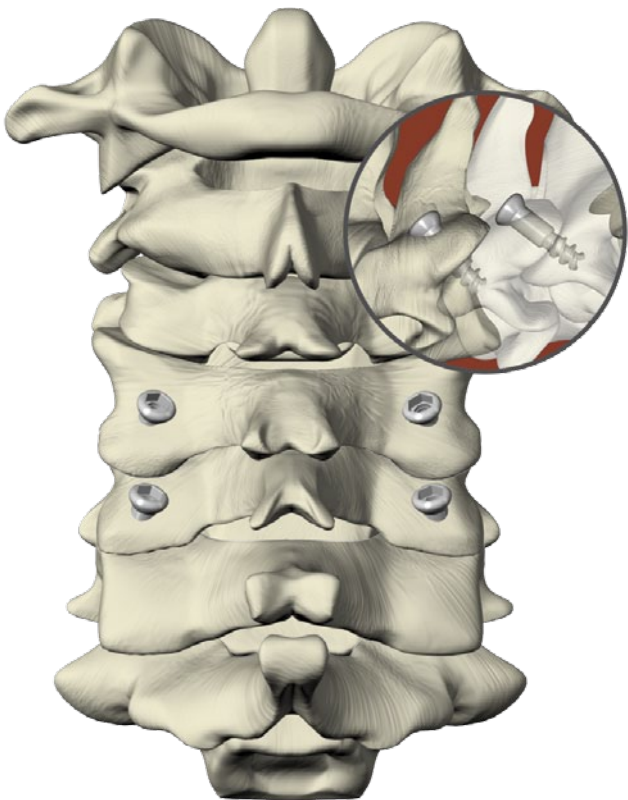


## Product Information and Surgical Technique

# PERPOS® Percutaneous Cervical System

The *first* and *only* percutaneous transfacet compression device for posterior stabilization of the cervical spine



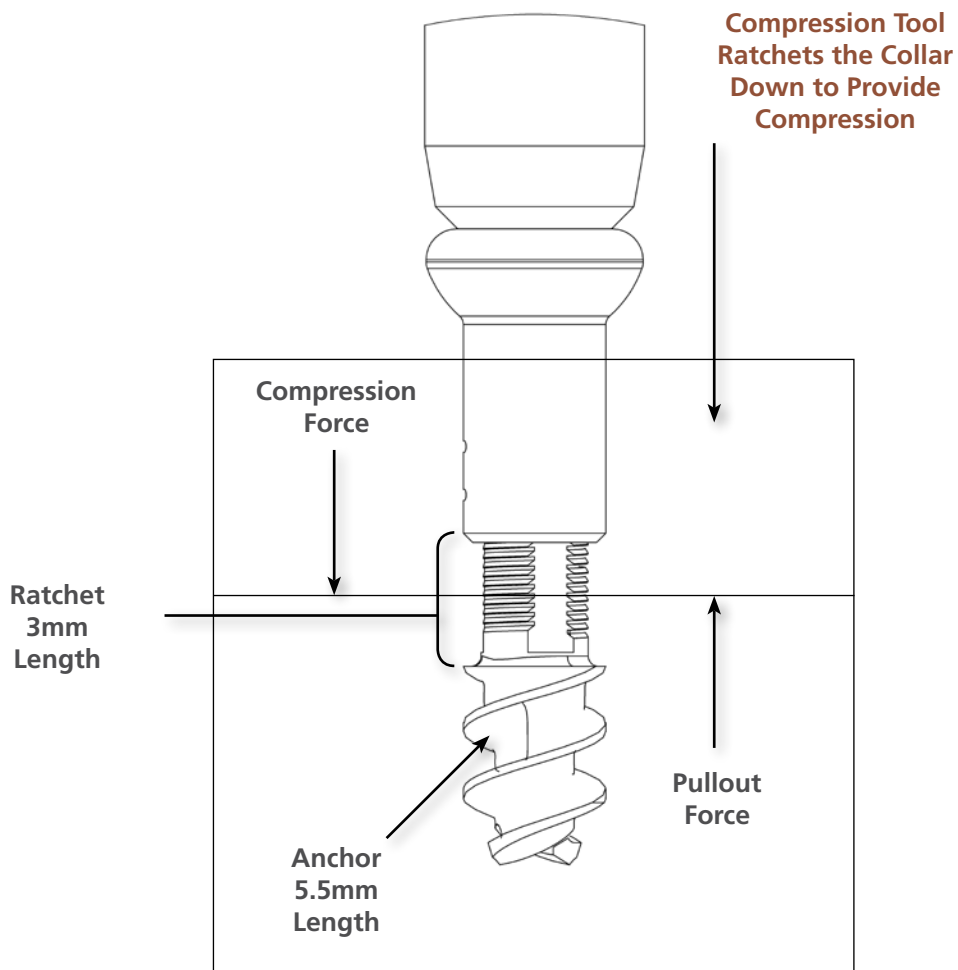
### CLASP® Technology

- Utilizes two-step compression technology allowing the surgeon to control the position of the distal tip
- Intraoperative flexibility of one size fits all implant
- Secondary axial compression is achieved independent of rotation – does not apply rotational force on the implant or bone
- Applies 45% more compression force than a conventional lag screw and has 24% greater pullout strength
- Is an adjunct to fusion: utilizes “Wolfe’s Law” by applying compression or load without stress shielding the graft, may result in better stability and likelihood of graft integration



## True Compression

Whether stabilizing a single-level segment, multi-level ACDF, or supporting a strut graft, COMPRESSION is important for inducing fusion between two segments of the cervical spine. Historically, technologies such as lag screws, rod constructs, and wires have been the standard of care for such techniques. Now there is a simpler, less invasive, and more effective technique for posterior cervical fusion. The PERPOS Percutaneous Cervical System is a comprehensive percutaneous transfacet compression system. This unique system incorporates the BONE-LOK® implant with its proven CLASP (Compression Locking Anchor with Secondary Purchase) technology with advanced instruments specifically designed for cervical applications. The BONE-LOK implant has a unique ratcheting collar that separates anchor insertion and compression into two independent steps to ensure proper placement of the implant and effective compression of the segment.



