Inspan®

Surgical Technique

Inspan®

About Inspan®

Inspan® is a medical device company that provides best in class interspinous devices, offering solutions for lumbar spinal stenosis and degenerative disc disease. The Inspan posterior technique is designed with outpatient less exposure surgery in mind.

With leading technologies and superior LES® approaches at the forefront, Inspan® innovates, recognizing the needs of the patients and surgeons.

About LESspine®

LESspine® was founded by practicing spine surgeons with the belief that, as surgeons, we are best able to identify our own needs as well as those of our patients. Our team of surgeons, engineers, and industry experts collaborate seamlessly on our innovations to develop a company that is driven to be a leader in cutting edge technology.

Our mission is to focus on surgeon needs, allowing us to improve patient care through innovative technologies.

About the LES® Philosophy

LES, or Less Exposure Surgery, is the philosophy of achieving optimum surgical exposure, maximally preserving the anatomy, minimizing exposure to radiation, and lessening the damaging effects of traditional surgical techniques. It optimizes surgical access, use of radiation, muscle dissection, anatomy removal, and implant selection into one pivotal focus: less exposure with optimal visualization.

LESS, Less Exposure Segmental Spine Surgery, is a component of the LES philosophy. LESS is the practice of applying the LES philosophy to spine surgery securing one segment at a time and repeating procedures segment by segment.

“Each multi-level condition in the spine could be treated and repeated for adjacent segments,” said Kingsley R. Chin, M.D. “The future of spine surgery is dependent upon devices and techniques for less exposure segmental spine surgery.”

About the LES Society®

The LES Society seeks to advance research, education, and technology for user friendly tissue sparing treatments with improved patient outcome. The LES Society is a non-profit, tax-exempt, educational organization whose purpose is to protect the health of the patient and to optimize surgical procedures for the surgeon by promoting the less exposure surgery philosophy.

The society provides a forum for dialogue amongst spine surgeons to discuss and debate the LES approach, to train, and contribute to educational endeavors. It is also a resource for other physicians and patients to learn the benefits of LES philosophy and technology.

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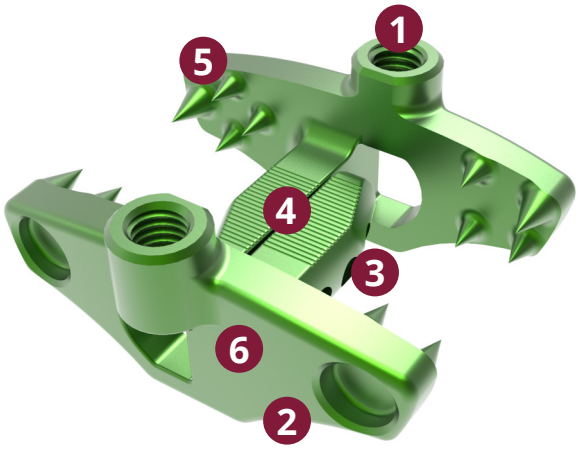
About the System

The Inspan® Spinous Process Plate System consists of a variety of sizes of plates, set screws, and instrumentation to facilitate implantation of this system. The plates are offered in seven hub diameters (8mm to 20mm in 2mm increments) and seven wing length configurations (35mm to 47mm in 2mm increments). The device height (measured from the base of the central hub to the top of the wing) is fixed across all configurations at 14mm for Inspan Slim™. Spikes are present on the sides of the plate that interface with the spinous process to restrain the plate from rotating post-operatively.

Set screws are pre-installed in each side of the assembly and are used to secure the assembly in its final compressed and implanted state. A torque limiting driver is provided to ensure that the appropriate screw torque is applied.

Anatomy of Inspan®

1. Pre-loaded Set Screws Top Loading Inserter
2. Contoured snugly against the lamina
3. Bonegraft platform
4. Distract 8-20mm
5. Staggered spikes
6. Slim design



