

**BIOLOX<sup>®</sup>**

## BIOLOX<sup>®</sup> OPTION – Ceramic Femoral Ball Heads for Hip Revision



Contains CD ROM  
with 3-D Animation

**A New Possibility to  
Optimize the Wear Couple**

**CeramTec**  
THE CERAMIC EXPERTS



## Optimize Revision

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### Cause and effect

Aseptic loosening is the most common cause for hip revision arthroplasty. Frequently, only the acetabular socket is affected, the femoral stem still being well fixed. With BIOLOX®OPTION, a ceramic femoral ball head can now be placed on a stem remaining in situ provided the stem taper is in a largely undamaged condition. This provides the option to use wear couples that are highly resistant to abrasion and wear in revision hip arthroplasty.



Source: OA Dr. H. Hessler, Klinik für Unfall- u. Wiederherstellungschirurgie, Allgemeines Krankenhaus Celle (Germany)

### A better solution: upgrading the wear couple

The newly introduced system allows the surgeon to implant a better performing and potentially longer lasting wear couple than the one used in primary surgery. As wear-induced aseptic loosening can also affect a revision prosthesis, optimizing the wear couple with ceramic components is an extremely attractive option for the patient. This optimization of the wear couple can reduce the possibility of a further revision due to wear related osteolysis.

In the very rare event of a ceramic component fracture, BIOLOX®OPTION ball heads if used in conjunction with a BIOLOX® liner offer the safest wear couple alternative. It rules out the risk of third body wear due to the fact that any undetected ceramic particles left in the surrounding tissues will have very little effect on the longevity of the wear couple.

BIOLOX®OPTION also gives the surgeon additional options for primary THA by providing additional neck length sizes such as the XL previously unavailable.

***A typical situation in revision surgery – acetabular osteolysis and a well fixed femoral stem***



## Enhancing Safety and Longevity

### Ceramics as a new alternative

In case of a revision when the femoral stem is well fixed in the bone, it is necessary to change the femoral ball head. Until recently, a metal femoral ball head was the only component that a surgeon could safely use. Ceramic femoral ball heads could not be recommended in these cases because of possible reliability issues resulting from a previously used stem taper.

**Optimal solution** – acetabular cup revision using a ceramic-on-ceramic wear couple. The BIOLOX®OPTION femoral ball head was placed on the primary stem remaining in situ.



Source: OA Dr. H. Hessler, Klinik für Unfall- u. Wiederherstellungschirurgie, Allgemeines Krankenhaus Celle (Germany)

BIOLOX®OPTION now allows the surgeon to choose a femoral ball head made of BIOLOX® *delta* with a specially designed metal sleeve designed to reduce the effect of stem taper imperfections on the reliability of the ball head used with a firmly fixed femoral stem. The BIOLOX®OPTION system was developed to provide revision patients with a ceramic-on-polyethylene or a ceramic-on-ceramic wear couple alternative in order to enhance the wear reduction capabilities of the implanted system.

### Double protection

The BIOLOX®OPTION system consists of an alumina matrix composite femoral ball head and a specially designed titanium sleeve. The sleeve acts to diminish the effect of minor damage to the taper and ensures an even distribution of stresses on the inside of the femoral ball head. Together with the superior material properties of the BIOLOX® *delta* alumina matrix composite it offers enhanced system reliability.

### The benefits of BIOLOX®OPTION

- Provides ceramic alternatives for hip revision
- Allows optimization of the wear couple during revision
- Offers additional options for primary THA
- Manufactured of high performance BIOLOX® *delta* ceramic material
- Specially designed titanium sleeve for enhanced reliability



## Optimizing the Wear Couple during Revision

Regardless of the type of wear couple used in primary arthroplasty, BIOLOX®OPTION gives you the option of choosing the lowest wear articulation when revising a hip prosthesis.

### From Me/PE to Ce/PE or Ce/Ce

For patients with an existing metal-on-polyethylene wear couple BIOLOX®OPTION offers the opportunity to upgrade to two of the bearings with the lowest wear rate available: ceramic-on-polyethylene or a ceramic-on-ceramic wear couple.

