RUMI® II LONG Handle

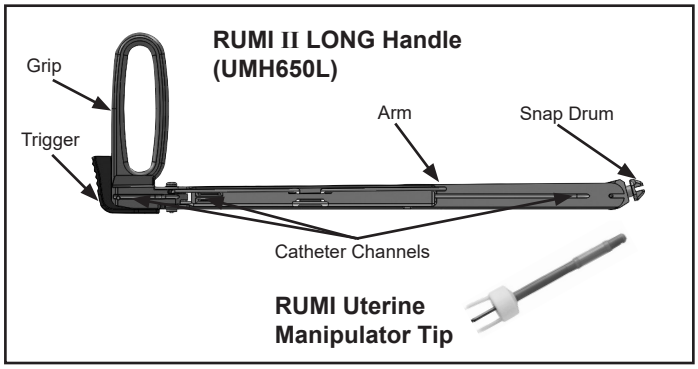
Reusable Uterine Manipulator Handle

UMH650L

Instructions for Use

NON-STERILE • STERILIZE BEFORE USE

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.



DEVICE DESCRIPTION

The RUMI® II Long Uterine Manipulator Handle (Handle) is a reusable device used with a sterile, single-use RUMI Uterine Manipulator Tip (Tip). The RUMI II Long Handle along with the RUMI tip are used for positioning the uterus during laparoscopic surgery and in dye delivery where chromopertubation is necessary.

The grip, trigger, arm and snap drum are constructed of medical grade autoclavable materials. The snap drum serves for attachment of the Tip.

Turning the grip while depressing the trigger permits the movement of the snap drum, thereby moving the position of the tip. When the trigger is released, it locks into the desired position.

Not made with natural rubber latex.

WARNINGS

- The uterus must be sounded for both depth and direction prior to application of the device.
- **DO NOT** use the Handle as a uterine sound.
- **NEVER** attempt uterine manipulation without a clear view of the uterus.
- As with all uterine manipulating devices, a careful clinical evaluation should be performed prior to use.
- Certain clinical conditions may present a uterus which is more prone to perforation and bleeding.
- Dye injection should be performed SLOWLY. Because of the efficient air/liquid seal created at the internal cervical os by the balloon, rapid injection of fluids (dye) may create intrauterine pressures, which could cause uterine damage and/or result in fallopian tube spasms.
- The Handle has only been tested for use with patients who have been anesthetized. Due to the need to dilate the cervix, the Handle is not recommended for use in non-anesthetized patients.
- **The tip is single use only. Never reuse a manipulator tip.**
- Contents supplied sterile. Do not use if sterile barrier is damaged.
- Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another Contamination of the device may lead to injury, illness or death of the patient. Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

INTENDED USE / INDICATIONS FOR USE

The Handle is designed for use in operative endoscopy (laparoscopy), where a uterus is present and where positioning of the uterus, fallopian tubes and ovaries or vagina is desirable. These types of surgeries include laparoscopic tubal ligation, diagnostic laparoscopy and/or operative laparoscopy. The Tips also provide for dye delivery in those procedures requiring chromopertubation.

CONTRAINDICATIONS

The Handle should not be used in patients who are pregnant or who are suspected of being pregnant, planned gamete intrafallopian transfer procedures, in patients who have an IUD in place, in patients with suspected pelvic infections and in cases where the surgeon deems it inadvisable or finds it difficult to insert the silicone tip into the cervix or uterus.

PRECAUTIONS

- Sterilize before use.
- Dilate the cervix to Hegar/Hank 8 (French 24) to ease patient insertion.
- Refer to the RUMI Uterine Manipulator Tip Directions for Use for further precautions.
- Inspect Handle prior to use for proper operation.

ADVERSE REACTIONS

The following adverse reactions have been suspected or reported to be associated with all uterine manipulators. The order of listing does not indicate frequency or severity: cramping, infection, uterine and fallopian tube spasm with associative temporary physiological blockage of patient fallopian tubes and uterine perforation.

INSTRUCTIONS FOR USE

Note: Refer to the RUMI Uterine Manipulator Tips Instructions for Use to ensure proper selection of Tip size and Tip attachment/detachment instructions.

1. Select a Tip which is less than or equal to the sounded depth of the uterus and attach it to the RUMI® II Long Handle.
2. Ensure the Tip catheters are secure in the catheter channels of the Handle (see Figure 1).

