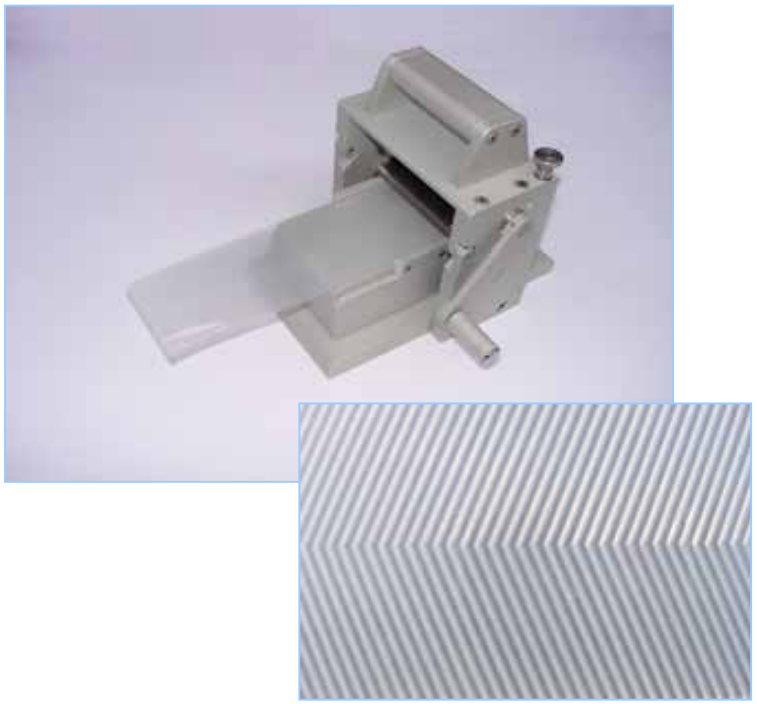
Humeca Mesher and V-carriers

Properties and instructions for use



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Contents

SECTION I HUMECA® V-CARRIERS

I-1. Introduction

Humeca introduces a new range of grooved skin graft carriers, called 'V-carriers'. The symmetric V-shaped groove pattern of these carriers prevents unwanted sideward movement during passage through the mesher. The standard length of these carriers is more, compared to existing carriers and care has been taken to ensure that the groove pattern of the carriers connect to each other. This enables cutting of extra long graft stripes. Different versions of these carriers are available making them compatible with existing meshgraft machines.

We also introduce a new carrier that only perforates the graft to allow drainage of fluids and prevent haematoma or seroma underneath the graft.

I-2. Working principle of meshing with grooved carriers

Skin graft meshing is the term used for cutting slits into a sheet graft and stretching it open prior to transplantation. To obtain such slits, the graft is passed through a mechanical meshing instrument, called a mesher. Depending on the design of the mesher, different types of carriers are used on which the graft is placed before cutting. When the mesher is provided with interrupted blades, flat carriers are used and in some meshers no carrier is used at all.

A well-known type of mesher contains circular blades and requires the use of grooved plastic carriers. In such an instrument the blades are forced under pressure to 'roll' over the grooved carrier, thus cutting the graft only at locations where the blades contact the carrier (upper part of the grooves), while the graft is left undisturbed at locations where the blades do not contact the carrier (lower part of the grooves).

Fig. 1 illustrates this working principle in cross section.

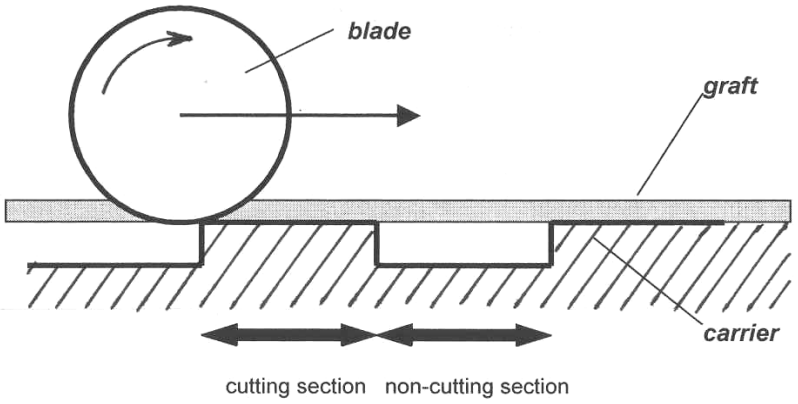

Fig. 1. Working principle of meshgraft using grooved carriers

Fig. 2 shows where the slits in the skin graft will appear as a result of this principle. As shown, the length of the slits depends on the width of the upper part of the grooves and of the angle of the grooves. The longer the slits are, the larger the expansion ratio will be.

