

The *multiSTATION*[®] *CLICK RELEASE*[™] *miniARM*[®]

Technology Guide

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

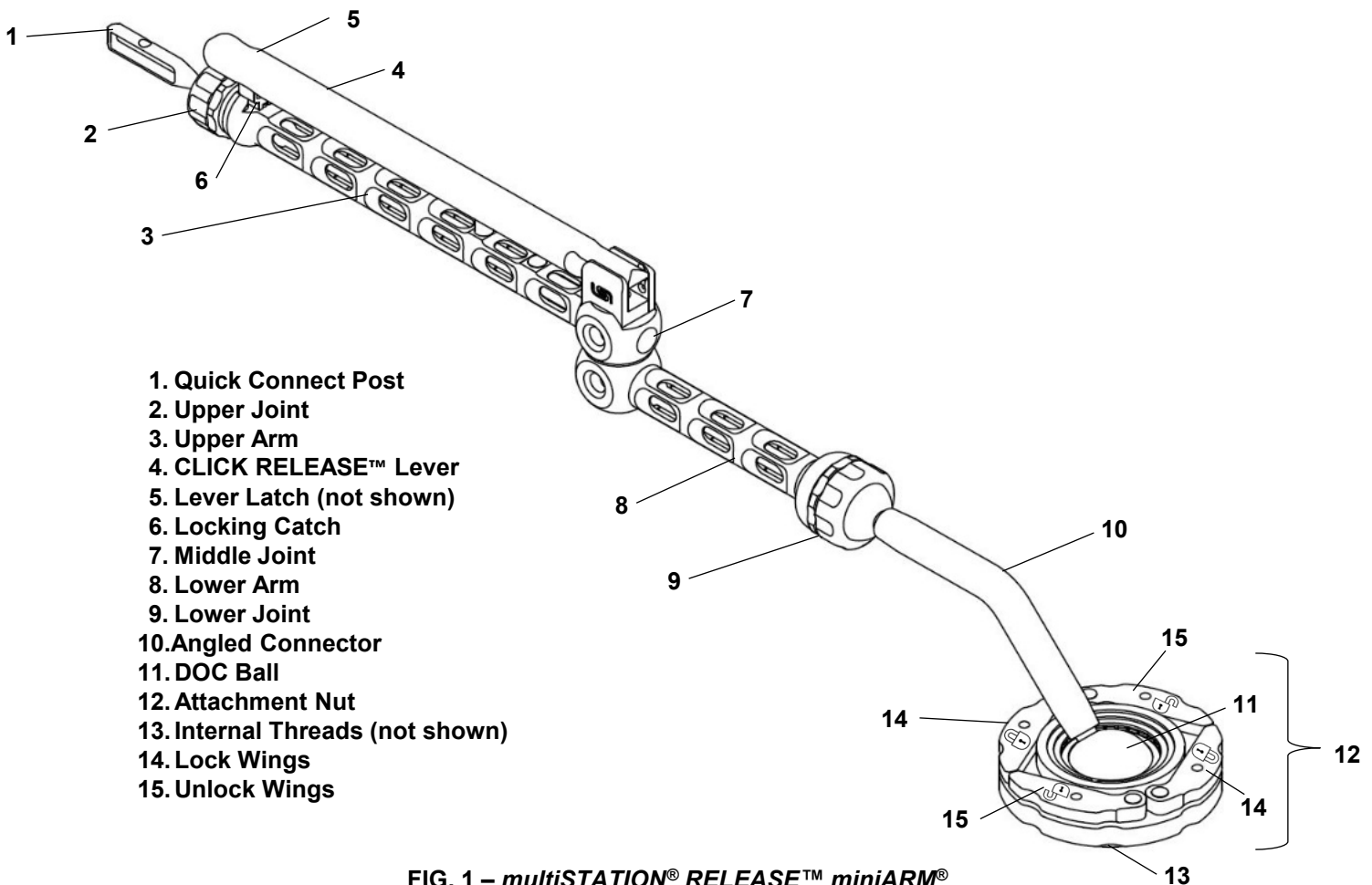




FIG. 1 – *multiSTATION*[®] *RELEASE*[™] *miniARM*[®]



multiSTATION[®] *CLICK RELEASE*[™] *miniARM*[®] DEVICE DESCRIPTION:

