Proactive Risk Management with closed incision negative pressure therapy (ciNPT)

A Solventum ciNPT Clinical Compendium

June 2024

Letter from the editor

Dear Colleagues,

It is our pleasure to bring you this updated compendium of evidence-based guidance for the use of 3M™ Prevena™ Therapy for proactive risk management in a variety of clinically specific applications. The use of negative pressure therapy over closed surgical incisions is established as an effective way to reduce surgical site complications in at-risk patients.

Prevena Therapy delivers negative pressure therapy to the closed incision to help optimize outcomes and reduce complications. Over 220 peer-reviewed publications studying Prevena Therapy provide validated guidance to therapeutic decision making. These documents are provided to complement clinical judgment in the care of appropriate patients.

We believe that use of Prevena Therapy for proactive risk management can help achieve better outcomes, including reduced risk of complications, accelerated recovery, and decreased total cost of care. We hope you find these documents of value.

Sincerely,

Sadhana Trivedi, MBBS
Global Medical Director
MedSurg, Solventum

Sadhana Trivedi, MBBS

Dr. Sadhana Trivedi is the Global Medical Director, MedSurg for Solventum. She is a Plastic & Reconstructive Surgeon and holds 15 years of clinical experience in Ireland & India. In her current role, she is responsible for new product introduction, post-market clinical follow-up, clinical trial designs and regulatory submissions.

Dr. Trivedi has worked with Bristol Myers Squibb for pre-launch preparation and launch of innovative medications. While working with Allianz Care, she led the Medical Affairs department of Allianz Care and delivered global value-based healthcare including the development of medical strategy, clinical services, medical education programs, and settlement of medical claims.

Dr. Trivedi is passionate about the future of healthcare and the potential of data and technology to transform the quality of healthcare and improve outcomes.

Dr. Trivedi has a keen interest in education and delivers lectures at the University College of Dublin, Ireland, and Griffith College Dublin, Ireland on medical innovations and transformation in healthcare. She is also a board member of the Irish Medtech Association, Chair of Medtech Connect, Vice chair of Research Development and Innovation working group of Irish Medtech in Ireland.

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

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Help protect your patients with 3M™ Prevena™ Therapy

Implement Proactive Risk Management (PRM)

PRM with 3M™ Prevena™ Therapy provides healthcare professionals with an evidence-based, standardized approach that helps to advance the standard of care for closed incision negative pressure therapy (ciNPT). This intuitive, actionable model is grounded in level 1, 2 and 3 clinical evidence to help support you through procedural and patient risk stratification.

The costly reality of at-risk incisions

In an increasingly complex healthcare environment, surgeons are faced with unique challenges that can negatively affect outcomes. Effectively managing the risk of postoperative complication is a priority.

- Surgical site infections (SSIs) account for 22%–36% of all healthcare-associated infections (HAIs)[1,2]
- Patients with an SSI are 6X more likely to have a 30-day readmission[3]
- The average added cost from SSIs is $38,656[4]
- A patient who develops an SSI has on average a 9.58 day longer hospital stay[4]
- A patient who develops an SSI has on average a 2.2X longer ICU stay[3]

In a 2023 Multi-Specialty Meta-Analysis, Prevena Therapy has demonstrated significant improvement in key patient outcomes across multiple specialties.[5]

46%	Reduction in surgical site complications (SSCs)[5]
48%	Reduction in SSIs[5]
36%	Reduction in return to OR[5]
23%	Reduction in readmission[5]

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.

References

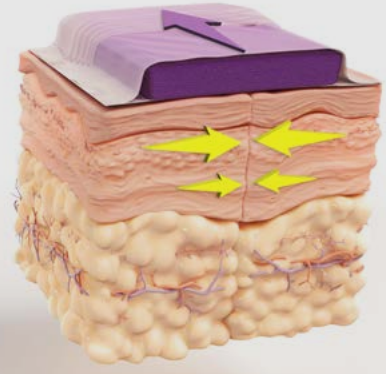
1. Zimlichman E, Henderson D, Tamir, et al. Health care-associated Infections a meta-analysis of costs and financial impact on the U.S. health care system. *JAMA Intern Med.* 2013;173(22):20-46. 2. Magill SS, Edwards JR, Bamberg W, et al. Multistate point-prevalence survey of health care-associated Infections. *N Engl J Med.* 2014;370:1198-208. 3. Shepard J, Ward W, Milstone A, et al. Financial impact of surgical site infections on hospitals. The hospital management perspective. *JAMA Surg.* 2013;148(10):907-914. 4. Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. *JAMA.* 2003;290(14):1868-1874. 5. Cooper HJ, Singh DP, Gabriel A, Mantyh C, Silverman R, Griffin L. Closed incision negative pressure therapy versus standard of care over closed surgical incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies. *Plast Reconstr Surg Glob Open.* 2023 Mar 16;11(3):e4722.

3M™ Prevena™ Therapy mechanism of action

Acts as a barrier to external contamination[1]

Delivers continuous -125 mmHg up to 14 days*

Removes fluids and infectious materials[2,†]



Direction of fluid

Appositional force

Helps to hold incision edges together[3]

Decreases lateral tensions of sutured/ stapled incisions[3,‡]

Reduces edema[4]

Additional benefits unique to 3M™ Prevena™ Dressings:

Under negative pressure, reticulated open-cell foam dressing collapses to its geometric center

Contours allow for even distribution of negative pressure

Skin interface layer contains 0.019% ionic silver to help reduce bacterial colonization in the fabric

Available in multiple sizes and configurations for a variety of patients

Prevena Therapy can support clinicians with earlier patient discharge to a home setting:

- Portable, single-use therapy for up to 14 days
- Audible and visual alarms
- Dedicated patient support line: **1-800-275-4524**

Watch the video

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. Colli A. First experience with a new negative pressure incision management system on surgical incisions after cardiac surgery in high risk patients. *J Cardiothorac Surg.* 2011 December 6;6(1):160. **2.** 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 Regen.* 2011;19(5):588-96. **3.** Wilkes RP, Kilpadi DV, Zhao Y, Kazala R, McNulty A. Closed incision management with negative pressure wound therapy (CIM): Biomechanics. *Surg Innov.* 2012 March 1;19(1):67-75. **4.** Glasser DA, Farnsworth CL, Varley ES, et al. Negative pressure therapy for closed spine incisions: A pilot study. *Wounds.* 2012;24(11):308-16.

* Dressing change required at 7 days
† In a canister
‡ In computer bench models

Closed incision negative pressure therapy versus standard of care over closed surgical incisions in the reduction of surgical site complications: A systematic review and meta-analysis

Cooper HJ, Singh DP, Gabriel A, et al. *Plast Reconstr Surg Glob Open.* 2023;11(3):e4722.
Published 2023 Mar 16.

Background

- Surgical site complications (SSCs), such as surgical site infection (SSI), dehiscence, seroma, hematoma and skin necrosis, can negatively affect patient outcomes and health care costs.
- Surgical site management options, including closed incision negative pressure therapy (ciNPT*), have been developed to help mitigate the risk of SSC development.
- ciNPT use has been associated with positive patient outcomes across many surgical specialties.[1-6]

Study purpose

This systematic review and meta-analysis evaluated the effect of ciNPT on post-surgical and health economic outcomes across published studies.

Methods

- A systematic literature search using PubMed, EMBASE, and QUOSA was performed.
- Publications written in English, comparing ciNPT to standard of care dressings (SOC) between January 2005 and August 2021 were assessed.
- Characteristics of study participants, surgical procedure, dressing used, duration of treatment, post-surgical outcomes, and follow-up data were extracted.

Results

- The literature search identified 84 studies for analysis.
- Significant reductions in SSC rates in favor of ciNPT use were found ($p<0.001$).
- Significant reductions in SSI ($p<0.001$), superficial SSI ($p<0.001$), deep SSI ($p=0.002$), seroma ($p=0.002$), dehiscence ($p=0.022$) and skin necrosis ($p=0.001$) were associated with ciNPT use ($p<0.05$).
- Reduced readmissions and reoperations were significant in favor of ciNPT ($p<0.05$).
- ciNPT patients had a 0.9 day shorter hospital stay than patients receiving SOC ($p<0.001$).
- Differences in post-operative pain scores and reported amounts of opioid usage were significant in favor of ciNPT use ($p<0.05$).
- While post-operative drainage and antibiotic usage were reduced in ciNPT patients, they were not significant.

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*3M™ Prevena™ Incision Management System (3M, St. Paul, MN)

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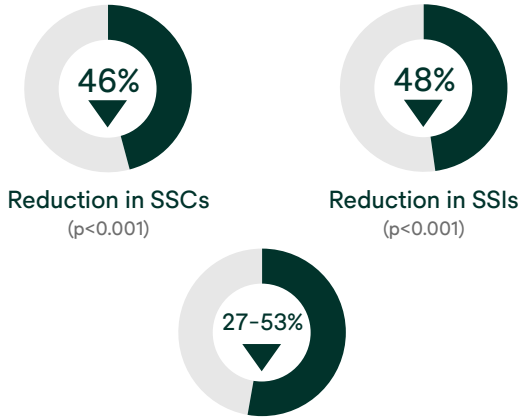
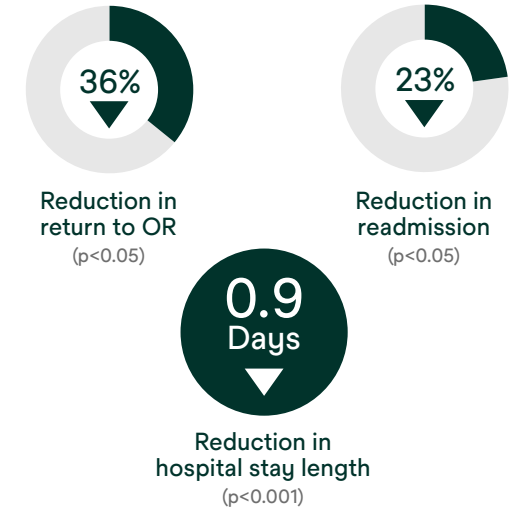
Clinical complications



Health economic outcomes



Conclusions

- For these meta-analyses, the use of ciNPT was associated with a statistically significant reduction in the incidence of SSCs, SSIs, seroma, dehiscence and skin necrosis.
- Reduced readmissions, reoperations, and length of hospital stay were also observed in ciNPT patients as well as decreased pain and opioid use.
- Study limitations include mix of observational studies and randomized controlled trials, a mix of surgical specialties, and differences in data reporting across the included articles.
- It should be noted that the data are related to one commercially available ciNPT system and may not be applicable to other available systems due to differences in the devices.
- Surgeons should consider all available data before considering whether or not to use a particular ciNPT device.

***NOTE: Hematoma did not reach significance but was trending towards the use of the treatment**

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

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.

References
1. Cooper HJ, Roc GC, Bas MA, et al. *Injury.* 218;49(2):386-391. 2. Ruggieri VG, Olivier ME, Aludaat C, et al. *Heart Surg Forum.* 2019;22(2):E092-E096. 3. Licari L, Campanella S, Carolla C, et al. *Cureus.* 2020;12(5):e8283. 4. Swift SH, Zimmerman MB, Hardy-Fairbanks AJ. *J Reprod Med.* 2015;60(5-6):211-218. 5. Ferrando PM, Ala A, Bussone R, et al. *Plast Reconstr Surg Glob Open.* 2018;6(6):e1732. 6. Pleger SP, Nink N, Elzien M, et al. *Int Wound J.* 2018;15(1):75-83.

[1]Columbia University Irving Medical Center, New York, New York; [2]University of Miami Health System and Miller School of Medicine, Miami, FL; [3]Plastic Surgery, Vancouver, WA; [4]Duke University School of Medicine, Durham, NC; [5]University of Maryland School of Medicine, Baltimore, MD; [6]3M, St Paul, MN

Read the full study here

Journal: *Plastic and Reconstructive Surgery - Global Open*

Title: Closed incision negative pressure therapy versus standard of care in reduction of surgical site complications: A systematic review and meta-analysis

Published: March 16, 2023

Cooper HJ, Singh DP, Gabriel A, et al. Closed incision negative pressure therapy versus standard of care in reduction of surgical site complications: A systematic review and meta-analysis. *Plast Reconstr Surg Glob Open.* 2023;11(3):e4722. Published 2023 Mar 16. OPEN ACCESS

Patients and procedures that may benefit from 3M™ Prevena™ Therapy[1]

A multidisciplinary group of surgical and infectious disease experts developed an algorithm to guide when to consider using closed incision negative pressure therapy (Prevena Therapy).

Consensus recommendations based on:

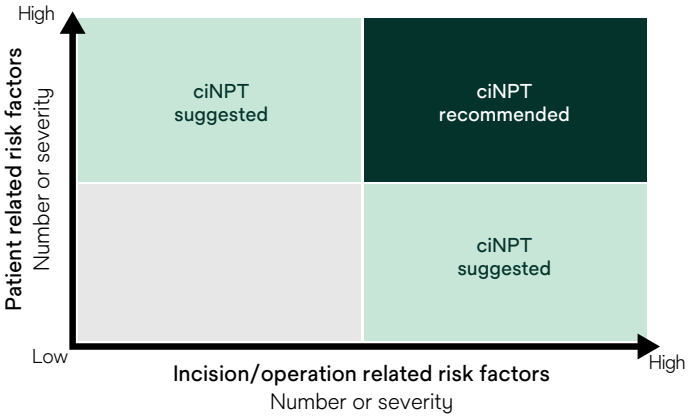
- Literature review
- ciNPT experiences
- Known risk factors for surgical site occurrences (SSOs)

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

Surgeons may consider using ciNPT for patients at high risk for developing SSOs or who are undergoing a high-risk procedure or a procedure that would have highly morbid consequences if an SSI occurred.

Risk factors assessment for closed incision negative pressure therapy (ciNPT):



Additional factors to consider:

Patient related risk factors

- Diabetes mellitus
- ASA Score ≥3
- Advanced age
- Obesity
- Active tobacco use
- Hypoalbuminemia
- Corticosteroid usage
- Active alcoholism
- Male sex
- Hematoma
- Chronic renal insufficiency
- Chronic obstructive pulmonary disease

General incision related risk factors

- High tension incision
- Repeated incisions
- Extensive undermining
- Traumatized soft tissue
- Edema
- Contamination
- Emergency procedure
- Prolonged operation time
- Post-surgical radiation
- Mechanically unfavorable site

Procedure/operation related risk factors

General

- Open general
- Open colorectal
- Open urology
- Open OB/Gyn
- Incisional hernia repair

Plastic

- Post-bariatric abdominoplasty
- Breast reconstruction
- Big soft tissue defects
- Soilage risk

Orthopedic

- Open reduction and internal fixation of fractures
- Fasciotomy
- Above/below knee amputation

Vascular

- Above/below knee amputation
- Synthetic graft implantations

Cardiovascular

- Sternotomy

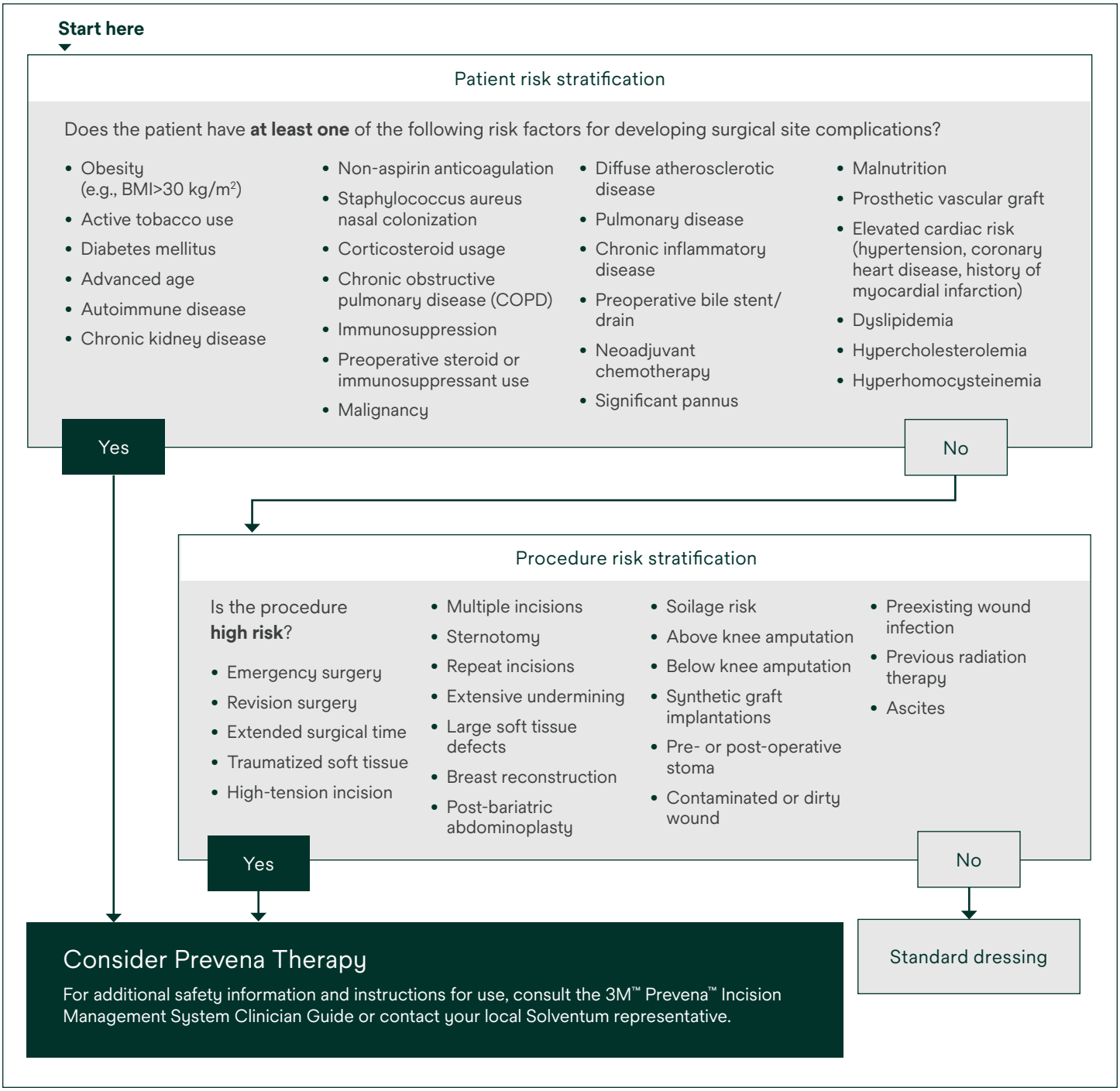
Read the full study here

Reference
1. 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.

Decision guide

Patient and procedure risk stratification backed by clinical evidence

While surgical patients may benefit from Prevena Therapy, patients at risk for complications such as surgical site infection may see added benefit. The following uses select study data[1-16] to provide an illustrative guide to aid in risk stratification. This is not an all-inclusive list of risk factors. Clinicians are advised to use their clinical judgment to identify at-risk patients and procedures.



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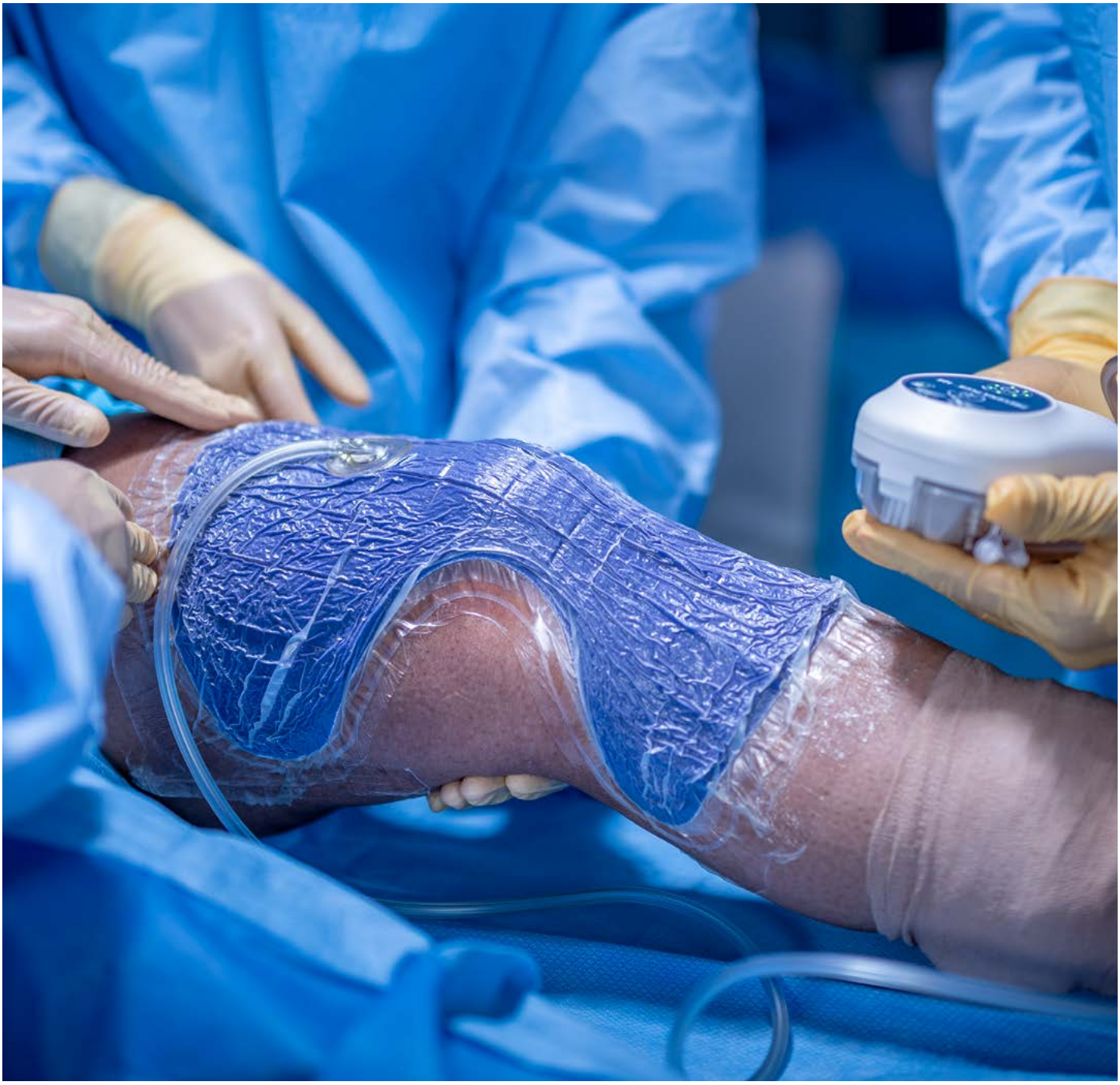
The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at hcbgregulatory.3m.com.

References

1. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: International multidisciplinary consensus recommendations. *Int Wound J.* 2017 Apr;14(2):385-398. OPEN ACCESS 2. Curran T, Alvarez D, Pastrana Del Valle J, Cataldo TE, Poylin V, Nagle D. Prophylactic closed incision negative pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds. *Colorectal Dis.* 2019 Jan;21(1):110-118. OPEN ACCESS 3. Javed AA, Teinor J, Wright M, et al. Negative pressure wound therapy for surgical-site infections: A randomized trial. *Ann of Surg.* 2019 Jun;269(6):1034-1040. 4. Zaidi A, El-Masry S. Closed incision negative pressure therapy in high-risk general surgery patients following laparotomy: A retrospective study. *Colorectal Dis.* 2017 Mar;19(3):283-287. OPEN ACCESS 5. Licari L, Campanella S, Carolla C, Viola S, Salamone G. Closed incision negative pressure therapy achieves better outcome than standard wound care: Clinical outcome and cost-effectiveness analysis in open ventral hernia repair with synthetic mesh positioning. *Cureus.* 2020;12(5):e8283. OPEN ACCESS 6. 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 Apr 1;88(4):429-433. 7. Cheong Chung JN, Ali O, Hawthornthwaite E, et al. Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis. *Surgery.* 2021 May 26:S0039-6060(21)00334-2. 8. Lakhani A, Jamel W, Riddiough GE, Cabalag CS, Stevens S, Liu DS. Prophylactic negative pressure wound dressings reduces wound complications following emergency laparotomies: A systematic review and meta-analysis. *Surgery.* 2022 Sep;172(3):949-954. 9. Grauhan O, Navasardyan A, Hofmann M, Muller P, Stein J, Hetzer R. Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy. *J Thorac Cardiovasc Surg.* 2013 May;145(5):1387-92. OPEN ACCESS 10. Suelo-Calanao RL, Thomson R, Read M, et al. The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high risk cases: A single centre retrospective study. *J Cardiothorac Surg.* 2020 Aug 19;15(1):222. OPEN ACCESS 11. Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, et al. The effectiveness of closed-incision negative-pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty: The PROMISES randomized controlled trial. *J Arthroplasty.* 2021 Jul;36(7S):S295-S302.e14. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use. 12. Newman JM, Siqueira MBP, Klika AK, Molloy RM, Barsoum WK, Higuera CA. Use of closed incisional negative pressure wound therapy after revision total hip and knee arthroplasty in patients at high risk for infection: A prospective, randomized clinical trial. *J Arthroplasty.* 2019 Mar;34(3):554-559. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use. 13. 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 Aug; 6(8):e1880. OPEN ACCESS 14. Kwon J, Staley C, McCullough M, et al. A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications. *J Vasc Surg.* 2018 Dec;68(6):1744-1752. OPEN ACCESS 15. Gombert A, Babilon M, Barbati ME, et al. Closed incision negative pressure therapy reduces surgical site infections in vascular surgery: A prospective randomised trial (AIMS trial). *Eur J Vasc Endovasc Surg.* 2018 Sept; 56(3):442-448. OPEN ACCESS 16. Pleger SP, Nink N, Elzien M, Kunold A, Koshty A, Böning A. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): A prospective, randomised, single-institution study. *Int Wound J.* 2018 Feb;15(1):75-83. OPEN ACCESS



PRM in orthopedic surgery

Prevena.com/orthopedics

3M™ Prevena Restor™ Dressings can be used on a variety of anatomical locations.

Closed incision negative pressure therapy vs standard of care over closed knee and hip arthroplasty surgical incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies

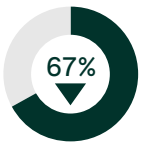
Cooper HJ, Silverman RP, Collinsworth A, Bongards C, Griffin L. *Arthroplast Today.* 2023 Apr 3;21:101120.

Study design
Systematic review and meta-analysis

Study purpose
Conduct a systematic review and meta-analysis to identify studies comparing Prevena Therapy to standard dressings on closed hip and knee arthroplasty incisions and to evaluate the effectiveness of Prevena Therapy versus standard 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 ciNPT to standard dressing following primary or revision knee or hip arthroplasty.
- Standard dressing groups received silver-impregnated occlusive dressings or conventional dry dressings.
- 12 studies were included: 4 randomized controlled trials, 2 prospective studies, 6 retrospective studies. 8 of these studies were on high-risk populations.
- Weighted risk ratios were used to combine studies and random effects models were used regardless of heterogeneity.
- Outcomes included SSCs, surgical site infections (SSIs), seroma, hematoma, dehiscence, and incisional drainage.
- Subgroup analyses were conducted to include studies done on high-risk cases.
- 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.

Results



Reduction of risk of SSC*
8 studies; risk ratio 0.332 (95% CI 0.236-0.467) (p<0.001)*

Reduction of risk of dehiscence*†
5 studies; risk ratio 0.380 (95% CI 0.176-0.820) (p=0.014)*

Reduction of risk of SSI*
7 studies; risk ratio 0.401 (95% CI 0.190-0.844) (p=0.016)*

Reduction of risk of drainage*
4 studies; risk ratio 0.399 (95% CI 0.218-0.728) (p=0.003)*

Reduction of risk of seroma*
3 studies; risk ratio 0.473 (95% CI 0.272-0.824) (p<0.008)*

Reduction of risk of ROR*
8 studies; risk ratio 0.418 (95% CI 0.246-0.712) (p=0.001)*

(Continued)

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

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.

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Additional outcomes

Outcome	High-risk subgroup analysis	# of studies	Risk ratio (95% CI)	p-value
SSC	Primary or revision	6	0.328 (0.229-0.469)	<0.001*
SSC	Primary	3	0.331 (0.206-0.533)	<0.001*
SSC	Silver dressing as standard dressing	5	0.332 (0.229-0.482)	<0.001*
SSI	Primary or revision	6	0.385 (0.164-0.906)	0.029*
SSI	Silver dressing as standard dressing	5	0.401 (0.163-0.986)	0.046*

Summary

- This systematic review and meta-analysis of 12 published studies demonstrated that the use of Prevena Therapy was associated with reduced risks of SSCs, SSIs,† seromas, dehiscence,† prolonged drainage, and ROR following hip or knee arthroplasty. There was no reduction in hematoma rates.
- Subgroup analyses of studies done on high-risk patients also demonstrated a reduced risk in SSCs and SSIs.
- Potential cost savings of $932 per patient with the use of Prevena Therapy to reduce the risk of SSCs.

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 and dehiscence has not been reviewed by the U.S. FDA

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.

Read the full study here

Journal: *Arthroplasty Today*

Title: Closed incision negative pressure therapy vs standard of care over closed knee and hip arthroplasty surgical incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies

Published: April 3, 2023

Cooper HJ, Silverman RP, Collinsworth A, Bongards C, Griffin L. Closed incision negative pressure therapy vs standard of care over closed knee and hip arthroplasty surgical incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies. *Arthroplast Today.* 2023 Apr 3;21:101120.

PROMISES study data suggests 3M™ Prevena™ Therapy can help advance the standard of care

Data from a multicenter randomized controlled trial showed that Prevena Therapy significantly reduced the risk of 90-day surgical site complications (SSCs) and postop readmissions vs. silver-impregnated dressings.

The PROMISES (Post-market, Randomized, Open-Label, Multicenter Study to evaluate Effectiveness) Trial

The effectiveness of closed incision negative pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, et al. *J Arthroplasty.* 2021 Jul;36(7S):S295-S302.e14.

Study design
Multi-center randomized controlled trial (Level I)

Study purpose
Evaluate the effectiveness of Prevena Therapy versus standard dressings in reducing surgical site complications (SSCs) in high-risk patients after revision knee arthroplasty (rTKA)

Methods

- 294 high-risk rTKA patients (15 centers) randomized to Prevena Therapy (n=147) or silver-impregnated dressing (n=147).
- Inclusion criteria: exhibit at least one risk factor for postoperative SSC: BMI >35 kg/m^2 use of non-aspirin blood thinners postoperatively; current/previous diagnosis of peripheral vascular disease; current tobacco use; history of prior infection history at operative site; operative limb lymphedema; insulin-dependent diabetes; current use of immunomodulators or corticosteroids; ongoing malignancy excluding localized skin cancer; rheumatoid arthritis; renal failure or dialysis; malnutrition; liver disease; solid organ transplant recipients; or human immunodeficiency virus infection.
- Primary outcome was 90-day incidence of SSCs. Secondary outcomes were the 90-day health care utilization parameters (readmission, reoperation, dressing changes, and visits) and patient-reported outcomes (PRO). Treatment-related adverse events were compared and stratified as severe and non-severe.
- Primary and secondary outcomes reported on an intention-to-treat basis. Adverse event reporting based on the Safety Analysis Dataset.

Results
Compared to SOC, patients in the Prevena Therapy group demonstrated:

- Significantly decreased rates of surgical site complications (Prevena Therapy 3.4% vs. SOC 14.3%, **p=0.0013***)
- Significantly lower readmission rates (Prevena Therapy 3.4% vs. SOC 10.2%, **p=0.0208***)
- Reduced dressing changes (Prevena Therapy 1.1±0.29 vs. SOC 1.3 ±0.96, **p=0.0003***)
- SSCs in Aseptic rTKA (Prevena Therapy 1.8% vs. SOC 14.3%, **p=0.0006***)
- Length of stay if readmitted (Prevena Therapy 2.2 ± 2.28 vs. SOC 8.6 ± 7.38, **p=0.0254***)
- Patients receiving >1 dressing change (Prevena Therapy 4.7% vs. SOC 17.86%, **p=0.0005***)

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

Key results

Outcome (90 days)	Prevena™ Therapy	Silver-impregnated dressing	p-value
SSC non-surgical interventions (90 days)	2.7% (4/147)	12.9% (19/147)	0.0017*
SSC surgical interventions (90 days)	0.7% (1/147)	4.8% (7/147)	0.0666

Cost effectiveness

All patients:

$989 Reduction in per-patient cost of care

$1,047 3M™ Prevena™ Therapy vs. $2,036 SOC

Higher-risk patients (CCI ≥2):

$2,536 Reduction in per-patient cost of care

$676 3M™ Prevena™ Therapy vs. $3,212 SOC

Conclusions

- Prevena Therapy significantly mitigated 90-day surgical site complications, readmission rates, and reduced frequency of dressing changes compared with the standard of care among high-risk rTKA patients.
- Treatment-related adverse effects were similar between both cohorts.
- There were no significant differences in specific SSC types, reoperation rates, number of visits, and patient reported outcomes.

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

*Statistically significant (p<0.05)

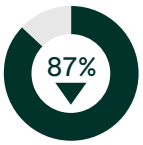
Results

Reduction in SSCs*

3.4% (5/147) Prevena Therapy vs. 14.3% (21/147) Silver-impregnated dressing (p=0.0013)*

Reduction in readmission rates*

3.4% (5/147) Prevena Therapy vs. 10.3% (15/147) Silver-impregnated dressing (p=0.0208)*

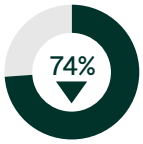


Reduction in 90-day SSCs*

1.8% (2/118) Prevena Therapy vs. 14.3% (15/119) Silver-impregnated dressing (p=0.0006)*

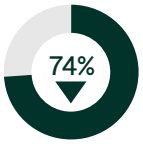
Fewer mean dressing changes*

1.1 ± 0.3 Prevena Therapy vs. 1.3 ± 1.0 Silver-impregnated dressing (p=0.0003)*



Shorter LoS if readmitted*

2.2 ± 2.28 Prevena Therapy vs. 8.6 ± 7.38 Silver-impregnated dressing (p=0.0254)*



Fewer patients receiving >1 dressing change*

4.7% (7/149) Prevena Therapy vs. 17.9% (25/140) Silver-impregnated dressing (p=0.0005)*

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.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: The effectiveness of closed-incision negative-pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty: The PROMISES randomized controlled trial

Published: March 5, 2021

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, et al. The effectiveness of closed-incision negative-pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty: The PROMISES randomized controlled trial. *J Arthroplasty.* 2021 Jul;36(7S):S295-S302.e14. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use.

Use of closed incisional negative pressure wound therapy after revision total hip and knee arthroplasty in patients at high risk for infection: A prospective, randomized clinical trial

Newman JM, Siqueira MBP, Klika AK, et al. *J Arthroplasty.* 2019 Mar;34(3):554-559.

Study design

Prospective, single-center, randomized controlled trial

Study purpose

The purpose of the Newman study was to compare the use of Prevena Therapy to a sterile silver-impregnated dressing in revision arthroplasty (rTHA, rTKA) patients at high risk to develop wound complications

Methods

- 160 patients undergoing elective rTHA and rTKA were prospectively randomized to receive Prevena Therapy or silver-impregnated dressing (AQUACEL® Ag) at a single institution.
- Patients had at least one risk factor for developing a wound complication.
- Primary outcome was wound complications (drainage, cellulitis, blisters, hematoma, skin necrosis, wound dehiscence, nonhealing wound, suture abscess, surgical site infection, periprosthetic joint infection).
- Additional outcomes included all-cause readmissions and hip/knee related reoperations.
- Data collected at 2, 4 and 12 weeks postoperatively. 12-week results reported here.
- Multivariate regression models were used to control for baseline differences between the groups (history of prior joint infection and inflammatory arthritis).