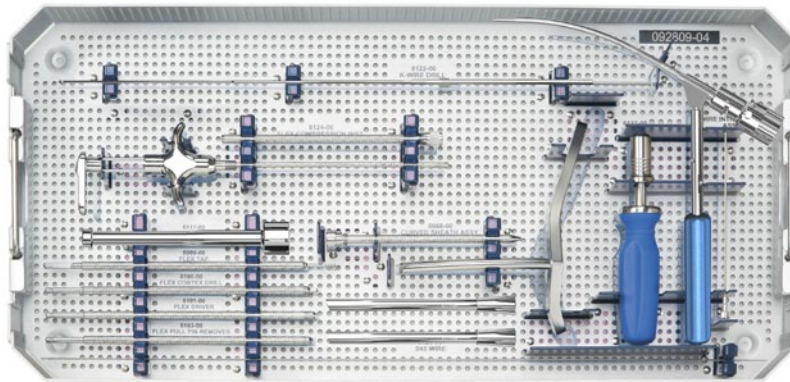
## Double Helix Thread Design combined with our CLASP Technology

BONE-LOK incorporates two intertwined screw threads to yield higher threads per inch (TPI). The double helix technology is proven to yield 24% greater pullout strength and due to our patented CLASP (Compression Locking Anchor with Secondary Purchase) technology 45% more compression force is achieved versus a conventional lag screw.

## Comprehensive Percutaneous Implant and Instrument System

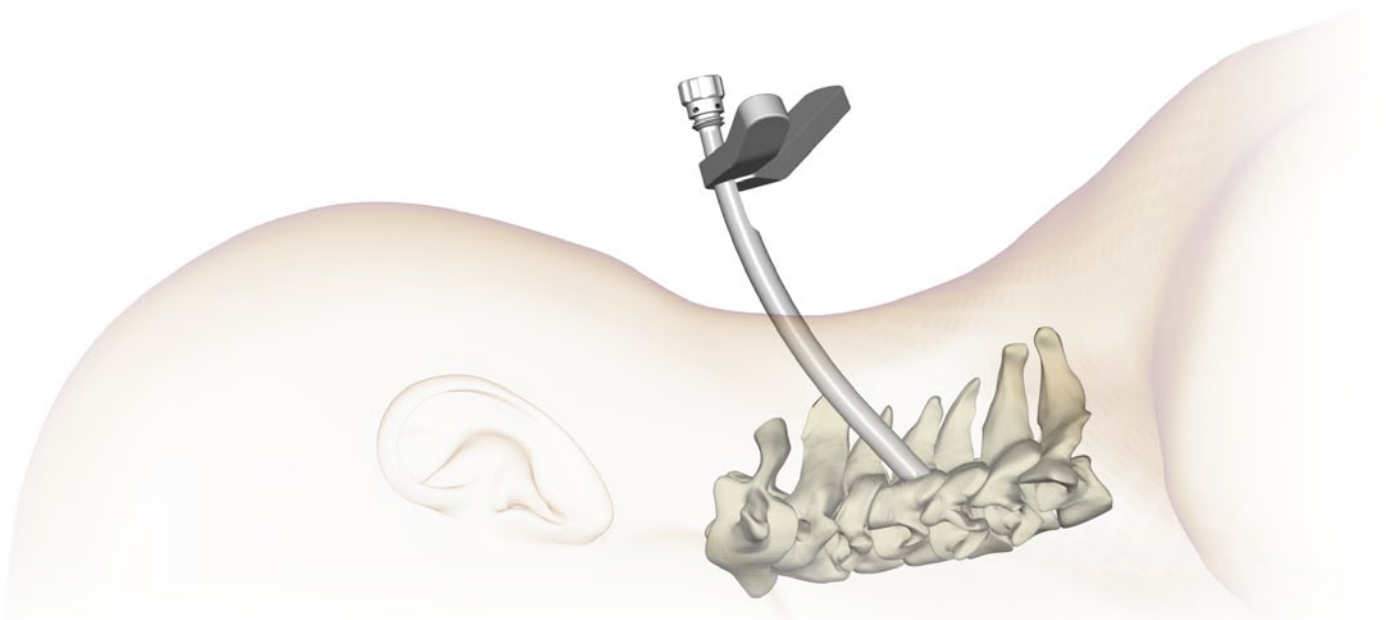
- Two 3.8mm diameter, one size fits all BONE-LOK implants required to fuse one level
- Truly percutaneous procedure is accomplished through one 10mm midline incision
- Ideal for single or multi-level cervical fusions and ACDF revisions
- Low-profile device design ideal for cervical applications

PERPOS® Percutaneous Cervical System Instruments with Tray  
Model Number 9032-00



