

The *multiSTATION*® *VIEWSITE*™ RETRACTOR

Technology Guide

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

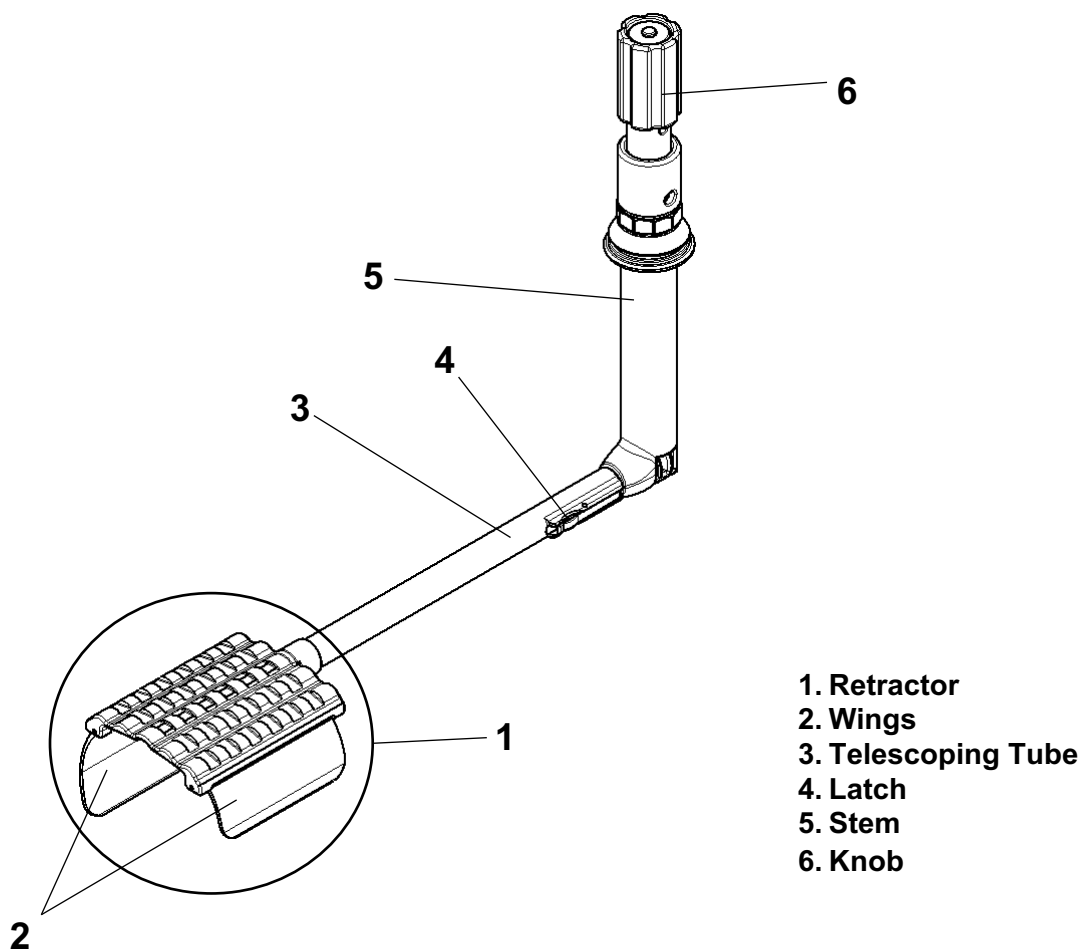


FIG. 1 *multiSTATION*® *VIEWSITE*™ RETRACTOR

***multiSTATION*® *VIEWSITE*™ RETRACTOR DEVICE DESCRIPTION:**

The *multiSTATION*® *VIEWSITE*™ RETRACTOR (FIG. 1) is a reusable soft tissue retractor. The Retractor 1 has asymmetric wings 2 to provide customized retraction of targeted tissue. The Telescoping Tube 3 is extended or shortened as desired to reach a target site by pressing and holding the latch 4. The stem 5 is inserted into a *multiSTATION*® CANNULA ADAPTER that can be held by a *RIGID miniARM*® or a *CLICK RELEASE*™ *miniARM*®. The knob 6 allows for opening and closing of the wings.