Features & Benefits

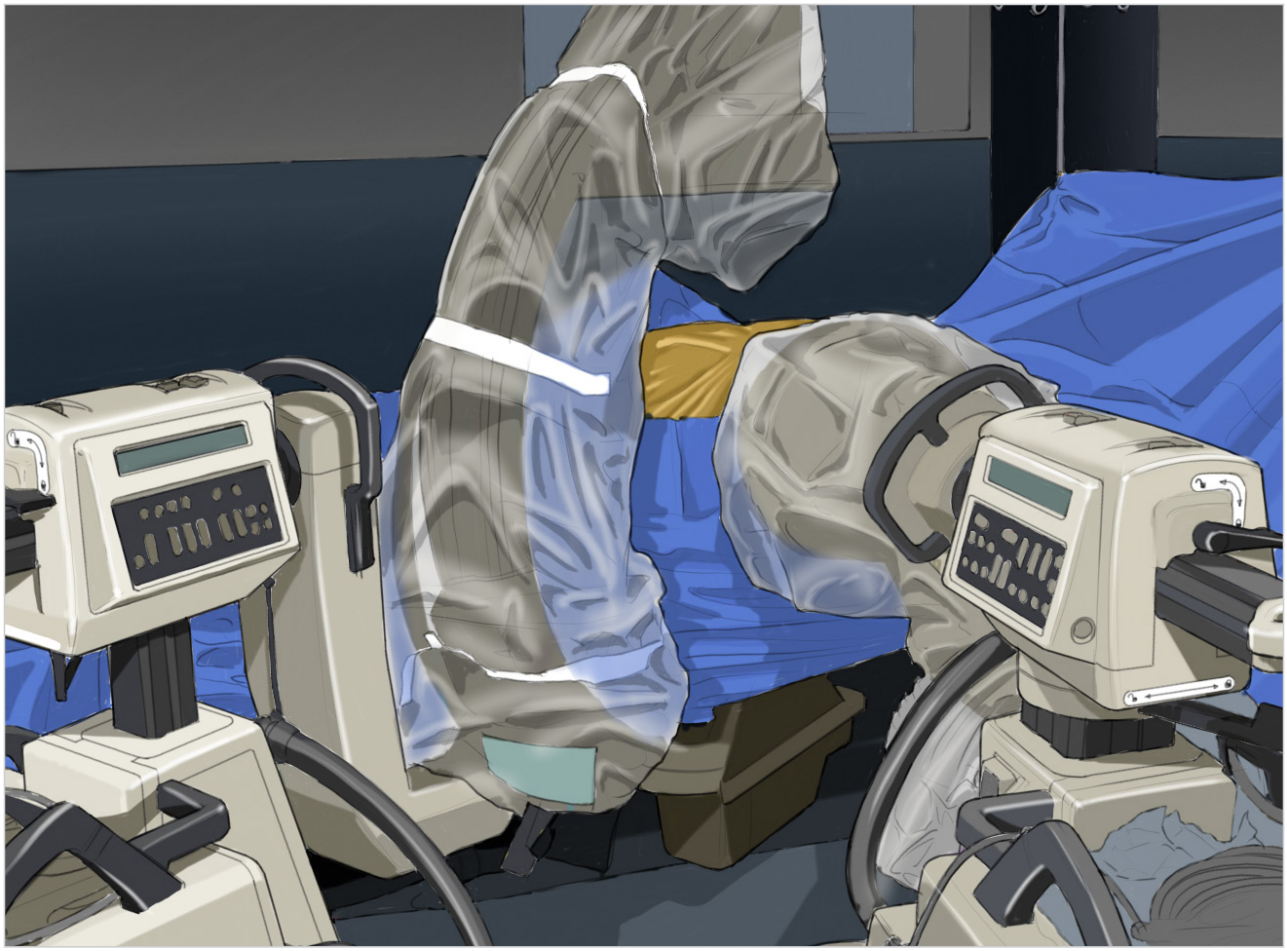
- Titanium implants provide superior strength and fixation
- Low profile design minimizes the implant footprint within the patient
- Cylindrical hub provide spinous process distraction
- Dual interlocking hub with dual set screws provides an exceptionally rigid design
- Compatible with the FacetFuse MIS Screw System
- Spikes are staggered to prevent fracture and provide optimal fixation
- Adapts to the anatomy of T1 through S1
- Design optimized for the LES midline approach
- Color Coded Implants for Ease of Identification

Surgical Technique Symbols

Additional Information

Warning

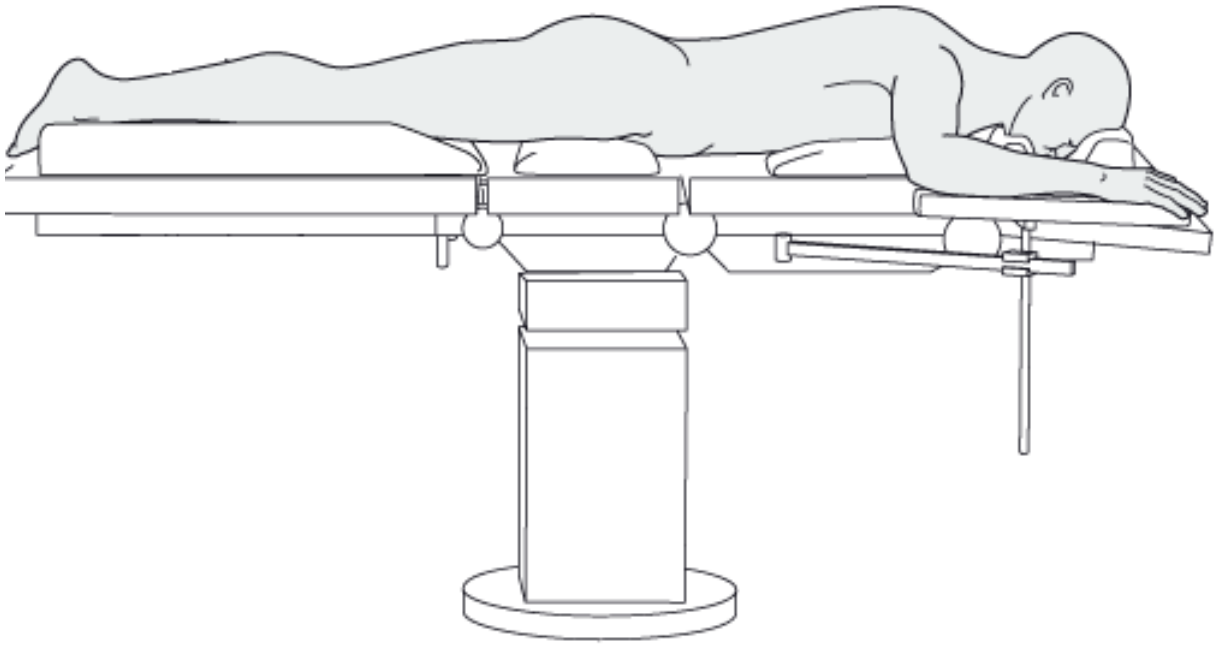
1. Pre-Operative Planning



- All necessary imaging studies (CT scans, X-rays, etc.) are recommended to be available to visualize patient anatomy and plan implant placement.
- Prior to surgery, estimate the appropriate size of the Inspan® device.

