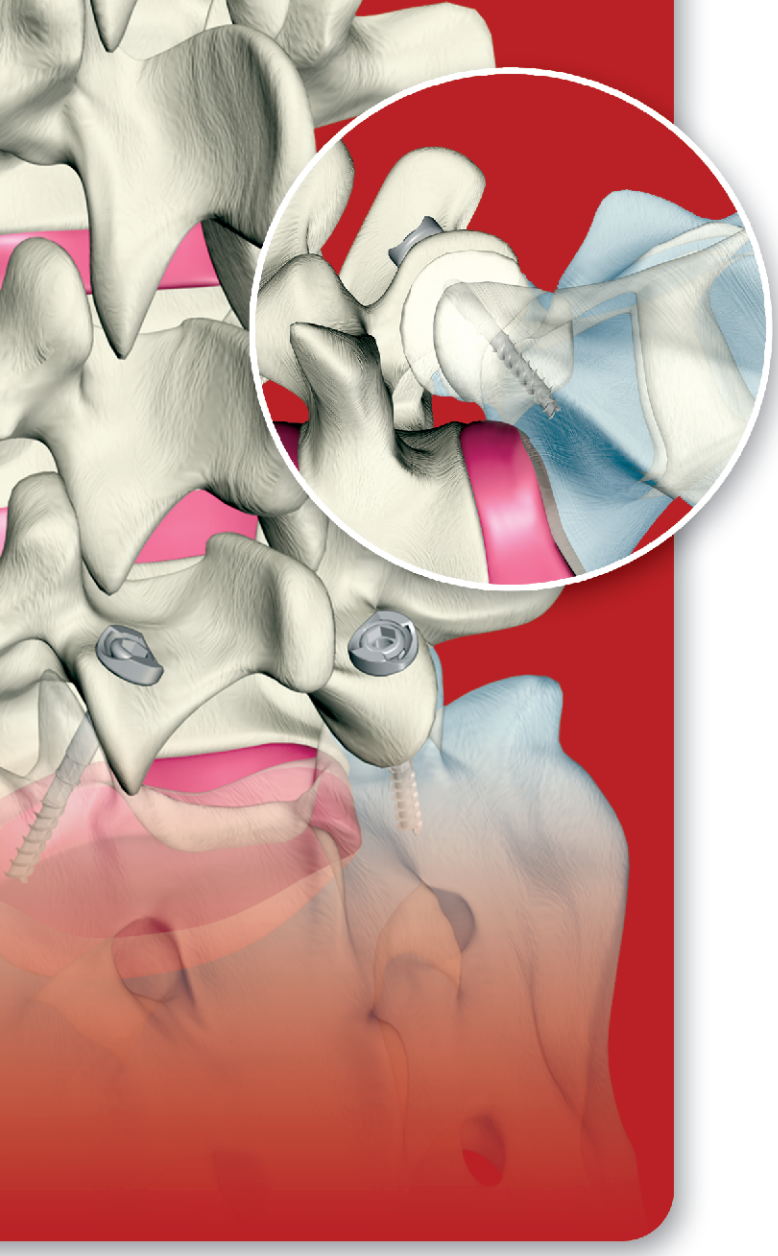
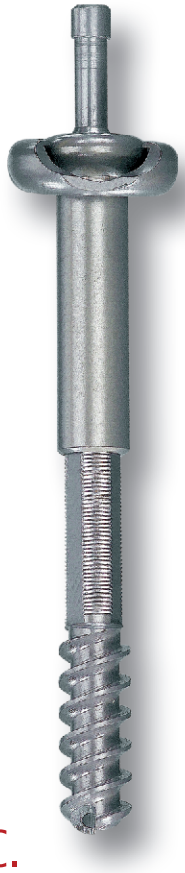


BONE-LOK®



OFTEN IMITATED, NEVER DUPLICATED™:

THE TRANSFACET-PEDICULAR COMPRESSION IMPLANT FOR LUMBAR STABILIZATION, WITH PATENTED CLASP® TECHNOLOGY, FROM INTERVENTIONAL SPINE®, INC.

