July 2023

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

A 3M ciNPT Clinical Compendium

Letter from the Editor

Dear Colleagues,

It is our pleasure to bring to you this document that includes evidence-based guidance for the use of 3M™ Prevena™ Therapy for proactive risk management in a variety of specific clinical circumstances. Negative pressure wound therapy is one of the most important innovations in wound care in the last 30 years. More recently, the use of negative pressure therapy over closed surgical incisions has been established as a reliable way to help reduce the risk of surgical site complications in patients that have a risk for suffering such complications.

Prevena Therapy provides negative pressure therapy to the closed incision and surrounding soft tissues to help optimise outcomes and reduce complications. One of the most common requests that I receive from surgeons is for specific advice regarding when exactly to choose Prevena Therapy for their patients. With over 200 peer reviewed publications studying Prevena Therapy, there is now sufficient evidence to provide evidence-based guidance to help support surgeon decision making. Of course, these guidance documents are not intended to be a replacement for clinical judgment and are simply provided for the surgeon's additional consideration based on the most recent available published literature.

We believe that the consistent use of Prevena Therapy in the appropriate patients for proactive risk management can help providers achieve better patient outcomes, reduce risk of complications, and lower total cost of care. We hope you find these documents useful.

Sincerely,

Ron Silverman, MD
Senior Vice President of Clinical Affairs and Chief Medical Officer, 3M Health Care Business Group

Ronald P. Silverman, MD, FACS

Senior Vice President,
Global Medical and Clinical Affairs,
Chief Medical Officer,
3M Health Care Business Group

Clinical Associate Professor of Surgery, University of Maryland

Adjunct Associate Professor of Plastic Surgery, Johns Hopkins

Dr. Ron Silverman is the Senior Vice President, Global Medical and Clinical Affairs, and Chief Medical Officer for 3M Health Care Business Group. He is also a practicing plastic and reconstructive surgeon at the University of Maryland Medical Centre. Prior to his CMO role, Dr. Silverman was the Chief of Plastic Surgery at the University of Maryland and holds academic appointments at both the University of Maryland and Johns Hopkins Schools of Medicine.

Ron completed his plastic surgery residency at Harvard/Massachusetts General Hospital in Plastic Surgery and graduated Cum Laude from the University of Maryland School of Medicine. Ron is certified by the American Board of Plastic Surgery and is a member of several professional organisations, including the American College of Surgeons, the American Society of Plastic Surgeons, the Plastic Surgery Research Council, and the American Association of Plastic Surgeons. He is a recipient of the Wayne W. Babcock award for outstanding performance in surgery and a member of the Alpha Omega Alpha honor society.

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

Contents

Help protect your patients with 3M™ Prevena™ Therapy.

Implement Proactive Risk Management (PRM)

Prevena Therapy can benefit surgical patients – choosing Prevena Therapy for your high-risk patients may aid in risk reduction of surgical site infection* and may result in cost savings. By implementing PRM, you can use procedural and patient risk stratification to help protect your high-risk patients.

Surgical Site Complications (SSCs) are not only costly, but they can lead to negative impacts on patient recovery.

Surgical Site Infections (SSIs) occur in **2%–5%** of all inpatients.[1]

Patients who develop an SSI are approximately **5X** likelier to be readmitted.[2]

Over **€5,000** average additional cost per SSI.[3]

Prevena Therapy has been shown to help reduce the risk of SSCs and overall cost of care.[4,5]

Prevena Therapy has demonstrated outcomes across multiple specialties, including plastic, vascular, cardiothoracic, spine, orthopaedic and general surgery.[6] Data from a multicentre randomised controlled trial and health economic analysis showed that Prevena Therapy significantly reduced the risk of 90-day surgical site complications (SSCs),[4] readmissions,[4] and surgical site management costs[5] vs. silver-impregnated dressings.

4x **Reduction in SSCs†4** — 3.4% (5/147) Prevena Therapy vs. 14.3% (21/47) SOC (p=0.0013)‡

3x **Reduction in readmission rates†4** — 3.4% (5/147) Prevena Therapy vs. 10.2% (15/47) SOC (p=0.0208)‡

15% **Fewer mean dressing changes†4** — 1.1 ± 0.29 Prevena Therapy vs. 1.3 ± 0.96 SOC (p=0.0003)‡

* 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.

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

‡ Statistically significant (p≤0.05).

The PROMISES (Post-market, Randomised, Open-Label, Multicentre study to evaluate Effectiveness) Trial measured 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.[4]

References

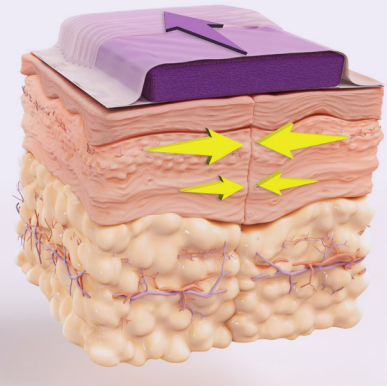
1. Anderson, DJ, *et al*. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update. *Infect Contol Hosp Epidemiol*. 2014;35(6):605–627. doi: 10.1086/676022. **2.** Canadian Surgical Site Infection Prevention Audit Month Report. Retrieved from http://www.patientsafetyinstitute.ca/en/toolsResources/Pages/SSI-Audit-Recap-Report-2016-12.aspx **3.** Jenks PJ, Laurent M, McQuarry S, Watkins R. Clinical and economic burden of surgical site infection (SSI) and predicted financial consequences of elimination of SSI from an English hospital. *J Hosp Infect*. 2014 Jan;86(1):24–33. **4.** Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett MP, Scuderi GR, Cushner FD, Piuzzi NS, Silverman RP. 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 Randomised 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. **5.** Cooper HJ, Bongards C, Silverman RP. Cost-Effectiveness of Closed Incision Negative Pressure Therapy [PREVENA] for Surgical Site Management After Revision Total Knee Arthroplasty: Secondary Analysis of a Randomised Clinical Trial. *Journal of Arthroplasty*. 2022 Aug;37(8S):S790–S795. **OPEN ACCESS** **6.** Cooper HJ, Roc GC, Bas MA, *et al.* Injury. 218;49(2):386–391.

3M™ Prevena™ Therapy mechanism of action.

Acts as a barrier to external contamination[5]

Delivers continuous -125mmHg up to 7 or 14 days[1§]

Removes fluids and infectious materials[2,*]



Helps to hold incision edges together[4]

Decreases lateral tensions of sutured/ stapled incisions[4,†]

Reduces oedema[3]

Direction of fluid

Appositional force

Additional benefits unique to 3M™ Prevena™ Dressings:

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

Contours allow for even distribution of negative pressure.

Skin interface layer contains 0.019% ionic silver.

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 7 or 14 days[§]
- Shower friendly[‡]
- Audible and visual alarms
- Dedicated clinical support

* In a canister.

† In computer bench models.

‡ See Prevena Therapy Patient and Clinician Guides for additional details.

§ Maximum length of therapy with Prevena Therapy Platform is 7 days. Maximum length of therapy with 3M™ Prevena Restor™ Therapy Platform is 14 days.

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.

References

1. 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;145:1387-1392. **2.** Kilpadi DV, Cunningham MR. Evaluation of closed incision management with negative pressure wound therapy (CIM): Haematoma/seroma and involvement of the lymphatic system. *Wound Repair and Regeneration.* 2011;19(5):588-96. **3.** Glasser, et al. Negative pressure therapy for closed spine incisions: a pilot study. *Wounds.* 2012;24(11):308-16. **4.** 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. **5.** Colli A. First experience with a new negative pressure incision management system on surgical incisions after cardiac surgery in high risk patients. *Journal of Cardiothoracic Surgery.* 2011 December 6;6(1):160.

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, H. John MD, Singh, Devinder P. MD, Gabriel, Allen MD, FACS, Mantyh, Christopher MD, Silverman, Ronald MD, Griffin, Leah MS. Closed Incision Negative Pressure Therapy versus Standard of Care in Reduction of Surgical Site Complications: A Systematic Review and Meta-analysis. *Plastic & Reconstructive Surgery-Global Open* 11(3):p e4722, March 2023.

Background

- Surgical site complications (SSCs), such as surgical site infection (SSI), dehiscence, seroma, haematoma 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 w ere extracted.

Results

- The literature search identified 84 studies for analysis.
- Significant reductions in SSC rates in favour 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 favour 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 favour 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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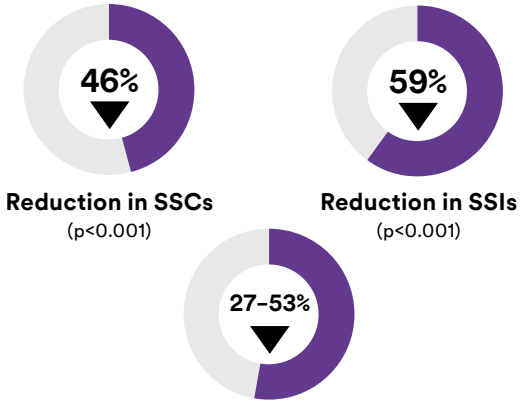
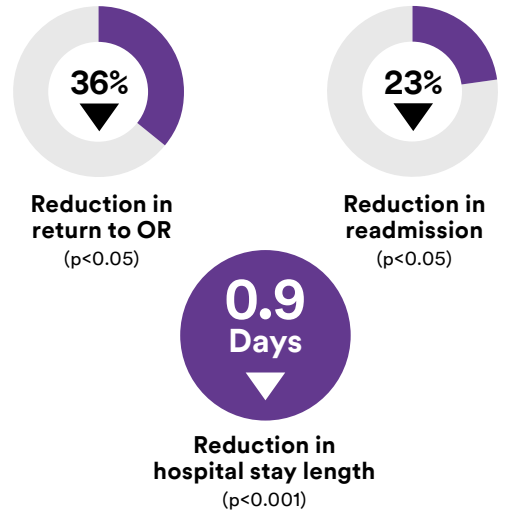
*3M™ Prevena™ Incision Management System (3M, St. Paul, MN)

(continued)

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 randomised 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: Haematoma did not reach significance but was trending towards the use of the treatment**

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 Centre, 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 2023

Cooper, H. John MD, Singh, Devinder P. MD, Gabriel, Allen MD, FACS, Mantyh, Christopher MD, Silverman, Ronald MD, Griffin, Leah MS. Closed Incision Negative Pressure Therapy versus Standard of Care in Reduction of Surgical Site Complications: A Systematic Review and Meta-analysis. *Plastic & Reconstructive Surgery-Global Open* 11(3):p e4722, March 2023. | DOI: 10.1097/GOX.0000000000004722 **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:

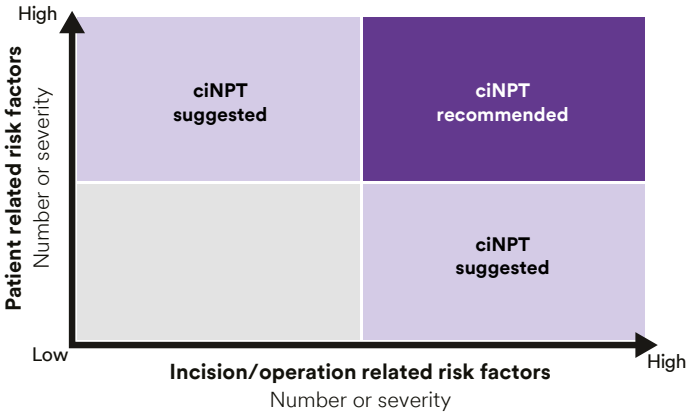
- Literature review
- ciNPT experiences
- Known risk factors for surgical site occurrences (SSOs)

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
- Haematoma
- Chronic renal insufficiency
- Chronic obstructive pulmonary disease

General incision related risk factors

- High tension incision
- Repeated incisions
- Extensive undermining
- Traumatised soft tissue
- Ooedema
- Contamination
- Emergency procedure
- Prolonged operation time
- Post-surgical radiation
- Mechanically unfavourable 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

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

Vascular
- Above/below knee amputation
- Synthetic graft implantations

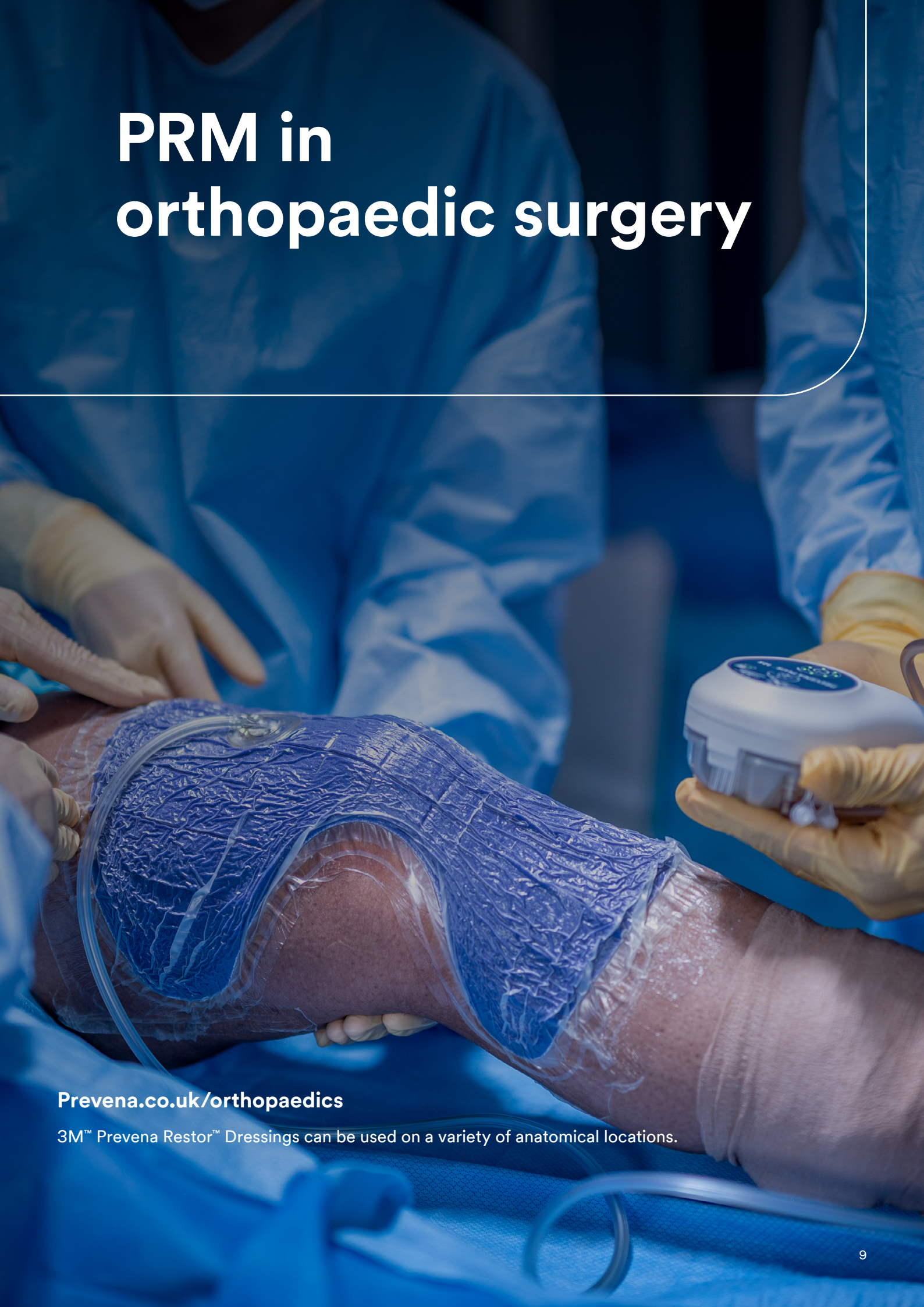
Cardiovascular
- Sternotomy

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. doi:10.1111/iwj.12612.

