

The *multiSTATION*[®] ACCESS ADAPTER Technology Guide

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

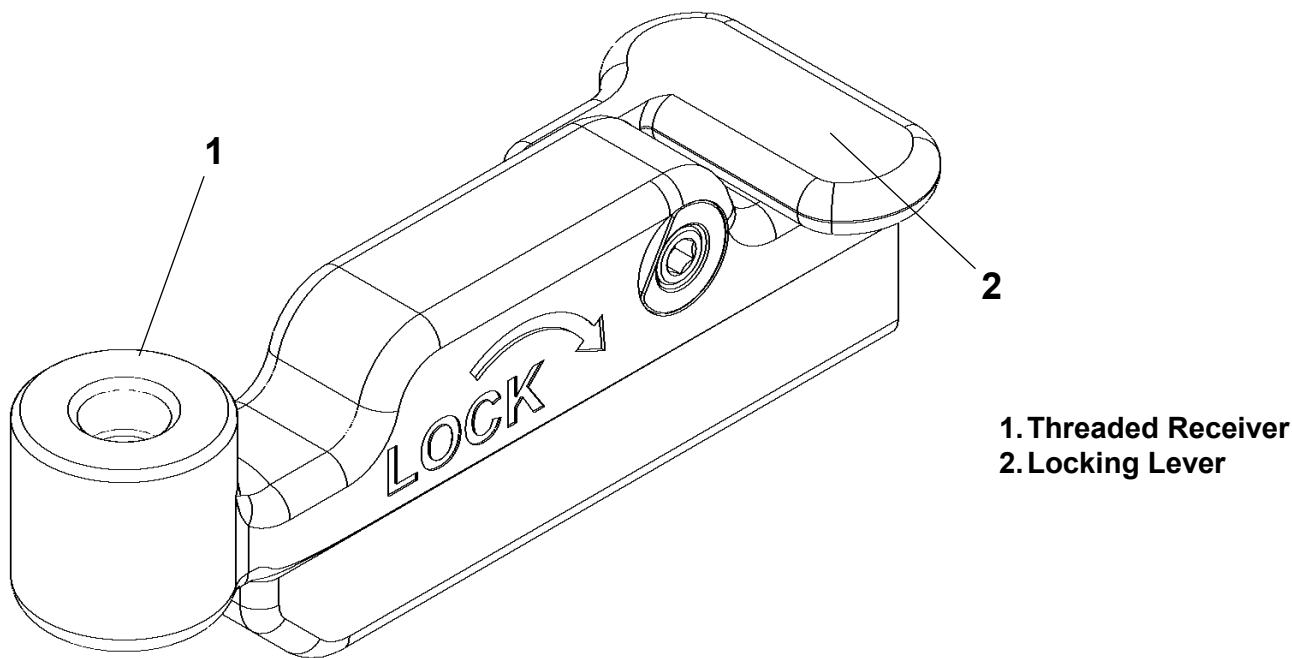


FIG. 1 – *multiSTATION*[®] ACCESS ADAPTER

LS SOLUTIONS[®]

***multiSTATION*[®] ACCESS ADAPTER DEVICE DESCRIPTION:**

The *multiSTATION*[®] ACCESS ADAPTER (FIG. 1) is used with the *RIGID miniARM*[®] or the *CLICK RELEASE*[™] *miniARM*[®]. The threaded receiver 1 provides a connection point onto which the mounting screw of a compatible LSI device is attached (refer to the Technology Guide of the selected device for more information before using the adapter). Rotating the locking lever 2 to the unlocked position allows the adapter to slide over the quick connect post of a *miniARM*[®]. The adapter is locked into place by rotating the locking lever to the locked position. The adapter is shown attached to a *miniARM*[®] with a compatible LSI device affixed to the threaded receiver in FIG. 2.

