Biolox® Delta and Biolox® Delta Option

Surgical Technique
Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions for Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.
**Intended Use**

MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of functional deformity; and,
4. Revision procedures where other treatments or devices have failed

Shells with Biofoam® metal foam coating are intended only for uncemented arthroplasty.

Dynasty® modular shells with porous metal bead coating are intended only for uncemented arthroplasty.

(European Union Only) BIOLOX® delta Option Heads are intended for use in revision hip arthroplasty.

**Contraindications**

Patients should be warned of these contraindications. Contraindications include:

1. Overt infection;
2. Distant foci of infections (which may cause hematogenous spread to the implant site);
3. Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4. Skeletally immature patients (patient is less than 21 years of age at the time of surgery);
5. Cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
6. Neuropathic joints;
7. Hepatitis or HIV infection;
8. Neurological or musculoskeletal disease that may adversely affect gait or weightbearing.

**Additional Contraindications**

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient’s weight, activity level, and occupation. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.

**Product Specific Warnings and Precautions**

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

**Modular Components**

Always follow the recommended surgical technique. Failure to adhere to the advised assembly instructions may have potential to increase risk of fretting corrosion, fretting fracture or disassociation of the product. Prior to assembly, surgical debris must be cleaned from the interior of the female seat to ensure proper locking. Ensure components are firmly seated to prevent disassociation. The femoral head, neck taper of the femoral component, modular neck tapers, body taper, female seat of the proximal body must be clean and dry before assembly. Impact according to the recommended surgical technique. Scratching of femoral heads, modular necks and proximal and distal stem tapers should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint. Do not resterilize femoral prostheses with ceramic femoral heads seated on the stem, as sterilization may cause undetectable ceramic damage. Please refer to the section below named Hip Bearing System or specific warnings and precautions regarding ceramic femoral heads.

Stems and modular necks with the 12/14 SLT Taper should only be used in combination femoral heads with the 12/14 SLT Taper.
Ceramic Femoral Heads
Do not place ceramic components on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

On rare occasions, in vivo fracturing of the ceramic components may occur. In order to minimize this risk, the components were individually examined before delivery. Extremely careful handling is required with ceramic devices, which must not be used if dropped, even in the absence of any apparent damage. Even small scratches or impact points can cause wear and tear or fracture and lead to complications. Cause of fracture can be an overload on the prosthesis, for example through incorrect placement of the ceramic head on the stem taper or a wrong or missing fit between the ceramic head and the stem taper. The use of prosthesis components which are not released by MicroPort for combination with a ceramic component can also lead to the fracture of the implant. The recommended position of the acetabular insert (inclination/anteversion) must be observed. Only use a plastic tip to introduce the ceramic devices.

Fracture of ceramic components is a serious complication. Only use a plastic tip to introduce ceramic devices. Impact according to the recommended surgical technique. Patients should be advised to report unusual noise and/or sharp pain as both can be an indication of fracture. Decision to revise should not be postponed as ceramic fragments can cause severe damage to surrounding soft tissue and metal components. Revision outcomes after ceramic fractures can be compromised by the remaining ceramic debris present in the tissue even after careful debridement. Damage has been reported in polyethylene and metal components used in revisions after ceramic fractures. Metal heads should not be used after a ceramic fracture. Surgeons are advised to carefully consider all available implant options on an individual basis.

It must be noted that removal of all components including femoral stems and acetabular shells may not prevent accelerated wear due to ceramic debris in the tissue. Partial or complete synovectomy has been recommended by some authors.

All sizes of the Alumina Matrix Composite Heads ("Biolox Delta Femoral Head" and the "Delta Option Heads" used with "Delta Option Sleeves") are indicated for use with titanium alloy, cobalt chrome, or MicroPort stainless steel (not available in the U.S. or Canada) femoral stems.

The cross-linked "Dynasty® A-Class® Poly (UHMWPE) Liners" are designed to articulate with the following ceramic femoral heads:
- Alumina Matrix Composite "Biolox Delta Femoral Head" (diameter range 28-40mm)
- Alumina Matrix Composite “Delta Option Head” (diameter range 28-44mm)

Ceramic femoral heads should not be placed on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

A ceramic "Delta Option Head" and a titanium “Delta Option Sleeve” must always be used together.
Preoperative Planning
Preoperative assessment of the appropriate size and position of the implant components will provide intraoperative guidance.

