Ackermann

User Manual

Arthroscopy Shaver System

- **Arthroscopy Shaver System** #16-2050
- **Handpiece** #16-2050-100
- **Footswitch** #16-2050-200

www.ackermannsurgical.com

SHAVER SYSTEM

CONTENTS

1. PRECAUTIONS

IMPORTANT ⚠

• The operating instruction shows how to operate, maintain and service the equipment, so that its working life is as long as possible. Proper service is essential for a long-term trouble-free operation of the device.

• Staff operating the device should familiarise themselves with the contents of this manual before installation and use of the device, and those who have access to it.

• The device can only be operated by doctors or assisting staff with appropriate qualifications.

• The device is made up in I safety class.

• **CAUTION:** To avoid risk of electric shock the device has to be connected only to a supplying network with protective earthing.

• Before connecting the device to the power outlet, make sure that the parameters of the power grid are identical to those in the device specifications. Supply voltage, frequency and power consumption are specified in the remainder of the documentation and on the rear panel of the device.

• Do not expose the device to strong humidity or rain.

• **WARNING!** Never use the device in the environments of flammable anesthetic gases.

• If flammable gases (including anesthetic gases) are released in the vicinity of the device, the latter should be immediately switched off and unplugged from the power socket.

• To avoid overheating the device, ensure that adequate ventilation is provided before starting the device. It is recommended to maintain a min. 10cm clearance from the left, right and rear sides of the device.

• Under no circumstances open the cover of the device when it is connected to power. Electric voltage inside the unit can reach 0.4 kV. Electric shock may result in permanent disability or death.

• NEVER place the device near hot surfaces or areas subject to vibration or shock.

• Repairs of the device, other than those specified in this operating instruction, can be performed only by manufacturer or by an authorised service provider specified by the manufacturer. The only repair that the user can perform, after familiarising themselves with the contents of the operating instruction: changing fuses for the electric power connection. Service address can be found in the last page of the operating instruction.

• Charging of the battery of wireless Footswitch should be carried out outside the operational theatre.

• Under no circumstances open the housing of Footswitch.

• Battery of wireless Footswitch mustn't be replaced by the user.

• In case of any disturbances or malfunctions in the functioning of the device, immediately turn it off using the power switch located on the rear panel. Taking into account the above guidance, the manufacturer feels responsible for the safety and reliability of the device. The manufacturer does not assume responsibility for damages which have arisen through abuse or incompatible with the intended operation of the device.

2. CLASSIFICATION OF THE DEVICE AND ITS INTENDED USE

2.1. INTENDED USE OF THE DEVICE

Shaver System 16-2050 in all variants has been specifically designed for driving of blades and surgical cutters, which are used during treatments of orthopedic reconstruction by using an endoscopic method named arthroscopy.
Table 1 presents components of Shaver System:

Table 1. Shaver System variants:

Pos.	Shaver System	Components of Shaver System Set
1	# 16-2050	Control Unit incl. Handpiece with manual lock and standard Footswitch

The device can be used only for treatment, such as: arthroscopy.
It is the user's responsibility to use the device properly as intended. Not complying to the operating instruction may result in danger for the patient or any of users.

2.2. CONTENTS OF STANDARD PACKAGE, OPTIONAL ACCESSORIES

Table 2. Standard package contains.

Pos.	Specification	Article no.	Qty.
1	Shaver System	16-2050	1
2	Power cord with EU plug	n/a	1
3	Operating instruction	n/a	1
4	Spare fuses	acc. to Table 5	2

The device is supplied in a package that should be kept for possible future transport. **Only proper packing of the device in its original packaging ensures safe transport**

2.3. DEVICE CLASSIFICATION

The Shaver System Set has been classified as Class IIa in accordance with rule 9 of Directive MDD/93/42/EEC. Cited standards are specified in Table 4.

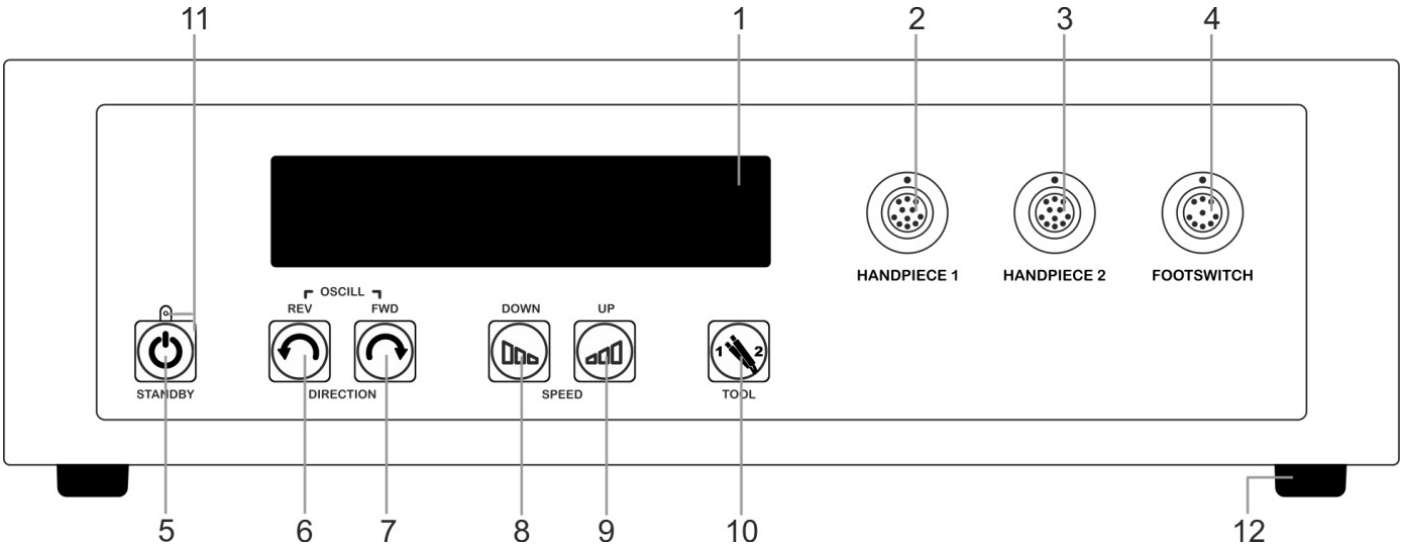
Table 4. List of standards, to which the manufacturer referred to during conformity assessment.

No.	Standard	Description
1	EN 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance1
2	EN 60601-1-2	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance - - Collateral standard — Electromagnetic compatibility — Requirements and tests
3	EN ISO 14971	Medical devices. Application of risk management to medical devices

4	EN 60601-1-6	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5	EN ISO 62366	Medical devices — Application of usability engineering to medical devices
6	EN ISO 62304	Medical device software - Software life cycle processes
7	EN ISO 17664	Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices
8	EN 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
9	EN 10993-18	Biological evaluation of medical devices — Part 18: Chemical characterization of materials
10	EN 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
11	EN 980	Symbols for use in the labelling of medical devices
12	EN 1041	Information supplied by the manufacturer of medical devices

