Biomet Orthopedics
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01-50-0929
Revision C
Date: 2014-07

Biomet Regenerex Cone Augments

ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet Regenerex Cone Augments were previously designated as Regenerex Porous Titanium Sleeve Augments and are designed for attachment to selected, commercially available Biomet tibial base plates and stemmed femoral components using bone cement. After attachment, the cone augments are intended for fixation as an assembled construct into either the proximal tibia or distal femur, with or without bone cement, in cases of severe bone loss.

MATERIALS

Tibial Cone Augment	Titanium Alloy
Femoral Cone Augment	Titanium Alloy

INDICATIONS

The Biomet Regenerex Cone Augments (femoral and tibial cone augments) are indicated for use with the following cemented systems: the Vanguard, Ascent, and Maxim knee systems, as well as the Biomet tibial augmentation components, stemmed tibial components, offset tibial trays and offset tibial tray adapters.

The Biomet Regenerex Cone Augments (femoral and tibial cone augments) are indicated for use with the following uncemented system: the Vanguard non-cemented porous coated knee components.

Specific indications are as follows:

1. Painful and disabled joint resulting from osteoarthritis, rheumatoid arthritis, or 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.

These are single-use implants.
Cemented and uncemented applications.

The Biomet Regenerex Cone Augments (femoral and tibial cone augments) are indicated for use with the OSS system. Specific indications are as follows:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement procedure.
4. Ligament deficiencies.
5. Tumor resection.
6. Trauma.

These are single-use implants.
Cemented applications only.

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, and/or (7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

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. 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 and instruments prior to performing surgery.

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, and 3) a good nutritional state of the patient.

1. 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.
2. 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.
3. It is the responsibility of the operating surgeon to determine whether there is adequate initial fixation and stability. Stem extensions are available if additional fixation and stability are needed.
4. Regenerex cone augments require the use of bone cement for attachment to their respective components.
5. Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must properly press-fit into the host bone which necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
6. Regenerex cone augments should only be used with compatible, FDA-cleared, Biomet tibial trays, femoral components, bearings, and stems.
7. 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. 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.

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, bone resorption, or while inserting the device.
4. Loosening, migration, or fracture 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, 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. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. 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.
15. Patellar tendon rupture and ligamentous laxity.
16. Intraoperative or postoperative bone fracture and/or postoperative pain.

MRI INFORMATION
The Biomet Regenerex Cone Augments 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 use implants from an opened or damaged package. Do not resterilize. Do not use implants past 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

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)

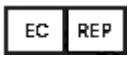
Use by date

WEEE device

REF — Catalogue number

LOT — Batch code

Flammable



Authorized representative in the European Community