PREVENA™
INCISION MANAGEMENT SYSTEM

Evidence Brochure

KCI
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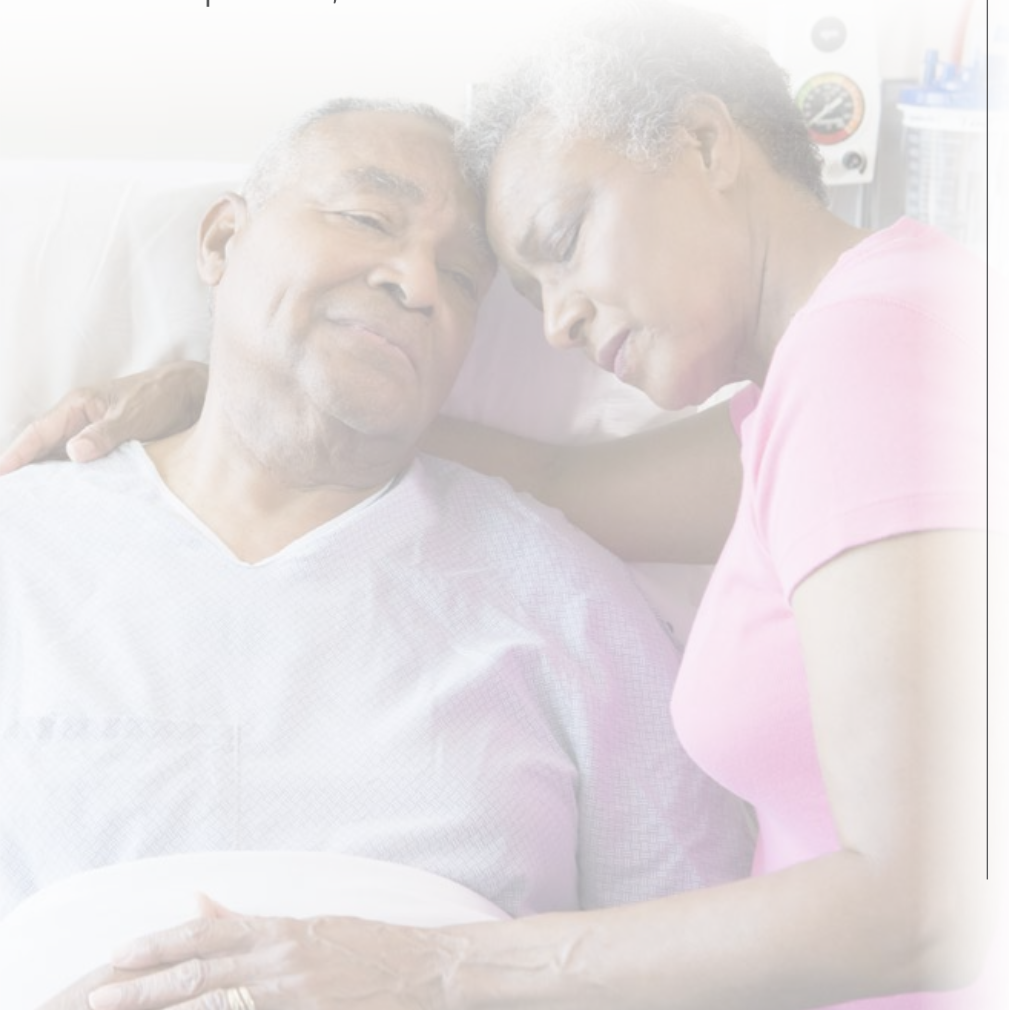
Incisions can be **COMPLICATED**

