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

A 3M ciNPT Clinical Compendium
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 optimize 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,

Ronald P. Silverman, MD, FACS
Senior Vice President, Global Medical and Clinical Affairs, and Chief Medical Officer, 3M Health Care Business Group
Clinical Associate Professor of Surgery, Johns Hopkins University
Adjunct Associate Professor of Plastic Surgery, Johns Hopkins University

Ron is certified by the American Board of Plastic Surgery and is a member of several professional organizations, 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.
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.

Prevena Therapy has been shown to help reduce the risk of SSCs and overall cost of care.†

Prevena Therapy has demonstrated outcomes across multiple specialties, including plastic, vascular, cardiothoracic, spine, orthopedic and general surgery.‡ Data from a multicenter randomized controlled trial and health economic analysis showed that 3M™ Prevena™ Therapy significantly reduced the risk of 90-day surgical site complications (SSCs),† readmissions, and surgical site management costs‡ vs. silver-impregnated dressings.

Surgical Site Infections (SSIs) occur in 2%–5% of all inpatients.†‡

Patients who develop anSSI are approximately 5x likelier to be readmitted.‡

A single SSI can cost up to $60,000 per patient.§

References


PREVENA for Surgical Site Management After Revision Total Knee Arthroplasty: The PROMISES Randomized Controlled Trial. Journal of Arthroplasty. 2021

Mitigating Surgical Site Complications in High-Risk Patients After Revision Knee Arthroplasty. The PROMISES Randomized Controlled Trial. J Arthroplasty. 2021


In computer bench models

In a canister

1-800-275-4524
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


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

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

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

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

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

References

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

©2018 Prevena, Inc. All rights reserved.
Prevena Therapy has received Investigational Device Exemption from the U.S. Food and Drug Administration (FDA) for use of this device in select patients undergoing a wide variety of surgical procedures, including general, orthopedic, thoracic, urologic, gynecologic, cardiovascular, oral/maxillofacial, and ophthalmic procedures. Prevena Therapy is indicated for the primary prevention of surgical site infection (SSI) in patients undergoing certain surgical procedures. Prevena Therapy is not for use on tractable wounds or skin lesions.

Prevena Therapy is contraindicated for use where total occlusion of the surgical incision may compromise the delivery of surgical care and/or intervention. Prevena Therapy is contraindicated for use if the patient has a pre-existing ulcer, varicose veins, or diabetes mellitus.

The effectiveness of Prevena Therapy has not been reviewed by the FDA. The use of Prevena Therapy is associated with a statistically significant reduction in the incidence of SSIs and seromas in surgical procedures and populations that have not been demonstrated. See full Indications for Use and Limitations at hcbgregulatory.3m.com.

Published: March 2023

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

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


*3M™ Prevena™ Incision Management System (3M, St. Paul, MN)
Patients and procedures that may benefit from
3M™ Prevena™ Therapy¹

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/m²); diabetes mellitus; tobacco use; or prolonged surgical time
- It is recommended that the surgeon assess the individual patient’s risk factors and surgical risks

Additional factors to consider:

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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):

Consensus recommendations based on:
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PRM in Orthopedic Surgery

Prevena.com/orthopedics

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

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

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

The Effectiveness of Closed Incision Negative Pressure Therapy versus Silver-Impregnated dressings in Mitigating Surgical Site Complications in High-Risk Patients After Revision Knee Arthroplasty

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett MP, Scuderi GR, Cusner FD, Puigui 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 Randomized Controlled Trial. J Arthroplasty. 2021 Jul;36(7S):S295-S302.e14. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use.

Study Design
Post-market, randomized, open-label, multicenter study.

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 centers) at high risk for wound complications were randomized 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 3M™ 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 utilization parameters (readmission, reoperation, dressing changes, and visits) and patient-reported outcomes (PRO). Treatment-related adverse events were compared and stratified as severe and non-severe.

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 11±0.29 vs. SOC 13±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)

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

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

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

Reduction in 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 dressing changes* 1.1±0.29 Prevena Therapy vs. 1.3±0.96 SOC (p=0.0003*)

Reduction in deep SSs* 0.7% (1/147) Prevena Therapy vs. 2.0% (3/147) SOC (p=0.2131)

Reduction in dehiscence† 79% (11/147) Prevena Therapy vs. 13% (19/147) SOC (p=0.0033)

Reduction in ROR* 4x (1/25) Prevena Therapy vs. 2x (2/10) SOC (p=0.008)

Reduction in ROR† 3x (1/25) Prevena Therapy vs. 1x (1/10) SOC (p=0.0421)

Reduction in ROR* 15% (6/40) Prevena Therapy vs. 5% (2/40) SOC (p=0.0626)

Reduction in ROR† 65% (26/40) Prevena Therapy vs. 19% (8/40) SOC (p=0.0001)

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

*Statistically significant (p<0.05)
†NOTE: The use of Prevena Therapy for the reduction in the incidence of deep SSs and dehiscence has not been reviewed by the U.S. FDA.

Read the full study here
Journal: The Journal of Arthroplasty
Title: The Effectiveness of Closed-Incision Negative-Pressure Therapy Versus Silver-Impregnated Dressings in Mitigating Surgical Site Complications in High-Risk Patients After Revision Knee Arthroplasty: The PROMISES Randomized Controlled Trial
Published: March 5, 2021

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett MP, Scuderi GR, Cushner FD, Puigui 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 Randomized Controlled Trial. J Arthroplasty. 2021 Jul;36(7S):S295-S302.e14. OPEN ACCESS Note that the length of therapy may be outside the range recommended in the Instructions for Use.
A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty


Study Design
Single institution retrospective review of records

Study Purpose
The purpose of the Anatone study was to evaluate when to use Prevena Therapy in primary total joint arthroplasties (TJAs). The author's risk stratification can be used as a potential guideline to identify patients who 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 unplanned postoperative interventions.

Results

<table>
<thead>
<tr>
<th>Risk Factor Algorithm Scoring System</th>
<th>Risk Factor</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE: &lt;65 kg/m²</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>65–69.9 kg/m²</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>70–74.9 kg/m²</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>75 kg/m² or more</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Immuno deficiency</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Active smoking</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Non-ASA</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Prior incision</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

(Continued)

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).

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

*Statistically significant (p<0.05).

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

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

Read the full study here

Reference
1. Hou Y. Incidence and impact of surgical site infections and surgical site complications on length of stay and cost of care in orthopedic open surgeries for spine, THA/TKA, and trauma. HEOR-2021-002-DAR.

