



BIOLOX^{®*} OPTION Ceramic Femoral Head

Data Sheet/
Surgical Technique

For Distribution in the
United States only



Final Setting onto the Stem

- The stem taper must be dry and free of any blood or debris (i.e., tissue, bone or cement particles).
- Place the *BIOLOX OPTION* head assembly on the stem taper with a twisting motion, while applying manual pressure until it locks.
- As a rule, it should be easy to 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 32mm: Seat the assembly using the plastic impactor on the pole of the femoral head and a light hammer.
- For heads with diameter 36mm and beyond: With the plastic impactor attachment and a mallet, strike the *BIOLOX OPTION* head assembly firmly/moderately a minimum of three times to ensure full seating on the stem taper (Fig. 4a).
- Test the assembly of the head fixation by trying to remove the head by hand.

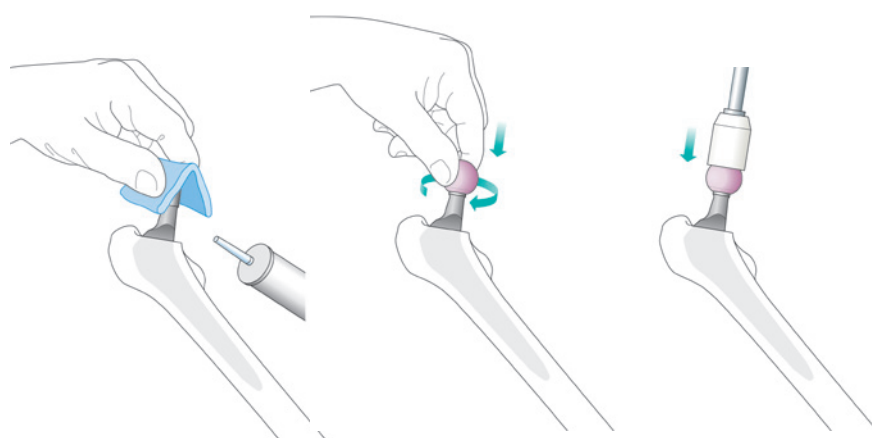


Fig. 4a

Note: The impactor should not be more than 20 degrees off the neck axis to avoid losing too much of the impact force (Fig. 4b).

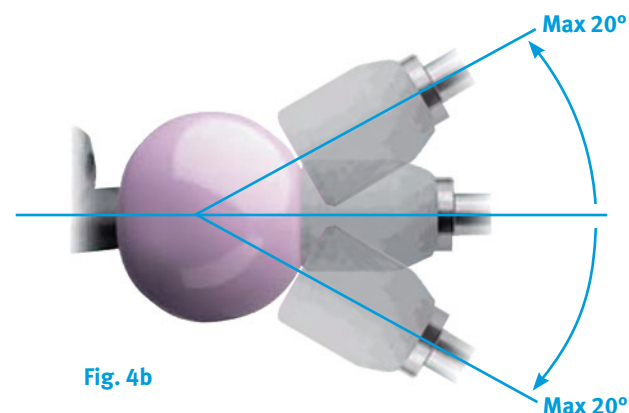


Fig. 4b

Ordering Information

Implants

BIOLOX OPTION Femoral Head System 12/14
Head: Alumina Matrix Composite
Head adapter: TiAl6V4
Sterile

Diameter	Neck Lengths	Taper	REF
28mm	S / -3.0	12/14	00-8777-028-01
	M / +0	12/14	00-8777-028-02
	L / +3.5	12/14	00-8777-028-03
	XL / +7.0	12/14	00-8777-028-04
32mm	S / -3.0	12/14	00-8777-032-01
	M / +0	12/14	00-8777-032-02
	L / +3.5	12/14	00-8777-032-03
	XL / +7.0	12/14	00-8777-032-04
36mm	S / -3.0	12/14	00-8777-036-01
	M / +0	12/14	00-8777-036-02
	L / +3.5	12/14	00-8777-036-03
	XL / +7.0	12/14	00-8777-036-04
40mm	S / -3.0	12/14	00-8777-040-01
	M / +0	12/14	00-8777-040-02
	L / +3.5	12/14	00-8777-040-03
	XL / +7.0	12/14	00-8777-040-04

References

- ¹ Kuntz M: Validation of a New High Performance Alumina Matrix Composite for use in Total Joint Replacement. Seminars in Arthroplasty 17, 2006, 141-5.
- ² CeramTec: BIOLOX delta – Nanocomposite for Arthroplasty, MT080011 – GB – 1.000.0805
- ³ Zagra L, et al: THA ceramic-ceramic coupling: The evaluation of the dislocation rate with bigger heads. In Lazennec JY, Dietrich M (eds): Bioceramics in Joint Arthroplasty, Darmstadt, Steinkopff, 2004, 163–168
- ⁴ Goldberg et al: A Multicentric retrieval study of the taper interfaces of a modular hip Prosthesis. Clin. Orthop. 401, 2002, 149 –161

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The CE mark is valid only if it is also printed on the product label.

