



PREVENA™
Incision Management System

The power to protect in orthopaedic surgery.

Enabling low-touch post-operative
care to protect patients, clinicians
and hospitals from the consequences
of surgical site complications.



We understand things have changed recently.

The COVID-19 pandemic has resulted in consequences which have rippled across the health care setting and beyond.

As we resume elective surgery, clinicians are redefining postoperative care and adopting their approaches to achieve:



Early
discharge



Home-based
recovery



Virtual
clinics



Low-touch
care



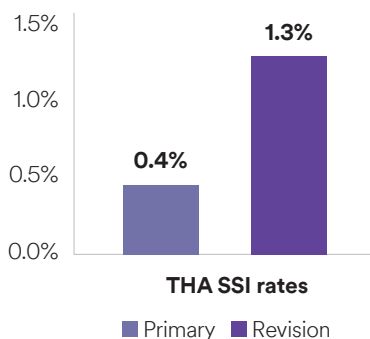
Minimal
complications



Low
readmissions

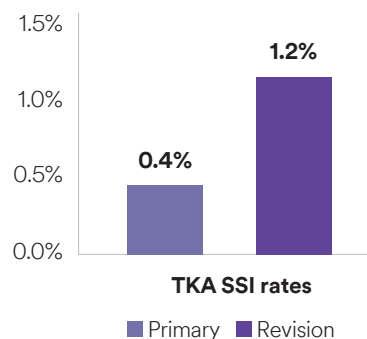
Surgical Site Complications are a major source of morbidity after hip and knee arthroplasty procedures.

THA and TKA* revision surgery is associated with



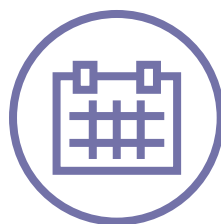
3x greater SSI rates

when compared with primary procedures.¹



SSIs are associated with an increased median length of hospital stay following THA and TKA.²

↑ **17 Days**
THA



↑ **7 Days**
TKA



18.8%

Unplanned 30-day readmission following THA and TKA due to SSI.³



€9,560

Additional average costs due to SSI following orthopedic and trauma surgery.⁴



By working to protect incisions from postoperative complications, PREVENA™ Therapy works to help stop the ripple effect before it begins, protecting patients, surgeons, staff, practices, and hospitals from potential consequences through low touch care.

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

PREVENA™ Therapy manages and protects surgical incisions by:



Reducing edema



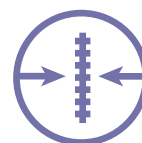
Helping to hold incision edges together



Acting as a barrier to external contamination



Delivering continuous
-125mmHg
up to 7 or 14 days**



Decreasing lateral
tension of sutured/
stapled incisions[†]



Removing fluids and
infectious materials*

“NICE
advice”

Did you know?

NICE have published a medical innovation briefing on the use of “Prevena Incision Management for Closed Surgical Incisions”. Access the full document at <https://www.nice.org.uk/advice/mib173>

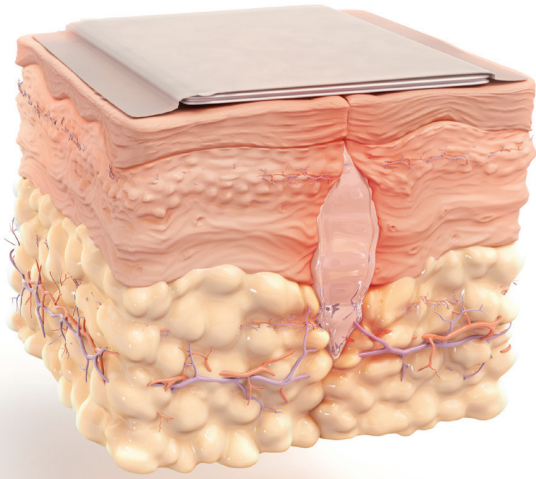
*In a canister

**length of therapy either 7 or 14 days with the PREVENA PLUS 125 Therapy Unit

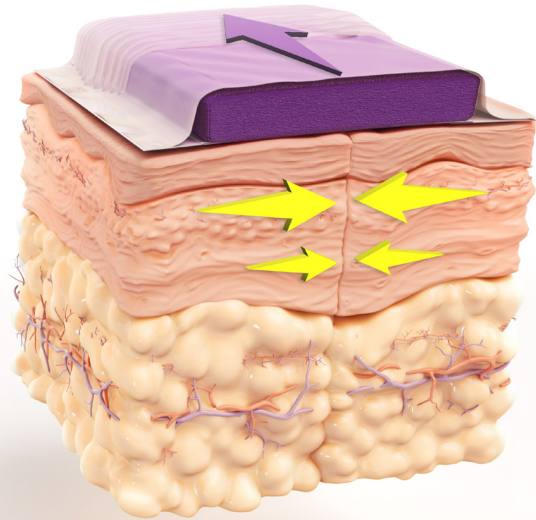
† In computer and bench models



PREVENA™ Therapy utilizes reticulated open cell foam technology and -125mmHg negative pressure.

Passive therapy



PREVENA™ Therapy

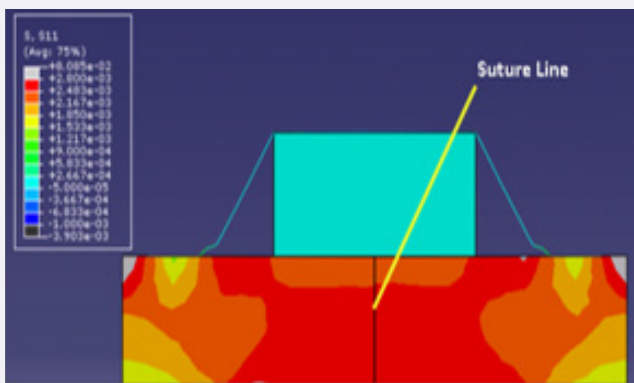


 Direction of fluid
 Appositional force

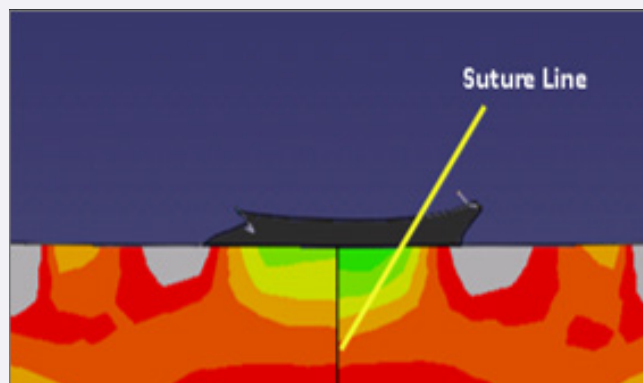
Under -125mmHg of negative pressure, the reticulated open cell foam dressing collapses to its geometric center. This brings the incision edges together, reduces lateral tension, and also allows for improved fluid management.⁵⁻⁷

Delivering a 50% reduction in lateral tension.⁵

Reducing lateral strain is important to maintain the integrity of closed surgical incision. Using a finite computer model on a simulated incision, PREVENA™ has been shown to reduce lateral strain by approximately 50% (0.9 to 1.2kPa) along the incision.



