3M | Prevena™ Incision Therapy

PRM | Proactive Risk Management (PRM) with 3M™ Prevena™ Therapy

Orthopedic Surgery

Advancing the standard of care

Helping to protect orthopedic surgery incisions beyond the OR

Orthopedic surgery patient care doesn't end in the OR

In an increasingly overwhelmed healthcare system, surgeons are asked to do more with fewer resources than ever before, creating complications for patients that extend beyond the operating room. Postoperative concerns include swelling, infection and improper tissue integration in and around the surgical site.

These complications can create a ripple effect of consequences, like disrupted healing, extended hospital stays and poor patient outcomes, which inevitably cause further disruption that impacts quality and cost of care. Today's complex care environment makes protecting against the ripple effect of these complications a high priority.

The cost of surgical complications

7.7-11.7 days

increased length of hospital stay due to surgical site infections (SSIs)[1]

18.8%

of unplanned 30-day readmission following THA and TKA* due to SSI[2]

$24,200 & $30,300

periprosthetic joint infection complications average hospital costs after THA and TKA, respectively[3]

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

Managing the ripple effect

Given the ever-increasing challenges of orthopedic surgery, clinicians and surgeons are looking for help to safeguard their work and improve the patient's healing journey. In their efforts to effectively manage the ripple effect of surgical complications they are often motivated to favor low-touch care, including solutions that promote:

- Efficiency and cost-effectiveness
- Minimal hospital stays
- Minimal complications
- Low re-admits
- Portability of care
- Home-based recovery
- Telehealth consultations

Consider how minimizing these ripple effects would affect your caseload and budgets, particularly readmissions and prolonged lengths of stay.

The power to help protect outcomes beyond the OR

3M™ Prevena™ Therapy is the first closed-incision negative pressure therapy (ciNPT) solution of its kind to help reduce the risk or incidence of seromas and superficial surgical site infections (SSIs) in Class I and II wounds.* It helps protect the incision site after surgery up to 7 days — extending your control over postoperative healing and helping patients at risk of developing complications.

Prevena Therapy offers orthopedic surgeons the confidence to help protect patients beyond the OR.

- **Acting as a barrier to external contamination**
- **Delivering continuous -125 mmHg up to 7 days**
- **Helping to hold incision edges together**
- **Decreasing lateral tension of sutured/stapled incisions[4]**
- **Removing fluids and infectious materials****
- **Reducing edema**

*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.

**In a canister.

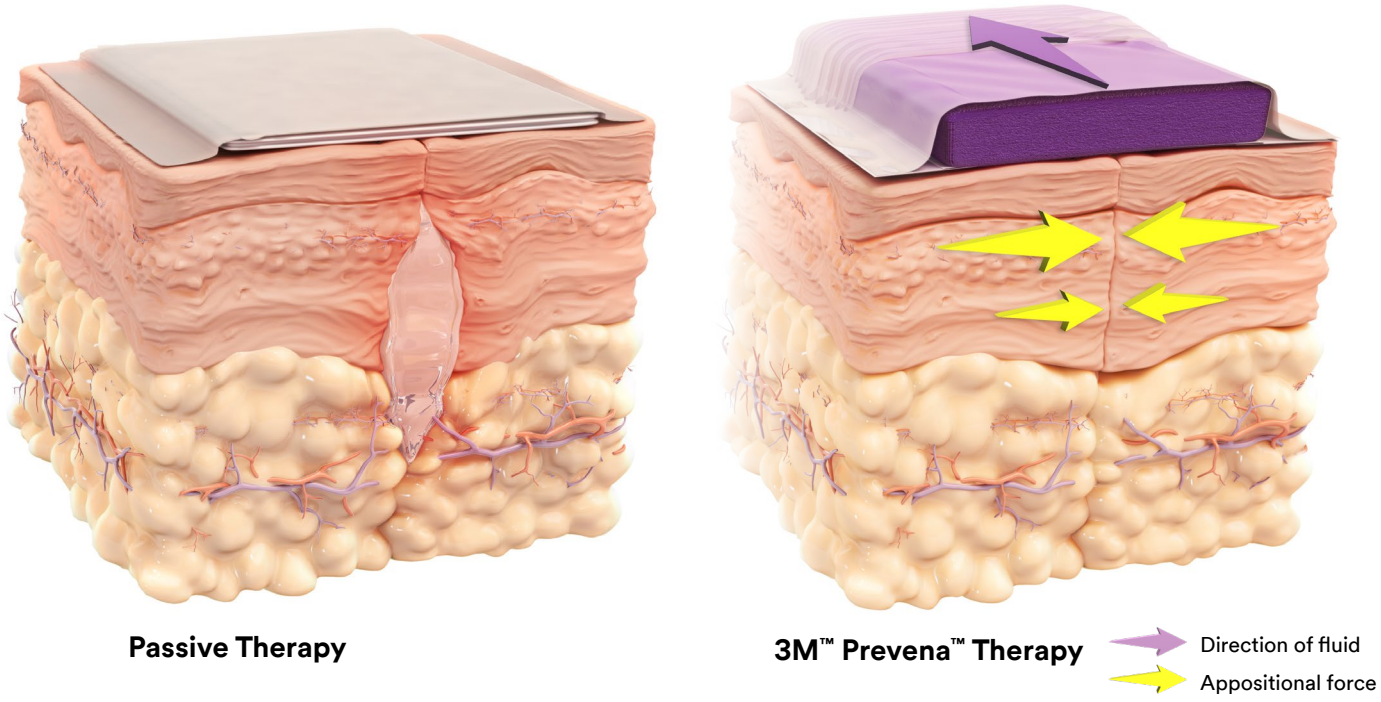
Prevena™ Dressings and Prevena Restor™ Dressings can be applied to various procedures and anatomical locations.

