OvertureTi Knee Resurfacing System Implants INSTRUCTIONS FOR USE

DESCRIPTION

The **OvertureTi Knee Resurfacing System Implants** are composed of femoral and tibial implants that are intended to be used in the partial replacement of the articular surfaces of the knee. These implants are designed with sizing options that allow the surgeon to replace only the diseased or damaged region of the joint while preserving healthy surrounding cartilage and meniscus. The tibial and femoral implant components are compatible across all sizes. Any size tibial component can be used with any sized femoral component and vice versa. The **OvertureTi Knee Resurfacing System Implants** are provided gamma sterilized.

MATERIALS

Implant	Material
Femoral Oblong/Round	Titanium-6Al-4V ELI per ASTM F3001, Titanium Nitride (TiN)
Tibial	Titanium-6Al-4V ELI per ASTM F3001, Vitamin-E infused Ultra-High Molecular Weight Polyethylene (GUR1020-E)

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:

- Cartilage lesions outside the treatable size range of Overture implants. See Overture Orthopaedics' Surgical Technique Guide for implant sizing.
- Meniscal extrusion greater than 3mm or radial displacement
- Patient with less than 50% intact meniscus.
- Infection, sepsis, osteomyelitis
- Signs of local inflammation
- Fever
- Morbid obesity
- Pregnancy
- Non-compliant patients
- Patients that may have sensitivity to the materials commonly used in orthopedic prosthetic devices or bone cements
- Comorbidities that may impair vasculature, skin, and bone healing
- Osteoporosis

POTENTIAL ADVERSE EVENTS

- Implant migration
- Stress shielding or bone fracture
- Breakage of the device
- Infection or allergic reaction
- Local wear and debris
- Compromised range of motion
- Postoperative pain
- Intraoperative and postoperative bone fracture
- Calcification and/or ossification

WARNINGS

- Never re-use **OvertureTi Knee Resurfacing System Implants**.
- Remove implants from packaging, using sterile technique, only after the correct size has been determined.
- Improper implant selection, implant size-selection, placement, and fixation of the device may reduce the functional life of the implant as well as cause additional harm to the patient.
- Do not modify implants; implants shall be used as provided.
- Implants that become scratched or deformed may impact their functional usage.

PRECAUTIONS

- Use of the **OvertureTi Knee Resurfacing System Implants** should only be undertaken after the surgeon has become thoroughly knowledgeable about knee anatomy and biomechanics; and has had experience with partial knee replacement.
- The surgeon should consider patient weight and activity level, ligament laxity, mechanical alignment, metabolic disorders affecting bone quality, and concomitant cartilage deficits outside the coverage area, and other patient conditions, etc. which may impact on the performance of the system.
- Patients with previous surgery at the affected level may have different outcomes than those without a previous surgery.
- 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.
- **OvertureTi Knee Resurfacing System Implants** should be used in conjunction with **OvertureTi Knee Resurfacing System Instruments**.

STERILIZATION

All **OvertureTi Knee Resurfacing System Implants** are provided sterilized. Do not re-sterilize or re-process the implant. Do not use implant if implant packaging appears damaged or open. Do not use implant if expired.

STORAGE

Sterilized implants should be stored at temperatures between -18°C-60°C and 15%-90% relative humidity.

MRI COMPATIBILITY

The **OvertureTi Knee Resurfacing System Implants** have 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 Implants** 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

- Refer to the Overture Orthopaedics' Surgical Technique Guide for preparation of surgical site.
- The surgical technique guide contains further information on the **OvertureTi Knee Resurfacing System Implants** and **OvertureTi Knee Resurfacing System Instruments** and may be obtained by contacting Overture Orthopaedics or visiting overtureortho.com.
- An electronic copy of the surgical technique guide may be obtained at www.overtureortho.com or by contacting Overture Orthopaedics.

Manufactured by *Overture Orthopaedics Inc.*
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CAUTION: USA law restricts this device to sale by or on the order of physician.

Symbols Glossary

Symbol No.	Symbol	Description
1		Indicates the manufacturer's catalogue number so that the medical device can be identified.
2		Indicates manufacturer's serial number so that a specific medical device can be identified.
3		Indicates date after which the medical device is not to be used.
4		Indicates medical device manufacturer.
5		Indicates quantity provided
6		Indicates used via prescription only
7		Indicates the medical device that has been sterilized using irradiation.
8		Indicates the medical device that is not to be resterilized.
9		Indicates the medical device is intended for one single use only.
10		Indicates user to consult the instructions for use and the instructions for use are available in an electronic format.
11		Indicates the medical device that should not be used if the package has been damaged or opened.