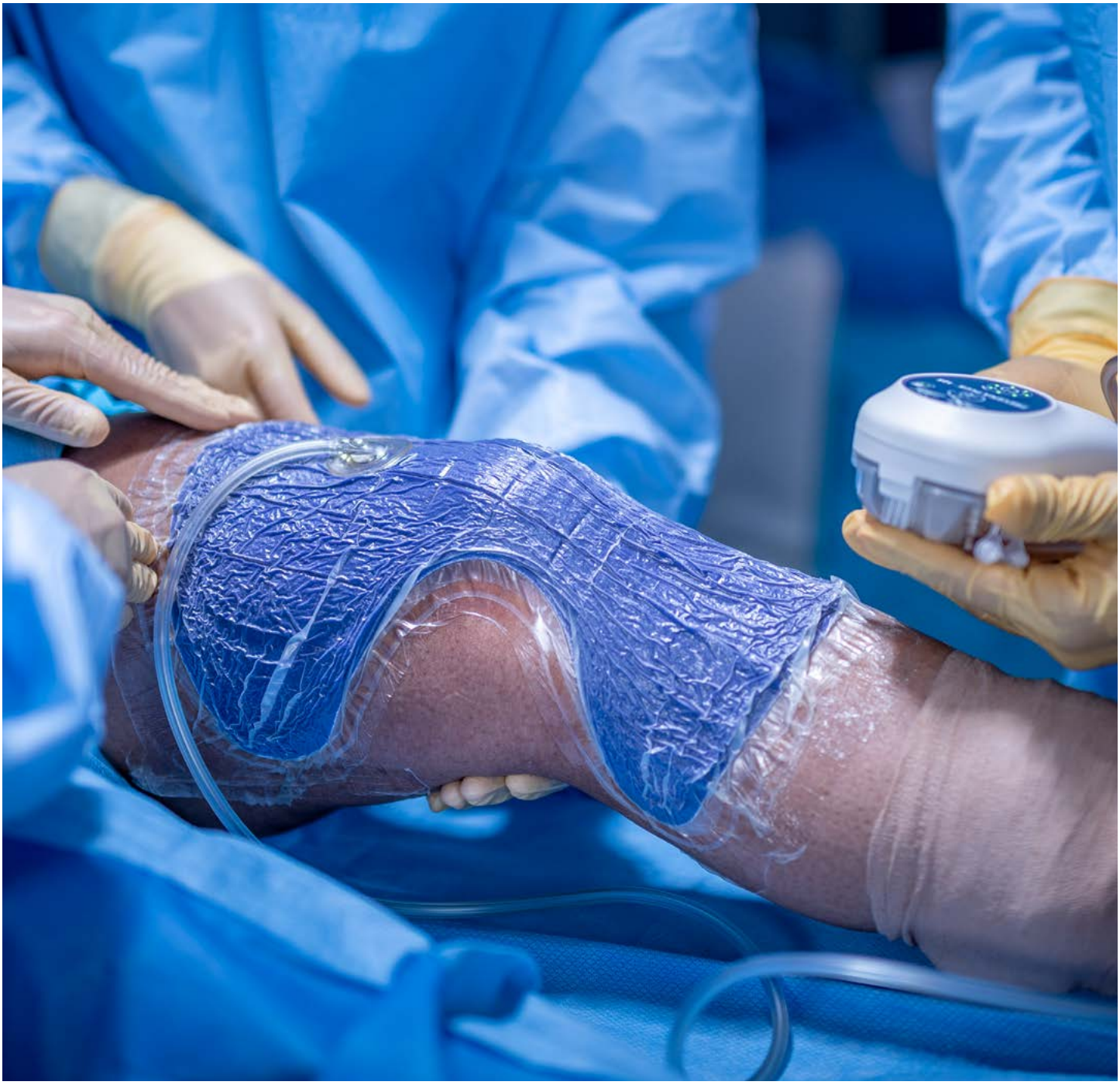


PRM in orthopedic surgery

Prevena.com/orthopedics

3M™ Prevena Restor™ Dressings can be used on a variety of anatomical locations.

Closed incision negative pressure therapy vs standard of care over closed knee and hip arthroplasty surgical incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies

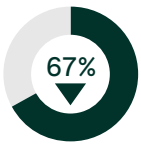
Cooper HJ, Silverman RP, Collinsworth A, Bongards C, Griffin L. *Arthroplast Today.* 2023 Apr 3;21:101120.

Study design
Systematic review and meta-analysis

Study purpose
Conduct a systematic review and meta-analysis to identify studies comparing Prevena Therapy to standard dressings on closed hip and knee arthroplasty incisions and to evaluate the effectiveness of Prevena Therapy versus standard dressings in reducing surgical site complications (SSCs).

Methods
- The systematic review included manuscripts and abstracts written in English and published between January 2005 to July 2021. Studies compared the use of ciNPT to standard dressing following primary or revision knee or hip arthroplasty.
- Standard dressing groups received silver-impregnated occlusive dressings or conventional dry dressings.
- 12 studies were included: 4 randomized controlled trials, 2 prospective studies, 6 retrospective studies. 8 of these studies were on high-risk populations.
- Weighted risk ratios were used to combine studies and random effects models were used regardless of heterogeneity.
- Outcomes included SSCs, surgical site infections (SSIs), seroma, hematoma, dehiscence, and incisional drainage.
- Subgroup analyses were conducted to include studies done on high-risk cases.
- Cost analysis was performed using SSC rates from the included studies, risk reduction results from the meta-analysis, and estimated SSC costs from the Premier Healthcare Database.

Results



Reduction of risk of SSC*
8 studies; risk ratio 0.332 (95% CI 0.236-0.467) (p<0.001)*

Reduction of risk of dehiscence*†
5 studies; risk ratio 0.380 (95% CI 0.176-0.820) (p=0.014)*

Reduction of risk of SSI*
7 studies; risk ratio 0.401 (95% CI 0.190-0.844) (p=0.016)*

Reduction of risk of drainage*
4 studies; risk ratio 0.399 (95% CI 0.218-0.728) (p=0.003)*

Reduction of risk of seroma*
3 studies; risk ratio 0.473 (95% CI 0.272-0.824) (p<0.008)*

Reduction of risk of ROR*
8 studies; risk ratio 0.418 (95% CI 0.246-0.712) (p=0.001)*

(Continued)

Calculation(s) are derived based on relative patient group incidence rate reported in this study

*Statistically significant (p<0.05)

†NOTE: The use of Prevena Therapy for reduction in the incidence of dehiscence has not been reviewed by the U.S. FDA

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 hcbgregulatory.3m.com.

(Continued)

Additional outcomes

Outcome	High-risk subgroup analysis	# of studies	Risk ratio (95% CI)	p-value
SSC	Primary or revision	6	0.328 (0.229-0.469)	<0.001*
SSC	Primary	3	0.331 (0.206-0.533)	<0.001*
SSC	Silver dressing as standard dressing	5	0.332 (0.229-0.482)	<0.001*
SSI	Primary or revision	6	0.385 (0.164-0.906)	0.029*
SSI	Silver dressing as standard dressing	5	0.401 (0.163-0.986)	0.046*

Summary

- This systematic review and meta-analysis of 12 published studies demonstrated that the use of Prevena Therapy was associated with reduced risks of SSCs, SSIs,† seromas, dehiscence,† prolonged drainage, and ROR following hip or knee arthroplasty. There was no reduction in hematoma rates.
- Subgroup analyses of studies done on high-risk patients also demonstrated a reduced risk in SSCs and SSIs.
- Potential cost savings of $932 per patient with the use of Prevena Therapy to reduce the risk of SSCs.

