



Prevena™
Incision Therapy

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

Cardiac Surgery

Advancing the standard of care

Helping to protect cardiac surgery
incisions beyond the OR



Cardiac surgery patient care doesn't end in the OR

In an increasingly overwhelmed healthcare system, surgeons are asked to do more with fewer resources than ever before, creating complications for patients that extend beyond the operating room. Postoperative concerns include swelling, infection and improper tissue integration in and around the surgical site.

These complications can create a ripple effect of consequences, like disrupted healing, extended hospital stays and poor patient outcomes, which inevitably cause further disruption that impacts quality and cost of care. Today's complex care environment makes protecting against the ripple effect of these complications a high priority.

The implications of postoperative complications

Open-heart cardiac surgery with median sternotomy access can sometimes be followed by severe complications, including sternal wound infections (SWIs). SWIs are a rare and life-threatening complication that's particularly challenging to treat in cardiothoracic surgery patients. The greatest concern with SWIs is the potential for progression to deep sternal wound infections (DSWIs) and subsequently lead to mediastinitis, which is associated with a high risk of mortality and cost.

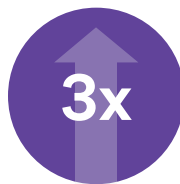
The most common source of infection for cardiac surgery patients is endogenous flora from the patient's own skin, including Methicillin-resistant Staphylococcus aureus (MRSA). These infections typically occur within the first three postoperative weeks, with increased rates in patients with comorbidities or previous cardiac surgery.¹

The incidence of SWIs is estimated to 9.8% and DSWIs occur less frequently, with an incidence of up to 3%.^{2,3}

Deep sternal wound infections have been associated with the following increased mortality and resource utilization:



Higher one-year mortality rates for patients with DSWI³



Higher length of stay for patients with DSWI³



Increase in cost to the hospital system³

Patient comorbidities such as obesity [body mass index (BMI) ≥ 30], diabetes, smoking, chronic obstructive pulmonary disease (COPD), and advanced age are all considered high-risk factors for developing postoperative SWIs.⁴

Managing the ripple effect

Given the ever-increasing challenges of cardiac surgery, clinicians and surgeons need support to safeguard their work and improve the patient's healing journey. In their efforts to effectively manage the ripple effect of surgical complications they are often motivated to favor low-touch care, including solutions that promote:

- Efficiency and cost-effectiveness
- Minimal hospital stays
- Minimal complications
- Low re-admits
- Portability of care
- Home-based recovery
- Telehealth consultations

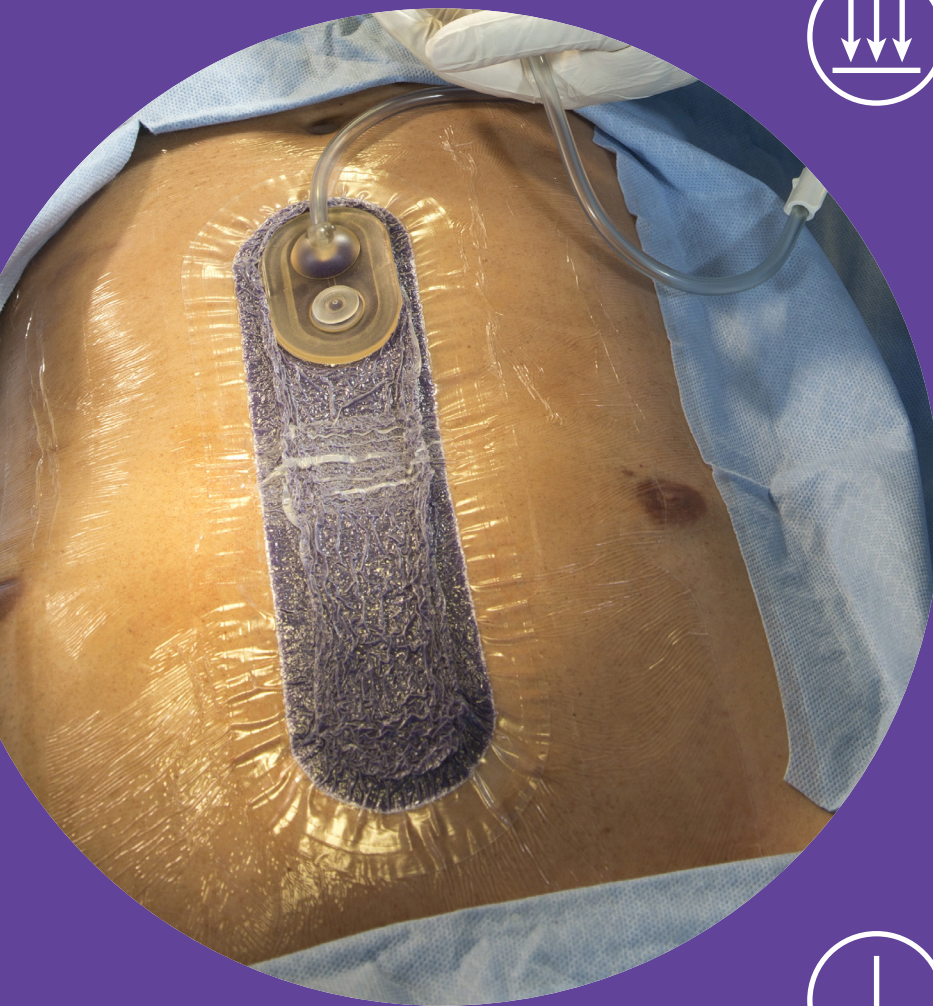
Consider how minimizing these ripple effects would affect your caseload and budgets, particularly readmissions and prolonged lengths of stay.



