-quality and five low-quality studies (Table 18).

Table 18. Comparison Trials of NPWT Devices Used to Secure Skin Graft

Reference	Wound Type	Comparator	Number of Patients Enrolled	Quality Score*
Korber et al. 2008(340)	Chronic leg	Standard of care (SOC)	54	Low
Vuerstaek et al. 2006(111)	Chronic leg	Conventional (hydrocolloids, alginates)	60	Moderate
Vidrine et al. 2005(342)	Skin grafted radial forearm	Bolster dressing plus splint	44	Low
Moisidis et al. 2004(112)	Clinically ready for skin graft	Bolster dressing	22	Moderate
Stone et al. 2004(133)	STSG	Cotton bolster dressing	40	Low
Scherer et al. 2002(132)	STSG	Cotton bolster dressing	61	Low
Genecov et al. 1998(131)	STSG	Opsite	10	Low

STSG Split thickness skin graft

Seven studies evaluated the use of NPWT to secure skin grafts (split-thickness, mesh and punch). Quality of the studies was moderate (k = 2) and low (k = 5). Comparators included bolster dressings (k = 4), standard of care (k = 1), Opsite dressing (k = 1) and conventional treatments (i.e., hydrocolloids, alginates) (k = 1). Study populations were small, ranging from 10 to 61 patients (Table 27).

Two moderate-quality studies randomized patients to NPWT or conventional and bolster dressings.(112,115) Vuerstaek et al.(115) evaluated 60 patients with chronic leg ulcers randomized to treatment by V.A.C.® or alginates/hydrocolloids. Time to complete healing was significantly reduced in the NPWT group (29 d (95% CI, 25.5 to 32.5) versus 45 d(95%CI, 36.2 to 53.8)). Results for secondary outcomes included a greater relapse at 1 year follow-up (52% of all healed V.A.C.® ulcers relapsed compared with 42%, control). Both groups reported

significant increases in quality of life and similar decreases in pain. See Table 30 for further details on measures of outcome.

Moisidis et al.(112) enrolled 22 patients (used as their own controls) with wounds clinically ready for skin graft. Total negative pressure (TNP) was used on the superior half of the wound in ten patients and inferior half in the remaining ten. At 2 weeks, a quantitative assessment by a clinician blinded to treatment reported the degree of epithelialization similar in both groups.

One low-quality study(340) evaluated 54 patients with 74 chronic leg ulcers of comparable size (Table 28). Complete healing of mesh grafts was significantly higher for V.A.C.® treated compared to standard of care (92.9% versus 67.4%). Age older than 70 years, diabetes mellitus and dermatoliposclerosis were strong predictors to poor graft take.

Three low-quality studies evaluated a bolster dressing as a comparator treatment. A four week assessment of 45 radial forearm donor sites indicated overall complete split-thickness skin graft (STSG) take rate higher in negative pressure dressing group compared to management by bolster dressing and splint.(342) Stone et al.(133) evaluated 40 trauma patients who received 46 STSGs. Similar results were reported for duration of dressing (4.8d versus 5.2d, control), mean hospital stay (20.9 ±10 versus 15.3 ±7.5, control), and graft failure. No grafts failed in the NPWT group while one graft failure was reported in the control group (Table 7).

Improved graft survival was reported by Scherer et al.(132) in an assessment of graft take when placed for burn (52%), soft tissue loss (44%) and fasciotomy-site coverage (3%). Repeated STSG to same site was significantly higher in controls compared to V.A.C.® (5 (19%) versus 1 (3%)). Although grafts were significantly larger in the control group (984 ±996 cm^2 versus 387 ±573 cm^2) the 6 repeated grafts were of small or moderate size.

In a seven day study, Genecov et al.(131) evaluated 10 patients who served as their own controls. Blinded assessors analyzed biopsies to measure degree of reepithelialization (Table 29). Results indicated faster reepithelialization with V.A.C.® (n = 7); no difference (n = 2); and more rapid reepithelialization with Opsite (n = 1).

Chronic Wounds

Table 19. Key Study Design Characteristics of Comparison Studies of NPWT Devices* Used to Treat Miscellaneous Chronic Wounds

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Moues et al. 2007(136)	RCT*	Full-thickness	54	Standard moist gauze	From July 1998 to October 2002, patients with a full-thickness wound that could not be closed immediately because of severely crushed tissue, infection or chronic character	Malignant disease, superficial bare blood vessels, deep fistulae, necrotic tissue, an unstable skin around the wound, sepsis, untreated Osteomyelitis, active bleeding, uncontrolled diabetes and psychiatric disorders	Ready for surgical readiness	V.A.C.® – 3 Control – 2
Braakenburg et al. 2006(114)	RCT*	Acute and chronic	65	Conventional therapy Hydrocolloid dressings, alginate, acetic acid, or Eusol (sodium hypochlorite)	Consecutive patients with any type of wound, acute or chronic, throughout all patient departments at the Rijnstate Hospital, Arnhem, The Netherlands between March 2002 and May 2004.	Steroid drugs, residual malignant cells in the wound, radiotherapy, deep fistulae, sepsis, underlying osteomyelitis, active bleeding, patients younger than 18 years, and psychiatric patients.	Complete granulated wound or a wound ready for skin grafting or healing by secondary intention	NR
Denzinger et al. 2007(135)	Non-RCT*	Inguinal wounds	16	Saline-moistened gauze	Patients with inguinal regions subjected to lymphadenectomy for penile cancer between 2000 and 2006.	NR	Complete wound closure	NR

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Siegel et al. 2007(119)	Non-RCT*	Radiation-associated	41	SOC	NPWT: 22 patients treated with V.A.C.® between Jan 2003 and Jan 2006 with soft tissue sarcomas treated with both surgical intervention and radiation therapy and developed either superficial or deep wound (16) complications: SOC: 19 patients with soft tissue sarcomas treated from Jan 2001 and Jan 2003 with similar history of radiation treatment, chemotherapy, wound size and patient age	NR	Until wound healing by either primary or secondary intention, skin grafting or soft tissue transposition	NR
Bickels et al. 2005(134)	Non-RCT*	Soft tissue defects	62	SOC	V.A.C.®: 23 consecutive patients with large defects after tumor resection treated in 2002 and 2003. Control: 39 patients with similar defects treated between May 1999 and May 2002	Patients with gross infection or residual tumor at the surgical site were excluded from V.A.C.®	Wound is covered with viable and thick granulation tissue allowing for primary closure, skin grafting or healing by secondary intention F/U 12-27 months (median 19 months)	NR

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Page et al. 2004(1)	Non-RCT*	Open foot	47	Saline-soaked gauze	Patients identified in a surgical log at Carl Hayden VA Medical Center aged 18 to 75 with an open foot wound of any etiology requiring surgical intervention, no presence of infection in the wound when therapy was initiated, a soft tissue defect at least 2 cm deep following surgical intervention (debridement/amputation) and wound treatment with either NPWT or wet-to-moist dressings after surgical intervention	Persistent wound infection, necrotic tissue in the wound bed, and interruption in treatment or use of alternative therapies during the wound cavity filling time	NR	NR

NR Not Reported
RCT Randomized controlled trial

* All studies reported using V.A.C.® (KCI, USA Inc.)

Table 20. Patient Characteristics in Comparison Studies of NPWT Devices* Used to Treat Miscellaneous Chronic Wounds

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Ulcer
Moues et al.(136)	RCT	V.A.C.®: 29	47.7 ±19.6	NR	Diabetes – 6 Vascular compromised – 8 Osteomyelitis – 8	29	NR	12 early treated, 17 late treated	NR
	RCT	Standard moist: 25	47.9 ±17.0	NR	Diabetes – 1 Vascular – 3 Osteomyelitis – 4 Spinal cord lesion – 5	25	NR	8 early treated, 17 late treated	NR
Braakenburg et al.(114)	RCT	V.A.C.®: 32	65.5 median	M20 F12	Diabetes – 12 (37%) Vascular surgery – 9 (28%) Cardiovascular disease – 11 (34%) Smoking – 8 (29%)	32	29.5 cm^2 (median) Range: 3 to 600 cm^2	Chronic – 64% Acute – 11% Subacute – 23	NR
	RCT	Control: 33	69.2 median	M16 F17	NR	33	30 cm^2 (median) Range: 6 to 152 cm^2	NR	NR
Denzinger et al.(135)	Non-RCT	V.A.C.®: 5	64	M5	No difference reported	6	34 cc Range: 24-54	NR	NR
	Non-RCT	SOC: 9	67	M9		10	37 cc Range: 24-84		
Siegel et al.(119)	Non-RCT	V.A.C.®: 22	41 (24-78)	NR	NR	22	111 cm^3 Range: 2.5-3,660	NR	NR
	Non-RCT	SOC: 19	46 (19-67)		NR	19	410 cm^3 Range: 4-3,800cm^3	NR	NR
Bickels et al.(134)	Non-RCT	V.A.C.®: 23	Median: 46.5 Range: 36-72	M8 F15	NR	23	Mean: 345 cm^2 Range: 64 cm^2 to 520 cm^2	NR	NR
	Non-RCT	SOC: 39		M21 F18	NR	NR	NR	NR	NR

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Ulcer
Page et al.(1)	Non-RCT	V.A.C.®: 22	66 (±12)	M22	Diabetes – 17 (77%)	22	Wound dimensions were not consistently recorded Wounds were divided into small, medium and large Small 2 (9%) Med 6 (27%) Lg 14 (64%)	NR	NR
	Non-RCT	Control: 25	60 (±11)	M25	Diabetes – 14 (56%)	25	Small 8 (32) Med 7 (28%) Lg 10 (40%)		
Moues et al.(136)	RCT	V.A.C.®: 29	47.7 ±19.6	NR	Diabetes – 6 Vascular compromised – 8 Osteomyelitis – 8	29	NR	12 early treated, 17 late treated	NR
	RCT	Standard moist: 25	47.9 ±17.0		Diabetes – 1 Vascular – 3 Osteomyelitis – 4 Spinal cord lesion – 5	25		8 early treated, 17 late treated	
Braakenburg et al.(114)	RCT	V.A.C.®: 32	65.5 median	M20 F12	Diabetes – 12 (37%) Vascular surgery – 9 (28%) Cardiovascular disease – 11 (34%) Smoking – 8 (29%)	32	29.5 cm^2 (median) Range: 3 to 600 cm^2	Chronic – 64% Acute – 11% Subacute – 23	NR
	RCT	Control: 33	69.2 median	M16 F17		33	30 cm^2 (median) Range: 6 to 152 cm^2		
Denzinger et al.(135)	Non-RCT	V.A.C.®: 5	64	M5	No difference reported	6	34 cc Range: 24-54	NR	NR
	Non-RCT	SOC: 9	67	M9		10	37 cc Range: 24-84		

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Ulcer
Siegel et al.(119)	Non-RCT	V.A.C.®: 22	41 (24-78)	NR	NR	22	111 cm^3 Range: 2.5-3,660	NR	NR
	Non-RCT	SOC: 19	46 (19-67)			19	410 cm^3 Range: 4-3,800 cm^3		
Bickels et al.(134)	Non-RCT	V.A.C.®: 23	Median: 46.5 Range: 36-72	M8 F15	NR	23	Mean: 345 cm^2 Range: 64 cm^2 to 520 cm^2	NR	NR
	Non-RCT	SOC: 39		M21 F18					
Page et al.(1)	Non-RCT	V.A.C.®: 22	66 (±12)	M22	Diabetes – 17 (77%)	22	Wound dimensions were not consistently recorded Wounds were divided into small, medium and large Small 2 (9%) Med 6 (27%) Lg 14 (64%)	NR	NR
	Non-RCT	Control: 25	60 (±11)	M25	Diabetes – 14 (56%)	25	Small 8 (32) Med 7 (28%) Lg 10 (40%)		

RCT Randomized controlled trial

Table 21. Treatment-Related Characteristics in Comparison Studies of NPWT Devices* Used to Treat Miscellaneous Chronic Wounds

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Moues et al.(136)	RCT	V.A.C.® Continuous pressure of 125 mmHg Polyurethane foam dressing with a pore size of 400-600 *u*m (V.A.C.® pack)	48 hrs	Trace of wound onto clear polyethylene film; after photocopying the tracing onto paper, the wound surface areas were scanned and calculated; tissue biopsies taken every 2-3d throughout treatment	Every 48 hrs	Ready for surgical readiness or 30 days or prior to 30 days if treatment terminated	NR	• Initially, surgical debridement: V.A.C.® 97%, control 88% • Secondly, surgical debridement: 4 V.A.C.®, 3 control • Thirdly, chemical debridement was clinically indicated in 20 out of 25 control wounds (80%) • Topical antimicrobial treatment used for 11 out of 25 control wounds (44%) • Special pressure relieving mattresses if bedridden
	RCT	Standard moist-saturated in either 0.9% saline, 0.2% nitrofuralam, 1% acetic acid or 2% sodium hypochlorite	2x/day minimum					
Braakenburg et al.(114)	RCT	V.A.C.® CNP: -125 mmHg Black polyurethane foam dressing with a pore size of 400 to 600 *u*m	3x/wk	Photos and bacteriologic swabs – 1x/wk Wound surface measured with a standardized drape – 2x/wk Pain assessed with visual analogue scale – 3x/wk	3x/wk	NR	NR	Surgical debridement
	RCT	Conventional	1 or more times/day					
Denzinger et al.(135)	Non-RCT	V.A.C.® Continuous negative pressure (125 mmHg) Foam dressing	Every 3d	NR	NR	Complete wound closure	Inguinal lymphadenectomy for penile cancer	• Surgical debridement • Secondary surgical debridement • Adjuvant radiotherapy or chemotherapy: 2 V.A.C.® and 3 SOC
	Non-RCT	SOC + hydrogel (n = 3) + hydrocolloid (n = 2)	Every other day					

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Siegel et al.(119)	Non-RCT	V.A.C.® Continuous 125 mmHg Sponge	Every 2-3d	NR	NR	Average: 41d over a 3 year period	Surgical resection and radiation	• Surgical debridement • Post-operative brachytherapy • Rotational soft tissue transposition (n = 6) • Free vascularized flap (n = 1) • Split thickness skin graft (n = 8)
	Non-RCT	SOC and/or additional soft tissue coverage procedures						

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Bickels et al.(134)	Non-RCT	V.A.C.® Continuous negative pressure: -125 mmHg Polyurethane foam dressing	48 hours for 7 to 19 days	NR	NR	When wound is covered with viable and thick granulation tissue, which allows primary closure, skin grafting, or healing by secondary intention Average 14.5d Range: (7-19d) Average: 9.5d for patients who did not have radiation (n = 7) or exposed bone or tendon (n = 6)	Chemotherapy – 9 Radiation – 7	• Surgical debridement • Skin graft – 14 • Healing by secondary intention – 2
	Non-RCT	SOC	Daily			NR	NR	• Surgical debridement (second surgical debridement for 24 patients) • Skin graft – 10 • Free flap transfer – 3 • Healing by secondary intention – 15 • Lower extremity amputation – 3
Page et al.(1)	Non-RCT	V.A.C.®	NR	NR	NR	NR	NR	NR
		Saline moistened gauze	NR	NR	NR	NR	NR	NR

NR Not Reported
RCT Randomized controlled trial

* All studies reported using V.A.C.® (KCI, USA Inc.)

Table 22. Results for Outcome Measures Reported in Comparison Studies of NPWT Devices* Used to Treat Miscellaneous Chronic Wounds

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Moues et al.(136)	RCT	V.A.C.®	29		3.8 ±0.5%/day (n = 15; reduction observed in 100%) Subgroup	Time to surgical readiness: 6.00 ±0.52 days	NR	2 (sepsis with unknown origin, ischaemic pain with increased tissue necrosis)
	RCT	Standard moist	25		1.7 ±0.6%/day (n = 13; reduction observed in 77%)	7.00 ±0.81d		
Braakenburg et al.(114)	RCT	V.A.C.®	32	26	Overall change: 0.1 cm^2/day	Median time in days (95% CI): 16 (9-23)	Overall change in the amount of granulation was not different between the two groups.	2 (due to pain during dressing changes)
	RCT	Conventional	33	21	Overall change: 0.1 cm^2/day	Median time in days (95% CI): 20 (16-24)		
Denzinger et al.(135)	Non-RCT	V.A.C.®	5	6	NR	38.9d (median)	Hospital stay: 13.2d (8-27)	NR
	Non-RCT	SOC	9	10		69.8d	28.4 (16-39)	
Siegel et al.(119)	Non-RCT	V.A.C.®	22	21	-329 cm^3	Split thickness graft – 8 Soft tissue transposition – 6 Free vascularized flap – 1 Primary closure – 2 Secondary intention – 4 Healed post-amputation – 1	Hospital stay: 3.1d (portable V.A.C.®) 41d (1 patient in hospital)	NR
	Non-RCT	SOC			NR	Split thickness graft – 3 Rotational flaps – 7 Free vascularized flap – 4 Secondary intention – 5	42d	

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Bickels et al.(134)	Non-RCT	V.A.C.®	23	23 (covered with viable)	Average 25% reduction (range, 10%-35%): 20 patients Wounds from 3 patients showed no reduction in size (2 soft tissue around leg and 1 sacral)	NR	Hospital stay: 4-30d (Mean: 18.5; Median: 20d)	NR
	Non-RCT	SOC	39	39	NR		Hospital stay: 15-72d (Mean: 37d; Median: 39d)	
Page et al.(1)	Non-RCT	V.A.C.®	22	NR	Median time of wound filling: 38d (95% CI: 26 to 70)	NR	Median time to closure: 110d (79,184)	NR
	Non-RCT	SOC	25		80d (95% CI: 55 to 98) Wilcoxon chi-square suggests a difference between groups during the earlier part of follow-up (p = 0.040); the likelihood ratio chi-square indicates no overall difference in wound cavity filling time between groups (p = 0.41)		124d (105,284) No difference in time to closure between groups (Wilcoxon chi-square, P = 0.29	

NR Not reported
RCT Randomized controlled trial
SOC Standard of care
VAS Visual analogue scale

* All studies reported using V.A.C.® (KCI, USA Inc.)

Table 23. Study Design Characteristics of Comparison Studies of NPWT Devices* Used to Treat Diabetic Foot and Pressure Ulcers

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Blume et al. 2008(108)	RCT*	Diabetic foot ulcers (DFU)	342	Advanced moist wound therapy (AMWT) AMWT: Hydrogel 47% Alginates 31% Other 16.9% Saline 10.2% Collagen 6.6% Hydrocolloid 0.6%	Diabetic adults ≥18 years with a stage 2 or 3 (Wagner's scale) calcaneal, dorsal, or plantar foot ulcer ≥2 cm^2 in area after debridement	Recognized active Charcot disease or ulcers resulting from electrical, chemical, or radiation burns and those with collagen vascular disease, ulcer malignancy, untreated osteomyelitis, or cellulitis; uncontrolled hyperglycemia (A1C >12%) or inadequate lower extremity perfusion; ulcer treatment with normothermic or hyperbaric oxygen therapy; concomitant medications such as corticosteroids, immunosuppressive medications or autologous growth factor products; skin and dermal substitutes within 30 days of study start; or use of any enzymatic debridement treatments; pregnant or nursing mothers.	Incidence of complete ulcer closure or 112d	NPWT: n = 55 1 lost to f/u 54 discontinued AMWT: n = 48 5 lost to f/u 43 discontinued

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Armstrong et al. 2007(109)	RCT*	Diabetic foot amputation	162	Standard wound therapy (SWT) SWT: Alginates Hydrocolloids Foams Hydrogel	Individuals aged ≥18 years, presence of a diabetic foot amputation wound up to the tarso-metatarsal level of the foot and evidence of adequate perfusion.	Active Charcot arthropathy of the foot, wounds resulting from burns or venous insufficiency; patients presenting with untreated cellulitis or osteomyelitis (following amputation), collagen vascular disease, malignancy in the wound or uncontrolled hyperglycaemia; treated with corticosteroids, immunosuppressive medications or chemotherapy; treated with V.A.C.® within the past 30 days, present or previous treatment with growth factors, normothermic therapy, hyperbaric medicine or bioengineered tissue products within the past 30 days.	Until wound closure or 112 days	19 NPWT and 19 SWT withdrew before wound closure
Wanner et al. 2003(118)	RCT*	Pressure sores of the pelvic region	22	Gauze soaked with Ringer's solution	Consecutive patients with pressure sores (deeper than grade 2 as described by Daniel et al.) of the pelvic region admitted to the Swiss Paraplegic Centre, Nottwil, Switzerland between January 1998 and May 1999. Patient population consisted of paraplegics or tetraplegics.	NR	NR	NR

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Ford et al. 2002(110)	RCT*	Full-thickness decubitus ulcers	28	Healthpoint System (HP)	Patients recruited from the plastic surgery clinic and inpatient referral at Boston Medical Center with one to three full-thickness ulcers present for a minimum of 4 weeks; albumin ≥2.0; age 21-80; ulcer volume after debridement = 10-150 ml	Fistulae to organs or body cavities, malignancy in the wound, pregnant or lactating female, Hashimoto's thyroiditis, Graves' disease, iodine allergy, systemic sepsis, electrical burn, radiation exposure, chemical exposure, cancer, connective tissue disease, chronic renal or pulmonary disease, uncontrolled diabetes, corticosteroids or immunosuppressive agents, cardiac pacemaker, ferromagnetic clamps, recent placement of orthopedic hardware	6 weeks	6
Joseph et al. 2000(113)	RCT*	Chronic non-healing	24	Saline wet-to-moist (WM) dressings	Patients with chronic non-healing wounds defined as an open wound in any anatomic location that had failed to close or show signs of healing within four weeks or greater; enrolled between January 1998-May 1999 at Boston Medical Center	Infection (urinary tract, pneumonia, wound infection); albumin <3.0 gm/dl; renal, pulmonary, or other chronic disease requiring ongoing therapy for stabilization; uncontrolled diabetes mellitus, thyroid disease, or hypertension; systemic steroids, other immunosuppressive therapy or anticoagulants; pregnant or breast feeding; Osteomyelitis as determined by bone biopsy; uncooperative or unsuitable candidates for participation in dressing changes; malignant or neoplastic diseases in wound margin; fistulae	6 weeks	NR

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Lavery et al. 2007(341)	Non-RCT*	Diabetic Foot Ulcer	1,721	Wet-to-moist	NPWT: Data from a proprietary database maintained by KCI from patients treated for wound care between 1996 and 2004; presence of wound categorized as diabetic/ulcer neuropathic ulcer, wound treated with NPWT, wound of chronic nature, debridement of necrotic tissue performed, comprehensive diabetes management included with the case plan, reduction in pressure of affected ulcer, as needed and description of the wound size and duration prior to NPWT. Control: Patients from 5 RCTs published between 1992 and 1998 and included in a meta-analysis by Margolis et al.; chronic wounds categorized as diabetic/neuropathic ulcers, appropriate offloading, as needed, the presence of adequate perfusion, infection control (if present) and debridement of necrotic tissue.	NPWT: If untreated osteomyelitis or cancer was present within the wound, if there was no record of treatment termination or no reason was given for treatment termination, or if multiple treatment termination entries were present.	NPWT: If closure through secondary intention or through a surgical intervention or if adequate granulation for closure by these methods was documented. Control: Wound was completely healed.	NR

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Schwien et al. 2005(126)	Non-RCT*	Pressure Ulcer	2,348 (60 V.A.C)	Any other wound care modality	Data from 1.94 million OASIS start-of-care assessments; start of care and end of care between July 1, 2002 and September 30, 2004; One stage III or one Stage IV pressure ulcer; primary diagnosis of 707.0 decubitus chronic skin ulcer	Patients who died at home; enteral or parenteral nutrition therapy; high risk factors or heavy smoking, alcohol dependency, or drug dependency; poor or unknown overall prognosis; secondary diagnosis of uncontrolled diabetes, cancer, systemic infections, or related to malnutrition/anemias/proteinemia	NR	NR
McCallon et al. 2000(120)	Non-RCT*	Diabetic Foot	10	Saline-moistened gauze	Patients selected from the Diabetic Foot Clinic at Louisiana State University Health Science Center aged 18 to 75 years of age with a non-healing foot ulceration which had been present for longer than 1 month	Patients presenting with venous disease, patients with active infections not resolved by initial debridement; and patients with coagulopathy	Until satisfactory healing	NR

NR Not Reported
RCT Randomized controlled trial

* All studies reported using V.A.C.® (KCI, USA Inc.)

Table 24. Patient Characteristics in Comparison Studies of NPWT Devices* Used to Treat Diabetic Foot and Pressure Ulcers

Reference	Study Type	Number of patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Ulcer
Blume et al.(108)	RCT	V.A.C.®: 172	58 ±12	M 141 F 28	Smoker: 34 Uses alcohol: 37 Diabetes (type1): 15 Diabetes (type2): 154	169	13.5 ±18.2	NR	198.3 ±323.5d
	RCT	Advanced Moist Wound Therapy: 169	59 ±12	M 122 F 44	Smoker: 32 Uses alcohol: 45 Diabetes (type1): 14 Diabetes (type2): 152	166	11.0 ±12.7		206.0 ±365.9d
Armstrong et al.(109)	RCT	77 V.A.C.®	57.2 ±13.4** 56 ±12.3 65 ±12.2	M 66* F 11	Diabetes, alcohol and tobacco use	63 acute 14 chronic	22.8 ±21.0 14.1 ±17.9	Acute and chronic	Acute: 0.4 (0.22) months Chronic: 5.0 (9.3) months
	RCT	85 Standard Wound Therapy	60.1 ±12.2* 56 ±12.3 65 ±12.2	M 66* F 19	Diabetes, alcohol and tobacco use	59 acute 26 chronic	22.8 ±21.0 14.1 ±17.9		

Reference	Study Type	Number of patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Ulcer
Wanner et al.(118)	RCT	11 V.A.C.®	49 (25-73)	7 M 4 F	Vascular disorders – 0 Zinc depletion – 5 Hypoalbuminaemia – 3 Hypoproteinaemia – 5 Anemia – 8 Nicotine – 3	11	50 (33) Wound volume (ml) Range: 3-132	Deeper than Grade 2 (at least a penetration in the sub-cutaneous fat)	NR
	RCT	11 gauze soaked with Ringer's	53 (34-77)	8 M 3 F	Vascular disorders – 2 Zinc depletion – 5 Hypoalbuminaemia – 1 Hypoproteinaemia – 3 Anemia – 5 Nicotine – 2	11	42 (16) Wound volume (ml) Range: 5-68		
Ford et al.(110)	RCT	N = 22 V.A.C.® – NR	41.7 average	NR	NR	20	NR	Stage III or IV	NR
	RCT	Healthpoint system – NR	54.4 average			15			

Reference	Study Type	Number of patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Ulcer
Joseph et al.(113)	RCT	N = 24 V.A.C.® NR	56	M 66%	NR	18 Pressure – 18 Dehiscence – 1 Trauma – 1 Venous insufficiency – 2 Radiation – 1	38 cm^3	NR	NR
	RCT	Saline wet-to-moist: NR	49	M 44%		18 Pressure – 14 Dehiscence – 3 Trauma – 1 Venous insufficiency – 0 Radiation – 0	24 cm^3		
Lavery et al.(341)	Non-RCT	V.A.C: 1,135	58.5 ±9.4	M 64.5%	NR	1,135	13.8 ±15.8	NR	26.5 ±24.7 (wks)
	Non-RCT	Wet-to-moist: 586	58	M 73.2%			1.61		30 (wks)

Reference	Study Type	Number of patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Ulcer
Schwien et al.(126)	Non-RCT	V.A.C.®: 60	65 ±18.27	M 28 F 32	Obesity – 13 (22%) No. of secondary diagnosis – 6 (10%) Diabetes as first secondary diagnosis – 5 At least one secondary diagnosis – 54	NR	NR	Stage III or IV	NR
	Non-RCT	Control: 2,288	71.4 ±18.14	M 961 F 1,327	Obesity – 290 (13%) No. of secondary diagnosis – 264 (12%) Diabetes as first secondary diagnosis – 138 (6%) At least one secondary diagnosis – 2,024	NR	NR		
McCallon et al.(120)	Non-RCT	V.A.C.®: 5	55.4 (±12.8)	NR	Hemoglobin, albumin, and blood glucose levels comparable at baseline	5	NR	Non-healing	NR
	Non-RCT	Control: 5	50.2 (±8.7)			5			

NR Not reported
RCT Randomized controlled trial

* All studies reported using V.A.C.® (KCI, USA Inc.)
** Patient characteristics retrieved from primary study(195)

Table 25. Treatment-Related Characteristics in Comparison Studies of NPWT Devices* Used to Treat Diabetic Foot and Pressure Ulcers

Reference	Study Type	Treatments (include type of NPWT dressing)	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Blume et al.(108)	RCT	V.A.C.® CNP: mmHg NR Foam dressing	Every 48-72 h No less than 3x/wk	Wound examination and tracings	Weekly for 4 weeks then every other week until day 112 or ulcer closure	Complete ulcer closure defined as skin closure (100% re-epithelization) without drainage or dressing requirements OR day 112	Treated for ulcer infection prior to randomization: 50	• Surgical debridement • Standard off-loading therapy • Wounds for 9.5% of NPWT and 8.4% of AMWT-treated were later surgically closed by split thickness skin graft, flaps, sutures, or amputations
	RCT	Advanced Moist Wound Therapy (AMWT)	As specified by Wound, Ostomy and Continence Nurses Society guidelines and institutional treatment protocols				Treated for ulcer infection prior to randomization: 45	
Armstrong et al.(109)	RCT	V.A.C.® Foam dressing	Every 48 hrs	Digital photos and tracing	Days 0, 7, 14, 28, 42, 56, 84, and 112	Until wound closure (100% reepithelialization without drainage) or until completion of 112 day period of assessment	NR	• Off- loading therapy with a pressure relief walker or sandal • Surgical debridement • 31 NPWT and 25 SWT had complete wound closure without surgical closure • 12 NPWT and 8 SWT had complete wound closure with surgical intervention • 15 NPWT and 33 SWT completed active phase of study without complete wound closure
	RCT	Standard Wound Therapy (SWT)	According to standardized guidelines					

Reference	Study Type	Treatments (include type of NPWT dressing)	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Wanner et al.(118)	RCT	V.A.C.® continuous at 125 mmHg Polyvinyl foam and transparent polyurethane dressing	Every 2-7 days	One wound assessor; volume was calculated by covering the ulcer with a transparent, elastic polymer (OpSite, Smith & Nephew). Sheet was punctured at the highest point and 0.9% saline solution was injected through a hypodermic needle until no air was left in the cavity. The injected volume was measured.	Every 7 days after initial measure in the operating room (value considered 100%)	Until wound volume had decreased by 50% (at which time the wound was closed with a flap)	NR	• Surgical debridement • Ulcers closed with a flap after study treatment
	RCT	Gauze soaked with Ringer's solution	3x/day until clean granulation tissue was observed. Then wound kept wet with Ringer's and dressing changed 1-3x/day					
Ford et al.(110)	RCT	V.A.C.®	Mon/Wed/Fri	At 3 weeks, a photograph of the wound site; a plaster wound impression; and measurement of wound dimensions. At 6 weeks, a series of post-treatment tests consisting of a photograph of wound site; a soft-tissue biopsy; a plaster wound impression; and measurement of wound dimensions. Repeat bone biopsy/ MRI if performed at pretest.	3 and 6 weeks	6 weeks (f/u ranged from 3-10 months)	Patients with osteomyelitis received a 6-week course of systemic antibiotics	• Surgical debridement • Strict pressure reduction with appropriate beds and positioning • patients with 3 wounds underwent additional 6 week treatment of opposing treatment • 6 wounds in the V.A.C.® group (30%) and 6 wounds in the HP group (40%) underwent flap surgery
	RCT	HP	once or twice/daily					

Reference	Study Type	Treatments (include type of NPWT dressing)	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Joseph et al.(113)	RCT	V.A.C.® Pressure NR Open-cell foam dressing	Every 48 hours	Photography and measured by volume displacement of alginate impression molds	3 and 6 weeks or until wound closure	Complete wound closure not a realistic end point since wounds were of variable sizes and anatomic locations	All patients had previously failed multiple medical and surgical wound treatments. Two patients (V.A.C.®) previously had bypass grafting for revascularization. Both eventually required amputation.	• Pressure-relieving surface • Debridement within 48h of treatment initiation • Rigorous nutritional assessment
	RCT	WM – closed system including Bioclusive Transparent Dressing (Johnson and Johnson)	3x/day plus saline applied 3x/day					
Lavery et al.(341)	Non-RCT	V.A.C.® NR	Every 48 hrs	NR	12 and 20 weeks	Successful treatment endpoint if closure through secondary endpoint or through a surgical intervention (i.e., flaps, grafts and primary closure) or if adequate granulation for closure by these methods was documented.	NR	Surgical debridement
	Non-RCT	Wet-to-moist	well-monitored care – patients from 5 RCTs			Successful treatment endpoint when either the wound was completely healed, i.e., wound closure (no drainage) or full epithelialization with no drainage.		

Reference	Study Type	Treatments (include type of NPWT dressing)	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Schwien et al.(126)	Non-RCT	V.A.C.® NR	NR	NR	Tracked while NPWT was applied plus 7 days following removal	NR	NR	NR
	Non-RCT	Control NR	NR		Tracked start of care through end of care	NR	NR	NR
McCallon et al. 2000(120)	Non-RCT	V.A.C.® Continuous at 125 mmHg for first 48 hours/ Intermittent suction (125 mmHg) applied thereafter Foam dressing as provided by the manufacturer	Every 48 hours	Wound border traced with fine-tipped marker onto a piece of clear acetate film. Progress assessed by photography.	Every 48 hours at each dressing change	Until satisfactory healing occurred and defined as: 1. Delayed primary intention. Split-thickness skin graft, myocutaneous flap, or suture closure 2. Secondary intention. Granulation tissue formation and epithelialization.	NR	• Surgical debridement • Strict non-weight bearing or bedrest
	Non-RCT	Saline-moistened gauze (wounds not allowed to desiccate)	Twice a day		3x/week			

NR Not reported
RCT Randomized controlled trial

* All studies reported using V.A.C.® (KCI, USA Inc.)

Table 26. Results for Outcome Measures Reported in Comparison Studies of NPWT Devices* Used to Treat Diabetic Foot and Pressure Ulcers

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Blume et al.(108)	RCT	V.A.C.®	169	73 (43.2%)	Reported for day 28 -4.32 (significant difference; *P* = 0.021)	63.6 ±36.57 days (mean ±SD)	NR	22
	RCT	Advanced Moist Wound Therapy (AMWT)	166	48 (28.9%)	Reported for day 28 -2.53	78.1 ±39.29 days (mean ±SD)		18
Armstrong et al.(109)	RCT	V.A.C.®	63 acute (51.6%) 14 chronic (35%)	34 acute (54%) 9 chronic (64.3%)	NR	Log-rank test comparing the time-to-event profiles was significant in favor of NPWT group over SWT for acute wounds (*P* = 0.030)	NR	NR
	RCT	Standard Wound Therapy (SWT)	59 acute (48.4%) 26 chronic (65%)	22 acute (37.3%) 11 chronic (42.3%)				
Wanner et al.(118)	RCT	V.A.C.®	11	11	Decrease over time similar in both groups. Increase in volume was often measured 7d after first measurements in both groups.	27 (10) d mean (SD)	NR	NR
	RCT	Gauze soaked with Ringer's solution	11	11		28 (7) d mean (SD)		
Ford et al.(110)	RCT	V.A.C.®	20	2 (10%)	51.8% - mean % reduction in volume Mean reduction in length, width, and depth respectively were 36.9 cm, 40.0 cm, and 33.6 cm	NR	NR	Coronary artery disease – 1 Respiratory arrest secondary to Guillain-Barre – 1 Treatment group not reported
	RCT	Healthpoint System (HP)	15	2 (13%)	42.1% - mean % reduction in volume Mean reduction in length, width and depth respectively were 18.7 cm, 19.0 cm, and 31.0 cm (p = 0.10, p = 0.11, p = 0.90 respectively)			

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Joseph et al.(113)	RCT	V.A.C.®	NR	NR	Percent change in wound volume over time: 78% (p = 0.038) Change in depth: 66% (p <0.00001) Change in width over time: p = 0.02 No significant difference in change in length between groups (p = 0.38)	NR	Granulation tissue formation in 13 (64% of wounds)	NR
	RCT	Moist wound therapy			Percent change in wound volume over time: 30% Change in depth: 20%		An adequate (100%) granulating bed rarely seen	
Lavery et al.(341)	Non-RCT	V.A.C.®	1135	39.5% (12 wk) 46.3% (20 wk)	NR	` NR	NR	NR
	Non-RCT	Wet-to-moist	586	23.9% (12 wk) 32.8% (20 wk)				

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Schwien et al.(126)	Non-RCT	V.A.C.®	NR		NR	NR	Instances of hospitalization for wound problem (n, %) Stage III –1 (3%) Stage IV – 2 (7%) Total – 3 (5%) Instances of emergent care for wound problem (n,%) Stage III – 0 Stage IV – 0 Total – 0	NR
	Non-RCT	Control	NR		NR	NR	Instances of hospitalization for wound problem (n, %) Stage III –194 (11%) Stage IV – 116 (20%) Total – 310 (14%) Instances of emergent care for wound problem (n,%) Stage III – 126 (7%) Stage IV – 63 (11%) Total – 189 (8%)	NR

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
McCallon et al. 2000(120)	Non-RCT	V.A.C.®	5	# of wounds decreased in size = 4 (healed by delayed primary intention) # of wounds increased in size = 1 (healed by secondary intention)	28.4% (±24.3) average decrease	Average: 22.8 (±17.4) days	NR	NR
	Non-RCT	Saline-moistened gauze	5	# of wounds decreased in size = 2 (healed by delayed primary intention) # of wounds increased in size = 3 (healed by secondary intention)	9.5% (±16.9) average increase	Average: 42.8 (±32.5) days	NR	NR

NR Not reported
RCT Randomized controlled trial

*All studies reported using V.A.C.® (KCI, USA Inc.)

Skin Graft

Table 27. Key Study Design Characteristics of Comparison Studies of NPWT Devices* Used to Secure Skin Graft

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Vuerstaek et al. 2006(115)	RCT	Chronic leg	60	Conventional (hydrocolloids, alginates)	All patients hospitalized with chronic, venous, combined venous and arterial, or microangiopathic (arteriolosclerotic) leg ulcers of >6 month's duration; after surgical treatment options had been exhausted and extensive ambulatory treatment (>6 months) in an outpatient clinic according to the Scottish Intercollegiate Guideline Network (SIGN) had failed	Ulcer chronicity <6 months duration, age >85 years old, the use of immune suppression, allergy to wound products, malignant or vasculitis origin, or ABI <0.60	12 months	11
Moisidis et al. 2004(112)	RCT	Split-thickness skin graft (STSG)	22 (patients used as own controls)	Bolster dressing	Adults admitted to Liverpool Hospital from July 2001 to July 2002 with wounds 25 cm^2 or larger and clinically ready for skin grafting	NR	2 weeks	2
Korber et al. 2008(340)	Non-RCT	Chronic leg ulcer	54	SOC	Mesh grafts transplanted in the Department of Dermatology, Essen, Germany from April 2003 to April 2005	NR	NR	NR
Vidrine et al. 2005(342)	Non-RCT	STSG	44	Bolster dressing plus splint	Consecutive skin-grafted radial forearm donor sites treated between October 2003 and November 2004	NR	4 weeks	NR

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Stone et al. 2004(133)	Non-RCT	STSG	40	Cotton bolster dressing	Trauma patients admitted between January 2001 and January 2003 to Charleston Area Medical Center, WV who received STSG	2 burn patients with heavily contaminated and extremely large wounds	Grafts considered completely successful or total failures	
Scherer et al. 2002(132)	Non-RCT	STSG	61	Cotton bolster dressing	Identified all patients on the trauma surgery service who required STSG during an 18-month period	NR	NR	NR
Genecov et al. 1998(131)	Non-RCT	STSG	10 (patients used as own controls)	OpSite	Patients requiring coverage of denuded surfaces	NR	7 days	NR

NR Not reported
RCT Randomized controlled trial

* All studies reported using V.A.C.® (KCI, USA Inc.)

Table 28. Patient Characteristics in Comparison Studies of NPWT Devices* Used to Secure Skin Graft

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Wound
Vuerstaek et al.(115)	RCT	V.A.C.®: 30	Median: 74 Range: 53-81	M7 F23	Smoking: 6 (21%) Diabetes mellitus type II: 5 (17%) Immobility: 12 (41%) Hypertension: 13 (45%) Infection signs: 8 (28%)	NR	Median: 33 Range: 2-150	Ulcer type Venous origin: 13 Combined venous/arterial origin: 4 Arteriolosclerotic origin: 13	8 Median (Range: 6-24)
	RCT	Control: 30	Median: 72 Range: 45-83	M7 F23	Smoking: 9 (30%) Diabetes mellitus type II: 5 (17%) Immobility: 13 (43%) Hypertension: 12 (40%) Infection signs: 6 (20%)		Median: 43 Range: 3-250	Venous origin: 13 Combined venous/arterial origin: 4 Arteriolosclerotic origin: 13	7 Median (Range: 6-12)
Moisidis et al.(112)	RCT	20	Median: 64 Range: 27-88	M12 F8	NR	20	128 cm^2 Range: 35 to 450 cm^2	Acute: 10 Subacute or chronic (>5d): 10	18d (Range: 0 to 90d)
Korber et al.(340)	Non-RCT	Total: 54 V.A.C.®: NR	66.1	M23 F31	Diabetes: 15	28	Comparable	NR	NR
	Non-RCT	Control: NR	69.8			46			
Vidrine et al.(342)	Non-RCT	V.A.C.®: NR	62	M16 to F19 ratio	NR	20	59 (21)	NR	NR
	Non-RCT	Control: NR	60	M18 to F25 ratio		25	56 (27)		

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Wound
Stone et al.(133)	Non-RCT	V.A.C.®: 17	35.4 ±14	NR	NR	21	105.6 (88)	Wound Site: Face:1 Torso: 3 Extremity: 17	NR
	Non-RCT	Control: 23	39.0 ±16.7			25	150.2 (78)		
Scherer et al.(132)	Non-RCT	V.A.C.®: 34	33 ±23	NR	NR	NR	Graft size, cm^2 387 ±573	NR	NR
	Non-RCT	Control: 27	41 ±20				984 ±996		
Genecov et al.(131)	Non-RCT	10	Range: 39 to 81	M4 F6	Paraplegia:2 Diabetes mellitus: 4 Systemic infections: 2 Hemodialysis dependence: 3 Traumatic wounds: 3	10	32-380 cm^2	NR	NR

NR Not Reported
RCT Randomized controlled trial

* All studies reported using V.A.C.® (KCI, USA Inc.)

Table 29. Treatment-Related Characteristics in Comparison Studies of NPWT Devices* Used to Secure Skin Graft

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Vuerstaek et al.(115)	RCT	V.A.C.® Continuous Negative Pressure (CNP): -125 mmHg Foam dressing	Day 4	NR	Twice a week until wound closure	<u>Wound healing</u> 1) Wound bed preparation defined as the time between debridement and application of the punch skin grafts 2) Time to complete healing (primary end point) defined as the period between debridement and 100% epithelialization (wound closure).	Ambulatory conservative local treatment (6 months)	• Debridement • Post-graft all patients received treatment with a non-adhesive dressing and compression bandage
	RCT	Control SOC according to SIGN guideline and compression therapy	Day 4					
Moisidis et al.(112)	RCT	V.A.C.® CNP: -100 mmHg Foam sponge	Left intact for 5d Patients used as own controls NPWT used on superior half in 10 patients and inferior half in remaining 10	At 2 weeks	NR	Graft take was recorded both quantitatively (expressed as a percentage of epithelialization (recorded by gross inspection) and qualitatively (rated as poor, satisfactory, good or excellent)	3 patients experienced prior graft failure	• If grafts were placed on lower limbs, patients were immobilized with leg elevation and deep venous thrombosis prophylaxis • Once dressing was removed, the entire graft was treated with daily petroleum gauze, saline-soaked gauze and crepe.
	RCT	Control Mepitel, Acriflavice wool and foam sponge						
Korber et al.(340)	Non-RCT	V.A.C.® Black sponge -125 mmHg	1st between postoperative day 5 or 7	NR	Between day 10 and 14	Mesh graft take	NR	Postoperative compression therapy for patients with venous leg ulcer or a mixed ulcer
		Control						
Vidrine et al.(342)	Non-RCT	V.A.C.®/Control	Removed between day 4 and 6	Senior author	Day 7 (1 week) and week 4	4 weeks	NR	NR
Stone et al.(133)	Non-RCT	V.A.C.®/control	NR	NR	NR	Completely successful graft take	NR	

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Scherer et al.(132)	Non-RCT	V.A.C.® CNP: -125 mmHg Control	4th postoperative day unless signs suggested infection	NR	NR	Successful graft take	NR	Bed rest, a sling, or a splint
Genecov et al.(131)	Non-RCT	V.A.C.® Control	Days 4 and 7	Blinded assessor analyzed biopsies		Degree of reepithelialization	NR	NR 3.33

CNP Continuous negative pressure
NR Not reported
RCT Randomized controlled trial
SOC Standard of care

* All studies reported using V.A.C.® (KCI, USA Inc.)

Table 30. Results for Outcome Measures Reported in Comparison Studies of NPWT Devices* Used to Secure Skin Graft

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Vuerstaek et al.(115)	RCT	V.A.C.®	30	29	NR	Primary endpoint Time to complete healing: 29d(95% CI: 25.5 to 32.5) Secondary endpoint Median percentage skin graft survival: 83%	Ulcer relapse at 1 year follow-up: 52% QOL measured by EQ-5D: 77 Pain measured by SF-MPQ: 1	NR
	RCT	Control	30	29		Time to complete healing: 45d (95% CI: 36.2 to 53.8) Median percentage skin graft survival: 70%	Ulcer relapse at 1 year follow-up: 42% QOL measured by EQ-5D: 76 Pain measured by SF-MPQ: 1	
Moisidis et al.(112)	RCT	V.A.C.®	20 patients used as own controls	20	NR	Quantitative (degree of epithelization): not significant Greater degree: 6 (30%) Same degree: 9 (45%) Less: 5 (25%) Qualitative Graft take: Subjectively determined to be significantly better: Better: 10 (50%) Equivalent: 7 (35%) Worse: 3 (15%)	NR	NR

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Korber et al.(340)	Non-RCT	V.A.C.®	NR (28 wounds)	26	NR	Mesh graft take rate: 92.9%	NR	NR
	Non-RCT	Control	NR (46 wounds)	31		67.4%		
Vidrine et al.(342)	Non-RCT	V.A.C.®	NR (20 wounds)	20	Average graft take at 1 wk: 99% Average graft take at 4 wk: 92%	Overall complete STSG take rate: 60%	NR	NR
	Non-RCT	Control	NR (25 wounds)	25	Average graft take at 1 wk: 97% Average graft take at 4 wk: 81	Overall complete STSG take rate: 52%		
Stone et al.(133)	Non-RCT	V.A.C.®	17 (21 grafts)	Graft take: 100%	n/a	Duration of dressing: 4.8 ±0.8	Mean hospital stay: 20.9 ±10	NR
	Non-RCT	Control	23 (25 grafts)	1 graft failure		5.2 ±2.4	15.3 ±7.5	
Scherer et al.(132)	Non-RCT	V.A.C.®	34	NR	NR	Graft take, % 96 ±6	Repeat STSG to same site 1 (3%) Total LOS, d 27 ±16	NR
	Non-RCT	Control	27			89 ±20	Repeat STSG to same site 5 (19%) Total LOS, d 32 ±25	

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Genecov et al.(131)	Non-RCT	V.A.C.®/ Control	10 (used as own controls)	10	NR	V.A.C.® re-epithelialize faster than control: 7 No difference in rate of reepithelialization: 2 More rapid reepithelialization with OpSite: 1	NR	NR

EQ-5D EuroQol group quality-of-life instrument
NR Not reported
RCT Randomized controlled trial
SF-MPQ Short Form-McGill Pain Questionnaire

* All studies reported using V.A.C.® (KCI, USA Inc.)

Acute Wounds

Table 31. Key Study Design Characteristics of Comparison Studies of NPWT Devices* Used to Treat Acute Wounds

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Stannard et al. 2006(125)	RCT	Postoperative wounds	Study 1: 44 Study 2: 44	Study 1: pressure dressing Study 2: post-operative dressing	Hematoma study: Age >18 years; involvement in traumatic injury with subsequent surgical incision which drained a minimum of 5d after surgery; and willingness to comply with the protocol. Fracture study: Patients with one of three high-risk fractures after high-energy trauma-calcaneus, pilon, and tibial plateau (Schatzker IV through VI); age >18 yrs; and willingness to comply with the study protocol.	Hematoma study: Surgical incisions that did not have at least moderate drainage for 5d after surgery; infection of the wound; neoplasm involving the wound; pregnancy; or the presence of a fistula. Fracture study: Low-energy fracture pattern tibial plateau fractures' nonoperative, percutaneous treatment, or external fixation as the primary form of stabilization; open fractures that require repeat debridement; skin or soft tissue neoplasm involving the incision site; and pregnancy.	NR	NR
Timmers et al.(106)	Non-RCT	Post-traumatic osteomyelitis	124	SOC	Consecutive patients with osteomyelitis with one recurrence who presented at the Leiden University Medical Center between March 1999 and February 2003.	NR	Until either two consecutive culture swabs taken within a few days had become sterile or when enough new granulation tissue had formed to permit surgical wound closure.	NR
Simek et al. 2008(123)	Non-RCT	Deep sternal	62	Conventional (debridement, chest rewiring, closed irrigation)	Patients undergoing treatment for deep sternal wound infection from March 2002 to December 2007	NR	1 year follow up	NR

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Yang et al.(72)	Non-RCT	Fasciotomy	68	Saline-soaked wet-to-dry dressings	Patients who underwent two-incision fasciotomies for documented, traumatic compartment syndrome of the leg with the release of all four compartments	NR	Time to definitive closure by either delayed primary closure with sutures or split-thickness skin graft coverage	NR
Fuchs et al. 2005(23)	Non-RCT	Deep sternal	68	Conventional	Incidence of deep sternal wound infections from bypass or heart valve replacements from 1998 to 2000 treated with conventional treatment and from 2000 to 2003 treated with V.A.C.®; sternal infections met the criteria of the Centers for Disease Control and Prevention	NR	Follow up at least until the sternum was rewired (primary wound healing), until wound healing was achieved without rewiring (secondary wound healing), or until the patient died with an open sternum	NR
Immer et al. 2005(130)	Non-RCT	Deep sternal wound infection (DSWI)	55	Sternal excision and musculocutaneous flap	Patients with DSWI (El Oakley class 2B) from sternotomies performed between January 1998 and December 2003; diagnosis based on sternal dehiscence and positive bacteriologic culture of the sternum or the anterior mediastinum.	NR	NR	NR
Segers et al. 2005(122)	Non-RCT	Post-sternotomy mediastinitis (PM)	63	Closed drainage technique (CDT)	All patients treated from PM after cardiac surgery at the Academic Medical Center between 1/1/92 and 12/31/03	NR	NR	29% (18 deaths; 9 NPWT, 9 control)

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Sjogren et al. 2005(139)	Non-RCT	PM	101	Conventional (open dressings, closed irrigation, pectoral muscle flaps or omentum flaps)	At least one of the following CDC criteria for PM: 1) an organism isolated from culture of mediastinal tissue or fluid; 2) evidence of mediastinitis was seen during operation; 3) one of the following conditions, chest pain, sterna instability, or fever (>38° C) was present and there was either purulent discharge from the mediastinum or an organism isolated from blood culture or culture of drainage of the mediastinal area.	Patients presenting signs of infection but with negative substernal tissue cultures; patients with sterile dehiscences or superficial sternal wound infections	NR	NR
Domkowski et al. 2003(129)	Non-RCT	PM	102	Standard of Care (SOC)	Between 1997 and 2002, patients from Duke University Hospital, The Durham VA Hospital	Patients with superficial wound infections or fat necrosis	NR	NR
Song et al. 2003(124)	Non-RCT	Sternal	35	SOC	35 consecutive patients who suffered complications of their cardiac procedure resulting in a sternal wound from March 1999 to March 2001; all patients had a median sternotomy and all sternal wounds involved the tissues superficial and deep to the sternum	NR	NR	NR
Doss et al. 2002(128)	Non-RCT	Post-sternotomy Osteomyelitis	42	SOC	Patients treated for post-sternotomy Osteomyelitis (SOM) between 1998 and 2000	NR	NR	NR

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Catarino et al. 2000(137)	Non-RCT	Post-sternotomy mediastinitis (PM)	17	Closed drainage and irrigation (CDI)	Patients with post-sternotomy mediastinitis (PM) occurring from September 1998 to August 1999 (group A) and from September 1997 to August 1998 (group B). All patients had sternal dehiscence and an infected mediastinum.	Superficial sternal wound infections, suture and wire abscesses, chronic sternal osteomyelitis, and sterile sternal dehiscences	Until wound closure	NR
Shilt et al. 2004(138)	Non-RCT	Traumatic Wounds	31	Standard of care (SOC)	Medical records of patients <18 years admitted to Wake Forest University School of Medicine, Winston-Salem, NC between 1992 and 2001 for treatment of lower extremity lawnmower injuries	Largest diameter of the wounds was <2 cm or if wound care consisted of primary closure	Upon wound healing or further reoperation	1 control lost to f/u
Kamolz et al. 2003(343)	Non-RCT	Burn	7	Silver sulphadiazine crème	All patients of the last 5 months with bilateral partial thickness hand burns	Patients not admitted within the time interval of 6h after trauma; children <20 years of age, pregnant, and patients with a history of allergic reactions	Upon further reoperation or wound heal	NR
Gabriel et al. 2008(339)	Non-RCT	Infected	30	SOC	Trunk and extremity wounds with documented qualitative cultures with $>10^5$ organisms, age >40 yrs, and documented necrotic tissue. V.A.C.®: patients with a diagnosis of complex, open, infected wounds treated with NPWT instillation between January 2005 and April 2006 Control: treated between January 2004 and December 2005	NR	Until wound closure	NR

Reference	Study Type	Wound Type	Number of Patients Enrolled	Comparison Treatment	Inclusion Criteria	Exclusion Criteria	Length of Study	Attrition
Ozturk et al. 2008(117)	Non-RCT	Fournier's gangrene	10	SOC	Between January 2006 and August 2007 patients with Fournier's gangrene and treated at the Dept of General Surgery, Uludag University School of Medicine, Bursa, Turkey	NR	Time to wound closure	NR
Rinker et al. 2008(121)	Non-RCT	Open Tibia Fracture	105 (55 subacute analyzed)	SOC	Hospital and clinic records of 105 consecutive patients who underwent a free muscle flap for treatment of a Gustilo grade IIIB or IIIC tibia fracture between 1991 and 2005.	NR	NR	NR
Huang et al. 2006(127)	Non-RCT	Limb	24	SOC (gauze soaked with saline)	A diagnosis of acute necrotizing fasciitis	NR	NR	NR
Labler et al. 2004(71)	Non-RCT	Soft-tissue	23	Epigard® dressing	Patients with severe open fractures of the lower extremity classified as type IIIA or IIIB (Gustilo) and admitted as an emergency; all fractures result of a high-energy trauma	All type IIIC fractures due to associated valcular injuries	12 months after definitive soft-tissue coverage	

NR Not reported
RCT Randomized controlled trial

* All studies reported using V.A.C.® (KCI, USA Inc.)

Table 32. Patient Characteristics in Comparison Studies of NPWT Devices* Used to Treat Acute Wounds

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2)or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Wound
Stannard et al.(125)	RCT	Hematoma study: 44 V.A.C.®: 13	48 yrs (21-96)	M 36 F 8	NR	44	NR	Injury Severity Scores (ISS) 14.1	<5d
	RCT	Control: 31						13.9	
	RCT	Fracture study: V.A.C.®: 20	41 yrs (19-78)	M 32 F 12	NR	20	NR	ISS 11.1	NR
	RCT	Control: 24				24		10.1	
Timmers et al.(106)	Non-RCT	V.A.C.®: 30	52 (26-81)	M14 F16	18 (60%) diabetes mellitus, smoker, cardiovascular disease, pulmonary disease	30	NR	NR	NR
		Control: 94	47 (9-85)	M58 F36	54 (57.4%) diabetes mellitus, smoker, cardiovascular disease, pulmonary disease	94			
Simek et al.(123)	Non-RCT	V.A.C.®: 34	66.4 ±9.8	M 52% F 48%	Diabetes mellitus: 52.9% COPD: 32.4% Immunosuppressive therapy: 14.7% Renal impairment: 23.5%	34	NR	NR	NR
	Non-RCT	Control: 28	71.2 ±7.9	M 68% F 32%	Diabetes mellitus: 60.7% COPD: 25% Immunosuppressive therapy: 10.7% Renal impairment: 35.7%	28			

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2)or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Wound
Yang et al.(72)	Non-RCT	V.A.C.®: 34 Control: 34	NR	NR	NR	68 70	NR	NR	NR
Fuchs et al.(23)	Non-RCT	V.A.C.®: 35	68.5 (63.9-74.5)	M 76%	Diabetes – 55% Coronary heart disease – 97%	35	NR	Type I: 0 Type II: 9 Type IIIa: 12 Type IIIb: 10 Type V: 4	NR
	Non-RCT	Control: 33	68.5 (64.4-74.9)	M 85%	Diabetes – 59% Coronary heart disease – 97%	33	NR	Type I: 4 Type II: 1 Type IIIa: 17 Type IIIb: 4 Type V: 7	NR
Immer et al.(130)	Non-RCT	V.A.C.® only: 19	60.1 ±11.8	M 13 F 6	COPD: 1 (5.3%) Diabetes: 7 (36.8) Immunosuppression: 2 (10.5%) Arterial hypertension: 13 (68.4%)	19	NR	NR	Diagnosis DSWI (days) 17.5 ±5.1
	Non-RCT	V.A.C.® plus Excision and flap: 19	66.6 ±7.2	M 14 F 5	COPD: 3 (15.8%) Diabetes 10 (52.6%) Immunosuppression: 1 (5.3%) Arterial hypertension: 14 (73.7%)	19	NR	NR	71.7 ±213.7
	Non-RCT	Excision plus flap: 17	69.5 ±8.1	M 10 F 7	COPD: 6 (35.3%) Diabetes: 7 (41.2%) Immunosuppression: 0 Arterial hypertension: 17 (100%)	17	NR	NR	36.7 ±46.5

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2)or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Wound
Segers et al.(122)	Non-RCT	V.A.C.®: 29	65.9 (38-81)	M 17 F 12	Diabetes: 11 (37.9%) COPD: 10 (34.5%)	29	NR	Type I: 4 (13.8%) Type II: 2 (6.9%) Type IIIa: 3 (10.3%) Type IIIb: 9 (31%) Type IVa: 9 (31%) Type V: 2 (6.9%)	Presenting within 6 weeks after operation
	Non-RCT	Control: 34	66.7 (20-81)	M 30 F 4	Diabetes: 8 (23.5%) COPD: 6 (17.6%)	34	NR	Type I: 7 (20.6%) Type II: 2 (5.9%) Type III: 8 (23.9%) Type IVa: 6 (17.6%) Type V: 1 (2.9%)	NR
Sjogren et al.(139)	Non-RCT	V.A.C.®: 61	67.3 (10.1)	M 44 F 17	Diabetes: 26 (43%) Obesity: 23 (38%) LVEF <0.30: 14 (23%) COPD: 12 (20%)	61	NR	Type I: 12 (20%) Type II: 7 (11%) Type IIIa: 13 (21%) Type IIIB: 26 (43%) Type IVa: 1 (2%) Type V: 2 (3%)	NR
	Non-RCT	Control: 40	68.9 (7.8)	M 38 F 2	Diabetes: 12 (30%) Obesity: 12 (30%) LVEF <0.30: 4 (10%) COPD: 4 (10%)	40		Type I: 10 (25%) Type II: 3 (8%) Type IIIa: 7(18%) Type IIIb: 7 (18%) Type IVa: 9 (23%) Type IVb: 2 (5%) Type V: 2 (5%)	
Domkowski et al.(129)	Non-RCT	Data only reported for total study population		NR	NR	NR	NR	NR	NR

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2)or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Wound
Song et al.(124)	Non-RCT	V.A.C.®: 17	63 (31-88)	M 10 F 7	CABG: 14 Valve: 1 Aortic dissection: 3 Mediastinitis: 15 Chronic infection: 2 Sterile wound:1	17	NR	NR	Up to 6 weeks
	Non-RCT	Control: 18	63 (23-77)	M 14 F 4	CABG: 13 Valve: 2 Heart transplant: 1 Pericardiectomy: 1 Mediastinitis: 13 Chronic infection: 3 Sterile wound:1	18	NR		
Doss et al.(128)	Non-RCT	V.A.C.®: 20	Median: 66 (45-82)	M 9 F 11	Bilateral internal mammary artery: 5 Diabetes: 9 COPD: 4 Overweight: 7	20	NR	NR	Postoperative presentation: day 7 to 21
	Non-RCT	Control: 22	66 (50-83)	M 19 F 3	Bilateral internal mammary artery: 9 Diabetes: 9 COPD: 6 Overweight: 8	22			day 5 to 31
Catarino et al.(137)	Non-RCT	V.A.C.®: 7	68 (64-74)	M 5 F 2	Coronary heart disease; diabetes; and high BMI	7	NR	NR	NR
	Non-RCT	Control: 10	66 (46-75)	M 7 F 3	Coronary heart disease; diabetes; and high BMI	10			

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2)or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Wound
Shilt et al.(138)	Non-RCT	V.A.C.®: 16	3.9 (1-8)	M 10 F 6	NR	16	NR	With fractures – 12	NR
	Non-RCT	Standard of Care (SOC): 15	8.5 (2-18)	M 8 F 7		15		With fractures – 8	
Kamolz et al.(343)	Non-RCT	V.A.C.®: 7 Patients used as their own controls	44.2 (22.4)	NR	NR	14	NR	Partial thickness	<6h
	Non-RCT	Silver sulphadiazine crème (SSD): 7							
Gabriel et al.(339)	Non-RCT	V.A.C.®: 15	57.13 ±11.64	NR	Necrotizing fasciitis – 3 Pressure ulcer – 2 Open joint – 5 Surgical wound – 1 Lower extremity wound – 1 Soft tissue loss of lower extremity – 2 Abdominal surgical wound dehiscence -1	15	127.33 ±137.87	NR	NR
	Non-RCT	Standard of Care (SOC): 15	59.40 ±10.29		Necrotizing fasciitis – 4 Pressure ulcer – 5 Open joint – 6	15	173.00 ±123.73		
Ozturk et al.(117)	Non-RCT	V.A.C.®: 5	56 (33-77)	M 4 F 1	NR	5	NR	3 local 2 disseminated	NR
	Non-RCT	Control: 5	56 (31-64)	M 3 F 3		5		3 local 2 disseminated	

Reference	Study Type	Number of Patients	Mean (SD) Age (years)	Sex	Comorbidities	Number of Wounds	Mean (SD) Baseline Wound Area (cm^2)or Volume (cm^3)	Severity of Wounds	Mean (SD) Duration of Wound
Rinker et al.(121)	Non-RCT	V.A.C.®: 17	Median: 40 (Range: 11-64)		NR	60 flaps	NR	NR	Subacute wounds had flap performed on post-injury days 8 to 42
	Non-RCT	Control: 38							
Huang et al.(127)	Non-RCT	V.A.C.®: 12	57.75	M 7 F 5	Diabetes – 6 Fever – 6 Leukocytosis – 7 Shock – 3 Trauma – 3 Infection- 9	12	Wounds varied between 30 and 15 cm in length and 13 and 3 cm in width	NR	NR
	Non-RCT	SOC: 12	62.58	M 9 F 3	Diabetes – 9 Fever – 9 Leukocytosis –6 Shock – 2 Trauma – 4 Spontaneous infection – 8	12	Wounds varied between 32 and 12 cm in length and 12 and 4 cm in width		
Labler et al.(71)	Non-RCT	VAC®: 12	Range: 18-68	M 8 F 4	NR	14	NR	Mangled Extremity Severity Score: 2 (n = 1); 3 (2); 4 (3); 5 (4); 6 (2); 7 (2)	
	Non-RCT	Control: 11	Range: 20-89	M 8 F 3	NR	12	NR	Mangled Extremity Severity Score: 2 (1); 3 (3); 4 (3); 5 (3); 6 (1); 9 (1)	

COPD Chronic obstructive pulmonary disease
LVEF Left ventricular ejection fraction
NR Not reported
NS Not significant
RCT Randomized controlled trial

* All studies reported using V.A.C.® (KCI, USA Inc.)

Negative Pressure Wound Therapy Devices

Table 33. Treatment-Related Characteristics in Comparison Studies of NPWT Devices* Used to Treat Acute Wounds

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Stannard et al.(125)	RCT	Hematoma study: V.A.C.®	At least every other day	NR	NR	Until cessation of drainage of hematoma	NR	If drainage continued at day 10, patients returned to the OR for an evacuation of the hematoma with irrigation and debridement
	RCT	Dressing	Daily					
	RCT	Fracture study: V.A.C.®	NR	NR	NR	Wound drainage had dropped to grade 3 or below	NR	NR
	RCT	Control						
Timmers et al.(106)	Non-RCT	V.A.C.® Polyvinyl alcohol (PVA) foam (instilled 2-3x/day) and pressures ranging from -300 mmHg to -600 mmHg	First day after debridement and subsequently every 3-4 days	Wound cultures	Each dressing change	Until two consecutive swabs taken a few days apart were either sterile or showed skin bacteria only, or when enough granulation tissue had grown into the wound to permit surgical wound closure. Alternatively, if spontaneous wound closure occurred during therapy, NPIT was ended.	NR	• Debridement • Antibiotic therapy for a minimum of six weeks
		Control	NR	NR				
Simek et al.(123)	Non-RCT	V.A.C.®	NR	NR	NR	Wound bed was free of infection, covered by well-vascularized granulation tissue and the C-reactive protein level dropped to 50 mg/l, the chest was reclosed	NR	NR
	Non-RCT	Control						

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Yang et al.(72)	Non-RCT	V.A.C.® CNP: -125 mmHg	Every 48 hours	NR	NR	Until wound closure by delayed primary fashion or covered with STSG	NR	Irrigation and debridement
		Control	NR					
Fuchs et al.(23)	Non-RCT	V.A.C.® CNP: -125 to -150 mmHg With severe pain, -75 mmHg 3 polyurethane foam sponges	3-7d	NR	NR	Freedom of the sternal wound from microbiological cultures	NR	• Wound Incision and removal of sternal wires • aggressive debridement
	Non-RCT	Control	NR					• Wound Incision and removal of sternal wires • aggressive debridement • irrigation • wound drainage • packing/delayed closure
Immer et al.(130)	Non-RCT	V.A.C.® Pressure between -75 mm and -125 mm	48-72 hrs	Bacteriologic cultures	NR	NR	NR	• Intravenous antibiotics • Debridement every 48-72 hours
	Non-RCT	V.A.C.® plus secondary sternal excision and musculocutaneous flap						
	Non-RCT	Sternal excision + flap						

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Segers et al.(122)	Non-RCT	V.A.C.® Continuous Negative Pressure (CNP): -125 mmHg Foam dressing	Initially after 48h; thereafter every 4-5d	NR	NR	A well-vascularized wound completely covered by granulation tissue, C-reactive protein levels were <50 mg/l and cultures did not show pathogenic bacteria, sternal closure was performed	NR	• Aggressive debridement
	Non-RCT	Control	nr					
Sjogren et al.(139)	Non-RCT	V.A.C.®		NR	NR	Wound considered clean including a bed of fresh granulation tissue, the sternum was rewired or, when necessary, additional wound-healing measures, i.e., omentoplasty and pectoralis flap	NR	• Surgical debridement
	Non-RCT	Control	Several times daily					
Domkowski et al.(129)	Non-RCT	V.A.C.®	NR	NR	NR	NR	NR	• Debridement
		SOC	NR	NR	NR	NR	NR	• Debridement
Song et al.(124)	Non-RCT	V.A.C.® CNP: -75 to -125 mmHg Foam dressing	Every other day	Plastic surgery and physical therapy staff	NR	Definitive closure determined by the gross appearance of the wound and hemodynamic stability of the patient	NR	• Surgical debridement • Antimicrobial layer of Acticoat* (Smith & Nephew)
	Non-RCT	Control	Twice a day					• Surgical debridement • Topical antimicrobial agent
Doss et al.(128)	Non-RCT	V.A.C.® -125 mmHg Foam dressing	Every 2-3d	NR	NR	Primary closure after granulation tissue filled the defect and all microbiological cultures were negative	NR	• Debridement
	Non-RCT	Control	NR					

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Catarino et al.(137)	Non-RCT	V.A.C.® CNP 125 mmHg Foam dressing	48-72 hrs	NR	NR	Until wound closure; evident granulation tissue and negative microbiological cultures	NR	• Debridement • broad-spectrum antibiotics
	Non-RCT	Control						
Shilt et al.(138)	Non-RCT	V.A.C.®	Every 72 hours	NR	NR	16.7d	Amputation 11	Oral antibiotics (9) Intravenous antibiotic (15)
	Non-RCT	Control					14	
Kamolz et al.(343)	Non-RCT	V.A.C.® Open-cell polyurethane foam	Controlled daily	Use of Indocyanine Green (ICG) video angiographies	Daily	NR	NR	Intravenous injections of 0.2 mg/kg ICG
	Non-RCT	Control						
Gabriel et al.(339)	Non-RCT	V.A.C.® Continuous Negative Pressure (CNP): -125 mmHg Foam dressing IV bag containing normal saline, sterile water or silver nitrate solution for instillation	NR	NR	Weekly	Until wound closure	NR	• Repeatedly sharply debrided
	Non-RCT	Control			NR			

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Ozturk et al.(117)	Non-RCT	V.A.C.® CNP 125 mmHg GranuFoam® large dressing	Every 72 hrs in the OR	NR	NR	After wounds were clinically healed or wound cultures were negative, tertiary wound closure or split thickness grafting was performed	NR	• Surgical debridement
	Non-RCT	Control	Daily or more if needed					• Surgical debridement • Taken into OR every 48 hours for dressing changes and jet lavage
Rinker et al.(121)	Non-RCT	V.A.C.® Intermittent: -125 mmHg; Petrolatum-impregnated gauze was placed between any exposed bone and the foam dressing	Every 48 hours	NR	NR	NR	NR	NR
	Non-RCT	Control (wet-to-dry gauze or a moist occlusive dressing)	NR					
Huang et al.(127)	Non-RCT	V.A.C.® Intermittent: -125 mmHg	48-72 hrs	NR	NR	Healed completely or when a minor procedure for closure was required, i.e., simple wound stitching or skin grafting		Mean debridement per patient: 4.41
	Non-RCT	Control	3-6x/d					3.33

Reference	Study Type	Treatments	Treatment Change	Wound Assessment	Frequency of Measurements	Treatment Duration	Prior Treatments	Concurrent Treatments
Labler et al.(71)	Non-RCT	VAC® Foam CNP: -125 mmHg	Every 48 hours depending on wounds and patient's condition	Bacterial cultures	Every 48 hours	Until primary or secondary closure	NR	• 3 debridements and primary immobilization of the fracture • "Second-look" operations carried out every 48 hours which included subsequent thorough debridements, fracture, redislocation and repeated irrigation with normal saline. • 3rd generation cephalosporin
	Non-RCT	Control						

CNP Continuous negative pressure
NPIT Negative pressure instillation therapy
NR Not reported
RCT Randomized controlled trial
STSG Split-thickness skin graft

*All studies reported using V.A.C.® (KCI, USA Inc.)

