# PREVENA™
INCISION MANAGEMENT SYSTEM

# Evidence Brochure

KCI
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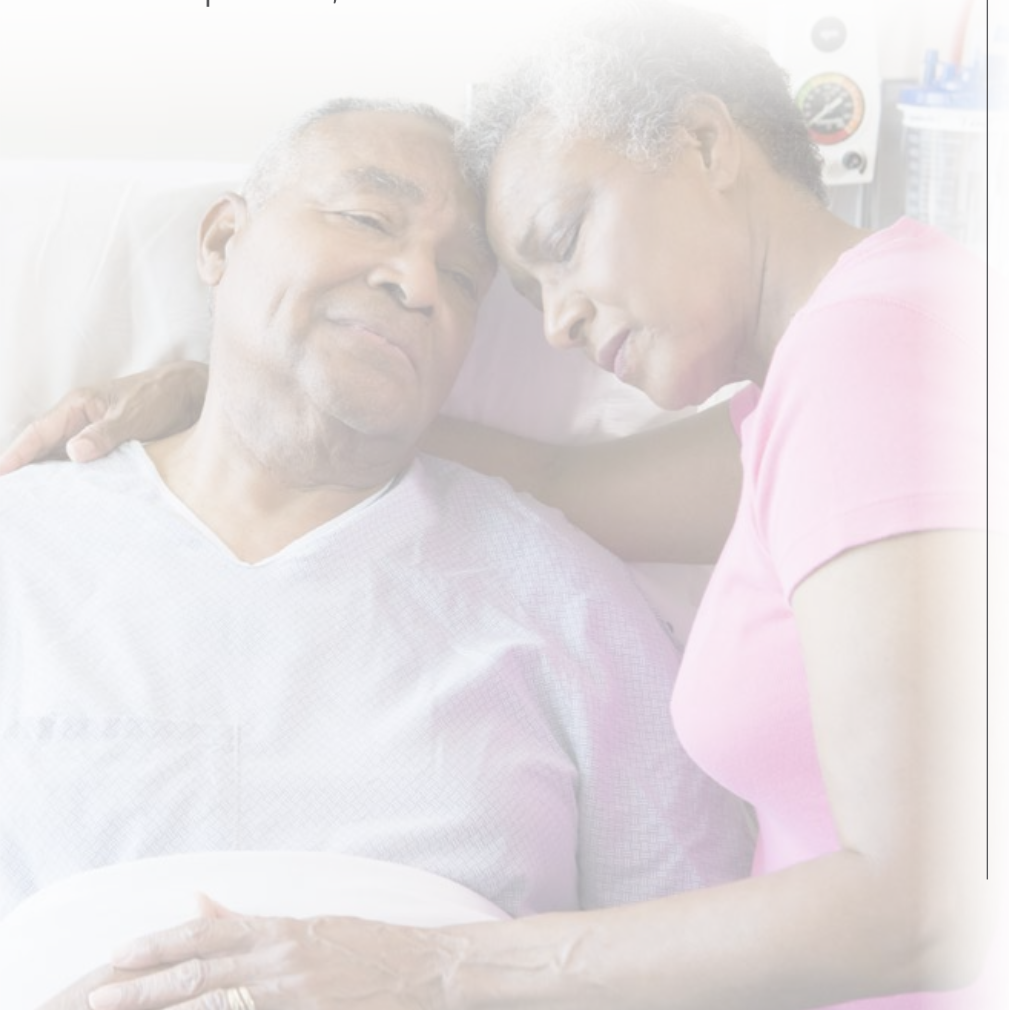
# Incisions can be **COMPLICATED**

## Certain surgical procedures and patient conditions can make healing difficult

Surgical procedures that most commonly lead to complications include sternotomies, C-sections, open hysterectomies, hip and knee arthroplasties, open reduction fractures, lower extremity bypasses, femoropopliteal bypasses, renal transplants, and breast reconstruction[1].



### RISK FACTORS THAT MAY COMPROMISE HEALING[2-4]

- Obesity
- Nicotine use
- Diabetes—poor control
- Radiation therapy
- Age >65
- Wound infection
- Pulmonary disease
- Peripheral vascular disease
- Hemodynamic instability
- Ostomies
- Hypoalbuminemia
- Systemic infection
- Uremia
- Hyperalimentation
- Ascites
- Malignancy
- Hypertension
- Length and depth of incision
- Anemia
- Jaundice
- Type of injury
- Steroid use
- Malnutrition

# Incisions can be **COSTLY**

There are

**8.2 Million**

people at risk for Surgical Site Infection (SSI) annually.[5]

**The Centers for Medicare & Medicaid Services emphasize the need to decrease costs and improve care by identifying hospital-acquired conditions that will not be reimbursed, including 3 SSIs[8]:**

- Mediastinitis following coronary artery bypass graft (CABG)
- SSIs following certain orthopedic procedures
- SSIs following bariatric surgery for obesity

## POST-SURGICAL COMPLICATIONS LEAD TO SIGNIFICANT COSTS

- SSIs are **21.8%** of all Healthcare Associated Infections.[6]
- Of the top 5 Healthcare Acquired Infections (HAIs), SSI is **33.7%** of the **$9.8 Billion** cost to the US healthcare system.*[5]
- SSIs increase average length of hospital stay by **9.58 days** at an additional cost of **$38,656**.[7]
- Other common complications include dehiscence, hematoma and seroma formation[2-4]

## CONSEQUENCES EXTEND BEYOND DISCHARGE

- Patients with SSI are **6 times** more likely to have a **30-day** readmission than the patients without an SSI.[7]
- Patients with SSIs have an ICU length of stay that is **2.2 times greater** than patients without SSIs.[7]
- Postoperative dehiscence increases average length of hospital stays by **9.42 days** and average costs by **$40,323.**[12]

* Top five HAIs are cental line-associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), Clostridium difficile infection (C diff), Surgical Site Infections (SSI) and catheter-associated urinary tract infection (CAUTI).

