



Prevena[™]
Incision Therapy

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

Vascular Surgery

Advancing the standard of care

Helping to protect vascular surgery
incisions beyond the OR



Vascular 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

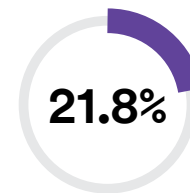
Surgical site infections (SSIs)



Patients affected each year¹



Cost to the healthcare system per year¹



SSIs percentage of all healthcare-associated infections (HAIs)²



Average increase in length of hospital stay from SSIs³



Average added cost from SSIs³



Readmission is necessary 5x more often⁴

Complications in vascular surgery



SSI rate following vascular groin incisions⁵⁻⁹



Mean incremental cost to treat surgical site complications following open lower extremity vascular surgery¹⁰

Managing the ripple effect

Given the ever-increasing challenges of vascular 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 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 vascular 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 incisions¹¹



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.

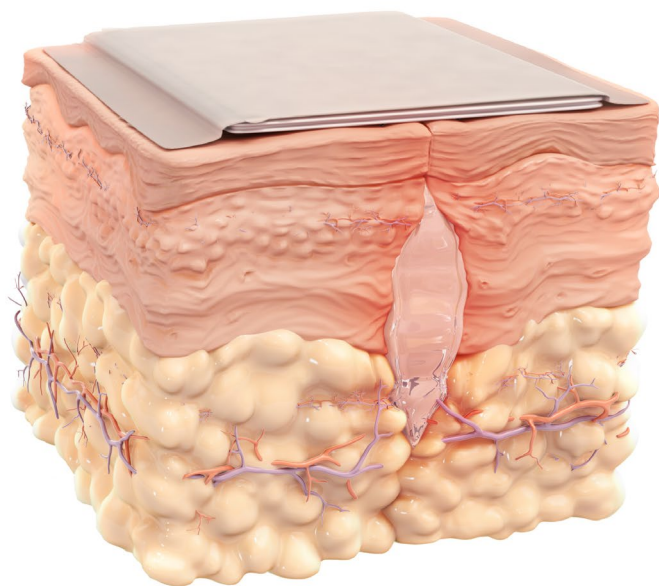
Prevena™ Dressings and Prevena Restor™ Dressings can be applied to various procedures and anatomical locations.

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).

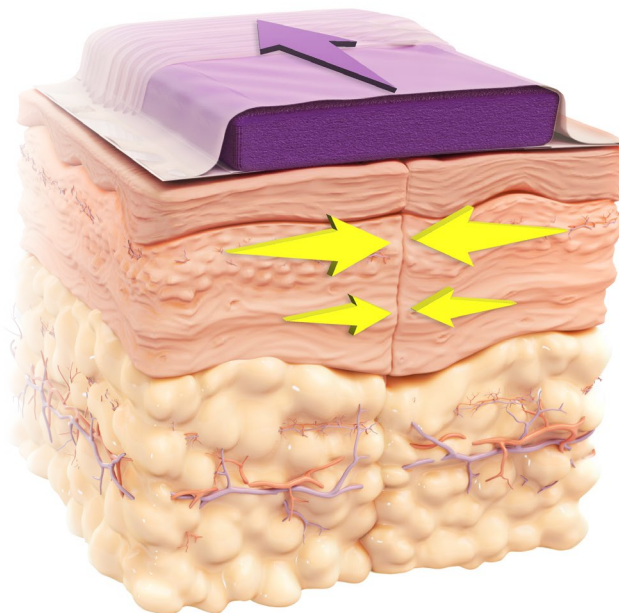
The advanced science of 3M™ Prevena™ Therapy

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.¹¹⁻¹³



Passive Therapy



3M™ Prevena™ Therapy  Direction of fluid
 Appositional force

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 guide when to consider using closed-incision negative pressure therapy (ciNPT).¹⁴ They recommend that surgeons consider using ciNPT for patients at high risk for developing surgical site occurrences (SSOs) or who are undergoing a high-risk procedure or a procedure that would have highly morbid consequences if a surgical site infection (SSI) occurred.

