EN

MicroPort Orthopedics

CLEANING AND HANDLING OF MICROPORT INSTRUMENTS

150802-1

The following languages are included in this packet:

English (en) Deutsch (de) Nederlands (nl) Français (fr)
Español (es) Italiano (it) Português (pt) 中文- Chinese (sch)
Türkçe (tk)

For additional languages, visit our website www.ortho.microport.com

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

MICROPORT ORTHOPEDICS INC.
CLEANING AND HANDLING OF MICROPORT INSTRUMENTS
(150802-1)

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Title [Additional Explanation]; Reference Number/ Standard[#]	Explanatory Text from Standard
	Batch code; 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number; 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Do not re-use; 5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Caution [consult warnings or precautions]; 5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult instructions for use [operating instructions]; 5.4.3	Indicates the need for the user to consult the instructions for use [operating instructions].
	Consult instructions for use [electronic IFU] [Where applicable, refer to http://www.ortho.microport.com/ifus or call +1 901-290-5290, for an urgent request call +1 901-354-8134, to obtain instructions for use.]; 5.4.3 A.15	Indicates that the instructions for use [warnings or precautions] are available in an electronic format.
	Use-by date; 5.1.4	Indicates the date after which the medical device is not to be used.
	Temperature limit; 5.3.7	Indicates the temperature limits to which the device can be safely exposed.
	Keep dry; 5.3.4	Indicates a medical device that needs to be protected from moisture.
	Keep away from sunlight; 5.3.2	Indicates a medical device that needs protection from light sources.
	Date of manufacture; 5.1.3	Indicates the date when the medical device was manufactured.

	Manufacturer; 5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
EC REP	Authorized Representative in the European Community; 5.1.2	Indicates the authorized representative in the European Community.
STERILE	Sterile; 5.2.1	Indicates a medical device that has been subjected to a sterilization process.
STERILE EO	Sterilized using ethylene oxide; 5.2.3	Indicates a medical device that has been sterilized using ethylene oxide.
STERILE R	Sterilized using radiation; 5.2.4	Indicates a medical device that has been sterilized using irradiation.
	Do not resterilize; 5.2.6	Indicates a medical device that is not to be resterilized.
	Non-sterile; 5.2.7	Indicates a medical device that has not been subjected to a sterilization process.
Rx ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician; 21 CFR 801.15(c)(1)(i)F; 21 CFR 801.109 – U.S. Code of Federal Regulations Title 21, Part 801 Labeling	Use of this device is not safe except under the supervision of a practitioner licensed by law to direct the use of such device.
	MR Conditional; ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (FDA Designation Number 8-349).	Indicates an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. If applicable, conditions can be found within the package insert or at www.ortho.microport.com/ifus.
	Do not use if package is damaged; 5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened.
CE	CE marking; 93/42/EEC European Union Medical Devices Directive, Annex XII CE Marking of Conformity	Indicates that the device fulfills the provisions of the European Medical Devices Directive.

Surgical instruments are supplied non-sterile or sterile. Instruments supplied sterile should be considered sterile unless the inner package has been open or damaged. If the inner package has been compromised, contact the manufacturer at +1 866 872 0211 for instructions.

Surgical instruments supplied non-sterile must be cleaned and sterilized before use. After use, these instruments must be, at minimum, properly decontaminated, cleaned, and stored. The following information outlines the proper steps for reprocessing MicroPort surgical instruments to help assure their long life. Cleaning may be entirely manual (Option 1 below) or may be assisted by an automated washer (Option 2).

INTRA-OPERATIVE PRECAUTIONS

Use medical devices in accordance with their labeled indications and MicroPort's instructions for use, especially during insertion and removal.

- Inspect instruments prior to use for items that may cause unacceptable functional deterioration that exceeds the instrument's use life:
    - Visual cues such as worn surfaces, dull edges, corrosion, pitting, cracking, or discoloration.

