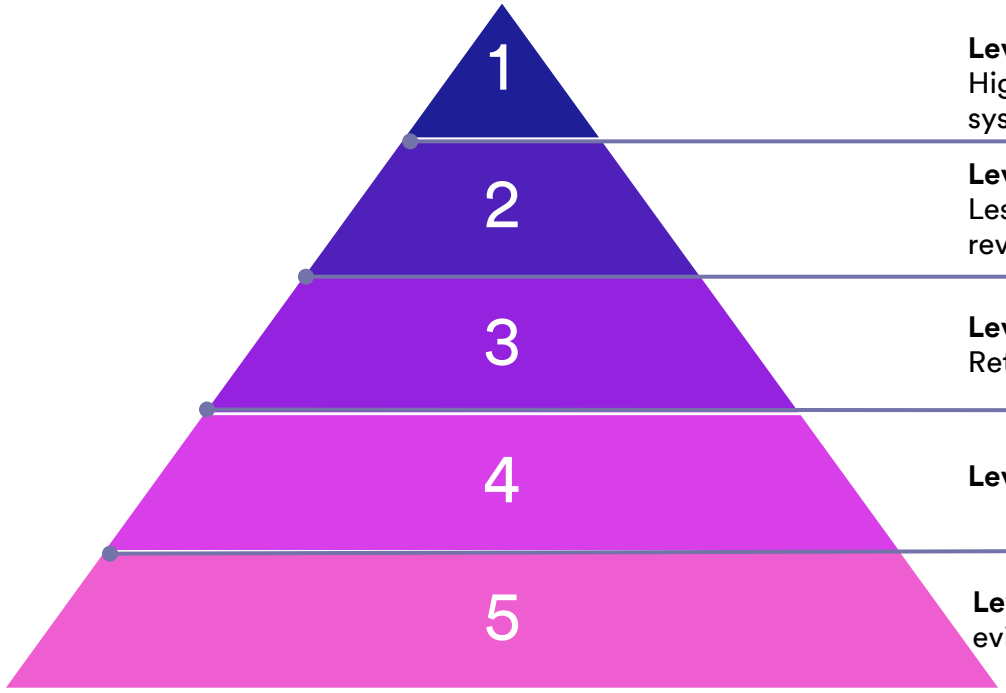
Clinical Evidence Summaries
Orthopedics

Negative Pressure Therapy for Incision Management

- For over 25 years, negative pressure vacuum-assisted closure (V.A.C.®) technology has been clinically shown to promote wound healing by reducing edema and promoting granulation tissue formation and perfusion through the removal of exudate and infectious materials.
- 3M extended the use of its negative pressure technology to closed surgical incisions with similarly positive clinical results, outlined in more than 200+ journal publications focused on closed incision negative pressure therapy (ciNPT)/3M™ Prevena™ Therapy.
- The Prevena Therapy clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale[1] and reflect the benefits of ciNPT for different incision types and surgical outcomes compared to the standard of care.



Level 1:
High-quality, multicenter or single-center, randomized controlled trial with adequate power; or systematic review of these

Level 2:
Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies.

Level 3:
Retrospective cohort or comparative study; case-control study; or systematic review of these studies

Level 4: Case series with pre/post test or only post test

Level 5: Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or “first principles”

Reference: 1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. Plast Reconstr Surg 2011;128(1):311-314

Systematic Review and Meta-Analysis of 3M™ Prevena™ Therapy over closed knee and hip arthroplasty incisions (1/2)

Level of Evidence 1

TKA & THA

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. Arthroplasty 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 Dressing 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 Prevena Therapy 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.

