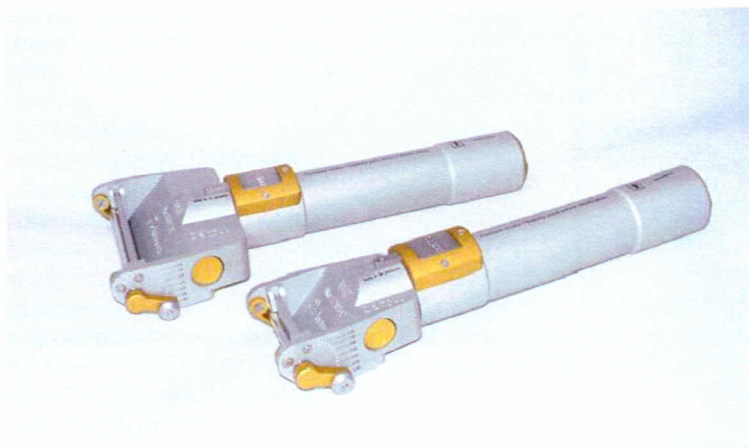




Manual & Instructions for use

Humecca cordless dermatomes
D42 and D80

with Li-Ion battery pack



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1. Application

The dermatome has been designed for the following applications:

- (split) skin harvesting
- debridement of open wounds

2. The main parts of the dermatome

The dermatome and accessories are shown in pictures 1, 2 and 3.

Reference is made to the following parts:

- | | |
|-----------------------------------|-------------------------|
| 1 Power shaft | 10 Battery cartridge |
| 2 Cutting head | 11 Disposable blades |
| 3 Power switch | 12 Battery charger |
| 4 Graft thickness adjusting lever | 13 Charger support unit |
| 5 Locking pin | 14 Sterile clamp |
| 6 Locking cap | 15 Width reducing clamp |
| 7 Buttons for opening cover | 16 Autoclave case |
| 8 Blade compartment cover | 17 Sterile funnel |
| 9 Motor cartridge | 18 Lock-unlock switch |

3. Operation

After the coupled motor- and battery cartridges (9 and 10) are inserted in the power shaft (1) and when the locking cap (6) has been closed, the motor can be switched on by pressing the power switch (3) at the upper side of the shaft. The motor puts a rectangular blade in a reciprocating motion. The graft thickness is adjusted by the graft thickness-adjusting lever (4). The standard graft width of 42 and 80 mm (for the D42 and D80 dermatome respectively) can be reduced by placing a width reducing clamp on the cutting head (2). A lock-unlock switch prevents accidental run of the dermatome for safety reasons.

4. Charging the batteries

The motor of the dermatome is incorporated in a motor cartridge (9). A battery cartridge (10) is coupled to the motor cartridge, as shown in fig. 4, steps 1, 2 and 3. Charging the batteries requires uncoupling of both cartridges. This is done by turning one of the cartridges a quarter turn, while holding the other one in position (fig. 4, steps 3, 2 and 1).

For charging the batteries you proceed as follows:

- Insert the power plug (12e) of the charger (12) into the female connector of the charger support unit (13), as shown in fig. 5.
- Put the battery cartridge in the round opening of the charger support unit (note that it only fits in one way, as the cartridge has two pins of different sizes and the charger support unit has two slits of different widths). Secure it with a quarter turn (fig. 6).
- Connect the charger to the mains.

4.1 The charger

Features

- For 7.4V Li-Ion or Li-Po battery packs from approx. 1.300mAh to 13.000mAh
- Automatic detection of full battery for optimum charging results
- Automatic detection of the battery pack
- Optical charge status indicators
- Faulty battery pack detection
- Overcharge protection
- Safety timer
- Switch mode power supply (100-240 V AC) for worldwide use.

Indicators

Green LED "Power": indicates the right connection to the mains supply.
Yellow LED "Charge": indicates the charging of the connected battery.
The yellow LED switches off to indicate the end of charging when the battery is at full capacity. A Flashing red LED indicates a defective or deeply discharged battery pack.



Attention! Important security advice!

Connect only Lithium-Ion or Lithium-Polymer battery packs with 2 cells.
Never connect other battery types. **Danger of explosion!**

Precautions

- Do not attempt to open or disassemble charger or batteries.
- Keep the charger in a dry place (indoor use only).
- Must not be operated under adverse circumstances (for example: inflammable gas, solvents, vapours, dust, humidity over 80% or temperatures under 0°C or above 40°C)
- In order to avoid risk of fire and/or electric shock, the charger must be protected against high humidity and condensation.
- Don't short circuit. Avoid contacting terminals with metal objects.
- Keep out of reach of children
- Read instructions carefully before use.
- Do not use this charger to charge battery packs with a capacity lower than 1.300mAh.
- Charge only rechargeable Li-ION or Li-Po batteries with an end of charge voltage of 4.2C per cell. It is forbidden to charge Li-ION or Li-Po batteries with an end charge voltage of 4.1C per cell. These batteries could be damaged or may even explode.

Failure to comply with the safety instructions may lead to damage to the charger and/or batteries and may cause serious injury to the user.

4.2 Operation

With the electronic power supply (100-240 V AC) the charger can be used worldwide. Attach the right primary mains adaptor to the charger (at the back of the charger there is a small slide that allows change of the adapters) and plug it into the mains socket. The green LED "Power" indicates the right connection.