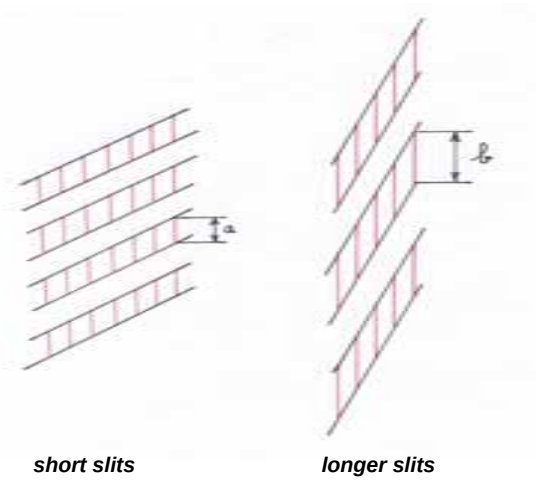

Fig. 2. Schematic detail of a grooved carrier and the location and length of the slits. The slits are represented by the red vertical lines.

The picture below shows the mesh structure that results from this principle.

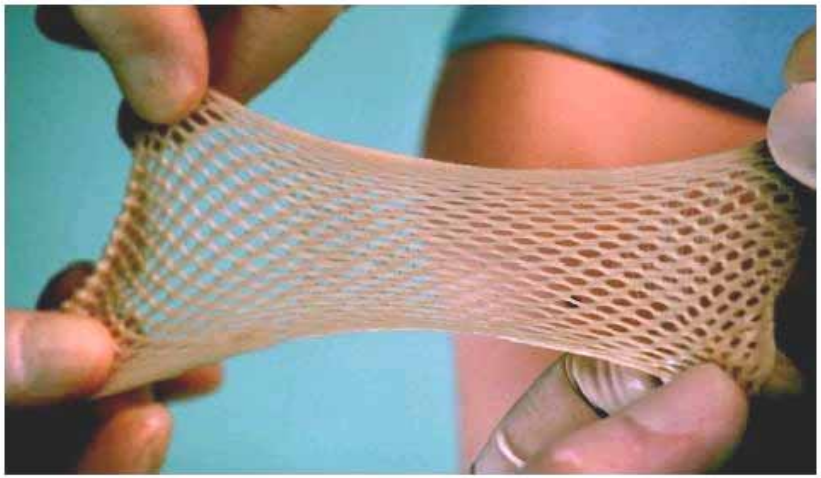

Fig. 3. Picture showing a meshed piece of skin graft

I-3. Application

Skin grafting is a well-known means of reconstructing a skin defect. Because a wound is re-epithelialized from the edges towards the centre, the perimeter of the graft is the only part that contributes to the epithelialization process. Expansion techniques are used to speed up that process. An expanded graft presents a larger cumulative perimeter through which epithelial outgrowth can proceed. Besides, with graft expansion, larger areas can be covered with smaller sections of skin. Various ways to expand grafts have been described. These include pinch grafts, relay transplantation, meshing and (MEEK) micrografting.

A more detailed description of the application of Humeca V-carriers is presented in the separate Humeca booklet “Humeca mesher and V-carriers: *Applications*”. You can download it from www.humeca.nl and it also comes standard with the mesher.

I-4. The shape of Humeca V-carriers

I-4.1 Symmetric groove pattern

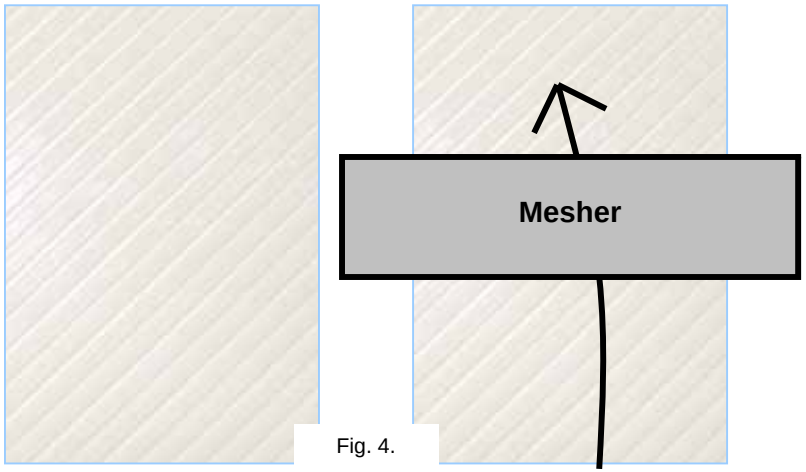

Fig. 4.

Conventional skin graft carriers have a groove pattern of straight lines from the left to the right under a certain angle (fig. 4). This configuration however often causes the carrier to distort during cutting in a mesher. To prevent such distortion, Humeca carriers have a symmetric V-shaped groove pattern (fig. 5).

