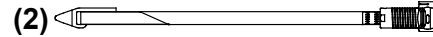


# LIMIFLEX™ DYNAMIC SAGITTAL TETHER

## INSTRUCTIONS FOR USE

REF KLF-3001



Please refer to the Surgical Technique Manual for additional device and procedure information.

### DEVICE DESCRIPTION

**LimiFlex Dynamic Sagittal Tether** – One (1) LimiFlex Dynamic Sagittal Tether consisting of two (2) dynamic titanium spring couplers each with a roller screw and a pre-attached Ultra High Molecular Weight (UHMW) polyethylene textile band. The LimiFlex Dynamic Sagittal Tether is packaged sterile with two (2) Leaders (single-use instruments) designed to facilitate placement of the bands around the spinous processes.

Prescription device: Federal U.S. law restricts this device to sale by, or on the order of, a physician.

### INDICATIONS FOR USE

The LimiFlex Dynamic Sagittal Tether is a motion-preserving spinal implant that is intended to provide dynamic flexion-restricting stabilization of the spine following a lumbar decompression. The LimiFlex Dynamic Sagittal Tether is indicated for use at one level from L3 to L5, in skeletally mature patients following surgical decompression for treatment of lumbar degenerative spondylolisthesis (Grade I per Meyerding classification in a lateral radiograph) with spinal stenosis. Patients consist of those with neurogenic claudication or radiculopathic symptoms, including leg pain, muscle weakness, and/or sensation abnormality, with or without back pain, who have been unresponsive for a minimum of three months of non-operative treatment and have a confirmed diagnosis through patient history and diagnostic studies using X-ray, MRI and/or CT.

### CONTRAINDICATIONS

- Posterior element anatomy inappropriate for interspinous fixation, including
  - Absence or fracture of spinous processes or posterior elements, or deformity that precludes secure device fixation,
  - Facet joint incompetence,
  - Prediction of resection of greater than 50% of spinous processes or facet joints during decompression of the instrumented segment;
  - Spondylolysis or isthmic spondylolisthesis at the instrumented level;
  - The estimated distance between the LimiFlex Dynamic Sagittal Tether strap attachment points (midpoint of the cranial edge of the cranial spinous process and the midpoint of the caudal edge of the caudal spinous process) is less than 30 mm on pre-operative lateral standing radiographs at the segment to be instrumented;
  - Posterior element tumor
  - Severe osteoporosis
- A primary diagnosis of facet-mediated back pain, defined as isolated axial back pain without associated buttock or leg pain, worsened by extension, in the presence of severe facet arthropathy on imaging and absence of radiographic neural compression;
- Symptomatic lumbar stenosis at the instrumented level that is not amenable to a direct surgical decompression;
- Documented allergy to implant materials, including titanium or polyethylene;
- Active systemic or local infection

### WARNINGS

- **It is important to read the Instructions for Use and Surgical Technique Manual prior to use of the LimiFlex Dynamic Sagittal Tether.**
- Do not use this product if you have not been properly trained in its use. Physicians using the LimiFlex Dynamic Sagittal Tether should be thoroughly familiar with the physiology and pathology of the selected anatomy and be trained in the performance of the LimiFlex Dynamic Sagittal Tether and the accompanying surgical technique.
- Do not alter the pre-assembled device, accessory or instruments prior to use of the devices.
- Use the LimiFlex Dynamic Sagittal Tether Instruments and Leaders (accessory) to implant the LimiFlex Dynamic Sagittal Tether.
- Appropriate surgical decompression is critical to the effectiveness of the LimiFlex Dynamic Sagittal Tether procedure. To the extent possible, the surgeon should preserve soft tissue structures during the posterior lumbar decompression stage with use of the LimiFlex Dynamic Sagittal Tether while ensuring thorough neural decompression. Please refer to the Surgical Technique Manual for specific considerations regarding the decompression.

### PRECAUTIONS

- Note that the LimiFlex Dynamic Sagittal Tether is not intended for pediatric use or correction of scoliosis.
- The effectiveness of the subject device has not been compared to decompression alone.
- The use of the subject device at a spinal segment treated with total disc replacement has not been studied.

The safety and effectiveness of the LimiFlex Dynamic Sagittal Tether has not been established in patients with the following conditions:

- More than one spinal level requiring surgical intervention, other than adjacent level decompression.
- More than one surgical procedure at any combination of lumbar levels other than adjacent level decompression.
- Prior surgery at any lumbar vertebral level with instrumentation.
- Prior surgery at the index lumbar vertebral level without instrumentation.
- History of Paget's disease, osteomalacia, or other metabolic bone disease.
- History of an autoimmune disease.
- Psychiatric or cognitive impairment.
- Current or recent history of illicit drug or alcohol abuse, or dependence as defined as the continued use of alcohol despite the development of social, legal, or health problems.

## **INSTRUCTIONS**

### **Preoperative**

- Do not engage the Driver with the LimiFlex Dynamic Sagittal Tether prior to implantation. The device is supplied pre-aligned to facilitate proper band threading.

### **Intraoperative**

- Operating surgeon is encouraged to limit the amount of tissue removal during the stage of posterior lumbar decompression.
  - The interspinous and supraspinous ligaments (ISL/SSL) at the implantation level may be resected and LimiFlex Dynamic Sagittal Tether will still restrict flexion. If possible, leave the ISL/SSL at the adjacent segments intact.
  - Partial, undercutting facetectomy laterally to the medial border of the pedicle may be performed; foraminotomy may be performed as indicated. Ensure that 50% of the articular surface of the facet is preserved.
  - Up to ½ of each spinous process (cranial-caudal, in the plane parallel to the slope of the spinous process) may be resected.
- Do not lock, unlock, or adjust the device unless both springs are properly loaded on the Holders and the Symbol Plate is in place. Use of improper instrumentation may damage the device.
- The LimiFlex Dynamic Sagittal Tether should be implanted only while using radiographic visualization; imaging should be utilized during implantation to ensure titanium springs are appropriately positioned and tensioned.
- Confirm patient positioning prior to tensioning. The patient should be in a neutral or slightly extended position approximating standing posture. Do not tension the device in a flexed or hyperextended position.
- During final locking, band retraction increases device tension. Ensure the spinous processes and surrounding anatomy can tolerate the applied forces.

### **LimiFlex Dynamic Sagittal Tether**

- The LimiFlex Dynamic Sagittal Tether and Leaders are provided sterile. Do not use if package is opened, damaged, or if the "Use By" date noted on the product label has passed.
- The LimiFlex Dynamic Sagittal Tether and/or Leaders are for single use only. Do not reuse, reprocess, refurbish, repair, modify, or re-sterilize any component as these actions may compromise the structural integrity of the device and / or create a risk of contamination of the device, which could result in patient injury, illness or death.
- The device consists of two (2) titanium tension springs with attached UHMW polyethylene textile bands. Both springs with bands must be used to provide adequate immobilization.
- Do not implant the device such that it is in contact with any non-titanium metal implants including stainless steel implants.