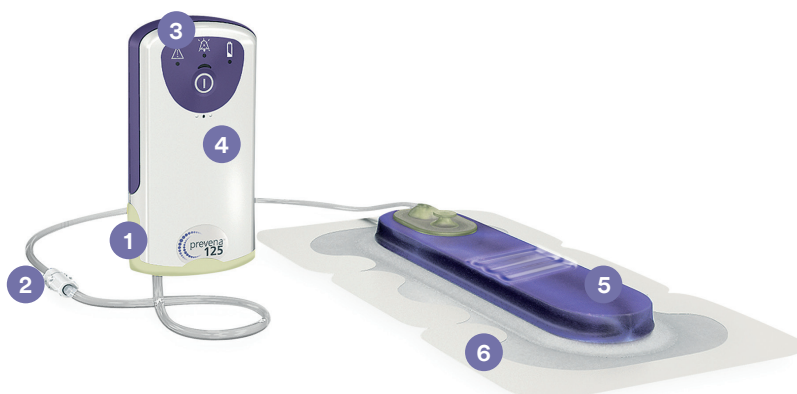
A Lateral strain on simulated incision without application of PREVENA™ therapy. Orange and red colours indicate high lateral strain.



B Lateral strain on simulated incision with application of PREVENA™ therapy. Yellow and green colours indicate low lateral strain.

The power of PREVENA™ Therapy.

PREVENA™ Therapy is packed with features specifically designed to help reduce the risk of surgical site complications.



- | | | |
|--|---|--|
| <p>1 Replaceable canister Store exudate and infectious fluids away from the surgical incision.</p> <p>2 V.A.C.® connector Connect to other V.A.C. devices within the hospital setting for greater flexibility.</p> | <p>3 Audible and visual alarms Rectify therapy issues at an early stage.</p> <p>4 -125mmHg To hold incision edges together and remove fluids.</p> | <p>5 Foam bolster Channels uniform negative pressure to the incision area, reducing lateral tension.</p> <p>6 Skin friendly interface layer Wicks fluid away from the surface, with 0.019% ionic silver to help reduce bacterial colonisation.</p> |
|--|---|--|

Both the PREVENA™ and PREVENA PLUS™ Therapy units can support clinicians with early discharge into a home setting:

- ▶ Portable, single use therapy
- ▶ No additional dressing changes for up to 7 days
- ▶ Shower friendly



PREVENA™ 125 Therapy Unit (7 days)

Included with:
PREVENA™ 13cm,
PREVENA™ 20cm
and PREVENA
DUO™ System Kits.



PREVENA PLUS™ 125 Therapy Unit (7 days)

Included with:
PREVENA™ 35cm
and PREVENA
CUSTOMIZABLE™
System Kits.
PREVENA PLUS™ 125
Therapy Unit (14 days) can
be purchased separately.

Multiple dressing sizes and configurations. With easy to use PEEL & PLACE™ dressings for linear incisions up to 35cm and CUSTOMIZABLE™ dressings for non-linear and intersecting incisions up to 90cm in length.



Designed to be flexible.

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

Clinically proven. Across specialities.^{8*}

A systematic literature review and associated meta-analysis supports 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.

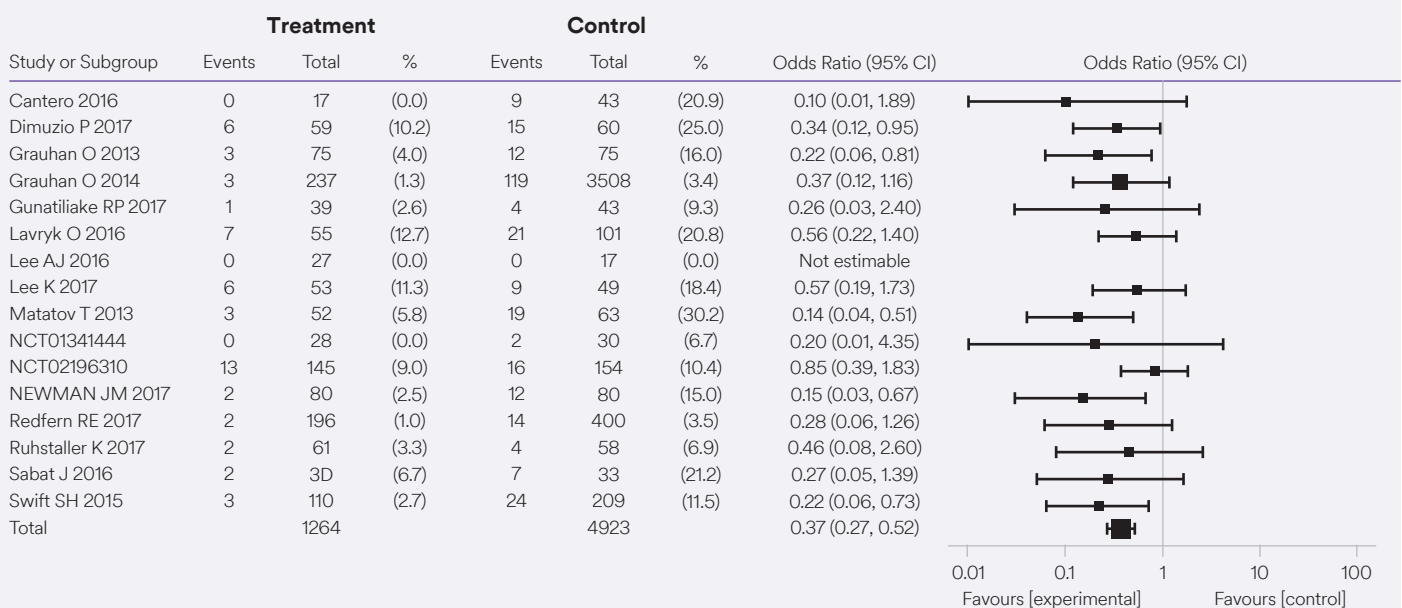
Study overview

- ▶ Out of 426 studies in the initial search, ultimately, sixteen (16) prospective studies were included in this meta-analysis for SSI characterisation
- ▶ 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
- ▶ A total of up to 952 evaluable patients were included in this meta-analysis for seroma with 366 in the PREVENA™ Therapy (treatment) group and 586 in the conventional wound dressing (control) group

