

BIOLOX[®]
delta

CERAMIC FEMORAL HEADS



▶ MECHANICAL
PERFORMANCE

▶ RELIABILITY

▶ WEAR REDUCTION



INTRODUCTION

Alumina ceramic femoral heads have been used since the 1970s as an alternative bearing material in total hip arthroplasty (THA). Alumina ceramic femoral heads offer excellent biocompatibility, good mechanical performance, high hardness and chemical and hydrothermal stability, which make them well suited for THA. With over 2.5 million ceramic femoral heads implanted, a significant amount of clinical follow-up is available.

While the clinical experience with alumina ceramic femoral heads has been generally good, there have been component fracture failures resulting from material issues in first generation alumina ceramics. Incremental material and processing changes have been implemented to reduce this risk. The introduction of high purity, chemically derived, sub-micron alumina powders — as well as improved processing technologies, such as hot isostatic pressing (HIPing) — has significantly improved material properties of alumina ceramics. The current generation of alumina material for orthopaedic applications, BIOLOX® *forte* (CeramTec AG), has been available since 1994.

While improvements to early alumina ceramics have been significant, limitations in the mechanical properties of pure alumina ceramics coupled with the higher demands of today's younger patients required the development of an advanced ceramic material. The result of that development is BIOLOX® *delta* ceramic, manufactured by CeramTec AG, a world leader in ceramics and the leading company in the manufacturing of bioceramics for orthopaedic applications.



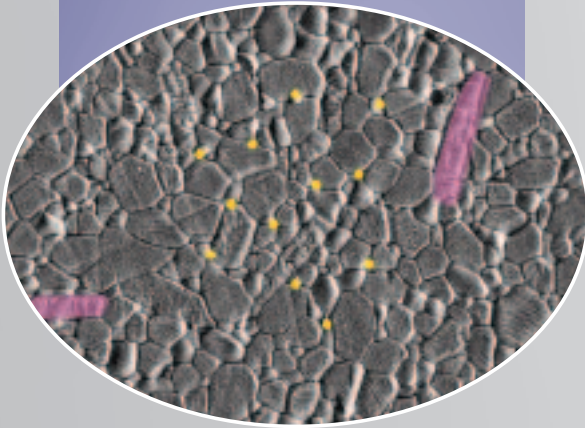
BIOLOX *DELTA* CERAMIC

AN ADVANCED MATERIAL

ALUMINA MATRIX

● Y-TZP PARTICLES

● MIXED OXIDE PLATELETS



BIOLOX *delta* is a zirconia-toughened, platelet-reinforced alumina ceramic (ZPTA), designed to incorporate the wear properties and stability of alumina with vastly improved material strength and toughness. BIOLOX *delta* contains approximately 74 percent alumina and 25 percent zirconia. Additives of chromium dioxide and strontium oxide enhance the performance of the material.

The alumina material provides BIOLOX *delta* with high hardness, excellent biocompatibility and hydrothermal stability. Ytria-stabilized zirconia particles (Y-TZP) are finely dispersed throughout the alumina matrix, increasing mechanical strength and fracture toughness over pure alumina. In zirconia-toughened alumina (ZTA) materials, some of the original hardness of the alumina material is lost. The addition of chromium oxide restores the desired material hardness to the matrix. Finally, strontium oxide (SrO) added to the material forms strontium aluminate ($\text{SrAl}_{12}\text{O}_{19}$) platelets during the sintering process. These platelets prevent microcracks in the material from advancing by dissipating crack energy. The result is a further increase in material strength and strength distribution, as well as an increase in fracture toughness.² The final product is a high-strength material with high hardness and high toughness, a material perfectly suited for applications in THA.

THE FINAL PRODUCT IS A HIGH-STRENGTH MATERIAL WITH HIGH HARDNESS AND HIGH TOUGHNESS, A MATERIAL PERFECTLY SUITED FOR APPLICATIONS IN THA.

MATERIAL PROPERTIES OF CERAMICS

Important characteristics of successful orthopaedic implants include good mechanical performance, reliability and wear resistance. These characteristics translate into the engineering material properties of strength, fracture toughness, hardness and stability.

- **Strength** refers to a material's ability to withstand applied loads.
- **Fracture toughness** is a measure of a material's resistance to crack propagation under stress.
- **Stability**
 - Chemical stability** indicates a material's resistance to microstructural changes during the service life of the implant.
 - Hydrothermal stability** indicates a material's resistance to change when exposed to elevated temperatures and humidity.
- **Hardness** is the resistance of a material to deformation and relates to a material's wear resistance.