When connecting the battery, the yellow "Charge" LED lights and indicates the charging process. After termination of the fast charge the charger switches off automatically and the yellow "Charge" LED is extinguished. The charger incorporates a battery voltage detection circuit to avoid the charging of a defective or deeply discharged battery pack. In this instance, the yellow "CHARGE" LED flashes and the charger gives a pulsed precharge current to the battery pack. If the battery pack accepts the charge and the voltage of the battery is in the specified range, the charger switches to the charge process and the yellow "CHARGE" LED lights continuously until the battery pack is fully charged. If the yellow "CHARGE" LED flashes for a long period of time

(this can be up to one hour depending on the battery capacity) and does not switch to the charge process, the battery pack may be defective.

4.3 Trouble Shooting Charger

Battery pack is connected properly but the charge LED "CHARGE" doesn't light yellow:

- a. Check the battery pack, the connected pack may be fully charged.
- b. Battery pack is not connected properly.
 - Disconnect and reconnect the charger to the battery pack.
- c. Contacts may be dirty.
 - Clean contacts of the charger and the battery pack.
- d. Faulty battery pack

The motor- and battery cartridges belong together. In order to prevent its loss, you can place the motor cartridge in the groove of the charger support unit during charging, as shown in fig. 8.

5. Placing the motor-/battery cartridge in the dermatome

The dermatome can be sterilized in a steam sterilizer, but the motor- and battery cartridges should not be sterilized, at no time !!

- Couple the motor cartridge (9) to the battery cartridge (10) by sliding them into each other, followed by a quarter turn. The lines on the two cartridges should be in the same position (fig. 4).
- A circulating nurse now holds the non-sterile motor-/battery cartridge with the marked line (10a) showing upwards.
- A second person inserts the sterile clamp (14) into the back of the cartridge and lifts it up a little, as shown in fig. 9. Now the motor-/battery cartridge can be handled without the risk of contamination.

Attention: do not hold the cartridge with the marking line downwards: the cartridge will fall off from the sterile clamp!

- Push the sterile funnel (17) over the backside of the dermatome, after having removed the locking cap (6 in fig. 2). Now push the motor-/battery cartridge in the dermatome and see to it that the marking line on the cartridge is in line with the marking 1a on the power shaft of the dermatome (see fig. 10).
- Remove the funnel (fig. 10 picture 4).
- Finally place the sterile cap at the end of the power shaft with one of the locking balls in line with the line on the power shaft and fix it with a quarter turn until it clicks (see fig. 11).
- By pressing the power switch 3, with the lock-unlock switch 18 in the unlock position, you can check if the motor is running (fig. 12).

6. Inserting and removing the blade

Note: Do not use other than Humeca blades in the D42 and D80 dermatome and do not use Humeca blades in other dermatomes.

Inserting the blade:

Hold the dermatome in one hand, the blade compartment cover (8) upwards. Press the round buttons (7) at both sides of the cutting head, using the thumb and index finger of the same hand and open the cover with the other hand (fig. 13).

Carefully put the blade (11) in the dermatome, the cutting edge to the front, taking care that the three pins (2a) interlock with the slots in the blade, as shown in fig. 14. Close the cover.

Removing the blade:

First open the blade compartment cover (see fig. 13) and then remove the blade by lifting the backside with a scalpel or forceps (see fig. 15). To facilitate lifting of the blade, a cavity has been made at the backside for easy access.

Attention: never try to lift the front (sharp) side of the blade (as shown in fig. 16) as this might seriously damage the instrument! Always lift it at the backside.

7. The cutting

7.1 Regular lubrication

Before sterilization (after cleaning) put a drop of oil (Humeca supplies Aesculap STERILIT[®] oil for this purpose) in the hole (1b) at the bottom of the shaft, situated closely behind the cutting head (Fig. 17). For smooth run, spread a drop of sterile water or salt solution (PBS) over the surface of the blade (fig.16).

7.2 Adjusting graft thickness

Pull the disk at the locking pin (5) of the lever (4) and adjust the lever to the desired graft thickness (Fig. 19). After releasing the locking pin the lever is fixed. The graft thickness is indicated in mm and can be precisely adjusted from 0,1 to 1,2 mm in 0,1 mm increments (Fig. 19). In later models the thickness is also indicated in inches).

7.3 Adjusting graft width

The standard graft width of the dermatome can be reduced by placing a width-reducing clamp on the head of the dermatome. For that purpose take the dermatome upside down in your hand (blade compartment cover upwards). Fig. 20 shows how the width-reducing clamp (15) is put into position. Push the upright hooks (15a) of the clamp behind the cover (8). Now move the clamp little by little forward, until its front closes round about the cover hinge (Fig. 21).

For the D42 dermatome clamps of 30 and 36 mm are provided.

For the D80 dermatome clamps of 35, 50 and 65 mm are provided.

7.4 Cutting strips of skin or tissue

Switch the motor on by pressing switch (3) at the upper side of the power shaft (fig. 12). When cutting, push the cutting head evenly forward under slight pressure over the tissue or skin, while keeping the switch pressed in (Fig. 22). For a good cutting result it is recommended to keep the skin slightly tightened on the spot. The cut off skin flap is gripped on the sloping side of the cutting head by hand or using forceps. To cut the strip straight off from the body, move the cutting head upwards, while the motor is still switched on.