Results

Reduction in wound complications*

10.1% (8/79) Prevena Therapy vs. 23.8% (19/80) Silver-impregnated dressing (p=0.022)*

Fewer returns to the OR*

2.5% (2/79) Prevena Therapy vs. 12.5% (10/80) Silver-impregnated dressing (p=0.017)*

Key points

- There were significant differences in the number of patients with 1) a history of prior joint infection and 2) inflammatory arthritis, with a higher incidence in the standard dressing arm. After multivariate regression to account for these differences, Prevena Therapy significantly decreased SSC rate (odds ratio 0.29, 95% confidence interval 0.11-0.75, p=0.010*).
- High-risk patients could benefit from Prevena Therapy to help reduce the risk of wound complications and reoperations after rTHA and rTKA.
- The authors suggest future multicenter clinical trials to further strengthen the results as well as a cost-benefit analysis.

(Continued)

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

*Statistically significant (p<0.05)

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.

Although the authors reported use of Prevena Therapy for a mean of 3.6 days (ranging from 2 to 15 days), this mean time of application is outside the recommendations for Optimum Use as stated in the 3M™ Prevena™ Incision Management System Clinician Guide Instructions for Use: The Prevena Incision Management System is to be continuously applied for a minimum of two days up to a maximum of seven days. Use for greater than 7 days is not recommended or promoted by 3M.

(Continued)

Additional outcomes

Types and number of wound complications	Prevena™ Therapy	Silver-impregnated dressing
Periprosthetic joint infection*	2.5% (2/79)	8.8% (7/80)
Dehiscence*	1.3% (1/79)	5.0% (4/80)
Drainage	6.3% (5/79)	20.0% (16/80)
Nonhealing wound	0% (0/79)	5% (4/80)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Newman et al outcomes

Hypothetical economic model	Prevena™ Therapy	Silver-impregnated dressing
Patients	79	80
Number of surgical site complications (a)	8	19
Cost per SSC[1] (b)	$16,173	$16,173
Per patient complication cost (a*b)/n	$1,638	$3,841
Per patient therapy cost†	$495	$39
Total cost per patient	$2,133	$3,880
Potential per incision savings using Prevena™ Therapy	$1,747	

Assumes cost per SSC for rTKA at higher end of total range of TKA/THA data.

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

†3M™ Prevena™ Peel and Place System Kit and AQUACEL® Ag SURGICAL price are 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 AQUACEL® Ag SURGICAL. 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
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.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: Use of closed incisional negative pressure wound therapy after revision total hip and knee arthroplasty in patients at high risk for infection: A prospective, randomized clinical trial

Published: November 16, 2018

Newman JM, Siqueira MBP, Klika AK, et al. Use of closed incisional negative pressure wound therapy after revision total hip and knee arthroplasty in patients at high risk for infection: A prospective, randomized clinical trial. *J Arthroplasty.* 2019 Mar;34(3):554-559. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use.

Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty

Pachowsky M, Gusinde J, Klein A, et al. *Int Orthop.* 2012 Apr;36(4):719-722.

Study design

Prospective, single-center, randomized control trial (Level II)

Study purpose

The purpose of the Pachowsky study was to evaluate the effect of Prevena Therapy on incisional healing and the prevention of seromas in clean, closed incisions after total hip arthroplasty (THA)

Methods

- Patients were randomized into two groups: 10 patients with a standard dressing, consisting of a dry wound coverage; and nine patients with Prevena Therapy placed over the sutured wound area for five days.
- Ultrasound was used to detect and measure seromas in both groups on days 5 and 10 postoperatively. Patients underwent ultrasound of the surgical site preoperatively as a control to assess for potential soft tissue abnormalities.
- Groups were comparable in age and incision size. All patients received perioperative treatment and antibiotics.
- Study endpoints included the number of patients with seromas and average volume size of seroma.

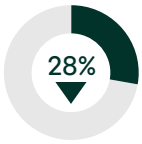
Summary

- This study showed fewer post-operative seromas and significantly lower seroma volume 10 days after surgery with the use of 3M™ Prevena™ Therapy.
- The authors concluded that application of Prevena Therapy on closed incisions after orthopedic surgery might help reduce the complications of a prolonged wound healing and postoperative seroma in the wound area.

Results

Reduction in mean seroma volume at day 10*

1.97 ± 3.21 mL Prevena Therapy vs. 5.08 ± 5.11 mL standard dressing (p=0.021)*



Reduction in antibiotic days*

8.44 ± 2.24 mL Prevena Therapy vs. 11.8 ± 2.82 mL standard dressing (p=0.005)*

Additional outcomes

Outcome	Prevena™ Therapy	Standard dressing	p-value
Seromas	44% (4/9)	90% (9/10)	Not reported
Seroma volume (mL) at day 5	0.58 ± 1.21	2.02 ± 2.74	0.102
Secretion from the wound after 5 days	11% (1/9)	50% (5/10)	Not reported
CRP (mg/L) day 10	22.39 ± 8.51	44.06 ± 30.66	0.069

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

*Statistically significant (p<0.05)

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.

Read the full study here

Journal: *International Orthopaedics*

Title: Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty

Published: July 15, 2011

Pachowsky M, Gusinde J, Klein A, et al. Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty. *Int Orthop.* 2012 Apr;36(4):719-722.

Closed incision negative pressure therapy effects on postoperative infection and surgical site complication after total hip and knee arthroplasty

Redfern RE, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer KJ. *J Arthroplasty.* 2017 Nov;32(11):3333-3339.

Study design

Single-center, prospective versus historic control comparative study

Study purpose

The purpose of the Redfern study was to examine the use of 3M™ Prevena™ Therapy over clean closed surgical incisions after primary total joint replacement and whether it would reduce the rates of wound complications

Methods

- The Prevena Therapy group was comprised of 192 patients representing 196 incisions, who were actively enrolled from 2013 to 2014.
- The historical control group consisted of 400 patients who underwent surgery from 2011 to 2012.
- Prevena Therapy was applied over the closed incision for 6-8 days postoperatively. The standard dressing group included a sterile gauze dressing with standard dressing changes.
- Study endpoints including the rate of surgical site complications requiring medical or surgical intervention, including surgical site infections (deep and superficial infections), wound dehiscence, hematomas, seromas, edema/swelling, and drainage were compared between groups.

Additional outcomes

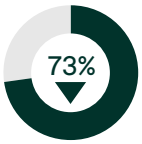
Outcome	Prevena™ Therapy	Standard dressing	p-value
Drainage	1.0% (2/196)	3.0% (12/400)	0.07
Reaction to dressing	13.8% (27/196)	2.25% (9/400)	<0.0001*

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

*Statistically significant (p<0.05)

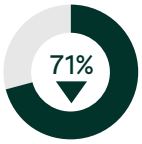
†NOTE: The use of Prevena Therapy for the reduction in the incidence of pain has not been reviewed by the U.S. FDA

Results



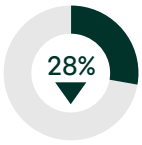
Reduction in SSCs*

1.5% (3/196) Prevena Therapy vs. 5.5% (22/400) standard dressing (p=0.02)*



Reduction in SSIs*

1.0% (2/196) Prevena Therapy vs. 3.5% (14/400) standard dressing (p=0.04)*



Reduction in pain 24h postop*†

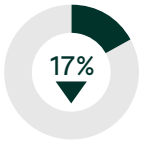
2.6+1.8 Prevena Therapy vs. 3.6+2.2 standard dressing (p=0.0001)*†

Reduction in hematomas*

0% (0/196) Prevena Therapy vs. 2.25% (9/400) standard dressing (p=0.02)*

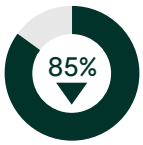
Reduction in superficial SSIs*

0% (0/196) Prevena Therapy vs. 2.25% (9/400) standard dressing (p=0.03)*



Reduction in length of stay*

1.9+0.6 Prevena Therapy vs. 2.3+0.5 standard dressing (p<0.0001)*



Reduction in edema/swelling*

0.5% (1/196) Prevena Therapy vs. 3.25% (13/400) standard dressing (p=0.02)*

Reduction in abnormal surrounding soft tissue appearance*

0% (0/196) Prevena Therapy vs. 3.75% (15/400) standard dressing (p=0.03)*

(Continued)

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Redfern et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Patients	196	400
Number of complications (a)	3	22
Cost per SSC[1] (b)	$16,173	$16,173
Per patient complication cost (a*b)/n	$248	$890
Per patient therapy cost*	$495	–
Total cost per patient	$743	$890
Potential per incision savings using Prevena™ Therapy	$147	

Key points

- In this study, Prevena Therapy reduced the overall incidence of complications requiring medical or surgical intervention for hip and knee arthroplasty.
- After logistic regression to examine the effects of Prevena Therapy, sex, BMI, surgical site (hip or knee), and health status on SSCs, only Prevena Therapy was associated with SSC reduction. Prevena Therapy patients were approximately four times less likely to develop an SSC when compared with control (odds ratio 4.251 (95% CI 1.172-15.414; p=0.0277).
- While reaction to the dressing was more frequent in the Prevena Therapy group, all cases were resolved with antibiotic ointment, the rate in this study was lower than other studies, and these reactions can be mitigated through dressing application technique.

*3M™ Prevena™ Peel and Place System Kit 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 gauze 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
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.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: Closed incision negative pressure therapy effects on postoperative infection and surgical site complication after total hip and knee arthroplasty

Published: June 16, 2017

Redfern RE, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer KJ. Closed incision negative pressure therapy effects on postoperative infection and surgical site complication after total hip and knee arthroplasty. *J Arthroplasty.* 2017 Nov;32(11):3333-3339. Note that the length of therapy may be outside the range recommended in the Instructions for Use.

Comparison of surgical site complications with negative pressure wound therapy vs silver impregnated dressing in high-risk total knee arthroplasty patients: A matched cohort study

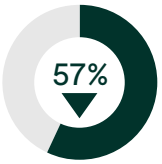
Doman DM, Young AM, Buller LT, Deckard ER, Meneghini RM. *J Arthroplasty.* 2021 Oct;36(10):3437-3442.

Study design
Retrospective comparative cohort study

Study purpose
To compare the rates of incisional and non-incisional wound complications, periprosthetic joint infections, and reoperations in high-risk primary TKA patients that receive Prevena Therapy versus standard dressing.

Methods
- The Prevena Therapy group comprised of 130 patients who had primary TKA between July 2018 and December 2019.
- The retrospective historical control group (AQUACEL® Ag SURGICAL) consisted of 130 TKAs, propensity matched 1:1, who underwent surgery between December 2016 and June 2018.
- High-risk criteria included active tobacco use, diabetes mellitus, BMI >35 kg/m^2, autoimmune disease, chronic kidney disease, *Staphylococcus aureus* nasal colonization, and non-aspirin anticoagulation.
- Study endpoints included incisional wound complications, defined as: cellulitis, focal swelling, suture reaction, dehiscence and hematoma. Non-incisional wound complications were also assessed and defined as dressing reactions, blistering and rashes.

Results



Reduction in Wound Complications*
6.9% (9/130) Prevena Therapy vs. 16.2% (21/130) Silver-impregnated dressing (p=0.031)*

Key points
- Among high-risk patients undergoing primary TKA, patients receiving Prevena Therapy had significantly fewer incisional wound complications when compared to patients receiving silver impregnated dressings.
- Although an increase in dressing reactions for Prevena Therapy patients was observed, compared to standard dressing (16.9% vs 1.5%; p<0.0001), none required clinical intervention.
- In a multiple logistic regression analysis, the occlusive silver-impregnated dressing was a significant effect on the development of SSCs (odds ratio 2.9, 95% CI 1.3-6.8; p=0.012), as was non-aspirin anticoagulation (odds ratio 2.5, 95% CI 1.1-5.6; p=0.028).
- Results support the use of ciNPT as part of a risk mitigation strategy to reduce post operative complications in primary TKA.

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Doman et al outcomes

Hypothetical economic model	Prevena™ Therapy	Silver-impregnated dressing
Patients	130	130
Number of surgical site complications (a)	9	21
Cost per SSC[1] (b)	$16,173	$16,173
Per patient complication cost (a*b)/n	$1,120	$2,613
Per patient therapy cost*	$495	$39
Total cost per patient	$1,615	$2,652
Potential per incision savings using Prevena™ Therapy	$1,037	

Cost per SSC is based on SSC cost for population with CCI>0 to represent High-Risk Study Population

*3M™ Prevena™ Plus Customizable Dressing and AQUACEL® Ag SURGICAL price are estimates; individual prices may vary. Authors report institution costs of $35.22 for AQUACEL® Ag SURGICAL and $389.99 for Prevena Peel and Place System Kit.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or AQUACEL® Ag SURGICAL. 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
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.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: Comparison of surgical site complications with negative pressure wound therapy vs silver impregnated dressing in high-risk total knee arthroplasty patients: A matched cohort study

Published: May 24, 2021

Doman DM, Young AM, Buller LT, Deckard ER, Meneghini RM. Comparison of surgical site complications with negative pressure wound therapy vs silver impregnated dressing in high-risk total knee arthroplasty patients: A matched cohort study. *J Arthroplasty.* 2021 Oct;36(10):3437-3442.

Randomized controlled trial of incisional negative pressure following high-risk direct total hip arthroplasty

Cooper HJ, Santos WM, Neuwirth AL, et al. *J Arthroplasty.* 2022 Aug;37(8S):S931-S936.

Study type

This was a prospective randomized controlled trial.

Study purpose

The purpose of this study is to determine whether ciNPT could decrease SSCs in high-risk patients undergoing DA THA. The direct anterior (DA) approach to total hip arthroplasty (THA) is associated with higher rates of surgical site complications (SSCs) compared to other approaches. Closed incision negative pressure therapy (ciNPT) is effective in reducing SSCs and surgical site infections (SSIs) in other populations.

Methods

- Population: Study enrolled high-risk DA THA patients at 3 centers. Inclusion criteria was if subjects had previously identified risk factors for SSC: body mass index (BMI) >30 kg/m^2, diabetes, active smoking or before hip surgery.
- Treatment: Patients were randomized after closure to either an occlusive (control) dressing or ciNPT dressing (3M™ Prevena™ Incision Management System) for 7 days. Both dressings were designed for 7-day use per manufacturer instructions.
- Follow up: All patients were followed for 90 days to assess SSCs.

Results

One hundred and twenty-two patients were enrolled and 120 completed the data collection. SSCs occurred in 18.3% (11/60) of control patients compared to 8.3% (5/60) of ciNPT patients (x^2=2.60, P=0.107).

- SSCs included dehiscence to the subcutaneous level (13) and prolonged drainage (3).
- Nine control (15.0%) and 2 ciNPT (3.3%) patients met CDC criteria for superficial SSI (P=0.027).
- Fifteen of 16 SSCs resolved with local wound care. One in the ciNPT group required reoperation for acute PJI.

Conclusion

It was determined that among high-risk patients undergoing DA THA, there were lower rates of SSC and a significant reduction in the risk of superficial SSI with ciNPT.

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.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: Randomized controlled trial of incisional negative pressure following high-risk direct anterior total hip arthroplasty

Published: March 15, 2022

Cooper HJ, Santos WM, Neuwirth AL, et al. Randomized controlled trial of incisional negative pressure following high-risk direct anterior total hip arthroplasty. *J Arthroplasty.* 2022 Aug;37(8S):S931-S936. OPEN ACCESS

A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty

Anatone AJ, Shah RP, Jennings EL, Geller JA, Cooper HJ. *Arthroplast Today.* 2018 Dec;4(4):493-98.

Study design

Single institution retrospective review of records

Study purpose

The purpose of the Anatone study was to evaluate when to use Prevena Therapy in primary total joint arthroplasties (TJAs). The author's risk stratification can be used as a potential guideline to identify patients that may benefit from Prevena Therapy.

Methods

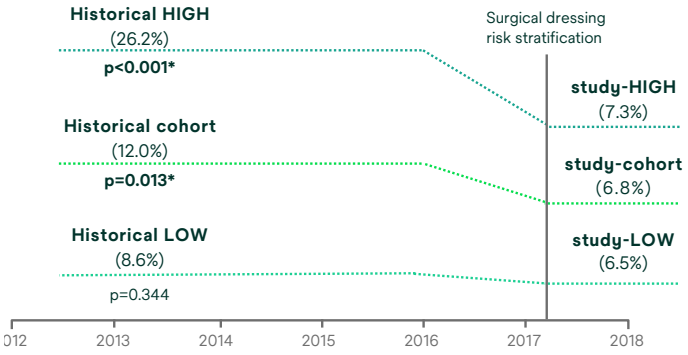
- Patients were considered low risk if their calculated risk score was <2 and patients were considered high risk if their risk score was ≥2.
- A study population of 323 consecutive primary TJAs were evaluated, where 123 (38%) of those patients were considered at elevated risk to receive Prevena Therapy. The remaining 200 patients received the standard postop dressing (AQUACEL® Ag SURGICAL cover dressing).
- A historical control population of 643 patients was identified who all received the standard postop dressing to test the impact of this risk score.
- Skin closure procedure was the same in both groups, and dressings were applied under sterile conditions in the operating room at the conclusion of the surgical procedure.
- The primary outcome measure was any postoperative surgical site complication (SSC†) that required intervention during the initial 90-day post-operative period.

Risk stratification algorithm scoring system

Risk factor	Weight
BMI	
<18.5 kg/m²	1
18.5–29.9 kg/m²	0
30–34.9 kg/m²	1
35–39.9 kg/m²	2
>40 kg/m²	3

Risk factor	Weight
Diabetes mellitus	2
Immunodeficiency	1.3
Active smoking	1
Non-ASA anticoagulation	1
Prior surgery	2

Results



Guidance

The authors' risk stratification can be used as a potential guideline to identify patients who may benefit from Prevena Therapy.

Key points

- Among high-risk patients, there was a marked improvement in the rate of SSCs when treated prophylactically with Prevena Therapy as compared with historical controls (26.2% vs. 7.3%; p<0.001).*
- Compared with historical controls, a modest but significant improvement in superficial SSCs after implementation of risk-stratification (12.0% vs 6.8%; p=0.013) was observed.*
- Low-risk patients who continued to be treated with standard postop dressings in historical controls demonstrated no significant improvement (8.6% vs 6.5%; p=0.344).

(Continued)

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

*Statistically significant (p<0.05)

†SSC was defined as any dehiscence, suture granuloma, drainage occurring beyond postoperative day 5, significant hematoma formation, or SSI as defined by the CDC that required unplanned postoperative interventions.

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Anatone et al outcomes

Hypothetical economic model	Prevena™ Therapy	Silver-impregnated dressing
Patients	123	122
Number of surgical site complications (a)	9	32
Cost per SSC[1] (b)	$16,173	$16,173
Per patient complication cost (a*b)/n	$1,183	$4,242
Per patient therapy cost*	$830	$39
Total cost per patient	$2,013	$4,281
Potential per incision savings using Prevena™ Therapy	$2,268	

Cost per SSC is based on SSC cost for population with CCI>0 to represent High-Risk Study Population.

*3M™ Prevena™ Plus Customizable Dressing and AQUACEL® Ag SURGICAL price are estimates; individual prices may vary; 3M™ Prevena™ Plus Customizable Dressing used on some patients and therefore the price is used for all patients in this model.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or AQUACEL® Ag SURGICAL. 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
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.

Read the full study here

Journal: *Arthroplasty Today*

Title: A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty

Published: October 15, 2018

Anatone AJ, Shah RP, Jennings EL, Geller JA, Cooper HJ. A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty. *Arthroplast Today*. 2018 Dec;4(4):493-98. OPEN ACCESS

Incisional negative pressure wound therapy in orthopaedic trauma: Indications & outcomes

Phillips R, Stannard JP, Crist BD. *J Orthop Trauma*. 2022;36(Suppl 4):S22-S25.

Study type

This was a literature review.

Study purpose

This review aims to discuss the indications and outcomes associated with the use of incisional negative pressure wound therapy (iNPWT) for the management of surgical incisions.

Outcomes

Indication for iNPWT: In patient population at high risk for developing SSIs, management of the surgical incision with iNPWT have reduced the incidence of SSIs.

Several meta-analyses and randomized controlled trials were evaluated to assess the efficacy of surgical site infections, wound dehiscence and other postoperative wound complications.

A 2019 meta-analysis analyzed a total of 6 studies including 2 randomized controlled trials (RCTs) and 4 cohort studies comparing a mix of iNPWT systems to conventional wound dressings for closed incisions in orthopaedic trauma surgery found that 14 statistically significant lower incidence of deep SSIs (P=0.002), superficial SSI (P=0.03) and wound dehiscence (P=0.02) was found in surgical incisions managed with iNPWT.

The results of 2 RCTs also support the use of iNPWT after primary and revision total joint arthroplasty. Total knee arthroplasty patients with a body mass index >35 kg/m² who were treated with incisional NPWT experienced fewer overall complications (1.3% vs. 21.6%; P=0.01) and fewer dressing-related concerns (1.3% vs. 10.8%; P=0.01) compared with standard of care dressings.

Duration of treatment

Most studies that have reported the use of iNPWT before the availability of a portable device typically used iNPWT for 3–5 days during the inpatient hospital stay. More recent studies have extended therapy to 7 days. However, there are some contraindications to the iNPWT which includes if there is necrotic tissue with eschar present, preexisting infection, patients at high risk of excessive postoperative bleeding, and those who have an allergic reaction to any part of the NPWT system.

Conclusion

The literature review suggested that iNPWT seems to be an effective tool for decreasing the rates of surgical site infections and wound dehiscence across multiple specialties. SSI risk factors should be considered for either patients or wounds that are at high risk for infection and/or dehiscence.

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

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.

Read the full study here

Journal: *Journal of Orthopaedic Trauma*

Title: Incisional negative pressure wound therapy in orthopaedic trauma: Indications & outcomes

Published: September 2022

Phillips R, Stannard JP, Crist BD. Incisional negative pressure wound therapy in orthopaedic trauma: Indications & outcomes. *J Orthop Trauma*. 2022;36(Suppl 4):S22-S25. OPEN ACCESS

How can negative pressure wound therapy pay for itself?—Reducing complications is important

Zelle BA, Kore L. *J Orthop Trauma.* 2022 Sep 1;36(Suppl 4):S31-S35.

Study type

This was a retrospective cohort study performed at a single, Level I trauma center using data from a lower extremity fracture registry.

Study purpose

The purpose of this study was to investigate cost savings in high-risk fractures and to determine if the use of iNPWT (3M™ Prevena™ Therapy) in high-risk orthopedic trauma patients reduces the costs. The hypothesis was that the use of iNPWT will provide an economic benefit in patients with OTA/AO type 41C and 43C closed fractures undergoing ORIF.

Methods

- Material: Patient data from single institution registry were retrospectively retrieved from January 2019 and September 2020.
- Population: The evaluation included all patients with closed OTA/AO type 41C or 43C fractures treated with ORIF (staged or immediately) during the study period.
- Procedure: Registry data were summarized to determine SSI rates in all patients with closed OTA/AO type 41C and 43C fractures. 3 health economic models were developed using SSI rates of 13%, 15% and 17% as reference rates. The incremental cost due to SSI was estimated to be $51,364.

Result

- Out of a total of 79 patients who underwent ORIF of a closed OTA/AO type 41C or 43C fractures, 27 (34%) were deemed high risk for SSI and had iNPWT applied over the closed incision.
- There was no significant difference in rates of SSI when comparing iNPWT with non-iNPWT group (7.4% vs. 11.5%, P=0.7086).
- Patients in iNPWT group had the external fixator in place for a significantly longer time (10.6 days vs. 6.8 days; P=0.0332). Length of hospital stay was longer for patients in the non-iNPWT group compared with the iNPWT group (10.2 vs. 5.4 days; P=0.0155).
- Health economic models: For assumed SSI rates of 13%, 15%, and 17%, the total infection costs for 100 patients would be $667,732, $770,460, and $873,188, respectively, the per patient cost would be $6,677, $7,704, and $8,732 respectively and iNPWT cohort, the total infection cost for 100 patients would be $380,094 or $3,801 per patient. Thus, when comparing the SSI rates, the differences in infection costs per patient were estimated to be $2,381, $3,409, and $4,436, respectively. Hence, this health economic model suggests the use of the iNPWT in patients with high-risk OTA/AO type 41C and 43C fractures may provide estimated cost savings per patient that range between $2,381 to $4,436.

Conclusion

Based on this health economic model, the use of iNPWT (Prevena Therapy) may reduce the costs of SSI in high-risk orthopaedic trauma patients undergoing ORIF of their closed OTA/AO type 41C and 43C fractures.

Read the full study here

Journal: *Journal of Orthopaedic Trauma*

Title: How can negative pressure wound therapy pay for itself?—Reducing complications is important

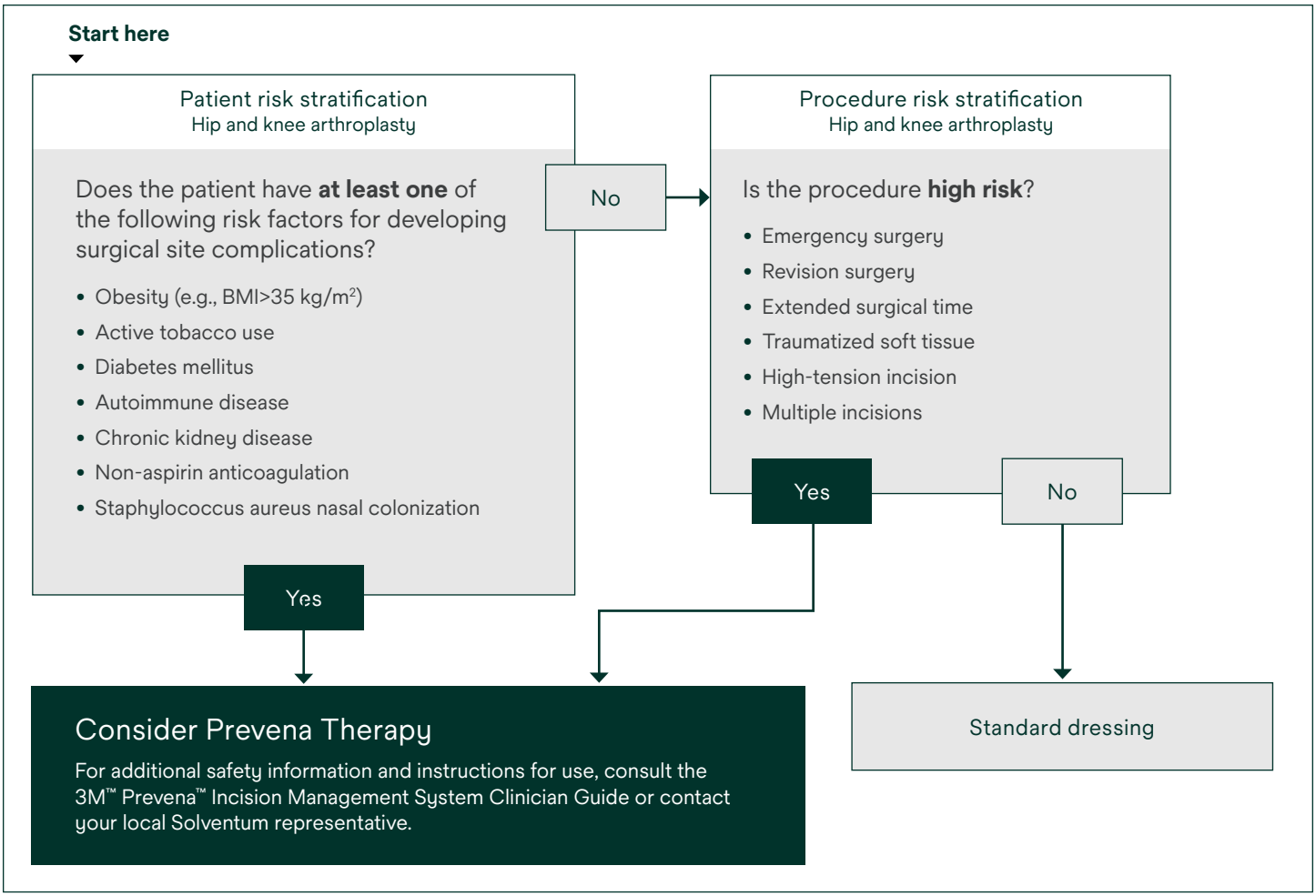
Published: September 2022

Zelle BA, Kore L. How can negative pressure wound therapy pay for itself?—Reducing complications is important. *J Orthop Trauma.* 2022 Sep 1;36(Suppl 4):S31-S35.

Decision guide

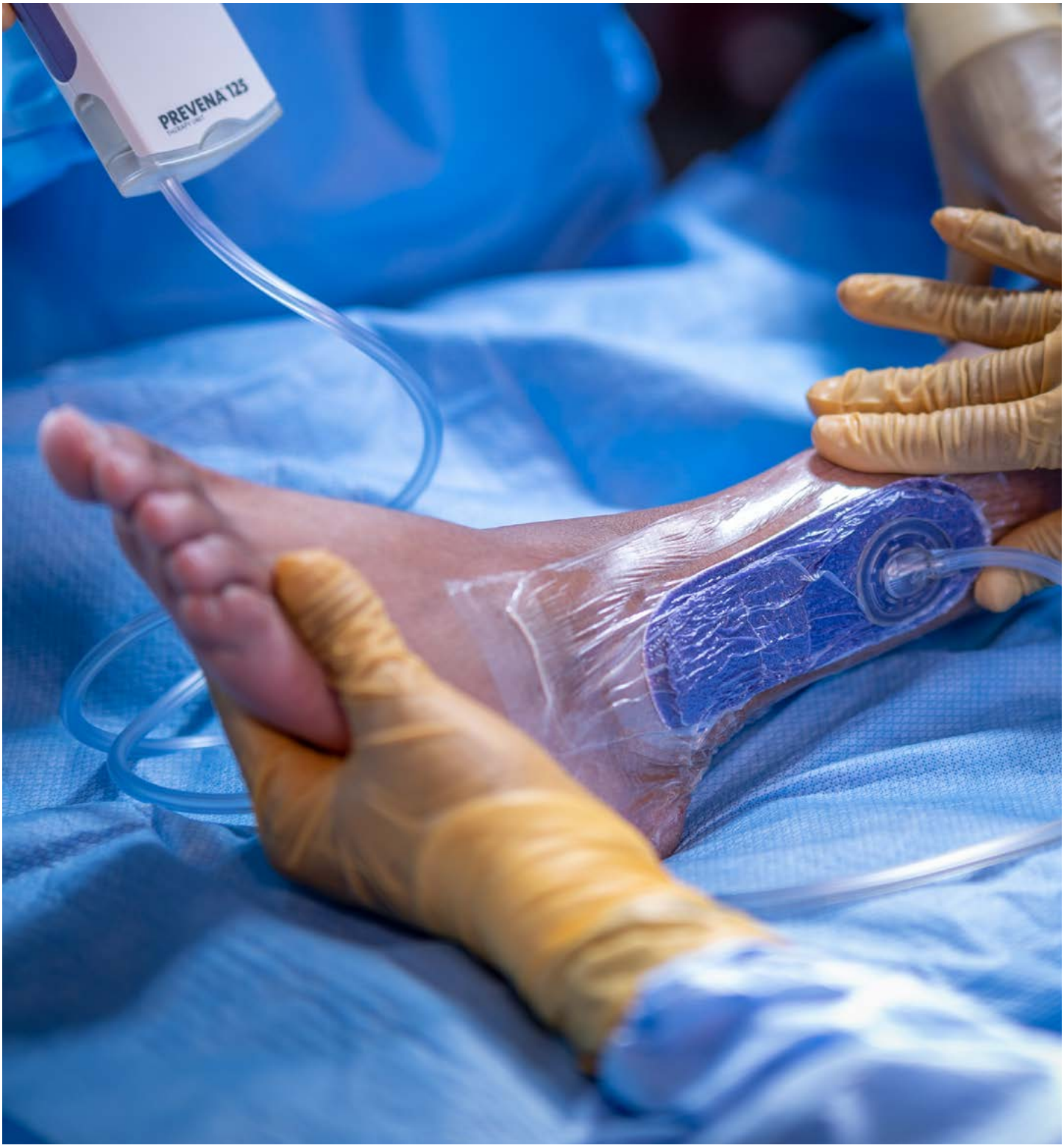
Patient and procedure risk stratification backed by clinical evidence

While surgical patients may benefit from Prevena Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data[1-3] to provide an illustrative guide to aid in risk stratification. This is not an all-inclusive list of risk factors. Clinicians are advised to use their clinical judgment to identify high-risk patients or high-risk procedures.



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.

References
1. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: International multidisciplinary consensus recommendations. *Int Wound J.* 2017 Apr;14(2):385-398. OPEN ACCESS 2. Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, et al. The effectiveness of closed-incision negative-pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty: The PROMISES randomized controlled trial. *J Arthroplasty.* 2021 Jul;36(7S):S295-S302.e14. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use. 3. Newman JM, Siqueira MBP, Klika AK, et al. Use of closed incisional negative pressure wound therapy after revision total hip and knee arthroplasty in patients at high risk for infection: A prospective, randomized clinical trial. *J Arthroplasty.* 2019 Mar;34(3):554-559. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use.



Case studies

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Bilateral primary total knee arthroplasty

R. Michael Meneghini, MD; Orthopaedic Surgery, Indiana University Health Hip and Knee Center and Indiana University School of Medicine, Indianapolis, IN

Patient

A 64-year-old male patient presented for a bilateral primary total knee arthroplasty. Patient comorbidities and risk factors included obesity, hypertension, hyperlipidemia, and gastroesophageal reflux disease.

Diagnosis

The patient required a bilateral primary total knee arthroplasty due to debilitating pain and stiffness from end-stage osteoarthritis that was refractory to non-operative measures.

Application

The patient received preoperative and postoperative prophylactic intravenous antibiotics for 24 hours. Immediately following surgery, the 3M™ Prevena Restor™ Arthro•Form™ Incision Management System was applied over the closed incisions with -125 mmHg negative pressure. The goals of therapy were to manage the surgical incision and surrounding soft tissue, hold the edges of the closed incision together, reduce tensile forces across the incision, and help reduce edema.

Discharge and follow-up

The patient was discharged home with the Prevena Restor™ Arthro•Form™ Incision Management System, and it was removed after 7 days during a follow-up visit. The arthroplasty incisions were healed without complication (**Figure 1**).

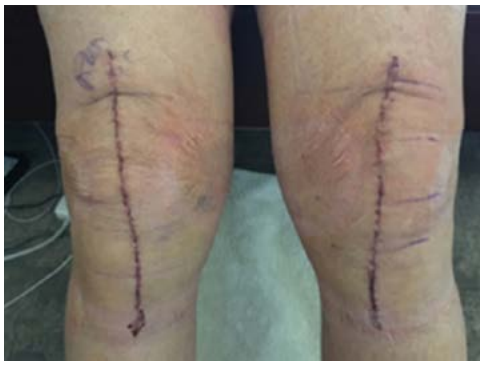
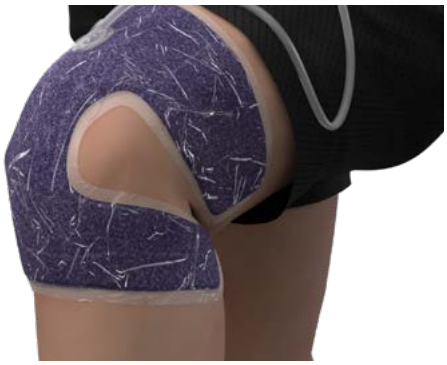


Figure 1. Bilateral total knee arthroplasty incisions after 7 days of Prevena Restor™ Arthro•Form™ Incision Management System use.