Calculation(s) are derived based on relative patient group incidence rate reported in this study

*Statistically significant (p<0.05)

†NOTE: The use of Prevena Therapy for reduction in the incidence of deep SSI and dehiscence has not been reviewed by the U.S. FDA

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 hcbgregulatory.3m.com.

Read the full study here

Journal: *Arthroplasty Today*

Title: Closed incision negative pressure therapy vs standard of care over closed knee and hip arthroplasty surgical incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies

Published: April 3, 2023

Cooper HJ, Silverman RP, Collinsworth A, Bongards C, Griffin L. Closed incision negative pressure therapy vs standard of care over closed knee and hip arthroplasty surgical incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies. *Arthroplast Today.* 2023 Apr 3;21:101120.

PROMISES study data suggests 3M™ Prevena™ Therapy can help advance the standard of care

Data from a multicenter randomized controlled trial showed that Prevena Therapy significantly reduced the risk of 90-day surgical site complications (SSCs) and postop readmissions vs. silver-impregnated dressings.

The PROMISES (Post-market, Randomized, Open-Label, Multicenter Study to evaluate Effectiveness) Trial

The effectiveness of closed incision negative pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, et al. *J Arthroplasty.* 2021 Jul;36(7S):S295-S302.e14.

Study design
Multi-center randomized controlled trial (Level I)

Study purpose
Evaluate the effectiveness of Prevena Therapy versus standard dressings in reducing surgical site complications (SSCs) in high-risk patients after revision knee arthroplasty (rTKA)

Methods

- 294 high-risk rTKA patients (15 centers) randomized to Prevena Therapy (n=147) or silver-impregnated dressing (n=147).
- Inclusion criteria: exhibit at least one risk factor for postoperative SSC: BMI >35 kg/m^2 use of non-aspirin blood thinners postoperatively; current/previous diagnosis of peripheral vascular disease; current tobacco use; history of prior infection history at operative site; operative limb lymphedema; insulin-dependent diabetes; current use of immunomodulators or corticosteroids; ongoing malignancy excluding localized skin cancer; rheumatoid arthritis; renal failure or dialysis; malnutrition; liver disease; solid organ transplant recipients; or human immunodeficiency virus infection.
- Primary outcome was 90-day incidence of SSCs. Secondary outcomes were the 90-day health care utilization parameters (readmission, reoperation, dressing changes, and visits) and patient-reported outcomes (PRO). Treatment-related adverse events were compared and stratified as severe and non-severe.
- Primary and secondary outcomes reported on an intention-to-treat basis. Adverse event reporting based on the Safety Analysis Dataset.

Results
Compared to SOC, patients in the Prevena Therapy group demonstrated:

- Significantly decreased rates of surgical site complications (Prevena Therapy 3.4% vs. SOC 14.3%, **p=0.0013***)
- Significantly lower readmission rates (Prevena Therapy 3.4% vs. SOC 10.2%, **p=0.0208***)
- Reduced dressing changes (Prevena Therapy 1.1±0.29 vs. SOC 1.3 ±0.96, **p=0.0003***)
- SSCs in Aseptic rTKA (Prevena Therapy 1.8% vs. SOC 14.3%, **p=0.0006***)
- Length of stay if readmitted (Prevena Therapy 2.2 ± 2.28 vs. SOC 8.6 ± 7.38, **p=0.0254***)
- Patients receiving >1 dressing change (Prevena Therapy 4.7% vs. SOC 17.86%, **p=0.0005***)

(Continued)

Calculation(s) are derived based on relative patient group incidence rate reported in this study

*Statistically significant (p<0.05)

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 hcbgregulatory.3m.com.

(Continued)

Key results

Outcome (90 days)	Prevena™ Therapy	Silver-impregnated dressing	p-value
SSC non-surgical interventions (90 days)	2.7% (4/147)	12.9% (19/147)	0.0017*
SSC surgical interventions (90 days)	0.7% (1/147)	4.8% (7/147)	0.0666

Cost effectiveness

All patients:

$989 Reduction in per-patient cost of care

$1,047 3M™ Prevena™ Therapy vs. $2,036 SOC

Higher-risk patients (CCI ≥2):

$2,536 Reduction in per-patient cost of care

$676 3M™ Prevena™ Therapy vs. $3,212 SOC

Conclusions

- Prevena Therapy significantly mitigated 90-day surgical site complications, readmission rates, and reduced frequency of dressing changes compared with the standard of care among high-risk rTKA patients.
- Treatment-related adverse effects were similar between both cohorts.
- There were no significant differences in specific SSC types, reoperation rates, number of visits, and patient reported outcomes.

Calculation(s) are derived based on relative patient group incidence rate reported in this study

*Statistically significant (p<0.05)

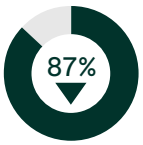
Results

Reduction in SSCs*

3.4% (5/147) Prevena Therapy vs. 14.3% (21/147) Silver-impregnated dressing (p=0.0013)*

Reduction in readmission rates*

3.4% (5/147) Prevena Therapy vs. 10.3% (15/147) Silver-impregnated dressing (p=0.0208)*

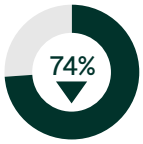


Reduction in 90-day SSCs*

1.8% (2/118) Prevena Therapy vs. 14.3% (15/119) Silver-impregnated dressing (p=0.0006)*

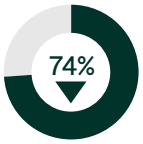
Fewer mean dressing changes*

1.1 ± 0.3 Prevena Therapy vs. 1.3 ± 1.0 Silver-impregnated dressing (p=0.0003)*



Shorter LoS if readmitted*

2.2 ± 2.28 Prevena Therapy vs. 8.6 ± 7.38 Silver-impregnated dressing (p=0.0254)*



Fewer patients receiving >1 dressing change*

4.7% (7/149) Prevena Therapy vs. 17.9% (25/140) Silver-impregnated dressing (p=0.0005)*

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 hcbgregulatory.3m.com.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: The effectiveness of closed-incision negative-pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty: The PROMISES randomized controlled trial

Published: March 5, 2021

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, et al. The effectiveness of closed-incision negative-pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty: The PROMISES randomized controlled trial. *J Arthroplasty.* 2021 Jul;36(7S):S295-S302.e14. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use.

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

Newman JM, Siqueira MBP, Klika AK, et al. *J Arthroplasty.* 2019 Mar;34(3):554-559.

Study design

Prospective, single-center, randomized controlled trial

Study purpose

The purpose of the Newman study was to compare the use of Prevena Therapy to a sterile silver-impregnated dressing in revision arthroplasty (rTHA, rTKA) patients at high risk to develop wound complications

Methods

- 160 patients undergoing elective rTHA and rTKA were prospectively randomized to receive Prevena Therapy or silver-impregnated dressing (AQUACEL® Ag) at a single institution.
- Patients had at least one risk factor for developing a wound complication.
- Primary outcome was wound complications (drainage, cellulitis, blisters, hematoma, skin necrosis, wound dehiscence, nonhealing wound, suture abscess, surgical site infection, periprosthetic joint infection).
- Additional outcomes included all-cause readmissions and hip/knee related reoperations.
- Data collected at 2, 4 and 12 weeks postoperatively. 12-week results reported here.
- Multivariate regression models were used to control for baseline differences between the groups (history of prior joint infection and inflammatory arthritis).

