
3M
Prevena™
Incision Therapy
Protecting.
Beyond.
Plastic surgery
and more.
PREVENA PLUS™ 125
PREVENA PLUS

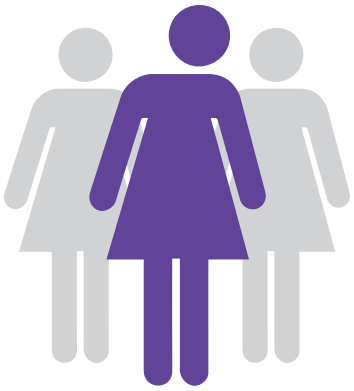
Surgical complications challenge multiple clinicians with consequences that “ripple” across care settings.

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

Complications in Plastic Surgery



Postmastectomy breast reconstruction is on the rise, and more patients are requesting and qualifying for immediate reconstruction, which has a higher complication rate. **The risks of complications,** such as SSIs and flap necrosis, in immediate breast reconstruction can be **as high as 20–30%.**[1–3]

Complications in breast reconstruction surgery have a mean cost of

$12,995*[4]

33%

overall complication rate for breast reconstruction.[5]

19%

of patients need reoperations.[5]

*Based on mean cost of $10,402. Exchange rate from USD to CAD correct of 01 APR 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.*

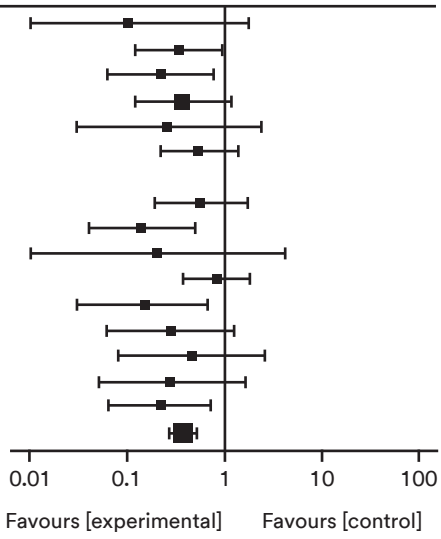
A systematic literature review and associated meta-analysis were used to support the safety and effectiveness of 3M™ Prevena™ Therapy over closed incisions in reducing the incidence of surgical site infections (SSIs) and seromas versus conventional wound dressings.

- 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.

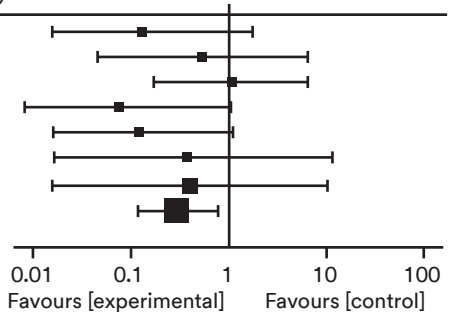
Forest Plot of Meta-Analysis on Surgical Site Infection

	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	(22.7))	0.14 (0.02, 1.32)
Gunatiliake RP 2017	1	39	(2.6)	2	43	(4.7)	0.54 (0.05, 6.19)
NCT01341444	3	28	(10.7)	3	30	(10.0)	1.08 (0.20, 5.85)
Pachowsky M 2012	4	9	(44.4)	9	10	(90.0)	0.09 (0.01, 1.03)
Pauser J 2014	4	11	(36.4)	8	10	(80.0)	0.14 (0.02, 1.03)
Pleger SP 2017	0	58	(0.0)a	1	71	(1.4)	0.40 (0.02, 10.05)
Refern RE 2017	0	196	(0.0)	2	400	(0.5)	0.41 (0.02, 8.49)
Total		366			586		0.31 (0.13, 0.75)

