The multiSTATION® triDOC®, monoDOC™, duoDOC™ L, duoDOC™ R RAIL CLAMP
Technology Guide

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

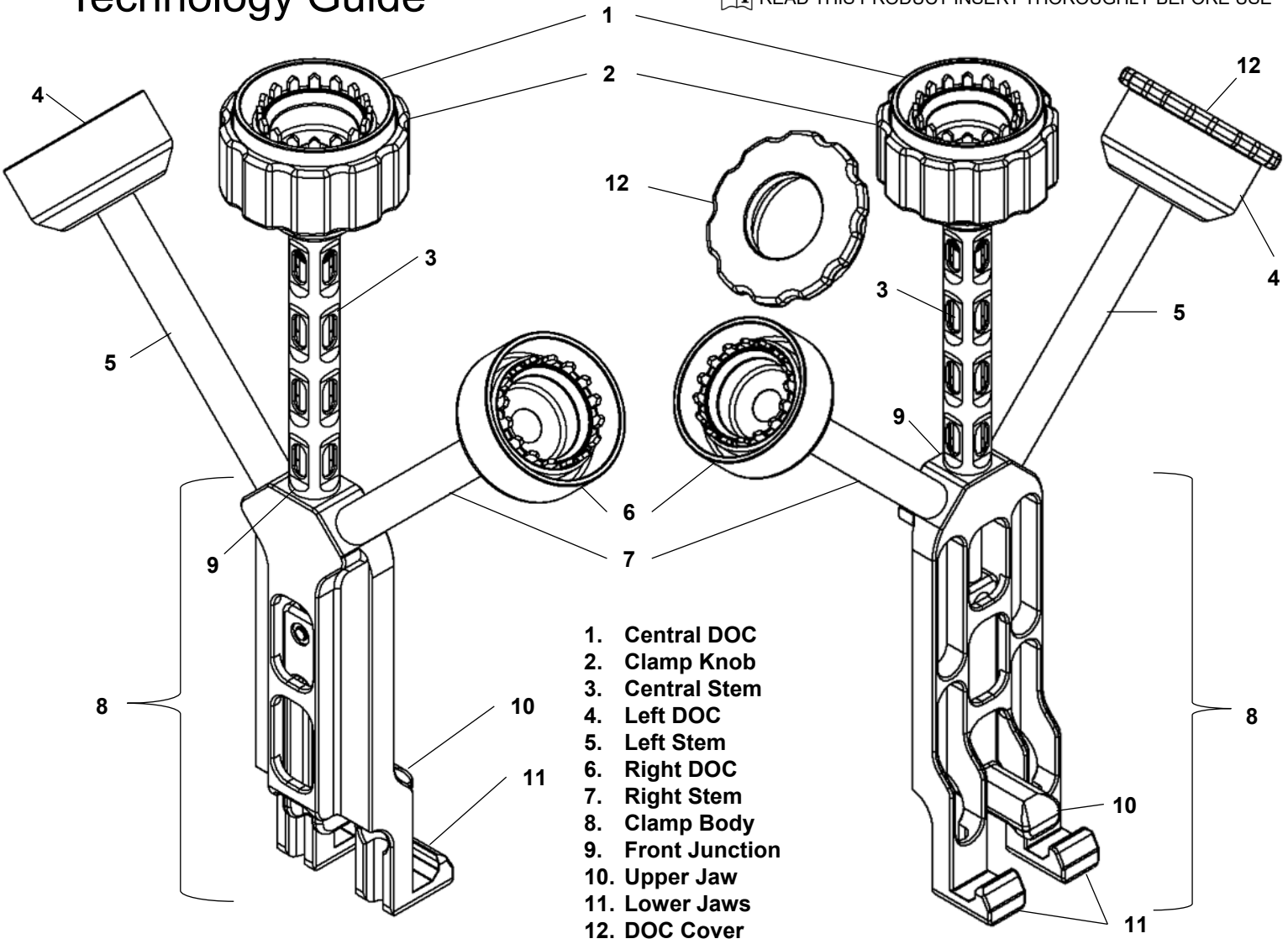

FIG 1A: multiSTATION® triDOC® *RAIL CLAMP* Front View

FIG 1B: multiSTATION® triDOC® *RAIL CLAMP* Back View

LSSOLUTIONS®

***multiSTATION® RAIL CLAMP* DEVICE DESCRIPTION:**

The *multiSTATION® RAIL CLAMP* device is a reusable, sterilizable, repositionable, multiple instrument holding metal base that clamps over the sterile drapes onto the underlying operating room table horizontal rail using a proprietary manually powered jaw mechanism for attachment of *multiSTATION® System* accessories. FIG. 1 shows the front and back view of the *triDOC® RAIL CLAMP* incorporating the crenellated central DOC **1**, which is the receiving socket for the attachment of these accessories above a clamp