

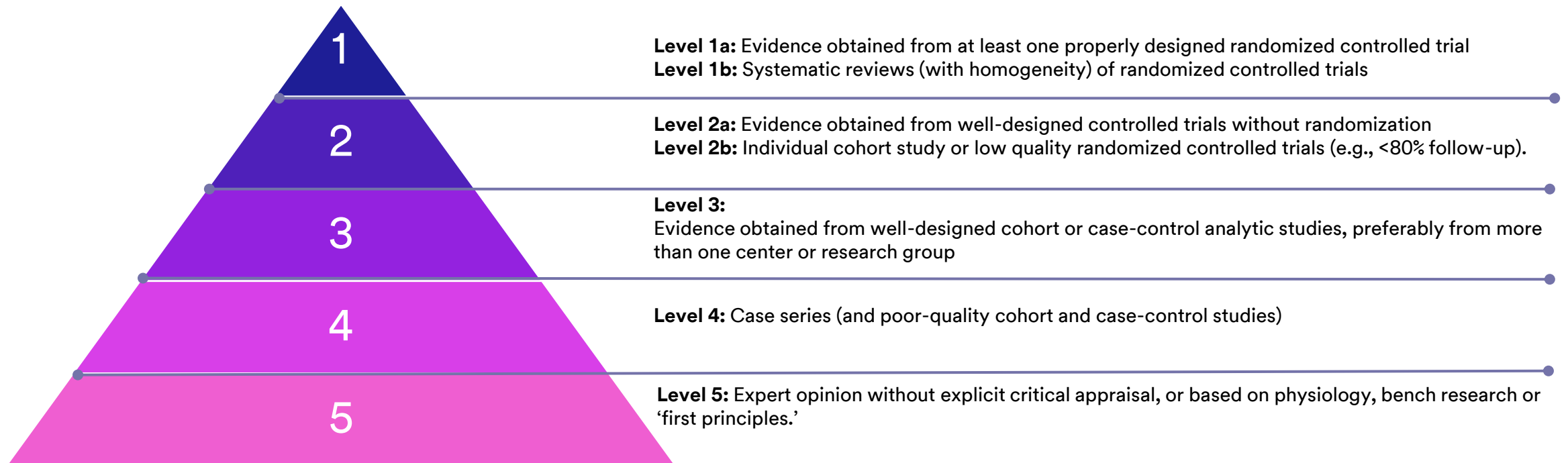


3M | **Prevena™**
Incision Therapy

Clinical Evidence
Plastic Surgery

Negative Pressure Therapy for Incision Management

- For over 25 years, negative pressure vacuum-assisted closure (V.A.C.®) technology has been clinically shown to promote wound healing by reducing edema and promoting granulation tissue formation and perfusion through the removal of exudate and infectious materials.
- 3M extended the use of its negative pressure technology to closed surgical incisions with similarly positive clinical results, outlined in more than 70+ journal publications focused on closed incision negative pressure therapy (ciNPT), with nearly half of the evidence specific to orthopedic cases.
- The 3M™ Prevena™ Incision Management System clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale¹ and reflect the benefits of ciNPT for different incision types and surgical outcomes compared to the standard of care.



Reference: 1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. *Plast Reconstr Surg* 2011;128(1):311-314

3M Prevena™ Therapy evidence table by specialty

- The body of evidence for using ciNPT has been growing steadily since 2006
- The table listed below is based on the Evidence Rating Scale for Therapeutic Studies developed by the American Society of Plastic Surgeons (ASPS)