    - Difficulty to move, lock, or mate pieces.
    - Damage during shipment or storage.
- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the condition of an implant or instrument is found to be unacceptable or damaged, retain it to assist with MicroPort's analysis of the event. Contact MicroPort Orthopedics' Customer Service department at +1 866 872 0211 to receive instructions for returning the device to the manufacturer for investigation.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a. The material composition of the fragment (if known);
    b. The size of the fragment (if known);
    c. The location of the fragment;
    d. The potential mechanisms for injury, e.g. migration, infection;
    e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Cleaning Accessories	
Water	Cold deionized or reverse osmosis water should be used, as temperatures above 140°F (60°C) will coagulate proteins, rendering them difficult to remove from contaminated items.
Detergent	Prepare detergent (for example, LIQUI-NOX®, Alconox, Inc. 8.5 pH) per manufacturer recommendations.
Enzymatic Cleaner	Prepare enzymatic cleaner (for example, ENDOZIME®, Ruhof Corporation 6.0-7.5 pH) per manufacturer recommendations.
Manual Cleaning Accessories	Brushes and/or Pipe Cleaners, Syringes, Gloves, Absorbent Disposable Cloth (for example, KIMWIPE®, Kimtech Science)
Ultrasonic Cleaner	Ultrasonic Cleaners should be monitored routinely to ensure they are working properly.

Limitations and Restrictions of Reprocessing

Surgical instruments are designed for their durability and ability for reuse. MicroPort's reusable instruments are typically manufactured from stainless steel, which permits a long life when handled and maintained properly. Repeated processing has minimal effect on these instruments. End of functional life is normally determined by wear and damage due to use.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Cleaning/ Disinfection

The manual and automated cleaning processes instructed below have been validated for reusable instruments in accordance with AAMI TIR30:2003, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*, and the instructions outline the minimum parameters required to maintain the effectiveness of the cleaning method.

Note: To ensure proper processing, please follow appropriate healthcare facility standards.

Warnings	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.
	Always double-wrap the components in an FDA-cleared CSR wrap or similar type non-woven, medical grade wrapping material. Flash-autoclaving of individual instruments should be avoided, whenever possible. Unwrapped components DO NOT maintain sterility.

Clean instruments as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with cold water or an appropriate detergent or enzymatic solution to delay drying. Clean all instruments whether or not they were used or inadvertently contacted with blood or saline solution.

Preparation for Cleaning	• The cleaning process must be conducted so that all parts of the surgical instrument are exposed as permitted by instrument design. The cleaning process should include an individual properly gowned with appropriate glove and personal protective equipment. • This may require opening all hinged items or the disassembly of those items with multiple or removable parts. • Those items with mating surfaces, i.e. ratchets, hinges, serrations, lumens, blind holes, etc. must be carefully cleaned to remove all visible debris from the items. • Additional assembly/disassembly instructions may be found in the product specific surgical technique.
Option 1: Manual Cleaning	1. **Separate** any mated instruments before cleaning. For any instruments with moving pieces, move the pieces throughout their range of motion during cleaning to clean moving pieces in all positions. 2. **Rinse** with cold tap water (approximately 16°C) to remove visible contamination. 3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes. 4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe. 5. **Rinse** with cold tap water (approximately 16°C) for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens. 6. **Bathe** in a neutral detergent solution prepared per manufacturer directions for 5 minutes. 7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe. 8. **Rinse** thoroughly/flush with deionized/reverse osmosis (RO/DI) water. 9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions. 10. **Rinse** thoroughly/flush with RO/DI water for 1 minute. 11. **Dry** with a clean, soft, absorbent, disposable cloth. 12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean. **Note:** Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Option 2: Automated Cleaning

Pre-cleaning

1. **Separate** any mated instruments before cleaning. For any instruments with moving pieces, move the pieces throughout their range of motion during cleaning to clean moving pieces in all positions.
2. **Rinse** with cold tap water (approximately 16°C) to remove visible contamination. While rinsing, scrub thoroughly with a soft brush and/or pipe cleaner and repeatedly flush lumens and blind holes with a syringe.
3. **Sonicate** in an enzymatic detergent solution (prepared per manufacturer directions) for 10 minutes.
4. **Rinse** with cold tap water (approximately 16°C) for a minimum of 1 minute; actuate moving parts while rinsing and repeatedly flush any lumens or blind holes with a syringe.
5. **Transfer** to washer for processing. See table below for cycle parameters

Washer Parameters

Phase	Recirculation Time (Minutes)	Water Temperature	Detergent Type
Pre-wash 1	01:00	Cold tap water (approximately 16°C)	N/A
Enzyme Wash	05:00	Hot tap water (approximately 43°C)	Enzymatic Detergent (pH: neutral to slightly basic)
Wash 1	06:00	65°C	Detergent (pH: neutral to slightly basic)
Rinse 1	01:00	Hot tap water (approximately 43°C)	N/A
Pure Water Rinse	00:10	Approximately 43°C	N/A
Drying	07:00	115.0°C	N/A

6. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary, re-clean until it is visibly clean.

