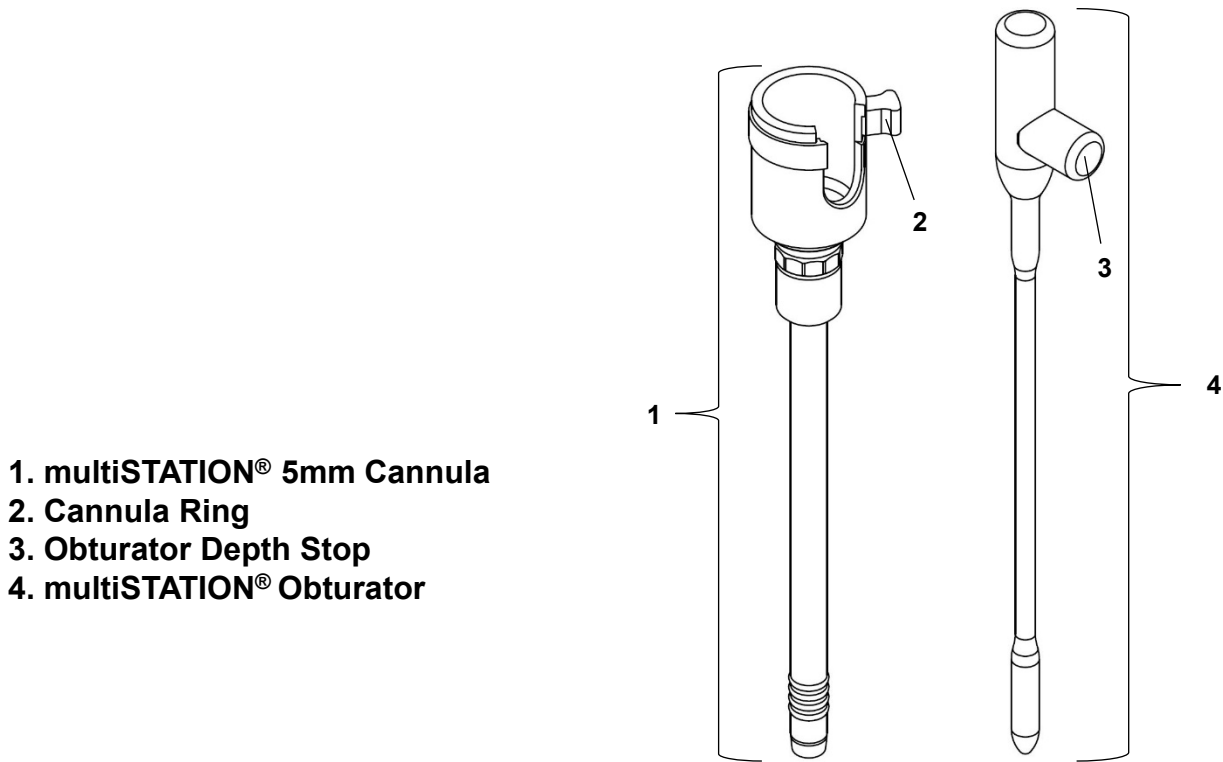


The *multiSTATION*[®] 5mm CANNULA WITH OBTURATOR Technology Guide

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE



1. *multiSTATION*[®] 5mm Cannula
2. Cannula Ring
3. Obturator Depth Stop
4. *multiSTATION*[®] Obturator

FIG. 1: *multiSTATION*[®] 5MM CANNULA WITH OBTURATOR

 **SOLUTIONS**[®]

***multiSTATION*[®] 5MM CANNULA WITH OBTURATOR DEVICE DESCRIPTION:**

The *multiSTATION*[®] 5mm CANNULA WITH OBTURATOR (FIG. 1) is a reusable accessory that secures a 5mm endoscope to a *multiSTATION*[®] RIGID *miniARM*[®] or a *multiSTATION*[®] CLICK RELEASE[™] *miniARM*[®]. The 5mm CANNULA 1, for use with compatible endoscopes, fits into the *multiSTATION*[®] Cannula Adapter, which secures the cannula to a selected *miniARM*[®]. The obturator 4 is placed into the proximal cannula opening and is secured in the cannula by the obturator depth stop 3, held in place by the movable cannula ring 2. The obturator enables the cannula to be passed through tissue exposed by a skin incision. After the obturator is removed, an endoscope may be placed into the cannula and held in place with the cannula ring.

