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Date: 2011-01

Recommendations for the Care and Handling of the Biomet® Active Articulation Bearing Press & Modular Head Removal Instruments

DESCRIPTION
The purpose of the Active Articulation Bearing Press & the Modular Head Removal instruments is to provide a method for mating a modular head with an Active Articulation head and for the removal of a modular head, up to 60mm in diameter, from the taper of a femoral stem.

Materials
Stainless Steel
Polymeric Materials
Titanaium Alloy

DISCLAIMER
Biomet® has verified through laboratory testing that its instruments are suitable for the specific cleaning and sterilization methods and cycles for which they have been tested. 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.

CLEANING AND DECONTAMINATION

Full Assemblies

Figure 1

Figure 2

Note that Figure 1 has the Bearing Press full assembly while Figure 2 has the Modular Head Removal instrument full assembly.

Disassembly for Cleaning
The following disassembly instructions are to be followed prior to cleaning the instruments.

Bearing Press

Figure 3

Figure 3 shows the disassemblies of the Bearing Press. The press is disassembled by rotating the locking nut counter-clockwise (1) which will allow the base plate (2) to be removed. No more disassembly is required. The components may be cleaned per the recommendations within the washing / disinfecting section listed below.

Modular Removal Tool

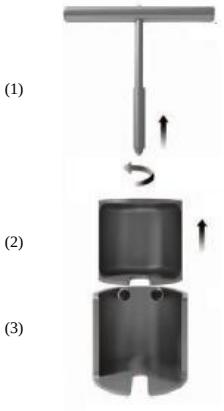

Figure 4

Figure 4 shows the disassemblies of the Modular Head Removal Tool. The tool is disassembled by rotating the T-handle (1) counter-clockwise which can be removed from the inner cylinder (2) which can be removed from the outer cylinder (3). No more disassembly is required. The components may be cleaned per the recommendations within the washing / disinfecting section listed below.

Removal of Visible Contamination
The effectiveness of subsequent decontamination processes depends on prior removal of visible soil. Visible soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. Care should be taken to avoid splashing and generating aerosols by holding instruments below the surface of the water in a sink into which water is running and continuously draining. Instruments should not be held under a running tap, as this is likely to result in splashing. Operatives should wear protective equipment including gloves and goggles. Care should be taken to avoid penetrating or cutting injuries. Particular attention should be taken to remove all debris from all cannulations, threaded areas, and obscure holes in the instruments.

Washing/Disinfecting
It is recommended that the instruments, disassembled as required, be decontaminated using an automatic washer-disinfection unit utilizing thermal disinfection. This should preferably be of the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. These detergents and/or rinse aids, however, should be of neutral or near neutral pH. Excessively acidic or alkaline solutions may corrode aluminum instruments. The following table provides a validated method for cleaning the instruments.

Phase	Time (Minutes)	Temperature & Water Quality	Detergent & Concentration
Pre-Wash	2:00	95°F (35°C) Tap Water	None
Detergent Wash	6:00	158°F (70°C) Tap Water	Enzol® 1oz./gallon
Wash	4:00	158°F (70°C) Tap Water	Renu-Klenz™ ¼ oz./gallon
Rinse	2:00	158°F (70°C) Tap Water	None
Drying	7:00	239°F (115°C)	None

PREPARATION AND ASSEMBLY
After cleaning/disinfecting, the disassembled instruments should be reassembled in the reverse order of the disassembly process.

Full Assemblies

Figure 1

Figure 2

Note that Figure 1 has the Bearing Press full assembly while Figure 2 has the Modular Head Removal instrument full assembly.