- ONLY the patented BONE-LOK Implant has CLASP (**C**ompression **L**ocking **A**nchor with **S**econdary **P**urchase) technology.

- CLASP technology has three unique benefits over a lag screw:
  1) Superior pullout strength
  2) Superior compression strength
  3) Intraoperative flexibility

ACCEPT NO SUBSTITUTE FOR YOUR PATIENTS.

Interventional Spine®
A New Pathway for Spine Therapy

BONE-LOK® Implants with CLASP® Technology

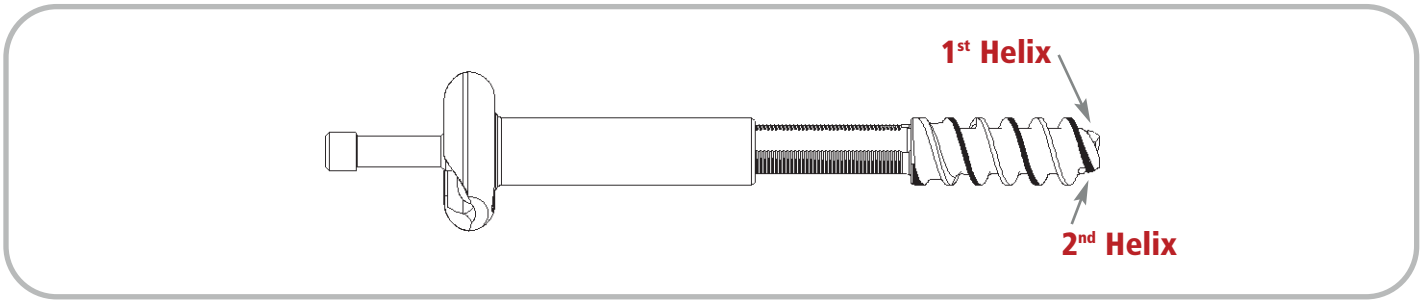
Introduction

BONE-LOK Implants with CLASP (Compression Locking Anchor with Secondary Purchase) technology were developed to address fixation problems associated with current lag screw technology. Adequate compression is an important factor for fixation. The BONE-LOK Implant has a unique ratcheting collar that separates anchor insertion and compression into two steps (secondary compression). This patented ratcheting collar mechansim is what Interventional Spine refers to as CLASP technology. CLASP Technology has three unique benefits over current lag screw technology:

1) Superior pullout strength
2) Superior compression strength
3) Intraoperative flexibility

Superior Pullout Strength

The unique double helix thread design of the BONE-LOK device provides superior pullout strength to standard screw threads (single helix). The double helix is two screw threads on one shaft offset 180 degrees from each other as shown below:



Typically, low threads per inch (TPI) threads are used for cancellous or "bad" bone. Higher TPI threads are used for cortical or dense bone. The double helix is comprised of two low TPI threads intertwined to become an overall higher TPI thread device. The design preserves features of both TPIs for use in all bone qualities. Increased pullout strength results in higher compression strength (see below) and can prevent postoperative screw loosening that occurs with current lag screws.