Note: The FDA indication to reduce the incidence of seromas and superficial surgical site infections in Class I & II wounds only applies to the Prevena 125 and Prevena Plus 125 Therapy Unit (7-day). The indication statement does not apply to the Prevena Plus 125 Therapy Unit (14-Day) that comes with the 3M™Prevena Restor™ kits or 3M™Prevena Restor™ Dressings (see Prevena Restor System Instructions for Use).

The advanced science of 3M™ Prevena™ Therapy

Prevena Therapy utilizes continuous -125 mmHg negative pressure therapy, reticulated open cell foam (ROCF) dressing technology, and optimized exudate management (replaceable canister) to help enhance healing. Visible and audible safety alarms automatically notify clinicians and patients of system alerts.

Prevena Therapy brings the incision edges together, reduces lateral tension, and allows for improved fluid management.[4-6]



Passive Therapy

3M™ Prevena™ Therapy

Additional features to help optimize postoperative care

- Contours in Prevena Dressings allow for even distribution of negative pressure
- Adhesive film creates a barrier to external contaminants
- Designed to conform to allow movement
- Multiple sizes and configurations
- Prevena Dressings are shower friendly*

***See Prevena Therapy Patient and Clinician Guides for additional details.**

Patients and procedures that may benefit from 3M™ Prevena™ Therapy

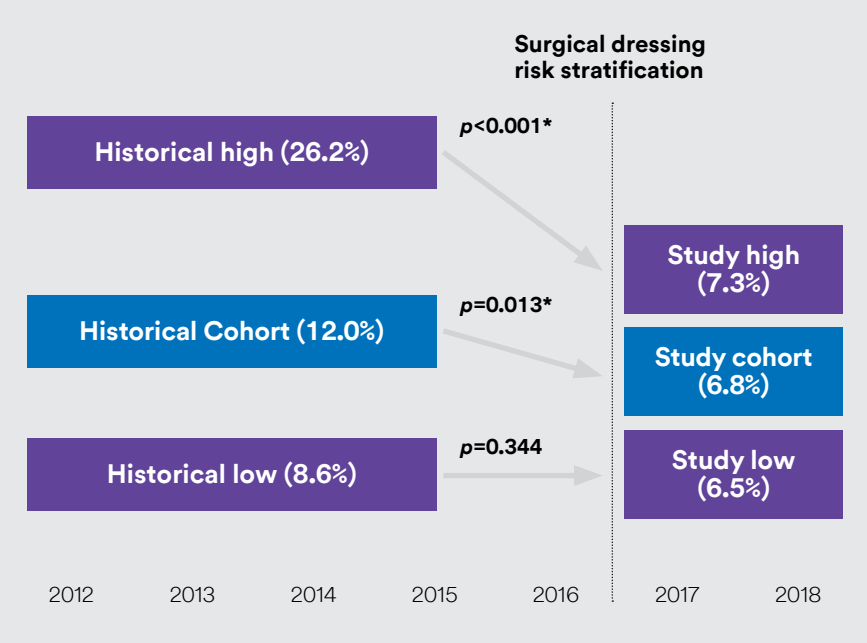
A multidisciplinary group of surgical and infectious disease experts developed an algorithm to help identify when a patient and procedure may benefit from Prevena Therapy.

