Reusable Surgical Instruments
Cleaning and Sterilization Instructions
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1 Processing Instructions
These processing instructions are intended to assist the processing unit in hospitals and health care centers to follow the necessary cleaning, sterilization and packaging practices for the best care of the Bodycad reusable instrument set.

1.1 Warnings and Precautions
- New and used instruments must be thoroughly processed according to the recommendations contained in that document prior to use.
- Hospitals must assume responsibility for cleaning, disinfection, packaging and sterilization of all reusable instrument sets before first use or re use.
- The user/processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in that document.
- Reprocessed instruments must be inspected at the central sterile supply department in each facility to verify that instruments have been adequately cleaned and decontaminated before repeating reprocessing procedures to prepare them for subsequent reuse.
- These recommendations are applicable to all reusable medical devices manufactured and/or distributed by Bodycad Laboratories Inc.
- General Precautions should be observed by all concerned personnel working with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- Use Personal Protective Equipment (PPE) 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.
- DO NOT use metal brushes or scouring pads during manual cleaning procedures. These materials cause damage the surface and finish of instruments. We recommend the use of soft-bristled, nylon brushes for cleaning.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Always perform manual scrubbing with brushes with the instrument below the surface of the cleaning solution to prevent formation of aerosols and splashing which may spread contaminants. Cleaning agents must be easily and completely rinsed from device surfaces to prevent accumulation of detergent residue.
- DO NOT place heavy instruments on top of delicate devices.
- DO NOT allow contaminated devices to dry prior to reprocessing. Dried soils and residues are hard to remove from instruments.
- DO NOT use saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide since they are corrosive for the instruments. DO NOT place or soak Instruments in Ringer’s Solution.
- DO NOT use mineral oil or silicone lubricants because they:
  1) coat microorganisms;
  2) prevent direct contact of the surface with steam; and
  3) are difficult to remove.
• Only devices manufactured and/or distributed by Bodycad should be included in Bodycad instrument cases. These validated reprocessing instructions are only applicable to manufactured and/or distributed Bodycad instrument and cases.

• **DO NOT** use descaling agents that include morpholine in steam sterilizers. These agents leave residue which can damage polymer instruments over time.

• **NEVER** reprocess single-use instruments.

1.2 General Recommendations

• Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning reusable devices. Alkaline agents with pH of 12 or less may be used to clean stainless steel and polymer instruments in countries where required by law or local ordinance. It is critical that alkaline cleaning agents are completely and thoroughly neutralized and rinsed from devices.

  *NOTE: Drill bits, rasps and other cutting devices should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are fit for use.*

  *NOTE: It is important to select enzymatic solutions intended for breakdown of blood, body fluids and tissues. Some enzymatic solutions are specifically for breakdown of organic contaminants and may not be suitable for use with orthopaedic instruments.*

• Repeated processing, according to the instructions in this manual has minimal effect on Bodycad reusable manual instruments unless otherwise noted. The 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.

• Where applicable, multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self-evident. Care must be taken to avoid losing small parts. If a part is lost, notify your Bodycad representative.

• Instruments must be removed from metal or polymer trays for manual and/or automated cleaning procedures. Do not clean instruments while in polymer or metal trays. Instrument trays, cases and lids must be cleaned separately from instruments.

• Polymers used in Bodycad 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 Bodycad representative if polymer devices need to be replaced.

• Most currently available polymers will not withstand conditions in washer/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 will occur under these conditions.

• Soaking in disinfectants may be a necessary step to control certain viruses. However, these agents may discolor or corrode instruments (household bleach contains or forms chlorine and chloride in solution and has a corrosive effect similar to saline). Disinfectants containing
glutaraldehyde, or other aldehydes, may denature protein based contaminants, causing them to harden and making them difficult to remove. Where possible, soaking in disinfectants should be avoided.

- Steam/moist heat is the recommended sterilization method for Bodycad instruments.
- Bodycad DOES NOT recommend the use of Ethylene Oxide (EO), Gas Plasma Sterilization, or vaporized hydrogen peroxide sterilization or dry heat sterilization methods for Bodycad reusable instruments.
- Instruments with removable polymer parts must be disassembled for sterilization (e.g. impactor, hammer, etc.)
- 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 so dark that they can obscure graduation marks, catalog and lot numbers, and other stamped or etched information. Acidic, anti-corrosion agents may be used to remove this discoloration. Avoid frequent use of these agents.
- 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. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.

