
3M
Prevena™
Incision Therapy
Protecting.
Beyond.
Cardiovascular surgery
and more.
prevena 125

How 3M™ Prevena™ Therapy can help

Expanded FDA indication

The FDA granted the following Indications for Use:*

3M™ Prevena™ 125 Therapy Unit and 3M™ Prevena™ Plus 125 Therapy Units manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, Prevena 125 Therapy Unit and Prevena Plus 125 Therapy Units 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 myKCI.com.

More. Clinical evidence supporting the new indication

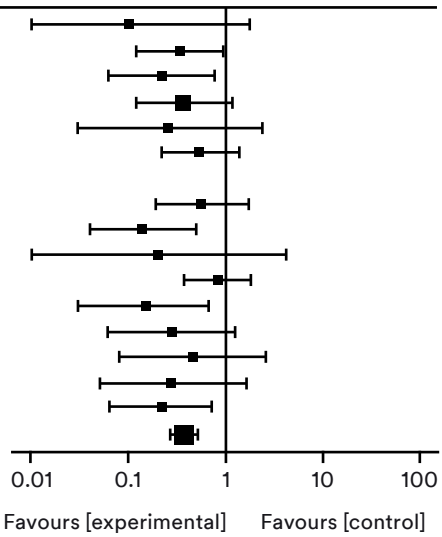
A systematic literature review and associated meta-analysis were used to support the safety and effectiveness of Prevena Therapy over closed incisions in reducing the incidence of surgical site infections (SSIs) and seromas versus conventional wound dressings.

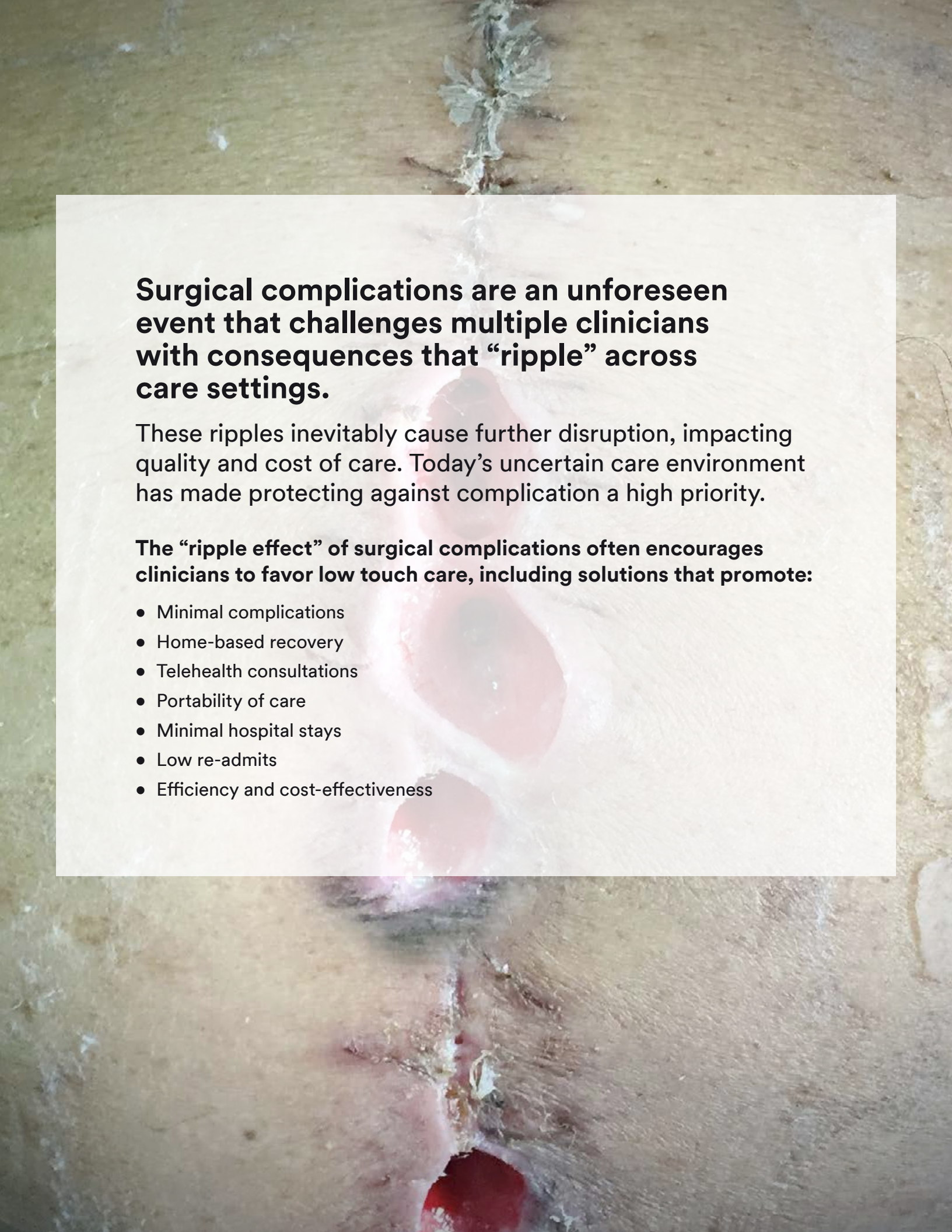
- Out of 426 studies in the initial search, ultimately, sixteen (16) prospective studies were included in this meta-analysis for SSI characterization
- A total of up to 6,187 evaluable patients were included in this meta-analysis for SSI with 1,264 in the Prevena Therapy (treatment) group and 4,923 in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