Surgical Incision	ASPS Level of Evidence	First Author (Year)	Surgical Incision Type	Control	Postoperative Clinical Endpoints*
Breast Surgery	3	Gabriel (2018)	Breast reconstruction	Steri-Strips	Surgical site infection (SSI), dehiscence, seroma, necrosis, surgical site complication (SSC), return to the operating room (ROR), drain days
		Ferrando (2018)	Oncological Breast Surgery	Steri-Strip Skin Adhesive for 14 days changed after 7 days	SSC, necrosis, scar assessment
		Savage (2020)	Bilateral Breast Reduction	SOC: Various Dressing materials, Fitted Garment, Drainage	SSC, Hospital length of stay (LOS), postoperative opioid use
Abdominal Wall Reconstruction with Concomitant Panniculectomy	3	Ayuso (2021)	Open abdominal wall reconstruction with Concomitant Panniculectomy	SOC : Standard Surgical Dressing	Wound occurrence, seroma, wound breakdown, cellulitis, deep wound infection, mesh infection, LOS, Readmission, ROR, and hernia recurrence
Pectoralis Major Muscle Flap for Deep Sternal Infections	3	Lo Torto (2017)	Sternotomy and monolateral pectoralis major muscle flap (MPMF)	SOC: Sterile Gauze/Elastic Bandages	postoperative complications: seroma, haematoma, dehiscence, surgical revision
Pressure Ulcer Reconstruction	3	Papp (2018)	Pressure Ulcer Reconstruction	SOC before implementation of ciNPT	Complications, acute and late reoperation, LOS, Rate of open Wounds at 3 month, HE in publication
Amputation	3	Chang (2021)	Major Lower Extremity Amputation (BKA & AKA)	SOC : Standard Surgical Dressing	Wound complications, SSIs (superficial and deep), necrosis, hematoma, readmission, revision surgery, and length of stay

* Clinical endpoints reflect the conditions and methods specific to each publication and should not be interpreted as general outcomes related to Prevena Therapy. Individual results for each case may vary, depending on the patient, circumstances, and conditions.

Reduced 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. Published 2018 Aug 7.

3
LOE

Plastic
Breast

Study Design

Retrospective, comparative study (Level III)

Study Purpose

The investigators compared incision management outcomes in patients who received 3M™ Prevena™ Therapy versus standard of care (SOC) after breast reconstruction mastectomy

Methods

- Single site retrospective observational study: 2009 - 2017
- 356 Patients (Prevena Therapy n=177 v SOC n=179);
- 665 closed breast incisions (Prevena Therapy n=331 vs. SOC n=334)
- SOC: 3M™ Steri-Strip™ Wound Closures
- 3M™ Prevena™ Plus Customizable Dressing
- Patients were discharged home after 1 night stay and returned for follow-up on POD 3 and 7.
- Patient demographics, chemotherapy exposure, surgical technique, number of drains, time to drain removal, and 90-day postoperative complication rates were analyzed

Calculation(s) are derived based on relative patient group incidence rate reported in this study

* Statistically significant (p<0.05)

Results

Surgical Site Complications

↓47%

Reduction in SSCs*

8.5 % (28/331) Prevena Therapy vs. 15.9 % (53/334) Control (p=0.0092)*

Surgical Site Infections

↓53%

Reduction in SSIs*

2.1 % (7/331) Prevena Therapy vs. 4.5 % (15/334) Control (p=0.0225)*

Return to OR

↓56%

Reduction in Reoperations*

2.4 % (8/331) Prevena Therapy vs. 5.4% (18/334) Control (p=0.0496)*

Key Points

With use of Prevena Therapy following post-mastectomy 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.

Dehiscence†

↓56%

Reduction in Dehiscence**

2.4 % (8/331) Prevena Therapy vs. 5.4 % (18/334) Control (p=0.0178)*

Necrosis†

↓45%

Reduction in Necrosis**†

5.1 % (17/331) Prevena Therapy vs. 9.3 % (31/334) Control (p=0.0070)*

Seroma

↓68%

Reduction in Seroma*

1.8 % (6/331) Prevena Therapy vs. 5.7 % (19/334) Control (p=0.0106)*

Cost Savings

Reduction in per patient cost for SSC

- \$2,010 Prevena Therapy vs. \$2,228 SOC
- Mean per Patient Cost Savings: **\$218**

Source: Gabriel A, Maxwell P. Economic analysis based on the use of closed-incision negative-pressure therapy after postoperative breast reconstruction. *Plast Reconstr Surg* 2019;143:365

† NOTE: The use of Prevena Therapy for reduction in the incidence of dehiscence and necrosis has not been reviewed by the U.S. FDA

Improved outcomes with use of ciNPT after breast surgery in high-risk patients

3

Plastic

Breast

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 LOE

Study Design

Prospective comparative (Italy) (Level II)