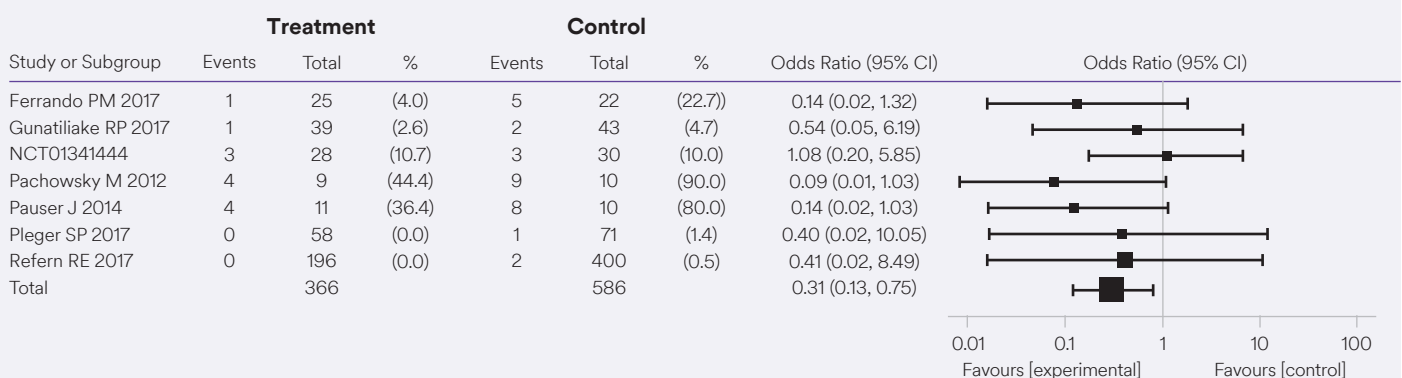
Findings

- ▶ PREVENA™ Therapy aids in reducing the incidence of seroma and surgical site infections in Class I and Class II wounds.
- ▶ PREVENA™ Therapy demonstrated the greatest benefit in reducing SSIs in high risk patients

Forest plot of meta-analysis on surgical site infection



Forest plot of meta-analysis on Seroma



*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.

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.⁹

Newman JM, Siqueira MBP, Klika AK, Molloy RM, Barsoum WK, Higuera CA. *Journal of Arthroplasty*. 2018.

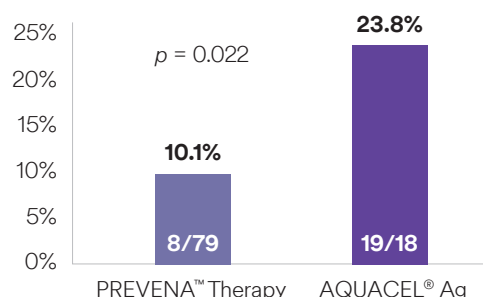
Study overview

- ▶ Prospective randomised study to compare the use of PREVENA™ Therapy to a sterile antimicrobial dressing (AQUACEL® Ag) in revision arthroplasty patients, at high risk of wound complications
- ▶ 160 patients undergoing elective revision arthroplasty were prospectively randomised 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

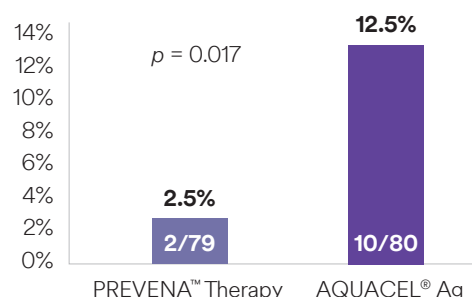
Findings

- ▶ 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)



Reoperation rate



†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 two days up to a maximum of seven days.' Use for greater than 7 days is not recommended or promoted by KCI.

Cost model

A hypothetical cost model applied to the clinical results of the Newman study shows potential cost savings of €1,381 per patient with the use of PREVENA™ Therapy.

| 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) | €17,528 | €17,528 |
| Total reoperation cost (a*b) | €35,056 | €175,280 |
| Per patient cost of reoperation (a*b)/n) | €406 | €2,191 |
| Per patient cost of therapy [‡] | €442 | €38 |
| Total cost per patient | €848 | €2,229 |

*Kallala RF, Ibrahim MS, Sarmah S, Haddad FS, Vanhegan IS. Financial analysis of revision knee surgery based on NHS tariffs and hospital costs. Does it pay to provide a revision service? *Bone Joint J* 2015;97B:197e201. Exchange rate from GBP to EUR correct as of Jun 2020.

‡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.

Closed-incision negative pressure therapy versus antimicrobial dressings after revision hip and knee surgery: a comparative study.¹⁰

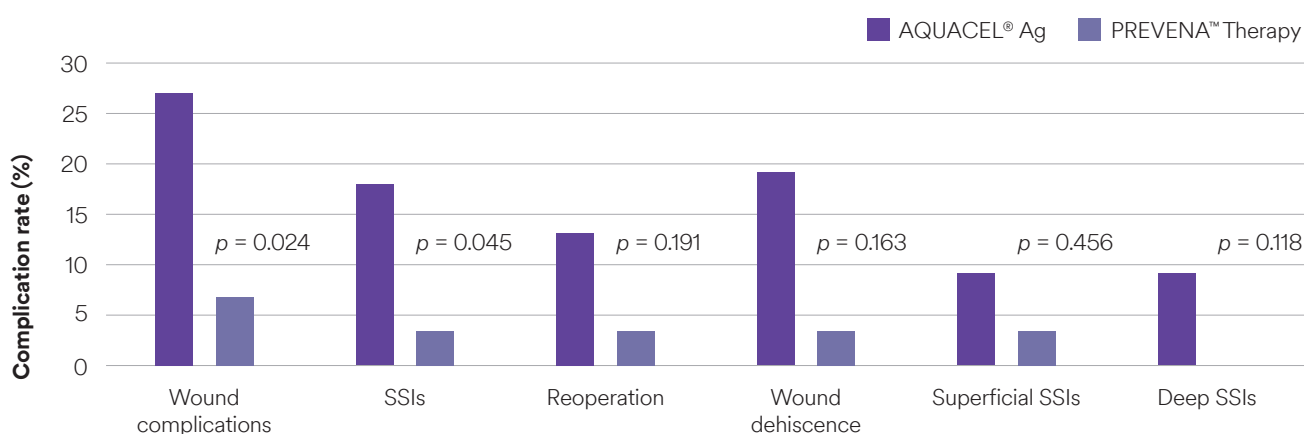
Cooper HJ, Bas MA. *J Arthroplasty*. 2016;31(5):1047–1052