**MRI INFORMATION**



**MRI Conditional Device**

A person with an Empirical Spine LimiFlex Dynamic Sagittal Tether device may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Empirical Spine LimiFlex Dynamic Sagittal Tether
Static Magnetic Field Strength (B0)	1.5T and 3.0T
Maximum Spatial Field Gradient	20 T/m (2000 G/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	First level Controlled Operating Mode
Scan Duration	1 hour of continuous scanning in Normal Operating Mode without a cooling period
MR Image Artifact	The presence of LimiFlex Dynamic Sagittal Tether may produce an image artifact of 10mm. Some manipulation of scan parameters may be needed to compensate for the artifact.

Patients who have other MR Conditional Devices can be scanned as long as all the MR Conditional Scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met. If information about a specific parameter is not included, there are no conditions associated with that parameter.

**DIRECTIONS FOR USE**

Refer to the Surgical Technique Manual for specific instructions on surgical use of the LimiFlex Dynamic Sagittal Tether and instruments.

**HOW SUPPLIED**

The LimiFlex Dynamic Sagittal Tether and Leaders are supplied sterile in peel-open packages. In the event of damage to the sterile packaging, do not use, and notify the manufacturer.

**STORAGE**

The LimiFlex Dynamic Sagittal Tether should be stored in its original packaging. Proper care should be taken to ensure that the LimiFlex Dynamic Sagittal Tether will not be damaged. Store in a cool, dry place.

**LIMITATION OF LIABILITY**

EMPIRICAL SPINE WILL NOT BE RESPONSIBLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES RESULTING FROM REUSE OR MODIFICATION OF THE LIMIFLEX DYNAMIC SAGITTAL TETHER, ITS INSTRUMENT SET, OR ACCESSORIES, OR FROM USE OF THE DEVICE FOR PURPOSES OTHER THAN THE INDICATIONS FOR USE AS STATED IN THE LIMIFLEX DYNAMIC SAGITTAL TETHER INSTRUCTIONS FOR USE.

IN NO EVENT SHALL EMPIRICAL BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE LIMIFLEX DYNAMIC SAGITTAL TETHER OR INSTRUMENT SET BASED UPON BREACH OF CONTRACT (INCLUDING BREACH OF WARRANTY).

**REQUESTS FOR INFORMATION**

For further information, please contact Empirical Spine, Inc., PO Box 885, San Carlos, CA 94070, 18655 Madrone Pkwy Suite 180, Morgan Hill, CA 95037, U.S.A. Phone: 650-585-6307.

U.S. Patents: [limiflex.com/patents](http://limiflex.com/patents).  
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**STERILE EO**

Sterilized using ethylene oxide



Do not re-sterilize



Do not re-use



Use-by date (YYYY-MM)

**LOT**

Batch code / Lot number



**Manufacturer:**  
**EMPIRICAL SPINE, INC.**  
PO Box 885  
San Carlos, CA 94070  
18655 Madrone Pkwy Suite 180  
Morgan Hill, CA 95037 USA  
650-585-6307



Do not use if package is damaged



Consult instructions for use



Caution

**REF**

Catalogue number



Keep dry



MR Conditional

## **SUMMARY OF PRIMARY CLINICAL STUDY**

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the LimiFlex Dynamic Sagittal Tether when used to treat at one level from L3-L5 in skeletally mature patients following surgical decompression for treatment of lumbar degenerative spondylolisthesis (Grade I per Meyerding classification in a lateral radiograph) with spinal stenosis in the US under IDE G090131. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

### **A. Study Design**

Subjects were treated between July 2017 to September 2020. The database for this PMA reflected data collected through September 28, 2022, and included a total of 299 subjects enrolled at 28 investigational sites.

The study was a prospective, multi-center, non-randomized, and non-blinded clinical study of the LimiFlex Dynamic Sagittal Tether. The prospective investigational and control arms were concurrently enrolled. The prospective control population was supplemented with retrospective control subjects (RCS). Balance between groups was achieved through subclassification using propensity scores. Subjects were considered enrolled in the study for the purposes of an intention-to-treat (ITT) analysis, only after they were treated (time of incision), with the exception of subjects for which no study device implantation was attempted due to violation of inclusion or exclusion criteria identified intra-operatively that could not reasonably be assessed prior to surgery. Subjects excluded prior to treatment, due to withdrawal of consent, arising medical difficulties (e.g., heart attack), documentation of ineligibility by circumstances unforeseen at the time of Informed Consent, etc. and subject excluded intra-operatively, are considered screening failures. Pre-operative data, including the reason for exclusion, was collected for screening failures. However, pre-operative data for screen failures may not be complete, as the subject may be determined to be a screen failure early in the screening process.

The control group was a combination of prospective and retrospective control subjects. The control group comprised subjects who were treated with a transforaminal lumbar interbody fusion (TLIF) with concomitant posterolateral fusion with pedicle screw instrumentation at a single level following decompression at one or two contiguous levels for treatment of lumbar degenerative spondylolisthesis (Grade I per Meyerding classification in a lateral radiograph) with spinal stenosis. Comparability of prospective and retrospective control subjects was ensured by requiring the same eligibility criteria for all subjects and confirmation of balance through subgroup analyses.

All radiographic endpoints were evaluated independently by a core laboratory (Medical Metrics, Inc.). Quantitative assessments (measurements) of intervertebral motion were produced by core lab trained analysts using specialized motion analysis software incorporating validated computerized techniques (i.e., 510(k) cleared QMA software) to ensure reproducibility.

Study oversight was provided by an independent Medical Monitor (MM), Data Safety and Monitoring Board (DSMB) and Clinical Events Committee (CEC). The MM oversaw the conduct of the clinical study including the safety of the subjects enrolled in the study. The

DSMB met periodically upon completion of each interim safety analysis, or as needed, to review the cumulative results of the study, including incidence of spinous process fracture, and to evaluate any safety or efficacy issues that occurred during the course of the study. The CEC was responsible for the adjudication of any events that may be considered serious and/or device related, including but not limited to all spinous process fractures reported either by the investigational site or noted by the radiographic core laboratory, protocol deviations and any decrease in neurological status at 24 months post-treatment (Month 24) compared to baseline.

### 1 Clinical Inclusion and Exclusion Criteria

Enrollment in the LimiFlex Dynamic Sagittal Tether study was limited to subjects who met the following inclusion criteria in **Table 1**. Subjects were not permitted to enroll in the LimiFlex Dynamic Sagittal Tether study if they met any of the following exclusion criteria in **Table 1**.

