AXIUS™

8mm Needle Driver

INSTRUCTIONS FOR USE

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PLEASE READ ALL INFORMATION CAREFULLY.

IMPORTANT: This package insert is designed to provide instructions for use of the AXIUS™ 8mm Needle Driver. No instruction for surgical technique is provided.

NOTICE: Any serious incident in relation to the device should be reported to the manufacturer and competent authority of the Member State in which the user and/or patient is established.

Rx ONLY

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1. DEVICE DESCRIPTION

The AXIUS™ 8mm Needle Driver is a reusable surgical device designed for use in endoscopic surgery. The device is packaged non-sterile and must be cleaned and sterilized prior to use per the cleaning, decontamination, and sterilization instructions in this Instructions for Use (IFU).

The AXIUS™ 8mm Needle Driver consists of a jaw (a), articulating tip or end-effector (b), shaft (c), frame (d), and handle (e). The handle allows for direct transmission of the surgeon's hand and wrist motions to the articulating tip. The rotation dial (f) located on the handle rotates the device 360-degrees. Two silicone caps (g) are used to cover the flush ports.

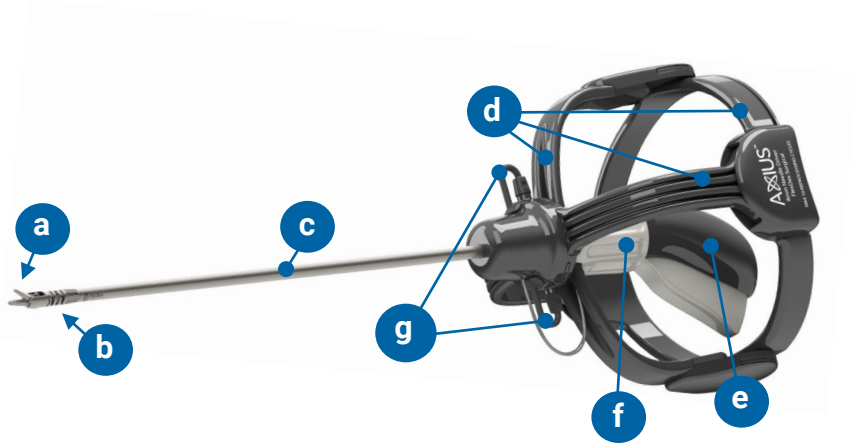

FIGURE 1: AXIUS™ 8mm Needle Driver

The AXIUS™ 8mm Needle Driver may be used for up to a maximum of 10 reprocessing cycles.

TABLE 1: AXIUS™ 8mm Needle Driver Shaft Lengths

NEEDLE DRIVER (NON-STERILE) 10 REPROCESSING CYCLES	MODEL NUMBER	SHAFT LENGTH
MEDIUM	8ND1M	37 cm
LONG	8ND1L	43 cm

1.1 PERFORMANCE CHARACTERISTICS

The AXIUS™ 8mm Needle Driver can articulate up to 70 degrees or greater with respect to the shaft in any direction and provides seven degrees of freedom and 360° rotation for the purpose of suturing in various orientations. The device is optimized for the use of needles between 0.4mm and 1.1mm in diameter and an 8mm trocar.

1.2 CLINICAL BENEFIT

The AXIUS™ 8mm Needle Driver provides benefit of minimally invasive endoscopic suturing with increased dexterity, allowing suturing to be performed with precision in any orientation.

1.3 INTENDED PURPOSE AND INDICATIONS FOR USE

Indications for Use: Intended for minimally invasive surgical applications involving endoscopic suturing.
Intended Purpose: Intended as a minimally invasive surgical tool for surgeons to perform endoscopic suturing with required tissue, excluding the central nervous system and central circulatory system.

1.4 INTENDED PATIENT GROUP(S)

AXIUS™ 8mm Needle Driver is intended for use in patients undergoing procedures that involve endoscopic suturing.

1.5 INTENDED USER(S) AND QUALIFICATIONS/TRAINING OF USER(S)

Primary User Group

- Surgeons – The AXIUS™ 8mm Needle Driver is intended to be used by surgeons to perform endoscopic suturing. Surgeons are trained in endoscopic surgery and trained in the performance of complex endoscopic procedures and manipulations.

Additional User Groups

- Operating Room (OR) Nurses and Technicians; Circulating and Scrub – The AXIUS™ 8mm Needle Driver will be handled by OR nurses and technicians who are trained to assist during endoscopic procedures. These tasks include handing the device

back and forth to the surgeon and packaging the device into the tray for reprocessing.

- Central Processing Department (CPD) – The AXIUS™ 8mm Needle Driver will be received by CPD to clean the device, prepare for use in future endoscopic procedures, and sterilize the device. CPD is trained in the cleaning and sterilization procedures of surgical instruments and tracking the number of reprocessing cycles per device.
- Hospital Purchasing and Receiving – The AXIUS™ 8mm Needle Driver will be purchased, received, and stocked by the hospital administrative staff, who are trained to perform these functions for all orders of medical devices.

1.6 ACCESSORIES

The AXIUS™ Instrument Tray, manufactured by Summit Medical, is required for reprocessing.