Table 34. Results for Outcome Measures Reported in Comparison Studies of NPWT Devices* Used to Treat Acute Wounds

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Stannard et al.(125)	RCT	Hematoma study: V.A.C.®	13	13	NR	Drainage (Mean) 1.6 (Range: 0-5)	Need for surgical evacuation: 1 (8%)	NR
	RCT	Control:	31	31		3.1 (Range: 0-11)	5 (16%)	
	RCT	Fracture study: V.A.C.®	20	20	NR	Drainage (Mean): 1.8 (0-6)	No significant difference in rates of infection or wound dehiscence	NR
	RCT	Control	24	24		4.8 (0-24)		
Timmers et al.(106)	Non-RCT	V.A.C.®	30	30	NR	7 (11.9%) of wounds failed to become sterile however due to the amount of new granulation tissue, surgical closure of the wound was undertaken.	Median duration of hospital stay (days)(Range) 36 (15-75) Recurrence of osteomyelitis: 3 (10%) Median duration of total hospital stay per patient (days)(Range) 36 (15-75)	NR
		Control	94			NR	Median duration of hospital stay (days)(Range) 27.3 (3 -196) (p = 0.624) Recurrence of osteomyelitis: 55 (58.5%) (p < 0.0001) Median duration of total hospital stay per patient (days)(Range) 73 (6-419) (p < 0.0001)	

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Simek et al.(123)	Non-RCT	V.A.C.®	34	NR	NR	5.8% failure rate	Overall length of therapy:14.9 ±7.9d In-hospital mortality 5.8% 1-year mortality: 14.7%	NR
	Non-RCT	Control	28			39.2% failure rate	Overall length of therapy:14.3 ±11.9d In-hospital mortality 21.4 1-year mortality: 39.2%	
Yang et al.(72)	V.A.C.®	34	Wounds healed (68 (100%)) Ratio of wound closure to skin-grafted wounds: 49:19	NR		Overall time to definitive wound closure by either delayed primary closure with sutures or STSG: 6.7 days(V.A.C.®) and 16.1 days (non-V.A.C.®) (p = 0.0001)	NR	NR
	Control	34	Wounds healed (70 (100%)) Ratio of wound closure to skin-grafted wounds: 45:25					

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Fuchs et al.(23)	Non-RCT	V.A.C.®	35	34	NR	Primary or secondary wound healing achieved: 21d (IQR:15 to 26d)	Time from diagnosis of sternal infection until freedom from infection: Significantly shorter: 16d (IQR: 10 to 26d) 1-year mortality rate: 2.9%	Death due to vacuum-related perforation: 1
	Non-RCT	Control	33	29		28d (IQR: 18 to 54d)	Time from diagnosis of sternal infection until freedom from infection: 26d (IQR: 19 to 51d) 1-year mortality rate: 25.3%	Deaths: 4 2 due to bleeding 2 due to septic shock
Immer et al.(130)	Non-RCT	V.A.C.®	19	NR	NR	NR	Survival: significantly better in Group 1 (V.A.C.® only) than Group 2 or Group 3 SF-36: Patients from groups 2 and 3 scored significantly lower in the aspects of physical function, general health and vitality than Group 1.	NR
	Non-RCT	V.A.C.® plus excision plus flap	19					
	Non-RCT	Excision plus flap	17					
Segers et al.(122)	Non-RCT	V.A.C.®	29	21 (73%)	NR	Therapy duration (d): 22.8 (4-68)	Hospital stay SSI (mean): 46.1 (Range: 10-74)	Mortality caused by SSI: 4 (13.8%)
	Non-RCT	Control	34	14 (41%)		Therapy duration(d): 16.5 (2-38)	35.7 (Range: 10-165)	7 (20.6%)

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Sjogren et al.(139)	Non-RCT	V.A.C.®	61	61	NR	Treatment duration: 12 ±9d (Range: 2-66) Total length of stay (LOS): 25 ±17d (Range: 7-103)	90-day mortality (significantly lower) 0 (p <0.01) Overall survival (significantly better) 97% at 6 mos. 93% at 1 year 83% at 5 years	NR
	Non-RCT	Control	40	40		Treatment duration: 10 ±14d (Range: 1-53) Total LOS: 25 ±20 (Range: 1-87)	90-day mortality: 6 (15%) Overall survival: 84% at 6 mos. 82% at 1 year 59% at 5 years	
Domkowski et al.(129)	Non-RCT	V.A.C.®	96	NR	NR	Omental transposition: 33 Pectoralis flap: 10 Secondary closure: 53	NR	Multisystem organ failure: 2 Overwhelming Sepsis: 2
	Non-RCT	Control	6					
Song et al.(124)	Non-RCT	V.A.C.®	17	15 (14 by definitive closure; 1 by secondary intention (V.A.C.®))	NR	Average days between initial debridement and definitive closure of the sternal wound (not significant) 6 ±1.3d	NR	Mortality: 3 (2 from aspiration pneumonia and 1 from multisystem organ failure)
	Non-RCT	Control	18	17		8 ±2.9d		Mortality: 1 patient died due to aspiration pneumonia

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Doss et al.(128)	Non-RCT	V.A.C.®	20	NR	Reduction in wound size: 4.63 cm^2/day (Range: 2.9-6.5)	NR	Duration of treatment: Mean: 17.2 ±5.8 Total hospital stay: Mean: 27.2 ±6.5d	Hospital mortality: 1 (5%)
	Non-RCT	Control	22		3.2 cm^2/day (Range: 2.7-3.6)		Duration of treatment: Mean: 22.9 ±10.8 Total hospital stay: Mean: 33.0 ±11.0d	Hospital mortality: 1 (4.5%)
Catarino et al.(137)	Non-RCT	V.A.C.®	7	7	NR	11d median (6-26d)	LOS: 27d median (22-49) Treatment failure: none (significantly greater for Control)	NR
	Non-RCT	Control	10			13d median (8-20)	LOS: 50d median (27-98) Treatment failure: 5	

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Shilt et al.(138)	Non-RCT	V.A.C.®	16	16	NR	Free flap: 3 Split thickness: 8 Cross-foot flaps: 3 Full-thickness: 1 1 lost to f/u	LOS – 16.8 (5-47) Modified Loder grade Excellent:10; Good: 1; Fair: 1; Poor: 4 Outcomes Loder Satisfactory: 11; Unsatisfactory: 5 Vosburgh (a functional outcome questionnaire): 23.0 (19-24) # of procedures: 4.6 (2-10)	None
	Non-RCT	Standard of Care (SOC)	15	15		Free flap: 8 Split thickness: 5 Cross-foot flaps: 1 Full-thickness: 1	LOS – 10.2 (3-24) Modified Loder (a functional outcome classification) grade Excellent: 6; Good: 1; Fair: 0; Poor: 7 Outcomes Loder Satisfactory: 7; Unsatisfactory: 7 Vosburgh: 22.6 (21-24) # of procedures: 3.4 (1-7)	
Kamolz et al.(343)	Non-RCT	V.A.C.®	7 patients used as own controls	14	NR	Skin grafts – 2; No operation – 3; Keratinocytes – 2	A massive reduction of edema formation (up to 50 ml) within the burn wound	NR
	Non-RCT	Silver sulphadiazine crème				Skin grafts – 4; No operation – 3		
Gabriel et al.(339)	Non-RCT	V.A.C.®	15	100%	NR	Days to wound closure: 13.20 ±6.75	Days to patient discharge: 14.67 ±9.18	NR
	Non-RCT	Control	15	66.7%		29.60 ±6.54	39.20 ±12.07	

Reference	Study Type	Treatments	N	Wounds Healed	Mean (SD) Change in Wound Area (cm^2) or Volume (cm^3)	Satisfactory Healing	Other Important Outcomes	Adverse Events Resulting in Discontinuation of Treatment
Ozturk et al.(117)	Non-RCT	V.A.C.®	5	5	NR	9d (Range: 7-15)	VAS 2.4 LOS: 14d; Range: 11-19	NR
	Non-RCT	Control	5	5		10d (8-16)	VAS 6.8 LOS: 13d;10-18	
Rinker et al.(121)	Non-RCT	V.A.C.®	17 (17 flaps)	17 (100%)	NR	Time to bony union (Significantly less) 4.9 months	LOS, days 20.8 ±10.5	NR
	Non-RCT	Control	38 (43 flaps)	36 (84%)		7.2 months	20.2 ±8.5	
Huang et al.(127)	Non-RCT	V.A.C.®	12	NR	Reduction: 47% in dimension and 49% in volume	NR	Hospital stay: 32.1d (mean)	Deaths: 1 (8%) Amputation: 2
	Non-RCT	Control	12		Reduction: 41% in dimension and 39% in volume		34.3d (mean)	Deaths: 1 (8%) Amputation: 2
Labler et al.(71)	Non-RCT	VAC®	12	11	NR	11 of 13 healed uneventfully	Rate of infection: 2 of 13	Early amputation: 1
	Non-RCT	Control	11	5		5 of 10 healed uneventfully	Rate of infection: 6 of 11	Early amputation: 1

LOS Length of hospital stay
NR Not reported
RCT Randomized controlled trial
SSI Surgical site infection

* All studies reported using V.A.C.® (KCI, USA Inc.)

Key Question 3

Table 35. Characteristics of Patients with Acute Wounds

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Bannasch et al. 2008(344)	5	Mean 37.8 Range: 8-58	4 M 1 F	1: DM	Pretibial bone exposure, exposure of calcaneus and Achilles tendon, exposure of all extensor tendons of the foot, exposed tibias and hardware (secondary to plate osteosynthesis), posterior aspect of lower leg	5	NR	NR
Bendewald et al. 2007(82)	5	Median: 21 Range: 16-63	3 M 2 F	NR	Complex pilonnidal disease underwent wide excision	5	Mean: 205 cm^3 Range: 90 cm^3-410 cm^3	NR
Bendo et al. 2007(76)	13	Mean: 58 Range: 34-83	5 M 8 F	6: diabetes 1: atrial fibrillation 1: HIV	Posterior lumbar wound drainage management of the spine prior to debridement	13	NR	NR
Brandi et al. 2008(345)	18	Avg: 56 Range: 45-78	NR	12: Peripheral vascular disease (PVD) and 4 of these with type 2 DM	Traumatic loss of tissue in the lower limbs involving exposure of bone and tendon structures	18	NR	NR
Dhir et al. 2008(346)	19	Mean: 63.2 Range: 48-75	17 M 2 F	16: hypertension 4: IDDM 9: malnutrition 7: CAD 7: PVD 4: NIDDM	Complex head and neck wounds	33	Larger cutaneous defects >10 cm^2	Neck and facial abscesses

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Rhode et al. 2008(347)	5	Mean: 41.2 Range: 33-59	5 F	BMI Range: 24.4 -36.1 2: smokers	Patients had radical excisional therapy for stage III vulvar hidradenitis suppurativa	5	NR	NR
Rozen et al. 2008(348)	9	Mean: 69 Range: 32-99	9 F	5: hypertension 1: asthma 5: smoking history 1: ESRF on dialysis 1: type II DM 2: COPD 2: AS 1: AF 3: stroke 2: IHD 3: hypercholesterolaemia 1: hyperparathyroidism 1: CCF 1: granulomatous hepatitis 1: anemia	Lower limb split skin grafts	9	NR	NR
Steiert et al. 2008(349)	42	Mean: 46 Range: 15-84	29 M 13 F	NR	Open extremity fractures	33 lower extremity 10 upper extremity	NR	Severe extremity trauma
Svensson et al. 2008(149)	28	Median: 75 Range: 48-88	Of the 33 wounds , 21 M 12 F	10: ≥80 yrs 12: women 14: DM 23: lower limb ischemia	Perivascular surgical site infections in groin	33	NR	Infected groins

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Bhattacharyya et al. 2007(350)	38	Infected Mean: 39 ±8.8 Non-infected Mean: 39 ±10.5	32 M 6 F	7: smokers 1: DM	Gustilo grade III B open fractures	38	10 cm or larger	11 wounds infected; 27 non-infected
Bollero et al. 2007(141)	35	Avg: 40, Range: 14-72	29 M 6 F	NR	Acute complex traumas of lower limbs	13 foot 5 ankle 15 leg 1 knee 3 thigh	NR	NR
Dedmond et al. 2007(27)	49	Avg: 36.8, Range: 18-70	40 M 10 F	NR	Grade/type III open tibial shaft fractures	24 IIIA 24 IIIB 2 IIIC	NR	NR
Helgeson et al. 2007(351)	NR	NR	NR	NR	Exposed tendon and/or bone Combat-related wounds	16 wounds treated 18 times: 6 leg 1 shoulder 6 foot 2 forearm 2 thigh 1 hip	Avg: 87 cm^2 Range: 15-275 cm^2 Median: 47 cm^2	NR
Labler and Trentz 2007(352)	13	Range: 13-71	10 M 3 F	NR	Severe soft tissue injuries as a result of high energy pelvic trauma	13	NR	NR
Machen 2007(74)	Over 50 patients	NR	NR	NR	Traumatic war wounds	Over 50 wounds	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Peck et al. 2007(353)	192	Range: 4-68	NR	NR	Major vascular injuries	134 extremity 33 neck and vessel 25 torso	NR	NR
Rao et al. 2007(163)	29	Median: 60, Range: 31-80	14 M 15 F	NR	Open abdominal wounds	29	NR	NR
Segers et al. 2007(354)	5	NR	NR	NR	Open window thoracostomy	5	NR	NR
Senchenkov et al. 2007(355)	17	Mean: 65 Range: 42-82	9 M 8 F	17: soft tissue sarcoma 2: DM 1: smoker	Irradiated extremity wounds reconstructed w/split thickness skin grafts	17	Skin graft size: Mean: 118 cm^2 Range: 23-240 cm^2	NR
Andrews et al. 2006(88)	12	Avgerage: 61.8 Range: 34-86	8 M 4 F	66.6%: Cardiac disease 66.6%: Cancer 58.3%: Pulmonary disease 58.3%: Hypertension 16.6%: Diabetes 8.3%: Liver and kidney disease	Complicated head and neck wounds	13	All in cm: 8x6 10x5 7x6 9x6 5x4 9x6 16x8 8x9 21x14 14x8 10x9 10x7	9: Bone exposure
Cothren et al. 2006(356)	14	Men: Mean: 41 ±5.7	79% M, 21% F	NR	Open abdomen	14	NR	NR
DeFranzo et al. 2006(156)	100	Range: infancy to 78	48 M 52 F	NR	Partial thickness and complete full-thickness abdominal wounds	63 partial thickness 37 complete full-thickness	Avg: 200 cm^2 Range: 30 cm^2 - 700 cm^2	45 of partial: contaminated/ infected 19 of full: contaminated/ infected

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Heller et al. 2006(87)	21	Mean: 48 Range: 5-75	11 M 10 F	10: Morbid obesity 11: Diabetes 4: Steroid use 6: Smoking 8: Hypertension 4: Preoperative chemotherapy	Abdominal wound dehiscence	21	NR	NR
Leininger et al. 2006(111)	77	NR	NR	NR	High-energy soft tissue wounds (trauma, deployed wartime environment)	39 lower extremity 12 back 7 chest 20 upper extremity 6 abdomen 4 buttock/ perineum	Only reported size of 33 wounds: Mean: 45.3 cm^2 SD: 30.6 cm^2 Median: 32 cm^2 Range: 12-160 cm^2	NR
Labler et al. 2005(357)	18	Range: 13-69	16 M 2 F	NR	Open abdomen after laparotomy	18	NR	NR
Rosenthal et al. 2005(89)	23	Average: 59	17 M 6 F	4: Diabetes requiring insulin therapy during wound management	Head and neck reconstruction	23	NR	NR
Stoeckel et al. 2005(358)	18	Mean: 52	18 F	2: smokers 4: previous radiation therapy to affected breast	Complex breast wounds	15	NR	NR
Savolainen et al. 2004(359)	36	Median: 72, Range: 46-98	21 M 15 F	NR	Inguinal wound in vascular surgery	36	NR	13 frank infection 11 non-infected 12 clinically contaminated
Stone et al. 2004(90)	48	NR	NR	NR	Abdominal trauma	48	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Herscovici et al. 2003(360)	21	Avg: 45.9, Range: 16-83	12 M 9 F	NR	High energy soft tissue injuries	6 tibial 10 ankle 1 forearm 1 elbow 1 femur 1 pelvis 1 below knee stump	Tibial: 73 cm^2, Range: 5-261 ankle & foot: 38 cm^2, Range: 8-52 forearm: 65 cm^2 elbow: 60 cm^2 femur: 156 cm^2 pelvis: 264 cm^2 below knee stump: 400 cm^2	NR
Stonerock et al. 2003(77)	15	NR	12 M 3 F	NR	Abdominal wounds	15	NR	Abdominal compartment syndrome, inability for abdominal closure at initial operation, or inability to close the abdomen upon re-exploration
Suliburk et al. 2003(166)	29	Men: Mean: 38 ±3	20 M 9 F	NR	Open abdomen after severe trauma	29	NR	NR
Garner et al. 2001(86)	14	Mean: 40.1 $\pm$ 4.7	4 M 10 F	NR	Open abdomens	14	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
DeFranzo et al. 2000(157)	75	NR	NR	NR	Lower extremity wounds w/ exposed bone	29 motor vehicle accidents 9 gunshot 11 other assorted trauma 13 dehisced or infected orthopedic surgical wounds 3 pressure sores 5 failed flaps 5 miscellan-eous	NR	NR
Avery et al. 2000(92)	15	NR	NR	NR	Radial forearm donor site with split skin graft	15	Mean: 36 cm^2	NR

Table 35a. Characteristics of Patients with Chronic Wounds

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Bapat et al. 2008(153)	Group A: 23 superficial sternal infection received V.A.C.® as definitive treatment	Group A: 69 ±13	Group A: 20 M, 3 F	Group A: BMI 30.9 ±3.7 9 DM	Superficial sternal infections and deep sternal infections	28 superficial 21 deep	NR	NR
	Group B: 5 superficial sternal infection received V.A.C.® followed by surgical closure	Group B: 69 ±12.1	Group B: 4 M, 1 F	Group B: BMI 30.3 ±2.9 1 DM				
	Group C: 12 deep sternal infection received V.A.C.® as definitive treatment	Group C: 69 ±11.4	Group C: 11 M, 1 F	Group C: BMI 31.8 ±4.6 3 DM				
	Group D: 9 deep sternal infection received V.A.C.® and surgery	Group D: 67 ±12	Group D: 8 M, 1 F	Group D: BMI: 30.7 ±5.1 4 DM				

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Baharestani et al. 2008(93)	11	Avg: 54 Median: 57 Range: 18-82	7 M, 4 F	7 DM 1 Malnourished 3 periperal vascular disease 2 Obesity	Necrotizing Fascitis	16	NR	NR
Chen et al. 2008(160)	26	Mean: 69, Range: 49-82	21 M 5 F		Deep sternal wound infections	26	NR	NR
Ennker et al. 2008(361)	45	Avg: 68	29 M 16 F	16: IDDM 35: hyperlipidemia 40: hypertension 19: COPD 7: Peripheral arterial disease 9: Carotid artery stenosis	Deep sternal wound infections	45	2 cm x 2 cm to 2 cm x 18 cm	NR
Fleck et al. 2008(362)	22	Mean: 61.5 ±15, Range: 8-79	15 M 7 F	NR	Open chest	22	NR	NR
Gdalevitch et al. 2008(154)	36	Median: 67.1, Range: 49-88	22 M 14 F	66.7% hyperlipidemia 64% smoking 58.3% DM 55.6% hypoalbuminemia 38.9% positive blood culture 25% CLD 22% high degree bony exposure and sternal instability 11.1% CKD 8.3% PVD 5.6% immunocompromised	Superficial and deep sternal wounds	36	Depth: 19.4% ≥4 cm 80.6% ≤4 cm	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Ha et al. 2008(140)	74	Median: 65.5, Range: 19-95	40 M 34 F	60.8% DM 86.7% of DM had PVD, Stroke, retinopathy, dialysis	Surgical wounds	25 foot 13 toe 13 groin 9 leg 9 thigh 7 trunk 1 neck	Median: 18.7 cm^2 Range: Length 0.5-20 cm, Width 0.5-15 cm	29 surgical incision breakdown 42 infected secondary to causes other than surgery 6 infected that dehisced after initial closure
Hamed et al. 2008(363)	10	Mean: 65 ±16	5 M 5 F	6: DM 7: hypertension	Lymphatic fistulae (LFs) and lymphoceles: 9 patients groin lymphatic complications 1 patient neck lymphatic complication	10	NR	NR
Horch et al. 2008(155)	21	Mean: 69.8, Range: 46-80	12 M 9 F	17: PAOD with or without concomitant renal insufficiency 2: autoimmune disease with immuno suppressive medication 10: diabetes 2: acute pancreatitis	Severe lower limb soft tissue loss and infection with exposed bone, infected ulcers of lower leg with exposed bones and joints	21	NR	All patients presented with necrotic tendons and or affected and exposed tibia or fistula bones
Labanaris et al. 2008(364)	80	Men: Mean: 63, Range: 53-84 Women: Mean: 66, Range: 50-82	64 M 16 F	NR	Chronic wounds	26 pressure ulcers 17 wound trauma 24 diabetic ulcer 13 venous stasis ulcer	NR	NR
Lopez et al. 2008(365)	8 with 10 V.A.C.® applications	Age at V.A.C.® application: 84.5 ±51 days	6 M 2 F	NR	Complex abdominal wounds	8	Mean: 13.6 ±6 cm^2 Range: 8.5-25 cm^2	Wound infection and dehiscence

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Mokhtari et al. 2008(366)	38	Mean: 69 ±SD 10.6	29 M 9 F	15: DM 10: BMI >30 9: COPD 16: recent MI 3: Renal Failure	Deep sternal wound infection	38	NR	NR
Ploumis et al. 2008(80)	73	Average: 58.4 Range: 21-82	34 M 39 F	Chronic leukocytic leukemia, lupus anticoagulant, chronic renal failure, alcohol abuse, metastatic colon cancer, obesity, malnutrition, diabetes, splenectomy, hodgkin disease, radiation exposure, rheumatoid arthritis, and smoking	Spinal wound infections	79	NR	NR
Wondberg et al. 2008(161)	30	Avg: 63, Range: 27-86	21 M	NR	Open abdomen caused by abdominal sepsis; origin of sepsis: 21 colon 3 stomach 5 stomach or bowel 1 unclear	30	NR	NR
Horn et al. 2007(78)	11	Range: 7-19	6 M 5 F	2: Myelomeningocele 2: Cerebral Palsy 1: Scoliosis after paraplegia from chemotherapy for acute myelogenous leukemia 1:Fusion for kyphotic deformity secondary to collapse of veterbral bodies from an aneurysmal bone cyst 4: Moderate to severe developmental delay	Infected spinal wounds	11	NR	Range of time of onset of infection: 2 weeks-5 years

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Jones et al. 2007(150)	13	Mean: 50.2, Range: 14-76	NS	Malignant disease, anemia	Deep infections of the spine	13	NR	6 Staph 1 complicated Candida 4 mixed bacterial infections 2 Pseudomonas aeruginosa infections 1 Serratia marcescens infection
Kotsis and Lioupis 2007(73)	8	Range: 24-74	NR	4: Hypertension 4: Morbid obesity 3: Diabetes mellitus II 2: Renal failure 1: Hepatitis C 1: Malignancy 1: Pulmonary insufficiency	Vascular graft infection confined to the groin	8	NR	NR
McCord et al. 2007(142)	68	Mean: 8.5 yrs Range: 7 days-18 yrs	36 M 32 F	NR	Pressure ulcers, extremity wounds, dehisced surgical wounds, open sternal wounds, wounds w/fistulae, complex abdominal wall defects	13 pressure ulcers 18 extremity wounds 19 dehisced surgical wounds 10 open sternal wounds 3 wounds w/fistulae 6 complex abdominal wall defects	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Perez et al. 2007(95)	37	Avg: 58 Range: 34-86	18 M 19 F	1: Gallbladder cancer 2: Pancreatic cancer 5: Stomach cancer 2: Colon Cancer 10: Diverticulitis 10: Bowel obstruction 3: Pancreatitis 2: Ulcer	21: Severe abdominal sepsis 16: Abdominal compartment syndrome	37	NR	NR
Shrestha et al. 2007(367)	9	Range: 30-67	5 M 4 F	NR	Deep wound infection after renal transplantation	9	NR	Dehiscence, associated with copious discharge
Strecker et al. 2007(318)	63 patients, 34 treated with V.A.C.®	63 patients: Avg: 68.5, Range: 29-83	63: 61.9% M, 38.1% F	63: 49.2% DM 90.5% arterial hypertension 19% COPD 27% smokers 23.8% Renal Failure	Deep sternal wound infections	34	NR	NR
van Rhee et al. 2007(368)	6	Avg: 12.6	3 M 3 F	NR	Deep wound infection after instrumented spinal fusion in pediatric neuromuscular scoliosis	6	NR	Wound dehiscence
Gorlitzer et al. 2006(369)	5	Avg: 69, Range: 24-72	3 M 2 F	1: DM 1: colon cancer, CRF, COPD, heart failure	Descending necrotizing mediastinitis	5	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Labler et al. 2006(370)	15	Mean: 48, Range: 18-75	4 M 11 F	2: Nicotine 3: alcohol 2: tumor 2: radiation before surgery 2: arterial hypertension 3: DM 3: CRF 2: Chronic Heart Disease (CHD) 1: COPD BMI's (kg/m^2) 36, 39, 28, 34, 32, 59	Deep subfascial infection after dorsal spinal surgery	15	NR	NR
Morgan et al. 2006(164)	9	Range: 56-85	7 M 2 F	7: DM 3: hypertension 2: MI 2: Renal disease 1: smoker 1: kidney transplant 3: Coronary artery disease (CAD) 2: Congestive heart failure (CHD) 1: CRF 1: Peripheral arterial disease (PAD)	Chronic lower extremity wounds	12	All cm: 3x3 3x4 3x3 3x4 3x3 3x3 3x3 3x3 3x5	Non-healing ulcerations

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Pelham et al. 2006(371)	10	Mean: 52, Range: 13-76	4 M 6 F	DM, obesity, hypertension and a history of smoking (number of patients not specified)	Chronic infected wounds with exposed orthopedic implants: 6 chronic wounds (present for more than 6 weeks) 4 subacute wounds (present for 1-4 weeks) All wounds classified as complex, defined as having exposed bone, exposed tendon, or exposed orthopedic implants and/or open joint space with stripped bone	10	8 patients had a wound exceeding 20 cm^2	Skin breakdown distal tibia; large anterior skin slough with exposed hardware; long-standing draining sinus with partially exposed lateral plate; long-standing exposed total knee arthroplasty hardware with large anterior skin and soft-tissue slough; long-standing exposed hardware; Infected total knee arthroplasty with skin breakdown; infected open reduction internal fixation; open wound exposed hardware, infected open reduction internal fixation, infected open reduction internal fixation
Sartipy et al. 2006(151)	5	Range: 58-79	2 M 3 F	1: DM 2: COPD, obesity	Deep sternal wound infection	5	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Agarwal et al. 2005(372)	103	Avg: 52, Range: 3-91	67 M 36 F	Pulmonary: 2 congenital 16 COPD Cardiovascular: 17 congenital 6 endocarditis/pericarditis 5 myopathy 65 CAD 14 CHF Renal: 6 insufficiency/failure 11 End-stage renal disease (ESRD) Autoimmune: 11 transplant 5 connective tissue 42 hypertension 37 DM	Sternal wounds	103	NR	16 superficial infections 21 sterile 66 mediastinitis
Cowan et al. 2005(373)	22	Mean: 67.9 ±10.9	68.2% M	BMI 30.9 ±7.8 40.9% smokers 54.6% DM 36.4% RF 31.8% CHF 58.1% hypertension 18.2% COPD	Deep sternal wounds with or without bony involvement	22	NR	82% dehiscence 59% sternal instability 73% fluid collection by computed tomography 41% osteomyelitis 50% staphylo-coccus aureus
Lee et al. 2005(374)	9	Range: 47-73	NR	NR	Refractory sternal infection: 2 patients type IVA mediastinitis after one failed therapeutic trial 7 patients type IVB mediastinitis after more than one failed therapeutic trial	9	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Mendonca et al. 2005(375)	15	Avg: 49.3, 22-80	9 M 6 F	10: DM 2: chronic osteomyelitis 2: Peripheral vascular disease (PVD) 1: spina bifida 11: peripheral neuropathy, RF, and wound dehiscence	Chronic, non-healing wounds on foot and ankle	18	Avg: 7.41 cm^2, Range: 2-10 cm^2	11 clinical evidence of active infection 5 stage II wounds 10 stage III wounds (stages are based on Wagner-Meggitt classification)
Sjogren et al. 2005(179)	46	Mean: 68.5 ±SD 10.3	32 M 14 F	11: DM 22: BMI >30 2: preoperative dialysis 23: recent MI 8: COPD 14: HF 6: RF	Post sternotomy mediastinitis	46	NR	NR
Mehbod et al. 2004(376)	20	Avg: 55, Range: 31-81	12 M 8 F	3: DM 3: previous splenectomy 10: smokers 1: lupus 1: Hodgkin lymphoma 1: HIV	Deep spine infections w/ exposed instrumentation	20	NR	16 draining wound 4 presented back pain & temperature

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
O'Conner et al. 2004(377)	17	Avg: 43.5, Range: 24-76	11 M 6 F	Group I: 1 DM and ESRD and steroids 1 chronic lymphocytic leukemia and prostate cancer 2 HIV positive	Chest wounds	Group I: 7 primary chest wall process	Avg 16x7 cm, Range: 7x3 cm to 21x11 cm	Group I: 4 necrotizing soft-tissue infections 3 penetrating trauma resulting in large contaminated wounds w/ significant loss of chest wall integrity
				Group II: 1 multiple sclerosis and PVD and steroids 1 closed head injury 1 DM and morbid obesity 1 cerebral abscess 1 DM and COPD and CAD 1 cerebral vascular accident 1 cardiomyopathy	Chest wounds	Group II: 10 with empyema with extension to chest wall	Avg 16x7 cm, Range: 7x3 cm to 21x11 cm	Group II: 2 with empyema necessitates 6 with postpneumonic empyema 4 with postoperative empyema
Routledge et al. 2004(378)	6	Range: 22-65	3 M 3 F	NR	Deep wound infections after heart and lung transplantation	6	NR	NR
Scholl et al. 2004(81)	13	Mean: 61 Range: 43-73	11 M 2 F	4: History of diabetes mellitus 5: History of CABG	Postoperative deep sternal wounds	13	NR	7: Acute purulent sternal infections 6: chronic sternal osteomyelitis
Demaria et al. 2003(145)	7	Mean: 74, 71-80	6 M 1 F	4: DM All: cardiopulmonary bypass	Non-healing infected sternal surgical wound	7	NR	Wound dehiscence w/local inflammation followed by cloudy discharge some had low grade fever
Gustafsson et al. 2003(146)	40	Median: 68, Range: 49-87	26 M 14 F	NR	Deep sternal wound infections	40	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Isago et al. 2003(91)	10	Mean: 61.2 ± 4.5 Range: 43-88	7 M 3 F	All paralyzed or bedridden	Pressure ulcers	10	Mean area: 62.6 cm^2 Mean depth: 1.9 cm	Stage IV - penetration into the deep fascia with involvement of muscle and bone
Wongworawat et al. 2003(75)	14	Average: 48 Range: 21-66	NR	NR	Orthopedic infections	14	Average: 70 cm^2 Range: 22.5-288 cm^2	NR
Armstrong et al. 2002(85)	31	Mean: 56.1 ± 11.7	24 M 7 F	Diabetes	Diabetic foot ulcers	31	Surface area: 27.9 ± 19.5 cm^2	3.2%: Grade 1 lesions 45.2%: Grade 2 lesions 51.6%: Grade 3 lesions (Grades based on University of Texas' diabetic foot classification system)
Clare et al. 2002(379)	17	Avg: 64.4	8 M 9 F	13: DM 9: IDDM 10: peripheral neuropathy 8: severe PVD	Non-healing wounds of lower extremity	5 midfoot/ forefoot 6 ankle/ hindfoot 6 lower limb	NR	6 postoperative dehiscence of surgical incision
Fleck et al. 2002(380)	11	Median: 64.4, Range: 50-78	5 M 6 F	NR	Sternal wound infection	11	NR	NR
Gustafsson et al. 2001(381)	16	Male: Median: 68, Range: 49-82 Female: Median: 67, Range: 63-73	13 M 3 F	NR	Deep sternal wound infections	16	NR	NR
Hersh et al. 2001(94)	16	Range: 45 – 79	6 M 10 F	NR	Deep sterna wounds	16	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
De Lange et al. 2000(167)	Group 1: 23	Group 1: Mean: 46, Range 17-77	NR	NR	Group 1: stage IV pressure sores	Group 1: 26	NR	NR
	Group 2: 42	Group 2: Mean: 62, Range: 20-89	NR	NR	Group 2: major postoperative wound infection in abdomen, groin, knee, ankle	Group 2: 42	NR	NR
	Group 3: 19	Group 3: Mean 67, Range: 46-85	NR	NR	Group 3: chest wall dehiscence after cardiac surgery complicated by mediastinitis	Group 3: 19	NR	NR
	Group 4: 13	Group 4: Mean: 44, Range: 21-80	NR	NR	Group 4: subacute wounds	Group 4: 13	NR	NR
	Group 5: 3	Group 5: Mean: 67, Range: 59-73	NR	NR	Group 5: soft tissue defect after radiation therapy, soft tissue defect after subcutaneous leakage chemo, diabetes ulcer on ankle	Group 5: 3	NR	NR
Deva et al. 2000(382)	30	Mean: 50.7, Range: 15.4-88.3	20 M 10 F	NR	Wounds unsuitable for surgical closure (pressure sores)	8 sacral 7 ischial 8 trochanter/hip 7 lower limb	Mean width: 5.7 cm, Range: 1.7-22 cm Mean length: 9.9 cm, Range: 1.9-27 cm Mean depth: 3 cm, Range: 0.5-9 cm Mean volume: 171 cm^3, Range: 16.1-2,228 cm^3	Grade III pressure sores (full thickness ulceration down to but not through deep fascia) Mean pretreatment duration: 418 days, Range: 8-1,650 days
Lang et al. 1999(159)	82	NR	68 M 14 F	NR	Soft tissue lesions of the ankle and foot	82	NR	NR

Table 35b. Characteristics of Patients with Mixed Wound Types

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Smith & Nephew Wound Management Unpublished Data(96)	132	Mean: 57, Range :20 - 92	73 M, 58F	NR	55: Surgical 14: Traumatic 29: Pressure ulcer 11: Diabetic foot ulcer 3: Leg ulcer 19: Graft site 1: Other	132	Median area: 25.6 cm^2 Range: 1 cm^2 – 1099.6 cm^2 Median depth: 1.5 cm Range: 0 cm – 18 cm	21 clinically infection
Campbell et al. 2008(84)	30	Mean: 72.3, Range: 32 – 96	9 M, 21 F	73%: Diabetes 40%: Venous disease 20%: Cancer 23%: RD	11: Chronic 11: Surgical dehiscence 8: Surgical incision	30	Medan volume: 43.9 cm^3 Area: 20.2 cm^2 Depth: 1.9 cm	NR
Gabriel et al. 2008(383)	58	Median: 10 yrs, Range: 10 days-16 yrs	28 M 30 F	NR	Acute and chronic	18 trauma 17 abnormal 15 surgical soft tissue deficit 5 stage III/IV pressure ulcer 3 fasciotomy	Abdominal 120 cm^3 Trauma 112 cm^3 Pressure ulcer 60 cm^3 Soft tissue 150 cm^3 Fasciotomy 60 cm^3	NR
Baharestani et al. 2007(162)	24	Median: 11 yrs, Range: 14 days - 18 yrs	10 M, 14 F	NR	Leg, lumbar/sacral, abdomen, and chest wounds	9 leg 7 lumbar/sacral 4 abdomen 4 chest	6 traumatic: median baseline area 22.4 cm^2 4 wounds treated were secondary to abdominal dehiscence: Median baseline area: 16.4 cm^2	12 infected wounds

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Ferron et al. 2007(83)	11	Mean: 70.5 Range: 50-81	11 F	NR	10: Severe chest wall radionecrosis after breast cancer treatment 1: Locally advanced breast cancer	11	Mean: 360 cm^2 Range: 80-750 cm^2	NR
Mendonca et al. 2007(143)	26	Mean: 54, Range: 16-91	19 M 6 F	7: DM	Mechanical trauma, debridement of necrotic tissue, chronic	13 chronic 7 debridement of necrotic tissue 6 mechanical trauma	Mean: 55.23 ±55.24 cm^2	NR
Wada et al. 2006(384)	29	Mean: 59.8, Range: 29-78	18 M 11 F	13: DM 11: hypertension 10: CD 3: saphenectomy 2: vasculitis	Complex wounds	19 lower extremities 7 sacral ulcers 1 abdomen 1 breast 1 trunk	NR	NR
Adamkova et al. 2005(152)	6	Range: 54-91	NR	CD hypertension, anemia	Subacute and chronic wounds	2 varicose ulcer lower extremity 2 loss of skin after an inflammation secondary to infection 1 high risk patient for deep burns 1 deep defect caused by inappropriate medical care	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Butter et al. 2005(144)	16	Avg: 12.1 yrs, Range: 1 month – 18 yrs	7 M 9 F	NR	8 tissue loss after pilonidal sinus excision 3 wound dehiscence of the abdomen 2 sternum 1 back 1 leg 1 after chronic perineal fistula post-abdominoperineal resection	16	NR	NR
Caniano et al. 2005(165)	51	Group 1: Avg: 16, Range: 10-20 Group 2, 3, 4: NR	NR	Group 1: 67% obese Group 2, 3, 4: NR	Group 1: pilonidal disease Group 2: sacral and extremity ulcers Group 3: traumatic soft tissue wounds Group 4: extensive tissue loss	Group 1: 21 Group 2: 9 Group 3: 9 Group 4: 12	NR	NR
Antony and Terrazas 2004(385)	42	Sternal: 72 Lower extremity: 62 Spinal: 59	Sternal: 8 M, 4 F Spinal: 5 M, 11 F Lower extremity: NR	Sternal: all DM and CAD Lower extremity: 8 DM, CAD, and PVD Spine: 8 DM, Rheumatoid arthritis (RA), and spinal stenosis	Non-healing sternal, spinal, and lower extremity wounds	12 sternal with variety of infections 14 lower extremity w/ variety of infections 16 spinal	NR	NR
Bihariesingh et al. 2004(386)	6	Mean: 60.2, Range: 33-76	3 M 3 F	NR	Complex soft-tissue defects following various orthopedic procedures	6	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Loree et al. 2004(387)	14	Median: 73, Range: 54-90	6 M, 8 F	NR	Chronic leg ulcers: 9 malleolar 3 foot 2 leg 1 tendon calcaneus	15	NR	Ulcer duration: 5 less than 6 months 6 between 6-24 months 4 between 24-360 months
Weed et al. 2004(37)	25	NR	NR	DM	Acute: lower extremity, trauma, sternal wound, and elbow trauma Chronic: pressure ulcers and diabetic ulcers	26 V.A.C.® applications	NR	Serial quantitative cultures
Molnar et al. 2003(388)	8	Mean: 40, Range: 2-60	NR	6: smokers 1: ovarian cancer, pulmonary embolus, chemo 1: DM and bladder cancer 1: CAD 1: hypertension	Complex wounds	5 trauma 2 wound dehiscence 1 tumor excision	Mean: 250 cm^2	Bone exposed in 62.5% joint exposed in 50% tendon exposed in 37.5% bowel exposed in 25%
Schimp et al. 2003(147)	27	Median: 51, Range: 21-77	27 F	BMI Median: 36 kg/m^2, Range: 14-62 6: smokers 8: history of radiation therapy 17: ≥2 abdominal surgeries 9: ≥2 comorbidities	Complex wound failures in gynecologic oncology patients	27	Median: 330 cm^3, Range: 2-4,400 cm^3	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Mooney et al. 2000(79)	27	Range: 3 days - 18 years	14 M 13 F	NR	Acute extremity wounds, chronic extremity wounds, chronic axial wounds	27	NR	Acute extremity: wounds associated with open fractures considered too extensive for acute or delyaed closure Chronic extremity: failed flap coverage, failed primary closure, extensive soft tissue and bony defects Chronic axial: abdominal or sternal dehiscence, myelodysplasia with compromised skin and soft tissue was treated for deep spinal wound infection
Wu et al. 2000(158)	26	NR	17 M 9 F	NR	Chronic, acute, and subacute	8 acute 7 subacute 11 chronic	NR	NR

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Argenta and Morykwas 1997(148)	300	NR	NR	NR	Chronic wounds, subacute, and acute	175 chronic 94 subacute 31 acute	Venous stasis or other vasculitic ulcers: Range: 6-120 cm^2	Subacute: 36 dehisced 37 open w/ exposed orthopedic hardware or bone, and other misc. wounds Acute: large soft tissue avulsions, contaminated wounds, hematomas, abscesses that were evacuated, gunshot wounds, eviscerations, extensive edema and contamination of exposed tissue

Reference	Patient Population (n)	Age (yrs)	Sex	Comorbidities	Wound Type	Number of Wounds	Wound Area (cm^2) or Volume (cm^3)	Severity of Wounds
Mullner et al. 1997(389)	Group A: 17	Group A: Mean: 82, Range: 71-88	Group A: 5 M, 12 F	NR	Group A: infected sacral pressure ulcers	Group A: 17	Group A: Mean: 43 cm^3, Range: 12-72	Group A: 66% of patients the sacrum was exposed, more than 50% of wounds had active secretions
	Group B: 12	Group B: Mean: 35, Range: 24-58	Group B: 5 M, 7 F		Group B: acute soft tissue defects	Group B: 12	Group B: Mean: 20 cm^3, Range: 6-80	Group B: 5 patients skin defect secondary to excision of necrotic skin overlying subcutaneous haematoma; 5 patients had deep infection and 30% of these had active secretions
	Group C: 16	Group C: Mean: 55, Range: 27-81	Group C: 10 M, 6 F		Group C: infected soft tissue defect involving exposed bone and/or implants	Group C: 16	Group C: Avg: 12 cm^3, Range: 8-18	

AF – Atrial Fibrillation
AS – Aortic Stenosis
CAD – Coronary Artery Disease
CAS – Carotid Artery Stenosis
CCF – Congestive Cardiac Failure
CD – Coronary Disease
CHD – Coronary Heart Disease
CHF – Congestive Heart Failure
CKD – Chronic Kidney Disease
CLD – Chronic Lung Disease
COPD – Chronic Obstructive Pulmonary Disease
CRF – Chronic Renal Failure
DM – Diabetes Mellitus
ESRD – End Stage Renal Disease
ESRF – End Stage Renal Failure
HF – Heart Failure
IDDM – Insulin Dependent Diabetes Mellitus

Negative Pressure Wound Therapy Devices

IHD – Ischaemic Heart Disease
MI – Myocardial Infarction
NIDDM – Non Insulin Dependent Diabetes Mellitus
NR – Not Reported
NS – Not Specified
PA – Peripheral Arteriopathy
PAD – Peripheral Arterial Disease
PAOD – Peripheral Artery Occlusive Disease
PVD – Peripheral Vascular Disease
RD – Renal Disease
RF – Renal Failure

Table 36. Treatment Details for All Wound Types

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Smith & Nephew Wound Management Unpublished Data(96)	VISTA™ or EZ-Care™ Smith and Nephew systems	Antimicrobial gauze, non-adherent gauze	NR	NR	7 days post treatment discontinuation
Baharestani et al. 2008(93)	V.A.C.®	GranuFoam®	NR	NR	NR
Bannasch et al. 2008(344)	V.A.C.®	NR	Doppler probe was placed against the drainage vein with the cuff secured around the vessel with nylon sutures, free flaps were split-skin grafted	Doppler probe	NR
Bapat et al. 2008(153)	V.A.C.®	Polyurethane (PU) foam	NR	Debridement and antibiotics	Group A: Median: 23, Range: 12-35 Group B: Median: 17.5, Range: 6-21 Group C: Median: 22.5, Range: 13-34 Group D: Median: 16, Range: 7-22
Brandi et al. 2008(345)	V.A.C.®	PU foam	Debridement, skin graft	Cryo-preserved homologous de-epidermalized dermis (DED)	Avg: 10 months
Campbell et al. 2008(84)	VISTA™, or Versatile-1™, or EZ-Care™ Smith and Nephew systems	Saline moistened antimicrobial gauze	NR	NR	NR
Chen et al. 2008(160)	V.A.C.®	PU foam	NR	Debridement, Median: 2 ±1, Range: 1-6	Median: 17, Range: 1-43

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Dhir et al. 2008(346)	V.A.C.®	Black V.A.C. GranuFoam® and white V.A.C. Vers-Foam®	NR	Incision, drainage, debridement; Hyperbaric oxygen treatment, dermal grafts, salivary diversion, regional flap reconstruction	NR
Ennker et al. 2008(361)	V.A.C.®	NR	NR	Debridement	NR
Fleck et al. 2008(362)	V.A.C.®	NR	NR	NR	NR
Gabriel et al. 2008(383)	V.A.C.®	38: PU GranuFoam® 14: GranuFoam® silver dressing 6: abdominal dressing system PVA foam under GranuFoam® in 3 fasciotomy cases	NR	NR	Mean: 12, Range: 3-34
Gdalevitch et al. 2008(154)	V.A.C.®	Black PU foam	NR	NR	NR
Ha et al. 2008(140)	V.A.C.®	NR	NR	Antibiotics	Median: 85 days, Range: 14-698 days
Hamed et al. 2008(363)	V.A.C.®	PU foam sponge	Heavy dressings and bed rest	NR	Median: 12, Range: 4-32
Horch et al. 2008(155)	V.A.C.®	PU sponge	Conservative treatment with repeated chemical debridement, 1 biologic debridement, and antibiotic therapy	Serial surgical debridement, general or spinal anesthesia for dressing changes or injection of 1% lidocaine	NR
Labanaris et al. 2008(364)	V.A.C.®	NR	NR	Debridement and intravenous antibiotics	NR

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Lopez et al. 2008(365)	V.A.C.®	GranuFoam®	NR	NR	NR
Mokhtari et al. 2008(366)	V.A.C.®	PU foam	NR	Debridement and irrigation	NR
Ploumis et al. 2008(80)	V.A.C.®	NR	NR	Irrigation and debridement for treatment preparartion and Intravenous antibiotics throughout treatment	Average: 14 Range: 12-28
Rhode et al. 2008(347)	V.A.C.®	NR	4 patients had skin graft approximately 1 week after surgery from lateral thigh	Wound beds irrigated, debrided with sharp curette	Avg: 12.6, Minimum: 7
Rozen et al. 2008(348)	Conventional disposable closed system suction drain w/ associated tubing[1]	Disposable foam base	NR	Antibiotics	NR
Steiert et al. 2008(349)	V.A.C.®	PU sponge	Fracture fixation	Initial debridement of necrotic tissue, perioperative antibiotic therapy minimum of 5 days	NR
Svensson et al. 2008(149)	V.A.C.®	PU sponge	NR	NR	Median: 16
Wondberg et al. 2008(161)	V.A.C.®	PU foam	NR	Antibiotic therapy	16 patients Median: 20.1, Range: 5-40

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Baharestani et al. 2007(162)	V.A.C.®	18: PU GranuFoam® 5: PVA 1: GranuFoam® silver	NR	7 chest wounds: white foam, Xeroform (2) and Vaseline gauze (5) 6 total parenteral nutrition (TPN) 3 received enteral feedings systemic antibiotic	NR
Bendewald et al. 2007(82)	V.A.C.®	NR	NR	NR	Range: 6-14
Bendo et al. 2007(76)	V.A.C.®	NR	NR	Antibiotics	NR
Bhattacharyya et al. 2007(350)	V.A.C.®	NR	NR	Serial debridement approximately every 48 hrs, antibiotics from presentation to 48 hrs after definitive wound closure	Infected: 20.6 ±13.2, noninfected: 14 ±5.5
Bollero et al. 2007(141)	V.A.C.®	NR	NR	Debridement	Avg: 265 days, Range: 33-874 days
Dedmond et al. 2007(27)	V.A.C.®	NR	NR	Irrigation, debridement, antibiotics	Avg: 19.6
Ferron et al. 2007(83)	V.A.C.®	PU foam	NR	NR	NR
Helgeson et al. 2007(351)	V.A.C.®	NR	NR	Irrigation and debridement	NR
Horn et al. 2007(78)	V.A.C.®	Vers-Foam® and GranuFoam® if necessary	NR	Debridements between dressing changes, sedation for dressing changes	NR
Jones et al. 2007(150)	V.A.C.®	PU sponge	NR	Debridement & irrigation, antibiotics	At least 90 days
Kotsis and Lioupis 2007(73)	V.A.C.®	NR	NR	NR	Mean: 17.2 Range: 1-28

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Labler and Trentz 2007(352)	V.A.C.®	PU foam	NR	Debridement, antibiotics	Avg: 19.8 ±1, Range: 7-38
Machen 2007(74)	V.A.C.®	Black sponges	NR	NR	NR
McCord et al. 2007(142)	V.A.C.®	White and black foam	NR	Debridement, intravenous analgesic or general anesthesia, or conscious sedation for dressing changes	Up to 7 months after negative pressure therapy start
Mendonca et al. 2007(143)	V.A.C.®	NR	Chronic: debridement and topical destroying gels, regular moist wound healing dressing, maggot debridement therapy, compression bandaging for venous ulcers	systemic antibiotics	NR
Peck et al. 2007(353)	V.A.C.®	NR	NR	Debridement, operative washout (during) every 48-72 hours	NR
Perez et al. 2007(95)	V.A.C.®	NR	NR	NR	Avg: 324 days Range: 70-445
Rao et al. 2007(163)	V.A.C.®	GranuFoam®	NR	NR	NR
Segers et al. 2007(354)	V.A.C.®	NR	NR	NR	Mean: 4.3 yrs, Range: 53-3,350 days
Senchenkov et al. 2007(355)	V.A.C.®	NR	Skin grafting	Debridement	NR
Shrestha et al. 2007(367)	V.A.C.®	NS	Percutaneous drainage of localized collections and regular change of dressings and antibiotics	NR	NR
Strecker et al. 2007(318)	V.A.C.®	NR	NR	radical debridement	23 ±13 months

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
van Rhee et al. 2007(368)	V.A.C.®	NR	NR	Surgical debridement, antibiotics	Avg: 25 months, Range: 9-42
Andrews et al. 2006(88)	V.A.C.®	PU foam	NR	Sharp debridement between dressings	NR
Cothren et al. 2006(356)	V.A.C.®	Large black sponges and white sponges "Covering bowel with multiple white sponges overlapped like patchwork, and the fascia is placed under moderate tension over the white sponges with number 1-polydioxanone sutures"	Subfascial 1010 Steri Drape (3M healthcare), blue towel, or laparotomy pad coverage, Jackson Pratt (Bard) drain placement and Ioben (3M) coverage for temporary closure	NR	NR
DeFranzo et al. 2006(156)	V.A.C.®	NR	NR	NR	28 had 2 yrs follow-up
Gorlitzer et al. 2006(369)	V.A.C.®	NR	NR	Mediastinal necrosectomy	NR
Heller et al. 2006(87)	V.A.C.®	PU and PVA foam	Saline soaked gauze dressings for 1-6 weeks	Debridement prior and during	At least 6
Labler et al. 2006(370)	V.A.C.®	PU foam	antibiotics, surgical interventions, implant removal / change	NR	14 patients Avg: 28.9, Range: 15-40
Leininger et al. 2006(111)	V.A.C.®	Sponge	NR	Debridement & operative irrigation, pulsatile lavage	All patients scheduled for f/u in outpatient clinic for 1-12 weeks after discharge

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Morgan et al. 2006(164)	V.A.C.®	NR	Total contact casting, regular casting, negative pressure therapy, enzymatic debridement, resection of infected bone/soft tissue, mechanical debridement, placement of various biological dressings	NR	Avg: 13, Range: 1-21
Pelham et al. 2006(371)	V.A.C.®	PU foam	NR	Irrigation and sharp surgical debridement; intravenous antibiotics	Mean: 24, Range: 14-32
Sartipy et al. 2006(151)	V.A.C.®	PU foam	NR	NR	NR
Wada et al. 2006(384)	V.A.C.®	NR	NR	NR	NR
Adamkova et al. 2005(152)	V.A.C.®	Black PU sponge	NR	Debridement	NR
Agarwal et al. 2005(372)	V.A.C.®	PU sponge	NR	Debridement, antibiotic	NR
Butter et al. 2005(144)	V.A.C.®	Black or white sponge	8 pilonidal sinus 24-48 hours wet to dry dressings	NR	Avg: 8
Caniano et al. 2005(165)	V.A.C.®	NR	NR	NR	Group 1: Avg: 13, Range: 8-36 Group 2, 3, 4: NR
Cowan et al. 2005(373)	V.A.C.®	PU foam	NR	Irrigation & debridement, antibiotics	NR
Labler et al. 2005(357)	V.A.C.®	PU foam	NR	NR	Range: 5-33
Lee et al. 2005(374)	V.A.C.®	PU sponge	Conventional methods	Debridement	Mean: 35, Range: 5-70

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Mendonca et al. 2005(375)	V.A.C.®	Open-cell foam	Surgically debrided and wound dressing, amputation, antibiotics	Debridement	Avg: 6.3, Range: 1-18
Rosenthal et al. 2005(89)	V.A.C.®	NR	NR	NR	Minimum: 5
Sjogren et al. 2005(179)	V.A.C.®	NR	NR	NR	Avg: 2.7 ±1.7 patient years, Range: 0-5.8 patient years
Stoeckel et al. 2005(358)	V.A.C.®	Foam	NR	NR	NR
Antony and Terrazas (2004(385)	V.A.C.®	PU foam	NR	Operative and non-operative debridement, pulse lavage irrigation, antimicrobials	NR
Bihariesingh et al. 2004(386)	V.A.C.®	Open-cell foam	Antibiotics and local wound management	Debridement	Mean: 514.8 days, Range: 246-693 days
Loree et al. 2004(387)	V.A.C.®	PU ether, open-cell foam	Multiple treatment modalities (not specified) and had been treated with at least 3 other modern materials used for debridement	Debridement, analgesia	NR
Mehbod et al. 2004(376)	V.A.C.®	NR	NR	Irrigation and debridement, antibiotic therapy	Avg: 10, Range: 6-24
O'Conner et al. 2004(377)	V.A.C.®	NR	NR	Sedation and analgesia with dressing changes	Avg: 7, Range: 3-21
Routledge et al. 2004(378)	V.A.C.®	PU foam and PVA foam	NR	Debridement and antibiotics	NR
Savolainen et al. 2004(359)	V.A.C.®	Polyvinyl foam	NR	Anesthesia	NR
Scholl et al. 2004(81)	V.A.C.®	PU foam	NR	NR	Mean: 14
Stone et al. 2004(90)	V.A.C.®	NR	NR	NR	NR

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Weed et al. 2004(37)	V.A.C.®	NR	NR	Debridement	NR
Demaria et al. 2003(145)	V.A.C.®	PU foam	Conventional therapies, polyvidone-iodine bandages, oral antimicrobial therapy	Surgical debridement, polyvidone-iodine applied & rinsed at dressing changes	NR
Gustafsson et al. 2003(146)	V.A.C.®	PU foam	NR	Antibiotics	Median: 13, Range: 3- 41
Herscovici et al. 2003(360)	V.A.C.®	PU ether sterile foam	NR	Surgical debridement	NR
Isago et al. 2003(91)	V.A.C.®	PU foam	NR	NR	NR
Molnar et al. 2003(388)	V.A.C.®	NR	NR	Integra incorporation (artificial skin substitute)	NR
Schimp et al. 2003(147)	V.A.C.®	Black PU foam or white PVA soft foam	NR	NR	Mean: 52 days, Range: 0-270 days
Stonerock et al. 2003(77)	V.A.C.®	PU foam	NR	NR	6
Suliburk et al. 2003(166)	V.A.C.®	PU sponge	NR	Washed out at each dressing	NR
Wongworawat et al. 2003(75)	V.A.C.®	PVA foam	NR	NR	NR
Armstrong et al. 2002(85)	V.A.C.®	NR	NR	Sharp debridement	NR
Clare et al. 2002(379)	V.A.C.®	Foam dressing	15 serial wound debridement, dressing changes, oral antibiotics 13 operative irrigation and debridement 6 revascularization procedures 5 had amputation	NR	NR

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Fleck et al. 2002(380)	V.A.C.®	PU foam	NR	Debridement, irrigation with 1 liter of dilute povidone-iodine solution (dressing changes), antibiotics	NR
Garner et al. 2001(86)	V.A.C.®	PU foam	NR	NR	NR
Gustafsson et al. 2001(381)	V.A.C.®	PU foam	NR	Antibiotics	At least 3 months
Hersh et al. 2001(94)	V.A.C.®	PU sponge	NR	Debridement	NR
DeFranzo et al. 2000(157)	V.A.C.®	Open-cell foam	NR	Debridement	Wounds have been stable from 6 months to 6 yrs
De Lange et al. 2000(167)	V.A.C.®	Open-cell PU foam	NR	Debridement, local or systemic anesthetic (lidocaine 1%)	Range: 2-35
Deva et al. 2000(382)	V.A.C.®	Foam	NR	NR	At least 3
Mooney et al. 2000(79)	V.A.C.®	NR	NR	Conscious sedation or brief general anesthesia for dressing changes	NR
Avery et al. 2000(92)	V.A.C.®	Opsite by Smith and Nephew	NR	NR	NR
Wu et al. 2000(158)	V.A.C.®	PU or PVA foam	NR	Debridement, non steroidal anti-inflammatory drugs or morphine	NR
Lang et al. 1999(159)	Vacuum sealing technique[1]	PVA	NR	Debridement	Avg: 13, Range: 3-35
Argenta and Morykwas 1997(148)	V.A.C.®	PU ether foam	Dressing changes, topical treatments, surgical procedures	Debridement	NR

Reference	Device	Dressing	Prior Treatments	Wound Preparation and Concurrent Treatments	Length of Follow-up (months)
Mullner et al. 1997(389)	V.A.C.®	PVA foam	Group A: wet to dry dressings Group B and C: irrigation, debridement & cultured, intravenous aminopenicillin and sulbactam 6.6 g per day for infected wounds or if cultures were positive, and wet to dry dressings	Group B: intravenous antibiotics	NR

Vacuum Assisted Closure (V.A.C.®) manufactured by KCI

[1] Manufacturer not specified

NR Not reported
PU Polyurethane
PVA Polyvinyl alcohol

Table 37. Outcomes Reported for All Wound Types

Reference	Duration of Treatment	Time to 50% Reduction of Initial Volume	Percent Change in Volume	Time to Complete Wound Closure	Percent of Wound Completely Healed	Healing of Infected Wounds	Reduction in Sepsis, Edema, or Amputation	Survival	Quality of Life/ Satisfaction with Treatment	Improved Wound Condition	Facilitation of Surgical Closure
Smith & Nephew Wound Management Unpublished Data(96)	X	X	X	X	X	X	X			X	
Baharestani et al. 2008(93)	X					X		X		X	X
Bannasch et al. 2008(344)	X				X		X			X	X
Bapat et al. 2008(153)	X					X				X	X
Brandi et al. 2008(345)	X										X
Campbell et al. 2008(84)	X	X	X		X					X	
Chen et al. 2008(160)	X				X	X		X		X	X
Dhir et al. 2008(346)					X						X
Ennker et al. 2008(361)	X										X
Fleck et al. 2008(362)	X			X				X		X	X
Gabriel et al. 2008(383)	X			X			X			X	X
Gdalevitch et al. 2008(154)	X										
Ha et al. 2008(140)	X				X	X		X		X	X

Reference	Duration of Treatment	Time to 50% Reduction of Initial Volume	Percent Change in Volume	Time to Complete Wound Closure	Percent of Wound Completely Healed	Healing of Infected Wounds	Reduction in Sepsis, Edema, or Amputation	Survival	Quality of Life/ Satisfaction with Treatment	Improved Wound Condition	Facilitation of Surgical Closure
Hamed et al. 2008(363)	X				X					X	
Horch et al. 2008(155)				X		X			X	X	X
Labanaris et al. 2008(364)	X						X				X
Lopez et al. 2008(365)	X			X				X		X	
Mokhtari et al. 2008(366)						X		X			X
Ploumis et al. 2008(80)	X			X	X	X				X	
Rhode et al. 2008(347)	X				X					X	X
Rozen et al. 2008(348)	X										X
Steiert et al. 2008(349)	X			X						X	X
Svensson et al. 2008(149)	X			X	X	X		X		X	X
Wondberg et al. 2008(161)	X			X			X		X	X	X
Baharestani et al. 2007(162)	X			X	X	X				X	X
Bendewald et al. 2007(82)	X			X	X					X	
Bendo et al. 2007(76)	X			X			X				
Bhattacharyya et al. 2007(350)				X		X				X	X

Reference	Duration of Treatment	Time to 50% Reduction of Initial Volume	Percent Change in Volume	Time to Complete Wound Closure	Percent of Wound Completely Healed	Healing of Infected Wounds	Reduction in Sepsis, Edema, or Amputation	Survival	Quality of Life/ Satisfaction with Treatment	Improved Wound Condition	Facilitation of Surgical Closure
Bollero et al. 2007(141)	X				X					X	X
Dedmond et al. 2007(27)	X			X	X	X				X	X
Ferron et al. 2007(83)	X			X	X	X	X	X	X	X	X
Helgeson et al. 2007(351)				X			X			X	X
Horn et al. 2007(78)	X			X		X				X	
Jones et al. 2007(150)	X										X
Kotsis and Lioupis 2007(73)	X				X		X				
Labler and Trentz 2007(352)	X					X				X	X
Machen 2007(74)					X	X	X			X	X
McCord et al. 2007(142)	X	X	X				X			X	X
Mendonca et al. 2007(143)	X	X	X		X	X			X	X	X
Peck et al. 2007(353)				X						X	X
Perez et al. 2007(95)	X							X	X	X	X
Rao et al. 2007(163)	X										
Segers et al. 2007(354)	X			X				X			
Senchenkov et al. 2007(355)	X			X	X					X	X

Reference	Duration of Treatment	Time to 50% Reduction of Initial Volume	Percent Change in Volume	Time to Complete Wound Closure	Percent of Wound Completely Healed	Healing of Infected Wounds	Reduction in Sepsis, Edema, or Amputation	Survival	Quality of Life/ Satisfaction with Treatment	Improved Wound Condition	Facilitation of Surgical Closure
Shrestha et al. 2007(367)	X				X	X				X	
Strecker et al. 2007(318)	X					X				X	X
van Rhee et al. 2007(368)				X		X				X	
Andrews et al. 2006(88)	X									X	X
Cothren et al. 2006(356)				X						X	
DeFranzo et al. 2006(156)	X			X	X	X		X		X	X
Gorlitzer et al. 2006(369)	X									X	X
Heller et al. 2006(87)	X						X			X	X
Labler et al. 2006(370)	X			X	X	X				X	X
Leininger et al. 2006(111)				X		X				X	X
Morgan et al. 2006(164)					X					X	X
Pelham et al. 2006(371)	X			X	X	X				X	X
Sartipy et al. 2006(151)	X							X			
Wada et al. 2006(384)	X			X						X	X
Adamkova et al. 2005(152)	X			X	X	X	X			X	X

Reference	Duration of Treatment	Time to 50% Reduction of Initial Volume	Percent Change in Volume	Time to Complete Wound Closure	Percent of Wound Completely Healed	Healing of Infected Wounds	Reduction in Sepsis, Edema, or Amputation	Survival	Quality of Life/ Satisfaction with Treatment	Improved Wound Condition	Facilitation of Surgical Closure
Agarwal et al. 2005(372)	X					X				X	X
Butter et al. 2005(144)	X			X	X					X	X
Caniano et al. 2005(165)	X				X					X	X
Cowan et al. 2005(373)	X	X	X	X		X	X	X		X	X
Labler et al. 2005(357)	X			X		X	X	X		X	X
Lee et al. 2005(374)	X			X	X	X				X	X
Mendonca et al. 2005(375)			X		X	X	X			X	X
Rosenthal et al. 2005(89)	X									X	X
Sjogren et al. 2005(179)								X			
Stoeckel et al. 2005(358)	X				X					X	X
Antony and Terrazas 2004(385)	X			X		X				X	
Bihariesingh et al. 2004(386)	X			X						X	X
Loree et al. 2004(387)	X		X							X	
Mehbod et al. 2004(376)	X			X						X	X
O'Conner et al. 2004(377)	X				X	X				X	X

Reference	Duration of Treatment	Time to 50% Reduction of Initial Volume	Percent Change in Volume	Time to Complete Wound Closure	Percent of Wound Completely Healed	Healing of Infected Wounds	Reduction in Sepsis, Edema, or Amputation	Survival	Quality of Life/ Satisfaction with Treatment	Improved Wound Condition	Facilitation of Surgical Closure
Routledge et al. 2004(378)	X				X	X				X	
Savolainen et al. 2004(359)	X				X	X				X	X
Scholl et al. 2004(81)	X			X	X	X				X	X
Stone et al. 2004(90)				X			X	X		X	X
Weed et al. 2004(37)	X				X	X				X	X
Demaria et al. 2003(145)	X				X	X				X	X
Gustafsson et al. 2003(146)	X										
Herscovici et al. 2003(360)	X										X
Isago et al. 2003(91)	X		X			X	X			X	X
Molnar et al. 2003(388)	X									X	X
Schimp et al. 2003(147)	X		X		X					X	X
Stonerock et al. 2003(77)	X			X			X			X	
Suliburk et al. 2003(166)	X			X						X	
Wongworawat et al. 2003(75)	X		X							X	
Armstrong et al. 2002(85)	X			X			X			X	

Reference	Duration of Treatment	Time to 50% Reduction of Initial Volume	Percent Change in Volume	Time to Complete Wound Closure	Percent of Wound Completely Healed	Healing of Infected Wounds	Reduction in Sepsis, Edema, or Amputation	Survival	Quality of Life/ Satisfaction with Treatment	Improved Wound Condition	Facilitation of Surgical Closure
Clare et al. 2002(379)	X				X					X	X
Fleck et al. 2002(380)	X				X	X		X		X	X
Garner et al. 2001(86)	X									X	
Gustafsson et al. 2001(381)	X			X		X				X	X
Hersh et al. 2001(94)	X					X		X		X	X
DeFranzo et al. 2000(157)						X	X			X	X
De Lange et al. 2000(167)	X				X	X	X			X	X
Deva et al. 2000(382)	X	X	X		X	X				X	X
Mooney et al. 2000(79)										X	X
Avery et al. 2000(92)	X									X	X
Wu et al. 2000(158)	X					X					X
Lang et al. 1999(159)	X			X	X	X				X	X
Argenta and Morykwas 1997(148)	X		X	X	X	X	X			X	X
Mullner et al. 1997(389)	X		X	X	X	X	X			X	X

Table 38. Adverse Events Reported for All Wound Types

Reference	Pain	Bleeding	Infection/ Bacterial Load	Mortality	Other Complications
Smith & Nephew Wound Management Unpublished Data(96)			X		
Baharestani et al. 2008(93)					
Bannasch et al. 2008(344)					
Bapat et al. 2008(153)			X	X	
Brandi et al. 2008(345)					
Campbell et al. 2008(84)					
Chen et al. 2008(160)					X
Dhir et al. 2008(346)					
Ennker et al. 2008(361)					
Fleck et al. 2008(362)					
Gabriel et al. 2008(383)					
Gdalevitch et al. 2008(154)			X		
Ha et al. 2008(140)	X				X
Hamed et al. 2008(363)					
Horch et al. 2008(155)			X		
Labanaris et al. 2008(364)					
Lopez et al. 2008(365)					
Mokhtari et al. 2008(366)					
Ploumis et al. 2008(80)					

Reference	Pain	Bleeding	Infection/ Bacterial Load	Mortality	Other Complications
Rhode et al. 2008(347)					
Rozen et al. 2008(348)					
Steiert et al. 2008(349)					
Svensson et al. 2008(149)		X	X	X	
Wondberg et al. 2008(161)					X
Baharestani et al. 2007(162)					X
Bendewald et al. 2007(82)					X
Bendo et al. 2007(76)					
Bhattacharyya et al. 2007(350)					
Bollero et al. 2007(141)	X				
Dedmond et al. 2007(27)					
Ferron et al. 2007(83)					
Helgeson et al. 2007(351)					
Horn et al. 2007(78)	X				
Jones et al. 2007(150)		X	X	X	
Kotsis and Lioupis 2007(73)					
Labler and Trentz 2007(352)					
Machen 2007(74)					
McCord et al. 2007(142)	X	X			X
Mendonca et al. 2007(143)	X				
Peck et al. 2007(353)					
Perez et al. 2007(95)					X

Reference	Pain	Bleeding	Infection/ Bacterial Load	Mortality	Other Complications
Rao et al. 2007(163)					X
Senchenkov et al. 2007(355)					
Segers et al. 2007(354)					
Shrestha et al. 2007(367)					
Strecker et al. 2007(318)					
van Rhee et al. 2007(368)					
Andrews et al. 2006(88)	X				
Cothren et al. 2006(356)					
DeFranzo et al. 2006(156)			X		
Gorlitzer et al. 2006(369)					
Heller et al. 2006(87)					X
Labler et al. 2006(370)					
Leininger et al. 2006(111)					
Morgan et al. 2006(164)					X
Pelham et al. 2006(371)					
Sartipy et al. 2006(151)		X		X	
Wada et al. 2006(384)					
Adamkova et al. 2005(152)		X			
Agarwal et al. 2005(372)					
Butter et al. 2005(144)	X				X
Caniano et al. 2005(165)					X

Reference	Pain	Bleeding	Infection/ Bacterial Load	Mortality	Other Complications
Cowan et al. 2005(373)					
Labler et al. 2005(357)					
Lee et al. 2005(374)					
Mendonca et al. 2005(375)					
Rosenthal et al. 2005(89)					
Sjogren et al. 2005(179)					
Stoeckel et al. 2005(358)					
Antony and Terrazas 2004(385)					
Bihariesingh et al. 2004(386)					
Loree et al. 2004(387)					
Mehbod et al. 2004(376)					
O'Conner et al. 2004(377)					
Routledge et al. 2004(378)					
Savolainen et al. 2004(359)					
Scholl et al. 2004(81)					
Stone et al. 2004(90)					X
Weed et al. 2004(37)			X		
Demaria et al. 2003(145)	X				
Gustafsson et al. 2003(146)	X				X
Herscovici et al. 2003(360)					
Isago et al. 2003(91)	X				

Reference	Pain	Bleeding	Infection/ Bacterial Load	Mortality	Other Complications
Molnar et al. 2003(388)					
Schimp et al. 2003(147)	X	X			
Stonerock et al. 2003(77)			X		
Suliburk et al. 2003(166)					X
Wongworawat et al. 2003(75)					
Armstrong et al. 2002(85)			X		X
Clare et al. 2002(379)					
Fleck et al. 2002(380)					
Garner et al. 2001(86)			X		
Gustafsson et al. 2001(381)					
Hersh et al. 2001(94)					
DeFranzo et al. 2000(157)			X		
De Lange et al. 2000(167)					X
Deva et al. 2000(382)					
Mooney et al. 2000(79)		X			
Avery et al. 2000(92)					
Wu et al. 2000(158)			X		
Lang et al. 1999(159)			X		
Argenta and Morykwas 1997(148)	X		X		X
Mullner et al. 1997(389)					

Systematic Reviews of NPWT Devices

Table 39. Characteristics of Systematic Reviews of NPWT Devices—High Quality Reviews

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Gregor et al. 2008(173) *Negative Pressure Wound Therapy* *A Vacuum of Evidence?*	To systematically examine the clinical effectiveness and safety of NPWT compared with conventional wound therapy	Searches were completed in MEDLINE, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials. Systematic reviews were identified by searching the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, and the HTA Database thru October 2005. The U.S. F.D.A., other health agencies, clinical experts, and 2 manufacturers were asked to provide clinical data.	Included RCTs and non-RCTs if they had a concurrent control group and evaluated the effect of NPWT versus conventional wound therapy on wound healing. All languages were included. Abstracts were excluded if 2 investigators classified them as not relevant or if not available as full-text articles.	Studies: 7 RCTs 10 non-RCTs Comparators: • Standard of care • Healthpoint System • Bolster dressing • OpSite N = 602 Wounds = 667 Quality Assessment: IQWIG Steering Committee Methods (2006)	Patients with the following wound types: • diabetic foot amputations • chronic diabetic wounds • pressure ulcers • chronic wounds • skin grafts • open wounds/ abdomen • infected sternotomy • acute burns	Included: • incidence of complete wound closure • time to wound closure	Authors reported benefit to patients treated with NPWT for surrogate variables of wound healing. Firstly, a significant advantage in favor of NPWT was reported in 4 of 7 studies reporting wound closure. Secondly, pooled data from 6 studies showed a significant reduction in wound size in favor of NPWT. In addition, 1 large RCT (Armstrong) reported a significantly faster rate of generation of granulation tissue in patients treated with NPWT. Despite these favorable results, overall evidence was insufficient to clearly prove an additional clinical benefit of NPWT.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Ubbink et al. 2008*(174) *Topical negative pressure for treating chronic wounds*	To assess the effects of NPWT on chronic wound healing	Studies were identified by searching Cochrane Wounds Group Specialised Register (searched 12/17/07), the Cochrane Central Register of Controlled Trials, Ovid MEDLINE (1950 to November 2007), Ovid EMBASE (1982 to 2007), and Ovid CINAHL (1980 to December 2007) databases. Reference lists of identified studies were searched as well as offer to Kinetic Concepts to submit unpublished or ongoing trials.	All RCTs evaluating the effects of NPWT on patients with chronic wounds and reporting at least one of the following outcomes: • time to complete healing • rate of change in wound area and/or volume • proportion of wounds completely healed • time to surgical readiness • survival rate (risk of graft failure) of split-thickness skin grafts	Studies: 7 RCTs Comparators: • soaked gauze in either 0.9% saline or Ringer's solution (k = 4) • hydrocolloid gel plus gauze (k = 1) • papain-urea topical (k = 1) • cadexomer iodine or hydrocolloid, hydrogels, alginate and foam (k = 1) N = 205 Quality Assessment: Based on the Dutch Cochrane Collaboration checklist	Patients with the following wound types: • non-healing ulcers • diabetic foot ulcers • wound management before surgical closure • pressure ulcers • soft tissue defects • full-thickness pressure ulcers • chronic ulcers	Outcomes included: • Time to complete healing • Change in wound surface area or volume • Time to surgical readiness	Authors conclude no significant benefit was shown in the treatment of chronic wounds with NPWT when compared to moistened gauze dressings or other topical agents. The methodological quality of the studies was rated poor due to small study populations, unclear allocation methods, lack in blinding of outcome assessors, and short duration of follow-up. The authors recommend upcoming trials should focus on more patient relevant outcomes such as time to complete wound healing; use validated measures when documenting QOL, pain, or comfort; and include longer term follow-up.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Wasiak and Cleland 2007(172) *Topical negative pressure (TNP) for partial thickness burns*	To assess the effectiveness of NPWT for those people with partial thickness burns	The Cochrane Wounds Group Specialised Register, the Cochrane Central Register of Controlled Trials, Ovid MEDLINE (1950 to April 2007), Ovid EMBASE (1980 to Week 18 2007) and Ovid CINAHL (1982 to April 2007); and hand searches of retrieved studies were undertaken for identifiable studies. Contact was made with authors of relevant studies to submit details of unpublished or ongoing investigations.	All RCTs and controlled clinical trials involving adults aged 18 years or older with partial thickness burns and evaluating the effectiveness of topical negative pressure (NPWT) were included.	Study: 1 RCT Comparator: Silver sulphadiazine (SSD) N = 20 Quality Assessment: based on the method outlined by Schultz (1995)	Patients aged 20-70 years with total burn surface areas ranging from 5-401% with bilateral thermal hand burns treated less than 24 hours.	Rate of change in wound area and treatment complications	Preliminary data from one study of 20 patients (serving as their own controls). Patients were randomized to receive either a 48 hour treatment of NPWT or silver sulphadiazine. A significant difference in burn size at days 3 and day 5 was reported however no difference was reported at day 14 for NPWT treatment. Methods of randomization and allocation concealment, as well as absence of reporting on clinically relevant outcomes were noted as study shortcomings. The Molnar study was reported as methodologically poor however this assessment was limited to the available text in the abstract.

