medaxis
microjet wound therapy

Instruction for use EN/EU

swiss medical technology

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Congratulations!

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Bahnhofstrasse 9
6430 Baar
Switzerland

With debritom⁺, you have acquired a high quality and innovative micro jet wound therapy device that sets new standards for wound debridement. debritom⁺ has an electronic control system with optical status indications. Most components that will be getting in contact with rinsing fluids are single use, which have to be disposed of after use according to your internal guidelines.
The size enables high flexibility and mobile use, and the extreme quietness of operation allows the user to concentrate on wound and patient for an efficient and safe debridement. The comprehensive range of accessories offers the medical professional a toolbox for their individual needs.

EC REP

Emergo Europe
Westervoortsedijk 60, 6827 AT Arn,
The Netherlands, Tel. +31 70 345 8570

UK REP

Emergo Consulting UK
c/o Cr360 - UL International, Vision Park Histon,
Cambridge CB24 9BZ UK, Tel. +44 1223 772 671

1 Warnings and safety instructions

⚠ WARNINGS
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION
Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

☛ SAFETY INSTRUCTION
Indicating useful information about the safe use of the device.

debritom⁺ is approved exclusively for the use as described in these instructions for use. Medaxis can only guarantee the safe functioning of the system when debritom⁺ is used in combination with the original debritom⁺ accessories (pump, handpiece, connection tube, power cord; see chapter 17 – Accessories).

debritom⁺ is EMC-tested in conformity with the requirements of IEC 60601-1-2:2014 and can be used in the vicinity of other EMC-tested devices that fulfill the requirements as outlined in the IEC 60601-1-2 standard. Untested HF sources, radio networks or the like can impair the function of the device and should not be operated in the vicinity of debritom⁺.

In case of a serious incident in combination with debritom⁺, the user and/or patient should report the event to the manufacturer and competent authority.

Please read and pay attention to the warning and safety instructions before operation.
These instructions for use must be kept with the device for later reference.

Please note that these Instructions for use are a general guide for the use of the product. Medical matters must be addressed by a physician.

Medaxis considers itself only responsible for the effect on BASIC SAFETY, reliability and performance of debritom⁺ if it is used in accordance with the Instructions for use.

Subject to change.

⚠ WARNING

- This manual must be read prior to the use of debritom⁺
- Please read and observe these warning and safety instructions before operation. These instructions for use must be kept with the device for later reference.
- The use of the device should only be carried out by medical, qualified personnel.
- Before cleaning the device you must disconnect the power supply.
- debritom⁺ was validated in combination with the accessories listed in chapter 17. For a correct and safe operation use debritom⁺ with these accessories only.
- Do not use debritom⁺ in MR environment.
- The device is not suitable for use in a hazardous explosive environment.
- The use of debritom⁺ for any other indication than intended is neither desired nor allowed.
- Wear gloves, protective googles and surgical masks for all operations.
- To avoid the risk of electric shock, this equipment must be connected to a power outlet with protective earth only.
- The device shall not be serviced or maintained while in use with a patient.
- Immediately disconnect the device from the supply mains and stop using it, if it is damaged.
- Modification of the device or combination with other devices is not allowed.
- When treating infants, make sure a second medical professional is securely holding the body part to be treated in place in order to prevent sudden movements.
- Adults must be asked to keep the body part to be treated securely in place.

⚠ CAUTION

- The intensity level to be set must be determined by a physician according to the patient's wound.
- Before connecting debritom⁺ to the power supply, please verify that the supply voltage corresponds to that given on the device specification plate.
- Incorrect use of debritom⁺ can cause pain and injury to the patient.
- When the sterile packaging is damaged, do not use contents.
- Non sterile and reusable accessories must be cleaned and disinfected according to chapter 10, General cleaning guidelines'.
- The device can be switched off at any time by pulling out the mains plug.

- debritom⁺ is a medical device that requires specific safety measures in regard to EMC. It must be installed and put into operation in accordance with the attached EMC information in chapter 16 ‚Technical documentation'.
- Portable and mobile RF communications equipment can affect medical devices.
- In each of the following cases, debritom⁺ must not be used and it must be repaired by customer service:
  - If the power cord or the plug are damaged.
  - If the device is not functioning according to routine check.
  - If the device is damaged.
  - If the device shows clear safety defects.
  - If a specific error reoccurs several times.
- debritom⁺ has no user serviceable parts inside (open device with cover removed). For safety reasons, it is required that debritom⁺ is repaired throughout its service life strictly and exclusively by Medaxis authorised service centres.
- Keep the power supply cord away from hot surfaces.
- The mains plug and the on/standby button must not come into contact with moisture. Never pull the mains plug out of the fixed mains socket by pulling on the power supply cord.
- Separation from the mains is only assured through the disconnection of the mains adapter and fixed socket connection.
- Never use the device at high room temperatures.
- Never place or immerse debritom⁺ in water or other liquids.
- When using single use, sterile products, please note that they are not intended to be reprocessed. Reuse could result in loss of mechanical and chemical properties and may lead to restricition in terms of biocompatibility.
- Contact your local Medaxis customer service representative for assistance with product operations.
- The device can be switched off at any time by pulling out the mains plug.
- Do not operate the device when tired.

These instructions for use must be kept for later reference!

2 Power supply

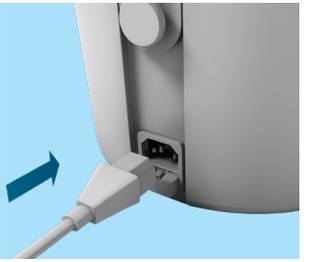
debritom⁺ is a mains-powered device. Before you plug in the device, please check that your local power supply is the same as the voltage given on the specification plate.

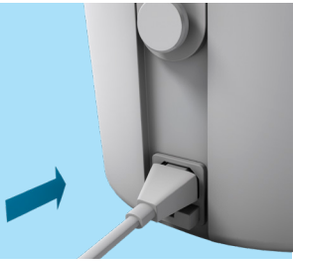
⚠ WARNING

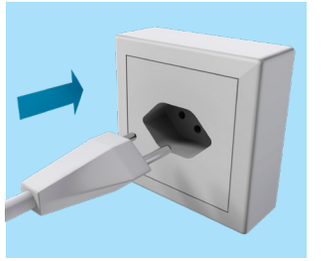
- To avoid the risk of electric shock, this equipment must be connected to a power outlet with protective earth only.
- Do not position the debritom⁺ in a way that it will be difficult to disconnect the power supply.

Plugging in the device

First plug in the power supply cord in the inlet port in the back of the appliance, then into the main outlet.







3 Description

Introduction
debritom⁺ is a high-quality micro water jet debridement device. The compact system controls the fluid pressure to provide a regulated water jet to clean acute and chronic wounds in a precise and tissue-preserving manner. This highly concentrated micro water jet removes wound surfaces such as fibrin, necrosis or biofilm, clears away foreign bodies from acute wounds, and is ideally suited for the effective irrigation of wounds.

This method involves mechanical cleaning and stimulation. During the procedure, a sterile solution – Ringer's solution, NaCl or a solution containing polyhexanide – is sprayed onto the wound surface using precisely controllable pressure. The pressure setting of the device, the distance between the wound and the nozzle, and the gentleness of the wiping motions determine how much of the wound is removed. The practitioner, patient and surrounding area are protected from contamination by a protective tent.

The wound cleansing is continued until all surfaces are removed. Minimal surface bleeding from the wound bed is a desired effect. With these intentionally generated micro bleedings, the practitioner achieves hyperemia, which accelerates the regenerative healing process of the wound during all four phases (exudation, proliferation, reparation, epithelialization). Medicating the patient with anticoagulants is generally unproblematic. Anytime micro water jet debridement is being applied, mircobleeding might occur. However, they are only one of the factors which greatly stimulate and activate the body's own wound healing ability.

debritom⁺ is intended for use on patients in appropriate care settings by a medical professional.
(not for use in homecare environment nor in vehicles)

Intended purpose
debritom⁺ is intended for cleaning, irrigating, and debriding wounds and other diseases of the skin by using micro water jet technology.

Indications
Chronic, badly healing and stalled wounds which, in the clinical judgement of the physician, require a cleaning or debridement procedure.
Acute wounds which, in the clinical judgement of physician, require a cleaning or debridement procedure.
Other disorders of the skin which, in the clinical judgement of the physician, require a cleaning or debridement procedure.