INDICATIONS FOR USE:

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

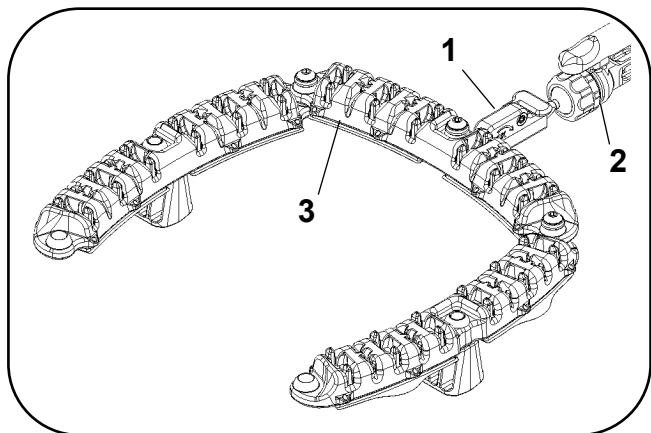


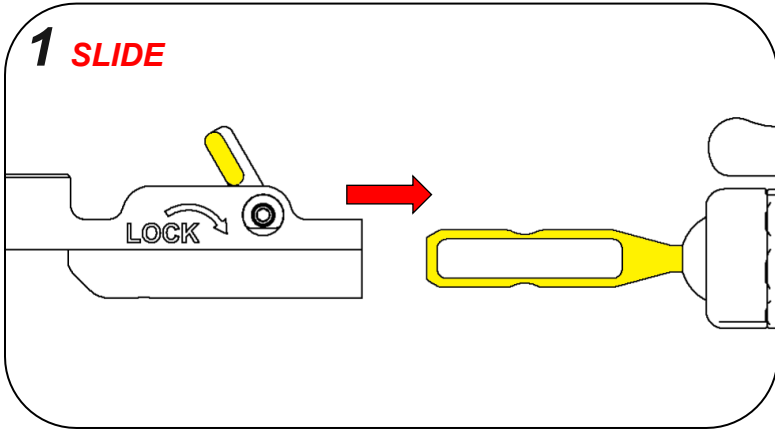
FIG. 2 – *multiSTATION*[®] ACCESS ADAPTER 1 attached to a *miniARM*[®] 2 with the *RAM*[®] Ring 3 attached to the threaded receiver.

FIG. 2

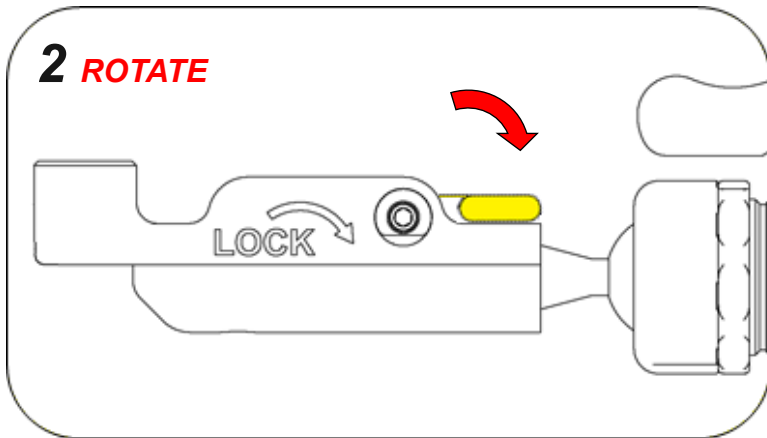
INSTRUCTIONS FOR USE

See the respective LSI SOLUTIONS® Technology Guides for full instructions for use and adjustment of LSI accessories in conjunction with the *multiSTATION*® ACCESS ADAPTER.