Key Results

Surgical Site Complications

⬇67%

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

Dehiscence†

⬇62%

Reduction of risk of Dehiscence*
5 studies
Risk Ratio 0.380 (95% CI 0.176-0.820)
(p=0.014)*

Surgical Site Infections

⬇60%

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

Prolonged incisional drainage

⬇60%

Reduction of risk of Drainage*
4 studies
Risk Ratio 0.399 (95% CI 0.218-0.728)
(p=0.003)*

Seroma

⬇53%

Reduction of risk of Seroma*
3 studies
Risk Ratio 0.473 (95% CI 0.272-0.824)
(p<0.008)*

Return to the Operating Room (ROR)

⬇58%

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

Calculation(s) are derived based on relative risk reduction 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

3M Prevena™ Therapy evidence table

- The body of evidence for using Prevena Therapy has been growing steadily since its launch in 2010
- The table listed below is based on the Evidence Rating Scale for Therapeutic Studies developed by the American Society of Plastic Surgeons (ASPS)[1]

Surgical Incision	ASPS Level of Evidence	First Author (Year)	Surgical Incision Type	Standard Dressing	Postoperative Clinical Endpoints*
Orthopedic Joint	1	Higuera (2021)**	rTKA	Silver-impregnated dressing	Surgical Site Complications (SSC), Readmission, Dressing Changes Cost Effectiveness study (Cooper 2023) included**
		Newman (2018)	rTHA; rTKA	Silver-impregnated dressing	SSC, Return to the operating room (ROR)
	2	Pachowsky (2012)	THA	Standard dressing	Seroma
		Redfern (2017)	THA; TKA	Standard dressing	SSC, Surgical Site Infection (SSI), Pain, Edema/Swelling, Hematoma, Length of Stay (LOS), Abnormal surrounding soft tissue appearance
	3	Anatone (2018)	THA; TKA	Silver-impregnated dressing	SSC, Risk Stratification
		Cooper (2016)	rTHA; rTKA	Silver-impregnated dressing	SSC; SSI
		Doman (2021)	TKA	Silver-impregnated dressing	SSC
Amputation	3	Chang (2021)	Major Lower Extremity Amputation (BKA & AKA)	Standard dressing	SSC

*Clinical endpoints reflect the conditions and methods specific to each publication and should not be interpreted as general outcomes related to Prevena Therapy. Individual results for each case may vary depending on the patient, circumstances, and conditions.
**Cooper 2022 is in included in Prevena Orthopedic Clinical Evidence Summary; Cooper 2022 is a cost-effectiveness study monetizing the outcomes of the Higuera 2021 clinical study

Reference: 1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. Plast Reconstr Surg 2011;128(1):311-314

Incision Type Key	
THA	Total Hip Arthroplasty
TKA	Total Knee Arthroplasty
rTHA	Revision Total Hip Arthroplasty
rTKA	Revision Total Knee Arthroplasty

Systematic Review and Meta-Analysis of 3M™ Prevena™ Therapy over closed knee and hip arthroplasty incisions (2/2)

Level of Evidence 1

TKA & THA

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. Arthroplasty 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 Dressing 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 Prevena Therapy 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.

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*

Calculation(s) are derived based on relative patient group incidence rate reported in this study
* Statistically significant ($p<0.05$)

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

† **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

Data suggests 3M™ Prevena™ Therapy can help advance the standard of care

Level of Evidence 1

rTKA

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;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 > 35kg/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.

Key Results

Surgical Site Complications

↓4x

Reduction in 90-day SSCs*
3.4% (5/147) Prevena Therapy vs.
14.3% (21/147) Silver-impregnated dressing
(p=0.0013)*

SSCs in Aseptic rTKA

↓87%

Reduction in 90-day SSCs*
1.8% (2/118) Prevena Therapy vs.
14.3% (15/119) Silver-impregnated dressing
(p=0.0006)*

90-Day Readmission

↓3x

Reduction in Readmission Rates*
3.4% (5/147) Prevena Therapy vs.
10.2% (15/147) Silver-impregnated dressing
(p=0.0208)*

Length of Stay (LoS) if Readmitted

↓45%

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

Dressing Changes

↓15%

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

Patients receiving >1 Dressing Change

↓74%

Fewer patients receiving >1 dressing change*
4.7% (7/149) Prevena Therapy vs.
17.86% (25/140) Silver-impregnated dressing
(p=0.0005)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Summary

- 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.

