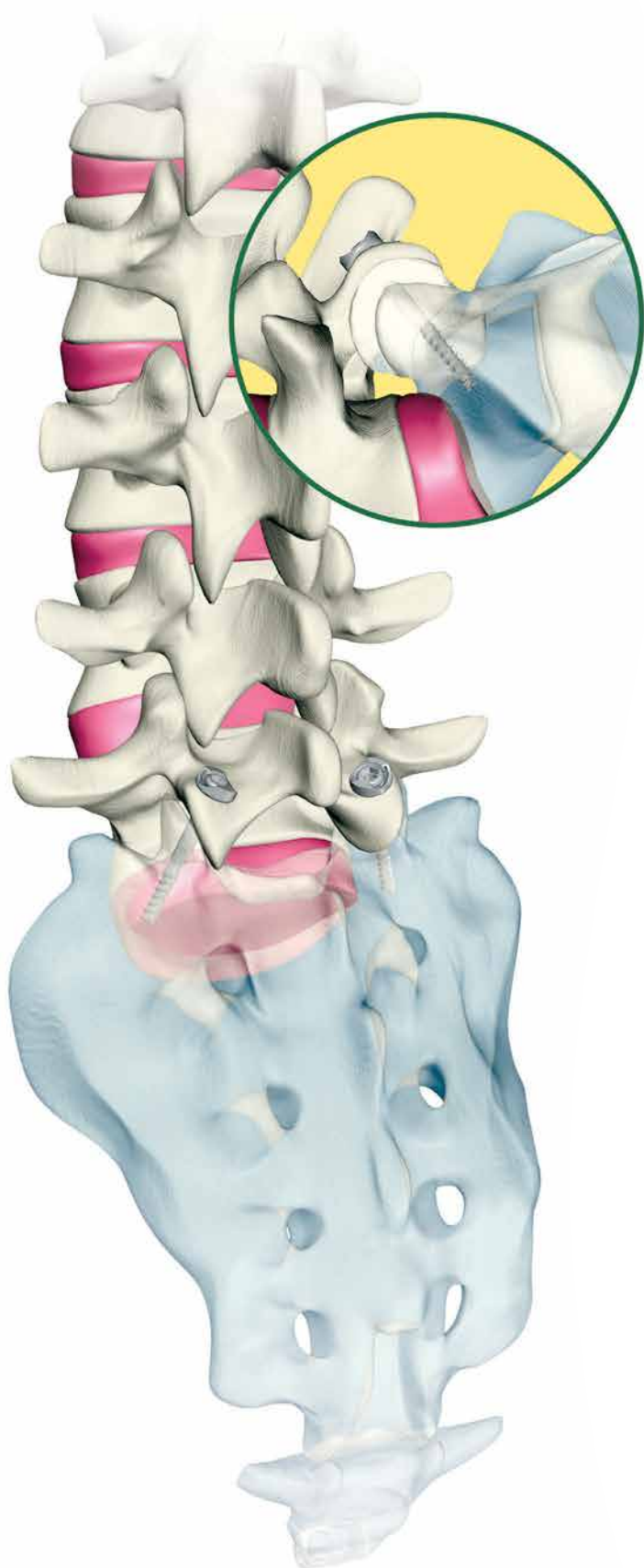


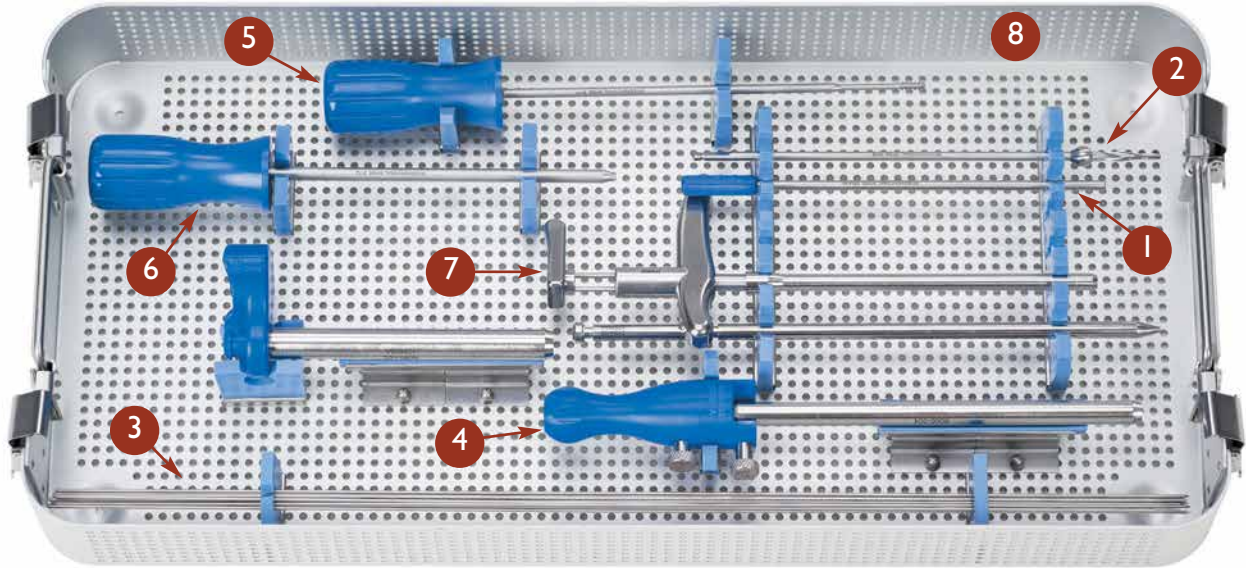
PERPOS® PLS System Surgical Technique



This brochure is intended to demonstrate general surgical technique. Interventional Spine, Inc. as the manufacturer does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs the implant procedure is responsible for determining and utilizing the appropriate technique for implanting the device in each individual patient. Interventional Spine, Inc. is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

As of date of print, Interventional Spine has several issued and pending U.S. patents. Interventional Spine®, PERPOS® PLS System, BONE-LOK®, CLASP®, and Teleport® are all marks registered with the U.S. Patent and Trademark Office.

PERPOS® PLS Instruments referenced in this guide



Item	Reference Number	Name/Description
1	6064-00	PERPOS® Pull Pin Remover
2	6070	PERPOS® 2-In-1 Drill
3	6072-00	PERPOS® K-wire
4	6086	11mm ID Teleport, re-usable
5	6111	PERPOS® Tap
6	6112	PERPOS® Device Driver
7	6113-00	PERPOS® Compression Tool
8	6115	Tray

These instruments are purchased separately from Interventional Spine

Operative Technique

The purpose of this guide is to provide specific information regarding Interventional Spine, Inc.'s 4.5mm BONE-LOK® PLS Implant. This technique is used to implant the 4.5mm BONE-LOK® PLS Implant for stabilizing the posterior elements of a spinal level, allowing for the normal healing process to create a solid boney fusion across the disc space. The following is utilized when the patient is positioned on the operating room table in the prone position in normal lordosis. The patient should be prepped and draped using sterile technique.

Step 1 Target Anatomy

A series of Lateral and AP fluoroscopy images are used to target the appropriate spinal level, the start point on the facet, the trajectory of the implant that is to be placed, and the entry point on the patient's skin.

The AP view should be adjusted for the lordosis of the lumbar level which is being treated. This is done by adjusting the fluoro image whereby the inferior endplate of the superior vertebral body of the disc level being treated appears as a single line.

A helpful technique with finding the start point on the facet is to use a K-Wire and marking pen on the skin and identify the following: the midline of the spine, the inferior endplate of the superior body of the level that is being treated, and a line drawn between the medial edge of the pedicle above and below.

A start point, defined as the point where the implant will enter the bone, is determined by using Anterior-Posterior (AP) and Lateral fluoroscopic images. From the AP view (Fig 1), the Cephalad/Caudal Start point is located using the transition of the pars and inferior articular process. Furthermore this point should be inline with the Inferior endplate of the superior vertebral body of the disc level being treated. The Medial/Lateral Start Point is the medial edge of a line drawn between the pedicles above and below.