Typical applications for use of debritom⁺
Infected, necrotic, ischemic, contaminated or otherwise poorly healing chronic wounds e.g. originating from the following diseases:
– Ulcers of various causes (venous, arterial, mixed)
– ischemia
– bedsore
– Diabetic foot syndrome
– Abscess and fistulas

Acute wounds, e.g. originating from
– Accidents
– Skin burns
– Operations (wound healing disturbance)

Removal of biofilm

Removal of foreign bodies from wounds, e.g. sand, textile fiber, metallic splinter etc.

Other suitable applications according to the clinical judgement of the physician.

Contraindications
– Malignant tumor types
– Open injury to vessels, unprotected exposed vessels
– Eyes, ears, nose
– Delicate vessels and structures, such as neurovascular bundles
– For complex or highly contaminated wounds
– Patients with HIV, hepatitis C or another contagious disease

Warnings with regard to the use of the device for the following conditions, since they are associated with higher risk:
– Patients with increased tendency to hemorrhage
– Contaminated wounds
If treatment is indicated for the above listed conditions (listed under warnings), this treatment should be done under medical guidance and supervision.

Side-effects
There could be undesirable side-effects such as excessive bleeding or pain. In such cases it's the physician's responsibility to decide whether the debridement procedure shall be continued and under what circumstances (analgesic, intensity level decrease), or if the treatment shall be stopped.

Intended user
The debritom⁺ system is designed for use by qualified health professionals.

Patient population
Any patient is eligible to receive the micro water jet treatment. Nevertheless, there is currently insufficient data supporting the use on pediatric patients.

Important note
Compliance with proper debridement procedures and techniques is the responsibility of the physician/user. Each physician must evaluate the appropriateness of the treatment based on his/her own knowledge

4 Overview debritom⁺ system

debritom⁺, REF 1000.00xx

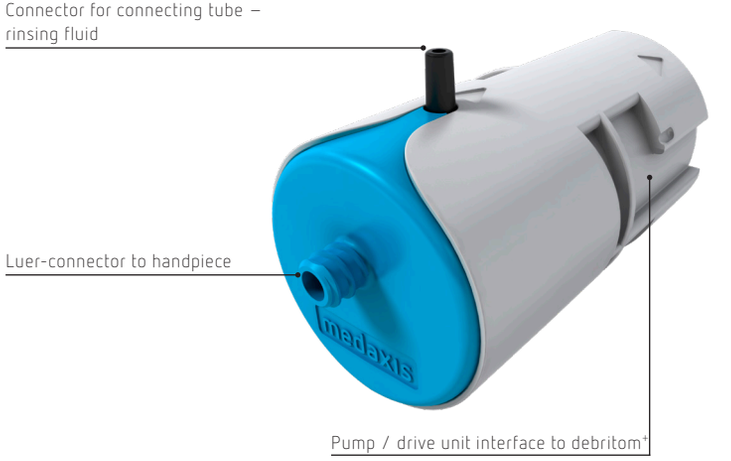
debritom⁺ for recurrent use, for multiple patients

debritom⁺ CH, REF 1000.0001
debritom⁺ EU, REF 1000.0002
debritom⁺ UK, REF 1000.0003
debritom⁺ IT, REF 1000.0004

debritom⁺ contains items according to chapter 6

debritom⁺ pump, REF 2000.020x

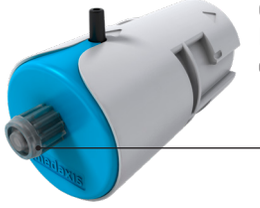
Pump versions depend on duration of use, either replace after application or after one day.



debritom⁺ Pump

REF 2000.0200

single use, sterile



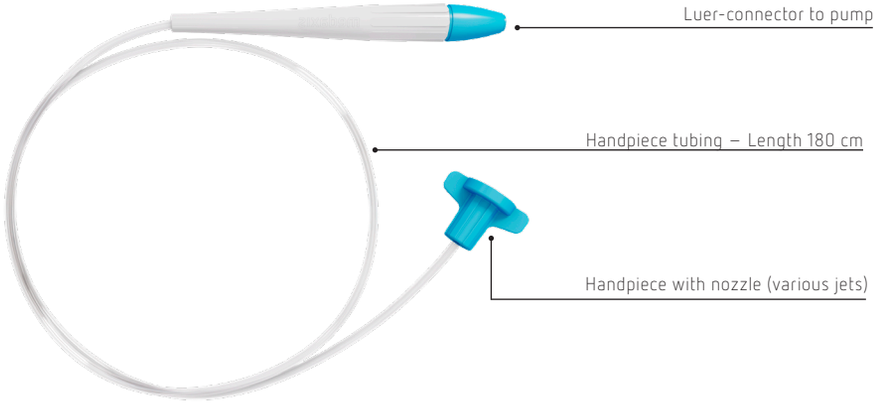
debritom⁺ Pump, one day

REF 2000.0201

one day use, multiple patients, sterile

debritom+ handpiece, REF 2000.000x

Single use, sterile, various jet shapes, details see chapter 7 ‚Optimal working parameters'



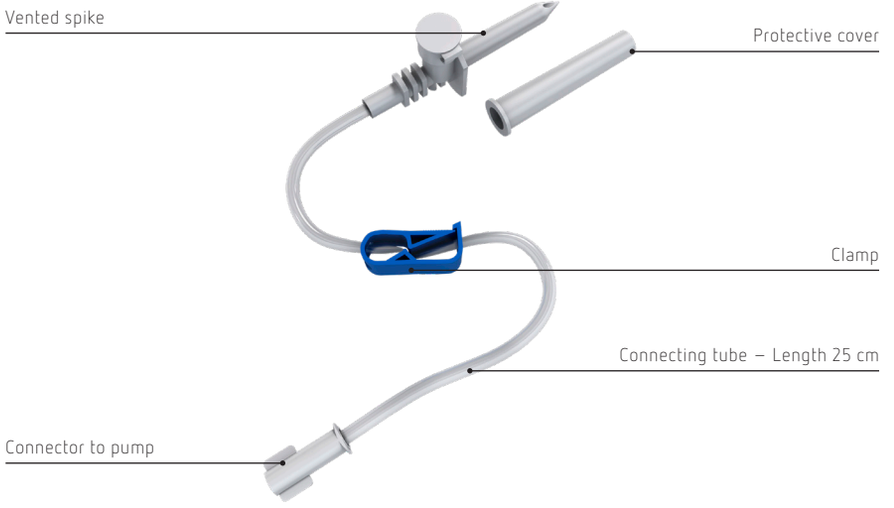
debritom+ handpiece
point jet
REF 2000.0003

debritom+ handpiece
flat jet narrow
REF 2000.0004

debritom+ handpiece
flat jet wide
REF 2000.0005

debritom+ connecting tube, REF 2000.0300

Sterile, details see chapter 8 ‚Replace rinsing fluid'



debritom+ foot on/off switch, REF 2000.5020

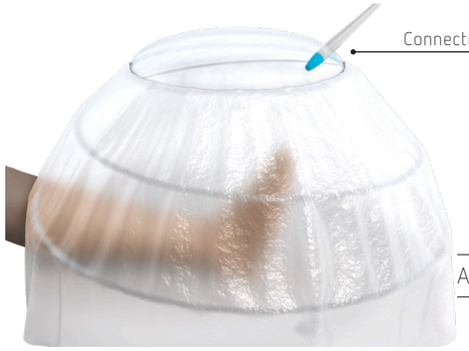
For recurrent use, for multiple patients

debritom+ power cord, REF 2000.50XX

For country-specific power cord see chapter 17

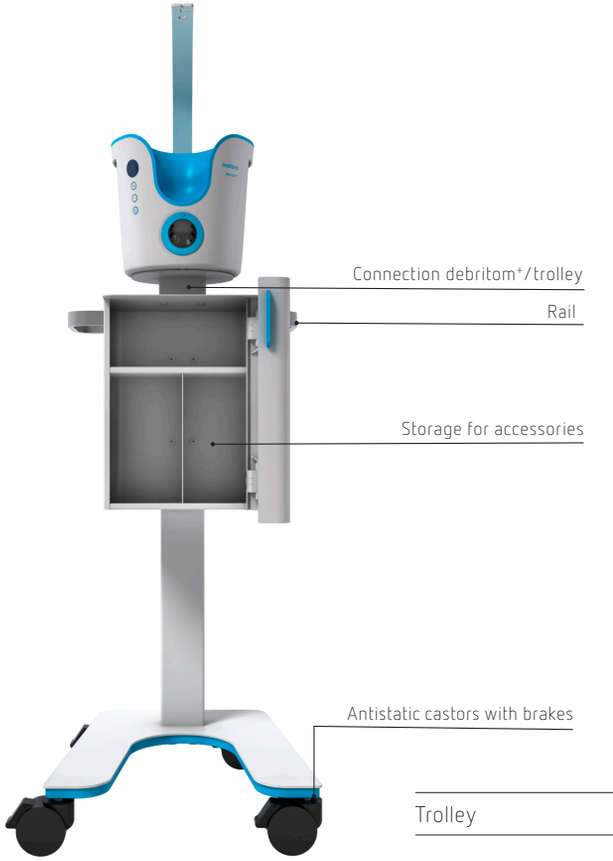
Optional accessories

DebriClip REF 2000.4001



Aeroguard "Jellyfish" REF 2000.2000

Aeroguard "Nebbia" REF 2000.2003



Trolley REF 1000.0500

5 Additional information

Intensity levels/running time

The handpiece and the pump are equipped with an RFID tag. These tags are set according to the connected handpiece, with its corresponding water jet, a preset intensity level at the console. By connecting
the handpiece, the intensity will be set at a standard level per handpiece. To increase the water jet's intensity press ‚+', to decrease the water jet intensity press ‚-'. See corresponding handpiece Instructions for intensity level and working distance.

