3M | PREVENA™
Incision Management System

Evidence Brochure

Expanded FDA Indication
PREVENA™ 125 and
PREVENA PLUS™ 125
Therapy Unit

Incisions can be complicated

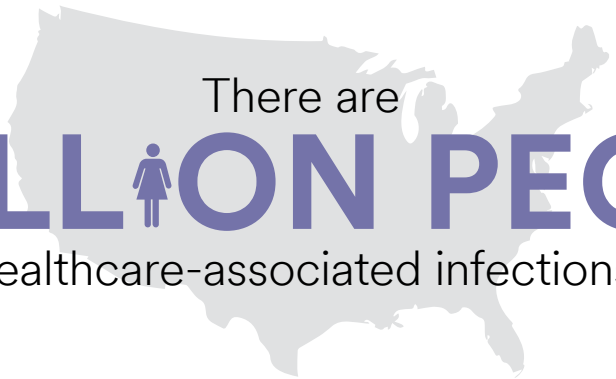
Certain surgical procedures and patient conditions can make healing difficult

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 MILLION PEOPLE

at risk for healthcare-associated infections annually.[5]

Post-surgical complications lead to significant costs

Surgical site infections (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 an SSI are **6 times** more likely to have a

30-DAY readmission

than 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[2, 8-10]

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[11]:

1. Mediastinitis following coronary artery bypass graft (CABG)
2. SSIs following certain orthopedic procedures
3. SSIs following bariatric surgery for obesity

*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

The FDA granted the following Indications for Use:*

PREVENA™ 125 and PREVENA PLUS™ 125 Therapy Units manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, PREVENA™ 125 and PREVENA PLUS™ 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.

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.

Clinical evidence supporting the new indication

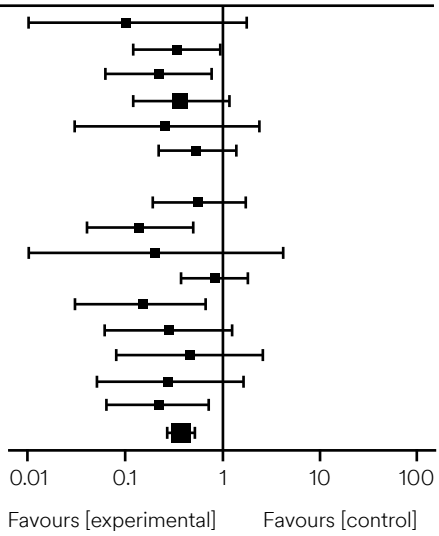
A systematic literature review and associated meta-analysis were used to support the safety and effectiveness of PREVENA™ Therapy over closed incisions in reducing the incidence of surgical site infections (SSIs) and seromas versus conventional wound dressings.

- Out of 426 studies in the initial search, ultimately, sixteen (16) prospective studies were included in thismeta-analysis for SSI characterization
- A total of up to 6,187 evaluable patients were included in this meta-analysis for SSI with 1,264 in the PREVENA™ Therapy (treatment) group and 4,923 in the conventional wound dressing (control) group
- 9 randomized controlled trials (RCTs) were included in a subgroup analysis for SSI in high risk patients

PREVENA™ Therapy demonstrated the greatest benefit in reducing SSIs in high risk patients