Results

Reduction in wound complications*

10.1% (8/79) Prevena Therapy vs. 23.8% (19/80) Silver-impregnated dressing (p=0.022)*

Fewer returns to the OR*

2.5% (2/79) Prevena Therapy vs. 12.5% (10/80) Silver-impregnated dressing (p=0.017)*

Key points

- There were significant differences in the number of patients with 1) a history of prior joint infection and 2) inflammatory arthritis, with a higher incidence in the standard dressing arm. After multivariate regression to account for these differences, Prevena Therapy significantly decreased SSC rate (odds ratio 0.29, 95% confidence interval 0.11-0.75, p=0.010*).
- High-risk patients could benefit from Prevena Therapy to help reduce the risk of wound complications and reoperations after rTHA and rTKA.
- The authors suggest future multicenter clinical trials to further strengthen the results as well as a cost-benefit analysis.

(Continued)

Calculation(s) are derived based on relative patient group incidence rate reported in this study

*Statistically significant (p<0.05)

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 hcbgregulatory.3m.com.

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 3M™ 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 3M.

(Continued)

Additional outcomes

Types and number of wound complications	Prevena™ Therapy	Silver-impregnated dressing
Periprosthetic joint infection*	2.5% (2/79)	8.8% (7/80)
Dehiscence*	1.3% (1/79)	5.0% (4/80)
Drainage	6.3% (5/79)	20.0% (16/80)
Nonhealing wound	0% (0/79)	5% (4/80)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Newman et al outcomes

Hypothetical economic model	Prevena™ Therapy	Silver-impregnated dressing
Patients	79	80
Number of surgical site complications (a)	8	19
Cost per SSC[1] (b)	$16,173	$16,173
Per patient complication cost (a*b)/n	$1,638	$3,841
Per patient therapy cost†	$495	$39
Total cost per patient	$2,133	$3,880
Potential per incision savings using Prevena™ Therapy	$1,747	

Assumes cost per SSC for rTKA at higher end of total range of TKA/THA data.

*NOTE: The use of Prevena Therapy for reduction in the incidence of deep SSI and dehiscence has not been reviewed by the U.S. FDA

†3M™ Prevena™ Peel and Place System Kit and AQUACEL® Ag SURGICAL price are an estimate; individual prices may vary.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or AQUACEL® Ag SURGICAL. 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.

Reference
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2023 Aug;14:31-45.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: 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

Published: November 16, 2018

Newman JM, Siqueira MBP, Klika AK, et al. 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 Mar;34(3):554-559. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use.

Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty

Pachowsky M, Gusinde J, Klein A, et al. *Int Orthop.* 2012 Apr;36(4):719-722.

Study design

Prospective, single-center, randomized control trial (Level II)

Study purpose

The purpose of the Pachowsky study was to evaluate the effect of Prevena Therapy on incisional healing and the prevention of seromas in clean, closed incisions after total hip arthroplasty (THA)

Methods

- Patients were randomized into two groups: 10 patients with a standard dressing, consisting of a dry wound coverage; and nine patients with Prevena Therapy placed over the sutured wound area for five days.
- Ultrasound was used to detect and measure seromas in both groups on days 5 and 10 postoperatively. Patients underwent ultrasound of the surgical site preoperatively as a control to assess for potential soft tissue abnormalities.
- Groups were comparable in age and incision size. All patients received perioperative treatment and antibiotics.
- Study endpoints included the number of patients with seromas and average volume size of seroma.

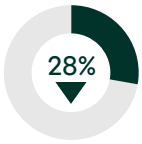
Summary

- This study showed fewer post-operative seromas and significantly lower seroma volume 10 days after surgery with the use of 3M™ Prevena™ Therapy.
- The authors concluded that application of Prevena Therapy on closed incisions after orthopedic surgery might help reduce the complications of a prolonged wound healing and postoperative seroma in the wound area.

Results

Reduction in mean seroma volume at day 10*

1.97 ± 3.21 mL Prevena Therapy vs. 5.08 ± 5.11 mL standard dressing (p=0.021)*



Reduction in antibiotic days*

8.44 ± 2.24 mL Prevena Therapy vs. 11.8 ± 2.82 mL standard dressing (p=0.005)*

Additional outcomes

Outcome	Prevena™ Therapy	Standard dressing	p-value
Seromas	44% (4/9)	90% (9/10)	Not reported
Seroma volume (mL) at day 5	0.58 ± 1.21	2.02 ± 2.74	0.102
Secretion from the wound after 5 days	11% (1/9)	50% (5/10)	Not reported
CRP (mg/L) day 10	22.39 ± 8.51	44.06 ± 30.66	0.069

Calculation(s) are derived based on relative patient group incidence rate reported in this study

*Statistically significant (p<0.05)

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 hcbgregulatory.3m.com.

Read the full study here

Journal: *International Orthopaedics*

Title: Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty

Published: July 15, 2011

Pachowsky M, Gusinde J, Klein A, et al. Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty. *Int Orthop.* 2012 Apr;36(4):719-722.

Closed incision negative pressure therapy effects on postoperative infection and surgical site complication after total hip and knee arthroplasty

Redfern RE, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer KJ. *J Arthroplasty.* 2017 Nov;32(11):3333-3339.

Study design

Single-center, prospective versus historic control comparative study

Study purpose

The purpose of the Redfern study was to examine the use of 3M™ Prevena™ Therapy over clean closed surgical incisions after primary total joint replacement and whether it would reduce the rates of wound complications

Methods

- The Prevena Therapy group was comprised of 192 patients representing 196 incisions, who were actively enrolled from 2013 to 2014.
- The historical control group consisted of 400 patients who underwent surgery from 2011 to 2012.
- Prevena Therapy was applied over the closed incision for 6-8 days postoperatively. The standard dressing group included a sterile gauze dressing with standard dressing changes.
- Study endpoints including the rate of surgical site complications requiring medical or surgical intervention, including surgical site infections (deep and superficial infections), wound dehiscence, hematomas, seromas, edema/swelling, and drainage were compared between groups.