3. DESCRIPTION OF COMPONENTS

3.1. FRONT PANEL DESCRIPTION



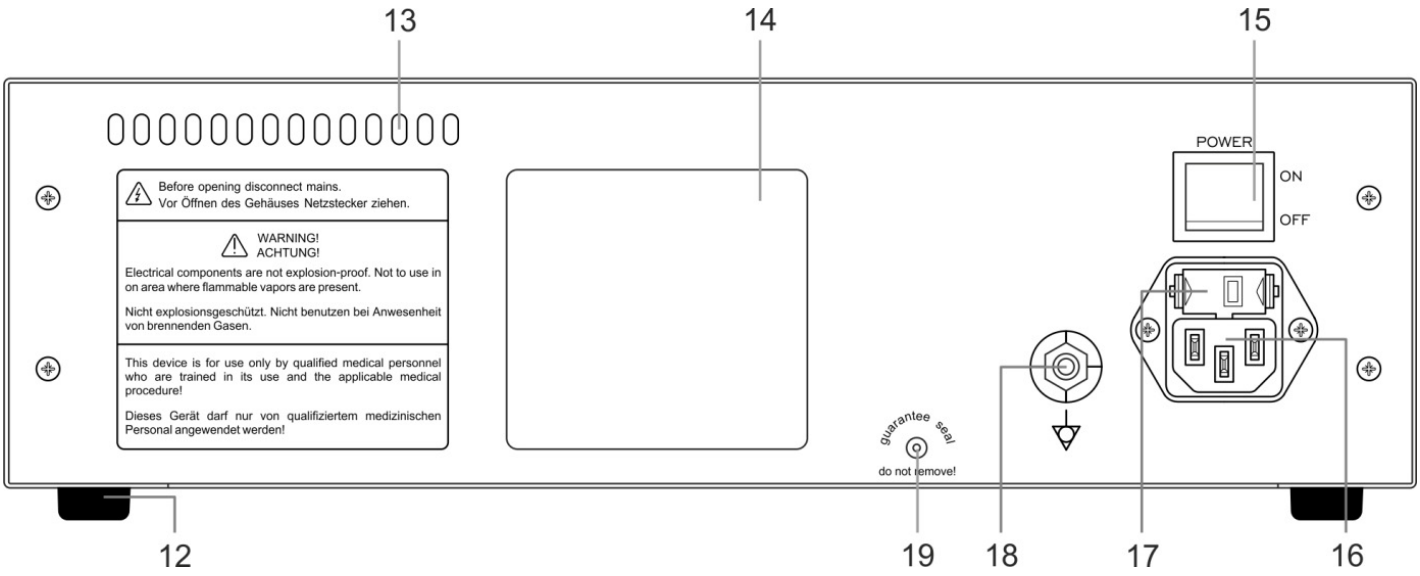
1. Display window: displays operating parameters in digital form.
2. "HANDPIECE 1" socket: socket for the Handpiece 1.
3. "HANDPIECE 2" socket: socket for the Handpiece 2.
4. "FOOTSWITCH" socket: socket for the Footswitch.
5. "STANDBY" button: switches the device from a "STANDBY" state of energy saving / sleep to a working state and vice versa.
6. "DIRECTION (REV)" button: function key to switch the shaver blade in the Handpiece to anti-clockwise rotation. If buttons (6) and (7) are pressed at the same time, the device will be working in the oscillation mode.
7. "DIRECTION (FWD)" button: function key to switch the shaver blade in the Handpiece to clockwise rotation. If buttons (6) and (7) are pressed at the same time, the device will be working in the oscillation mode.
8. "SPEED DOWN" button: stepwise reduction of the speed to the lower level of rotational speed.

9. "SPEED UP" button: stepwise increase of the speed to the next higher level of rotational speed.
10. "TOOL" button: function key which enables switching between two connected tools. It is available only if both tools are present in sockets "HANDPIECE 1" and "HANDPIECE 2".
11. "STANDBY" LED: illumination corresponds to the following states:

- the "Standby" LED blinks at a frequency of 0.5Hz - this means that the device is in a "Standby" state,
- the "Standby" LED illuminates continuously - the device is switched on and working properly.

12. Rubber feet of the device

3.2. REAR PANEL DESCRIPTION



13. Outlet for the warm air: used to remove warm air from inside of the Control Unit.
14. Device label: contains information on the device type, wattage, power supply fuses, serial number and date of manufacturing.
15. Power switch: single pole ON/OFF switch used to enable and disable power to the device.
16. Power cable socket: power cable socket with fuse drawer. The nominal values for fuses are specified on the device label Table 5. It is imperative to disconnect the power cord during maintenance, cleaning or replacement of fuses.
17. Fuse drawer: where protecting the device power supply fuses are installed. Changing the fuses is described in the point 7.1.
18. POAG stud for the equipotential bonding system: connector for equalising the electrical potential of the housing of the Control Unit with the potential of other devices.
19. Security seal: mechanical element securing the device from unauthorised opening. Damage or removal of seal will result in absolute loss of warranty and transfer of responsibility for the operation of the device to the user.

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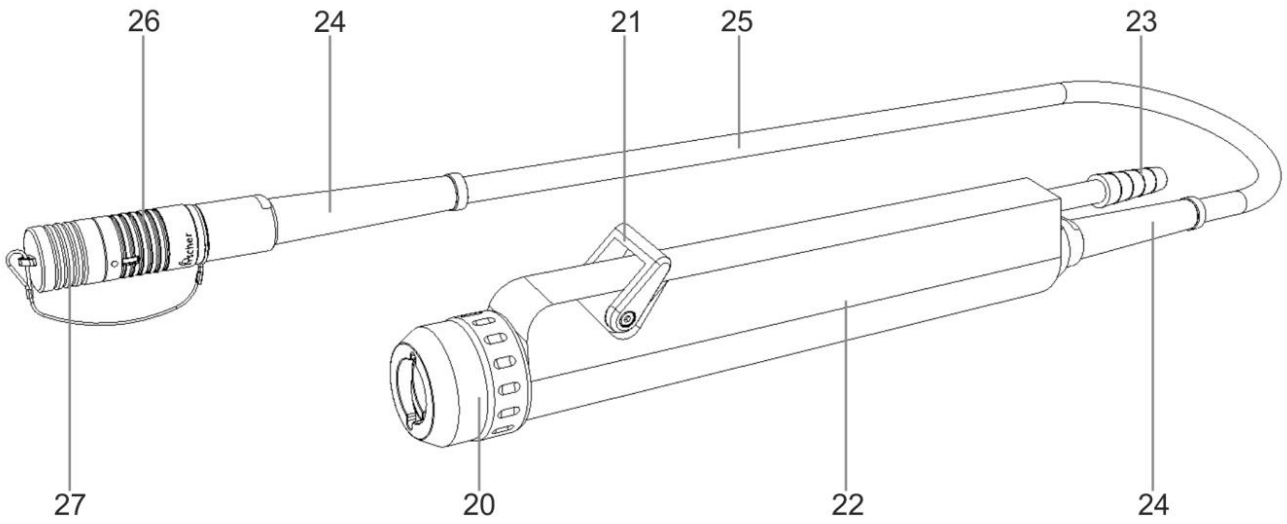
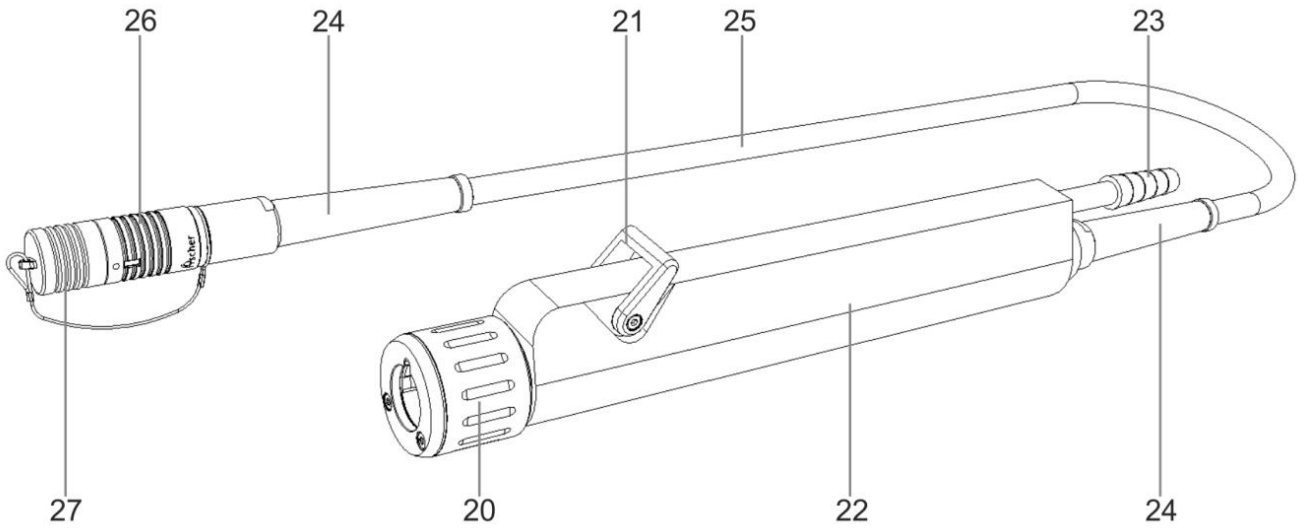
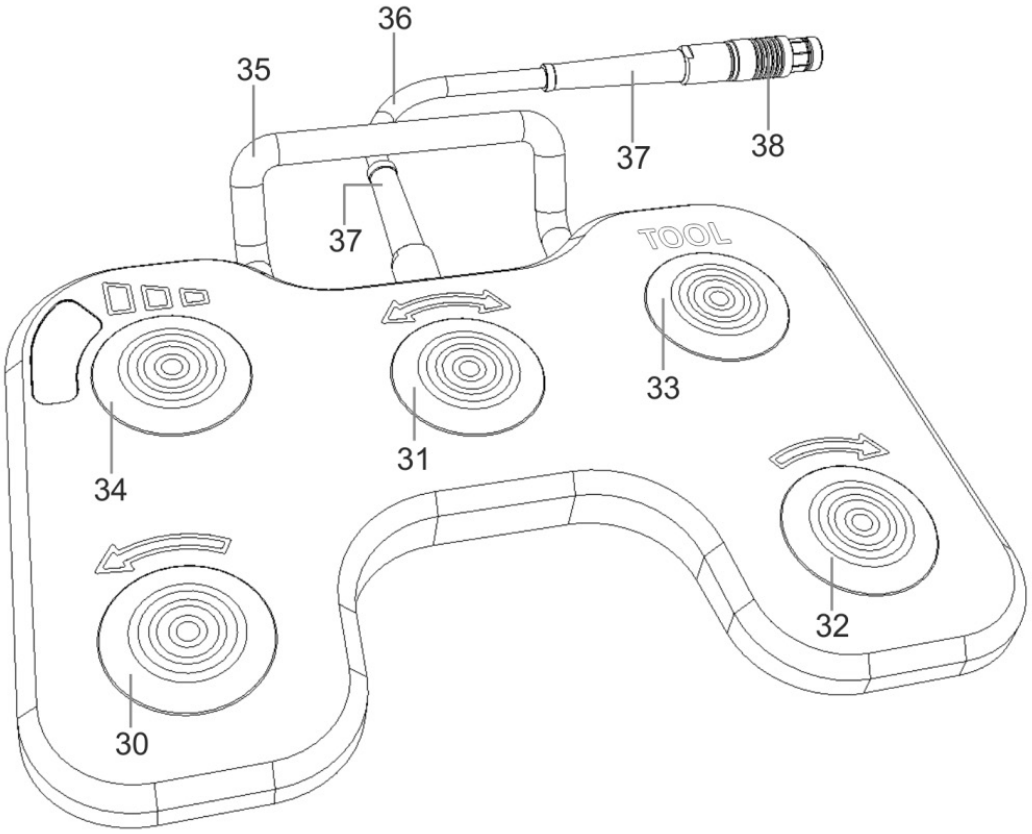
3.3. HANDPIECE DESCRIPTION

