Bio-Modular® Shoulder System
Reverse Conversion Option

Surgical Technique
Introduction

The Bio-Modular® Reverse Conversion Humeral Tray was designed to allow for a conversion from a primary to a reverse shoulder while maintaining a well-fixed Bio-Modular® humeral stem, when joint space allows (Figure 1). By using this unique humeral tray in conjunction with the Comprehensive® Reverse humeral bearing and glenoid components, a reverse conversion is possible (Figure 2).

Note: The Bio-Modular® Shoulder System was originally designed to be used for a primary fracture, hemi, or total shoulder arthroplasty. The Bio-Modular® Reverse Conversion Option is offered for revision applications and must be used in conjunction with the Comprehensive® Reverse Shoulder System’s humeral bearing and glenoid components, referencing the Comprehensive® Reverse surgical technique BOI0383.0.
Design

The Bio-Modular® Reverse Conversion Humeral Tray is specifically designed to work with the Bio-Modular® humeral stem by taking into account the proximal collar, volcano neck taper and 55 degree neck/shaft angle (Figure 3).

The Bio-Modular® Humeral Tray was designed with a 10 degree increase in the superior to inferior angle. This will convert the 55 degree neck angle of the Bio-Modular® stem to 45 degrees. When used in conjunction with the Comprehensive® Humeral Bearing, the neck angle becomes 147/33 degrees, identical to that of the Comprehensive® Shoulder System (Figure 4).
Surgical Procedure

Humeral Head and Glenoid Removal

Separate the humeral head from the humeral stem by sliding the removal fork between the head and the stem to disengage the tapers (Figure 5).

Note: If a total shoulder arthroplasty has been performed, the glenoid component will also need to be removed.

Caution: If severe contracture is seen once the humeral head prosthesis has been removed, a reverse conversion may not be possible. If this is the case, revision to a Comprehensive® humeral stem may be required. In the event of a stem revision to a Comprehensive® Humeral Stem, refer to the Comprehensive® Reverse Surgical Technique BOI0383.0 for proper humeral resection guidance and instrumentation.

Glenoid Preparation

If it appears there is an appropriate amount of joint space, functioning deltoid and adequate glenoid bone stock, continue with preparation of the glenoid referencing the Comprehensive® Reverse Shoulder System Surgical Technique BOI0383.0, Glenoid Preparation section (Figure 6).
**Trial**

Once the glenoid has been prepared, place the trial glenosphere onto the glenoid baseplate (reference BOI0383.0, Glenosphere Selection section). Place the one-piece humeral tray/bearing trial onto the humeral stem (reference BOI0383.0, Humeral Tray and Bearing Preparation section). Perform a trial reduction and evaluate range of motion and joint tension (Figure 7). The shoe horn, included in the instrument set, may be helpful in reducing the joint. The trial reduction should show very limited distraction (1 mm or less).

**Note:** Given the neck angle of the well-fixed Bio-Modular® stem, the 10 degree angled tray may be difficult to implant/reduce due to limited joint space.

**Insert Components**

Assemble the glenosphere and taper adaptor with the assessed amount of offset (reference BOI0383.0, Glenosphere Assembly, Glenosphere/Taper Adaptor Offset Direction Determination and Glenosphere Orientation/Impaction sections) and engage into the glenoid baseplate in the correct orientation.

Assemble the humeral tray and humeral bearing (reference BOI0383.0, Humeral Tray and Bearing Assembly section) and engage into the humeral stem.

Reduce the joint with aid of the shoe horn and assess final range of motion (Figure 8).
## Implants

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## Instruments

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<td>Shoehorn</td>
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Use clean gloves when handling implants. Laboratory testing indicates that increase the risk of component loosening due to non-anatomic loading subsequent reduction in the service life of the prosthetic components. The use of implant components may result in unusual stress conditions which may lead to improper selection, placement, positioning, alignment and fixation of the components.

**WARNINGS**

Leads to excessive wear and/or failure of the implant or procedure. Inadequate conditions. Malalignment of the components or inaccurate implantation can compromise the success of the procedure. The patient is to be advised of the importance of postoperative care. 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 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.

**MATERIALS**

Biomet® Bio-Modular® Shoulder System Reverse Conversion Option

**DESCRIPTION**

Biomet® Bio-Modular® Reverse Shoulder products are intended for total shoulder replacement in a reverse configuration.

**ATTENTION OPERATING SURGEON**

**INDICATIONS**

Biomet® Bio-Modular® 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 Bio-Modular® 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.

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

Interlock® 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 precloure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that 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 precloure 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 articulating surfaces.

**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.

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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 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. Perticular calcification or ossification, with or without impeding 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, 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.

**BIOMET® IMPLANTS IN THE MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT**

Biomet® 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).

Non-clinical MRI studies on representative Bio-Modular® Reverse Shoulder orthopedic implants were conducted in accordance to ASTM F2503-08 Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment.

**MRI Information**

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

- Static magnetic field of 1.5-Tesla (1.5T) and 3.0-Tesla (3.0T)
- Spatial gradient field of 10 T/m (1000 G/cm) or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 1.2-W/kg for 15 minutes of scanning per pulse sequence

The effects of MRI procedures using MR systems and conditions above these levels have not been determined. Local RF transmit coils have not been tested and are not recommended in the area of the implant. It is recommended that patients with these implants not be sedated prior to MRI scanning.

**MR Related Heating**

In non-clinical testing of Biomet representative metallic shoulder orthopedic implants using the body radiofrequency (RF) coil to transmit and receive RF energy for both 1.5T and 3.0T MR systems using normal operating mode yielded the following results:

1. **1.5T MR system**
   (64MHz, Siemens Espree clinical scanner, SYNGO MR B15 Software, Munich, Germany).
   - A temperature rise of 7.0°C or less at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 1.2-W/kg for 15-minutes of MR scanning per pulse sequence.

2. **3.0T MR system**
   (128MHz, Siemens Trio clinical scanner, SYNGO MR A30 4VA30A Software, Munich, Germany).
   - A temperature rise of 21.0°C or less was observed at a maximum MR system-reported whole body averaged SAR of 3.3-W/kg for 15-minutes of MR scanning per pulse sequence.

The observed temperature rises in both 1.5T & 3.0T MR systems are less than the cure temperatures of the Bone Cement used to fixate most shoulder implants. Based on testing, there could be a potential for heating.

**Image Artifacts**

MR image quality may be compromised if the area of interest is relatively close to the device. Distortion extended as much as 5.2 cm from the implant in 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.

**STERILITY**

Titanium/CoCrMo/E1 components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation.

- Ethylene Oxide Gas (EtO)
- 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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**Authorized Representative**: Biomet U.K., Ltd.
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