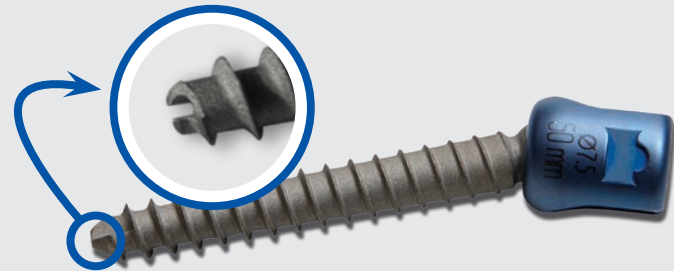


The science to achieve optimal screw fixation

Premia
Spine

The secret is in biology and design of Premia Spine's Pedicle Screws

The Premia Spine patented screw and rod system offers a unique surface finish and conical screw shape which creates a significant advantage for fixation at the screw-bone interface.



- **Proximal Cortical Threads for better bite in the pedicle**
- **Distal Conical Cancellous Threads for better bite in the vertebral body**
- **Calcium Phosphate Blasted Surface Treatment for greater Pull-Out and Torque-Out Resistance**
- **Sterile Packed for greater Quality Control and Traceability**
- **Clinically Proven over a decade and thousands of screws**

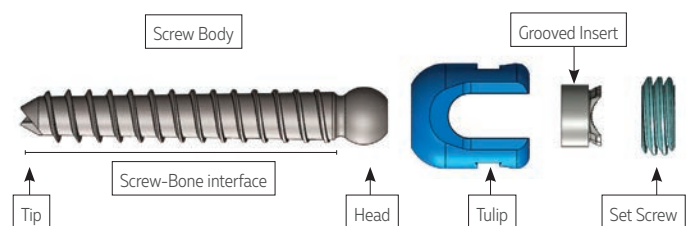
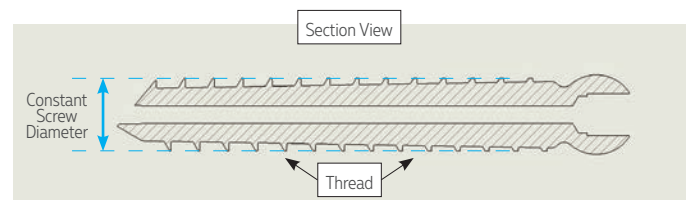
It's in the Screw design!

Our screws offer a unique buttress thread, a conical shape, and grooved insert.

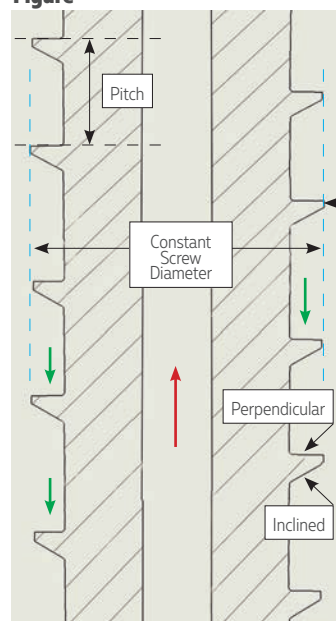
- **Both a constant shaft diameter and a conical shape.**
Creates a press-fit interface in the pedicle at the proximal portion of the screw, while interlocking the large-surface thread to bone from the distal shaft to the screw tip.
- **Press-fit fixation.**
The time-tested implant fixation method for hips and knees.
- **Self-tapping, self-drilling.**
Tip and threads produce self-tapping and self-cutting action to contour the bone for the screw body during insertion. Increased surface area together with the surface treatment enhance bone fixation after implantation.
- **Grooved insert with a Torx set screw.**
Features tiny grooves that augment the gripping capacity between the screw and the rod.

Solid screw fixation in the vertebral bone is critical for the long-term stability of pedicle screw-based implants.

Optimal screw fixation can eliminate problems of screw loosening, screw breakage, and rod breakage. This translates into reduced revisions and lower costs to hospitals.



Figure



Characteristic

The screw pitch is defined as the vertical distance between two consecutive threads. The Premia pedicle screws have a 3mm fixed pitch. The screws come in a diameter of 5.5mm, 6.5mm and 7.5 mm.