Potential Cost Savings
Reduction in per patient cost for SSC in Primary TJA High-Risk Population $1,652 Prevena Therapy vs $4,083 SOC

Potential Cost Savings

Illustration of the 3M™ Prevena™ Therapy Incision Management System

Cost Effectiveness Based on Anatone et al Outcomes

Primary TKA and THA in High-Risk Population

Hypothetical Economic Model

<table>
<thead>
<tr>
<th>Prevena™ Therapy</th>
<th>AQUACEL® Ag SURGICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>123</td>
</tr>
<tr>
<td>Number of Surgical Site Complications (a)</td>
<td>9</td>
</tr>
<tr>
<td>Cost per SSC (b)</td>
<td>$11,332</td>
</tr>
<tr>
<td>Per Patient Complication Cost (a)x(n)</td>
<td>$1,122</td>
</tr>
<tr>
<td>Per Patient Therapy Cost*</td>
<td>$830</td>
</tr>
<tr>
<td>Total Cost Per Patient</td>
<td>$1,952</td>
</tr>
</tbody>
</table>

Potential Per Incision Savings Using Prevena™ Therapy

$2,308
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


Study Design
Retrospective comparative cohort study

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

Methods
• The Prevena Therapy group comprised of 130 patients who had primary TKA between July 2018 and December 2019.
• The retrospective historical control group (AQUACEL Ag SURGICAL) consisted of 130 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/m², autoimmune disease, chronic kidney disease, Staphylococcus aureus nasal colonization, and non-aspirin antiaggregation.
• Study endpoints included incisional wound complications, defined as: cellulitis, focal swelling, suture reaction, dehiscence and hematoma. Non-incisional wound complications were also assessed and defined as dressing reactions, blistering and rashes.

Results
- Red 57% 
- Presence of Drainage
- Prevena Therapy
- Control
- Partial
- Prevalence of Drainage
- Prevena Therapy
- Control
- Partial

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 cNPT as part of a risk mitigation strategy to reduce post operative complications in primary TKA.

Potential Per Incision Savings Using Prevena Therapy
$960

Reference
1. Hou Y. Incidence and impact of surgical site infections and surgical site complications on length of stay and cost of care in orthopedic open surgeries for spine, THA/TKA, and trauma. HEO-2021-002-DAR.
Use of Closed Incisional Negative Pressure Wound Therapy After Revision Total Hip and Knee Arthroplasty in Patients at High Risk for Infection: A Prospective, Randomized Clinical Trial


Study Design
Prospective, single-center, randomized controlled trial

Study Purpose
The purpose of the Newman study was to compare the use of Prevena Therapy to a sterile 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 randomized 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 (SSCs), 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 multicenter clinical trials to further strengthen the results as well as a cost-benefit analysis.

Results

<table>
<thead>
<tr>
<th>Incisional Negative Pressure Wound Therapy</th>
<th>57%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in Wound Complications*</td>
<td></td>
</tr>
<tr>
<td>Prevena Therapy vs. SOC (p=0.022)*</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Incisional Negative Pressure Wound Therapy</th>
<th>72%</th>
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<tbody>
<tr>
<td>Reduction in Periprosthetic Joint Infection</td>
<td></td>
</tr>
<tr>
<td>Prevena Therapy vs. SOC (p=0.017)*</td>
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</table>

<table>
<thead>
<tr>
<th>Incisional Negative Pressure Wound Therapy</th>
<th>80%</th>
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</thead>
<tbody>
<tr>
<td>Fewer Returns to the OR*</td>
<td></td>
</tr>
<tr>
<td>Prevena Therapy vs. SOC (p=0.07)*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incisional Negative Pressure Wound Therapy</th>
<th>74%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in dehiscence†</td>
<td></td>
</tr>
<tr>
<td>Prevena Therapy vs. SOC (p=0.005)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Incisional Negative Pressure Wound Therapy</th>
<th>15%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer Readmissions</td>
<td></td>
</tr>
<tr>
<td>Prevena Therapy vs. SOC (p=0.03)</td>
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</tbody>
</table>

(Continued)

(Continued)

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

<table>
<thead>
<tr>
<th>Revision TKA Surgery in High-Risk Prevena Hypothetical Economic Model</th>
<th>Prevena® Therapy</th>
<th>AQUACEL® Ag SURGICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>79</td>
<td>80</td>
</tr>
<tr>
<td>Number of Surgical Site Complications (a)</td>
<td>8</td>
<td>19</td>
</tr>
<tr>
<td>Cost per SSC (a)</td>
<td>$19,733</td>
<td>$19,733</td>
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<tr>
<td>Per Patient Complication Cost (a)/n</td>
<td>$1,610</td>
<td>$3,776</td>
</tr>
<tr>
<td>Per Patient Therapy Cost*</td>
<td>$495</td>
<td>$39</td>
</tr>
<tr>
<td>Total Cost Per Patient</td>
<td>$2,105</td>
<td>$3,815</td>
</tr>
<tr>
<td>Potential Per Incision Savings Using Prevena® Therapy</td>
<td>$1,710</td>
<td></td>
</tr>
</tbody>
</table>

Potential Cost Savings

Reduction in per patient cost for SSC $1,520 Prevena Therapy vs. $3,815 SOC

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

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. The model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference
1. Hou Y. Incidence and impact of surgical site infections and surgical site complications on length of stay and cost of care in orthopedic open surgeries for spine, THA, TKA, and trauma. HEDR-2021-002-DAR.

Read the full study here

Journal: The Journal of Arthroplasty
Title: Use of Closed Incisional Negative Pressure Wound Therapy After Revision Total Hip and Knee Arthroplasty in Patients at High Risk for Infection: A Prospective, Randomized Clinical Trial
Published: November 16, 2018

Newman JM, Siqueira MBP, Kilka AK, Molloy RM, Barsoum WK, Higuera CA. Use of Closed Incisional Negative Pressure Wound Therapy After Revision Total Hip and Knee Arthroplasty in Patients at High Risk for Infection: A Prospective, Randomized Clinical Trial. 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


Study Design
Single-center, prospective versus historic control comparative study

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, hematomas, seromas, edema/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.

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

*Statistically significant (p<0.05)

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

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

*Statistically significant (p<0.05)
Randomized Controlled Trial of Incisional Negative Pressure following High-Risk Direct Total Hip Arthroplasty

H. John Cooper, MD, Wallakia M. Santos, BS, Alexander L. Neuwirth, MD, Jeffrey A. Geller, MD, Jose A. Rodriguez, MD, Sebastian Rodriguez-Elizalde, MD, Roshan P. Shah, MD, JD

Study Type
This was a prospective randomized controlled trial.