**Table 1: Study Inclusion and Exclusion Criteria**

Study Inclusion Criteria	Study Exclusion Criteria
<ul style="list-style-type: none"> <li>• Lumbar degenerative spondylolisthesis (Grade I per Meyerding classification), at one level from L1 to S1, with radiographic confirmation using X-ray;               <ul style="list-style-type: none"> <li>○ Grade I spondylolisthesis per Meyerding classification includes up to 25% anterior translation of a vertebra relative to the superior endplate of the subjacent vertebra at the index level. A patient is considered to have spondylolisthesis with a minimum 10% anterolisthesis at the affected level in a lateral x-ray image.</li> </ul> </li> <li>• Lumbar spinal stenosis requiring decompression at up to two contiguous levels from L1 to S1, inclusive of the level diagnosed with degenerative spondylolisthesis, and confirmed radiographically using CT or MRI;               <ul style="list-style-type: none"> <li>○ At the index level, lumbar spinal stenosis is at least moderate lumbar canal stenosis, defined as more than 25% reduction of the canal cross-sectional area compared with the next adjacent normal level, with nerve root crowding compared with the normal level, as determined by the investigator on CT scan or MRI.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• A primary and predominate diagnosis of discogenic back pain;</li> <li>• A primary and predominate diagnosis of facet-mediated back pain;</li> <li>• Back or non-radicular leg pain of unknown etiology;</li> <li>• Significant peripheral vascular disease-causing vascular claudication;</li> <li>• Significant peripheral neuropathy caused by conditions other than spinal stenosis;</li> <li>• History of fixed or permanent neurologic deficit related to spinal cord injury;</li> <li>• History of any previous surgery* at any level in the lumbosacral spine except for a discectomy or decompression;</li> <li>• History of any previous surgery* at the level(s) planned for treatment;               <ul style="list-style-type: none"> <li>*previous surgery includes spinal stimulator placement but does NOT include epidural injections, rhizotomy or nerve ablation</li> </ul> </li> <li>• Isthmic spondylolisthesis or spondylolysis (pars fracture) at any level in the lumbar spine;</li> <li>• Clinically significant compromise of vertebrae at L1 to S1 levels due to osteoporotic vertebral compression fracture or any traumatic, neoplastic, metabolic or</li> </ul>

Study Inclusion Criteria	Study Exclusion Criteria
<ul style="list-style-type: none"> <li>• Neurogenic claudication or radiculopathy symptoms including leg pain, muscle weakness, and/or sensation abnormality, with or without back pain as evidenced by patient history;</li> <li>• Persistent symptoms despite at least 3 months of conservative treatment that may include but is not limited to physical therapy, medications, and/or epidural injections;</li> <li>• A pre-operative Visual Analog Scale (VAS) leg pain score of <math>\geq 50</math> on a 100 mm scale;               <ul style="list-style-type: none"> <li>*Leg pain includes hip and/or buttock pain on the same side</li> </ul> </li> <li>• A pre-operative Oswestry Disability Index (ODI) score <math>\geq 35</math> points on a 100-point scale;</li> <li>• Candidate for surgical decompression at a single level or two contiguous levels, with stabilization at only one level between L1-S1;</li> <li>• Posterior element anatomy is appropriate for interspinous fixation including prediction of presence of spinous processes of segment to be instrumented following decompression (investigational AND control groups) and a prediction of <math>&gt;50\%</math> of facet joints present following decompression (investigational group only);</li> <li>• <math>\geq 25</math>-80 years of age and skeletally mature;</li> <li>• Patient has the necessary mental capacity to participate and is willing and able to participate in the study for the duration of the study follow-up and is able to comply with study requirements; and</li> <li>• Patient is willing and able to provide Informed Consent for study participation.</li> </ul>	<ul style="list-style-type: none"> <li>infectious pathology or congenital abnormality;</li> <li>• Spinous process fracture(s) or other posterior element fracture(s) of the segment to be instrumented that would preclude secure fixation of the LimiFlex Dynamic Sagittal Tether Device to the spinous process;</li> <li>• Spinous process insufficiency or deformity that would preclude secure fixation of the LimiFlex Dynamic Sagittal Tether Device to the spinous process including spinous process length <math>&lt;10</math> mm from lamina to dorsal tip or other significant deformity due to trauma, or congenital abnormality such as spina bifida occulta at the planned instrumented level that would preclude secure fixation of the LimiFlex Dynamic Sagittal Tether Device to the spinous process;</li> <li>• The estimated distance between the LimiFlex Dynamic Sagittal Tether Device strap attachment points (midpoint of the cranial edge of the cranial spinous process and the midpoint of the caudal edge of the caudal spinous process) is <math>&lt;30</math>mm on pre-operative lateral standing radiographs at the segment to be instrumented;</li> <li>• Degenerative lumbar scoliosis with a Cobb angle <math>&gt;10^\circ</math> at the affected motion segment;</li> <li>• Symptomatic lumbar stenosis that is not amenable to a direct surgical decompression (i.e. patients with stenosis requiring indirect, interbody decompression)</li> <li>• Ankylosed motion segment at the target operative level</li> <li>• Severe osteoporosis, defined as history of fragility fracture and DXA bone mineral density T-score <math>&lt;-2.5</math> or QCT bone mineral density T-score <math>&lt; 80</math>mg/cubic cm. History of a fragility fracture requires that a DXA scan or QCT scan is completed;</li> <li>• Planned hip or knee replacement surgery, severe osteoarthritis or other musculoskeletal pathology of the hip or leg</li> </ul>

Study Inclusion Criteria	Study Exclusion Criteria
	<p>that could preclude reliable patient self-reporting assessment scales and/or that would likely progress to surgery during study period;</p> <ul style="list-style-type: none"> <li>• Documented allergy to titanium or polyethylene;</li> <li>• Active local or systemic infection;</li> <li>• Receiving immunosuppressant or long-term steroid-therapy;</li> <li>• Known history of bone metabolic disorder, including Paget's disease, hyperparathyroidism, renal osteodystrophy, and osteomalacia;</li> <li>• Disease or condition that would preclude accurate clinical evaluation of the safety and effectiveness of the study treatment or any significant medical conditions which would place the patient at excessive risk for surgery, such as; <ul style="list-style-type: none"> <li>○ Severe rheumatoid arthritis or other surgery, such as:</li> <li>○ Active hepatitis (viral or serum) or HIV positive</li> <li>○ Unstable cardiac disease</li> <li>○ Uncontrolled diabetes</li> <li>○ Renal failure</li> <li>○ Severe muscular, neural or vascular diseases that endanger the spinal column</li> <li>○ Cauda equina syndrome</li> <li>○ Severe neurologic disorders including paralysis</li> </ul> </li> <li>• Morbid obesity defined as BMI &gt;40;</li> <li>• Active malignancy or history of metastatic malignancy within the last five years;</li> <li>• Women who are pregnant or are interested in becoming pregnant within the study period;</li> <li>• Currently seeking or receiving worker's compensation for back pain or spinal condition;</li> <li>• Currently involved in spinal litigation that potentially is associated with secondary financial gain;</li> </ul>

