Final setting onto the stem:
- The stem taper must be dry and free of any blood or debris.
- Slightly loosen the acetabular cup.
- Place the BIOLOX OPTION head assembly on the stem taper and a twisting motion, while applying manual pressure until tight.
- As a rule, it is better to securely place the head with the assembled adapter onto the stem taper. Do not use the BIOLOX OPTION head system if pressure is necessary to seat the device.
- For heads with diameter 28 and 32 mm: Seat the assembly with the plastic impactor on the pole of the femoral head assembly firmly/moderately a minimum of three times to ensure full seating on the stem taper (Fig. 4a).
- Flexible assembly of the head flutes by trying to remove the head by hand.

For trial reposition, check range of motion and stability using the corresponding instruments and trial heads of the selected femoral stem and acetabular cup.

For heads with diameter 36 mm and beyond:
- With the BIOLOX OPTION head assembly firmly/moderately a minimum of three times to ensure full seating on the stem taper (Fig. 4a).
- The impactor should not be more than 20° off the neck axis to avoid losing too much of the impact force (Fig. 4b).
- The CE mark is valid only if it is also printed on the product label.
- This documentation is intended exclusively for physicians and is not intended for laypersons.
- Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to cover all contingencies or to be applicable to every individual with respect to every product or procedure, the physician should inform himself/herself on the matter by independent research for such consideration and it is advised to consult the appropriate references before exercising any decision or taking any action. Please refer to the package insert for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.

What is BIOLOX delta?
- The new alumina matrix composite BIOLOX delta meets the increased demands in hip replacement. This high-performance ceramic offers the same advantages as alumina: i.e. excellent biocompatibility, low wear, high toughness, superb chemical and hydrothermal stability, but with higher strength than alumina ceramic. 1

BIOLOX OPTION Ceramic Femoral Head System
- Consists of a head and metal head adapter, for primary and revision cases.

Benefits
- Additional neck length for diameter > 28 mm
- Additional diameters providing more ROM and stability
- Same benefits as BIOLOX forte for metal-on-metal cases

For distribution in the United States only.

For Distribution in the United States only.

Ordering Information

BIOLOX OPTION Ceramic Femoral Head System 12/14

Head: Alumina Matrix Composite
Head adapter: TiAl6V4
Sterile

<table>
<thead>
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<th>Diameter</th>
<th>Neck Length</th>
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<th>REF</th>
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</tr>
</tbody>
</table>

Instrument Non-sterile

For trial reposition, check range of motion and stability using the corresponding instruments and trial heads of the selected femoral stem and acetabular cup.

References
2  CeramTec: BIOLOX delta – Nanocomposite for Arthroplasty, Darmstadt, Steinkopff, 2004, 163–168
5  MT080011 – GB – 1.000.0805

Sizing

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Neck Length</th>
<th>28mm</th>
<th>32mm</th>
<th>36mm</th>
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Note: The impactor cannot be more than 20 degrees off the neck axis to avoid losing too much of the impact force (Fig. 4a).

BIOLOX®* Ceramic Femoral Head System

For Distribution in the United States only.
Improved Mechanical Properties
The excellent wear characteristics and the high radiopacity of BIOLOX delta material make it suitable for articulating against highly cross-linked polyethylene.

Mechanical Properties and Benefits of Third-Generation Zirconia and Alumina Matrix Ceramic Composites

<table>
<thead>
<tr>
<th>Property</th>
<th>BIOLOX forte</th>
<th>BIOLOX delta</th>
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</thead>
<tbody>
<tr>
<td>Sinking strength (MPa)</td>
<td>400</td>
<td>2,000</td>
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<tr>
<td>Hardness (HRA)</td>
<td>93</td>
<td>90</td>
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<tr>
<td>Microhardness (HV)</td>
<td>1,600</td>
<td>1,800</td>
</tr>
<tr>
<td>Wear (10^7 mm²/Nm)</td>
<td>0.004</td>
<td>0.006</td>
</tr>
<tr>
<td>Wear coefficient (µm/N)</td>
<td>0.25</td>
<td>0.9</td>
</tr>
<tr>
<td>Breakdown strength (MPa)</td>
<td>160</td>
<td>1,380</td>
</tr>
<tr>
<td>Fracture toughness (J/m²)</td>
<td>1,800</td>
<td>2,800</td>
</tr>
<tr>
<td>Microstructure</td>
<td>3.0 µm (1.8 µm)</td>
<td>0.4 µm</td>
</tr>
</tbody>
</table>

