3M | Prevena™ Incision Therapy

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

Plastic Surgery

Advancing the standard of care

Helping to protect plastic surgery incisions beyond the OR

Plastic surgery patient care doesn't end in the OR

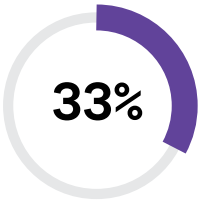
In an increasingly overwhelmed healthcare system, surgeons are asked to do more with fewer resources than ever before, creating complications for patients that extend beyond the operating room. Postoperative concerns include swelling, infection and improper tissue integration in and around the surgical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

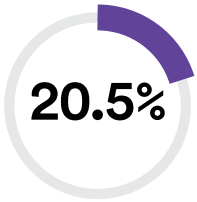
The impact of complications

Post mastectomy or breast reconstruction

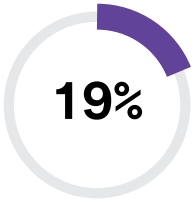
Postmastectomy breast reconstruction is on the rise, and more patients are requesting and qualifying for immediate reconstruction, which has a higher complication rate.



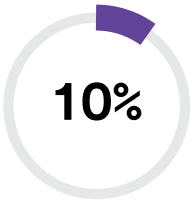
Overall complication rate[2]



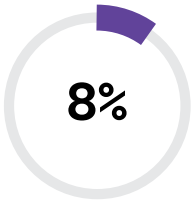
Infection rate[1]



Patients needing reoperations[2]



Surgical site infection (SSI) rate[2]

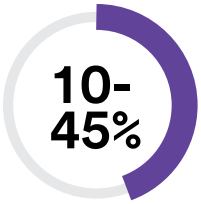


Necrosis rate[3]

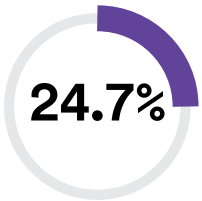
Mean cost of complications in breast reconstruction surgery[4]

Post abdominal surgery

Perfusion-related complications like infection, seroma, hematoma and necrosis are common with abdominal surgeries, and many may become complex and costly complications.



Complication rate in abdominoplasty procedures[5]



Complication rate with deep inferior epigastric perforators flap surgery[6]

Managing the ripple effect

Given the ever-increasing challenges of plastic 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.

Surgical success is largely in the eyes of the patient

In addition to stopping the ripple effect and protecting patients, surgeons and hospitals from potential consequences, clinicians are increasingly aware of the aesthetic outcomes that are top of mind for patients:

- Aesthetic and clinical outcomes will be judged negatively by patients
- Seromas, hematomas and/or infections will result in the need for additional procedures
- Anxious patients will add a layer of scrutiny to the surgical process

The power to help protect outcomes beyond the OR

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

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

- **Acting as a barrier to external contamination**
- **Delivering continuous -125 mmHg up to 7 days**
- **Helping to hold incision edges together**
- **Decreasing lateral tension of sutured/stapled incisions[7]**
- **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.