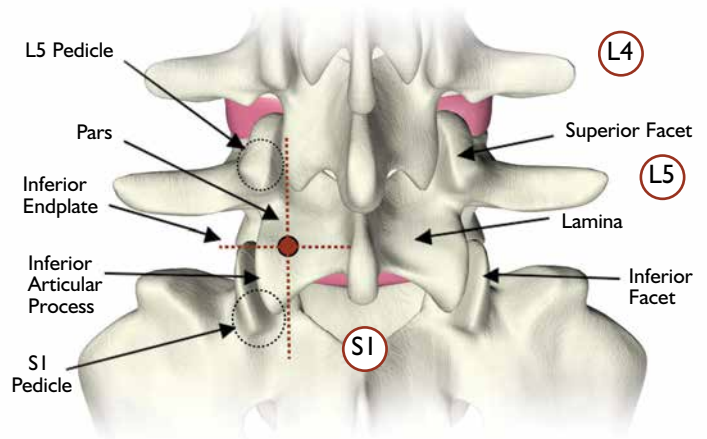


Figure 1 - AP view for Entry Point

The lateral view (Fig. 2) is used to confirm that the start point will allow for the K-Wire to go through the superior and inferior facet, into the center of the pedicle of the vertebral body below.

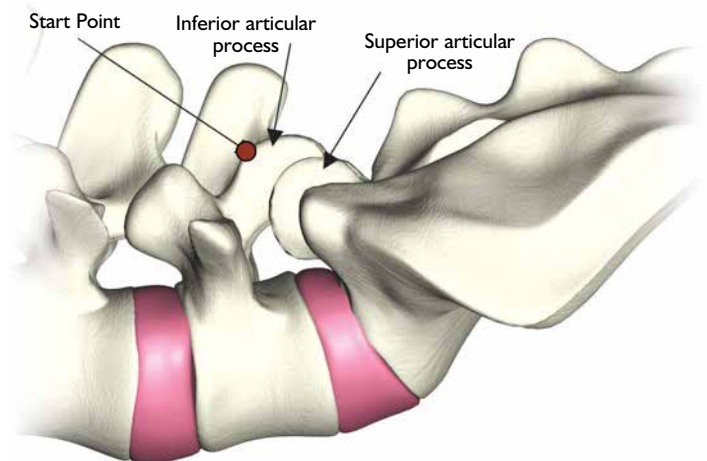


Figure 2 - Lateral view for Entry Point

Step 2

Entry Point

The entry point is the location on the patient's skin where the appropriately sized Access Needle is inserted. Typically the entry point will be at the spinous process of the vertebral body one or two levels above the level to be treated (i.e. L3 for a L5/S1). This is a general guide, but patient anatomy will dictate actual position.

Step 3

Trajectory

Using Lateral and AP fluoroscopy images and the anatomy, the trajectory of the implant is determined, as shown in Fig 3 and Fig 4 below. The AP trajectory is medial to lateral.