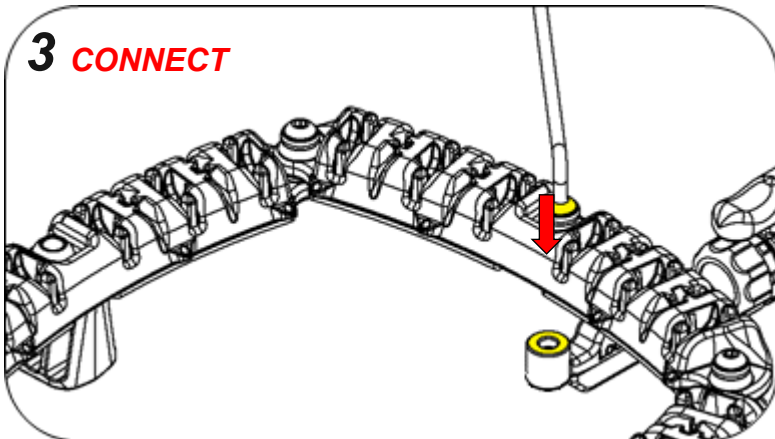
The *multiSTATION*® ACCESS ADAPTER may be attached to the *miniARM*® either before or after attaching the *miniARM*® to a *multiSTATION*® RAIL CLAMP.



1. SLIDE the 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 adapter onto the *miniARM*®.

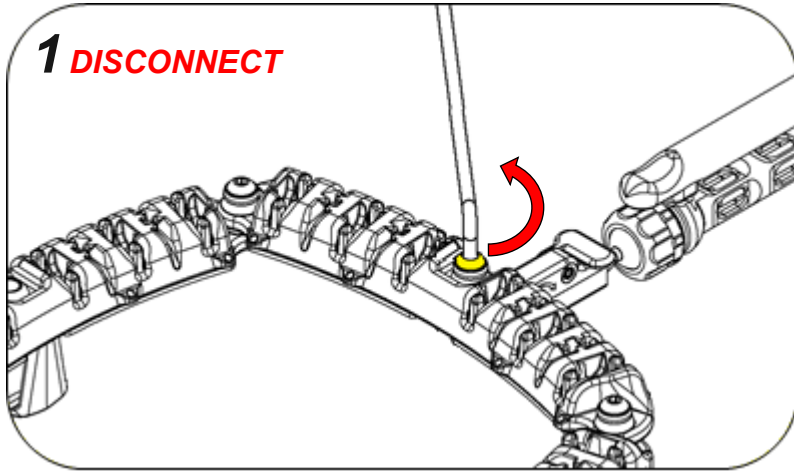


3. CONNECT the mounting screw of a compatible LSI accessory (*RAM*® Ring is shown here) to the adapter threaded receiver, using the 1/8" hex key (included with the *RAM*® Ring). Rotate the mounting screw clockwise to tighten..

REMOVAL AND CLEANUP

DISASSEMBLY

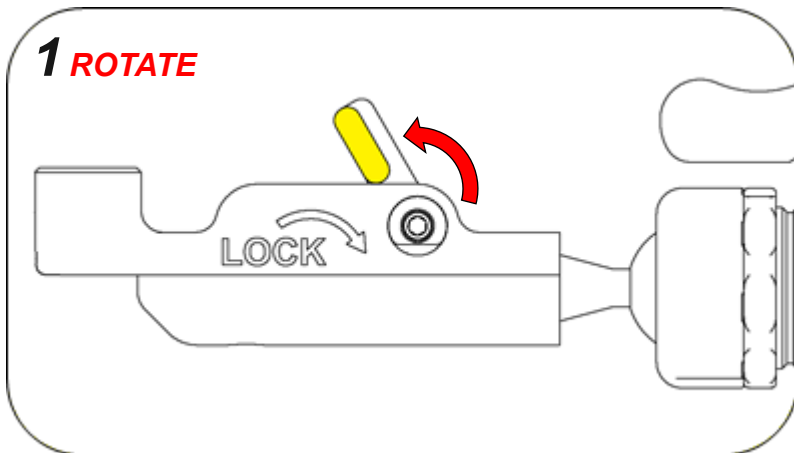
The *RAM® Ring* is a single-use device that should be disposed of in accordance with local regulations and hospital procedures. The *multiSTATION® ACCESS ADAPTER* can be reprocessed using the instructions in this technology guide.