Remark:

If the Humeca MEEK technique is applied for skin grafting on burns or other large skin defects, **never - during cutting - use oil or any other fatty substance as lubricant on the skin of the patient.** This would stand in the way of a good tack of the adhesive used in the MEEK technique. You can use water or a physiological salt solution (PBS) instead of oil.

8. Lubrication

For a good operation and a long service life of the dermatome regular lubrication of the mechanism is recommended.

- Before each sterilization (after cleaning) put a drop of oil in the hole (1b) at the bottom of the shaft, which is situated closely behind the cutting head (Fig. 17). Humeca supplies Aesculap STERILIT[®] oil for this purpose.
- For a smooth run spread some water or salt solution on both sides of the blade before use (fig. 18).
- Have the technical department freshly greased every six months (or after about 20 cleaning/sterilization cycles) the crown gear wheels and the lever bearings. To that end the covering plate has to be taken off (Fig. 23). Loosen the screws 2b and take off the cover plate by lifting it with a screwdriver at the position indicated in fig. 23. Put some oil on the bearings 2c and 2d and in the chink, indicated by 2e in fig. 24.

9. Cleaning

Before cleaning the motor- and battery cartridge have to be removed from the instrument. These parts are not cleaned or sterilized. Cleaning can be performed by hand or by use of washing machines common used for cleaning surgical instruments.

Most parts of the dermatome 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).

Strong 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 dermatome. Furthermore deterioration of the surface can be expected when softened water is used for rinsing and disinfection.

Hot air drying temperatures higher than 90°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 H₂O₂ (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 (section „publications“).

10. Sterilization

!! Never sterilize the motor-/battery cartridge !!

Accidental sterilization of motor and/or battery is prevented when the Humeca autoclave case is used, because the dermatome does not fit in this case when the motor-/ battery cartridge is still inside the instrument. Therefore we strongly recommend the use of the Humeca autoclave case!

For sterilization you proceed as follows (see the pictures of Fig. 26):

- Remove and discard the disposable blade.
- Open the locking cap (6) (turn it a quarter and remove it) and take out the motor-/battery cartridge from the dermatome. Put this cartridge aside; it is not to be sterilized.
- Open the autoclave case 16. Inside this case there are some cams, as indicated in Fig. 26A.
- Put the cap (6) between the two cams 16b and place the funnel (17) over the four cams 16d, as shown in Fig. 26B.
- Put the dermatome, with the blade compartment cover (8) opened, in the case in such a way that the security cam 16c comes in the backside of the power shaft. The two cams 16b interlock with the slots, indicated as 2f in Fig. 26. For good cleaning we advise to put the thickness adjustment lever (4) at maximum thickness position.
- Put the width reduction clamps and the sterile clamp in the case.
- All parts, except for the motor-/battery cartridge can be sterilized with saturated steam using common and accepted procedures for surgical instruments in the hospital.
- Close the cover of the autoclave case and sterilize it at the common temperature of 134 °C or 121°C (prolonged exposure time).

11. Atmospheric conditions during use and storage

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

- | | |
|------------------------|----------------------------------|
| - Ambient temperature | 15 - 45 °C |
| - Relative humidity | 35 - 80% |
| - Atmospheric pressure | 850 - 1070 hPa (640 - 800 mm Hg) |

12. Guarantee

There is a two years guarantee on all parts of the dermatome. The batteries are under a one-year warranty.

This guarantee does not include repairs or replacements if:

- the batteries were charged using a different type of charger,
- the motor- and/or battery cartridge was sterilized,
- 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 and charger. In case of problems please contact your local distributor.

13. Rules, CE-hallmark, responsibilities

- The management system of Humecca for design, production and sales has been certified according to EN ISO 13485:2003.
- EMC data of the Humecca dermatomes are included in a rational of the technical dossier. This record (Rational D003) may be seen at the office of Humecca. The device is electromagnetic compatible, which means that it does not interfere with other equipment in its environment.
- According to the European Medical Device Directory 93 / 42 / EEC the dermatome and the blades come under the head of class IIa products.
- According to IEC 601-1:1998, the Humecca dermatomes are classified as "Type BF Applied Part".
- The CE-hallmark is indicated on the dermatome and on the package of the blade.
- Do not use other than Humecca blades in the D42 and D80 dermatome and do not use Humecca blades in other dermatomes.
- Do not use a dermatome blade in case the package is damaged.
- Humecca D42 and D80 dermatomes are not for use in the presence of flammable anaesthetics (AP/APG classification).
- The manufacturer considers being only responsible for the safety and performance of the dermatome and the battery charger, 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. In connection with safety and performance it is only allowed to charge the battery cartridge using the original charger.