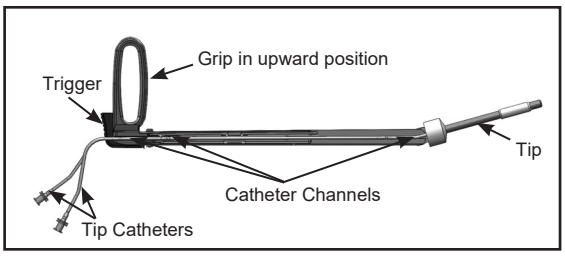


Figure 1

UTERINE POSITIONING

The RUMI II LONG Handle is always intended to be used with the grip in the upward position (see Figure 1).

TO ANTEVERT or insert into an anteverted uterus (see Figure 2): depress the trigger and turn the grip clockwise lifting the uterus to achieve the desired degree of anteversion, up to 90°. Release the trigger to lock the desired position.

TO RETROVERT or insert into a retroverted uterus (see Figure 3): depress the trigger and turn the grip counterclockwise.

A counterclockwise rotation of the grip will result in the uterus being lowered to a retroverted position down to 50°. Release the trigger to lock the desired position.

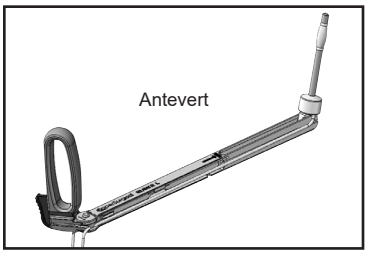


Figure 2

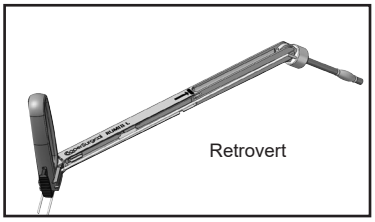


Figure 3

REPROCESSING INSTRUCTIONS FOR THE RUMI II LONG HANDLE

1. INTRODUCTION

This section is intended to provide detailed instructions for effectively processing the reusable RUMI II LONG Handle. All reusable instruments should be thoroughly cleaned and sterilized to prepare them for use.

CooperSurgical, Inc. has validated the processes provided in these instructions to be capable of effective instrument processing. Equipment, operators, cleaning agents and procedures all contribute to the efficacy of processing. Healthcare facilities should ensure that selected processing steps are safe and effective within their systems.

Alternative methods of processing these instruments outside the instructions described in this document may be suitable for reprocessing; however, these have not been evaluated by CooperSurgical, Inc. Operators and healthcare facilities which choose to perform processes outside the instructions described in this document must validate these processes before use. In the event that national or regional government requirements conflict with the recommendations provided here, these shall override the recommendations of CooperSurgical,Inc., but must be validated before use.

Reusable instruments must be rinsed thoroughly after use and after cleaning to ensure removal of gross soil and residual cleaners and solvents. Gross soil is damaging to instrument surfaces and inhibits thorough cleaning and subsequent sterilization. Residual cleaners and solvents can impede further processing and may affect the surface finish of the instrument over time.

2. CLEANING

There are two methods for cleaning that have been validated by CooperSurgical, Inc. Any healthcare facility should be able to perform the manual cleaning process. For those facilities that use automated washer-disinfectors, an automated method has also been validated.

Personnel are cautioned to use personal protective apparel due to the unknown and potentially hazardous nature of biological fluids and soils present. Specific detergents or cleaning solutions vary in requirements for concentrations and temperatures required for optimal cleaning performance. Use temperatures in this document as guidance, to be superseded by the detergent/cleaner manufacturer's directions for use. Any processes outside the recommendations in this document must be validated before use.

The quality of water used to prepare solutions and rinse reusable instruments can affect the efficacy of the process and the instrument reuse life. CooperSurgical, Inc. recommends the use of freshly prepared purified water or sterile water for dilutions of solution and rinsing of instruments. Non-purified water can add mineral deposits and recontaminate instruments with microorganisms. Mineral deposits can impede sterilization and affect the condition of the instrument, resulting in staining, corrosion, and/or other damage.