Study Inclusion Criteria	Study Exclusion Criteria
	<ul style="list-style-type: none"> <li>• Current involvement in a study of another investigational product for similar purpose;</li> <li>• Demonstrates three or more Waddell’s Signs of Inorganic Behavior;</li> <li>• Active treatment of major psychiatric condition, such as depression, anxiety disorder, bipolar disorder, schizophrenia, personality disorder, that could prevent accurate completion of self-reporting assessment scales;</li> <li>• Current history (withing 12 months) of substance abuse; including alcohol abuse; or</li> <li>• A prisoner.</li> </ul>

## 2 Follow-up Schedule

All subjects were expected to return for follow-up examinations at 6 weeks, and 3, 6, 12, and 24 months post-operatively. Demographics and medical history were collected pre-operatively. Pre-operatively and post-operatively, objective parameters measured during the study included obtaining x-rays, neurological assessments, Oswestry disability Index (ODI), Visual Analog Scale (VAS) scores for leg and back pain, Zurich Claudication Questionnaire (ZCQ), SF-12 Physical Component Score (PCS), SF-12 Mental Component Score (MCS), and medication use for pain, as reported in

**Table 2.** Adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

**Table 2: Follow-Up Schedule**

Event	Screening/ Baseline ≤ 2 months to surgery	Procedure	Post-Procedure @ Discharge	6 Week ± 2 Weeks	3 Month ± 2 Weeks	6 Month ± 1 Month	Both Groups: 12, 24, 36, 48, & 60 Month ± 2 months	Unplanned Visit
CT myelogram or MRI	X <sup>R,1</sup>							
Informed Consent	X <sup>R,2</sup>							
Eligibility Criteria	X <sup>R</sup>							
Pregnancy Test (premenopausal women)	X							
Radiographs  *Note: All radiographs are to be obtained in concordance with Radiographic Evaluation Protocol	X <sup>R, 4</sup>		X <sup>3</sup>	X <sup>5</sup>	X <sup>6</sup>	X <sup>7</sup>	X <sup>4, 7</sup>	As Necessary
Osteoporotic Self- Assessment Tool (OST)	X							
DXA or QCT scan (only required if patient has history of fragility fracture)	X							
Physical/Neuro Exam	X <sup>R</sup>		X	X	X	X	X	X
Physical/Medical Therapy	X		X	X	X	X	X	X
Medication Use for Pain			X	X	X	X	X	X
VAS Pain Scale (leg and back)				X	X	X	X	
Zurich Claudication Questionnaire				X	X	X	X	



Event	Screening/ Baseline ≤ 2 months to surgery	Procedure	Post-Procedure @ Discharge	6 Week ± 2 Weeks	3 Month ± 2 Weeks	6 Month ± 1 Month	Both Groups: 12, 24, 36, 48, & 60 Month ± 2 months	Unplanned Visit
Oswestry Disability Index				X	X	X	X	
SF-12				X	X	X	X	
Intra-operative Data		X		X	X	X	X	
Days to Return to Work				X	X	X	X	
Patient Satisfaction				X	X	X	X	
Adverse Events		X	X	X	X	X	X	X
Device/Procedure Observations		X						

R: Minimum required data for RCS or historical control subject (HCS) eligibility

- 1: MRI or CT Myelogram within 12 months prior to procedure is acceptable if documented that symptoms are stable
- 2: Informed consent requirements for RCS determined by site's governing IRB or ethics committee.
- 3: If patient safety/comfort precludes standing films for patients being discharged same-day, the option is to take radiographs in a supine position or with fluoroscopy at closure.
- 4: AP & lateral, flexion and extension (within 4 months prior to surgery)
- 5: AP & Lateral
- 6: Both Groups: AP + lateral Required for Investigational Group & Optional for Control Group: flexion and extension
- 7: AP & lateral, flexion and extension

### 3 Clinical Endpoints

The safety of the LimiFlex Dynamic Sagittal Tether was assessed by comparison to the control group with respect to nature and frequency of adverse events (overall and in terms of severity and relationship to the implant), subsequent index level surgical procedures, and maintenance of neurological status. The sponsor gathered all AE data and had all safety data adjudicated by an independent CEC.

The effectiveness of the LimiFlex Dynamic Sagittal Tether was assessed by comparison to the control group with respect to a primary endpoint, as described below. Effectiveness was further evaluated by assessing the individual elements of the primary endpoint including improvement in VAS, ZCQ, SF-12, patient satisfaction, and other clinical and life parameters. Similar criteria were used to measure success in both groups.

Study success was based on the hypothesis that treatment with the LimiFlex Dynamic Sagittal Tether is non-inferior to the fusion control in achieving Month 24 composite clinical success (CCS). More specifically, the primary study hypothesis is that the probability of clinical success at Month 24 for subjects implanted with the LimiFlex Dynamic Sagittal Tether following decompression is within a non-inferiority delta of the probability of clinical success at Month 24 for subjects receiving TLIF with concomitant posterolateral instrumented fusion (PLF) following decompression. The null and alternative hypotheses are:

$$H_0: P_{\text{Investigational}} - P_{\text{Fusion}} \leq -0.125$$

$$H_a: P_{\text{Investigational}} - P_{\text{Fusion}} > -0.125$$

With regard to success/failure criteria, each subject was evaluated per the primary composite endpoint as described below.

#### Primary Endpoint

The primary endpoint was a composite endpoint which required a subject meet all the following criteria to be considered a clinical success:

- Improvement of at least 15 points (100-point scale) on ODI at Month 24 compared to baseline
- Absence of a decrease in neurologic status (motor or sensory) at Month 24 compared to baseline, unless attributable to a concurrent medical condition or other cause unrelated to the device and/ or study procedure
- Absence of additional surgical intervention, defined as revision, removal, reoperation or supplemental fixation/fusion\*, in a separate surgery subsequent to the index procedure, at the instrumented level or levels adjacent to the instrumented level, over the initial 24 months post-treatment
- Absence of device integrity failures, defined as device breakage, device separation or disassembly, or device dislocation over the initial 24 months post-treatment

\*The following definitions were used for Additional Surgical Intervention, based upon the FDA Guidance Document for the Preparation of IDEs for Spinal Systems (<https://www.fda.gov/media/71777/download>):

- Revision – procedure that adjusts or in any way modifies or removes part of the original implant system, with or without replacement of a component; or a procedure in which the original implant system is removed followed by replacement of the entire system. A revision may also include adjusting the position of the original implant system.
- Removal – procedure in which all of the original implant system is removed without replacement.
- Reoperation – any surgical procedure at the instrumented level or levels adjacent to the instrumented level that does not remove, modify, or add any implant components to the system.
- Supplemental fixation/fusion – procedure in which additional instrumentation is implanted at the instrumented level or levels adjacent to the instrumented level.