The authors of a 2018 study implemented a risk-stratification algorithm (Table 1) for the use of Prevena Therapy.[7] Working with patients undergoing primary total joint arthroplasties, they used the algorithm to categorize patients as high-risk (≥2 score) and low-risk (score <2), and compared outcomes of patients treated prophylactically with closed-incision negative pressure therapy (ciNPT) dressings with historical control groups.

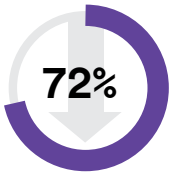
Table 1

Risk factor	Weight
Body mass index	
<18.5kg/m^2	1
18.5-29.9kg/m^2	0
30-34.9kg/m^2	1
35-39.9kg/m^2	2
>40kg/m^2	3
Diabetes mellitus	2
Immunodeficiency	1.3
Active smoker	1
Non-acetylsalicylic acid anticoagulation	1
Prior surgery	2

Table 2



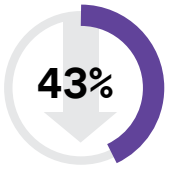
High-risk patients



Reduction in surgical site complications**
7.3% (9/123) Prevena Therapy vs.
26.2% (32/122) Control

(p<0.001)***

All patients



Reduction in surgical site complications
6.8% (22/323) Prevena Therapy vs.
12.0% (77/643) Control

(p<.013)***

Calculation(s) are derived based on relative patient group incidence rate reported in this study.
*Percentages determined by calculating the difference between 26.2% to 7.3% and 12.0% to 6.8%, respectively.
**Surgical site complication was defined as any dehiscence, suture granuloma, drainage occurring beyond postoperative day 5, significant hematoma formation, or surgical site infection, as defined by the CDC, that required unplanned postoperative interventions.
***Statistically significant (p=<0.05).

Additional important factors to consider:[8]

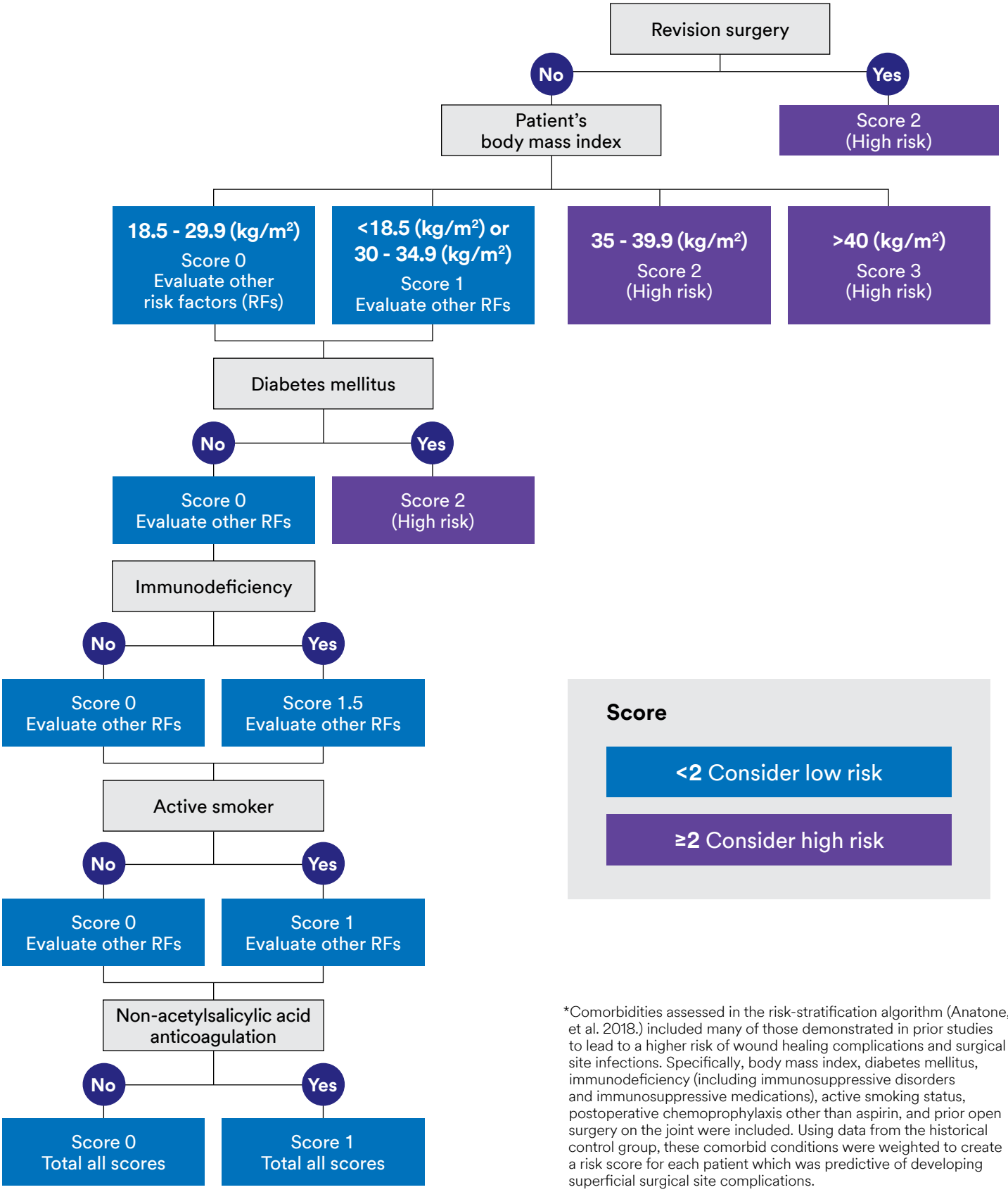
Patient-related risk factors		General incision-related factors	
• Diabetes mellitus • Acetylsalicylic acid Score ≥3 • Advanced age • Obesity • Active tobacco use • Hypoalbuminemia • Corticosteroid usage	• Active alcoholism • Male sex • Hematoma • Chronic renal insufficiency • Chronic obstructive pulmonary disease	• High tension incision • Repeated incisions • Extensive undermining • Traumatized soft tissue • Edema • Contamination • Emergency procedure	• Prolonged operation time • Post-surgical radiation • Mechanically unfavorable site