The power to help protect outcomes beyond the OR

3M™ Prevena™ Therapy is the first closed-incision negative pressure therapy (ciNPT) solution of its kind to help reduce the risk or incidence of seromas and superficial surgical site infections (SSIs) in high-risk patients with Class I and II wounds.* It helps protect the incision site after surgery up to 7 days — extending your control over postoperative healing while helping patients at risk of developing complications.

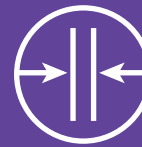
Prevena Therapy offers surgeons the confidence to help protect patients beyond the OR.



Acting as a barrier to external contamination



Delivering continuous -125 mmHg up to 7 days



Helping to hold incision edges together



Decreasing lateral tension of sutured/stapled incisions⁵



Removing fluids and infectious materials**



Reducing edema

*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.

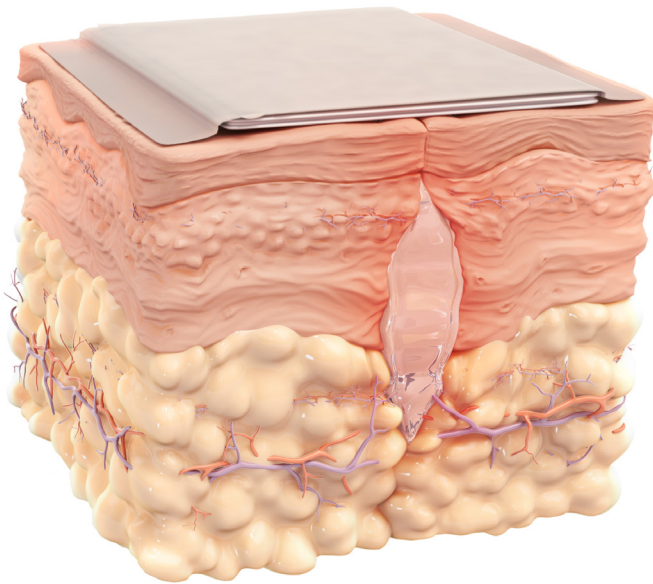
**In a canister.

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

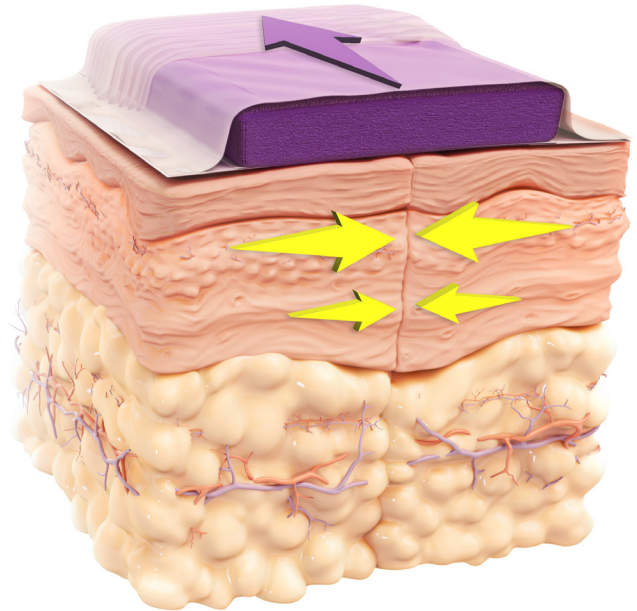
The advanced science of 3M™ Prevena™ Therapy

Prevena Therapy utilizes continuous -125 mmHg negative pressure wound therapy, reticulated open cell foam (ROCF) dressing technology, and optimized exudate management (replaceable canister) to help enhance healing. Visible and audible safety alarms automatically notify clinicians and patients of system alerts.

