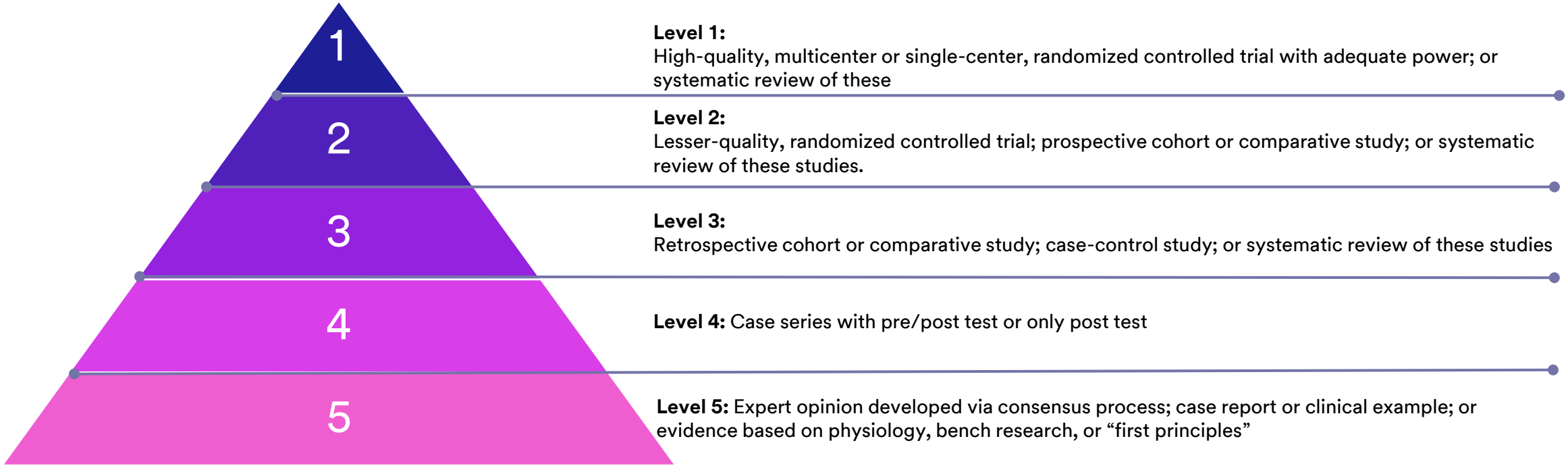
Clinical Evidence Summaries

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 200+ journal publications focused on closed incision negative pressure therapy (ciNPT)/3M™ Prevena™ Therapy.
- The 3M™ Prevena™ Therapy clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale[1] 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

Systematic Review and Meta-Analysis of 3M™ Prevena™ Therapy over closed plastic surgery incisions to reduce surgical site complications (1/2)

Gabriel A, Singh D, Silverman RP, Collinsworth A, Bongards C, Griffin L. Closed Incision Negative Pressure Therapy Versus Standard of Care Over Closed Plastic Surgery Incisions in the Reduction of Surgical Site Complications: A Systematic Review and Meta-Analysis of Comparative Studies. Eplasty. 2023 Mar 31;23:e22. PMID: 37187870; PMCID: PMC10176484.

Study Design

Systematic Review and Meta-Analysis

Study Purpose

Conduct a systematic review and meta-analysis to identify studies comparing Prevena Therapy to Control on plastic surgery incisions and to evaluate the effectiveness of closed incision negative pressure therapy (Prevena Therapy) versus Control dressings in reducing surgical site complications (SSCs)

Methods

- The systematic review included manuscripts and abstracts written in English and published between January 2005 to July 2021. Studies compared the use of Prevena Therapy to Control following plastic surgery.
- 16 studies were included: 1 randomized controlled trials, 4 prospective studies, 11 retrospective studies.
- Weighted risk ratios, difference in means, and standardized difference in means were used to combine studies and random effects models were used regardless of heterogeneity.
- Outcomes included SSCs, surgical site infections (SSIs), seroma, dehiscence, necrosis, return to operating room (ROR), Length of stay (LOS), incisional drainage and scaring.
- Cost analysis was performed using SSC rates from the included studies, risk reduction results from the meta-analysis, and estimated SSC costs from the Premier Healthcare Database.

