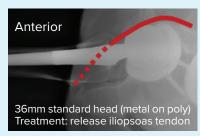


BIOLOX CONTOURA® FEMORAL HEAD

Over the last decade, use of larger-diameter femoral heads has minimized dislocation risk in total hip arthroplasty.



lliopsoas- Large Head Impingement⁵

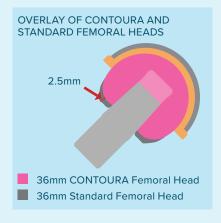
Despite the benefits of improved stability, these larger heads may impinge on native soft tissues, leading to anterior hip or groin pain post-operatively. Up to 7% of total hip patients report activity-related groin pain following arthroplasty. While there are multiple causes that lead to this symptom, iliopsoas impingement with a prominent head is well-documented. 6-11

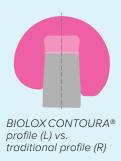
INNOVATION

The BIOLOX CONTOURA® Femoral Head is an anatomically friendly implant that offers the benefits of a smaller head while using a larger head size. It retains the outer diameter profile of conventional implants and incorporates a contoured shoulder with a lesser radius to reduce the volume of material exposed to the soft tissue.

REDUCED PROFILE

The CONTOURA head's reduced distal profile removes potential impingement material in order to relieve potential strain on the iliopsoas, without reducing the articulation surface of the outer head diameter.







ADVANCED MATERIALS FOR SUPERIOR RESULTS

BIOLOX® delta ceramic out-performs previous ceramic materials in mechanical properties, strength and fracture toughness without compromising previous advantages ceramics provided: extremely low wear rate, proven long-term clinical history, complete implant stability and excellent biocompatibility. 12, 13

Klassic HD® and Klassic® Blade Stem tapers are specifically tailored to fit with the BIOLOX*delta* and BIOLOX CONTOURA ceramic femoral heads.



BIOLOX®delta Femoral Head



BIOLOX CONTOURA® Femoral Head

EXCELLENT BIOCOMPATIBILITY

BIOLOX*delta* particles fail to stimulate an inflammatory response and do not cause any DNA damage or oxidative stress in human cells in clinically-relevant doses.

BIOLOX CONTOURA HEAD: TESTING

BURST STRENGTH TEST 100 80 II 20 20 28-12/14 L CONTOURA Femoral Head Standard Ceramic Femoral Head

PULL-OFF TEST 2000 1500 I I I I Z Standard Ceramic Femoral Head Femoral Head Standard Ceramic Femoral Head

CONTOURA Head has equivalent testing results in burst strength and pull-off force





Reduced profile of the BIOLOX CONTOURA® Head (L) vs. a traditional head (R)

- ¹ Bartelt RB, Yuan BJ, Trousdale RT, Sierra RJ. The prevalence of groin pain after metal-onmetal total hip arthroplasty and total hip resurfacing. Clin Orthop Relat Res. 2010;468(9).
- ² Ala Eddine T, Remy F, Chantelot C, Giraud F, Migaud H, Duquennoy A. Anterior iliopsoas impingement after total hip arthroplasty: diagnosis and conservative treatment in 9 cases. Rev Chir Orthop Reparatrice Appar Mot. 2001;87(8):815-9.
- ³ Bricteux S, Beguin L, Fessy MH. Iliopsoas impingement in 12 patients with a total hip arthroplasty. Rev Chir Orthop Reparatrice Appar Mot. 2001;87(8):820-5.
- ⁴ Lavigne M, Laffosse JM, Ganapathi M, Girard J, Vendittoli P. Residual groin pain at a minimum of two years after metal-on-metal THA with a twenty-eight-millimeter femoral head, THA with a large-diameter femoral head, and hip resurfacing. *J Bone Joint Surg Am*. 2011;93 Suppl 2:93-8.
- ⁵ Bin Nasser A, Beaulé PE, O'Neill M, Kim PR, Fazekas A. Incidence of groin pain after metal-on-metal hip resurfacing. Clin Orthop Relat Res. 2010;468(2):392-9.
- ⁶ Baumgarten KM, McKenzie MJ. Iliopsoas Tendon Impingement after total hip arthroplasty with use of a large-diameter femoral head a case report. *JBJS Case Connect*. 2012;2(2):e22 1-5.

EQUIVALENT STRENGTH AND WEAR

CONTOURA heads are made to meet the same exacting requirements as the standard BIOLOX*delta* ceramic heads that have successfully been used since 2003. Burst strength, dissociation strength, and wear properties are indistinguishable between the two, and two times or more past the internationally accepted standards.¹⁴ Wear rates are similarly equivalent between the two heads.

BURST STRENGTH



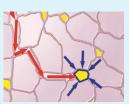
BIOLOX*delta* ceramic femoral heads resist loads over 80 kilonewtons when testing with a 28mm. Loads are higher with larger heads. Burst (fracture) strength test is the amount

of axial load a head can stand before material failure. 15

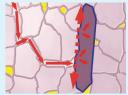
FRACTURE TOUGHNESS

Two mechanisms provide fracture toughness:

- Zirconia Oxide absorbs propogating impact forces with the alumina matrix¹⁶
- Crack propogation is further addressed by platelet shaped cystals within the material which are formed from the oxides during the sintering process¹⁷







Crack propagation

- ⁷ Browne JA, Polga DJ, Sierra RJ, Trousdale RT, Cabanela ME. Failure of larger-diameter metal-on-metal total hip arthroplasty resulting from anterior iliopsoas impingement. *J Arthroplasty*. 2011;26(6):978 e5-8.
- 8 Trousdale R. How do we manage the painful metal-on-metal arthroplasty. 2nd Annual Spring Hip & Knee Course, ICJR 2011.
- ⁹ Yoshio M, Murakami G, Sato T, Sato S, Noriyasu S. The function of the psoas major muscle: passive kinetics and morphological studies using donated cadavers. *J Orthop Sci.* 2002;7(2):199-207.
- ¹⁰ Cobb JP, Davda K, Ahmad A, Harris SJ, Masjedi M, Hart AJ. Why large-head metal-on-metal hip replacements are painful: the anatomical basis of psoas impingement on the femoral head-neck junction. *J Bone Joint Surg Br.* 2011;93(7):881-5.
- Bernthal NM, Celestre PC, Stavrakis AI, Ludington JC, Oakes DA. Disappointing short-term results with the DePuy ASR XL metal-on-metal total hip arthroplasty. *J Arthroplasty*. 2012;27(4):539-44.
- ¹² CeramTec: BIOLOX® delta Nanocomposit for Arthoplasty
- ¹³ Kuntz M. Validation of a new high performance alumina matrix composite for use in total joint replacement. Seminars in Arthroplasty. 2006;17:141-5.
- ¹⁴ Data on file
- 15 Data on file
- ¹⁶ Data on file
- ¹⁷ Data on file