



# MicroPort Orthopedics

## HANDLING OF MICROPORT DISPOSABLE PROPHECY® CUSTOM-MADE INSTRUMENTS

150807-1

**The following languages are included in this packet:**

English (en)

For additional languages, visit our website [www.ortho.microport.com](http://www.ortho.microport.com)

**For additional information and translations please contact the  
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**R** ONLY

March 2016

*Attention Operating Surgeon*  
**IMPORTANT MEDICAL INFORMATION**  
**MICROPORT**

**HANDLING OF MICROPORT DISPOSABLE PROPHECY® INSTRUMENTS**  
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**OUTLINE**

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**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	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Sterilized using radiation

STERILE GAS	Sterilized using gas plasma
STERILE A	Sterilized using aseptic processing techniques
⌘ ONLY	For prescription use only
<b>Abbreviation</b>	<b>Material</b>
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

## GENERAL PRODUCT INFORMATION

These surgical instruments are designed for single use only. 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. In addition, these surgical instruments are manufactured with certain patient-specific features, which render them unusable in cases other than that for which they were designed.

These surgical instruments are supplied clean and non-sterile, and must be sterilized before use. After use, these instruments must be properly disposed of. The following information outlines the proper steps for processing MicroPort disposable surgical instruments.

### A. INTENDED USE

The surgical total knee alignment instruments are custom-made in accordance with a duly qualified medical practitioner's written prescription which gives, under his or her responsibility, specific design characteristics and is intended for the sole use of a particular patient.

### B. LIMITATIONS AND RESTRICTIONS OF REPROCESSING

The medical provider must match the case number provided on design paperwork with the case number on the device labeling. End of functional life is intended to be the conclusion of the case for which the device was designed. These instruments are created based on patient-specific data which may be subject to change at varying rates depending on the patient condition. It is up to the medical provider to determine if the patient's condition or anatomy may have changed sufficiently to require redesign of the device. Extreme care should be taken not to drop or contaminate the device during surgery. All unused devices must be destroyed upon the conclusion of the case for which the devices were designed.

### C. PACKAGING

MicroPort packaging is 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 validated 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 is not responsible or liable for the sterility of the instrumentation supplied by MicroPort.

## D. STERILIZATION

MicroPort instruments manufactured from Nylon may be steam sterilized with no detrimental effects. All items to be sterilized must be 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 instruments, to minimize bioburden and particulates.

### WARNINGS

- When handling 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.

### STERILIZATION

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

1. Double wrap the component in an FDA-cleared CSR wrap or a 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)	Preconditioning Pulses	3
	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	16 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with ANSI/AAMI ST79:2006 and A1:2008 & A2:2009, Table 5, Row 1 and have been developed and validated using specific equipment to achieve a sterility assurance level (SAL) of 10<sup>-6</sup>. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

### MANUAL CLEANING

The following manual cleaning instructions have been validated as an alternative cleaning method for MicroPort Orthopedics PROPHECY® Custom Made Instruments. This cleaning procedure has only been validated for use prior to the initial sterilization of the product for its intended patient.

1. **Disassemble** as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination (if appropriate).
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 for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens

6. **Bathe** in a 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 solutions 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.
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 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.

#### **E. STORAGE**

Surgical instruments that will not be utilized within a short time should be stored clean, and completely dry. The packaging that items are in may offer an effective barrier to prevent contamination of the item. The type of packaging required for steam sterilization is an FDA-cleared CSR wrap or non-woven medical grade wrapping material. This packaging type offers a level of protection from contamination, which must be consistent with the final intent of the item. The surgical instruments must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

#### **F. REFERENCES**

ISO 17664:2004(E) Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for device manufacturers

ANSI/AAMI/ISO17665-1:2006, Sterilization of health care products - Moist heat - Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices