

## SOBER dermatome

### *Instructions for use*



IFU SD 13/02



CE 0344

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### **VIDEO:**

**This booklet explains how to handle and use the SOBER dermatome. We recommend to watch the video (DVD) provided with each set first. You can also watch the video on our website [www.humeca.com](http://www.humeca.com) (section 'SOBER products', sub 'video SOBER dermatome') or scan the code below:**



Video 'SOBER dermatome'

## 1. Introduction

The ability to cut a split-thickness skin graft free-handedly has been regarded as a skill acquired only by long experience. Several devices have been improvised to simplify this task. However, the size and elaborate arrangements of dermatomes often preclude their use, especially if the need is in an emergency room, a clinic or at the patient's bedside. Besides sophisticated dermatomes are costly and more adequate for harvesting larger skin grafts with precise thickness.

In close co-operation with the Dutch surgeon dr. Willem Nugteren, Humeca developed a very simple dermatome for freehanded harvesting of a 30 mm (1¼ ") wide split skin graft with a pre-determined thickness of about 0.25 mm (0.001")

The new product is called the "SOBER" dermatome, from an English translation of the phonetic last name of the inventor, dr. Nugteren. Based on his experience with surgery in third world countries, it became clear that a portable, economical and simple, yet efficient dermatome would be a very useful mechanical tool for skin grafting.

We believe the SOBER dermatome offers the surgeon a low-cost alternative to the more elaborate mechanical dermatomes whenever small grafts are needed.

### REMARK:

Before using the SOBER dermatome, we recommend to read this manual and to look at the DVD that was supplied with the instrument.

### **Warning:**

***Always pay attention to the presence of a very sharp blade in the SOBER dermatome. Remove it before cleaning and always handle it with care to prevent cutting accidents!***

## 2. The parts of the SOBER dermatome

The front- and backside of the SOBER dermatome are shown in the pictures below. Indicated are the following parts:

- |   |                    |   |                             |
|---|--------------------|---|-----------------------------|
| 1 | Dermatome head     | 2 | Blade cover                 |
| 3 | Blade fixing screw | 4 | Deepened area for the blade |
| 5 | Shaft              | 6 | Area for finger positioning |

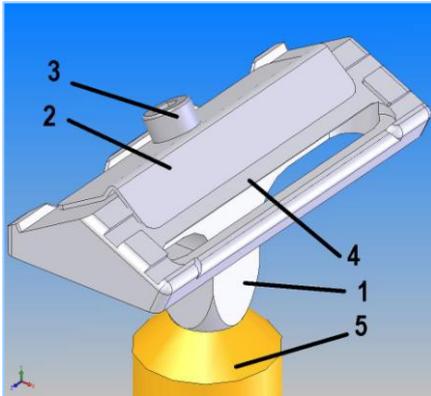


Fig. 1 Front side

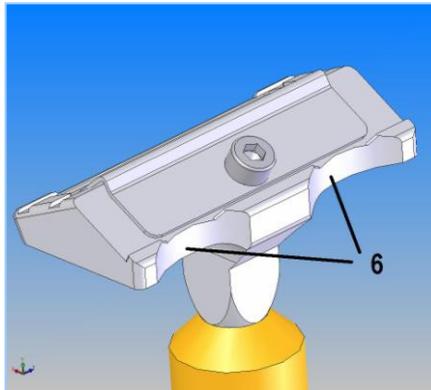
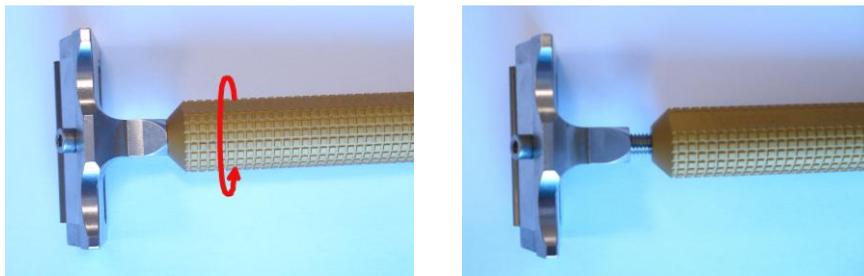


Fig. 2 Backside

The little screw (3) cannot be separated from the blade cover (2) in order to prevent its loss.

The dermatome is supplied with an extra stainless steel hexagonal tool for turning the blade fixing screw (3).

However, such a hexagonal tool is also integrated in the shaft of the dermatome. Simply remove the shaft from the head by turning it counter clockwise while preventing the head from rotation (see fig. 3a and b).