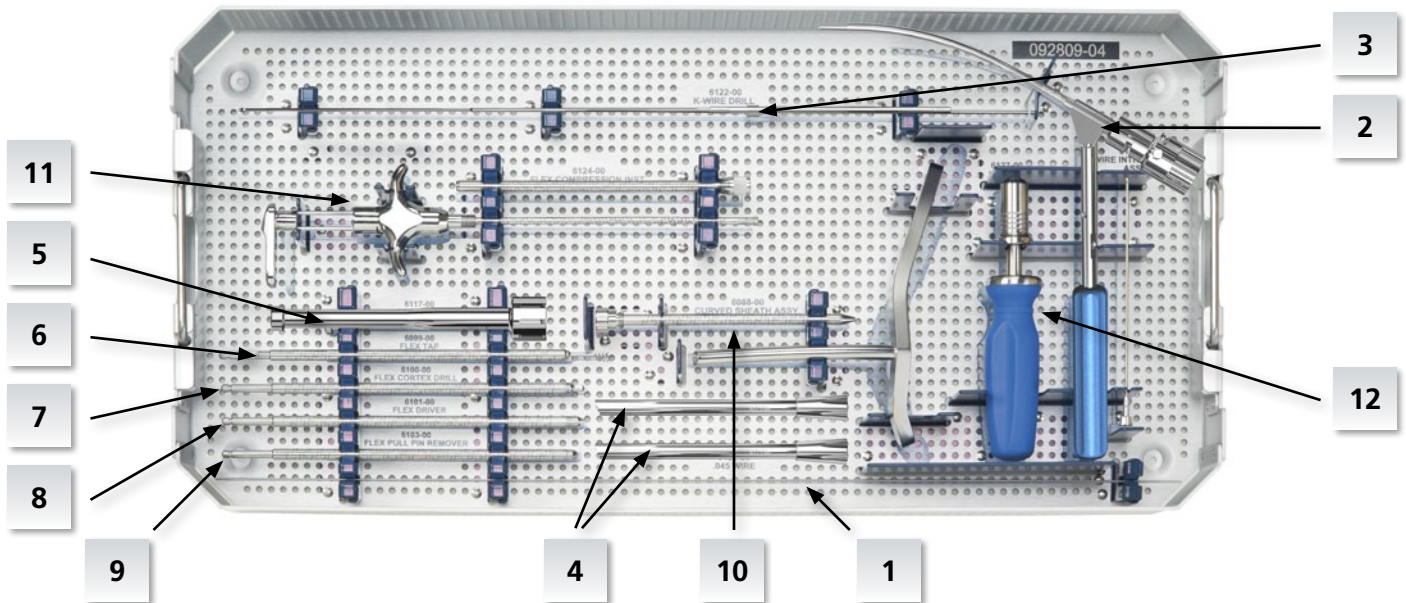
## Advanced Percutaneous Instrument System

- Instrument system specifically designed to avoid interference with the occiput for use during a percutaneous procedure
- All instruments made with unique flexible shaft design for use with curved Teleport®



## PERPOS® Percutaneous Cervical System - Surgical Technique

### PERPOS® Percutaneous Cervical System Instruments



| Item | Description                                 | Quantity | Part Number |
|------|---|----------|-------------|
| 1    | PERPOS® Cervical K-wire, .045"              | 3        | 6123-00     |
| 2    | PERPOS® Cervical Wire Introducer/Drill Stop | 1        | 8040-00     |
| 3    | PERPOS® Cervical K-wire Drill               | 1        | 6122-00     |
| 4    | PERPOS® Straight Cannula                    | 2        | 6171-00     |
| 5    | PERPOS® Cervical Strike Pin                 | 1        | 6117-00     |
| 6    | PERPOS® Cervical Flex Tap                   | 1        | 6099-00     |
| 7    | PERPOS® Cervical Flex Cortex Drill          | 1        | 6100-00     |
| 8    | PERPOS® Cervical Flex Driver                | 1        | 6101-00     |
| 9    | PERPOS® Cervical Flex Pull Pin Remover      | 1        | 6103-00     |
| 10   | Curved Teleport Assembly                    | 1        | 6088-00     |
| 11   | PERPOS® Cervical Flex Compression Tool      | 1        | 6124-00     |
| 12   | Quick Connect Handle                        | 1        | 6127-00     |

### Surgical Technique

The purpose of this guide is to provide specific information regarding Interventional Spine, Inc.'s PERPOS® Percutaneous Cervical System. The PERPOS® Cervical device is a transfacet compression device designed to immobilize the facet joints, at single or multiple levels in the spine (ranging from C2 to S1).

## Step 1 Patient Position

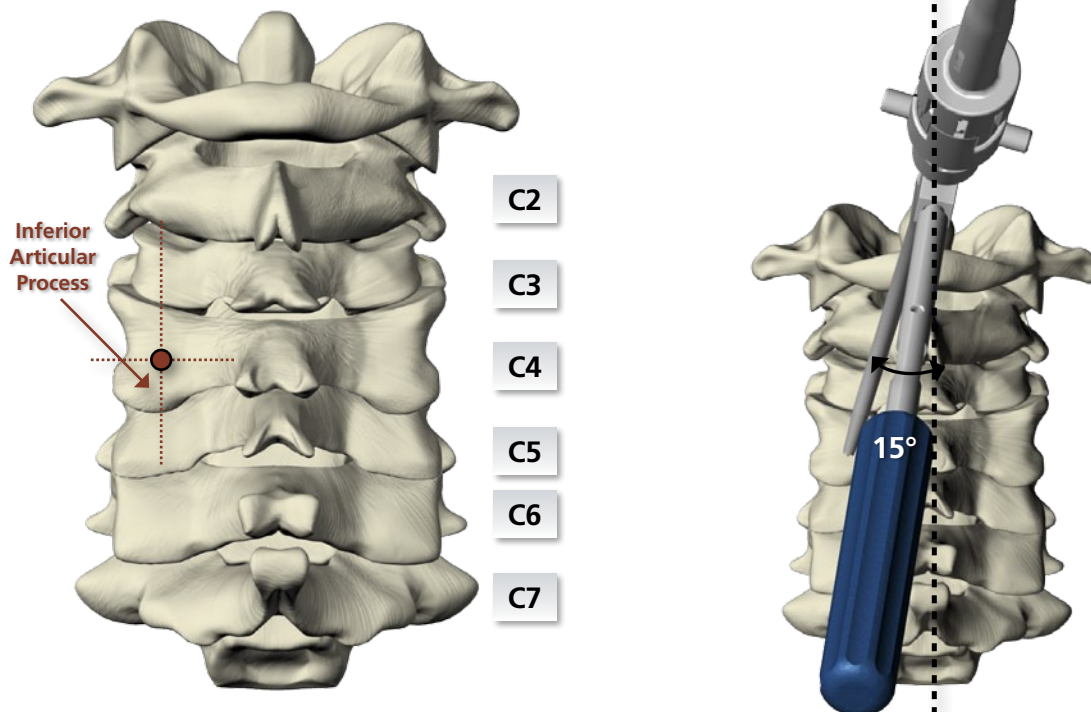
The patient is positioned on a radiolucent operating room table in the surgical position determined to be optimal by the surgeon under general or regional anesthesia. The patient is placed in the prone position on a spinal frame (e.g. Mayfield) or padded chest bolsters. The area is then prepped and draped using sterile technique.

