3M | Prevena™ Incision Therapy

Clinical Evidence (Level II): Cardiac surgery

# Sternotomy patients that used 3M™ Prevena™ Therapy experienced significant reduction in wound infection.

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

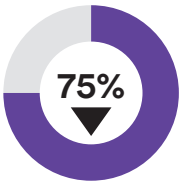
### Summary of Study[1] Findings

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[1] and other[2] study data showed a potential 69% reduction in mean per patient cost for SSI in high-risk patients.[3]

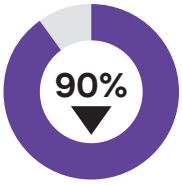
**Potential per-patient cost of $2,404 Prevena Therapy vs. $7,635 Standard of Care (SOC)[3].**

### Results




**Reduced Rate of SSI**

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




**Reduced Rate of Wound Infection with Gram-Positive Skin Flora***

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

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

### Study Design

Prospective, single-centre, 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 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/m$^2$
- 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

*1. 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.*

*2. 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.*

*3. 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.*

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

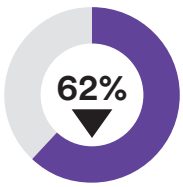
### Summary of Study[4] Findings

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[4] and other[2] study data showed a potential 32% reduction in mean per patient cost for SSI in all patients.[5]

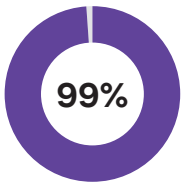
**Potential per-patient cost of $1,099 Prevena Therapy vs. $1,618 Standard of Care (SOC)[5].**

### Results




**Reduced Rate of SSI**

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




**Primary Wound Closure at Day 6/7 on Removal***

98.7% (234/237) Prevena Therapy.

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

### Study Design

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

### 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 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 3,508 patients
- No defined High Risk Inclusion Criteria
- Prevena Therapy placed immediately after suturing. Post Op dressing removal at day 6–7
- The primary end point was wound infection within 30 days

*4. 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.*

*5. 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.*

# Understanding relevant risk factors for cardiac procedures.

## Patient Risk Stratification

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

Clinical data[1] suggests that patients should receive Prevena Therapy if they have a BMI > 30 kg/m$^2$ or **two or more** of the following risk factors:

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

Scan this QR code to learn more about when to use Prevena Therapy.

*1. 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.*

# It's time to update your dress code.


Available in Canada from your authorized 3M+KCI distributors.
KCI USA Inc., a 3M Company
KCI owned and operated by 3M Company

**KCI Medical Canada Inc.**
75 Courtneypark Dr., W.,
Unit 4
Mississauga, ON
L5W 0E3

**KCI USA, Inc.**
12930 IH 10 West
San Antonio, TX
78249

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

**NOTE: Specific indications, limitations, contraindications, warnings, precautions, and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. This material is intended for healthcare professionals only.**