14. Trouble shooting

Problem	Possible cause	Solution
Dermatome doesn't run and motor axis doesn't run when outside the dermatome the button of the microswitch at the coupled cartridge is pressed	Battery not charged	Charge battery and try again
	Battery out of order	Check battery cartridge. See section 7. Repair or replace if necessary
	Problem with charging	Check charger and battery support. See section 9. Repair or replace if necessary
	Motor cartridge out of order	Check motor cartridge. See section 8. Repair or replace if necessary
	Microswitch broken	Replace microswitch
Dermatome doesn't run, but you can hear the motor running in the power shaft	Motor axis cross pen broken or lost or cylinder on axis loose (no.5 and 6 in fig. 15 of the service manual)	Send motor cartridge to manufacturer for repair
Dermatome doesn't run and motor doesn't run, but motor runs when outside the dermatome the button of the microswitch at the coupled cartridge is pressed	Some moving part is mechanically blocked, probably caused by dirt or too less lubrication	Clean and lubricate all parts of the cutting head (see service manual, section 5.1) and try again. If necessary also check and clean the gearwheel of the coupling of the power shaft (service manual, section 6.2)
Dermatome runs, but the blade doesn't move at all	Pins on the lever (service manual, fig. 9) broken or lever worn out	Replace the lever (service manual, section 5.4)
Dermatome runs, but the blade hardly moves	Slot-shaped hole in the lever (service manual, fig. 9) worn out	Replace the lever (service manual, section 5.4)
Buttons for opening the cover are stuck	Persistent dirt on the blocking rings (service manual, fig. 7f and 8)	Clean blocking rings with fine-grain sandpaper (service manual, section 5.2)
Dermatome doesn't cut at low position of thickness adjusting lever. Only at relatively high thickness value of the lever, the dermatome starts cutting	Thickness not correctly adjusted or initial adjustment changed	Send dermatome to manufacturer

Problem	Possible cause	Solution
Blade compartment cover cannot be closed	Movement of the brass rings (service manual, fig. 8) hindered by persistent dirt	Clean brass rings with fine-grain sandpaper and lubricate before assembling again.
Motor/battery cartridge doesn't fit in the power shaft	One of the screws at the outside of the motor- or battery cartridge is loose	Fix screws
	One of the "wings" (indicated with an arrow in fig. 15 of the service manual) of the motor cartridge stands out	Carefully bend back the "wing" in such a way that its fits the circle of the housing of the cartridge
	Marking line on the cartridge not in line with the mark on the dermatome	Take out cartridge and reposition corresponding lines and mark
Battery pack is connected properly but the charge LED "CHARGE" doesn't light yellow	Batteries may be fully charged	Do not charge batteries
	Battery pack is not connected properly	Check all connections
	Contacts are dirty	Clean contacts
	Faulty battery pack	Replace battery pack
Charger is connected but green LED doesn't light	No current on mains	Check mains power supply
	Faulty charger	Replace charger
Yellow charge LED remains flashing and it doesn't switch to light continuously	Wrong polarity of battery pack	Check battery pack
	Battery cartridge not correctly connected to the charger support	Connect correctly
	Faulty battery pack	Replace battery pack

15. Technical datasheet

Dermatome

Weight type D42 / D80, incl. cartridges	1.115 / 1.323 g
Weight motor cartridge / battery cartridge	332 / 220 g
Length	300 mm
Width head type D42 / D80	64 / 104 mm
Max. diameter power shaft	45 mm
Cutting width D42 / D80	42 / 80 mm
Cutting width using clamps D42	36 and 30 mm
Cutting width using clamps D80	65, 50 and 35 mm
Graft thickness / increments in mm	0,1-1,2 / 0,1
Graft thickness / increments in inches	0,0004-0,0048 / 0,0004
Motor capacity	15 W
Strokes with fully charged batteries, unloaded	7.042 min ⁻¹
Stroke of blade	3,0 mm

Battery cartridge

Voltage power battery pack (2x3,7V)	7,4 V
Capacity battery pack	2,4 Ah
Battery type (more info on next page)	Li-Ion

Charger

Capacity range	1300-13000 mAh
Charging current	1300 mA ± 10%
Power supply primary	100-240 VAC/50-60 Hz
Power supply secondary	7,4 VDC

Disposable blades

Type	Double facet grinded
Width / Thickness	19 / 0,38 mm
Length D42 / D80	50 / 90 mm

Autoclave case

Dimensions D42 / D80 (lxwxh)	373 x 90/130 x 52 mm
Weight D42 / D80	720 / 885 g

16. Ordering

For ordering, please use the following order numbers:

Startset D42 / D80 (all items)	4.D42STS / 4.D80STS
Dermatome D42 / D80, incl. Cartridges	4.D42 / 4.D80
Charger Li-Ion batteries	4. 9C94142
Charger support unit	4.SU01
Motor cartridge	4.MCX15
Battery cartridge	4.BPC7.4V
Sterile clamp	4.SCL01
Sterile funnel	4.SF02
Autoclave case for D42 / D80	4.D42AC1 / 4.D80AC1
D80 width reducing clamp 65 mm	4.D80CL65
D80 width reducing clamp 50 mm	4.D80CL50
D80 width reducing clamp 35 mm	4.D80CL35
D42 width reducing clamp 36 mm	4.D42CL36
D42 width reducing clamp 30 mm	4.D42CL30
Blades, box 10 pcs for D42 / D80	4.D42BL10 / D80BL10
Aesculap STERILIT [®] oil 50 ml	2.JG 598

For more information, please contact local Humecca representative or:

Humecca BV
P.O. Box 40175
7504 RD Enschede
The Netherlands

Het Bijvank 251-a
7544 DB Enschede
The Netherlands

phone: +31 53 4762619
fax: +31 53 4771905
e-mail: info@humecca.nl
web: www.humecca.nl

Humecca is an EN ISO 13485:2003 certified company.

