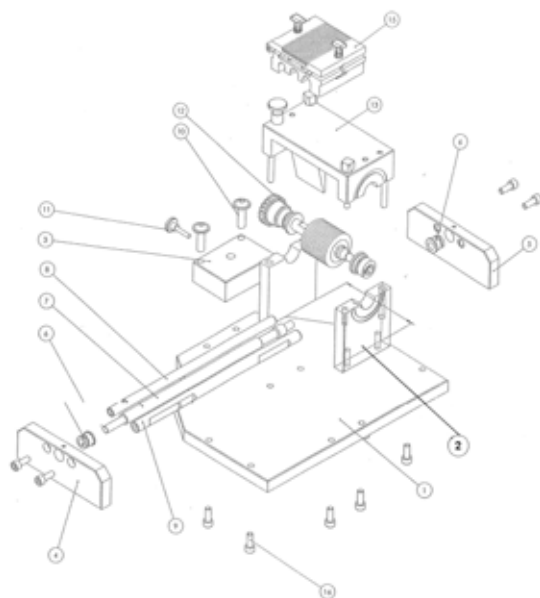




MEEK Micrografting

Technical data and trouble shooting



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1. Introduction

This leaflet provides technical data of the MEEK cutting machine and disposables. Exploded view presentations of separated parts (so-called “sub-assy’s”) are presented. This allows the user to replace parts and service the machine independently. Material data, ordering numbers and functions of major parts are given. Different types of MEEK machines are presented and explained.

2. The MEEK cutting machine in general

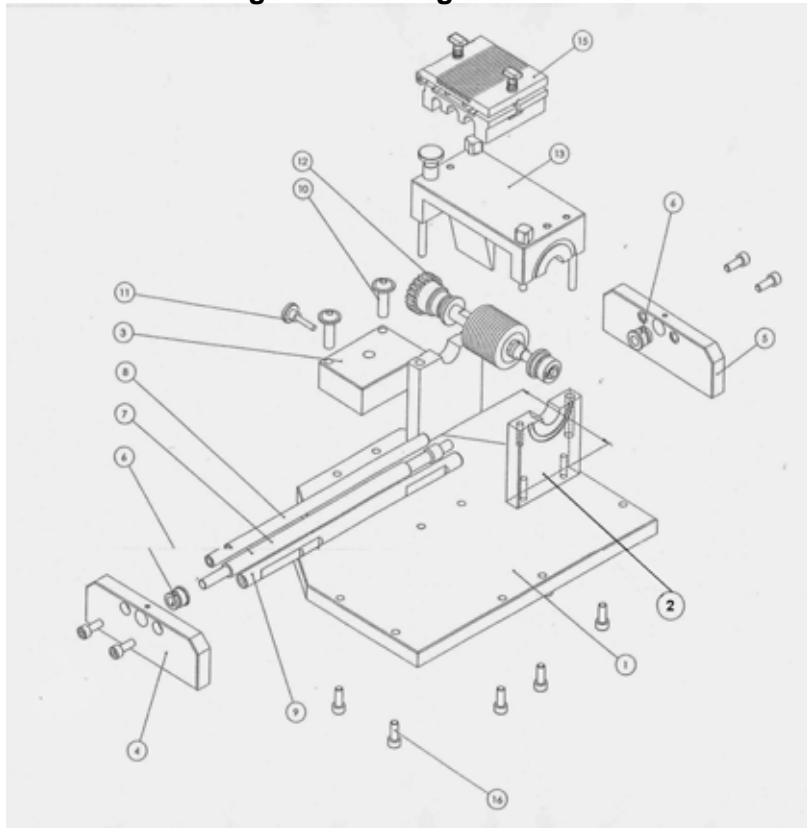


Fig. 1. The MEEK cutting machine

Each type of cutting machine consists of the following major parts (see fig.1):

- **Main frame,**
- **3.KN13/38 Blades Axis,** see chapter 4.
- **3.CB01 or 3.CB02 Cutting block, single or double,** see chapter 5.
- (if hand drive was provided) **3,SHD/BL or /CYL Hand drive set,** see chapter 6.
- (if motor driven) **3.RM004 Pneumatic motor or 3.087 Archimedes cylindrical motor,** see chapter 7.
- (if motor driven) **3.017 Motor housing,** see chapter 8.
- (if motor driven) **3.CP4 Foot pedal,** see chapter 9.
- (if motor driven) **Pneumatic components,** see chapter 10.
- **3.SW01 Serrated wedge,** see chapter 11.
- **3.CA01 Cutting aid,** see chapter 12.
- **2.JG598 Sterile oil,** see chapter 13.
- (in some cases) **3.GWS Gear wheels set,** see chapter 14.

