

6.5 Wound treatment with DebrisClip

Basis: **Microjet Wound Therapy System ready for use**



1. Remove DebrisClip from packaging.



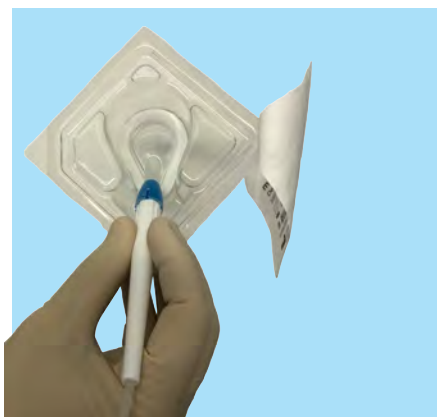
2. Open sterile package.



3. Snap the Handpiece into the opening provided.



4. The microjet can be aligned by turning the Handpiece (like a spatula).



5. Remove the DebrisClip from the packaging with the engaged handpiece.



6. Apply the DebrisClip compact to the wound and treat according chapter 6.4.

⚠ CAUTION

DebrisClip is only suitable for use with debritom⁺ handpiece flat jet narrow (REF 2000.0004). Not to be used with the debritom⁺ handpiece point jet (REF 2000.0003), since it delivers a stronger and more intense microjet. If used in combination with DebrisClip, the microjet would be too close to the wound, much closer than the recommended minimum distance.

for use with:
2000.0004



6.5.1 Mechanical cleaning



Clean the wound and wound edges mechanically with the sponge.

⚠ CAUTION

Not to be used with the debritom⁺ handpiece point jet (REF 2000.0003), since the Handpiece point jet delivers a stronger and more intense microjet. If used in combination with DebrisClip, the jet would be too close to the wound, much closer than the recommended minimum distance.

6.5.2 Adjustment of microjet 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 temporally stopped.

Continue with the treatment according to this instruction for use after adjusting the intensity level with +/-.

👉 SAFETY INSTRUCTION

Use a sterile gauze in order to absorb rinsing fluid.

To increase the microjet intensity
=> press ,+'



To decrease the microjet intensity
=> press ,-'



⚠ CAUTION

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

6.5.3 Replace rinsing fluid container

If you should have to replace the rinsing fluid container 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 Microjet 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 soiled 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 Microjet, and continue the treatment.

6.6 After completion of the treatment procedure

As soon as the treatment procedure is completed, proceed with the following steps:

1. Press the  for 3 seconds to set the Microjet 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, REF 2000.0200

3a. Remove all single patient use components in following order:

- Close the clip.
- Remove the rinsing fluid container
- Remove the spile of the venting tube



- Rotate the 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 connecting tube and, if applied, DebrisClip) according to your facility guidelines. Follow the hospital's internal guidelines regarding period of use of the rinsing fluid.



Steps after using debritom⁺ pump, one day REF 2000.0201

The 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 from pump one day and dispose it together with DebrisClip if applied.



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 in this instruction for use.

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.

7 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 1 x LR6 / AA, chapter 9.3).



Pump in use for too long
Troubleshooting: Replace pump.



Handpiece in use 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 9.3) and operate the Foot on/off switch. If the Foot on/off switch is still not detected, repeat the pairing procedure (see chapter 9.4)



Foot on/off switch time-out
General error of Foot on/off switch
Troubleshooting: Please contact the Medaxis service department immediately

8 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.



8.1 Safety instructions

- Never place electrical devices into water or other liquids
- Do not spray or pour liquid directly onto Microjet – Microjet Wound Therapy System product range cannot be sterilized.
- Rinsing the Microjet Wound Therapy System product range in a washing machine is not permitted.
- Immersion disinfection, thermal disinfection and ultrasound cleaning for the Microjet Wound Therapy System 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.

8.2 Disposable parts – Handpiece, Pump, DebrisClip, Connecting Tube

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

Exception – Pump, one day

The 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 Pump, one day, must be disposed of and is not intended to be reprocessed.

The Microjet Wound Therapy System comprises metals and plastics and should be disposed of in accordance with local guidelines. The electronic components must be disposed of separately, in accordance with the local regulations. Please take care that you dispose of the Microjet 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.

