PREVENA™ INCISION MANAGEMENT SYSTEM
Product Monograph
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Introduction
This publication will describe the current standard of care for surgical incisions and review the medical literature regarding the use of negative pressure wound therapy (NPWT; V.A.C.® Therapy, KCI USA, Inc., San Antonio, TX) over surgical incisions (incisional NPWT). The monograph will also provide clinical experience and scientific evidence regarding the Prevena™ Incision Management System (KCI USA, Inc., San Antonio, TX), which provides incisional NPWT in an easy-to-use design.

Prevena™ Incision Management System Description
Prevena Therapy incorporates all of the functional elements of NPWT that are necessary for management of closed surgical incisions.² The system has the added advantages of being simple in concept and having anatomically adaptable dressings which are uniquely designed to manage and protect surgical incisions following primary closure. The dressings are easy to apply and use in the operating room (OR). The system may also transition from the OR to the hospital and/or outpatient setting for use by multiple care givers.

The Prevena Incision Management System consists of the following components:

- The Prevena™ Incision Dressings are applied over clean sutured or stapled incisions in a simple process.
  - Prevena™ Peel & Place™ Dressing:
    - The dressing (Figure 1) has a built-in pressure indicator that when compressed indicates that the negative pressure in the system is between -75mmHg to -125mmHg. A raised pressure indicator button indicates that the negative pressure is less than -75mmHg.

  ![Figure 1. Prevena™ Incision Management System with Prevena™ Peel & Place™ Dressing](image)

  - A polyurethane coated, polyester fabric interface layer with 0.019% ionic silver wicks fluid from the skin surface. The silver is not intended to treat infection but only to reduce bacterial colonization within the fabric.
  - The polyurethane foam bolster that covers the interface layer has a pore size of 400-600 microns and a violet colorant; the foam manifolds negative pressure to the incision site.
  - A polyurethane film with acrylic adhesive provides adhesion of the dressing to the skin surrounding the incision.
  - A polyurethane shell encapsulates the foam bolster and interface layer, providing a closed system.
  - The Prevena Peel & Place Dressing is designed to manage incisions ≤ 8” (20 cm) long and should not be altered to fit longer, shorter, or curving incisions.
  - This dressing can be used with the Prevena™ 125 Therapy Unit (above). The V.A.C.® Connector included in the dressing kit also allows physicians to use this dressing with other V.A.C. Therapy Units.
Prevena™ Customizable™ Dressing:

- This self-adhesive foam dressing (Figure 2A) has a unique configuration which allows the clinician to alter the dressing to cover closed surgical incisions of different sizes and shapes, including linear incisions > 8 inches (20 cm), intersecting incisions or non-linear incisions.

**Figure 2:** Prevena™ Incision Management System with Prevena™ Customizable™ Dressing. (A) Prevena™ Customizable™ Dressing with hydrocolloid on either side of the foam to help secure it to the skin (extra hydrocolloid strips also provided); (B) Prevena™ 125 Therapy Unit; (C) Interface Pad with built-in pressure indicator.

- While the Prevena Customizable Dressing is primarily intended for use with the Prevena 125 Therapy Unit (Figure 2B), the dressing has a connector that allows it to be used with other V.A.C. Therapy Units as well.
- The Interface Pad used with the Prevena Customizable Dressing also has the built-in pressure indicator (Figure 2C), which, when compressed, indicates that negative pressure in the system is between -75mmHg to -125mmHg. A raised pressure indicator button indicates that the negative pressure is less than -75mmHg.

- The Prevena 125 Therapy Unit delivers 7 days of continuous negative pressure at -125 mmHg through the dressing to the incision site; the unit is battery powered, lightweight, easily portable and designed for single-patient use.
- The Prevena 45mL Canister for collection of incision exudate.
- Prevena Patch Strips, which may be used to help seal leaks around the dressing.

All patient-contact materials are free of latex and DEHP [Di(2-ethylhexl)phthalate].

**Design of Prevena™ Incision Dressings**

The design of the Prevena Incision Dressings was derived from the NPWT dressing system described by a number of clinicians in their reported clinical studies of incisional NPWT. The dressing utilized in these clinical studies was constructed from commercially available materials:

- A skin interface layer (typically, a non-adhering dressing)
- V.A.C.® GranuFoam™ Dressing
- V.A.C.® Drape
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It was configured as shown in Figure 3 (Incisional NPWT Dressing) and was manually prepared by the surgeon using costly OR time to construct.

Figure 3 (Prevena Incision Dressings) illustrates the configuration of these same elements in the Prevena Incision Dressings, which are provided in a pre-constructed configuration that takes only several minutes to apply. Table 1 directly compares these dressing materials.

Figure 3. Cross-Section of Dressings Systems (as applied to patient)

These dressing systems differ primarily only in the type of skin interface material that is used. The purpose of the non-adhering dressing was to protect the skin from direct contact with the V.A.C. GranuFoam Dressing while allowing uninhibited delivery of negative pressure to the wound site and fluid removal from the wound site. The equivalent Prevena Incision Dressing skin interface layer is a polyester knit fabric that performs the same functions as the non-adhering dressing in that it protects the skin from contact with the foam bolster, while allowing delivery of negative pressure and fluid removal.

In addition, the Prevena 125 Therapy Unit delivers negative pressure wound therapy at -125 mmHg equivalent to the V.A.C. Therapy Units, which have been described in the referenced clinical studies of incisional NPWT.

The equivalency of Prevena Therapy to the incisional NPWT reported in the medical literature is thus established, and the clinical outcomes reported in those studies are also applicable to Prevena Therapy.

Indications and Use

The Prevena Incision Management System is marketed in the U.S. as a device that is intended to manage the environment of clean closed surgical incisions (ie, sutured or stapled) that continue to drain by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.2

The Prevena Therapy System is applied immediately post-surgery (ie, in a sterile field) to clean closed incisions for a minimum of 2 days and up to a maximum of 7 days. The only contraindication is sensitivity to silver due to its presence in the skin interface layer, although the concentration is very low (0.019%).1

Complete safety information is provided in product labeling and available on KCI1.com.
Standard of Care (SOC) for Surgical Incisions

Surgical incisions have traditionally been closed by primary intention using sutures, staples, tissue adhesives, paper tape, or a combination of these methods.

- Easterlin and colleagues reported that a drawback of sutures and staples is that they are tensioning devices, which concentrate the spreading force to small points along the incision. These tension points may result in ischemia and, possibly, necrosis of the tissue.

- In 2009, Livesey et al in a randomized controlled trial (RCT) compared skin adhesive versus surgical staples in total hip replacement surgeries. They reported that staples were quicker and easier to use than skin adhesive, and surgeons found skin adhesive to be more technically challenging. However, laparoscopic surgeons have found that proficient use of tissue adhesive comes with experience. A disadvantage to the use of tissue adhesive over incisions is that the adhesive may interfere with healing since it can act as a barrier to epithelialization.

- Paper tape has been used alone or in conjunction with sutures or staples for the treatment of surgical incisions. Atkinson reported in an RCT that paper tape was fast to apply, significantly decreased scar volume and prevented hypertrophic scars. A disadvantage to the use of paper tape is that it is not effective in moist or bleeding wounds, as moisture may wash away the adhesive or compromise the integrity of the paper itself. Atkinson recommends that paper tape should not be applied until after 5 days post-surgery or after the surgical incision has epithelialized.

Many products have been used for the treatment of closed surgical incisions. These include traditional gauze dressings and advanced therapies such as hydrocolloids, growth factors, cultured skin, low energy ultrasound, and NPWT. Advanced therapies, such as topically applied growth factors, cultured skin, and NPWT, were initially developed to assist patients with open chronic and acute wounds that were difficult to heal and then found to be useful over closed incisions.

Literature Review of Incisional NPWT

NPWT as delivered by V.A.C. Therapy (KCI USA, Inc., San Antonio, Texas) has become a proven advanced wound therapy system for treating acute and chronic open wounds. Physicians and clinicians recognize the potential utility of this adjunctive therapy in their day-to-day practice and report using it in novel ways to address patient needs.

The body of evidence for using NPWT over clean closed surgical incisions has been growing steadily since 2006. Based on the Evidence Rating Scale for Therapeutic Studies (Table 2), developed by the American Society of Plastic Surgeons (ASPS), there are currently 4 Level 1 RCTs reporting clinical experience with incisional NPWT and Prevena Therapy. Figure 4 categorizes the 18 incisional NPWT and Prevena Therapy journal articles according to their ASPS levels of evidence: 4 RCTs (Level I), 1 prospective comparative study (Level II), 7 retrospective cohort or comparative studies (Level III), 4 case series (Level IV), and 2 case reports (Level V). As shown in Figure 4, the types of wounds treated with incisional NPWT and Prevena Therapy continue to expand and include fractures (eg, hip, lower extremity), abdominal wall reconstruction, laparotomy, sternal, and vascular surgical sites.
The incisional NPWT and Prevena Therapy clinical publication summaries below and in Table 3 are listed in order according to their ASPS rating level.

- In a prospective multicenter RCT, Stannard and colleagues compared the use of incisional NPWT against standard postoperative dressings (Control) over clean closed surgical incisions after high-energy fractures. The study population consisted of 249 patients with 263 calcaneus, pilon, or tibial plateau fractures. 4 (Evidence Level I)
  - Of those patients, 130 with 141 fractures were randomized to incisional NPWT and 119 with 122 fractures were randomized to Control (standard postoperative dressings).
  - The results revealed 23 total infections in the Control group compared to 14 in the NPWT group (P=0.049) and 20 cases of dehiscence in the Control group compared to only 12 in the NPWT group (P=0.044). 4
  - These findings illustrate the effective use of NPWT over clean closed surgical incisions after high-energy fractures.