Procedure/operation-related risk factors:

General	Plastic	Orthopedic	Vascular	Cardiovascular
• Open general • Open colorectal • Open urology • Open obstetrics/ gynecology • Incisional hernia repair	• Post-bariatric abdominoplasty • Breast reconstruction • Big soft tissue defects • Soilage risk	• Open reduction and internal fixation of fractures • Fasciotomy • Above/below knee amputation	• Above/below knee amputation • Syntetic graft implantations	• Sternotomy

Identification tool for high-risk patients*

Decision tree developed from Anatone, et al. 2018.[7]



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

> It's changed how I practice... 3M™ Prevena™ Therapy allows me to have more confidence in taking on these more complicated and challenging surgical cases."*
>
> – *Dr. Timothy Alton, Orthopedic Surgeon*
> *3M Paid Consultant*

*Individual results may vary.
3M™ Prevena™ Dressings and 3M™ Prevena Restor™ Dressings can be applied to various procedures and anatomical locations.

FDA indications support

3M™ Prevena™ 125 Therapy Unit and 3M™ Prevena™ Plus 125 Therapy Unit manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125 mmHg continuous negative pressure. When used with legally marketed compatible dressings, Prevena 125 Therapy Unit and Prevena Plus 125 Therapy Unit are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection (SSI) in Class I and Class II wounds.

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 Prevena.com.

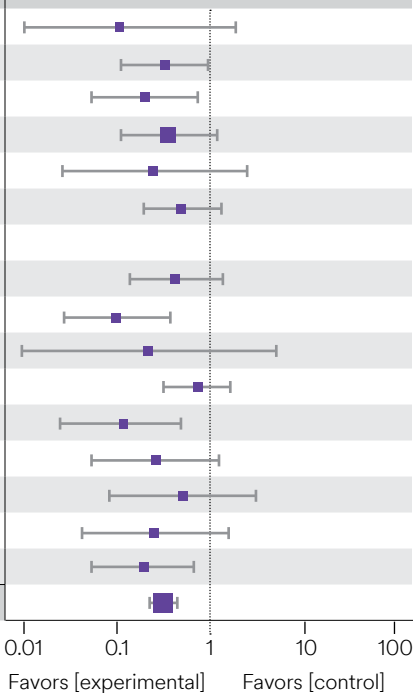
Clinical evidence supporting the FDA indications is growing