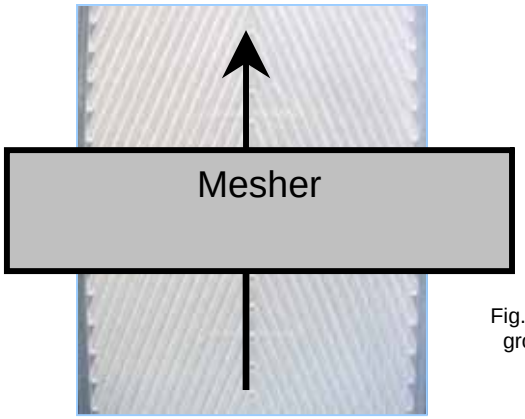

Fig. 5. Detail of the symmetric V-shaped groove pattern of the Humeca carrier. No distortion will take place during cutting in a mesher

I-4.2 *Connecting grooves*

In all Humeca V-carriers, the pattern of the grooves in one carrier connects exactly to that of the following carrier. In other words, when the carriers are passed to the mesher one after another even very long grafts can be processed easily. Fig. 6 below shows how the first carrier connects to the second one.

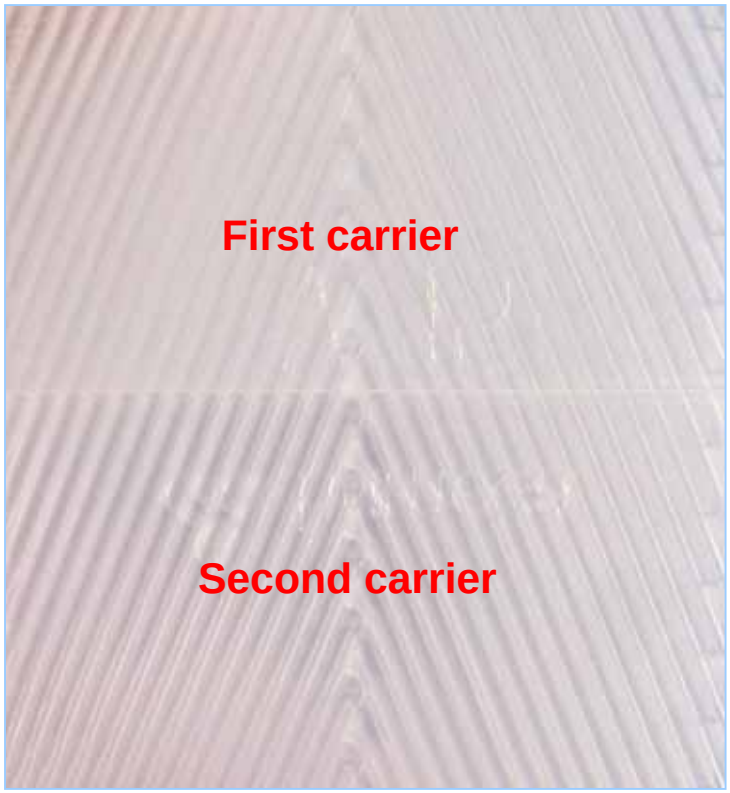

Fig. 6. Detail showing how two V-carriers connect to each other. The groove pattern continues from one carrier to the other

I-5. Different types of Humeca V-carriers

Humeca supplies six different versions of the V-carriers:
- two different carrier thicknesses for each type of carrier,
- two different expansion ratios and
- one perforation carrier 1:1

Thickness
The V-carriers have a thickness of either 1.0 or 1.5 mm. For some meshers (like Zimmer®) a thickness of 1.0 mm is needed, while others (like Aesculap® / B.Braun®) require 1.5 mm thick carriers. The Humeca® mesher can be adjusted to accept both types of carriers.

Expansion ratio
The V-carriers are available in expansion ratios 1:1.5 and 1:3. When larger expansion ratios are desired, we recommend the Humeca MEEK Micrograft technique for faster healing and better results.

Perforation
We introduce a special carrier with ratio 1:1, which is to be used for perforation only (not for expansion purposes). Such perforation allows drainage of fluids through full sheet grafts. Drainage prevents separation of the graft from its wound bed by haematoma or seroma.

I-6. Instructions for use

- Place the graft on the carrier and put it in the mesher in the direction indicated by the ‘arrow’ of the grooves.

ATTENTION:
Be sure to use the right carrier in the right machine: If the blades of the mesher do not touch the carrier at all, the type V10 carrier (for Humeca® and Zimmer® meshers) probably must be replaced by a type V15 carrier (for Humeca® and Aesculap®/ B.Braun® meshers). If, on the other hand, a carrier cannot be passed through the machine, because it seems to be too thick, please remove it immediately and replace it by a type V10 carrier.

- Push the carrier in the direction of the blades and turn the handle clockwise until the carrier moves forward.
- Now gently keep turning the handle to move the carrier through the mesher.

