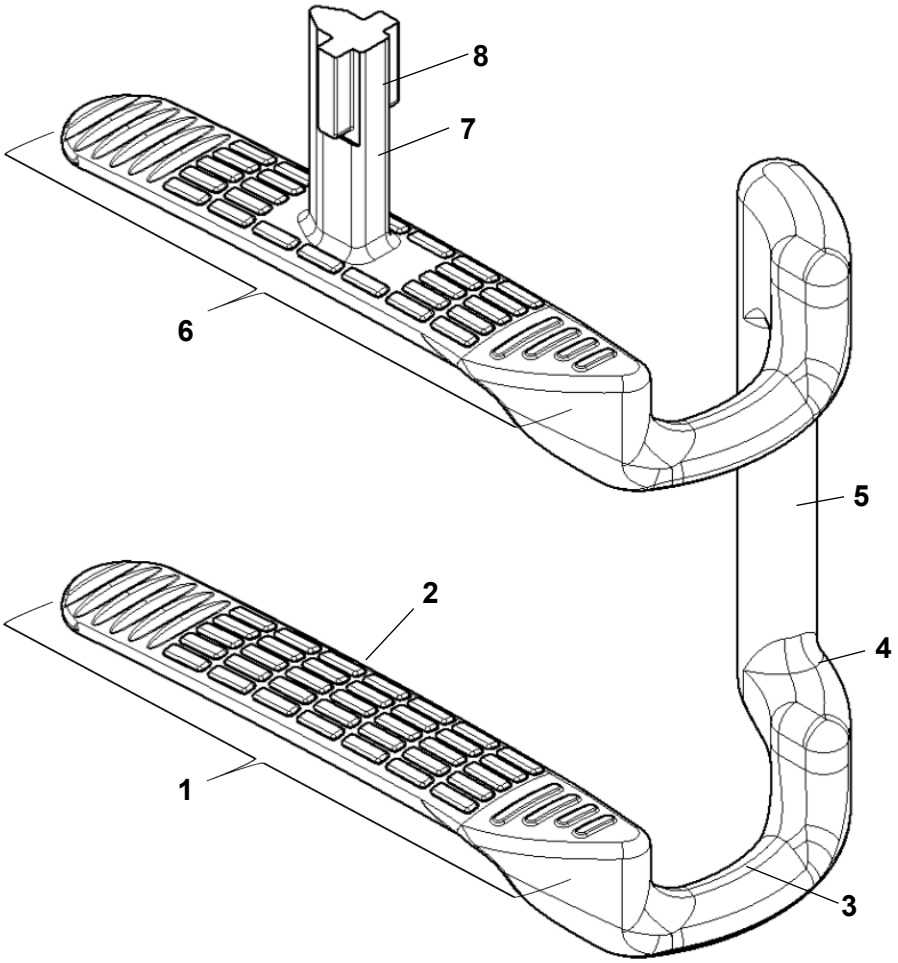
The *multiSTATION® BITA RetroSterno™ PADDLE* Technology Guide

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE



1. **Retractor Paddle**
2. **Textured Zone**
3. **LITA Notch**
4. **Rib Bolster**
5. **Connector Post**
6. **Paddle Replicator**
7. **Paddle Post**
8. **Attachment Stud**

SOLUTIONS®

FIG. 1 – *multiSTATION® BITA RetroSterno™ PADDLE*

***multiSTATION® BITA RetroSterno™ PADDLE* DEVICE DESCRIPTION:**

The *BITA RetroSterno™ PADDLE* (FIG. 1) is a reusable accessory to the *SubX™ STERNAL ASCENDER™ SYSTEM* (sold separately). The retractor paddle **1** is positioned within a thoracotomy incision to retract the sternum, providing bilateral internal thoracic artery (BITA) exposure. The retractor paddle has a textured zone **2** to grip the substernal tissue during retraction. The LITA notch **3** provides a working channel for left ITA access. The rib bolster **4** engages with the rib to provide less traumatic retraction. The connector post **5** joins the retractor paddle and the paddle replicator **6**. The paddle replicator provides an extracorporeal indicator of the retractor paddle's location and orientation within the incision. The paddle post **7** with attachment stud **8** is used to connect the *BITA RetroSterno™ PADDLE* to the *SubX™ STERNAL ASCENDER™*.

