



# PREVENA™ RCT

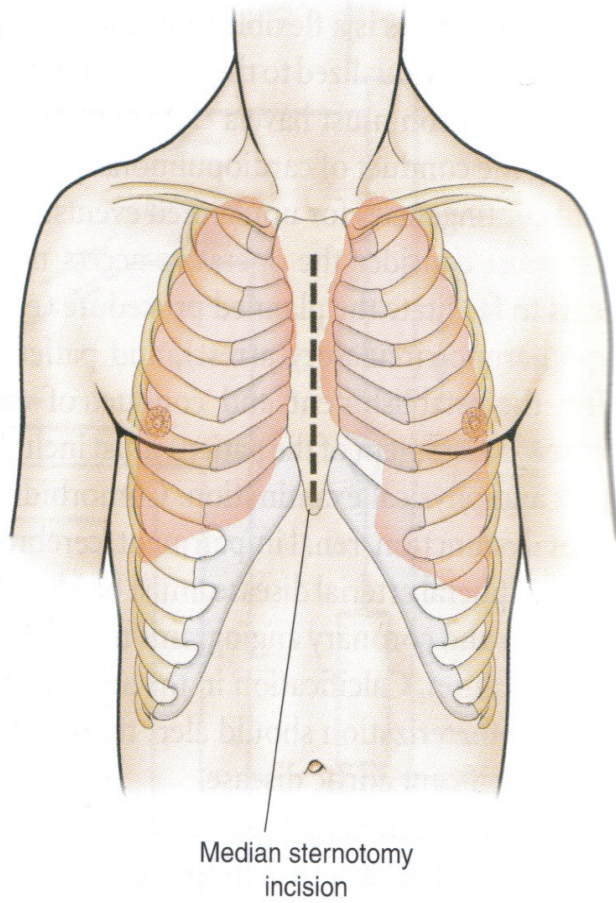


Dr. A.L.P. Markou, Cardio-thoracaal chirurg  
CNE onderwijs Utrecht  
16 februari 2016

