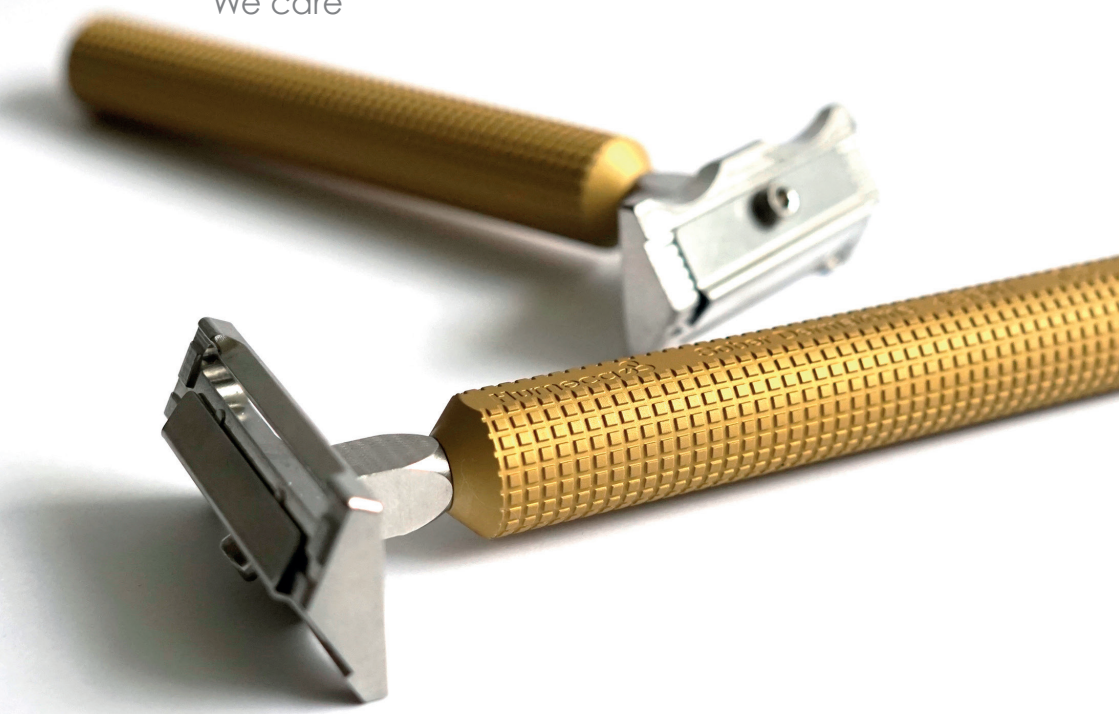


SKIN TRANSPLANTATION
We care



SOBER Dermatome

Instructions for use - English

SOBER Dermatome
SOBER Dermatome Blade

CE
CE 0344

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Please read this manual carefully before using any parts of the Humeca Sober Dermatome

The Humeca Dermatome and equipment should only be used by qualified medical professionals in operation room (OR) environment.

Intended use & indications

The SOBER Dermatome is primarily intended for (split-thickness) skin graft in plastic surgery and/or burn treatment.

Warnings & precautions

- To avoid injury to the user(s) or failure of the Dermatome, please ensure that the Instructions for Use, including the Warnings & Precautions, Inspection & System Setup, Operative Instructions and Cleaning & Disinfection Instructions, are understood by all users prior to initial use.
- To avoid injury to the user(s), please use extreme caution while handling the Dermatome Blades or the Dermatome with Dermatome Blade in place. Cutting risk exists.
- Prior to each use, please:
- Inspect the Dermatome and accessory equipment for any defects. A system that is not functioning properly should not be used until all necessary repairs have been made and the unit has been tested to ensure that it is functioning in accordance with Humeca specifications.
- Verify proper cleaning and sterilization of the Dermatome and accessory equipment.
- Prior to cleaning the Dermatome, please refer to the cleaning instructions for a list of restricted cleaning agents. The use of some cleaning agents may result in damage to the device.
- Use of equipment other than those spe-

cified and sold by Humeca may result in damage to the Dermatome machinery. Use original Dermatome Blades only.