Additionally, the RFID tags ensure a maximal running time of the pump and handpiece, in order to prevent wear and blockage of the system.

6 Installation

Check initial delivery

Check the delivery package of debritom⁺ for completeness and general condition.

debritom⁺ basic unit

REF 1000.0000

with type label and transportation safety bolt

Pole for rinsing fluid

REF 8000.0001

Knurled head screw for pole

REF 8000.0000

debritom⁺ power cord

REF 2000.50XX

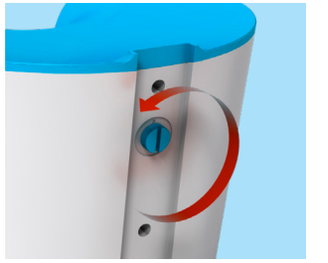
debritom⁺ foot on/off switch

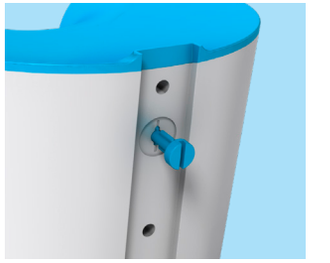
REF 2000.5020

debritom⁺ instruction for use

REF 9000.5503

Initial start up





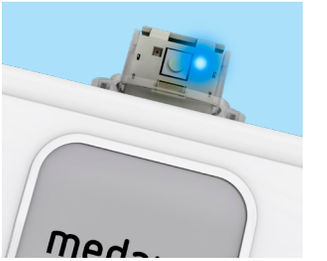
Remove transportation safety bolt

Cover transportation safety hole with sticker

Install pole for rinsing fluid, using the knurled head screw

Activate the foot on/off switch and check whether the blue indicator light flashes.

Please note - Your foot on/off switch that comes with your device is already paired.



7 Preparation for use/operating instructions

⚠ WARNING
- The use of the device should only be carried out by medical/qualified personnel.
- Wear gloves, protective googles and surgical masks for all operations.
- Adapt intensity levels in the case of pain-sensitive patients.

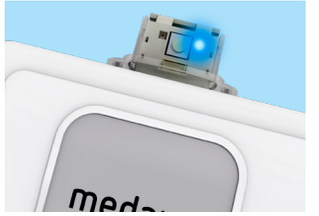
⚠ CAUTIONS
- Wehn the sterile packaging is damaged, do not use contents.
- Sterile products should be opened just before use.
- Non sterile and reusable accessories must be cleaned and disinfected according to chapter 10, 'General Cleaning Guidelines'.

Frequently used functions
- Insert pump
- Insert spike of connection tube into rinsing fluid bottle or bag
- Connect rinsing fluid with pump
- Connect handpiece to pump
- Open clamp and filter port (connection tube)
- Debridement of wound with micro water jet (jet on/off with foot pedal / intensity level / distance and angle of micro water jet to wound)
- Remove handpiece
- Remove pump

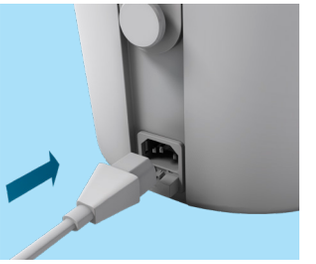
Checks before use

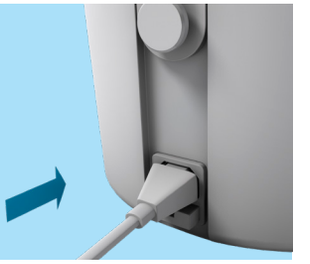
Check the debritom⁺ system before use for damage of the power cord or plug, obvious device damage or safety defects and proper functioning of the device.

- Check that the blue seal for the drive unit is correctly placed.
- Check all accessories prior to use:
  - handpiece, pump and connecting tube for cracks, brittle spots or other damages - replace if necessary.
  - Check whether the blue LED lights up as the foot on/off switch will be activated. If needed replace batteries as shown in chapter 11 – Battery type 2 x LR03 / AAA



Connect debritom⁺ to mains





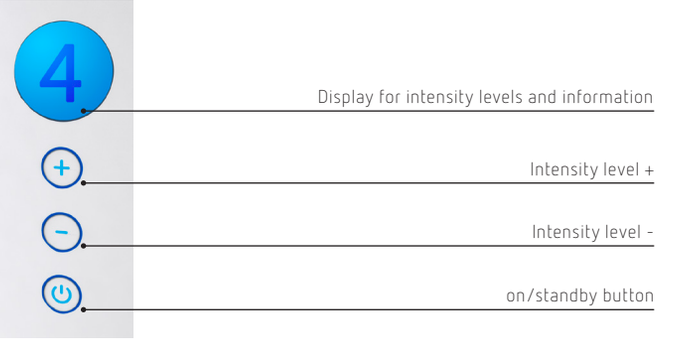
Turn on debritom⁺

General Button Operation
debritom⁺ is a mains-powered device. Before you plug in the device, please check that your local power supply is the same as the voltage given on the specification plate.

- To avoid the risk of electric shock, this equipment must be connected to a power outlet with protective earth only
- Do not position the debritom⁺ in a way that it will be difficult to disconnect the power supply.
- Press any button for a short period of time to turn on the device or to adjust/change intensity settings.
- To switch off the device, press the on/standby button for 3 seconds.
- The on/standby button will also be used to acknowledge any type of error, the button lights up red in the event of error messages. (see chapter 9)

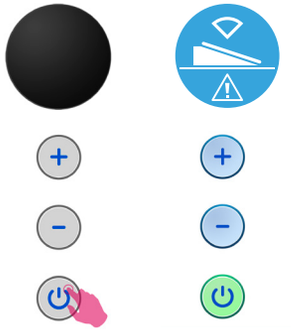
Note: the intensity level of the micro water jet will be chosen automatically depending on type of handpiece (pre-programmed)

debritom⁺ Display



Connecting foot on/off switch with debritom+

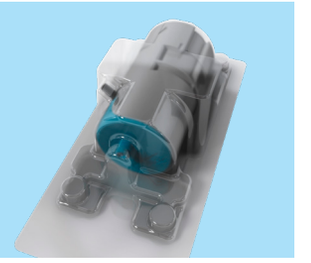
1. Press ⏻ to turn on debritom+.
The device immediately goes into the ‚Connecting mode' for the foot on/off switch



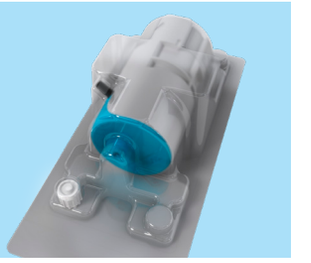
2. Connect the foot on/off switch with debritom+ by pressing the foot on/off switch once. The symbol ‚foot on/off switch connected' is displayed and debritom+ is in standby mode.

If a connection to the foot on/off switch can not be established or a new foot on/off switch is used, this must be paired with the device. (Chapter 11 ‚Pairing foot on/off switch with debritom+')

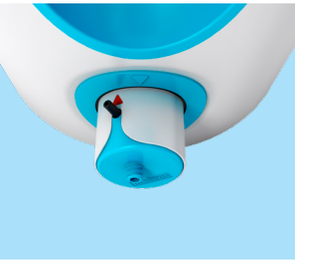
Insert debritom+ pump



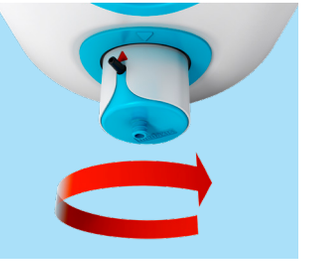
1.a debritom+ pump: Open sterile blister pack and remove the pump.



