spinefrontier®
Less Exposure Surgery Technologies

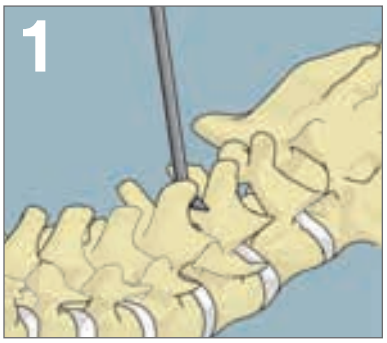
Inspan®
Spinous Process Plate System

INSPAN SURGICAL TECHNIQUE

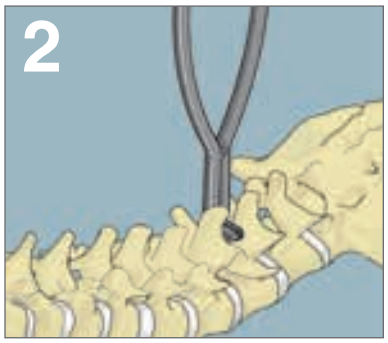
LES Less Exposure Surgery
lessociety.org

LESS time in surgery
IS MORE time in action

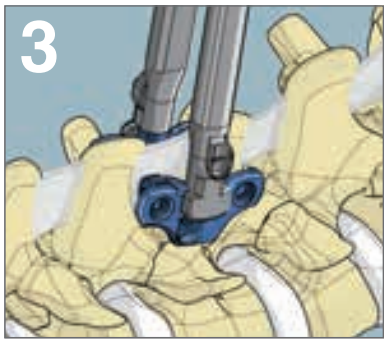
Quick Steps: Inspan at a glance:



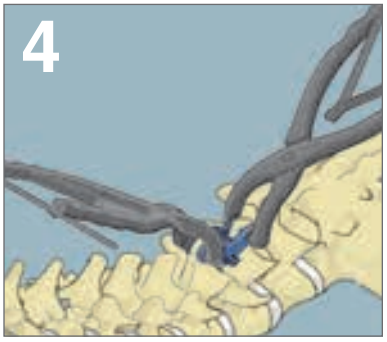
Dilation



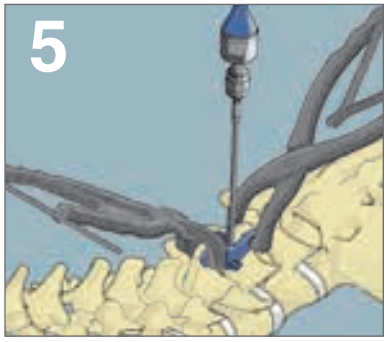
Distraction



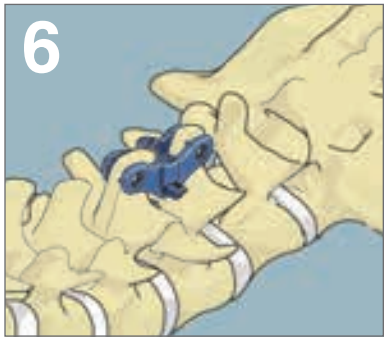
Insertion



Compression



Locking



Graft Placement

Table of Contents

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.

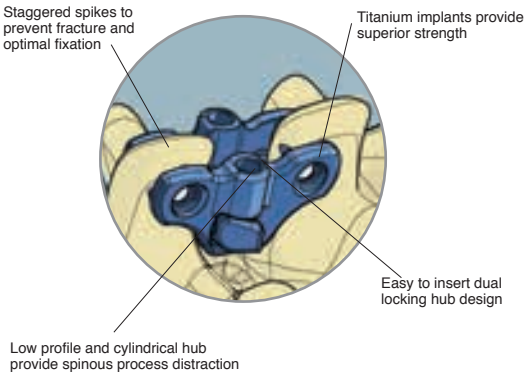
“Each multi-level condition in the spine could be treated and repeated for adjacent segments,” said Kingsley R. Chin, M.D. “The future of spine surgery is dependent upon devices and techniques for less exposure segmental spine surgery.”