1.7 CONTRAINDICATIONS

- Do NOT use the AXIUS™ 8mm Needle Driver when minimally invasive procedures are contraindicated.
- Do NOT use the AXIUS™ 8mm Needle Driver as a grasper or dissector.
- Do NOT use the AXIUS™ 8mm Needle Driver in procedures within the central nervous system or central circulatory system.

1.8 GENERAL WARNINGS, CAUTIONS, AND NOTES

⚠ **WARNING:** The design of the AXIUS™ 8mm Needle Driver provides a low barrier to adoption for surgical use. However, only trained users or those who have developed adequate skills to perform the tasks associated with each of its features should use the device. Training in the use of the device is provided by FlexDex but does not replace the necessary medical training and experience required to perform endoscopic surgery.

⚠ **WARNING:** All surgical devices are subject to wear and tear as a result of normal use. End of useful life of the device is 10 reprocessing cycles. However, inspect for damage and verify proper function prior to use. Replace if damaged, worn or bent. Do not attempt to straighten or repair. If an improperly functioning or damaged device is used, this may lead to patient injury.

WARNING: Inspect packaging for damage. Do not use the device if packaging is opened or damaged.

WARNING: Care should be taken when working with materials that can be transferred to the device through handling (e.g., latex proteins, disinfecting solutions).

CAUTION: Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated devices. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated devices. PPE includes gloves, gown, mask, goggles or face shield and shoe covers.

CAUTION: Prior to inserting or removing the device through the trocar, ensure that the device jaws are closed, and the articulating tip is straight, otherwise damage to device or trocar is possible.

CAUTION: Do not back-drive, or flex the articulating tip, by any means other than the handle, otherwise damage may occur.

CAUTION: The AXIUS™ 8mm Needle Driver can accommodate needles between the diameters of 0.4 mm and 1.1 mm. Use of needles outside of this range may reduce the device performance.

NOTE: Follow AAMI/ISO 17665-1:2006/(R)013 or BS EN ISO 17665-1:2006 and the specifications of the sterilization device manufacturer.

NOTE: Do not use equipment (e.g. steam cleaning devices) or procedures that employ pre-cleaning temperatures > 140°F (60°C). High temperatures may fix residual soil to the surface and make cleaning more difficult.

NOTE: Use only process chemicals that conform to legal and regulatory requirements for safety as required by the jurisdiction in question.

1.9 KNOWN / POSSIBLE ADVERSE EVENTS (residual risks)

Failure to observe the warnings and precautions associated with this device may result in health consequences such as blood loss, infection,

biological reaction, perforations, adhesions, or other events causing additional medical intervention.

1.10 GLOSSARY

Accessories: Components that are used in conjunction with instruments

Cold water: Unless otherwise specified, the term “cold water” refers to tap water that is 50-77° F (10-25° C) and potable or better as defined by AAMI TIR34.

Critical Water: Examples of critical water include deionized (DI) water, reverse osmosis (RO), and distilled water. Critical water is a type of water defined by AAMI TIR34. Critical water is extensively treated (usually by a multi-step treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that microorganisms and the inorganic and organic material are removed from the water.

Flush Tube: The long plastic tube inside of the shaft that permanently connects to the top flush port and carries fluid to the end of the instrument shaft during flushing.

Prep and Pack: An area in hospitals and other healthcare facilities where medical devices that have already been cleaned in the Decontamination Area are inspected, packaged, and sterilized.

Soil: Also called “residual soil.” Body fluids or tissue that remain on the device after reprocessing.

2. INSTRUCTIONS FOR USE

⚠ **WARNING:** Device must be cleaned and sterilized prior to each use, including first use.

2.1 PRIOR TO EACH USE

1. Using sterile technique, remove the device from the sterilization wrap and AXIUS™ Instrument Tray.
2. Ensure **flush ports are closed.** If not, insert the caps into the flush ports and twist to ensure caps are fully seated.

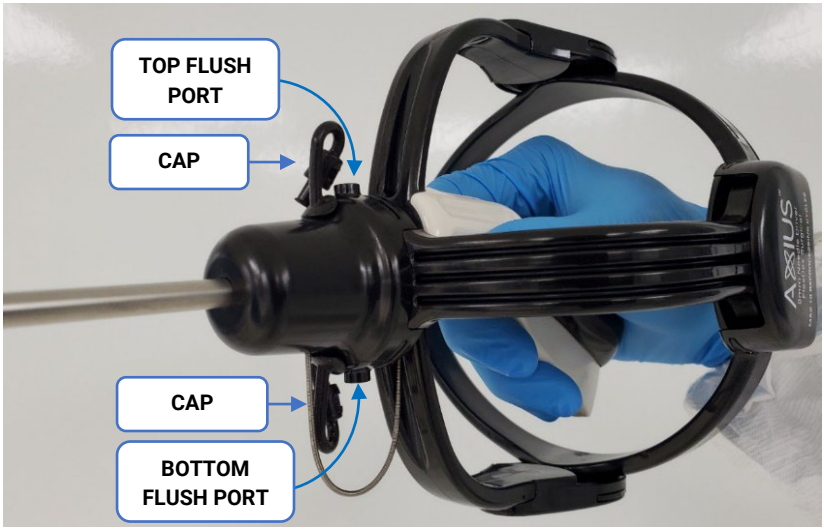

FIGURE 2: AXIUS™ 8mm Needle Driver flush ports shown open before cap insertion.