INDICATIONS FOR USE:

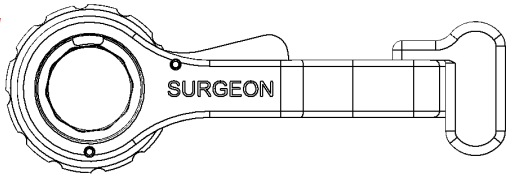
The *multiSTATION*[®] 5mm CANNULA WITH OBTURATOR is indicated for use by surgeons to hold instruments in a fixed position for a period of time.

multiSTATION® 5mm CANNULA ASSEMBLY AND POSITIONING

The multiSTATION® cannula adapter may be attached to the *miniARM®* either before or after attaching the *miniARM®* to a *multiSTATION® RAIL CLAMP*.

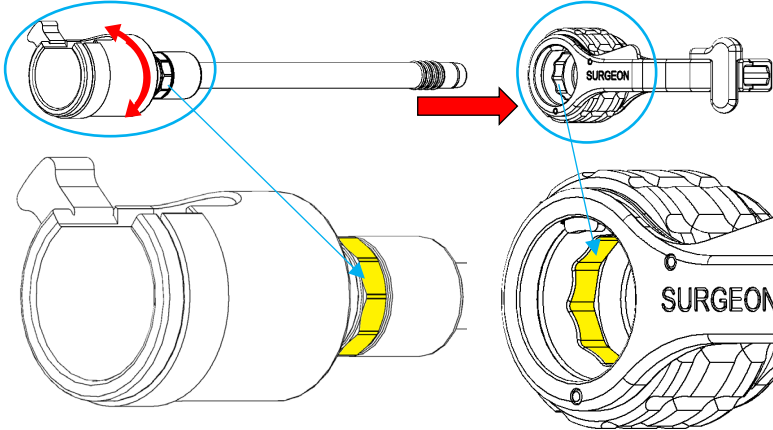
Note: The cannula and obturator are supplied non-sterile and must be cleaned and sterilized before each use.

1 POSITION



1. **POSITION** the cannula adapter so that the word "SURGEON" is facing the user.

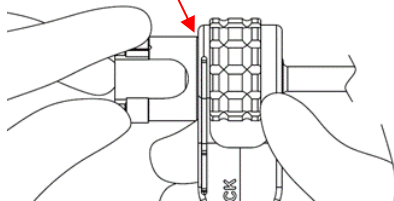
2 INSERT



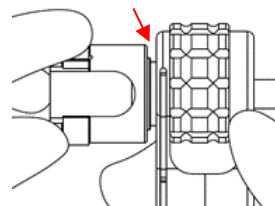
2. **INSERT** the cannula or coupler from the "SURGEON" side until it is fully seated and secured by the cannula latch.

Note: The cannula may have to be rotated slightly during insertion to align the engagement features.

NOTE: cannula should be fully seated

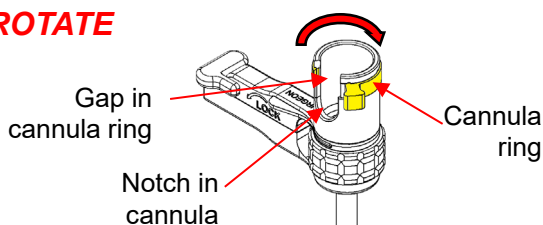


If a gap is visible, cannula is NOT fully seated



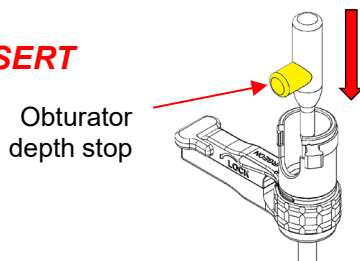
multiSTATION® OBTURATOR USE:

1 ROTATE



1. **ROTATE** the cannula ring clockwise until the gap in the cannula ring aligns with the notch in the cannula.

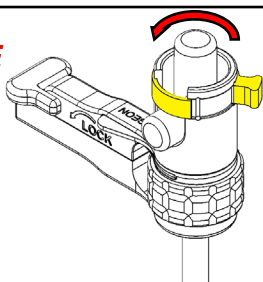
2 INSERT



2. **INSERT** the obturator into the cannula with the obturator depth stop passing through the gap in the cannula ring into the notch in the cannula.