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

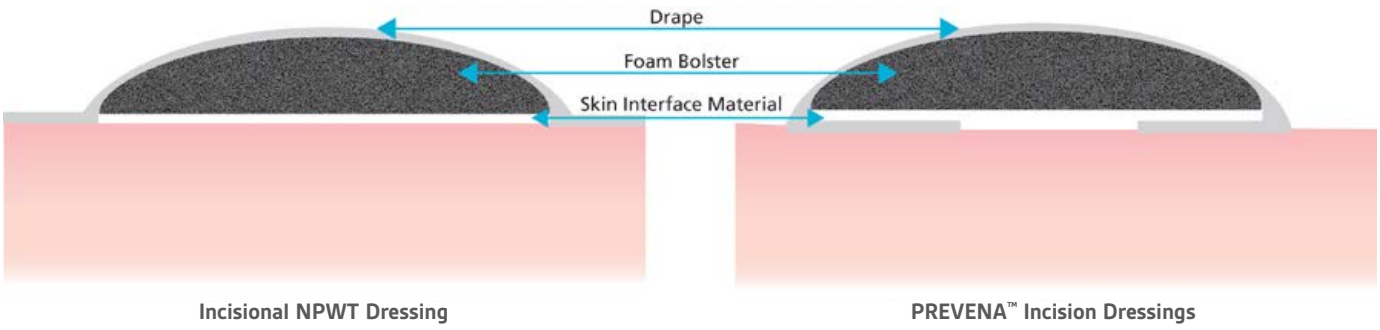
The design of the PREVENA™ Incision Dressings was derived from the NPWT dressing system described by a number of clinicians in their reported clinical studies of incisional NPWT.[9-14] The dressing utilized in these clinical studies was constructed from commercially available materials:

- 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

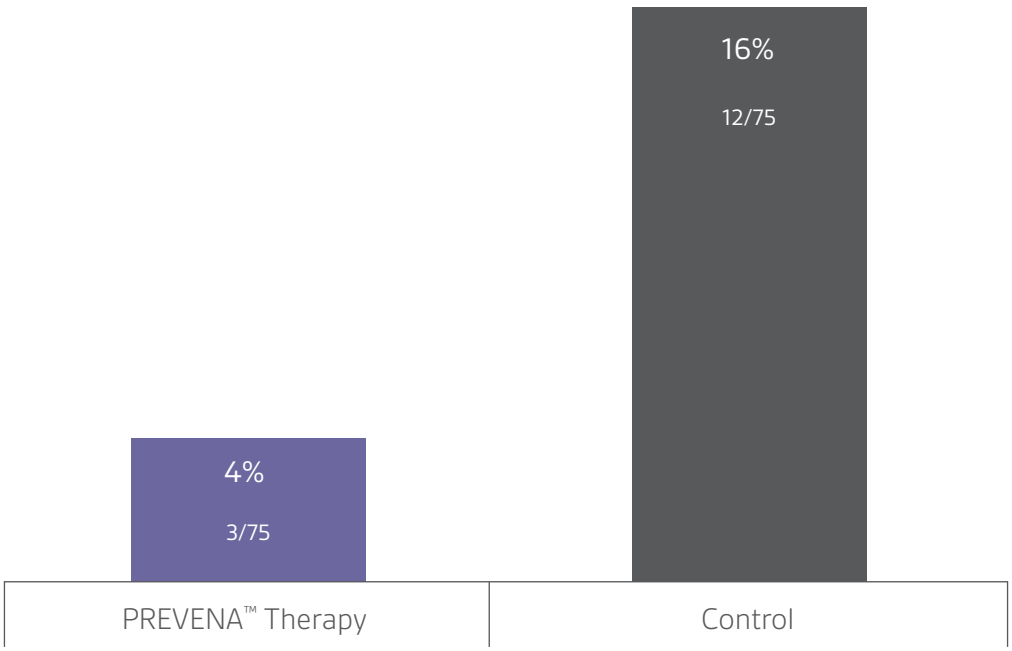
Clinical summary of Grauhan study

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 • 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