INDICATIONS FOR USE:

The *multiSTATION*® *VIEWSITE*™ RETRACTOR is indicated for use in the retraction and stabilization of soft tissue.

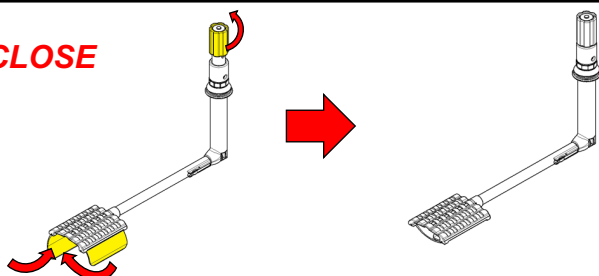
INSTRUCTIONS FOR USE

multiSTATION® VIEWSITE™ RETRACTOR ASSEMBLY AND POSITIONING

The *multiSTATION® VIEWSITE™ RETRACTOR* attaches to the selected *miniARM®* using the *multiSTATION® CANNULA ADAPTER*.

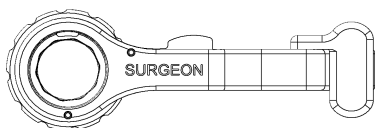
The *VIEWSITE™ RETRACTOR* must be cleaned and sterilized before each use.

1 CLOSE



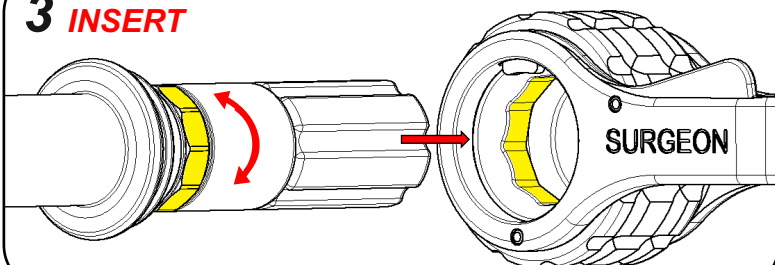
1. **CLOSE** the wings by turning the knob counterclockwise.

2 ORIENT



2. **ORIENT** the cannula adapter so that the word "SURGEON" is facing the user.

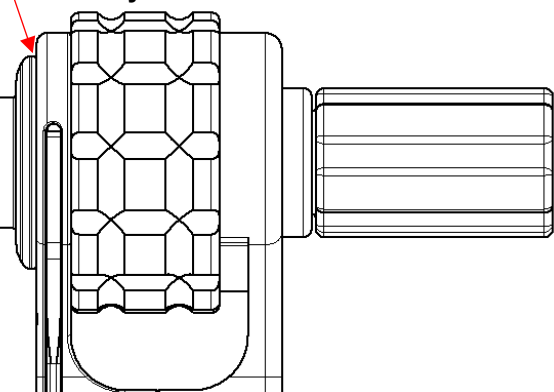
3 INSERT



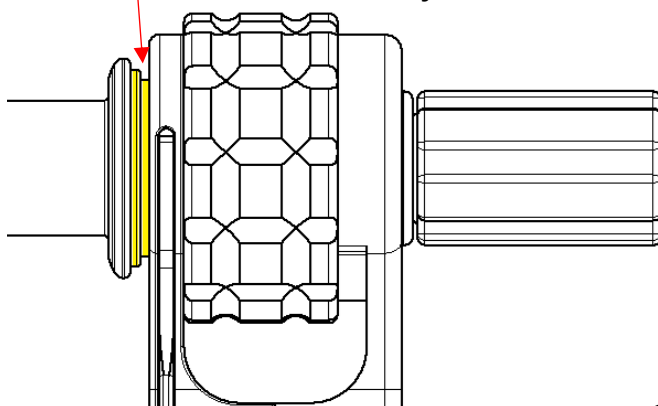
3. **INSERT** the retractor stem from the "SURGEON" side into the cannula adapter until it is fully seated and secured by the adapter latch.

NOTE: The stem may have to be rotated slightly during insertion to align the engagement features.