NOTE (1):

If during meshing the graft “sticks” to the blades of the mesher, please use a forceps to remove it from the blades and place it on the carrier again. Be careful in such case not to damage the blades.

NOTE (2):

If the graft length exceeds the length of the carrier, first mesh part of it on a V-carrier and then continue meshing by connecting a second carrier to the first one. The grooves connect to each other and if care is taken that the seam between both carriers is minimal, the mesh pattern will not be interrupted.
Another well known method of meshing a long stripe of graft is to fold it on the carrier double down and mesh as usual.

- After meshing, use a forceps to remove the graft from the carrier.
- After complete pass, remove the carrier from the mesher and apply the graft to the wound.

If more meshing cycles have to be performed during the same operation, the carrier may be used several times. However do not re-sterilize the carrier and use it again at another operation. The quality and cleanness of the product cannot be guaranteed after re-sterilization.

I-7 Labelling

The figure on the next page explains the meaning of the signs on the label on the package of a Humeca V-carrier. It is important to take notice of the expiry date and LOT number. In case of any complaint, you will have to refer to these data. Sterility cannot be guaranteed when the package is damaged. Please do not use the product in such case.

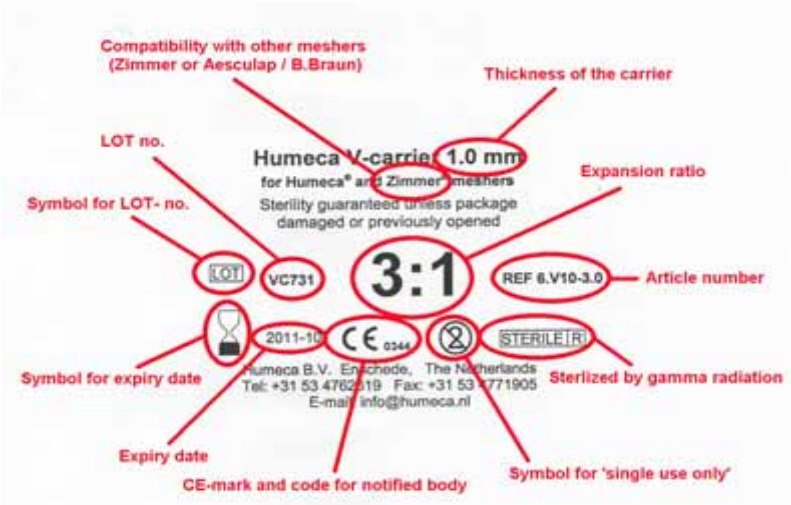

Fig. 7 Example of the label of a Humeca® V-carrier

I-8. Technical data Humeca® V-carriers

Humeca® V-carriers are made of high quality medical grade polypropylene. The material was chosen for its high flexibility, radiation resistance, translucency and hardness. The pouch used is made of a 60 grams medical paper, sealed to PET/PE.

Dimensions carriers (length x width): 280 x 78.8 mm.
Dimensions box, 10 pcs. (length x width x height): 400 x 120 x 25 mm.

Weights:

6.V10-1.0	thickness 1.0 mm and expansion ratio 1	18.9 g
6.V10-1.5	thickness 1.0 mm and expansion ratio 1.5	17.5 g
6.V10-3.0	thickness 1.0 mm and expansion ratio 3	17.3 g
6.V15-1.0	thickness 1.5 mm and expansion ratio 1	26.3 g
6.V15-1.5	thickness 1.5 mm and expansion ratio 1.5	26.8 g
6.V15-3.0	thickness 1.5 mm and expansion ratio 3	25.4 g

I-9. Storage

When using or storing the V-carriers, please take care of the following atmospheric conditions:

- Ambient temperature 15-45 °C
- Relative humidity 35-90%
- Atmospheric pressure 850-1070 hPa (640-800 mm Hg)

I-10 Warranty

- In case of any complaint or request for replacement, please return the original package or refer to the LOT number and expiry date as indicated on the label.
- Humeca will replace such products free of charge.
- Humeca will not guarantee the quality of V-carriers that have been re-sterilized or have been used after the expiry date. In such case Humeca will not replace them free of charge.

I-11. Ordering and delivery V-carriers

The Humeca® V-carriers are packed in carton boxes containing 10 pcs. Ordering numbers are as follows:

For Humeca® and Zimmer® meshers:

6.V10-1.0 thickness 1.0 mm and expansion ratio 1
6.V10-1.5 thickness 1.0 mm and expansion ratio 1.5
6.V10-3.0 thickness 1.0 mm and expansion ratio 3

For Humeca® and Aesculap® / B.Braun® meshers:

6.V15-1.0 thickness 1.5 mm and expansion ratio 1
6.V15-1.5 thickness 1.5 mm and expansion ratio 1.5
6.V15-3.0 thickness 1.5 mm and expansion ratio 3

Humeca supplies the V-carriers ex works (EXW) in accordance with Incoterms 2000.