A growing body of evidence supports the use of 3M™ Prevena™ Therapy to address the challenges of surgical incision complications. A systematic literature review and associated meta-analysis support the safety and effectiveness of Prevena Therapy over closed incisions in reducing the incidence of surgical site infections (SSIs) and seromas versus conventional wound dressings.[9]

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

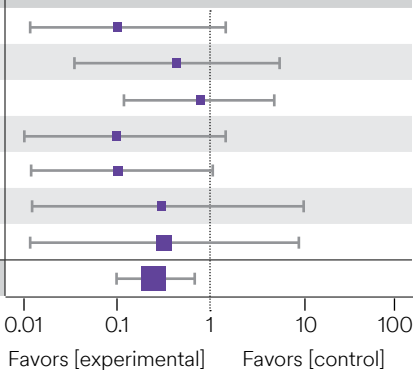
Forest plot of meta-analysis on surgical site infection

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



Forest plot of meta-analysis on seroma

	Treatment			Control			
Study or subgroup	Events	Total	%	Events	Total	%	Odds ratio, 95% CI
Ferrando PM 2017	1	25	(4.0)	5	22	8.7%	0.14 (0.02, 1.32)
Gunatiliake RP 2017	1	39	(2.6)	2	43	12.8%	0.54 (0.05, 6.19)
NCT01341444	3	28	(10.7)	3	30	15.8%	1.08 (0.20, 5.85)
Pachowsky M 2012	4	9	(10.7)	9	10	1.8%	0.09 (0.01, 1.03)
Pauser J 2014	4	11	(36.4)	8	10	35.3%	0.14 (0.02, 1.03)
Pleger SP 2017	0	58	(0.0)a	1	71	0.7%	0.40 (0.02, 10.05)
Redfern RE 2017	0	196	(0.0)	2	400	9.0%	0.41 (0.02, 8.49)
Total		**366**			**586**		**0.31 (0.13, 0.75)**



Prevena Therapy demonstrated the greatest benefit in reducing SSIs and seromas in high-risk patients.

Clinical evidence of SSI reduction in high-risk patients

PROMISES randomized controlled trial (RCT) multicenter data suggests 3M™ Prevena™ Therapy can help advance the standard of care.

Study Design:

The PROMISES study was a multicenter (15) RCT involving 294 patients undergoing elective revision knee arthroplasty. Patients were prospectively randomized to receive either Prevena Therapy or an antimicrobial silver-impregnated dressing.

- Patients had at least one risk factor for developing wound complications
- Study endpoints included wound complications (such as surgical site infection (SSI) or drainage), health care utilization parameters (readmission, reoperation, dressing changes, and visits), and patient recorded outcomes

Summary

Data from a multicenter (15) RCT and subsequent cost-effectiveness analysis affirms that Prevena Therapy significantly reduced the risk of 90-day surgical site complications (SSCs)[10], readmissions[10], and surgical site management costs[11] compared with silver-impregnated dressings.

A follow-up health economic assessment was completed to determine the cost-benefit of closed-incision negative pressure therapy in revision total knee arthroplasty (rTKA) surgical site management by reducing 90-day cost for SSC-related interventions based on RCT study data.

Readmission reduction[9]

3X

3.4% (5/147) Prevena Therapy vs.
10.2% (15/147) SOC

(p=0.0208)*

Surgical site complication reduction[9]

4X

3.4% (5/147) Prevena Therapy vs.
14.3% (21/147) SOC

(p=0.0013)*

Per-patient cost-of-care reduction[10]

1.9X

$1,047 Prevena Therapy vs.
$2,036 SOC

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

Clinical evidence supporting 3M™ Prevena™ Therapy in orthopedic surgery

Level of clinical evidence rating[12]