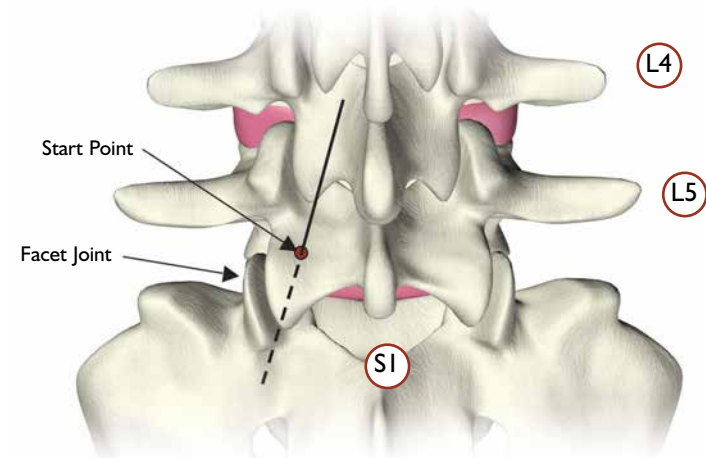


Figure 3 - AP View Trajectory

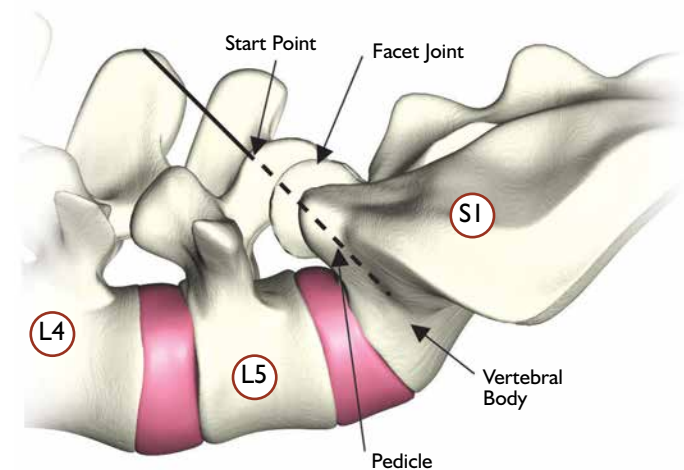


Figure 4 - Lateral View Trajectory

Step 3 (cont.)

Trajectory

One technique to help see the proper trajectory is to place a K-wire near or on the patient while the fluoroscopy images are being taken. Adjusting the position of the wire will determine the best trajectory. This information is used to determine the Entry Point on the patient's skin and Start Point on the facet.

A small mid-line stab incision is made to accommodate the Access Needle. The Access Needle is inserted, with the bevel facing up (to prevent the Access Needle from "slipping" off of the facet), through the skin, along the proper trajectory until the tip is at the Start Point on the bony anatomy. A series of AP and Lateral views may be needed to confirm precise positioning. At this point the bevel of the access needle can be rotated to guide the K-wire. The wire will favor the long side of the beveled tip. This can be used in the AP or Lateral views to improve the trajectory.

Use care when tapping into the bone, so as not to bend the Access Needle.

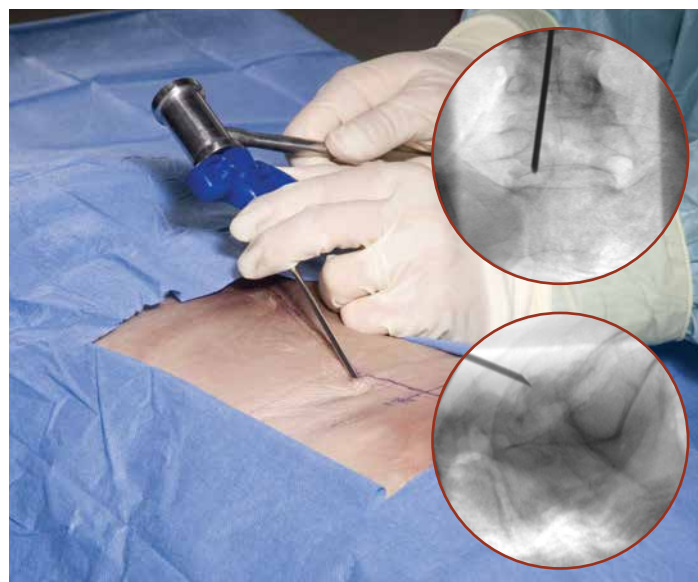


Figure 5 - Access Needle

Step 4

PERPOS® K-Wire

With the inner stylet removed, the .062 K-Wire is passed through the Access Needle and driven across the facet joint with the guidance of a drill, through the center of the pedicle, to (approximately) mid-portion of the inferior vertebral body (Fig. 6). This should be accompanied by a series of fluoroscopy images to insure the K-wire tip reaches the appropriate position and that the trajectory does not change as the wire goes across the facet joint into the center of the pedicle. The Access Needle is then removed while maintaining wire placement.