PRM in orthopaedic surgery



Prevena.co.uk/orthopaedics

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

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

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett MP, Scuderi GR, Cushner FD, Piuzzi NS, Silverman RP. 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 Randomised Controlled Trial. *J Arthroplasty.* 2021 Jul;36(7S):S295–S302.e14.

The PROMISES (Post-market, Randomised, Open-Label, Multicentre study to evaluate Effectiveness) Trial.

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

Study design

Post-market, randomised, open-label, multicentre study (United States).

Study purpose

Evaluate the effectiveness of closed incision negative pressure therapy (ciNPT) versus standard of care (SOC) dressings in reducing surgical site complications (SSCs).

Methods

- A total of 294 revision total knee arthroplasty (rTKA) patients (15 centres) at high risk for wound complications were randomised to ciNPT or SOC (n=147 each) and stratified by revision type (aseptic vs. septic). Demographics, comorbidities, causes of revision and duration of treatment were similar between cohorts (p>0.05).
- 242 patients with incisions completed follow-up, including 124 patients treated with Prevena Therapy (ciNPT) and 118 patients treated with an antimicrobial silver-impregnated dressing (SOC).
- Primary outcome was the 90-day incidence of SSCs with stratification in accordance with revision type. Secondary outcomes were the 90-day health care utilisation 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.

Results

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

- Significantly decreased rates of surgical site complications (ciNPT 3.4% vs. SOC 14.3%, **p=0.0013***)
- Significantly lower readmission rates (ciNPT 3.4% vs. SOC 10.2%, **p=0.0208***)
- Reduced dressing changes (ciNPT 1.1±0.29 vs. SOC 1.3 ±0.96, **p=0.0003***)

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.
- The benefit of ciNPT on specific SSCs and post-rTKA patient-reported outcomes (PRO) was not established and further studies are warranted.

(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.

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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):

$2,318

Reduction in per-patient cost of care

$894 3M™ Prevena™ Therapy vs. $3,212 SOC

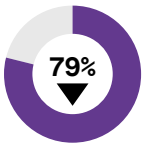
Results

Reduction in SSCs*

3.4% (5/147) Prevena Therapy vs. 14.3% (21/147) SOC **(p=0.0013)***

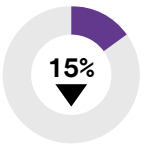
Reduction in readmission rates*

3.4% (5/147) Prevena Therapy vs. 10.3% (15/147) SOC **(p=0.0208)***



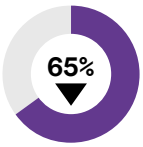
Reduction in dehiscence†

0.7% (1/147) Prevena Therapy vs. 2.0% (5/147) SOC **(p=0.2133)†**



Fewer mean dressing changes*

1.1 ± 0.3 Prevena Therapy vs. 1.3 ± 1.0 SOC **(p=0.0003)***



Reduction in deep SSIs†

0.7% (1/147) Prevena Therapy vs. 2.0% (3/147) SOC **(p=0.6221)†**

Calculation(s) are derived based on relative patient group incidence rate reported in Cooper HJ, Bongards C, Silverman RP. Cost-Effectiveness of Closed Incision Negative Pressure Therapy for Surgical Site Management After Revision Total Knee Arthroplasty: Secondary Analysis of a Randomized Clinical Trial. *J Arthroplasty*. 2022 Aug;37(8S):S790–S795.

*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: *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 Randomised Controlled Trial

Published: 5 March 2021

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett MP, Scuderi GR, Cushner FD, Piuzzi NS, Silverman RP. 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 Randomised 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.

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. A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty. *Arthroplasty Today.* 2018 Dec;4(4):493–98.

Study design

Single institution retrospective review of records (United States).

Study purpose

The purpose of the Anatone study was to evaluate when to use 3M™ 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

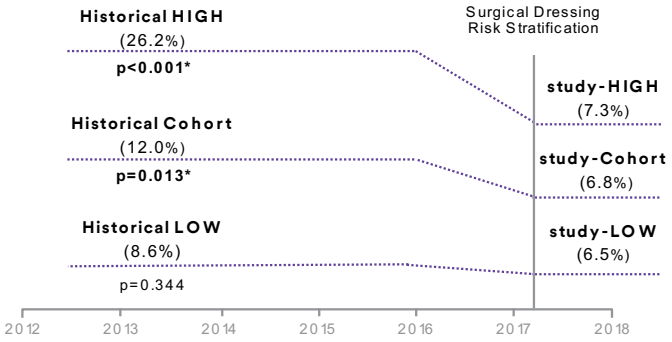
- Patients were considered low risk if their calculated risk score was <2 and patients were considered high risk if their risk score was ≥2.
- A study population of 323 consecutive primary TJAs were evaluated, where 123 (38%) of those patients were considered at elevated risk to receive Prevena Therapy. 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 postoperative 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).

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 haematoma 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.

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: December 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. *Arthroplasty Today*. 2018 Dec;4(4):493-98. **OPEN ACCESS**

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. 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. *Journal of Arthroplasty.* 2021 Oct;36(10):3437–3442.

Study design

Retrospective comparative cohort study (United States).

Study purpose

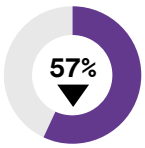
To compare high-risk primary TKA patients' rate of incisional and non-incisional wound complications, periprosthetic joint infections and reoperations.

Methods

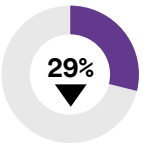
- The 3M™ Prevena™ Therapy group comprised of 130 patients who had primary TKA between July 2018 and December 2019.
- The retrospective historical control group (AQUACEL® Ag SURGICAL) consisted of 130 patients, propensity matched 1:1, who underwent surgery between December 2016 and June 2018.
- High-risk criteria included active tobacco use, diabetes mellitus, BMI > 35 kg/m^2, autoimmune disease, chronic kidney disease, *Staphylococcus aureus* nasal colonisation, and non-aspirin anticoagulation.
- Study endpoints included incisional wound complications, defined as: cellulitis, focal swelling, suture reaction, dehiscence and Haematoma. Non-incisional wound complications were also assessed and defined as dressing reactions, blistering and rashes.

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

Results



Reduction in wound complications*
6.9% (9/130) Prevena Therapy vs. 16.2% (21/130) Control **(p=0.031)***



Presence of drainage
3.8% (5/130) Prevena Therapy vs. 5.4% (7/130) Control **(p=0.769)**

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, the clinical impact was minimal.
- Results support the use of ciNPT as part of a risk mitigation strategy to reduce post operative complications in primary TKA.

*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: *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: 24 May 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. *Journal of Arthroplasty.* 2021 Oct;36(10):3437-3442. **PMID 34140207.**

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

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, Randomised Clinical Trial. *Journal of Arthroplasty.* 2019 Mar;34(3):554–559.

Study design

Prospective, single-centre, randomised controlled trial (United States).

Study purpose

The purpose of the Newman study was to compare the use of Prevena Therapy to a sterile antimicrobial dressing (AQUACEL® Ag SURGICAL cover dressing) in revision arthroplasty (rTHA, rTKA) patients at high risk to develop wound complications.

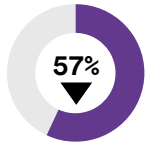
Methods

- 160 patients undergoing elective rTHA and rTKA were prospectively randomised to receive Prevena Therapy or AQUACEL® Ag at a single institution.
- Patients had at least one risk factor for developing a wound complication.
- All patients received perioperative treatment and antibiotics.
- Study endpoints included wound complications (SSC including: SSIs, drainage and cellulitis), readmission and reoperation rates.
- Data collected at 2, 4 and 12 weeks postoperatively.

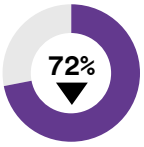
Key points

- High-risk patients could benefit from closed incision negative pressure therapy (ciNPT) to help reduce the risk of wound complications and reoperations after rTHA and rTKA.
- The authors suggest future multicentre clinical trials to further strengthen the results as well as a cost-benefit analysis.

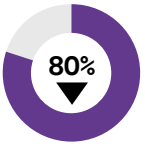
Results



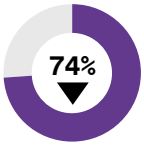
Reduction in wound complications*
10.1% (8/79) Prevena Therapy vs. 23.8% (19/80) SOC **(p=0.022)***



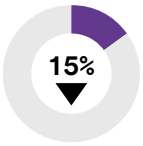
Reduction in periprosthetic joint infection
2.5% (2/79) Prevena Therapy vs. 8.8% (7/80) SOC



Fewer returns to the OR*
2.5% (2/79) Prevena Therapy vs. 12.5% (10/80) SOC **(p=0.017)***



Reduction in dehiscence†
1.3% (1/79) Prevena Therapy vs. 5.0% (4/80) SOC†



Fewer Readmissions
20.3% (16/79) Prevena Therapy vs. 23.8% (19/80) SOC **(p=0.595)**

(continued)

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

*Statistically significant (p<0.05).

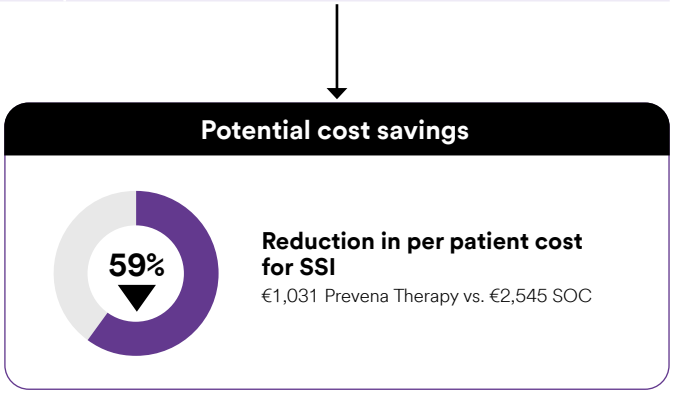
The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at hcbgregulatory.3M.com.

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 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 Newman *et al* outcomes

Revision TKA surgery in high-risk population hypothetical economic model	Prevena Therapy	AQUACEL® Ag SURGICAL
Patients	79	80
Number of surgical site infections (a)	2	7
Cost per SSI[1] (b)	€29,053	€29,053
Per patient infection cost (a*b)/n	€736	€2,542
Per patient therapy cost*	€295	€3
Total cost per patient	€1,031	€2,545
Potential per incision savings using Prevena Therapy	**€1,514**	



The infection cost assumption calculated form Hardstock et al. 2020 by subtracting the cost of a non-infected patient (13,781€) from the cost of an infected patient (42,834€) utilising 365-d follow-up costs (€) per patient-year.

*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. Hardtstock, F., Heinrich, K., Wilke, T. *et al.* Burden of Staphylococcus aureus infections after orthopedic surgery in Germany. *BMC Infect Dis* 20, 233 (2020). https://doi.org/10.1186/s12879-020-04953-4 SSi cost calculated using 365-d follow-up costs (€) per patient-year for infected and non-infected patients.

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, Randomised Clinical Trial

Published: 16 November 2018

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, Randomised Clinical Trial. *Journal of 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.

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 SK, Chen JT, 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. doi: 10.1016/j.arth.2017.06.019. Epub 2017 Jun 17.

Study design

Single-centre, prospective versus historic control comparative study (United States).

Study purpose

The purpose of the Redfern study was to examine the use of closed incision negative pressure therapy (ciNPT) over clean closed surgical incisions after primary total joint replacement and whether 3M™ Prevena™ Therapy would reduce the rates of wound complications.

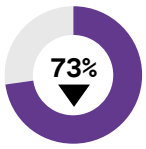
Methods

- 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 control group standard of care included a sterile gauze dressing with standard dressing changes.
- The rate of surgical site complications requiring medical or surgical intervention, including surgical site infections (deep and superficial infections), wound dehiscence, Haematomas, seromas, oedema/swelling, and drainage were compared between groups.

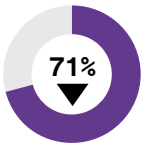
Key points

In this study, Prevena Therapy reduced the overall incidence of complications requiring medical or surgical intervention for hip and knee arthroplasty.

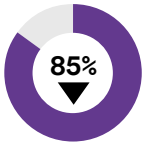
Results



Reduction in wound complications*
1.5% (3/196) Prevena Therapy vs. 5.5% (22/400) Control **(p=0.02)***

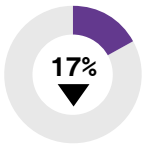


Reduction in SSIs*
1.0% (2/196) Prevena Therapy vs. 3.5% (14/400) Control **(p=0.04)***

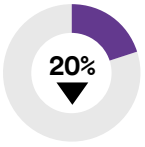


Reduction in oedema/swelling*
0.5% (1/196) Prevena Therapy vs. 3.25% (13/400) Control **(p=0.02)***

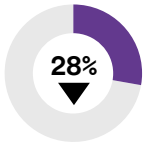
Reduction in superficial SSIs*
0% (0/196) Prevena Therapy vs. 2.25% (9/400) Control **(p=0.03)***



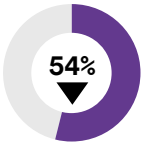
Reduction in length of stay*
1.9+0.6 Prevena Therapy vs. 2.3+0.5 Control **(p=0.0001)***



Reduction in deep SSIs†
1.0% (2/196) Prevena Therapy vs. 1.25% (5/400) Control **(p=0.81)†**



Reduction in pain 24h postop*†
2.6+1.8 Prevena Therapy vs. 3.6+2.2 Control **(p=0.0001)*†**



Reduction in dehiscence†
1.5% (3/196) Prevena Therapy vs. 3.25% (13/400) Control **(p=0.2)†**

(continued)

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

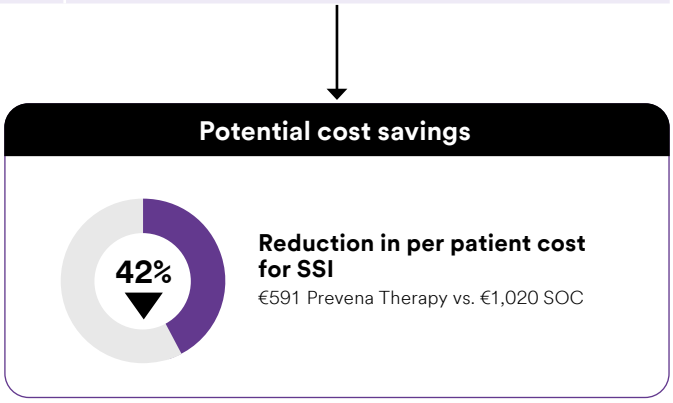
*Statistically significant ($p<0.05$).