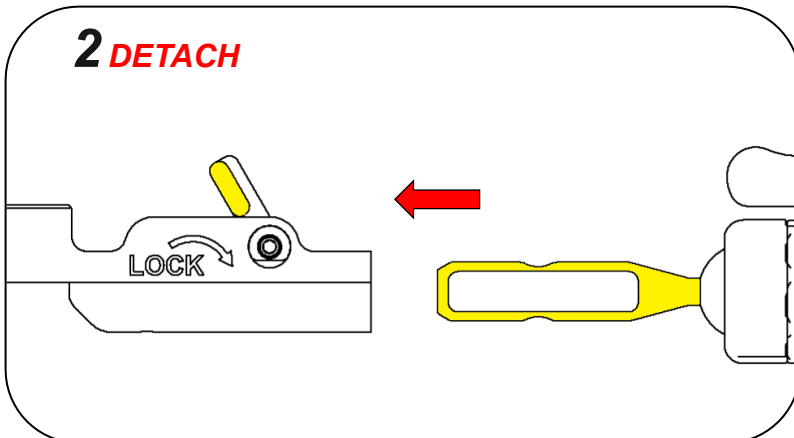
1. **DISCONNECT** the mounting screw of the LSI accessory (*RAM® Ring* is shown here) from the adapter threaded receiver, using the 1/8" hex key. Rotate the mounting screw counterclockwise.

REMOVING THE *multiSTATION® ACCESS ADAPTER* FROM THE *miniARM®*

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



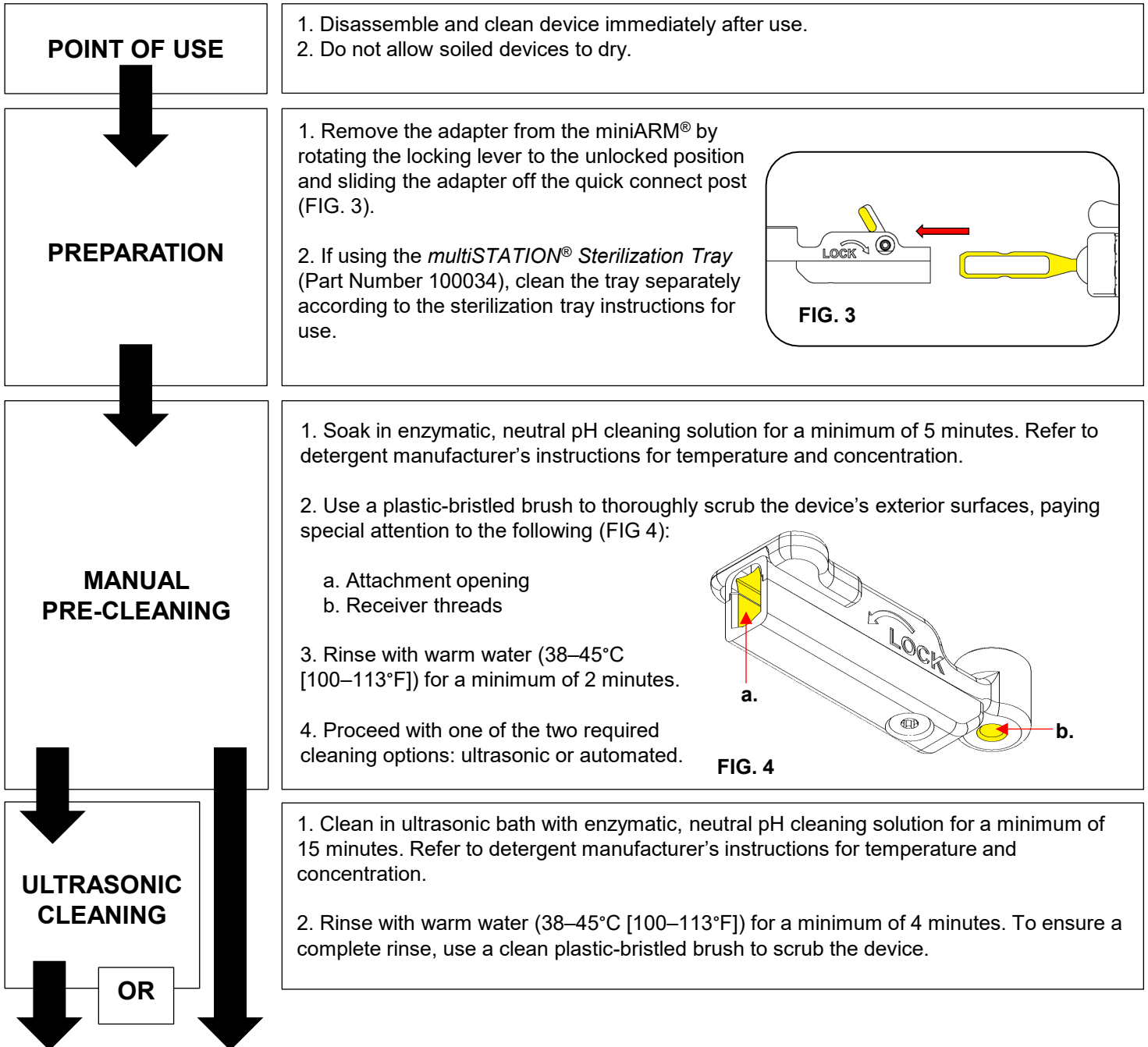
1. **ROTATE** the locking lever to the unlocked position.



