LESspine
Less Exposure Surgery Technologies

INSPAN® Spinous Process Plate System Instructions for Use

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 20mm in 2mm increments) and five wing length configurations (35mm to 47mm 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 reusable, 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® 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, or 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.

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. Osteoporosis 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).

MRI SAFETY INFORMATION: The InSpan® Spinous Process Plate System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of **InSpan® Spinous Process Plate System** in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

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. Additional-sterile 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:

Instruments are to be disassembled as needed according to CI-60-00001 "Inspan System Assembly/Disassembly Instructions for Cleaning" and cleaned according to CI-99-00001 "LESspine Cleaning Instructions - Instruments" prior to sterilization and introduction into the sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned prior to sterilization and reintroduction into a sterile surgical field.
All devices should be positioned to allow sterilant to come in 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 LESspine. 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 LESspine 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:
LESSPINE 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 LESSPINE, 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.

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