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 Redfern *et al* outcomes

Primary TKA/THA not limited to high-risk patients hypothetical economic model	Prevena Therapy	SOC – gauze dressing
Patients	196	400
Number of surgical site infections (a)	2	14
Cost per SSI[1] (b)	€29,053	€29,053
Per patient infection cost (a*b)/n	€296	€1,017
Per patient therapy cost*	€295	€3
Total cost per patient	€591	€1,020
Potential Per Incision Savings Using Prevena Therapy	**€429**	



The infection cost assumption calculated form Hardstock *et al.* 2020 by subtracting the cost of a non-infected patient (13,781€) from the cost of an infected patient (42,834€) utilising 365-d follow-up costs (€) per patient-year.

*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. Hardtstock, F., Heinrich, K., Wilke, T. *et al.* Burden of Staphylococcus aureus infections after orthopedic surgery in Germany. *BMC Infect Dis* 20, 233 (2020). https://doi.org/10.1186/s12879-020-04953-4 SSi cost calculated using 365-d follow-up costs (€) per patient-year for infected and non-infected patients.

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: 16 June 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. *Journal of Arthroplasty.* 2017 Nov;32(11):3333–3339. **PMID 28705547** Note that the length of therapy may be outside the range recommended in the Instructions for Use.

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

Cooper HJ, Santos WM, Neuwirth AL, Geller JA, Rodriguez JA, Rodriguez-Elizalde S, Shah RP. Randomised Controlled Trial of Incisional Negative Pressure Following High-Risk Direct Anterior Total Hip Arthroplasty. *J Arthroplasty.* 2022 Aug;37(8S):S931–S936.

Study type

This was a prospective randomised controlled trial (United States).

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 centres. 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 randomised 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 = .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 = .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.

Read the full study here

Journal: *The Journal of Arthroplasty*

Title: Randomised Controlled Trial of Incisional Negative Pressure Following High-Risk Direct Anterior Total Hip Arthroplasty

Published: 15 March 2022

Cooper HJ, Santos WM, Neuwirth AL, Geller JA, Rodriguez JA, Rodriguez-Elizalde S, Shah RP. Randomised Controlled Trial of Incisional Negative Pressure Following High-Risk Direct Anterior Total Hip Arthroplasty. *J Arthroplasty.* 2022 Aug;37(8S):S931–S936. doi: 10.1016/j.arth.2022.03.039. **OPEN ACCESS**

Incisional negative pressure wound therapy in orthopaedic trauma: indications and outcomes.

Phillips, Rachel MD; Stannard, James P. MD; Crist, Brett D. MD. Incisional Negative Pressure Wound Therapy in Orthopaedic Trauma: Indications & Outcomes. *Journal of Orthopaedic Trauma* 36():p S22–S25, September 2022.

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 randomised controlled trials were evaluated to assess the efficacy of surgical site infections, wound dehiscence and other postoperative wound complications.

A 2019 meta-analysis analysed a total of 6 studies including 2 randomised 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.

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, Rachel MD; Stannard, James P. MD; Crist, Brett D. MD. Incisional Negative Pressure Wound Therapy in Orthopaedic Trauma: Indications & Outcomes. *Journal of Orthopaedic Trauma* 36():p S22-S25, September 2022. | DOI: 10.1097/BOT.0000000000002425 **OPEN ACCESS**

How Can negative pressure wound therapy pay for itself? – reducing complications is important.

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.

Study type

This was a retrospective cohort study performed at a single, level-1 trauma centre using data from a lower extremity fracture registry (United States).

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 orthopaedic 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 summarised 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

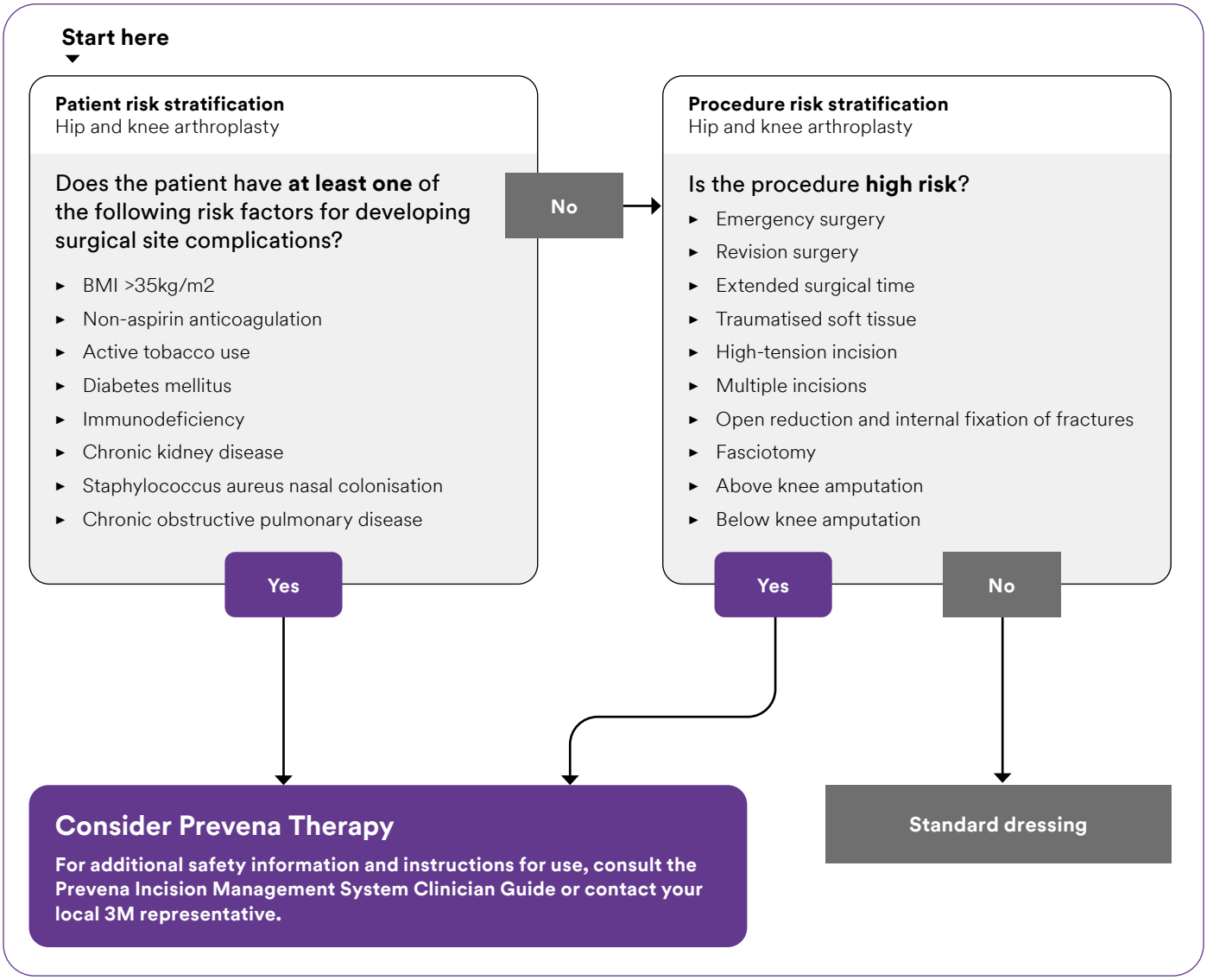
Published: September 2022

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. doi: 10.1097/BOT.0000000000002427. **PMID: 35994307**.

Decision guide

Patient and procedure risk stratification in orthopaedic surgery backed by clinical evidence.

While most surgical patients may benefit from 3M™ 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, De Santis G, Gabriel A, Grauhan O, Guerra OM, Lipsky BA, Malas MB, Mathiesen LL, Singh DP, Reddy VS. 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, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett MP, Scuderi GR, Cushner FD, Piuzzi NS, Silverman RP. 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 Randomised 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, 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, Randomised Clinical Trial. *Journal of 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.

Author biographies*

*Where available and permitted to use.

H. John Cooper, MD

Associate Professor of Orthopaedic Surgery

Columbia University Irving Medical Centre

New York-Presbyterian Hospital, New York City, NY

Dr. Cooper is a paid consultant for 3M.

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 Orthopaedic residency at Lenox Hill Hospital, before spending a year in Chicago for a fellowship in adult reconstructive surgery at Rush University Medical Centre.

Dr. Cooper currently works as an associate professor of Orthopaedic surgery at Columbia University Irving Medical Centre 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 Orthopaedic 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

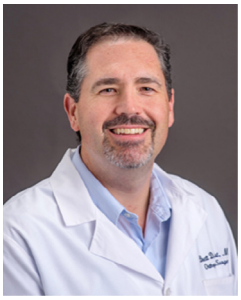
Dr. Higuera-Rueda is a paid consultant for 3M.

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 Centre. Dr. Higuera completed his residency at the Cleveland Clinic and a clinical fellowship at Thomas Jefferson University Hospital.

Dr. Higuera specialises in hip and knee arthroplasty surgery. He uses alternative approaches for primary hip and knee arthroplasty to optimise recovery. He is interested in complex revision procedures including infections. His research interest is mainly in periprosthetic joint infections including diagnostic tools, patient optimissation 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 1 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-Rueda



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 3M.

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 specialises 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 standardised 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.co.uk/plastics

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

Patients that used 3M™ Prevena™ Therapy experienced reduced complications and reoperation after breast reconstruction.

Gabriel A, et al. (Loma Linda University). The Impact of Closed Incision Negative Pressure Therapy on Postoperative Breast Reconstruction Outcomes. *Plast Reconstr Surg Glob Open.* 2018;6:e1880.

Study design

Retrospective, comparative study (United States).

Study purpose

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

Methods

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

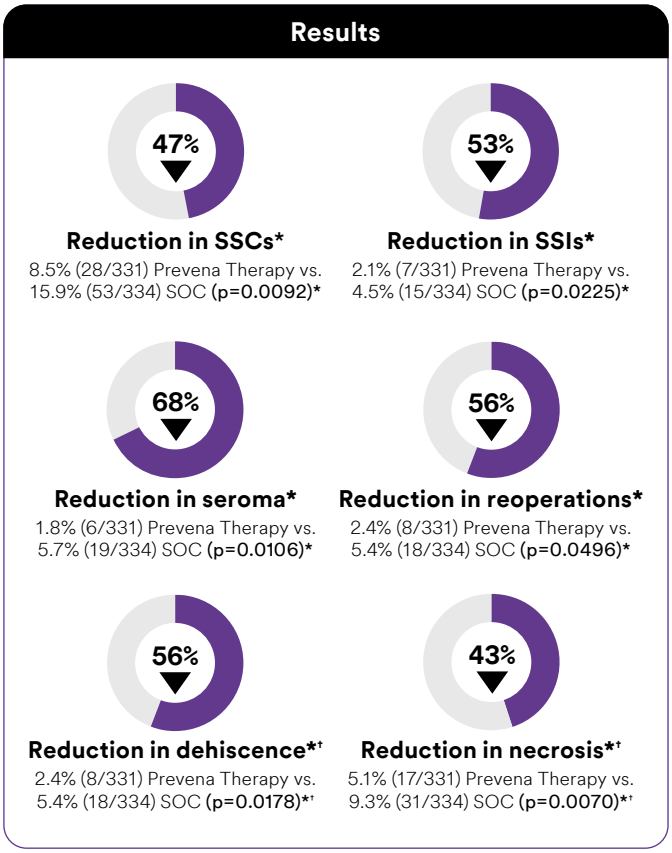
Summary of findings

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.

In addition to the above observed clinical outcomes, an economic analysis relying on this study data showed a mean per patient cost saving for SSC of $218.[1]

$2,010 Prevena Therapy vs. $2,228 standard of care.

Results



(continued)

Cost assessment includes variable hospital costs (for both the index hospitalisation 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.

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.

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)

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, Storm-Dickerson T, Rice J, Maxwell P, Griffin L. The impact of closed incision negative pressure therapy on postoperative breast reconstruction outcomes. *Plastic and Reconstructive Surgery Global Open.* 2018 Aug; 6(8):e1880. **OPEN ACCESS**

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

Ferrando PM, Ala A, Bussone R, Bergamasco L, Actis Perinetti F, Malan F. Closed Incision Negative Pressure Therapy in Oncological Breast Surgery: Comparison with Standard Care Dressings. *Plast Reconstr Surg Glob Open*. 2018 Jun 15;6(6):e1732.

Study design

Prospective, comparative study (Italy).

Study purpose

Evaluated the use of Prevena Therapy for oncological breast surgery patients that were high-risk for unfavourable healing.

Methods

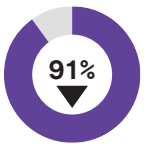
- From January 2015 to June 2015, 47 patients were prospectively selected. Patients were undergoing oncological breast surgery.
- Inclusion criteria: patients had a minimum of 4 risk factors with at least 1 high risk factor.
- 17 patients (25 surgeries) voluntary treated with ciNPT; the remaining 20 patients (22 surgeries) chose conventional post-surgery dressing.
- SOC: 3M™ Steri-Strip™ Wound Closures.
- 3M™ Prevena™ Plus Customizable Dressing for 7 days.
- 90 days follow-up to evaluate postsurgical complications.
- At 12 months, the quality of life, scar, and overall aesthetic outcomes were assessed.

Summary of study findings

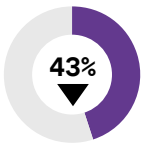
This study demonstrates that the use of Prevena Therapy in oncological breast surgery resulted in a statistically significant reduction in surgical site complications.