- Dermatome Blades are single-use products. Do not resterilize and/or reuse.
- Please return the Dermatome and accessory equipment to Humeca when it needs servicing or repair.
- **NOTE:** Humeca cannot be held liable for any device malfunctioning as a result of repairs / service performed by an unauthorized service center. Do not attempt to disassemble the equipment.
- **DO NOT** manually modify any component of the Dermatome. No difficulties should occur with set-up or use of the Dermatome.
- Please be aware that the cutting thickness is solely an indication of true graft thickness, as true cutting thickness may differ due to variation in Dermatome use (including applied pressure and cutting angle). These differences are not a result of Dermatome settings

Inspection & system setup

Upon receipt, please check the Dermatome and accessory equipment for completeness and examine thoroughly for external signs of damage.

Operative setup

Placement of blade in the Dermatome

DO NOT use single-use Dermatome Blades if the package is damaged. Sterility cannot be guaranteed.

Operative instructions

- Screw the head of the dermatome loose from the Shaft, seen in Figure 1.
- Use the hexagonal tip of the Shaft (or a 2.5mm hex key) to loosen the Blade Fixing Screw and Blade Cover on the head. As shown in Figure 2. [3 full rotations suffices].

- Cautiously place the Blade in the Dermatome, as shown in Figure 3, **assuring that the two slots in the blade interlock with the two pins on the head, assuring the blade is flat on the head and beneath the blade cover.**
- Tighten the Blade Fixing Screw and Blade Cover with the tip on the Shaft.
- Screw the shaft back on the head.

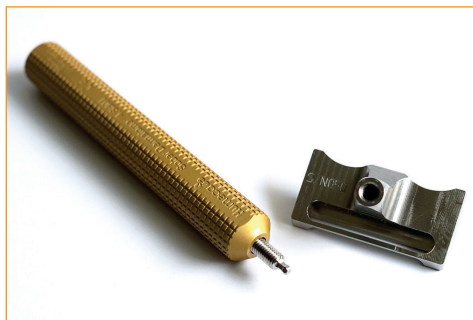


Figure 1. Disassembling SOBER dermatome



Figure 2. Loosening Blade Cover



Figure 3. Blade Placement

Graft thickness

The SOBER Dermatome has a predetermined graft thickness of 0.25mm (0.001").

NOTE: Please be aware that the cutting thickness displayed is solely an indication of true graft thickness, as true cutting thickness may differ due to variation in Dermatome use (including applied pressure and cutting angle). These differences are not a result of Dermatome settings

Graft width

Standard graft width of the SOBER Dermatome is 30 mm (1.18").

Skin graft harvesting

- Place your index and middle fingers on the dermatome head
 - To start cutting push the SOBER Dermatome head slightly into the skin.
 - When cutting, pull the Dermatome Head backwards while applying pressure evenly over the tissue at an angle of 30 to 45 degrees. (Figure 4).
- NOTE:** For optimum cutting results and minimum resistance it is recommended (1) to keep the skin slightly tightened and (2) to moisten the skin with water, saline or oil. If the Dermatome is used in combination with the MEEK Micrograft technique do not use oil.

- When desired length of graft strip is cut, tilt the Dermatome Head upwards.
- Carefully grasp the graft strip on the sloping side of the Dermatome Head by hand or forceps and remove it from the SOBER Dermatome.

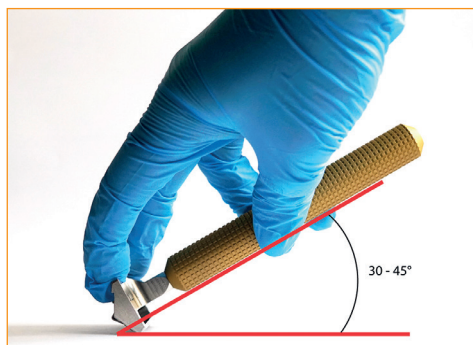


Figure 4. Usage of the Dermatome

Cleaning & disinfection instructions

Cleaning precautions

The Dermatome is manufactured from anodized aluminium and stainless steel. Those materials are corrosion resistant to a large range of chemicals used as cleaning and disinfection agents for surgical instruments. However, before cleaning and sterilization of the Dermatome equipment, please pay attention to the following (please consult your Central Sterile Services Department (CSSD):

- Cleaning agents that contain chlorine or chloride as active ingredient are corrosive to stainless steel and must not be used.
- The use of neutral cleaning agents in combination with demineralized water is preferred. Strong alkaline cleaning agents (pH>10) and intermediate acidic rinsing used in alkaline cleaning process cause clearly visible changes of the aluminium surfaces, such as marks and color fading. H₂O₂ (hydrogen peroxide) must not be used.
- The instructions for use of the cleaning agent should indicate whether or not the product is suitable for cleaning and disinfecting anodized aluminium. Please find out if this is the case and if necessary contact the supplier for this information.