## Step 2 AP Trajectory & Wire Introducer Placement

The fluoroscope should be centered on the level of interest to minimize parallax effects. The right to left angulation should be adjusted to center the spinous process of the level below between the pedicle shadows on AP views. The cephalad/caudal angulation should be adjusted to coincide with the lordotic curve of the cervical spine.

The Entry Point is the location on the posterior elements at which the PERPOS® Cervical device is to be placed. Fluoroscopic AP and Lateral images are recommended to best identify the Entry Point landmarks. The Cephalad/Caudal (Sagittal) entry point is located at the center of the inferior articular process of the superior vertebral body (treated level). The Medial/Lateral (Coronal) entry point is at the center of the inferior articular process of the superior vertebra (treated level).

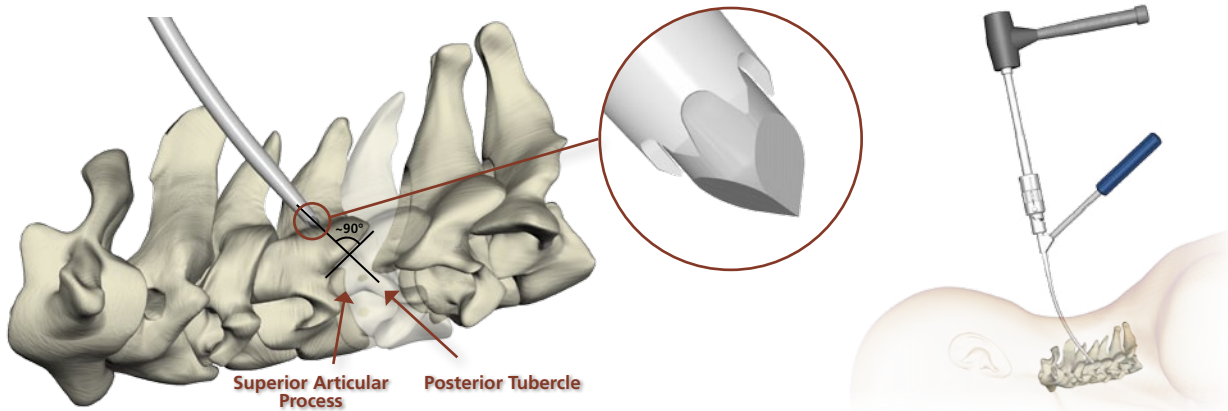
Once this position is located, the proximal end of the Wire Introducer is then moved approximately 15° medially to obtain the ideal medial/lateral trajectory, which should be directed towards the posterior tubercle of the transverse process, or lateral to the foramen transversarium (foramen for the vertebral artery). Once the entry point and AP trajectory have been determined, the Wire Introducer is then inserted up to the bone along the determined trajectory. The Wire Introducer may need to be backed off and repositioned to insure that the trajectory will enter at the appropriate anatomical location. Several AP and lateral fluoro images should be taken during the positioning process. The Wire Introducer should be tapped or seated into the bone so that the entry point is maintained.



Figures 1 and 2: Entry Point, C4/C5 Procedure

## Step 3 Lateral Trajectory & Wire Introducer Placement

Upon determining the AP trajectory and entry point, the lateral trajectory is then decided. The initial lateral trajectory is anterior-caudal, perpendicular to the facet joint, towards the posterior tubercle of the transverse process, and up to the cortical wall of the superior articular process. Once the lateral trajectory has been determined, the Wire Introducer should be tapped and seated into the bone along the trajectory using the strike pin and a mallet. A series of lateral fluoroscopy images should be utilized to determine the correct trajectory. An AP view is then taken to assure that the needle is positioned correctly that there is no compromise of the nerve root or the spinal canal.



Figures 3 and 4: Lateral View, Wire Introducer Placement

## Step 4 K-wire Drill

1. Once the Wire Introducer is seated, the strike pin is removed by pulling it off of the drill stop.
2. The drill stop setting is adjusted to 12mm by rotating the inner knob counterclockwise. Always start at 12mm.
3. The K-wire Drill is advanced through the Wire Introducer and into the vertebra. The K-wire Drill should not be advanced beyond the distal cortical wall of the superior articular process.
4. The drill stop setting should be adjusted and the K-wire drill advanced until desired depth is achieved.\*
5. The K-wire Drill is then removed, leaving the Wire Introducer in place. It may be helpful to attach the Wire Introducer to an articulating arm to help prevent migration of the instrument.

