

Technical specifications



Indications for use

The SERPENT Articulating Instruments are intended for use in surgical procedures to examine or treat the nasal, paranasal and similar ear, nose, and throat tissues.

Device classification

This device is considered Class I in accordance to MDD 93/42/EC.

Main standards applied

- ISO 13485 – Medical devices – quality management systems – requirements for regulatory purposes
- ISO 14971 – Medical devices – application of risk management to medical devices

Product description

1. Configurations
 - a. 510-30110: SERPENT articulating thru-cutting forceps – vertical jaw
 - b. 510-30120: SERPENT articulating grasping forceps – vertical jaw
 - c. 510-30210: SERPENT articulating thru-cutting forceps – horizontal jaw
 - d. 510-30220: SERPENT articulating grasping forceps – horizontal jaw
2. Dimensions



3. Materials: surgical grade stainless steel

Packaging

1. Instruments are delivered via a corrugated box lined with protective foam.
2. Box size is 31.5cm X 23.0cm X 5.9cm.
3. Sterilization: NON-STERILE

Storage and transportation conditions

1. Instruments can be shipped using normal transit methods. No special handling is required.
2. Instruments should be stored in an environment typically used for storing medical devices. No special storage conditions are required.

Shelf life

Not applicable as the devices are reusable instruments.

Dispose condition

Instruments are reusable medical devices and can be cleaned and sterilized prior to the next intended use. It is recommended that the user follow the cleaning and sterilization instructions provided in each instrument's IFU.

Cleaning and sterilization instructions

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

Manual 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 nonabrasive 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.

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 the 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 30ml of the detergent through the cannula of each instrument until liquid dispersing from the distal tip runs clear.
4. Actuate the device 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 to crevices and/or difficult-to-clean areas.
6. Flush the cannula and links at the distal end of the instrument with 30ml 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 break down 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 30ml 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.

Automated cleaning with neutral pH cleaner

1. Prior to transferring device 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 10cc 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 30ml 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 break down 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 device 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.

Sterilization

Cycle	Configuration	Cycle temperature	Cycle time	Drying time
Gravity steam	Wrapped	132° C (270° F)	15 minutes	15 minutes
Prevacuum steam	Wrapped	3 preconditioning pulses 132° C (270° F)	4 minutes	30 minutes
Flash gravity steam	Unwrapped	132° C (270° F)	10 minutes	N/A

Post-sterilization storage

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

Special handling instructions

1. Lubrication

- Before each sterilization cycle, lubricate the instrument with a water-soluble lubricant appropriate for instruments 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.

2. Maintenance and inspection

- The instrument should be inspected after cleaning, and before use.
- Visually inspect the instrument to check for damage or wear.
- Cutting edges should be free of nicks and have a continuous edge.
- Jaws and teeth should align properly.
- Moveable parts should have smooth movement without excessive play or stiff, binding action.

Not made with natural rubber latex

As detailed above, the SERPENT° Articulating Instruments are primarily composed of stainless steel and thus are not made with natural rubber latex parts. The manufacturer recommends that all manufacturing/assembly be conducted using nitrile or similar gloves not made with natural rubber latex in order to prevent the accidental introduction of latex particles.

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