Biomet Orthopedics
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Biomet Sports Medicine
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Recommendations for the Care and Handling Biomet Orthopedics and Biomet Sports Medicine Surgical Instruments and Instrument Cases

DESCRIPTION

Biomet Orthopedics and Biomet Sports Medicine instruments and instrument cases are generally composed of aluminum, stainless steel, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases are perforated to allow steam to penetrate these various materials and components. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing a sterilization and drying cycle that has been validated by the user for the equipment and procedures employed at the user facility. **Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.**

Materials
Aluminum
Stainless Steel
Polymeric Materials

DISCLAIMER

Biomet Orthopedics and Biomet Sports Medicine instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. Biomet 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.

CLEANING AND DECONTAMINATION

1. **Removal of Visible Contamination-**The effectiveness of subsequent decontamination processes depends on prior removal of visible soil. Visible 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. Operatives should wear protective equipment including gloves and goggles. Care should be taken to avoid penetrating or cutting injuries. Particular attention should be taken to remove all debris from all cannulations and obscure holes in the instruments.
2. **Disassembly-**The majority of surgical instruments and trial prostheses are constructed in such a way that they will not require disassembly. However, 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. Screws or bolts on some instruments can be loosened for cleaning but are self-retaining to prevent loss.
3. **Manual Pre-cleaning-** Soak instruments in enzymatic solution diluted per manufacturer recommendations for 10 minutes. Brush instruments for a minimum of 2 minutes. Actuate movable parts while brushing. For difficult to access areas such as lumens, springs, mated surfaces flush with a minimum of 60mL of clean detergent water using an irrigation syringe. Repeat as needed until all visible soil is removed. Rinse instruments with purified water while actuating movable parts. Rinse difficult to access areas with a minimum of 60mL of purified water using an irrigation syringe. Visually inspect. Repeat cleaning if soil is visible. After the manual pre-cleaning, begin the wash cycle as indicated below.
4. **Washing/Disinfecting-** It is recommended that the 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. 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. The following table provides a validated method for cleaning instruments and the minimum recommended parameters for cleaning instruments.

Phase	Time (Minutes)	Temperature & Water Quality	Detergent & Concentration
Pre-wash	**2:00**	**95°F (35°C) Tap water**	**None**
Detergent Wash	**6:00**	**158°F (70°C) Tap water**	**Enzol® per manufacturer instruction**
Wash	**4:00**	**158°F (70°C) Tap water**	**Prolystica® 2X Concentrate Neutral per manufacturer instruction**
Rinse	**2:00**	**158°F (70°C) Purified water**	**None**
Drying	**7:00**	**239°F (115°C)**	**None**

PREPARATION AND ASSEMBLY

After cleaning/disinfecting, the disassembled instruments should be reassembled and placed in their proper locations in the instrument cases.

CARE AND HANDLING OF INSTRUMENTS

1. **General.** Surgical instruments and instrument cases are susceptible to damage for a variety of reasons including prolonged use, misuse, rough or improper handling. Care must be taken to avoid compromising their exacting performance. To minimize damage and risk of injury, the following should be done:
   - Inspect the instrument case and instruments for damage upon receipt and after each use and cleaning. Incompletely cleaned instruments should be cleaned until visibly clean, repeating as necessary. Instruments in need of repair should be set aside for repair service or returned to Biomet. Instruments returned to Biomet or its distributors should be cleaned and sterilized prior to shipment. ISO 17664 *Sterilization of Medical Devices* and 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 Biomet or your distributor for further instruction.
   - Only use an instrument for its intended purpose.
   - When handling sharp instruments use extreme caution to minimize risk of injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
2. **General Cleaning.** Thoroughly clean instruments until visibly clean, repeating as necessary, prior to initial sterilization and as soon as possible after use. Do not allow soil 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. Wash all instruments whether or not they were used or inadvertently came into contact with blood or saline solution.
3. **Ultrasonic Cleaners** can be used with hot tap water per manufacturer's recommended temperature (usually 90º-140ºF or 32º-60ºC) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading patterns, instrument cassettes, water temperature,

and other external factors may change the effectiveness of the equipment.

4. **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.

RESPONSIBILITIES OF THE USER

General. 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.

Cleaning/Decontamination. The health care facility is responsible to ensure that conditions essential to safe handling and decontamination can be achieved. ISO 17664 *Sterilization of Medical Devices* and ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care* provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, and process performance.

Sterility. ISO 17664 *Sterilization of Medical Devices* and ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care* 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

Unless otherwise indicated, instrument sets are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.

Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided.

All trial, packaging and instrument components must be removed prior to closing the surgical site. Do not implant.

STORAGE AND SHELF LIFE

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.

STERILITY

Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.

