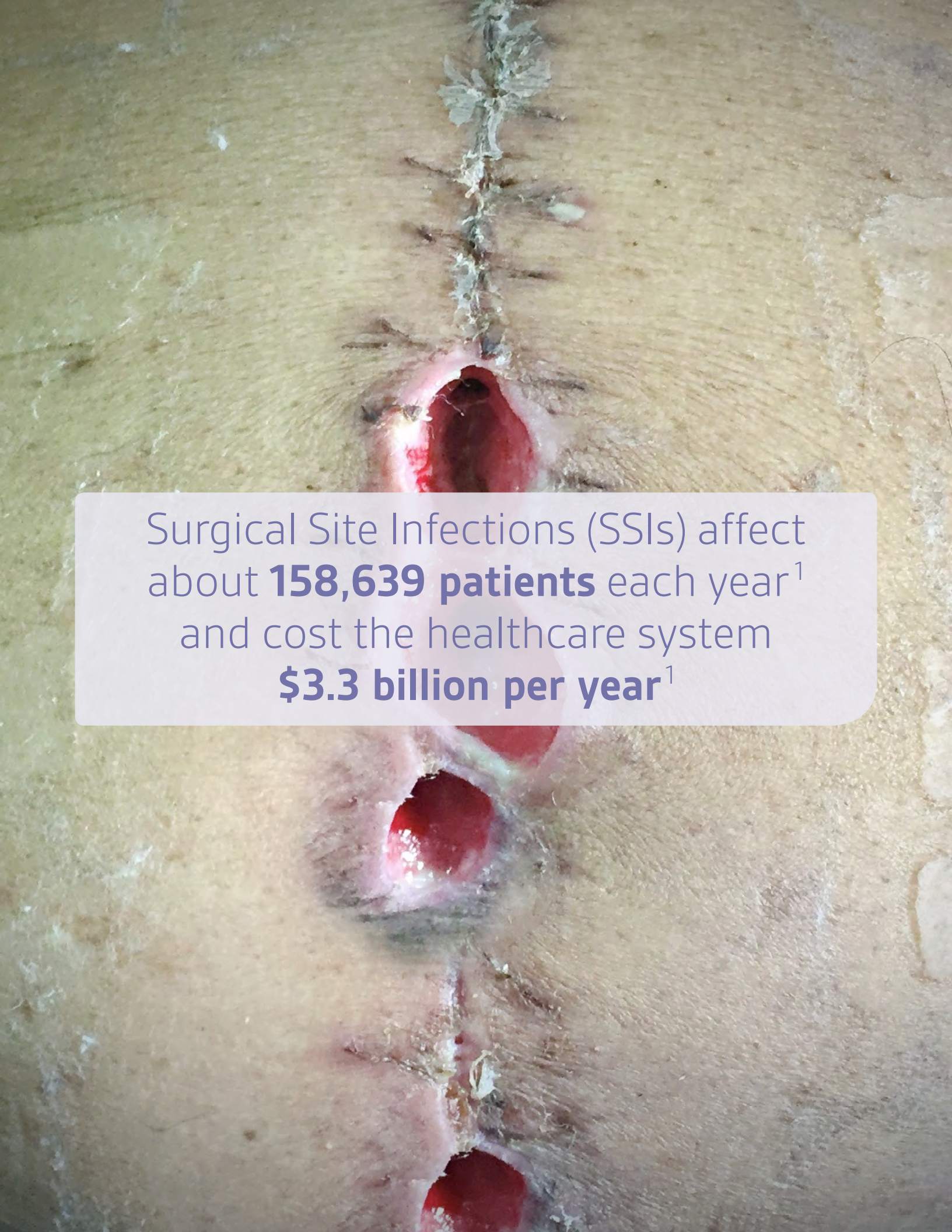
PREVENA™
INCISION MANAGEMENT SYSTEM

PREVENA™ THERAPY
IN ORTHOPEDICS

KCI
AN ACELITY COMPANY



Surgical Site Infections (SSIs) affect about **158,639 patients** each year[1] and cost the healthcare system **$3.3 billion per year**[1]

COMPLICATIONS IN **ORTHOPEDIC SURGERY**:

7.7 TO 11.7 DAYS

Increased length of hospital stay due to SSIs[2]

18.8%

of unplanned 30-day readmission
following THA and TKA due to SSI[3]

$24,200
AND
$30,300

Periprosthetic joint infection average hospital costs after TKA and THA, respectively[4]