Study overview

- ▶ Retrospective quality improvement analysis of 138 consecutive revision hip and knee operations performed by a single surgeon 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
- ▶ Rates of wound complications, SSIs and reoperation were compared with patients treated with a sterile antimicrobial dressing. (Aquacel® Ag)
- ▶ Aquacel® Ag dressings were used in 108 patients, where as PREVENA™ Therapy was used in 30 patients

Findings

- ▶ 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%, $P = .163$), fewer deep periprosthetic joint infections (0.0% vs 9.3%, $P = .0118$), and fewer reoperations (3.3% vs 13.0%, $P = 0.191$) among patients treated with PREVENA™ Therapy
- ▶ The authors from the study concluded that ciNPT may reduce wound complications, SSIs and reoperations in patients undergoing lower extremity periprosthetic fracture surgery



| | PREVENA™ Therapy N = 30 n (%) | AQUACEL® Ag N = 108 n (%) | p-value |
|-----------------------------|-------------------------------------|---------------------------------|-----------|
| Overall wound complications | 2 (6.7%) | 29 (26.9%) | p = 0.024 |
| Total SSIs | 1 (3.3%) | 20 (18.5%) | p = 0.045 |
| Reoperation rate | 1 (3.3%) | 14 (13.0%) | p = 0.191 |

A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty.¹¹

Anatone AJ, Shah RP, Jennings EL, Geller JA, Cooper J. *Arthroplasty Today*. 2018;4(4):493-498.

Study overview

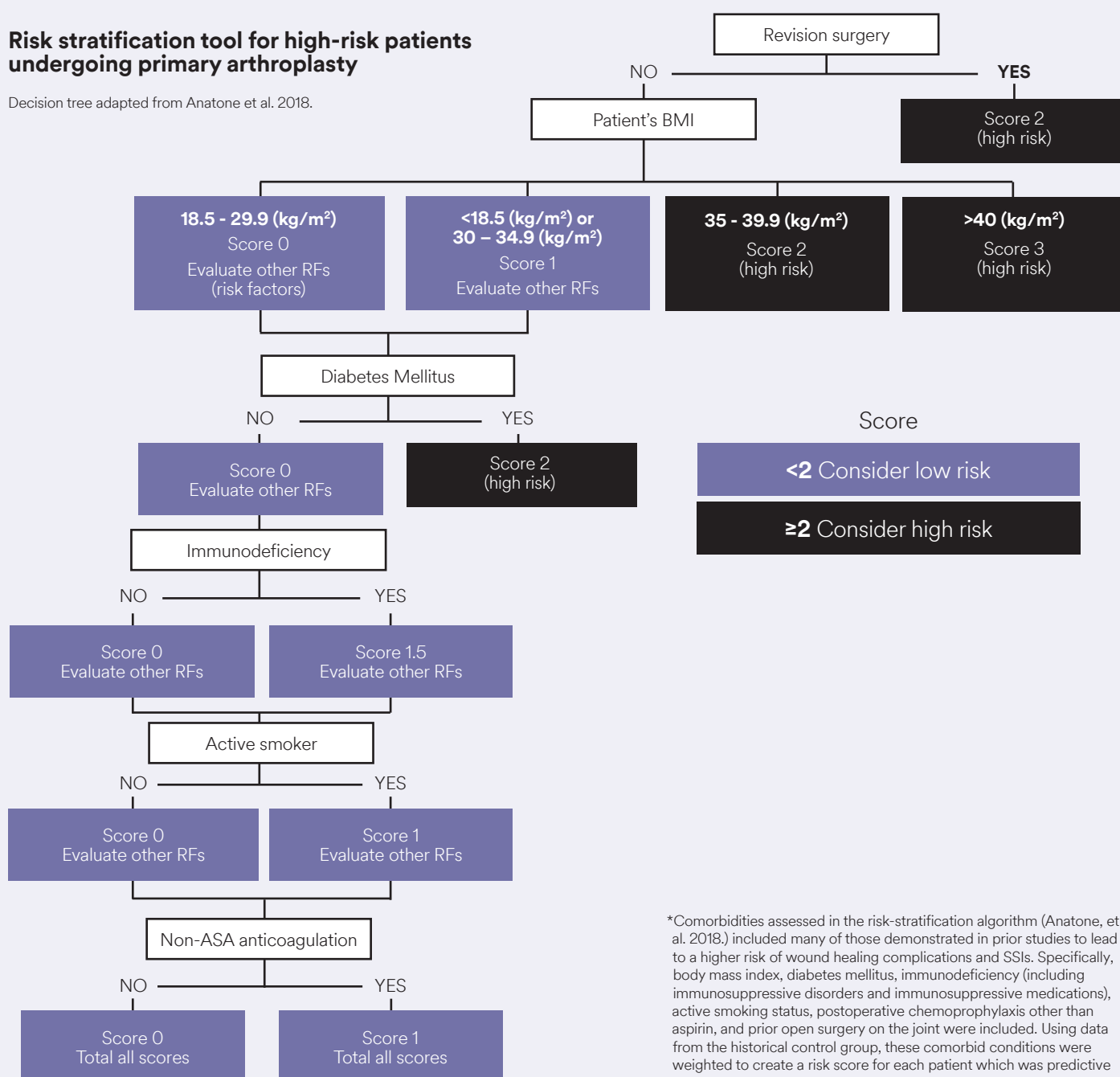
- Develop a risk stratification algorithm to guide the use of PREVENA™ Therapy and test its use in normalising the rate of superficial surgical site complications (SSCs) among high risk patients

Findings

- Compared with historical controls, a modest but significant improvement in superficial SSCs was observed after implementation of risk-stratification (12.0% vs 6.8%; $p=0.013$)
- Among high-risk patients, there was a marked improvement in SSCs when treated prophylactically with PREVENA™ dressings as compared with historical controls receiving Aquacel Ag® (26.2% vs 7.3%; $P < 0.001$)
- Low-risk patients, who continued to be treated with standard postoperative dressings, demonstrated no significant improvement (8.6% vs 6.5%; $p = 0.344$)

Risk stratification tool for high-risk patients undergoing primary arthroplasty

Decision tree adapted from Anatone et al. 2018.



*Comorbidities assessed in the risk-stratification algorithm (Anatone, et al. 2018.) included many of those demonstrated in prior studies to lead to a higher risk of wound healing complications and SSIs. Specifically, body mass index, diabetes mellitus, immunodeficiency (including immunosuppressive disorders and immunosuppressive medications), active smoking status, postoperative chemoprophylaxis other than aspirin, and prior open surgery on the joint were included. Using data from the historical control group, these comorbid conditions were weighted to create a risk score for each patient which was predictive of developing superficial surgical site complications.

Left tibial plafond fracture.

Animesh Agarwal, MD, Director of Orthopaedic Trauma and Professor of Orthopaedic Surgery at University of Texas Health Science Center, San Antonio, USA.