Prevena Therapy helps hold the incision edges together, reduces lateral tension, and allows for improved fluid management.⁵⁻⁷



Passive Therapy



3M™ Prevena™ Therapy  Direction of fluid
 Appositional force

Additional features to help optimize postoperative care

- Contours in Prevena Dressings allow for even distribution of negative pressure
- Adhesive film creates a barrier to external contaminants
- Designed to conform to allow movement
- Multiple sizes and configurations
- Prevena Dressings are shower friendly*



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

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

A multidisciplinary group of surgical and infectious disease experts developed an algorithm to guide when to consider using closed-incision negative pressure therapy (ciNPT).⁸ They recommend that surgeons consider using ciNPT for patients at high risk for developing surgical site occurrences (SSOs) or who are undergoing a high-risk procedure or a procedure that would have highly morbid consequences if a surgical site infection (SSI) occurred.

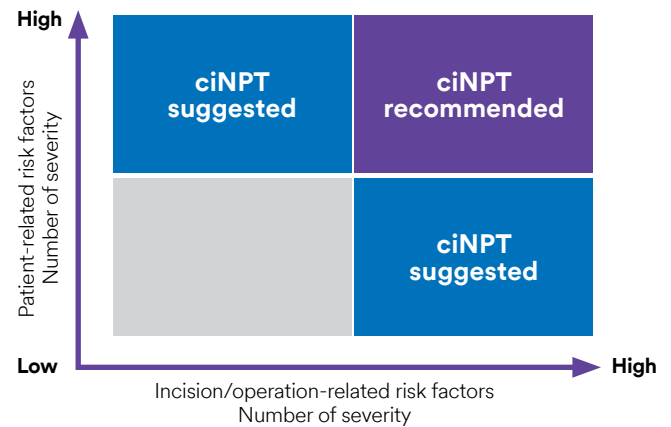
Consensus recommendations based on:

- Literature review
- ciNPT experiences
- Known risk factors for 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

Risk factor assessment for ciNPT



Additional factors to consider:

Patient-related risk factors		General incision-related factors	
<ul style="list-style-type: none"> • Diabetes mellitus • Acetylsalicylic acid Score ≥ 3 • Advanced age • Obesity • Active tobacco use • Hypoalbuminemia • Corticosteroid usage 	<ul style="list-style-type: none"> • Active alcoholism • Male sex • Hematoma • Chronic renal insufficiency • Chronic obstructive pulmonary disease 	<ul style="list-style-type: none"> • High tension incision • Repeated incisions • Extensive undermining • Traumatized soft tissue • Edema • Contamination • Emergency procedure 	<ul style="list-style-type: none"> • Prolonged operation time • Post-surgical radiation • Mechanically unfavorable site

Procedure/operation-related risk factors:

General	Plastic	Orthopedic	Vascular	Cardiovascular
<ul style="list-style-type: none"> • Open general • Open colorectal • Open urology • Open obstetrics/gynecology • Incisional hernia repair 	<ul style="list-style-type: none"> • Post-bariatric abdominoplasty • Breast reconstruction • Big soft tissue defects • Soilage risk 	<ul style="list-style-type: none"> • Open reduction and internal fixation of fractures • Fasciotomy • Above/below knee amputation 	<ul style="list-style-type: none"> • Above/below knee amputation • Synthetic graft implantations 	<ul style="list-style-type: none"> • Sternotomy

“

When we operate in the chest area these patients have pacing cables and telemetry wires all over their chests. Prevena Therapy creates an important barrier for the incision from all sorts of external contaminants.”

– Dr. V. Seenu Reddy, Chief of Cardiothoracic Surgery
3M paid consultant



Note: Individual results may vary.

FDA indications for use

3M™ Prevena™ 125 Therapy Unit and 3M™ Prevena™ Plus 125 Therapy Unit manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125 mmHg continuous negative pressure. When used with legally marketed compatible dressings, Prevena 125 Therapy Unit and Prevena Plus 125 Therapy Unit are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.