Prevena Therapy demonstrated the greatest benefit in reducing SSIs in high risk patients

Forest Plot of Meta-Analysis on Surgical Site Infection

	Treatment			Control				
Study or Subgroup	Events	Total	%	Events	Total	%	Odds Ratio (95% CI)	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)	





Surgical complications are an unforeseen event that challenges multiple clinicians with consequences that “ripple” across care settings.

These ripples inevitably cause further disruption, impacting quality and cost of care. Today’s uncertain care environment has made protecting against complication a high priority.

The “ripple effect” of surgical complications often encourages clinicians to favor low touch care, including solutions that promote:

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

Protecting against SSIs. Protecting against more.

Surgical site infections (SSIs)

affect about **158,669** patients each year

cost the healthcare system **$3.3 billion** per year[1]

21.8%

of Hospital Acquired Infections (HAIs) are SSIs[2]

SSIs increase average length of hospital stay by **9.58 days** at an additional cost of **$38,656**[3]

5x Readmission is necessary 5x more often[4]

Complications in cardiovascular surgery

up to **16%** SSI rate following cardiac surgery[5]

$37,513

Increase in mean cost for cardiovascular surgery hospitalization with SSI[6]

up to **30%**

SSI rate following **vascular groin incisions**[7-11]

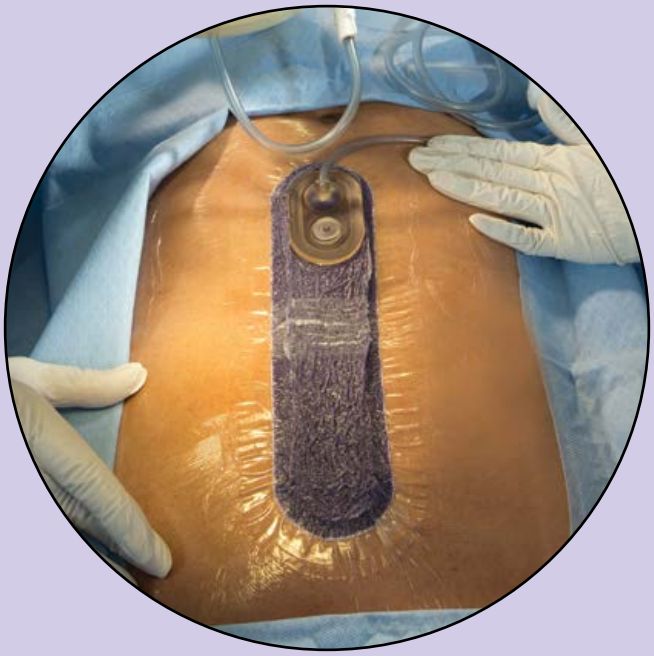
$11,973

Mean incremental cost to treat surgical site complications following **open lower extremity vascular surgery**[12]

3M™ Prevena™ Incision Management System is uniquely designed to manage and protect surgical incisions by:

Helping to hold incision edges together

Reducing edema



Acting as a barrier to external contamination

Delivering continuous -125mmHg up to 7 days

Decreasing lateral tension of sutured/ stapled incisions*,[13]

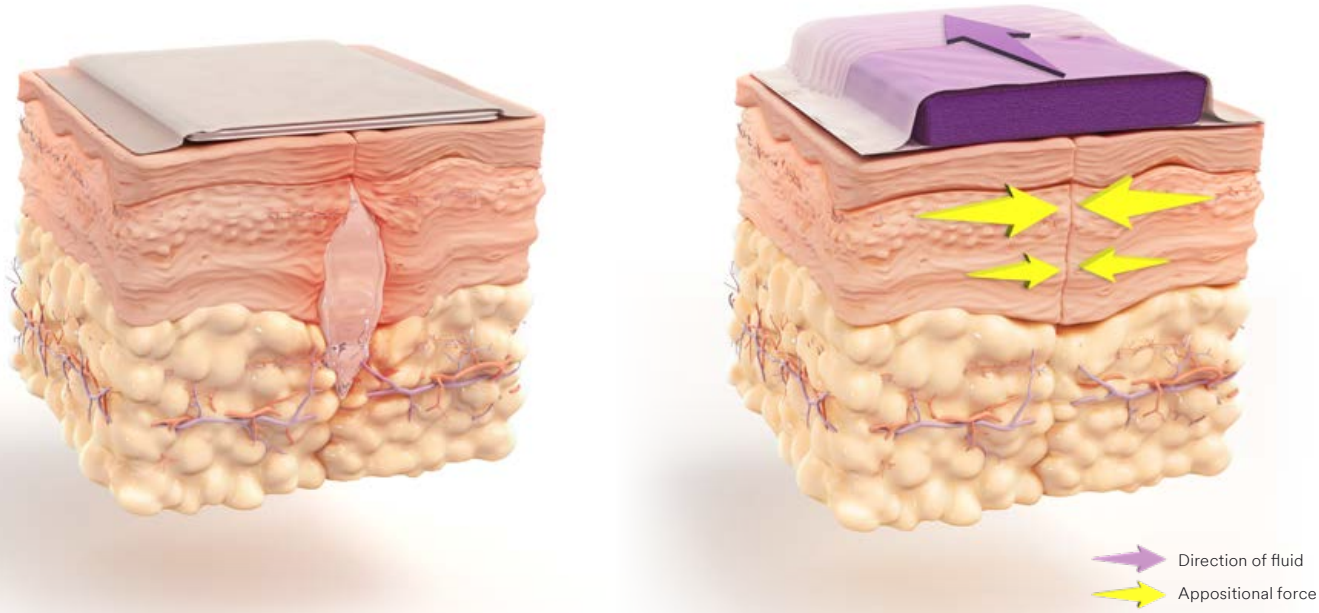
Removing fluids and infectious materials

*In computer and bench models

3M™ Prevena™ Therapy utilizes reticulated open cell foam technology and -125mmHg pressure

Passive Therapy

3M™ Prevena™ Therapy



Under -125mmHg of negative pressure, the Reticulated Open Cell Foam dressing collapses to it's geometric center. This brings the incision edges together, reduces lateral tension, and also allows for improved fluid management.[13-15]

- Contours in 3M™ Prevena™ Dressing allow for even distribution of negative pressure
- Adhesive film creates a barrier to external contaminants
- Designed to conform to articulating joints to allow movement
- Skin interface layer contains 0.019% ionic silver, which reduces bacterial colonization in the fabric
- Multiple sizes and configurations
- Prevena 125 Therapy Unit and Prevena Dressings are shower friendly*

*See Prevena Therapy Patient and Clinician Guides for additional details

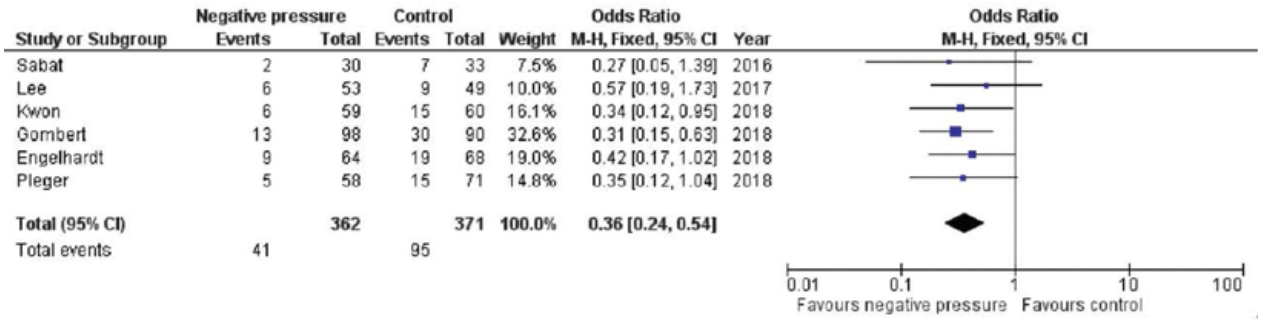
Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery[16]

Prophylactic NPWT confers 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.

NPWT should be considered as a prophylactic measure in patients who have risk factors for developing surgical site complications, such as diabetes mellitus, obesity, or revision surgery.

A review of six RCT studies, all of which compared 3M™ Prevena™ Therapy vs standard of care dressings, with a total of 733 groin wounds, resulted in:

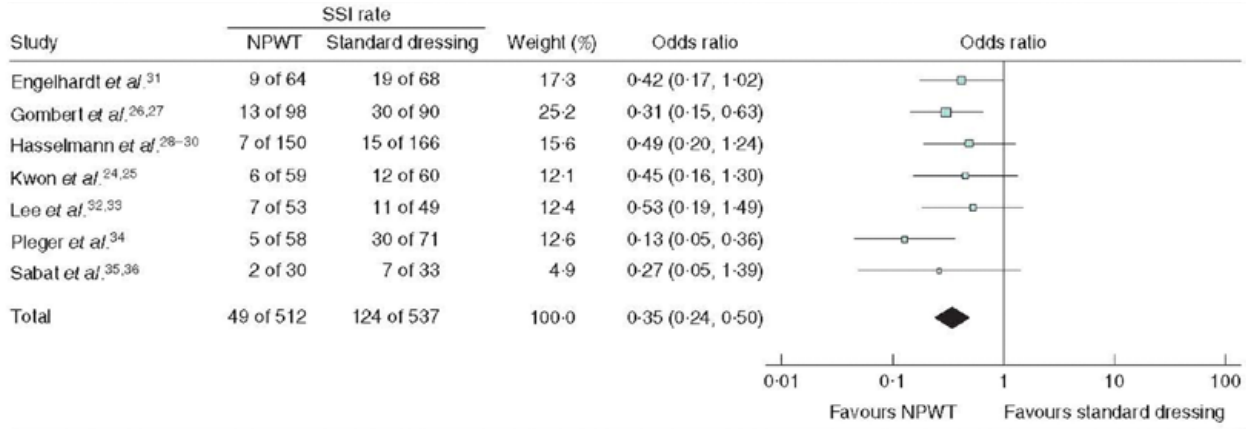
- Patients with Prevena Therapy had a lower risk of developing SSIs by 79% (41 events with Prevena Therapy and 95 events with control) (OR, 0.36; 95% CI, 0.24-0.54)
- Prevena Therapy patients had a reduced length of hospital stay (weighted mean difference,-2.14; 95% CI, -3.78 to 0.49)
- Patients with Prevena Therapy had a lower risk of revision surgery (OR, 0.44; 95% CI, 0.22-0.88)