Biomet Orthopedics and Biomet Sports Medicine instruments can be steam autoclaved and repeated autoclaving will not adversely affect them, unless otherwise indicated in the labeling. If you have any problems when using Biomet Orthopedics and Biomet Sports Medicine instruments, please bring this to Biomet's or its distributor's attention when you return them. Instruments returned to Biomet or its distributors should be cleaned and sterilized prior to shipment. ISO 17664 *Sterilization of Medical Devices* and ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health care Facilities* provides guidelines for return or contact Biomet or your distributor for further information.

Unless otherwise indicated, instruments must be thoroughly cleaned and sterilized prior to surgical use. Set forth below is a recommended minimum cycle for steam sterilization that has been validated by Biomet under laboratory conditions.

Instruments that have been used in a surgical environment should be thoroughly cleaned, repeating as necessary, until visibly clean prior to autoclaving. Use of ISO 17664 *Sterilization of Medical Devices* and ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care* is recommended. Wraps used during the steam sterilization process are to be FDA cleared wraps (e.g. Bio-Shield® Sterilization Wrap).

The following cycle parameters are for instrument cases up to 25 lbs (11 kgs).

U.S. PARAMETERS

DYNAMIC-AIR-REMOVAL STEAM STERILIZER
270ºF (132ºC) –Wrapped per manufacturer's instructions
5 minutes exposure time – 30 minutes drying time (allow for cool down)

INTERNATIONAL PARAMETERS

DYNAMIC-AIR-REMOVAL STEAM STERILIZER
134º - 137ºC (273º - 278ºF) –Wrapped per manufacturer's instructions
5 minutes exposure time - 30 minutes drying time (allow for cool down)

Multi-Level Instrument Cases

In some instrument case designs, two or three individual instrument cases may be supplied with an outer transportation container. These instrument cases may be sterilized individually following the instructions above, or may be sterilized by placing the individual cases within the supplied transportation container. To sterilize two or three instrument cases within the supplied outer transportation container, the following sterilization cycle parameters are recommended. Wraps used during the steam sterilization process are to be FDA cleared wraps (e.g. Bio-Shield® Sterilization Wrap).

The following cycle parameters are for instrument cases up to 35 lbs. (16 kgs.).

U.S. PARAMETERS

DYNAMIC-AIR-REMOVAL STEAM STERILIZER
270ºF (132ºC) – Wrapped per manufacturer's instructions
10 minutes exposure time - 30 minutes drying time (allow for cool down)

INTERNATIONAL PARAMETERS

DYNAMIC-AIR-REMOVAL STEAM STERILIZER
134º - 137ºC (273º - 278ºF) –Wrapped per manufacturer's instructions
10 minutes exposure time - 30 minutes drying time (allow for cool down)

Reusable Rigid Sterilization Containers

Some instrument trays are designed to fit within a supplied reusable rigid sterilization container for sterilization. Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization. Biomet utilizes the Aesculap® SterilContainer™ System and the care and handling of these systems can be found at www.aesculapusa.com under instructions-for-use. NOTE: THE STERILIZATION PARAMETERS WITHIN THE AESCULAP INSTRUCTIONS-FOR-USE DO NOT SUPERSEDE THE STERILIZATION PARAMETERS OUTLINED BELOW. Rigid containers used during the steam sterilization process are to be FDA cleared (e.g. Aesculap SterilContainer System, Lid JK489/Base JK444/Filter US751).

The following cycle parameters are for instrument trays in rigid container systems up to 36 lbs (17 kgs).

U.S. PARAMETERS

DYNAMIC-AIR-REMOVAL STEAM STERILIZER
270ºF (132ºC)
10 minutes exposure time - 30 minutes drying time (allow for cool down)

INTERNATIONAL PARAMETERS

DYNAMIC-AIR-REMOVAL STEAM STERILIZER
134º - 137ºC (273º - 278ºF)
10 minutes exposure time - 30 minutes drying time (allow for cool down)

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding Biomet Orthopedics and Biomet Sports Medicine devices or instruments can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

Bio-Shield® is a registered trademark of Carefusion 2200, Inc.
Enzol® is a registered trademark of Johnson & Johnson Corp.
Prolystica® is a registered trademark of Steris Corporation.
Aesculap® is a registered trademark and
SterilContainer™ is a trademark of B. Braun or its affiliates.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

EC REP Authorized Representative:

Biomet UK Limited
Waterton Industrial Estate
Bridgend
CF31 3XA
United Kingdom

CE 0086 CE

Symbol Legend

Manufacturer

Date of manufacture

Do not reuse

Do not resterilize

Caution, see instructions for use

STERILE EO Sterilized using ethylene oxide

STERILE R Sterilized using irradiation

STERILE Sterile

STERILE A Sterilized using aseptic processing techniques

STERILE Sterilized using steam or dry heat

Rx Only Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Do not use if package is damaged (Pack Damaged)

Use by date

WEEE device

REF Catalogue number

LOT Batch code

FLAMMABLE Flammable

EC REP Authorized representative in the European Community