Forest Plot of Meta-Analysis on Surgical Site Infection

	Treatment			Control				
Study or Subgroup	Events	Total	(%)	Events	Total	(%)	Odds Ratio (95% CI)	Odds Ratio (95% CI)
Cantero 2016	0	17	(0.0)	9	43	(20.9)	0.10 (0.01, 1.89)	
Dimuzio P 2017	6	59	(10.2)	15	60	(25.0)	0.34 (0.12, 0.95)	
Grauhan O 2013	3	75	(4.0)	12	75	(16.0)	0.22 (0.06, 0.81)	
Grauhan O 2014	3	237	(1.3)	119	3508	(3.4)	0.37 (0.12, 1.16)	
Gunatiliake RP 2017	1	39	(2.6)	4	43	(9.3)	0.26 (0.03, 2.40)	
Lavryk O 2016	7	55	(12.7)	21	101	(20.8)	0.56 (0.22, 1.40)	
Lee AJ 2016	0	27	(0.0)	0	17	(0.0)	Not estimable	
Lee K 2017	6	53	(11.3)	9	49	(18.4)	0.57 (0.19, 1.73)	
Matatov T 2013	3	52	(5.8)	19	63	(30.2)	0.14 (0.04, 0.51)	
NCT01341444	0	28	(0.0)	2	30	(6.7)	0.20 (0.01, 4.35)	
NCT02196310	13	145	(9.0)	16	154	(10.4)	0.85 (0.39, 1.83)	
NEWMAN JM 2017	2	80	(2.5)	12	80	(15.0)	0.15 (0.03, 0.67)	
Redfern RE 2017	2	196	(1.0)	14	400	(3.5)	0.28 (0.06, 1.26)	
Ruhstaller K 2017	2	61	(3.3)	4	58	(6.9)	0.46 (0.08, 2.60)	
Sabat J 2016	2	3D	(6.7)	7	33	(21.2)	0.27 (0.05, 1.39)	
Swift SH 2015	3	110	(2.7)	24	209	(11.5)	0.22 (0.06, 0.73)	
Total		1264			4923		0.37 (0.27, 0.52)	



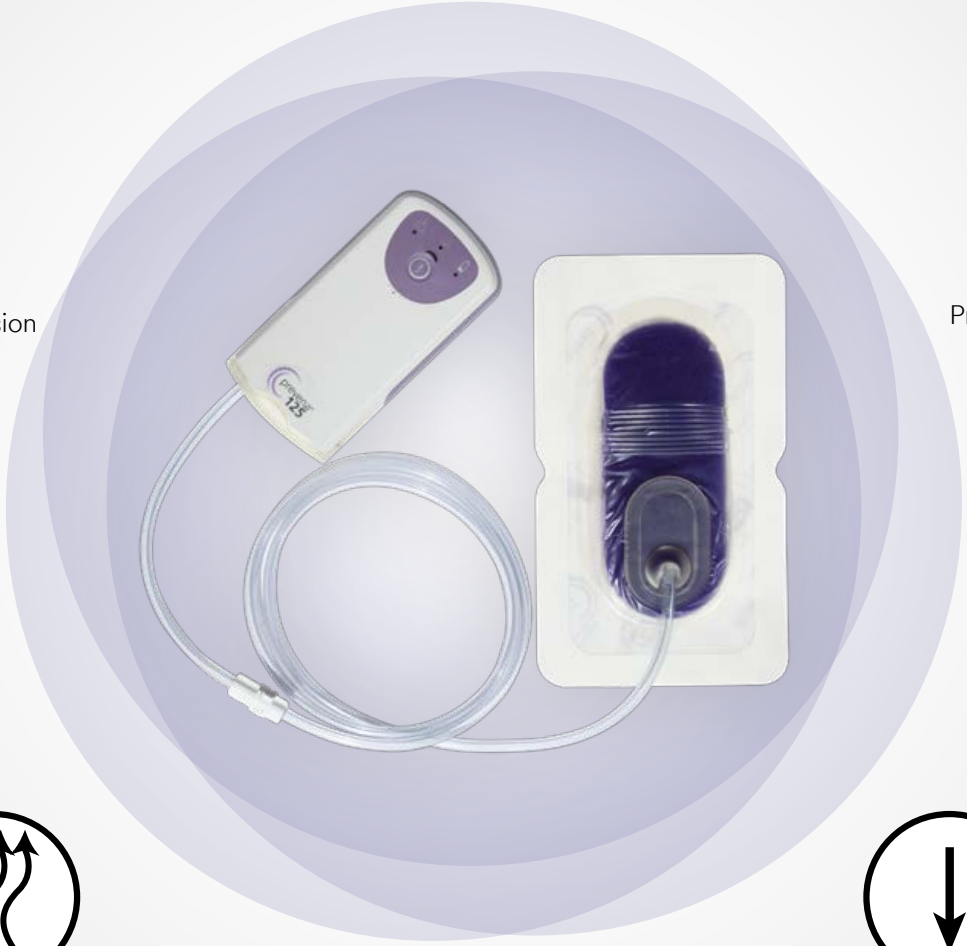
***The effectiveness of PREVENA™ Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at myKCI.com.**

†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.

