medaxis

Instructions for use

Microjet Wound Therapy

swiss medical technology

Instructions for use EN

Microjet Wound Therapy

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Congratulations!

Medaxis AG
Bahnhofstrasse 9
6430 Baar
Switzerland

With the Microjet Wound Therapy System, you have acquired a high-quality and innovative solution that sets new standards in wound therapy. It features an electronic control display with visual status indicators. Most components that come into contact with rinsing fluids are single-use and must be disposed of after use in accordance with your internal guidelines. Its compact size ensures high flexibility and portable application, while its extremely quiet operation allows the user to focus on the wound and the patient for efficient and safe wound therapy treatment. The comprehensive range of accessories provides medical professionals with a versatile toolbox to meet their individual needs.

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.

The Microjet Wound Therapy System is approved exclusively for the use as described in these instructions for use. Medaxis can only guarantee the safe functioning of the system when it is used in combination with the original accessories. The Microjet Wound Therapy System is EMC-tested in conformity with the requirements of IEC 60601-1-2 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.

In case of a serious incident in combination with the Microjet Wound Therapy System, 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 Microjet Wound Therapy System if it is used in accordance with the Instructions for use.

⚠ WARNING

- These instructions for use must be read prior to the use of Microjet Wound Therapy System.
- 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 medically, qualified personnel.
- Before cleaning the device, you must disconnect from the power supply.
- The Microjet Wound Therapy System was validated in combination with the accessories listed in this instruction for use. For a correct and safe operation, use the Microjet Wound Therapy System with these accessories only.
- Do not use the Microjet Wound Therapy System in MR environment.
- The device is not suitable for use in a hazardous explosive environment.
- The use of the Microjet Wound Therapy System 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 other then stated in the accessories list in this instruction for use is not allowed.
- When treating infants, make sure a second medical professional is holding the body to be treated securely in place in order to prevent sudden movement.
- Adults must be asked to keep the body to be treated securely in place.
- Not for use at home or in vehicles.
- While using the device, pull brakes of castors.
- Do not use the device as moving aid.

⚠ CAUTION

- The intensity level to be set must be determined by a physician according to the patient‘s wound.
- Before connecting the Microjet Wound Therapy System to the power supply, please verify that the supply voltage corresponds to that given on the type label.
- Incorrect use of the device can cause pain and injury to the patient.
- Do not use sterile accessories when the sterile packaging is damaged.
- Non sterile and reusable accessories must be cleaned and disinfected.
- The device can be switched off at any time by pulling out the mains plug.

☛ SAFETY INSTRUCTION

- The Microjet Wound Therapy System is a medical device that requires specific safety measures regarding to EMC. It must be installed and put into operation in accordance with the attached EMC information in this instruction for use.
- Portable and mobile RF communications equipment can affect medical devices.
- In each of the following cases, the Microjet Wound Therapy System 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.
- The device has no user serviceable parts inside (open device with cover removed). For safety reasons, it is required that the device is repaired throughout its service life strictly and exclusively by Medaxis authorized service centers.
- 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 the Microjet Wound Therapy System 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 restriction 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 Description

2.1 Introduction

Microjet Wound Therapy System is a medical device with high precision microjet technology. The compact system produces a fine microjet to clean acute and chronic wounds in a precise and tissue-preserving manner. This highly concentrated and versatile microjet has multiple settings, for all applications such as the gentle removal of foreign bodies via washing, irrigation, jet lavage and pulsed lavage, for the removal of biofilm, necrotic and fibrotic tissue, and to generate micro bleeding on the treated tissue.

Using a sterile washing or debridement solution, a hand piece and pressure setting on the device are chosen to deliver the Microjet Wound Therapy of choice. The gentleness of the wiping motions, the angle and the distance to the wound allow further refinement of the degree of wound irrigation or wound therapy applied. The practitioner, patient and surrounding area can be protected from contamination by a protective cover.