1.b debritom+ pump, one day:
Open sterile blister pack and remove the pump. Keep the protective cap still in the blister pack. This will be used later as described under. ‘Steps using debritom+ pump, one day REF 2000.0201’



2. Align triangle on pump with triangle on blue ring and insert pump horizontal as shown until it stops.



3. Turn pump clockwise until second triangle is aligned with the triangle on blue seal of drive unit. You will feel a ‚click' as the pump reaches it's final run position.

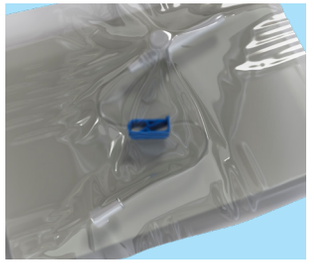
⚠ **CAUTION**
When the pump is not installed correctly, a leakage of the treatment fluid could happen.
In this case do not use the device any more and disconnect it from mains.

Rinsing fluid

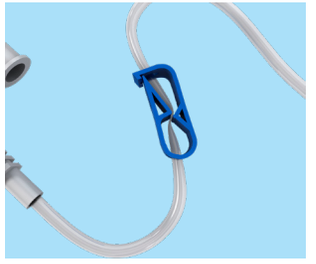
The user decides what type of rinsing fluid should be used to debride. These are generally saline solutions, or fluids containing polyhexanide.
The fluid pole's versatile hanger is designed to attach the most common fluid bottles, (with volumes up to 1000ml), that are equiped with a shackle.
In chapter 17, you will find a list of rinsing fluids that are tested for compatibility with debritom⁺.

NOTE: Approx. 1000ml rinsing fluid is used during 12 minutes of uninterrupted use on the high intensity level.

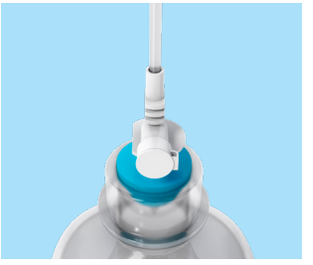
Attach the connecting tube



1. Open sterile pouch.



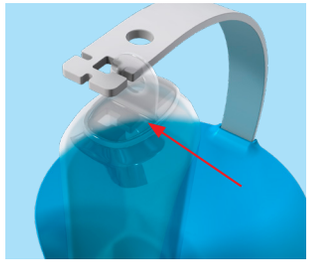
2. Make sure the clamp is in closed position.



3. Push the spike into the rinsing fluid.

4. Open the venting cover.

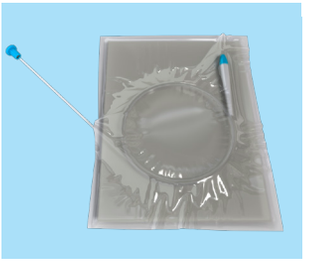
Attach rinsing fluid



Connect the connecting tube with pump

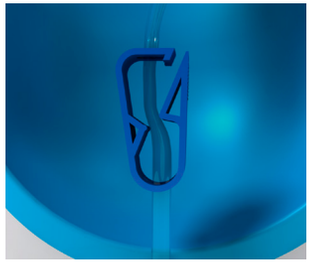
Attach the debritom⁺ handpiece

⚠ WARNING
Use the handpiece solely in combination with debritom⁺ pump and do not re-use (single use).



1. Open sterile pounch. Recommendation: due to hygienic reason, keep the handpiece within the pouch until start of treatment.

2. Attach the luer connection to the pump. Make sure the connection is tightened securely. If leakage is visible, tighten stronger.



3. Open the clamp before start of treatment

Placement of connected handpiece

The opening in the fluid pole serves as a short time parking position for the handpiece during treatment interruptions. Insert the handpiece as shown.

⚠ WARNING
After each patient, the fluid pole, especially the opening for the handpiece, needs to be desinfected thoroughly.

Completely assembled device

Further optional accessories

- Trolley see chapter 17.

- Aeroguard «Jellyfish» separate IFU 9000.5502.

- Aeroguard «Nebbia» separate IFU 9000.5506.

- DebriClip see chapter 27.

Wound treatment with debritom⁺

How it works
As you activate the foot on/off switch, the device starts pumping rinsing fluid through the handpiece onto the patient's wound.

The pressure to generate the micro water jet is being created inside the pump. The rinsing fluid will be pressed through the integrated nozzle within the handpiece, which creates the micro water jet. The regulation of the micro water jet's intensity level is managed by the motor's revolution.

Should the user realize, that the intensity level inadvertently increases, without any handling changes at the device, the foot on/off switch should not be pressed anymore, and the handpiece needs to be brought into a safe position, away from patient and user. The jet can also be interrupted by pressing any button on the debritom⁺ device. Then debritom⁺ needs to be switched off by pressing the on/standby button for 3 seconds. If the user is unable to turn the device off, either the water supply or the electrical power needs to be disconnected.

All fluid conveying parts (handpiece, pump, connecting tube) are sterile and need to be disposed according to facility guidelines. This prevents cross contamination.

⚠ Wound treatment steps

NOTE: Always wear protective gear according to internal guidelines during the treatment. Recommended are gloves, eye wear and surgical masks

1. For chronic and algesic wounds it is recommendable to apply a local anesthetic. (Please follow the instruction of the manufacturer)

2. The patient needs to be in a comfortable position.

3. Put an absorbent cover underneath the wound location and make sure that the rinsing fluid can easily drain from the wound area.

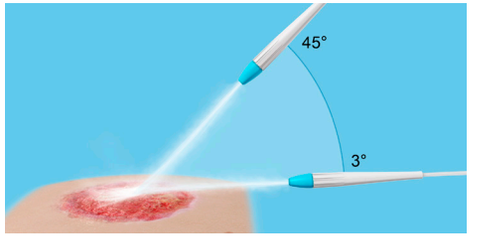
4. Visually assess the micro water jet (correct shape: standard or flat, wide or narrow) as well as the jet's intensity on your palm – distance approx. 20cm.
If ok, move on to 5.
If not ok, replace the handpiece and repeat 4.

5. For a patient that undergoes his/her first debritom⁺ treatment, demonstrate the micro water jet also on his palm with a minimum distance of 20cm. This will increase his confidence into the new debridement treatment.

6. Start the treatment with either the pre-set intensity level for the chosen handpiece, or set your desired intensity level manually.

7. Press the foot on/off switch and start the procedure with the micro water jet tangentially to the wound, nozzle distance at working distance to the wound as prescribed below. Guide the jet starting at the wound edge, and move the jet slightly back and forth.

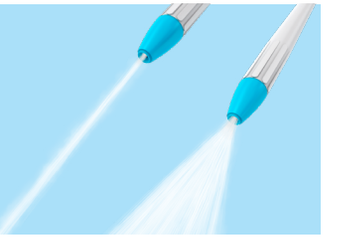
8. The optimal working angle lies between 3 and 45 degrees to the wound surface.



Optimal working parameters

Intensity levels at START of each handpiece : Level 4 (Level 1-5 / weak-strong)

debritom⁺ handpiece point jet Working distance recommended	REF 2000.0003 **15-20cm**
debritom⁺ handpiece flat jet narrow Working distance recommended	REF 2000.0004 **4-10cm**
debritom⁺ handpiece flat jet wide Working distance recommended	REF 2000.0005 **3-8cm**

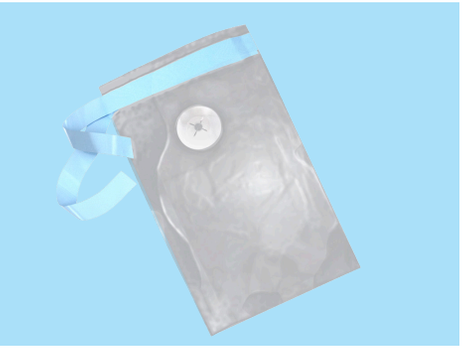


NOTE flat jet: The flat jet should be used like a spatula to the wound. (FIG)

Aerosol containment during wound treatment (optional accessories)

For further protection regarding aerosols. Medaxis recommends to use the AeroGuard Jellyfish as per separate instruction for use. Unfold the AeroGuard and use according to the instructions.