SECTION II THE HUMECA® MESHER

II-1. Application

The mesher has been designed for the following applications:

- Meshing of (split) skin and other biological tissues
- Perforation of these tissues with the Humeca V-carriers 1:1

II-2. The main parts of the Humeca® mesher

The dermatome and accessories are shown in pictures 8, 9 and 10. Reference is made to the following parts:

1	Base block	7	Disposable skin graft carrier
1a	Groove (2x)	8	Gear wheels
2	Bridge	9	Bearing of blades axis (2x)
3	Grip	10	Lubrication hole (2x)
4	Locking screws (2x)	11	Carrier thickness adjustment screws
5	Blades axis		
6	Handle	12	Transport axis

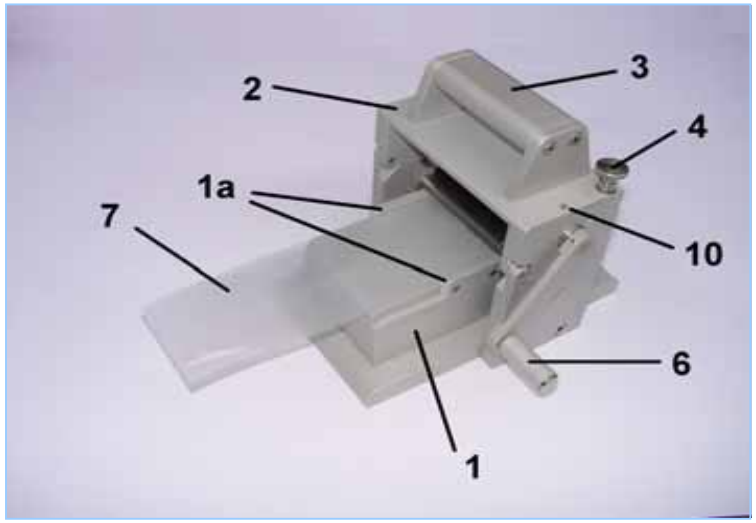

Fig. 8. Humeca® mesher, side view

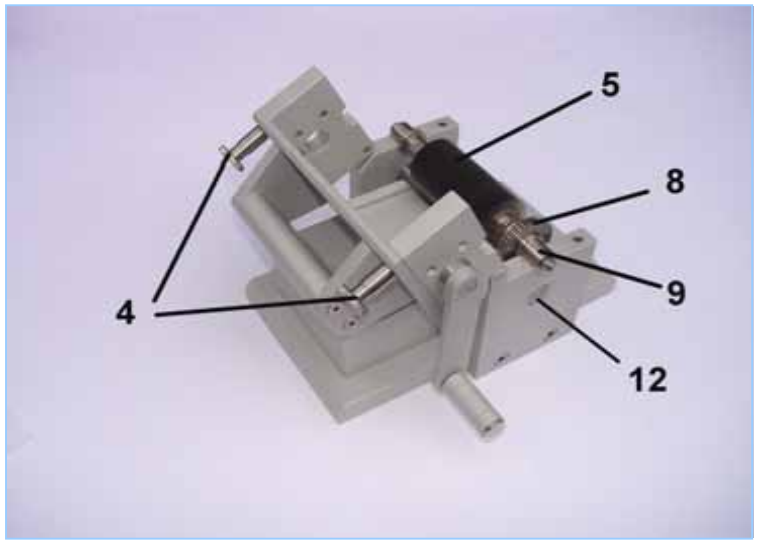

Fig. 9. Humeca® mesher, bridge

Fig. 10. Humeca® mesher, underside

II-3. Cleaning and sterilization

The entire Humeca mesher can be cleaned and steam sterilized. Most parts of the mesher are made out of anodised aluminium. The least damage to anodised aluminium is observed when neutral cleaning agents are used in combination with demineralised water. The quality of water in the cleaning process is of crucial importance. An unfavourable water composition can have a detrimental effect on the materials of surgical instruments. The most critical water constituents are chlorides, since high chloride concentrations may cause pitting corrosion on instruments and it can seriously damage the surface of anodised aluminium. The chloride content of the water should not exceed a level of approx. 120 mg/l (equivalent to 200 mg/l NaCl=sodium chloride).

All alkaline cleaning methods will cause clearly visible changes to the surface of the aluminium like stains and colour fading. The acidic intermediate rinse, used after cleaning also attacks the anodised surface of the mesher. Furthermore deterioration of the surface can be expected when softened water is used for rinsing and disinfection. This is caused by the fact that softened water turns alkaline (pH-value>8.5) by soda formation when it is heated (93^{o}C).

Hot air drying temperatures higher than 90^{o}C should be avoided to prevent crazing of the anodised surface. Intensive and extended drying with hot air of such temperature is hardly a necessity and lower temperatures can be used without any problems.