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

Methods
- **Population:** Study enrolled high-risk DA THA patients at 3 centers. Inclusion criteria was if subjects had previously identified risk factors for SSC: Body mass index (BMI) >30 kg/m², diabetes, active smoking or before hip surgery.
- **Treatment:** Patients were randomized after closure to either an occlusive (control) dressing or cNPT dressing (3M™ Prevena™ Incision Management System) for 120 completed the data collection. SSCs occurred in 18.3% (11/60) of control patients compared to 8.3% (5/60) of cNPT patients (x² = 2.60, P = .107).
- **SSCs:** Included dehiscence to the subcutaneous level (13) and prolonged drainage (3).
- **Nine control (15.0%) and 2 cNPT (3.3%) patients met CDC criteria for superficial SSI (P = .027).**
- **Fifteen of 16 SSCs resolved with local wound care. One in the cNPT 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 cNPT.

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 cNPT patients (x² = 2.60, P = .107).

- **SSCs included dehiscence to the subcutaneous level (13) and prolonged drainage (3).**
- **Nine control (15.0%) and 2 cNPT (3.3%) patients met CDC criteria for superficial SSI (P = .027).**
- **Fifteen of 16 SSCs resolved with local wound care. One in the cNPT group required reoperation for acute PJI.**

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.

Incisional Negative Pressure Wound Therapy in Orthopaedic Trauma: Indications & Outcomes

Rachel Phillips, MD, James P. Stannard, MD, and Brett D. Crist, MD

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:** Incisional Negative Pressure Wound Therapy in Orthopaedic Trauma: Indications and Outcomes
**Published:** September 2022

**Journal:** Journal of Orthopaedic Trauma
**Title:** Incisional Negative Pressure Wound Therapy in Orthopaedic Trauma: Indications & Outcomes
**Published:** September 2022

NOTE: The use of Prevena Therapy for the reduction in the incidence of dehiscence and deep SSI has not been reviewed by the U.S. FDA.
How Can Negative Pressure Wound Therapy Pay for Itself?—Reducing Complications Is Important

Zelle, Boris A. MD, Kore, Lydia MD

Study Type
This was a retrospective cohort study performed at a single, level-1 trauma center using data from a lower extremity fracture registry.

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

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

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

There was no significant difference in rates of SSI when comparing iNPWT with non-iNPWT group (7.4% vs. 11.5%, P = 0.706).

Patients in iNPWT group had the external fixator in place for a significantly longer time (10.6 days vs. 6.8 days, P = 0.0322). 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 = 0.015).

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.

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.

The effectiveness of Prevena Therapy in reducing the incidence of SSIs and sepsis in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at hcbgregulatory.3m.com.
Use of 3M™ Prevena Restor™ Roto•Form™ Incision Management System after total hip arthroplasty

Evan Argintar, MD and Yavonne Johnson PA-C, Medstar Health, Washington, DC

Patient and diagnosis
A 62-year-old female presented for a total hip arthroplasty of the right hip. The patient’s medical history included hypertension, coronary heart disease, anticoagulant usage, lumbar spondylosis, and short leg syndrome.

Procedure
Preoperative antibiotics were given. In the operating room, a total hip arthroplasty was performed using one 8 cm incision on the right anterior hip. The incision was closed in the operating room using surgical staples (Figure 1).

Application of 3M™ Prevena Restor™ Roto•Form™ Incision Management System
Prevena Restor™ Roto•Form™ Incision Management System was chosen to help manage the surgical incision and surrounding soft tissue, bolster the incision and surrounding soft tissue envelope, reduce lateral tension across the incision,1 and hold the incision edges together. In the operating room, 3M™ Prevena Restor™ Therapy was applied over the incision followed by initiation of negative pressure at -125 mmHg (Figure 2).

Discharge and follow-up
After surgery, the patient was discharged home following anesthesia recovery. A dressing change was performed in the office on postoperative day (POD) 6 (Figure 3). After 6 days, the incision remained intact with no edema in the surrounding tissue. Prevena Restor Therapy was continued for 7 additional days to help support optimal healing (Figure 4). On POD 14, Prevena Restor Therapy was discontinued, and the Roto•Form™ Dressing was removed. On POD 21, the patient returned for staple removal. The incision showed healing without complications and a reduction of postoperative swelling was noted. Six weeks after surgery, the incision was fully healed without complications (Figure 5).


Patient data and images courtesy of Evan Argintar, MD and Yavonne Johnson PA-C, Medstar Health, Washington, DC. Evan Argintar, MD and Yavonne Johnson PA-C are paid consultants of 3M. As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient’s circumstances and condition.
Management of total knee arthroplasty revision with 3M™ Prevena Restor™ Arthro•Form™ Incision Management System

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

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

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

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

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

The Application of 3M™ Prevena Restor™ Therapy to Manage a Surgical Incision Post Open Reduction Internal Fixation for Proximal Humerus Fracture and Dislocation

Nishant Suneja, MD; Department of Orthopaedic Surgery, Brigham and Women’s Hospital, Harvard Medical School, Boston, MA; and NYC Health and Hospitals/Lincoln/Kings County, New York, NY.

Patient
A 43-year-old male was involved in a motor vehicle collision and admitted to the hospital. The patient, who was operating his electric bicycle while delivering food, was struck by a motor vehicle and sustained a shoulder fracture dislocation from the impact and fall. At initial presentation, trauma and severe soft tissue swelling were noted. The patient presented with a proximal humerus head split fracture (Figure 1), which creates more susceptibility to developing avascular necrosis. Aside from current tobacco usage, the patient had no chronic medical conditions. Residents within the emergency room initially tried closed reduction while the patient was under sedation; however, the attempt was unsuccessful as this fracture pattern was complex and difficult to treat.

Procedure
Orthopedic surgery was delayed three days due to unavailability of a specialist. On the day of the procedure, blisters surrounding the shoulder were noted upon the patient’s arrival to the operating room. To access the proximal humerus fracture, a 15 cm deltopectoral incision (Figure 2A and 2B) was made. Approaching the posteriorly dislocated head from the standard anterior deltopectoral approach presents as a challenge in this procedure. To approach the glenohumeral dislocation and perform the reduction, the subscapular muscle of the rotator cuff was released along with a small fragment of the lesser tuberosity and repaired at the end. The dislocated and fractured head of the humerus was reduced to the shaft and fixed using a proximal humerus locking plate (ORIF) (Figure 3A and 3B). Incisional closure was achieved using staples. The patient received perioperative antibiotics.