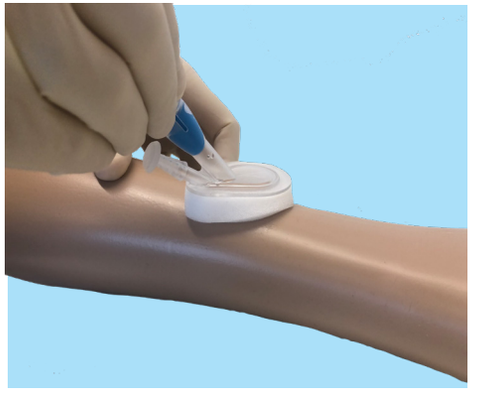
AeroGuard «Nebbia» is best suited for lower legs and arms. Do not use the product for any wounds on a head! This product protects user and patient from aerosols during mechanical wound cleansing/debridement.



The DebriClip is an additional attachment for debritom⁺ handpieces and is used to reduce aerosols and to collect rinsing fluid with debris during mechanical wound cleansing. (Detailed description p. 27)

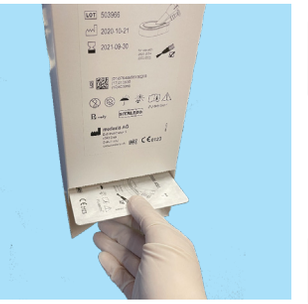
Suitable for use with flat jet (wide and narrow).

for use with:
2000.0004
2000.0005

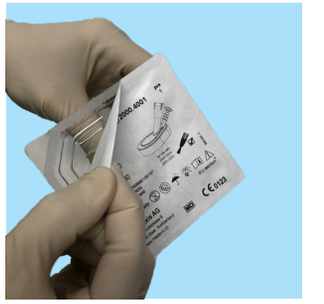


Wound treatment with DebriClip (aerosol insulation with mechanical wound cleansing)

Basis: **debritom⁺ ready for use**

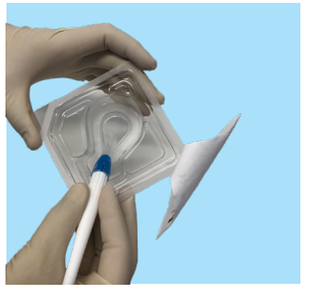


Remove DebriClip from packaging

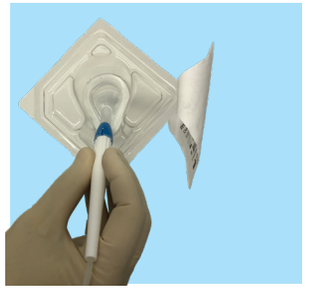


Open sterile package

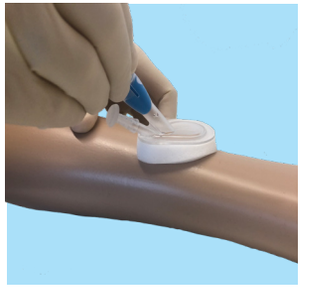
Snap the handpiece into the opening provided



The jet can be aligned by turning the handpiece (like a spatula)



Remove the DebriClip from the packaging with the engaged handpiece

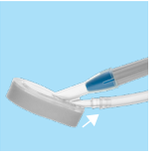


Apply the DebriClip compact to the wound and debride according to IFU 9000.5503.

Additional function

4.1 Suction

Remove plug



Select and connect suitable suction hose

Start the suction system (select and connect a suitable suction system with a free flow rate of 10l/min to 30l/min)

4.2 Mechanical cleaning

Clean the wound and wound edges mechanically with the sponge

⚠ CAUTION!

Not to be used with the point jet REF 2000.0003, since the point jet delivers a stronger and more intense water jet. If used in combination with DebriClip, the jet would be too close to the wound, much closer than the recommended minimum distance according to chapter «Optimal working parameter» (page 27).

Adjustment of water jet intensity

Adjust the Intensity level during the treatment

– Increase the distance between handpiece and wound => intensity level will decrease
– Decrease the distance between handpiece and wound => intensity level will increase

Adjust the intensity level at the device itself

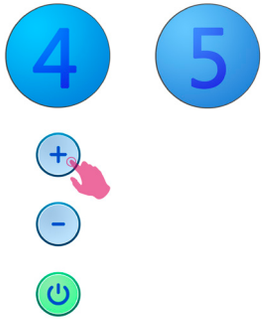
⚠ **CAUTION**

Before adjusting the intensity level, the treatment MUST be temporaily stopped.
Continue with the treatment according to chapter 7 after adjusting the intensity level with +/-.

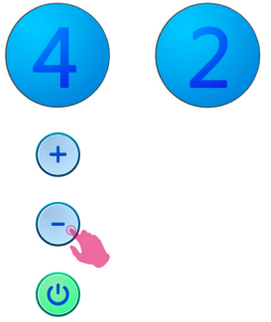
☛ **SAFETY INSTRUCTION**

Use a sterile gauze in order to absorb rinsing fluid.

To increase the water jet's intensity
=> press ‚+'



To decrease the water jet intensity
=> press ‚-'



⚠ **CAUTION**

– Switching off the device is possible at any time by pulling out the power plug.

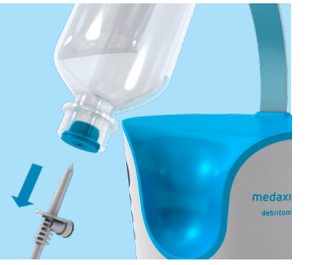
After completion of the debridement procedure
As soon as the debridement procedure is completed, proceed with the following steps:

1. Press the ⏻ for 3 seconds to set the debritom⁺ into standby mode and clamp the connecting tube.

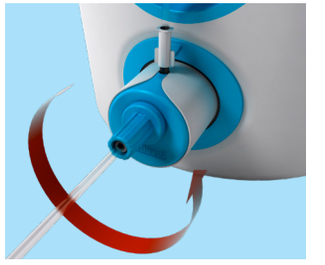
2. Take care of your patient according to your facility's protocol.

Steps after using debritom⁺ pump, single use REF 2000.0200

3a. Remove all single patient use components in following order:
– Remove the spike of the venting tube.



– Rotate the single patient use-pump by 30 degrees counter clockwise and remove from the device. (There is no need to disconnect handpiece and connecting tube from the pump for disposal)



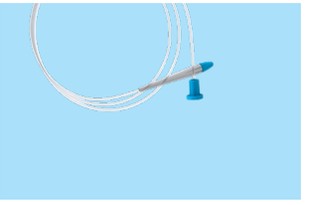
4a. Dispose of the complete unit (pump, handpiece and connecting tube) according to your facility guidelines. Follow the hospital's internal guidelines regarding period of use of the rinsing fluid.

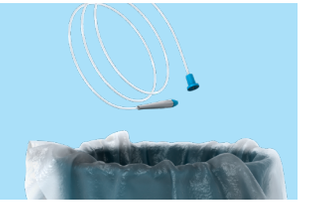
5a. If you are not planning on using debritom⁺ soon again, disconnect the device from mains. (Pull power cord)

Steps after using debritom⁺ pump, one day REF 2000.0201

debritom⁺ pump, one day, can be used for multiple patients within one day. Therefore we recommend to keep all connections to the pump in place (rinsing fluid and connecting tube) until you either replace the pump or the rinsing fluid. If you replace the rinsing fluid, we recommend to also replace the connecting tube.

3b. Clamp connecting tube, then remove handpiece and dispose of it.





4b. Use the protective cap to close the luer connection at the pump. (The cap can be found in the pump's blister package.)

5b. Before attaching the next handpiece, remove the protective cap and store it in a clean place. (Opening downwards)

6. Unclamp connecting tube and start the treatment as described under ‚Wound treatement with debritom⁺'

Repeat steps 3b – 5b until your last treatment of the day. Then proceed with steps 3a – 5a.

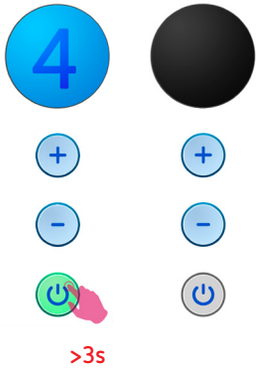
⚠ CAUTION

– Cover the pump's luer connection with the cap immediately after removing the handpiece.

8 Replace rinsing fluid

If you should have to replace the rinsing fluid during a treatment, perform the following steps. Always make sure that the handpiece is being stored within a sterile setting and in a non critical position for patient and user.

1. Press ⏻ for 3 seconds to set the debritom⁺ into standby mode.



2. Prepare the new rinsing fluid bottle in order to keep the time to switching over as short as possible.

3. Remove the spike of the connecting tube from the empty bottle and insert into the new bottle immediately. Make sure that the spike is not soild or contaminated.
Unhook the empty bottle and attach the new one.