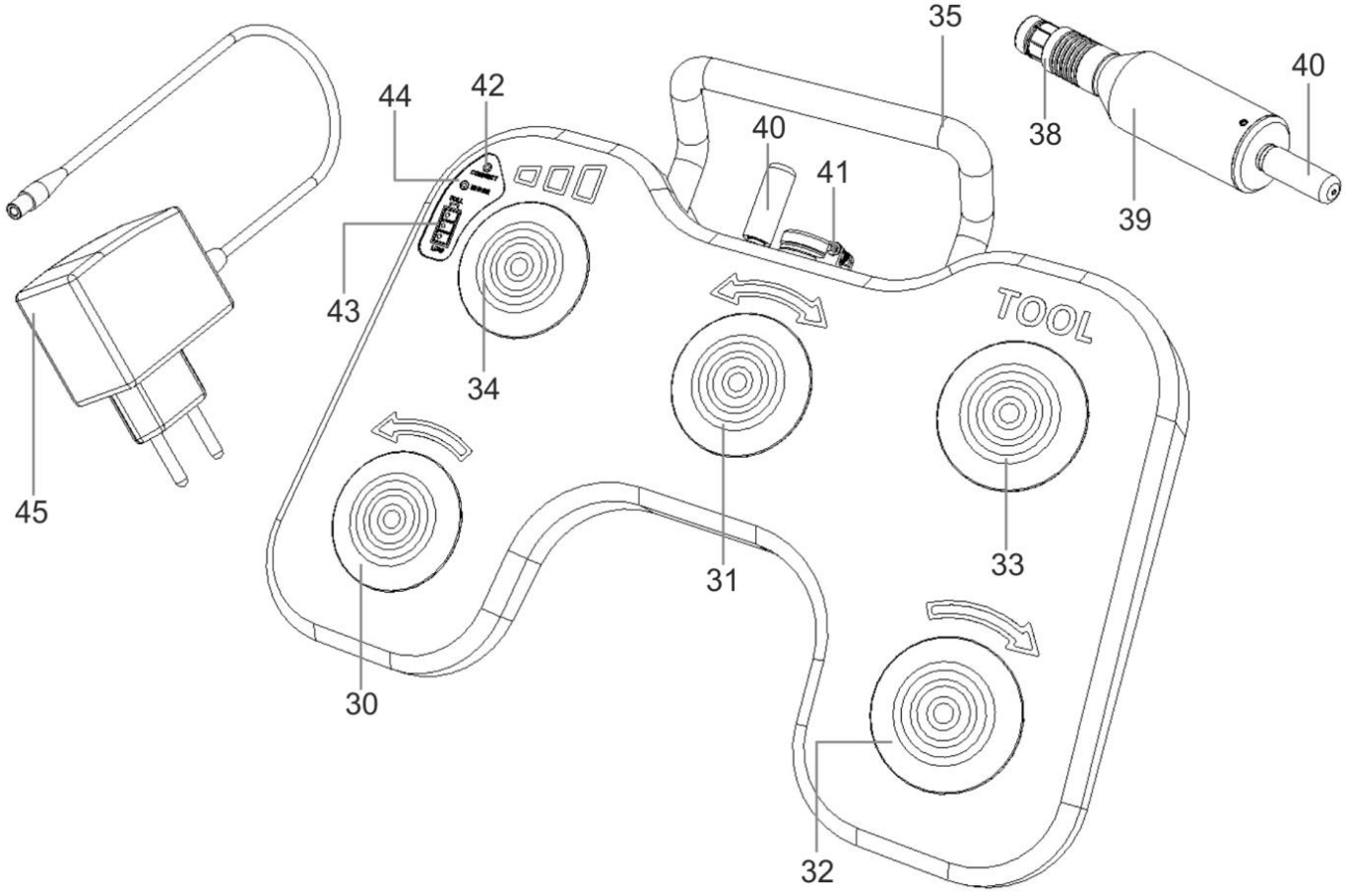




20. Receiving ring of the Handpiece: the shaver blades are securely engaged when the locking device has snapped shut visibly and clicking sound can be heard. The shaver blade cannot be released, not even after repeated pulling.
21. Valve control: to regulate the extraction of saline solution from the operative site.
22. Casing of Handpiece
23. Aspiration port: when the tube of the vacuum pump is mounted onto this nozzle, the saline solution is sucked off through the Handpiece.
24. Protective cap: for increased stability of the connection between the Handpiece and the cable.
25. Cable: 3 meters long cable for comfortable attachment to the Control Unit.
26. Plug: connection to attach the Handpiece to the Control Unit. An integrated lock at the plug protects the cable of the Handpiece from being pulled out by accident.
27. Protective cap for the plug: protects the plug during cleaning, disinfection and sterilization process.

3.4. FOOTSWITCH DESCRIPTION





30. REV: pedal button to switch the shaver blade in the Handpiece to anti-clockwise rotation. The number of rotations depends on the set speed which can be adjusted via the Unit Control buttons (8) and (9) or Footswitch button (34).
31. OSCILLATION: pedal button to switch to oscillating mode. The number of rotations depends on the set speed which can be adjusted via the Control Unit buttons (8) and (9) or Footswitch button (34). The oscillation frequency depends on settings.
32. FWD: pedal button to switch the shaver blade in the Handpiece to clockwise rotation. The number of rotations depends on the set speed which can be adjusted via the Control Unit buttons (8) and (9) or Footswitch button (34).
33. TOOL: pedal button to initiate the change function of the steerable device "HANDPIECE 1" (2), "HANDPIECE 2" (3) connected to the Control Unit.
34. SPEED: pedal button to regulate the speed of the shaver blade in the Handpiece during use. Each time the button is pressed, the speed is increased to the next higher level.
35. Handle: used for lifting and carrying of the Footswitch.
36. Cable: connection between the Footswitch and the Control Unit, serves to transmit the selected functions of the individual Footswitch buttons (30-34).
37. Protective cap: for increased stability of the connection and protection against fracture.
38. Plug: connection to attach the Footswitch to the Control Unit. An integrated lock at the plug protects the cable of the Footswitch from being pulled out by accident.
39. Receiver: as a part of the Footswitch serves to transmit information from the Footswitch to the Control Unit, with which is connected electrically.
40. Antenna: necessary for communication between the Footswitch console and the receiver attached to the Control Unit.
41. Charging socke: used to connect the charger (45). Charging should be done outside of the treatment room. While charging, functions of the Footswitch are disabled.
42. Connection LED: flashing on blue diode signals the proper communication between the Footswitch console and the receiver (39).
43. Battery charge status LED: lighting on green, shows the accumulator level.
44. Error LED: lighting on red diode signals the incorrect charger connection or not compatible charger connection.
45. Battery charger: dedicated to charge the accumulator of the Footswitch. Should be used only outside the operating room.