Meta-analysis of negative pressure wound therapy of closed groin incisions in arterial surgery[17]

A meta-analysis review of 7 RCTs, 6 of which compared Prevena Therapy and standard of care dressings, with a total of 1,049 incisions, resulted in:

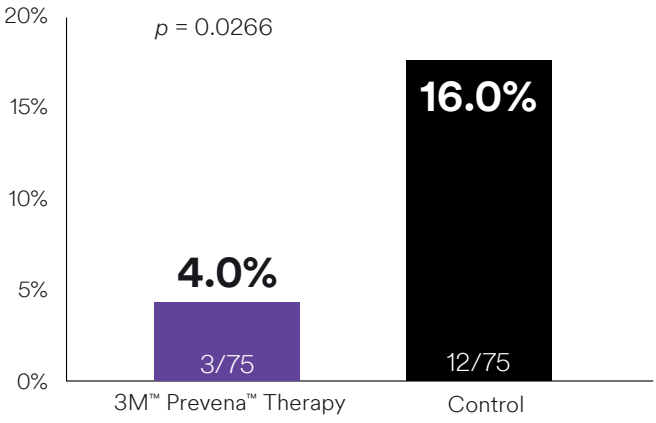
- A reduced incidence of SSIs in the Closed Incision Negative Pressure Therapy (ciNPT) group of 9.6% compared with the standard dressing group of 23.1% (OR, 95% CI 0.24 to 0.50)
- In a subgroup analysis of 3 of the studies comprising lower limb revascularization procedures alone, ciNPT showed a reduction of SSIs (OR, 0.37; 0.22-0.63)



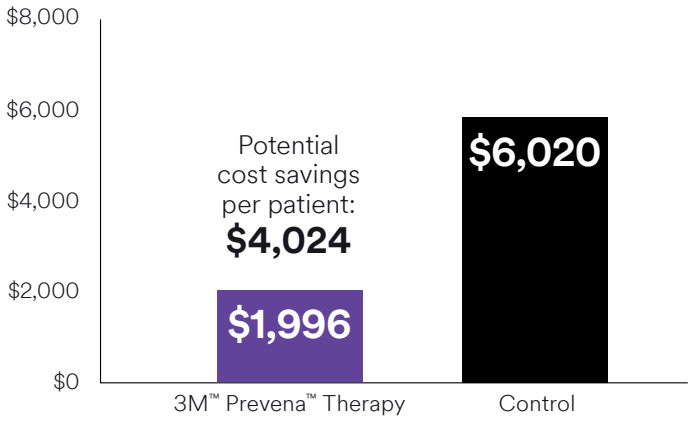
Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy[18]

- A prospective, single center clinical trial evaluated the use of 3M™ Prevena™ Therapy compared to standard post-operative dressings (Control) for the prevention of wound infection within 90 days after median sternotomy procedures in 150 consecutive obese (BMI ≥ 30) patients.
- **Patients treated with Prevena Therapy developed fewer wound infections** (3/75 [4%] vs 12/75 [16%], *p*=0.0266) than patients treated with standard post-operative dressings.
- Wound infections with Gram-positive skin flora were found in only 1 patient in the Prevena Therapy group compared with 10 patients in the control group (*p*=0.0090).
- A hypothetical cost model applied to the clinical results of this study shows a **potential cost savings per patient of $4,024 with the use of Prevena Therapy**.

Infection Rate



Total Cost Per Patient



Economic Model

Post-sternotomy Hypothetical Economic Model	3M™ Prevena™ Therapy (n = 75)	Control (n = 75)
Number of Infections (a)	3	12
Percent of Infections	4.0%	16.0%
Cost per Infection[6] (b)	$37,513	$37,513
Cost of Infection Per Patient (a*b)/n)	$1,501	$6,002
Cost of Therapy Per Patient†	$495	$18
Total Cost Per Patient	**$1,996**	**$6,020**

†3M estimate based on price of 3M™ Prevena™ Peel and Place System Kit and Control therapy (gauze) changed once a day at $18 a week.

