Instructions for the Care, Cleaning, Maintenance, Handling, and Sterilization of Biomet Surgical Instruments and Instrument Cases

DESCRIPTION
Biomet 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 sterilizer utilizing a 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.

WARNINGS AND PRECAUTIONS
- 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. Do not use an instrument that has become bent from its original shape as this will affect the performance of the instrument. Bent instruments should be disposed of.
- The Surgeon is to be familiar with the equipment, instruments, surgical technique and surgical procedure prior to performing surgery. Visit the company website or contact your local Biomet Representative to obtain the latest surgical technique.
- Surgical instruments should only be used for their intended purpose.
- 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.
- 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.
- 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.
- The patient is to be warned by his/her physician of all surgical risks.
- Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.
- Instruments must be thoroughly cleaned prior to sterilization.
- Instruments that are not clean may not be effectively sterilized.
- Automated cleaning using a washer/disinfector alone may not be effective for complex instruments with lumens, cannulations, blind holes, mated surfaces and other features.
- Do not clean soiled instruments while in polymer or metal trays.
- Single Use Instruments are for single use only and are not Reusable. These devices are single-use but can be reprocessed if not used unless labeling indicates the instrument is not to be reprocessed.
- Note: not used refers to those single-use components that have not been in contact with blood, bone, tissue, or other body fluids. Any unused, single-use device that has been exposed to blood, bone, tissue, or body fluids must not be reprocessed and must be discarded.
- Single-use devices must be cleaned separately from soiled instruments.

Responsibilities of the User
A. Cleaning/Disinfection
The health care facility is responsible to ensure that conditions essential to safe handling and cleaning/disinfection 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. Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Care should be taken to avoid penetrating or cutting injuries. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers. Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.

B. Sterilization
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 the following: prolonged use; misuse; and rough or improper handling. Care must be taken to avoid compromising the performance of the surgical instruments and instrument cases. 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 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 instruction.
- Only use an instrument for its intended purpose.
- When handling sharp instruments, use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
- Alkaline detergents with pH ≤ 12 may be used to clean stainless steel and polymer instruments; however, it is critical that alkaline cleaning agents are thoroughly neutralized and rinsed from devices. The use of alkaline cleaning agents might be corrosive to the surface of aluminum and titanium instruments. Drill bits, reamers, rasps and other cutting devices should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are fit for use.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Do not stack instruments or place heavy instruments on top of delicate devices.
• Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.
• Descaling agents that include morpholine should not be used in steam sterilizers. These agents leave residue which can damage polymer instruments over time. Steam Sterilizers should be descaled in accordance with the manufacturer's instructions.
• Repeated processing according to these instructions has minimal effect on Biomet reusable manual instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended surgical use and not to reprocessing.
• Polymers used in Biomet instrument sets can be sterilized using steam/moist heat. Polymer materials have a limited useful life. If polymer surfaces turn "chalky," show excessive surface damage (e.g. crazing or delamination), or if polymer devices show excessive distortion or are visibly warped, they should be replaced. Notify your Biomet representative if polymer devices need to be replaced.
• Most currently available polymers will not withstand conditions in washers/sterilizers that operate at temperatures equal to or greater than 141°C / 285°F, and use live-steam jets as cleaning features. Severe surface damage to polymer devices may occur under these conditions.
• Stainless steel instruments may be treated with rust removal agents approved for surgical instruments if needed.
• Titanium and titanium alloy devices are especially susceptible to discoloration from steam impurities and detergent residues which form multi-colored surface layers of oxide deposits. Upon repeated sterilization, these oxide layers, while not harmful to the patient, may become dark and obscure graduation marks, item and lot numbers, and other stamped or etched information. Acidic, anti-corrosion agents may be used to remove this discoloration as needed.
• Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments.

CLEANING AND DISINFECTION

A. Point-of-Use Preparation for Reprocessing

Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning. Note: Soaking in proteolytic enzyme solutions or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic solutions as well as enzymatic foam sprays break down protein material and prevent blood and protein based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed. For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning. Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk. Do not place soiled instruments back into the instrument case.

