# multiSTATION® DOC-X 15™ EXTENDER Technology Guide

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

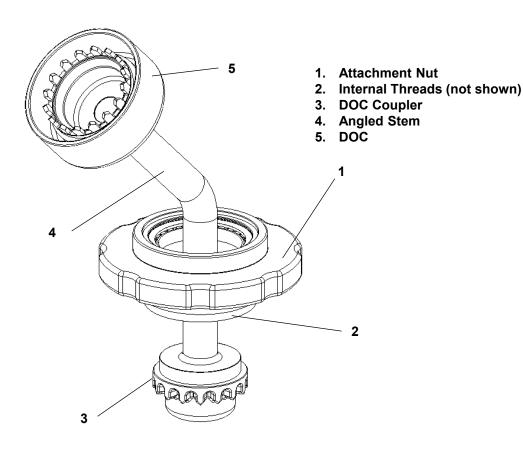


FIG. 1: DOC-X 15™ EXTENDER



#### DOC-X 15™ EXTENDER DEVICE DESCRIPTION:

The DOC-X 15™ EXTENDER (FIG 1) is a multiSTATION® accessory. It is a secure, repositionable and reusable device that attaches to a selected multiSTATION® RAIL CLAMP to extend the reach of a miniARM® (CLICK RELEASE™ or RIGID). The EXTENDER attachment nut 1 features internal threads 2 (not shown) that, along with the DOC coupler 3 allows it to be secured to the RAIL CLAMP. The EXTENDER angled stem 4 joins the DOC coupler to the threaded, crenellated DOC 5 that can receive the desired miniARM®. The DOC-X 15™ EXTENDER changes the angle from the RAIL CLAMP to the miniARM® by 45° and extends the system reach by 15 cm.

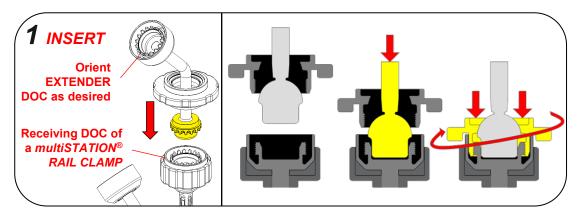
#### **INDICATIONS FOR USE:**

The *DOC-X* 15<sup>™</sup> EXTENDER is indicated for use by surgeons to hold instruments in a fixed position for a period of time.

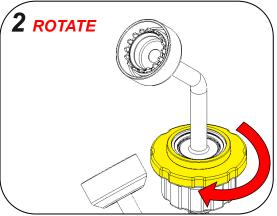
# INSTRUCTIONS FOR USE GENERAL SETUP & USE:

The *DOC-X 15™ EXTENDER* must be cleaned and sterilized before each use.

The DOC-X 15™ EXTENDER is designed to extend the reach of a miniARM® (CLICK RELEASE™ or RIGID).



1. **INSERT** the **EXTENDER** DOC coupler into the receiving DOC of the RAIL CLAMP, while orienting the EXTENDER DOC in the desired position.



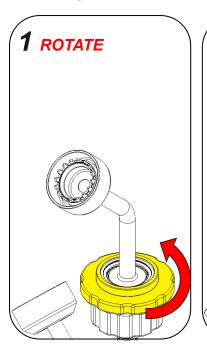
**2. ROTATE** the EXTENDER attachment nut clockwise, threading it onto RAIL CLAMP DOC.

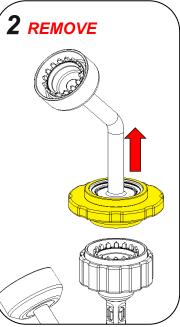
**NOTE:** If threading is difficult, turn the attachment nut counterclockwise to unscrew, then carefully re-align the attachment nut with the DOC and repeat the clockwise rotation. Do not force the attachment nut to rotate, as doing so can cause the EXTENDER and RAIL CLAMP to bind.

**3. ATTACH** the *miniARM*<sup>®</sup> to the EXTENDER DOC per the *miniARM*<sup>®</sup> Instructions for Use.

#### **REMOVAL**

Ensure that the *miniARM*<sup>®</sup> and any attached accessories have been removed from the EXTENDER before removing the EXTENDER from the RAIL CLAMP. Refer to each device's instructions for use.





