Biomet Orthopedics
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Revision F
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Biomet Unicondylar Knee Joint Replacement Prostheses

ATTENTION OPERATING SURGEON

DESCRIPTION
The Unicondylar Knee Joint Replacement Prosthesis incorporates a low profile cobalt chromium or titanium femoral component and three styles of tibial components. The three styles of tibial components available include an all-polyethylene, a modular metal-backed component, and a single-piece, polyethylene/metal-backed component. Reconstruction with this implant rebalances the knee utilizing the remaining undisturbed compartmental structures and appropriate soft tissue tensions as reference points.

MATERIALS

Femoral Components	CoCrMo Alloy/Titanium Alloy
Tibial Components	ArCom UHMWPE/Tantalum/ Titanium/CoCrMo Alloy
Tibial Plates	Titanium Alloy

INDICATIONS
Partial replacement of the articulating surfaces of the knee when only one side 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.

These devices are single-use implants intended for implantation with bone cement.

CONTRAINDICATIONS
Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, neuromuscular disease, 8) incomplete 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. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture, and/or excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris, or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Do not modify implants. The surgeon is to be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.

1. The all-polyethylene and the single-piece polyethylene/metal-backed tibial components are designed to be used in treatment of low demand, less active sedentary patients. Patients that will remain active and/or overweight patients are not candidates for all- polyethylene and/or single-piece polyethylene/metal-backed tibial components.
2. Malalignment or soft tissue imbalance can place inordinate forces on the components, which may cause excessive wear to the patellar or tibial bearing articulating surfaces. Revision surgery may be required.
3. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.
4. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

Biomet joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of certain implants by loosening, fracture, dislocation, subluxation and/or wear. All-polyethylene and single-piece, polyethylene/metal-backed implants may fracture due to loosening and/or migration/subsidence. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity levels, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

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, even momentarily, placed in a different patient.

Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

PRECAUTIONS
Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.

POSSIBLE ADVERSE EFFECTS
1. Material sensitivity reactions. 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 and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of 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/subsidence of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and/or excessive activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation/loosening, migration/subsidence, strenuous activity, malalignment, trauma, non-union, 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 deformity.
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, and 5) delayed wound healing.

MRI INFORMATION
This device has not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.

STERILITY
Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Single Use Only. Do Not Reuse. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

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

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

EC REP Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend
CF31 3XA, U.K.

CE 0086

Symbol Legend
Manufacturer
Date of manufacture
Do not reuse

Caution, see instructions for use
Do not resterilize
STERILE EO — Sterilized using ethylene oxide
STERILE R — Sterilized using irradiation
STERILE — Sterile
STERILE A — Sterilized using aseptic processing techniques
STERILE — Sterilized using steam or dry heat
Rx Only — Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Do not use if package is damaged (Pack Damaged)
Use by date
WEEE device
REF — Catalogue number
LOT — Batch code
FLAMMABLE — Flammable
EC REP — Authorized representative in the European Community