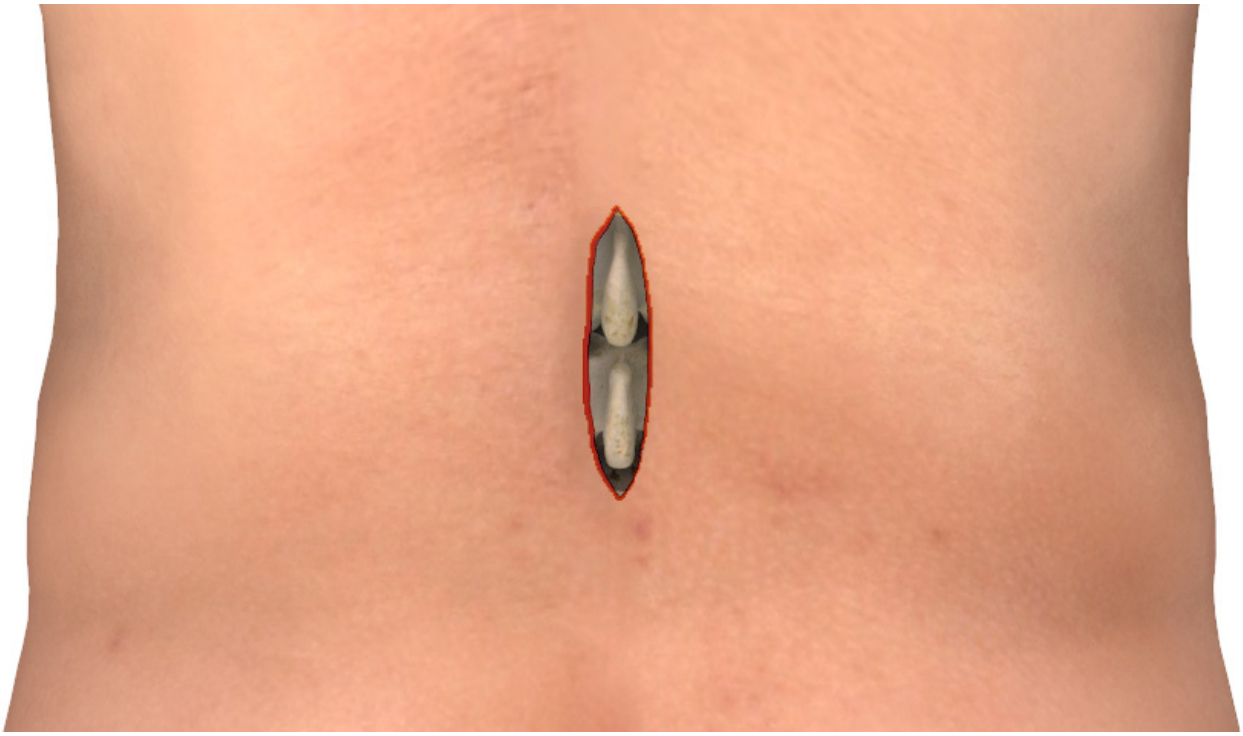
Care must be taken throughout the procedure to ensure that no damage is caused to the dura or spinous process.

2. Patient Positioning



- Patient should be positioned in the prone position on the operating table.

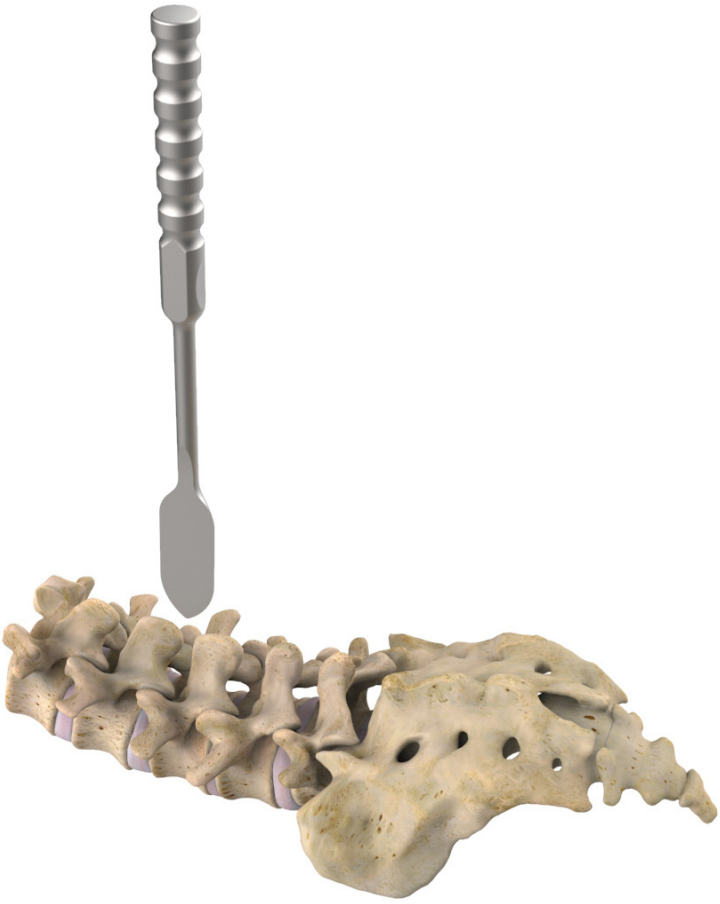
3. Site Identification and Incision

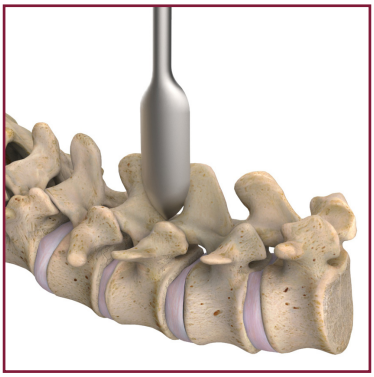


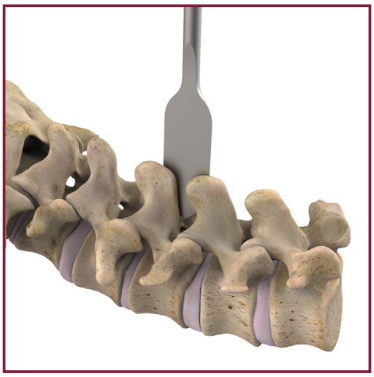
- Identify the spinous processes at the level to be joined by using manual palpation and intraoperative imaging.
- Make a midline incision.