knob **2** that rotates on the top of the fenestrated central stem **3**. When viewed from the front, to the left of the central stem is the crenellated left DOC **4** and the left stem **5**; to the right, the crenellated right DOC **6** and the right stem **7**. The stems connect to the clamp body **8** at the front junction **9**. A connector passing through the fenestrated central stem links the central DOC to a mobile upper jaw **10** positioned above two fixed lower jaws **11**. Side DOCs also include removable DOC covers **12**. The *RAIL CLAMP* is available in four configurations based on the number of side DOCs and their locations: the *triDOC®* (FIG. 1, FIG. 2A), *the monoDOC™* (FIG. 2B), the *duoDOC™ L {left}* (FIG. 2C) and the *duoDOC™ R {right}* (FIG. 2D).

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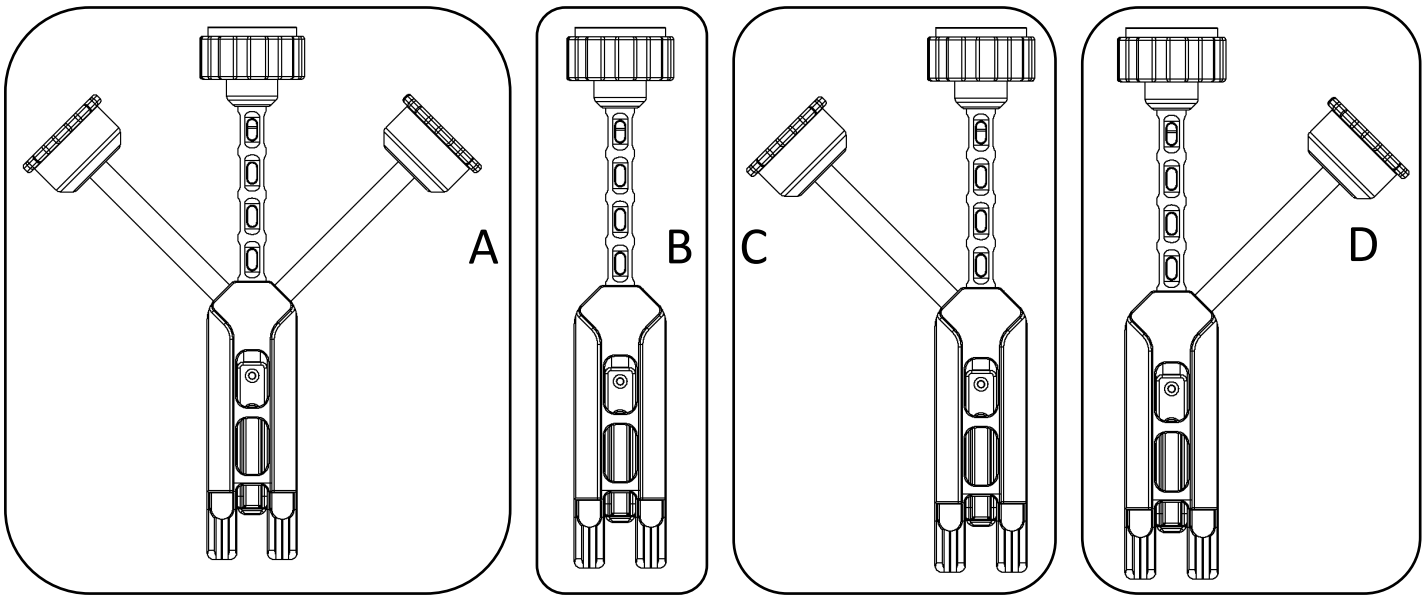