# How PREVENA™ Therapy can help

## PREVENA™ Therapy manages and protects surgical incisions utilizing unique PREVENA™ PEEL & PLACE™ Dressings through:

- Delivering continuous negative pressure (-125mmHg) for up to 7 days
- Helping hold incision edges together
- Removing fluids and infectious materials
- Protecting the incision from external infectious sources

## Indication for Use

The PREVENA™ Incision Management System is intended to manage the environment for surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

## Contraindication:

Sensitivity to Silver.

## Optimum Use*

For maximum benefit, the PREVENA™ Incision Management System should be applied immediately post surgery to surgically closed incisions. It is to be continuously applied for a minimum of 2 days up to a maximum of 7 days. It can transition home with the patient.

*Refer to the PREVENA™ Incision Management System Clinician Guide for additional information relating to Optimum Use, Indications and Contraindications, Warnings and Precautions, and Important Safety Information.

# Design of PREVENA™ Incision Dressings

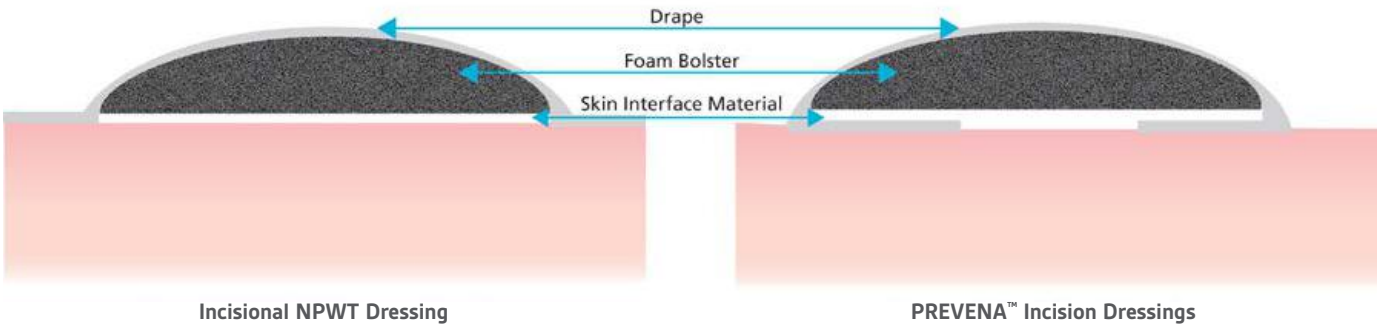
The design of the PREVENA™ Incision Dressings was derived from the NPWT dressing system described by a number of clinicians in their reported clinical studies of incisional NPWT.[9-14] The dressing utilized in these clinical studies was constructed from commercially available materials:

- A skin interface layer (typically, a non-adhering dressing)
- V.A.C.® GRANUFOAM™ Dressing
- V.A.C.® Drape

The dressing was configured as shown in **Figure 1** (Incisional NPWT Dressing) and was manually prepared by the surgeon using costly OR time to construct.

**Figure 1** Illustrates the configuration of these same elements in the PREVENA™ Incision Dressings, which are provided in a pre-constructed configuration that facilitates more efficient dressing application.

**Figure 1.** 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 -125mmHg 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.

# *Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy*[17]

Grauhan O, Navasardyan A, Hofmann M, et al. J Thorac Cardiovasc Surg 2013; 145: 1387 - 92