**Humecca cordless dermatomes
type D42 and D80**

Images

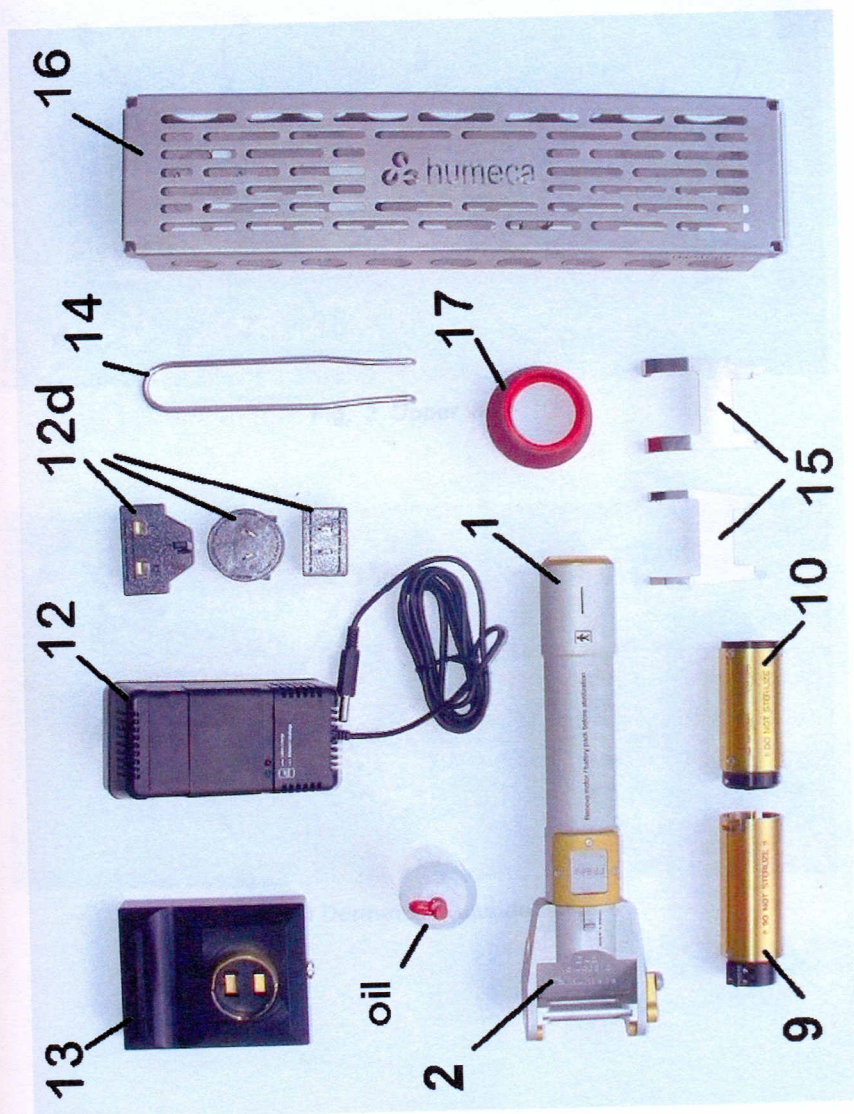


Fig. 1 The dermatome with accessories

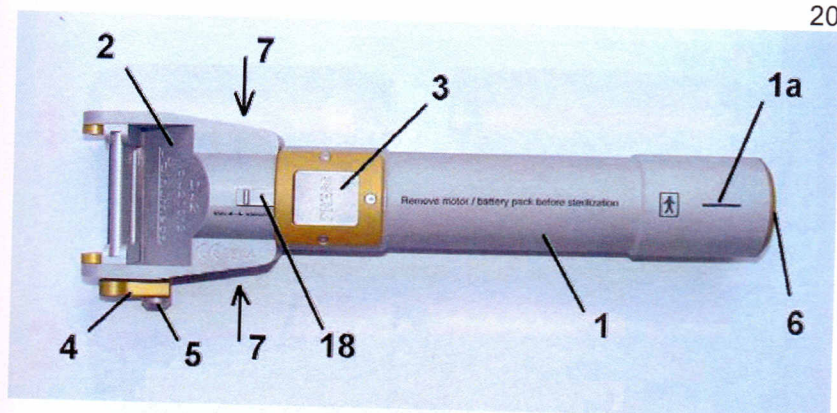


Fig. 2 Upper view

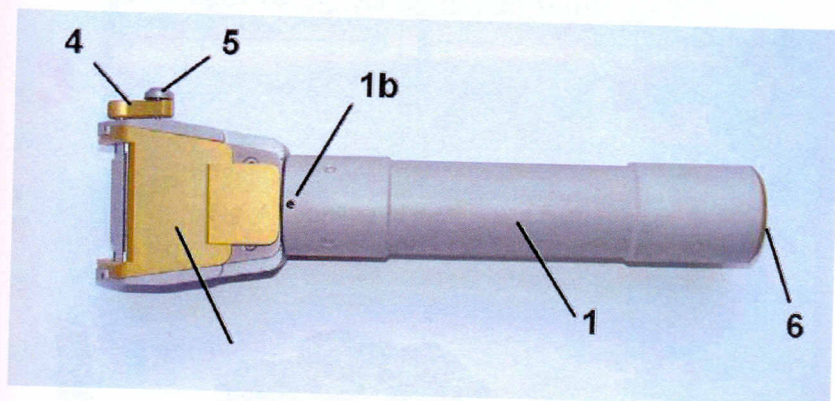


Fig. 3 Dermatome upside down

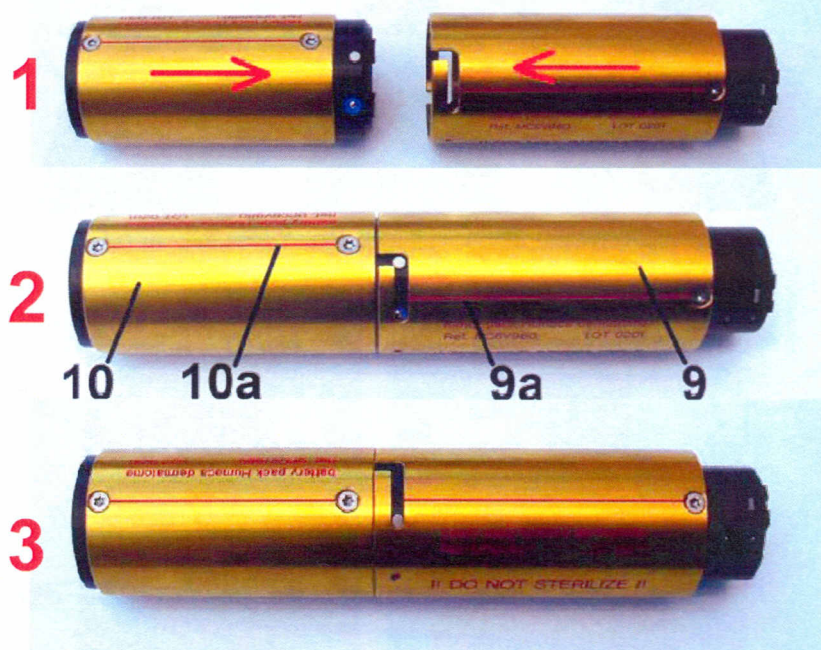


Fig. 4 Coupling of motor- and battery pack

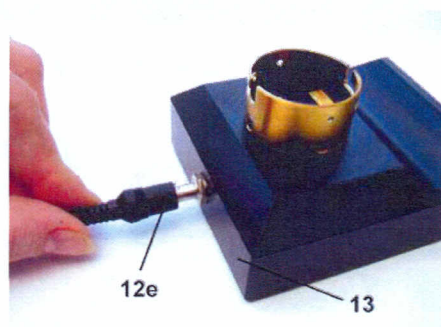