HTA Health technology assessment

* Reports contain duplicate studies however one report focuses on chronic wounds(174) and excludes 5 studies.

Table 39a. Characteristics of Systematic Reviews of NPWT Devices—Moderate Quality Reviews

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Schimmer et al. 2008(175) *Management of post-sternotomy mediastinitis: experience and results of different therapy modalities*	To provide an overview of current literature referring to the primary treatment of post-sternotomy mediastinitis, and to outline the treatment options used in all 79 German heart centers	A systematic search of the MEDLINE database from years 2000-2006 for text written in English or German. A questionnaire distributed from November 2006 to January 2007 to 79 German heart centers.	Articles including "treatment of deep sternal wound infection" and "post-sternotomy mediastinitis" and including an overview of V.A.C.® therapy or referring to both V.A.C.® therapy and primary closure with suction/irrigation systems.	Studies: 2 retrospective 8 non-randomized comparisons Comparators • primary closure with suction/ irrigation systems • removal of the sternum and a thoracic closure by means of plastic reconstruction (k = 1) N = 611 Quality Assessment: NR	Patients with post-sternotomy mediastinitis (PM)	1. mortality 2. recurrence rate 3. overall survival 4. quality of life (QOL) 5. hospital stay 6. treatment failure 7. infection	This review included 2 retrospective studies evaluating V.A.C.® therapy and 8 non-randomized comparisons evaluating use of V.A.C.® and primary sternal closure, with a closed mediastinal catheter suction/irrigation system. Benefits to treatment with V.A.C.® included less treatment failure, shorter postoperative stay, lower rates of recurring infection, improved QOL, and increase in overall survival. Study flaws mentioned include the lack of differentiation of patients according to PM types, small study populations, and the lack of randomized trials.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Ubbink et al. 2008*(183) *A systematic review of topical negative pressure therapy for acute and chronic wounds*	To summarize up-to-date, high-level evidence on the effectiveness of NPWT on wound healing, in both acute and chronic settings	A search of the following databases: CINAHL, EMBASE and MEDLINE to June 2007 and the Cochrane controlled trials register to issue 4, 2007. One manufacturer, (Kinetic Concepts, Inc.) was contacted to submit unpublished articles.	RCTs evaluating the use and effectiveness of NPWT in patients aged 18 years and over with wounds with various etiologies. Included trials assessed wound healing as primary endpoint; also assessed change in wound surface area, proportion of wounds healed within the trial period, survival rate of split-thickness skin grafts or wound condition ready for surgery or skin grafting. Secondary endpoints were infection, pain, quality of life, edema, microcirculation, bacterial load, adverse events and duration of hospital stay.	Studies: 13 RCTs Comparators: • soaked gauze in either 0.9% saline or Ringer's solution • hydrocolloid gel plus gauze • papain-urea topical • cadexomer iodine or hydrocolloid, hydrogels, alginate and foam • Compression dressing • Bolster dressing N = 554 patients (573 wounds) Quality Assessment: Based on the Dutch Cochrane Collaboration checklist	Patients with the following wound types: • Chronic (venous, arterial, diabetic or pressure • Acute including split skin grafts	See inclusion criteria.	In this review, Ubbink and co-investigators evaluated the use of NPWT in the treatment of chronic and acute wounds. The authors conclude that there is "no worthwhile evidence to support the use of NPWT in the treatment of various wounds."

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
van den Boogaard et al. 2008(107) *The effectiveness of topical negative pressure in the treatment of pressure ulcers: a literature review*	To gain insight into the effectiveness of NPWT in the treatment of pressure ulcers	A systematic search of MEDLINE, EMBASE, and CINAHL databases was undertaken. There were no language or publication restrictions.	Randomized controlled clinical studies evaluating the effect of topical negative pressure (TNP) compared to a control intervention in patients with pressure ulcers were included. Key inclusion criteria also included: (a) a group of examined patients consists entirely or partly of patients with pressure ulcers; (b) the outcome measurement is in any case wound healing in terms of volume and or surface reduction or increase in granulation tissue; (c) the control intervention has been described.	Studies: 5 RCTs Comparators: • Healthpoint System (k = 1) • standard of care (k = 3) • various dressings (k = 1) N = 193 Quality Assessment: Dutch Cochrane quality criteria for RCTs	Patients with pressure ulcers	Outcomes included: • wound volume • wound healing • granulation tissue formation • wound surface • cost	2 RCTs only including patients with pressure sores found no significant differences for wound healing. Remaining 3 studies examining wounds with different etiologies found significant differences in wound healing specifically in the decrease of wound treatment time. Study authors conclude that topical negative pressure wound therapy has not proven to be more effective than various control interventions.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Vikatmaa et al. 2008(178) *Negative Pressure Wound Therapy: a Systematic Review on Effectiveness and Safety*	To review the use of NPWT for problematic wounds	Literature searches of MEDLINE, MEDLINE in-progress, PubMed and Cochrane Controlled Trials Register from 1996. Cochrane Database of Systematic Reviews, Database of Abstracts of Review of Effectiveness, NHS Economic Evaluation Database, and Health Technology Assessment Database; Cliniclaltrials.gov, National Research Register and meta Register; Aggressive Research Intelligence Facility and manufacturers Web sites were also searched. Searches undertaken in July 2006 and updated in January 2008.	RCT in which NPWT was compared with any other local wound therapy for any wound indication were included.	Studies: 14 RCTs Comparators: • Healthpoint System • Gauze soaked with Ringer's • standard of care • hydrocolloids, foams or hydrogels, alginates • pressure dressing • Mepitel ® silicone-dressing Quality Assessment: Method according to Samson et al.(182)	Patients with the following wound types: • pressure • post-traumatic • DFU • chronic	Primary outcomes included: • total healing • time to halve the wound volume • time to reach minimal incision drainage • area of skin graft loss • 100% reepithelialization before 112 days • wound volume decrease • definitive closure • wound healing time	NPWT appears to be a safe alternative treatment and is at least as good as or better than current local treatment for wounds. The effectiveness of NPWT is clearly warranted in the treatment of chronic leg ulcers and post-traumatic ulcers. A majority of the studies were classified as having poor internal validity.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Costa et al. 2005 (modified 2007)(181) *Vacuum-assisted wound closure therapy (V.A.C.®)* McGill University Health Centre (MUHC) Technology Assessment Unit (TAU)		Articles published through March 27, 2005 in PubMed, EMBASE, Cochrane Database of Systematic Reviews, and CHSPR, ICES, MCHP, and INAHTA databases published in English/French. Hand searches of reference lists of clinical studies, systematic reviews, and technology assessment reports were also undertaken.	Comparative clinical and economic studies, or systematic reviews	Studies: 4 RCTs 2 non-randomized prospective 1 cross-over with subjects receiving a randomly selected alternate 2 week treatment 1 trial in which different halves of wounds received V.A.C.® and moist dressing treatment 5 retrospective reviews 1 systematic review (N not reported) Comparators: • Standard of care • OpSite Total study population reported by: Patients = 312 Wounds = 96 Quality Assessment: NR	Patients aged 4-81 years with the following wound types: • decubitus ulcers • diabetic foot • skin graft • pressure sores • lawnmower injuries • post-sternotomy osteomyelitis • sternal • post-sternotomy mediastinitis	Included: • wound area • wound volume/ depth • complete healing • graft appearance • time to surgery • hospital stay • % graft take • N requiring free flap • treatment duration • treatment failure	Authors conclude there is insufficient evidence to recommend the routine use of V.A.C.® therapy. Study results are inconsistent although the more credible evidence suggested no benefit from V.A.C.® therapy. Additional study weaknesses include small and possible heterogeneity of patient populations, inadequate reporting of baseline wound dimensions, and high attrition rates.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Kanakaris et al. 2007(25) *The efficacy of negative pressure wound therapy in the management of lower extremity trauma: Review of clinical evidence*	To present the existing clinical evidence on the usefulness of NPWT in the acute setting of lower limb trauma	A search was undertaken of MEDLINE and OVID through 1/08/07.	Studies evaluating NPWT in the acute phase (1st week) of lower limb trauma were included. Studies including less than 6 patients; studies in non-English languages; and manuscripts that evaluated clinical applications in different clinical conditions were excluded.	Studies: Acute lower limb trauma • 1 RCT • 1 prospective comparative • 1 retrospective comparative • 8 case series • Burn wounds • 1 RCT • 2 non-randomized controlled trials • 2 case series Comparators: • SSD • Standard of care N = 430 Quality Assessment: NR	Patients with acute lower limb trauma and burn wounds	Outcomes included: • Time to closure • Complications • Hospitalization stay	Based on evidence from a limited number of controlled trials, authors recommend the use of NPWT in the acute phase of blunt, penetrating and thermal trauma of the extremities.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Vlayen et al. 2007(180) Vacuumgeassisteerde Wondbehandeling: een Rapid Assessment	To provide a clear synthesis of the evidence on the clinical effectiveness, safety and cost-effectiveness of NPWT	HTA database, Cochrane Library [OVID], MEDLINE [OVID], Pre-MEDLINE [OVID], EMBASE [Embase.com], CINAHL [OVID], and British Nursing Index [OVID] were searched. Grey literature was accessed via Google and with contact by suppliers and manufacturers.	HTA, systematic reviews, meta-analysis, and RCTs; use of subatmospheric pressure for the treatment of acute or chronic wounds; major outcomes of interest: wound closure, adverse events, and health-related quality of life were included. Excluded were narrative reviews, letters, commentaries, case series, case studies; articles on primary closed wound drainage, the sandwich-vacuum pack technique, etc. and target conditions other than mentioned above.	Studies: • 7 HTAs • 15 RCTs • 5 SRs Comparators: • Modified NPWT system • Healthpoint System • Gauze (saline or Ringers) • Bolster dressing • Conventional grafting • Standard of care N = 726 Quality Assessment: INAHTA checklist to assess HTA reports and Dutch Cochrane Centre checklist for SRs and RCTs	Patients with the following wound types: • traumatic • DFU • pressure ulcers • skin grafts • complex and traumatic • other	Outcomes included • time to complete healing • time to recurrence • % graft loss • change in amount of wound surface • total nursing time • complete wound closure • second amputation • surgical readiness	Previously identified HTA and SR authors reported that the evidence to-date did not justify widespread use of NPWT. The study authors concluded that the newly available evidence did not allow them to make a clear statement about the clinical efficacy and safety of NPWT. RCT study flaws included low methodological quality and small patient populations. Of the 15 RCTs reviewed, only 2 were found to be of moderate quality while none were considered to be of good quality. With the exception of one study (Armstrong, n = 162), study populations ranged from 10 to 65 patients.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Ontario Health Technology Advisory Committee (OHTAC) 2006(184) *Negative Pressure Wound Therapy: Update*	To update a 2004 report from the Medical Advisory Secretariat's (MAS) which concluded that no additional funding be provided for V.A.C.® therapy	MEDLINE, EMBASE, MEDLINE In-Process and Non-Indexed Citations, INAHTA, Cochrane Database of Systematic Reviews, and a vacuum therapy Web Site (http://www.vacuumtherapo.co.uk/index.htm) were searched.	Peer-reviewed, published RCTs with sample size of 20 or more patients involved in a human study analyzing negative pressure wound therapy were included. Non-randomized trials were excluded.	Studies: 6 RCTs Comparators: • standard of care (k = 3) • Healthpoint System (k = 1) • Saline gauze (k = 1) • Bolster dressing (k = 1) N = 346 Quality Assessment: Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria	Patients with mean age ranging between 42 and 64 years with the following wound types: • surgical wounds after amputation (k = 1) • non-healing wounds (k = 2) • decubitus ulcers (k = 2) • pressure sores (k = 1)	Outcomes included: • wound area • wound volume • complete wound closure	This report's recommendation was based on 1 highly rated RCT due to the "low" or "very low" quality rating of the remaining 5 RCTs. Armstrong & Lavery, a 16 week multicentre study, included 162 patients who had acute, surgical wounds from partial foot amputations and were randomized to NPWT or standard care. In addition some underwent surgical wound closure. OHTAC concludes there was not a statistically significant difference between NPWT and standard care in the rate of complete wound closure in patients who had complete wound closure but did not undergo surgical wound closure. It was not possible to discuss whether or not NPWT decreased the time to complete wound closure due to the lack of reporting on this outcome for patients who did not undergo surgical wound closure.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Pham et al. 2006(176) *The safety and efficacy of topical negative pressure in non-healing wounds: a systematic review*	To compare the efficacy and safety outcomes of NPWT with those of conventional methods in treating particular wound types	MEDLINE, PreMEDLINE, EMBASE, Current Contents, PubMed and Cochrane Library were searched for articles published until October 2004. The York (UK) Centre for Reviews and Dissemination databases, clinicaltrials.gov, National Research Register, Grey Literature Reports, relevant online journals and Internet were searched in October 2004. Searches were again performed in July 2005 for new RCTs.	Articles were chosen if the abstract included safety and efficacy data in the form of RCTs, other controlled or comparatives studies, or case series with consecutive patients; and if wound type was stated. If relevant safety and efficacy data was present then conference abstracts, manufacturers information, and English abstracts from foreign-language articles was also included.	Studies: • 2 SRs • 10 RCTs • 4 non-randomized comparative • 7 case series Comparators: • Gauze • Healthpoint System • Bolster dressings • Compression dressings • OpSite dressing • Conventional dressings Quality Assessment: NR	Patients with the following wound types: • DFUs • Skin grafts • Pressure ulcers • Sternal wounds • Chronic wounds and complex/ severe wounds	Outcomes included: • Wound size • Rate of epithelialization • Required repeat split-thickness grafts • Time to reach surgical readiness • Median hospital stay • Treatment duration	Some studies demonstrated a benefit to treatment by NPWT, although a majority of studies were probably too small to detect significant differences. Both foot ulcers and chronic and complex wounds treated with NPWT demonstrated significantly greater reduction in wound volume, depth and treatment duration compared to those managed with saline-moistened gauze and wet-to-moist treatment, respectively. NPWT appears to be more effective than absorbent film-backed dressing and bolster dressings in skin-graft management. Authors conclude that NPWT appears to be a promising alternative for the management of various wounds.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Gray & Peirce 2004(177) *Is Negative Pressure Wound Therapy Effective for the Management of Chronic Wounds?*	To respond to the following questions: 1. Does NPWT improve healing of chronic wounds when compared to topical treatments? 2. Does NPWT improve skin graft survival when compared to other topical treatments? 3. What adverse side effects have been associated with the use of NPWT?	Searches were undertaken of the MEDLINE and CINAHL databases from January 1966 to January 2004; and OVID databases search service including ACP Journal Club, Cochrane Database of Systematic Review, Cochrane Central Register of Controlled Trials and Database of Abstracts of Reviews of Effects.	Articles reporting original research, English-language abstracts and review articles or chapters from key references in the wound, ostomy, and continence (WOC) nursing literature were included. Research used to judge efficacy was limited to systematic literature reviews, results of experimental (RCTs), and quasi-experimental studies. Results from individual case studies and clinical series (summaries of experience based on multiple case studies) were included to address Question 3 (safety).	Studies: 2 systematic reviews including 2 RCTs 3 non-randomized comparison 1 interim analysis and 3 quasi-experimental Comparators: • saline (gauze or Ringer's) (k = 3) • Healthpoint System (k = 1) • conventional (k = 1) • gel and gauze (k = 1) • silver sulfadine or mafenide acetate and gauze (k = 1) • OpSite dressing (k = 1) • bolster dressing (k = 1) N = 279 Quality Assessment: NR	Patients with the following wound types: • pressure • wound dehiscence • venous insufficiency • radiation • trauma • diabetic foot wounds • sternal • burn	Outcomes included: • healing time • change in wound dimensions • duration of treatment • time to suture removal	Key questions addressing the benefit of NPWT compared to other topical treatments and the adverse side effects associated with the treatment were included in this review. The authors concluded that NPWT may be superior to saline-moistened gauze in the treatment of chronic wounds. In addition, superiority of NPWT was determined in the treatment of soft-tissue flaps and skin grafts when compared to topical antimicrobial agents and gauze. Authors were unable to determine whether NPWT is superior to advanced dressings in the treatment of pressure ulcers and diabetic foot ulcers. The study also confirms previous reports that adverse events with NPWT are uncommon.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Samson et al. 2004(182) *Wound-Healing Technologies: Low-Level Laser and Vacuum-Assisted Closure* Prepared for the Agency for Healthcare Research and Quality	To systematically review evidence on low-level laser and V.A.C.® on wound healing outcomes	Searches were completed of MEDLINE, EMBASE, and the Cochrane Controlled Trials Register. Kinetic Concepts Inc., manufacturer of V.A.C. ® was invited to submit clinical data.	Only RCTs of vacuum-assisted closure compared to other wound healing interventions or with sham intervention. Trials must report on one of the outcomes of interest.	Studies: 6 RCTs Comparators: • Standard of care dressings (k = 5) • Healthpoint System (k = 1) N = 148 Quality Assessment: U.S. Preventive Services Task Force	Patients with mean ages ranging from 41.7 to 56 with the following wound types: • Full-thickness wounds • Pressure ulcers • Non-healing wounds • DFUs	Primary outcomes included: • incidence of complete wound closure • time to complete closure • adverse events Secondary outcomes included: • need for debridement • infections • pain • quality of life	Only 6 RCTs qualified for inclusion in this review; five studies included fewer than 25 patients. All studies were of poor quality with only one study having a clearly stated randomization method. Study authors concluded that V.A.C.® trials did not find a significant advantage for intervention on primary endpoint, complete healing and did not consistently find significant differences on secondary endpoints.

DFU Diabetic foot ulcer
HTA Health technology assessment
NR Not reported
SR Systematic review

* Reports contain duplicate studies however one report focuses on chronic wounds(174) and excludes 5 studies.

Table 39b. Characteristics of Systematic Reviews of NPWT Devices—Low Quality Reviews

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Contractor et al. 2008(185) *Negative Pressure Wound Therapy With Reticulated Open Cell Foam in Children: An Overview*	To discuss the versatility of NPWT/ROCF in exclusively pediatric patients with infected wounds	NR	Articles discussing NPWT with reticulated open cell foam (NPWT/ROCF) exclusively in pediatric patients were included.	Studies: • 9 retrospective reviews • 11 case studies Comparators: N/A Quality Assessment: NR	Children ranging in age from neonates to young adults with the following wound types: • Open fracture • Traumatic soft tissue • Chronic extremity wound • Pressure ulcer • Pilonidal disease • Sternal • Spine fusion • Fistula • Burns	Outcomes included: • Frequency of change • Pain • Complications • Time for wound closure • Recurrence • Infection	This review focused on the unique challenges facing the use of NPWT in pediatric patients with infected wounds. The evaluation of single case studies revealed V.A.C.® as a safe alternative to traditional methods in treating axial, chronic extremity wounds and complex lawnmower injuries. Additional benefits included a reduction in infection rates in tibial shaft fractures and spinal fusions. RCTs are necessary to determine consensus on foam (white or black) selection, optimum amount of negative pressure, frequency of NPWT/ROCF dressing changes, and interposing contact layer selection.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Schintler and Prandl 2008(170) *Vacuum-assisted closure – what is evidence based?*	NR	Articles were identified by search of PubMed and MEDLINE	Included experimental animal studies, RCTs, observations of clinical applications and case reports	Studies: • 7 RCTs • 3 SRs • 2 retrospective reviews • 1 cost-effective analysis • 1 consensus study Comparators: • standard of care • saline gauze • gel products N = 445 (RCTs) Quality Assessment: NR	Patients with the following wound types: • chronic leg ulcers • acute and chronic • post-amputation stumps • chronic non-healing • DFU	• Wound dimensions • Time to surgery • rate of granulation tissue formation • # of wounds healed • Need for further surgery	A majority of this review focused on the mechanisms of action of vacuum therapy (VT). The investigators concluded that VT, when used by experienced surgeons, is an excellent option to support wound healing.
Raja and Berg 2007(186) *Should vacuum-assisted closure therapy be routinely used for management of deep sternal wound infection after cardiac surgery?*	To address the question whether V.A.C.® should be routinely used for management of deep sternal wound infection after cardiac surgery	MEDLINE 1996 to November 2006 using OVID interface, EMBASE 1980 to 2006 Week 52	NR	Studies: • 7 retrospective analysis • 2 reviews • 4 case series Comparators: • Standard of care • V.A.C.® plus myocutaneous flap or primary wound closure Quality Assessment: NR	Patients with deep sternal wounds	Outcomes included: • In-hospital stay • Rewiring • Survival	Current evidence is weak to support the routine use of V.A.C.® for management of deep sternal wound infection after cardiac surgery.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Mendonca et al. 2006(187) *Negative-pressure wound therapy: a snapshot of the evidence*	To provide an overview of clinical studies using NPWT and propose avenues for further research to elucidate the exact mechanism of NPWT	MEDLINE, PubMed and Cochrane databases were searched from 1995-2006.	NR	Studies: • 1 SR • 5 RCTs • 10 case series • 5 basic science Comparators: • Saline gauze • Standard of care Quality Assessment: NR	Patients with the following wound types: • Acute and chronic • Traumatic wounds • Sternal, spinal and lower limb • High-energy • Pressure ulcers • DFUs • Infected wounds	Outcomes included: • Rate of wound healing • Wound volume • Need for further surgery • Readmission rate • Complication rate	Key points stated by the authors include benefits and complications to treatment by NPWT, role for future research, cost savings and clinical effectiveness. Due to the mixed results in the few RCTs examined, authors cannot confirm a clear clinical effectiveness of TNP. The benefits to treatment, however, include a decrease in time to healing and limb salvage for DFUs; an aid in the healing of skin grafts; and a valuable adjunct to conventional treatment of sternal wound infection.
Gupta & Cho 2004(188) *A Literature Review of Negative Pressure Wound Therapy*	To assess existing published data supporting the use of NPWT in multiple clinical situations	A search of the MEDLINE database and a hand search of bibliographies were conducted. Authors also asked clinicians who may be considered experts in wound reconstruction and wound care to submit references.	Retrospective case studies, individual case reports, published letters/comments, animal studies and prospective trials were included.	NR Quality Assessment: rating system developed by study authors	Patients with the following wound types: • sternal wounds • skin grafts • pressure sores • abdominal wall/laparotomy • enterocutaneous fistulae • diabetic wounds • lower extremity wounds/trauma	NR	Authors conclude that the clinical outcomes demonstrate significance in all of the comparative studies with overall outcome data supporting its effectiveness.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Fisher and Brady 2003(168) *Vacuum assisted wound closure therapy* The Canadian Coordinating Office for Health Technology Assessment (CCOHTA)	NR	NR	NR	Studies: 4 randomized controlled trials (RCTs) 1 interim analysis Comparators: • saline gauze (k = 2) • OpSite (k = 1) • conventional treatment (k = 1) • Healthpoint System (k = 1) N = 145 Quality Assessment: NR	Patients with the following wound types: • post-operative diabetic foot • requiring skin grafts • elective surgery patients – postoperative ventral hernia repair • pressure ulcers (interim analysis)	Included: • Changes in wound volume/depth • Duration of treatment • Length of hospital stay • Time to suture removal	Outcomes from four small RCTs and 1 interim analysis treated with vacuum assisted closure (V.A.C.®) therapy include a statistically significant positive impact on healing rate, faster healing and a greater reduction in wound surface area. Due to study flaws including short-term follow-up, questionable methods of randomization and allocation concealment, the authors conclude that the studies provide only poor quality data and weak evidence that V.A.C.® therapy may be superior to conventional methods used in healing wounds.

Citation	Objective	Search Strategy	Key Inclusion/ Exclusion Criteria	Evidence Base/ Method of Assessing Study Quality	Participant Characteristics	Outcomes Assessed	Results and/or Authors' Conclusions
Higgins 2003(169) *The effectiveness of vacuum assisted closure (V.A.C.®) in wound healing* Clayton, Australia, Centre for Clinical Effectiveness (CCE)	To assess the effectiveness of V.A.C.® in terms of healing time and wound closure compared to passive wound therapy	The Cochrane Library; Ovid Biological Abstracts, MEDLINE, EBM Reviews, CINAHL, and PreMEDLINE; Australasian Medical Index; National Guidance Clearinghouse; Scottish Intercollegiate Guideline Network and Web site "www.vacuumtherapy.co.uk/index.htm" were all searched through August 2003.	Studies comparing vacuum assisted closure with any other form of dressing in patients with acute and chronic wounds were included. Level III and IV Evidence, studies published in non-English language, presenting data published in another report and narrative reviews were excluded.	Studies: 1 Systematic review including 2 RCTs 1 RCT 1 interim analysis Comparators: • saline gauze (k = 2) • wet-to-dry/ wet-to-wet dressings (gauze soaked with Ringers solution) (k =1) • Healthpoint System (k = 1) N = 78 Quality Assessment: based on NHMRC guidelines (2000)	Patients with the following wound types: • pressure sores (paraplegic or tetraplegic patients) • chronic wounds • diabetic foot ulcers • ischial, sacral, malleolar, trochanteric and calcaneal	Outcomes included: • Time for wound size to reduce to 50% of the initial volume • Time to complete healing • Rate of change in wound area • Wound volume • Proportion of wounds completely healed within trial period	In this update to the Evans and Land (2003) systematic review, investigators confirm previous findings that V.A.C.®, when compared to other wound therapies, may provide an additional treatment benefit to patients. The methodological limitations and small study size of the four included studies, however, limits the validity of any study conclusions.

DFU Diabetic foot ulcer
NR Not reported
SR Systematic review

Table 40. Study Inclusion in Systematic Reviews

Reference	Contractor 2008(185)***	Costa 2005(181)	Fisher 2003(CCOHTA)(168)	Gray 2004(177)	Gregor 2008(173)	Gupta 2004(188)*	Higgins 2003(169)	Kanakaris 2007(25)**	Mendonca 2006(187)**	Noble-Bell and Forbes 2008(70)	OHTAC 2006(184)	Pham 2006(176)**	Raga and Berg 2007(186)**	Samson 2004(182)	Schimmer 2008(175)	Schintler and Prandl 2008(170)	Ubbink 2008(174)	Ubbink 2008(183)	van den Boogaard 2008(107)	Vikatmaa 2008(178)	Vlayen et al. 2007(180)	Wasiak 2007(172)
Argenta 1997									X							X						
Armstrong 2005					X					X	X					X		X		X	X	
ASERNIP 2003																					X	
Augustin 2007																X						
Avalia-T 2005																					X	
Berg 2000															X							
Braakenburg 2006																X		X	X	X	X	
Catarino 2000		X										X			X							
Costa 2005																						
Cowan 2005															X							
Davydov 1994			X	X								X										
Domkowski 2003															X							
Doss 2002		X			X							X										
Eginton 2003		X		X	X					X		X		X		X	X	X		X	X	
Etoz 2004					X					X								X		X	X	
Evans 2006																						

Reference	Contractor 2008(185)***	Costa 2005(181)	Fisher 2003(CCOHTA)(168)	Gray 2004(177)	Gregor 2008(173)	Gupta 2004(188)*	Higgins 2003(169)	Kanakaris 2007(25)**	Mendonca 2006(187)**	Noble-Bell and Forbes 2008(70)	OHTAC 2006(184)	Pham 2006(176)**	Raga and Berg 2007(186)**	Samson 2004(182)	Schimmer 2008(175)	Schintler and Prandl 2008(170)	Ubbink 2008(174)	Ubbink 2008(183)	van den Boogaard 2008(107)	Vikatmaa 2008(178)	Vlayen et al. 2007(180)	Wasiak 2007(172)
Evans 2001		X																				
Fleck 2002															X							
Ford 2002		X	X	X	X		X				X	X		X		X	X	X	X	X	X	
Fuchs 2005															X							
Genecov 1998		X	X	X	X							X									X	
Greer 1999												X										
Gupta 2004																						
Gustafsson 2002															X							
Heath 2002												X										
Higgins 2003 (CCE)																					X	
IQWiG 2006																						
Jeschke 2004												X						X			X	
Joseph 2000		X	X	X			X		X		X	X		X		X	X	X	X	X	X	
Kamotz 2004					X																	
Llanos 2006																		X		X	X	
Loree 2004									X													
Luckraz 2003															X							

Reference	Contractor 2008(185)***	Costa 2005(181)	Fisher 2003(CCOHTA)(168)	Gray 2004(177)	Gregor 2008(173)	Gupta 2004(188)*	Higgins 2003(169)	Kanakaris 2007(25)**	Mendonca 2006(187)**	Noble-Bell and Forbes 2008(70)	OHTAC 2006(184)	Pham 2006(176)**	Raga and Berg 2007(186)**	Samson 2004(182)	Schimmer 2008(175)	Schintler and Prandl 2008(170)	Ubbink 2008(174)	Ubbink 2008(183)	van den Boogaard 2008(107)	Vikatmaa 2008(178)	Vlayen et al. 2007(180)	Wasiak 2007(172)
MAAS 2006																					X	
McCallon 2000			X	X	X		X			X		X		X		X	X	X		X	X	
McGill 2005																					X	
Mendonca 2006																X					X	
Moisidis 2004		X			X						X	X						X		X	X	
Molnar 2004																						X
Morris 2007																X						
Moues 2004		X			X				X		X	X		X		X	X	X	X	X	X	
OHTAC 2006																						
Page 2003		X			X				X												X	
Pham 2006																						
Samson 2004																X						
Scherer 2004		X		X	X							X									X	
Schrank 2004					X																X	
Schwien 2005																						
Segers 2005															X							
Shilt 2004		X						X														

Reference	Contractor 2008(185)***	Costa 2005(181)	Fisher 2003(CCOHTA)(168)	Gray 2004(177)	Gregor 2008(173)	Gupta 2004(188)*	Higgins 2003(169)	Kanakaris 2007(25)**	Mendonca 2006(187)**	Noble-Bell and Forbes 2008(70)	OHTAC 2006(184)	Pham 2006(176)**	Raga and Berg 2007(186)**	Samson 2004(182)	Schimmer 2008(175)	Schintler and Prandl 2008(170)	Ubbink 2008(174)	Ubbink 2008(183)	van den Boogaard 2008(107)	Vikatmaa 2008(178)	Vlayen et al. 2007(180)	Wasiak 2007(172)
Sjogren 2005															X							
Sjogren 2005																						
Song 2003		X		X								X										
Stannard 2006								X												X	X	
Stone 2004					X																	
Vuerstaek 2006																X	X	X		X	X	
Wanner 2003		X		X	X		X				X	X		X		X	X	X	X	X	X	
Weed 2004									X													
Wild 2004					X																	
Willy 2006																					X	
Yang 2006								X														
Total Studies	***	**14**	**5**	**9**	**16**	**NR**	**4**	**3****	**6**	**4**	**6**	**16**	**NI**	**6**	**10**	**14**	**7**	**13**	**5**	**13**	**25**	**1**

NI Not included
NR Not reported

* Did not reference study by name
** Case series or chart reviews not included in listing
*** Based on 9 retrospective reviews and 11 case studies not listed

We assessed the quality of each review using the Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool.(171) The AMSTAR consists of 11 items, which have been tested for face and content validity. The items assess whether or not a systematic review includes important elements, such as a comprehensive literature search, assessment of study quality, appropriate methods to combine study findings, and assessment of publication bias. Responses to each item are checked as “Yes” if the review includes that item, “No” if it does not, “CA” if the item cannot be answered by the information provided in the review, or “NA” if the item is not applicable. The AMSTAR does not provide a method for rating the quality of a review. To rate the quality of the reviews, we applied the following criteria: a rating of “High” if the review received mostly “yes” responses (at least 8), a rating of “Low” if the review received mostly “no” responses (at least 8), and a rating of “Moderate” if the review received mixed responses.

Table 41. Quality of Systematic Reviews

Reference	Was an "a priori" design provided?	Was there duplicate study selection and abstraction?	Was a comprehensive literature search performed?	Was the status of publication (i.e., English only) used as inclusion criterion?	Was a list of studies (included and excluded) provided?	Were the characteristics of the included studies assessed and documented?	Was the scientific quality of the included studies assessed and documented?	Was the scientific quality of the included studies used appropriately in formulating the conclusions?	Were methods used to combine the findings of studies appropriate?	Was the likelihood of publication bias assessed?	Was any conflict of interest stated?	Overall Rating
Contractor et al. 2008(185)	N	N	N	N	N	N	N	N	NA	N	N	Low
Gregor et al. 2008(173)	CA	Y	Y	Y	N	N	Y	Y	Y	Y	Y	High
Noble-Bell and Forbes 2008(70)	CA	Y	Y	Y	Y	N	N	Y	NA	N	N	Moderate
Schimmer et al. 2008(175)	CA	N	N	Y	N	N	N	Y	NA	N	N	Moderate
Schintler and Prandl 2008(170)	CA	N	Y	N	N	N	N	N	NA	N	N	Low
Ubbink et al. 2008(174)	Y	Y	Y	Y	Y	Y	Y	Y	NA	Y	Y	High
Ubbink et al. 2008(183)	CA	Y	Y	Y	N	N	Y	Y	NA	N	N	Moderate
van den Boogaard et al. 2008(107)	Y	Y	Y	Y	N	N	Y	Y	NA	N	N	Moderate

Reference	Was an "a priori" design provided?	Was there duplicate study selection and abstraction?	Was a comprehensive literature search performed?	Was the status of publication (i.e., English only) used as inclusion criterion?	Was a list of studies (included and excluded) provided?	Were the characteristics of the included studies assessed and documented?	Was the scientific quality of the included studies assessed and documented?	Was the scientific quality of the included studies used appropriately in formulating the conclusions?	Were methods used to combine the findings of studies appropriate?	Was the likelihood of publication bias assessed?	Was any conflict of interest stated?	Overall Rating
Vikatmaa et al. 2008(178)	CA	Y	Y	Y	N	N	Y	Y	N	N	Y	Moderate
Kanakaris et al. 2007(25)	CA	N	Y	Y	N	N	N	Y	NA	N	Y	Moderate
Raja and Berg 2007(186)	Y	N	Y	N	N	N	N	N	NA	N	N	Low
Vlayen et al. 2007(180)	CA	Y	Y	Y	Y	Y	Y	Y	NA	N	N	Moderate
Wasiak and Cleland 2007(172)	Y	Y	Y	Y	Y	Y	Y	Y	NA	Y	Y	High
Mendonca et al. 2006(187)	CA	N	Y	N	N	N	N	N	NA	N	N	Low
Ontario Health Technology Advisory Committee (OHTAC) 2006(184)	N	N	Y	Y	Y	Y	Y	Y	NA	N	N	Moderate
Pham et al. 2006(176)	Y	Y	Y	Y	N	N	Y	Y	NA	N	N	Moderate

Reference	Was an "a priori" design provided?	Was there duplicate study selection and abstraction?	Was a comprehensive literature search performed?	Was the status of publication (i.e., English only) used as inclusion criterion?	Was a list of studies (included and excluded) provided?	Were the characteristics of the included studies assessed and documented?	Was the scientific quality of the included studies assessed and documented?	Was the scientific quality of the included studies used appropriately in formulating the conclusions?	Were methods used to combine the findings of studies appropriate?	Was the likelihood of publication bias assessed?	Was any conflict of interest stated?	Overall Rating
Costa et al. 2005(181)	CA	N	Y	Y	N	N	N	NA	NA	N	N	Moderate
Gray & Peirce 2004(177)	ca	N	Y	Y	N	N	Y	Y	NA	N	N	Moderate
Gupta & Cho 2004(188)	N	N	N	Y	N	N	N	N	NA	N	N	Low
Samson et al. 2004(182)	CA	Y	Y	Y	Y	Y	Y	Y	NA	N	N	Moderate

Source: Shea et al. 2007, AMSTAR: a measurement tool to assess the quality of systematic reviews.(171)

ECRI Institute applied overall assessment ratings using the following criteria: "High" if a study had mostly yes's (at least 8), "Moderate" if a mix of yes, no's, and can't answer, and "Low" if a study had mostly no's (at least 8)

CA Can't answer
NA Not applicable

Table 42. Adverse Events Described in Systematic Reviews

Reference	Included Study	Wound Type	Treatment(s)	Complication	Comorbidities
Contractor et al. 2008(185)	Trop 2006	Burn	NPWT	Massive hematoma in 2 burn patients in the absence of anticoagulation therapy in both a graft and a graft-donor site	NR
	Baharestani 2007	Open fracture, abdominal compartment syndrome, sacral, sternal, degloving injury	NPWT	Enterocutaneous fistula developing in a patient's exposed bowel	NR
	McCord 2007	Pressure ulcers, extremity, dehisced surgical, sternal, fistulae, abdominal defects	NPWT	6 wounds failed to heal	Included infection, an enterocutaneous fistula, and/or immunosuppression
Gregor et al. 2008(173)	Armstrong 2005	DFU	NPWT	Infections – more common in NWPT	NR
			Standard of care		
Noble-Bell and Forbes 2008(70)	McCallon 2000	DFU	NPWT	Bleeding and pain at time of dressing change	NR
	Etoz 2004		NPWT	Bleeding and pain at time of dressing change	
	Eginton 2003		NPWT	Withdrawal due to incorrect pressure setting (too low)	
Schimmer et al. 2008(175)	Segers 2005	Post-sternotomy mediastinitis	V.A.C.®		NR
			Primary closure with suction/ irrigation system	Higher rates of recurring infection, therapeutic failure at discharge	

Reference	Included Study	Wound Type	Treatment(s)	Complication	Comorbidities
Ubbink et al. 2008(174)	Joseph 2000	Chronic	TNP vs. gauze	3 complications in the NPWT group (n = 18) and 8 (n = 18) in the gauze group (RR: 2.67; 95% CI: 0.84 to 8.46). Difference not statistically significant	NR
	Vuerstaek 2006	Chronic ulcers	TNP vs. choice of hydrocolloid or alginate dressing	No significant difference in the complication rate between groups (40% in the NPWT group compared with 23% in the wound gel group; (RD: 0.17; 95%CI: -0.06 to 0.40) No significant difference in mean score for present pain intensity (PPI) in the eighth week of treatment (0.2 (SD 0.7) for NPWT and 0.4 (SD: 0.6) for the control group; (WMD: -0.20; 95% CI: -0.53 to 0.13)	NR
Raja and Berg 2007(186)	Gustafsson 2003	Sternal	V.A.C.®	Subcutaneous fistulae – 3	NR
	Domkowski 2003	Sternal	V.A.C.®	Hospital mortality – 4 (3.7%) for all patients	NR
			Standard of care		
	Luckraz 2003	Sternal	V.A.C.®	Mortality – 4	NR
			V.A.C.® followed by a myocutaneous flap or primary wound closure	Mortality – 7.7% Treatment failure rate – 15%	
	Doss 2002	Sternal	V.A.C.®	Mortality – 1	NR
			Standard of care	Mortality – 1	NR

Reference	Included Study	Wound Type	Treatment(s)	Complication	Comorbidities
Vlayen et al. 2007(180)	Armstrong 2005	DFU	NPWT	Infection – 17% Treatment related adverse events – 12%	NR
			Standard of care	Infection – 6% Treatment related adverse events – 13%	
	Joseph 2000	Chronic non-healing	NPWT	Infection – 0%	NR
			Gauze	Infection – 33%	
	Vuerstaek 2006	Leg ulcers	NPWT	Infection – 0% Cutaneous damage secondary to therapy – 23%	NR
			Standard of care	Infection – 3% Cutaneous damage secondary to therapy – 7%	
	Braakenburg 2006	Chronic and acute	NPWT	Discontinuation of treatment – 2 patients due to pain during dressing changes or during NPWT	NR
			Various dressings		
Mendonca et al. 2006(187)	DeFranzo 2001	Lower extremity	NPWT	3 cases of osteomyelitis	NR
OHTAC 2006(184)	Armstrong 2005	DFU	NPWT	Infection – 13 (17%) 4 severe	NR
			Standard of care	Infection – 5 (6%) 2 were severe	

Reference	Included Study	Wound Type	Treatment(s)	Complication	Comorbidities
Costa et al. 2005(181)	Song 2003	Sternal	NPWT	Osteomyelitis – 1 (6%) Calcaneal fractures – 2 (11%)	NR
			Standard of care	Osteomyelitis – 2 (11%) Fistulae – 2 (11%) Wound infection – 6 (33%)	
	Genecov 1998	Skin grafts	NPWT	Chronically draining wound – 1 (7%) Mediastinitis – 1 (7%) Omental flap losses – 0 Intestinal evisceration – 0 Hernia - 0	NR
			OpSite	Chronically draining wound – 1 (6%) Mediastinitis – 1 (6%) Omental flap losses – 2 (12%) Intestinal evisceration – 1 (6%) Hernia – 1 (6%)	
	Argenta 1997	Mixed	V.A.C.®	Pain – traumatic wounds required narcotics due to pain level Bleeding – excessive ingrowth of granulation tissue particularly if dressing kept >48 hours Erosion of adjacent tissue – when positioned over bone or if patient lies on the tube Fistulae – 1 case Wound infection – 2 (5.4%) – due to overgrowth of granulation tissue	NR

Reference	Included Study	Wound Type	Treatment(s)	Complication	Comorbidities
Gray and Peirce 2004(177)	Evans 2004 (SR)	NR	NPWT	Calcaneal bone fractures – 2 Osteomyelitis – 1	NR
			Topical treatment		
	Fisher et Brady 2003 (SR)	NR	NPWT	Pain – induced from application of pressure or the intermittent pressure associated with sponge changes	
	Argenta 1997	NR	NPWT	Tissue erosion – around the egress tube when placed too close to a bony prominence or when excessive pressure is placed over the sponge dressing	NR
	Gwan-Nulla and Casal 2001*	NR	NPWT	Toxic shock syndrome – 1	NR
	Chester and Waters 2002*	NR	NPWT	Bacteremia and sepsis – 1	NR
			Standard of care	NR	NR
Samson et al. 2004(182)	Ford 2002	Decubitus ulcers	V.A.C.® vs. Healthpoint System	• 2 deaths (group assignment NR) • 1 patient required distal lower-extremity amputation	• NR • diabetes, hypertension, vascular insufficiency and sepsis
	Joseph 2000	Chronic non-healing	V.A.C.®	3 of 18 V.A.C.® wounds developed complications including fistulae, wound infection, osteomyelitis, and calcaneal fractures	NR
			Standard care	8 of 18 wounds developed complications including fistulae, wound infection, osteomyelitis, and calcaneal fractures	NR

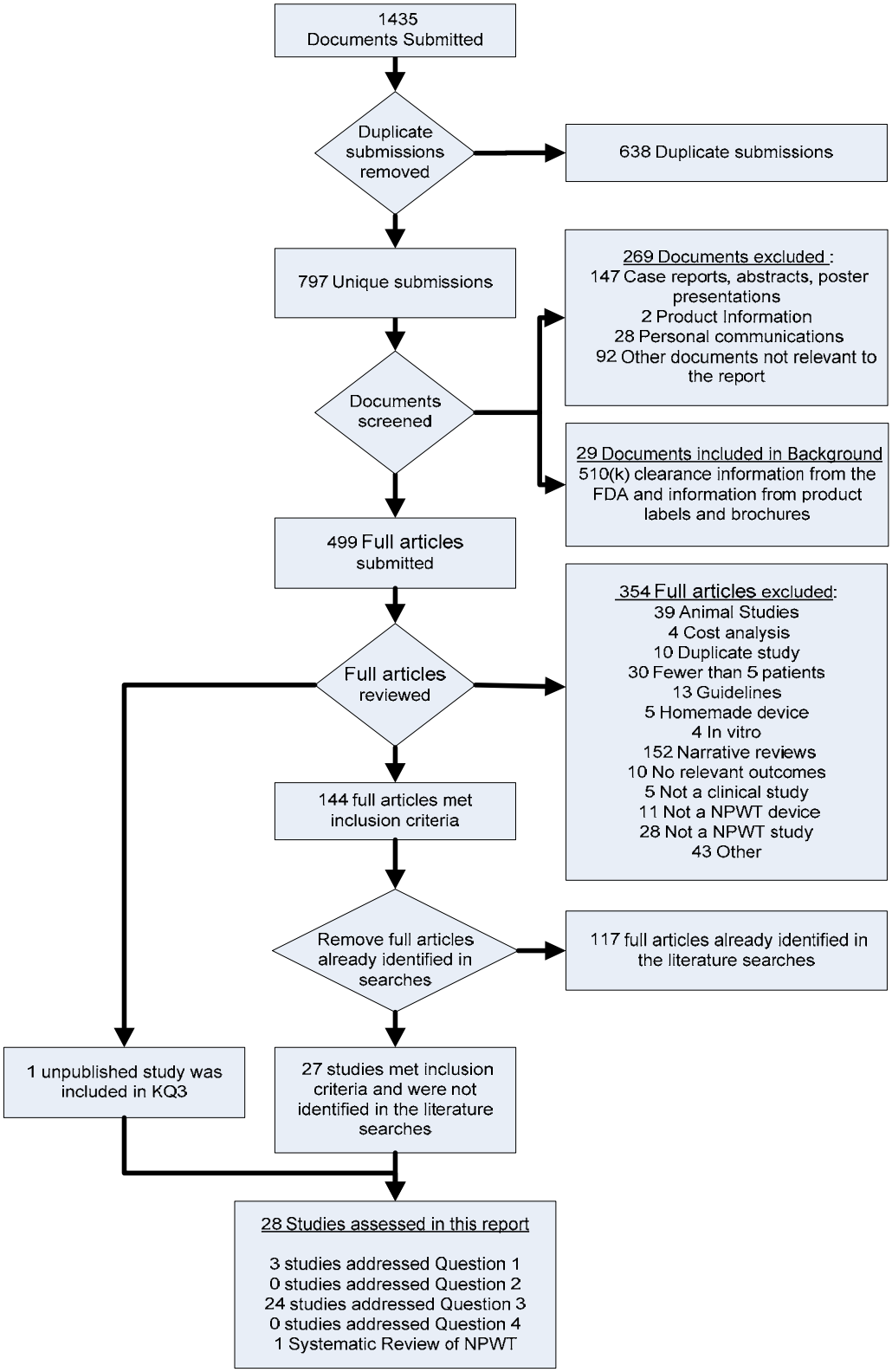
SR – Systematic review

* Case study

The Medical Advisory Secretariat performed a post hoc calculation to determine if the difference in the rate of wound infections was statistically significant between groups, and calculated a statistically significant higher rate of wound infection in the NPWT group compared to control (P = 0.04), based on a 2-tailed Fisher's exact test. MAS did not take into account the severity of the wounds.

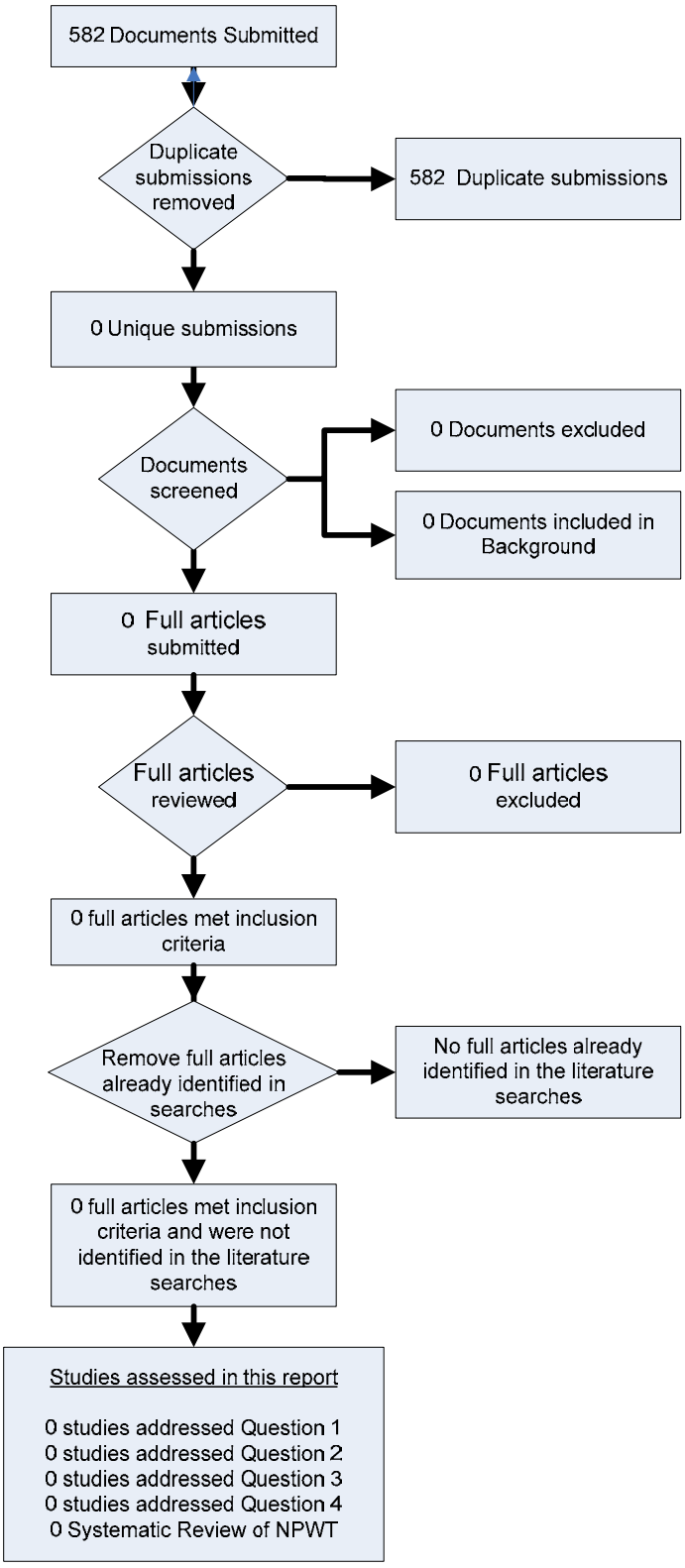
Appendix D: Stakeholder Submissions

Figure 5. Disposition of Documents Submitted by Interested Stakeholders



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Figure 6. Disposition of Submission by American Association for the Advancement of Wound Care



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Table 43. Status of Submissions by American Association for the Advancement of Wound Care

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(390)	Abai B, Zickler RW, Pappas PJ, Lal BK, Padberg FT Jr. Lymphorrhea responds to negative pressure wound therapy. J Vasc Surg 2007 Mar;45(3):610-3.			✓	Fewer than five patients	
(152)	Adamkova M, Tymonova J, Zamecnikova I, Kadlcik M, Klosova H. First experience with the use of vacuum assisted closure in the treatment of skin defects at the Burn Center. Acta Chir Plast 2005;47(1):24-7.	✓	KQ3			
(372)	Agarwal JP, Ogilvie M, Wu LC, Lohman RF, Gottlieb LJ, Franczyk M, Song DH. Vacuum-assisted closure for sternal wounds: A first-line therapeutic management approach. Plast Reconstr Surg 2005 Sep 15;116(4):1035-40.	✓	KQ3			
(391)	Agrawal S, Hayhurst C, Joseph T, Prinsloo D, Morgan RH, Pherwani AD. Successful salvage of infected and exposed non-absorbable mesh following decompressing laparostomy after emergency repair of ruptured abdominal aortic aneurysm using vacuum-assisted closure system. Eur J Vasc Endovasc Surg 2008 Jan;15(1):1-2.			✓	Narrative	
(392)	Aguinaga S, Welber A, Stephens S. Positive steps towards negative pressure wound therapy. Medsurg Nurs 2007 Jun;16(3):181-2, 189.			✓	Narrative	
(393)	Alvarez AA, Maxwell GL, Rodriguez GC. Vacuum-assisted closure for cutaneous gastrointestinal fistula management. Gynecol Oncol 2001 Mar;80(3):413-6.			✓	Case report	
(394)	Andrabi SI, Ahmad J, Rathore MA, Yousaf M. Vacuum assisted closure of laparostomy wounds "a novel technique". J Ayub Med Coll Abbottabad 2007 Jul-Sep;19(3):89-92.			✓	Case report	
(395)	Andrabi SI, Ahmad J. Negative pressure therapy for laparotomy wounds--a word of caution. J Wound Ostomy Continence Nurs 2007 Jul-Aug;34(4):425-7.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(396)	Andrews BT, Smith RB, Chang KE, Scharpf J, Goldstein DP, Funk GF. Management of the radial forearm free flap donor site with the vacuum-assisted closure (VAC) system. Laryngoscope 2006 Oct;116(10):1918-22.			✓	No relevant outcomes	
(88)	Andrews BT, Smith RB, Goldstein DP, Funk GF. Management of complicated head and neck wounds with vacuum-assisted closure system. Head Neck 2006 Nov;28(11):974-81.	✓	KQ3			✓
(397)	Andrews BT, Smith RB, Hoffman HT, Funk GF. Orocutaneous and pharyngocutaneous fistula closure using a vacuum-assisted closure system. Ann Otol Rhinol Laryngol 2008 Apr;117(4):298-302.			✓	Fewer than five patients	
(398)	Andros G, Armstrong DG, Attinger C, Boutlon AJ, Frykberg RG, Joseph WS, Lavery LA, Morbach S, Niezgoda JA, Toursarkissian B. Consensus statement on negative pressure wound therapy (VAC Therapy) for the management of diabetic foot wounds. Wounds 2006 Jun;52(6 Suppl):1-32.			✓	Guideline	
(385)	Antony S, Terrazas S. A retrospective study: Clinical experience using vacuum-assisted closure in the treatment of wounds. J Natl Med Assoc 2004;96(8):1073-7.	✓	KQ3			
(192)	Apelqvist J, Armstrong DG, Lavery LA, Boulton AJ. Resource utilization and economic costs of care based on a randomized trial of vacuum-assisted closure therapy in the treatment of diabetic foot wounds. Am J Surg 2008 Jun;195(6):782-8.			✓	Cost analysis	
(399)	Arca MJ, Somers KK, Derks TE, Goldin AB, Aiken JJ, Sato TT, Shilyansky J, Winthrop A, Oldham KT. Use of vacuum-assisted closure system in the management of complex wounds in the neonate. Pediatr Surg Int 2005 Jul;21(7):532-5. Epub 2005 Jun 17.			✓	Fewer than five patients	
(400)	Archdeacon MT, Messerschmitt P. Modern papineau technique with vacuum-assisted closure. J Orthop Trauma 2006 Feb;20(2):134-7.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(401)	Argenta LC, Morykwas MJ, Marks MW, DeFranzo AJ, Molnar JA, David LR. Vacuum-assisted closure: state of clinic art. Plast Reconstr Surg 2006 Jun;117(7 Suppl):127S-142S.			✓	Narrative	
(148)	Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. Ann Plast Surg 1997 Jun;38(6):563-76; discussion 577.	✓	KQ3			✓
(402)	Argenta PA, Rahaman J, Gretz HF 3rd, Nezhat F, Cohen CJ. Vacuum-assisted closure in the treatment of complex gynecologic wound failures. Obstet Gynecol 2002 Mar;99(3):497-501.			✓	Fewer than five patients	
(403)	Armstrong DG, Attinger CE, Boulton AJ, Frykberg RG, Kirsner RS, Lavery LA, Mills JL. Guidelines regarding negative wound therapy (NPWT) in the diabetic foot. Ostomy Wound Manage 2004 Apr;50(4B Suppl):3S-27S.			✓	Guideline	
(404)	Armstrong DG, Boulton AJ, Banwell P. Negative pressure wound therapy in treatment of diabetic foot wounds: a marriage of modalities. Ostomy Wound Manage 2004 Apr;50(4A Suppl):9-12.			✓	Narrative	
(194)	Armstrong DG, Kunze K, Martin BR, Kimbriel HR, Nixon BP, Boulton AJ. Plantar pressure changes using a novel negative pressure wound therapy technique. J Am Podiatr Med Assoc 2004 Sep-Oct;94(5):456-60.			✓	Not a NPWT study	
(85)	Armstrong DG, Lavery LA, Abu-Rumman P, Espensen EH, Vazquez JR, Nixon BP, Boulton AJ. Outcomes of subatmospheric pressure dressing therapy on wounds of the diabetic foot. Ostomy Wound Manage 2002 Apr;48(4):64-8.	✓	KQ3			✓
(109)	Armstrong DG, Lavery LA, Boulton AJ. Negative pressure wound therapy via vacuum-assisted closure following partial foot amputation: what is the role of wound chronicity?. Int Wound J 2007 Mar;4(1):79-86.	✓	KQ1, KQ3			
(195)	Armstrong DG, Lavery LA, Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. Lancet 2005 Nov 12;366(9498):1704-10.			✓	Study population reported in(109)	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(405)	Armstrong DG, Lavery LA. Decreasing foot pressures while implementing topical negative pressure (vacuum-assisted closure) therapy. Int J Low Extrem Wounds 2004 Mar;3(1):12-5.			✓	Narrative	
(406)	Attar KH, Imran D, Iyer S. Vacuum-assisted closure (VAC) therapy in the management of digital pulp defects. Acta Chir Plast 2007;49(3):75-6.			✓	Case report	
(92)	Avery C, Pereira J, Moody A, Gargiulo M, Whitworth I. Negative pressure wound dressing of the radial forearm donor site. Int J Oral Maxillofac Surg 2000 Jun;29(3):198-200.	✓	KQ3			
(407)	Aydin U, Ozgenel Y. A simple solution for preventing air leakage in VAC therapy for sacral pressure sores. J Plast Reconstr Aesthet Surg 2008 Oct;61(10):1267-9.			✓	Narrative	
(408)	Ayello EA, Baranoski S, Morey J. VAC heals complex wounds. Nurs Spectrum (Phila Tri- State) 2003 Dec;15(24):16-17.			✓	Narrative	
(409)	Azad SM, Allison K, Khwaja N, Moiemen N. Frostbite of the gluteal region. Burns 2003 Nov;29(7):739-44.			✓	No abstract available	
(410)	Baharestani M, de Leon J, Mendez-Eastman S, Powell G, Weir D, Niezgoda J, Payne W, Nanney LB, Pelham F, Gupta S. Consensus statement: a practical guide for managing pressure ulcers with negative pressure wound therapy utilizing vacuum-assisted closure. Understanding the treatment algorithm. Adv Skin Wound Care 2008 Jan;21(Suppl 1):1-20.			✓	Guideline	
(411)	Baharestani MM, Driver VR, de Leon JM, Gabriel A, Kaplan M, Lantis J, Lavery L, Pelham F, Powell G, Webb L. Optimizing clinical and cost effectiveness with early intervention of V.A.C. therapy. Ostomy Wound Manage 2008;54(11 Suppl):1-15.			✓	Narrative	
(199)	Baharestani MM, Houliston-Otto DB, Barnes S. Early versus late initiation of negative pressure wound therapy: examining the impact on home care length of stay. Ostomy Wound Manage 2008 Nov;54(11):48-53.			✓	No relevant outcomes	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(93)	Baharestani MM. Negative pressure wound therapy in the adjunctive management of necrotizing fascitis: examining clinical outcomes. Ostomy Wound Manage 2008 Apr;54(4):44-50.	✓	KQ3			
(412)	Baharestani MM. Negative pressure wound therapy: an examination of cost-effectiveness. Ostomy Wound Manage 2004 Nov;50(11A Suppl):29S-33S.			✓	Cost analysis	
(162)	Baharestani MM. Use of negative pressure wound therapy in the treatment of neonatal and pediatric wounds: a retrospective examination of clinical outcomes. Ostomy Wound Manage 2007 Jun;53(6):75-85.	✓	KQ3			
(413)	Ballard K, McGregor F. Use of vacuum-assisted closure therapy following foot amputation. Br J Nurs 2001 Aug;10(15 Suppl):S6-12.			✓	Case report	
(344)	Bannasch H, Iblher N, Penna V, Torio N, Felmerer G, Stark GB, Momeni A. A critical evaluation of the concomitant use of the implantable Doppler probe and the Vacuum Assisted Closure system in free tissue transfer. Microsurgery 2008;28(6):412-6.	✓	KQ3			
(414)	Banwell PE, Ahmed S, Teot L. Topical negative pressure versus closed surgical wound drainage: a difference in philosophy. J Wound Care 2005 Oct;14(9):445-7.			✓	Narrative	
(415)	Banwell PE, Musgrave M. Topical negative pressure therapy: mechanisms and indications. Int Wound J 2004 Jun;1(2):95-106.			✓	Narrative	
(416)	Banwell PE, Teot L. Topical negative pressure (TNP): the evolution of a novel wound therapy. J Wound Care 2003 Jan;12(1):22-8.			✓	Narrative	
(417)	Banwell PE. Topical negative pressure therapy in wound care. J Wound Care 1999 Feb;8(2):79-84.			✓	Narrative	
(418)	Banwell PE. Topical negative pressure therapy: advances in burn wound management. Ostomy Wound Manage 2004 Nov;50(11A-Suppl):9S-14S.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(153)	Bapat V, El-Muttardi N, Young C, Venn G, Roxburgh J. Experience with vacuum-assisted closure of sternal wound infections following cardiac surgery and evaluation of chronic complications associated with its use. J Card Surg 2008 May;23(3):227-33.	✓	KQ3			
(200)	Barker DE, Kaufman HJ, Smith LA, Ciraulo DL, Richart CL, Burns RP. Vacuum pack technique of temporary abdominal closure: a 7-year experience with 112 patients. J Trauma 2000 Feb;48(2):201-6; discussion 206-7.			✓	Homemade device	
(202)	Barringer CB, Gorse SJ, Burge TS. The VAC dressing—a cautionary tale. Br J Plast Surg 2004 Jul;57(5):482.			✓	No abstract available	
(419)	Baxandall T. Tissue viability. Healing cavity wounds with negative pressure. Nurs Stand 1996 Oct 30;11(6):49-51.			✓	Narrative	
(420)	Baynham SA, Kohlman P, Katner HP. Treating stage IV pressure ulcers with negative pressure therapy: a case report. Ostomy Wound Manage 1999 Apr;45(4):28-32, 34-5.			✓	Case report	
(421)	Benbow M, Beldon P, Butcher M, Newton H, Hampton S, Baxter H. Topical negative pressure: a systemic review of the available evidence. J Community Nurs 2007 Jun;21(6)			✓	Not relevant - focus on access and usage of total negative pressure	
(422)	Benbow M. Update on VAC therapy.Journal of Community Nursing-Online; 2006 Apr [accessed 2006 Nov 15]. Available: http://www.jcn.com.uk/.			✓	Narrative	
(82)	Bendewald FP, Cima RR, Metcalf DR, Hassan I. Using negative pressure wound therapy following surgery for complex pilonidal disease: a case series. Ostomy Wound Manage 2007 May;53(5):40-6.	✓	KQ3			✓
(76)	Bendo JA, Quirno M, Pelham F, Barone JA, Awad J. Posterior lumbar wound drainage management with vacuum-assisted closure. World Spine J 2007 Sep;2(4):187-90.	✓	KQ3			✓

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(423)	Bennett W. Novel use of VAC therapy in a patient with lymphocele after varicose surgery. Wounds UK 2007 Dec;3(4):129-32.			✓	Case report	
(424)	Bernstein BH, Tam H. Combination of subatmospheric pressure dressing and gravity feed antibiotic instillation in the treatment of post-surgical diabetic foot wound: a case series. Wounds 2005 Feb;17(2):37-48.			✓	Narrative	
(425)	Bertelsen CA, Wille-Jorgensen P. Use of topical negative pressure to manage a complex wound with a vesicocutaneous fistula. J Wound Care 2006 Apr;15(4):172-3.			✓	Case report	
(350)	Bhattacharyya T, Mehta P, Smith M, Pomahac B. Routine use of wound vacuum-assisted closure does not allow coverage delay for open tibia fractures. Plast Reconstr Surg 2008 Apr;121(4):1263-6.	✓	KQ3			
(134)	Bickels J, Kollender Y, Wittig JC, Cohen N, Meller I, Malawer MM. Vacuum-assisted wound closure after resection of musculoskeletal tumors. Clin Orthop Relat Res 2005 Dec;441:346-50.	✓	KQ1, KQ3			
(426)	Birchall L, Street L, Clift H. Developing a trust-wide centralised approach to the use of TNP. J Wound Care 2002 Sep;11(8):311-4.			✓	Narrative	
(427)	Blackburn JH 2d, Boemi L, Hall WW, Jeffords K, Hauck RM, Banducci DR, Graham WP 3d. Negative-pressure dressings as a bolster for skin grafts. Ann Plast Surg 1998 May;40(5):453-7.			✓	Narrative	
(108)	Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care 2008 Apr;31(4):631-6.	✓	KQ1, KQ3			
(141)	Bollero D, Carnino R, Risso D, Gangemi EN, Stella M. Acute complex traumas of the lower limbs: A modern reconstructive approach with negative pressure therapy. Wound Repair Regen 2007 Jul;15(4):589-94.	✓	KQ3			
(428)	Bolton LL. Negative pressure wound therapy. Wounds 2005 Apr;17(4):A29-A32.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(429)	Bonnet F, Pavy B, Beaudoin S, Dubousset J, Mitrofanoff M. Treatment of a large defect of the chest wall in a child using a negative pressure wound dressing. Scand J Plast Reconstr Surg Hand Surg 2007;41(3):143-5.			✓	Case report	
(430)	Bookout K, McCord S, McLane K. Case studies of an infant, a toddler, and an adolescent treated with a negative pressure wound treatment system. J Wound Ostomy Continence Nurs 2004 Jul-Aug;31(4):184-92.			✓	Fewer than five patients	
(207)	Bovill E, Banwell PE, Teot L, Eriksson E, Song C, Mahoney J, Gustafsson R, Horch R, Deva A, Whitworth I, International Advisory Panel on Topical Negative Pressure. Topical negative pressure wound therapy: a review of its role and guidelines for its use in the management of acute wounds. Int Wound J 2008 Oct;5(4):511-29.			✓	Narrative	
(114)	Braakenburg A, Obdeijn MC, Feitz R, van Rooij IA, van Griethuysen AJ, Klinkenbijl JH. The clinical efficacy and cost effectiveness of the vacuum-assisted closure technique in the management of acute and chronic wounds: a randomized controlled trial. Plast Reconstr Surg 2006 Aug;118(2):390-7; discussion 398-400.	✓	KQ1, KQ3			
(431)	Brace JA. Negative pressure wound therapy for abdominal wounds. J Wound Ostomy Continence Nurs 2007 Jul-Aug;34(4):428-30.			✓	Narrative	
(345)	Brandi C, Grimaldi L, Nisi G, Silvestri A, Brafa A, Calabro M, D'Aniello C. Treatment with vacuum-assisted closure and cryo-preserved homologous de-epidermalised dermis of complex traumas to the lower limbs with loss of substance, and bones and tendons exposure. J Plast Reconstr Aesthet Surg 2008 Dec;61(12):1507-11.	✓	KQ3			
(432)	Brogna L. Home care management of an ostomy within a dehisced abdominal wound. J Wound Ostomy Continence Nurs 2005 May-Jun;32(3):200-2; discussion 202-4.			✓	Case reports	