Care must be taken throughout the procedure to ensure that no damage is caused to the dura or spinous processes.

4. Access and Dissection







Contralateral Decompression

After incising, use the Decompression Knife to retract tissue and gain access to the interspinous region.

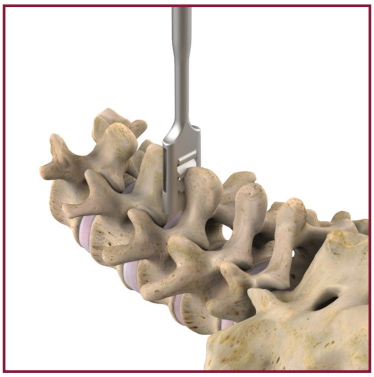
Ensure the surface that is laser marked “MEDIAL” is facing the spinous process and advance the knife anteriorly until it reaches the lamina.

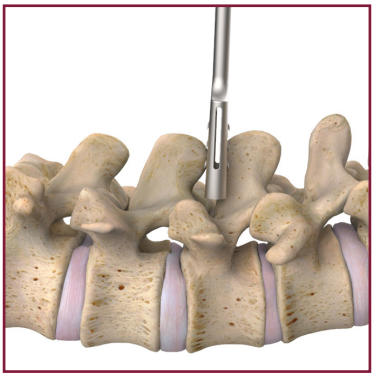
- Using an inferior-superior rocking motion, separate the tissue from the spinous process.
- Repeat for contralateral side.

Optional: General instrumentation, such as a Cobb Elevator and a Cerebellar Retractor may be used if desired.

Take care not to overadvance.

4. Access and Dissection (Cont.)





Lateral View

Place the Broach over the interspinous space, with the cutting blades perpendicular to spine.

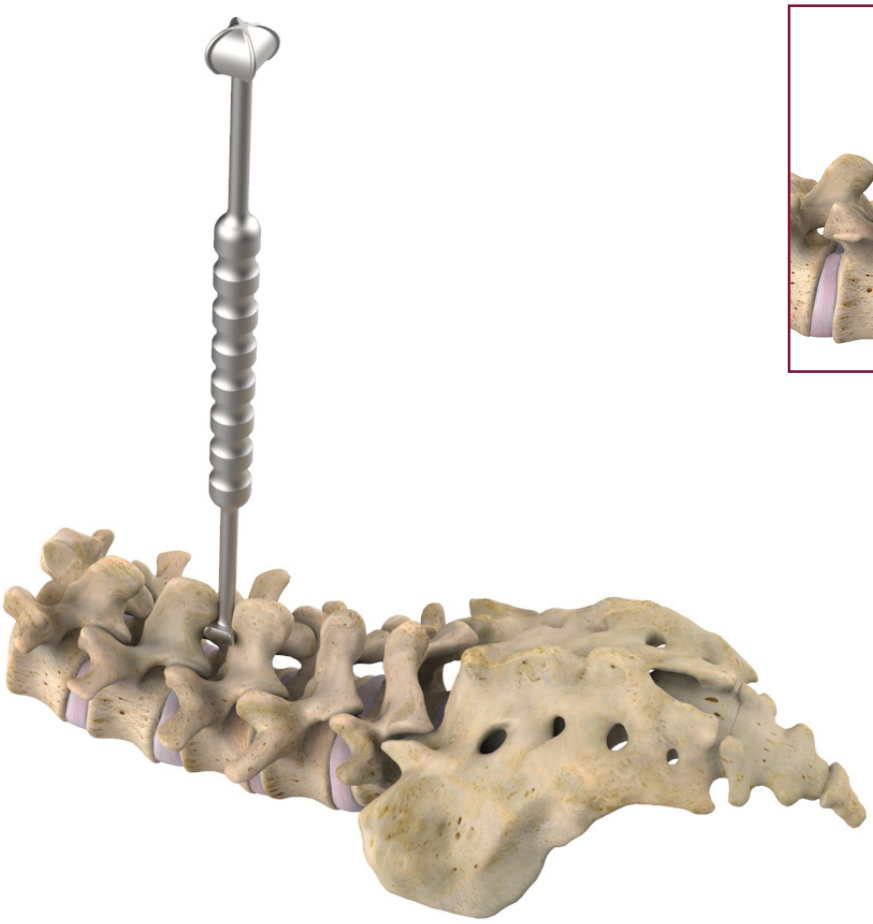
Using lateral fluoroscopy and a Mallet:

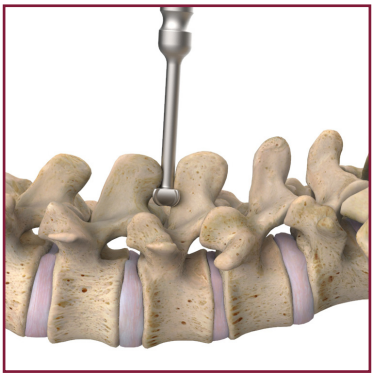
- Impact the Broach to cut through supraspinous and interspinous ligaments.
- Use appropriate instrumentation, such as a Leksell Rongeur, as necessary to remove the ligaments and clear the interspinous space.

Optional: General instrumentation, such as a Cobb Elevator and a Cerebellar Retractor may be used if desired.

Take care not to overadvance.

5. Distraction and Sizing





The Trial Sizer has two hub sizes on either end, marked to indicate size.

- Starting with the 10mm trial size, insert the Trial Sizer in the interspinous space.
- If sufficient distraction has not been achieved, increase the trial size to distract the spinous processes as desired to determine appropriate implant size.
- Once the appropriate size has been determined, the Trial Sizer can be left in between the spinous processes to help relax the surrounding ligaments.