### Secondary Endpoints

Subjects in each treatment arm were evaluated on the following Secondary Endpoints:

- Each of the individual components of the primary endpoint described above
- Estimated blood loss and units of blood transfused
- Length of procedure (skin to skin)
- Hospital stay
- Length of time for a subject to return to their normal activities of daily living
- Work status and days to return to work (as appropriate)
- Medication use for pain, including narcotic, usage
- VAS leg pain
- VAS back pain
- ZCQ
- SF-12 Health Survey to assess quality of life
- Treatment satisfaction
- Radiographic – Radiographic evidence demonstrating the absence of spontaneous fusion in those treated with the investigational device, and radiographic evidence demonstrating fusion in those treated with TLIF with concomitant PLF with pedicle screw instrumentation at Month 24

### Clinical Events Committee and Data and Safety Monitoring Board

A CEC was utilized to mitigate reporting bias of safety-related events. The CEC was comprised of three (3) independent spine surgeons, and a CEC charter was used to define the role of the CEC. The CEC reviewed all Serious Adverse Events (SAEs), all device- or procedure-related AEs, and all spinous process fracture AEs to confirm or re-classify the event term, seriousness, severity, and relationship to study device, procedure or other. For events determined to be SAEs, the CEC reviewed for the potential to re-classify the event as an Unanticipated Adverse Device Effect (UADE) or not an UADE. The CEC reviewed all cases of spinous process fracture to assess severity, causality and clinical significance. The CEC reviewed neurologic data in all cases of decline at Month 24 compared to baseline to determine if it met the primary endpoint failure criteria. Lastly, protocol deviations were reviewed and classified as ‘major’ or ‘minor’ per the definitions in the CEC Charter.

The purpose of the DSMB was to safeguard study participants’ interests and monitor the overall conduct of the clinical trial. The DSMB met periodically upon completion of each interim safety

analysis, or as needed, to review the cumulative results of the study and to evaluate any safety or efficacy issues that may arise during the course of the study. The DSMB reviewed all data used to conduct the Interim Safety Analyses for the LimiFlex Dynamic Sagittal Tether related to spinous process fractures and found that the incidence of spinous process fractures did not reach the modified Stopping Rule safety boundary.

#### B. Accountability of PMA Cohort

At the time of database lock, a total of 299 subjects (140 investigational and 159 control) were enrolled in the IDE study. Nineteen (19) control arm subjects were excluded per FDA request, and the remaining 280 subjects were assessed via the PS subclassification sequential modeling process. One-hundred and forty (140) investigational subjects and one-hundred and twenty-three (123) control subjects were PS-selected, comprising the primary “ITT-PS” analysis set, as described below. Of the 263 subjects in the primary ITT-PS analysis set, 85.9% (226/263) were evaluable for the primary endpoint at Month 24 (89.3% (125/140) investigational; 82.1% (101/123) control). Analysis sets specified in the study protocol were defined as follows:

- (1) **ITT – PS Selected Analysis Set:** The ITT – PS Selected analysis set included all subjects assigned to either the investigational or control groups in which treatment was attempted as defined by the recording of incision time, with the exception of subjects for which no study device implantation was attempted due to violation of inclusion or exclusion criteria identified intra-operatively that could not reasonably be assessed prior to surgery (i.e., intra-operative screening failures). Subjects were classified by the group in which they were assigned, regardless of whether or not that treatment was actually completed. Intra-operative failures were included in primary non-inferiority testing as composite clinical endpoint failures. Analyses of the primary endpoint were conducted using the ITT – PS Selected analysis set. A subject must have been selected into a PS subclass in order to be included in analyses. The PS subclassification procedure was designed to retain all subjects receiving the investigational device, if possible. Since selection into a PS subclass is the observational study equivalent to randomization in a randomized study, control subjects not selected into a PS subclass were not to be included in the ITT – PS analysis set, and not included in the primary effectiveness and safety analyses.
- (2) **Safety Analysis Set:** The Safety analysis set definition included all subjects in the ITT – PS Selected analysis set, and any investigational device subjects who were not selected into a PS subclass. As all investigational subjects were selected into a PS subclass, the Safety analysis set and ITT-PS Selected analysis set represent the same set of subjects. Subjects were classified according to the treatment actually received. Primary safety analyses were conducted using the SA set.
- (3) **Per-Protocol (PP) Analysis Set:** The PP analysis set included subjects in the ITT – PS Selected analysis set with no major protocol violations of inclusion or exclusion criteria, as determined by the CEC and who were evaluable for the Month 24 primary endpoint. It also excluded subjects with confounding medical events or treatments following index surgery that are expected to bias determination of the primary endpoint, as determined by the CEC. Secondary endpoint analyses were conducted using the PP analysis set.
- (4) **Screen Failure Analysis Set:** The Screen Failure analysis set included all subjects consented who did not satisfy or meet inclusion and exclusion criteria, and/ or in whom treatment was not attempted. Please note, these subjects were not followed after surgery and were not

included in the ITT – PS Selected analysis set, with the exception of the RCS screen fail patients who received low-dose BMP (“X Small” kit), but otherwise met all inclusion/exclusion criteria, and were followed after surgery.

Subject accounting is presented in **Table 3** with “I” representing the investigational group, and “C” representing the control group. Accounting information is also presented graphically via a subject accounting tree in **Figure 1** below.

The number of subjects available for certain evaluations in the table below may differ from the actual number of subjects evaluated at Month 24 follow-up. At Month 24, 89.3% (125/140) of investigational subjects and 82.1% (101/123) of control subjects were evaluated with for CCS. Nine (9) subjects had Month 24 assessments prior to the start of their follow-up window. Of these, eight (8) were within 2 months of their visit window, and one was evaluated for the Month 24 visit 203 days prior to their follow-up window.

**Table 3: Accounting and Follow-up Information**

	Pre-Op		Month 12		Month 24	
	I	C	I	C	I	C
[1] Theoretical due (TD)	140	123	140	123	140	123
[2] Not implanted	0	0	2	4	2	4
[3] Cumulative deaths	0	0	0	0	0	1
[4] Cumulative SSIs at index or adjacent level at end of interval	0	0	6	4	10	13
[5] Not Yet Overdue	0	0	0	0	0	0
[6] (Deaths + SSIs) among theoretically due	0	0	6	4	10	13
[7] Expected due for clinic visit = [1] - [2] - [5] - [6]	140	123	132	115	128	106
[7a] Adding subjects with observed clinical data prior to SSI in interval to denominator	140	123	133	115	129	107
[8] SSIs among theoretically due	0	0	6	4	10	13
[9] Expected due + SSI's + Not implanted among TD = [7] + [8] + [2]	140	123	140	123	140	123
<b>All Evaluated Accounting [Actual<sup>B</sup>] Among Expected Due Procedures</b>						
[10] # of procedures with any completed patient reported outcomes	140	123	130	99	125	88
<b>[11] All Evaluated Visit Compliance [%] = [10] / [7a]</b>	<b>100%</b>	<b>100%</b>	<b>97.7%</b>	<b>86.1%</b>	<b>96.9%</b>	<b>82.2%</b>
[12] ODI Responder status (censored for SSI)	140	123	130	99	125	87
[13] Neurological Status [Motor and Sensory]					120	95
[14] Device integrity (censored for SSI)					114	88
<b>[15] Composite clinical success (CCS)</b>					<b>125</b>	<b>101</b>
<b>[16] Actual<sup>B</sup> % Follow-up for CCS [16] = [15] / [9]</b>					<b>89.3%</b>	<b>82.1%</b>
<b>Within Window Accounting [Actual<sup>A</sup>] Among Expected Due</b>						
[17] ODI Responder status determined Clinical visit within window					109	71
[18] Within window compliance [18] =[17]/[7a]					<b>84.5%</b>	<b>66.4%</b>
[19] Neurological Status [Motor and Sensory]					102	73
[20] Device integrity					99	66