Additional outcomes

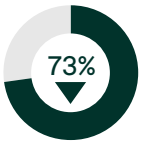
Outcome	Prevena™ Therapy	Standard dressing	p-value
Drainage	1.0% (2/196)	3.0% (12/400)	0.07
Reaction to dressing	13.8% (27/196)	2.25% (9/400)	<0.0001*

Calculation(s) are derived based on relative patient group incidence rate reported in this study

*Statistically significant (p<0.05)

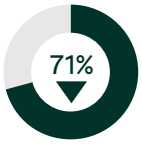
†NOTE: The use of Prevena Therapy for the reduction in the incidence of pain has not been reviewed by the U.S. FDA

Results



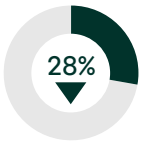
Reduction in SSCs*

1.5% (3/196) Prevena Therapy vs. 5.5% (22/400) standard dressing (p=0.02)*



Reduction in SSIs*

1.0% (2/196) Prevena Therapy vs. 3.5% (14/400) standard dressing (p=0.04)*



Reduction in pain 24h postop*†

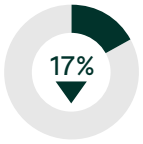
2.6+1.8 Prevena Therapy vs. 3.6+2.2 standard dressing (p=0.0001)*†

Reduction in hematomas*

0% (0/196) Prevena Therapy vs. 2.25% (9/400) standard dressing (p=0.02)*

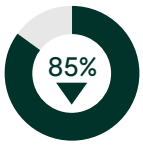
Reduction in superficial SSIs*

0% (0/196) Prevena Therapy vs. 2.25% (9/400) standard dressing (p=0.03)*



Reduction in length of stay*

1.9+0.6 Prevena Therapy vs. 2.3+0.5 standard dressing (p<0.0001)*



Reduction in edema/swelling*

0.5% (1/196) Prevena Therapy vs. 3.25% (13/400) standard dressing (p=0.02)*

Reduction in abnormal surrounding soft tissue appearance*

0% (0/196) Prevena Therapy vs. 3.75% (15/400) standard dressing (p=0.03)*

(Continued)

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 hcbgregulatory.3m.com.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Redfern et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Patients	196	400
Number of complications (a)	3	22
Cost per SSC[1] (b)	$16,173	$16,173
Per patient complication cost (a*b)/n	$248	$890
Per patient therapy cost*	$495	–
Total cost per patient	$743	$890
Potential per incision savings using Prevena™ Therapy	$147	

Key points

- In this study, Prevena Therapy reduced the overall incidence of complications requiring medical or surgical intervention for hip and knee arthroplasty.
- After logistic regression to examine the effects of Prevena Therapy, sex, BMI, surgical site (hip or knee), and health status on SSCs, only Prevena Therapy was associated with SSC reduction. Prevena Therapy patients were approximately four times less likely to develop an SSC when compared with control (odds ratio 4.251 (95% CI 1.172-15.414; p=0.0277).
- While reaction to the dressing was more frequent in the Prevena Therapy group, all cases were resolved with antibiotic ointment, the rate in this study was lower than other studies, and these reactions can be mitigated through dressing application technique.

*3M™ Prevena™ Peel and Place System Kit is an estimate; individual prices may vary.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or gauze dressing. 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.

Reference
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2023 Aug;14:31-45.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: Closed incision negative pressure therapy effects on postoperative infection and surgical site complication after total hip and knee arthroplasty

Published: June 16, 2017

Redfern RE, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer KJ. Closed incision negative pressure therapy effects on postoperative infection and surgical site complication after total hip and knee arthroplasty. *J Arthroplasty.* 2017 Nov;32(11):3333-3339. Note that the length of therapy may be outside the range recommended in the Instructions for Use.

Comparison of surgical site complications with negative pressure wound therapy vs silver impregnated dressing in high-risk total knee arthroplasty patients: A matched cohort study

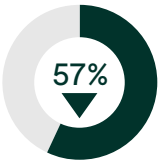
Doman DM, Young AM, Buller LT, Deckard ER, Meneghini RM. *J Arthroplasty.* 2021 Oct;36(10):3437-3442.

Study design
Retrospective comparative cohort study

Study purpose
To compare the rates of incisional and non-incisional wound complications, periprosthetic joint infections, and reoperations in high-risk primary TKA patients that receive Prevena Therapy versus standard dressing.

Methods
- The Prevena Therapy group comprised of 130 patients who had primary TKA between July 2018 and December 2019.
- The retrospective historical control group (AQUACEL® Ag SURGICAL) consisted of 130 TKAs, propensity matched 1:1, who underwent surgery between December 2016 and June 2018.
- High-risk criteria included active tobacco use, diabetes mellitus, BMI >35 kg/m^2, autoimmune disease, chronic kidney disease, *Staphylococcus aureus* nasal colonization, and non-aspirin anticoagulation.
- Study endpoints included incisional wound complications, defined as: cellulitis, focal swelling, suture reaction, dehiscence and hematoma. Non-incisional wound complications were also assessed and defined as dressing reactions, blistering and rashes.

Results



Reduction in Wound Complications*
6.9% (9/130) Prevena Therapy vs. 16.2% (21/130) Silver-impregnated dressing (p=0.031)*

Key points
- Among high-risk patients undergoing primary TKA, patients receiving Prevena Therapy had significantly fewer incisional wound complications when compared to patients receiving silver impregnated dressings.
- Although an increase in dressing reactions for Prevena Therapy patients was observed, compared to standard dressing (16.9% vs 1.5%; p<0.0001), none required clinical intervention.
- In a multiple logistic regression analysis, the occlusive silver-impregnated dressing was a significant effect on the development of SSCs (odds ratio 2.9, 95% CI 1.3-6.8; p=0.012), as was non-aspirin anticoagulation (odds ratio 2.5, 95% CI 1.1-5.6; p=0.028).
- Results support the use of ciNPT as part of a risk mitigation strategy to reduce post operative complications in primary TKA.

(Continued)

Calculation(s) are derived based on relative patient group incidence rate reported in this study

*Statistically significant (p<0.05)

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 hcbgregulatory.3m.com.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Doman et al outcomes

Hypothetical economic model	Prevena™ Therapy	Silver-impregnated dressing
Patients	130	130
Number of surgical site complications (a)	9	21
Cost per SSC[1] (b)	$16,173	$16,173
Per patient complication cost (a*b)/n	$1,120	$2,613
Per patient therapy cost*	$495	$39
Total cost per patient	$1,615	$2,652
Potential per incision savings using Prevena™ Therapy	$1,037	

Cost per SSC is based on SSC cost for population with CCI>0 to represent High-Risk Study Population

*3M™ Prevena™ Plus Customizable Dressing and AQUACEL® Ag SURGICAL price are estimates; individual prices may vary. Authors report institution costs of $35.22 for AQUACEL® Ag SURGICAL and $389.99 for Prevena Peel and Place System Kit.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or AQUACEL® Ag SURGICAL. 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.

Reference
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2023 Aug;14:31-45.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: Comparison of surgical site complications with negative pressure wound therapy vs silver impregnated dressing in high-risk total knee arthroplasty patients: A matched cohort study

Published: May 24, 2021

Doman DM, Young AM, Buller LT, Deckard ER, Meneghini RM. Comparison of surgical site complications with negative pressure wound therapy vs silver impregnated dressing in high-risk total knee arthroplasty patients: A matched cohort study. *J Arthroplasty.* 2021 Oct;36(10):3437-3442.

Randomized controlled trial of incisional negative pressure following high-risk direct total hip arthroplasty

Cooper HJ, Santos WM, Neuwirth AL, et al. *J Arthroplasty.* 2022 Aug;37(8S):S931-S936.

Study type

This was a prospective randomized controlled trial.

Study purpose

The purpose of this study is to determine whether ciNPT could decrease SSCs in high-risk patients undergoing DA THA. The direct anterior (DA) approach to total hip arthroplasty (THA) is associated with higher rates of surgical site complications (SSCs) compared to other approaches. Closed incision negative pressure therapy (ciNPT) is effective in reducing SSCs and surgical site infections (SSIs) in other populations.