The *CLICK RELEASE*[™] *miniARM*[®] (FIG. 1) is an accessory in the *multiSTATION*[®] System. It is a reusable, sterilizable, repositionable support member providing an exceptionally stable base, when used with a separately available *multiSTATION*[®] *RAIL CLAMP*, on which interchangeable adapters are connected. Adapters and devices can be attached at the quick connect post 1 as needed for surgery. The upper joint 2 allows the quick connect post to be positioned accurately relative to the upper arm 3. With the first manual squeeze of the upper arm's *CLICK RELEASE*[™] lever 4, the integrated lever latch 5 (not shown) connects with the locking catch 6 and locks the *miniARM*[®] in the selected orientation. The next squeeze of the *CLICK RELEASE*[™] lever releases the *miniARM*[®] for repositioning. A subsequent lever squeeze again locks the *miniARM*[®]; this locking and unlocking pattern alternates with each lever squeeze. The middle joint 7 allows for the articulation of the upper arm relative to the lower arm 8. The lower joint 9 allows for the articulation of the lower arm relative to the angled connector 10, which terminates in a DOC ball 11 with a spherical articulating surface that engages the receiving socket of the *multiSTATION*[®] *RAIL CLAMP*.

The attachment nut 12 compresses the upper hemisphere of the DOC ball into the receiving socket when the attachment nut and its internal threads 13 (not shown) are rotated clockwise, threading into the receiving socket. As it is tightened into the socket, the DOC ball and the angled connector are compressed so that they can no longer move. The two lock wings 14 engraved with the lock symbol () can swivel approximately 90° away from their storage positions on the attachment nut to ease clockwise threading. Once the attachment nut is tightened, the lock wings can be swiveled back into their storage position. To loosen the attachment nut, both unlock wings 15 labeled with the unlock symbol () can swivel from their storage position to ease counterclockwise threading.

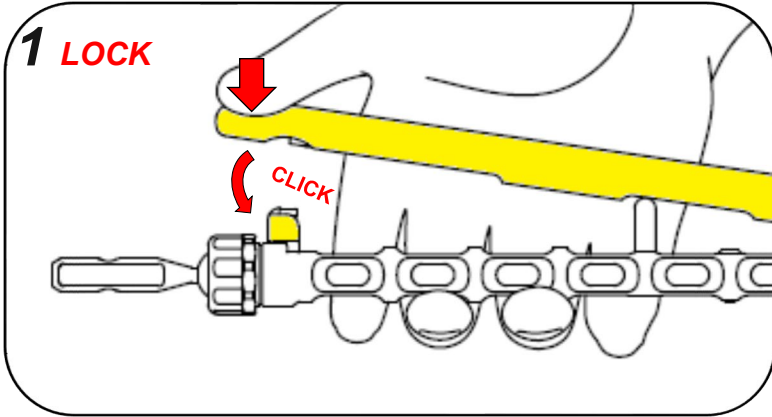
INDICATIONS FOR USE:

The *multiSTATION*[®] *CLICK RELEASE*[™] *miniARM*[®] is indicated for use by surgeons to hold instruments in a fixed position for a period of time.

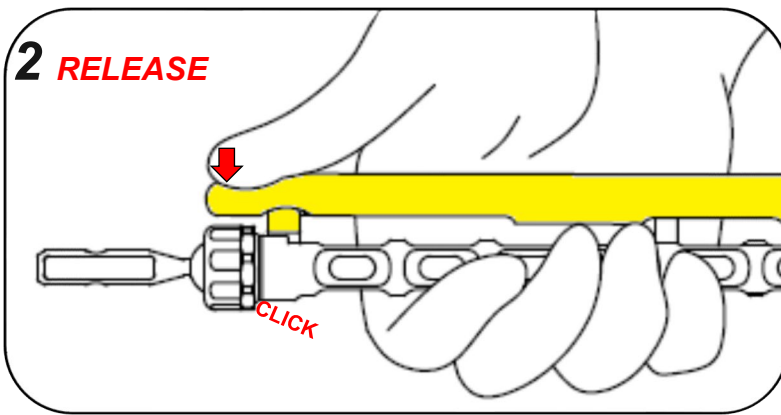
INSTRUCTIONS FOR USE

LOCKING, RELEASING, and PLACING the *multiSTATION*[®] *CLICK RELEASE*[™] *miniARM*[®]