Key Results

Surgical Site Complications

⬇47%

Reduction of risk of SSC*
11 studies
Risk Ratio 0.532 (95% CI 0.396, 0.715)
(p<0.001)*

Dehiscence†

⬇53%

Reduction of risk of Dehiscence*
9 studies
Risk Ratio 0.475 (95% CI 0.309, 0.73)
(p=0.001)*

Skin Necrosis†

⬇54%

Reduction of risk of Skin Necrosis*†
5 studies
Risk Ratio 0.460 (95% CI 0.284, 0.746)
(p=0.002)*

Length of Stay (LOS)

-0.6 days

Reduction of risk of Dehiscence*
Reduction of LOS*
5 studies
Difference in Means -0.610
(95% CI -0.822, -0.338) **(p<0.001)***

Calculation(s) are derived based on relative risk reduction or difference in means reported in this study
* Statistically significant (p<0.05)

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

Systematic Review and Meta-Analysis of 3M™ Prevena™ Therapy over closed plastic surgery incisions to reduce surgical site complications (2/2)

Gabriel A, Singh D, Silverman RP, Collinsworth A, Bongards C, Griffin L. Closed Incision Negative Pressure Therapy Versus Standard of Care Over Closed Plastic Surgery Incisions in the Reduction of Surgical Site Complications: A Systematic Review and Meta-Analysis of Comparative Studies. Eplasty. 2023 Mar 31;23:e22. PMID: 37187870; PMCID: PMC10176484.

Study Design

Systematic Review and Meta-Analysis

Study Purpose

Conduct a systematic review and meta-analysis to identify studies comparing Prevena Therapy to Control on plastic surgery incisions and to evaluate the effectiveness of closed incision negative pressure therapy (Prevena Therapy) versus Control dressings in reducing surgical site complications (SSCs)

Methods

- The systematic review included manuscripts and abstracts written in English and published between January 2005 to July 2021. Studies compared the use of Prevena Therapy to Control following plastic surgery.
- 16 studies were included: 1 randomized controlled trials, 4 prospective studies, 11 retrospective studies.
- Weighted risk ratios, difference in means, and standardized difference in means were used to combine studies and random effects models were used regardless of heterogeneity.
- Outcomes included SSCs, surgical site infections (SSIs), seroma, dehiscence, necrosis, return to operating room (ROR), Length of stay (LOS), incisional drainage and scaring.
- Cost analysis was performed using SSC rates from the included studies, risk reduction results from the meta-analysis, and estimated SSC costs from the Premier Healthcare Database.

Additional Results

Outcome	Statistic	# of Studies	Value (95% CI)	p-value
Drainage (mL)	Difference in Means	4	-157.500 mL (-327.156, -12.157)	0.069
Drain Days	Difference in Means	5	-1.966 days (-4.259, 0.327)	0.093
Return to the Operating Room	Risk Ratio	8	0.647 (0.401, 1.044)	0.074
Scarring 90 days (VSS)	Difference in Means	2	-5.111 VSS (-5.935, -4.287)	<0.001*
Scaring 12 month	Standardized Difference in Means	2	-1.728 (-3.44, -0.017)	0.048*
Scarring Overall (90 days + 12 month)	Standardized Difference In Means	3	-2.543 (-4.564, -0.521)	0.014

Calculation(s) are derived based on relative risk reduction or difference in means reported in this study
* Statistically significant (p<0.05)

Summary

- This systematic review and meta-analysis of 16 published studies demonstrated that the use of Prevena Therapy was associated with reduced risks of SSCs, dehiscence, necrosis, and hospital length of stay following plastic surgery.
- Potential cost savings of $904 per patient with the use of Prevena Therapy to help reduce the risk of SSCs.

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

3M Prevena™ Therapy evidence table

Plastic Surgery

- The body of evidence for using Prevena Therapy has been growing steadily since its launch in 2010
- The table listed below is based on the Evidence Rating Scale for Therapeutic Studies developed by the American Society of Plastic Surgeons (ASPS)[1]

