Freedom Partial Knee System

DESCRIPTION

The Freedom Partial Knee consists of a femoral and a tibial component. The low profiled prosthesis is minimally constrained. This allows optimization of weight distribution and lower shear forces. The anatomically designed femoral component is asymmetrically shaped conforming to the natural knee in the coronal and sagittal planes. The post, keel, and anterior bossed hole are designed to provide anteroposterior and mediolateral stability. Cobalt Chrome Alloy is used to fabricate the femoral component which is available in three sizes. The tibial component is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE). It incorporates a hemispherical shaped articular surface to optimize contact area. The component is minimally constraining and designed to optimize weight distribution. Dovetailed channels on the undersurface allow for mechanical lock between the implant and the cement mantle. The thickness of the component under the area of the femoral-tibial articulation has the potential to help improve longevity and to minimize the possibility of material fatigue failure. Nine sizes are available to enhance surgical latitude in preoperative planning. Tibial and femoral instruments and trials are also available to facilitate implantation.

Materials:

Femoral Components: CoCrMo Alloy ASTM F- 75

Tibial Components: UHMWPE ASTM F-648 / CoCrMo Alloy ASTM F- 75

INDICATIONS

The Freedom Partial Knee System is solely indicated for medial compartment replacement of the articulating surface of the knee when only the medial compartment of the joint is affected with primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures or revision of previous arthroplasty procedures. ***This device is a single-use implant intended for implantation with bone cement.***

CONTRAINDICATIONS

Contraindications include: (1) infection, (2) avascular necrosis, (3) sepsis, (4) sclerosis of the lateral patellar facet, (5) osteomyelitis, (6) patients involved in heavy labor, (7) muscular atrophy, (8) neurological or inflammatory disease, (9) osteoporosis, osteomalacia or other metabolic disease which may impair bone formation, (10) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenograms, (11) distant foci of infection which may spread to the implant site, (12) tricompartmental disease and (13) fixed deformities requiring corrective soft tissue releases or deficient soft tissue surrounding the knee.

WARNINGS

Improper selection, placement, positioning, alignment and/or fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components and/ or lead to loosening. Malalignment of the components or inaccurate implantation can lead to excessive wear, loosening and/or failure of the implant or procedure. The tibial component must be aligned properly to maximize support of the cortical rim. Incomplete removal of surgical debris can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage to the implant can lead to crevice corrosion, fretting, fatigue fracture, and/or excessive wear. The surgeon should be familiar with the implants, trials, instruments, and surgical technique prior to performing surgery.

1. Malalignment or soft tissue imbalance can result in inordinate stresses on the components, which may result in excessive wear to the articulating surfaces, loosening or subsidence. Revision surgery may be required.
2. Care should be taken to ensure complete support of all parts of the device embedded in/on bone cement to prevent stress concentrations, which may lead to failure of the procedure. Fastidious cleaning and removal of bone cement, metallic and other surgical debris at the implant site is important to minimize wear of the implant's articulating surfaces.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving weight bearing and rehabilitation can compromise the success of the procedure. The patient should be advised with respect to the limitations of the reconstruction and activity level until adequate fixation and healing have occurred. Excessive activity, trauma, falls, and/or excessive weight gain have been implicated with premature failure of the implant by loosening, fracture, and/or wear. The tibial component may fracture due to loosening, migration or subsidence. Loosening of the implants can result in increased production of wear particles that can accelerate bone loss and affect the success of subsequent surgery. The patient should be made aware of, and warned about general surgical risks, possible adverse effects as listed, and advised to follow the instructions of the treating physician.

The Freedom Partial Knee device is not intended to be used in the lateral knee compartment.

PRECAUTIONS

Patient selection factors to be considered include: 1) the necessity for obtaining pain relief and improving function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity level, 3) nutritional state and general health, and 4) the patient must have reached full skeletal maturity, 5) partial disease with correctable deformity with no ligament releases, and 6) intact anterior cruciate ligament.

Specialized instruments are available to facilitate surgery and help ensure accurate implantation of the implant. The use of instruments or implant components from other systems can result in an inaccurate fit, sizing, excessive wear, and/or device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear under normal usage. Instruments that have been extensively used or used with excessive force are susceptible to fracture. Bone screws should not be used to enhance fixation.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been placed, even if momentarily, in a different patient. All instruments should be carefully and regularly inspected to detect wear or other damage.

ADVERSE EFFECTS

1. Metal sensitivity reactions can occur. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to, or during the healing process. Particulate wear debris from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. Wear debris may initiate a cellular response which results in osteolysis. Osteolysis can also occur subsequent to loosening of the implant.
2. Early or late postoperative infection and/or allergic reaction.
3. Intraoperative bone perforation or fracture may occur particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, or bone resorption.
4. Loosening and/or migration and subsidence of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and excessive activity.
5. Periarticular calcification or ossification, with or without effect on joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation can occur the result of inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of components can occur as a result of loss of fixation/loosening, migration/subsidence, strenuous activity, malalignment, trauma, nonunion, and/or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Valgus-varus deformity.
13. Transient peroneal palsy secondary to surgical manipulation and increased joint movement has been reported following knee arthroplasty in patients with severe flexion and valgus deformities.
14. Patellar tendon rupture and ligamentous laxity.
15. Intraoperative or postoperative bone fracture and/or postoperative pain. Intraoperative and early postoperative complications can include: 1) damage to blood vessels, 2) temporary or permanent nerve damage resulting in pain or numbness to the affected limb, 3) cardiovascular disorders including venous thrombosis, pulmonary embolism or myocardial infarction, 4) hematoma, 5) infection 6) arthrofibrosis and 7) delayed wound healing.

STERILITY

Prosthetic components are supplied sterile in protective packaging to a Sterility Assurance Level (SAL) of 10-6 using Ethylene Oxide. Do not resterilize. Do not use any component if the package is opened or damaged. Do not use implants after expiration date.

The Freedom Partial Knee Instrumentation is available non-sterile only. Non-sterile instruments must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Steam sterilization is recommended, using the process parameters below:

Method*	Cycle*	Temperature*	Exposure Time*	Drying Time
Steam	Gravity	270F (132C)	40 Minutes	60 Minutes
Steam	Pre-Vacuum	270F (132C)	8 Minutes	45 Minutes

*Note: These parameters have been validated for a Sterility Assurance Level (SAL) of 10^{-6} according to AAMI 11134 - 1993. ANSI/AAMI/ISO 17665-1:2006, Sterilization of Health Care Products - Requirements for Validation and Routine Control - Industrial Moist Heat Sterilization. Because of the many variables involved in sterilization, each medical facility should validate appropriate sterilization cycles (e.g. temperatures and times) for its own equipment.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Warning: This device is intended for cemented use only.

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