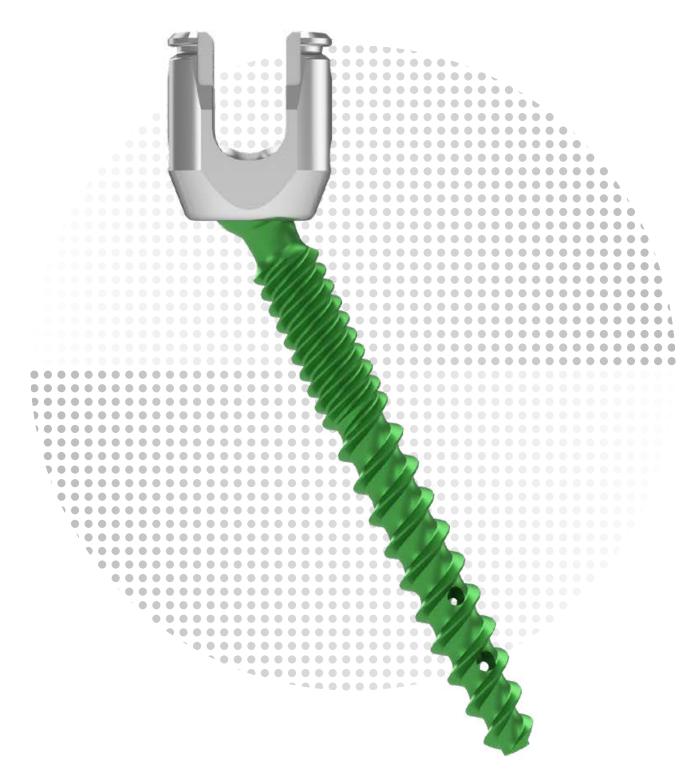
TriALTISTM

Spine System

Implant Peformance





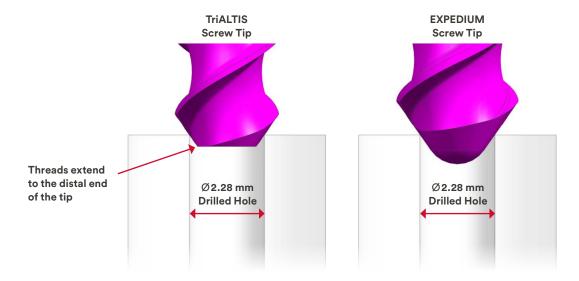
Introduction

TriALTIS™ Spine System offers a comprehensive product portfolio while providing a hyper focus on implant performance. System instrumentation is designed for integration with enabling technology, reliable interface with mating implants, and consistent user experience across the TriALTIS System.

Starting Efficiency

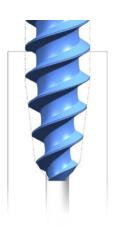
Quick catch tip improves implant starting efficiency¹

The TriALTIS Screw design features a quick catch tip which consists of an end feature that allows for immediate bone engagement of the screw by extending threads to the distal tip. This design features a bullet-shaped distal tip where threads extend all the way to the tip and the effective diameter of the start of the threads is larger. Compared to EXPEDIUM™ 5.5 Spine System, TriALTIS Screws offer improved starting efficiency.



Fully threaded tapered tip minimizes the need to tap¹

The distal portion of the TriALTIS Screw shank is tapered. The quick catch tip is small enough to fit in the prepared hole and the diameter of the screw increases over the distal-most 10 mm of the implant to its full size. This is designed to gradually remove material from the pilot hole as the screw advances. This tapered geometry removes the need for tapping the bone prior to screw insertion.



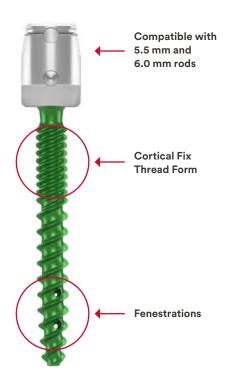
Fixation

Cortical Fix Thread Form

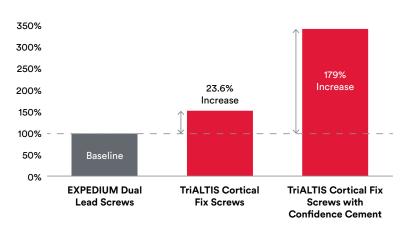
The cortical fix thread form is designed to enhance pedicle fixation and increase the resistance to screw pullout by up to 23.6% compared to EXPEDIUM Spine System dual lead thread² by doubling the number of contact points within the cortical wall of the pedicle.

Fenestrations

Fenestrations allow for the injection of bone cement through the screw for additional fixation in patients with advanced stage tumors involving the thoracic and lumbar spine.

