

Technical specifications

Indications for use

The SERPENT Sterilization Tray is used for loading SERPENT articulating instruments in order to conveniently organize, sterilize, transport, and store the instruments between uses.

Device classification

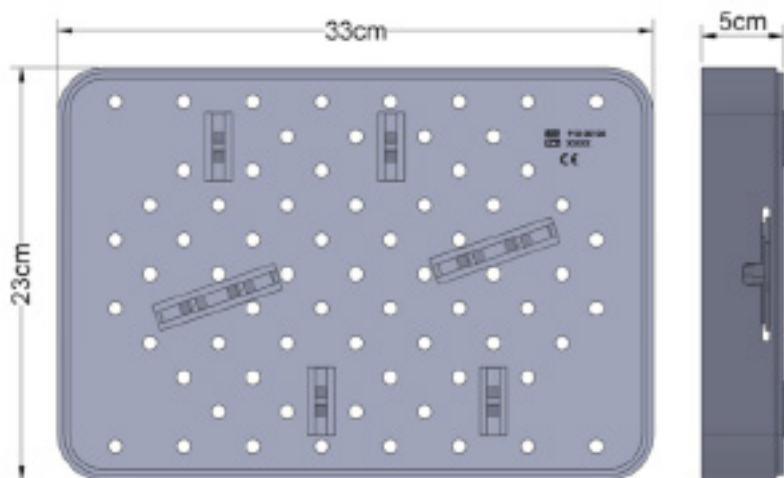
This device is considered Class I in accordance to MDD 93/42/EC.

Main standards applied

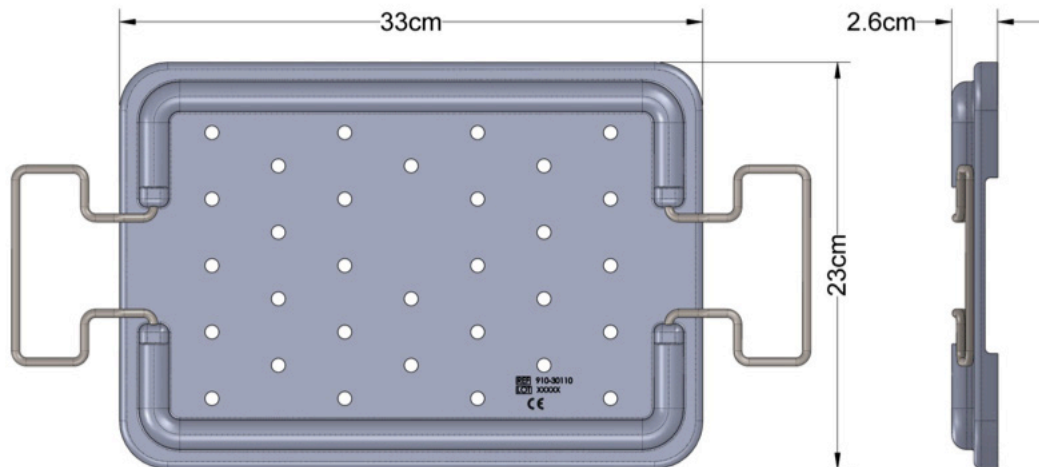
- ISO 13485 – Medical devices – quality management systems – requirements for regulatory purposes
- ISO 14971 – Medical devices – application of risk management to medical devices

Product description

1. Configurations
 - a. 910-30105: SERPENT Sterilization Tray base
 - b. 910-30110: SERPENT Sterilization Tray lid
 - c. 910-30100: SERPENT Sterilization Tray set
2. Tray size
 - a. 910-30105 SERPENT Sterilization Tray base:



b. 910-30110 SERPENT® Sterilization Tray lid:



3. Materials: Both the base and lid are made of Radel® R Polyphenylsulfone and surgical grade stainless steel hardware.

Packaging

1. Instruments are delivered sealed in a poly bag
2. Box size is 45.7cm X 31.8cm X 8.3cm
3. Sterilization: Supplied NON-STERILE

Storage and transportation conditions

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

Shelf life

Not applicable as the trays are reusable instruments

Dispose condition

The tray is a reusable instrument 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 the tray's IFU.

Cleaning and sterilization instructions

1. Manual cleaning:
 - a. Wear protective gloves to disassemble the tray into basic components (base, lid).
 - b. The SERPENT® Sterilization Tray is made of Radel R-500, which is compatible with common enzymatic agents and disinfectants. Soak components in enzymatic detergent solution (prepared per detergent manufacturer's instructions) for at least 5 minutes.
 - c. Manually scrub the components using a soft bristle brush until all visible soil residues are removed. Small brushes should be used to allow sufficient access to holes and locations inaccessible by large brushes to ensure thorough cleaning.
 - d. Rinse with warm water for at least 1 minute, and dry with absorptive paper towels.

2. Sterilization

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

Special handling instructions

1. Precautions

- a. Do not load trays into sterilizer on sides or upside down with lid side on the shelf of cart. Load trays on cart or shelf so that the lid is always facing upward. This will allow for proper drying.
- b. Do not use solvents, abrasives cleaners, metal brushes or abrasive pads in the cleaning of this device.
- c. After the autoclave door is opened, all cases must be allowed to cool thoroughly. The potential for condensation may increase if the case is not allowed to cool properly.

2. Maintenance and inspection

- a. Tray inspection and maintenance should be performed by trained medical facility staff.
- b. Inspect for damage before use. Do not use a damaged or worn tray.
 - i. Make sure all latches and handles are secure and in working order.
 - ii. Inspect tray and silicon organizers. Discard if cracking or crazing is found.

Not made with natural rubber latex

As detailed above, the SERPENT® Sterilization Tray is primarily composed of Radel® R Polyphenylsulfone and surgical grade stainless steel hardware and thus is not made from natural rubber latex parts. Smith & Nephew 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.