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

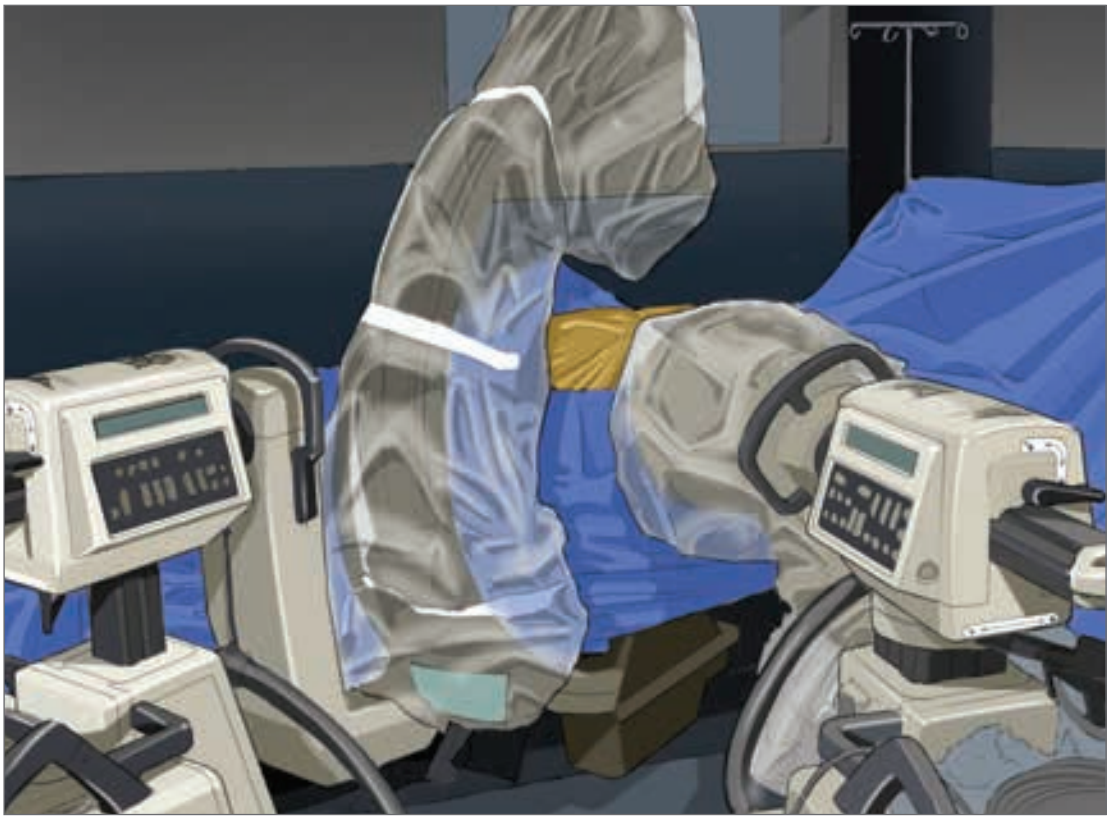
About the System

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

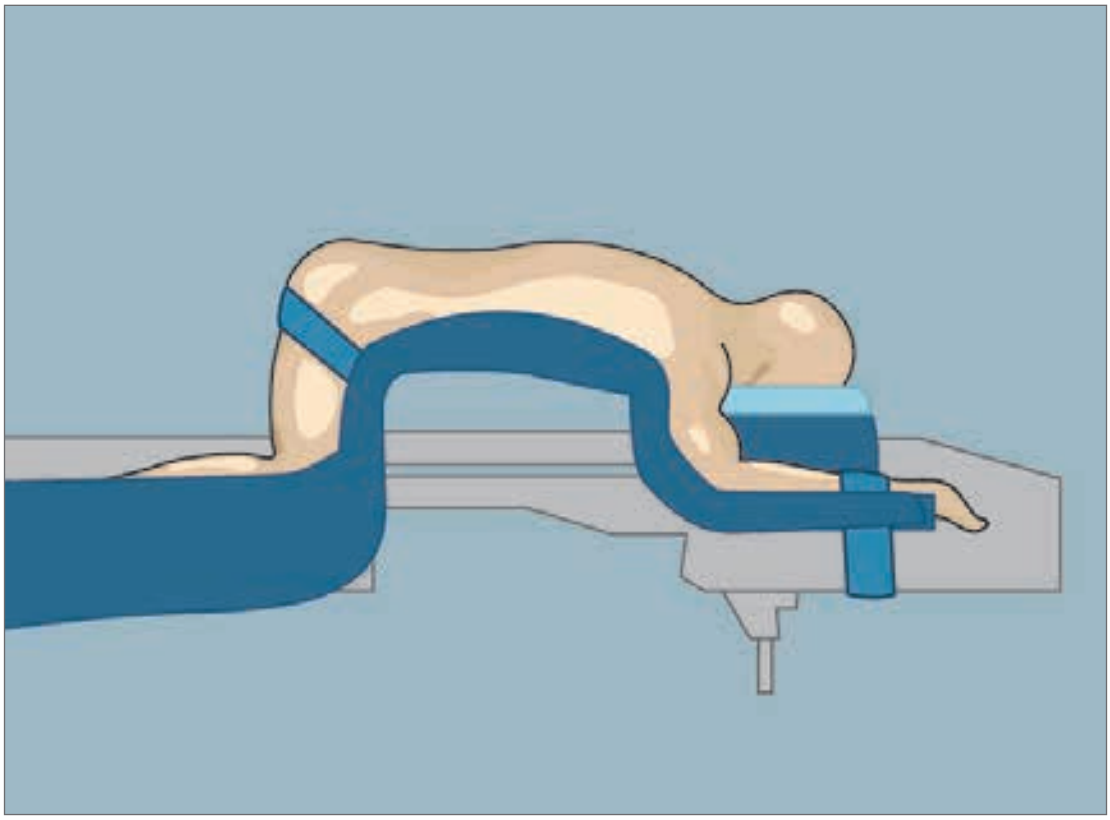
⚠ Warning ⓘ Additional Information



1 Preoperative Planning

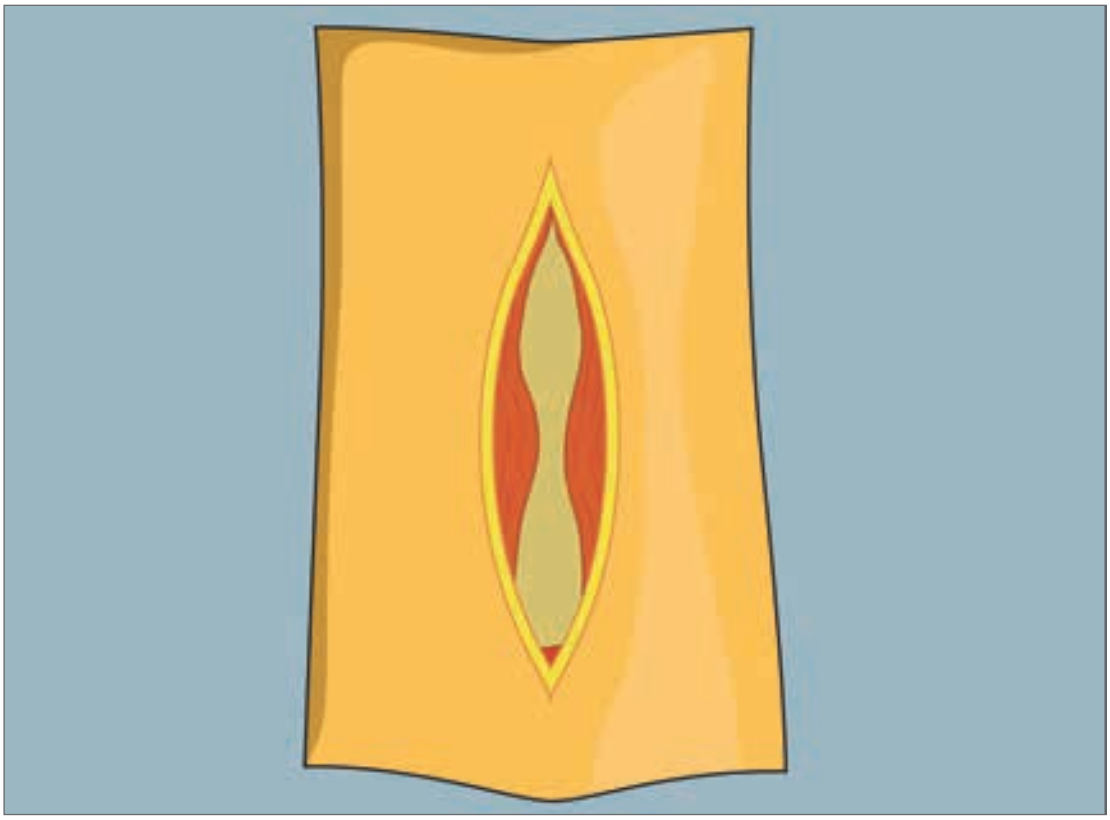
All necessary imaging studies should be available to visualize patient anatomy and plan implant placement.