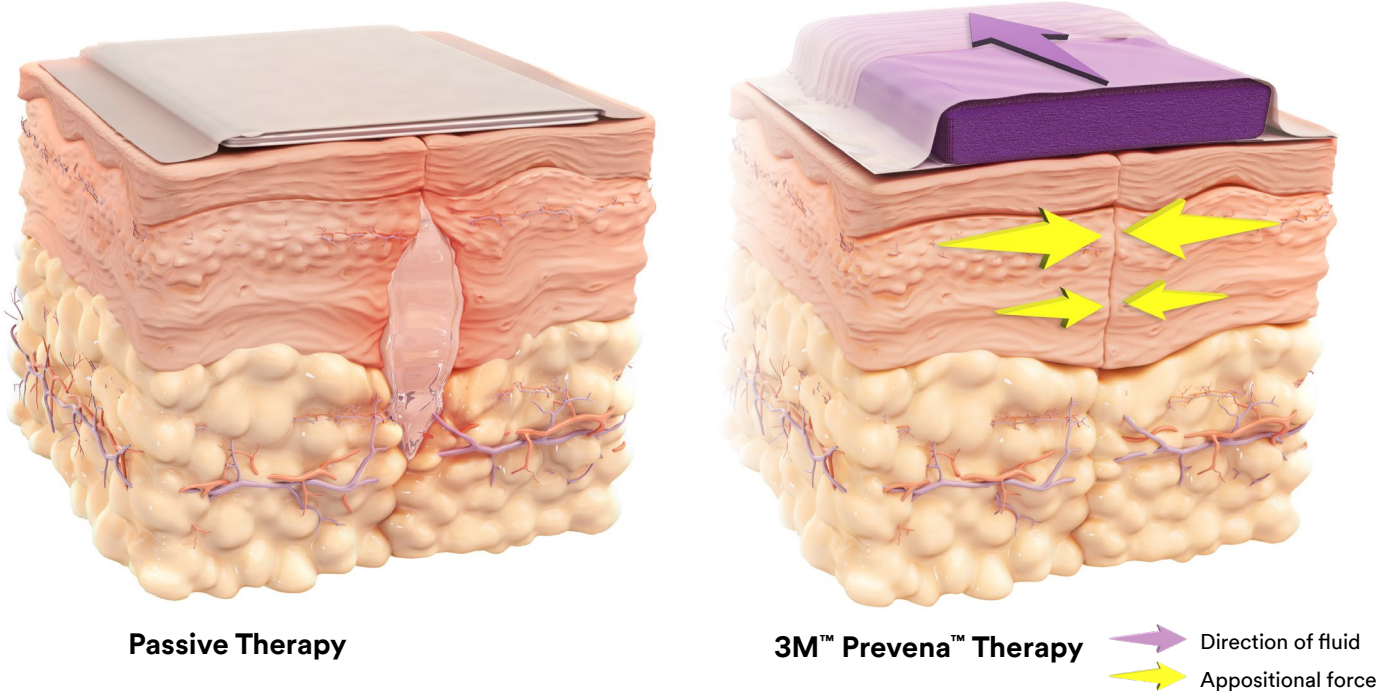
Prevena™ Dressings and Prevena Restor™ Dressings can be applied to various procedures and anatomical locations.

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.[7-9]



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.**

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.

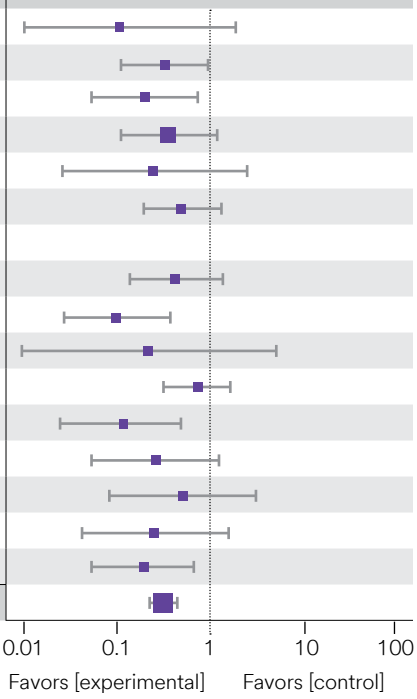
Clinical evidence supporting the FDA indications is growing

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.[10]

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

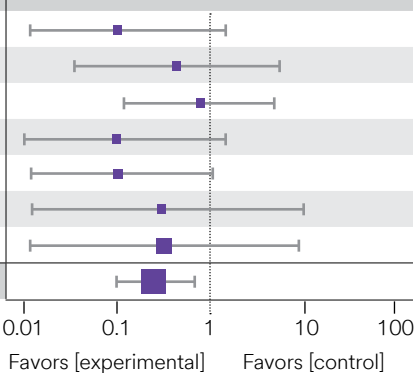
Forest plot of meta-analysis on surgical site infection

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



Forest plot of meta-analysis on seroma

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



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

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).[11] 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.

