



## CLEANING AND STERILIZATION OF THE BIOMET 3i™ SLIM KIT 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 the BIOMET 3i Slim Kit and the instruments housed within.

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### 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), disassembly is required; please consult disassembly instructions accompanying the product.

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### Recommended Procedures For Cleaning And Sterilization Of Surgical Instruments And Kit

#### MATERIALS REQUIRED FOR PROCEDURES

##### Solutions

- Neutral-pH detergent, or specialized cleaning solution
- Proteolytic enzyme detergent
- Ethyl alcohol (Ethanol); do not use rubbing alcohol (isopropyl alcohol)
- 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 Slim 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 KIT FOR STERILIZER

12. Pour ethyl alcohol over the surgical tray, the lid, and onto the instruments to rinse and remove residual soap and water minerals. 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.

#### STEAM STERILIZATION PER ANSI/AAMI ST79 STANDARD \*

14. GRAVITY DISPLACEMENT STERILIZER (FULL CYCLE)  
The exposure time is a minimum of fifteen (15) minutes at a temperature of 270 – 275°F (132-135°C).  
– Or –  
PRE-VACUUMED STERILIZER (HI-VAC)  
The exposure time is a minimum of four (4) minutes, four (4) pulses at a temperature of 270 – 275°F (132-135°C).
15. Post-sterilization drying time is a minimum of thirty (30) minutes.

#### STORAGE

16. Instruments should be dried completely and stored in a moisture-free environment. Failure to do so may result in stainless steel corrosion or staining.
17. 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.
18. 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 recommended sterilization procedures have been validated by BIOMET 3i with its Slim Kit.

BIOMET 3i cannot control individual clinic handling procedures, cleaning methods, bioburden levels, and other conditions, and therefore assumes no responsibility for sterilization of product by the user, even when the recommended guidelines above are followed.

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OBSOLETE

 Non-Sterile	: Batch Code
 Catalogue number	: Consult Instructions for use
: Do not use if package is damaged	: Caution: Law prohibits dispensing without prescription
	: Date of Manufacture



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