Methods

- Population: Study enrolled high-risk DA THA patients at 3 centers. Inclusion criteria was if subjects had previously identified risk factors for SSC: body mass index (BMI) >30 kg/m^2, diabetes, active smoking or before hip surgery.
- Treatment: Patients were randomized after closure to either an occlusive (control) dressing or ciNPT dressing (3M™ Prevena™ Incision Management System) for 7 days. Both dressings were designed for 7-day use per manufacturer instructions.
- Follow up: All patients were followed for 90 days to assess SSCs.

Results

One hundred and twenty-two patients were enrolled and 120 completed the data collection. SSCs occurred in 18.3% (11/60) of control patients compared to 8.3% (5/60) of ciNPT patients (x^2=2.60, P=0.107).

- SSCs included dehiscence to the subcutaneous level (13) and prolonged drainage (3).
- Nine control (15.0%) and 2 ciNPT (3.3%) patients met CDC criteria for superficial SSI (P=0.027).
- Fifteen of 16 SSCs resolved with local wound care. One in the ciNPT group required reoperation for acute PJI.

Conclusion

It was determined that among high-risk patients undergoing DA THA, there were lower rates of SSC and a significant reduction in the risk of superficial SSI with ciNPT.

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 hcbgregulatory.3m.com.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: Randomized controlled trial of incisional negative pressure following high-risk direct anterior total hip arthroplasty

Published: March 15, 2022

Cooper HJ, Santos WM, Neuwirth AL, et al. Randomized controlled trial of incisional negative pressure following high-risk direct anterior total hip arthroplasty. *J Arthroplasty.* 2022 Aug;37(8S):S931-S936. OPEN ACCESS

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

Anatone AJ, Shah RP, Jennings EL, Geller JA, Cooper HJ. *Arthroplast Today.* 2018 Dec;4(4):493-98.

Study design

Single institution retrospective review of records

Study purpose

The purpose of the Anatone study was to evaluate when to use Prevena Therapy in primary total joint arthroplasties (TJAs). The author's risk stratification can be used as a potential guideline to identify patients that may benefit from Prevena Therapy.

Methods

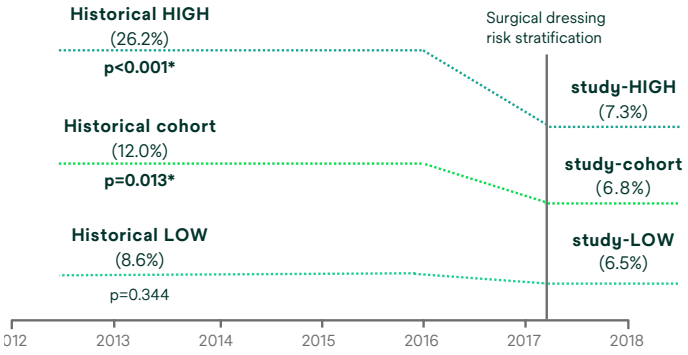
- Patients were considered low risk if their calculated risk score was <2 and patients were considered high risk if their risk score was ≥2.
- A study population of 323 consecutive primary TJAs were evaluated, where 123 (38%) of those patients were considered at elevated risk to receive Prevena Therapy. The remaining 200 patients received the standard postop dressing (AQUACEL® Ag SURGICAL cover dressing).
- A historical control population of 643 patients was identified who all received the standard postop dressing to test the impact of this risk score.
- Skin closure procedure was the same in both groups, and dressings were applied under sterile conditions in the operating room at the conclusion of the surgical procedure.
- The primary outcome measure was any postoperative surgical site complication (SSC†) that required intervention during the initial 90-day post-operative period.

Risk stratification algorithm scoring system

Risk factor	Weight
BMI	
<18.5 kg/m²	1
18.5–29.9 kg/m²	0
30–34.9 kg/m²	1
35–39.9 kg/m²	2
>40 kg/m²	3

Risk factor	Weight
Diabetes mellitus	2
Immunodeficiency	1.3
Active smoking	1
Non-ASA anticoagulation	1
Prior surgery	2

Results



Guidance

The authors' risk stratification can be used as a potential guideline to identify patients who may benefit from Prevena Therapy.

Key points

- Among high-risk patients, there was a marked improvement in the rate of SSCs when treated prophylactically with Prevena Therapy as compared with historical controls (26.2% vs. 7.3%; p<0.001).*
- Compared with historical controls, a modest but significant improvement in superficial SSCs after implementation of risk-stratification (12.0% vs 6.8%; p=0.013) was observed.*
- Low-risk patients who continued to be treated with standard postop dressings in historical controls demonstrated no significant improvement (8.6% vs 6.5%; p=0.344).

(Continued)

Calculation(s) are derived based on relative patient group incidence rate reported in this study

*Statistically significant (p<0.05)

†SSC was defined as any dehiscence, suture granuloma, drainage occurring beyond postoperative day 5, significant hematoma formation, or SSI as defined by the CDC that required unplanned postoperative interventions.

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 hcbgregulatory.3m.com.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Anatone et al outcomes

Hypothetical economic model	Prevena™ Therapy	Silver-impregnated dressing
Patients	123	122
Number of surgical site complications (a)	9	32
Cost per SSC[1] (b)	$16,173	$16,173
Per patient complication cost (a*b)/n	$1,183	$4,242
Per patient therapy cost*	$830	$39
Total cost per patient	$2,013	$4,281
Potential per incision savings using Prevena™ Therapy	$2,268	

Cost per SSC is based on SSC cost for population with CCI>0 to represent High-Risk Study Population.

*3M™ Prevena™ Plus Customizable Dressing and AQUACEL® Ag SURGICAL price are estimates; individual prices may vary; 3M™ Prevena™ Plus Customizable Dressing used on some patients and therefore the price is used for all patients in this model.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or AQUACEL® Ag SURGICAL. 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.

Reference
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2023 Aug;14:31-45.

Read the full study here

Journal: *Arthroplasty Today*

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

Published: October 15, 2018

Anatone AJ, Shah RP, Jennings EL, Geller JA, Cooper HJ. A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty. *Arthroplast Today*. 2018 Dec;4(4):493-98. OPEN ACCESS

Incisional negative pressure wound therapy in orthopaedic trauma: Indications & outcomes

Phillips R, Stannard JP, Crist BD. *J Orthop Trauma*. 2022;36(Suppl 4):S22-S25.

Study type

This was a literature review.

Study purpose

This review aims to discuss the indications and outcomes associated with the use of incisional negative pressure wound therapy (iNPWT) for the management of surgical incisions.

Outcomes

Indication for iNPWT: In patient population at high risk for developing SSIs, management of the surgical incision with iNPWT have reduced the incidence of SSIs.

Several meta-analyses and randomized controlled trials were evaluated to assess the efficacy of surgical site infections, wound dehiscence and other postoperative wound complications.

A 2019 meta-analysis analyzed a total of 6 studies including 2 randomized controlled trials (RCTs) and 4 cohort studies comparing a mix of iNPWT systems to conventional wound dressings for closed incisions in orthopaedic trauma surgery found that 14 statistically significant lower incidence of deep SSIs (P=0.002), superficial SSI (P=0.03) and wound dehiscence (P=0.02) was found in surgical incisions managed with iNPWT.