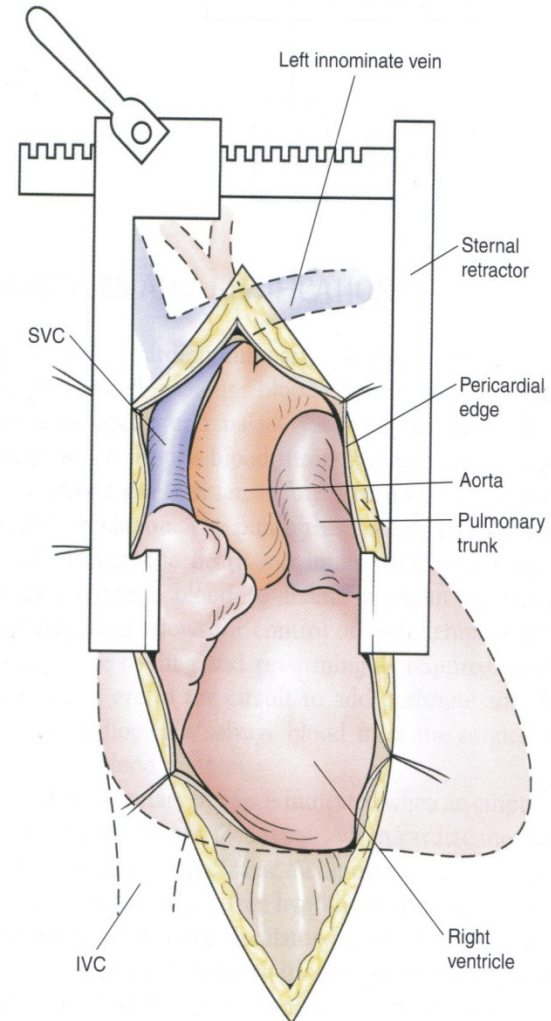
# Isala Hartcentrum Zwolle



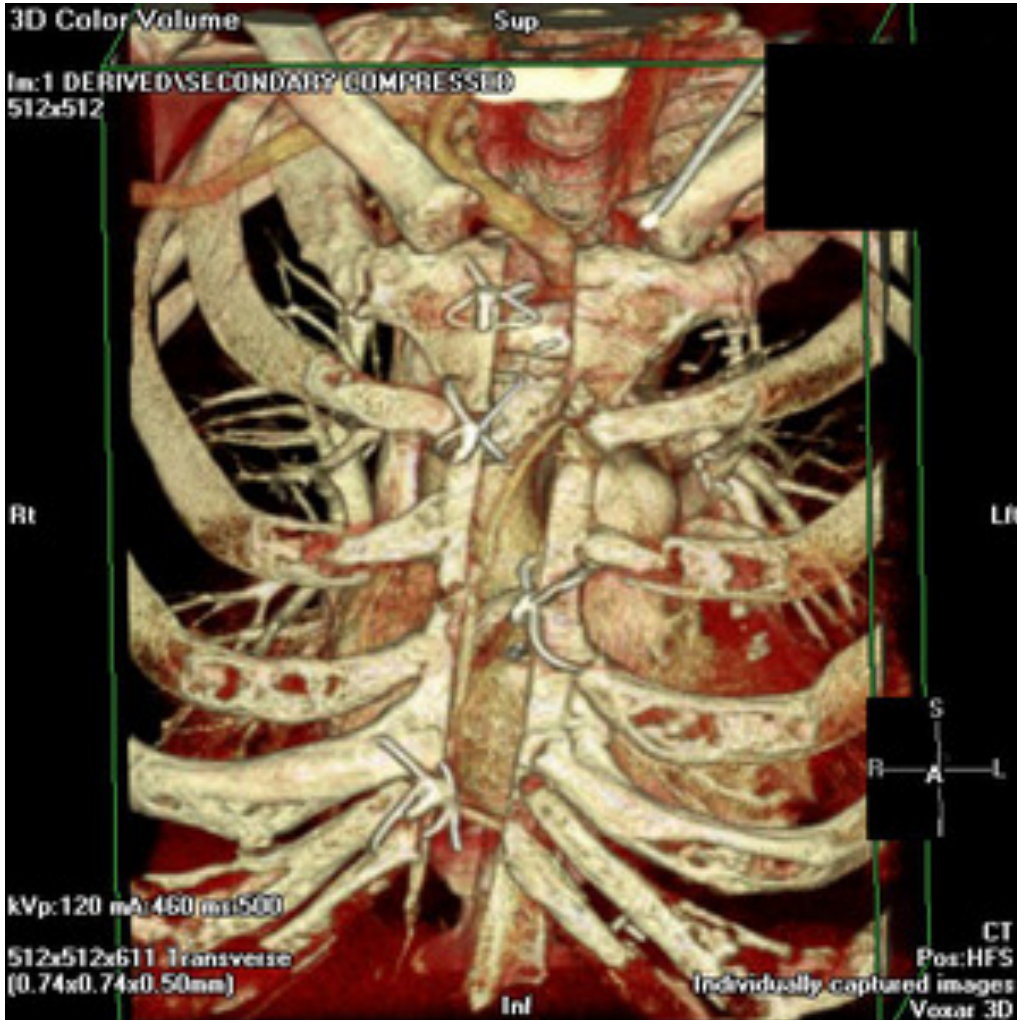
# Mediane Sternotomie



# Mediastinitis



# Sternumdehiscentie



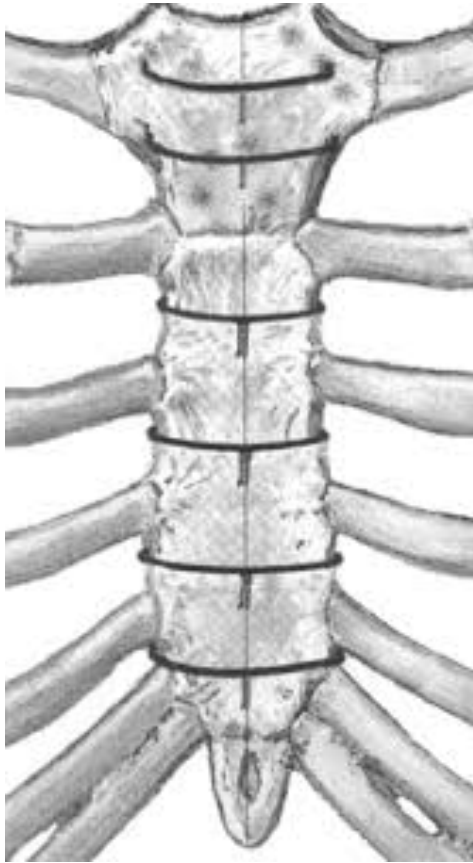
# Andere entiteit

Mechanische dehiscentie

**Geen** infectie

COPD/ (Prednison)!

# Sternumdehiscentie

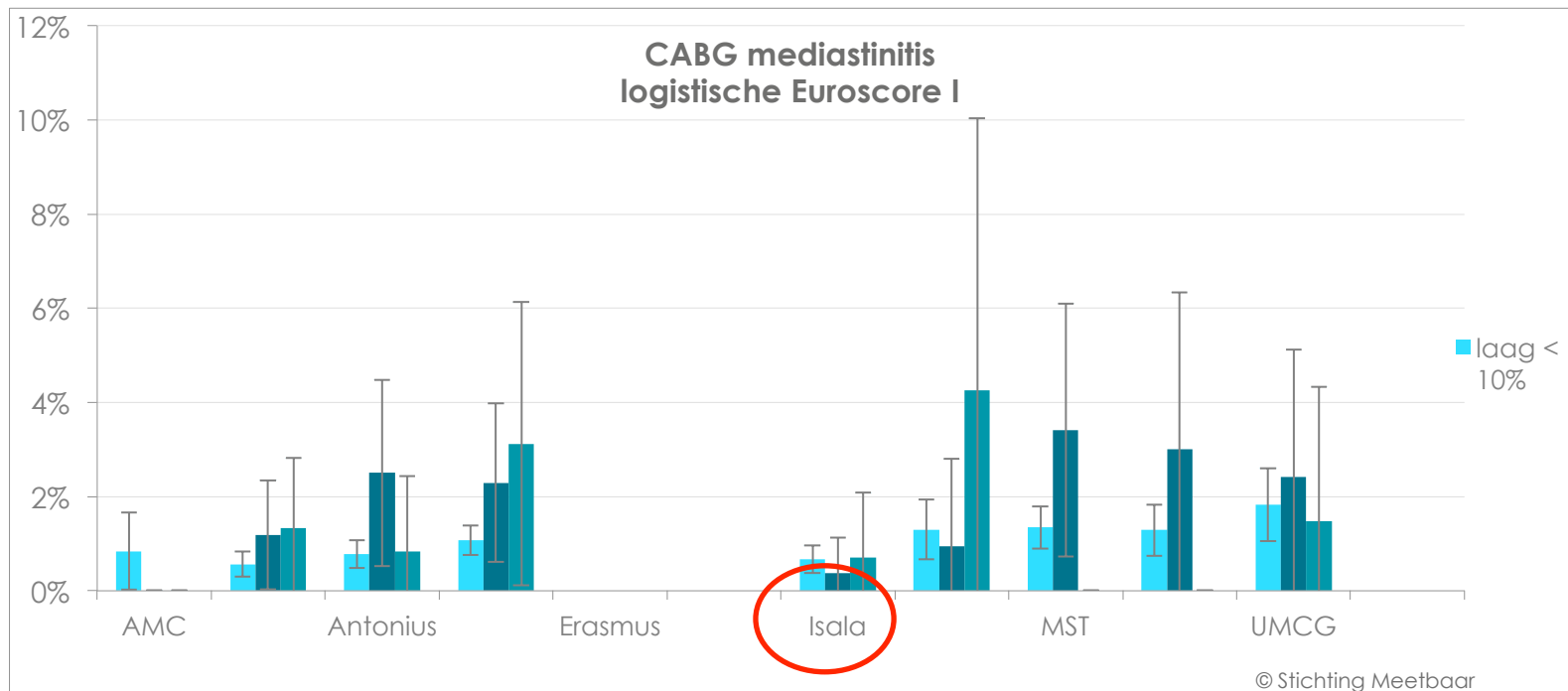


# SSI's after cardiac surgery

**Diep sternaal wondinfect <1%**

**Oppervlakkig sternum wondinfect (SSI)? (10%?)**

**PREVENA™**



# Hoog risico patiënten voor opp. sternumwondinfecties



# Voorkomen is beter dan genezen....



ELSEVIER  
MASSON



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[www.sciencedirect.com](http://www.sciencedirect.com)

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[www.em-consulte.com](http://www.em-consulte.com)

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**Médecine et  
maladies infectieuses**

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Médecine et maladies infectieuses 43 (2013) 403–409

General review

## Epidemiology and prevention of surgical site infections after cardiac surgery

*Épidémiologie et prévention des infections du site opératoire après chirurgie cardiaque*

D. Lepelletier<sup>a,\*</sup>, C. Bourigault<sup>a</sup>, J.C. Roussel<sup>b</sup>, C. Lasserre<sup>a</sup>, B. Leclère<sup>a</sup>, S. Corvec<sup>a,d</sup>,  
S. Pattier<sup>b</sup>, T. Lepoivre<sup>e</sup>, O. Baron<sup>b,c</sup>, P. Despins<sup>b,c</sup>

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Available online 26 August 2013



# Verwekkers

Table 1

Microbiological documentation of mediastinitis after cardiac surgery.