Note: The process above is validated; however, variations in process parameters or equipment may compromise the sterility assurance level.

Exceptions
The above automated cleaning parameters may be used with all of MicroPort Orthopedics' reusable instruments, except those products listed below.
(Some products may not be available in the U.S. or Canada)

The following devices must be cleaned and sterilized using a specialized package insert:

Device no.	Instrument Name	Package Insert
E6001001	EVOLUTION® Revision Knee Femoral Impactor/ Extractor	155992

The products in the list below may not be automatically cleaned and require manual cleaning with the method prescribed in the previous section.

Device no.	Instrument Name
E4001006	EVOLUTION® Patella Caliper
PRMOD451	PROFEMUR® Pocket Stem Inserter Modular
48032310	CONSERVE® Plus Reamer Shaft (Lumen Only)
E2102005	EVOLUTION® MP Tibia Prox Rod Non Spiked Short
E1100103	EVOLUTION® MP DCF CALIPER FOR FIXED STYLUS

Inspection, Maintenance, and Testing

Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their exacting performance. To minimize damage, the following should be done: • Inspect the instrument case and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair set aside for repair service or return to MicroPort. • After cleaning, the disassembled instruments should be reassembled and placed in their proper locations in the instrument cases where appropriate. • Only use an instrument for its intended purpose. • For devices with hinged/mating surfaces or moving components, a biocompatible, surgical-grade lubricant intended for heat sterilized medical instruments should be used per the manufacturer's guidelines.

MicroPort does not accept responsibility or liability of this instrument nor any of the component parts upon which repairs and/or modifications have been made or attempted except as performed by MicroPort.

Packaging

MicroPort instrument cases are intended to protect instrumentation during shipping. 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. MicroPort does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by MicroPort that should have been cleaned and sterilized by the end user.

Sterilization

MicroPort instruments manufactured of stainless steel may be steam sterilized with no detrimental effects. Non-sterile plastics can be steam sterilized. All items to be sterilized must be thoroughly cleaned and packaged appropriately for the type of sterilization. The package must permit contact of the sterilant with the item, while also serving as a barrier to microorganisms, during any storage period. Users should wear non-linting gloves, i.e. Latex or Nitrile, when handling reusable instruments, to minimize bioburden and particulates. Inspect the product packaging for tears, holes, moisture or other defects. If these concerns are present, segregate these items and reprocess them.

Steam Sterilization

The minimum recommended steam sterilization conditions for MicroPort reusable instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270˚F (132˚C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves.

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and validated using specific equipment. Variations in process parameters or equipment may compromise the sterility assurance level.

Storage

Surgical instruments that will not be utilized within a short time and will not be immediately returned to MicroPort, should be stored clean, decontaminated and completely dry. The packaging that items are sterilized in may offer an effective barrier to prevent contamination of the item. Those items in a sealed paper or polyethylene Tyvek® pouch may be stored in a sealed polyethylene bag, and sterilized at a later date. All instruments returned to MicroPort must be cleaned and decontaminated before shipping. The four main types of packaging for steam sterilization consist of textiles, nonwovens, pouch packaging and rigid container systems. These packaging types offer various levels of protection from contamination, which must be consistent with the final intent of the item.

References

ISO 17664:2004(E) *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*.
ISO 17665:2006 *Sterilization of Health Care Product – Moist heat*.
ANSI/AAMI ST79:2010 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.
AAMI TIR12:2010 *Designing, testing and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for device manufacturers*.
AAMI TIR30:2011 A *compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*.
Adherence to ISO 17664, ISO 17665, AAMI TIR12 and AAMI TIR30 is noted within sterility validation procedure L1140015. Validations are conducted to AAMI ST79, ISO 17665 and AAMI TIR30 as applicable and are noted as such.