OBTURATOR USE (continued):

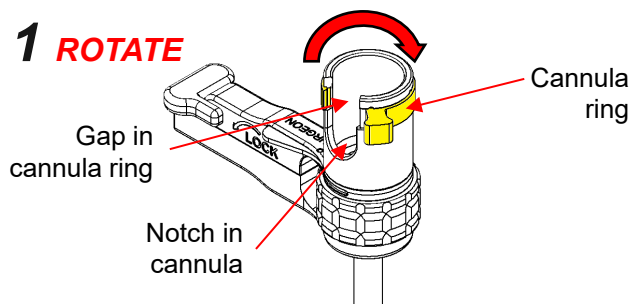
3 SECURE



3. **SECURE** the obturator in the cannula by rotating the cannula ring counter-clockwise over the obturator depth stop.

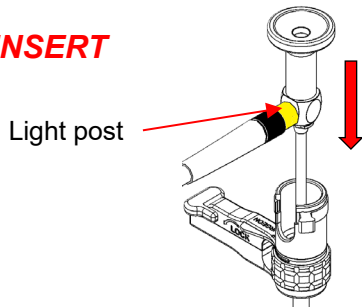
ENDOSCOPE USE:

1 ROTATE



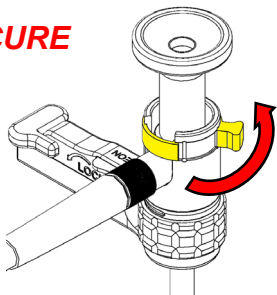
1. **ROTATE** the cannula ring clockwise until the gap in the cannula ring aligns with the notch in the cannula.

2 INSERT



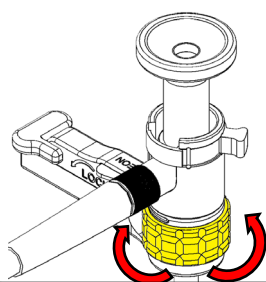
2. **INSERT** the endoscope into the cannula with the light post passing through the gap in the cannula ring into the notch in the cannula.

3 SECURE

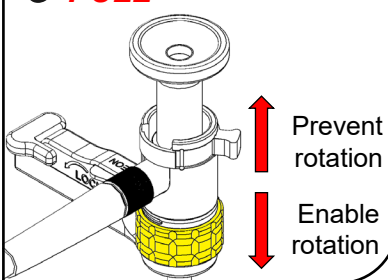


3. **SECURE** the endoscope in the cannula by rotating the cannula ring counter-clockwise over the light post.

4 ROTATE



5 PULL



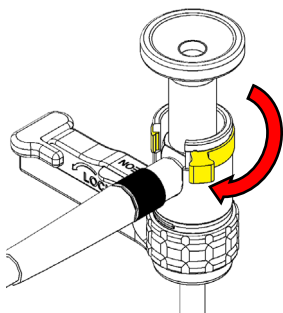
4. **ROTATE** the scope or other instrument with the cannula rotation dial to achieve desired orientation.

5. **PULL** the rotation dial toward surgeon side to lock the rotation dial; push the rotation dial away from the surgeon side to unlock the rotation dial.

REMOVAL AND CLEANUP

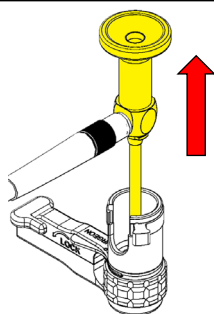
This process may be made easier by having the *miniARM*® locked while handling.

1 ROTATE



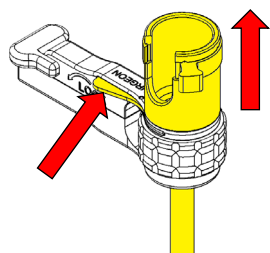
1. **ROTATE** the cannula ring clockwise until the gap in the cannula ring aligns with the notch in the cannula to release the obturator or endoscope.

2 REMOVE



2. **REMOVE** the obturator or endoscope.