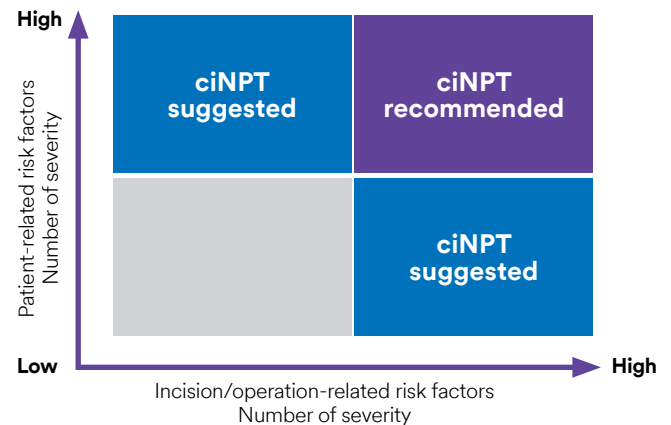
Consensus recommendations based on:

- Literature review
- ciNPT experiences
- Known risk factors for SSOs

Findings:

- Numerous publications reported SSI risk factors, with the most common including obesity (body mass index ≥ 30 kg/m²); diabetes mellitus; tobacco use; or prolonged surgical time
- It is recommended that the surgeon assess the individual patient's risk factors and surgical risks

Risk factor assessment for ciNPT



Additional factors to consider:

Patient-related risk factors		General incision-related factors	
<ul style="list-style-type: none"> • Diabetes mellitus • Acetylsalicylic acid Score ≥ 3 • Advanced age • Obesity • Active tobacco use • Hypoalbuminemia • Corticosteroid usage 	<ul style="list-style-type: none"> • Active alcoholism • Male sex • Hematoma • Chronic renal insufficiency • Chronic obstructive pulmonary disease 	<ul style="list-style-type: none"> • High tension incision • Repeated incisions • Extensive undermining • Traumatized soft tissue • Edema • Contamination • Emergency procedure 	<ul style="list-style-type: none"> • Prolonged operation time • Post-surgical radiation • Mechanically unfavorable site

Procedure/operation-related risk factors:

General	Plastic	Orthopedic	Vascular	Cardiovascular
<ul style="list-style-type: none"> • Open general • Open colorectal • Open urology • Open obstetrics/gynecology • Incisional hernia repair 	<ul style="list-style-type: none"> • Post-bariatric abdominoplasty • Breast reconstruction • Big soft tissue defects • Soilage risk 	<ul style="list-style-type: none"> • Open reduction and internal fixation of fractures • Fasciotomy • Above/below knee amputation 	<ul style="list-style-type: none"> • Above/below knee amputation • Syntetic graft implantations 	<ul style="list-style-type: none"> • Sternotomy

“

We found that in a multi-variant regression, 3M™ Prevena™ Therapy was a consistent predictor that helped effect against surgical site infections.”^{15,*}

– Dr. Ellen D. Dillavou, Chief of Vascular Surgery
3M Paid Consultant

*Individual results may vary.



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 in Class I and Class II wounds.

