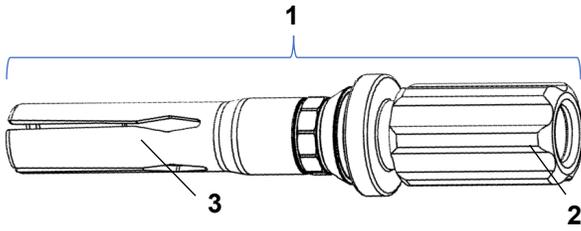


multiSTATION® 10mm COUPLER

Technology Guide

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE



1. 10mm Coupler
2. Locking Knob
3. Shaft

FIG. 1: multiSTATION® 10mm COUPLER



DEVICE DESCRIPTION:

The multiSTATION® 10mm COUPLER (FIG. 1) 1 is used with the multiSTATION® CANNULA ADAPTER to securely hold a 10mm instrument. The Locking Knob 2 secures the 10mm Instrument (for 10.0mm - 10.3mm diameter shafts). The Shaft 3 locks into the multiSTATION® Cannula Adapter.

INDICATIONS FOR USE:

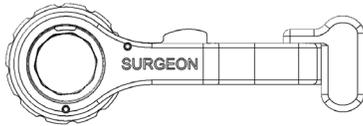
The multiSTATION® 10mm COUPLER is indicated for use by surgeons to hold instruments in a fixed position for a period of time.

multiSTATION® 10mm COUPLER ASSEMBLY AND POSITIONING

The 10mm Coupler attaches to the selected miniARM® using the multiSTATION® CANNULA ADAPTER.

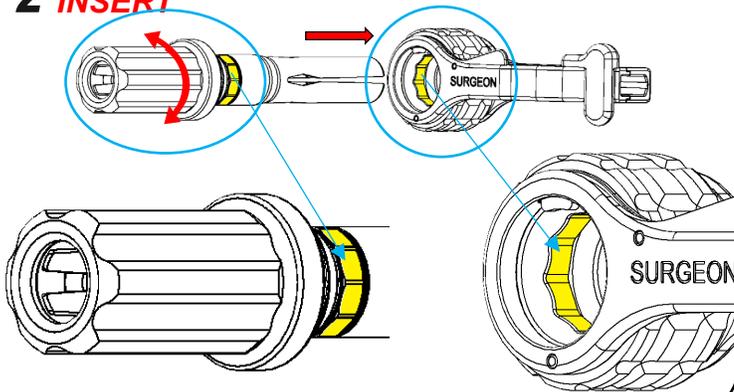
The 10mm Coupler must be cleaned and sterilized before each use.

1 ORIENT



1. **ORIENT** the cannula adapter so that the word “SURGEON” is facing the user.

2 INSERT



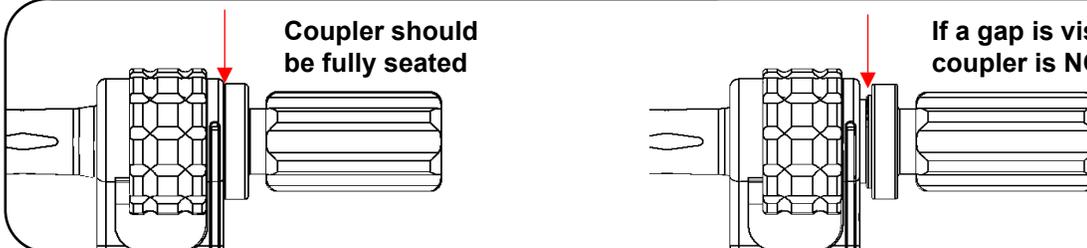
2. **INSERT** the coupler from the “SURGEON” side until it is fully seated and secured by the cannula latch.

NOTE: The coupler may have to be rotated slightly during insertion to align the engagement features.

NOTE: After insertion, the coupler can be rotated and secured as desired. See the multiSTATION® CANNULA ADAPTER Instructions for Use.