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*NPWT = Incisional NPWT as delivered by V.A.C.® Therapy  †Calcaneus, pilon, and tibial plateau fractures
• Stannard et al presented interim results from 2 RCTs that compared the use of incisional NPWT against standard postoperative dressings (Control) for draining hematomas and clean closed surgical incisions after high energy fractures.3 (Evidence Level I)
  o A total of 44 patients were randomized into the hematoma study. The Control group (n = 31) drained for a mean of 3.1 days compared to only 1.6 days for the NPWT group (n = 13) (P =0.03).
  o An additional 44 patients were randomized into the fracture study. The Control group (n=24) drained for 4.8 days compared to only 1.8 days for the NPWT group (n = 20) (P =0.02).
  o These preliminary findings demonstrated decreased drainage time following NPWT treatment of patients with hematomas or severe fractures.3

• In the RCT by Masden and colleagues, 81 high-risk patients with multiple comorbidities were randomized to receive either incisional NPWT or standard dry silver dressing over closed surgical incisions.28 (Evidence Level I)
  o While there were various wound types, the majority (74/81) of patients underwent lower extremity wound closure post amputation.
  o All incisions were evaluated on postoperative day 3, at first outpatient visit, and at subsequent visits. Average follow-up period was 113 days.
  o There were no differences in demographic, preoperative, and operative variables between groups.
  o Wound complication rates between the groups did not achieve statistical significance:
    • Infection: NPWT, 3/44 (6.8%) vs. Control, 5/37 (13.5%), p = 0.46;
    • Dehiscence: NPWT, 16/44 (36.4%) vs. Control, 11/37 (29.7%), p = 0.53;
    • Reoperation: NPWT, 9/44 (21%) vs. Control, 8/37 (22%), p = 0.89;
    • Overall, 40% of NPWT and 35% of Control groups experienced wound infection, dehiscence, or both.28

• The first prospective RCT of the Prevena Incision Management System was published in 2011 by Pachowsky et al.29 The study included 19 consecutive patients treated with Prevena Therapy or standard postoperative dressings (Control) over closed incisions following total hip arthroplasty.29 (Evidence Level I)
  o Ten patients were randomized to the Control arm and 9 to the Prevena Therapy arm.
  o Postoperative seromas were measured in both groups on the fifth and tenth postoperative days.
  o Results showed significantly decreased volume of postoperative seromas in the Prevena Therapy group versus the Control on day 10 (1.97 vs. 5.08 ml; P=0.021). A seroma was present in 44% of the NPWT patients and 90% of Control patients.
  o In addition, the Prevena Therapy group required significantly fewer days of antibiotics (8.44 ± 2.24 vs 11.8 ± 2.82 days, P =0.005), and a secretion in the wound after day 5 was reported in fewer patients in the Prevena Therapy group versus the Control (1 vs. 5 patients, respectively).
  o The authors concluded that in their study the use of NPWT decreased the development of postoperative seromas and improved wound healing.29

• In a prospective comparative study, Grauhan and associates analyzed 150 consecutive obese (BMI ≥ 30) cardiac surgery patients, whose sternotomy wound incisions were treated with either Prevena Therapy (n=75) or conventional sterile wound dressings (Control; n=75).30 (Evidence Level II)
  o Wound infection within 90 days was the primary study endpoint.
  o Patients were assigned to treatment groups by alternating based on time of operation. Patients with diabetes were assigned “half and half to both groups, with priority.”
  o Prevena Therapy dressing was placed under sterile conditions in the OR and remained in place at a negative pressure of -125mmHg for the first 6 to 7 postoperative days. Control dressings were changed on the first or second postoperative day and every 1-2 days thereafter.
  o All patients in both groups were followed for at least 90 days. There were no significant preoperative differences between the groups.
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- Prevena Therapy group had significantly fewer wound infections than the Control group: 3/75 (4%) vs. 12/75 (16%), respectively; P= 0.0266; odds ratio, 4.57; 95% confidence interval (CI), 1.23-16.94.
- Prevena Therapy group also had significantly fewer patients that had wound infections with Gram-positive skin flora: 1 vs. 10, respectively; P= 0.0090; odds ratio, 11.39; 95% CI, 1.42-91.36.
- In the Prevena Therapy group, 71/75 (95%) of the incisions were primarily closed when the dressing was removed in 6 to 7 days. No wound infections occurred after this closure. In contrast, 9 of the 12 reported Control group wound infections occurred beyond postoperative day 7 and up to day 35.
- The authors concluded that Prevena Therapy over clean, closed surgical incisions for the first 6 to 7 postoperative days significantly reduced wound infection after median sternotomy for high-risk obese cardiac surgery patients.30

- In a retrospective review, Atkins et al reported on 57 adult cardiac surgery patients whose sternotomy incisions were treated with NPWT for 4 days.5 (Evidence Level III)
  - These patients were deemed high risk for sternal wound infections after sternotomy based on a risk assessment model using pooled data from the Society of Thoracic Surgeons National Cardiac Database.40
  - Risk factors included obesity, diabetes, length of cardiopulmonary bypass, and need for intra-aortic balloon pump. Of the 57 NPWT-treated patients, 77.2% were obese, 54.4% were diabetic and 50.9% were both obese and diabetic.
  - Based on preoperative and intraoperative risk factor analysis, a minimum of 3 predicted cases of sternal wound infection (SWI) (based on the average estimated risk, 6.1±4%, for postoperative SWI) were anticipated.
  - No complications were observed in the NPWT group.
  - The authors recommended that NPWT should be strongly considered for sternotomy patients with increased SWI risk.5

- Reddix et al retrospectively reviewed patient records from a 9-year period and presented the results of 19 morbidly obese (Body Mass Index (BMI) >40) patients who had NPWT applied to clean, closed surgical incisions after surgery for acetabular fractures.7 (Evidence Level III)
  - Mean follow-up period was 21 months.
  - There were no incision complications or infections during the perioperative period and no complications at the final follow-up.
  - The authors concluded that NPWT over clean closed incisions may be a useful adjunctive therapy for reducing postoperative complications in morbidly obese patients with acetabular fractures.7

- In a more recent retrospective study by Reddix et al, comparisons of wound infection and dehiscence were made in patients 5 years (August 1996-June 2001) before NPWT over incisions was used as part of the postoperative protocol for acetabular fracture surgery and 4 years (July 2001-April 2005) after NPWT over incisions became standard at the author’s institution.8 (Evidence Level III)
  - Sixty-six consecutive patients treated with standard institutional postoperative care in the previous 5 years had 4 (6.06%) deep wound infections and 2 (3.03%) dehiscences.
  - After establishment of NPWT, 235 patients had 3 (1.27%) deep wound infections and 1 (0.426%) had a dehiscence.
  - The authors noted that their NPWT infection rate of 1.27% represented a significant decrease in comparison to other groups (infection rates of 4.2%,41 4%,42  and 5%43) of similar size (P = .0282; reference rate =4%), and concluded that the application of NPWT decreased their incidence of perioperative incision complications.8

- Tauber and associates conducted a retrospective comparative review of 24 patients who underwent 45 inguinal lymph node dissections (LNDs) as treatment for penile or urethral cancer.31 (Evidence Level III)
  - Sixteen patients with 30 LNDs were treated with conventional wound care (compression dressings; Control) and 8 patients with 15 LNDs received incisional NPWT using V.A.C.® WhiteFoam Dressing. The NPWT dressing remained in place for up to 7 days.
  - Compared to NPWT, Control patients tended to have:
    - Higher levels of maximum drained fluid per day (p=0.496)
    - Longer duration of drainage (p=0.632)
    - More reinterventions (23% (7 patients) vs. 7% (1 patient), respectively; p=0.631).
Control patients also had significantly longer hospitalization (p=0.049).
NPWT patients had significantly fewer wound complications (p= 0.032) than Control patients: 20% vs 62% incidence of lymphoceles, 7% vs 45% persistent lymphorrhoea, 0% vs 46% lower extremity lymphoedema, respectively.
Along with shorter hospital stay, the authors commented that NPWT patients benefitted because “. . . further oncological treatments could be administered without delay.”

Condé-Green and colleagues conducted a retrospective review of patients who underwent abdominal wall reconstruction to repair large ventral hernias. Between September 2008 and May 2011, 23 patients were treated with incisional NPWT (group I) and 33 patients with standard gauze dressings (group II). Incisional NPWT dressing was applied intraoperatively, maintained at a continuous negative pressure of -125 mmHg, and removed after 5 days.
Compared to standard dressing patients, incisional NPWT patients had significantly better overall wound complication rates: 63.6% vs. 22%, respectively (P=0.020).
Skin dehiscence rates: 39% vs. 9%, respectively (P=0.014).
Rates of infection, skin and fat necrosis, seroma, and hernia recurrence were also lower for incisional NPWT patients.

The comparative retrospective study by Matatov and associates evaluated the infection incidence and severity in 90 pts with 115 groin incisions that were treated with either Prevena Therapy (n=41 pts with 52 incisions) or a skin adhesive or absorbent (n=49 pts with 63 incisions; Control).
Severity of infection was graded using the Szilagyi scale, which ranks degree of infection from grade I (lowest) to grade 3 (highest).
Prevena Therapy was applied intraoperatively and removed after 5-7 days.
Mean times of wound evaluation in the Prevena Therapy group were 7 and 33 days postoperatively vs 10 and 40 days in the Control group.
Prevena Therapy-treated incisions had a significantly lower overall rate of infection: 3/52 (6%) vs 19/63 (30%), p=0.0011.
The 3 infections in the Prevena Therapy group were all rated as Szilagyi grade I, whereas the 19 in the Control group included 10 (16%) grade I, 7 (11%) grade II, and 2 (3%) grade III infections.
The authors reported that Prevena Therapy “significantly decreased the incidence of groin wound infection in patients after vascular surgery.”