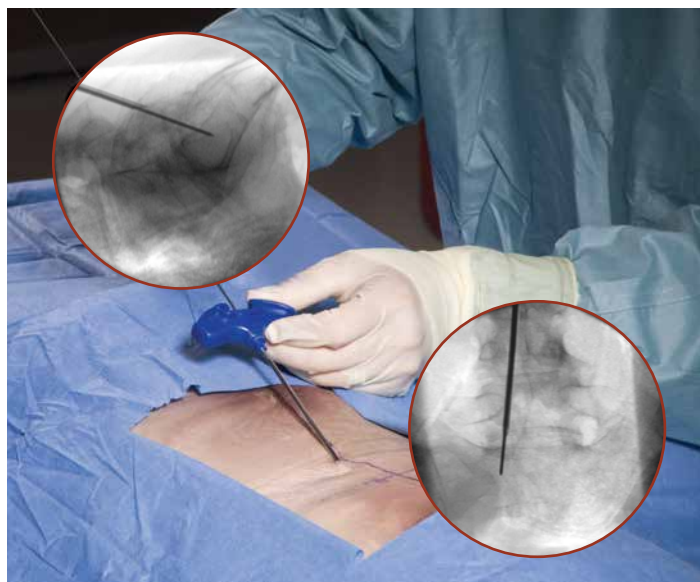


Figure 6 - K-wire

Step 5

Dilation

Once the K-Wire has been placed, make a 15mm incision through skin and fascia. The fascia needs to be incised inferiorly to the skin incision to accommodate Interventional Spine, Inc.'s 11mm ID Teleport®. (Fig 7 & 8).

The Teleport® is placed over the K-wire and advanced until the first retractor comes in contact with the facet. This should be confirmed in the lateral view.

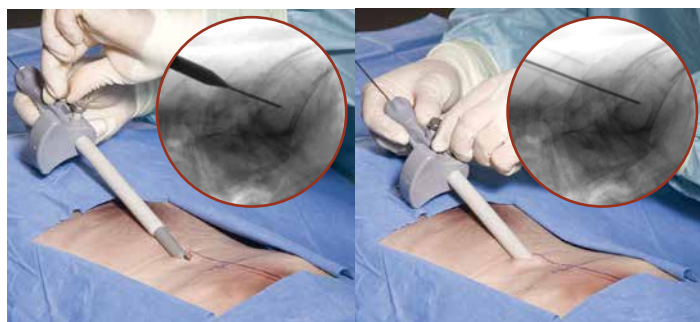


Figure 7 & 8 - Dilating with the Interventional Spine, Inc. 11mm ID Teleport®

Step 5 (cont.)

Dilation

Pull the first button (labeled "Pull 1") of the Teleport®, and then apply forward pressure to advance the second tissue retractor down to the facet. Pull the second button of the Teleport® (labeled "Pull 2") and then apply forward pressure to advance the third retractor down to the facet. Use a lateral fluoroscopic image to verify proper placement of the Teleport®. After confirmation of the final placement of the outer dilator of the Teleport®, hold the flat distal handle in place, remove the proximal handle. The first and second dilator will come out and remain as one unit.

For procedures where the Teleport® is utilized more than once, remove the instrument from the initial surgical location. Reassemble the Teleport® by pulling the first button (labeled "Pull 1"), releasing the first retractor from the second retractor until "locked" in place. Place the third retractor over the first and second retractors, pull the first button (labeled "Pull 2"), and "lock into place. The Teleport® is now ready for use. Repeat the instructions above for the placement of the next BONE-LOK® PLS Implant (LSW-45-3040).*

*Note: The washer on the 4.5mm BONE-LOK® PLS Implant is 10.5mm in diameter - The selection of a proper retraction system (Minimum 11mm ID) is necessary to be able to accommodate the device.

Step 6

PERPOS® 2-in-1 Drill

The cannulated 2-in-1 Drill is passed over the K-Wire. The drill is advanced until the depth limiting feature (30mm "positive stop") contacts the bone. This is confirmed through fluoroscopy.

The fluoroscopy image is saved and "flipped" to the second fluoroscopy screen. The tip of the drill is 30mm from the sphere - This image can be used as a reference for gauging the depth of the tap and placement of the BONE-LOK® PLS Implant.