Appropriate distraction can be also determined visually from lateral fluoroscopy.

Do not overdistract spinous processes. Overdistraction could damage the spinous processes.

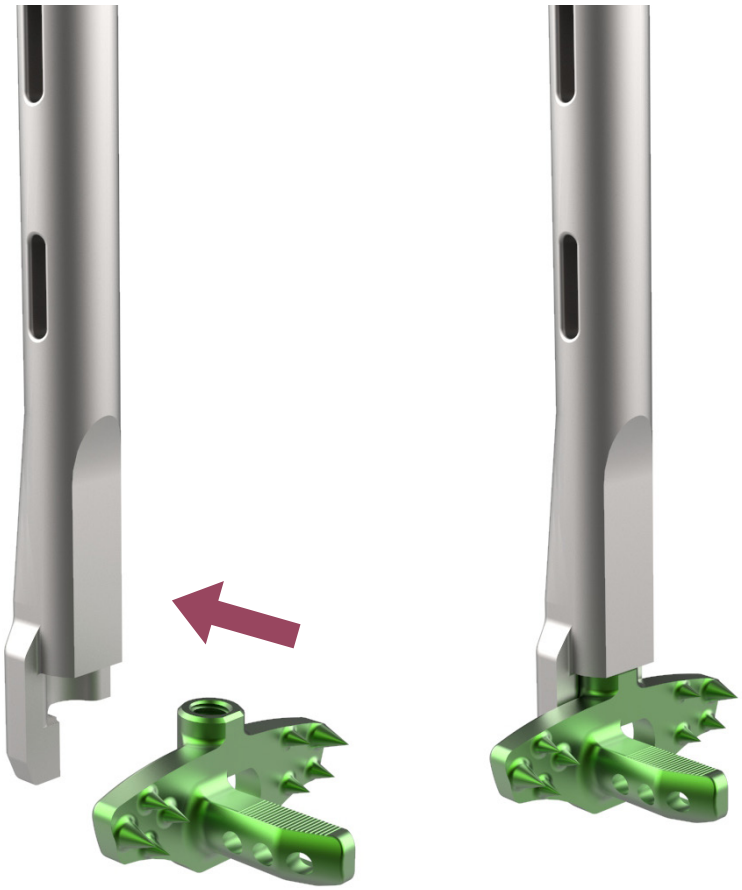
6. Implant Selection

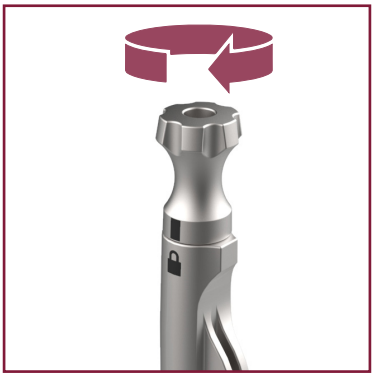
Hub Size	Color	Part Number
8mm	silver	01-61100-0835
10mm	gold	01-61100-1037
12mm	dark blue	01-61100-1239
14mm	green	01-61100-1441
16mm	bronze	01-61100-1643
18mm	purple	01-61100-1845
20mm	aqua	01-61100-2047

Using the size determined in step 5, select two of the appropriate implants.

Ensure both plates are the same size.

7. Implant Insertion



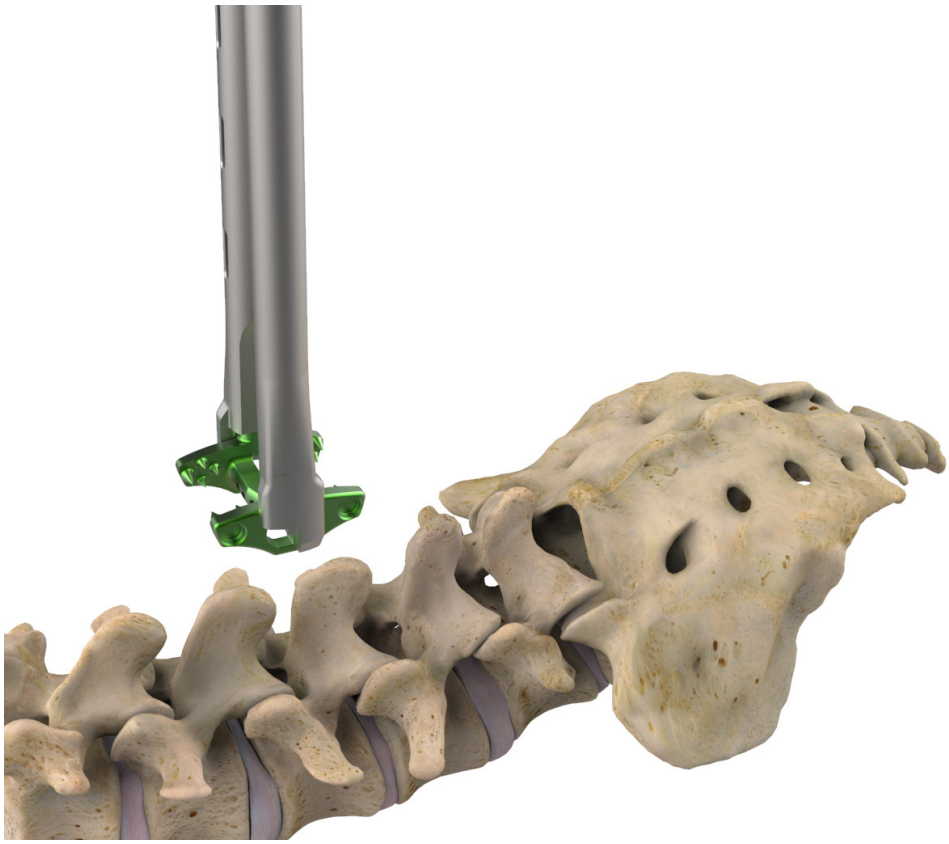


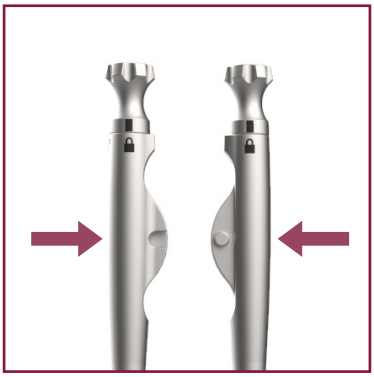
Seat the back of the implant into the distal end of the outer shaft of the Inserter.