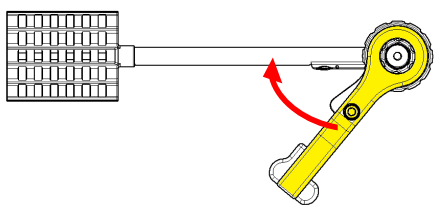
Retractor should be fully seated



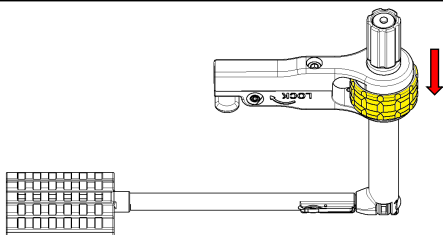
If a gap is visible, the retractor is NOT fully seated



4 ALIGN



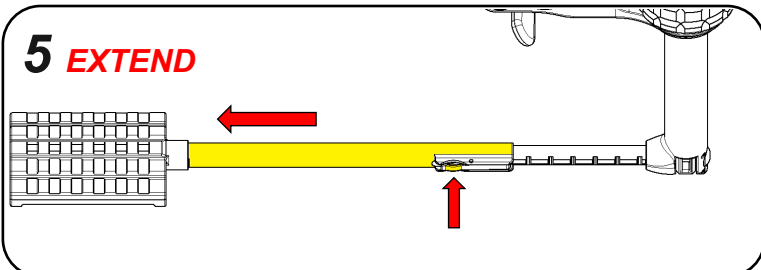
LOCK



4. **ALIGN** the cannula adapter with the telescoping tube, then **LOCK** the cannula adapter rotation by pulling downward on the cannula adapter rotation dial.

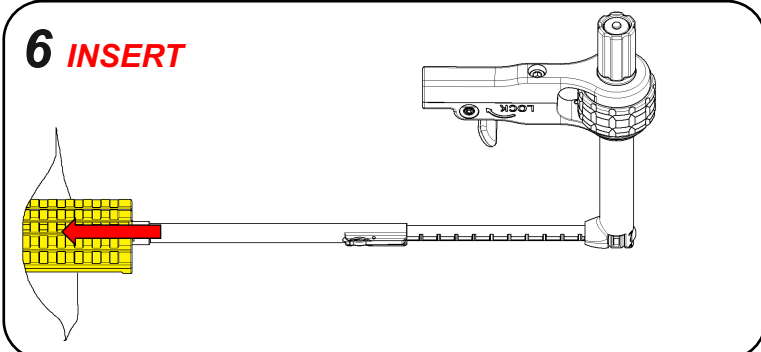
ASSEMBLY AND POSITIONING (continued)

5 EXTEND



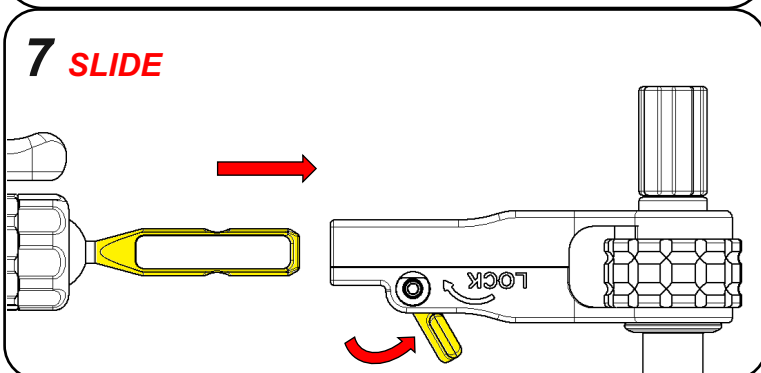
5. **EXTEND** the telescoping tube to the desired length by pulling the tube while pressing and holding down the latch.

