

SKIN TRANSPLANTATION

We care



Humeca Mesher

Instructions for use - English

Humeca Mesher **CE**
Humeca V-carrier **CE 0344**

Contents

Description.....	3
Configurations.....	3
Intended use & indications	3
Contraindications.....	3
Warnings & precautions	3
Inspection & system setup.....	4
Operative instructions.....	4
Operative setup.....	4
Meshing of the graft	4
Cleaning & disinfection instructions.....	5
Cleaning precautions	5
Precleaning	5
Cleaning and disinfection.....	5
Sterilization instructions	7
Maintenance & service	8
Troubleshooting	9
Warranty	10
Product information	10
Symbols	10
Specifications	11
Storage conditions V-carrier.....	11
Components	11



PLEASE READ THIS MANUAL CAREFULLY BEFORE USING ANY PARTS OF HUMECA MESHER

The Humeca Mesher should only be used by qualified medical professionals in operative room environment.

Description

The Humeca Mesher can be used for meshing skin grafts in plastic surgery and/or burn treatment. Single-use Humeca V-carriers are available for guidance of the skin graft through the Humeca Mesher and to assure perforation and meshing of the graft at controlled spots (on the ridges of the V-carrier). Movement of the hand wheel causes the carrier, with skin graft, to move through the Mesher where circular blades cut through the skin graft.

Configurations

The Humeca Mesher is available in a V10 or V15 configuration supplied by Humeca:

- Type V10 carriers, also compatible with Zimmer® Meshgraft II System
- Type V15 carriers, also compatible with Aesculap® / B.Braun® meshers

The configuration of the Humeca Mesher is shown at the sides.

Different expansion ratios of the Humeca V-carriers are available (1:1 (solely perforation) 1:1.5, 1:2, 1:3, 1:6), to allow the user to select the appropriate expansion ratio for the specific surgical procedure.

Intended use & indications

The Humeca Mesher is primarily indicated for the treatment of patients with skin grafting. The Humeca Mesher is intended for

meshing and perforating the (split-thickness) skin graft.

Contraindications

The equipment should not be used for the preparation of skin grafts > 1mm (0.04 inch) thickness.

Warnings & precautions

- To avoid injury to the user(s) or failure of the Humeca Mesher, 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 Humeca Mesher Blades Axle. Cutting risk exists.
- Prior to each use, please:
 - Inspect the Humeca Mesher for any defects. A system that is not functioning properly should not be used until all necessary repairs have been made and the unit is tested to ensure that it is functioning in accordance with Humeca specifications
 - Verify proper cleaning and sterilization of the Humeca Mesher.
 - Ensure that the Humeca Mesher is placed stably.
- Prior to cleaning the Humeca Mesher, 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 the Humeca Mesher Blades Axle with extreme caution, to avoid user injury and damage to the blades. Damaged blades may result in improper cutting of the skin graft and damage to the machinery.
 - **DO NOT place the Humeca Mesher Blades Axle on a hard surface (table).**

- Use of equipment other than those specified and sold by Humeca may result in damage to the Humeca Mesher machinery. Use the original Humeca V-carriers only.
 - **DO NOT use any other graft carriers than the Humeca V-carriers.**
 - **DO NOT cut any (biological) material other than allografts or autografts.**
- Humeca V-carriers are single-use products. Do not resterilize and/or reuse.
- Please return the Humeca Mesher to Humeca if 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 other than described in the Cleaning & disinfection instructions.

Inspection & system setup

Upon receipt, please check the Humeca Mesher for completeness and examine thoroughly for external signs of damage. After unpacking your Humeca Mesher, please save packaging material, as this will offer proper protection during future shipment of the device.

DO NOT use V-carriers if the package is damaged. Sterility cannot be guaranteed.

Operative instructions

Operative setup

Function checks of Humeca Mesher, as described below, must be carried out prior to each surgical procedure.

DO NOT use single-use Humeca V-carriers if the package is damaged. Sterility cannot be guaranteed.

Check whether the Humeca Mesher Blades Axle is in the right position. Both bearings should be placed in the corresponding holders, positioning the gear on the hand wheel side. Close the Bridge and fasten the screws manually. Check proper operation by rotating the hand wheel a few turns. It should run easily.