*Documentation microbiologique des médiastinites après chirurgie cardiaque.*

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## Microbiology of mediastinitis

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### Gram positive Cocci

*Staphylococcus aureus*

40%

Coagulase negative *Staphylococcus*

30%

### Gram negative Bacilli

*Escherichia coli*

5%

*Enterobacter* spp.

10%

*Klebsiella* spp.

3%

*Proteus* spp.

2%

*Pseudomonas* spp.

2%

### Other

*Candida*

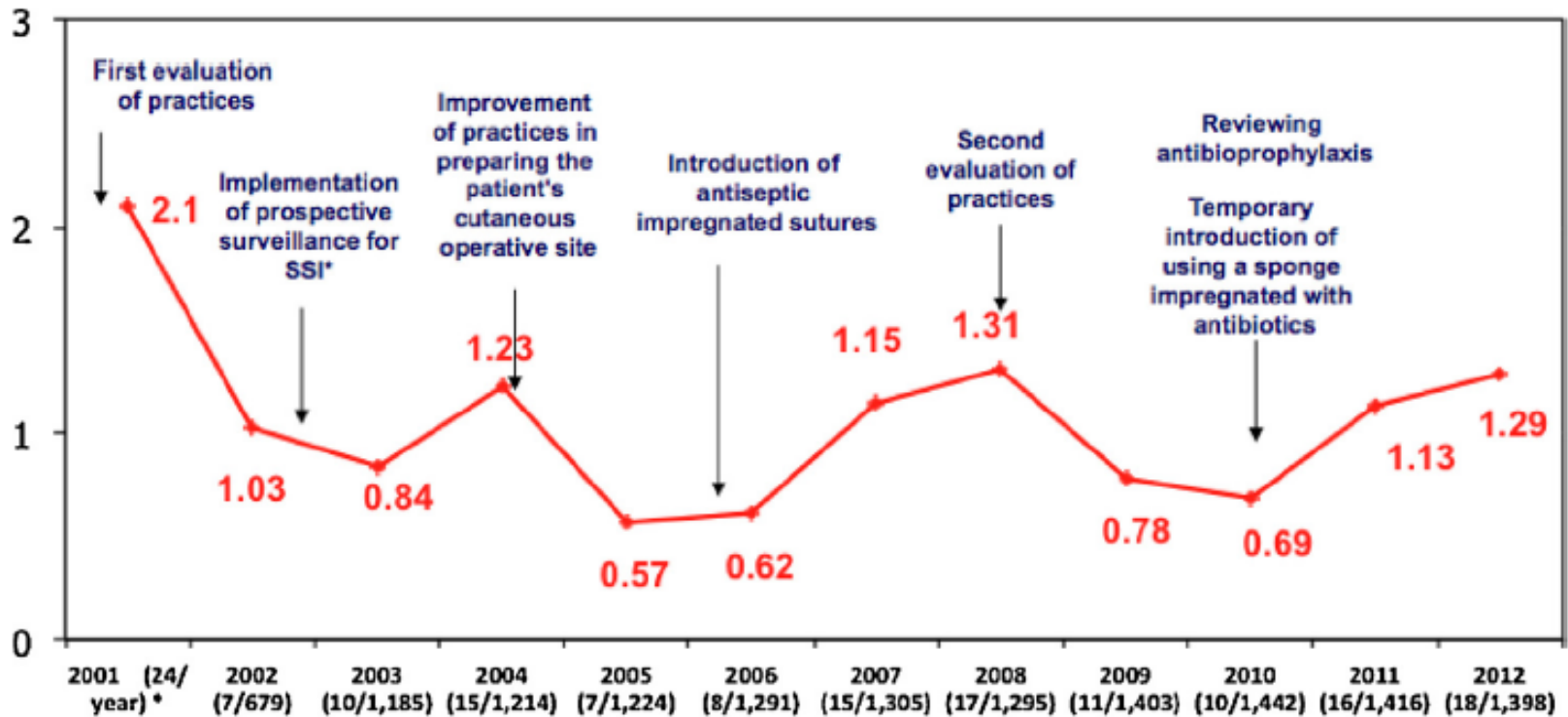
< 2%

Polymicrobial

10–40%

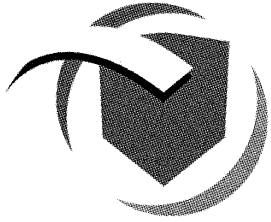
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# Preventieve maatregelen door de jaren heen



\*Simulated data with a retrospective survey

\*\*SSI: surgical site infection



**APIC**<sup>TM</sup>

# **Guide for the Prevention of Mediastinitis Surgical Site Infections Following Cardiac Surgery**

# Aanbevelingen APIC (2008)

- Hand hygiëne
- Antibiotica profylaxe Aanpassing aan BMI!
- Bloed glucose handhaving 3 x meer SSI's bij glucosewaarden > 15
- Preoperatief scheren Tondeuze/ holding
- Ontsmetten van de huid Geen voorkeur jodium/ chloorhexidine
- Aseptisch werken
- Chirurgische techniek LIMA/ BIMA/ Sternumfixatie
- Postoperatief verband/ wondbedekking Vochtdoorlatende dressing
- Preoperatief douchen Chloorhexidine scrub (2x), evidence??
- Nasale dekolonisatie 25-30% drager, 2 – 9 x meer SSI

# Douche instructies

## Preoperative Surgery Showering Instructions

To keep your skin as clean as possible and to help prevent infection, please follow these instructions:

1. Shower with an antibacterial soap.  
**\*\*Note\*\*** If using CHG cleanser, do not use it on mucous membranes, such as your genital area. Do not get the soap in ears or eyes. CHG is absorbed by cotton washcloths and may cause discoloration. Follow directions on the package.
2. In the shower, wet skin and wash body from the neck down.
3. Pay special attention to the area where you will have surgery as well as the genital area, belly button, hands and feet.
4. Ask someone for help if you are unable to wash certain areas of your body.
5. Rinse well.
6. Gently dry with a clean towel.