Patient information

Patient, a 40-year-old male who fell from a height of 20 feet, was transferred from an outside facility. He sustained an open tibial plafond fracture that was open on the medial side. Patient also had an open distal femur fracture, right closed ankle fracture, and right calcaneus fracture. Patient had a history of hypertension and a 1 pack-per day smoking habit.

Diagnosis

Patient was diagnosed with a left Grade 3 open tibial plafond fracture with an open wound on the medial side. He had extensive comminution and was originally treated with irrigation and debridement of the open fracture with placement of a bridging external fixation. There was significant swelling at the time of the injury without evidence of compartment syndrome. Due to the soft tissue injury on the medial side and the amount of fracture comminution, it was felt that a lateral extensile approach would be best warranted.

Initial incision treatment/application of PREVENA™ Therapy

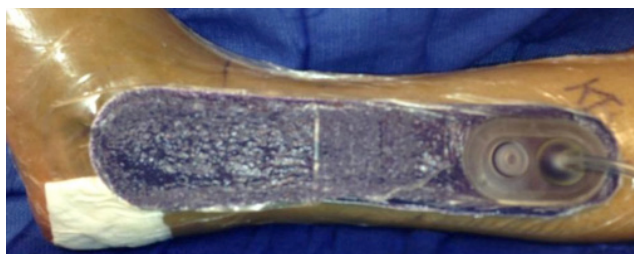
Following surgery (Figure A), the PREVENA™ Incision Management System with the PREVENA™ PEEL & PLACE™ Dressing (KCI, a 3M company, San Antonio, TX) was applied over the closed incision at -125 mmHg (Figure B).

Discharge and follow-up

PREVENA™ Therapy was discontinued after 7 days (Figure C). Enlargement of sections of the incision at this time showed excellent approximation of wound edges and what clinically appeared to be a much more mature incision at seven days than usually observed (Figure D). Due to his multiple injuries, the patient remained in the hospital and was discharged from the hospital on Day 9, which was 2 days after PREVENA™ Therapy was discontinued. The patient returned to his hometown and unfortunately was lost to further follow-up.



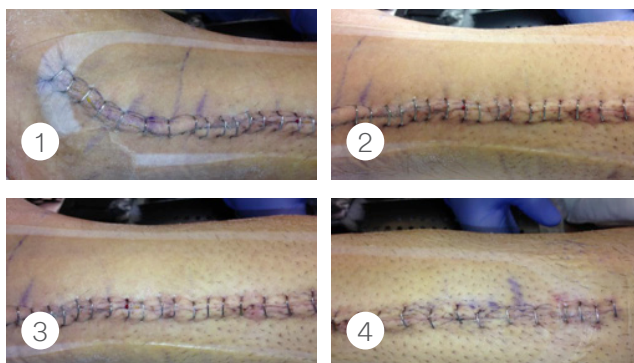
A. Clean, stapled incision post surgery for a left tibial plafond fracture.



B. Application of PREVENA™ Therapy with the PREVENA™ PEEL & PLACE™ Dressing over closed incision.



C. Incision after 7 days of PREVENA™ Therapy.



D. Enlargement of incision sections after 7 days of PREVENA™ Therapy, from the ankle (1) up through the length of the incision (2-3) to the top (4).

Revision Total Knee Arthroplasty (TKA).

H. John Cooper, M.D. Assistant Professor Columbia University, New York, New York.

Patient information

A 74-year-old woman with a past surgical history of bilateral knee replacement (Figure 1), complicated by a posterior dislocation of her right knee in 2013 that resulted in vascular compromise to her lower leg due to ruptured popliteal vessels. This was treated with reduction of the dislocation, right lower extremity vascular bypass, a needed a subsequent evacuation of a postoperative right leg hematoma. The patient's medical history was significant for morbid obesity (body mass index 40.5kg/m²), lymphedema, peripheral vascular disease, recurrent venous thromboembolic disease, hypertension, dyslipidemia, and hypothyroidism.

Diagnosis

The patient suffered a second posterior dislocation of the right knee (Figure 2). The second posterior dislocation was reduced in the emergency department (Figure 3), and limb was placed in an immobilizer. The patient was referred for revision surgery. The patient underwent a right TKA revision in which the knee joint was revised to a hinge (Figure 4). The procedure was performed without pneumatic tourniquet placement, and the patient was prescribed the anticoagulant, rivaroxaban (Xarelto®; Janssen Pharmaceutica NV, Beerse, Belgium) immediately postoperatively.¹

Initial incision treatment/application of PREVENA™ Therapy

Following the revision TKA procedure, the PREVENA PLUS™ Incision Management System with PEEL & PLACE™ Dressing – 35cm (KCI, an 3M Company, San Antonio, TX) was applied over the closed incision at -125mmHg of subatmospheric pressure to reconstitute the integumentary integrity (Figure 5). The PEEL & PLACE™ Dressing – 35cm remained over the closed incision until removal on postoperative Day 7.

Discharge and follow-up

On postoperative Day 7, the patient returned to the physician's office for dressing removal (Figure 6). After 7 days of PREVENA PLUS™ Incision Management System usage, the incision was intact, and no postoperative complications, infection or dehiscence were noted.

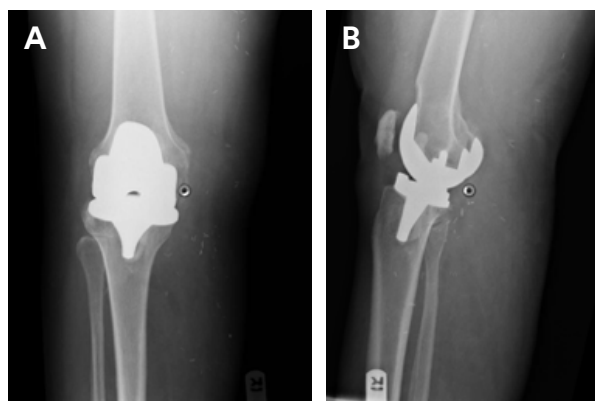


Figure 1. TKA of the right knee.

A. Radiographic image depicting frontal view of right knee following TKA.

B. Radiographic image depicting sagittal view of right knee following TKA.

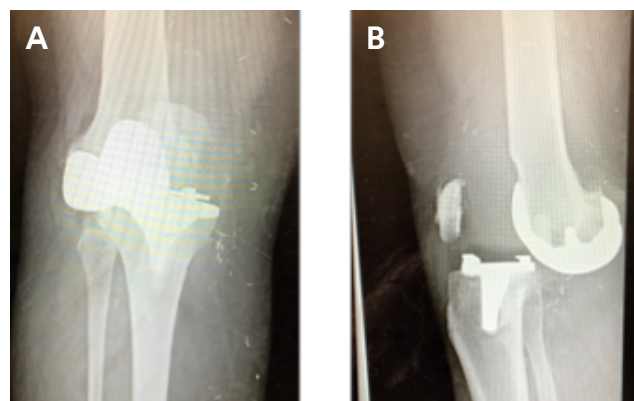


Figure 2. Right TKA after second posterior dislocation.

