

OvertureTi Knee Resurfacing System Reusable Instruments INSTRUCTIONS FOR USE

DESCRIPTION

The **OvertureTi Knee Resurfacing System Reusable Instruments** are designed to be used in the sizing, spacing, and delivery of **OvertureTi Knee Resurfacing System Implants**. The **OvertureTi Knee Resurfacing System Reusable Instruments** are designed for repeated use, with proper care and handling.

INDICATIONS

The **OvertureTi Knee Resurfacing System** is intended to be used in the partial replacement of the articulating surfaces of the knee in instances where, due to compartmental degenerative disease, post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity, or previous arthroplasty, only the one side of the joint is affected. This device is intended to be used with bone cement.

DETAILED DIRECTIONS FOR USE

Step-by-step instructions on how to use the **OvertureTi Knee Resurfacing System Reusable Instruments** are provided in the Overture Orthopaedics' **OvertureTi Knee Resurfacing System Reusable Instruments Surgical Technique Guide**.

PRECAUTIONS

- Use of the **OvertureTi Knee Resurfacing System Reusable Instruments** should only be undertaken after the surgeon has become thoroughly knowledgeable about knee anatomy and biomechanics; and has had experience with partial knee replacement.
- Carefully inspect instruments for damage prior to use.
- If instruments are found to be damaged, contact the manufacturer.

CLEANING AND DECONTAMINATION

All **OvertureTi Knee Resurfacing System Reusable Instruments** that have been taken into a sterile field must be decontaminated and cleaned before re-sterilizing and re-introducing them into a sterile surgical field. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Instruments and cases may be processed using manual cleaning and/or automated cleaning with manual pre-cleaning using the steps listed below.

Point-Of-Use cleaning:

- All **OvertureTi Knee Resurfacing System Reusable Instruments** must be cleaned at the point-of-use including the removal of contaminants with water.
- Special care should be made to ensure that any contaminants are removed from all **OvertureTi Knee Resurfacing System Reusable Instruments** prior to drying.

Preparation prior to cleaning:

- All **OvertureTi Knee Resurfacing System Reusable Instruments** must be disassembled (if applicable).
- To prevent injury, separate pointed and sharp instruments and place them in a separate tray.

Manual cleaning method:

- Rinse soiled instruments under running cold tap water. Actuate all instruments through their full range of motion. While rinsing, remove all gross visible soil with a damp gauze pad, wipe, or soft-bristled brush. Flush hard-to-reach areas with 120mL of fluid using a 60mL syringe.
- Prepare a mild pH enzymatic cleaning solution such as Prolystica per the manufacturer's instructions. Immerse all instruments in the cleaning solution. Thoroughly scrub all instruments with a soft bristled brush while immersed in the solution to prevent aerosolization of contaminants. Scrubbing must also include any lumens with an appropriately sized round brush or flushing with 120mL of fluid using a 60mL syringe and cold water. Actuate joints, handles, and other movable instrument features to expose areas to the cleaning solution several times.
- Thoroughly clean all instruments under water.
- Prepare a fresh mild pH enzymatic cleaning solution such as Prolystica per the manufacturer's instructions in a sonicator. Transfer all instruments to the fresh enzymatic cleaning solution in the sonicator. Actuate all instruments through their full range of motion. Flush hard-to reach areas with 120mL of fluid using a 60mL syringe. Ultrasonically clean all instruments while immersed in the cleaning solution for at least 15 minutes.
- Remove all instruments from the cleaning solution and rinse all instruments thoroughly with critical water. Actuate all movable parts through their full range of motion. Flush all hard-to-reach areas with 120mL of fluid using a 60mL syringe.
- Verify that all instruments are visually clean; if not, repeat the cleaning process from the beginning until all instruments are clean.
- Dry instruments with a clean and soft cloth, with clean compressed air, and/or allow to air dry.

Automated cleaning method (Note: the washer/disinfector should fulfill the requirements specified in ISO 15883):

- Rinse soiled instruments under running cold tap water. Actuate all instruments through their full range of motion. While rinsing, remove all gross visible soil with a damp gauze pad, wipe, or soft-bristled brush. Flush hard-to-reach areas with 120mL of fluid using a 60mL syringe.
- Transfer all instruments into the washer for processing.
- Pre-wash with cold water for 2 minutes.

- Wash with a mild pH enzymatic cleaning solution such as Prolystica per the manufacturer's instructions for 10 minutes.
- Rinse with warm water for 2 minutes.
- Rinse with warm critical water for 2 minutes
- Thermal disinfection at ≥94°C for 7 minutes.
- Dry at ≥90°C for 40 minutes.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some instruments; these solutions should not be used.

STERILIZATION

All **OvertureTi Knee Resurfacing System Reusable Instruments** are provided non-sterile. The user facility must sterilize them before use. The instruments are recommended to be steam sterilized by the hospital using an FDA-cleared wrap using the following parameters:

Method	Exposure Temperature	Exposure Time	Min. Dry Time
Gravity Displacement	121°C (250°F)	60 min	40 min
Pre-Vacuum	132°C (270°F)	4 min	30 min

These sterilization recommendations follow the guidelines for sterilization per ANSI/AAMI ST79. Remove all packaging materials prior to sterilization. Use only sterile products in the operating field.

The distributor and manufacturer accept no responsibility for sterilization procedures performed by the customer that are not performed according to these recommendations.

FURTHER INFORMATION

- The surgical technique contains further information on the **OvertureTi Knee Resurfacing System Reusable Instruments** and may be obtained by contacting Overture Orthopaedics or visiting overtureortho.com
- OvertureTi Knee Resurfacing System Reusable Instruments** should only be used with **OvertureTi Knee Resurfacing System Implants**.
- Refer to **OvertureTi Knee Resurfacing System Implants IFU** for **OvertureTi Knee Resurfacing System** contraindications, potential adverse events, and warnings.

Manufactured by *Overture Orthopaedics Inc.*

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CAUTION: USA law restricts this device to sale by or on the order of physician.