PROMISEs RCT data demonstrates 3M™ Prevena™ Therapy can help reduce overall cost

Cost Effectiveness Study

rTKA

Cooper HJ, Bongards C, Silverman RP. Cost-Effectiveness of Closed Incision Negative Pressure Therapy for Surgical Site Management After Revision Total Knee Arthroplasty: Secondary Analysis of a Randomized Clinical Trial. J Arthroplasty. 2022;37(8S):S790-S795.

Study Design

Health Economic assessment of RCT study

Study Purpose

The aim of this study was to determine the cost-benefit of Prevena Therapy in post-revision total knee arthroplasty (rTKA) surgical site management by reducing 90-day cost for surgical site complication (SSC)-related interventions.

Methods

- The 2021 Higuera-Rueda et al. PROMISES randomized controlled trial (RCT) compared SSC rates in rTKA patients receiving Prevena Therapy or silver impregnated dressings on their closed incisions.
- Study data from the PROMISES RCT were used to determine the type and frequency of SSC-related interventions, which were grouped into surgical and non-surgical interventions.
- A health economic model was used to determine the mean per-patient costs, including costs for post-operative dressings, surgical interventions, readmission, and non-surgical interventions.
- A sub-analysis was also performed by dividing patients into “lower risk” (Charlson Comorbidity Index [CCI] <2) and “higher risk” (CCI ≥2) groups.

Key Results

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

Calculation(s) are derived based on the relative patient group incidence rate reported in this study; * Statistically significant (p<0.05)

Cost of Care

Hypothetical Economic Model	Prevena Therapy	Silver-impregnated dressing
Mean Product Cost	$ 666	$ 52
Mean Readmission Cost	$ 231	$ 970
Mean Surgical costs	$ 135	$ 944
Mean Non-Surgical costs	$ 15	$ 70
TOTAL	**$ 1,047**	**$ 2,036**

Summary

- For the full study population, the total estimated cost of care for the study population was $153,857 for Prevena Therapy and $299,281 for silver-impregnated dressings. The total estimated cost of care per patient was $1,047 for Prevena Thera and $2,036 for silver-impregnated dressings for a cost savings of $989.
- 109 patients had a “higher-risk” profile (CCI≥2) with 1.8% of Prevena Therapy developing an SSC compared to 16.7% of silver-impregnated dressing patients (p=0.0081*). The mean per-patient cost for these patients was $676 for Prevena Therapy and $3,212 for silver-impregnated dressings.
- Despite having higher upfront costs for postoperative dressings, Prevena Therapy was cost-effective, decreasing the mean per-patient cost of care after rTKA by 49% in this study population and by 72% in higher-risk patients.

Potential reduction of complications with 3M™ Prevena™ Therapy

Level of Evidence 1

rTKA, rTHA

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 Mar;34(3):554-559

Study Design

Prospective, single-center, randomized controlled trial (Level I)

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 join 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 join infection and inflammatory arthritis).

Key Results

Wound Complications

⬇57%

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

Reoperation

⬇80%

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

Calculation(s) are derived based on the relative patient group incidence rate reported in this study; * Statistically significant (p<0.05)

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)

Summary

- 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

† **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

NOTE: Although the authors reported use of Prevena Therapy for a mean of 3.6 days (ranging from 2 to 15 days), this range of 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.

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
Number of Incisions (n)	79	80
Number of Surgical Site Complications (a)	8	19
Cost per SSC[1] (b)	$16,173	$16,173
Per Incision Complication Cost [c=(a*b)/n]	$1,638	$3,841
Per Incision Therapy Cost* (d)	$495	$39
Total Cost Per Incision (c+d)	**$2,133**	**$3,880**
Potential Per Incision Savings Using Prevena Therapy	**$1,747**	

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

*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: 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 Mar;34(3):554-559

Reduction of seromas in total hip arthroplasty closed incisions with 3M™ Prevena Therapy

Level of Evidence 2

THA

Pachowsky, M., Gusinde, J., Klein, A., Lehrl, S., Schulz-Drost, S., Schlechtweg, P., Pauser, J., Gelse, K., & Brem, M. H. (2012). Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty. International orthopaedics, 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

Key Results

Seroma Volume

↓61%

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)*

Antibiotic Days

↓28%

Reduction in Antibiotic days*
8.44 ± 2.24 mL Prevena Therapy vs.
11.8 ± 2.82 mL Standard Dressing
(p=0.005)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study;
Statistically significant (p<0.05)

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 the relative patient group incidence rate reported in this study; * Statistically significant (p<0.05)

Summary

- This study showed fewer post-operative seromas and significantly lower seroma volume 10 days after surgery with the use of 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.