CARE AND HANDLING OF INSTRUMENTS

1. **General.** Surgical instruments 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 exacting performance. To minimize damage and the risk of injury, the following should be done:
   - Inspect the instruments for damage upon receipt and after each use and cleaning. Incompletely cleaned instruments should be cleaned until visibly clean, repeating as necessary. Instruments in need of repair should be set aside for repair service or returned to Biomet. Instruments returned to Biomet or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* provides guidelines for return, or contact Biomet or your distributor for further instructions.
   - Only use an instrument for its intended purpose.
   - When handling sharp instruments, use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
2. **General Cleaning.** Thoroughly clean instruments until visibly clean, repeating as necessary prior to initial sterilization and as soon as possible after use. Do not allow soil to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Wash all instruments whether or not they were used or inadvertently came into contact with blood or saline solution.
3. **Ultrasonic Cleaners** can be used with hot tap water per manufacturer's recommended temperature (usually 90ºF-140ºF or 32ºC-60ºC) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading patterns, instrument cassettes, water temperature, and other external factors may change the effectiveness of the equipment.
4. **Washer-Decontamination Equipment** will wash and decontaminate instruments. Complete removal of soil from crevices and serrations depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, and thus may require prior brushing. Be familiar with equipment manufacturers' use and operation instructions. Be aware that loading, detergent, water temperature, and other external factors may change the effectiveness of the equipment.

RESPONSIBILITIES OF THE USER
General. 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.

Cleaning/Decontamination. The health care facility is responsible to ensure that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* provides guidelines for design and personal considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, and process performance.

Sterility. ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. Guidelines are provided by this standard for cleaning and decontamination, preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

WARNINGS AND PRECAUTIONS
Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.

Instruments should NOT be flash-autoclaved inside an instrument case. Flash-autoclaving of individual instruments should be avoided.

STORAGE AND SHELF LIFE
Instruments that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of wrapped instruments to prevent damage to the sterile barrier. 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, with handling, and whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

STERILITY
Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly and properly cleaned and sterilized prior to use.

Biomet® 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 Biomet® instruments, please bring this to Biomet's or its distributor's attention when you return them (Instruments returned to Biomet or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* provides guidelines for return or contact Biomet or your distributor for further information.)

Unless otherwise indicated, instruments must be thoroughly cleaned and sterilized prior to surgical use. Set forth below is a recommended minimum cycle for steam sterilization that has been validated by Biomet under laboratory conditions.

Instruments that have been used in a surgical environment should be thoroughly cleaned, repeating as necessary, until visibly clean prior to autoclaving. Use of ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* is recommended. Wraps used during the steam sterilization process are to be FDA cleared wraps (e.g., Kimguard® Sterilization Wrap, K082554).

<u>DYNAMIC-AIR-REMOVAL STEAM STERILIZER</u>
270ºF (132ºC) – Single-wrapped
4 minutes exposure time - 20 minutes drying time

Since Biomet is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Biomet assumes no responsibility for sterilization of product by a hospital even if the general above guidelines are followed.

Comments regarding Biomet devices or instruments can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

CLEANING AND STERILIZATION METHODS

Biomet® Bearing Press & Modular Removal instruments - Suitable for Steam Autoclaving Aluminum, Stainless Steel, Radel® (registered trademark of Amoco)	
Processing Steps	Suggested Method.
Removal of visible contamination & disassembly	By hand submerged in water with continuous flow with mechanical aid (e.g. brush) wearing protective gloves & goggles. Disassemble instruments into individual parts.
Washing & Disinfecting	Automatic washer-disinfection unit utilizing thermal disinfection (ultrasonic or continuous tunnel process preferable) – Temperatures, cycles & disinfectant type used as instructed by manufacturer of washer-disinfection unit.
Sterilization	Steam autoclave.
Steam Autoclave Cycle Parameters*	Dynamic-Air-Removal Steam Sterilizer 270ºF (132ºC) – Single-wrapped 4 minutes exposure time – 20 minutes drying time *Validated by Biomet under laboratory conditions.
Precautions	When handling sharp instruments, use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact. Unless otherwise indicated, instrument sets are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.

Symbol Legend

 Manufacturer

 Date of Manufacture

 Do Not Reuse

 Caution

STERILE EO Sterilized using Ethylene Oxide

STERILE R Sterilized using Irradiation

STERILE Sterile

STERILE A Sterilized using Aseptic Processing Techniques

STERILE Sterilized using Steam or Dry Heat

Use By

WEEE Device

REF Catalogue Number

LOT Batch Code

FLAMMABLE Flammable

EC REP Authorized Representative in the European Community