Each of these components will now be described in detail in the following chapters.

3. Main frame

The main frame consists of:

No. in (fig. 1)	Ordering no.	Description	Material
1	0118	bottom plate	anodised aluminium
2	0120	bridge stand	anodised aluminium
3	01441	motor stand	anodised aluminium
4	0116	axis stand front	anodised aluminium, bronze bearing
5	10061	axis stand rear	anodised aluminium, bronze bearing
	013	sub-assy hand wheel (see fig. 2)	see separate section below
7	0134	spindle	steel, chemically nickel plated, titanium nitride ceramic coated
8	0132	guiding axis L	Aisi 304 stainless steel
9	0133	guiding axis R	Aisi 304 stainless steel
13	012	bridge	anodised aluminium, st. steel

Sub-assy handwheel:

The sub-assy handwheel is shown in the picture below.

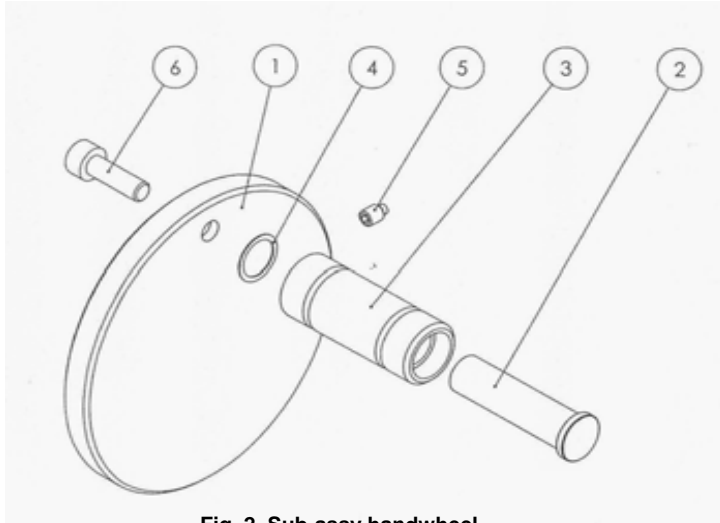


Fig. 2. Sub-assy handwheel

The sub-assy handwheel consists of:

No. in fig. 2	Ordering no.	Description	Material
1	01351	hand wheel	anodised aluminium
2	0138	turning knob axis	Aisi stainless steel
3	0137	turning knob	anodised aluminium
4	01391	ring	brass
5		DIN915 – M4x6-N hexagon socket set screw	Aisi 304 stainless steel
6		DIN912 M5x16 – 16C hex.socket head cap screw	Aisi 304 stainless steel

Note: All additional screws of the main frame are made out of A2 stainless steel.

The function of the main frame is to support the blades axis and the cutting block and keep them at a precise distance in order to allow total cutting of the skin and only partial cutting of the cork plate. Furthermore the main frame allows horizontal movement of the

cutting block over the guiding axis by turning the spindle by means of the hand wheel.

Total weight of the main frame is 4,1 kg.

4. Blades axis

The blades axis 3.KN13/38 or 3.KN13/39 is shown in fig. 3.