As a rule, it is advisable to use only demineralised water for the final rinse. The least damage to anodised aluminium and stainless steel surfaces will occur when a neutral cleaning agent is used in combination with demineralised water. Do not use H_2O_2 (hydrogen peroxide) in the washing process, as it will damage the instrument.

A brochure about cleaning and sterilizing surgical instruments can be downloaded from the website www.a-k-i.org (under „publications“).

For cleaning and sterilization please proceed as follows:

- Remove disposable skin graft carrier from the mesher.
- Loosen the two locking screws (4) until they do not come out anymore.
- Put your hand in the grip (3) and open the bridge (2) carefully.
- Take out the blades axis (5) (hold it at the bearings 9) and clean the spaces between the blades with a soft brush and water with some detergent (particles of biological tissue might have been captured in these spaces). Either put the axis back in its position in the mesher or put it in the sterilization container Humeca supplies for that purpose. DO NOT PLACE THE BLADES AXIS ON SOME HARD SURFACE, AS THIS WILL SERIOUSLY DAMAGE THEM!
- Put the mesher (bridge opened) and the blades axis in the sterilization container.
- All parts can be sterilized with saturated steam at the common temperature of 134^{o}C (usually 5-10 minutes) or 121^{o}C (prolonged exposure time of approx. 20 minutes).

II-4. Lubrication

Prior to use (or prior to sterilization) put some drops of surgical oil into the two holes (10) on the top of the bridge (next to the grip). Humeca supplies STERILIT® oil for that purpose (this type of oil has to be applied before sterilization).

II-5. First use

II-5.1. Check carrier adjustment

The mesher is suitable for different kinds of skin graft carriers. Best results are obtained with the Humeca® V-carriers, but the instrument can also be used in combination with Zimmer® and Aesculap® / B.Braun® carriers. At first use a one-time check must be performed to adjust the instrument to the carrier to be used. Humeca standard adjusts the mesher for use with the Humeca V-carriers of the type V10 and for Zimmer® carriers.

To adjust the mesher to the desired carrier, please proceed as follows:

- Put the mesher on a table with the backside towards you, put your hand under the transport axis and lift it a little, as shown in fig. 11.
- If you actually can lift the axis a little (about 0.5 mm) and so the axis has some play, the mesher is adjusted to Aesculap® / B.Braun® carriers and Humeca® V-15 carriers.
- If there's no vertical movement in the axis, the mesher is adjusted to Zimmer® and Humeca® V-10 carriers.

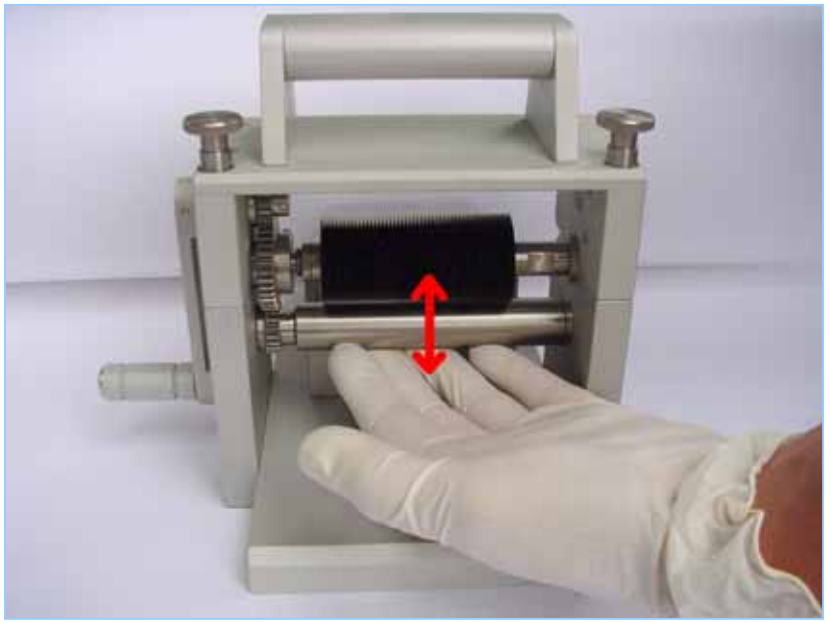

Fig. 11. Checking the carrier adjustment of the mesher

II-*5.2. Change carrier adjustment*
If you want to change the adjustment of the type of carrier to be used, please proceed as follows:

A) Change from Aesculap®/B.Braun® and Humeca® V-15 carriers to Zimmer® and Humeca® V-10 carriers.

Turn both adjustment screws (11) at the bottom of the mesher (shown in fig. 10) clockwise with a screwdriver until they are complete fixed. Now there will be no play left in the transport axis and the mesher is ready for use with Zimmer® and Humeca® V-10 carriers.