Blackham et al conducted a comparative retrospective study to assess the effectiveness of negative pressure therapy (incisional NPWT using V.A.C.® Therapy) in reducing surgical site infections (SSIs) in surgical oncology pts at high-risk for surgical wound complications.
Data for 189 patients who underwent 191 surgical procedures for pancreatic, colorectal, or peritoneal surface malignancies were analyzed in this comparative study.
Control patients (n=87 cases) were treated with standard sterile dressings (SSDs).
Patients treated with NPWT (n=104 cases) had multiple risk factors for development of SSIs. These factors included morbid obesity, multiple comorbidities, colorectal resection, operation time >6 hours, and estimated blood loss >1L.
Compared to SSD pts, NPWT patients had significantly more neoadjuvant chemotherapy (P=0.024), more clean-contaminated operations (P<0.001), longer operation times (P<0.001), greater intraoperative blood loss (P<0.001) and more frequent blood transfusions (P=0.002).
NPWT patients had significantly fewer incisional SSIs compared to SSD pts: 6.7% vs 19.5%, p=0.015.
In a subset analysis of clean-contaminated cases, NPWT was associated with “fewer superficial incisional SSIs (6.0% vs 27.4%, P=0.001), fewer total SSIs (16.0% vs 35.5%, P=0.011), and fewer wound openings for any reason (16.0% vs 35.5%, P=0.011).”
In this retrospective study, the authors concluded that NPWT decreased incidence of SSIs in surgical oncology patients. They also stated that an RCT is planned to further evaluate the efficacy of incisional NPWT in this patient population.
• The first case series evaluating use of the Prevena Incision Management System was published in 2011 by Colli.\(^{35}\) (Evidence Level IV)
  o A total of 10 patients with mean Fowler risk score of 15.1 received application of Prevena Therapy over clean, closed sternal incisions for 5 days following cardiac surgery.
  o All wounds and surrounding skin showed complete wound healing and an absence of skin lesions following removal of the dressing.
  o There were no cases of infection. No device-related complications were observed and no other wound complications occurred during the 30-day follow up period.
  o Authors concluded that the system “may help achieve uncomplicated wound healing in patients at risk of developing wound complications following cardiothoracic surgery.”\(^{35}\)

• Along with a case series of 4 patients, Stannard and colleagues present an overview of incisional NPWT and practical considerations for using this technique.\(^{36}\) (Evidence Level IV)
  o Use of incisional NPWT was reported for 1 patient with coronary artery bypass grafting, 1 patient with a transmetatarsal amputation, and 2 patients with abdominal hysterectomies.
  o Patient comorbidities included obesity, diabetes, hypertension, and peripheral artery disease.
  o Three patients healed without complication; one patient with an abdominal hysterectomy experienced superficial skin separation (3mm – 5 mm) after staple removal.
  o Authors also shared practical tips, including a patient grading scale to help identify patients who could benefit from incisional NPWT or Prevena Therapy.\(^{36}\)

• In a case series by Gomoll et al, NPWT was placed over clean closed sutured incisions of 35 patients.\(^{6}\) (Evidence Level IV)
  o The procedures included revision hip arthroplasty, proximal femoral and tibial fracture fixation and foot and ankle trauma.
  o The average length of NPWT per patient was just over 3 days, and no infections occurred during the 3-month follow up.
  o The authors concluded that using NPWT over incisions in their practice made a difference in postoperative care for procedures associated with large dead spaces, obese patients, and areas prone to postoperative edema.\(^{6}\)

• Bollero and colleagues evaluated use of Prevena Therapy after excision of wide pathological scars in a series of 8 patients.\(^{37}\) (Evidence Level IV)
  o Mean age of the patients was 33 years (range 20-60 years) and treated scars were mature and usually the result of hypertrophic scars.
  o Scar sites were located in body areas with skin stretch during flexion/extension movements. Prevena Therapy was placed to improve incision edge apposition.
  o Prevena Therapy Dressing was applied intraoperatively and remained in place for 8 days at continuous -125 mmHg.
  o Seven of 8 patients completed treatment successfully.
    • One incision was longer than the Prevena Therapy Dressing but closed without complications.
  o The scar of one patient was close to the pubic area and, even though the area was shaved, an air-tight seal could not be achieved. Consequently, the patient discontinued treatment after 1 day.
  o The authors concluded that “Easy intraoperative application and postoperative management, associated with good compliance of patients, make Prevena [Therapy] a safe home-care device.”\(^{37}\)

• A single case study of a patient with a distal lower limb incision site treated with Prevena Incision Management System following popliteal-tibial bypass grafting has also been reported.\(^{38}\) (Evidence Level V)
  o The author noted that the incision did not become edematous or deteriorate at any time, even after the Prevena Dressing was removed.
  o Ongoing tissue healing was maintained without any complications, and the patient was discharged on postoperative day 12 after regaining full mobility and removal of sutures.\(^{38}\)
• In a case report Dutton and Curtis reported using incisional NPWT as a “splinting” technique to help prevent laparotomy breakdown.39 (Evidence Level V)
  o The patient had multiple factors (obesity, malnutrition, fistula, and previous surgeries in the area of wound breakdown) that increased likelihood of wound complications.
  o In addition to laying the foam NPWT dressing over the vertical incision, three bars of foam were placed horizontally along the length of the incision to both splint the incision and provide support for the weight of the pannus.
  o NPWT was applied for 7 days with only small, superficial breakdown at distal end of the incision. At follow-up 4 and 6 weeks later, no further complications were reported.39

Current Clinical Research: Conference Presentations
Recent conference presentations have reported use of incisional NPWT and Prevena Therapy over clean closed surgical incisions in a variety of wound types. These studies are described below in descending ASPS evidence level and are summarized in Table 4.
• Gabriel et al conducted a prospective pilot study evaluating the use of NPWT over closed incisions in 15 patients with comorbidities and risk factors.44
  o Incision sites ranged from abdomen and chest to lower extremities.
  o Only patients with 3 or more of the following risk factors for wound complications were enrolled: BMI>35, diabetes, peripheral vascular disease, smoking, radiation, steroid use and malnutrition (as measured by albumin and prealbumin).
  o In the operating room each incision was covered first with a non-adherent layer and then with V.A.C. GranuFoam Silver® and NPWT was applied with a continuous negative pressure of -125mmHg for 3 to 5 days.
  o All 15 patients completed treatment successfully with no additional procedures, wound breakdowns, or other complications reported.44
• Daley et al conducted a retrospective chart review, comparing rates of wound complications following cesarean section (C-section) in morbidly obese women before and after standard treatment with incisional NPWT.45
  o Inclusion criteria specified all women with BMI>45 who underwent C-section between September 1, 2008 and September 30, 2010 in a single institution.
  o Patients treated with Incisional NPWT (September 2009-2010) were compared to those treated with standard (Control) wound dressings (September 2008-2009).
  o Main outcome measure was wound complication defined by ICD-9cm codes.
  o Of the 63 women who met inclusion criteria, 21 received NPWT.
  o Only three parameters differentiated Control group from NPWT: length of surgery (64 versus 76 minutes, P = .03), length of labor (78 versus 261 minutes, P = .02), and age (29.5 versus 26.1), respectively.
  o Control group had 6 (12.5%) wound complications compared to none (0%) for the NPWT group.
  o According to the authors, this pilot study indicates a trend toward fewer wound complications in morbidly obese women receiving incisional NPWT post C-section.45
• Gassman et al conducted a retrospective comparative review of patients who underwent ventral hernia operations at two sites between May 2008 and July 2011.46
  o Collected data included patient demographics, comorbidities, surgical materials, technique, length of stay (LOS), length of follow-up (LOF), surgical site infection (SSI), hernia recurrence, flap necrosis, and hematoma and/or seroma formation.
  o Of the 63 patients who met inclusion criteria, 31 had primary closure alone, 22 had primary closure with 7 days of overlying NPWT, and 10 had secondary closure with NPWT.
  o Student T-test and multinomial regression were used to analyze the data. Significance was p < 0.05.
  o Compared to patients treated with primary closure alone, patients treated with primary closure with overlying NPWT had:
    • Shorter average LOS: 7 vs. 10 days; p>0.05
• Fewer SSIs: 18% vs 55%; p<0.01
• Lower recurrence rates: 5% vs. 23%; p<0.05
  o Compared to primary closure alone, primary and secondary closures with NPWT were associated with a 2-fold and 8.5-fold decreased odds ratio for SSI, respectively (p<0.02).
  o In this abdominal wall reconstruction study the authors stated that use of NPWT was associated with lower rates of SSI and recurrence.46
• Karl and Woeste conducted a retrospective comparative study to evaluate the wound complication rate between vascular surgery patients treated with Prevena Therapy and those treated with the prior standard of care.47
  o Prevena Therapy was used on patients with ≥ 2 risk factors for developing wound complications.
  o Frequency of wound complications after vascular surgery was compared between the two groups.
  o Both groups were comparable with regard to age (76.4 vs. 73.6 years), comorbidities (diabetes mellitus 5 vs. 6) and gender ratio (1:1).
  o The Prevena Therapy group had a higher score (5.1 vs. 3.8), which was primarily due to the higher number of relapse interventions.
  o Only 1 Prevena Therapy patient experienced a complication (infected seroma) that required revision, whereas 2 Control patients required surgery to resolve wound complications.
  o Authors concluded that “prophylactic use of [Prevena Therapy] appears to be able to reduce the rate of wound healing complications in vascular surgery, particularly with a large percentage of high-risk patients.”47
• Payrits assessed the use of Prevena Therapy in a case series of 13 patients with 14 groin wounds.48
  o All patients had at least one risk factor (pathological obesity, diabetes mellitus, age>80, relapse surgery) for development of wound complications.
  o Prevena Therapy was placed in the sterile operating theatre and left for 4-7 days.
  o Incisions were assessed immediately upon removal of the Prevena Therapy dressing and upon discharge from clinic or upon removal of stitches.
  o Thirteen of 14 wounds were free of infection and healed without complications.
  o After removal of the Prevena Therapy dressing, 1 patient developed a lymph fistula, which was treated with V.A.C.® Therapy. Additional surgery was not required.
  o According to the author, Prevena Therapy was easy to use for both patient and staff and could help reduce wound infection rate in the groin.48
• In a case series Lehner and colleagues reported that using Prevena Therapy over clean closed incisions post resection of soft tissue sarcoma tumors in 20 patients resulted in a wound complication rate lower than reported in the literature.49
  o Many factors placed these patients at risk for developing wound complications, including intraoperative radiation (14/20) and adjuvant chemotherapy (10/20). Large tumor size (average volume was 209 cm³) and correspondingly large dead spaces could also contribute to delayed healing.
  o In this series of patients treated with Prevena Therapy over their incisions, the healing rate was 80% (16/20). While the literature reports wound complication rates as high as 40% in this patient population, this study had a 20% wound complication rate, which consisted of 3 patients with seromas that had to be aspirated and one with a wound dehiscence.
  o Based on the decreased rate of complications, the authors stated that Prevena Therapy “appears to have a positive impact on wound healing, is easy to use, and may help reduce complications, when applied over clean, closed surgical incisions.”49
• Gabriel and Slovic applied Prevena Therapy over closed surgical incisions resulting from abdominal wall reconstruction.50
  o Five patients (1 male and 4 female) presented with failed ventral hernias with mesh. Patient comorbidities included diabetes and obesity.
  o All patients were treated with components separation, application of surgical mesh, primary closure with staples, and placement of Prevena Therapy over the closed incision.
Prevena Therapy at the continuous preset pressure of -125mmHg was applied for 6-7 days.

