

The multiSTATION® LOCKING COUPLER Technology Guide

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

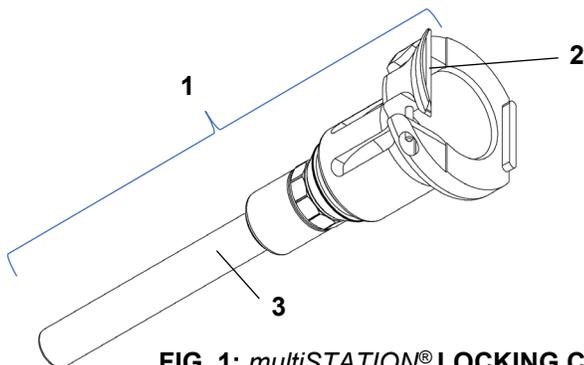


FIG. 1: multiSTATION® LOCKING COUPLER

1. multiSTATION® Locking Coupler
2. Release Tab
3. Locking Coupler Shaft



DEVICE DESCRIPTION:

The multiSTATION® LOCKING COUPLER 1 is used with either the multiSTATION® CANNULA ADAPTER or the multiSTATION® CLAMPING ADAPTER to securely hold the Olympus® ENDOEYE FLEX® 5mm HD surgical video camera (LTF-S190-5). The camera is released from the coupler by pressing the release tab 2. The multiSTATION® CLAMPING ADAPTER secures the Coupler by gripping the locking coupler shaft 3.

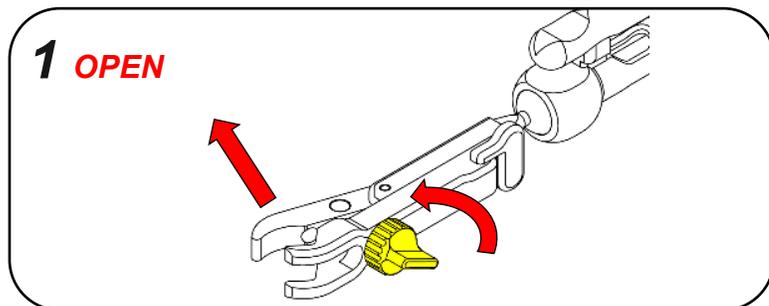
INDICATIONS FOR USE:

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

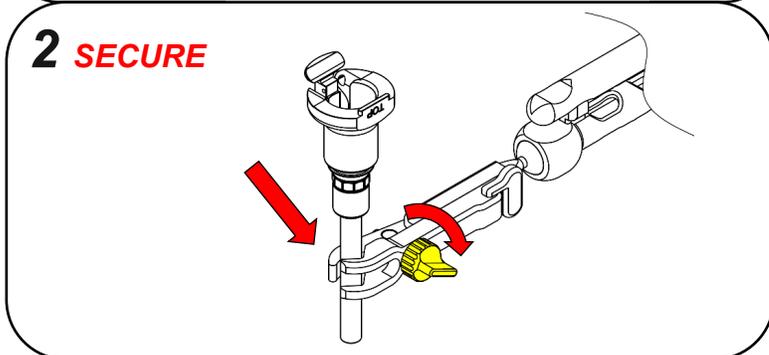
multiSTATION® LOCKING COUPLER ASSEMBLY AND POSITIONING

The multiSTATION® LOCKING COUPLER may be attached to the miniARM® using either the multiSTATION® CLAMPING ADAPTER or the multiSTATION® CANNULA ADAPTER.

USE WITH THE CLAMPING ADAPTER:



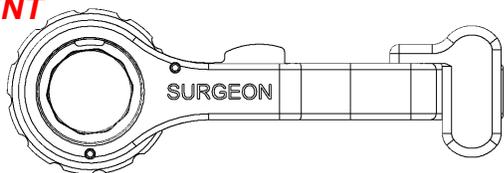
1. **OPEN** the clamping adapter jaw by rotating the actuation thumb screw counterclockwise.



