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PERPOS[™] PLS SYSTEM FROM INTERVENTIONAL SPINE

Percutaneous Transfacet-Pedicular Stabilization with an AxiaLIF[®] Approach to Fusion

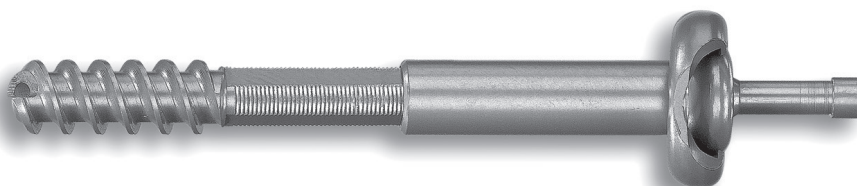
Interbody fusion has become an accepted treatment for patients with discogenic back pain originating from the L5-S1 disc space. Over the last decade, minimally invasive approaches, including percutaneous placement of effective fixation devices and the development of specialized instrumentation for retraction and visualization, have replaced more traditional open approaches.^{1,2,3,4} Minimally invasive approaches have been shown to have a significant and positive impact on outcome,⁵ reducing potential injury to adjacent structures while achieving the same goal of rigid fixation. Additional advantages of this approach include less nerve retraction, less blood loss, improved cosmetic results, and shortened hospital stay.⁶

The AxiaLIF[®] system was developed as a fully percutaneous, minimally invasive method to successfully perform an L5-S1 interbody fusion. Mitchell A. Hardenbrook, MD, an orthopedic surgeon with The Boston Spine Group (Newton, MA), has been performing lumbar fusion using the AxiaLIF approach for about three years. Dr. Hardenbrook was attracted to this technique and the TranS1 system because it gained him access to the disc space without having to utilize a vascular surgeon as might be required with an anterior approach and because it caused absolutely no injury to the posterior muscle. "AxiaLIF is an innovative approach to interbody fusion and it clearly seemed like the least traumatic approach to get to the L5-S1 disc space," notes Dr. Hardenbrook.

Dr. Hardenbrook has now moved his practice beyond the usual approach to posterior stabilization of an AxiaLIF by incorporating the

PERPOS[™] PLS System from Interventional Spine, Inc. (Irvine, CA). "I was initially intrigued by this alternative technology for the same reason I was attracted to the AxiaLIF: the percutaneous approach to placement and the potential limitation of trauma to the posterior muscles, combined with improved procedure recovery. With a half-inch incision and a half-inch channel through the muscle fibers in the back, we can get adequate posterior fixation while minimizing the trauma through the posterior muscles."

The PERPOS PLS System is the first and only percutaneous transfacet-pedicular compression system for posterior stabilization during a fusion procedure of the lower spine. Surgeons can perform posterior lumbar stabilization and achieve lumbar fusion at single or multiple levels without cumbersome rod and screw technology. The PERPOS System contains a complete set of instruments engineered for percutaneous implantation of **BONE-LOK[®]** implants. Developed with the company's **CLASP[®]** custom compression fit technology and designed to achieve facet-to-pedicle fixation, the PERPOS PLS System is intended to provide secure fixation, leaving less hardware in the patient and preserving the adjacent facet joint(s). Utilizing the innovative **Teleport[®] Tissue Retractor**, surgeons can access the spine using only a single 15-mm percutaneous entry site, minimizing disruption to the soft tissue. The axial compression of the 'one-size-fits-all' device allows the BONE-LOK to size to appropriate length *in vivo*. The PERPOS System offers surgeons not only a less invasive method of fixing the lumbar spine, but one that is designed to provide consistent results time after time.



The PERPOS[™] PLS System from Interventional Spine contains a complete set of instruments engineered for percutaneous implantation of one-size-fits-all BONE-LOK[®] implants.

