CLEANING AND STERILIZATION OF BIOMET 3i KITS AND INSTRUMENTS

Surgical instruments and instrument cases are susceptible to damage for a variety of reasons, including prolonged use, misuse, and rough or improper handling. Care must be taken to avoid compromising their performance. To maintain the quality of surgical instruments, a standardized cleaning and sterilization protocol should be adopted.

The recommended cleaning and sterilization procedures in this document apply to all BIOMET 3i kits and the instruments housed within. Additionally, as indicated in Section G, Combination Cleaning and Disinfection Instructions for Instruments apply to BIOMET 3i and Zimmer Dental instruments.

WARNINGS AND PRECAUTIONS

- Universal Precautions should be observed by all clinic/hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- 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.
- Metal brushes or scouring pads **must not** be used during manual cleaning procedures. These materials will damage the surface and finish of the instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- 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 instruments 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.
- **DO NOT** stack instruments or place heavy instruments on top of delicate devices.
- Dry, soiled surgical instruments are more difficult to clean. **DO NOT** allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline, or disinfectants to dry on used instruments.
- **DO NOT** place used instruments back into the tray prior to proper cleaning per the following cleaning procedure.
- 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.
- The performance of a drill's internal irrigation system may be adversely affected after passing multiple sterilization cycles.
- Only devices manufactured and/or distributed by BIOMET 3i should be included in BIOMET 3i instrument trays and cases. These validated reprocessing instructions are not applicable to BIOMET 3i trays and cases that include devices that are not manufactured and/or distributed by BIOMET 3i.
- Unless otherwise indicated, instruments and kits are **NOT** sterile and must be thoroughly cleaned and sterilized prior to use.
- Instruments should **NOT** be flash-autoclaved inside the instrument case or individually.
- Unwrapped instrument cases **DO NOT** maintain sterility.
- The following procedures **DO NOT** apply to powered instrumentation.
- Instruments that are able to be disassembled should be disassembled prior to cleaning and sterilization. Care must be taken to avoid losing small parts.
- The user/processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual.

Recommended Procedures for Cleaning and Sterilization of Surgical Instruments and Kits

To maintain the quality of BIOMET 3i Instrumentation, the following procedures on the BIOMET 3i validated process for cleaning and the validated sterilization cycles must be followed.

A. Materials Required for Procedures

Solutions

- Neutral-pH detergent, or specialized cleaning solution
- Proteolytic enzyme detergent
- Tap water
- Purified water

Tools

- PPE: Personal Protective Equipment (gloves, goggles, apron, etc.)
- Glass beakers
- Soft bristled brushes of various sizes
- Thin nylon-wire brush (pipe cleaner brush)
- Autoclave-approved wraps or pouches

Equipment

- Ultrasonic cleaning unit
- Steam autoclave
- Automated Thermo-disinfector (for automated cleaning and disinfection)

B. Limitations and Restrictions:

- Neutral pH, enzymatic, and alkaline (pH ≤ 12) cleaning agents are recommended and preferred for cleaning BIOMET 3i reusable devices. Alkaline agents with pH ≤ 12 may be used to clean stainless steel and polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob Disease (CJD) are a concern. **It is critical that alkaline cleaning agents are thoroughly neutralized and completely rinsed from devices.**
  NOTE: 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 fecal matter or other organic contaminants and may not be suitable for use with BIOMET 3i instruments.
- 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.
- At point of use, soiled instruments must be removed from metal or polymer trays and moistened to prevent debris from drying before transportation to the reprocessing area for manual and/or automated cleaning procedures. Do not clean soiled instruments while in polymer or metal trays.
  NOTE: Any unused, single-use device that has been exposed to blood, bone, tissue, or body fluids must not be reprocessed and must be discarded.
- 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 (e.g. ultra-filter (UF), reverse-osmosis (RO), deionized (DI) distilled water (DW), or equivalent).
- **Do not** allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning. Place used instruments in a container (e.g. glass beaker) filled with purified water if immediate cleaning is not possible.
  NOTE: Soaking in proteolytic enzyme solutions or other precleaning 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 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.
- Prior to first use, the empty Dental Wash Tray (ZBDWT01) must be processed following the steps provided in section F or section G of this document.
- Reusable instruments may be cleaned and disinfected using an automated thermodisinfector when housed within Dental Wash Tray (ZBDWT01). An appropriate mesh basket can be used for the instruments that cannot be housed in Dental Wash Tray due to their size.
- **Do not** sterilize instruments in the Dental Wash Tray. Instruments should be wrapped individually or in a surgical tray as stated in section I or section J, respectively. Instruments must be sterilized following the parameters stated in section K of this document.
- 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.
- Repeated processing, according to the instructions in this manual has minimal effect on the reusable 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.

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 3i does not recommend any specific brand.
- 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).