⚠ 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

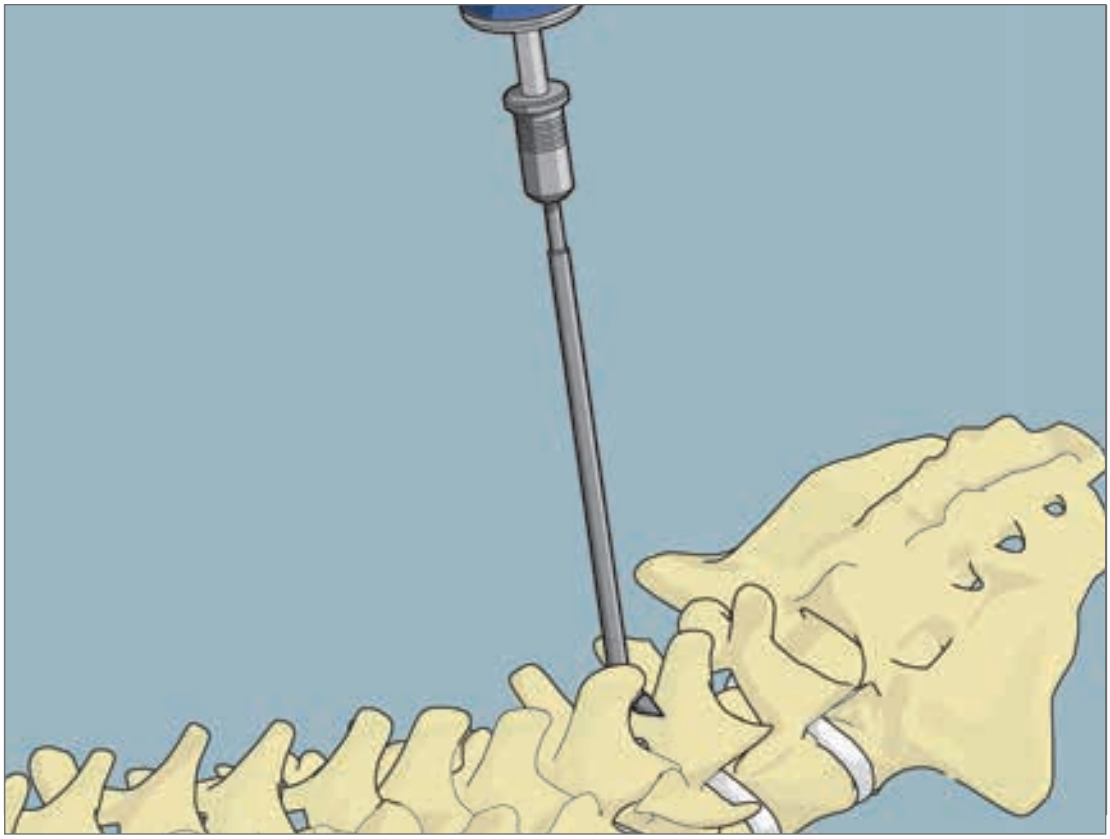
Identify the spinous processes at the level to be joined by using manual palpitation and intraoperative imaging.

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

TOOLS:

11-60001 Flat Rasp

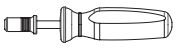
⚠ Care must be taken throughout the procedure to ensure that no damage is caused to the dura or spinous process. Overdecortication can cause weakening of the spinous process.



4 Tissue Dilation

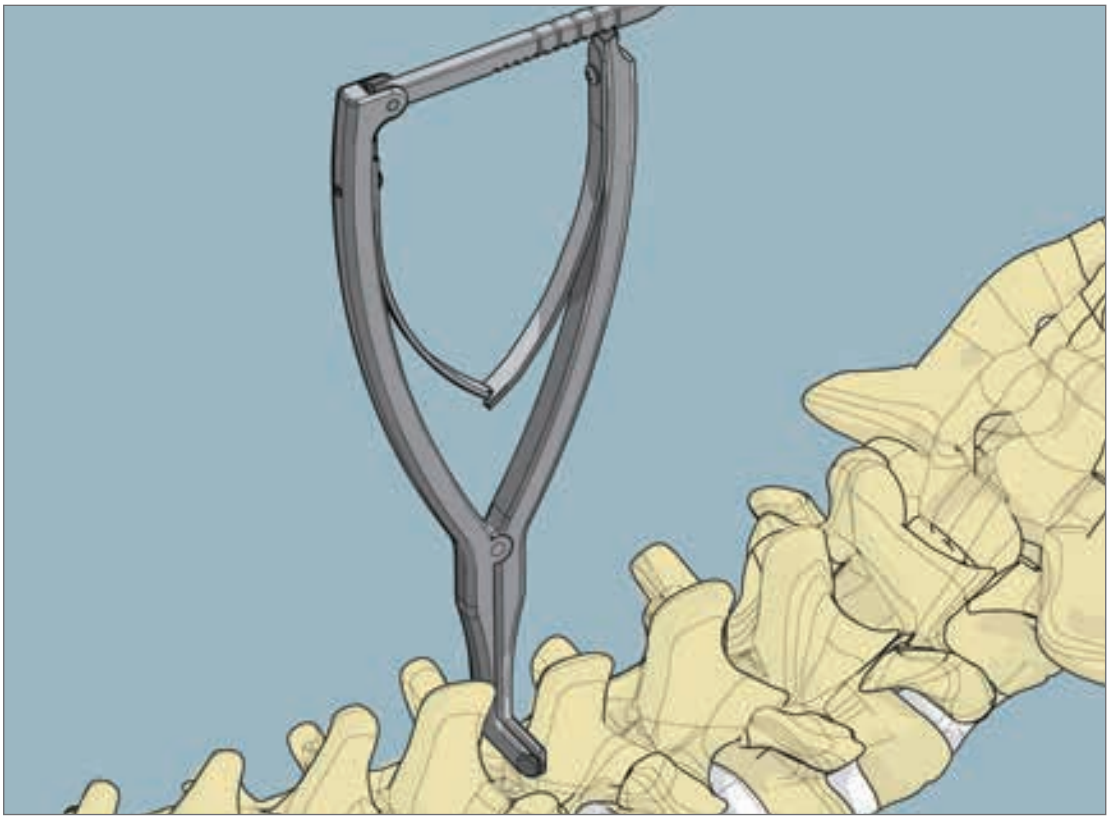
Using the Hooked Dilator, punch a hole through the anterior region of the interspinous ligament. Make sure that the Hooked Dilator is placed at midpoint between the adjacent spinous processes.

TOOLS:



SI00090 AO Handle

11-60006 Hooked Dilator



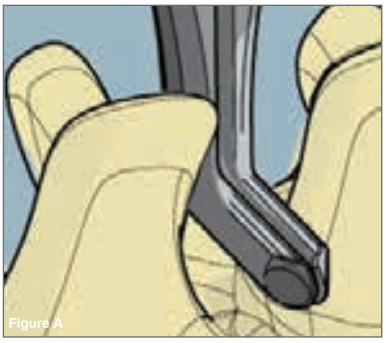


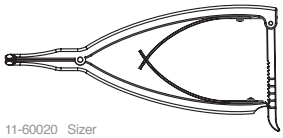
Figure A

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.

TOOLS:


11-60020 Sizer

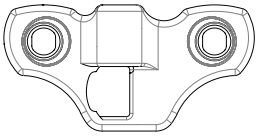
⚠ Ensure the indicator is fully seated against the inside of the handle prior to use to ensure correct hub sizing.

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

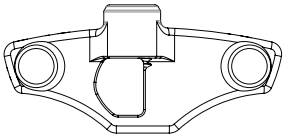
Ensure that the hub sizes are the same size or they will not mate and the hubs will not pass through the opposing plate's hub cavity.