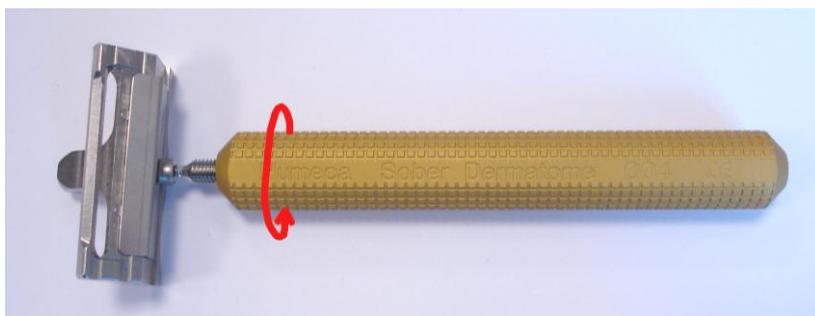


**Fig. 3a and 3b. Removing the shaft from the head**

After the shaft (fig. 4) has been separated from the head, you can use the hexagonal tip of the shaft as your tool, as shown in fig. 5.



**Fig. 4. The shaft with hexagonal tip can be used as a tool**



**Fig. 5. The shaft used as a tool to fix or remove the blade cover**

### 3. Cleaning and sterilization

All parts of the dermatome are made out of stainless steel, except for the shaft (anodized aluminium). Strong alkaline cleaning methods (pH>10) might cause visible changes to the surface of the shaft, like stains and colour fading. The least damage to anodized aluminium and stainless steel surfaces will occur when a neutral cleaning agent is used in combination with demineralised water. Don't use H<sub>2</sub>O<sub>2</sub> (hydrogen peroxide) in the washing process; it will damage the shaft.

For optimum cleaning results the cleaning solution should have access to all parts of the dermatome. For that reason either remove blade cover and clean them separately, or at least loosen the blade fixing screw some turns during cleaning. The instrument can be sterilized by any conventional method, suitable for sterilization of surgical instruments. Recommended is steam sterilization in an autoclave at a common temperature of 134 °C (=273 °F) for usually 5-10 minutes, or at 121°C (=250 °F) for about 20 minutes).

A suitable procedure for cleaning and sterilization and advisory on cleaning agents is presented in a joint publication of Humeca and Diversey. It is available on request. You can also download it from [www.humeca.com](http://www.humeca.com)

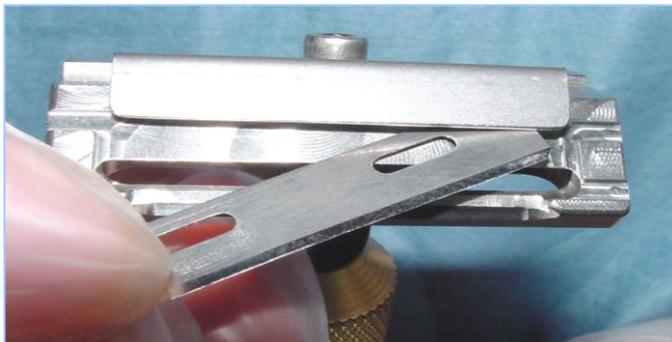
### 4. Inserting the blade

#### **Warning:**

The blade of the SOBER dermatome is a single-use product. According to the amendment 2007/47/EC of the Medical Device Directive we want to point out that there are risks in using blades more than once. Persons involved in re-sterilizing the blades and others might cut themselves when handling and packaging the blades. Also packaging of the blades might be inappropriate to prevent accidental cutting by user and/or damage of the sealed pouch that assures sterility. Therefore Humeca will not accept any responsibility for second use of its dermatome blades.

The following procedure describes how to insert the blade:

- Replace the blade fixing screw with blade cover.
- Turn the screw (3) a few turns counter clockwise to loosen the blade cover a little (do not remove the cover; just lift it a little).
- Insert a sterile blade under the blade cover, as shown in fig. 6.

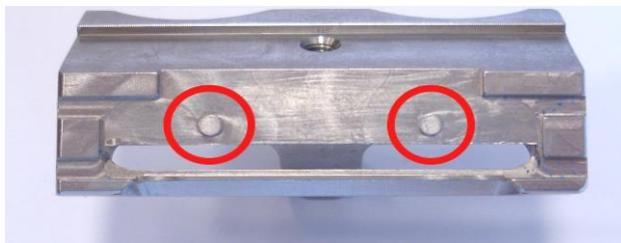


**Fig. 6 Inserting a blade in the SOBER dermatome**

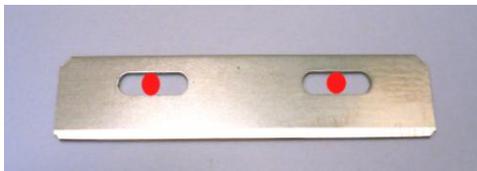
- Now find the correct position of the blade by assuring that the two holes in the blade match with the two little cams on the dermatome head. This is shown in fig. 7-10 (here the blade cover is removed for better explanation; in fact it only needs to be lifted a little).