D. Cleaning/Disinfection Options:

Method	Description	Section
Rigorous Manual Cleaning Instructions for Instruments	Enzymatic or alkaline soak and scrub followed by sonication.	E
Rigorous Manual Cleaning Instructions for Trays	Enzymatic or alkaline soak and scrub.	F
Combination Cleaning and Disinfection Instructions for Instruments	Enzymatic soak and scrub with sonication or alkaline soak with sonication followed by automated washer/disinfector cycle.	G

- BIOMET 3i recommends using Rigorous Manual Cleaning process for instruments (Section E) and trays (Section F).
- Instances where the local laws and ordinances require instruments to be disinfected prior to sterilization, Combination Cleaning and Disinfection method can be used. Combination Cleaning and Disinfection Instructions for Instruments are validated for BIOMET 3i and Zimmer Dental instruments when used with Dental Wash Tray (ZBDWT01) for automated washer / disinfector cycle.

E. Rigorous Manual Cleaning Instructions for Instruments:

1. Completely submerge instruments in an enzymatic or alkaline (pH ≤12) 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, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
2. Remove the instruments from the enzymatic or alkaline solution and rinse in purified water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
3. Prepare a neutral-pH cleaning agent solution in a sonication unit. Completely submerge devices in cleaning solution and sonicate for 10 minutes at 40-50 kHz.
4. Remove the instruments from the cleaning solution and rinse in purified water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
5. Repeat the sonication and rinse steps 3 and 4 above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
7. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning process.

F. Rigorous Manual Cleaning Instructions for Trays:

1. Completely submerge trays in an enzymatic or alkaline (pH ≤12) 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, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
2. Remove the trays from the enzymatic or alkaline solution and rinse in purified water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
3. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
4. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning process.

G. Combination Cleaning and Disinfection Instructions for Instruments:

NOTE: This section applies to BIOMET 3i and Zimmer Dental instruments.

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. 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).
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 their appropriate locations in the Dental Wash Tray (ZBDWT01) and process through a standard instrument washer/disinfector cleaning cycle. An appropriate mesh basket can be used for the instruments that cannot be housed within Dental Wash Tray due to their size. The following minimum parameters are essential for thorough cleaning and disinfection.

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

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

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

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

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 approval, and validation according to ISO 15883) should be used.

H. Inspection for Wear and Damage:

- Visually inspect all devices for completeness, damage and/or excessive wear (e.g. corrosion or rust build-up on the instrument surface, structural wear or damage, partial or complete fracture). If damage or wear is noted that may compromise the function of the instrument, contact your BIOMET 3i representative for replacement.

I. Wrapping 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 the table below. Ensure that the pouch or wrap is large enough to contain the device without stressing the seals or tearing the pouch or wrap.

- 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.

J. Wrapping Instruments Sets in BIOMET 3i Trays and Cases:

- Re-assemble the surgical kit (tray) if necessary and place the cleaned instruments into specified locations. Areas designated for specific devices shall contain only devices specifically intended for these areas.
- Only devices manufactured and/or distributed by BIOMET 3i should be included in BIOMET 3i instrument trays. These validated reprocessing instructions are not applicable to BIOMET 3i trays that include devices that are not manufactured and/or distributed by BIOMET 3i.
- Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.
- Trays and cases with lids may also be placed in an approved sterilization container with gasket lid for sterilization. Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers.

K. Steam Sterilization:

Sterilize the kit and instruments at the recommended cycles noted in the following table. The recommended sterilization procedures have been validated by BIOMET 3i.

Catalog Number (Kit)	Gravity Displacement Sterilizer (Full Cycle)			Pre-Vacuum Sterilizer (HI-VAC)
	15 Minutes 132°C to 135°C (270°F to 275°F) **30 Minute Dry Time**	**20 Minutes** 132°C to 135°C (270°F to 275°F) **30 Minute Dry Time** **30 Minute Cool Down**	**40 Minutes** 132°C to 135°C (270°F to 275°F) **30 Minute Dry Time** **30 Minute Cool Down**	**4 Minute, 4 Pulse** 132°C to 135°C (270°F to 275°F) **30 Minute Dry Time**
SGKIT, SGTIKIT			**X**	**X***
NPSDK0, NCATD0, NCATD0C			**X**	**X**
QNTSK20, QNTSK40, QNTSK40U		**X**		**X**
PSKT01, PSKT10, PSKT20, PSKT30, PSKT30U, PSKT35, PSKT40, PTT100, OST00, OST10, OST20, NTOST0, NTOST0A	**X***			**X**
All Other Kits	**X**			**X**
Stand-alone Instruments	**X**			**X**

***NOTE: Requires an additional 30 Minute Cool Down for the indicated cycle.**

NOTE: The autoclave manufacturer's instructions should be strictly adhered to for the pressure selection during the aforementioned sterilization cycles. The pressure requirements during the sterilization are the responsibility of the autoclave manufacturers to determine and validate.

L. Storage Instructions:

- Instruments should be dried completely prior to storage. Sterile, wrapped 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. Failure to do so may result in stainless steel corrosion or staining.
- Sterile instrument wraps 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, 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.

The instructions provided in this reprocessing manual have been validated by Biomet 3i in the laboratory and are capable of preparing reusable devices for use. It is the responsibility of the clinic or the hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

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