

Value Analysis Committee Resource Guide

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Premia Spine's

**ProMIS™**  
**Fixation System**

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Saves operating room time with faster and accurate spinal fusion procedure



Reduces x-ray exposure to surgeon, operating room staff and patient



Sterile factory-packed implants save hospital costs, speed response time, and reduce infection rates



Small instrument set reduces sterilization costs

## **Dear Hospital Administrator,**

Premia Spine is focused on introducing novel spine products and surgical techniques to improve patient care and reduce healthcare costs.

Premia has engaged surgeons in deep discussions and analyzed competing open and minimally invasive lumbar fusion procedures to bring you the ProMIS™ Fixation System—the state-of-the-art fusion system in the market.

Our sterile implants and small instrument set provide a range of surgical techniques to treat each spine patient optimally. We know that surgeons and operating room staff will benefit from the versatility, ease-of-use, and effectiveness of the ProMIS™ System.

Our value proposition is simple: to improve the quality of care for your patients and staff while reducing costs to your hospital.

- Faster and accurate screw placement,
- Reduced x-ray exposure to your staff and patients, and
- Decreased sterilization costs

This document details our value proposition to facilitate the ProMIS™ System approval.

Sincerely,



Ron Sacher  
CEO, Premia Spine  
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## Summary of Benefits

The ProMIS™ Fixation System is a novel lumbar spine fusion system for minimally invasive and open spine procedures. With ProMIS, surgeons and staff can treat a wide range of advanced lumbar spine diseases.

Key benefits of ProMIS include:

### Sterile, Packaged Pedicle Screws

- Saves cost of sterile processing (\$200 - \$400 per procedure)
- Increases supply chain efficiencies with easy EMR implant tracking
- Eliminates risk of cross contamination
- Minimizes infection, reducing risk of reoperation

### Surface Treated Pedicle Screws

- Demonstrates significant resistance to pullout and torsion forces to reduce screw loosening
- Promotes bone ingrowth to reduce revision surgeries

### Pre-bent, Sterile Rods

- Creates intraoperative time efficiency
- Saves cost of sterile processing (\$200 - \$400 per procedure)

### Multiple Screw Placement Techniques in one instrument set

- Direct One-Step Skin-to-Screw placement
- Innovative k-wireless (dilator) technique
- Tap-Shidi approach
- Traditional Jamshidi technique with reusable instrumentation

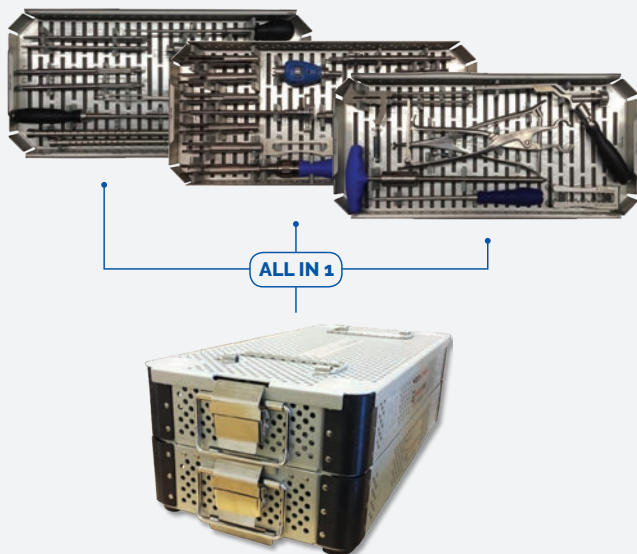
### Cut Unnecessary Operative Steps

- Simplifies the surgical technique
- Shortens surgery time (saves \$300 - \$1,500 per procedure)
- Eliminates additional operating room capital for screw placement
- Enhances surgical navigation and robotic systems

### Ergonomically Designed Instruments

- Minimizes trays on the back table (saves \$200 - \$400 per procedure)
- Increases ease of use for surgical technicians

## Fewer Instruments. More Economical Reprocessing



## Individually Packed Sterile Implants



# Extraordinary Pedicle Screw

There is a tendency to think that "a screw is a screw." But that's not true. Premia Spine has made great investments to produce a unique pedicle screw.

## Patented Screw Surface

Premia Spine is at the forefront of treating pedicle screw surfaces to enhance bony ingrowth.

Premia Spine's patented approach involves blasting the screw surface with calcium phosphate—a member of the HA (hydroxyapatite) chemical family. The screw is then passivated, resulting in a unique roughened screw surface with crevices and undercuts that dramatically increase the screw surface and promote very effective bony ingrowth and fixation.

Pre-clinical testing led by Dr. Barbara Boyan, **Premia's pedicle screw with the patented screw surface treatment requires 2.32 times the pull-out force for screw removal** versus the same pedicle screw without the treatment<sup>1</sup>. This translates into reduced incidence of screw loosening.<sup>2</sup>

## Sterile Pack

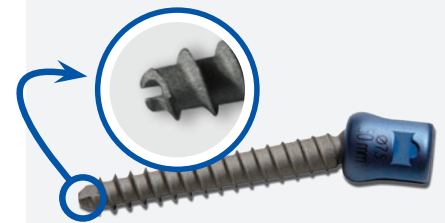
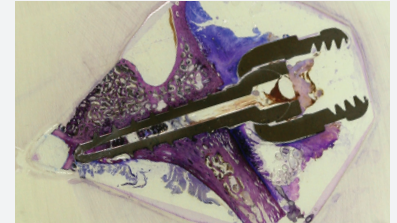
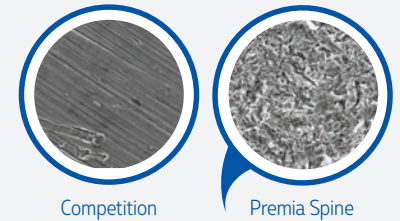
Studies provide strong evidence that exposure to an increased number of reprocessing cycles leads to greater rates of contamination, corrosion, deterioration and implant damage<sup>3</sup>. Premia Spine pedicle screws are delivered in sterile double blister packaging to eliminate cross contamination and to minimize risk of infection. In addition, Premia Spine's UDI/barcode packaged implants increase supply chain efficiencies and provide the sterile processing department with cost savings.

## Robust Design

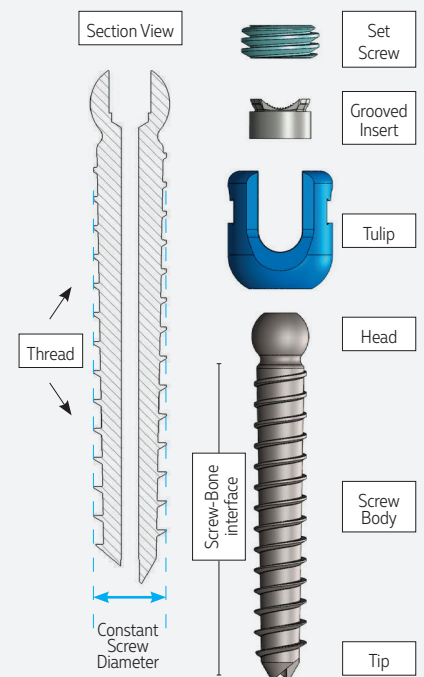
Solid screw fixation in the vertebral bone is critical for the long-term stability of pedicle screw-based implants. Optimal screw fixation can eliminate problems of screw loosening, screw breakage, and rod breakage. This translates into reduced revisions and lower costs to hospitals.

The unique screw tip and threads produce a self-tapping and self-drilling/cutting action which contour the bone to the screw body during implantation. An insert with tiny grooves augments the gripping capacity between the screw and the rod.

**Premia's screw design, surface treatment, and sterile pack are part of our high standards and effort to increase surgical success.**



*Premia's pedicle screws have both a constant shaft diameter and a conical shape. The Distal Conical Cancellous Threads achieves better bite in the vertebral body while the Proximal Cortical Threads are designed for better bite in the pedicle space. This creates a press-fit interface in the pedicle area at the proximal portion of the screw, while positioning the large surface-treated threads and body to interlock with bone from the shaft to the screw tip.*



1 Effect of Micro Meter Scale Roughness of the Surface of Ti6Al4V Pedicle Screws in Vivo in and Vitro. Schwartz, Boyan, et. al. Journal of Joint and Bone Surgery. 2008

2 IDE Study with Premia Spine pedicle screws yielded zero incidence of screw loosening in over 80 screw placements at over 2 years follow-up. Data on file at Premia Spine

3 Reprocessing Of Single Use Screws: A Study on the Effects of Repeated Reprocessing on Single-use Screws in Screw Caddies. Terry McAuley. Sterilisation & Infection Prevention and Control Consultant, with the cooperation of the Canberra Hospital, Australia and the Sterilising Research and Advisory Council of Australia

# Five Advanced Pedicle Screw Placement Techniques

Typical spinal fusion systems offer only one or two screw placement techniques. Premia Spine offers five different techniques including a traditional open approach in one small instrument kit. With different techniques from which to choose, the surgeon can select the safest, most effective, and most time optimizing technique for each screw placement. ProMIS surgeons use multiple techniques in the same surgery based on the size of the patient's pedicle, anatomy, and level of screw placement. Premia has created interchangeable and multi-functional instruments so that the instrument kit is small and versatile, and the screw insertion time is minimized.