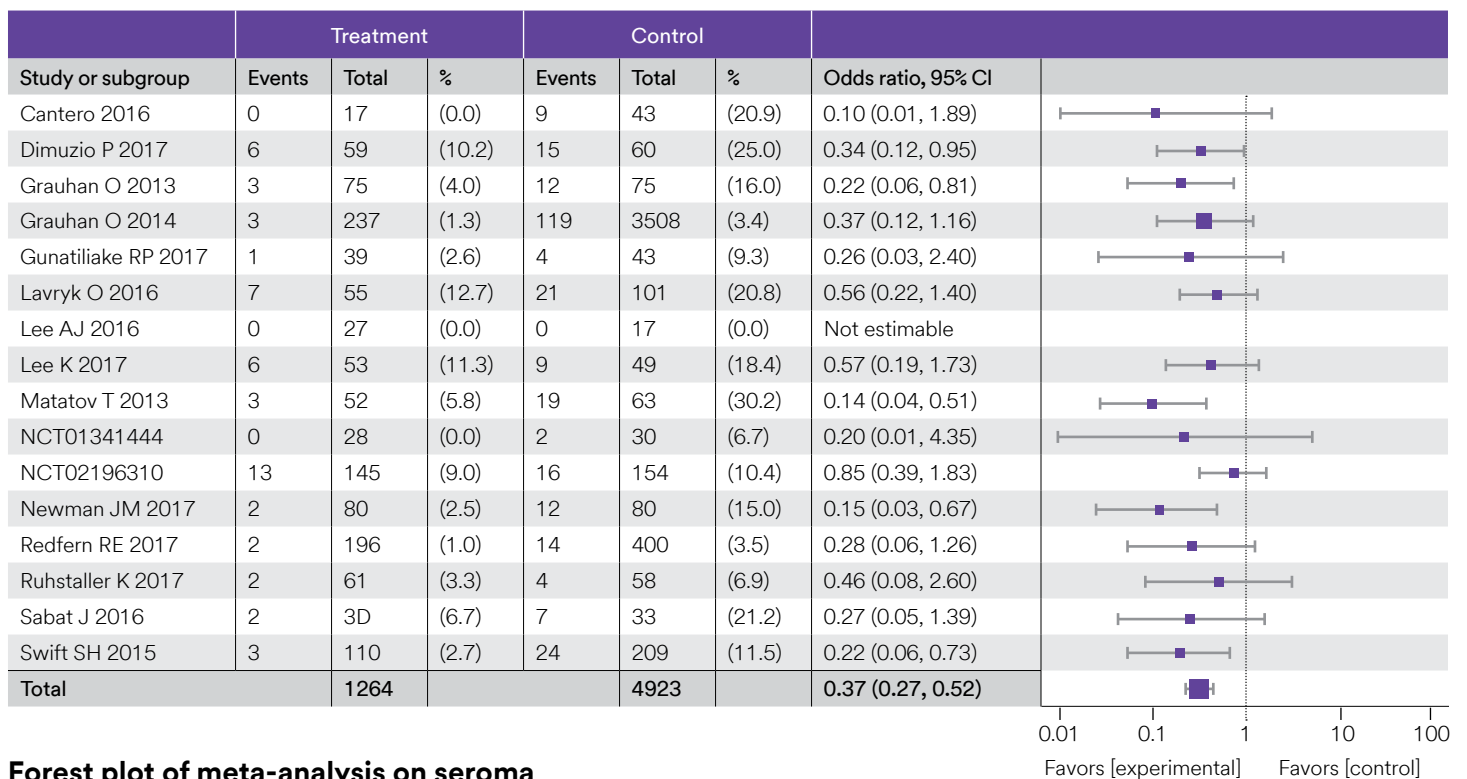
The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at [Prevena.com](https://www.Prevena.com).

Clinical evidence supporting the FDA indications is growing

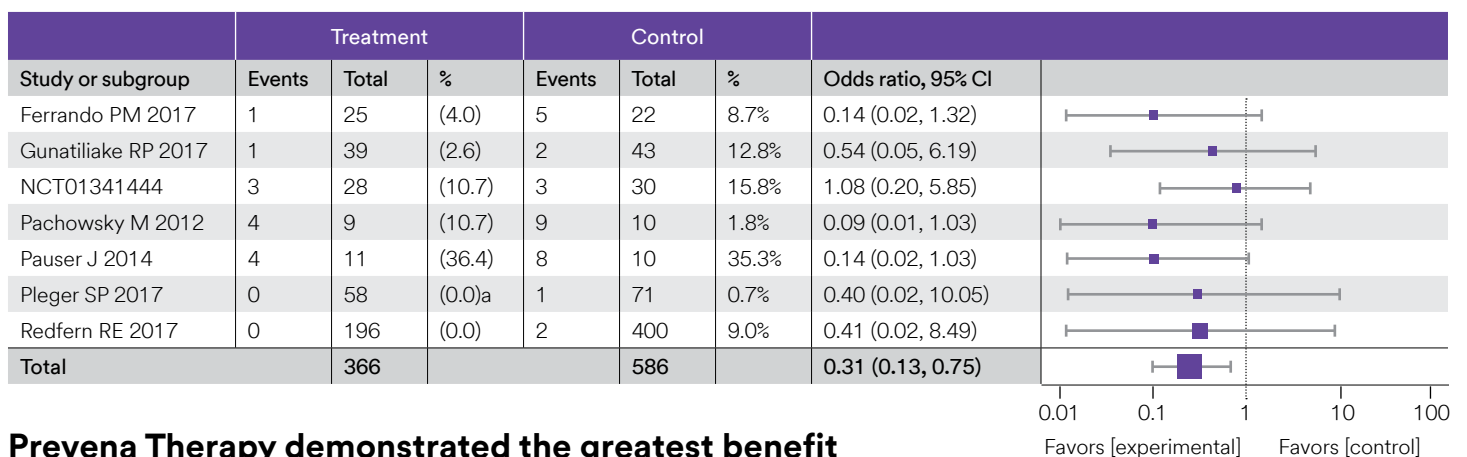
A growing body of evidence supports the use of 3M™ Prevena™ Therapy to address the challenges of surgical incision complications. A systematic literature review and associated meta-analysis support the safety and effectiveness of Prevena Therapy over closed incisions in reducing the incidence of surgical site infections (SSIs) and seromas versus conventional wound dressings.¹⁶