# Douche instructies

## Please Remember:

1. **DO NOT SHAVE ANY BODY PARTS** from the neck down (your legs or underarms). Shaving can increase your risk of infection when you have surgery.
2. **AFTER YOUR SHOWER**, do not use any powder, deodorant, perfumes or lotions prior to surgery.
3. **WEAR FRESHLY LAUNDERED** pajamas to bed that night and sleep on freshly laundered sheets.
4. **SHOWER AGAIN** with antibacterial soap in the morning, following the above instructions.
5. **WEAR FRESHLY LAUNDERED** clothes to the hospital.

# SSI na hartchirurgie

## Risicofactoren (geïdentificeerd in 3 of meer studies)

- Diabetes Mellitus
- High Body Mass Index/ *Obesitas*
- Lange operatieduur
- ECC en AoX tijd
- Reoperatie/ resternotomie
- BIMA gebruik
- Postoperatief respiratoir falen
- Hoge leeftijd
- COPD
- Roken (+)
- Vrouwelijk geslacht
- Hoge NYHA klasse/ hartfalen/ cardiogene shock
- Nierfalen/ hemodialyse



# Mediastinitis/ SSI

## Preoperatieve risicofactoren

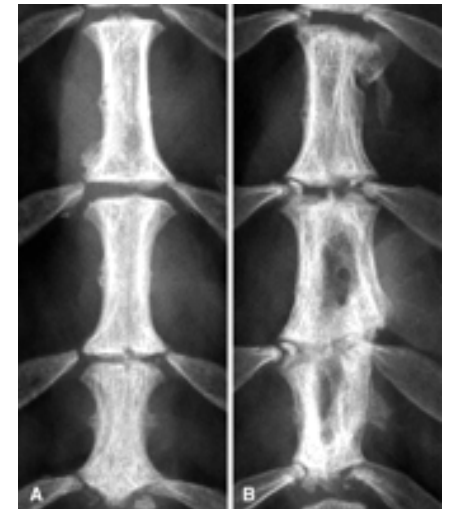
- Minimaliseren preoperatieve preoperatieve risico factoren (bv. staken antistolling)
- Preoperatieve screening Staphylococcus Aureus
- Gebruik van Mupirocine/ Bactroban (STS Class IA aanbeveling 2007)
- Scheren met tondeuse, tijdstip?
- Profylactische AB toediening (Cefazoline, 24 hr)
- Controle van hyperglykemie
- Langdurige ZH opname preoperatief
- ***Innovatieve benadering van infectie preventie***



# Mediastinitis/ SSI

## Peroperatieve risicofactoren

- Gebruik van of BIMA
- Gebruik van beenwas
- (Overmatig) gebruik van diathermie
- Type AB profylaxe en tijdstip van toediening
- OK duur, AoX-tijd, ECC-tijd
- Complexiteit chirurgie
- Methode van sternum sluiting



# Mediastinitis/ SSI

## Postoperatieve risicofactoren

- Verlengde beademingsduur
- Reoperatie
- Postoperatieve bloedtransfusies
- Nierproblemen en pulmonale complicaties
- Inotropie afhankelijkheid
- Cardiogene shock
- Spoedoperatie

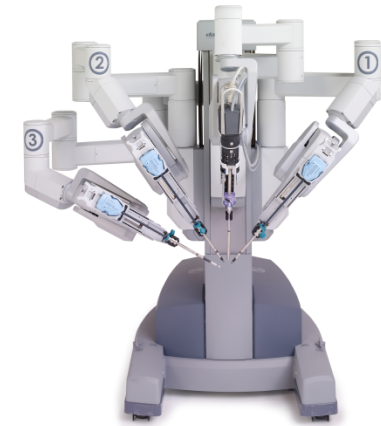


# Nieuwe benadering infectie preventie

Geen mediane sternotomie →

Minimaal invasieve hartchirurgie

- Robot gefaciliteerde CABG
- Robot gefaciliteerde MVP



Innovatieve wond management technieken

KCI/ Acelity Prevena™ incisie management systeem



# Prevena™ Incisie Management Systeem

## Negatieve druk therapie (NPWT)

- Gesloten sternotomie wonden
- Hoog risico patiënten voor SSI
- Single centrum studie, retrospectief
- Gemiddelde leeftijd  $60,4 \pm 10$
- 77% Obesitas (BMI  $35,3 \pm 6,7$ )
- 54% Diabetes Mellitus
- NPWT in situ 4 dagen postoperatief
  
- N = 57
- Geschat risico op SSI  $6,1 \pm 4\%$
- **Geen** patiënten ontwikkelden SSI
- Makkelijke toepasbaarheid
- Goed verdragen door patiënten

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10.1177/1553350608314821  
<http://vix.sagepub.com>

## Does Negative Pressure Wound Therapy Have a Role in Preventing Poststernotomy Wound Complications?

Broadus Zane Atkins, MD, Mary Kay Wooten, MSN, Jean Kistler, NP, Kista Hurley, PA-C, G. Chad Hughes, MD, and Walter G. Wolfe, MD

**Background:** Sternal wound infection (SWI) remains a devastating complication after cardiac surgery, decreasing long-term and short-term survival. In treating documented SWI, negative pressure wound therapy (NPWT) reduces wound edema and time to definitive closure and improves peristernal blood flow after internal mammary artery (IMA) harvesting. The authors evaluated NPWT as a form of "well wound" therapy in patients at substantial risk for SWI based on existing risk stratification models. **Methods:** Records of 57 adult cardiac surgery patients (September 2006 to April 2008) were reviewed. After preoperative risk assessment, NPWT was instituted on the clean, closed sternotomy immediately after surgery and continued 4 days postoperatively. Adverse postoperative events, including SWI, need for readmission, and other complications, were documented. **Results:** Mean age was  $60.4 \pm 10$  years, and 89.5% were male; 77.2% were obese (mean body mass index

$35.3 \pm 6.7$ ), 54.4% were diabetic, and 29 (50.9%) were both obese and diabetic. Coronary artery bypass (CAB) with single IMA was performed in 50.9% of the patients followed in frequency by combined CAB/valve, non-CAB surgery, and CAB with bilateral IMA. Estimated risk for SWI was  $6.1 \pm 4\%$ . All patients tolerated NPWT to completion. Thirty-day and in-hospital mortality was 1.8% and unrelated to DSWI. No treatment of SWI was required. **Conclusions:** In this high-risk cohort, 3 postoperative SWI cases were anticipated but may have been mitigated by NPWT. This is an easily applied and well-tolerated therapy and may stimulate more effective wound healing. Among patients with increased SWI risk, strong consideration should be given to NPWT as a form of "well wound" therapy.