After intensive use the colored parts of the Dermatome might fade. This is considered a normal process and does not harm the instrument.

Precleaning

NOTE: Please carefully remove, and discard, the Dermatome Blade from the Cutting Head before cleaning and sterilization. Leave the Blade Cover loosened after removal of the Blade.

- Remove all visible contamination from the Dermatome as soon as possible. Clean the device with water and a soft brush.

Cleaning

The charts on the next page detail the cleaning and disinfecting process for the Dermatome. While following the cleaning procedure, visually inspect for damage and/or wear.

Cleaning

Step	Description	Instruction	Accessories	Duration
1	Removal of tissue and body fluids	Rinse with warm water and use soft brush	Soft brush and tap water	Until all visible pollution is removed
2	Pre-soak (optional)	Immerse device into water and liquid cleaner	- Tap water - Neutral pH disinfectant/cleaner	Minimum 15 minutes
3	Pre-soak rinse	Rinse product under warm tap water and clean with soft brush	- Tap water - Neutral pH disinfectant/cleaner	Minimum 30 seconds
4	Drying	Dry with wipe and/or air	- Wipe - Dry air	Until product is visually dry
5	Automated washer	Place device in washer	Washer - Cleaning solution - Washer neutralizing solution (if applicable)	Minimum total cycle time 34 minutes when including all steps below

Automatic washer cycle

Step	Minimum time	Recommended temperature °C
Pre-wash	3 minutes	65
Cleaning I	3 minutes	85
Cleaning II or neutralizing	1 minute	20
Rinse I	1 minute	20
Final rinse	1 minute	80
Thermal disinfection and drying	25 minutes	110

- Pre-soak cleaner may be surfactant or protease/enzymatic based cleaning solution compatible with aluminum
- Washer cleaning solution should be a neutral pH or solution compatible with aluminum
- Neutralizing solution should be appropriate for the utilized cleaning solution, based upon the manufacturer's recommendation.

Sterilization instructions

Steam sterilize the Dermatome according to the instructions in the chart below.

Sterilization autoclaves should comply with the requirements of, and be validated and maintained in accordance with EN 285, EN 13060, EN ISO 17665, and ANSI/ AAMI ST79.

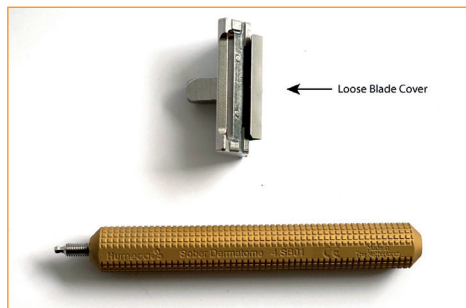


Figure 5. Dermatome sterilization case configuration

Recommended steam sterilization parameters

Cycle type	Minimum temperature	Minimum exposure time ⁴ wrapped ^{5,6} , unwrapped ⁸	Minimum dry time ^{3,7}
Prevacuum / Pulsating vacuum ^{1,3}	134 °C / 273 °F	3 min	8 minutes
Prevacuum / Pulsating vacuum ^{2,3}	132 °C / 270 °F	4 min	

1. Minimum validated steam sterilization time required to achieve a 10⁻⁶ assurance level (SAL).
2. Minimum validated steam sterilization temperature required to achieve a 10⁻⁶ assurance level (SAL).
3. Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed here.
4. Steam sterilization cycles with longer times than those listed are also acceptable.
5. Medical grade steam sterilization compatible wrap equivalent to four thicknesses of 140-thread-count muslin
6. Rigid sterilization container that complies with ANSI/ AAMI ST 46.
7. Drying times vary according to load size and should be increased for larger loads.
8. Flash (unwrapped) sterilization should only be used as an emergency procedure.