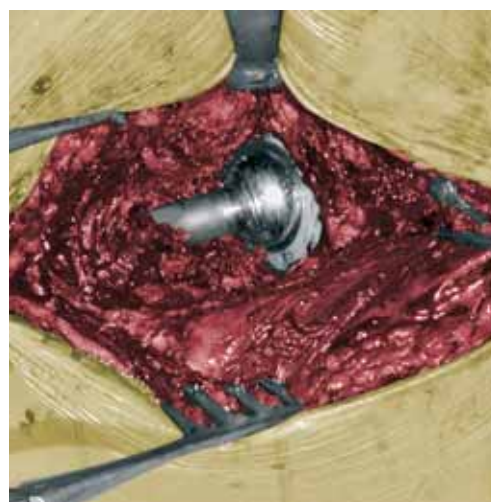
### From Me/Me to Ce/PE or Ce/Ce

If the patient needing the revision has a metal-on-metal articulation, the new system provides the choice of using either the ideal ceramic-on-ceramic or the standard ceramic-on-polyethylene wear couple. Either one of these wear couples would minimize metal toxicity as well as potential hypersensitivity to metal.

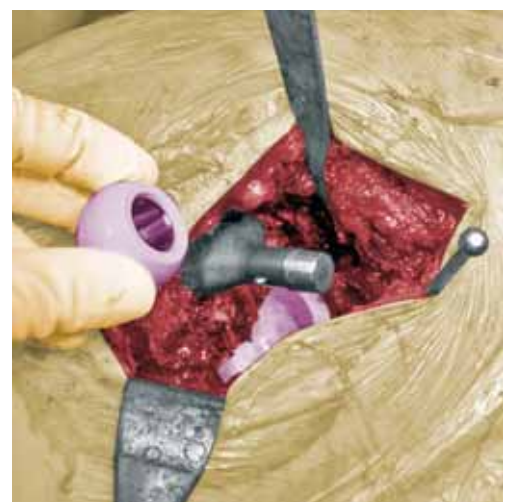
### More ROM

BIOLOX®OPTION also gives the surgeon the opportunity to utilize a larger wear couple diameter, thereby providing a greater range of motion (ROM) and also reducing the risk of impingement and subluxation.

*One of the major causes of revision in systems using the metal on metal wear couple is related to metal sensitivity and allergic reactions.*



*Replacement by a system using the ceramic-on-ceramic wear couple (with a BIOLOX®OPTION femoral ball head) eliminates this potential situation.*





## Expanded Options

### After ceramics: ceramics

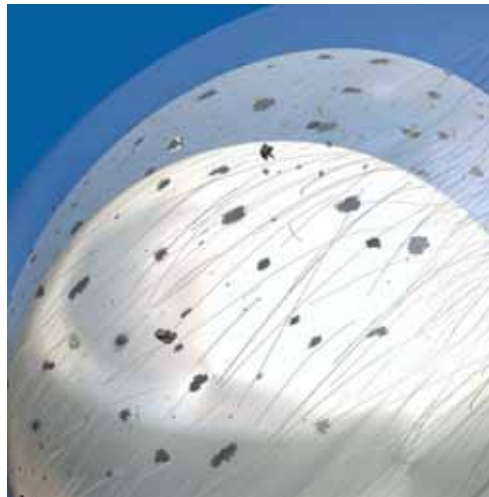
Until recently, surgeons faced a serious dilemma in the very rare event of a ceramic component fracture. As it is practically impossible to remove all fracture particles from the surrounding tissues during revision, the new implant system's articulation could be damaged by third body wear. Similar damage can be created by debris from the fracture of periarticular osteosynthesis implants.

Third body wear can only be avoided with a ceramic-on-ceramic wear couple. Because of its diamond-like hardness on both sides of the articulation, it is largely not affected by any foreign particles. BIOLOX® OPTION allows you to change to a wear couple offering increased safety when leaving a well-fixed stem in place.