FIG. 2A-D: Front View of the 4 different *multiSTATION® RAIL CLAMP* product offerings. 2A: *triDOC®*, 2B: *monoDOC™*, 2C: *duoDOC™ L*, 2D: *duoDOC™ R*

***multiSTATION® RAIL CLAMP* DEVICE DESCRIPTION** (continued): FIG 3. shows a left cutaway of the front of a *triDOC® RAIL CLAMP* with a purple colorized central DOC, connector link and mobile upper jaw in the "Up" position (FIG. 3A) compared to the upper jaw "Down" position (FIG. 3B) relative to a surgical table horizontal rail. With the fixed bottom jaws positioned (FIG. 3A) under the bottom surface of the targeted section of the draped operating room table rail, clockwise rotation of the clamp knob drives the mobile upper jaw down onto the upper surface of the table rail (FIG. 3B), thereby securely affixing the *RAIL CLAMP* over the drape and onto the table. Each uncovered crenellated DOC is threaded and contoured to enable precise attachment and orientation of *multiSTATION® System* accessories (e.g. *CLICK RELEASE™ miniARM®* or *RIGID miniARM®)*. After removal of all *miniARMs®* from each crenellated DOC, the *RAIL CLAMP* can be repositioned or removed by counterclockwise rotation of the clamp mounting knob to pull the mobile upper jaw away (FIG. 3A) from its clamped position.