Artist rendering of Prevena Restor™ Arthro•Form™ Incision Management System applied to a knee. For illustration purposes only.

Patient data and photo courtesy of R. Michael Meneghini, MD, Orthopaedic Surgery, Indiana University Health Hip and Knee Center and Indiana University School of Medicine, Indianapolis, IN.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

Management of total knee arthroplasty revision with 3M™ Prevena Restor™ Arthro•Form™ Incision Management System

Yavonne L. Johnson, PA-C, Evan Argintar, MD; Washington, DC

Patient

A 72-year-old female presented to the hospital, requiring a revision following a total knee arthroplasty of the right knee. The patient's medical history included heart murmurs, tobacco use, and obesity.

Procedure

The patient underwent a total knee arthroplasty revision, resulting in a <15 cm incision on the right knee (**Figure 1**). The incision was closed using staples, and the patient received clindamycin for prophylactic antibiotic control.

Application of 3M™ Prevena Restor™ Arthro•Form™ Incision Management System

Immediately after incision closure, 3M™ Prevena Restor™ Therapy was initiated using a 3M™ Prevena Restor™ Arthro•Form™ Dressing, which covered the full length of the incision and the area above and below the knee (**Figure 2**). Negative pressure was applied at -125 mmHg.

Discharge and follow-up

The patient was discharged on postoperative day 5. Seven days after surgery, Prevena Restor™ Therapy was discontinued, and the incision remained closed (**Figure 3**). On postoperative day 14, the incision remained closed without any complications. The patient reported less pain and swelling and improved post-surgical range of motion in the right knee following Prevena Restor™ Therapy with Prevena Restor™ Arthro•Form™ Dressing use compared to the previous total knee arthroplasty procedure.

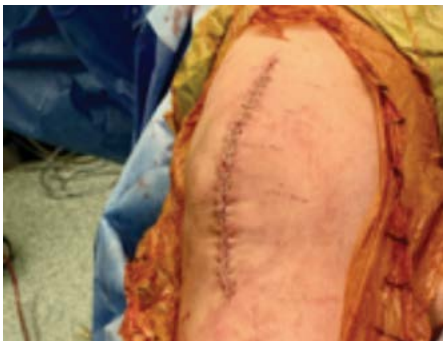


Figure 1. Closed surgical incision.

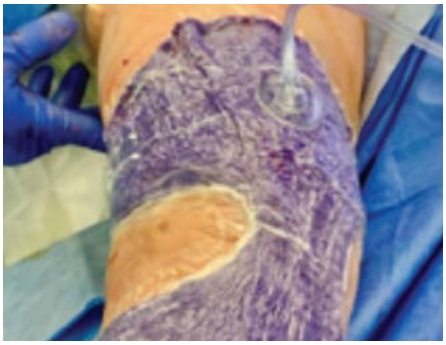


Figure 2. Application of 3M™ Prevena Restor™ Therapy System with 3M™ Prevena Restor™ Arthro•Form™ Dressing

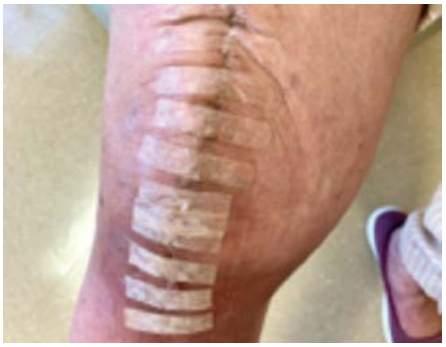


Figure 3. Surgical incision 7 days after 3M™ Prevena Restor™ Therapy System with 3M™ Prevena Restor™ Arthro•Form™ Dressing.

Patient data and photos courtesy of Yavonne L. Johnson, PA-C, Evan Argintar, MD; Washington, DC.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on the patient's circumstances and condition.

Periprosthetic femur fracture

H. John Cooper, MD; Lenox Hill Hospital, New York, NY

Patient

A 67-year-old male with a history of obesity (BMI=36.9) presented with a periprosthetic femur fracture (**Figure 1**).

Diagnosis

Patient underwent total hip arthroplasty (THA) revision to repair the injury (**Figure 2**). After replacement of the THA hardware, fascial closure could not be obtained.

Initial incision treatment/application of 3M™ Prevena™ Therapy

The 3M™ Prevena™ Incision Management System with the 3M™ Prevena™ Customizable Dressing was applied over the closed incision at -125 mmHg.

Discharge and follow-up

Prevena Therapy was discontinued after 7 days, and the patient was discharged to a rehabilitation facility. At the postoperative month 5 follow-up visit, the incision remained intact (**Figure 3**) with no postoperative incision complications.

Patient data and photo courtesy of H. John Cooper, MD; Lenox Hill Hospital, New York, NY.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

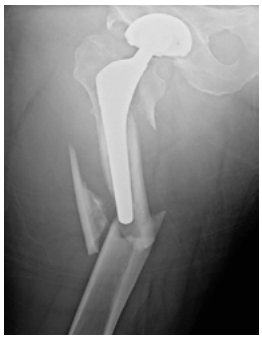


Figure 1. Periprosthetic femur fracture at initial presentation

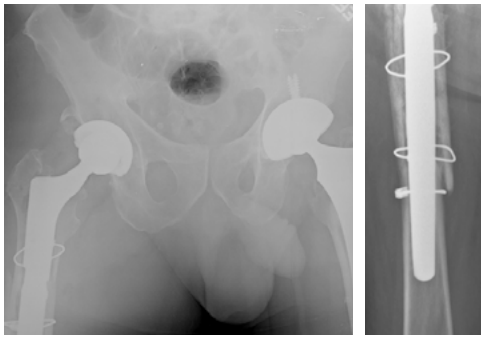


Figure 2. Total hip arthroplasty repair

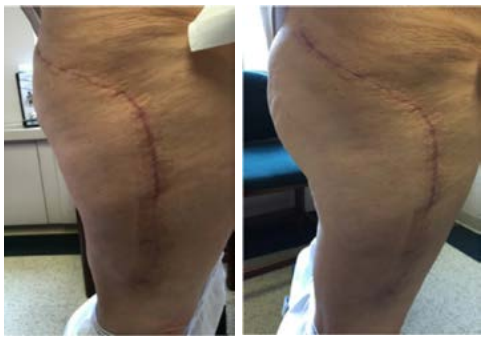
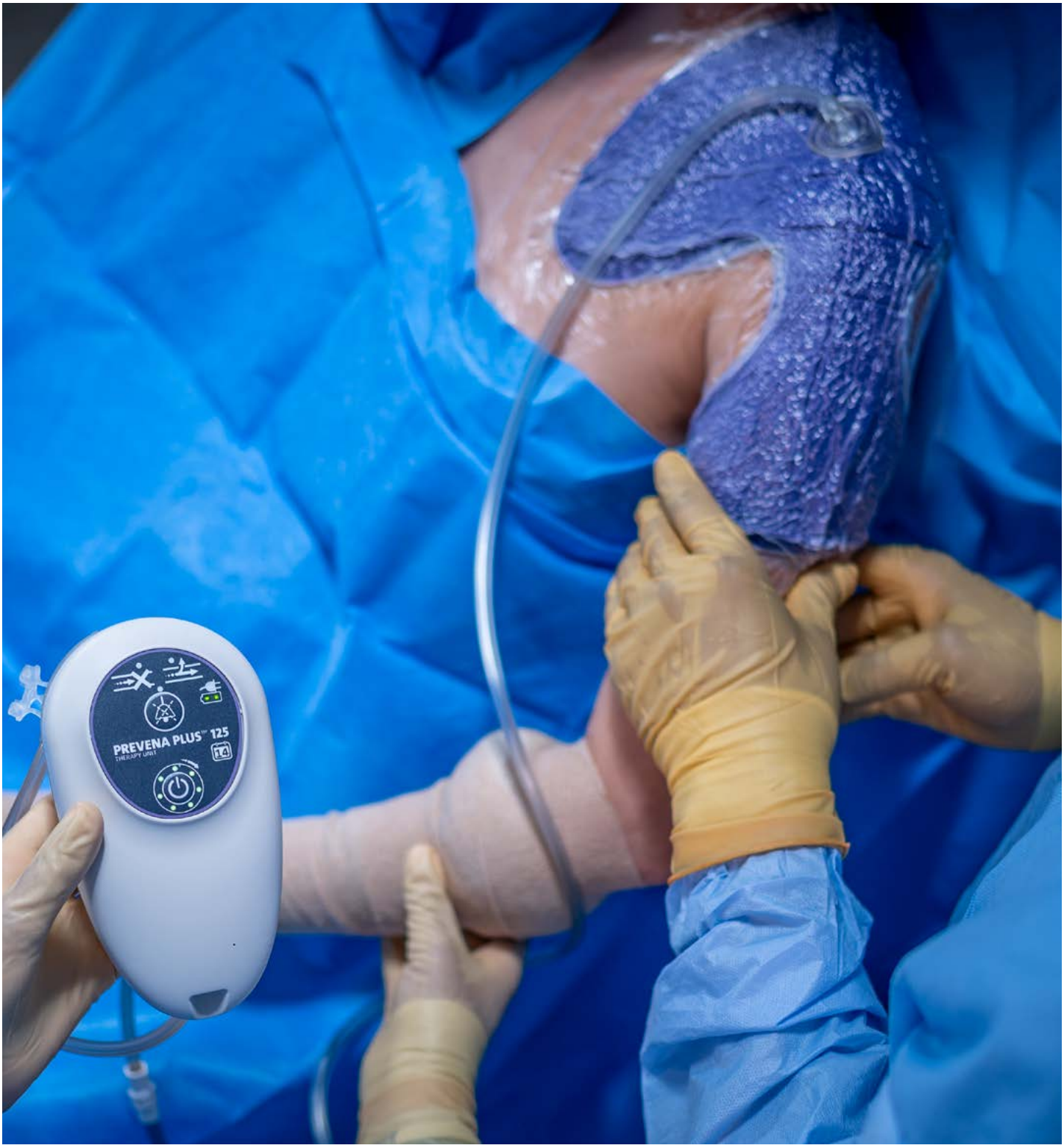


Figure 3. Wound appearance at postoperative month 5 follow-up visit



Author biographies*

*Where available and permitted to use.

3M™ Prevena Restor™ Dressings can be used on a variety of anatomical locations.

H. John Cooper, MD

Associate Professor of Orthopedic Surgery

Columbia University Irving Medical Center

New York-Presbyterian Hospital,
New York City, NY

Dr. Cooper is a paid consultant for Solventum.

Originally from South Carolina, Dr. Cooper graduated from Duke University with a degree in mechanical engineering and materials science. He completed his medical education at Columbia University and his Orthopedic residency at Lenox Hill Hospital, before spending a year in Chicago for a fellowship in adult reconstructive surgery at Rush University Medical Center.

Dr. Cooper currently works as an associate professor of Orthopedic surgery at Columbia University Irving Medical Center in New York City. He has considerable experience in direct anterior hip arthroplasty, robotic knee arthroplasty, and complex primary and revision joint replacement.

Dr. Cooper is a well-respected clinician, educator and researcher. He has published over 130 peer-reviewed articles and book chapters on clinical outcomes and complications of hip and knee replacements and has been an invited and awarded speaker on these topics at national and international Orthopedic meetings.

"I employ 3M™ Prevena™ Therapy as a proactive risk management tool, using an evidence-based approach to stratify patients on their unique patient-specific and procedure-specific risk factors. In my experience, proactively using Prevena Therapy on the high-risk patients has significantly improved their clinical outcomes (and mine as well)."

— Dr. Cooper

Carlos Higuera-Rueda, MD

Cleveland Clinic Florida, Weston, FL

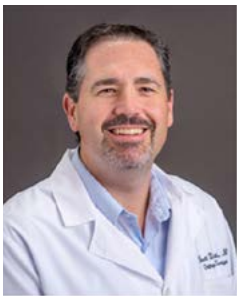
Dr. Higuera-Rueda is a paid consultant for Solventum.

Dr. Carlos Higuera-Rueda is currently a staff surgeon at the Cleveland Clinic Florida, where he divides his time between leadership, research and patient care. He is the Chairman of the Levitetz Department of Orthopaedic Surgery at Cleveland Clinic Florida and Director of the Orthopaedic and Rheumatology Center. Dr. Higuera completed his residency at the Cleveland Clinic and a clinical fellowship at Thomas Jefferson University Hospital.

Dr. Higuera specializes in hip and knee arthroplasty surgery. He uses alternative approaches for primary hip and knee arthroplasty to optimize recovery. He is interested in complex revision procedures including infections. His research interest is mainly in periprosthetic joint infections including diagnostic tools, patient optimization and overall outcomes after arthroplasty. He is currently working on developing new technologies to diagnose and treat such infections. He is the past-president of the Musculoskeletal Infection Society.

"Based on the Level I clinical evidence in adult reconstruction revision surgery, we use 3M™ Prevena™ Therapy on our high-risk patient population to reduce the risk of SSC, SSI, readmissions and reoperations. In our experience, the portability and ease-of-use of the technology has also helped to reduce length of stay and office visits."

— Dr. Higuera



Brett D. Crist, MD, FACS, FAAOS

Professor

Vice Chair of Business Development

Director Orthopaedic Trauma Service

Director Orthopaedic Trauma Fellowship

Department of Orthopaedic Surgery

University of Missouri School of Medicine, Columbia, MO

Dr. Crist is a paid consultant for Solventum.

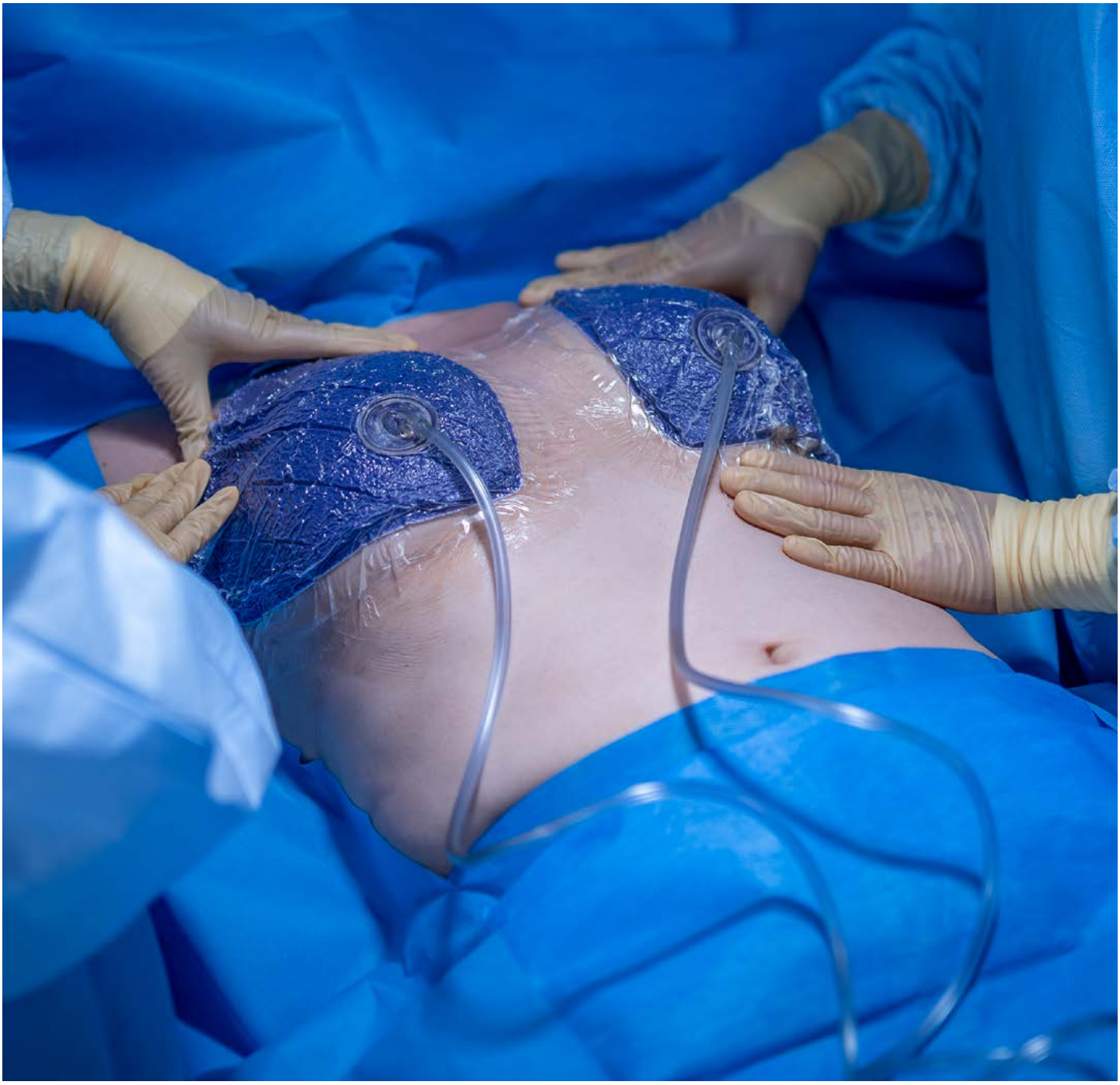
After obtaining a bachelor's degree from Tabor College in Hillsboro, Kansas, Dr. Crist earned his medical degree from the University of Kansas School of Medicine. He completed his residency at the University of Kansas School of Medicine, Wichita, and a fellowship in Orthopaedic trauma at the University of California-Davis.

Dr. Crist specializes in Orthopaedic trauma/fracture care, limb deformity correction, hip and pelvis reconstruction including total hip arthroplasty, and young adult hip disorders/hip preservation. Areas of interest include:

- Anterior total hip arthroplasty
- Fractures
- Hip and pelvic reconstruction surgery
- Hip arthroscopy
- Minimally invasive surgery
- Orthopaedic rehabilitation
- Orthopaedic trauma surgery
- Pelvic surgery
- Skeletal trauma
- Limb deformity correction

"In my practice, I have standardized my approach for using 3M™ Prevena™ Therapy. Leveraging Proactive Risk Management (PRM), I stratify my patients based on common procedural/ patient risk factors to reduce the risk of SSIs, thereby improving patient outcomes. I place a Prevena dressing on most of my high-risk patients."

— Dr. Crist



PRM in plastic surgery

Prevena.com/plastics

3M™ Prevena Restor™ Dressings can be used on a variety of anatomical locations.

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

Gabriel A, Singh D, Silverman RP, Collinsworth A, Bongards C, Griffin L. *ePlasty*. 2023 Mar 31;23:e22.

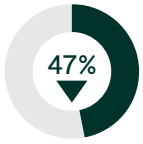
Study design
Systematic review and meta-analysis

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.

Summary
- This systematic review and meta-analysis of 12 published studies demonstrated that the use of Prevena Therapy was associated with reduced risks of SSCs, SSIs, seromas, dehiscence, prolonged drainage, and ROR following hip or knee arthroplasty. There was no reduction in hematoma rates.
- Subgroup analyses of studies done on high-risk patients also demonstrated a reduced risk in SSCs and SSIs.
- Potential cost savings of $904 per patient with the use of Prevena Therapy to reduce the risk of SSCs.

Results



Reduction of risk of SSC*
11 studies; risk ratio 0.532 (95% CI 0.396, 0.715) (p=0.001)*

Reduction of risk of dehiscence*†
9 studies; risk ratio 0.475 (95% CI 0.309, 0.73) (p=0.001)*

Reduction of risk of skin necrosis*†
5 studies; risk ratio 0.460 (95% CI 0.284, 0.746) (p=0.002)*

Reduction of risk of dehiscence* reduction of LOS*
5 studies; difference in means -0.610 (95% CI -0.822, -0.338) (p=0.03)*

(Continued)

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 skin necrosis and dehiscence has not been reviewed by the U.S. FDA

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.

(Continued)

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	Standardized difference In means	3	-2.543 (-4.564, -0.521)	0.014

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

*Statistically significant (p<0.05)

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.

Read the full study here

Journal: *ePlasty*

Title: 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

Published: March 31, 2023

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.

The impact of closed incision negative pressure therapy on postoperative breast reconstruction outcomes

Gabriel A, Sigalove S, Sigalove N, et al. *Plast Reconstr Surg Glob Open*. 2018;6(8):e1880.

Summary
The use of Prevena Therapy following post-mastectomy breast reconstruction was associated with significantly lower rates of infection, dehiscence, necrosis and seromas. A significantly shorter time to drain removal and fewer returns to the OR were also achieved.

Cost savings
Reduction in per patient cost for SSC[1]

- $2,010 Prevena Therapy vs. $2,228 standard dressing
- Mean per patient cost savings: **$218**

Study design
Retrospective, comparative study

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 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

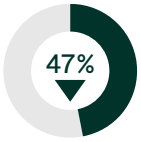
(Continued)

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.

References
1. 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.

(Continued)

Results



Reduction in SSCs*

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

Reduction in SSIs*

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

Reduction in seroma*

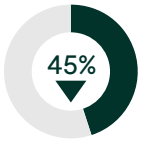
1.8% (6/331) Prevena Therapy vs. 5.7% (19/334) Adhesive skin closure (p=0.0106)*

Reduction in reoperations*

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

Reduction in dehiscence*†

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



Reduction in necrosis*†

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

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 the reduction in the incidence of dehiscence and necrosis has not been reviewed by the U.S. FDA

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.

Read the full study here

Journal: *Plastic and Reconstructive Surgery - Global Open*

Title: The impact of closed incision negative pressure therapy on postoperative breast reconstruction outcomes

Published: August 2018

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 Aug; 6(8):e1880. OPEN ACCESS

Closed incision negative pressure therapy in oncological breast surgery: Comparison with standard care dressings

Ferrando PM, Ala A, Bussone R, et al. *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.

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.

Results

Reduction in SSCs*

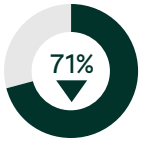
4 % (1/25) Prevena Therapy vs.
45 % (10/22) Adhesive skin closure
(p=0.001)*

Reduction in skin necrosis*†

4% (1/25) Prevena Therapy vs.
32% (7/22) Adhesive skin closure
(p=0.002)*

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)*



Improved surgeon-assessed OSAS score (max 50)*

7 (6-13) Prevena Therapy vs.
24 (17-29) Adhesive skin closure
(p=0.01)*

Improved surgeon-assessed MSS score (max 18)*

7 (5-12) Prevena Therapy vs.
12 (9-15) Adhesive skin closure (p=0.01)*

(Continued)

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 the reduction in the incidence of necrosis has not been reviewed by the U.S. FDA

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Ferrando et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	25	22
Number of surgical site complications (a)	1	10
Cost per SSC[1] (b)	$9,526	$9,526
Per patient complication cost [c=(a*b)/n]	$381	$4,330
Per patient therapy cost* (d)	$830	–
Total cost per patient (c+d)	$1,211	$4,330
Potential per patient savings using Prevena™ Therapy	$3,119	

*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.

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.

Reference
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18

Read the full study here

Journal: *Plastic and Reconstructive Surgery - Global Open*

Title: Closed incision negative pressure therapy in oncological breast surgery: Comparison with standard care dressings

Published: June 2018

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.

Managing no-drain mastectomy with closed incision negative pressure wound therapy using full-coverage foam dressings

Pieri A, Aisling E, Kay K, et al. *Eur J Surg Oncol.* 2023 Feb;49(2):e94.

Study design

This was a single center, case-control trial.

Study purpose

The trial was aimed to evaluate whether the mastectomies managed with ciNPT using full coverage foam dressings exhibited reduced need for seroma intervention and reduced seroma aspiration volumes.

Methods

Seroma intervention data was retrospectively gathered from a single center for patients undergoing simple mastectomy, mastectomy with sentinel lymph node biopsy, or mastectomy with axillary lymph node clearance. 30 sequential patients treated with conventional dressings in control arm and 25 sequential patients treated with ciNPT with full-coverage foam dressings (3M™ Prevena Restor™ Bella•Form™ Dressing) were selected for intervention arm.

Results

There were 31 mastectomy cases in each arm (including bilateral cases). There was no significant difference in surgery type between the groups.

1. Compared to control group, fewer patients in the intervention group developed postoperative seroma (20 control versus 15 intervention).
2. More subjects needed aspiration in control group than intervention group (16 control vs 12 intervention).
3. Fewer visits to the seroma clinic were needed for intervention group than control group (1 control vs. 0 intervention, p=0.012).
4. Intervention group had lower total aspiration volumes (843 mL control vs. 368 mL intervention, p=0.023).

Conclusion

The study indicated that the patients managed with ciNPT with full-coverage foam dressings required fewer seroma-related clinical episodes and experienced reduced total seroma volume. The use of ciNPT has reduced the costs and improved the services and therefore it has been adopted as the standard practice at this center.

Read the full study here

Journal: *European Journal of Surgical Oncology*

Title: Managing no-drain mastectomy with closed incision negative pressure wound therapy using full-coverage foam dressings

Published: February 2023

Pieri A, Aisling E, Kay K, et al. Managing no-drain mastectomy with closed incision negative pressure wound therapy using full-coverage foam dressings. *Eur J Surg Oncol.* 2023 Feb;49(2):e94.

The impact of closed incision negative pressure therapy on postoperative breast reconstruction outcomes

Gabriel A, Sigalove S, Sigalove N, et al. *Plast Reconstr Surg Glob Open*. 2018;6(8):e1880.

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.

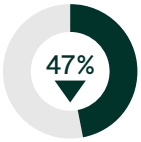
Methods

- 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

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.

Results



Reduction in SSCs*

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

Reduction in dehiscence*†

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

Reduction in SSI*

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

Reduction in necrosis*†

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

Reduction in reoperations*

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

Reduction in seroma*

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

(Continued)

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 the reduction in the incidence of dehiscence and necrosis has not been reviewed by the U.S. FDA

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.

(Continued)

Read the full study here

Journal: *Plastic and Reconstructive Surgery - Global Open*

Title: The impact of closed incision negative pressure therapy on postoperative breast reconstruction outcomes

Published: August 2018

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.

Incisional negative pressure wound therapy in bilateral breast reduction patients

Savage N, Jain M, Champion R, et al. *AJOPS*. 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.

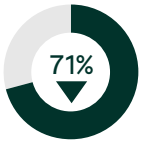
Methods

- 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

Summary

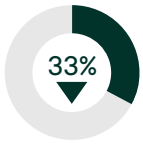
- This is the first study to provide evidence for the use of Prevena Therapy in bilateral breast reduction. This study indicates that Prevena Therapy could be associated with a significant reduction in surgical site complication occurrences, decreased total ward opioid use, and decreased hospital length 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.

Results



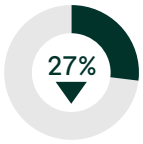
Reduction in complications*

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



Reduction in LOS*

1.35 ± 0.49 days Prevena Therapy vs. 2.03 ± 0.33 days standard dressing (p=0.001)*



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)*

Reduction in wound breakdown*

0 % (0/23) Prevena Therapy vs. 24.1 % (7/29) standard dressing (p=0.013)*

Reduction in opioids prescribed discharge (mean)*

125.5 mg ± 63.6 Prevena Therapy vs. 230.0 mg ± 115 standard dressing (p=0.0070)*

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

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	

*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
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.

Read the full study here

Journal: *Australasian Journal of Plastic Surgery*

Title: Incisional negative pressure wound therapy in bilateral breast reduction patients

Published: March 23, 2020

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

Closed incision negative pressure therapy in oncoplastic breast surgery: A comparison of outcomes

Wareham CM, Karamchandani MM, Ku GC, et al. *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.

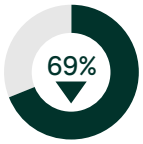
Methods

- 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 6 month to 2 year follow-up.
- Secondary outcomes were rates of minor complications not requiring significant medical or clinical intervention.

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.

Results



Reduction in wound complications requiring intervention*

5.3% (4/75) Prevena Restor Therapy vs. 16.9% (24/142) Adhesive skin closure (p=0.016)*

Reduction in dehiscence*†

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

(Continued)

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 the reduction in the incidence of dehiscence has not been reviewed by the U.S. FDA

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Wareham et al outcomes

Hypothetical economic model	Prevena™ 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	

*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.

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.

Reference
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.

Read the full study here

Journal: *Plastic and Reconstructive Surgery - Global Open*

Title: Closed incision negative pressure therapy in oncoplastic breast surgery: A comparison of outcomes

Published: April 2023

Wareham CM, Karamchandani MM, Ku GC, et al. Closed incision negative pressure therapy in oncoplastic breast surgery: A comparison of outcomes. *Plast Reconstr Surg Glob Open*. 2023 Apr 25;11(4):e4936.

Utility of negative pressure wound therapy: Raising the bar in chest masculinization surgery

Abu El Hawa AA, Dekker PK, Mizher R, Orra S, Fan KL, Del Corral G. *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 5 mm.
- 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 20 mL for two consecutive days.
- Postoperative follow-up care was standardized across all patients in the study population.

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.

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

*Statistically significant (p<0.05)

Results

Reduction in wound complications*

18% (13/72) Prevena Therapy vs. 42% (80/190) standard dressing (p<0.001)*

Reduction nipple hypopigmentation*

8.3% (6/72) Prevena Therapy vs. 18.9% (36/190) standard dressing (p=0.024)*

Reduction in seromas*

1.4% (1/72) Prevena Therapy vs. 7.9% (15/190) standard dressing (p=0.037)*

Reduction in partial NGL*

12.5% (9/72) Prevena Therapy vs. 24.7% (47/190) standard dressing (p=0.031)*

Reduction in time to drain removal*

7 days Prevena Therapy vs. 9 days standard dressing (p≤0.001)*

(Continued)

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.

(Continued)

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 patients (n)	72	190
Number of surgical site complications (a)	13	80
Cost per SSC[1] (b)	$9,526	$9,526
Per patient complication cost [c=(a*b)/n]	$1,720	$4,011
Per patient therapy cost* (d)	$495	–
Total cost per patient (c+d)	$2,215	$4,011
Potential per patient savings using Prevena™ Therapy	$1,796	

*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.

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Reference
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.

Read the full study here

Journal: *Plastic and Reconstructive Surgery - Global Open*

Title: Utility of negative pressure wound therapy: Raising the bar in chest masculinization surgery

Published: February 2022

Abu El Hawa AA, Dekker PK, Mizher R, et al.. Utility of negative pressure wound therapy: Raising the bar in chest masculinization surgery. *Plast Reconstr Surg Glob Open*. 2022 Feb 11;10(2):e4096.

Reducing donor-site complications in DIEP flap breast reconstruction with closed incisional negative pressure therapy: A cost-benefit analysis

Munro SP, Dearden A, Joseph M, O'Donoghue JM. *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

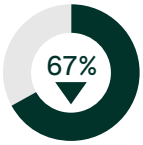
Methods

- 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

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.

Results



Reduction in donor site complications*

16.7% (4/24) Prevena Therapy vs. 50% (10/20) standard dressing (p=0.018)*

Reduction in seroma*

12.5% (3/24) Prevena Therapy vs. 45% (9/20) standard dressing (p=0.016)*

Reduction in SSIs*

0% (0/24) Prevena Therapy vs. 25.0% (5/20) standard dressing (p=0.014)*

Reduced cost of SSC care and postoperative follow-up cost*†

£509 Prevena Therapy vs. £930 standard dressing (p=0.031)*

(Continued)

Calculation(s) are derived based on 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

(Continued)

Read the full study here

Journal: *Journal of Plastic Reconstruction Aesthetic Surgery*

Title: Reducing donor-site complications in DIEP flap breast reconstruction with closed incisional negative pressure therapy: A cost-benefit analysis

Published: August 4, 2022

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.

Closed-incision negative pressure therapy decreases wound morbidity in open abdominal wall reconstruction with concomitant panniculectomy

Ayuso SA, Elhage SA, Okorji LM, et al. *Ann Plast Surg*. 2022 Apr 1;88(4):429-433.

Study design

Retrospective Cohort Study

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 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 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 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).

Results

Reduction in wound complications*

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

Reduction in number of OR visits *

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

Reduction in superficial wound breakdown

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

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

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	

*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 standard dressings. 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.

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.

Reference
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.

Read the full study here

Journal: *Annals of Plastic Surgery*

Title: Closed-incision negative pressure therapy decreases wound morbidity in open abdominal wall reconstruction with concomitant panniculectomy

Published: April 2022

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 Apr 1;88(4):429-433.

Preliminary result with incisional negative pressure wound therapy and pectoralis major muscle flap for median sternotomy wound infection in a high-risk patient population

Lo Torto F, Monfrecola A, Kaciulyte J, et al. *Int Wound J.* 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.

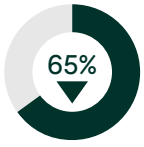
Methods

- 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.

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.

Results



Reduction in adverse events & complications*

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

Incidence in dehiscence*†

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

(Continued)

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 the reduction in the incidence of dehiscence has not been reviewed by the U.S. FDA

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.

(Continued)

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	

*3M™ Prevena™ Peel and Place System Kit 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 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.

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.

Reference
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.

Read the full study here

Journal: *International Wound Journal*

Title: Preliminary result with incisional negative pressure wound therapy and pectoralis major muscle flap for median sternotomy wound infection in a high-risk patient population

Published: September 13, 2017

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.

Incisional negative pressure therapy reduces complications and costs in pressure ulcer reconstruction

Papp A. *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.

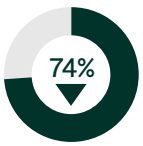
Methods

- 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:

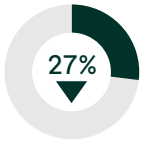
- Grade 3-4 with full-thickness skin loss exposing fat or deeper tissues
- Underlying bone exposure
- Documentation of osteomyelitis
- Lack of progression in wound healing in 3 months after optimization of patient variables

Results



Reduction in complications*

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



Reduction in hospital LOS*

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

Reduction in number of open wounds at 3 months postoperative*

5.4% Prevena Therapy vs. 25.0% Adhesive skin closure (p=0.0481)

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.

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

*Statistically significant (p<0.05)

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.

Read the full study here

Journal: *International Wound Journal*

Title: Incisional negative pressure therapy reduces complications and costs in pressure ulcer reconstruction

Published: December 12, 2018

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

The use of closed incision negative pressure therapy for incision and surrounding soft tissue management: Expert panel consensus recommendations

Silverman RP, Apostolides J, Chatterjee A, et al. *Int Wound J.* 2022;19(3):643-655.

Study type
The study type was an Expert Panel convened to develop consensus recommendations. In the absence of high-quality studies, an expert panel of plastic surgeons reviewed the current literature and formed consensus utilizing a modified Delphi technique.

Study purpose
The purpose of the study was to identify conditions in which ciNPT with full-coverage dressings is most appropriate, and address challenges to the implementation and sustainability of ciNPT.

Methods
Consensus building was done using modified Delphi technique, which involved three rounds of input to gather feedback and identify topics with potential for agreement. Consensus was defined as ≥80% agreement among panel members.

Selected panelists had experience using ciNPT with both conventional and novel dressings, previously presented or published on the use of ciNPT, were able to present their cases demonstrating use of ciNPT in the panel meetings and were able to understand and participate in consensus formation process.

The panel recommended use of ciNPT with full-coverage dressings when 2 or more risk factors for surgical site complications are present.

Results
The panel was able to establish 10 consensus statements. Recommendations for the use of ciNPT with full coverage dressings were provided for patient and incision related risk factors, therapy duration, appropriate pressure settings to be used, and lastly, techniques used for ciNPT. The panel recommended that future studies on ciNPT should focus on identifying the benefits of use and overcoming implementation barriers.