PREVENA™ THERAPY manages and protects surgicial incisions ultilizing unique PREVENA™ DRESSINGS by:

Delivering continuous
-125mmHg up to 7 days

Helping to hold incision
edges together



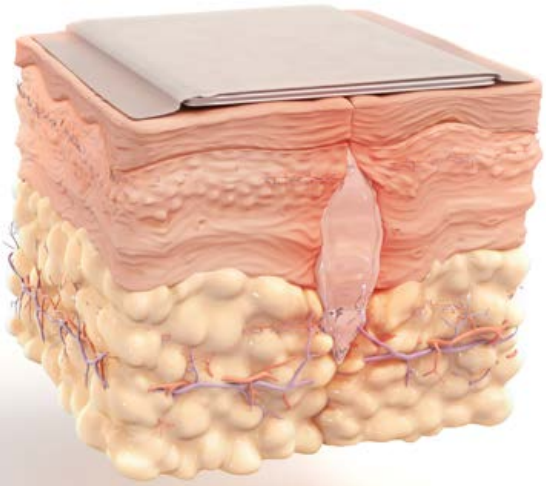
Protecting the incision
from external
infectious sources

Removing fluids
and infectious
materials

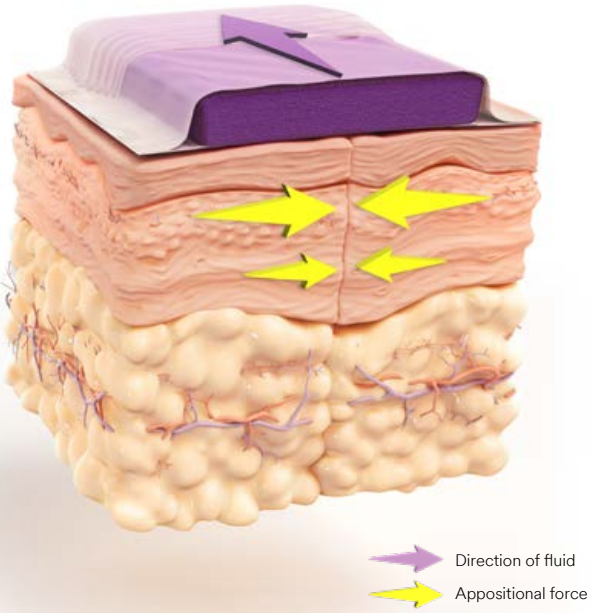
Reducing
edema

PREVENA™ THERAPY utilizes reticulated open cell foam technology and -125mmHg pressure

Passive Therapy



PREVENA™ Therapy



Under -125mmHg of negative pressure, the Reticulated Open Cell Foam dressing collapses to it's geometric center. This brings the incision edges together, reduces lateral tension, and also allows for improved fluid management.[12-14]

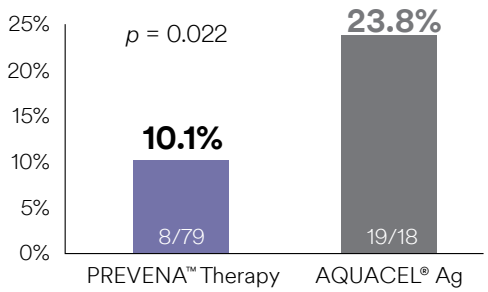
- Contours in PREVENA™ Therapy Dressings allow for even distribution of negative pressure
- Adhesive film creates a barrier to external contaminants
- Designed to conform to articulating joints to allow movement
- Skin interface layer contains 0.019% ionic silver, which reduces bacterial colonization in the fabric
- Multiple sizes and configurations
- PREVENA™ 125 Therapy Unit and PREVENA™ Dressings are shower friendly†

†See PREVENA™ Therapy Patient and Clinician Guides for additional details

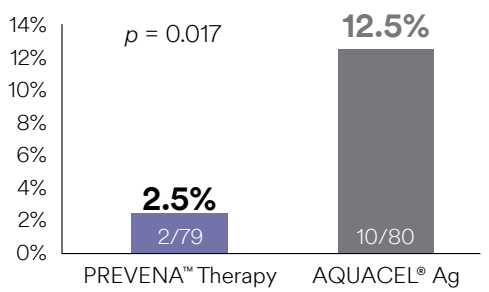
Use of closed incisional negative pressure wound therapy after revision total hip and knee arthroplasty in patients at high risk for infection: A prospective, randomized clinical trial[15]