3 REMOVE



3. **REMOVE** the cannula by pressing the cannula latch and pulling the cannula out of the adapter.

multiSTATION® 5mm CANNULA WITH OBTURATOR REPROCESSING

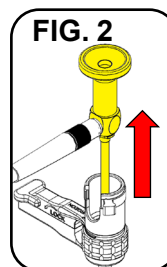
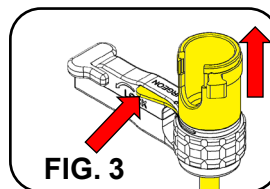
- Disassemble and clean the device immediately after use. Do not allow a soiled device to dry.
- The device is not validated to be cleaned or sterilized with the adapter, obturator, or cannula still assembled.
- Cleaning agent used in validation: Steris Prolystica® 2X (enzymatic, neutral pH).
- Perform 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 other multiSTATION® devices according to each device's instructions for use.
- 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

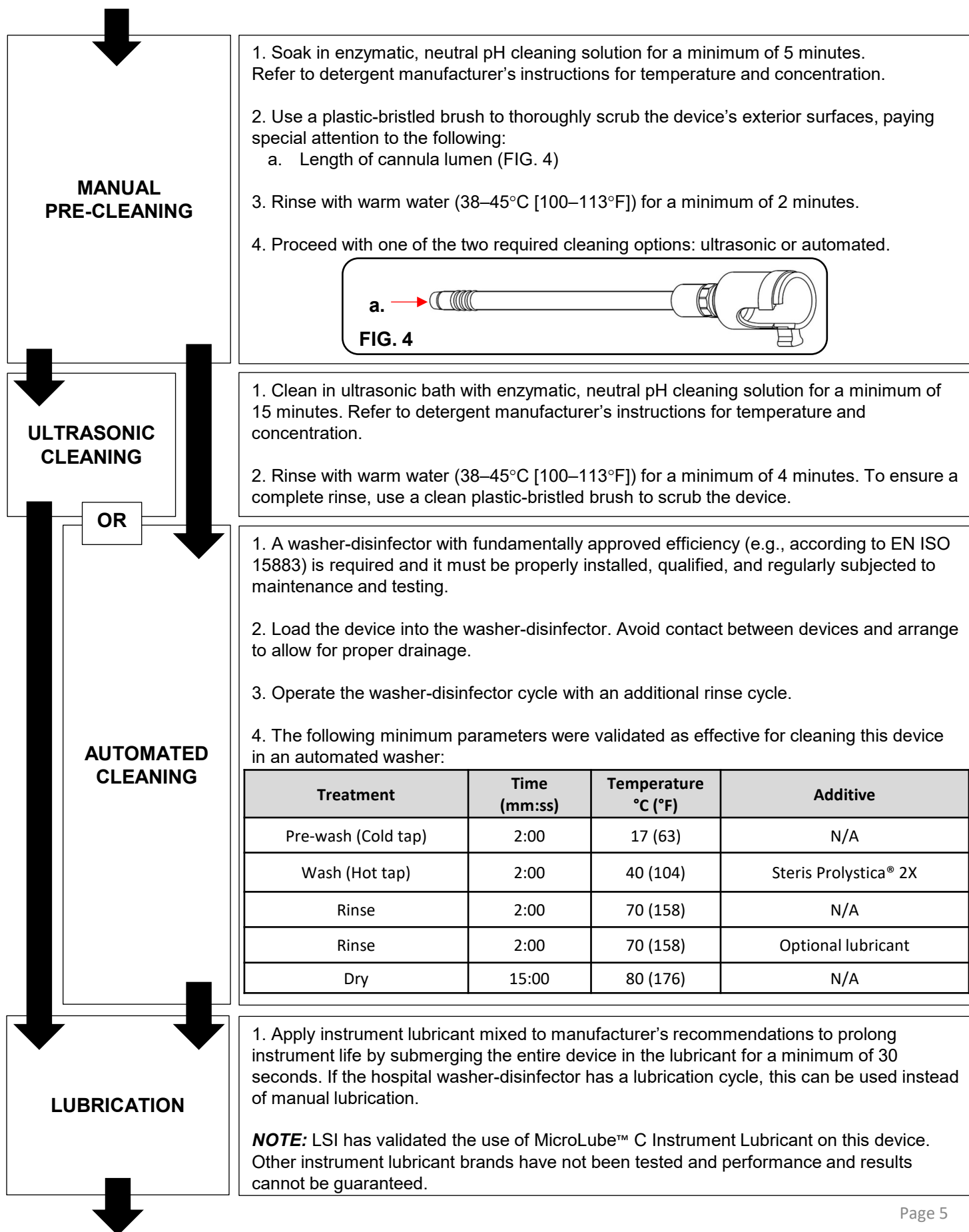
1. Disassemble and clean device immediately after use.
2. Do not allow soiled devices to dry.

