Cleaning & Reprocessing:
All devices should be positioned to allow sterilant to come in contact with all surfaces. Care should be taken to protect devices from mechanical damage.

1. Disassemble device, if device is able to be disassembled, prior to reprocessing. Unthread end caps of depth gauge and handles to remove the inner shaft prior to reprocessing. Remove the inner shaft from outer sleeve.
2. Further detailed instrument Dismantling instructions are available from your local sales representative.
3. Open devices with ratchets, box locks or hinges.
4. Remove sharp devices for manual cleaning or place into a separate tray.
5. Lumens/cannula of devices should be manually processed prior to cleaning. Lumens/cannula should first be cleared of debris. Lumens/cannula should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannulation to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the surface of a lumen/cannulation.
6. Pre-Cleaning: Remove gross contaminants by immersing the devices in room temperature neutral pH enzymatic cleaner (i.e. Metrizyme). Scrub with appropriate soft bristle brush until visibly and thoroughly clean.
7. Washing: Immerse devices in washer/cleaner with room temperature neutral pH enzymatic cleaner and wash for 10 minutes.
8. Rinsing: Thoroughly rinse the devices with deionized or distilled water for 2 minutes, three (3) times.
9. Verification: Examine devices under normal lighting to ensure no visual contamination. Repeats steps 1-4 if not visibly clean.
10. Drying: Allow devices to air dry a minimum of 45 minutes prior to inspection and sterilization preparation.
11. Preparation: After cleaning/disinfection, visually inspect the devices. Check for burrs or scraps.
12. Sterilization: It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specified in this package insert.

Cleaning instructions have been validated.
Reassembly of instruments can be accomplished by following step 2 in reverse.

It is recommended that devices should be reprocessed as soon as is reasonably practical following use.

Visually inspect all reusable devices for signs of wear and tear before each use. Any devices with corrosion, discoloration, or cracked seals should be disposed of properly.

**Instruments and Implants Provided Non-Sterile:**

Products that are supplied non-sterile must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an FDA approved wrap or container. Due to the variations in steam sterilization systems, sterilization parameters should be determined and validated by reference to current ANSI/AAMI standards in addition to your facility’s own procedures. The following parameters have been validated to a sterility assurance level (SAL) of $\leq 10^{-6}$:

<table>
<thead>
<tr>
<th>Method</th>
<th>Steam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle Type</td>
<td>Pre-Vacuum</td>
</tr>
<tr>
<td>Minimum Temperature</td>
<td>132°C</td>
</tr>
<tr>
<td>Full Cycle Time</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Minimum Dry Time</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

Other sterilization methods have not been validated and may damage the product resulting in a device malfunction, injury to the patient, or both. FDA-cleared wraps should be utilized for steam sterilization.