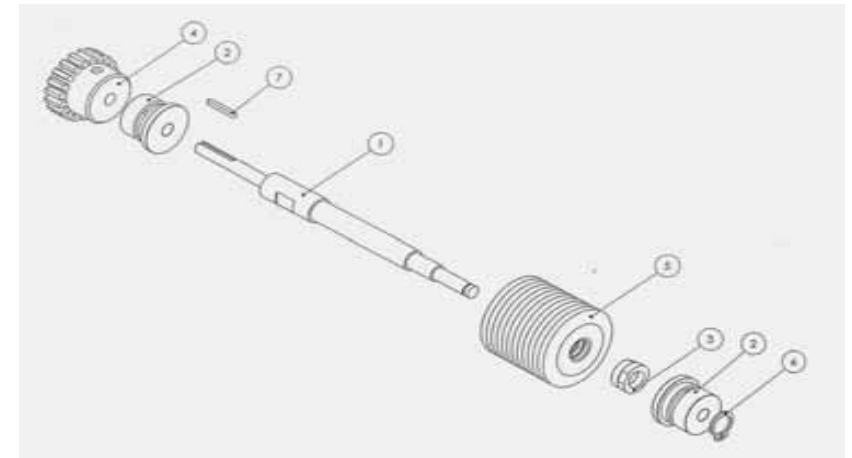


Fig. 3. Blades axis

The blades axis consists of:

No. in fig. 3	Ordering no.	Description	Material
1	0130	axis	Aisi 304 stainless steel
2	0128	bearing	bronze
3	0119	round nut	Aisi 304 stainless steel
4	01461	coupling hub	chemically nickered plated steel
5	3.BL38 or 3.BL39	blade	stainless steel 1.4034, coated with titanium nitride diam. 38 or 39 mm
6	013	axis locking ring DIN 471 ø6x0,7	Aisi 304 stainless steel
7	0127	cotter DIN 6885	Aisi 304 stainless steel

The function of the blades axis is to align the blades in exact position and to cut the skin by rotation of the axis by means of a hand drive or pneumatic motor.

Total weight of the blades axis is 454 grams.

5. Cutting blocks

There are two different types of the cutting block: single and double. They are shown in fig. 4 and 5 respectively.

5a. Single cutting block

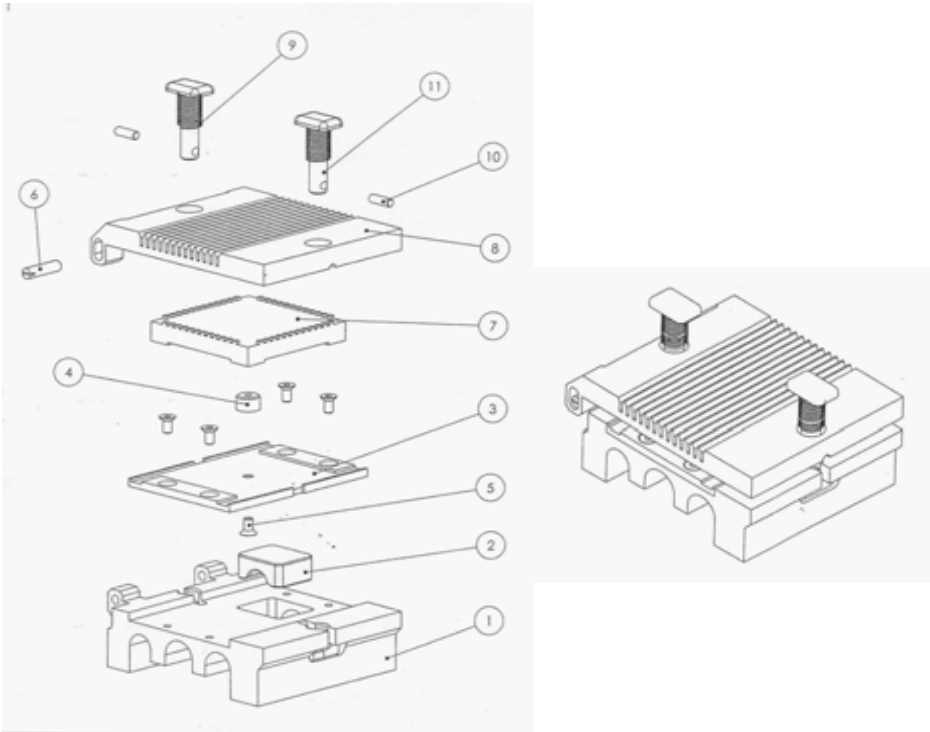


Fig. 4. Single cutting block in exploded view and assembled

The single cutting block (fig. 4) consists of:

No. in fig. 4	Ordering no.	Description	Material
1	0105	base block	anodised aluminium
2	0115	half nut	brass
3	01051	single base plate - K	anodised aluminium
4	01052	central cam	Aisi 304 stainless steel
5	01053	countersunk screw DIN7991 M3x8 A2	A2 stainless steel
6	0112	hinge axis	Aisi 304 stainless steel
7	0101	cork holder	anodised aluminium
8	000101	single grating cover	anodised aluminium
9	0106	locking pin	Aisi 304 stainless steel
10	0104	spring D21760	stainless steel
11	0103	locking handle	stainless steel

Weight of a single cutting block is 297 grams.