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(433)	Bronchard R, de Vaumas C, Lasocki S, Jabbour K, Geffroy A, Kermarrec N, Montravers P. Vacuum-assisted closure in the treatment of perineal necrotizing skin and soft tissue infections. Intensive Care Med 2008 Jul;34(7):1345-7.			✓	No abstract available	
(434)	Bronson N, Menon R, Butler J, Gordon I. Parathyroidectomy, excision and skin grafting with topical negative pressure for calciphylactic ulcers. J Wound Care 2007 Jul;16(7):295-7.			✓	Case report	
(435)	Brown KM, Harper FV, Aston WJ, O'Keefe PA, Cameron CR. Vacuum-assisted closure in the treatment of a 9-year-old child with severe and multiple dog bite injuries of the thorax. Ann Thorac Surg 2001 Oct;72(4):1409-10.			✓	Case report	
(436)	Burton L. Nonhealing foot ulcer. Ostomy Wound Manage 1999 Sep;45(9):20-1.			✓	Case report	
(144)	Butter A, Emran M, Al-Jazaeri A, Ouimet A. Vacuum-assisted closure for wound management in the pediatric population. J Pediatr Surg 2006 May;41(5):940-2.	✓	KQ3			
(437)	Canavese F, Gupta S, Krajbich JI, Emara KM. Vacuum-assisted closure for deep infection after spinal instrumentation for scoliosis. J Bone Joint Surg Br 2008 Mar;90(3):377-81.	✓	KQ3			
(165)	Caniano DA, Ruth B, Teich S. Wound management with vacuum-assisted closure: experience in 51 pediatric patients. J Pediatr Surg 2005 Jan;40(1):128-32; discussion 132.	✓	KQ3			
(438)	Canter HI, Isci E, Erk Y. Vacuum-assisted wound closure for the management of a foot ulcer due to Buerger's disease. J Plast Reconstr Aesthet Surg 2007 Nov 1;Epub ahead of print.			✓	Case report	
(439)	Carson SN, Overall K, Lee-Jahshan S, Travis E. Vacuum-assisted closure used for healing chronic wounds and skin grafts in the lower extremities. Ostomy Wound Manage 2004 Mar;50(3):52-8.			✓	Narrative	

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(137)	Catarino PA, Chamberlain MH, Wright NC, Black E, Campbell K, Robson D, Pillai RG. High-pressure suction drainage via a polyurethane foam in the management of poststernotomy mediastinitis. Ann Thorac Surg 2000 Dec;70(6):1891-5.			✓	Not relevant (suction drainage)	
(440)	Chandawarkar RY, Piorkowski J, Amjad I, Deckers PJ. Combination therapy of a large, recurrent keloid. Dermatol Surg 2007 Feb;33(2):229-35.			✓	Case report	
(441)	Chaouat M, Bonnet F, Seroussi D, Smarrito S, Mimoun M. Topical negative pressure for the treatment of complex cavity wounds associated with osteitis. J Wound Care 2006 Jul;15(7):292-4.			✓	Fewer than five patients	
(442)	Chariker ME, Jeter KF, Tintle TE, Bottsford JE. Effective management of incisional and cutaneous fistulae with close suction wound drainage. Contemp Surg 1989 Jun;34:59-63.			✓	Homemade device	
(443)	Chave H, Ahmed S, Fu B, Webber J, Banwell P, Tiernan E. Salvage of infected dermal collagen implants with topical negative pressure therapy. J Wound Care 2006 Apr;15(4):156-8.			✓	Case report	
(444)	Chen SZ, Li J, Li XY, Xu LS. Effects of Vacuum-assisted Closure on Wound Microcirculation: An Experimental Study. Asian J Surg 2005 Jul;28(3):211-7.			✓	Animal study	
(160)	Chen Y, Almeida AA, Mitnovetski S, Goldstein J, Lowe C, Smith JA. Managing deep sternal wound infections with vacuum-assisted closure. ANZ J Surg 2008 May;78(5):333-6.	✓	KQ3			
(445)	Chesher E. Use of vacuum-assisted closure in the community. Prim Intent 1998 Feb;6(1):12-15.			✓	Case report	
(446)	Chester DL, Waters R. Adverse alteration of wound flora with topical negative-pressure therapy: a case report. Br J Plast Surg 2002 Sep;55(6):510-1.			✓	Case report	
(447)	Childress B, Stechmiller JK, Schultz GS. Arginine metabolites in wound fluids from pressure ulcers: a pilot study. Biol Res Nurs 2008 Oct;10(2):87-92.			✓	No relevant outcomes	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(448)	Chung CJ, David LR, Morykwas M, Argenta L. Case review: management of life-threatening sepsis and wound healing in a Klippel-Trenaunay patient using serial surgical debridements and vaccum-assisted closure. Eur J Plastic Surg 2003 Jul;26(4):214-16.			✓	Case report	
(379)	Clare MP, Fitzgibbons TC, McMullen ST, Stice RC, Hayes DF, Henkel L. Experience with the Vacuum Assisted Closure negative pressure technique in the treatment of non-healing diabetic and dysvascular wounds. Foot Ankle Int 2002 Oct1;23(10):896-901.	✓	KQ3			
(449)	Coggrave M, West H, Leonard B. Topical negative pressure for pressure ulcer management. Br J Nurs 2002 Mar;11(6 Suppl):S29-36.			✓	Case reports	
(450)	Colwell AS, Donaldson MC, Belkin M, Orgill DP. Management of Early Groin Vascular Bypass Graft Infections with Sartorius and Rectus Femoris Flaps. Ann Plast Surg 2004;52(1):49-53.			✓	Not relevant - focus on effectiveness of muscle flaps	
(185)	Contractor D, Amling J, Brandoli C, Tosi LL. Negative pressure wound therapy with reticulated open cell foam in children: an overview. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S167-76.	✓	Previous Systematic Reviews			
(451)	Copson D. Topical negative pressure and necrotising fasciitis. Nurs Stand 2003 Oct 22-28;18(6):71-4, 76, 78 passim.			✓	Case report	
(356)	Cothren CC, Moore EE, Johnson JL, Moore JB, Burch JM. One hundred percent fascial approximation with sequential abdominal closure of the open abdomen. Am J Surg 2006 Aug;192(2):238-42.	✓	KQ3			
(373)	Cowan KN, Teague L, Sue SC, Mahoney JL. Vacuum-assisted wound closure of deep sternal infections in high-risk patients after cardiac surgery. Ann Thorac Surg 2005 Dec;80(6):2205-12.	✓	KQ3			
(452)	Cravero L, Taveggia A, Boriani F, Bruschi S, Boriani F. Osteomyelitis: A possible diagnostic mistake after vacuum-assisted therapy. J Plast Reconstr Aesthet Surg 2006;59(11):1250-1.			✓	Case report	

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(453)	Cresti S, Ouaissi M, Sielezneff I, Chaix JB, Pirro N, Berthet B, Consentino B, Sastre B. Advantage of vacuum assisted closure on healing of wound associated with omentoplasty after abdominoperineal excision: a case report. World J Surg Oncol 2008 Dec 23;6(1):136.			✓	Case reports	
(454)	Cro C, George KJ, Donnelly J, Irwin ST, Gardiner KR. Vacuum assisted closure system in the management of enterocutaneous fistulae. Postgrad Med J 2002 Jun;78(920):364-5.			✓	Fewer than five patients	
(455)	Crumbley DR, Perciballi JA. Negative pressure wound therapy in a contaminated soft-tissue wound. J Wound Ostomy Continence Nurs 2007 Sep-Oct;34(5):507-12.			✓	No abstract available	
(456)	Culliford AT 4th, Spector JA, Levine JP. A novel technique for vacuum assisted closure device application in noncontiguous wounds. J Plast Reconstr Aesthet Surg 2007;60(1):99-100.			✓	Case report	
(457)	Dakin J, Thompson S. Use of topical negative pressure therapy with an abdominal dressing in management of a laparostomy. J Wound Care 2006 Oct;15(9):386-8.			✓	Case report	
(458)	Datiashvili RO, Knox KR. Negative pressure dressing: an alternative to free tissue transfers?. Wounds 2005 Aug;17(8):206-12.			✓	Narrative	
(459)	Davis L, Barker A. Coordination and management of TNP from acute to primary care: overcoming the issues. J Wound Care 2006 Apr;15(4):169-71.			✓	Narrative	
(460)	Davydov IuA, Malafeeva EV, Smirnov AP, Flegontov VB. Vacuum therapy in the treatment of suppurative lactation mastitis. Vestn Khir Im I I Grek 1986 Nov;137(11):66-70.			✓	Not a NPWT device	
(461)	Davydov YA, Larichev AB, Abramov AY, Menkov KG. Concepts for clinical biological management of the wound process in the treatment of purulent wounds using vacuum therapy] translated from Russian. Vestnik Khirurgii 1991 Feb;132-5. (Rus).			✓	Not a NPWT device	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(462)	Davydov YA, Larichev AB, Menlov KG. The bacteriological and cytological assessment of vacuum therapy of purulent wounds] translated from Russian. Vestnik Khirurgii 1988 Oct;48-52.			✓	Not a NPWT device	
(460)	Davydov YA, Malafeeva EV, Smirnov AP, Flegontov VB. [Vacuum therapy in the treatment of purulent lactation mastitis] translated from Russian. Vestnik Khirurgii 1986 Sep;66-70. (Rus).			✓	Not a NPWT device	
(463)	de Geus HR, van der Klooster JM. Vacuum-assisted closure in the treatment of large skin defects due to necrotizing fasciitis. Intensive Care Med 2005 Apr;31(4):601.			✓	Case report	
(464)	de la Torre JI, Martin SA, Oberheu AM, Vasconez LO. Healing a wound with an exposed Herrington rod: a case study. Ostomy Wound Manage 2002 May;48(5):18-9.			✓	Case report	
(167)	De Lange MY, Schasfoort RA, Obdeijn MC, Van Der Werff JFA, Nicolai JPA. Vacuum-assisted closure: Indications and clinical experience. Eur J Plastic Surg 2000 May;23(4):178-82.	✓	KQ3			
(8)	de Leon J. Negative pressure wound therapy in pressure ulcer management. Ostomy Wound Manage 2005 Feb;51(2A Suppl):3-8.			✓	Case reports	
(465)	de Weerd L, Kjaeve J, Aghajani E, Elvenes OP. The sandwich design: a new method to close a high-output enterocutaneous fistula and an associated abdominal wall defect. Ann Plast Surg 2007 May;58(5):580-3.			✓	Case report	
(27)	Dedmond BT, Kortesis B, Punger K, Simpson J, Argenta J, Kulp B, Morykwas M, Webb LX. The use of negative-pressure wound therapy (NPWT) in the temporary treatment of soft-tissue injuries associated with high-energy open tibial shaft fractures. J Orthop Trauma 2007 Jan;21(1):11-7.	✓	KQ3			
(222)	Dedmond BT, Kortesis B, Punger K, Simpson J, Argenta J, Kulp B, Morykwas M, Webb LX. Subatmospheric pressure dressings in the temporary treatment of soft tissue injuries associated with type III open tibial shaft fractures in children. J Pediatr Orthop 2006 Nov;26(6):728-32.			✓	Duplicate study(27)	

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(466)	Dee A. The successful management of a dehisced surgical wound with TNP following femoropopliteal bypass. J Wound Care 2007 Jan;16(1):42-4.			✓	Case report	
(157)	DeFranzo AJ, Argenta LC, Marks MW, Molnar JA, David LR, Webb LX, Ward WG, Teasdall RG. The use of vacuum-assisted closure therapy for the treatment of lower-extremity wounds with exposed bone. Plast Reconstr Surg 2001 Oct;108(5):1184-91.	✓	KQ3			
(467)	DeFranzo AJ, Marks MW, Argenta LC, Genecov DG. Vacuum-assisted closure for the treatment of degloving injuries. Plast Reconstr Surg 1999 Dec;104(7):2145-8.			✓	Fewer than five patients	
(156)	DeFranzo AJ, Pitzer K, Molnar JA, Marks MW, Chang MC, Miller PR, Letton RW, Argenta LC. Vacuum-assisted closure for defects of the abdominal wall. Plast Reconstr Surg 2008 Mar;121(3):832-9.	✓	KQ3			
(468)	Demaria R, Giovannini UM, Teot L, Chaptal PA. Using VAC to treat a vascular bypass site infection. J Wound Care 2001 Feb;10(2):12-3.			✓	Case report	
(145)	Demaria RG, Giovannini U, Teot L, Frapier JM, Albat B. A new technique for the treatment of delayed sternotomy healing: the vacuum therapy. Heart Surg Forum 2003;6(5):434-7.	✓	KQ3			
(135)	Denzinger S, Lubke L, Roessler W, Wieland WF, Kessler S, Burger M. Vacuum-assisted closure versus conventional wound care in the treatment of wound failures following inguinal lymphadenectomy for penile cancer: a retrospective study. Eur Urol 2007 May;51(5):1320-5.	✓	KQ1, KQ3			
(135)	Denzinger S, Lubke L, Roessler W, Wieland WF, Kessler S, Burger M. Vacuum-assisted closure versus conventional wound care in the treatment of wound failures following inguinal lymphadenectomy for penile cancer: a retrospective study. Eur Urol 2007 May;51(5):1320-5.	✓	KQ1, KQ3			

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(469)	Derrick KL, Norbury K, Kieswetter K, Skaf J, McNulty AK. Comparative analysis of global gene expression profiles between diabetic rat wounds treated with vacuum-assisted closure therapy, moist wound healing or gauze under suction. Int Wound J 2008 Dec;5(5):615-24.			✓	Animal study	
(382)	Deva AK, Buckland GH, Fisher E, Liew SC, Merten S, McGlynn M, Gianoutsos MP, Baldwin MA, Lendvay PG. Topical negative pressure in wound management. Med J Aust 2000 Aug 7;173(3):128-31.	✓	KQ3			
(470)	Deva AK, Siu C, Nettle WJ. Vacuum-assisted closure of a sacral pressure sore. J Wound Care 1997 Jul;6(7):311-2.			✓	Case report	
(471)	Dickie SR, Dorafshar AH, Song DH. Definitive closure of the infected median sternotomy wound: a treatment algorithm utilizing vacuum-assisted closure followed by rigid plate fixation. Ann Plast Surg 2006 Jun;56(6):680-5.			✓	Algorithm	
(472)	Dieu T, Leung M, Leong J, Morrison W, Cleland H, Archer B, Oppy A. Too much vacuum-assisted closure. ANZ J Surg 2003 Dec;73(12):1057-60.			✓	Narrative	
(473)	Dobke MK, Nguyen D, Trott SA. A novel approach to acute infection of the glenohumeral joint following rotator cuff repair? A case series. Wounds 2005 Jun;17(6):137-40.			✓	No relevant outcomes	
(129)	Domkowski PW, Smith ML, gonyon Jr DL, Drye C, Wooten MK, Levin LS, wolfe WG. Evaluation of vacuum-assisted closure in the treatment of poststernotomy mediastinitis. J Thorac Cardiovasc Surg 2003 Aug 1;126(2):386-90.	✓	KQ1, KQ3			
(474)	Donovan DJ, Person DA. Giant eccrine adenocarcinoma of the scalp with intracranial invasion: resection and reconstruction using a vacuum-assisted closure device: technical case report. Neurosurgery 2006 Apr;58(4 Suppl 2):ONS-E371; discussion ONS.			✓	Case report	

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(475)	Dosluoglu HH, Schimpf DK, Schultz R, Cherr GS. Preservation of infected and exposed vascular grafts using vacuum assisted closure without muscle flap coverage. J Vasc Surg 2005 Nov;42(5):989-92.			✓	Fewer than five patients	
(128)	Doss M, Martens S, Wood JP, Wolff JD, Baier C, Moritz A. Vacuum-assisted suction drainage versus conventional treatment in the management of poststernotomy osteomyelitis. Eur J Cardiothorac Surg 2002 Dec 1;22(6):934-8.	✓	KQ1, KQ3			
(476)	Dunbar A, Bowers DM, Holderness H Jr. Silicone net dressing as an adjunct with negative pressure wound therapy. Ostomy Wound Manage 2005 Apr;51(4):18, 20.			✓	Case report	
(477)	Durai R, Hoque H, Davies TW. 'Indirect VAC': a novel technique of applying vacuum-assisted closure dressing. J Perioper Pract 2008 Oct;18(10):437-9.			✓	Narrative	
(478)	Duxbury MS, Finlay IG, Butcher M, Lambert AW. Use of a vacuum assisted closure device in pilonidal disease. J Wound Care 2003 Oct;12(9):355.			✓	Case report	
(479)	Easterlin B, Bromberg W, Linscott J. A novel technique of vacuum assisted wound closure that functions as a delayed primary closure. Wounds 19(12):331-3.			✓	Narrative	
(480)	Eberlein T, Fendler H. Case studies of Prospera NPWT. Available: http://www.prospera-npwt.com/clincal_references.htm.			✓	Case reports	
(481)	Edwards AR. Vacuum device closes gap in wound care. Biomechanics 2001 Dec;8(12):27-34.			✓	Narrative	
(226)	Eginton MT, Brown KR, Seabrook GR, Towne JB, Cambria RA. A prospective randomized evaluation of negative-pressure wound dressings for diabetic foot wounds. Ann Vasc Surg 2003 Nov;17(6):645-9.			✓	Fewer than five patients	
(482)	Emohare O, Kowal-Vern A, Wiley D, Latenser BA. Vacuum-assisted closure use in calciphylaxis. J Burn Care Rehabil 2004 Mar-Apr;25(2):161-4.			✓	Fewer than five patients	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(483)	Ennis WJ. (President, Association for the Advancement of Wound Care). Personal communication. 2009 Feb 5. 2 p.			✓	Personal communication	
(484)	Erba P, Rieger UM, Pierer G, Kalbermatten DF. Vacuum-assisted closure (VAC) for venous congestion of the nipple-areola complex. J Plast Reconstr Aesthet Surg 2008 Jul;61(7):852-4.			✓	Case report	
(485)	Erdmann D, Drye C, Heller L, Wong MS, Levin SL. Abdominal wall defect and enterocutaneous fistula treatment with the Vacuum-Assisted Closure (V.A.C.) system. Plast Reconstr Surg 2001 Dec;108(7):2066-8.			✓	Case report	
(486)	Espensen EH, Nixon BP, Lavery LA, Armstrong DG. Use of subatmospheric (VAC) therapy to improve bioengineered tissue grafting in diabetic foot wounds. J Am Podiatr Med Assoc 2002 Jul-Aug;92(7):395-7.			✓	Narrative	
(487)	Evans D, Land L. Topical negative pressure for treating chronic wounds: a systematic review. Br J Plast Surg 2001 Apr;54(3):238-42.			✓	(169) update	
(488)	Ferdinando E, Guerin L, Jervis AO, Obidigbo H. Negative-pressure wound therapy and external fixation for infection and hematoma after hallux abducto valgus surgery. J Am Podiatr Med Assoc 2007 Sep-Oct;97(5):410-4.			✓	Case report	
(489)	Ferreira MC, Wada A, Tuma Jr P. The vacuum assisted closure of complex wounds: report of 3 cases. Rev Hosp Clin Fac Med Sao Paulo 2003 Jul-Aug;58(4):227-30.			✓	Fewer than five patients	
(83)	Ferron G, Garrido I, Martel P, Gesson-Paute A, Classe JM, Letourneur B, Querleu D. Combined laparoscopically harvested omental flap with meshed skin grafts and vacuum-assisted closure for reconstruction of complex chest wall defects. Ann Plast Surg 2007 Feb;58(2):150-5.	✓	KQ3			✓
(490)	Fette A. Treatment of pressure ulcers with topical negative pressure versus traditional wound management methods: a research sampler. Plast Surg Nurs 2005 Oct-Dec;25(4):176-80.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(491)	Fife CE, Otto G, Walker D, Turner T, Smith L. Healing dehisced surgical wounds with negative pressure wound therapy. Ostomy Wound Manage 2004 Apr;50(4A Suppl):28-31.			✓	Narrative	
(492)	Fischer JE. A cautionary note: the use of vacuum-assisted closure systems in the treatment of gastrointestinal cutaneous fistula may be associated with higher mortality from subsequent fistula development. Am J Surg 2008 Jul;196(1):1-2.			✓	Narrative	
(168)	Fisher A, Brady B. Vacuum assisted wound closure therapy. Issues Emerg Health Technol 2003 Mar;(44):1-6.	✓	Previous Systematic Reviews			
(493)	Fitzmaurice M, Lawson D, Friedman H. A novel approach for the application of the vacuum assisted closure device to the difficult anatomy. J Plast Reconstr Aesthet Surg 2006;59(11):1249-50.			✓	Case report	
(494)	Flack S, Apelqvist J, Keith M, Trueman P, Williams D. An economic evaluation of VAC therapy compared with wound dressings in the treatment of diabetic foot ulcers. J Wound Care 2008 Feb;17(2):71-8.			✓	Cost analysis	
(495)	Fleck T, Gustafsson R, Harding K, Ingemansson R, Lirtzman MD, Meites HL, Moidl R, Price P, Ritchie A, Salazar J, Sjogren J, Song DH, Sumpio BE, Toursarkissian B, Waldenberger F, Wetzel-Roth W. The management of deep sternal wound infections using vacuum assisted closure (V.A.C.) therapy. Int Wound J 2006 Dec;3(4):273-80.			✓	Narrative	
(362)	Fleck T, Kickinger B, Moidl R, Waldenberger F, Wolner E, Grabenwoger M, Wisser W. Management of open chest and delayed sternal closure with the vacuum assisted closure system: Preliminary experience. Interact Cardiovasc Thorac Surg 2008 Oct;7(5):801-4.	✓	KQ3			
(496)	Fleck T, Moidl R, Giovanoli P, Aszmann O, Bartunek A, Blacky A, Grabenwoger M, Wolner E. A conclusion from the first 125 patients treated with the vacuum assisted closure system for postoperative sternal wound infection. Interact Cardiovasc Thorac Surg 2006 Apr;5(2):145-8.			✓	Not relevant - focus on management of infection	

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(497)	Fleck T, Simon P, Burda G, Wolner E, Wollenek G. Vacuum assisted closure therapy for the treatment of sternal wound infections in neonates and small infants. Interact Cardiovasc Thorac Surg 2006 Jun;5(3):285-8.			✓	Fewer than 5 patients	
(380)	Fleck TM, Fleck M, Moidl R, Czerny M, Koller R, Giovanoli P, Hiesmayer MJ, Zimpfer D, Wolner E, Grabenwoger M. The vacuum-assisted closure system for the treatment of deep sternal wound infections after cardiac surgery. Ann Thorac Surg 2002 Nov 1;74(5):1596-1600.	✓	KQ3			
(498)	Fleck TM, Koller R, Giovanoli P, Moidl R, Czerny M, Fleck M, Wolner E, Grabenwoger M. Primary or delayed closure for the treatment of poststernotomy wound infections. Ann Plast Surg 2004 Mar;52(3):310-4.			✓	Not relevant	
(499)	Fleischmann W, Strecker W, Bombelli M, Kinzl L. [Vacuum sealing as treatment of soft tissue damage in open fractures]. Unfallchirurgie 1993;96(9):488-92.			✓	Narrative	
(232)	Foo A, Kin-Sze Chong A, Shenthilkumar N. The 'hand-in-gloves' technique: vacuum-assisted closure dressing for multiple finger wounds. J Plast Reconstr Aesthet Surg 2008 Sep 5;Epub ahead of print.			✓	Case report	
(110)	Ford CN, Reinhard ER, Yeh D, Syrek D, De Las Morenas A, Bergman SB, Williams S, Hamori CA. Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the Healthpoint system in the management of pressure ulcers. Ann Plast Surg 2002 Jul;49(1):55-61; discussion 61.	✓	KQ1,KQ3			
(500)	Ford SJ, Rathinam S, King JE, Vaughan R. Tuberculous osteomyelitis of the sternum: successful management with debridement and vacuum assisted closure. Eur J Cardiothorac Surg 2005 Oct;28(4):645-7.			✓	Case report	
(501)	Ford-Dunn S. Use of vacuum assisted closure therapy in the palliation of a malignant wound. Palliat Med 2006 Jun;20(4):477-8.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(502)	Fox A, Tadros A, Perks AG. An unusual complication of Vacuum Assisted Closure in the treatment of a pressure ulcer. J Wound Care 2004 Sep;13(8):344-5.			✓	Case report	
(503)	Fox MP, Fazal MA, Ware HE. Vacuum assisted wound closure. A new method for control of wound problems in total knee arthroplasty. J Bone Joint Surg Br 2000 Jan;82-B(Suppl 1):19.			✓	Fewer than 5 patients	
(504)	Fredeking AE, Silverman RA. Successful treatment of trigeminal trophic syndrome in a 6-year-old boy with negative pressure wound therapy. Arch Dermatol 2008 Aug;144(8):984-6.			✓	Case report	
(505)	Friedman T, Westreich M, Shalom A. Vacuum-assisted closure treatment complicated by anasarca. Ann Plast Surg 2005 Oct;55(4):420-1.			✓	Case report	
(506)	Froiland KG. Nursing interventions in oncology complex wound care: use of negative pressure therapy for wound healing in an ovarian cancer patient. [internet]. [accessed 2001 Oct 23]. Available: http://www.thecancergroup.org/kathrynfroiland.htm.			✓	Case report	
(507)	Frykberg F. When is NPWT appropriate for amputation wounds?. APMA News 2005 May;26(5 Suppl):20-3.			✓	Narrative	
(508)	Frykberg RG, Williams DV. Negative-pressure wound therapy and diabetic foot amputations: a retrospective study of payer claims data. J Am Podiatr Med Assoc 2007 Sep-Oct;97(5):351-9.			✓	Cost analysis	
(23)	Fuchs U, Zittermann A, Stuettgen B, Groening A, Minami K, Koerfer R. Clinical outcome of patients with deep sternal wound infection managed by vacuum-assisted closure compared to conventional therapy with open packing: a retrospective analysis. Ann Thorac Surg 2005 Feb;79(2):526-31.	✓	KQ1,KQ3			
(509)	Gabriel A, Gollin G. Management of complicated gastroschisis with porcine small intestinal submucosa and negative pressure wound therapy. J Pediatr Surg 2006 Nov;41(11):1836-40.			✓	Animal study	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(510)	Gabriel A, Heinrich C, Shores JT, Baqui WK, Rogers FR, Gupta S. Reducing bacterial bioburden in infected wounds with vacuum assisted closure and a new silver dressing - a pilot study. Wounds 2006 Sep;18(9):245-55.			✓	Duplicate study(383)	
(339)	Gabriel A, Shores J, Heinrich C, Baqai W, Kalina S, Sogioka N, Gupta S. Negative pressure wound therapy with instillation: A pilot study describing a new method for treating infected wounds. Int Wound J 2008 Jun;5(3):399-413.	✓	KQ1, KQ3			
(86)	Garner GB, Ware DN, Cocanour CS, Duke JH, McKinley BA, Kozar RA, Moore FA. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. Am J Surg 2001 Dec;182(6):630-8.	✓	KQ3			✓
(154)	Gdalevitch P, Afilalo J, Lee C. Predictors of vacuum-assisted closure failure of sternotomy wounds. J Plast Reconstr Aesthet Surg 2008 Nov 21;Epub ahead of print.	✓	KQ3			
(511)	Geller S. A closer look at NPWT in the wound care clinic setting. APMA News 2005 May;26(5 Suppl):43-5.			✓	Narrative	
(512)	Geller S. How to use NPWT successfully in the home care setting. APMA News 2005 May;26(5 Suppl):33-4.			✓	Narrative	
(513)	Geller SM, Longton JA. Ulceration of pyoderma gangrenosum treated with negative pressure wound therapy. J Am Podiatr Med Assoc 2005 Mar-Apr;95(2):171-4.			✓	Case report	
(131)	Genecov DG, Schneider AM, Morykwas MJ, Parker D, White WL, Argenta LC. A controlled subatmospheric pressure dressing increases the rate of skin graft donor site reepithelialization. Ann Plast Surg 1998 Mar;40(3):219-25.	✓	KQ1, KQ3, Previous Systematic Reviews			
(514)	Gerry R, Kwei S, Bayer L, Breuing KH. Silver-impregnated vacuum-assisted closure in the treatment of recalcitrant venous stasis ulcers. Ann Plast Surg 2007 Jul;59(1):58-62.			✓	Fewer than 5 patients	

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(515)	Ghersi MM, Ricotti C, Nousari CH, Newman MI. Negative pressure dressing in the management of pyoderma gangrenosum ulcer. Arch Dermatol 2007 Oct;143(10):1249-51.			✓	Case report	
(516)	Gomoll AH, Lin A, Harris MB. Incisional vacuum-assisted closure therapy. J Orthop Trauma 2006 Nov-Dec;20(10):705-9.			✓	Narrative	
(517)	Goverman J, Yelon JA, Platz JJ, Singson RC, Turcinovic M. The "Fistula VAC," a technique for management of enterocutaneous fistulae arising within the open abdomen: report of 5 cases. J Trauma 2006 Feb;60(2):428-31; discussion 431.			✓	Not relevant	
(177)	Gray M, Peirce B. Is negative pressure wound therapy effective for the management of chronic wounds. J Wound Ostomy Continence Nurs 2004 May/June;31(3):101-5.	✓	Previous Systematic Reviews			
(518)	Greene AK, Puder M, Roy R, Arsenault D, Kwei S, Moses MA, Orgill DP. Microdeformational wound therapy: effects on angiogenesis and matrix metalloproteinases in chronic wounds of 3 debilitated patients. Ann Plast Surg 2006 Apr;56(4):418-22.			✓	Fewer than 5 patients	
(519)	Greer S, Sims CD, Borud L, Thorne C, Kasabian A. The use of a subatmospheric pressure dressing to salvage a septic ankle with concomitant osteomyelitis and avert a free flap. Foot Ankle Int 1997 Sep;18(3):151-6.			✓	Case report	
(520)	Greer SE, Adelman M, Kasabian A, Galiano RD, Scott R, Longaker MT. The use of subatmospheric pressure dressing therapy to close lymphocutaneous fistulae of the groin. Br J Plast Surg 2000 Sep;53(6):484-7.			✓	Narrative	
(521)	Greer SE, Duthie E, Cartolano B, Koehler KM, Maydick-Youngberg D, Longaker MT. Techniques for applying subatmospheric pressure dressing to wounds in difficult regions of anatomy. J Wound Ostomy Continence Nurs 1999 Sep;26(5):250-3.			✓	Narrative	

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(522)	Greer SE, Longaker MT, Margiotta M, Mathews AJ, Kasabian A. The use of subatmospheric pressure dressing for the coverage of radial forearm free flap donor-site exposed tendon complications. Ann Plast Surg 1999 Nov;43(5):551-4.			✓	Narrative	
(173)	Gregor S, Maegele M, Sauerland S, Krahn JF, Peinemann F, Lange S. Negative pressure wound therapy: a vacuum of evidence?. Arch Surg 2008 Feb;143(2):189-96.	✓	Previous Systematic Reviews			
(523)	Grimm A, Dimmler A, Stange S, Labanaris A, Sauer R, Grabenbauer G, Horch RE. Expression of HIF-1 alpha in irradiated tissue is altered by topical negative-pressure therapy. Strahlenther Onkol 2007 Mar;183(3):144-9.			✓	No relevant outcomes	
(524)	Gudbjartsson T, Sigurdsson HK, Sigurdsson E, Kjartansson J. Vacuum-assisted closure for successful treatment of a major contaminated gunshot chest-wound: A case report. Eur J Trauma Emerg Surg 2008 July 25;Epub			✓	Case report	
(525)	Gunn LA, Follmar KE, Wong MS, Lettieri SC, Levin LS, Erdmann D. Management of enterocutaneous fistulae using negative-pressure dressings. Ann Plast Surg 2006 Dec;57(6):621-5.			✓	Not relevant	
(10)	Gupta S, Baharestani M, Baranoski S, de Leon J, Engel SJ, Mendez-Eastman S, Niezgoda JA, Pompeo MQ. Guidelines for managing pressure ulcers with negative pressure wound therapy. Adv Skin Wound Care 2004 Nov-Dec;17(Suppl 2):1-16.			✓	Guideline	
(236)	Gupta S, Cho T. A literature review of negative pressure wound therapy. Ostomy Wound Manage 2004 Apr;50(4A Suppl):6-8.			✓	Duplicate study(188)	
(526)	Gupta S, Gabriel A, Shores J. The perioperative use of negative pressure wound therapy in skin grafting. Ostomy Wound Manage 2004 Apr;50(4A Suppl):32-4.			✓	Narrative	
(381)	Gustafsson R, Johnsson P, Algotsson L, Blomquist S, Ingemansson R. Vacuum-assisted closure therapy guided by C-reactive protein level in patients with deep sternal wound infection. J Thorac Cardiovasc Surg 2002 May;123(5):895-900.	✓	KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(146)	Gustafsson RI, Sjogren J, Ingemansson R. Deep Sternal Wound Infection: A Sternal-Sparing Technique with Vacuum-Assisted Closure Therapy. Ann Thorac Surg 2003;76(6):2048-2053.	✓	KQ3			
(527)	Guzzo J, Bluman EM. Technique tip: easing subatmospheric wound dressing application and increasing sponge conformity. Foot Ankle Int 2007 May;28(5):638-9.			✓	Narrative	
(528)	Gwan-Nulla DN, Casal RS. Toxic shock syndrome associated with the use of the vacuum-assisted closure device. Ann Plast Surg 2001 Nov;47(5):552-4.			✓	Case report	
(140)	Ha J, Phillips M. A retrospective review of the outcomes of vacuum-assisted closure therapy in a vascular surgery unit. Wounds 2008 Aug;20(8):221-9.	✓	KQ3			
(529)	Hallock GG, Cipolle MD, Bradow BP. Enterocutaneous fistula associated with an unrecognized retained vacuum-assisted closure sponge. Plast Reconstr Surg 2008 Aug;122(2):84e-5e.			✓	Case report	
(363)	Hamed O, Muck PE, Smith JM, Krallman K, Griffith NM. Use of vacuum-assisted closure (VAC) therapy in treating lymphatic complications after vascular procedures: new approach for lymphoceles. J Vasc Surg 2008 Dec;48(6):1520-3, 1523.e1-4.	✓	KQ3			
(530)	Hanasono MM, Skoracki RJ. Securing skin grafts to microvascular free flaps using the vacuum-assisted closure (VAC) device. Ann Plast Surg 2007 May;58(5):573-6.			✓	Narrative	
(531)	Hardcastle MR. The application of negative pressure in wound healing. Prim Intent 1998 Feb;5-10			✓	Narrative	
(532)	Hardwicke J, Paterson P. A role for vacuum-assisted closure in lower limb trauma: a proposed algorithm. Int J Low Extrem Wounds 2006 Jun;5(2):101-4.			✓	Narrative	
(533)	Harlan JW. Treatment of open sternal wounds with the vacuum-assisted closure system: a safe, reliable method. Plast Reconstr Surg 2002 Feb;109(2):710-2.			✓	Narrative	

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(534)	Hartnett JM. Use of vacuum-assisted wound closure in three chronic wounds. J Wound Ostomy Continence Nurs 1998 Nov;25(6):281-90.			✓	Fewer than five patients	
(351)	Helgeson MD, Potter BK, Evans KN, Shawen SB. Bioartificial dermal substitute: A preliminary report on its use for the management of complex combat-related soft tissue wounds. J Orthop Trauma 2007 Jul;21(6):394-9.	✓	KQ3			
(87)	Heller L, Levin SL, Butler CE. Management of abdominal wound dehiscence using vacuum assisted closure in patients with compromised healing. Am J Surg 2006 Feb;191(2):165-72.	✓	KQ3			✓
(360)	Herscovici Jr D, Sanders RW, Scaduto JM, Infante A, DiPasquale T. Vacuum-assisted wound closure (VAC therapy) for the management of patients with high-energy soft tissue injuries. J Orthop Trauma 2003;17(10):683-8.	✓	KQ3			
(94)	Hersh RE, Jack JM, Dahman MI, Morgan RF, Drake DB. The vacuum-assisted closure device as a bridge to sternal wound closure. Ann Plast Surg 2001 Mar;46(3):250-4.	✓	KQ3			✓
(535)	Hersh RE, Kaza AK, Long SM, Fiser SM, Drake DB, Tribble CG. A technique for the treatment of sternal infections using the Vacuum Assisted Closure device. Heart Surg Forum 2001;4(3):211-5.			✓	Narrative	
(536)	Heugel JR, Parks KS, Christie SS, Pulito JF, Zegzula DH, Kemalyan NA. Treatment of the exposed achilles tendon using negative pressure wound therapy: a case report. J Burn Care Rehabil 2002 May-Jun;23(3):167-71.			✓	Case report	
(537)	Heuser M, Laabs SO, Plothe KD. Extraperitoneal bladder leakage after provision of topical negative therapy: a case report. J Wound Care 2005 Oct;14(9):406.			✓	Case report	

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(538)	Hopf HW, Ueno C, Aslam R, Burnand K, Fife C, Grant L, Holloway A, Iafrati MD, Mani R, Misare B, Rosen N, Shapshak D, Benjamin Slade J Jr, West J, Barbul A. Guidelines for the treatment of arterial insufficiency ulcers. Wound Repair Regen 2006 Nov-Dec;14(6):693-710.			✓	Guideline	
(78)	Horn PL, Ruth B, Kean JR. Use of wound V.A.C. therapy in pediatric patients with infected spinal wounds: a retrospective review. Orthop Nurs 2007 Sep-Oct;26(5):317-22; quiz 323-4.	✓	KQ3			✓
(127)	Huang WS, Hsieh SC, Hsieh CS, Schoung JY, Huang T. Use of vacuum-assisted wound closure to manage limb wounds in patients suffering from acute necrotizing fasciitis. Asian J Surg 2006 Jul;29(3):135-9.	✓	Previous Systematic Reviews			
(539)	Huljev D, Kucisec-Tepes N. Necrotizing fascilitis of the abdominal wall as a post-surgical complication: a case report. Wounds 2005 Jul;17(7):169-77.			✓	Case report	
(540)	Humburg J, Holzgreve W, Hoesli I. Negative pressure wound therapy in post-cesarian superficial wound disruption: a report of 3 cases. Wounds 2006 Jun;18(6):166-9.			✓	Fewer than five patients	
(242)	Hunter JE, Teot L, Horch R, Banwell PE. Evidence-based medicine: Vacuum-assisted closure in wound care management. Int Wound J 2007 Sep;4(3):256-69.			✓	Narrative	
(541)	Hunter S, Langemo D, Hanson D, Anderson J, Thompson P. The use of negative pressure wound therapy. Adv Skin Wound Care 2007 Feb;20(2):90-5.			✓	Narrative	
(542)	Hutchinson L, Thompson J. Vacuum-assisted closure: a method of facilitating wound healing. World Counc Enteros Ther J 1999 Jul-Sep;19(3):17-21.			✓	Case reports	
(130)	Immer FF, Durrer M, Muhlemann KS, Erni D, Gahl B, Carrel TP. Deep sternal wound infection after cardiac surgery: modality of treatment and outcome. Ann Thorac Surg 2005 Sep;80(3):957-61.	✓	KQ1, KQ3, Previous Systematic Reviews			

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(543)	Isago T, Nozaki M, Kikuchi Y, Honda T, Nakazawa H. Effects of different negative pressures on reduction of wounds in negative pressure dressings. J Dermatol 2003 Aug;30(8):596-601.			✓	Animal study	
(91)	Isago T, Nozaki M, Kikuchi Y, Honda T, Nakazawa H. Negative-pressure dressings in the treatment of pressure ulcers. J Dermatol 2003 Apr;30(4):299-305.	✓	KQ3			✓
(544)	Isago T, Nozaki M, Kikuchi Y, Honda T, Nakazawa H. Skin graft fixation with negative-pressure dressings. J Dermatol 2003 Sep;30(9):673-8.			✓	Narrative	
(545)	Iusupov IuN, Epifanov MV. [Active drainage of a wound. Vestn Khir Im I I Grek 1987 Apr;138(4):42-6.			✓	Animal study	
(546)	Jacobs S, Simhaee DA, Marsano A, Fomovsky GM, Niedt G, Wu JK. Efficacy and mechanisms of vacuum-assisted closure (VAC) therapy in promoting wound healing: a rodent model. J Plast Reconstr Aesthet Surg 2008 Jul 8;Epub ahead of print.			✓	Animal study	
(547)	Jehle KS, Rohatgi A. Use of porcine dermal collagen graft and topical negative pressure on infected open abdominal wounds. J Wound Care 2007 Jan;16(1):36-7.			✓	Case report	
(246)	Jeschke MG, Rose C, Angele P, Fuchtmeier B, Nerlich MN, Bolder U. Development of new reconstructive techniques: use of Integra in combination with fibrin glue and negative-pressure therapy for reconstruction of acute and chronic wounds. Plast Reconstr Surg 2004 Feb;113(2):525-30.			✓	Not relevant – dual therapy	
(150)	Jones GA, Butler J, Lieberman I, Schlenk R. Negative-pressure wound therapy in the treatment of complex postoperative spinal wound infections: complications and lessons learned using vacuum-assisted closure. J Neurosurg Spine 2007 May;6(5):407-11.	✓	KQ3			
(548)	Jones SM, Banwell PE, Shakespeare PG. Advances in wound healing: topical negative pressure therapy. Postgrad Med J 2005 Jun;81(956):353-7.			✓	Narrative	

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(247)	Jones SM, Banwell PE, Shakespeare PG. Interface dressings influence the delivery of topical negative-pressure therapy. Plast Reconstr Surg 2005 Sep 15;116(4):1023-8.			✓	Healthy volunteers	
(113)	Joseph E, Hamori CA, Bergman S, Roaf E, Swann NF, Anastasi GW. A prospective, randomized trial of vacuum-assisted closure versus standard therapy of chronic non-healing wounds. Wounds 2000;12(3):60-7. Also available: http://www.medscape.com/viewarticle/407550_print.	✓	KQ1, KQ3			
(549)	Josty IC, Ramaswamy R, Laing JH. Vaccum assisted closure: an alternative strategy in the management of degloving injuries of the foot. Br J Plast Surg 2001 Jun;54(4):363-5.			✓	Case report	
(550)	Kadohama T, Akasaka N, Nagamine A, Nakanishi K, Kiyokawa K, Goh K, Sasajima T. Vacuum-assisted closure for pediatric post-sternotomy mediastinitis: are low negative pressures sufficient. Ann Thorac Surg 2008 Mar;85(3):1094-6.			✓	Case reports	
(343)	Kamolz LP, Andel H, Haslik W, Winter W, Meissl G, Frey M. Use of subatmospheric pressure therapy to prevent burn wound progression in human: first experiences. Burns 2004 May;30(3):253-8.	✓	KQ1, KQ3			
(25)	Kanakaris NK, Thanasas C, Keramaris N, Kontakis G, Granick MS, Giannoudis PV. The efficacy of negative pressure wound therapy in the management of lower extremity trauma: Review of clinical evidence. Injury 2007;38:S8-S10,S11-S17.	✓	Previous Systematic Reviews			
(551)	Kang GC, Yam A. Vacuum-assisted closure of a large palmar defect after debriding a midpalmar tuberculous abscess. Int Wound J 2008 Mar;5(1):45-8.			✓	Case report	
(552)	Kaplan M, Banwell P, Orgill DP, Ivatury RR, Demetriades D, Moore FA, Miller P, Nicholas J, Henry S. Guidelines for the management of the open abdomen. Wounds 2005 Oct;17(Suppl 1):S1-S24.			✓	Guideline	
(553)	Kaplan M. Abdominal compartment syndrome. Ostomy Wound Manage 2004 Apr;50(4A Suppl):20-1.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(554)	Kaplan M. Managing the open abdomen. Ostomy Wound Manage 2004 Jan;50(1A Suppl):C2, 1-8, quiz.			✓	Narrative	
(555)	Kaplan M. Negative pressure wound therapy in the management of abdominal compartment syndrome. Ostomy Wound Manage 2004 Nov;50(11A Suppl):20S-25S.			✓	Case reports	
(556)	Kaplan M. Negative pressure wound therapy in the management of abdominal compartment syndrome. Ostomy Wound Manage 2005 Feb;51(2A Suppl):29-35.			✓	Narrative	
(557)	Kaufman MW, Pahl DW. Vacuum-assisted closure therapy: wound care and nursing implications. Dermatol Nurs 2003 Aug;15(4):317-20, 323-5; quiz 326.			✓	Narrative	
(558)	Kendrick AS, Chase CW. Salvage of an infected breast tissue expander with an implant sizer and negative pressure wound management. Plast Reconstr Surg 2008 Mar;121(3):138e-139e.			✓	Case report	
(559)	Kennedy A, Van Zant RS. Diverse applications of negative pressure wound therapy: a multiple case report. Physiother Theory Pract 2006 Apr;22(2):83-90.			✓	Case reports	
(560)	Kilbride KE, Cooney DR, Custer MD. Vacuum-assisted closure: A new method for treating patients with giant omphalocele. J Pediatr Surg 2006 Jan;41(1):212-5.			✓	Fewer than five patients	
(561)	Kilpadi D, Stechmiller J, Childress B, Cowan L, Comerio M, Kieswetter K, Schultz G. Composition of wound fluid from pressure ulcers treated with negative pressure wound therapy using VAC therapy in home health or extend care patients: a pilot study. Wounds 2006;18(5):119-26.			✓	No relevant outcomes	
(562)	Kilpadi DV, Feeley TD, Kiel JW. V.A.C. Therapy normalizes vascular response of injured tissue in full-thickness wounds in rabbits. Ann Plast Surg 2007 May;58(5):555-60.			✓	Animal study	
(251)	Kim EK, Hong JP. Efficacy of negative pressure therapy to enhance take of 1-stage allodermis and a split-thickness graft. Ann Plast Surg 2007 May;58(5):536-40.			✓	Homemade device	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(563)	Kirby JP, Fantus RJ, Ward S, Sanchez O, Walker E, Mellett MM, Maltz SB, Lerner TT. Novel uses of a negative-pressure wound care system. J Trauma 2002 Jul;53(1):117-21.			✓	Narrative	
(564)	Klayman MH, Trowbridge CC, Stammers AH, Wolfgang GL, Zijerdi DA, Bitterly TJ. Autologous platelet concentrate and vacuum-assisted closure device use in a nonhealing total knee replacement. J Extra Corpor Technol 2006 Mar;38(1):44-7.			✓	Case report	
(565)	Kloth LC. 5 questions-and answers-about negative pressure wound therapy. Adv Skin Wound Care 2002 Sep-Oct;15(5):226-9.			✓	Narrative	
(566)	Koehler C, Niederbichler AD, Jung FJ, Scholz T, Labler L, Perez D, Jandali A, Comber M, Kuenzi W, Wedler V. Wound therapy using the vacuum-assisted closure device: clinical experience with novel indications. J Trauma 2008 Sep;65(3):722-31; discussion 731.			✓	No abstract available	
(567)	Kopp J, Kneser U, Bach AD, Horch RE. Buried chip skin grafting in neuropathic diabetic foot ulcers following vacuum-assisted wound bed preparation: enhancing a classic surgical tool with novel technologies. Int J Low Extrem Wounds 2004 Sep;3(3):168-71.			✓	Narrative	
(568)	Kopp J, Strnad V, Bach AD, Sauer R, Horch RE. Vacuum application increases therapeutic safety and allows intensified local radiation treatment of malignant soft-tissue tumors. Strahlenther Onkol 2005 Feb;181(2):124-30.			✓	Fewer than five patients	
(340)	Korber A, Franckson T, Grabbe S, Dissemond J. Vacuum assisted closure device improves the take of mesh grafts in chronic leg ulcer patients. Dermatology 2008;216(3):250-6.	✓	KQ1, KQ3			
(569)	Kordasiewicz LM, Schultz RO. A paraplegic with stage IV pressure ulcers: risk factors and wound care. J Wound Ostomy Continence Nurs 2003 Mar;30(2):84-9.			✓	Case report	
(570)	Kostiuchenok BM, Kolker II, Karlov VA, Ignatenko SN, Muzykant LI. Vacuum treatment in the surgical management of suppurative wounds. Vestn Khir Im I I Grek 1986 Sep;137(9):18-21.			✓	Not a NPWT device	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(73)	Kotsis T, Lioupis C. Use of vacuum assisted closure in vascular graft infection confined to the groin. Acta Chir Belg 2007 Jan-Feb;107(1):37-44.	✓	KQ3			✓
(571)	Kovacs LH, Kloeppel M, Papadopulos NA, Reeker W, Biemer E. Necrotizing fasciitis. Ann Plast Surg 2001 Dec;47(6):680-2.			✓	Case report	
(253)	Krasner DL. Managing wound pain in patients with vacuum-assisted closure devices. Ostomy Wound Manage 2002 May;48(5):38-43.			✓	Case report	
(572)	Kumar S, O'Donnell ME, Khan K, Dunne G, Carey PD, Lee J. Successful treatment of perineal necrotising fasciitis and associated pubic bone osteomyelitis with the vacuum assisted closure system. World J Surg Oncol 2008;6:67.			✓	Case report	
(364)	Labanaris AP, Polykandriotis E, Horch RE. The effect of vacuum-assisted closure on lymph vessels in chronic wounds. J Plast Reconstr Aesthet Surg 2008 Jun 2;Epub ahead of print.	✓	KQ3			
(370)	Labler L, Keel M, Trentz O, Heinzelmann M. Wound conditioning by vacuum assisted closure (V.A.C.) in postoperative infections after dorsal spine surgery. Eur Spine J 2006 Sep;15(9):1388-96.	✓	KQ3			
(71)	Labler L, Keel M, Trentz O. Vacuum-assisted closure (VAC) for temporary coverage of soft-tissue injury in type III open fracture of lower extremities. Eur J Trauma 2004;30(5):305-12.	✓	KQ1, KQ3			✓
(352)	Labler L, Trentz O. The use of vacuum assisted closure (VAC™) in soft tissue injuries after high energy pelvic trauma. Langenbecks Arch Surg 2007 Sep;392(5):601-9.	✓	KQ3			
(357)	Labler L, Zwingmann J, Mayer D, Stocker R, Trentz O, Keel M. V.A.C. Abdominal Dressing System: A temporary closure for open abdomen. Eur J Trauma 2005 Oct;31(5):488-94.	✓	KQ3			
(573)	Lam WL, Garrido A, Stanley PR. Use of topical negative pressure in the treatment of chronic osteomyelitis. A case report. J Bone Joint Surg Am 2005 Mar;87(3):622-4.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(256)	Lambert KV, Hayes P, McCarthy M. Vacuum assisted closure: a review of development and current applications. Eur J Vasc Endovasc Surg 2005 Mar;29(3):219-26.			✓	Narrative	
(574)	Langley-Hawthorne C. Economics of negative pressure wound therapy. Ostomy Wound Manage 2004 Apr;50(4A Suppl):35-7.			✓	Narrative	
(575)	Laverty D, DeFranzo A. Negative pressure wound therapy in the management of orthopedic wounds. Ostomy Wound Manage 2004 Nov;50(11A Suppl):18S-19S.			✓	Narrative	
(576)	Lavery L. Disease management programs: can they make a difference?. APMA News 2005 May;26(5-Suppl):27-29.			✓	Narrative	
(577)	Lavery L. Treating heel pressure unlcers with NPWT. APMA News 2005 May;26(5-Suppl):13-15.			✓	Narrative	
(257)	Lavery LA, Barnes SA, Keith MS, Seaman JW Jr, Armstrong DG. Prediction of healing for postoperative diabetic foot wounds based on early wound area progression. Diabetes Care 2008 Jan;31(1):26-9.			✓	Duplicate study(109)	
(341)	Lavery LA, Boulton AJ, Niezgoda JA, Sheehan P. A comparison of diabetic foot ulcer outcomes using negative pressure wound therapy versus historical standard of care. Int Wound J 2007 Jun;4(2):103-13.	✓	KQ1, KQ3			
(578)	Lee AT, Fanton GS, McAdams TR. Acute compartment syndrome of the thigh in a football athlete: a case report and the role of the vacuum-assisted wound closure dressing. J Orthop Trauma 2005 Nov-Dec;19(10):748-50.			✓	Case report	
(374)	Lee SS, Lin SD, Chen HM, Lin TM, Yang CC, Lai CS, Chen YF, Chiu CC. Management of intractable sternal wound infections with topical negative pressure dressing. J Card Surg 2005 May-Jun;20(3):218-22.	✓	KQ3			
(579)	Leijnen M, Steenvoorde P, van Doorn L, Zeillemaker AM, da Costa SA, Oskam J. Does VAC increase the risk of venous thromboembolism. J Wound Care 2007 May;16(5):211-2.			✓	No abstract available	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(111)	Leininger BE, Rasmussen TE, Smith DL, Jenkins DH, Coppola C. Experience with wound VAC and delayed primary closure of contaminated soft tissue injuries in Iraq. J Trauma 2006 Nov;61(5):1207-11.	✓	KQ1, KQ3			
(580)	Lemaire V, Brilmaker J, Kerzmann A, Jacquemin D. Treatment of a groin lymphatic fistula with negative pressure wound therapy. Eur J Vasc Endovasc Surg 2008 Oct;36(4):449-51.			✓	Case report	
(581)	Lemmon JA, Ahmad J, Ghavami A, Bidic SM. Vacuum-assisted closure over an external fixation device. Plast Reconstr Surg 2008 Apr;121(4):234e-5e.			✓	Case report	
(582)	Lentz S. Use of the vacuum-assisted closure system in management of the gynecologic surgical wound: a case report. J Pelvic Med Surg 2002 Jan;8(1):53-6.			✓	Case report	
(583)	Levin LS. Principles of definitive soft tissue coverage with flaps. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S161-6.			✓	Narrative	
(584)	Liao EC, Breuing KH. Breast mound salvage using vacuum-assisted closure device as bridge to reconstruction with inferolateral AlloDerm hammock. Ann Plast Surg 2007 Aug;59(2):218-24.			✓	No abstract available	
(585)	Lindstedt S, Malmsjo M, Gesslein B, Ingemansson R. Evaluation of continuous and intermittent myocardial topical negative pressure. J Cardiovasc Med (Hagerstown) 2008 Aug;9(8):813-9.			✓	Animal study	
(586)	Lindstedt S, Malmsjo M, Gesslein B, Ingemansson R. Topical negative pressure effects on coronary blood flow in a sternal wound model. Int Wound J 2008 Oct;5(4):503-9.			✓	Animal study	
(587)	Lindstedt S, Malmsjo M, Ingemansson R. Blood flow changes in normal and ischemic myocardium during topically applied negative pressure. Ann Thorac Surg 2007 Aug;84(2):568-73.			✓	Animal study	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(588)	Lindstedt S, Malmsjo M, Ingemansson R. No hypoperfusion is produced in the epicardium during application of myocardial topical negative pressure in a porcine model. J Cardiothorac Surg 2007;2:53.			✓	Animal study	
(589)	Lindstedt S, Malmsjo M, Sjogren J, Gustafsson R, Ingemansson R. Impact of different topical negative pressure levels on myocardial microvascular blood flow. Cardiovasc Revasc Med 2008 Jan-Mar;9(1):29-35.			✓	Animal study	
(590)	Lindstedt S, Paulsson P, Mokhtari A, Gesslein B, Hlebowicz J, Malmsjo M, Ingemansson R. A compare between myocardial topical negative pressure levels of -25 mmHg and -50 mmHg in a porcine model. BMC Cardiovasc Disord 2008;8:14.			✓	Animal study	
(591)	Literature review on Negative pressure wound therapy submission to AHRQ by the Association for the Advancement of Wound Care (AAWC) [unpublished]. 140 p.			✓	Table of Contents	
(259)	Llanos S, Danilla S, Barraza C, Armijo E, Pineros JL, Quintas M, Searle S, Calderon W. Effectiveness of negative pressure closure in the integration of split thickness skin grafts: a randomized, double-masked, controlled trial. Ann Surg 2006 Nov;244(5):700-5.			√	Homemade device	
(592)	Loos B, Kopp J, Hohenberger W, Horch RE. Post-malignancy irradiation ulcers with exposed alloplastic materials can be salvaged with topical negative pressure therapy (TNP). Eur J Surg Oncol 2007 Sep;33(7):920-5.			✓	Fewer than five patients	
(593)	Lopez Almodovar LF, Bustos G, Lima P, Canas A, Paredes I, Buendia JA. Transverse plate fixation of sternum: a new sternal-sparing technique. Ann Thorac Surg 2008 Sep;86(3):1016-7.			✓	Case reports	
(365)	Lopez G, Clifton-Koeppel R, Emil S. Vacuum-assisted closure for complicated neonatal abdominal wounds. J Pediatr Surg 2008 Dec;43(12):2202-7.	✓	KQ3			
(594)	Lynch JB, Laing AJ, Regan PJ. Vacuum-assisted closure therapy: a new treatment option for recurrent pilonidal sinus disease. Report of three cases. Dis Colon Rectum 2004 Jun;47(6):929-32.			✓	Case reports	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(74)	Machen MS. Management of traumatic war wounds using vacuum-assisted closure dressings in an austere environment. Army Med Dept J 2007 Jan-Mar;17-23.	✓	KQ3			✓
(595)	Maguina P, Kalimuthu R. Posterior rectal hernia after vacuum-assisted closure treatment of sacral pressure ulcer. Plast Reconstr Surg 2008 Jul;122(1):46e-47e.			✓	Case report	
(596)	Malli S. Keep a close eye on vacuum-assisted wound closure. Nursing 2005 Jul;35(7):25.			✓	Case report	
(597)	Malmsjo M, Ingemansson R, Sjogren J. Mechanisms governing the effects of vacuum-assisted closure in cardiac surgery. Plast Reconstr Surg 2007 Oct;120(5):1266-75.			✓	Narrative	
(598)	Mandal A, Addison P, Stewart K, Neligan P. Vacuum-assisted closure therapy on pyoderma gangrenosum. J Plast Surg 2006 Apr;28(8):529-31.			✓	Fewer than five patients	
(599)	Mandal A. Role of topical negative pressure in pressure ulcer management. J Wound Care 2007 Jan;16(1):33-5.			✓	Narrative	
(600)	Marathe US, Sniezek JC. Use of the vacuum-assisted closure device in enhancing closure of a massive skull defect. Laryngoscope 2004 Jun;114(6):961-4.			✓	Case report	
(601)	Marsh DJ, Abu-Sitta G, Patel H. The role of vacuum-assisted wound closure in blast injury. Plast Reconstr Surg 2007 May;119(6):1978-9.			✓	No abstract available	
(602)	Matzi V, Lindenmann J, Porubsky C, Neuboeck N, Maier A, Smolle-Juettner FM. Intrathoracic insertion of the VAC device in a case of pleural empyema 20 years after pneumonectomy. Ann Thorac Surg 2007 Nov;84(5):1762-4.			✓	Not relevant	
(120)	McCallon SK, Knight CA, Valiulus JP, Cunningham MW, McCulloch JM, Farinas LP. Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. Ostomy Wound Manage 2000 Aug;46(8):28-32, 34.	✓	KQ1, KQ3			

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(142)	McCord SS, Naik-Mathuria BJ, Murphy KM, McLane KM, Gay AN, Bob Basu C, Downey CR, Hollier LH, Olutoye OO. Negative pressure therapy is effective to manage a variety of wounds in infants and children. Wound Repair Regen 2007 May-Jun;15(3):296-301.	✓	KQ3			
(603)	McEwan W, Brown TL, Mills SM, Muller MJ. Suction dressings to secure a dermal substitute. Burns 2004 May;30(3):259-61.			✓	Narrative	
(604)	McGuinness JG, Winter DC, O'Connell PR. Vacuum-assisted closure of a complex pilonidal sinus. Dis Colon Rectum 2003 Feb 1;46(2):274-6.			✓	Case report	
(605)	McNulty A.K., Schmidt, M., Feeley, Teri, Villaneuva, P., Kieswetter, K. 2009. Effects of negative pressure wound therapy on cellular energetics in fibroblasts grown in a provisional wound (fibrin) matrix [In Press]. Wound Repair Regen			✓	In vitro	
(606)	McNulty AK, Schmidt M, Feeley T, Kieswetter K. Effects of negative pressure wound therapy on fibroblast viability, chemotactic signaling, and proliferation in a provisional wound (fibrin) matrix. Wound Repair Regen 2007 Nov-Dec;15(6):838-46.			✓	In vitro	
(607)	Meara JG, Guo L, Smith JD, Pribaz JJ, Breuing KH, Orgill DP. Vacuum-assisted closure in the treatment of degloving injuries. Ann Plast Surg 1999 Jun;42(6):589-94.			✓	Narrative	
(376)	Mehbod AA, Ogilvie JW, Pinto MR, Schwender JD, Transfeldt EE, Wood KB, Le Huec JC, Dressel T. Postoperative deep wound infections in adults after spinal fusion: Management with vacuum-assisted wound closure. J Spinal Disord Tech 2005;18(1):14-7.	✓	KQ3			
(608)	Mendez-Eastman S. Give stubborn wounds a helping hand. Nursing Made Incredibly Easy 2007 Sep;5(5):18-20.			✓	Narrative	
(609)	Mendez-Eastman S. Guidelines for using negative pressure wound therapy. Adv Skin Wound Care 2001 Nov-Dec;14(6):314-22; quiz 324-5.			✓	Guideline	

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(610)	Mendez-Eastman S. Negative pressure wound therapy. Plast Surg Nurs 1998 Spring;18(1):27-9, 33-7.			✓	Narrative	
(611)	Mendez-Eastman S. New treatment for an old problem: negative-pressure wound therapy. Nursing 2002 May;32(5):58-63; quiz 64.			✓	Narrative	
(612)	Mendez-Eastman S. Use of hyperbaric oxygen and negative pressure therapy in the multidisciplinary care of a patient with nonhealing wounds. J Wound Ostomy Continence Nurs 1999 MAR;26(2):67-76.			✓	Case report	
(375)	Mendonca DA, Cosker T, Makwana NK. Vacuum-assisted closure to aid wound healing in foot and ankle surgery. Foot Ankle Int 2005 Sep;26(9):761-6.	✓	KQ3			
(143)	Mendonca DA, Drew PJ, Harding KG, Price PE. A pilot study on the effect of topical negative pressure on quality of life. J Wound Care 2007 Feb;16(2):49-53.	✓	KQ3			
(187)	Mendonca DA, Papini R, Price PE. Negative-pressure wound therapy: a snapshot of the evidence. Int Wound J 2006 Dec;3(4):261-71.	✓	Previous Systematic Reviews			
(613)	Meyer W, Schmiden, V. Bier's hyperemic treatment in surgery, medicine and the specialties a manual of it's practical application. 2nd ed. Philadelphia: W.B. Saunders Company;			✓	Duplicate(614)	
(614)	Meyer W, Schmieden V. Biers hyperemic treatment. Philadelphia: W.B. Saunders Company; 78-153 p.			✓	Narrative	
(281)	Miller PR, Thompson JT, Faler BJ, Meredith JW, Chang MC. Late fascial closure in lieu of ventral hernia: the next step in open abdomen management. J Trauma 2002 Nov;53(5):843-9.	✓		✓	Study arms both received V.A.C.®	
(281)	Miller PR, Thompson JT, Faler BJ, Meredith JW, Chang MC. Late fascial closure in lieu of ventral hernia: the next step in open abdomen management. J Trauma 2002 Nov;53(5):843-9.			✓	Case report	
(615)	Miller Q, Bird E, Bird K, Meschter C, Moulton MJ. Effect of subatmospheric pressure on the acute healing wound. Curr Surg 2004 Mar-Apr;61(2):205-8.			✓	Animal study	

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(112)	Moisidis E, Heath T, Boorer C, Ho K, Deva AK. A prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in skin grafting. Plast Reconstr Surg 2004 Sep 15;114(4):917-22.	✓	KQ1,KQ3			
(366)	Mokhtari A, Sjogren J, Nilsson J, Gustafsson R, Malmsjo M, Ingemansson R. The cost of vacuum-assisted closure therapy in treatment of deep sternal wound infection. Scand Cardiovasc J 2008;42(1):85-9.	✓	KQ3			
(388)	Molnar JA, DeFranzo AJ, Hadaegh A, Morykwas MJ, Shen P, Argenta LC. Acceleration of integra incorporation in complex tissue defects with subatmospheric pressure. Plast Reconstr Surg 2004 Apr 15;113(5):1339-46.	✓	KQ3			
(616)	Molnar JA, DeFranzo AJ, Marks MW. Single-stage approach to skin grafting the exposed skull. Plast Reconstr Surg 2000 Jan;105(1):174-7.			✓	Fewer than five patients	
(617)	Molnar JA, Simpson JL, Voignier DM, Morykwas MJ, Argenta LC. Management of an acute thermal injury with subatmospheric pressure. J Burns Wounds 2005;4:e5.			✓	Case report	
(618)	Molnar JA. Applications of negative pressure wound therapy to thermal injury. Ostomy Wound Manage 2004 Apr;50(4A Suppl):17-9.			✓	Narrative	
(619)	Montecamozzo G, Leopaldi E, Baratti C, Previde P, Ferla F, Pizzi M, Sposato J, Pariani D, Sartani A, Trabucchi E. Incarcerated massive incisional hernia: extensive necrosis of the colon in a very obese patient. Surgical treatment and vacuum-assisted closure therapy: a case report. Hernia 2008 Dec;12(6):641-3.			✓	Case report	
(79)	Mooney JF 3rd, Argenta LC, Marks MW, Morykwas MJ, DeFranzo AJ. Treatment of soft tissue defects in pediatric patients using the V.A.C. system. Clin Orthop Relat Res 2000 Jul;(376):26-31.	✓	KQ3			✓
(620)	Moore K. VAC therapy: interactions in the healing process. Wounds UK 2005 May;1(1):86-90.			✓	Narrative	

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(621)	Moran SG, Windham ST, Cross JM, Melton SM, Rue LW 3rd. Vacuum-assisted complex wound closure with elastic vessel loop augmentation: a novel technique. J Wound Care 2003 Jun;12(6):212-3.			✓	Narrative	
(622)	Moreno-Coutino G, Estrada-Chavez G, Dominguez-Cherit J. Hip ulcer secondary to foreign body reaction and vacuum-assisted closure therapy: report of a case. Int Wound J 2005 Mar;2(1):81-3.			✓	Case report	
(623)	Morris GS, Brueilly KE, Hanzelka H. Negative pressure wound therapy achieved by vacuum-assisted closure: Evaluating the assumptions. Ostomy Wound Manage 2007 Jan;53(1):52-7.			✓	Narrative	
(624)	Morton N. Use of topical negative pressure therapy in postoperative dehisced or infected wounds. J Wound Care 2004 Sep;13(8):346-8.			✓	Narrative	
(33)	Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Ann Plast Surg 1997 Jun;38(6):553-62.			✓	Animal study	
(625)	Morykwas MJ, Argenta LC. Nonsurgical modalities to enhance healing and care of soft tissue wounds. J South Orthop Assoc 1997 Winter;6(4):279-88.			✓	Narrative	
(626)	Morykwas MJ, David LR, Schneider AM, Whang C, Jennings DA, Canty C, Parker D, White WL, Argenta LC. Use of subatmospheric pressure to prevent progression of partial-thickness burns in a swine model. J Burn Care Rehabil 1999 Jan-Feb;20(1 Pt 1):15-21.			✓	Animal study	
(36)	Morykwas MJ, Faler BJ, Pearce DJ, Argenta LC. Effects of varying levels of subatmospheric pressure on the rate of granulation tissue formation in experimental wounds in swine. Ann Plast Surg 2001 Nov;47(5):547-51.			✓	Animal study	
(627)	Morykwas MJ, Howell H, Bleyer AJ, Molnar JA, Argenta LC. The effect of externally applied subatmospheric pressure on serum myoglobin levels after a prolonged crush/ischemia injury. J Trauma 2002 Sep;53(3):537-40.			✓	Animal study	