3. Before use, perform a functionality check following the instructions in the next section.

⚠ **WARNING:** All surgical devices are subject to wear and tear as a result of normal use. End of useful life of the device is 10 reprocessing cycles. However, inspect for damage and verify proper function prior to use. Replace if damaged, worn or bent. Do not attempt to straighten or repair. If an improperly functioning or damaged device is used, this may lead to patient injury.

2.2 USING THE DEVICE

1. Use the handle to fully articulate the distal tip up, down, left, and right (FIGURE 3). Ensure the distal tip articulates smoothly in a continuous motion.

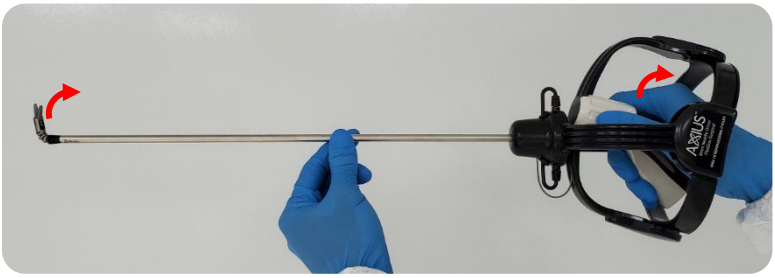

FIGURE 3: Articulating the AXIUS™ 8mm Needle Driver tip up.

⚠ **CAUTION:** Do not back-drive, or flex the articulating tip, by any means other than the Handle, otherwise damage may occur.

2. Use the rotation dial to rotate the device 360 degrees in both directions (FIGURE 4). It should rotate freely.

FIGURE 4: Rolling the AXIUS™ 8mm Needle Driver

3. Fully squeeze the handle lever to lock the jaw and fully squeeze again to unlock to ensure that the lever mechanism is operating correctly (FIGURE 5). An audible and/or tactile click will be heard and/or felt when fully squeezing the lever. The lever will not return to the open position unless it is fully squeezed against the handle. Ensure the jaws close securely when locking the handle lever.

FIGURE 5: Locking and unlocking of the AXIUS™ 8mm Needle Driver jaws via the handle lever.

NOTE: It is recommended to rinse or soak the articulating tip of the device when not in use to prevent and/or remove buildup of biomass.

WARNING: If the device does not rotate or articulate freely, or the lever and lock mechanism is not operating correctly, the system may be damaged and should be replaced. Using a damaged device may lead to patient injury.

2.3 DEVICE ENTRY AND REMOVAL FROM TROCAR

1. Upon entry and removal from the 8mm trocar, ensure the distal tip of the device is aligned with the shaft of the device and the jaws are closed, as shown in FIGURE 6.

FIGURE 6: AXIUS™ 8mm Needle Driver with closed jaws for entry / removal from trocar

⚠ **CAUTION:** Failure to have the distal tip aligned with the shaft and jaws closed may result in difficult removal of the device, damage to the device or trocar, and/or possible reduction of insufflation.

2. Rinse the device from visible soil immediately after use or within a maximum of 2 hours.

2.4 PROPER NEEDLE ORIENTATION

The figure below shows the optimal needle holding position in the jaws.

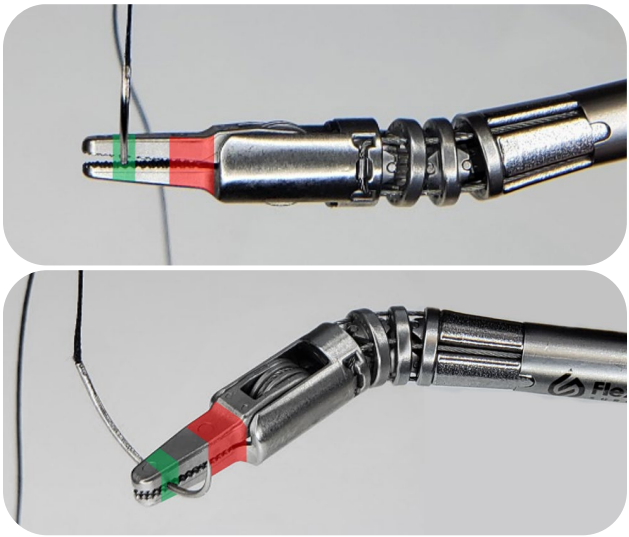

FIGURE 7: Optimal needle holding position (green).
Holding the needle at the base of the jaws (red) may result in suboptimal device performance.

3. CLEANING AND REPROCESSING

The instructions contained in this section shall be performed prior to initial use and following each surgical procedure.

SUPPLIES NEEDED FOR REPROCESSING

- Large container or sink to fit device (29 inches or 73.6cm minimum length, 10 inches or 25.4 cm in width and 10 inches or 25.4 cm in height)
- pH-neutral to mildly alkaline enzymatic solution (pH 7-11)
- Syringe with Luer tip (20 mL minimum)
- Running cold water
- Pressurized water
- Critical water, per AAMI TIR34:2014
- Clean nylon brush
- Low-linting wipe
- Magnifying glass (4X or greater)
- Ultrasonic Bath with the following recommended parameters:
    - Ultrasonic Performance: 48 watts/gallon (13 watts/liter) or greater
    - Ultrasonic Frequency: 38 kHz or greater
    - Ultrasonic Bath Size: Large enough to fully submerge devices with at least 1-inch (25 mm) clearance all around ultrasonic bath edges.

