

# **STERISSETS CONVECTIVE WARMING BLANKETS**

Prevent & Treat Hypothermia



# History



**Sterisets products increase the efficiency of hospitals and reduce the cost of patient care. Prices are kept low by Sterisets own large-scale, highly rationalized production methods.**

**The most popular solution that we provide are our custom-made sets. These allow you to select the products you require.**

Since the start of Sterisets International B.V. in 1991 we have been growing our activities in Europe and beyond, with manufacturing facilities in Portugal, The Netherlands and China.

With an experience of almost 30 years, our company now has several high quality products in the medical disposable market.

Over the years, we have developed a broad range of products to meet the technical requirements of a market in permanent evolution and transformation.

We have invested hugely in the improvement of our manufacturing processes, not only in products but also in staff and equipment.

Attentive to the changes in the medical field, Sterisets International continuously performs market analysis, in order to find new opportunities and new necessities in different European countries.

Today our sales is established in more than 30 different countries. For most of these countries, products are produced at Sterisets Medical Products in Guilhufe, Portugal. Sterisets Medical Products has become the main manufacturing company within Sterisets International and will only be focused on manufacturing, where all the sales and marketing is done at Sterisets in The Netherlands.

# Preventing hypothermia

## WHY IS IT IMPORTANT TO WARM THE PATIENT?

### The facts:

A constant body temperature between 36 °C and 37,5 °C is important. The body system will take care of thermoregulation, but not when this function is shut down by anesthesia.

If the core temperature is too low, this may result in a greater risk of infection. Hypothermia may cause complications and with that increase costs.

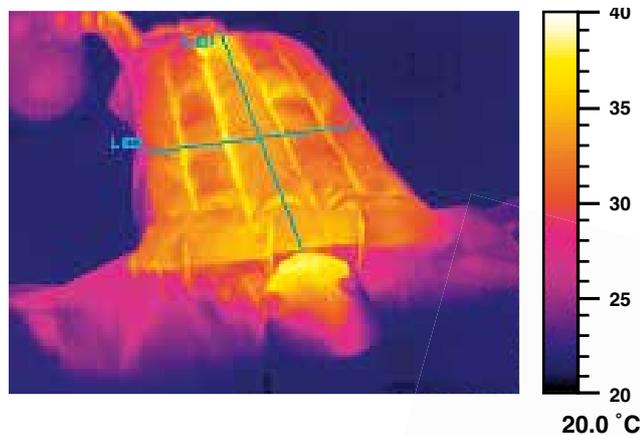
There are many reasons that the temperature can drop very rapidly, such as:

#### PRE-OPERATIVE STAGE

- Low in-house temperature
- Low temperature of the bed and linen
- Thin clothing
- Preparation of the patient

#### DURING OPERATION

- Low in-house temperature
- Low temperature of the bed and linen
- Duration
- Infusion of low temperature fluids
- Certain bodyparts are not covered in the OR
- Anesthesia



*'Anesthesia will cool down the body fast!'*



# Convective Warming Blankets

## CAN THIS BLANKET BE USED ON MOST COMMON BLOWERS?

### The answer is: YES

Most manufacturers will tell you otherwise to protect their market and keep the prices high, they make you believe that the blanket is part of the active warming process. The legislation is absolutely clear about that.

European Medical Device Directive guideline:

#### **Manual on borderline and classification in the community Regulatory framework for medical devices**

*Version 1.11 (12-2011) – Background*

This matter relates to the classification of warming blankets. It concerns a manufacturer who markets warming blankets on the basis of warm air, produced by an extra warming device. The manufacturer considers the blanket to be an accessory to the active device and as such the manufacturer considered it Class I.

#### **Outcome**

##### *Medical device or not?*

The medical purpose has to be clearly identified and substantiated to qualify these products as medical devices. If the blanket and the generator are sold separately:

- The blanket sold separately cannot be considered as an active medical device and is a Class I medical device in accordance with rule 1.
- The generator sold would be class IIa or class IIb in accordance with classification rule 9.

The manufacturer will have to specify the use of such generator.

#### **Conclusion**

A Blanket (Class I; low risk) cannot malfunction on its own. The machine is the active device and therefore is Class IIA or IIB, with the higher risk. Therefore they control and validate:

- Temperature output
- Back pressure between blanket and machine safety alarm
- Alarm system to warn in case the machine would malfunction

Sterisets blankets are tested with most common machines, without any malfunction for the machine and blanket. The unique micro pores in the Sterisets blanket will provide air permeation without residue.

