The multiSTATION® ARTICULATING ADAPTER

Technology Guide

(i) READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

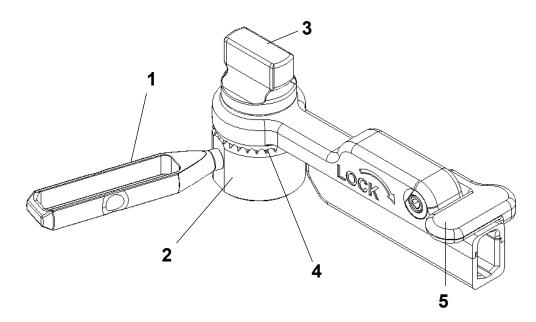


FIG. 1 - multiSTATION® ARTICULATING ADAPTER

- 1. Quick Connect Post
- 2. Pivot Joint
- 3. Thumb Screw
- 4. Locking Teeth
- 5. Locking Lever



multiSTATION® ARTICULATING ADAPTER DEVICE DESCRIPTION:

The reusable *multiSTATION*® *ARTICULATING ADAPTER* (FIG. 1) provides a secure connection between a selected *miniARM*® (e.g., *CLICK RELEASE™*, *RIGID*) and a selected *multiSTATION*® ADAPTER (e.g., *CLAMPING ADAPTER, CANNULA ADAPTER, ACCESS ADAPTER*)(FIG. 2). The *ARTICULATING ADAPTER* extends the reach of the selected *miniARM*® and provides additional adjustability for the selected *multiSTATION*® ADAPTER. The quick connect post 1 provides a connection point onto which a *multiSTATION*® ADAPTER is attached. The pivot joint 2 can be rotated to reposition the attached adapter. When the thumb screw 3 is tightened, the locking teeth 4 are brought together to lock in the selected angle of the attached adapter relative to the *miniARM*®. Loosening the thumb screw releases the locking teeth and allows the quick connect post to freely pivot. The locking lever 5 is rotated to the locked or unlocked position to respectively attach or remove the *ARTICULATING ADAPTER* to a selected *miniARM*®.

INDICATIONS FOR USE:

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

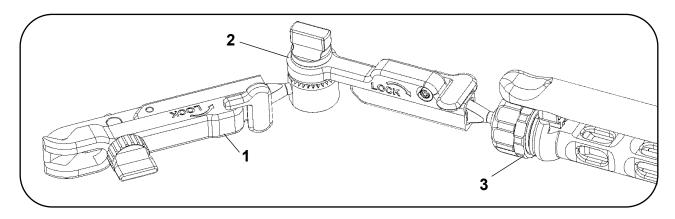


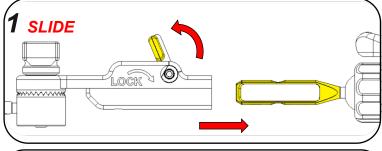
FIG. 2 – multiSTATION® CLAMPING ADAPTER 1 attached to a multiSTATION® ARTICULATING ADAPTER 2 that is connected to a CLICK RELEASE™ miniARM® 3.

INSTRUCTIONS FOR USE

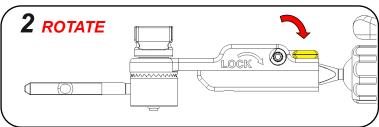
The multiSTATION® ARTICULATING ADAPTER must be cleaned and sterilized before each use.

Refer to the respective instructions for use for each device used in conjunction with the *multiSTATION*® *ARTICULATING ADAPTER*.

Connecting the ARTICULATING ADAPTER to the selected miniARM®

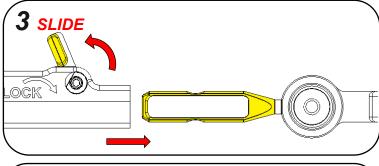


1. SLIDE the ARTICULATING ADAPTER onto the quick connect post of the *miniARM*[®] while the locking lever is rotated to the unlocked position.