All incisions were healed without complications at the time of follow-up (5-14 months).

- Reddy used Prevena Therapy on the incisions of 8 patients with multiple comorbidities (including poor tissue quality, low albumin, and morbid obesity) who underwent complex cardiothoracic procedures.

- He selected Prevena Therapy because it helps hold incision edges together and protects the incision from external contamination.

- Following aortic valve replacement, coronary artery bypass grafting, or complex sternal reconstruction, 8 patients were treated with Prevena Therapy for an average duration of 5.7 days.

- One patient had sternal wound infection that was noted on Day 35 and resolved with local wound care. No other cases of infection, dehiscence, or additional procedures were reported.

Collectively, findings from these studies demonstrate the potential value of NPWT over clean closed surgical incisions. This evidence also supports the ability of the Prevena Incision Management System to provide incisional NPWT comparable to traditional V.A.C. Therapy Systems. Findings published in the literature report that patients benefiting from incisional NPWT or Prevena Therapy were often those at greater risk for infection, seroma, hematoma, and dehiscence. These patients were often found to have one or more risk factors that might affect wound healing and/or were undergoing high-risk surgery. Stannard and associates have proposed the use of a Patient Grading System, which may be helpful in determining candidates for incisional NPWT or Prevena Therapy (Figure 5).

Figure 5. Patient Grading System

*No pre-existing medical conditions (i.e., otherwise healthy patient)
†Known Risk Factors: diabetes, obesity, smoker, hypertension, steroid use, radiation, peripheral arterial disease, etc.
Science Supporting Prevena™ Therapy – Bench and Animal Studies

As adjunctive therapy, the Prevena Incision Management System provides a closed environment for managing clean, closed surgical incisions through application of negative pressure wound therapy. Data from bench testing, computer modeling and animal studies have shown that Prevena Therapy helps hold the closed incision edges together and protects the incision from external contamination. Preliminary data suggest that Prevena may play a role in realigning and reducing tensile forces across the incision and improving fluid flow; however, such results have not been confirmed in humans. Tables 6A and 6B summarize the biomechanical and physiological study results, respectively, of the Prevena Incision Management System.

Biomechanical Properties

When there is a disruption in the skin’s integrity from an incision, the edges immediately retract. Typically, sutures or staples are used to re-approximate the incision edges; however, these closure methods may not be sufficient for some incisions, which re-open as a result of excessive edema or other factors. Both bench and computer finite element studies (summarized below and in Table 6A) have provided insight into the biomechanical effects of NPWT over closed incisions.

- Because lateral tension (appositional tension/force) can increase the risk of a dehisced incision, a simulated closed incision model was used to determine the force required to separate sutured or stapled incisions with and without Prevena Therapy. The data showed that a force of 61.7 ± 0.3N was required to extend the sutured incision edges approximately 10 mm compared to a force of 92.9 ± 2.6N when the Prevena Therapy was applied over the closed incision (P<0.05), resulting in an increase of 51% in force for the same displacement without the therapy. Furthermore, a force of 69.3 ± 0.4N was required to extend the stapled incision edges approximately 10 mm compared to a force of 98.8 ± 0.0N with Prevena Therapy (P<0.05), resulting in an increase of 43% in force for the same displacement without the therapy. These results are summarized in Table 7 and suggest that Prevena Therapy in conjunction with sutures or staples may aid in holding together incision edges subjected to appositional forces, more than either sutures or staples alone.

To further evaluate the biomechanical effects of Prevena Therapy on the integrity of the incisional closure, a scientific study was performed using 2 finite element computer models.

- The first finite element computer model assessed the effects of Prevena Therapy on lateral tension. This model simulated a sutured incision with the incision being sutured throughout the depth. Lateral tension in the range of 2.2 to 2.5 kPa at the skin surface was then created by computer software. When negative pressure was applied with Prevena Therapy, the simulated lateral strain was reduced by approximately 50% (0.9 to 1.2 kPa) along the incision (Figure 6), which helped relieve the tension created by the sutures. Literature suggests that reduction in lateral strain is important for maintaining the integrity of the closed incision.
The second computer model simulated a cross-section of an incision with sutures, represented as tied surfaces, at the epidermal and subdermal levels (Figure 7A).\textsuperscript{57} Skin tension was applied as a smooth increase from 0 to 150 kPa (-125 mmHg) over 0.2 seconds (s). Negative pressure was applied from 0 to 16.7 kPa (-125 mmHg), starting at 0.4 s and attaining target negative pressure at 1 s. With only sutures in place, the lateral tensile stress was substantial at the superficial (27.8 kPa) and deep (8.4 kPa) layers (Figure 7B).\textsuperscript{57} With the Prevena Incision Dressing under negative pressure, the gap in the simulated incision closed and the vertical compression in the sides of the incision was eliminated (Figure 7C). The lateral tensile stress at the superficial sutures decreased to 15.4 kPa (decrease of 45%) and at the deep suture to 4.2 kPa (decrease of 50%).\textsuperscript{57}

These bench evaluations showed that the Prevena Incision Dressing system significantly increased the force required to disrupt the closed incision approximately 50% as compared with closure alone. With negative pressure, the direction of the stress was normalized to a distribution typical of intact tissue, and appositional forces were bolstered at the incision.
Figure 7. Finite Element Analysis model 2: lateral stress color contour plot of the incision (A). Prevena Therapy model results for strain, after application of skin tension over a sutured incision. Red arrows indicate direction and relative magnitude of principal strain at each element. Tensile loads across the incision were concentrated at the sutures (B). Prevena Therapy model results for strain, after application of skin tension and then negative pressure (-125mmHg) through the Prevena Incision Dressing. Red arrows indicate direction and relative magnitude of principal strain at each element (C). Tensile loads were distributed more evenly across the incision plane, without local shear and in a direction commensurate with intact native tissue.57

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Physiological Properties

The data from appositional and finite element models showed that Prevena Therapy may favorably alter the biomechanical environment of the incision area. The increased apposition of tissue and the decreased tension along the incision may also allow for improved fluid flow. This may be because flow of fluid through the capillaries, interstitium and lymphatics is modulated by the biomechanical environment of the extracellular matrix. By relieving tension on tissue and redistributing tension in a more uniform manner (similar to native tissue), vessels may remain open and less constricted, supporting lymph flow and edema reduction, and reduction of inflammation which may ultimately facilitate healing of the closed incision.

In vivo studies summarized below and in Table 6B have provided evidence of improved fluid flow with the Prevena Incision Management System. However, these results have not been confirmed in clinical studies.

- A hematoma/seroma study used a porcine model in which subcutaneous voids with overlying sutured incisions were created on the ventral sides of 8 swine.58
  - Stable isotope-labeled nanospheres were introduced into each subcutaneous dead space.
  - Each contralateral incision was randomly assigned to Prevena Therapy or the Control (semipermeable film dressing; 3M™ Tegaderm™ Dressing) for 4 days.
  - After therapy, the hematoma/seroma in each defect was weighed (with differences averaged for each animal), fluid levels in the canister were monitored, 5 pre-identified lymph nodes were harvested, and 5 key organs were biopsied.
  - Results showed a 63% decrease in hematoma/seroma mass with the Prevena Incision Dressing versus the Control (mean 15 ± 3 g vs 41 ± 8 g, respectively; P<0.002), without any fluid collection in the Prevena Canister.
  - In lymph nodes, there were ~60 μg (~50%) more 30- and 50-nm nanospheres from Prevena Therapy-treated incisions compared to Control sites (P=0.04 and 0.05, respectively).
  - Nanosphere incidence was significantly greater from Prevena Therapy sites versus Control sites in lungs, liver and spleen (P <0.05); no nanospheres were found in kidney biopsies.
  - In this scientific model, application of Prevena Therapy significantly decreased hematoma/seroma levels without fluid collection in the canister, which may be explained by increased lymph clearance.58
- Another porcine study compared Prevena Therapy to standard dry dressings (Control) over closed spinal incisions. Scar quality, biomechanical characteristics, and histology were endpoints of interest.59
  - In 8 mature miniature pigs, the two dressings were applied to adjacent sutured incisions over the spine.
  - After 3 or 5 days, incisions were assessed using scar scale, biomechanical (eg, failure load, failure energy, and stress), and histological testing. ANOVAs compared the groups (3 vs. 5 days, Prevena Therapy vs. Control, P<0.05).
  - Incisions treated with Prevena Therapy had a significantly improved scar scale height grade (P<0.026) compared to those treated with standard dressings, which showed inflammation, edema and swelling around the incision (Figures 8A and 8B). The incision line treated with Prevena Therapy was barely visible, indicating progression of healing.
  - Control group scores were lower for failure load (4.9 ± 4.0 vs. Prevena Therapy, 16.5 ± 14.6N), energy absorbed (8.0 ± 9.0 vs. 26.9 ± 23.0 mJ), and ultimate stress (62 ± 53 vs. 204 ± 118 N/mm²).
  - Histological analysis demonstrated no differences in incision scar width between the two groups.
  - In this porcine study the authors noted “a trend toward improved early healing strength and in a significantly improved incision appearance” for incisions treated with Prevena Therapy.59

Figure 8. (A) Representative sample with scar height score 1 (score of 5/8 control-treated incisions. (B) Representative sample with scar height score 0 (score of 8/8 Prevena™ Therapy-treated and 3/8 control-treated incisions.)
The impact of Prevena Therapy was assessed by means of a whole-genome microarray study that measured the biological processes that the Prevena Incision Management System may affect at later time periods.60
- Samples were obtained from contralateral sutured porcine incisions treated with Prevena Therapy versus ABD pads (Control) for 5 days.
- Signal intensities across microarrays were normalized. Features with signal/noise values ≥ 3 and quality flag values <5000 were considered “detected” and were subjected to analysis with a P value of <.05.
- Pilot study analysis indicated there was decreased inflammation (expressed by key chemokine and cytokine markers) in Prevena Therapy-treated incisions versus the Control.
- Additionally, Prevena Therapy affected fewer genes compared to the Control, thereby resuming negative pressure gene expression to a normalized skin phenotype.60
- This decreased gene expression in Prevena-treated incisions may be correlated to the observed biomechanical strength of negative pressure-treated incisions in porcine models.61

In a pilot study performed by Lessing et al, contralateral incisions of swine were sutured and treated with Prevena Therapy or ABD pads (Control) for 5 days. Incisions were then left untreated.61
- At 40 days post-surgery, peak stress, strain energy density, and modulus were higher in Prevena Therapy-treated incisions versus the Control (Table 8).
- These data suggest that short-term negative pressure treatment over incisions may improve scar biomechanics compared to ABD pads, potentially enhancing tissue compliance and function and reducing the likelihood of scar dehiscence.61 However, these animal results have not been confirmed in humans.
- These results parallel a previous porcine incision study that showed Prevena Therapy-treated incisions had significantly improved scar height grade versus Control-treated samples.59 Strength testing in that study also suggested that negative pressure may have greater effect at earlier stages of healing.59 A previous study by Aarabi and colleagues showed that increased strength of a healed incision may be a result of early reduced incisional tension, which has been shown to decrease hypertrophic scarring.62 These results have not been confirmed for Prevena Therapy or NPWT over closed incisions in humans.