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

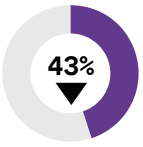
Results



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



Reduction in necrosis*
4.0% (1/25) Prevena Therapy
vs. 31.8% (7/22) Control **(p=0.02)***



Improved PSAS outcome at 12 months*
11 (6–18) Prevena Therapy
vs. 20 (14–34) Control **(p=0.002)***

(continued)

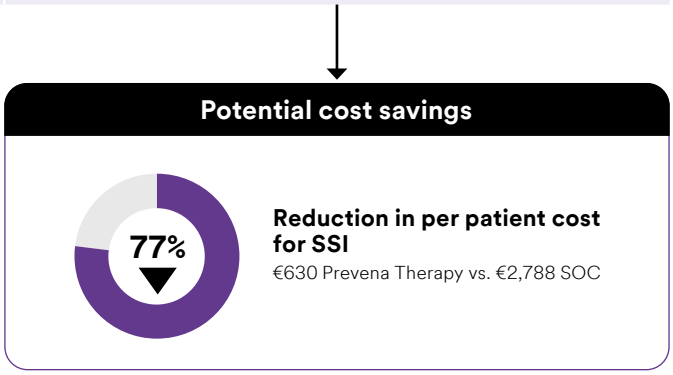
Calculation(s) are derived based on relative patient group incidence rate reported in this study.

*Statistically significant ($p<0.05$).

(continued)

Illustration of the 3M™ Prevena™ Therapy Incision Management System cost-effectiveness based on Ferrando *et al* outcomes

Oncological breast surgery hypothetical economic model	Prevena Therapy	Steri-strip
Patients	25	22
Number of surgical site infections (a)	1	10
Cost per SSI[1] (b)	€6,133	€6,133
Per patient infection cost (a*b)/n	€245	€2,788
Per patient therapy cost*	€385	–
Total cost per patient	€630	€2,788
Potential per incision savings using Prevena Therapy	**€2,158**	



Hypothetical attributable cost of GER SSI/SSC taken from DRG Code J25Z Cancer related simple skin sparing mastectomy for low risk patient, no NPWT used, no post operative complications €3,464.63: Compared to J06Z. Cancer related complex breast reconstruction pathway for high risk patient, use of NPWT and 14 days LOS €9,598.09. Resulting in hypothetic cost of SSI/SSC as €6,133 (Complex Mamma Wound Care Grouping J35Z only 0.01% or 147 cases per year reached diagnosis DRG: J35Z 21 Days 14,400 €).

*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. https://www.g-drg.de/content/download/10834/file/Fallpauschalenkatalog_2022_20211123.pdf

Read the full study here

Journal: *Plastic and Reconstruction Surgery – Global Open*

Title: Closed Incision Negative Pressure Therapy in Oncological Breast Surgery: Comparison with Standard Care Dressings

Published: 15 June 2018

Ferrando PM, Ala A, Bussone R, Bergamasco L, Actis Perinetti F, Malan F. Closed Incision Negative Pressure Therapy in Oncological Breast Surgery: Comparison with Standard Care Dressings. *Plast Reconstr Surg Glob Open*. 2018 Jun 15;6(6):e1732. **OPEN ACCESS**

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

Savage N, Jain M, Champion R, Snell B. Incisional negative pressure wound therapy in bilateral breast reduction patients. *Australas J Plast Surg.* 2020; 3(1):30–38.

Study design

Retrospective comparative cohort study (Australia).

Study purpose

Evaluate the effect of Prevena Therapy, on surgical complications, opioid use and hospitalisation length after bilateral breast reduction.

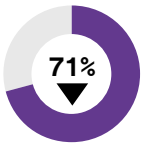
Methods

- Consecutive bilateral breast reductions performed by a single surgeon June 2015 to August 2017. 52 patients analyzed: SOC (n=29) and Prevena Therapy (n=23).
- Prevena Therapy was used for 7 days with no drains and no fitted garment.
- SOC: application of an adhesive non-woven fabric dressing, gauze and adhesive fabric dressing again, drains removed on post-operative day 1, fitted garment used post OP .
- Discharge criteria defined as able to mobilise, 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 of study findings

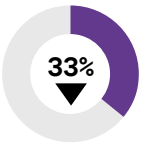
- This is the first study to provide evidence for the use of ciNPT in bilateral breast reduction. This study indicates that Prevena Therapy could be associated with a significant reduction in surgical site complication occurrences, decreased total ward opioid use and discharge opioid prescription as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

Results



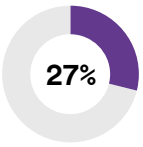
Reduction in SSIs*

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



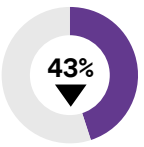
Reduction in LOS*

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



Less opioid use (mg)* in the ward

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



Fewer opioids at discharge (mg)*

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

(continued)

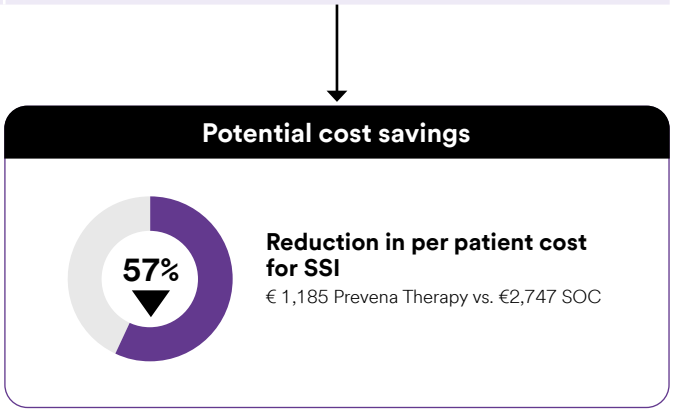
Calculation(s) are derived based on relative patient group incidence rate reported in this study.

*Statistically significant (p<0.05).

(continued)

Illustration of the 3M™ Prevena™ Therapy Incision Management System cost-effectiveness based on Savage *et al* outcomes

Oncological breast surgery hypothetical economic model	Prevena Therapy	Steri-strip
Patients	23	29
Number of surgical site infections (a)	3	13
Cost per SSI[1] (b)	€6,133	€6,133
Per patient infection cost (a*b)/n	€800	€2,749
Per patient therapy cost*	€385	–
Total cost per patient	€1,185	€2,749
Potential per incision savings using Prevena Therapy	**€1,564**	



Hypothetical attributable cost of GER SSI/SSC taken from DRG Code J25Z Cancer related simple skin sparing mastectomy for low risk patient, no NPWT used, no post operative complications €3,464.63: Compared to J06Z. Cancer related complex breast reconstruction pathway for high risk patient, use of NPWT and 14 days LOS €9,598.09. Resulting in hypothetic cost of SSI/SSC as €6,133 (Complex Mamma Wound Care Grouping J35Z only 0.01% or 147 cases per year reached diagnosis DRG: J35Z 21 Days 14,400 €).

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

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Reference

1. https://www.g-drg.de/content/download/10834/file/Fallpauschalenkatalog_2022_20211123.pdf

Read the full study here

Journal: *Australian Journal of Plastic Surgery*

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

Published: 23 March 2020

Savage N, Jain M, Champion R, Snell B. Incisional negative pressure wound therapy in bilateral breast reduction patients. *Australas J Plast Surg.* 2020; 3(1):30–38.

ciNPT for open abdominal wall reconstruction with concomitant panniculectomy.

Ayuso SA, Elhage SA, Okorji LM, Kercher KW, Colavita PD, Heniford BT, Augenstein VA. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. *Ann Plast Surg.* 2022 Apr 1;88(4):429–433.

Study design

Retrospective cohort study (United States).

Study purpose

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

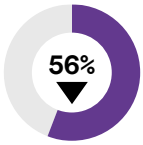
Methods

- Prospective institutional database identified 67 patients that received 3M™ Prevena™ Therapy. These patients were matched 1:1 to 67 patients that received standard surgical dressings before the use of ciNPT.
- In the study period, patient prehabilitation and perioperative protocols at the institution were the same which aids in eliminating confounders.
- From 2016 onward all patient rehabilitation and perioperative protocols at the institution were the same.
- Prevena Therapy was used for 7 days.
- Concomitant Panniculectomy makes this a study on high-risk patients.
- Primary outcomes: wound complications defined as seroma requiring drainage, cellulitis requiring antibiotics, deep wound infection and superficial wound breakdown.

Key points

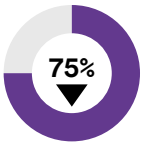
Patients undergoing abdominal wall reconstruction with concomitant panniculectomy can be at higher risk for wound complications due to the need for large incisions and tissue undermining. In this study, the use of Prevena Therapy helped significantly decrease the risk of postoperative wound occurrences including superficial wound breakdown. The study also demonstrated the lessened need for wound-related reoperations in ciNPT patients.

Results



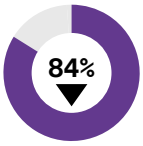
Reduction in wound occurrences*

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



Reduction in Deep SSI†

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



Reduction in superficial wound breakdown

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

Reduction in number of OR Visits*

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

(continued)

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

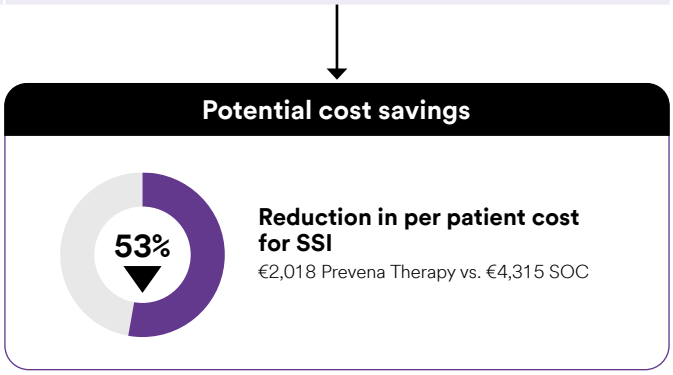
*Statistically significant (p<0.05)

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

Plastics AWR with CP hypothetical economic model	Prevena Therapy	Control
Number of patients (n)	67	67
Number of surgical site infections (a)	10	24
Cost per SSI[1] (b)	€11,545	€11,545
Per patient infection cost (a*b)/n	€1,723	€4,315
Per patient therapy cost*	€295	–
Total cost per patient	€2,018	€4,315
Potential per incision savings using Prevena Therapy	**€2,297**	



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

Attributable cost of SSI in abdominal surgery obtained from the median difference in resource costs including inpatient costs, surgery costs, surgical ward costs, medication costs, laboratory and diagnostic costs of €11,545 illustrated in Strobel *et al.* 2020.

Reference

1. Strobel, R.M., Leonhardt, M., Förster, F. *et al*. The impact of surgical site infection—a cost analysis. *Langenbecks Arch Surg* 407, 819–828 (2022). https://doi.org/10.1007/s00423-021-02346-y.

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, Kercher KW, Colavita PD, Heniford BT, Augenstein VA. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. *Ann Plast Surg.* 2022 Apr 1;88(4):429-433. doi: 10.1097/SAP.0000000000002966. **PMID: 34670966.**

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

Pieri A, Aisling E, Kay K, Irving J, Robert T, Cain H, Kalra L, Critchley A. Managing No-Drain Mastectomy with Closed Incision Negative Pressure Wound Therapy using Full-Coverage Foam Dressings. *European Journal of Surgical Oncology.* 2023 Feb; 49(2):e94.

Study Design

This was a single centre, case-control trial (United Kingdom).

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 centre 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 (843ml control vs. 368ml 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 centre.

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, Irving J, Robert T, Cain H, Kalra L, Critchley A. Managing No-Drain Mastectomy with Closed Incision Negative Pressure Wound Therapy using Full-Coverage Foam Dressings. *European Journal of Surgical Oncology.* 2023 Feb; 49(2):e94. **doi: 10.1016/j.ejso.2022.11.287**.

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

Ronald P. Silverman MD, John Apostolides MD, FACS, Abhishek Chatterjee MD, MBA, Anthony N. Dardano DO, FACS, Regina M. Fearmonti MD, FACS Allen Gabriel MD, FACS Robert T. Grant MD, MSc, FACS, Owen N. Johnson III MD, FACS, Suresh Koneru MD, Anna A. Kuang MD, Andrea A. Moreira MD, Steven R. Sigalove MD, FACS

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 utilising 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: 21 August 2021

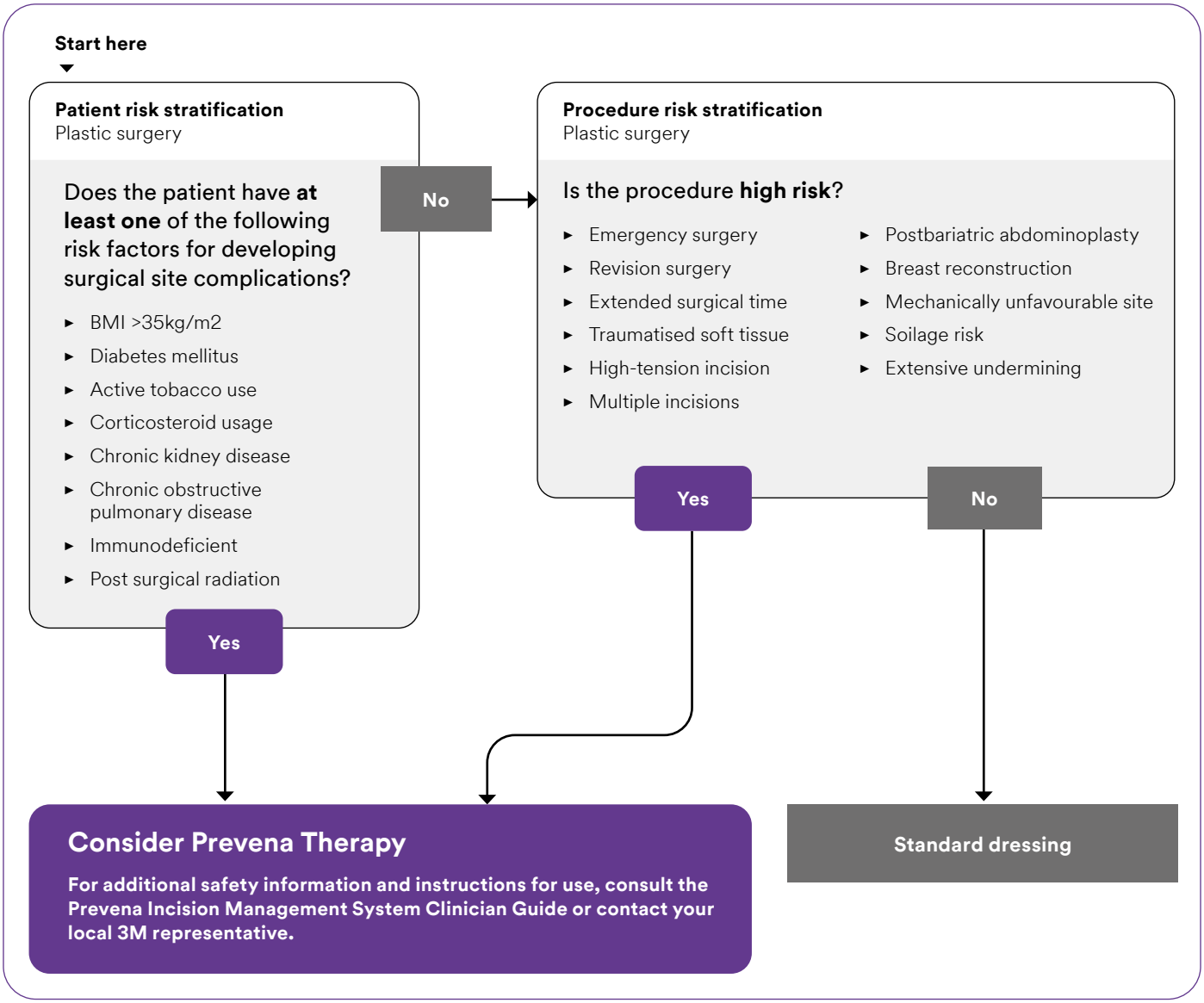
Silverman, RP, Apostolides, J, Chatterjee, A, *et al.* The use of closed incision negative pressure therapy for incision and surrounding soft tissue management: Expert panel consensus recommendations. *Int Wound J.* 2022;19(3): 643–655. https://doi.org/10.1111/iwj.13662

OPEN ACCESS

Decision guide

Patient and procedure risk stratification in plastic surgery backed by clinical evidence.