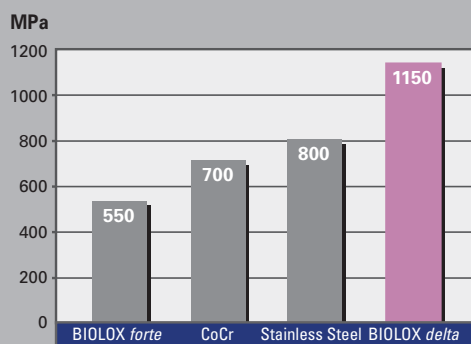
The material properties listed above are controlled in ceramics by managing material composition, density, porosity and grain size.



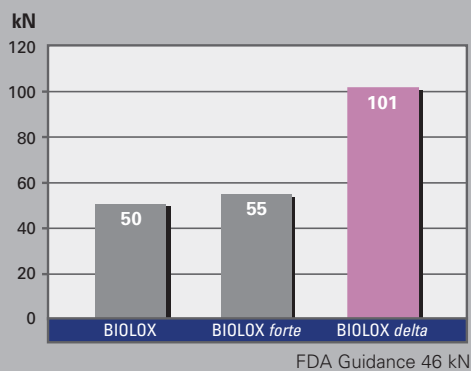
MECHANICAL PERFORMANCE

STRENGTH

FLEXURAL STRENGTH



BURST STRENGTH



The strength of a ceramic is controlled in part by the grain size and sintered density of the material. A reduction in grain size contributes to an increase in strength.³ Advances in the manufacturing of alumina ceramics have decreased the grain size considerably over early generation alumina materials. These advances have also increased density by reducing porosity of the material. BIOLOX *delta* takes advantage of these manufacturing advances (improved raw material, HIPing, tempering) and offers an alumina matrix with a grain size of less than 1.5 μm . The zirconia particles in the matrix have a grain size of 0.2 – 0.6 μm .

One measure used to test the strength of a ceramic femoral head is a burst test, which measures the load required to fracture a ceramic head assembled on a stem taper. Due to their unique material composition, BIOLOX *delta* femoral heads exhibit substantially improved burst strength compared to early generation alumina ceramic heads (SEE CHART). The improved strength and strength distribution of BIOLOX *delta* allow a greater factor of component safety.

STRENGTH REFERS TO A MATERIAL'S ABILITY TO WITHSTAND APPLIED LOADS.

FRACTURE TOUGHNESS

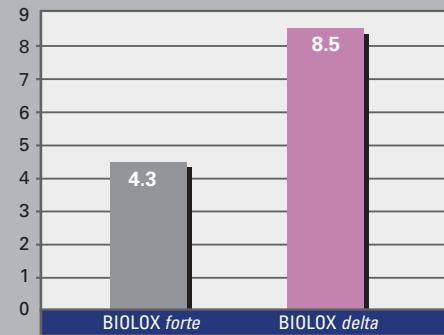
Ceramic materials have low fracture toughness and are considered brittle materials. As such, they are more likely to break rather than deform under load. Metal and ceramic implants exhibit scratches and microcracks as a result of polishing and finishing. Maximizing fracture toughness reduces the opportunity for these scratches and microcracks to propagate, potentially resulting in component failure. The addition of zirconia particles and strontium oxide to the alumina matrix provides this increase in fracture toughness to BIOLOX *delta*.³

This increase in fracture toughness for the BIOLOX *delta* material over pure alumina is demonstrated in both the burst strength and flexural strength (SEE CHARTS).

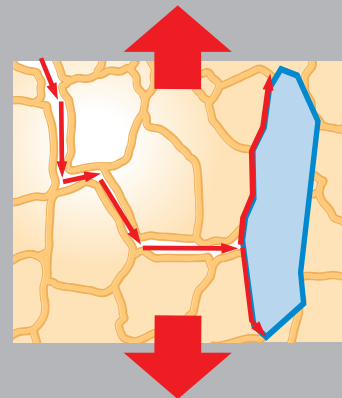
FRACTURE TOUGHNESS IS A MEASURE OF A MATERIAL'S RESISTANCE TO CRACK PROPAGATION UNDER STRESS.