Prior to each use, test the *CLICK RELEASE*[™] *miniARM*[®] by confirming that acceptable holding strength is achieved. Discontinue use if holding strength is inadequate. These instructions for attaching a *CLICK RELEASE*[™] *miniARM*[®] to a receiving DOC apply to use with the receiving DOC of any separately available *multiSTATION*[®] *RAIL CLAMP* already attached to a draped table rail.

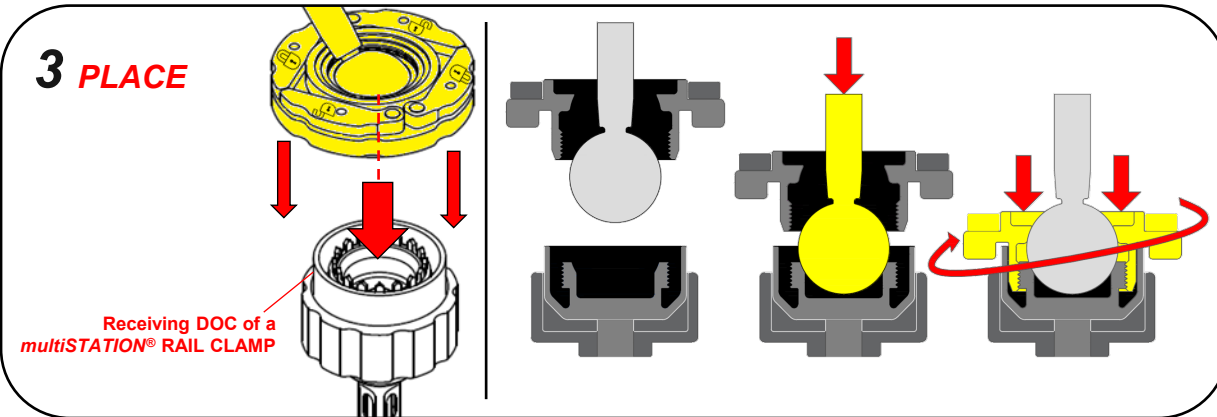


1. LOCK the *miniARM*[®] by squeezing the *CLICK RELEASE*[™] lever down toward the lever catch. The *CLICK RELEASE*[™] lever hinges at the middle joint until the *CLICK RELEASE*[™] lever is in its locked position, parallel to the upper arm. An audible click indicates that the lever latch and locking catch are engaged.

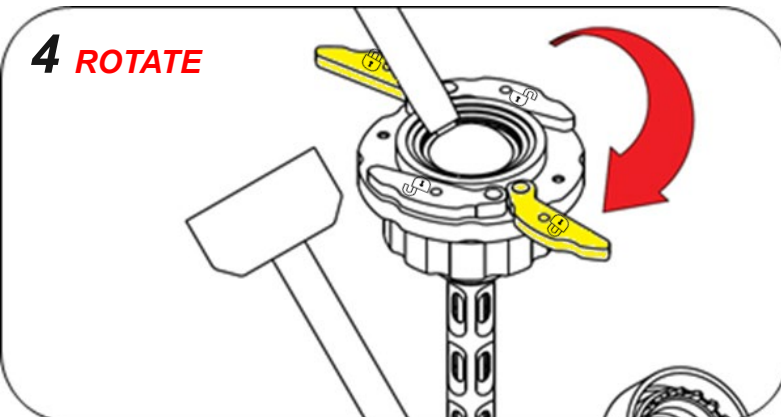


2. RELEASE the *miniARM*[®] by fully squeezing the *CLICK RELEASE*[™] lever down toward the locking catch. An audible click indicates that the lever latch is now disengaged, allowing the *CLICK RELEASE*[™] lever to hinge at the middle joint to reach its unlocked position. If necessary, manually raise the *CLICK RELEASE*[™] lever away from the upper arm to the unlocked position.