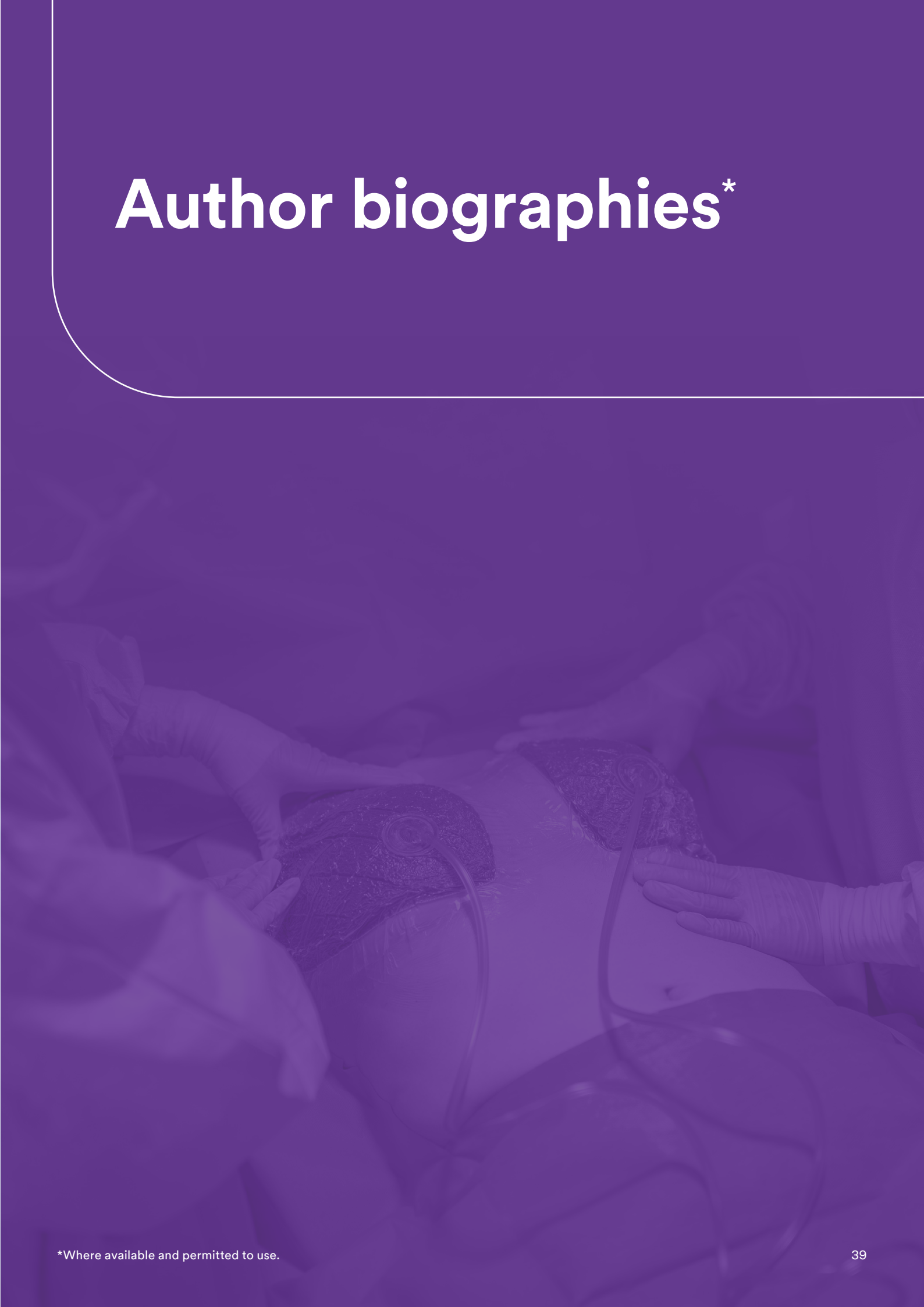
While most surgical patients may benefit from 3M™ Prevena™ Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data[1–2] to provide an illustrative guide to aid in risk stratification. This is not an all-inclusive list 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, De Santis G, Gabriel A, Grauhan O, Guerra OM, Lipsky BA, Malas MB, Mathiesen LL, Singh DP, Reddy VS. 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, Storm-Dickerson T, Rice J, Maxwell P, Griffin L. The impact of closed incision negative pressure therapy on postoperative breast reconstruction outcomes. *Plastic and Reconstructive Surgery Global Open.* 2018 Aug; 6(8):e1880. **OPEN ACCESS**

Author biographies*



*Where available and permitted to use.

Abhishek Chatterjee, MD, MBA

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

Dr. Chatterjee is a paid consultant for 3M.

Dr. Chatterjee is a board-certified plastic surgery and fellowship trained breast oncologic surgeon practicing at Tufts Medical Centre 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 Centre 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 Centre 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 3M.

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 organisations 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 standardised approach of the therapy. We then published the figure, which we still use today."

Dr. Gabriel

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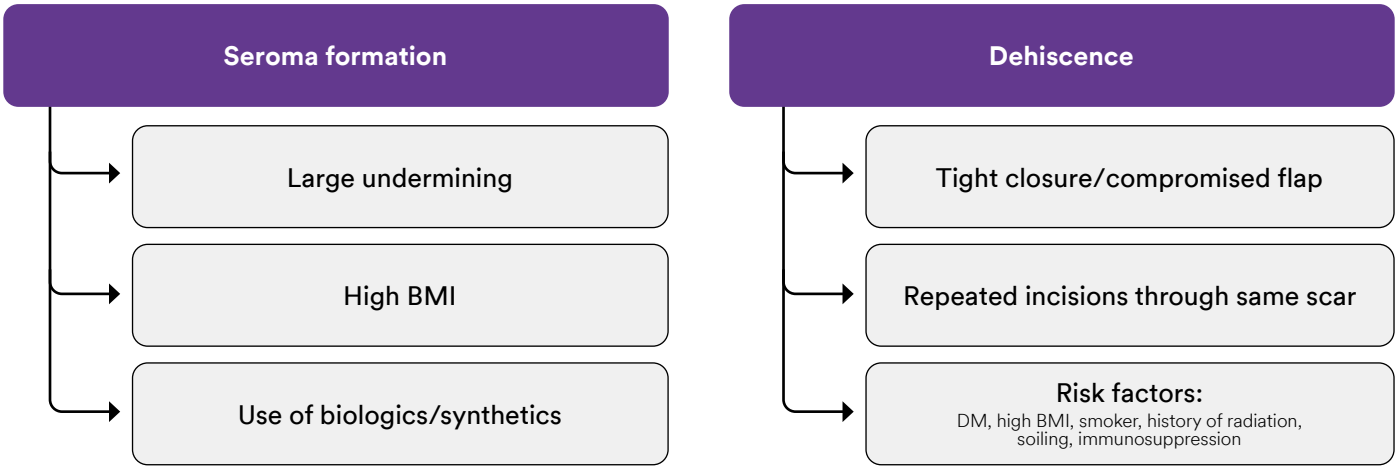
Incisions at risk for surgical complications[1]



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. *Plastic and Reconstructive Surgery Global Open.* 2016 Jul 22;4(7):e819. **OPEN ACCESS**

Andrew Pieri
MBBS, MRes, FRCS

The Newcastle upon Tyne Hospitals NHS Foundation Trust · Department of Surgery

Mr Pieri is a paid consultant for 3M.

Mr Pieri is a consultant oncoplastic breast surgeon working within the NHS at the Royal Victoria Infirmary in Newcastle upon Tyne and at several private hospitals in the Northeast of England, performing cancer and cosmetic breast surgery. He performs a comprehensive range of oncoplastic procedures including perforator flaps, mammoplasty surgery and autologous or implant-based breast reconstructions. In the private sector, he performs both cancer and cosmetic breast surgery.

With numerous research publications and a surgical device patent to his name, Mr Pieri has a keen interest in surgical device innovation. He has introduced and formally evaluated a number of novel technologies. His unit was the first in the UK to progress from wire-guided breast conservation surgery – Mr Pieri published the benefits of seeds over wires. He has recently introduced ICG-guided sentinel node biopsy and axilla reverse mapping and is working with industry to develop a Newcastle-based programme of education for colleagues in this technique.

He is education lead for the breast unit in Newcastle, being involved in both undergraduate and post graduate education programmes.

"The question is no longer whether you should use negative pressure therapy to reduce the risk of surgical site complications; it's in which patients and in which procedures should it be used.

We have been using Prevena Therapy for many years in patients undergoing therapeutic mammoplasties, implant reconstructions or patients with high risk factors such as obesity or active smoking."

Mr. Pieri

PRM in vascular surgery

Prevena.co.uk/vascular

Patients that used 3M™ Prevena™ Therapy experienced significant reduction in complications, reoperation and readmission rates for high-risk groin incision procedures.

Kwon J, Staley C, McCullough M, Goss S, Arosemena M, Abai B, Salvatore D, Reiter D, DiMuzio P. A randomised clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications. *J Vasc Surg.* 2018 Dec;68(6):1744–1752.

Study design

Prospective, single-centre, randomised controlled trial (United States).

Study purpose

This prospective RCT evaluated negative pressure therapy (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: re-operative surgery, BMI > 30, pannus, prosthetic graft, poor nutrition, immunosuppression, or HbA1c>8.
- 1:1 Randomised to standard gauze (n=60) vs. Prevena Therapy (n=59).
- Outcomes evaluated at post-operative day 30: SSI, wound complications, length of stay (LOS), reoperation, readmission.

Summary of findings

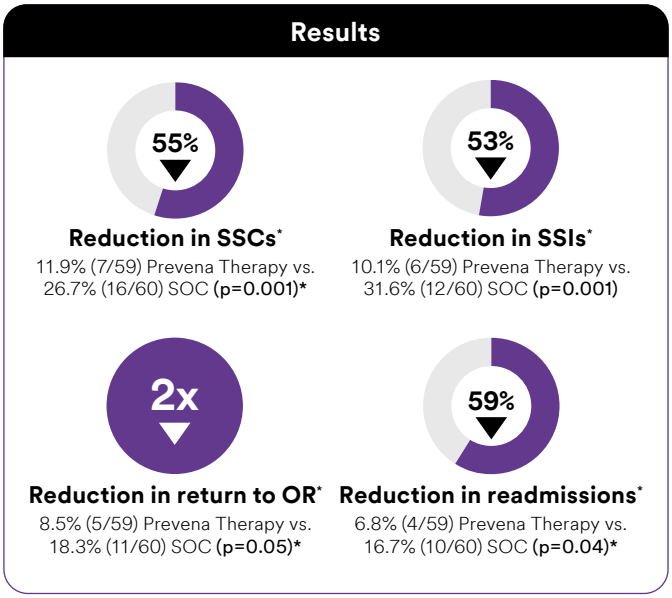
Study suggests that negative pressure therapy for patients at high risk for groin wound complications:

- Significantly reduces major wound complication
- Significantly reduces reoperation and readmission rates
- Closed incision negative pressure therapy (ciNPT) may lead to a reduction in hospital cost

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.

Results



ciNPT is recommended for all groin incisions considered at high risk for wound complications. In addition to the above observed clinical outcomes, this study data[1] showed per patient cost saving of $6,045 for Prevena Therapy patients.

$30,492 Prevena Therapy vs. $36,537 SOC

Cost assessment includes variable hospital costs (for both the index hospitalisation 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.

Reference

1. Cost Assessment includes variable hospital costs (for both the index hospitalisation 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.

Read the full study here

Journal: *Journal of Vascular Surgery*
Title: A randomised clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications
Published: 17 August 2018

Kwon J, Staley C, McCullough M, Goss S, Arosemena M, Abai B, Salvatore D, Reiter D, DiMuzio P. A randomised clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications. *J Vasc Surg.* 2018 Dec;68(6): 1744–1752. doi: 10.1016/j.jvs.2018.05.224.
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. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study. *International Wound Journal.* 2018 Feb;15(1):75–83. **OPEN ACCESS**

Study design

Single centre randomised controlled trial (Germany).

Study purpose

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

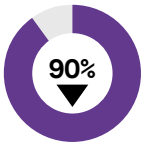
Methods

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

Key points

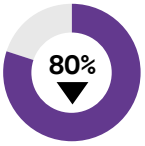
This study found that the use of ciNPT demonstrated a statistically significant reduction of postoperative wound healing complications in the groin on postoperative days 5–7 and 30-day revision surgery.

Results



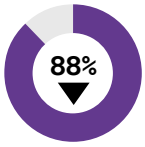
Reduction in SSI*

17% (1/58) Prevena Therapy vs. 16.9% (12/71) Control **(p<0.02)***



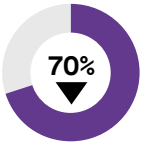
Reduction in wound healing complications*

8.6% (5/58) Prevena Therapy vs. 42.3% (30/71) Control **(p<0.0005)***



Reduction in local SSI*

1.7% (1/58) Prevena Therapy vs. 14.1% (10/71) Control **(p=0.02)***

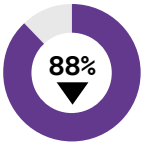


Reduction in deep wound dehiscence†

1.7% (1/58) Prevena Therapy vs. 5.6% (4/71) Control **(p=0.387)†**

Reduction in DSSI†

0% (0/58) Prevena Therapy vs. 2.8% (2/71) Control **(p=0.501)†**



Reduction in revision surgery*

1.7% (1/58) Prevena Therapy vs. 14.1% (10/71) Control **(p=0.022)***

(continued)

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

*Statistically significant (p<0.05)

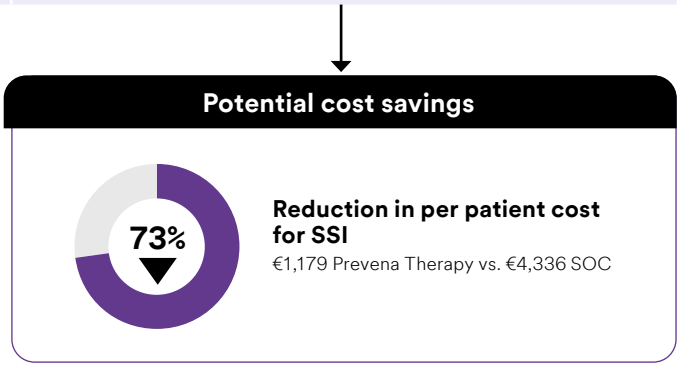
The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated.See full indications for use and limitations at hcbgregulatory.3M.com.