Fig. 5 Connect charger to support unit



Fig. 6 Putting the battery cartridge in the charger support unit

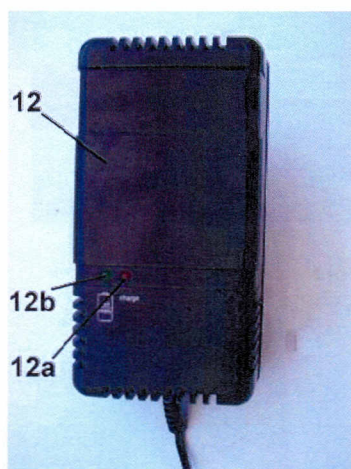


Fig. 7 The charger



Fig. 8 Charging

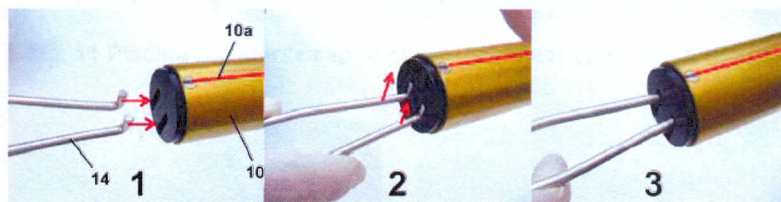


Fig. 9 The use of the sterile clamp to handle the motor-/battery cartridge

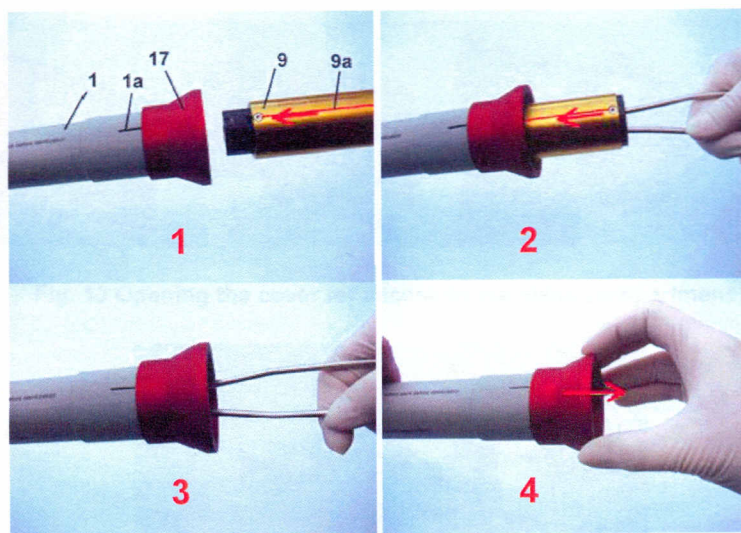


Fig. 10 Placing the motor-/battery cartridge in the dermatome, using the sterile funnel



