

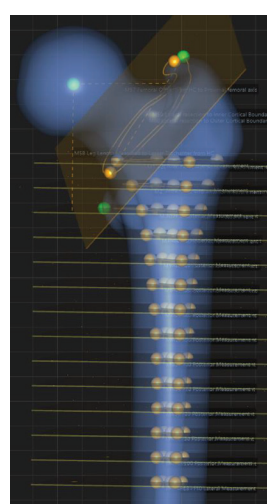
Scientific evidence behind Insignia design

Stryker engineers studied a large number of CT scans in SOMA database to design the Insignia stem. Several peer reviewed posters have been presented/accepted at orthopedic conferences that discuss the scientific evidence behind the design. A brief description of the scientific evidence on Insignia design is presented below.

SOMA based stem design

SOMA analysis of femoral canal morphology (presented ORS 2021)^{1,2}

In this study, we demonstrated that 1300+ CT scans were analyzed to understand the inner geometry of femur to design the Insignia stem for an optimal AP/ML fit. This research builds on our prior work on the clinically successful Accolade II design³ that focused on enhancing the ML fit. Enhanced AP and ML fit is designed to result in excellent fixation².

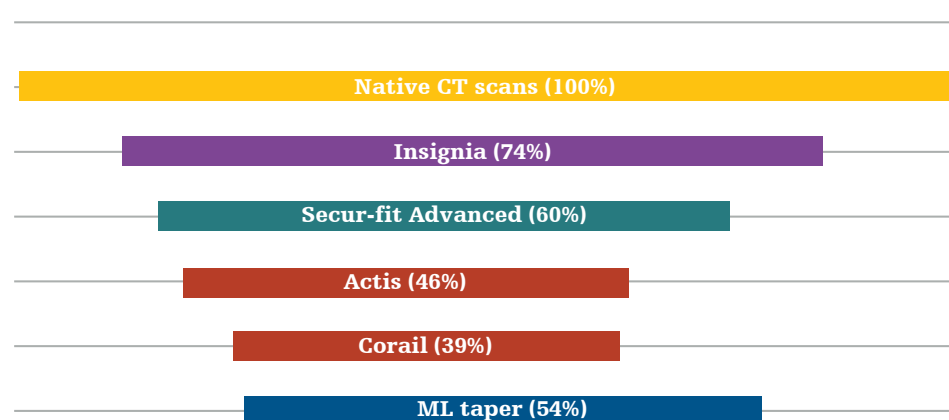


Head center coverage advantages with Insignia system (presented ORS 2021)^{2,4}

Our second SOMA study showed variations in the head center coverage for various competitive stem designs. The analysis demonstrates that the Insignia design allows us to provide wider head center coverage that is expected to help surgeons create desired leg length and offset. The direct lateral offset option in Insignia offers wider head center coverage compared to most stem designs².



Head center femoral offset comparisons



Broaching efficiency

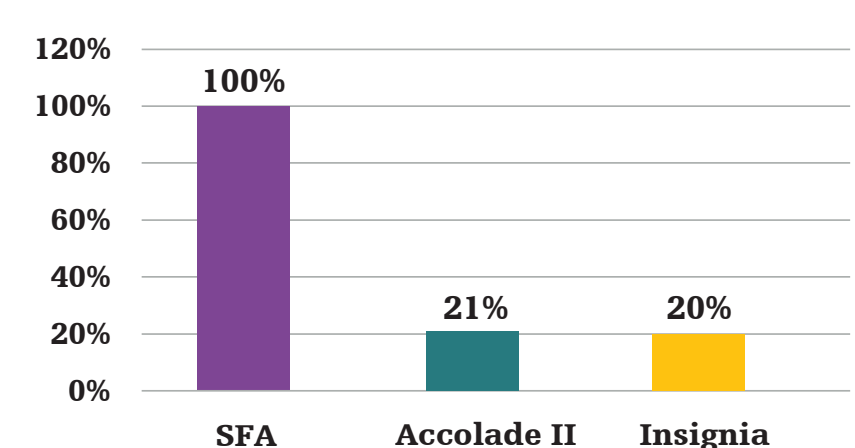
Broaching effort for Insignia is equivalent to Accolade II (to be presented ORS 2022)^{2,5}

This lab testing data demonstrates that the broaching effort for Insignia is not only significantly less than the clinically successful Secur-Fit Advanced system⁶ (fit & fill) but is also equivalent to Accolade II (tapered wedge) system. This data highlights the benefits of the unique features in the new broaches².

