
INSTRUCTION FOR USE (IFU)

Flushing- and extraction systems

A. DEVICE DESCRIPTION

Meise GmbH Flushing- and extraction systems can consist of the following tube sets or combinations of the following tube sets. For specific part numbers, refer to the manual for the pump used in the procedure:

Inflow Tube Sets: Inflow tube sets provide irrigation to the sterile field

ReDeuce™ tubing: ReDeuce tube sets are two-piece inflow tube sets which include a pump side tubing and patient side tubing. Patient side tubing must be replaced after every procedure

Outflow Tube Sets: Outflow tube sets provide two suction lines labeled Cannula (Blue) and Shaver (Clear) and a waste tubing labeled Waste (Red)

Y-Tubing: Y-Tubing allow up to four irrigation fluid bags to be attached to the inflow tubing

Extension Tubing: Extension tubing allows single use inflow tube sets to be used for an entire surgical day or can be used for extra tubing length

NOTE: All Meise GmbH Flushing- and extraction systems is latex free

B. WARNINGS

1. Caution: Federal law restricts this device to sale by or on the order of a physician
2. This device is intended to be used by a trained medical professional
3. Detailed instructions on the use and limitations of this device should be given to the patient
4. Biohazard waste, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy
5. Serious incidents should be reported to Meise GmbH Inc., or an in-country representative, and to the health authority where the incident occurred

C. PACKAGING AND LABELING

1. Meise GmbH devices should be accepted only if the factory packaging and labeling arrive intact
2. Contact Customer Service if the package has been opened or altered

D. STERILIZATION AND REUSE

1. This device is provided sterile. Check the package labeling for more information. This device should never be re-sterilized under any conditions
2. Single use inflow tubing can be used for an entire operating day when used with extension tubing
3. ReDeuce pump side tubing can be used for an entire surgical day when used with ReDeuce patient side tubing
4. Y-Tubing can be used for an entire surgical day when used with extension tubing or ReDeuce tubing, as described above
5. All other tubing is single (patient) use

E. STORAGE CONDITIONS

Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date

F. INFORMATION

1. In CE Accepting Countries: Procedures carried out using these devices may be used on the general population
2. In CE Accepting Countries: The clinical benefits associated with the use of these devices outweigh the known clinical risks
3. In CE Accepting Countries: There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices

G. PRECAUTION

1. Meise GmbH tubing systems do not contain phthalates, which are classified as Category 1 or Category 2 carcinogenic, genotoxic, and toxic substances under Annex I of Directive 67/548/EEC
2. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Meise GmbH provides detailed surgical techniques in print, video, and electronic formats. The Meise GmbH website also provides detailed surgical technique information and demonstrations. Or, contact your Meise GmbH representative for an onsite demonstration

H. DIRECTIONS FOR USE

WARNING: USING FLUID TO DISTEND ANY JOINT CARRIES WITH IT THE POSSIBILITY OF FLUID EXTRAVASATION INTO SURROUNDING TISSUE.

Always use the lowest possible pressure settings to achieve the desired amount of distension and control of bleeding

WARNING: PROPER OPERATION OF THIS DEVICE REQUIRES THE ESTABLISHMENT OF ADEQUATE FLUID OUTFLOW AND MONITORING OF THE SURGICAL FIELD.

At pressures exceeding 10 mmHg above the patient's diastolic pressure, carefully monitor and maintain fluid outflow and assess the patient regularly to avoid extravasation or any other adverse patient condition

1. Prepare the pump per the Operator's Manual
2. Prepare the arthroscope or the cannula for use with the tubing set

I. INFLOW TUBING OR REDEUCE PUMP SIDE TUBING:

1. Using sterile technique, carefully remove the tubing set from the package and pass it onto the sterile Field
2. Close all clamps, check the integrity of the remaining connections, and transfer the bag spikes out of the sterile field
3. Remove the orange clip and connect the pressure sensor line on top of the drip chamber to the front panel receptacle until an audible "click" is heard. Ensure that the drip chamber hangs in a vertical position
4. Using the green connector on the tubing set and the green indicator on the pump roller housing as references, wrap the tubing boot (the larger diameter, more flexible section of the tubing set) around

the pump rollers in a clockwise manner NOTE: Avoid twisting the tubing boot as it is wrapped around the rollers. Center tubing on the rollers before closing the cover NOTE: When only one bag of liquid is to be connected, the unused bag spike must remain clamped CAUTION: Do not disconnect the sensor line unless the tubing set is to be discarded. The pressure sensor calibration may become inaccurate if reconnected. If the sensor line becomes disconnected for any reason, discard the tubing set