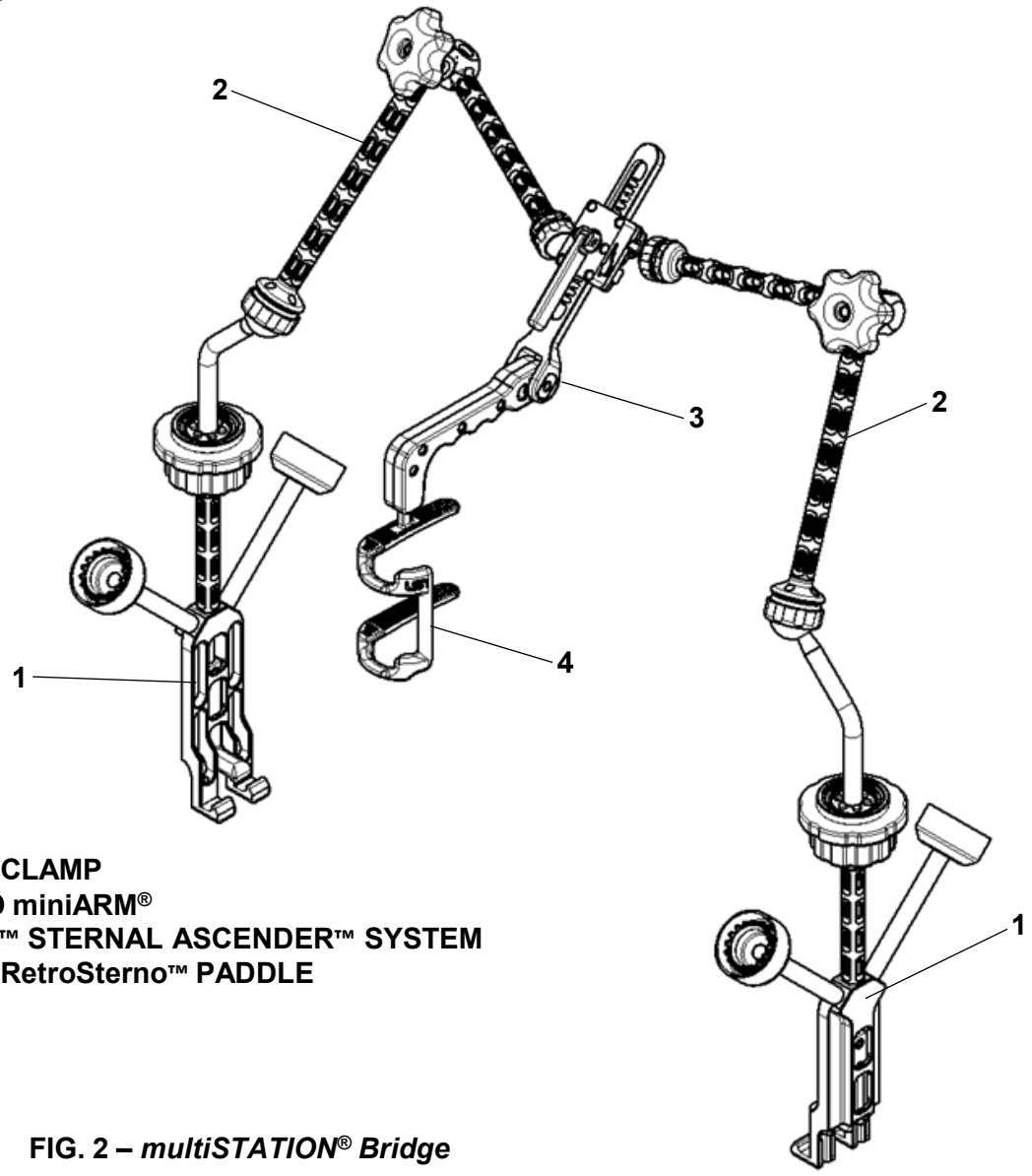
INDICATIONS FOR USE:

The *multiSTATION® BITA RetroSterno™ PADDLE* is indicated for use for retraction of bone and soft tissue.

INSTRUCTIONS FOR USE

SETTING UP, POSITIONING, and ATTACHING the multiSTATION® Bridge

Note: Full setup instructions are found in the instructions for use for components 1-3 below.



1. RAIL CLAMP
2. RIGID miniARM®
3. SubX™ STERNAL ASCENDER™ SYSTEM
4. BITA RetroSterno™ PADDLE

FIG. 2 – *multiSTATION® Bridge*

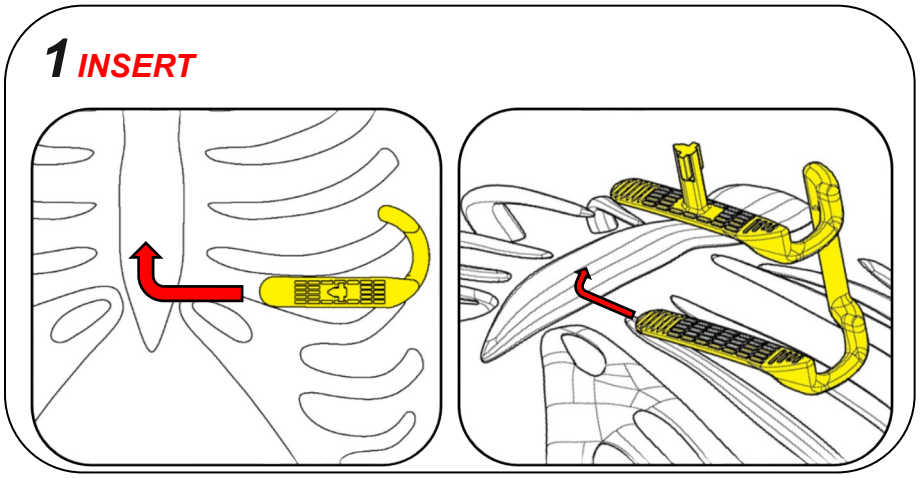
***multiSTATION® Bridge* DESCRIPTION:**

The *multiSTATION® Bridge* (FIG. 2) comprises two *RIGID miniARM®s,* two *multiSTATION® RAIL CLAMPS,* a *SubX™ STERNAL ASCENDER™ SYSTEM*, and a compatible accessory such as a *BITA RetroSterno™ PADDLE.*

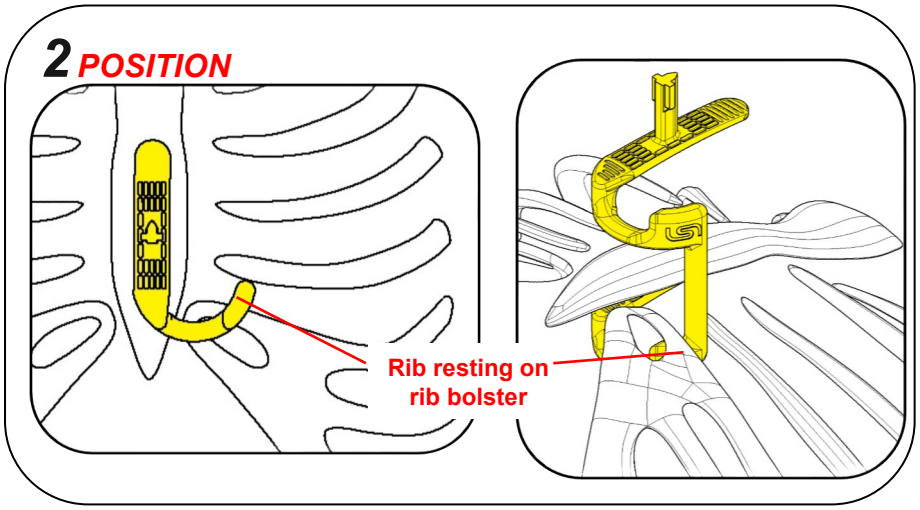
The bridge is assembled by attaching the rail clamps to draped surgical table rails, connecting a *miniARM®* to the rail clamp, and then connecting the ascender to the *miniARM®* s. This configuration provides a stable, rigid system with which compatible accessories may be securely raised and lowered.
The *miniARM®*s may be connected to either a side or center receiving DOC of the rail clamp to provide positional adjustability. The ascender, with a compatible accessory attached, is connected to the two *miniARM®*s and adjusted into position. Once the desired position of the bridge is reached, the system is locked into place. The swivel bar is used to raise the compatible accessory, providing a stable opening to the surgical site. The accessory paddle can be lowered by rotating the swivel bar clockwise while pressing the ratcheting latch. The bridge can then be repositioned, or a different accessory paddle can be installed.