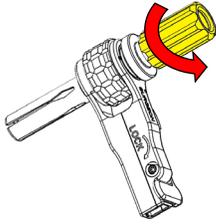
Coupler should be fully seated

If a gap is visible, the coupler is NOT fully seated



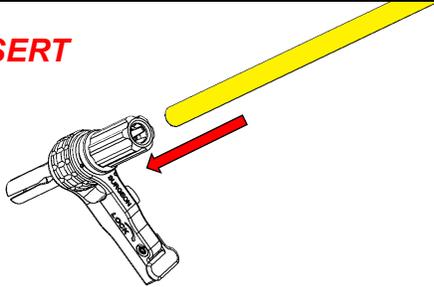
INSERTING THE INSTRUMENT:

1 TURN



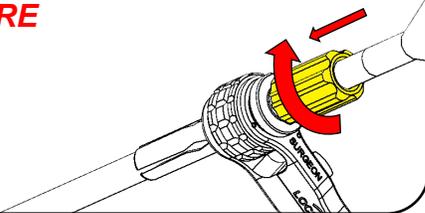
1. **TURN** the locking knob counter-clockwise 4 full turns while holding the Cannula Adapter Rotation Dial to ensure the coupler is fully unlocked.

2 INSERT



2. **INSERT** the end of the 10mm instrument (10.0mm - 10.3mm diameter shafts) through the locking knob. Advance to the desired position.

3 SECURE

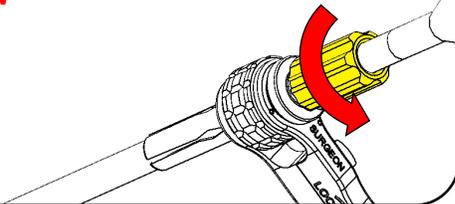


3. **SECURE** the instrument in the coupler by pushing down slightly while turning the locking knob clockwise until the locking knob is snug.

DISASSEMBLY:

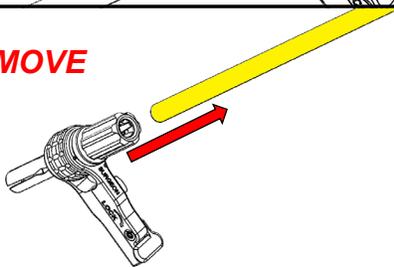
NOTE: To avoid damage to the instrument, ensure that the coupler is fully unlocked before removing the instrument.

1 TURN



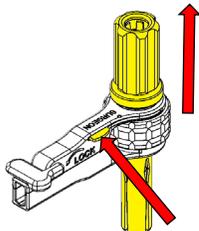
1. **TURN** the locking knob counter-clockwise 4 full turns to ensure the coupler is fully unlocked.

2 REMOVE



2. **REMOVE** the instrument from the coupler.

