

multiSTATION® DOC-X 25™ and DOC-X 45™ EXTENDERS Technology Guide

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

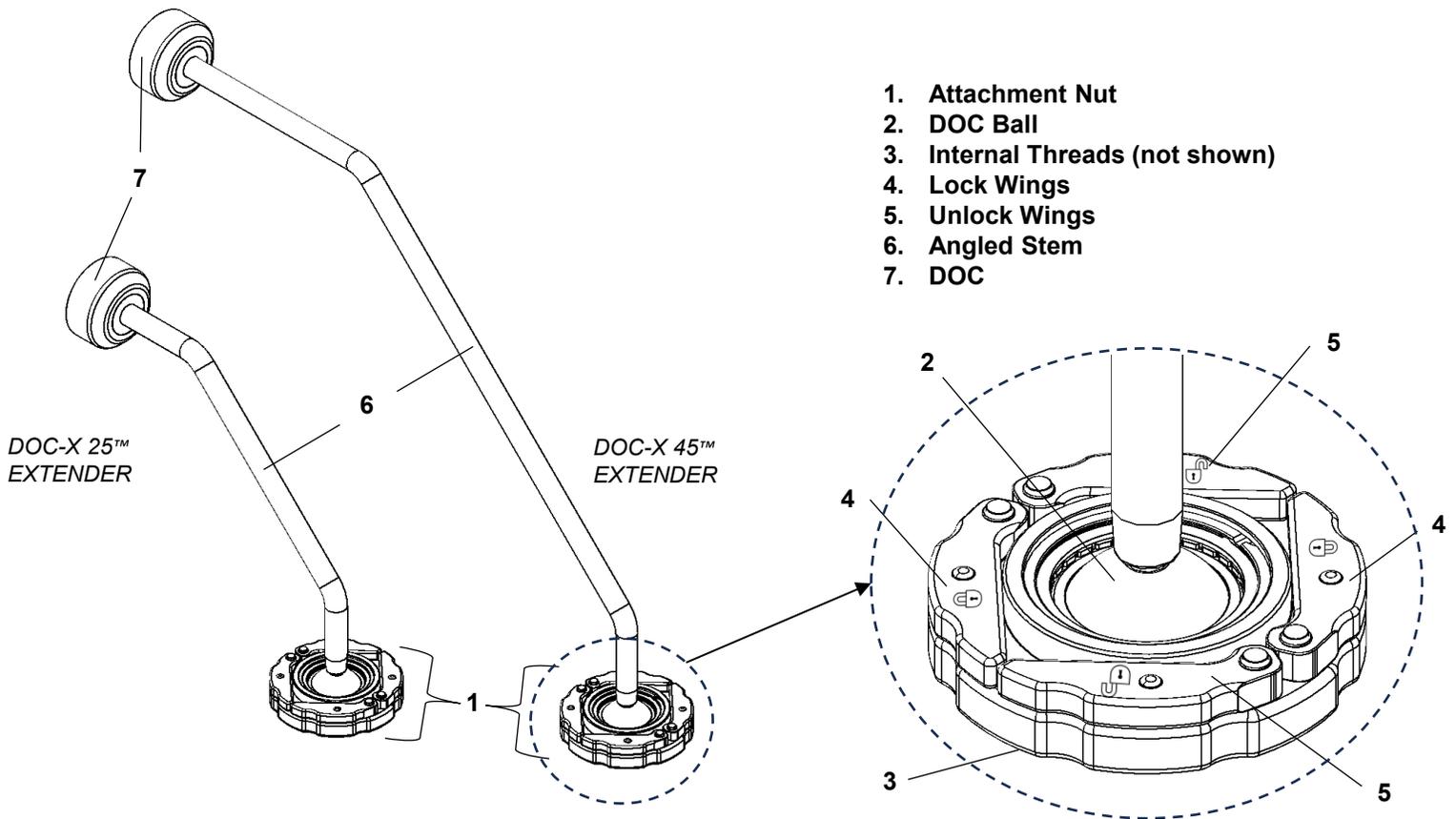


FIG. 1: DOC-X 25™ EXTENDER and DOC-X 45™ EXTENDER



DOC-X 25™ and DOC-X 45™ EXTENDER DEVICE DESCRIPTION:

The DOC-X 25™ and DOC-X 45™ EXTENDERS (FIG. 1) are multiSTATION® accessories. They are secure, repositionable and reusable devices that attach to a selected multiSTATION® RAIL CLAMP to extend the reach of a miniARM®. The attachment nut 1 compresses the upper hemisphere of the DOC ball 2 into the RAIL CLAMP receiving socket when the attachment nut and its internal threads 3 (not shown) are rotated clockwise, threading into the receiving socket. As the DOC ball is tightened into the socket, it is compressed so that the angled stem 6 can no longer move. The two lock wings 4 engraved with the lock symbol (🔒) can swivel approximately 90° away from their storage positions on the attachment nut to ease clockwise threading. Once the attachment nut is tightened, the lock wings can be swiveled back into their storage position. To loosen the attachment nut, both unlock wings 5 engraved with the unlock symbol (🔓) can swivel from their storage position to ease counterclockwise threading. The angled stem joins the DOC ball to the threaded, crenellated DOC 7 that can receive the desired miniARM®. The DOC-X 25™ EXTENDER extends the system reach by 25cm. The DOC-X 45™ EXTENDER extends the system reach by 45cm.

INDICATIONS FOR USE:

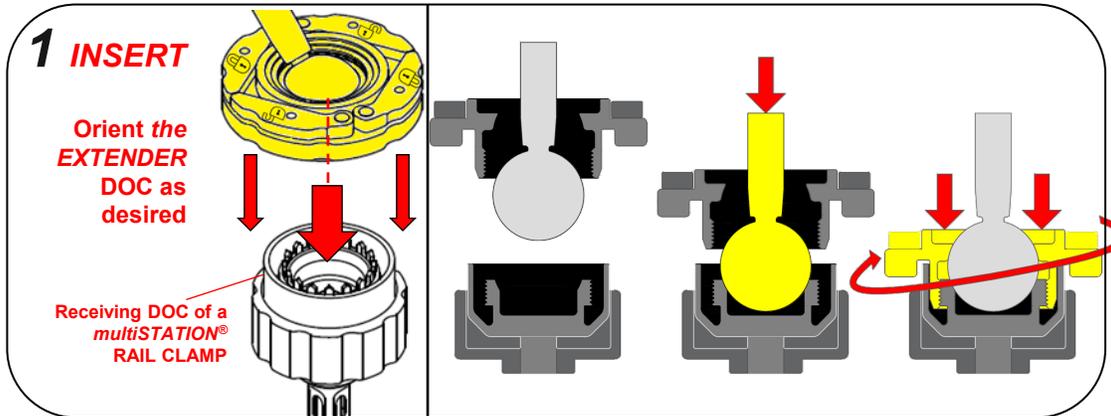
The DOC-X 25™ and DOC-X 45™ EXTENDERS are indicated for use by surgeons to hold instruments in a fixed position for a period of time.

INSTRUCTIONS FOR USE

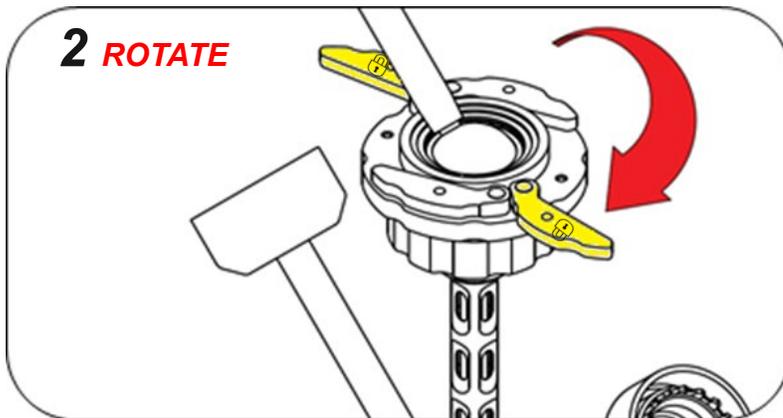
GENERAL SETUP & USE:

The DOC-X 25™ and DOC-X 45™ EXTENDERS must be cleaned and sterilized before each use.

The DOC-X 25™ and DOC-X 45™ EXTENDERS are designed to extend the reach of a *multiSTATION*® CLICK RELEASE™ *miniARM*®.



1. INSERT the EXTENDER'S DOC ball into the receiving socket of the *multiSTATION*® RAIL CLAMP, while orienting the EXTENDER'S DOC in the desired position.

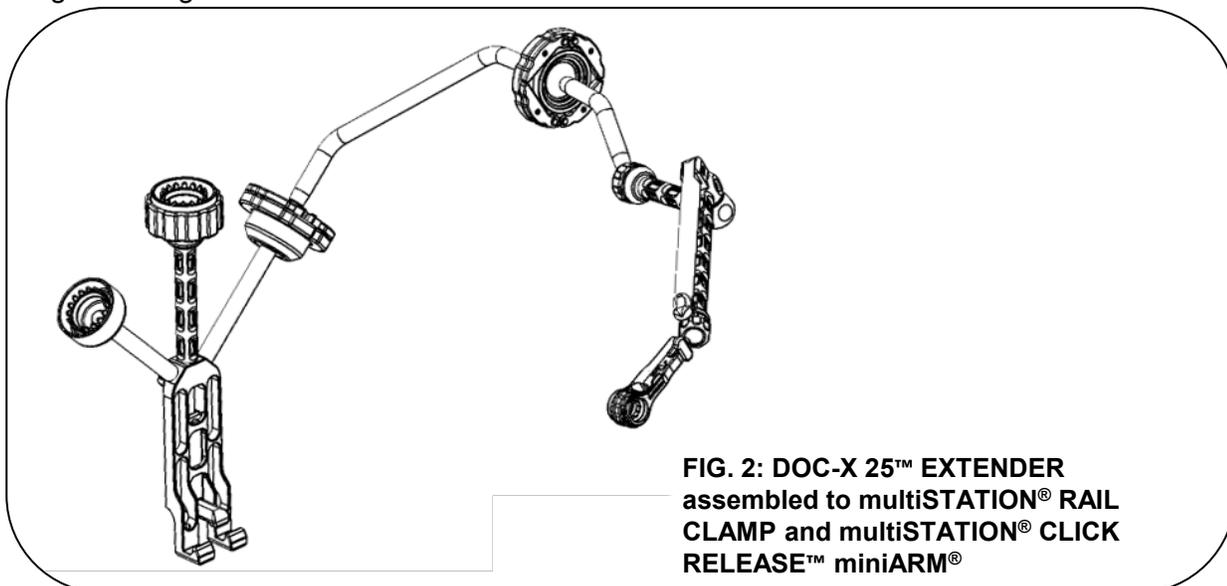


2. ROTATE the attachment nut using opposing lock wings () to turn the attachment nut clockwise, threading it onto RAIL CLAMP DOC.

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

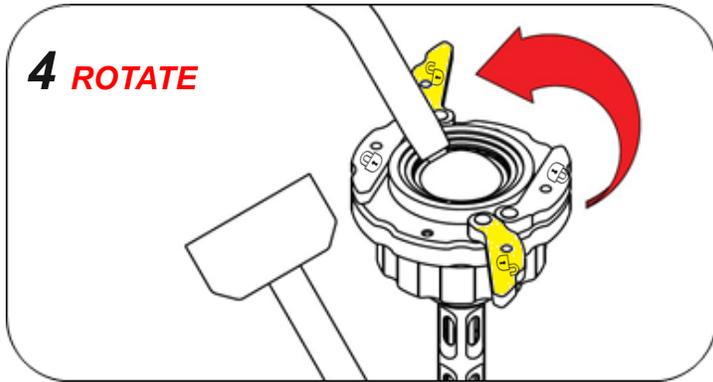
3. ATTACH the *multiSTATION*® CLICK RELEASE™ *miniARM*® to the EXTENDER DOC per the CLICK RELEASE™ Instructions for Use.

NOTE: If the EXTENDER'S angled stem sags, further tighten the EXTENDER'S attachment nut using the opposing lock wings.



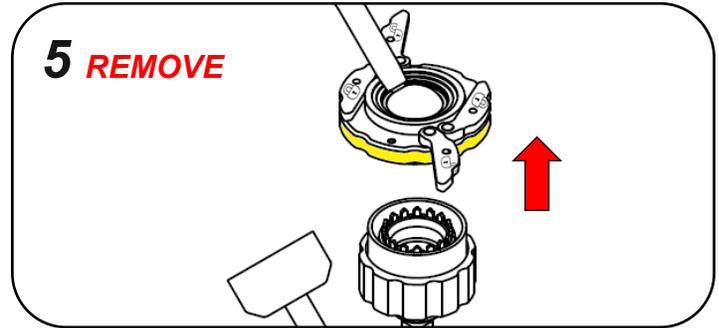
REMOVAL

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.



4. **ROTATE** the attachment nut off the *multiSTATION*® RAIL CLAMP DOC using both opposing unlock wings (U). Turn the attachment nut counterclockwise to unscrew from the DOC.

5. **REMOVE** the EXTENDER from the RAIL CLAMP DOC.



