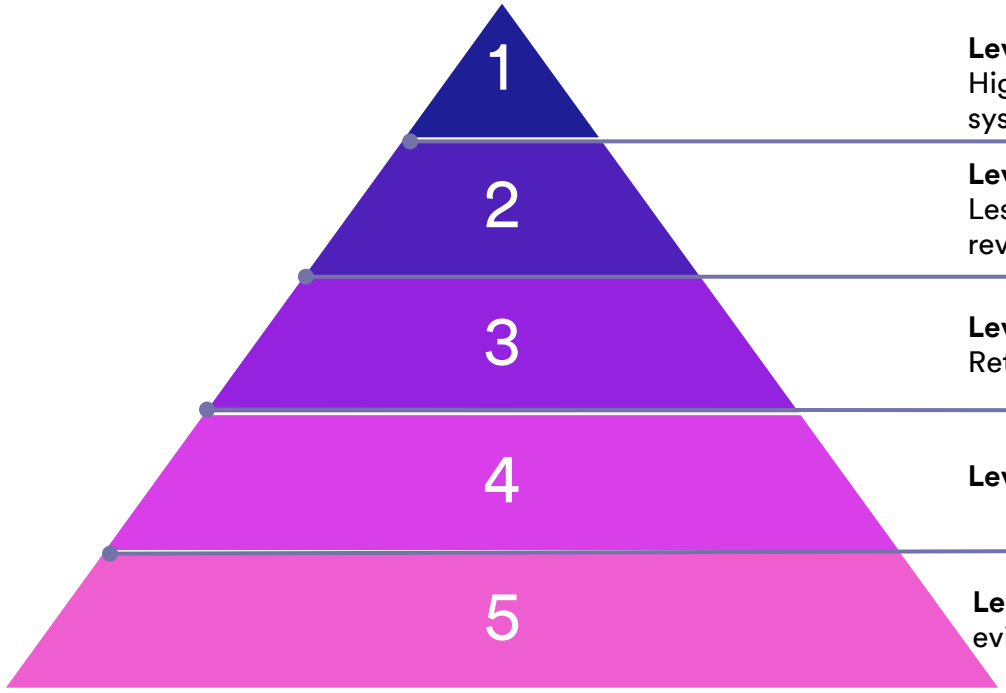
Clinical Evidence Summaries
Cardiac Surgery

Negative Pressure Therapy for Incision Management

- For over 25 years, negative pressure vacuum-assisted closure (V.A.C.®) technology has been clinically shown to promote wound healing by reducing edema and promoting granulation tissue formation and perfusion through the removal of exudate and infectious materials.
- 3M extended the use of its negative pressure technology to closed surgical incisions with similarly positive clinical results, outlined in more than 200+ journal publications focused on closed incision negative pressure therapy (ciNPT)/3M™ Prevena™ Therapy.
- The Prevena Therapy clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale[1] and reflect the benefits of ciNPT for different incision types and surgical outcomes compared to the standard of care.



Level 1:
High-quality, multicenter or single-center, randomized controlled trial with adequate power; or systematic review of these

Level 2:
Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies.

Level 3:
Retrospective cohort or comparative study; case-control study; or systematic review of these studies

Level 4: Case series with pre/post test or only post test

Level 5: Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or “first principles”

Reference: 1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. Plast Reconstr Surg 2011;128(1):311-314

3M Prevena™ Therapy evidence table

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

Surgical Incision	ASPS Level of Evidence	First Author (Year)	Surgical Incision Type	Control	Postoperative Clinical Endpoints*
Sternotomy	2	Grauhan (2013)	Median Sternotomy - In high-risk patients	Standard dressing	Surgical Site Infection (SSI); SSI w/Gram-positive Skin Flora
		Grauhan (2014)	Median Sternotomy – All Patients	Standard dressing	SSI
	3	Nguyen (2022)	Median sternotomy, unilateral thoracotomy, and bilateral anterior (clamshell) thoracotomy	Standard dressing	Surgical Wound Infection (SWI), Readmissions for Wound infection
		Suelo-Calanao RL et al (2020)	Median Sternotomy	Standard dressing	SWI

* Clinical endpoints reflect the conditions and methods specific to each publication and should not be interpreted as general outcomes related to Prevena Therapy. Individual results for each case may vary, depending on the patient, circumstances, and conditions.

Reference: 1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. Plast Reconstr Surg 2011;128(1):311-314

Reduction in the incidence of wound infection after median sternotomy in a high-risk obese patients with 3M™ Prevena™ Therapy

Level of Evidence 2

Sternotomy

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

Study Design

Prospective, single-center, controlled trial (Level II)

Study Purpose

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

Methods

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

Key Results

Surgical Site Infections

⬇75%

Reduced rate of SSIs*
4% (3/75) Prevena Therapy vs.
16% (12/75) Standard Dressing
(p=0.0266)*

Gram Positive Infections

⬇90%

Reduced rate of wound infection with Gram-Positive Skin Flora*
1.3% (1/75) Prevena Therapy vs.
13.3% (10/75) Standard Dressing
(p=0.0090)*

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

Summary

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

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Grauhan et al 2013 Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	75	75
Number of Surgical Site Infections (a)	3	12
Cost per SSI[1] (b)	$45,578	$45,578
Cost of SSI per Patient [c=(a*b)/n]	$1,823	$7,292
Per Patient Therapy Cost* (d)	$495	---
Total Cost Per Patient (c+d)	**$2,318**	**$7,292**
Potential Per Patient Savings Using Prevena Therapy	**$4,974**	

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

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

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

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

Effect of 3M™ Prevena™ Therapy on wound infections in post sternotomy patient population

Level of Evidence 2

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

Prospective study with retrospective historical control, single-center study (Level II)

Study Purpose

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

Methods

- The study group (Prevena Therapy) included ALL prospective patients undergoing median sternotomy from September - October 2013 totalling 237 patients.
- The control group (standard dressing) included ALL median sternotomy patients retrospectively analysed for the period of January 2008 – December 2009 totalling 3508 patients.
- The study population included 'all comers' with no defined high risk inclusion criteria.
- Prevena Therapy was placed immediately after suturing. Post Op dressing removal at day 6-7.
- The primary end point was sternal wound infection (SWI) within 30 days requiring surgical revision and application of NPWT to the open surgical wound in most cases.

Key Results

Surgical Site Infections

⬇62%

Reduced rate of SWI requiring revision*
1.3% (3/237) Prevena Therapy vs.
3.4% (119/3508) Standard Dressing
(p<0.05)*

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

Summary

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

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Grauhan et al 2014 Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	237	3508
Number of Surgical Site Infections (a)	3	119
Cost per SSI[1] (b)	$45,578	$45,578
Cost of SSI per Patient [c=(a*b)/n]	$577	$1,546
Per Patient Therapy Cost* (d)	$495	---
Total Cost Per Patient (c+d)	**$1,072**	**$1,546**
Potential Per Patient Savings Using Prevena Therapy	**$474**	

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

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

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Reference: 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

3M™ Prevena™ Therapy helped reduce the rate of postop wound infections and associated readmissions in cardiothoracic surgical patients

Level of Evidence 3

Sternotomy, Thoracotomy

Nguyen KA, Taylor GA, Webster TK, et al. Incisional Negative Pressure Wound Therapy Is Protective Against Postoperative Cardiothoracic Wound Infection. Ann Plast Surg. 2022;88(3 Suppl 3):S197-S200. doi:10.1097/SAP.0000000000003196

Study Design

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

Study Purpose

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

Methods

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

Key Results

Sternal Wound Infection

⬇52%

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

Readmissions for wound infection

⬇73%

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

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

Summary

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

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

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	706	493
Number of Surgical Site Infections (a)	21	31
Cost per SSI[1] (b)	$45,578	$45,578
Cost of SSI per Patient [c=(a*b)/n]	$1,356	$2,866
Per Patient Therapy Cost* (d)	$495	---
Total Cost Per Patient (c+d)	**$1,851**	**$2,866**
Potential Per Patient Savings Using Prevena Therapy	**$1,015**	

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

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Reference: Nguyen KA, Taylor GA, Webster TK, et al. Incisional Negative Pressure Wound Therapy Is Protective Against Postoperative Cardiothoracic Wound Infection. Ann Plast Surg. 2022;88(3 Suppl 3):S197-S200. doi:10.1097/SAP.0000000000003196

Effect of 3M™ Prevena™ Therapy for the prevention of sternal wound infection for high-risk patients

Level of Evidence 3

Sternotomy

Suelo-Calanao RL et al (UK). The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high-risk cases: a single center retrospective study. J Cardiothoracic Surg. 2020 Aug 19;15(1):222

Study Design

Retrospective cohort study (Level III)

Study Purpose

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

Methods

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

Key Results

Sternal Wound Infection (SWI) in High-Risk Patients

⬇54%

Reduced rate of SWIs*
5.7% (9/158) Prevena Therapy vs.
12.3% (20/162) Standard Dressing
(p=0.049)*

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

Summary

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

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

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	158	162
Number of Surgical Site Infections (a)	9	20
Cost per SSI[1] (b)	$45,578	$45,578
Cost of SSI per Patient [c=(a*b)/n]	$2,596	$5,627
Per Patient Therapy Cost* (d)	$495	---
Total Cost Per Patient (c+d)	**$3,091**	**$5,627**
Potential Per Patient Savings Using Prevena Therapy	**$2,536**	

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

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Reference: 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

3M™ Prevena™ Therapy for the high-risk Sternotomy patient

How to identify the patient as high-risk for surgical site infection or complication:

Sternotomy Incisions

Patients are high-risk if they have

- BMI > 30 kg/m^2

or ≥ 2 of the following risk factors:

- Age ≥ 80
- Chronic obstructive pulmonary disease (COPD)
- Diabetes

References:

1. *Suelo-Calanao RL et al (UK). The impact of closed incision negative pressure therapy on prevention of median sternotomy infection for high-risk cases: a single center retrospective study. J Cardiothoracic Surg. 2020 Aug 19;15(1):222*
2. *Grauhan O, Navasardyan A, Hofmann M, Muller P, Stein J, Hetzer R. Prevention of post sternotomy wound infections in obese patients by negative pressure wound therapy. J Thorac Cardiovasc Surg 2013;145:1387-1392.*