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)

Illustration of the 3M™ Prevena™ Therapy Incision Management System cost-effectiveness based on Pleger *et al* outcomes

Vascular groin hypothetical economic model	Prevena Therapy	Control
Number of incisions (n)	58	71
Number of surgical site infections (a)	5	30
Cost per infection[1] (b)	€10,262	€10,262
Cost of infection per incision (a*b)/n	€884	€4,336
Cost of therapy per incision*	€295	–
Total cost per incision	€1,179	€4,336
Potential per incision savings using Prevena Therapy	**€3,157**	



Hypothetical cost of SSI taken from DRG Code F08C Non –Diabetic Bypass Patient with SSI, Dehiscence, Revision Surgery €17,308.52 : Compared to F59C. Non-Diabetic Vascular DRG with mean LOS Post-Op Stay of 6.3 Days €7,046.52. Resulting in hypothetic cost of Ssi/Complications as **10,262.33€**

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. https://www.g-drg.de/content/download/10834/file/Fallpauschalenkatalog_2022_20211123.pdf

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: 25 October 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. *International Wound Journal.* 2018 Feb;15(1):75-83. **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, Keszei A, von Trotha KT, Jalaie H, Kalder J, Kotelis D, Greiner A, Langer S, Jacobs MJ, Grommes J. 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.

Study design

Prospective, multi-centre, randomised controlled trial (Germany).

Study purpose

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

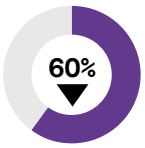
Methods

- 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 randomised and assessed for the study.
- 30-day SSIs were assessed using the Szilagyi classification.

Key points

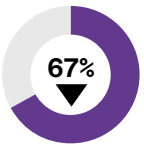
- Study found closed incision negative pressure therapy (ciNPT) was associated with a reduced incidence of SSIs when compared to control group.
- High-risk patients could benefit from ciNPT to help reduce the risk of total SSI.

Results



Reduction in SSI*

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



Reduction in Szilagyi I SSIs*

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

(continued)

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

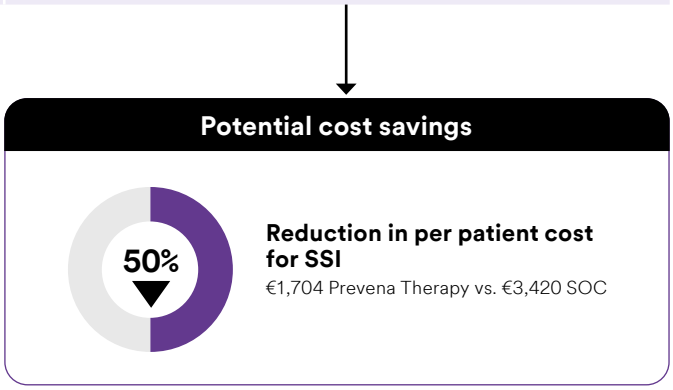
*Statistically significant ($p<0.05$).

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

Vascular groin hypothetical economic model	Prevena Therapy	Control
Number of patients (n)	98	90
Number of Surgical Site Infections (a)	13	30
Cost per SSI[1] (b)	€10,292	€10,292
Cost of SSI per patient (a*b)/n	€1,409	€3,420
Cost of therapy per patient*	€295	–
Total cost per patient	€1,704	€3,420
Potential per incision savings using Prevena Therapy	**€1,716**	



Hypothetical cost of SSI taken from DRG Code F08C Non –Diabetic Bypass Patient with SSI, Dehiscence, Revision Surgery € 17,308.52: Compared to F59C. Non-Diabetic Vascular DRG with mean LOS Post-Op Stay of 6.3 Days €7,046.52. Resulting in hypothetic cost of Ssi/Complications as **€10,262.33**

*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. https://www.g-drg.de/content/download/10834/file/Fallpauschalenkatalog_2022_20211123.pdf

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: 2 July 2018

Gombert A, Babilon M, Barbati ME, Keszei A, von Trotha KT, Jalaie H, Kalder J, Kotelis D, Greiner A, Langer S, Jacobs MJ, Grommes J. 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**

A systematic review and meta-analysis of randomised controlled trials for the reduction of surgical site infection in closed incision management versus standard of care dressings over closed vascular groin incisions.

Gombert A, Dillavou E, D'Agostino R Jr, Griffin L, Robertson JM, Eells M. A systematic review and meta-analysis of randomised controlled trials for the reduction of surgical site infection in closed incision management versus standard of care dressings over closed vascular groin incisions. *Vascular.* 2020 Jun;28(3):274–284.

Study type

This study was a systematic review and meta-analysis of randomised controlled trials.

Study purpose

The purpose of the study was to assess the effect of ciNPT (3M™ Prevena™ Incision Management System; KCI, San Antonio, TX) versus traditional postsurgical dressing use on SSI rates over closed groin incisions following vascular surgery.

Methods

- Literature search: A systematic literature search using PubMed, OVID, EMBASE and QUOSA was performed on 3 January 2019 by two independent reviewers to assess the literature between 1 January 2005 and 31 December 2018. The review conformed to the statement and reporting checklist of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses.
- Inclusion criteria: Inclusion criteria were abstracts or manuscripts written in English, published study, conference abstract, randomised controlled trial (RCT), comparison of ciNPT use over closed groin incisions to traditional postoperative dressings, endpoint/outcome of SSI, and a study population ≥10.
- Data type: Characteristics of study participants, surgical procedure, type of dressing used, duration of treatment, incidence of surgical site infection, and length of follow-up were extracted.
- Statistical methods used: The odds ratios (OR) were calculated to assess the effect of ciNPT versus SOC on vascular groin incision SSIs. Weighted odds ratios and 95% confidence intervals (CI) were calculated to pool study and control groups in each publication for analysis. high-risk patients, normal-risk patients, and Szilagyi I, II, III outcomes were assessed between ciNPT and control groups.

Results

Out of 615 publications that were identified during the literature search, 303 abstracts and titles were screened against the inclusion and exclusion criteria. Six RCTs were included in the analysis. The screening process is shown in **Figure 1**. There was a total of 733 incisions, of which 362 (49.4%) received ciNPT and 371 (50.6%) received standard of care. Patients treated with ciNPT had a lower risk of developing an SSI when compared to the control arm (OR = 3.06, 95% CI [2.05, 4.58], $p < 0.05$) showing highly significant effect in favour of ciNPT. High-risk, normal-risk, Szilagyi I, and Szilagyi II meta-analyses were also statistically significant in favour of ciNPT use ($p < 0.05$). However, risk of bias in selecting meta-analysis, differences in inclusion/exclusion criteria and selection of procedure type pose major limitation for the study.

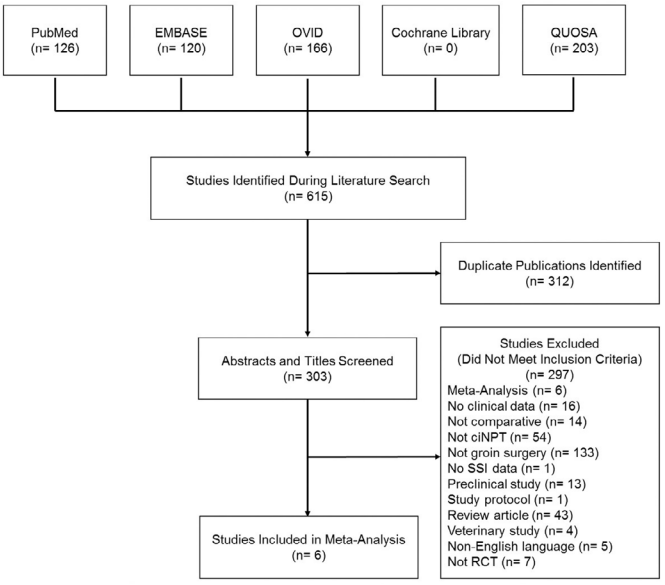


Figure 1: A Prisma flowchart showing the process of identifying articles to be included in systemic review and meta-analysis.

(continued)

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Conclusion

The study shows that ciNPT usage demonstrated a statistically significant reduction in the incidence of SSI relative to traditional postsurgical dressings in patients undergoing vascular surgery with groin incisions.

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: *Vascular*

Title: A systematic review and meta-analysis of randomised controlled trials for the reduction of surgical site infection in closed incision management versus standard of care dressings over closed vascular groin incisions

Published: 19 January 2020

Gombert A, Dillavou E, D'Agostino R Jr, Griffin L, Robertson JM, Eells M. A systematic review and meta-analysis of randomised controlled trials for the reduction of surgical site infection in closed incision management versus standard of care dressings over closed vascular groin incisions. *Vascular.* 2020 Jun;28(3):274–284. **OPEN ACCESS**

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. A Cost-Utility Analysis of the Use of Closed-Incision Negative Pressure System in Vascular Surgery Groin Incisions. *The American Surgeon.* 2022;0(0).

Study type

The study was literature review looking at prospective randomised 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 utilised. 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 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, favouring 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

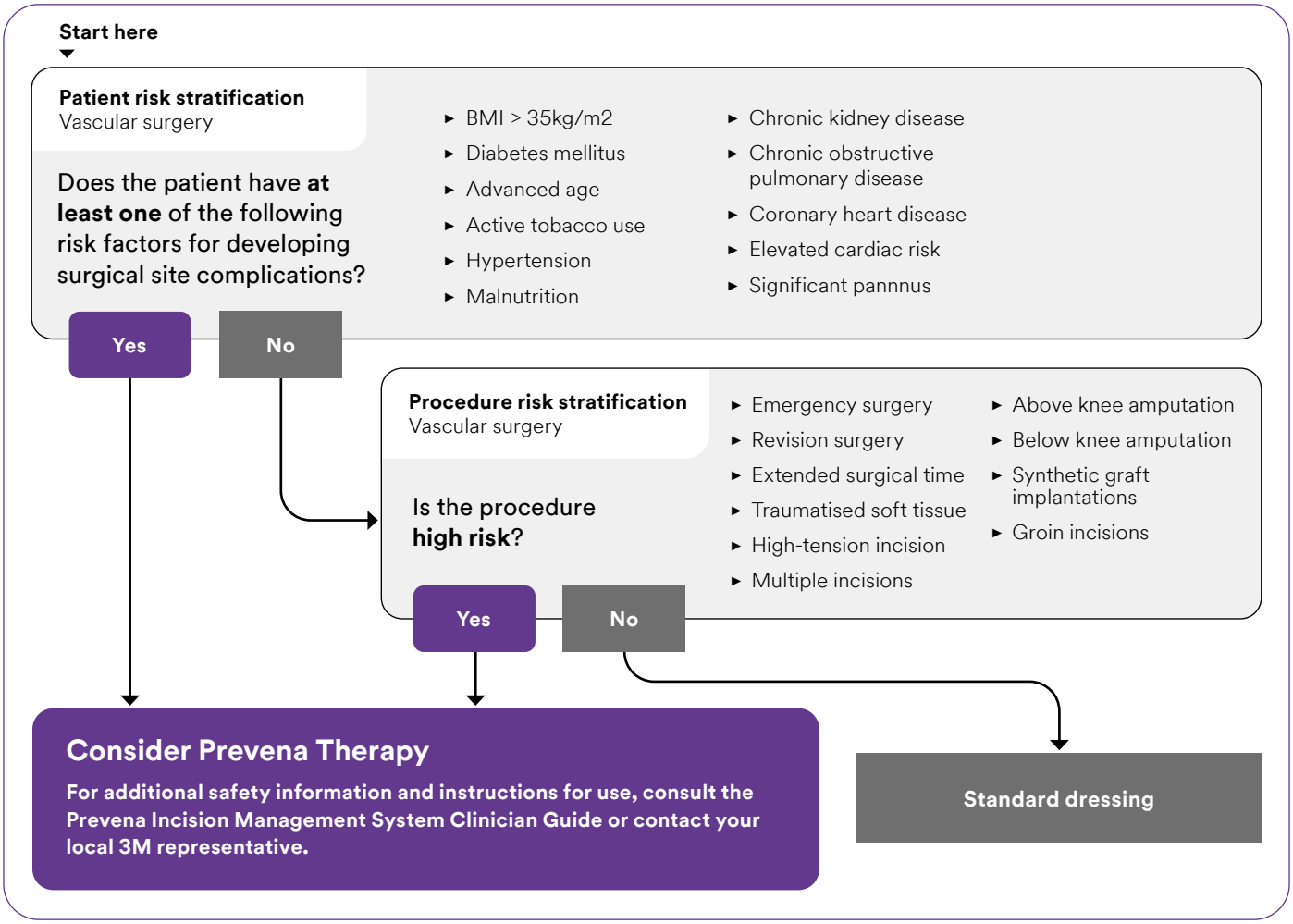
Published: 7 April 2022

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. *The American Surgeon.* 2022;0(0). **doi:10.1177/00031348221087395**

Decision guide

Patient and procedure risk stratification in vascular surgery backed by clinical evidence.

While most surgical patients may benefit from 3M™ 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.



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References
1. Willy C, Agarwal A, Andersen CA, De Santis G, Gabriel A, Grauhan O, Guerra OM, Lipsky BA, Malas MB, Mathiesen LL, Singh DP, Reddy VS. 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, Goss S, Arosemena M, Abai B, Salvatore D, Reiter D, DiMuzio P. A randomised 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, Keszei A, von Trotha KT, Jalaie H, Kalder J, Kotelis D, Greiner A, Langer S, Jacobs MJ, Grommes J. 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. *International Wound Journal.* 2018 Feb;15(1):75-83. **OPEN ACCESS**

Author biographies*

*Where available and permitted to

Ellen Dillavou, MD, FACS, RPVI

Medical Director,
Vascular Surgery
WakeMed Hospitals
Raleigh, NC

Dr. Dillavou is a paid consultant for 3M.