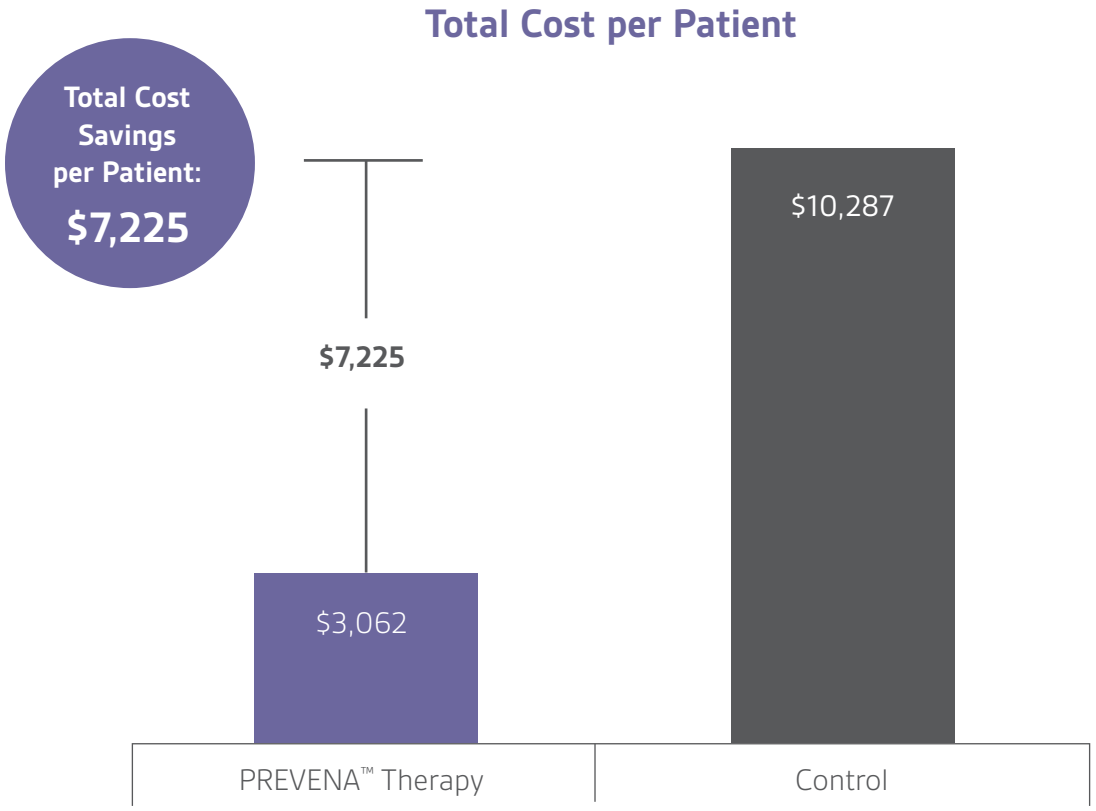


Economic analysis of the Grauhan clinical study results, using Thompson Cost Data[18]

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.



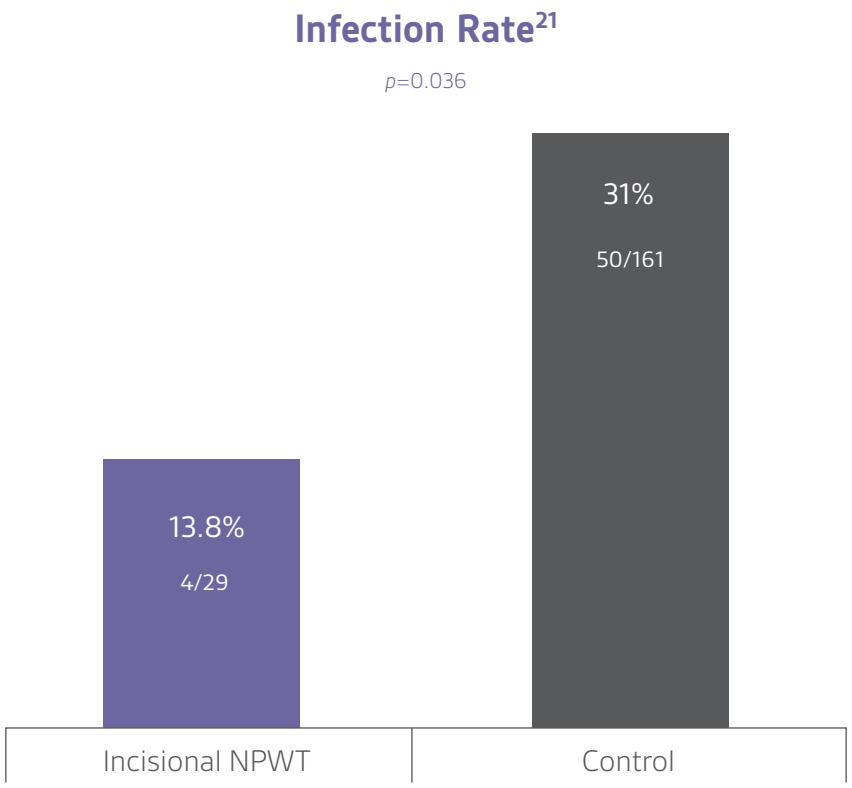
Incisional Negative Pressure Wound Therapy Significantly Reduces Surgical Site Infection in Open Colorectal Surgery[21]