Equipment and Materials Required for Manual Cleaning

- Personal protective apparel/equipment as recommended by cleaning solution supplier.
- Cleaning bath, sink, or other vessel large enough to accommodate full immersion of instruments.
- Freshly prepared cleaning solution intended for manual cleaning (use enzymatic, neutral, or alkaline detergents).
- Soft-bristled brushes and sponges.
- Clean, low-lint or lint-free cloth.

Equipment and Materials Required for Automated Cleaning

- Personal protective apparel/equipment as recommended by cleaning solution supplier.
- Legally marketed (FDA-cleared and/or CE-marked) medical device washer or washer-disinfector.
- Cleaning solution intended for automated cleaning (use enzymatic, neutral, or alkaline detergents).
- Racks and accessories to hold and support instruments during processing.

Point of Use

During and immediately after the clinical procedure, instruments should be treated to reduce and remove gross soil materials. Instruments should be wiped with low-lint or lint-free absorptive materials, such as low-lint or lint-free wipes to remove solid tissues and the majority of bodily fluids. Immediately after use, all disposable single-use accessories should be removed and discarded into appropriate biohazardous waste containers. Instruments should be placed into a transport container that will protect them from damage during transport and should be kept moist.

Transport to Processing Area

Transport the instruments to the processing area as soon as practical. Minimize holding time before removing organic debris. Ensure that lighter instruments are not mixed with heavier instruments to avoid damage to the instruments due to mechanical abrasion. Seal or enclose the transport container to prevent fluid loss and the potential for cross-contamination of other areas.

Preparation

- Remove all single-use accessories such as the RUMI Tips or Koh Efficient and discard in an appropriate waste container designed for biohazardous materials if this has not been performed at point of use.
- The only accessory for the RUMI II LONG Handle that is reusable is the Koh Cup. Refer to specific reprocessing instructions included with the Koh Cup device packaging.

Cleaning

Cleaning should take place as soon after use as practical. Soils should not be allowed to dry onto the instrument surfaces. The manual process and the automated process were validated independently and are considered equivalently effective when performed according to the instructions in this document. Do not use metal-bristled brushes on the instruments.

Manual Cleaning Processes

1. Ensure that all single-use tips and colpotomy attachments are removed from the instrument and discarded in an appropriate biohazardous waste container.
2. Detach the Koh Cup from the RUMI II LONG Handle.
3. Prepare a neutral or alkaline enzymatic detergent specifically designed for manual cleaning of medical instruments. Prepare a fresh solution of detergent at the detergent manufacturer's recommended concentration using water at the detergent manufacturer's recommended temperature.
4. Ensure that the instruments are fully immersed in the prepared solution. Soak the instrument for a minimum of ten (10) minutes at room temperature (68-77°F/20-25°C) or longer if indicated on the detergent manufacturer's instructions for use.
5. After the soak time, scrub the handle with a soft sponge for large surfaces. Using a soft-bristled brush, scrub the regions with mated surfaces, such as the trigger/grip and the snap drum on the RUMI II LONG Handle. Scrub regions with crevices and lumens on the sides of the handles and near the tips. Actuate the moving parts of the RUMI II LONG Handle while submerged to ensure contact between the instrument surfaces and the brush/detergent.
6. Rinse the instrument in warm tap water (100-120°F/ 38-49°C) for one (1) minute. Ensure that all crevices, lumens and mated surfaces are flushed. Actuate the moving parts of the RUMI II LONG Handle during rinsing.
7. Place the instrument into a prepared ultra-sonicator containing a neutral or alkaline detergent specifically designed for manual cleaning of medical instruments and labeled for use with an ultra-sonicator. Ultra-sonicate the instrument in the detergent solution for ten (10) minutes.
8. Rinse the instrument with purified or sterile water for one (1) minute or until all visible signs of detergent residue are removed, whichever is longer. Ensure that all crevices, lumens and mated surfaces are flushed. Actuate the moving parts of the RUMI II LONG Handle during rinsing.
9. Examine the instrument for signs of residual soil. If there are any signs of residual soil on the instrument, repeat the cleaning process.
10. Dry the instrument with a low-lint or lint-free towel or wipe.