$31,141

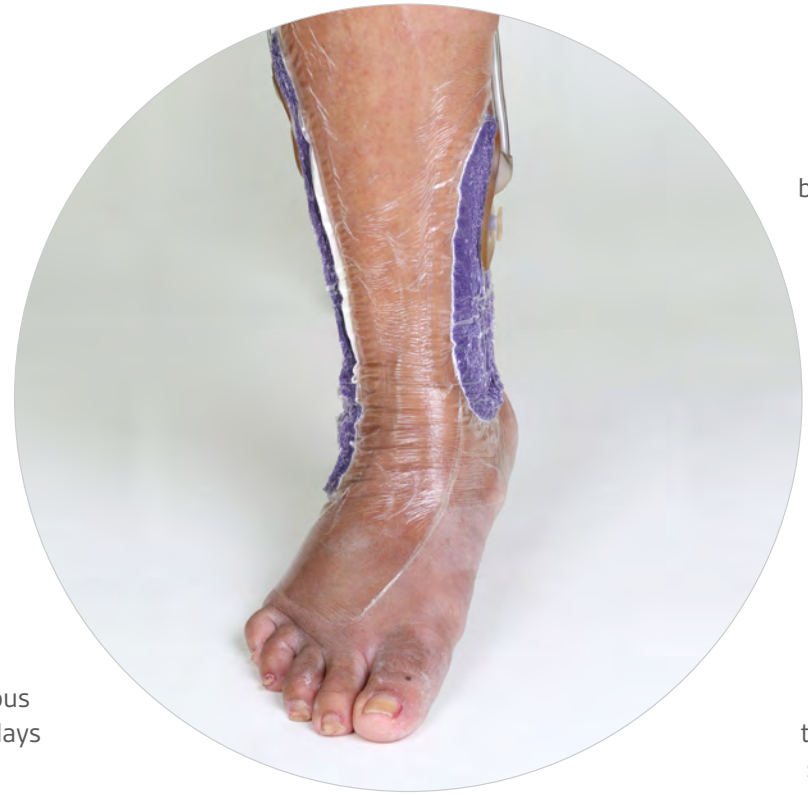
Median readmission cost to treat infected **orthopedic** trauma injuries[5]

* Total knee arthroplasty = TKA; Total hip arthroplasty = THA

PREVENA™ Incision Management System is uniquely designed to **manage and protect surgical incisions by:**

Helping to hold incision edges together

Reducing edema

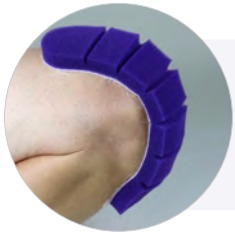


Acting as a barrier to external contamination

Delivering continuous -125mmHg up to 7 days

Decreasing lateral tension of sutured/ stapled incisions†6

Removing fluids and infectious materials*



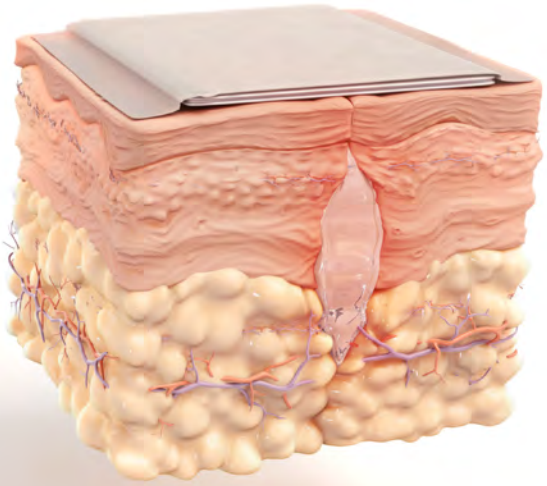
Designed to be flexible

PREVENA™ Incision Dressings are designed to allow for movement, enhancing the post-operative rehabilitation process

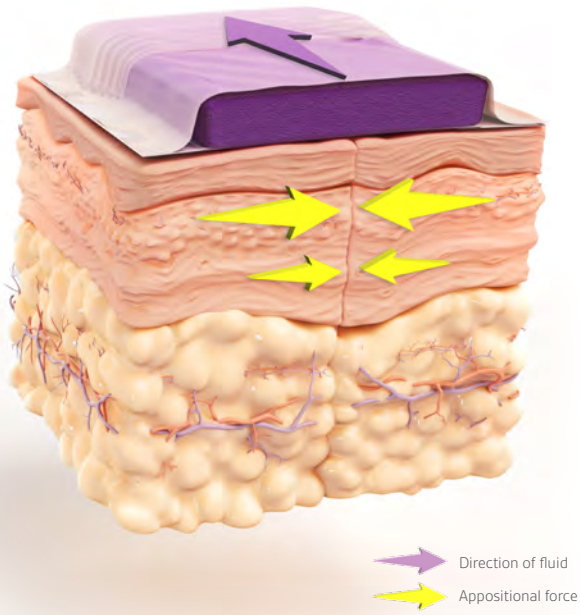
*In a canister † In computer and bench models

