

Description

ILLuminOSS offers sets with a variety of standard, reusable surgical instruments to assist orthopedic surgeons with the implantation procedure for the ILLuminOSS Photodynamic Bone Stabilization System. The intended purpose of the ILLuminOSS Reusable Instruments is for use in conjunction with the ILLuminOSS implants, for obtaining access to the bone, the preparation of the bone canal, the delivery of the implant, and if needed the removal of the implant. The ILLuminOSS Reusable Surgical Instruments are used only in conjunction with the ILLuminOSS Photodynamic Bone Stabilization System, and therefore the indications, contraindications, intended patient population, and intended users that govern their use are those of the implant, the ILLuminOSS Photodynamic Bone Stabilization System.

These reusable surgical instruments must be cleaned and sterilized before use. The information provided is for the reusable surgical instruments only, and does not apply to the Photodynamic Bone Stabilization System catheters (implant), or sterile disposable ancillary devices. Refer to the implant Instructions for Use for the implant indications, contraindications, warnings, precautions and risks (ref: 900356 found on www.illuminoss.com).

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. A neutral pH / enzymatic detergent is to be used in the cleaning process.

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 utility 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 challenging design feature a minimum of 1 minute, or approximately 5 times (5x).
4. After the enzymatic soak, rinse instruments thoroughly with clean warm utility 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 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 utility 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 (35-43°C) critical water and again scrub the instruments, ensuring all the surfaces are scrubbed, including the lumens, interfaces, and crevices. Scrub each challenging design feature a minimum of 1 minute or approximately 5 times (5x). Rinse each instrument again for at least one minute under clean critical water (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 instrument air to dry the lumens, holes, and interfaces. 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 manual cleaning process.

Optional Automated Cleaning Instructions:

Automated washer/disinfector systems are not validated as the sole cleaning method for surgical instruments. Instruments should be cleaned following the manual or combination manual and automated cleaning procedure. A neutral pH / enzymatic detergent is to be used in the optional automated cleaning process.

Step	Description	Minimum Temperature	Minimum Time
1	Pre-Wash	Cold Tap Water	5 minutes
2	Detergent Wash	60°C (140°F)	10 minutes
3	Rinse	Hot Utility Water	1 minute
4	Thermal Disinfection (A ₀ = 3000)	93°C (194°F)	Approximately 10 minutes
5	Hot Air Drying	110°C (230°F)	20 minutes

Upon completion, unload the washer-disinfector. Perform a visual inspection of the instruments and verify they are clean, dry, and in proper working order. If the instruments are not visually clean, repeat both the manual and automated cleaning processes.

Sterilization:

- 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.
- 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. Cutting edges should have continuous edge and be free of nicks. Jaws and teeth should align and engage properly. Movable parts should move smoothly without excessive play and locking mechanisms should fasten securely. Do not use worn or damaged instruments. Contact IlluminOss immediately for return, repair, or replacement of damaged or worn instruments.
- 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.