2. **SECURE** the coupler in the clamping adapter by rotating the actuation thumb screw clockwise to close the jaw around the coupler shaft

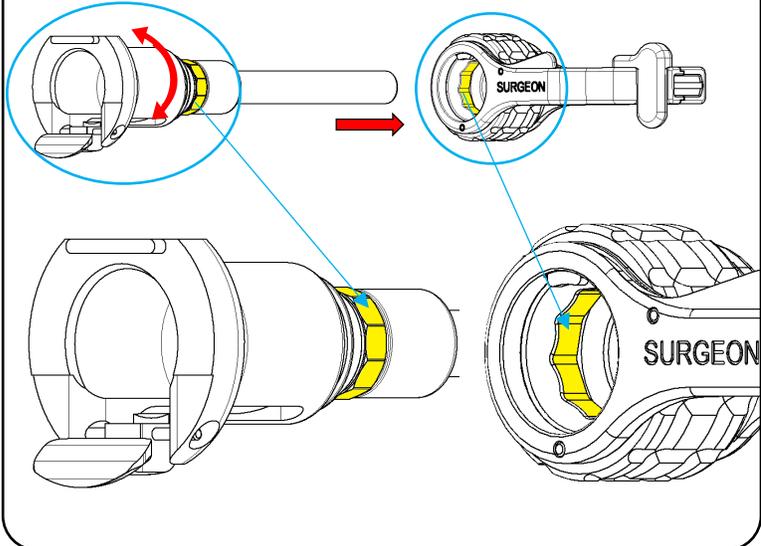
USE WITH THE CANNULA ADAPTER:

1 ORIENT



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

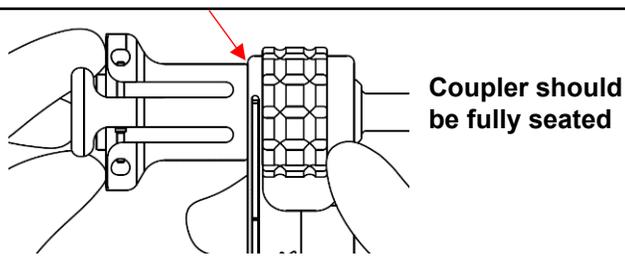
2 INSERT



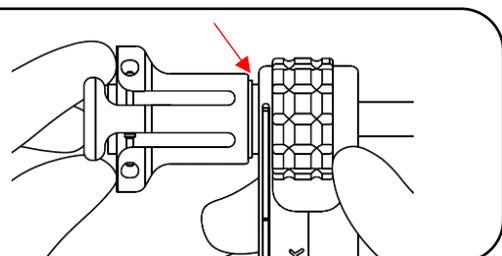
2. **INSERT** the coupler from the "SURGEON" side until it is fully seated and secured by the cannula latch.

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.



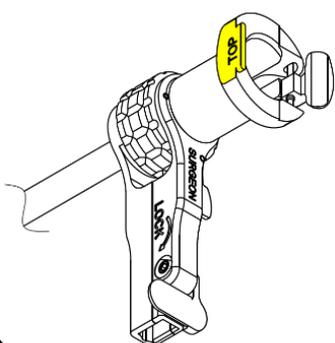
If a gap is visible, the coupler is NOT fully seated



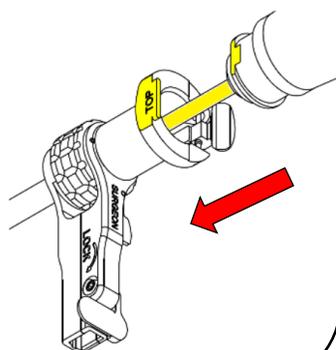
INSERTING THE OLYMPUS[®] ENDOEYE FLEX[®] SURGICAL VIDEO CAMERA:

Note: To avoid damage to the camera's distal tip, ensure that the camera is not flexed before insertion.