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

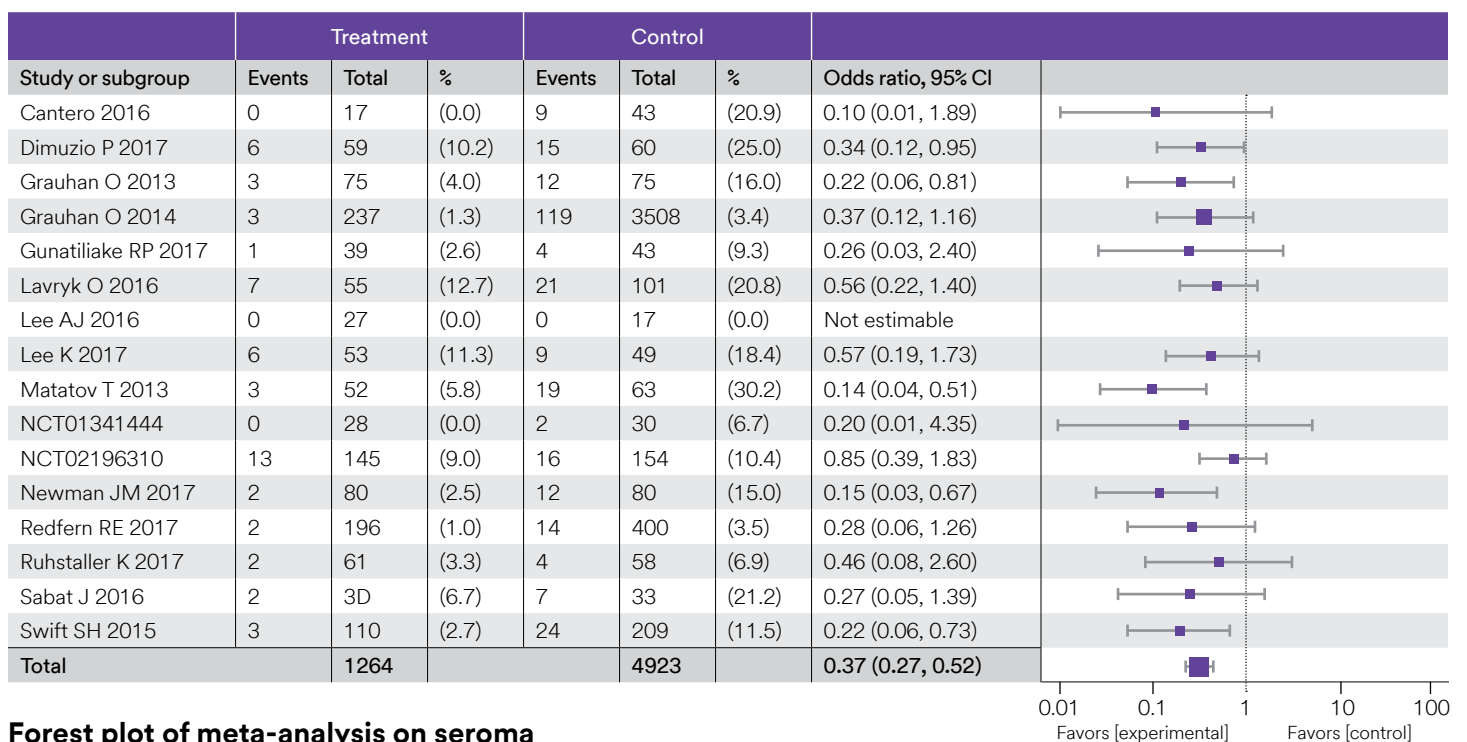


Clinical evidence supporting the use of 3M™ Prevena™ Therapy is growing

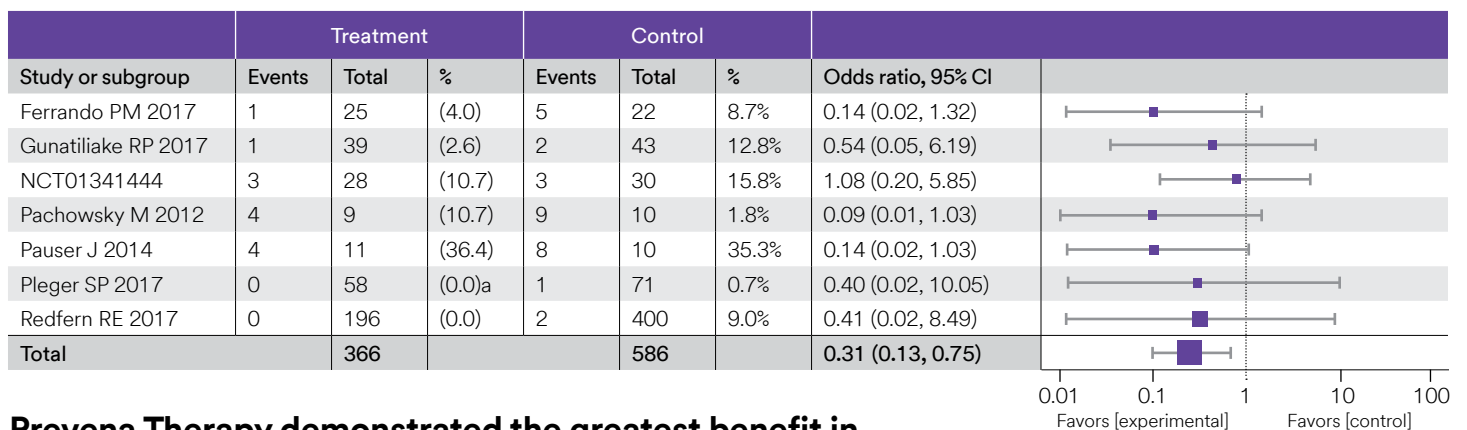
A growing body of evidence supports the use of Prevena Therapy to address the challenges of surgical incision complications. A systematic literature review and associated meta-analysis support the safety and effectiveness of Prevena Therapy over closed incisions in reducing the incidence of surgical site infections (SSIs) and seromas versus conventional wound dressings.⁹

- Out of 426 studies in the initial search, ultimately, sixteen (16) prospective studies were included in this meta-analysis for SSI characterization
- 9 randomized controlled trials (RCTs) were included in a subgroup analysis for SSI in high-risk patients
- A total of up to 6,187 evaluable patients were included in this meta-analysis for SSI with 1,264 in the Prevena Therapy (treatment) group and 4,923 in the conventional wound dressing (control) group

Forest plot of meta-analysis on SSIs



Forest plot of meta-analysis on seroma



Prevena Therapy demonstrated the greatest benefit in reducing the incidence of SSIs and seromas in high-risk patients.*

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

3M™ Prevena™ Therapy for cardiothoracic patients

Prevena Therapy helped reduce the rate of postoperative wound infections and associated readmissions in cardiothoracic patients.

Nguyen KA, Taylor GA, Webster TK, et al. *Incisional Negative Pressure Wound Therapy Is Protective Against Postoperative Cardiothoracic Wound Infection. Annals of Plastic Surgery. 2022 May 1;88(3 Suppl 3):S197-S200.*

