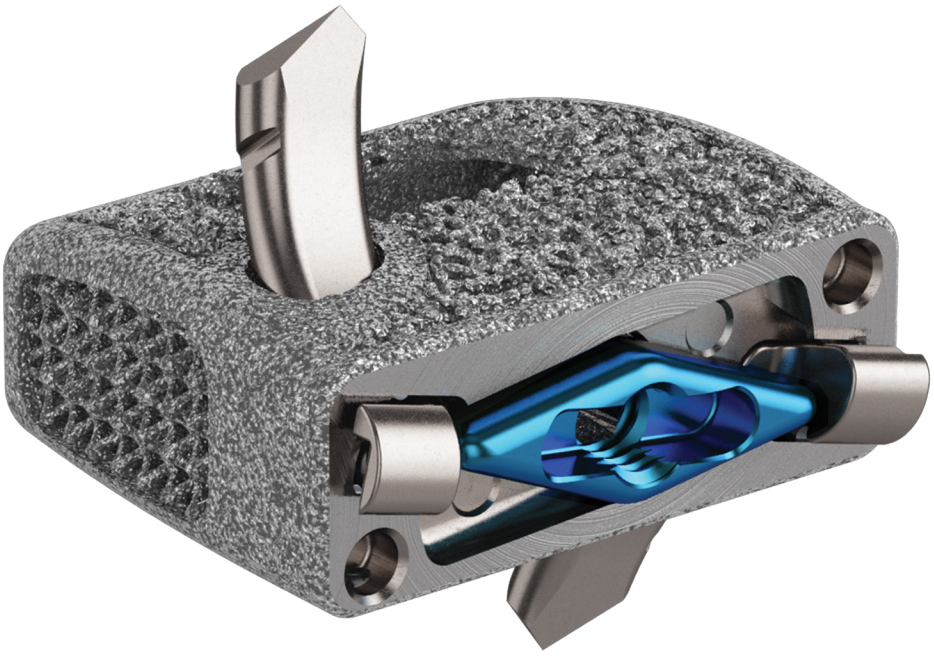
BLACKHAWK® TI

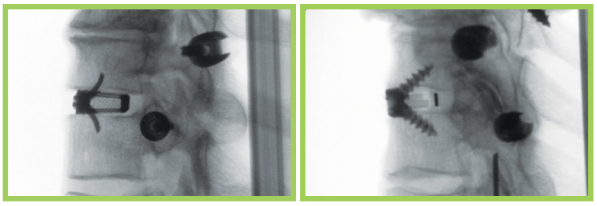
Cervical Standalone Spacer System



Biomechanics

ChoiceSpine™

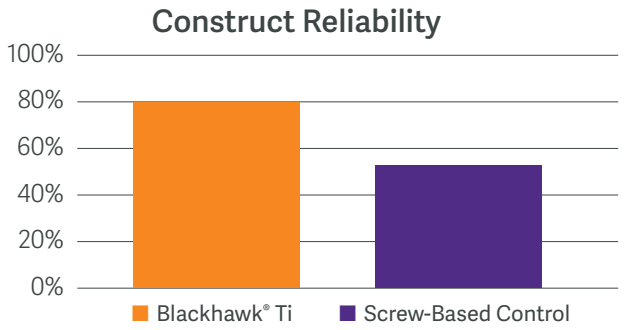
Biomechanics Summary



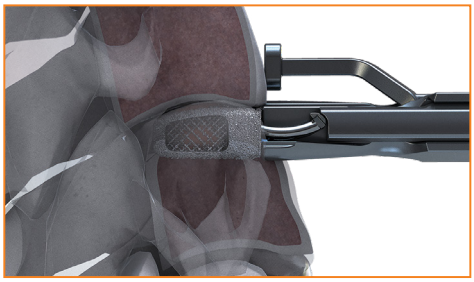
The Blackhawk® Ti Cervical Standalone Spacer System was evaluated in a standalone in vitro cadaveric fusion model to assess the biomechanical stability and performance compared to a traditional screw-based standalone ACDF device*. The testing included Range of Motion, Fatigue, Interface, and Bone Damage. Blackhawk Ti was found to be a fast, reliable, and equivalent ACDF device in a standalone application.