(Continued)
Application of 3M™ Prevena Restor™ Roto•Form™ Incision Management System

Following the ORIF procedure, 3M™ Prevena Restor™ Roto•Form™ Incision Management System was enlisted to manage the closed deltopectoral incision and surrounding soft tissue, hold incision edges together, and reduce tensile forces across the incision. Immediately postoperatively, 3M™ Prevena Restor™ Roto•Form™ Dressing was applied over the incision (Figure 4), and 3M™ Prevena Restor™ Therapy was initiated (-125 mmHg negative pressure).

Discharge and Follow-up

The patient spent 1 post-surgical day as an inpatient prior to discharge. The application of the Prevena Restor™ Roto•Form™ Dressing afforded the orthopedic surgery team confidence to discharge the patient home on postoperative day 1. After 7 days, the Prevena Restor™ Roto•Form™ Dressing was removed by the healthcare provider and the incision examined. No blistering under the Prevena Restor™ Roto•Form™ Dressing was observed. Original blisters surrounding the shoulder were resolving. Additionally, the patient on follow-up had significantly less swelling than expected. A new Prevena Restor™ Roto•Form™ Dressing was placed over the incision to address postoperative swelling surrounding the incision and the posterior aspect of the shoulder given the dislocated head and delayed surgery.

Given that the zone of injury extended posteriorly from the initial trauma and the subsequent anterior trauma caused by the approach, the injury was well served by placement of Prevena Restor™ Roto•Form™ Dressing. Prevena Restor™ Therapy was discontinued after 14 days (Figure 5A and 5B).

In this patient, the Prevena Restor™ Roto•Form™ Dressing was integral to providing coverage over the entire zone of injury. At the follow-up appointment (Figure 6), no complications were noted post incision management with Prevena Restor™ Therapy using Prevena Restor™ Roto•Form™ Dressing.

The Application of 3M™ Prevena Restor™ Therapy to Manage a Surgical Incision Post Reverse Total Shoulder Arthroplasty

Nishant Suneja, MD; Department of Orthopaedic Surgery, Brigham and Women’s Hospital, Harvard Medical School, Boston, MA; and NYC Health and Hospitals/Lincoln/Kings County, New York, NY.

Patient

A 72-year-old female was admitted to the hospital with a comminuted proximal fracture of the proximal humerus sustained two months’ prior (Figure 1). She had a four-part fracture to the left proximal humerus for which orthopedic surgery was delayed due to medical optimization. At initial presentation, soft tissue swelling and bruising was noted. Patient comorbidities included diabetes, uncontrolled hypertension, coronary heart disease, peripheral vascular disease, and anticoagulant use.

Procedure

Given the delay in treatment due to medical optimization, shoulder stiffness was present at the time of surgery. It was imperative that immediate range of motion (ROM) of the shoulder had to be allowed post-surgery. To address the injury, a reverse total shoulder arthroplasty (RTSA) was performed using a deltopectoral approach to the shoulder (Figure 2). The surgical incision was 15 cm in length. Specifically, a significant amount of callus was present that was required to be taken down, which would result in extensive hemorrhaging along with subcutaneous fluid collection and edema. Following the RTSA (Figure 3), the incision was closed using staples.

(Continued)
Application of 3M™ Prevena® Roto•Form™
Incision Management System

3M™ Prevena® Roto•Form™ Dressing was applied over the closed incision (Figure 4) and 3M™ Prevena® Therapy (-125 mmHg negative pressure) was initiated. The objectives of administering the 3M™ Prevena® Roto•Form™ Incision Management System were to manage the closed incision and its surrounding soft tissue to reduce the tensile force across the incision.

Discharge and Follow-up

Prior to discharge, the length of the post-surgical hospital stay was 2 days. 3M™ Prevena® Therapy was discontinued after 7 days and the 3M™ Prevena® Roto•Form™ Dressing was removed by the healthcare provider (Figure 5). Following the removal of the Prevena® Roto•Form™ Dressing, the incision was healing well, had remained dry, and demonstrated no signs of erythema or infec­tion.

In this patient, the Prevena® Roto•Form™ Dressing was integral to helping obtain a positive outcome post rTSA to resolve four-part proximal humerus fractures. No complications to the incision were noted post incision management with Prevena® Therapy using Prevena® Roto•Form™ Dressing.

Bilateral primary total knee arthroplasty

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

Patient

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

Diagnosis

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

Application

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

Discharge and Follow-up

The patient was discharged home with the Prevena® Arthro•Form™ Incision Management System, and it was removed after 7 days during a follow-up visit. The arthroplasty incisions were healed without complication (Figure 1).
Originally from South Carolina, Dr. Cooper graduated from Duke University with a degree in mechanical engineering and materials science. He completed his medical education at Columbia University and his Orthopedic residency at Lenox Hill Hospital, before spending a year in Chicago for a fellowship in adult reconstructive surgery at Rush University Medical Center.

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

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

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

— Dr. Cooper

H. John Cooper, MD
Associate Professor of Orthopedic Surgery
Columbia University Irving Medical Center
New York Presbyterian Hospital, New York City, NY

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

- Anterior Total Hip Arthroplasty
- Fractures
- Hip and Pelvis Reconstruction Surgery
- Hip Arthroscopy
- Minimally Invasive Surgery
- Orthopaedic Rehabilitation
- Orthopaedic Trauma Surgery
- Pelvic Surgery
- Skeletal Trauma
- Limb Deformity Correction

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

— Dr. Crist

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

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

“Based on the level 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

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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


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

Study Design
Retrospective, comparative study.

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

Methods
- Single site retrospective observational study: 2009–2017
- 356 patients (Prevena Therapy n=177 vs 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 30-day postoperative complication rates were analyzed.

(Continued)
ciNPT for open abdominal wall reconstruction with concomitant panniculectomy


Study Design
Retrospective Cohort Study

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.

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 SSIs 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: Annals of Plastic Surgery
Title: Closed- Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy
Published: April 2022

Managing No-Drain Mastectomy with Closed Incision Negative Pressure Wound Therapy using Full-Coverage Foam Dressings


Study Design
This was a single center, case-control trial.

