

Protecting. Beyond.

Cardiovascular surgery and more.

prevena 125

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 favour 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

Help protect patients at risk for developing post-operative complications.





Increase in mean cost for cardiovascular surgery hospitalization with SSI⁶



\$15,123*5 Mean incremental cost to treat surgical site complications following open lower

extremity vascular surgery¹²

*Original costing in USD. Exchange rate from USD to CAD correct of 24 Aug 2021.

How 3M[™] Prevena[™] Therapy can help.

Indications for use:

The 3M[™] Prevena[™] Incision Management System is intended to manage the environment of closed surgical incisions and surround intact skin in patients at risk for developing post-operative complications, such as infection, by maintaining a closed environment via the application of a negative pressure wound therapy system to the incision. The 3M[™] Prevena[™] Incision Dressing skin interface layer with silver reduces microbial colonization in the fabric.



Supported by clinical evidence.*

A systematic literature review and associated meta-analysis were used to support the safety and effectiveness of 3M[™] 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 3M[™] 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

3M[™] Prevena[™] Therapy demonstrated the greatest benefit in reducing SSIs in high risk patients.

Forest Plot of Meta-Analysis on Surgical Site Infection

	Tre	eatme	nt	C	Contro						
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)		⊢_∎ 1		
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)		·∎1		
Total		1264			4923		0.37 (0.27, 0.52)		H a h I		
										1	
								0.01	0.1 1	10	100

Favours [experimental] Favours [control]

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



Acting as a barrier to external contamination*

*3M Data on File. †In a canister. ‡In computer and bench models.

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



3M[™] Prevena[™] Therapy

Under -125 mmHg of negative pressure, the Reticulated Open Cell Foam dressing collapses to its geometric center. This helps bring the incision edges together, reduces lateral tension, and also allows for improved fluid management.^{6–8}

• Contours in 3M[™] Prevena[™] Dressing allow for even distribution of negative pressure

Passive Therapy

- 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
- 3M[™] Prevena[™] 125 Therapy Unit and 3M[™] Prevena[™] Dressings are shower friendly*

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 3M[™] Prevena[™] Therapy had a lower risk of developing SSIs by 79% (41 events with 3M[™] Prevena[™] Therapy and 95 events with control) (OR, 0.36; 95% CI, 0.24-0.54)
- 3M[™] Prevena[™] Therapy patients had a reduced length of hospital stay (weighted mean difference,-2.14; 95% CI, -3.78 to 0.49)
- Patients with 3M[™] Prevena[™] Therapy had a lower risk of revision surgery (OR, 0.44; 95% CI, 0.22-0.88)

	Negative pre	ssure	Contr	ol		Odds Ratio		Odd	s Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl	Year	M-H, FD	red, 95% Cl	
Sabat	2	30	7	33	7.5%	0.27 [0.05, 1.39]	2016		+	
Lee	6	53	9	49	10.0%	0.57 [0.19, 1.73]	2017			
Kwon	6	59	15	60	16.1%	0.34 [0.12, 0.95]	2018		-	
Gombert	13	98	30	90	32.6%	0.31 [0.15, 0.63]	2018			
Engelhardt	9	64	19	68	19.0%	0.42 [0.17, 1.02]	2018		-	
Pleger	5	58	15	71	14.8%	0.35 [0.12, 1.04]	2018			
Total (95% CI)		362	100	371	100.0%	0.36 [0.24, 0.54]		+	-	
Total events	-41		95					1		
								0.01 0.1 Favours negative pressure	10 Favours control	100

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 3M[™] 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)