In cases of doubt, please contact Humeca or your local distributor before using the instrument.

Maintenance & service

The SOBER Dermatome requires no user maintenance or calibration.

The Dermatome should be returned to Humeca when servicing or repair is needed. When it is necessary to return the instrument for inspection and maintenance or repair, please contact your local Humeca representative. Humeca cannot be held liable for any instrument malfunction resulting from repairs or service performed by an unauthorized service center. The Dermatome must be properly packaged when returned. A

completed decontamination form must accompany all equipment for repair. Humeca Dermatomes and accessory equipment requiring service or repair may be returned to:

Humeca BV.

Oostermaat 5
7623 CS Borne
The Netherlands
Email: repairs@humeca.com
T: +31 74 727 10 01
F: +31 74 727 10 02

Troubleshooting

Please consult the table below if any problems occur with the Dermatome. If pro-

blem continues or is not listed in the table, please contact Humeca at +31 74 727 10 01 or info@humeca.com.

Troubleshooting		
Problem	Possible cause	Recommendations
Blade does not fit	Competitor blade used	Place Humeca blade
Dermatome does not cut	Blade is dull	Place new blade
Graft is incomplete	Blade is dull	Place new Blade

Warranty

There is a two years warranty on all parts of the dermatome. This warranty 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.

Warranty includes free of charge repairs, if these are necessary as a result of defects that occurred during normal use of dermatome. All original Humeca parts that are replaced in repairs will receive a new warranty according to the above mentioned conditions. When it is necessary to return the instrument for repair, please contact your local Humeca representative.

Product information

Specifications















Weight 107 g
 Length 140 mm
 Width head 46 mm
 Materials: Aluminium
 Stainless Steel

Storage:

Standard warehouse conditions

Ordering information

SOBER dermatome 4.SB01
 SOBER blades, box 10 pcs 5.BLSB10

Symbols	
Caution	
Follow Instructions for Use	
This device complies with medical device directive 93/42/EEC	
Serial Number	
Caution: federal law in the U.S.A. restricts the sale, distribution or use of this device to, by or on the order of a licensed medical practitioner.	
Do not use if package is damaged	
Do not re-use	
Sterilized using irradiation	
Catalogue number	
Batch code	
Use-by date	
Manufacturer	
Collect electrical and electronic equipment waste separately	
Date of manufacture	

Components (figure 6)

1. Dermatome Head
2. Threaded Hex Wrench
3. Dermatome Shaft
4. Blade Cover
5. Cap Screw (Hex)
6. SOBER Dermatome Blade

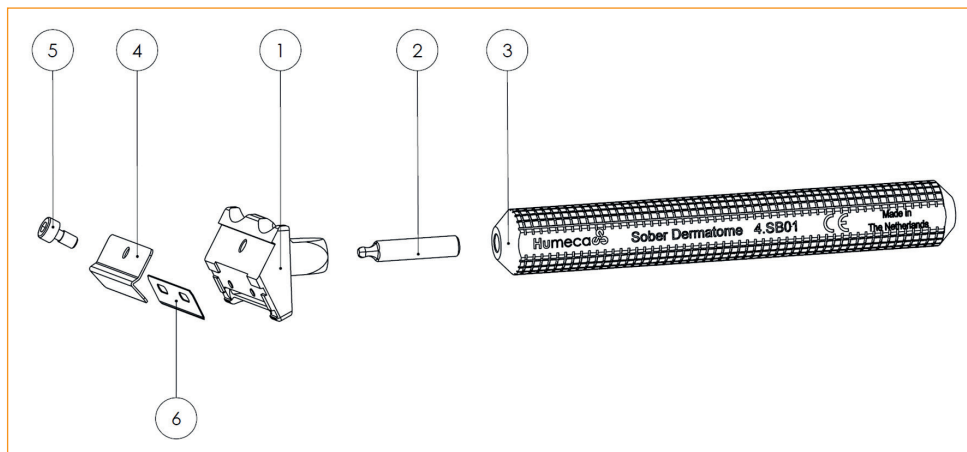


Figure 6. Components

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins or other markings on the paper.



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SOBER Dermatome 
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