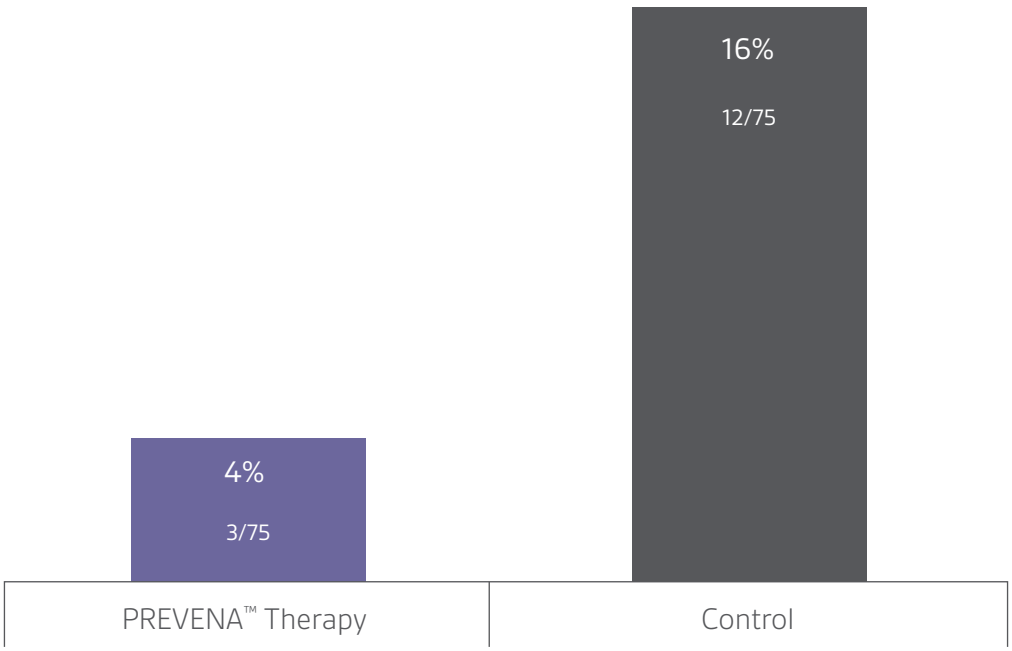
## Clinical summary of Grauhan study

| | |
|---|---|
| Study Purpose | The majority of wound infections after median sternotomy in obese patients are triggered by the breakdown of skin sutures and subsequent seepage of skin flora. The purpose of this study was to evaluate negative pressure wound dressing treatment for the prevention of infection. We hypothesized that negative pressure wound dressing treatment for 6 to 7 days applied immediately after skin closure reduces the numbers of wound infections. |
| Study Design | Prospective, single center clinical trial |
| Subjects | 150 patients with a BMI of 30kg/m$^2$ with cardiac surgery via median sternotomy |
| Treatment | • PREVENA™ Therapy: 75 patients<br>• Standard post-operative dressings: 75 patients |
| Outcome measures | Infection within 90 days |
| Results | |

| | PREVENA™ Therapy | Control | |
|---|---|---|---|
| Patients | 75 | 75 | |
| Total Infections | 3 | 12 | $p$=0.0266 |
| % Infection | 4% | 16% | |

### Infection Rate[17]

$p$=0.0266

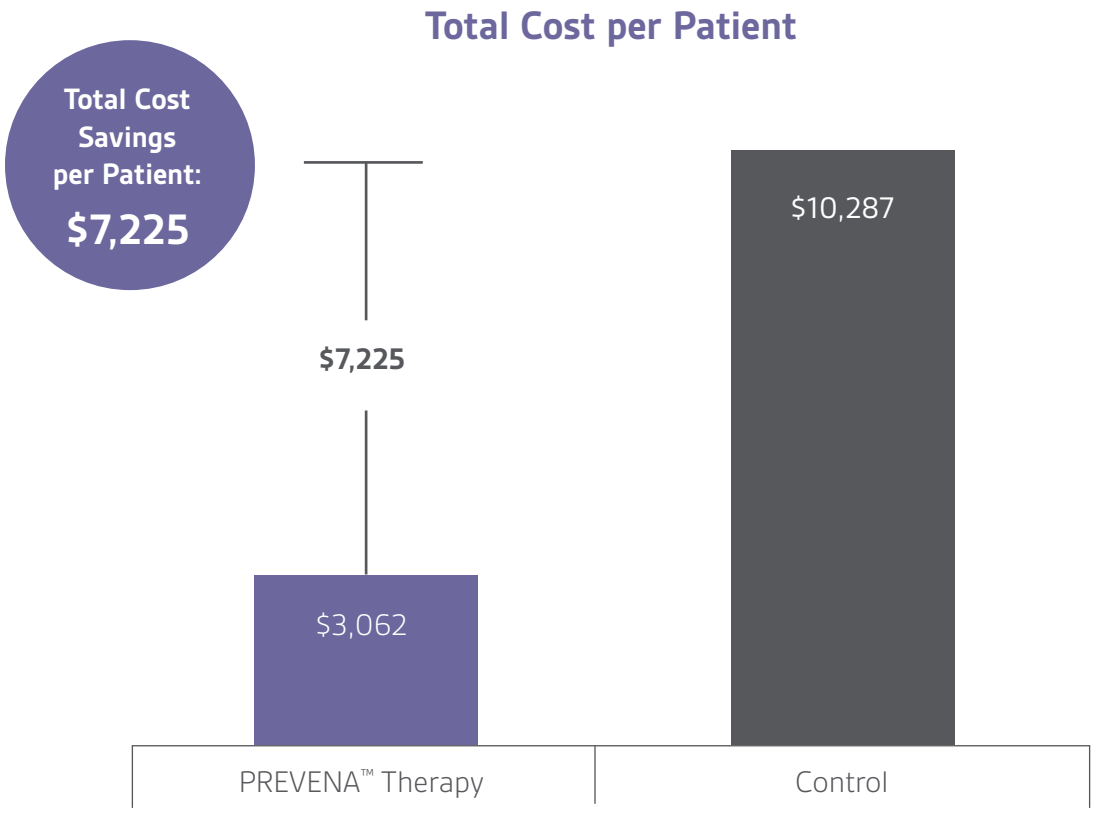


Economic analysis of the Grauhan clinical study results, using Thompson Cost Data[18]

| Sternomoty Incisions | PREVENA™ Therapy | Control |
|---|---|---|
| Patients | 75 | 75 |
| Number of Infections | 3 (4.0%) | 12 (16.0%) |
| Total Infection Cost (Incremental cost of infection = $64,183 per patient) | $192,549 | $770,196 |
| Per Patient Infection Cost (Total Infection Cost / number of patients) | $2,567 | $10,269 |
| Per Patient Cost of Therapy* | $495 | $18 |
| Total Cost Per Patient | $3,062 | $10,287 |

* KCI estimate based on price of PREVENA™ PEEL & PLACE™ Dressing System and Control therapy (gauze) changed once a day at $18 a week.