The Prevena Incision Management System also facilitates incision healing by protecting the incision from external contamination.

The protection provided by the polyurethane shell was assessed by challenging the film with one of the smallest non-pathogenic viruses.
- The Phi-X174 bacteriophage (27nm in size)63 was used in a phage penetration test.
- Test squares were cut from the polyurethane film drape on the dressing and clamped into a penetration test cell.
- The top side of the film was exposed to air and the bottom side of the film was in contact with the foam.
- A 60 mL bacteriophage suspension was introduced into the top side of the test cell for 5 minutes.
- After this time, a 2 pound –force per square inch gauge (PSIG) pressure was applied to the viral suspension for a 1 minute interval.
- The film was monitored for penetration before and after pressure was applied.
- A total of 4 samples were prepared from the films at random locations.
- Resulting bacteriophage concentrations64 are listed in Table 9.
- The biological assay and visual inspection showed no penetration.
- These results indicate that the exterior drape of the Prevena Incision Dressing can act as a microbial barrier to viral contamination (as small as 27nm)64 and bacterial sources.
Case Studies
Clinical experience with the Prevena Incision Management System is reported in the following case studies in which Prevena Therapy was used over clean closed surgical incisions.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient’s circumstances and condition.

Case Study 1: Sternotomy Incision (Figure 9)
A 70-year-old male patient presented with a non-ST elevation myocardial infarction. Medical history included type II diabetes, peripheral vascular disease, renal insufficiency, hyperlipidemia and pulmonary hypertension. After further investigation, patient was diagnosed with triple vessel coronary artery disease and severe mitral insufficiency. An urgent triple coronary artery bypass grafting (CABG) and mitral valve replacement (MVR) were performed.

Due to the patient’s critical state, comorbidities, and combined procedures, he was at elevated risk for postoperative incision complications (Figure 9A). The Prevena Incision Dressing was applied along the incision with special care taken to leave enough distance between the inferior aspect of the incision and the chest tubes to secure a proper seal (Figure 9B). On postoperative Day 3, the patient cardiopulmonary arrested, requiring immediate resuscitative chest compressions. However, the integrity of the Prevena Incision Dressing was maintained.

When the Prevena Incision Dressing was removed, the incision edges appeared well apposed and were healing appropriately (Figure 9C). In contrast, the chest tube sites, which were not treated with Prevena Therapy, demonstrated some drainage. The patient was discharged home on postoperative Day 18 with his incision continuing to heal well.

Figure 9. Postoperative CABG and MVR via sternotomy on a 70-year-old male patient. (A) Clean closed surgical incision. (B) Application of Prevena Incision Management System. (C) Surgical incision following removal of Prevena Incision Dressing at postoperative Day 8.

Patient data and photos courtesy of Broadus Z. Atkins, MD
Case Study 2: Cesarean Section (Figure 10)
A 30-year-old female gravida 4, para 3 underwent C-section at 39 weeks gestation with a history of late prenatal care. Medical history also included anemia, smoking, pre pregnancy weight of 250lbs (BMI = 40.4), and Class III Obesity (BMI = 41.4) (Figure 10A) at time of surgery. Prevena Incision Management System was applied to the incision post C-section (Figure 10B) and removed on postoperative day 7 (Figures 10C and 10D).

Figure 10. C-section on a 30-year-old female patient. (A) Day 0: Patient prior to surgery. (B) Day 0: Application of the Prevena Incision Management System. (C) Day 7: Prevena Incision Dressing prior to removal. (D) Day 7: Surgical incision after dressing removal.

Patient data and photos courtesy of Lance T. Frye, MD, FACOG
Case Study 3: Abdominal Wall Reconstruction (Figure 11)
A 32-year-old male presented with a failed ventral hernia repair (Figure 11A). Components separation was initially performed followed by application of a surgical mesh (porcine acellular dermal matrix) as an under- and overlay. Primary closure was achieved with staples (Figure 11B). The Prevena Incision Management System was applied over incision (Figures 11C and 11D) and remained in place for 7 days. Figures 11A and 11E contrast the original failed ventral hernia (Figure 11A) to the healed incision (Figure 11E) at follow-up (4.5 months) after surgery.

Figure 11. Abdominal wall reconstruction for failed ventral hernia with mesh. (A) Failed ventral hernia repair. (B) Clean closed surgical incision after primary closure. (C) Placement of Prevena Incision Dressing. (D) Prevena Therapy applied for 7 days (E) Healed incision 4.5 months post abdominal wall reconstruction.

Summary
This monograph contains a review of clinical journal and conference literature on the use of incisional NPWT and Prevena Therapy over clean closed surgical incisions. Additionally, it describes the bench testing, computer modeling, and published scientific studies of proposed biomechanical and physiological mechanisms of the Prevena Incision Management System. Actual patient results are presented as case studies to transition from scientific evidence to clinical experience. Additional clinical research is still needed to fully understand the scientific and medical impact of incisional NPWT and the Prevena Incision Management System in the surgical arena.
Table 1. Comparison of Dressing Materials

<table>
<thead>
<tr>
<th>Dressing Component</th>
<th>Incisional V.A.C.® Therapy Dressing Configuration</th>
<th>Prevena™ Peel &amp; Place™ Dressing and Prevena™ Customizable™ Dressing Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin interface layer</td>
<td>Non-adhering Dressing (petrolatum-coated gauze dressing)</td>
<td>Fabric with 0.019% silver (currently marketed as InterDry™ Ag [Coloplast®, Minneapolis, MN], which is used for skin fold management)</td>
</tr>
<tr>
<td>Foam bolster (no patient contact)</td>
<td>V.A.C.® GranuFoam™ Dressing (polyurethane foam with black pigment)</td>
<td>Same V.A.C.® GranuFoam Dressing (with black pigment replaced by pigment violet 23)</td>
</tr>
<tr>
<td>Drape</td>
<td>V.A.C.® Drape (polyurethane film with acrylic adhesive)</td>
<td>Polyurethane film with acrylic adhesive</td>
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</table>

Table 2. ASPS Evidence Rating Scale for Therapeutic Studies

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Qualifying Studies</th>
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<tbody>
<tr>
<td>I</td>
<td>High-quality, multicenter or single-center, randomized controlled trial with adequate power; or systematic review of these studies</td>
</tr>
<tr>
<td>II</td>
<td>Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies</td>
</tr>
<tr>
<td>III</td>
<td>Retrospective cohort or comparative study; case-control study; or systematic review of these studies</td>
</tr>
<tr>
<td>IV</td>
<td>Case series with pre/post test or only post test</td>
</tr>
<tr>
<td>V</td>
<td>Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research or “first principles”</td>
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Table 3. Literature review of the use of NPWT and Prevena Therapy over surgical incisions