FRACTURE TOUGHNESS

MPa m^{1/2}



BIOLOX DELTA PARTICLE REINFORCEMENT MECHANISM FOR INCREASED FRACTURE TOUGHNESS

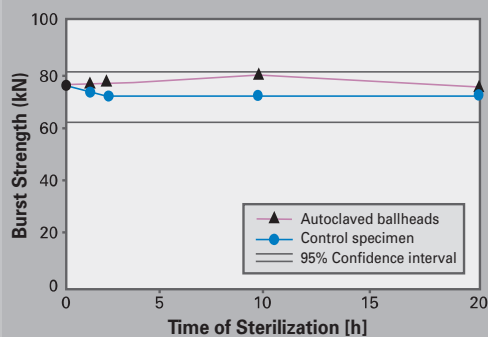


In the event that a microcrack advances through the material, the crack energy is dissipated by large grains (mixed oxide platelets).

RELIABILITY

STABILITY

MATERIAL STABILITY



CHEMICAL STABILITY INDICATES A MATERIAL'S RESISTANCE TO MICROSTRUCTURAL CHANGES DURING THE SERVICE LIFE OF THE IMPLANT.

HYDROTHERMAL STABILITY INDICATES A MATERIAL'S RESISTANCE TO CHANGE WHEN EXPOSED TO ELEVATED TEMPERATURES AND HUMIDITY.

Reliability is the extent to which a product yields the same result on repeated uses; it is a measure of the predictability of a product's performance.

Two key factors for the long term in vivo performance of ceramic implants are chemical and hydrothermal stability.

CHEMICAL STABILITY

Oxide ceramics (alumina and zirconia) are well known and accepted in biomedical applications with respect to their chemical stability and biocompatibility. These ceramics exhibit excellent corrosion resistance in vivo. In addition, the biocompatibility of oxide ceramic bulk materials and particulate debris has been proven through years of clinical use.

HYDROTHERMAL STABILITY

BIOLUX *dé*lta (a zirconia-toughened, platelet-reinforced alumina ceramic) is based on an alumina matrix. Microstructurally, medical grade alumina is a single-phase material and therefore offers excellent phase stability.

In contrast, zirconia ceramic is a complex, multi-phase material. One benefit of this material, if manufactured appropriately, is increased fracture toughness through a process called "transformation toughening." If a microcrack in the material reaches a tetragonal phase particle, a phase transformation changes the zirconia particle from a tetragonal to a monoclinic state, where the particle increases in volume approximately 3 to 4 percent. The resulting increase in volume can close the microcrack, making

STABILITY

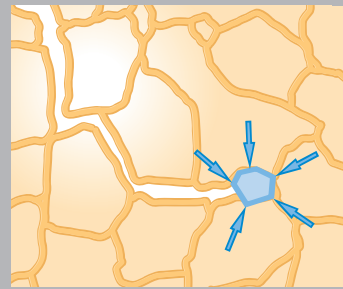
the material more fracture resistant. This controlled process is used in many mechanical applications of high-strength ceramics.

Under some hydrothermal conditions (elevated heat and humidity), such as those encountered in an autoclave, an uncontrolled phase transformation of zirconia ceramics can occur. An uncontrolled phase transformation affects multiple particles simultaneously, creating internal strains and reducing material strength.⁴ The addition of yttria to zirconia as a stabilizing agent is a well-accepted practice used to prevent an uncontrolled transformation.

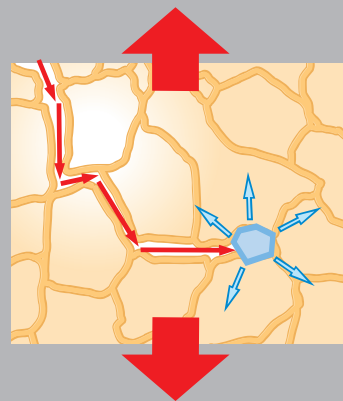
The fracture toughness of BIOLOX *delta* is attained through a fine distribution of yttria stabilized zirconia particles in an alumina matrix. The distribution of the zirconia particles allows the benefits of transformation toughening to close microcracks, but because the zirconia particles do not share grain boundaries with each other a chain effect of transformation is prevented. Compressive forces within the alumina matrix prevent an uncontrolled phase transformation of the zirconia particles in the absence of a microcrack because there is no room for volume expansion.