3.1 DECONTAMINATION PREP

1. CHECK DEVICE REPROCESSING CYCLES

Using the hospital tracking system, check the number of times the device has been reprocessed.

- If the device has been reprocessed 10 times (expired):
  - Dispose of according to hospital policy.
- If the device has been reprocessed fewer than 10 times:
  - Proceed to Step 2.

2. CHECK JAW POSITION & FLUSH PORT

Ensure the handle is unlatched and jaws are **open**.

Confirm the flush tube is seated properly in the top flush port (located opposite of the metal tube, per FIGURE 9) and:

- NOT obstructed
- NOT pushed in
- NOT pushed out
- NOT missing.

Per FIGURE 8, the flush tube position is acceptable if the lumen (in the center of the flush tube) is visible.

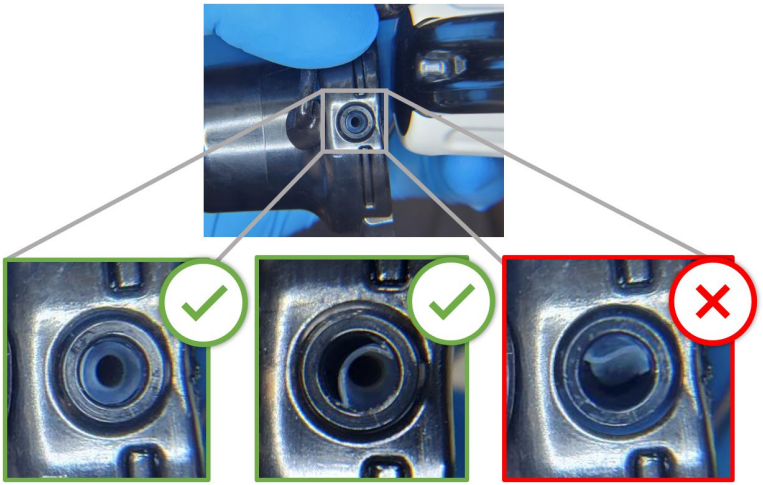

FIGURE 8: Proper location and geometry of Flush Tube in the top flush port.

WARNING: Reprocessing a device without a proper flush tube may result in incomplete reprocessing.

3. PREPARE CLEANING SOLUTION

Prepare fresh pH-neutral to mildly alkaline enzymatic solution (pH 7-11) in a suitable container, sink, or bin, enough to soak entire device.

WARNING: Use care in handling chemicals and contaminated solutions, as skin contact, inhalation, or ingestion may cause injury.

CAUTION: Use only the following reprocessing cleaners:

- In Operating Room, pH-neutral or water only
- In Decontamination Area, pH-neutral to mildly alkaline (pH 7-11)
- For mildly alkaline, use ≤ 1% (v/v) or 1:100 maximum concentration.
- Do NOT use cleaners that are:
  - Acidic (pH < 7)
  - Strong alkaline (pH > 11)
  - Bleach-based
  - Hydrogen Peroxide (H2O2)-based cleaning agents
  - Rinse aids

CAUTION: Failure to follow these precautions may result in device damage (e.g. pad printed graphics may fade, laser marking may deteriorate, or device may corrode).

NOTE: Follow the manufacturer's instructions for the preparation and use of cleaning solutions, including temperature and concentration.

3.2 CLEANING

1. PRIME

Ensure both flush ports are open, as shown in FIGURE 9.
Using a syringe or other device with a Luer tip, flush at least 20 mL of enzymatic solution into the top flush port while gently articulating the tip of the device (by moving the handle in space) in all directions (i.e. full circles while articulated) at least three times.

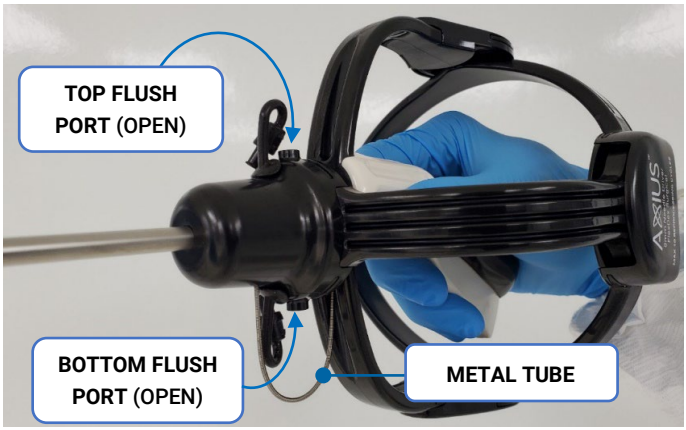

FIGURE 9: AXIUS™ 8mm Needle Driver Top Flush Port, located opposite of the metal tube