	Pre-Op		Month 12		Month 24	
	I	C	I	C	I	C
[21] Composite clinical success (CCS) (Clinical visit within window)					107	83
[22] Actual <sup>A</sup> % Follow-up for CCS [22] = [21] / [9]					76.4%	67.5%

### Notes for Accounting and Follow-up Table

**[1] Theoretically due:** The number of subjects that would have been examined if all patients returned on the exact surgical anniversary within the respective visit window. Visit windows were +/-60 days at month 12 and month 24; +/- 30 days at month 6; and +/- 14 days for month 3 and week 6.

**[2] Not implanted:** Subjects for which surgery began but the intended device was not implanted.

**(3) Cumulative deaths:** Cumulative deaths up to the date of the exact anniversary defining the current interval. Deaths occurring after the exact anniversary are recorded in the next interval. Note: One additional death in a Investigational subject occurred after the exact anniversary of Month 36 and so is not included in this table.

**[4] Cumulative SSIs at index or adjacent level at end of interval:** Additional surgical intervention, defined as revision, removal, reoperation or supplemental fixation/fusion in a separate surgery subsequent to the index procedure at the instrumented level or levels adjacent to the instrumented level. This row includes all subsequent surgical interventions (SSIs) whether theoretically due or not. **Note: The number of cumulative SSI's is up to end of interval to match CCS analysis.** There was one SSI at day 747 in LimiFlex and 2 SSI's at Days 742 and 750 among controls that occurred after Day 730 but prior to end-of-interval, Day 790.

**(5) Not Yet Overdue:** Subjects in this category are those who were a) theoretically due; and b) within the evaluation time window and were not counted as a theoretically due death or revision, but had not yet been evaluated at the time of data lock.

**[6] Deaths + SSIs among theoretical due:** This row records the number of patients experiencing either death or SSI (index or adjacent level) among theoretically up to the date of the exact anniversary defining the current interval.

**[7] Expected due for clinic visit [7] = [1] - [2] - [5] - [6]:** Row [7] computes Expected due based on interval counts. Expected due for clinic visit is equal to Theoretical due (row [1]) minus Not Implanted (row [2]) minus Not yet overdue (row [5]) minus cumulative deaths and SSIs among the theoretically due (row [6]).

**[7a] Adding subjects with observed clinical data prior to SSI in interval to denominator:** There are 5 instances in which ODI was evaluated in the same interval as an SSI, but earlier in the interval. Only patient reported outcomes (PROs) subsequent to SSI are censored. PROs obtained prior to an SSI reflect impact of the index surgery and so are not censored. These values are included in data summary tables. Therefore, in order to include all subjects with potentially observed data in the denominators of visit compliance, row [7a] adds these subjects back to the denominator. The five cases in which row [7] and row [7a] are identified by **bold** font. The following summarizes the five specific cases.

**There are two subjects, one in each group that had Month 24 clinical evaluation of ODI prior to an SSI.** These two subjects are added to row [7] to determine row [7a] since their pre SSI values are available. Thus, the counts in row [7a] are 129 instead of 128 and 107 instead of 106. Investigational 08-006-BHS had ODI recorded on Day 726 and had SSI on Day 747. Control 12-014-JEG had ODI recorded on Day 696 and had SSI on Day 742. There were 3 other such cases prior to Month 24. Investigational 08-030-DEM had a clinic visit before an SSI on Day 418 in the Month 12 interval, Control 12-010-JLB had a clinic visit before an SSI on Day 208 in the Month 6 interval, and Control subject 21-014-MDS had a clinic visit before an SSI on Day 54 in the Week 6 interval. These three subjects are also added to row [7] to determine row [7a] since their pre SSI values are available.

**[8] SSIs among theoretical due:** SSIs among theoretically due are the count of theoretically due SSIs. Note that these SSIs are added back to the expected due count in order for row [9] to serve as the correct denominator for the overall success outcomes calculated in row [15] and row [21].

**[9] Expected due and SSI's among theoretical due [7] + [8] + [2]:** Expected due plus theoretically due SSIs is computed by adding expected due in row [7] to the number of cumulative SSIs among theoretical procedures in row [8] to the number of Not Implanted. This row serves as the denominator for overall success outcomes since overall success status is known to be failure for those with SSI.

**[10] # of procedures with any completed patient reported outcomes:** This row provides the number of subjects among those included in row [7] with any completed patient reported outcome (i.e., ODI, ZCQ, VAS, PCS, MCS) among expected due.

**[11] All Evaluated Visit Compliance [%] [11] = [10] / [7a]:** All Evaluated Visit Compliance (%) is computed as number of subjects with any clinical data in the specified interval row [10] expressed as a percentage of row [7a]. The exception is at baseline, where [11] = [10] / [9] in order to capture visit compliance including non-implanted. All evaluated compliance is based on the presence of any clinical data, even if incomplete, and demonstrates that the procedure was actively followed at least up to the specific interval.

**[12] ODI Responder status determined:** This is the count of subjects with ODI responder status determined among patients in row [7a]. **Note:** clinical scores, including ODI, are censored at the time of SSI. That is, among those with an SSI, ODI scores are not 'expected due' for the purpose of determining ODI follow-up compliance.

**[13] Neurological Status [Motor and Sensory]:** This row is the count of procedures for which the primary neurological endpoint used in CCS is evaluable. Neurological test results are not censored for SSI.

**[14] Device integrity:** This row is the count of procedures with evaluable device condition endpoint used in the CCS. Device integrity is censored for SSI.

**[15] Composite clinical success (CCS):** This row is the count of patients evaluable for the primary endpoint, Month 24 composite clinical success (CCS).

**[16] Actual<sup>B</sup> % Follow-up for CCS [16] = [15] / [9]:** The number of procedures with evaluable overall success is taken from row [15] while the denominator is taken from row [9].

**[17] ODI Responder status determined:** This row is the count of subjects with ODI responder status obtained within the protocol-defined visit window.