DOC-X 25™ and DOC-X 45™ EXTENDER REPROCESSING

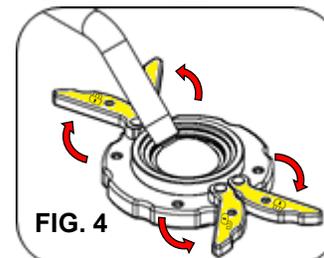
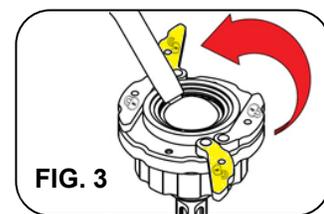
- Disassemble and clean the device immediately after use. Do not allow a soiled device to dry.
- The device is not validated to be cleaned or sterilized with a *miniARM*® and/or a RAIL CLAMP attached.
- Cleaning agent used in validation: Steris Prolystica 2X (enzymatic, neutral pH).
- Perform the final 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.

POINT OF USE

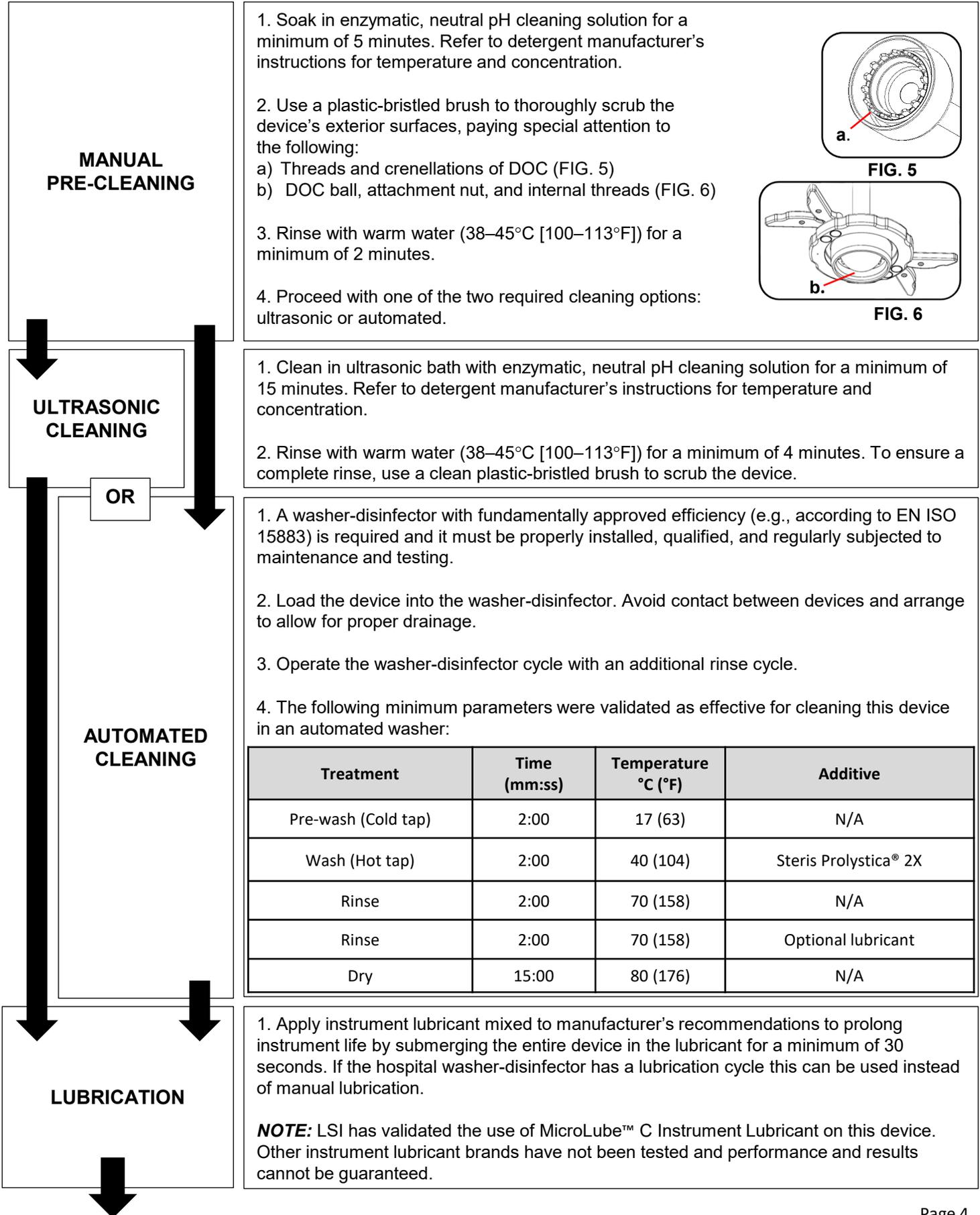
1. Disassemble and clean device immediately after use.
2. Do not allow soiled devices to dry.