Meshing of the Graft



Using a Humeca V15 carrier in a Humeca V10 mesher may seriously damage the blades! Considerable force will be required to turn the hand wheel. In such a case immediately counterturn the hand wheel, remove the carrier and replace it with the correct carrier type.



When using a Humeca V10 carrier in a Humeca V15 mesher, the graft will not be cut (properly). Remove the carrier and replace it with the correct carrier type.

- Spread the harvested graft on the carrier. Be sure the type of carrier matches with the configuration of the mesher. In case of doubt, please check (see Inspection & System Setup)
- Place the carrier on the Humeca Mesher Base Plateau, positioning it in the Carrier Slids at both sides of the Base Plateau. Push the carrier forward until it is stuck between the Humeca Mesher Blades Axle and Rotator Axle (Figure 1).
- Rotate the Hand Wheel clockwise while gently pushing the carrier through the axles.
Note: The graft tends to stick to the Humeca Blades Axle, particularly during the first turn. If this occurs, please gently separate the graft and press it back on the carrier.

- When the carrier has been completely guided through the Mesher, remove the carrier from the Humeca Mesher. Gently remove the meshed skin graft from the carrier with forceps and apply it to the wound bed (dermal side down).



Figure 1. Graft/carrier insertion in Mesher



Be careful when using metal instruments while handling the Humeca Blades Axle, as these can damage the blades.

Note:

Place one hand over the Mesher Grip on the Bridge to stabilize the Humeca Mesher during the cutting process.

Cleaning & disinfection instructions

Cleaning precautions

The Humeca Mesher is manufactured from anodized aluminum 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 Humeca Mesher, 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.
- Saline solution has a corrosive effect on stainless steel and should 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 aluminum 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 aluminum. 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 Humeca Mesher machine might fade. This is considered a normal process and does not harm the instrument.

Precleaning

- Remove all visible contamination from the Humeca Mesher Blades axle as soon as possible. Loosen the two screws of the bridge and open the bridge to take out the Humeca Mesher Blades axle. Clean it with water and a soft brush.

Cleaning and disinfection

The charts on the next page detail the cleaning and disinfecting process for the Humeca Mesher. 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 Humeca Mesher according to the instructions in the chart below.

Note: Please remove the Humeca Mesher Blades Axle from the Humeca Mesher foundation before sterilization.

It is recommended to use the Humeca Mesher sterilization case for sterilization (Figure 2). 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. The sterilizer Manufacturer's Instructions for operation and load configuration should be followed explicitly.



Figure 2. Humeca Mesher sterilization case

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	

configuration

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 Humeca Mesher is designed with lubeless bearings and requires no user maintenance or calibration. If desired, however, the bearings may be lubricated by placing 1 small drop of surgical instrument lubricant in the grooves. Run the machine for a moment to spread the oil evenly before sterilizing the instrument.

The Humeca Mesher should be returned to Humeca if servicing or repair is required. 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 Humeca Mesher must be properly packaged when returned. A completed decontamination form must accompany all equipment for repair.

Humeca Meshers 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 Humeca Mesher. 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
Operating the Humeca Mesher is heavy	Wrong type of carrier used or mesher not correctly adjusted	Check if the type of carrier (V10 or V15) applied matches the configuration of your Humeca Mesher. Do not use a different type of carrier than either V10 or V15.
	Blades Axle runs heavily unloaded	Open the Bridge, and check if axle can be easily run manually by rotating the gear.
The carrier is not moved through the Humeca Mesher, while turning the handle	Wrong carrier thickness	Check carrier type (V10 or V15)
Skin graft is not cut, only partly, or faulty	Wrong carrier thickness	Check carrier type (V10 or V15)
	Wrong usage of the carrier	Check if the carrier is placed with the grooved side up. Do not reuse the carrier.
	Blades are blunt and / or damaged	Remove the Blades Axle from the device and look at the cutting sides of the blades. If blade sides are damaged or shiny, replace Humeca Mesher Blades Axle.
	Screws on Bridge are not fastened properly	Check whether the Bridge is placed correctly. Adjust if needed.
Graft migrates on carrier during cutting	Graft was too thick and (part) of the subcutaneous (fat) layer was included	The meshing technique should not be used for the preparation of skin grafts > 1mm (0,04 inch) thickness. Please check thickness of graft.

Warranty

There is a two years warranty on all parts of the Humeca Mesher, except for the blades. There is a one year warranty on the blades.

