

Instrument Sterility, Cleaning and Decontamination

The Surgical Instrument Kits and all instruments are supplied non-sterile and must be sterilized before use unless otherwise indicated. Thoroughly clean instruments prior to initial sterilization. When handling sharp instruments, use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact. Instruments returned to IlluminOss or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 “Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings” provides guidelines for return, or contact IlluminOss or your distributor for further instruction.

Cleaning:

Clean instruments as soon as possible, after use. Do not allow blood to dry on the instruments. Wash all instruments whether or not they were used or inadvertently came in contact with blood or saline solution. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.

1. Immediately after use in the surgical procedure and instrument disassembly, remove as much visible debris as possible from each instrument and its components using moist clean gauze pads or wipes. Instruments should be soaked immediately after use. If the instruments cannot be soaked immediately, they should be wrapped in a clean moist towel. Soiled instruments must be kept moist to prevent the soil from drying.
2. Prepare an enzymatic cleaning solution with warm clean tap water (35-43°C) per the instructions of the solution manufacturer. Perform an enzymatic soak for a minimum of 20 minutes making sure the instruments are completely immersed in the solution. Actuate all moving mechanisms a minimum of 5 times (5x) to ensure the enzymatic solution contacts all parts.
3. While in the soak solution, use a soft brush or clean cloth to manually remove all the exterior soil. Use appropriately sized brushes to thoroughly clean the entire length of any lumens including all other challenging design features such as holes, hinge/mated surfaces, crevices, serrations, etc. Scrub each design feature a minimum of 5 times (5x).
4. After the enzymatic soak, rinse instruments thoroughly with clean warm tap water (35-43°C), taking care to flush all lumens and crevices. Rinse thoroughly for at least one minute under a continuous stream of clean water (at a minimum flow rate of 1 Liter/minute) ensuring all surfaces are rinsed and the instruments visibly clean. If rinse water does not run clear or there are any visual signs of soil, repeat cleaning process.
5. Prepare a fresh enzymatic cleaning solution with warm clean tap water (35-43°C) per the instructions of the solution manufacturer. This solution will be used in the ultrasonic bath. The instruments should be fully immersed in the cleaning solution and all mechanisms actuated a minimum of 5 times (5x). Run the ultrasonic cleaning unit for a minimum of 15 minutes.

6. Place the instrument in clean warm (35-43°C) deionized (DI) or reverse osmosis (RO) purified water and again scrub the instruments, ensuring all the surfaces are scrubbed, including the lumens, interfaces, and crevices. Scrub each design feature a minimum of 5 times (5x). Rinse each instrument again for at least one minute under clean warm DI or RO (35-43°C) running water (at a minimum flow rate of 1 Liter/minute), including all design features. Ensure that all surfaces are free of visible contamination or any traces of the cleaning solution (e.g. foam) and the fluid runs clear.
7. Dry the instruments with a clean soft cloth and use clean compressed air to dry the lumens, holes, and interfaces.
8. Perform a visual inspection on the instruments and verify that they are clean, dry, and in proper working order. If the instruments are not visually clean, repeat the cleaning process.
9. All instruments should be placed in their designated instrument trays and the tray wrapped with an FDA-approved wrap prior to sterilization. Effective sterilization is predicated on thorough cleaning and drying processes. Failure to do so may compromise the sterilization process and render the processed instruments unsuitable for clinical use.

Sterilization:

- Wrap Instrument Cases in an FDA approved CSR sterilization wrap and sterilize in FDA cleared sterilizer.
- Do not stack trays during sterilization.
- Sterilize instruments using PreVac steam autoclave or Gravity steam autoclave.
- For PreVac autoclave, cycle for a minimum of 4 minutes at 270°F (132°C) and a minimum dry time of 20 minutes at 270°F (132°C), or for Gravity autoclave cycle for a minimum of 15 minutes at 270°F (132°C) and a minimum dry time of 15 minutes at 270°F (132°C).
 - NOTE: Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

Inspection:

- Inspect the instrument case and instruments for damage upon receipt and after each use and cleaning.
- Instruments with dents, burs, signs of corrosion or spotting, or raised surfaces which could cause damage to surgical gloves should be set aside for repair service or returned to IlluminOss.
- Incompletely cleaned instruments should be re-cleaned.
- Properly dispose of any used single-use instruments. Do not reuse or attempt to clean/sterilize single use instruments.