Instruments

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.



Description	REF
Adapter extractor	01.00009.101



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 ceramic, i.e. excellent biocompatibility, low wear, high hardness, 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.

The *BIOLOX delta* Ceramic Head is made from a new alumina matrix composite developed by CeramTec GmbH.

Benefits

- Improved mechanical properties compared to alumina heads¹
- Additional neck length for diameter ≥28mm
- Additional diameters providing more ROM and stability
- Same benefits as *BIOLOX forte* remain for *BIOLOX delta*, i.e. appropriate for patients who are sensitive to specific metal elements

Sizing

Diameter/ Neck Length	28mm	32mm	36mm	40mm
S/ -3.0mm	•	•	•	•
M/ 0	•	•	•	•
L/ +3.5mm	•	•	•	•
XL/ +7.0mm	•	•	•	•

Caution: Do not use *BIOLOX OPTION* head without the head adapter.



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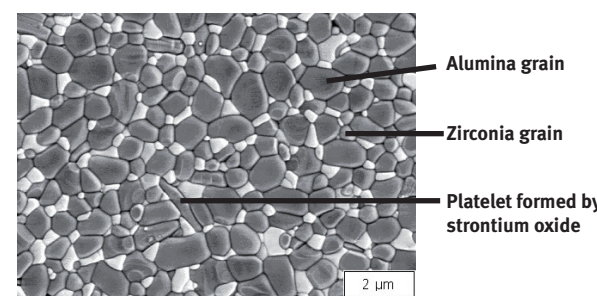


Science behind BIOLOX delta Material

BIOLOX delta is an aluminum oxide matrix composite ceramic consisting of approx. 82% alumina (Al₂O₃), 17% zirconia (ZrO₂) and other trace elements (percent by volume). The pink color is due to the chromium oxide (Cr₂O₃) that increases the hardness of the composite material.

Alumina provides the material's hardness and wear resistance, while zirconia, together with other additives, provides improved mechanical properties. The high density of the material and the very small grain size also contribute to the improved properties.

The result is a high-performance ceramic that offers the same advantages as *BIOLOX forte*: excellent biocompatibility, low wear, high hardness, good mechanical performance, superb chemical and hydrothermal stability.¹



Microstructure of *BIOLOX delta* (Courtesy of CeramTec GmbH)

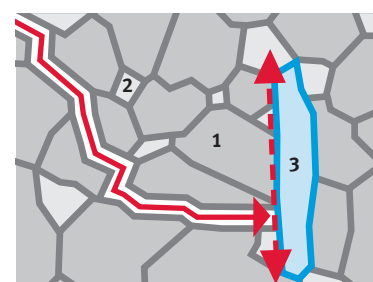
The Microstructure

The first toughening mechanism used in *BIOLOX delta* material results from the introduction of small, homogeneously distributed yttria-stabilized tetragonal zirconia particles (Y-TZP) in a stable alumina matrix. The spatial separation of these zirconia particles reduces the likelihood of structural transformation and prevents the initiation or propagation of cracks.



The principle of transformation-toughening by small zirconia particles, which are dispersed in the alumina matrix.
1. Alumina grain;
2. Zirconia grain.

The second toughening mechanism is achieved by the addition of strontium oxide, which forms platelet-like crystals. These platelets dissipate energy by deflecting cracks, thereby increasing material strength and toughness.



The principle of reinforcement by platelet-like crystals in an alumina matrix.
1. Alumina grain;
2. Zirconia grain;
3. Platelet-like crystal.

Improved Mechanical Properties

The excellent flexural strength and reduced grain size of *BIOLOX delta* material explain its value as an alternative bearing material, when articulating against highly-crosslinked polyethylene.