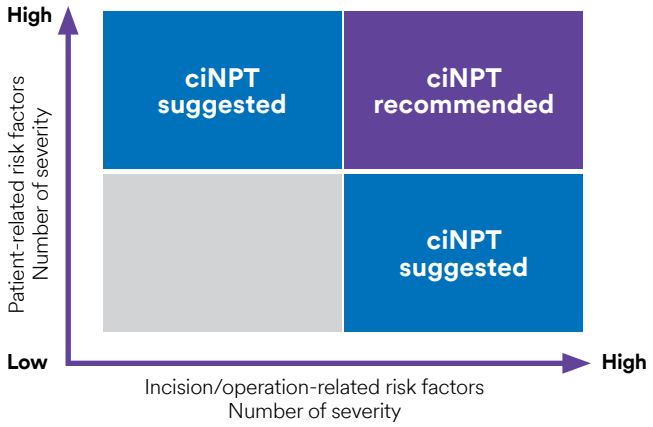
Consensus recommendations based on:

- 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/m^2); 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	
• Diabetes mellitus	• Active alcoholism	• High tension incision	• Prolonged operation time
• Acetylsalicylic acid Score ≥3	• Male sex	• Repeated incisions	• Post-surgical radiation
• Advanced age	• Hematoma	• Extensive undermining	• Mechanically unfavorable site
• Obesity	• Chronic renal insufficiency	• Traumatized soft tissue	
• Active tobacco use	• Chronic obstructive pulmonary disease	• Edema	
• Hypoalbuminemia		• Contamination	
• Corticosteroid usage		• Emergency procedure	

Procedure/operation-related risk factors:

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

Clinical evidence in breast surgery

3M™ Prevena™ Therapy has been shown to aid in the reduction of postsurgical complications and reoperation after breast reconstruction.

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(8):e1880.

Study Design:

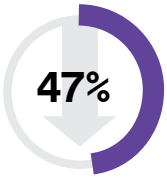
In a retrospective, comparative study the investigators compared incision management outcomes in patients who received Prevena Therapy versus standard of care (SOC) after breast reconstruction mastectomy.

- The study was a single-site retrospective observational study between 2009 to 2017
- The study included 356 patients (Prevena Therapy n=177 v SOC n=179); 665 closed breast incisions (Prevena Therapy n=331 vs. SOC n=334)
- Patients were discharged after 1 night stay and returned for follow-up on postoperative days 3 and 7
- Patient demographics, chemotherapy exposure, surgical technique, number of drains, time to drain removal, and 90-day postoperative complication rates were analyzed

Summary

With use of Prevena Therapy following postmastectomy breast reconstruction significantly lower rates of infection, dehiscence, necrosis, and seromas was achieved, a significant shorter time to drain removal, and significantly fewer returns to the OR.

Surgical site complication reduction



8.5% (28/331) Prevena Therapy vs.
15.9% (53/334) Control

(*p*=0.0092)*

Surgical site infection reduction

2.1% (7/331) Prevena Therapy vs.
4.5% (15/334) Control

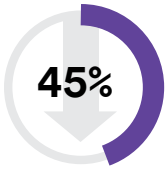
(*p*=0.0225)*

Dehiscence reduction**

2.4% (8/331) Prevena Therapy vs.
5.4% (18/334) Control

(*p*=0.0178)*

Necrosis reduction**



5.1% (17/331) Prevena Therapy vs.
9.3% (31/334) Control

(*p*=0.0070)*

Seroma reduction

1.8% (6/331) Prevena Therapy vs.
5.7% (19/334) Control

(*p*=0.0106)*

Reoperation reduction

2.4% (8/331) Prevena Therapy vs.
5.4% (18/334) Control

(*p*=0.0496)*

Per-patient cost savings

$2,010 Prevena Therapy vs.
$2,228 SOC

Calculation(s) are derived based on relative patient group incidence rate reported in this study. *Statistically significant ($p<0.05$)
**The use of Prevena Therapy for reduction in the incidence of dehiscence and necrosis has not been reviewed by the U.S. FDA.

Clinical evidence in breast surgery

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

Ferrando PM, Ala A, Bussone R, et al. Closed Incision Negative Pressure Therapy in Oncological Breast Surgery: Comparison with Standard Care Dressings. Plast Reconstr Surg Glob Open. 2018;6(6):e1732.

Study Design:

In a single-center prospective, comparative study the investigators evaluated the use of closed-incision negative pressure therapy (ciNPT) (Prevena Therapy) versus standard of care for oncological breast surgery patients that were high-risk for unfavorable healing.

