INSPAN SURGICAL TECHNIQUE
Quick Steps: Inspan at a glance:

1. Dilation
2. Distraction
3. Insertion
4. Compression
5. Locking
6. Graft Placement
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About SpineFrontier

SpineFrontier 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, helping us develop SpineFrontier into a company that is driven to be a leader in cutting edge technology.

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

SpineFrontier would like to thank all the surgeons that contributed to the development of the InSpan Spinous Process Plate System and the surgical technique.

About the LES Philosophy

LES, or Less Exposure Surgery, is the philosophy of achieving optimum surgical exposure while maximally preserving the anatomy and lessening the exposure to radiation and damaging effects of 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 tissue sparing treatments that allow for ease of application for the surgeon with improved outcome for the patient. The LES Society is a non-profit, tax-exempt, educational organization whose purpose is to protect the health of the patient and to optimize the surgical procedure for the surgeon by promoting the less exposure surgeon philosophy.

The society provides a forum for dialogue amongst spine surgeons and gives them a place to discuss and debate the LES approach, as well as train and contribute to educational endeavors. It will also be a resource to other physicians and patients on the benefits of LES and the latest technologies all in the effort to ease patient healing time post-surgery.
Anatomy of Inspan

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
• Easy to insert dual locking hub design
• Design optimized for the LES midline approach

About the System

The InSpan® Spinous Process Plate System consists of a variety of sizes of plates, set screws, and instrumentation to facilitate installation of this system. The plates are offered in five hub diameters (8mm to 16mm in 2mm increments) and five wing length configurations (35mm to 43mm 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 18.85mm for InSpan® and 13.89mm 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 both are used to secure the assembly in its final compressed and implanted state. A torque limiting driver is provided to ensure the appropriate screw torque is applied.

Surgical Technique Symbols

⚠️ Warning ⏺️ Additional Information
1 Preoperative Planning

All necessary imaging studies should be available to visualize patient anatomy and plan implant placement.

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 palpitation and intraoperative imaging.

Make a midline incision (5-7cm) and distract, clearing tissue between spinous processes to be joined. Use general discectomy surgical tools and Rasps as needed to prepare device site.

 опасности: Care must be taken throughout the procedure to ensure that no damage is caused to the dura or spinous process. Overdecoration can cause weakening of the spinous process.

TOOLS:

11-60001 Flat Rasp
4 Tissue Dilation

Using the Hooked Dilator, punch a hole through the anterior region of the interspinous ligament. Make sure that the Hooked Dilator is placed at midpoint between the adjacent spinous processes.

TOOLS:

- AO Handle
- Hooked Dilator
5 Distraction and Sizing

Insert the Distractor into the hole created by the Hooked Dilator and spread spinous processes. Begin to distract adjacent spinous processes and determine appropriate implant size.

The Distractor has a ratcheting bar at the top of the instrument that indicates which implant size to use.

Ensure the indicator is fully seated against the inside of the handle prior to use to ensure correct hub sizing.

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

Ensure that the hub sizes are the same size or they will not mate and the hubs will not pass through the opposing plate’s hub cavity.

Ensure that plate’s wing size is wide enough to properly attach to the spinous process. If the plate’s wing width is under sized the plate may detach from the spinous process.

TOOLS:

11-60020 Sizer
InSpan® Surgical Technique

6 Implant Attachment

Using the size determined in step 5, select the appropriate implant.

Attach each implant to each Inserter by turning the knob at the end of the Inserter to screw the Inserter into the top of the implant.

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Size</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-61002-0835 or 01-61006-0835</td>
<td>8mm Hub</td>
<td>silver</td>
</tr>
<tr>
<td>01-61002-1037 or 01-61006-1037</td>
<td>10mm Hub</td>
<td>gold</td>
</tr>
<tr>
<td>01-61002-1239 or 01-61006-1239</td>
<td>12mm Hub</td>
<td>dark blue</td>
</tr>
<tr>
<td>01-61002-1441 or 01-61006-1441</td>
<td>14mm Hub</td>
<td>green</td>
</tr>
<tr>
<td>01-61002-1643 or 01-61006-1643</td>
<td>16mm Hub</td>
<td>bronze</td>
</tr>
</tbody>
</table>

Ensure that the plate is fully seated onto the inserter.

Ensure the Inserter’s hub adaptor size corresponds with the chosen plate’s hub size. If the hub adaptor size does not match the plate’s hub size the inserter will not attach to the plate properly and/or at all.

Ensure both plates are the same version. Inspan® is not compatible with Inspan SLIM™.
7 Implant Insertion - Ligament Removed

With the implants attached to the Inserters, assemble the Inserters to each other by sliding the alignment pin into the adjacent slot on the other Inserter.

By positioning your hand on the proximal end of the inserts and squeezing, the implants will be held apart for posterior insertion into the cavity between the adjacent spinous processes.

Using the Inserters, slide the implants into position. If necessary, use a hammer to tap the ends of the Inserters to position the implants.

Slide your hand down the shaft towards the distal end of the Inserter until your hand is below the pivot point of the Inserters.