Read the full study here

Journal: *International Wound Journal*

Title: The use of closed incision negative pressure therapy for incision and surrounding soft tissue management: Expert panel consensus recommendations

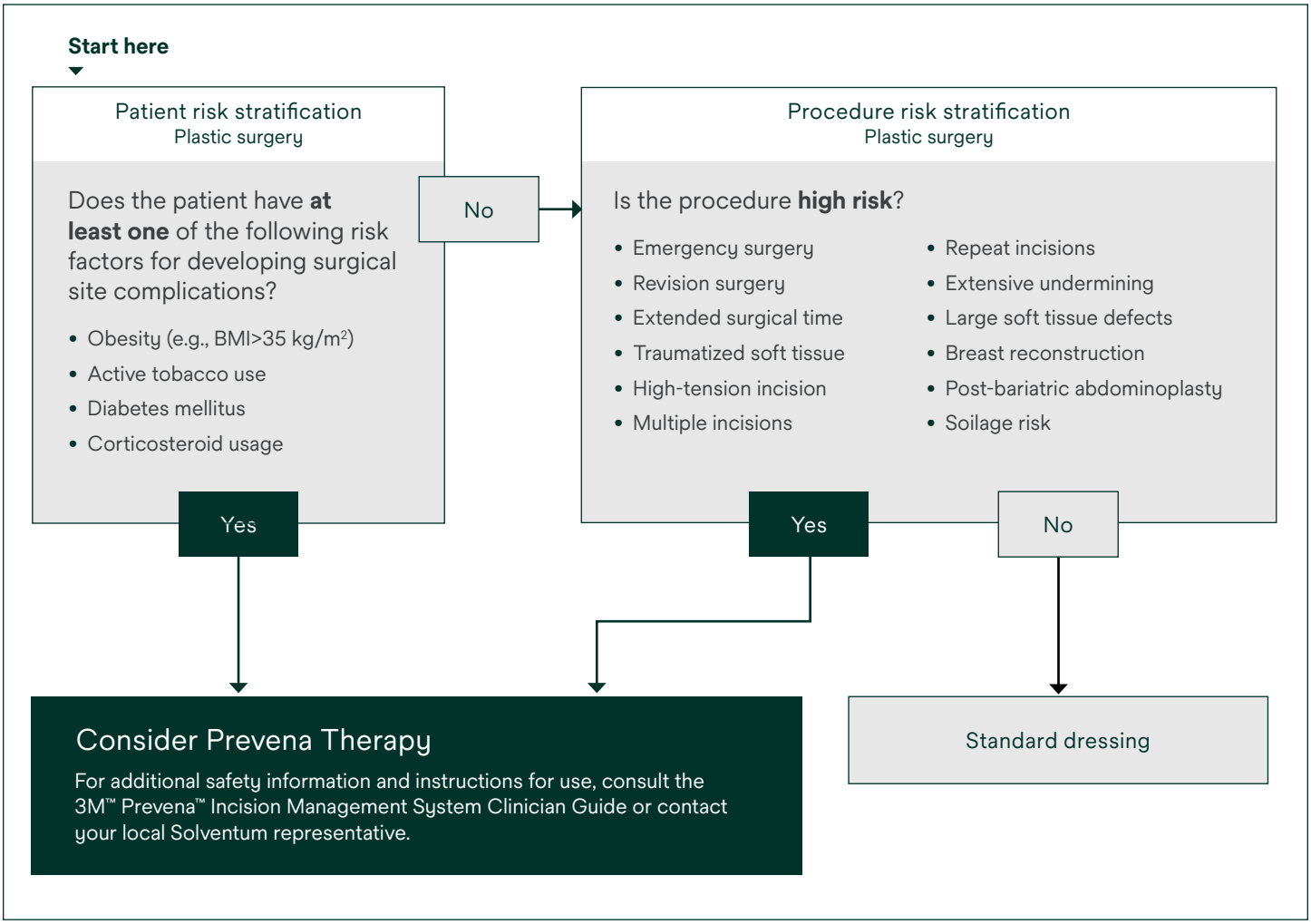
Published: August 21, 2021

Silverman RP, Apostolides J, Chatterjee A, et al. The use of closed incision negative pressure therapy for incision and surrounding soft tissue management: Expert panel consensus recommendations. *Int Wound J.* 2022;19(3):643-655.
OPEN ACCESS

Decision guide

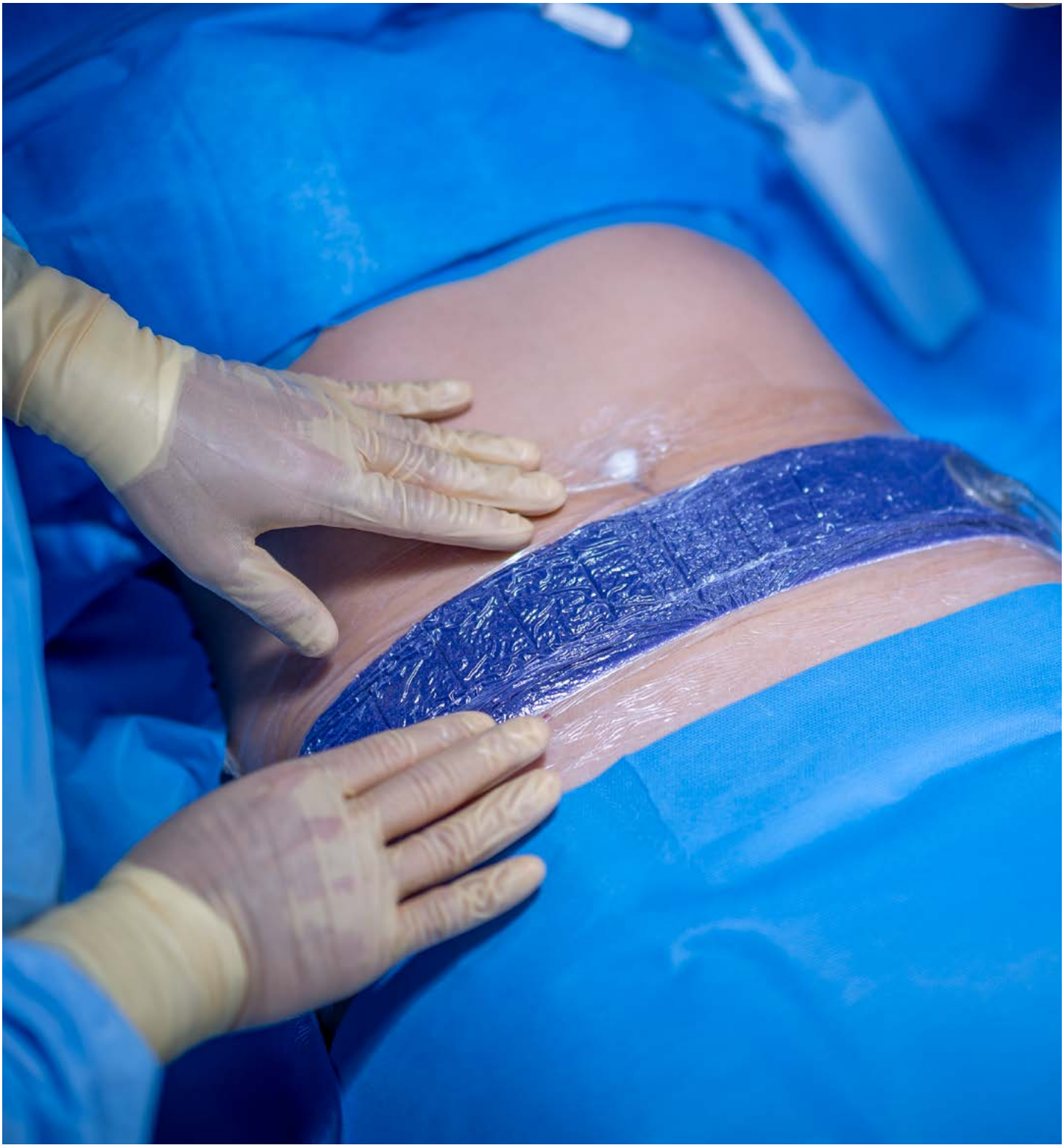
Patient and procedure risk stratification backed by clinical evidence

While surgical patients may benefit from Prevena Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data[1-2] to provide an illustrative guide to aid in risk stratification. This is not an all-inclusive list of risk factors. Clinicians are advised to use their clinical judgment to identify high-risk patients or high-risk procedures.



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.

References
1. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: International multidisciplinary consensus recommendations. *Int Wound J.* 2017 Apr;14(2):385-398. OPEN ACCESS 2. 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 Aug; 6(8):e1880. OPEN ACCESS



Case studies

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Management of bilateral breast reconstruction with 3M™ Prevena Restor™ Bella•Form™ Incision Management System

Abhishek Chatterjee, MD, MBA, Tufts Medical Center, Boston, MA

Patient

A 73-year-old female with symptomatic macromastia and left breast cancer presented to the clinic for oncoplastic surgery and a possible breast reduction with removal of axillary excess skin and fat (**Figure 1**). The patient was obese with high cholesterol and hypertension, and she had previously undergone surgery for breast cancer.

Procedure

The patient underwent oncoplastic surgery on her left side that included a large left sided partial mastectomy with a left sided breast reduction. She also underwent a symmetric right sided breast reduction. Both breast surgeries were closed using inverted-T incisions. Intraoperatively, the left nipple appeared blue secondary to indocyanine blue injection and venous congestion (**Figure 2**).

Application of Prevena Restor™ Bella•Form™ Incision Management System

Therapy with the Prevena Restor™ Bella•Form™ Incision Management System was initiated at -125 mmHg over both breasts (**Figure 3**). The goal of therapy was the management of the surgical incision and reduction of tensile forces across the incision.

Discharge and follow-up

The patient was discharged home the day of surgery. After 7 days, Prevena Restor Therapy was discontinued, with the goals of therapy having been achieved. The incision had healed well and there were no signs of seroma or other postoperative complications. Upon follow-up 2 months post surgery, the incisions remained closed (**Figure 4**).

Patient data and photos courtesy of Abhishek Chatterjee, MD, MBA, Tufts Medical Center, Boston, MA.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on the patient's circumstances and condition.

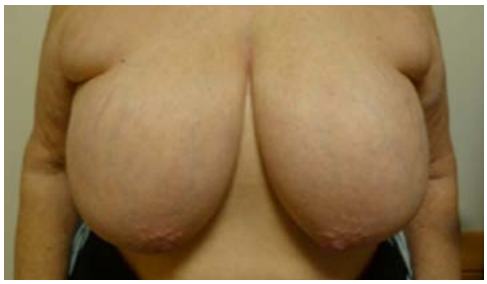


Figure 1. Patient appearance at presentation.

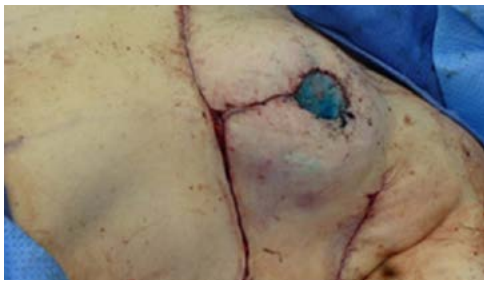


Figure 2. Blue coloring of the left nipple during breast reduction surgery, secondary to indocyanine blue injection and venous congestion.

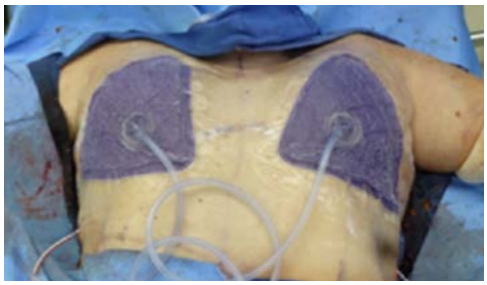


Figure 3. Application of therapy using Prevena Restor™ Bella•Form™ Incision Management System over both breasts.

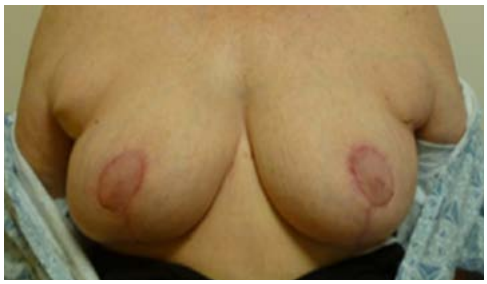


Figure 4. The incisions remained closed on both breasts at 2 months post surgery.

Management of double mastectomy with 3M™ Prevena Restor™ Bella•Form™ Incision Management System

Allen Gabriel, MD, FACS; Global Surgical Consulting; Camas, WA

Patient

A 50-year-old female patient presented to the surgical clinic requiring bilateral mastectomy for breast cancer (**Figure 1**). She had no notable prior medical history.

Procedure

The patient underwent a bilateral mastectomy with immediate reconstruction, resulting in a 7-cm inframammary incision on each breast. The incisions were sutured closed over drains, and the patient was administered cephalexin for prophylactic antibiotic control.

Application of 3M™ Prevena Restor™ Bella•Form™ Incision Management System

3M™ Prevena Restor™ Therapy was initiated using 3M™ Prevena Restor™ Bella•Form™ Dressing, which covered each inframammary incision and the entirety of each breast (**Figure 2**). Negative pressure was applied at -125 mmHg continuously for 6 days.

Discharge and follow-up

The patient was discharged home the day after surgery. After 6 days, Prevena Restor Therapy was discontinued, and the incision remained closed (**Figure 3**). When the patient returned for follow-up on postoperative day 9, there were no complications and the drain was removed (**Figure 4**). At 30 days post-surgery, the incision remained closed, and there was no incidence of surgical site infection, seroma, or any other surgical complication.

The Prevena Restor Incision Management System is indicated for the management of closed surgical incisions that continue to drain following sutured or stapled closure, by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

The Prevena Restor Incision Management System is suitable for a variety of anatomical locations.

Patient data and photos courtesy of Allen Gabriel, MD, FACS; Global Surgical Consulting; Camas, WA.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on the patient's circumstances and condition.

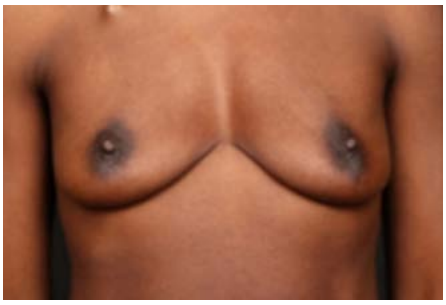


Figure 1. Breast appearance pre-mastectomy.

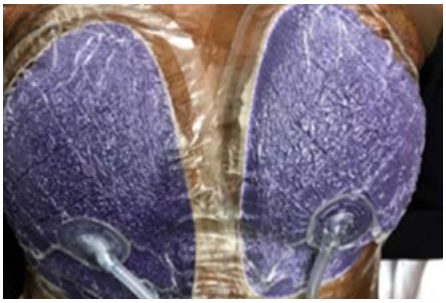


Figure 2. Application of 3M™ Prevena Restor™ Therapy with 3M™ Prevena Restor™ Bella•Form™ Dressing post mastectomy.

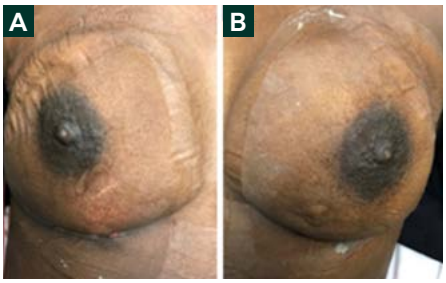


Figure 3. Appearance after 6 days of 3M™ Prevena Restor™ Therapy with 3M™ Prevena Restor™ Bella•Form™ Dressing **A.** Right breast. **B.** Left breast.

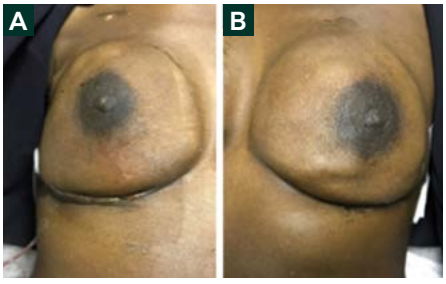


Figure 4. Appearance on postoperative day 9. **A.** Right breast. **B.** Left breast.

Closure of a complex lower extremity wound with the use of multiple negative pressure therapy modalities

Eldenburg E, Pfaffenberger M, Gabriel A (July 17, 2020) Closure of a Complex Lower Extremity Wound With the Use of Multiple Negative Pressure Therapy Modalities. *Cureus* 12(7): e9247. DOI 10.7759/cureus.9247.

Patient

A 25-year-old female presented with an actively draining Morel-Lavallée lesion of the left lateral thigh, sustained after being struck by a motor vehicle. She was initially evaluated and admitted for the avulsion injury approximately two weeks prior, and had a drain placed at that time. However, due to issues with compliance, she had not been re-evaluated since, and ultimately presented with a suspected infection of her left lower extremity.

Procedure

The patient was placed on intravenous cefazolin and underwent several rounds of excisional debridement and irrigation. The patient was then managed operatively by a plastic surgery service. This care included three rounds of tissue advancement, followed by a seven-day course of NPWTi-d. Cycles consisted of normal saline instillation with a one-second dwell time, followed by six hours of continuous negative pressure at –125 mmHg. The patient was then taken back for a final round of reconstruction with tissue advancement. A split-thickness skin graft (STSG) was used at that time to cover the remaining area of the wound that the advancement could not close. A seven-day course of ciNPT with the 3M™ Prevena Restor™ Bella•Form™ System was then applied to manage the incisions and bolster the graft. This was followed by simple dressing changes several times weekly for four weeks.

Results

After seven days of ciNPT, the patient was evaluated in the clinic and the 3M™ Prevena Restor™ Bella•Form™ dressing was removed. On removal of the dressings, the skin graft appeared viable. The wound edges also appeared well-approximated, dry, and intact. Therefore, it was decided to discontinue treatment with the 3M™ Prevena Restor™ Incision Management System.

Non-adherent silicone dressings (3M™ Adaptic™ Non-Adhering Dressing) were placed over the skin graft recipient site, followed by abdominal pads. These were secured in place with an adhesive tape. The patient returned to the clinic once a week for wound evaluation and dressing changes, while also performing dressing changes frequently at home.

At four weeks postoperatively, the wound appeared well-approximated with normal scabbing, so staples were removed. At six weeks post-STSG placement and delayed primary closure, the wound remained well-healed, with minimal scabbing.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on the patient's circumstances and condition.

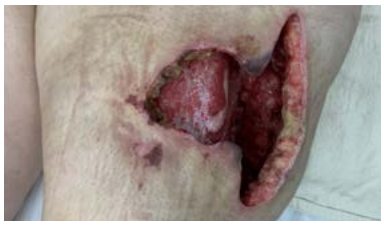


Figure 1. Initial presentation of the infected medial left leg wound.

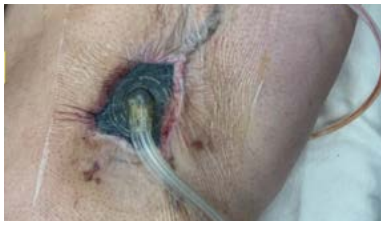


Figure 2. Application of irrigating negative pressure therapy.

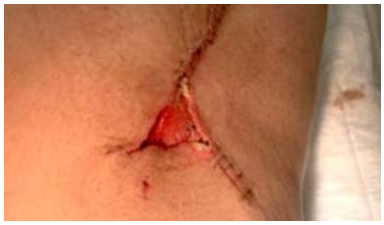


Figure 3. Pre-closure of the donor site with a STSG.

Figure 4. Application of closed incision negative pressure.

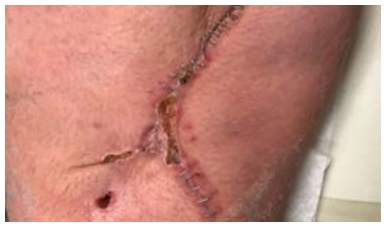


Figure 5. Wound at four weeks post-operatively.

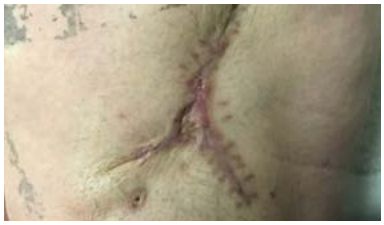


Figure 6. Wound at six weeks post-operatively.

Panniculectomy

Dr. Devinder Singh and Dr. Ron Silverman, University of Maryland, School of Medicine, Baltimore, MD and Senior Vice President and Chief Medical Officer, Acelity, San Antonio, TX.

Patient

An obese female patient presented with end-stage renal disease. She was on dialysis and awaiting a renal transplant. However, the patient's transplant surgeon requested a plastic surgery consultation prior to her renal transplant to evaluate the patient for a panniculectomy for her large, overhanging abdominal pannus (**Figure 1**) in order to reduce the complexity and risk of the renal transplant procedure.

Diagnosis

After consultation with the plastic surgeons, the patient underwent a panniculectomy for her abdominal pannus.

Initial incision treatment/application of 3M™ Prevena™ Therapy:

Post panniculectomy (**Figures 2 and 3**), 3M™ Prevena™ Incision Management System with the 3M™ Prevena™ Customizable Dressing was placed over the complete closed incision at -125 mmHg (**Figures 4 and 5**). The patient was discharged home on postoperative day 1 with the dressing in place.

Discharge and follow-up

Prevena Therapy was discontinued after 7 days. At postoperative day 13, the incision remained intact with good reapproximation (**Figure 6**). The patient did not have any postoperative incision complications.

Patient data and photos courtesy of Dr. Devinder Singh and Dr. Ron Silverman, University of Maryland, School of Medicine, Baltimore, MD and Senior Vice President and Chief Medical Officer, Acelity, San Antonio, TX.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on the patient's circumstances and condition.

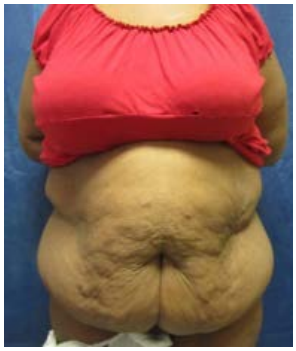


Figure 1. Patient with overhanging abdominal pannus.

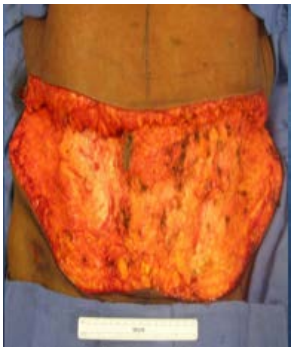


Figure 2. Removal of pannus.

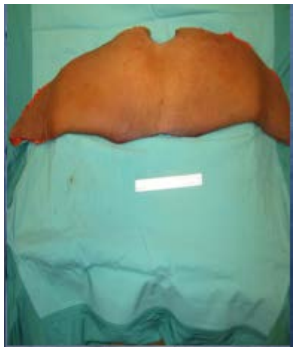


Figure 3. Removed pannus.

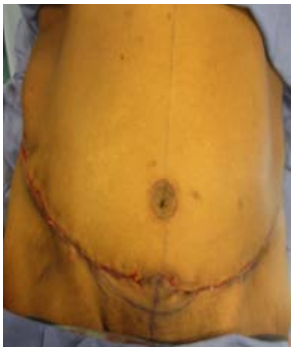


Figure 4. Complete closed incision.

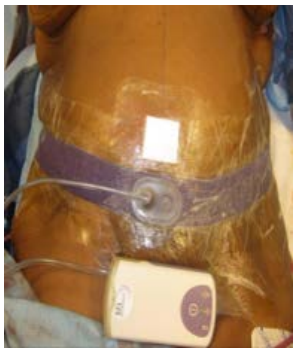


Figure 5. Application of 3M™ Prevena™ Therapy for 7 days.

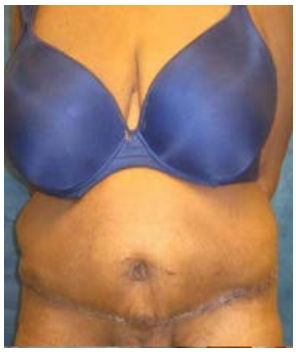
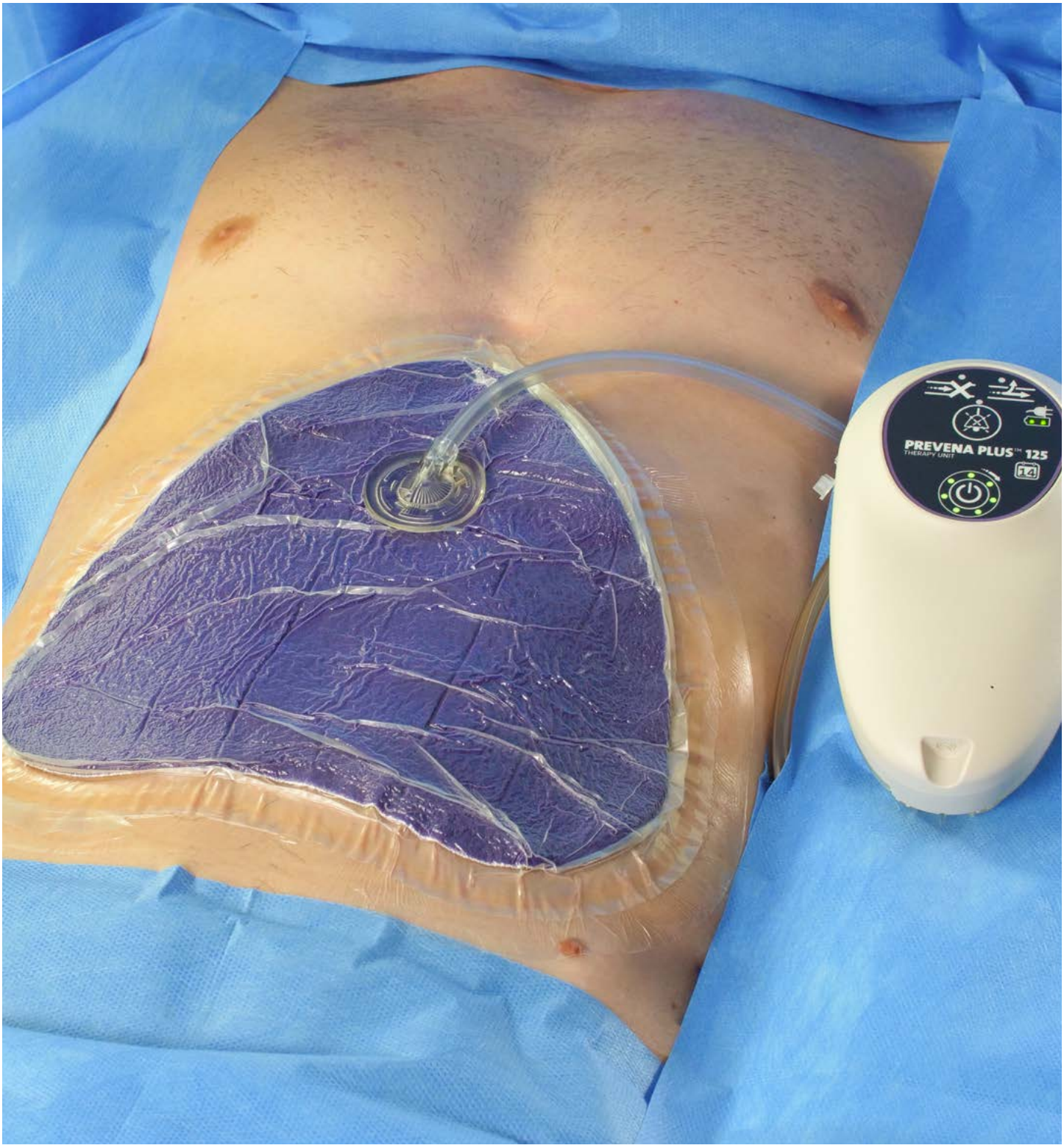


Figure 6. Incision at postoperative day 13.



Author biographies*

*Where available and permitted to use.

3M™ Prevena Restor™ Dressings can be used on a variety of anatomical locations.

Abhishek Chatterjee, MD, MBA

Chief of the Division of Plastic Surgery
Division of Surgical Oncology
Tufts Medical Center
Boston, MA

Dr. Chatterjee is a paid consultant for Solventum.

Dr. Chatterjee is a board-certified plastic surgery and fellowship trained breast oncologic surgeon practicing at Tufts Medical Center in Boston, MA. After completing his MD/MBA training at the University of Connecticut, he went on to do eight years of surgical residency at Dartmouth Hitchcock Medical Center in New Hampshire in plastic surgery and followed this with a one-year breast surgical oncology fellowship at the University of Pennsylvania. With this unique training in oncology and plastic surgery, much of Dr. Chatterjee's practice involves the removal of cancer and the reconstruction using oncoplastic surgical techniques. He is active within his own institution as the President of the Medical Staff and sits on several committees as a member in both national breast oncologic and plastic surgery societies. He is presently Associate Professor of Surgery at Tufts Medical Center and is the Chief of Plastic Surgery.

Academically, he enjoys training surgical residents daily and has published more than 90 peer-reviewed journal articles, most of which are either first or senior authored.

"My use of ciNPT began when I wanted to reduce my wound complication rates in high-risk breast cancer patients, so that I could get my patients to adjuvant therapy after surgery without delay. Now I continue to use ciNPT on all of my patients with any high-risk incisions to decrease my overall complication rates regardless of anatomical location."

— Dr. Chatterjee

Allen Gabriel, MD, FACS

Private Practice
Vancouver, Washington

Dr. Gabriel is a paid consultant for Solventum.

Allen Gabriel, MD, is an Assistant Professor and Director of Research in the Department of Surgery at Loma Linda University, Loma Linda, California. He is a board-certified plastic surgeon that believes plastic and reconstructive surgery provides a unique opportunity to deal with a wide variety of needs ranging from addressing congenital anomalies, to breast reconstruction following mastectomy, to aesthetic procedures such as breast and facial cosmetic procedures.

In 2001, Dr. Gabriel was chosen by the prestigious Loma Linda University to join the Integrated Plastic Surgery Residency Program. While at Loma Linda University, he volunteered on a medical mission to Ethiopia with Operation Good Samaritan. In addition, he served on several leadership committees and was the chief resident prior to completing his residency. In 2007, Dr. Gabriel was selected by Dr. G. Patrick Maxwell to enter a Breast and Aesthetic Surgery Fellowship in conjunction with Baptist Hospital in Nashville, Tennessee. Completion of this program provided him with advanced training in breast and aesthetic surgery.

Dr. Gabriel is one of the few medical students in the country to have received the prestigious Humanism in Medicine Award. This award led to the creation of the University of Nevada's Humanism in Medicine Honor Society, of which Dr. Gabriel is still an active member. During medical school, he was involved with both clinical and basic science research, earning several research awards and publications prior to graduating. Dr. Gabriel has been invited to speak nationally and internationally on breast and aesthetic surgery. Dr. Gabriel is a Fellow of the American College of Surgeons. He is also a member of several prestigious organizations including the American Board of Plastic Surgery, American Society of Bariatric Plastic Surgeons, American Society of Plastic Surgeons, and California Society of Plastic Surgeons.

Since 1995, Dr. Gabriel has authored more than three dozen abstracts and chapters in peer-reviewed publications, including articles on liposuction, tummy tuck, breast anatomy and breast embryology.

"In 2012, we started using closed incision negative pressure therapy in complex reconstructions in my practice. Subsequently in 2014, we decided to expand use of the technology into breast reconstructions because of the positive clinical results on key patient outcomes. At that time, my colleagues wanted to better understand how to leverage a risk stratification algorithm to inform a more standardized approach of the therapy. We then published the figure [shown on the next page], which we still use today."

— Dr. Gabriel

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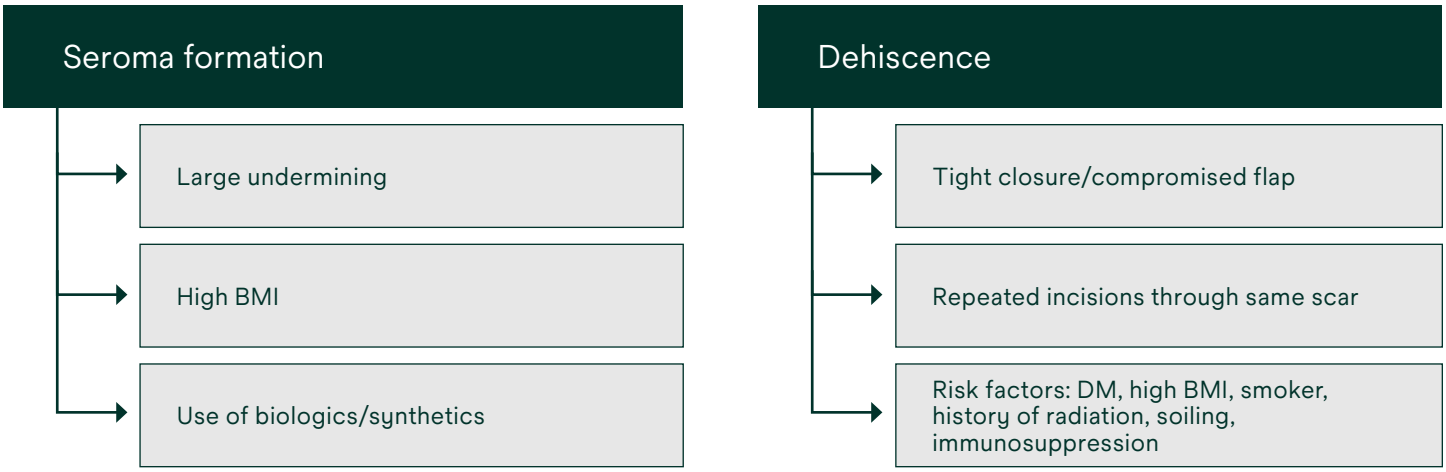
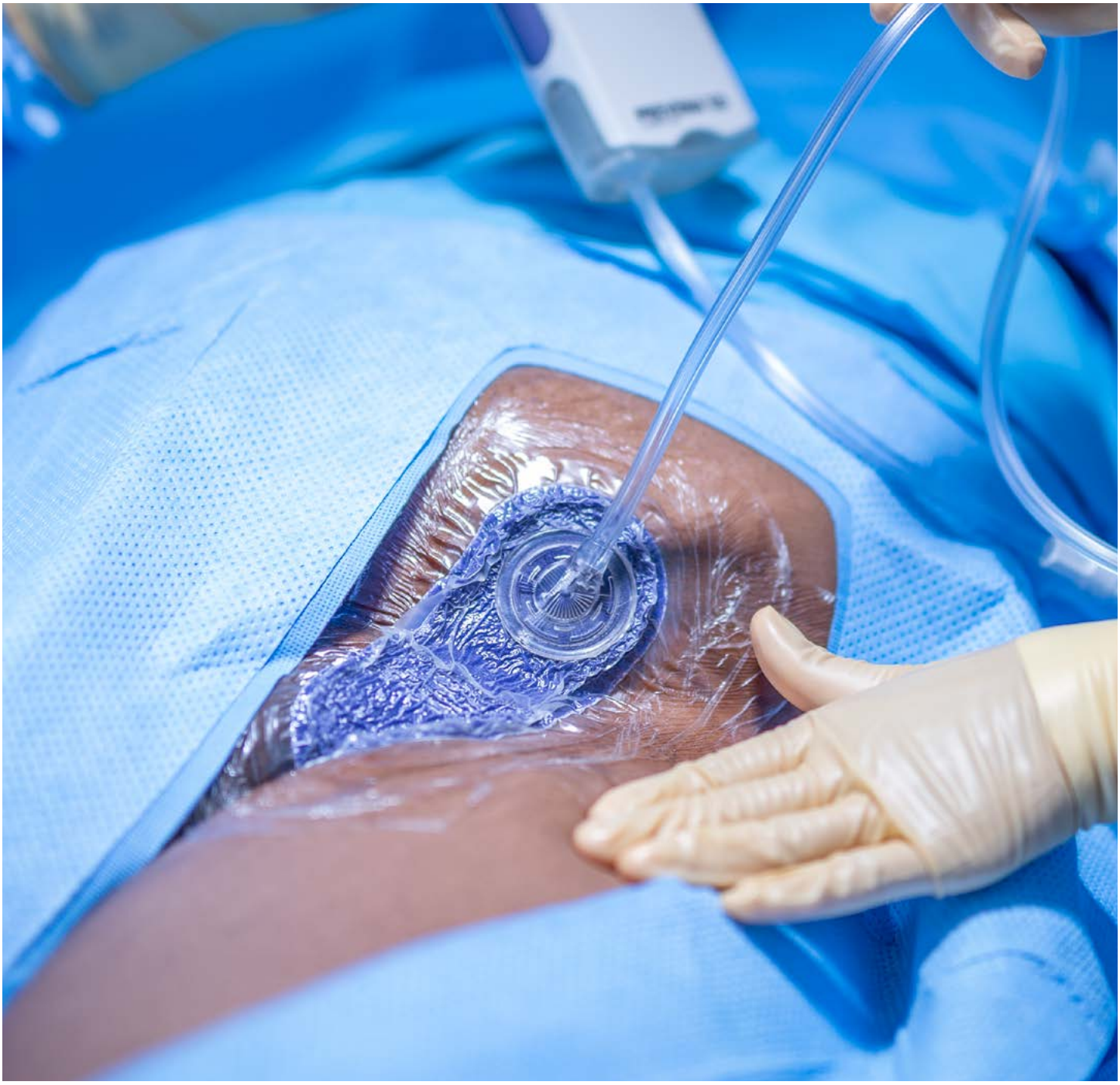
Incisions at risk for surgical complications[1]



BMI - body mass index; DM - diabetes mellitus

Checklist of potential risk factors for surgical complications

Reference
1. Gabriel A, Sigalove SR, Maxwell GP. Initial experience using closed incision negative pressure therapy after immediate postmastectomy breast reconstruction. *Plast Reconstr Surg Glob Open*. 2016 Jul 22;4(7):e819. OPEN ACCESS



PRM in vascular surgery

Prevena.com/vascular

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery

Antoniou G, Onwuka C, Antoniou S, et al. *J Vasc Surg.* 2019;70(5):1700-1710.

