

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.

Manuel cleaning precautions

- Do not cold soak in glutaraldehyde, 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.

7 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.

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

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

9 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

Flash gravity steam sterilization

Minimum temperature: 132°C
Full cycle time: 10 minutes
Minimum dry time: N/A
Instrument configuration: Unwrapped

Prevacuum steam sterilization

Preconditioning pulses: 3
Minimum temperature: 132°C
Full cycle time: 4 minutes
Minimum dry time: 30 minutes
Instrument configuration: Wrapped

Gravity steam sterilization

Minimum temperature: 132°C
Full cycle time: 15 minutes
Minimum dry time: 15 minutes
Instrument configuration: Wrapped

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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