

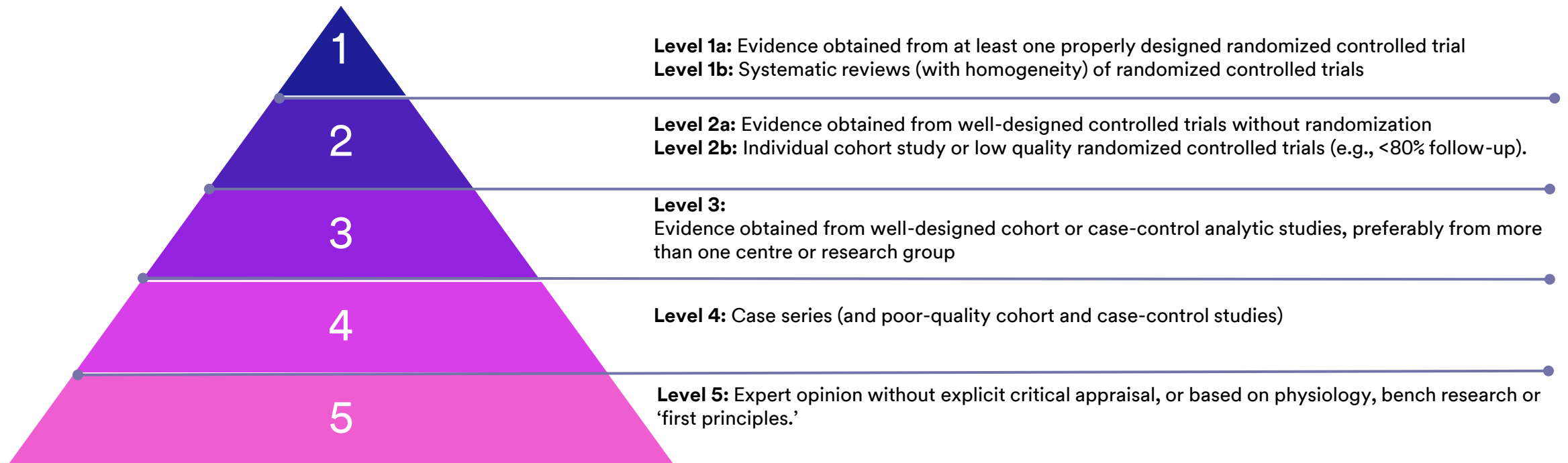


Prevena™
Incision Therapy

Clinical Evidence *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 70+ journal publications focused on closed incision negative pressure therapy (ciNPT), with nearly half of the evidence specific to orthopedic cases.
- The 3M™ Prevena™ Incision Management System clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale¹ and reflect the benefits of ciNPT for different incision types and surgical outcomes compared to the standard of care.



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

- The body of evidence for using ciNPT has been growing steadily since 2015
- 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 O (GE) (2013)	Median Sternotomy	Conventional wound dressings	Surgical Site Infection (SSI); SSI w/Gram-positive Skin Flora
		Grauhan O (GE) (2014)	Median Sternotomy – All Patients	Conventional wound tape dressings	SSI
	3	Suelo-Calanao RL et al (UK). (2020)	Median Sternotomy	Standard wound dressing before NPT use	SSI

* 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.

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

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.

2
LOE

Sternotomy

Study Design

Prospective, single-centre, controlled trial (Germany)

Study Purpose

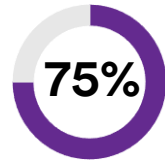
To evaluate negative pressure wound dressing treatment (3M™ Prevena™ Therapy) for infection prevention.

Methods

- The study included 150 consecutive obese patients who underwent a median sternotomy at a single site in Germany between April 2010 and October 2011.
- Inclusion criteria was a body mass index ≥ 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.

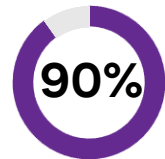
Results

Surgical Site Infections



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

Gram Positive Infections



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

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

Key Points

Summary

ciNPT reduces the rate of post sternotomy wound infection in high-risk obese patients.

Illustration of the 3M™ Prevena™ Incision Management System cost effectiveness based on Grauhan et al 2013 clinical outcomes.

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.