- 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



Forest plot of meta-analysis on seroma



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

Growing clinical evidence

Meta-analysis and trial-sequential analysis of prophylactic negative pressure therapy (NPT) for groin wounds in vascular surgery

Antoniou G, Onwuka C, Antoniou S, et al. Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery. *Journal of Vascular Surgery*. 2019;70(5):1700-1710.

Study Design:

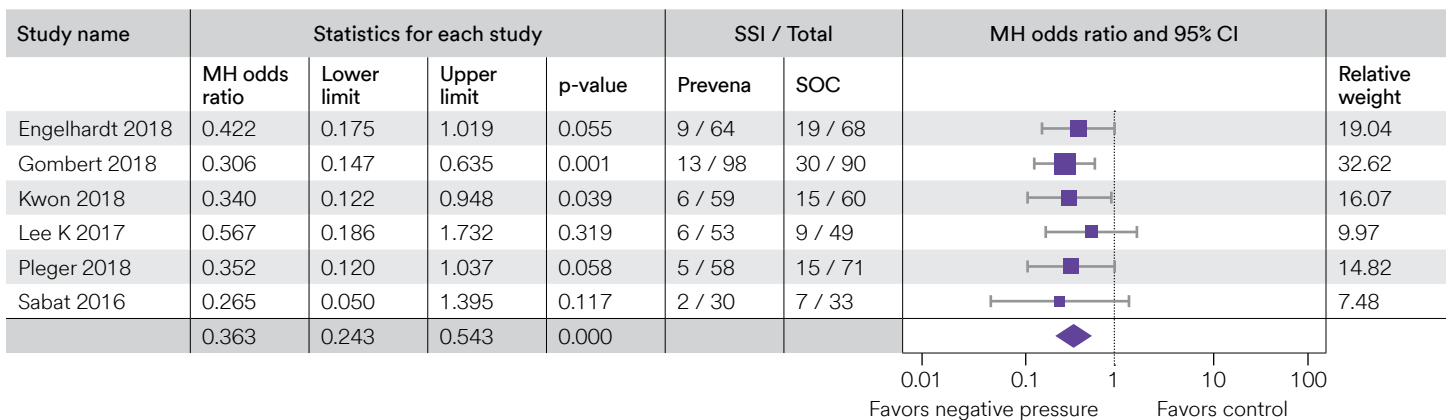
A review of six randomized controlled trials (RCTs) studies, all of which compared 3M™ Prevena™ Therapy vs. standard of care (SOC) dressings, with a total of 733 groin wounds.

Summary

Prophylactic NPT shows improved outcomes in patients undergoing arterial surgery via groin incision compared with standard surgical wound care, as indicated by a reduction in the risk of surgical site infection (SSI).