PREPARATION

1. Remove the DOC-X EXTENDER from the RAIL CLAMP by rotating the unlock wings away from their storage position and then turning the attachment nut counterclockwise (FIG. 3).
2. Rotate both sets of lock and unlock wings away from their storage positions to their open positions (FIG. 4).
3. If using the *multiSTATION*® Sterilization Tray (Part Number 100034), clean the tray separately according to the sterilization tray instructions for use.



DOC-X 25™ and DOC-X 45™ EXTENDER REPROCESSING CONTINUED



DOC-X 25™ and DOC-X 45™ EXTENDER REPROCESSING CONTINUED

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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. 5-6. 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.

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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 device into the tray according to FIG. 7.

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



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STERILIZATION

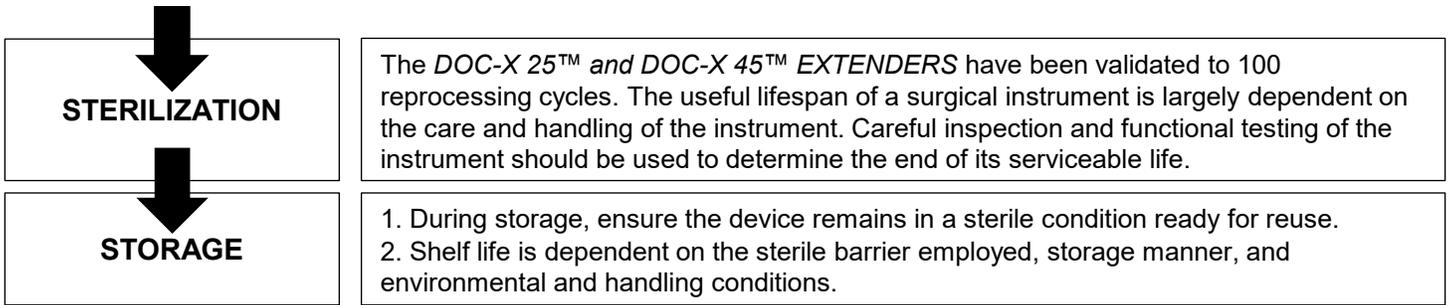
1. The device must be properly cleaned prior to sterilization.
2. Perform sterilization cycle according to TABLE 1:

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® System Sterilization Tray P/N 100034</i>	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.

DOC-X 25™ and DOC-X 45™ EXTENDER REPROCESSING CONTINUED



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 25™ and DOC-X 45™ EXTENDERS* shall be used in accordance with these instructions for use.
- Improper use of the *DOC-X 25™ and DOC-X 45™ EXTENDERS* may cause serious injury. In addition, improper care and maintenance of the devices may render the devices non-sterile prior to patient use and may cause serious injury to the health care provider or the patient.
- When using the *DOC-X 25™ or DOC-X 45™ EXTENDER*, patient must be immobilized or anesthetized.
- Discontinue use of the *DOC-X 25™ or DOC-X 45™ EXTENDER* when moving patient or when patient is moving.
- Do not attach a *DOC-X 25™ or DOC-X 45™ EXTENDER* to another *DOC-X 15™, DOC-X 25™ or DOC-X 45™ EXTENDER*.
- Do not use the *DOC-X 25™ or DOC-X 45™ EXTENDER* with *RIGID miniARMS®* 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 25™ or DOC-X 45™ 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.

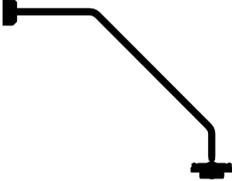
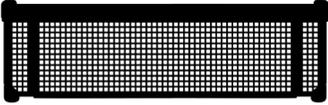
PRECAUTIONS

- **The *DOC-X 25™ and DOC-X 45™ EXTENDERS* are 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 25™ or DOC-X 45™ 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 25™ or DOC-X 45™ 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 25™ or DOC-X 45™ 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 080770	DOC-X 25™ EXTENDER	1 Shelf Box
	REF 080780	DOC-X 45™ EXTENDER	1 Shelf Box
	REF 100034	multiSTATION® System Sterilization Tray*	1 Shelf Box

LSI SOLUTIONS®

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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

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