8.3 Reusable parts – Microjet, Trolley, 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 to 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 to 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®	Mikrozid® AF Wipes,
Metrex® Research	Schülke & Mayr GmbH
Address: 1717 West Collins Avenue	Address: Robert-Koch-Str. 2,
Orange, CA 92867, USA	22851 Norderstedt, DEUTSCHLAND
Homepage: http://www.metrex.com	Homepage: http://www.schuelke.com
Phone: +1 800 841 1428	Telefon: +49 40 521 00 0
E-Mail: metrexcustcare@sybrondental.com	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

9 Warranty, maintenance and checks

9.1 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 Microjet Wound Therapy System by unauthorized persons. This warranty is subject to the appliance being returned to Medaxis.

9.2 Maintenance

Maintenance according to EN/IEC 62353

Medaxis recommends performing an inspection of the Microjet Wound Therapy System 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.

9.3 Installation or replacement of battery on the Foot on/off switch

If the Foot on/off switch needs a battery installation or replacement follow the instructions below:

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.



9.4 Pairing Foot on/off switch with Microjet

If the Foot on/off switch needs to be paired with the Microjet again, turn on the Microjet by pressing the on/standby button and follow the instructions below:

1. Simultaneously press the on/standby and, „+“ buttons for > 1 second on Microjet.



2. As soon as the symbol  appears, press down the footswitch once.



3. If the pairing was successful, the following symbol  appears on the display within 30 sec.

If the pairing was not successful, repeat steps 1 and 2.

In case the pairing is not possible, replace the battery according Chapter 9.3 and repeat the pairing. If the pairing is still not possible, contact Medaxis.



9.5 Symbols on Microjet display

Symbols for the error messages are described in Chapter 7 in this instruction for use.



Search for Bluetooth device for pairing

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



Microjet connected with Foot on/off switch

This symbol appears on the display as the Foot on/off switch is connected to Microjet.



Intensity levels

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

Safety check

There are no assigned 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 the Microjet. 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 the Microjet Wound Therapy System is repaired 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 instruction for use must be observed.

9.6 Information about Cybersecurity

When using the Microjet Wound Therapy System, the following needs to be considered to minimize the potential risk of security attacks during use:

- Do not use third party devices with Microjet Wound Therapy System
- Do not leave Microjet Wound Therapy System unattended during use

No specific software updates or patches are required as part of the device's routine maintenance.

Any suspected cybersecurity incident, unusual device behavior, or potential security breach must be reported to Medaxis immediately.

In case of cybersecurity incidents, software updates may be performed as part of field safety corrective actions:

- The user is requested to comply at its earliest convenience with the field safety corrective actions communicated by Medaxis
- All device corrective actions will be addressed by Medaxis AG personnel
- Users are not responsible for managing security software updates themselves

This products contains software components including both open-source and proprietary software. A Software Bill of Materials (SBOM) , available in a machine-readable format, provides a complete list of these components to enable customers to track potential security vulnerabilities and understand their software's origin.

Contact Medaxis AG to request the SBOM in a machine-readable format.

10 Technical Specifications

	Microjet	Trolley
Weight	5.3kg/11.7lbs	37.2kg/82lbs
VAC	100 – 240 V	n/a
Hz	50/60 Hz	n/a
VA	200 VA	n/a
Transport/Storage	Humidity 15 to 93% Temperature 5 to 40°C / 41 to 104°F	Humidity 15 to 93% Temperature -25 to 50°C / 13 to 122° F
Operation	Humidity 15 to 93% Temperature 5 to 37°C / 41 to 98°F	Humidity 15 to 93% Temperature 5 to 37°C / 41 to 98°F
Operation	44x25x24 cm / 18x10x10"	92x37x44 cm / 36x15x18"

Fuse Microjet: 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 electric equipment class I
- Continuous operation
- Protection class IP20
- The Handpiece is an applied part type B as a possible conductive water jet will touch the patient