Study Design:

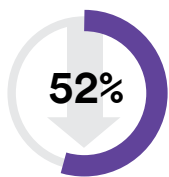
This single-center retrospective cohort study evaluated closed-incision negative pressure therapy (ciNPT) (Prevena Therapy) for reducing the rate of postoperative wound infections and improving patient outcomes.

- The study included 1,199 adult patients undergoing nontraumatic cardiothoracic surgery at a single institution between 2016 and 2018
- Surgeries included: coronary artery bypass grafting, aortic or mitral valve repair or replacement, lung transplant, heart transplant, aorta repair, left ventricular assist device, right ventricular assist device, and Ross procedure
- Patient characteristics, clinical variables, and surgical outcomes were compared between those who did and did not receive ciNPT intraoperatively
- Multivariable logistic regression analysis determined factors predictive or protective of the development of complications
- The primary outcome of this study was the incidence of wound infection; secondary outcomes included death from wound infection, surgical debridement, and readmission for sternal wound infection

Summary

The use of Prevena Therapy on sternal wound incisions significantly helped reduce the rate of postoperative wound infections, readmissions, and extracorporeal membrane oxygenation (ECMO) utilization. Investigators stated ciNPT was a protective factor against surgical wound infection complication after controlling for confounding variables (odds ratio, 0.497; 95% confidence interval, 0.262–0.945). No significant difference between ciNPT and control groups for surgical debridement or death from wound infection complication.

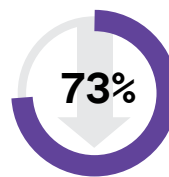
Surgical site complication



3.0% (21/706) Prevena Therapy vs.
6.3% (31/493) Control

($p=0.01$)*

Readmission



0.7% (5/706) Prevena Therapy vs.
2.6% (13/493) Control

($p=0.01$)*

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

3M™ Prevena™ Therapy for high-risk cardiothoracic patients

Prevena Therapy reduced the incidence of wound infection after median sternotomy in high-risk obese patients.

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

Study Design:

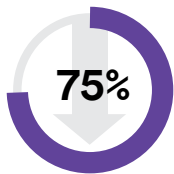
This prospective single-center randomized controlled trial evaluated closed-incision negative pressure therapy (ciNPT) (Prevena Therapy) on reducing the incidence of surgical site infections in high-risk obese patients.

- 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: Body mass index (BMI) \geq 30 kg/m²
- The control group, conventional wound dressings, comprised 75 patients with a dressing change on day 1-2
- The ciNPT group (Prevena Therapy) consisted of 75 patients with therapy placed after sutures in the operating room and dressing removed at day 6-7
- The primary data endpoint was wound infection within 90 days

Summary

The use of Prevena Therapy helped reduce the post-sternotomy wound infection rate in high-risk obese patients.

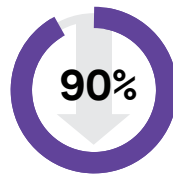
Surgical site infection



4% (3/75) Prevena Therapy vs.
16% (12/75) Control

 $(p=0.0266)^*$

Surgical site complication



Reduced rate of wound infection
with Gram-positive skin flora
1.3% (1/75) Prevena Therapy vs.
13.3% (10/75) Control

 $(p=0.0090)^*$

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

3M™ Prevena™ Therapy for median sternotomies

Prevena Therapy helped reduce the incidence of wound infection and facilitated primary wound closure after median sternotomy.

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

Study Design:

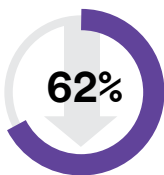
This prospective single-center study with retrospective historical control evaluated closed-incision negative pressure therapy (ciNPT) (Prevena Therapy) vs. conventional wound dressings over closed surgical incisions in reducing wound infections.

- The study group (Prevena Therapy) included all prospective patients undergoing median sternotomy from September to October 2013, totaling 237
- The control group (conventional wound dressings) included all median sternotomy patients retrospectively analyzed for the period of January 2008 to December 2009, totaling 3,508 patients
- No defined high-risk inclusion criteria
- Prevena Therapy was placed after sutures in the operating room, dressing removed at day 6-7
- The primary endpoint was wound infection within 30 days

Summary

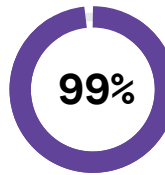
Application of Prevena Therapy on clean, closed surgical incisions helped reduce the rate of poststernotomy wound infection.

Surgical site infection



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

Wound closure on day 6-7 upon removal



98.7% (234/237) Prevena Therapy

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

Clinical evidence supporting 3M™ Prevena™ Therapy in cardiac surgery

Level of clinical evidence rating¹⁰

- **Level 1:** Evidence obtained from at least one properly designed randomized controlled trial
- **Level 1b:** Systematic reviews (with homogeneity) of randomized controlled trials
- **Level 2:** Evidence obtained from well-designed controlled trials without randomization
- **Level 2b:** Individual cohort study or low quality randomized controlled trials (e.g., <80% follow-up)
- **Level 3:** Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- **Level 4:** Case series (and poor quality cohort and case-control studies)
- **Level 5:** Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”