1 ORIENT

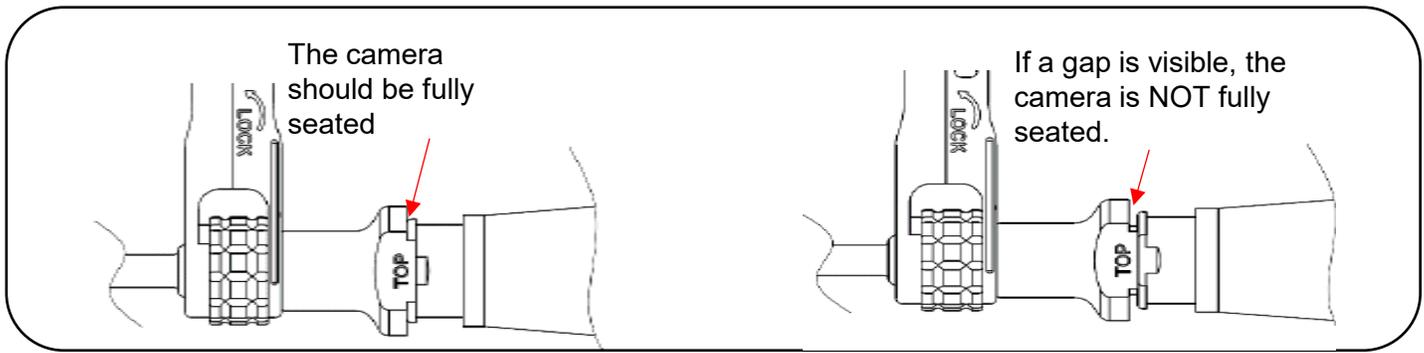


2 INSERT



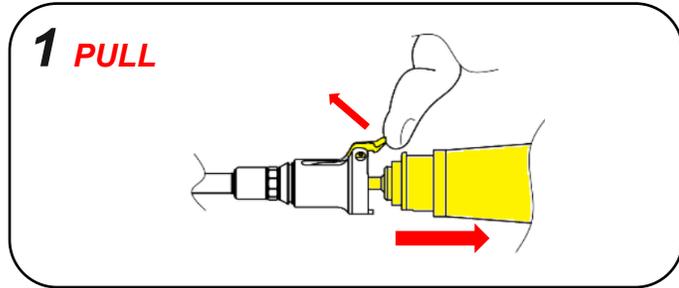
1. **ORIENT** the coupler so that the word "TOP" is facing the user.

2. **INSERT** the camera into the coupler, making sure that the flat portion of the camera aligns with the flat portion of the coupler labeled "TOP," as shown.

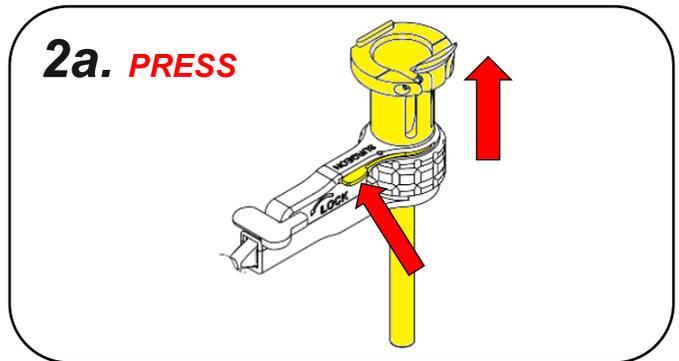


DISASSEMBLY:

NOTE: To avoid damage to the camera's distal tip, ensure that the camera is not flexed before removal.

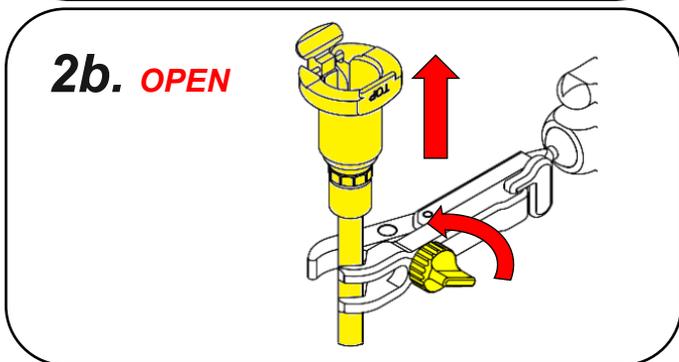


1. **PULL** the release tab to disengage the camera from the coupler, then carefully remove the camera.