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 • Occlusive dressings: 161
Outcome measures	Presence or absence of surgical site infection
Results	Incisional NPWT* / Control Patients: 29 / 161 Total Infections: 4 / 50 p =0.036 % 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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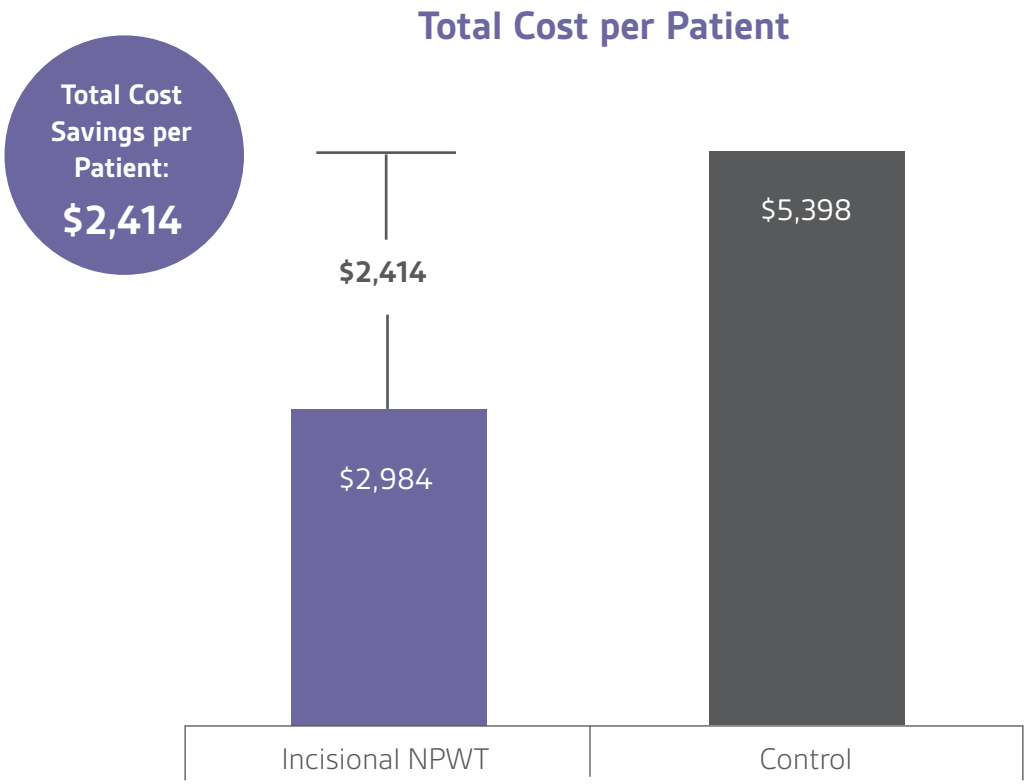


Experience with a new negative pressure incision management system in prevention of groin wound infection in vascular surgery patients[19]