Wound/ Surgery Type	Level of Evidence	Citation
Cardiothoracic surgery	2	Colli A. First Experience With a New Negative Pressure Incision Management System on Surgical Incisions After Cardiac Surgery in High Risk Patients. <i>Journal of Cardiothoracic Surgery</i> . 2011 Dec 6;6(1):160.
	3	Nguyen KA, Taylor GA, Webster TK, et al. Incisional Negative Pressure Wound Therapy Is Protective Against Postoperative Cardiothoracic Wound Infection. <i>Annals of Plastic Surgery</i> . 2022 May 1;88(3 Suppl 3):S197-S200.
	5	Dohmen PM, Markou T, Ingemansson R, et al. Use of incisional negative pressure wound therapy on closed median sternal incisions after cardiothoracic surgery: clinical evidence and consensus recommendations. <i>Medical Science Monitor</i> . 2014 Oct 4;20:1814-25.
	5	Wu RT, Sumpio BJ, Miller S, et al. Use of Closed-Incision Negative-Pressure Therapy: Cardiothoracic and Vascular Surgery. <i>Plastic and Reconstructive Surgery</i> . 2019 Jan;143(Suppl 1):31S-35S.
Sternotomy	2	Grauhan O, Navasardyan A, Hofmann M, et al. Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy. <i>Journal of Thoracic and Cardiovascular Surgery</i> . 2013 May;145(5):1387-92.
	2	Grauhan O, Navasardyan A, Tutkun B, et al. Effect of surgical incision management on wound infections in a poststernotomy patient population. <i>International Wound Journal</i> . 2014 Jun;11(Suppl 1):6-9.
	3	Suelo-Calanao RL, Thomson R, Read M, et al. The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high risk cases: a single centre retrospective study. <i>Journal of Cardiothoracic Surgery</i> . 2020 Aug 19;15(1):222.
	4	Jennings S, Vahaviolos J, Chan J, et al. Prevention of Sternal Wound Infections by use of a Surgical Incision Management System: First Reported Australian Case Series. <i>Heart, Lung and Circulation</i> . 2016 Jan;25(1):89-93.
	4	Philip B, McCluskey P, Hinchion J. Experience using closed incision negative pressure wound therapy in sternotomy patients. <i>Journal of Wound Care</i> . 2017 Aug 2;26(8):491-495.
	4	Reddy VS. Use of Closed Incision Management with Negative Pressure Therapy for Complex Cardiac Patients. <i>Cureus</i> . 2016 Feb 23;8(2):e506.
Sternotomy and pectoralis major muscle flap	3	Lo Torto F, Monfrecola A, Kaciulyte J, et al. Preliminary result with incisional negative pressure wound therapy and pectoralis major muscle flap for median sternotomy wound infection in a high-risk patient population. <i>International Wound Journal</i> . 2017 Dec;14(6):1335-1339.
	3	Nickl S, Steindl J, Langthaler D, et al. First Experiences with Incisional Negative Pressure Wound Therapy in a High-Risk Poststernotomy Patient Population treated with Pectoralis Major Muscle Flap for Deep Sternal Wound Infection. <i>Journal of Reconstructive Microsurgery</i> . 2018 Jan;34(1):1-7. Epub 2017 Oct 9.

3M™ Prevena™ Therapy dressings with 3M negative pressure wound therapy devices



3M™ Prevena™ Plus 125 Therapy Unit

One single-use negative pressure wound therapy unit compatible with all 3M™ Prevena™ Dressings.

Negative pressure options:

- Pre-set, continuous negative pressure therapy at -125 mmHg for up to 7 or 14 days (with dressing changes every 7 days)
- Disposable, single patient use
- Rechargeable battery

Specifications:

- Dimensions: Approx 8.9 × 16.3 × 5.49cm
- Weight with empty canister: 0.64lbs (0.29kg)



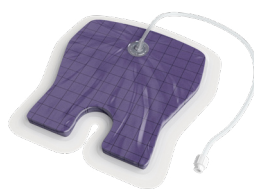
Prevena Dressings are also compatible with 3M traditional negative pressure wound therapy devices: 3M™ V.A.C.® Ultra Therapy Unit and 3M™ ActiV.A.C.® Therapy Unit

3M™ Prevena Restor™ Dressings

3M™ Prevena Restor™ Therapy extends negative pressure wound therapy beyond the incision site to include the surrounding soft tissue. It helps provide comprehensive protection, optimize surgical site recovery, and helps patients start rehab with confidence.



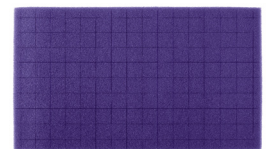
3M™ Prevena Restor™ Arthro•Form™ Dressing



3M™ Prevena Restor™ Axio•Form™ Dressing



3M™ Prevena Restor™ Bella•Form™ Dressing



3M™ Prevena Restor™ Adapti•Form™ Dressing

The same proven technology as the original 3M™ Prevena™ Incision Management System with new features to help optimize postoperative care.