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type</th>
<th>Patients</th>
<th>Results/Conclusions</th>
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</thead>
<tbody>
<tr>
<td>JP Stannard et al⁴</td>
<td>RCT V.A.C.® Therapy (NPWT) vs Standard Postoperative Dressings</td>
<td>• 249 patients with 263 calcaneus, pilon and tibial plateau fractures • Randomization: NPWT, 130 patients (141 fractures) vs Control, 119 patients (122 fractures).</td>
<td>• Significant decrease for incidence of dehiscence (12 cases [NPWT] vs 20 cases [Control]; P = 0.044) • Significant decrease for total infections (14 cases [NPWT] vs 23 cases [Control]; P = 0.049) • Incidence of acute infection trended lower with NPWT (1 case) vs control (5 cases)</td>
</tr>
<tr>
<td>JP Stannard et al³</td>
<td>RCT (Interim Analysis) V.A.C.® Therapy (NPWT) vs Standard Postoperative Dressings</td>
<td>• 44 patients with high-energy trauma wounds with draining hematomas (31 Control and 13 NPWT) • 44 patients with high-energy fractures (24 Control and 20 NPWT)</td>
<td>• High-energy trauma wounds: Control group drained a mean of 3.1 days compared to only 1.6 days for NPWT (P = 0.03) • High-energy fractures: Control group drained a mean of 4.8 days compared to only 1.8 days for NPWT (P = 0.02)</td>
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<tr>
<td>Author</td>
<td>Study Type</td>
<td>Patients</td>
<td>Results/Conclusions</td>
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<tr>
<td>Masden et al&lt;sup&gt;28&lt;/sup&gt; (Annals of Surgery, 2012)</td>
<td>RCT NPWT vs Standard dry silver dressings (Control)</td>
<td>• 81 high-risk patients with multiple comorbidities whose closed surgical incisions were treated with: &lt;br&gt;  - NPWT (n=44) &lt;br&gt;  - Control (n=37) &lt;br&gt;  - Majority (74/81) of patients underwent lower extremity wound closure post amputation. &lt;br&gt;  - All incisions were evaluated on postoperative day 3, at first outpatient visit, and at subsequent visits. Average follow-up period was 113 days.</td>
<td>• No differences in demographic, preoperative, and operative variables between groups. &lt;br&gt;  - Wound complication rates did not achieve statistical significance between the groups: &lt;br&gt;    - Infection: NPWT, 3/44 (6.8%) vs. Control, 5/37 (13.5%), p = 0.46 &lt;br&gt;    - Dehiscence: NPWT, 16/44 (36.4%) vs. Control, 11/37 (29.7%), p = 0.53 &lt;br&gt;    - Reoperation: NPWT, 9/44 (21%) vs. Control, 8/37 (22%), p = 0.89 &lt;br&gt;  - Overall, 40% of NPWT and 35% of Control groups experienced wound infection, dehiscence, or both.</td>
</tr>
<tr>
<td>M Pachowsky et al&lt;sup&gt;29&lt;/sup&gt; (International Orthopaedics, 2011)</td>
<td>RCT Prevena Incision Management System (NPWT) vs Standard Postoperative Dressings</td>
<td>• 19 patients (10 Control and 9 NPWT) with closed incisions after total hip arthroplasty. &lt;br&gt;  - Postoperative seromas were measured in both groups on the fifth and tenth postoperative days.</td>
<td>• Significantly decreased development of postoperative seromas in the NPWT group on postoperative day 10 (average volume of 1.97 ml) compared to Control (5.08 ml) (P = 0.021) &lt;br&gt;  - A seroma was present in 44% of the NPWT patients and 90% of the Control patients &lt;br&gt;  - The NPWT group received significantly fewer days of antibiotics (8.44 ± 2.24 vs 11.8 ± 2.82 days, P = 0.005) &lt;br&gt;  - A secretion in the wound after day 5 was reported in fewer patients in the NPWT group (1 vs 5 patients)</td>
</tr>
<tr>
<td>O Grauhan et al&lt;sup&gt;30&lt;/sup&gt; (Journal of Thoracic and Cardiovascular Surgery, e-pub 2012)</td>
<td>Prospective Comparative Study Prevena Incision Management System (NPWT) vs conventional sterile wound dressings (Control)</td>
<td>• 150 consecutive obese (BMI ≥ 30) patients, whose sternotomy wound incisions were treated with: &lt;br&gt;  - NPWT (n=75) &lt;br&gt;  - Control (n=75) &lt;br&gt;  - Primary study endpoint: Wound infection within 90 days &lt;br&gt;  - Patients allocated to treatment groups by alternating based on time of operation. &lt;br&gt;    - Patients with diabetes assigned “half and half to both groups, with priority.” &lt;br&gt;  - Dressing changes: &lt;br&gt;    - NPWT Therapy: Placed under sterile OR conditions; kept at 125mmHg for the first 6 to 7 postoperative days. &lt;br&gt;    - Control: Changed on the first or second postoperative day and every 1-2 days thereafter. &lt;br&gt;  - No significant preoperative patient differences between groups. &lt;br&gt;  - All patients followed for at least 90 days.</td>
<td>• Prevena Therapy group, compared to Control group, had significantly fewer &lt;br&gt;    - Wound infections: 3/75 (4%) vs. 12/75 (16%), respectively; P= 0.0266; odds ratio, 4.57; 95% confidence interval (CI), 1.23-16.94. &lt;br&gt;    - Patients whose wound infections had Gram-positive skin flora: 1 vs. 10, respectively; P=.0090; odds ratio, 11.39; 95% CI, 1.42-91.36. &lt;br&gt;    - Timing of wound infection incidence: &lt;br&gt;      - NPWT Therapy group: 71/75 (95%) of the incisions were primarily closed when the dressing was removed in 6 to 7 days. No wound infections occurred after postoperative day 7. &lt;br&gt;      - Control group: 9/12 wound infections occurred beyond postoperative day 7 and up to day 35. &lt;br&gt;  - Authors concluded that Prevena Therapy over clean, closed surgical incisions for the first 6 to 7 postoperative days significantly reduced wound infection after median sternotomy for high-risk obese cardiac surgery patients</td>
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</table>
**Table 3. Literature review of the use of NPWT and Prevena Therapy over surgical incisions (cont.)**

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type</th>
<th>Patients</th>
<th>Results/Conclusions</th>
</tr>
</thead>
</table>
| BZ Atkins et al\(^5\)   | Retrospective Review of Patient Records                                      | V.A.C. Therapy (NPWT)                                                    | • 57 adult sternal wound patients at high-risk for infection  
  • Based on risk assessment, at least 3 sternal wound infections were anticipated but none were reported in the NPWT-treated patients.  
  • NPWT was easily applied and well tolerated therapy that may stimulate more effective wound healing  
  • The authors recommended that strong consideration should be given to NPWT as a form of “well wound” therapy for patients at risk for increased sternal wound infections |
| RN Reddix et al\(^7\)   | Retrospective Review of Patient Records                                      | V.A.C. Therapy (NPWT)                                                    | • 19 morbidly obese patients (BMI>40) with acetabular fractures  
  • NPWT was applied postoperatively  
  • No reported complications among 19 obese patients |
| RN Reddix et al\(^8\)   | Retrospective Review of Patient Records                                      | V.A.C. Therapy (NPWT)                                                    | • 66 patients with acetabular fractures treated with standard postoperative care (Control)  
  • 235 patients with acetabular fractures treated with NPWT  
  • The authors noted that their infection rate of 1.27% represented a significant decrease in comparison to other groups (infection rates of 4.2%, 4%, and 5%) of similar size (P=0.0282; reference rate =4%).  
  • Application of NPWT over incisions decreased incidence of perioperative incision complications at the author's institution |
| R Tauber et al\(^31\)   | Retrospective Review of Patient Records                                      | V.A.C. Therapy (NPWT) vs Conventional Compression Dressings (Control)    | • 24 patients who underwent 45 inguinal lymph node dissections (LNDs) as treatment for penile or urethral cancer  
  • NPWT: 8 patients (15 LNDs)  
  • Control: 16 patients (30 LNDs)  
  • NPWT was applied using V.A.C.\(^®\) WhiteFoam Dressing, and NPWT dressings remained in place for up to 7 days  
  • Compared to NPWT, Control patients tended to have:  
    - Higher levels of maximum drained fluid per day (P=0.496)  
    - Longer duration of drainage (P=0.632)  
    - More reinterventions (7 vs 1, respectively; P=0.631).  
  • NPWT patients had significantly fewer wound complications (p= 0.032) than Control patients:  
    - 20% vs 62% incidence of lymphoceles, respectively  
    - 7% vs 45% persistent lymphorrhoea  
    - 0% vs 46% lower extremity lymphoedema  
  • Along with shorter hospital stay, the authors commented that NPWT patients benefitted because “... further oncological treatments could be administered without delay.” |
Table 3. Literature review of the use of NPWT and Prevena Therapy over surgical incisions (cont.)

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type</th>
<th>Patients</th>
<th>Results/Conclusions</th>
</tr>
</thead>
</table>
| A Condé-Green et al32   | Retrospective Review of  | V.A.C. Therapy (NPWT) vs Standard Gauze Dressings (Control)             | • Overall wound complications rates significantly favored the incisional NPWT group vs. Control: 22% vs. 63.6%, respectively (P=0.020)  
• Skin dehiscence rate was also significantly lower for incisional NPWT group: 9% vs. 39%, (P=0.014)  
• Rates for other wound complications (infection, skin and fat necrosis, seroma, and hernia recurrence) were also lower for the NPWT group.  
• According to authors, study results suggest that incisional NPWT “significantly improves rates of wound complication and skin dehiscence when compared to conventional dressings.” |
|                         | Patient Records          | 56 patients were treated with either incisional NPWT (n=23) or gauze dressings (n=33) after abdominal wall reconstruction to repair large ventral hernias |                                                                                     |
| T Matatov et al33       | Retrospective Review of  | V.A.C. Therapy (NPWT) vs Skin Adhesive or Absorbent (Control)           | • Used Szilagyi scale to rate degree of infection from grade I (lowest) to grade 3 (highest)  
• Prevena Therapy was applied intraoperatively and removed after 5-7 days.  
• Mean times of wound evaluation: Prevena Therapy, 7 and 33 days postoperatively vs Control: 10 and 40 days  
• Prevena Therapy-treated incisions had significantly lower overall rate of infection: 3/52 (6%) vs 19/63 (30%), p=0.0011  
• Incidence and severity of infections by group:  
  o Prevena Therapy: 3 infections, all Szilagyi grade I  
  o Control: 19 infections, 10 (16%) Szilagyi grade I, 7 (11%) grade II, and 2 (3%) grade III  
• According to the authors, Prevena Therapy “significantly decreased the incidence of groin wound infection in patients after vascular surgery.” |
|                         | Patient Records          | 90 vascular surgery patients with 115 groin incisions for longitudinal or transverse femoral cut-down  
  o Prevena Therapy: 41 patients (52 incisions)  
  o Control: 49 patients (63 incisions) |                                                                                     |
| AU Blackham et al34     | Retrospective Review of  | V.A.C. Therapy (NPWT) vs standard sterile dressings (Control)           | • Patients evaluated as being at risk for development of SSIs were treated with NPWT  
• Compared to Control patients, NPWT patients had significantly:  
  o More neoadjuvant chemotherapy (P=0.024)  
  o More clean-contaminated operations (P<0.001)  
  o Longer operation times (P<0.001)  
  o Greater intraoperative blood loss (P<0.001)  
  o More frequent blood transfusions (P=0.002)  
• NPWT patients had significantly fewer incisional SSIs compared to SSD patients  
• In a subset analysis of clean-contaminated cases, NPWT was associated with significantly fewer:  
  o Superficial incisional SSIs (6.0% vs 27.4%, P=0.001)  
  o Total SSIs (16.0% vs 35.5%, P=0.011)  
  o Wound openings for any reason (16.0% vs 35.5%, P=0.011)  
• In this study NPWT decreased incidence of SSIs in surgical oncology patients  
• An RCT is planned to further evaluate the efficacy of incisional NPWT in this patient population |
|                         | Patient Records          | 189 patients underwent 191 surgical procedures for pancreatic, colorectal, or peritoneal surface malignancies  
  o NPWT: 104 cases  
  o Control: 87 cases |                                                                                     |
<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type</th>
<th>Patients</th>
<th>Results/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Colli et al&lt;sup&gt;35&lt;/sup&gt; (Journal of Cardiothoracic Surgery, 2011)</td>
<td>Case series</td>
<td>Prevena Therapy (NPWT)</td>
<td>10 patients with closed sternal incisions and mean Fowler risk score of 15.1 following cardiac surgery • Wounds and surrounding skin showed complete wound healing with absence of skin lesions following dressing removal • No infections occurred during 30 day follow-up time • No device-related or other complications were observed with Prevena Therapy</td>
</tr>
<tr>
<td>Stannard et al&lt;sup&gt;36&lt;/sup&gt; (Ostomy Wound Management, 2009)</td>
<td>Case series</td>
<td>V.A.C. Therapy (NPWT)</td>
<td>Incisional NPWT was used for 4 patients: o 1 with coronary artery bypass grafting, o 1 with a transmetatarsal amputation o 2 with abdominal hysterectomies • Patient comorbidities included obesity, diabetes, hypertension, and peripheral artery disease. • Three patients healed without complication; one patient with an abdominal hysterectomy experienced superficial skin separation (3 mm – 5 mm) after staple removal. • Authors also shared practical tips, including a patient grading scale to help identify patients who could benefit from incisional NPWT or Prevena Therapy.&lt;sup&gt;34&lt;/sup&gt;</td>
</tr>
<tr>
<td>AH Gomoll et al&lt;sup&gt;6&lt;/sup&gt; (Journal of Orthopaedic Trauma, 2006)</td>
<td>Case Series</td>
<td>V.A.C. Therapy (NPWT)</td>
<td>35 patients with foot and ankle trauma, revision hip arthroplasty, proximal femoral and tibial fracture fixation • Average time of NPWT use was just over 3 days • Use of NPWT saved an average of 4 conventional dressing changes and reduced risk of external contamination • No infections had occurred in high-risk patients 3 months post operation</td>
</tr>
<tr>
<td>D Bollero et al&lt;sup&gt;37&lt;/sup&gt; (International Wound Journal, 2013)</td>
<td>Case Series</td>
<td>Prevena Therapy</td>
<td>8 patients undergoing surgical excision of wide pathological scars • First use of Prevena Therapy after pathological scar excision • Scar sites were located in body areas with skin stretch during flexion/extension movements. • Prevena Therapy Dressing was applied intraoperatively and maintained for 8 days at -125 mmHg • 7 of 8 patients completed treatment successfully • 1 patient discontinued treatment after 1 day because scar was close to pubic area and, despite shaving, it was not possible to achieve and maintain an air-tight seal. • The authors concluded that “Easy intraoperative application and postoperative management, associated with good compliance of patients, make Prevena [Therapy] a safe home-care device.”&lt;sup&gt;37&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
Table 4. Summaries of Conference Presentations Reporting Use of Incisional NPWT and Prevena Therapy