The screw threads have one flank that is perpendicular while the other is inclined. This buttress thread is advantageous in applications involving exceptionally high stresses along the thread axis. In terms of spinal biomechanics this design withstands heavy thrust and excellent pull-out resistance. It also directs compressive loads to increase bone density. The red arrow represents the pull out load acting on the pedicle screw. Green arrows represent the reactive loads acting on the perpendicular flanks of the pedicle screw on the bone/screw interface.

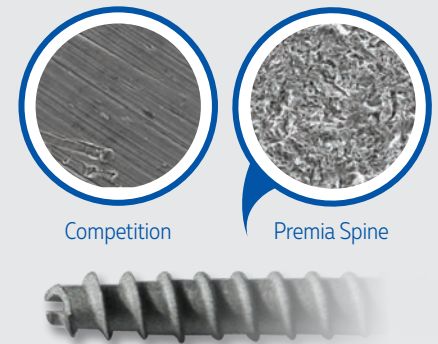
It's in the Biology of Screw Integration!

Screw loosening is caused by excessive micro-motions at the screw-bone interface under loads acting on the screw.

In a failed fusion where there is a non-union, the micro-motions are never optimized and the toggling on the screw eventually leads to failure. Premia Spine has mitigated this problem through a patented surface treatment that allows the bone to firmly engage the pedicle screw and accelerate the osseointegration process.

- Premia Spine's Blasted Surface Treatment is a proven long-term method for roughening the screw surface. The textured surface is created by a proprietary blasting of the screw with calcium phosphate particles, followed by passivation to remove residual media. It creates an enhanced textured surface with crevices for speedy bone ingrowth. An in vitro cell culture study proves the hypothesis that osteoblasts are sensitive to surface morphology produced by grit blasting of a Ti-6Al-4V titanium surface. The effects of the surface are similar to those seen in cells cultured on pure Ti.
- The in vitro experiment conducted at Georgia Institute of Technology demonstrated that grit blasting Ti-6Al-4V surfaces accelerated osteoblast proliferation and differentiation. The data was analyzed by ANOVA and significant differences were determined using the Bonferroni modification of Student's t-test. * $p < 0.05$, v. plastic; # $p < 0.05$, v. smooth Ti-6Al-4V; + $p < 0.05$, v. Ti-6Al-4V surface with Ra of $3 \mu\text{m}$.
- A randomized sheep study was conducted to investigate osseointegration of pedicle screws in bone after 12-week implantation with and without Premia's Blasted Surface Treatment. According to Professor Barbara Boyan, micrometer-scale roughness of the surface of the pedicle screw surface promotes osteointegration by stimulating osteoblast activity. The results proved that the bone-to-implant contact in the treated group was 73.5% versus 59.6% in the non-treated group. Moreover, **to remove the Blasted Surface-treated screws was 2.3 times higher** than the non-treated screws.

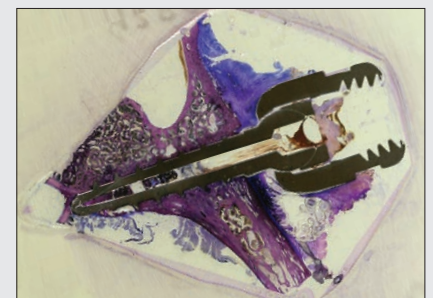
Patented screw surface



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Effect of Micrometer-scale Roughness of the Surface of Ti6Al4V Pedicle screws in Vitro and in Vivo

By Zvi Schwartz, DMD, PhD, Perry Raz, DMD, PhD, Ge Zhao, MD, PhD, Yael Barak, BS, Michael Tauber, MD, Hai Yao, PhD, and Barbara D. Boyan PhD



Individually packed sterile implants



| General Specification | Note |
|--|---|
| Screw Packaging | Supplied sterile, double blister. |
| Rod Packaging | Supplied sterile, double blister in standard sizes. Non-sterile in long configurations. |
| Screw and Rod material | Titanium alloy: Titanium Ti6Al4V |
| Screw Diameter: 5.5mm, 6.5mm and 7.5mm | Larger screws are available on special order. |
| Screw Length 25mm to 60mm, in 5mm increments | 40mm to 55mm standard supply. Other sizes available on special order. |
| Polyaxial heads: 20° (± 10°) x 360° | Very flexible screw placement. |
| Compatible with 6.0mm rods | Compatible with fusion fixation (ProMIS® System) 6.0mm rods. |
| Rod length: 35mm to 180mm in 5mm increments | The longer lengths available on special order. |