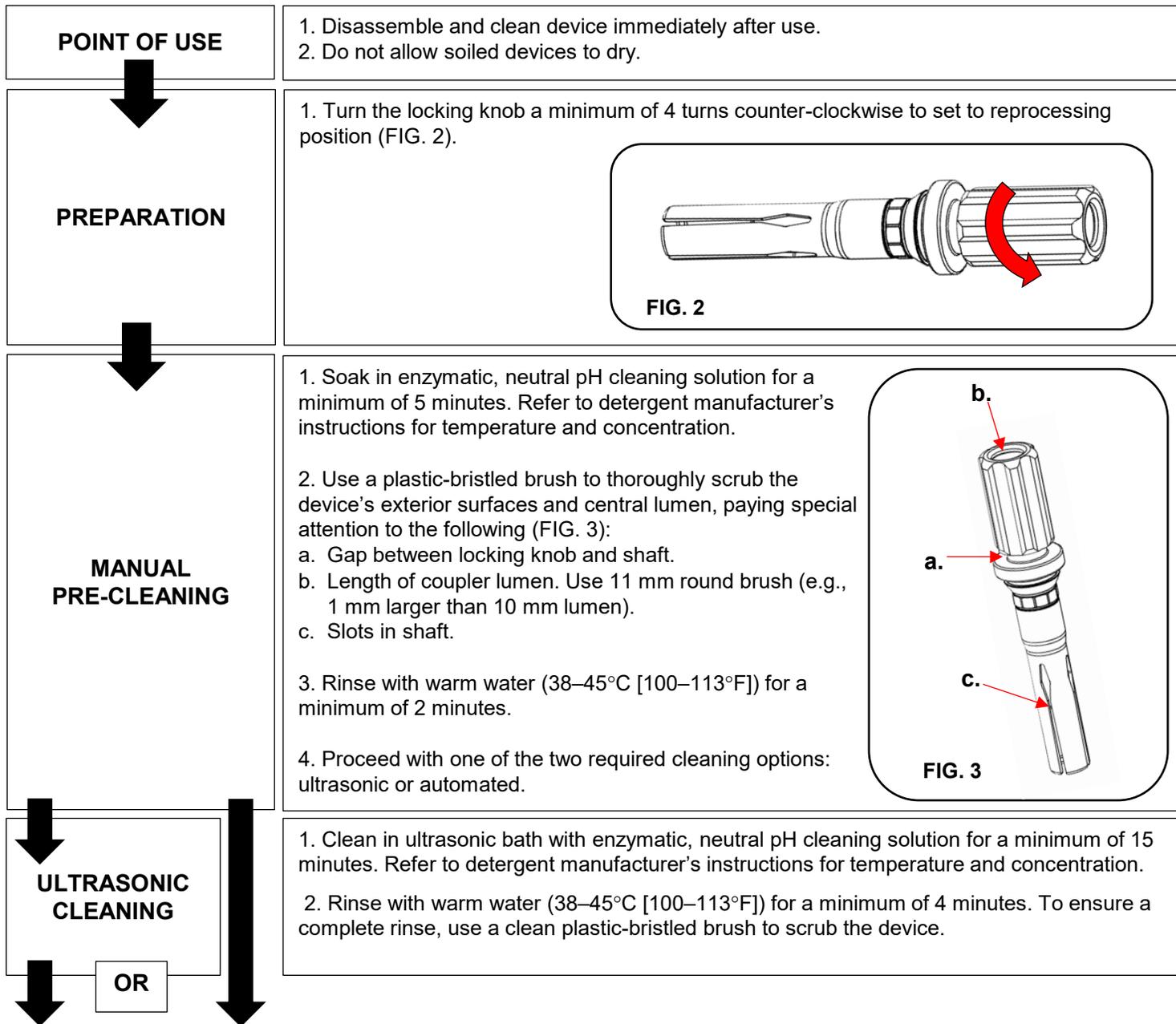
3 PRESS



3. **PRESS** the cannula adapter latch while pulling the coupler out of the cannula adapter.

multiSTATION® 10mm COUPLER REPROCESSING

- Disassemble the coupler from the cannula adapter and clean the coupler immediately after use. Do not allow a soiled device to dry.
- The device is not validated to be cleaned or sterilized with an instrument attached or while still attached to the cannula adapter.
- Cleaning agent used in validation: Steris Prolystica® 2X (enzymatic, neutral pH).
- Perform the final rinse using only freshly prepared purified water/highly purified water.
- Never use metal brushes or steel wool for cleaning.
- This device is unaffected by pressure changes associated with reprocessing.
- The sterilization tray is NOT designed for cleaning devices. It must be processed separately. The tray is only intended for sterilization, transport, and storage of reusable instruments. For more tray information, see the sterilization tray instructions for use.