PREVENA™ Therapy utilizes **Reticulated Open Cell Foam** technology and -125mmHg pressure

Passive Therapy



PREVENA™ Therapy



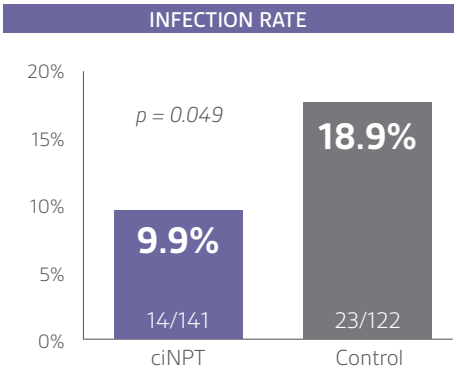
Under -125mmHg of negative pressure, the Reticulated Open Cell Foam dressing collapses to it's geometric center. This brings the incision edges together, reduces lateral tension, and also allows for improved fluid management.[6-8]

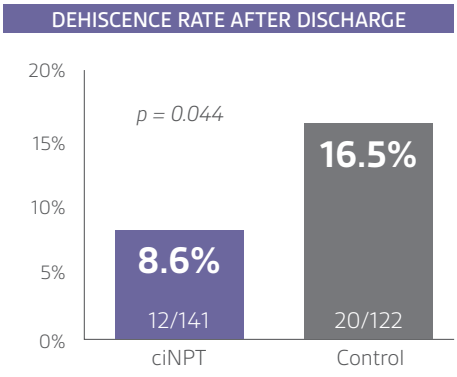
- Contours in PREVENA™ dressing allow for even distribution of negative pressure
- Adhesive film creates a barrier to external contaminants
- Designed to conform to articulating joints to allow movement
- Skin interface layer contains 0.019% ionic silver, which reduces bacterial colonization in the fabric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

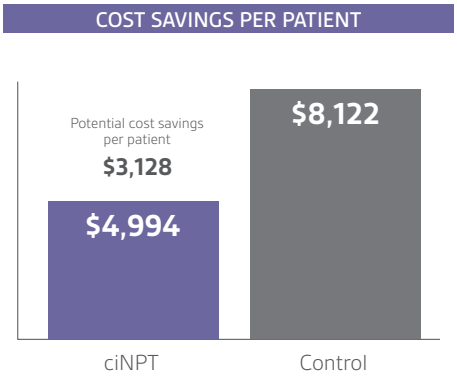
*See PREVENA™ Therapy Patient and Clinician Guides for additional details

Closed incision negative pressure therapy **decreased the incidence of SSI and dehiscence** after **lower extremity fractures** in this prospective RCT[§]

- This prospective multicenter RCT investigated the use of negative pressure wound therapy over closed incisions (ciNPT) to prevent wound dehiscence and infection after high-risk lower extremity fractures.
- There were a total of **23 infections in the Control group** (standard postoperative dressings) and **14 in the ciNPT group**, which **represented a significant difference in favor of ciNPT** ($p = 0.049$).
- The relative **risk of developing an infection was 1.9 times higher in control patients** than in patients treated with ciNPT (95% confidence interval, 1.03-3.55).
- A conservative hypothetical cost model applied to the clinical results of this study shows **potential cost savings during the inpatient stay per patient of $3,128** with the use of ciNPT.







Economic Model

High Risk Lower Extremity Fractures - Hypothetical Economic Model	ciNPT (n=130)	Control (n=119)
Number of Infections†	14	23
Number of Dehiscence†	12	20
Total Infection Cost (Incremental cost of infection = $31,141 per patient)‡	$435,974	$716,243
Total Dehiscence Cost (Incremental cost of dehiscence = $12,407 per patient)◊	$148,884	$248,140
Per Patient Infection Cost (Total Infection Cost / n)	$3,354	$6,019
Per Patient Dehiscence Cost (Total Dehiscence Cost / n)	$1,145	$2,085
Per Patient Cost of Therapyϕ	$495	$18
Total Cost Per Patient	**$4,994**	**$8,122**

† Model assumes that patients could only have 1 infection and 1 dehiscence

§ Stannard JP, Volgas DA, McGwin G III, et al. Incisional negative pressure wound therapy after high-risk lower extremity fractures. J Orthop Trauma. 2012:26(1):37-42.

‡ Thakore RV, et al. Surgical site infection in orthopedic trauma: A case-control study evaluating risk factors and cost. Journal of Clinical Orthopaedics and Trauma. 2015;(6):220-226. The median cost for treatment for patients with SSIs was $31,141.

◊ Weighted national estimates from HCUP National (Nationwide) Inpatient Sample (NIS), 2014, Agency for Healthcare Research and Quality (AHRQ), based on data collected by individual States and provided to AHRQ by the States.