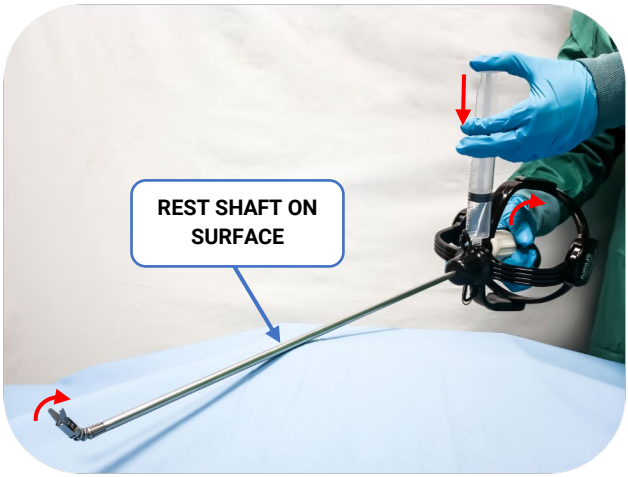

FIGURE 10: To assist with flushing and articulating at the same time, it may be helpful to rest the shaft on a surface, such as the edge of the sink.

2. **SOAK**

Soak the device fully submerged in the enzymatic solution for **30 minutes**.

3. **FLUSH**

Before flushing, point the device tip away from you. Using cold pressurized water, flush using the top flush port for **20 seconds** and the bottom flush port for **20 seconds**. Continue to flush until the water runs clear.

WARNING: Confirm that the flush tube is present inside of the top flush port and is not dislodged or obstructed. Reprocessing a device without the flush tube may result in incomplete reprocessing.

WARNING: If water does not run clear, or if water does not flow freely through all flush ports, do not use the device, because it may be damaged. Contact FlexDex Surgical Customer Service.

4. **SPRAY**

   a. **SUBMERGE**

   Submerge the entire device in cold water.

   b. **SPRAY JAWS & ARTICULATING TIP**

   While submerged, spray the jaws and articulating tip with pressurized cold water for at least **30 seconds** while articulating through its full range of motion (by moving the handle in space) in all directions (i.e. full circles while articulated). A running sink/hose is recommended, so one operator can use both hands.

FIGURE 11: Area to spray includes both the jaws and articulating tip.

NOTE: Be sure to spray all surfaces of the tip.

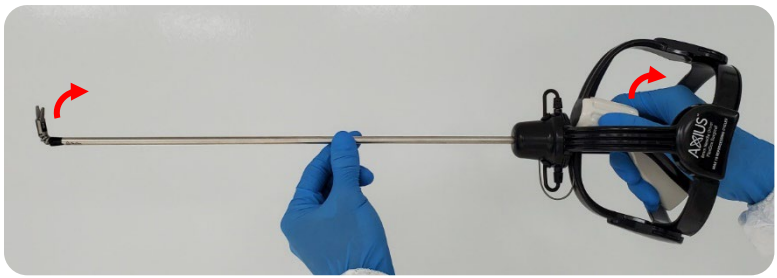

FIGURE 12: Articulating up. While spraying the articulating tip, repeat in all directions (up, down, left, right) by moving the handle in space.

c. **SPRAY ALL CREVICES IN THE FRAME**
Spray all joints and interfaces in the frame and handle that could accumulate biomass.

5. BRUSH

Using a soft nylon brush, brush all outside surfaces of the device while either submerged or under running water.

- Brush the shaft and end effector for **60 seconds**.
- Brush the frame for an additional **5 minutes** (300 seconds).

WARNING: Do not use brushes, pipe cleaners, or other objects in the shaft through the flush port. Doing so may result in device damage or incomplete reprocessing.

CAUTION: Use only nylon (soft-bristled) brushes for cleaning. The use of metal brushes or abrasive materials for cleaning may result in device damage.

NOTE: Be sure to brush all crevices of the end effector, paying close attention to the areas in FIGURE 13.

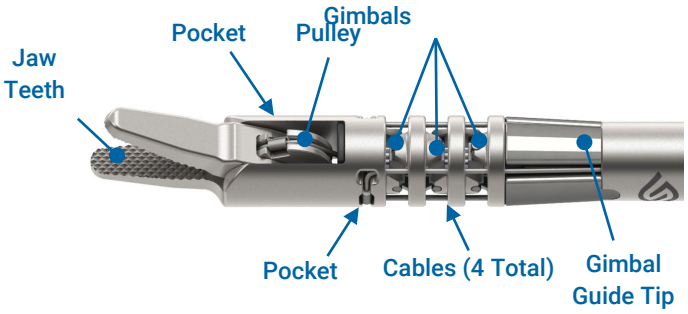

FIGURE 13: Take caution to brush these areas well.

6. RINSE

Rinse the entire device under cold running water for **60 seconds**.

7. ULTRASONIC CLEANING

CAUTION: Prolonged exposure to either ultrasonic cleaning or cleaning agents may result in device damage.

NOTE: Manual preparation of the solution (a) and filling of the bath (b) may not be required if ultrasonic cleaner is equipped with these functions.

a. **PREPARE SOLUTION**
Prepare fresh pH-neutral to mildly alkaline enzymatic solution (pH 7-11) by following cleaning solution manufacturer's instructions for use, temperature, and concentration.

b. **FILL ULTRASONIC BATH**
Fill ultrasonic bath with the prepared solution.

c. **PRIME**
Insert the syringe's Luer tip fully into the top flush port and inject at least 15mL of cleaning solution into the top flush port while gently articulating the tip of the device (by moving the handle in space) in all directions (i.e. full circles while articulated) at least three times.