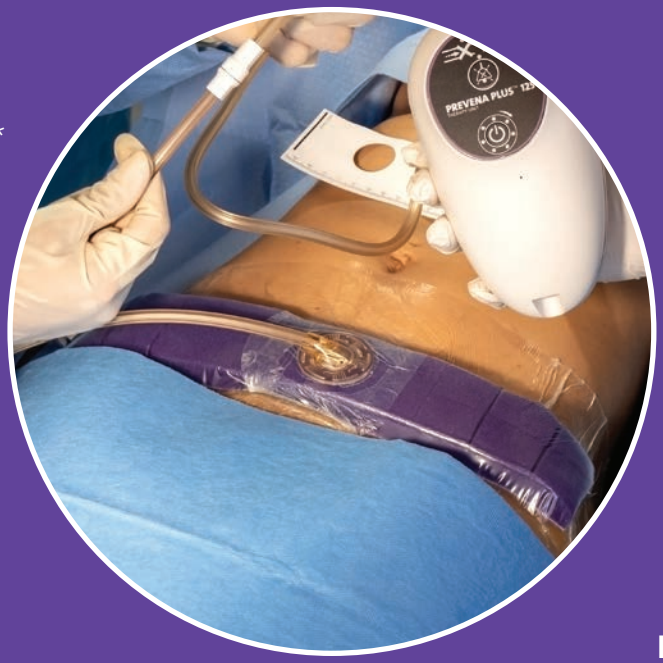


*3M Data on File.

3M™ Prevena™ Therapy manages and helps protect surgical incisions utilizing 3M™ Prevena™ Dressings by:

Removing fluids and infectious materials*†

Delivering continuous -125 mmHg up to 7 days*



Reducing edema*

Decreasing lateral tension of sutured/ stapled incisions[6]*‡

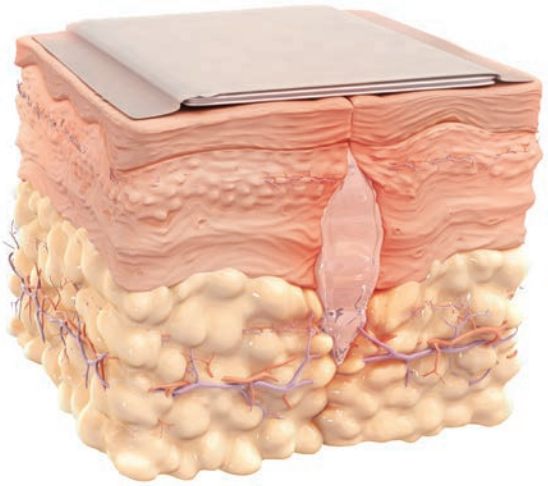
Helping to hold incision edges together*

Acting as a barrier to external contamination*

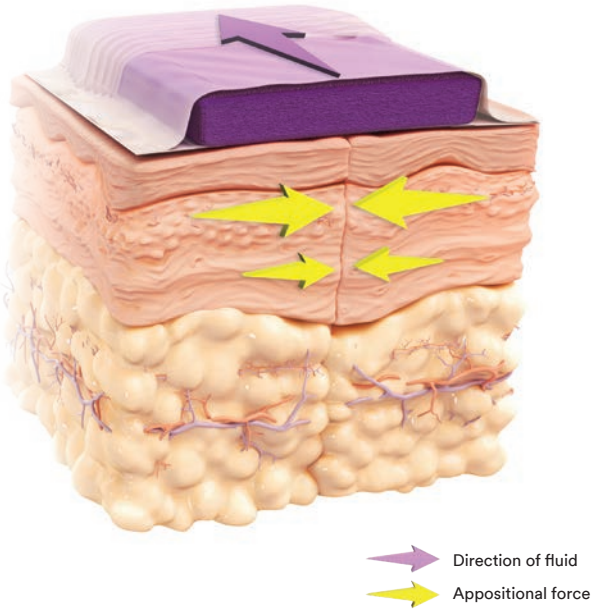
*3M Data on File.
†In a canister.
‡In computer and bench models.