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type</th>
<th>Patients</th>
<th>Results/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Gabriel et al (Clinical Symposium on Advances in Skin and Wound Care [CSWC] 2012)</td>
<td>Prospective Cohort Study V.A.C. Therapy (NPWT)</td>
<td>15 patients with incisions on lower extremities, abdomen, or chest</td>
<td>Each patient had a minimum of 3 of the following risk factors: BMI&gt;35, diabetes mellitus, peripheral vascular disease, smoking, history of radiation, steroid use and malnutrition (as measured by albumin and prealbumin). Incisions of all 15 patients were treated with incisional NPWT using V.A.C. GranuFoam Silver® over a non-adherent layer. Mean follow-up was 9 months. All wounds healed without recurrence, infection, wound breakdown, seroma or return to operating room. Authors recommend use of incisional NPWT on “high-risk patients who are undergoing elective or emergent procedures to minimize wound breakdown and improve healing.”</td>
</tr>
</tbody>
</table>
Table 4. Summaries of Conference Presentations Reporting Use of Incisional NPWT and Prevena Therapy (cont.)

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type</th>
<th>Patients</th>
<th>Results/Conclusions</th>
</tr>
</thead>
</table>
| KS Daley et al\(^{45}\)  
(American College of Obstetricians and Gynecologists, 2012) | Retrospective Comparative Study Prevena Therapy vs. Control (standard wound dressings) | 63 women with BMI>45 who underwent C-section between September 1, 2008 and September 30, 2010  
- 21 patients were treated with Incisional NPWT (Sept 2009-2010)  
- The rest had standard (Control) wound dressings (Sept 2008-2009) | - Main outcome measure was wound complication defined by ICD-9cm codes  
- Only three parameters differentiated Control group from NPWT:  
  - Length of surgery: 64 versus 76 minutes, respectively (P = .03)  
  - Length of labor (78 versus 261 minutes, P = .02)  
  - Age (29.5 versus 26.1 years)  
- Control group had 6 (12.5%) wound complications compared to none (0%) in the NPWT group  
- According to the authors, these results indicate trend toward fewer wound complications in morbidly obese women receiving incisional NPWT post C-section. |
| A Gassman et al\(^{46}\)  
(American College of Surgeons Annual Clinical Congress, 2012) | Retrospective Comparative Study Primary closure alone vs. Primary closure with NPWT vs. Secondary closure with NPWT | 63 patients requiring ventral hernia operations:  
- 31 primary closure alone  
- 22 primary closure with 7 days of overlying NPWT  
- 10 secondary closure with NPWT. | - Compared to patients treated with primary closure alone, patients treated with primary closure with overlying NPWT had:  
  - Shorter average LOS: 7 vs. 10 days; p>0.05  
  - Fewer SSIs: 18% vs 55%; p<0.01  
  - Lower recurrence rates: 5% vs. 23%; p<0.05  
- Compared to primary closure alone, primary and secondary closures with NPWT were associated with a 2-fold and 8.5-fold decreased odds ratio for SSI, respectively (p<0.02).  
- In this abdominal wall reconstruction study, the authors stated that use of NPWT was associated with lower rates of SSI and recurrence. |
| T Karl & S Woeste\(^{47}\)  
(European Wound Management Association [EWMA], 2012) | Retrospective Comparative Study Prevena Therapy vs. Prior Standard of Care | 20 vascular surgery patients treated with Prevena Therapy since 01.02.2011  
- Patients treated with standard of care in the year before initiation of Prevena Therapy (Control) | - Prevena Therapy used on patients with ≥2 risk factors for developing wound complications.  
- Frequency of wound complications after vascular surgery was compared between the two groups.  
- Both groups were comparable with regard to age (76.4 vs. 73.6 years), comorbidities (diabetes mellitus 5 vs. 6) and gender ratio (1:1).  
- The Prevena Therapy group had a higher score (5.1 vs. 3.8), which was primarily due to the higher number of relapse interventions.  
- Only 1 Prevena Therapy patient experienced a complication (infected seroma), whereas 2 Control patients required surgery to resolve their wound complications.  
- Authors concluded that “prophylactic use of [Prevena Therapy] appears to be able to reduce the rate of wound healing complications in vascular surgery, particularly with a large percentage of high-risk patients.” |
| T Payrits\(^{48}\)  
(EWMA, 2012) | Case Series Prevena Therapy | 13 patients with 14 groin wounds | - All patients had at least one risk factor (pathological obesity, diabetes mellitus, age≥80, relapse surgery) for development of wound complications.  
- Prevena Therapy was placed in the sterile operating theatre and left for 4-7 days.  
- Incisions were assessed immediately upon removal of the Prevena Therapy dressing and upon discharge from clinic or upon removal of stitches.  
- Thirteen of 14 wounds were free of infection and healed without complications.  
- After removal of the Prevena Therapy dressing, 1 patient developed a lymph fistula, which was treated with V.A.C. Therapy. Additional surgery was not required.  
- According to the author, Prevena Therapy was easy to use for both patient and staff and could help reduce wound infection rate in the groin. |
### Table 4. Summaries of Conference Presentations Reporting Use of Incisional NPWT and Prevena Therapy (cont.)

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type</th>
<th>Patients</th>
<th>Results/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>B Lehner et al49</td>
<td>Case Series</td>
<td>20 patients: o 15 with high-grade soft tissue sarcomas</td>
<td>• Literature reports high wound complication rates ranging up to 40% for this patient population because of patient comorbidities, treatment (radiation and chemotherapy) and wound characteristics (size and location).</td>
</tr>
<tr>
<td>(World Union of Wound Healing Societies, 2012)</td>
<td>o 5 with aggressive fibromatosis</td>
<td>• Prevena Therapy was applied over post-resection incisions in 20 patients.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Average tumor volume was 209 cm³. Majority of wounds were in lower extremities</td>
<td>• 80% (16/20) patients healed without complications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Four patients (20%) had wound complications: 3 with seromas that required aspiration and 1 with wound dehiscence.</td>
<td>• Because of the lower complication rate, authors use Prevena Therapy as part of their treatment regime for patients with soft tissue sarcomas.</td>
</tr>
<tr>
<td>A Gabriel &amp; S Slovic50</td>
<td>Case Series</td>
<td>5 patients with abdominal wall reconstruction</td>
<td>• All patients (1 male and 4 female) had failed ventral hernias with mesh</td>
</tr>
<tr>
<td>(CSWC, 2012)</td>
<td></td>
<td>• Patient comorbidities included diabetes and obesity</td>
<td>• After components separation, application of surgical mesh and primary closure with staples, Prevena Therapy was placed over the closed incisions for 6-7 days at a continuous negative pressure of -125mmHg.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Procedures included aortic valve replacement, coronary artery bypass grafting, or complex sternal reconstruction</td>
<td>• At follow-up (5-14 months), all incisions were healed without complications</td>
</tr>
<tr>
<td>VS Reddy51</td>
<td>Case Series</td>
<td>8 patients with multiple comorbidities who underwent complex cardiothoracic procedures</td>
<td>• Patient comorbidities included poor tissue quality, low albumin, and morbid obesity</td>
</tr>
<tr>
<td>(CSWC, 2012)</td>
<td></td>
<td>• Procedures included aortic valve replacement, coronary artery bypass grafting, or complex sternal reconstruction</td>
<td>• Prevena Therapy was applied over the incision in the operating room</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Average duration of Prevena Therapy was 5.7 days</td>
<td>• Seven of the 8 patients healed without wound complications. One patient developed a sternal wound infection on Day 35 that resolved with local wound care.</td>
</tr>
</tbody>
</table>

### Table 5. Patient Risk Factors53-55

- Age > 65
- Wound infection
- Pulmonary disease
- Vascular disease
- Hemodynamic instability
- Ostomies
- Hypoalbuminemia
- Systemic infection
- Obesity
- Uremia
- Hyperalimentation
- Ascites
- Malignancy
- Hypertension
- Length and depth of incision
- Foreign body in the wound
- Anemia
- Jaundice
- Diabetes – poor control
- Active smoker
- Type of injury
- Radiation therapy
- Steroid use
Table 6A. Biomechanical properties of the Prevena Incision Management System