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

Methods
Seroma intervention data was retrospectively gathered from a single center for patients undergoing simple mastectomy, mastectomy with sentinel lymph node biopsy, or mastectomy with axillary lymph node clearance. 30 sequential patients treated with conventional dressings were selected for intervention arm.

Results
There were 31 mastectomy cases in each arm (including bilateral cases). There was no significant difference in surgery type between the groups.
1. Compared to control group, fewer patients in the intervention group developed postoperative seroma (20 control versus 15 intervention).
2. More subjects needed aspiration in control group than intervention group (16 control vs 12 intervention).
3. Fewer visits to the seroma clinic were needed for intervention group than control group (1 control vs. 0 intervention, p=0.012).
4. Intervention group had lower total aspiration volumes (843 mL control vs. 368 mL intervention, p=0.023).

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

Read the full study here

Title: Managing No-Drain Mastectomy with Closed Incision Negative Pressure Wound Therapy using Full-Coverage Foam Dressings
Published: February 2023

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 utilizing a modified Delphi technique.

Study Purpose
The purpose of the study was to identify conditions in which CiNPT with full-cover 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.

Results
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-cover dressings when 2 or more risk factors for surgical site complications are present.

Conclusion
The panel was able to establish 10 consensus statements. Recommendations for the use of CiNPT with full-cover 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

Title: The use of closed incision negative pressure therapy for incision and surrounding soft tissue management: Expert panel consensus recommendations
Published: August 21, 2021

The effectiveness of Prevena therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at Prevena.com/plastics.
**Case Studies**

**Patient and Procedure Risk Stratification Backed By Clinical Evidence**

While surgical patients may benefit from Prevena Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data 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.

### Decision Guide

#### Patient Risk Stratification

**Plastic Surgery**

Does the patient have at least one of the following risk factors for developing surgical site complications?

- Obesity (e.g., BMI > 35 kg/m²)
- Active tobacco use
- Diabetes mellitus
- Corticosteroid usage

**Procedure Risk Stratification**

**Plastic Surgery**

Is the procedure high risk?

- Emergency surgery
- Revision surgery
- Extended surgical time
- Traumatized soft tissue
- High-tension incision
- Multiple incisions

### Consider Prevena Therapy

For additional safety information and instructions for use, consult the 3M™ Prevena™ Incision Management System Clinician Guide or contact your local 3M representative.

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**References**


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

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

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

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

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

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

Figure 1. Patient appearance at presentation.
Figure 2. Blue coloring of the left nipple during breast reduction surgery, secondary to indocyanine blue injection and venous congestion.
Figure 3. Application of therapy using Prevena Restor Bella•Form™ Incision Management System over both breasts.
Figure 4. The incisions remained closed on both breasts at 2 months post surgery.

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

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

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

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

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

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

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

Figure 1. Breast appearance pre-mastectomy.
Figure 2. Application of 3M™ Prevena Restor™ Therapy with 3M™ Prevena Restor™ Bella•Form™ Dressing post mastectomy.
Figure 3. Appearance after 6 days of 3M™ Prevena Restor™ Therapy with 3M™ Prevena Restor™ Bella•Form™ Dressing.
Figure 4. Appearance on postoperative day 9. A. Right breast. B. Left breast.
Closure of a Complex Lower Extremity Wound With the Use of Multiple Negative Pressure Therapy Modalities


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

Procedure
The patient was placed on intravenous cefazolin and underwent several rounds of excisional debridement and irrigation. The patient was then managed operatively by a plastic surgery service. This care included three rounds of tissue advancement, followed by a seven-day course of NPWTi-d. Cycles consisted of normal saline instillation with a one-second dwell time, followed by six hours of continuous negative pressure at −125 mm Hg. The patient was then taken back for a final round of reconstruction with tissue advancement. A split-thickness skin graft (STSG) was placed over the skin graft recipient site, followed by abdominal pads. These were secured in place with an adhesive tape. The patient returned to the clinic once a week for wound evaluation and dressing changes, while also performing dressing changes frequently at home.

Results
After seven days of ciNPT, the patient was evaluated in the clinic and the ciNPT dressings were removed. On removal of the dressings, the skin graft appeared viable. The wound edges also appeared well-approximated, dry, and intact. Therefore, it was decided to discontinue treatment with the 3M™ Prevena Restor™ Bella•Form™ System. Non-adherent silicone dressings (3M™ Adaptic™ Non-Adhering Silicone Dressing) were placed over the skin graft recipient site, followed by abdominal pads. These were secured in place with an adhesive tape. The patient returned to the clinic once a week for wound evaluation and dressing changes, while also performing dressing changes frequently at home.

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

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on the patient’s circumstances and condition.
Dr. Chatterjee is a board-certified plastic surgery and fellowship trained breast oncologic surgeon practicing at Tufts Medical Center in Boston, MA. After completing his MD/MBA training at the University of Connecticut, he went on to do eight years of surgical residency at Dartmouth Hitchcock Medical Center in New Hampshire in plastic surgery and followed this with a one-year breast surgical oncology fellowship at the University of Pennsylvania. With this unique training in oncology and plastic surgery, much of Dr. Chatterjee’s practice involves the removal of cancer and the reconstruction using oncoplastic surgical techniques. He is active within his own institution as the President of the Medical Staff and sits on several committees as a member in both national breast oncologic and plastic surgery societies. He is presently Associate Professor of Surgery at Tufts Medical Center and is the Chief of Plastic Surgery. Academically, he enjoys training surgical residents daily and has published more than 90 peer-reviewed journal articles, most of which are either first or senior authored.

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

— Dr. Chatterjee

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

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

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

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

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

— Dr. Gabriel

(Continued)
Incisions at Risk for Surgical Complications

Seroma Formation
- Large Undermining
- High BMI
- Use of Biologics/Synthetics

Dehiscence
- Tight Closure/Compromised Flap
- Repeated Incisions Through Same Scar

Risk Factors:
- DM
- High BMI
- Smoker
- History of Radiation
- Soiling
- Immunosuppression

BMI - body mass index; DM - diabetes mellitus

Checklist of potential risk factors for surgical complications

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


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

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 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 hospitalization and all readmission days within 30 days related to any wound complication.

Hospital variable costs (not charges) for each admission were obtained from hospital administration.