5b. Double cutting block

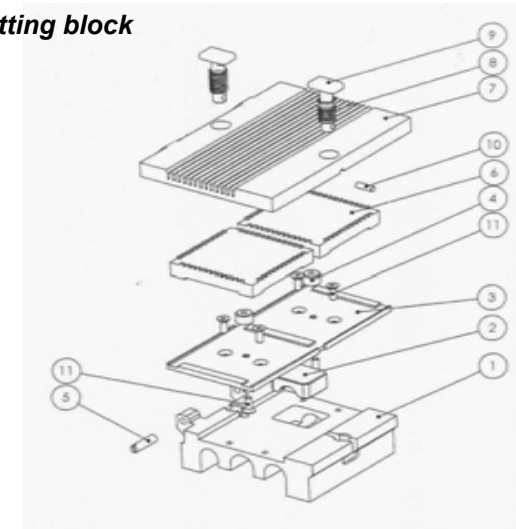


Fig. 5. Double cutting block

Major parts of the double cutting block are the same as for the single cutting block with the exception of the base plate, the grating cover and the springs.

The details of these parts are as follows:

No. in fig. 5	Ordering no.	Description	Material
3	02053	double base plate - L	anodised aluminium
7	000201	double grating cover	anodised aluminium
8	0106	spring D21960	stainless steel

Weight of a double block is 332 grams.

The function of the cutting blocks is to keep the graft in place during cutting.

6. Hand drive set

The hand drive set is shown in fig. 6 below.

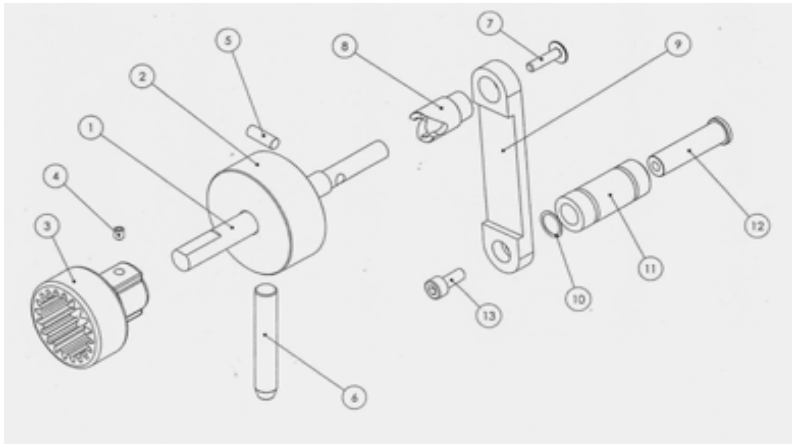


Fig. 6. Hand drive set

The hand drive set consists of:

No. in fig. 6	Ordering no.	Description	Material
1	0157	drive axis	Aisi 304 stainless steel
2	01581	locking cylinder	nylon
3	0158	coupling shell ø10	nylon
4		hex. socket set screw DIN916 M4x5 -N	A2 stainless steel
5	01582	pin	Aisi 304 stainless steel
6	01583	standing pin	Aisi 304 stainless steel
7	0161	screw ULF M4x16 A2 70	A2 stainless steel
8	01591	one-way runner	anodised aluminium
9	0135	lever	anodised aluminium
10	01391	ring	brass
11	0137	turning knob	anodised aluminium
12	0138	turning knob axis	Aisi 304 stainless steel
13		DIN912 M5x12 – 12C	hex. socket screw

The function of the hand drive set is to drive the blades axis by hand in case:

- the motor is not working, or
- no pressurized air is available, or
- no motor was requested.

In case no motor was requested at all, the hand drive is provided without the standing pin. Weight of a hand drive is 222 grams with standing pin and 195 grams without standing pin.