Potential reduction of complications requiring medical/surgical intervention (1/2)

Level of Evidence 2

THA, TKA

Redfern R, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer K. (2017). Closed Incision Negative Pressure Therapy Effects on Postoperative Infection and Surgical Site Complication After Total Hip and Knee Arthroplasty. J Arthroplasty. 2017; 32(11), 3333–3339.

Study Design

Single-center, prospective versus historic control comparative study (Level II)

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 consecutive patients representing 196 incisions, who were actively enrolled from 2013 to 2014.
- The historical control group consisted of 400 consecutive 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

Key Results

Surgical Site Complications

↓73%

Reduction in SSCs*
1.5% (3/196) Prevena Therapy vs.
5.5% (22/400) Standard Dressing
(p=0.02)*

Pain 24 hr Postop

↓28%

Reduction in Pain*
2.6 ± 1.8 Prevena Therapy vs.
3.6 ± 2.2 Standard Dressing
(p<0.0001)*

Surgical Site Infections (SSIs)

↓71%

Reduction in SSIs*
1.0% (2/196) Prevena Therapy vs.
3.5% (14/400) Standard Dressing
(p=0.04)*

Hematomas

↓100%

Reduction in Hematomas*
0% (0/196) Prevena Therapy vs.
2.25% (9/400) Standard Dressing
(p=0.02)*

Superficial SSIs (sSSIs)

↓100%

Reduction in sSSIs*
0% (0/196) Prevena Therapy vs.
2.25% (9/400) Standard Dressing
(p=0.03)*

Surrounding Soft Tissue Appearance

↓100%

Reduction in abnormal surrounding soft tissue appearance*
0% (0/196) Prevena Therapy vs.
3.75% (15/400) Standard Dressing
(p=0.003)*

Edema/Swelling

↓85%

Reduction in Edema/Swelling*
0.5% (1/196) Prevena Therapy vs.
3.25% (13/400) Standard Dressing
(p=0.02)*

Hospital Length of Stay

↓17%

Reduction in LOS*
1.9+0.6 Prevena Therapy vs.
2.3+0.5 Standard Dressing
(p<0.0001)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study;
Statistically significant (p<0.05)

Potential reduction of complications requiring medical/surgical intervention (2/2)

Level of Evidence 2

THA, TKA

Redfern R, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer K. (2017). Closed Incision Negative Pressure Therapy Effects on Postoperative Infection and Surgical Site Complication After Total Hip and Knee Arthroplasty. J Arthroplasty. 2017; 32(11), 3333–3339.

Study Design

Single-center, prospective versus historic control comparative study (Level II)

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 consecutive patients representing 196 incisions, who were actively enrolled from 2013 to 2014.
- The historical control group consisted of 400 consecutive 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 the relative patient group incidence rate reported in this study;
* Statistically significant (p<0.05)

Summary

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.

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Redfern et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Incisions (n)	196	400
Number of Surgical Site Complications (a)	3	22
Cost per SSC[1] (b)	$16,173	$16,173
Per Incision Complication Cost [c=(a*b)/n]	$248	$890
Per Incision Therapy Cost* (d)	$495	---
Total Cost Per Incision (c+d)	**$743**	**$890**
Potential Per Incision Savings Using Prevena Therapy	**$147**	

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

*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: Redfern R, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer K. (2017). Closed Incision Negative Pressure Therapy Effects on Postoperative Infection and Surgical Site Complication After Total Hip and Knee Arthroplasty. J Arthroplasty. 2017; 32(11), 3333–3339

Identifying patients who may benefit from 3M™ Prevena™ Therapy

Level of Evidence 3

TKA, THA

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.

Study Design

Single institution retrospective review of records (Level III)

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.