6 INSERT



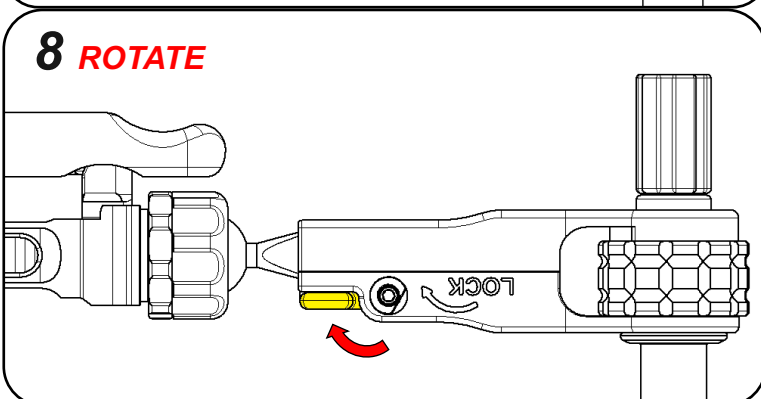
6. **INSERT** the retractor gently into the surgical site.

7 SLIDE



7. **SLIDE** the *miniARM*® quick connect post into the cannula adapter while the locking lever is rotated to the unlocked position.

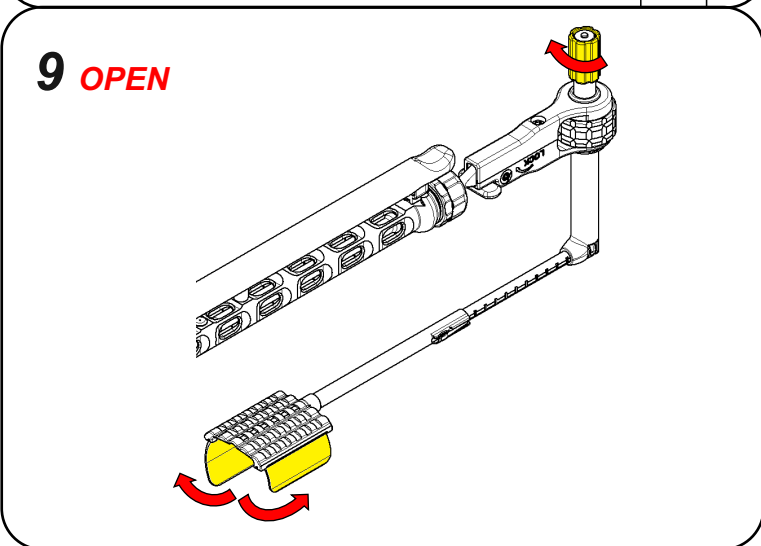
8 ROTATE



8. **ROTATE** the cannula adapter locking lever to the locked position to secure the adapter to the *miniARM*®.

Adjust the *miniARM*® and then lock it in the desired position. Refer to the *miniARM*® Instructions for Use.

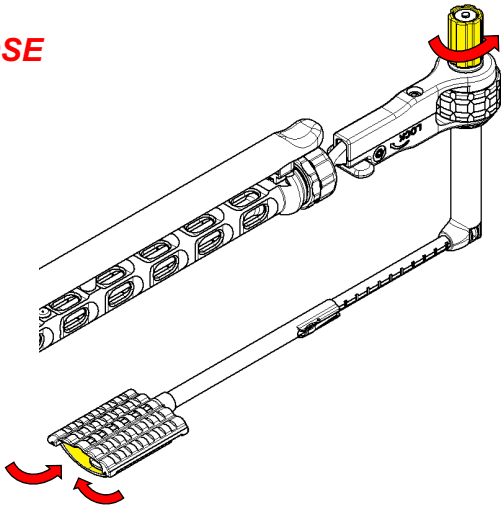
9 OPEN



9. **OPEN** the wings by turning the knob clockwise.