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4. INSTALLATION AND STARTING THE DEVICE

This chapter describes the correct installation and start-up of the device. The first step is the correct installation of the Control Unit. The language select feature allows the operator to select the language of his choice. If the subsequent steps described in chapters 4.1. to 4.6. have been followed correctly, the device is now ready for use and the shaver blades can be attached.

Attention: When the Shaver System Set is not in active use, protect the device against inadvertent actuation of the Footswitch and the Handpiece!

4.1. DEVICE INSTALLATION

Before installation, make sure that the device has sufficient ventilation by maintaining a minimum distance of 10 cm from the right, left and rear sides of the device.

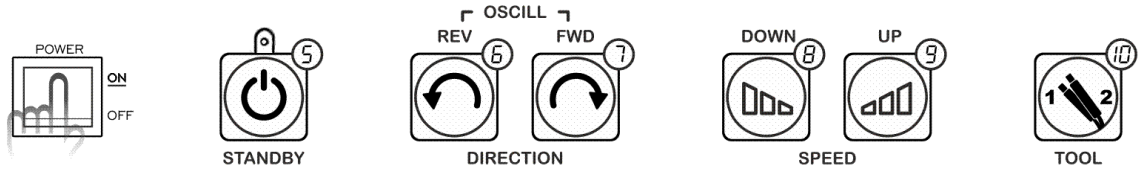
Device installation:
• the only intended position of the Control Unit is horizontal, in which the device is placed on a flat surface on its four rubber feet (12). In addition, adequate ventilation around the Control Unit must be provided,
• the place of installation should be a flat, dry and clean surface. This can be a table, shelf of an endoscopy trolley or other elements meant for installation of medical devices.

Connecting the device to power:
• connect, using an appropriate lead, the equipotential bolt located on the rear of the Control Unit to an equipotential strip. The cable insulation should be yellow-green,

SHAVER SYSTEM

• connect the power cord provided with the device to the socket (16) on the back of the Control Unit,
• plug the power cord into the power socket. The voltage should be within the range indicated on the device label.

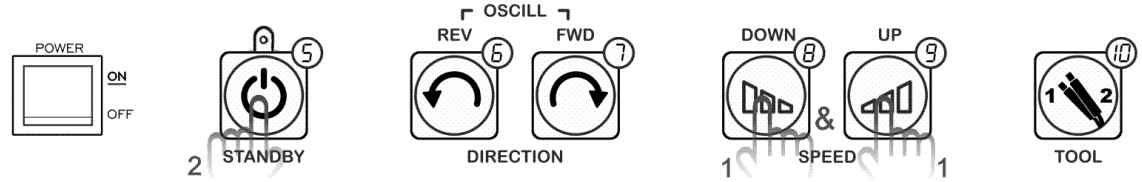
Turn on the device:
• A properly installed and connected device should be started using the "ON/OFF" switch (15) located on the rear panel.



The "STANDBY" button (5) will start flashing at a frequency of 0,5Hz, indicating that the device has switched to standby mode.

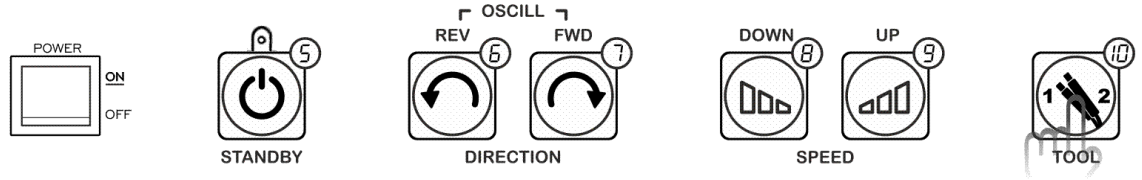
4.2. BASIC SETTINGS

• Once the device is in standby mode (see chapter 4.1.), press simultaneously and hold down the "SPEED DOWN" (8) and "SPEED UP" (9) buttons with your right hand.
• Still holding buttons (8) and (9) briefly press the "STANDBY" button (5) with your left hand.



• Once you are in the required menu, you can release these buttons. You can now select the language you require. The last selected language is shown.

To change the language, press buttons "SPEED DOWN" (8) or "SPEED UP" (9). The user can choose between German, English, French, Russian, Polish and Turkish. The selected language must be confirmed by pressing the button "TOOL" (10).



• Once the selected language has been confirmed, the next settings can be selected: oscillation time and brightness of the VDF display. Again, the settings are selected by pressing the buttons "SPEED DOWN" (8) or "SPEED UP" (9). Confirm settings with the button "TOOL" (10). The control unit memorizes the settings and automatically returns to normal operating mode.

4.3. CONNECTION OF HANDPIECE TO CONTROL UNIT

• The plug (26) at the end of the cable of the Handpiece has to be connected to one of the sockets "HANDPIECE 1" (2) or "HANDPIECE 2" (3) at the front panel of the Control Unit. Up to two Handpieces can be connected to the Control Unit at the same time.
• The plug (26) of the Handpiece is marked with a notch and a red dot. When connecting the plug, make sure that the red dot on the plug is in the same position as the red dot on sockets (2) or (3) of the Control Unit. The pins inside the plug (26) might otherwise get damaged.
• When the Control Unit is activated (see chapter 4.6.), the Handpiece is ready for use. The Handpiece can be operated via the Control Unit and/or the Footswitch.

The Control Unit is provided with a so-called priority circuit for the Handpiece that was connected first irrespective of whether socket "HANDPIECE 1" (2) or "HANDPIECE 2" (3) was chosen. When two Handpieces are connected at the same time, activate the required Handpiece by pressing the button TOOL (10).

The maximum speed for Shaver System is 8000 rpm.
Attention: Handpieces must have come to a standstill before they can be removed from the socket (2) and/or (3) of the Control Unit. Hold Handpieces only by their case (22) during use.

4.4. CONNECTION OF WIRED FOOTSWITCH TO CONTROL UNIT

• The plug (38) at the end of the Footswitch cable has to be connected to the "FOOTSWITCH" (4) socket at the front panel of the Control Unit. Only one Footswitch can be connected.
• The plug (38) of the Footswitch is marked with a notch and a red dot. When connecting the plug, make sure that the red dot on the plug is in the same position as the red dot on the socket (4) of the Control Unit. The pins inside the plug might otherwise get damaged during connection.
• To avoid damage, make sure to pull at the plug (38) itself and not the cable when removing the plug. When the Control Unit is activated (see chapter 4.6.), the Handpiece can be operated via the Footswitch.

4.5. CONNECTION OF WIRELESS FOOTSWITCH TO CONTROL UNIT

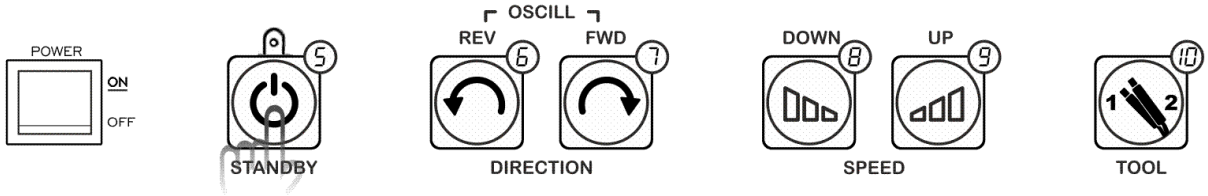
• The plug (38) has to be connected to the "FOOTSWITCH" (4) socket at the front panel of the Control Unit. Only one Footswitch can be connected. Before connecting the plug (38) to the "FOOTSWITCH" (4) socket please make sure that the three-number-codes on the receiver and the Footswitch console are the same, otherwise the Footswitch will not work.
• The plug (38) of the Footswitch is marked with a notch and a red dot. When connecting the plug, make sure that the red dot on the plug is in the same position as the red dot on the socket (4) of the Control Unit. The pins inside the plug might otherwise get damaged during connection.
• When the Control Unit is activated (see chapter 4.6.), the Handpiece can be operated via the Footswitch.