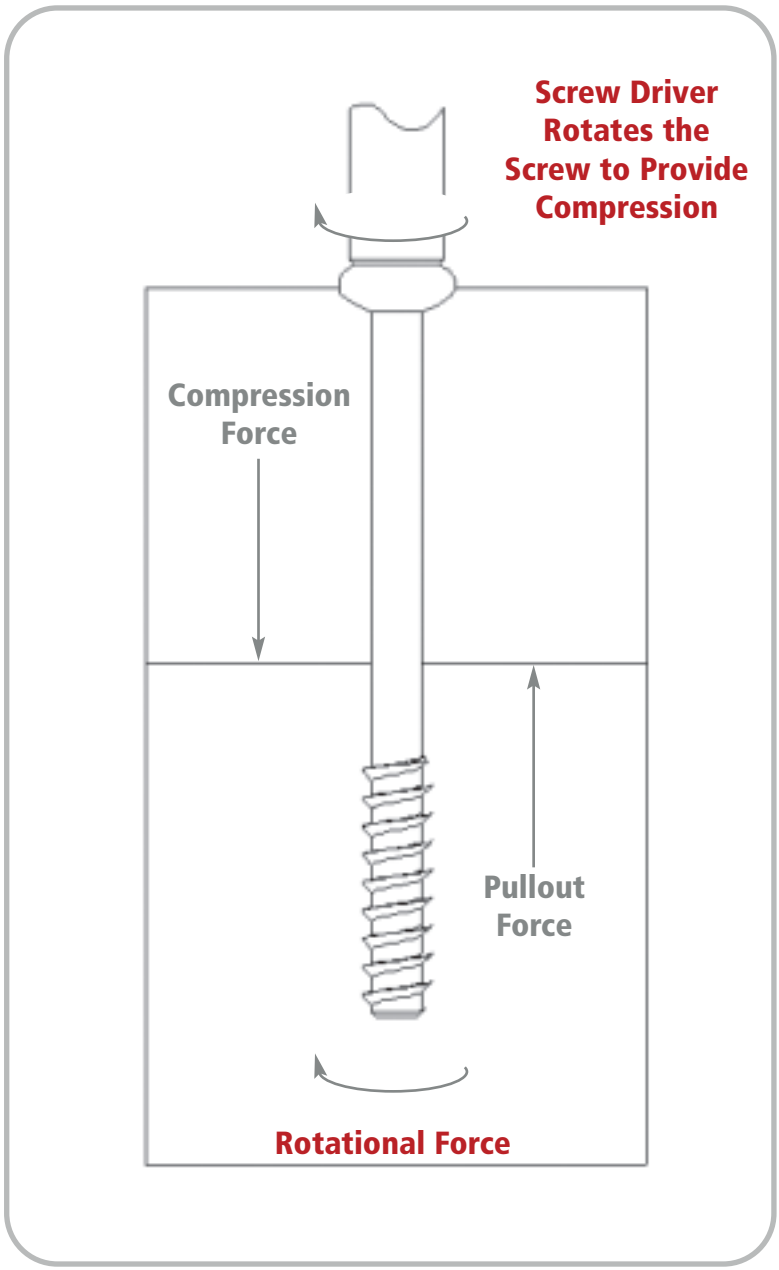
	Foam Density	BONE-LOK® Implant 4.5mm	LAG SCREW NuVasive Triad® 4.5mm
Foam Pullout (avg.)	7lb/ft³	88.52 N	71.56 N
	12lb/ft³	184.12 N	150.38 N

