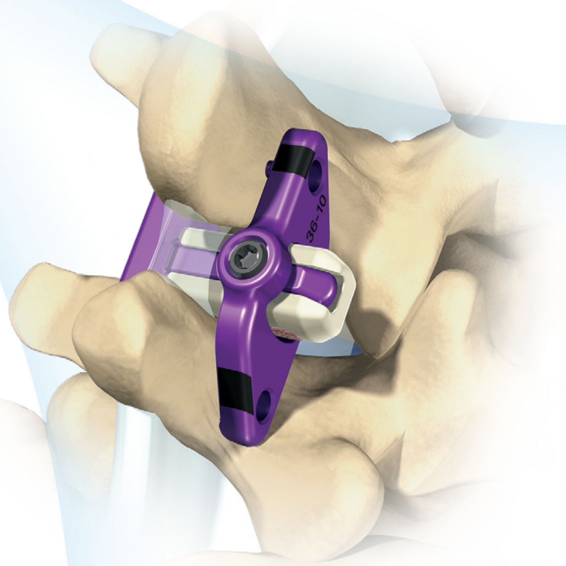
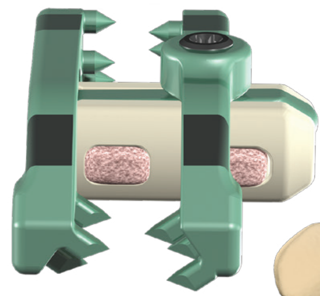
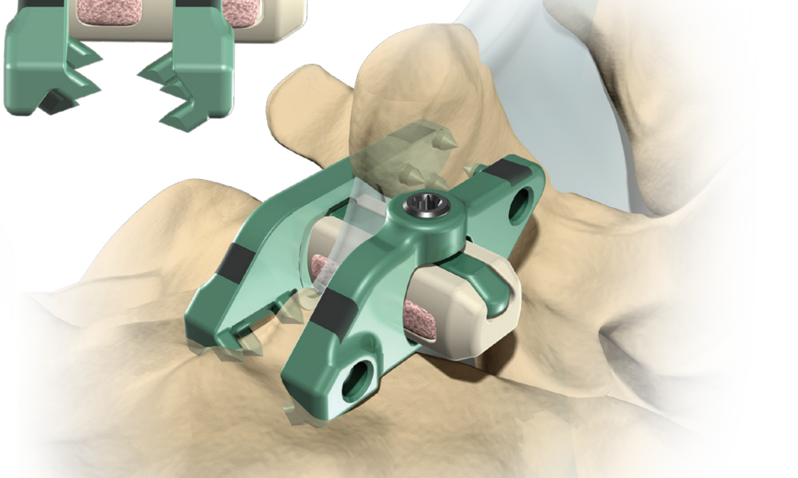
Product Overview







Axle®

- Modular design
- Titanium or PEEK insert
- H-GRAFT™ Allograft
- Minimal tissue disruption
- Integrates bone graft

Axle-X™

- Angled and recessed spikes allow for maximum anterior purchase
- Aids in L5-S1 capture and non-linear anatomy
- Multiple lengths allow for anatomical variation
- PEEK and Titanium inserts offered to aid in spinous process distraction

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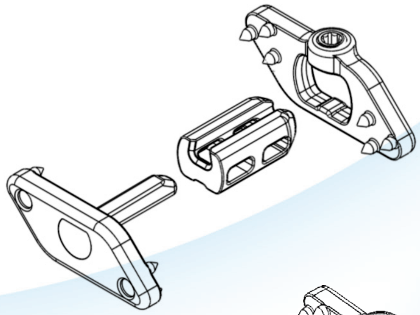
F-1000.33 Rev A

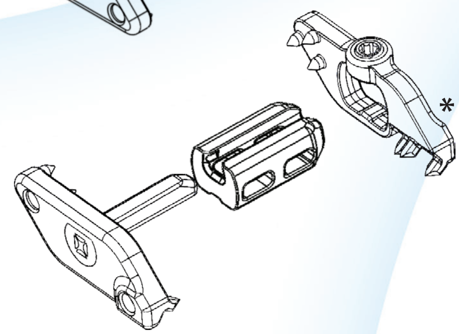
AXLE® Interspinous Fusion System

Design Rationale

AXLE-X™ Interspinous Fusion System

Modular Insert:



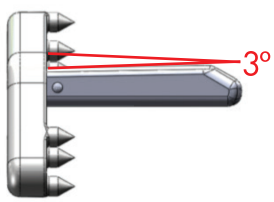


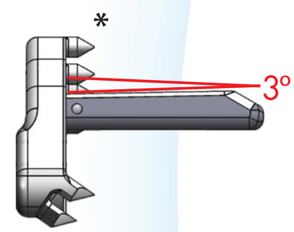
Modularity is a unique feature to the Axle® and Axle-X™ products. It readily adapts to varying patient anatomy by utilizing non-fixated inserts to allow surgeons to dictate plate length and insert size on the implant. Both plates and inserts are made from Titanium Alloy (Ti-6Al-4V ELI) and are offered in sizes ranging from 8mm-18mm in 2mm increments. PEEK inserts are also offered in sizes ranging from 8mm-18mm in 2mm increments.

Axle® and Axle-X™ inserts are also a unique shape, bulleted nose and elliptical, to allow ease of passage through the Interspinous Ligament as well as to contribute as a load sharing member of the construct. The elliptical shape of the inserts allow placement of the implant as anterior as needed without compromising height by using a round barrel or bone block.

Each insert allows bone graft to be packed inside as well as on top of the insert due to the flat design.

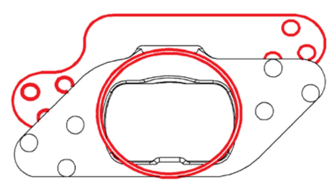
Provisional Tightening:

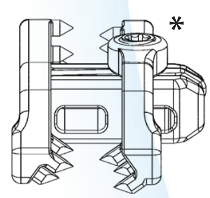




The Cross Bar Plate is tapered by 3°, towards the end plate, to allow for provisional tightening. Once the Cross Bar Plate has been provisionally tightened, this helps prevent the plates from separating while being adjusted for placement and final compression/tightening.

Plate Height:

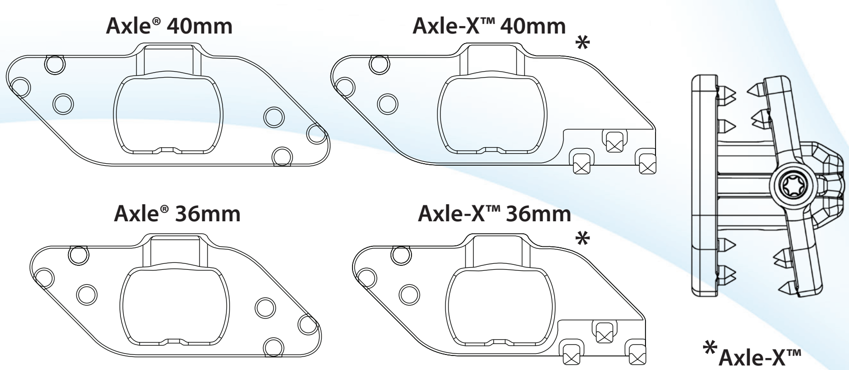




Utilizing a shorter plate height with elliptical insert allows the Axle® device to seed its spikes more anterior, 4-6mm, without compromising the structural rigidity of the plate. As compared to competitive devices, this also minimizes the high/low points of the plate keeping them more linear to the insert.

Axle-X™ features angled spikes that are 35° off of the sagittal plane. This angle allows a lower engagement of the construct on the spinous process and to be closer to the lamina (more anteriorly) to better account for variations in spinal anatomy.

Plate Length:



*Axle-X™

Offering various plate length sizes allows surgeons to dictate the correct combination of plate length and preferred insert size. The plate also wags 9° to fit varying patient anatomy.