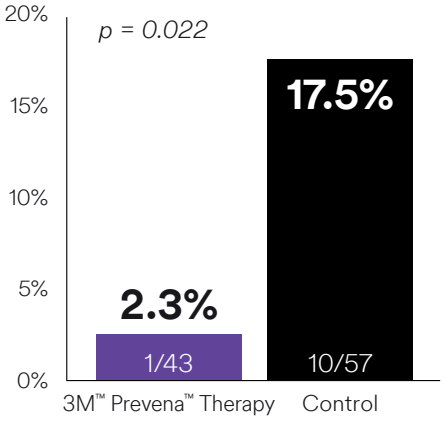
The hypothetical economic model uses select study data to provide an illustration of estimates of costs for use of Prevena Therapy or standard post-operative dressings (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results.

The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

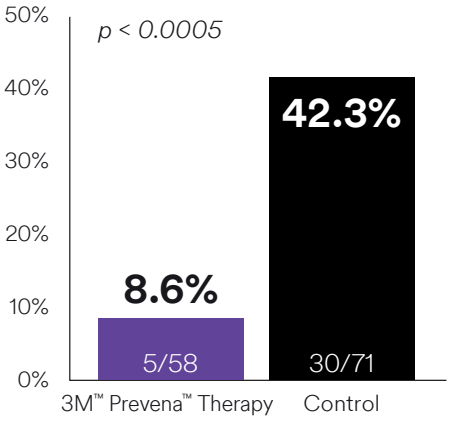
Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomized single-institution study[19]

- The aim of this prospective, randomized, single-institution study was to investigate the effectiveness of 3M™ Prevena™ Therapy compared to conventional adhesive dressing (Control) on groin incisions after vascular surgery.
- The Prevena Therapy group had 43 patients and 58 groin incisions and the control group consisted of 57 patients and 71 groin incisions.
- Wound evaluation based on the Szilagyi classification (Grade I, II, and III) took place postoperatively on days 5–7 and 30.
- In this study, patients with cutaneous wound dehiscence, skin necrosis and single local infection signs were classified as grade I. Wound dehiscence in the subcutaneous layer, hematoma, lymphatic fistula, lymphocele, seroma, single local infection signs and systemic infection parameters were classified as grade II. All classical local infection signs (pain, swelling, redness and hyperaemia, warmth, dysfunction), systemic infection parameters and arterial graft infections were classified as grade III.
- **Prevena Therapy significantly reduced the incidence of local infection** compared to the conventional dressing (1/43 [2.3%] vs 10/57 [17.5%], respectively; p=0.022).
- Compared to the control group, **the Prevena Therapy group showed a significant reduction in wound complications** after both evaluation periods (5/58 [8.62%] vs 30/71 [42.3%], p<0.0005).
- **Prevena Therapy showed a significant reduction in revision surgeries** (1/58 [1.7%] vs 10/71 [14.1%], respectively; p=0.022) until 30 days postoperatively compared to the control group.
- A hypothetical cost model applied to the clinical results of this study shows a **potential cost savings per patient of $2,694 with the use of Prevena Therapy.**

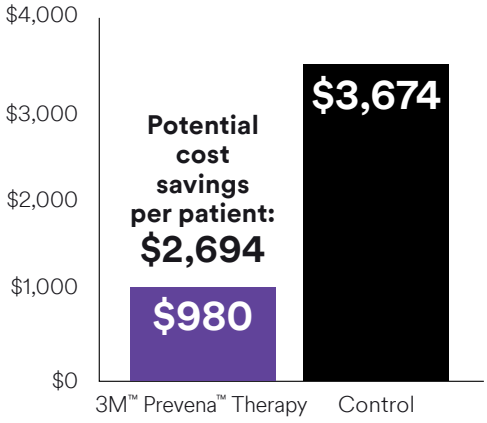
Local Infection Rate



Wound Complications At Both Evaluation Periods



Total Per Patient Cost



Vascular Groin Hypothetical Economic Model	3M™ Prevena™ Therapy	Control
Number of Patients (n)	43	57
Number of Local Infections (a)	1	10
Percent of Local Infections	2.3%	17.5%
Cost Per Local Infection[6] (b)	$20,842	$20,842
Cost of Local Infection Per Patient (a*b)/n)	$485	$3,656
Cost of Therapy Per Patient[†]	$495	$18
Total Cost Per Patient	**$980**	**$3,674**

[†]3M estimate based on price of 3M™ Prevena™ Peel and Place System Kit and Control therapy (gauze) changed once a day at $18 a week.

The hypothetical economic model uses select study data to provide an illustration of estimates of costs for use of Prevena Therapy or standard post-operative dressings (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results.

