GI001B-EN (Rev D)	GENERAL INSTRUMENT CARE, CLEANING, AND STERILIZATION

05/2025

GLOBUS MEDICAL

GLOBUS MEDICAL, INC.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
USA
Customer Service:
Phone 1-866-GLOBUS1 (OR)
1-866-456-2871
Fax 1-866-GLOBUS3 (OR)
1-866-456-2873

IMPORTANT INFORMATION ON GENERAL INSTRUMENT CARE, CLEANING, AND STERILIZATION

EC REP: AJW Technology Consulting GmbH
Breite Straβe 3 40213 Düsseldorf, Germany

CH REP: AJW Technology Consulting GmbH
Kreuzplatz 2, 8032 Zurich, Switzerland

AUSTRALIA SPONSOR:
GLOBUS MEDICAL AUSTRALIA PTY LIMITED,
Unit 9/5-7 Inglewood Place Baulkham Hills NSW 2153,
Australia

CE 0297

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

ENGLISH

OUTSIDE THE UNITED STATES ONLY

IMPORTANT INFORMATION ON GENERAL INSTRUMENT CARE, CLEANING, AND STERILIZATION

GENERAL INFORMATION

This insert provides information for general care, cleaning, and sterilization for Globus Medical reusable instruments sterilized by the hospital. These instruments include: PRESERVE™ Anterior Cervical Instruments, PRESERVE™ Anterior Instruments, PRESERVE™ Posterior Instruments, PRESERVE™ TLIF, PLIF Instruments, Posterolateral Instruments, Anterior Auxiliary Instruments, Posterior Auxiliary Instruments, LAMINEX™ Instrument Set, Bi-Lateral Instruments, MIS LIF Auxiliary Instruments, Guided Instruments, Universal ACDF Instruments. In addition, this insert provides information on 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 **"Single Use Only"** symbol. Refer to the last page of this insert for symbols.

INTENDED USE

Reusable instruments are Intended for use during various orthopedic surgeries. Some instruments can be used to assist in the retraction, manipulation, cutting, and removal of bony and/or soft tissue anatomy. Other instruments are used for the implantation or removal of hardware.

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.

Surgical Instruments generally have a long life of service; however, mishandling or inadequate protection can also diminish their functional life span. 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.

CLEANING REUSABLE INSTRUMENTS

WARNINGS AND PRECAUTIONS

- **Universal Precautions should be observed** by all hospital personnel 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 procedures, as this could cause damage and corrosion to the surface and finish of the instruments.
- 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) agents 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 processes.
- **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 used. Instruments must not be placed or soaked in Ringers Solution.
- Mineral oil or silicone lubricant should not be used. Only surgical grade lubricant oil may be used.
- **Instruments should be inspected for damage prior to each 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), deionized (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 instruments.**

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.

Disinfection 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 disinfection solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline chemicals (pH>12) 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. These methods have been validated per AAMI TIR30, *"A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices".*

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 another enzymatic detergent) per the 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. 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 another 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, repeat the cleaning process starting with Step 3.

Additional Instructions for Cannulated Instruments (containing holes or tubes)

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

Additional Instructions for Articulating Instruments (having moveable parts)

- When cleaning, fully immerse the instruments in the disinfection 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 moveable 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 disinfection 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 of the instruments with filtered compressed air.

Automated Cleaning Instructions

The following methods have been validated per DIN EN ISO 17664, DIN EN ISO 15883-1, DIN EN ISO 15883-2, DIN ISO/TS 15883-5, DIN EN ISO/IEC 17025, AAMI TIR12, and AAMI TIR30.

- The following manual pre-cleaning steps should be performed prior to automated cleaning:
  - Wipe the instruments with a soft cloth damped in cold tap water
  - Disassemble instruments that can be disassembled. Rinse all instruments with cold tap water for 10 seconds, and repeat 3 times to remove visible contamination.
  - Immerse the instruments in cold tap water with 0.8% Cidezyme (or another enzymatic detergent) for 2 minutes.
  - Brush the instruments with a soft brush for 60 seconds. Brush the lumen with a suitable bottle brush with 2 strokes.
  - Flush all cavities and hard to reach areas with a sterile syringe with the enzymatic cleaning solution.
  - Place all instruments in an ultrasonic bath with 0.8% Cidezyme (or another enzymatic detergent) in tap water (room temperature). Fill the cavities and lumens with the cleaning solution and sonicate the instruments for 3 minutes.
  - Rinse the instruments with deionized water for 2 minutes.
- 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: Pre-clean for a minimum of 2 minutes in cold tap water (10°C-25°C), and drain.
  - Main wash: Clean for 5 minutes with 55°C tap water and 0.5% cleaning solution (neodisher Mediclean forte or equivalent), and drain.
  - Rinsing/Neutralizing: Rinse for 2 minutes with cold deionized water (10°C-25°C), and drain.
  - Disinfection: Thermally disinfect for 5 minutes at 90°C with deionized water, and drain.

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 bubbling 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.
- Do not use blunt or damaged instruments; non-functional or damaged instruments should be returned to Globus Medical.

PACKAGING

- If desired, use instrument trays to contain instruments that are provided in sets.
- Biological or Chemical Indicators (BI 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 ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ ISO 14937, 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

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 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 device-specific insert), sterilization is recommended as shown below.

The parameters below have been validated following ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO 14937 to assure a Sterility Assurance Level (SAL) of 10^{-6}. The use of a sterilization wrap is recommended. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that are designed for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus instruments and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- The container must have a minimum filter area of 176 in^2 or 1135 cm^2 .
- All filter material should completely cover the perforated area, and the device holding the filter in place should provide a secure, uniform mating surface that keeps the filter from dislodging.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For instrument-only systems (without a separate device-specific insert) provided NON-STERILE, moist heat sterilization (wrapped or containerized) is recommended using the parameters outlined below. *Please refer to the device-specific insert for sterilization instructions for implant and instrument systems*.