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

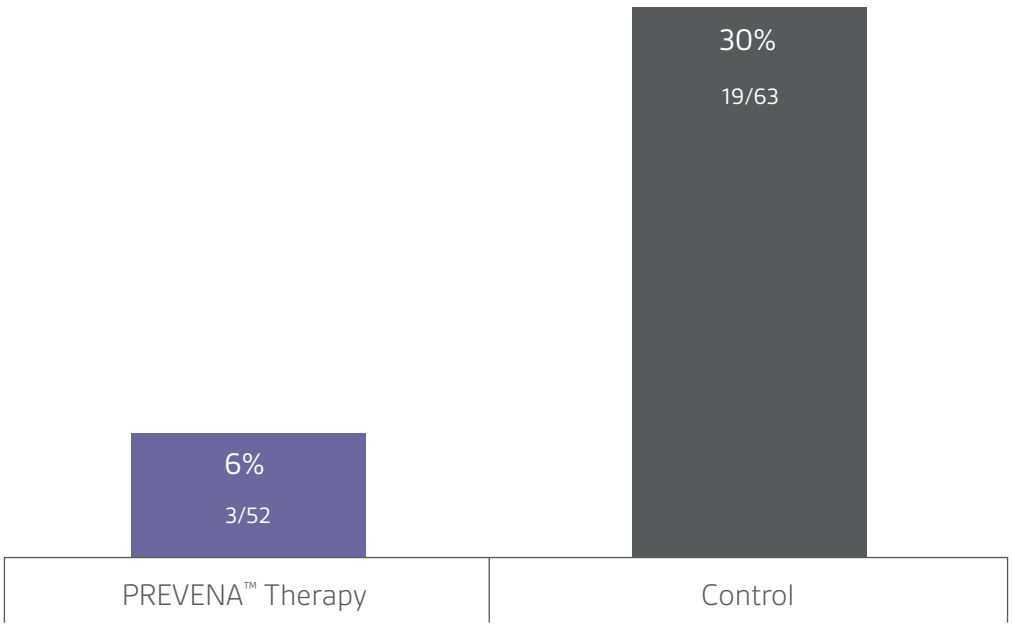
Clinical summary of Matatov study

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 • 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

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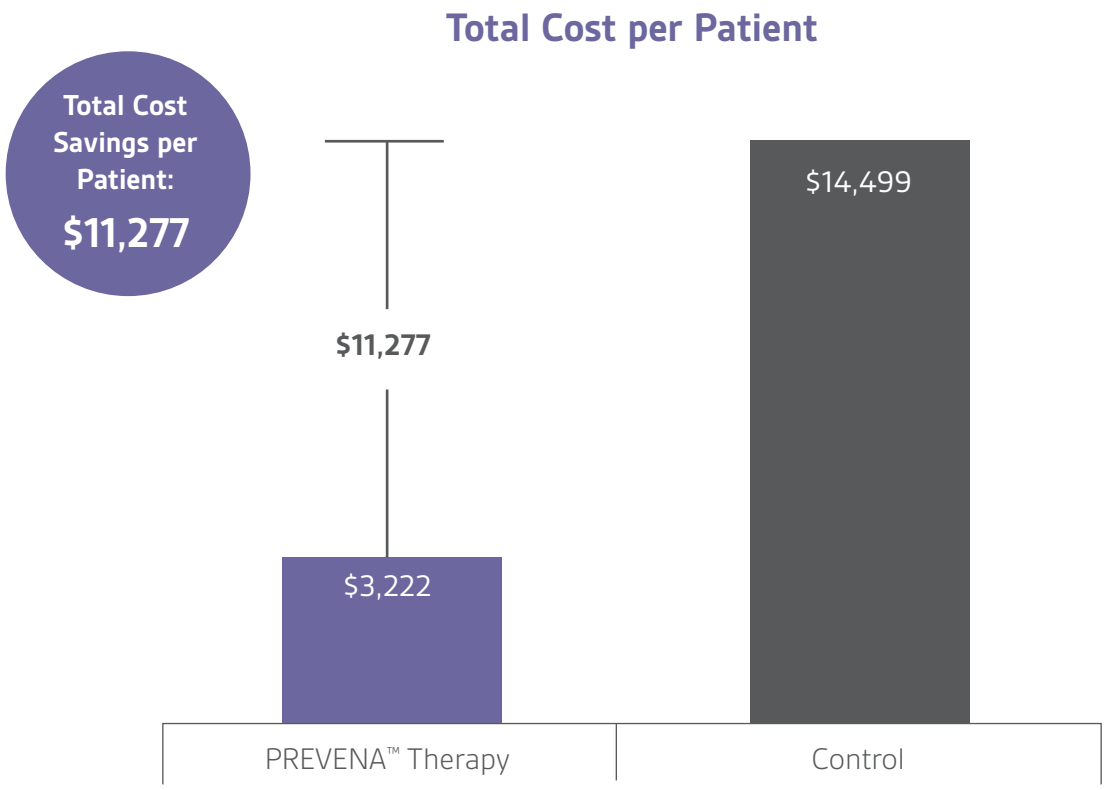