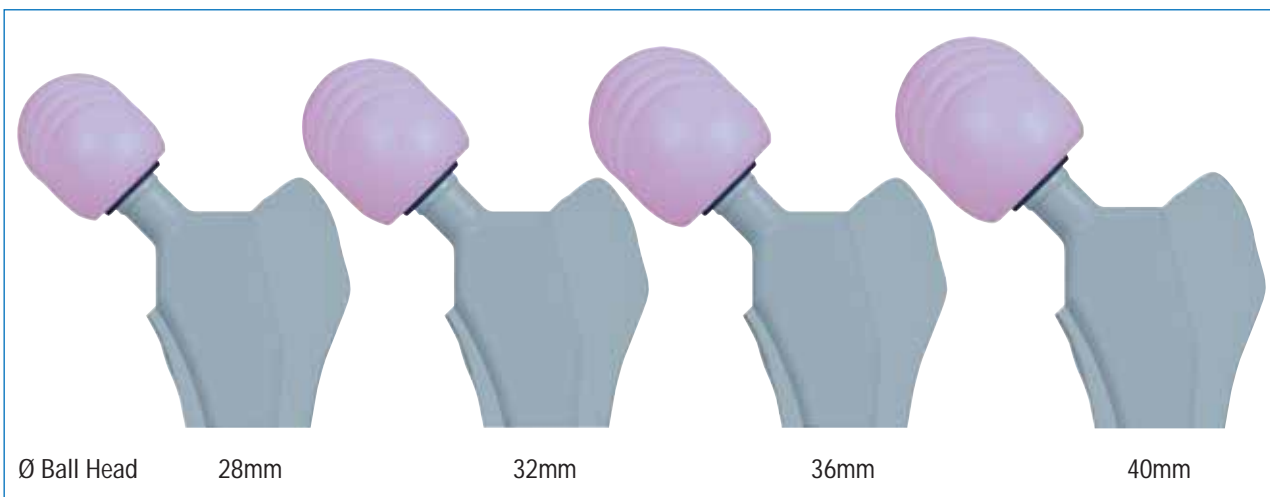
*The numerous available neck and sleeve sizes allow the surgeon to place an implant in the optimum position for a given patient's anatomy.*

### Additional options for primary THA

CeramTec's standard range of neck sizes S, M and L are complemented by the additional XL neck size alternative offered as part of the BIOLOX® OPTION system providing greater offset and additional options to optimize the implant position relative to the patient's anatomy.



*Third body particles present a serious threat to articulating surfaces of metal and polyethylene. Third body particles can damage them and eventually create increased abrasion.*





## High-Tech for Patients and Surgeons

### Simple modules

The BIOLOX®OPTION femoral ball heads are made of the wear resistant alumina matrix composite ceramics, BIOLOX® *delta*. They are available in diameters of 28mm, 32mm, 36mm and 40mm.

### BIOLOX® *delta* femoral ball heads can be combined with BIOLOX® *forte* liners.

The titanium sleeves are manufactured using a clinically proven alloy of titanium – TiAl<sub>6</sub>V<sub>4</sub>. They are available for neck sizes S, M, L and XL. Their skirt-free design does not affect the range of motion (ROM).

The BIOLOX® OPTION femoral ball head and the sleeve use a specially designed 16/18 taper. The inside of the sleeve uses either an 8/10, 10/12 or a 12/14 design taper in order to interact with the femoral stem tapers commonly used globally.

The BIOLOX® OPTION system is available for these sizes:

Taper diameter (mm)	Taper angle
8/10	5°46'
10/12	6°
12/14	5°46'

**Numerous combinations:**  
The BIOLOX®OPTION femoral ball heads can be used in combination with the ceramic liners of the BIOLOX® family as well as with liners made of conventional and highly crosslinked polyethylene.

Head-Ø	28mm	32mm	36mm	40mm
BIOLOX® <i>delta</i>				
BIOLOX® <i>forte</i>				
PE / XPE				

BIOLOX® *forte*
 BIOLOX® *delta*
 Polyethylene / XPE



## Superior Material

### Superior mechanical properties

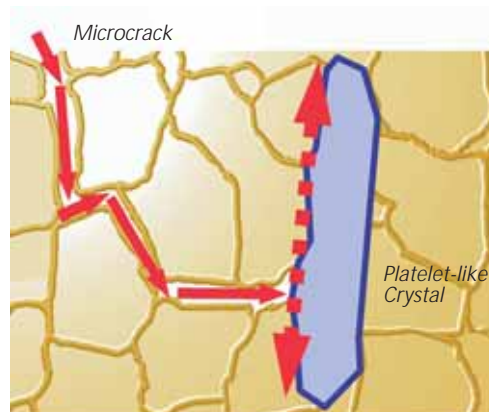
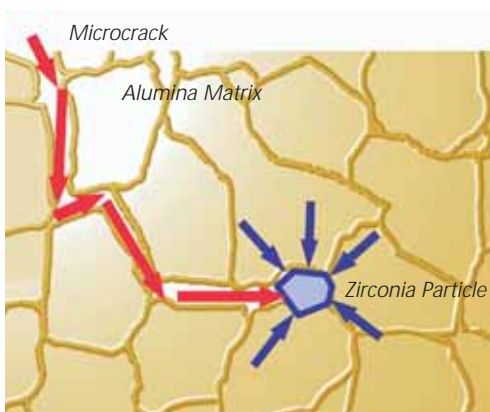
BIOLOX<sup>®</sup>OPTION femoral ball heads are made of an extremely hard alumina matrix composite ceramic material with excellent material properties. The extraordinary properties are created by structural mechanisms designed to interact with one another in order to enhance the mechanical properties. The mechanisms drastically increase the strength and toughness of the ceramic material. These mechanical properties allow our designers to create component geometries which were impossible with the ceramic materials used in the past.