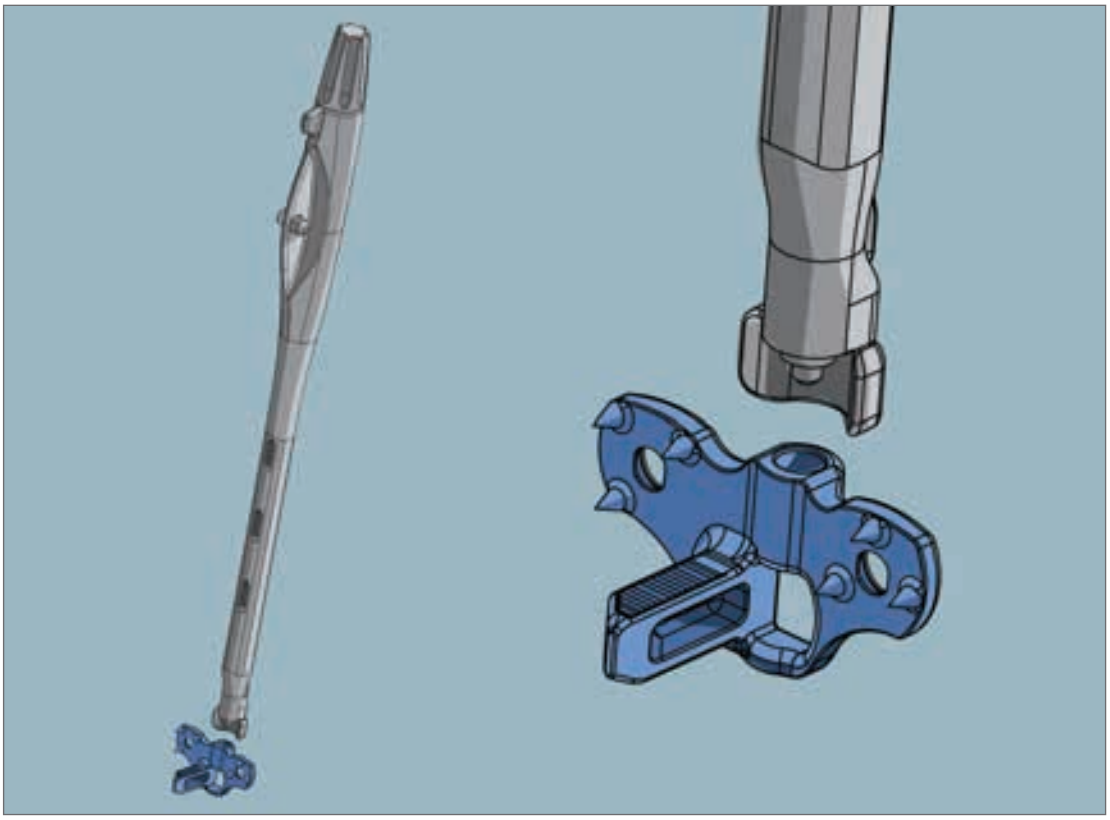
Ensure that plate's wing size is wide enough to properly attach to the spinous process. If the plate's wing width is under sized the plate may detach from the spinous process.

Inspan®
Spinous Process Plate System



Inspan® SLIM™
Spinous Process Plate System





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.

TOOLS:

11-60054 Inserter - Right

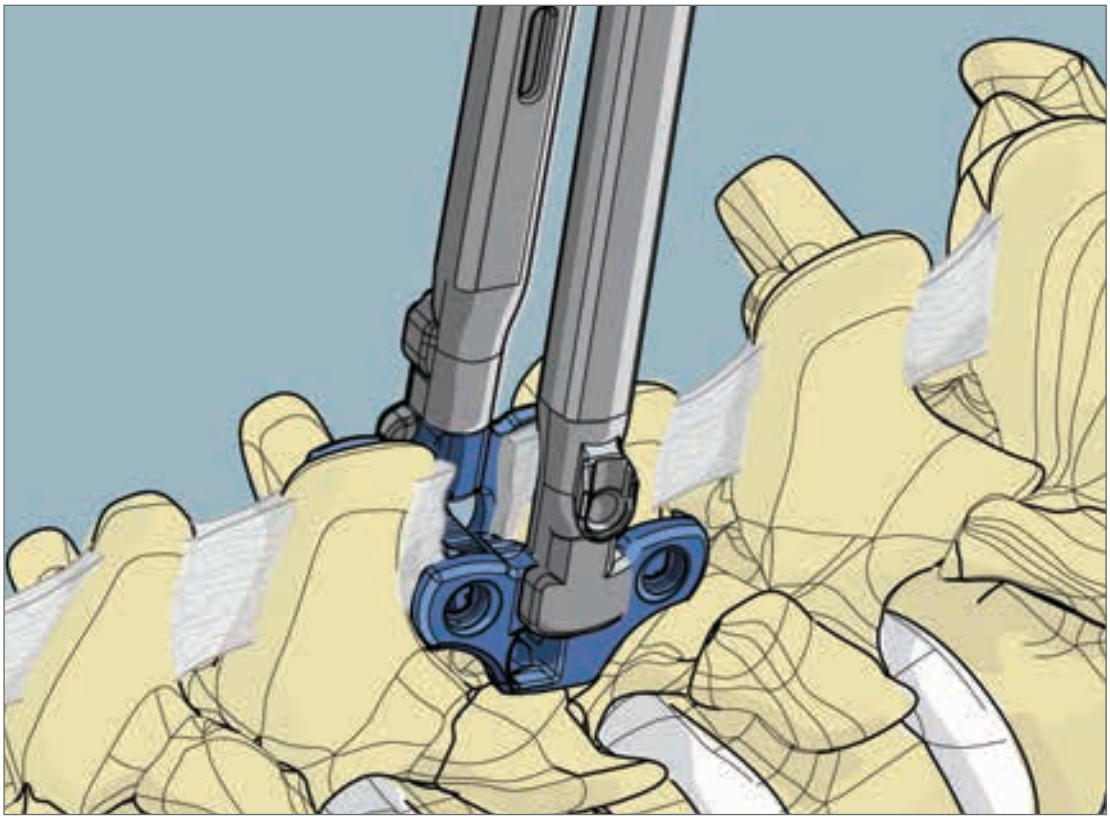
11-60055 Inserter – Left

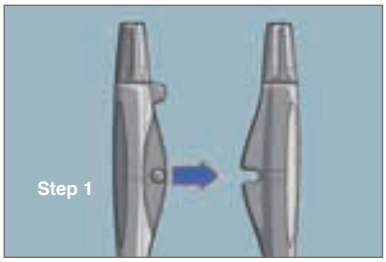
Part Number	Size	Color
01-61002-0835 or 01-61006-0835	8mm Hub	silver
01-61002-1037 or 01-61006-1037	10mm Hub	gold
01-61002-1239 or 01-61006-1239	12mm Hub	dark blue
01-61002-1441 or 01-61006-1441	14mm Hub	green
01-61002-1643 or 01-61006-1643	16mm Hub	bronze

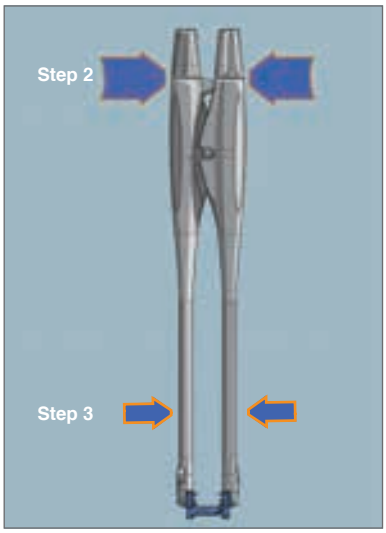
⚠ Ensure that the plate is fully seated onto the inserter.

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™







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

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.

