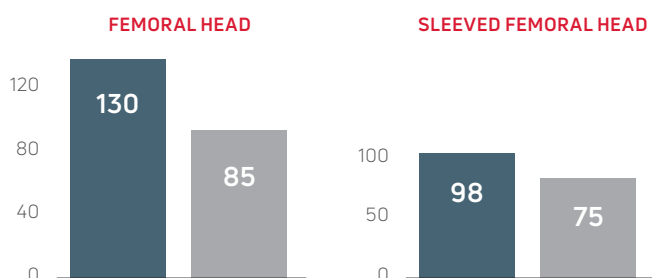


SPECIFICALLY DESIGNED FOR ORTHOPEDICS

Ceramys™ ceramic heads are manufactured using alumina toughened zirconia. Material and mechanical properties were tested and compared against the industry standard, BIOLOX® delta.¹ In key tests, ceramys™ heads performed equivalently or better than BIOLOX® delta heads.^{2,3,4} Additionally, ceramys™ ceramic heads have been in clinical use globally for 18 years. Over 144,500 heads have been implanted in a combined 16 countries with 0 instances of failure due to fracture.⁵

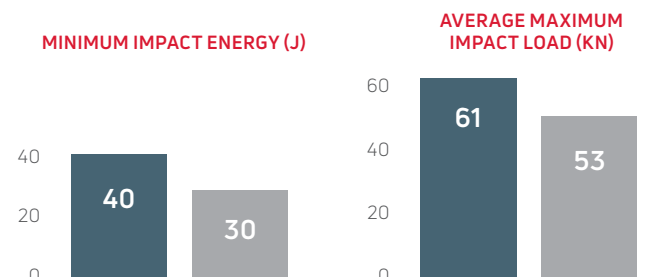
BURST STRENGTH² (kN)



Burst strength was tested by combining each head (28L standard, 28XL sleeved) with the Enovis 12/14 taper femoral stems and loading in compression until failure (n=5) per ISO 7206-10.

The ceramys™ femoral head burst strength exceeds both BIOLOX® delta and the FDA requirement of 46kN. The burst strength of ceramys™ ceramic heads is significantly higher than BIOLOX® delta ceramic heads for both direct femoral heads and sleeved femoral heads (p < 0.0001 and p = 0.0016 respectively).

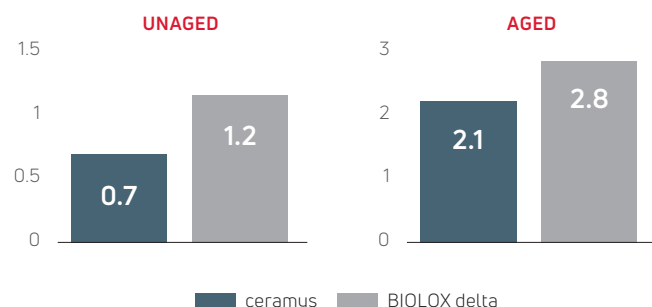
IMPACT STRENGTH³



Impact strength was tested by attaching each head (32XL) with the Enovis 12/14 taper femoral stems and subjecting an impact force until femoral head fracture (n=5) per ISO 11491. Minimum impact resistance and maximum loads were then recorded.

ceramys™ ceramic heads have a higher impact strength than BIOLOX® delta, withstanding 10J more of impact energy before head fracture and maintaining an average maximum impact load 8kN greater.

AVERAGE LINER WEAR RATE⁴ (mg/Mc)



Average wear rate was tested by attaching the worst-case of each head (44) with the Enovis EMPower Acetabular® Liner and applying hip joint forces (n=3) per ISO 14242-1. Mass measurements of the liners were taken each 0.5 million cycles (Mc); the average wear rate from 0.5 to 5.0Mc for unaged and aged ceramic heads was calculated.

Wear rates for both ceramic heads were negligible and wear of the acetabular liner was seen to be ~40% and ~25% better with ceramys™ ceramic heads than BIOLOX® delta ceramic heads for unaged and aged heads respectively.

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References

1. Tateiwa T, et al. (2020). Burst Strength of BIOLOX® delta Femoral Heads and Its Dependence on Low-Temperature Environmental Degradation. Materials (Basel), 13(2), 350.
2. Data on file. Enovis Surgical Test Reports #PR22-010-01, #PR22-013-01, #PR22-011-01, and #PR22-014-01..
3. Data on file. Enovis Surgical Test Report #PR23-043-01.
4. Data on file. Enovis Surgical Test Report #PR22-015-01 and #PR23-029-01.
5. Data on file. Enovis Surgical MEMO-HIP044-003.

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