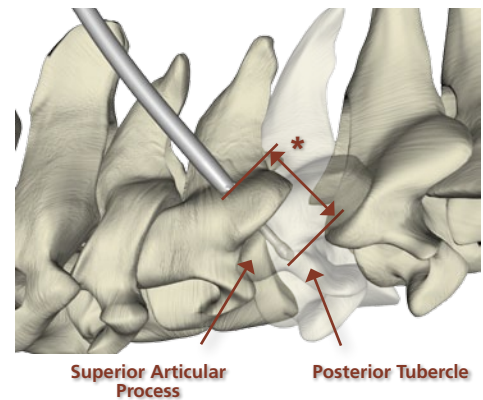
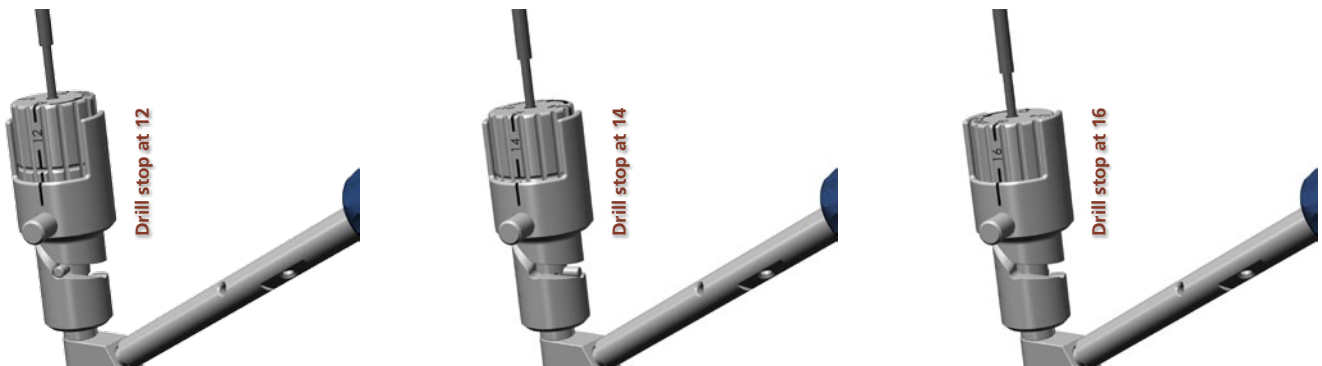


Figure 5: Lateral View, K-Wire Drill Placement



\* The distance between the arrows represents the depth of the drill.

## Step 5 K-wire Placement and Incision

1. Once the appropriate drilled hole has been completed, the blunt K-wire is placed through the Wire Introducer and into the hole.
2. The Wire Introducer is then carefully removed while keeping the K-wire securely in place within the bone.
3. An incision is made in the skin and fascia just large enough for the chosen tubular retractor (i.e. 8-10mm for the Interventional Spine Curved Teleport® Tissue Retractor).
4. The appropriate procedure for the selected tubular retractor is followed to allow access to the bone. A tubular retractor with a minimum 7mm inner diameter should be utilized to perform the procedure percutaneously.

NOTE: The procedure may also be completed using an open or mini-open technique.

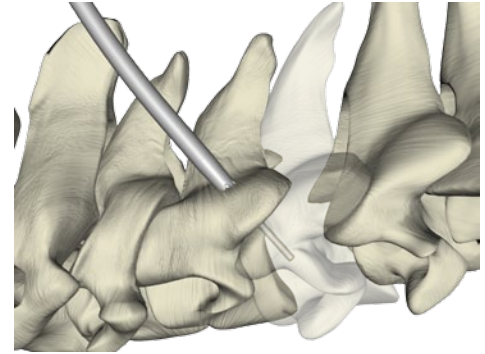


Figure 6: Lateral View, Kirschner Wire Placement

## Step 6a Teleport Placement (Optional)

The Teleport is placed over the K-wire, through the skin incision, and down to the bone. The inner stylet is disengaged by rotating it counterclockwise and the outer sheath of the Teleport is advanced to the bone.

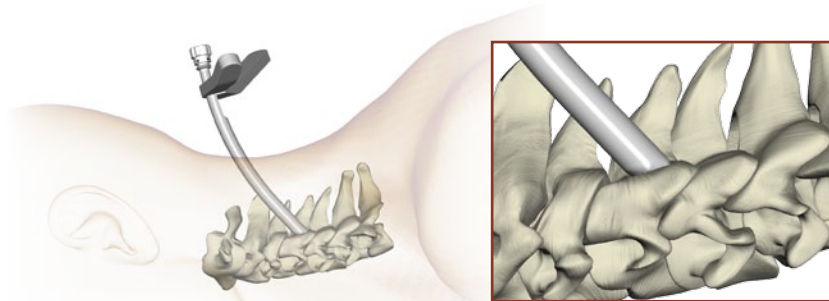


Figure 7: Lateral View, Teleport Placement

## Step 6b Straight Cannula Placement (Optional)

If the procedure is being performed as mini-open or open then the Straight Cannula should be used instead of the curved Teleport.

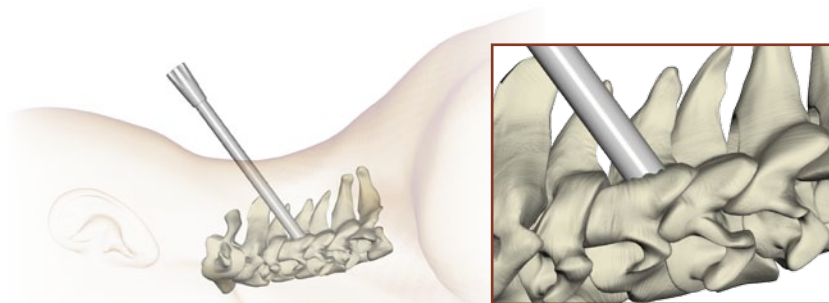
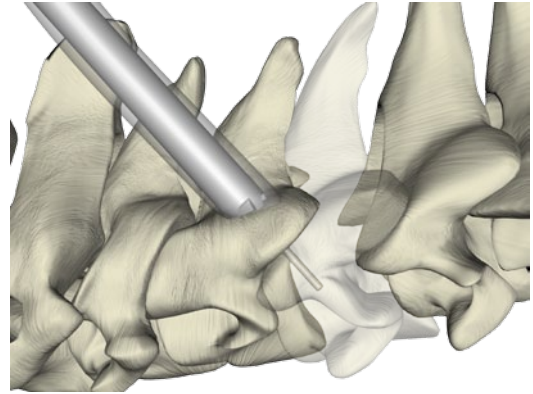
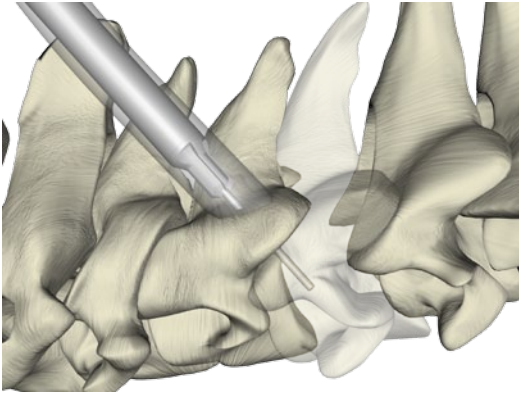