Surgical Incision	ASPS Level of Evidence	First Author (Year)	Surgical Incision Type	Control	Postoperative Clinical Endpoints*
Breast Surgery – Breast Incision	2	Ferrando (2018)	Oncological Breast Surgery	Adhesive Skin closure	Surgical site complication (SSC), necrosis, scar assessment
	3	Gabriel (2018)	Breast reconstruction	Adhesive Skin closure	Surgical site infection (SSI), dehiscence, seroma, necrosis, SSC, return to the operating room (ROR), drain days
		Savage (2020)	Bilateral Breast Reduction	Standard Dressing	SSC, Wound Breakdown, Hospital length of stay (LOS), postoperative opioid use
		Wareham (2023)	Oncological Breast Surgery	Adhesive Skin Closure	SSC, dehiscence
		Abu (2022)	Chest Masculinization	Standard Dressing	SSC, seroma, partial nipple graft loss, nipple hypopigmentation, drain days
Breast Surgery – Donor Site	3	Munro (2022)	Deep inferior epigastric perforator abdominal flap incision	Standard Dressing	SSI, SSC, seroma, health economics (HE)
Abdominal Wall Reconstruction with Concomitant Panniculectomy	3	Ayuso (2021)	Open abdominal wall reconstruction with Concomitant Panniculectomy	Standard Dressing	Wound complication, wound breakdown, ROR
Pectoralis Major Muscle Flap	3	Lo Torto (2017)	Monolateral pectoralis major muscle flap (MPMF)	Standard Dressing	postoperative complications, dehiscence
Pressure Ulcer Reconstruction	2	Papp (2018)	Pressure Ulcer Reconstruction	Adhesive Skin Closure	Complications, LOS, Rate of open Wounds at 3 month, HE in publication
Amputation	3	Chang (2021)	Major Lower Extremity Amputation	Standard Dressing	Wound complications

* 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.

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

Improved outcomes with use of 3M™ Prevena™ Therapy after breast surgery in high-risk patients

Level of Evidence 3

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

Study Design

Prospective comparative (Level II)

Study Purpose

The study evaluated the use of Prevena Therapy for oncological breast surgery patients that were high-risk for unfavorable healing

Methods

- From January 2015 to June 2015, 37 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) received Prevena Therapy and 20 patients (22 surgeries) received Standard Care which involved Adhesive skin closure
- 90 days follow-up to evaluate postsurgical complications
- At 12 months, the quality of life, scar, and overall aesthetic outcomes were assessed

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

Key Results

Surgical Site Complications

⬇91%

Reduction in SSCs*
4 % (1/25) Prevena Therapy vs.
45 % (10/22) Adhesive skin closure
(p=0.001)*

Skin Necrosis†

⬇88%

Reduction in Skin Necrosis*†
4% (1/25) Prevena Therapy vs.
32% (7/22) Adhesive skin closure
(p=0.02)*

Patient Scar Assessment Scale (PSAS)

⬇45%

Improved patient-assessed PSAS score (max 50) at 12 months*
11 (6-18) Prevena Therapy vs.
20 (14-34) Adhesive skin closure
(p=0.002)*

Observer Scar Assessment Scale (OSAS)

⬇71%

Improved surgeon-assessed OSAS score (max 50)*
7 (6-13) Prevena Therapy vs.
24 (17-29) Adhesive skin closure
(p=0.01)*

Manchester Scar Scale (MSS)

⬇42%

Improved surgeon-assessed MSS score (max 18)*
7 (5-12) Prevena Therapy vs.
12 (9-15) Adhesive skin closure
(p=0.001)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Summary

- This study demonstrated 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 Manchester Scar Scale) and the patient (Patient Scar Assessment Scale) on level of satisfaction showed a significant difference in favor of Prevena Therapy.

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

Hypothetical Economic Model	Prevena™ Therapy	Adhesive Skin Closure
Number of Incisions (n)	25	22
Number of Surgical Site Complications (a)	1	10
Cost per SSC[1] (b)	$9,526	$9,526
Per Incision Complication Cost [c=(a*b)/n]	$381	$ 4,330
Per Incision Therapy Cost* (d)	$830	---
Total Cost Per Incision (c+d)	**$1,211**	**$ 4,330**
Potential Per Incision Savings Using Prevena™ Therapy	**$3,119**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

*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 versus Adhesive Skin Closure. 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: 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.

Reduced complications and reoperation after breast reconstruction with 3M™ Prevena™ Therapy

Level of Evidence 3

Breast

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. Pu

Study Design

Retrospective, comparative study (Level III)

Study Purpose

The investigators compared incision management outcomes in patients who received 3M™ Prevena™ Therapy after breast reconstruction mastectomy

Methods

- Single site retrospective observational study of adult female patients undergoing breast reconstruction post mastectomy between 2009 – 2017.
- Standard Care (179 patients/334 breasts) Adhesive skin closure; 3M™ Prevena™ Plus Customizable Dressing (177 patients; 331 breasts)
- July 2009 to July 2014 Standard Care; July 2014 to February 2016 mix of Standard Dressing and Prevena Therapy where high-risk patients received Prevena Therapy; March 2016 to October 2017 Prevena Therapy
- 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 were analyzed after propensity score stratification.
- Event reporting based on the Safety Analysis Dataset.

