**Proxisure™ Suturing Device**

**Cleaning and Sterilization Instructions**

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### Step 1: Pre-Cleaning

1. **Open flush port.** Immerse device for at least 10 minutes in neutral pH enzymatic detergent (e.g. Enzol).
   - **10 min.**

2. **Flush shaft with a neutral pH enzymatic detergent until the fluid exiting the distal tip is visibly clear.**
   - **30 sec.**

3. **Brush the interior and exterior of the opened jaws, exterior crevices, seams, joints and handle with a soft nylon brush.**
   - **1 min.**

4. **Flush shaft with tap water until the fluid exiting the distal tip is visibly clear.**
   - **30 sec.**

5. **Rinse the exterior of the device under running tap water for at least 1 minute.**
   - **1 min.**

6. **Immerse the device in an ultrasonic bath containing fresh neutral pH enzymatic detergent.**
   - **4 min.**

7. **Flush shaft with tap water until the fluid exiting the distal tip is visibly clear.**
   - **30 sec.**

8. **Rinse the interior and exterior of the device under running tap water for at least 1 minute.**
   - **1 min.**

**Note:** If the water is not visibly clear, repeat 1-7.

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### Step 2: Automated Cleaning - or - Manual Cleaning

**Automated Cleaning**

1. **Place the device in a clean sterilization tray.** Ensure the distal tip is aligned with the shaft, the jaws are parallel, and the flush port is open.
   - **1 Place the tray without the lid attached into the automatic washer.**

2. **Place the tray without the lid attached into the automatic washer.**
   - **2 Place the automatic washer to “Instrument Cycle” or an equivalent cycle.**

3. **Set the automatic washer to “Instrument Cycle” or an equivalent cycle including: an enzymatic wash, rinse, neutral pH detergent wash, rinse with critical or high purity water (e.g. reverse osmosis, deionized, or distilled), and drying.**
   - **3 Set the automatic washer to “Instrument Cycle” or an equivalent cycle.**

4. **Optional** A high-level disinfection step can be included as part of the automatic cleaning cycle. The device may be thermally disinfected at greater than 200°F (93°C) for a minimum of 5 minutes to render the device safe for handling.
   - **4 Optional**

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**Manual Cleaning**

1. **Immerse device for at least 10 minutes in neutral pH detergent.**
   - **10 min.**

2. **Flush shaft with a neutral pH detergent until the fluid exiting the distal tip is visibly clear.**
   - **30 sec.**

3. **Brush the interior and exterior of the opened jaws, exterior crevices, seams, joints and handle with a soft nylon brush.**
   - **1 min.**

4. **Flush shaft with critical or high purity water (e.g. reverse osmosis, deionized, or distilled) until the fluid exiting the distal tip is visibly clear.**
   - **30 sec.**

5. **Rinse the interior and exterior of the device with critical or high purity water (e.g. reverse osmosis, deionized, or distilled) for at least 1 minute.**
   - **1 min.**

6. **Dry the device with a clean, absorbent lint-free cloth, with pressurized air or by hanging the device with the shaft and distal tip pointing down.**
   - **6 Dry the device with a clean, absorbent lint-free cloth, with pressurized air or by hanging the device with the shaft and distal tip pointing down.**

**Caution:** Do not load more than one device in the sterilization tray as it may result in damage to the jaws and other parts of the device and compromise sterilization.

**Warning:** The flush port must be open during cleaning and sterilization. If the flush port is not open during cleaning and sterilization, the cleaning process may be less effective and sterility of the device may be compromised.

**Note:** Drying should not exceed 273°F (134°C).
Step 3: Inspection & Functional Testing

**Warning:** All surgical devices are subject to wear and tear as a result of normal use. End of useful life of the device is generally determined by wear or damage from handling or surgical use. If after repeated cleaning cycles, soil or blood is still present on the device, the device is beyond its useful life. If any of the inspection or functional testing below fails, the device is beyond its useful life. 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.

**Caution:** Do not grasp the distal tip to articulate the device. This may damage the device and compromise functionality. Use only the articulation knob on the handle of the device.

1. Soil Removal
   - Verify complete removal
   - Repeat pre-clean if needed
2. Tray Inspection
   - Inspect tray for damage
   - Do not use if damaged
3. Cartridge Release Lever
   - Verify pivot jaw opens and closes smoothly without excessive force
4. Articulation Knob
   - Articulate 45 degrees in both directions
   - Distal end should remain fixed and without excessive play
5. Rotation Knob
   - Rotate the jaws 360 degrees in both directions
   - Distal end should move freely without excessive force
6. Trigger
   - Squeeze and release trigger
   - The movement should be smooth, the trigger force should be constant and not excessive, and the ratcheted mechanism should be heard
   - The trigger ratchet should engage through the middle of the stroke and prevent the trigger from returning until the completion of the trigger stroke
7. Metal Components
   - Ensure all markings are visible and there are no sharp edges or damage
8. Handle
   - Check for any cracks in the handle
9. Luer Cap
   - Ensure the luer cap is tethered to the port
10. Lubrication
    - Lubricate the distal end of the device using a water-based lubricant (e.g. Steris Hinge-Free®)
    - Lubrication can be conducted as part of the automatic washer cycle
    - Perform manual lubrication by dipping distal end of the device into lubricant and squeezing the trigger

**Warning:** Only non-silicone water-based lubricants should be used. Silicone or oil-based lubricants should not be used because this may compromise the ability to sterilize the device.

**Note:** Consult the IFU section “Inspection and Functional Testing after Cleaning” for more detailed instructions

Step 4: Autoclave Sterilization

**1. Ensure flush port is open and luer cap is tethered to the port.**

**2. Place the device in a sterilization tray.**

**Caution:** Do not load more than one PROXISURE™ Suturing Device in the sterilization tray as it may result in damage to the jaws and other parts of the device and compromise sterilization. The sterilization tray with its contents must not weigh more than 6 lbs (2.7kg).

**3. Place lid on tray and secure fasteners.**

**4. Select one of the autoclave cycle parameter sets listed in the table below and sterilize accordingly.**

**Caution:** Do not externally stack the sterilization tray in the autoclave as it may compromise sterilization of the device.

**Warning:** If the flush port is not open during sterilization, the sterility of the device may be compromised.

The following autoclave cycle parameters are approved for use.

<table>
<thead>
<tr>
<th>Method</th>
<th>Sterilizer Type</th>
<th>Cycle Time (at temperature)</th>
<th>Temperature Set Points</th>
<th>Preconditioning Pulses</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped</td>
<td>Prevacuum</td>
<td>4 Minutes</td>
<td>270°F (132°C)</td>
<td>3</td>
<td>50 Minutes</td>
</tr>
<tr>
<td>Unwrapped</td>
<td>Prevacuum</td>
<td>3 Minutes</td>
<td>270°F (132°C)</td>
<td>3</td>
<td>50 Minutes</td>
</tr>
<tr>
<td>Wrapped</td>
<td>Gravity</td>
<td>15 Minutes</td>
<td>270°F (132°C)</td>
<td>Not Applicable</td>
<td>50 Minutes</td>
</tr>
</tbody>
</table>

**Caution:** The PROXISURE™ Suturing Device must be sterilized using an autoclave. It has not been validated for other sterilization processes.

**Note:** The IFU contains additional Notes for sterilization and sterilization cycles approved for use outside of the US.

*Not intended to replace the IFU

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