An A/P X-ray of the pelvis will aid in leg length and offset assessment. Accurate preoperative templating requires good quality standardized radiographs of the pelvis and operative hip. Leg length discrepancies should be determined preoperatively and addressed intraoperatively. Radiographic overlays for the implants are available in 15 percent magnification.

**CAUTION:** Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively.

**Biolox Delta Head (Sleeveless)**
The ceramic femoral head is placed on the stem taper by twisting lightly and using axial manual pressure until it sits firmly.

Place the plastic head impactor on the pole of the ceramic femoral head, and with a moderate tap of the hammer in an axial direction, firmly and definitively fix it on the stem taper. The surface structure of the metal taper becomes distorted plastically by the tapping of the impactor, causing an optimal distribution of pressure and a torsion-resistant fixation.

**Biolox® Option System**
Trial heads must be used to determine the neck length and to check the tissue balance and the range of motion. A ceramic “Delta Option Head” and a titanium “Delta Option Sleeve” must always be used together.

The Biolox® Option femoral head and sleeve must be assembled and then implanted together into the patient. The ceramic femoral head is placed on the sleeve on a flat surface, and pressure is applied until resistance can be felt. It should be ensured that the ceramic femoral head is not canted or placed at an angle on the sleeve. Before impacting the femoral head and sleeve, the Biolox® Option system is placed on the implanted stem taper with a twisting motion, while applying manual pressure until it locks. As a rule, it should be easy to place the Biolox® Option system on the stem taper. Should pressure be necessary to seat the Biolox® Option system, the system must not be used.

The operating surgeon must place the plastic impactor on the pole of the Biolox® Option femoral head and then fix it firmly on the stem taper with one moderate tap on the impactor in an axial direction. It is possible to use more than one moderate tap to fix the Biolox® Option femoral head and sleeve on the stem taper. The surface structure of the metal sleeve and the stem taper becomes plastically deformed by the tapping of the impactor, thus producing an optimal pressure distribution and torsion-resistant fixation. The successful assembly of the head fixation must be tested by an attempt to remove the head by hand.

**CAUTION:** A metal hammer must never be used on the Biolox® Option femoral head.

Only unused and undamaged Biolox® Option systems packaged in their original packaging may be implanted. This means, for example, that a component of the BIOLOX® OPTION system that has been placed once on a stem, and later removed, must not be placed on the stem a second time. Likewise, a Biolox® Option system revealing any kind of damage must not be used, but must be discarded instead. This also applies to a Biolox® Option system that has fallen to the floor, for example.

**Revision Surgery**

**NOTE:** If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.
In case of revision surgery, the remaining femoral head (and sleeve, if applicable) must be extracted with a suitable extraction instrument to avoid unnecessary damage to the stem taper. After extraction, the remaining stem taper must be inspected. If the taper is undamaged, the BIOLOX® OPTION system can be used with the taper. If the taper is damaged, the operating surgeon must inspect the degree of damage and make sure that this damage is acceptable. Inspection of the stem taper and decision criteria:
Acceptable condition is used stem tapers displaying fine marks from head-stem disassembly.
Remove all ceramic particles. Any existing polyethylene acetabular bearing must also be removed, even if it is fixed in place.

**IMPORTANT:** Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions for Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.
### Biolox® Delta Head System

#### Biolox® Delta® Heads (CERAKITA)

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<th>Catalog No.</th>
<th>Head Diameter</th>
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<tr>
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#### Biolox® Delta® Option Heads and Sleeves (CERAKITC)

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<td>PHA044MD</td>
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<tr>
<td>PHA044LG</td>
<td>Long (+3.5) Neck Sleeve</td>
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<tr>
<td>PHA044XL</td>
<td>X-Long (+7) Neck Sleeve</td>
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<td>PHA04444</td>
<td>44mm Head</td>
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**NOTE:** Order 44mm separately as needed.
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