Key Results

Surgical Site Complications

⬇47%

Reduction in SSCs*
8.5 % (28/331) Prevena Therapy vs.
15.9 % (53/334) Adhesive skin closure
(p=0.0092)*

Dehiscence†

⬇56%

Reduction in Dehiscence*†
2.4 % (8/331) Prevena Therapy vs.
5.4 % (18/334) Adhesive skin closure
(p=0.0178)*

Surgical Site Infections

⬇53%

Reduction in SSIs*
2.1 % (7/331) Prevena Therapy vs.
4.5 % (15/334) Adhesive skin closure
(p=0.0225)*

Necrosis†

⬇45%

Reduction in Necrosis*†
5.1 % (17/331) Prevena Therapy vs.
9.3 % (31/334) Adhesive skin closure
(p=0.0070)*

Return to OR

⬇56%

Reduction in Reoperations*
2.4 % (8/331) Prevena Therapy vs.
5.4% (18/334) Adhesive skin closure
(p=0.0496)*

Seroma

⬇68%

Reduction in Seroma*
1.8 % (6/331) Prevena Therapy vs.
5.7 % (19/334) Adhesive skin closure
(p=0.0106)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant ($p<0.05$)

Summary

- 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.

Cost Savings

Reduction in per patient cost for SSC

- $2,010 Prevena Therapy vs. $2,228 Standard Dressing
- 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;143:36S

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

Reduced wound complications and opioid use after bilateral breast reduction with 3M™ Prevena™ Therapy

Level of Evidence 3

Breast

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

Study Design

Retrospective comparative cohort study (Level III)

Study Purpose

The purpose of the study was to evaluate the effect of closed incision negative pressure therapy (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 2014 to December 2018. 52 patients analyzed: Standard Dressing (n=29) and Prevena Therapy (n=23).
- Prevena Therapy was used for 7 days with no drains and no fitted garment
- Standard Dressing: 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

Key Results

Patients with Complications

⬇71%

Reduction in Complications*
13.0 % (3/23) Prevena Therapy vs.
44.8 % (13/29) Standard Dressing
(p=0.014)*

Hospital Length of Stay (LOS)

⬇33%

Reduction in LOS*
1.35 ± 0.49 days Prevena Therapy vs.
2.03 ± 0.33 days Standard Dressing
(p< 0.001)*

Wound Breakdown

⬇100%

Reduction in Wound Breakdown*
0 % (0/23) Prevena Therapy vs.
24.1 % (7/29) Standard Dressing
(p=0.013)*

Opioid Use

⬇27%

Reduction in opioid use in the total ward (mean)*
45.5 mg ± 38.25 Prevena Therapy vs.
62.5 mg ± 39.6 Standard Dressing
(p= 0.045)*

⬇45%

Reduction in opioids prescribed discharge (mean)*
125.5 mg ± 63.6 Prevena Therapy vs.
230.0 mg ± 115 Standard Dressing
(p< 0.001)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Summary

- This is the first study to provide evidence for the use of Prevena Therapy 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 decreased hospital length of stay.
- The authors report that the reduced opioid prescription at discharge represents almost 14 tablets of 5 mg oxycodone hydrochloride that were not prescribed.
- Regarding other complications, differences in wound infection, fat necrosis, and suture abscess were not statistically significant, and nipple necrosis was not observed in either group.
- The study was not limited to high-risk patients.

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

Hypothetical Economic Model	Prevena™ Therapy	Standard Dressing
Number of Patients (n)	23	29
Number of Surgical Site Complications (a)	3	13
Cost per SSC[1] (b)	$9,526	$9,526
Per Patient Complication Cost [c=(a*b)/n]	$1,243	$ 4,270
Per Patient Therapy Cost* @ $495 x 2 (d)	$990	---
Total Cost Per Patient (c+d)	**$2,233**	**$ 4,270**
Potential Per Patient Savings Using Prevena™ Therapy	**$2,037**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

*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 Dressing. 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: 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.

3M™ Prevena Restor™ Therapy in Oncoplastic Breast Surgery

Level of Evidence 3

Breast

Wareham CM, Karamchandani MM, Ku GC, Gaffney K, Sekigami Y, Persing SM, Homsy C, Nardello S, Chatterjee A. Closed Incision Negative Pressure Therapy in Oncoplastic Breast Surgery: A Comparison of Outcomes. Plast Reconstr Surg Glob Open. 2023 Apr 25;11(4):e4936.