**Keywords:** subatmospheric pressure; wound healing; cardiac surgery; median sternotomy

**S**ternal wound infection (SWI) remains a dreaded complication of cardiac surgery. To illustrate, 1-year mortality rates for SWI after coronary artery bypass (CAB) surgery approach 33%,<sup>1,2</sup> and long-term survival after CAB is also significantly

reduced by the development of SWI.<sup>1-4</sup> Recent estimates for the incidence of SWI after cardiac surgery range from 1% to 10% depending on the specific definition used and the population of subjects studied.<sup>1-20</sup> Several preoperative and perioperative variables have been recognized as contributing to higher rates of sternal wound complications, especially obesity and diabetes (see Table 1).

Standard treatment of documented SWI typically involves sternal debridement and muscle flap repair of the resulting mediastinal defect.<sup>10,11,21,22</sup> Although this approach has reduced rates of mortality from mediastinitis,<sup>21,22</sup> it can be associated with significant morbidity and physical disfigurement.<sup>22</sup> In addition, the hospital system incurs substantial

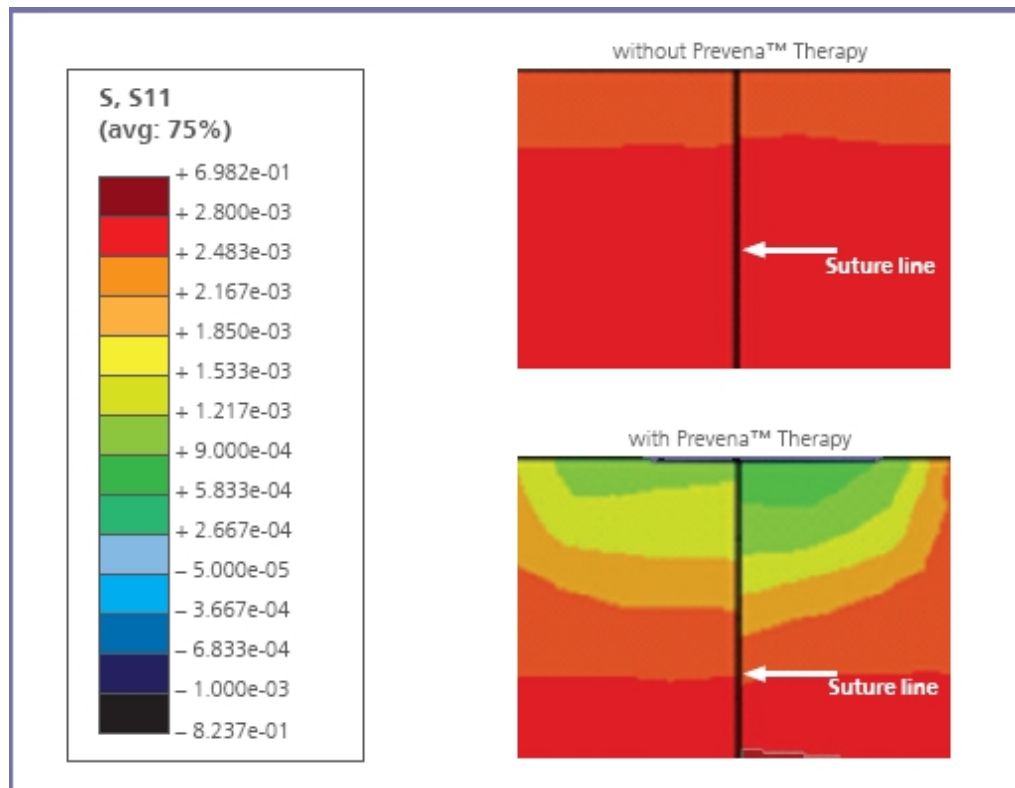
From the Department of Surgery, Durham Veteran Affairs Medical Center (BZA, MKW, JK, KH, WGW); Department of Surgery, Duke University Medical Center (JK, GCH, WGW), Durham, North Carolina.

The views expressed represent those of the authors and do not represent the official policy of the Department of Veterans Affairs or the US Government.

Address correspondence to: Broadus Zane Atkins, MD, Surgical Services, #112, 508 Fulton St, Durham, NC 27705; e-mail: [Broadus.atkins@va.gov](mailto:Broadus.atkins@va.gov)

# Werking Prevena

## Vermindering spanning van de wondranden



**Boven:** Resultaat op spanning na applicatie van hechtingen (huidspanning).

**Onder:** Resultaat van laterale spanning na aanbrengen hechtingen en Prevena™ Therapy (met 125mmHg).

Kleur geeft relatieve grootte van laterale spanning.

**Rood** en **Oranje** = hoge laterale spanning  
**Geel** en **Groen** = lage laterale spanning

# Werking Prevena

Negatieve druk heeft een positieve impact op huid perfusie

ORIGINAL ARTICLE

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## The Effects of Varying Degrees of Pressure Delivered by Negative-Pressure Wound Therapy on Skin Perfusion