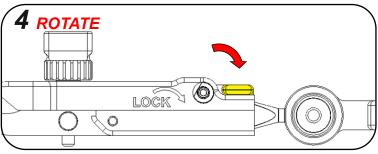


2. ROTATE the locking lever to the locked position to secure the **ARTICULATING ADAPTER** onto the **miniARM**[®].

Connecting the selected multiSTATION® ADAPTER to the ARTICULATING ADAPTER

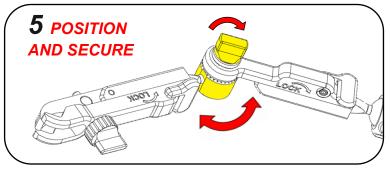


3. SLIDE the selected *multiSTATION*® ADAPTER onto the quick connect post of the *ARTICULATING ADAPTER* while the selected adapter locking lever is rotated to the unlocked position.



4. ROTATE the selected adapter's locking lever to the locked position to secure the selected adapter onto the **ARTICULATING ADAPTER** .

Positioning the selected *multiSTATION®* ADAPTER



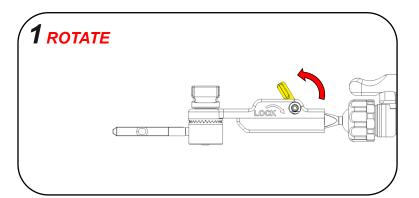
5. POSITION the selected *multiSTATION*® ADAPTER into the desired orientation and **SECURE** the *ARTICULATING ADAPTER* by turning the thumb screw clockwise. Ensure that the locking teeth are appropriately meshed to hold the adapter position.

REMOVAL AND CLEANUP

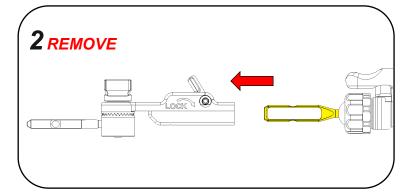
DISASSEMBLY

Ensure that the selected *multiSTATION®* ADAPTER and any attached accessories have been removed from the *ARTICULATING ADAPTER* before removing the *ARTICULATING ADAPTER* from the *miniARM®*. Refer to each device's instructions for use.

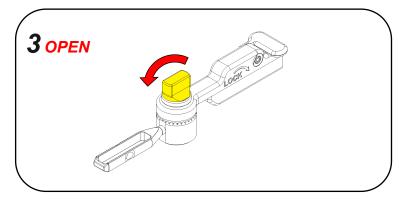
This process may be made easier by having the *miniARM*® locked while handling.



1. **ROTATE** the locking lever to the unlocked position.



2. REMOVE the ARTICULATING ADAPTER by sliding it off the *miniARM*[®] quick connect post.



3. *OPEN* the thumb screw fully by rotating counterclockwise until it stops.

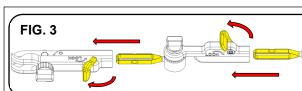
multiSTATION® ARTICULATING ADAPTER REPROCESSING

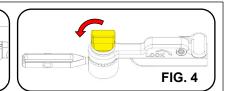
- Disassemble and clean the device immediately after use. Do not allow a soiled device to dry.
- The device is not validated to be cleaned or sterilized with a miniARM® and/or selected adapter attached.
- Cleaning agent used in validation: Steris Prolystica® 2X (enzymatic, neutral pH).
- Perform the final rinse using only freshly prepared purified water/highly purified water.
- · Never use metal brushes or steel wool for cleaning.
- Prepare and reprocess miniARM® and selected adapter according to each device's instructions for use.

multiSTATION® ARTICULATING ADAPTER REPROCESSING (continued)

POINT OF USE

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





PREPARATION

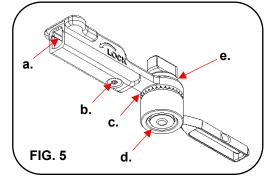
- 1. Remove the selected adapter from the ARTICULATING ADAPTER and the ARTICULATING ADAPTER from the *miniARM*® by rotating the locking levers to the unlocked position and sliding the components apart (FIG. 3).
- 2. Open the thumb screw by rotating it counterclockwise until it stops (FIG. 4)
- 3. If using the *multiSTATION*[®] *Sterilization Tray* (Part Number 100034), clean the tray separately according to the sterilization tray instructions for use.