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(628)	Morykwas MJ, Kennedy A, Argenta JP, Argenta LC. Use of subatmospheric pressure to prevent doxorubicin extravasation ulcers in a swine model. J Surg Oncol 1999 SEP;72(1):14-7.			✓	Animal study	
(629)	Morykwas MJ, Simpson J, Punger K, Argenta A, Kremers L, Argenta J. Vacuum-assisted closure: state of basic research and physiologic foundation. Plast Reconstr Surg 2006 Jun;117(7 Suppl):121S-126S.			✓	Narrative	
(630)	Motta GJ, Corbett LQ. Impact of an antimicrobial gauze upon bacterial colonies in wounds that require packing. Ostomy Wound Manage 2004 Aug;50(8):48-62.			✓	Narrative	
(136)	Moues CM, van den Bemd GJ, Heule F, Hovius SE. Comparing conventional gauze therapy to vacuum-assisted closure wound therapy: a prospective randomised trial. J Plast Reconstr Aesthet Surg 2007;60(6):672-81.	✓	KQ1, KQ3			
(285)	Moues CM, van den Bemd GJ, Meerding WJ, Hovius SE. An economic evaluation of the use of TNP on full-thickness wounds. J Wound Care 2005 May;14(5):224-7.			✓	Duplicate study(38)	
(631)	Moues CM, van Toorenenbergen AW, Heule F, Hop WC, Hovius SE. The role of topical negative pressure in wound repair: expression of biochemical markers in wound fluid during wound healing. Wound Repair Regen 2008 Jul-Aug;16(4):488-94.			✓	No relevant outcomes	
(38)	Moues CM, Vos MC, van den Bemd GJ, Stijnen T, Hovius SE. Bacterial load in relation to vacuum-assisted closure wound therapy: a prospective randomized trial. Wound Repair Regen 2004 Jan-Feb;12(1):11-7.			✓	Duplicate study(136)	
(389)	Mullner T, Mrkonjic L, Kwasny O, Vecsei V. The use of negative pressure to promote the healing of tissue defects: a clinical trial using the vacuum sealing technique. Br J Plast Surg 1997 Apr;50(3):194-9.	✓	KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(632)	Nagell CF, Holte K. Treatment of anastomotic leakage after rectal resection with transrectal vacuum-assisted drainage (VAC). A method for rapid control of pelvic sepsis and healing. Int J Colorectal Dis 2006 Oct;21(7):657-60.			✓	Fewer than five patients in study arm	
(633)	Neubauer G, Ujlaky R. The cost-effectiveness of topical negative pressure versus other wound-healing therapies. J Wound Care 2003 Nov;12(10):392-3.			✓	No abstract available available	
(634)	Newton H, Benbow M, Hampton S, Beldon P, Butcher M, Baxter H. TNP therapy in the community: findings of a national survey. Wounds UK 2006 Dec;2(4):31-5.			✓	Narrative	
(635)	Ng R, Sebastin SJ, Tihonovs A, Peng YP. Hand in glove--VAC dressing with active mobilisation. J Plast Reconstr Aesthet Surg 2006;59(9):1011-3.			✓	Narrative	
(636)	Nienhuijs SW, Manupassa R, Strobbe LJ, Rosman C. Can topical negative pressure be used to control complex enterocutaneous fistulae. J Wound Care 2003 Oct;12(9):343-5.			✓	Not relevant	
(637)	Niezgoda JA, Mendez-Eastman S. The effective management of pressure ulcers. Adv Skin Wound Care 2006 Jan-Feb;19 Suppl 1:3-15.			✓	Narrative	
(638)	Niezgoda JA. Combining negative pressure wound therapy with other wound management modalities. Ostomy Wound Manage 2005 Feb;51(2A Suppl):36-8.			✓	Narrative	
(639)	Niezgoda JA. Incorporating negative pressure therapy into the management strategy for pressure ulcers. Ostomy Wound Manage 2004 Nov;50(11A Suppl):26-9.			✓	Case reports	
(640)	Niezgoda JA. The economic value of negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):44-7.			✓	Narrative	
(641)	No Authors. Position Document: Topical negative pressure in wound management. European Wound Management 2007 May;1-17.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(642)	No Authors. Topical negative pressure for chronic wounds? Drugs and Therapeutics Bulletin 2007 Aug;45(8):57-61.			✓	Narrative	
(643)	No Authors. V.A.C. Therapy: Proceedings of the 2nd World Union of Wound Healing Societies Meeting (8-13 July 2004, Paris France). Wounds 2004 Dec;16(12-Suppl A):1-19.			✓	Narrative	
(70)	Noble-Bell G, Forbes A. A systematic review of the effectiveness of negative pressure wound therapy in the management of diabetes foot ulcers. Int Wound J 2008 Jun;5(2):233-42.	✓	Previous Systematic Reviews			✓
(644)	Norbury K, Kieswetter K. Vacuum-assisted closure therapy attenuates the inflammatory response in a porcine acute wound healing model. Wounds 2007 Apr;19(4):97-106.			✓	Animal study	
(645)	Norton SE, De Souza B, Marsh D, Moir G. Vacuum-assisted closure (VAC Therapy) and the risk of fluid loss in acute trauma. Ann Plast Surg 2006 Feb;56(2):194-5.			✓	Case report	
(646)	NPWT Info and history of NPWT. St. Petersburg (FL): Smith & Nephew, Inc.; 2009 Feb. 13 p.			✓	Background information	
(647)	Nugent N, Lannon D, O'Donnell M. Vacuum-assisted closure – a management option for the burns patient with exposed bone. Burns 2005 May;31(3):390-3.			✓	Case reports	
(648)	Obdeijn MC, de Lange MY, Lichtendahl DH, de Boer WJ. Vacuum-assisted closure in the treatment of poststernotomy mediastinitis. Ann Thorac Surg 1999 Dec;68(6):2358-60.			✓	Fewer than five patients	
(377)	O'Connor J, Kells A, Henry S, Scalea T. Vacuum-assisted closure for the treatment of complex chest wounds. Ann Thorac Surg 2005 Apr;79(4):1196-200.	✓	KQ3			
(649)	Oczenski W, Waldenberger F, Nehrer G, Kneifel W, Swoboda H, Schwarz S, Fitzgerald RD. Vacuum-assisted closure for the treatment of cervical and mediastinal necrotizing fasciitis. J Cardiothorac Vasc Anesth 2004 Jun;18(3):336-8.			✓	Narrative	

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(10)	Orgill DP, Austen WG Jr, Butler CE, Fine NA, Horvath KA, Mihaljevic T, Song DH, Wolfe WG. Guidelines for the treatment of complex chest wounds with negative pressure wound therapy. Wounds 2004 Dec;(Suppl B):1-23.			✓	Guideline	
(20)	Orgill DP. Advancing the treatment options of chest wounds with negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):39-43.			✓	Narrative	
(650)	Orgill DP. Utilizing negative pressure wound therapy on open chest/sternotomy wounds. Ostomy Wound Manage 2004 Nov;50(11A Suppl):15S-17S.			✓	Case report	
(651)	O'Rourke ME. Vacuum-assisted closure therapy. Clin J Oncol Nurs 2006 Dec;10(6):825-6.			✓	No abstract available	
(652)	Ovington LG. 1,2,3 s-t-r-e-t-c-h; vacuum-enhances wound closure. Adv Wound Care 1999 Jan;(Suppl):125-7.			✓	Narrative	
(653)	Ozer K, Smith W. A simple technique for applying vacuum-assisted closure therapy over the circular type external fixation device. Ann Plast Surg 2006 Jun;56(6):693-4.			✓	Case report	
(1)	Page JC, Newswander B, Schwenke DC, Hansen M, Ferguson J. Retrospective analysis of negative pressure wound therapy in open foot wounds with significant soft tissue defects. Adv Skin Wound Care 2004 Sep;17(7):354-64.	✓	KQ1,KQ3			
(654)	Page JC. Utilizing NPWT for large soft tissue defects. APMA News 2005 May;26(5 Suppl):30-2.			✓	Narrative	
(655)	Pape HC, Webb LX. History of open wound and fracture treatment. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S133-4.			✓	Narrative	
(296)	Parrett BM, Matros E, Pribaz JJ, Orgill DP. Lower extremity trauma: Trends in the management of soft-tissue reconstruction of open tibia-fibula fractures. Plast Reconstr Surg 2006 Apr 1;117(4):1315-22.			✓	Narrative	

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(656)	Patane F, Zingarelli E, Sansone F, Cappuccio G, Rinaldi M. Vacuum-assisted sternal closure after a 'depression induced ischemic test' in severe mediastinitis. J Cardiovasc Med (Hagerstown) 2008 Jun;9(6):622-4.			✓	Case report	
(657)	Patel CT, Kinsey GC, Koperski-Moen KJ, Bungum LD. Vacuum-assisted wound closure. Am J Nurs 2000 Dec;100(12):45-8.			✓	Case report	
(658)	Pattison PS, Gordon JK, Muto PM, Mallen JK, Hoerner J. Case report: using dual therapies-negative pressure wound therapy and modified silicone gel liner-to treat a limb postamputation and dehiscence. Wounds 2005 Aug;17(8):233-40.			✓	Case report	
(41)	Paul JC. Vacuum assisted closure therapy: a must in plastic surgery. Plast Surg Nurs 2005 April/June;25(2):61-65.			✓	Case report	
(298)	Peinemann F, McGauran N, Sauerland S, Lange S. Disagreement in primary study selection between systematic reviews on negative pressure wound therapy. BMC Med Res Methodol 2008;8:41.			✓	Methodology paper	
(189)	Peinemann F, McGauran N, Sauerland S, Lange S. Negative pressure wound therapy: Potential publication bias caused by lack of access to unpublished study results data. BMC Med Res Methodol 2008;(8):Article Number: 4.	✓	Previous Systematic Reviews			
(371)	Pelham FR, Kubiak EN, Sathappan SS, Di Cesare PE. Topical negative pressure in the treatment of infected wounds with exposed orthopaedic implants. J Wound Care 2006 Mar;15(3):111-6.	✓	KQ3			
(659)	Penn E, Rayment S. Management of a dehisced abdominal wound with VAC therapy. Br J Nurs 2004 Feb 26-Mar 10;13(4):194-201.			✓	Case report	
(95)	Perez D, Wildi S, Demartines N, Bramkamp M, Koehler C, Clavien PA. Prospective evaluation of vacuum-assisted closure in abdominal compartment syndrome and severe abdominal sepsis. J Am Coll Surg 2007 Oct;205(4):586-92.	✓	KQ3			✓

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(660)	Petersson U, Acosta S, Bjorck M. Vacuum-assisted wound closure and mesh-mediated fascial traction--a novel technique for late closure of the open abdomen. World J Surg 2007 Nov;31(11):2133-7.			✓	Not relevant	
(661)	Petrie N, Potter M, Banwell P. The management of lower extremity wounds using topical negative pressure. Int J Low Extrem Wounds 2003 Dec;2(4):198-206.			✓	Narrative	
(662)	Petzina R, Ugander M, Gustafsson L, Engblom H, Hetzer R, Arheden H, Ingemansson R, Malmsjo M. Topical negative pressure therapy of a sternotomy wound increases sternal fluid content but does not affect internal thoracic artery blood flow: assessment using magnetic resonance imaging. J Thorac Cardiovasc Surg 2008 May;135(5):1007-13.			✓	Animal study	
(663)	Petzina R, Ugander M, Gustafsson L, Engblom H, Sjogren J, Hetzer R, Ingemansson R, Arheden H, Malmsjo M. Hemodynamic effects of vacuum-assisted closure therapy in cardiac surgery: assessment using magnetic resonance imaging. J Thorac Cardiovasc Surg 2007 May;133(5):1154-62.			✓	Animal study	
(176)	Pham CT, Middleton PF, Maddern GJ. The safety and efficacy of topical negative pressure in non-healing wounds: a systematic review. J Wound Care 2006 Jun;15(6):240-50.	✓	Previous Systematic Reviews			
(664)	Phelps JR, Fagan R, Pirela-Cruz MA. A case study of negative pressure wound therapy to manage acute necrotizing fasciitis. Ostomy Wound Manage 2006 Mar;52(3):54-9.			✓	Case report	
(665)	Philbeck TE Jr, Whittington KT, Millsap MH, Briones RB, Wight DG, Schroeder WJ. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients. Ostomy Wound Manage 1999 Nov;45(11):41-50.			✓	Patients treated with dual therapies	
(666)	Philbeck TE, Schroeder WJ, Whittington KT. Vacuum-assisted closure therapy for diabetic foot ulcers: clinical and cost analyses. Home Health Care Consult 2001 Mar;8(3):27-34.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(667)	Pirela-Cruz MA, Machen MS, Esquivel D. Management of large soft-tissue wounds with negative pressure therapy-lessons learned from the war zone. J Hand Ther 2008 Apr-Jun;21(2):196-202; quiz 203.			✓	Narrative	
(668)	Plikaitis CM, Molnar JA. Subatmospheric pressure wound therapy and the vacuum-assisted closure device: basic science and current clinical successes. Expert Rev Med Devices 2006 Mar;3(2):175-84.			✓	Narrative	
(80)	Ploumis A, Mehbod AA, Dressel TD, Dykes DC, Transfeldt EE, Lonstein JE. Therapy of spinal wound infections using vacuum-assisted wound closure: risk factors leading to resistance to treatment. J Spinal Disord Tech 2008 Jul;21(5):320-3.	✓	KQ3			✓
(669)	Pollak AN. Use of negative pressure wound therapy with reticulated open cell foam for lower extremity trauma. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S142-5.			✓	Narrative	
(670)	Poulakidas S, Cologne K, Kowal-Vern A. Treatment of frostbite with subatmospheric pressure therapy. J Burn Care Res 2008 Nov-Dec;29(6):1012-4.			✓	Case report	
(671)	Poulakidas S, Kowal-Vern A. Facilitating residual wound closure after partial graft loss with vacuum assisted closure therapy. J Burn Care Res 2008 Jul-Aug;29(4):663-5.			✓	Case report	
(672)	Powell ET 4th. The role of negative pressure wound therapy with reticulated open cell foam in the treatment of war wounds. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S138-41.			✓	Narrative	
(673)	Principles of best practice: vacuum assisted closure: recommendations for use. A consensus document. [internet]. The Medical Education Partnership (MEP); 2008 Jun [10]. Available: http://www.mepltd.co.uk/oneoffsdetail.html?p=vaccon.			✓	Guideline	
(301)	Pu LL. An alternative approach for soft-tissue coverage of a complex wound in the foot and ankle with vacuum-assisted closure over artificial dermis and subsequent skin graft. J Plast Reconstr Aesthet Surg 2008 Nov 20;Epub ahead of print.			✓	Narrative	

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(674)	Quah HM, Maw A, Young T, Hay DJ. Vacuum-assisted closure in the management of the open abdomen: a report of a case and initial experiences. J Tissue Viability 2004 Apr;14(2):59-62.			✓	Case report	
(186)	Raja SG, Berg GA. Should vacuum-assisted closure therapy be routinely used for management of deep sternal wound infection after cardiac surgery. Interact Cardiovasc Thorac Surg 2007 Aug;6(4):523-7.	✓	Previous Systematic Reviews			
(675)	Ramnarine IR, McLean A, Pollock JC. Vacuum-assisted closure in the paediatric patient with post-cardiotomy mediastinitis. Eur J Cardiothorac Surg 2002 Dec;22(6):1029-31.			✓	Case report	
(163)	Rao M, Burke D, Finan PJ, Sagar PM. The use of vacuum-assisted closure of abdominal wounds: a word of caution. Colorectal Dis 2007 Mar;9(3):266-8.	✓	KQ3			
(676)	Rapp SM. Negative pressure wound therapy reduces infections in lower extremity fractures. Orthop Today 2008 Feb;28(54) Also available: http://www.orthosupersite.com/print.asp?rID=26142. Accessed on Feb 7, 2008.			✓	Narrative	
(677)	Reed SF, Novosel TJ, Weireter LJ, Collins JN, Britt RC, Alvey C, Merkh K, Britt LD. A novel technique for vacuum assisted closure on injured tissue or in confined spaces. J Trauma 2008 May;64(5):1406-7.			✓	Narrative	
(678)	Reed T, Economon D, Wiersema-Bryant L. Colocutaneous fistula management in a dehisced wound: a case study. Ostomy Wound Manage 2006 Apr;52(4):60-4, 66.			✓	Case report	
(679)	Reid DJ, Linneman P, Lentz CW. Negative pressure dressing to secure skin grafts. Surg Phys Assist 2001 Feb;9-13.			✓	Case report	
(680)	Reisler T. A simple method of securing an interface dressing and vacuum-assisted closure foam pad to difficult wounds. Ann Plast Surg 2007 Aug;59(2):230-1.			✓	Narrative	

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(681)	Reitsma AM, Rhodeheaver GT. Effectiveness of a new antimicrobial gauze dressing as a bacterial barrier. [internet]. Charlottesville (VA): University of Virginia Health System; 2001 Sep 1 Available: http://www.kendallhq.com/imageServer.aspx?contentID=7598&contenttype=application/pdf.			✓	Narrative	
(682)	Renner R, Rogalski C, Friedlein H, Simon JC. [Vacuum therapy in dermatology: a review. J Dtsch Dermatol Ges 2006 Jun;4(6):468-76.			✓	Narrative	
(683)	Repta R, Ford R, Hoberman L, Rechner B. The use of negative-pressure therapy and skin grafting in the treatment of soft-tissue defects over the Achilles tendon. Ann Plast Surg 2005 Oct;55(4):367-70.			✓	Fewer than five patients	
(684)	Rhee P, Velmahos GC. Traumatic wounds. Ostomy Wound Manage 2004 Apr;50(4A Suppl):22-5.			✓	Case report	
(121)	Rinker B, Amspacher JC, Wilson PC, Vasconez HC. Subatmospheric pressure dressing as a bridge to free tissue transfer in the treatment of open tibia fractures. Plast Reconstr Surg 2008 May;121(5):1664-73.	✓	KQ1, KQ3			
(685)	Robson MC, Cooper DM, Aslam R, Gould LJ, Harding KG, Margolis DJ, Ochs DE, Serena TE, Snyder RJ, Steed DL, Thomas DR, Wiersma-Bryant L. Guidelines for the treatment of venous ulcers. Wound Repair Regen 2006 Nov-Dec;14(6):649-62.			✓	Guideline	
(89)	Rosenthal EL, Blackwell KE, McGrew B, Carroll WR, Peters GE. Use of negative pressure dressings in head and neck reconstruction. Head Neck 2005 Nov;27(11):970-5.	✓	KQ3			✓
(686)	Rosser CJ, Morykwas MJ, Argenta LC, Bare RL. A new technique to manage perineal wounds. Infect Urol 2000 Mar/Apr;13(2):45-7.			✓	Case report	
(378)	Routledge T, Saeb-Parsy K, Murphy F, Ritchie AJ. The use of vacuum-assisted closure in the treatment of post-transplant wound infections: A case series. J Heart Lung Transplant 2005;24(9):1444.e15-6.	✓	KQ3			

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(687)	Saad SA, Shakov E, Sebastian V, Saad A. The use of wound vacuum-assisted closure (VAC) system in the treatment of recurrent or complex pilonidal cystDisease: experience in 4 adolescent patients. Internet J Surg 2007 Jan;11(1)			✓	Fewer than five patients	
(688)	Sadat U, Chang G, Noorani A, Walsh SR, Hayes PD, Varty K. Efficacy of TNP on lower limb wounds: a meta-analysis. J Wound Care 2008 Jan;17(1):45-8.			✓	Narrative	
(689)	Saeed MU, Kennedy DJ. A retained sponge is a complication of vacuum-assisted closure therapy. Int J Low Extrem Wounds 2007 Sep;6(3):153-4.			✓	Case report	
(690)	Saiki Y, Hata M, Akasaka J, Saito T, Tabayashi K. Vacuum-assisted closure system for the treatment of mediastinitis after total aortic arch replacement. Jpn J Thorac Cardiovasc Surg 2005 Dec;53(12):638-40.			✓	Case report	
(691)	Salazard B, Niddam J, Ghez O, Metras D, Magalon G. Vacuum-assisted closure in the treatment of poststernotomy mediastinitis in the paediatric patient. J Plast Reconstr Aesthet Surg 2008;61(3):302-5.			✓	Fewer than five patients	
(151)	Sartipy U, Lockowandt U, Gabel J, Jideus L, Dellgren G. Cardiac Rupture During Vacuum-Assisted Closure Therapy. Ann Thorac Surg 2006 Sep;82(3):1110-1.	✓	KQ3			
(34)	Saxena V, Hwang CW, Huang S, Eichbaum Q, Ingber D, Orgill DP. Vacuum-assisted closure: microdeformations of wounds and cell proliferation. Plast Reconstr Surg 2004 Oct;114(5):1086-96; discussion 1097-.			✓	Not a clinical study	
(692)	Saxena V, Orgill D, Kohane I. A set of genes previously implicated in the hypoxia response might be an important modulator in the rat ear tissue response to mechanical stretch. BMC Genomics 2007;8:430.			✓	Animal study	
(693)	Schaffzin DM, Douglas JM, Stahl TJ, Smith LE. Vacuum-assisted closure of complex perineal wounds. Dis Colon Rectum 2004 Oct;47(10):1745-8.			✓	Case reports	

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(132)	Scherer LA, Shiver S, Chang M, Meredith JW, Owings JT, Tominaga GT, Schecter WP, Parks SN, Peck J, Mayberry J. The vacuum assisted closure device: a method of securing skin grafts and improving graft survival. Arch Surg 2002;137(8):930-4.	✓	KQ1, KQ3			
(35)	Scherer SS, Pietramaggiori G, Mathews JC, Prsa MJ, Huang S, Orgill DP. The mechanism of action of the vacuum-assisted closure device. Plast Reconstr Surg 2008 Sep;122(3):786-97.			✓	Animal study	
(694)	Scheufler O, Peek A, Kania NM, Exner K. Problem-adapted application of vacuum occlusion dressings: case report and clinical experience. Eur J Plastic Surg 2000 Oct;23(7):386-90.			✓	Case report	
(307)	Schimmer C, Sommer SP, Bensch M, Leyh R. Primary treatment of deep sternal wound infection after cardiac surgery: a survey of German heart surgery centers. Interact Cardiovasc Thorac Surg 2007 Dec;6(6):708-11.			✓	Does not address key question	
(147)	Schimp VL, Worley C, Brunello S, Levenback CC, Wolf JK, Sun CC, Bodurka DC, Ramirez PT. Vacuum-assisted closure in the treatment of gynecologic oncology wound failures. Gynecol Oncol 2004 Feb;92(2):586-91.	✓	KQ3			
(695)	Schintler M, Maier A, Matzi V, Smolle-Juttner FM. Vacuum assisted closure system in the management of cervical anastomotic leakage after gastric pull-up. Interact Cardiovasc Thorac Surg 2004 Mar;3(1):92-4.			✓	Case report	
(696)	Schintler M, Marschitz I, Trop M. The use of topical negative pressure in a paediatric patient with extensive burns. Burns 2005 Dec;31(8):1050-3.			✓	Case report	
(697)	Schipper J, Ridder GJ, Maier W, Teszler CB, Horch RE. Laryngotracheal reconstruction using prefabricated and preconditioned composite radial forearm free flaps. A report of two cases. Auris Nasus Larynx 2007 Jun;34(2):253-8.			✓	Not relevant	

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(308)	Schlatterer D, Hirshorn K. Negative pressure wound therapy with reticulated open cell foam-adjunctive treatment in the management of traumatic wounds of the leg: a review of the literature. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S152-60.			✓	Narrative	
(698)	Schlatterer D, Webb LX. Orthopedic indications for negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):27-8.			✓	Case report	
(699)	Schneider AM, Morykwas MJ, Argenta LC. A new and reliable method of securing skin grafts to the difficult recipient bed. Plast Reconstr Surg 1998 Sep;102(4):1195-8.			✓	No abstract available	
(700)	Schoemann MB, Lentz CW. Treating surgical wound dehiscence with negative pressure dressings. Ostomy Wound Manage 2005 Feb;51(2A Suppl):15-20.			✓	Narrative	
(81)	Scholl L, Chang E, Reitz B, Chang J. Sternal osteomyelitis: use of vacuum-assisted closure device as an adjunct to definitive closure with sternectomy and muscle flap reconstruction. J Card Surg 2004 Sep-Oct;19(5):453-61.	✓	KQ3			✓
(701)	Schuster R, Moradzadeh A, Waxman K. The use of vacuum-assisted closure therapy for the treatment of a large infected facial wound. Am Surg 2006 Feb;72(2):129-31.			✓	Case report	
(126)	Schwien T, Gilbert J, Lang C. Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes. Ostomy Wound Manag 2005;51:47-60.	✓	KQ1, KQ3			
(311)	Segers P, de Jong AP, Kloek JJ, Spanjaard L, de Mol BA. Risk control of surgical site infection after cardiothoracic surgery. J Hosp Infect 2006 Apr;62(4):437-45.			✓	Case report	
(310)	Segers P, de Jong AP, Kloek JJ, van der Horst CM, Spanjaard L, de Mol BA. Topical negative pressure therapy in wounds after cardiothoracic surgery: successful experience supported by literature. Thorac Cardiovasc Surg 2006 Aug;54(5):289-94.			✓	Not a clinical study	

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(354)	Segers P, Kloek JJ, Strackee DS, de Mol BA. Open window thoracostomy: a new therapeutic option using topical negative presure wound therapy. Wounds 2007 Oct;19(10):264-9.	✓	KQ3			
(702)	Senchenkov A, Knoetgen J, Chrouser KL, Nehra A. Application of vacuum-assisted closure dressing in penile skin graft reconstruction. Urology 2006 Feb;67(2):416-9.			✓	Narrative	
(355)	Senchenkov A, Petty PM, Knoetgen J 3rd, Moran SL, Johnson CH, Clay RP. Outcomes of skin graft reconstructions with the use of Vacuum Assisted Closure (VAC) dressing for irradiated extremity sarcoma defects. World J Surg Oncol 2007;5:138.	✓	KQ3			
(703)	Sentenac J. Facilitating wound healing with VAC therapy: a pharmacist's role. European Journal of Hospital Pharmacists 2008 May;14(5):57-8.			✓	Narrative	
(138)	Shilt JS, Yoder JS, Manuck TA, Jacks L, Rushing J, Smith BP. Role of vacuum-assisted closure in the treatment of pediatric lawnmower injuries. J Pediatr Orthop 2004;24(5):482-487.	✓	KQ1, KQ3			
(704)	Shirakawa M, Isseroff RR. Topical negative pressure devices: Use for enhancement of healing chronic wounds. Arch Dermatol 2005 Nov;141(11):1449-53.			✓	Narrative	
(705)	Short B, Claxton M, Armstrong DG. How to use VAC therapy on chronic wounds. Podiatry Today 2002 Jul;15(7):48-54.			✓	Narrative	
(367)	Shrestha BM, Nathan VC, Delbridge MC, Parker K, Throssell D, McKane WS, Karim MS, Raftery AT. Vacuum-assisted closure (VAC) therapy in the management of wound infection following renal transplantation. Kathmandu Univ Med J (KUMJ) 2007 Jan-Mar;5(1):4-7.	✓	KQ3			
(706)	Shvartsman HS, Langstein H, Worley C, Malpica A, Ramondetta LM. Use of a vacuum-assisted closure device in the treatment of recurrent Paget's disease of the vulva. Obstet Gynecol 2003 Nov;102(5 Pt 2):1163-6.			✓	Case report	

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(119)	Siegel HJ, Long JL, Watson KM, Fiveash JB. Vacuum-assisted closure for radiation-associated wound complications. J Surg Oncol 2007 Dec 1;96(7):575-82.	✓	KQ1, KQ3			
(707)	Silberstein J, Grabowski J, Parsons JK. Use of a Vacuum-Assisted Device for Fournier's Gangrene: A New Paradigm. Rev Urol 2008 Winter;10(1):76-80.			✓	Case report	
(708)	Simek M, Nemec P, Zalesak B, Kalab M, Hajek R, Jecminkova L, Kolar M. Vacuum-assisted closure in the treatment of sternal wound infection after cardiac surgery. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub 2007 Dec;151(2):295-9.			✓	Duplicate study(123)	
(709)	Simman R, Forte R, Silverberg B, Moriera-Gonzalez A, Williams F. A comparative histological study of skin graft take with tie-over bolster dressing versus negative pressure wound therapy in a pig model: a preliminary study. Wounds 2004 Feb;16(2):76-80.			✓	Animal study	
(710)	Simon DH, Key JJ, Blume PA. Lower extremity wounds respond to negative pressure. Biomechanics 2008 Aug;15(8):53-9.			✓	Narrative	
(711)	Simon S, Hammoudeh J, Low C, Nathan N, Armstrong M, Thaller S. Complex wound management with an artificial dermal regeneration template. Wounds 2008 Nov;20(11):299-302.			✓	Case reports	
(712)	Singh K, Samartzis D, Heller JG, An HS, Vaccaro AR. The management of complex soft-tissue defects after spinal instrumentation. J Bone Joint Surg Br 2006 Jan;88(1):8-15.			✓	Narrative	
(713)	Singh S, Mackey S, Soldin M. VAC it - Some techniques on the application of VAC dressings. Ann R Coll Surg Engl 2008 Mar;90(2):161-2.			✓	Narrative	
(714)	Sjogren J, Gustafsson R, Koul B, Ingemansson R. Selective mediastinal tamponade to control coagulopathic bleeding. Ann Thorac Surg 2003 Apr;75(4):1311-3.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(139)	Sjogren J, Gustafsson R, Nilsson J, Malmsjo M, Ingemansson R. Clinical outcome after poststernotomy mediastinitis: Vacuum-assisted closure versus conventional treatment. Ann Thorac Surg 2005;79(6):2049-55.	✓	KQ1, KQ3, Previous Systematic Reviews			
(715)	Sjogren J, Gustafsson R, Wackenfors A, Malmsjo M, Algotsson L, Ingemansson R. Effects of vacuum-assisted closure on central hemodynamics in a sternotomy wound model. Interact Cardiovasc Thorac Surg 2004 Dec;3(4):666-71.			✓	Animal study	
(716)	Sjogren J, Malmsjo M, Gustafsson R, Ingemansson R. Poststernotomy mediastinitis: a review of conventional surgical treatments, vacuum-assisted closure therapy and presentation of the Lund University Hospital mediastinitis algorithm. Eur J Cardiothorac Surg 2006 Dec;30(6):898-905.			✓	Narrative	
(717)	Sjogren J, Mokhtari A, Gustafsson R, Malmsjo M, Nilsson J, Ingemansson R. Vacuum-assisted closure therapy for deep sternal wound infections: the impact of learning curve on survival and predictors for late mortality. Int Wound J 2008 Jun;5(2):216-23.			✓	Not relevant	
(179)	Sjogren J, Nilsson J, Gustafsson R, Malmsjo M, Ingemansson R. The impact of vacuum-assisted closure on long-term survival after post-sternotomy mediastinitis. Ann Thorac Surg 2005 Oct;80(4):1270-5.	✓	Previous Systematic Reviews			
(718)	Skillman J, Kirkpatrick N, Coombes A, Coghlan B, Waterhouse N, Joshi N, Kelly M. Vacuum Assisted Closure (VAC) dressing for skin graft application following exenteration of the orbit. Orbit 2003 Mar;22(1):63-5.			✓	Case report	
(719)	Smith APS. A closer look at the potential of hyperbaric oxygen therapy. APMA News 2005 May;26(5-Suppl):39-42.			✓	Not relevant	
(720)	Smith APS. Case study: treating a diabetic puncture wound. APMA News 2005 May;26(5-Suppl):16-18.			✓	Case report	
(315)	Smith N. The benefits of VAC therapy in the management of pressure ulcers. Br J Nurs 2004 Dec 9-2005 Jan 12;13(22):1359-65.			✓	Reanalysis of already published data	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(721)	Snyder N, Gould LJ. Scrotal and penile reconstruction using the vacuum-assisted closure device. Can J Plast Surg 2005 Dec;13(4):205-6.			✓	No abstract available	
(124)	Song DH, Wu LC, Lohman RF, Gottlieb LJ, Franczyk M. Vacuum assisted closure for the treatment of sternal wounds: the bridge between debridement and definitive closure. Plast Reconstr Surg 2003 Jan;111(1):92-7.	✓	KQ1,KQ3, Previous Systematic Reviews			
(316)	Sposato G, Molea G, Di Caprio G, Scioli M, La Rusca I, Ziccardi P. Ambulant vacuum-assisted closure of skin-graft dressing in the lower limbs using a portable mini-VAC device. Br J Plast Surg 2001 Apr;54(3):235-7.			✓	Narrative	
(125)	Stannard JP, Robinson JT, Anderson ER, McGwin G Jr, Volgas DA, Alonso JE. Negative pressure wound therapy to treat hematomas and surgical incisions following high-energy trauma. J Trauma 2006 Jun;60(6):1301-6.	✓	KQ1, KQ3			
(722)	Stawicki SP, Grossman M. "Stretching" negative pressure wound therapy: Can dressing change interval be extended in patients with open abdomens. Ostomy Wound Manage 2007 Jan;53(1):26-9.			✓	Narrative	
(723)	Stawicki SP, Schwarz NS, Schrag SP, Lukaszczyk JJ, Schadt ME, Dippolito A. Application of vacuum-assisted therapy in postoperative ascitic fluid leaks: an integral part of multimodality wound management in cirrhotic patients. J Burns Wounds 2007 Apr 16;6:91-9.			✓	Fewer than five patients	
(724)	Steed DL, Attinger C, Colaizzi T, Crossland M, Franz M, Harkless L, Johnson A, Moosa H, Robson M, Serena T, Sheehan P, Veves A, Wiersma-Bryant L. Guidelines for the treatment of diabetic ulcers. Wound Repair Regen 2006 Nov;14(6):680-92.			✓	Guideline	
(725)	Steenvoorde P, de Roo RA, Oskam J, Neijenhuis P. Negative pressure wound therapy to treat peri-prosthetic methicillin-resistant Staphylococcus aureus infection after incisional herniorrhaphy. A case study and literature review. Ostomy Wound Manage 2006 Jan;52(1):52-4.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(726)	Steenvoorde P, Rozeboom AI, Melief P, Elzo Kraemer CV, Bonsing BA. Failure of the topical negative pressure abdominal dressing system in the "fat" open abdomen: report of a case and review of literature. Wounds 2006 Feb;18(2):44-50.			✓	Case report	
(727)	Steenvoorde P, Slotema E, Adhin S, Oskam J. Deep infection after ilioinguinal node dissection: vacuum-assisted closure therapy. Int J Low Extrem Wounds 2004 Dec;3(4):223-6.			✓	Case report	
(728)	Steenvoorde P, van Engeland A, Bonsing B, da Costa SA, Oskam J. Combining topical negative pressure and a Bogota bag for managing a difficult laparostomy. J Wound Care 2004 Apr;13(4):142-3.			✓	Case report	
(349)	Steiert AE, Gohritz A, Schreiber TC, Krettek C, Vogt PM. Delayed flap coverage of open extremity fractures after previous vacuum-assisted closure (VAC) therapy - worse or worth. J Plast Reconstr Aesthet Surg 2008 Mar 24;Epub ahead of print.	✓	KQ3			
(729)	Steinberg JS. Exploring adjunctive combination therapy for wound bed preparation. APMA News 2005 May;26(5 Suppl):24-6.			✓	Narrative	
(730)	Stinson JA, Powell JL. Necrotizing fasciitis in women at a community teaching hospital. J Pelvic Med Surg 2005 Jul-Aug;11(4):209-13.			✓	Not relevant to topic	
(358)	Stoeckel WT, David L, Levine EA, Argenta AE, Perrier ND. Vacuum-assisted closure for the treatment of complex breast wounds. Breast 2006 Nov;15(5):610-3.	✓	KQ3			
(731)	Stokes TH, Follmar KE, Silverstein AD, Weizer AZ, Donatucci CF, Anderson EE, Erdmann D. Use of negative-pressure dressings and split-thickness skin grafts following penile shaft reduction and reduction scrotoplasty in the management of penoscrotal elephantiasis. Ann Plast Surg 2006 Jun;56(6):649-53.			✓	Not relevant	
(90)	Stone PA, Hass SM, Flaherty SK, DeLuca JA, Lucente FC, Kusminsky RE. Vacuum-assisted fascial closure for patients with abdominal trauma. J Trauma 2004 Nov;57(5):1082-6.	✓	KQ3			✓

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(77)	Stonerock CE, Bynoe RP, Yost MJ, Nottingham JM. Use of a vacuum-assisted device to facilitate abdominal closure. Am Surg 2003 Dec;69(12):1030-4; discussion 1034-5.	✓	KQ3			✓
(320)	Suess JJ, Kim PJ, Steinberg JS. Negative pressure wound therapy: evidence-based treatment for complex diabetic foot wounds. Curr Diab Rep 2006 Dec;6(6):446-50.			✓	Narrative	
(166)	Suliburk JW, Ware DN, Balogh Z, McKinley BA, Cocanour CS, Kozar RA, Moore FA. Vacuum-Assisted Wound Closure Achieves Early Fascial Closure of Open Abdomens after Severe Trauma. J Trauma Inj Infect Crit Care 2003;55(6):1155-60.	✓	KQ3			
(732)	Summaries of current clinical evidence Engenex NPWT system. Skillman (NJ): ConvaTec, Inc.; 2 p.			✓	Poster presentation	
(733)	Sunog T. Closing time. Adv Nurs 2003 Aug;18(34):39.			✓	No abstract available	
(734)	Svedman, et al. A dressing system providing fluid supply and suction drainage used for continuous or intermittent irrigation. Ann Plast Surg 1986 Aug;17(2):125-33.			✓	Narrative	
(149)	Svensson S, Monsen C, Kolbel T, Acosta S. Predictors for Outcome after Vacuum Assisted Closure Therapy of Peri-vascular Surgical Site Infections in the Groin. Eur J Vasc Endovasc Surg 2008 Jul;36(1):84-9.	✓	KQ3			
(735)	Tan D, Rajanayagam J, Schwarz F. Treatment of long-standing, poor-healing diabetic foot ulcers with topical negative pressure in the Torres Strait. Aust J Rural Health 2007 Aug;15(4):275-6.			✓	Case report	
(736)	Tang AT, Ohri SK, Haw MP. Novel application of vacuum assisted closure technique to the treatment of sternotomy wound infection. Eur J Cardiothorac Surg 2000 Apr;17(4):482-4.			✓	Narrative	
(737)	Tang AT, Okri SK, Haw MP. Vacuum-assisted closure to treat deep sternal wound infection following cardiac surgery. J Wound Care 2000 May;9(5):229-30.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(323)	Tanna N, Clary MS, Conrad DE, Lenert J, Sadeghi N. Vacuum-assisted closure for wound dehiscence in head and neck reconstruction. Plast Reconstr Surg 2009 Jan;123(1):19e-21e.			✓	Case report	
(738)	Tarkin IS. The versatility of negative pressure wound therapy with reticulated open cell foam for soft tissue management after severe musculoskeletal trauma. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S146-51.			✓	Narrative	
(739)	Taub PJ, Schulman MR, Sett S, Koch RM. Revisiting vascularized muscle flaps for complicated sternal wounds in children. Ann Plast Surg 2005 Nov;55(5):535-7.			✓	Case report	
(229)	Teot L, Lambert L, Ourabah Z, Bey E, Steenman C, Wierzbiecka E, Malikov S, Charles JP, Vives F, Bohbot S. Use of topical negative pressure with a lipidocolloid dressing: results of a clinical evaluation. J Wound Care 2006 Sep;15(8):355-8.			✓	Homemade device	
(740)	Terrazas SG. Adjuvant dressing for negative pressure wound therapy in burns. Ostomy Wound Manage 2006 Jan;52(1):16, 18.			✓	No abstract available	
(741)	Thomas S. An introduction to the use of vacuum assisted closure. In: World Wide Wounds [serial online]. ; 2001 May [accessed 2001 Jun 11]. [25 screens]. Available: http://www.worldwidewounds.com/2001/may/Thomas/Vacuum-Assisted-Closure.htm.			✓	Narrative	
(742)	Thomas T. (Executive Director, Association for the Advancement of Wound Care. Malvern, PA). Personal communication – Full submission packet. 2009 Feb 1. 142 p p.			✓	Personal communication	
(743)	Thompson JT, Marks MW. Negative pressure wound therapy. Clin Plast Surg 2007 Oct;34(4):673-84.			✓	Narrative	
(326)	Timmers MS, Le Cessie S, Banwell P, Jukema GN. The effects of varying degrees of pressure delivered by negative-pressure wound therapy on skin perfusion. Ann Plast Surg 2005 Dec;55(6):665-71.			✓	No relevant outcomes	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(744)	Torbrand C, Ingemansson R, Gustafsson L, Paulsson P, Malmsjo M. Pressure transduction to the thoracic cavity during topical negative pressure therapy of a sternotomy wound. Int Wound J 2008 Oct;5(4):579-84.			✓	Animal study	
(745)	Torbrand C, Wackenfors A, Lindstedt S, Ekman R, Ingemansson R, Malmsjo M. Sympathetic and sensory nerve activation during negative pressure therapy of sternotomy wounds. Interact Cardiovasc Thorac Surg 2008 Dec;7(6):1067-70.			✓	Animal study	
(746)	Trop M, Schintler M, Urban E, Roedl S, Stockenhuber A. Are 1:4 mesh and donor site contraindications for vacuum-assisted closure device. J Trauma 2006 Nov;61(5):1267-70.			✓	No abstract available	
(747)	Trueman P, Flack S, Loonstra A, Hauser T. The feasibility of using V.A.C. Therapy in home care patients with surgical and traumatic wounds in the Netherlands. Int Wound J 2008 Jun;5(2):225-31.			✓	Not a clinical study	
(748)	Trueman P. Cost-effectiveness considerations for home health V.A.C. Therapy in the United States of America and its potential international application. Int Wound J 2008 Jun;5 Suppl 2:23-6.			✓	Cost effectiveness	
(174)	Ubbink DT, Westerbos SJ, Evans D, Land L, Vermeulen H. Topical negative pressure for treating chronic wounds (Review). In: Cochrane Database of Systematic Reviews [internet]. Issue 3. Hoboken (NJ): John Wiley & Sons, Ltd.; 2008 [Art. No.: CD001898].	✓	Previous Systematic Reviews			
(183)	Ubbink DT, Westerbos SJ, Nelson EA, Vermeulen H. A systematic review of topical negative pressure therapy for acute and chronic wounds. Br J Surg 2008 Jun;95(6):685-92.	✓	Previous Systematic Reviews			
(228)	Using topical negative pressure with a lipidocolloid dressing. Ostomy Wound Manage 2008 Jun;54(6):12-4.			✓	No abstract available	
(749)	Uygur F, Duman H, Ulkur E, Ceikoz B. The role of the vacuum-assisted closure therapy in the salvage of venous congestion of the free flap: case report. Int Wound J 2008 Mar;5(1):50-3.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(750)	Vallet C, Saucy F, Haller C, Meier P, Rafoul W, Corpataux JM. Vacuum-assisted conservative treatment for the management and salvage of exposed prosthetic hemodialysis access. Eur J Vasc Endovasc Surg 2004 Oct;28(4):397-9.			✓	Case reports	
(107)	van den Boogaard M, de Laat E, Spauwen P, Schoonhoven L. The effectiveness of topical negative pressure in the treatment of pressure ulcers: a literature review. Eur J Plastic Surg 2008 Apr;31(1):1-7.	✓	KQ1, KQ3			
(368)	van Rhee MA, de Klerk LW, Verhaar JA. Vacuum-assisted wound closure of deep infections after instrumented spinal fusion in six children with neuromuscular scoliosis. Spine J 2007 Sep-Oct;7(5):596-600.	✓	KQ3			
(751)	Varker KA, Ng T. Management of empyema cavity with the vacuum-assisted closure device. Ann Thorac Surg 2006 Feb;81(2):723-5.			✓	Case report	
(752)	Venturi ML, Attinger CE, Mesbahi AN, Hess CL, Graw KS. Mechanisms and clinical applications of the vacuum-assisted closure (VAC) Device: a review. Am J Clin Dermatol 2005;6(3):185-94.			✓	Narrative	
(753)	Verhaalen Al. Isolation of an entercutaneous fistula within a vacuum-assisted wound closure system. Gen Surg 2006 Aug;33(8)			✓	Case report	
(754)	Verrillo SC. Negative pressure therapy for infected sternal wounds: a literature review. J Wound Ostomy Continence Nurs 2004 Mar-Apr;31(2):72-4.			✓	Narrative	
(342)	Vidrine DM, Kaler S, Rosenthal EL. A comparison of negative-pressure dressings versus Bolster and splinting of the radial forearm donor site. Otolaryngol Head Neck Surg 2005 Sep;133(3):403-6.	✓	KQ1, KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(178)	Vikatmaa P, Juutilainen V, Kuukasjarvi P, Malmivaara A. Negative Pressure Wound Therapy: a Systematic Review on Effectiveness and Safety. Eur J Vasc Endovasc Surg 2008 Oct;36(4):438-48.	✓	Previous Systematic Reviews			
(755)	von Gossler CM, Horch RE. Rapid aggressive soft-tissue necrosis after beetle bite can be treated by radical necrectomy and vacuum suction-assisted closure. J Cutan Med Surg 2000 Oct;4(4):219-22.			✓	Case report	
(115)	Vuerstaek JD, Vainas T, Wuite J, Nelemans P, Neumann MH, Veraart JC. State-of-the-art treatment of chronic leg ulcers: A randomized controlled trial comparing vacuum-assisted closure (V.A.C.) with modern wound dressings. J Vasc Surg 2006 Nov;44(5):1029-37; discussion 1038.	✓	KQ1, KQ3			
(756)	Wackenfors A, Gustafsson R, Sjogren J, Algotsson L, Ingemansson R, Malmsjo M. Blood flow responses in the peristernal thoracic wall during vacuum-assisted closure therapy. Ann Thorac Surg 2005 May;79(5):1724-30; discussion 1730-.			✓	Animal study	
(757)	Wackenfors A, Sjogren J, Algotsson L, Gustafsson R, Ingemansson R, Malmsjo M. The effect of vacuum-assisted closure therapy on the pig femoral artery vasomotor responses. Wound Repair Regen 2004 Mar-Apr;12(2):244-			✓	Animal study	
(40)	Wackenfors A, Sjogren J, Gustafsson R, Algotsson L, Ingemansson R, Malmsjo M. Effects of vacuum-assisted closure therapy on inguinal wound edge microvascular blood flow. Wound Repair Regen 2004 Nov-Dec;12(6):600-6.			✓	Animal study	
(384)	Wada A, Ferreira MC, Tuma Junior P, Arrunategui G. Experience with local negative pressure (vacuum method) in the treatment of complex wounds. Sao Paulo Med J 2006 May 4;124(3):150-3.	✓	KQ3			
(118)	Wanner MB, Schwarzl F, Strub B, Zaech GA, Pierer G. Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. Scand J Plast Reconstr Surg Hand Surg 2003;37(1):28-33.	✓	KQ1,KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(172)	Wasiak J, Cleland H. Topical negative pressure (TNP) for partial thickness burns. Cochrane Database Syst Rev 2007;(3):CD006215.	✓	Previous Systematic Reviews			
(758)	Webb LX, Lavery D, DeFranzo A. Negative pressure wound therapy in the management of orthopedic wounds. Ostomy Wound Manage 2004 Apr;50(4A Suppl):26-7.			✓	Narrative	
(759)	Webb LX, Pape HC. Current thought regarding the mechanism of action of negative pressure wound therapy with reticulated open cell foam. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S135-7.			✓	Narrative	
(760)	Webb LX. New techniques in wound management: vacuum-assisted wound closure. J Am Acad Orthop Surg 2002 Sep-Oct;10(5):303-11.			✓	Narrative	
(37)	Weed T, Ratliff C, Drake DB. Quantifying bacterial bioburden during negative pressure wound therapy: does the wound VAC enhance bacterial clearance. Ann Plast Surg 2004 Mar;52(3):276-9; discussion 279-80.	✓	KQ3			
(761)	Weinfeld AB, Kelley P, Yuksel E, Tiwari P, Hsu P, Choo J, Hollier LH. Circumferential negative-pressure dressing (VAC) to bolster skin grafts in the reconstruction of the penile shaft and scrotum. Ann Plast Surg 2005 Feb;54(2):178-83.			✓	Case reports	
(762)	Wessel LC, Cunningham BL. Patient with compartment syndrome of the lower extremity. J Wound Ostomy Continence Nurs 2002 Jul;29(4):210-5.			✓	Case report	
(763)	Whelan C, Stewart J, Schwartz BF. Mechanics of wound healing and importance of Vacuum Assisted Closure in urology. J Urol 2005 May;173(5):1463-70.			✓	Narrative	
(764)	White RA, Miki RA, Kazmier P, Anglen JO. Vacuum-assisted closure complicated by erosion and hemorrhage of the anterior tibial artery. J Orthop Trauma 2005 Jan;19(1):56-9.			✓	Case report	

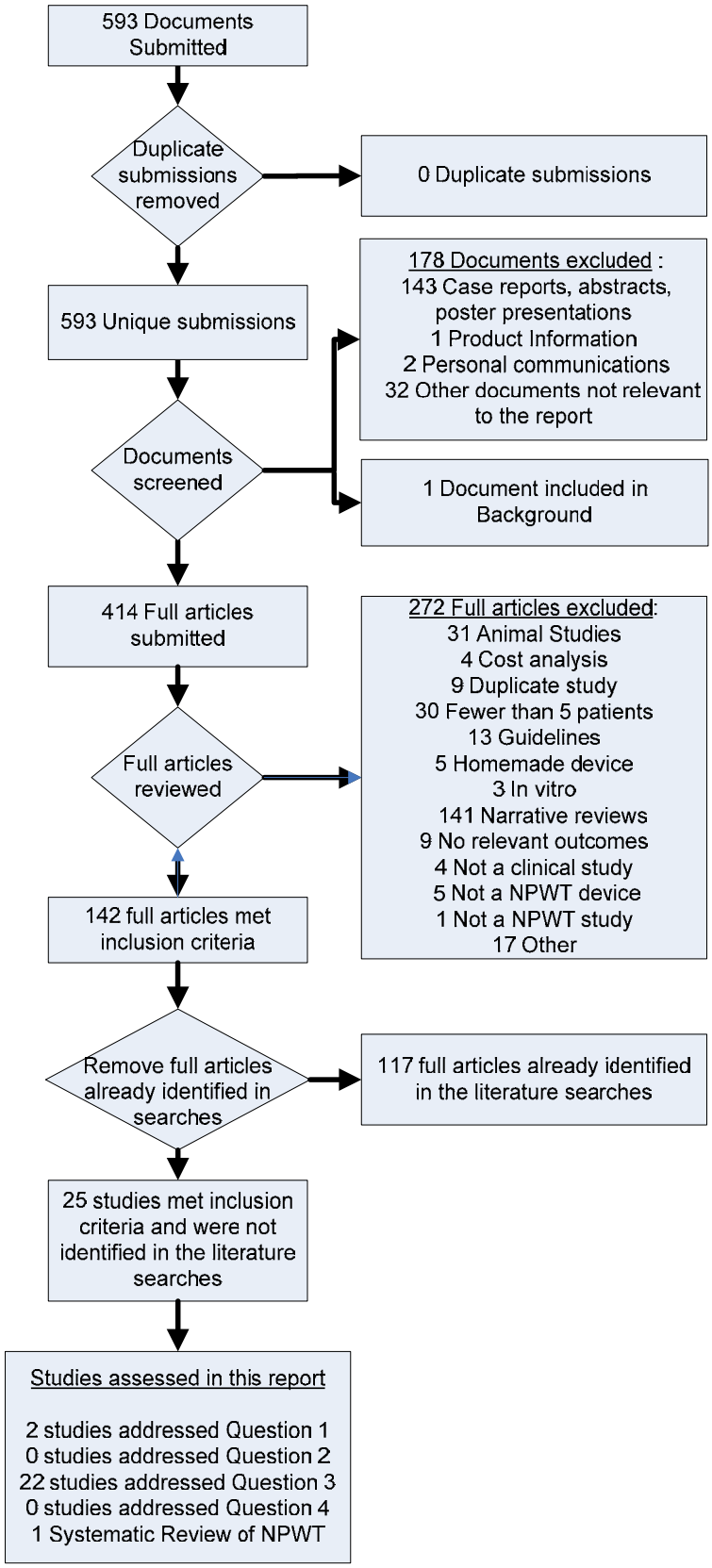
Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(765)	Whitney J, Phillips L, Aslam R, Barbul A, Gottrup F, Gould L, Robson MC, Rodeheaver G, Thomas D, Stotts N. Guidelines for the treatment of pressure ulcers. Wound Repair Regen 2006 Nov-Dec;14(6):663-79.			✓	Guideline	
(116)	Wild T, Stremitzer S, Budzanowski A, Hoelzenbein T, Ludwig C,Ohrenberger G. Definition of efficiency in vacuum therapy – A randomised controlled trial comparing Redon drains with V.A.C. Therapy™. Int Wound J 2008 Dec;5(5):641-7.	✓	KQ2			
(766)	Wilkes R, Zhao Y, Kieswetter K, Haridas B. Effects of Dressing Type on 3D Tissue Microdeformations During Negative Pressure Wound Therapy: A Computational Study. J Biomech Eng 2009 Mar;131(3):031012.			✓	Not a clinical study	
(767)	Willy C, Voelker HU, Engelhardt M. Literature on the subject of vacuum therapy: review and update 2006. Eur J Trauma Emerg Surg 2007 Feb;33(1):33-9.			✓	Not relevant - not a systematic review of wound healing data	
(768)	Wiseman J, Cullington JR, Schaeferle M 3rd, Beckham PH, Salisbury M, Ersek RA. Aesthetic aspects of neurofibromatosis reconstruction with the vacuum-assisted closure system. Aesthetic Plast Surg 2001 Sep-Oct;25(5):326-31.			✓	Case Report	
(769)	Wolvos T. Wound instillation with negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):21S-6S.			✓	Narrative	
(770)	Wolvos T. Wound instillation--the next step in negative pressure wound therapy. Lessons learned from initial experiences. Ostomy Wound Manage 2004 Nov;50(11):56-66.			✓	Narrative	
(161)	Wondberg D, Larusson HJ, Metzger U, Platz A, Zingg U. Treatment of the open abdomen with the commercially available vacuum-assisted closure system in patients with abdominal sepsis: low primary closure rate. World J Surg 2008 Dec;32(12):2724-9.	✓	KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(771)	Wong LK, Nesbit RD, Turner LA, Sargent LA. Management of a circumferential lower extremity degloving injury with the use of vacuum-assisted closure. South Med J 2006 Jun;99(6):628-30.			✓	Case Report	
(75)	Wongworawat MD, Schnall SB, Holtom PD, Moon C, Schiller F. Negative pressure dressings as an alternative technique for the treatment of infected wounds. Clin Orthop Relat Res 2003 Sep;(414):45-8.	✓	KQ3			✓
(772)	Woo KY, Sibbald RG. Vacuum-assisted closure home care training: a process to link education to improved patient outcomes. Int Wound J 2008 Jun;5 Suppl 2:1-9.			✓	Narrative	
(773)	Wound wonder. Middle East Medical 2003 May-Jun;61-5.			✓	Narrative	
(774)	Wu S. Case study: treating a patient with a diabetic neuropathic ulceration. APMA News 2005 May;26(5-Suppl):19.			✓	Case Report	
(775)	Wu SC, Lavery LA, Armstrong DG. Closing difficult wounds. Podiatry Today 2006 Mar;19(3):44-54.			✓	Narrative	
(776)	Wu Sc, Yoon H, Armstrong DG. Therapy with advanced modalities: can it expedite healing?. Podiatry Today 2005 Sep;18(9):18-24.			✓	Narrative	
(158)	Wu SH, Zecha PJ, Feitz R, Hovius SE. Vacuum therapy as an intermediate phase in wound closure: A clinical experience. Eur J Plastic Surg 2000 May;23(4):174-7.	✓	KQ3			
(777)	Wustmann O, Ulrich HC. German patent specification. Appliance for the drainage of wounds. No. 847 475 Class 30 K Group 17 04. 1952			✓	Not relevant	
(72)	Yang CC, Chang DS, Webb LX. Vacuum-assisted closure for fasciotomy wounds following compartment syndrome of the leg. J Surg Orthop Adv 2006 Spring;15(1):19-23.	✓	KQ1			✓
(778)	Yoong S, Dunne G, Cochrane J, Lee B, Lee J. Vacuum-assisted closure for the treatment of parastomal skin necrosis: a novel approach to an unusual complication. Report of a case. Dis Colon Rectum 2008 Oct;51(10):1577-9.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(779)	Yousaf M, Witherow A, Gardiner KR, Gilliland R. Use of vacuum-assisted closure for healing of a persistent perineal sinus following panproctocolectomy: report of a case. Dis Colon Rectum 2004 Aug;47(8):1403-7; discussion 1407-8.			✓	Case report	
(780)	Yuan-Innes MJ, Temple CL, Lacey MS. Vacuum-assisted wound closure: a new approach to spinal wounds with exposed hardware. Spine 2001 Feb 1;26(3):E30-3.			✓	Fewer than five patients	
(781)	Yuh DD, Albaugh M, Ullrich S, Conte JV. Treatment of ventricular assist device driveline infection with vacuum-assisted closure system. Ann Thorac Surg 2005 Oct;80(4):1493-5.			✓	Case report	
(782)	Zamierowski D. United States Patent. Wound dressing and treatment method. No. 4969880. 1990.			✓	Patent	
(783)	Zehnder SW, Place HM. Vacuum-assisted wound closure in postoperative spinal wound infection. Orthopedics 2007 Apr;30(4):267-72.			✓	Narrative	
(784)	Zutt M, Haas E, Kruger U, Distler M, Neumann C. Successful use of vacuum-assisted closure therapy for leg ulcers caused by occluding vasculopathy and inflammatory vascular diseases—a case series. Dermatology 2007;214(4):319-24.			✓	Case reports	

KQ Key question

Figure 7. Disposition of Submission by Kinetic Concepts, Inc.



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Table 44. Status of Submissions by Kinetic Concepts, Inc.

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(390)	Abai B, Zickler RW, Pappas PJ, Lal BK, Padberg FT Jr. Lymphorrhea responds to negative pressure wound therapy. J Vasc Surg 2007 Mar;45(3):610-3.			✓	Fewer than five patients	
(152)	Adamkova M, Tymonova J, Zamecnikova I, Kadlcik M, Klosova H. First experience with the use of vacuum assisted closure in the treatment of skin defects at the Burn Center. Acta Chir Plast 2005;47(1):24-7.	✓	KQ3			
(372)	Agarwal JP, Ogilvie M, Wu LC, Lohman RF, Gottlieb LJ, Franczyk M, Song DH. Vacuum-assisted closure for sternal wounds: A first-line therapeutic management approach. Plast Reconstr Surg 2005 Sep 15;116(4):1035-40.	✓	KQ3			
(391)	Agrawal S, Hayhurst C, Joseph T, Prinsloo D, Morgan RH, Pherwani AD. Successful salvage of infected and exposed non-absorbable mesh following decompressing laparostomy after emergency repair of ruptured abdominal aortic aneurysm using vacuum-assisted closure system. Eur J Vasc Endovasc Surg 2008 Jan;15(1):1-2.			✓	Narrative	
(392)	Aguinaga S, Welber A, Stephens S. Positive steps towards negative pressure wound therapy. Medsurg Nurs 2007 Jun;16(3):181-2, 189.			✓	Narrative	
(393)	Alvarez AA, Maxwell GL, Rodriguez GC. Vacuum-assisted closure for cutaneous gastrointestinal fistula management. Gynecol Oncol 2001 Mar;80(3):413-6.			✓	Case report	
(394)	Andrabi SI, Ahmad J, Rathore MA, Yousaf M. Vacuum assisted closure of laparostomy wounds "a novel technique". J Ayub Med Coll Abbottabad 2007 Jul-Sep;19(3):89-92.			✓	Case report	
(395)	Andrabi SI, Ahmad J. Negative pressure therapy for laparotomy wounds--a word of caution. J Wound Ostomy Continence Nurs 2007 Jul-Aug;34(4):425-7.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(396)	Andrews BT, Smith RB, Chang KE, Scharpf J, Goldstein DP, Funk GF. Management of the radial forearm free flap donor site with the vacuum-assisted closure (VAC) system. Laryngoscope 2006 Oct;116(10):1918-22.			✓	No relevant outcomes	
(88)	Andrews BT, Smith RB, Goldstein DP, Funk GF. Management of complicated head and neck wounds with vacuum-assisted closure system. Head Neck 2006 Nov;28(11):974-81.	✓	KQ3			✓
(397)	Andrews BT, Smith RB, Hoffman HT, Funk GF. Orocutaneous and pharyngocutaneous fistula closure using a vacuum-assisted closure system. Ann Otol Rhinol Laryngol 2008 Apr;117(4):298-302.			✓	Fewer than five patients	
(398)	Andros G, Armstrong DG, Attinger C, Boutlon AJ, Frykberg RG, Joseph WS, Lavery LA, Morbach S, Niezgoda JA, Toursarkissian B. Consensus statement on negative pressure wound therapy (VAC Therapy) for the management of diabetic foot wounds. Wounds 2006 Jun;52(6 Suppl):1-32.			✓	Guideline	
(385)	Antony S, Terrazas S. A retrospective study: Clinical experience using vacuum-assisted closure in the treatment of wounds. J Natl Med Assoc 2004;96(8):1073-7.	✓	KQ3			
(192)	Apelqvist J, Armstrong DG, Lavery LA, Boulton AJ. Resource utilization and economic costs of care based on a randomized trial of vacuum-assisted closure therapy in the treatment of diabetic foot wounds. Am J Surg 2008 Jun;195(6):782-8.			✓	Cost analysis	
(399)	Arca MJ, Somers KK, Derks TE, Goldin AB, Aiken JJ, Sato TT, Shilyansky J, Winthrop A, Oldham KT. Use of vacuum-assisted closure system in the management of complex wounds in the neonate. Pediatr Surg Int 2005 Jul;21(7):532-5. Epub 2005 Jun 17.			✓	Fewer than five patients	
(400)	Archdeacon MT, Messerschmitt P. Modern papineau technique with vacuum-assisted closure. J Orthop Trauma 2006 Feb;20(2):134-7.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(401)	Argenta LC, Morykwas MJ, Marks MW, DeFranzo AJ, Molnar JA, David LR. Vacuum-assisted closure: state of clinic art. Plast Reconstr Surg 2006 Jun;117(7 Suppl):127S-142S.			✓	Narrative	
(148)	Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. Ann Plast Surg 1997 Jun;38(6):563-76; discussion 577.	✓	KQ3			✓
(402)	Argenta PA, Rahaman J, Gretz HF 3rd, Nezhat F, Cohen CJ. Vacuum-assisted closure in the treatment of complex gynecologic wound failures. Obstet Gynecol 2002 Mar;99(3):497-501.			✓	Fewer than five patients	
(785)	Argenta A, Webb K, Simpson J, Gordon S, Kortesis B, Wanner M, Kremers L, Morykwas M. Deformation of superficial and deep abdominal tissues with application of a controlled vacuum. In: European Tissue Repair Society, Focus group meeting Topical Negative Pressure (TNP) Therapy; 4–6 December 2003; London.			✓	Focus on cellular and biochemistry measurements	
(403)	Armstrong DG, Attinger CE, Boulton AJ, Frykberg RG, Kirsner RS, Lavery LA, Mills JL. Guidelines regarding negative wound therapy (NPWT) in the diabetic foot. Ostomy Wound Manage 2004 Apr;50(4B Suppl):3S-27S.			✓	Guideline	
(404)	Armstrong DG, Boulton AJ, Banwell P. Negative pressure wound therapy in treatment of diabetic foot wounds: a marriage of modalities. Ostomy Wound Manage 2004 Apr;50(4A Suppl):9-12.			✓	Narrative	
(194)	Armstrong DG, Kunze K, Martin BR, Kimbriel HR, Nixon BP, Boulton AJ. Plantar pressure changes using a novel negative pressure wound therapy technique. J Am Podiatr Med Assoc 2004 Sep-Oct;94(5):456-60.			✓	Not a NPWT study	
(85)	Armstrong DG, Lavery LA, Abu-Rumman P, Espensen EH, Vazquez JR, Nixon BP, Boulton AJ. Outcomes of subatmospheric pressure dressing therapy on wounds of the diabetic foot. Ostomy Wound Manage 2002 Apr;48(4):64-8.	✓	KQ3			✓