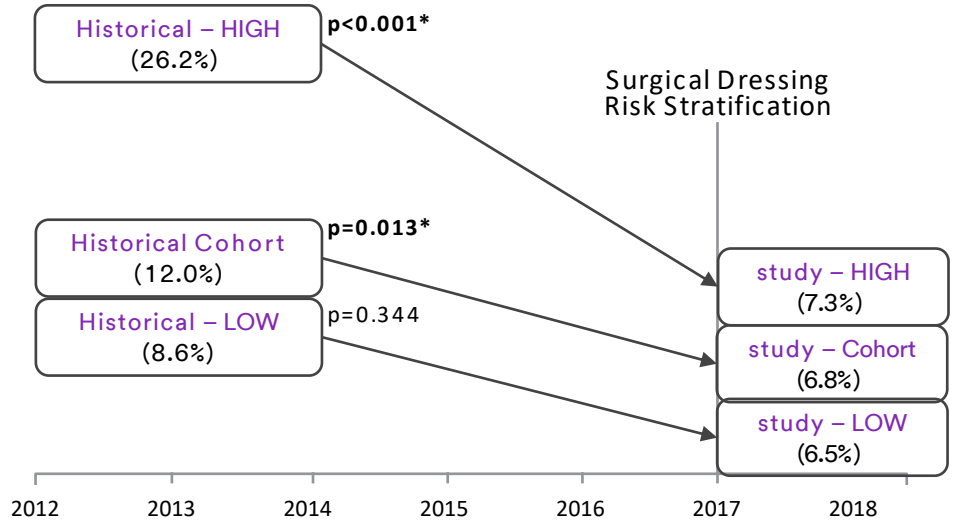
Methods

- 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 silver impregnated dressings (AQUACEL® Ag SURGICAL).
- 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
- 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.

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
Diabetes mellitus	2
Immunodeficiency	1.5
Active smoking	1
Non-ASA anticoagulation	1
Prior surgery	2

Key Results



* Statistically significant (p<0.05)

Summary

- 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).

Guidance

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

* Statistically significant (p<0.05)

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Antone et al Outcomes

Hypothetical Economic Model	Prevena™ Therapy	Silver-impregnated dressing
Incisions (n)	123	122
Number of Surgical Site Complications (a)	9	32
Cost per SSC[1] (b)	$16,173	$16,173
Per Incision Complication Cost [c=(a*b)/n]	$1,183	$4,242
Per Incision Therapy Cost* (d)	$830	$39
Total Cost Per Incision (c+d)	**$2,013**	**$4,281**
Potential Per Incision Savings Using Prevena™ Therapy	**$2,268**	

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

* 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 therefor 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: 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 Mar;34(3):554-559.

Efficacy of 3M™ Prevena™ Therapy compared to an antimicrobial dressing

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.

Level of Evidence 3

rTKA, rTHA

Study Design

Single institution/single surgeon retrospective cohort study (Level III)

Study Purpose

The purpose of this study was to evaluate the efficacy of Prevena Therapy compared to a sterile antimicrobial dressing on wound complications and surgical site infections (SSIs) after hip or knee revision surgery (rTHA, rTKA).

Methods

- Charts were reviewed from 138 consecutive patients who underwent rTHA and rTKA by a single surgeon over a 34-month period.
- Prevena Therapy was used selectively in 30 patients with multiple risk factors for SSIs over the last 15 months of the study period. The sterile antimicrobial dressing was used in the Standard Dressing group of 108 patients.
- All patients received standard perioperative SSI prevention measures when possible, including preoperative and postoperative antibiotics.
- Rates of wound complications, SSIs and reoperation were compared.

Key Results

Wound Complications

↓75%

Reduction in Wound Complications*
6.7% (2/30) Prevena Therapy vs.
26.9% (29/108) Silver-impregnated dressing
(p=0.024)*

Surgical Site Complications

↓82%

Reduction in SSIs*
3.3% (1/30) Prevena Therapy vs.
18.5% (20/108) Silver-impregnated dressing
(p=0.045)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant ($p<0.05$)

Summary

- rTHA and rTKA continue to burden the healthcare system and have been a focus area for hospitals to improve quality and control costs.
- Despite being at higher risk for developing postoperative wound complications, patients treated with Prevena Therapy had fewer wound complications and SSIs than those treated with an antimicrobial dressing.