		SSI rate						
Study	NPWT Standard dressing		Weight (%)	Odds ratio	Odds ralio			
Engelhardl et al.31	9 of 64	19 of 68	17-3	0.42 (0.17, 1.02)	-0-			
Gombert et al.26,27	13 of 98	30 of 90	25.2	0.31 (0.15, 0.63)	-0-	- 1		
Hasselmann et al. 28-30	7 of 150	15 of 166	15.6	0.49 (0.20, 1.24)				
Kwon et al.24,25	6 of 59	12 of 60	12-1	0-45 (0-16, 1-30)				
Lee et al. 32,33	7 of 53	11 of 49	12.4	0.53 (0.19, 1.49)				
Pleger et al.34	5 of 58	30 of 71	12.6	0-13 (0-05, 0-36)				
Sabat et al. 35,36	2 of 30	7 of 33	4.9	0.27 (0.05, 1.39)	G			
Total	49 of 512	124 of 537	100.0	0-35 (0-24, 0-50)				
				-1	-1		1	1.
				0.01	0.1	1	10	100
					Favours NPWT	Favours	standard dr	essing

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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 3M[™] 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 3M[™] 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 3M[™] Prevena[™] Therapy.





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

†KCl estimate based on price of 3M[™] Prevena[™] Peel and Place Dressing System 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 3M[™] 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 3M[™] 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.

- 3M[™] 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 3M[™] 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).
- 3M[™] 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 3M[™] Prevena[™] Therapy.**

Total Per Patient Cost



Wound Complications At

Both Evaluation Periods

Local Infection Rate

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

†KCl estimate based on price of 3M[™] Prevena[™] Peel and Place[™] Dressing System 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 3M 3M[®] 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.

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 viscusOstomy formation/closure	Previous radiotherapy to surgical siteMultiple incisions
Breast/plastic	Corony artery diseaseBleeding risk	 Breast Reconstruction Risk Assessment (BRA) score[†]
Obstetric	 Multiple (>3) caesarean sections Anticoagulants Operative blood loss >1.51 	Pre-eclampsiaChorioamnionitis
Orthopedic	Implant/prosthesisRheumatoid 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).



There are 70+ closed incision negative pressure therapy journal publications using 3M KCI products. The following publications are specific to cardiothoracic and 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. <i>Int Wound J.</i> 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). <i>Eur J Vasc Endovasc Surg.</i> 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. <i>J Vasc Surg.</i> 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. <i>Interact Cardiovasc Thorac Surg.</i> 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. <i>J Vasc Surg.</i> 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. <i>Int Wound J.</i> 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. <i>J Cardiothoracic Surg</i> . 2011;6(1):160.	Sternotomy	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.	Vascular bypass	2	
Grauhan O, et al. Effect of surgical incision management on wound infections in a poststernotomy patient population. <i>Int Wound J.</i> 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. <i>J Vasc Surg.</i> 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. <i>Ostomy Wound Manage</i> . 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.]. <i>Zentralblatt fur Chirurgie</i> . 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? <i>Surg Innov.</i> 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. <i>Int Wound J.</i> 2011;8(1):56-62.	Sternotomy	4	
Reddy VS. Use of Closed Incision Management with Negative Pressure Therapy for Complex Cardiac Patients. <i>Cureus</i> . 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.]. <i>Zentralblatt fur Chirurgie</i> . 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 •	
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. <i>Med Sci Monit.</i> 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. <i>Br J Diabetes Vasc Dis</i> . 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. <i>Plast Reconstr Surg.</i> 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."

Ordering Information

ltem#	Description	Unit of Measure (UOM)
PRE1101	3M™ Prevena™ Peel and Place System Kit – 13 cm	Each
PRE1155	3M™ Prevena™ Peel and Place Dressing – 13 cm	Case of 5
PRE1001	3M™ Prevena™ Peel and Place System Kit – 20 cm	Each
PRE1055	3M™ Prevena™ Peel and Place Dressing – 20 cm	Case of 5
PRE3201	3M™ Prevena™ Peel and Place System Kit – 35 cm	Each
PRE3255	3M™ Prevena™ Peel and Place Dressing – 35 cm	Case of 5
PRE4001CA	3M™ Prevena™ Plus Customizable System Kit	Each
PRE4055	3M™ Prevena™ Plus Customizable Dressing	Case of 5
PRE1121	3M [™] Prevena [™] Duo Incision Management Sustem with Peel and Place Dressing – 13 cm / 13 cm	Each
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
PRE4010	3M™ Prevena™ Plus 125 Therapy Unit – 14 day	Each

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