Please adhere to the following steps to initialize the Footswitch work:
• Turn the Footswitch on by pressing any button. The connection between the wireless Footswitch console and the receiver (39) will be established automatically, which may take 5 sec. and in extreme cases up to 20 sec. (time of receiver (39) verification increases e.g. because of many Bluetooth devices around). Proper data transmission is signaled by flashing, Connection LED (42).
• Before starting the work, make sure that the accumulator is appropriately charged. If the wireless Footswitch console is not connected with the receiver (39), the accumulator level is displayed till the connection with the receiver (39) will be established or till the Footswitch console will be switched to stand-by mode. If the Footswitch console is connected with the receiver (39), to check the accumulator level please press "TOOL"(33) button for about 3 seconds, the current level is displayed on the three, green diodes (43). Diodes are turned after 10 sec. off.
• The communication range between the Footswitch console and the receiver (39) is from 0 to 3m. It is recommended to place no obstructions on the line Footswitch console – the receiver (39), such as: metal elements connected to GND potential, thick-walled materials absorbing radio waves frequency 2,4 GHz, that can reduce transmitted signal power.
• After breaking the communication (for example in the case of too large distance from the receiver (39)), establishing the new connection can take 7 sec., in extreme cases up to 20 sec.
• The Footswitch is automatically switched to stand-by mode, after turning off the Control Unit with Mains switch POWER ON/OFF (15), to save the accumulator energy. The communication is stopped. In both cases, to activate the Footswitch (after turning off or longer not using the Footswitch) press any button on the Footswitch console. The communication will be established again.
• To charge the accumulator please connect the battery charger (45) to the socket (41) on the Footswitch console. While charging, connection between the Footswitch console and the receiver (39) is stopped. (the Footswitch is inactive).
• The average charging time is 4 h and is dependent on the discharging level.
• If the red Error Diode (44) is turned on continuously then an incorrect connection of the charger is signalized or a wrong type of charger was used.
• If the Error Diode (44) is pulsating the transmission errors related to disconnection of the receiver (39) in the Console are signalized.

The Footswitch should be recharged only outside operating and treatment rooms. The charger attached to the set is not a medical purpose device.

4.6. STARTING THE DEVICE

• Once the device is in standby mode (see chapter 4.1.), press the "STANDBY" button (5). The main display (1) will display the logo and the model of device and all buttons of the interface or the "STANDBY" LED will be lit continuously.



Device is ready to work. "Ready" mode.

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5. OPERATION OF THE COMPONENTS

5.1. CONTROL UNIT

Unauthorized removal of the seal voids all warranty claims and results in the manufacturer disclaiming all liability for subsequent defects and/or restrictions of use. The same applies if the Handpiece and the Footswitch are opened by unauthorized personnel.

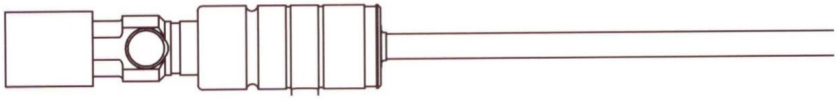
• **Ventilation**: always ensure good ventilation at the rear panel of the Control Unit to prevent
• **Protection:** Unintentional opening of the Control Unit is prevented by an anti-tamper seal.
• **Power supply**: device works at a voltage range of 100 to 240 Volts (50 or 60 Hz). Prior to initial start-up, make sure that all necessary fuses are present in the fuse box. The device is supplied with spare fuses. These must be installed as explained in chapter 7.1. The power cable should be connected to the power cable box (16) at the rear panel of the device and to the socket.
• **Initial start-up:** switch the device on by turning the "POWER ON/OFF" switch (15) on the rear panel of the Control Unit into "ON" position. Press the "STANDBY" button (5) upon which the display will switch itself on and perform a brief self-test, after which the last used settings are reloaded.
• **Keyboard:** the keyboard on the front panel can be used to control all connected Handpieces and to access the language and oscillation mode select menu. The additional "STANDBY" (5) button on the front panel allows the device to be switched off into stand-by mode - without entirely cutting off the power supply. Blinking "STANDBY" button or LED lit continuously (5) while buttons (6) to (10) are dimmed indicates that the device is in stand-by mode. If you wish to turn off the device completely, turn the main "POWER ON/OFF" (15) switch on the rear panel into "OFF" position.

5.2. FOOTSWITCH

The settings for the active Handpiece, i.e. speed, rotation and/or oscillation, can be controlled via the Footswitch. The Footswitch is provided with 3 buttons (30-32) (see chapter 3.4.) to select the direction in which the shaver blade is to move in the Handpiece. The speed can be increased and decreased in intervals via the buttons (8) and (9) on the Control Unit or via the button (34) on the Footswitch.

5.3. HANDPIECE

All functions of the shaver blades in the Handpieces can be controlled via the Footswitch or the Control Unit, i.e. direction of rotation, oscillation and speed. With the adaptor illustrated below, all shaver blades: Linvatec type are suited for the Handpieces that come with the Control Unit.



5.3.1. HANDPIECE WITH AUTOMATIC RECEIVING RING OF THE SHAVER BLADES

Please adhere to the following steps when locking the shaver blades into the Handpiece:

• Insert the shaver blade into the opening of the Handpiece until you can feel resistance. The shaver blade is properly engaged when you can hear a clearly audible sound and the instrument cannot be removed, even by pulling.
• To remove the shaver blade, turn the receiving ring (20) of the Handpiece in anti-clockwise direction, which automatically releases the shaver blade. Remove the shaver blade above the operating table only. Hold the Handpiece in upright position to avoid uncontrolled ejection.
• We recommend to work at an appropriate speed, depending on the type of used shaver blade. For information on the respective maximum speeds, please refer to the instructions for use provided with the shaver blades.
• The tube of the vacuum pump in the operating theatre is connected to the aspiration port (23) to ensure proper drainage of the saline solution containing tissue residues.
• The Handpiece can be used by both left and right handed operators. It is essential to make sure that the valve control (21) on the Handpiece faces upwards at all times so that it is always ready for use. When the valve control (21) is switched to its front position (towards the receiving ring (20), the drainage of the contaminated saline solution is reduced to a minimum. Maximum drainage takes place when the valve control (21) is switched to the rear (i.e. towards the cable (25)). Between these two positions, the valve is infinitely variable.

5.3.2. HANDPIECE WITH MANUAL RECEIVING RING OF THE SHAVER BLADES

Please adhere to the following steps when locking the shaver blades into the Handpiece:

• The receiving ring (20) of the Handpiece should be opened (oval cuttings of the lock of receiving ring (20) should be in vertical position). Insert the shaver blade in such a way that pins, on its sides, come into the cuttings of the socket. Push until you can feel resistance. Next, the lock of receiving ring (20) should be turned the range of 90°. The shaver blade is properly engaged when you can hear a clearly audible sound and the instrument cannot be removed, even by pulling.
• These activities should be repeated in adverse order to remove the shaver blade from the socket. Remove the shaver blade above the operating table only. Hold the Handpiece in upright position to avoid uncontrolled ejection.
• We recommend to work at an appropriate speed, depending on the type of used shaver blade. For information on the respective maximum speeds, please refer to the instructions for use provided with the shaver blades.
• The tube of the vacuum pump in the operating theatre is connected to the aspiration port (23) to ensure proper drainage of the saline solution containing tissue residues.
• The Handpiece can be used by both left and right handed operators. It is essential to make sure that the valve control (21) on the Handpiece faces upwards at all times so that it is always ready for use. When the valve control (21) is switched to its front position (towards the receiving ring (20), the drainage of the contaminated saline solution is reduced to a minimum. Maximum drainage takes place when the valve control (21) is switched to the rear (i.e. towards the cable (25)). Between these two positions, the valve is infinitely variable.

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6. MAINTENANCE AND CARE

6.1. GENERAL INFORMATION

The Handpiece must be cleaned, disinfected and sterilized prior to every use. The Control Unit and the Footswitch must also be cleaned and disinfected, but they do not require sterilization. This also applies to the very first use after delivery, because all components of the Control Unit are supplied in non-sterile condition and without having been disinfected. Thorough cleaning and disinfection are essential preconditions for an effective sterilization.

The division/entity in charge of reprocessing has to make sure that:

• validated cleaning, disinfecting and sterilization methods are used,
• the washer /disinfector and the sterilizer are checked and serviced in regular intervals,
• the validated parameters are followed during every reprocessing procedure.

In addition to the above, the country specific legal provisions regarding reprocessing of medical devices have to be observed!