The results of 2 RCTs also support the use of iNPWT after primary and revision total joint arthroplasty. Total knee arthroplasty patients with a body mass index >35 kg/m² who were treated with incisional NPWT experienced fewer overall complications (1.3% vs. 21.6%; P=0.01) and fewer dressing-related concerns (1.3% vs. 10.8%; P=0.01) compared with standard of care dressings.

Duration of treatment

Most studies that have reported the use of iNPWT before the availability of a portable device typically used iNPWT for 3–5 days during the inpatient hospital stay. More recent studies have extended therapy to 7 days. However, there are some contraindications to the iNPWT which includes if there is necrotic tissue with eschar present, preexisting infection, patients at high risk of excessive postoperative bleeding, and those who have an allergic reaction to any part of the NPWT system.

Conclusion

The literature review suggested that iNPWT seems to be an effective tool for decreasing the rates of surgical site infections and wound dehiscence across multiple specialties. SSI risk factors should be considered for either patients or wounds that are at high risk for infection and/or dehiscence.

NOTE: The use of Prevena Therapy for the reduction in the incidence of dehiscence and deep SSI has not been reviewed by the U.S. FDA.

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 hcbgregulatory.3m.com.

Read the full study here

Journal: *Journal of Orthopaedic Trauma*

Title: Incisional negative pressure wound therapy in orthopaedic trauma: Indications & outcomes

Published: September 2022

Phillips R, Stannard JP, Crist BD. Incisional negative pressure wound therapy in orthopaedic trauma: Indications & outcomes. *J Orthop Trauma*. 2022;36(Suppl 4):S22-S25. OPEN ACCESS

How can negative pressure wound therapy pay for itself?—Reducing complications is important

Zelle BA, Kore L. *J Orthop Trauma.* 2022 Sep 1;36(Suppl 4):S31-S35.

Study type

This was a retrospective cohort study performed at a single, Level I trauma center using data from a lower extremity fracture registry.

Study purpose

The purpose of this study was to investigate cost savings in high-risk fractures and to determine if the use of iNPWT (3M™ Prevena™ Therapy) in high-risk orthopedic trauma patients reduces the costs. The hypothesis was that the use of iNPWT will provide an economic benefit in patients with OTA/AO type 41C and 43C closed fractures undergoing ORIF.

Methods

- Material: Patient data from single institution registry were retrospectively retrieved from January 2019 and September 2020.
- Population: The evaluation included all patients with closed OTA/AO type 41C or 43C fractures treated with ORIF (staged or immediately) during the study period.
- Procedure: Registry data were summarized to determine SSI rates in all patients with closed OTA/AO type 41C and 43C fractures. 3 health economic models were developed using SSI rates of 13%, 15% and 17% as reference rates. The incremental cost due to SSI was estimated to be $51,364.

Result

- Out of a total of 79 patients who underwent ORIF of a closed OTA/AO type 41C or 43C fractures, 27 (34%) were deemed high risk for SSI and had iNPWT applied over the closed incision.
- There was no significant difference in rates of SSI when comparing iNPWT with non-iNPWT group (7.4% vs. 11.5%, P=0.7086).
- Patients in iNPWT group had the external fixator in place for a significantly longer time (10.6 days vs. 6.8 days; P=0.0332). Length of hospital stay was longer for patients in the non-iNPWT group compared with the iNPWT group (10.2 vs. 5.4 days; P=0.0155).
- Health economic models: For assumed SSI rates of 13%, 15%, and 17%, the total infection costs for 100 patients would be $667,732, $770,460, and $873,188, respectively, the per patient cost would be $6,677, $7,704, and $8,732 respectively and iNPWT cohort, the total infection cost for 100 patients would be $380,094 or $3,801 per patient. Thus, when comparing the SSI rates, the differences in infection costs per patient were estimated to be $2,381, $3,409, and $4,436, respectively. Hence, this health economic model suggests the use of the iNPWT in patients with high-risk OTA/AO type 41C and 43C fractures may provide estimated cost savings per patient that range between $2,381 to $4,436.

Conclusion

Based on this health economic model, the use of iNPWT (Prevena Therapy) may reduce the costs of SSI in high-risk orthopaedic trauma patients undergoing ORIF of their closed OTA/AO type 41C and 43C fractures.

Read the full study here

Journal: *Journal of Orthopaedic Trauma*

Title: How can negative pressure wound therapy pay for itself?—Reducing complications is important

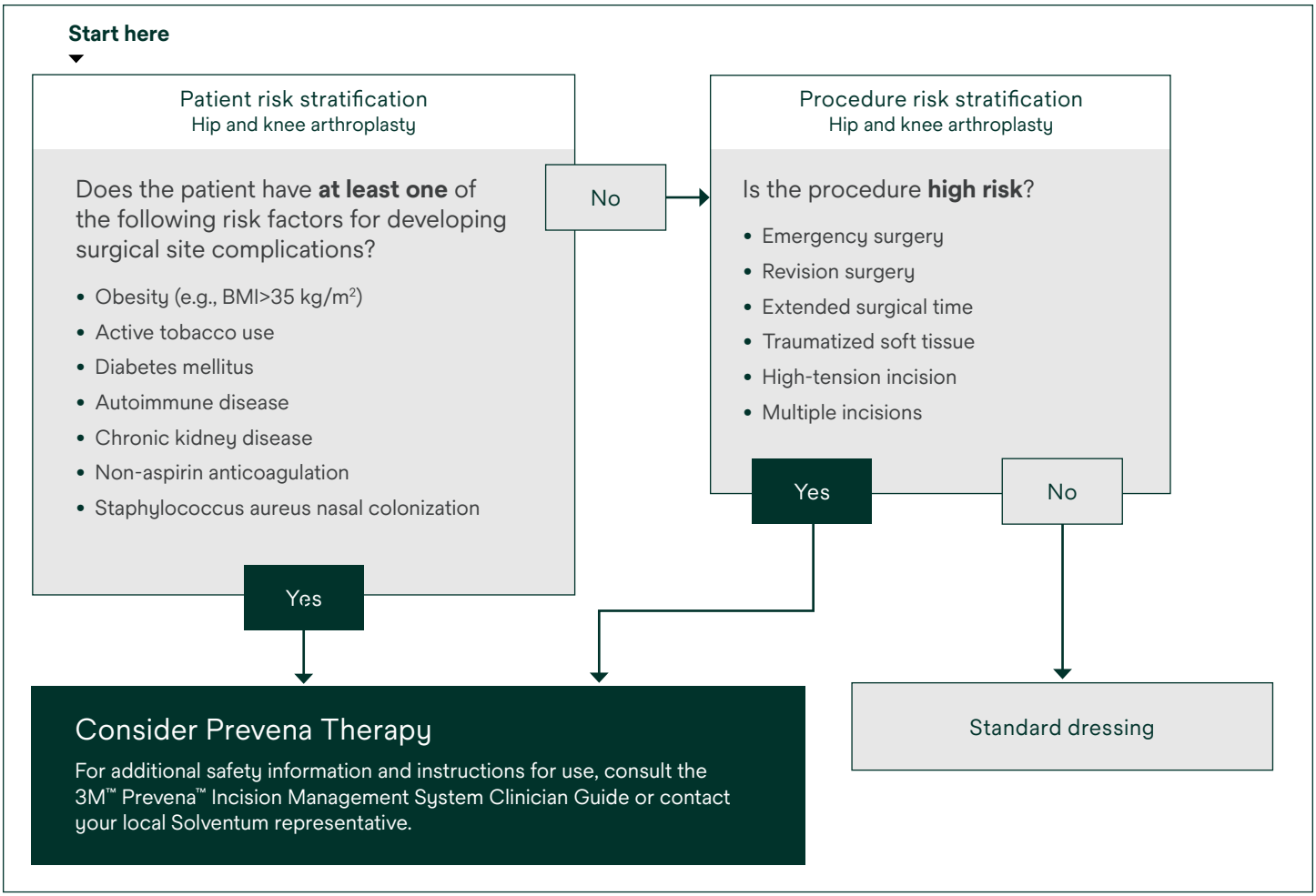
Published: September 2022

Zelle BA, Kore L. How can negative pressure wound therapy pay for itself?—Reducing complications is important. *J Orthop Trauma.* 2022 Sep 1;36(Suppl 4):S31-S35.