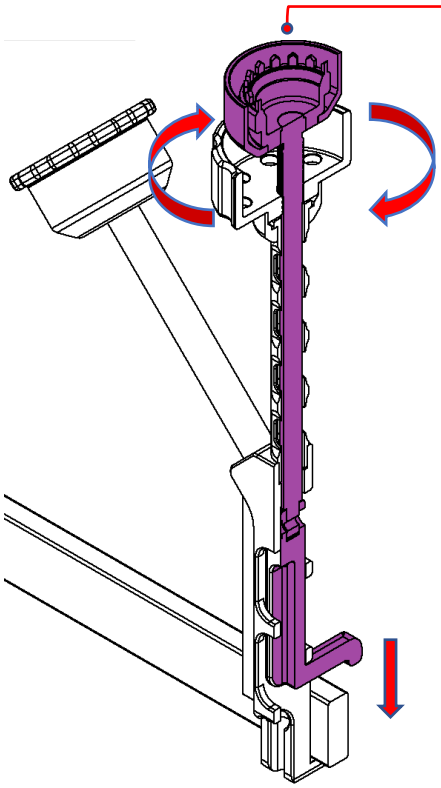


FIG. 3A: *triDOC® RAIL CLAMP* in the "Up" Position

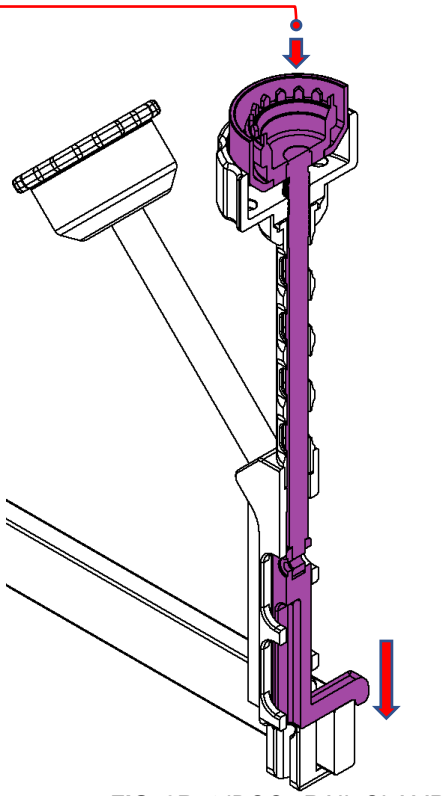


FIG. 3B: *triDOC® RAIL CLAMP* in the "Down" Position

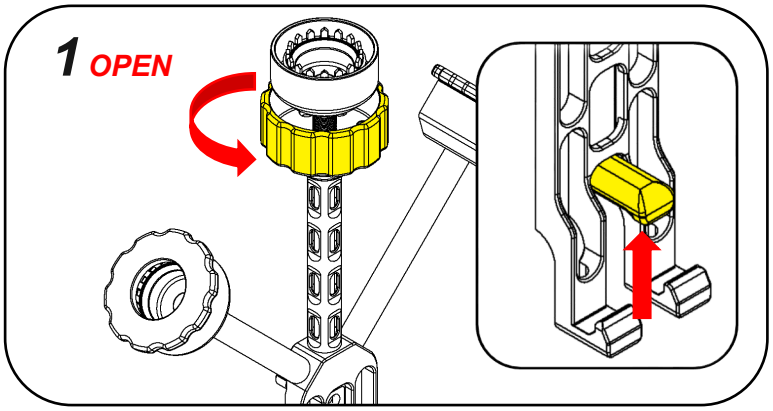
INDICATIONS FOR USE:

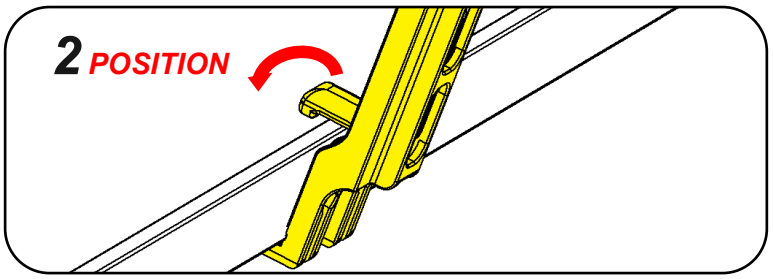
The *multiSTATION® monoDOC™*, the *duoDOC™ L*, the *duoDOC™ R*, and the *triDOC® RAIL CLAMPs* are indicated for use by surgeons to hold instruments in a fixed position for a period of time.