<table>
<thead>
<tr>
<th>Days</th>
<th>Reduction in SSIs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11.0% (7/63) Prevena Therapy vs. 24.7% (15/60) SOC (p=0.001)*</td>
</tr>
<tr>
<td>2</td>
<td>10.7% (8/60) Prevena Therapy vs. 33.3% (20/60) SOC (p&lt;0.001)</td>
</tr>
</tbody>
</table>

Results

Reduction in SSIs*
11.0% (7/63) Prevena Therapy vs. 24.7% (15/60) SOC (p=0.001)*
10.7% (8/60) Prevena Therapy vs. 33.3% (20/60) SOC (p<0.001)

Reduction in readmissions*
8.8% (5/59) Prevena Therapy vs. 15.3% (9/60) SOC (p=0.037)
6.8% (4/59) Prevena Therapy vs. 16.7% (10/60) SOC (p=0.04)

Reduction in return to OR*
8.5% (5/59) Prevena Therapy vs. 19.3% (12/63) SOC (p=0.008)

Study Design
Prospective, single-center, randomized controlled trial

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

Methods

- The study included 119 femoral incisions closed primarily after elective vascular surgery procedures.
- High-risk inclusion criteria: BMI > 30, pannus, re-operative surgery, prosthesis graft, poor nutrition, immunosuppression, or HbA1c>8
- 1:1 Randomized to standard gauze (n=60) vs. Prevena Therapy (n=59)
- Outcomes evaluated at post-operative day 3: wound complications, SSI, length of stay (LOS), reoperation, readmission

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 sepsis in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at Prevena.com/vasc.

References
1. Cost Assessment includes variable hospital costs for both the index hospitalization and all readmission days within 30 days related to any wound complication. Hospital variable costs (not charges) for each admission were obtained from hospital administration.
Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study


Study Design
Single Center Randomized Controlled Trial German

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.

Although the authors reported use of Prevena Therapy for a mean of 3.6 days (ranging from 2 to 10 days), a mean time of application outside the recommendation for Optimum Use as stated in the 3M™ Prevena™ Incision Management System Clinical Guidance Instructions for Use. The Prevena Infection 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.

*Statistically significant (p<0.05)

Hypothetical Economic Model

<table>
<thead>
<tr>
<th>Vascular Groin</th>
<th>Hypothetical Economic Model</th>
<th>Prevena™ Therapy</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Incisions (n)</td>
<td>58</td>
<td>71</td>
<td></td>
</tr>
<tr>
<td>Number of Infections (a)</td>
<td>1</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Cost Per Infection (a)</td>
<td>$21,927</td>
<td>$21,927</td>
<td></td>
</tr>
<tr>
<td>Cost of Infection per incision (a/n)</td>
<td>$376</td>
<td>$3,689</td>
<td></td>
</tr>
<tr>
<td>Cost of Therapy Per Infection</td>
<td>$495</td>
<td>-</td>
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</tr>
<tr>
<td>Total Cost Per Infection</td>
<td>$871</td>
<td>$3,689</td>
<td></td>
</tr>
<tr>
<td>Potential Per Infection Savings Using Prevena™ Therapy</td>
<td>$2,818</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Potential Cost Savings

<table>
<thead>
<tr>
<th>Vascular Groin</th>
<th>Hypothetical Economic Model</th>
<th>Prevena™ Therapy</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in per patient cost for SSI</td>
<td>$871 Prevena Therapy vs. $3,689 SOC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in per patient cost for SSCs</td>
<td>$2,034 Prevena Therapy vs. $7,544 SOC</td>
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<td></td>
</tr>
</tbody>
</table>

*3M™ Prevena™ Peel and Place System Kit and Control therapy (gauze) changed once a day at $10 a week; individual prices may vary.

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

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

<table>
<thead>
<tr>
<th>Surgical Site Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular Groin</td>
</tr>
<tr>
<td>Number of Incisions (n)</td>
</tr>
<tr>
<td>Number of Complications (a)</td>
</tr>
<tr>
<td>Cost Per Complication (a)</td>
</tr>
<tr>
<td>Cost of Complication per incision (a/n)</td>
</tr>
<tr>
<td>Cost of Therapy Per Infection</td>
</tr>
<tr>
<td>Total Cost Per Infection</td>
</tr>
<tr>
<td>Potential Per Infection Savings Using Prevena™ Therapy</td>
</tr>
</tbody>
</table>

Potential Cost Savings

<table>
<thead>
<tr>
<th>Vascular Groin</th>
<th>Hypothetical Economic Model</th>
<th>Prevena™ Therapy</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in Deep Wound Dehiscence†</td>
<td>1.7% (1/58) Prevena Therapy vs. 5.6% (4/71) Control (p=0.31)**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in Local SSI*</td>
<td>1.7% (1/58) Prevena Therapy vs. 14.1% (10/71) Control (p=0.01)**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in Wound Healing Complications*</td>
<td>8.6% (5/58) Prevena Therapy vs. 42.3% (30/71) Control (p=0.0005)**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in SSI*</td>
<td>5.0% (3/58) Prevena Therapy vs. 23% (16/71) Control (p=0.01)**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in DSSI</td>
<td>0.0% (0/58) Prevena Therapy vs. 2.4% (2/71) Control (p=0.69)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in Revision Surgery*</td>
<td>1.7% (1/58) Prevena Therapy vs. 14.1% (10/71) Control (p=0.01)**</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Statistically significant (p<0.05)

Although the authors reported use of Prevena Therapy for a mean of 3.6 days (ranging from 2 to 10 days), a mean time of application outside the recommendation for Optimum Use as stated in the 3M™ Prevena™ Incision Management System Clinical Guidance Instructions for Use. The Prevena Infection 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.

Read the full study here

Journal: International Wound Journal
Title: Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study
Published: October 25, 2017

Hou Y. Incidence and impact of surgical site infections on length of stay and cost of care in open surgical procedures. HEOR-2021-003-DAR. 2. Hou Y. Incidence and impact of surgical site complications on length of stay and cost of care in open surgical procedures. HEOR-2021-004-DAR.

Reference

Closed Incision Negative Pressure Therapy Reduces Surgical Site Infections in Vascular Surgery: A Prospective Randomised Trial (AIMS Trial)


Study Design
Prospective, multi-center, randomized controlled trial

Study Purpose
This prospective RCT aimed to assess the potential benefit of ciNPT (3M™ Prevena™ Therapy) application to reduce the risk of total SSI.

