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05/2025	**IMPORTANT INFORMATION ON GENERAL INSTRUMENT CARE, CLEANING, AND STERILIZATION**

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For symbols glossary, please refer to www.globusmedical.com/eIFU

ENGLISH

WITHIN THE UNITED STATES ONLY

IMPORTANT INFORMATION ON GENERAL INSTRUMENT CARE, CLEANING, AND STERILIZATION

GENERAL INFORMATION

This insert provides information for general instrumentation care, cleaning, and sterilization for Globus Medical reusable instruments sterilized by the hospital. In addition, this insert provides sterilization information on those instruments that are provided sterile.

Hospitals should comply with all applicable internal procedures, local, state and federal and international laws which may be more stringent than those detailed in this insert.

Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special CJD (Creutzfeldt - Jakob Disease) inactivation processing procedures. Consult WHO and local regulations for further information.

Alkaline agents with pH ≤12 may be used to clean stainless steel or polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt - Jakob Disease (CJD) are a concern. **It is critical that alkaline cleaning agents are completely and thoroughly neutralized and rinsed from instruments**.

Instruments that cannot be reused may be labeled with the **"Do not reuse"** symbol. Refer to the symbols glossary for symbols.

Instruments that cannot be resterilized may be labeled with the **"Do not resterilize"** symbol. Refer to the symbols glossary for symbols.

INSTRUMENT CARE

During surgery, instruments become contaminated from blood, tissue and bone. These instruments may also become contaminated with body fluids containing hepatitis virus, HIV or other etiological agents and pathogens. All health care workers should be familiar with the necessary Universal Precautions of preventing injuries caused by sharp or cutting instruments when handling these devices during and after surgical procedures and during cleaning. Instruments used in surgical procedures do not have an infinite functional life span. Instruments are subjected to stresses due to bone contact, impaction, routing, cleaning, and sterilization. In addition, instruments are subjected to irrigation fluids that are often used in copious amounts during surgical procedures and will exert a corroding effect on the instruments. Surgery requires instruments which may have multiple components, articulating or rotating parts, removable handles, plastic replacement parts, and series of gauges or other measuring devices in graduated sizes. These instruments are supplied in trays and/or containers which may be arranged by size, color, or by the order needed for a specific surgical procedure. Surgical Instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper care should be returned to Globus Medical to be discarded. Notify your Globus Medical representative of any instrument problems.

INSTRUMENT CLEANING

Warnings and Precautions

- **Universal Precautions should be observed** by all hospital personal that work with contaminated or potentially contaminated surgical instruments. Caution should be exercised when handling surgical instruments that contain sharp points or cutting edges.
- **Personal Protective Equipment (PPE) should be worn** when handling or working with contaminated or potentially contaminated instruments. PPE includes gown, mask, goggles or face shield, gloves, and shoe covers.
- **Metal brushes or scouring pads must not be used** during manual cleaning procedure, as this could cause damage and corrosion to the surface and finish of the instruments. It is recommended that a soft-bristle, nylon brush and pipe cleaners be used for hand cleaning.
- To ensure instrument metal is not subjected to corrosion, discoloration or stress fractures, do not use high acidic (pH<4) or high alkaline (pH>12) during disinfection or cleaning.
- Where applicable, multi-component instruments should be disassembled prior to cleaning. Care must be taken to avoid losing small parts.
- Complex instruments such as those containing tubes, hinges, retractable components, mated components, and textured surface finishes, require special attention during the cleaning process.
- **Do not place heavy instruments on top of delicate instruments, as this may cause scratches, dents and/or breakage.**
- **Do not allow contaminated instruments to dry prior to cleaning.** All subsequent cleaning steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline or disinfectants to dry on used instruments.
- Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.
- Saline and cleaning/disinfection agent containing aldehyde, mercury, active chlorine, bromine, bromide, iodine or iodide are corrosive and should not be use. Instruments must not be placed or soaked in Ringers Solution.
- Mineral oil or silicone lubricant should not be used because they: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove. Only surgical grade lubricant oil may be used.
- **Instruments should be inspected for damage prior to each surgical procedure**. To prevent a possible risk of loss of metal fragments in a surgical procedure, damaged instruments should be replaced or repaired.
- Drill bit reamers, rasps and other cutting instruments should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are not damaged.
- Instruments must be removed from metal or polymer trays for manual and/or automated cleaning procedures. Instrument trays, cases and lids must be cleaned separately.
- Use of hard water is not recommended for rinsing instruments. Softened tap water may be used for initial rinsing. For the final rinse, purified water should be used to eliminate mineral deposits on instruments. To purify water, one or more of the following processes may be used: ultra-filter (UF), reverse-osmosis (RO), deionzed (DI), or equivalent.
- Ethylene Oxide (EO), Gas Plasma Sterilization and dry heat sterilization methods are not recommended for sterilization of Globus Medical reusable instruments.
- **These instructions DO NOT APPLY to single-use instrumentation.**