NOTE: When pivoting the *CLICK RELEASE*[™] lever from the locked to unlocked position, make sure to support the *miniARM*[®].

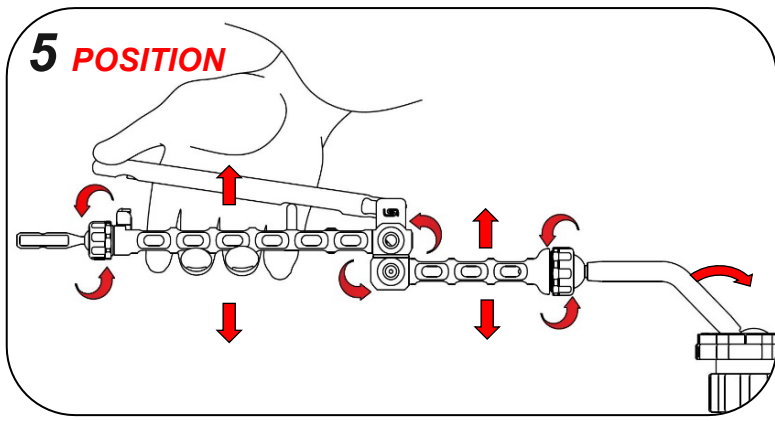


3. PLACE the attachment nut and the DOC ball onto the receiving DOC of the *RAIL CLAMP* to attach the *miniARM*[®] to the DOC.



4. ROTATE the attachment nut onto the DOC using both opposing lock wings (Ⓔ) to turn the attachment nut clockwise, threading it onto *RAIL CLAMP* DOC.

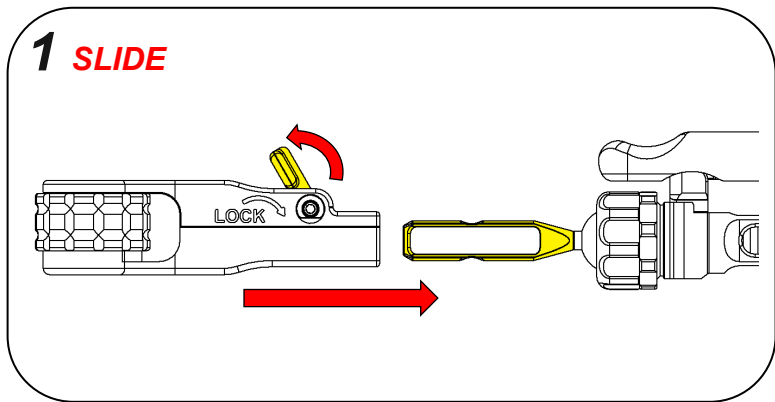
NOTE: If threading is difficult, turn the attachment nut counterclockwise to unscrew, then carefully realign the attachment nut with the DOC and repeat the clockwise rotation using the lock wings. Do not force the attachment nut to rotate, as doing so can cause the *miniARM*[®] and *RAIL CLAMP* to bind.



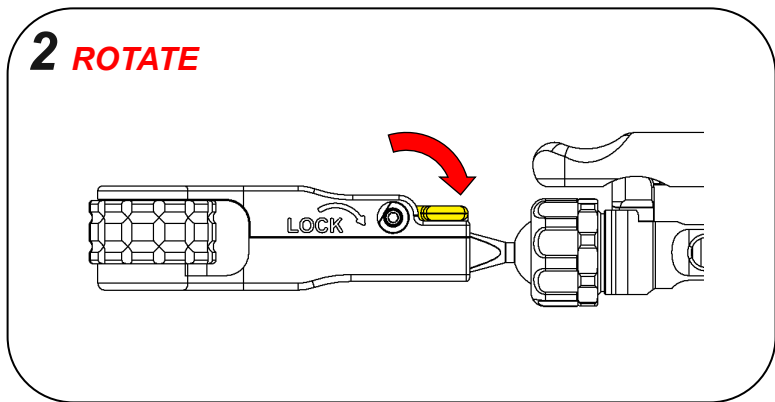
5. POSITION the *miniARM*[®] while in its unlocked state by pushing, pulling, or rotating the quick connect post, upper arm, lower arm, and angled connector about the three joints and DOC ball for adjustability in all directions. When the *miniARM*[®] has been positioned as desired, lock the system by squeezing the CLICK RELEASE™ lever onto the locking latch.