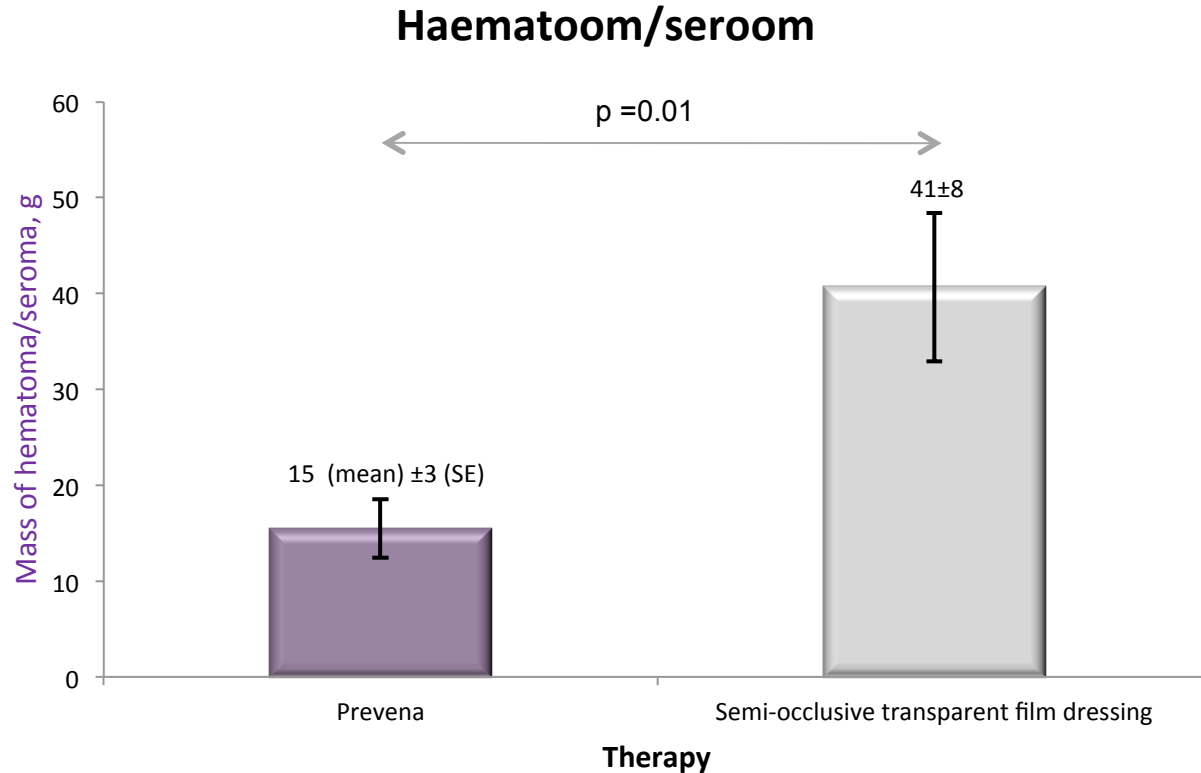
*M. S. Timmers,\* S. Le Cessie, PhD,† P. Banwell, FRCS(Plast),‡ and G. N. Jukema, MD, PhD\**

Dressings werden geplaatst bij gezonde vrijwilligers op intacte huid van de onderarm met 3 laser Doppler meters in de foam om het effect op de perfusie te meten

Resultaat was een **5.6-voudige toename van de perfusie van de huid** met de GranuFoam™ dressing

# Werking Prevena

## Vermindering van hematoom/ seroom



63% minder hematoom/ oedeem in een varkensmodel  
Vocht niet in de opvangbeker.....

| Current Product                     | Holds Incision Edges Together | Incision Protection | Fluid Removal | Microbial Reduction   |
|-------------------------------------|-------------------------------|---------------------|---------------|-----------------------|
| Sutures                             | +                             |                     |               |                       |
| Steri-Strips™                       | +                             |                     |               |                       |
| Surgical Staples                    | +                             |                     |               |                       |
| Skin Adhesives                      | +                             | +                   |               |                       |
| Drains                              |                               |                     | +             |                       |
| Compression garments                |                               | +                   |               |                       |
| ABD Pads                            |                               | +                   | +             |                       |
| Prophylactic antibiotics            |                               |                     |               | +                     |
| Prevena Incision Management System™ | +                             | +                   | +             | +(in the fabric only) |



# Prevena™ Incisie Management Systeem

- Prevena™ 125 Therapie Unit
- Prevena™ canister (steriel, 45 ml)
- Prevena™ dressing met negatieve druk indicator
  - Huid interface met zilver (0,019%)
  - Volledig disposable systeem
  - Faciliteert patiënt zijn mobiliteit
  - Blijft 3-5 dagen in situ



# Moeilijk te plaatsen?

EENVOUDIG  
AAN TE  
BRENGEN\*\*



**1** Breng het verband aan over schone, gesloten incisies

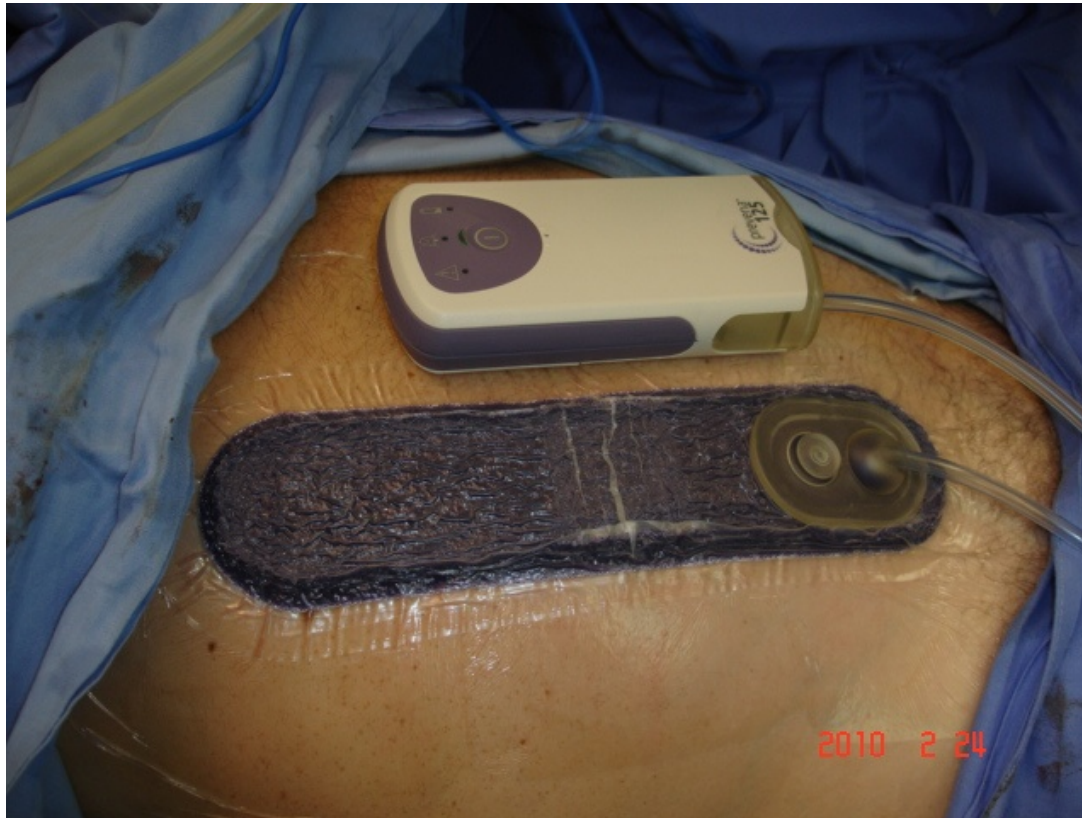


**2** Sluit het verband aan op de opvangbeker; plaats de opvangbeker in het apparaat



**3** Inschakelen en 2-7 dagen laten zitten

# Steriel aan brengen op gesloten wond



# Risico stratificatie systeem voor SSI

## Mediane sternotomie wonden

### *Gerandomiseerde Europese Multicenter Trial*

- Major risicofactoren 4 of zelfs 8 punten
- Intermediaire risicofactoren 2 punten
- Minor risicofactoren 1 punten