7. Pneumatic motor

A pneumatic motor can drive the MEEK cutting machine. This motor is a compact piston air motor, using the radial piston principle. In this motor radially arranged driving pistons travel along a curve and are inevitably controlled by the centre. The motor and the principle of operation are shown in fig. 7 and 8 below.



Fig. 7. The pneumatic motor

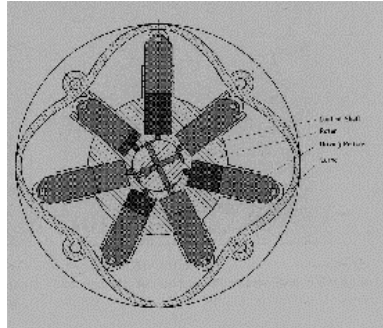


Fig. 8. Radial piston principle

The static control shaft supplies the driving pistons with the necessary air. Air supply and release openings along the static driving shaft are periodically opened and closed by the rotating shaft to pressurise or release the pistons in an appropriate sequence. Three of the seven driving pistons are actively contributing to the torque at any moment. Once reaching the highest point on the curve, the control unit releases the air driving the piston and the piston is forced into its lowermost position. Due to the power transmission of the pistons along the large external diameter of the curve, the compact piston air motor has a high torque at low speed of rotation. The friction along the curve is low, due to the installation of rollers at the tip of the pistons. This results in high lifetime of the drive. Because of the use of pistons, low internal friction and negligible internal air leakage, the air consumption of the motor is extremely low.

Technical data:

Dimensions (lxwxh):	93x85x85 mm
Weight:	2,15 kg
Starting torque at 6 bar:	4 Nm
Operating pressure in MEEK machine:	4-8 bar
Rotational speed unloaded at 6 bar	1000 RPM
Average air consumption at 6 bar	3 litre/s
Material:	aluminium/st. steel

Maintenance:

This type of motor does not require any lubrication.
It is advised to use a 5-micron air filter in the air supply.
Ordering number of the motor is 3.RM004

8. Motor housing

The motor is incorporated in a housing, made out of stainless steel plate material. Fig. 9 shows the motor with housing, while fig. 10 shows a drawing of the housing.

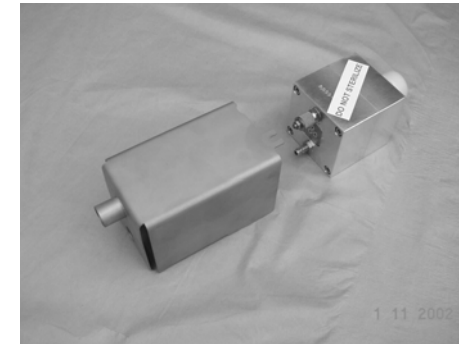


Fig. 9. Motor RM004 with housing

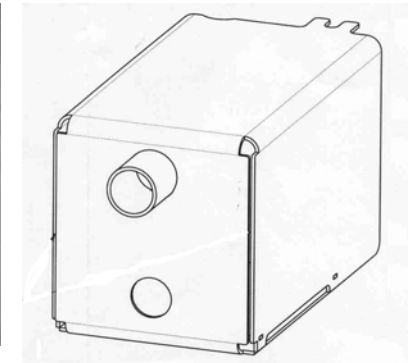


Fig. 10. Drawing of the housing

Technical data:

Dimensions (lxwxh):	185x90x96 mm
Material:	Aisi 304 stainless steel
Weight:	760 grams

Ordering number of the housing is 3.017.

9. Foot pedal

Fig. 11
Foot pedal

The pneumatic motor is switched on and off by means of a pneumatic foot pedal. It is shown in fig. 11. The pedal has one air inlet and one air outlet.

Technical data:

Material:	Cast iron / steel
Operating pressure:	2-8 bar
Flow rate at 6 bar	950 l/min
Weight:	700 grams
Port size:	G 1/4
Dimensions (lxwxh):	193x83x70

Ordering number of the foot pedal is 3.CP4.