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Study Description</th>
<th>Nonclinical Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helps hold closed incision edges together</td>
<td><em>In vitro simulated incision model</em> 57</td>
<td><em>Sutures plus Prevena Therapy resisted separation 51% better than sutures only (92.9 ± 2.6N vs 61.7 ± 0.3N, respectively; (P &lt; 0.05)</em></td>
</tr>
<tr>
<td></td>
<td>• Measured force needed to separate sutured and stapled incision edges 10 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Compared sutures plus Prevena Therapy to sutures only and staples plus Prevena Therapy to staples only</td>
<td></td>
</tr>
<tr>
<td>May help realign and reduce tensile forces across the incision</td>
<td><em>Finite element computer model</em> 157</td>
<td><em>Sutures only: tensile loads concentrated at sutures</em></td>
</tr>
<tr>
<td></td>
<td>• Evaluated tensile forces in a cross-section of a simulated incision closed with sutures</td>
<td><em>Sutures plus Prevena Therapy: tensile loads realigned and more evenly spread across a simulated incision</em></td>
</tr>
<tr>
<td></td>
<td>• Compared sutures only to sutures plus Prevena Therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Finite element computer model</em> 257</td>
<td><em>High lateral strain areas normally surround the incision line</em></td>
</tr>
<tr>
<td></td>
<td>• Simulated a sutured incision with lateral tension</td>
<td><em>Prevena Therapy led to reduced lateral strain around the suture lines of the incision</em></td>
</tr>
<tr>
<td></td>
<td>• Evaluated strain levels with and without Prevena Therapy</td>
<td></td>
</tr>
</tbody>
</table>

Table 6B. Physiological Properties of Prevena Incision Management System

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Study Description</th>
<th>Nonclinical Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>May help improve fluid flow</td>
<td><em>In vivo porcine model was developed to evaluate effect of negative pressure (Prevena Therapy) on hematoma/seroma formation, fluid removal into the canister, and lymph system involvement</em> 58</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Two sets of contralateral subcutaneous voids with overlying sutured incisions were created on the ventral sides of each of 8 swine</td>
<td><em>Hematoma/seroma mass significantly reduced (63%) for Prevena Therapy vs SOC (mean 15 ± 3g vs 41 ± 10g, respectively; P = 0.002)</em></td>
</tr>
<tr>
<td></td>
<td>• Uniquely labeled 30 and 50nm nanospheres were introduced into each subcutaneous void</td>
<td><em>No fluid found in Prevena Canister</em></td>
</tr>
<tr>
<td></td>
<td>• Incisions were assigned to Prevena Therapy or standard of care (SOC) (3M™ Tegaderm™ Dressing) over sutures for 4 days</td>
<td><em>Lymph nodes had ~60 μg (~50%) more 30- and 50-nm nanospheres from Prevena Therapy-treated incisions compared to Control sites (P=0.04 and 0.05, respectively).</em></td>
</tr>
<tr>
<td></td>
<td>• After therapy, the hematoma/seroma in each defect was weighed (with differences averaged for each animal), fluid levels in the canister were monitored, 5 pre-identified lymph nodes were harvested, and 5 key organs were biopsied</td>
<td><em>Nanosphere incidence significantly greater from Prevena Therapy sites versus Control sites in lungs, liver and spleen (P &lt;0.05); no nanospheres found in kidney biopsies.</em></td>
</tr>
<tr>
<td></td>
<td><em>In vivo porcine incision model compared Prevena Therapy to standard dry dressings (Control)</em> 59</td>
<td><em>According to the authors, in this scientific model, application of Prevena Therapy significantly decreased hematoma/seroma levels without fluid collection in the canister, which may be explained by increased lymph clearance.</em> 58</td>
</tr>
<tr>
<td></td>
<td>• In 8 mature mini-pigs, the two dressings were applied to adjacent sutured incisions over the spine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• After 3 or 5 days, incisions were assessed using scar scale rating, biomechanical testing (eg, failure load, failure energy, and stress), and histological analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Prevena Therapy incisions had a significantly improved scar scale height grade (P&lt;0.026)</td>
<td><em>The representative Control incision showed inflammation, edema and swelling around the incision (Figure 8A)</em></td>
</tr>
<tr>
<td></td>
<td>• The representative Prevena Therapy incision line was barely visible (Figure 8B)</td>
<td><em>Control group scores were lower for failure load (4.9 ± 4.0 vs. 16.5 ± 14.6N), energy absorbed (8.0 ± 9.0 vs. 26.9 ± 23.0 mJ), and ultimate stress (62 ± 53 vs. 204 ± 118 N/mm²)</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Histology showed no differences in incision scar width between the two groups</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>In this porcine study, authors noted “a trend toward improved early healing strength and in a significantly improved incision appearance“ for incisions treated with Prevena Therapy</em></td>
</tr>
</tbody>
</table>
Table 6B. Physiological Properties of Prevena Incision Management System (cont.)

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Study Description</th>
<th>Nonclinical Results</th>
</tr>
</thead>
</table>
| Helps facilitate incision healing | - *in vivo* porcine model used to assess whole-genome microarrays to gain insight into the biological processes of closed incision management (CIM).\(^{60}\)  
  o Total RNA was isolated from the tissue  
  o Quality and quantity of RNA were determined using the Experion™ Automated Electrophoresis System (Bio-Rad, Hercules, CA). | - Genomic pathway analysis via PANTHER™ (Gen-Probe™, San Diego, CA) indicated:  
  o Increased integrin signaling in CIM-treated incisions as compared to SOC-treated incisions (normalized to naïve)  
  o Decreased inflammation mediated by key chemokine and cytokine marker expression in CIM-treated incisions compared to SOC-treated incisions (normalized to naïve)  
  - CIM affects gene expression differently than SOC |

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Study Description</th>
<th>Nonclinical Results</th>
</tr>
</thead>
</table>
| • *in vivo* porcine model used to compare the biomechanics of CIM-treated incisions to SOC-treated controls 40 days post-surgery.\(^{61}\)  
  o Three adult female Yucatan swine (70-76 kg) received 4 cm long full-thickness dorsal incisions.  
  o Incisions were closed with 2-0 Prolene sutures using a simple interrupted pattern.  
  o Contralateral incisions received SOC (ABD Pads) or CIM for 5 days, then SOC for 5 days.  
  o The Incisions were left untreated until term (Day 40)  
  o The tissue surrounding the scar was trimmed to a 10cm X 1cm strip including the epidermis, dermis, subdermal fat layer, and subcutaneous fat layer.  
  o A Test Resources 100R system (Shakopee, MN) with 250 lb load cell was used for testing. | - The test values (MPa) of the scar mechanical properties (Peak Stress, Strain Energy, Modulus) of CIM-treated incisions were higher than those for SOC treated incisions. (Table 7)  
  - CIM, provided by the Prevena Incision Management System, creates an environment that helps to:  
    o Hold incision edges together,  
    o Protect the incision site from external infectious sources, and  
    o Remove fluids and infectious materials from the surgical site. |

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Study Description</th>
<th>Nonclinical Results</th>
</tr>
</thead>
</table>
| • *in vitro* viral penetration study\(^{64}\) confirmed that Prevena Dressing protects the incision from external contamination  
  o Test squares were cut from the polyurethane film and clamped into a penetration test cell  
  o A 60mL bacteriophage suspension was introduced into top side of test cell (5 min)  
  o Film was monitored for penetration before and after 2 PSIG pressure was applied for 1 min | - Both biological assay (Table 8) and visual inspection showed no penetration  
  - These results indicate that the exterior drape of the Prevena™ Incision Management System may be a microbial barrier to viral contamination (as small as 27nm) and bacterial sources |

Table 7. Appositional Model Results Measured the Amount of Force Needed to Separate Closed Incision Edges by 10 mm\(^{57}\)

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Maximum Tension Measured (N)</th>
<th>% Increase in Appositional Forces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sutures Only</td>
<td>61.7 ± 0.3</td>
<td>51%</td>
</tr>
<tr>
<td>Sutures and Prevena™ Incision Dressing</td>
<td>92.9 ± 2.6*</td>
<td></td>
</tr>
<tr>
<td>Staples Only</td>
<td>69.3 ± 0.4</td>
<td>43%</td>
</tr>
<tr>
<td>Staples and Prevena™ Incision Dressing</td>
<td>98.8 ± 0.0*</td>
<td></td>
</tr>
</tbody>
</table>

*(P<0.05)
Table 8. Characteristics of Clean, Closed Surgical Incisions in Yucatan Swine 40 Days Post-Surgery\textsuperscript{61}

<table>
<thead>
<tr>
<th></th>
<th>(N=3)</th>
<th>SOC</th>
<th>Prevena™ Therapy</th>
<th>p-Value</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak Stress (MPa)</td>
<td>2.92 ± 0.20</td>
<td>4.83 ± 0.57</td>
<td>&lt;0.05</td>
<td>65%</td>
<td></td>
</tr>
<tr>
<td>Strain Energy Density (MPa)</td>
<td>706 ± 30</td>
<td>1415 ± 207</td>
<td>&lt;0.1</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Modulus (MPa)</td>
<td>33.3 ± 2.2</td>
<td>43.7 ± 4.5</td>
<td>&lt;0.1</td>
<td>31%</td>
<td></td>
</tr>
</tbody>
</table>

Table 9. Bacteriophage concentrations from penetration study\textsuperscript{64}

<table>
<thead>
<tr>
<th>Dressing Area</th>
<th>Concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Top Side/Pre-Pressure</td>
<td>8.7x10^8 PFU/mL</td>
</tr>
<tr>
<td>Top Side/Post-Pressure</td>
<td>9.4x10^8 PFU/mL</td>
</tr>
<tr>
<td>Bottom Side Assay</td>
<td>&lt;1 PFU/mL</td>
</tr>
</tbody>
</table>

* According to Nelson Labs, an assay titer value of <1 Plaque Forming Units (PFU)/mL is reported for assay plates showing no growth.
References


(5) Atkins BZ, Wooten MK, Kistler J, Hurley K, Hughes GC, Wolfe WG. Does negative pressure wound therapy have a role in preventing poststernotomy wound complications? Surgical Infections 2009 June 1;16(2):140-6.


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(55) Abbas SM, Hill AG. Smoking is a major risk factor for wound dehiscence after midline abdominal incision; case-control study. ANZ Journal of Surgery 2009 April 1;79(4):247-50.


Follow local institutional protocols for infection control and waste disposal procedures. Local protocols should be based on the applicable federal, state and/or local government environmental regulations.

NOTE: Specific indications, contraindication, warnings, precautions and safety information exist for the Prevena Incision Management System. Please consult a physician and product instructions for use prior to application. Rx only.