Manual Cleaning Instructions

All instruments that can be disassembled must be disassembled for cleaning. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

Manual Cleaning – Additional Instructions for Cannulated Instruments (those instruments containing holes or tubes)

- Scrub the cannula, lumen or hole by using a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner. Using a twisting motion, push the cleaning brush or pipe cleaner in and out to remove debris from the cannula, lumen or hole. Use a syringe filled with an enzymatic cleaning solution to flush those hard to reach internal areas.
- When rinsing, pay particular attention to flush the cannulations, lumens, or holes with warm tap water.
- Dry internal areas of the instruments with filtered compressed air.

Manual Cleaning – Additional Instructions for Articulating Instruments (those instruments containing movable parts)

- When cleaning, fully immerse the instruments in the cleaning solution to avoid aerosol generation.
- Brush with soft non-metallic bristle brush to remove all traces of blood and debris. Pay special attention to threads, crevices, seams and any hard to reach areas. Actuate any movable mechanisms, such as hinged joints, box locks or spring-loaded features, to free trapped blood and debris. If the components of the instrument can be retracted, retract or open the part while cleaning the area. For those instruments with flexible shafts, bend or flex the instrument under the cleaning solution while brushing the flexible area.

- When rinsing, pay particular attention to internal areas and movable parts. Actuate moveable parts while rinsing. If the components of the instrument can be retracted, retract or open the part while rinsing the area. For instruments with flexible shafts, flex the instrument under the rinse solution.
- Dry internal areas with filtered compressed air.

Automated Cleaning Instructions

- Manual cleaning steps 1 to 13 should be performed prior to automated cleaning.
- Brush the instrument, actuate mechanisms, agitate and/or irrigate under the surface of the cleaning solution to prevent the creation of aerosols. Use MIS injector unit to process lumens and cannulations.
- Clean using the "INSTRUMENTS" cycle in a validated washer disinfector that fulfills requirements specified in ISO 15883 and a pH neutral cleaning agent intended for use in automated cleaning. The cleaning cycle should incorporate enzymatic prewash, wash, rinse, thermal rinse, and drying steps.
- Place instruments in a suitable washer/disinfector basket.
- Load instruments so that hinges are open and cannulations and holes are allowed to drain. Be sure the instruments are secured in place and that they are not allowed to overlap or come in close contact.
- Place heavier instruments on the bottom of containers. **Do not place any heavy instruments on top of delicate instruments.**
- For instruments with concave surfaces, such as curettes, place instruments with the concave surface facing downward to facilitate draining.
- Set washer/disinfector to process parameters outlined below:
  - Pre-wash: for a minimum of 2 minutes in cold tap water.
  - Wash: in cold tap water (<40°C/104°F) for a minimum of 2 minutes using the cleaning agent.
  - Wash: in warm tap water (>40°C/104°F) for a minimum of 5 minutes using the cleaning agent.
  - Rinse: in warm deionized water or purified water (>40°C/104°F) for a minimum of 2 minutes.
  - Thermal disinfection: 82-95°C/180-203°F for a minimum of 5 minutes.
  - Purified water rinse: 83-92°C/181-198°F for a minimum of 10 seconds.
  - Hot air dry: >75°C/167°F for a minimum of 15-30 minutes.