- The purpose of the Newman study was to compare the use of PREVENA™ Therapy to a sterile antimicrobial dressing (AQUACEL® Ag) in revision arthroplasty patients who were at high risk to develop wound complications.
- 160 patients undergoing elective revision arthroplasty were prospectively randomized to receive either PREVENA™ Therapy or AQUACEL® Ag in a single institution.
- Patients were included if they had at least 1 risk factor for developing wound complication.
- Study endpoints included wound complications (such as SSI, drainage, and cellulitis) readmission, and reoperation rates were collected at 2, 4, and 12 weeks postoperatively.
- **The postoperative wound complication rate was significantly higher in the AQUACEL® Ag compared to the PREVENA™ Therapy group** (19 [23.8%] vs 8 [10.1%], $p = 0.022$).
- There was no significant difference between the AQUACEL® Ag and PREVENA™ Therapy cohorts in terms of readmissions (19 [23.8%] vs 16 [20.3%], $p = 0.595$).
- **Reoperation rate was higher in AQUACEL® Ag patients compared to PREVENA™ Therapy patients** (10 [12.5%] vs 2 [2.5%], $p = 0.017$).
- After adjusting for the history of a prior periprosthetic joint infection and inflammatory arthritis, **the PREVENA™ Therapy cohort had a significantly decreased wound complication rate** (odds ratio 0.28, 95% confidence interval 0.11-0.68).

Wound Complications (wks. 2, 4, and 12)[15]



Reoperation Rate[15]



NOTE: Although the authors reported use of PREVENA™ Therapy for a mean of 3.6 days (ranging from 2 to 15 days), this mean time of application is outside the recommendations for Optimum Use as stated in the PREVENA™ Incision Management System Clinician Guide Instructions for Use: "The PREVENA™ Incision Management System is to be continuously applied for a minimum of 2 days up to a maximum of 7 days." Use for greater than 7 days is not recommended or promoted by KCI.

A hypothetical cost model applied to the clinical results of the Newman study shows potential cost savings per patient of $1,959 with the use of PREVENA™ Therapy.

Economic Model

Revision Hip (THA) and Knee (TKA) Surgery Hypothetical Economic Model	PREVENA™ Therapy (n = 79)	AQUACEL® Ag (n = 80)
Number of Reoperations at 2, 4, and 12 weeks (a)	2	10
Average Estimated Cost of Reoperation* (b)	$24,200	$24,200
Total Reoperation Cost (a*b)	$48,400	$242,000
Per Patient Cost of Reoperation (a*b)/n)	$613	$3,025
Per Patient Cost of Therapy◊	$495	$42
Total Cost per Patient	**$1,108**	**$3,067**

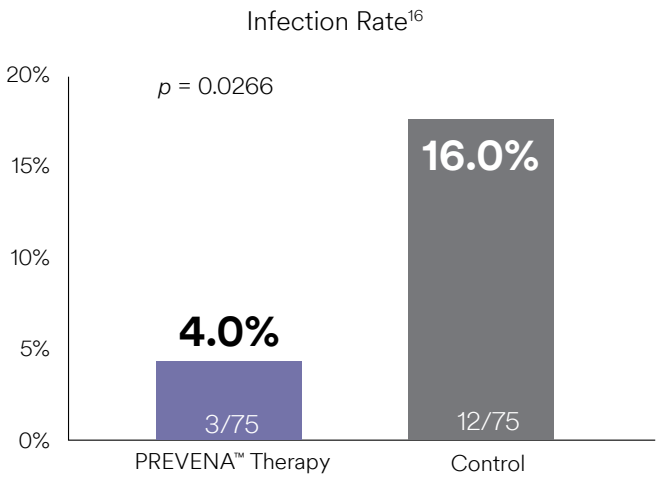
*Kurtz, Steven M. et al. Economic Burden of Periprosthetic Joint Infection in the United States. *J Arthroplasty*. 2012 Sep;27(8 Suppl):61-5.e1.