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

Passive Therapy



3M™ Prevena™ Therapy

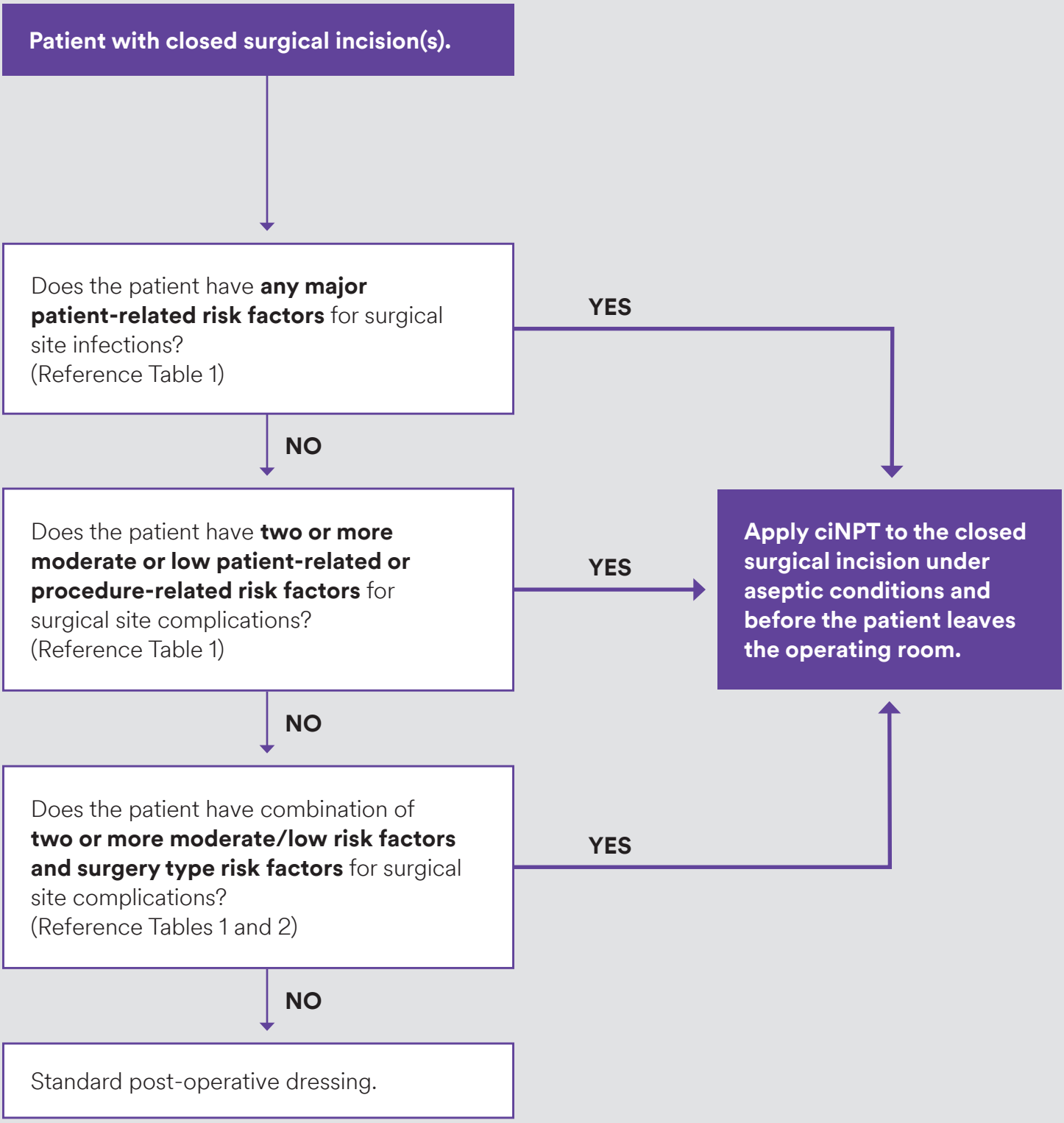


Under -125 mmHg of negative pressure, the Reticulated Open Cell Foam dressing collapses to its geometric centre. This helps bring the incision edges together, reduces lateral tension, and also allows for improved fluid management.[6–8]

- Contours in 3M™ Prevena™ Dressing allow for even distribution of negative pressure
- 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*

*See 3M™ Prevena™ Therapy Patient and Clinician Guides for additional details.

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: 19–21.

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.[12–17]

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, e.g., coronary artery bypass graft has a T of 5 hours and caesarean section has a T of 1 hour.[18]

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).

3M™ Prevena™ Therapy has been shown to aid in the reduction of post-surgical complications and improve scar outcomes in high-risk oncological breast surgery patients.[9]

In a single-center, prospective, comparative study, patients treated with closed incision negative pressure therapy (ciNPT, 3M™ Prevena™ Therapy) (17 patients/25 surgeries) had significantly fewer complications than patients treated with the standard of care (SOC) (SOC, 20 patients/22 breasts), even though the 3M™ Prevena™ Therapy group had a higher prevalence of high-risk factors.

91%* reduction
in overall complication rate (1/25) vs. SOC (10/22).

88%* decrease
in skin necrosis (1/25) vs. SOC (7/22).

3M™ Prevena™ Therapy was shown to be well-tolerated, adaptable and reliable in oncological breast surgery.

