



Reusable Instrument Cleaning & Sterilization Instructions

CAUTION

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- NON-STERILE: Sterilize before use.

CARE

Thorough maintenance will ensure proper function of Zinnanti Surgical instruments. It is important to clean and sterilize each instrument according to instructions. Proper maintenance will extend the life of the instrument. Do not allow this device to come into contact with corrosive chemicals. **Do not scrub instruments with wire brushes or scratch pads.** Handle each instrument carefully.

For electrosurgical devices, carefully evaluate the device for wear or damage to insulation. Do not use electrosurgical devices that have wear or damage to insulation. It is recommended that the device be replaced when there is visible wear of Teflon tip.

RECOMMENDED CLEANING INSTRUCTIONS

Rinse and clean instruments immediately following use when possible. Enzymatic cleaning agents reduce organic matter and facilitate its removal. Wear protective gloves during the cleaning procedure. Never use corrosive cleaning agents (i.e. bleach). Neutral pH (7.0) cleaning agents are recommended (if unknown, check MSDS or check with distributor).

1. Submerge the instrument in an enzymatic detergent. Prepare the detergent according to the manufacturer's recommendations. Soak the instrument for ten (10) minutes or as directed.
2. Scrub the submerged instrument with a soft sponge and agitate. Clean lumens and crevices, using a pipe cleaner/brush or flush with a syringe when appropriate. Actuate any moving parts to loosen trapped soil. **Do not use wire brush or scratch to pads to scrub instruments.**
3. Rinse with distilled water for one (1) minute. Thoroughly flush all lumens, if present, and other difficult to reach areas. Actuate while rinsing.
4. Dry the instrument thoroughly with a clean, lint-free cloth.
5. Repeat this cleaning procedure if the instrument appears to be soiled after initial cleaning until there is no sign of soil on the device.

STORAGE

Instruments must be stored dry in a moisture free area. The instruments should be stored individually in a protective tray with partitions, if possible. Protect with cloth or gauze if stored in drawers.

RECOMMENDED STEAM AUTOCLAVE STERILIZATION PARAMETERS

- The instrument must be thoroughly cleaned of all foreign matter prior to sterilization.
- Follow the manufacturer's instructions for operation and loading of steam autoclave.
- There must be direct steam exposure to all surfaces of the instrument being sterilized.
- Autoclave temperatures should not exceed 280°F (138°C); pressure should not exceed 32 psi (2.2 atmospheres).
- Standard cycle of 270°F (132°C) for 10 minutes will vary depending on autoclave model, autoclave size, load size, and load configuration.



Allow longer times for lower temperatures. Allow instruments to cool down from autoclave to room temperature. Do not immerse in any fluid until the instrument has been allowed to cool.

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(Cleaning & Sterilization Instructions, continued)

Pre-vacuum Cycle

Preconditioning Pulses: 4

Exposure temperature: 270°F–273°F (132°C–134°C)

Exposure time: 4 minutes

Gravity Displacement Cycles

Exposure temperature: 270°F–275°F (132°C–135°C)

Exposure time: 15 minutes

Exposure temperature: 250°F–253°F (121°C–123°C)

Exposure time: 40 minutes

RECOMMENDED HOSPITAL ETHYLENE OXIDE STERILIZATION PARAMETERS

- Items must be thoroughly cleaned of all foreign matter prior to sterilization.
- Follow the manufacturer's instructions for operation and loading of sterilizer.
- There must be direct exposure to all surfaces of the instruments being sterilized.
- Instruments should be sterilized in their "open" position.
- Contact of plastic to bare metal should be avoided.

Ethylene Oxide Cycle

Temperature 125°F–130°F (52 °C– 54°C)

50% RH (pre-humidity) 60 minutes -0/+10 minutes

Pre-vacuum 24" Hg \pm 2" Hg (61 cm Hg \pm 5 cm Hg)

Gas Pressure 6–8 psig (550–660 mg/L EO)

Exposure Time 4 hours minimum

Post Vacuum 24" Hg 2X \pm 2" Hg (61 cm Hg 2X \pm 5 cm Hg)

Aeration 12 -0/+1 hour at 120°F (49°C)

NOTE: The particular EO cycle must be validated per the equipment manufacturer's requirements. It is recommended that each institution employ procedures, which include the use of biological indicators in order to determine the effectiveness of the ethylene oxide process.

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