IF USING THE CANNULA ADAPTER:

2a. **PRESS** the cannula latch while pulling the locking coupler from the cannula adapter.



IF USING THE CLAMPING ADAPTER:

2b. **OPEN** the clamping adapter jaw by rotating the actuation thumb screw counterclockwise to release the coupler.

multiSTATION® LOCKING COUPLER REPROCESSING

- Disassemble and clean the device immediately after use. Do not allow a soiled device to dry.
- The device is not validated to be cleaned or sterilized with a camera attached or while still attached to a cannula adapter or clamping 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® LOCKING COUPLER REPROCESSING (continued)

POINT OF USE

1. Disassemble and clean device immediately after use.
2. Do not allow soiled devices to dry.

PREPARATION

NOTE: To avoid damage to the camera's distal tip, ensure that the camera is not flexed before removal.

1. Pull the release tab to disengage the camera from the coupler, then carefully remove the camera. (FIG. 2)

If using the Cannula Adapter:

- 2a. PRESS the cannula latch while pulling the coupler from the cannula adapter. (FIG. 3)

If using the Clamping Adapter:

- 2b. OPEN the clamping adapter jaw by rotating the actuation thumb screw counterclockwise to release the coupler. (FIG. 4)

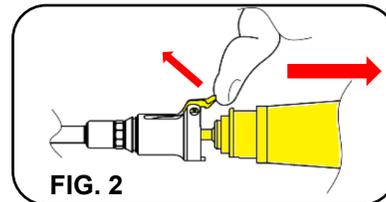


FIG. 2

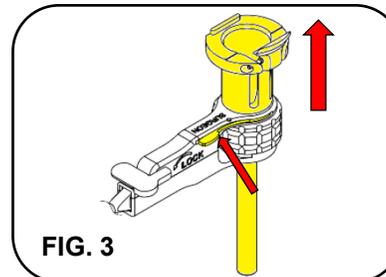


FIG. 3

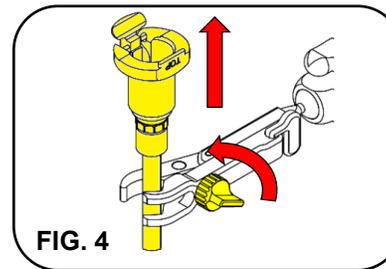


FIG. 4

MANUAL PRE-CLEANING

1. Soak in enzymatic, neutral pH cleaning solution for a minimum of 5 minutes. Refer to detergent manufacturer's instructions for temperature and concentration.

2. Use a plastic-bristled brush to thoroughly scrub the device's exterior surfaces, paying special attention to the following (FIG. 5):

- a. Release tab pin pocket,
- b. Length of coupler lumen. Use round brush 1 mm larger than lumen (e.g., use 7 mm brush for 6 mm lumen).

3. Rinse with warm water (38–45°C [100–113°F]) for a minimum of 2 minutes.

4. Proceed with one of the two required cleaning options: ultrasonic or automated.

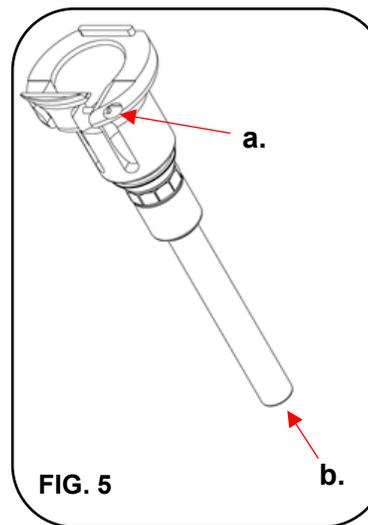


FIG. 5

ULTRASONIC CLEANING

1. Clean in ultrasonic bath with enzymatic, neutral pH cleaning solution for a minimum of 15 minutes. Refer to detergent manufacturer's instructions for temperature and concentration.

