



BIOLOX^{®*} delta OPTION Ceramic Femoral Head

Data Sheet/
Surgical Technique



What is delta?

The new alumina matrix composite *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, outstanding chemical and hydrothermal stability, but with higher strength than alumina ceramic.

BIOLOX delta Head Family

The *BIOLOX delta* head family consists of two product lines:

- **BIOLOX delta Ceramic Femoral Heads**
a standard head, only for cases with new femoral stem components
- **BIOLOX OPTION Ceramic Femoral Head System**
a head and metal adapter, for primary and revision cases

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

Benefits

- Improved mechanical properties compared to alumina heads
- Additional neck length for diameter ≥ 32 mm
- 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/ -3.5mm	•	•	•	•
M/ 0	•	•	•	•
L/ +3.5mm	•	•	•	•
XL/ +7.0mm	•	•	•	•

Caution: Must only be used in combination with *BIOLOX OPTION* Adapter.

* Trademark of CeramTec AG.

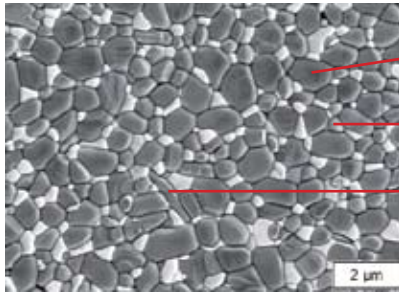


Science behind BIOLOX delta Material

BIOLOX delta is an aluminum oxide matrix composite ceramic consisting of approx. 75% alumina (Al_2O_3), 24% zirconia (ZrO_2) and other trace elements. The pink color is due to the chromium oxide (Cr_2O_3) 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, outstanding chemical and hydrothermal stability.



Microstructure of BIOLOX delta
(Courtesy of CeramTec AG)

Improved Mechanical Properties

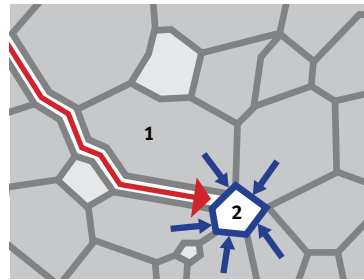
The excellent flexural strength and reduced grain size of *BIOLOX delta* material explain its value as an alternative bearing material, when articulating against highly-crosslinked polyethylene.

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

Property	Provides	Third-generation alumina	BIOLOX delta
Bending strength (MPa)	Improved mechanical properties	> 550	> 950
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
Laser marking	Improved product safety	yes	yes
Hipped	Reduced grain size, homogenous distribution	yes	yes
Proof tested (100%)	Quality control process	yes	yes
Bearing combination	Suitable for ceramic-on-polyethylene	yes	yes

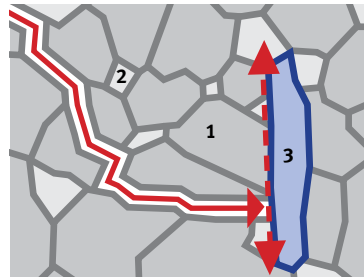
The Microstructure

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.

Enhanced Variety with BIOLOX delta

The *BIOLOX delta* head and *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.

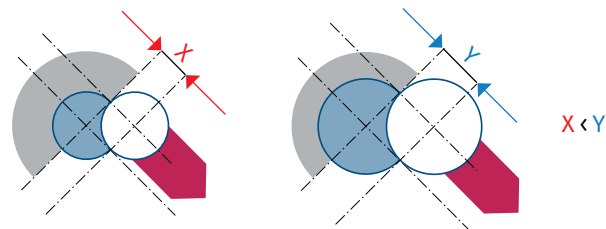
The *BIOLOX delta* head and *BIOLOX OPTION* head system may only be used in combination with highly cross-linked or conventional polyethylene (PE). To determine whether these devices have been authorized for use in a desired combination, please contact your Zimmer sales representative or visit the Zimmer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

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

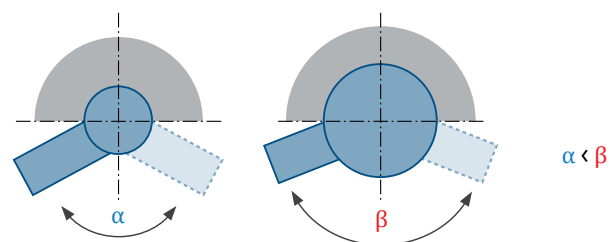
More Stability and Range of Motion

A large diameter articulation offers increased stability due to the increased displacement distance ($X < Y$) and a greater technical range of motion ($\alpha < \beta$) compared to a conventional 28 mm 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 36 mm ceramic-on-ceramic coupling (0.88%) when compared to 28 mm femoral heads (4.64%) in THR.¹



Stability



Range of Motion

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 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:

- An adapter sleeve and a
- *BIOLOX delta* ceramic femoral head

The adapter sleeve 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 sleeve. The adapter can plastically deform to accommodate the small damaged areas (less than 0.25mm high) that could be present on the taper of a non-revised stem to maintain the optimal distribution of pressure on the ceramic head.