Benefits
- Possibility for low-wear ceramic solutions in revision and primary cases.
- Femoral head systems can be associated with primax or used stem taper.
- Malleable does not reduce the range of motion.
- Improved mechanical properties compared to alumina heads.
- Easy assembly of head and adapter.
- Same benefits for BIOLOX forte material in BIOLOX delta.

Sizing
- Head diameters: 28, 32, 36 and 40 mm
- 1 1/3 taper angle adapters.

Surgical Technique Considerations BIOLOX Option Head System

The BIOLOX delta femoral head is used in combination with Zimmer articulations, and in combination with highly cross-linked or conventional polyethylene.

Preparation Planning
- Planning of the operation is based on the information available concerning the size and shape of the remaining femoral head.
- The stem taper type can be found on our home page.
- Contact your Zimmer sales representative or visit the Zimmer Web site: www.productcompatibility.zimmer.com.

The BIOLOX option head system can be either used or in revision cases.

Head Removal and Inspection of the Stem Taper
- In case of revision surgery, inspect the remaining femoral head (head+stem) and stem taper, if applicable, with a suitable retraction instrument to avoid an unnecessary (head + stem removal).
- Inspection of the stem taper and decision.
- Confirmation of implantation, used stem taper and decision.
- Head removal and inspection of the (head + stem) components.

Revision Surgery
- In case of revision surgery, inspect the remaining femoral head (head + stem) and stem taper, if applicable, with a suitable retraction instrument to avoid an unnecessary (head + stem removal).

- Inspection of stem taper deformation (low, high, middle, high).

Warning: Articulation with other ceramics or with metal is not recommended. Articulation with other ceramics or with metal is not recommended.

BIOLOX OPTION Head System

The BIOLOX delta head system addresses the needs of the orthopaedic surgical community for a system that can be used in cases of primary and revision surgery in order to offer the patient a low-wear bearing system. Additional neck lengths and stem options are available for total hip replacements, and the BIOLOX head system addresses the needs of the orthopaedic surgical community for a system that can be used in cases of primary and revision surgery in order to offer the patient a low-wear bearing system. Additional neck lengths and stem options are available for total hip replacements.

- The BIOLOX delta head system consists of two components:
  - A head adapter
  - A BIOLOX delta ceramic femoral head
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  - A head adapter
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Benefits
- Possibility for low-wear ceramic solution in revision and primary cases.
- Femoral head systems can be associated with primax or used stem taper.
- Malleable does not reduce the range of motion.
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- Easy assembly of head and adapter.
- Same benefits for BIOLOX forte material in BIOLOX delta.

BIOLOX OPTION Ceramic Femoral Head Data Sheet

Use trial heads
- Determine the neck length
- Check neck-balance
- Check range of motion

Assembly of Femoral Head and Adaptor
- Ensure selection of the correct BIOLOX OPTION head system (i.e., diameter, taper size, neck length, material, and taper length). The BIOLOX Option femoral head and adaptor must be implanted together. Before the final positioning of the BIOLOX ceramic femoral head, the operating surgeon must assemble the BIOLOX head system in the package shell according to the diagrams illustrated.

- Please note, the BIOLOX head head and adaptor are packaged together.

Hand Removal and Inspection of the Stem Taper
- In case of revision surgery, inspect the remaining femoral head (head+stem) and stem taper, if applicable, with a suitable retraction instrument to avoid an unnecessary (head + stem removal).

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