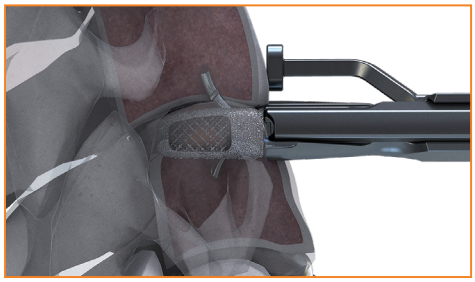
Blackhawk® Ti: Fast and Reliable

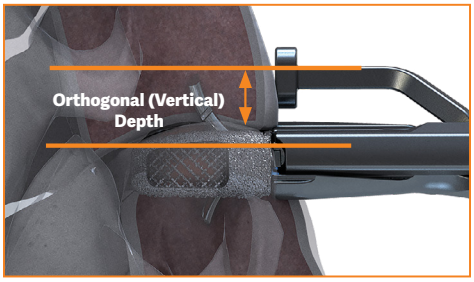
The Blackhawk® Ti Cervical Standalone Spacer System is packaged pre-assembled. This eliminates steps and surgical time compared to competitive devices to place the fixation components (blades or screws) in the sterile field. The streamlined instrumentation was observed to enable simultaneous and controlled deployment of the anchors along the fixed trajectories established by the implant design. This high-performing deployment design resulted in an 80% reliability rate for a stable and acceptable construct compared to the 53% rate achieved by the traditional screw-based control group.



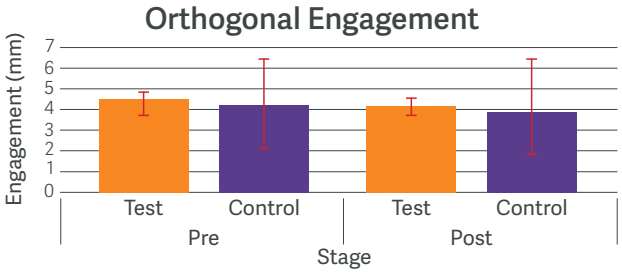
The unique design of the anchors and integrated channels within the interbody results in substantial orthogonal (vertical) anchor penetration. The blades simultaneously move into both the superior and inferior endplates with the inline deployment force through the inserter.

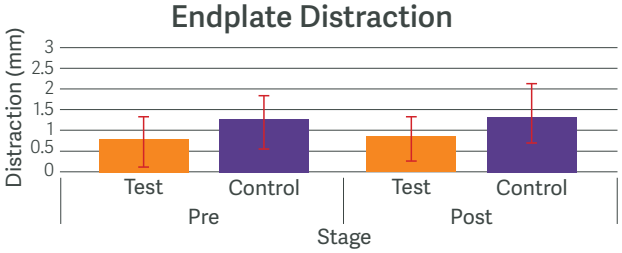






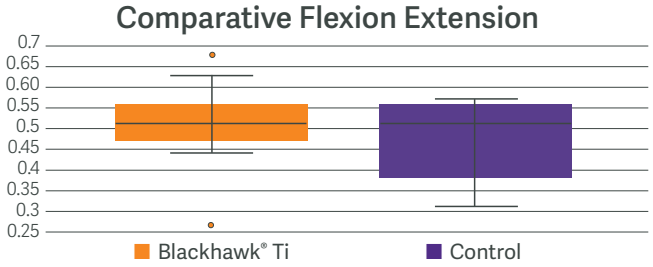
The Blackhawk® Ti Cervical Standalone device was substantially equivalent in the orthogonal engagement of the anchors and unintended distraction when compared to the screw-based control.