B. Preparation before Cleaning

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 cleaning. 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. Care should be exercised to avoid losing small screws and components. If a part is lost, notify your Biomet representative when the instrument set is returned. Instruments with removable polymer sleeves must be disassembled for sterilization (e.g. acetabular reamer shaft with sleeve, side cutters, etc.).

C. Preparation of Cleaning Agents

Neutral pH, enzymatic, and alkaline cleaning agents with low foaming surfactants are recommended. Alkaline agents with pH ≤ 12 may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and/or thorough rinsing. Only agents with proven efficacy (FDA approved, VAH listed, or CE mark) should be used. As a large variety of cleaning agents and disinfectants exists around the globe, Biomet does not recommend any specific brand. Agents used during the validation of these processing instructions are: Steris® Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner, Prolystica® 2X Concentrate Neutral Detergent, neodisher® FA Alkaline Detergent, and neodisher® Z Acid Neutralizer. All cleaning agents should be prepared at the use dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents. Dry powdered cleaning agents should be completely dissolved prior to use to avoid staining or corrosion of instruments and to ensure correct concentration. Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Note: It is important to select enzymatic solutions intended for breakdown of blood, body fluids and tissues. Some enzymatic solutions are specifically formulated for deep clean of fecal matter or other organic contaminants and may not be suitable for use with instruments.

D. Combination Cleaning and Disinfection Instructions

1. Completely submerge the instruments in an enzyme or alkaline (pH ≤ 12) solution and allow to soak and sonicate for 10 minutes at 40-50 kHz. If using enzymatic cleaning agents, use a soft nylon bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristled brush (i.e. pipe cleaner).

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

2. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.

3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. The minimum parameters in Tables 1 and 2 are essential for thorough cleaning and disinfection.

Note: The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with approved efficacy (e.g. CE mark, FDA clearance, and validation according to ISO 15883) should be used.

Table 1 - Typical U.S. Automated Washer/Disinfector Cycle for Surgical Instruments

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 minute prewash with cold tap water</td>
</tr>
<tr>
<td>2</td>
<td>20 second enzyme spray with hot tap water</td>
</tr>
<tr>
<td>3</td>
<td>1 minute enzyme soak</td>
</tr>
<tr>
<td>4</td>
<td>15 second cold tap water rinse (X2)</td>
</tr>
<tr>
<td>5</td>
<td>2 minutes detergent wash with hot tap water (64-66 °C/146-150 °F)</td>
</tr>
<tr>
<td>6</td>
<td>15 second hot tap water rinse</td>
</tr>
<tr>
<td>7</td>
<td>2 minute thermal rinse (80-93 °C/176-200 °F)</td>
</tr>
<tr>
<td>8</td>
<td>10 second purified water rinse with optional lubricant (64-66 °C/146-150 °F)</td>
</tr>
<tr>
<td>9</td>
<td>7 to 30 minute hot air dry (116 °C/240 °F)</td>
</tr>
</tbody>
</table>

Table 2 - Typical European Automated Washer/Disinfector Cycle for Surgical Instruments

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 min pre-rinse with cold tap water</td>
</tr>
<tr>
<td>2</td>
<td>10 min alkaline cleaning agent wash at 55 °C</td>
</tr>
<tr>
<td>3</td>
<td>2 min rinse with neutralizer</td>
</tr>
<tr>
<td>4</td>
<td>1 min rinse with cold tap water</td>
</tr>
<tr>
<td>5</td>
<td>Disinfection at 93 °C with hot purified water until A0 3000 is reached (approx. 10 min)</td>
</tr>
<tr>
<td>6</td>
<td>40 min hot air drying at 110 °C</td>
</tr>
</tbody>
</table>


INSPECTION, MAINTENANCE, TESTING, AND LUBRICATION

1. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.