Figure 8: Lateral View, Straight Cannula Placement

### Step 7 Cortex Drill

The cannulated, flexible Cortex Drill may be connected to the provided cannulated handle or to a power drill by an AO style quick connect. The Cortex Drill is driven into the bone until it reaches the built-in stop or the appropriate depth, which should be verified by fluoroscopy.



Figures 9 and 10: Lateral View, Cortex Drill

### Step 8 Tap

The cannulated Tap is connected to the provided cannulated handle by an AO style quick connect; it must never be used with power. The Tap is driven into the bone until the tip reaches the appropriate depth where the distal tip of the device is targeted, which should be verified by fluoroscopy. Care should be taken not to tap past the distal end of the K-wire

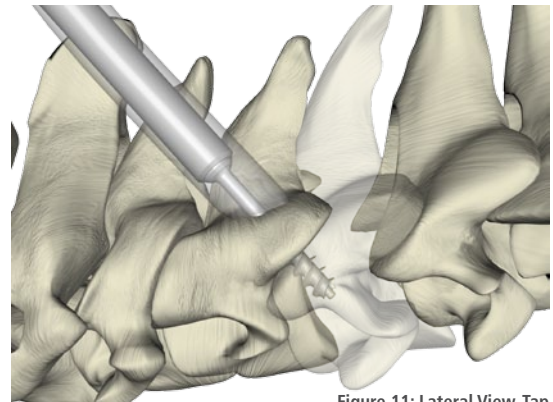
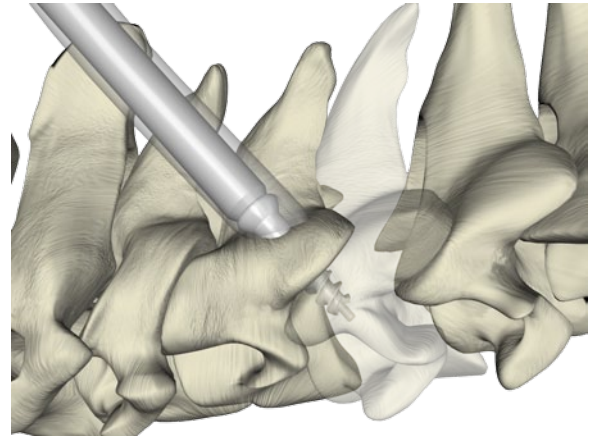
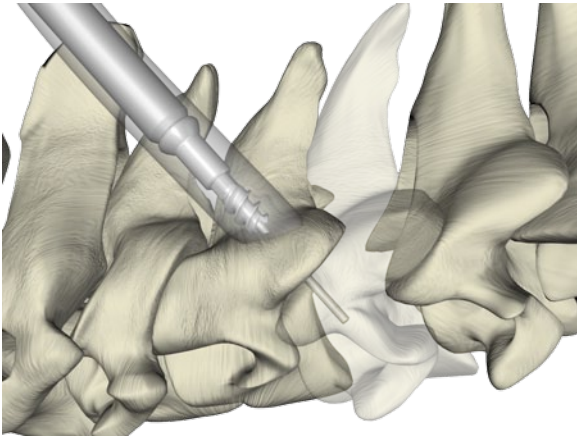


Figure 11: Lateral View, Tap

### Step 9 PERPOS® Cervical Device Placement

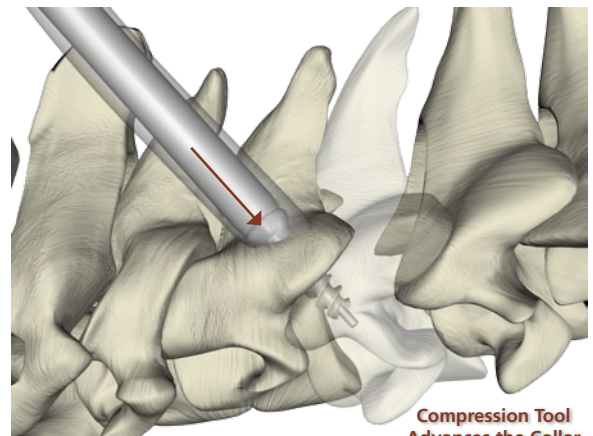
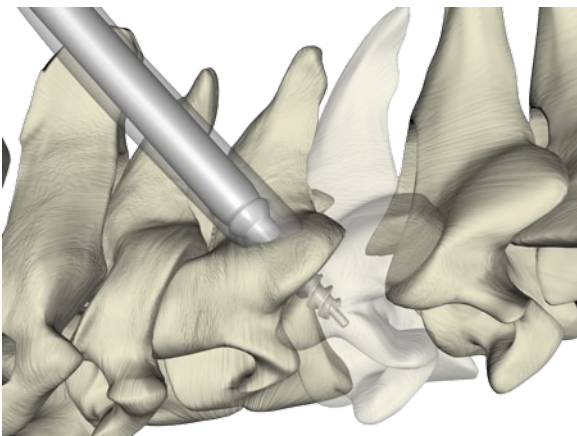
The cannulated Driver is connected to the provided cannulated handle by an AO style quick connect; it must never be used with power. The PERPOS® Cervical facet compression device is loaded onto the Driver, passed over the K-wire, and advanced into the bone to the appropriate depth. This should be accompanied by fluoroscopy to insure proper depth. The head of the collar should be left slightly proud so that compression of the facet joint may be obtained using the Compression Tool. After the proper position of the PERPOS® Cervical facet compression device has been established, the Driver is then removed by gently pulling it off of the device.