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(109)	Armstrong DG, Lavery LA, Boulton AJ. Negative pressure wound therapy via vacuum-assisted closure following partial foot amputation: what is the role of wound chronicity?. Int Wound J 2007 Mar;4(1):79-86.	✓	KQ1, KQ3			
(195)	Armstrong DG, Lavery LA, Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. Lancet 2005 Nov 12;366(9498):1704-10.			✓	Study population reported in(109)	
(405)	Armstrong DG, Lavery LA. Decreasing foot pressures while implementing topical negative pressure (vacuum-assisted closure) therapy. Int J Low Extrem Wounds 2004 Mar;3(1):12-5.			✓	Narrative	
(406)	Attar KH, Imran D, Iyer S. Vacuum-assisted closure (VAC) therapy in the management of digital pulp defects. Acta Chir Plast 2007;49(3):75-6.			✓	Case report	
(92)	Avery C, Pereira J, Moody A, Gargiulo M, Whitworth I. Negative pressure wound dressing of the radial forearm donor site. Int J Oral Maxillofac Surg 2000 Jun;29(3):198-200.	✓	KQ3			✓
(407)	Aydin U, Ozgenel Y. A simple solution for preventing air leakage in VAC therapy for sacral pressure sores. J Plast Reconstr Aesthet Surg 2008 Oct;61(10):1267-9.			✓	Narrative	
(408)	Ayello EA, Baranoski S, Morey J. VAC heals complex wounds. Nurs Spectrum (Phila Tri- State) 2003 Dec;15(24):16-17.			✓	Narrative	
(409)	Azad SM, Allison K, Khwaja N, Moiemen N. Frostbite of the gluteal region. Burns 2003 Nov;29(7):739-44.			✓	No abstract available	
(410)	Baharestani M, de Leon J, Mendez-Eastman S, Powell G, Weir D, Niezgoda J, Payne W, Nanney LB, Pelham F, Gupta S. Consensus statement: a practical guide for managing pressure ulcers with negative pressure wound therapy utilizing vacuum-assisted closure. Understanding the treatment algorithm. Adv Skin Wound Care 2008 Jan;21(Suppl 1):1-20.			✓	Guideline	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(411)	Baharestani MM, Driver VR, de Leon JM, Gabriel A, Kaplan M, Lantis J, Lavery L, Pelham F, Powell G, Webb L. Optimizing clinical and cost effectiveness with early intervention of V.A.C. therapy. Ostomy Wound Manage 2008;54(11 Suppl):1-15.			✓	Narrative	
(199)	Baharestani MM, Houliston-Otto DB, Barnes S. Early versus late initiation of negative pressure wound therapy: examining the impact on home care length of stay. Ostomy Wound Manage 2008 Nov;54(11):48-53.			✓	No relevant outcomes	
(93)	Baharestani MM. Negative pressure wound therapy in the adjunctive management of necrotizing fascitis: examining clinical outcomes. Ostomy Wound Manage 2008 Apr;54(4):44-50.	✓	KQ3			✓
(412)	Baharestani MM. Negative pressure wound therapy: an examination of cost-effectiveness. Ostomy Wound Manage 2004 Nov;50(11A Suppl):29S-33S.			✓	Cost analysis	
(162)	Baharestani MM. Use of negative pressure wound therapy in the treatment of neonatal and pediatric wounds: a retrospective examination of clinical outcomes. Ostomy Wound Manage 2007 Jun;53(6):75-85.	✓	KQ3			
(413)	Ballard K, McGregor F. Use of vacuum-assisted closure therapy following foot amputation. Br J Nurs 2001 Aug;10(15 Suppl):S6-12.			✓	Case report	
(344)	Bannasch H, Iblher N, Penna V, Torio N, Felmerer G, Stark GB, Momeni A. A critical evaluation of the concomitant use of the implantable Doppler probe and the Vacuum Assisted Closure system in free tissue transfer. Microsurgery 2008;28(6):412-6.	✓	KQ3			
(414)	Banwell PE, Ahmed S, Teot L. Topical negative pressure versus closed surgical wound drainage: a difference in philosophy. J Wound Care 2005 Oct;14(9):445-7.			✓	Narrative	
(415)	Banwell PE, Musgrave M. Topical negative pressure therapy: mechanisms and indications. Int Wound J 2004 Jun;1(2):95-106.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(416)	Banwell PE, Teot L. Topical negative pressure (TNP): the evolution of a novel wound therapy. J Wound Care 2003 Jan;12(1):22-8.			✓	Narrative	
(417)	Banwell PE. Topical negative pressure therapy in wound care. J Wound Care 1999 Feb;8(2):79-84.			✓	Narrative	
(418)	Banwell PE. Topical negative pressure therapy: advances in burn wound management. Ostomy Wound Manage 2004 Nov;50(11A-Suppl):9S-14S.			✓	Narrative	
(153)	Bapat V, El-Muttardi N, Young C, Venn G, Roxburgh J. Experience with vacuum-assisted closure of sternal wound infections following cardiac surgery and evaluation of chronic complications associated with its use. J Card Surg 2008 May;23(3):227-33.	✓	KQ3			
(200)	Barker DE, Kaufman HJ, Smith LA, Ciraulo DL, Richart CL, Burns RP. Vacuum pack technique of temporary abdominal closure: a 7-year experience with 112 patients. J Trauma 2000 Feb;48(2):201-6; discussion 206-7.			✓	Homemade device	
(202)	Barringer CB, Gorse SJ, Burge TS. The VAC dressing—a cautionary tale. Br J Plast Surg 2004 Jul;57(5):482.			✓	No abstract available	
(419)	Baxandall T. Tissue viability. Healing cavity wounds with negative pressure. Nurs Stand 1996 Oct 30;11(6):49-51.			✓	Narrative	
(420)	Baynham SA, Kohlman P, Katner HP. Treating stage IV pressure ulcers with negative pressure therapy: a case report. Ostomy Wound Manage 1999 Apr;45(4):28-32, 34-5.			✓	Case report	
(421)	Benbow M, Beldon P, Butcher M, Newton H, Hampton S, Baxter H. Topical negative pressure: a systemic review of the available evidence. J Community Nurs 2007 Jun;21(6)			✓	Not relevant - focus on access and usage of total negative pressure	
(422)	Benbow M. Update on VAC therapy.Journal of Community Nursing-Online; 2006 Apr [accessed 2006 Nov 15]. Available: http://www.jcn.com.uk/.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(82)	Bendewald FP, Cima RR, Metcalf DR, Hassan I. Using negative pressure wound therapy following surgery for complex pilonidal disease: a case series. Ostomy Wound Manage 2007 May;53(5):40-6.	✓	KQ3			✓
(76)	Bendo JA, Quirno M, Pelham F, Barone JA, Awad J. Posterior lumbar wound drainage management with vacuum-assisted closure. World Spine J 2007 Sep;2(4):187-90.	✓	KQ3			✓
(423)	Bennett W. Novel use of VAC therapy in a patient with lymphocele after varicose surgery. Wounds UK 2007 Dec;3(4):129-32.			✓	Case report	
(424)	Bernstein BH, Tam H. Combination of subatmospheric pressure dressing and gravity feed antibiotic instillation in the treatment of post-surgical diabetic foot wound: a case series. Wounds 2005 Feb;17(2):37-48.			✓	Narrative	
(425)	Bertelsen CA, Wille-Jorgensen P. Use of topical negative pressure to manage a complex wound with a vesicocutaneous fistula. J Wound Care 2006 Apr;15(4):172-3.			✓	Case report	
(350)	Bhattacharyya T, Mehta P, Smith M, Pomahac B. Routine use of wound vacuum-assisted closure does not allow coverage delay for open tibia fractures. Plast Reconstr Surg 2008 Apr;121(4):1263-6.	✓	KQ3			
(134)	Bickels J, Kollender Y, Wittig JC, Cohen N, Meller I, Malawer MM. Vacuum-assisted wound closure after resection of musculoskeletal tumors. Clin Orthop Relat Res 2005 Dec;441:346-50.	✓	KQ1, KQ3			
(386)	Bihariesingh VJ, Stolarczyk EM, Karim RB, van Kooten EO. Plastic solutions for orthopaedic problems. Arch Orthop Trauma Surg 2004;124(2):73-6.	✓	KQ3			✓
(426)	Birchall L, Street L, Clift H. Developing a trust-wide centralised approach to the use of TNP. J Wound Care 2002 Sep;11(8):311-4.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(427)	Blackburn JH 2d, Boemi L, Hall WW, Jeffords K, Hauck RM, Banducci DR, Graham WP 3d. Negative-pressure dressings as a bolster for skin grafts. Ann Plast Surg 1998 May;40(5):453-7.			✓	Narrative	
(108)	Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care 2008 Apr;31(4):631-6.	✓	KQ1, KQ3			
(141)	Bollero D, Carnino R, Risso D, Gangemi EN, Stella M. Acute complex traumas of the lower limbs: A modern reconstructive approach with negative pressure therapy. Wound Repair Regen 2007 Jul;15(4):589-94.	✓	KQ3			
(428)	Bolton LL. Negative pressure wound therapy. Wounds 2005 Apr;17(4):A29-A32.			✓	Narrative	
(429)	Bonnet F, Pavy B, Beaudoin S, Dubousset J, Mitrofanoff M. Treatment of a large defect of the chest wall in a child using a negative pressure wound dressing. Scand J Plast Reconstr Surg Hand Surg 2007;41(3):143-5.			✓	Case report	
(430)	Bookout K, McCord S, McLane K. Case studies of an infant, a toddler, and an adolescent treated with a negative pressure wound treatment system. J Wound Ostomy Continence Nurs 2004 Jul-Aug;31(4):184-92.			✓	Fewer than five patients	
(207)	Bovill E, Banwell PE, Teot L, Eriksson E, Song C, Mahoney J, Gustafsson R, Horch R, Deva A, Whitworth I, International Advisory Panel on Topical Negative Pressure. Topical negative pressure wound therapy: a review of its role and guidelines for its use in the management of acute wounds. Int Wound J 2008 Oct;5(4):511-29.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(114)	Braakenburg A, Obdeijn MC, Feitz R, van Rooij IA, van Griethuysen AJ, Klinkenbijl JH. The clinical efficacy and cost effectiveness of the vacuum-assisted closure technique in the management of acute and chronic wounds: a randomized controlled trial. Plast Reconstr Surg 2006 Aug;118(2):390-7; discussion 398-400.	✓	KQ1, KQ3			
(431)	Brace JA. Negative pressure wound therapy for abdominal wounds. J Wound Ostomy Continence Nurs 2007 Jul-Aug;34(4):428-30.			✓	Narrative	
(345)	Brandi C, Grimaldi L, Nisi G, Silvestri A, Brafa A, Calabro M, D'Aniello C. Treatment with vacuum-assisted closure and cryo-preserved homologous de-epidermalised dermis of complex traumas to the lower limbs with loss of substance, and bones and tendons exposure. J Plast Reconstr Aesthet Surg 2008 Dec;61(12):1507-11.	✓	KQ3			
(432)	Brogna L. Home care management of an ostomy within a dehisced abdominal wound. J Wound Ostomy Continence Nurs 2005 May-Jun;32(3):200-2; discussion 202-4.			✓	Case reports	
(433)	Bronchard R, de Vaumas C, Lasocki S, Jabbour K, Geffroy A, Kermarrec N, Montravers P. Vacuum-assisted closure in the treatment of perineal necrotizing skin and soft tissue infections. Intensive Care Med 2008 Jul;34(7):1345-7.			✓	Abstract not available	
(434)	Bronson N, Menon R, Butler J, Gordon I. Parathyroidectomy, excision and skin grafting with topical negative pressure for calciphylactic ulcers. J Wound Care 2007 Jul;16(7):295-7.			✓	Case report	
(435)	Brown KM, Harper FV, Aston WJ, O'Keefe PA, Cameron CR. Vacuum-assisted closure in the treatment of a 9-year-old child with severe and multiple dog bite injuries of the thorax. Ann Thorac Surg 2001 Oct;72(4):1409-10.			✓	Case report	
(436)	Burton L. Nonhealing foot ulcer. Ostomy Wound Manage 1999 Sep;45(9):20-1.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(144)	Butter A, Emran M, Al-Jazaeri A, Ouimet A. Vacuum-assisted closure for wound management in the pediatric population. J Pediatr Surg 2006 May;41(5):940-2.	✓	KQ3			
(437)	Canavese F, Gupta S, Krajbich JI, Emara KM. Vacuum-assisted closure for deep infection after spinal instrumentation for scoliosis. J Bone Joint Surg Br 2008 Mar;90(3):377-81.	✓	KQ3			
(165)	Caniano DA, Ruth B, Teich S. Wound management with vacuum-assisted closure: experience in 51 pediatric patients. J Pediatr Surg 2005 Jan;40(1):128-32; discussion 132.	✓	KQ3			
(438)	Canter HI, Isci E, Erk Y. Vacuum-assisted wound closure for the management of a foot ulcer due to Buerger's disease. J Plast Reconstr Aesthet Surg 2007 Nov 1;Epub ahead of print.			✓	Case report	
(439)	Carson SN, Overall K, Lee-Jahshan S, Travis E. Vacuum-assisted closure used for healing chronic wounds and skin grafts in the lower extremities. Ostomy Wound Manage 2004 Mar;50(3):52-8.			✓	Narrative	
(137)	Catarino PA, Chamberlain MH, Wright NC, Black E, Campbell K, Robson D, Pillai RG. High-pressure suction drainage via a polyurethane foam in the management of poststernotomy mediastinitis. Ann Thorac Surg 2000 Dec;70(6):1891-5.			✓	Not relevant (suction drainage)	
(440)	Chandawarkar RY, Piorkowski J, Amjad I, Deckers PJ. Combination therapy of a large, recurrent keloid. Dermatol Surg 2007 Feb;33(2):229-35.			✓	Case report	
(441)	Chaouat M, Bonnet F, Seroussi D, Smarrito S, Mimoun M. Topical negative pressure for the treatment of complex cavity wounds associated with osteitis. J Wound Care 2006 Jul;15(7):292-4.			✓	Fewer than five patients	
(442)	Chariker ME, Jeter KF, Tintle TE, Bottsford JE. Effective management of incisional and cutaneous fistulae with close suction wound drainage. Contemp Surg 1989 Jun;34:59-63.			✓	Homemade device	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(443)	Chave H, Ahmed S, Fu B, Webber J, Banwell P, Tiernan E. Salvage of infected dermal collagen implants with topical negative pressure therapy. J Wound Care 2006 Apr;15(4):156-8.			✓	Case report	
(444)	Chen SZ, Li J, Li XY, Xu LS. Effects of Vacuum-assisted Closure on Wound Microcirculation: An Experimental Study. Asian J Surg 2005 Jul;28(3):211-7.			✓	Animal study	
(160)	Chen Y, Almeida AA, Mitnovetski S, Goldstein J, Lowe C, Smith JA. Managing deep sternal wound infections with vacuum-assisted closure. ANZ J Surg 2008 May;78(5):333-6.	✓	KQ3			
(445)	Chesher E. Use of vacuum-assisted closure in the community. Prim Intent 1998 Feb;6(1):12-15.			✓	Case report	
(446)	Chester DL, Waters R. Adverse alteration of wound flora with topical negative-pressure therapy: a case report. Br J Plast Surg 2002 Sep;55(6):510-1.			✓	Case report	
(447)	Childress B, Stechmiller JK, Schultz GS. Arginine metabolites in wound fluids from pressure ulcers: a pilot study. Biol Res Nurs 2008 Oct;10(2):87-92.			✓	No relevant outcomes	
(448)	Chung CJ, David LR, Morykwas M, Argenta L. Case review: management of life-threatening sepsis and wound healing in a Klippel-Trenaunay patient using serial surgical debridements and vaccum-assisted closure. Eur J Plastic Surg 2003 Jul;26(4):214-16.			✓	Case report	
(379)	Clare MP, Fitzgibbons TC, McMullen ST, Stice RC, Hayes DF, Henkel L. Experience with the Vacuum Assisted Closure negative pressure technique in the treatment of non-healing diabetic and dysvascular wounds. Foot Ankle Int 2002 Oct1;23(10):896-901.	✓	KQ3			
(449)	Coggrave M, West H, Leonard B. Topical negative pressure for pressure ulcer management. Br J Nurs 2002 Mar;11(6 Suppl):S29-36.			✓	Case reports	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(450)	Colwell AS, Donaldson MC, Belkin M, Orgill DP. Management of Early Groin Vascular Bypass Graft Infections with Sartorius and Rectus Femoris Flaps. Ann Plast Surg 2004;52(1):49-53.			✓	Not relevant - focus on effectiveness of muscle flaps	
(185)	Contractor D, Amling J, Brandoli C, Tosi LL. Negative pressure wound therapy with reticulated open cell foam in children: an overview. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S167-76.	✓	Previous Systematic Reviews			
(451)	Copson D. Topical negative pressure and necrotising fasciitis. Nurs Stand 2003 Oct 22-28;18(6):71-4, 76, 78 passim.			✓	Case report	
(356)	Cothren CC, Moore EE, Johnson JL, Moore JB, Burch JM. One hundred percent fascial approximation with sequential abdominal closure of the open abdomen. Am J Surg 2006 Aug;192(2):238-42.	✓	KQ3			
(373)	Cowan KN, Teague L, Sue SC, Mahoney JL. Vacuum-assisted wound closure of deep sternal infections in high-risk patients after cardiac surgery. Ann Thorac Surg 2005 Dec;80(6):2205-12.	✓	KQ3			
(452)	Cravero L, Taveggia A, Boriani F, Bruschi S, Boriani F. Osteomyelitis: A possible diagnostic mistake after vacuum-assisted therapy. J Plast Reconstr Aesthet Surg 2006;59(11):1250-1.			✓	Case report	
(453)	Cresti S, Ouaissi M, Sielezneff I, Chaix JB, Pirro N, Berthet B, Consentino B, Sastre B. Advantage of vacuum assisted closure on healing of wound associated with omentoplasty after abdominoperineal excision: a case report. World J Surg Oncol 2008 Dec 23;6(1):136.			✓	Case reports	
(454)	Cro C, George KJ, Donnelly J, Irwin ST, Gardiner KR. Vacuum assisted closure system in the management of enterocutaneous fistulae. Postgrad Med J 2002 Jun;78(920):364-5.			✓	Fewer than five patients	
(455)	Crumbley DR, Perciballi JA. Negative pressure wound therapy in a contaminated soft-tissue wound. J Wound Ostomy Continence Nurs 2007 Sep-Oct;34(5):507-12.			✓	No abstract available	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(456)	Culliford AT 4th, Spector JA, Levine JP. A novel technique for vacuum assisted closure device application in noncontiguous wounds. J Plast Reconstr Aesthet Surg 2007;60(1):99-100.			✓	Case report	
(457)	Dakin J, Thompson S. Use of topical negative pressure therapy with an abdominal dressing in management of a laparostomy. J Wound Care 2006 Oct;15(9):386-8.			✓	Case report	
(458)	Datiashvili RO, Knox KR. Negative pressure dressing: an alternative to free tissue transfers?. Wounds 2005 Aug;17(8):206-12.			✓	Narrative	
(459)	Davis L, Barker A. Coordination and management of TNP from acute to primary care: overcoming the issues. J Wound Care 2006 Apr;15(4):169-71.			✓	Narrative	
(460)	Davydov IuA, Malafeeva EV, Smirnov AP, Flegontov VB. Vacuum therapy in the treatment of suppurative lactation mastitis. Vestn Khir Im I I Grek 1986 Nov;137(11):66-70.			✓	Not a NPWT device	
(461)	Davydov YA, Larichev AB, Abramov AY, Menkov KG. Concepts for clinical biological management of the wound process in the treatment of purulent wounds using vacuum therapy] translated from Russian. Vestnik Khirurgii 1991 Feb;132-5. (Rus).			✓	Not a NPWT device	
(462)	Davydov YA, Larichev AB, Menlov KG. The bacteriological and cytological assessment of vacuum therapy of purulent wounds] translated from Russian. Vestnik Khirurgii 1988 Oct;48-52.			✓	Not a NPWT device	
(460)	Davydov YA, Malafeeva EV, Smirnov AP, Flegontov VB. [Vacuum therapy in the treatment of purulent lactation mastitis] translated from Russian. Vestnik Khirurgii 1986 Sep;66-70. (Rus).			✓	Not a NPWT device	
(463)	de Geus HR, van der Klooster JM. Vacuum-assisted closure in the treatment of large skin defects due to necrotizing fasciitis. Intensive Care Med 2005 Apr;31(4):601.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(464)	de la Torre JI, Martin SA, Oberheu AM, Vasconez LO. Healing a wound with an exposed Herrington rod: a case study. Ostomy Wound Manage 2002 May;48(5):18-9.			✓	Case report	
(167)	De Lange MY, Schasfoort RA, Obdeijn MC, Van Der Werff JFA, Nicolai JPA. Vacuum-assisted closure: Indications and clinical experience. Eur J Plastic Surg 2000 May;23(4):178-82.	✓	KQ3			
(8)	de Leon J. Negative pressure wound therapy in pressure ulcer management. Ostomy Wound Manage 2005 Feb;51(2A Suppl):3-8.			✓	Case reports	
(465)	de Weerd L, Kjaeve J, Aghajani E, Elvenes OP. The sandwich design: a new method to close a high-output enterocutaneous fistula and an associated abdominal wall defect. Ann Plast Surg 2007 May;58(5):580-3.			✓	Case report	
(27)	Dedmond BT, Kortesis B, Punger K, Simpson J, Argenta J, Kulp B, Morykwas M, Webb LX. The use of negative-pressure wound therapy (NPWT) in the temporary treatment of soft-tissue injuries associated with high-energy open tibial shaft fractures. J Orthop Trauma 2007 Jan;21(1):11-7.	✓	KQ3			
(222)	Dedmond BT, Kortesis B, Punger K, Simpson J, Argenta J, Kulp B, Morykwas M, Webb LX. Subatmospheric pressure dressings in the temporary treatment of soft tissue injuries associated with type III open tibial shaft fractures in children. J Pediatr Orthop 2006 Nov;26(6):728-32.			✓	Duplicate study(27)	
(466)	Dee A. The successful management of a dehisced surgical wound with TNP following femoropopliteal bypass. J Wound Care 2007 Jan;16(1):42-4.			✓	Case report	
(157)	DeFranzo AJ, Argenta LC, Marks MW, Molnar JA, David LR, Webb LX, Ward WG, Teasdall RG. The use of vacuum-assisted closure therapy for the treatment of lower-extremity wounds with exposed bone. Plast Reconstr Surg 2001 Oct;108(5):1184-91.	✓	KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(467)	DeFranzo AJ, Marks MW, Argenta LC, Genecov DG. Vacuum-assisted closure for the treatment of degloving injuries. Plast Reconstr Surg 1999 Dec;104(7):2145-8.			✓	Fewer than five patients	
(156)	DeFranzo AJ, Pitzer K, Molnar JA, Marks MW, Chang MC, Miller PR, Letton RW, Argenta LC. Vacuum-assisted closure for defects of the abdominal wall. Plast Reconstr Surg 2008 Mar;121(3):832-9.	✓	KQ3			
(468)	Demaria R, Giovannini UM, Teot L, Chaptal PA. Using VAC to treat a vascular bypass site infection. J Wound Care 2001 Feb;10(2):12-3.			✓	Case report	
(145)	Demaria RG, Giovannini U, Teot L, Frapier JM, Albat B. A new technique for the treatment of delayed sternotomy healing: the vacuum therapy. Heart Surg Forum 2003;6(5):434-7.	✓	KQ3			
(135)	Denzinger S, Lubke L, Roessler W, Wieland WF, Kessler S, Burger M. Vacuum-assisted closure versus conventional wound care in the treatment of wound failures following inguinal lymphadenectomy for penile cancer: a retrospective study. Eur Urol 2007 May;51(5):1320-5.	✓	KQ1, KQ3			
(135)	Denzinger S, Lubke L, Roessler W, Wieland WF, Kessler S, Burger M. Vacuum-assisted closure versus conventional wound care in the treatment of wound failures following inguinal lymphadenectomy for penile cancer: a retrospective study. Eur Urol 2007 May;51(5):1320-5.	✓	KQ1, KQ3			
(469)	Derrick KL, Norbury K, Kieswetter K, Skaf J, McNulty AK. Comparative analysis of global gene expression profiles between diabetic rat wounds treated with vacuum-assisted closure therapy, moist wound healing or gauze under suction. Int Wound J 2008 Dec;5(5):615-24.			✓	Animal study	
(382)	Deva AK, Buckland GH, Fisher E, Liew SC, Merten S, McGlynn M, Gianoutsos MP, Baldwin MA, Lendvay PG. Topical negative pressure in wound management. Med J Aust 2000 Aug 7;173(3):128-31.	✓	KQ3			

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(470)	Deva AK, Siu C, Nettle WJ. Vacuum-assisted closure of a sacral pressure sore. J Wound Care 1997 Jul;6(7):311-2.			✓	Case report	
(471)	Dickie SR, Dorafshar AH, Song DH. Definitive closure of the infected median sternotomy wound: a treatment algorithm utilizing vacuum-assisted closure followed by rigid plate fixation. Ann Plast Surg 2006 Jun;56(6):680-5.			✓	Algorithm	
(472)	Dieu T, Leung M, Leong J, Morrison W, Cleland H, Archer B, Oppy A. Too much vacuum-assisted closure. ANZ J Surg 2003 Dec;73(12):1057-60.			✓	Narrative	
(473)	Dobke MK, Nguyen D, Trott SA. A novel approach to acute infection of the glenohumeral joint following rotator cuff repair? A case series. Wounds 2005 Jun;17(6):137-40.			✓	No relevant outcomes	
(129)	Domkowski PW, Smith ML, gonyon Jr DL, Drye C, Wooten MK, Levin LS, wolfe WG. Evaluation of vacuum-assisted closure in the treatment of poststernotomy mediastinitis. J Thorac Cardiovasc Surg 2003 Aug 1;126(2):386-90.	✓	KQ1, KQ3			
(474)	Donovan DJ, Person DA. Giant eccrine adenocarcinoma of the scalp with intracranial invasion: resection and reconstruction using a vacuum-assisted closure device: technical case report. Neurosurgery 2006 Apr;58(4 Suppl 2):ONS-E371; discussion ONS.			✓	Case report	
(475)	Dosluoglu HH, Schimpf DK, Schultz R, Cherr GS. Preservation of infected and exposed vascular grafts using vacuum assisted closure without muscle flap coverage. J Vasc Surg 2005 Nov;42(5):989-92.			✓	Fewer than five patients	
(128)	Doss M, Martens S, Wood JP, Wolff JD, Baier C, Moritz A. Vacuum-assisted suction drainage versus conventional treatment in the management of poststernotomy osteomyelitis. Eur J Cardiothorac Surg 2002 Dec 1;22(6):934-8.	✓	KQ1, KQ3			
(476)	Dunbar A, Bowers DM, Holderness H Jr. Silicone net dressing as an adjunct with negative pressure wound therapy. Ostomy Wound Manage 2005 Apr;51(4):18, 20.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(477)	Durai R, Hoque H, Davies TW. 'Indirect VAC': a novel technique of applying vacuum-assisted closure dressing. J Perioper Pract 2008 Oct;18(10):437-9.			✓	Narrative	
(478)	Duxbury MS, Finlay IG, Butcher M, Lambert AW. Use of a vacuum assisted closure device in pilonidal disease. J Wound Care 2003 Oct;12(9):355.			✓	Case report	
(479)	Easterlin B, Bromberg W, Linscott J. A novel technique of vacuum assisted wound closure that functions as a delayed primary closure. Wounds 19(12):331-3.			✓	Narrative	
(480)	Eberlein T, Fendler H. Case studies of Prospera NPWT.Available: http://www.prospera-npwt.com/clincal_references.htm.			✓	Case reports	
(481)	Edwards AR. Vacuum device closes gap in wound care. Biomechanics 2001 Dec;8(12):27-34.			✓	Narrative	
(226)	Eginton MT, Brown KR, Seabrook GR, Towne JB, Cambria RA. A prospective randomized evaluation of negative-pressure wound dressings for diabetic foot wounds. Ann Vasc Surg 2003 Nov;17(6):645-9.			✓	Fewer than five patients	
(482)	Emohare O, Kowal-Vern A, Wiley D, Latenser BA. Vacuum-assisted closure use in calciphylaxis. J Burn Care Rehabil 2004 Mar-Apr;25(2):161-4.			✓	Fewer than five patients	
(483)	Ennis WJ. (President, Association for the Advancement of Wound Care). Personal communication. 2009 Feb 5. 2 p.			✓	Personal communication	
(484)	Erba P, Rieger UM, Pierer G, Kalbermatten DF. Vacuum-assisted closure (VAC) for venous congestion of the nipple-areola complex. J Plast Reconstr Aesthet Surg 2008 Jul;61(7):852-4.			✓	Case report	
(485)	Erdmann D, Drye C, Heller L, Wong MS, Levin SL. Abdominal wall defect and enterocutaneous fistula treatment with the Vacuum-Assisted Closure (V.A.C.) system. Plast Reconstr Surg 2001 Dec;108(7):2066-8.			✓	Case report	

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(486)	Espensen EH, Nixon BP, Lavery LA, Armstrong DG. Use of subatmospheric (VAC) therapy to improve bioengineered tissue grafting in diabetic foot wounds. J Am Podiatr Med Assoc 2002 Jul-Aug;92(7):395-7.			✓	Narrative	
(487)	Evans D, Land L. Topical negative pressure for treating chronic wounds: a systematic review. Br J Plast Surg 2001 Apr;54(3):238-42.			✓	(169)update	
(786)	Evidence summary. San Antonio (TX): Kinetic Concepts, Inc.; 19 p.			✓	Narrative – individual studies captured in bibliography	
(488)	Ferdinando E, Guerin L, Jervis AO, Obidigbo H. Negative-pressure wound therapy and external fixation for infection and hematoma after hallux abducto valgus surgery. J Am Podiatr Med Assoc 2007 Sep-Oct;97(5):410-4.			✓	Case report	
(489)	Ferreira MC, Wada A, Tuma Jr P. The vacuum assisted closure of complex wounds: report of 3 cases. Rev Hosp Clin Fac Med Sao Paulo 2003 Jul-Aug;58(4):227-30.			✓	Fewer than five patients	
(83)	Ferron G, Garrido I, Martel P, Gesson-Paute A, Classe JM, Letourneur B, Querleu D. Combined laparoscopically harvested omental flap with meshed skin grafts and vacuum-assisted closure for reconstruction of complex chest wall defects. Ann Plast Surg 2007 Feb;58(2):150-5.	✓	KQ3			✓
(490)	Fette A. Treatment of pressure ulcers with topical negative pressure versus traditional wound management methods: a research sampler. Plast Surg Nurs 2005 Oct-Dec;25(4):176-80.			✓	Narrative	
(491)	Fife CE, Otto G, Walker D, Turner T, Smith L. Healing dehisced surgical wounds with negative pressure wound therapy. Ostomy Wound Manage 2004 Apr;50(4A Suppl):28-31.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(492)	Fischer JE. A cautionary note: the use of vacuum-assisted closure systems in the treatment of gastrointestinal cutaneous fistula may be associated with higher mortality from subsequent fistula development. Am J Surg 2008 Jul;196(1):1-2.			✓	Narrative	
(168)	Fisher A, Brady B. Vacuum assisted wound closure therapy. Issues Emerg Health Technol 2003 Mar;(44):1-6.	✓	Previous Systematic Reviews			
(493)	Fitzmaurice M, Lawson D, Friedman H. A novel approach for the application of the vacuum assisted closure device to the difficult anatomy. J Plast Reconstr Aesthet Surg 2006;59(11):1249-50.			✓	Case report	
(494)	Flack S, Apelqvist J, Keith M, Trueman P, Williams D. An economic evaluation of VAC therapy compared with wound dressings in the treatment of diabetic foot ulcers. J Wound Care 2008 Feb;17(2):71-8.			✓	Cost analysis	
(495)	Fleck T, Gustafsson R, Harding K, Ingemansson R, Lirtzman MD, Meites HL, Moidl R, Price P, Ritchie A, Salazar J, Sjogren J, Song DH, Sumpio BE, Toursarkissian B, Waldenberger F, Wetzel-Roth W. The management of deep sternal wound infections using vacuum assisted closure (V.A.C.) therapy. Int Wound J 2006 Dec;3(4):273-80.			✓	Narrative	
(362)	Fleck T, Kickinger B, Moidl R, Waldenberger F, Wolner E, Grabenwoger M, Wisser W. Management of open chest and delayed sternal closure with the vacuum assisted closure system: Preliminary experience. Interact Cardiovasc Thorac Surg 2008 Oct;7(5):801-4.	✓	KQ3			
(496)	Fleck T, Moidl R, Giovanoli P, Aszmann O, Bartunek A, Blacky A, Grabenwoger M, Wolner E. A conclusion from the first 125 patients treated with the vacuum assisted closure system for postoperative sternal wound infection. Interact Cardiovasc Thorac Surg 2006 Apr;5(2):145-8.			✓	Not relevant -focus on management of infection	

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(497)	Fleck T, Simon P, Burda G, Wolner E, Wollenek G. Vacuum assisted closure therapy for the treatment of sternal wound infections in neonates and small infants. Interact Cardiovasc Thorac Surg 2006 Jun;5(3):285-8.			✓	Fewer than 5 patients	
(380)	Fleck TM, Fleck M, Moidl R, Czerny M, Koller R, Giovanoli P, Hiesmayer MJ, Zimpfer D, Wolner E, Grabenwoger M. The vacuum-assisted closure system for the treatment of deep sternal wound infections after cardiac surgery. Ann Thorac Surg 2002 Nov 1;74(5):1596-1600.	✓	KQ3			
(498)	Fleck TM, Koller R, Giovanoli P, Moidl R, Czerny M, Fleck M, Wolner E, Grabenwoger M. Primary or delayed closure for the treatment of poststernotomy wound infections. Ann Plast Surg 2004 Mar;52(3):310-4.			✓	Not relevant	
(499)	Fleischmann W, Strecker W, Bombelli M, Kinzl L. [Vacuum sealing as treatment of soft tissue damage in open fractures]. Unfallchirurgie 1993;96(9):488-92.			✓	Narrative	
(232)	Foo A, Kin-Sze Chong A, Shenthilkumar N. The 'hand-in-gloves' technique: vacuum-assisted closure dressing for multiple finger wounds. J Plast Reconstr Aesthet Surg 2008 Sep 5; Epub ahead of print.			✓	Case report	
(110)	Ford CN, Reinhard ER, Yeh D, Syrek D, De Las Morenas A, Bergman SB, Williams S, Hamori CA. Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the Healthpoint system in the management of pressure ulcers. Ann Plast Surg 2002 Jul;49(1):55-61; discussion 61.	✓	KQ1,KQ3			
(500)	Ford SJ, Rathinam S, King JE, Vaughan R. Tuberculous osteomyelitis of the sternum: successful management with debridement and vacuum assisted closure. Eur J Cardiothorac Surg 2005 Oct;28(4):645-7.			✓	Case report	
(501)	Ford-Dunn S. Use of vacuum assisted closure therapy in the palliation of a malignant wound. Palliat Med 2006 Jun;20(4):477-8.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(502)	Fox A, Tadros A, Perks AG. An unusual complication of Vacuum Assisted Closure in the treatment of a pressure ulcer. J Wound Care 2004 Sep;13(8):344-5.			✓	Case report	
(503)	Fox MP, Fazal MA, Ware HE. Vacuum assisted wound closure. A new method for control of wound problems in total knee arthroplasty. J Bone Joint Surg Br 2000 Jan;82-B(Suppl 1):19.			✓	Fewer than 5 patients	
(504)	Fredeking AE, Silverman RA. Successful treatment of trigeminal trophic syndrome in a 6-year-old boy with negative pressure wound therapy. Arch Dermatol 2008 Aug;144(8):984-6.			✓	Case report	
(505)	Friedman T, Westreich M, Shalom A. Vacuum-assisted closure treatment complicated by anasarca. Ann Plast Surg 2005 Oct;55(4):420-1.			✓	Case report	
(506)	Froiland KG. Nursing interventions in oncology complex wound care: use of negative pressure therapy for wound healing in an ovarian cancer patient. [internet]. [accessed 2001 Oct 23]. Available: http://www.thecancergroup.org/kathrynfroiland.htm.			✓	Case report	
(787)	Fruchterman T. (Senior Vice President, Research & Development & Chief Technology Officer). Kinetic Concepts, Inc. submission of information for use in review of Negative Pressure Wound Therapy (NPWT). 2009 Feb 4. 3 p.			✓	Cover letter	
(507)	Frykberg F. When is NPWT appropriate for amputation wounds?. APMA News 2005 May;26(5 Suppl):20-3.			✓	Narrative	
(508)	Frykberg RG, Williams DV. Negative-pressure wound therapy and diabetic foot amputations: a retrospective study of payer claims data. J Am Podiatr Med Assoc 2007 Sep-Oct;97(5):351-9.			✓	Cost analysis	
(23)	Fuchs U, Zittermann A, Stuettgen B, Groening A, Minami K, Koerfer R. Clinical outcome of patients with deep sternal wound infection managed by vacuum-assisted closure compared to conventional therapy with open packing: a retrospective analysis. Ann Thorac Surg 2005 Feb;79(2):526-31.	✓	KQ1,KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(509)	Gabriel A, Gollin G. Management of complicated gastroschisis with porcine small intestinal submucosa and negative pressure wound therapy. J Pediatr Surg 2006 Nov;41(11):1836-40.			✓	Animal study	
(383)	Gabriel A, Heinrich C, Shores J, Cho D, Baqai W, Moores D, Miles D, Gupta S. Outcomes of vacuum-assisted for the treatment of wounds in a paediatric population: case series of 58 patients. J Plast Reconstr Aesthet Surg 2008 Oct 2;Epub ahead of print.	✓	KQ3			
(510)	Gabriel A, Heinrich C, Shores JT, Baqui WK, Rogers FR, Gupta S. Reducing bacterial bioburden in infected wounds with vacuum assisted closure and a new silver dressing - a pilot study. Wounds 2006 Sep;18(9):245-55.			✓	Duplicate study(383)	
(339)	Gabriel A, Shores J, Heinrich C, Baqai W, Kalina S, Sogioka N, Gupta S. Negative pressure wound therapy with instillation: A pilot study describing a new method for treating infected wounds. Int Wound J 2008 Jun;5(3):399-413.	✓	KQ1, KQ3			
(86)	Garner GB, Ware DN, Cocanour CS, Duke JH, McKinley BA, Kozar RA, Moore FA. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. Am J Surg 2001 Dec;182(6):630-8.	✓	KQ3			✓
(154)	Gdalevitch P, Afilalo J, Lee C. Predictors of vacuum-assisted closure failure of sternotomy wounds. J Plast Reconstr Aesthet Surg 2008 Nov 21;Epub ahead of print.	✓	KQ3			
(511)	Geller S. A closer look at NPWT in the wound care clinic setting. APMA News 2005 May;26(5 Suppl):43-5.			✓	Narrative	
(512)	Geller S. How to use NPWT successfully in the home care setting. APMA News 2005 May;26(5 Suppl):33-4.			✓	Narrative	
(513)	Geller SM, Longton JA. Ulceration of pyoderma gangrenosum treated with negative pressure wound therapy. J Am Podiatr Med Assoc 2005 Mar-Apr;95(2):171-4.			✓	Case report	

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(131)	Genecov DG, Schneider AM, Morykwas MJ, Parker D, White WL, Argenta LC. A controlled subatmospheric pressure dressing increases the rate of skin graft donor site reepithelialization. Ann Plast Surg 1998 Mar;40(3):219-25.	✓	KQ1, KQ3, Previous Systematic Reviews			
(514)	Gerry R, Kwei S, Bayer L, Breuing KH. Silver-impregnated vacuum-assisted closure in the treatment of recalcitrant venous stasis ulcers. Ann Plast Surg 2007 Jul;59(1):58-62.			✓	Fewer than 5 patients	
(515)	Ghersi MM, Ricotti C, Nousari CH, Newman MI. Negative pressure dressing in the management of pyoderma gangrenosum ulcer. Arch Dermatol 2007 Oct;143(10):1249-51.			✓	Case report	
(516)	Gomoll AH, Lin A, Harris MB. Incisional vacuum-assisted closure therapy. J Orthop Trauma 2006 Nov-Dec;20(10):705-9.			✓	Narrative	
(517)	Goverman J, Yelon JA, Platz JJ, Singson RC, Turcinovic M. The "Fistula VAC," a technique for management of enterocutaneous fistulae arising within the open abdomen: report of 5 cases. J Trauma 2006 Feb;60(2):428-31; discussion 431.			✓	Not relevant	
(177)	Gray M, Peirce B. Is negative pressure wound therapy effective for the management of chronic wounds. J Wound Ostomy Continence Nurs 2004 May/June;31(3):101-5.	✓	Previous Systematic Reviews			
(518)	Greene AK, Puder M, Roy R, Arsenault D, Kwei S, Moses MA, Orgill DP. Microdeformational wound therapy: effects on angiogenesis and matrix metalloproteinases in chronic wounds of 3 debilitated patients. Ann Plast Surg 2006 Apr;56(4):418-22.			✓	Fewer than 5 patients	
(519)	Greer S, Sims CD, Borud L, Thorne C, Kasabian A. The use of a subatmospheric pressure dressing to salvage a septic ankle with concomitant osteomyelitis and avert a free flap. Foot Ankle Int 1997 Sep;18(3):151-6.			✓	Case report	
(520)	Greer SE, Adelman M, Kasabian A, Galiano RD, Scott R, Longaker MT. The use of subatmospheric pressure dressing therapy to close lymphocutaneous fistulae of the groin. Br J Plast Surg 2000 Sep;53(6):484-7.			✓	Narrative	

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(521)	Greer SE, Duthie E, Cartolano B, Koehler KM, Maydick-Youngberg D, Longaker MT. Techniques for applying subatmospheric pressure dressing to wounds in difficult regions of anatomy. J Wound Ostomy Continence Nurs 1999 Sep;26(5):250-3.			✓	Narrative	
(522)	Greer SE, Longaker MT, Margiotta M, Mathews AJ, Kasabian A. The use of subatmospheric pressure dressing for the coverage of radial forearm free flap donor-site exposed tendon complications. Ann Plast Surg 1999 Nov;43(5):551-4.			✓	Narrative	
(173)	Gregor S, Maegele M, Sauerland S, Krahn JF, Peinemann F, Lange S. Negative pressure wound therapy: a vacuum of evidence?. Arch Surg 2008 Feb;143(2):189-96.	✓	Previous Systematic Reviews			
(523)	Grimm A, Dimmler A, Stange S, Labanaris A, Sauer R, Grabenbauer G, Horch RE. Expression of HIF-1 alpha in irradiated tissue is altered by topical negative-pressure therapy. Strahlenther Onkol 2007 Mar;183(3):144-9.			✓	No relevant outcomes	
(524)	Gudbjartsson T, Sigurdsson HK, Sigurdsson E, Kjartansson J. Vacuum-assisted closure for successful treatment of a major contaminated gunshot chest-wound: A case report. Eur J Trauma Emerg Surg 2008 July 25;Epub			✓	Case report	
(525)	Gunn LA, Follmar KE, Wong MS, Lettieri SC, Levin LS, Erdmann D. Management of enterocutaneous fistulae using negative-pressure dressings. Ann Plast Surg 2006 Dec;57(6):621-5.			✓	Not relevant	
(10)	Gupta S, Baharestani M, Baranoski S, de Leon J, Engel SJ, Mendez-Eastman S, Niezgoda JA, Pompeo MQ. Guidelines for managing pressure ulcers with negative pressure wound therapy. Adv Skin Wound Care 2004 Nov-Dec;17(Suppl 2):1-16.			✓	Guideline	
(236)	Gupta S, Cho T. A literature review of negative pressure wound therapy. Ostomy Wound Manage 2004 Apr;50(4A Suppl):6-8.			✓	Duplicate study(188)	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(526)	Gupta S, Gabriel A, Shores J. The perioperative use of negative pressure wound therapy in skin grafting. Ostomy Wound Manage 2004 Apr;50(4A Suppl):32-4.			✓	Narrative	
(381)	Gustafsson R, Johnsson P, Algotsson L, Blomquist S, Ingemansson R. Vacuum-assisted closure therapy guided by C-reactive protein level in patients with deep sternal wound infection. J Thorac Cardiovasc Surg 2002 May;123(5):895-900.	✓	KQ3			
(146)	Gustafsson RI, Sjogren J, Ingemansson R. Deep Sternal Wound Infection: A Sternal-Sparing Technique with Vacuum-Assisted Closure Therapy. Ann Thorac Surg 2003;76(6):2048-2053.	✓	KQ3			
(527)	Guzzo J, Bluman EM. Technique tip: easing subatmospheric wound dressing application and increasing sponge conformity. Foot Ankle Int 2007 May;28(5):638-9.			✓	Narrative	
(528)	Gwan-Nulla DN, Casal RS. Toxic shock syndrome associated with the use of the vacuum-assisted closure device. Ann Plast Surg 2001 Nov;47(5):552-4.			✓	Case report	
(140)	Ha J, Phillips M. A retrospective review of the outcomes of vacuum-assisted closure therapy in a vascular surgery unit. Wounds 2008 Aug;20(8):221-9.	✓	KQ3			
(529)	Hallock GG, Cipolle MD, Bradow BP. Enterocutaneous fistula associated with an unrecognized retained vacuum-assisted closure sponge. Plast Reconstr Surg 2008 Aug;122(2):84e-5e.			✓	Case report	
(363)	Hamed O, Muck PE, Smith JM, Krallman K, Griffith NM. Use of vacuum-assisted closure (VAC) therapy in treating lymphatic complications after vascular procedures: new approach for lymphoceles. J Vasc Surg 2008 Dec;48(6):1520-3, 1523.e1-4.	✓	KQ3			
(530)	Hanasono MM, Skoracki RJ. Securing skin grafts to microvascular free flaps using the vacuum-assisted closure (VAC) device. Ann Plast Surg 2007 May;58(5):573-6.			✓	Narrative	
(531)	Hardcastle MR. The application of negative pressure in wound healing. Prim Intent 1998 Feb;5-10			✓	Narrative	

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(532)	Hardwicke J, Paterson P. A role for vacuum-assisted closure in lower limb trauma: a proposed algorithm. Int J Low Extrem Wounds 2006 Jun;5(2):101-4.			✓	Narrative	
(533)	Harlan JW. Treatment of open sternal wounds with the vacuum-assisted closure system: a safe, reliable method. Plast Reconstr Surg 2002 Feb;109(2):710-2.			✓	Narrative	
(534)	Hartnett JM. Use of vacuum-assisted wound closure in three chronic wounds. J Wound Ostomy Continence Nurs 1998 Nov;25(6):281-90.			✓	Fewer than five patients	
(351)	Helgeson MD, Potter BK, Evans KN, Shawen SB. Bioartificial dermal substitute: A preliminary report on its use for the management of complex combat-related soft tissue wounds. J Orthop Trauma 2007 Jul;21(6):394-9.	✓	KQ3			
(87)	Heller L, Levin SL, Butler CE. Management of abdominal wound dehiscence using vacuum assisted closure in patients with compromised healing. Am J Surg 2006 Feb;191(2):165-72.	✓	KQ3			✓
(360)	Herscovici Jr D, Sanders RW, Scaduto JM, Infante A, DiPasquale T. Vacuum-assisted wound closure (VAC therapy) for the management of patients with high-energy soft tissue injuries. J Orthop Trauma 2003;17(10):683-8.	✓	KQ3			
(94)	Hersh RE, Jack JM, Dahman MI, Morgan RF, Drake DB. The vacuum-assisted closure device as a bridge to sternal wound closure. Ann Plast Surg 2001 Mar;46(3):250-4.	✓	KQ3			✓
(535)	Hersh RE, Kaza AK, Long SM, Fiser SM, Drake DB, Tribble CG. A technique for the treatment of sternal infections using the Vacuum Assisted Closure device. Heart Surg Forum 2001;4(3):211-5.			✓	Narrative	
(536)	Heugel JR, Parks KS, Christie SS, Pulito JF, Zegzula DH, Kemalyan NA. Treatment of the exposed achilles tendon using negative pressure wound therapy: a case report. J Burn Care Rehabil 2002 May-Jun;23(3):167-71.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(537)	Heuser M, Laabs SO, Plothe KD. Extraperitoneal bladder leakage after provision of topical negative therapy: a case report. J Wound Care 2005 Oct;14(9):406.			✓	Case report	
(538)	Hopf HW, Ueno C, Aslam R, Burnand K, Fife C, Grant L, Holloway A, Iafrati MD, Mani R, Misare B, Rosen N, Shapshak D, Benjamin Slade J Jr, West J, Barbul A. Guidelines for the treatment of arterial insufficiency ulcers. Wound Repair Regen 2006 Nov-Dec;14(6):693-710.			✓	Guideline	
(78)	Horn PL, Ruth B, Kean JR. Use of wound V.A.C. therapy in pediatric patients with infected spinal wounds: a retrospective review. Orthop Nurs 2007 Sep-Oct;26(5):317-22; quiz 323-4.	✓	KQ3			✓
(127)	Huang WS, Hsieh SC, Hsieh CS, Schoung JY, Huang T. Use of vacuum-assisted wound closure to manage limb wounds in patients suffering from acute necrotizing fasciitis. Asian J Surg 2006 Jul;29(3):135-9.	✓	Previous Systematic Reviews			
(539)	Huljev D, Kucisec-Tepes N. Necrotizing fascilitis of the abdominal wall as a post-surgical complication: a case report. Wounds 2005 Jul;17(7):169-77.			✓	Case report	
(540)	Humburg J, Holzgreve W, Hoesli I. Negative pressure wound therapy in post-cesarian superficial wound disruption: a report of 3 cases. Wounds 2006 Jun;18(6):166-9.			✓	Fewer than five patients	
(242)	Hunter JE, Teot L, Horch R, Banwell PE. Evidence-based medicine: Vacuum-assisted closure in wound care management. Int Wound J 2007 Sep;4(3):256-69.			✓	Narrative	
(541)	Hunter S, Langemo D, Hanson D, Anderson J, Thompson P. The use of negative pressure wound therapy. Adv Skin Wound Care 2007 Feb;20(2):90-5.			✓	Narrative	
(542)	Hutchinson L, Thompson J. Vacuum-assisted closure: a method of facilitating wound healing. World Counc Enteros Ther J 1999 Jul-Sep;19(3):17-21.			✓	Case reports	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(130)	Immer FF, Durrer M, Muhlemann KS, Erni D, Gahl B, Carrel TP. Deep sternal wound infection after cardiac surgery: modality of treatment and outcome. Ann Thorac Surg 2005 Sep;80(3):957-61.	✓	KQ1, KQ3, Previous Systematic Reviews			
(543)	Isago T, Nozaki M, Kikuchi Y, Honda T, Nakazawa H. Effects of different negative pressures on reduction of wounds in negative pressure dressings. J Dermatol 2003 Aug;30(8):596-601.			✓	Animal study	
(91)	Isago T, Nozaki M, Kikuchi Y, Honda T, Nakazawa H. Negative-pressure dressings in the treatment of pressure ulcers. J Dermatol 2003 Apr;30(4):299-305.	✓	KQ3			✓
(544)	Isago T, Nozaki M, Kikuchi Y, Honda T, Nakazawa H. Skin graft fixation with negative-pressure dressings. J Dermatol 2003 Sep;30(9):673-8.			✓	Narrative	
(545)	Iusupov IuN, Epifanov MV. [Active drainage of a wound. Vestn Khir Im I I Grek 1987 Apr;138(4):42-6.			✓	Animal study	
(546)	Jacobs S, Simhaee DA, Marsano A, Fomovsky GM, Niedt G, Wu JK. Efficacy and mechanisms of vacuum-assisted closure (VAC) therapy in promoting wound healing: a rodent model. J Plast Reconstr Aesthet Surg 2008 Jul 8;Epub ahead of print.			✓	Animal study	
(547)	Jehle KS, Rohatgi A. Use of porcine dermal collagen graft and topical negative pressure on infected open abdominal wounds. J Wound Care 2007 Jan;16(1):36-7.			✓	Case report	
(246)	Jeschke MG, Rose C, Angele P, Fuchtmeier B, Nerlich MN, Bolder U. Development of new reconstructive techniques: use of Integra in combination with fibrin glue and negative-pressure therapy for reconstruction of acute and chronic wounds. Plast Reconstr Surg 2004 Feb;113(2):525-30.			✓	Not relevant – dual therapy	
(150)	Jones GA, Butler J, Lieberman I, Schlenk R. Negative-pressure wound therapy in the treatment of complex postoperative spinal wound infections: complications and lessons learned using vacuum-assisted closure. J Neurosurg Spine 2007 May;6(5):407-11.	✓	KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(548)	Jones SM, Banwell PE, Shakespeare PG. Advances in wound healing: topical negative pressure therapy. Postgrad Med J 2005 Jun;81(956):353-7.			✓	Narrative	
(247)	Jones SM, Banwell PE, Shakespeare PG. Interface dressings influence the delivery of topical negative-pressure therapy. Plast Reconstr Surg 2005 Sep 15;116(4):1023-8.			✓	Healthy volunteers	
(113)	Joseph E, Hamori CA, Bergman S, Roaf E, Swann NF, Anastasi GW. A prospective, randomized trial of vacuum-assisted closure versus standard therapy of chronic non-healing wounds. Wounds 2000;12(3):60-7. Also available: http://www.medscape.com/viewarticle/407550_print.	✓	KQ1, KQ3			
(549)	Josty IC, Ramaswamy R, Laing JH. Vaccum assisted closure: an alternative strategy in the management of degloving injuries of the foot. Br J Plast Surg 2001 Jun;54(4):363-5.			✓	Case report	
(550)	Kadohama T, Akasaka N, Nagamine A, Nakanishi K, Kiyokawa K, Goh K, Sasajima T. Vacuum-assisted closure for pediatric post-sternotomy mediastinitis: are low negative pressures sufficient. Ann Thorac Surg 2008 Mar;85(3):1094-6.			✓	Case reports	
(343)	Kamolz LP, Andel H, Haslik W, Winter W, Meissl G, Frey M. Use of subatmospheric pressure therapy to prevent burn wound progression in human: first experiences. Burns 2004 May;30(3):253-8.	✓	KQ1, KQ3			
(25)	Kanakaris NK, Thanasas C, Keramaris N, Kontakis G, Granick MS, Giannoudis PV. The efficacy of negative pressure wound therapy in the management of lower extremity trauma: Review of clinical evidence. Injury 2007;38:S8-S10,S11-S17.	✓	Previous Systematic Reviews			
(551)	Kang GC, Yam A. Vacuum-assisted closure of a large palmar defect after debriding a midpalmar tuberculous abscess. Int Wound J 2008 Mar;5(1):45-8.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(552)	Kaplan M, Banwell P, Orgill DP, Ivatury RR, Demetriades D, Moore FA, Miller P, Nicholas J, Henry S. Guidelines for the management of the open abdomen. Wounds 2005 Oct;17(Suppl 1):S1-S24.			✓	Guideline	
(553)	Kaplan M. Abdominal compartment syndrome. Ostomy Wound Manage 2004 Apr;50(4A Suppl):20-1.			✓	Case report	
(554)	Kaplan M. Managing the open abdomen. Ostomy Wound Manage 2004 Jan;50(1A Suppl):C2, 1-8, quiz.			✓	Narrative	
(555)	Kaplan M. Negative pressure wound therapy in the management of abdominal compartment syndrome. Ostomy Wound Manage 2004 Nov;50(11A Suppl):20S-25S.			✓	Case reports	
(556)	Kaplan M. Negative pressure wound therapy in the management of abdominal compartment syndrome. Ostomy Wound Manage 2005 Feb;51(2A Suppl):29-35.			✓	Narrative	
(557)	Kaufman MW, Pahl DW. Vacuum-assisted closure therapy: wound care and nursing implications. Dermatol Nurs 2003 Aug;15(4):317-20, 323-5; quiz 326.			✓	Narrative	
(788)	KCI, Inc. ongoing clinical trials. San Antonio (TX): Kinetic Concepts, Inc.; 1 p.			✓	List of six ongoing trials evaluating protein profiling (k=2), gene expression (k=2), and markers of cellular energetics (k=2)	
(789)	KCI, Inc. referenced data on file. San Antonio (TX): Kinetic Concepts, Inc.; 1 p.			✓	List of two in vitro studies	
(790)	KCI, Inc. unpublished clinical trials. San Antonio (TX): Kinetic Concepts, Inc.; 2 p.			✓	Not relevant - trials discontinued	

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(558)	Kendrick AS, Chase CW. Salvage of an infected breast tissue expander with an implant sizer and negative pressure wound management. Plast Reconstr Surg 2008 Mar;121(3):138e-139e.			✓	Case report	
(559)	Kennedy A, Van Zant RS. Diverse applications of negative pressure wound therapy: a multiple case report. Physiother Theory Pract 2006 Apr;22(2):83-90.			✓	Case reports	
(560)	Kilbride KE, Cooney DR, Custer MD. Vacuum-assisted closure: A new method for treating patients with giant omphalocele. J Pediatr Surg 2006 Jan;41(1):212-5.			✓	Fewer than five patients	
(561)	Kilpadi D, Stechmiller J, Childress B, Cowan L, Comerio M, Kieswetter K, Schultz G. Composition of wound fluid from pressure ulcers treated with negative pressure wound therapy using VAC therapy in home health or extend care patients: a pilot study. Wounds 2006;18(5):119-26.			✓	No relevant outcomes	
(562)	Kilpadi DV, Feeley TD, Kiel JW. V.A.C. Therapy normalizes vascular response of injured tissue in full-thickness wounds in rabbits. Ann Plast Surg 2007 May;58(5):555-60.			✓	Animal study	
(251)	Kim EK, Hong JP. Efficacy of negative pressure therapy to enhance take of 1-stage allodermis and a split-thickness graft. Ann Plast Surg 2007 May;58(5):536-40.			✓	Homemade device	
(563)	Kirby JP, Fantus RJ, Ward S, Sanchez O, Walker E, Mellett MM, Maltz SB, Lerner TT. Novel uses of a negative-pressure wound care system. J Trauma 2002 Jul;53(1):117-21.			✓	Narrative	
(564)	Klayman MH, Trowbridge CC, Stammers AH, Wolfgang GL, Zijerdi DA, Bitterly TJ. Autologous platelet concentrate and vacuum-assisted closure device use in a nonhealing total knee replacement. J Extra Corpor Technol 2006 Mar;38(1):44-7.			✓	Case report	
(565)	Kloth LC. 5 questions-and answers-about negative pressure wound therapy. Adv Skin Wound Care 2002 Sep-Oct;15(5):226-9.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(566)	Koehler C, Niederbichler AD, Jung FJ, Scholz T, Labler L, Perez D, Jandali A, Comber M, Kuenzi W, Wedler V. Wound therapy using the vacuum-assisted closure device: clinical experience with novel indications. J Trauma 2008 Sep;65(3):722-31; discussion 731.			✓	No abstract available	
(567)	Kopp J, Kneser U, Bach AD, Horch RE. Buried chip skin grafting in neuropathic diabetic foot ulcers following vacuum-assisted wound bed preparation: enhancing a classic surgical tool with novel technologies. Int J Low Extrem Wounds 2004 Sep;3(3):168-71.			✓	Narrative	
(568)	Kopp J, Strnad V, Bach AD, Sauer R, Horch RE. Vacuum application increases therapeutic safety and allows intensified local radiation treatment of malignant soft-tissue tumors. Strahlenther Onkol 2005 Feb;181(2):124-30.			✓	Fewer than five patients	
(340)	Korber A, Franckson T, Grabbe S, Dissemond J. Vacuum assisted closure device improves the take of mesh grafts in chronic leg ulcer patients. Dermatology 2008;216(3):250-6.	✓	KQ1, KQ3			
(569)	Kordasiewicz LM, Schultz RO. A paraplegic with stage IV pressure ulcers: risk factors and wound care. J Wound Ostomy Continence Nurs 2003 Mar;30(2):84-9.			✓	Case report	
(570)	Kostiuchenok BM, Kolker II, Karlov VA, Ignatenko SN, Muzykant LI. Vacuum treatment in the surgical management of suppurative wounds. Vestn Khir Im I I Grek 1986 Sep;137(9):18-21.			✓	Not a NPWT device	
(73)	Kotsis T, Lioupis C. Use of vacuum assisted closure in vascular graft infection confined to the groin. Acta Chir Belg 2007 Jan-Feb;107(1):37-44.	✓	KQ3			✓
(571)	Kovacs LH, Kloeppel M, Papadopulos NA, Reeker W, Biemer E. Necrotizing fasciitis. Ann Plast Surg 2001 Dec;47(6):680-2.			✓	Case report	
(253)	Krasner DL. Managing wound pain in patients with vacuum-assisted closure devices. Ostomy Wound Manage 2002 May;48(5):38-43.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(572)	Kumar S, O'Donnell ME, Khan K, Dunne G, Carey PD, Lee J. Successful treatment of perineal necrotising fasciitis and associated pubic bone osteomyelitis with the vacuum assisted closure system. World J Surg Oncol 2008;6:67.			✓	Case report	
(364)	Labanaris AP, Polykandriotis E, Horch RE. The effect of vacuum-assisted closure on lymph vessels in chronic wounds. J Plast Reconstr Aesthet Surg 2008 Jun 2;Epub ahead of print.	✓	KQ3			
(370)	Labler L, Keel M, Trentz O, Heinzelmann M. Wound conditioning by vacuum assisted closure (V.A.C.) in postoperative infections after dorsal spine surgery. Eur Spine J 2006 Sep;15(9):1388-96.	✓	KQ3			
(71)	Labler L, Keel M, Trentz O. Vacuum-assisted closure (VAC) for temporary coverage of soft-tissue injury in type III open fracture of lower extremities. Eur J Trauma 2004;30(5):305-12.	✓	KQ1, KQ3			✓
(352)	Labler L, Trentz O. The use of vacuum assisted closure (VAC™) in soft tissue injuries after high energy pelvic trauma. Langenbecks Arch Surg 2007 Sep;392(5):601-9.	✓	KQ3			
(357)	Labler L, Zwingmann J, Mayer D, Stocker R, Trentz O, Keel M. V.A.C. Abdominal Dressing System: A temporary closure for open abdomen. Eur J Trauma 2005 Oct;31(5):488-94.	✓	KQ3			
(573)	Lam WL, Garrido A, Stanley PR. Use of topical negative pressure in the treatment of chronic osteomyelitis. A case report. J Bone Joint Surg Am 2005 Mar;87(3):622-4.			✓	Case report	
(256)	Lambert KV, Hayes P, McCarthy M. Vacuum assisted closure: a review of development and current applications. Eur J Vasc Endovasc Surg 2005 Mar;29(3):219-26.			✓	Narrative	
(574)	Langley-Hawthorne C. Economics of negative pressure wound therapy. Ostomy Wound Manage 2004 Apr;50(4A Suppl):35-7.			✓	Narrative	
(575)	Laverty D, DeFranzo A. Negative pressure wound therapy in the management of orthopedic wounds. Ostomy Wound Manage 2004 Nov;50(11A Suppl):18S-19S.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(576)	Lavery L. Disease management programs: can they make a difference?. APMA News 2005 May;26(5-Suppl):27-29.			✓	Narrative	
(577)	Lavery L. Treating heel pressure unlcers with NPWT. APMA News 2005 May;26(5-Suppl):13-15.			✓	Narrative	
(257)	Lavery LA, Barnes SA, Keith MS, Seaman JW Jr, Armstrong DG. Prediction of healing for postoperative diabetic foot wounds based on early wound area progression. Diabetes Care 2008 Jan;31(1):26-9.			✓	Duplicate study(109)	
(341)	Lavery LA, Boulton AJ, Niezgoda JA, Sheehan P. A comparison of diabetic foot ulcer outcomes using negative pressure wound therapy versus historical standard of care. Int Wound J 2007 Jun;4(2):103-13.	✓	KQ1, KQ3			
(578)	Lee AT, Fanton GS, McAdams TR. Acute compartment syndrome of the thigh in a football athlete: a case report and the role of the vacuum-assisted wound closure dressing. J Orthop Trauma 2005 Nov-Dec;19(10):748-50.			✓	Case report	
(374)	Lee SS, Lin SD, Chen HM, Lin TM, Yang CC, Lai CS, Chen YF, Chiu CC. Management of intractable sternal wound infections with topical negative pressure dressing. J Card Surg 2005 May-Jun;20(3):218-22.	✓	KQ3			
(579)	Leijnen M, Steenvoorde P, van Doorn L, Zeillemaker AM, da Costa SA, Oskam J. Does VAC increase the risk of venous thromboembolism. J Wound Care 2007 May;16(5):211-2.			✓	No abstract available	
(111)	Leininger BE, Rasmussen TE, Smith DL, Jenkins DH, Coppola C. Experience with wound VAC and delayed primary closure of contaminated soft tissue injuries in Iraq. J Trauma 2006 Nov;61(5):1207-11.	✓	KQ1, KQ3			
(580)	Lemaire V, Brilmaker J, Kerzmann A, Jacquemin D. Treatment of a groin lymphatic fistula with negative pressure wound therapy. Eur J Vasc Endovasc Surg 2008 Oct;36(4):449-51.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(581)	Lemmon JA, Ahmad J, Ghavami A, Bidic SM. Vacuum-assisted closure over an external fixation device. Plast Reconstr Surg 2008 Apr;121(4):234e-5e.			✓	Case report	
(582)	Lentz S. Use of the vacuum-assisted closure system in management of the gynecologic surgical wound: a case report. J Pelvic Med Surg 2002 Jan;8(1):53-6.			✓	Case report	
(583)	Levin LS. Principles of definitive soft tissue coverage with flaps. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S161-6.			✓	Narrative	
(584)	Liao EC, Breuing KH. Breast mound salvage using vacuum-assisted closure device as bridge to reconstruction with inferolateral AlloDerm hammock. Ann Plast Surg 2007 Aug;59(2):218-24.			✓	No abstract available	
(585)	Lindstedt S, Malmsjo M, Gesslein B, Ingemansson R. Evaluation of continuous and intermittent myocardial topical negative pressure. J Cardiovasc Med (Hagerstown) 2008 Aug;9(8):813-9.			✓	Animal study	
(586)	Lindstedt S, Malmsjo M, Gesslein B, Ingemansson R. Topical negative pressure effects on coronary blood flow in a sternal wound model. Int Wound J 2008 Oct;5(4):503-9.			✓	Animal study	
(587)	Lindstedt S, Malmsjo M, Ingemansson R. Blood flow changes in normal and ischemic myocardium during topically applied negative pressure. Ann Thorac Surg 2007 Aug;84(2):568-73.			✓	Animal study	
(588)	Lindstedt S, Malmsjo M, Ingemansson R. No hypoperfusion is produced in the epicardium during application of myocardial topical negative pressure in a porcine model. J Cardiothorac Surg 2007;2:53.			✓	Animal study	
(589)	Lindstedt S, Malmsjo M, Sjogren J, Gustafsson R, Ingemansson R. Impact of different topical negative pressure levels on myocardial microvascular blood flow. Cardiovasc Revasc Med 2008 Jan-Mar;9(1):29-35.			✓	Animal study	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(590)	Lindstedt S, Paulsson P, Mokhtari A, Gesslein B, Hlebowicz J, Malmsjo M, Ingemansson R. A compare between myocardial topical negative pressure levels of -25 mmHg and -50 mmHg in a porcine model. BMC Cardiovasc Disord 2008;8:14.			✓	Animal study	
(591)	Literature review on Negative pressure wound therapy submission to AHRQ by the Association for the Advancement of Wound Care (AAWC) [unpublished]. 140 p.			✓	Table of Contents	
(259)	Llanos S, Danilla S, Barraza C, Armijo E, Pineros JL, Quintas M, Searle S, Calderon W. Effectiveness of negative pressure closure in the integration of split thickness skin grafts: a randomized, double-masked, controlled trial. Ann Surg 2006 Nov;244(5):700-5.			√	Homemade device	
(592)	Loos B, Kopp J, Hohenberger W, Horch RE. Post-malignancy irradiation ulcers with exposed alloplastic materials can be salvaged with topical negative pressure therapy (TNP). Eur J Surg Oncol 2007 Sep;33(7):920-5.			✓	Fewer than five patients	
(593)	Lopez Almodovar LF, Bustos G, Lima P, Canas A, Paredes I, Buendia JA. Transverse plate fixation of sternum: a new sternal-sparing technique. Ann Thorac Surg 2008 Sep;86(3):1016-7.			✓	Case reports	
(365)	Lopez G, Clifton-Koeppel R, Emil S. Vacuum-assisted closure for complicated neonatal abdominal wounds. J Pediatr Surg 2008 Dec;43(12):2202-7.	✓	KQ3			
(594)	Lynch JB, Laing AJ, Regan PJ. Vacuum-assisted closure therapy: a new treatment option for recurrent pilonidal sinus disease. Report of three cases. Dis Colon Rectum 2004 Jun;47(6):929-32.			✓	Case reports	
(74)	Machen MS. Management of traumatic war wounds using vacuum-assisted closure dressings in an austere environment. Army Med Dept J 2007 Jan-Mar;17-23.	✓	KQ3			✓
(595)	Maguina P, Kalimuthu R. Posterior rectal hernia after vacuum-assisted closure treatment of sacral pressure ulcer. Plast Reconstr Surg 2008 Jul;122(1):46e-47e.			✓	Case report	

