





CeraSurf[®]-p CERAMIC FOR TOTAL HIP ARTHROPLASTY

CoorsTek CeraSurf[®]-p is a state of the art material used for ceramic bearing surfaces in total hip arthroplasty. Comprised of an alumina matrix composite, CeraSurf[®]-p incorporates advanced toughening mechanisms to improve the performance of the material.

CeraSurf[®]-p is proven to provide excellent wear performance and longevity for acetabular liners and femoral heads. Both biocompatible and stable, CeraSurf[®]-p offers favorable performance as compared to the leading ceramic material used for bearing surfaces in total hip arthroplasty.

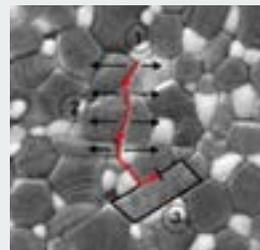
CoorsTek Bioceramics offers standard specifications for femoral heads and acetabular liners. CoorsTek also offers custom design and manufacturing capabilities for orthopaedic hip implant components.

TOUGHENING MECHANISMS

CeraSurf[®]-p alumina matrix composite is comprised of a proprietary blend of alumina and zirconia. The distinct composition of the CeraSurf[®]-p alumina matrix composite promotes the formation of platelets that enhance the toughness of the material via crack deflection. The homogenous distribution of tetragonal zirconia particles in the composite further increase the toughness via compression of the advancing crack.

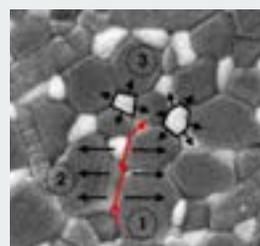
The microstructure of CeraSurf[®]-p enhances toughness by two mechanisms: the first mechanism is crack deflection that occurs at the β -Alumina platelets. The second toughening phenomenon is crack suppression, which is promoted by the homogenous distribution of Zirconia particles within the Alumina Matrix. These toughening mechanisms are depicted on the right.

Figure 1: Crack Deflection at the β -Alumina Platelets



- 1: Crack Forms
- 2: Crack advances in tensile field
- 3: β -Alumina grain deflects the crack away from the tensile field and arrests propagation.

Figure 2: Crack Compression by Zirconia Particles



- 1: Crack forms
- 2: Crack advances in tensile field
- 3: Zirconia particles expand as the crack advances which compresses the fracture and arrests propagation.

CLINICAL USE

In over eight years of clinical use, CeraSurf®-p femoral heads and acetabular liners have performed comparable to competitive ceramic materials in terms of survivorship.

QUALITY SYSTEMS & CERTIFICATIONS

CoorsTek Bioceramics offers best in class quality standards and testing procedures. CeraSurf®-p ceramics are manufactured in an ISO 13485 certified facility that is FDA CFR 820 compliant. CeraSurf®-p ceramic femoral heads and acetabular liners undergo strict quality control throughout the manufacturing process, from the preparation of the ceramic material through final testing.

CUSTOMER REGULATORY CERTIFICATIONS & CLEARANCES

- US FDA 510k clearance for CeraSurf®-p heads in 2016
- European CE mark in 2012
- ANVISA clearance in Brazil 2011

CoorsTek Bioceramics maintains comprehensive technical files containing technical data and laboratory test results on the biological, mechanical, and tribological properties of the CeraSurf®-p ceramic materials and products for total hip arthroplasty. These files are used to support the regulatory process for device submissions incorporating CeraSurf®-p ceramic femoral heads and acetabular liners.

SPECIFICATIONS

Standard Femoral Heads

| ARTICULATION DIAMETER | 35mm TAPER | 37mm TAPER | 39mm TAPER | 41mm TAPER | 44mm TAPER | 48mm TAPER | 52mm TAPER |
|-----------------------|------------|------------|------------|------------|------------|------------|------------|
| 28mm | X | X | X | X | X | X | X |
| 32mm | | | X | X | X | X | X |
| 36mm | | | | | X | X | X |
| 40mm | | | | | | X | X |
| 44mm | | | | | | | X |

Standard Acetabular Liners

| ARTICULATION DIAMETER | SHORT OFFSET (S) | MEDIUM OFFSET (M) | LONG OFFSET (L) | EXTRA LONG OFFSET (XL) |
|-----------------------|------------------|-------------------|-----------------|------------------------|
| 28mm | -3.5mm | 0mm | +3.5mm | |
| 32mm | -4mm | 0mm | +4mm | +7mm |
| 36mm | -4mm | 0mm | +4mm | +8mm |
| 40mm | -4mm | 0mm | +4mm | +8mm |
| 44mm | -4mm | 0mm | +4mm | +8mm |

PARTNER WITH COORSTEK

Our customer focus is the reason we have become the world's leading manufacturer of technical ceramics. To learn more about CoorsTek and our bioceramic capabilities, contact us:

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COORSTEK BIOCERAMICS

CoorsTek Bioceramics manufactures state-of-the-art technical ceramics for the medical device industry. Since 2005, CoorsTek Bioceramics has manufactured over 5.5 million products from implant grade materials. With a focus on orthopaedic reconstruction with total hip arthroplasty being the primary market, our ceramics are also used in other implantable devices such as spinal disc replacements, cochlear implants, pacemakers, and neurostimulators.

CoorsTek is a leading global supplier of technical ceramics and the partner of choice for technology and manufacturing companies worldwide. With unsurpassed materials expertise, vertically integrated manufacturing, and over 30 facilities across three continents, CoorsTek provides amazing solutions to complex technical challenges in virtually every industry in the global marketplace. For information on our materials, manufacturing capabilities and company history since 1910, visit www.coorstek.com.

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