PREPARATION

1. Remove the obturator or endoscope (FIG. 2)
2. Remove the cannula by pressing the cannula latch and pulling the cannula out of the adapter. (FIG. 3)
3. If using the multiSTATION® Sterilization Tray (Part Number 100034), clean the tray separately according to the sterilization tray instructions for use.



multiSTATION® 5mm CANNULA WITH OBTURATOR REPROCESSING (continued)



multiSTATION® 5mm CANNULA WITH OBTURATOR REPROCESSING (continued)

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 following location (FIG. 4): length of cannula lumen. 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.
4. Perform a functional check for adequate cannula ring function (refer to pages 2-3).

PACKAGING

1. If using a sterilization pouch, place one disassembled device (cannula and obturator) 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. 5.
2. Package the device according to TABLE 1 below. 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

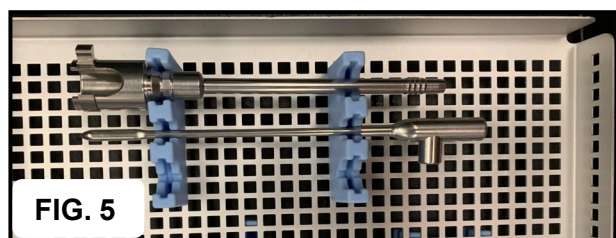


FIG. 5

STERILIZATION

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

TABLE 1: multiSTATION® 5mm CANNULA WITH OBTURATOR 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

multiSTATION® 5mm CANNULA WITH OBTURATOR REPROCESSING (continued)

 STERILIZATION (continued)	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 <i>multiSTATION® 5mm CANNULA WITH OBTURATOR</i> 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 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

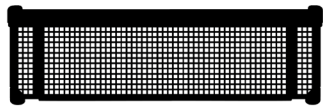
- Federal law restricts this device to sale, distribution and use by, or on, the order of a physician.
- Read and become familiar with all instructions, warnings, and cautions before using this product.
- The *multiSTATION® 5mm CANNULA WITH OBTURATOR* shall be used in accordance with these instructions for use.
- Improper use of the device 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® 5mm CANNULA WITH OBTURATOR*, patients must be immobilized or anesthetized.
- Discontinue use of the *multiSTATION® 5mm CANNULA WITH OBTURATOR* 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 relative to techniques, complications, and hazards should be consulted prior to use.
- When using the *multiSTATION® 5mm CANNULA WITH OBTURATOR*, an insufficient skin incision may cause increased penetration force which may reduce the surgeon's control during entry.

PRECAUTIONS

- **The *multiSTATION® 5mm CANNULA WITH OBTURATOR* is packaged as non-sterile.** Clean and sterilize prior to use.
- If there are any variations between these instructions for use and 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® 5mm CANNULA WITH OBTURATOR* for a task other than what it is intended for can result in a damaged or broken device.
- Prior to use, inspect the *multiSTATION® 5mm CANNULA WITH OBTURATOR* 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® 5mm CANNULA WITH OBTURATOR*.
- Always use caution when inserting or removing devices through the cannula. Lateral pressure on a cannulated instrument during removal can damage the working tip and/or shaft of the device. Be sure any instrument tips are closed and the device is pulled straight out until completely clear of the cannula.
- 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.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the country competent authority.

TABLE 2: <i>multiSTATION</i> ® 5mm CANNULA WITH OBTURATOR PRODUCT ORDERING			
	REORDER	PRODUCT	DESCRIPTION
	REF 081890	<i>multiSTATION</i>® 5mm CANNULA WITH OBTURATOR	1 Shelf Box
	REF 100034	<i>multiSTATION</i>® Sterilization Tray*	1 Shelf Box

LSI SOLUTIONS®

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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

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