***‘A Blanket cannot malfunction on its own!’***

#### **SPECS**

- **Soft PP fabric on both sides for a comfortable feel**
- **Latex free**
- **Low linting**
- **Strong 2-ply material**
- **Fluid resistant**

#### **DESIGN**

- **Maximum drape-ability**
- **Complete range of models**
- **The blankets provide uniform airflow and distribution for effective patient warming**
- **Universal hose port for most common temperature units**

# Blanket warming unit

## FEATURES:

- Microprocessor controlled
- 4,5 meter power cord
- LED filter indicator
- Easy to replace filter
- Over-heating detection



## SPECIFICATIONS

Ref. 85000

|                              |  |
|------------------------------|--|
| <b>ELECTRICAL</b>            |  |
| <b>Power supply</b>          | 220 VAC, medical grade   |
| <b>Protection</b>            | Over-heating detection   |
| <b>TECHNICAL</b>             |  |
| <b>Filter type</b>           | 0,2 micron HEPA filter with efficiency 99,97%                            |
| <b>CLASSIFICATION</b>        |  |
| <b>Device classification</b> | MDD 93/42/EEC- class IIb   |
| <b>PERFORMANCE</b>           |  |
| <b>Temperature options</b>   | 32°C - 38°C - 43°C – room temperature<br>(air blowing only, not heating) |
| <b>Temperature accuracy</b>  | ± 2°C  |
| <b>Noise</b>                 | Less than 60db   |
| <b>PHYSICAL</b>              |  |
| <b>Dimensions</b>            | 25 x 28 x 36 cm  |
| <b>Weight</b>                | 4,7 Kilograms  |
| <b>Power cord</b>            | 4,5 meter, medical grade<br>US, EU & UK plugs are available              |
| <b>Installation</b>          | The unit can be attached to the IV stand                                 |
| <b>Timer</b>                 | LED indicator for replacing filter                                       |
| <b>Hose</b>                  | 1.8 meters   |

# Pre-warming Blanket



## PRODUCT INFORMATION

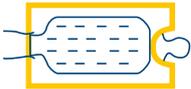
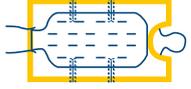
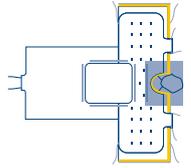
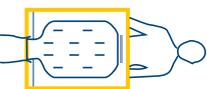
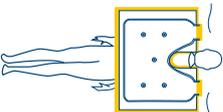
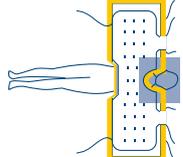
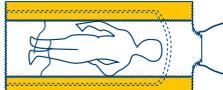
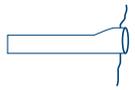
- Outer layer polypropylene
- Inner layer polyester
- Provides comfort and protection to the patient
- Pre-heatable in the warming unit
- Can be disposed with the normal hospital waste
- Latex free
- Meets flammability test
- Low linting
- Anti static
- Breathable
- Size 110 x 220 cm
- Packaging: 5 packs of 5 pieces per carton

The disposable pre-warming blanket maintains the body temperature of the patient during transportation and stay in the OR. In some cases the blanket can stay on the patient during surgery. The disposable blanket replaces the reusable molton blanket which may not be used any longer in the OR because of the particle release.

### The blue – green color has been chosen for several reasons:

- Privacy of the patient (white shines through)
- Safety during surgery, the 2 colors give a clear difference between sterile and non-sterile during surgery, same as the different colors of surgical drapes.

# Product information

| item  | description             | size (cm) | packaging |
|---|-------------------------|-----------|-----------|
|  85100   | Full Body               | 195 x 100 | 4 x 10    |
|  85110   | Multi Access            | 195 x 100 | 4 x 10    |
|  85120   | Abdominal Access        | 192 x 180 | 4 x 10    |
|  85150  | Adult Tube              | 217 x 91  | 4 x 10    |
|  85200 | Lower Body              | 120 x 100 | 4 x 10    |
|  85300 | Upper Body ARM IN       | 124 x 94  | 4 x 10    |
|  85310 | Upper Body ARM OUT      | 192 x 57  | 4 x 10    |
|  85400 | Pediatric Neonatal      | 92 x 89   | 4 x 10    |
|  85410 | Pediatric Child         | 99 x 136  | 4 x 10    |
|  85450 | Pediatric Tube          | 113 x 56  | 4 x 10    |
|  85600 | Multi Purpose Hose Sock | 100 x 12  | 4 x 20    |

## WOUNDCARE PRODUCTS

NON WOVENS/DRAPES/  
GOWNS/SMS/PAPER

TRAYS & BOWLS

INSTRUMENTS

PROCEDURE TRAYS & SETS

MISCELLANEOUS



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