The model uses select study data to provide an illustration of estimates of costs for use of PREVENA™ Therapy or Standard of Care (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.



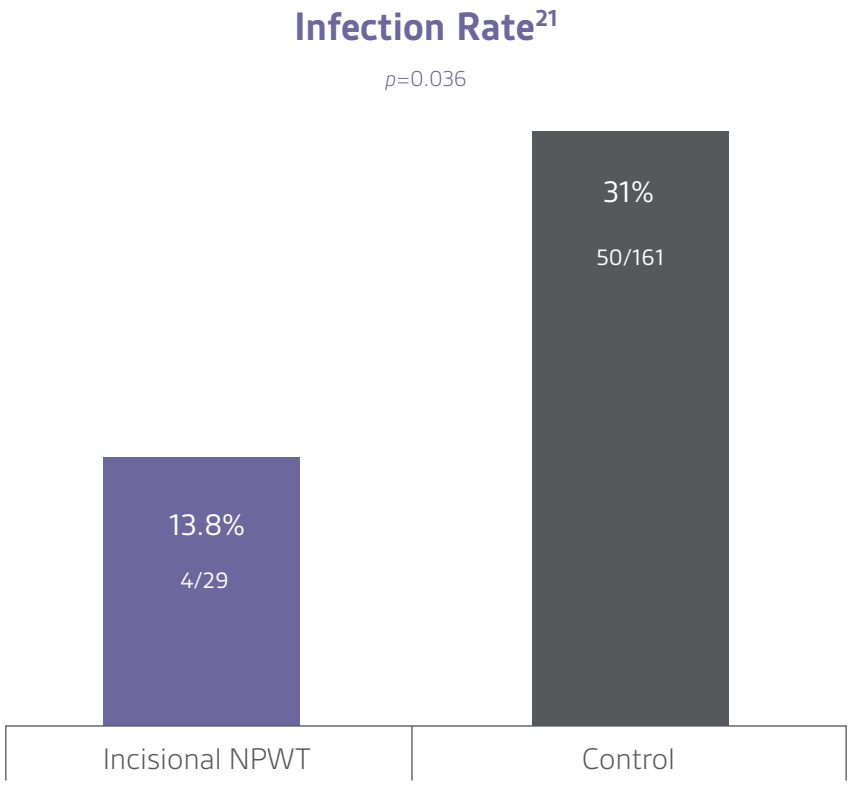
# *Incisional Negative Pressure Wound Therapy Significantly Reduces Surgical Site Infection in Open Colorectal Surgery*[21]

Bonds AM, Novick TK, Dietert JB, et al. Dis Colon Rectum. 2013;56(12):1403-1408. Note: see sub set data page 1406

## Clinical summary of Bonds study

| | |
|---|---|
| Study Purpose | Surgical site infections in colorectal surgery remain a common problem and are associated with an increase in cost of care and length of stay. This study aims to evaluate the effect of known risk factors and the use of incisional negative pressure wound therapy on surgical site infection rates. |
| Study Design | Retrospective chart review at two main hospitals in a single tertiary academic medical center. |
| Subjects | 190 non-emergent patients undergoing open colectomy from 2009 and 2011 were studied. |
| Treatment | • Incisional NPWT at -75mmHg, applied equivalently to PREVENA™ Therapy: 29<br>• Occlusive dressings: 161 |
| Outcome measures | Presence or absence of surgical site infection |
| Results | Incisional NPWT* / Control<br>Patients: 29 / 161<br>Total Infections: 4 / 50 $p$ =0.036<br>% Infection: 13.8% / 31% |

*PREVENA™ Therapy is functionally equivalent to the incisional NPWT reported in this study, and the reported clinical outcomes can be applied to PREVENA™ Therapy.



Economic analysis of the Bonds clinical study results, using Thompson Cost Data[22]

| Colorectal Incisions | Incisional NPWT | Control |
|---|---|---|
| Patients | 29 | 161 |
| Number of Infections | 4 | 50 |
| Total Infection Cost (Incremental cost of infection = $17,324 per patient) | $69,296 | $866,200 |
| Per Patient Infection Cost (Total Infection Cost / number of patients) | $2,389 | $5,380 |
| Per Patient Cost of Therapy* | $595 | $18 |
| Total Cost Per Patient | $2,984 | $5,398 |

* KCI estimate based on the price of PREVENA™ Customizable™ Dressing System to Control therapy (gauze) changed once a day at $18 a week.