A. Frontal view of radiographic image depicting dislocated TKA.

B. Sagittal view of radiographic image depicting dislocated TKA.



Figure 3. Right knee underwent closed reduction and was referred for revision surgery.

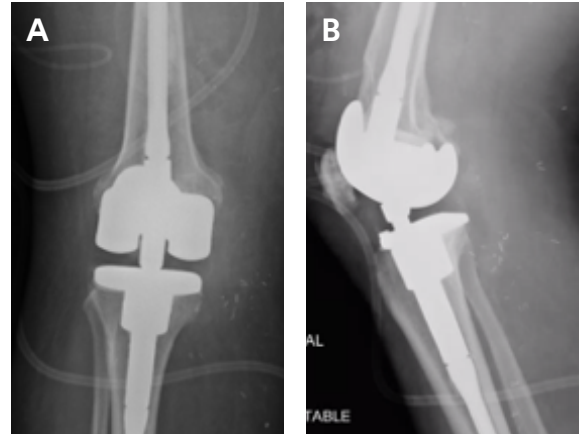


Figure 4. Right knee after TKA revision procedure.

A. Radiographic image depicting frontal view of knee following TKA revision with a hinge joint.

B. Radiographic image depicting sagittal view of knee following TKA revision with a hinge joint.

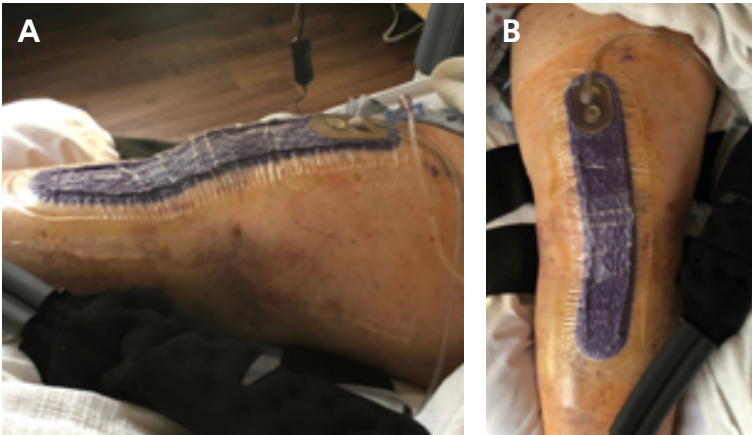


Figure 5. PREVENA PLUS™ Incision Management System with PEEL & PLACE™ Dressing – 35cm was applied postoperatively to the incision.

A. Lateral view of PEEL & PLACE™ Dressing – 35cm.

B. Anterior view of PEEL & PLACE™ Dressing – 35cm.

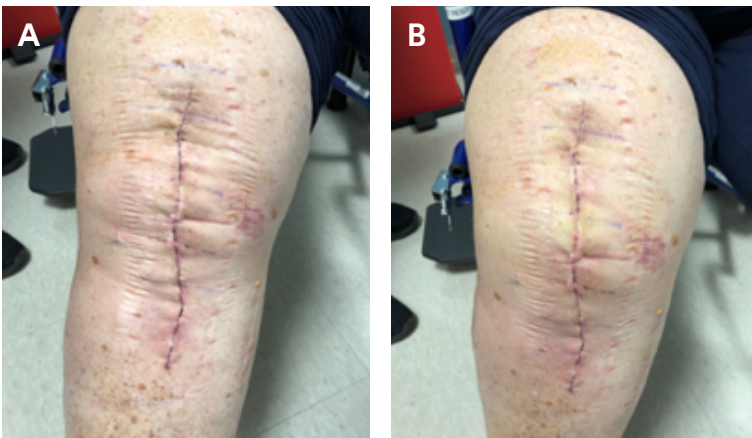


Figure 6. Patient follow-up on postoperative day 7 demonstrating intact incision.

A. Knee in an extended position after removal of PEEL & PLACE™ Dressing – 35cm.

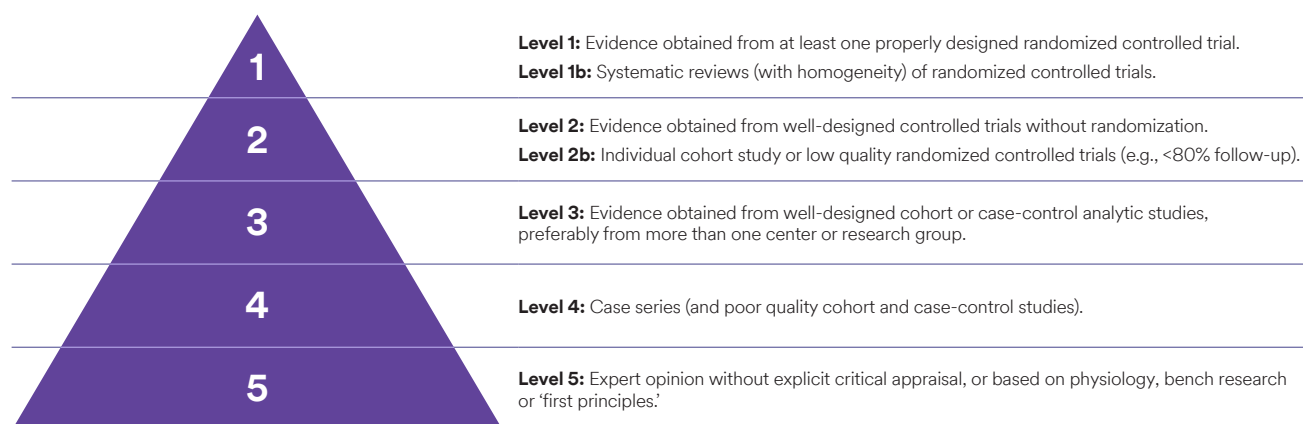
B. Knee in a flexed position after removal of PEEL & PLACE™ Dressing – 35cm.

Patient data and photos courtesy of H. John Cooper, M.D. Assistant Professor Columbia University, New York, New York.

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

There are 70+ ciNPT journal publications using our products. The following publications are specific to orthopedics.