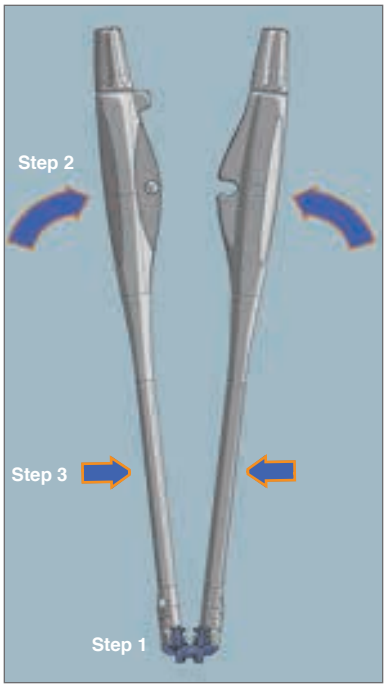
Slide your hand down the shaft towards the distal end of the Inserter until your hand is below the pivot point of the Inserters.

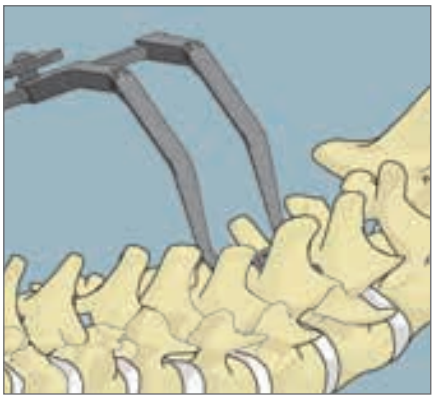
Squeeze the Inserters together to slide the mating halves of the implant together.

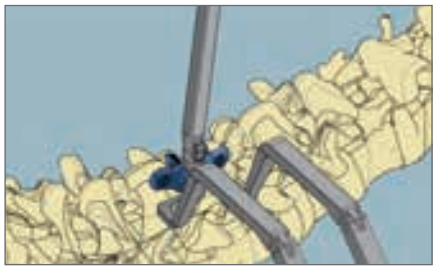
Ensure that each plate's hub passes through the opposing plate's hub cavity. If the plates are not properly mated the plate system cannot be assembled.

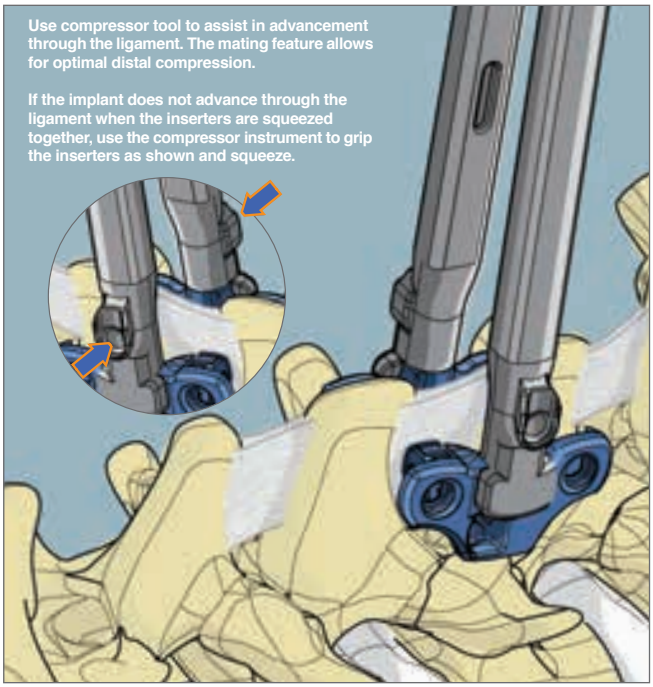
Ensure both plates' spikes penetrate the spinous process. If the plates' spikes are not impacting the spinous process proper fixation may not occur.

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

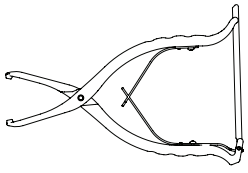
Step 2. Align the proximal ends of the Inserters as shown

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

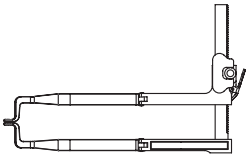
TOOLS:

11-60054 Inserter - Right

11-60055 Inserter – Left



11-60084 Compressor



11-60048 Cephalocaudal Distractor

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.

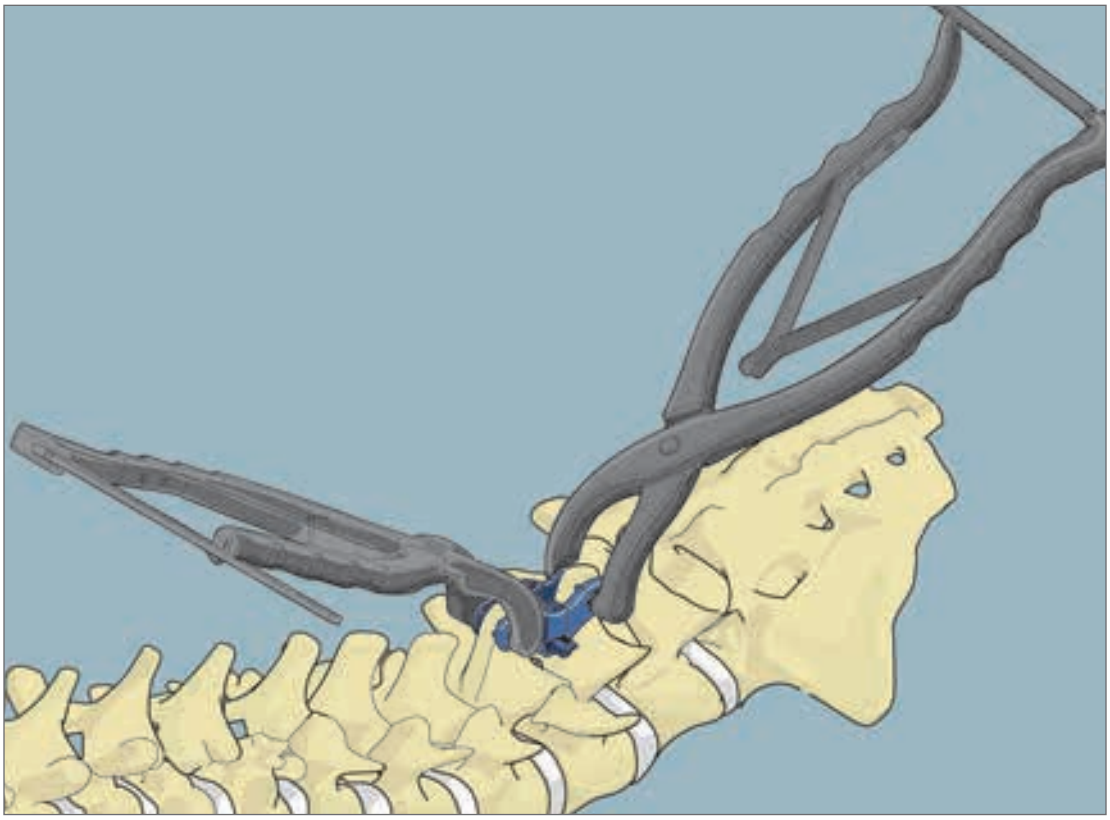
Note: If inserting the implants through the ligament is difficult, use the Cephalocaudal distractor to re-create the distraction necessary to squeeze the implants together through the ligament. To use the cephalocaudal distractor, place the distractor arms through the hole created by the hooked dilator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

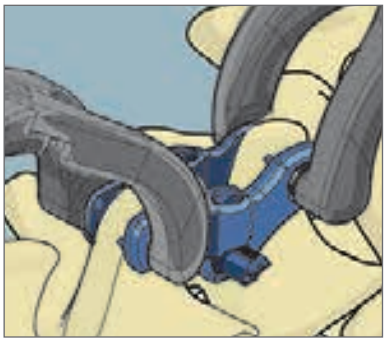
⚠ Ensure that each plate's hub passes through the opposing plate's hub cavity. If the plates are not properly mated the plate system cannot be assembled.