Automated Cleaning Process

1. Ensure that all gross soil has been wiped or rinsed from the surfaces of the instruments.
2. Use only a legally marketed (FDA-cleared and/or CE-marked) medical device washer or medical device washer-disinfector. Industrial use and household use dishwashers are not acceptable for the cleaning of medical devices.
3. Place the instruments loosely within a rack designed for the medical washer or medical washer-disinfector, using a hold-down screen if indicated by the washer/washer-disinfector manufacturer.
4. Load the rack with the instruments into the washer/washer-disinfector and close the door.
5. Select a cycle intended for instruments that has the following parameters at a minimum:

PARAMETER	TOLERANCE
Detergent	Neutral or Alkaline medical device detergent
Pre-wash rinse	Minimum of one
	Minimum of 00:15 (mm:ss)
	Cold tap water or better quality
Wash	Minimum of one repetition
	Minimum of 02:00 (mm:ss)
	Warm tap or purified water (minimum of 140°F/60°C)
	Minimum concentration per detergent manufacturer's IFU
Post-wash rinse	Minimum of one
	Minimum of 00:15 (mm:ss)
	Warm tap or purified water (minimum of 110°F/43.3°C)
Thermal rinse*	Minimum of one
	Minimum of 01:00 (mm:ss)
	Purified water (minimum of 180°F/82.2°C)
Drying**	Minimum of default cycle setting

**Only heat-based medical device washer-disinfectors will include a thermal rinse. Medical device washers that do not include a thermal disinfection phase should be set to have a minimum of a 01:00 (mm:ss) rinse following the post-wash rinse using purified water.*

*** Drying time will be variable dependent on the size and composition of the load, altitude, environmental conditions, and air temperature and source characteristics.*

***NOTE:** automated wash processes that include additional phases or longer phase durations are anticipated to deliver equivalent or better cleaning efficacy as the minimal validated parameters. Additional phases and longer phase durations may be added if they are within the healthcare facility's normal procedures.*

6. Start the cycle and allow it to run through conclusion.
7. Medical washer-disinfector default cycles often use high heat during the final stages of the processing cycle. Use caution and heat-protective gloves when opening and removing the wash rack at the end of the cycle.
8. Examine the instruments for signs of residual soil. If there are any signs of residual soil on the instrument, repeat the cleaning process.
9. If the instruments are not thoroughly dry following the automated process, dry the instruments with low-lint or lint-free towels or wipes.

3. INSPECTION

All instruments must be inspected for signs of damage, wear or residual soil each time they are reprocessed. If residual soil is observed during inspection, the cleaning process must be repeated for the instrument. Remaining soils can impede effective sterilization by shielding remaining microorganisms and can lead to tissue reactions in subsequent patients.

Surface Finish

Inspect the surface of the instrument; the surface should be smooth. Some staining and discoloration may occur depending on the exact formulation of the detergents used and the water quality. Staining will not impact performance of the handles as long as there are no signs of corrosion or surface pitting.

Grooves and Mated Surfaces

Carefully inspect the grooved and recessed areas of the shaft, particularly between the shaft and the guide pins, for signs of trapped soil. Inspect the mated surfaces near the snap drum and near the grip for potential trapped soil.

Articulations

Fully articulate the moving components of the handle using the trigger and grip. The motion should be smooth. Jerking and catching within the range of motion may be signs of damage or retained material between the mated surfaces. Ensure that the trigger moves easily when depressed and that it automatically drops down when released. The un-actuated position should be locked into the articulating dial end of the shaft. When the trigger is engaged in the articulating end of the shaft, the instrument should not shift or rotate. Damage to the trigger locking mechanism may allow slippage during a procedure. Corrosion may weaken the materials leading to a break under normal load. Signs of damage or poor motion quality may indicate a need to replace the instrument or have it repaired.

Debris

Look carefully at any areas that appear to be a different color than the overall instrument as these may be signs of residual soil adhered to the surface.

4. WRAPPING

Prior to terminal sterilization, the instruments must be packaged to preserve sterility after processing during storage. Legally marketed sterilization packaging (e.g. CSR wrap) that is compatible with and labeled for use with the chosen sterilization method should be used. CooperSurgical, Inc. has not evaluated the sterilization efficacy of the processes recommended in this document using containment systems (e.g. procedure/case trays, cassettes, rigid reusable sterilization containers), therefore, users who choose to use a containment system in the sterilization of these instruments should verify that the process is effective under these conditions. Containment systems can impede the ingress and egress of sterilant (moist heat). CooperSurgical, Inc. recommends individually wrapping the instruments prior to sterilization. The instruments should be wrapped using one of the common closure techniques, using properly sized material and secured with tape or adhesive designed and labeled for use with the sterilization process chosen. Instruments should be labeled with identifying information and sterilization date to facilitate selection for use after processing.