Level of clinical evidence rating.



| Citation | Wound/surgery type | Level of clinical evidence* | |
|---|---|-----------------------------|---|
| Newman JM, Siqueira MBP, Klika AK, Molloy RM, Barsoum WK, Higuera CA. 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. <i>Journal of Arthroplasty</i> . 2018 Nov 17. [Epub Ahead of Print] | Total hip and knee arthroplasty | 1b | ● |
| Crist BD, Oladeji LO, Khazzam M, Della Rocca GJ, Murtha YM, Stannard JP. Role of acute negative pressure wound therapy over primarily closed surgical incisions in acetabular fracture ORIF: A prospective randomized trial. <i>Injury</i> . 2017 Apr 27;pii: S0020-1383(17)30283-8. | Acetabular fractures | 1b | ● |
| Pauser J, Nordmeyer M, Biber R, Jantsch J, Kopschina C, Bail HJ, Brem MH. Incisional negative pressure wound therapy after hemiarthroplasty for femoral neck fractures - reduction of wound complications. <i>International Wound Journal</i> . 2014;13(5):663-667. | Hemiarthroplasty for femoral neck fractures | 1b | ● |
| Manoharan V, Grant A, Harris A, Hazratwala K, Wilkinson M, McEwen P. Closed Incision Negative Pressure Wound Therapy vs Conventional Dry Dressings After Primary Knee Arthroplasty: A Randomized Controlled Study. <i>J Arthroplasty</i> . 2016 Apr 28. pii: S0883-5403(16)30083-3. | Knee arthroplasty | 1b | ● |
| Howell RD, Hadley S, Strauss E, Pelham FR. Blister formation with negative pressure dressings after total knee replacement. <i>Current Orthopaedic Practice</i> . 2011 Mar;22(2):176-179. | Knee arthroplasty | 1b | ● |
| Stannard JP, Robinson JT, Anderson ER, McGwin G Jr, Volgas DA, Alonso JE. Negative pressure wound therapy to treat hematomas and surgical incisions following high-energy trauma. <i>Journal of Trauma</i> . 2006 Jun;60(6):1301-6. | Lower extremity fractures | 1b | ● |
| Stannard JP, Volgas DA, McGwin G, Stewart RL, Obremskey W, Moore T, Anglen JO. Incisional negative pressure wound therapy after high-risk lower extremity fractures. <i>Journal of Orthopedic Trauma</i> . 2012 Jan;26(1):37-42. | Lower extremity fractures | 1b | ● |
| Stannard JP, Volgas DA, Stewart R, McGwin G Jr, Alonso JE. Negative pressure wound therapy after severe open fractures: a prospective randomized study. <i>Journal of Orthopedic Trauma</i> . 2009 Sep;23(8):552-7. | Lower extremity fractures | 1b | ● |
| Pachowsky M, Gusinde J, Klein A, Lehl S, Schulz-Drost S, Schlechtweg P, Pauser J, Gelse K, Brem MH. Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty. <i>International Orthopaedics</i> . 2012 Apr;36(4):719-22. | Total hip arthroplasty | 1b | ● |
| Redfern RE, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer KJ. Closed incision negative pressure therapy effect on postoperative infection and surgical site complication after total hip and knee arthroplasty. <i>J Arthroplasty</i> 2017 Nov;32(11):3333-3339. | Hip and knee arthroplasty | 2 | ● |
| Reddix RN Jr, Leng XI, Woodall J, Jackson B, Dedmond B, Webb LX. The effect of incisional negative pressure therapy on wound complications after acetabular fracture surgery. <i>Journal of Surgical Orthopaedic Advances</i> . 2010 Jun;19(2):91-7. | Hip arthroplasty | 3 | ● |
| Cooper HJ, Roc GC, Bas MA, Berliner ZP, Hepinstall MS, Rodriguez JA, Weiner LS. Closed incision negative pressure therapy decreases complications after periprosthetic fracture surgery around the hip and knee. <i>Injury</i> . 2018 Feb;49(2):386-391. doi: 10.1016/j.injury.2017.11.010. Epub 2017 Nov 14. | Periprosthetic fracture surgery | 3 | ● |
| Cooper HJ, Bas MA. Closed-Incision Negative-Pressure Therapy Versus Antimicrobial Dressings After Revision Hip and Knee Surgery: A Comparative Study. <i>J Arthroplasty</i> . 2016 May;31(5):1047-52. | Revision knee and hip | 3 | ● |
| Anatone AJ, Shah RP, Jennings EL, Geller JA, Cooper J. A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty. <i>Arthroplasty Today</i> . 2018;4(4):493-498. doi:10.1016/j.artd.2018.09.004. | Hip and knee arthroplasty | 3 | ● |
| Curley AJ, Terhune EB, Velott AT, Argintar EH. Outcomes of Prophylactic Negative Pressure Wound Therapy in Knee Arthroplasty. <i>Orthopedics</i> . 2018;41(6):e837-e840. doi:10.3928/01477447-20181010-02. | Knee arthroplasty | 3 | ● |