ATTACHING AN ADAPTER TO THE *multiSTATION*[®] CLICK RELEASE™ *miniARM*[®]

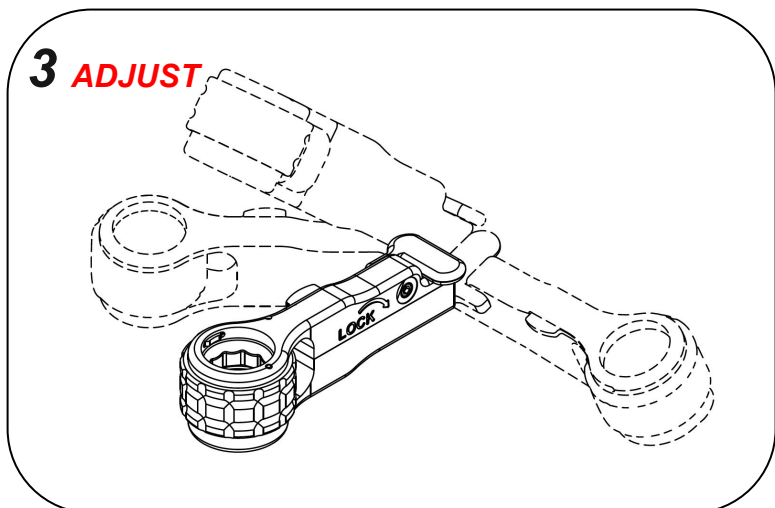
Steps 1–3 show one example of how *multiSTATION*[®] adapters (separately available) are attached and adjusted to the CLICK RELEASE™ *miniARM*[®]. The adapter may be attached to the CLICK RELEASE™ *miniARM*[®] either before or after attaching the *miniARM*[®] to a *multiSTATION*[®] RAIL CLAMP.



1. SLIDE the desired adapter onto the quick connect post while the adapter locking lever is rotated to the unlocked position.



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

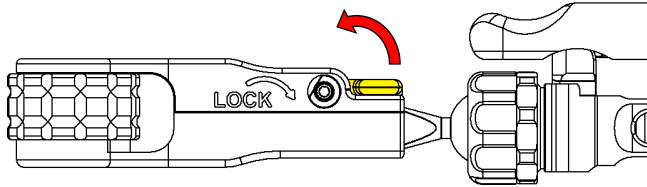


3. ADJUST the upper joint of the CLICK RELEASE™ *miniARM*[®] manually for minor repositioning without unlocking the *miniARM*[®].

REMOVAL and CLEANUP

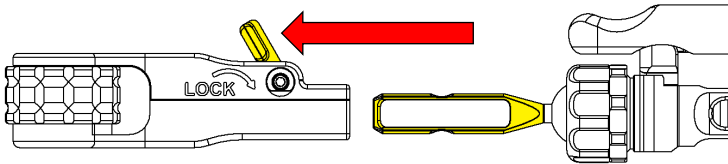
Removal of the *CLICK RELEASE™ miniARM®* may be eased by keeping the *miniARM®* in its locked position.

1 ROTATE



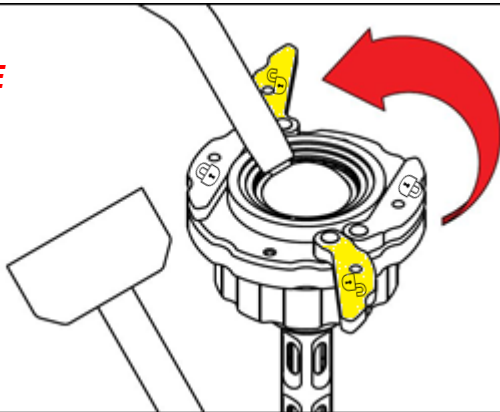
1. **ROTATE** the locking lever of the attached adapter to the unlocked position.