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 Centre. Her work centres 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 Centre of Vascular Surgery Aachen-Maastricht,
Clinic for Vascular Surgery,
University of Aachen, Germany

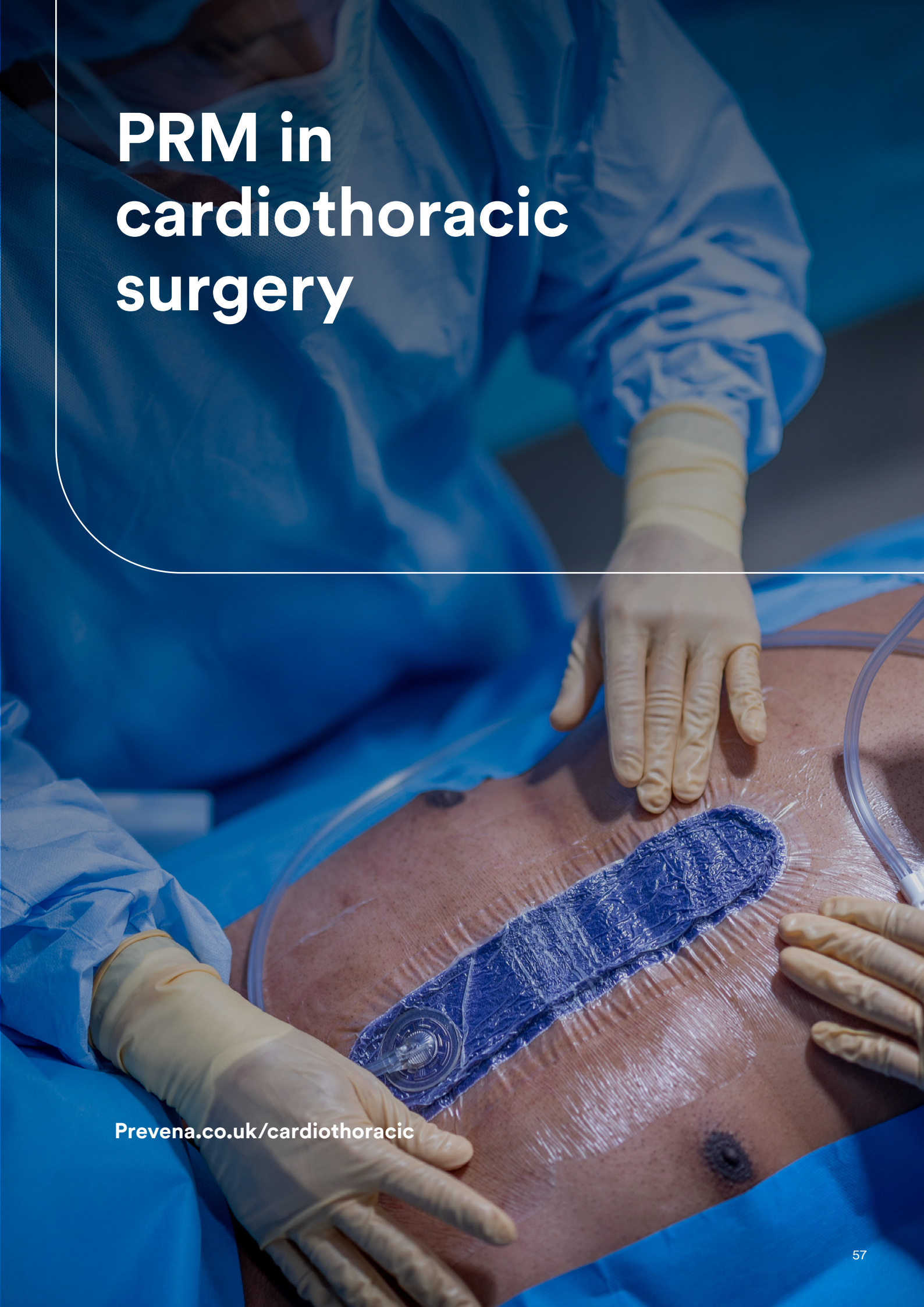
Dr. Gombert is a paid consultant for 3M.

PD Dr. med. Gombert was born in 1983. He is working as a consultant of Vascular Surgery at one of the largest centres for Vascular Surgery in Germany, the European Vascular Centre Aachen-Maastricht. He is the initiator and principal investigator of the "Aachen Incision management system (AIMS) trial," a randomised, prospective, multicentre 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 Centre 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.

"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 utilise Prevena on every at-risk patient and procedure, advancing the standard of care for surgical patients."

Dr. Gombert

PRM in cardiothoracic surgery



Prevena.co.uk/cardiothoracic

High risk, obese sternotomy patients that used 3M™ Prevena™ Therapy experienced significant reduction in rate of wound infection.

Grauhan O, Navasardyan A, Hofmann M *et al.* Prevention of post sternotomy wound infections in obese patients by negative pressure wound therapy. *J Thorac Cardiovasc Surg* 2013;145:1387–1392.

Study design

Prospective, single-centre, controlled trial (Germany).

Study purpose

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

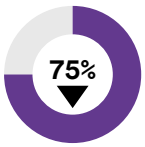
Methods

- The study included 150 consecutive obese patients who underwent a median sternotomy at a single site in Germany between April 2010 and October 2011.
- Inclusion criteria was a body mass index ≥ 30kg/m².
- The control group, (conventional wound dressings) consisted of 75 patients. Post Op dressing change day 1–2.
- ciNPT (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.

Summary of study findings

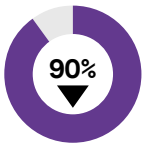
Closed incision negative pressure therapy (ciNPT) reduces the rate of post sternotomy wound infection in high-risk, obese patients.

Results



Reduced rate of SSI

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



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

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

(continued)

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

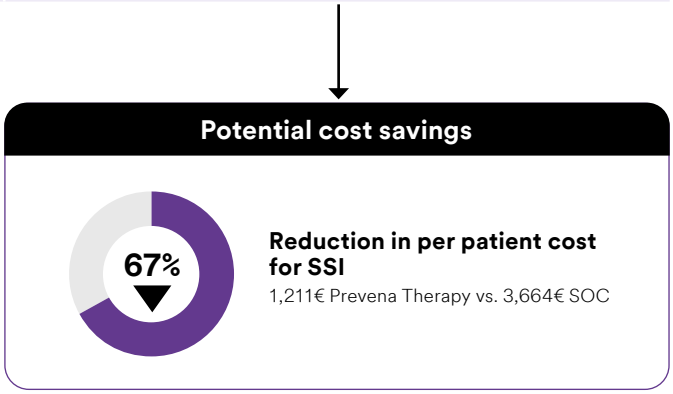
*Statistically significant (p<0.05).

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	Control
Number of patients (n)	75	75
Number of Surgical Site Infections (a)	3	12
Cost per SSI[1] (b)	€22,905	€22,905
Cost of SSI per patient (a*b)/n	€916	€3,664
Cost of therapy per patient*	€295	–
Total cost per patient	€1,211	€3,664
Potential per incision savings using Prevena Therapy	**€2,453**	



Difference in the median cost of infected CABG patient (€36,261) and non-infected pateint (€13,355) is an attributable median cost of SSI of **€22,905.**

*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. Graf K, Ott E, Vonberg RP, Kuehn C, Haverich A, Chaberny IF. Economic aspects of deep sternal wound infections. *Eur J Cardiothorac Surg.* 2010 Apr;37(4):893-6. doi: 10.1016/j.ejcts.2009.10.005. Epub 2009 Nov 6. PMID: 19896860.

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: 29 October 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. *Journal of Thoracic and Cardiovascular Surgery.* 2013 May;145(5):1387–92. **OPEN ACCESS**

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

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.

Study design

Prospective, single-centre, controlled trial (Germany).

Study purpose

To evaluate Prevena Therapy vs. conventional wound dressings over closed surgical incisions in reducing wound infections.

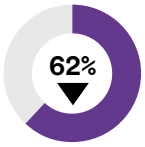
Methods

- 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 analysed for the period of January 2008 – December 2009 totalling 3,508 patients.
- 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 wound infection within 30 days.

Summary of study findings

Application of surgical incision management using ciNPT on clean, closed surgical incisions reduced the rate of post sternotomy wound infection.

Results



Reduced rate of SSI
1.3% (3/237) Prevena Therapy
vs. 3.4% (119/3508) SOC **(p=0.05)***

Primary wound closure at day 6/7 on removal*
98.7% (234/237) Prevena Therapy

(continued)

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

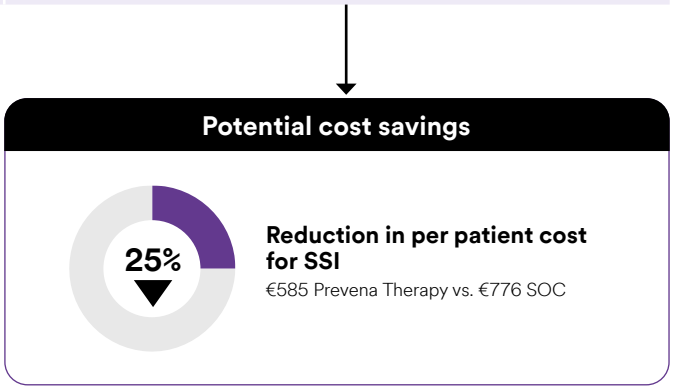
*Statistically significant ($p<0.05$).

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* (2014) outcomes

Hypothetical economic model	Prevena Therapy	Control
Number of patients (n)	237	3,508
Number of Surgical Site Infections (a)	3	119
Cost per SSI[1] (b)	€22,905	€22,905
Cost of SSI per patient (a*b)/n	€289	€776
Cost of therapy per patient*	€295	–
Total cost per patient	€585	€776
Potential per incision savings using Prevena Therapy	**€191**	



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Read the full study here

Journal: *International Wound Journal*

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

Published: 23 May 2014

Grauhan O, Navasardyan A, Tutkun B, Hennig F, Müller P, Hummel M, Hetzer R. Effect of surgical incision management on wound infections in a poststernotomy patient population. *Int Wound J.* 2014 Jun;11 Suppl 1(Suppl 1):6-9. **OPEN ACCESS**

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. The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high risk cases: a single centre retrospective study. *Journal of Cardiothoracic Surgery.* 2020 Aug 19;15(1):222. **OPEN ACCESS**

Study design

Retrospective cohort study (United Kingdom).

Study purpose

To assess the effect of closed incision negative pressure therapy (ciNPT) on the infection rate of patients at high risk for sternal wound infection (SWI).

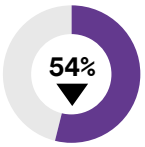
Methods

- This study included patients who underwent full median sternotomies between January 2009 to December 2016.
- Retrospective study included patients 3 years before the introduction of ciNPT (3M™ Prevena™ Therapy) and 3 years after introduction.
- No clinician change in practice other than the use of Prevena Therapy for high-risk patients.
- High-Risk patients: ≥ 2 risk factors: Obesity, COPD, Age ≥ 80, Diabetes.
- All patients followed up at 6 weeks following discharge.
- Before the introduction of ciNPT, 162 high-risk patients received SOC. After the introduction of ciNPT, 158 received ciNPT.

Key point

ciNPT reduced the incidence of post sternotomy sternal wound infections (SWIs) in high-risk patients.

Results



Reduction in SSI

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

(continued)

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

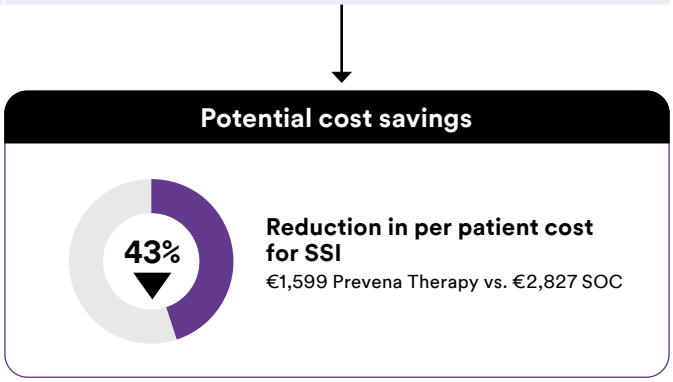
*Statistically significant (p<0.05).

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	Control
Number of patients (n)	158	162
Number of Surgical Site Infections (a)	9	20
Cost per Surgical Site Infection[1] (b)	€22,905	€22,905
Cost of SSI per patient (a*b)/n	€1,305	€2,827
Cost of therapy Per patient*	€295	–
Total cost per patient	€1,599	€2,827
Potential per incision savings using Prevena Therapy	**€1,228**	



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Reference

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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

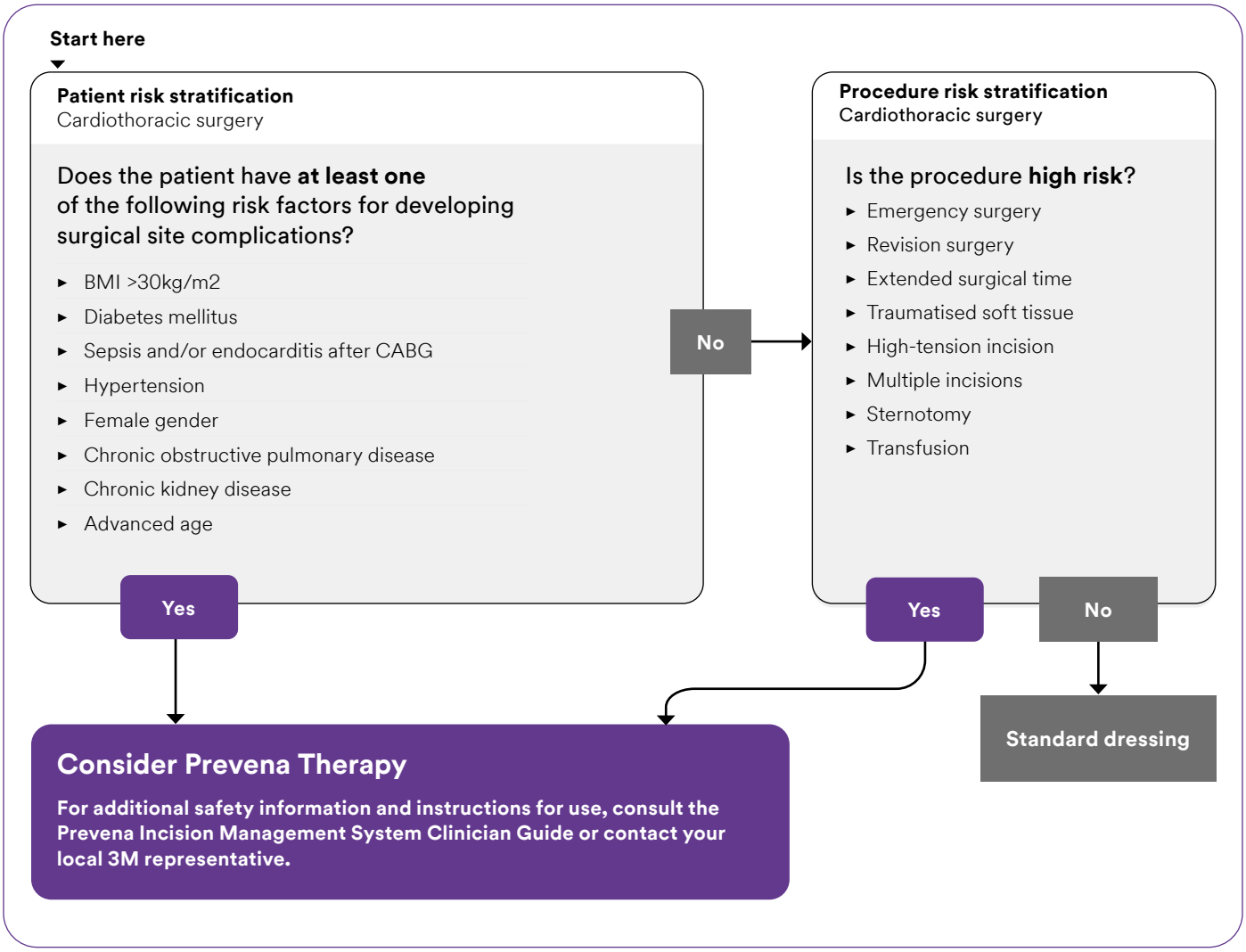
Published: 19 August 2020

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. *Journal of Cardiothoracic Surgery*. 2020 Aug 19;15(1):222. **OPEN ACCESS**

Decision guide

Patient and procedure risk stratificationin cardiothoracic surgery backed by clinical evidence.