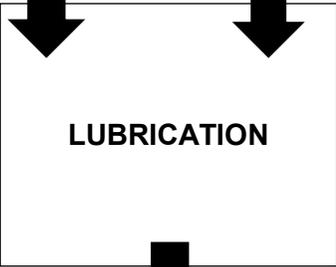


multiSTATION® 10mm COUPLER REPROCESSING (continued)



1. A washer-disinfector with fundamentally approved efficiency (e.g., according to EN ISO 15883) is required and it must be properly installed, qualified, and regularly subjected to maintenance and testing.
2. Load the device into the washer-disinfector. Avoid contact between devices and arrange to allow for proper drainage.
3. Operate the washer-disinfector cycle with an additional rinse cycle.
4. The following minimum parameters were validated as effective for cleaning this device in an automated washer:

Treatment	Time (mm:ss)	Temperature °C (°F)	Additive
Pre-wash (Cold tap)	2:00	17 (63)	N/A
Wash (Hot tap)	2:00	40 (104)	Steris Prolystica® 2X
Rinse	2:00	70 (158)	N/A
Rinse	2:00	70 (158)	Optional lubricant
Dry	15:00	80 (176)	N/A



1. Apply instrument lubricant mixed to manufacturer's recommendations to prolong instrument life by submerging the entire device in the lubricant for a minimum of 30 seconds. If the hospital washer-disinfector has a lubrication cycle, this can be used instead of manual lubrication.
- NOTE: LSI has validated the use of MicroLube C® Instrument Lubricant on this device. Other instrument lubricant brands have not been tested and performance and results cannot be guaranteed.



1. Carefully inspect the device to assure that all visible soil has been removed. Generally, unmagnified visual inspection under good light conditions is sufficient. Particular attention should be paid to the following locations: the gap between knob and shaft, length of coupler lumen, and the slots in the shaft. Refer to FIG. 3 on previous page. Repeat cleaning process if soil is detected.
2. Visually inspect the device for mild or excessive corrosion. If corrosion is present, discontinue use of the device in surgery, but complete reprocessing.
3. Visually inspect the device for damage. If parts are damaged, discontinue use of the device in surgery, but complete reprocessing.



1. Confirm that all instruments are present. If using a sterilization pouch, place each instrument in its own individual pouch. If using a sterilization tray, read the sterilization tray instructions for use before proceeding. Ensure that the sterilization tray has been cleaned according to the sterilization tray instructions for use and load device into the tray. See FIG. 4 for placement of components in tray.
2. Package the device according to TABLE 1 (Page 5). The barrier system for sterilized reusable instruments should meet the following requirements:
 - ISO 11607-1
 - Suitable for pre-vacuum steam sterilization
 - Appropriate for medical use
 - Grade appropriate for weight of loaded tray per sterilization tray instructions for use and facility procedures

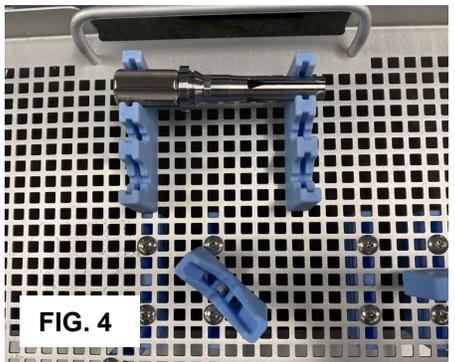


FIG. 4

multiSTATION® 10mm COUPLER REPROCESSING (continued)



STERILIZATION

1. The device must be properly cleaned prior to sterilization.
2. Perform sterilization cycle according to TABLE 1.

TABLE 1: multiSTATION® 10mm COUPLER Sterile Packaging and Processing			
Method	Moist heat (steam) sterilization according to ANSI/AAMI ST79	Moist heat (steam) sterilization according to ANSI/AAMI ST79	Immediate Use Steam Sterilization according to ANSI/AAMI ST79
Container	multiSTATION® System Sterilization Tray P/N 100034	No tray	No tray
Cycle	Pre-vacuum (Pre-vac)	Pre-vacuum (Pre-vac)	Pre-vacuum (Pre-vac)
Packaging	2-layer polypropylene wrap	Pouch	No packaging
Temperature	132-137°C (270–279°F)	132-137°C (270–279°F)	132-137°C (270–279°F)
Exposure Time	4 – 18 minutes	4 – 18 minutes	4 – 18 minutes
Dry Time	65 minutes (minimum)	25 minutes (minimum)	N/A

Device(s) processed by immediate use sterilization should be transferred immediately, using aseptic technique, from the sterilizer to the point of use.

