BIOLOX® 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 E1™ bearings show wear rates similar to that of metal-on-metal articulations.²

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

The 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 Diameters</th>
<th>Neck Sleeve Taper</th>
<th>Neck Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>40mm</td>
<td>Type I</td>
<td>-6, -3, Std., +3, +6</td>
</tr>
<tr>
<td>44mm</td>
<td>12/14</td>
<td>-3, Std., +4, +7</td>
</tr>
</tbody>
</table>

![Graph showing volumetric wear rates](image)

![Diagram of BIOLOX® delta Option Ceramic Femoral Head Component](image)
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 and antioxidant infused 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.

Impact the modular head components onto the stem with a light tap that firmly and definitively seats the head 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>
</tr>
</thead>
<tbody>
<tr>
<td>650-1058</td>
<td>BIOLOX® delta Option Ceramic Head</td>
<td></td>
</tr>
<tr>
<td>650-1059</td>
<td>BIOLOX® delta Option Ceramic Head</td>
<td></td>
</tr>
<tr>
<td>650-1064</td>
<td>BIOLOX® delta Option Type I Insert</td>
<td>-6mm</td>
</tr>
<tr>
<td>650-1065</td>
<td>BIOLOX® delta Option Type I Insert</td>
<td>-3mm</td>
</tr>
<tr>
<td>650-1066</td>
<td>BIOLOX® delta Option Type I Insert</td>
<td>Std</td>
</tr>
<tr>
<td>650-1067</td>
<td>BIOLOX® delta Option Type I Insert</td>
<td>+3mm</td>
</tr>
<tr>
<td>650-1068</td>
<td>BIOLOX® delta Option Type I Insert</td>
<td>+6mm</td>
</tr>
<tr>
<td>650-1060</td>
<td>BIOLOX® delta Option 12/14 Insert</td>
<td></td>
</tr>
<tr>
<td>650-1061</td>
<td>BIOLOX® delta Option 12/14 Insert</td>
<td>Std</td>
</tr>
<tr>
<td>650-1062</td>
<td>BIOLOX® delta Option 12/14 Insert</td>
<td>+4mm</td>
</tr>
<tr>
<td>650-1063</td>
<td>BIOLOX® delta Option 12/14 Insert</td>
<td>+7mm</td>
</tr>
</tbody>
</table>

## Instruments

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>31-173740</td>
<td>M²a-Magnum™ Head Trial</td>
<td></td>
</tr>
<tr>
<td>31-173744</td>
<td>M²a-Magnum™ Head Trial</td>
<td></td>
</tr>
<tr>
<td>31-482590</td>
<td>Type I Neck Trial</td>
<td>-6mm</td>
</tr>
<tr>
<td>31-482591</td>
<td>Type I Neck Trial</td>
<td>-3mm</td>
</tr>
<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>
</tr>
<tr>
<td>31-482594</td>
<td>Type I Neck Trial</td>
<td>+6mm</td>
</tr>
<tr>
<td>31-502691</td>
<td>12/14 Neck Trial</td>
<td>-3mm</td>
</tr>
<tr>
<td>31-502692</td>
<td>12/14 Neck Trial</td>
<td>Std</td>
</tr>
<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 M²a-Magnum™ instrument sets.
ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet® Biolox™ delta Option Ceramic modular head components are a Transition-
Toughened-Platelet Alumina Composite ceramic (TTTA) material with highly polished surfaces in a
variety of head sizes. The highly polished surface is designed to reduce friction and minimizes wear.
The ceramic heads are 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 - TTTA Ceramic
Sleeve - Titanium Alloy (Ti-6Al-4V)

INDICATIONS

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Sleeves labeled “Type I Taper” are to be used with femoral stem components labeled “Type
   I Taper”. Do not use Biomet
3. Malalignment of the components or inaccurate implantation can lead to crevice corrosion, fretting, fatigue
   and/or excessive wear, are susceptible to fracture. Surgical instruments should only be used on trunnions with scratches or defects
   greater than 0.25mm in height. Do not use ceramic heads that have been dropped, rubbed, scratched, or
   disfigured. Blemishes can be expected to cause failure.
4. Do not use a metallic hammer when seating the ceramic head. Use a nylon

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 ceramic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preoperative 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 adhe-

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 im-

POSSIBLE ADVERSE EFFECTS

Blomert® 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 postop-
erative 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 certain implants 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 of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PRECAUTIONS

Surgical instruments are designed for Blomert® joint replacement systems to aid in the accu-

Blomert® 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 postop-
erative 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 certain implants 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 of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PRECAUTIONS

Surgical instruments are designed for Blomert® joint replacement systems to aid in the accu-
rate 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. Blomert 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 func-
tion, 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 histologi-
cal 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 ostoidosis or ossification 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

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet at the contact information provided herein.

5
The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet at the contact information provided herein.
References

1. www.ceramtec.com