Biomet Orthopedics
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Biomet Vanguard 360 Knee Joint Replacement Prostheses

ATTENTION OPERATING SURGEON

DESCRIPTION

Biomet manufactures a variety of knee joint replacement prostheses intended for application with or without bone cement. Knee joint replacement components include femoral, tibial, and patellar components. Components are available in a variety of designs and size ranges intended for both primary and revision applications. Specialty components are available including; femoral stems, femoral screws, femoral augments, tibial stems, tibial screws, tibial augments, tibial cement plugs and modular pegs.

MATERIALS

Femoral Components	CoCrMo Alloy/Titanium Alloy
Tibial Trays	CoCrMo Alloy/Titanium Alloy
Tibial Bearings	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Patellar Components	UHMWPE/Titanium Alloy/316LVM Stainless Steel
Femoral Stems	Titanium Alloy
Tibial Stems	Titanium Alloy
Femoral Screws	Titanium Alloy
Tibial Screws	Titanium Alloy
Augment Components	Titanium Alloy
Stem Components	Titanium Alloy
Tibial Cement Plugs	UHMWPE
Modular Pegs	CoCrMo Alloy

INDICATIONS

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

The Regenerex femoral augments are indicated for use with the Vanguard Total Knee System.

The Regenerex tibial augments are indicated for use with standard and offset Biomet Tibial Trays.

Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok) femoral components, tibial tray components and all-polyethylene patellar components are indicated for cemented application only. Regenerex and OsseoTi* components are intended only for uncemented biologic fixation application.

The Vanguard DA 360 components are not intended for use with the Vanguard PS Open Box Porous Femoral Components. **The Vanguard DA 360 components are not approved for sale in the United States or Canada.**

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) an uncooperative patient or a patient with neurologic disorders who is 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, and/or 8) incomplete or deficient soft tissue surrounding the knee.

Biomet Microplasty Tibial Trays are contraindicated for use with constrained bearings.

WARNINGS

Improper selection, placement, positioning, alignment and 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. 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. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the surgical technique, implants and instruments prior to performing surgery.

1. The 23mm Single-Peg Patella components should be used only with an inset mill surgical technique. Product numbers for the 23mm Single-Peg Patella components ◊* include the following: 185185, 185186, 185187 and 185188.
2. The locking bar used to secure the tibial plate and tibial-bearing components together must lock securely into place with an audible click at the time of implantation. Disassociation of the locking bar from the modular tibial plate component has been reported. Inadequate seating of the locking bar can cause disassociation of the locking bar from the tibial plate component, requiring revision surgery.
3. 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 to prevent component failure.
4. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to reduce the risk of 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.
5. It is the responsibility of the operating surgeon to determine whether there is adequate initial fixation and stability. Stem extension and bone cement are available if additional fixation or stability are needed.
6. 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, in advance 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 the implant by loosening, fracture, dislocation, subluxation and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone, making successful revision

◊ 23mm Single-Peg Patella components are not Licensed for Sale in Canada
* Where Available

surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed in advance, 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 level, 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 infections 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. Prior to surgery, Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

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. Where suspected, material sensitivity tests are to be made prior to implantation.
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, bone resorption, or while inserting the device.
4. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, non-union, bone resorption and/or excessive unusual and/or awkward movement and/or 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, malalignment, malposition, excessive unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. 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, strenuous activity, malalignment, trauma, non-union, 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. Interoperative or postoperative bone fracture and/or postoperative pain.

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Biomet Vanguard Knee Implants in the Magnetic Resonance (MR) Environment

Biomet Vanguard Knee implants are manufactured of non-ferromagnetic materials such as, titanium alloy (Ti-6Al-4V), commercially pure titanium (CP-Titanium), cobalt-chromium-molybdenum alloy (Co-Cr-Mo), and ultra high molecular weight polyethylene (UHMWPE).

Biomet has performed non-clinical Magnetic Resonance Imaging (MRI) studies on Vanguard Knee implants which are determined to be MR Conditional in accordance to ASTM F2503-08 Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

NOTE: The knees and legs of the patient should not touch one another during MRI.

MR Information

Safety information for the use of MRI procedures (i.e. imaging, angiography, functional imaging, spectroscopy, etc.) pertains to shielded MRI systems under the following specifications:

- Static magnetic field of 1.5-Tesla (1.5T) and 3.0-Tesla (3.0T)
- Spatial gradient field of 2500-Gauss/cm or less
- Maximum MR System reported, whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning for patient landmark above the acetabulum and 0.5 W/kg for patient landmark below the acetabulum.
- Normal operation mode of the MR system.
- The effects of MRI procedures using MR systems and conditions above these levels have not been determined.
- The effects of local RF transmit coils have not been tested and are not recommended in the area of the implant.
- Cylindrical Quadrature transmit coils only.

MR Heating

Non-clinical testing was performed according to ASTM F2182-09 and yielded the following:

<u>1.5T MR system</u>

64 MHz, GE Signa MR System whole body coil model 46-258170G1; S/N10146MR9. The magnet producing the static field was not present. RF power was applied continuous wave (CW) with an HP8640B, S/N1716A06448 preamplifier and an ENI power amplifier model 3200L, S/N 469.

- A temperature rise of 9.6°C or less was measured at a whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of RF power application.

<u>3.0T MR system</u>

128MHz, GE Signa HDx 3T, Software Version=14\LX\MR Software release.14.0.M5A.0828.b, General Electric Healthcare, Milwaukee, WI. Active-shielded, horizontal field scanner.

- A temperature rise of 7°C or less was measured at a whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of RF power application.

Image Artifacts

MR image quality may be compromised if the area of interest is relatively close to the position of the device. Distortion extended as much as 8 cm from the implant in image distortion tests performed according to ASTM F2119-07 in a 3.0 T MR system using a gradient echo pulse sequence. Therefore, it may be necessary to optimize MR imaging parameters for the presence of these implants.

Other: Testing indicated no known risks of magnetically induced displacement force or torque. The maximum deflection angle was measured to be 5° or less in the 3.0T MRI System in tests performed in accordance with ASTM F2052-06e1.

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 the use of this device can be directed to Attn: Regulatory Affairs, 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, South Wales
CF31 3XA UK

CE 0086

Symbol Legend

Manufacturer

Date of manufacture

Do not reuse

Do not resterilize

Caution, see instructions for use

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

℞ 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)

MR Conditional

Use by date

WEEE device

REF Catalogue number

LOT Batch code

FLAMMABLE Flammable

EC REP Authorized representative in the European Community

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