Example of Legacy Centerpulse Taper Micrographs



Brand-new taper structure



Deformed taper structure after 61 months *in vivo*

Benefits

- Possibility for low-wear ceramic solution in revision cases
- Femoral head can be combined with new stems, unused or slightly damaged stem tapers – i.e., those with scratches of less than 0.25mm
- Adapter 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* 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 is only cleared 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 adapter sleeve 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 used on a:

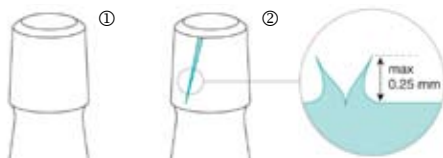
- new stem taper for primary and revision cases, or on a
- implanted or slightly damaged stem taper in revision cases

Definition regarding stem taper condition:

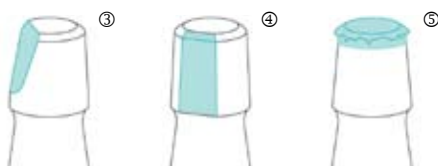
- **Implanted stem taper:** condition of the stem taper after removal of the intact head
- **Slightly damaged stem taper:** condition of the stem taper after revision of the femoral head

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:
 - Pristine taper (see fig. 1)
 - Tolerable condition with scratches of less than 0.25mm (see fig. 2)



- Intolerable condition (see figs. 3 through 5)
Do not use the *BIOLOX OPTION* head system with tapers in these circumstances!

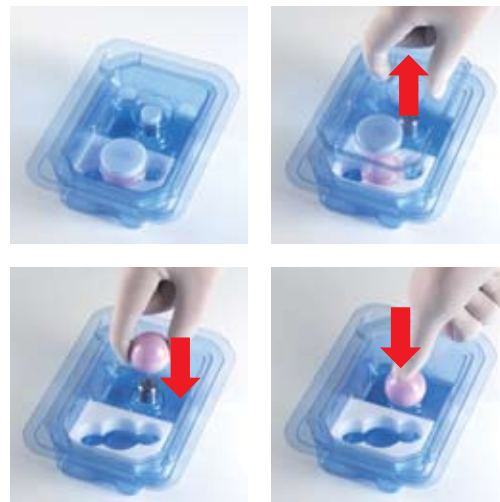


Use trial heads

- 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.

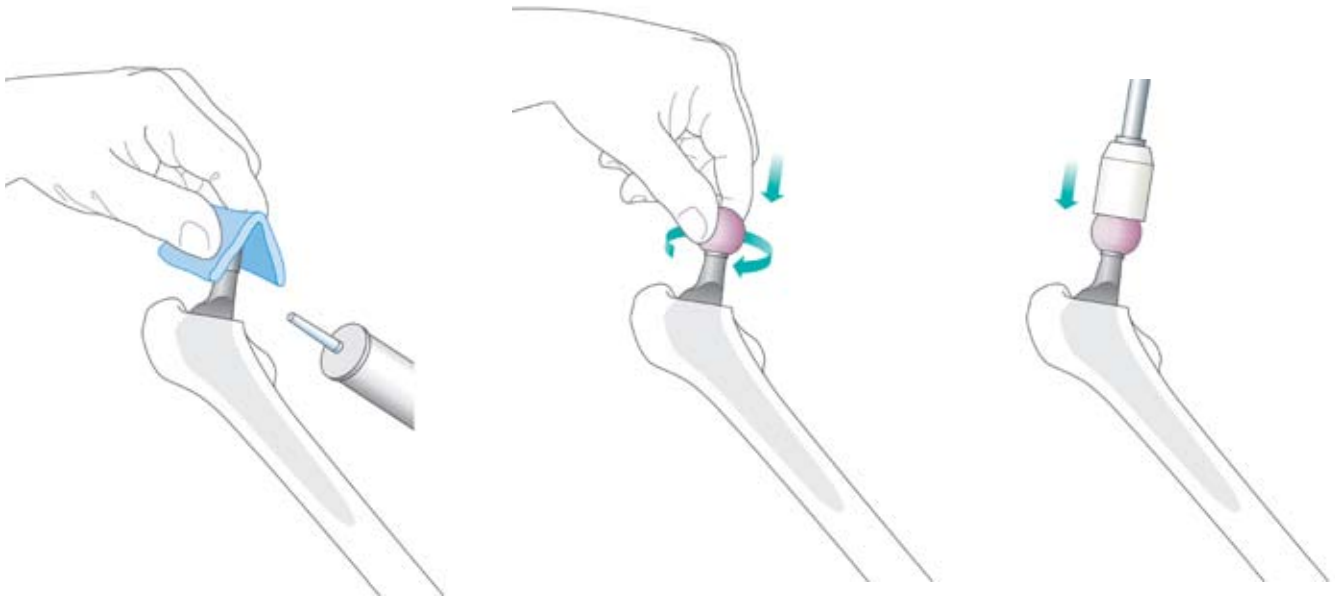


Assembling of the *BIOLOX OPTION* Head System

- The ceramic femoral head is placed on the adapter sleeve, 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.

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.
- Seat the assembly using the plastic impactor on the pole of the femoral head and a light hammer.
- Test the assembly of the head fixation by trying to remove the head by hand.



Ordering Information

Implants

BIOLOX OPTION Femoral Head System 12/14

Head: Alumina Matrix Composite

Adapter Sleeve: TiAl6V4 (ISO 5832-3)

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

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

Femoral Head	BIOLOX OPTION Head System
	00-8777-028-01
	00-8777-040-04



Stem Taper	Taper 12/14
Hard/Soft Bearing	Conventional Polyethylene Highly Crosslinked Polyethylene (Durasul® and Longevity® Polyethylene)

References

- ¹ 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

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