Study Purpose

The study evaluated the use of ciNPT (3M™ Prevena™ Therapy) for oncological breast surgery patients that were high-risk for unfavorable healing

Methods

- 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; the remaining 20 patients (22 surgeries) chose conventional post-surgery dressing.
- SOC: 3M™ Steri-Strip™ Wound Closures
- 3M™ Prevena™ Plus Customizable Dressing for 7 days
- 90 days follow-up to evaluate postsurgical complications
- At 12 months, the quality of life, scar, and overall aesthetic outcomes were assessed

Results

Surgical Site Complications

↓91%

Reduction in SSCs*

4 % (1/25) Prevena Therapy vs.
45 % (10/22) Control
($p=0.001$)*

Patient Scar Assessment

↓45%

Improved PSAS outcome at 12 months*

11 (6-18) Prevena Therapy vs.
20 (14-34) Control
($p=0.002$)*

Necrosis†

↓45%

Reduction in Necrosis**

5.4% (2/37) Prevena Therapy vs.
25.0% (5/24) Control
($p=0.0481$)*

Key Points

This study demonstrates that the use of Prevena Therapy in oncological breast surgery resulted in a statistically significant reduction in surgical site complications.

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.

Calculation(s) are derived based on relative patient group incidence rate reported in this study

* Statistically significant ($p<0.05$)

† **NOTE:** The use of Prevena Therapy for reduction in the incidence of necrosis has not been reviewed by the U.S. FDA

Illustration of the 3M™ Prevena™ Incision Management System

Cost-Effectiveness Based on Ferrando et al Outcomes

Oncological Breast Surgery Hypothetical Economic Model	Prevena™ Therapy	Steri-Strip™
Patients	25	22
Number of Complications (a)	1	10
Cost per SSC ¹ (b)	\$9,782	\$9,782
Per Patient Complication Cost (a*b)/n	\$391	\$ 4,446
Per Patient Therapy Cost*	\$830	---
Total Cost Per Patient	\$1,221	\$ 4,446
Potential Per Incision Savings Using Prevena™ Therapy	\$3,225	

Cost Savings

➔

↓

73%

Reduction in per patient cost for SSCs
 \$1,221 Prevena Therapy vs.
 \$4,446 SOC

1. Hou Y. Incidence and impact of surgical site complications on length of stay and cost of care in open surgical procedures. HEOR-2021-004-DAR.

*3M™ Prevena™ Plus Customizable Dressing is an estimate; individual prices may vary

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena™ Therapy or Steri-Strip™. 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.

Reduced wound complications and opioid use after bilateral breast reduction

Savage N, Jain M, Champion R et al. Incisional negative pressure wound therapy in bilateral breast reduction patients. Australian Journal of Plastic Surgery. 2020; 3(1):30-38.

1
LOE

Plastic
Breast

Study Design

Retrospective comparative cohort study – Australia (Level III)

Study Purpose

The purpose of the study was to evaluate the effect of closed incision negative pressure therapy (ciNPT), 3M™ Prevena™ Therapy, on surgical complications, opioid use and hospitalization length after bilateral breast reduction.

Methods

- Consecutive bilateral breast reductions performed by a single surgeon June 2015 to August 2017. 52 patients analyzed: SOC (n=29) and Prevena Therapy (n=23).
- Prevena Therapy was used for 7 days with no drains and no fitted garment
- SOC: application of an adhesive non-woven fabric dressing, gauze and adhesive fabric dressing again, drains removed on post-operative day 1, fitted garment used post OP
- Discharge criteria defined as able to mobilize, subjective pain score less than 4, feeling subjectively well
- Outcome Measure: SSC including local inflammatory response, dehiscence, surgical site infection, delayed healing, nipple necrosis, abscess; Opioid use measured in oral morphine equivalents

Results

Surgical Site Complications

↓71%

Reduction in SSCs*

13.0% (3/23) Prevena Therapy vs. 44.8% (13/29) Control (p=0.014)*

Opioid Use and Prescription

↓27%

Less Opioid use (mg)* in the Ward

45.5 (± 38.25) Prevena Therapy vs. 62.5 (± 39.6) Control (p= 0.045)*

Hospital Length of Stay (LOS)