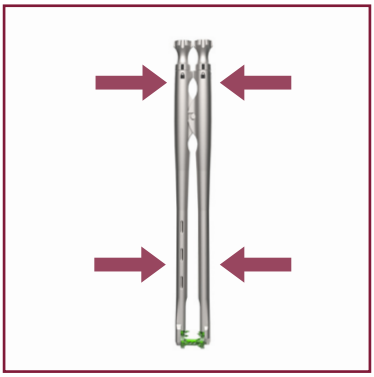
- While holding the implant in the distal end of the outer shaft, insert the stylet into the proximal end of the outer shaft while aligning the marking on the knob with the “UNLOCK” symbol on the outer shaft.
- Apply a downward force onto the knob and rotate clockwise until the marking on the knob aligns with the “LOCK” symbol on the outer shaft.
- Repeat these steps for the other implant.

Ensure both plates are the same size.
If the stylet does not engage the implant set screw, remove and re-insert the stylet until distal tip is seated in the set screw. (subject to final validation)

7. Implant Insertion (Cont.)





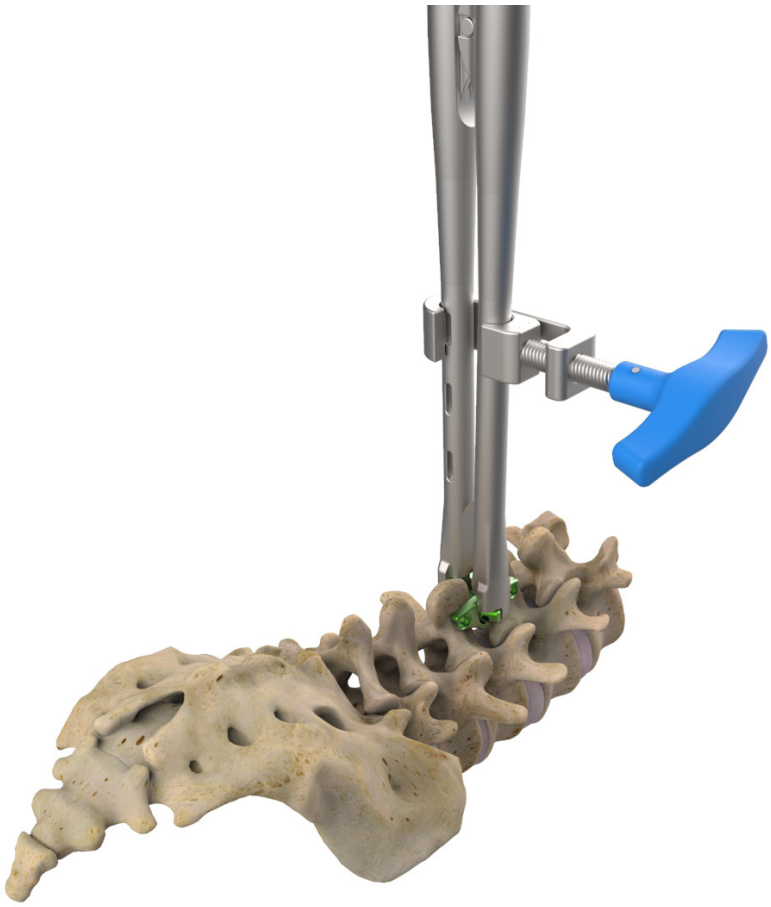


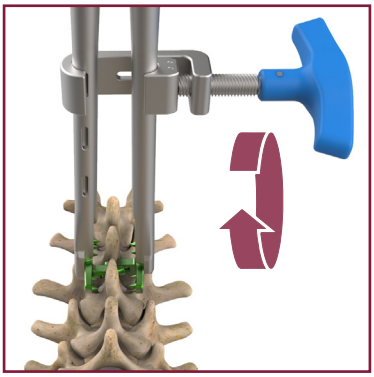
- With the implants attached to the Inserters, assemble the Inserters to each other by sliding the alignment pin on the first Inserter into the slot on the second Inserter.
- By positioning your hand on the proximal end of the Inserters and squeezing, the implants will be held apart for posterior insertion into the interspinous space.
- Using the Inserters, slide the implants into position under lateral fluoroscopy until the implant is seated on the lamina. If necessary, use a Mallet to impact the Inserters to position the implants.
- Slide your hand down the shaft towards the distal end of the Inserters until your hand is below the pivot point of the Inserters and squeeze the Inserters together to slide the mating halves of the implant together.

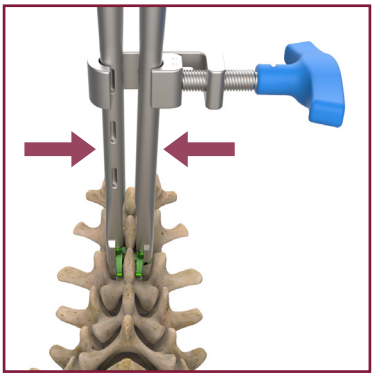
Ensure that the implant hub can freely enter the hub cavity on the opposing implant prior to insertion.

Take care not to over-impact the Inserter.