Axle® Plate Lengths: 28mm, 32mm, 36mm, 40mm and 55mm

Axle-X™ Plate Lengths: 32mm, 36mm and 40mm

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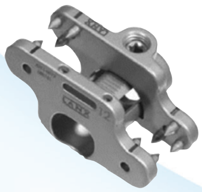
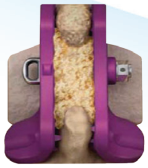
Competitive Products



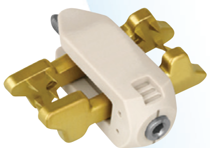
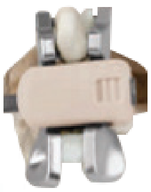

Lanx - Aspen® and Aspen Flared 5-1®

- Variable, high and low points of fixation
- Non-modular, as insert size increases plate size increases
- Lack of Provisional Lock Technique due to flat design of Cross Bar Plate
- All titanium

NuVasive – Affix® and Affix II®

- Unable to pack bone inside the device
- Have to take the Supraspinous and Interspinous Ligaments down
- Distraction element is separate procedure not integrated into the plate

Globus – SP-Fix® and SP-Fix ARC Plate®

- Excess crossbar is removed by cutting the rod after it's affixed to the Spinous Process
- Have to take the Supraspinous and Interspinous Ligaments down to attached device
- Ratcheting lock mechanism does not allow for variance in the Spinous Process anatomy

Medtronic - Spire™

- Unable to pack bone inside the device
- Bone packing is limited to the external portions of the device
- Lack of Provisional Lock Technique due to flat design of Cross Bar Plate

Pioneer®

- Non-modular, as insert size increases plate size increases
- Smaller compression holes hinder surgeon engagement of instrumentation
- Integrated distraction element has small surface area for load sharing capability

OsteoMed - PrimaLOK SP™

- One step compression does not allow for variance in the Spinous Process anatomy
- Bone packing is limited to the external portions of the device
- Have to take the Supraspinous and Interspinous Ligaments down to attached device

Life Spine - Octave™

- Variable, high and low points of fixation
- Non-modular, as insert size increases plate size increases
- Lack of Provisional Lock Technique due to flat design of Cross Bar Plate

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Biomechanical Performance

Biomechanical Testing:

During development, the Axle® system underwent extensive biomechanical testing procedures including a combination of ASTM F1717 and ASTM F2624 as well as finite element analysis.

- Static compression and torsion tests utilized ASTM F1717 with modified blocks based on ASTM F2624.
    - ASTM F1717 is the standard used to evaluate spinal implants that attach onto or near the vertebral body and its elements. The standard sets the testing of the implant assemblies in static and fatigue modes. The goal of the protocol is to establish a set of standard tests and conditions to compare spinal implant assemblies, new and old, on a standard comparison platform. This protocol also allows for comparison between assemblies with different intended spinal locations and methods of application.
    - ASTM F2624 is the standard used to evaluate Extra-Discal Spinal implant assemblies in static, dynamic and wear assessment modes. The protocol is intended to establish test methods to enable comparison of extra-discal implants in regard to kinematic, functional and wear characteristics when tested under specified conditions.
- Dissociation testing utilized custom fixtures designed to cradle and pull apart the two plates of the implants.
- Spike pull out testing also used custom fixtures to hold bone foam to which the implant was inserted and locked down, then they were pulled apart vertically.

Dissociation / Spike Pullout:

Dissociation: Implants were placed in custom fixtures and locked to manufacturer torque specifications. The load was applied in the axis of crossbar for dissociation until the screw slipped on the crossbar.

Spike Pullout: For the spike pullout strength test, the implant construct was attached to 2 equal thickness pieces of bone substitute, locked and the foam was pulled apart vertically until the spikes were pulled through the foam.