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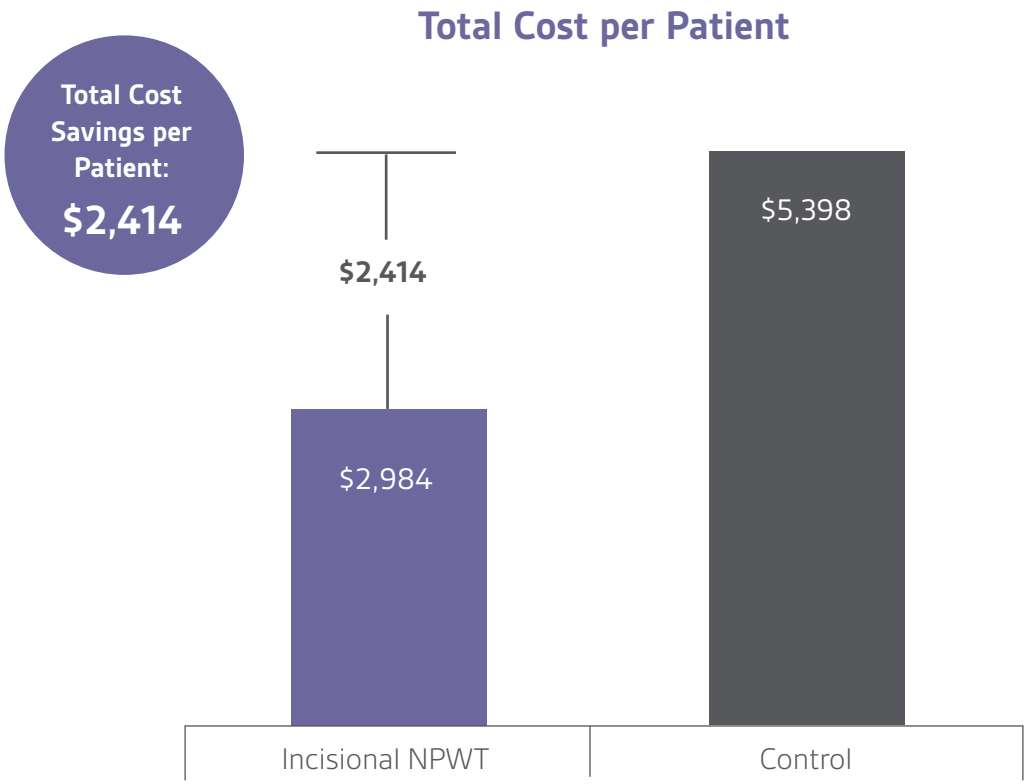


# *Experience with a new negative pressure incision management system in prevention of groin wound infection in vascular surgery patients*[19]

Matatov T, Reddy KN, Doucet LD, et al. J Vasc Surg 2013 January 9.

## Clinical summary of Matatov study

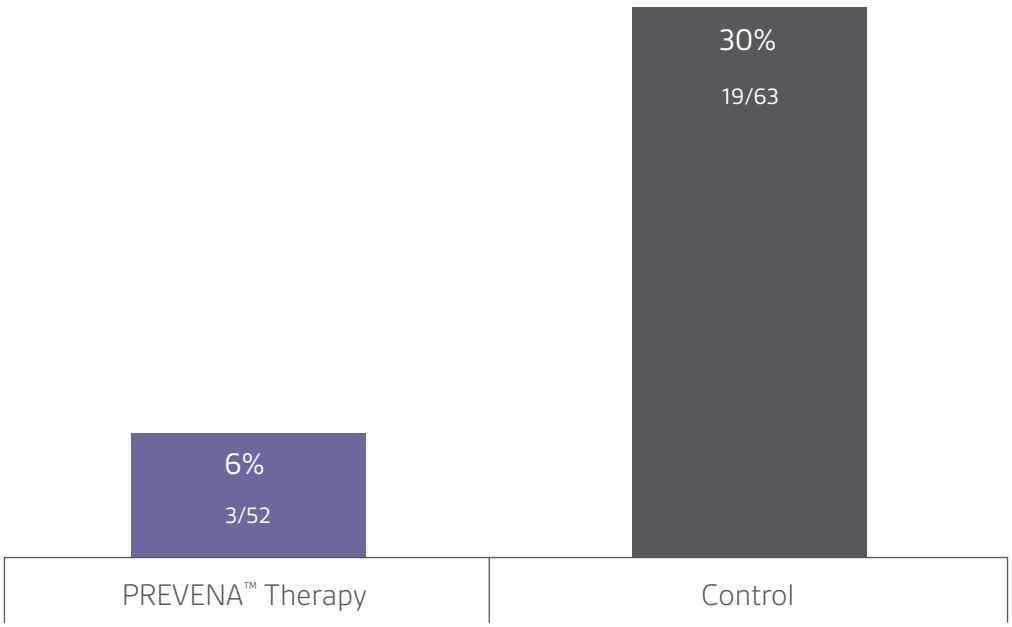
| | |
|---|---|
| Study Purpose | Groin wound infection is an important cause of postoperative morbidity in vascular surgery patients, especially when prosthetic grafts are involved. The objective of this study was to investigate if PREVENA™ Therapy, a negative pressure incision management system, could reduce the risk of groin wound infection in patients after vascular surgery. |
| Study Design | Retrospective chart review of consecutive patients at a single center |
| Subjects | 90 patients with 115 groin incisions who underwent femoral cutdown for vascular procedures. |
| Treatment | • PREVENA™ Therapy: 41 patients<br>• Skin adhesive or absorbent dressing: 49 patients |
| Outcome measures | Groin wound infection, graded based on Szilzgyi classifications. |

**Results**

| | PREVENA™ Therapy | Control |
|---|---|---|
| Patients | 41 | 49 |
| Incisions | 52 | 63 |
| Total Infections | 3 (all grade I) | 19 (10 grade I; 7 grade II and 2 grade III) $p$=0.0011 |
| % Infection | 6% | 30% |

