Freedom Partial Knee System

Caution:
Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions of use.
Federal Law restricts this device to sale by or on the order of a physician.
Maxx Orthopedics' Freedom Partial Knee is intended to be used with Maxx Orthopedics designed instruments and prosthetics only. The surgeon should be fully familiar with the surgical technique. Supplementary information about the surgical technique is available on request.

SYSTEM DESCRIPTION

The Freedom Partial Knee System consists of a femoral component, a tibial insert, and a tibial baseplate. It is designed to achieve a reconstructive replacement in a single compartment of the deficient and damaged tibiofemoral joint surfaces using metal femoral and tibial components, and provide a low-friction articulation with a polyethylene bearing. This system is designed to restore optimum function and provide longevity of the partial knee replacement.

Femoral Component

The femoral component is an anatomic, asymmetrically designed prosthesis manufactured from cast cobalt chromium/molybdenum, Co-Cr-Mo, (ASTM F75). The femoral component is intended for use with bone cement. The femoral components are offered in 12 unique part numbers, in medial/lateral versions ranging from sizes 1 to 6. The partial knee prosthesis is designed for optimal weight transmission and flexion as well as giving maximum contact area to reduce material stress on the tibial insert. The asymmetric implant mirrors the anatomic shape of the femoral condyles through angled anterior-posterior curvature. Hence, the femoral component for the right medial condyle can also be used for the left lateral condyle, and similarly the femoral component for the right lateral condyle can be used for the left medial condyle. The external articulating surface of the femoral component is polished to Ra 0.05µm. The internal fixation surfaces are textured through dry abrasive blasting to Ra 4-8µm for enhanced cement fixation. The femoral design features two parallel pegs that significantly protrude from planar resection, which are designed to further aid fixation.

Tibial Baseplate

The tibial baseplate is manufactured from wrought Titanium alloy, Ti-6Al-4V, (ISO5832-3 and ASTM F136). The tibial baseplate is intended for use with bone cement. The inferior fixation surfaces of the tibial baseplate are dry abrasive blasted to Ra 4-6µm to enhance cement fixation. Two pegs and a single keel on the inferior surface further assist the fixation of the tibial baseplate. The superior surface engages with a modular tibial insert. The tibial baseplates are asymmetrical and available in medial and lateral versions, ranging from sizes 1-6 for a total of 12 unique part numbers.

Tibial Insert

The tibial insert is manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) to ASTM F648. The UHMWPE is Type 1 resin per ASTM F648, otherwise known as GUR 1020. The tibial insert is designed with an underside to secure a firm connection to the capture features on the tibial baseplate. The articulating surface was designed for unconstrained femoral motion. The tibial inserts are asymmetrical and available in six sizes: 1, 2, 3, 4, 5 and 6 with poly thickness options ranging from 9mm-11mm. The minimum polyethylene thickness is 6mm. The articulating surface of the tibial insert has a finish with maximum surface roughness Ra 1.0µm or better.

SYSTEM INSTRUMENTATION

The associated instruments for the Freedom Partial Knee System consist of manual orthopedic surgical instruments. Refer to the surgical technique for the specific instructions for the appropriate use of each instrument. Unless specifically marked, Freedom Partial Knee instruments, including straight pins, are re-usable. Re-usable instruments are delivered non-sterile. A complete guide for reprocessing reusable instruments may be provided upon request.

INDICATIONS FOR USE

The Maxx Orthopedics Freedom Partial Knee comprising the femoral component, tibial component and tibial insert is designed for a single compartment replacement of the native knee joint. The Freedom Partial Knee is indicated for cemented use in partial/unicompartmental knee arthroplasty procedures. Partial replacement of the articulating surfaces of the knee is indicated only when only one compartment of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

CONTRAINDICATIONS

The Maxx Orthopedics Freedom Partial Knee system is contraindicated for use under the following conditions:

- Progressive local or systemic infection
- Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable.
- Osteoporosis
- Metabolic disorders which may impair bone formation
- Osteomalacia
- Rapid joint destruction, marked bone loss or bone resorption apparent on the roentgenogram.
- Incomplete or deficient soft tissue surrounding the knee.
- Severe instability secondary to advanced destruction of condylar structures.
- Permanent valgus or varus deformity that requires correction post-op
- Mental or Neuromuscular disorders
- Allergy to materials used in the components

MATERIAL COMPOSITION

The material for each component is provided on the part package label. The femoral component is made of Co-Cr-Mo and the tibial baseplate is made of Ti-6Al-4V. The tibial insert is made of ultra-high molecular weight polyethylene (UHMWPE).

POTENTIAL ADVERSE EFFECTS

Following are specific adverse effects which should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that may occur in surgery, but are important considerations particular to the devices included in this document.