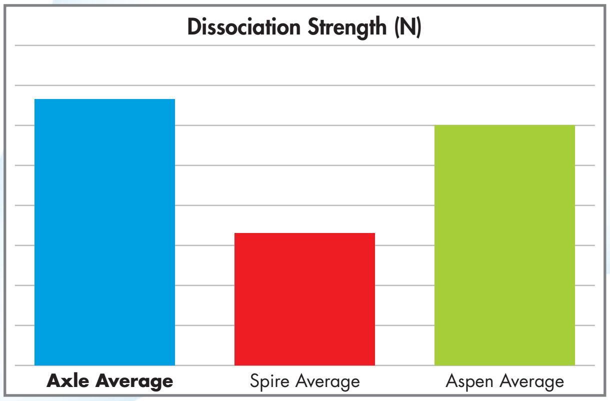

Fig 1 : Axle Dissociation Strength was 101% stronger than Spire and 11% stronger than Aspen.

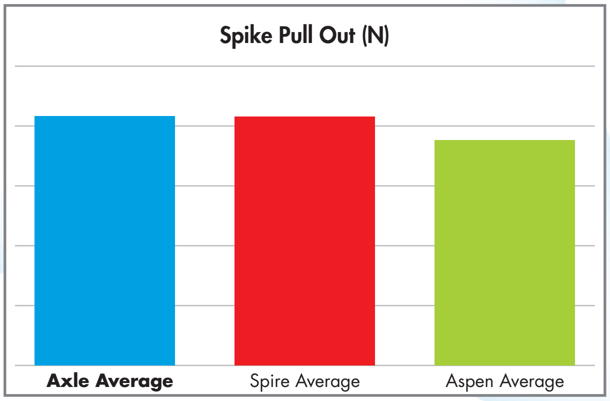

Fig 2 : Axle Spike Pull Out was 7% stronger than Aspen and 1% over Spire.

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Biomechanical Performance

Compression Testing:

All compression testing was run on Servo-Hydraulic MTS machinery utilizing a modified ASTM F1717 setup and custom test fixtures via ASTM F2624. All devices were torqued to manufacturer specification for testing. It should be noted that peak load is reported due to true ultimate load not being reached as the fixtures touched before complete implant failure as seen by loss of load.

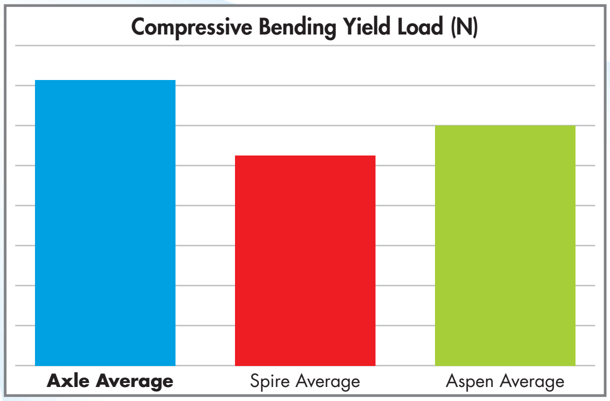

Fig 1 : Axle was 35% stronger in Bending Yield Load than Spire and 17% over the Aspen.

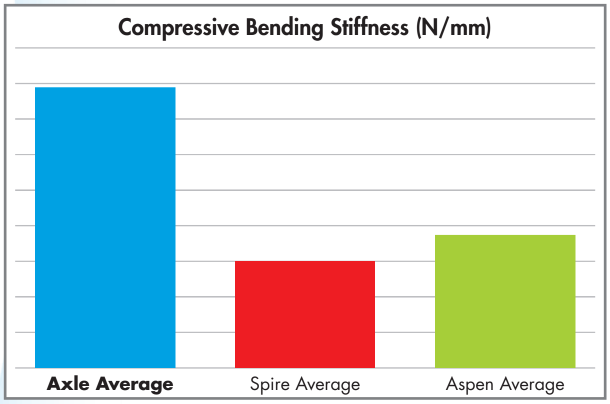

Fig 2 : In Bending Stiffness Axle was 159% stronger than Spire and 115% over the Aspen.