Study design

Meta-analysis and trial sequential analysis

Study purpose

To compare the efficacy of Prevena Therapy with standard dressing in closed surgical wound incisions in vascular surgery

Methods

- Systematic Review of literature to identify RCTs comparing prophylactic ciNPT (3M™ Prevena™ Therapy) with standard dressing in closed groin incisions in vascular surgery
- Fixed-effect model was used to calculate pooled odds ratio or risk difference and 95% confidence intervals
- All studies identified compared 3M™ Prevena™ Therapy to standard dressing
- Primary outcome: Surgical Site Infection
- Secondary outcomes: revision surgery, in-hospital mortality, hospital length of stay, and readmission
- Identified 6 RCTs on a total of 733 groin surgical wounds: Prevena Therapy n=362 vs. standard dressing n=371 (all published between (2016-2018)
  - Gombert et al 2018
  - Engelhardt et al 2018
  - Pleger et al 2018
  - Kwon et al 2018
  - Lee et al 2017
  - Sabat et al 2016

Summary

- Prophylactic use of negative pressure wound therapy (NPWT) helps improve over standard dressing aiding in the reduction in the risk of SSI in vascular surgical groin patients
- Prevena Therapy patients have reduced risk for:
  - surgical site infection (p<0.0001)
  - revision surgeries (p=0.02)
- Shorter hospital stay for patients with Prevena Therapy (p=0.01)
- Differences in secondary outcomes in-hospital mortality and readmission were not statistically significant
- "All studies included in our analysis were published recently (2016-2019) representing contemporary clinical practice in the Western world."
- "Evidence can be considered to be conclusive and that no more trials are required to investigate the primary outcome."

Results

Reduction of risk of SSIs*

6 studies; odd ratio 0.36 (95% CI 0.24, 0.54) **(p<0.001)*** Prevena Therapy 11.3% (41/362) vs standard dressing 25.6% (95/371)

Reduction of risk of revision surgery*

4 studies; odd ratio 0.44 (95% CI 0.22, 0.88) **(p=0.02)*** Prevena Therapy 4.9% (13/268) vs standard dressing 10.4% (28/270)

Reduction of LOS*

2 studies
Weighted mean difference -2.14 days (95% CI -3.78, -0.49) **(p=0.01)***

Risk-reduction is calculated based on risk ratio derived from related odd ratios and prevalence rate

*Statistically significant (p<0.05)

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.

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	3M™ Prevena™ Therapy		Standard dressing			
	Events	Total	Events	Total	Estimate (95% CI)	p-value
Szilagyi I	22 (7.9%)	279	48 (16.6%)	289	OR 0.40 (0.24, 0.69)	0.001*
Szilagyi II	12 (4.3%)	279	24 (8.3%)	289	OR 0.51 (0.25, 1.04)	0.06
Szilagyi III	3 (1.1%)	279	11 (3.8%)	289	RD -0.03 (-0.05, 0.00)	0.05

OR: odd ratio, RD: risk difference

Risk-reduction is calculated based on risk ratio derived from related odd ratios and prevalence rate

*Statistically significant (p<0.05)

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.

Read the full study here

Journal: *Journal of Vascular Surgery*

Title: Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery

Published: May 21, 2019

Antoniou G, Onwuka C, Antoniou S, et al. Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery. *J Vasc Surg*. 2019;70(5):1700-1710.

A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications

Kwon J, Staley C, McCullough M, et al. *J Vasc Surg.* 2018 Dec;68(6):1744-1752.

Summary of findings

- Study was evaluated and stopped at 80% enrollment target, as predetermined stop criteria for high-risk population were meet. Results demonstrated >50% reduction (p<0.001) in wound complication and reduced hospital costs with Prevena Therapy.
- Study suggests that negative pressure therapy for patients at high risk for groin wound complications significantly reduces major wound complication, reoperation and readmission rates and Prevena Therapy may lead to a reduction in hospital cost.
- The study authors calculated the potential cost saving per patient was $6,045 (p=0.11) and report it is likely an underestimate as it does not include outpatient costs for infection treatment as well as readmission penalties.

  Cost assessment includes variable hospital costs (for both the index hospitalization and all readmission days within 30 days related to any wound complication). Hospital variable costs (not charges) for each admission were obtained from hospital administration.

- Prevena Therapy is recommended for all groin incisions considered at high risk for wound complications.

Study design

Prospective, single-center, randomized controlled trial

Study purpose

This prospective RCT evaluated negative pressure therapy (3M™ Prevena™ Therapy) to decrease wound complications and associated healthcare costs.

Methods

- The study included 119 femoral incisions closed primarily after elective vascular surgery procedures
- High-risk inclusion criteria: BMI >30, pannus, re-operative surgery, prosthetic graft, poor nutrition, immunosuppression, or HbA1c>8
- 1:1 Randomized to standard gauze (n=60) vs. Prevena Therapy (n=59)
- Outcomes evaluated at post-operative day 30: wound complications, SSI, length of stay (LOS), reoperation, readmission

Results

Reduction in wound complications*

11.9% (7/59) Prevena Therapy vs. 26.7% (16/60) standard dressing (p=0.001)*

Reduction in major SSIs*

10.1% (6/59) Prevena Therapy vs. 31.6% (12/60) standard dressing (p=0.001)

Reduction in return to OR*

8.5% (5/59) Prevena Therapy vs. 18.3% (11/60) standard dressing (p=0.05)*

Reduction in readmissions*

6.8% (4/59) Prevena Therapy vs. 16.7% (10/60) standard dressing (p=0.04)*

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

	3M™ Prevena™ Therapy	Standard dressing
Szilagyi I	1.7% (1/59)	3.3% (2/60)
Szilagyi II	3.4% (2/59)	5.0% (3/60)
Szilagyi III	5.1% (3/59)	11.7% (7/60)

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

*Statistically significant ($p<0.05$)

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.

Read the full study here

Journal: *Journal of Vascular Surgery*

Title: A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications

Published: August 17, 2018

Kwon J, Staley C, McCullough M, et al. A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications. *J Vasc Surg.* 2018 Dec;68(6):1744-1752. OPEN ACCESS

Closed incision negative pressure therapy reduces surgical site infections in vascular surgery: A prospective randomised trial (AIMS trial)

Gombert A, Babilon M, Barbati ME, et al. *Eur J Vasc Endovasc Surg.* 2018 Sept; 56(3):442-448.

Study design

Prospective, multi-center, randomized controlled trial

Study purpose

This prospective RCT aimed to assess the potential benefit of 3M™ Prevena™ Therapy application to reduce the surgical site infection risk after groin incision for vascular surgery.

Methods

- The study evaluated 188 patients who underwent vascular surgery for peripheral artery disease (PAD) with a longitudinal groin incision at two sites in Germany between July 2015 and May 2017.
- High-risk inclusion criteria: smoking, cardiac risk factors including hypertension, coronary heart disease, or history of myocardial infarction, metabolic disorders including diabetes, dyslipidaemia, hyperhomocysteinaemia or chronic renal failure.
- When a groin incision was performed on both sides, only one side was randomized and assessed for the study.
- 30-day SSIs were assessed using the Szilagyi classification.

Key points

- Study found Prevena Therapy and fewer antibiotic treatments for SSI when compared to standard dressing group.
- No device-related complications (skin laceration, allergic reaction, reduced mobility, or negative pressure related pain) or device failures were observed in this trial.
- High-risk patients could benefit from Prevena Therapy to help reduce the risk of total SSI.
- Subgroup analysis demonstrated for populations with increased SSI risk such as patient with PAD stage ≥3, BMI >25 kg/m², and previous groin incisions a significantly reduced SSI rate with Prevena Therapy, indicating Prevena Therapy benefit for high-risk population.

Results

Reduction in SSI*

13.2% (13/98) Prevena Therapy vs. 33.3% (30/90) standard dressing (p=0.0015)*

Reduction in Szilagyi I SSIs*

8.1% (8/98) Prevena Therapy vs. 26.7 % (24/90) standard dressing (p=0.0012)*

Reduction in antibiotics

13.2% (13/98) Prevena Therapy vs. 31.1% (28/90) standard dressing (p=0.004)*

SSI Rates per subgroups	Prevena™ Therapy	Standard dressing	p-value
Szlagyi all	13.2% (13/98)	33.3% (30/90)	0.0015
BMI >25 kg/m²	17% (10/59)	50% (25/50)	<0.001
PAD score ≥3	4% (2/46)	40.4% (17/42)	<0.001
Previous groin incision	10.8% (5/46)	33.3% (13/39)	0.016
Diabetes	14% (6/42)	36% (8/22)	0.06
CKD	16% (5/32)	27% (7/26)	0.34

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Gombert et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	98	90
Number of surgical site infections (a)	13	30
Cost per SSI[1] (b)	$20,864	$20,864
Per patient infection cost [c=(a*b)/n]	$2,768	$6,955
Per patient therapy cost* (d)	$495	–
Total cost per patient (c+d)	$3,263	$6,955
Potential per patient savings using Prevena™ Therapy	$3,692	

*3M™ Prevena™ Peel and Place System Kit 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. 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
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

Read the full study here

Journal: *European Journal of Vascular and Endovascular Surgery*

Title: Closed incision negative pressure therapy reduces surgical site infections in vascular surgery: A prospective randomised trial (AIMS trial)

Published: July 2, 2018

Gombert A, Babilon M, Barbati ME, et al. Closed incision negative pressure therapy reduces surgical site infections in vascular surgery: A prospective randomised trial (AIMS trial). *Eur J Vasc Endovasc Surg.* 2018 Sept; 56(3):442-448. OPEN ACCESS

Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): A prospective, randomised, single-institution study

Pleger SP, Nink N, Elzien M, Kunold A, Koshty A, Böning A. *Int Wound J.* 2018 Feb;15(1):75-83.

Study design
Single Center Randomized Controlled Trial German

Study purpose
The purpose of the study was to investigate the effectiveness of 3M™ Prevena™ Therapy compared to conventional therapy on vascular surgical groin incisions.

Methods
- Patients were randomised and treated with either Prevena Therapy or the control therapy, a conventional adhesive plaster.
- 100 patients with 129 groin incisions were analyzed: Prevena Therapy consisted of 43 patients/58 incisions; standard dressing consisted of 57 patients/71 incisions.
- Inclusion criteria for high-risk patients: age >50 years, diabetes mellitus, renal insufficiency, malnutrition, obesity and chronic obstructive pulmonary disease.
- Prevena Therapy was applied intraoperatively and removed on days 5–7 postoperatively.
- Wound evaluation based on the Szilagyi classification (adapted to include complications) took place postoperatively on days 5–7 and 30.

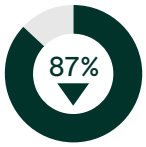
Key points
- With the use of Prevena Therapy after vascular surgery in high-risk patients, post-operative surgical site infections, wound complications, and revision surgeries were significantly reduced.
- Additionally, subgroup analysis revealed that Prevena Therapy had a significant effect in WHC reduction in patients with age >50 year, renal insufficiency, malnutrition and overweight.

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

*Statistically significant (p<0.05)

Results

Per patient evaluation



Reduction in local SSI*
2.3% (1/43) Prevena Therapy vs. 17.5% (10/57) standard dressings (p=0.022)*

Reduction in hematomas*
0% (0/43) Prevena Therapy vs. 14% (8/57) standard dressings (p=0.02)*

Per incision evaluation

Reduction in wound healing complications*
8.6% (5/58) Prevena Therapy vs. 42.3% (30/71) standard dressings (p<0.0005)*

Reduction in revision surgery*
1.7% (1/58) Prevena Therapy vs. 14.1% (10/71) standard dressings (p=0.022)*

Wound complications	Prevena™ Therapy	Standard dressing	p-value
Total number	8.6% (5/58)	42.3% (30/71)	<0.0005*
Szilagyi grade I	6.9% (4/58)	11.3% (8/71)	0.545
Szilagyi grade II	1.7% (1/58)	28.2% (20/71)	<0.0005*
Szilagyi grade III	0	2.8% (2/71)	0.501

(Continued)

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.

Although the authors reported use of Prevena Therapy for a mean of 3.6 days (ranging from 2 to 15 days), this mean time of application is outside the recommendations for Optimum Use as stated in the 3M™ Prevena™ Incision Management System Clinician Guide Instructions for Use: The Prevena Incision Management System is to be continuously applied for a minimum of two days up to a maximum of seven days. Use for greater than 7 days is not recommended or promoted by 3M.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Pleger et al outcomes

Surgical site infection

Vascular groin hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	43	57
Number of infections (a)	1	10
Cost per infection[1] (b)	$20,864	$20,864
Per patient infection cost [c=(a*b)/n]	$485	$3,660
Per patient therapy cost* (d) @$495×1.35	$668	–
Total cost per patient (c+d)	$1,153	$3,660
Potential per patient savings using Prevena™ Therapy	$2,507	

Surgical site complication

Vascular groin hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of incisions (n)	58	71
Number of complications (a)	5	30
Cost per complication[2] (b)	$18,325	$18,325
Per incision complication cost [c=(a*b)/n]	$1,580	$7,743
Per incision therapy cost* (d)	$495	–
Total cost per incision (c+d)	$2,075	$7,743
Potential per incision savings using Prevena™ Therapy	$5,668	

*3M Prevena Peel and Place System Kit is an estimate; individual prices may vary. Per patient Prevena Therapy Cost accounts for 1.35 incisions/patient.

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
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

2. 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.

Read the full study here

Journal: *International Wound Journal*

Title: Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): A prospective, randomised, single-institution study

Published: October 25, 2017

Pleger SP, Nink N, Elzien M, Kunold A, Koshty A, Böning A. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): A prospective, randomised, single-institution study. *Int Wound J.* 2018 Feb;15(1):75-83. OPEN ACCESS

Deep learning-based risk model for best management of closed groin incisions after vascular surgery

Chang B, Sun Z, Peiris P, et al. *J Surg Res.* 2020;254:408-406.

Study design

Single center retrospective cohort study (Level III)

Study purpose

- Apply a prediction model to a cohort of vascular surgery patients to assess the appropriate use of 3M™ Prevena™ Therapy for the management of incisions after vascular surgery
- Assess impact of adoption of this prediction model on financial outcomes

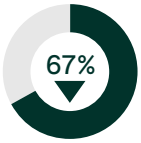
Methods

- A deep learning-based, risk-based prediction model was retrospectively applied to a data set of 370 patients undergoing vascular surgery at Duke University.
- Prevena Therapy or standard dressing were applied over closed incisions at the surgeon's discretion.
- Predictive risk scores were generated for each patient and used to categorize patients as "high" and "low" predicted risk for SSI.
- Patients were further divided into four groups for analysis: (1) low-risk patients who received standard dressing, (2) low-risk patients who received Prevena Therapy, (3) high-risk patient who received standard dressing, and (4) high-risk patients who received Prevena Therapy.
- SSI event rates were calculated for each group.

Summary

- Retrospective application of the predictive model to the patient population suggested that only 55.4% of patients were appropriately matched with their intervention (158 high risk patients receiving Prevena Therapy, 57 low risk patients receiving SOC).
- If 100% of patients were matched appropriately by their risk profile to an intervention (perfect utilization), the predicted SSI events in the entire cohort would be 7.3% (versus 12.4% in actual study population).
- Applying the risk-based model with perfect utilization of Prevena Therapy projected a medium cost reduction of 26% ($401) per patient considering already for the Prevena Therapy cost. This corresponds to a relative SSI rate reduction of 41.3%.
- Using a risk prediction model to aid decision making in the care of closed incisions after vascular surgery can help optimize the utilization of Prevena Therapy, outcomes, and associated costs.

Results



Reduction in surgical site infections

6.8% (10/148) High-risk Prevena Therapy vs. 20.9% (28/134) high-risk standard dressing (p<0.001)*

Average per-patient cost

Prevena Therapy on high risk: $1143 (medium range estimate); No risk stratification: $1,544 (actual); Mean per patient cost savings: $401 (medium range estimate)

Retrospective risk stratification	Prevena™ Therapy	Standard dressing	p-value
Actual SSI rate in high-risk population	6.8% (10/148)	20.9% (28/134)	<0.001*
Actual SSI rate in low-risk population	9.7% (3/31)	8.8% (5/57)	0.99

(Continued)

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

*Statistically significant (p<0.05)

Cost estimates were calculated by the study authors using assumptions described in the article and presented as low, medium and high. The medium cost saving is presented.

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.

(Continued)

Read the full study here

Journal: *Journal of Surgical Research*

Title: Deep learning-based risk model for best management of closed groin incisions after vascular surgery

Published: March 20, 2020

Chang B, Sun Z, Peiris P, et al. Deep learning-based risk model for best management of closed groin incisions after vascular surgery. *J Surg Res*. 2020;254:408-406.

Utilizing closed incisional negative pressure therapy reduces peripheral bypass infection rates without increasing costs

Frisbie JJ, Bordoli SJ, Simmons JM, Frisbie JJ, Zuiderveen SK. *Cureus.* 2020 Jul 16;12(7):e9217.

Study type

Retrospective before/after comparative cohort study (Level III)

Study purpose

The study investigated the effect of 3M™ Prevena™ Therapy on the incidence of surgical site infections (SSI) and cost effectiveness of its use for vascular bypass patients.

Methods

- Retrospective review of outcomes before and after institutional implementation of 3M™ Prevena™ Therapy.
- The standard dressing group, (standard wound dressings) consisted of 102 patients who underwent lower extremity bypass surgery between September 2017 and April 2018.
- The Prevena Therapy group included of 113 patients from September 2018 and April 2019.
- Study endpoints determined at day 30: total SSI, deep SSI and superficial SSI and on year follow up for graft infections.
- Cost analysis was separately performed utilizing hospital metrics.

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 has not been reviewed by the U.S. FDA

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.

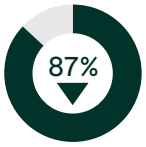
Summary

- Prevena Therapy resulted in a decrease in surgical site infections.
- Reduced SSI rate led to a minimum of $62,000 in infection related cost savings between the two groups in this study, even when accounting for the total cost of Prevena Therapy.
- As a result of this study, the institution implemented routine use of Prevena Therapy for all lower extremity vascular bypass patients.

Results

Reduction in SSIs*

3.5% (4/113) Prevena Therapy vs. 11.8% (12/102) standard dressing (p=0.0218)*



Reduction in DSSIs*†

0.9% (1/113) Prevena Therapy vs. 6.9% (7/102) standard dressing (p=0.0169)*

Reduction in per patient cost for SSI

$912 Prevena Therapy vs. $1,618 standard dressing

Per Patient Cost Savings: **$706**

Read the full study here

Journal: *Cureus*

Title: Utilizing closed incisional negative pressure therapy reduces peripheral bypass infection rates without increasing costs

Published: July 16, 2020

Frisbie JJ, Bordoli SJ, Simmons JM, Frisbie JJ, Zuiderveen SK. Utilizing closed incisional negative pressure therapy reduces peripheral bypass infection rates without increasing costs. *Cureus.* 2020 Jul 16;12(7):e9217.

Negative pressure wound therapy reduces surgical site infections

Benrashid E, Youngwirth LM, Guest K, Cox MW, Shortell CK, Dillavou ED. *J Vasc Surg.* 2020 Mar;71(3):896-904.

Study type

Single center retrospective study (Level III)

Study purpose

Primary objective of the study was to determine whether the use of 3M™ Prevena™ Therapy decreased perioperative SSIs in vascular surgery patients

Methods

- Retrospective analysis of all patients with lower extremity or infrainguinal incisions between January 2016 and December 2017.
- A multidisciplinary team created a vascular surgery specific SSI reduction bundle which included preoperative optimization of anemia and glucose management, standardized preparation with chlorhexidine gluconate-based solutions, standardized preoperative hair clipping, and appropriate antibiotic administration. Intraoperatively, OR traffic was limited, normothermia and euglycemia was maintained, and a dedicated wound closure tray was used.
- All patients were treated with the same perioperative care bundle to reduce SSI.
- Prevena Therapy, not part of the bundle, was applied at the discretion of the surgeon in 225 patients. 279 patients received standard dressings.
- The 90-day outcomes were SSI, any wound complication, return to operating room, death, and readmission.

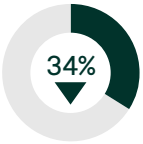
Summary

- In a population undergoing vascular surgery with an SSI care bundle implemented, patients that received Prevena Therapy had decreased SSIs, SSCs, mortality, and reoperations for wound related complications (seroma, infection, nonhealing incision, dehiscence).
- Readmissions, length of stay, major amputations, and reoperations (for any reason) were not significantly different between groups.
- Improved outcomes were observed in the Prevena Therapy group despite having significantly more women, more active smokers, and increased operative times (all of which are factors associated with increased infections and complications).
- A multiple logistic regression analysis , demonstrated a decreased risk of SSI for Prevena Therapy patients (OR 0.32; 95% CI 0.17-0.63; p<0.01).
- Using Prevena Therapy devices as part of institutional perioperative SSI reduction care bundles may help mitigate SSI risk and wound complications in patients undergoing infrainguinal vascular surgical procedures.

Results

Reduction in SSIs*

9.8% (22/225) Prevena Therapy vs. 19.0% (53/279) standard dressing (p<0.01)*

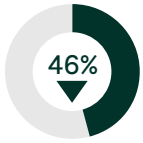


Reduction in SSCs*

20.0% (v45/225) Prevena Therapy vs. 30.5% (85/279) standard dressing (p<0.01)*

Reduction in 90-day mortality*

5.8% (13/225) Prevena Therapy vs. 11.2% (31/279) standard dressing (p=0.04)*



Reduction in return to the OR*

26.2% (16/225) Prevena Therapy vs. 48.3% (37/279) standard dressing (p<0.01)*

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Benrashid et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	225	279
Number of surgical site infections (a)	22	53
Cost per SSI[1] (b)	$20,864	$20,864
Per patient infection cost [c=(a*b)/n]	$2,040	$3,963
Per patient therapy cost* (d)	$830	–
Total cost per patient (c+d)	$2,870	$3,963
Potential per patient savings using Prevena™ Therapy	$1,093	

*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 standard dressings. 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
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

Read the full study here

Journal: *Journal of Vascular Surgery*

Title: Negative pressure wound therapy reduces surgical site infections

Published: August 27, 2019

Benrashid E, Youngwirth LM, Guest K, Cox MW, Shortell CK, Dillavou ED. Negative pressure wound therapy reduces surgical site infections. *J Vasc Surg.* 2020 Mar;71(3):896-904.

A cost-utility analysis of the use of closed-incision negative pressure system in vascular surgery groin incisions

Bloom JA, Tian T, Homsy C, Singhal D, Salehi P, Chatterjee A. *Am Surg.* 2022;0(0).

Study type

The study was literature review looking at prospective randomized control trials that determined the probabilities and outcomes for femoral-popliteal bypass with and without ciNPT.

Study purpose

The aim of the study was to perform a cost-effectiveness analysis evaluating closed incision negative pressure therapy (ciNPT, 3M™ Prevena™ Incision Management System, KCI Medical San Antonio, TX) use in femoral-popliteal bypass with prosthetic graft.

Methods

Population selected: 65-year-old male with Vascular surgery such as lower extremity claudication and tissue loss.

Model: The model used femoral-popliteal graft with vs without prosthetic graft. Under each decision tree data was obtained incorporating the probability of health states and the costs and utilities associated with them such as post operative minor and major wound infections, sartorius flap reconstruction, excision of graft and axillary femoral bypass, amputation and death.

Analysis

Data from retrospective analysis was used to create a Decision analysis tree to highlight the more cost-effective strategy.

Cost data from Medicare charge and reimbursement defined as sum of hospital cost and surgeon reimbursement fees were utilized. Utility scores converted to QALYs obtained for all health states from previously published utility scores representing health states ranging from 0 (death) to 1 (healthy) were used for analysis.

Incremental cost effectiveness ratio (ICER) was performed with willingness to pay $50,000.

Results

The decision tree analysis demonstrated that femoral-popliteal bypass with 3M™ Prevena™ Therapy has a higher clinical effectiveness (QALY) of 6.14 compared to without Prevena Therapy (6.13) and is more cost effective (with $40,138 vs without $41,774) resulting in a negative ICER of -234,764.03, favoring ciNPT. This indicated a dominant strategy.

In one-way sensitivity analysis, femoral-popliteal bypass without Prevena Therapy was cost-effective strategy if the probability of successful surgery in the Prevena Therapy arm was less than 84.9% or if cost of Prevena Therapy exceeds $3,139.

Conclusion

Despite the added cost of Prevena Therapy, its use is more cost-effective in vascular surgical operations using groin incisions.

Read the full study here

Journal: *The American Surgeon*

Title: A cost-utility analysis of the use of closed-incision negative pressure system in vascular surgery groin incisions

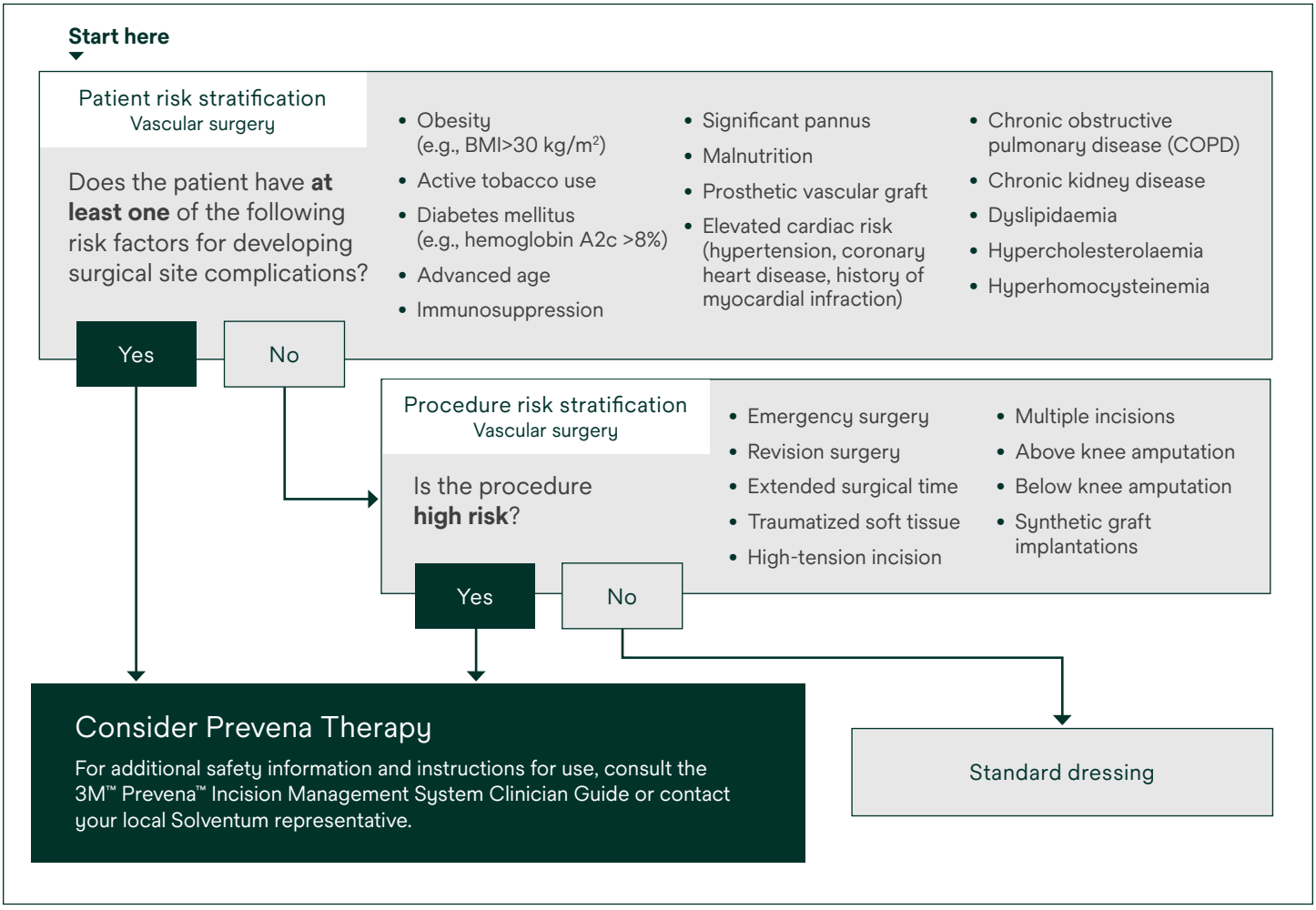
Published: April 7, 2022

Bloom JA, Tian T, Homsy C, Singhal D, Salehi P, Chatterjee A. A cost-utility analysis of the use of closed-incision negative pressure system in vascular surgery groin incisions. *Am Surg.* 2022;0(0).

Decision guide

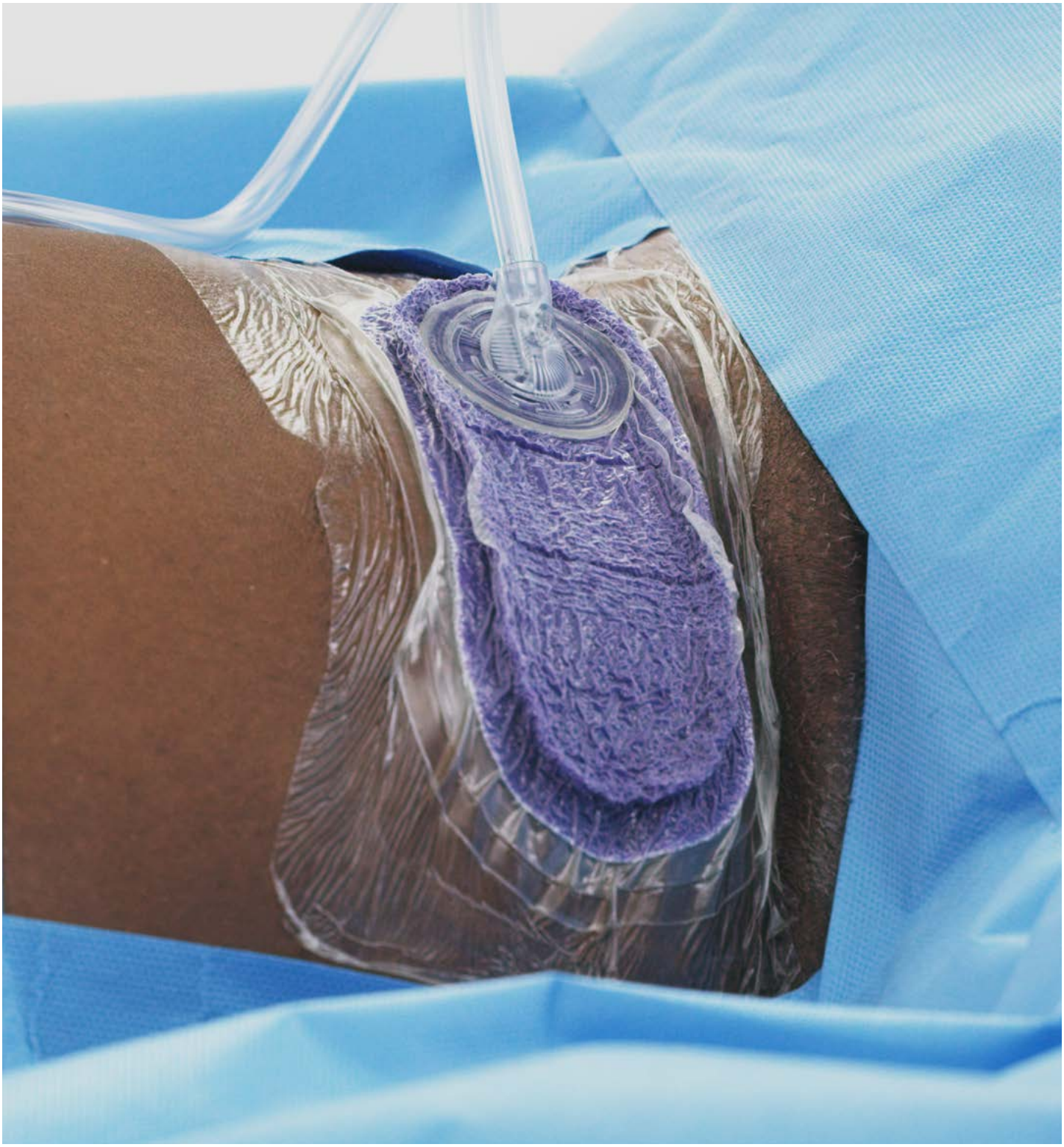
Patient and procedure risk stratification backed by clinical evidence

While surgical patients may benefit from Prevena Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data[1-4] to provide an illustrative guide to aid in risk stratification. This is not an all-inclusive list of risk factors. Clinicians are advised to use their clinical judgment to identify high-risk patients or high-risk procedures.



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.

References
1. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: International multidisciplinary consensus recommendations. *Int Wound J.* 2017 Apr;14(2):385-398. OPEN ACCESS 2. Kwon J, Staley C, McCullough M, et al. A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications. *J Vasc Surg.* 2018 Dec;68(6):1744-1752. OPEN ACCESS 3. Gombert A, Babilon M, Barbati ME, et al. Closed incision negative pressure therapy reduces surgical site infections in vascular surgery: A prospective randomised trial (AIMS trial). *Eur J Vasc Endovasc Surg.* 2018 Sept; 56(3):442-448. OPEN ACCESS 4. Pleger SP, Nink N, Elzien M, Kunold A, Koshty A, Böning A. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): A prospective, randomised, single-institution study. *Int Wound J.* 2018 Feb;15(1):75-83. OPEN ACCESS



Author biographies*

*Where available and permitted to use.

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Ellen Dillavou, MD, FACS, RPVI

Medical Director,
Vascular Surgery
WakeMed Hospitals
Raleigh, NC

Dr. Dillavou is a paid consultant for Solventum.