Safety precautions!
Always wear protective clothing during the reprocessing of contaminated medical instruments, i.e. eye and mouth protectors, chemical-resistant gloves and moisture repellent clothes. Blood, residual tissues and other infectious materials pose an increased risk of infection.

6.2. CLEANING AND DISINFECTION OF CONTROL UNIT AND FOOTSWITCH

Always make sure to remove the power cable from the plug and the power cable socket (15) on the rear panel of the Control Unit prior to cleaning. During the cleaning process, the device must not be connected to the power supply in any way. The Control Unit and the Footswitch must be cleaned and disinfected after every use. To remove dust and other dirt or contamination use a clean cloth moistened with cleaning and disinfectant solution. Make sure that the cloth is just moist and not soaking wet to prevent moisture from entering the sockets (2), (3) and (4) of the Control Unit.

When choosing the cleaning and disinfection solution, make sure:

- to use a product that is suitable for wet wipe disinfection of metal and plastic components,
- to choose a product with proven suitability (e.g. approved by the German Association for Hygiene and Microbiology (DGHM) or the Association for Applied Hygiene (VAH), authorized by the FDA or provided with a CE mark), for example Microbac forte, Velox AF or other.
- that the detergent is compatible with the disinfectant,
- that both agents are compatible with the Control Unit and its accessories (see chapter 6.3.9. material compatibility).

The concentration and immersion time indicated by the manufacturer of the detergents and disinfectants have to be strictly observed.

6.3. CLEANING, DISINFECTION AND STERILIZATION OF HANDPIECE

6.3. 1. GENERAL INFORMATION

Give preference to mechanical cleaning and disinfection of the Handpiece in the washer /disinfector. Manual reprocessing (including ultrasonic bath) should only be chosen if mechanical reprocessing is not an option.
Manual cleaning and disinfection may only take place if the division/entity in charge is in possession of an officially approved device and product specific process validation and they are prepared to assume responsibility for the process.
In both cases, pre-cleaning is absolutely essential!
Reusable instruments, such as shaver blades, must be reprocessed as indicated in the instruction pamphlet enclosed with the instruments or according to the information provided by the manufacturer.

6.3. 2. PRE-CLEANING

Any visible contamination must be removed from the Handpiece immediately (within two hours at the very latest).

Procedure:
1. When removing the Handpiece from the Control Unit, make sure to pull it out by holding the plug (26) and not by pulling the cable. Seal plug with protective cap (27).
2. Use a soft brush or a soft clean cloth with tap water or a disinfectant solution to remove any contamination from the Handpiece. If using a disinfectant solution, make sure that this is free of aldehyde (risk of protein fixation) and suitable for disinfecting the materials involved (see chapter 6.3.9 material compatibility). Choose a product with proven suitability (e.g. approved by the German Association for Hygiene and Microbiology (DGHM) or the Association for Applied Hygiene (VAH), authorized by the FDA or provided with a CE mark).
3. For pre-cleaning the inner lumina choose a brush with matching diameter. This applies to the suction channel and the receiving ring (20). Move valve control (21) back and forth repeatedly during cleaning.
4. Next, place the Handpiece into an ultrasonic bath filled with cleaning solution. Place the Handpiece in upright position,

with the receiving ring (20) facing downwards. The Handpiece and the cable must be completely covered by cleaning solution. The valve control (21) must be set in MAX position, when choosing the cleaning solution, make sure that:

- the solution is suitable for cleaning instruments with metal and plastic components,
- all chemicals contained in the solution are compatible with the medical devices (see chapter 6.3.9 material compatibility),
- the solution is suitable for ultrasonic baths (i.e. no foaming).

5. Rinse the entire Handpiece. Rinse all lumina, e.g. the suction channel and the closing mechanism of the receiving ring with a water pistol with cold water for at least 10 seconds (static water pressure: 3.8 bar). Make sure that the valve control (21) is in MAX position to prevent any contamination from remaining in the receiving ring or in the suction channel.

Please note that the above pre-cleaning process and the cleaning agents used (see point 2 and 3) merely serve to protect the person carrying out the reprocessing procedure. This does not in any way replace the disinfection cycle which is absolutely essential.

For manual removal of contamination (see point 2 and 3), only use soft brushes and soft clean clothes that are intended for this purpose. The use of metal brushes and steel wool is not permitted as these would damage the surface. Take great care when cleaning the Handpiece, especially when cleaning the lumina in the receiving ring and the suction channel (see point 3 and 5). In absence of an ultrasonic bath (see point 4), an ordinary bath is acceptable in exceptional cases, in which case a minimum immersion time of 20 minutes must be observed.

The suitability of these medical devices for effective pre-cleaning was tested and proved by an independent test laboratory. The detergent Neodisher Mediclean forte (0.5 %) (Dr. Wiegert GmbH & Co. KG, Hamburg) was used. The above work flow was determined by the tests in the test laboratory.

6.3. 3. MECHANICAL CLEANING AND DISINFECTION

When choosing the washer / disinfector, make sure that:

- the suitability of the washer/disinfector has been proven (e.g. authorized by the FDA or provided with a CE mark pursuant to DIN EN ISO 15883),
- a program for thermal disinfection is available (Ao value> 3000 or - in older devices - a minimum hold time of 5 minutes at 90°C). A chemical disinfection involves the risk of residues being left on the Handpiece,
- the program is suitable for these medical devices and that it comprises a sufficient number of rinsing cycles,
- the final rinse is done with sterile water, almost sterile water or water with a low content of Endotoxin (max. number of Endotoxin units: 0,25/ml) (e.g. processed water),
- the air used for drying is filtered,
- the washer / disinfector is serviced and checked in regular intervals.

When choosing the detergent, make sure that:

- it is suitable for cleaning medical devices with metal and plastic components,
- if thermal disinfection is not an option, a suitable disinfectant with proven suitability (e.g. approved by the German Association for Hygiene and Microbiology (DGHM) or the Association for Applied Hygiene (VAH), authorized by the FDA or provided with a CE mark) must be used. The disinfectant must be compatible with the detergent,
- all chemicals used during the process must be compatible with the present medical devices (see chapter 6.3.9 material compatibility).

The concentrations specified by the manufacturers of the detergents and disinfectants have to be strictly observed.

Work flow:

1. Loosely coil up the cable of the Handpiece with a diameter of 30 cm.
2. Immerse the Handpiece in the washer /disinfector. Make sure that the Handpiece does not touch any other instruments and that the receiving ring (20) is facing downwards. It can be placed in vertical or diagonal position.
3. The aspiration port (23) of the suction channel must be connected to a flexible tube at the basket. Make sure that the valve control (21) is in MAX position.
4. Start the program.

5. Once the entire cycle is completed, remove the Handpiece from the washer /disinfector.
6. Check the Handpiece to make sure that it is ready for use. Wrap immediately after removal from the washer /disinfector (see chapter 6.3.5 Inspection/lubricants and 6.3.6 Packaging). If the Handpiece is still wet, dry at a clean place.

The suitability of these medical devices for effective mechanical cleaning and disinfection was tested and proved by an independent test laboratory. A washer /disinfector G7735 CD (Co. Miele & Cie. KG, Gutersloh, Germany) and the detergent Neodisher Mediclean forte (0.5 %)(Dr. Wiegert GmbH &Co. KG, Hamburg) were used. The above work flow was determined by the tests in the test laboratory.

6.3. 4. MANUAL CLEANING AND DISINFECTION

Manual reprocessing (including ultrasonic bath) should only be chosen if mechanical reprocessing is not an option. Manual cleaning and disinfection may only take place if the division/entity in charge is in possession of an officially approved device and product specific process validation and if they are prepared to assume responsibility for the process.

When choosing the detergent, make sure that:

• it is suitable for cleaning medical devices with metal and plastic components,
• its suitability has been proved (e.g. approved by the German Association for Hygiene and Microbiology (DGHM) or the Association for Applied Hygiene (VAH), authorized by the FDA or provided with a CE mark),
• all chemicals used are compatible with the present medical device (see chapter 6.3.9 material compatibility).

We recommend a combined solution for cleaning and disinfection, for example Korsolex plus (Co. Bode Chemie). The concentration and immersion time specified by the manufacturers of the detergents and disinfectants have to be strictly observed. Use sterile water, almost sterile water or water with a low content of Endotoxin (max. number of Endo-toxin units: 0.25/ml)(e.g. processed water) only. The air used for drying must be filtered.

Work flow:

1. Immerse the Handpiece in a bath filled with cleaning/disinfectant solution. Make sure that the Handpiece is in upright position, with the receiving ring (20) facing downwards. The Handpiece and the cable must be completely covered with cleaning solution. The valve control (21) must be in MAX position.
2. During the immersion time, clean the lumina of the receiving ring and the suction channel several times with a brush of matching diameter, whilst moving the valve control (21) back and forth.
3. Lift the Handpiece out of the bath and rinse with sterile or almost sterile water for at least 10 minutes. Make sure that the receiving ring (20) and the suction channel are completely free of residues of tissue and chemicals.
4. Dry the Handpiece with filtered compressed air. Ensure that the receiving ring and the suction canal are free of any residual moisture.
5. Check the Handpiece to make sure that it is ready for use and wrap immediately (see chapter 6.3.5 Inspection/lubricants and 6.3.6 Packaging). If the Handpiece is still wet, dry at a clean place.

6.3. 5. INSPECTION/LUBRICANTS

After cleaning and disinfection, remove the protective cap (27) from the plug (26) and check the Handpiece for corrosion, damaged surfaces, spalling and visual contamination. Discard damaged Handpieces (see chapter 6.4 Reusability). In case of residual contamination, repeat the complete cleaning and disinfecting process.
The inside of the Handpiece must not be moistened with any type of lubricant!

6.3. 6. PACKAGING

Place the protective cap (27) back onto the plug (22). The valve control (21) must be open (MAX position) when the Handpiece is sterilized, which is why you have to ensure during wrapping that the valve control is in correct position. Loosely coil up the cable of the Handpiece with a diameter of 30 cm. Wrap the Handpiece in disposable sterilization pouches (single or double) and/or in a sterilization container, according to the following conditions:

• EN ISO 11607/ ANSI AAMI ISO 11607,

• suitable for steam sterilization (heat resistant up to 141°C, sufficient permeability),
• the Handpiece is adequately protected from mechanical damage,
• sterilization containers must be serviced in regular intervals according to the instructions of the manufacturer.

6.3. 7. STERILIZATION

Use the below described method of sterilization only. All other methods are prohibited.

Steam sterilization:

• fractionated vacuum and gravitation method (with sufficient drying time (at least 10 minutes)). The gravitation method is less effective and should only be used if no fractionated vacuum is available,
• steam sterilizer according to DIN EN 13060/DIN EN 285,
• validated according to ISO 17665 (previously DIN EN 554/ ANSI AAMI ISO 11134)(Start-up and product specific performance assessment),
• the temperature during sterilization must not exceed 138°C (280°F plus tolerance) according to DIN EN ISO 17665 (previously DIN EN 554/ANSI AAMIISO 11134),
• sterilization time (hold time of the sterilization temperature):
    • fractionated vacuum: at least 3 minutes at 132°C (270°F)/134°C (273°F),
    • gravitation method: at least 20 minutes at 121°C (250°F).

The suitability of these medical devices for effective sterilization was tested and proved by an independent test laboratory. A sterilizer Selectomat HP 666-1 HRED (co. MMM Münchener Medizin Mechanik GmbH, Planegg, Germany) was used for the fractionated vacuum and gravitation methods. The above work flow was determined by the tests in the test laboratory.

⚠ The Handpiece has to cool down at room temperature.
Do not use while still warm.
Accelerated cooling with water or a wet cloth is not permitted.

Attention!
• The Control Unit, the Footswitch and the receiver (32) must not be sterilized.
• A reduction of the indicated drying time during the sterilization process can cause irreversible damage or reduce the performance.
• Do not exceed the maximum sterilization temperature during the sterilization process. This can cause irreversible damage or reduce the performance.

6.3. 8. STORAGE

After reprocessing and before the next use, store the Handpiece in sterile packaging in a dry place, away from dust.

6.3. 9. MATERIAL COMPATIBILITY

Make sure that the chosen detergents and/or disinfectants do not contain any of the below listed chemicals:

• organic, mineral or oxidizing acids (lower limit for the pH-value: 5.5),
• strong bases (upper limit for the pH-value: 11, alkaline products are recommended),
• organic solvents (e.g. ether, ketone, benzine),
• oxidants (e.g. peroxides),
• halogens (chlorine, iodine, bromine),
• aromatic and halogenated hydrocarbon.

Do not use metal brushes or steel wool for cleaning the Handpiece. Do not exceed a temperature of 138°C (280°F).

6.4. REUSABILITY

The individual components can be reused as long as they perform adequately and the instruments can be fixed properly, provided that they are used with due care and reprocessed, inspected and packed correctly. Any (further) use of damaged or contaminated instruments is on the sole responsibility of the user. The durability of the product largely depends on careful handling during use and reprocessing, which is why the number of possible reprocessing cycles cannot be determined. The manufacturer declines all liability in case of non-observance of these instructions.

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7. INSPECTIONS, SERVICE, TECHNICAL SUPPORT

7.1. REPLACING FUSES

WARNING!
Follow these steps before replacing the fuses:
• turn the device off using the power switch "POWER ON/OFF" (15) located on the rear panel,
• disconnect the power cord from the power socket and then from the socket of the device (15). When equipment was switched on, please wait 3-4 minutes for disconnecting.

Replacing fuses is to be performed only if they are damaged.

Use only such fuses as indicated in Table 5.

To replace the fuses:
• remove defective fuses. Fuses are located in the drawer (17) installed in the power socket (16) of the device,
• new time-delay fuses, the values of which should be selected on the basis of Table 5, should be inserted in the slots in the fuse drawer.

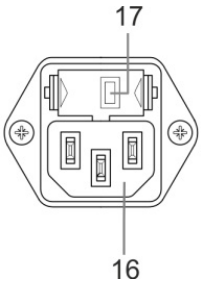


Table 5. Values of fuses intended for specific models of the Control Unit of Shaver System:

Pos.	Type of Control Unit	Value and type of fuse
1	# 16-2050	2x T 1,25A L 250 V

• Slide the fuse drawer (17) into the power socket of the device (16). Proper installation will be signalled by an audible "click" , the sound of latches closing in the drawer locking mechanism.
• Connect the power cord. The device can be restarted.

7.2. PERIODIC INSPECTIONS OF THE DEVICE

For long-lasting and trouble-free operation of the device, the manufacturer imposes obligatory inspections, which should take place at intervals of no less than every 12 months (once a year).

The inspection must be conducted by the manufacturer or its authorised service provider. See service provider data in the last page.

The inspection consists of:
• checking the technical state of the device,
• cleaning the interior of collected dust and other contaminants,
• measurement of operational parameters,
• performance of an electrical safety test in accordance with EN 60601-1,
• software update.

Each inspection involves a subsequent report, whose copy will be delivered to the client with the device. If malfunctions are found during the inspection, the inspector will prepare an offer for removal of such defects, which will be sent to the customer by e-mail or fax.

7.3. WARRANTY AND POST-WARRANTY SERVICE

The device manufacturer provides warranty and post-warranty service under the following conditions:

• a damaged device should be sent in its original packaging directly to manufacturer (address can e found in last page Manufacturer and service provider data) or to local manufacturer's distributor, together with a detailed description of the malfunction. The service provider has the right to refuse warranty repairs of a device improperly packaged or in non-original packaging,
• under no circumstances repairs should be carried out by unqualified personnel. Only the manufacturer and/or authorised service partners are authorised to perform them. The device is protected from unauthorized opening by the warranty seals. A damaged or broken seal voids the warranty and implies to the manufacturer refusing any responsibility for any subsequent malfunctions and/or limitations in the functioning of the device,
• the manufacturer's warranty does not cover damage caused by random events such as flooding, fall, power surge caused by a storm, burning in a fire etc.,
• warranty repairs may be carried out solely by the equipment manufacturer or an authorised service provider, whose address is given by the manufacturer,
• before shipping, decontaminate the device and its accessories according to chapter 6 "Maintenance and care" in order to protect the service personnel. Manufacturer and authorized service provider has the right to reject contaminated products for repair.