2. **DETACH** the adapter by sliding it off the *miniARM®*'s quick connect post.

multiSTATION® ACCESS 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 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 miniARM®s or rail clamps according to each device's instructions 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.



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

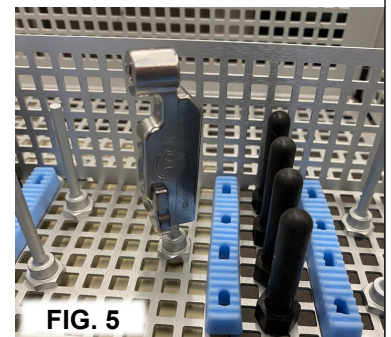
1. Carefully inspect the device to assure that all visible soil has been removed. Generally, unmagnified visual inspection under good light conditions is sufficient. Particular attention should be paid to the locations in FIG. 4. Repeat cleaning process if soil is detected.
2. Visually inspect the device 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.

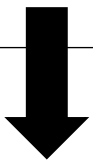
PACKAGING

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. 5.

2. 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

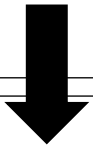
1. The device must be properly cleaned prior to sterilization.
2. Perform sterilization cycle according to TABLE 1:

TABLE 1: <i>multiSTATION</i>[®] ACCESS 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	<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 *multiSTATION*[®] ACCESS 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.



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 *multiSTATION*[®] ACCESS ADAPTER shall be used in accordance with these instructions for use.
- Improper use of the *multiSTATION*[®] ACCESS 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*[®] ACCESS ADAPTER, patients must be immobilized or anesthetized.
- Discontinue use of the *multiSTATION*[®] ACCESS ADAPTER when 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 relating to techniques, complications, and hazards should be consulted prior to use.

PRECAUTIONS

- **The *multiSTATION*[®] ACCESS 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.

PRECAUTIONS (CONTINUED)


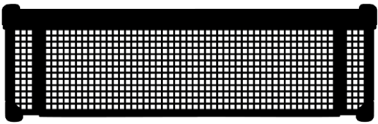
- Use of the *multiSTATION*[®] *ACCESS ADAPTER* for a task other than what it is intended for can result in a damaged or broken device.
- Prior to use, inspect the *multiSTATION*[®] *ACCESS ADAPTER* to ensure proper function and condition. Do not use devices if they do not satisfactorily perform their 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*[®] *ACCESS 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.
- 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*[®] *ACCESS ADAPTER* PRODUCT ORDERING

	REORDER	PRODUCT	DESCRIPTION
	REF 080670	<i>multiSTATION</i> [®] <i>ACCESS ADAPTER</i>	1 Shelf Box
	REF 100034	<i>multiSTATION</i> [®] <i>Sterilization Tray</i> *	1 Shelf Box



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*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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