2. Rinse with warm water (38–45°C [100–113°F]) for a minimum of 4 minutes. To ensure a complete rinse, use a clean plastic-bristled brush to scrub the device.

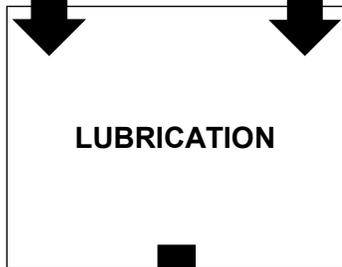
OR

multiSTATION® LOCKING COUPLER REPROCESSING (continued)

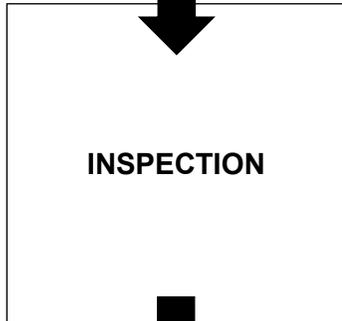


1. A washer-disinfector with fundamentally approved efficiency (e.g., according to EN ISO 15883) is required and it must be properly installed, qualified, and regularly subjected to maintenance and testing.
2. Load the device into the washer-disinfector. Avoid contact between devices and arrange to allow 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: Release tab pin pocket, Length of coupler lumen. 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. 6 for placement of components in tray.
2. Package the device according to TABLE 1 (Page 6). 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

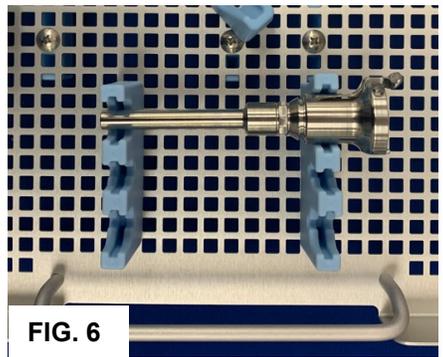


FIG. 6

multiSTATION® LOCKING 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® LOCKING 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® 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® LOCKING 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.

WARNINGS

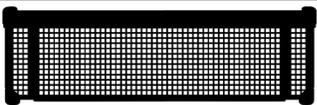
- Federal law restricts this device to sale, distribution and use by, or on, the order of a physician.
- Read and become familiar with all instructions, warnings, and cautions before using this product.
- The multiSTATION® LOCKING COUPLER shall be used in accordance with these instructions for use.
- 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® LOCKING COUPLER, patients must be immobilized or anesthetized.
- Discontinue use of the multiSTATION® LOCKING 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.
- Do not use the multiSTATION® LOCKING COUPLER as a cannula.

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*[®] **LOCKING 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*[®] **LOCKING 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*[®] **LOCKING COUPLER**.
- To avoid damage to the camera's distal tip, ensure that the camera is not flexed before insertion or removal.
- 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.

TABLE 2: <i>multiSTATION</i>[®] LOCKING COUPLER PRODUCT ORDERING			
	REORDER	PRODUCT	DESCRIPTION
	REF 080555	<i>multiSTATION</i> [®] LOCKING COUPLER [†]	1 Shelf Box
	REF 100034	<i>multiSTATION</i> [®] Sterilization Tray [*]	1 Shelf Box

† For Use with the Olympus[®] ENDOEYE FLEX[®] 5mm HD surgical video camera (LTF-S190-5) (NOTE: the *multiSTATION*[®] Locking Coupler requires either the *multiSTATION*[®] Cannula Adapter (#080415) OR the *multiSTATION*[®] Clamping Adapter (#080519) in order to be attached to the *miniARM*[®])

LSI SOLUTIONS[®]

LSI SOLUTIONS, Inc.
7796 Victor-Mendon Road
Victor, New York 14564 U.S.A.
Phone: +1 585.869.6600
Customer Service: +1 866.575.3493
Technical Support: +1 866.428.9092
Fax: +1 585.742.8086
www.lsisolutions.com

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

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