INSTRUCTIONS FOR USE

INSERTING and POSITIONING the BITA RetroSterno™ PADDLE in the chest and ATTACHING to the SubX™ STERNAL ASCENDER™



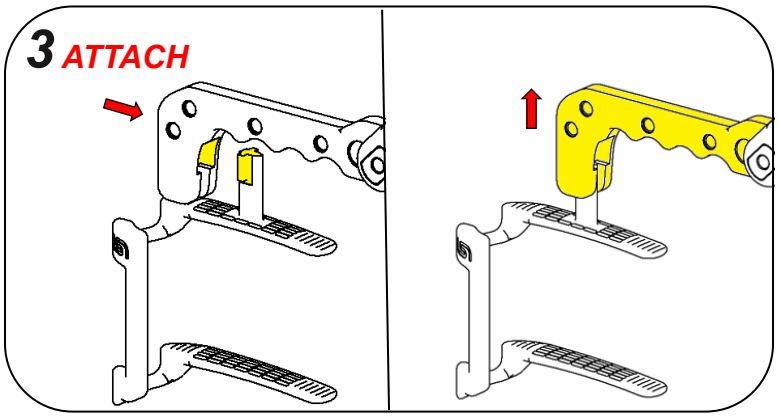
1. ***INSERT*** the retractor paddle through the incision into the chosen intercostal space.



2. ***POSITION*** the paddle by pivoting until paddle replicator is aligned directly above the sternum and the rib bolster is against the base of the chosen rib.

NOTE: The paddle replicator represents the location and orientation of the retractor paddle. The retractor paddle should always be kept parallel to the sternum.

NOTE: Ensure that the SubX™ STERNAL ASCENDER™ arch keystone is at the top of the rack to allow for maximum retraction. Refer to the *SubX™ STERNAL ASCENDER™* instructions for more information.

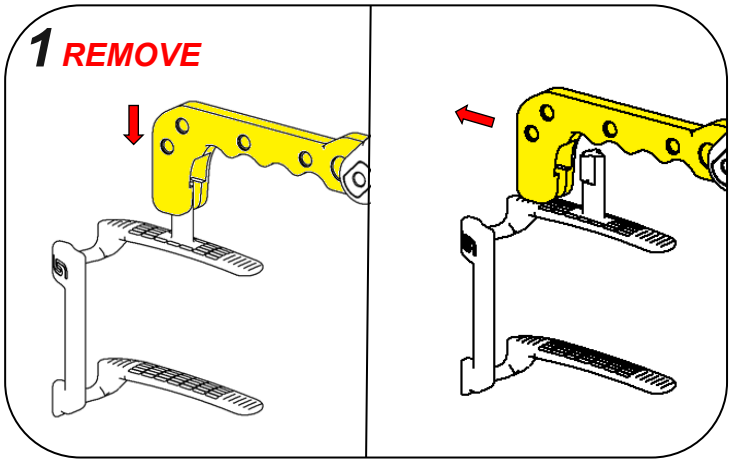


3. ***ATTACH*** the SubX™ STERNAL ASCENDER™ to the paddle by sliding the SubX™ accessory slot of the hand grip over the BITA attachment stud and pulling up to secure.

Refer to the *SubX™ STERNAL ASCENDER™* instructions to complete the system setup.

PRECAUTION: Like all metal implements used in surgery, the components of this system conduct electricity and can be associated with electrical shock or arcing from cautery or other sources of current. If dissecting the LITA, the user must exercise good clinical judgement when dissecting near the LITA relief.