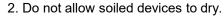
- 1. **ROTATE** the EXTENDER attachment nut counterclockwise, unthreading it from the RAIL CLAMP DOC.
- **2. REMOVE** the EXTENDER from the RAIL CLAMP DOC.

### **DOC-X 15™ EXTENDER 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 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 miniARMs® or RAIL CLAMPS according to each device's instruction for use.
- Avoid the risk of damaging gloves or injuring skin on the crenellations within the DOC.

#### **POINT OF USE**

1. Disassemble and clean device immediately after 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:
- a) Threads and crenellations of DOC (FIG. 2)
- b) DOC coupler, attachment nut, and internal threads (FIG. 3)
- 3. Rinse with warm water (38–45 $^{\circ}$ C [100–113 $^{\circ}$ F]) for a minimum of 2 minutes.
- 4. Proceed with one of the two required cleaning options: ultrasonic or automated.

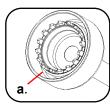


FIG. 2

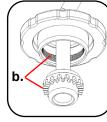
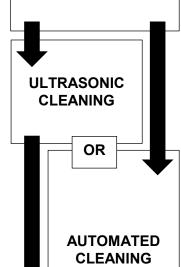


FIG. 3

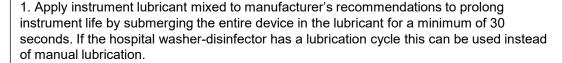


- 1. Clean in ultrasonic bath with enzymatic, neutral pH cleaning solution for a minimum of 15 minutes. Refer to detergent manufacturer's instructions for temperature and concentration.
- 2. Rinse with warm water (38–45°C [100–113°F]) for a minimum of 4 minutes. To ensure a complete rinse, use a clean plastic-bristled brush to scrub the device.
- 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.

**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**



**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. 2-3. 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 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 device into the tray according to FIG. 4.
- 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







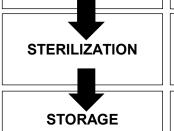
- 1. The device must be properly cleaned prior to sterilization.
- 2. Perform sterilization cycle according to TABLE 1:

<b>TABLE 1</b> : <i>DOC-X 15™ EXTENDER</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	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	

**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 *DOC-X* 15<sup>TM</sup> *EXTENDER* 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.

- 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<sup>®</sup>.
- 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 *DOC-X 15™ EXTENDER* shall be used in accordance with these instructions for use.
- Improper use of the DOC-X 15™ EXTENDER 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 *DOC-X 15™ EXTENDER*, patient must be immobilized or anesthetized.
- Discontinue use of the *DOC-X 15™ EXTENDER* when moving patient or when patient is moving.
- Do not attach a *DOC-X 15™ EXTENDER* to another *DOC-X™ EXTENDER*.
- Do not use the *DOC-X* 15™ *EXTENDER* with *RIGID miniARM*® 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 relative to techniques, complications, and hazards should be consulted prior to use.
- Avoid touching with sterile gloved hands any part of the *DOC-X 15™ EXTENDER* 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.

- The DOC-X 15™ EXTENDER 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 a DOC-X 15<sup>™</sup> EXTENDER for a task other than for which it is intended for can result in a damaged or broken device.
- Prior to use, inspect the *DOC-X 15™ EXTENDER* 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 that electrical isolation or grounding are
  not compromised.
- Avoid mechanical shock or overstressing of the DOC-X 15™ EXTENDER.
- Avoid inappropriate contact with the crenellations within the DOC, which could damage gloves or cause injury. Glove perforation can lead to contamination of the surgical field.
- Only the cleaning and sterilization processes which are defined within these instructions for use have been validated.
- Store at room temperature.

#### **ADVERSE REACTIONS**

No documented adverse reactions.

#### ORDERING INFORMATION

TABLE 2: DOC-X™ EXTENDER PRODUCT ORDERING				
	REORDER	PRODUCT	DESCRIPTION	
1	REF 081370	DOC-X 15™ EXTENDER	1 Shelf Box	
	REF 100034	multiSTATION® Sterilization Tray*	1 Shelf Box	

## **S**SOLUTIONS®

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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\*
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