Complications at 30-day follow-up.†

4% 3M™ Prevena™ Therapy 1/25

45% SOC 10/22

Self-evaluation vs. surgeon evaluation of scars: significant superiority after 3M™ Prevena™ Therapy.

For all tests, the higher the scores, the lower the level of satisfaction. With the exception of the Body Image Scale (BIS), all other scores clearly vouched for a significant superiority of the 3M™ Prevena™ Therapy post-surgery approach.

Outcome of Questionnaires on the Level of Satisfaction

Questionnaire	3M™ Prevena™ Therapy	SOC	P
Body Image Scale (BIS) (max 30)	6 (1–14)	6 (3–14.5)	0.58
Patients Scar Assessment Scale (PSAS) (max 50)	11 (6–18)	20 (14–34)	0.002
Observer Scar Assessment Scale (OSAS) (max 50)	7 (6–13)	24 (17–29)	0.01
Manchester Scare Scale (MSS) (max 18†)	7 (5–12)	12 (19–15)	0.001

*This calculation was derived based on relative patient group incidence rate reported in this study.
†At the 30-day post-surgery follow-up, in the SOC group,10/22 surgeries (45%) were followed by complications (3 had 2 each: 2 seroma and skin necrosis; 1 hematoma and skin necrosis; 8 had a single complication [4 necrosis, 3 seromas, and 1 hematoma]); in the 3M™ Prevena™ Therapy group, only 1/25 (4%) was followed by complications.

3M™ Prevena™ Therapy and Standard of Care (SOC) over breast incisions after immediate reconstruction: a hypothetical cost model and postoperative complication rates.[4]

A hypothetical cost model was applied to clinical outcomes of a previous retrospective study† comparing the use of closed-incision negative-pressure therapy (3M™ Prevena™ Therapy) and standard of care (SOC) over breast incisions after immediate reconstruction. The adjusted complication cost for a mastectomy with reconstruction was a mean of $10,402 and was calculated using a database of inpatient, outpatient, and carrier claims.

Previous retrospective study:† 665 breasts (ciNPT, 331; SOC, 334) and 356 female patients (ciNPT=177, SOC=179) and reported on complication rates at the breast level: 8.5% (28/331) for the 3M™ Prevena™ Therapy breast group versus 15.9% (53/334) for the SOC group (*p*=0.0092).

in the 3M™ Prevena™ Therapy Group

24/177 patients

(13.6%) had a complication.

in the SOC Group

38/179 patients

(21.2%) had a complication.

Based on the adjusted mean complication cost of $10,402, total complication cost for the **3M™ Prevena™ Therapy group was $250,000** vs. **$395,000 for the SOC group** with a per patient cost **savings of $218.00 with 3M™ Prevena™ Therapy.**†

Summary of Postoperative Complication Rates†

	3M™ Prevena™ Therapy n=331 n (%)	SOC n=334 n (%)	P
Any complication	28 (8.5)	53 (15.9)	0.0092
Surgical site infection	7 (2.1)	15 (4.5)	0.0225
Dehiscence	8 (2.4)	18 (5.4)	0.0178
Seroma	6 (1.8)	19 (5.7)	0.0106
Hematoma	5 1.5)	3 (0.9)	0.2737
Expander exposed	3 (0.9)	5 (1.5)	0.3635
Expander removed	3 (0.9)	4 (1.2)	0.0918
Return to OR	8 (2.4)	18 (5.4)	0.0496

Hypothetical Economic Model†

	3M™ Prevena™ Therapy	SOC
Patients	177	179
Percent of complications	13.60%	21.20%
Mean cost per complication	$10,402	$10,402
Total complication cost‡	$250,000	$395,000
Cost of complication per patient§	$1,410.00	$2,210.00
Cost of therapy per patient‖	$600	$18
Total cost per patient¶	$2,010	$2,228
Cost savings per patient	$218	

‡Number of patients × percent of complications × cost per complication.
§Total complication cost/number of patients.
‖KCI estimate based on the price of 3M™ Prevena™ Customizable Dressing and SOC therapy changed once a day at $18 a week.
¶Cost of complication per patient + cost of therapy per patient.