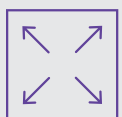
Extended therapy time

Up to 14 days (dressing change required after 7 days)



Precision designed

Dressings seamlessly conform to the patient



Expanded coverage area

Large dressings deliver therapy to the incision and surrounding soft tissue envelope



Easy to use

A variety of peel-and-place dressings are available, plus a customizable option

Additional customer resources:



Live clinical training and product support
25,000+ professionals trained annually



Clinical services and
reimbursement hotlines



Free product evaluation program



Centralized, on demand clinical
and technical support

Ordering Information

SKU	Description	UOM
Therapy Devices		
PRE4000US	3M™ Prevena™ Plus 125 Therapy Unit – 7 day	Each
PRE4010	3M™ Prevena™ Plus 125 Therapy Unit – 14 day	Each
Dressings		
PRE1055US	3M™ Prevena™ Peel and Place Dressing – 20 cm	Case of 5
PRE1155US	3M™ Prevena™ Peel and Place Dressing – 13 cm	Case of 5
PRE3255US	3M™ Prevena™ Plus Peel and Place Dressing – 35 cm	Case of 5
PRE4055US	3M™ Prevena™ Plus Customizable Dressing	Case of 5
PRE5055	3M™ Prevena Restor™ Arthro●Form™ Dressing – 33 cm x 30 cm	Case of 5
PRE5155	3M™ Prevena Restor™ Arthro●Form™ Dressing – 46 cm x 30 cm	Case of 5
PRE5255	3M™ Prevena Restor™ Bella●Form™ Dressing – 21 cm x 19 cm	Case of 5
PRE5355	3M™ Prevena Restor™ Bella●Form™ Dressing – 24 cm x 22 cm	Case of 5
PRE5455	3M™ Prevena Restor™ Bella●Form™ Dressing – 29 cm x 27 cm	Case of 5
PRE5555	3M™ Prevena Restor™ Axio●Form™ Dressing – 29 cm x 28 cm	Case of 5
PRE6055	3M™ Prevena Restor™ Adapti●Form™ Dressing – 49 cm x 28 cm	Case of 5
Accessories		
PRE1095	3M™ Prevena™ 45 ml Canister	Case of 5
PRE4095	3M™ Prevena™ Plus 150 ml Canister	Case of 5
PRE9090	3M™ Prevena™ Therapy V.A.C.® Connector	Case of 10
Kits		
PRE1001US	3M™ Prevena™ Incision Management System – 20 cm	Each
PRE1101US	3M™ Prevena™ Incision Management System – 13 cm	Each
PRE3201US	3M™ Prevena™ Plus Incision Management System – 35 cm	Each
PRE4001US	3M™ Prevena™ Plus Customizable Incision Management System	Each
PRE1121US	3M™ Prevena™ Duo Incision Management System – 13 cm/13 cm	Each
PRE3321US	3M™ Prevena™ Plus Duo Incision Management System – 13 cm/20 cm	Each
PRE3021US	3M™ Prevena™ Plus Duo Incision Management System – 20 cm/20 cm	Each
PRE5001	3M™ Prevena Restor™ Arthro●Form™ Incision Management System – 33 cm x 30 cm	Each
PRE5101	3M™ Prevena Restor™ Arthro●Form™ Incision Management System – 46 cm x 30 cm	Each
PRE5221	3M™ Prevena Restor™ Bella●Form™ Incision Management System – 21 cm x 19 cm	Each
PRE5321	3M™ Prevena Restor™ Bella●Form™ Incision Management System – 24 cm x 24 cm	Each
PRE5421	3M™ Prevena Restor™ Bella●Form™ Incision Management System – 29 cm x 27 cm	Each
PRE5501	3M™ Prevena Restor™ Axio●Form™ Incision Management System – 29 cm x 28 cm	Each
PRE6001	3M™ Prevena Restor™ Adapti●Form™ Incision Management System – 49 cm x 28 cm	Each

Help protect your patients beyond the OR with 3M™ Prevena™ Therapy.

For more information or to request an evaluation, contact your 3M representative or visit [3M.com/PrevenaCentral](https://www.3M.com/PrevenaCentral).

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

References:

1. Vos RJ, Van Putte BP, Kloppenburg GTL. Prevention of deep sternal wound infection in cardiac surgery: a literature review. *J Hosp Infect.* 2018;100:411–420.
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7. Glaser DA, Farnsworth CL, Varley ES, et al. Negative pressure therapy for closed spine incisions: A pilot study. *Wounds.* 2012;24(11):308-316.
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9. Federal Drug Administration. De Novo Classification Request for Prevena 125 and Prevena Plus 125 Therapy Units. De Novo Summary (DEN180013), 2019. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180013.pdf
10. Sullivan D, Chung KC, Eaves FF, et al. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. *Plast Reconstr Surg.* 2011;128(1):311-314.



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