10. Other pneumatic components

A motor driven machine is supplied with some pneumatic components. Humeca supplies the connection between the motor and the foot pedal at delivery of the machine. However Humeca cannot readily supply the connection between the foot pedal and the air outlet in the operation theatre, because different hospitals have different types of connections. For that reason Humeca supplies a hose that can be connected to the foot pedal by means of a quick connector. The other side of that hose has to be connected to the air outlet of the operation theatre by qualified personal of the hospital itself.

It is also possible to use an air cylinder as a pressure supply. Never use oxygen for driving the machine, as this causes a serious risk of explosion!

If desired, one can remove the Humeca hose and replace it by any other hose that is normally used in the hospital. Connectors are supplied for fixing different sizes of hoses to the quick connector. Fig. 12 explains what type of connector should be used in case of small and larger diameter hoses.

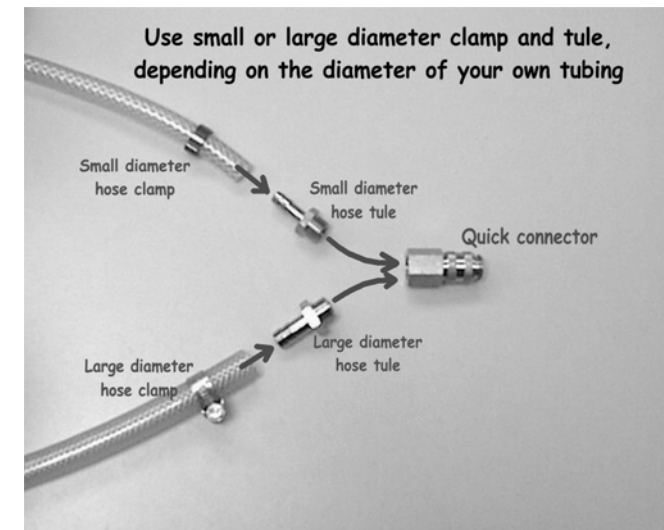
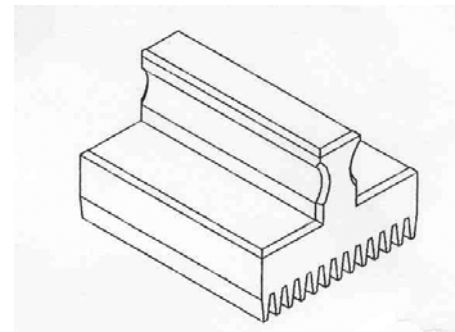


Fig. 12. Pneumatic components

11. Serrated wedge

The serrated wedge, also called “cam”, is used whenever the graft of the patient adheres to the cover of the cutting block when opening it. It is shown in the drawing below.



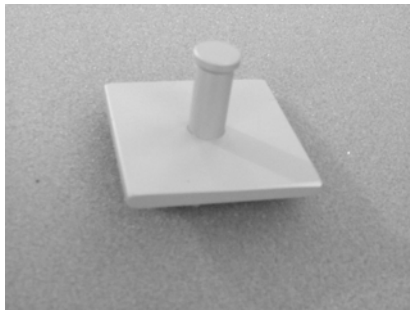
Material: anodised aluminium
Weight: 77 grams
Dimensions: 45x38x30 mm

Ordering number: 3.SW01

Fig. 13 Serrated wedge or “cam”

12. Cutting aid

The cutting aid is used to as a “ruler” to cut the graft on the cork plate. When the cutting aid is placed and centered on top of the graft on the cork plate and the graft is cut alongside the edges of the cutting aid, the size of the graft will be exactly 41x41 mm, which is just a little smaller than the cork plate itself (measuring 42x42 mm), thus preventing the graft to overhang the edges of the cork plate. The picture below shows the cutting aid.