NOTE: Some ultrasonic baths do not fill until the lid is closed. In this case, prime the shaft and place the device in the ultrasonic bath taking care to prevent cleaner from exiting the shaft.

d. **SUBMERGE**
Place the device into the ultrasonic bath with flush ports open.

e. **SONICATE**
Ultrasonically clean for **15 minutes** using the recommended parameters for the ultrasonic bath.

NOTE: Follow manufacturer's instructions for use of the ultrasonic bath.

NOTE: If ultrasonic bath has an automated rinse and flush capability proceed to "Inspection" step; otherwise, proceed to "Flush."

8. **FLUSH**

WARNING: Confirm that the flush tube is present inside of the top flush port and is not dislodged or obstructed. Reprocessing a device without the flush tube may result in incomplete reprocessing.

Before flushing, point the device tip away from you. Using cold pressurized water, flush the device using the top flush port for **20 seconds** and the bottom flush port for **20 seconds**. Continue to flush until the water runs clear.

WARNING: If water does not run clear, or if water does not flow freely through all flush ports, do not use the device, because it may be damaged. Contact FlexDex Surgical Customer Service.

9. FINAL RINSE

Rinse the entire device for at least **60 seconds** until all visible soil and cleaning agents are removed.

NOTE: The use of critical water is recommended per AAMI TIR34:2014.

10. INSPECT

Inspect the entire device for soil under magnification (4x). If soil is present, repeat entire cleaning process.

11. THERMAL DISINFECTION (OPTIONAL)

If Thermal Disinfection is performed, device shall be properly packed into the AXIUS™ Instrument Tray prior to Thermal Disinfection. Refer to 3.3 Device Prep and Pack Step 4 (Pack) for detailed instructions. Perform disinfection per hospital policy and regional guidelines. Thermal disinfection is not a substitute for reprocessing.

TEMPERATURE	194˚ F – 199˚ F (90˚ C - 93˚ C)
TIME	1-5 minutes

12. TRANSFER

Transfer the device to prep and pack in the clean AXIUS™ Instrument Tray.

NOTE: AXIUS™ Instrument Tray reprocessing instructions are its Instructions for Use.

3.3 DEVICE PREP AND PACK

FIGURE 14: Image of device standing vertically.

1. **DRY**
   a. **DRAIN WATER**
      Empty excess water from the device by lightly shaking the device in the orientation shown in FIGURE 14 and letting it sit in the orientation shown.

   b. **DRY**
      Dry all device surfaces with a low-linting wipe.

   c. **BLOW AIR** (optional)
      Blow clean dry air through the flush ports and housing as needed.

   NOTE: Ensure device is dry before moving to the next step.

2. **FINAL INSPECTION**

WARNING: After reprocessing, always inspect devices for any defects or damage. Failure to inspect may result in patient harm and/or additional device damage.

   a. **INSPECT FOR SOIL**
      Inspect entire device under magnification (4x) to confirm that no soil is present. If present, repeat the cleaning process.

   b. **INSPECT FOR DAMAGE**
      Inspect entire device for damage. Examples of damage include:

- Cracked or damaged device housing
- Bent or broken jaws or tips
- Broken or frayed cables

c. **INSPECT FLUSH TUBE**

Confirm the flush tube is seated properly in the top flush port and:

- NOT obstructed
- NOT pushed in
- NOT pushed out
- NOT missing.

Per FIGURE 15, the flush tube position is acceptable if the lumen (in the center of the flush tube) is visible.

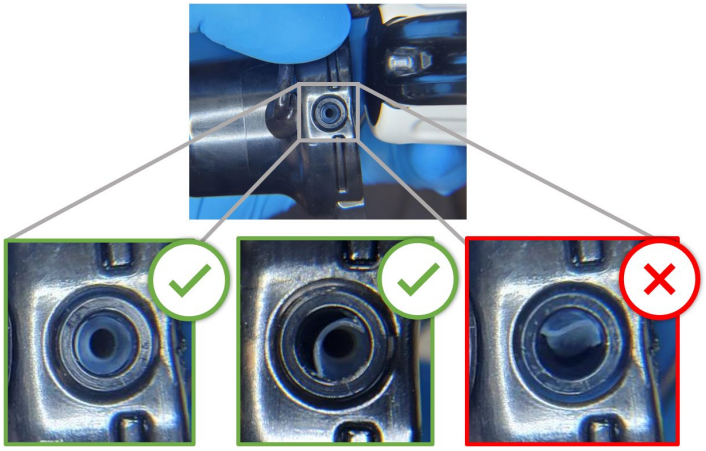

FIGURE 15: Proper location and geometry of Flush Tube in the top flush port.

NOTE: If damaged, contact FlexDex Customer Service.

3. LUBRICATE

NOTE: Do not apply lubricant to the jaw surfaces (teeth) of the end-effector.

NOTE: Use a legally marketed, steam permeable, pH-neutral lubricant. Refer to lubricant manufacturer's labeling instructions for use.

Apply 1-2 drops of lubricant to the cable locations, including the pulley.