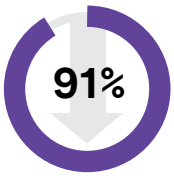
- From January 2015 to June 2015, 47 patients were prospectively selected. Patients were undergoing oncological breast surgery. Inclusion criteria: patients had a minimum of 4 risk factors with at least 1 high risk factor
- 17 patients (25 surgeries) voluntary treated with ciNPT for 7 days; the remaining 20 patients (22 surgeries) chose conventional postsurgery dressing
- Postsurgical complications evaluate 90 days follow-up and at 12 months, the quality of life, scar, and overall aesthetic outcomes were assessed

Summary

This study demonstrates that the use of Prevena Therapy in oncological breast surgery resulted in a statistically significant reduction in surgical site complications and shown to be well-tolerated, adaptable and reliable.

At the 12-month follow-up, questionnaires completed by both the plastic surgeon (Observer Scar Assessment Scale) and the patient (Patient Scar Assessment Scale) on level of satisfaction showed a significant difference in favor of ciNPT.

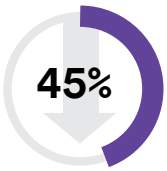
Surgical site complication reduction



4% (1/25) Prevena Therapy vs.
45% (10/22) Control

(p=0.001)*

Necrosis reduction**



5.4% (2/37) Prevena Therapy vs.
25% (5/24) Control

(p=0.0481)*

Improved patient scar assessment outcomes**

11 (6-18) Prevena Therapy vs.
20 (14-34) Control

(p=0.020)*

Calculation(s) are derived based on relative patient group incidence rate reported in this study.
*Statistically significant (p<0.05).
**The use of Prevena Therapy for improved patient scar outcomes or reduction in the incidence of necrosis has not been reviewed by the U.S. FDA.

Clinical evidence in abdominal surgery

3M™ Prevena™ Therapy in ventral hernia repair with concurrent panniculectomy decreased the rate of wound complications in high-risk populations.

Ayuso SA, Elhage SA, Okorji LM, et al. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. Ann Plast Surg. 2022;88(4):429-433.

Study Design:

In a retrospective, cohort study the investigators evaluated the use of closed-incision negative pressure wound (ciNPT) (Prevena Therapy) and its effects on postoperative wound complications in open abdominal wall reconstruction patients with concomitant panniculectomy.

- Concomitant panniculectomy makes this a study on high-risk patients
- A prospective institutional database identified 67 patients that received Prevena Therapy. Prevena Therapy was used for 7 days
- These patients were matched 1:1 to 67 patients that received standard surgical dressings before the use of ciNPT
- In the study period, patient prehabilitation and perioperative protocols at the institution were the same which aids in eliminating confounders. From 2016 onward all patient rehabilitation and perioperative protocols at the institution were the same
- Primary outcomes: wound complications defined as seroma requiring drainage, cellulitis requiring antibiotics, deep wound infection, and superficial wound breakdown

Summary

Patients undergoing abdominal wall reconstruction with concomitant panniculectomy can be at higher risk for wound complications due to the need for large incisions and tissue undermining.

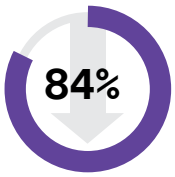
In this study, the use of Prevena Therapy significantly decreased the risk of postoperative wound occurrences including superficial wound breakdown and demonstrated the lessened need for wound-related reoperations in ciNPT patients.

Wound occurrence reduction

15.6% Prevena Therapy vs.
35.5% Control

(p=0.001)*

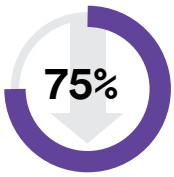
Superficial wound breakdown reduction



3.1% Prevena Therapy vs.
19.7% Control

(p<0.01)*

Deep wound infection reduction**



1.6% Prevena Therapy vs.
6.6% Control

(p=0.020)*

Return to OR reduction

0% (0/67) Prevena Therapy vs.
13.3% (8/67) Control

(p<0.01)*

Calculation(s) are derived based on relative patient group incidence rate reported in this study.
*Statistically significant (p<0.05).
**The use of Prevena Therapy for reduction in the incidence of deep wound infection has not been reviewed by the U.S. FDA.

Clinical evidence in reconstructive surgery

3M™ Prevena™ Therapy demonstrated to aid in the reduction of complications for at-risk flap patients.