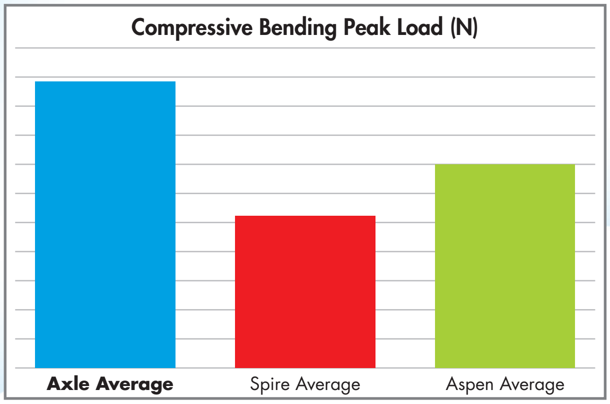

Fig 3 : In Bending Peak Load Axle was stronger than Spire by 69% and 26% over the Aspen.

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Biomechanical Performance

Torsional Testing:

All torsional testing was run on Servo-Hydraulic MTS machinery utilizing a modified ASTM F1717 setup and custom test fixtures via ASTM F2624. All devices were torqued to manufacturer specification for testing. The fixtures were rotated clockwise until failure.

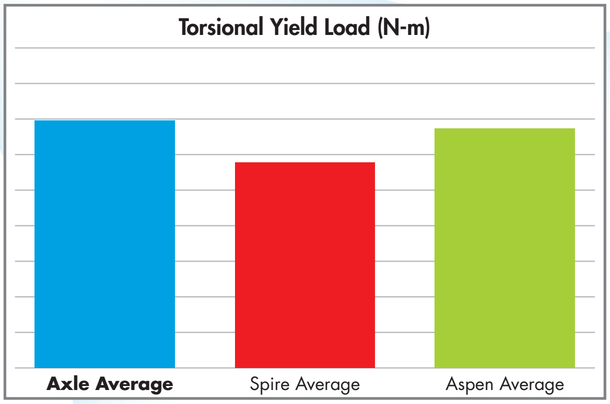

Fig 1 : Axle demonstrated it was 21% stronger in Torsional Yield Load than Spire and 1% over the Aspen.

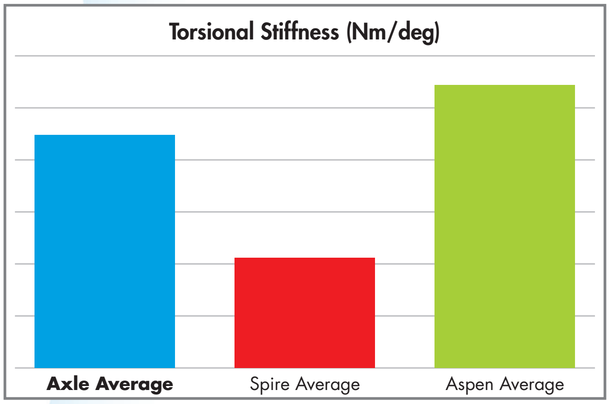

Fig 2 : Axle was 114% stronger in Torsional Stiffness than Spire. The Aspen was 17% stiffer than the Axle.

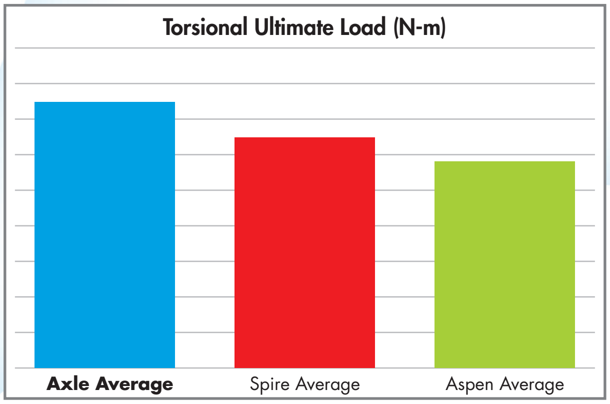

Fig 3 : Axle was 15% stronger in Torsional Ultimate Load than Spire plate and 31% stronger than Aspen.

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