Step 7

PERPOS® Tap

The cannulated Tap is driven by hand (Fig 9) into the bone until the tip reaches the appropriate depth (slightly past the distal tip of the drill, identified on the saved image from the second monitor), which is determined and verified by fluoroscopy. Once the appropriate depth is achieved, the tap is removed.

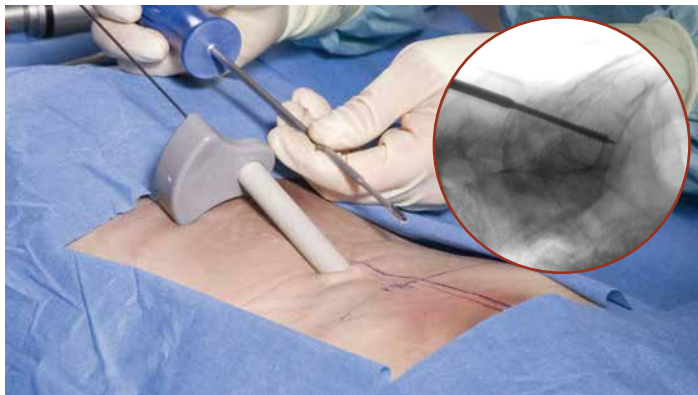


Figure 9 - Tap

Step 8

Implant Placement

The 4.5mm BONE-LOK® PLS Implant is fully seated onto the Driver and care is taken not to remove the plastic clip until implant is placed over the K-Wire. The anti-compression clip is then removed (Fig 10) and the device is advanced to, and then into, the bone. The placement of the implant should be with a continuous forward clockwise motion, using a series of fluoroscopy images to insure proper depth. Do not “pull back” on the Driver when inserting the implant – This may disengage the implant from the Driver, which could cause the premature advancement of the compression collar of the implant.

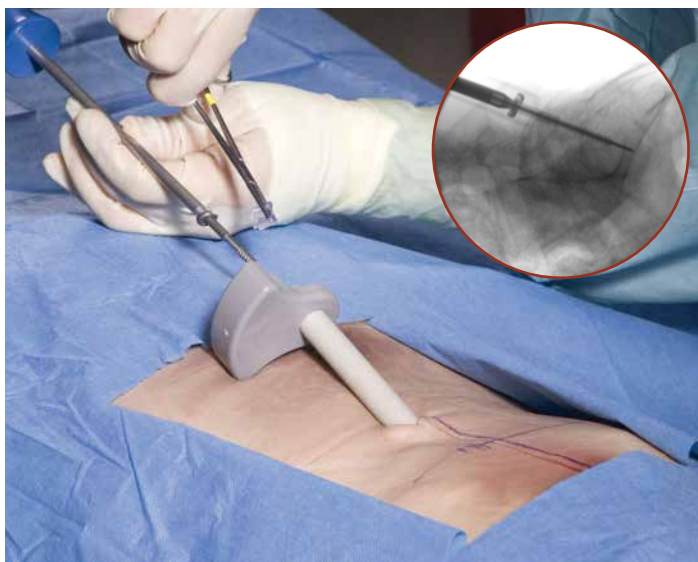


Figure 10 - BONE-LOK® PLS Implant

Step 8 (cont.) Implant Placement

The 4.5mm BONE-LOK® PLS Implant is inserted until the distal tip is at the desired location (as determined by the surgeon), leaving the proximal head of the implant slightly “proud” to allow for compression. After the proper position of the distal tip has been established, the driver is removed by pulling straight back.

(Note: Step 9 is used to fully seat the implant to the bone and gain compression of the facet joint.)

Step 9 Compression of Implant

The Compression Tool is passed over the K-Wire and over the Pull Pin (Fig 11).