2 DETACH



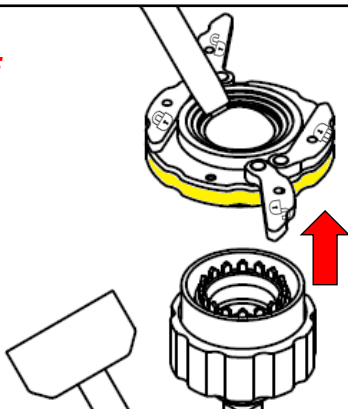
2. **DETACH** the adapter by sliding it off the quick connect post.

3 ROTATE



3. **ROTATE** the attachment nut off the *multiSTATION® RAIL CLAMP DOC* using both opposing unlock wings (U). Turn the attachment nut counterclockwise to unscrew from the DOC.

4 REMOVE

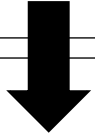


4. **REMOVE** the *CLICK RELEASE™ miniARM®* from the *RAIL CLAMP DOC*.

multiSTATION® CLICK RELEASE™ miniARM® 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 an adapter and/or a rail clamp 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 any adapters or rail clamps according to each device's instruction for use.
- 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.

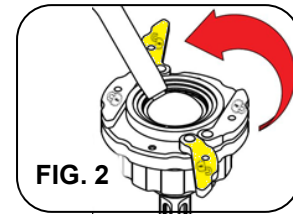
POINT OF USE



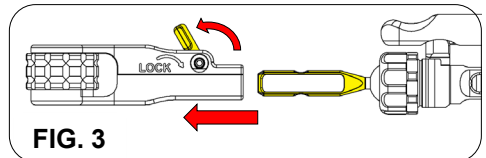
1. Disassemble and clean device immediately after use.
2. Do not allow soiled devices to dry.

PREPARATION

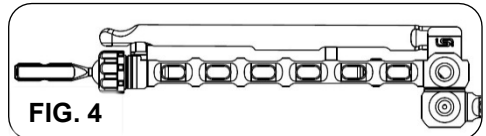
1. Remove the *CLICK RELEASE™ miniARM®* from the rail clamp by rotating the unlock wings away from their storage position and then turning the attachment nut counterclockwise (FIG. 2).



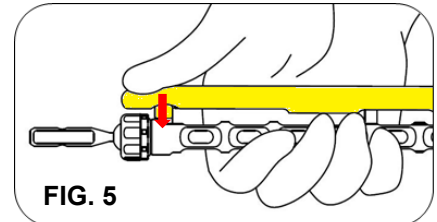
2. Remove any adapters from the *CLICK RELEASE™ miniARM®* by rotating the adapter locking lever and sliding the adapter off the quick connect post (FIG. 3).



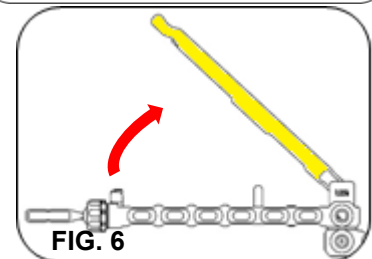
NOTE: FIG. 3 shows the cannula adapter being removed; other adapters are removed in the same manner.



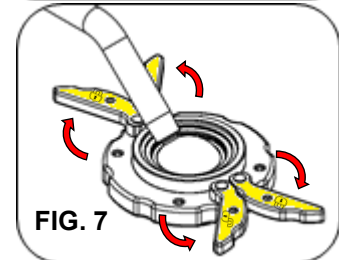
3. If the *CLICK RELEASE™* lever is in the locked position (FIG. 4), release the lock by fully squeezing the lever (FIG. 5) until an audible click indicates that the lever latch is disengaged from the locking catch. If necessary, manually raise the *CLICK RELEASE™* lever away from the upper arm.