**Fig. 7 There are two holes in the blade....**



**Fig. 8 ....and two cams on the dermatome head**

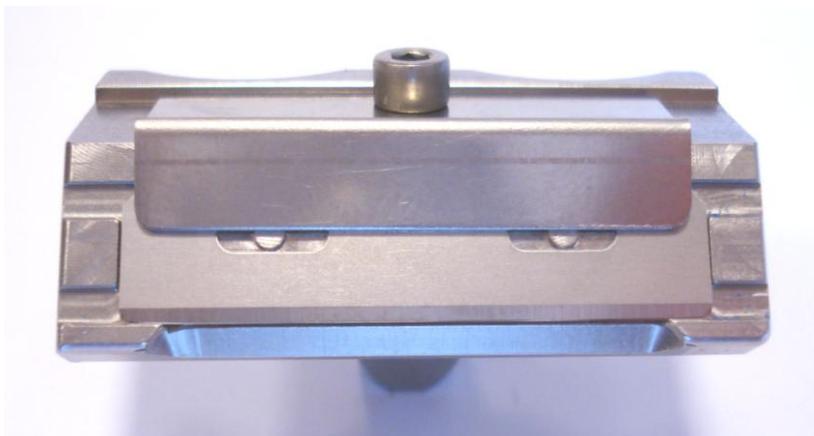


**Fig. 9** The cams should come into the two holes (red dots indicate position of cams)



**Fig. 10** Correct position of the blade

- Finally fix the blade cover and check if the cams are still in the holes of the blade (fig. 11). Re-position if necessary.
- After fixing the shaft to the head again, the SOBER dermatome is ready for use



**Fig. 11** Final situation with the blade cover fixed

## 5. Surgery

- Before harvesting the skin, the donor site area of the patient is shaved and cleaned with a disinfectant. The skin is then smoothed with paraffin oil or some other lubricant.

**Note:** In case the graft will be harvested prior to the application of the Humeca MEEK grafting method, please do not use any fatty substance to smoothen the skin, as this will prevent adherence of the MEEK grafts to the prefolded gauzes. You can use sterile water or a buffered salt solution instead.

- Stretch the skin to be harvested (preferably this is done by an assistant). No wrinkles or folds should be seen and the skin should be completely smooth.
- Put the dermatome on the skin at the starting position for cutting under an angle of about  $45^{\circ}$ , as shown in fig. 12.



**Fig. 12** Starting position of the dermatome

- Put your index finger and middle finger in the areas for finger position, (no. 6 in fig. 2) as shown in fig. 13 and fig. 14.



**Fig. 13** Picture showing how to hold the SOBER dermatome; side view



**Fig. 14** Picture showing how to hold the SOBER dermatome; front view

- Press the dermatome firmly to the skin and cut a stripe of graft by moving the instrument in a straight line over the donor site. Please do not make any lateral movements. See fig. 15.



**Fig. 15 Harvesting the graft; no lateral movements are made**

- Remove the graft from the dermatome by means of a forceps.
- After use, please remove the blade immediately to prevent possible danger at cleaning procedures to follow.

## **6. Atmospheric conditions during use and storage**

When using and storing the instrument, please take care of the following atmospheric conditions:

Ambient temperature 15-50 °C (59-122 °F) and rel. humidity 25-90%.

## **7. Guarantee**

There is a two years guarantee on all parts of the dermatome, except for the blades. This guarantee does not include repairs or replacements if:

- other than original spare parts were used for repair by user,
- the dermatome was used for other applications than the ones mentioned in this manual.

Guarantee includes free of charge repairs, if these are necessary as a result of trouble / defects that occurred during normal use of dermatome. In case of problems please contact Humecca or your local dealer.

## 8. Rules, CE–hallmark, responsibilities

- The management system of Humecca for design, production and sales has been certified according to EN ISO 13485:2003.
- According to the European Medical Device Directory 93/42/ EEC the SOBER dermatome comes under the head of class I products. The sterile blades come under the head of class IIA sterile products.
- The CE-hallmark is indicated on the dermatome and on the package of the blade.
- Do not use other than Humecca blades in the SOBER dermatome nor use Humecca blades in other dermatomes.
- Do not use a dermatome blade in case the package is damaged or previously opened.

## 9. Technical data

### Dermatome

Weight	107 g (3.77 oz)
Width dermatome head	46 mm (1.8")
Length	140 mm (5.5")
Max. diameter shaft	16 mm (0.63")
Cutting width	32 mm (1.26")
Graft thickness	0.25 mm (0.01")
Material shaft	anodized aluminium
Material head	stainless steel

### Disposable blades

Type	double facet grinded
Width / Thickness	8,0 / 0,254 mm (0.31 / 0.01")
Length D42 / D80	38 mm (1.5")
Material	stainless steel

## 10. Ordering info

For ordering, please use the following article numbers:

SOBER dermatome, set with 10 blades	4.SB01
Sterile blades for SOBER dermatome, box 10 pcs.	5.BLSB10
Non-sterile blade for SOBER dermatome	5.011

Spare parts:

Hexagonal key, stainless steel	4.200
Blade cover SOBER dermatome	4.202
Shaft, anodized aluminium	4.206
SOBER dermatome head	4.208



**Fig. 16 SOBER dermatome set in suitcase with a box of 10 sterile blades, as supplied by Humecca**

## 11. Contact address

For any assistance please contact your local dealer or:

Humecca BV  
 Het Bijvank 251-a  
 7544 DB Enschede  
 The Netherlands

Phone: +31 53 4762619

Fax: +31 53 4771905

Email: [info@humecca.com](mailto:info@humecca.com)

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