Ellen Dillavou, MD, FACS, is the medical director of vascular surgery at the WakeMed hospital system in Raleigh, NC. She earned a BA at Macalester College in St. Paul, MN, an MD at the University of Arizona, completed general surgery training at Thomas Jefferson University of Philadelphia, and a vascular surgery fellowship at The University of Pittsburgh Medical Center. Her work centers on complicated dialysis access, surgical quality improvement and surgical site infection prevention.

"I became aware of 3M™ Prevena™ Therapy while investigating interventions that help mitigate the risk of Surgical Site Infections. As I dug into the research, it became quite clear that Prevena is one of the most impactful therapies available to reduce SSIs for groin incisions in vascular surgery. I now use Prevena on all of my patients who are considered high risk for incisions at the groin or below."

— Dr. Dillavou

PD Dr. med. Alexander Gombert, PhD, FEBVS

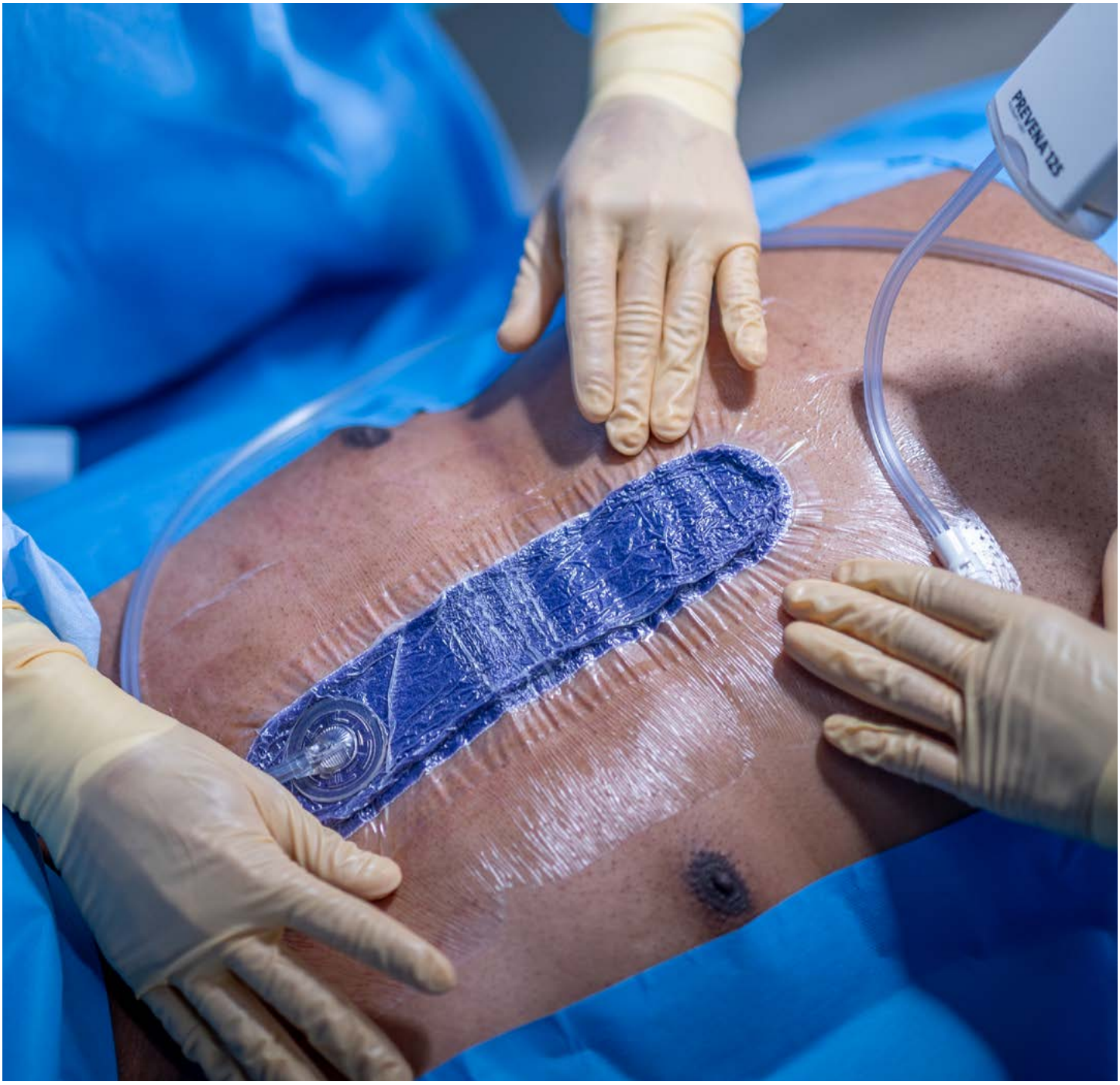
Endovascular Specialist, Consultant of vascular surgery, European Center of Vascular Surgery Aachen-Maastricht, Clinic for Vascular Surgery, University of Aachen, Germany

Dr. Gombert is a paid consultant for Solventum.

PD Dr. med. Gombert was born in 1983. He is working as a consultant of Vascular Surgery at one of the largest centers for Vascular Surgery in Germany, the European Vascular Center Aachen-Maastricht. He is the initiator and principal investigator of the "Aachen Incision management system (AIMS) trial," a randomized, prospective, multicenter study, comparing the effect of 3M Prevena™ incision management system with standard wound dressings after groin incision for vascular surgical procedures. Furthermore, he is establishing one of the biggest databases for tissue samples of patients undergoing thoracoabdominal aortic surgery. Beneath his activity in the fields of wound healing and thoracic aortic aneurysm research, he is working in the venous research group of the European Vascular Center Aachen-Maastricht. He is an active reviewer of different high-ranked vascular surgery journals. PD Dr. Gombert is the author of several high-ranked peer-reviewed publications focusing on different aspects of vascular surgery. Furthermore, he is frequently invited to speak at vascular surgical and general surgical meetings around the world. He is living together with his wife and three children in the area of Aachen.

"3M™ Prevena™ Therapy is an extremely valuable proactive risk management tool that can help improve patient outcomes, while reducing costs associated with surgical site infections (SSIs). With more than 200 peer-reviewed publications studying Prevena, several common patient and procedural risk factors within the literature have been elevated to help support clinical decision making. In my practice, we utilize Prevena on every at-risk patient and procedure, advancing the standard of care for surgical patients."

— Dr. Gombert



PRM in cardiothoracic surgery

Prevena.com/cardiothoracic

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Surgical site infection outcomes of two different closed incision negative pressure therapy systems in cardiac surgery: Systematic review and meta-analysis

Loubani M, Cooper M, Silverman R, Bongards C, Griffin L. *Int Wound J.* 2024;21(1):e14599.

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 cardiac surgery incisions and to evaluate the effectiveness of closed incision negative pressure therapy (Prevena Therapy) versus Control dressings in reducing surgical site infections (SSIs)

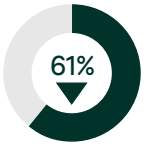
Methods
- The systematic review included English language manuscripts and abstracts published between January 2005 and June 2022. Studies compared the use of Prevena Therapy to Control following cardiac surgery.
- Eight studies were identified in the systematic review: 2 prospective studies, 1 prospective study with historic control, and 5 retrospective comparative studies. One retrospective study did not report overall SSI counts and was not included in the analysis.
- The endpoint assessed was the overall SSI rate for Prevena Therapy patients compared to Control patients.
- A subgroup analysis was conducted for studies that included patients at high-risk for SSI development.
- Health Economic (HE) models were created for both the all-patient and high-risk patient analyses. The HE models examined the possible impact of the use of Prevena Therapy.

Summary

- This systematic review and meta-analysis of 8 published studies, 7 of which were included in the analysis of SSIs for all patients and 2 for studies conducted with high-risk patients. Both analyses demonstrated that the use of Prevena Therapy was associated with reduced risks of SSIs following cardiac surgery.
- A potential cost savings of $554 and $3,242 per patient with the use of Prevena Therapy to reduce the risk of SSIs was found for all patients and high-risk patients respectively.

Results

Reduction of risk of SSI*
7 studies;
risk ratio 0.507
(95% CI 0.362, 0.709)
(p<0.001)*



Reduction of risk of SSI high risk patients
2 studies;
risk ratio 0.390
(95% CI 0.205, 0.741)
(p=0.004)*

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

†Statistically significant (p<0.05)

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.

Read the full study here

Journal: *International Wound Journal*

Title: Surgical site infection outcomes of two different closed incision negative pressure therapy systems in cardiac surgery: Systematic review and meta-analysis

Published: January 17, 2024

Loubani M, Cooper M, Silverman R, Bongards C, Griffin L. Surgical site infection outcomes of two different closed incision negative pressure therapy systems in cardiac surgery: Systematic review and meta-analysis. *Int Wound J.* 2024;21(1):e14599.

Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy

Grauhan O, Navasardyan A, Hofmann M, et al. *J Thorac Cardiovasc Surg* 2013;145:1387-1392.

Summary

- Prevena Therapy reduces the rate of postoperative wound infection after median sternotomy in high-risk group of obese patients.
- 71 of 75 (95%) of wounds were closed at time of Prevena Therapy dressing removal after 6 to 7 days.
- No infections in the Prevena Therapy group occurred after dressing removal.
- Of the 12 infections in the Control group, 9 occurred after the first post-operative week and up to day 35.

Study design

Prospective, single-center, controlled trial

Study purpose

To evaluate negative pressure wound dressing treatment (Prevena Therapy) for infection prevention

Methods

- The study included 150 consecutive obese patients who underwent a median sternotomy at a single site in Germany between April 2010 and October 2011.
- Patients were allocated to 2 study groups, alternating according to the time of operation.
- Inclusion criteria was a body mass index ≥ 30 kg/m2.
- The control group, (standard dressings) consisted of 75 patients. Post Op dressing change day 1–2.
- The Prevena Therapy group consisted of 75 patients. Placed immediately after suturing. Post Op dressing removal at day 6–7.
- The primary end point was wound infection within 90 days.

Results

Reduced rate of SSI*

4% (3/75) Prevena Therapy vs. 16% (12/75) standard dressing (p=0.0266)*

Reduced rate of wound infection with gram-positive skin flora*

1.3% (1/75) Prevena Therapy vs. 13.3% (10/75) standard dressing (p=0.0090)*

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Grauhan et al 2013 outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	75	75
Number of surgical site infections (a)	3	12
Cost per SSI[1] (b)	$45,578	$45,578
Cost of SSI per patient [c=(a*b)/n]	$1,823	$7,292
Per patient therapy cost* (d)	$495	–
Total cost per patient (c+d)	$2,318	$7,292
Potential per patient savings using Prevena™ Therapy	$4,974	

*3M™ Prevena™ Peel and Place System Kit 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 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
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

Read the full study here

Journal: *The Journal of Thoracic and Cardiovascular Surgery*

Title: Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy

Published: October 29, 2012

Grauhan O, Navasardyan A, Hofmann M, Muller P, Stein J, Hetzer R. Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy. *J Thorac Cardiovasc Surg.* 2013 May;145(5):1387-92. OPEN ACCESS

Effect of surgical incision management on wound infections in a post sternotomy patient population

Grauhan O, Navasardyan A, Tutkun B, et al. *Int Wound J.* 2014;11:6-9.

Summary

- This study demonstrated that the application of Prevena Therapy over clean, closed sternotomy incisions reduced the likelihood for post operative wound infection in a comprehensive patient population that was not limited to high-risk patients.
- In this comprehensive study population the incidence of SWI requiring revision was significantly reduced from 3.4% in the Group receiving standard dressing to 1.3% in the Prevena Therapy group.
- Additionally, of the 237 Prevena Therapy patients without an infection, 234 (98.7%) had incisions that were primarily closed at dressing removal.
- No wound infections occurred after the removal of Prevena Therapy on day 6–7.
- Based on the study findings Prevena Therapy has the potential to be cost-effective in the comprehensive population of patient's undergoing median sternotomies as evaluated by the authors.

Study design

Prospective study with retrospective historical control, single-center study

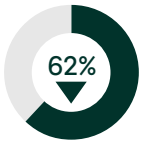
Study purpose

The purpose of this study was to evaluate Prevena Therapy vs. standard dressings over closed surgical incisions in reducing wound infections in a comprehensive post-sternotomy patient population.

Methods

- The study group (Prevena Therapy) included ALL prospective patients undergoing median sternotomy from September–October 2013 totaling 237 patients.
- The control group (conventional wound dressings) included ALL median sternotomy patients retrospectively analyzed for the period of January 2008 –December 2009 totaling 3,508 patients.
- The study population included 'all comers' with no defined high risk inclusion criteria.
- Prevena Therapy placed immediately after suturing. Post Op dressing removal at day 6–7.
- The primary end point was sternal wound infection (SWI) within 30 days requiring surgical revision and application of NPWT to the open surgical wound in most cases.

Results



Reduced rate of SWI requiring revision*

1.3% (3/237) Prevena Therapy vs. 3.4% (119/3508) standard dressing ($p<0.05$)*

(Continued)

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

*Statistically significant ($p<0.05$)

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Grauhan et al 2014 outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	237	3508
Number of surgical site infections (a)	3	119
Cost per SSI[1] (b)	$45,578	$45,578
Cost of SSI per patient [c=(a*b)/n]	$577	$1,546
Per patient therapy cost* (d)	$495	–
Total cost per patient (c+d)	$1,072	$1,546
Potential per patient savings using Prevena™ Therapy	$474	

*3M™ Prevena™ Peel and Place System Kit 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 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
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

Read the full study here

Journal: *International Wound Journal*

Title: Effect of surgical incision management on wound infections in a post sternotomy patient population

Published: May 23, 2014

Grauhan O, Navasardyan A, Tutkun B, et al. Effect of surgical incision management on wound infections in a post sternotomy patient population. *Int Wound J.* 2014;11:6-9.

Incisional negative pressure wound therapy is protective against postoperative cardiothoracic wound infection

Nguyen KA, Taylor GA, Webster TK, et al. *Ann Plast Surg.* 2022;88(3 Suppl 3):S197-S200.

Study type
Retrospective, single-center, cohort study (Level III)

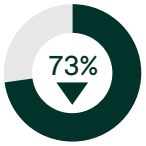
Study purpose
The study aimed to evaluate the effect of closed incision negative pressure therapy on wound infections over cardiothoracic closed incisions (3M™ Prevena™ Therapy).

Methods
- Study included adult patients who underwent nontraumatic cardiothoracic surgery at a single center between 2016 and 2018 (n = 1199).
- 706 patients received Prevena Therapy (58.9%); 493 patients were in the control group (41.1%).
- Patient characteristics, clinical variables, and surgical outcomes were compared between those who did incisional negative pressure therapy intraoperatively.
- Surgeries included coronary artery bypass (CABG) grafting, aortic or mitral valve repair or replacement, lung transplant, heart transplant, aorta repair, left ventricular assist device, right ventricular assist device, and Ross procedures; incision types included median sternotomy, unilateral thoracotomy, and bilateral anterior (clamshell) thoracotomy.
- Multivariable logistic regression analysis determined factors predictive or protective of the development of complications.

Summary
- Significant reductions in wound infections and readmissions for wound infection in patients receiving Prevena Therapy after nontraumatic cardiothoracic surgery were demonstrated in this study.
- Multivariable logistic regression found that Prevena Therapy was an independent protective factor against surgical site infection (p=0.03)* after controlling for confounding factors.
- The use of Prevena Therapy was associated with a 50.4% decrease in the odds of infection (odds ratio, 0.497; 95% CI 0.262-0.945; p=0.03*).

Results

Reduced rate of SWIs*
3.0% (21/706) Prevena Therapy vs. 6.3 % (31/493) standard dressing (p=0.01)*



Reduced rate of readmissions*
0.7% (5/706) Prevena Therapy vs. 2.6 % (13/493) standard dressing (p=0.01)*

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Nguyen et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	706	493
Number of surgical site infections (a)	21	31
Cost per SSI[1] (b)	$45,578	$45,578
Per patient infection cost [c=(a*b)/n]	$1,356	$2,866
Per patient therapy cost* (d)	$495	–
Total cost per patient (c+d)	$1,851	$2,866
Potential per patient savings using Prevena™ Therapy	$1,015	

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

The above model uses selected study data to provide an illustration of 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
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

Read the full study here

Journal: *Annals of Plastic Surgery*

Title: Incisional negative pressure wound therapy is protective against postoperative cardiothoracic wound infection

Published: May 2022

Nguyen KA, Taylor GA, Webster TK, et al. Incisional negative pressure wound therapy is protective against postoperative cardiothoracic wound infection. *Ann Plast Surg.* 2022;88(3 Suppl 3):S197-S200.

The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high risk cases: A single centre retrospective study

Suelo-Calanao RL, Thomson R, Read M, Matheson E, Isaac E, Chaudhry M, Loubani M. *J Cardiothorac Surg.* 2020 Aug 19;15(1):222.

Study design

Retrospective cohort study (United Kingdom)

Study purpose

To assess the institutional sternal wound infection (SWI) rate in high-risk Sternotomy patients before and after the introduction of closed incision negative pressure therapy (Prevena Therapy).

Methods

- This study included patients who underwent an open-heart procedure requiring full median sternotomy (e.g., coronary artery bypass grafting (CABG), CABG plus valve repair, valve repair solely, and other cardiac procedures) by two surgeons at a single center between January 2009 to December 2016.
- During this period, there was no clinician change in practice other than the use of Prevena Therapy for high-risk patients.
- High-Risk patients were defined as ≥ 2 risk factors: obesity (BMI >32 kg/m²), COPD, Age ≥ 80, diabetes.
- Before introduction of Prevena Therapy at the institution 162 of 927 patients were considered high risk, these patients received standard dressings.
- After introduction of Prevena Therapy at the institution 158 of 932 patients were consider to be high risk, these patients received Prevena Therapy.

Key points

- This study demonstrated that Prevena Therapy can help reduce the incidence of SWI in high-risk patients.
- Amongst the high-risk patient groups, the SWI rate was reduced from 12.3% for Control and 5.6% for patients receiving Prevena Therapy (p=0.049).
- In the high-risk patient group:
  - Superficial SWI was observed in 16 of 20 patients receiving Standard dressing vs. all 9 patients receiving Prevena Therapy.
  - Debridement for SWI was required for 4 patients receiving standard dressing while no debridement was necessary for SWI in the Prevena Therapy group.
- After implementation of Prevena Therapy for high-risk patients, the overall incidence of SWI in the total sternotomy patient population dropped from 8.7% to 4.4% (p=0.0005).

Results

Reduction rate of SWIs*

5.6% (9/158) Prevena Therapy vs. 12.3% (20/162) standard dressing (p=0.049)*

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Suelo-Calanao et al 2020 clinical outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	158	162
Number of surgical site infections (a)	9	20
Cost per surgical site infection[1] (b)	$45,578	$45,578
Cost of SSI per patient [c=(a*b)/n]	$2,596	$5,627
Per patient therapy cost* (d)	$495	–
Total cost per patient (c+d)	$3,091	$5,627
Potential per incision savings using Prevena™ Therapy	$2,536	

*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
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

Read the full study here

Journal: *Journal of Cardiothoracic Surgery*

Title: The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high risk cases: A single centre retrospective study

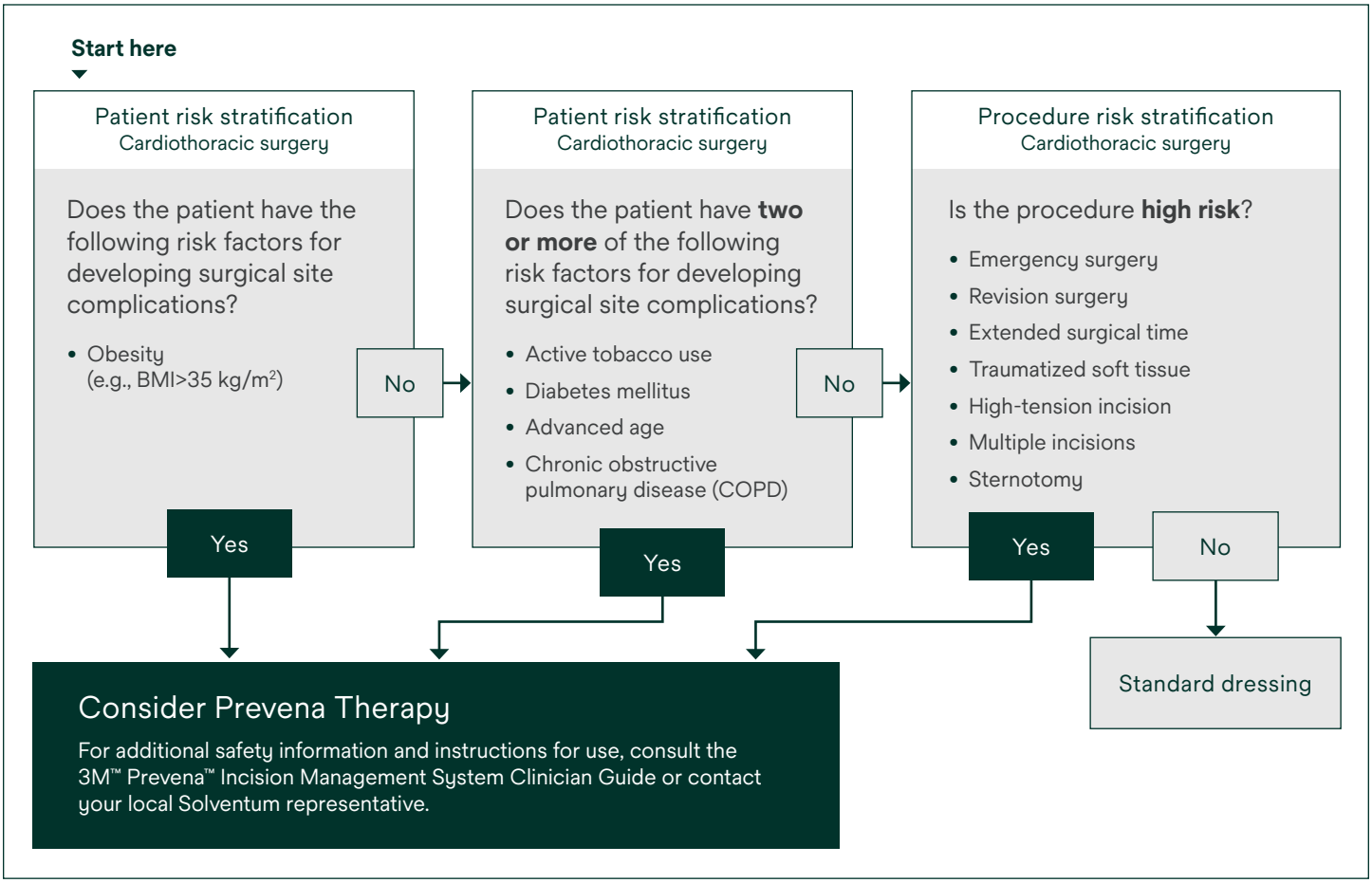
Published: August 19, 2020

Suelo-Calanao RL, Thomson R, Read M, Matheson E, Isaac E, Chaudhry M, Loubani M. The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high risk cases: A single centre retrospective study. *J Cardiothorac Surg*. 2020 Aug 19;15(1):222. OPEN ACCESS

Decision guide

Patient and procedure risk stratification backed by clinical evidence

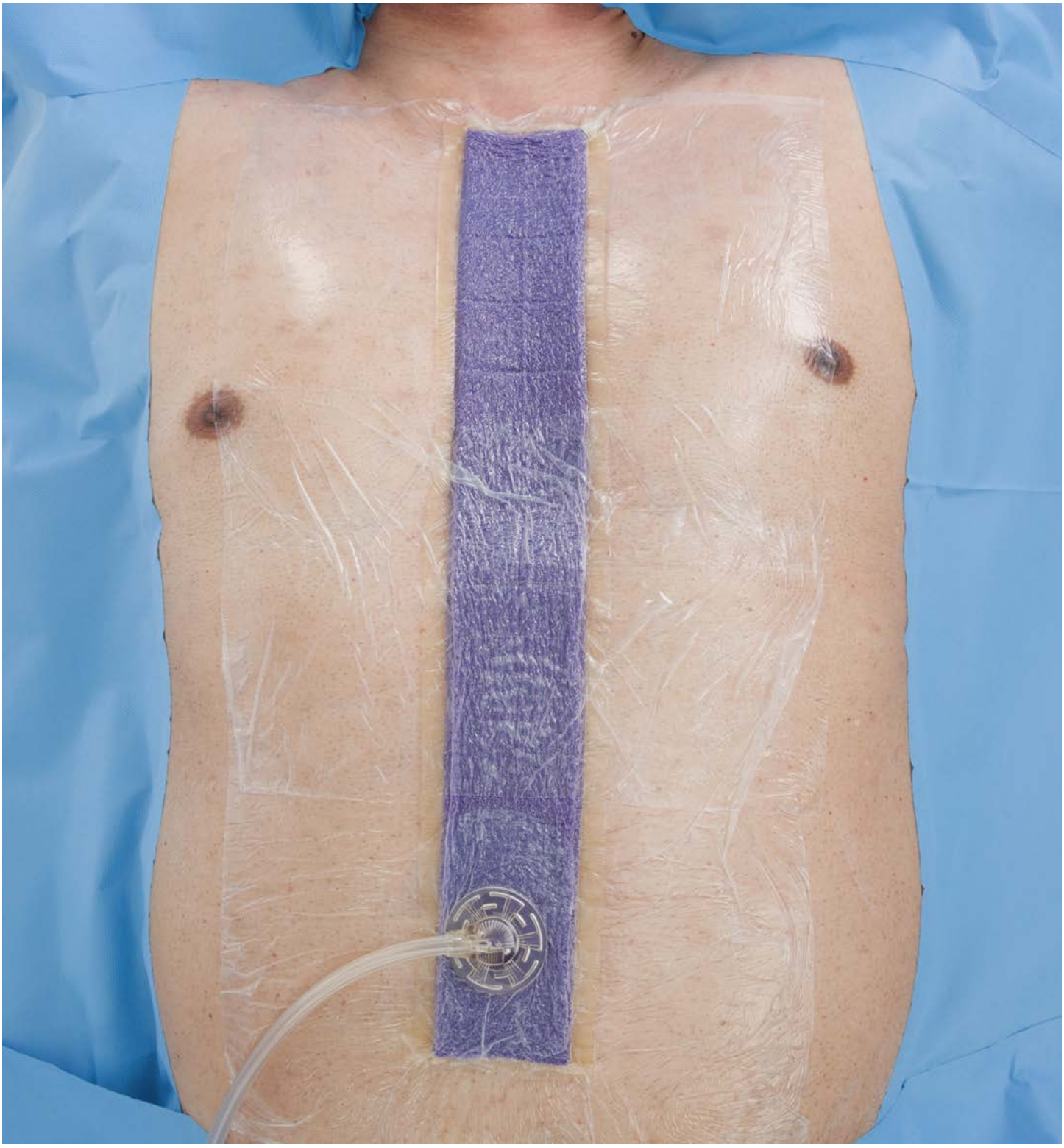
While surgical patients may benefit from Prevena Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data[1-3] to provide an illustrative guide to aid in risk stratification. This is not an all-inclusive list of risk factors. Clinicians are advised to use their clinical judgment to identify high-risk patients or high-risk procedures.



Read the full Willy Consensus Study here

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.

References
1. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: International multidisciplinary consensus recommendations. *Int Wound J.* 2017 Apr;14(2):385-398. OPEN ACCESS 2. Grauhan O, Navasardyan A, Hofmann M, Muller P, Stein J, Hetzer R. Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy. *J Thorac Cardiovasc Surg.* 2013 May;145(5):1387-92. OPEN ACCESS 3. Suelo-Calanao RL, Thomson R, Read M, et al. The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high risk cases: A single centre retrospective study. *J Cardiothorac Surg.* 2020 Aug 19;15(1):222. OPEN ACCESS



Case studies

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Sternotomy incision

V. Sreenath (Seenu) Reddy, MD, MBA, FACS, Chief, Division of Cardiothoracic Surgery, Centennial Heart & Vascular, Nashville, TN

Patient

A 67-year-old female with a previous history of cholecystectomy and myocardial infarction presented with dyspnea on exertion and angina with activity. Patient comorbidities included diabetes, obesity, sleep apnea, degenerative joint disease, osteoporosis, hypertension, and hyperlipidemia.

Diagnosis

Blood work was initiated and revealed creatinine levels of 1.6 mg/dL, chronic kidney disease Stage III, and normal hematocrit. The patient was admitted to the hospital with acute myocardial infarction.

Initial incision treatment/application of 3M™ Prevena™ Therapy:

The patient was taken to the operating room for an aortic valve replacement and coronary artery bypass graft. Following closure of the incision (**Figure 1**), 3M™ Prevena™ Incision Management System with the 3M™ Prevena™ Peel and Place Dressing was placed over the incision at -125 mmHg (**Figure 2**).

Discharge and follow-up

Prevena Therapy was discontinued after 5.5 days. The patient was discharged from the hospital on day 6 with no complications. The incision was well approximated on postoperative day 10 (**Figure 3**). At follow-up (13-weeks post surgery), the incision remained intact with good reapproximation.

Patient data and photos courtesy of Dr. V. Seenu Reddy.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on the patient's circumstances and condition.

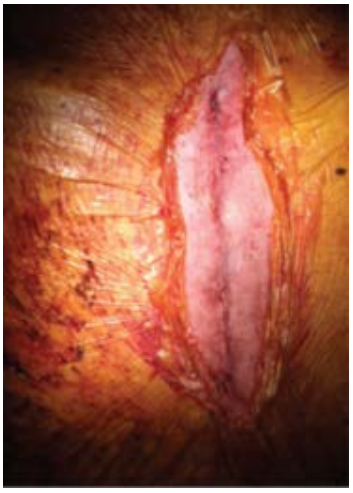


Figure 1. Clean closed 15cm incision.

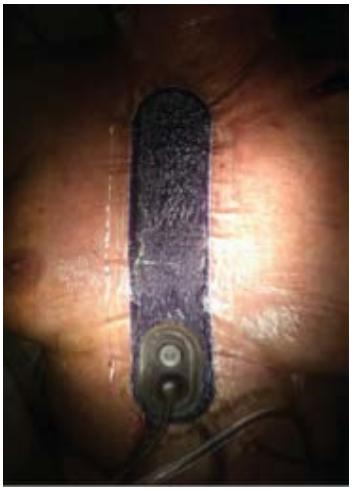


Figure 2. 3M™ Prevena™ Dressing in place with negative pressure applied.

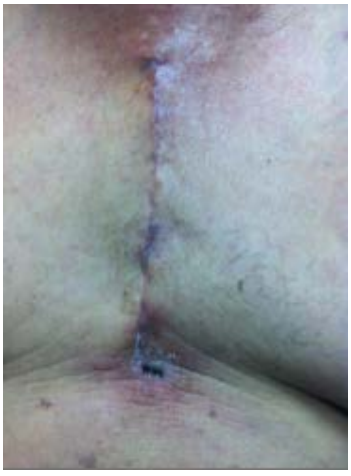


Figure 3. Incision was well approximated on postoperative day 10.

Sternotomy incision

V. Sreenath (Seenu) Reddy, MD, MBA, FACS, Chief, Division of Cardiothoracic Surgery, Centennial Heart & Vascular, Nashville, TN

Patient

A 64-year-old male presented with dyspnea on exertion and angina with minimal activity. Patient comorbidities included diabetes, obesity, hypertension, hyperlipidemia, and chronic obstructive pulmonary disease. Medical history included severe, poorly-control diabetes (HbA1c of 8) and poor nutrition with low preoperative albumin (3.1 g/dL).

Diagnosis

The patient was admitted to the hospital with multivessel artery disease and acute myocardial infarction.

Initial incision treatment/application of 3M™ Prevena™ Therapy:

The patient was taken to the operating room for an aortic valve replacement. 3M™ Prevena™ Incision Management System with the 3M™ Prevena™ Peel and Place Dressing was placed over the closed incision at -125 mmHg (**Figure 1**).

Discharge and follow-up

Prevena Therapy was discontinued after 5 days. The patient was discharged from the hospital with no complications on day 5. The incision was well approximated on postoperative day 10 (**Figure 3**). At follow-up (13-weeks post surgery), the incision remained intact with good reapproximation.

Patient data and photos courtesy of Dr. V. Seenu Reddy.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on the patient's circumstances and condition.

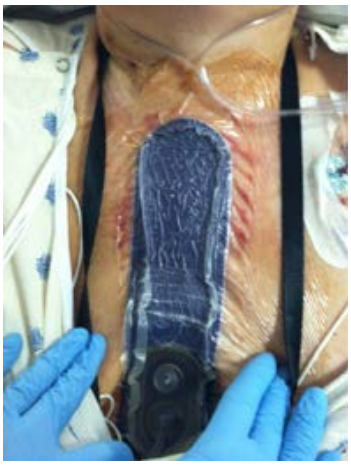


Figure 1. Placement of 3M™ Prevena™ Dressing over the closed 17cm incision.

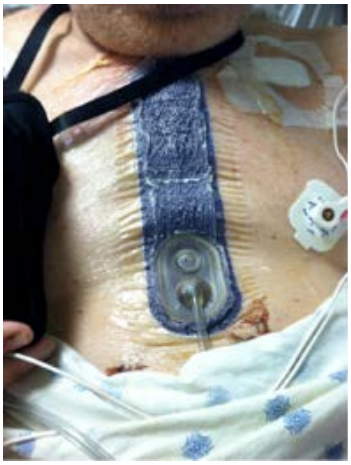


Figure 2. 3M™ Prevena™ Therapy applied for 5 days.