The Microjet Wound Therapy (MWT) continues until the desired degree of irrigation or wound therapy is achieved. Upon completion of the Microjet Wound Therapy, the gentle removal of foreign bodies, biofilm, necrotic and fibrotic tissue, and/or the creation of bleeding tissue, leaves the wound optimally prepared for healing. Any time, the Microjet Wound Therapy System is being applied, microbleeding might occur as a direct outcome.

The Microjet Wound Therapy System is intended for use on patients in professional care settings by a medical professional (not for use in homecare environment nor in vehicles).

2.2 Intended purpose

The Microjet Wound Therapy System is intended for jet lavage, cleaning, irrigating, and debriding wounds and other diseases of the skin through the use of micro water jet technology.

2.3 Indications

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

Typical applications for use of microjet wound therapy

Infected, necrotic, ischemic, contaminated or other poorly healing chronic wounds that, by example, may originate from the following diseases:

- Ulcers of various origin (venous, arterial, mixed)
- Ischemia
- Bedsores
- Diabetic foot syndrome
- Abscesses and fistulas

Acute wounds that, by example, may originate from the following

- Accidents
- Bruns
- Surgery

Removal of biofilm, removal of foreign bodies from wounds, e.g. sand, textile fiber, metallic or wooden splinters, creation of microbleeing.

2.4 Contraindications

- Malignant tumor types
- Open injury to blood vessels and unprotected blood vessels
- Eyes, ears, nose
- Delicate vessels and structures, such as neurovascular bundles
- Patients with HIV, hepatitis C and other contagious diseases

A warning regarding the use of the device for the following conditions, since they are associated with higher risk. If treatment is indicated for the following conditions, they should only be performed under medical guidance and supervision:

- Patients with increased tendency to hemorrhage and arterial ulcers
- Infected wounds

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 shall be continued and under what circumstances (analgesic, intensity level decrease), or if the treatment shall be stopped.

2.5 Intended user

The Microjet Wound Therapy System is designed for use by qualified healthcare professionals.

Patient population

Any patient is eligible to receive the Microjet Wound Therapy. Nevertheless, there is currently insufficient data supporting the use on pediatric patients.

2.6 Important note

Compliance with the proper irrigation and wound therapy procedures and techniques remains the responsibility of the physician. Each physician must evaluate the appropriateness of the treatment based upon their own knowledge and experience.

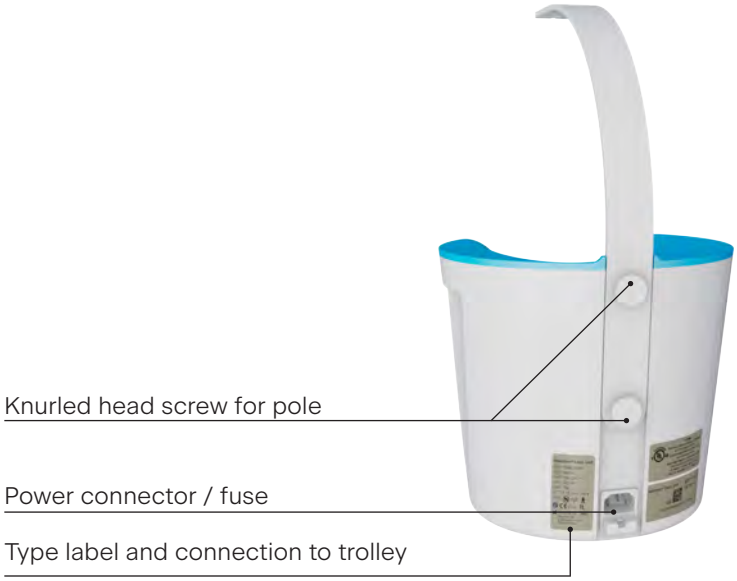
3 Overview

3.1 Microjet Wound Therapy System

The Microjet Wound Therapy System consists of several accessories. Some of the accessories are optional.

