

multiSTATION[®] DOC-X 15[™] EXTENDER

Technology Guide

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

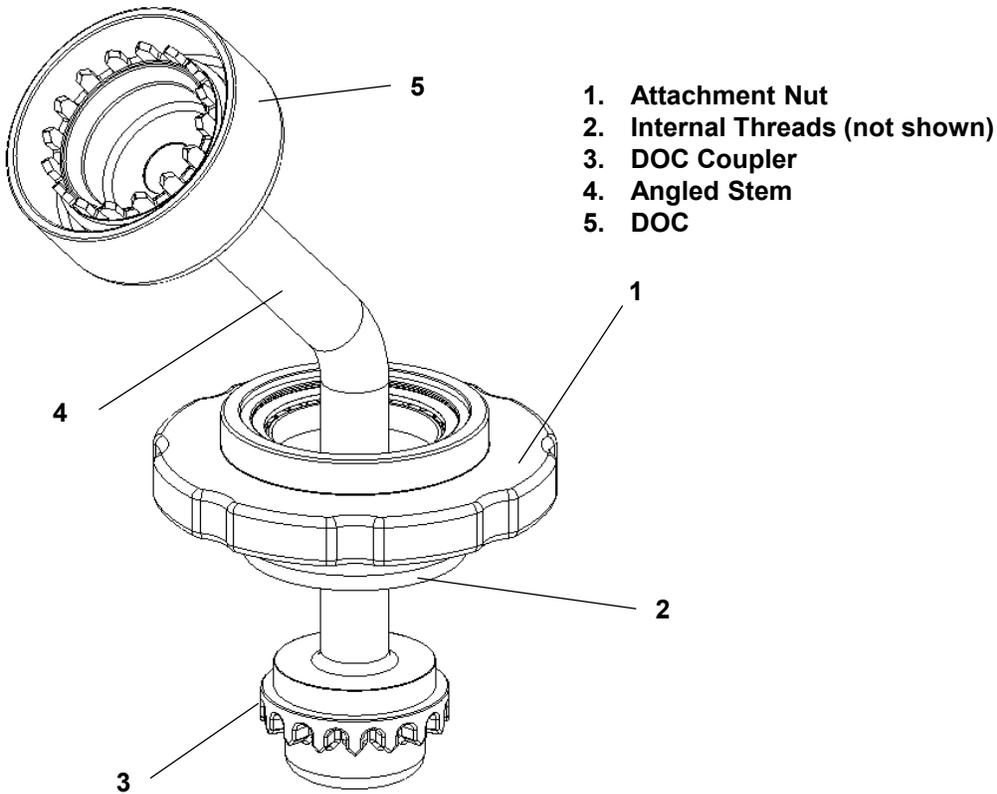


FIG. 1: DOC-X 15[™] EXTENDER



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:

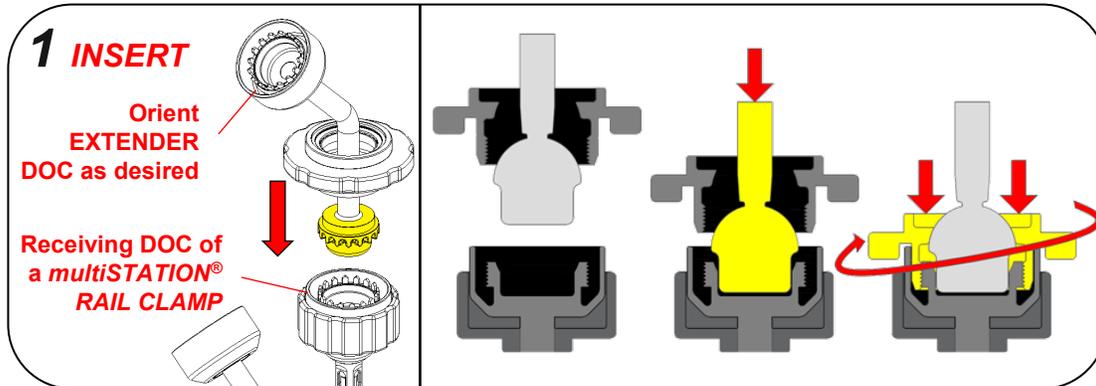
The DOC-X 15[™] EXTENDER is indicated for use by surgeons to hold instruments in a fixed position for a period of time.

INSTRUCTIONS FOR USE

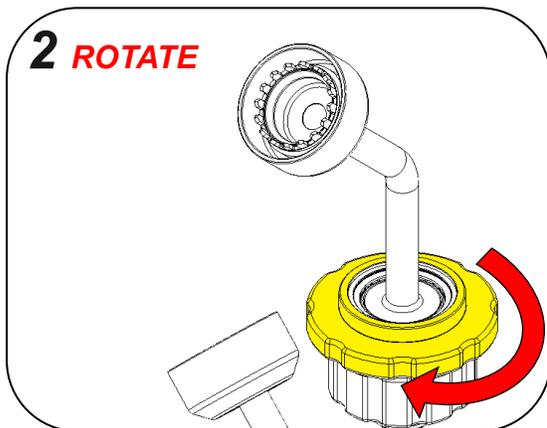
GENERAL SETUP & USE:

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.