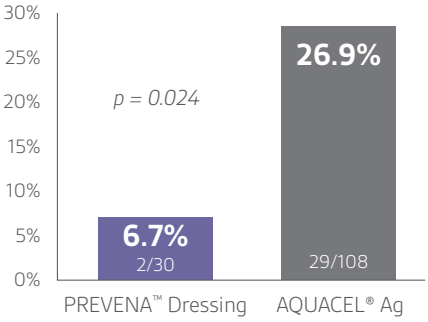
ϕ KCI estimate based on price of PREVENA™ PEEL & PLACE™ Dressing System and Control therapy (gauze) changed once a day at $18 a week

The economic model based on the clinical assessment on ortho trauma patients uses select study data to provide an illustration of estimates of costs for use of ciNPT or standard postoperative dressings (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.

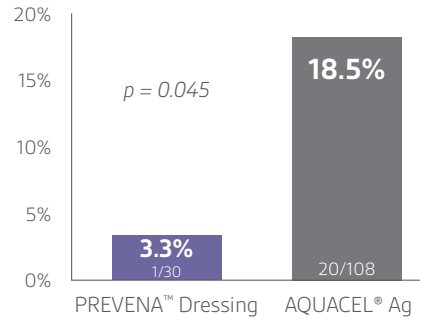
PREVENA™ Therapy **decreased the incidence of SSI and wound complications** on **hip and knee revision** patients in this retrospective study*†

- This study evaluated the efficacy of PREVENA™ Therapy compared to a sterile antimicrobial dressing (AMD) AQUACEL™ Ag on wound complications, surgical site infections (SSIs), and reoperations after hip and knee revision surgery over a 34-month period.
- PREVENA™ Therapy was used selectively in **higher-risk patients with multiple risk factors for SSIs** over the last 15 months of the study period.
- A hypothetical cost model applied to the clinical results of this study shows **potential cost savings per patient of $1,499 with the use of PREVENA™ Therapy.**
- Patients treated with PREVENA™ Therapy developed **fewer overall wound complications** (6.7% vs 26.9%, $p = 0.024$) and **fewer total SSIs** (3.3% vs 18.5%, $p = 0.045$) than patients treated with AQUACEL™ Ag.
- There were trends toward a **lower rate of superficial wound dehiscence** (6.7% vs 19.4%, $p = 0.163$), **fewer deep periprosthetic joint infections** (0.0% vs 9.3%, $p = 0.118$), and **fewer reoperations** (3.3% vs 13.0%, $p = 0.191$) among patients treated with PREVENA™ Therapy.

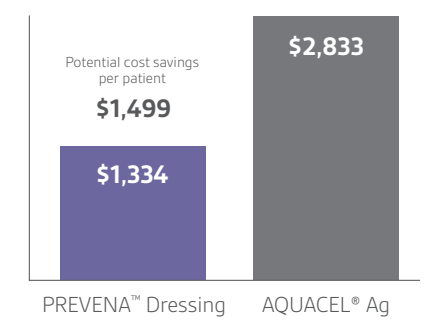
WOUND COMPLICATIONS



SSI INCIDENCE



COST SAVINGS PER PATIENT



† Cooper HJ, Bas MA. Closed-Incision Negative-Pressure Therapy Versus Antimicrobial Dressings After Revision Hip and Knee Surgery: A Comparative Study. J Arthroplasty 2016;31:1047-1052.

* Although the authors reported use of ciNPT for a mean of 9.2 days (ranging from 6 to 14 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 two days up to a maximum of seven days." Use for greater than 7 days is not recommended or promoted by KCI.

Economic Model

Hip (THA) and Knee (TKA) Surgery Revision Hypothetical Economic Model	PREVENA™ Therapy (n = 30)	AQUACEL Ag (n = 108)
Number of Infections (a)	1	20
Percent of SSIs	3.3%	18.5%
Cost per SSI‡ (b)	$15,129	$15,129
Cost of SSI Per Patient (a*b)/n)	$504	$2,802
Cost of Therapy Per Patient◊	$830	$31
Total Cost Per Patient	**$1,334**	**$2,833**

‡ de Lissovoy G, Fraeman K, Hutchins V, Murphy D, Song D, Vaughn BB. Surgical site infection: incidence and impact on hospital utilization and treatment costs. Am J Infect Control. 2009 Jun;37(5):387-97

◊KCI estimate based on price of Incisional NPWT plus three days of inpatient NPT, and Control therapy changed once a day, at $18 a week.

◊KCI estimate based on price of PREVENA™ PEEL & PLACE™ Dressing System and AQUACEL Ag price is an estimate; 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.

Risk factors for surgical site complications are dependent on many factors **including both patient-related and surgical procedure factors**.