Lo Torto F, Monfrecola A, Kaciulyte J, et al. 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;14(6):1335-1339.

Study Design:

In a retrospective single-center comparative cohort study, investigators compared closed-incision negative pressure therapy (ciNPT) (Prevena Therapy) vs. standard of care after sternotomy and monolateral pectoralis major muscle flap (MPMF) coverage in patients at risk for deep sternal wound infections (DSWI) for postoperative complications.

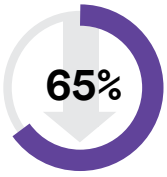
- All patients presented post-sternotomy DSWI following cardiac surgery
- After excision of the wound margins and deep debridement with resection of all necrotic parts of the sternum and the ribs, the muscle monoliteral flap was placed upon the sternal defect and fixated without tension
- Study included 30 ciNPT (Prevena Therapy) patients and 48 standard of care (sterile gauze/elastic bandages) patients
- Patients presented with major risk factors: defined as body mass index ≥ 30, diabetes mellitus, smokers, ≥ 66 years, female gender

Summary

Prevena Therapy was introduced at this institution as a mechanism to reduce wound tension in order to decrease complication rates in patients at risk after flap surgery for DSWI.

The findings of this study support ciNPT aids in improving the outcomes of deep sternal wound infection treatment with MPMF in high-risk patients.

Deep wound infection reduction*



13% (4/30) Prevena Therapy vs.
37.5% (18/48) Control

(p=0.0228)**

Dehiscence reduction*

0% (0/30) Prevena Therapy vs.
15% (7/48) Control

(p=0.0394)**

Revision surgery reduction

3% (1/30) Prevena Therapy vs.
15% (7/48) Control

(p=0.1433)

Calculation(s) are derived based on relative patient group incidence rate reported in this study.
*The use of Prevena Therapy for reduction in the incidence of deep wound infections and dehiscence has not been reviewed by the U.S. FDA.
**Statistically significant (p<0.05).

Clinical evidence by surgery type

Level of Clinical Evidence Rating[12]

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

Wound/ Surgery Type	Level of Evidence	Citation
Breast reconstruction	1b	Muller-Sloof E, de Laat HEW, Hummelink SLM, et al. 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.
	2	Ferrando PM, Ala A, Bussone R, et al. Closed Incision Negative Pressure Therapy in Oncological Breast Surgery: Comparison with Standard Care Dressings. *Plastic and Reconstructive Surgery - Global Open*. 2018;6(6):e1732.
	3	Gabriel A, Sigalove S, Storm-Dickerson T, et al. The Impact of Closed Incision Negative Pressure Therapy on Postoperative Breast Reconstruction Outcomes. *Plastic and Reconstructive Surgery - Global Open*. 2018;6(8):e1880.
Pressure ulcer formation through spinal cord injury	2	Papp AA. Incisional negative pressure therapy reduces complications and costs in pressure ulcer reconstruction. *International Wound Journal*. December 2018.
Abdominoplasty	2	Renno I, Boos AM, Horch RE, et al. 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.
	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;28(7):2096-2104.
Ventral hernia repair	2	Swanson EW, Cheng HT, Susarla SM, at al. 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.
	3	Diaconu SC, McNichols CHL, Ngaage LM, et al. Closed-incision negative-pressure therapy decreases complications in ventral hernia repair with concurrent panniculectomy. *Hernia*. 2018 December 17. (Epub ahead of print)
Abdominal hernia repairs	3	Conde-Green A, Chung TL, Holton LH 3rd, et al. Incisional negative-pressure wound therapy versus conventional dressings following abdominal wall reconstruction: a comparative study. *Annals of Plastic Surgery*. 2013;71(4):394-7.
Muscle flap reconstruction of sternal wound complications	3	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).
Pectoralis major muscle flap for sternotomy wound infections	3	Lo Torto F, Monfrecola A, Kaciulyte J, et al. 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;14(6):1335-1339.
Inguinal lymph node dissection	3	Jorgensen MG, Toyserkani NM, Thomsen JB, et al. 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 March 2.
	3	Jorgensen MG, Toyserkani NM, Thomsen JB, et al. 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.