Fig. 11 Placing the sterile cap to close the power shaft of the dermatome

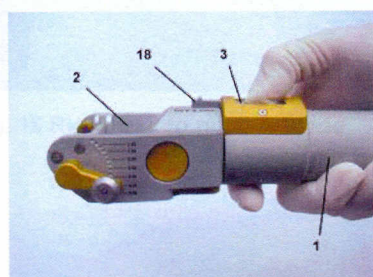


Fig. 12 Switching on the dermatome



Fig. 13 Opening the cover for access to the blade compartment

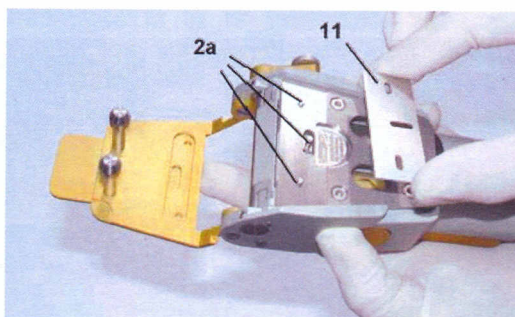


Fig. 14. Inserting blade

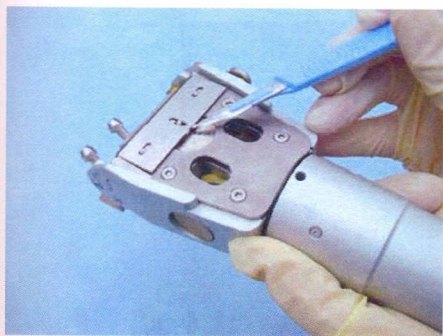


Fig. 15 Right way to remove blade

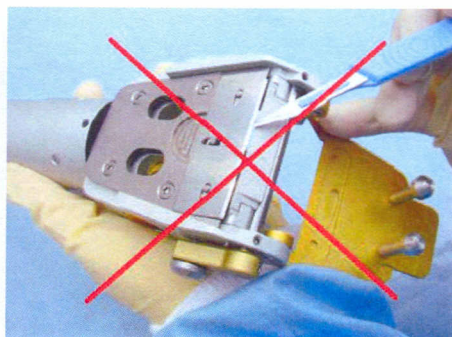


Fig. 16 Wrong way to remove blade

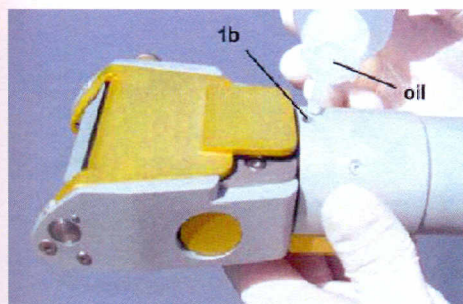


Fig. 17 External lubrication

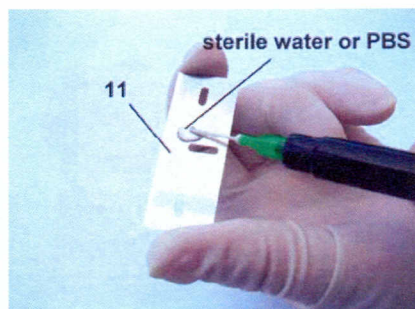


Fig. 18 Smoothing the blade

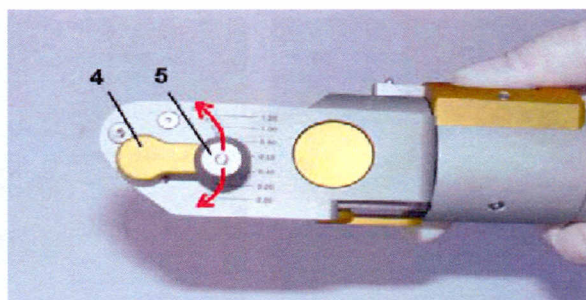


Fig. 19 Adjusting the graft thickness

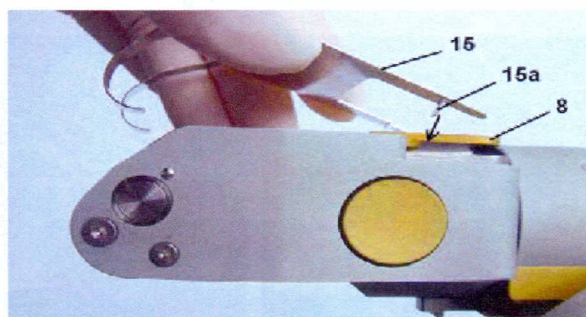


Fig. 20 Placing width reducing clamp (1)