Study Design

Retrospective, comparative study (Level III)

Study Purpose

This study evaluated the effect of 3M™ Prevena Restor™ Bella•Form™ Incision Management System vs. standard care to reduce clinically relevant wound complications in Oncoplastic breast surgery.

Methods

- 217 patients with breast conservation surgery involving partial mastectomy with immediate volume displacement or replacement techniques between Jan 2015 and Dec 2021 were included in this study.
- 75 patients received Prevena Restor Bella•Form™ Therapy and were compared to 142 standard care patients who received skin glue and adhesive skin closure tape
- The decision to use Prevena Restor Therapy was based on individual surgeons' discretion, primarily based on patients predisposing risk factors such as obesity smoking, previous skin incisions, immunosuppression etc.
- Primary outcome was clinically significant complications (hematoma, seroma, fat necrosis, wound dehiscence, nipple loss, hypertrophic scarring and infection) which required medical or operative intervention occurring during a 6month to 2 year follow-up
- Secondary outcomes were rates of minor complications not requiring significant medical or clinical intervention.

Key Results

Wound Complications

⬇69%

Reduction in Wound Complications requiring intervention*
5.3% (4/75) Prevena Restor Therapy vs.
16.9% (24/142) Adhesive skin closure
(p=0.016)*

Dehiscence†

⬇100%

Reduction in Dehiscence*†
0% (0/75) Prevena Restor Therapy vs.
5.6% (8/142) Adhesive skin closure
(p=0.036)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
Statistically significant (p<0.05)

Additional Results

Number of Complications	Prevena Restor Therapy N=75	Adhesive skin closure N=142	p-value
0	84.7% (71/75)	83.1% (118/142)	0.044*
1	5.3% (4/75)	14.1% (20/142)	
≥ 2	0% (0/75)	2.8% (4/142)	

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Summary

- In this study, patients receiving Prevena Restor Therapy had statistically significant lower rates of wound complications and dehiscence. There were no statistically significant differences in the rates of other complications.
- Prevena Restor™ Bella•Form™ dressing use was at the surgeons' discretion, primarily on high-risk patients. This group had higher baseline BMIs, ASA levels, and preoperative macromastia symptoms, which increased their risk for complication. Complications were lower in this population despite their increased risk.
- The authors recommend to consider 3M™ Prevena Restor™ Therapy in the oncoplastic population, especially for patients with increased risk for postoperative complications.

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

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

Hypothetical Economic Model	Prevena Restor™ Therapy	Adhesive skin closure
Number of Patients (n)	75	142
Number of Surgical Site Complications (a)	4	24
Cost per SSC[1] (b)	$9,526	$9,526
Per Patient Complication Cost [c=(a*b)/n]	$508	$1,610
Per Patient Therapy Cost* (d)	$750	---
Total Cost Per Patient (c+d)	**$1,258**	**$1,610**
Potential Per Patient Savings Using Prevena™ Therapy	**$352**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

*3M™ Prevena Restor™ Bella•Form™ Incision Management System 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 Adhesive skin closure. 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: Wareham CM, Karamchandani MM, Ku GC, Gaffney K, Sekigami Y, Persing SM, Homsy C, Nardello S, Chatterjee A. Closed Incision Negative Pressure Therapy in Oncoplastic Breast Surgery: A Comparison of Outcomes. Plast Reconstr Surg Glob Open. 2023 Apr 25;11(4):e4936

3M™ Prevena™ Therapy for Chest Masculinization Gender-Affirming Surgery

Level of Evidence 3

Breast

Abu El Hawa AA, Dekker PK, Mizher R, Orra S, Fan KL, Del Corral G. Utility of Negative Pressure Wound Therapy: Raising the Bar in Chest Masculinization Surgery. Plast Reconstr Surg Glob Open. 2022 Feb 11;10(2):e4096

Study Design

Retrospective, comparative study (Level III)

Study Purpose

This study compared outcomes in patients undergoing chest masculinization with free nipple graft (FNG) that received closed incision negative pressure therapy (3M™ Prevena™ Therapy) vs. standard dressings.

Methods

- Single center/Single provider retrospective study of transgender patients with simple mastectomy with FNG between 2018 and 2020.
- 131 patients / 262 breasts (Prevena Therapy n=72; n=190 Standard Dressing (occlusive petrolatum gauze).
- Minor complications included uncomplicated hematoma, surgical site infection, or partial nipple graft loss/necrosis. Partial nipple graft loss defined as any skin changes greater than 5mm.
- Major complications included hematomas requiring surgical decompression, wound dehiscence, or total FNG necrosis.
- 90-day complication rates were evaluated. Drains (1 per breast) were removed when output was less than 20ml for two consecutive days.
- Postoperative follow-up care was standardized across all patients in the study population.