## Direct Skin-to-Screw Placement

The Direct Skin-to-Screw driver is comprised of a patented screwdriver, tower, pedicle screw, k-wire and our novel control handle. It is assembled on the back table. The patented instrument allows the surgeon to independently control the pedicle screw and k-wire. Typically, a surgeon extends the k-wire a couple millimeters beyond the screw tip, anchors the driver at the desired bone entry point, advances the screw, backs the k-wire into the body of the cannulated screw and safely completes the screw advancement.

The time from skin incision to screw placement for a single-level fusion is 3 minutes<sup>4</sup>, saving an average of 15 minutes of operating room time. The technique eliminates all the complications associated with a traditional k-wire technique.



Watch video here:  
<https://goo.gl/Tq99Xq>

Watch videos here:  
<https://goo.gl/85Qc2T>



## Traditional Jamshidi Technique

Premia Spine provides a reusable Jamshidi instrument. Our Jamshidi offers a more robust interface than a plastic Jamshidi and the ability to directly aspirate via its cannulated core or our pedicle screw, saving \$150-\$300 per procedure.



## Novel Tapshidi Technique

As part of the Jamshidi technique, surgeons often use a tap to overcome hard bone. In these situations, Premia reduces the 10-step Jamshidi technique to 6 steps. The reusable Tapshidi instrument integrates the threads of a tap with the function of a Jamshidi. The result is a single tool for tapping and concurrently placing a k-wire deep into the pedicle—saving operating time and \$150-\$300 per procedure.



## Novel K-wireless / Dilator Technique

Surgeons have concerns with k-wires, such as breaching the anterior wall of the vertebral body and hitting major blood vessels. Premia's dilator approach allows surgeons to place a screw through a tube to protect the soft tissues from the screw threads and avoid a k-wire breach. The technique relies on three dilators to widen the initial entry point created by the pedicle awl and to precisely and accurately guide the screwdriver to pedicle screw's ideal bicortical position.



4 200 Timed Screw Placements with ProMIS System. Dr. Steve DeLuca. UPMC West Shore Hospital. Harrisburg, PA.



## Robust Instruments. Real Solutions.

Premia Spine simplifies open and MIS procedures without compromising on safety or accuracy. The ProMIS System delivers incremental improvements at critical junctions in the procedure.

### Quick Reduction

Surgeons often need to realign the spine by performing a reduction. Premia Spine offers an in-tower reduction for big reductions and a novel Quick Reduction Instrument—a tower and set screw inserter attachment that quickly reduces a 7-millimeter spondylolisthesis, saving surgery time compared traditional reduction techniques.

[Watch video here:  
https://goo.gl/MVYFdv](https://goo.gl/MVYFdv)

### Robust Towers and Reduction

During the procedure, surgeons may want to remove the towers for easier access to the disc space, but want to reattach for final compression or distraction. Most towers are fiddly or pop off at the wrong moment during the procedure. The ProMIS spring-activated Tower System stays on—even under high forces—and releases easily with a unique release mechanism.

[Watch video here:  
https://goo.gl/iThXHv](https://goo.gl/iThXHv)

### Rod Inserter

Premia Spine offers a solid-state fixation Rod Inserter for easy rod passage. A unique swivel release frees the rod from the inserter.

[Watch video here:  
https://goo.gl/mou1aH](https://goo.gl/mou1aH)

### Compressor/Distractor

Premia Spine offers robust compression and distraction instruments for maximum cage-bone interface and optimal sagittal balance.

[Watch video here:  
https://goo.gl/JDn51R](https://goo.gl/JDn51R)