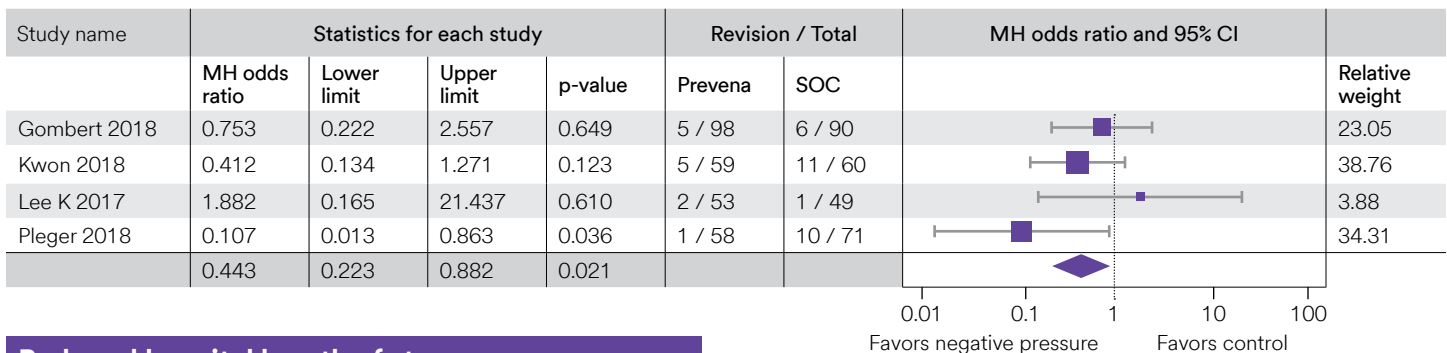
Reduced surgical site infections

Patients with Prevena Therapy had a lower risk of developing SSIs by 79% (41 events with Prevena Therapy and 95 events with control) (OR, 0.36; 95% CI, 0.24-0.54).



Reduced revision surgery

Patients with Prevena Therapy had a lower risk of revision surgery (OR, 0.44; 95% CI, 0.22-0.88).



Reduced hospital length of stay



Shorter hospital length of stay
-2.14 days (95% CI: -3.78 to -.049)
(p=0.01)*

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

Supporting ciNPT clinical evidence

Randomized controlled trials (RCT) demonstrates closed-incision negative pressure therapy (ciNPT) reduces major complications, reoperation, and readmission rates for high-risk groin incisions

Kwon J, Staley C, McCullough M, et al. A Randomized Clinical Trial Evaluating Negative Pressure Therapy to Decrease Vascular Groin Incision Complications. *Journal of Vascular Surgery*. 2018;68(6):1744-1752.

Study Design:

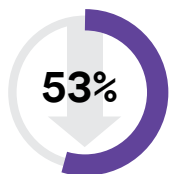
This prospective RCT evaluated negative pressure therapy (NPT) (3M™ Prevena™ Therapy) to decrease wound complications and associated health care costs.

- The study included 119 femoral incisions closed primarily after elective vascular surgery procedures
- High-risk inclusion criteria: Body mass index > 30, pannus, re-operative surgery, prosthetic graft, poor nutrition, immunosuppression, or HbA1c>8
- 1:1 Randomized to standard gauze (n=60) vs. Prevena Therapy (n=59)
- Outcomes evaluated at postoperative day 30: wound complications, surgical site infections, length of stay, reoperation, readmission

Summary

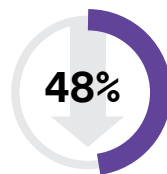
The RCT suggests that NPT for patients at high risk for groin wound complications significantly reduces major wound complications, reoperation and readmission rates and ciNPT may lead to a reduction in hospital cost. ciNPT is recommended for all groin incisions considered at high risk for wound complications.

Surgical site infection reduction

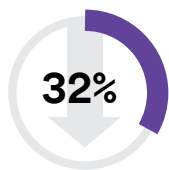


10.1% (6/59) Prevena Therapy vs. 21.6% (12/60) SOC

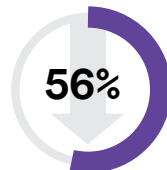
($p=0.001$)*



1.7% (1/59) Prevena Therapy vs. 3.3% (2/60) SOC (Szilagyi I)

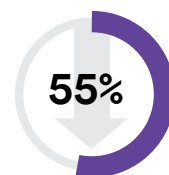


3.4% (2/59) Prevena Therapy vs. 5.0% (3/60) SOC (Szilagyi II)