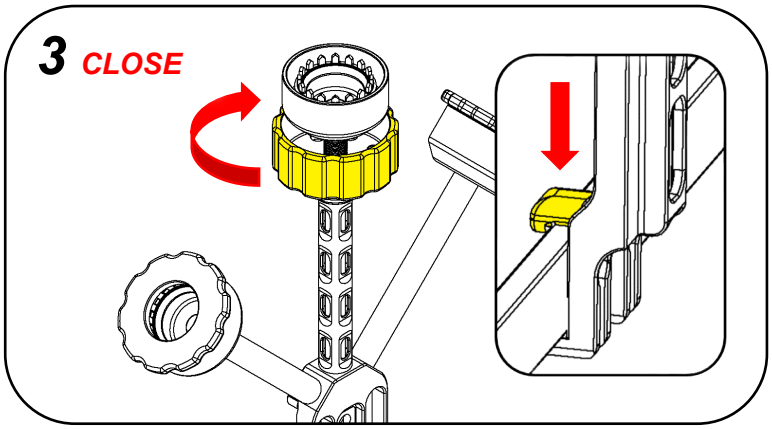
INSTRUCTIONS FOR USE

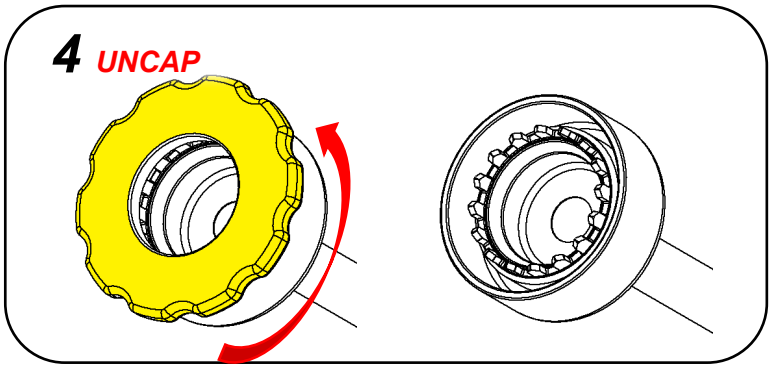
GENERAL SETUP & USE:

The steps below show the *triDOC® RAIL CLAMP*. The same attachment technique applies to the *monoDOC™, duoDOC™ L,* and *duoDOC™ R RAIL CLAMP* configurations. The *RAIL CLAMP* is designed to attach to a surgical table's horizontal rail with dimensions of 9–10 mm in width x 25–30 mm in height (0.35–0.39 in. x 0.98–1.18 in.).









ATTACHMENT TO A SURGICAL TABLE

1. ***OPEN*** the space between the mobile upper jaw and the fixed lower jaws of the clamp body to become wide enough to receive the selected portion of the operating room rail by turning the clamp knob counterclockwise to draw the mobile jaw away from the fixed lower jaws. DOC covers should be attached on side DOCs to reduce exposure of DOC crenellations.

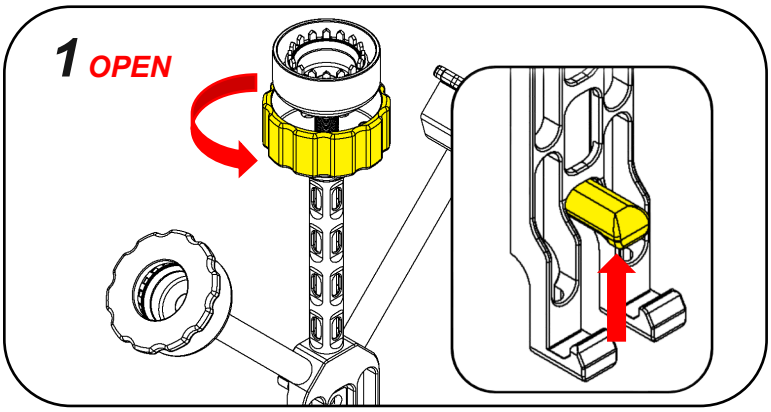
2. ***POSITION*** the jaws of the clamp body over the draped table rail with the front of the rail clamp facing away from the table and angled straight up. Avoid damaging the surgical drapes.

3. ***CLOSE*** the mobile upper jaw of the rail clamp down onto the fixed lower jaws by turning the clamp knob clockwise until it comes to a firm stop. Do not touch below level of sterility described in your hospital's policies. Care should be taken to not touch the crenellations within the DOCs, which could damage gloves or cause injury if inappropriately handled.

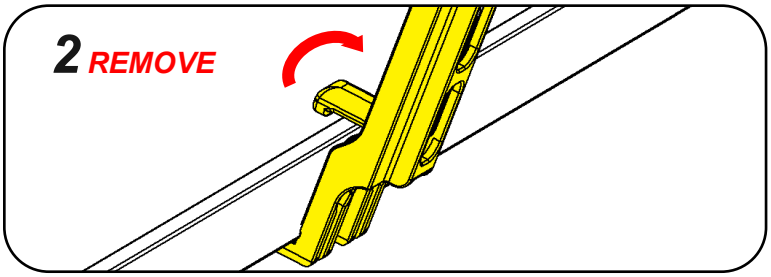
4. ***UNCAP*** crenellated side DOC(s) by turning the DOC cover(s) counterclockwise until fully unthreaded from the rail clamp. Keep the DOC cover(s) within the sterile field for reinstallation if accessory is detached and/or prior to rail clamp removal. Compatible accessories may now be attached per each component's instructions for use technology guide.