Hypothetical Economic Model	3M™ Prevena™ Therapy	Control
Number of Patients (n)	75	75
Number of Surgical Site Infections (a)	3	12
Cost Per Surgical Site Infection ^{1(b)}	\$47,721	\$47,721
Cost of SSI per Patient (a*b)/n	\$1,909	\$7,635
Cost of Therapy Per Patient*	\$495	---
Total Cost Per Patient	\$2,404	\$7,635
Potential Per Incision Savings Using Prevena Therapy	\$5,231	



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.

*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 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.

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

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

LOE

Study Design

Prospective study with retrospective historical control, single-centre study (Germany)

Study Purpose

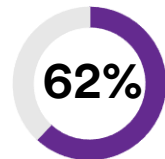
The purpose of this study was to evaluate 3M™ Prevena™ Therapy vs. conventional wound dressings over closed surgical incisions in reducing wound infections.

Methods

- The study group (Prevena Therapy) included ALL prospective patients undergoing median sternotomy from September - October 2013 totalling 237 patients.
- The control group (conventional wound dressings) included ALL median sternotomy patients retrospectively analysed for the period of January 2008 – December 2009 totalling 3508 patients.
- No defined High-Risk Inclusion Criteria
- Prevena Therapy placed immediately after suturing. Post Op dressing removal at day 6-7.
- The primary end point was wound infection within 30 days.

Results

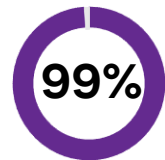
Surgical Site Infections



Reduction in SSIs

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

Wound Closure



Primary Wound Closure at day 6/7 on removal*

98.7% (234/237) Prevena Therapy

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

Key Points

Summary

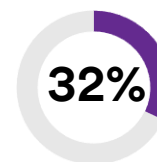
Application of surgical incision management using ciNPT on clean, closed surgical incisions reduced the rate of post sternotomy wound infection.

Illustration of the 3M™ Prevena™ Incision Management System cost effectiveness based on Grauhan et al 2014 clinical outcomes.

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

Hypothetical Economic Model	3M™ Prevena™ Therapy	Control
Number of Patients (n)	237	3508
Number of Surgical Site Infections (a)	3	119
Cost Per Surgical Site Infection ^{1(b)}	\$47,721	\$47,721
Cost of SSI per Patient (a*b)/n	\$604	\$1,618
Cost of Therapy Per Patient*	\$495	---
Total Cost Per Patient	\$1,099	\$1,618
Potential Per Incision Savings Using Prevena Therapy	\$519	

Cost Savings



Reduction in per patient cost for SSI in ALL patients
 \$1,099 Prevena Therapy vs. \$1,618 SOC

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.

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Effect of ciNPT for the prevention of sternal wound infection for high-risk patients.

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

LOE

Study Design

Retrospective cohort study (United Kingdom)

Study Purpose

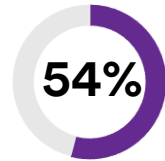
To assess the effect of closed incision negative pressure therapy (ciNPT) on the infection rate of patients at high-risk for sternal wound infection (SWI).

Methods

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

Results

Sternal Wound Infection



Reduction in SSI

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

Key Points

Summary

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

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

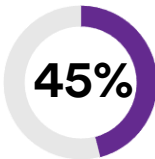
*Statistically significant ($p<0.05$)

Illustration of the 3M™ Prevena™ Incision Management System cost effectiveness based on Suelo-Calanao et al 2020 clinical outcomes.

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

Hypothetical Economic Model	3M™ Prevena™ Therapy	Control
Number of Patients (n)	158	162
Number of Surgical Site Infections (a)	9	20
Cost Per Surgical Site Infection ¹ (b)	\$47,721	\$47,721
Cost of SSI per Patient (a*b)/n	\$2,718	\$5,891
Cost of Therapy Per Patient*	\$495	---
Total Cost Per Patient	\$3,213	\$5,891
Potential Per Incision Savings Using Prevena Therapy	\$2,678	

Cost Savings



Reduction in Per-Patient Cost for SSI
 \$3,213 Prevena Therapy vs. \$5,891 SOC

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.

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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/m²

or ≥ 2 of the following risk factors:

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

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

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.



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