Superior Compression Strength

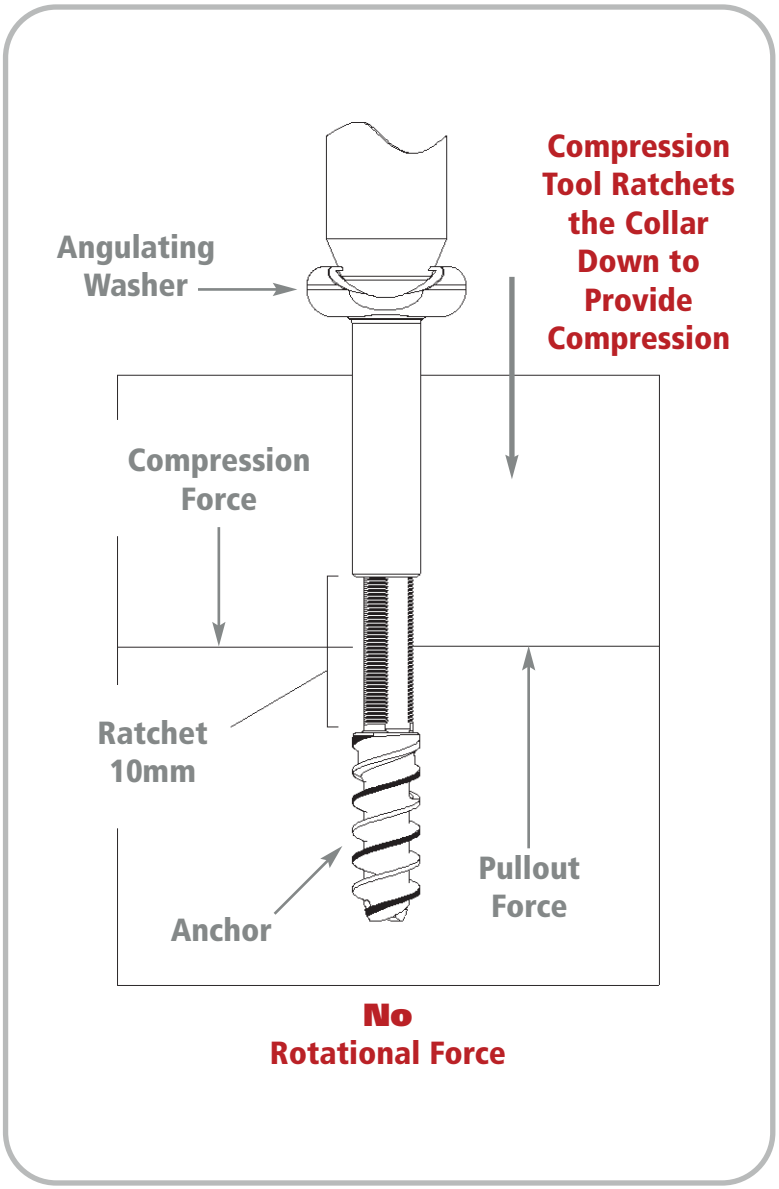
How does CLASP technology provide superior compression strength?

Interventional Spine has separated anchor placement and compression into two steps. The BONE-LOK device is comprised of four components: Angulating Washer, Dual Helix Anchor, Adjustable Collar and Pull Pin. With a lag screw, compression is achieved by rotating the lag screw into the bone and when the head of the screw comes into contact with the proximal cortex, compression is realized. As opposed to a lag screw, the BONE-LOK anchor is positioned into the bone first and compression is applied as a secondary step. ***The elimination of the anchor movement during compression is the primary reason why the BONE-LOK Implant with CLASP technology achieves superior compression to a typical lag screw.***

For a lag screw:



For BONE-LOK® Implant:



Compression Strength (avg.)	Foam Density	BONE-LOK® Implant 4.5mm	LAG SCREW NuVasive Triad® 4.5mm
	7lb/ft³	121.7 N	84.78 N
	12lb/ft³	197.9 N	136.47 N

Complete test is on file at Interventional Spine, Inc.

Intraoperative Flexibility

Another key benefit of CLASP Technology is that it provides surgeons intraoperative flexibility. Each BONE-LOK device comes with a built in 10mm length range, as opposed to a fixed length found in a lag screw. ***In effect the BONE-LOK Implant has a one size-fits-all characteristic unique to the design. Sizing is achieved in vivo.***
Not only does this significantly reduce inventory, but provides surgeons the intraoperative flexibility to precisely position the tip of the BONE-LOK device to maximize its purchase. For a variety of reasons, surgeons have reported selecting the wrong length screw. A screw that is too long may not provide as much compression as desired because it can only be screwed in so far (stops at the distal cortex) or can penetrate through the distal cortex into adjoining tissue that may include nerve roots or spinal cord. These situations can cause the patient pain and/or tissue irritation and/or healing problems as well more serious conditions. A screw too short can result in lower compression or complete loss of purchase, which results in fixation problems as described before. Using the BONE-LOK Implant makes choosing the correct screw size one less thing for the surgeon to be concerned with. Typical lag screws only come in 5mm size increments. With the BONE-LOK Implant, a surgeon can accurately compress to an exact size in vivo while maximizing compression and purchase.

Summary

BONE-LOK Implants with CLASP Technology provides higher compression strength which can lead to better stability and likelihood of fusion. It can also prevent postoperative loosening as well as providing intraoperative flexibility for surgeons.