Material: anodised aluminium
Dimensions: 41x41x24 mm
Weight: 21 grams

Ordering number: 3.CA01

Fig. 14. Cutting aid

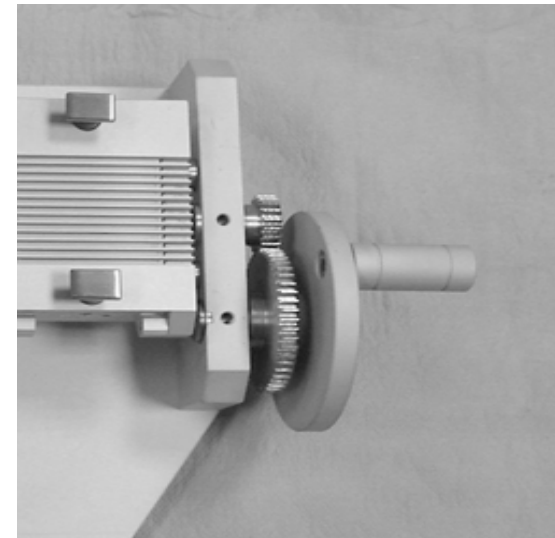
13. Sterile oil

The MEEK machine has to be lubricated every now and then. The recommended lubricating oil is Aesculap STERILIT[®] oil. This oil is commercially available in the market from the B.Braun company and also supplied by Humeca. This oil is applied prior to sterilization. The oil is validated for steam sterilization methods according to EN 554/ISO13683, as well as for dry heat (heated air) sterilization up to a temperature of 180 °C / 356 °F.

The oil is supplied as drip oiler in a bottle of 50 ml.
Ordering number is 2.JG598.

14. Gearwheels set

If desired, the MEEK cutting machine can be provided with two gearwheels in order to speed up the movement of the cutting block over the guiding axis.



The gearwheels are mounted at the handwheel side of the machine (see fig. 15).

Fig. 15 Gearwheels

Machines without gearwheels can be modified in order to place the gearwheel set afterwards.

Material: stainless steel.
Transmission ratio: 1: 2,5

Ordering number: 3.GWS

15. Different types of machines

MEEK cutting machines are available in different types.

There are hand driven and motor driven versions.

A motor driven version can be provided with gearwheels to speed up movement of the cutting block.

There are single and double cutting blocks available.

For details and advises concerning the type of machine suitable in a specific situation, please contact Humeca or your local distributor.

16. Trouble shooting

Problem	Possible cause	Solution
Motor does not run	Air leakage	Check all hose connections and repair if leakage occurs
	Air pressure too low	Increase air pressure to at least 4 bars
	Rotation of blades axis blocked	Remove the motor from the axis. Check whether the blades axis can be run by hand easily (rotate the coupling on the axis). If not, remove the bridge, apply oil to the bearings and try again. If rotation still blocked, contact supplier. If rotation only blocked when the bridge is placed, contact supplier.
	Motor defect	Take motor out of the machine and connect it to the air supply via the foot pedal. Switch on, while pressure is at least 4 bars. If the motor does not run, try higher air pressure (do not exceed 8 bars). If motor still does not work, contact supplier.
Motor runs, but blades do not rotate	Bolts on the blades axis are loose. In that case the axis rotates, but the blades don't (during cutting)	Fasten the two bolts on the blades axis (first fasten the bolt that is closest to the blades, then the other one).
	Coupling on the motor is loose. In that case the coupling rotates, but the blades axis doesn't.	Take the motor out of the device and connect it to the air supply via the foot pedal. Switch on and check if the coupling on the motor is running (try to stop the coupling while the motor is running; this should not be possible). If the coupling is loose, fasten the screw in the coupling or if the screw is missing, order a new one.

Problem	Possible cause	Solution
Cutting block does not fit on the guiding axes or it moves too heavy	Screws at the end of the guiding axes are loose, or for some other reason, the position of the guiding axes has been changed.	Humeca has to re-position the guiding axes. Send machine and cutting block to Humeca or distributor for repair
	Guiding axis or underside of cutting block is damaged	Check if there are any burrs on irregularities at the guiding axes or at the cutting block and remove them with sandpaper
	Movement of spindle or hand wheel is blocked	Remove the block from the guiding axis and rotate the handwheel. If rotation is blocked or too heavy, apply oil and try again. If still problematic, contact supplier.
Skin is not cut or only partly cut	Wrong diameter of the blades	Measure diameter of blades and check this info with Humeca.
	Wrong thickness of the cork holder	Measure thickness of cork holder at the edges and check this info with Humeca
	Cork plate too thin	Measure the thickness of the cork plate. It should not be less than 2 mm
	Blades are blunt	Take the blades axis out of the machine and look to the cutting sides of the blades. These sides should not be shiny. If they are, replace the blades of replace the blades axis as a whole
	Blades or blades axis do not rotate	See sections above that relate to that matter
	Position of guiding axis changed	Humeca has to re-position the guiding axes.
	Screws of the bridge were not fastened properly	Fasten the two screws of the bridge and check whether or not the bridge is positioned correctly.
Skin sticks to the cover of the cutting block when it is opened, even after proper use of the cam and moistening the cover.	A "biofilm" was formed at the underside of the grating of the cover or it is polluted by other substances (like MEEK adhesive).	Clean the underside of the cover thoroughly (preferably with some abrasive liquid cleaner).