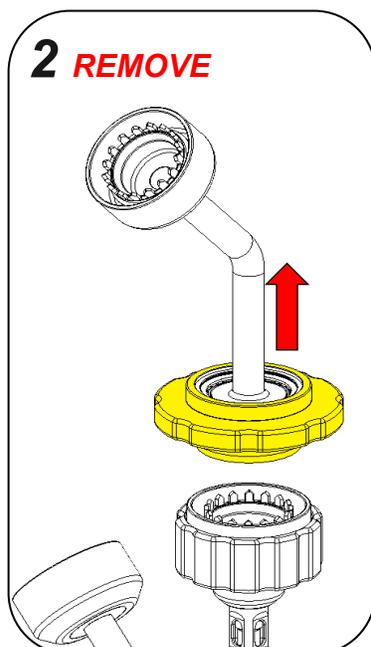
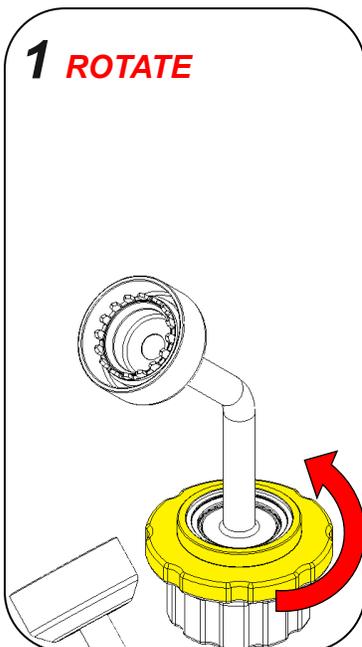
2. **ROTATE** the *EXTENDER* attachment nut clockwise, threading it onto *RAIL CLAMP* DOC.

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®* to the *EXTENDER* DOC per the *miniARM®* Instructions for Use.

REMOVAL

Ensure that the *miniARM®* 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.