†Adapted from: Gabriel A, Sigalove S, Sigalove N, et al. The impact of closed incision negative pressure therapy on postoperative breast reconstruction outcomes. *Plast Reconstr Surg Glob Open*. 2018;6:e1880.

ciNPT (3M™ Prevena™ Therapy) in ventral hernia repair with concurrent panniculectomy decreased the rate of wound complications in high risk populations.[10]

An 8-year, retrospective cohort study was conducted of 104 patients; 62 treated with 3M™ Prevena™ Therapy and 42 treated with standard sterile dressings/standard of care (SSD/SOC) .

- Ventral hernia repair with concurrent panniculectomy
- 3M™ Prevena™ Therapy (n=62) vs. SOC (n=42)
- 3M™ Prevena™ Therapy cohort was older (p=0.029), had a larger hernia size (p=0.031), higher rate of prior hernia repair (p=0.009), higher rate required mesh use (p=0.013) and higher rate with a component separation (p=0.002)

Summary of Complication Outcomes

	3M™ Prevena™ Therapy	SOC	*P*
n	62	42	
Surgical site occurrences (SSO)	29 (47%)	29 (69%)	0.025
Infection	23 (37%)	16 (38%)	0.918
Wound dehiscence	12 (19%)	12 (29%)	0.274
Skin necrosis	4 (7%)	7 (17%)	0.114
Chronic wound	21 (34%)	12 (29%)	0.569
Seroma	13 (21%)	8 (19%)	0.811
Hematoma	0 (0%)	3 (7%)	0.03
SSO-procedure intervention	21 (34%)	21 (50%)	0.027*

*Logistic regression used to determine effect of 3M™ Prevena™ Therapy while adjusting for potential confunders.

Patients in the 3M™ Prevena™ Therapy group had fewer total complications (57% vs. 83%, *p*=0.004) and **fewer surgical site occurrences**† (SSO) (47% vs. 69%, *p*=0.025).

After adjusting for potential confounding variables through logistic regression analysis, **the use of 3M™ Prevena™ Therapy was shown to significantly decrease surgical site occurrence procedure intervention by nearly fourfold** (OR=0.28, *p*=0.027) compared to standard surgical dressings.

†Surgical site occurrence (SSO) included surgical site infection (SSI), wound dehiscence, skin necrosis, non-healing incisional wound, seroma, and hematoma.

3M™ Prevena™ Therapy publications specific to plastic surgery.

