Cleaning and sterilization instructions

The cleaning and sterilization instructions listed below are an excerpt from the Instructions for Use (IFU).

Manual cleaning with neutral pH cleaner
1 Prepare enzymatic cleaner (such as MetriZyme® enzymatic detergent) according to manufacturer’s recommendations using water (no less than 23°C).
2 Immerse entire instrument (jaws open or dismantled if appropriate) ensure all surfaces are in contact with the solution and allow to soak for 20 minutes.
3 Use a syringe to flush at least 30 ml of the detergent through the cannula of each instrument until liquid dispersing from the distal tip runs clear.
4 Actuate the instrument so that the tip is articulated to the maximum right and left angles at least three times to allow the detergent to reach all areas.
5 While submerged in the enzymatic detergent, clean the instrument with a soft bristle brush (M-16, Spectrum) until all visible soil has been removed. Pay particular attention crevices and/or the difficult-to-clean areas.
6 Flush the cannula and links at the distal end of the instrument with 30 mL of the prepared detergent until all visual evidence of debris is removed.
7 Prepare pH neutral cleaner (such as MetriWash® pH neutral detergent) according to manufacturer’s recommendations using tap water.
8 Repeat steps 3 through 6 using the pH neutral detergent.
   NOTE: Use of an enzymatic detergent is necessary to breakdown the soil/debris following clinical use. Use of a pH neutral detergent is necessary to wash the soil/debris away.
9 Thoroughly rinse the instrument in RO/DI water.
10 Using a sterile syringe, flush instruments with 30 ml of reverse osmosis/deionized (RO/DI) water through the cannula of each instrument until detergent cannot be observed dispersing from the distal tip.
11 Flush links at the distal end of the instrument with 30ml RO/DI water.
12 Wipe off excess moisture with a clean, soft cloth.
13 Using the naked eye and normal lighting conditions, visually examine instrument for visible soil/detergent/debris.
   NOTE: The entire cleaning procedure should be repeated if there is residual soil on the instrument.

Manual cleaning precautions
- Do not cold soak in gluteraldehyde, chlorine or ammonium solutions as they may damage the finish.
- Do not use metal brushes or scouring pads during the cleaning process as they will damage the surface and finish of the instruments. Use a soft-bristled nylon brush or other non-abrasive cleaning tool.
- Cleaning agents must be completely rinsed from the instrument to prevent accumulation of detergent residue.
- Use RO/DI water during the cleaning process to prevent stains.

Automated cleaning with neutral pH cleaner
1 Prior to transferring instruments to the washer, rinse each instrument thoroughly under warm (approximately 33 °C) running tap water to remove visible soil for two minutes.
2 Using a 10 cc syringe, flush all visible ports with tap water until there is no noticeable debris or discolored fluid exiting the instrument.
3 Prepare enzymatic cleaner (such as MetriZyme® enzymatic detergent) according to manufacturer’s recommendations using water (no less than 20 °C).
4 Use a syringe to flush at least 30 ml of the cleaner through the cannula of each instrument until liquid dispersing from the distal tip runs clear.
5 Repeat step 4 until liquid dispersing from the distal tip runs clear.
6 Prepare pH neutral cleaner (such as MetriWash® pH neutral detergent) according to manufacturer’s recommendations using tap water.
Repeat steps 4 through 5 using the pH neutral cleaner.

NOTE: Use of an enzymatic detergent is necessary to breakdown the soil/debris following clinical use. Use of a pH neutral detergent is necessary to wash the soil/debris away.

Place instrument into the washer and follow the recirculation instructions below:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Minimum Recirculation Time (Minutes:Seconds)</th>
<th>Temperature</th>
<th>Detergent Type and Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash 1</td>
<td>02:00</td>
<td>Cold tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Enzyme Wash</td>
<td>02:00</td>
<td>Hot tap water</td>
<td>MetriZyme® enzymatic cleaner, 1/2 oz/gallon, or equivalent enzymatic detergent</td>
</tr>
<tr>
<td>Wash 1</td>
<td>02:00</td>
<td>66.0°C (Set point)</td>
<td>MetriZyme® neutral pH cleaner, 1/4 oz/gallon, or equivalent neutral pH detergent</td>
</tr>
<tr>
<td>Rinse 1</td>
<td>00:15</td>
<td>Hot tap water</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Examine instrument for visible soil/detergent/debris.

NOTE: The entire cleaning procedure should be repeated if there is residual soil on the instrument.

**Disinfection**

Disinfect the instrument with a non-corrosive disinfection solution compatible with stainless steel and nitinol metals or by a terminal autoclave sterilization cycle appropriate for complex instrumentation with cannulation.

**Drying**

Dry the instrument immediately after final rinse. Use filtered compressed air to dry internal areas.

**Lubrication**

- Before each sterilization cycle, lubricate the instrument with a water-soluble lubricant appropriate for instrument being autoclaved, such as instrument milk or equivalent.
- Mineral oil or silicone lubricants should not be used because they coat microorganisms, prevent direct contact of the surface with steam and are difficult to remove.
- Follow the lubricant manufacturer's instructions regarding expiration dates for both stock and use-dilution concentrations.

**Sterilization**

<table>
<thead>
<tr>
<th>Method</th>
<th>Minimum temperature</th>
<th>Full cycle time</th>
<th>Minimum dry time</th>
<th>Instrument configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash gravity steam sterilization</td>
<td>132°C</td>
<td>10 minutes</td>
<td>N/A</td>
<td>Unwrapped</td>
</tr>
<tr>
<td>Prevacuum steam sterilization</td>
<td>132°C</td>
<td>4 minutes</td>
<td>30 minutes</td>
<td>Wrapped</td>
</tr>
<tr>
<td>Gravity steam sterilization</td>
<td>132°C</td>
<td>15 minutes</td>
<td>15 minutes</td>
<td>Wrapped</td>
</tr>
</tbody>
</table>

**Post-sterilization storage**

Sterile, packaged instruments should be stored in a manner that protects the integrity of the sterile barrier.

For additional information, please see Instructions for Use (IFU) for the SERPENT® Articulating Instrumentation.

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