Compatible with 3M negative pressure therapy devices

3M™ Prevena™ Plus 125 Therapy Unit

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

Negative pressure options:

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

Specifications:

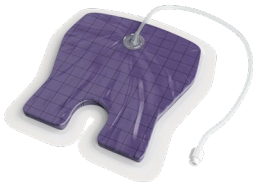
- Dimensions: Approx 8.9 × 16.3 × 5.49cm
- Weight with empty canister: 0.64lbs (0.29kg)

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

3M™ Prevena Restor™ Dressings

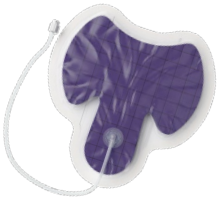
3M™ Prevena Restor™ Therapy extends negative pressure therapy beyond the incision site to include the surrounding soft tissue. It helps provide comprehensive protection, optimize surgical site recovery, and helps patients start rehab with confidence.

3M™ Prevena Restor™ Arthro•Form™ Dressing

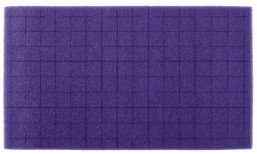


3M™ Prevena Restor™ Axio•Form™ Dressing

3M™ Prevena Restor™ Bella•Form™ Dressing



3M™ Prevena Restor™ Roto•Form™ Dressing



3M™ Prevena Restor™ Adapti•Form™ Dressing

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

Extended therapy time
Up to 14 days (dressing change required after 7 days)

Precision designed
Dressings seamlessly conform to the patient

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

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

Additional customer resources:

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

Ordering Information

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

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

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

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

References:

1. Jagsi R, Jiang J, Momoh AO, et al. Complications After Mastectomy and Immediate Breast Reconstruction for Breast Cancer: A Claims-Based Analysis. *Ann Surg*. 2016;263(2):219-27.
2. Bennett KG, Qi J, Kim HM, et al. Comparison of 2-Year Complication Rates Among Common Techniques for Postmastectomy Breast Reconstruction. *JAMA Surg*. 2018;153(10):901–908.
3. Sue GR, Long C, Lee GK. Management of Mastectomy Skin Necrosis in Implant Based Breast Reconstruction. *Ann Plast Surg*. 2017;78(5 Suppl 4):S208-S211.
4. Gabriel A, Maxwell GP. Economic analysis based on the use of closed-incision negative-pressure therapy after postoperative breast reconstruction. *Plast Reconstr Surg*. 2019;143(1S Management of Surgical Incisions Utilizing Closed-Incision Negative Pressure Therapy):36S-40S.
5. Bullocks J, Basu CB, Hsu P, et al. Prevention of Hematomas and Seromas. *Semin Plast Surg*. 2006;20(4):233-240.
6. Krishnan NM, Purnell C, Nahabedian MY, et al. The cost effectiveness of the DIEP flap relative to the muscle-sparing TRAM flap in postmastectomy breast reconstruction. *Plast Reconstr Surg*. 2015;135(4):948-958.
7. Wilkes RP, Kilpadi DV, Zhao Y, et al. Closed Incision Management With Negative Pressure Wound Therapy (CIM): Biomechanics. *Surgical Innovation*. 2012;19(1):67-75.
8. Kilpadi DV, Cunningham MR. Evaluation of Closed Incision Management with Negative Pressure Wound Therapy (CIM): Hematoma/Seroma and Involvement of the Lymphatic System. *Wound Repair and Regeneration*. 2011;19:588-596.
9. Glaser DA, Farnsworth CL, Varley ES, et al. Negative pressure therapy for closed spine incisions: A pilot study. *Wounds*. 2012;24(11):308-316.
10. Federal Drug Administration. De Novo Classification Request for Prevena 125 and Prevena Plus 125 Therapy Units. De Novo Summary (DEN180013), 2019. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180013.pdf
11. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: International multidisciplinary consensus recommendations. *Int Wound J*. 2017;14(2):385-398.
12. Sullivan D, Chung KC, Eaves FF, et al. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. *Plast Reconstr Surg*. 2011;128(1):311-314.

3M Company
2510 Conway Ave
St. Paul, MN 55144 USA

Phone 1-800-275-4524 (NPWT products)
1-800-228-3957
Web 3M.com/medical