Citation	Wound/Surgery Type	Level of Clinical Evidence*	
Muller-Sloof E, de Laat HEW, Hummelink SLM, Peters JWB, Ulrich DJO. The effect of postoperative closed incision negative pressure therapy on the incidence of donor site wound dehiscence in breast reconstruction patients: DEhiscence PREvention Study (DEPRES), pilot randomized controlled trial. Journal of Tissue Viability. 2018;27(4):262–266.	Breast reconstruction	1b	●
Ferrando PM, Ala A, Bussone R, Bergamasco L, Actis Perrinetti F, Malan F. Closed Incision Negative Pressure Therapy in Oncological Breast Surgery: Comparison with Standard Care Dressings. Plastic and Reconstructive Surgery - Global Open. 2018 Jun;6(6):e1732.	Breast reconstruction	2	●
Papp AA. Incisional negative pressure therapy reduces complications and costs in pressure ulcer reconstruction. International Wound Journal. December 2018. doi:10.1111/iwj.13045.	Pressure ulcer formation through spinal cord injury	2	●
Renno I, Boos AM, Horch RE, Ludolph I. Changes of perfusion patterns of surgical wounds under application of closed incision negative pressure wound therapy in postbariatric patients. Clinical Hemorheology and Microcirculation. January 2019. doi:10.3233/CH-180450.	Abdominoplasty	2	●
Swanson EW, Cheng HT, Susarla SM, Lough DM, Kumar AR. Does negative pressure wound therapy applied to closed incisions following ventral hernia repair prevent wound complications and hernia recurrence? A systematic review and meta-analysis. Plastic Surgery. 2016 Summer;24(2):113–8.	Ventral hernia repair	2	●
Chowdhry SA, Wilhelmi BJ. Comparing Negative Pressure Wound Therapy with Instillation and Conventional Dressings for Sternal Wound Reconstructions. Plastic and Reconstructive Surgery - Global Open. 2019;7(1). doi:10.1097/ gox.0000000000002087.	Muscle flap reconstruction of sternal wound complications	3	●
Conde-Green A, Chung TL, Holton LH 3rd, Hui-Chou HG, Zhu Y, Wang H, Zahiri H, Singh DP. Incisional negative-pressure wound therapy versus conventional dressings following abdominal wall reconstruction: a comparative study. Annals of Plastic Surgery. 2013 Oct;71(4):394–7.	Abdominal hernia repairs	3	●
Jorgensen MG, Toyserkani NM, Thomsen JB, Sorensen JA. Prophylactic incisional negative pressure wound therapy shows promising results in prevention of wound complications following inguinal lymph node dissection for Melanoma: A retrospective case-control series. J Plast Reconstr Aesthet Surg. 2019 Mar 2.	Inguinal lymph node dissection	3	●
Jorgensen MG, Toyserkani NM, Thomsen JB, Sorensen JA. Prophylactic incisional negative pressure wound therapy shows promising results in prevention of wound complications follow inguinal lymph node dissection for Melanoma: A retrospective case-control series. Journal of Plastic, Reconstructive & Aesthetic Surgery. 2019;000:1–6. doi:10.1016/j. bjps.2019.02.013.	Inguinal lymph node dissection	3	●
Lo Torto F, Monfrecola A, Kaciulyte J, Ciudad P, Casella D, Ribuffo D, Carlesimo B. Preliminary result with incisional negative pressure wound therapy and pectoralis major muscle flap for median sternotomy wound infection in a high-risk patient population. Int Wound J. 2017 Dec;14(6):1335–1339.	Pectoralis major muscle flap for sternotomy wound infections	3	●
Gabriel A, Sigalove S, Storm-Dickerson T, Rice J, Maxwell P, Griffin L. The Impact of Closed Incision Negative Pressure Therapy on Postoperative Breast Recostruction Outcomes. Plastic and Reconstructive Surgery. Global Open. 2018 Aug;6(8):e1880.	Breast reconstruction	3	●
Diaconu SC, McNichols CHL, Ngaage LM, Liang Y, Ikheloa E, Bai J, Grant MP, Nam AJ, Rasko YM. Closed-incision negative-pressure therapy decreases complications in ventral hernia repair with concurrent panniculectomy. Hernia. 2018 Dec 17. [Epub Ahead of Print]	Ventral hernia repairs	3	●
Abatangelo S, Saporiti E, Giatsidis G. Closed Incision Negative-Pressure Therapy (ciNPT) Reduces Minor Local Complications in Post-bariatric Abdominoplasty Body Contouring: a Retrospective Case. Obese Surg. 2018 Jul;28(7):2096–2104.	Abdominoplasty	3	●

● 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."

Meet the 3M™ Prevena Restor™ Bella•Form™ Incision Management System.

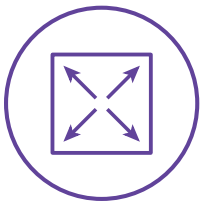
The same proven technology as the original 3M™ Prevena™ Incision Management System — **with new features to optimize care**.

3M™ Prevena Restor™ Incision Management System: Is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure therapy.

- ✓ Delivers continuous -125 mmHg to the incision site
- ✓ Helps hold incision edges together[6]
- ✓ Removes fluid and infectious materials[7]
- ✓ Creates a barrier to external contaminants[11]
- ✓ Reduces edema[8]

Extended Therapy Time

Up to 14 days.

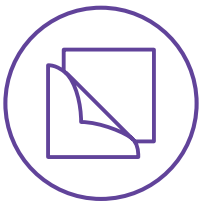


Precision Designed

Dressing seamlessly conforms to the patient.

Expanded Coverage Area

Large dressing delivers therapy to the incision and surrounding soft tissue envelope.



Easier to Use

Simply peel and place the form-fitting dressing.

Ordering Information

Item#	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
PRE1101	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 System with Peel and Place Dressing – 13 cm / 13 cm	Each
PRE5221	3M™ Prevena Restor™ Bella●Form™ System Kit – 21 cm x 19 cm	Each
PRE5321	3M™ Prevena Restor™ Bella●Form™ System Kit – 24 cm x 22 cm	Each
PRE5421	3M™ Prevena Restor™ Bella●Form™ System Kit – 29 cm x 27 cm	Each
PRE4010	3M™ Prevena™ Plus 125 Therapy Unit – 14 day	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

For more information about 3M™ Prevena™ Therapy, contact your local representative or visit **3M.ca/Prevena**.

References:

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