debritom+, REF 1000.0005

Microjet for recurrent use, for multiple patients



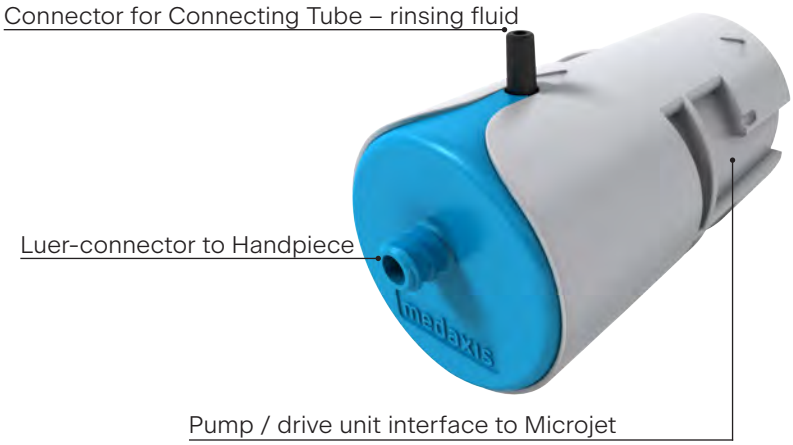
debritom+ foot on/off switch, REF 2000.5030

For recurrent use, for multiple patients

Power cord, REF 2000.5008

Design of cable depends on country version

Pump, REF 2000.020x
Pumps are responsible for the pressure generation. The pump has been designed as a two piston mechanism. It is a disposable device. Usage duration depends on the pump version, either replace after one application or after one day.

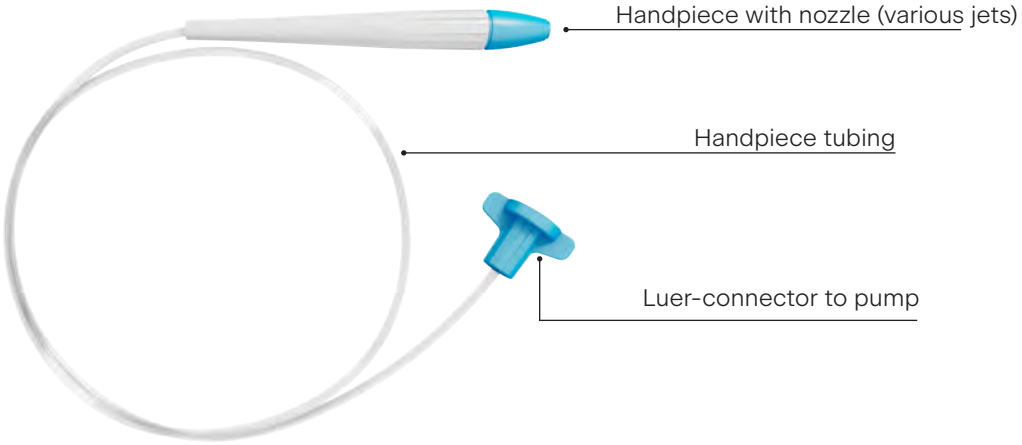


debritom⁺ pump, REF 2000.0200
single use, sterile
Runtime: 20 min
Lifetime: 120 min

debritom⁺ pump, one day, REF 2000.0201
one day use, multiple patients, sterile
Runtime: 100 min
Lifetime: 24 h

Handpiece, REF 2000.000x

There are two different handpieces. The operator has to dispose of the handpiece after the usage on one patient. It is directly threaded to the pump with a luer connector. The Microjet can detect the type of handpiece through an RFIDtag, in addition this tag controls the life- and working time of the handpiece. The handpieces are single-use and sterile. Details see chapter 6.3, Optimal working parameter'.

