Biomet Comprehensive Reverse Shoulder Products

ATTENTION OPERATING SURGEON

DESCRIPTION
Biomet Comprehensive Reverse Shoulder products are intended for total shoulder replacement in a reverse configuration.

MATERIALS

- **Baseplates**: Titanium Alloy
- **Baseplate Screws**: Titanium Alloy
- **Humeral Tray**: Titanium Alloy / CoCrMo Alloy
- **Locking Ring**: CP Titanium
- **Glenospheres**: CoCrMo Alloy / Titanium Alloy
- **Humeral Bearings**: UHMWPE
- **Surface Coating**: Titanium Alloy / Hydroxyapatite (HA)
- **Taper Adaptor**: Titanium Alloy
- **Humeral Stem**: Titanium Alloy

INDICATIONS

Biomet Comprehensive Reverse Shoulder products are indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Titanium glenospheres are intended for patients with Cobalt Alloy material sensitivity. The wear of these devices has not been tested but, based on pin on disk testing, the wear rate is inferior to that of cobalt alloy glenospheres. A Cobalt Alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok finish humeral stems are intended for cemented use and the MacroBond coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

CONTRAINDICATIONS

Absolute contraindications include infection, sepsis, and osteomyelitis.

Relative contraindications include:
1. Uncooperative patient or patient with neurologic disorders who is incapable or unwilling to follow 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.

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. The use of a reverse shoulder prosthesis in patients with a deficient rotator cuff could increase the risk of component loosening due to non-anatomic loading conditions. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclusion 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. Humeral and glenosphere components should be used only when there is good quality bone.
2. Disassociations of modular components have been reported. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry tapers prior to attachment of modular components to avoid crevice corrosion and improper seating. All additional locking screws must be adequately tightened.
3. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Complete preclusion 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.
4. Implant fracture due to cement failure has been reported.
5. 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 bearing 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 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, and the patient must have a functional deltoid muscle.

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 or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption and/or excessive activity.

5. If glenoid component is not securely fixed, micromotion can lead to peripheral screw failure.

6. Periarticular calcification or ossification, with or without impediment of joint mobility.

7. Inadequate range of motion due to improper selection or positioning of components, lack of rotator cuff, and inadequate function of the deltoid.

8. Undesirable shortening or lengthening of limb.

9. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity or excessive activity can also contribute to these conditions.

10. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.

11. Fretting and crevice corrosion can occur at interfaces between components.

12. Wear and/or deformation of articulating surfaces.

13. Intraoperative or postoperative bone fracture and/or postoperative pain.

14. Scapular notching and bone erosion has been reported with the use of reverse shoulder implants. Scapular notching may lead to early failure of glenoid fixation.

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) hematoma, (4) delayed wound healing, and (5) pulmonary embolism. Surgery, in general, can result in other cardiovascular events such as venous thrombosis or myocardial infarction.

MRI INFORMATION

The Comprehensive Reverse Shoulder components have 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

Titanium/CrCoMo/E1 components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. ArComXL components are sterilized by exposure to one of the following methods:

- Gas Plasma

Do not resterilize. Single use only. Do Not Reuse. Do not use any component from an opened or damaged package. 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 this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

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