5. STERILIZATION - MOIST HEAT (STEAM)

Individually packaged instruments using legally marketed sterile barriers with labeling consistent with the following parameters may be sterilized prior to use and between subsequent uses. Legally marketed (FDA-cleared and/or CE-marked) moist heat (steam) sterilizers should be used. The following parameters have been validated for use with the instruments within the scope of this document:

STERILIZATION PROCESS	EXPOSURE TEMPERATURE	EXPOSURE TIME	DRY TIME
Gravity Displacement	250°F/121°C	30 minutes	30 minutes
Pre-vacuum	270°F/132°C	4 minutes	30 minutes
Pre-vacuum	273°F/134°C	3 minutes	30 minutes

6. STORAGE

Individually packaged instruments should be cooled to a safe handling temperature following moist heat sterilization prior to final storage. Individually packaged instruments should be transported to a clean, temperature and humidity controlled, sterile supply storage area. If instrument packaging is compromised during storage (becomes wet, torn, or seals are open), the instrument must be reprocessed through cleaning, inspection, and sterilization prior to use. Do not stack instruments or allow other product or instruments to be stacked on top of them. Protection from dust and moisture is recommended. Ensure that traceability and identity is maintained throughout storage and up to subsequent use.

7. VALIDATION OF PROCESSES

CooperSurgical, Inc. performed validations for the cleaning of the instruments. The following detergents were used in the validations demonstrating efficacy: Klenzyme™, Manu-Klenz®, ENZOL®, Neutrad®, Prolystica® Ultra-Concentrate Neutral Detergent and Prolystica® Ultra-Concentrate Alkaline Detergent.

CooperSurgical, Inc. does not endorse the use of the identified products in lieu of other similar products designed for use with medical devices, however, this information may provide a basis for comparing the formulations to select an appropriate alternate in facilities or locations where these detergents are not readily available.

The parameters listed in the automated cleaning section as the minimum parameters for automated cleaning are identical to the parameters used in the validation, with the exception of the dry time. Post-cleaning dry time was eliminated for the cleaning process validation to facilitate detection of soil residuals, if present, in order to reduce the potential for a false negative result.

WARRANTY

The RUMI II LONG Uterine Manipulator Handle is warrantied by CooperSurgical, Inc. for a period of 120 days from shipment. This warranty applies only to the original purchaser and only against defects in workmanship or materials, which under normal use render the instrument inoperable. The original purchaser shall prepay the shipping costs for returning a CooperSurgical, Inc. instrument for warranty service. CooperSurgical, Inc. will, at its option and without charge, either repair or replace any instrument, which CooperSurgical, Inc. determines to be defective in material or workmanship. Instrument damage caused by misuse or accident, shall void this warranty.

CooperSurgical, Inc. disclaims any liability for special, incidental, consequential, punitive or exemplary damages arising out of the use of any CooperSurgical, Inc. instrument. CooperSurgical, Inc.'s liability in all events is limited to, and shall not exceed, the purchase price paid. Except as expressly provided in this limited warranty section, CooperSurgical, Inc. makes no representations or warranties, expressed or implied, as to the instruments, including warranties of merchantability and fitness for a particular purpose, all of which are hereby expressly disclaimed and excluded. No warranty or affirmation of fact, express or implied, other than as set forth in this limited warranty, is made or authorized by CooperSurgical, Inc.

EXPLANATION OF SYMBOLS

REF Reorder Number

SN Serial Number

NON STERILE Non-sterile

Caution

Consult Instructions for Use

Do Not Reuse (Tips Only)

LATEX Not made with natural rubber latex.

℞ Only **CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a physician.

Manufacturer

Klenzyme™ is a trademark of STERIS CORPORATION
Manu-Klenz® and Prolystica® are a registered trademarks of STERIS CORPORATION
ENZOL® is a registered trademark of of Johnson and Johnson
Neutrad® is a registered trademark of Decon Labs, Inc.

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