↓33%

Reduction in LOS*

1.35 (±0.49) Prevena Therapy vs. 2.03 (±0.33) Control (p< 0.001)*

↓45%

Fewer Opioids at Discharge (mg)*

125.5 (±63.6) Prevena Therapy vs. 230.0 (±115) Control (p< 0.001)*

Key Points

- This is the first study to provide evidence for the use of ciNPT in bilateral breast reduction. This study indicates that Prevena Therapy could be associated with a significant reduction in surgical site complication occurrences, decreased total ward opioid use and discharge opioid prescription as well as decreased hospital length of stay.
- The study was not limited to high-risk patients.

Calculation(s) are derived based on relative patient group incidence rate reported in this study

* Statistically significant (p<0.05)

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost Effectiveness Based on Savage et al Outcomes

Breast Reduction Hypothetical Economic Model	Prevena™ Therapy	SOC***
Patients	23	29
Number of Complications (a)	3	13
Cost per SSC ¹ (b)	\$9,782	\$9,782
Per Patient Complication Cost (a*b)/n	\$1,276	\$ 4,385
Per Patient Therapy Cost*	\$830	---
Total Cost Per Patient	\$2106	\$ 4,385
Potential Per Incision Savings Using Prevena™ Therapy	\$2,279	

Cost Savings

↓ 52%

Reduction in per patient cost for SSCs

\$2,106 Prevena Therapy vs. \$4,385 SOC

1. Hou Y. Incidence and impact of surgical site complications on length of stay and cost of care in open surgical procedures. HEOR-2021-004-DAR.

*3M™ Prevena™ Plus Customizable Dressing is an estimate; individual prices may vary

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena™ Therapy or SOC. 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.

Reference: Papp A. Incisional negative pressure therapy reduces complications and costs in pressure ulcer reconstruction. Int Wound J. 2019;16(2):394-400.

Reduced Complications and Costs in Pressure Ulcer Reconstruction

Papp A. Incisional negative pressure therapy reduces complications and costs in pressure ulcer reconstruction. Int Wound J. 2019;16(2):394-400.

Study Design

Prospective Non-Randomized Trial with historical control (Level III-Canada)

Study Purpose

Study aims to decrease postoperative wound-healing complications with incisional negative pressure wound therapy (3M™ Prevena™ Therapy) following Pressure Ulcer Reconstruction in patients with spinal cord impairment.

Methods

- 37 Surgically treated pressure ulcer patients receiving Prevena Therapy included prospectively.
- 24 Surgically treated patients receiving SOC (3M™ Steri-Strip™ Wound Closures & Mephore) data assessed retrospectively.
- Prevena Therapy remained in-situ for 7 days.
- 90 Day Follow Up.

Indications for Operative Management:

- Grade 3-4 with full-thickness skin loss exposing fat or deeper tissues
- Underlying bone exposure
- Documentation of osteomyelitis
- Lack of progression in wound healing in 3 months after optimization of patient variables

Results

Wound Complications

↓75%

Reduction in general in-hospital complications*
10.8% (4/37) Prevena Therapy vs.
41.7% (10/24) Control
(**p=0.0051**)*

Hospital Length of Stay

↓27%

Reduction in hospital length of stay*
24.8 days Prevena Therapy vs.
33.8 days Control
(**p=0.0103**)*

Dehisced Wound †

↓73%

Reduction in number of open wounds at 3 months post operative*†
5.4% (2/37) Prevena Therapy vs.
25.0% (5/24) Control
(**p=0.0481**)*

Key Points

Results showed benefit to use Prevena Therapy following pressure ulcer reconstruction sites no complications or side-effects related to the use of the dressing.

The use of incisional negative pressure wound therapy resulted in a significant decrease in overall complications, significantly reduced length of stay in hospital, and significantly decreased the number of open recurrent wounds at 3 months after discharge from the hospital.