Stem seating height for Insignia is equivalent to Accolade II (to be presented ORS 2022)^{7,2}

The Sawbones testing data demonstrates that broach to implant seating relationship for Insignia is equivalent to that for the Accolade II system. The reproducible broach to implant relationship for Accolade II has contributed to its long-term clinical success³. Based on this data, the Insignia broach system was able to demonstrate similar reproducibility².

Average broaching effort for various systems in Sawbones test*



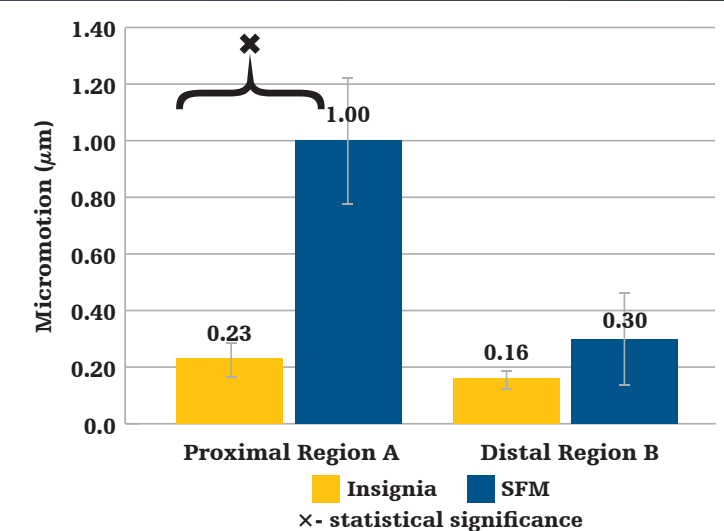
*Sawbones test may not be true representation of human bone

Stem stability in Sawbones

Insignia stem demonstrated reduced micromotion compared to a clinically successful fit-and-fill stem in Sawbones testing (ORS 2022)^{2,8}

In this bench study, micromotion was measured under simulated stair climbing conditions for both Insignia and Secur-Fit Max (SFM) systems in Sawbones. The data showed that the Insignia system had lower stem micromotion than the clinically successful SFM system⁶ in the proximal region. This indicates that Insignia is designed to provide a highly stable construct².

Mean resultant vector micromotion at 10,000 cycles



References:

1. Faizan et al. Variations in anterior-posterior dimensions of the proximal femur canal: a CT-based morphological analysis. ORS 2021
2. Stryker internal reports (D0000041320, D0000064399, D0000097336, D0000107461)
3. Kolisek et al. Mid-Term Follow Up of Newer-Generation Morphometric Wedge Stems for Total Hip Arthroplasty (THA). STI 2020
4. Faizan et al. Comparison of head center coverage in various femoral stem designs using a large CT database. ORS 2021
5. Imami et al. Comparison of impaction effort required in various femoral broach designs. ORS 2022 (accepted)
6. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) Hip, Knee Shoulder Arthroplasty: 2021 Annual Report, Adelaide; AOA 2021:1-423
7. Imami et al. Comparison of femoral hip stem seating heights in two femoral broach designs. ORS 2022 (accepted)
8. Caba et al. In Vitro Comparison of Hip Stem Micromotion Under Stair Climb Activity Utilizing Digital Image Correlation. ORS 2022 (accepted) A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. We do not dispense medical advice and recommend that surgeons be trained in the use of any particular product before using it in surgery.

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