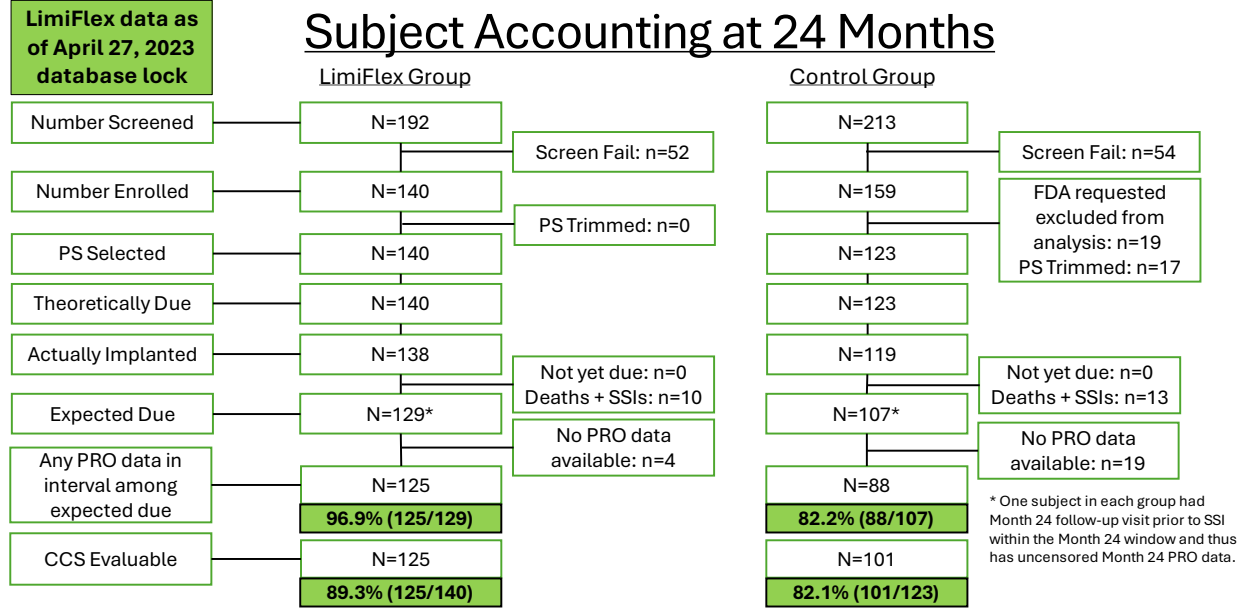
**[18] Within Window Visit ODI Compliance [%] [18] = [17] / [7a]:** Within Window Visit ODI Compliance (%) is computed as number of subjects with the ODI component of the CCS measured within the interval. This row expresses row [18] as a percentage of expected due row [7].

**[19] Neurological status determined:** This row is the count of subjects with Neurological responder status obtained within the visit window.

**[20] Device Integrity status determined:** This row is the count of subjects with radiographic imaging used to determine Device Integrity status obtained within the visit window.

**[21] Composite clinical success (CCS) Within Window:** This row is the count of patients evaluable for the primary endpoint, Month 24 composite clinical success (CCS) within the visit window. Subjects that are CCS successes must have all components within-window. For subjects that are CCS failures, the component(s) defining failure must be within window except for terminal failures (Implanted, SSI, Device Integrity), where a subject failing any of these components prior to the end of the Month 24 window is considered to have CCS within window.

**[22] Actual<sup>A</sup>% Follow-up for CCS [22] = [21] / [9]:** The number of subjects with evaluable overall success is taken from row [21] while the denominator is taken from row [9]. Within window follow-up was significantly impacted by the extenuating circumstances presented by the COVID-19 Public Health Emergency overlapping the Month 24 visits when sites were delaying or cancelling elective surgeries and nonessential research related patient visits to healthcare facilities and limited access to clinical monitors. Of the 263 ITT-PS selected subjects, 94.3% (248/263) were due for their Month 24 visit during the COVID-19 Public Health Emergency.



**Figure 1: Subject Accounting Tree**

### C. Study Population Demographics and Baseline Parameters

The tables below provide a summary of pre-operative and demographic variables for investigational and control subjects in ITT-PS analysis set. **Table 4** presents age, height, weight and BMI, stratified by treatment group and gender, as well as baseline functional scores. The 95% confidence intervals for group differences adjusted for PS subclass demonstrate no statistical evidence of a group difference in any of the demographic or baseline functional status continuous variables. **Table 5** identifies gender, ethnicity and race demographics of investigational and control subjects.