A reduction in length of stay by 9 days can account for significant cost savings. The cost benefit analyses performed by the author showed a cost savings of over \$4400 CAD per patient

Calculation(s) are derived based on relative patient group incidence rate reported in this study

* Statistically significant (p<0.05)

† **NOTE:** The use of Prevena Therapy for reduction in the incidence of dehiscence has not been reviewed by the U.S. FDA

Cost illustration of the 3M™ Prevena™ Therapy Incision Management System Cost Effectiveness Based on Papp et al Outcomes

Plastics Pressure Ulcer Hypothetical Economic Model	Prevena™ Therapy	Control
Number of Patients (n)	37	24
Number of complications (a)	4	10
Cost Per Complication ¹ (b)	\$9,782 CAD	\$9,782 CAD
Cost of Complication per Patient (a*b)/n	\$1,057 CAD	\$4,075 CAD
Cost of Therapy per Patient*	\$830 CAD	---
Total Cost Per Patient	\$1,887 CAD	\$4,075 CAD
Potential Per Incision Savings Using Prevena™ Therapy	\$2,188 (CAD)	



1. *Hou Y. Incidence and impact of surgical site complications on length of stay and cost of care in open surgical procedures. HEOR-2021-004-DAR.

*3M™ Prevena™ Plus Customizable Dressing is an estimate; individual prices may vary

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena™ Therapy or SOC. 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.

Reference: Papp A. Incisional negative pressure therapy reduces complications and costs in pressure ulcer reconstruction. Int Wound J. 2019;16(2):394-400.

ciNPT for open abdominal wall reconstruction with concomitant panniculectomy

3

Plastic

AWR

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.

LOE

Study Design

Retrospective Cohort Study (USA) - Level III

Study Purpose

To evaluate the use of closed-incision negative pressure therapy (ciNPT) and its effects on postoperative wound complications in open Abdominal Wall Reconstruction (AWR) patients with Concomitant Panniculectomy (CP)

Methods

- Prospective institutional database identified 67 patients that received 3M™ Prevena™ Therapy. 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.
- Prevena Therapy was used for 7 days
- Concomitant Panniculectomy makes this a study on high-risk patients
- Primary outcomes: wound complications defined as seroma requiring drainage, cellulitis requiring antibiotics, deep wound infection, and superficial wound breakdown

Calculation(s) are derived based on relative patient group incidence rate reported in this study

* Statistically significant (p<0.05)

Results

Wound Occurrences

↓ 56%

Reduction in Wound Occurrences*

15.6% Prevena Therapy vs.
35.5% Control
(p=0.001)*

Deep SSI†

↓ 75%

Reduction in Deep SSI†

1.6% Prevena Therapy vs.
6.6% Control
(p=0.20)

Wound Breakdown

↓ 84%

Reduction in Superficial Wound Breakdown*

3.1% Prevena Therapy vs.
19.7% Control
(p<0.01)*

Return to the Operating Room

Reduced ROR

Reduction in number of OR Visits*

0% (0/67) Prevena Therapy vs.
13.3% (8/67) Control
(p<0.01)*

Key Points

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. The study also demonstrated the lessened need for wound-related reoperations in ciNPT patients.

† NOTE: The use of Prevena Therapy for reduction in the incidence of deep SSI has not been reviewed by the U.S. FDA

Cost illustration of the 3M™ Prevena™ Therapy Incision Management System Cost Effectiveness Based on Ayuso et al Outcomes

Plastics AWR with CP Hypothetical Economic Model	Prevena™ Therapy	Control
Number of Patients (n)	100	100
Number of Wound Occurrences (a)	16	36
Cost Per Complication ¹ (b)	\$9,782	\$9,782
Cost of Complication per Patient (a*b)/n	\$1,565	\$3,522
Cost of Therapy per Patient*	\$495	---
Total Cost per Patient	\$2,060	\$3,522
Potential Per Incision Savings Using Prevena™ Therapy	\$1,462	

Cost Savings

↓ 42%

Reduction in per patient cost for Wound Occurrences
 \$1,462 Prevena Therapy vs.
 \$3,522 SOC

1. *Hou Y. Incidence and impact of surgical site complications on length of stay and cost of care in open surgical procedures. HEOR-2021-004-DAR.