"It's a larger procedure to implant pedicle screws—even percutaneously—as it involves a great deal of muscle destruction," points out Dr. Hardenbrook. "It requires two incisions—one on each side—and a split of the muscles through the multifidus muscle belly, which is the important dynamic stabilizer of the lumbar spine. I have seen significantly more post-operative pain when using the pedicle screws. Blood loss tends to be higher and I generally have to add a day to the post-operative stay." As for his results with the BONE-LOK implants, Dr. Hardenbrook points out "Without question, my results have been better. Of course, as with every surgical procedure, patient selection is essential to ensure the best possible results. That having been said, I have found that by minimizing the trauma of surgery, my patients have a quicker recovery, less pain post-operatively, and a more complete recovery with a higher level of activity more quickly."

Dr. Hardenbrook finds that the BONE-LOK implant and its unique compression fit complement the rest of the device elements, fostering fusion in his patients. "You want to have stability posteriorly to minimize micromotion as much as you can in the interbody space and thereby promote fusion. Now, how much motion is beneficial versus how much motion promotes a non-union? No one really knows the answer to that. But, clearly, pedicle screw constructs provide very rigid constructs while the facet screws allow for a less rigid, less traumatic application, yet still provide enough stability for a good interbody fusion. The compression fit component of the BONE-LOK implant is a nice feature that allows me to control how much force is used to put in the implant and thereby control the rigidity of the system." Dr. Hardenbrook further notes that the AxiaLIF trajectory needed to treat L5-S1 and the PERPOS PLS System trajectory for posterior stabilization at that level are compatible. "The AxiaLIF

is placed through the sacrum into the L-5 body towards the mid-line, whereas the PERPOS facet screws are placed more laterally, so the trajectory of the two implants doesn't come close to each other and they are easily compatible."

Some studies have shown that pedicle screw fixation is losing popularity because of complications related, directly or indirectly, to pain from the wide exposure.^{7,8,9,10,11} Dr. Hardenbrook points out that "Patients seem to have a feeling for pedicle screws deep in their back and as they try to increase their activities, they have a sense there is something large and metallic in their back. BONE-LOK implants are relatively flush with the facets and I've found patients can sense the difference. Patients seem to progress more quickly through therapy and increase their activities faster with the BONE-LOK implants than with the pedicle screw system." Dr. Hardenbrook also explains a secondary problem he has encountered with pedicle screws, particularly done minimally invasively. "There is a population of those patients who, after successful fusion and full recovery, develop painful retained hardware. In as many as 15 to even 20 percent of cases, I have had to go back and take out the pedicle screws about a year or so after surgery. I've never had to remove a BONE-LOK implant for painful retained hardware. The system has an extremely low profile and therefore less likelihood of soft-tissue irritation post-operative. In fact, it's the lowest profile construct that one could put in for a patient."

Dr. Hardenbrook believes that as far as learning the PERPOS PLS System stabilization procedure, the actual technique is quite straightforward. "If you can do a kyphoplasty or can percutaneously perform pedicle screws, then certainly putting in a percutaneous facet screw with the PERPOS System is well within your skill set." Dr. Hardenbrook also comments that the procedure is faster. "It is

probably about an hour to put in pedicle screws versus thirty minutes to put in the BONE-LOK implants."

Mitchell A. Hardenbrook completed a general surgical internship and an orthopedic surgery fellowship at the University of Maryland Medical Center/SHOCK Trauma Institute. Dr. Hardenbrook also completed a fellowship in reconstructive spine surgery at New England Baptist Hospital. After completion of his fellowship, Dr. Hardenbrook served in the United States Navy as Director of Spine Surgery at Naval Medical Center, Portsmouth. Dr. Hardenbrook is currently with the Boston Spine Group and is actively involved with numerous research projects including basic science, motion preservation, muscle-sparing approaches to the cervical and lumbar spine, clinical studies in minimally invasive surgery of the lumbar and cervical spine, and use of robotics in spine surgery.

To Learn More

To learn more about **Interventional Spine** or the **PERPOS™ PLS System**, please call 1-800-497-0484, or visit the Web site at www.i-spineinc.com.



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