Decision guide

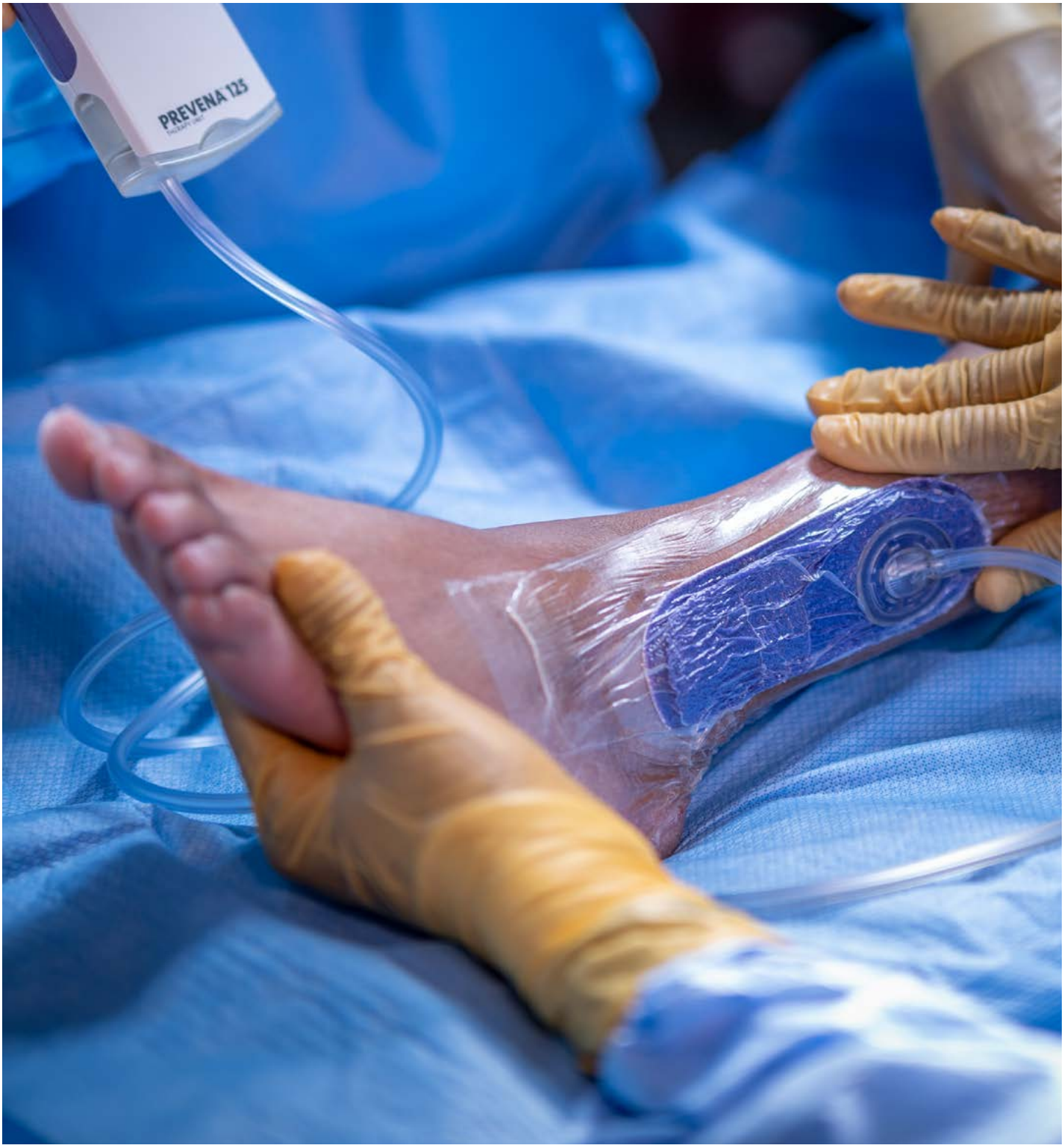
Patient and procedure risk stratification backed by clinical evidence

While surgical patients may benefit from Prevena Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data[1-3] to provide an illustrative guide to aid in risk stratification. This is not an all-inclusive list of risk factors. Clinicians are advised to use their clinical judgment to identify high-risk patients or high-risk procedures.



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 hcbgregulatory.3m.com.

References
1. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: International multidisciplinary consensus recommendations. *Int Wound J.* 2017 Apr;14(2):385-398. OPEN ACCESS 2. Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, et al. The effectiveness of closed-incision negative-pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty: The PROMISES randomized controlled trial. *J Arthroplasty.* 2021 Jul;36(7S):S295-S302.e14. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use. 3. Newman JM, Siqueira MBP, Klika AK, et al. 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 Mar;34(3):554-559. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use.



Case studies

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Bilateral primary total knee arthroplasty

R. Michael Meneghini, MD; Orthopaedic Surgery, Indiana University Health Hip and Knee Center and Indiana University School of Medicine, Indianapolis, IN

Patient

A 64-year-old male patient presented for a bilateral primary total knee arthroplasty. Patient comorbidities and risk factors included obesity, hypertension, hyperlipidemia, and gastroesophageal reflux disease.

Diagnosis

The patient required a bilateral primary total knee arthroplasty due to debilitating pain and stiffness from end-stage osteoarthritis that was refractory to non-operative measures.

Application

The patient received preoperative and postoperative prophylactic intravenous antibiotics for 24 hours. Immediately following surgery, the 3M™ Prevena Restor™ Arthro•Form™ Incision Management System was applied over the closed incisions with -125 mmHg negative pressure. The goals of therapy were to manage the surgical incision and surrounding soft tissue, hold the edges of the closed incision together, reduce tensile forces across the incision, and help reduce edema.

Discharge and follow-up

The patient was discharged home with the Prevena Restor™ Arthro•Form™ Incision Management System, and it was removed after 7 days during a follow-up visit. The arthroplasty incisions were healed without complication (**Figure 1**).

