

**Recommendations for the Care and Handling
Biomet Microfixation's Non-sterile, Non-powered Reusable Instruments and Instrument Cases**

DESCRIPTION

Biomet Microfixation instruments and instrument cases are generally composed of aluminum, stainless steel, titanium 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/or 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 autoclave utilizing a cleaning, sterilization and drying cycle that has been validated by the user for the equipment and procedures employed at the user facility.

WARNINGS AND PRECAUTIONS

When handling sharp instruments use extreme caution to avoid injury: Avoid undue stress or strain when handling or cleaning instruments. **Wear protective gloves and goggles during cleaning and** consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact. Unless otherwise indicated, instruments are NOT sterile and must be sterilized prior to use. Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided, whenever possible. **Unwrapped instrument cases DO NOT maintain sterility.**

STORAGE AND SHELF LIFE

Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extreme temperature and moisture. Care must be exercised in handling wrapped cases to prevent damage to the sterile barrier and/or tape indicator. The health care facility should establish a shelf life for wrapped instrument cases, based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling, whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

Surgical instruments should not be stored in areas containing chemicals which develop corrosive vapors.

Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.

CLEANING INSTRUCTIONS FOR INSTRUMENTS MADE WITH THE FOLLOWING MATERIALS:

Aluminum, Stainless Steel, Titanium, Polymeric Materials (for instruments made from other materials, contact Biomet Microfixation)

NOTE: DO NOT ALLOW SOILED INSTRUMENTS TO DRY.

- Immerse or use damp towels with deionized or distilled water to keep soiled instruments moist prior to cleaning.
- For instruments contaminated with blood and body fluids (e.g. protein), use of an enzyme product or ultrasonic cleaning following the manufacturer's recommendations is recommended to facilitate cleaning.
- Use of a residue free, PH 7 detergent is recommended.
- Mechanical cleaning (i.e. washer-disinfection/washer-decontamination equipment) using equipment designed for medical devices is recommended. Automatic washers/disinfectors should be operated as instructed by the manufacturer.

Cleaning Instructions using an Automatic Washer/Disinfectant and Detergent

1. Disassemble reusable instruments from powered hand piece, as applicable.
2. Pre-rinse by hand: Remove gross contamination from all soiled instruments under cool to tepid running tap water (72 degrees F) using a nylon instrument brush to scrub all surfaces of each instrument until they are visibly clean. Instruments with box locks must be opened and free from any protein residues, and their functions checked accordingly. Anodized aluminum instruments and trays are susceptible to acidic and alkaline solutions, check the detergent PH level to assure it is no higher than 7, if not removal of colors and/or bleaching may occur.
3. Load the Instrument Case: After visually removing gross contamination, the instruments may be placed into the

appropriate instrument case. Make sure that the case lid closes properly. If the case lid will not close, the case is overloaded. Remove excess instrumentation and close the lid over the top of the case.

Pre-wash cycle: optional (if not available, proceed to instruction #4)

Do not use detergent in this cycle. Pre-wash in deionized or distilled water.

Minimum cycle parameters: 4 minutes at 49 °C or 120 °F.

4. Wash Cycle: Use a residue free detergent (with a neutral ph of 7) per autoclave manufacturer's instructions.

Minimum cycle parameters: 12 minutes at 49 °C or 120 °F.

5. Final Rinse/Thermal Disinfect Rinse: **DO NOT USE cleaning agents during this final cycle.**

After the wash cycle, a final rinse cycle using deionized water for a minimum of 4 minutes at 30 °C or 86 °F or a thermal disinfect cycle at an elevated temperature of 85 °C or 185 °F should be used.

6. Visual Inspection: At the end of the cleaning cycle, visually inspect the instruments to ensure they are "visually clean". If they are not, repeat cleaning instructions 2-6.

Precaution for reusable instruments and instrument cases:

All instruments and cases should be regularly inspected for wear or disfigurement. DO NOT USE instruments or cases that are disfigured, cracked, corroded, or otherwise damaged. These should be disposed of appropriately.

STERILITY

Biomet Microfixation instruments can be steam autoclaved and repeated autoclaving will not adversely affect them, unless otherwise indicated in the labeling. If you have any problems when using our instruments or instrument cases, please bring this to our immediate attention by contacting the Biomet Microfixation CAPA coordinator or customer service department as well as enclosing information if you are returning any items. NOTE: ALL USED INSTRUMENTS BEING RETURNED TO BIOMET MICROFIXATION MUST BE THOROUGHLY CLEANED AND STERILIZED PRIOR TO SHIPMENT. IF THIS IS NOT POSSIBLE, THE OUTER SHIPPING BOX MUST BE IDENTIFIED WITH CAUTIONARY LABELING SUCH AS: BIOHAZARDOUS.

Staining and spotting may result on instruments that are steam sterilized if the instruments are not completely rinsed and free from residual chemicals. It is vital that proper drying cycles and the equipment manufacturer's recommendations are followed to prevent the formation of excess moisture and resultant water spotting.

Unless supplied sterile, instruments must be sterilized prior to surgical use. Following is a recommended minimum cycle for steam sterilization that has been validated by Biomet Microfixation under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters described below.

Surgical instruments may be autoclaved using a full cycle. Instruments that have been used in a surgical environment should be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI St-46-1993 is recommended. Flash autoclaving should be avoided, whenever possible. Instruments should never be flash autoclaved in an instrument case.

[Instruments with box locks should be autoclaved in an opened position.](#)

Loaner instrument sets supplied by Biomet Microfixation have been thoroughly cleaned, inspected and tested for proper function prior to shipment. Unless otherwise indicated, these sets are NOT STERILE and must be sterilized prior to use. INSTRUMENTS SHOULD NOT BE FLASH-AUTOCLAVED INSIDE THE INSTRUMENT CASE.

PRE-VACUUMED STERILIZER (HI-VAC) Wrapped

Exposure time: 4 minutes exposure

Temperature: 270 degrees F (132 degrees C)

Drying time: 30 minutes MINIMUM

Health care personnel bear the ultimate responsibility 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. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Since Biomet Microfixation is not familiar with individual hospital handling methods, cleaning methods and bioburden, Biomet Microfixation cannot assume responsibility for sterility even though the guideline is followed.

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

Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities which they are involved in the handling and use of this product.

Comments regarding Biomet Microfixation devices or instruments or requests for a hard copy, can be directed to Attn: Regulatory Dept., Biomet Microfixation, 1520 Tradeport Drive, Jacksonville, FL USA, FAX: 904-741-3912 or by calling 904-741-4400.

Authorized Representative

Biomet UK, Ltd
Waterton Industrial Estate,
Bridgend, South Wales
CF31 3XA, U.K.
Tel. +44 1656 655221
Fax +44 1656 645454

European Sales Headquarters

Biomet Microfixation Europe
Toermalijnring 600
3316 LC Dordrecht
Netherlands
Tel. +31 78 629 29 10
Fax +31 78 629 29 12