B) Change from Zimmer® and Humeca® V-10 carriers to Aesculap® /B.Braun® and Humeca® V-15 carriers.

Loosen both adjustment screws (11) at the bottom of the mesher (shown in fig. 10) counter clockwise about two turns. The surface of the crew heads should be approximately equal to the surface of the bottom plate of the mesher (when placed on a table, the mesher should not stand on the screws, but on the bottom plate). Now there will be vertical play in the transport axis and the mesher is ready for use with Aesculap® /B.Braun® and Humeca® V-15 carriers.

II-6. The procedure of meshing

II-6.1 Mounting the mesher after sterilization
After sterilization the bridge of the mesher is open and the blades axis might be stored separately. To prepare the mesher for cutting, please proceed as follows:

- Replace the blades axis at its correct position in the mesher.
- Close the bridge (turn the handle a little if the gearwheels don't grip) and fix the locking screws (4 in fig. 17) by turning them clockwise until complete fixation.
- Check proper operation by rotating the handle (6) a few turns. It should run easily.

II-6.2 Meshing
- Spread the graft, mostly dermal side down, on a grooved skin graft carrier. Be sure the type of carrier matches with the adjustment of the mesher. In case of doubt, please check (see section 5.1).

Warning: ***Using an Aesculap®/B.Braun® carrier or a Humeca® type V-15 carrier in a mesher that is adjusted for Zimmer® and Humeca® V-10 carriers, might seriously damage the blades! Considerable force will be required to turn the handle. In such a case immediately counterturn the handle, take out the carrier and replace it or re-adjust the mesher to the carrier to be used.***

If a Zimmer® or Humeca® V-10 carrier is used in a mesher that is adjusted for use with Aesculap® /B.Braun® and Humeca® type V-15 carriers, the mesher will not cut properly. There will be no damage to the instrument, but probably the graft will not be cut at all. The handle will turn very easily. In such case replace the carrier or re-adjust the mesher.

- Place the carrier on the base block (1 in fig. 17) and push it in the grooves (1a). Some carriers might be too small to fit under both grooves. In that case push it only under one groove.
- Push the carrier forward until it sticks between the blades axis and the transport axis.
- Turn the handle (4) clockwise while pushing the carrier until the axes grips it.
- Turn the handle clockwise until the carrier completely passed the mesher. In case the cut graft sticks to the blades, please take it off from there with a forceps and replace it on the carrier.
- After complete pass, remove the carrier from the mesher and apply the graft to the wound.

Note: Carriers are frequently used more than once during the same operation. However, please do not re-sterilize the carrier and use it again at another operation. The quality and cleanness of the product cannot be guaranteed after re-sterilization.

Note: If the graft length exceeds the length of the carrier and Humeca® V-carriers are used, please use the procedure described in chapter I-6 (note 2).

Note: Some surgeons prefer to place a graft on the carrier epidermal side down, instead of dermal side down. In that case the graft can be placed on the wound while still on the carrier. The carrier with the graft is pressed carefully to the wound bed and afterwards the graft is loosened from the carrier by bending the carrier and peeling it off. For this reason, the carrier is very flexible to allow bending without breakage.

Note: In conventional meshers, differences in carrier thickness might cause incomplete cuttings and excessive pressure on the blades. As a unique feature, the Humeca® mesher is provided with two stainless steel springs that overcome such problems. The springs equalize pressure differences.

II-7. Exchanging the blades

After frequent use the blades might have become blunt and cutting results may be insufficient. In such case the blades have to be replaced by new ones. You can simply change the whole blades axis for a new one and send the old one to Humeca or your local dealer. Humeca will then replace the blades on the old axis and return it. However, if you want to exchange the blades only, please read the following instructions and have a look at fig. 12.

- Take the axis out of the mesher and put it on some soft surface in order to prevent damage.
- Remove the locking ring from the axis at the opposite side of the gearwheel (no. 6A in fig. 12). There are special tongs to remove

such locking rings, but you might also do it with a screwdriver (with each delivery of blades, Humeca will also add a new locking ring, so don't mind if you damage it or lose it).

- Remove the bearing ring at that side (no. 1 in fig. 12).