*3M™ Prevena™ Peel and Place System Kit is an estimates; individual prices may vary

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena™ Therapy or Standard of Care (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. Results are based on selected study data and may not be typical. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference: Ayuso SA, Elhage SA, Okorji LM, Kercher KW, Colavita PD, Heniford BT, Augenstein VA. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. Ann Plast Surg. 2021 Oct 7. doi: 10.1097/SAP.0000000000002966. Epub ahead of print. PMID: 34670966.



3M™ Prevena™ Therapy for pectoralis major muscle flap for sternal wound infections

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. International Wound Journal. 2017;14(6):1335-1339.

3
LOE

Plastic

DSWI

Study Design

Retrospective Single Centre Comparative Cohort Study (Italy) Level III

Study Purpose

To evaluate the effect of closed incision negative pressure therapy (ciNPT) after sternotomy and monolateral pectoralis major muscle flap (MPMF) coverage in patients at risk for Deep Sternal Wound Infections (DSWI)

Methods

- 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 monolateral flap was placed upon the sternal defect and fixated without tension.
- 30 ciNPT (Prevena Therapy) patients; 48 SOC (Sterile Gauze/Elastic Bandages) patients.
- All patients had major risk factors: defined as BMI ≥ 30 , Diabetes Mellitus, Smokers, ≥ 66 years, female gender.
- Postoperative complications included seroma, hematoma, dehiscence, and surgical revision

Calculation(s) are derived based on relative patient group incidence rate reported in this study

* Statistically significant ($p < 0.05$)

Results

Wound Complications

↓ 65%

Reduction in Wound Complications*

13% (4/30) Prevena Therapy vs.
37.5% (18/48) Control
($p=0.0228$)*

Wound Dehiscence†

0

Incidence in Dehiscence**

0% (0/30) Prevena Therapy vs.
15% (7/48) Control
($p=0.0394$)*

Revision Surgery

↓ 5x

Reduction in Wound Complications*

13% (4/30) Prevena Therapy vs.
37.5% (18/48) Control
($p=0.0228$)*

Key Points

Using a risk prediction model to aid decision making in the care of closed incisions after vascular surgery and can help optimize the utilization of ciNPT, its outcomes, and associated costs.

† **NOTE:** The use of Prevena Therapy for reduction in the incidence of dehiscence has not been reviewed by the U.S. FDA

Cost illustration of the 3M™ Prevena™ Therapy Incision Management System

Cost-Effectiveness Based on La Torto et al Outcomes

Plastics MPMF & DSWI Hypothetical Economic Model	Prevena™ Therapy	Control
Number of Patients (n)	30	48
Number of Wound Occurrences (a)	4	18
Cost Per Occurrence ¹ (b)	\$9,782	\$9,782
Cost of Occurrence per Patient (a*b)/n	\$1,304	\$3,668
Cost of Therapy per Patient	\$495	---
Total Cost per Patient	\$1,799	\$3,668
Potential Per Incision Savings Using Prevena™ Therapy	\$1,869	

Cost Savings

↓ 51%

Reduction in per patient cost for Wound Complications
 \$1,799 Prevena Therapy vs.
 \$3,668 SOC

1. *Hou Y. Incidence and impact of surgical site complications on length of stay and cost of care in open surgical procedures. HEOR-2021-004-DAR.

*3M™ Prevena™ Peel and Place System Kit is an estimates; individual prices may vary

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena™ Therapy or Standard of Care (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. Results are based on selected study data and may not be typical. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference: 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. International Wound Journal. 2017;14(6):1335-1339.

Decreased rate of wound complication occurrence observed in patients with vascular disease undergoing major lower extremity amputation

Chang H, Maldonado TS, Rockman CB, Cayne NS, Berland TL, Barfield ME, Jacobowitz GR, Sadek M. Closed incision negative pressure wound therapy may decrease wound complications in major lower extremity amputations. Journal of Vascular Surgery. 2021 Mar;73(3):1041-1047.