Mechanical Properties and Benefits of Third Generation Alumina and Alumina Matrix Composite Ceramic²

Property	Provides	<i>BIOLOX forte</i> third-generation alumina	<i>BIOLOX delta</i> fourth-generation ceramic
Bending strength (MPa)	Mechanical properties	630	1380
Hardness (HV)	High hardness – low wear	2000	1925
Microstructure (µm)	Small grain size – increased strength	≤ 1.8	≤ 1.0
Density (g/cm ³)	High density – better surface finish	3.98	4.37
Young's modulus (GPa)	High Young's modulus – good stability (low deformation)	380	350
Fracture toughness (MPa m ^{0.5})	High reliability – reduced risk of fracture	3.2	6.5

Enhanced Variety with BIOLOX delta

The *BIOLOX OPTION* head system can be used in conjunction with compatible acetabular and femoral stem components for total hip arthroplasty. A variety of diameters and neck lengths are available for various patient anatomies, adjustment of the tension of the ligaments, and reconstruction of the center of the physiological head of the femur. The size of the femoral head selected must match the inner diameter of the articulating surface.

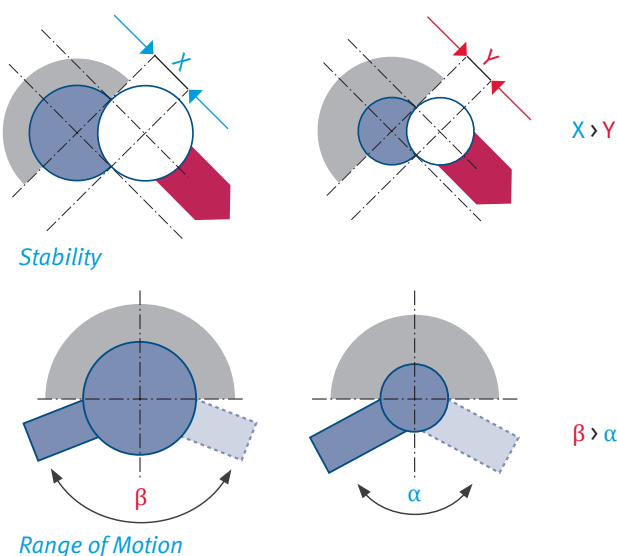
The *BIOLOX OPTION* head system may only be used in combination with highly cross-linked or conventional polyethylene (PE). To determine whether these devices have been authorized for use in a desired combination, please contact your Zimmer sales representative or visit the Zimmer Web site: www.productcompatibility.zimmer.com.

Caution: Articulation with other ceramics or with metal is not approved in the US.

Increased Stability and Range of Motion

A large diameter articulation offers increased stability due to the increased displacement distance ($X > Y$) and a greater technical range of motion ($\beta > \alpha$) compared to a conventional 28mm articulation. These obvious clinical benefits, in combination with low-wear alternative bearings (ceramic on highly cross-linked polyethylene), result in improved functionality and durability.

Clinical studies confirm that there is a statistically significant decrease in impingement, subluxation and dislocations with 36mm ceramic-on-ceramic coupling (0.88%) when compared to 28mm femoral heads (4.64%) in THR.³



BIOLOX OPTION Head System

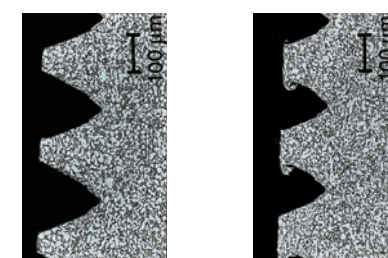
The *BIOLOX OPTION* head system addresses the needs of the orthopaedic surgical community for a system that can be used in cases of primary and revision surgery in order to offer the patient a low-wear bearing option. Additional neck lengths and taper options are available for total hip replacement. This makes the *BIOLOX OPTION* head system a flexible system with a wide range of combination possibilities.

The *BIOLOX OPTION* head system consists of two components:

- A head adapter and a
- *BIOLOX delta* ceramic femoral head

The head adapter is made of titanium alloy TiAl6V4 (ISO 5832-3), with an 12/14 inner taper that interlocks with the femoral stem. The ceramic femoral head with a specially designed inner taper matches the outer taper of the adapter. The surface structure of the metal stem and the head adapter taper plastically deform during tapping with the impactor, which results in an optimal distribution of pressure and a torsion-resistant fixation.