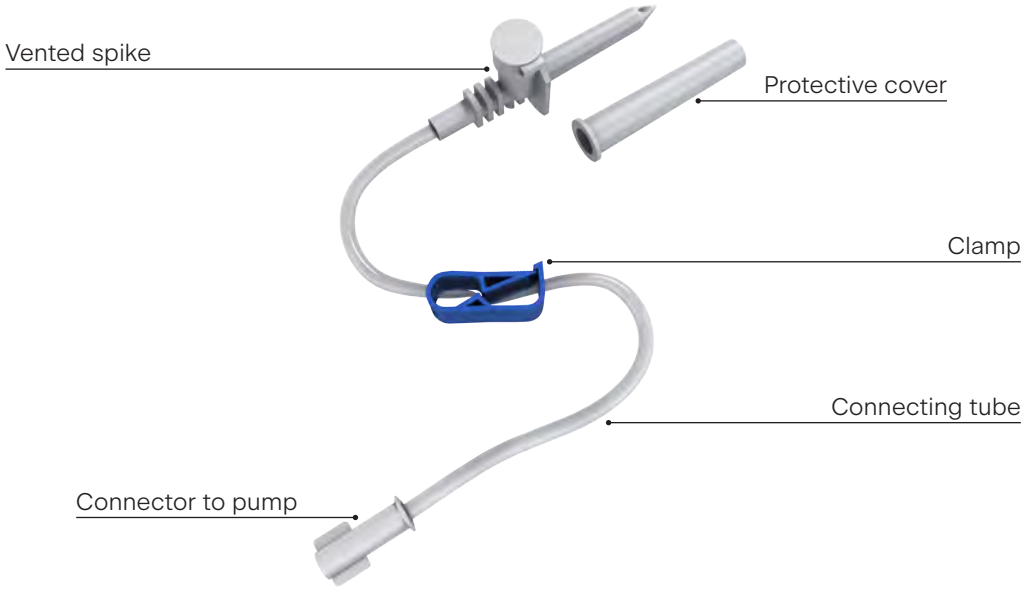


debritom⁺ handpiece point jet
REF 2000.0003
single use, sterile
Runtime: 20 min
Lifetime: 120 min

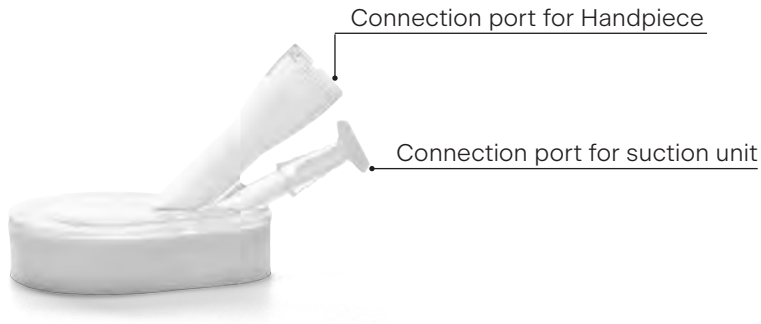
debritom⁺ handpiece flat jet narrow
REF 2000.0004
single use, sterile
Runtime: 20 min
Lifetime: 120 min

debritom⁺ connecting tube, REF 2000.0301

Connecting tube is used to connect the pump with rinsing fluid container. The product is provided sterile.



3.2 Optional accessories



DebriClip is an additional attachment to **Handpiece flat jet narrow** (only) for reducing aerosols and collecting irrigation fluid with debris during mechanical wound cleansing.

DebriClip	REF 2000.4001

To protect patient and user from aerosoles that might originate during mechanical wound treatment.

Aeroguard Jellyfish	REF 2000.2000

Containment of aerosol spread in use with medical devices.