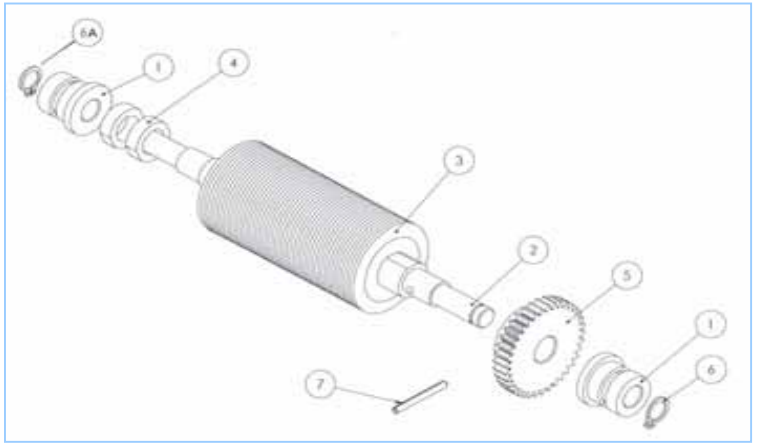

Fig. 12. Exploded view drawing of the blades axis

- Loosen the two nuts (no. 4 in fig. 12) carefully with a spanner 16 mm. To prevent the axis from rotation, you have to can fix it with a second spanner (13 mm) on the flat sides in the area between the gearwheel and the blades.
- Now carefully remove the blades from the axis.
- Clean the axis if necessary and place new blades.
- Then re-assemble the axis in the reverse way.

II-8. Storage

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

- Ambient temperature 15-45 °C
- Relative humidity 35-90%
- Atmospheric pressure 850-1070 hPa (640-800 mm Hg)

II-9. Warranty

There is a two years warranty on all parts of the mesher, except for the blades.

This warranty does not include repairs or replacements if:

- the wrong type of carrier was used,
- other than original spare parts were used for repair by user,
- the mesher was used for other applications than the ones mentioned in this manual (section II-1).

Warranty includes free of charge repairs if necessary as a result of trouble / defects that occurred during normal use of the mesher. In case of trouble please contact your local distributor.

II-10. Technical data Humeca® Mesher

Material	Anodised Alum. / St. steel
Measurements (lxwxh)	220x212x183 mm
Total weight	4.3 kg
Number of blades	50
Diameter of the blades	36 mm
Interspacing of the blades	1.5 mm
Gearwheels ratio	1:2.4
Carrier thickness adjustment	1.0 or 1.5 mm
Maximum carrier width	78 mm
Transported length of carrier in 1 turn	46 mm
Size of sterilization container (lxwxh)	277x232x197 mm

II-12. Ordering and delivery

For ordering, please refer to the following article numbers:

6.HM01	Humeca® Mesher, complete set
6.KN50/36	Blades axis containing 50 blades Ø 36 mm
6.BLHM01	Single blade Ø 36 mm
6.HMAC01	Autoclave case for Humeca® Mesher
6.HMAC02	Autoclave case for blades axis.

Humeca delivers the equipment ex works (EXW) in accordance with Incoterms 2000.

II-13. Trouble shooting

Problem	Possible cause	Solution
Turning the handle requires too much force	Wrong type of carrier used or mesher not correctly adjusted	Check the type of carrier (V10 or V15) and re-adjust the mesher if needed (section II-5)
	Bearings are dry	Apply oil (section II-4)
	Screws at the bottom of the mesher are not loosened enough	Loosen these screws a little more (section II-5-B). Screw heads should be equal to the surface of the bottom plate.
Graft is not cut properly	Wrong type of carrier used (V10 instead of V15) or mesher not correctly adjusted	Check the type of carrier (V10 or V15) and re-adjust the mesher if needed (section II-5)
	Blades are blunt	Replace blades or complete cutting axis
	Carrier was used too many times	Replace carrier for a new one
	Bridge not closed properly	Check and close bridge and tighten screws
Graft slips over carrier during cutting	Graft is too thick (fatty layer present at the dermal side of the graft)	Harvest new, thinner graft
		Try to remove fatty layer and try again
		Put the graft on the carrier epidermal side down and try again
Graft is cut into separated stripes; no slits are cut	Carrier was placed in the mesher upside down (flat side up)	Replace the carrier in the mesher with the grooved side up
The grooves of two different carriers do not connect to each other	Two carriers of different expansion ratio were used	Replace carriers by two carriers of the same expansion ratio and try again
	The second carrier was put in the mesher 180° turned with respect to the first carrier	Turn the second carrier 180° and try again.

SECTION III RULES AND RESPONSIBILITIES

Rules, CE–hallmark, responsibilities

- The management system of Humeca 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 mesher comes under the head of class I products.
- The V-carriers come under the head of Class I sterile products.
- The CE-hallmark and serial number are indicated on the mesher and on the package of each V-carrier.
- Do not use a V-carrier in case the package is damaged.
- Do not use V-carriers after the expiry date (see package).
- In case of any complaint or request for replacement, please return the original package or refer to the LOT number and expiry date as indicated on the label.
- The manufacturer considers being only responsible for the safety and performance of the mesher and V-carriers, if these are used in the way as described in this manual. For replacements only original spare parts have to be used. Replacements have to be carried out by the manufacturer or by his authorized local representative. Repairs are only carried out if the product is carrying the users official repair form. All repairs carried out will be specified on a delivery note.

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Humeca is an EN ISO 13485:2003 certified company.