Biomet Orthopedics
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01-50-0911
Revision C
Date: 2013-11

Biomet® Comprehensive Segmental Revision System

ATTENTION OPERATING SURGEON

DESCRIPTION
Biomet manufactures a variety of shoulder and elbow joint replacement prostheses intended for partial or total primary and revision joint arthroplasty for use in cemented and uncemented biological fixation applications.

The Comprehensive Segmental Revision System components include humeral stems, humeral heads, proximal and distal bodies. Components are available in a variety of designs and size ranges for both primary and revision applications. Specialty components include screws, augments, flanges and intercalary segments.

MATERIALS

Proximal Body	Titanium alloy
Distal Humeral Body	Titanium alloy
Humeral Head	CoCrMo alloy
Humeral Stems	CoCrMo alloy or titanium alloy
Tissue Attachment Augments	Titanium alloy
Intercalary Segments	Titanium alloy
Coupler	Titanium alloy
Flanges	Titanium alloy
Porous Coating	Titanium alloy

INDICATIONS
The Comprehensive Segmental Revision System is intended for use in cases of:
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Oncology applications including bone loss due to tumor resection.

When used in a proximal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for:
Treatment of acute or chronic fractures with humeral head (shoulder) involvement, which are unmanageable using other treatment methods.

When used as a distal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for:
Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement, which are unmanageable using other treatment methods.

The Comprehensive Segmental Revision System is intended for use with or without bone cement in the proximal shoulder.

The Comprehensive Segmental Revision System is intended for use with bone cement in distal humeral and total humeral applications.

Tissue Attachment Augments provide the option for tissue stabilization and attachment.

When components of the Comprehensive Segmental Revision System are used with Biomet's Comprehensive Shoulder System, the user should refer to the package insert contained with the Comprehensive components for additional information (01-50-0944).

When components of the Comprehensive Segmental Revision System are used with Biomet's Discovery Elbow System, the user should refer to the package insert contained with the Discovery components for additional information (01-50-0901).

When components of the Comprehensive Segmental Revision System are used with Biomet's Comprehensive Reverse Shoulder System, the user should refer to the package insert contained with the Comprehensive Reverse components for additional information (01-50-0903). The Comprehensive Segmental Revision System is not cleared for reverse shoulder applications in the United States.

When components of the Comprehensive Segmental Revision System are used with Biomet's Compress Segmental Humeral Replacement System, the user should refer to the package insert contained with the Compress components for additional information including indications (01-50-1205).

The Comprehensive Segmental Revision System is not cleared for hemiarthroplasty in the United States.

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

Relative contraindications include:
1. Uncooperative patient or 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. 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 has 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.

1. Properly align and completely seat connecting components including tapers. Disassociation of the humeral head component from the humeral stem component has been reported. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry all connectors, including tapers prior to attachment of modular components to avoid crevice corrosion and improper seating.
2. Care is to be taken to assure complete support of parts of the device embedded in bone cement to prevent stress concentrations that 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. Inadequate supporting bone may result in failure of the system.
4. The use of a glenoid prosthesis in patients with a deficient rotator cuff could increase the risk of glenoid component loosening due to non-anatomic loading conditions.
5. Super Extended Articular Surface Heads are intended for use with Proximal Tumor Bodies only.
6. Comprehensive Segmental Revision System components should not be used with components from any other manufacturer.
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 activity, trauma and excessive

weight have been implicated with premature failure of the implant by loosening, fracture 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. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

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.

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.

PRECAUTIONS
Specialized instruments are designed for Biomet® joint replacement systems to aid in the proper implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, 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 result in loosening of the implant.
2. Early or late postoperative infection and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock inserting the device.
4. Periarticular calcification or ossification, or bone resorption with or without impediment of joint mobility.
5. Inadequate range of motion due to improper selection or positioning of components.
6. Undesirable shortening or lengthening of limb.
7. Dislocation, subluxation, loosening, migration, screw back-out and/or fracture of the implants can occur due to inadequate fixation, malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, excessive range of motion, excessive activity and/or other factors. Muscle and fibrous tissue laxity can also contribute to these conditions.
8. Fretting and crevice corrosion can occur at interfaces between components.
9. Wear and/or deformation of articulating surfaces.
10. Accelerated wear of glenoid articular cartilage.
11. Intraoperative or postoperative bone fracture and/or postoperative pain.
12. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.

Biomet® Comprehensive Segmental Revision System in the Magnetic Resonance (MR) Environment

Biomet® Comprehensive Segmental Revision System is composed of non-ferromagnetic materials such as Titanium (Ti-6Al-4V), Cobalt Chrome (Co-Cr-Mo) and ultra high molecular weight polyethylene (UHMWPE).

Biomet has performed bench testing and numerical simulations on the Comprehensive Segmental Revision System components in a Magnetic Resonance Imaging (MRI) environment. These tests determined the non-clinical effects of MRI based on scientifically relevant characteristics of the Comprehensive Segmental Revision System components. 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 Safety Information
The Comprehensive Segmental Revision System is 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. It can be scanned safely under the following conditions.

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 up to 1-W/kg for up to 15 minutes of scanning.
- Normal mode of the MR system, Maximum whole-body-averaged SAR of 1-W/kg.
- The effects of local RF transmit coils have not been tested and are not recommended in the area of the implant.
- Recommended Good Clinical Practices
  - The use of porous insulation between the patient and the edge of the bore.
  - Prevention of patient's legs from touching each other and arms/hands from touching body.

MR Information
Temperature evaluations of Comprehensive Segmental Revision System components in the patient during MRI yielded the following in-vitro rises:

<u>1.5T MR Systems</u>
A temperature rise of 4.0 °C or less was calculated when scaled to whole-body-averaged SAR of 1 W/kg for 15-minutes of RF power application.

<u>3.0T MR Systems</u>
A temperature rise of 3.0 °C or less was calculated when scaled to whole-body-averaged SAR of 1 W/kg for 15-minutes of RF power application.

Image Artifacts
Image artifacts extend as much as 10cm from the implant in image distortion tests performed according to ASTM F2119-07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants in a 3.0 T MR system with a gradient echo scan sequence. Therefore, it may be necessary to optimize MR imaging parameters for the presence of these implants.

Other: Testing of materials used in the Comprehensive Segmental Revision System indicated no known risks of magnetically induced displacement force or torque for the field conditions given above.

The Comprehensive SRS, when used in conjunction with the Compress Segmental Humeral Replacement System referenced in this document, has not been evaluated for safety and compatibility in the MR environment, nor tested for heating or migration in the MR environment.

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 any component from an opened or damaged package. Do not use implants after expiration date has passed.

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.

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

CE 0086

Symbol Legend

 Manufacturer

 Date of manufacture

 Do not reuse

 Caution, see instructions for use

Sterilized using ethylene oxide

Sterilized using irradiation

Sterile

Sterilized using aseptic processing techniques

Sterilized using steam or dry heat

MR Conditional

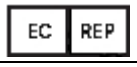
 Use by date

 WEEE device

Catalogue number

Batch code

Flammable



Authorized representative in the European Community