Key Results

Wound Complications

⬇57%

Reduction in Wound Complications*
18% (13/72) Prevena Therapy vs.
42% (80/190) Standard Dressing
(p<0.001)*

Partial Nipple Graft Loss (PGL)

⬇49%

Reduction in Partial NGL*
12.5% (9/72) Prevena Therapy vs.
24.7% (47/190) Standard Dressing
(p=0.031)*

Seromas

⬇82%

Reduction in Seromas*
1.4% (1/72) Prevena Therapy vs.
7.9% (15/190) Standard Dressing
(p=0.037)*

Nipple Hypopigmentation

⬇56%

Reduction Nipple Hypopigmentation*
8.3% (6/72) Prevena Therapy vs.
18.9% (36/190) Standard Dressing
(p=0.024)*

Drain Days

-2 days

Reduction in Time to Drain Removal*
7 days Prevena Therapy vs.
9 days Standard Dressing
(p≤0.001)*

Calculation(s) are derived based on the 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 partial nipple graft loss (PGL) and nipple hypopigmentation has not been reviewed by the U.S. FDA

Summary

- In this study, patients receiving Prevena Therapy following chest masculinization gender-affirming surgery with FNG had significantly lower rates of wound complications, seroma formations, partial NGL, and nipple hypopigmentation. Time to drain removal was also significantly shorter for Prevena Therapy patients. Differences in total nipple graft loss, dehiscence, SSI, and Hematoma were not statistically significant.
- Lower rates of partial FNG necrosis in the Prevena Therapy cohort occurred across all BMI categories (20-25, 25-30, >35).
- Reducing complications after chest masculinization surgery is important for optimizing patient care but also optimizing access to surgical care for the transgender population.

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

Hypothetical Economic Model	Prevena™ Therapy	Standard Dressing
Number of Incisions (n)	72	190
Number of Surgical Site Complications (a)	13	80
Cost per SSC[1] (b)	$9,526	$9,526
Per Incision Complication Cost [c=(a*b)/n]	$1,720	$4,011
Per Incision Therapy Cost* (d)	$495	---
Total Cost Per Incision (c+d)	**$2,215**	**$4,011**
Potential Per Incision Savings Using Prevena™ Therapy	**$1,796**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

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

The above model uses selected study data to illustrate estimates of costs for the use of the Prevena™ Therapy or Standard Dressing. 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: Abu El Hawa AA, Dekker PK, Mizher R, Orra S, Fan KL, Del Corral G. Utility of Negative Pressure Wound Therapy: Raising the Bar in Chest Masculinization Surgery. Plast Reconstr Surg Glob Open. 2022 Feb 11;10(2):e4096

Cost-Benefit of 3M™ Prevena™ Therapy for DIEP Flap Donor Sites

Level of Evidence 3

Flap Donor Site

Munro SP, Dearden A, Joseph M, O'Donoghue JM. Reducing donor-site complications in DIEP flap breast reconstruction with closed incisional negative pressure therapy: A cost-benefit analysis. J Plast Reconstr Aesthet Surg. 2023 Mar;78:13-18

Study Design

Retrospective, comparative study (Level III)

Study Purpose

The study objective was to determine clinical and cost benefit in patients who received 3M™ Prevena™ Therapy versus Standard Dressing for deep inferior epigastric perforator (DIEP) flap donor sites

Methods

- Single site retrospective comparative study conducted Mar 2017 – Sep 2021 with patients undergoing microsurgical autologous breast reconstruction with DIEP flaps
- 44 donor site incisions were included (3M™ Prevena™ Plus Incisional Management System n=24 vs. Standard Dressing n=20)
- Prevena Therapy was removed before day seven and was compared to standard post operative dressings
- Patient demographics, wound drainage volumes and postoperative outcomes were compared.
- Cost-benefit analysis using National Health Service (NHS) tariff costs compared the overall cost associated with each complication and differences in length of stay between study groups.