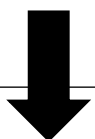
4. Raise the *CLICK RELEASE™* lever completely to ensure the *CLICK RELEASE™ miniARM®* is fully open and in the reprocessing position (FIG. 6).

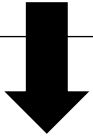


5. Rotate both sets of lock and unlock wings away from their storage positions to their open positions (FIG. 7).



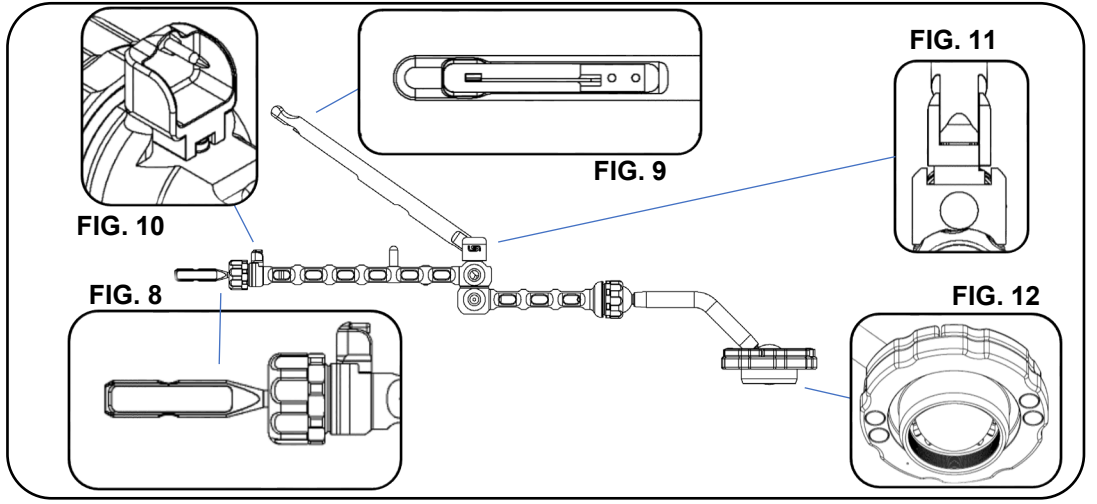
6. If using the *Sterilization Tray* (Part Number 100034), Clean the tray separately according to the sterilization tray instructions for use.





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 exterior surfaces, paying special attention to the following:
 - a. Retaining ring and upper ball joint (FIG. 8)
 - b. *CLICK RELEASE™* lever latch (FIG. 9) and locking catch (FIG. 10)
 - c. *CLICK RELEASE™* lever pivot point (FIG. 11)
 - d. DOC Ball, attachment nut, and internal threads (FIG.12)
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.



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.

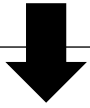
OR



AUTOMATED CLEANING

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:

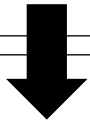
Treatment	Time (mm:ss)	Temperature °C (°F)	Additive
Pre-wash (Cold tap)	2:00	17 (63)	N/A
Wash (Hot tap)	2:00	40 (104)	Steris Prolystica® 2X
Rinse	2:00	70 (158)	N/A
Rinse	2:00	70 (158)	Optional lubricant
Dry	15:00	80 (176)	N/A



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 Instrument Lubricant on this device. Other instrument lubricant brands have not been tested and performance and results cannot be guaranteed.



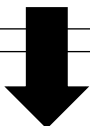
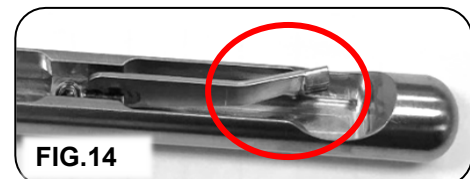
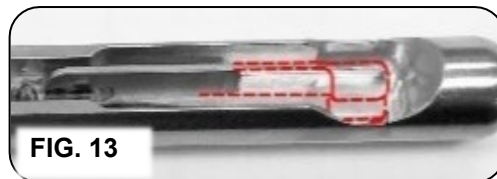
INSPECTION

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 FIGS. 8-12. 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 damaged latches or other parts. For example, see the broken lever latch outline of FIG. 13 and the bent lever latch of FIG. 14. If parts are damaged, discontinue use of the device in surgery, but complete reprocessing.