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. Overdistraction 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

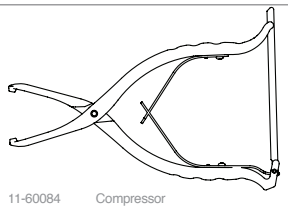
After the implant is in desired position, insert the first Compressor onto the plates. Attach the Compressor to the plates by aligning the divots on the Compressor arms with the alignment features on the plate.

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.

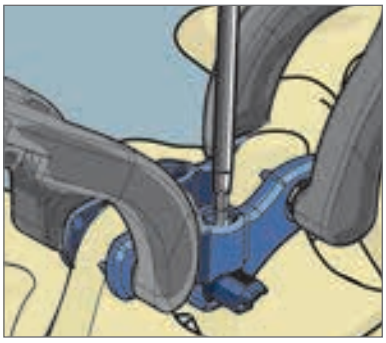
TOOLS:

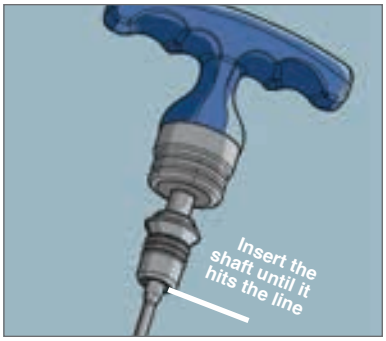


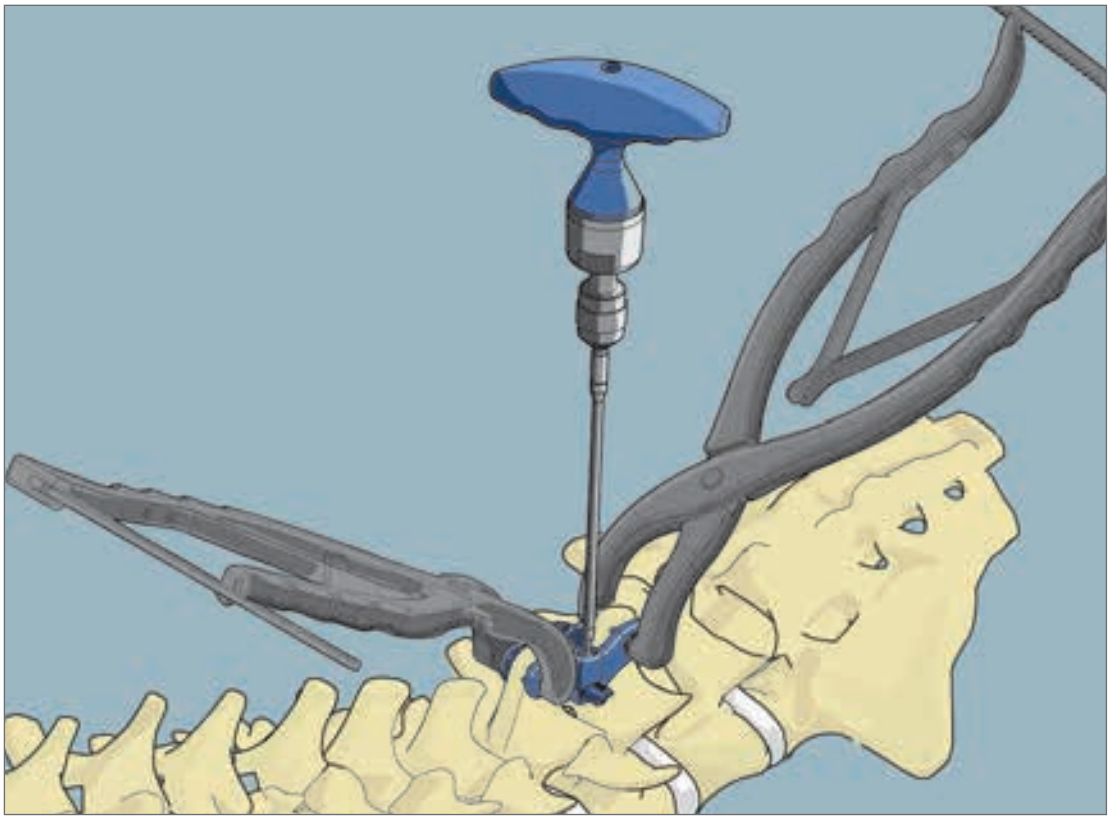
11-60084 Compressor

⚠ 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.

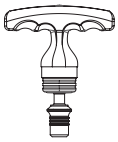
Check to ensure the line on the Set Screw Driver is flush with the bottom of the Torque Handle.

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.

TOOLS:

11-60063 Set Screw Driver



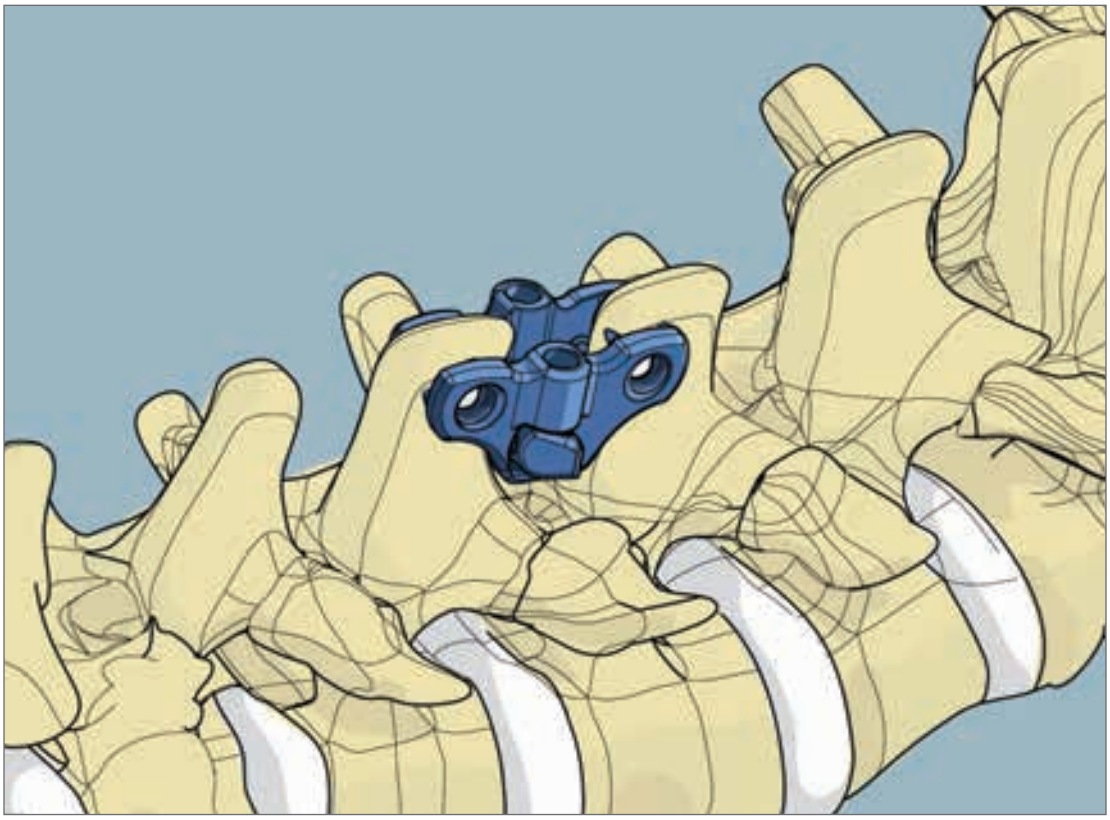
11-60040 Torque Handle

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.