Incisional negative pressure wound therapy after high-risk lower extremity fractures[15]

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 • Standard post-operative dressings: 119 patients
Outcome measures	Acute and chronic wound dehiscence and infection

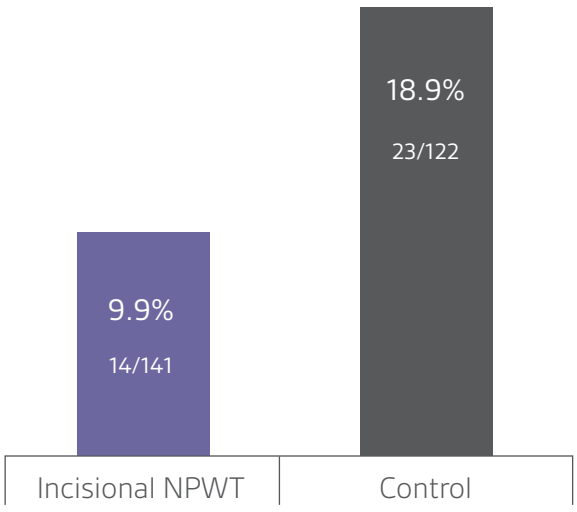
Results

	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.

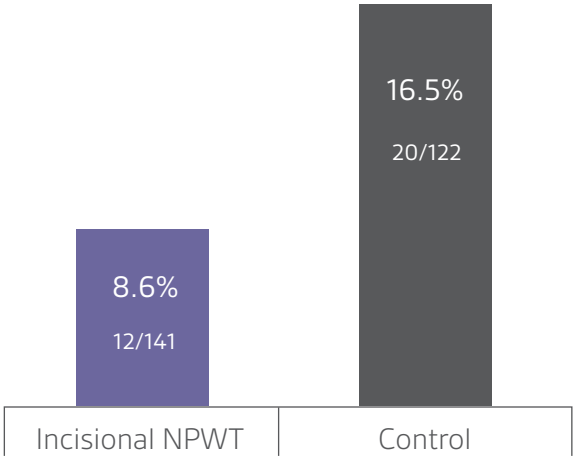
Infection Rate

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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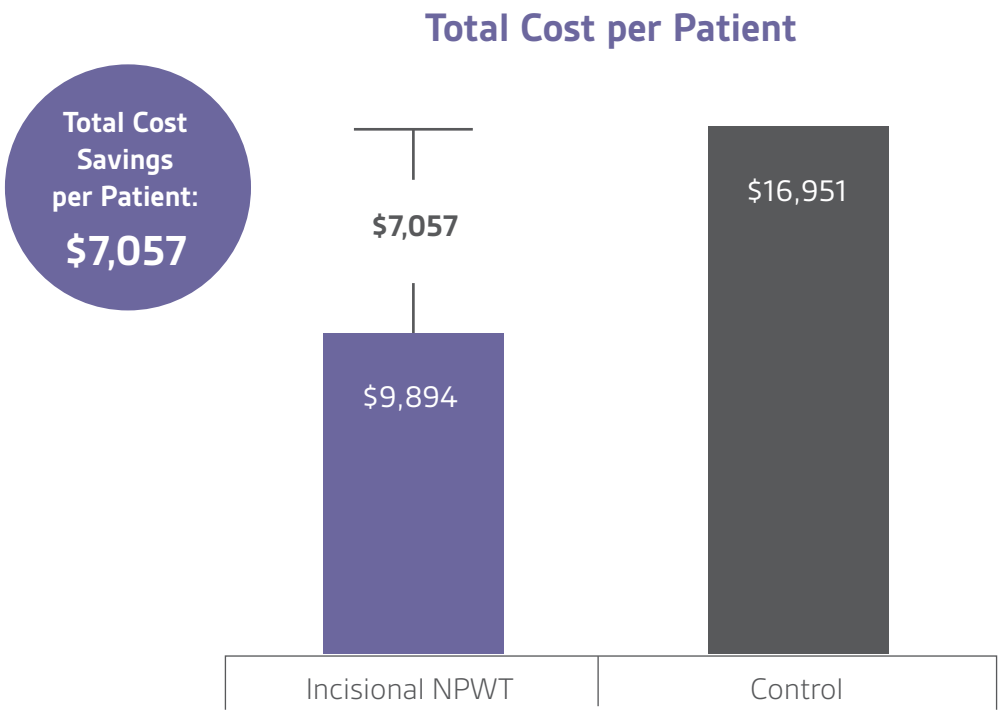

