

**01-50-0912**

**Revision F**

**Date: 2014-10**



**Vanguard XP Knee Joint Replacement Prostheses**

**ATTENTION OPERATING SURGEON**

**DESCRIPTION**

The Vanguard XP Knee System is a total knee replacement system that consists of a femoral component composed of Co-Cr-Mo, two styles of tibial trays/plates manufactured of Co-Cr-Mo (with locking bar), and dual bearings machined of E1 poly. Biomet patellae <sup>◇\*</sup> can be used with the Vanguard XP Knee System. Both the femoral and CR tibial components are available with a PPS porous plasma spray of titanium alloy and Biomet's Interlok coarse blasted finish. The Vanguard XP tibial components are available in Biomet's Interlok coarse blasted finish. Porous coated femoral and tibial components are indicated for cemented and uncemented biological fixation application. Non-coated coarse blasted (Interlok) femoral and tibial components are indicated for cemented application only. Accessory components are available including removable femoral pegs and femoral augments.

When selecting individual Vanguard XP tibial components for surgery consult the following sizing chart prior to implantation.

Tibial Tray	63	65	67	69	71	73	75	79	83	87	91
XP Bearings	63			71				79		87	
AS Bearings	63	67		71		75		79	83	87	91
Locking Bar	63,65,67			69,71,73,75				79,83,87,91			

The Vanguard XP femoral components (PN 195905-195952) may also be used with the Vanguard standard line (i.e., CR, CR-L and AS bearings) E1 Polyethylene and UHMWPE (Arcom) bearing components (when used with Vanguard tibial trays). See additional information for the Vanguard Complete Knee System in IFU 01-50-0975 and the Biomet E-Poly Tibial Bearings in IFU 01-50-0988.

**MATERIALS**

Femoral Components	CoCrMo Alloy
Tibial Plates	CoCrMo Alloy
Tibial Bearings	Ultra-High Molecular Weight Polyethylene (UHMWPE) $\alpha$ -tocopherol
Removable Femoral Pegs	CoCrMo Alloy
Locking Bar	Titanium Alloy
Porous Coating	Titanium 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.

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.

<sup>◇</sup> 23mm Single-Peg Patella components are not Licensed for Sale in Canada

\* Where Available

Regenerex components\* are intended only for uncemented biologic fixation application.

**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.

**WARNINGS**

Refer to the Vanguard XP Surgical Technique. 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 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 <sup>◇\*</sup> include the following: 185185, 185186, 185187, and 185188.
2. The Vanguard XP tibial tray locking bar slot contains a removable, protective cover to minimize the risk of cement penetration during cementing of the tibial tray. This cover should be removed and discarded prior to inserting the locking bar; do not implant this protective cover.
3. The Vanguard XP Locking Bars are to be used only with the Vanguard XP Tibial Trays. The Biomet Tibial Locking Bar (i.e., catalogue number 141205) is not to be used with the Vanguard XP Tibial trays.
4. 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.
5. 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.
6. Care is to be taken to ensure complete support of all parts of the device embedded in bone cement to minimize 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.
7. It is the responsibility of the operating surgeon to determine whether there is adequate initial fixation and stability.
8. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.
9. Vanguard XP Tibial Trays are only compatible with Vanguard XP Bearings.
10. Use only matching bearing components for medial and lateral condyles. The use of mismatched component has not been evaluated and could lead to premature failure of the device.

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 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 surgery more difficult. In advance, 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 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 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. Prior to surgery, Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

1. All trial components must be removed prior to closing the surgical site.
2. The device may contain a component used for packaging purposes. The packaging component is not to be implanted.
3. During the implanting of this device, instruments used are not to be implanted.

## 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, 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 and/or excessive weight.
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. Intraoperative or postoperative bone fracture and/or postoperative pain.
16. Locking bar disassociation /failure requiring surgical intervention.



## Biomet Vanguard XP Knee System in the Magnetic Resonance (MR) Environment

The Vanguard XP femoral components (PN 195905-195952) when used with Vanguard standard line (i.e., CR, CR-L and AS bearings) E1 Polyethylene and UHMWPE (Arcom) bearings and tibial components have not been evaluated by the U.S. FDA for safety and compatibility 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. In the US, the below MR information applies only to the Vanguard XP Knee System including the XP femoral components when used with Vanguard XP tibial trays and bearings, Biomet patellae<sup>o\*</sup> and accessory components (i.e., removable femoral pegs and femoral augments).

Biomet Vanguard Knee implants are manufactured of non-ferromagnetic materials such as, titanium alloy (Ti-6Al-4V), 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 Medical 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.

### 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 mode of the MR system. The effects of MRI procedures using MR systems and conditions above these levels have not been determined.

### MR Heating

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

#### 1.5T MR system

64MHz, 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.

#### 3.0T MR system

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. 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.

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

### STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Single Use Only. 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.

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	Catalogue number
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