⚠ **CAUTION**

– Immediately connect the spike of the connecting tube to the new rinsing fluid bottle.

4. Press ⏻ to turn on debritom⁺, and continue the treatment.

If the foot on/off switch should not be connected anymore, follow the instructions ‚connecting foot on/off switch' in chapter 7.

9 Error messages

NOTE: The on/standby button lights up red as an error message occurs. This button can be used to acknowledge the message.

Battery foot on/off switch almost empty
Troubleshooting: Replace batteries (Battery type 2 x LR03 / AAA, chapter 11)

Pump in use for too long
Troubleshooting: Replace pump.

Handpiece used multiple times or for too long
Troubleshooting: Replace handpiece

Handpiece missing or handpiece not recognized
Troubleshooting: Replace handpiece. If the error can not be resolved, contact the Medaxis service department immediately.

Nozzle blocked or motor overheated
Troubleshooting: Change handpiece and pump if necessary. If the error can not be resolved, contact the Medaxis service department immediately.

Pump not inserted correctly
Troubleshooting: Replace pump and reinsert it correctly, or replace it.

General system error
Troubleshooting: Please contact the Medaxis service department immediately.

No foot on/off switch detected
Troubleshooting: Press the foot on/off switch. If foot on/off switch cannot be detected, replace the batteries (see chapter 11) and operate the foot pedal. If the foot on/off switch is still not detected, repeat the pairing procedure (see chapter 11)

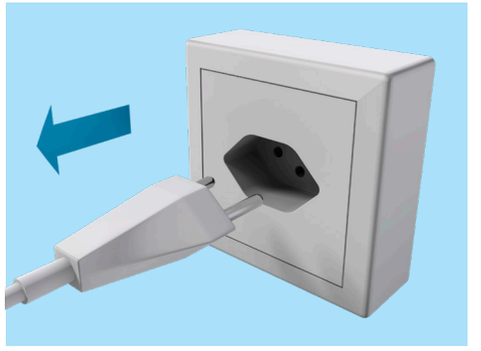
Foot on/off switch time-out
The symbol appears if the foot on/off switch is pressed too slowly or the foot on/off switch is not pressed all the way down.
Troubleshooting: Release the foot on/off switch completely to acknowledge the error. Press the foot pedal all the way down to start the water jet. If the fault cannot be rectified, contact the Medaxis service department immediately.

10 General cleaning guidelines

⚠ WARNING

After each use, the parts that have been in contact with aspirated secretions are to be cleaned and disinfected or disposed.

Before cleaning the device, pull the mains plug out of the fixed mains socket.



☛ Safety instructions

- Never place electrical devices into water or other liquids
- Do not spray or pour liquid directly onto debritom⁺.
- debritom⁺ product range cannot be sterilized.
- Rinsing the debritom⁺ product range in a washing machine is not permitted.
- Immersion disinfection, thermal disinfection and ultrasound cleaning for the debritom⁺ product range are not permitted.
- Higher temperature than 45°C, 113°F can cause protein coagulation which can lead to problems further in the process.
- Clean all surfaces immediately after use to avoid residues from drying and to prevent growth of microorganisms.
- Do not use cleaning agent/detergent based on phenol.
- Do not use steel brushes or steel wool for cleaning.
- Store medical products dry and dust free.

Disposables

⊗ This Symbol indicates a single used product. This product is not intended to be reprocessed. Reuse could result in loss of mechanical and chemical properties and may lead to restriciton in terms of biocompatibility.

Exception – debritom⁺ pump, one day
The debritom⁺ pump, one day, is intended to be used for multiple patients within one day. The sterile package for the pump contains a luer cap, which is intended to cover the luer connection for the handpiece between switching patients.

After one day, the debritom⁺ pump, one day, has to be disposed of and is not intended to be reprocessed.

Reusable parts – debritom⁺, foot on/off switch

1. Thorough cleaning
Thorough cleaning can either be done at the point of use with sterile cold water only or in dedicated health care facilities with the additional use of enzymatic detergents according the manufacturer's instructions for use.

⚠ CAUTION
Make sure that the wiping towel is not too wet, so that it does not drip onto the device.

1.1 Disconnect the power plug from the power socket.
1.2 Disinfect your hands and put on disposable gloves and proper protective gear.
1.3 Separate all individual parts. Dispose of single use products in accordance with internal hospital guidelines.
1.4 Remove visible dirt with lint free nonwoven wipes wetted with sterile cold water (<40 °C, 104 °F)
1.5 Ensure that all surfaces are thoroughly wetted and keep moist for a minimum of 5 minutes, then repeat this step with another wipe.
1.6 Dispose protective gloves and disinfect your hands.

2. Intermediate level disinfection
2.1 Disinfect your hands and put on disposable gloves and proper protective gear.
2.2 Use disinfecting wipes* according the manufacturer's instructions for use.
2.3 Let product work in for 5 minutes and wipe afterwards with another disinfecting wipe*.
2.4 Allow the surface to dry for a minimum of 5 minutes.
2.5 Dispose protective gloves and disinfect your hands.

*Recommended agent for intermediate level disinfection:

CaviWipes®
Metrex® Research
Address: 1717 West Collins Avenue
Orange, CA 92867, USA
Homepage: http://www.metrex.com
Phone: +1 800 841 1428
E-Mail: metrexcustcare@sybrondental.com

Mikrozid® AF Wipes,
Schülke & Mayr GmbH
Address: Robert-Koch-Str. 2,
22851 Norderstedt, DEUTSCHLAND
Homepage: http://www.schuelke.com
Telefon: +49 40 521 00 0
E-Mail: info@schuelke.com

3. Storage
3.1 After appropriate cleaning and disinfecting check the device before re-use.
3.2 Store products dry and dust free under storing conditions

11 Warranty, maintenance and checks

Warranty

Medaxis AG warrants the device will be free from defects in materials and workmanship for a period of 2 years from the date of delivery ex works. Faulty material will be replaced free of charge during this period if not resulting from abuse or misapplication. This will not apply to parts subject to wear and tear in use. To ensure compliance with this warranty as well as optimum service from Medaxis products, we recommend the exclusive use of Medaxis accessories with our appliances.
In no event shall Medaxis AG be liable for claims which exceed the scope of warranty described including liability for consequential damages, etc. The right to the replacement of faulty parts will not be recognized by Medaxis if any work has been carried out on debritom⁺ by unauthorized persons.
This warranty is subject to the appliance being returned to a Medaxis service centre.

Maintenance

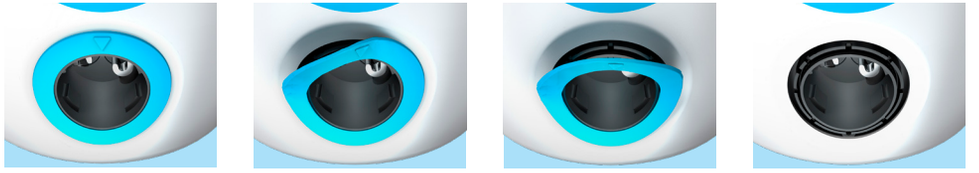
Maintenance according to EN/IEC 62353
Medaxis recommends performing an inspection of the debritom+ once a year. The inspection needs to be carried out according to EN/IEC 62353 and should include the following procedures:

- Visual examination of the device, in particular the silicone sealing ring
- Measurement of grounding conductor according EN/IEC 62353; measure at the metal piece, which will be seen after the pump has been removed (Note – do not measure at the two plungers!)
- Measurement of the insulation resistance according to EN/IEC 62353; the pole for rinsing fluids is an example of an exposed conductive part (measurement should be performed at the threaded part of the knurled head screw).
- Measurement of leakage current according to EN/IEC 62353 is inapplicable. Alternatively, the earth leakage current could be measured according to IEC 60601-1:2005
- Function control: the power consumption should not exceed the value given on the type label – measured with running motor at highest intensity level setting. As you remove the pump during operation (Note: pump could be damaged), there has to be an error message displayed and the device will be shut down immediately.

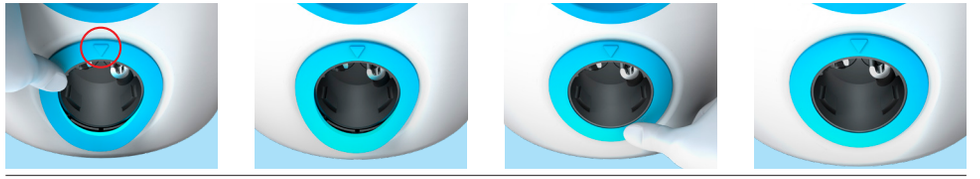
For any test described above, there is no need to open the device.