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Risk factors for surgical site complications are dependent on many factors including both patient-related and surgical procedure factors

Table 1. General risk factors for SSI[adapted from 20-25]

Category	Patient-related risk factors	Procedure-related risk factors
Major risk factors	• BMI ≥40kg/m2 or ≤18kg/m2 • Uncontrolled insulin dependent diabetes mellitus • Dialysis	• Extended duration of surgery* • Emergency surgery • Hypothermia
Moderate risk factors	• ASA Physical Status >II • BMI 30–39.9kg/m2 • Diabetes mellitus • Chronic obstructive pulmonary disease ≥GOLD class 2 • Renal insufficiency/chronic kidney disease • Immunosuppression • Steroids for a chronic condition • Chemotherapy • Pre-existing infection at a body site remote from operative site • Serum albumin <2.5g/dl • Smoking (current)	• Anaemia/blood transfusion • High wound tension after closure • Dual antiplatelet treatment • Suboptimal timing or omission of prophylactic antibiotics • Tissue trauma/large area of dissection/large area of undermining
Minor risk factors	• BMI 25–29.9kg/m2 • Extended pre-operative hospitalization or residency in a nursing home • Peripheral vascular disease • Congestive cardiac failure with left ventricular ejection fraction <30%	• Failure to obliterate dead space • Location of incision • Previous surgery • Surgical drains

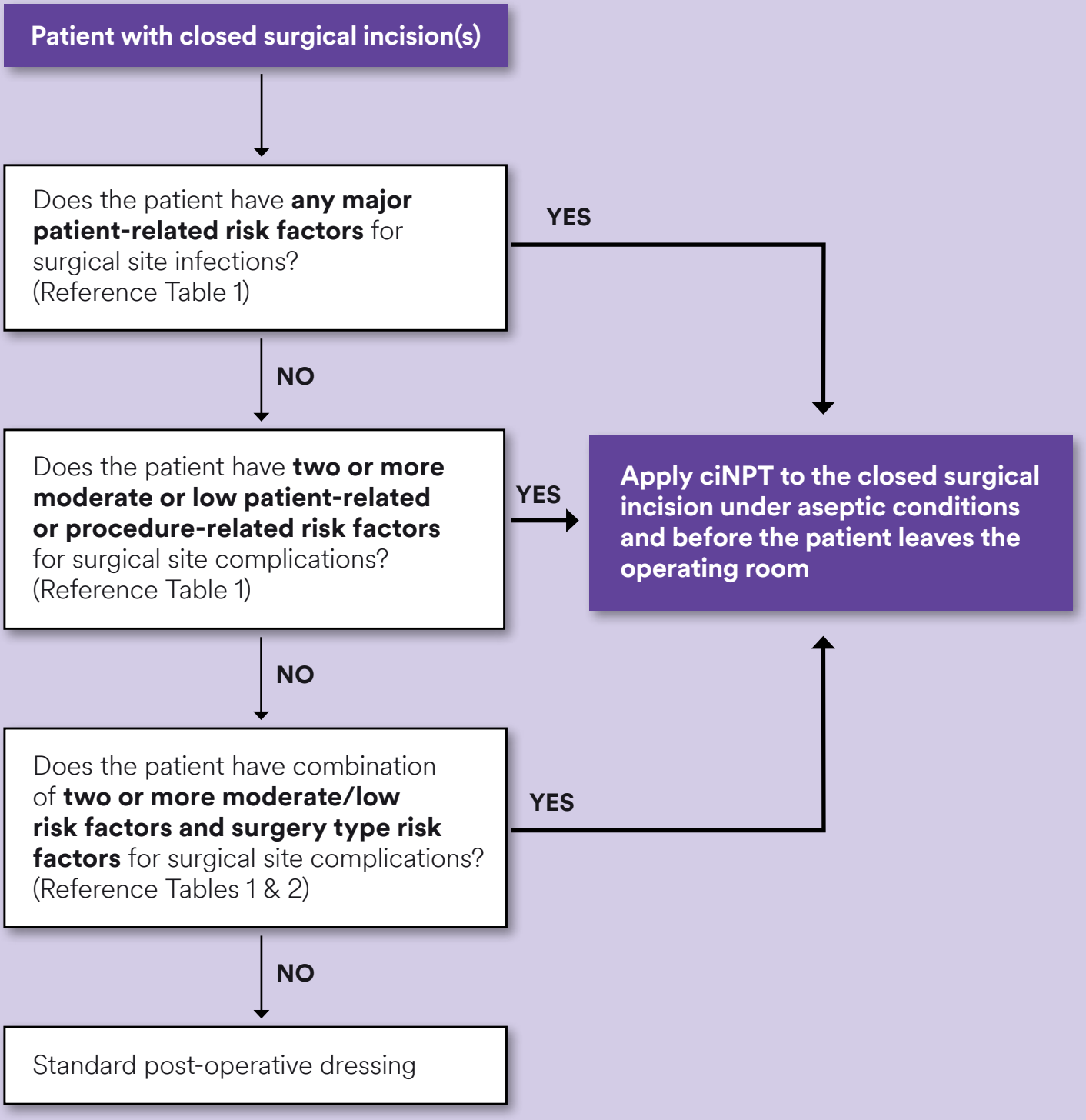
*Defined as >T (hours) which is dependent on the type of surgical procedure, and is the 75th centile of duration of surgery for a particular procedure, eg, coronary artery bypass graft has a T of 5 hours and caesarean section has a T of 1 hour[26]