Refer to ANSI/AAMI ST79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.

The multiSTATION® 10mm COUPLER has been validated to 20 reprocessing cycles. The useful lifespan of a surgical instrument is largely dependent on the care and handling of the instrument. Careful inspection and functional testing of the instrument should be used to determine the end of its serviceable life.



STORAGE

1. During storage, ensure the device remains in a sterile condition ready for reuse.
2. Shelf life is dependent on the sterile barrier employed, storage manner, and environmental and handling conditions.

CONTRAINDICATIONS

- This device is not intended for use except as indicated.
- Do not use the multiSTATION® 10mm COUPLER as a cannula.

WARNINGS

- Federal law restricts this device to sale, distribution and use by, or on, the order of a physician.
- Read and become familiar with all instructions, warnings, and cautions before using this product.
- The multiSTATION® 10mm COUPLER shall be used in accordance with these instructions for use.
- Improper use of the device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and may cause serious injury to the health care provider or the patient.
- When using the multiSTATION® 10mm COUPLER, patients must be immobilized or anesthetized.
- Discontinue use of the multiSTATION® 10mm COUPLER when the patient is moving or being moved.
- Surgical or endoscopic procedures should be performed only by physicians having adequate training and familiarity with relevant techniques and anatomy. Medical literature relative to techniques, complications, and hazards should be consulted prior to use.

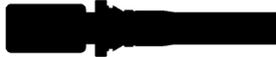
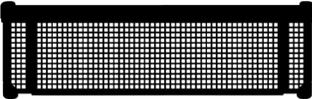
PRECAUTIONS

- **The device is packaged as non-sterile.** Clean and sterilize prior to use.
- If there are any variations between these instructions for use and either your facility's policies and/or your cleaning/sterilizing equipment manufacturer's instructions, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with cleaning and sterilizing your device.
- Use of a *multiSTATION*[®] 10mm COUPLER for a task other than what it is intended for can result in a damaged or broken device.
- Prior to use, inspect the *multiSTATION*[®] 10mm COUPLER to ensure proper function and condition. Do not use the device if it does not satisfactorily perform its intended function or if it has physical damage.
- Surgical instruments vary between manufacturers. Before instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure electrical isolation or grounding are not compromised.
- Avoid mechanical shock or overstressing the *multiSTATION*[®] 10mm COUPLER.
- Only the cleaning and sterilization processes which are defined within these instructions for use have been validated.
- Store at room temperature.

ADVERSE REACTIONS

No documented adverse reactions.

ORDERING INFORMATION

TABLE 2: <i>multiSTATION</i>[®] 10mm Coupler PRODUCT ORDERING			
	REORDER	PRODUCT	DESCRIPTION
	REF 080550	<i>multiSTATION</i> [®] 10mm COUPLER	1 Shelf Box
	REF 100034	<i>multiSTATION</i> [®] System Sterilization Tray *	1 Shelf Box

LSI SOLUTIONS[®]

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 Technical Support: +1 866.428.9092
 Fax: +1 585.742.8086
 www.lsisolutions.com

*The *multiSTATION*[®] System Sterilization Tray is manufactured by Summit Medical, 815 Vikings Parkway, Suite 100, St. Paul, MN 55121 U.S.A.

MADE IN THE USA

This Product Comes with our LSI SOLUTIONS[®] **Perfect Performance Policy[®]**
 Call us at 866.575.3493 any time.

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