



Precautionary Statement (01-50-0916)

Biomet Orthopedics, Inc.

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Date: 12/08

Biomet® BioloX™ delta Option Modular Head Hip Joint Prostheses

ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet® BioloX™ *delta* Option Ceramic modular head components are a Transition-Toughened-Platelet Alumina Composite ceramic (TTPA) material with highly polished surfaces in a variety of head sizes. The highly polished surface is designed to reduce friction and minimizes wear. The titanium sleeves adapt the ceramic heads to either a Biomet® Type I or a Biomet® 12/14 taper and allows them to be used in both primary and revision total hip arthroplasty.

MATERIALS

Head - TTPA Ceramic

Sleeve - Titanium Alloy (Ti-6Al-4V)

INDICATIONS

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. Revision procedures where other devices or treatments have failed.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are 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) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) 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, have 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. Use Biomet® Biolox™ delta Option ceramic modular head with Biomet® metallic femoral components. Do not use Biomet® Biolox™ delta Option ceramic modular heads with femoral stems or acetabular components offered by other manufacturers. Mismatching of components or taper sizes can be expected to cause intraoperative or postoperative fracture of ceramic heads.
2. Sleeves labeled "Type I Taper" are to be used with femoral stem components labeled "Type I Taper".
3. Sleeves labeled "12/14" are to be used with femoral stem components labeled "12/14" taper.
4. Use only with Ultra-High Molecular Weight Polyethylene (UHMWPE) or metal-backed UHMWPE acetabular components.
5. Do not use ceramic heads that have been dropped, rubbed, scratched, or disfigured. Blemishes can be expected to cause failure.
6. Do not use a metallic hammer when seating the ceramic head. Use a nylon or polyethylene seating instrument. Do not use excessive force. The TTPA ceramic head can fracture with excessive force.
7. The femoral stem trunion, sleeves and the bore of the ceramic head should be dry and free of contamination prior to assembly.
8. During a revision surgery, extraction of the femoral head should be done with suitable extraction instruments to avoid unnecessary damage to the trunion.
9. Biomet® Biolox™ delta Option modular head components should not be used on trunnions with scratches or defects greater than 0.25mm in height. The surgeon should inspect the taper for damage prior to placement of the modular head components by measuring, with a measuring device, any scratches or defects, and verifying that the height is less than 0.25mm (see Figure A) . The conditions shown in Figures B, C and D are also considered unsuitable for the use of the Biomet® Biolox™ delta Option Ceramic Head and can be expected to cause failure:



Taper with scratch/defect at a Height of 0.25mm – Figure A



Taper with Broad Truncation – Figure B



Slanted Taper – Figure C



Crushed Taper – Figure D

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 limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation, subluxation 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.

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, and/or 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.

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.

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.

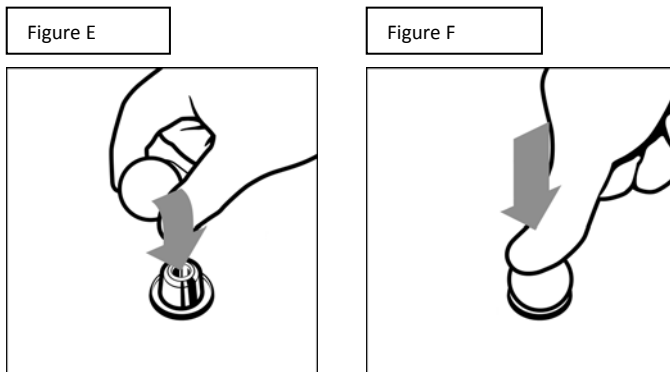
POSSIBLE ADVERSE EFFECTS

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 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, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, non-union, bone resorption, and or excessive, unusual and/or awkward movement and/or activity. The trunnion must also be free of scratches or defects greater than 0.25mm in height, free of slants, free of broad truncations, and free of crushed ends (see warning #9 for clarification).
5. Periarticular calcification or ossification, with or without impediment 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, malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fretting and crevice corrosion can occur at interfaces between components.
10. Wear and/or deformation of articulating surfaces.
11. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
12. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
13. The TTPA ceramic modular head is composed of ceramic material with limited clinical history. Although mechanical testing demonstrates that, when used with polyethylene acetabular components, ceramic balls produce a relatively low amount of particles, the total amount of particulate produced remains undetermined. Because of the limited clinical and preclinical experience, the long-term biological effects of these particulates are unknown.
14. Intraoperative and postoperative bone fracture and/or postoperative pain.
15. Ceramic head fractures have been reported.

ASSEMBLY INSTRUCTIONS

1. The modular head components must be assembled together before positioning them onto the stem.
2. Verify that the appropriate head size and matching tapers are being utilized before assembly.
3. The modular head components are assembled by placing the head onto the sleeve as shown in Figure E and Figure F. Assure that the tapers are clean and dry and that they are aligned axially before applying pressure. The tapers are engaged once resistance is felt.



4. Impact the modular head components onto the stem with several brisk mallet strikes using a plastic head impactor only. Metal impactors or any other metallic objects may scratch or crack the modular head bearing surface and, therefore, should not be used.
5. If the modular ceramic head becomes scratched or cracked, the head and sleeve must be replaced.

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, distribution, or use 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 46582 USA, FAX: 574-372-3968.

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BioloX™ is a trademark of CERASIV GMBH

	Manufacturer
	Date of Manufacture
	Do Not Reuse
	Consult Accompanying Documents
STERILE EO	Sterilized using Ethylene Oxide
STERILE R	Sterilized using Irradiation
STERILE	Sterile
STERILE A	Sterilized using Aseptic Technique
STERILE 	Sterilized using Steam or Dry Heat
	Expiry Date
	WEEE Device
REF	Catalogue Number
LOT	Lot Number