Method	Cycle Type	Temperature	Minimum Exposure Time	Minimum Drying Time
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132°C (270°F)	4 minutes	30 minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 4	134°C (273°F)	3 minutes	30 minutes

These parameters are only validated for surgical instruments. If other products are added to 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.

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 last page of this insert for sterilization symbols.

Sterile instrument packaging 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).

REPROCESSING SUMMARY

<table>
<tr><td>Warnings</td><td>• Universal precautions should be observed and PPE should be worn.
• Metal brushes or scouring pads must not be used, and highly acidic or highly alkaline disinfection solutions should not be used.
• Heavy instruments should not be placed on top of delicate instruments, and contaminated instruments should not be dry prior to cleaning.
• The use of hard water, EO, Gas Plasma Sterilization, and dry heat sterilization methods is not recommended.
• For a full list of warnings, refer to the WARNINGS above</td></tr>
<tr><td>Limitations on Reprocessing</td><td>Instruments should be inspected prior to use to ensure they are in working order and there is no unacceptable deterioration. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.</td></tr>
<tr><td colspan="2">Instructions</td></tr>
<tr><td>Point of use</td><td>Instruments should be wiped down to remove all visible soil and kept from drying by</td></tr>
<tr><td>Preparation before cleaning</td><td>Instruments that can be disassembled, should be disassembled before cleaning.</td></tr>
<tr><td>Automated Cleaning</td><td>• The following manual pre-cleaning steps should be performed prior to automated cleaning:
- Wipe the instruments with a soft cloth damped in cold tap water
- Disassemble instruments that can be disassembled. Rinse all instruments with cold tap water for 10 seconds, and repeat 3 times to remove visible contamination. - Immerse the instruments in cold tap water with 0.8% Cidezyme (or another enzymatic detergent) for 2 minutes.
- Brush the instruments with a soft brush for 60 seconds. Brush the lumen with a suitable bottle brush with 2 strokes.
- Flush all cavities and hard to reach areas with a sterile syringe with the enzymatic cleaning solution.
- Place all instruments in an ultrasonic bath with 0.8% Cidezyme (or another enzymatic detergent) in tap water (room temperature). Fill the cavities and lumens with the cleaning solution and sonicate the instruments for 3 minutes.
- Rinse the instruments with deionized water for 2 minutes.
• Pre-wash: Pre-clean for a minimum of 2 minutes in cold tap water (10°C-25°C) and drain.
• Main wash: Clean for 5 minutes with 55°C tap water and 0.5% cleaning solution (neodisher Mediclean forte or equivalent), and drain.
• Rinsing/Neutralizing: Rinse for 2 minutes with cold deionized water (10°C-25°C), and drain.
• Disinfection: Thermally disinfect for 5 minutes at 90°C with deionized water, and drain.</td></tr>
<tr><td>Manual Cleaning</td><td>• 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.
• Disassemble all instruments that can be disassembled.
• 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.
• Prepare Enzol® (or another enzymatic detergent) per manufacturer's recommendations.
• Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
• Use a soft bristled brush to thoroughly clean the instruments. Pay close attention to hard to reach areas.
• 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.
• Remove the instruments from the detergent and rinse them in running warm tap water.
• Prepare Enzol® (or another enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
• 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.
• Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
• Dry instruments using a clean soft cloth and filtered pressurized air.
• Visually inspect each instrument for visible soil. If visible soil is present, the repeat cleaning process.</td></tr>
<tr><td>Disinfection</td><td>Disinfection occurs concurrently with manual or automated cleaning.</td></tr>
<tr><td>Drying</td><td>Dry instruments using a clean soft cloth and filtered pressurized air</td></tr>
<tr><td>Maintenance, Inspection, and Testing</td><td>All instruments should be inspected prior to sterilization or storage to ensure all soil has been removed, and instruments are free of damage and wear. If needed, apply a small amount of surgical grade lubrication oil to hinges. Damaged instruments should be returned to Globus Medical.</td></tr>
<tr><td>Packaging</td><td>Instrument trays can be used to contain instruments that are provided in sets, as desired. Double wrap instruments with protective sterilization wrap in accordance with local procedures, using standard wrapping techniques such as those describes in ANSI/AAMI ST79 and label the contents of the wrapped tray.</td></tr>
<tr><td>Sterilization</td><td>For instrument-only systems (without a separate device-specific insert) that are provided NON-STERILE, moist heat sterilization (wrapped or containerized) is recommended using the parameters outlined below. Please refer to the device-specific insert for sterilization instructions for implant and instrument systems.

<table>
<tr><th>Method</th><th>Cycle Type</th><th>Temperature</th><th>Minimum Exposure Time</th><th>Minimum Drying Time</th></tr>
<tr><td>Steam</td><td>Pre-vacuum (Wrapped) Preconditioning Pulses: 3</td><td>132°C (270°F)</td><td>4 minutes</td><td>30 minutes</td></tr>
<tr><td>Steam</td><td>Pre-vacuum (Wrapped) Preconditioning Pulses: 4</td><td>134°C (273°F)</td><td>3 minutes</td><td>30 minutes</td></tr>
</table></td></tr>
<tr><td>Storage</td><td>Instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, and temperature/humidity extremes.</td></tr>
<tr><td>Contact Information</td><td>Globus Medical may be contacted at +1 866 GLOBUS1, or +1 866 456 2871.</td></tr>
</table>

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.