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(596)	Malli S. Keep a close eye on vacuum-assisted wound closure. Nursing 2005 Jul;35(7):25.			✓	Case report	
(597)	Malmsjo M, Ingemansson R, Sjogren J. Mechanisms governing the effects of vacuum-assisted closure in cardiac surgery. Plast Reconstr Surg 2007 Oct;120(5):1266-75.			✓	Narrative	
(598)	Mandal A, Addison P, Stewart K, Neligan P. Vacuum-assisted closure therapy on pyoderma gangrenosum. J Plast Surg 2006 Apr;28(8):529-31.			✓	Fewer than five patients	
(599)	Mandal A. Role of topical negative pressure in pressure ulcer management. J Wound Care 2007 Jan;16(1):33-5.			✓	Narrative	
(600)	Marathe US, Sniezek JC. Use of the vacuum-assisted closure device in enhancing closure of a massive skull defect. Laryngoscope 2004 Jun;114(6):961-4.			✓	Case report	
(601)	Marsh DJ, Abu-Sitta G, Patel H. The role of vacuum-assisted wound closure in blast injury. Plast Reconstr Surg 2007 May;119(6):1978-9.			✓	No abstract available	
(602)	Matzi V, Lindenmann J, Porubsky C, Neuboeck N, Maier A, Smolle-Juettner FM. Intrathoracic insertion of the VAC device in a case of pleural empyema 20 years after pneumonectomy. Ann Thorac Surg 2007 Nov;84(5):1762-4.			✓	Not relevant	
(120)	McCallon SK, Knight CA, Valiulus JP, Cunningham MW, McCulloch JM, Farinas LP. Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. Ostomy Wound Manage 2000 Aug;46(8):28-32, 34.	✓	KQ1, KQ3			
(142)	McCord SS, Naik-Mathuria BJ, Murphy KM, McLane KM, Gay AN, Bob Basu C, Downey CR, Hollier LH, Olutoye OO. Negative pressure therapy is effective to manage a variety of wounds in infants and children. Wound Repair Regen 2007 May-Jun;15(3):296-301.	✓	KQ3			
(603)	McEwan W, Brown TL, Mills SM, Muller MJ. Suction dressings to secure a dermal substitute. Burns 2004 May;30(3):259-61.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(604)	McGuinness JG, Winter DC, O'Connell PR. Vacuum-assisted closure of a complex pilonidal sinus. Dis Colon Rectum 2003 Feb 1;46(2):274-6.			✓	Case report	
(605)	McNulty A.K., Schmidt, M., Feeley, Teri, Villaneuva, P., Kieswetter, K. 2009. Effects of negative pressure wound therapy on cellular energetics in fibroblasts grown in a provisional wound (fibrin) matrix [In Press]. Wound Repair Regen			✓	In vitro	
(606)	McNulty AK, Schmidt M, Feeley T, Kieswetter K. Effects of negative pressure wound therapy on fibroblast viability, chemotactic signaling, and proliferation in a provisional wound (fibrin) matrix. Wound Repair Regen 2007 Nov-Dec;15(6):838-46.			✓	In vitro	
(607)	Meara JG, Guo L, Smith JD, Pribaz JJ, Breuing KH, Orgill DP. Vacuum-assisted closure in the treatment of degloving injuries. Ann Plast Surg 1999 Jun;42(6):589-94.			✓	Narrative	
(376)	Mehbod AA, Ogilvie JW, Pinto MR, Schwender JD, Transfeldt EE, Wood KB, Le Huec JC, Dressel T. Postoperative deep wound infections in adults after spinal fusion: Management with vacuum-assisted wound closure. J Spinal Disord Tech 2005;18(1):14-7.	✓	KQ3			
(608)	Mendez-Eastman S. Give stubborn wounds a helping hand. Nursing Made Incredibly Easy 2007 Sep;5(5):18-20.			✓	Narrative	
(609)	Mendez-Eastman S. Guidelines for using negative pressure wound therapy. Adv Skin Wound Care 2001 Nov-Dec;14(6):314-22; quiz 324-5.			✓	Guideline	
(610)	Mendez-Eastman S. Negative pressure wound therapy. Plast Surg Nurs 1998 Spring;18(1):27-9, 33-7.			✓	Narrative	
(611)	Mendez-Eastman S. New treatment for an old problem: negative-pressure wound therapy. Nursing 2002 May;32(5):58-63; quiz 64.			✓	Narrative	
(612)	Mendez-Eastman S. Use of hyperbaric oxygen and negative pressure therapy in the multidisciplinary care of a patient with nonhealing wounds. J Wound Ostomy Continence Nurs 1999 MAR;26(2):67-76.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(375)	Mendonca DA, Cosker T, Makwana NK. Vacuum-assisted closure to aid wound healing in foot and ankle surgery. Foot Ankle Int 2005 Sep;26(9):761-6.	✓	KQ3			
(143)	Mendonca DA, Drew PJ, Harding KG, Price PE. A pilot study on the effect of topical negative pressure on quality of life. J Wound Care 2007 Feb;16(2):49-53.	✓	KQ3			
(187)	Mendonca DA, Papini R, Price PE. Negative-pressure wound therapy: a snapshot of the evidence. Int Wound J 2006 Dec;3(4):261-71.	✓	Previous Systematic Reviews			
(613)	Meyer W, Schmiden, V.Bier's hyperemic treatment in surgery, medicine and the specialties a manual of it's practical application. 2nd ed. Philadelphia: W.B. Saunders Company;			✓	Duplicate study(614)	
(614)	Meyer W, Schmieden V. Biers hyperemic treatment. Philadelphia: W.B. Saunders Company; 78-153 p.			✓	Narrative	
(281)	Miller PR, Thompson JT, Faler BJ, Meredith JW, Chang MC. Late fascial closure in lieu of ventral hernia: the next step in open abdomen management. J Trauma 2002 Nov;53(5):843-9.	✓	KQ1			✓
(281)	Miller PR, Thompson JT, Faler BJ, Meredith JW, Chang MC. Late fascial closure in lieu of ventral hernia: the next step in open abdomen management. J Trauma 2002 Nov;53(5):843-9.			✓	Case report	
(615)	Miller Q, Bird E, Bird K, Meschter C, Moulton MJ. Effect of subatmospheric pressure on the acute healing wound. Curr Surg 2004 Mar-Apr;61(2):205-8.			✓	Animal study	
(112)	Moisidis E, Heath T, Boorer C, Ho K, Deva AK. A prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in skin grafting. Plast Reconstr Surg 2004 Sep 15;114(4):917-22.	✓	KQ1,KQ3			
(366)	Mokhtari A, Sjogren J, Nilsson J, Gustafsson R, Malmsjo M, Ingemansson R. The cost of vacuum-assisted closure therapy in treatment of deep sternal wound infection. Scand Cardiovasc J 2008;42(1):85-9.	✓	KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(388)	Molnar JA, DeFranzo AJ, Hadaegh A, Morykwas MJ, Shen P, Argenta LC. Acceleration of integra incorporation in complex tissue defects with subatmospheric pressure. Plast Reconstr Surg 2004 Apr 15;113(5):1339-46.	✓	KQ3			
(616)	Molnar JA, DeFranzo AJ, Marks MW. Single-stage approach to skin grafting the exposed skull. Plast Reconstr Surg 2000 Jan;105(1):174-7.			✓	Fewer than five patients	
(617)	Molnar JA, Simpson JL, Voignier DM, Morykwas MJ, Argenta LC. Management of an acute thermal injury with subatmospheric pressure. J Burns Wounds 2005;4:e5.			✓	Case report	
(618)	Molnar JA. Applications of negative pressure wound therapy to thermal injury. Ostomy Wound Manage 2004 Apr;50(4A Suppl):17-9.			✓	Narrative	
(619)	Montecamozzo G, Leopaldi E, Baratti C, Previde P, Ferla F, Pizzi M, Sposato J, Pariani D, Sartani A, Trabucchi E. Incarcerated massive incisional hernia: extensive necrosis of the colon in a very obese patient. Surgical treatment and vacuum-assisted closure therapy: a case report. Hernia 2008 Dec;12(6):641-3.			✓	Case report	
(79)	Mooney JF 3rd, Argenta LC, Marks MW, Morykwas MJ, DeFranzo AJ. Treatment of soft tissue defects in pediatric patients using the V.A.C. system. Clin Orthop Relat Res 2000 Jul;(376):26-31.	✓	KQ3			✓
(620)	Moore K. VAC therapy: interactions in the healing process. Wounds UK 2005 May;1(1):86-90.			✓	Narrative	
(621)	Moran SG, Windham ST, Cross JM, Melton SM, Rue LW 3rd. Vacuum-assisted complex wound closure with elastic vessel loop augmentation: a novel technique. J Wound Care 2003 Jun;12(6):212-3.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(622)	Moreno-Coutino G, Estrada-Chavez G, Dominguez-Cherit J. Hip ulcer secondary to foreign body reaction and vacuum-assisted closure therapy: report of a case. Int Wound J 2005 Mar;2(1):81-3.			✓	Case report	
(623)	Morris GS, Brueilly KE, Hanzelka H. Negative pressure wound therapy achieved by vacuum-assisted closure: Evaluating the assumptions. Ostomy Wound Manage 2007 Jan;53(1):52-7.			✓	Narrative	
(624)	Morton N. Use of topical negative pressure therapy in postoperative dehisced or infected wounds. J Wound Care 2004 Sep;13(8):346-8.			✓	Narrative	
(33)	Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Ann Plast Surg 1997 Jun;38(6):553-62.			✓	Animal study	
(625)	Morykwas MJ, Argenta LC. Nonsurgical modalities to enhance healing and care of soft tissue wounds. J South Orthop Assoc 1997 Winter;6(4):279-88.			✓	Narrative	
(626)	Morykwas MJ, David LR, Schneider AM, Whang C, Jennings DA, Canty C, Parker D, White WL, Argenta LC. Use of subatmospheric pressure to prevent progression of partial-thickness burns in a swine model. J Burn Care Rehabil 1999 Jan-Feb;20(1 Pt 1):15-21.			✓	Animal study	
(36)	Morykwas MJ, Faler BJ, Pearce DJ, Argenta LC. Effects of varying levels of subatmospheric pressure on the rate of granulation tissue formation in experimental wounds in swine. Ann Plast Surg 2001 Nov;47(5):547-51.			✓	Animal study	
(627)	Morykwas MJ, Howell H, Bleyer AJ, Molnar JA, Argenta LC. The effect of externally applied subatmospheric pressure on serum myoglobin levels after a prolonged crush/ischemia injury. J Trauma 2002 Sep;53(3):537-40.			✓	Animal study	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(628)	Morykwas MJ, Kennedy A, Argenta JP, Argenta LC. Use of subatmospheric pressure to prevent doxorubicin extravasation ulcers in a swine model. J Surg Oncol 1999 SEP;72(1):14-7.			✓	Animal study	
(629)	Morykwas MJ, Simpson J, Punger K, Argenta A, Kremers L, Argenta J. Vacuum-assisted closure: state of basic research and physiologic foundation. Plast Reconstr Surg 2006 Jun;117(7 Suppl):121S-126S.			✓	Narrative	
(630)	Motta GJ, Corbett LQ. Impact of an antimicrobial gauze upon bacterial colonies in wounds that require packing. Ostomy Wound Manage 2004 Aug;50(8):48-62.			✓	Narrative	
(136)	Moues CM, van den Bemd GJ, Heule F, Hovius SE. Comparing conventional gauze therapy to vacuum-assisted closure wound therapy: a prospective randomised trial. J Plast Reconstr Aesthet Surg 2007;60(6):672-81.	✓	KQ1, KQ3			
(285)	Moues CM, van den Bemd GJ, Meerding WJ, Hovius SE. An economic evaluation of the use of TNP on full-thickness wounds. J Wound Care 2005 May;14(5):224-7.			✓	Duplicate study(38)	
(631)	Moues CM, van Toorenenbergen AW, Heule F, Hop WC, Hovius SE. The role of topical negative pressure in wound repair: expression of biochemical markers in wound fluid during wound healing. Wound Repair Regen 2008 Jul-Aug;16(4):488-94.			✓	No relevant outcomes	
(38)	Moues CM, Vos MC, van den Bemd GJ, Stijnen T, Hovius SE. Bacterial load in relation to vacuum-assisted closure wound therapy: a prospective randomized trial. Wound Repair Regen 2004 Jan-Feb;12(1):11-7.			✓	Duplicate study(136)	
(389)	Mullner T, Mrkonjic L, Kwasny O, Vecsei V. The use of negative pressure to promote the healing of tissue defects: a clinical trial using the vacuum sealing technique. Br J Plast Surg 1997 Apr;50(3):194-9.	✓	KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(632)	Nagell CF, Holte K. Treatment of anastomotic leakage after rectal resection with transrectal vacuum-assisted drainage (VAC). A method for rapid control of pelvic sepsis and healing. Int J Colorectal Dis 2006 Oct;21(7):657-60.			✓	Fewer than five patients in study arm	
(286)	Nelson EA. Vacuum assisted closure for chronic wounds: a review of the evidence. EWMA J 2007 Oct;7(3):5-11.			✓	Guideline	
(633)	Neubauer G, Ujlaky R. The cost-effectiveness of topical negative pressure versus other wound-healing therapies. J Wound Care 2003 Nov;12(10):392-3.			✓	No abstract available	
(634)	Newton H, Benbow M, Hampton S, Beldon P, Butcher M, Baxter H. TNP therapy in the community: findings of a national survey. Wounds UK 2006 Dec;2(4):31-5.			✓	Narrative	
(635)	Ng R, Sebastin SJ, Tihonovs A, Peng YP. Hand in glove—VAC dressing with active mobilisation. J Plast Reconstr Aesthet Surg 2006;59(9):1011-3.			✓	Narrative	
(636)	Nienhuijs SW, Manupassa R, Strobbe LJ, Rosman C. Can topical negative pressure be used to control complex enterocutaneous fistulae. J Wound Care 2003 Oct;12(9):343-5.			✓	Not relevant	
(637)	Niezgoda JA, Mendez-Eastman S. The effective management of pressure ulcers. Adv Skin Wound Care 2006 Jan-Feb;19 Suppl 1:3-15.			✓	Narrative	
(638)	Niezgoda JA. Combining negative pressure wound therapy with other wound management modalities. Ostomy Wound Manage 2005 Feb;51(2A Suppl):36-8.			✓	Narrative	
(639)	Niezgoda JA. Incorporating negative pressure therapy into the management strategy for pressure ulcers. Ostomy Wound Manage 2004 Nov;50(11A Suppl):26-9.			✓	Case reports	
(640)	Niezgoda JA. The economic value of negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):44-7.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(641)	No Authors. Position Document: Topical negative pressure in wound management. European Wound Management 2007 May;1-17.			✓	Narrative	
(642)	No Authors. Topical negative pressure for chronic wounds? Drugs and Therapeutics Bulletin 2007 Aug;45(8):57-61.			✓	Narrative	
(643)	No Authors. V.A.C. Therapy: Proceedings of the 2nd World Union of Wound Healing Societies Meeting (8-13 July 2004, Paris France). Wounds 2004 Dec;16(12-Suppl A):1-19.			✓	Narrative	
(70)	Noble-Bell G, Forbes A. A systematic review of the effectiveness of negative pressure wound therapy in the management of diabetes foot ulcers. Int Wound J 2008 Jun;5(2):233-42.	✓	Previous Systematic Reviews			✓
(644)	Norbury K, Kieswetter K. Vacuum-assisted closure therapy attenuates the inflammatory response in a porcine acute wound healing model. Wounds 2007 Apr;19(4):97-106.			✓	Animal study	
(645)	Norton SE, De Souza B, Marsh D, Moir G. Vacuum-assisted closure (VAC Therapy) and the risk of fluid loss in acute trauma. Ann Plast Surg 2006 Feb;56(2):194-5.			✓	Case report	
(646)	NPWT Info and history of NPWT. St. Petersburg (FL): Smith & Nephew, Inc.; 2009 Feb. 13 p.			✓	Background information	
(647)	Nugent N, Lannon D, O'Donnell M. Vacuum-assisted closure – a management option for the burns patient with exposed bone. Burns 2005 May;31(3):390-3.			✓	Case reports	
(648)	Obdeijn MC, de Lange MY, Lichtendahl DH, de Boer WJ. Vacuum-assisted closure in the treatment of poststernotomy mediastinitis. Ann Thorac Surg 1999 Dec;68(6):2358-60.			✓	Fewer than five patients	
(377)	O'Connor J, Kells A, Henry S, Scalea T. Vacuum-assisted closure for the treatment of complex chest wounds. Ann Thorac Surg 2005 Apr;79(4):1196-200.	✓	KQ3			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(649)	Oczenski W, Waldenberger F, Nehrer G, Kneifel W, Swoboda H, Schwarz S, Fitzgerald RD. Vacuum-assisted closure for the treatment of cervical and mediastinal necrotizing fasciitis. J Cardiothorac Vasc Anesth 2004 Jun;18(3):336-8.			✓	Narrative	
(10)	Orgill DP, Austen WG Jr, Butler CE, Fine NA, Horvath KA, Mihaljevic T, Song DH, Wolfe WG. Guidelines for the treatment of complex chest wounds with negative pressure wound therapy. Wounds 2004 Dec;(Suppl B):1-23.			✓	Guideline	
(20)	Orgill DP. Advancing the treatment options of chest wounds with negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):39-43.			✓	Narrative	
(650)	Orgill DP. Utilizing negative pressure wound therapy on open chest/sternotomy wounds. Ostomy Wound Manage 2004 Nov;50(11A Suppl):15S-17S.			✓	Case report	
(651)	O'Rourke ME. Vacuum-assisted closure therapy. Clin J Oncol Nurs 2006 Dec;10(6):825-6.			✓	No abstract available	
(652)	Ovington LG. 1,2,3 s-t-r-e-t-c-h; vacuum-enhances wound closure. Adv Wound Care 1999 Jan;(Suppl):125-7.			✓	Narrative	
(653)	Ozer K, Smith W. A simple technique for applying vacuum-assisted closure therapy over the circular type external fixation device. Ann Plast Surg 2006 Jun;56(6):693-4.			✓	Case report	
(1)	Page JC, Newswander B, Schwenke DC, Hansen M, Ferguson J. Retrospective analysis of negative pressure wound therapy in open foot wounds with significant soft tissue defects. Adv Skin Wound Care 2004 Sep;17(7):354-64.	✓	KQ1,KQ3			
(654)	Page JC. Utilizing NPWT for large soft tissue defects. APMA News 2005 May;26(5 Suppl):30-2.			✓	Narrative	
(655)	Pape HC, Webb LX. History of open wound and fracture treatment. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S133-4.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(296)	Parrett BM, Matros E, Pribaz JJ, Orgill DP. Lower extremity trauma: Trends in the management of soft-tissue reconstruction of open tibia-fibula fractures. Plast Reconstr Surg 2006 Apr 1;117(4):1315-22.			✓	Narrative	
(656)	Patane F, Zingarelli E, Sansone F, Cappuccio G, Rinaldi M. Vacuum-assisted sternal closure after a 'depression induced ischemic test' in severe mediastinitis. J Cardiovasc Med (Hagerstown) 2008 Jun;9(6):622-4.			✓	Case report	
(657)	Patel CT, Kinsey GC, Koperski-Moen KJ, Bungum LD. Vacuum-assisted wound closure. Am J Nurs 2000 Dec;100(12):45-8.			✓	Case report	
(658)	Pattison PS, Gordon JK, Muto PM, Mallen JK, Hoerner J. Case report: using dual therapies-negative pressure wound therapy and modified silicone gel liner-to treat a limb postamputation and dehiscence. Wounds 2005 Aug;17(8):233-40.			✓	Case report	
(41)	Paul JC. Vacuum assisted closure therapy: a must in plastic surgery. Plast Surg Nurs 2005 April/June;25(2):61-65.			✓	Case report	
(298)	Peinemann F, McGauran N, Sauerland S, Lange S. Disagreement in primary study selection between systematic reviews on negative pressure wound therapy. BMC Med Res Methodol 2008;8:41.			✓	Methodology paper	
(189)	Peinemann F, McGauran N, Sauerland S, Lange S. Negative pressure wound therapy: Potential publication bias caused by lack of access to unpublished study results data. BMC Med Res Methodol 2008;(8):Article Number: 4.	✓	Previous Systematic Reviews			
(371)	Pelham FR, Kubiak EN, Sathappan SS, Di Cesare PE. Topical negative pressure in the treatment of infected wounds with exposed orthopaedic implants. J Wound Care 2006 Mar;15(3):111-6.	✓	KQ3			
(659)	Penn E, Rayment S. Management of a dehisced abdominal wound with VAC therapy. Br J Nurs 2004 Feb 26-Mar 10;13(4):194-201.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(95)	Perez D, Wildi S, Demartines N, Bramkamp M, Koehler C, Clavien PA. Prospective evaluation of vacuum-assisted closure in abdominal compartment syndrome and severe abdominal sepsis. J Am Coll Surg 2007 Oct;205(4):586-92.	✓	KQ1			✓
(660)	Petersson U, Acosta S, Bjorck M. Vacuum-assisted wound closure and mesh-mediated fascial traction--a novel technique for late closure of the open abdomen. World J Surg 2007 Nov;31(11):2133-7.			✓	Not relevant	
(661)	Petrie N, Potter M, Banwell P. The management of lower extremity wounds using topical negative pressure. Int J Low Extrem Wounds 2003 Dec;2(4):198-206.			✓	Narrative	
(662)	Petzina R, Ugander M, Gustafsson L, Engblom H, Hetzer R, Arheden H, Ingemansson R, Malmsjo M. Topical negative pressure therapy of a sternotomy wound increases sternal fluid content but does not affect internal thoracic artery blood flow: assessment using magnetic resonance imaging. J Thorac Cardiovasc Surg 2008 May;135(5):1007-13.			✓	Animal study	
(663)	Petzina R, Ugander M, Gustafsson L, Engblom H, Sjogren J, Hetzer R, Ingemansson R, Arheden H, Malmsjo M. Hemodynamic effects of vacuum-assisted closure therapy in cardiac surgery: assessment using magnetic resonance imaging. J Thorac Cardiovasc Surg 2007 May;133(5):1154-62.			✓	Animal study	
(176)	Pham CT, Middleton PF, Maddern GJ. The safety and efficacy of topical negative pressure in non-healing wounds: a systematic review. J Wound Care 2006 Jun;15(6):240-50.	✓	Previous Systematic Reviews			
(664)	Phelps JR, Fagan R, Pirela-Cruz MA. A case study of negative pressure wound therapy to manage acute necrotizing fasciitis. Ostomy Wound Manage 2006 Mar;52(3):54-9.			✓	Case report	
(665)	Philbeck TE Jr, Whittington KT, Millsap MH, Briones RB, Wight DG, Schroeder WJ. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients. Ostomy Wound Manage 1999 Nov;45(11):41-50.			✓	Patients treated with dual therapies	

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(666)	Philbeck TE, Schroeder WJ, Whittington KT. Vacuum-assisted closure therapy for diabetic foot ulcers: clinical and cost analyses. Home Health Care Consult 2001 Mar;8(3):27-34.			✓	Narrative	
(667)	Pirela-Cruz MA, Machen MS, Esquivel D. Management of large soft-tissue wounds with negative pressure therapy-lessons learned from the war zone. J Hand Ther 2008 Apr-Jun;21(2):196-202; quiz 203.			✓	Narrative	
(668)	Plikaitis CM, Molnar JA. Subatmospheric pressure wound therapy and the vacuum-assisted closure device: basic science and current clinical successes. Expert Rev Med Devices 2006 Mar;3(2):175-84.			✓	Narrative	
(80)	Ploumis A, Mehbod AA, Dressel TD, Dykes DC, Transfeldt EE, Lonstein JE. Therapy of spinal wound infections using vacuum-assisted wound closure: risk factors leading to resistance to treatment. J Spinal Disord Tech 2008 Jul;21(5):320-3.	✓	KQ3			✓
(669)	Pollak AN. Use of negative pressure wound therapy with reticulated open cell foam for lower extremity trauma. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S142-5.			✓	Narrative	
(670)	Poulakidas S, Cologne K, Kowal-Vern A. Treatment of frostbite with subatmospheric pressure therapy. J Burn Care Res 2008 Nov-Dec;29(6):1012-4.			✓	Case report	
(671)	Poulakidas S, Kowal-Vern A. Facilitating residual wound closure after partial graft loss with vacuum assisted closure therapy. J Burn Care Res 2008 Jul-Aug;29(4):663-5.			✓	Case report	
(672)	Powell ET 4th. The role of negative pressure wound therapy with reticulated open cell foam in the treatment of war wounds. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S138-41.			✓	Narrative	
(673)	Principles of best practice: vacuum assisted closure: recommendations for use. A consensus document. [internet]. The Medical Education Partnership (MEP); 2008 Jun [10]. Available: http://www.mepltd.co.uk/oneoffsdetail.html?p=vaccon.			✓	Guideline	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(791)	Product labeling information. San Antonio (TX): Kinetic Concepts, Inc.; 176 p.			✓	Product labeling	
(301)	Pu LL. An alternative approach for soft-tissue coverage of a complex wound in the foot and ankle with vacuum-assisted closure over artificial dermis and subsequent skin graft. J Plast Reconstr Aesthet Surg 2008 Nov 20;Epub ahead of print.			✓	Narrative	
(674)	Quah HM, Maw A, Young T, Hay DJ. Vacuum-assisted closure in the management of the open abdomen: a report of a case and initial experiences. J Tissue Viability 2004 Apr;14(2):59-62.			✓	Case report	
(186)	Raja SG, Berg GA. Should vacuum-assisted closure therapy be routinely used for management of deep sternal wound infection after cardiac surgery. Interact Cardiovasc Thorac Surg 2007 Aug;6(4):523-7.	✓	Previous Systematic Reviews			
(675)	Ramnarine IR, McLean A, Pollock JC. Vacuum-assisted closure in the paediatric patient with post-cardiotomy mediastinitis. Eur J Cardiothorac Surg 2002 Dec;22(6):1029-31.			✓	Case report	
(163)	Rao M, Burke D, Finan PJ, Sagar PM. The use of vacuum-assisted closure of abdominal wounds: a word of caution. Colorectal Dis 2007 Mar;9(3):266-8.	✓	KQ3			
(676)	Rapp SM. Negative pressure wound therapy reduces infections in lower extremity fractures. Orthop Today 2008 Feb;28(54) Also available: http://www.orthosupersite.com/print.asp?rID=26142. Accessed on Feb 7, 2008.			✓	Narrative	
(677)	Reed SF, Novosel TJ, Weireter LJ, Collins JN, Britt RC, Alvey C, Merkh K, Britt LD. A novel technique for vacuum assisted closure on injured tissue or in confined spaces. J Trauma 2008 May;64(5):1406-7.			✓	Narrative	
(678)	Reed T, Economon D, Wiersema-Bryant L. Colocutaneous fistula management in a dehisced wound: a case study. Ostomy Wound Manage 2006 Apr;52(4):60-4, 66.			✓	Case report	

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(679)	Reid DJ, Linneman P, Lentz CW. Negative pressure dressing to secure skin grafts. Surg Phys Assist 2001 Feb;9-13.			✓	Case report	
(680)	Reisler T. A simple method of securing an interface dressing and vacuum-assisted closure foam pad to difficult wounds. Ann Plast Surg 2007 Aug;59(2):230-1.			✓	Narrative	
(681)	Reitsma AM, Rhodeheaver GT. Effectiveness of a new antimicrobial gauze dressing as a bacterial barrier. [internet]. Charlottesville (VA): University of Virginia Health System; 2001 Sep 1 Available: http://www.kendallhq.com/imageServer.aspx?contentID=7598&contenttype=application/pdf.			✓	Narrative	
(682)	Renner R, Rogalski C, Friedlein H, Simon JC. [Vacuum therapy in dermatology: a review. J Dtsch Dermatol Ges 2006 Jun;4(6):468-76.			✓	Narrative	
(683)	Repta R, Ford R, Hoberman L, Rechner B. The use of negative-pressure therapy and skin grafting in the treatment of soft-tissue defects over the Achilles tendon. Ann Plast Surg 2005 Oct;55(4):367-70.			✓	Fewer than five patients	
(684)	Rhee P, Velmahos GC. Traumatic wounds. Ostomy Wound Manage 2004 Apr;50(4A Suppl):22-5.			✓	Case report	
(121)	Rinker B, Amspacher JC, Wilson PC, Vasconez HC. Subatmospheric pressure dressing as a bridge to free tissue transfer in the treatment of open tibia fractures. Plast Reconstr Surg 2008 May;121(5):1664-73.	✓	KQ1, KQ3			
(685)	Robson MC, Cooper DM, Aslam R, Gould LJ, Harding KG, Margolis DJ, Ochs DE, Serena TE, Snyder RJ, Steed DL, Thomas DR, Wiersma-Bryant L. Guidelines for the treatment of venous ulcers. Wound Repair Regen 2006 Nov-Dec;14(6):649-62.			✓	Guideline	
(89)	Rosenthal EL, Blackwell KE, McGrew B, Carroll WR, Peters GE. Use of negative pressure dressings in head and neck reconstruction. Head Neck 2005 Nov;27(11):970-5.	✓	KQ3			✓

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(686)	Rosser CJ, Morykwas MJ, Argenta LC, Bare RL. A new technique to manage perineal wounds. Infect Urol 2000 Mar/Apr;13(2):45-7.			✓	Case report	
(378)	Routledge T, Saeb-Parsy K, Murphy F, Ritchie AJ. The use of vacuum-assisted closure in the treatment of post-transplant wound infections: A case series. J Heart Lung Transplant 2005;24(9):1444.e15-6.	✓	KQ3			
(687)	Saad SA, Shakov E, Sebastian V, Saad A. The use of wound vacuum-assisted closure (VAC) system in the treatment of recurrent or complex pilonidal cystDisease: experience in 4 adolescent patients. Internet J Surg 2007 Jan;11(1)			✓	Fewer than five patients	
(688)	Sadat U, Chang G, Noorani A, Walsh SR, Hayes PD, Varty K. Efficacy of TNP on lower limb wounds: a meta-analysis. J Wound Care 2008 Jan;17(1):45-8.			✓	Narrative	
(689)	Saeed MU, Kennedy DJ. A retained sponge is a complication of vacuum-assisted closure therapy. Int J Low Extrem Wounds 2007 Sep;6(3):153-4.			✓	Case report	
(690)	Saiki Y, Hata M, Akasaka J, Saito T, Tabayashi K. Vacuum-assisted closure system for the treatment of mediastinitis after total aortic arch replacement. Jpn J Thorac Cardiovasc Surg 2005 Dec;53(12):638-40.			✓	Case report	
(691)	Salazard B, Niddam J, Ghez O, Metras D, Magalon G. Vacuum-assisted closure in the treatment of poststernotomy mediastinitis in the paediatric patient. J Plast Reconstr Aesthet Surg 2008;61(3):302-5.			✓	Fewer than five patients	
(151)	Sartipy U, Lockowandt U, Gabel J, Jideus L, Dellgren G. Cardiac Rupture During Vacuum-Assisted Closure Therapy. Ann Thorac Surg 2006 Sep;82(3):1110-1.	✓	KQ3			
(34)	Saxena V, Hwang CW, Huang S, Eichbaum Q, Ingber D, Orgill DP. Vacuum-assisted closure: microdeformations of wounds and cell proliferation. Plast Reconstr Surg 2004 Oct;114(5):1086-96; discussion 1097-.			✓	Not a clinical study	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(692)	Saxena V, Orgill D, Kohane I. A set of genes previously implicated in the hypoxia response might be an important modulator in the rat ear tissue response to mechanical stretch. BMC Genomics 2007;8:430.			✓	Animal study	
(693)	Schaffzin DM, Douglas JM, Stahl TJ, Smith LE. Vacuum-assisted closure of complex perineal wounds. Dis Colon Rectum 2004 Oct;47(10):1745-8.			✓	Case reports	
(132)	Scherer LA, Shiver S, Chang M, Meredith JW, Owings JT, Tominaga GT, Schecter WP, Parks SN, Peck J, Mayberry J. The vacuum assisted closure device: a method of securing skin grafts and improving graft survival. Arch Surg 2002;137(8):930-4.	✓	KQ1, KQ3			
(35)	Scherer SS, Pietramaggiori G, Mathews JC, Prsa MJ, Huang S, Orgill DP. The mechanism of action of the vacuum-assisted closure device. Plast Reconstr Surg 2008 Sep;122(3):786-97.			✓	Animal study	
(694)	Scheufler O, Peek A, Kania NM, Exner K. Problem-adapted application of vacuum occlusion dressings: case report and clinical experience. Eur J Plastic Surg 2000 Oct;23(7):386-90.			✓	Case report	
(307)	Schimmer C, Sommer SP, Bensch M, Leyh R. Primary treatment of deep sternal wound infection after cardiac surgery: a survey of German heart surgery centers. Interact Cardiovasc Thorac Surg 2007 Dec;6(6):708-11.			✓	Does not address key question	
(147)	Schimp VL, Worley C, Brunello S, Levenback CC, Wolf JK, Sun CC, Bodurka DC, Ramirez PT. Vacuum-assisted closure in the treatment of gynecologic oncology wound failures. Gynecol Oncol 2004 Feb;92(2):586-91.	✓	KQ3			
(695)	Schintler M, Maier A, Matzi V, Smolle-Juttner FM. Vacuum assisted closure system in the management of cervical anastomotic leakage after gastric pull-up. Interact Cardiovasc Thorac Surg 2004 Mar;3(1):92-4.			✓	Case report	
(696)	Schintler M, Marschitz I, Trop M. The use of topical negative pressure in a paediatric patient with extensive burns. Burns 2005 Dec;31(8):1050-3.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(697)	Schipper J, Ridder GJ, Maier W, Teszler CB, Horch RE. Laryngotracheal reconstruction using prefabricated and preconditioned composite radial forearm free flaps. A report of two cases. Auris Nasus Larynx 2007 Jun;34(2):253-8.			✓	Not relevant	
(308)	Schlatterer D, Hirshorn K. Negative pressure wound therapy with reticulated open cell foam-adjunctive treatment in the management of traumatic wounds of the leg: a review of the literature. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S152-60.			✓	Narrative	
(698)	Schlatterer D, Webb LX. Orthopedic indications for negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):27-8.			✓	Case report	
(699)	Schneider AM, Morykwas MJ, Argenta LC. A new and reliable method of securing skin grafts to the difficult recipient bed. Plast Reconstr Surg 1998 Sep;102(4):1195-8.			✓	No abstract available	
(700)	Schoemann MB, Lentz CW. Treating surgical wound dehiscence with negative pressure dressings. Ostomy Wound Manage 2005 Feb;51(2A Suppl):15-20.			✓	Narrative	
(81)	Scholl L, Chang E, Reitz B, Chang J. Sternal osteomyelitis: use of vacuum-assisted closure device as an adjunct to definitive closure with sternectomy and muscle flap reconstruction. J Card Surg 2004 Sep-Oct;19(5):453-61.	✓	KQ3			✓
(701)	Schuster R, Moradzadeh A, Waxman K. The use of vacuum-assisted closure therapy for the treatment of a large infected facial wound. Am Surg 2006 Feb;72(2):129-31.			✓	Case report	
(126)	Schwien T, Gilbert J, Lang C. Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes. Ostomy Wound Manag 2005;51:47-60.	✓	KQ1, KQ3			
(311)	Segers P, de Jong AP, Kloek JJ, Spanjaard L, de Mol BA. Risk control of surgical site infection after cardiothoracic surgery. J Hosp Infect 2006 Apr;62(4):437-45.			✓	Case report	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(310)	Segers P, de Jong AP, Kloek JJ, van der Horst CM, Spanjaard L, de Mol BA. Topical negative pressure therapy in wounds after cardiothoracic surgery: successful experience supported by literature. Thorac Cardiovasc Surg 2006 Aug;54(5):289-94.			✓	Not a clinical study	
(354)	Segers P, Kloek JJ, Strackee DS, de Mol BA. Open window thoracostomy: a new therapeutic option using topical negative presure wound therapy. Wounds 2007 Oct;19(10):264-9.	✓	KQ3			
(702)	Senchenkov A, Knoetgen J, Chrouser KL, Nehra A. Application of vacuum-assisted closure dressing in penile skin graft reconstruction. Urology 2006 Feb;67(2):416-9.			✓	Narrative	
(355)	Senchenkov A, Petty PM, Knoetgen J 3rd, Moran SL, Johnson CH, Clay RP. Outcomes of skin graft reconstructions with the use of Vacuum Assisted Closure (VAC) dressing for irradiated extremity sarcoma defects. World J Surg Oncol 2007;5:138.	✓	KQ3			
(703)	Sentenac J. Facilitating wound healing with VAC therapy: a pharmacist's role. European Journal of Hospital Pharmacists 2008 May;14(5):57-8.			✓	Narrative	
(138)	Shilt JS, Yoder JS, Manuck TA, Jacks L, Rushing J, Smith BP. Role of vacuum-assisted closure in the treatment of pediatric lawnmower injuries. J Pediatr Orthop 2004;24(5):482-487.	✓	KQ1, KQ3			
(704)	Shirakawa M, Isseroff RR. Topical negative pressure devices: Use for enhancement of healing chronic wounds. Arch Dermatol 2005 Nov;141(11):1449-53.			✓	Narrative	
(705)	Short B, Claxton M, Armstrong DG. How to use VAC therapy on chronic wounds. Podiatry Today 2002 Jul;15(7):48-54.			✓	Narrative	
(367)	Shrestha BM, Nathan VC, Delbridge MC, Parker K, Throssell D, McKane WS, Karim MS, Raftery AT. Vacuum-assisted closure (VAC) therapy in the management of wound infection following renal transplantation. Kathmandu Univ Med J (KUMJ) 2007 Jan-Mar;5(1):4-7.	✓	KQ3			

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(706)	Shvartsman HS, Langstein H, Worley C, Malpica A, Ramondetta LM. Use of a vacuum-assisted closure device in the treatment of recurrent Paget's disease of the vulva. Obstet Gynecol 2003 Nov;102(5 Pt 2):1163-6.			✓	Case report	
(119)	Siegel HJ, Long JL, Watson KM, Fiveash JB. Vacuum-assisted closure for radiation-associated wound complications. J Surg Oncol 2007 Dec 1;96(7):575-82.	✓	KQ1, KQ3			
(707)	Silberstein J, Grabowski J, Parsons JK. Use of a Vacuum-Assisted Device for Fournier's Gangrene: A New Paradigm. Rev Urol 2008 Winter;10(1):76-80.			✓	Case report	
(708)	Simek M, Nemec P, Zalesak B, Kalab M, Hajek R, Jecminkova L, Kolar M. Vacuum-assisted closure in the treatment of sternal wound infection after cardiac surgery. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub 2007 Dec;151(2):295-9.			✓	Duplicate study(123)	
(709)	Simman R, Forte R, Silverberg B, Moriera-Gonzalez A, Williams F. A comparative histological study of skin graft take with tie-over bolster dressing versus negative pressure wound therapy in a pig model: a preliminary study. Wounds 2004 Feb;16(2):76-80.			✓	Animal study	
(710)	Simon DH, Key JJ, Blume PA. Lower extremity wounds respond to negative pressure. Biomechanics 2008 Aug;15(8):53-9.			✓	Narrative	
(711)	Simon S, Hammoudeh J, Low C, Nathan N, Armstrong M, Thaller S. Complex wound management with an artificial dermal regeneration template. Wounds 2008 Nov;20(11):299-302.			✓	Case reports	
(712)	Singh K, Samartzis D, Heller JG, An HS, Vaccaro AR. The management of complex soft-tissue defects after spinal instrumentation. J Bone Joint Surg Br 2006 Jan;88(1):8-15.			✓	Narrative	
(713)	Singh S, Mackey S, Soldin M. VAC it - Some techniques on the application of VAC dressings. Ann R Coll Surg Engl 2008 Mar;90(2):161-2.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(714)	Sjogren J, Gustafsson R, Koul B, Ingemansson R. Selective mediastinal tamponade to control coagulopathic bleeding. Ann Thorac Surg 2003 Apr;75(4):1311-3.			✓	Case report	
(139)	Sjogren J, Gustafsson R, Nilsson J, Malmsjo M, Ingemansson R. Clinical outcome after poststernotomy mediastinitis: Vacuum-assisted closure versus conventional treatment. Ann Thorac Surg 2005;79(6):2049-55.	✓	KQ1, KQ3, Previous Systematic Reviews			
(715)	Sjogren J, Gustafsson R, Wackenfors A, Malmsjo M, Algotsson L, Ingemansson R. Effects of vacuum-assisted closure on central hemodynamics in a sternotomy wound model. Interact Cardiovasc Thorac Surg 2004 Dec;3(4):666-71.			✓	Animal study	
(716)	Sjogren J, Malmsjo M, Gustafsson R, Ingemansson R. Poststernotomy mediastinitis: a review of conventional surgical treatments, vacuum-assisted closure therapy and presentation of the Lund University Hospital mediastinitis algorithm. Eur J Cardiothorac Surg 2006 Dec;30(6):898-905.			✓	Narrative	
(717)	Sjogren J, Mokhtari A, Gustafsson R, Malmsjo M, Nilsson J, Ingemansson R. Vacuum-assisted closure therapy for deep sternal wound infections: the impact of learning curve on survival and predictors for late mortality. Int Wound J 2008 Jun;5(2):216-23.			✓	Not relevant	
(179)	Sjogren J, Nilsson J, Gustafsson R, Malmsjo M, Ingemansson R. The impact of vacuum-assisted closure on long-term survival after post-sternotomy mediastinitis. Ann Thorac Surg 2005 Oct;80(4):1270-5.	✓	Previous Systematic Reviews			
(718)	Skillman J, Kirkpatrick N, Coombes A, Coghlan B, Waterhouse N, Joshi N, Kelly M. Vacuum Assisted Closure (VAC) dressing for skin graft application following exenteration of the orbit. Orbit 2003 Mar;22(1):63-5.			✓	Case report	
(719)	Smith APS. A closer look at the potential of hyperbaric oxygen therapy. APMA News 2005 May;26(5-Suppl):39-42.			✓	Not relevant	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(720)	Smith APS. Case study: treating a diabetic puncture wound. APMA News 2005 May;26(5-Suppl):16-18.			✓	Case report	
(315)	Smith N. The benefits of VAC therapy in the management of pressure ulcers. Br J Nurs 2004 Dec 9-2005 Jan 12;13(22):1359-65.			✓	Reanalysis of already published data	
(721)	Snyder N, Gould LJ. Scrotal and penile reconstruction using the vacuum-assisted closure device. Can J Plast Surg 2005 Dec;13(4):205-6.			✓	No abstract available	
(124)	Song DH, Wu LC, Lohman RF, Gottlieb LJ, Franczyk M. Vacuum assisted closure for the treatment of sternal wounds: the bridge between debridement and definitive closure. Plast Reconstr Surg 2003 Jan;111(1):92-7.	✓	KQ1,KQ3, Previous Systematic Reviews			
(316)	Sposato G, Molea G, Di Caprio G, Scioli M, La Rusca I, Ziccardi P. Ambulant vacuum-assisted closure of skin-graft dressing in the lower limbs using a portable mini-VAC device. Br J Plast Surg 2001 Apr;54(3):235-7.			✓	Narrative	
(125)	Stannard JP, Robinson JT, Anderson ER, McGwin G Jr, Volgas DA, Alonso JE. Negative pressure wound therapy to treat hematomas and surgical incisions following high-energy trauma. J Trauma 2006 Jun;60(6):1301-6.	✓	KQ1, KQ3			
(722)	Stawicki SP, Grossman M. "Stretching" negative pressure wound therapy: Can dressing change interval be extended in patients with open abdomens. Ostomy Wound Manage 2007 Jan;53(1):26-9.			✓	Narrative	
(723)	Stawicki SP, Schwarz NS, Schrag SP, Lukaszczyk JJ, Schadt ME, Dippolito A. Application of vacuum-assisted therapy in postoperative ascitic fluid leaks: an integral part of multimodality wound management in cirrhotic patients. J Burns Wounds 2007 Apr 16;6:91-9.			✓	Fewer than five patients	

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(724)	Steed DL, Attinger C, Colaizzi T, Crossland M, Franz M, Harkless L, Johnson A, Moosa H, Robson M, Serena T, Sheehan P, Veves A, Wiersma-Bryant L. Guidelines for the treatment of diabetic ulcers. Wound Repair Regen 2006 Nov;14(6):680-92.			✓	Guideline	
(725)	Steenvoorde P, de Roo RA, Oskam J, Neijenhuis P. Negative pressure wound therapy to treat peri-prosthetic methicillin-resistant Staphylococcus aureus infection after incisional herniorrhaphy. A case study and literature review. Ostomy Wound Manage 2006 Jan;52(1):52-4.			✓	Case report	
(726)	Steenvoorde P, Rozeboom Al, Melief P, Elzo Kraemer CV, Bonsing BA. Failure of the topical negative pressure abdominal dressing system in the "fat" open abdomen: report of a case and review of literature. Wounds 2006 Feb;18(2):44-50.			✓	Case report	
(727)	Steenvoorde P, Slotema E, Adhin S, Oskam J. Deep infection after ilioinguinal node dissection: vacuum-assisted closure therapy. Int J Low Extrem Wounds 2004 Dec;3(4):223-6.			✓	Case report	
(728)	Steenvoorde P, van Engeland A, Bonsing B, da Costa SA, Oskam J. Combining topical negative pressure and a Bogota bag for managing a difficult laparostomy. J Wound Care 2004 Apr;13(4):142-3.			✓	Case report	
(349)	Steiert AE, Gohritz A, Schreiber TC, Krettek C, Vogt PM. Delayed flap coverage of open extremity fractures after previous vacuum-assisted closure (VAC) therapy - worse or worth. J Plast Reconstr Aesthet Surg 2008 Mar 24;Epub ahead of print.	✓	KQ3			
(729)	Steinberg JS. Exploring adjunctive combination therapy for wound bed preparation. APMA News 2005 May;26(5 Suppl):24-6.			✓	Narrative	
(730)	Stinson JA, Powell JL. Necrotizing fasciitis in women at a community teaching hospital. J Pelvic Med Surg 2005 Jul-Aug;11(4):209-13.			✓	Not relevant to topic	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(358)	Stoeckel WT, David L, Levine EA, Argenta AE, Perrier ND. Vacuum-assisted closure for the treatment of complex breast wounds. Breast 2006 Nov;15(5):610-3.	✓	KQ3			
(731)	Stokes TH, Follmar KE, Silverstein AD, Weizer AZ, Donatucci CF, Anderson EE, Erdmann D. Use of negative-pressure dressings and split-thickness skin grafts following penile shaft reduction and reduction scrotoplasty in the management of penoscrotal elephantiasis. Ann Plast Surg 2006 Jun;56(6):649-53.			✓	Not relevant	
(133)	Stone P, Progozen J, Hofeldt m, Hass S, DeLuca J, Flaherty S. Bolster versus negative pressure wound therapy for securing split-thickness skin grafts in trauma patients. Wounds 2004;16(7):219-23.	✓	KQ1, KQ3			
(90)	Stone PA, Hass SM, Flaherty SK, DeLuca JA, Lucente FC, Kusminsky RE. Vacuum-assisted fascial closure for patients with abdominal trauma. J Trauma 2004 Nov;57(5):1082-6.	✓	KQ3			✓
(77)	Stonerock CE, Bynoe RP, Yost MJ, Nottingham JM. Use of a vacuum-assisted device to facilitate abdominal closure. Am Surg 2003 Dec;69(12):1030-4; discussion 1034-5.	✓	KQ3			✓
(320)	Suess JJ, Kim PJ, Steinberg JS. Negative pressure wound therapy: evidence-based treatment for complex diabetic foot wounds. Curr Diab Rep 2006 Dec;6(6):446-50.			✓	Narrative	
(166)	Suliburk JW, Ware DN, Balogh Z, McKinley BA, Cocanour CS, Kozar RA, Moore FA. Vacuum-Assisted Wound Closure Achieves Early Fascial Closure of Open Abdomens after Severe Trauma. J Trauma Inj Infect Crit Care 2003;55(6):1155-60.	✓	KQ3			
(732)	Summaries of current clinical evidence Engenex NPWT system. Skillman (NJ): ConvaTec, Inc.; 2 p.			✓	Poster presentation	
(733)	Sunog T. Closing time. Adv Nurs 2003 Aug;18(34):39.			✓	No abstract available	

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(734)	Svedman, et al. A dressing system providing fluid supply and suction drainage used for continuous or intermittent irrigation. Ann Plast Surg 1986 Aug;17(2):125-33.			✓	Narrative	
(149)	Svensson S, Monsen C, Kolbel T, Acosta S. Predictors for Outcome after Vacuum Assisted Closure Therapy of Peri-vascular Surgical Site Infections in the Groin. Eur J Vasc Endovasc Surg 2008 Jul;36(1):84-9.	✓	KQ3			
(735)	Tan D, Rajanayagam J, Schwarz F. Treatment of long-standing, poor-healing diabetic foot ulcers with topical negative pressure in the Torres Strait. Aust J Rural Health 2007 Aug;15(4):275-6.			✓	Case report	
(736)	Tang AT, Ohri SK, Haw MP. Novel application of vacuum assisted closure technique to the treatment of sternotomy wound infection. Eur J Cardiothorac Surg 2000 Apr;17(4):482-4.			✓	Narrative	
(737)	Tang AT, Okri SK, Haw MP. Vacuum-assisted closure to treat deep sternal wound infection following cardiac surgery. J Wound Care 2000 May;9(5):229-30.			✓	Case report	
(323)	Tanna N, Clary MS, Conrad DE, Lenert J, Sadeghi N. Vacuum-assisted closure for wound dehiscence in head and neck reconstruction. Plast Reconstr Surg 2009 Jan;123(1):19e-21e.			✓	Case report	
(738)	Tarkin IS. The versatility of negative pressure wound therapy with reticulated open cell foam for soft tissue management after severe musculoskeletal trauma. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S146-51.			✓	Narrative	
(739)	Taub PJ, Schulman MR, Sett S, Koch RM. Revisiting vascularized muscle flaps for complicated sternal wounds in children. Ann Plast Surg 2005 Nov;55(5):535-7.			✓	Case report	
(229)	Teot L, Lambert L, Ourabah Z, Bey E, Steenman C, Wierzbiecka E, Malikov S, Charles JP, Vives F, Bohbot S. Use of topical negative pressure with a lipidocolloid dressing: results of a clinical evaluation. J Wound Care 2006 Sep;15(8):355-8.			✓	Homemade device	

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(740)	Terrazas SG. Adjuvant dressing for negative pressure wound therapy in burns. Ostomy Wound Manage 2006 Jan;52(1):16, 18.			✓	No abstract available	
(741)	Thomas S. An introduction to the use of vacuum assisted closure. In: World Wide Wounds [serial online]. ; 2001 May [accessed 2001 Jun 11]. [25 screens]. Available: http://www.worldwidewounds.com/2001/may/Thomas/Vacuum-Assisted-Closure.htm.			✓	Narrative	
(742)	Thomas T. (Executive Director, Association for the Advancement of Wound Care. Malvern, PA). Personal communication – Full submission packet. 2009 Feb 1. 142 p p.			✓	Personal communication	
(743)	Thompson JT, Marks MW. Negative pressure wound therapy. Clin Plast Surg 2007 Oct;34(4):673-84.			✓	Narrative	
(326)	Timmers MS, Le Cessie S, Banwell P, Jukema GN. The effects of varying degrees of pressure delivered by negative-pressure wound therapy on skin perfusion. Ann Plast Surg 2005 Dec;55(6):665-71.			✓	No relevant outcomes	
(744)	Torbrand C, Ingemansson R, Gustafsson L, Paulsson P, Malmsjo M. Pressure transduction to the thoracic cavity during topical negative pressure therapy of a sternotomy wound. Int Wound J 2008 Oct;5(4):579-84.			✓	Animal study	
(745)	Torbrand C, Wackenfors A, Lindstedt S, Ekman R, Ingemansson R, Malmsjo M. Sympathetic and sensory nerve activation during negative pressure therapy of sternotomy wounds. Interact Cardiovasc Thorac Surg 2008 Dec;7(6):1067-70.			✓	Animal study	
(746)	Trop M, Schintler M, Urban E, Roedl S, Stockenhuber A. Are 1:4 mesh and donor site contraindications for vacuum-assisted closure device. J Trauma 2006 Nov;61(5):1267-70.			✓	No abstract available	
(747)	Trueman P, Flack S, Loonstra A, Hauser T. The feasibility of using V.A.C. Therapy in home care patients with surgical and traumatic wounds in the Netherlands. Int Wound J 2008 Jun;5(2):225-31.			✓	Not a clinical study	

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(748)	Trueman P. Cost-effectiveness considerations for home health V.A.C. Therapy in the United States of America and its potential international application. Int Wound J 2008 Jun;5 Suppl 2:23-6.			✓	Cost effectiveness	
(174)	Ubbink DT, Westerbos SJ, Evans D, Land L, Vermeulen H. Topical negative pressure for treating chronic wounds (Review). In: Cochrane Database of Systematic Reviews [internet]. Issue 3. Hoboken (NJ): John Wiley & Sons, Ltd.; 2008 [Art. No.: CD001898].	✓	Previous Systematic Reviews			
(183)	Ubbink DT, Westerbos SJ, Nelson EA, Vermeulen H. A systematic review of topical negative pressure therapy for acute and chronic wounds. Br J Surg 2008 Jun;95(6):685-92.	✓	Previous Systematic Reviews			
(228)	Using topical negative pressure with a lipidocolloid dressing. Ostomy Wound Manage 2008 Jun;54(6):12-4.			✓	No abstract available	
(749)	Uygur F, Duman H, Ulkur E, Ceikoz B. The role of the vacuum-assisted closure therapy in the salvage of venous congestion of the free flap: case report. Int Wound J 2008 Mar;5(1):50-3.			✓	Case report	
(750)	Vallet C, Saucy F, Haller C, Meier P, Rafoul W, Corpataux JM. Vacuum-assisted conservative treatment for the management and salvage of exposed prosthetic hemodialysis access. Eur J Vasc Endovasc Surg 2004 Oct;28(4):397-9.			✓	Case reports	
(107)	van den Boogaard M, de Laat E, Spauwen P, Schoonhoven L. The effectiveness of topical negative pressure in the treatment of pressure ulcers: a literature review. Eur J Plastic Surg 2008 Apr;31(1):1-7.	✓	KQ1, KQ3			
(368)	van Rhee MA, de Klerk LW, Verhaar JA. Vacuum-assisted wound closure of deep infections after instrumented spinal fusion in six children with neuromuscular scoliosis. Spine J 2007 Sep-Oct;7(5):596-600.	✓	KQ3			
(751)	Varker KA, Ng T. Management of empyema cavity with the vacuum-assisted closure device. Ann Thorac Surg 2006 Feb;81(2):723-5.			✓	Case report	

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(752)	Venturi ML, Attinger CE, Mesbahi AN, Hess CL, Graw KS. Mechanisms and clinical applications of the vacuum-assisted closure (VAC) Device: a review. Am J Clin Dermatol 2005;6(3):185-94.			✓	Narrative	
(753)	Verhaalen Al. Isolation of an entercutaneous fistula within a vacuum-assisted wound closure system. Gen Surg 2006 Aug;33(8)			✓	Case report	
(754)	Verrillo SC. Negative pressure therapy for infected sternal wounds: a literature review. J Wound Ostomy Continence Nurs 2004 Mar-Apr;31(2):72-4.			✓	Narrative	
(342)	Vidrine DM, Kaler S, Rosenthal EL. A comparison of negative-pressure dressings versus Bolster and splinting of the radial forearm donor site. Otolaryngol Head Neck Surg 2005 Sep;133(3):403-6.	✓	KQ1, KQ3			
(178)	Vikatmaa P, Juutilainen V, Kuukasjarvi P, Malmivaara A. Negative Pressure Wound Therapy: a Systematic Review on Effectiveness and Safety. Eur J Vasc Endovasc Surg 2008 Oct;36(4):438-48.	✓	Previous Systematic Reviews			
(755)	von Gossler CM, Horch RE. Rapid aggressive soft-tissue necrosis after beetle bite can be treated by radical necrectomy and vacuum suction-assisted closure. J Cutan Med Surg 2000 Oct;4(4):219-22.			✓	Case report	
(115)	Vuerstaek JD, Vainas T, Wuite J, Nelemans P, Neumann MH, Veraart JC. State-of-the-art treatment of chronic leg ulcers: A randomized controlled trial comparing vacuum-assisted closure (V.A.C.) with modern wound dressings. J Vasc Surg 2006 Nov;44(5):1029-37; discussion 1038.	✓	KQ1, KQ3			
(756)	Wackenfors A, Gustafsson R, Sjogren J, Algotsson L, Ingemansson R, Malmsjo M. Blood flow responses in the peristernal thoracic wall during vacuum-assisted closure therapy. Ann Thorac Surg 2005 May;79(5):1724-30; discussion 1730-.			✓	Animal study	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(757)	Wackenfors A, Sjogren J, Algotsson L, Gustafsson R, Ingemansson R, Malmsjo M. The effect of vacuum-assisted closure therapy on the pig femoral artery vasomotor responses. Wound Repair Regen 2004 Mar-Apr;12(2):244-			✓	Animal study	
(40)	Wackenfors A, Sjogren J, Gustafsson R, Algotsson L, Ingemansson R, Malmsjo M. Effects of vacuum-assisted closure therapy on inguinal wound edge microvascular blood flow. Wound Repair Regen 2004 Nov-Dec;12(6):600-6.			✓	Animal study	
(384)	Wada A, Ferreira MC, Tuma Junior P, Arrunategui G. Experience with local negative pressure (vacuum method) in the treatment of complex wounds. Sao Paulo Med J 2006 May 4;124(3):150-3.	✓	KQ3			
(118)	Wanner MB, Schwarzl F, Strub B, Zaech GA, Pierer G. Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. Scand J Plast Reconstr Surg Hand Surg 2003;37(1):28-33.	✓	KQ1,KQ3			
(172)	Wasiak J, Cleland H. Topical negative pressure (TNP) for partial thickness burns. Cochrane Database Syst Rev 2007;(3):CD006215.	✓	Previous Systematic Review			
(758)	Webb LX, Lavery D, DeFranzo A. Negative pressure wound therapy in the management of orthopedic wounds. Ostomy Wound Manage 2004 Apr;50(4A Suppl):26-7.			✓	Narrative	
(759)	Webb LX, Pape HC. Current thought regarding the mechanism of action of negative pressure wound therapy with reticulated open cell foam. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S135-7.			✓	Narrative	
(760)	Webb LX. New techniques in wound management: vacuum-assisted wound closure. J Am Acad Orthop Surg 2002 Sep-Oct;10(5):303-11.			✓	Narrative	
(37)	Weed T, Ratliff C, Drake DB. Quantifying bacterial bioburden during negative pressure wound therapy: does the wound VAC enhance bacterial clearance. Ann Plast Surg 2004 Mar;52(3):276-9; discussion 279-80.	✓	KQ3			

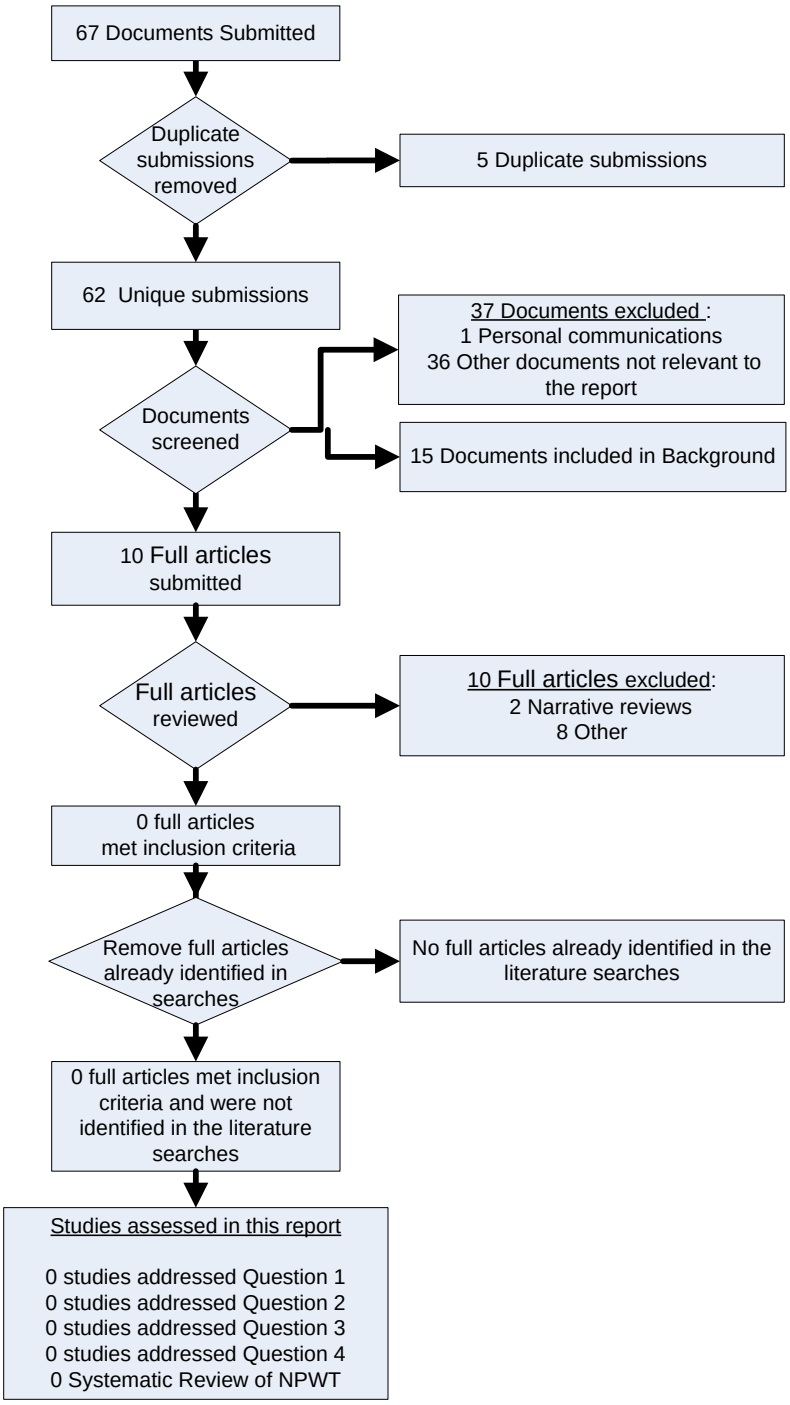
Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(761)	Weinfeld AB, Kelley P, Yuksel E, Tiwari P, Hsu P, Choo J, Hollier LH. Circumferential negative-pressure dressing (VAC) to bolster skin grafts in the reconstruction of the penile shaft and scrotum. Ann Plast Surg 2005 Feb;54(2):178-83.			✓	Case reports	
(762)	Wessel LC, Cunningham BL. Patient with compartment syndrome of the lower extremity. J Wound Ostomy Continence Nurs 2002 Jul;29(4):210-5.			✓	Case report	
(763)	Whelan C, Stewart J, Schwartz BF. Mechanics of wound healing and importance of Vacuum Assisted Closure in urology. J Urol 2005 May;173(5):1463-70.			✓	Narrative	
(764)	White RA, Miki RA, Kazmier P, Anglen JO. Vacuum-assisted closure complicated by erosion and hemorrhage of the anterior tibial artery. J Orthop Trauma 2005 Jan;19(1):56-9.			✓	Case report	
(765)	Whitney J, Phillips L, Aslam R, Barbul A, Gottrup F, Gould L, Robson MC, Rodeheaver G, Thomas D, Stotts N. Guidelines for the treatment of pressure ulcers. Wound Repair Regen 2006 Nov-Dec;14(6):663-79.			✓	Guideline	
(116)	Wild T, Stremitzer S, Budzanowski A, Hoelzenbein T, Ludwig C,Ohrenberger G. Definition of efficiency in vacuum therapy - A randomised controlled trial comparing Redon drains with V.A.C. Therapy™. Int Wound J 2008 Dec;5(5):641-7.	✓	KQ2			
(766)	Wilkes R, Zhao Y, Kieswetter K, Haridas B. Effects of Dressing Type on 3D Tissue Microdeformations During Negative Pressure Wound Therapy: A Computational Study. J Biomech Eng 2009 Mar;131(3):031012.			✓	Not a clinical study	
(767)	Willy C, Voelker HU, Engelhardt M. Literature on the subject of vacuum therapy: review and update 2006. Eur J Trauma Emerg Surg 2007 Feb;33(1):33-9.			✓	Not relevant - not a systematic review of wound healing data	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(768)	Wiseman J, Cullington JR, Schaeferle M 3rd, Beckham PH, Salisbury M, Ersek RA. Aesthetic aspects of neurofibromatosis reconstruction with the vacuum-assisted closure system. Aesthetic Plast Surg 2001 Sep-Oct;25(5):326-31.			✓	Case Report	
(769)	Wolvos T. Wound instillation with negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):21S-6S.			✓	Narrative	
(770)	Wolvos T. Wound instillation--the next step in negative pressure wound therapy. Lessons learned from initial experiences. Ostomy Wound Manage 2004 Nov;50(11):56-66.			✓	Narrative	
(161)	Wondberg D, Larusson HJ, Metzger U, Platz A, Zingg U. Treatment of the open abdomen with the commercially available vacuum-assisted closure system in patients with abdominal sepsis : low primary closure rate. World J Surg 2008 Dec;32(12):2724-9.	✓	KQ3			
(771)	Wong LK, Nesbit RD, Turner LA, Sargent LA. Management of a circumferential lower extremity degloving injury with the use of vacuum-assisted closure. South Med J 2006 Jun;99(6):628-30.			✓	Case Report	
(75)	Wongworawat MD, Schnall SB, Holtom PD, Moon C, Schiller F. Negative pressure dressings as an alternative technique for the treatment of infected wounds. Clin Orthop Relat Res 2003 Sep;(414):45-8.	✓	KQ3			✓
(772)	Woo KY, Sibbald RG. Vacuum-assisted closure home care training: a process to link education to improved patient outcomes. Int Wound J 2008 Jun;5 Suppl 2:1-9.			✓	Narrative	
(773)	Wound wonder. Middle East Medical 2003 May-Jun;61-5.			✓	Narrative	
(774)	Wu S. Case study: treating a patient with a diabetic neuropathic ulceration. APMA News 2005 May;26(5-Suppl):19.			✓	Case Report	
(775)	Wu SC, Lavery LA, Armstrong DG. Closing difficult wounds. Podiatry Today 2006 Mar;19(3):44-54.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(776)	Wu Sc, Yoon H, Armstrong DG. Therapy with advanced modalities: can it expedite healing?. Podiatry Today 2005 Sep;18(9):18-24.			✓	Narrative	
(158)	Wu SH, Zecha PJ, Feitz R, Hovius SE. Vacuum therapy as an intermediate phase in wound closure: A clinical experience. Eur J Plastic Surg 2000 May;23(4):174-7.	✓	KQ3			
(777)	Wustmann O, Ulrich HC. German patent specification. Appliance for the drainage of wounds. No. 847 475 Class 30 K Group 17 04. 1952			✓	Not relevant	
(72)	Yang CC, Chang DS, Webb LX. Vacuum-assisted closure for fasciotomy wounds following compartment syndrome of the leg. J Surg Orthop Adv 2006 Spring;15(1):19-23.	✓	KQ1			✓
(778)	Yoong S, Dunne G, Cochrane J, Lee B, Lee J. Vacuum-assisted closure for the treatment of parastomal skin necrosis: a novel approach to an unusual complication. Report of a case. Dis Colon Rectum 2008 Oct;51(10):1577-9.			✓	Case report	
(779)	Yousaf M, Witherow A, Gardiner KR, Gilliland R. Use of vacuum-assisted closure for healing of a persistent perineal sinus following panproctocolectomy: report of a case. Dis Colon Rectum 2004 Aug;47(8):1403-7; discussion 1407-8.			✓	Case report	
(780)	Yuan-Innes MJ, Temple CL, Lacey MS. Vacuum-assisted wound closure: a new approach to spinal wounds with exposed hardware. Spine 2001 Feb 1;26(3):E30-3.			✓	Fewer than five patients	
(781)	Yuh DD, Albaugh M, Ullrich S, Conte JV. Treatment of ventricular assist device driveline infection with vacuum-assisted closure system. Ann Thorac Surg 2005 Oct;80(4):1493-5.			✓	Case report	
(782)	Zamierowski D. United States Patent. Wound dressing and treatment method. No. 4969880. 1990.			✓	Patent	
(783)	Zehnder SW, Place HM. Vacuum-assisted wound closure in postoperative spinal wound infection. Orthopedics 2007 Apr;30(4):267-72.			✓	Narrative	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(784)	Zutt M, Haas E, Kruger U, Distler M, Neumann C. Successful use of vacuum-assisted closure therapy for leg ulcers caused by occluding vasculopathy and inflammatory vascular diseases—a case series. Dermatology 2007;214(4):319-24.			✓	Case reports	

Figure 8. Disposition of Submission by CMS



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Table 45. Status of CMS submission: Publications

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(792)	Biblehimer HL. Dealing with a wound that drains 1.5 liters a day. RN 1986 Aug;49(8):21-3.			✓	Case study/ Technical description	
(114)	Braakenburg A, Obdeijn MC, Feitz R, van Rooij IA, van Griethuysen AJ, Klinkenbijl JH. The clinical efficacy and cost effectiveness of the vacuum-assisted closure technique in the management of acute and chronic wounds: a randomized controlled trial. Plast Reconstr Surg 2006 Aug;118(2):390-7; discussion 398-400.	✓	KQ1, KQ3			
(442)	Chariker ME, Jeter KF, Tintle TE, Bottsford JE. Effective management of incisional and cutaneous fistulae with close suction wound drainage. Contemp Surg 1989 Jun;34:59-63.			✓	Case series/ Technical description	
(793)	Coleman D. No wound is too big for resourceful nurses. RN 1988 Dec;51(12):22-5.			✓	Case study/ Technical description	
(110)	Ford C, Reinhard E, Yeh D, Syrek D, de las Morenas A, Bergman S, Williams S, Hamori C. Interim analysis of a prospective randomized trial of vacuum-assisted closure versus the healthpoint system in the management of pressure ulcers. Ann Plast Surg 2002;49(1):7 p.	✓	KQ1, KQ3			
(794)	Garcia-Rinaldi R, Defore WW Jr, Green ZD, McBride C. Improving the efficiency of wound drainage catheters. Am J Surg 1975 Sep;130(3):372-3.			✓	Case study/ Technical description	
(795)	Miller MS, Lowery CA. Negative pressure wound therapy: 'a rose by any other name'. Ostomy Wound Manage 2005 Mar;51(3):44-6, 48-9.			✓	Narrative review	
(796)	Q209 hospital purchasing manager survey. Charlotte (NC): Wachovia Capital Markets, LLC; 2009 Apr 7. 13 p.			✓	Survey	
(797)	Q2 2008 wound care nurse survey. Charlotte (NC): Wachovia Capital Markets, LLC; 2008 May 21. 13 p.			✓	Survey	
(798)	Q208 hospital purchasing manager survey. Charlotte (NC): Wachovia Capital Markets, LLC; 2008 Apr 21. 16 p.			✓	Survey	
(799)	Q4 2007 wound care nurse survey. Charlotte (NC): Wachovia Capital Markets, LLC; 2007 Dec 6. 11 p.			✓	Survey	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(800)	Q4 2008 wound care nurse survey. Charlotte (NC): Wachovia Capital Markets, LLC; 2008 Dec 1. 15 p.			✓	Survey	
(801)	RAFFL AB. The use of negative pressure under skin flaps after radical mastectomy. Ann Surg 1952 Dec;136(6):1048.			✓	Case study/ Technical description	
(802)	Ramirez OM, Granick MS, Futrell JW. Optimal wound healing under Op-Site dressing. Plast Reconstr Surg 1984 Mar;73(3):474-5.			✓	Case study/ Technical description	
(182)	Samson D, Lefevre F. Wound-healing technologies: low-level laser and vacuum-assisted closure. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2004.	✓	Previous Systematic Reviews			
(34)	Saxena V, Hwang CW, Huang S, Eichbaum Q, Ingber D, Orgill DP. Vacuum-assisted closure: microdeformations of wounds and cell proliferation. Plast Reconstr Surg 2004 Oct;114(5):1086-96; discussion 1097-.			✓	Case study/ Technical description	
(803)	Schwab PM, Kelly KA. Primary closure of the perineal wound after proctectomy. A new technique. Mayo Clin Proc 1974 Mar;49(3):176-9.			✓	Case study/ Technical description	
(312)	Sibbald RG, Mahoney J, V.A.C. Therapy Canadian Consensus Group. A consensus report on the use of vacuum-assisted closure in chronic, difficult-to-heal wounds. Ostomy Wound Manage 2003 Nov;49(11):52-66.	✓		✓	Narrative	
(804)	VanDuren T. (Case Manager. University of Utah Health Plans & Healthy-U). BlueSky Versatile One. Case study. University of Utah. 2004 Jan 13. 7 p.			✓	Case study	
(805)	Wolvos T. Feature: wound instillation-the next step in negative pressure wound therapy. Lessons learned from initial experiences. Ostomy Wound Manag 2004;50(11):56-66.			✓	Case study/ Technical description	

KQ Key question

Table 46. Status of CMS submission: Government Documents

Reference Number	Reference	Disposition in Report
(806)	Beninger P. (Director. Division of General and Restorative Devices. Office of Device Evaluation. Center for Devices and Radiological Health). 510(k) notification of intent to market VACPLUS. K945062. 1995 Mar 14. 50 p.	Used as background information
(807)	Bowman J. Personal Communication. FDA account of NPNT safety issues as summarized by CMS. 2005. 1 p.	Not used in this report
(808)	Dillard J. (Acting Director. Division of General and Restorative Devices. Office of Device Evaluation. Center for Devices and Radiological Health). Approval of 510(k) notification of intent to market. V.A.C. plus. K992448. 2000 Jan 18. 3 p.	Used as background information
(809)	Food and Drug Administration, Center for Devices and Radiological Health. Guidance document for powered suction pump 510(k)s. Rockville (MD): Food and Drug Administration, Center for Devices and Radiological Health; 1998. 5 p.	Not used in this report
(810)	Food and Drug Administration, Center for Devices and Radiological Health. 510(k) premarket notification database. Annelid. K940886. [internet]. Silver Spring (MD): Food and Drug Administration, Center for Devices and Radiological Health; 2002 Nov 5 [updated 2009 Jan 16]; [accessed 2002 Nov 5]. [1 p]. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=96760.	Used as background information
(811)	Food and Drug Administration, Center for Devices and Radiological Health. 510(k) premarket notification database. Vacuum assisted closure. K021500. [internet]. Silver Spring (MD): Food and Drug Administration, Center for Devices and Radiological Health; 2002 Dec 20 [accessed 2005 Nov 11]. [5 p]. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=8137.	Used as background information
(812)	Food and Drug Administration. 510 (k) summary statement. V.A.C. plus device, 510(k) No. K945062. [database online]. Silver Spring (MD): Food and Drug Administration; 2000 Jan 18 [2 p].	Used as background information
(813)	Hake C. (Director, CMS HCPCS Workgroup). Personal communication. Request to establish a code for portable powered suction pump, trade name: versatile wound vacuum system. 2005. 2 p.	Not used in this report
(814)	Hake C. (Director. CMS HCPCS Workgroup). Personal Communication. Request to establish three new codes for negative pressure wound therapy (NPWT) pumps, canisters and dressings which provide wound site pressure feedback. 2006. 2 p.	Not used in this report
(815)	Hake C. Doctors interviewed by the house ways and means reportedly support foam as superior to gauze. 2008. 3 p.	Not used in this report
(816)	Harbour J, Kinetic Concepts, Inc. 510 (k) Summary. Ambulatory Suction Pump. 1997 May 22. 5 p.	Used as background information
(817)	Smith T. Kinetic Concepts patent not infringed. 2006. 1 p.	Not used in this report
(818)	United States patent and trademark office. V.A.C. United States Patent and Trademark Office; 1996 Jun 25. 33 p.	Not used in this report
(819)	Wilson C. Personal communication. FW: Alliance for LTC on Wound VAC/NPWT. 2006. 2 p.	Not used in this report
(820)	Witten C. (Director. Division of General and Restorative Devices, Office of Device Evaluation, Center for Devices and Radiological Health). Approval of 510(k) notification of intent to market. AmbuVAC Device. 1997 May 22. 3 p.	Used as background information

Reference Number	Reference	Disposition in Report
(821)	Witten C. (Director. Division of General, Restorative and Neurological Devices, Office of Device Evaluation, Center for Devices and Radiological Health). Approval of 510(k) notification of intent to market. V.A.C. family of devices: mini V.A.C. V.A.C. Freedom V.A.C. ATS. K032310. 2003 Oct 10. 5 p.	Used as background information
(822)	Witten C. (Director. Division of General, Restorative and Neurological Devices. Office of Device Evaluation. Center for Devices and Radiological Health). 510(k) notification of intent to market Versatile 1 Wound Vacuum System. K042134. 2004 Nov 15. 7 p.	Used as background information
(823)	Witten C. (Director. Division of General, Restorative and Neurological Devices, Office of Device Evaluation, Center for Devices and Radiological Health). Approval of 510(k) notification of intent to market. V.A.C. granufoam silver dressing. K041642. 2005 Jan 25. 3 p.	Used as background information

Table 47. Status of CMS submission: Miscellaneous Material

Reference Number	Reference	Disposition in Report
(824)	AllegroMedical.com. Invacare aspirator product description. [internet]. Mesa (AZ): AllegroMedical.com; 2005 [accessed 2005 Aug 15]. Available: http://www.allegromedical.com/oxygen_therapy/nebulizers/invacare/aspirator.P189899.	Not used in this report
(825)	BlueSky Medical Group, Inc. Negative pressure wound therapy. V1STA Versatile 1 portable. Carlsbad (CA): BlueSky Medical Group, Inc.; 2005. 4 p. – product brochure	Used as background information
(826)	Hake C. (Director, CMS' HCPCS Workgroup). Personal communication. Negative pressure wound therapy devices. 2008 Jan 23. 5 p. Includes list of materials submitted by CMS for this report.	Personal communication
(827)	Kinetic Concepts, Inc. Advanced Dressings. Dedicated dressings for specific wound applications. San Antonio (TX): Kinetic Concepts, Inc. (KCI); 2005. 6 p. – product brochure	Used as background information
(828)	Kinetic Concepts, Inc. V.A.C. A portable system for advanced wound healing. San Antonio (TX): Kinetic Concepts, Inc. (KCI); 2005. 6 p. – product brochure	Used as background information
(829)	Lewis P. Smith & Nephews acquires BlueSky medical group. Remington Rep 2007; news release	Not used in this report
(830)	Medela, Inc. Medela Clario home care pump. Product Description. [internet]. MCHenry (IL): Medela, Inc.; 2005 [accessed 2005 Sep 16]. [1 p]. – product brochure	Used as background information
(831)	United Publications, Inc. Are negative pressure wound therapy codes created equal?. [internet]. Yarmouth (ME): United Publications, Inc.; 2009 [accessed 2009 Jan 12]. [3 p]. – news report	Not used in this report
	V.A.C. Annotated Peer-reviewed Article Bibliography prepared by KCI	We examined the bibliography for studies not identified in our searches
(832)	Weston R. (President, BlueSky Medical). Personal Communication. BlueSky medical wound drainage kit. 2003. 5 p. – also included product information and brochure	Used as background information