PERPOS® PLS System

The ***first*** and ***only***
PERCUTANEOUS transfacet-pedicular compression system for **posterior stabilization** during a **fusion procedure** of the **lower spine.**

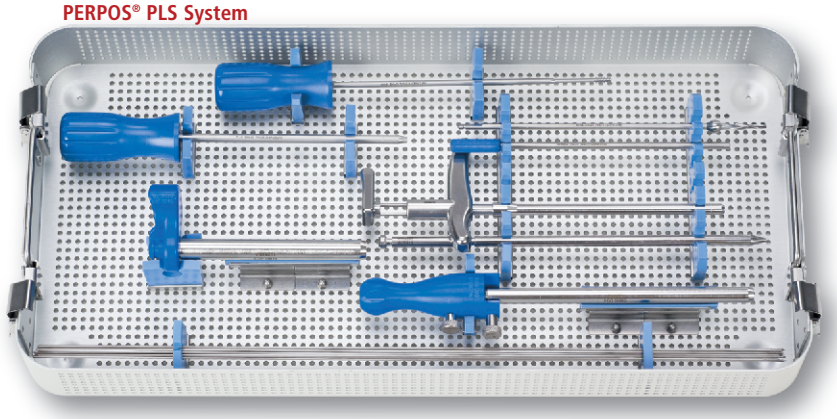
BONE-LOK® Implants

Access Needle

Compression Tool (sold separately)

TELEPORT® Tissue Retractor (sold separately)

PERPOS® PLS System

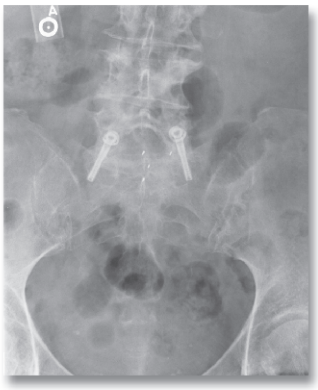


- ONLY the BONE-LOK Implant can be implanted with the PERPOS PLS System and the Teleport® Tissue Retractor to achieve PERCUTANEOUS lumbar stabilization.

PERPOS-Fuse℠

***100%* PERCUTANEOUS Facet-Pedicular System for Fusion**
using the **PERPOS® PLS System**, the
BONE-LOK® Implant, and the
PERPOS® Fusion Facet Prep Kit,
from **Interventional Spine®**

In addition, a PERPOS Fusion Facet Prep Kit can be used in conjunction with the PERPOS PLS System to promote fusion of the facet joints. Fusion of the facet joints provides an added element of spinal stability to the treated segment.



Early post-operative AP radiograph showing bilateral BONE-LOK® device at L5-S1.

- The PERPOS PLS System including the BONE-LOK Implant and the PERPOS Fusion Facet Prep Kit can provide secure bilateral immobilization of the facet joints, allowing the normal healing process to create fusion.
- A PERPOS-Fuse procedure combines demonstrated stability through transfacet-pedicular compression with; ease of use, time savings, over the wire control, and mated cannulated instrumentation.
- A PERPOS-Fuse procedure can reduce patient trauma and recovery time when compared to open surgical procedures for fusion.
- A PERPOS-Fuse procedure is cost effective: as the one size fits all BONE-LOK Implant reduces inventory; the PERPOS PLS System reduces demands on central sterilization units; and OR room and staff support time can be reduced with bilateral BONE-LOK Implants.

Interventional Spine, Inc.
13700 Alton Parkway, Suite 160
Irvine, CA 92618
949-472-0006
800-497-0484
www.i-spineinc.com

Interventional Spine, Inc is certified to IS EN ISO 13485:2003.

As of the date of print, Interventional Spine® has several issued and pending U.S. patents.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

The products have been assessed in conjunction with the Notified Body as applicable, and are considered to meet the Essential Requirements and so bear the CE Marking of Conformity.

 PN5033 Rev. B, DCR936