1.3 Initial Inspection

- Inspect instrument sets upon receipt in the hospital or health care unit for completeness. Inspect for detachable handles or heads. The organizing case has outlines, catalog numbers, and instrument names marked on the case.
- Orthopaedic surgical procedures follow a precise order in which the instruments are used. Also, many instruments have dimensional features which govern bone resections, determine implant sizes, depth of drill holes, etc. Therefore, it is very important that all requested sizes of a specific instrument series are available.
- Markings on instruments used for measuring anatomical dimensions must be legible. Notify your Bodycad representative if markings are not legible.

1.4 Point-of-Use Processing

- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in 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 facilitates cleaning, especially in instruments with complex features and hard-to-reach areas. These enzymatic solutions break down protein matter 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.
Reusable Surgical Instruments - Cleaning and Sterilization Instructions

- Instruments should be cleaned within 30 minutes of use 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.
- Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small components. If a part is lost, notify your Bodycad representative when the instrument set is returned.

Cleaning Agents:

- We recommend neutral pH enzymatic and cleaning agents with low foaming surfactants. Alkaline agents with pH of 12 or less may be used in countries where required by law or local ordinance. After using alkaline agents a neutralizer and thorough rinsing should follow.
- 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.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

1.5 Manual Cleaning/Disinfection

1. Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, mated surfaces, connectors and other hard-to-clean areas.
2. Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly flush holes and other difficult-to-reach areas.
3. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
4. Rinse instrument in purified water for at least 5 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Actuate the hinged instruments during the rinse time. Thoroughly flush holes and other difficult-to-reach areas.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

*NOTE: Open and close hinged instruments several times when placed in cleaning solution and during rinsing.*
NOTE: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

1.6 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 Bodycad representative for a replacement.

3. Check the action of moving parts (e.g. hinges) to ensure smooth operation throughout the intended range of motion.

4. Hinged or articulating instruments should be lubricated with a water soluble product (e.g. Instrument Milk or equivalent lubricant) intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. To remain effective, the expiration date specified by the manufacturer should be adhered to for both stock and use-dilution concentrations.

   NOTE: Mineral oil or silicone lubricants should not be used because they
       1) coat microorganisms;
       2) prevent direct contact of the surface with steam; and
       3) are difficult to remove.

   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.

2 Sterile Packaging

2.1 Packaging individual instruments

- Commercially available, rigid sterilization containers designed for steam sterilization of the appropriate sizes may be used to pack Bodycad instrument case for terminal sterilization. Rigid sterilization container manufacturer instructions must be strictly followed.

- Standard medical grade, steam sterilization wrap may be used to package the instrument case (including the whole instrument set). The package should be prepared using the AAMI double wrap or equivalent method. Sterilization wrap instructions must be strictly followed.

   NOTE: If sterilization wraps are used they must be free of detergent residues. We do not recommend the use of reusable wraps.
3 Sterilization Instructions

- 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.
- Moist heat/steam sterilization is the preferred and recommended method for Bodycad orthopaedic reusable instrument sets. See Table 2 for recommended minimum sterilization parameters.
- Always follow sterilizer manufacturer recommendations. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer’s stated maximum load is not exceeded.
- Instrument sets should be properly prepared and packaged in trays and/or containers that will allow steam to penetrate and make direct contact with all surfaces.
- DO NOT use ethylene oxide, gas plasma or vaporized hydrogen peroxide sterilization methods.
- Gravity displacement sterilization cycles are not recommended because cycle times are too long to be practical.

![Table 1: Recommended Steam Sterilization Parameters](image)

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Minimum Temperature</th>
<th>Minimum Exposure Time</th>
<th>Minimum Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum/Pulsating Vacuum</td>
<td>132°C/270°F</td>
<td>4 min</td>
<td>30 min</td>
</tr>
</tbody>
</table>

3.1 Storage Instructions

- 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.
- 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 repackaged 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 re-sterilized.*

4 Abbreviations

AAMI Association for the Advancement of Medical Instrumentation
5 Flowchart

Initial Inspection

Point of use Processing

Thorough Cleaning

Inspection, Maintenance, Test and Lubrication

Packaging

Sterilization

Storage