## Infection Rate[19]

$p$=0.0011

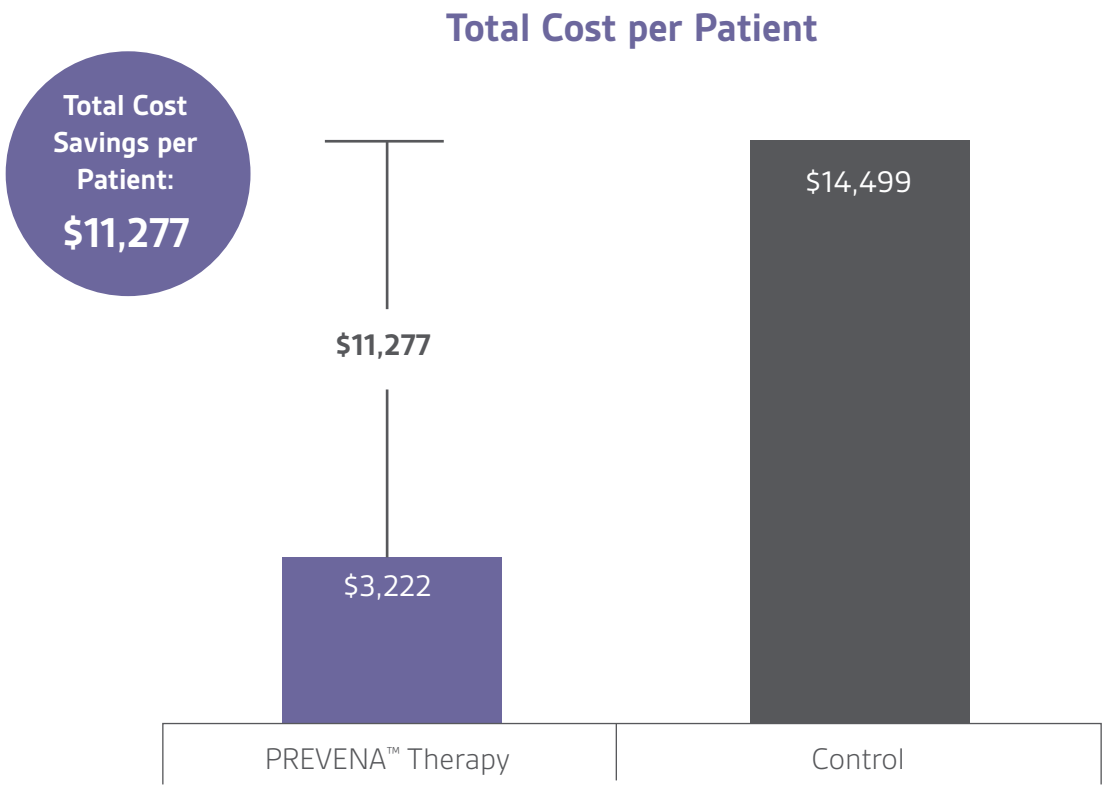


Economic analysis of the Matatov clinical study results, using Thompson Cost Data[20]

| Groin Incisions | PREVENA™ Therapy | Control |
|---|---|---|
| Patients | 41 | 49 |
| Incisions | 52 | 63 |
| Number of Infections* | 3 | 19 |
| Total Infection Cost (Incremental cost of infection = $37,274 per patient) | $111,822 | $708,206 |
| Per Patient Infection Cost (Total Infection Cost / number of patients) | $2,727 | $14,453 |
| Per Patient Cost of Therapy** | $495 | $46 |
| Total Cost Per Patient | $3,222 | $14,499 |

* Model assumes that patients could only have 1 infection.
**KCI estimate based on PREVENA™ PEEL & PLACE™ Dressing System and Non-PREVENA™ Therapy of Dermabond™ is changed once a week at $45.83 ($275/6 for 6 vials), see: http://www.claflinequip.com/ethicon-high-viscosity-dermabond-topical-skin-adhesive.html?childid=60829#60829

The model uses select study data to provide an illustration of estimates of costs for use of PREVENA™ Therapy or Dermabond™ (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.



# *Incisional negative pressure wound therapy after high-risk lower extremity fractures*[15]

Stannard JP, Volgas DA, McGwin G III, et al. J Orthop Trauma. 2012:26(1):37-42.

## Clinical summary of Stannard study

| | |
|---|---|
| Study Purpose | To investigate negative pressure wound therapy (NPWT) to prevent wound dehiscence and infection after high-risk lower extremity trauma. |
| Study Design | Prospective, randomized multicenter clinical trial |
| Subjects | 249 blunt trauma patients with one of three high risk fracture types (tibial plateau, pilon, calcaneus) requiring surgical stabilization |
| Treatment | • Incisional NPWT at -125mmHg, applied equivalently to PREVENA™ Therapy: 130 patients<br>• Standard post-operative dressings: 119 patients |
| Outcome measures | Acute and chronic wound dehiscence and infection |