Figures 12 and 13: Lateral View, Device Placement

### Step 10 Compression

The Compression Tool is placed over the K-wire and down to the device. The Compression Tool should be advanced until it is fully seated over the pull pin of the device. Once seated, the Compression Tool is squeezed (using one hand only) to advance the collar and apply compression to the device. Lateral fluoroscopy should be used to confirm compression of the device. Once compression has been confirmed, release the squeeze on the Compression Tool and gently remove it.

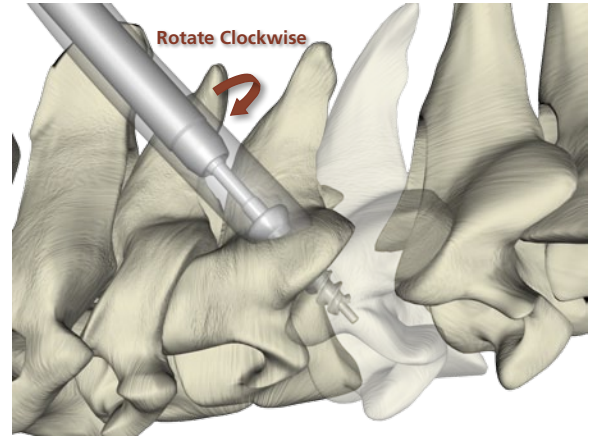
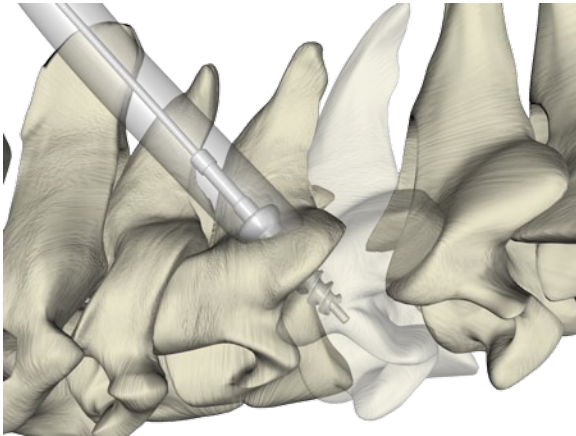


Compression Tool Advances the Collar

Figures 14 and 15: Lateral View, Compression

### Step 11 Remove Pull Pin

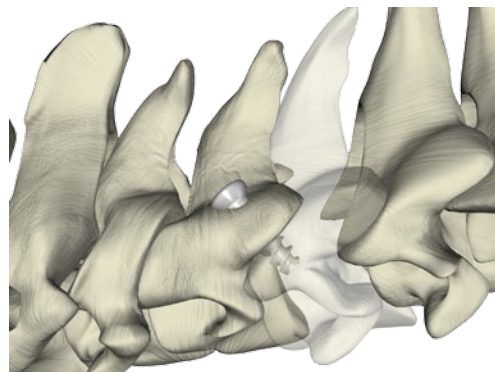
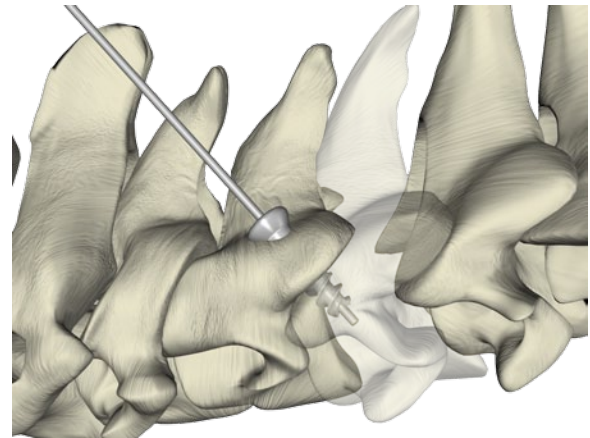
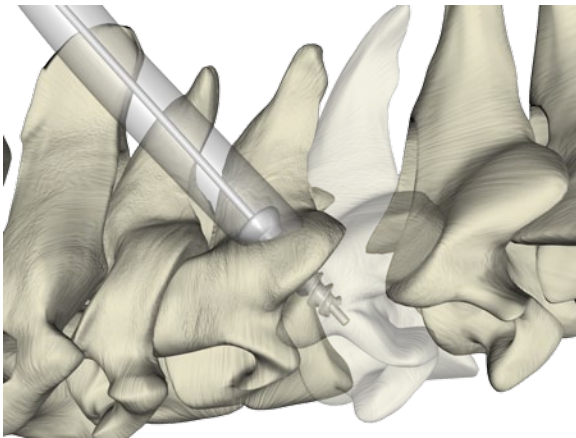
The cannulated Pull Pin Remover is connected to the provided cannulated handle by an AO style quick connect. Place the Pull Pin Removal Tool over the K-wire and down to the device. With forward pressure rotate the instrument **CLOCKWISE** approximately 5 complete turns to loosen the pull pin from the device.



Figures 16 and 17: Lateral View, Pull Pin Removal

### Step 12 Remove Teleport and K-wire

Confirmation of proper device placement AND removal of pull pin should be confirmed prior to removing the K-wire. Otherwise it may be extremely difficult to find the location of the device percutaneously. The Teleport may then be removed (if utilized in the procedure), followed by the K-wire.



Figures 18, 19, and 20: Lateral View, Teleport and K-wire Removal

### Step 13 Repeat Procedure

The devices are intended to be used bilaterally, so the procedure should be repeated for the contralateral facet at the treated level(s).