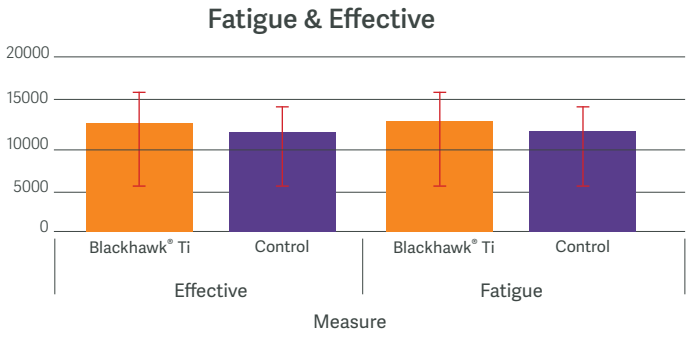


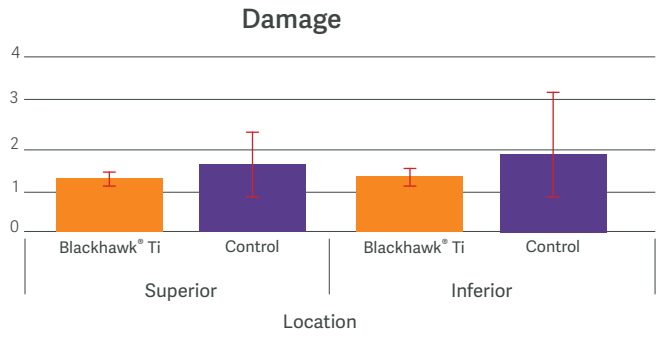
Blackhawk® Ti: Strong and Stable

The Blackhawk® Ti Cervical Standalone Spacer System was found to deliver a stable result in normalized Range of Motion (ROM), Fatigue, and Bone Damage. Evaluation of the construct was performed in Flexion-Extension (FE), Lateral Bending (LB), and Axial Torsion (AT). The worst-case loading modality was identified to be Flexion-Extension (FE), and the Blackhawk Ti device was found to be substantially equivalent to the screw-based control.

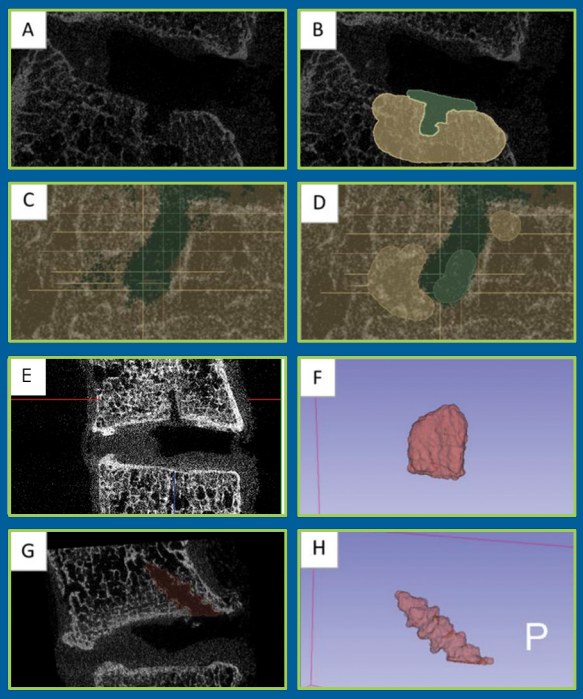


The Blackhawk® Ti Cervical Standalone Spacer System was found to be substantially equivalent to the screw-based solution during cadaveric cyclical testing to evaluate the effective life and fatigue life performance of the test and control groups. The damaging nature of loaded anchors (screw or blade) into the endplate was evaluated using micro-CT segmentation. The Blackhawk Ti Standalone Cervical System was found to have acceptable and equivalent endplate damage compared to the traditional screw-based standalone control.





Bone Damage Evaluation Methods



A) The bone anchor void before segmentation. B) A sample slice showing manually segmented void (green with non-void (yellow). C) After the 'Grow from Seeds' tool is utilized to interpolate segment boundaries for all slices. D) Manual corrections made to the slide from C. E&F) Example of void from Test cohort G&H) Example of void from Control cohort

Interoperative X-ray Image

3-Month, Post-Surgery CT Scan

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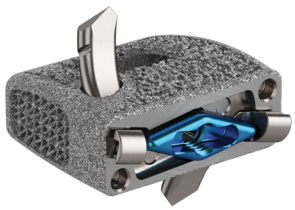

* Internal report from 510(k).

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