Table 2. Example of additional risk factors for surgical site complications by selected surgery type

Type of Surgery	Additional risk factors	
Cardiothoracic	• **Bilateral internal mammary artery harvesting** • **Chest wall radiotherapy** • **Left ventricular assist device (LVAD)**	• **Transplant** • **Cardiopulmonary bypass time extended** • **Delayed closure**
Vascular	• **Groin incision**	
Abdominal	• Perforated viscus • Ostomy formation/closure	• Previous radiotherapy to surgical site • Multiple incisions
Breast/plastic	• Corony artery disease • Bleeding risk	• Breast Reconstruction Risk Assessment (BRA) score†
Obstetric	• Multiple (>3) caesarean sections • Anticoagulants • Operative blood loss >1.5l	• Pre-eclampsia • Chorioamnionitis
Orthopedic	• Implant/prosthesis • Rheumatoid arthritis	• Nasal carriage of Staphylococcus aureus

†The BRA Score calculates risk (as %) of a range of complications, eg, SSI, seroma, dehiscence, flap loss, explantation and reoperation, based on factors including reconstructive modality, BMI, age, ASA Physical Status class, bleeding disorder, history of percutaneous cardiac intervention or cardiac surgery (www.brascore.org)

The World Union of Wound Healing Societies (WUWHS) consensus panel proposed the following clinical guideline for the use of Closed Incision Negative Pressure Therapy (CINPT)



*Adapted from: 27-29

There are 70+ closed incision negative pressure therapy journal publications using 3M products. The following publications are specific to cardiothoracic & vascular surgery

Citation	Wound/Surgery Type	Level of Clinical Evidence*
Engelhardt M, Rashad NA, Willy C, Müller C, Bauer C, Debus S, Beck T. Closed-incision negative pressure therapy to reduce groin wound infections in vascular surgery: a randomised controlled trial. *Int Wound J*. 2018;doi: 10.1111/iwj.12848	Groin wounds	1b ●
Gombert A, Babilon M, Barbati ME, Keskei A, et al. Closed incision negative pressure therapy reduces surgical site infections in vascular surgery: a prospective randomised trial (AIMS Trial). *Eur J Vasc Endovasc Surg*. 2018;doi:10.1016/j.ejvs.2018.05.018	Groin wounds	1b ●
Kwon J, Staley C, McCullough M, Goss, S, et al. A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications. *J Vasc Surg*. 2018;1-9	Groin wounds	1b ●
Lee AJ, Sheppard CE, Kent WD, Mewhort H, Sikdar KC, Fedak PW. Safety and efficacy of prophylactic negative pressure wound therapy following open saphenous vein harvest in cardiac surgery: a feasibility study. *Interact Cardiovasc Thorac Surg*. 2017;24(3):324-328.	Open saphenous vein harvest in cardiac surgery	1b ●
Lee K, Murphy PB, Ingves MV, Duncan A, DeRose G, Dubois L, Forbes TL, Power A. Randomized clinical trial of negative pressure wound therapy for high-risk groin wounds in lower extremity revascularization. *J Vasc Surg*. 2017;66(6):1814-19.	Groin wounds	1b ●
Pleger SP, Nink N, Elzien M, Kunold A, Koshty A, Böning A. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study. *Int Wound J*. 2018;15(1):75–83. doi: 10.1111/iwj.12836.	Groin incisions	1b ●
Colli A. First Experience With a New Negative Pressure Incision Management System on Surgical Incisions After Cardiac Surgery in High Risk Patients. *J Cardiothoracic Surg*. 2011;6(1):160.	Sternotomy	2 ●
Weir G. The use of a surgical incision management system on vascular surgery incisions: a pilot study. *Int Wound J*. 2014;11 Suppl 1:10-2.	Vascular bypass	2 ●
Grauhan O, et al. Effect of surgical incision management on wound infections in a poststernotomy patient population. *Int Wound J*. 2014;11 Suppl 1:6-9.	Sternotomy	2b ●
Grauhan O, et al. Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy. *J Thorac Cardiovasc Surg*. 2013;145(5):1387-92.	Sternotomy	2b ●
Matatov T, et al. Experience with a new negative pressure incision management system in prevention of groin wound infection in vascular surgery patients. *J Vasc Surg*. 2013;57(3):791-5.	Vascular bypass	3 ●
Santarpino G, Gazdag L, Sirch J, Vogt F, Ledwon M, Fischlein T, Pfeiffer S. A Retrospective Study to Evaluate Use of Negative Pressure Wound Therapy in Patients Undergoing Bilateral Internal Thoracic Artery Grafting. *Ostomy Wound Manage*. 2015 ec;61(12):26-30.	Thoracic artery grafting	3 ●
Simon K, et al. [Use of Negative Pressure Wound Therapy on Surgical Incisions (Prevena™) after Surgery of Pectus Deformities Reduces Wound Complications.]. *Zentralblatt fur Chirurgie*. 2014. [German language]	Sternotomy	3 ●
Atkins BZ, Tetterton JK, Petersen RP, et al. Does Negative Pressure Wound Therapy Have a Role in Preventing Poststernotomy Wound Complications? *Surg Innov*. 2009;16(2):140-6.	Sternotomy	4 ●
Atkins BZ, et al. Laser Doppler flowmetry assessment of peristernal perfusion after cardiac surgery: beneficial effect of negative pressure therapy. *Int Wound J*. 2011;8(1):56-62.	Sternotomy	4 ●
Reddy VS. Use of Closed Incision Management with Negative Pressure Therapy for Complex Cardiac Patients. *Cureus*. 2016;8(2):e506.	Sternotomy	4 ●
Simon K, et al. [Use of Negative Pressure Wound Therapy on Surgical Incisions (Prevena™) after Surgery of Pectus Deformities Reduces Wound Complications.]. *Zentralblatt fur Chirurgie*. 2014. [German language]	Sternotomy	3 ●
Chopra K, Tadisina KK, Singh DP. The 'French Fry' VAC Technique: Hybridization of Traditional Open Wound NPWT with Closed Incision NPWT. *Int Wound J*. 2016;13(2):216-9.	Massive localized lymphoedema	5 ●