Squeeze the Inserters together to slide the mating halves of the implant together.

Ex Situ Assembly:

Step 1. Assemble the two Inserter halves together as shown

Step 2. Squeeze the proximal ends of the Inserters together to keep the implants open and opposed

Step 3. With the implants properly positioned In Situ, squeeze the distal ends of the Inserter as shown

TOOLS:

11-60054 Inserter - Right

11-60055 Inserter – Left

Ensure that each plate’s hub passes through the opposing plate’s hub cavity. If the plates are not properly mated the plate system cannot be assembled.

Ensure both plates’ spikes penetrate the spinous process. If the plates’ spikes are not impacting the spinous process proper fixation may not occur.

After ensuring the implants are assembled to the hub adapters properly/securely, assemble the two inserters together, rotating the implants into each other to ensure that each plates hub passes into the receiving cavity.
In Situ Assembly:

Step 1. Insert the first implant through the ligament, align the tip of the second implant to the first.

Step 2. Align the proximal ends of the Inserters as shown.

Step 3. Squeeze the distal end of the assembled Inserters as shown.

8 Implant Insertion - Ligament Preserved

With the implants attached to each Inserter, use one of the Inserters to slide the hub through the hole created in step 4.

Using the tip of the implant as a guide, slide the second Inserter/Implant into position such that the tip of the second implant is adjacent to the tip of the first implant. Ensure the tips of the implants are on the correct side facing each other. This correct placement is the flat face of each implant should be coincident.

With the implants aligned, align the distal ends of the Inserter to each other by sliding the pin on one Inserter half into the slot on the mating Inserter. With the Inserters properly aligned, slide your hand below the pivot point and squeeze.

At this point, the implants should squeeze together through the ligament, recreating the proper distraction determined in step 5. If squeezing the implants through the ligament by hand is difficult, you can use the Compressors to squeeze the distal end of the Inserters together. Locate the Compressors on the round location point on the lateral side of each Compressor and squeeze. By twisting the Inserters perpendicularly to the coronal plane and using the Compressors, squeeze the implants through the ligament.

Note: If inserting the implants through the ligament is difficult, use the Cephalocaudal distractor to re-create the distraction necessary to squeeze the implants together through the ligament. To use the cephalocaudal distractor, place the distractor arms through the hole created by the hooked dilator (as anterior as possible) and distract until the proper tension/opening is achieved. Once the implants are in place, remove the distractor.

TOOLS:

- 11-60054 Inserter - Right
- 11-60055 Inserter – Left
- 11-60084 Compressor
- 11-60048 Cephalocaudal Distractor

Ensure that each plate’s hub passes through the opposing plate’s hub cavity. If the plates are not properly mated the plate system cannot be assembled.

Ensure both plates’ spikes penetrate the spinous process. If the plates’ spikes are not impacting the spinous process proper fixation may not occur.

Do not over distract the spinous processes. Overdistract could damage the spinous process.

After ensuring the implants are assembled to the hub adapters properly/securely, assemble the two inserters together, rotating the implants into each other to ensure that each plates hub passes into the receiving cavity.
9 **Compression**

After the implant is in desired position, insert the first Compressor onto the plates. Attach the Compressor to the plates by aligning the divots on the Compressor arms with the alignment features on the plate.

Insert the second Compressor onto the opposite end of the plates and lightly compress.

To remove the Inserters, turn the knob at the distal end of each Inserter counter clockwise until the Inserter disengages from the implant. Remove the Inserters posteriorly. Take a lateral x-ray to ensure proper placement of the implant.

Begin sequential compression by squeezing on the handles of each Compressor. Tighten each alternately until desired compression is reached.

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**Warning:**

Do not over compress spinous process.

Ensure the locking mechanism on both Inserters are in the unlocked position before attempting to remove the Inserters. If the Inserter’s locking mechanism are not unlocked the Inserter will not release from the plate.
10 Construct Locking

Attach the ¼" square drive Torque Limiting Handle to the ¼" Square Drive Connection of the Set Screw Driver.

Check to ensure the line on the Set Screw Driver is flush with the bottom of the Torque Handle.

Insert the Driver into the Set Screw and begin tightening. The Torque Limiting Handle will click once the desired torque is reached. Repeat for second Set Screw.

Once both set screws are tight, remove the compressors from the construct.

If the plate’s set screws are not properly locked down the plates may separate from each other over time.

Be sure to use the Torque Limiting Handle to tighten down the both plates’ set screws. If the Torque Limiting Handle is not used the Set Screw can over tightened and/or under tightened causing the plates to separate from each other over time.

When inserting Set Screw Driver into the Set Screw, keep the Set Screw Driver aligned perpendicularly to the Set Screw. Do not twist or angle the Set Screw Driver off axis.

Avoid angling the Set Screw Driver off axis to the set screw. Any bending of the Set Screw Driver will damage the Set Screw within the implant.
11 Bone Grafting

Bone Grafting can now be performed. Implant per manufacturer’s recommended method.
12 Final Implant Position

Visually inspect the implant for secure fixation. Check placement of the implant using x-ray.