References

1. Shrestha BM, Nathan VC, Delbridge MS, et al. Vacuum-assisted closure (VAC) therapy in the management of wound infection following renal transplantation. Kathmandu Univ Med J. 2007;5:4-7.
2. Riou JP, Cohen JR, Johnson H Jr. Factors influencing wound dehiscence. Am J Surg. 1992;163:324-330.
3. Wilson JA, Clark JJ. Obesity: impediment to postsurgical wound healing. Adv Skin Wound Care. 2004;17:426-435.
4. Abbas SM, Hill AG. Smoking is a major risk factor for wound dehiscence after midline abdominal incision; case-control study. ANZ J Surg. 2009;79:247-250.
5. Zimlichman E, Henderson D, Tamir, et al. Health Care-Associated Infections A Meta-analysis of Costs and Financial Impact on the US Health Care System. JAMA Intern ed.2013;173(22):2039-46.
6. Magill SS, Edwards JR, Bamberg W, et al. Multistate Point-Prevalence Survey of Health Care-Associated Infections. N Engl JMed: 2014;370:1198-208.
7. Shepard J, Ward W, Milstone A, et al. Financial Impact of Surgical Site Infections on Hospitals. The Hospital Management Perspective. JAMA Surg. 2013;148(10):907-914. doi:10.1001/jamasurg.2013.2246 Published online August 21, 2013.
8. US Department of Health and Human Services. Hospital-Acquired Conditions and Present on Admission Indicator Reporting Provision. ICN 901046. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/wPOAFactSheet. Published September 2014. Accessed June 10, 2015.
9. Olsen K. Prevention of Surgical Site Infections: Improving Compliance With the Surgical Care Improvement Project Measures. http://www.medscape.com/viewarticle/705366. Accessed September 20, 2010.
10. Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep. 2007;122:160-166.
11. National Nosocomial Infections Surveillance report, data summary from October 1986-April 1996, issued May 1996. A report from the National Nosocomial Infections Surveillance System. Am J Infect Control. 1996;24:380-388.
12. Riou JP, Cohen JR, Johnson H Jr. Factors influencing wound dehiscence. Am J Surg. 1992;163:324-330.
13. Wilson JA, Clark JJ. Obesity: impediment to postsurgical wound healing. Adv Skin Wound Care. 2004;17:426-435.
14. Abbas SM, Hill AG. Smoking is a major risk factor for wound dehiscence after midline abdominal incision; case-control study. ANZ J Surg. 2009;79:247-250.
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.
16. 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.

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.

21. Bond AM, Novick TX, Dietert JB, et al. Incisional Negative Pressure Wound Therapy Significantly Reduces Surgical Site Infection in Open Colorectal Surgery. Diseases of the Colon & Rectum Volume 56: 12 (2013). 1403-1408. note: see sub set data page 1406

22. Wick EC, Hirose K, Shore AD, et al. Surgical site infections and cost in obese patients undergoing colorectal surgery. Arch Surg. 2011 Sep; 146 (9): 1068-72.

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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