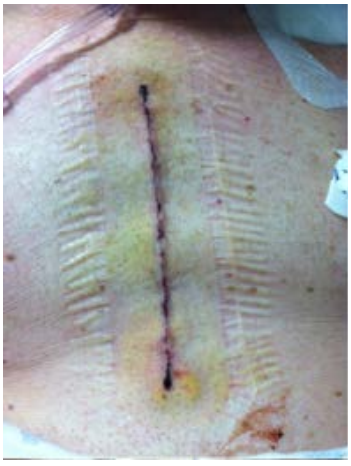
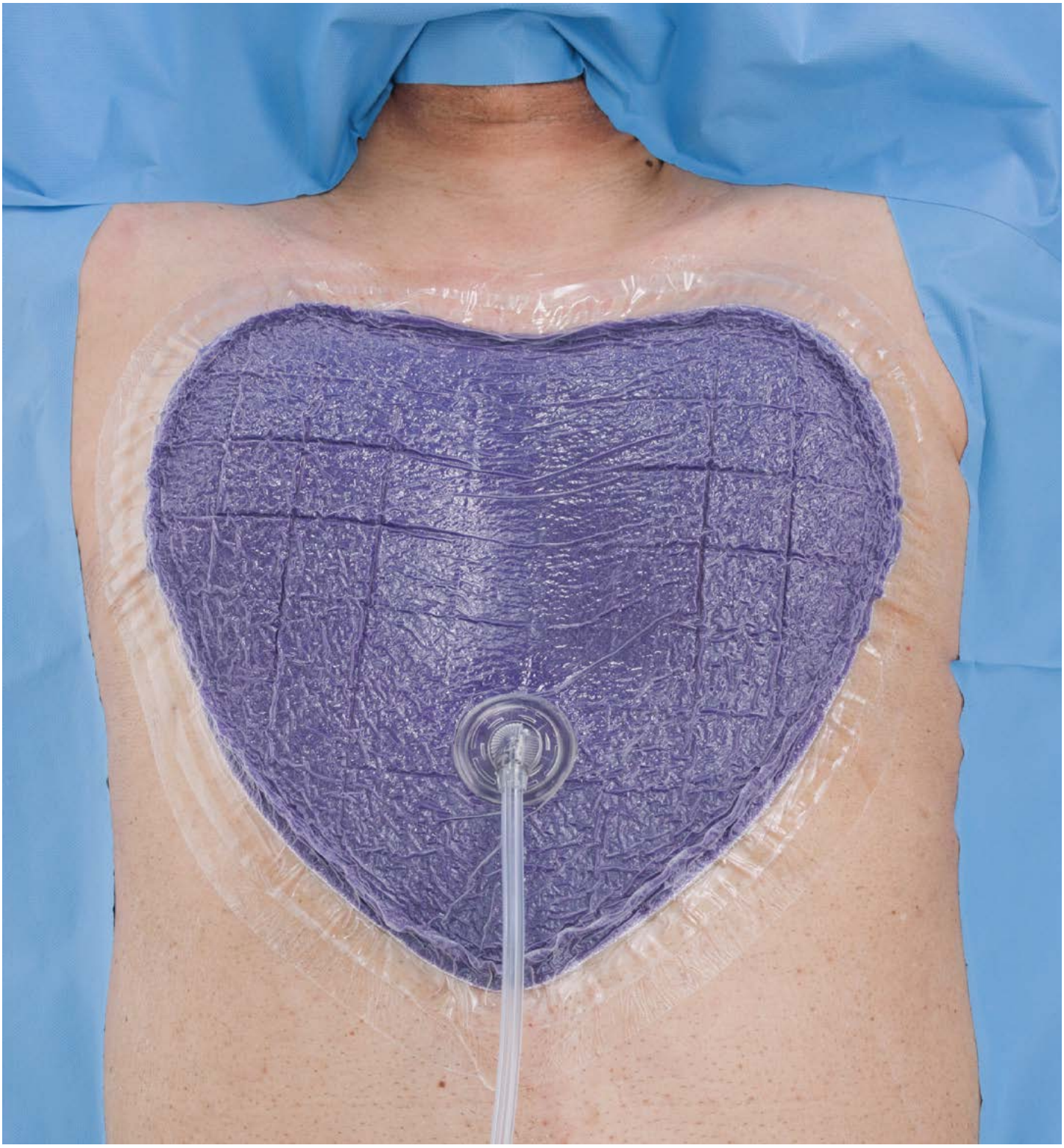


Figure 3. Incision edges were well-approximated at dressing removal (postoperative day 5).



Author biographies*

*Where available and permitted to use.

3M™ Prevena Restor™ Dressings can be used on a variety of anatomical locations.

V. Sreenath (Seenu) Reddy, MD, MBA, FACS

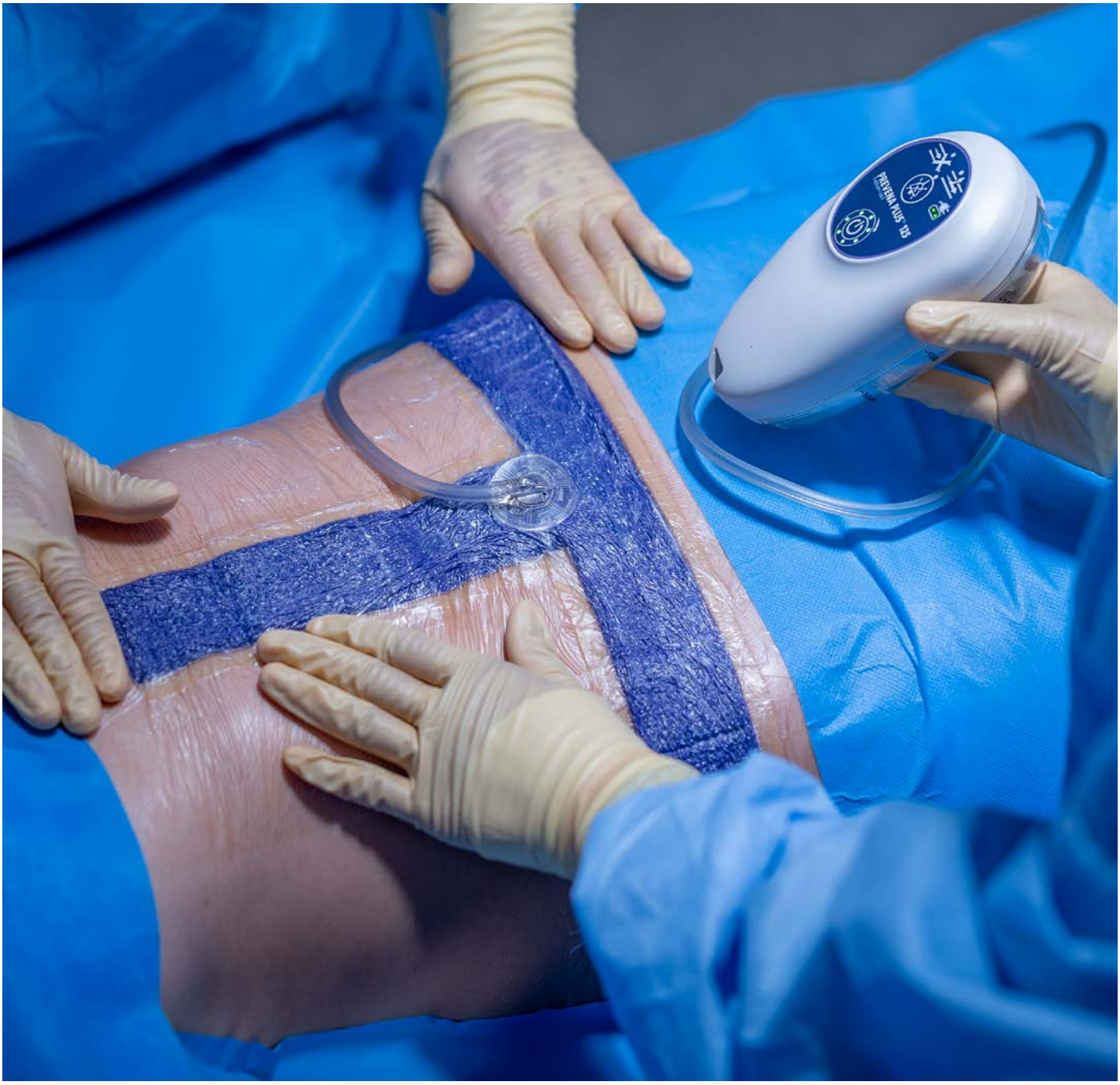
Chief, Division of Cardiothoracic Surgery,
Centennial Heart & Vascular,
Nashville, TN

Dr. Reddy is a paid consultant for Solventum.

V. Sreenath (Seenu) Reddy, MD, MBA, FACS is Chief, Division of Cardiothoracic Surgery at Centennial Heart & Vascular Center in Nashville, TN. He earned his Medical Doctorate from The University of Alabama School of Medicine. He then served his internship and completed a residency in General Surgery at Vanderbilt University Medical Center. Dr. Reddy then received his training in Cardiovascular and Thoracic Surgery at Emory University Medical Center. In addition, he completed a fellowship in advanced endovascular surgery at Emory University Medical Center.

"The available clinical evidence in vascular, plastic, orthopedic, cardiothoracic and spine surgery demonstrates that 3M™ Prevena™ Therapy should be the standard of care for high-risk patients or high-risk procedures. We have integrated Proactive Risk Management, or PRM, into my practice and routinely use Prevena on these groups of patients."

— Dr. Reddy



PRM in general surgery

Prevena.com/generalsurgery

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Closed incision negative pressure therapy versus standard of care over closed abdominal incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies

Mantyh C, Silverman R, Collinsworth A, Bongards C, Griffin L. *ePlasty.* 2024;24:e33.

Study type
A Systematic Review and Meta-Analysis

Study purpose
This systematic review and meta-analysis evaluated the effect of ciNPT on post-surgical and healthcare utilization outcomes for patients undergoing open abdominal surgical procedures.

Methods
- A systematic literature search using PubMed, EMBASE, and QUOSA was performed for publications written in English, comparing ciNPT to standard of care (SOC) dressings for patients undergoing abdominal surgical procedures between January 2005 and August 2021.
- Characteristics of study participants, surgical procedure, dressing used, duration of treatment, post-surgical outcomes, and follow up data were extracted.
- Meta-analyses were performed using random-effects models.
- Dichotomous outcomes were summarized using risk ratios and mean differences were used to assess continuous variables.
- A cost analysis was conducted using inputs from the meta-analysis and cost estimates from a national database.

Summary
- 22 studies were identified for inclusion in the analysis, including 6 randomized controlled trials, 4 prospective studies, and 12 retrospective studies.
- The included studies focused on a variety of elective and/or emergency abdominal procedures including laparotomy (n=11), hernia repair (n=4), colorectal surgery (n=3), loop ileostomy reversal (n=2), abdominal incision repair (n=1) and pancreaticoduodenectomy (n=1).
- Patients who received ciNPT had significantly reduced risk of SSC, surgical site infection (SSI), superficial SSI, deep SSI, dehiscence, and readmission and shorter length of stay compared to patients who received SOC dressings.
- The relative risk of developing an SSC for patients who received ciNPT was 0.568 (95% CI, 0.393-0.821; p=0.003), indicating that ciNPT reduced the risk of an SSC by approximately 43% compared to SOC dressings.
- Patients who received ciNPT were 44% less likely to be readmitted and had a 2.6 day decrease in length of stay compared to patients receiving SOC dressings.
- The estimated cost savings associated with ciNPT use in abdominal procedures was $5,146 per patient.

(Continued)

(Continued)

Clinical complications†

3M Prevena Therapy significantly reduced the relative risk of:

SSCs[1]
11 studies; p=0.003‡

Surgical site infections (SSIs)[1]
20 studies; p<0.001‡

Superficial SSIs (sSSIs)[1]
8 studies; p<0.001‡

Deep SSIs (dSSIs)*[1]
9 studies; p=0.033‡

Dehiscence*[1]
12 studies; p=0.042‡

Health economic outcomes†

3M Prevena Therapy significantly reduced:

Readmission[1]
7 studies; p=0.014‡

Hospital length of stay[2]
8 studies; p<0.0001‡

1. Relative risk reduction
2. Difference in means

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

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

‡Statistically significant (p<0.05)

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.

Read the full study here

Journal: *ePlasty*

Title: Closed incision negative pressure therapy versus standard of care over closed abdominal incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies.

Published: June 1, 2019

Mantyh C, Silverman R, Collinsworth A, Bongards C, Griffin L. Closed incision negative pressure therapy versus standard of care over closed abdominal incisions in the reduction of surgical site complications: A systematic review and meta-analysis of comparative studies. *ePlasty.* 2024;24:e33.

Negative pressure wound therapy for surgical-site infections: A randomized trial

Javed A, Teinor J, Wright M, et al. *Ann Surg.* 2019;269(6):1034-1040.

Summary of findings

This randomized controlled trial from Johns Hopkins Hospital demonstrated significantly lower SSI rates in high-risk patients receiving Prevena Therapy after pancreaticoduodenectomy (31.1% vs. 9.7%; p=0.003)*.

- The SSI rate for all patients (low and high risk) undergoing pancreaticoduodenectomy at this institution during the same time period was 16.3%.
- The authors noted 30-day readmission rate of 19.7% in the standard dressing group vs. 8.1% in the Prevena Therapy group, however this was not statistically significant (p=0.07). There were no statistically significant differences in the other secondary outcome measures.
- SSIs resulted in an increased hospitalization cost of $9,778 per patient as determined by the authors.
- Implementing Prevena Therapy into surgical practice can help reduce potential complications and associated costs to patient health and care.

Study design

Randomized Controlled Trial, Single-Center

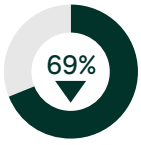
Study purpose

The purpose of the Javed RCT was to evaluate efficacy of closed incision negative pressure therapy (ciNPT), Prevena Therapy, to decrease surgical site infections (SSI) after open pancreaticonduodenectomy.

Methods

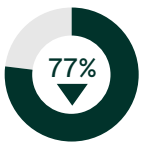
- Patients undergoing pancreaticoduodenectomy procedures were eligible if considered to be high risk for SSI.
- Patients who received neoadjuvant chemo-therapy and/or preoperative biliary stents were considered high risk.
- A total of 123 patients analyzed: Prevena Therapy (n=62) v. operative dressings (removed on postoperative day two) (n=61).
- Preoperative and operative characteristics were not significantly different between the two groups.
- The primary outcome was 30-day SSI (superficial or deep). Secondary outcomes included length of ICU stay, length of hospital stay, reoperation, readmission, and allergic reactions.

Results



Reduction in SSIs*

9.7% (6/62) Prevena Therapy vs. 31.1% (19/61) standard dressing (p=0.003)*



Reduction in superficial SSI*

6.5% (4/62) Prevena Therapy vs. 27.9% (17/61) standard dressing (p=0.002)*

(Continued)

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

*Statistically significant (p<0.05)

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Javed et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	62	61
Number of infections (a)	6	19
Cost per SSI[1] (b)	$18,533	$18,533
Per patient infection cost [c=(a*b)/n]	$1,794	$5,773
Per patient therapy cost* (d)	$830	–
Total cost per patient (c+d)	$2,624	$5,773
Potential per patient savings using Prevena™ Therapy	$3,149	

*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 Standard of Care. 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.

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.

Reference
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

Read the full study here

Journal: *Annals of Surgery*

Title: Negative pressure wound therapy for surgical-site infections: A randomized trial

Published: June 1, 2019

Javed AA, Teinor J, Wright M, et al. Negative pressure wound therapy for surgical-site infections: A randomized trial. *Ann Surg.* 2019 Jun;269(6):1034-1040.

Closed-incision negative-pressure therapy in high-risk general surgery patients following laparotomy: A retrospective study

Zaidi A, El-Masry S. *Colorectal Dis.* 2017;19(3):283-287.

Study type

Retrospective observational study (Level III)

Study purpose

The aim of this study was to compare the rate of wound complications requiring intervention in high-risk surgical patients who received closed incision negative pressure therapy (ciNPT), Prevena™ Therapy, or adherent gauze dressing following laparotomy

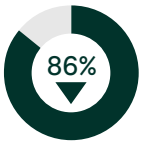
Methods

- Charts were retrospectively reviewed for 181 high-risk patients who presented for elective or emergency laparotomy; Prevena Therapy (n=69); standard dressing (n=112).
- High-risk inclusion criteria were obesity (BMI ≥ 35 kg/m^2), or ≥ 2 of the following risk factors: malignancy, smoking, immunosuppression, malnutrition, emergency surgery, diffuse atherosclerotic disease.
- Prevena Therapy (n=69) was applied over the closed incision in the operating room immediately after skin closure and remained in place for 7 days.
- All patients were followed until postoperative day 30.

Summary

- Prevena Therapy was a safe and effective method of postsurgical management in general surgery patients considered to have risk of developing wound complications following emergency or elective laparotomy.
- The rate of deep SSI requiring intervention was significantly reduced in patients receiving Prevena Therapy (1.4%) vs. standard dressing (20.5%); (p<0.0002).*
- There was not a statistically significant difference in wound dehiscence.
- The study concluded that Prevena Therapy was associated with a positive clinical outcome.

Results



Reduction in wound complications*

2.9% (2/69) Prevena Therapy vs. 20.5% (23/112) standard dressing (p<0.0009)*

Reduction in dSSIs*†

1.4% (1/69) Prevena Therapy vs. 20.5% (23/112) standard dressing (p<0.0002)*

(Continued)

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 has not been reviewed by the U.S. FDA

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Zaldi et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	69	112
Number of deep surgical site infections (a)	1	23
Cost per deep SSI[1] (b)	$21,142	$21,142
Per patient infection cost [c=(a*b)/n]	$306	$4,342
Per patient therapy cost* (d)	$830	–
Total cost per patient (c+d)	$1,136	$4,342
Potential per patient savings using Prevena™ Therapy	$3,205	

*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 Standard of Care. 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.

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.

Reference
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

Read the full study here

Journal: *Colorectal Disease*

Title: Closed-incision negative-pressure therapy in high-risk general surgery patients following laparotomy: A retrospective study

Published: July 15, 2016

Zaidi A, El-Masry S. Closed-incision negative-pressure therapy in high-risk general surgery patients following laparotomy: A retrospective study. *Colorectal Dis.* 2017;19(3):283-287.

Prophylactic closed-incision negative-pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds

Curran T, Alvarez D, Pastrana Del Valle J, Cataldo TE, Poylin V, Nagle D. *Colorectal Dis.* 2019;21(1):110-118.

Study type

Retrospective comparative cohort study (Level III)

Study purpose

The aim of this study was to compare the incidence of surgical site infection (SSI) in colorectal surgery patients who received closed incision negative pressure therapy, Prevena™ Therapy, or standard dressing following high-risk open colorectal surgery.

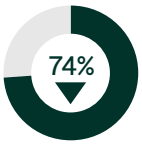
Methods

- National Surgical Quality Improvement Program (NSQIP) reviewed patients at high-risk for SSI undergoing open abdominal colorectal surgery were selected.
- NSQIP facilitated standardized assignment of SSI status with uniform 30-day follow-up.
- High-risk defined patients defined as having ≥ 1 of the following risk factors: pre or post-operative stoma, diabetes, obesity, preoperative steroid or immunosuppressant use, contaminated or dirty wound.
- 77 patients received Prevena Therapy while 238 patients received standard dressings; within the standard dressing group a risk matched cohort subset of 79 patients were identified and presented here.
- Outcomes reported for matched cohort was a composite of superficial SSI, deep SSI or dehiscence at 30 days, as well as unplanned re-admission.

Summary

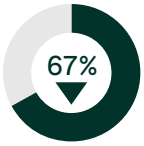
- The study concluded that Prevena Therapy was associated to a significant reduction in overall wound complications.
- In the overall patient population Surgical site infection was higher in patients receiving standard dressings 15% (35/238) compared to patients receiving Prevena Therapy 7% (5/77) (p=0.05).
- Within the matched cohorts there was a significant reduction in wound complications, and superficial SSI (p<0.01).* However differences in deep SSI and dehiscence were not significantly significant.
- In addition the authors conclude Prevena Therapy offers potential for improvement in quality outcomes for high-risk patients undergoing open colorectal surgery.

Results



Reduction in wound complications*

6.5% (5/77) Prevena Therapy vs. 25.3% (20/79) standard dressing (p<0.01)*



Reduction unplanned readmissions*

8% Prevena Therapy vs. 24% standard dressing (p<0.01)*

(Continued)

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

*Statistically significant (p<0.05)

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Curran et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	77	79
Number of surgical site complications (a)	5	20
Cost per SSC[1] (b)	$17,142	$17,142
Per patient complication cost [c=(a*b)/n]	$1,113	$4,340
Per patient therapy cost* (d)	$830	–
Total cost per patient (c+d)	$1,943	$4,340
Potential per patient savings using Prevena™ Therapy	$2,397	

*3M™ Prevena™ Plus Customizable 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 Standard of Care. 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.

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.

Reference
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.

Read the full study here

Journal: *Colorectal Disease*

Title: Prophylactic closed-incision negative-pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds

Published: July 26, 2018

Curran T, Alvarez D, Pastrana Del Valle J, Cataldo TE, Poylin V, Nagle D. Prophylactic closed-incision negative-pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds. *Colorectal Dis.* 2019;21(1):110-118.

Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis

Cheong Chung JN, Ali O, Hawthornthwaite E, et al. *Surgery*. 2021;170(5):1568-1573.

Study type

Retrospective comparative cohort study (Level III)

Study purpose

The purpose of the study was to evaluate with a propensity matched analysis whether the use of closed incision negative pressure therapy (ciNPT), Prevena Therapy, decreases surgical site infections (SSI) compared to standard surgical dressings after emergency laparotomy.

Methods

- A registry-based, cohort study was undertaken using data from the NELA registry.
- The National Emergency Laparotomy Audit (NELA) is part of the National Clinical Audit and Patient Outcomes Program (NCAPOP), overseen by the Healthcare Quality Improvement Partnership (HQIP) in the UK.
- 1484 patients identified from the NELA dataset.
- Propensity score matching resulted in two equally matched cohorts with 237 patients in each arm.
- Prevena Therapy applied of midline incision and left in situ for 7 days or until discharge if before.
- Primary outcome was SSI per Centers for Disease standard dressing criteria. Secondary outcomes included 30-day postoperative morbidity and grade, duration of stay, 30-day mortality, and readmission rates.

Summary

- This registry-based cohort study using the NELA registry uses real world data to shows the use of Prevena Therapy in emergency laparotomy patients is associated with a significant reduction of surgical site infections (33.8% vs 16.9%; **p<0.001***).
- The study also demonstrated a reduction in both superficial and deep SSI. However, secondary outcomes were not statistically significant.
- Bivariate logistic regression revealed the use of a standard surgical dressing and undergoing an emergency colorectal procedure were associated with a higher risk of developing an SSI (p=0.01).*

Results

Reduction in SSIs*

16.9% (40/237) Prevena Therapy vs. 33.8% (80/237) standard dressing (p<0.001)*

Additional outcomes

Classification of SSI	Prevena™ Therapy	Standard dressing
Superficial	8.0% (19/237)	19.8% (47/237)
Deep†	1.3% (3/237)	5.1% (12/237)
Organ Space	5.9% (14/237)	7.2% (17/237)
Unspecified	1.7% (4/237)	1.7% (4/237)

(Continued)

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 and organ space infections has not been reviewed by the U.S. FDA

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Chung et al outcomes

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	237	237
Number of infections(a)	40	80
Cost per SSI[1] (b)	$18,533	$18,533
Per patient infection cost [c=(a*b)/n]	$3,128	$6,256
Per patient therapy cost* (d)	$830	–
Total cost per patient (c+d)	$3,958	$6,256
Potential per patient savings using Prevena™ Therapy	$2,298	

*3M™ Prevena™ Customizable 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 Standard of Care. 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.

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.

Reference
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18

Read the full study here

Journal: *Surgery*

Title: Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis

Published: May 26, 2021

Cheong Chung JN, Ali O, Hawthornthwaite E, et al. Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis. *Surgery.* 2021;170(5):1568-1573.

Prophylactic negative-pressure dressings reduce wound complications and resource burden after emergency laparotomies

Liu D, Cheng C, Islam R, et al. *J Surg Res.* 2021 Jan;257:22-31.

Study type

Retrospective comparative cohort study (Level III)

Study purpose

The purpose of study was to examine whether closed incision negative pressure therapy, Prevena™ Therapy, reduced the rate of wound complications following emergency laparotomy surgery.

Methods

- 227 consecutive laparotomies reviewed retrospectively between Jan 2018 and October 2019 at Northern Hospital, Victoria, Australia.
- 70 patients receiving Prevena Therapy were 1:1 propensity score matched to patients receiving standard dressings.
- Prevena Therapy wounds closed with staples and Negative Pressure Therapy applied for 5-7 days. Standard dressings in the comparison group applied for 7 days.
- Primary endpoint was SSI.
- Secondary Endpoints included length of post operative hospital stay, wound dehiscence, hematoma, hospital service utilization, and readmissions.

Summary

- The use of Prevena Therapy reduced the rates of total wound complications, SSIs, and dehiscence following emergency laparotomy. This reduction in wound complication rates resulted in substantial health resource savings with reduced length of stay and wound-related readmissions to the hospital.
- Further multivariate analysis confirmed that Prevena Therapy was associated with reduced infection risk (OR 0.30; 95% CI: 0.12,0.78, P=0.013) and reduced risk of wound breakdown (OR 0.18, 95% CI: 0.04-0.83, P=0.034).

Results

Reduction in wound complications*

12.9% (9/70) Prevena Therapy vs. 31.4% (22/70) standard dressing (p=0.010)*

Reduction in length of stay*

10.5 ± 6.3 Prevena Therapy vs. 14.6 ± 11.2 standard dressing (p=0.010)*

Reduction in SSI*

8.6% (6/70) Prevena Therapy vs. 27.1% (19/70) standard dressing (p=0.006)*

Reduced hospital readmissions*

0% (0/70) Prevena Therapy vs. 5.7% (4/70) standard dressing (p=0.042)*

Additional outcomes

	Prevena™ Therapy	Standard dressing	p-value
Wound breakdown/ wound dehiscence†	4.3% (3/70)	14.3% (10/70)	P=0.054

(Continued)

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

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.

(Continued)

Illustration of the 3M™ Prevena™ Therapy incision management system cost-effectiveness based on Liu et al outcomes

Surgical site infection

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	70	70
Number of infections (a)	6	19
Cost per infection[1] (b)	$18,533	$18,533
Per patient infection cost [c=(a*b)/n]	$1,589	$5,030
Per patient therapy cost	$830	–
Total cost per patient (c+d)	$ 2,419	$5,030
Potential per patient savings using Prevena™ Therapy	$2,612	

Wound complications

Hypothetical economic model	Prevena™ Therapy	Standard dressing
Number of patients (n)	70	70
Number of complications (a)	9	22
Cost per complication[2] (b)	$17,142	$17,142
Per patient complication cost [c=(a*b)/n]	$2,204	$5,387
Per patient therapy cost* (d)	$830	–
Total cost per patient (c+d)	$3,034	$5,387
Potential per incision savings using Prevena™ Therapy	$2,354	

*3M™ Prevena™ Customizable 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 Standard of Care. 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.

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.

References
1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. *Surg Open Sci.* 2022 Nov 8;11:1-18.

2. 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.

Read the full study here

Journal: *Journal of Surgical Research*

Title: Prophylactic negative-pressure dressings reduce wound complications and resource burden after emergency laparotomies

Published: August 17, 2020

Liu D, Cheng C, Islam R, et al. Prophylactic negative-pressure dressings reduce wound complications and resource burden after emergency laparotomies. *J Surg Res.* 2021 Jan;257:22-31.

Closed-incision negative pressure therapy decreases wound morbidity in open abdominal wall reconstruction with concomitant panniculectomy

Ayuso SA, Elhage SA, Okorji LM, et al. *Ann Plast Surg*. 2022;88(4):429-433.

Study type

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.

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).

Results

Reduction in wound complications*

15.6% Prevena Therapy vs. 35.5% standard dressing (p<0.01)*

Reduction in number of OR visits*

0% Prevena Therapy vs. 13.3% standard dressing (p<0.01)*

Reduction in superficial wound breakdown*†

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

(Continued)

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 wound breakdown has not been reviewed by the U.S. FDA

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.

(Continued)

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	

*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 standard dressings. 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.

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.

Reference
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.

Read the full study here

Journal: *Annals of Plastic Surgery*

Title: Closed-incision negative pressure therapy decreases wound morbidity in open abdominal wall reconstruction with concomitant panniculectomy

Published: April 2022

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.

Closed incision negative pressure therapy achieves better outcome than standard wound care: Clinical outcome and cost-effectiveness analysis in open ventral hernia repair with synthetic mesh positioning

Licari L, Campanella S, Carolla C, Viola S, Salamone G. *Cureus*. 2020. 12(5):e8283.

Summary of findings

- The use of Prevena Therapy significantly decreased the rate of complications and reduced the length of stay for high-risk populations following VHR with synthetic mesh significantly while the rate of seroma and dehiscence was not statistically different.
- The improved clinical outcome with Prevena Therapy resulted in a positive economic outcome based on reduced cost for surgery related inpatient stay as well as reduced cost to manage complications post discharge (readmissions and outpatient care).

Study design

Retrospective comparative cohort study (Level III)

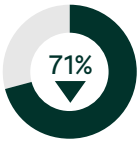
Study purpose

The purpose of the study was to evaluate closed incision negative pressure therapy (ciNPT), Prevena Therapy, to standard dressing in regard to post-operative clinical outcomes and economical benefits for use in ventral hernia repair (VHR) with synthetic mesh positioning.

Methods

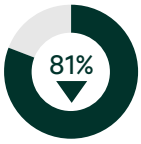
- Patients who underwent elective open VHR with synthetic mesh positioning from January 2015 to December 2017 at a single center in Italy
- Prevena™ Therapy (n=70) v. standard dressing (n=110)
- Patients followed for 90 days postoperatively
- High Risk Inclusion Criteria: ≥ 1 risk factor
  - Age >65
  - Pre-existing wound infection
  - Pulmonary disease
  - BMI >25
  - Malnutrition
  - Ascites
  - Hypertension
  - Diabetes
  - Active smoking
  - Previous radiation therapy
  - Steroid use
  - Immunosuppression
  - Chronic inflammatory disease

Results



Reduction in major complications*

12.8% (9/70) Prevena Therapy vs. 43.6% (48/110) standard dressing (p<0.00001)*

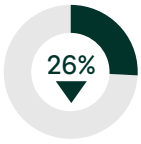


Reduction in superficial infections*

4.3% (3/70) Prevena Therapy vs. 22.7% (25/110) standard dressing (p=0.0006)*

Reduction in mean in-hospital length of stay*

3 ± 1.37 Prevena Therapy vs. 6 ± 2.39 standard dressing (p<0.00001)*



Reduction in mean total cost per patient*

Prevena inpatient cost: 4,230 €; standard dressing inpatient cost: 5,695 € (p=0.02)*; Patient cost saving: 1,465€

Reduction in deep infections*†

0% (0/70) Prevena Therapy vs. 6.4% (7/110) standard dressing (p=0.04)*†

(Continued)

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 has not been reviewed by the U.S. FDA

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.

(Continued)

Additional outcomes

	Prevena Therapy	Standard dressing	p-value
Re-hospitalization rate	2.8% (2/70)	10% (11/110)	p=0.08
Fever (minor complication)†	28.6% (20/70)	54.4% (60/110)	p=0.0006*
Leukocytosis (minor complication)†	21.4% (15/70)	45.4% (50/110)	P=0.001*

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 fever and leukocytosis has not been reviewed by the U.S. FDA

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.

Read the full study here

Journal: *Cureus*

Title: Closed incision negative pressure therapy achieves better outcome than standard wound care: Clinical outcome and cost-effectiveness analysis in open ventral hernia repair with synthetic mesh positioning

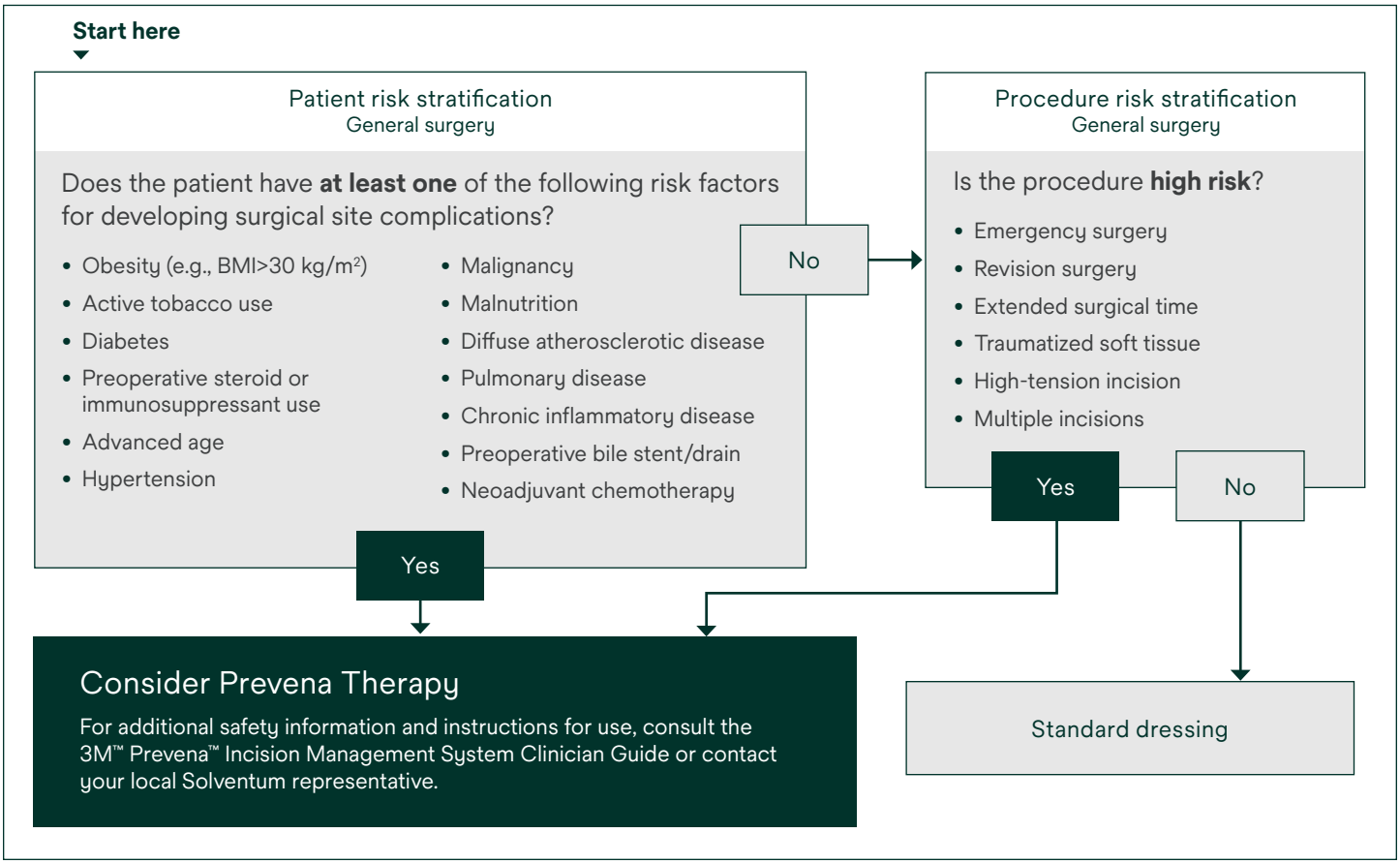
Published: May 26, 2020

Licari L, Campanella S, Carolla C, Viola S, Salamone G. Closed incision negative pressure therapy achieves better outcome than standard wound care: Clinical outcome and cost-effectiveness analysis in open ventral hernia repair with synthetic mesh positioning. *Cureus*. 2020. 12(5):e8283. OPEN ACCESS

Decision guide

Patient and procedure risk stratification backed by clinical evidence

While surgical patients may benefit from Prevena Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data[1-8] to provide an illustrative guide to aid in risk stratification. This is not an all-inclusive list of risk factors. Clinicians are advised to use their clinical judgment to identify high-risk patients or high-risk procedures.



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.