| Citation | Wound/surgery type | Level of clinical evidence* |
|---|---------------------------|-----------------------------|
| Reddix RN, Tyler HK, Kulp B, Webb LX. Incisional vacuum-assisted wound closure in morbidly obese patients undergoing acetabular fracture surgery. <i>The American Journal of Orthopedics</i> . 2009 Sep;38(9):32-5. | Acetabular fractures | 4 ● |
| Hansen E, Durinka JB, Costanzo JA, Austin MS, Deirmengian GK. Negative pressure wound therapy is associated with resolution of incisional drainage in most wounds after hip arthroplasty. <i>Clinical Orthopaedics and Related Research</i> . 2013 Oct;471(10):3230-6. | Hip arthroplasty | 4 ● |
| Stannard JP, Atkins BZ, O-Malley D, Singh H, Bernstein B, Fahey M, Masden D, Attinger CE. Use of negative pressure therapy on closed surgical incisions: A case series. <i>Ostomy Wound Management</i> . 2009 Aug;55(8):58-66. | Lower extremity fractures | 4 ● |
| Gomoll AH, Lin A, Harris MB. Incisional vacuum-assisted closure therapy. <i>Journal of Orthopaedic Trauma</i> . 2006 Nov-Dec;20(10):705-9. | Orthopaedic trauma | 4 ● |
| Stannard JP, Gabriel A, Lehner B. Use of Negative Pressure Wound Therapy Over Clean, Closed Surgical Incisions. <i>International Wound Journal</i> . 2012;9:32-39. | Orthopaedic trauma | 4 ● |
| Berkowitz MJ. Use of a Negative Pressure Incisional Dressing After Surgical Treatment of Calcaneal Fractures. <i>Techniques in Foot and Ankle Surgery</i> . 2013 Dec;12(4):172-174. | Calcaneal fractures | 5 ● |
| Brem MH, Bail HJ, Biber R. Value of Incisional Negative Pressure Wound Therapy in Orthopedic Surgery. <i>International Wound Journal</i> . 2014 Jun;11(Suppl 1):3-5. | Mixed | 5 ● |
| Suleiman LI, Mesko DR, Nam D. Intraoperative Considerations for Treatment/Prevention of Prosthetic Joint Infection. <i>Current Reviews in Musculoskeletal Medicine</i> . 2018:1-8. | Hip and knee arthroplasty | 5 ● |
| Chotanaphuti T, Courtney PM, Fram B, Kleef N.J., Kim TK, Kuo FC, Lustig S, Moojen DJ, Nijhof M, Oliashirazi A, Poolman R, Purtill JJ, Rapisarda A, Rivero-Boschert S, Veltman ES. Hip and Knee Section, Treatment, Algorithm: Proceedings of International Consensus on Orthopedic Infections. <i>The Journal of Arthroplasty</i> . 34(2S):S393-S397. doi: 10.1016/j.arth.2018.09.024. | Hip and knee arthroplasty | 5 ● |
| DeCarbo WT, Hyer CF. Negative-Pressure Wound Therapy Applied to High-Risk Surgical Incisions. <i>Journal of Foot and Ankle Surgery</i> . 2010 May;49(3):299-300. | Orthopaedic trauma | 5 ● |
| Nam D, Sershon RA, Levine BR, Della Valle CJ. The Use of Closed Incision Negative-Pressure Wound Therapy in Orthopaedic Surgery. <i>J Am Acad Orthop Surg</i> . 2018:1-8. doi: 10.5435/JAAOS-D-17-00054. | Orthopaedic surgery | 5 ● |
| Al-Houraihi RK, Aalirezaie A, Adib F, Anoushiravani A, Bhashyam A, Binlaksar R, Blevins K, Bonanzinga T, Chih-Kuo F, Cordova M, Deirmengian GK, Fillingham Y, Frenkel T, Gomez J, Gundtoft P, Harris MA, Harris M, Heller S, Jennings JA, Jimenez-Garrido C, Karam JA, Khlopas A, Klement MR, Komnos G, Krebs V, Lachiewicz P, Miller AO, Mont MA, Montanez E, Romero CA, Schwarzkopf R, Shaffer A, Sharkey PF, Smith BM, Sodhi N, Thienpont E, Villanueva AO, Yazdi H. General Assembly, Prevention, Wound Management: Proceedings of International Consensus on Orthopedic Infections. <i>The Journal of Arthroplasty</i> . 2019;34(2):S157-S168. doi:10.1016/j.arth.2018.09.066. | Orthopaedic infections | 5 ● |
| Agarwal A. Management of Closed Incisions Using Negative-Pressure Wound Therapy in Orthopedic Surgery. <i>Plastic and reconstructive surgery</i> . 2019;143(1 Management of Surgical Incisions Utilizing Closed Incision Negative Pressure Therapy):21S-26S. | Orthopedic trauma surgery | 5 ● |
| ● Available on request. | | |

References

- Public Health England. Surveillance of surgical site infections in NHS hospitals in England April 2018 to March 2019. Published December 2019.
- Jenks, P.J. Clinical and economic burden of surgical site infection (SSI) and predicted financial consequences of elimination of SSI from an English hospital, Volume 86 (2014), Issue 1, pg 24–33.
- Merkow R, . Underlying reasons associate with hospital readmission following surgery in the US. . 2015;313(5):483–95.
- M. Nobile, P. Navone, A. Orzella, *et al.* Developing a model for analysis the extra costs associated with surgical site infections (SSIs): an orthopaedic and traumatological study run by the Gaetano Pini Orthopaedic Institute, 4 (2015), p. P68.
- Wilkes RP, Kilpadi DV, Zhao Y, . Closed Incision Management With Negative Pressure Wound Therapy (CIM): Biomechanics. 2012;19(1):67–75.
- Kilpadi DV, Cunningham MR. Evaluation of Closed Incision Management with Negative Pressure Wound Therapy (CIM): Hematoma/Seroma and Involvement of the Lymphatic System. . 2011;19:588–596.
- Glaser DA, Farnsworth CL, Varley ES. Negative pressure therapy for closed spine incisions: A pilot study. 2012;24(11):308–316.
- Federal Drug Administration. De Novo Classification Request for PREVENA 125 and PREVENA PLUS 125 Therapy Units. De Novo Summary (DEN180013), 2019. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180013.pdf
- Newman JM, Siqueira MBP, Klika AK, Molloy RM, Barsoum WK, Higuera CA. 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. *J Arthroplasty*. 2019;34(3):554–559.
- 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(5):1047–1052.
- Anatone AJ, Shah RP, Jennings EL, Geller JA, Cooper J. A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty. *Arthroplasty Today*. 2018;4(4):493-498. doi:10.1016/j.artd.2018.09.004.

PREVENA™ Therapy System Kits

| Size | Code | Contents |
|------|---------|--|
| 13cm | PRE1101 | 1 x PREVENA™ 125 Therapy Unit, 1 x 13cm PREVENA PEEL & PLACE™ Dressing, Patch Strips, V.A.C.® Connector |
| 20cm | PRE1001 | 1 x PREVENA™ 125 Therapy Unit, 1 x 20cm PREVENA PEEL & PLACE™ Dressing, Patch Strips, V.A.C.® Connector |
| 35cm | PRE3201 | 1 x PREVENA™ PLUS Therapy Unit, 1 x 35cm PREVENA PEEL & PLACE™ Dressing, Patch Strips, V.A.C.® Connector |
| 90cm | PRE4001 | 1 x PREVENA™ PLUS Therapy Unit, 1 x 90cm PREVENA CUSTOMIZABLE™ Dressing with SENSAT.R.A.C.™ |

PREVENA™ Therapy Dressing Kits

| Size | Code | Contents |
|------|---------|--|
| 13cm | PRE1155 | 5 x 13cm PREVENA PEEL & PLACE™ Dressings |
| 20cm | PRE1055 | 5 x 20cm PREVENA PEEL & PLACE™ Dressings |
| 35cm | PRE3255 | 5 x 35cm PREVENA PEEL & PLACE™ Dressings |
| 90cm | PRE4055 | 5 x 90cm PREVENA CUSTOMIZABLE™ Dressings with SENSAT.R.A.C.™ |

PREVENA™ Therapy Accessories

| Size | Code | Contents |
|-------------------|---------|---|
| 45ml Canister | PRE1095 | 5 x 45ml PREVENA™ Canister |
| 150ml Canister | PRE4095 | 5 x 150ml PREVENA PLUS™ Canister |
| V.A.C.® Connector | PRE9090 | 10 x PREVENA™ Therapy V.A.C.® Connector |

For more information about the PREVENA™ Therapy System, contact your local representative.

Note: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. This material is intended for healthcare professionals.

© 2020 3M. All rights reserved. 3M and the other marks shown are marks and/or registered marks. Unauthorised use prohibited. PRA-PM-SG-00041 (10/20)