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

Wound/ Surgery Type	Level of Evidence	Citation
Revision total knee arthroplasty	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.
Total hip and knee arthroplasty	1b	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;34(3):554-559.
Knee arthroplasty	1b	Manoharan V, Grant A, Harris A, et al. Closed Incision Negative Pressure Wound Therapy vs Conventional Dry Dressings After Primary Knee Arthroplasty: A Randomized Controlled Study. *J Arthroplasty*. 2016;31(11):2487-2494.
	3	Curley AJ, Terhune EB, Velott AT, et al. Outcomes of Prophylactic Negative Pressure Wound Therapy in Knee Arthroplasty. *Orthopedics*. 2018;41(6):e837-e840.
Total hip arthroplasty	1b	Pachowsky M, Gusinde J, Klein A, et al. Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty. *International Orthopaedics*. 2012;36(4):719-22.
Hip and knee arthroplasty	2	Redfern RE, Cameron-Ruetz C, O'Drobinak S, et al. 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.
	3	Anatone AJ, Shah RP, Jennings EL, et al. A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty. *Arthroplasty Today*. 2018;4(4):493-498.
	5	Suleiman LI, Mesko DR, Nam D. Intraoperative Considerations for Treatment/Prevention of Prosthetic Joint Infection. *Current Reviews in Musculoskeletal Medicine*. 2018:1-8.
	5	Chotanaphuti T, Courtney PM, Fram B, et al. Hip and Knee Section, Treatment, Algorithm: Proceedings of International Consensus on Orthopedic Infections. *The Journal of Arthroplasty.* 2019;34(2S):S393-S397.
Periprosthetic fracture surgery	3	Cooper HJ, Roc GC, Bas MA, et al. Closed incision negative pressure therapy decreases complications after periprosthetic fracture surgery around the hip and knee. *Injury.* 2018 Feb;49(2):386-391.
Revision knee and hip	3	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):1047-52.
Orthopedic surgery	5	Nam D, Sershon RA, Levine BR, et al. The Use of Closed Incision Negative-Pressure Wound Therapy in Orthopaedic Surgery. *J Am Acad Orthop Surg*. 2018;26(9):295-302.
Orthopedic infections	5	Al-Houraibi RK, Aalirezaie A, Adib F, et al. General Assembly, Prevention, Wound Management: Proceedings of International Consensus on Orthopedic Infections. *The Journal of Arthroplasty*. 2019;34(2):S157-S168.

Compatible with 3M negative pressure therapy devices

3M™ Prevena™ Plus 125 Therapy Unit

One single-use negative pressure therapy unit compatible with all 3M™ Prevena™ Dressings.

Negative pressure options:

- Pre-set, continuous negative pressure therapy at -125 mmHg for up to 7 or 14 days (with dressing changes every 7 days)
- Disposable, single patient use
- Rechargeable battery

Specifications:

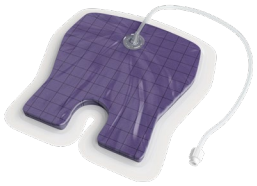
- Dimensions: Approx 8.9 × 16.3 × 5.49cm
- Weight with empty canister: 0.64lbs (0.29kg)

Prevena Dressings are also compatible with 3M traditional negative pressure therapy devices:
3M™ V.A.C.® Ulta Therapy Unit and 3M™ ActiV.A.C.® Therapy Unit

3M™ Prevena Restor™ Dressings

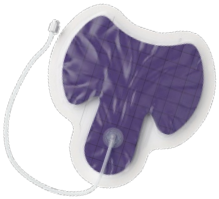
3M™ Prevena Restor™ Therapy extends negative pressure therapy beyond the incision site to include the surrounding soft tissue. It helps provide comprehensive protection, optimize surgical site recovery, and helps patients start rehab with confidence.

3M™ Prevena Restor™ Arthro•Form™ Dressing

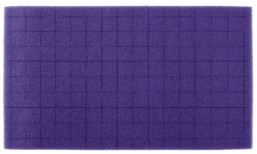


3M™ Prevena Restor™ Axio•Form™ Dressing

3M™ Prevena Restor™ Bella•Form™ Dressing



3M™ Prevena Restor™ Roto•Form™ Dressing



3M™ Prevena Restor™ Adapti•Form™ Dressing

The same proven technology as the original 3M™ Prevena™ Incision Management System with new features to help optimize postoperative care.

Extended therapy time

Up to 14 days (dressing change required after 7 days)

Precision designed

Dressings seamlessly conform to the patient

Expanded coverage area

Large dressings deliver therapy to the incision and surrounding soft tissue envelope

Easy to use

A variety of peel-and-place dressings are available, plus a customizable option

Additional customer resources:

- Live clinical training and product support 25,000+ professionals trained annually
- Free product evaluation program
- Clinical services and reimbursement hotlines
- Centralized, on demand clinical and technical support