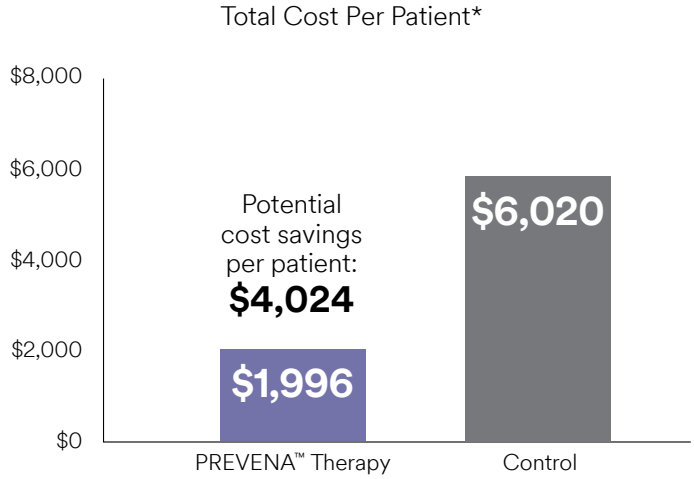
◊KCI estimate based on price of PREVENA™ PEEL & PLACE™ Dressing System and AQUACEL® Ag; individual prices may vary.

The hypothetical economic model uses select study data to provide an illustration of estimates of costs for use of PREVENA™ Therapy or AQUACEL® Ag. 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.

Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy[16]

- A prospective, single center clinical trial evaluated the use of PREVENA™ Therapy compared to standard post-operative dressings (Control) for the prevention of wound infection within 90 days after median sternotomy procedures in 150 consecutive obese (BMI ≥ 30) patients.
- **Patients treated with PREVENA™ Therapy developed fewer wound infections** (3/75 [4%] vs 12/75 [16%], *p*=0.0266) than patients treated with standard post-operative dressings.
- Wound infections with Gram-positive skin flora were found in only 1 patient in the PREVENA™ Therapy group compared with 10 patients in the control group (*p*=0.0090).
- A hypothetical cost model applied to the clinical results of this study shows a **potential cost savings per patient of $4,024 with the use of PREVENA™ Therapy**.*





Economic Model

Post-sternotomy Hypothetical Economic Model	PREVENA™ Therapy (n = 75)	Control (n=75)
Number of Infections (a)	3	12
Percent of Infections	4.0%	16.0%
Cost per Infection[66] (b)	$37,513	$37,513
Cost of Infection Per Patient (a*b)/n)	$1,501	$6,002
Cost of Therapy Per Patient†	$495	$18
Total Cost Per Patient	**$1,996**	**$6,020**

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†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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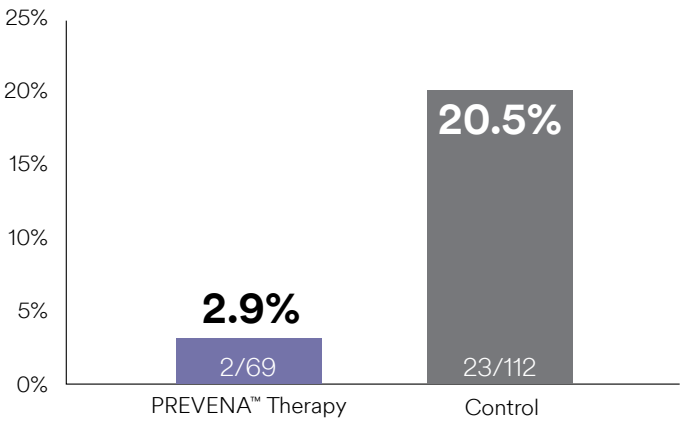
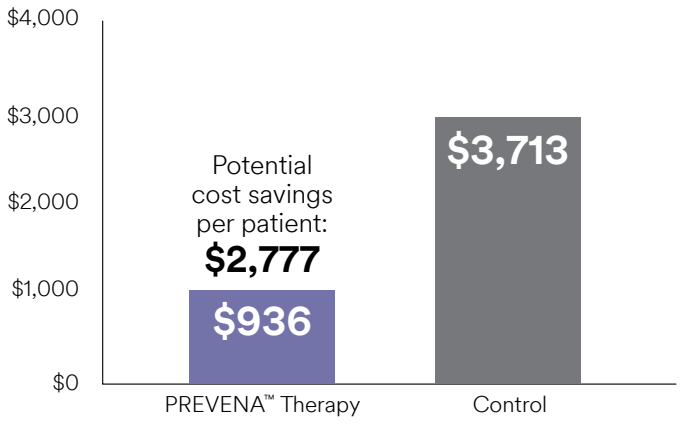
Using closed incision negative pressure therapy (ciNPT) in high-risk general surgery patients following laparotomy: A retrospective study[17]

