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Recommendations for the Care and Handling Biomet Microfixation's Non-sterile, TraumaOne Case

DESCRIPTION

Biomet Microfixation 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 cases are perforated to allow steam to penetrate these various materials and components. The 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

Unless otherwise indicated, cases are NOT sterile and must be sterilized prior to use. Instruments should NOT be flash-autoclaved inside the case. **Unwrapped cases DO NOT maintain sterility.**

STORAGE AND SHELF LIFE

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 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.

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

CLEANING INSTRUCTIONS USING AN AUTOMATIC WASHER/DISINFECTOR 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. PH levels higher than 7 may cause removal of colors and/or bleaching.
3. Load the instrument case: After visually verifying removal of gross contamination, the instruments may be placed into the 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.
4. Pre-wash cycle: Pre-wash cycle is optional. If not available, proceed to instruction #5. 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
5. 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
6. Final rinse or thermal disinfect rinse: **DO NOT USE cleaning agents during this final cycle. Rinse with deionized water.**
Final rinse minimum cycle parameters: 4 minutes at 30 °C or 86 °F
Thermal disinfect minimum cycle parameters: 4 minutes at 85 °C or 185 °F
7. 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 -#7.

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

STERILITY

Biomet Microfixation cases can be steam autoclaved and repeated autoclaving will not adversely affect them. If you have any problems using our 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 cases that are steam sterilized if the cases 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.

Instrument cases must be sterilized prior to surgical use. The following recommended minimum cycle for steam sterilization 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.

PRE-VACUUMED STERILIZER (HI-VAC) Wrapped

Exposure time: 10 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, Inc., 1520 Tradeport Drive, Jacksonville, FL USA, FAX: 904-741-3912 or by calling 904-741-4400.