Aeroguard Nebbia	REF 2000.2003

Trolley	REF 1000.0500

⚠ WARNINGS

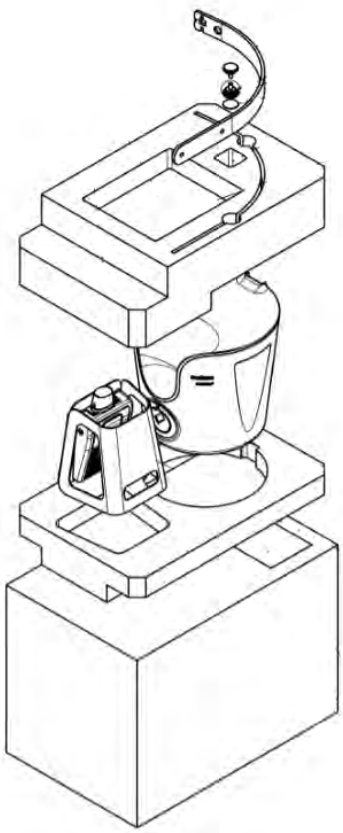
The Microjet Wound Therapy System was validated in combination with the accessories listed in this instruction for use. For correct and safe operation, use Microjet Wound Therapy System with these accessories only. Further information is supplied with the individual accessory.

4 Installation

4.1 Microjet

4.1.1 Check initial delivery

Check the delivery package of Microjet for completeness and general condition.



debritom⁺ basic unit REF 1000.0000
with type label and transportation safety bolt

Microjet Wound Therapy instructions for use
REF 9000.5514

Fluidpole
REF 8000.0001

Knurled head screws for pole
REF 8000.0000

Transportation safety bolt
REF 8000.0005
(part of debritom⁺ basic unit)

Power cord
REF 2000.5008

debritom⁺ foot on/off switch
REF 2000.5030

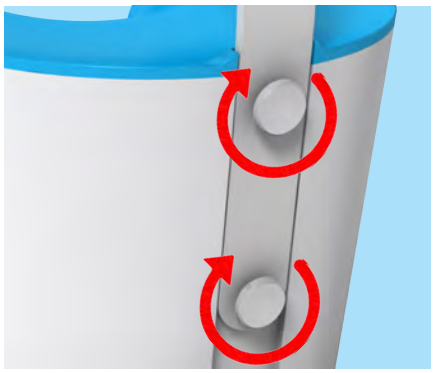
Cover pad
REF 8000.0013

4.1.2 Installation Microjet

1. Remove the Fluidpole together with the Knurled head screws for pole and Power cord from the cardboard box.
2. Remove the device and Foot on/off switch from the cardboard box.

1. Remove Transportation safety bolt.

2. Cover transportation safety hole with Cover pad.

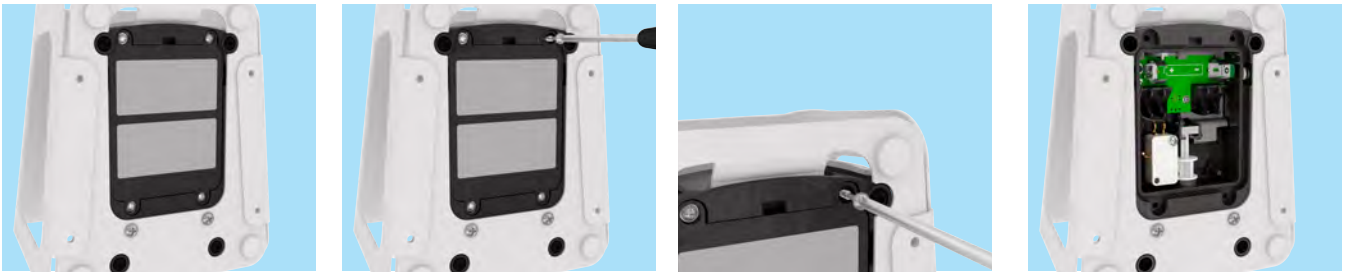


3. Install Fluidpole, using the Knurled head screw for pole.

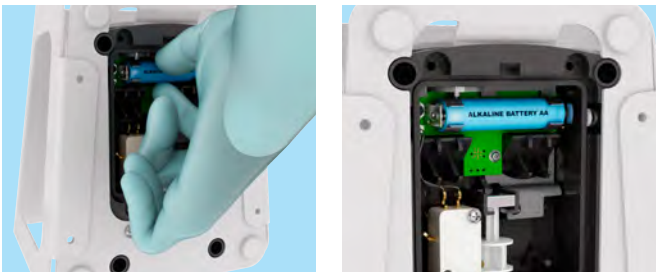
4.1.3 Initial set-up of Foot on/off switch

The Foot on/off switch is delivered without a battery installed.