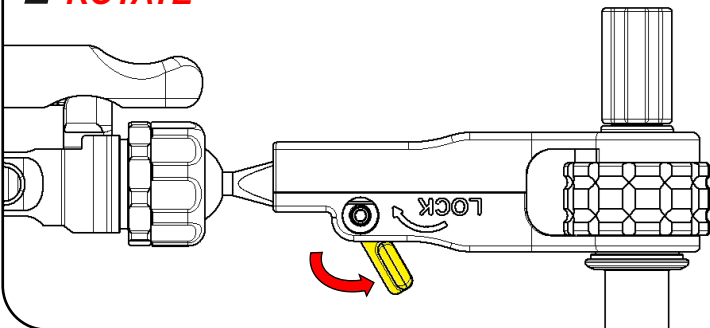
REMOVAL

1 CLOSE



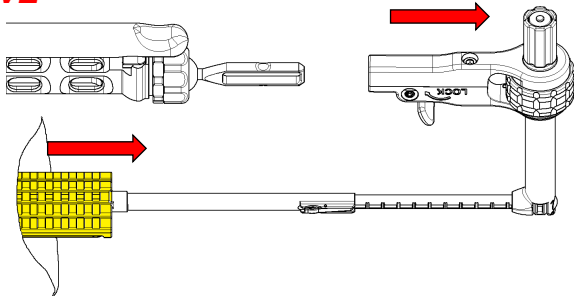
1. **CLOSE** the wings by turning the knob counterclockwise.

2 ROTATE



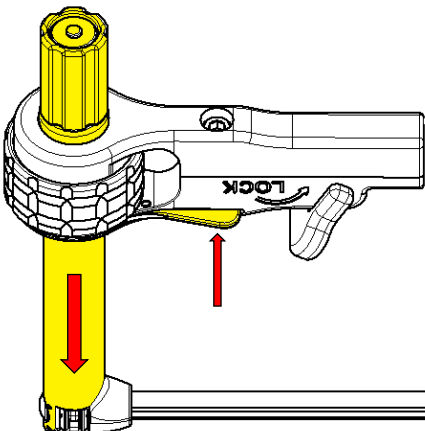
2. **ROTATE** the cannula adapter locking lever to the unlocked position.

3 REMOVE



3. **REMOVE** the retractor and attached cannula adapter gently from the surgical site.

4 REMOVE



4. **REMOVE** the retractor from the cannula adapter by pressing the cannula latch and pulling the stem out of the adapter.

multiSTATION® VIEWSITE™ RETRACTOR 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 while attached to the cannula adapter.
- 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 the multiSTATION® CANNULA ADAPTER according to its instructions for use.

POINT OF USE

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

PREPARATION

1. Set the retractor to the cleaning position by (a) rotating the knob clockwise until the wings are fully open with the knob flush port aligned with the stem flush port (FIG. 2) and (b) by pressing the latch and extending the tube to its full length (FIG. 3).

2. If using the multiSTATION® Sterilization Tray (Part Number 100034), clean the tray separately according to the sterilization tray instructions for use.

FIG. 2

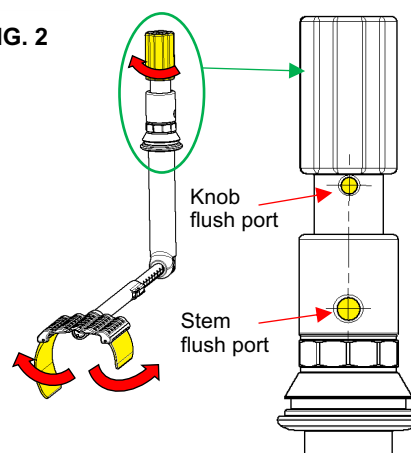
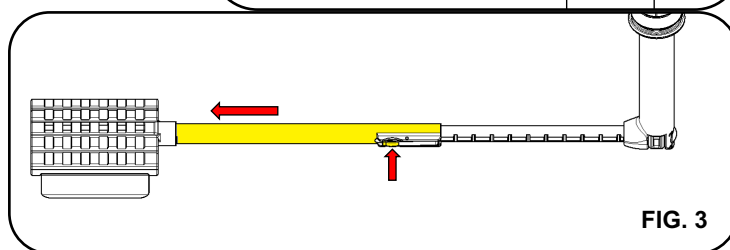


FIG. 3



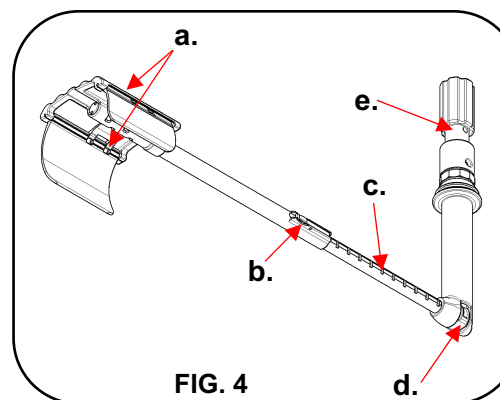
MANUAL PRE-CLEANING

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 (FIG. 4):