While most surgical patients may benefit from 3M™ 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, De Santis G, Gabriel A, Grauhan O, Guerra OM, Lipsky BA, Malas MB, Mathiesen LL, Singh DP, Reddy VS. 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. *Journal of Thoracic and Cardiovascular Surgery.* 2013 May;145(5):1387-92. **OPEN ACCESS**
3. 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. *Journal of Cardiothoracic Surgery.* 2020 Aug 19;15(1):222. **OPEN ACCESS**

Author biographies*

*Where available and permitted to use.

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

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

Dr. Reddy is a paid consultant for 3M.

V. Sreenath (Seenu) Reddy, MD, MBA, FACS is Chief, Division of Cardiothoracic Surgery at Centennial Heart & Vascular Centre 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 Centre. Dr. Reddy then received his training in Cardiovascular and Thoracic Surgery at Emory University Medical Centre. In addition, he completed a fellowship in advanced endovascular surgery at Emory University Medical Centre.

"The available clinical evidence in vascular, plastic, orthopaedic, 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.co.uk/general

Negative pressure wound therapy for surgical-site infections: a randomised trial.

Javed A, Teinor J, Wright M, Ding D, Burkhart R, Hundt J, Cameron J, Makary M, He J, Eckhauser F, Wolfgang C, Weiss M. Negative pressure wound therapy for surgical-site infections: a randomised trial. *Annals of Surgery.* 2019; 269(6):1034–1040.

Study design

Randomised controlled trial, single-centre (John Hokins Hospital, United States).

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.
- High risk for SSI was defined as a risk score of ≥1 defined by Poruk et al† where preoperative bile stent/ drain received 1 point and neoadjuvant chemotherapy received 1 point. Points were summed for each patient.
- A total of 123 patients analysed: Prevena Therapy (n=62) v. Standard of Care (SOC) (n=61).
- Preoperative and operative characteristics were not significantly different between the two groups.
- The primary outcome was 30-day SSI (superficial or deep).

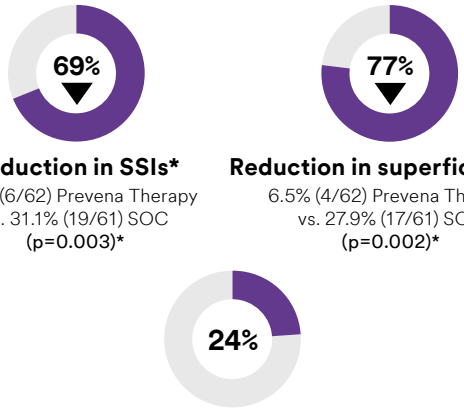
Summary of findings

This randomised controlled trial from Johns Hopkins Hospital demonstrated significantly lower SSI rates in high-risk patients receiving 3M™ Prevena™ Therapy after pancreaticoduodenectomy (31.1% vs. 9.7%; p=0.003)*.

SSIs resulted in an increased hospitalisation cost of **$9,778 per patient.**

Implementing Prevena Therapy into surgical practice can help reduce the risk of potential complications and associated healthcare costs.

Results



Reduction in SSIs*
9.7% (6/62) Prevena Therapy
vs. 31.1% (19/61) SOC
(p=0.003)*

Reduction in superficial SSI*
6.5% (4/62) Prevena Therapy
vs. 27.9% (17/61) SOC
(p=0.002)*

Inpatient cost due to SSI
Median inpatient cost per non-SSI patient: $41,085
Additional inpatient cost due to SSI: $9,778

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

*Statistically significant (p<0.05).

†Poruk et al. A novel, validated risk score to predict surgical site infection after pancreaticoduodenectomy. HBP (Oxford). 2016;18:893–899.

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: *Annals of Surgery*

Title: Negative Pressure Wound Therapy for Surgical-site Infections: A Randomised Trial

Published: 1 June 2019

Javed AA, Teinor J, Wright M, Ding D, Burkhart RA, Hundt J, Cameron JL, Makary MA, He J, Eckhauser FE, Wolfgang CL, Weiss MJ. Negative Pressure Wound Therapy for Surgical-site Infections: A Randomised Trial. *Ann Surg.* 2019 Jun;269(6):1034–1040. doi: 10.1097/SLA.0000000000003056. **PMID: 31082899.**

Reduction of wound complication risk and length of stay with 3M™ Prevena™ Therapy.

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.

Study design

Retrospective comparative cohort study (Italy).

Study purpose

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

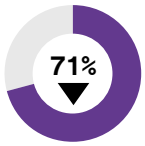
Methods

- Patients who underwent elective open VHR with synthetic mesh positioning from January 2015 to December 2017 at a single centre in Italy.
- Prevena Therapy (n=70) v. SOC (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

Summary of findings

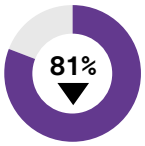
The use of Prevena Therapy in high-risk populations following VHR with synthetic mesh significantly decreased the rate of complications and reduced the length of stay which resulted in a positive economic outcome.

Results



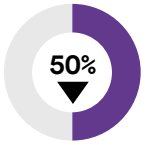
Reduction in major complications*

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



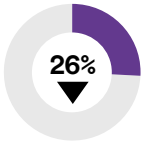
Reduction in superficial infections*

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



Reduction in mean in-hospital length of stay*

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

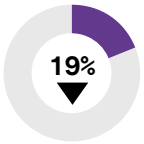


Reduction in mean total cost per patient*

Prevena inpatient cost: € 4,230
SOC 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) SOC **(p=0.04)*†**



Reduction in wound dehiscence†

2.9% (2/70) Prevena Therapy vs. 3.6% (4/110) SOC **(p=0.7)†**

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 deep infections and wound 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: *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: 26 May 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

Reduction of the incidence of surgical site infection with 3M™ Prevena™ Therapy in emergency laparotomy patients.

Cheong Chung JN, Ali O, Hawthornthwaite E, Watkinson T, Blyth U, McKigney N, Harji DP, Griffiths B. Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis. *Surgery*. 2021 Nov;170(5):1568–1573.

Study design

Retrospective comparative cohort study (United Kingdom).

Study purpose

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 the NELA registry.
- The National Emergency Laparotomy Audit (NELA) is part of the National Clinical Audit and Patient Outcomes Programme (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.
- Standard surgical dressing (Opsite dressing).
- Primary outcome was SSI per Centers for Disease Control criteria.

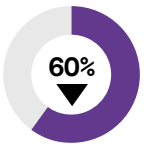
Summary of findings

- 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.

Results

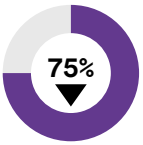
Reduction in SSIs*

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



Reduction in sSSIs*

8.0% (19/237) Prevena Therapy
vs. 19.8% (47/237) SOC



Reduction in dSSIs

1.3% (3/237) Prevena Therapy
vs. 5.1% (12/237) SOC

(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 deep infections and wound 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)

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.

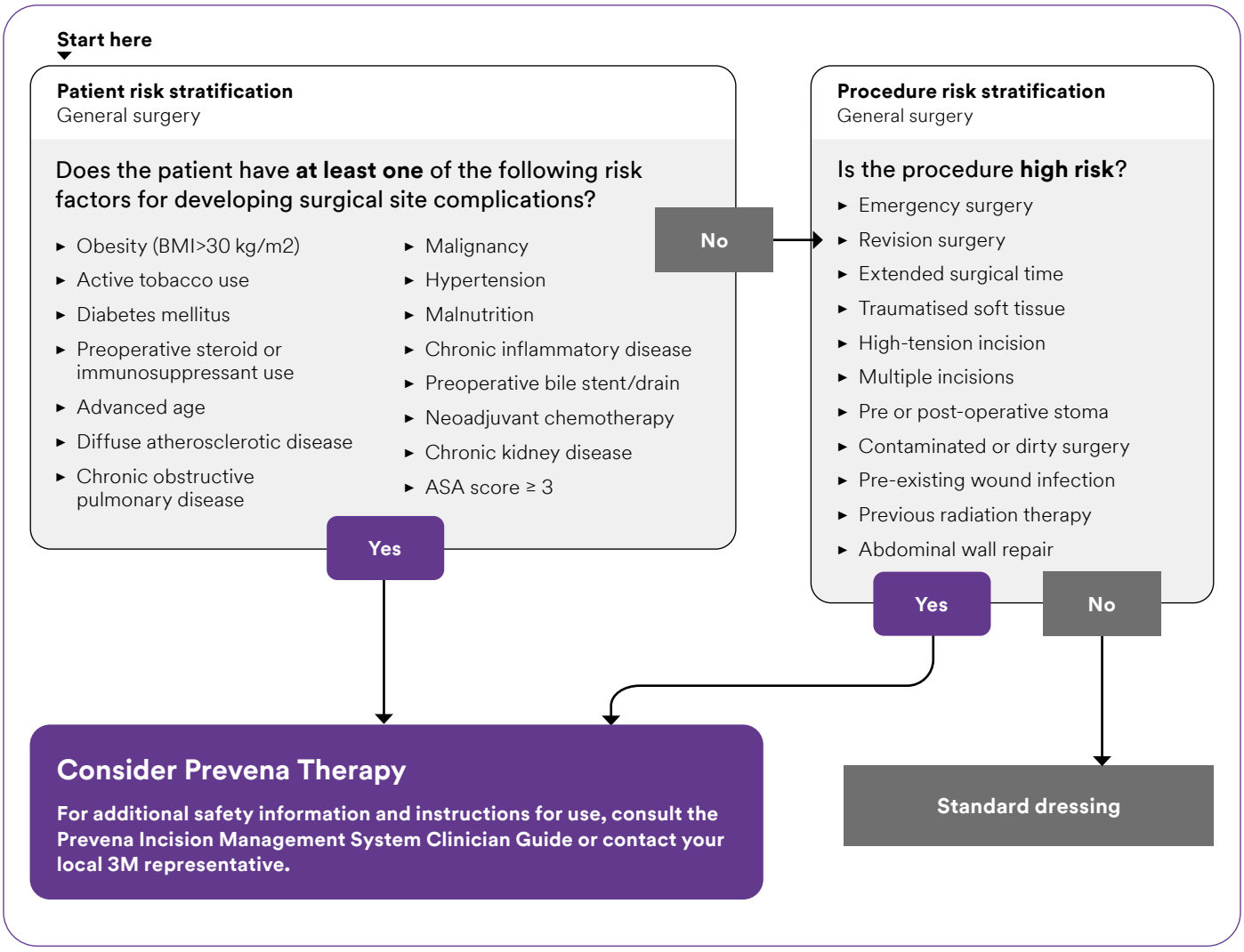
Published: 26 May 2021

Cheong Chung JN, Ali O, Hawthornthwaite E, Watkinson T, Blyth U, McKigney N, Harji DP, Griffiths B. Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis. *Surgery*. 2021 Nov;170(5):1568–1573. **OPEN ACCESS**

Decision guide

Patient and procedure risk stratification in gneral surgery backed by clinical evidence.

While most surgical patients may benefit from 3M™ 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.

References

1. Willy C, Agarwal A, Andersen CA, De Santis G, Gabriel A, Grauhan O, Guerra OM, Lipsky BA, Malas MB, Mathiesen LL, Singh DP, Reddy VS. 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, Ding D, Burkhart RA, Hundt J, Cameron JL, Makary MA, He J, Eckhauser FE, Wolfgang CL, Weiss MJ. Negative Pressure Wound Therapy for Surgical-site Infections: A Randomised Trial. *Annals of Surgery.* 2019 Jun;269(6):1034-1040. **PMID 31082899** 4. Zaidi A, El-Masry S. Closed incision negative pressure therapy in high-risk general surgery patients following laparotomy: a retrospective study. *Colorectal Disease.* 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, Kercher KW, Colavita PD, Heniford BT, Augenstein VA. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. *Ann Plast Surg.* 2022 Apr 1;88(4):429-433. **PMID 34670966** 7. Cheong Chung JN, Ali O, Hawthornthwaite E, Watkinson T, Blyth U, McKigney N, Harji DP, Griffiths B. 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. **PMID 34052025** 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. **PMID 35779950**

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

3M™ Prevena™ Peel and Place Dressings

3M™ Prevena™ Peel
and Place Dressing –
13 cm

3M™ Prevena™ Peel and
Place Dressing – 20 cm

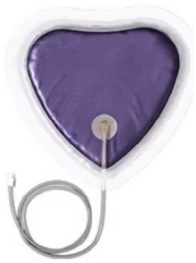
3M™ Prevena™ Peel and
Place Dressing – 35 cm

3M™ Prevena™ Plus Customizable Dressing

3M™ Prevena™ Plus
Customizable Dressing

3M™ Prevena Restor™ Dressings

3M™ Prevena Restor™
Arthro·Form™ Dressing



3M™ Prevena Restor™
Bella·Form™ Dressing

Note: The availability of Prevena Therapy Units and Dressings may vary by country. To get precise information about availability, we recommend reaching out to your local sales representative.

Healthcare professionals:

Visit Prevena Central to learn more, request a trial or connect with 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. This material is intended for healthcare professionals.

3M™ Prevena™ Therapy and 3M™ Prevena Restor™ Therapy Indications for Use:
Prevena Incision Management System and Prevena Restor Incision Management Systems are intended to manage the environment of closed surgical incisions and surrounding intact skin in patients at risk for developing post-operative complications, such as infection, by maintaining a closed environment via the application of a negative pressure wound therapy system to the incision. The Prevena Dressing skin interface layer with silver reduces microbial colonisation in the fabric.

*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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