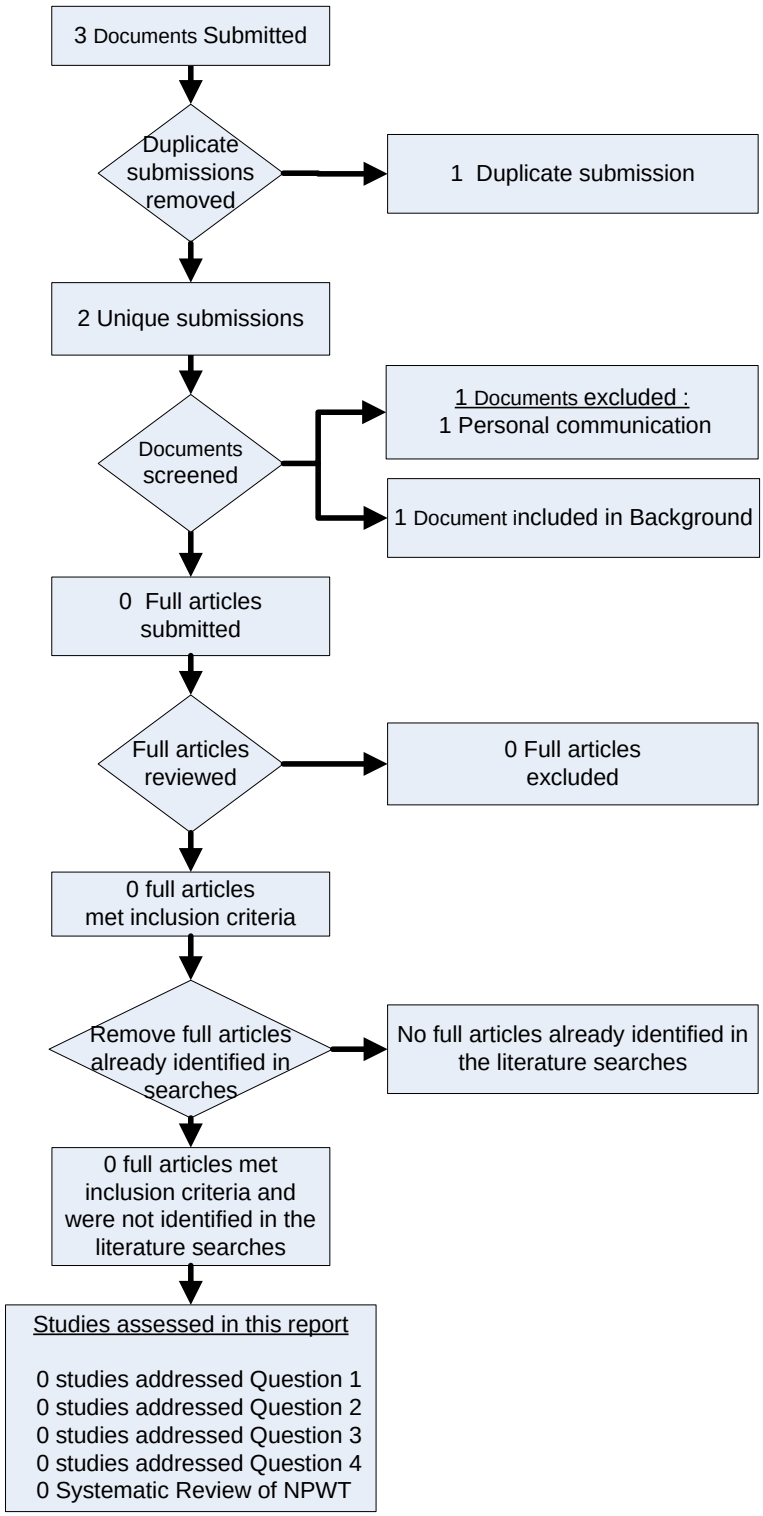
Table 48. Status of CMS submission: Material from KCI or related to KCI

Reference Number	Reference	Disposition in Report
(833)	Cynthia S. Hake. CMS meeting with KCI. 2005. 68 p. KCI presentation to CMS comparing V.A.C. to BlueSky Versatile 1	Not used in this report
(834)	House small business subcommittee on rural and urban entrepreneurship. Statement by Linwood A. Staub, President, Global V.A.C therapy, Kinetic Concepts, Inc. (KCI) on behalf of the Advanced Medical Technology Association (AdvaMed). Washington (DC): U.S. House of Representatives; 2008 May 21. 11 p. Also available: http://www.house.gov/smbiz/hearings/hearing-05-21-08-DME/Staub.pdf.	Not used in this report
(835)	Kinetic Concepts, Inc. (KCI). Personal Communication. KCI comments on CMS' preliminary decision to include BlueSky and KCI NPNT devices in the same code. 2005. 20 p.	Not used in this report
(836)	Kinetic Concepts, Inc. Personal communication. Comments following the June 23, 2005 CMS HCPCS workgroup meeting agenda item #11; HCPCS request #05.09. 2005. 3 p.	Not used in this report
(836)	Kinetic Concepts, Inc. Personal communication. Comments following the June 23, 2005 CMS HCPCS workgroup meeting agenda item #11; HCPCS request #05.09. 2005. 3 p. KCI comments regarding BlueSky V1	Not used in this report
(837)	Larichev A. Vacuum therapy in wounds and wound infection: negative pressure wound therapy.Carlsbad (CA): BlueSky Publication; 2005 [2 p]. - page from Library of Congress Online Catalog	Not used in this report
(838)	Matherne C. (Senior Attorney. LSU, Health Sciences Center). Personal Communication. V.A.C. System. Medical center of Louisiana. 2001 Sep 21. 1 p.	Not used in this report
(839)	Morris S. (Vice President, Health policy & Government Affairs KCI). Personal communication. Public meeting registration for KCI. 2006. 1 p.	Not used in this report
(840)	Morris S. (Vice President, Reimbursement Policy and Compliance). Personal Communication. HCPCS code request for negative pressure wound therapy pumps. 2006. 4 p.	Not used in this report
(841)	Morris S. Additional V1 failures/VAC rescues. 2006. 2 p. Case reports submitted by KCI to CMS	Not used in this report
(842)	Moton T. (Briefing Coordinator). Meeting with Kinetic Concepts Incorporated (KCL). 2006. 30 p. KCI presentation to CMS	Not used in this report
(843)	NPWT HCPCS coding: KCI V.A.C. therapy system. Update for the Centers for Medicare and Medicaid Services. San Antonio (TX): Kinetic Concepts, Inc. (KCI); 2006. 173 p. KCI submission to CMS	Not used in this report
(844)	Quirk, W. Personal Communication. VAC plus premarket notification No. K945062. 2002 Oct 22. 4 p. Letter sent from KCI to BlueSky.	Not used in this report
(845)	Schroeder, W. (Vice President, Medical Department, Kinetic Concepts, Inc.). Misuse of the V.A.C technology. 2000 Feb 01. 2 p.	Not used in this report
(846)	Tarplin R. Letters that raise concerns about the CMS HCPCS coding decision. 2006. 83 p. Letters from Congress and clinicians sent to CMS.	Not used in this report

Table 49. Status of CMS submission: Material from BlueSky or related to BlueSky

Reference Number	Reference	Disposition in Report
(847)	BlueSky Medical Group, Inc. HCPSC coding request Versatile 1 wound vacuum system. Carlsbad (CA): BlueSky Medical Group, Inc.; 2005. 5 p. – BlueSky presentation to CMS	Not used in this report
(848)	BlueSky Medical. Information for Centers for Medicare and Medicaid Services on negative pressure wound therapy. Baltimore (MD): BlueSky Medical; 2002 Oct 25. 45 p. – package of information sent to CMS by BlueSky Medical	Not used in this report
(849)	Guimond J. (Marketing & Sales. BlueSky Medical Group, Inc.). Personal Communication. BlueSky's product line, VISTA Versatile 1 portable. 2006. 3 p. – announcement about failure of KCI infringement lawsuit	Not used in this report
(850)	Weston R. (President. BlueSky Medical Group, Inc.). Personal Communication. Petition and request to decrease reimbursement levels. 2002 Jun 11. 2 p.	Not used in this report
(851)	Weston R. Personal communication. BlueSky's 2005 HCPCS code request. 2004. 5 p.	Not used in this report

Figure 9. Disposition of Submission by ConvaTec

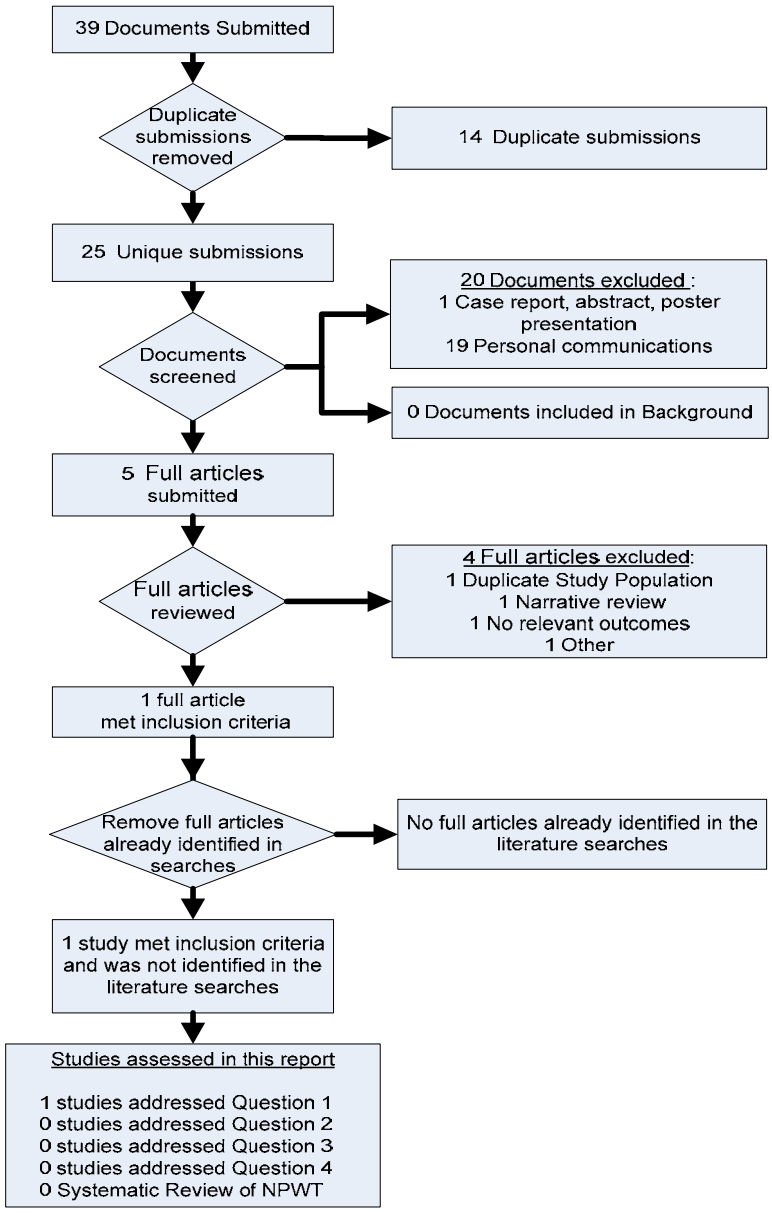


Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Table 50. Status of Submission by ConvaTec

Reference Number	Reference	Included	Placement in Report	Disposition in Report
(852)	Engenex Advanced Negative Pressure Wound Therapy System. Instructions for use. Skillman (NJ): ConvaTec, Inc.; 2008 Dec. 33 p. – product information	✓	Background	
(853)	Rolley J. (Vice President, Global Government Affairs and Health Policy, ConvaTec). Personal communication. 2009 Feb 6. 3 p.			Not included in this report – personal communication
(732)	Summaries of current clinical evidence Engenex NPWT system. Skillman (NJ): ConvaTec, Inc.; 3 p. ConvaTec provided 6 references to poster presentations at wound care meetings. A total of 14 patients of various wound types were treated with the Engenex® NPWT system using the Bio-Dome™ dressing set.			Not included in this report – poster presentation

Figure 10. Disposition of Submission by Individuals



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Table 51. Status of Submission by Individuals

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(854)	Andersen C. (Chief Vascular/Endovascular/LimbPreservation Surgery Service, Madigan Army Medical Center. Ft. Lewis, WA). Personal communication. Re: AHRQ review of NPWT. 2009 Feb 6. 2 p.			✓	Personal communication	
(855)	Annest S. (MD, FACS. Denver, CO). Personal communication. NPWT Comments from Annest. 2009 Feb 3. 1 p.			✓	Personal communication	
(195)	Armstrong DG, Lavery LA, Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. Lancet 2005 Nov 12;366(9498):1704-10.			✓	Study population reported in(109)	
(856)	Arnold DA. (Midwest Hernia Institute, P.C.). Personal communication. Comments on NPWT from Midwest Hernia Institute. 2009 Jan 30. 1 p.			✓	Personal communication	
(857)	Bernstein BH. (DPM, FACFAS). Personal communication. Comparison of types of NPWT, limb salvage specialist's point of view. 2009 Feb 4. 2 p.			✓	Personal communication	
(108)	Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care 2008 Apr;31(4):631-6.	✓	KQ1, KQ3			
(858)	Chaiken N. (Wound Ostomy Continence, Swedish Covenant Hospital). Personal communication. Comments on wound VACs. 2009 Feb 3. 1 p.			✓	Personal communication	
(859)	Clinical V.A.C. therapy slides from the practice of Dr. C. Douglas Fogg, MD, FACS. New Bedford (MA): New Bedford Rehabilitation Hospital Wound Care Center; 14 p.			✓	Case studies	
(860)	Coliauta EA. Personal communication. Support of KCI wound VAC system. 2009 Feb 6. 1 p.			✓	Personal communication	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(861)	Cummings SF. (Director, Wound Recovery and Hyperbaric Medicine Service, Kent Hospital. Warwick, RI). Personal communication. NPWT Response from Kent Hospital. 2009 Jan 30. 1 p.			✓	Personal communication	
(862)	DosRemedios E. (Clinical Assistant Professor of Orthopaedic Surgery, Warren Alpert School of Medicine at Brown University. Providence, Rhode Island.). Personal communication. Comments on NPWT from Brown University. 2009 Feb 2. 1 p.			✓	Personal communication	
(863)	Fetterly MA. (RNFA, CPSN, CNOR. O Plastic & Reconstructive Surgery. Reno, NV). To AHRQ in regards to KCI VAC devices. 2009 Jan 29. 1 p.			✓	Personal communication	
(362)	Fleck T, Kickinger B, Moidl R, Waldenberger F, Wolner E, Grabenwoger M, Wisser W. Management of open chest and delayed sternal closure with the vacuum assisted closure system: Preliminary experience. Interact Cardiovasc Thorac Surg 2008 Oct;7(5):801-4.	✓	KQ3			
(496)	Fleck T, Moidl R, Giovanoli P, Aszmann O, Bartunek A, Blacky A, Grabenwoger M, Wolner E. A conclusion from the first 125 patients treated with the vacuum assisted closure system for postoperative sternal wound infection. Interact Cardiovasc Thorac Surg 2006 Apr;5(2):145-8.			✓	Narrative	
(497)	Fleck T, Simon P, Burda G, Wolner E, Wollenek G. Vacuum assisted closure therapy for the treatment of sternal wound infections in neonates and small infants. Interact Cardiovasc Thorac Surg 2006 Jun;5(3):285-8.			✓	Fewer than five patients	
(864)	Fleck T. (Department of Cardiothoracic Surgery, AKH Vienna, Medical University of Vienna). Response to the review of NPWT of the AHRQ. 2009 Jan 29. 1 p. Dr. Fleck provided a list of 12 studies and abstracts. These were reviewed for possible inclusion.			✓	Five studies with Dr. Fleck as the first author were considered for this report. Two were included(362,380) and three were excluded.(496-498)	

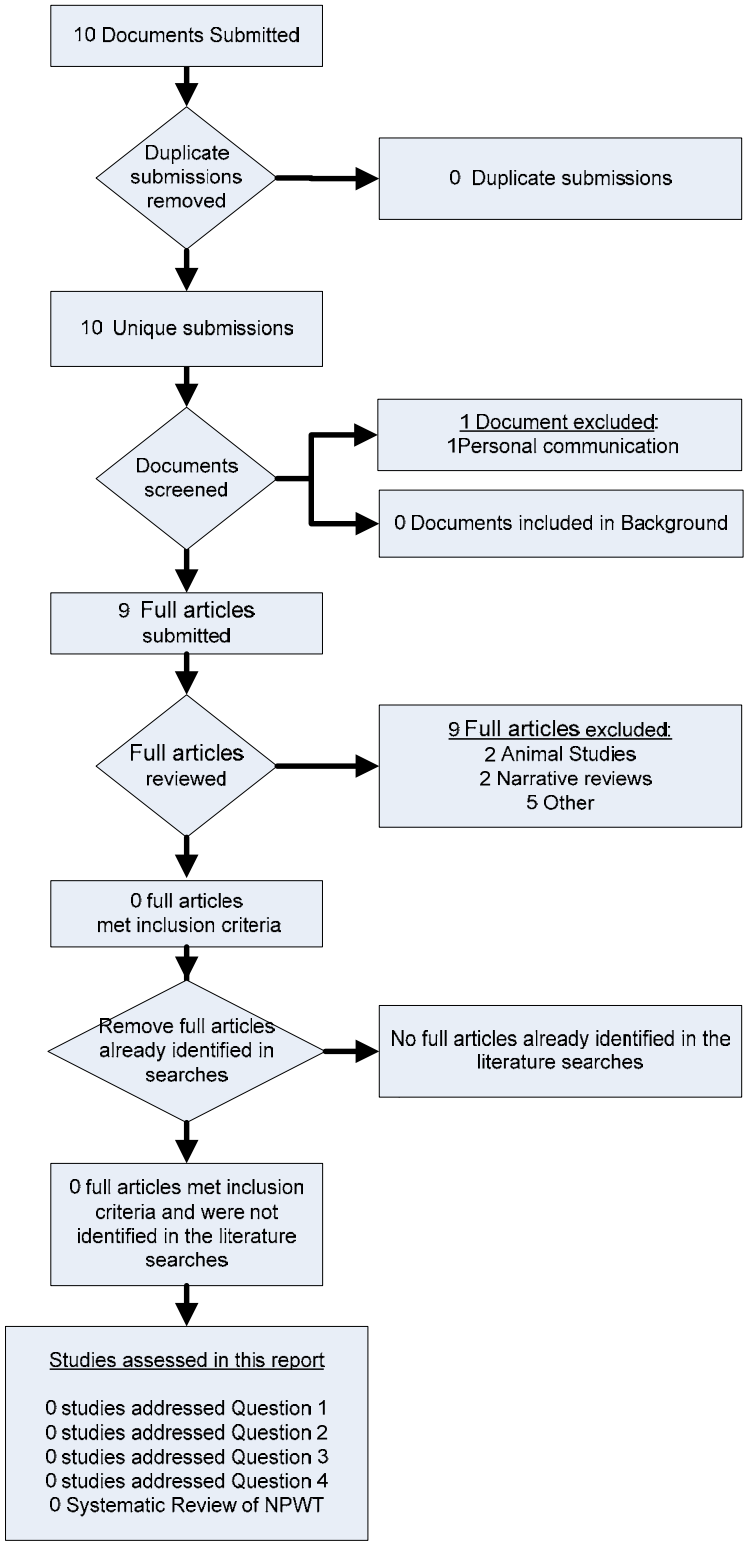
Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(380)	Fleck TM, Fleck M, Moidl R, Czerny M, Koller R, Giovanoli P, Hiesmayer MJ, Zimpfer D, Wolner E, Grabenwoger M. The vacuum-assisted closure system for the treatment of deep sternal wound infections after cardiac surgery. Ann Thorac Surg 2002 Nov 1;74(5):1596-1600.	✓	KQ3			
(498)	Fleck TM, Koller R, Giovanoli P, Moidl R, Czerny M, Fleck M, Wolner E, Grabenwoger M. Primary or delayed closure for the treatment of poststernotomy wound infections. Ann Plast Surg 2004 Mar;52(3):310-4.			✓	Not relevant	
(865)	Fogg CD. (Medical Director, New Bedford Rehabilitation Hospital Wound Care Center). Advocacy for V.A.C. therapy. 1 p.			✓	Personal communication	
(866)	Gestring M, Manaker S, Wilson KC. Vacuum assisted wound closure [unpublished]. 2008 Apr 10. 7 p.			✓	Narrative	
(341)	Lavery LA, Boulton AJ, Niezgoda JA, Sheehan P. A comparison of diabetic foot ulcer outcomes using negative pressure wound therapy versus historical standard of care. Int Wound J 2007 Jun;4(2):103-13.	✓	KQ1, KQ3			
(867)	Marston WA. (Professor and Chief, Division of Vascular Surgery, University of North Carolina School of Medicine. Chapel Hill, NC). Personal communication. Review of Negative Pressure Wound Therapy devices. 2009 Feb 3. 1 p.			✓	Personal communication	
(868)	Mooney TM. (DPM, AACFAS, Western Nevada Foot & Ankle Center, LLC. Reno, NV). Personal communication. 2009. 1 p.			✓	Personal communication	
(869)	Nelson G. (Program Coordinator, Advanced Wound Center, Rogue Valley Medical Center. Medford, OR). Personal communication. Concerns about negative pressure therapy. 2009 Feb 5. 2 p.			✓	Personal communication	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(870)	Pelham FR. (Department of Orthopedic Surgery, Musculoskeletal Research Center, New York University Hospital for Joint Diseases, New York, NY). Personal communication. Re: VAC therapy. 2009 Feb 6. 13 p. Dr. Pelham provided a manuscript describing a retrospective case-series of patients with stage III and IV pressure ulcers treated with V.A.C. therapy, but requested that the data not be shared with the public.			✓	The study provided by Dr. Pelham was not included in the report. The study did not address Key Questions 1, 2, or 4. The study could have been considered under Key Question 3, but the study did not report that they collected data on complications.	
(671)	Poulakidas S, Kowal-Vern A. Facilitating residual wound closure after partial graft loss with vacuum assisted closure therapy. J Burn Care Res 2008 Jul-Aug;29(4):663-5.			✓	Case report	
(871)	Ritzman D. (Fremont-Rideout Home Health). Personal communication. HCPS code for KCI Wound Vac. 2009 Jan 31. 1 p.			✓	Personal communication	
(872)	Robins M. (Wound Care Clinic at Utah Valley Regional Medical Center). NPWT study. 2009 Feb 6. 4 p. Dr. Robins provided a review of NPWT(866) and three publications.(174,183,195)			✓	A review of NPWT(866) and three publications.(174,183,195)	
(308)	Schlatterer D, Hirshorn K. Negative pressure wound therapy with reticulated open cell foam-adjunctive treatment in the management of traumatic wounds of the leg: a review of the literature. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S152-60.			✓	Review article	
(873)	Schultz G. (Professor, Department of Obstetrics and Gynecology, Institute for Wound Research, University of Florida. Gainesville, FL). Personal communication. Re: scientific data on effects of NPWT. 2009 Feb 6. 1 p. Dr. Schultz provided references to two publications.			✓	The publications were not used in this report because they did not report wound healing outcomes considered in this report	
(874)	Snow R. (Director, Baptist Wound Care & Hyperbaric Medicine Program @ Princeton). Personal communication Re: negative pressure Rx. 2009 Feb 3. 1 p.			✓	Personal communication	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(738)	Tarkin IS. The versatility of negative pressure wound therapy with reticulated open cell foam for soft tissue management after severe musculoskeletal trauma. J Orthop Trauma 2008 Nov-Dec;22(10 Suppl):S146-51.			✓	Case reports	
(875)	Tedford S. (WOCN Program Coordinator, Sutter VNA & Hospice). Personal communication. HCPCS code response from WOCN. 2009 Jan 30. 1 p.			✓	Personal communication	
(106)	Timmers MS, Graafland N, Bernards AT, Nelissen RGHH, Van Dissel JT, Jukema GN. Negative pressure wound treatment with polyvinyl alcohol foam and polyhexanide antiseptic solution instillation in posttraumatic osteomyelitis. Wound Repair Regen 2009 Mar-Apr;17(2):278-86.	✓	Key Question 1			✓
(174)	Ubbink DT, Westerbos SJ, Evans D, Land L, Vermeulen H. Topical negative pressure for treating chronic wounds (Review). In: Cochrane Database of Systematic Reviews [internet]. Issue 3. Hoboken (NJ): John Wiley & Sons, Ltd.; 2008 [Art. No.: CD001898].	✓	Previous Systematic Reviews			
(183)	Ubbink DT, Westerbos SJ, Nelson EA, Vermeulen H. A systematic review of topical negative pressure therapy for acute and chronic wounds. Br J Surg 2008 Jun;95(6):685-92.	✓	Previous Systematic Reviews			
(876)	Ward RS. (President, American Physical Therapy Association. Alexandria, VA). APTA's response to AHRQ's request for information on Negative Pressure Wound Therapy. 2009 Feb 4. 2 p. Dr. Ward provided copies of six publications, all identified by our searches; three were included in the report and three were excluded. Included publications:(75,108,341) Excluded publications: (738) – case reports (308) – review article (671) – case report			✓	Cover letter	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(75)	Wongworawat MD, Schnall SB, Holtom PD, Moon C, Schiller F. Negative pressure dressings as an alternative technique for the treatment of infected wounds. Clin Orthop Relat Res 2003 Sep;(414):45-8.	✓	KQ3			
(877)	Yee EM. (Sierra Infectious Diseases, Reno, NV). Personal communication. Comments on proposed code change. 2009 Jan 30. 1 p.			✓	Personal communication	

Figure 11. Disposition of Submission by Medela, Inc.

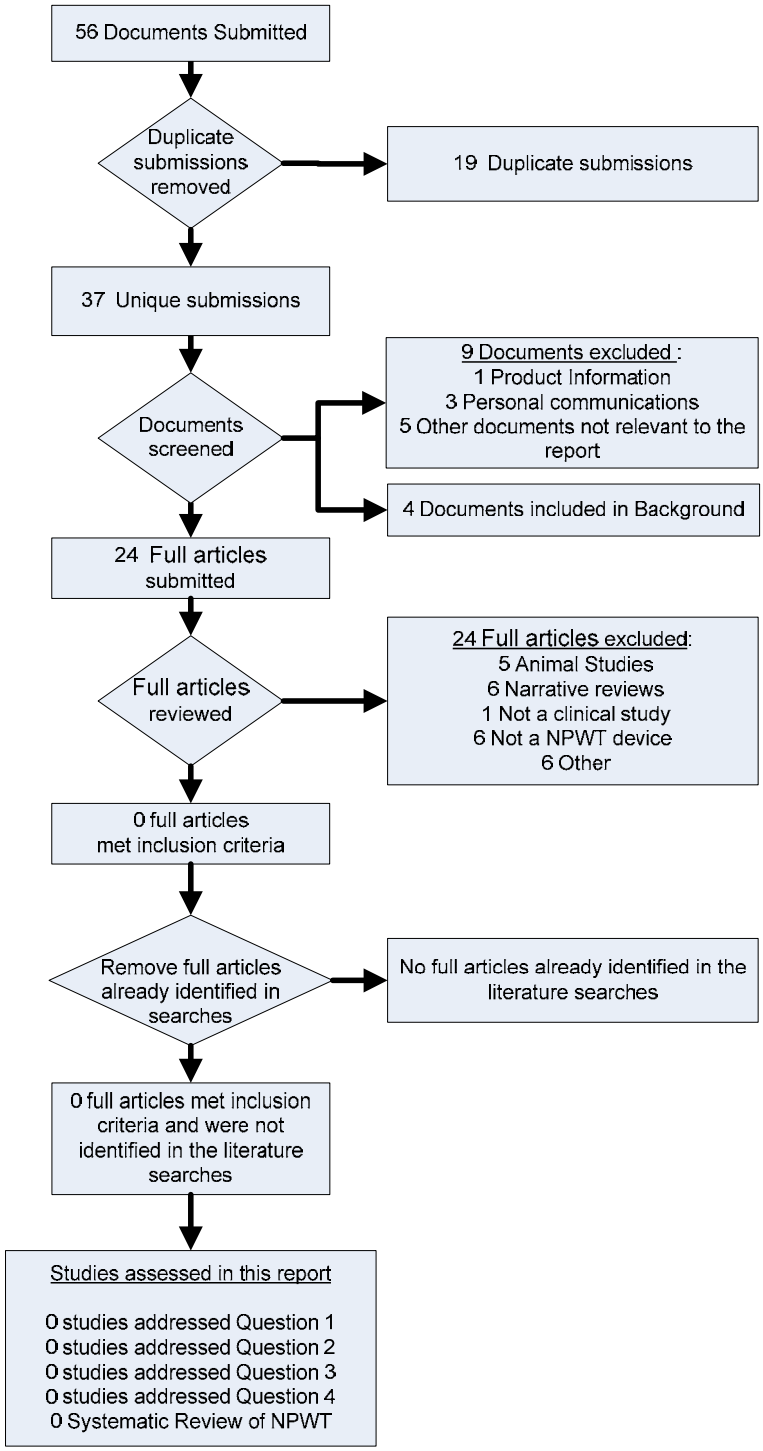


Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Table 52. Status of Submission by Medela

Reference Number	Reference	Included	Excluded	Reason for Exclusion
(878)	Best practice statement: gauze-based negative pressure wound therapy. HealthComm UK Limited; 2008 Nov. 19 p.		✓	Narrative review
(879)	Case study 2: Four challenging LE wounds: can these chronic wounds be healed with use of negative pressure wound therapy. McHenry (IL): Medela Healthcare, Inc.; 1 p.		✓	Case study
(880)	Case study: gauze-based NPWT: various wound types from different wound locations. McHenry (IL): Medela Healthcare, Inc.; 1 p.		✓	Case study
(881)	Comparative analysis of gauze-based NPWT systems versus foam-based NPWT systems. McHenry (IL): Medela Healthcare, Inc.; 7 p. – A short description of a retrospective analysis of 55 patients treated with the Invia® wound Therapy system.		✓	Insufficient reporting of study design and results
(882)	Gauze based clinical study 1: Safety and effectiveness of the Invia (vacuum) wound care system versus a saline wet-to-dry gauze dressing. McHenry (IL): Medela Healthcare, Inc.; 5 p.		✓	Protocol for planned RCT
(883)	Gauze based clinical study 2: Gauze versus foam for topical negative pressure wound therapy (NPWT) in postoperative subcutaneous wound infections after abdominal operations. First clinical observations. McHenry (IL): Medela Healthcare, Inc.; 22 p.		✓	Case study
(884)	Long C. (Director, Medela Healthcare. McHenry, IL). Submission letter from Medlea Healthcare regarding NPWT. 2009 Feb 3. 1 p. – cover letter		✓	Cover letter
(885)	McHenry (IL): Medela Healthcare; 2009. Introduction to NPWT. p. 3. – short discussion of NPWT		✓	Narrative
(886)	Pre-clinical study: a comparison of various dressings combined with NPWT. McHenry (IL): Medela Healthcare, Inc.; 2008. 15 p. Also available: http://www.etrs.org/malta3.html.		✓	Animal study
(887)	The effect of an antimicrobial gauze dressing impregnated with 0.2% polyhexamethylene biguanide (PHMB) as a barrier to prevent pseudomonas aeruginosa wound invasion. McHenry (IL): Medela Healthcare, Inc.; 7 p.		✓	Animal study

Figure 12. Disposition of Submission by Prospera



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Table 53. Status of Submissions by Prospera

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(888)	Advancing the art and science of NPWT. Fort Worth (TX): Prospera; 2008. CD-ROM. – product information			✓	Product Information	
(889)	Ahearn C. (Director of Clinical Services, Prospera). Prospera response to ECRI Institute's December 20, 2008 request for information regarding our Negative Pressure Wound Therapy system. 2009 Feb 2. 1 p. – cover letter			✓	Cover letter	
(890)	Allison Hendrickson M, Reaves L, Ulbrich M. Optimizing wound care by integrating negative pressure wound therapy (NPWT), adjunctive topical treatments and surgical debridement. Grapevine (TX): Ethicus Long Term Acute Care Hospital; 1 p.			✓	Case study	
(891)	AMD antimicrobial gauze dressings [slide]. Fort Worth (TX): Prospera; 1 p.			✓	Not a NPWT device	
(892)	Bonham PA, Ramundo JM. Commentary: surgical wound case studies with the Versatile 1 wound vacuum system for negative pressure wound therapy. J Wound Ostomy Continence Nurs 2006 Mar-Apr;33(2):185-90.			✓	Narrative review	
(893)	Borgquist O, Torbrand C, Ingemansson R, Malmsjo M. Biological effects of negative pressure wound therapy (NPWT) at low levels of negative pressure - intermittent and variable NPWT [confidential info prepared for ECRI on behalf of AHRQ]. 2009 Feb. 5 p.			✓	Animal study	
(894)	Borgquist O, Torbrand C, Ingemansson R, Malmsjo M. Biological effects of negative pressure wound therapy at low levels of negative pressure - intermittent and variable NPWT. 2 p.			✓	Animal study	
(207)	Bovill E, Banwell PE, Teot L, Eriksson E, Song C, Mahoney J, Gustafsson R, Horch R, Deva A, Whitworth I, International Advisory Panel on Topical Negative Pressure. Topical negative pressure wound therapy: a review of its role and guidelines for its use in the management of acute wounds. Int Wound J 2008 Oct;5(4):511-29.			✓	Narrative review	
(84)	Campbell PE, Smith GS, Smith JM. Retrospective clinical evaluation of gauze-based negative pressure wound therapy. Int Wound J 2008 Jun;5(2):280-6.	✓	KQ3			✓

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(895)	Case studies: Prospera PRO-I negative pressure wound therapy [MR124-02/08]. Fort Worth (TX): Prospera; 2008. 7 p.			✓	Case study	
(896)	Caudill T. Clinical and economic benefit to surgical patients with the use of an antimicrobial impregnated surgical dressing. 2 p.			✓	Not a NPWT device	
(442)	Chariker ME, Jeter KF, Tintle TE, Bottsford JE. Effective management of incisional and cutaneous fistulae with close suction wound drainage. Contemp Surg 1989 Jun;34:59-63.			✓	Did not use a commercially available NPWT system	
(897)	Clinical and patient testimonials [Confidential info prepared for ECRI on behalf of AHRQ]. Fort Worth (TX): Prospera; 2009 Feb. 5 p.			✓	Testimonials were not used in this report	
(898)	CPT - continuous pressure therapy [graph]. Fort Worth (TX): Prospera; 1 p.			✓	Graph	
(461)	Davydov YA, Larichev AB, Abramov AY, Menkov KG. [Concepts for clinical biological management of the wound process in the treatment of purulent wounds using vacuum therapy] translated from Russian. Vestnik Khirurgii 1991 Feb;132-5. (Rus).			✓	Not a NPWT device	
(462)	Davydov YA, Larichev AB, Menlov KG. [The bacteriological and cytological assessment of vacuum therapy of purulent wounds] translated from Russian. Vestnik Khirurgii 1988 Oct;48-52.			✓	Not a NPWT device	
(460)	Davydov YA, Malafeeva EV, Smirnov AP, Flegontov VB. [Vacuum therapy in the treatment of purulent lactation mastitis] translated from Russian. Vestnik Khirurgii 1986 Sep;66-70. (Rus).			✓	Not a NPWT device	
(899)	Donahue K. (Administrative Assistant, Health Technology Assessment Information Service and Evidence-Based Practice Center, ECRI Institute. Plymouth Meeting, PA). ECRI Institute's request for submissions on NPWT from interested stakeholders. 2008 Dec 30. 2 p. – copy of letter from ECRI Institute to Prospera			✓	Communication	
(900)	Eberlein T, Fedler H. Using a new technique of negative pressure wound therapy (NPWT): variable pressure therapy (VPT) for the management of chronic, non-healing wounds [poster]. Neuremberg, Germany: Gesundheits Manager Health and Wound Management; 1 p.			✓	Case study	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(901)	Eberlein T, Fendler H, Ahearn C. Using a new technique for negative pressure wound therapy (NPWT) for the management of chronic, non-healing wounds [poster]. Neuremberg, Germany: Gesundheits Manager Health and Wound Management; 1 p.			✓	Case study	
(902)	Eberlein T, Fendler H, Ahearn C. Using a new technique of negative pressure wound therapy (NPWT): variable pressure therapy (VPT) for the management of chronic, non-healing wounds. 4 p. – A short description of unpublished data from a prospective analysis of 37 patients treated with the Prospera® NPWT system.			✓	Insufficient reporting of study design and results	
(903)	Etoz A, Ozgenel Y, Ozcan M. The use of negative pressure wound therapy on diabetic foot ulcers: a preliminary controlled trial. Wounds 2004 Aug;16(8):264-9.			✓	Did not use a commercially available NPWT system	
(811)	Food and Drug Administration, Center for Devices and Radiological Health. 510(k) premarket notification database. Vacuum assisted closure. K021500. [internet]. Silver Spring (MD): Food and Drug Administration, Center for Devices and Radiological Health; 2002 Dec 20 [accessed 2005 Nov 11]. [5 p]. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=8137.	✓	Background			
(904)	Guiding principles/documentation behind Prospera variable pressure therapy (VPT). Fort Worth (TX): Prospera; 1 p. – list of references			✓	List of references	
(905)	Guiding principles/documentation behind the use of Lower Pressure Settings. Fort Worth (TX): Prospera; 1 p. – list of references			✓	List of references	
(906)	Introducing the all-new PRO-II [MR-131-09/08]. Fort Worth (TX): Prospera; 2008. 6 p. – product information	✓	Background			
(543)	Isago T, Nozaki M, Kikuchi Y, Honda T, Nakazawa H. Effects of different negative pressures on reduction of wounds in negative pressure dressings. J Dermatol 2003 Aug;30(8):596-601.			✓	Animal study	

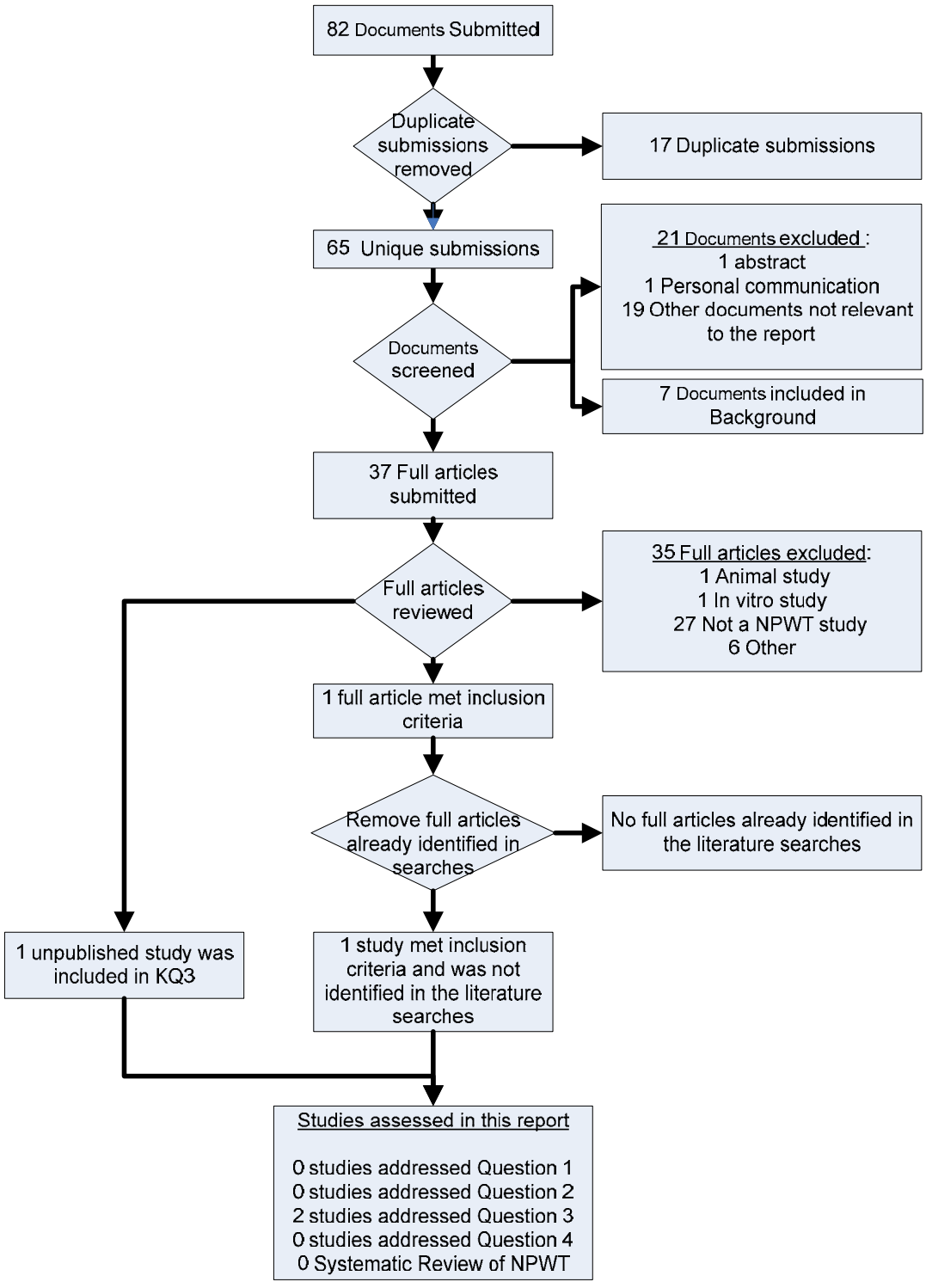
Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(907)	Kairinos N, Solomons M, Hudson DA. The paradox of negative pressure wound therapy - in vitro studies. J Plast Reconstr Aesthet Surg 2008 Nov 24;Epub ahead of print.			✓	Not a clinical study	
(908)	Kirby M. Negative pressure wound therapy. Br J Diabetes Vasc Dis 2007 Sep;7(5):230-4.			✓	Narrative review	
(570)	Kostiuchenok BM, Kolker II, Karlov VA, Ignatenko SN, Samykina TD. [The vacuum effect in the surgical treatment of purulent wounds] translated from Russian. Vestnik Khirurgii 1986;18-21. (Rus).			✓	Not a NPWT device	
(253)	Krasner DL. Managing wound pain in patients with vacuum-assisted closure devices. Ostomy Wound Manage 2002 May;48(5):38-43.			✓	Narrative review	
(909)	Malmsjo M, Ingemansson R, Martin R, Huddleston E. Negative pressure wound therapy using gauze or polyurethane open cell foam: similar effects on pressure transduction and wound contraction. Lund, Sweden: Lund University; 1 p.			✓	Animal study	
(910)	Miller MS. Commentary: new microvascular blood flow research challenges practice protocols in negative pressure wound therapy. Wounds 2005;17(10):290-4.			✓	Narrative review	
(911)	Molnar JA. The science behind negative pressure wound therapy. Ostomy Wound Manage 2004 Apr;50(4A Suppl):2-5.			✓	Narrative review	
(33)	Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Ann Plast Surg 1997 Jun;38(6):553-62.			✓	Animal study	
(912)	Motta GJ, Corbett LQ, Milne CT. Impact of an antimicrobial gauze upon bacterial colonies in wounds that require packing. 11 p.			✓	Not a NPWT device	
(913)	NovaSpine LLC. 510(k) summary of safety and effectiveness. K062456. Rockville (MD): U.S. Food and Drug Administration; 2006 Sep 27. 5 p.	✓	Background			

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(665)	Philbeck TE Jr, Whittington KT, Millsap MH, Briones RB, Wight DG, Schroeder WJ. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients. Ostomy Wound Manage 1999 Nov;45(11):41-50.			✓	Patients treated with dual therapies	
(914)	Price RD, Nagarajan M, Srinivasan JR. Local anesthetic for change of vacuum-assisted closure dressings. Plast Reconstr Surg 2006 Jun;117(7):2537-8.			✓	Letter to the editor	
(915)	PRO-I [MR-125-04/08]. Fort Worth (TX): Prospera; 2008. 4 p. – product information	✓	Background			
(916)	Prospera overview [confidential info prepared for ECRI on behalf of AHRQ]. Forth Worth (TX): Prospera; 2009 Feb. 1 p. – discussion of Prospera approach to NPWT			✓	Narrative	
(917)	Rationale for the Choice AMD gauze dressing system. Fort Worth (TX): Prospera; 2 p. – discussion of Prospera's reasons for selecting gauze dressings			✓	Narrative	
(918)	Sargent RL, Mudro P, Mele J, Sons J. The use of antimicrobial gauze in a home care setting: a cost effective, proactive wound management plan. 2 p.			✓	Not a NPWT device	
(126)	Schwien T, Gilbert J, Lang C. Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes. Ostomy Wound Manag 2005;51:47-60.	✓	KQ1, KQ3			
(919)	Shah CB, Swogger E, James G. Efficacy of AMD dressings against MRSA and VRE. 2006 Jul. 4 p.			✓	Not a NPWT device	
(704)	Shirakawa M, Isseroff RR. Topical negative pressure devices: Use for enhancement of healing chronic wounds. Arch Dermatol 2005 Nov;141(11):1449-53.			✓	Narrative review	
(920)	Similar physical properties of gauze and polyurethane foam in delivery of negative pressure wound therapy. St. Petersburg (FL): Smith & Nephew; 2008. 2 p.			✓	Animal study	
(921)	Tillery T. The use of a gauze-based dressing for negative pressure wound therapy (NPWT): clinical and financial outcomes. 2008. 2 p.			✓	Case study	

Reference Number	Reference	Included	Placement in Report	Excluded	Reason for Exclusion	Included but Not identified in ECRI Search
(183)	Ubbink DT, Westerbos SJ, Nelson EA, Vermeulen H. A systematic review of topical negative pressure therapy for acute and chronic wounds. Br J Surg 2008 Jun;95(6):685-92.	✓	Previous Systematic Reviews			
(922)	Usupov YN, Yepifanov MV. [Active wound drainage] translated from Russian. Vestnik Khirurgii 1987;42-5. (Rus).			✓	Animal study	
(923)	VPT variable pressure therapy [graph]. Forth Worth (TX): Prospera; 1 p.			✓	Graph	
(756)	Wackenfors A, Gustafsson R, Sjogren J, Algotsson L, Ingemansson R, Malmsjo M. Blood flow responses in the peristernal thoracic wall during vacuum-assisted closure therapy. Ann Thorac Surg 2005 May;79(5):1724-30; discussion 1730-.			✓	Animal study	
(40)	Wackenfors A, Sjogren J, Gustafsson R, Algotsson L, Ingemansson R, Malmsjo M. Effects of vacuum-assisted closure therapy on inguinal wound edge microvascular blood flow. Wound Repair Regen 2004 Nov-Dec;12(6):600-6.			✓	Animal study	
(760)	Webb LX. New techniques in wound management: vacuum-assisted wound closure. J Am Acad Orthop Surg 2002 Sep-Oct;10(5):303-11.			✓	Narrative review	
(32)	Willy C, editor(s). The theory and practice of vacuum therapy. Scientific basis, indications for use, case reports, practical advice. Ulm,Germany: Lindqvist book publishing; 2006. 405 p.	✓	Background			
(767)	Willy C, Voelker HU, Engelhardt M. Literature on the subject of vacuum therapy: review and update 2006. Eur J Trauma Emerg Surg 2007 Feb;33(1):33-9.			✓	Systematic review, but did not evaluate wound healing outcomes	

KQ Key question

Figure 13. Disposition of Submission by Smith & Nephew



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Table 54. Status of Submissions by Smith and Nephew

Reference Number	Reference	Included	Placement In Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(924)	Baffie A, Fromantin L. Clinical case: V1STA. J Wound Tech 2008 Jun;1:24.			✓	Case study	
(925)	Beneke MJ, Doner J. Observation of nosocomial surgical-site infection rates with utilization of antimicrobial gauze dressing in an acute care setting. Mansfield (MA): Tyco Healthcare; 2005 Jun. 4 p.			✓	Not a NPWT study	
(926)	BlueSky Medical Group, Inc. 510(k) summary for BlueSky VISTA Wound Vacuum System. K061367. Rockville (MD): U.S. Food and Drug Administration (FDA); 2006 Aug 10. 5 p.	✓	Background			
(927)	BlueSky Medical Group, Inc. 510(k) summary for Versatile 1 EZCare Wound Vacuum System. K061919. Rockville (MD): U.S. Food and Drug Administration (FDA); 2007 Feb 5. 4 p.	✓	Background			
(928)	Bogart A. The use of antimicrobial gauze dressing on an infected lower extremity vascular bypass wounds. Mansfield (MA): Tyco Healthcare; 2005 Oct. 4 p.			✓	Not a NPWT study	
(929)	Brooks B. (HCPCS Medical Analyst, SADMERC). Letter regarding the consensus coding decision of SADMERC and the four durable medical equipment regional carriers (DMERCs) for Kerlix A.M.D. antimicrobial Large roll and Kerlix A.M.D. antimicrobial super sponge. 2002 Sep 23. 1 p.			✓	Not part of report	
(930)	Brown C. (PDAC Medicare Pricing, Data Analysis, and Coding / Data Analyst, Noridian Administrative Services, Ltd.). Response to inquiry for coding verification of Renasys EZ (model # 66800059). Xref 7118176. 2008 Dec 22. 2 p.			✓	Not part of report	
(84)	Campbell PE, Smith GS, Smith JM. Retrospective clinical evaluation of gauze-based negative pressure wound therapy. Int Wound J 2008 Jun;5(2):280-6.	✓	KQ3			√
(931)	Carson R. (Manager, Health Policy & Reimbursement, North America. Smith & Nephew Wound Management). Additional evidence for consideration in review of Negative Pressure Wound Therapy (NPWT). 2009 Feb 5. 3 p; binder of material			✓	Cover letter	

Reference Number	Reference	Included	Placement In Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(932)	Case JM. Microbial challenge test for porous materials using methylicillin resistant staphylococcus aureus. Mansfield (MA): Tyco Healthcare; 2001 Jul. 6 p.			✓	Not a NPWT study	
(442)	Chariker ME, Jeter KF, Tintle TE, Bottsford JE. Effective management of incisional and cutaneous fistulae with close suction wound drainage. Contemp Surg 1989 Jun;34:59-63.			✓	Homemade device	
(96)	Clinical in-market evaluation interim report. Hull, United Kingdom: Smith & Nephew Medical, Ltd.; 2009 Feb 2. 30 p. This report provides unpublished data from a non-comparative study of 132 patients treated with NPWT systems made by Smith and Nephew. These data were included under Key Question 3.	✓	KQ3			✓
(933)	Comstock M. Process improvement project: reduction of surgical site infections utilizing antimicrobial dressings. Mansfield (MA): Covidien; 2008 Sep. 4 p.			✓	Not a NPWT study	
(934)	Coutts P, Fierheller M, Broughton C, Sibbald RG. Effective wound management influences quality of life. Mansfield (MA): Covidien; 2008 Sep. 1 p.			✓	Not a NPWT study	
(935)	Davis S, Mertz P, Cazzaniga A, Serralta V, Orr R, Eaglstein W. The use of a new antimicrobial gauze dressing: effects on the rate of epithelization of partial thickness wounds. Mansfield (MA): Tyco Healthcare; 2001 Apr. 4 p.			✓	Not a NPWT study	
(226)	Eginton MT, Brown KR, Seabrook GR, Towne JB, Cambria RA. A prospective randomized evaluation of negative-pressure wound dressings for diabetic foot wounds. Ann Vasc Surg 2003 Nov;17(6):645-9.			✓	Fewer than five patients	
(936)	EZCARE negative pressure wound therapy. User guide. Smith & Nephew, Inc.; 31 p.	✓	Background			
(937)	Fierheller M, Coutts P, Sibbald RG. Holistic effect of an antimicrobial gauze dressing with Claggett's Window. Mansfield (MA): Covidien; 2008 Sep. 1 p.			✓	Not a NPWT study	

Reference Number	Reference	Included	Placement In Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(938)	Findley RD, McGaha EC. The successful use of Negative Pressure Would Therapy after left above the knee amputation (AKA) revision, in a challenging patient.			✓	Case study	
(499)	Fleischmann W, Strecker W, Bombelli M, Kinzl L. [Vacuum sealing as treatment of soft tissue damage in open fractures]. Unfallchirurgie 1993;96(9):488-92.			✓	Article in German	
(110)	Ford CN, Reinhard ER, Yeh D, Syrek D, De Las Morenas A, Bergman SB, Williams S, Hamori CA. Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the Healthpoint system in the management of pressure ulcers. Ann Plast Surg 2002 Jul;49(1):55-61; discussion 61.	✓	KQ1, KQ3			
(939)	Harris R. Analysis of surgical site infection rates and cost benefits associated with plain gauze dressings versus gauze dressings impregnated with polyhexamethylene biguanide (PHMB). Mansfield (MA): Covidien; 4 p.			✓	Not a NPWT study	
(940)	Hoover J, Kent DJ. Polyhexamethylene biguanide (PHMB) impregnated gauze for use in treating a gunshot wound. Mansfiled (MA): Covidien; 2008 Sep. 4 p.			✓	Not a NPWT study	
(941)	Howe T, Graham R. The successful management and wound closure of a challenging patient with necrotizing fasciitis with enteric fistula using negative pressure wound therapy.			✓	Case study	
(942)	Hutton CL. The use of antimicrobial gauze packing in an infected coronary artery bypass graft surgical incision. Mansfield (MA): Tyco Healthcare; 2005 Jun. 4 p.			✓	Not a NPWT study	
(39)	Ichioka S, Watanabe H, Sekiya N, Shibata M, Nakatsuka T. A technique to visualize wound bed microcirculation and the acute effect of negative pressure. Wound Repair Regen 2008;16:460-5.			✓	Animal study	
(943)	Jonjo SF. Length of stay: reducing a "weighty" problem in wound care saving time and improving outcomes. Mansfield (MA): Tyco Healthcare; 2007 Apr. 1 p.			✓	Not a NPWT study	

Reference Number	Reference	Included	Placement In Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(113)	Joseph E, Hamori CA, Bergman S, et al. A prospective randomized trial of vacuum-assisted closure versus standard therapy of chronic nonhealing wounds. Wounds 2002;12(3):60-7.	✓	KQ1, KQ3			
(907)	Kairinos N, Solomons M, Hudson DA. The paradox of negative pressure wound therapy - in vitro studies. J Plast Reconstr Aesthet Surg 2008 Nov 24; Epub ahead of print.			✓	In vitro study	
(944)	LCD for negative pressure wound therapy pumps (L11489). Baltimore (MD): Centers for Medicare and Medicaid Services (CMS); 10 p.			✓	Not part of report	
(945)	LCD for negative pressure wound therapy pumps (L11500). Baltimore (MD): Centers for Medicare and Medicaid Services (CMS); 10 p.			✓	Not part of report	
(946)	LCD for negative pressure wound therapy pumps (L27025). Baltimore (MD): Centers for Medicare & Medicaid Services; 10 p.			✓	Not part of report	
(947)	LCD for negative pressure wound therapy pumps (L5008). Baltimore (MD): Centers for Medicare & Medicaid Services; 11 p.			✓	Not part of report	
(259)	Llanos S, Danilla S, Barraza C, Armijo E, Pineros JL, Quintas M, Searle S, Calderon W. Effectiveness of negative pressure closure in the integration of split thickness skin grafts: a randomized, double-masked, controlled trial. Ann Surg 2006 Nov;244(5):700-5.			✓	Homemade device	
(948)	Lovelace L. Antimicrobial dressing intervention associated with reduction in surgical site infection rate. Mansfield (MA): Tyco Healthcare; 2008 Jun. 1 p.			✓	Not a NPWT study	
(949)	Material safety data sheet for DeRoyal Solidifier, MSDS-002. Product numbers 71-1200, 71-1500, 71-2500, 71-3000, 71-9000, 71-18000, 71-0500, 71-1000. Powell (TN): DeRoyal Industries, Inc.; 2005 Dec 9. 2 p.			✓	Not part of report	
(950)	Material safety data sheet for Flexible polyurethane foam. CAS # 9009-54-5. 2008. 4 p.			✓	Not part of report	

Reference Number	Reference	Included	Placement In Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(951)	Material safety data sheet for Kerlix AMD super sponges, Kerlix AMD rolls, Excilon AMD sponges, Telfa AMD sponges. Product numbers 6662,6665, 6660, 3331,3332,7088,7089,7662,7663,7665,7666,7667,7668. Mansfield (MA): Tyco Healthcare / Kendall; 2004 May 14. 6 p.			✓	Not part of report	
(952)	Material safety data sheet for Medical Adhesive Tape Technologies, product # 09-9000 blue tape. St. Hubert, Quebec: Medical Adhesive Tape Technologies; 2008 Sep 3. 2 p.			✓	Not part of report	
(953)	Material safety data sheet for negative pressure non-adherent gauze. Toronto (ON): Derma Sciences, Inc.; 2008 May 2. 4 p.			✓	Not part of report	
(954)	Material safety data sheet for Skin Prep Wipes. Largo (FL): Smith & Nephew, Inc.; 2003 Dec 8. 3 p.			✓	Not part of report	
(955)	Material safety data sheet for sodium chloride solution, 0.85% MSDS. Catalog code: SLS2752. Houston (TX): Sciencelab.com, Inc.; 2008 Nov 6. 6 p.			✓	Not part of report	
(956)	Material safety data sheet for Styrene-acrylonitrile copolymer (SAN). CAS registry number: 9003-54-7. IRPC Public Company Limited; 2006 Dec. 4 p.			✓	Not part of report	
(142)	McCord SS, Naik-Mathuria BJ, Murphy KM, McLane KM, Gay AN, Bob Basu C, Downey CR, Hollier LH, Olutoye OO. Negative pressure therapy is effective to manage a variety of wounds in infants and children. Wound Repair Regen 2007 May-Jun;15(3):296-301.	✓	KQ3			
(957)	McCullin C. The use of an antimicrobial dressing to help improve outcomes for patients with pressure ulcers in a skilled nursing facility. Mansfield (MA): Tyco Healthcare; 2005 Oct. 1 p.			✓	Not a NPWT study	
(958)	McKendrick C. Impact on surgical dressings on coronary artery bypass graft surgery with resultant influence on patient safety. Mansfield (MA): Covidien; 2008. 4 p.			✓	Not a NPWT study	

Reference Number	Reference	Included	Placement In Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(606)	McNulty AK, Schmidt M, Feeley T, Kieswetter K. Effects of negative pressure wound therapy on fibroblast viability, chemotactic signaling, and proliferation in a provisional wound (fibrin) matrix. Wound Repair Regen 2007 Nov-Dec;15(6):838-46.			✓	In vitro study	
(959)	Mertz P, Cazzaniga A, Serralta V, Davis S, Orr R, Eaglstein W. The effect of an antimicrobial gauze dressing impregnated with 0.2% polyhexamethylene biguanide (PHMB) as a barrier to prevent pseudomonas aeruginosa wound invasion. Mansfield (MA): Tyco Healthcare; 2000 May. 7 p.			✓	Not a NPWT study	
(960)	Morehouse T, Hager J. Drainage management of enterocutaneous fistula within an abdominal wound.			✓	Case study	
(33)	Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Ann Plast Surg 1997 Jun;38(6):553-62.			✓	Animal study	
(626)	Morykwas MJ, David LR, Schneider AM, Whang C, Jennings DA, Canty C, Parker D, White WL, Argenta LC. Use of subatmospheric pressure to prevent progression of partial-thickness burns in a swine model. J Burn Care Rehabil 1999 Jan-Feb;20(1 Pt 1):15-21.			✓	Animal study	
(36)	Morykwas MJ, Faler BJ, Pearce DJ, Argenta LC. Effects of varying levels of subatmospheric pressure on the rate of granulation tissue formation in experimental wounds in swine. Ann Plast Surg 2001 Nov;47(5):547-51.			✓	Animal study	
(961)	Motta GJ, Trigilia D. Impact of antimicrobial drain sponge dressing upon specific bacterial isolates at tracheostomy sites. Mansfield (MA): Tyco Healthcare; 2003 May. 8 p.			✓	Not a NPWT study	
(38)	Moues CM, Vos MC, van den Bemd GJ, Stijnen T, Hovius SE. Bacterial load in relation to vacuum-assisted closure wound therapy: a prospective randomized trial. Wound Repair Regen 2004 Jan-Feb;12(1):11-7.			✓	Duplicate study(136)	
(962)	Mullaney B, Lane C. Antimicrobial efficacy by elution of gauze using methycillin resistant staphlococcus aureus (MRSA). Mansfield (MA): Tyco Healthcare; 2001 Jul. 4 p.			✓	Not a NPWT study	

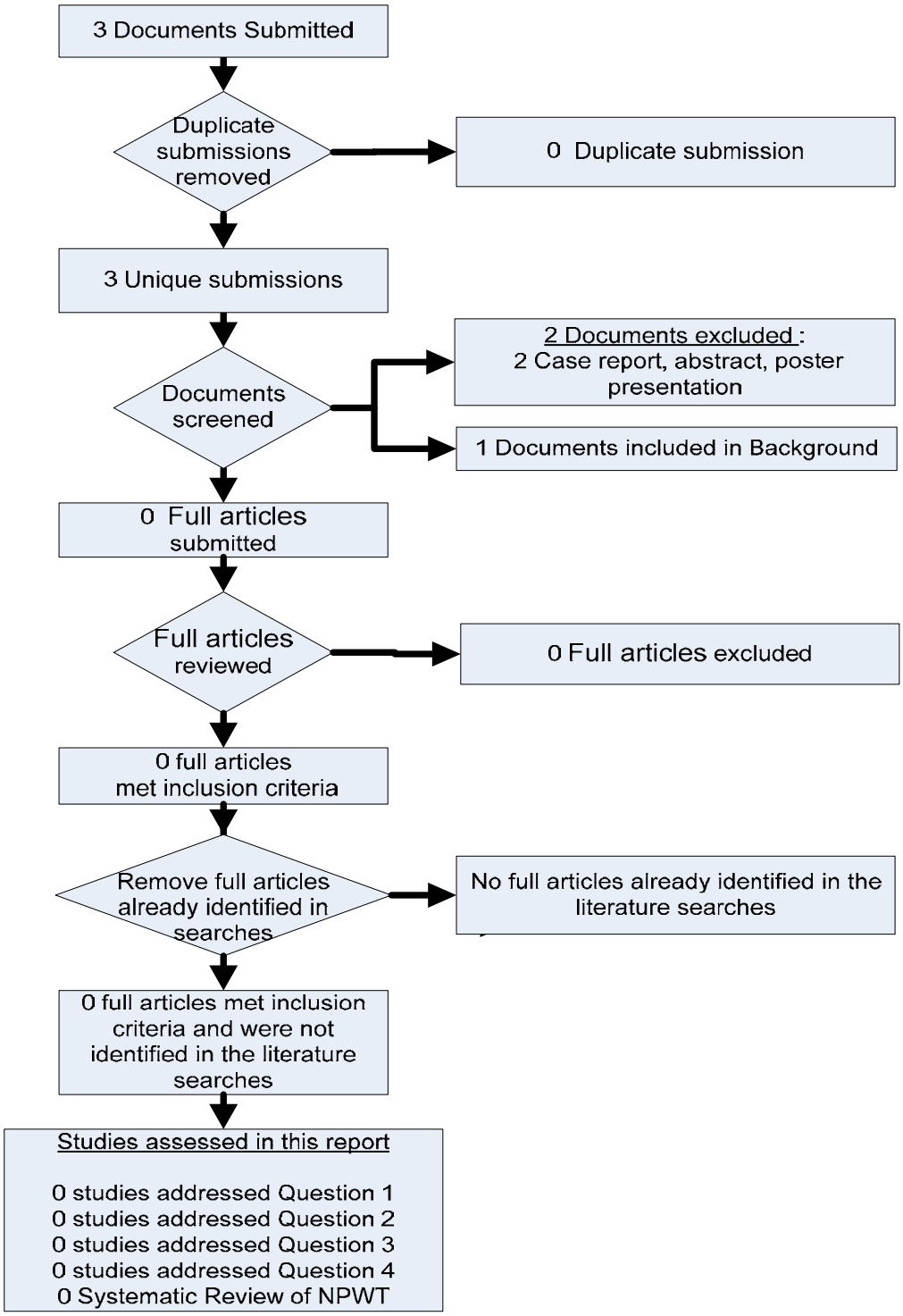
Reference Number	Reference	Included	Placement In Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(963)	Mullaney B, Lane C. Antimicrobial efficacy by elution of gauze using vancomycin resistant enterococcus faecalis. Mansfield (MA): Tyco Healthcare; 2001 Jul. 4 p.			✓	Not a NPWT study	
(964)	Neitzel PJ. Reduction of SSIs during a one year study of CABG procedures in a 393-bed acute care community hospital. Mansfield (MA): Tyco Healthcare; 2007 Jun. 1 p.			✓	Not a NPWT study	
(646)	NPWT Info and history of NPWT. St. Petersburg (FL): Smith & Nephew, Inc.; 2009 Feb. 13 p. Review of the history, mode of action, mechanism of action, level of negative pressure, context between vacuum source and clinical outcomes, and clinical evidence relating to the use of V1STA and EZCARE NPWT systems.	✓	Relevant clinical evidence(96) included in KQ3			
(965)	O'Brien JA, Broderick GB, Lalikos JF, Ignotz R, Strom H, Dunn RM. Negative pressure wound therapy as dressing for split-thickness skin grafts: our experience. 2 p.			✓	Abstract only	
(966)	Orr R, Eggleston T, Shelanski MV. Determination of the irritating and sensitizing propensities of Kerlix A.M.D. antimicrobial gauze dressing on scarified human skin. Mansfield (MA): Tyco Healthcare; 2003 Jan. 4 p.			✓	Not a NPWT study	
(967)	Orr R. In vitro efficacy of Kerlix A.M.D. gauze when used with a primary dressing. Mansfield (MA): Tyco Healthcare; 2001 Nov. 1 p.			✓	Not a NPWT study	
(968)	PDAC Medicare pricing, data analysis and coding for EZCARE system. Model 66800187. [internet]. Fargo (ND): Noridian Adminstrative Services, Ltd.; 2008 [accessed 2009 Feb 4]. [1 p]. Available: https://www.dmepdac.com/dmecsapp/do/productdetail?hcpcs_product_id=18187.			✓	Not part of report	
(969)	PDAC Medicare pricing, data analysis and codinng for VERSATILE 1 model number: 100.010. [internet]. Fargo (ND): Noridian Administrative Services, Ltd.; 2008 [accessed 2009 Feb 4]. [1 p]. Available: http://www.dmepdac.com/dmecsapp/do/productdetail?hcpcs_product_id=8929.			✓	Not part of report	

Reference Number	Reference	Included	Placement In Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(970)	Penn RG, Vyhlidal SK, Roberts S, Miller S. The reduction of vascular surgical site infections with the use of antimicrobial gauze dressing. Mansfield (MA): Tyco Healthcare; 2 p.			✓	Not a NPWT study	
(971)	Product data sheet for PerfecForm 35858-W, Ionomer-based thermoforming film. Perfecseal, a Bemis Company; 2005 Dec 14. 2 p.			✓	Not part of report	
(972)	Published pricing for EZCare, V1STA, RENASYS-EZ, RENASYS-F, Supply kits. 2009 Jan 1. 1 p.			✓	Not part of report	
(55)	Reitsma AM, Rodeheaver GT. Effectiveness of a new antimicrobial gauze dressing as a bacterial barrier. Mansfield (MA): Tyco Healthcare; 2001 Sep. 4 p.			✓	Not a NPWT study	
(973)	RENASYS EZ negative pressure wound therapy. Smith & Nephew, Inc.; 22 p.	✓	Background			
(974)	Russell F. The use of V1STA in open abdominal wounds and to facilitate fistulae management. 3 p.			✓	Case study	
(34)	Saxena V, Hwang CW, Huang S, Eichbaum Q, Ingber D, Orgill DP. Vacuum-assisted closure: microdeformations of wounds and cell proliferation. Plast Reconstr Surg 2004 Oct;114(5):1086-96; discussion 1097-.			✓	Not a clinical study	
(35)	Scherer SS, Pietramaggiori G, Mathews JC, Prsa MJ, Huang S, Orgill DP. The mechanism of action of the vacuum-assisted closure device. Plast Reconstr Surg 2008 Sep;122(3):786-97.			✓	Animal study	
(975)	Shah CB. Comparison of efficacy and safety of a new antimicrobial packing strip with PHMB to the current industry standard iodoform and plan packing strips. Mansfield (MA): Tyco Healthcare; 3 p.			✓	Not a NPWT study	
(976)	Shah CB. Testing of antimicrobial efficacy of wound dressing by in vitro elution model. Mansfield (MA): Tyco Healthcare; 4 p.			✓	Not a NPWT study	
(977)	Smith & Nephew labeling information. Smith & Nephew, Inc.; 33 p.			✓	Not part of report	

Reference Number	Reference	Included	Placement In Report	Excluded	Reason for Exclusion	Included but Not Identified in ECRI Search
(978)	Smith & Nephew, Inc. 510(k) premarket notification of intenet to market Renasys-F NPWT foam dressing kits. K082211. Rockville (MD): U.S. Food and Drug Administration (FDA); 2008 Nov 14. 2 p.	✓	Background			
(979)	Smith & Nephew, Inc. 510(k) premarket notification of intent to market RENASYS EZ. K082426. Rockville (MD): U.S. Food and Drug Administration (FDA); 2008 Sep 5. 3 p.	✓	Background			
(980)	Sutterfield R. Resolution of araplegic pressure ulcer within a challenging home setting.			✓	Not a NPWT study	
(981)	V1STA negative pressure wound therapy. User guide. Smith & Nephew, Inc.; 33 p.	✓	Background			
(40)	Wackenfors A, Sjogren J, Gustafsson R, Algotsson L, Ingemansson R, Malmsjo M. Effects of vacuum-assisted closure therapy on inguinal wound edge microvascular blood flow. Wound Repair Regen 2004 Nov-Dec;12(6):600-6.			✓	Animal study	
(37)	Weed T, Ratliff C, Drake DB. Quantifying bacterial bioburden during negative pressure wound therapy: does the wound VAC enhance bacterial clearance. Ann Plast Surg 2004 Mar;52(3):276-9; discussion 279-80.	✓	KQ3			
(982)	Werthen M, Davoudi M, Sonesson A, Nitsche P, Morgelin M, Blom K, Schmidtchen A. Pseudomonas aeruginosa-induced infection and degradation of human wound fluid and skin proteins ex vivo are eradicated by a synthetic cationic polymer. J Antimicrob Chemother 2004;54(4):772-9.			✓	Not a NPWT study	
(983)	Zanotti EA, Rosenbloom RD. Use of negative pressure wound therapy over matrix regeneration grafts.			✓	Case study	

KQ Key question

Figure 14. Disposition of Submission by Talley Group Ltd.



Note: Language has been corrected to reflect screening of meeting abstracts, poster presentations and other documents in addition to abstracts and full articles.

Table 55. Status of Submission by Talley Group Ltd.

Reference Number	Reference	Included	Placement in Report	Disposition in Report
(984)	Spruce P. (Clinical Director, TVRE Consulting). AHRQ submission on behalf of Talley Group Ltd. 2009 Feb 5. 1 p. A list of 8 case reports or case series was provided. The reports were either published as meeting presentations or available on the company Web site.			Case reports were not included in this report. The case-series studies did not report outcomes of interest to this report
(985)	Submission of clinical evidence for the VENTURI negative pressure wound therapy system. United Kingdom: Talley Group Ltd.; 2009. 31 p. An outline of studies, primarily case reports but also animal and in vitro studies, was provided.			Case reports were not included in this report The case-series studies did not report outcomes of interest to this report Animal and in vitro studies were not considered in this report
(986)	Venturi advanced vacuum system for negative pressure wound therapy. United Kingdom: Talley Group Ltd.; 2 p. – product brochure	✓	Background	