General risk factors for SSI (adapted from [9-14])

Category	Patient-related risk factors	Procedure-related risk factors
Major risk factors	• BMI ≥40kg/m2 or ≤18kg/m2 • Uncontrolled insulin dependent diabetes mellitus • Renal dialysis	• Extended duration of surgery* • Emergency surgery • Hypothermia
Moderate risk factors	• ASA Physical Status >II • BMI 30–39.9kg/m2 • Diabetes mellitus • Chronic obstructive pulmonary disease ≥GOLD class 2 • Renal insufficiency/chronic kidney disease • Immunosuppression • Steroids for a chronic condition • Chemotherapy • Pre-existing infection at a body site remote from operative site • Serum albumin <2.5g/dl • Smoking (current)	• Anaemia/blood transfusion • High wound tension after closure • Dual antiplatelet treatment • Suboptimal timing or omission of prophylactic antibiotics • Tissue trauma/large area of dissection/large area of undermining
Minor risk factors	• BMI 25–29.9kg/m2 • Extended pre-operative hospitalization or residency in a nursing home • Peripheral vascular disease • Congestive cardiac failure with left ventricular ejection fraction <30%	• Failure to obliterate dead space • Location of incision • Previous surgery • Surgical drains

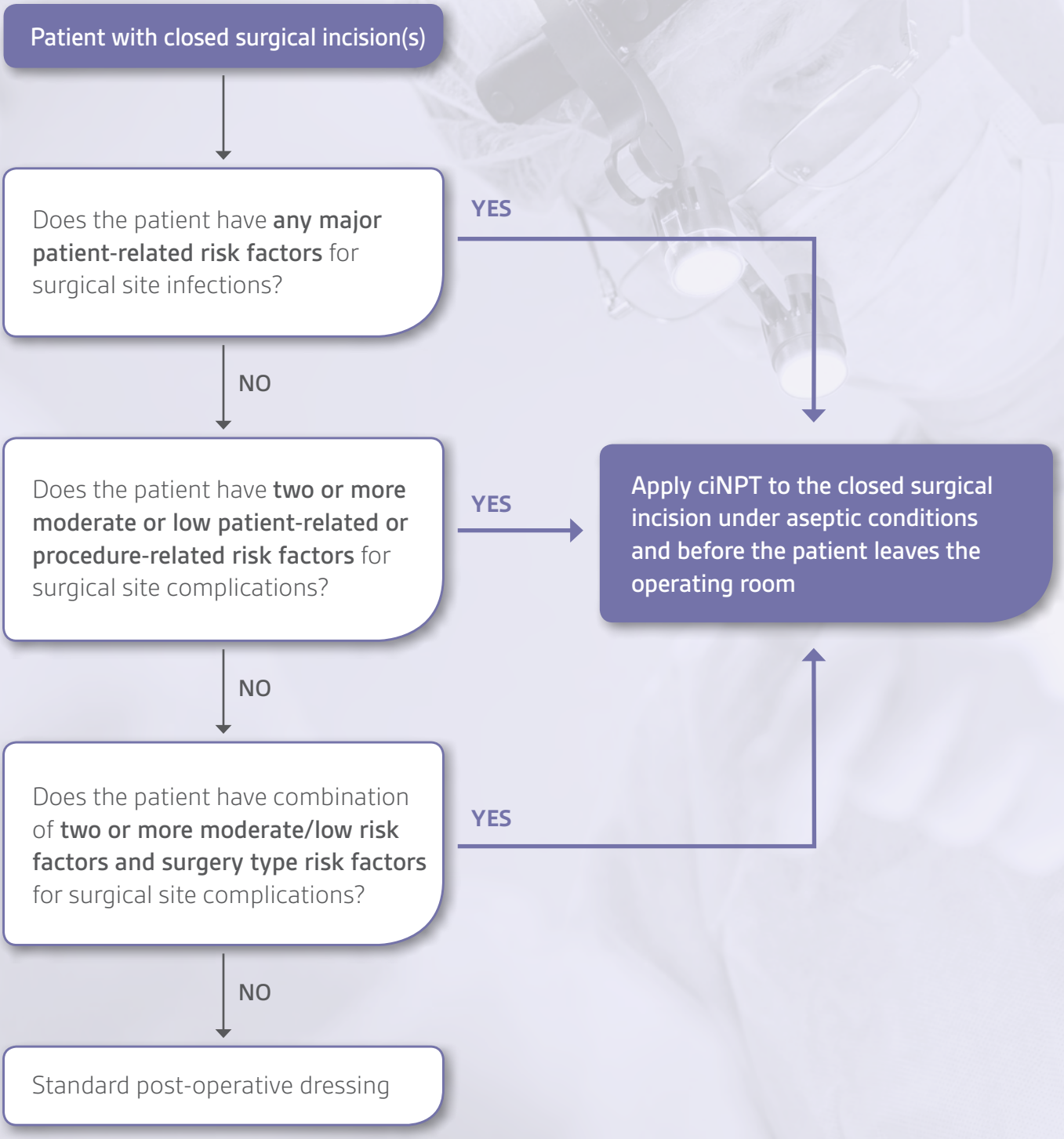
*Defined as >T (hours) which is dependent on the type of surgical procedure, and is the 75th centile of duration of surgery for a particular procedure, e.g. coronary artery bypass graft has a T of 5 hours and caesarean section has a T of 1 hour[81]