Ordering Information

SKU	Description	UOM
Therapy Devices		
PRE4000US	3M™ Prevena™ Plus 125 Therapy Unit – 7 day	Each
PRE4010	3M™ Prevena™ Plus 125 Therapy Unit – 14 day	Each
Dressings		
PRE1055US	3M™ Prevena™ Peel and Place Dressing – 20 cm	Case of 5
PRE1155US	3M™ Prevena™ Peel and Place Dressing – 13 cm	Case of 5
PRE3255US	3M™ Prevena™ Plus Peel and Place Dressing – 35 cm	Case of 5
PRE4055US	3M™ Prevena™ Plus Customizable Dressing	Case of 5
PRE5055	3M™ Prevena Restor™ Arthro•Form™ Dressing – 33 cm x 30 cm	Case of 5
PRE5155	3M™ Prevena Restor™ Arthro•Form™ Dressing – 46 cm x 30 cm	Case of 5
PRE5255	3M™ Prevena Restor™ Bella•Form™ Dressing – 21 cm x 19 cm	Case of 5
PRE5355	3M™ Prevena Restor™ Bella•Form™ Dressing – 24 cm x 22 cm	Case of 5
PRE5455	3M™ Prevena Restor™ Bella•Form™ Dressing – 29 cm x 27 cm	Case of 5
PRE5555	3M™ Prevena Restor™ Axio•Form™ Dressing – 29 cm x 28 cm	Case of 5
PRE5655	3M™ Prevena Restor™ Roto•Form™ Dressing – 29 cm x 31 cm	Case of 5
PRE6055	3M™ Prevena Restor™ Adapti•Form™ Dressing – 49 cm x 28 cm	Case of 5
Accessories		
PRE1095	3M™ Prevena™ 45 ml Canister	Case of 5
PRE4095	3M™ Prevena™ Plus 150 ml Canister	Case of 5
PRE9090	3M™ Prevena™ Therapy V.A.C.® Connector	Case of 10
Kits		
PRE1001US	3M™ Prevena™ Incision Management System – 20 cm	Each
PRE1101US	3M™ Prevena™ Incision Management System – 13 cm	Each
PRE3201US	3M™ Prevena™ Plus Incision Management System – 35 cm	Each
PRE4001US	3M™ Prevena™ Plus Customizable Incision Management System	Each
PRE1121US	3M™ Prevena™ Duo Incision Management System – 13 cm/13 cm	Each
PRE3321US	3M™ Prevena™ Plus Duo Incision Management System – 13 cm/20 cm	Each
PRE3021US	3M™ Prevena™ Plus Duo Incision Management System – 20 cm/20 cm	Each
PRE5001	3M™ Prevena Restor™ Arthro•Form™ Incision Management System – 33 cm x 30 cm	Each
PRE5101	3M™ Prevena Restor™ Arthro•Form™ Incision Management System – 46 cm x 30 cm	Each
PRE5221	3M™ Prevena Restor™ Bella•Form™ Incision Management System – 21 cm x 19 cm	Each
PRE5321	3M™ Prevena Restor™ Bella•Form™ Incision Management System – 24 cm x 22 cm	Each
PRE5421	3M™ Prevena Restor™ Bella•Form™ Incision Management System – 29 cm x 27 cm	Each
PRE5501	3M™ Prevena Restor™ Axio•Form™ Incision Management System – 29 cm x 28 cm	Each
PRE5601	3M™ Prevena Restor™ Roto•Form™ Incision Management System – 29 cm x 31 cm	Each
PRE6001	3M™ Prevena Restor™ Adapti•Form™ Incision Management System – 49 cm x 28 cm	Each

Help protect your patients beyond the OR with 3M™ Prevena™ Therapy.

For more information or to request an evaluation, contact your 3M representative or visit 3M.com/PrevenaCentral.

Note: Specific indications, limitations, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

References:

1. de Lissovoy G, Fraeman K, Hutchins V, et al. Surgical site infection: incidence and impact on hospital utilization and treatment costs. *Am J Infect Control.* 2009;37(5):387-97.
2. Merkow R, et al. Underlying reasons associate with hospital readmission following surgery in the US. *JAMA.* 2015;313(5):483-95.
3. Kurtz SM, Lau E, Watson H, et al. Economic burden of periprosthetic joint infection in the United States. *J Arthroplasty.* 2012;27(8 Suppl):61-5.e1. Epub 2012 May 2.
4. Wilkes RP, Kilpadi DV, Zhao Y, et al. Closed Incision Management With Negative Pressure Wound Therapy (CIM): Biomechanics. *Surgical Innovation.* 2012;19(1):67-75.
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