REMOVAL AND CLEANUP

Remove all previously attached accessories from the *miniARM*® as well as each *miniARM*® from the rail clamp according to each component's instructions for use. Reattach sterile DOC cover(s) to side DOC(s).



1. ***OPEN*** the rail clamp jaws by turning the clamp knob counterclockwise until the rail clamp jaws fully release from the surgical table rail.



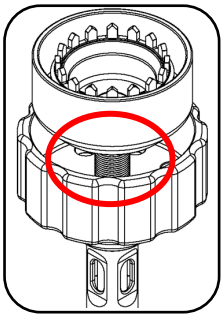
2. ***REMOVE*** rail clamp with attached DOC cover or covers by grasping the upper portion of a side stem and passing the rail clamp off from the surgical field.

multiSTATION® *RAIL CLAMP* 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 adapter attached including all DOC covers.
- 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*® or adapters according to each device's instruction for use.
- Avoid the risk of damaging gloves or injuring skin on the crenellations within the DOCs.
- 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. Turn the rail clamp knob counterclockwise until all threads (in the red circle) are visible and the rail clamp knob stops turning (FIG. 4) and the *multiSTATION*® *RAIL CLAMP* is as high as it goes (FIG. 5)

FIG. 4



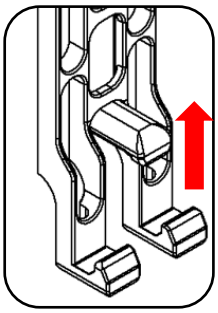


FIG. 5

MANUAL PRE-CLEANING

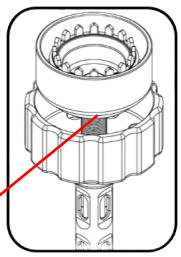
1. Soak in enzymatic, neutral pH cleaning solution for a minimum of 5 minutes. Refer to detergent manufacturer's instructions for temperature and concentration.

2. Use a plastic-bristled brush to thoroughly scrub the device's exterior surfaces, paying special attention to the following:
   a) Threads of central doc stem (FIG. 6)
   b) Inside the side DOC socket (FIG. 7)
   c) Note that for the *triDOC® RAIL CLAMP* there are 2 side DOCs to consider (FIG. 7)

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. 6



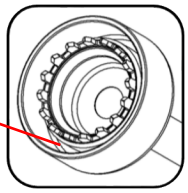


FIG. 7

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. 6-7. Repeat cleaning process if soil is detected.

2. Visually inspect the device for mild or excessive corrosion as seen in FIG. 8. If corrosion is present, discontinue use of the device in surgery, but complete reprocessing.

FIG. 8

INSPECTION (CONTINUED)

3. Visually inspect the device for damage. If parts are damaged, discontinue use of the device in surgery, but complete reprocessing.

4. Perform a functional check for adequate tightening and release by turning the clamp knob clockwise and counterclockwise.

PACKAGING

1. Ensure the upper jaw is in the fully open reprocessing position (FIGs. 4, 5, 9).

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. 9. Place detached DOC cover(s) in general instrument cleaning area.