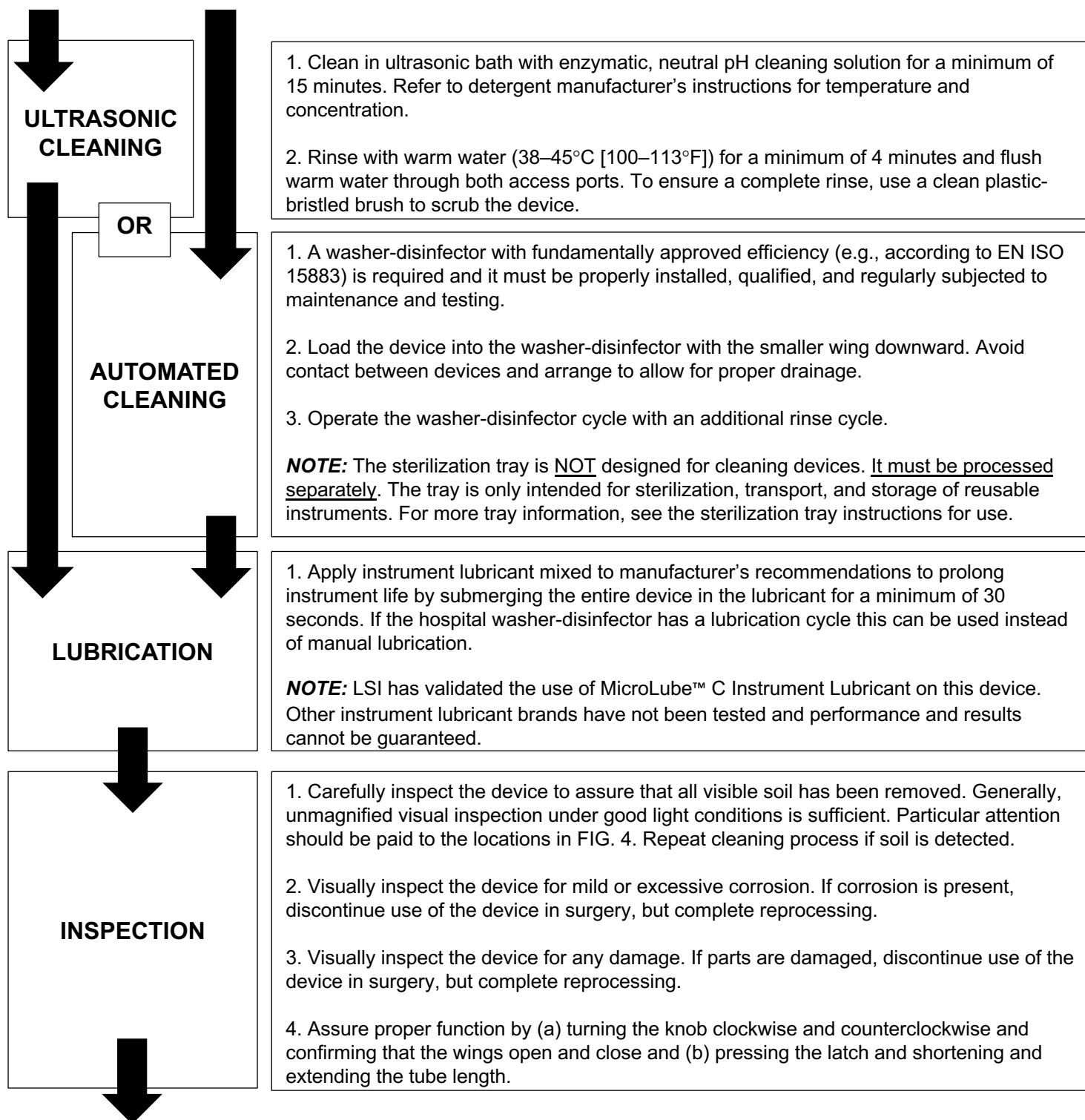
- a. Retractor assembly, top and bottom
- b. Latch
- c. Notches on tube
- d. Joint between stem and tube
- e. Gap between knob and stem