Problem	Possible cause	Solution
Skin moves on the cork plate during cutting	The thickness of the graft was too much: it not only consists of an epidermal and a dermal layer, but also a layer of fatty tissue was taken. The fatty tissue is very slippery and it causes the graft to move during cutting	Reduce the thickness of the graft taken from the patient by modifying the adjustment of the dermatome. If the graft was already taken off, scrub or cut the fatty tissue layer from the graft and repeat the MEEK technique.
	The cover of the cutting block was not properly closed	Check whether the cover is locked properly. Also check the springs in the locks. If a spring broke, replace it.
	The cutting block was moved under the bridge in the wrong direction. Always put the block on the machine at the side of the hand wheel.	
Motor makes too much noise	Sound reducer not present or defect	Place a new sound reducer at the rear side of the motor
	Air pressure too high	Reduce pressure (max. 8 bars)
The drive of the machine is too heavy; the required work to drive the blades seems to be too high.	Blades axis runs too heavy unloaded	Remove the cutting block and the motor from the machine and run the blades axis by hand. It should "freewheel" easily. If not, please contact your supplier for further assistance and trouble shooting.
	The blades cut too deep into the cork plate	Place a cork plate in the machine and cut it. Check the depth of the cuttings. The depth should be approx. 0.5 mm. If it is far more, please contact your supplier for further assistance.
	The cork plate was not moistened before use	Immerse the cork plate in water or physical salt solution before use.
	The blades are blunt	Take the blades axis out of the machine and look to the cutting sides of the blades. These sides should not be shiny. If they are, replace the blades or replace the blades axis as a whole

Problem	Possible cause	Solution
Graft does not stick to the prefolded gauze: after pressing the cork plate to the gauze and removing it, the graft is still on the cork plate instead of sticking to the prefolded gauze.	Not enough glue was applied	Try again, using more glue. After spraying the whole surface of the graft should have a glossy appearance.
	Drying time of the glue was too short	Allow the glue to dry for at least 5 minutes (a longer drying time does not harm). When much glue was applied, the drying time should be increased.
	A fatty substance (like paraffin oil) was used during harvesting of the skin to establish easy run of the dermatome	Use water or physical salt solution when harvesting the skin, but at no means use oil. Oil prevents the glue from sticking. If accidentally oil was used, try to clean the epidermal side of the graft.
After unfolding the gauze, the graft islands do not separate properly: a significant number of islands or a complete row remains unseparated when unfolding the gauze.	The graft was larger than the cork plate	Trim the margins of the graft to the size of the cork plate
	The cutting was not complete	See section "Skin is not cut" above
	Far too much glue was used. The glue penetrated in the seems between the graft islands and stuck them together.	Use less glue
Movement of cutting block under the bridge is blocked: the block cannot pass under the bridge.	The cover of the cutting block was not locked; the two screws rise above the level of the blades axis.	Take out the cutting block, close the cover and lock it

17. Service, rules, CE-hallmark, responsibilities

- The Micrograft cutting machine is guaranteed for two years, except for the blades. This guarantee implies free repair of the machine and accessories when used in a normal way. If properly handled, replacement of the blades is only necessary after several years. They are coated with a ceramic layer and can withstand thousands of cutting procedures. Blunt blades can be sharpened once. Of course new ones can also replace blunt blades.
- 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 MEEK cutting machine come under the head of class I products.
- The CE-hallmark is indicated on the bridge of the machine and on the package of the plissees.
- Do not use other than Humeca blades in the cutting machine.
- Do not use MEEK plissees and/or cork plates in case the package is damaged.
- The manufacturer considers being only responsible for the safety and performance of the MEEK cutting machine, if it is 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.

18. Supplier

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