1. Remove battery cover from Foot on/off switch as shown by removing all 4 screw (Phillips screw driver needed) and remove the battery lid.



2. Replace the battery (Alkaline, AA), then close the battery cover. Attention: do not use lithium or rechargeable batteries!

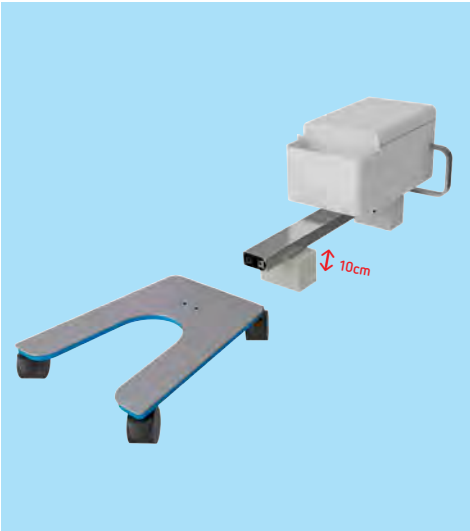


3. Reassemble the battery cover of the Foot on/off switch in reverse order.

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

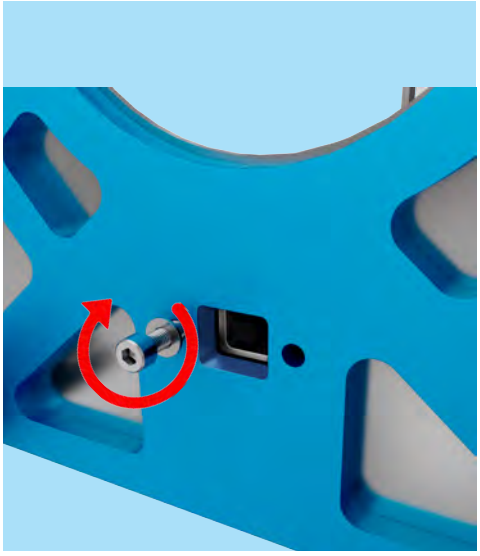
4.2.3 Initial set up Trolley

Assemble Base plate with the Pole compartment unit:



1. Place Pole compartment approx. 10cm above floor.

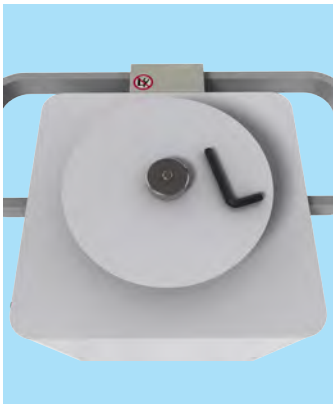
2. Lift Base plate and align borings to bottom part of pole.



3. Attach and tighten corresponding screws with delivered washers underneath, tighten securely with allen key 6mm; activate brakes on all castors to turn the Trolley upright.

4.2.4 Assemble Microjet with Trolley

1. Connection for Microjet and Trolley.

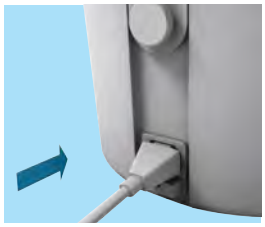


2. Get the allen key 6mm ready for tightening.

3. Place the Microjet on to connection of the Trolley.

4. Lift and tighten the screw with the allen key 6mm.

5. Fully tighten the screw.



Connect the Power cord to the Microjet.