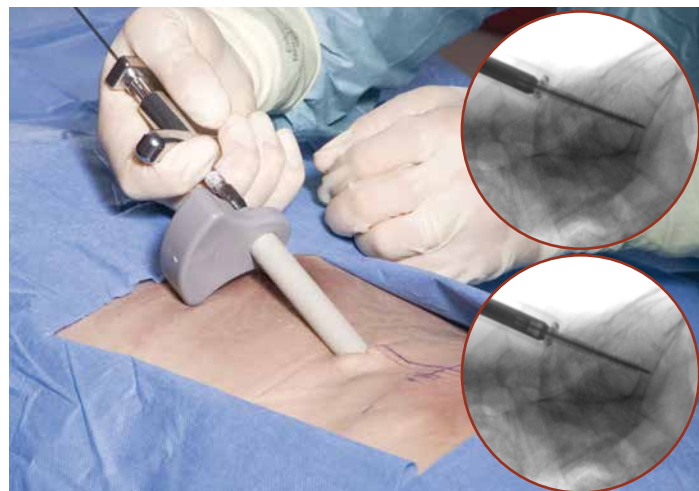


Figure 11 - Compression

The device is designed to accommodate a range of 30 to 40 mm. This leaves a maximum of 10mm of available compression, but the actual amount of compression needed is determined by the patient's anatomy and the surgeon's preference. (see step 8).

Using only one hand to compress, the surgeon can tell when the implant is properly positioned under fluoro by watching the self-retaining washer tilt and lay flat against the bone, indicating that the device is fully compressed. The amount of compression needed is verified using “continuous fluoroscopy” and tactile feedback.

Step 10 PERPOS® Pull Pin Removal

Once the appropriate compression has been achieved, the Pull Pin **must be** removed. The Pull Pin Remover is placed over the K-Wire and down to the Device (Fig 12). The Pull Pin Remover is turned clockwise while applying light downward force.



Figure 12 – Pull Pin Remover

Typically, it will take no more than 4 full turns for the threads to release, at which point the surgeon will hear and/or feel a clicking that will indicate that the Pull Pin has disengaged from the implant. At this point, the Pull Pin Remover can be removed from the site, making sure to verify that the Pull Pin is still engaged with the Pull Pin Remover. Final images are taken.

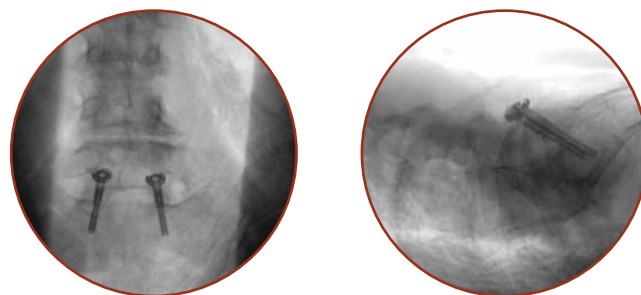
If the Pull Pin is not engaged with the removal device, the Compression Tool can be used to grab it. While the K-Wire is still in place, re-introduce the Compression Tool. Once seated (this should be verified with fluoroscopy), pull the Compression Tool handle and hold it as you remove it from the port. The Pull Pin will be held by the Compression Tool until the handle is released.

Step 11 Remove Guide Wire

Remove the K-Wire with the wire driver. At this time you should also remove the retractor through which the procedure was done.

Step 12 Repeat Procedure

The 4.5mm BONE-LOK® PLS Implant is intended to be used bilaterally. Utilizing the same incision, repeat the procedure for the contra-lateral side of the patient.





Step 13 Closure

Once the devices are placed, and it's been verified that the Pull Pins, the K-Wires and the tubular retractor have been removed; a standard closing procedure is utilized.



Applicable to the following device:
9024-00, Ø4.5mm BONE-LOK® PLS Implant

	
<p><u>Manufacturer</u> Interventional Spine, Inc. 13700 Alton Parkway, Suite 160 Irvine, CA 92618 Phone: +1 949-472-0006 Fax: +1 949-472-0016 www.i-spineinc.com</p>	<p><u>European Authorized Representative</u> Donawa Lifescience Consulting Srl. Piazza Albania, 10 00153 Rome Italy Phone: +39 06 578-2665 Fax: +39 06 574-3786</p>

Caution: US Federal Law restricts this device to sale by or on the order of a physician

Interventional Spine, Inc.
13700 Alton Parkway, Suite 160
Irvine, CA 92618
Ph. +1 (949) 472-0006
Fax +1 (949) 472-0016
www.i-spineinc.com