NOTE: Although the authors reported use of Prevena Therapy 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 3M

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Cooper et al Outcomes

Surgical Site Complications

Hypothetical Economic Model	Prevena Therapy	Silver-impregnated dressing
Incisions (n)	30	108
Number of Wound Complications (a)	2	29
Cost per SSC[1] (b)	$16,173	$16,173
Per Incision Complication Cost [c=(a*b)/n]	$1,078	$4,343
Per Incision Therapy Cost* (d)	$830	$39
Total Cost Per Incision (c+d)	**$1,908**	**$4,382**
Potential Per Incision Savings Using Prevena Therapy	**$2,474**	

Surgical Site Infections

Hypothetical Economic Model	Prevena Therapy	Silver-impregnated dressing
Incisions (n)	30	108
Number of SSI(a)	1	20
Cost per SSI[1] (b)	$18,899	$18,899
Per Incision Complication Cost [c=(a*b)/n]	$630	$3,500
Per Incision Therapy Cost* (d)	$830	$39
Total Cost Per Incision (c+d)	**$1,460**	**$3,539**
Potential Per Incision Savings Using Prevena Therapy	**$2,079**	

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

2. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2022 Nov 8;11:1-18

* 3M™ Prevena™ Plus Customizable Dressing and AQUACEL® Ag SURGICAL price are estimates; individual prices may vary. Prevena Plus Customizable Dressing used on some patients and therefor 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: 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.

Potential reduction in wound complications when using 3M™ Prevena™ Therapy

Level of Evidence 3

TKA

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. Journal of Arthroplasty. 2021; 36(10):3437-3442

Study Design

Retrospective comparative cohort study (Level III)

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 primary TKAs that were treated 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.

Key Results

Incisional Wound Complications

⬇57%

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

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Summary

- Among high-risk patients undergoing primary TKA, incisions receiving Prevena Therapy had significantly fewer incisional wound complications when compared to incisions 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 Prevena Therapy as part of a risk mitigation strategy to reduce postoperative complications in primary TKA.

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
Incisions (n)	130	130
Number of Surgical Site Complications (a)	9	21
Cost per SSC[1] (b)	$16,173	$16,173
Per Incision Complication Cost [c=(a*b)/n]	$1,120	$2,613
Per Incision Therapy Cost* (d)	$495	$39
Total Cost Per Incision (c+d)	**$1,615**	**$2,652**
Potential Per Incision Savings Using Prevena Therapy	**$1,037**	

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

*3M™ Prevena™ Peel and Place System Kit 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: 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. Journal of Arthroplasty. 2021; 36(10):3437-3442

Decreased rate of wound complication occurrence observed in patients with vascular disease undergoing major lower extremity amputation with 3M™ Prevena™ Therapy

Level of Evidence 3

Amputations

Chang H, Maldonado TS, Rockman CB, Cayne NS, Berland TL, Barfield ME, Jacobowitz GR, Sadek M. Closed incision negative pressure wound therapy may decrease wound complications in major lower extremity amputations. Journal of Vascular Surgery. 2021 Mar;73(3):1041-1047.

Study Design

Retrospective, comparative study (Level III)

Study Purpose

This study evaluated 3M™ Prevena™ Therapy vs. standard dressings in decreasing the complication risk in patients with peripheral vascular disease undergoing major lower extremity amputations (LEAs)

Methods

- The study included 54 patient limbs with history of peripheral arterial disease that underwent below-knee or above-knee amputations
- Retrospective review of prospectively maintained database from Jan 2018 to Dec 2019
- 23 amputations in the NPWT group and 31 amputations in the standard dressing group (Standard Dressing)
- Patients in the NPWT arm of the study presented a higher incidence of comorbidities (tobacco use, previous amputation, COPD, etc.) vs Standard Dressing group
- Amputation incisions assessed and wound complications recorded 30 days postoperatively.
- Outcomes included: Surgical Site Infections, Wound Complications, Necrosis, Hematoma, Readmission, Revision Surgery, and Hospital Length of Stay (LOS)

