Biomet Orthopedics
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P.O. Box 587
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Biomet Biologics
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Revision A
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Recommendations for the Care and Handling Biomet PerFuse Handle, Slap Hammer, Slap Hammer Adapter, and Strike Cap Instruments and Instrument Cases

DESCRIPTION

Biomet Orthopedics and Biomet Biologics individual 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, and holders. 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 or rigid container to maintain sterility.**

MATERIALS

Stainless Steel

WARNINGS

Correct handling of instruments is extremely important. Do not modify instruments. Do not notch or bend instruments. Notches, scratches or other damage and/or wear in the instrument occurring during surgery may contribute to breakage.

Do not reshape or bend instruments in any way. If an instrument should become bent from its original shape, do not use, as this will affect the performance of the instrument. Bent instruments should be returned to Biomet, Inc.

The Surgeon is to be familiar with the equipment, instruments and surgical procedure prior to performing surgery.

PRECAUTIONS

Specialized instruments are designed for Biomet® implant systems to aid in the proper implantation of Biomet fixation or prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure.

- Intraoperative fracture or breaking of instruments has been reported for general instruments.
- Single Use Instruments are for single use only and are not Reusable. Do not attempt to re-clean or re-sterilize this product.
- Surgical instruments are subject to wear with normal usage. Instruments with cutting functions or points may become dull with normal use and no longer perform as intended. Inspect prior to use to verify the cutting ability and sharpness of edges.
- Instruments that have experienced extensive use or excessive force are susceptible to fracture.
- Surgical instruments should only be used for their intended purpose.
- Biomet recommends that all instruments be regularly inspected for wear and disfigurement prior to use. All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.
- The patient is to be warned by his/her physician of all surgical risks in advance.

RESPONSIBILITIES OF THE USER

Cleaning/Decontamination. The health care facility is responsible to ensure that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, and process performance. Operatives should wear protective equipment including gloves and goggles. Care should be taken to reduce penetrating or cutting injuries.

Sterility. The health care facility is responsible 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. ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* provides guidelines for preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

CARE AND HANDLING OF INSTRUMENTS

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 reduce 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. 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. 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 reduce injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.

CLEANING AND DECONTAMINATION

1. **Removal of Visible Contamination-** The effectiveness of subsequent decontamination processes depends on prior removal of visible soil. 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. Do not placed soiled instruments back into the instrument case. Wash all instruments whether or not they were used or inadvertently came into contact with blood or saline solution. Visible soil should be removed under running water using a mechanical aid, such as a brush with rigid nylon bristles or pipe cleaner. Care should be taken to reduce 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.
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. Particular attention should be taken to remove all debris from all cannulations, crevices, serrations, and obscure holes in the instruments.
3. **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.

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**	**Renu-Klenz™ per manufacturer instruction**
Rinse	**2:00**	**158°F (70°C) Tap water**	**None**
Drying	**7:00**	**239°F (115°C)**	**None**

PREPARATION AND ASSEMBLY FOR STERILIZATION
After cleaning/disinfecting, the disassembled instruments should be reassembled and placed in their proper locations in their designated instrument case. Individual instruments without a recommended instrument case should be sterilized in a separate container or pouch.

STERILITY
Unless otherwise indicated, instruments 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.
Biomet Orthopedics and Biomet Biologics individual 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 Biologics instrumentation 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. 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.

Set forth below is a recommended minimum cycle for steam sterilization that has been validated by Biomet under laboratory conditions.

Use of ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* is recommended. Sterilization wraps and rigid containers used during the steam sterilization process are to be FDA cleared.

Individual instruments should be sterilized within a Tyvek® pouch of suitable size or placed in an empty mesh tray that can be wrapped or placed inside a rigid container. Individual instruments may be sterilized using the same cycle parameters that are recommended for instrument cases.

The following cycle parameters are for instrument cases up to 22.5 lbs (10kgs).

U.S. PARAMETERS

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

INTERNATIONAL PARAMETERS

DYNAMIC-AIR-REMOVAL STEAM STERILIZER
134º - 137ºC (274º - 278ºF) –Wrapped per manufacturer's instructions
3 minutes exposure time - 30 minutes drying time (allow for cooling)

STORAGE AND SHELF LIFE
Instrument cases or individual instruments 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 or individual instruments to prevent damage to the sterile barrier. The health care facility should establish a shelf life for sterilized instrumentation based upon the type of sterile wrap or rigid container used and the recommendations of the sterile wrap or rigid container 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 this device to sale by or on the order of a physician.

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

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

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate,
Bridgend, South Wales
CF31 3XA, U.K.

CE 0086

Symbol Legend

 Manufacturer

 Date of manufacture

 Do not reuse

 Caution, see instructions for use

Sterilized using ethylene oxide

Sterilized using irradiation

Sterile

Sterilized using aseptic processing techniques

Sterilized using steam or dry heat

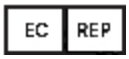
 Use by date

 WEEE device

Catalogue number

Batch code

Flammable



Authorized representative in the European Community