8. Compression





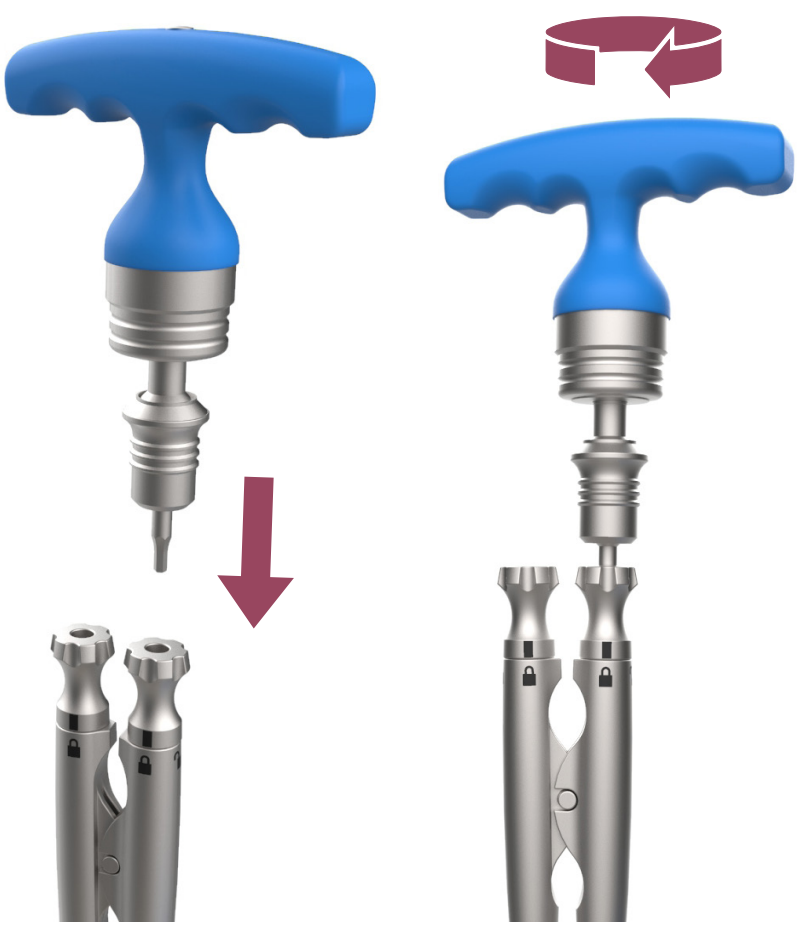


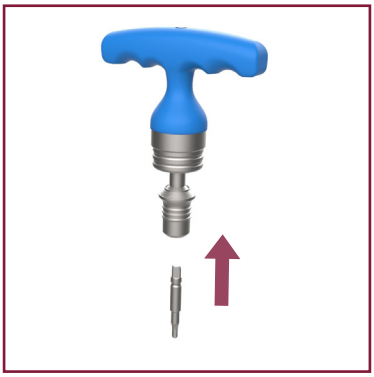
After the implant is in position:

- Slide the Compressor onto the Inserter and align the 'THIS SIDE UP" laser marking towards the proximal end of the Inserter.
- Rotate the handle clockwise until desired compression is reached.
- Confirm correct placement of the implant under fluoroscopy.

Over compression of the implants may fracture the spinous processes.
Ensure the hubs have cleared the hub windows on the lateral side of the opposing implant.
The Set Screws should make full contact with the hub ridges before final locking.

