The EAS Humeral Head

A Conservative Approach to Rotator Cuff Arthropathy

The EAS humeral head is a bone-sparing option that can successfully address symptoms associated with rotator cuff arthropathy. By providing metal-on-bone articulation with the acromion, significant pain relief can be achieved.

Benefits of the Extended Articular Surface Heads:

• Designed for cuff tear arthropathy
• Bone sparing
• Simple surgical technique
• Innovative instrumentation
• Utilized with Bio-Modular® and Comprehensive® humeral stems
• No additional resections required
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1. Once the Atlas Fracture Stem and the glenoid components of the Bio-Modular Shoulder System are removed, the glenoid components are removed by separating the humeral head from the glenoid components.

2. Uncemented glenoid components should be used only when there is good quality bone and no significant shoulder instability.

3. 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 tapers prior to attachment of modular head component to avoid crevice corrosion and improper seating.

4. Dislocation of the bipolar shoulder component has been reported. Closed reduction should be attempted with caution to prevent disassociation of the bipolar component. Do not use excessive force during closed reduction. The bipolar component may impinge against the glenoid component.

5. 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 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.

6. The use of Bio-Modular® III stems is not recommended for fractures of the proximal humerus.

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 and excessive weight bearing have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Lossening of the implants can result in increased production of wear particles, as well as accelerated 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.

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 contact, 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 forces, 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.

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.

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. Passive transfer of debris and dislocation from metallic and polyethylene components of joint implants may be present in adjacent tissue. If fluid is 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 allergic reaction.

3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteosclerosis, bone defects from previous surgery, bone resorption, or while inserting the device.

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

5. Penarncalcalisation or ossification, with or without impidement 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. Fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight bearing.

10. Ligamentous and muscular injury may occur at interfaces between components.

11. Wear and/or deformation of articulating surfaces.


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

STERILITY
Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after 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, P.O. 587, Warsaw, IN 46581 USA, FAX 574-372-1683.

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INDICATIONS
1. Non-inflammatory degenerative joint disease including osteoarthritis and aseptic necrosis.

2. Rheumatoid arthritis.

3. Revision of worn or failed devices or implants have failed.


5. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.

6. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be successful or may be inadequate.

Humeral components with a MacroBond® surface coating are indicated for either cemented or uncemented press-fit applications.

Humeral/glenoid components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation).

Humeral components with a corrosion (interlock®) surface are indicated for cemented application only.

Polyethylene glenoid components not attached to a metal back are indicated for cementation application only.

The Comprehensive® Humeral Positioning Sleeves are for cement use only.

The Comprehensive® Humeral Fracture Stem is intended for use with the Bio-Modular® humeral heads and glenoid components.

The Versa-Dial® Humeral Head Prosthesis is intended for use only with the Comprehensive® Humeral Fracture Stem and the glenoid components of the Bio-Modular® Shoulder System.

In addition to those specified above, the Proximal Shoulder Replacement prostheses are indicated for use in oncology applications, complex humeral fractures and revisions.

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 level, 3) a good nutritional state of the patient and 4) the patient must have reached full skeletal maturity.

CONTRAINDICATIONS
Absolute contraindications include infection, spondylosis, and osteomyelitis.

Relative contraindications include: 1. Uncooperative patient or patient with neurologic disorders who is incapacitated 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, malformed 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 glenoid prosthesis in patients with a deficient rotator cuff could increase the risk in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components.

Fracture Stem and the glenoid components.

Components are available in a variety of designs and size ranges for both primary and revision applications.

Joint replacement components include humeral stems, humeral heads, and glenoid components.

Specialty components include glenoid screws, centering sleeves, taper adaptors, and bipolar heads.

MATERIALS
Humeral Stems CoCrMo Alloy or Titanium Alloy
Humeral Head CoCrMo Alloy or Titanium Alloy
Glenoid Components Ultra High Molecular Weight Polyethylene (UHMWPE)/Titanium Alloy/316 L/Medium Stainless Steel / CoCrMo Alloy
Glenoid Screws Titanium Alloy
Centering Sleeves Polyethylene/Polyethylene (PE/PE) or Polyethylene/Polyethylene (PE/PMMA)
Positioning Sleeves Polyethylene/Polyethylene (PE/PE) or Polyethylene/Polyethylene (PE/PMMA)
Bipolar Heads CoCrMo Alloy / UHMWPE / Titanium Alloy
Surface Coating Titanium Alloy / Hydroxyapatite (HA)
Taper Adapter CoCrMo Alloy

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

Shoulder joint replacement components include humeral stems, humeral heads, and glenoid components.

Components are available in a variety of designs and sizes ranges for both primary and revision applications.

Specially components include glenoid screws, centering sleeves, taper adaptors, and bipolar heads.

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