BIOLOX *delta* benefits from the improved strength of transformation toughening, while maintaining hydrothermal stability. Multiple cycles in an autoclave show no degradation in the mechanical strength of the material, as compared to a non-sterile control (SEE GRAPH).

BIOLOX *DELTA* TRANSFORMATION TOUGHENING MECHANISM FOR INCREASED FRACTURE TOUGHNESS



A metastable zirconia particle maintains its tetragonal phase due to compressive forces within the surrounding alumina matrix.

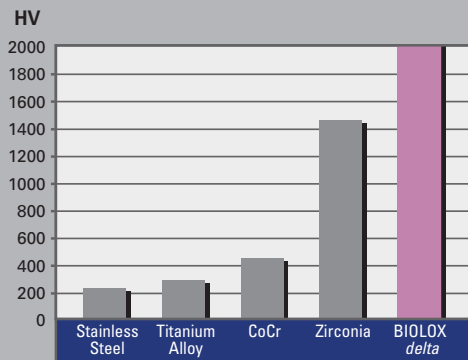


If the leading edge of a microcrack encounters a tetragonal zirconia particle, the crack energy causes a phase transformation, increasing the particle volume and closing the crack tip.

WEAR REDUCTION

HARDNESS

MATERIAL HARDNESS



In order to minimize wear at the articular surface of a total hip replacement, it is essential to use femoral heads with a smooth surface finish. An exceptionally smooth surface can be achieved with high hardness materials such as BIOLOX *delta* through precise polishing processes. The BIOLOX *delta* ceramic offers an extreme material hardness of about 2000 HV, nearly as hard as diamond (SEE CHART).^{3,5}

In addition, this high level of hardness can provide substantial resistance to surface scratching from third body particulate and the potential for wear reduction benefits in vivo.

HARDNESS IS THE RESISTANCE OF A MATERIAL TO DEFORMATION AND RELATES TO A MATERIAL'S WEAR RESISTANCE.

QUALITY ASSURANCE PROGRAM

All BIOLOX *delta* ceramic femoral heads are 100 percent Proof Tested. Each femoral head produced is subjected to an overload in a manner that ensures the part is not damaged in any way, yet minimizes the possibility of an internal flaw not being discovered. The Proof Test is only part of an entire quality system, which performs several specific and ongoing checks throughout the entire

manufacturing process. Product characteristics such as chemical composition, microstructure (grain size, density, homogenous distribution of elements), surface finish and dimensional compliance are inspected to ensure design specifications are consistently met. This standard of quality provides high product reliability.

SURGICAL TECHNIQUE



FIGURE 1

1 Ensure the new femoral stem taper is clean and free of all debris.



FIGURE 2

2 Select the appropriate femoral head and place it onto the new stem taper. Apply finger pressure to firmly seat the head onto the femoral component.



FIGURE 3

3 Utilizing the femoral head impactor, impact the femoral head onto the stem taper with two moderate blows.

NOTE: CERAMIC FEMORAL HEADS SHOULD ONLY BE USED ON NEW "AS MANUFACTURED" TAPERS. USE OF CERAMIC FEMORAL HEADS ON DAMAGED OR USED TAPERS IS CONTRAINDICATED AND COULD RESULT IN DAMAGE TO THE COMPONENT.

Articul/eze® BIOLOX *delta*
ceramic femoral heads

28 mm 12/14 Taper

Cat. No.	Size
1365-28-310	+1.5
1365-28-320	+5.0
1365-28-330	+8.5

32 mm 12/14 Taper

Cat. No.	Size
1365-32-310	+1
1365-32-320	+5
1365-32-330	+9

36 mm 12/14 Taper

Cat. No.	Size
1365-36-310	+1.5
1365-36-320	+5.0
1365-36-330	+8.5
1365-36-340	+12.0

S-ROM® BIOLOX *delta*
ceramic femoral heads

28 mm 11/13 Taper

Cat. No.	Size
1365-28-210	+0
1365-28-220	+3
1365-28-230	+6

32 mm 11/13 Taper

Cat. No.	Size
1365-32-210	+0
1365-32-220	+3
1365-32-230	+6

36 mm 11/13 Taper

Cat. No.	Size
1365-36-210	+0
1365-36-220	+3
1365-36-230	+6
1365-36-240	+9

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Consult the package insert for complete labeling information.

BIOLOX is a registered trademark of CeramTec A.G.

For more information about the DePuy products, visit our web site at www.jnjgateway.com.



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