This warranty does not include repairs or replacements if:

- other than original spare parts were used for repair by user,
- the Humeca Mesher 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 the Humeca Mesher. 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 device for repair, please contact your local Humeca representative.

Product information

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	
Date of manufacture	
Medical Device	
Single sterile barrier system with protective packaging inside	

Specifications

Humeca mesher

Weight: 4.3 kg, 9.5 lbs
 Length: 220 mm, 8.66 in
 Width: 212 mm, 8.35 in
 Height: 183 mm, 7.2 in
 Materials: Aluminium
 Stainless Steel
 Configurations: V10 and V15

V-carrier

Length: 280 mm, 11 in
 Width: 78.8 mm, 3.1 in
 Thickness:
 Type V10: 1 mm, 0.04 in
 Type V15: 1.5 mm, 0.06 in
 Materials: Polymer

Storage conditions V-carrier

Temperature: 15-45 °C (59-113 °F)
 Humidity: 35-90%

Components (figure 4)

1. Humeca Mesher Foundation
2. Humeca Mesher Hand Wheel
3. Humeca Mesher Blades Axle
4. Humeca Mesher Rotator Axle
5. Humeca Mesher Base Plateau
6. Carrier Slid
7. Mesher Grip
8. Mesher Bridge
9. Screw
10. Configuration

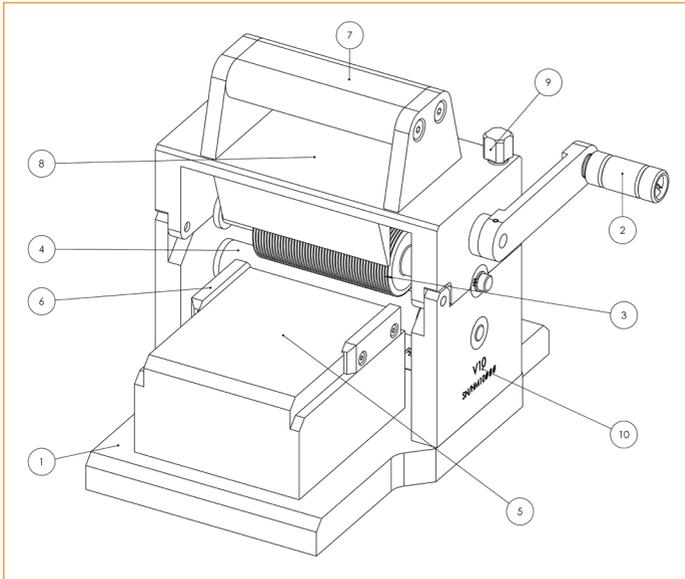
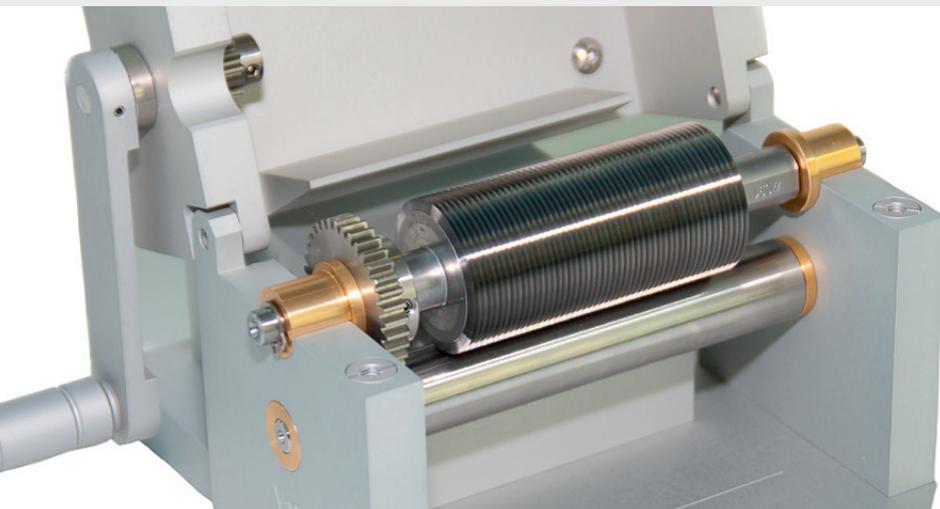


Figure 3. Components



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