2. Visually inspect for completeness, damage and/or excessive wear.
Note: If damage or wear is noted that may compromise the function of the instrument, contact your Biomet Representative for a replacement.

3. Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.

4. If necessary, hinged, rotating, or articulating instruments can be lubricated with an instrument product (e.g., Instrument Milk or equivalent lubricant) specifically designed for compatibility with steam sterilization.

Note: These lubrication instructions are not applicable to air-powered or electrical instruments. These devices have different requirements and should be lubricated according to the manufacturer’s instructions.

Note: Lubricants not specifically designed for compatibility with steam sterilization should not be used because they may: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

5. Check instruments with long slender features (particularly rotating instruments) for distortion.

6. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

STERILE PACKAGING

A. Packaging Individual Instruments

- Single devices should be packaged in a medical grade sterilization pouch or wrap which conforms to the recommended specifications for steam sterilization provided in Table 3. Ensure that the pouch or wrap is large enough to contain the device without stressing the seals or tearing the pouch or wrap.
- The sterilization wrap used should be specifically designed for sterilization.
- Standard medical grade, steam sterilization wrap may be used to package individual instruments. The package should be prepared using the AAMI double wrap or equivalent method.

Note: If sterilization wraps are used, they must be free of detergent residues. Reusable wraps are not recommended.

B. Packaging Instrument Sets in Rigid Trays and Cases with Lids

- Safety Precaution: The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs. Instrument cases may be placed in an approved sterilization container (e.g., Aesculap) with gasketed lids at the user’s discretion. The total weight of the instrument set, case, and sterilization container, must not exceed 11.4kg/25lbs (other local limits below 25 lbs. may apply).
- Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.
- The sterilization wrap used should be FDA cleared.
- Trays and cases with lids may also be placed in an approved sterilization container with gasketed lid for sterilization.
- Follow the sterilization container manufacturer’s instructions for inserting and replacing sterilization filters in sterilization containers.
- Areas designated for specific devices shall contain only devices specifically intended for these areas.

STEREILIZATION

- Flash (immediate-use) steam sterilization is not recommended.
- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.
- Steam sterilizer manufacturer recommendations should always be followed. When steam sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer’s maximum load is not exceeded.
- Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contract with all surfaces.
- See Table 3 for recommended minimum steam sterilization parameters that have been validated to provide a 10^6 sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table.

Note: The Sterilizer Manufacturer’s instructions for operation and load configuration should be followed explicitly.

Table 3 – Recommended Steam Sterilization Parameters

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Minimum Dry Time</th>
<th>Minimum Cool Time</th>
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<tbody>
<tr>
<td>U.S. Prevacuum</td>
<td>132 °C / 270 °F</td>
<td>4 minutes</td>
<td>30 minutes</td>
<td>30 minutes</td>
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<tr>
<td>U.K. Prevacuum</td>
<td>134 °C / 273 °F</td>
<td>3 minutes</td>
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<tr>
<td>Prevacuum1,2</td>
<td>134 °C / 273 °F</td>
<td>18 minutes</td>
<td></td>
<td></td>
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</tbody>
</table>

1 Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.
2 This cycle is not to be used for the inactivation of prions.
3 Drying times vary according to load size and should be increased for larger loads.
4 Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

STERILE INSTRUMENTS

Reusable medical devices sold sterile may be reprocessed using these instructions. Single use devices sold sterile may be reprocessed if not used unless labeling indicates the instrument is not to be reprocessed. Single use devices must be cleaned separately from soiled instruments. Always consult the device labeling and instructions for use for specific recommendations or restrictions on processing within a health care setting.

STORAGE AND SHELF LIFE

- Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- 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.
- Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

Note: Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned, repackage and sterilized.

Note: If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the instrument set resterilized.

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

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

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Steris® and Prolystica® are registered trademarks of Steris Corporation.

Neodisher® is a registered trademark of Chemische Fabrik Dr. Weigert GmbH.

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
<table>
<thead>
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<th>Symbol</th>
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