- The aim of this study was to compare wound complication (skin wound dehiscence or deep incisional infection) occurrence in patients with multiple comorbidities who received PREVENA™ Therapy or conventional care (Control) within 30 days following laparotomy.
- Inclusion criteria were obesity (BMI ≥ 35 kg/m2), or two or more of the following risk factors: malignancy, history of smoking, immunosuppression, malnutrition, emergency surgery, diffuse atherosclerotic disease.
- Compared to the control group, **patients treated with PREVENA™ Therapy had** significantly fewer wound complications (2/69 [2.9%] vs 23/112 [20.5%], respectively; *p*<0.0009).
- The relative risk of a wound complication in the PREVENA™ Therapy group was 0.12 (95% CI 0.03-0.51) compared with the control group of 0.14 (95% CI 0.03-0.58); suggesting that infection is less likely to occur in PREVENA™ Therapy treated incisions.
- A hypothetical cost model applied to the clinical results of this study shows **potential cost savings per patient of $2,777 with the use of PREVENA™ Therapy**.*

Total Wound Complications[17]



Total Per Patient Cost*



Economic Model

Laparotomy Hypothetical Economic Model	PREVENA™ Therapy (n = 69)	Control (n=112)
Deep Incisional Infection	1	23
Skin Wound Dehiscence	1	0
Total Wound Complications	2	23
Total Infection Cost (Incremental cost of infection = $17,995 per patient)[66]	$17,995	$413,885
Total Dehiscence Cost (Incremental cost of dehiscence = $12,407 per patient)[65]	$12,407	$0
Total Complication Cost (a)	$30,402	$413,885
Complication Cost Per Patient (a/n)	$441	$3,695
Cost of Therapy Per Patient†	$495	$18
Total Cost Per Patient	**$936**	**$3,713**

*The hypothetical economic model uses select study data to provide an illustration of estimates of costs for use of PREVENA™ Therapy or standard post-operative dressings (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results.

†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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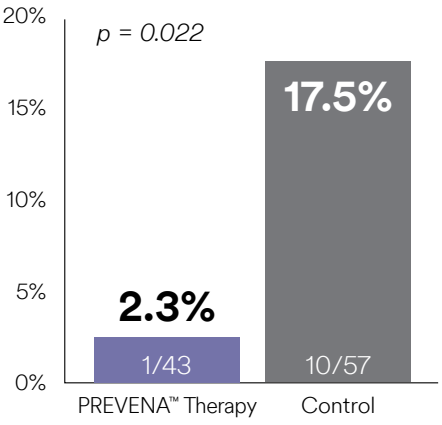
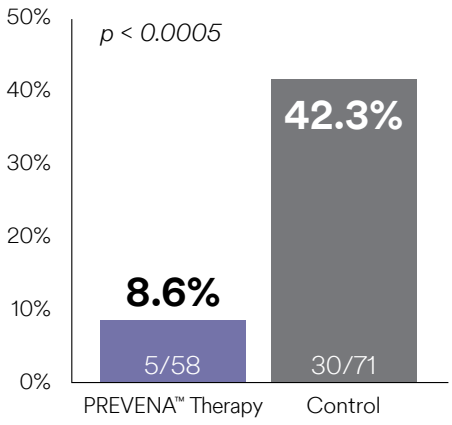
Reduction of wound groin complications in vascular surgery patients using closed incision negative pressure therapy: A prospective, randomized single-institution study[18]

- The aim of this prospective, randomized, single-institution study was to investigate the effectiveness of PREVENA™ Therapy compared to conventional adhesive dressing (Control) on groin incisions after vascular surgery.
- The PREVENA™ Therapy group had 43 patients and 58 groin incisions and the control group consisted of 57 patients and 71 groin incisions.
- Wound evaluation based on the Szilagyi classification (Grade I, II, and III) took place postoperatively on days 5–7 and 30.
- In this study, patients with cutaneous wound dehiscence, skin necrosis and single local infection signs were classified as grade I. Wound dehiscence in the subcutaneous layer, hematoma, lymphatic fistula, lymphocele, seroma, single local infection signs and systemic infection parameters were classified as grade II. All classical local infection signs (pain, swelling, redness and hyperaemia, warmth, dysfunction), systemic infection parameters and arterial graft infections were classified as grade III.
- **PREVENA™ Therapy significantly reduced the incidence of local infection** compared to the conventional dressing (1/43 [2.3%] vs 10/57 [17.5%], respectively; p=0.022).
- Compared to the control group, the PREVENA™ Therapy group showed a significant reduction in wound complications after both evaluation periods (5/58 [8.62%] vs 30/71 [42.3%], p<0.0005).
- PREVENA™ Therapy showed a significant reduction in revision surgeries (1/58 [1.7%] vs 10/71 [14.1%], respectively; p=0.022) until 30 days postoperatively compared to the control group.
- A hypothetical cost model applied to the clinical results of this study shows a **potential cost savings per patient of $2,694 with the use of PREVENA™ Therapy**.*