4. Perform a functional check for adequate device lock and release.



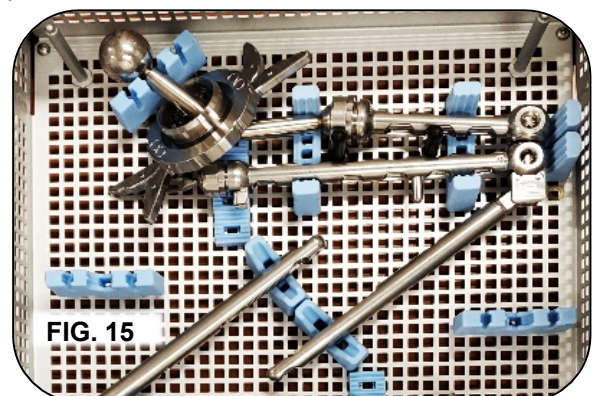
PACKAGING

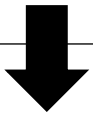
1. Ensure the *multiSTATION*® *CLICK RELEASE*™ *miniARM*® is in the fully open reprocessing position (refer to FIG. 6).

2. 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. 15.

3. Package the device according to TABLE 1. The barrier system for sterilized re-usable 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





STERILIZATION

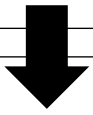
1. The device must be properly cleaned prior to sterilization.
2. Perform sterilization cycle according to TABLE 1:

TABLE 1: <i>multiSTATION</i>® <i>CLICK RELEASE</i>™ <i>miniARM</i>® 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	<i>multiSTATION</i> ® 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 *CLICK RELEASE*™ *miniARM*® has been validated to 100 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

- 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 *CLICK RELEASE*™ *miniARM*® shall be used in accordance with these instructions for use.
- Improper use of the *CLICK RELEASE*™ *miniARM*® 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 *CLICK RELEASE*™ *miniARM*®, patients must be immobilized or anesthetized.
- Discontinue use of the *CLICK RELEASE*™ *miniARM*® when moving the patient or when the patient is moving.
- 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.


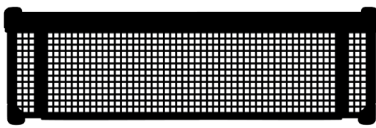
PRECAUTIONS

- The **CLICK RELEASE™ miniARM®** 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 the **CLICK RELEASE™ miniARM®** for a task other than what it is intended for can result in a damaged or broken device.
- Prior to use, inspect the **CLICK RELEASE™ miniARM®** 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 **CLICK RELEASE™ miniARM®**.
- Only the cleaning and sterilization processes which are defined within these instructions for use have been validated.
- Check stability of surgical table accessory rails or rail adapters before table mounting the **CLICK RELEASE™ miniARM®**. Only mount to secure surgical tables and well-affixed horizontal table rails; avoid attaching rail clamps to structures that are loose or not secure.
- When pivoting the **CLICK RELEASE™** lever from the locked to unlocked position, make sure to support the **miniARM®**. An unlocked and unsupported **miniARM®** can fall and may cause harm, damage to the device, damage to the affixed **multiSTATION®** adapter, or injury to the patient or user.
- Store at room temperature.

ADVERSE REACTIONS

- No documented adverse reactions.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the country competent authority.

ORDERING INFORMATION

TABLE 2: multiSTATION® CLICK RELEASE™ miniARM® PRODUCT ORDERING			
	REORDER	PRODUCT	DESCRIPTION
	REF 081010	multiSTATION® CLICK RELEASE™ miniARM®	1 Shelf Box
	REF 100034	multiSTATION® Sterilization Tray*	1 Shelf Box

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.

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:
www.lsisolutions.com/symbols

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

The Basic UDI-DI for this device is 0850200006multistationDF.

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