# Implant Information

Part No.	Name of the Component
86120	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 5.5x25 mm
86121	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 5.5x30 mm
86122	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 5.5x35 mm
86123	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 5.5x40 mm
86124	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 5.5x45 mm
86125	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 5.5x50 mm
86126	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 5.5x55 mm
86390	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 5.5x60 mm
86127	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 6.5x25 mm
86128	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 6.5x30 mm
86129	Polyaxial Pedicle Screw Cannulated, Torx Setscrew Grooved 6.5x35 mm
86130	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 6.5x40 mm
86131	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 6.5x45 mm
86132	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 6.5x50 mm
86133	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 6.5x55 mm
86391	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 6.5x60 mm
86134	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 7.5x25 mm
86135	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 7.5x30 mm
86136	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 7.5x35 mm
86137	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 7.5x40 mm
86138	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 7.5x45 mm
86139	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 7.5x50 mm
86140	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 7.5x55 mm
86392	Polyaxial Pedicle Screw Cannulated, Torx Setscrew, Grooved 7.5x60 mm
86211	Torx set screw
87315	Pre-Bent Rod ø6.0x30mm R128 Hex Edge
86794	Pre-Bent Rod ø6.0x35mm R128 Hex Edge
86241	Pre-Bent Rod ø6.0x40mm R128 Hex Edge
86401	Pre-Bent Rod ø6.0x45mm R128 Hex Edge
86242	Pre-Bent Rod ø6.0x50mm R128 Hex Edge
86402	Pre-Bent Rod ø6.0x55mm R128 Hex Edge
86243	Pre-Bent Rod ø6.0x60mm R128 Hex Edge
86403	Pre-Bent Rod ø6.0x65mm R128 Hex Edge
86244	Pre-Bent Rod ø6.0x70mm R128 Hex Edge
86404	Pre-Bent Rod ø6.0x75mm R128 Hex Edge
86245	Pre-Bent Rod ø6.0x80mm R128 Hex Edge
86405	Pre-Bent Rod ø6.0x85mm R128 Hex Edge
86246	Pre-Bent Rod ø6.0x90mm R128 Hex Edge
86406	Pre-Bent Rod ø6.0x95mm R128 Hex Edge
86247	Pre-Bent Rod ø6.0x100mm R128 Hex Edge
86407	Pre-Bent Rod ø6.0x105mm R128 Hex Edge
86408	Pre-Bent Rod ø6.0x110mm R128 Hex Edge
86409	Pre-Bent Rod ø6.0x115mm R128 Hex Edge
86255	Pre-Bent Rod ø6.0x120mm R128 Hex Edge
86410	Pre-Bent Rod ø6.0x125mm R128 Hex Edge
86411	Pre-Bent Rod ø6.0x130mm R128 Hex Edge
86412	Pre-Bent Rod ø6.0x135mm R128 Hex Edge
86256	Pre-Bent Rod ø6.0x140mm R128 Hex Edge
86413	Pre-Bent Rod ø6.0x145mm R128 Hex Edge
86414	Pre-Bent Rod ø6.0x150mm R128 Hex Edge
86415	Pre-Bent Rod ø6.0x155mm R128 Hex Edge
86257	Pre-Bent Rod ø6.0x160mm R128 Hex Edge
86416	Pre-Bent Rod ø6.0x165mm R128 Hex Edge
86417	Pre-Bent Rod ø6.0x170mm R128 Hex Edge
86418	Pre-Bent Rod ø6.0x175mm R128 Hex Edge
86258	Pre-Bent Rod ø6.0x180mm R128 Hex Edge
86871	Pre-Bent Rod ø6.0x190mm R128 Hex Edge
86872	Pre-Bent Rod ø6.0x200mm R128 Hex Edge
86873	Pre-Bent Rod ø6.0x210mm R128 Hex Edge
86874	Pre-Bent Rod ø6.0x220mm R128 Hex Edge
87349	Pre-Bent Rod ø6.0x300mm R128 Hex Edge
87316	Pre-Bent Rod ø6.0x340mm R128 Hex Edge
87343	Rod ø6.0x250mm Hex Edge
87344	Rod ø6.0x300mm Hex Edge
87345	Rod ø6.0x350mm Hex Edge
87346	Rod ø6.0x400mm Hex Edge
87347	Rod ø6.0x500mm Hex Edge
86264	K-Wire, Blunt End Sharp Tip, L=470mm, D=1.7mm
87209	K-Wire, Blunt End Beveled Tip, L=230mm, D=1.7mm
87208	K-Wire, Blunt End Beveled Tip, L=470mm, D=1.7mm
86830	K-Wire, Blunt End Blunt Tip, L=470mm, D=1.7mm
86828	K-Wire, Blunt End Sharp Tip, L=230mm, D=1.7mm
86864	K-Wire, Blunt End Sharp Tip, L=335mm, D=1.7mm
86289	K-Wire, Blunt End Thread Tip, L=470mm, D=1.7mm
86779	K-Wire, Blunt Tip, L=470mm, D=1.7mm
86266	K-Wire, Round End, L=300mm, D=1.7mm
86829	K-Wire, Round End thread Tip, L=470mm, D=1.7mm
86723	K-Wire, Round End, Blunt Tip, L=470mm, D=1.7mm
86265	K-Wire, Round End, L=330mm, D=1.7mm
86780	K-Wire, Thread Tip, L=470mm, D=1.7mm
87010	Nitinol K-Wire Blunt End Blunt Tip 470mm D=1.7mm
87009	Nitinol K-Wire Blunt End Sharp Tip 470mm D=1.7mm
87284	K wire, Blunt End Sharp Tip, L=355mm, D=1.7mm
87271	CrCo K wire, Blunt End Sharp Tip, L=380mm, D=1.6
87302	Blunt end, Sharp Tip, L=445 mm

A small group of surgeons and engineers set out to improve spinal surgery in 2003. More than 15 years later, we have grown from a few ideas to a portfolio of innovative spinal products backed by over 50 worldwide patents.

Premia Spine employs capable and knowledgeable individuals in the United States and Europe. We are joined by a network of excellent distributors who support our surgeons and hospital staff to provide better healthcare to spine surgery patients.



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