Inclusie Prevena™ RCT indien **totaal score  $\geq 8$  punten**

# Risico stratificatie systeem voor SSI

## Mediane sternotomie wonden



### Major risico factoren = 4 of 8 punten

- BMI > 40 kg/m<sup>2</sup> (8 punten)
- BMI < 18 en > 30 kg/m<sup>2</sup>
- Insuline afhankelijke DM
- Dialyse bij chronisch nierfalen

(Klaring < 30 ml/min/1,73 m<sup>2</sup> > 3 maanden)

# Risico stratificatie systeem voor SSI

## Mediane sternotomie wonden

### Intermediaire risico factoren = 2 punten

- Gebruik van BIMA
- Diabetes Mellitus (NIDDM)
- COPD > GOLD klasse 2
- Langdurig gebruik van immuunsuppressiva
- Chronisch nierfalen zonder nierdialyse
- Thoracale bestraling in VG
- Roker
- Grote borsten (> cup D)



# Risico stratificatie systeem voor SSI

## Mediane sternotomie wonden

### Minor risico factoren = 1 punt

- Reoperatie
- Perifeer vaatlijden
- LVEF < 30%
- Vrouwelijk geslacht
- Leeftijd > 75 year
- Acuut myocardinfarct < 90 dagen voorafgaand aan operatie
- $\geq 7$  dagen ziekenhuis opname preoperatief



# International Consensus Document



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Accepted: 2014.06.21  
Published: 2014.10.04

REVIEW ARTICLES

e-ISSN 1643-3750  
© Med Sci Monit, 2014; 20: 1814-1825  
DOI: 10.12659/MSM.891169

## Use of Incisional Negative Pressure Wound Therapy on Closed Median Sternal Incisions after Cardiothoracic Surgery: Clinical Evidence and Consensus Recommendations

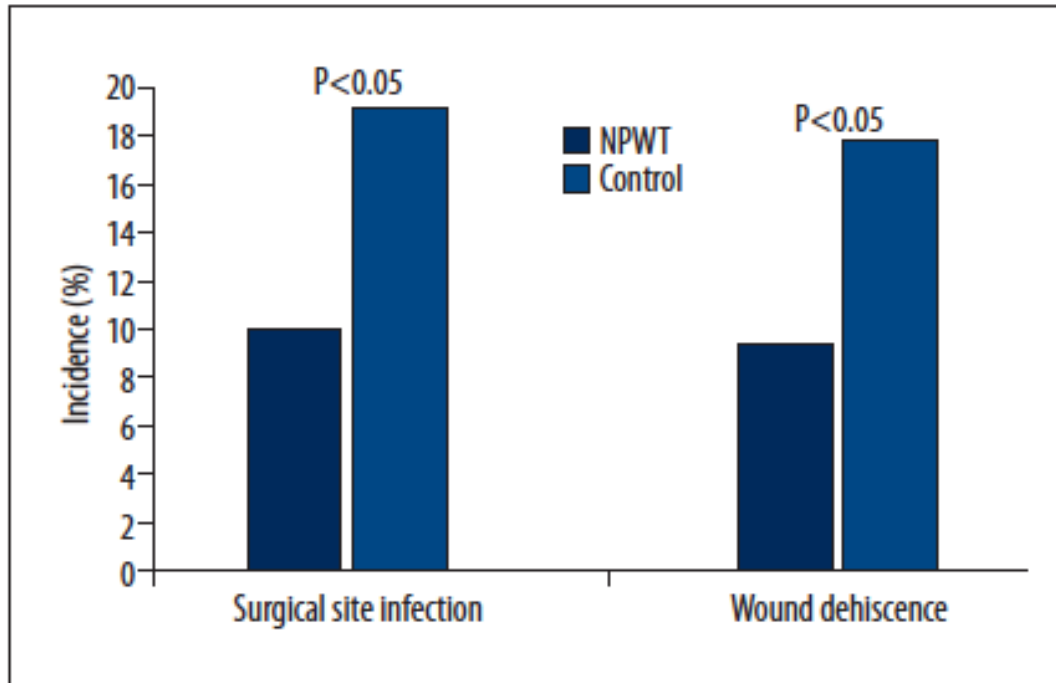
Authors' Contribution:  
Study Design A  
Data Collection B  
Statistical Analysis C  
Data Interpretation D  
Manuscript Preparation E  
Literature Search F  
Funds Collection G

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# In ortopaedie meer evidence



**Figure 2.** Incidence of surgical site infection and wound dehiscence in a randomised, controlled study of negative pressure wound therapy (NPWT) versus standard dressings over surgical incisions after open reduction and internal fixation of 263 fractures in 249 patients [50].

Reddix RN Jr, Leng XI, Woodall J et al: The effect of incisional negative pressure therapy on wound complications after acetabular fracture surgery. J Surg Orthop Adv, 2010; 19: 91–97

# Het leven voor Prevena™ RCT in Zwolle.....

- > 170 hoog risico patiënten
- Verschillende type hartoperaties met mediane sternotomie
- Risicofratificatie toegepast

## Resultaten

- 1 patiënt met mediastinitis (??)
- **GEEN SSI**

# Case report Prevena™

Vrouw

77 jaar

Electieve CABG

L 1.56 m/ W 140 kg/ **BMI 57,5 (Morbide adipositas)**

IDDM

Hele grote mammae

VSM niet bruikbaar (varisectomie beiderzijds)