- Prosthesis dislocation
- Early or late loosening, tibial subsidence, bending, fissure fracture, fracture, deformation or wear of one or more of the prosthetic components.
- Early or late infection which may require removal of the implant followed by arthrodesis or 2-stage re-implantation.
- Pain, dislocation, subluxation, flexion contracture, mobility reduction, leg shortening or lengthening, resulting from improper positioning, loosening or wear of components.
- Excessive wear of the polyethylene component due to damage to the femoral component, loose cement or bone fragments and/or high levels of activity and weight.
- Fracture of the tibia or femur.
- Cardiovascular disorders and thromboembolic diseases including thrombosis, embolism, and myocardial infarction.
- Tissue reactions, osteolysis and/or implant loosening caused by metal corrosion, allergy, wear debris, or loose cement particles.
- Myositis ossificans

PATIENT SELECTION PRECAUTIONS

The following factors may be relevant to the success of the procedure:

- The patient's body mass. An obese patient may place increased loads on the prosthesis which can lead to failure of the device or loosening in the bone. The risk increases with smaller size implants and increasing patient weight.
- The patient's regular type and level of activity or employment may affect the durability of the components. If the patient's occupation or activity includes significant impact loads, the increased forces can cause failure of the implant or failure of the fixation of the device to bone. High levels of physical activity over time can accelerate the normal wear process that occurs with the bearing surface of prosthetic joints.
- Mental illness, or substance dependence which may tend to reduce the patient's compliance with prescribed precautions and limitations on physical activities, which may cause implant failure or other complications.
- Material sensitivity. Patients should be screened for potential sensitivity to the constituent materials composing the device. If sensitivity is suspected, preoperative tests should be conducted.

PREOPERATIVE

Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient. Care should be taken when handling the components of the Freedom Partial Knee to avoid damaging the devices. Denting, notching or scratching can greatly reduce the compression strength, fatigue resistance or wear properties of the components potentially leading to fracture or failure of the devices. Surgical technique information is available for the subject devices. The surgeon should familiarize themselves thoroughly with the technique prior to consideration of the use of the devices for any specific patient. Implants are only to be used with approved Maxx Orthopedics instrumentation. The surgical instrumentation prescribed within the technique for the implantation of these devices should not be used for any other device or in a manner contrary to its intended use. Failure or breaking of instruments can occur. Instruments have a limited service life and should be examined for wear or damage and replaced prior to surgery if required. Instrumentation should be sterilized according to the manufacturer's protocols. Do not resterilize component parts which have been assembled, or implants connected to surgical instruments. Do not cool hot components in cold water.

MRI SAFETY INFORMATION

The Maxx Orthopedics Freedom Partial Knee components 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 Freedom Partial Knee 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. Maxx Orthopedics does not recommend MR imaging for any patients implanted with product from the Freedom Partial Knee System without prior consultation with an expert radiologist for assessment of potential adverse events.

INTRAOPERATIVE

Correct implant selection is extremely important. The use of preoperative imaging and templating is recommended to facilitate the choice of an optimum size. The patients overall anatomical and medical condition should also be considered in conjunction with age, expected activity level, life expectancy and potential for future revision surgeries. The incorrect selection of implant size may result in failure of the device and/or bone. Implants should be inspected before use. Do not use any implants that have visible damage such as chipping or bending. Do not use any implants that have been dropped on the floor. Implants removed from the patient at revision surgery should never be re-implanted as the fatigue state of the implant cannot be determined by visual examination. Removed implants must be treated as biological hazards and are required to be treated or disposed of according to the country's waste regulations where the implant is removed. The wound site should be thoroughly cleaned of debris before closure.

POSTOPERATIVE CARE

To secure the long-term treatment outcomes, it is advised to provide comprehensive regular patient follow up after implant treatment and provide information and precautions about their activities post-op.

PACKAGING AND LABELING

Components should only be used if the factory packaging and labeling are intact. If the sterile barrier has been broken, return the component to Maxx Orthopedics.

STERILIZATION AND RESTERILIZATION

Implants are supplied sterile and have been double sterile packaged. The method of sterilization is noted on the package label. Dispose of the implant if the packaging is damaged. Resterilization of the implants is not recommended, as it may alter the mechanical integrity of the device. Unless specifically labelled sterile, instruments are supplied non-sterile and must be sterilized prior to use. A complete guide for reprocessing reusable instruments may be provided upon request.

STORAGE AND HANDLING

Always handle implants with sterile powder-free gloves. Prior to use, implants should be stored in clean, dry conditions and should not be exposed to direct sunlight, ionizing radiation, and extremes of temperature or contamination. Instruments are to be stored in dry, clean surroundings at room temperature, in their sterilization tray.

CONTACT INFORMATION

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Maxx Orthopedics location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Maxx Orthopedics location as listed below.

CAUTION: FEDERAL LAW (U.S.A) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.

Freedom® Total Knee System

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SYMBOL KEY LEGEND	
	MANUFACTURER
REF	CATALOG NUMBER
LOT	BATCH CODE
	DATE OF MANUFACTURE
	USE BY DATE
	CAUTION
	DO NOT RE-USE
STERILE EO	STERILIZED WITH ETYLENE OXIDE