Example of additional risk factors for surgical site complications for by selected surgery type (adapted from[15-18])

Type of Surgery	Additional risk factors	
Abdominal	• Perforated viscus • Ostomy formation/closure	• Previous radiotherapy to surgical site • Multiple incisions
Breast/plastic	• Corony artery disease • Bleeding risk	• Breast Reconstruction Risk Assessment (BRA) score*
Cardiothoracic	• Bilateral internal mammary artery harvesting • Chest wall radiotherapy • Left ventricular assist device (LVAD)	• Transplant • Cardiopulmonary bypass time extended • Delayed closure
Obstetric	• Multiple (>3) caesarean sections • Anticoagulants • Operative blood loss >1.5l	• Pre-eclampsia • Chorioamnionitis
Orthopedic	• Implant/prosthesis • Rheumatoid arthritis	• Nasal carriage of Staphylococcus aureus
Vascular	• Groin incision	

*The BRA Score calculates risk (as %) of a range of complications, e.g. SSI, seroma, dehiscence, flap loss, explantation and reoperation, based on factors including reconstructive modality, BMI, age, ASA Physical Status class, bleeding disorder, history of percutaneous cardiac intervention or cardiac surgery (www.brascore.org)
** However, prematurity does not appear to be a risk factor for SSI or for a resulting mortality-related event[112]

The World Union of Wound Healing Societies (WUWHS) consensus panel proposed the following clinical guideline for the use of NPWT on **closed surgical incisions***



*Adapted from: 19, 20, 21

There are **70+ ciNPT journal publications using KCI™/Acelity™ products**. The following publications are specific to orthopedics