### The benefits of BIOLOX<sup>®</sup> delta

- Increased material and mechanical properties
- Additional design flexibility
- Higher reliability
- Diamond-like hardness
- Excellent biocompatibility

### Proven advantages

BIOLOX<sup>®</sup> delta exceeds previously used ceramic materials in mechanical properties, strength and fracture toughness. At the same time it offers the proven advantages of established ceramic components: extremely low wear rate, proven long-term clinical history, complete implant stability and excellent biocompatibility.



**The principle of transformation toughening** (left): Nano-sized zirconia particles dispersed in the stable alumina matrix absorb impact forces in a manner similar to an automotive airbag.

**The principle of platelet reinforcement** (right): Platelet-like crystals dissipate the energy of a microcrack progressing on the microstructure.



## Is the BIOLOX®OPTION System Compatible with the Implanted Femoral Stem?

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Assistance in identifying the stem taper design can be found at [www.hiprevision.de](http://www.hiprevision.de)

Exact matching of the stem taper

A large variety of past and presently used stem types with different tapers have been implanted over the years. Quite often not all the data needed for clear identification is available when a revision becomes necessary. The web portal [www.hiprevision.de](http://www.hiprevision.de) provides useful information that helps surgeons to recognize the type of stem and the stem taper details of a stem that is going to be left in the patient after a revision. Because of the need for the stem taper to match the exact characteristics of the BIOLOX®OPTION system to be used, it is important to identify the implant manufacturer who will provide you with the BIOLOX®OPTION components you need.

It is critical that the type of stem and accompanying stem taper be an exact match. If this cannot be clearly identified, you should contact the manufacturer before performing the revision surgery. A mismatch between taper and sleeve can severely affect the reliability of the system.



The internet portal, [www.hiprevision.de](http://www.hiprevision.de) is constantly updated and supported by all leading orthopaedic implant suppliers.





## Stem Taper Damage – What are our Recommendations?

In order to avoid unnecessary damage to the stem taper during the surgical procedure, the femoral ball head found in place should only be extracted with a suitable extraction instrument. Even then, the taper may be damaged in the removal process. Minor damage as described below is tolerated by the BIOLOX®OPTION system. Major damage, however, can substantially compromise the longevity of the implants and is therefore contraindicated. The surgeon can classify the degree of damage using the illustrations shown below.

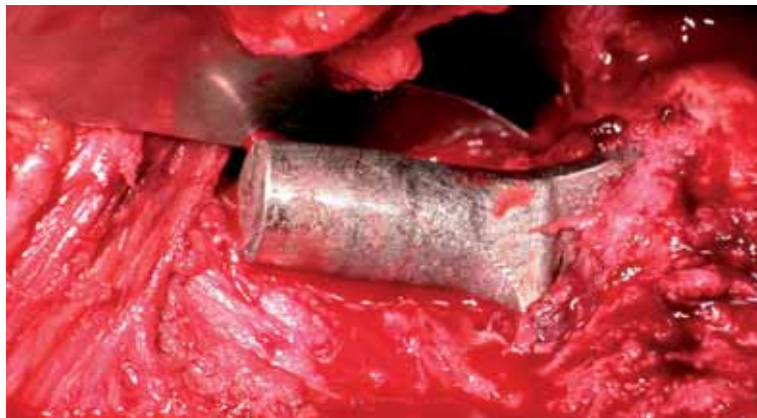
### Caution:

In cases in which the BIOLOX®OPTION system can only be placed on the stem taper by force using heavy pressure due to scratches of more than 0.25mm or other damage, the BIOLOX®OPTION system should not be used.