Citation	Wound/Surgery Type	Level of Clinical Evidence*
Dohmen PM, et al. Can post-sternotomy mediastinitis be prevented by a closed incision management system? *GMS Hyg Infect Control.* 2014;9(3):Doc19.	Sternotomy	5 ●
Dohmen PM, et al. Use of incisional negative pressure wound therapy on closed median sternal incisions after cardiothoracic surgery: clinical evidence and consensus recommendations. *Med Sci Monit.* 2014;20:1814-25.	Sternotomy	5 ●
Haghshenasskashani A, Varcoe RL. A New Negative Pressure Dressing (Prevena) to Prevent Wound Complications Following Lower Limb Distal Arterial Bypass. *Br J Diabetes Vasc Dis.* 2011;11(1):21-4.	Vascular bypass	5 ●
Wu RT, Sumpio BJ, Miller S, Sumpio BE. Use of closed-incision negative pressure therapy: cardiothoracic and vascular surgery. *Plast Reconstr Surg.* 2019;143:31S.	Sternotomy	5 ●

● Available on request.

***Level of Clinical Evidence Rating: 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."

3M™ Prevena™ Therapy resources

- Live Clinical Training & Product Support (25,000 Professionals Trained Annually)
- Clinical Services & Reimbursement Hotlines
- Free Product Evaluation Program
- 24/7 Centralized, On Demand Clinical & Technical Support
- 3M™ Prevena™ Therapy Financial Protection

Ordering information

Item#	Description	Unit of Measure (UOM)
PRE1001US	3M™ Prevena™ Peel and Place Incision Management System – 20cm	Each
PRE1055US	3M™ Prevena™ Peel and Place Dressing – 20cm	Case of 5
PRE1101US	3M™ Prevena™ Peel and Place Incision Management System – 13cm	Each
PRE1155US	3M™ Prevena™ Peel and Place Dressing – 13cm	Case of 5
PRE3201US	3M™ Prevena™ Plus Peel and Place Incision Management System – 35cm	Each
PRE3255US	3M™ Prevena™ Peel and Place Dressing – 35cm	Case of 5
PRE4001US	3M™ Prevena™ Plus Customizable Incision Management System	Each
PRE4055US	3M™ Prevena™ Plus Customizable Dressing	Case of 5
PRE1121US	3M™ Prevena™ Duo Incision Management System with Peel and Place Dressing - 13cm/13cm	Each
PRE3321US	3M™ Prevena™ Plus Duo Incision Management System with Peel and Place Dressing - 13cm/20cm	Each
PRE3021US	3M™ Prevena™ Plus Duo Incision Management System with Peel and Place Dressing - 20cm/20cm	Each
PRE4000US	3M™ Prevena™ Plus 125 Therapy Unit	Each
PRE1095	3M™ Prevena™ 45ml Canister	Case of 5
PRE4095	3M™ Prevena™ Plus 150ml Canister	Case of 5
PRE9090	3M™ Prevena™ Therapy V.A.C.® Connector	Case of 10

References:

1. Zimlichman E, Henderson D, Tamir O, et al. Health care–associated infections. A meta-analysis of costs and financial impact on the US health care system. *JAMA Intern Med*. 2013;173(22):2039-2046. doi:10.1001/jamainternmed.2013.9763.
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Today, the SARS-CoV-2 pandemic has made protecting against risk a priority

Moving forward, this means that:

Elective surgical procedures, products and protocols that help to protect against risk should be utilized when appropriate

Protecting patients, physicians, staff and hospitals from unnecessary risk should be a priority when making decisions in care

The ripple effect of postoperative complications can increase the need for different types of "high-touch care," exposing stakeholders to a greater number of person-to-person exposures and challenging hospitals with an increased need to free up capacity in hospital and intensive care unit (ICU) beds[2]

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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.

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