Examine the complete device on the outside for any cracks in the housing, and replace the silicone sealing ring if you should discover wear and tear or brittleness

Replacement with new silicone sealing ring



Only in case of broken sealing ring

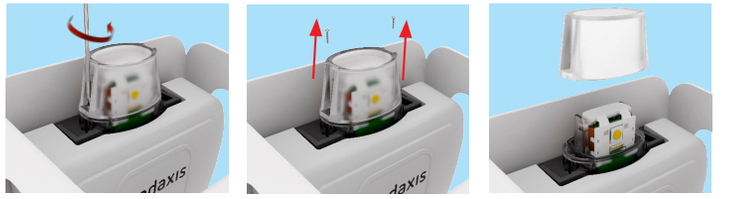


Installation or replacement of battery on the foot on/off switch

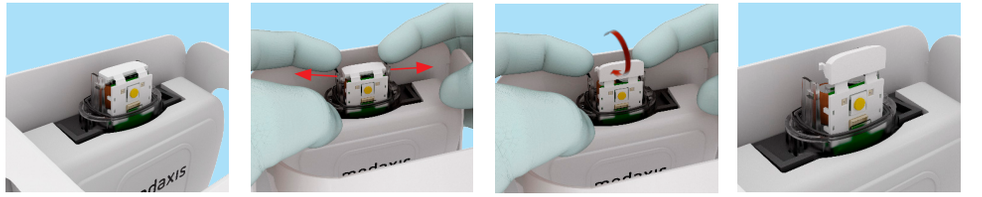
If the foot on/off switch needs a battery installation or replacement, turn on debritom⁺ by pressing the ON button, and follow the instructions below:

1a. Remove protective cover from foot on/off switch as shown (phillips screw driver needed)

1b. Remove protective cover (phillips screw driver needed).

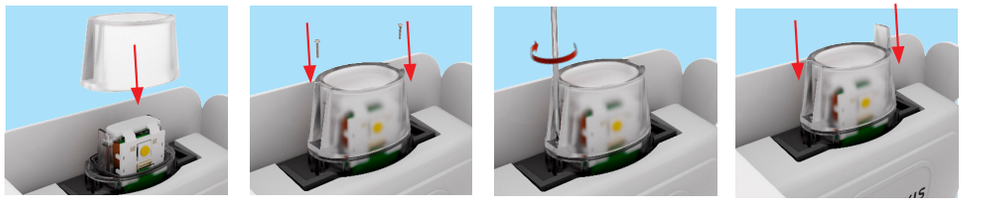


2. Open battery cover: open with both fingers



3. Replace the two batteries, then close the battery case. Check that the LED lights blink blue when the foot on/off switch is pressed.
Attention: do not use lithium or rechargeable batteries!

4. Reassemble the protective cap of the foot on/off switch in reverse order.

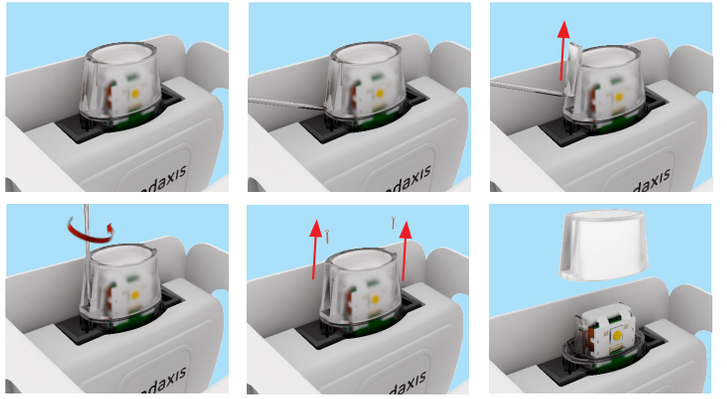


Pairing foot on/off switch with debritom+

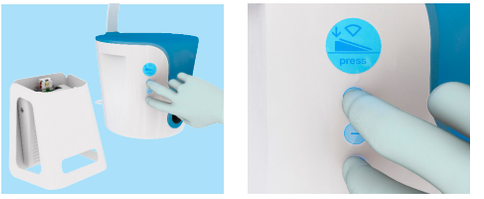
If the foot on/off switch needs to be paired with the debritom+ again, turn on the device by pressing the on/standby button and follow the instructions below:

1a. Remove protective cover from foot on/off switch as shown (phillips screw driver needed)

1b. Remove protective cover (phillips screw driver needed).



2. Simultaneously press the on/standby and, „+" buttons for > 1 second on debritom+.



3. As soon as the symbol 

appears, press the yellow button on the foot switch.

4. As soon as the symbol 

appears,

press the yellow button **within 5 seconds** on the foot on/off switch again to complete the pairing.

5. If the pairing was successful, the following symbol  appears on the display → continue with step 6.
If the pairing was not successful, press the yellow button on the foot on/off switch for more than 7 seconds (existing pairing will be deleted) and repeat steps 2 to 5.

6. Reassemble the protective cap of the foot switch in reverse order.
(see step 4 on page 37)

Safety check

There are no prescribed or recommended safety checks to be carried out.
Each time the device is switched on, a self-test is carried out which checks the internal functions of debritom+.
Due to the device layout and construction design, Medaxis does not expect electrical safety to be affected at any time during the life of the product - provided that debritom+ is e-paired throughout its service life strictly and exclusively by Medaxis authorized service centers and that it is used properly in accordance with the intended use.

The safety instructions must be observed.

12 Disposal

debritom+ comprises metals and plastics and should be disposed of in accordance with the European directives 2002/95/EC and 2002/96/EC. Additional, local guidelines must also be observed. The electronic components must be disposed of separately, in accordance with the local regulations. Please take care that you dispose of debritom+ and its accessories in accordance with the hospital disposal guidelines.

User information for the disposal of electrical and electronic equipment
This symbol means that the electrical and electronic equipment must not be disposed of in as normal household refuse. The correct disposal of this device protects and prevents possible damage to the environment or human health. For more information about disposal, contact the manufacturer, your local caregiver, or healthcare provider.
This symbol is only valid in the European Union. Please respect the relevant state laws and rules in your country for the disposal of electrical and electronic equipment.

13 Accessories

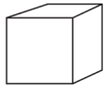
⚠ WARNINGS

debritom+ was validated in combination with the accessories listed in Chapter 17. For correct and safe operation use debritom+ with these accessories only. Further information is supplied with the individual accessory.

14 Technical Specifications

5.3kg / 11.7lbs

[VAC] 100 – 240
[Hz] 50/60
[VA] 200



HxWxD
44x25x24cm
18x10x10**"**


Transport / Storage
Humidity 15 – 93%
Temperature 5 – 40°C / 41 – 104°F


Operation
Humidity 15 – 93%
Temperature 5 – 37°C / 41 – 98°F

Fuse: Schurter AG, P/N: 0001.2512, SPT 5 x 20 mm, T 6.3AH, 250 VAC

Operation below 2000 m (to sea level)

Classification according to 60601-1
– Medical equipment class I, external power supply
– Continuous operation
– Protection class IP20
– The Handpiece is an applied part type B, as a possible conductive water jet will touch the patient

Required accessories


Storage
Humidity 15 – 93%
Temperature 5 – 35°C / 41 – 95°F

15 Signs and symbols

CE 0123 This symbol indicates the compliance with the essential requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

This symbol indicates that the product or company has successfully met stringent standards for product safety.

UDI This symbol is used to mark and identify medical devices within the healthcare supply chain.

§ This symbol indicates the legal specifications of the system.

This symbol indicates to follow instructions for use.

This symbol indicates to consult instructions for use.

This symbol indicates a CAUTION associated with the device.

This symbol indicates a safty related tip.

This symbol indicates a Warning.

IP20 This symbol indicates the protection against ingress of solid foreign objects and against harmful effects due to the ingress of water.

This symbol indicates a single use device. Do not reuse the device.

This symbol indicates MR UNSAFE

This symbol indicates that interferences may occur in the vicinity of equipment marked with this symbol.

This symbol indicates the manufacturer.

This symbol indicates the date of manufacture (four digits for the date).

This symbol indicates that the device should not be used after the end of the date shown.

This symbol indicates do not use the device if package is damaged.

℞ only This symbol indicates a prescription device. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. (for US only).

debritom⁺ handpiece point jet

debritom⁺ handpiece flat jet narrow

debritom⁺ handpiece flat jet wide

MD Indicates the item is a medical device.

REF This symbol indicates a manufacturer's catalogue number.