9. Final Locking

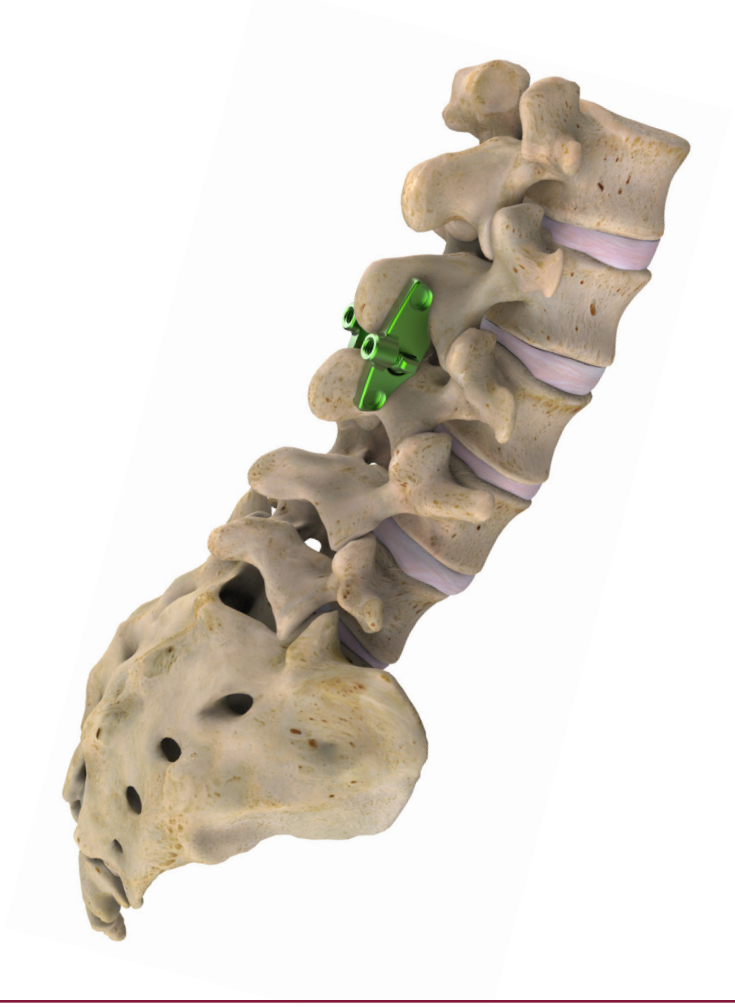


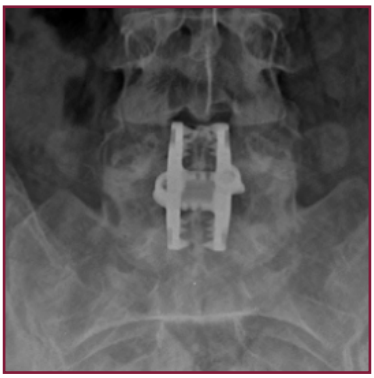


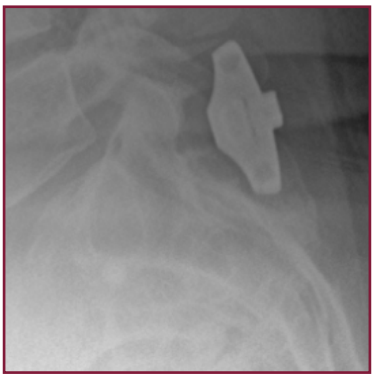
- Attach the Final Locking Driver to the Torque Limiting Handle.
- Insert the Final Locking Driver into the proximal end of the Inserter and rotate clockwise. The Torque Limiting Handle will click once the desired torque is reached.
- Repeat for second set screw.
- Remove the Compressor from the Inserter once both set screws are final locked.
- Turn each knob counter clockwise until the marking on the knob aligns with the "UNLOCK" symbol.
- Squeeze the proximal ends of the Inserters and remove them from the surgical site.

If the Torque Limiting Handle is not used the set screw can be over tightened or under tightened causing the plates to separate from each other over time.

10. Final Implant Placement







Confirm implant placement using lateral and A/P fluoroscopy.

11. Revision (Optional)

The following steps are taken to revise the implant:

- Gain access to implant.
- Remove any tissue or bone impending access to the implant.
- Loosen both set screws.
- Attach forceps to implant and remove.

Revision could be necessary under the following situations, including, but not limited to:

- Larger implant preferred after initial implant inserted
- Misplaced implant; too anterior or not straight
- Implant placed too far into interspinous process space
- Implant fracture during insertion
- Wrong level surgery
- Loss of neurologic function of unknown cause
- Spinous process fracture during procedure
- Removal following fusion
- Non-Union
- Infection
- Psychological patient fear of having a device in forever
- Painful hardware irritating soft tissues or nerves
- Plate migration causing neural compression
- Spinous process fracture around implant
- Spinous process fracture

Indications & Sterilization

Indications

The InSpan® ScrewLES Fusion System is a posterior non-pedicle supplemental fixation system intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion for the following indications: spondylolisthesis, trauma (fracture or dislocation), tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), or lumbar spinal stenosis. The device is intended for use with bone graft material and is not intended for stand-alone use.

Sterilization

Unless marked sterile and clearly labeled as such, the InSpan® Spinous Process Plate System components described in this insert are provided non-sterile and must be sterilized prior to use. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications listed below:

Method	Steam
Cycle	Pre-Vacuum
Temperature	270° F (132°C)
Exposure Time	4 Minutes
Dry Time	20 Minutes

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Instruments cases are not to be externally stacked.

Implants & Instruments

Implants

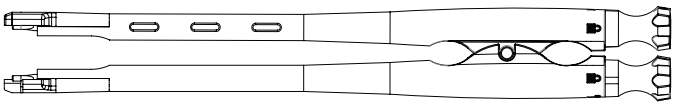
* Implant is located in the Inspan case.

** Optional Implant Available Upon Surgeon Request

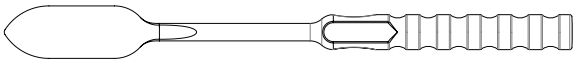
01-61100-0835	Inspan Slim ISP Plate Assy.	8x35mm*
01-61100-0843	Inspan Slim ISP Plate Assy.	8x43mm**
01-61100-1037	Inspan Slim ISP Plate Assy.	10x37mm*
01-61100-1239	Inspan Slim ISP Plate Assy.	12x39mm*
01-61100-1441	Inspan Slim ISP Plate Assy.	14x41mm*
01-61100-1643	Inspan Slim ISP Plate Assy.	16x43mm*
01-61100-1845	Inspan Slim ISP Plate Assy.	18x45mm*
01-61100-2047	Inspan Slim ISP Plate Assy.	20x47mm*

01-61006-0835	Inspan Slim ISP Plate Assy.	8x35mm**
01-61006-1037	Inspan Slim ISP Plate Assy.	10x37mm**
01-61006-1239	Inspan Slim ISP Plate Assy.	12x39mm**
01-61006-1441	Inspan Slim ISP Plate Assy.	14x41mm**
01-61006-1643	Inspan Slim ISP Plate Assy.	16x43mm**

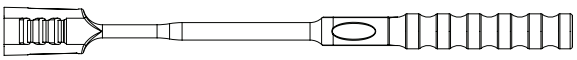
Instruments



13-60002 - Inserter



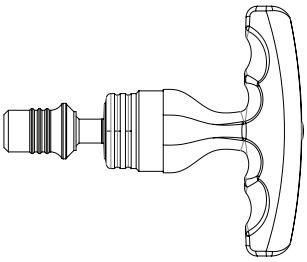
11-60103 - Decompression Knife



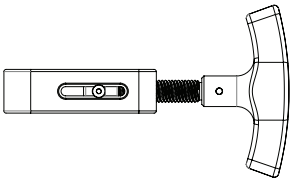
11-60104 - Broach

11-60105 - Trial Sizer

Instruments (Cont.)



11-60040 - 30 IN-LB Torque Limiting Handle



11-60102 - Central Compressor

11-60101 - Final Locking Driver

Outpatient Technologies for Less Exposure Surgery.

ST-60-00007 Rev A Inspan® Surgical Technique

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Less Exposure Surgery Technologies
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Malden, MA 02148 U.S.A. P: (978) 232-3990 F: (978) 232-3991