Citation	Wound/Surgery Type	Level of Clinical Evidence*
Pauser J, Nordmeyer M, Biber R, et al. Incisional Negative Pressure Wound Therapy After Hemiarthroplasty for Femoral Neck Fractures - Reduction of Wound Complications. International Wound Journal. 2014 Aug 14.	Hemiarthroplasty for femoral neck fractures	1b ●
Howell RD, Hadley S, Strauss E, et al. Blister Formation with Negative Pressure Dressings after Total Knee Replacement. Current Orthopedic Practice. 2011 Mar;22(2):176-179.	Knee arthroplasty	1b ■
Stannard JP, Volgas DA, Stewart R, et al. Negative Pressure Wound Therapy After Severe Open Fractures: A Prospective Randomized Study. Journal of Orthopedic Trauma. 2009 Sep;23(8):552-7.	Lower extremity fractures	1b ■
Stannard JP, Robinson JT, Anderson ER, et al. Negative Pressure Wound Therapy to Treat Hematomas and Surgical Incisions Following High-Energy Trauma. Journal of Trauma. 2006 Jun;60(6):1301-6.	Lower extremity fractures	1b ●
Stannard JP, Volgas DA, McGwin G 3rd, et al. Incisional Negative Pressure Wound Therapy After High-Risk Lower Extremity Fractures. Journal of Orthopedic Trauma. 2012 Jan;26(1):37-42.	Lower extremity fractures	1b ●
Pachowsky M, Gusinde J, Klein A, et al. Negative Pressure Wound Therapy to Prevent Seromas and Treat Surgical Incisions After Total Hip Arthroplasty. International Orthopedics. 2012 Apr;36(4):719-22.	Total hip arthroplasty	1b ●
Redfern RE, Cameron-Ruetz C, O'Drobinak SK, et al. Closed Incision Negative Pressure Therapy Effects on Postoperative Infection and Surgical Site Complication After Total Hip and Knee Arthroplasty. The Journal of Arthroplasty. 2017. [Epub ahead of print].	Hip and knee arthroplasty	2 ●
Reddix RN Jr, Leng XI, Woodall J, et al. The Effect of Incisional Negative Pressure Therapy on Wound Complications After Acetabular Fracture Surgery. Journal of Surgical Orthopedic Advances. 2010 Jun;19(2):91–7.	Hip arthroplasty	3 ▲
Cooper JH, Bas MA, et al. Closed-Incision Negative-Pressure Therapy Versus Antimicrobial Dressings After Revision Hip and Knee Surgery: A Comparative Study. The Journal of Arthroplasty. 2015 Oct:1-6.	Revision Knee & Hip	3 ●
H. John Cooper, Gilbert C. Roc, Marcel A. Bas, et al. Closed incision negative pressure therapy decreases complications after periprosthetic fracture surgery around the hip and knee. Injury. 2017. [Epub ahead of print].	Hip and knee arthroplasty periprosthetic fracture	3 ●
Hansen E, Durinka JB, Costanzo JA, et al. Negative Pressure Wound Therapy is Associated With Resolution of Incisional Drainage in Most Wounds After Hip Arthroplasty. Clinical Orthopedics and Related Research. 2013 Oct;471(10):3230-6.	Hip arthroplasty	4 ■
Reddix RN Jr, Tyler HK, Kulp B, et al. Incisional Vacuum-Assisted Wound Closure in Morbidly Obese Patients Undergoing Acetabular Fracture Surgery. The American Journal of Orthopedics. 2009 Sep;38(9):32-5.	Acetebular fractures	4 ▲
Stannard JP, Atkins BZ, O'Malley D, et al. Use of Negative Pressure Therapy on Closed Surgical Incisions: A Case Series. Ostomy Wound Management. 2009 Aug;55(8):58-66.	Lower extremity fractures	4 ■
Gomoll AH, Lin A, Harris MB. et al. Incisional Vacuum-Assisted Closure Therapy. Journal of Orthopedic Trauma. 2006 Nov-Dec;20(10):705-9.	Orthopaedic trauma	4 ●
Brem MH, Bail HJ, Biber R. Value of Incisional Negative Pressure Wound Therapy in Orthopedic Surgery. International Wound Journal. 2014 Jun;11(Suppl 1):3-5.	NA	5 ■
Berkowitz MJ. Use of a Negative Pressure Incisional Dressing After Surgical Treatment of Calcaneal Fractures. Techniques in Foot and Ankle Surgery. 2013 Dec;12(4):172-174.	Calcaneal fractures	5 ■
Karlakki S, Brem M, Giannini S, et al. Negative Pressure Wound Therapy for Management of the Surgical Incision in Orthopaedic Surgery: A Review of Evidence and Mechanisms for an Emerging Indication. Bone and Joint Research. 2013 Dec 1; 2(12):276-84.	NA	5 ■
Stannard JP, Gabriel A, Lehner B. Use of Negative Pressure Wound Therapy Over Clean, Closed Surgical Incisions. International Wound Journal. 2012;9:32-39.	Orthopaedic trauma	5 ■
DeCarbo WT, Hyer CF. Negative-Pressure Wound Therapy Applied to High-Risk Surgical Incisions. Journal of Foot and Ankle Surgery. 2010 May;49(3):299-300.	Orthopaedic trauma	5 ■

● Available on request. Contact your local Acelity sales representative.

▲ Not available for distribution.

■ Available through Acelity Medical Information: pubsmgt@acelity.com

***Level of Clinical Evidence Rating: Level 1:** Evidence obtained from at least one properly designed randomized controlled trial. **Level 1b:** Systematic reviews (with homogeneity) of randomized controlled trials. **Level 2:** Evidence obtained from well-designed controlled trials without randomization. **Level 2b:** Individual cohort study or low quality randomized controlled trials (e.g., <80% follow-up). **Level 3:** Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group. **Level 4:** Case series (and poor quality cohort and case-control studies). **Level 5:** Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles."

References:

1. Zimlichman E, et al. Health Care-Associated Infections A Meta-analysis of Costs and Financial Impact on the US Health Care System. JAMA Intern Med. 2013;173(22):2039-46.
2. de Lissovoy G, Fraeman K, Hutchins V, Murphy D, Song D, Vaughn BB. Surgical site infection: incidence and impact on hospital utilization and treatment costs. Am J Infect Control. 2009 Jun;37(5):387-97.
3. Merkow R, et al. Underlying reasons associate with hospital readmission following surgery in the US. JAMA 2015;313(5):483-95.
4. Kurtz SM, Lau E, Watson H, Schmier JK, Parvizi J. Economic burden of periprosthetic joint infection in the United States. J Arthroplasty. 2012 Sep;27(8 Suppl):61-5.e1. doi: 10.1016/j.arth.2012.02.022. Epub 2012 May 2.
5. Thakore RV, et al. Surgical site infection in orthopedic trauma: A case-control study evaluating risk factors and cost. Journal of Clinical Orthopaedics and Trauma. 2015;(6):220-226.
6. Wilkes RP, Kilpadi DV, Zhao Y, et al. Closed Incision Management With Negative Pressure Wound Therapy (CIM): Biomechanics. Surgical Innovation. 2012;19(1):67-75.
7. Kilpadi DV, Cunningham MR. Evaluation of Closed Incision Management with Negative Pressure Wound Therapy (CIM): Hematoma/Seroma and Involvement of the Lymphatic System. Wound Repair and Regeneration. 2011;19:588-596.
8. Glaser DA, Farnsworth CL, Varley ES, et al. Negative pressure therapy for closed spine incisions: A pilot study. Wounds. 2012;24(11):308-316.
9. Reddy HV, Ujwala J, Swetha M, Ramya SB. Seroma: an interesting case report. Int J Reproduction Contraception Obs Gynecol. 2014; 3(1): 254-257.
10. Carlson MA. Acute wound failure. Surg Clin Nor Am. 1997; 77(3):607–36.
11. Son D, Harijan A. Overview of surgical scar prevention and management. J Korean Med Sci 2014; 29: 751-57.
12. Mangram AJ, Horan TC, Pearson ML, et al. Guidelines for prevention of surgical site infection, 1999. Inf Control Hosp Epidemiol. 1999; 20(4): 247-78.
13. Culver DH, Horan TC, Gaynes RP, et al. Surgical wound infection rates by wound class, operative procedure, and patient risk index. Am J Med 1991; 91 (suppl 3B): 152-157.
14. Jones ME, Hardy CJ, Ridgway JM. Head and neck keloid management: a retrospective early review on a new approach using surgical excision, platelet rich plasma and in-office superficial photon X-ray radiation. Edorium J Otolaryngol 2015; 2: 14-19.
15. Kim HJ, Levin LF. The management of patients on dual antiplatelet therapy undergoing orthopaedic surgery. HSSJ. 2010; 6: 182-89.
16. Korol E, Johnston K, Waser N, et al. A systematic review of risk factors associated with surgical site infections among surgical patients. PLOS One 2013;8(12):e83743.
17. Tran TS, Jamulitrat S, Chonsuvivatwong V, Geater A. Risk factors for postcesarean surgical site infection. Obs Gynecol. 2000; 95(3): 367-71.
18. Inui T, Bandyk DF. Vascular surgical site infection: risk factors and preventive measures. Semin Vasc Surg. 2015; 28(3-4): 201-7.
19. Willy, C., Agarwal, A., Andersen, C. A., et al. (2017), Closed incision negative pressure therapy: international multidisciplinary consensus recommendations. Int Wound J, 14: 385–398. doi:10.1111/iwj.12612
20. Stannard, J., Atkins, B., O'Malley, D., et al. (2009). Use of Negative Pressure Therapy on Closed Surgical Incisions: A Case Series. Ostomy/wound management. 55. 58-66.
21. World Union of Wound Healing Societies (WUWHS) Consensus Document. Closed surgical incision management: understanding the role of NPWT. Wounds International, 2016

PREVENA™ Therapy Resources

- Live Clinical Training & Product Support (25,000 Professionals Trained Annually)
- Free Product Evaluation Program
- PREVENA™ Therapy Financial Protection
- Clinical Services & Reimbursement Hotlines
- 24/7 Centralized, On Demand Clinical & Technical Support

Ordering information

Item#	Description	Unit of Measure (UOM)
PRE1001US	PREVENA™ PEEL & PLACE™ System Kit – 20cm	Each
PRE1055US	PREVENA™ PEEL & PLACE™ Dressing – 20cm	Case of 5
PRE1101US	PREVENA™ PEEL & PLACE™ System Kit – 13cm	Each
PRE1155US	PREVENA™ PEEL & PLACE™ Dressing – 13cm	Case of 5
PRE3201US	PREVENA PLUS™ PEEL & PLACE™ 35cm System Kit	Each
PRE3255US	PREVENA PEEL & PLACE™ 35cm Dressings	Case of 5
PRE4001US	PREVENA PLUS™ CUSTOMIZABLE™ System Kit	Each
PRE4055US	PREVENA PLUS™ CUSTOMIZABLE™ Dressing	Case of 5
PRE1121US	PREVENA DUO™ System with PEEL & PLACE™ 13cm/13cm Dressings	Each
PRE3321US	PREVENA PLUS DUO™ System with PEEL & PLACE™ 13cm/20cm Dressings	Each
PRE3021US	PREVENA PLUS DUO™ System with PEEL & PLACE™ 20cm/20cm Dressings	Each
PRE4000US	PREVENA PLUS™ 125 Therapy Unit	Each
PRE1095	PREVENA™ 45ml Canister	Case of 5
PRE4095	PREVENA PLUS™ 150ml Canister	Case of 5
PRE9090	PREVENA™ Therapy V.A.C.® Connector	Case of 10

Note: Ordering information is comprehensive. Confirm which products available at time of print.

Please contact your local KCI Representative for more information.

NOTE: Specific indications, 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.

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