Key Results

Donor Site Complications

⬇67%

Reduction in donor site complications*
16.7% (4/24) Prevena Therapy vs.
50% (10/20) Standard Dressing
(p=0.018)*

Seroma

⬇72%

Reduction in Seroma*
12.5% (3/24) Prevena Therapy vs.
45% (9/20) Standard Dressing
(p=0.016)*

Surgical Site Infections (SSIs)

⬇100%

Reduction in SSIs*
0% (0/24) Prevena Therapy vs.
25.0% (5/20) Standard Dressing
(p=0.014)*

Cost of Complications**

⬇45%

Reduced Cost of SSC Care and postoperative follow-up cost*
£509 Prevena Therapy vs.
£930 Standard Dressing
(p=0.031)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant ($p<0.05$)

**Excluding cost for dressings of £200 for 3M™ Prevena™ Plus Incisional Management System and £10 for Standard Dressing

Summary

- The study suggests that Prevena Therapy is a cost-effective option for reducing postoperative complications for donor site incisions compared to standard dressings.
- The Prevena Therapy patients had significantly lower rates of SSCs, SSIs, and Seromas. There was no difference in drainage volumes or time to drain removal.
- There was a significant difference in cost of complications of £420 per patient (Prevena Therapy £509 vs. Standard Dressing £930; p=0.031) which is greater than the cost of the dressing at £200. Therefore, the increased costs of Prevena Therapy is possibly outweighed by the reduction in postoperative follow-up and cost of complications.

3M™ Prevena™ Therapy for open abdominal wall reconstruction with concomitant panniculectomy

Level of Evidence 3

Abdominal Wall Reconstruction

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

Retrospective Cohort Study (Level III)

Study Purpose

To evaluate the use of closed-incision negative pressure therapy (Prevena Therapy) 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 historical patients that received standard surgical dressings.
- In the study period, patient prehabilitation and perioperative protocols at the institution were the same which aids in eliminating confounders.
- 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

Key Results

Wound Complications

⬇56%

Reduction in Wound Complications*
15.6% Prevena Therapy vs.
35.5% Standard Dressing
(p=0.01)*

Wound Breakdown

⬇84%

Reduction in Superficial Wound Breakdown*
3.1% Prevena Therapy vs.
19.7% Standard Dressing
(p<0.01)*

Return to Operating Room

⬇100%

Reduction in number of OR Visits*
0% Prevena Therapy vs.
13.3% Standard Dressing
(p<0.01)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

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 complications, including superficial wound breakdown. Reductions in the other wound complication types were not statistically significant.
- The study also demonstrated the lessened need for wound-related reoperations in Prevena Therapy patients. Reductions in length of stay, readmission, and hernia recurrence were not statistically significant.
- Using the Carolinas Equation for Determining Associated Risks (CEDAR) application, the absolute risk reduction for wound complications was calculated to be 11.9% when Prevena Therapy was used.
- In a logistic regression analysis, the use of Prevena Therapy was predictive of a lower rate of wound complications (95% CI 0.14,0.86; p = 0.02).

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

Hypothetical Economic Model	Prevena™ Therapy	Standard Dressing
Number of Patients (n)	100	100
Number of Surgical Site Complications (a)	16	36
Cost per SSC[1] (b)	$9,526	$9,526
Per Patient Complication Cost [c=(a*b)/n]	$1,524	$3,429
Per Patient Therapy Cost* (d)	$830	---
Total Cost Per Patient (c+d)	**$2,354**	**$3,429**
Potential Per Patient Savings Using Prevena™ Therapy	**$1,075**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

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

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Reference: 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

3M™ Prevena™ Therapy for pectoralis major muscle flap for sternal reconstruction

Level of Evidence 3

Major Muscle Flap

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.

Study Design

Retrospective Single Centre Comparative Cohort Study (Level III)

Study Purpose

To evaluate the effect of Prevena Therapy after monolateral pectoralis major muscle flap (MPMF) for sternal reconstruction.

Methods

- All patients presented with a deep sternal wound infection (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.
- 30 patients received Prevena Therapy; 48 patients received standard dressings.
- 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

Key Results

Adverse Event & Complications

⬇65%

Reduction in Adverse Events & Complications*
13% (4/30) Prevena Therapy vs.
37.5% (18/48) Standard Dressing

Dehiscence†

⬇100%

Incidence in Dehiscence*†
0% (0/30) Prevena Therapy vs.
15% (7/48) Standard Dressing
(p=0.0394)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Summary

- Prevena Therapy reduced significantly wound complications after pectoralis major muscle flap surgery for treatment of DSWI.
- Most remarkable was the significant reduction in sternum dehiscence with use of Prevena Therapy after major muscle flap surgery for treatment of DSWI. There were no statistically significant differences for seroma or hematoma rates.
- Adverse events occurred in 37.5% of patients receiving standard dressings compared to only 13% of patients receiving Prevena Therapy.
- Although not statistically significant (p = 0.1433), 7 of 48 patients (15%) receiving standard dressings required surgical revision compared to only 1 of 30 patients (3%) receiving Prevena Therapy.