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

Key Points
- Study found 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

<table>
<thead>
<tr>
<th>Reduction in SSI*</th>
<th>60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.2% (13/98) Prevena Therapy vs. 33.3% (32/98) SOC (p=0.0015)*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reduction in SSIs*</th>
<th>67%</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1% (8/98) Prevena Therapy vs. 26.7% (26/98) SOC (p=0.0012)*</td>
<td></td>
</tr>
</tbody>
</table>

Cost-Effectiveness Based on Gombert et al Outcomes

<table>
<thead>
<tr>
<th>Vascular Groin Hypothetical Economic Model</th>
<th>Prevena™ Therapy</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients (n)</td>
<td>98</td>
<td>90</td>
</tr>
<tr>
<td>Number of Surgical Site Infections (a)</td>
<td>13</td>
<td>30</td>
</tr>
<tr>
<td>Cost Per SSI (b)</td>
<td>$21,827</td>
<td>$21,827</td>
</tr>
<tr>
<td>Cost of SSI per Patient*(a*b)/n</td>
<td>$2,895</td>
<td>$7,276</td>
</tr>
<tr>
<td>Cost of Therapy Per Patient*</td>
<td>$495</td>
<td>–</td>
</tr>
<tr>
<td>Total Cost Per Patient</td>
<td>$3,390</td>
<td>$7,276</td>
</tr>
</tbody>
</table>

Potential Per Incision Savings Using Prevena™ Therapy

$3,886

Illustration of the 3M™ Prevena™ Therapy Incision Management System

Read the full study here

Journal: European Journal of Vascular and Endovascular Surgery
Title: Closed Incision Negative Pressure Therapy Reduces Surgical Site Infections in Vascular Surgery: A Prospective Randomised Trial (AIMS Trial)
Published: July 2, 2018

*Statistically significant (p<0.05)

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

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy. The model is not intended to provide a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference
1. Hou Y. Incidence and impact of surgical site infections on length of stay and cost of care in open surgical procedures. HEOR-2021-003-DAR.
A systematic review and meta-analysis of randomized controlled trials for the reduction of surgical site infection in closed incision management versus standard of care dressings over closed vascular groin incisions

Alexander Gombert, Ellen Dillavou, Ralph D’Agostino, Jr, Leah Griffin, Julie M Robertson, and Mark Eells

Study Type
This study was a systematic review and meta-analysis of randomized 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, randomized 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 favor of ciNPT. High-risk, normal-risk, Szilagyi I, and Szilagyi II meta-analyses were also statistically significant in favor of ciNPT use (p < 0.05).

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

(Continued)
A Cost-Utility Analysis of the Use of Closed-Incision Negative Pressure System in Vascular Surgery Groin Incisions

Joshua A Bloom, MD, Tina Tian, MD, Christopher Homisy, MD, Dhruv Singhal, MD, Payam Salehi, MD, PhD, and Abhishek Chatterjee, MD, MBA, FACS

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

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

Methods

Population included: Patients undergoing femoral-popliteal bypass with prosthetic graft.

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

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

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

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

The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seroma in the all surgical procedures and populations has not been demonstrated.

References
5. Carlyle D, Zuckerman J, Lessinger J, Jacobson M, Joseph M, Mark I. Chronic obstructive pulmonary disease (COPD) and the costs and utilities associated with them such as lower extremity claudication and tissue necrosis.

Patient and Procedure Risk Stratification Backed By Clinical Evidence

While surgical patients may benefit from Prevena Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data 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.
Ellen Dillavou, MD, FACS, is the medical director of vascular surgery at the WakeMed hospital system in Raleigh, NC. She earned a BA at Macalester College in St. Paul, MN, an MD at the University of Arizona, completed general surgery training at Thomas Jefferson University of Philadelphia, and a vascular surgery fellowship at The University of Pittsburgh Medical Center. Her work centers on complicated dialysis access, surgical quality improvement and surgical site infection prevention.

Ellen Dillavou, MD, FACS, RPVI
Medical Director, Vascular Surgery
WakeMed Hospitals
Raleigh, NC

Dr. Dillavou is a paid consultant for 3M.

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

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

— Dr. Gombert
PRM in Cardiothoracic Surgery

Prevena.com/cardiothoracic
Sternotomy patients that used 3M™ Prevena™ Therapy experienced significant reduction in rate of wound infection


Reduction in the incidence of wound infection after median sternotomy in high-risk, obese patients

Summary of study findings
Closed incision negative pressure therapy (ciNPT) reduces the rate of post sternotomy wound infection in high-risk, obese patients. In addition to the above clinical outcomes, an illustrative hypothetical economic model relying on this and other study data showed a potential 69% reduction in mean per patient cost for SSI in high risk patients.

Potential per patient cost of $2,404 Prevena Therapy vs. $7,635 SOC

3M™ modeling based on selected study data from citations 1 and 2, and reasonable product cost estimates, to illustrate cost estimates/potential savings for use of Prevena Therapy versus Standard of Care. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. Results are based on selected study data, estimated costs; they may not be typical and individual prices may vary. The model is meant as an illustration only to assist in an overall assessment of products and pricing.

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 ≥ 30 kg/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.

Results

| Reduced rate of SSI | 75% |
| Reduced rate of wound infection with gram-positive skin flora* | 90% |

| 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 https://prevena.com.

Study Design
Prospective, single-center, controlled trial

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

Summary of study findings

Application of surgical incision management using ciNPT on clean, closed surgical incisions reduced the rate of post sternotomy wound infection. In addition to the above clinical outcomes, an illustrative hypothetical economic model relying on this and other study data showed a potential 32% reduction in mean per patient cost for SSI in all patients.

Potential per patient cost of $1,099 Prevena Therapy vs. $1,618 SOC

3M modeling based on selected study data from citations 4 and 2, and reasonable product cost estimates, to illustrate cost estimates/potential savings for use of Prevena Therapy versus Standard of Care. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. Results are based on selected study data, estimated costs; they may not be typical and individual prices may vary. The model is meant as an illustration only to assist in an overall assessment of products and pricing.

Study Design
Prospective study with retrospective historical control, single-center study

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 totaling 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 90 days.

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 https://prevena.com.

References

Results

| Reducing the rate of SSI | 65% |
| Primary wound closure at day 6/7 on removal* | 99% |

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 https://prevena.com.

References

Journal: The Journal of Thoracic and Cardiovascular Surgery
Title: Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy
Published: October 29, 2012

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


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 and 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.