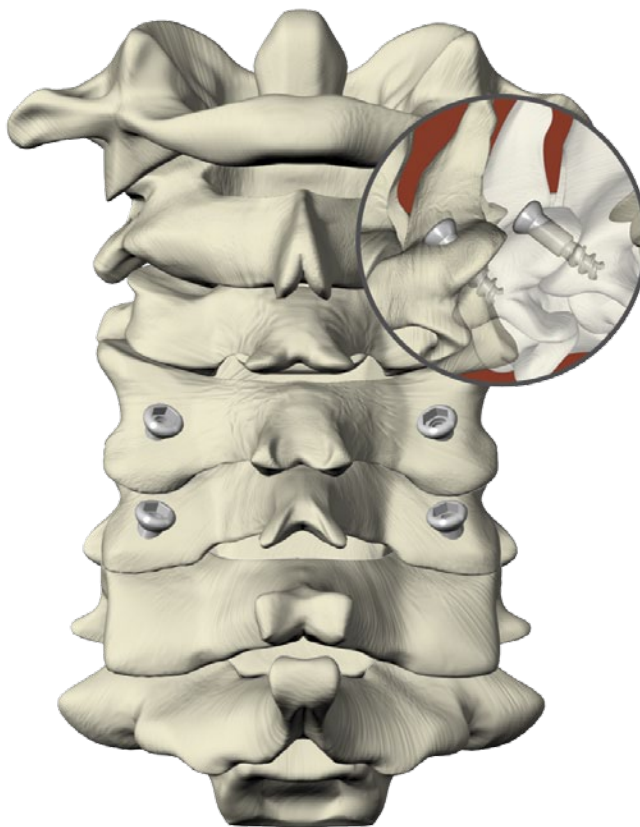


Figure 21: AP View, Final Device Placement

### Step 14 Closure

Once both PERPOS® Cervical facet compression devices are installed, fluoroscopy is utilized to verify that both Pull Pins have been removed and that the devices are appropriately positioned. A standard closing procedure is utilized for all incisions.

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.

## INDICATIONS FOR USE:

The Facet Compression Device is indicated for spondylolisthesis, spondylolysis, degenerative disc disease (DDD) as defined by neck and/or back pain of discongenetic origin as confirmed by radiographic studies, degeneration of the facets with instability and fracture, pseudoarthrosis, or failed previous fusion. The intended use of the Facet Compression Device is to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints.

- The 3.8mm CS (without washer) or CSW (with washer) Facet Compression Device is intended for bilateral facet fixation with or without bone graft, at single or multiple levels ranging from C2 to S1.

## WARNINGS:

The following are specific warnings, precautions, and adverse effects, which must be understood by the operating surgeon and given to the patient. These warnings do not include all adverse effects, which may occur with the surgical procedure in general, but are important considerations, which are specific to metallic fixation devices. General surgical risks need to be explained to the patient, prior to the procedure.

- As a facet screw system, these devices are intended only for use as specified above in the Indications for Use section in the cervical spine as facet screw system this subject is intended only for the following: bilateral facet fixation.
- Correct device selection - While proper selection of the implant is important in minimizing risks, the size and shape of the patient's bones also must be considered.
- Failed Fusion – Metallic implant devices cannot withstand the same activity levels or loads equal to those placed on normal healthy spines. These devices are not designed to withstand the full weight bearing load. If fusion is delayed, or a pseudoarthrosis occurs, the device may break. The patient should understand that stress on an implant, may in some cases result in failure of that implant.
- Infection – This device is contra-indicated in the presence of an active infection.
- Osteoporotic bone – Extremely osteoporotic bone may not be suitable for traditional forms of posterior spinal fixation and may increase the risk of implant failure. Should extremely osteoporotic bone be determined intraoperatively, the device may be removed and an alternative approach should be considered.
- Conservative treatment – This device is contraindicated when conservative treatment is appropriate.
- Corrosion – Metal implants in the human body are subjected to a chemical environment consisting of salts, acids and proteins that may cause corrosion due to galvanic corrosion effects. Dissimilar metals in contact with each other can accelerate the corrosion process; mixing of implant components from different manufacturers is never recommended for metallurgical, mechanical and functional reasons.
- Histological conditions – Certain degenerative diseases or physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, and risk implant failure.
- This device is packaged and sterilized for single use only. Do not reuse or reprocess. Reuse or reprocessing may compromise the structural integrity of the device, and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

## PRECAUTIONS:

- The operating surgeon should be trained to the appropriate Surgical Technique, in order to produce a successful outcome.
- Device performance – Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.
- Implant re-usage – Implants should never be reused. An explanted metal implant must never be re-implanted.
- Handling of implants – Extreme care should be taken in the handling of the device. No bending or changing of the implants shape should be attempted. These may produce internal stresses, which may cause eventual breakage.
- Implant removal after fusion – Metallic implants may loosen, fracture, corrode, migrate, cause pain, or stress shield bone once a fusion has occurred, particularly in active healthy patients. While the surgeon must make the final decision on implant removal, most experts recommend that whenever possible and practical for the patient, fixation devices should be removed once their service as an aid to fusion is accomplished. Implant removal should be followed by the appropriate postoperative management to ensure continued spinal stability.
- Instructions to patient – Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful fusion management. The patient must be made aware of the limitations of the implant. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and with time will fracture under normal weight bearing or load bearing in the absence of a fusion. Mental or physical impairment, which compromises or prevents a patient's ability to comply with the necessary limitations or precautions, may place that patient at a particular risk during postoperative rehabilitation.

## POSSIBLE ADVERSE EFFECTS:

- Mis-aligned Screws may perforate the cortical walls of the pedicle, penetrating the spinal canal or foraminal openings and causing damage to the neural elements and vascular structures.
- Implant breakage due to a Pseudoarthrosis or delayed fusion.
- Metal sensitivity or an allergic reaction to a foreign body.
- Decrease in bone density.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma.
- Bone necrosis.
- Vascular changes.



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