**Minor damage on stem taper – BIOLOX®OPTION may be used**



**Major damage on stem taper – BIOLOX®OPTION must not be used**



Source: OA Dr. H. Hessler, Klinik für Unfall- u. Wiederherstellungschirurgie, Allgemeines Krankenhaus Celle (Germany)

### Allowed:



- Previously used but largely undamaged stem taper
- Stem taper with light scratches (less than 0.25mm in width)

### Not allowed:

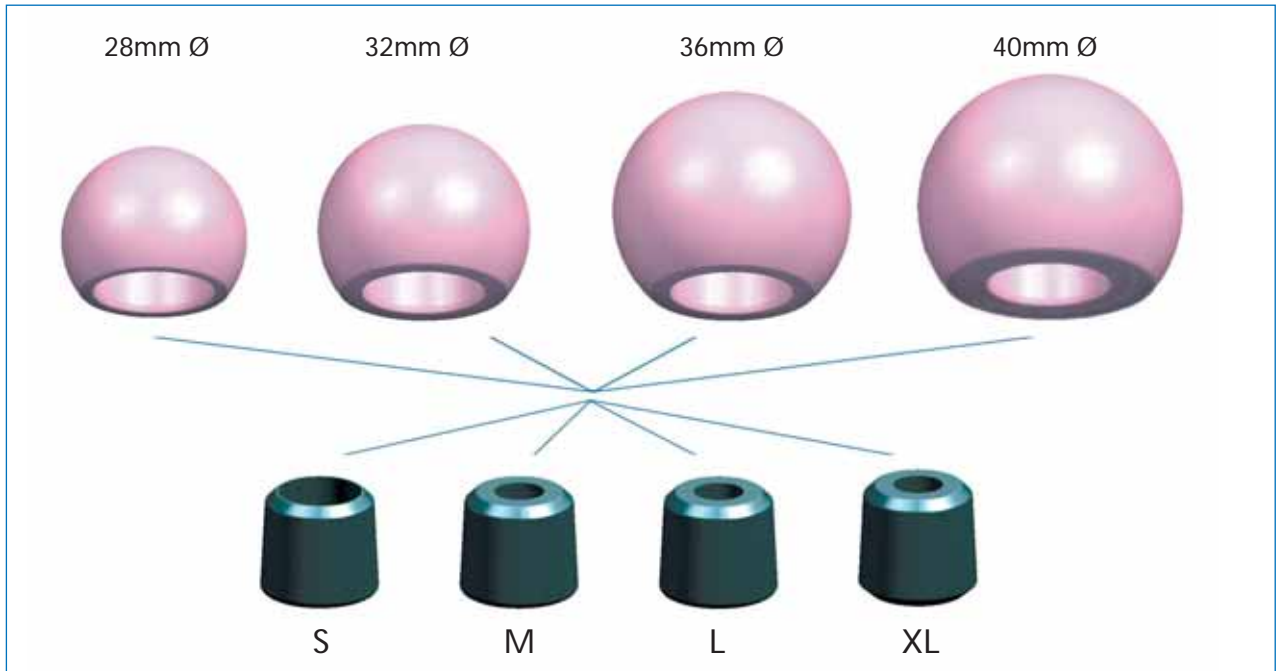


- Heavily scratched stem taper (scratches of more than 0.25mm in width)
- Taper with broad truncation
- Crushed taper



## Easy to Handle

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**The BIOLOX®OPTION system:** All femoral ball heads can be combined with all sleeves.

The BIOLOX®OPTION system is easy to use intraoperatively. It is packaged in a specially designed package which allows for the sleeve and the femoral ball head to be combined prior to the placement on the existing femoral stem. Once this is done, the sleeve and femoral ball head are placed on the clean, dry stem taper and impacted according to the instructions of the implant manufacturer.

In order to ensure optimum results from the BIOLOX®OPTION system, the instructions for use provided by CeramTec AG and by the orthopaedic implant companies must be followed carefully.





## Availability of the BIOLOX®OPTION system

The BIOLOX®OPTION system is marketed and sold by our customers, the orthopaedic implant manufacturers. Surgeons are asked to contact their orthopaedic implant suppliers for more information.

## Disclaimer

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For detailed information please refer to the enclosed CD ROM. The pictures, animations and presentation files, whether in total or as single slides, may be used freely for scientific and educational purposes. The 3-D animations are included in files ending with the postfix "AVI".

## References

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## Ceramics in Orthopaedics



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THE CERAMIC EXPERTS

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