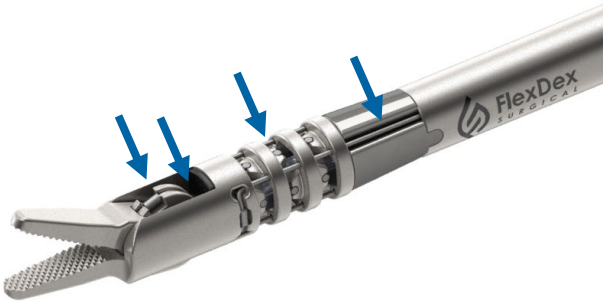

FIGURE 16: Areas of Lubrication

4. **PACK**
    a. **POSITION DEVICE IN TRAY**

    Place device in the AXIUS™ Instrument Tray, and ensure device is secure in the device holders. Slide the black piece, as required, as shown in FIGURE 20. Per FIGURES 18-21, check:

    - Handle is unlatched and jaws are open
    - Flush ports are open (caps detached)
    - Flush ports are oriented at the top and bottom of the tray
    - Back of handle is contacting the blue silicone at back of tray
    - Gimbal guides (FIGURE 17) are aligned in slots (FIGURE 21).

FIGURE 17: Gimbal Guides

⚠ **WARNING:** The flush ports must be open (caps must be detached) during cleaning and sterilization. If the flush ports are closed during cleaning and/or sterilization, the sterility of the device may be compromised.

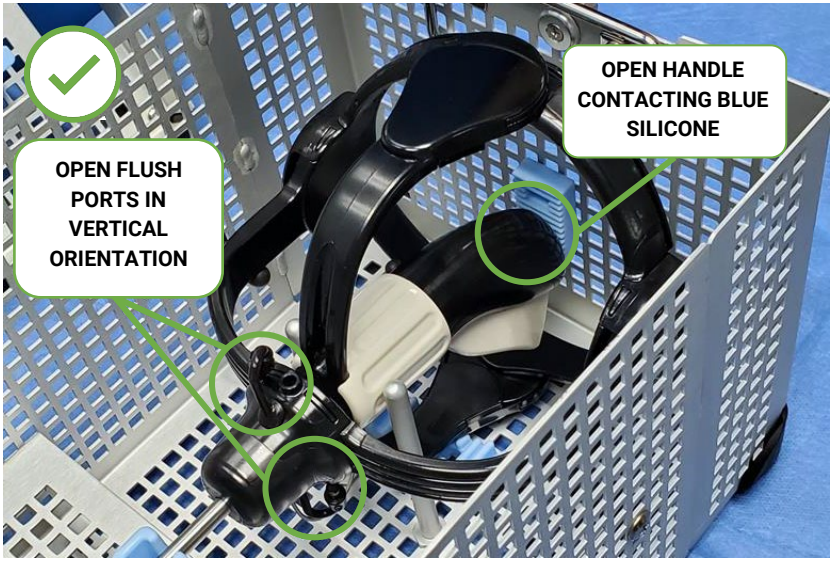

FIGURE 18: Correct device orientation in AXIUS™ Instrument Tray

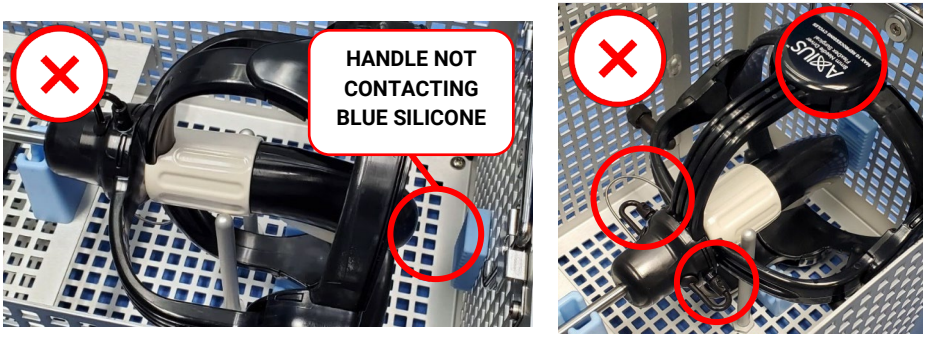

FIGURE 19: Incorrect device orientation
(LEFT: device too far forward such that the back of the handle is not contacting blue silicone piece,
RIGHT: flush port caps oriented sideways and closed, AXIUS™ logo facing upwards).

⚠ **CAUTION:** Misplacement of the device in the tray may result in permanent damage to the articulating end-effector and reduce device performance.

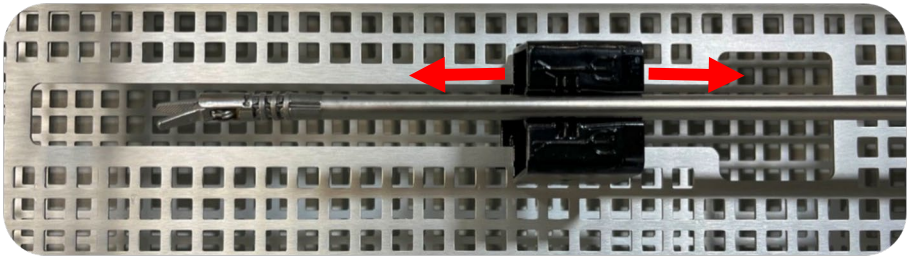

FIGURE 20: Black piece that holds the gimbals can slide along the slot in AXIUS™ Instrument Tray to accommodate different shaft lengths. Slide to position device as shown in FIGURE 21.