Cleaning Inspection Instructions

- Inspect all instruments before sterilization or storage to ensure the complete removal of all soil from surfaces, tubes and holes, and moveable parts.
- For those areas that are difficult to inspect visually for traces of blood, immerse or flush the instrument in a 3% hydrogen peroxide solution. If bubble is observed, blood is present. Rinse instruments thoroughly after using the hydrogen peroxide solution.
- If soil is still present, repeat the cleaning procedures until instruments are clear of all soil.

Functional Testing Inspection Instructions

- Inspect all instruments for damage and wear.
- Mechanically test the working parts to verify that each instrument functions properly.
- Instruments should be free of burrs or surface disruptions.
- Cutting edges should be free of nicks and have a continuous edge.
- Jaws and teeth and other aligned features on the instruments should align properly.
- Tip should not be bent or fractured.
- Moveable parts should have smooth movement without excessive play.
- Locking mechanisms should fasten securely and close easily.
- Long, thin instruments should be free of bending and distortion.

Instrument Maintenance

- Apply a small quantity of surgical grade lubrication oil to hinges.
- Discard blunt or damaged instruments.

Packaging

- If desired, use instrument trays to contain instruments that are provided in sets.
- Biological or Chemical Indicators (BIs or CIs) used for monitoring the performance of sterilization process should be placed in the middle racks within wrapped trays. They should be tested in accordance to the BI or CI manufacturer's directions.
- Double wrap instruments with protective sterilization wrap in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/AAMI ST79 *"Comprehensive Guide Steam sterilization and sterility assurance in health care facilities"* and AORN, *"Standards, recommended practices and guidelines."*
- Label the contents of the wrapped tray using an indelible marker or other sterilization-compatible label system.

STERILIZATION INFORMATION

For all **NON-STERILE** components, **hospitals must sterilize the instruments prior to use**.

- Use a validated, properly maintained and calibrated steam sterilizer.
- Sterilization with a pre-vacuum autoclave or gravity displacement autoclave should be performed under recommended exposure time, temperatures and other information as specified in the product specific insert.
- For instrument-only systems (without a separate product-specific insert), sterilization is recommended as shown below.

The parameters below have been validated following ANSI/AAMI ISO 11134-1993: *"Guidelines for steam sterility validation"* to assure a Sterility Assurance Level (SAL) of 10^{-6}. Per AAMI ST79, *"Comprehensive guide to steam sterilization and sterility assurance in health care facilities,"* the use of an FDA cleared wrap is recommended.
Moist heat sterilization is recommended using the parameters outlined below:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Gravity (Wrapped)	132 °C (270 °F)	25 minutes	45 minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132 °C (270 °F)	15 minutes	30 minutes

These parameters are only validated for surgical instruments. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item may be expressed in terms of probability. While this probability may be reduced to a very low number, it can never be reduced to zero. This probability can only be assured for validated processes.

Other sterilization cycles may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques. Proper validation of the autoclave is required to ensure proper sterilization temperatures and cycle times.

These reprocessing instructions have been validated by Globus Medical. It is the responsibility of the hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid any potential adverse consequences.

STERILE-PACKED INSTRUMENTS

Instruments that are provided to the hospitals **STERILE** are sterilized either by gamma radiation or by ethylene oxide and are validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. These instruments are considered sterile unless the packaging has been opened or damaged. Refer to the symbols glossary for sterilization symbols.

Sterile instrument packages should be carefully examined to ensure that package integrity has not been compromised. The expiration date on sterile products should be checked; **do not use if expired**.

STORAGE

Sterile-packaged instruments and instruments sterilized at the hospital should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, and temperature/humidity extremes.

LOANER INSTRUMENTS AND HOSPITAL RESPONSIBILITY

Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to Globus Medical. Documentation of decontamination should be provided with instruments being returned to Globus Medical.

Missing or damaged instruments from loaner sets should be brought to the attention of the operating room supervisor, to the director of the central supply department, and to your Globus Medical representative to ensure that the next hospital will receive a complete set of instruments in good working condition.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871).

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the Order of a Physician.