II. INFLOW TUBING WITH EXTENSION TUBING:

1. Using sterile technique, carefully remove the Extension Tubing from the package and pass it onto the sterile field
2. Connect the Extension Tubing to the Inflow Tubing at the luer lock
3. Open All Clamps

III. REDEUCE PATIENT SIDE TUBING:

1. Using sterile technique, carefully remove the Patient Side Tubing from the package and pass it onto the sterile field
2. Connect the Patient Side Tubing to the Pump Side Tubing at the large-bore, shielded connectors
3. Open all Clamps

IV. ALL TUBING:

1. Activate the pump to start fluid flow through the tubing and out of the open end
2. To avoid air bubbles in the system, let fluid flow through the tubing until all air is purged
3. Clamp tube set
4. Upon completion of the arthroscopic procedure, close all tubing clamps
5. If Extension Tubing or ReDeuce Patient Side Tubing was used:
 - Dispose in an accepted waste container
 - Prepare the Pump Side Tubing for a subsequent procedure
6. Using sterile technique, place the sterile connector cap from the Patient Side Tubing packaging onto the connector on the Pump Side Tubing
7. Secure the tubing to prevent contamination
8. Upon completion of the surgical day, dispose of all tubing

CAUTION: Prior to each use, it is important to check the setup of the pump to ensure proper function. A red light will flash near the tubing connection if a secure connection is not made. The pump will not run if this condition persists. If the pump runs continuously after the tubing has been clamped, check all luer connections If the pump still runs continuously, replace the tubing

WARNING: DO NOT DISCONNECT AND RECONNECT THE SAME TUBING SET UNDER ANY CIRCUMSTANCES ONCE DISCONNECTED FROM THE PUMP, THE TUBING SET MUST BE DISCARDED AND A NEW TUBING SET INSTALLED. FAILURE TO DO SO MAY RESULT IN PUMP FAILURE AND PATIENT INJURY.

Failure to follow these instructions may pose a danger to the patient. Do not use the unit if the rollers turn continuously after the tubing has been clamped. If the pump still fails to perform as designed, it should be returned (with the Flushing- and extraction systems set) to Meise GmbH for inspection

V. OUTFLOW TUBING:

1. Open the Outflow Tubing using sterile technique and pass it on to the sterile field
2. The clear tube labeled, “Shaver” should be attached to the shaver hand piece
3. The blue tube labeled, “Cannula” can be attached to a cannula, if desired Note: If the cannula tube is not attached to a device, the clamp should be left open
4. Remove the outflow cassette and wrap the tubing loop around the suction roller and then insert the cassette into place. The pump will recognize the outflow cassette and change the display to show the inflow/outflow icon
5. Close outflow door
6. Once cassette is loaded, visually inspect the tubing cassette. While facing the pump ensure that clear tube is on the left, blue tube is in the middle, and red is on the right
 - a. Waste canister

NOTE: Leave canister open to allow air to flow out b. Vacuum System

NOTE: Vacuum setting should be between -200 and -500 mmHg

VI. Y- TUBING:

1. The Y-Tubing may be used to connect four (4) bags of irrigation fluid to any inflow tube set
2. Open the Y-Tubing sterile package and remove the two (2) Y-Tubing tube sets
3. Close all clamps
4. Using standard sterile technique, remove the spike covers and insert each spike into a separate bag of irrigation fluid
5. Using standard sterile technique, remove the end covers from the Y-Tubing and insert the Flushing- and extraction systems spikes into the Y-Tubing
6. Open the tubing clamps

K. MANUFACTURE

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