Key Results

Wound Complications

⬇67%

Reduction in SSCs*
13 % (3/23) Prevena™ Therapy vs.
39 % (12/31) Standard Dressing
(p=0.037)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Additional Outcomes

Outcome	Prevena Therapy	Standard dressing	p-value
Overall Wound Complications	13% (3/23)	39% (12/31)	**0.037***
Deep SSI†	4% (1/23)	13% (4/31)	0.283
Superficial SSI	4% (1/23)	10% (3/31)	0.046
Necrosis†	4% (1/23)	13% (4/31)	0.283
Hematoma†	0% (0/23)	3% (1/31)	0.385

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

Summary

- Perioperative wound complications were significantly reduced within the Prevena Therapy group although there were increased comorbidities and risk factors.
- The reduction of perioperative wound complications and superficial SSI was statistically significant while there was no difference in other outcomes measured.
- Study suggest that Prevena Therapy may reduce the incidence of wound complications in vascular patients undergoing major lower extremity amputations, including high risk patients.
- Prevena Therapy may be considered for use in major lower extremity amputations.

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Chang et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	23	31
Number of Surgical Site Complications (a)	3	12
Cost per SSC[1] (b)	$9,526	$9,526
Per Patient Complication Cost [c=(a*b)/n]	$1,243	$3,687
Per Patient Therapy Cost* (d)	$830	---
Total Cost Per Patient (c+d)	**$2,073**	**$3,687**
Potential Per Incision Savings Using Prevena Therapy	**$1,615**	

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

*3M™ Prevena™ Plus Customizable Dressing 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 Standard of Care (Standard Dressing). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. Results are based on selected study data and may not be typical. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference: Chang H, Maldonado TS, Rockman CB, Cayne NS, Berland TL, Barfield ME, Jacobowitz GR, Sadek M. Closed incision negative pressure wound therapy may decrease wound complications in major lower extremity amputations. Journal of Vascular Surgery. 2021 Mar;73(3):1041-1047.

3M™ Prevena™ Therapy for the high-risk TKA or THA patient

Inclusion criteria for patients at high-risk for complications:

Primary hip and knee arthroplasty

Common risk factors to identify high-risk Patients:

- BMI > 35 kg/m^2
- non-aspirin anticoagulation
- active tobacco use
- diabetes mellitus
- autoimmune disease\immunosuppressive medications\immunodeficiency due to disease or medication

Additional risk factors considered by Doman at al.

- chronic kidney disease (stage 3 or higher)
- *Staphylococcus aureus* nasal colonization

Additional risk factors considered by Anatone et al.

- prior surgery to the operative joint

References:

1. *Doman DM, Young AM, Buller LT et al. 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. Journal of Arthroplasty. 2021; 36(10):3437-3442*
2. *Anatone A, Shah R, Jennings E et al. A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty. Arthroplasty Today 2018; 4:493-498*

Revision hip and knee arthroplasty

Patients are high-risk if they have ≥ 1 of the following risk factors:

- BMI > 35kg/m^2
- current/previous diagnosis of peripheral vascular disease
- insulin-dependent diabetes
- current tobacco use
- current use of immunomodulators or corticosteroids
- rheumatoid arthritis
- renal failure or dialysis
- malnutrition
- liver disease
- solid organ transplant recipients
- human immunodeficiency virus infection

Additional risk factors considered by Newman et al.

- depression
- use of non-aspirin blood thinners
- diabetes (non-insulin-dependent)
- history of prior joint infection in the operative limb
- current history of cancer or hematological malignancy
- Inflammatory arthritis

Additional risk factors considered by Higuera-Rueda et al.

- use of non-aspirin blood thinners postoperatively
- operative limb lymphedema
- history of prior infection at operative site
- ongoing malignancy excluding localized skin cancer

References:

1. *Higuera-Rueda C, 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;36(7S):S295-S302.e14*
2. *Newman JM, Siqueira MBP, Klika A 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. Journal of Arthroplasty 2019; 34(3):554-559*