7.4. BASIC TROUBLESHOOTING

Table 6. Specification of the most common problems associated with using the device and methods of their detection and elimination:

1: The Control Unit does not work	
Issue	**Solution**
Power cord is not connected	Connect power cord to the power cable socket (16)
No power at place of installation	Make sure that the voltage in the power grid is correct
Damaged or missing fuse	Check fuses (See point 7.1.)
"POWER ON/OFF"(15) switch was not actuated	After installation actuate "POWER ON/OFF"(15) switch at the rear panel of the Control Unit

2: The Handpiece does not work

Issue	Solution
The Handpiece was not connected to the Control Unit	Connect the Handpiece to the socket "HANDPIECE 1(2) or "HANDPIECE 2"(3) or check that the Handpiece is properly locked in place
The Footswitch was not connected to the Control Unit	connect the Footswitch to the socket "FOOTSWITCH"(4) or check that the Footswitch is properly locked in place
The other Handpiece is activated	activate the socket for the required Handpiece by pressing the "TOOL"(10) button at the Control Unit

3: The Footswitch does not work

Issue	Solution
Blade is blocked in the Handpiece	Replace the shaver blade for a well-functioning one
The Footswitch has not been connected to the Control Unit	Connect the Footswitch to the Control
Too low battery level in the wireless Footswitch	Charge the battery according to recommendations (See point 4.5.)
Connection error between the Footswitch console and the receiver	Re-initiate the connection procedure in accordance with paragraph 4.5.

4: The Handpiece overheats

Issue	Solution
Prolonged overloading of the Handpiece	Remove the Handpiece from the connection socket at the Control Unit and allow to cool down to room temperature. Make sure if installed shaver blade is not the cause of the Handpiece overloading

Any anomalies or defects not included in the aforementioned table must be reported to the manufacturer's service department. Until all defects of the device are removed, it should be excluded from operation and marked accordingly.

8. TECHNICAL SPECIFICATIONS

Table 7. Control Unit technical specification:

Parameter	Control Unit
Power consumption	65 VA
Supply voltage	100-240 V AC
Power frequency	50/60 Hz
Protection class	Class I, application part type B

Weight	5.1 kg
External dimensions	D: 306 mm x W: 330 mm x H: 96 mm
Fuses	According to Table 5
Ambient temperature	During operation: +10°C to +40°C During storage and transport: -20° C to +45°C
Maximum relative humidity	During operation: 70% During storage and transport: 70%
Protection against harmful ingress of water or particulate or particulate matter	IP X0 , Not protected against water / moisture

Do not use in the environment of flammable anesthetic gases.

All electromagnetic compatibility standards were applied and the device was tested accordingly. However, some devices may interfere with the Control Unit. It is recommended to keep such devices away from the Control Unit.

The CE mark on the device label certifies compliance with all European requirements and with Directive MDD/93/42/EWG.

Table 8. Handpiece technical specification, depending on the device variant:

Parameter	**Handpiece**	
Type of Handpiece	**with manual lock**	**with automatic lock**
Length	180 g	184 g
Weight	400 g without cable	
Speed	800 – 8000 rpm (±10%)	
Oscillation frequency	Slow (0,5 s), normal (0,3 s), fast (0,2 s)	
Cable length	3 m	
Sterilization method	Steam sterilization	
Ambient temperature	During operation: +10°C to +40°C During storage and transport: -20° C to +45°C	
Maximum relative humidity	During operation: 100% During storage and transport: 90%	
Protection against harmful ingress of water or particulate or particulate matter	IP X8, Protection against the effects of continuous immersion in water	

The CE mark on the device label certifies compliance with all European requirements and with Directive MDD/93/42/EWG.

Table 9. Footswitch technical specification, depending on the device variant:

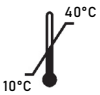
Parameter	**Footswitch**	
Type of Footswitch	**standard**	**standard wireless**
Weight	2.45 kg	2.2 kg
Cable length	3 m	wireless + receiver
Battery type	n/a	lithium-polymer accumulator, not to be replaced by the user
Charging time	n/a	4 h
Charger	n/a	5 V DC / 700 mA
Battery lifetime	n/a	> 300 charging cycles (>70% capacity)
Dimensions	28 x 280 x 215 mm	
Ambient temperature	During operation: +10°C to +40°C During storage and transport: -20° C to +45°C	
Maximum relative humidity	During operation: 100% During storage and transport: 90%	
Protection against harmful ingress of water or particulate or particulate matter	IP X8, Protection against the effects of continuous immersion in water	
The CE mark on the device label certifies compliance with all European requirements and with Directive MDD/93/42/EWG.		

9. SYMBOLS AND MARKINGS

9.1. SYMBOLS USED ON LABELLING

Table 10. Summary of symbols and their meanings:

Symbol and description	**Symbol and description**	**Symbol and description**
Follow the instructions for use	Type B applied part	Year of production
Legal manufacturer	CE 0483 mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart, Germany	ON Symbol:on
OFF Symbol: off	SN Serial number	REF Article number
Information relating to the disposal of electronic equipment in the EU	IP Tightness class	Protective earthing

 Information relating to the disposal of battery in the EU	 Equipotential (equalising potential)	 Temperature range 10°C-40°C
 Caution, glass fragile	 Protect against moisture	 This way up, do not turn over!
 Code of the receiver and of the console of wireless footswitch	 Caution, consult accompanying documents	 Source of non-ionizing radiation

9.2. PACKAGE LABEL

The package label contains information about the contents of the package, such as: product name, reference number, quantity, date of manufacture, name and address of the manufacturer.

The unit label contains necessary information about: the type of equipment, manufacturer, date of manufacture, supply voltages, power draw and type of fuses. It also identifies the unit by serial number and reference number.

The labels should under no circumstances be removed or damaged.
An illegible label makes it impossible to identify important parameters. A unit without a label or with a damaged label that does not contain identification data for the product is not subject to the

9.3. DISPOSAL OF USED ELECTRONIC PRODUCTS

Prior to disposal, follow chapter 6 "Maintenance and care"

In the European Union:
The current EU-wide legislation, implemented in each member state, requires that all electrical and electronic Equipment marked with this symbol is disposed separately of other waste. This includes electronic devices or electrical accessories such as cables, electronics, etc. When disposing of such products, please follow the advice of your local authorities. The symbol shown on electrical and electronic products only applies in current EU member states.

Outside the European Union:
When disposing of used electronic and electrical products outside the European Union, please contact your local authorities to obtain information on the proper method of disposal.

10. INFORMATION ABOUT POTENTIAL ELECTROMAGNETIC INTERFERENCES

Table 11. Guidance and manufacturer's declaration – electromagnetic emissions:

EMC – guidance and manufacturer's declaration (EN 60601-1-2: 2007) Arthroscopy Shaver System 16-2050

The Arthroscopy Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the Arthroscopy Shaver System should assure that it is used in such environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	50/60 Hz	The Arthroscopy Shaver System uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby equipment.

RF emissions CISPR 11	50/60 Hz	The Arthroscopy Shaver System is suitable for use in all establishments, including domestic establishments and directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	n/a
Voltage fluctuations IEC 61000-3-3	Consistent	n/a

Table 12. Guidance and manufacturer's declaration – Electromagnetic immunity:

The Arthroscopy Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the Arthroscopy Shaver System should assure that it is used in such environment.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±4kV, ±8kV, ±15kV air	Lack of visible influence on device. Complies - possible artefact visible on the display.	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines, ±1 kV for input/output lines	Lack of visible influence on device. The device is treated as a single component (no wires in/out)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±2 kV line-toground, ±1 kV line-to-line	Lack of visible influence on device	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Lack of visible influence on device Lack of visible influence on device Lack of visible influence on device When supply is turned up again, the device is turned on in standby mode and with turned off tool - possible starting normally.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC 61000-4-8	30 A/m	It is not tested.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the mains voltage prior to application of the test level.

Table 13. Guidance and manufacturer's declaration – Electromagnetic immunity:

The Arthroscopy Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the Arthroscopy Shaver System should assure that it is used in such environment.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000- 4-6	3 Vrms 150 kHz to 80 MHz	3,000 V	Recommended separation distance: d=1,16 √P d=1,16 √P 80 MHz to 800 MHz d=2,33 √P 800 MHz to 2,5G Hz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3,004 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from

a) Fidel strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ASS device is used exceeds the applicable RF compliance level above, the ASS device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ASS device.
b) Over the frequency range 150 kHz to 80 MHz, Fidel strengths should be less than 3 V/m.

Table 14. Recommended separation distances between portable and mobile RF communications equipment and the device:

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz d=1,16 √Prms	80 kHz to 800 MHz d=1,16 √Prms	800 kHz to 2,5 GHz d=2,33 √Prms
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,16	1,16	2,33
10	3,67	3,67	7,36
100	11,6	11,6	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11. APPENDIX

All product codes covered by these instructions are listed below:

- Shaver System Set **#16-2050**
- Handpiece with manual lock **#16-2050-100**
- Shaver standard footswitch **#16-2050-200**

12. CONTACT DETAILS

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