Example of Legacy Centerpulse Taper Micrographs



Pristine taper structure

Deformed taper structure after 61 months *in vivo*

Benefits

- Possibility for low-wear ceramic solution in primary and revision cases
- Femoral Head System can be assembled with pristine or used stem tapers
- Adapter does not reduce the range of motion
- Improved mechanical properties¹ compared to alumina heads
- Easy assembly of head and adapter
- Same benefits for *BIOLOX forte* remain for *BIOLOX delta*

Sizing

- 4 head diameters: 28, 32, 36 and 40mm
- 4 neck lengths: S/-3.0, M/+0, L/+3.5 and XL/+7.0mm
- 12/14 stem taper adapters



Surgical Technique Considerations BIOLOX OPTION Head System

The *BIOLOX OPTION* head system may only be used with Zimmer stems, and in combination with highly cross-linked or conventional Zimmer polyethylene.

Preoperative Planning

Planning of the operation is based on the information available. Identification of the stem, which remains *in situ*, and the condition of the stem taper, is of prime importance during the preoperative planning. The inner taper of the head adapter must fit the stem taper.

Technical information concerning compatibility and stem taper type can be found on our home page www.productcompatibility.zimmer.com.

The *BIOLOX OPTION* head system can be either used on a:

- new stem taper for primary and revision cases, or on a
- used stem taper in revision cases

Head Removal and Inspection of the Stem Taper

- In case of revision surgery, extract the remaining femoral head (and adapter, if applicable) with a suitable extraction instrument to avoid unnecessary damage to the stem taper.
- Inspection of the stem taper and decision:
 - Tolerable condition: used stem tapers displaying fine marks from head/stem disassembly and/or up to a score of 3 as described by Goldberg⁴ (taper surface discolored or dull, or <10% of taper surface containing black debris, pits, or etch marks; Several bands of fretting scars or single band involving more than three machine lines).
 - Intolerable stem taper deformation (see Figs. 1 through 3). Do not use the *BIOLOX OPTION* head system with tapers in these circumstances!

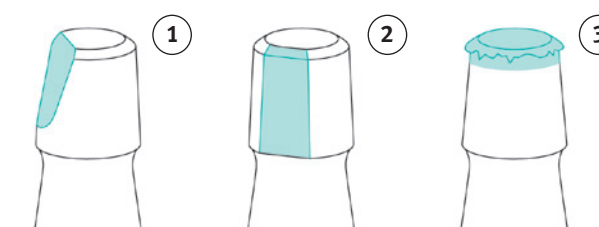


Fig. 1: Slanted stem taper; not tolerable

Fig. 2: Stem taper with broad truncation; not tolerable

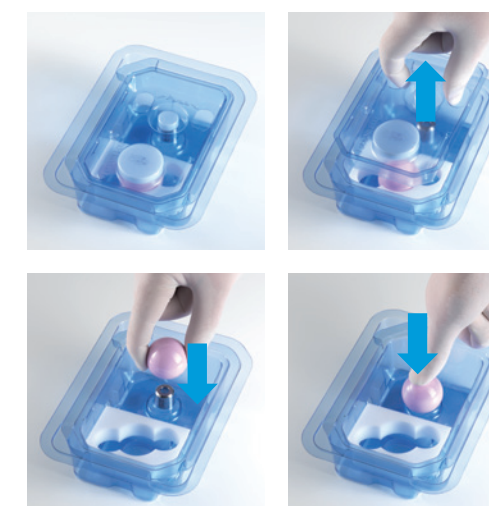
Fig. 3: Crushed stem taper; not tolerable

Use trial heads

- Determine the neck length
- Check tissue balance
- Check range of motion

Assembly of Femoral Head and Adapter

- Ensure selection of the correct *BIOLOX OPTION* head system (i.e., diameter, taper size, neck length, material, manufacturer, etc.)
- The *BIOLOX OPTION* femoral head and adapter must be implanted together. Before the final positioning of the *BIOLOX OPTION* ceramic femoral head, the operating surgeon must assemble the *BIOLOX OPTION* head system in the packaging shell according to the diagrams (see figures below).
- Please note, the *BIOLOX OPTION* head and adapter are packaged together.



Assembling of the BIOLOX OPTION Head System

- The ceramic femoral head is placed on the head adapter, which remains in its position, and pressure is applied until resistance is felt. The ceramic femoral head must be placed straight down on the sleeve.
- The system components are ready for assembly on the femoral stem; no washing or cleaning is necessary.