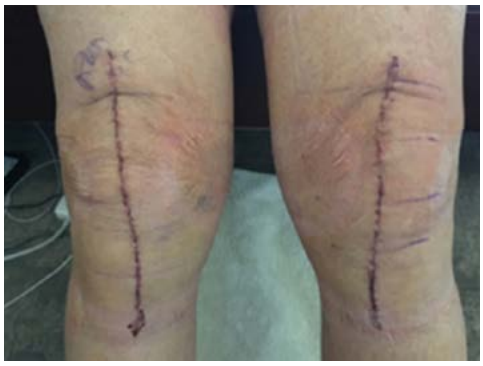
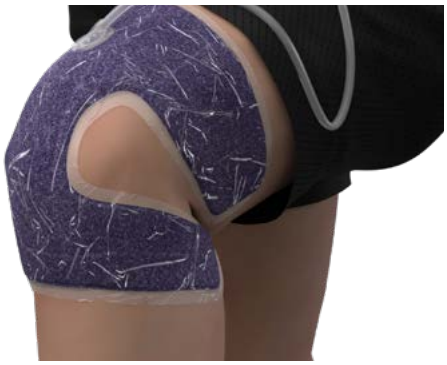


Figure 1. Bilateral total knee arthroplasty incisions after 7 days of Prevena Restor™ Arthro•Form™ Incision Management System use.



Artist rendering of Prevena Restor™ Arthro•Form™ Incision Management System applied to a knee. For illustration purposes only.

Patient data and photo courtesy of R. Michael Meneghini, MD, Orthopaedic Surgery, Indiana University Health Hip and Knee Center and Indiana University School of Medicine, Indianapolis, IN.

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.

Management of total knee arthroplasty revision with 3M™ Prevena Restor™ Arthro•Form™ Incision Management System

Yavonne L. Johnson, PA-C, Evan Argintar, MD; Washington, DC

Patient

A 72-year-old female presented to the hospital, requiring a revision following a total knee arthroplasty of the right knee. The patient's medical history included heart murmurs, tobacco use, and obesity.

Procedure

The patient underwent a total knee arthroplasty revision, resulting in a <15 cm incision on the right knee (**Figure 1**). The incision was closed using staples, and the patient received clindamycin for prophylactic antibiotic control.

Application of 3M™ Prevena Restor™ Arthro•Form™ Incision Management System

Immediately after incision closure, 3M™ Prevena Restor™ Therapy was initiated using a 3M™ Prevena Restor™ Arthro•Form™ Dressing, which covered the full length of the incision and the area above and below the knee (**Figure 2**). Negative pressure was applied at -125 mmHg.

Discharge and follow-up

The patient was discharged on postoperative day 5. Seven days after surgery, Prevena Restor™ Therapy was discontinued, and the incision remained closed (**Figure 3**). On postoperative day 14, the incision remained closed without any complications. The patient reported less pain and swelling and improved post-surgical range of motion in the right knee following Prevena Restor™ Therapy with Prevena Restor™ Arthro•Form™ Dressing use compared to the previous total knee arthroplasty procedure.

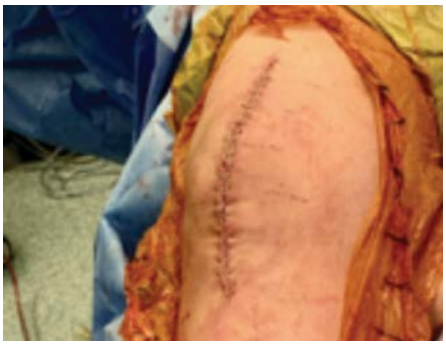


Figure 1. Closed surgical incision.

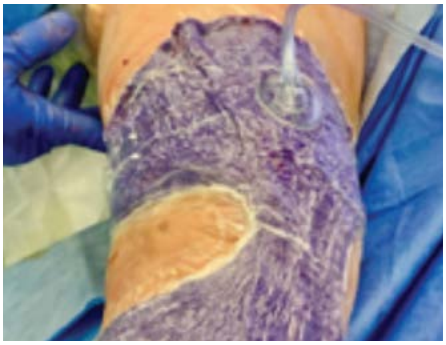


Figure 2. Application of 3M™ Prevena Restor™ Therapy System with 3M™ Prevena Restor™ Arthro•Form™ Dressing

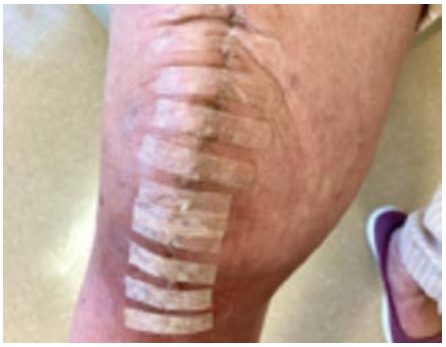


Figure 3. Surgical incision 7 days after 3M™ Prevena Restor™ Therapy System with 3M™ Prevena Restor™ Arthro•Form™ Dressing.

Patient data and photos courtesy of Yavonne L. Johnson, PA-C, Evan Argintar, MD; Washington, DC.

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.

Periprosthetic femur fracture

H. John Cooper, MD; Lenox Hill Hospital, New York, NY

Patient

A 67-year-old male with a history of obesity (BMI=36.9) presented with a periprosthetic femur fracture (**Figure 1**).

Diagnosis

Patient underwent total hip arthroplasty (THA) revision to repair the injury (**Figure 2**). After replacement of the THA hardware, fascial closure could not be obtained.

Initial incision treatment/application of 3M™ Prevena™ Therapy

The 3M™ Prevena™ Incision Management System with the 3M™ Prevena™ Customizable Dressing was applied over the closed incision at -125 mmHg.

Discharge and follow-up

Prevena Therapy was discontinued after 7 days, and the patient was discharged to a rehabilitation facility. At the postoperative month 5 follow-up visit, the incision remained intact (**Figure 3**) with no postoperative incision complications.

Patient data and photo courtesy of H. John Cooper, MD; Lenox Hill Hospital, New York, NY.

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.

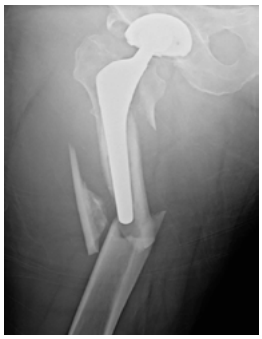


Figure 1. Periprosthetic femur fracture at initial presentation

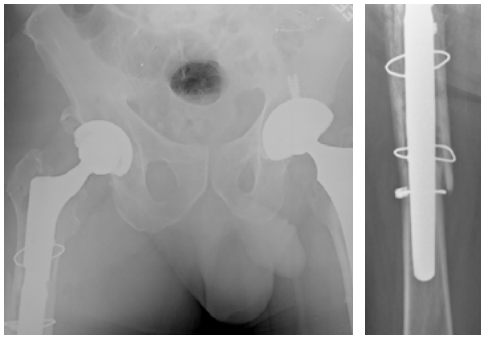


Figure 2. Total hip arthroplasty repair

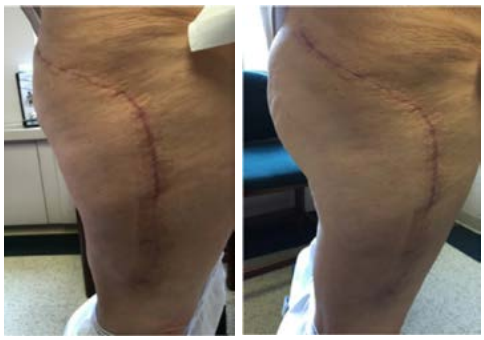


Figure 3. Wound appearance at postoperative month 5 follow-up visit