5 Preparation for use/operating instructions

5.1 for Microjet Wound Therapy System

⚠WARNING

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

⚠CAUTIONS

- When 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 this instruction for use.

5.1.1 Checks before use

- Check the Microjet Wound Therapy 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 of the Microjet 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 orange LED lights up as the Foot on/off switch will be activated. In case the orange LED lights up and is blinking, replacement of the battery is required (see chapter 9.3 - Battery type 1x LR6 / AA). If the orange LED lights up constantly, please contact Medaxis.

5.1.2 Insert Pump

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

As soon as the pump is plugged in and the device is connected to the power supply, the lifetime of the pump decreases.

Open sterile blister pack and remove the pump.

Align triangle on the end of the pump with triangle on blue ring and insert pump horizontally as shown until it stops. (Note: Apply more pressure if resistance increases)

Turn pump clockwise until second triangle is aligned with the triangle on blue seal ring on Microjet.
You will feel a "click" as the pump reaches its final run position.

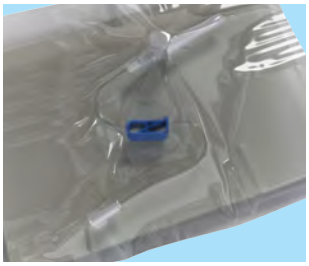
5.1.3 Rinsing fluid

The user decides what type of rinsing fluid should be used for the treatment. These are generally saline solutions or other fluids used to treat wounds. The fluid pole's versatile hanger is designed to attach the most common fluid bottles, (with volumes up to 1000ml), that are equipped with a shackle.

The Microjet Wound Therapy 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 Medaxis 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.

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

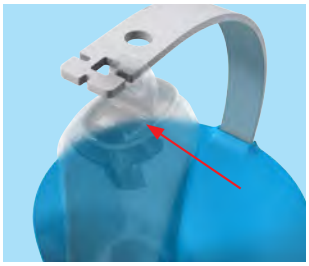


1. Open sterile pouch.

2. Make sure the clamp is in closed position.

3. Push the spike into the rinsing fluid container.

4. Open the venting cover.



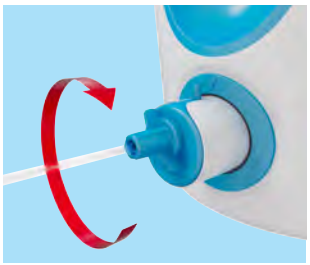
5. Attach rinsing fluid to the fluidpole.

6. Attach connecting tube to the pump.

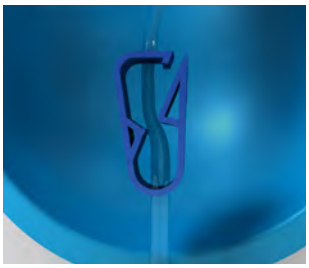
5.1.5 Attach the Handpiece

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

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

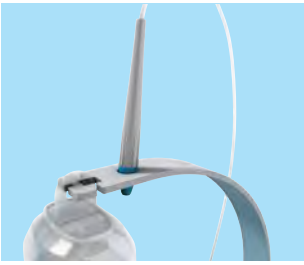


2. Attach the luer connection to the pump. Make sure the connection is tightened securely. If leakage is visible, tighten stronger.



3. Open the clamp of the connecting tube before start of treatment.

5.1.6 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 disinfected thoroughly.

Completely assembled device

5.1.7 Connect Microjet to mains

Turn on Microjet

General Button Operation
The Microjet Wound Therapy System 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 device label.

- To avoid the risk of electric shock, this equipment must be connected to a power outlet with protective earth only
- Do not position the Microjet Wound Therapy System 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, to recognize as the button lights up red in the event of error messages.