(Continued)

Results

Reduction in SSI

5.6% (10/181) Prevena Therapy vs. 12.3% (20/162) SOC (p=0.049)*

(Continued)

Illustration of the 3M™ Prevena™ Therapy Incision Management System

Cost-Effectiveness Based on Suelo-Calanao et al 2020 Clinical Outcomes

<table>
<thead>
<tr>
<th>Hypothetical Economic Model</th>
<th>Prevena™ Therapy</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients (n)</td>
<td>158</td>
<td>162</td>
</tr>
<tr>
<td>Number of Surgical Site Infections (a)</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Cost Per Surgical Site Infection (b)</td>
<td>$47,721</td>
<td>$47,721</td>
</tr>
<tr>
<td>Cost of SSI per Patient (a*b)/n</td>
<td>$2,718</td>
<td>$5,891</td>
</tr>
<tr>
<td>Cost of Therapy Per Patient*</td>
<td>$495</td>
<td>–</td>
</tr>
<tr>
<td>Total Cost Per Patient</td>
<td>$3,213</td>
<td>$5,891</td>
</tr>
</tbody>
</table>

Potential Per Incision Savings Using Prevena™ Therapy

$2,678

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

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

Reference
1. Hou Y. Incidence and impact of surgical site infections on length of stay and cost of care in open surgical procedures. HEOR-2021-003-DAR.

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 sepsis in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at Prevena.com/cardiothoracic.

Read the full study here

Journal: Journal of Cardiathoracic Surgery
Title: The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high risk cases: a single centre retrospective study
Published: August 19, 2020

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

Author Biography*

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

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

— Dr. Reddy
Negative Pressure Wound Therapy for Surgical-site Infections: A Randomized Trial


Summary of findings
This randomized controlled trial from Johns Hopkins Hospital demonstrated significantly lower SSI rates in high-risk patients receiving Prevena Therapy after pancreaticoduodenectomy (31.1% vs. 9.7%; p=0.003)*. SSIs resulted in an increased hospitalization cost of $9,778 per patient.

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

Study Design
Randomized Controlled Trial, Single-Center (Johns Hopkins Hospital)

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 pancreatoduodenectomy.

Methods
• Patients undergoing pancreatoduodenectomy 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/

The effectiveness of Prevena Therapy in reducing the incidence of SSIs and sepsis 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 Randomized Trial
Published: June 1, 2019

Reduction of Wound Complication Risk and Length of Stay with 3M™ Prevena™ Therapy


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.

Study Design
Retrospective comparative cohort study

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 center 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

The effectiveness of Prevena Therapy in reducing the incidence of SSIs and sepsis 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)
†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.
Patient and Procedure Risk Stratification Backed By Clinical Evidence

While surgical patients may benefit from Prevena Therapy, patients at high risk for complications such as surgical site infection may see added benefit. The following uses select study data 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.

**Start here**

### Patient Risk Stratification

**General Surgery**

Does the patient have at least one of the following risk factors for developing surgical site complications?

- Obesity (e.g., BMI >30 kg/m²)
- Active tobacco use
- Depository or immunosuppressant use
- Advanced age
- Hypertension
- Malignancy
- Malnutrition
- Diffuse atherosclerotic disease
- Pulmonary disease
- Chronic inflammatory disease
- Peptic ulcer disease
- Nocoadjuvant chemotherapy

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### Procedure Risk Stratification

**General Surgery**

Is the procedure high risk?

- Emergency surgery
- Revision surgery
- Extended surgical time
- Traumatized soft tissue
- High-tension incision
- Multiple incisions

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### Consider Prevena Therapy

For additional safety information and instructions for use, consult the 3M™ Prevena Incision Management System Clinician Guide or contact your local 3M representative.

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

**References**


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For additional safety information and instructions for use, consult the 3M™ Prevena Incision Management System Clinician Guide or contact your local 3M representative.

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

**References**

PRM in Spine Surgery
Effect of Incisional Negative Pressure Wound Therapy vs Standard Wound Dressing on the Development of Surgical Site Infection after Spinal Surgery: A Prospective Observational Study

Mueller, Kyle B MD; D’Antuono, Matthew BS; Patel, Nirali MD; Pivazyan, Gnel MD; Aulisi, Edward F MD; Evans, Karen K MD; Nair, M Nathan MD, MPH, MBA

Study Type
This was a prospective observational study.

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

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

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

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

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

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.
Case Studies

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

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

Patient
A 56-year-old female presented to the hospital with worsening back pain and neurogenic claudication. Medical history included diabetes, hypertension, hyperlipidemia, morbid obesity (BMI 42 kg/m²), and diminished mobility. Laboratory examination revealed prealbumin levels at 11 mg/dL and albumin at 3.0 g/dL, indicative of malnutrition. The patient was diagnosed with degenerative disc disease with sagittal malalignment and severe lumbar stenosis.

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

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

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

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

(Continued)
Discharge and Follow-up

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

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

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

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

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

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

Patient

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

Procedure

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

Application of 3M™ Prevena™ Incision Management System

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

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

(Continued)
Discharge and Follow-up

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

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

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

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient’s circumstances and condition.
Dr. Kyle Mueller is an Assistant Professor in the Department of Neurosurgery at the University of Pennsylvania. Dr. Mueller is a graduate of Texas A&M Health Science Center College of Medicine. He completed a residency in neurosurgery at Georgetown University Medical Center in Washington, D.C., followed by a fellowship in spine biomechanics research in the Department of Orthopedic Surgery at Medstar Union Memorial Hospital in Baltimore, Maryland, under Dr. Bryan Cunningham. Subsequently, he completed a complex spine fellowship in the Department of Neurosurgery at Warren Alpert Medical School of Brown University/Rhode Island Hospital under Dr. Ziya Gokaslan.

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

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

— Dr. Mueller

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

Dr. Mueller is a paid consultant for 3M.

Product Overview

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

3M™ Prevena™ Therapy Units

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™ Restor™ Dressings

3M™ Prevena™ Restor™ Ante•Form™ Dressing

3M™ Prevena™ Restor™ Auto•Form™ Dressing

3M™ Prevena™ Restor™ Bella•Form™ Dressing

3M™ Prevena™ Restor™ Roto•Form™ Dressing

3M™ Prevena™ Restor™ Adapti•Form™ Dressing

Healthcare Professionals:
Visit prevena.com to learn more, request a demonstration, or contact a sales representative.

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

The 3M™ Prevena Restor™ Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy. 3M™ Prevena™ 125 and 3M™ Prevena™ Plus 125 Therapy Units manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, Prevena 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and II wounds.

NOTE: Applicable therapy units include Prevena 125 and Prevena Plus 125 Therapy Unit 7 day. The indication statement does not apply to the Prevena Plus 125 Therapy Unit 14-day that comes with the Prevena Restor System Kits (see Prevena Restor System indications for use).

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

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