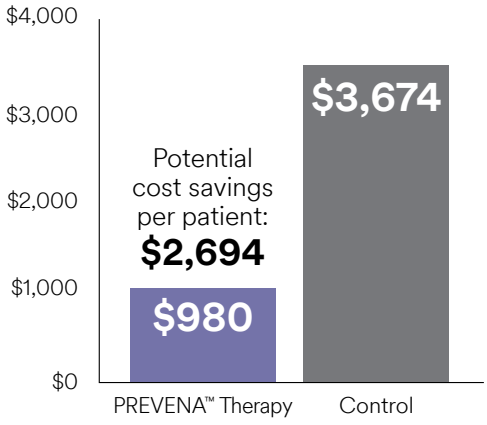
Local Infection Rate[18]



Wound Complications At Both Evaluation Periods[18]



Total Per Patient Cost*



Economic Model

Vascular Groin Hypothetical Economic Model	PREVENA™ Therapy	Control
Number of Patients (n)	43	57
Number of Local Infections (a)	1	10
Percent of Local Infections	2.3%	17.5%
Cost Per Local Infection[66] (b)	$20,842	$20,842
Cost of Local Infection Per Patient (a*b)/n)	$485	$3,656
Cost of Therapy Per Patient†	$495	$18
Total Cost Per Patient	**$980**	**$3,674**

*The hypothetical economic model uses select study data to provide an illustration of estimates of costs for use of PREVENA™ Therapy or standard post-operative dressings (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results.

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

The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

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™ Dressings by:

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

*Among negative pressure based incision management systems

Ordering information

Item #	Product Name	Qty
PRE1001US	PREVENA™ PEEL & PLACE™ System Kit – 20cm	1
PRE1055US	PREVENA™ PEEL & PLACE™ Dressing – 20cm	5
PRE1101US	PREVENA™ PEEL & PLACE™ System Kit – 13cm	1
PRE1155US	PREVENA™ PEEL & PLACE™ Dressing – 13cm	5
PRE3201US	PREVENA PLUS™ PEEL & PLACE™ 35cm System Kit	1
PRE3255US	PREVENA PEEL & PLACE™ 35cm Dressings	5
PRE4001US	PREVENA PLUS™ CUSTOMIZABLE™ System Kit	1
PRE4055US	PREVENA PLUS™ CUSTOMIZABLE™ Dressing	5

Item #	Product Name	Qty
PRE1121US	PREVENA DUO™ System with PEEL & PLACE™ 13cm/13cm Dressings	1
PRE3321US	PREVENA PLUS DUO™ System with PEEL & PLACE™ 13cm/20cm Dressings	1
PRE3021US	PREVENA PLUS DUO™ System with PEEL & PLACE™ 20cm/20cm Dressings	1
PRE4000US	PREVENA PLUS™ 125 Therapy Unit	1
PRE4010	PREVENA PLUS™ 125 Therapy Unit (14 Day)	1
PRE1095	PREVENA™ 45ml Canister	5
PRE4095	PREVENA PLUS™ 150ml Canister	5
PRE9090	PREVENA™ V.A.C.® Connector	10

For more information, call **800-275-4524** or visit **myKCI.com**

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3M Health Care
3M Medical Solutions Division
2510 Conway Ave.
St. Paul, MN 55144 USA

Phone 1-800-228-3957
Web 3M.com/Medical

The effectiveness of PREVENA™ Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at myKCI.com.

NOTE: Specific indications, limitations, contraindications, warnings, precautions, and safety information exist for PREVENA™ Therapy. Please consult the applicable PREVENA™ System Clinician Guide instructions for use prior to application. Rx only.