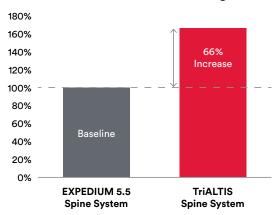


TriALTIS Spine System Pullout Comparison



TriALTIS Spine System fenestrated cortical fix screws augmented with CONFIDENCE SPINAL CEMENT SYSTEM™ provided a 179% improvement in pullout load as compared to EXPEDIUM Spine System dual lead pedicle screws.²

TriALTIS Spine System Cannulated Screw Strength



TriALTIS Spine System cannulated screws have improved strength compared to EXPEDIUM Spine System solid screws³

Screw Head and Set Screw Interface

Designed to help reduce the risk of cross-threading:

The set screw thread has square cross-sectional geometry that helps prevent the user from misaligning the set screw during insertion.⁴

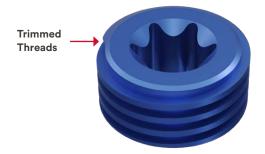


The set screws feature a coarse thread pitch that helps prevent misalignment during insertion. The distance between threads is 1.4 mm for TriALTIS set screws compared to 1.0 mm for Expedium 5.5 screws.⁴

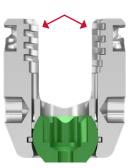




The threads of the set screw are trimmed in the lead-in regions to allow increased binary user feedback if the set screw is misaligned during insertion.⁴



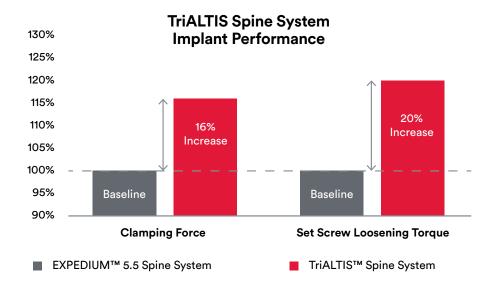
Tulip heads are machined with a precisely-timed, threaded feature to create a consistent full thread in the most proximal region of the tulip head.⁴



Construct Performance

Set Screw Loosening

The TriALTIS Spine System offers an increased final tightening torque specification (11.3 Nm) compared to existing DePuy Synthes Spine systems. The result is a 16% increase in set screw clamping force compared to the EXPEDIUM 5.5 Spine System. In addition, the TriALTIS System features a 20% improvement in set screw loosening torque.⁵



Polyaxial Drag

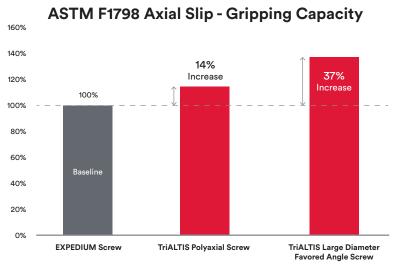
The head has been designed to have an interference fit between the shank sphere/flex ball and the drag ring. This frictional fit allows for the polyaxial heads to maintain their user designated position in-situ.⁶



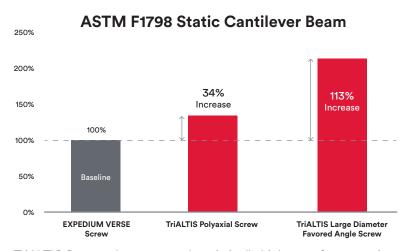
Gripping Capacity and Cantilever Beam

A common connection of a spinal implant assembly is a pedicle screw fastened to a rod via a set screw. Failure of this mechanism may cause surgical complications, such as fretting (relative micro-movement), which can cause wear, or slip, potentially causing segmental misalignment.

The resistance to this movement is called the gripping capacity, and it is the peak force within a determined distance of permanent displacement.



TriALTIS Screws demonstrated statistically higher gripping capacity compared to EXPEDIUM VERSE Screws.^{7,8}



TriALTIS Screws demonstrated statistically higher performance in cantilever beam testing compared to EXPEDIUM Screws.^{9,10}

The results of these tests indicate that TriALTIS Screws meet the high standards of security and performance established by and validated through long clinical history of EXPEDIUM Spine System and Expedium VERSE Spine System.

Deformity Correction

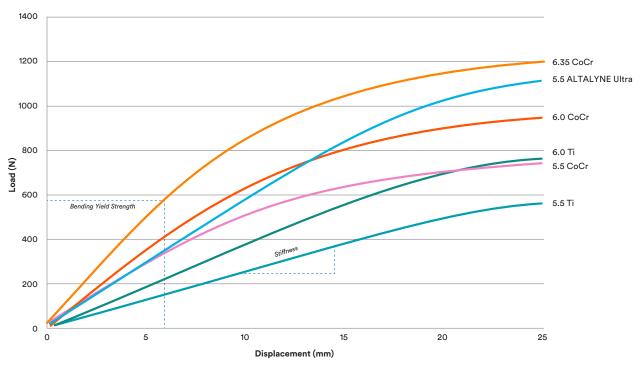
Rod Options

The TriALTIS Spine System offers an increased availability of rod options and materials for various clinical applications and anatomies.

The graph below illustrates the forces required to bend a rod. The slope of the curve is indicative of the rod's stiffness. The points at which the rod permanently deforms, or bends is the yield load, which is its strength.

Four Point Bending Load-Displacement Curve

With 2% Offset Yield Points Shown



Fatigue Performance

In addition, TriALTIS Spine System includes a 6.0 mm rod option that has improved fatigue performance compared to 5.5 mm rods of respective material.

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- 9. DePuy Synthes, TriALTIS System Poly Static Cantilever Beam Testing. December 12, 2023. Windchill #501452609 Rev A.
- 10. DePuy Synthes, TriALTIS System LDFA Static Cantilever Beam Testing. December 12, 2023. Windchill #501452678 Rev A.

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