OvertureTi Knee Resurfacing System INSTRUCTIONS FOR USE

DESCRIPTION

The **OvertureTi Knee Resurfacing System** is a partial replacement implant device for the articulating surfaces of the knee. The implants are available in varying configurations of tibial, femoral round, and femoral oblong implants to accommodate patient anatomy. The **OvertureTi Knee Resurfacing System** implant is provided gamma sterilized and instruments are supplied non-sterile.

MATERIALS

Titanium-6Al-4V ELI per ASTM F3001, Medikote C TiN, Ultra-High Molecular Weight Polyethylene

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.

CONTRAINDICATIONS

Contraindications include but are not limited to:

1. Infection
2. Signs of local inflammation
3. Fever
4. Morbid obesity
5. Pregnancy
6. Non-compliant patients

POTENTIAL ADVERSE EVENTS

1. Implant migration
2. Stress shielding or bone fracture
3. Breakage of the device
4. Infection
5. Non-union or delayed union
6. Nerve damage
7. Vascular damage, hematoma, or hemorrhage of blood vessels
8. Paralysis
9. Death

WARNINGS

- The **OvertureTi Knee Resurfacing System** should not be used in patients with severe osteoporosis

PRECAUTIONS

- Use of the **OvertureTi Knee Resurfacing System** should only be undertaken after the surgeon has become thoroughly knowledgeable about knee anatomy and biomechanics; has had experience with partial knee replacement; and has had sufficient training in the use of this device.
- The correct choice of the implant size for each patient is crucial to the success of the procedure.
- The surgeon should consider patient weight and activity level, and other patient conditions, etc. which may impact on the performance of the system.
- Patients with a previous surgery at the affected level may have different outcomes than those without a previous surgery.
- Instruments are provided non-sterile. The user facility must sterilize them before use.
- Implants must never be re-used or re-implanted.
- Physician's postoperative directions and warning to the patient and the corresponding patient compliance are extremely important. Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as a result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the knee joint.

CLEANING AND DECONTAMINATION

All **OvertureTi Knee Resurfacing System** 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** 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** instruments prior to drying.

Preparation prior to cleaning:

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

Manual cleaning method:

1. 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.
2. 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.
3. Thoroughly clean all instruments under water.
4. 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.
5. 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.
6. Verify that all instruments are visually clean; if not, repeat the cleaning process from the beginning until all instruments are clean.
7. 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):

1. 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.
2. Transfer all instruments into the washer for processing.
3. Pre-wash with cold water for 2 minutes.
4. Wash with a mild pH enzymatic cleaning solution such as Prolystica per the manufacturer's instructions for 10 minutes.
5. Rinse with warm water for 2 minutes.
6. Rinse with warm critical water for 2 minutes
7. Thermal disinfection at ≥94°C for 7 minutes.
8. 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** implants are provided sterile. Instruments are provided non-sterile. 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.

MRI COMPATIBILITY

The **OvertureTi Knee Resurfacing System** implant has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the **OvertureTi Knee Resurfacing System** implant in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

FURTHER INFORMATION

Never re-use an **OvertureTi Knee Resurfacing System** implant. Although the device may appear undamaged, internal stresses or other small defects may not be visible and may lead to early breakage.
The surgical technique contains further information on the **OvertureTi Knee Resurfacing System** device and may be obtained by contacting *Overture Orthopaedics*.

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