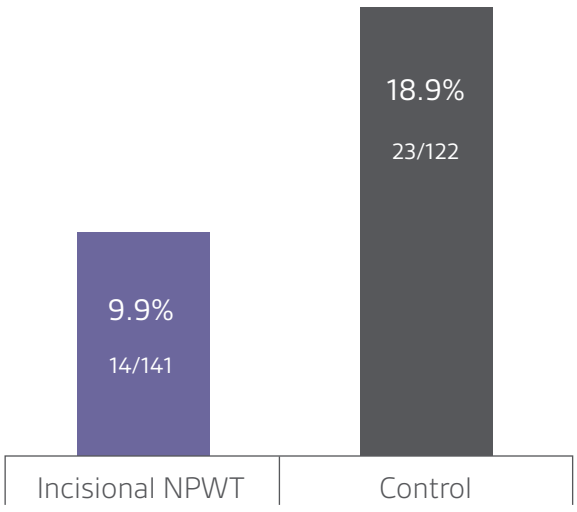
**Results**

| | Incisional NPWT* | Control | |
|---|---|---|---|
| Patients | 130 | 119 | |
| Fractures | 141 | 122 | |
| Total Infections | 14 | 23 | |
| % Infection | 9.9% | 18.9% | $p$=0.049 |
| Total Dehiscence | 12 | 20 | |
| % Dehiscence | 8.6% | 16.5% | $p$=0.044 |

*PREVENA™ Therapy is functionally equivalent to the incisional NPWT reported in this study, and the reported clinical outcomes can be applied to PREVENA™ Therapy.

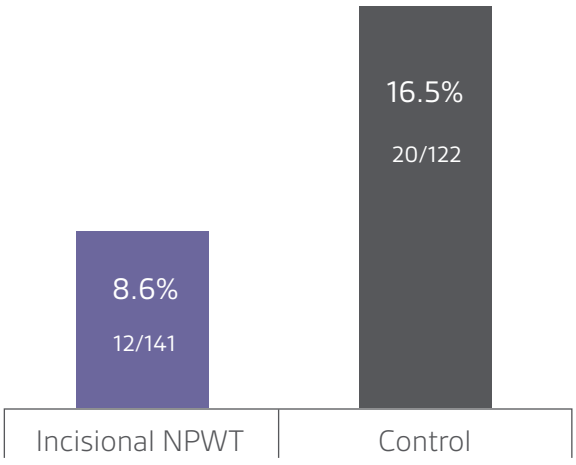
### Infection Rate

$p$=0.049




### Dehiscence Rate

$p$=0.044



Economic analysis of the Stannard clinical study results, using Thompson Cost Data[16]

| Orthopedic Incisions | Incisional NPWT | Control |
|---|---|---|
| Patients | 130 | 119 |
| Number of Infections* | 14 | 23 |
| Number of Dehiscence* | 12 | 20 |
| Total Infection Cost (Incremental cost of infection = $64,611 per patient) | $904,554 | $1,486,053 |
| Total Dehiscence Cost (Incremental cost of dehiscence = $26,447 per patient) | $317,364 | $528,940 |
| Per Patient Infection Cost (Total Infection Cost / number of patients) | $6,958 | $12,488 |
| Per Patient Dehiscence Cost (Total Dehiscence Cost / number of patients) | $2,441 | $4,445 |
| Per Patient Cost of Therapy** | $495 | $18 |
| Total Cost Per Patient | $9,894 | $16,951 |

* Model assumes that patients could only have 1 infection and 1 dehiscence.
** KCI estimate based on price of PREVENA™ PEEL & PLACE™ Dressing System and Control therapy (gauze) changed once a day at $18 a week.

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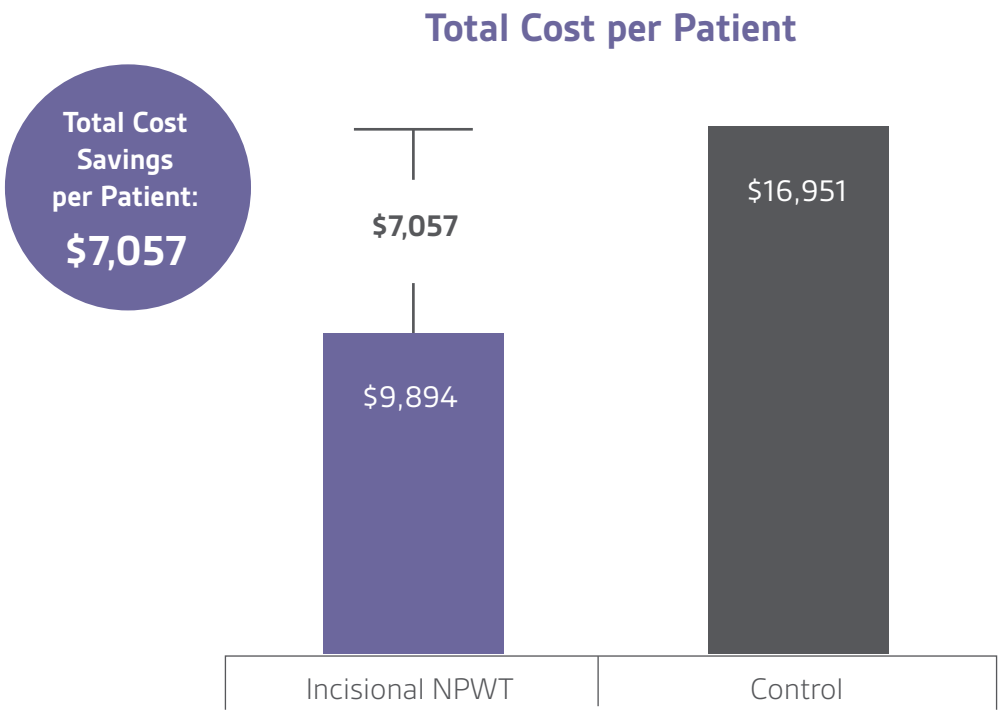

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15. Stannard JP, Volgas DDA, McGwin G, et al. Incisional negative pressure wound therapy after high-risk lower extremity fractures. Journal of Orthopedic Trauma. 2012; 26(1):37-42.
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17. Grauhan O, Navasardyan A, Hofmann M, et al. Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy. J Thorac Cardiovasc Surg 2013; 145: 1387 - 92 .

18. Market Research National Level Report. Data from the Marketscan Projected Inpatient, Hospital Drug and Medpar Databases: Calendar Year 2011. New York, NY: Thomson Reuters; 2013 Mar.

19. Matatov T, Reddy KN, Doucet LD, et al. Experience with New Negative Pressure in Incision Management System in Prevention of Groin Wound Infection in Vascular Surgery Patients. J Vasc Surg 2013 January 9.

20. Market Research National Level Report. Data from the Marketscan Projected Inpatient, Hospital Drug and Medpar Databases: Calendar Year 2008. New York, NY: Thomson Reuters; 2009 Oct 1 Incremental cost of infection is based on a national average of all patients with ICD9 39.29 –other shunt and vascular bypass and a co-occurring complication of infection.

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# THE NEGATIVE PRESSURE INCISION MANAGEMENT SYSTEM WITH THE MOST PUBLISHED CLINICAL EVIDENCE*

## PREVENA™ THERAPY HELPS MANAGE AND PROTECT CLOSED SURGICAL INCISIONS UTILIZING A UNIQUE PREVENA™ PEEL & PLACE™ DRESSING

- Helps hold incision edges together
- Removes fluids and infectious materials
- Acts as a barrier to external contamination
- Delivers continuous negative pressure at -125mmHg, for up to 7 days

*Among negative pressure based incision management systems

## Help manage closed surgical incisions with PREVENA™ Therapy

| Item # | Product Name | Qty | Components |
|---|---|---|---|
| **PREVENA™ PEEL & PLACE™ SYSTEM** | | | |
| **PRE1001US** | PREVENA™ PEEL & PLACE™ System – 20cm (For use on up to 20cm linear incisions) | 1 | PREVENA™ 125 Therapy Unit • PREVENA™ PEEL & PLACE™ Dressing with Pressure Indicator – 20cm • PREVENA™ Patch Strips • PREVENA™ 45ml Canister • PREVENA™ Carrying Case • V.A.C.® Therapy Unit Connector |
| **PRE1055US** | PREVENA™ PEEL & PLACE™ Dressing – 20cm (For use on up to 20cm linear incisions) | 5 | PREVENA™ PEEL & PLACE™ Dressings with Pressure Indicator – 20cm • PREVENA™ Patch Strips • V.A.C.® Therapy Unit Connector |
| **PRE1101US** | PREVENA™ PEEL & PLACE™ System – 13cm (For use on up to 13cm linear incisions) | 1 | PREVENA™ 125 Therapy Unit • PREVENA™ PEEL & PLACE™ Dressing with Pressure Indicator – 13cm • PREVENA™ Patch Strips • PREVENA™ 45ml Canister • PREVENA™ Carrying Case • V.A.C.® Therapy Unit Connector • Ruler with sticker |
| **PRE1155US** | PREVENA™ PEEL & PLACE™ Dressing – 13cm (For use on up to 13cm linear incisions) | 5 | PREVENA™ PEEL & PLACE™ Dressings with Pressure Indicator – 13cm • PREVENA™ Patch Strips • V.A.C.® Therapy Unit Connector • Ruler with sticker |
| **PREVENA™ CUSTOMIZABLE™ SYSTEM** | | | |
| **PRE2001US** | PREVENA™ CUSTOMIZABLE™ System Kit (For use on non-linear or up to 90cm linear incisions) | 1 | PREVENA™ 125 Therapy Unit • PREVENA™ CUSTOMIZABLE™ Dressing with Hydrocolloid – 90cm • PREVENA™ Therapy Interface Pad with Pressure Indicator • Hydrocolloid Strips • V.A.C.® Drape • Ruler with sticker • PREVENA™ 45ml Canister • PREVENA™ Carrying Case • V.A.C.® Therapy Unit Connector |
| **PRE2055US** | PREVENA™ CUSTOMIZABLE™ Dressing (For use on non-linear or up to 90cm linear incisions) | 5 | PREVENA™ CUSTOMIZABLE™ Dressing with Hydrocolloid • PREVENA™ Therapy Interface Pad with Pressure Indicator • Hydrocolloid Strips • V.A.C.® Drape • Ruler with sticker • V.A.C.® Therapy Unit Connector |
| **PRE1095** | PREVENA™ 45ml Canister | 5 | 45ml Canister |

## For more information, contact your KCI representative or visit acelity.com.

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

**NOTE: Specific indications, warnings, precautions and safety information exist for the PREVENA™ Incision Management system. Please consult the PREVENA™ Incision Management System Clinician Guide Instructions for Use prior to application. Rx only.**



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