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

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

Hypothetical Economic Model	Prevena™ Therapy	Standard Dressing
Number of Patients (n)	30	48
Number of Surgical Site Complications (a)	4	18
Cost per SSC[1] (b)	$9,526	$9,526
Per Patient Complication Cost [c=(a*b)/n]	$1,270	$3,572
Per Patient Therapy Cost* (d)	$495	---
Total Cost Per Patient (c+d)	**$1,765**	**$3,572**
Potential Per Patient Savings Using Prevena™ Therapy	**$1,807**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

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

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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.

Reduced Complications and Costs in Pressure Ulcer Reconstruction with 3M™ Prevena™ Therapy

Level of Evidence 2

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 Standard Dressing (Level II)

Study Purpose

Study aims to decrease postoperative wound-healing complications with 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 Adhesive skin closure data was 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

Key Results

General in-hospital complications

⬇74%

Reduction in complications*
10.8% Prevena Therapy vs.
41.7% Adhesive skin closure
(p=0.0051)*

Hospital Length of Stay (LOS)

⬇27%

Reduction in hospital LOS*
24.8 days Prevena Therapy vs.
33.8 days Adhesive skin closure
(p=0.0103)*

Open Wounds 3 months postoperative

⬇78%

Reduction in number of open wounds at 3 months postoperative*
5.4% Prevena Therapy vs.
25.0% Adhesive skin closure
(p=0.0481)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Summary

- Results showed benefit to use Prevena Therapy following pressure ulcer reconstruction sites no complications or side-effects related to the use of the dressing.
- Patients receiving Adhesive skin closure were 4.3 times more likely to have a complication (OR 0.232; 95% CI 0.060, 0.897).
- 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 with Prevena Therapy

Decreased rate of wound complication occurrence observed in patients with vascular disease undergoing major lower extremity amputation with 3M™ Prevena™ Therapy

Level of Evidence 3

Amputations

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 (Level III)

Study Purpose

This study evaluated 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 patient limbs with history of peripheral arterial disease that 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 (Standard Dressing)
- Patients in the NPWT arm of the study presented a higher incidence of comorbidities (tobacco use, previous amputation, COPD, etc.) vs Standard Dressing 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)

Key Results

Wound Complications

⬇67%

Reduction in Wound Complications*
13 % (3/23) Prevena™ Therapy vs.
39 % (12/31) Standard Dressing
(p=0.037)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Additional Outcomes

Outcome	Prevena Therapy	Standard dressing	p-value
Overall Wound Complications	13% (3/23)	39% (12/31)	**0.037***
Deep SSI†	4% (1/23)	13% (4/31)	0.283
Superficial SSI	4% (1/23)	10% (3/31)	0.046
Necrosis†	4% (1/23)	13% (4/31)	0.283
Hematoma†	0% (0/23)	3% (1/31)	0.385

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

Summary

- Perioperative wound complications were significantly reduced within the Prevena Therapy group although there were increased comorbidities and risk factors.
- The reduction of perioperative wound complications and superficial SSI was statistically significant while there was no difference in other outcomes measured.
- Study suggest that Prevena Therapy may reduce the incidence of wound complications in vascular patients undergoing major lower extremity amputations, including high risk patients.
- Prevena Therapy may be considered for use in major lower extremity amputations.

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

Hypothetical Economic Model	Prevena™ Therapy	Standard Dressing
Number of Patients (n)	23	31
Number of Surgical Site Complications (a)	3	12
Cost per SSC[1] (b)	$9,526	$9,526
Per Patient Complication Cost [c=(a*b)/n]	$1,243	$3,687
Per Patient Therapy Cost* (d)	$830	---
Total Cost Per Patient (c+d)	**$2,073**	**$3,687**
Potential Per Incision Savings Using Prevena™ Therapy	**$1,615**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

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Reference: 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.

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

References:

1. *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*
2. *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.*

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

Inclusion criteria for patients at high-risk for complications:

Pectoralis Major Muscle Flap

All Pectoralis Major Muscle Flap patients included had at least 1 major risk factor:

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

Reference:

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.

Abdominal Wall Reconstruction with Concomitant Panniculectomy

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

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

Oncological Breast Surgery

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

Reference:

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