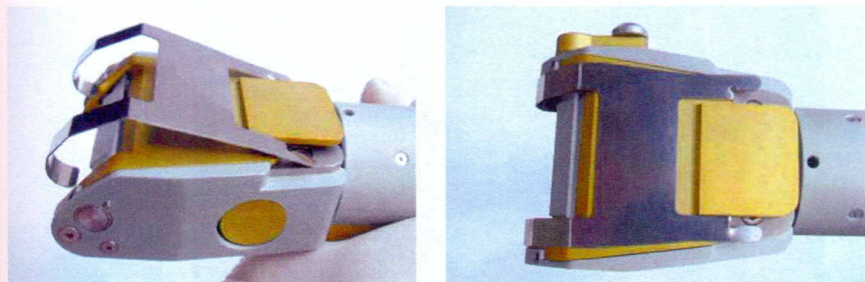


Fig. 21 Placing width reducing clamp (2)

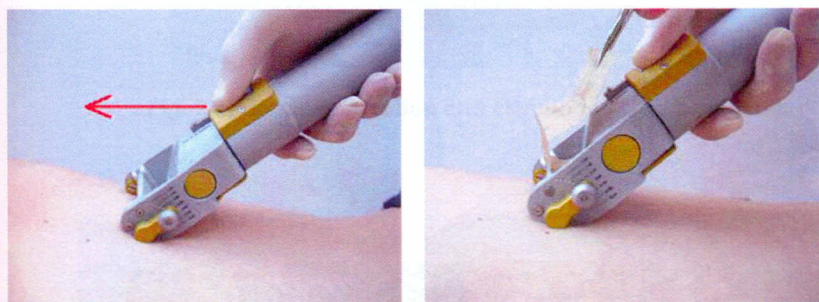


Fig. 22 Skin harvesting

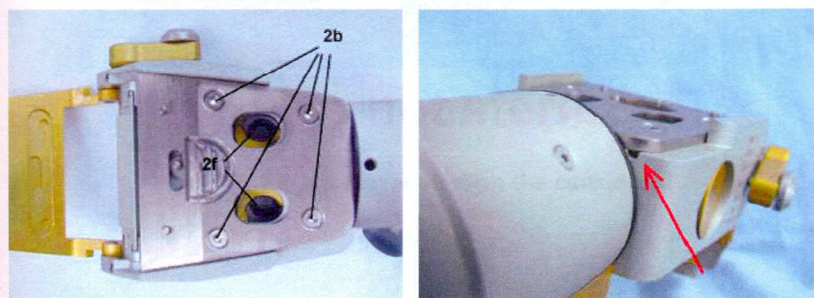


Fig. 23 Removing the covering plate

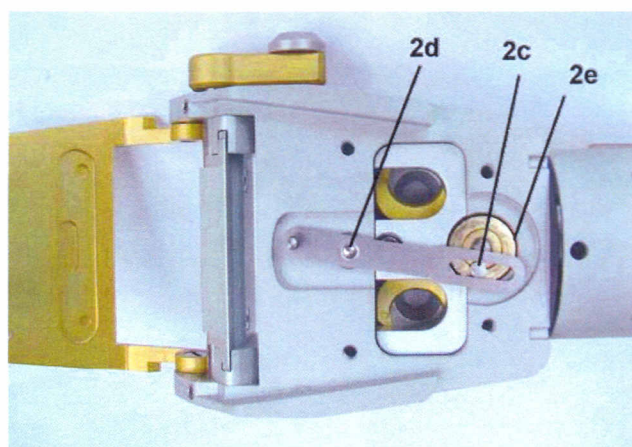


Fig. 24 internal lubrication and cleaning of the dermatome



!!Do not sterilize!!

Fig. 25 Never sterilize the cartridges!

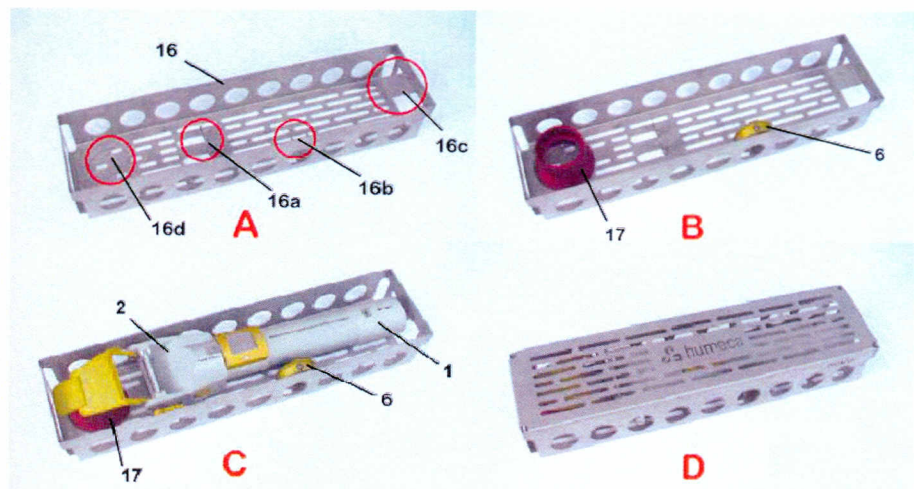


Fig. 26. The use of the autoclave case for sterilization of the dermatome and its accessories