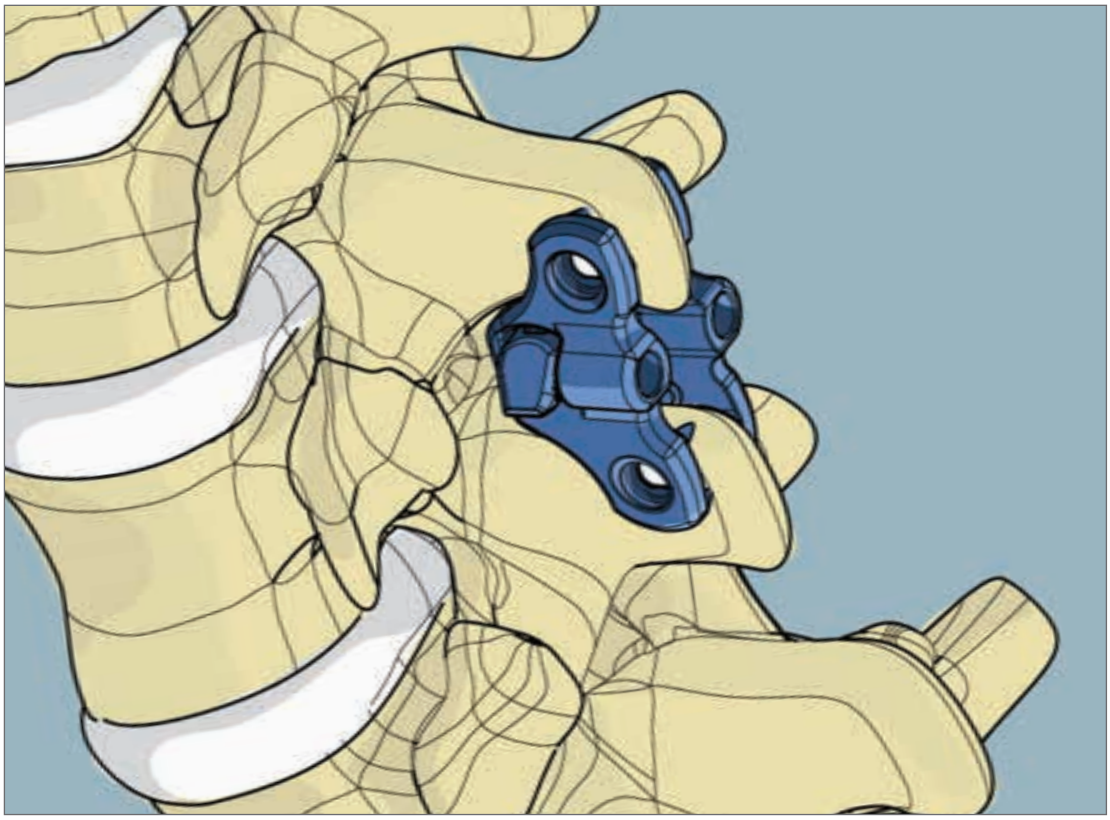
When inserting Set Screw Driver into the Set Screw, keep the Set Screw Driver aligned perpendicularly to the Set Screw. Do not twist or angle the Set Screw Driver off axis.

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

InSpan® Spinous Process Plate System Package Insert
Caution: USA Law restricts this device to sale by or on the order of a Physician.

DESCRIPTION:

The **InSpan® Spinous Process Plate System** consists of a variety of sizes of plates, set screws, and associated instruments. The plates are offered in five hub diameters (8mm to 16mm in 2mm increments) and five wing length configurations (35mm to 43mm 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.

InSpan® Spinous Process Plate System implants are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136.

Instruments in the **InSpan® Spinous Process Plate System** are supplied non-sterile, are re-usable, and are fabricated from commercially pure titanium alloy (ASTM F 67), titanium alloy (ASTM F 1295), or stainless steel.

It is essential to use the **InSpan® Spinous Process Plate System** with the instruments specifically designed for use with the system.

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.

CONTRAINDICATIONS:

Contraindications include but are not limited to:
1. Active infectious process or significant risk of infection (immunocompromised).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC different count.
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis. Osteoperosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
10. Suspected or documented metal allergy or intolerance.
11. Any case not needing a bone graft and fusion.
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
13. Any case where multiple levels of device implantation are desired
14. Any case that requires the mixing of metals from two different components or systems.
15. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
16. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
17. Any patient unable or unwilling to follow postoperative instructions.
18. Alcoholism or heavy smoking
19. Any case not described in the indications.

POTENTIAL ADVERSE EVENTS:

All of the possible adverse events associated with spinal fixation/fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes but is not limited to:
1. Early loosening of any or all components.
2. Improper compression of the configuration causing non-union (or pseudarthrosis), delayed union, mal-union.
3. Disassembly, bending, and/or breakage of any or all the components.
4. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
5. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Burstis. Tissue or nerve damage caused by improper positioning and placement of implant or instruments.
6. Post operative change in spinal curvature, loss of correction, height, and/or reduction.
7. Infection.
8. Dural tears, pseudomeningocele, fistula, pesisten CSF leakage, meningitis.
9. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete in incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual defects.
10. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoidtis, and/or muscle loss.
11. Urinary retention or loss of bladder control or other types of urological system compromise.
12. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
13. Fracture, microfracture, resorption, damage, or penetration of any special spinal bone (including the sacrum, spinous process, and/or vertebral body) and/or bone graft or bone graft harvest site at, above and/or below the level of surgery.
14. Herniated nucleus pulposus, disc disruption or degeneration at, above or below the level of surgery.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stresses shielding.
19. Graft donor site complications including pain, fracture, or would healing problems.
20. Ileus, gastric, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNINGS AND PRECAUTIONS:

WARNINGS
The following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient before surgery.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, fracture of the vertebra, neurological injury, and vascular or visceral injury.