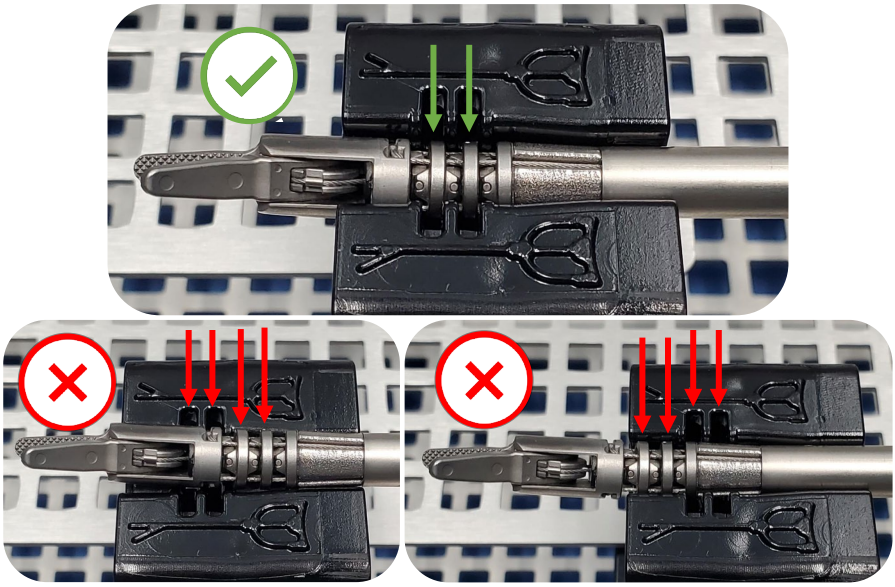

FIGURE 21: Shaft placement in AXIUS™ Instrument Tray.
Correct orientation (TOP) shows the jaws open and alignment of the gimbals with the two slots.

b. **LOCK LID**

Place the lid on tray. Lock the lid latches.

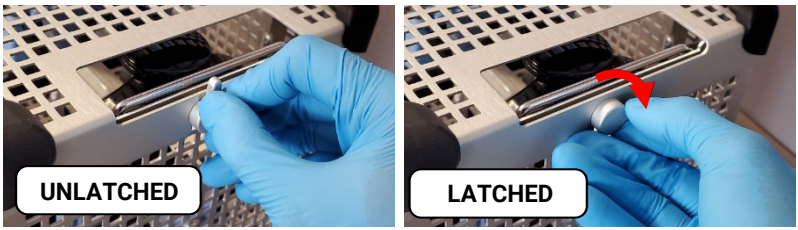

FIGURE 22: Lock tray latches

5. WRAP TRAY

Double wrap according to both sterilization system and tray manufacturers' instructions.

6. STERILIZE

TABLE 2: Pre-Vacuum Steam Sterilization Table

TEMPERATURE	270˚ F (132˚ C)
FULL CYCLE EXPOSURE TIME	4 minutes
DRY TIME	30 – 50 minutes Drying time will vary depending on the packing system used, steam quality and load size of the sterilizer, and the environmental conditions. Drying times after steam sterilization are between 30 and 50 minutes. Per ANSI/AAMI ST79:2010, "drying should be evaluated by controlled, random sampling and opening selected sets at the completion of the drying/cooling time. Health care facility policy will dictate the frequency of sampling."

NOTE: Dry time may vary with use of other trays, other tray configurations, autoclave type, and autoclave load.

NOTE: The minimum sterilization time and temperature validated for compatibility are 3 minutes and 132˚C.

NOTE: The maximum sterilization time and temperature validated for compatibility are 18 minutes and 134˚C.

7. UPDATE HOSPITAL TRACKING SYSTEM

Using the hospital tracking system, update the number of times the device has been reprocessed.

8. STORE

Store the sterilized device in a clean, dry place.

NOTE: The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing the medical device for reuse for up to 10 reprocessing cycles. It remains the responsibility of the processor to ensure that the processing, as actually performed using the equipment, materials, and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

4. DISPOSAL OF THE AXIUS™ 8MM NEEDLE DRIVER

Dispose of used device as a biohazard per institution biohazard protocol and all applicable national and local laws and guidelines.

A device that has undergone 10 reprocessing cycles is a used device. A device that does not function adequately upon functionality check prior to use is also considered a used device.

5. APPENDIX A: SYMBOL DEFINITIONS

SYMBOL	DEFINITION
	MODEL NUMBER
	SERIAL NUMBER
	DATE OF MANUFACTURE
	MANUFACTURER
	QUANTITY OF PRODUCT IN PACKAGING
	U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
	MEDICAL DEVICE
	CONSULT OPERATING INSTRUCTIONS
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY / EUROPEAN UNION
	“WARNING” notes indicate that a hazard might severely injure or cause death if not instruction not followed.
	“CAUTION” notes indicate minor to moderate injury to user or patient or damage to equipment if instruction not followed.
	“NOTE” symbol indicates additional explanation or attention required before or after an instruction.

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