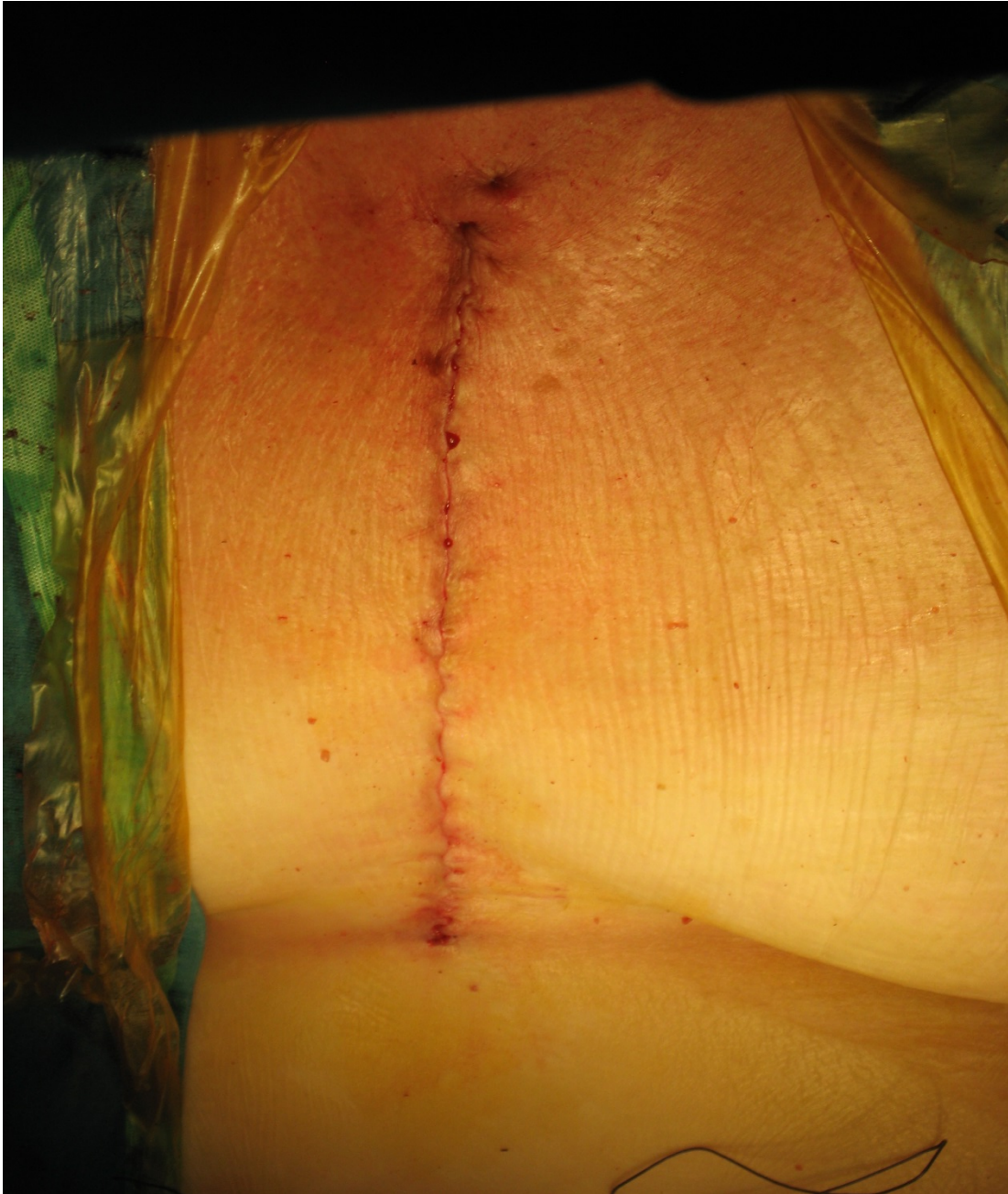
Langdurig Prednison gebruik

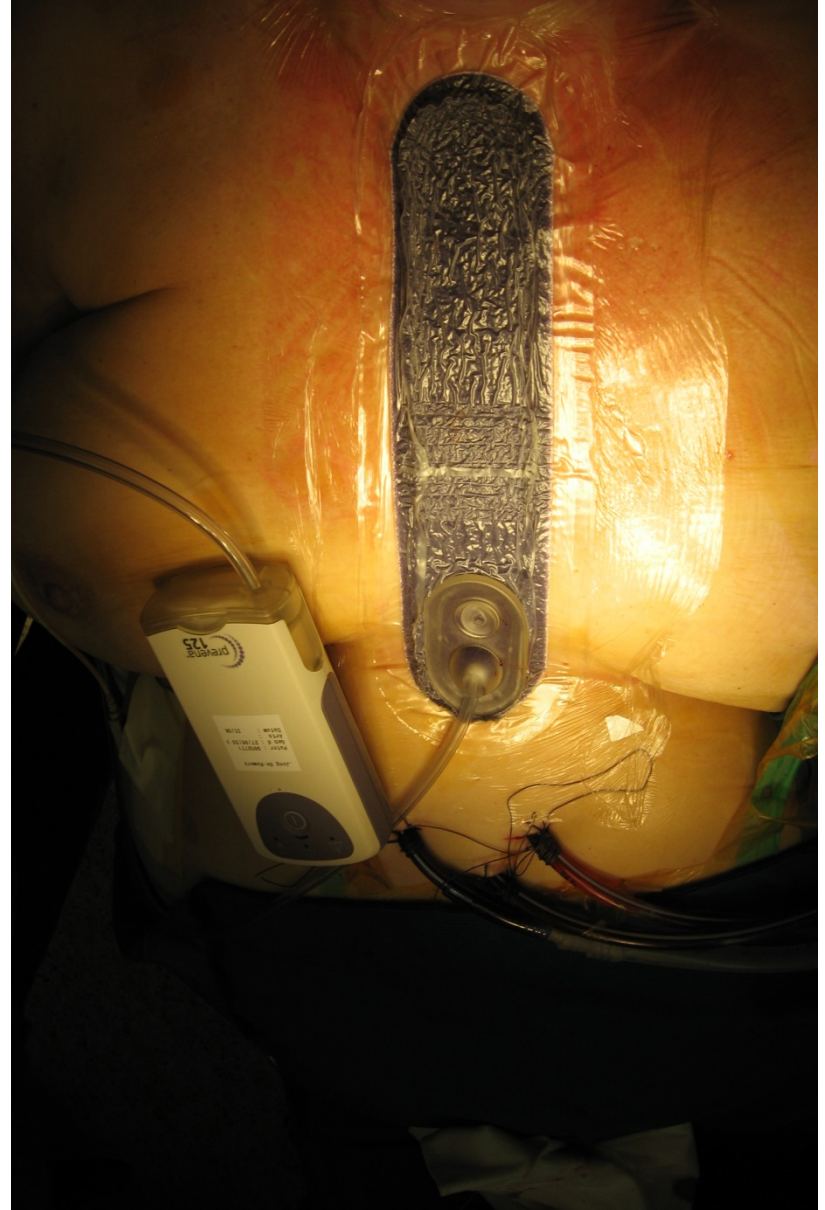
COPD Gold klasse II

Allentest: arteria radialis niet bruikbaar

Revasularisatie met BIMA







# Na 6 dagen KCl Prevena™