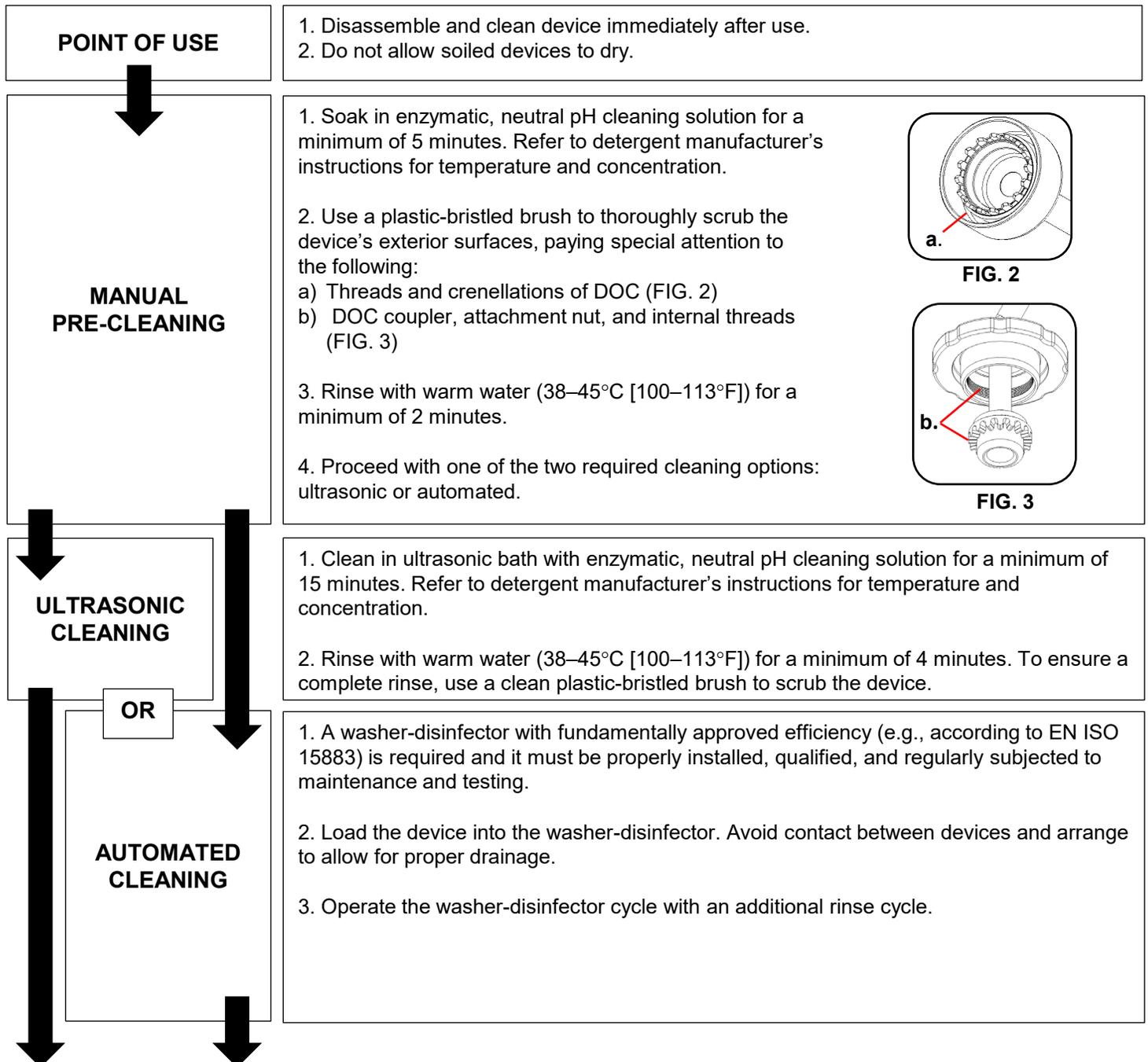


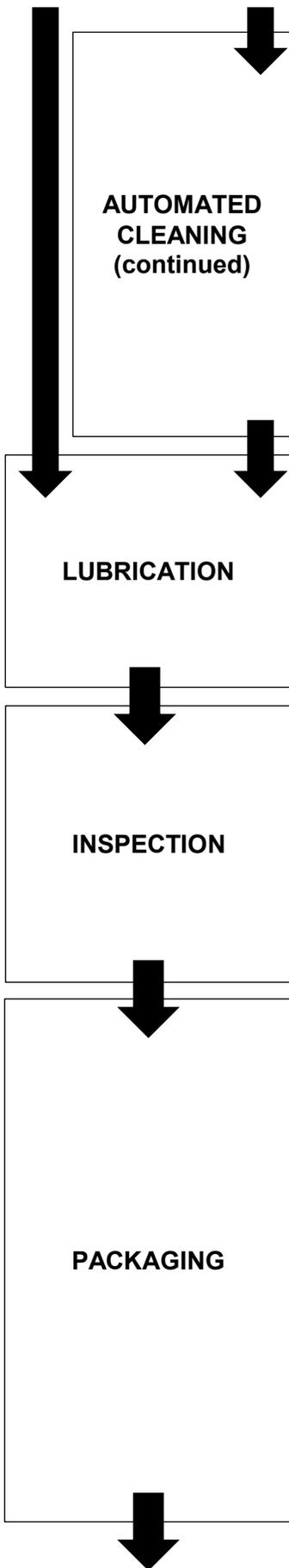
1. **ROTATE** the *EXTENDER* attachment nut counterclockwise, unthreading it from the *RAIL CLAMP* DOC.

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.
- 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.





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

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.

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



 STERILIZATION	<p>1. The device must be properly cleaned prior to sterilization.</p> <p>2. Perform sterilization cycle according to TABLE 1:</p> <table border="1"> <thead> <tr> <th colspan="4">TABLE 1: DOC-X 15™ EXTENDER Sterile Packaging and Processing</th> </tr> <tr> <th>Method</th> <td>Moist heat (steam) sterilization according to ANSI/AAMI ST79</td> <td>Moist heat (steam) sterilization according to ANSI/AAMI ST79</td> <td>Immediate Use Steam Sterilization according to ANSI/AAMI ST79</td> </tr> <tr> <th>Container</th> <td><i>multiSTATION</i>® Sterilization Tray P/N 100034</td> <td>No tray</td> <td>No tray</td> </tr> <tr> <th>Cycle</th> <td>Pre-vacuum (Pre-vac)</td> <td>Pre-vacuum (Pre-vac)</td> <td>Pre-vacuum (Pre-vac)</td> </tr> <tr> <th>Packaging</th> <td>2-layer polypropylene wrap</td> <td>Pouch</td> <td>No packaging</td> </tr> <tr> <th>Temperature</th> <td>132-137°C (270–279°F)</td> <td>132-137°C (270–279°F)</td> <td>132-137°C (270–279°F)</td> </tr> <tr> <th>Exposure Time</th> <td>4 – 18 minutes</td> <td>4 – 18 minutes</td> <td>4 – 18 minutes</td> </tr> <tr> <th>Dry Time</th> <td>65 minutes (minimum)</td> <td>25 minutes (minimum)</td> <td>N/A</td> </tr> </thead> </table> <p>Device(s) processed by immediate use sterilization should be transferred immediately, using aseptic technique, from the sterilizer to the point of use.</p> <p>Refer to ANSI/AAMI ST79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.</p>	TABLE 1: DOC-X 15™ EXTENDER 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
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 STERILIZATION	<p>The <i>DOC-X 15™ EXTENDER</i> 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.</p>																																
 STORAGE	<p>1. During storage, ensure the device remains in a sterile condition ready for reuse.</p> <p>2. Shelf life is dependent on the sterile barrier employed, storage manner, and environmental and handling conditions.</p>																																

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 *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.

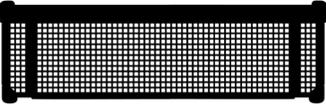
PRECAUTIONS

- 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™ 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
	REF 081370	DOC-X 15™ EXTENDER	1 Shelf Box
	REF 100034	multiSTATION® Sterilization Tray*	1 Shelf Box

LSI SOLUTIONS®

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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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