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. Attachment opening
 - b. Screw head
 - c. Locking teeth
 - d. Pivot recess
 - e. Between thumb screw and body
- 3. Rinse with warm water for a minimum of 2 minutes.
- 4. Proceed with one of the two required cleaning options: ultrasonic or automated.



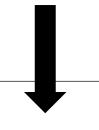


OR

AUTOMATED 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 for a minimum of 4 minutes. To ensure a complete rinse, use a clean plastic-bristled brush to scrub the device.
- 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.

multiSTATION® ARTICULATING ADAPTER REPROCESSING (continued)



NOTE: The sterilization tray is <u>NOT</u> designed for cleaning devices. <u>It must be processed separately</u>. The tray is only intended for sterilization, transport, and storage of reusable instruments. For more tray information, see the sterilization tray instructions for use.

LUBRICATION

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 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 locations in FIG. 5. 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 any damage. If parts are damaged, discontinue use of the device in surgery, but complete reprocessing.



- 1. 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 the tray bottom according to FIG. 6.
- 2. Package the device according to TABLE 1. 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

procedures



PACKAGING



multis TATION® ARTICULATING ADAPTER REPROCESSING (continued)

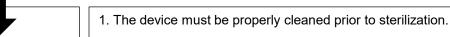
2. Perform sterilization cycle according to TABLE 1:

(minimum)

65 minutes

(minimum)

4 minutes (minimum)



Temperature

Exposure

Dry Time

Time

TABLE 1: multiSTATION® ARTICULATING ADAPTER					
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		
Tammaratura	132°C (270°F)	132°C (270°F)	132°C (270°F)		

(minimum)

4 minutes (minimum)

25 minutes (minimum)

(minimum)

N/A

4 minutes (minimum)

STERILIZATION

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*® *ARTICULATING ADAPTER* 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.



- 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

- Do not use with attachments other than accessories provided by LSI SOLUTIONS[®].
- These devices are 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® ARTICULATING ADAPTER shall be used in accordance with these instructions for use.
- Improper use of the *multiSTATION® ARTICULATING ADAPTER* 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® ARTICULATING ADAPTER, patients must be immobilized or anesthetized.
- Discontinue use of the multiSTATION® ARTICULATING ADAPTER when patient is moving or being moved.
- Do not attach a multiSTATION® ARTICULATING ADAPTER to a second multiSTATION® ARTICULATING ADAPTER.
- Do not use a multiSTATION® ARTICULATING ADAPTER with RIGID miniARMs® in the bridge configuration.
- Surgical or endoscopic procedures should be performed only by physicians having adequate training and familiarity with relevant techniques and anatomy. Medical literature relating to techniques, complications, and hazards should be consulted prior to use.
- Use of the multiSTATION® ARTICULATING ADAPTER for a task other than what it is intended for can result in a
 damaged or broken device.

- The multiSTATION® ARTICULATING ADAPTER is packaged as non-sterile. Clean and sterilize prior to use.
- If there are any variations between these instructions for use and the policies of your facility and/or the instructions of your cleaning/sterilizing equipment manufacturer, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with cleaning and sterilizing your device.
- Prior to use, inspect the multiSTATION® ARTICULATING ADAPTER to ensure proper function and condition. Do not use devices if they do not satisfactorily perform their intended function or if they have 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® ARTICULATING ADAPTER.
- Only the cleaning and sterilization processes that are defined within these instructions for use have been validated.
- Store at room temperature.

ADVERSE REACTIONS

No documented adverse reactions.

ORDERING INFORMATION

TABLE 2: multiSTATION® ARTICULATING ADAPTER PRODUCT ORDERING					
	REORDER	PRODUCT	DESCRIPTION		
	REF 081400	multiSTATION® ARTICULATING ADAPTER	1 Shelf Box		
	REF 100034	multiSTATION® Sterilization Tray*	1 Shelf Box		





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.

Patents: www.lsisolutions.com/patents

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Symbol Glossary:

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