Close the patient using standard techniques.
13 Removal and/or Revision of Implants

Revision could be necessary under the following situations:

A. Intra-operative Revision

1. Larger implant preferred after initial implant inserted
2. Misplaced implant; too anterior or not straight
3. Implant placed too far into interspinous process space
4. Implant fracture during insertion
5. Wrong level surgery
6. Loss of neurologic function of unknown cause
7. Spinous process fracture during procedure

B. Post-Operative Revision

1. Removal following fusion
2. Non-Union
3. Infection
4. Psychological patient fear of having a device in forever
5. Painful hardware irritating soft tissues or nerves
6. Plate migration causing neural compression
7. Spinous process fracture around implant
8. Spinous process fracture

The following steps are taken to revise the implant.

Step 1. Gain access to Implant
Step 2. Remove any tissue or bone impeding access to the implant.
Step 3. Loosen both set screws.
Step 4. Attach forceps to implant and remove laterally
IsInSpan® Surgical Technique

InSpan® Surgical Plate System Package Insert

InSpan® Surgical Technique

WARNING

The following are specific warnings, precautions and adverse effects that should be understood by the surgeon and patient. These warnings, precautions and adverse effects can occur with surgery in general, but are important considerations particular to metal internal fixation devices. General surgical principles should be followed. Potential risks related to the use of the device system, which may require additional surgery include: device component fractures, loss of fixation, loosening, fracture of the vertebrae, neurological injury, and/or vascular injury or or visceral injury.

1. CORRECT SELECTION OF THE INSTRUMENT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper shape, size, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone.

2. TITANIUM—When selecting for the appropriate load-bearing applications, titanium is chosen due to its low modulus of elasticity and low weight-bearing.

3. A SPECIFIC SURGERY WHEN SUBJECT TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices. The potential for bone healing is enhanced by reducing the stresses on the bone and transferring them to the implant. Evidence suggests that if bone or bone graft does not or does not occur, the implant may eventually break due to metal fatigue. The degree of bone union and the healing potential remains correlated with the amount of load transferred to the bone. The implant must be fully告知 the risks of implant failure.

4. Mechanical and Material Properties. There are many forms of corrosive damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion occurs on all implanted metals and alloys. The rate of corrosion attack on a metal is a function of the frequency, duration, and extent of exposure to the corrosive environment. Disease metal in contact, such as titanium and stainless steel, accelerate the corrosion process. Hypertrophic tissue is often characterized by accelerated metatases and fibrosis of the tissues. The amount of metal compounds released into the system is a function of the design and material used. In all cases that are encountered, the patient should be informed of the risks of implant failure.

5. Patient Selection: In selecting patients for internal fixation devices, the following factors must be evaluated:

a. Previous spinal surgery: Patients with previous spinal surgery at the level(s) to be treated should be counseled concerning the risks of surgery and the possible sequelae. If the patient has undergone a laminectomy, he/she should not return to these activities until the spine is fully healed. Even with full healing the patient may not be able to return to a functional state.

b. Condition of mental, renal, thyroid, or adrenal cortex. These conditions, among others, may cause the patient to spasm certain irrelevant conditions and precautions in the use of the appliance, leading to implant failure or other complications.

c. Pellagra, malnutrition, or Kwashiorkor.

d. Adrenal-Insufficiency. In cases where the degree of the respective disease may be so advanced at the time of implantation that it may substantially decrease the patient's ability to withstand the surgical and postoperative stress. The patient may experience a general, mental, cardiovascular, or other systemic collapse due to the excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, and possible paralysis of the functioning tissues. By the mechanism of fatigue, these stresses can cause the eventual loosening, bending, and/or breakage of any or all the components.

6. PERSISTENT PAIN. Pain may persist at an increased level of intensity and duration, and/or the patient may experience a general, mental, cardiovascular, or other systemic collapse due to the excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, and possible paralysis of the functioning tissues. By the mechanism of fatigue, these stresses can cause the eventual loosening, bending, and/or breakage of any or all the components.

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21. PERSISTENT PAIN. Pain may persist at an increased level of intensity and duration, and/or the patient may experience a general, mental, cardiovascular, or other systemic collapse due to the excessive ble...
**Indications**

The InSpan® Spinous Process Plate 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, or degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies). 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:

<table>
<thead>
<tr>
<th>Method</th>
<th>Steam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Pre-Vacuum</td>
</tr>
<tr>
<td>Temperature</td>
<td>270° F (132°C)</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>4 Minutes</td>
</tr>
<tr>
<td>Dry Time</td>
<td>20 Minutes</td>
</tr>
</tbody>
</table>

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

11-60001 Flat Rasp

11-60006 Hooked Dilator

11-60063 Set Screw Driver

11-60044 Round Rasp

SII00090 AO Handle

11-60040 Torque Handle

11-60054 Inserter - Right

11-60055 Inserter – Left

11-60047 Compressor
11-60004
11-60079
11-60084

11-60020 Sizer

11-60048 Cephalocaudal Distractor
Notes:
Outpatient Technologies for Less Exposure Surgery