Study Design
Retrospective, comparative study

Study Purpose
This study evaluated closed incision negative pressure therapy (ciNPT; 3M™ Prevena™ Therapy) vs. standard dressings in decreasing the complication risk in patients with peripheral vascular disease undergoing major lower extremity amputations (LEAs)

Methods

- The study included 54 patients with history of peripheral arterial disease underwent below-knee or above-knee amputations
- Retrospective review of prospectively maintained database from Jan 2018 to Dec 2019
- 23 amputations in the NPWT group and 31 amputations in the standard dressing group (control)
- Patients in the NPWT arm of the study presented a higher incidence of comorbidities (tobacco use, previous amputation, COPD, etc.) vs control group
- Amputation incisions assessed and wound complications recorded 30 days postoperatively.
- Outcomes included: Surgical Site Infections, Wound Complications, Necrosis, Hematoma, Readmission, Revision Surgery, and Hospital Length of Stay (LOS)

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

Results

Wound Complications	Hematoma †
↓66% Reduction in SSCs* 13% (3/23) Prevena™ Therapy vs. 39% (12/31) Control (p=0.037)*	↓100% Reduction in Hematoma† 0% (0/23) Prevena™ Therapy vs. 3% (1/31) Control (p=0.385)
Superficial Surgical Site Infections (sSSIs)	Readmissions
↓55% Reduction in sSSIs 4% (1/23) Prevena™ Therapy vs. 10% (3/31) Control (p=0.460)	↓55% Reduction in Readmissions 4% (1/23) Prevena™ Therapy vs. 10% (3/31) Control (p=0.460)
Deep Surgical Site Infections (dSSIs)†	Revision Surgery
↓66% Reduction in dSSIs† 4% (1/23) Prevena™ Therapy vs. 13% (4/31) Control (p=0.283)	↓57% Reduction in Amputation Revision 4% (1/23) Prevena™ Therapy vs. 10% (3/31) Control (p=0.460)
Necrosis†	Length of Stay
↓66% Reduction in Necrosis† 4% (1/23) Prevena™ Therapy vs. 13% (4/31) Control (p=0.283)	↓11% Reduction in Postoperative Stay 8.9 days (+5.9) Prevena™ Therapy vs. 10.0 days (+6.4) Control (p=0.554)

Key Points

- Study suggest that ciNPT may reduce the incidence of wound complications in vascular patients undergoing major lower extremity amputations, including high risk patients
- ciNPT may be considered for use in major lower extremity amputations



3M™ Prevena™ Therapy for the high-risk Plastic Surgery patient

Inclusion criteria for patients at high-risk for complications:

Post-sternotomy DSWI following cardiac surgery

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. International Wound Journal. 2017;14(6):1335-1339.

All Post-sternotomy DSWI surgery patients included had at least 1 major risk factor:

- BMI ≥ 30
- Diabetes
- Smoking
- age ≥ 66
- female

Abdominal Wall Reconstruction with Concomitant Panniculectomy

Ayuso SA, Elhage SA, Okorji LM, Kercher KW, Colavita PD, Heniford BT, Augenstein VA. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. Ann Plast Surg. 2021 Oct 7. doi: 10.1097/SAP.0000000000002966. Epub ahead of print. PMID: 34670966

All patients with abdominal wall reconstruction with concomitant panniculectomy are at high-risk

Oncological Breast Surgery

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

Patients are high risk for SSC with 4+ of the below risk factors including at least 1 high risk factor (indicated as bold):

Patient-related factors:

- age ≥ 65
- **BMI ≥ 30**
- **breast conformation (large size, ptosis)**
- **Smoking**
- Diabetes
- Hypertension
- **Corticosteroids**
- Peripheral artery disease
- Liver disease
- Chemotherapy
- **Radiation**

Surgery-related factors:

- **Previous surgery ≤ 30 days**
- Previous surgery > 30 days
- **Extensive undermining**
- **Type of reconstruction (1-stage)**
- **Use of acellular dermal matrix**
- Autologous reconstruction

3M™ Prevena™ Therapy for the high-risk Plastic Surgery patient

Inclusion criteria for patients at high-risk for complications:

Patients are high-risk if they have ≥ 1 of the following risk factors

Patient-related factors:

- BMI ≥ 30
- Smokers
- Radiation
- Corticosteroids
- Revision surgery within 30 days
- Extensive undermining

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

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. International Wound Journal. 2017;14(6):1335-1339.