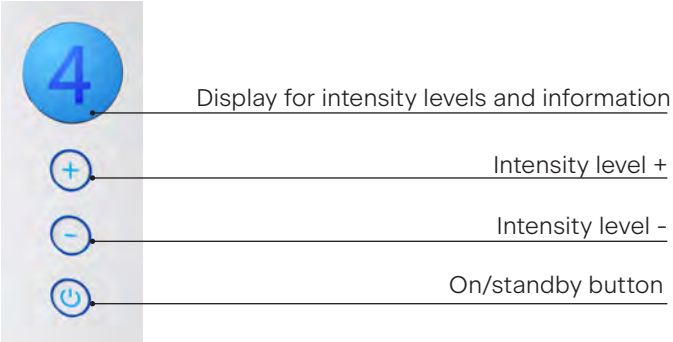
Note: The intensity level of the Microjet Wound Therapy System will be chosen automatically depending on type of handpiece (pre-programmed)

Connecting On/off switch with Microjet Wound Therapy System

a) Press ⏻ to turn on Microjet Wound Therapy System.
The device immediately goes into the ‚Connecting mode' for the Foot on/off switch.

b) Connect the Foot on/off switch with Microjet by pressing the Foot on/off switch once. The symbol ‚foot on/off switch connected' is displayed within 1 minute and Microjet is in standby mode. If a connection to the Foot on/off switch cannot be established or a new Foot on/off switch is used, this must be paired with the device (see Chapter 9.4).

Microjet display



6 Wound treatment with Microjet Wound Therapy System

6.1 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 microjet is being created inside the pump. The rinsing fluid will be pressed through the integrated nozzle within the handpiece, which forms the microjet.

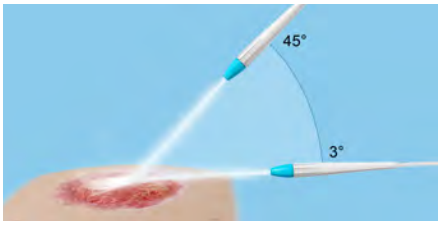
Should the user realize, that the intensity level inadvertently increases, without any handling changes at the device, the Foot on/off switch should not be pressed anymore, and the handpiece needs to be brought into a safe position, away from patient and user. The Microjet Wound Therapy System can also be interrupted by pressing any button on the Microjet. Then Microjet 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 fluid 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.

6.2 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 microjet (correct shape: point jet or flat jet narrow) as well as the jets 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 Microjet Wound Therapy System treatment, demonstrate the microjet also on his/her palm with a minimum distance of 20cm. This might 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 microjet tangentially to the wound, nozzle distance at working distance to the wound as prescribed below. Guide the microjet starting at the wound edge, and move the microjet slightly back and forth.
8. The optimal working angle lies between 3 and 45 degrees to the wound surface.

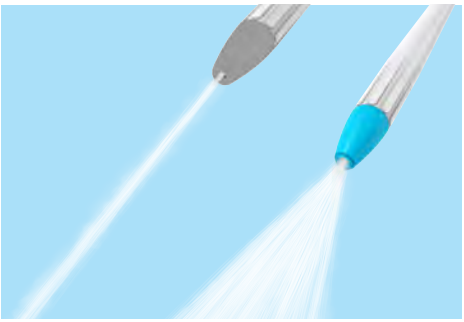


6.3 Optimal working parameters

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

debritom⁺ handpiece point jet REF 2000.0003
Working distance recommended **15-20cm**

debritom⁺ handpiece flat jet narrow REF 2000.0004
Working distance recommended **4-10cm**



NOTE: The Handpiece flat jet narrow should be used like a spatula to the wound.

Intensity levels/running time

The handpiece and the pump are equipped with an RFID tag. These tags set according to the connected handpiece, with its corresponding microjet, 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 microjet's intensity press ‚+', to decrease the microjet 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.

6.4 Aerosol containment during wound treatment (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 the Handpiece flat jet narrow and is used to reduce aerosols and to collect rinsing fluid with debris during mechanical wound cleansing if connected with suction pump.