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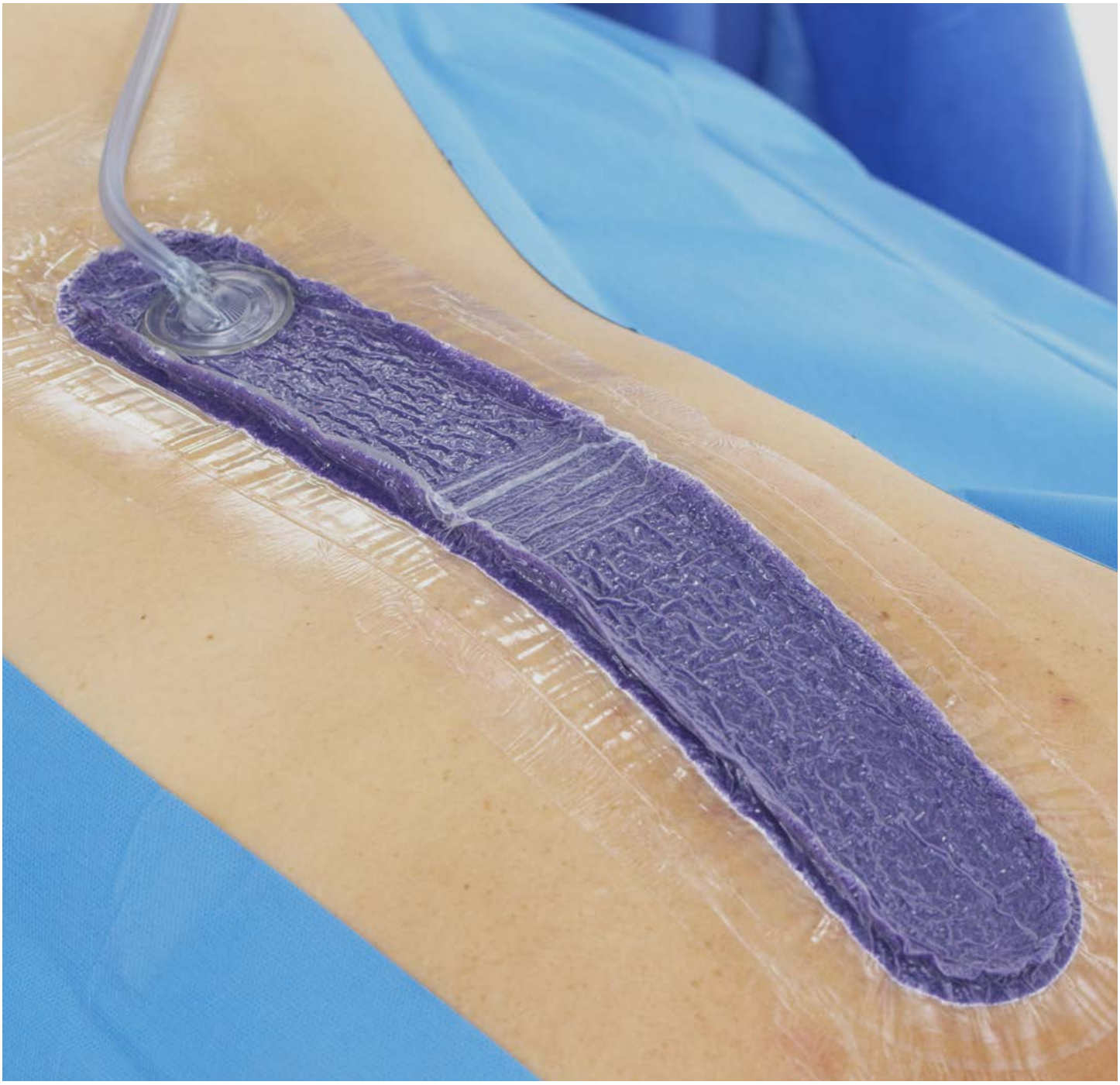

PRM in spine surgery

Prevena.com/spine

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Effect of incisional negative pressure wound therapy vs standard wound dressing on the development of surgical site infection after spinal surgery: A prospective observational study

Mueller KB, D'Antuono M, Patel N, et al. *Neurosurgery*. 2021 Apr 15;88(5):E445-E451.

Study type
This was a prospective observational study.

Study purpose
This study was performed to evaluate the effect of a ci-NPT dressing as compared with the standard dressing on SSI development after instrumented and non-instrumented spine surgery.

Methods
This was a prospective observational study over a 2-year period.

- Inclusion/exclusion criteria: Inclusion criteria was degenerative disease, deformity, malignancy, trauma, and patients undergoing decompression alone or decompression with fusion. Exclusion criteria included anterior and lateral approaches to the spine, intraoperative durotomy, or use of minimally invasive techniques.
- SSI was the main outcome variable and SSIs were recorded 60 days following the surgery.
- Statistical significances were determined by Pearson's chi squared test and Fisher's exact test. Relative risk (RR) and 95% CIs were calculated for each of the categorical variables.

Results
A total of 274 patients were included in the study. The SSI rate (SSIR) was significantly lower with ci-NPT dressing as compared to standard dressing (3.4% vs 10.9%, P=0.02, RR = 0.679, 95% CI= 0.536-0.859). There was a statistically significant reduction in SSIs with the use of ci-NPT dressing in cases that required instrumentation (3.2 vs 11.4%, P=.03). Reduced SSIs were seen in patients' higher risk such as having instrumentation, deformity, and malignancy; however, the results were not significant. No complications were reported in either group that affected the patients' length of stay or the overall care.

Conclusion
SSI rates were significantly reduced with a ci-NPT dressings versus with a standard dressing in patients who underwent spinal surgery.

Read the full study here

Journal: *Neurosurgery*

Title: Effect of incisional negative pressure wound therapy vs standard wound dressing on the development of surgical site infection after spinal surgery: A prospective observational study

Published: April 15, 2021

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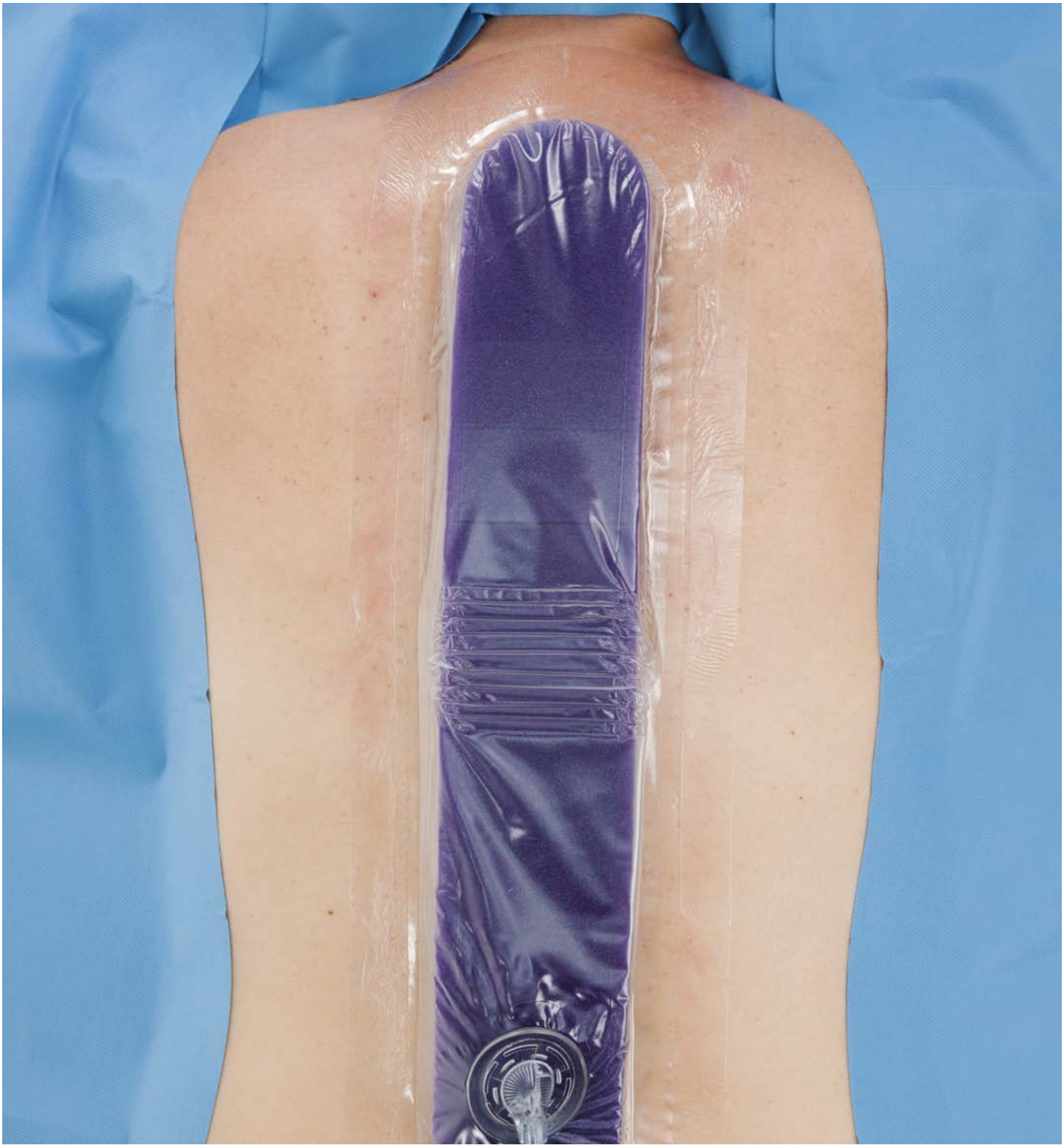

Case studies*

*Where available and permitted to use.

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Use of 3M™ Prevena™ Therapy to manage a high-risk incision after multi-level lumbar fusion

Kyle Mueller, MD; Department of Neurosurgery,
Brown University & Rhode Island Hospital, Providence, RI

Patient

A 56-year-old female presented to the hospital with worsening back pain and neurogenic claudication. Medical history included diabetes, hypertension, hyperlipidemia, morbid obesity (BMI 42 kg/m^2), and diminished mobility. Laboratory examination revealed prealbumin levels at 11 mg/dL and albumin at 3.0 g/dL, indicative of malnutrition. The patient was diagnosed with degenerative disc disease with sagittal malalignment and severe lumbar stenosis.

Procedure

The patient was admitted for staged multi-level lumbar fusion. Stage 1 consisted of L4-S1 anterior lumbar interbody fusion (**Figure 1-2**). Stage 2 consisted of L3-4 lateral lumbar interbody fusion and L3-pelvis fusion with multi-level decompression with posterior column osteotomies.

Application of Prevena Incision Management System

For the posterior incision (**Figure 3**), suprafascial vancomycin powder was applied, and a 15F subfascial silicone channel drain and 15F suprafascial silicone channel drain were placed. In the operating room, 3M™ Prevena™ Plus Customizable Dressing was cut to the appropriate length and applied to the posterior incision. A seal was created using -125 mmHg negative pressure (**Figure 4**). The drape border was lined with foam tape to ensure that a seal is maintained while the patient recovers in the supine position postoperatively*.

The anterior incision resulting from Stage 1 surgery was closed via staples by the vascular team and received standard incision care only.

***To create a continuous seal, clinicians may use sealing strips provided with the dressing. 3M does not recommend use of accessories or materials not provided with 3M™ Prevena™ Incision Management System. For additional safety information, refer to the product's instructions for use.**

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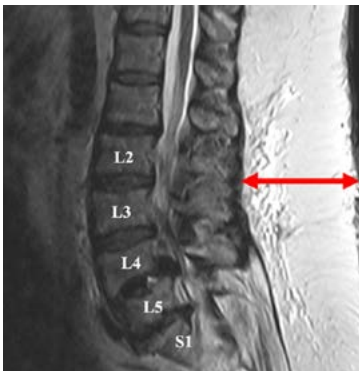

Figure 1. MRI scan of lumbar region before staged surgical procedure. The red arrow highlights the large suprafascial distance (7 cm). A distance greater than 3 cm is associated with a higher risk of wound healing complications.

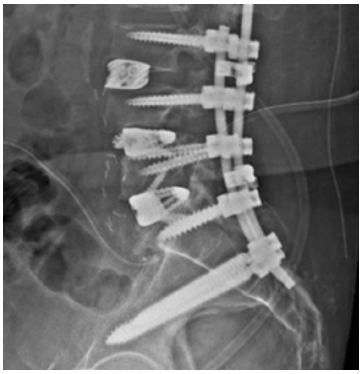

Figure 2. X-ray showing instrumented multi-level lumbar fusion.

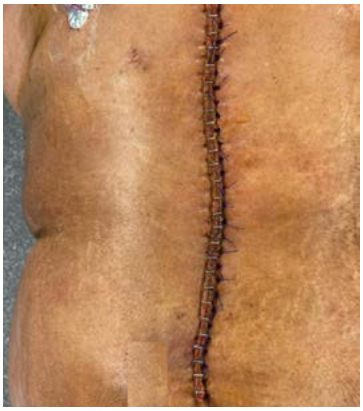

Figure 3. Appearance of the incision immediately after closure.

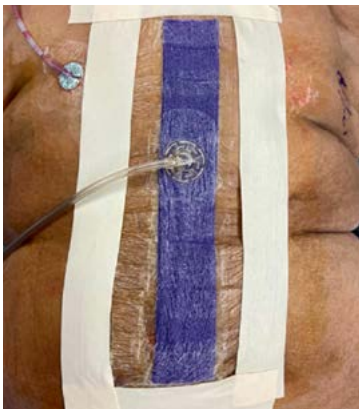

Figure 4. Placement of Prevena Plus Customizable Dressing and application of negative pressure. Foam tape was placed over the drape edges.

(Continued)

Discharge and follow-up

Multi-level fusion in the lumbar-sacral region is associated with an elevated risk of incision healing complications. This risk was further increased by the presence of multiple comorbidities and postoperative immobility. The large suprafascial distance caused concern for increased fluid collection and risk of seroma formation.

On postoperative day 7, Prevena Therapy was discontinued on the posterior incision, which remained closed and without complication (**Figure 5**). In contrast, the anterior incision treated with standard care alone showed signs of breakdown. The anterior incision was managed with standard negative pressure wound therapy until closure was achieved at 3 months.

The patient had a prolonged hospitalization and was discharged after 22 days. She followed up in clinic every 2 weeks for the next 6 weeks for incisional checks. The subfascial drain was removed when output was <50 mL over 24 hours. The suprafascial drain was removed when output was <30 mL over 24 hours. Given the high tensile stress across the incision, the staples were left in place for 6 weeks. Sutures were removed after 8 weeks. After incision healing and rehabilitative therapy, the patient's back and leg pain were resolved.

Prevena Therapy helped pull the incision edges together, removed exudate, and facilitated uneventful healing of the posterior incision, despite the patient's high risk for incision breakdown. This was especially beneficial in the postoperative period, given that mobilization and pain control were a challenge.

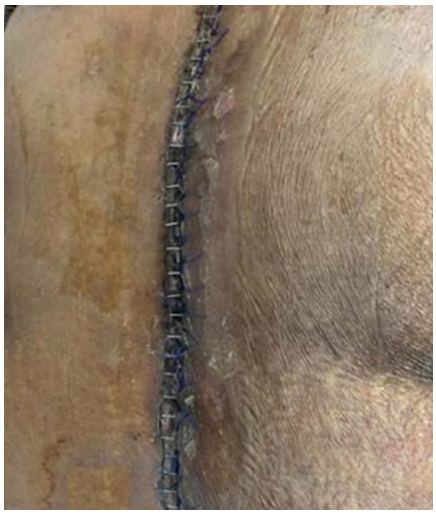

Figure 5. Incision appearance after 7 days of Prevena Therapy. No signs of complication were observed.

Photo courtesy of Kyle B. Mueller, MD, Department of Neurosurgery, Brown University and Rhode Island Hospital, Providence, RI.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

Use of 3M™ Prevena™ Therapy after spinal fusion complicated by metastatic cancer

Kyle Mueller, MD; Department of Neurosurgery, Brown University & Rhode Island Hospital, Providence, RI

Patient

A 56-year-old male presented with increasing back pain and difficulty walking. Patient medical history included diabetes, smoking, hypertension, and hypersensitivity lung disease. Upon physical examination, diminished sensation and muscle strength was observed in both legs. Laboratory work revealed prealbumin levels at 8 mg/dL and albumin at 2.5 g/dL, indicative of malnutrition. The patient was diagnosed with T10 pathological fracture with severe stenosis and myelopathy.

Procedure

The patient was admitted for a multi-level T6-L2 posterior instrumented fusion with a T10 corpectomy with cement reconstruction (**Figures 1** and **2**).

Application of 3M™ Prevena™ Incision Management System

After closure of the spinal incision, a 3M™ Prevena™ Plus Customizable Dressing was applied with -125 mmHg negative pressure (**Figure 3**) with the 3M™ Prevena™ Plus 125 Therapy Unit. The drape border was lined with foam tape to ensure that a seal is maintained while the patient recovers in the supine position postoperatively.* Two subfascial 15F silicone channel drains were placed; no suprafascial drains were used due to the limited space and adequate tension-free closure of the fascia and muscle. 3M™ Prevena™ Therapy was continued for 7 days postoperatively.

***To create a continuous seal, clinicians may use sealing strips provided with the dressing. 3M does not recommend use of accessories or materials not provided with 3M™ Prevena™ Incision Management System. For additional safety information, refer to the product's instructions for use.**

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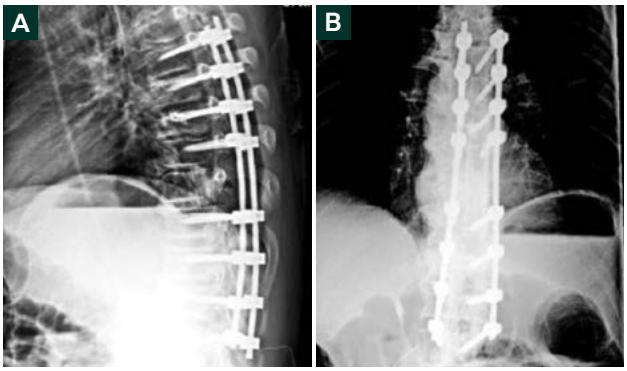

Figure 1. X-rays showing T6-L2 instrumented fusion from the left lateral (**A**) and dorsal (**B**) perspectives.

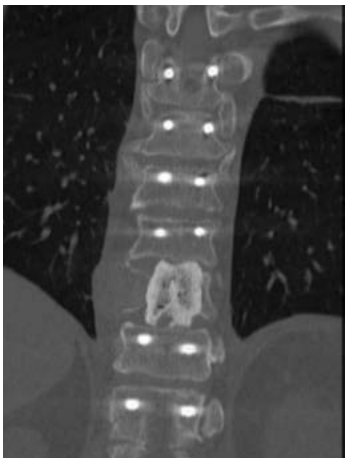

Figure 2. CT scan showing instrumented fusion with T10 corpectomy with cement reconstruction.

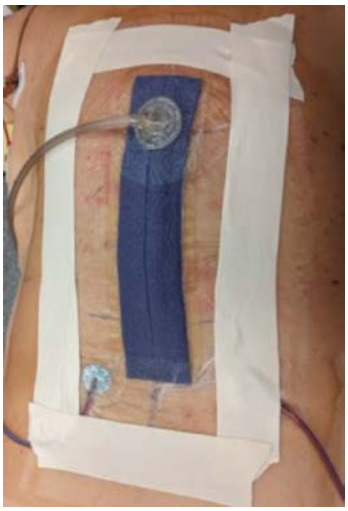

Figure 3. Placement of 3M™ Prevena™ Customizable Dressing and application of negative pressure.

(Continued)

Discharge and follow-up

The patient was concurrently diagnosed with metastatic lung adenocarcinoma, adding to existing risk factors for postoperative complications. Subfascial drains were taken out when output was <50 mL over 24 hours.

After conclusion of Prevena Therapy on postoperative day 7, the incision was cleaned with a chlorhexidine gluconate and isopropyl alcohol solution. The patient was discharged to acute rehab on postoperative day 9. Six weeks after completion of Prevena Therapy, the incision was completely healed with no complications (**Figure 4**).

Due to the presence of multiple comorbidities and the highly invasive nature of surgery, the patient had an elevated risk of surgical site infection, which can delay oncologic therapy and have a prognostic impact. In this case, Prevena Therapy provided the conditions for optimized incision healing.

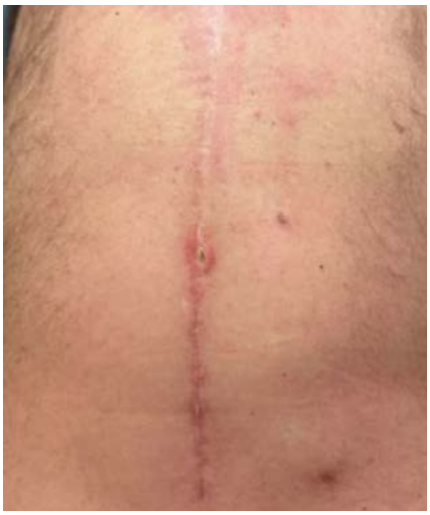

Figure 4. Incision healed six weeks after completion of 3M™ Prevena™ Therapy.

Photo courtesy of Kyle B. Mueller, MD, Department of Neurosurgery, Brown University and Rhode Island Hospital, Providence, RI.

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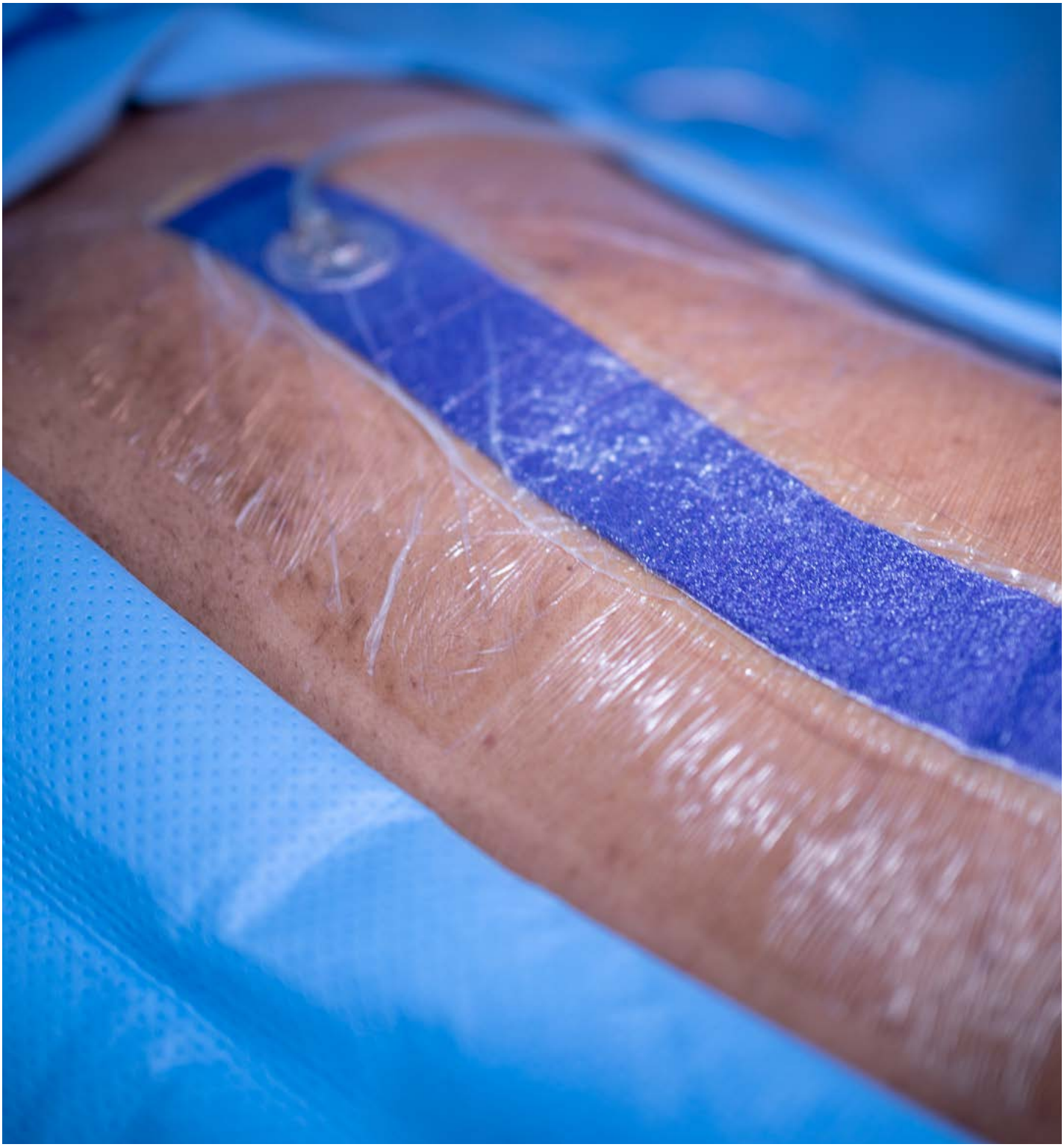


Author biography*

*Where available and permitted to use.

3M™ Prevena™ Dressings can be applied to various procedures and anatomical locations.

Kyle Mueller, MD

Assistant Professor
Department of Neurosurgery
Perelman School of Medicine at the University of Pennsylvania
Philadelphia, PA

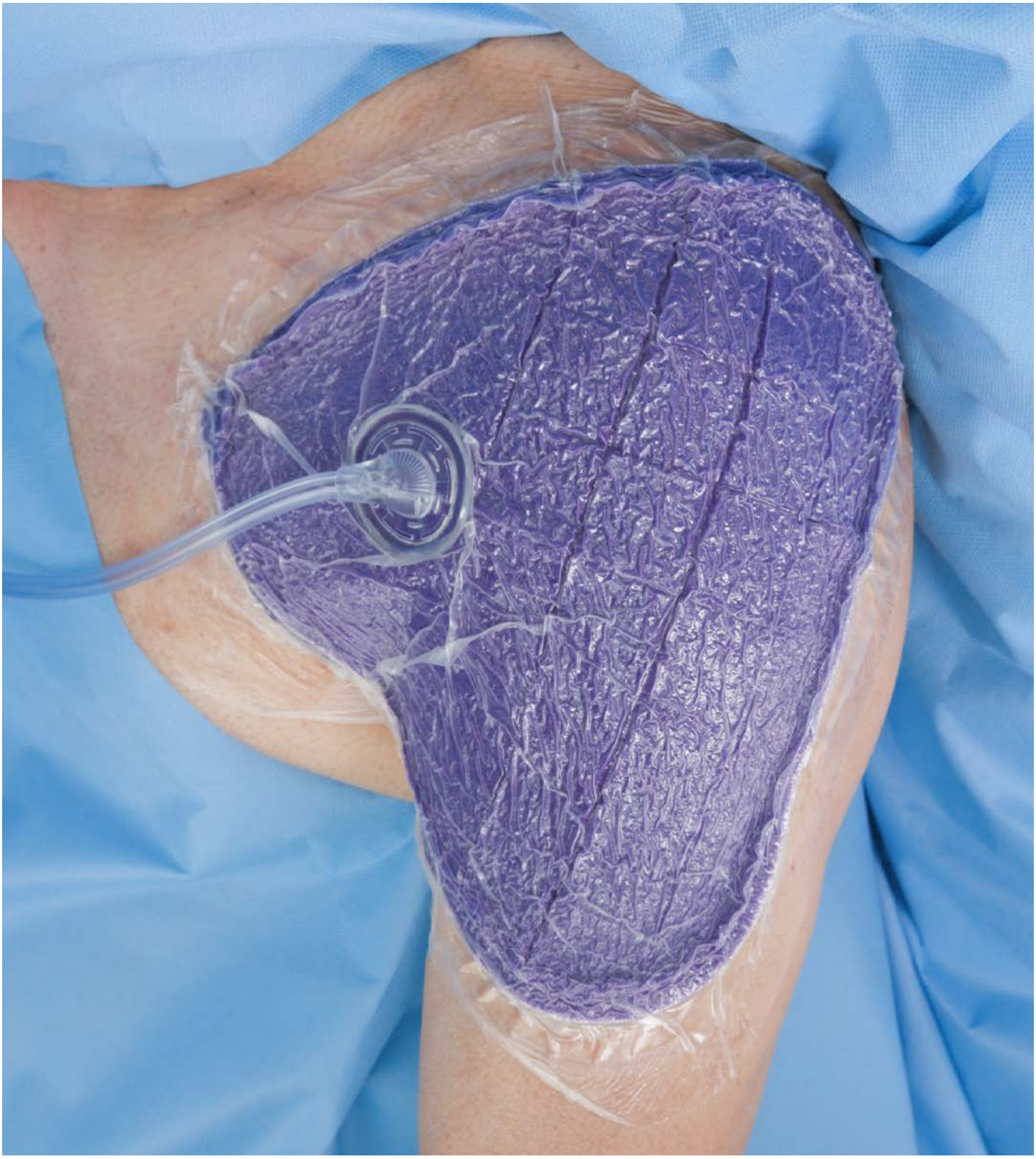
Dr. Mueller is a paid consultant for Solventum.

Dr. Kyle Mueller is an Assistant Professor in the Department of Neurosurgery at the University of Pennsylvania. Dr. Mueller is a graduate of Texas A&M Health Science Center College of Medicine. He completed a residency in neurosurgery at Georgetown University Medical Center in Washington, D.C., followed by a fellowship in spine biomechanics research in the Department of Orthopedic Surgery at Medstar Union Memorial Hospital in Baltimore, Maryland, under Dr. Bryan Cunningham. Subsequently, he completed a complex spine fellowship in the Department of Neurosurgery at Warren Alpert Medical School of Brown University/Rhode Island Hospital under Dr. Ziya Gokaslan.

Dr. Mueller's clinical focus is general neurosurgery and complex spine surgery, and he has a particular clinical interest in spinal oncology and spinal deformities. He performs the full range of surgical procedures from the least invasive – including minimally invasive and endoscopic – to the most complex surgical revisions. He has won several grants and authored numerous book chapters and manuscripts including most recently the largest prospective study to date evaluating closed-incisional negative pressure therapy and spine surgery. In addition, Dr. Mueller is passionate about optimization of patient pathways, research related to outcomes, and spine education.

"I became aware of 3M™ Prevena™ Therapy while researching incision management strategies to reduce the risk of surgical site complications. Based on this investigation, I have implemented an evidence-based approach in my practice, utilizing Prevena Therapy as a proactive risk management tool on high-risk patients and complex/challenging spine incisions."

— Dr. Mueller



Health economic impact

3M™ Prevena Restor™ Dressings can be used on a variety of anatomical locations.

PRM economic impact

The utilization of Prevena Therapy in at-risk patients and procedures across multiple specialties has shown to help reduce the incidence of costly postoperative complications when compared to the standard of care.

The table below outlines potential per patient complication cost avoidance by implementing PRM with 3M™ Prevena™ Therapy.

Variables		a	b	a*b=c	d	c*d=e
Specialty	Complication type	Mean cost per complication	Incidence	Mean complication cost per patient	Complication reduction with Prevena	Reduced complication cost per patient with Prevena
Orthopedic surgery	Surgical site complication	$16,173[1]	5.2%[1]	$841.0	67%[3]	$563
Orthopedic surgery	Surgical site infections	$18,899[2]	1.2%[2]	$226.8	60%[3]	$136
Plastic surgery	Surgical site complication	$9,526[1]	18.4%[1]	$1,752.8	47%[4]	$824
General/ abdominal surgery	Surgical site complication	$17,142[1]	10.9%[1]	$1,868.5	43%[5]	$803
General/ abdominal surgery	Surgical site infections	$18,533[2]	5.0%[2]	$926.7	49%[5]	$454
Cardiac	Surgical site infections	$45,478[2]	1.7%[2]	$773.1	49%[6]	$379
Vascular	Surgical site infections	$20,864[2]	2.6%[2]	$542.5	56%[7]	$304

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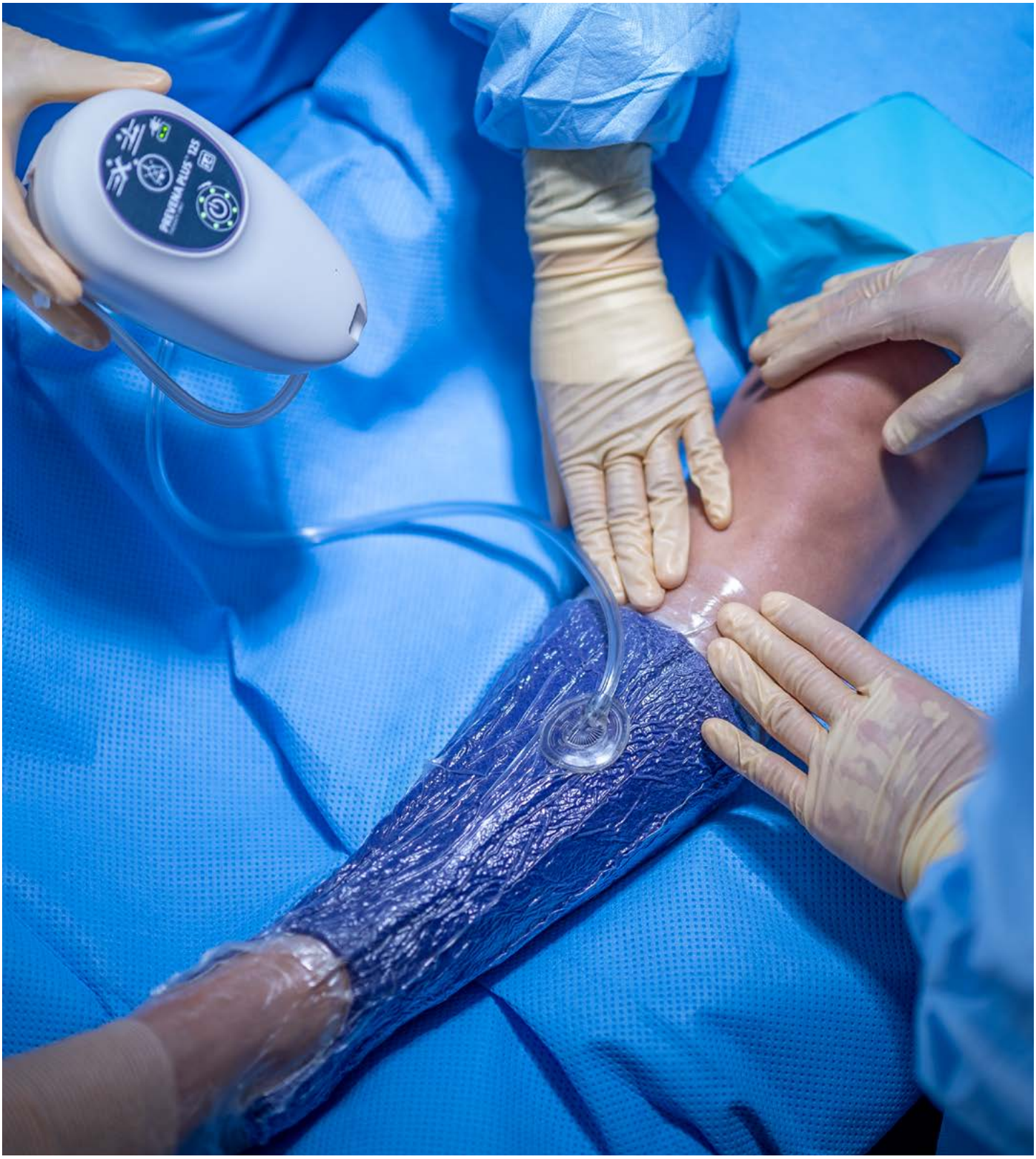
The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at hcbgregulatory.3m.com..



Product overview

3M™ Prevena Restor™ Dressings can be used on a variety of anatomical locations.

3M™ Prevena™ Therapy Units

3M™ Prevena™
125 Therapy Unit

3M™ Prevena™ Plus
125 Therapy Unit (7 or 14 day)

3M™ Prevena™ Dressings and 3M™ Prevena Restor™ Dressings

3M™ Prevena™ Peel and Place Dressings

3M™ Prevena™ Peel
and Place Dressing –
13 cm

3M™ Prevena™ Peel and
Place Dressing – 20 cm

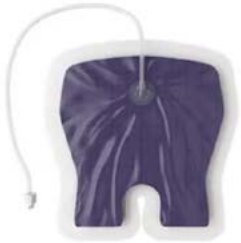
3M™ Prevena™ Peel and
Place Dressing – 35 cm

3M™ Prevena™ Plus Customizable Dressing

3M™ Prevena™ Plus
Customizable Dressing

3M™ Prevena Restor™ Dressings

3M™ Prevena Restor™
Arthro•Form™
Dressing



3M™ Prevena Restor™
Axio•Form™ Dressing

3M™ Prevena Restor™
Bella•Form™ Dressing

3M™ Prevena Restor™
Adapti•Form™ Dressing

Healthcare professionals:

Visit prevena.com to learn more, request a demonstration, or contact a sales representative.

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.

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

3M™ Prevena™ 125 and 3M™ Prevena™ Plus 125 Therapy Units 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 and Prevena Plus 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and II wounds.

NOTE: Applicable therapy units include 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 Prevena Restor System Kits (see Prevena Restor System indications for use).

*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

Notes

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