REMOVAL



1. REMOVE the *SubX™ STERNAL ASCENDER™* from the paddle by pulling the hand grip down and sliding it forward.

multiSTATION® BITA RetroSterno™ PADDLE REPROCESSING

- Disassemble and clean the device immediately after use. Do not allow a soiled device to dry.
- The *BITA RetroSterno™ PADDLE* is not validated to be cleaned or sterilized attached to the *SubX™ STERNAL ASCENDER™*.
- 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 other multiSTATION® components 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.

POINT OF USE	1. Disassemble and clean device immediately after use. 2. Do not allow soiled device to dry.
PREPARATION	1. 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. 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. 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. 3.

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
- Grade appropriate for weight of loaded tray per sterilization tray instructions for use and facility procedures

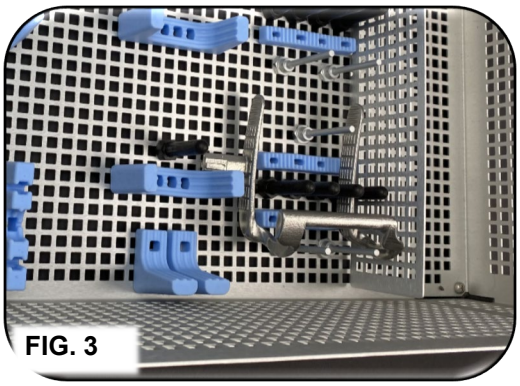


FIG. 3

STERILIZATION

1. The device must be properly cleaned prior to sterilization.

2. Perform sterilization cycle according to TABLE 1:

TABLE 1: ***multiSTATION® BITA RetroSterno™ PADDLE* 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.

BITA RetroSterno™ PADDLE 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.

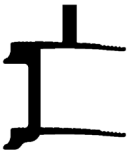
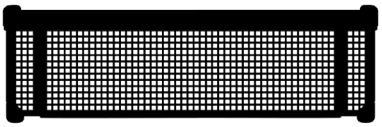
CONTRAINDICATIONS
- Do not use with attachments other than accessories provided by LSI SOLUTIONS®.
- These devices are not intended for use except as indicated.

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 *BITA RetroSterno™ PADDLE* shall be used in accordance with these instructions for use.
- Improper use of *BITA RetroSterno™ PADDLE* may cause serious injury or death. 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 *BITA RetroSterno™ PADDLE,* patients must be immobilized or anesthetized.
- Discontinue use of the *BITA RetroSterno™ PADDLE* when patient is moving or being moved.
- Do not use this retraction system without adequate knowledge or experience regarding surgical retraction, including sternal and rib retraction. Avoid compressing, tensioning, displacing, or compromising tissue structures, such as the heart, that may be injured or lead to interoperative or postoperative loss of function.
- 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 *BITA RetroSterno™ PADDLE is* packaged as non-sterile.** Clean and sterilize prior to use.
- Proper cleaning, sterilization, packaging, storage and deployment are required to ensure sterility and safe 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.
- Use of the *BITA RetroSterno™ PADDLE* for a task other than what it is intended for can result in a damaged or broken device, and/or injury or death.
- Prior to use, inspect the *BITA RetroSterno™ PADDLE* 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**.**
- Ensure system connections, fittings and engagement features are secured appropriately, fully and accurately positioned to confer the required function.
- Ensure placement of system components to not compromise patient access during surgery or injure patient or tissue structures.
- Ensure retractors are placed in contact with tissue structures under adequate visualization. Do not force system components against non-targeted tissue.
- Ensure all system components are appropriately removed from the patient and operating room table prior to patient movement.
- 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.
- Like all metal implements used in surgery, the components of this system conduct electricity and can be associated with electrical shock or arcing from cautery or other sources of current.
- Avoid mechanical shock or overstressing *BITA RetroSterno™ PADDLE*.
- 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® BITA RetroSterno™ PADDLE* PRODUCT ORDERING			
	REORDER	PRODUCT	DESCRIPTION
	REF 081581	***multiSTATION® BITA RetroSterno™ PADDLE***	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.

Rx Only NON STERILE MD

Symbol Glossary: www.lsisolutions.com/symbols

P/N 081592D 18-FEB-2026