


DI218A-EN (Rev C)	CLEANING AND STERILIZATION OF HIP AND KNEE ARTHROPLASTY INSTRUMENTS	
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 THE CLEANING AND STERILIZATION OF HIP AND KNEE ARTHROPLASTY INSTRUMENTS	

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

ENGLISH

WITHIN THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE CLEANING AND STERILIZATION OF HIP AND KNEE ARTHROPLASTY INSTRUMENTS

DESCRIPTION

Reusable surgical instruments for hip and knee arthroplasty are designed for durability and are produced from stainless steel and/or polymeric materials. Surgical instruments are non-sterile and must be cleaned and sterilized before each use. Instrument cases are produced from aluminum or polymeric materials and are provided to hold surgical instrumentation in place and for protection during handling and storage. Instrument cases also serve to facilitate sterilization of instrument sets. The cases are perforated to allow sterilization of the contents to occur in a steam autoclave utilizing a sterilization cycle and drying cycle that has been validated by the user facility. Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.

Globus/StelKast has verified through laboratory testing that its instrument cases are suitable for the specific sterilization methods and cycles for which they have been tested. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to ensure that conditions essential to sterilization can be achieved. Globus/StelKast does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by Globus/StelKast that should have been properly cleaned and/or sterilized by the end user.

CLEANING AND DECONTAMINATION

Surgical instruments should be cleaned prior to initial sterilization and as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Clean all instruments whether or not they were used or inadvertently came into contact with blood or saline solution. The effectiveness of the decontamination processes depends on prior removal of gross soil from the instrument. Gross soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. Care should be taken to avoid splashing and generating aerosols by holding instruments below the surface of the water in a sink into which water is running and continuously draining. Instruments should not be held under a running tap, as this is likely to result in splashing. Individuals cleaning instruments should be properly gowned with appropriate gloves and personal protective equipment including goggles. Care should be taken to avoid penetrating or cutting injuries. Particular attention should be taken to remove debris from all cannulations and blind holes in the instruments.

The cleaning process must be conducted so that all parts of the surgical instrument are exposed as permitted by design. The majority of surgical instruments and trial components are constructed in such a way that they do not require disassembly. Some of the more complex instruments are made of several components and these should be disassembled into their individual parts prior to decontamination. In most cases the method of disassembly is self-evident. Loosen and/or disassemble instruments with removable parts.

Ultrasonic Cleaners can be used with hot water per manufacturer's recommended temperature (usually 90°-140°F or 32°-60°C) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading patterns, instrument cases, water temperature, and other external factors may change the effectiveness of the equipment.

Washer-Decontamination Equipment will wash and decontaminate instruments. Complete removal of soil from crevices and serrations depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, and thus may require prior brushing. Be familiar with equipment manufacturers' use and operation instructions. Be aware that loading, detergent, water temperature, and other external factors may change the effectiveness of the equipment.

It is recommended that instruments, disassembled as required, be decontaminated using an automatic washer-disinfection unit utilizing thermal disinfection. This should preferably be of the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. (Typical initial cleaning

temperature is at or below 95°F (35°C), followed by a hot water disinfectant rinse where the surface temperature of the instruments should reach a minimum temperature of 160°F (71°C) for a minimum of 3 minutes, 176°F (80°C) for a minimum of 1 minute, or 194°F (90°C) for 1 second.) Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. These detergents and/or rinse aids, however, should be of neutral or near neutral pH. Excessively acidic or alkaline solutions may corrode aluminum instruments or instrument cases.

CARE AND HANDLING OF INSTRUMENTS

Surgical instruments and instrument cases are susceptible to damage for various reasons including prolonged use, misuse, rough or improper handling. Care must be taken to avoid compromising their exacting performance. To minimize damage, the following should be done:

- Only use an instrument for its intended purpose.
- Inspect instrument cases and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned.
- After cleaning, any disassembled instruments should be reassembled and placed in their proper locations in the instrument case where appropriate.
- Instruments in need of repair should be returned to Globus.

Globus does not accept responsibility or liability for any instrument or component part upon which repairs or modifications have been made or attempted except as performed by Globus. Instruments returned to Globus 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 guidance for return.

STERILITY

Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use. Hip and knee arthroplasty instruments can be steam autoclaved. Repeat processing has minimal effects on instrumentation. Below is a recommended minimum cycle for steam sterilization that has been validated by Globus/StelKast under laboratory conditions. Validation was conducted on instrument cases that were double-wrapped in an FDA cleared non-woven medical grade wrapping material.

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your facility. Individual user facilities must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters.

Surgical instruments may be autoclaved using a full cycle. Instruments that have been used in a surgical environment should be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI ST46 Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended.

RESPONSIBILITIES OF THE USER

Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance. The health care facility is responsible to ensure that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, and process performance.

Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved and that specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. ANSI/AAMI ST33 Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities covers the selection and use of reusable rigid sterilization container systems. Guidelines are provided by this standard for cleaning and decontamination, preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

WARNINGS AND PRECAUTIONS

Use extreme caution to avoid injury when handling sharp instruments. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact. Unless otherwise indicated, instrument sets are NOT sterile and must be cleaned and sterilized prior to use. Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided. Always double-wrap instrument cases in an FDA-cleared non-woven medical grade wrapping material. Unwrapped instrument cases DO NOT maintain sterility.

STORAGE

Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of wrapped cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped instrument cases based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence

of a contaminating event increases over time, with handling, and whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.