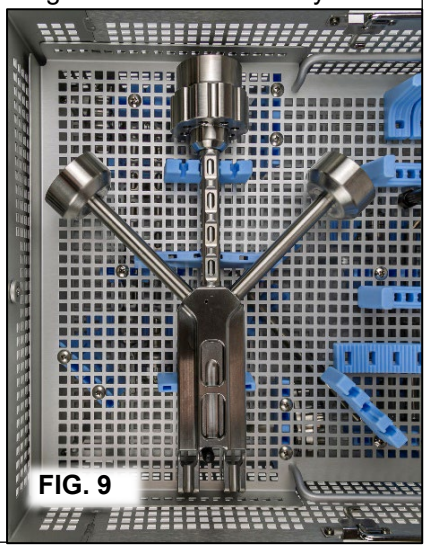


FIG. 9

3. 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

STERILIZATION

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

2. Perform sterilization cycle according to TABLE 1:

TABLE 1: *multiSTATION® RAIL CLAMP* 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.

STERILIZATION (CONTINUED)	The *multiSTATION® RAIL CLAMP* 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®.
- 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® RAIL CLAMP* shall be used in accordance with these instructions for use.
- Improper use of the *multiSTATION® RAIL CLAMP* 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® RAIL CLAMP*, patients must be immobilized or anesthetized.
- Discontinue use of the *multiSTATION® RAIL CLAMP* when moving patient or when 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 relative to techniques, complications, and hazards should be consulted prior to use.
- Avoid touching with sterile gloved hands any part of the rail clamp that extends below the level considered sterile in your operating room. For example, many hospitals consider any item below a gowned person's waist to be no longer in the sterile field.
- Treat all breaches (e.g., holes, tears and perforations) in the protective sterile drape as a site that is no longer sterile. Any section of a breached drape or part of a rail clamp that contacts a rail under a breached drape should be treated as contaminated. Avoid contact by sterile gloves, instruments, cords, tubes, etc. with any potential contamination source.

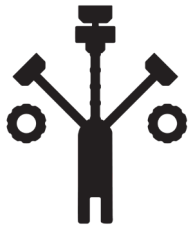
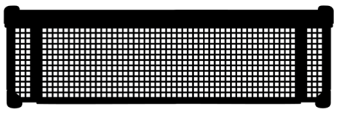
PRECAUTIONS

- **The *multiSTATION® RAIL CLAMP* is packaged as non-sterile.** Clean and sterilize prior to use.
- Ensure the patient is well secured to the surgical table and never in direct contact with the rail clamp.
- 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® RAIL CLAMP* for a task other than what it is intended for can result in a damaged or broken device.
- Prior to use, inspect the *multiSTATION® RAIL CLAMP* 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® RAIL CLAMP*.
- Avoid inappropriate contact with the crenellations within the DOCs, which could damage gloves or cause injury. Glove perforation can lead to contamination of the surgical field.
- Keep the DOC cover(s) within the sterile field for reinstallation if desired.
- Only the cleaning and sterilization processes which are defined within these instructions for use have been validated.
- Check stability of surgical table rails or rail adaptors before table mounting the *multiSTATION® RAIL CLAMP*. Only mount to secure surgical tables and well-affixed horizontal table rails; avoid attaching rail clamps to structures that are loose or not secure.
- The *multiSTATION® RAIL CLAMP* is compatible with USA, EU and Swiss operating room table rail sizes, 9–10 mm wide x 25–30 mm tall (0.35–0.39 in. wide x 0.98–1.18 in. tall).
- 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.

TABLE 2: multiSTATION® RAIL CLAMP PRODUCT ORDERING			
	REORDER	PRODUCT	DESCRIPTION
	REF 081000	***multiSTATION® triDOC® RAIL CLAMP***	1 Shelf Box
	REF 081022	***multiSTATION® monoDOC™ RAIL CLAMP***	1 Shelf Box
	REF 081023	***multiSTATION® duoDOC™ L RAIL CLAMP***	1 Shelf Box
	REF 081024	***multiSTATION® duoDOC™ R RAIL CLAMP***	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

Rx Only NON STERILE MD

Symbol Glossary:
www.lsisolutions.com/symbols

CE

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

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

P/N 080960J 18-MAY-2026