SN This symbol indicates a manufacturer's serial number.

LOT This symbol indicates a manufacturer's batch code.

STERILE EO This symbol indicates the device is sterilized using ethylene oxide.

HIBC HIBC is a direct code-decode system for the UDI.

°C This symbol indicates the temperature limitation for operation, transport and storage.

This symbol indicates the humidity limitation for operation, transport and storage.

5 This symbol indicates the number of pieces per package.

This symbol indicates to not dispose of the device together with unsorted municipal waste (for EU only).

This symbol indicates that the material is part of a recovery/recycling process.

This symbol indicates a carton package.

This symbol indicates to keep the device away from sunlight.

This symbol indicates a medical device that must not be re-sterilized.

This symbol indicates that the product is not sterile.

This symbol indicates to handle the fragile device with care.

This symbol indicates to keep the device dry.

This symbol indicates the electrical specifications of the system.

This symbol indicates alternating current.

This symbol indicates the weight of the system.

This symbol indicates sterile barrier / sterile packaging.

This symbol indicates the dimensions (H x W x D) of the debritom+ basic unit.

pcs This symbol indicates the number of items.

This symbol indicates the device does not contain latex.

This symbol indicates a type B applied part.

EC REP EU representative

This symbol shows sterile barrier system / sterile packaging wrapped in a non-sterile protective packaging.

UK REP UK representative

Symbols on debritom+ display

Symbols for the error messages are described in chapter 9 ‚Error messages'

Search for Bluetooth device for pairing
Pressing the on/standby and ‚+' buttons for > 1 s at debritom+ will show the ‚Search for Bluetooth device' symbol for pairing a new or replacement of the foot on/off switch.

Bluetooth signal of foot on/off switch detected - confirm
As soon as debritom+ has detected the Bluetooth signal of the foot on/off switch, this symbol appears on the display.

debritom+ connected with foot on/off switch
This symbol appears on the display as the foot on/off switch is connected to debritom+.

Intensity levels
The intensity levels can be adjusted between 1 - 5. (1 weakest/5 strongest)

16 Technical Documentation

EMC

debritom+ is EMC-tested in conformity with the requirements of IEC 60601-1-2:2014 and can be used in the vicinity of other EMC-tested devices that fulfill the requirements of the relevant IEC 60601-1-2 standard. Untested HF (high-frequency) sources, radio networks or the like can influence the operation of the device and may not be operated in combination with the system. Debritom+ is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the attached EMC information. Portable and mobile RF communication devices (mobile telephones) can affect debritom+.
The debritom+ system is suitable for use in hospital environments, except for near active HF surgical equipment and except for RF shielded room of a magnetic resonance imaging system.
The debritom+ does not provide any Essential Performance according to 60601-1. The EMC immunity was tested in the "Ready to run" operating mode, the main focus of the immunity testing was to avoid an unintended start of the water jet.

The following precautions should be taken to prevent adverse events to the patient and operator due to electromagnetic disturbances:

- Mains power quality should be that of a typical commercial and/or hospital environment.
- Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 10 %.
- Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

⚠ WARNING
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within this user manual are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

⚠ WARNING
Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Debritom+ System, including cables specified by the manufacturer. Otherwise, degradation of equipment performance could result.

To maintain basic safety and essential performance in regards to EMC no service is necessary.

The debritom+ System was tested according to IEC 60601-1-2:2014 with the following limits:

Emissions Test	Compliance
RF emissions CISPR 11	Group 1 Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies

Immunity Test	Test Level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0% U_T for 250 cycles
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz – 2.7GHz 80% AM at 1 kHZ Proximity fields from RF wireless communications equipment: 385 MHz 27 V/m 450 MHz 28 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 9 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 28 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz 9 V/m
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V in ISM Bands

RF Transmitter/Receiver used in the equipment
Bluetooth 4.0 (single mode/Bluetooth smart): max RFoutput power 3.2mW 2.402-2.480 GHz, ISM band. RFID 13.56MHz, phase jitter modulation, max. Power: 200mW

Service:
Requirements for service personnel: The service personnel must be trained by Medaxis AG in order to service the debritom+ and its accessories.
Medaxis AG will make available, on request, circuit diagrams, component part lists, descriptions, calibration instructions, or other information for Medaxis authorized service centers.

17 Required and optional accessories

Required accessories

Pumps

debritom+ pump	REF 2000.0200
debritom+ pump, one day (contains pump and luer cap)	REF 2000.0201

Handpiece

debritom+ handpiece point jet	REF 2000.0003
debritom+ handpiece flat jet narrow	REF 2000.0004
debritom+ handpiece flat jet wide	REF 2000.0005

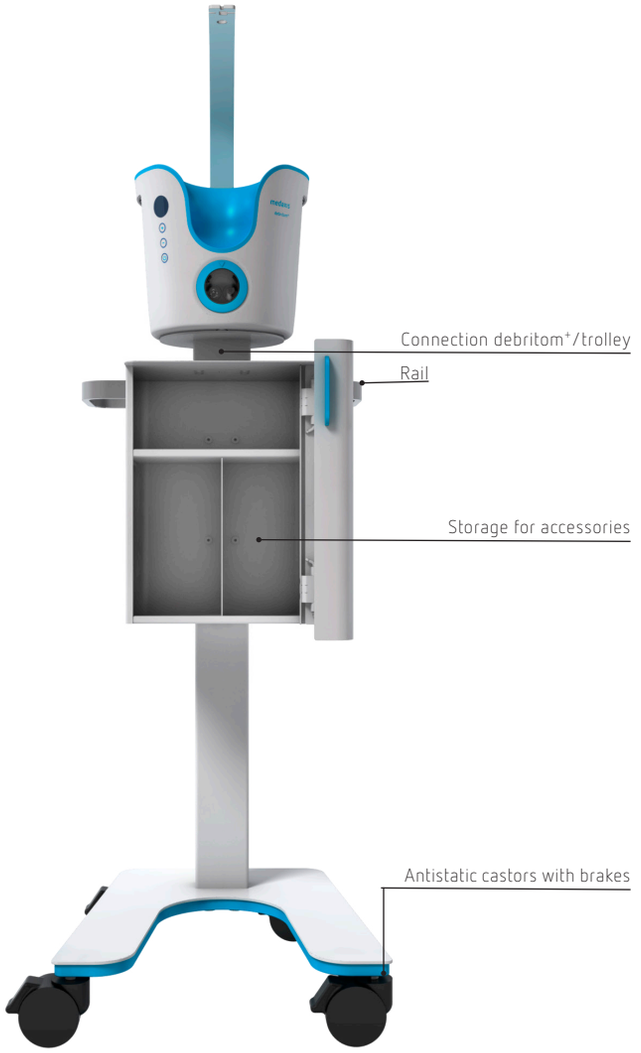
Connecting tube

debritom+ connecting tube	REF 2000.0300

Optional accessories

AeroGuard ‚Jellyfish'	REF 2000.2000
DebriClip	REF 2000.4001
AeroGuard ‚Nebbia'	REF 2000.2003
Trolley	REF 1000.0500

Trolley 1000.0500



To install debritom+, follow the steps below

Tool for attaching: hex wrench 6mm

Spare parts

debritom+ power cord (CH)	L= 2.5m	REF 2000.5003
debritom+ power cord (EU)*	L= 2.5m	REF 2000.5001
debritom+ power cord (UK)	L= 5 m	REF 2000.5007
debritom+ power cord (IT)	L= 2.5m	REF 2000.5004

*Plug CEE 7/7

Knurled head screw for pole rinsing fluid	REF 8000.0000
Pole for rinsing fluid	REF 8000.0001
Seal drive unit	REF 8000.0002
Transportation safety bolt	REF 8000.0005
Foot on/off switch	REF 2000.5020

Rinsing fluid

The debritom+ system was validated with the rinsing fluids listed below: NaCl 0.9% and ringer solution.

There have been other rinsing fluids tested – please do not hesitate to contact us for further information.

Other rinsing fluids, antimicrobial fluids, disinfecting agents can be used as per prescription by a medical professional.

Should any questions regarding the use of other fluids arise, please contact the manufacturer of the rinsing solution.

☛ SAFETY INSTRUCTION

Medaxis' purpose of testing a variety of rinsing fluids is to make sure that these fluids work properly with debritom+ to not cause any harm to the system.

In order to make sure the fluids you intend to use do not cause any harm to the patient, you must contact the manufacturer of the rinsing fluid.

The manufacturer of the rinsing fluid must be contacted for questions regarding medical application.

The debritom+ system was tested with bottles and bags up to 1000 ml.

medaxis

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CE 0123

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