Biomet Orthopedics
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01-50-1205
Revision A
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Compress Segmental Humeral Replacement System

ATTENTION OPERATING SURGEON

DESCRIPTION

The Compress Segmental Humeral Replacement System is a metallic segmental fixation system intended to replace the resected part of the humerus in cases of severe bone loss. The design of the Compress System allows a compressive load to be applied at the prosthetic implant-bone interface at the time of device insertion. This is accomplished through a spring system built into the stem.

MATERIALS

Titanium Alloy
CoCrMo Alloy
UHMWPE
Stainless Steel
Hydroxyapatite (HA) Coating

INDICATIONS

The Compress Segmental Humeral Replacement System is indicated for:

1. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
2. Tumor resections.
3. Revision of previously failed total joint arthroplasty.
4. Trauma.

The Compress Segmental Humeral Replacement System components are intended for uncemented use.

The Discovery Elbow components when used in conjunction with the Compress Segmental Humeral Replacement System are restricted to the Compress Segmental Humeral Replacement System indications and are intended to be inserted with bone cement.

The Modular Hybrid Glenoid when used in conjunction with the Compress Segmental Humeral Replacement System is restricted to the Compress Segmental Humeral Replacement System indications and is intended to be used with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

CONTRAINDICATIONS

1. Active infection.
2. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
3. Patient conditions including vascular insufficiency, insufficient quantity of cortical thickness (see table below), insufficient quality of bone, or latent infections.

Cortical Thickness* (mm)	Anchor Plug**	Force Level (lbf)
<1.0	Contraindicated	Contraindicated
1.0 – 1.4	13-Hole Anchor Plug	400
1.5 – 2.4	9-Hole Anchor Plug	400
2.5 – 3.9	5-Hole Anchor Plug	400
4.0 – 5.4	5-Hole Anchor Plug	600
5.5 and above	5-Hole Anchor Plug	800

*Cortical thickness should not fall below range anywhere between the anchor plug and the interface.
**Any cortical defect between the anchor plug and interface is a contraindication for this system.

4. Pathologic soft tissue conditions or skeletal conditions, which would prevent secure fixation of the device in the bone.

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. Do not modify implants. The Hydroxyapatite (HA) coating on the device should only be handled while wearing surgical gloves. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery and should verify that all articular components are compatible per the accessory component labeling.

NOTE: The patient is to be kept non-load bearing during the 1st 6 weeks, and partial load bearing (50% or less) during the 2nd 6 weeks while early stable fixation takes place.

1. Firmly seat modular components to prevent disassociation. Thoroughly clean and dry tapers of the modular components to avoid crevice corrosion and improper seating.
2. Malalignment or soft tissue imbalance can place inordinate forces on the components which may cause excessive wear to the associated articulating surfaces. Revision surgery may be required to prevent component failure.
3. Complete preclosure cleaning and removal of metallic debris or other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.

4. The force level of the spindle assembly is not intended to be adjusted in the operating room.
5. Remove and dispose of the compression cap after the nut is tightened on the spindle assembly.
6. In order to utilize the optional locking screw with the proximal taper of the intercalary segment, a cap must first be inserted into the end of the spindle before the taper is engaged.
7. Consult the Force Chart in the Surgical Technique to determine the appropriate force level for the spindle.
8. Complete loss of spindle/anchor plug space indicates that the Compress device has lost compression and revision is warranted to prevent further complications.
9. Loss of spindle/anchor plug space may lead to fracture of the anchor plug traction bar if not revised.

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 and/or compromised stability in or around the implant site.

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**.**

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.

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, 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, which 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.

- Patient must avoid placing excessive loads on the implant.
- Patient must avoid lifting more than 5lbs with the operated arm after surgery.
- Patient must avoid putting full body weight on the operated arm when rising from a seated position.
- Patient must avoid sudden or strenuous pulling activities after surgery, as these can produce excessive stress on the operated arm.

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/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. Infection is a rather common problem in elbow procedures
5. Impairment due to injury of the ulnar nerve is a major concern in elbow procedures.
6. Loosening, migration, and/or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, bone resorption, and/or excessive, unusual and /or awkward movement and/or activity.
7. Periarticular calcification or ossification, with or without impediment of joint mobility.
8. Inadequate range of motion due to improper selection or positioning of components.
9. Undesirable shortening or lengthening of limb.
10. Dislocation and subluxation due to inadequate fixation, malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, excessive range of motion, and/or excessive activity. Muscle and fibrous tissue laxity can also contribute to these conditions.
11. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
12. Fretting and crevice corrosion can occur at interfaces between components.
13. Wear and/or deformation of articulating surfaces.

14. Accelerated wear of glenoid articular cartilage.
15. Intraoperative or postoperative bone fracture and/or postoperative pain.
16. Axle or bearing components may disassociate causing the elbow to disarticulate.
17. Revision and post-traumatic patients are susceptible to higher wear rates if varus/valgus constraints are compromised.

Potential risks associated with the use of the Compress Segmental Humeral Replacement System include: 1. presence of the Compress Segmental Humeral Replacement could generate loads at the osteotomy line of a magnitude great enough to induce pressure necrosis in the host bone; 2. loads applied to the transverse fixation pins could potentially cause loosening or migration of the pins through the shaft of the humerus causing unpredictable wear of the implant; 3. spring failure resulting in loss of fixation and revision surgery; and, 4. bone resorption that may contribute to deteriorating fixation and loosening and failure of the device.

MRI Information
The Compress Segmental Humeral Replacement System has not been evaluated for safety and compatibility in the MR environment. The Compress Segmental Humeral Replacement System has not been 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. Do not resterilize. Do not use implants after expiration date. Do not use any component from an opened or damaged package. Single Use Only – Do not reuse.

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.

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

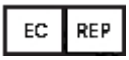
 Use by date

 WEEE device

 Catalogue number

 Batch code

 Flammable

 Authorized representative in the European Community