BIOLOX® \textit{delta} Option
Ceramic Femoral Head System

Product Features and Instructions for Use
Product Features

BIOLOX® *delta* ceramic heads are composed of 75% aluminum oxide and approximately 25% zirconia. The combination of these two materials provides low wear and higher strength as compared to alumina ceramics.\(^1\)

In addition, BIOLOX® *delta* ceramic heads combined with Antioxidant Infused Technology E-Poly® bearings show wear rates similar to that of metal-on-metal articulations.\(^2\)

**BIOLOX® *delta* Option Ceramic Femoral Head Component**

The new BIOLOX® *delta* Option Ceramic Femoral Head is a two-piece component consisting of a titanium neck sleeve and a BIOLOX® *delta* ceramic head. Unlike the traditional BIOLOX® *delta* one piece ceramic head, which is indicated for primary arthroplasty only, the BIOLOX® *delta* Option component is designed to allow surgeons to utilize a ceramic head in both primary and revision arthroplasty.

<table>
<thead>
<tr>
<th>Head Diameter</th>
<th>Neck Sleeve Taper</th>
<th>Neck Length</th>
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</thead>
<tbody>
<tr>
<td>40mm</td>
<td>Type I</td>
<td>-6, -3, Std., +3, +6</td>
</tr>
<tr>
<td></td>
<td>12/14</td>
<td>-3, Std., +4, +7</td>
</tr>
</tbody>
</table>

-6mm, -3mm, Std, +6mm
Instructions for Use

BIOLOX® delta Option ceramic femoral heads and titanium neck sleeves are compatible with Biomet Type 1 and 12/14 stem tapers and can be utilized in both primary and revision total hip arthroplasty with Biomet polyethylene liners.

Head Removal

In the case of a revision surgery, extraction of the existing femoral head should be done with suitable extraction instruments to avoid unnecessary damage to the trunnion.

Stem Trunnion Inspection

The BIOLOX® delta Option Ceramic Head component can be used on both a new stem, or a previously implanted stem.

BIOLOX® delta Option Ceramic Head components should not be used on trunnions with scratches or defects greater than 0.25mm in height. Inspect the taper for damage prior to placement of the modular head components by measuring scratches or defects, verifying that the height is less than 0.25mm (Figure 1).

The conditions shown in Figures 2, 3 and 4 are also considered unsuitable for the use of the Biomet® BIOLOX® delta Option Ceramic Head and can be expected to cause failure.

Biomet does not practice medicine. Each surgeon is responsible for determining the appropriate device and surgical technique to utilize on each individual patient.
**Trialing**
Verify the taper type on the existing stem or the stem to be inserted, taking care to select the correct trial and final implant that matches the stem taper. Determine the appropriate neck length and verify joint stability.

**Assembly Instructions**
Verify the correct selection of BIOLOX® delta Option Ceramic Head and neck sleeve as predetermined during the trialing process. Any neck sleeve can be used with any BIOLOX® delta Option Ceramic Head.

*Note:* Heads and neck sleeves are packaged separately.

Assemble the modular head components prior to positioning them onto the stem by aligning the head onto the neck sleeve axially and apply pressure. A slight resistance will be felt once the taper is engaged (Figure 5 & 6).

**Head/Stem Positioning**
Assure that all tapers, neck sleeve to ceramic head and ceramic head component to stem trunnion, are clean and dry before assembly.

Place the ceramic head on the shaft taper by twisting lightly while applying manual pressure. Impact the modular head component onto the stem with several brisk mallet strikes, using a plastic head impactor only.

*Note:* The use of metal impactors or any other metallic objects may scratch or crack the modular head bearing surface, compromising the integrity of the component. If the modular ceramic head becomes scratched or cracked, the head and neck sleeve must be replaced.

To verify fixation of the head, attempt to remove the head by hand.
## BIOLOX® delta Option Ceramic Femoral Head

### Implants

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Size</th>
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<tbody>
<tr>
<td>650-1058</td>
<td>BIOLOX® delta Option Ceramic Head</td>
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<tr>
<td>650-1064</td>
<td>BIOLOX® delta Option Type I Insert</td>
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<tr>
<td>650-1065</td>
<td>BIOLOX® delta Option Type I Insert</td>
<td>-3mm</td>
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<td>650-1066</td>
<td>BIOLOX® delta Option Type I Insert</td>
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<tr>
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<td>BIOLOX® delta Option Type I Insert</td>
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<tr>
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<tr>
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<tr>
<td>650-1063</td>
<td>BIOLOX® delta Option 12/14 Insert</td>
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### Instruments

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<th>Description</th>
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<tr>
<td>31-173740</td>
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<tr>
<td>31-482590</td>
<td>Type I Neck Trial</td>
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<td>31-482591</td>
<td>Type I Neck Trial</td>
<td>-3mm</td>
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<tr>
<td>31-482592</td>
<td>Type I Neck Trial</td>
<td>Std</td>
</tr>
<tr>
<td>31-482593</td>
<td>Type I Neck Trial</td>
<td>+3mm</td>
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<td>31-482594</td>
<td>Type I Neck Trial</td>
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<tr>
<td>31-502691</td>
<td>12/14 Neck Trial</td>
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<tr>
<td>31-502692</td>
<td>12/14 Neck Trial</td>
<td>Std</td>
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<tr>
<td>31-502696</td>
<td>12/14 Neck Trial</td>
<td>+4mm</td>
</tr>
<tr>
<td>31-502697</td>
<td>12/14 Neck Trial</td>
<td>+7mm</td>
</tr>
</tbody>
</table>

**Note:** The head trial and Type 1 neck trials are currently available in the M’a-Magnum™ instrument sets.
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 surfaces are designed to reduce friction and minimize 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 osteoarthrits and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of congenital hip deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques. Patients with high activity levels and loads of normal healthy bone and joint tissue.
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 focal of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenograms, 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 inadequate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate precision 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 abrasion resistance and lower wear compared to implants subjected to body fluids alone. The patient 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 metallic stems or acetabular components offered by other manufacturers. Mismatching of components or taper sizes can be expected to cause intraoperative or postoperative fracture or loosening 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:

**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. Particular wear debris and dislocation 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 trunion 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 S4 for clarification).
5. Periarticular calcification or ossification, with or without impingement 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. 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:

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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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References

1. www.ceramtec.com