FIG. 4



3. Flush access ports (FIG. 2) with enzymatic, neutral pH cleaning solution.
4. Rinse with warm water (38–45°C [100–113°F]) for a minimum of 2 minutes and flush both access ports with warm water.
5. Proceed with one of the two required cleaning options: ultrasonic or automated.

multiSTATION® VIEWSITE™ RETRACTOR REPROCESSING (continued)



PACKAGING

1. If using a sterilization pouch, place each instrument in its own individual pouch. Place the devices in the sterilizer with the small wing facing down. 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 top shelf according to FIG. 5.

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

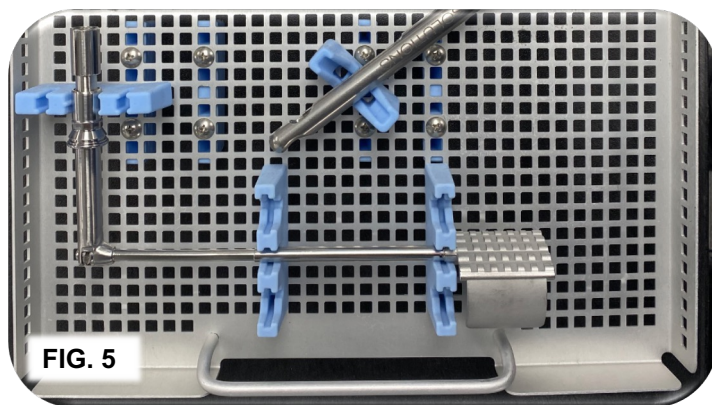


FIG. 5

STERILIZATION

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

2. Perform sterilization cycle according to TABLE 1:

TABLE 1: <i>multiSTATION® VIEWSITE™ RETRACTOR</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	<i>multiSTATION® Sterilization Tray</i> 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.

The *multiSTATION® VIEWSITE™ RETRACTOR* has been validated to 20 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 that 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

- This device is not intended for use except as indicated.

WARNINGS

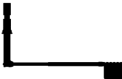
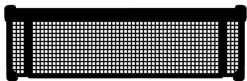
- Federal law restricts this device to sale, distribution, and use by, or on, the order of a physician.
- Read and become familiar with all instructions, warnings, and cautions before using this product.
- The *multiSTATION® VIEWSITE™ RETRACTOR* shall be used in accordance with these instructions for use.
- Improper use of the *multiSTATION® VIEWSITE™ RETRACTOR* 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® VIEWSITE™ RETRACTOR*, patients must be immobilized or anesthetized.
- Discontinue use of the *multiSTATION® VIEWSITE™ RETRACTOR* when the patient is moving or being moved.
- 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.
- The *multiSTATION® VIEWSITE™ RETRACTOR* must be carefully deployed, applied, and gently opened to avoid damaging the retracted tissue.
- Direct contact between sensitive tissue structures and foreign materials can lead to tissue injury or damage.
- Leaving tissue under tension for a prolonged period of time can cause tissue ischemia or damage. This device is for temporary use during a surgical procedure by operators trained and competent in related techniques.

PRECAUTIONS

- **The *multiSTATION® VIEWSITE™ RETRACTOR* is packaged as non-sterile.** Clean and sterilize prior to 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 *multiSTATION® VIEWSITE™ RETRACTOR* for a task other than what it is intended for can result in a damaged or broken device.
- Prior to use, inspect the *multiSTATION® VIEWSITE™ RETRACTOR* 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.
- 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® VIEWSITE™ RETRACTOR*.
- 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.

TABLE 2: <i>multiSTATION® VIEWSITE™ RETRACTOR</i> PRODUCT ORDERING			
	REORDER	PRODUCT	DESCRIPTION
	REF 080630	<i>multiSTATION® VIEWSITE™ RETRACTOR</i>	1 Shelf Box
	REF 100034	<i>multiSTATION® Sterilization Tray*</i>	1 Shelf Box



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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

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