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, 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. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
3. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.
4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be extremely important to the eventual success of the procedure:

a. Previous Spinal Surgery: Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
b. The patient's weight. An overweight or obese patient can produce loads on the device which can lead to failure of the appliance and the operation.
c. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing the patient may not be able to return to these activities successfully.
d. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
e. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
f. Foreign body sensitivity. Where material allergy or sensitivity is suspected, appropriate tests (such as skin sensitivity testing) should be made prior to implant selection or use. The surgeon is advised that no pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
g. Smoking. Smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

5. PREVENT NERVE DAMAGE. Caution should be taken when using instruments to avoid the spinal cord and nerve roots.
6. DELAYED FUSION. If bony fusion does not occur within an expected period of time, the system may become fatigued due to the high and sus¬tained loading of these devices. This has been noted in patients with delayed, pseudarthrosis or non-union and can result in the need to revise the device(s).
7. MAGNETIC RESONANCE (MR). The **InSpan® Spinous Process Plate System** has not been evaluated for safety and compatibility in the MR environment. The **InSpan® Spinous Process Plate System** has not been tested for heating or migration in the MR environment.

PRECAUTIONS

1. The implantation of the **InSpan® Spinous Process Plate System** should be performed only by experienced spinal surgeons with specific training in the use of this spinous process plate system because this is technically demanding procedure presenting a risk of serious injury to the patient.
2. A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.
3. Surgical implants must never be reused. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the **InSpan® Spinous Process Plate System** components should never be reused under any circumstances.
4. Preoperative and operating procedure, including knowledge of surgical techniques and proper selection & placement of the fixation implants are important considerations in the successful utilization of the system by the surgeon.

PHYSICAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

DEVICE FIXATION:
Refer to the **InSpan® Spinous Process Plate System** surgical technique for instructions for implant and instrument use.

PREOPERATIVE:

1. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should understand that implants are not as strong as normal healthy bone and may loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration of the devices and damage to nerves or blood vessels.
2. Only patients that meet the criteria described in the indications should be selected.
3. Patient condition and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
4. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
5. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
6. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the device to verify that all parts and necessary instruments are present before surgery begins. The **InSpan® Spinous Process Plate System** components (described in the DESCRIPTION section) are not be combined with the components from another manufacturer. Different metal types should never be used together due to the possibility that it accelerates corrosion.
7. All components and instruments should be cleaned and sterilized before use. Additionalsterile components should be available in case of an unexpected need.
8. Before use, instruments and implants should be visually inspected and function should be tested to assure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, are cracked or have other irregularities, DO NOT USE!
9. Before use, all instruments are to be checked for debris, or other foreign contaminants. If any instruments or implants are observed to have any foreign debris or other contaminants, the entire convenience kit is to be returned to central processing for cleaning per the listed instructions. DO NOT USE!

INTRAOPERATIVE:

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Be sure to use to properly compress the plates. All configurations allow a maximum final construct width of 10mm (plate surface to plate surface). If the configuration is compressed and the construct's width is over 10mm, the assembly is not connected and is not in its final compressed and implanted stated.
4. Do not over-compress the implants as this may cause fracture/breakage of the spinous process
5. Over decorticating of the spinous process may cause the bone to fracture or non-union of the implant.
6. During dilation of the spinous process ligament be sure not to tear the spinous process ligament.
7. Two **InSpan® Spinous Process Plate Systems** of the same hub diameter and wing length should be used for fixation/attachment to the spinous process.
8. Before closing the soft tissue, all the set screws should be tighten firmly 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. Recheck the tightness of all mating components and set screws after finishing make sure that none loosened during the tightening of the other set screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE:

The physician's postoperative direction and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If the partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgen graphic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures) prophylactic antibiotics may be considered, especially for high-risk patients.
6. **InSpan® Spinous Process Plate System** of implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

CLEANING AND DECONTAMINATION:

All instruments and implants must first be cleaned according to DOC60023 InSpan® Instrumentation Cleaning Instructions prior to sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and disinfecting of instruments can be performed with alkali aldehyde-free solvents at higher temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, certain instruments may require dismantling before cleaning. Refer to SpineFrontier DOC60023 InSpan® Instrumentation Cleaning Instructions for further details. All devices should be positioned to allow sterilant to come into contact with all surfaces.

CARE AND HANDLING:

- Torque wrenches require service every 6 months, 3000 cycles or 200 autoclave cycles
- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Before use instruments should be visually inspected and function should be tested to assure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, are cracked or have other irregularities. Do Not 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	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270° F (132°C)	4 Minutes	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.

PRODUCTS COMPLAINTS:

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or SpineFrontier. Further, if any of the implanted **InSpan® Spinous Process Plate System** component(s) ever "malfunctions", (i.e. does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any SpineFrontier product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

LIMITED WARRANTY AND DISCLAIMER:
SPINEFRONTIER PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT SPINEFRONTIER, FOR CURRENT INFORMATION

FURTHER INFORMATION:
In case of complaint, or for supplementary information, or further directions for use of this system, please see the address on this page.

Customer Service Department
SpineFrontier Inc
500 Cummings Center Suite 3500
Beverly MA 01915 USA
(978)232.3990 ; (866)914.7717

DOC60001 Rev. B

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.

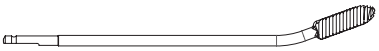
Sterilization

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:

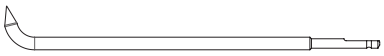
Method	Steam
Cycle	Pre-Vacuum
Temperature	270° F (132°C)
Exposure Time	4 Minutes
Dry Time	20 Minutes

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

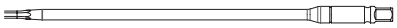
The InSpan® System



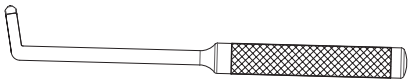
11-60001 Flat Rasp



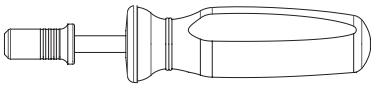
11-60006 Hooked Dilator



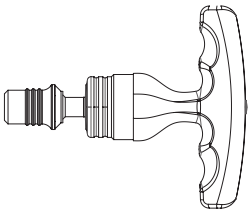
11-60063 Set Screw Driver



11-60044 Round Rasp



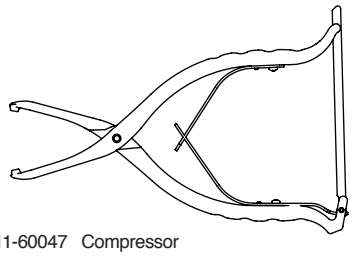
SI00090 AO Handle



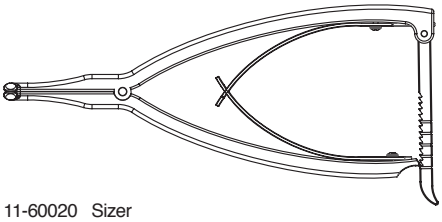
11-60040 Torque Handle

11-60054 Inserter - Right

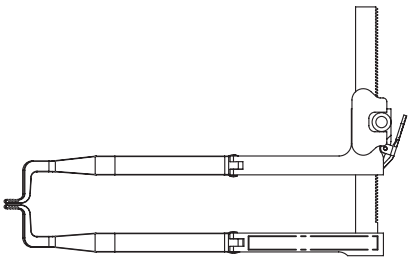
11-60055 Inserter – Left



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



11-60020 Sizer



11-60048 Cephalocaudal Distractor

Notes:

Notes:

spinefrontier®
Less Exposure Surgery Technologies

Inspan®
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Outpatient Technologies for Less Exposure Surgery

LES Less Exposure Surgery
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IS MORE time in action

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DOC60002 Rev K