

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.

WARNINGS AND PRECAUTIONS

- DO NOT place used instruments back into the tray prior to proper cleaning per the following procedure (Steps 1-8).
- Unless otherwise indicated, instrument kits 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.
- Unwrapped instrument cases DO NOT maintain sterility.
- The following procedures DO NOT apply to powered instrumentation.
- For the High Torque Indicating Ratchet Wrench (H-TIRW) and the Low Torque Indicating Ratchet Wrench (L-TIRW), disassembly is required; please consult disassembly instructions accompanying the product.
- Instruments that are able to be disassembled should be disassembled prior to cleaning and sterilization.
- A thermodisinfection washer **MAY NOT BE USED** to clean Biomet 3i surgical instruments and kits.

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.

MATERIALS REQUIRED FOR PROCEDURES

Solutions

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

Tools

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

Equipment

- Ultrasonic cleaning unit
- Steam autoclave

STEP-BY-STEP INSTRUCTIONS

CLEANING OF INSTRUMENTS

Note: Individuals who clean surgical instruments need to wear appropriate personal protective equipment.

1. Following completion of a clinical surgical procedure, gather all instruments, prepare a solution for soaking using tap water (tepid or lukewarm) and a neutral-pH detergent at a dilution recommended by the detergent manufacturer. Place instruments in a single layer at the bottom of a glass beaker containing the dilute solution. Soak the instruments for at least ten (10) minutes. **Note:** It is important to clean instruments as soon as possible; if immediate cleaning is not possible, continue to soak the instruments to prevent blood from drying on the surfaces.

2. Rinse with running tap water for a minimum of two (2) minutes while brushing exteriors of items individually with a soft bristled brush to remove visible debris; clean interior lumens of specified instruments with small brushes.
3. For internally irrigated instruments, ream each lumen with a thin wire to remove any remaining debris. **Note:** This step should be performed as soon as possible after use to remove any bone fragments or organic material that could clog the canal and prevent the flow of water.
4. Using a clean beaker, prepare a solution for ultrasonic cleaning using distilled water with a specialized enzymatic detergent per the detergent manufacturer's recommendations.
5. Place all instruments in a single layer into the beaker of solution. Place the beaker containing the instruments into the ultrasonic bath and turn on for five (5) minutes.
6. Remove each instrument and repeat the scrubbing procedure; ream lumens of instruments having interior canals. **Note:** The performance of a drill's internal irrigation system may be adversely affected after passing multiple sterilization cycles.
7. Rinse by flushing instruments for one (1) minute with a steady stream of running tap water. **Note:** This step is important to prevent spotting.
8. Inspect each instrument visually and check for cleanliness, any remaining bone fragments, visible soil or residual debris, and for visible damage and/or wear. Repeat the scrubbing procedure as necessary. Set aside the instruments specific to BIOMET 3i Kit for packaging.

CLEANING OF SURGICAL KIT

9. Detach the insert from the surgical tray. Scrub all surfaces of the surgical tray and the insert with mild soap using a soft bristled brush.
10. Rinse both pieces with running tap water for a minimum of two (2) minutes and inspect surfaces for cleanliness.
11. Re-assemble the surgical kit by placing the insert back into the tray and replacing the cleansed instruments into specified grommets.

PACKAGING FOR STERILIZER

12. Allow the instruments to dry before wrapping.
13. Close the surgical kit and wrap it with autoclave paper twice, or place it within two (2) autoclave-approved bags/pouches. When sterilizing individual instruments, place one instrument within one (1) autoclave-approved bag/pouch.

STEAM STERILIZATION

14. 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.


STORAGE

15. Instruments should be dried completely and stored in a moisture-free environment. Failure to do so may result in stainless steel corrosion or staining.
16. Prior to use, the exterior of each sterilized package should be inspected for integrity. If a package is suspect, it should not be used and should be reprocessed as per the above sterilization procedure.
17. Shelf life and sterility of wrapped instrument cases are dependent on storage in a manner to avoid extreme temperature, moisture, and/or other contamination. Care must be exercised in the handling of wrapped cases to prevent damage to the sterile barrier. The probability of an occurrence of contamination increases over time, with handling, and based on the packaging method.

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.

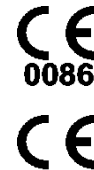
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 : Date of Manufacture	 : Batch code		
 : Catalogue number	 : Caution, consult accompanying documents		
 : Do not re-sterilize	 : Do not re-use		
 : Consult Instructions for Use www.ifu.biomet3i.com	 : Sterilized using gamma irradiation		
 : Use by date	 : Do not use if package is damaged		
 : By prescription only	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td>EC</td><td>REP</td></tr></table> : Authorized European Representative	EC	REP
EC	REP		
 : Legal Manufacturer	 : Non- sterile		



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Obsolete