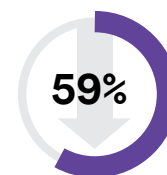
5.1% (3/59) Prevena Therapy vs. 11.7% (7/60) SOC (Szilagyi III)

Surgical site complication reduction



11.9% (7/59) Prevena Therapy vs. 26.7% (16/60) SOC

($p=0.001$)*



6.8% (4/59) Prevena Therapy vs. 16.7% (10/60) SOC

($p<0.04$)*

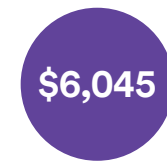
Return to OR reduction



8.5% (5/59) Prevena Therapy vs. 18.3% (11/60) SOC

($p<0.05$)*

Cost savings per patient



\$30,492 Prevena Therapy vs. \$36,537 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 vascular surgery

Level of clinical evidence rating¹⁷

- **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
Groin wounds	1b	Engelhardt M, Rashad NA, Willy C, et al. Closed-incision negative pressure therapy to reduce groin wound infections in vascular surgery: a randomised controlled trial. <i>Int Wound J.</i> 2018;15(3):327-332.
	1b	Gombert A, Babilon M, Barbati ME, et al. Closed incision negative pressure therapy reduces surgical site infections in vascular surgery: a prospective randomised trial (AIMS Trial). <i>Eur J Vasc Endovasc Surg.</i> 2018; 56(3):442-448.
	1b	Kwon J, Staley C, McCullough M, et al. A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications. <i>J Vasc Surg.</i> 2018;68(6):1744-1752.
	1b	Lee K, Murphy PB, Ingves MV, et al. Randomized clinical trial of negative pressure wound therapy for high-risk groin wounds in lower extremity revascularization. <i>J Vasc Surg.</i> 2017;66(6):1814-19.
Groin incisions	1b	Pleger SP, Nink N, Elzien M, et al. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single institution study. <i>Int Wound J.</i> 2018;15(1):75-83.
Open saphenous vein harvest in cardiac surgery	1b	Lee AJ, Sheppard CE, Kent WD, et al. Safety and efficacy of prophylactic negative pressure wound therapy following open saphenous vein harvest in cardiac surgery: a feasibility study. <i>Interact Cardiovasc Thorac Surg.</i> 2017;24(3):324-328.
Vascular bypass	2	Weir G. The use of a surgical incision management system on vascular surgery incisions: a pilot study. <i>Int Wound J.</i> 2014;11 Suppl 1:10-2.
	3	Matatov T, et al. Experience with a new negative pressure incision management system in prevention of groin wound infection in vascular surgery patients. <i>J Vasc Surg.</i> 2013;57(3):791-5.
	5	Haghshenasskashani A, Varcoe RL. A New Negative Pressure Dressing (Prevena) to Prevent Wound Complications Following Lower Limb Distal Arterial Bypass. <i>Br J Diabetes Vasc Dis.</i> 2011;11(1):21-4.
Thoracic artery grafting	3	Santarpino G, Gazdag L, Sirch J, et al. A Retrospective Study to Evaluate Use of Negative Pressure Wound Therapy in Patients Undergoing Bilateral Internal Thoracic Artery Grafting. <i>Ostomy Wound Manage.</i> 2015;61(12):26-30.



“ We implemented a lot of new protocols and one of them was to start using 3M™ Prevena™ Therapy on all of our incision in the infrainguinal areas. By the end of our four-month rollout we had significantly reduced the incidence of surgical site infections.”*

– Dr. Ellen D. Dillavou, Chief of Vascular Surgery
3M Paid Consultant

*Individual results may vary.

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.® Ultra 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™ ArthroForm™ Dressing



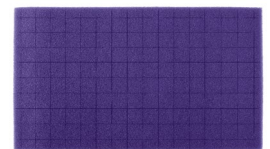
3M™ Prevena Restor™ AxioForm™ Dressing



3M™ Prevena Restor™ BellaForm™ Dressing



3M™ Prevena Restor™ RotoForm™ Dressing



3M™ Prevena Restor™ AdaptiForm™ Dressing

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



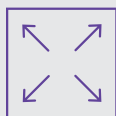
Extended therapy time

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



Clinical services and
reimbursement hotlines



Free product evaluation program



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 – 22 cm x 24 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:

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