11 Signs and symbols

	This symbol indicates compliance with the EU requirements concerning medical devices		This symbol identifies a type B applied part complying with IEC 60601-1
	This symbol indicates a carrier that contains unique device identifier information		This symbol indicates a medical device that has been sterilized using ethylene oxide
	This symbol indicates to follow instructions for use		This symbol indicates a medical device that has not been subjected to a sterilization process
	This symbol indicates the need for the user to consult the instructions for use		This symbol indicates the medical device is MR Unsafe and should be kept away from magnetic resonance (MR) imaging equipment
	This symbol indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences		This symbol indicates that interferences may occur in the vicinity of equipment marked with this symbol
	This symbol indicates a safety related tip		This symbol indicates the medical device manufacturer
	This symbol indicates a Warning		This symbol indicates the date when the medical device was manufactured
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 that the device should not be used after the end of the date shown
	This symbol indicates separate collection for electrical and electronic equipment		This symbol indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	This symbol indicates a medical device that needs protection from light sources		Handpiece point jet
	This symbol indicates the manufacturer's catalogue number so that the medical device can be identified		Handpiece flat jet narrow
	This symbol indicates the manufacturer's serial number so that a specific medical device can be identified		This symbol indicates the item is a medical device
	This symbol indicates the manufacturer's batch code so that the batch or lot can be identified		This symbol indicates a medical device that can be broken or damaged if not handled carefully
	This symbol indicates the authorized representative in UK		This symbol indicates a medical device that needs to be protected from moisture
	Indicates the Swiss Authorised Representative to meet the requirements of Medical Devices Ordinance 812.213 Article 51		This symbol indicates that the equipment is suitable for alternating current only
	This symbol indicates the authorized representative in the European Community / European Union		Mass and safe working load of the complete microjet wound therapy system is below 47 kg/104 lbs
			This symbol indicates the temperature limits to which the medical device can be safely exposed
	This symbol indicates a medical device that is not to be re-sterilized		This symbol indicates the device does not contain latex
	This symbol indicates a single use device. Do not reuse the device		This symbol shows sterile barrier system / sterile packaging
pcs	This symbol indicates the number of items		This symbol show sterile barrier system / sterile packaging wrapped in a non-sterile protective packaging
	This symbol indicates the number of items		This symbol indicates the entity distributing the medical device into the locale
	This symbol indicates the range of humidity to which the medical device can be safely exposed		

12 Technical Documentation

EMC

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 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.

Microjet Wound Therapy System 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 Microjet Wound Therapy System.

The Microjet Wound Therapy 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 Microjet Wound Therapy System 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 microjet.

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 Microjet Wound Therapy 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 Microjet 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 61000-4-4	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 interrup- tions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle 0% UT for 1 cycle 70% UT for 25 cycles 0% UT 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 6.0 (single mode/Bluetooth smart): max RF output 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 Microjet Wound Therapy System 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.

The lifetime of Microjet is 5 years.

FCC

This device contains a BLE radio module certified under FCC ID: XPYNORAB12.

The host device has been evaluated for compliance with FCC Part 15 Subpart B under the Supplier's Declaration of Conformity (SDoC) procedure.

- Trade name: debritom⁺
- Model number: 1000.000
- Responsible Party:
Medaxis LLC
1101 Corporate Drive McHenry,
IL 60050, United States
www.medaxis.com
+1 877 735 1626
- US-Agent:
Americas Compliance Consulting LLC, dba iCertifi
5809 US-2, Suite B, Albeni Plaza, Priest River
Idaho 83856, United States

FCC Part 15 Class-B

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference.
- (2) This device must accept any interference, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Modification Statement

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Spare parts

debritom ⁺ power cord (US)	L= 5 m	REF 2000.5008
Knurled head screw for pole		REF 8000.0000
Fluidpole		REF 8000.0001
Seal Drive Unit		REF 8000.0002
Transportation safety bolt		REF 8000.0005
Cover pad		REF 8000.0013
debritom ⁺ foot on/off switch		REF 2000.5030

SAFETY INSTRUCTION

Medaxis' purpose of testing a variety of rinsing fluids is to make sure that these fluids work properly with Microjet Wound Therapy System 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 Microjet Wound Therapy System was tested with bottles and bags up to 1000 ml.



Manufactured by:
Medaxis AG, Bahnhofstrasse 9, 6340 Baar, Switzerland,
info@medaxis.ch, T +41 62 823 88 00
www.medaxis.com

Distributed by:
Medaxis LLC, 1101 Corporate Drive McHenry, IL 60050,
www.medaxis.com

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