**Table 4: Summary of Baseline and Demographic Continuous Variables ITT-PS Analysis Set**

	Investigational						Controls						Investigational - Controls <sup>1</sup>		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff	LB	UB
<b>Demographics - All</b>															
Age at surgery (yrs)	140	65.8	7.7	66.1	47.4	80.0	123	64.6	8.9	64.8	31.5	80.7	0.61	-2.53	3.75
Height (cm)	140	169.1	10.2	167.6	147.3	198.1	123	165.8	9.7	164.6	133.4	193.0	0.38	-2.62	3.37
Weight (kg)	140	80.7	17.1	77.8	46.3	133.8	123	80.6	17.2	80.3	42.6	133.8	0.75	-5.24	6.74
BMI (k/m <sup>2</sup> )	140	28.1	4.7	27.2	17.4	39.1	123	29.2	5.2	28.9	18.3	42.5	0.15	-1.42	1.73
Osteo Self Assessment Test	140	2.99	3.97	2.56	-6.1	13.6	123	3.21	4.12	3.14	-7.6	17.6	0.03	-1.37	1.43
<b>Demographics - Male</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>Med</b>	<b>Min</b>	<b>Max</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>Med</b>	<b>Min</b>	<b>Max</b>	<b>Diff</b>	<b>LB</b>	<b>UB</b>
Age at surgery (yrs)	59	66.6	7.1	67.9	48.0	80.0	37	66.8	7.7	68.0	48.0	80.1	-2.22	-9.00	4.55
Height (cm)	59	178.2	6.9	180.3	162.6	198.1	37	176.7	7.2	177.3	162.6	193.0	1.09	-1.46	3.65
Weight (kg)	59	89.5	16.5	87.8	56.7	133.8	37	92.9	14.1	90.7	72.6	133.8	-2.75	-8.03	2.53
BMI (k/m <sup>2</sup> )	59	28.0	4.0	27.4	20.2	36.5	37	29.7	3.7	30.4	23.0	37.9	-1.35	-2.74	0.04
Osteo Self Assessment Test	59	4.58	3.80	4.11	-3.7	13.6	37	5.23	3.45	4.49	-0.6	14.7	-0.11	-1.93	1.72
<b>Demographic - Female</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>Med</b>	<b>Min</b>	<b>Max</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>Med</b>	<b>Min</b>	<b>Max</b>	<b>Diff</b>	<b>LB</b>	<b>UB</b>
Age at surgery (yrs)	81	65.2	8.1	65.5	47.4	80.0	86	63.6	9.3	64.5	31.5	80.7	1.46	-1.91	4.82
Height (cm)	81	162.6	6.4	162.6	147.3	175.3	86	161.2	6.2	162.6	133.4	176.5	-0.70	-3.36	1.95
Weight (kg)	81	74.3	14.7	72.1	46.3	109.8	86	75.3	15.6	74.8	42.6	119.5	1.08	-4.87	7.04
BMI (k/m <sup>2</sup> )	81	28.1	5.2	26.2	17.4	39.1	86	29.0	5.8	28.4	18.3	42.5	0.63	-1.21	2.47
Osteo Self Assessment Test	81	1.83	3.69	1.50	-6.1	10.4	86	2.34	4.10	2.15	-7.6	17.6	-0.07	-1.64	1.49
<b>Baseline Functional Status</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>Med</b>	<b>Min</b>	<b>Max</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>Med</b>	<b>Min</b>	<b>Max</b>	<b>Diff</b>	<b>LB</b>	<b>UB</b>
Oswestry Disability Index (ODI)	140	52.6	11.9	51.5	22.0	84.0	123	51.6	13.5	47.0	32.0	92.0	1.14	-3.11	5.39
VAS Back Pain	140	67.4	23.9	73.5	0.0	99.0	122	68.3	23.0	73.0	0.0	100.0	-1.46	-8.39	5.47
VAS Worse Leg Pain	140	78.8	13.2	81.0	22.0	100.0	111	78.7	15.9	80.0	31.0	100.0	-2.32	-6.51	1.88
VAS Left Leg Pain	140	61.7	28.6	71.5	0.0	97.0	109	57.1	31.1	62.0	0.0	100.0	3.19	-6.48	12.85
VAS Right Leg Pain	140	65.7	27.2	75.0	0.0	100.0	110	59.1	32.3	66.5	0.0	100.0	5.43	-5.32	16.17
ZCQ Severity Score	139	3.54	0.53	3.57	2.00	4.86	94	3.47	0.58	3.43	2.14	5.00	0.05	-0.17	0.27
ZCQ Physical Score	139	2.75	0.44	2.80	1.40	3.60	94	2.78	0.50	2.80	1.00	4.00	-0.10	-0.24	0.03
<b>Notes:</b>															
<sup>1</sup> ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.															

**Table 5: Summary of Baseline and Demographic Categorical Variables PS Selected Analysis Set**

	Investigational			Controls			Investigational - Controls <sup>1</sup>		
	N	n	% (n/N)	N	n	% (n/N)	Diff (%)	LB	UB
<b>Males</b>	140	59	42.1%	123	37	30.1%	5.3%	-9.9%	20.6%
<b>Females</b>	140	81	57.9%	123	86	69.9%			
<b>Ethnicity</b>	N	n	%	N	n	%	Diff (%)	LB	UB
Hispanic or Latino	140	13	9.3%	123	10	8.1%	4.1%	-1.8%	10.1%
Not Hispanic or Latino	140	127	90.7%	123	113	91.9%			
<b>Race</b>	N	n	%	N	n	%	Diff (%)	LB	UB
White	140	121	86.4%	123	113	91.9%	-3.8%	-14.7%	7.1%
Asian	140	10	7.1%	123	4	3.3%			
Black	140	2	1.4%	123	6	4.9%			
Other	140	7	5.0%	123	0	0.0%			
<b>Notes:</b>									
<sup>1</sup> ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.									

Index level of surgery was also recorded in this clinical trial. In the investigational group, surgery occurred at: L2-L3 – 0.7% (1/140); L3-L4 – 14.3% (20/140); and L4-L5 – 85% (119/140). In the control group, surgery occurred at: L2-L3 – 1.6% (2/123); L3-L4 – 6.5% (8/123); L4-L5 – 87% (107/123); and L5-S1 – 4.9% (6/123). A total of 20.0% (28/140) of the investigational cohort and 19.5% (24/123) of the control cohort underwent adjacent level decompression. In this clinical trial, only 2 control subjects required a transfusion during their surgery.

Additionally, baseline history of spinal diagnoses was collected. All investigational and control subjects were diagnosed with degenerative spondylolisthesis. In the investigational group, 54.3% (76/140) of subjects were also diagnosed with degenerative disc disease, and 2.9% (4/140) were identified as having a vertebral compression fracture. In the control group, 64.2% (79/123) of subjects were also diagnosed with degenerative disc disease, and 0.8% (1/123) were identified as having a vertebral compression fracture. A total of 9.3% (13/140) of investigational subjects and 15.4% (19/123) of control subjects had other diagnoses, including but not limited to spinal stenosis, radiculopathy, annular tears, and disc herniation.

Details on lumbar spinal stenosis type and severity are shared in **Table 6** below. The severity of stenosis was predominantly recorded as moderate in both investigational and control subjects. Over half of subjects in both groups were reported to have foraminal stenosis.

**Table 6: Lumbar Spinal Stenosis Type and Severity**

	Investigational (N=140)			Controls (N=123)		
<b>Lumbar Spinal Stenosis Characterization</b>						
<b>Central Canal Stenosis Severity</b>	<b>N</b>	<b>n</b>	<b>% (n/N)</b>	<b>N</b>	<b>n</b>	<b>% (n/N)</b>
Mild	140	0	0.0	122	1	0.8
Moderate	140	87	62.1	122	72	59.0
Severe	140	53	37.9	122	47	38.5
None	140	0	0.0	122	2	1.6
N/A <sup>1</sup>					1	
<b>Right Lateral Recess Stenosis Severity</b>	<b>N</b>	<b>n</b>	<b>%</b>	<b>N</b>	<b>n</b>	<b>%</b>
Mild	140	4	2.9	122	8	6.6
Moderate	140	74	52.9	122	43	35.2
Severe	140	41	29.3	122	45	36.9
None	140	21	15.0	122	26	21.3
N/A					1	
<b>Left Lateral Recess Stenosis Severity</b>	<b>N</b>	<b>n</b>	<b>%</b>	<b>N</b>	<b>n</b>	<b>%</b>
Mild	140	11	7.9	122	7	5.7
Moderate	140	69	49.3	122	44	36.1
Severe	140	41	29.3	122	45	36.9
None	140	19	13.6	122	26	21.3
N/A					1	
<b>Right Foraminal Stenosis</b>	<b>N</b>	<b>n</b>	<b>%</b>	<b>N</b>	<b>n</b>	<b>%</b>
Yes	140	82	58.6	122	94	77.0
No	140	58	41.4	122	28	23.0
N/A					1	
<b>Left Foraminal Stenosis</b>	<b>N</b>	<b>n</b>	<b>%</b>	<b>N</b>	<b>n</b>	<b>%</b>
Yes	140	82	58.6	122	90	73.8
No	140	58	41.4	122	32	26.2
N/A					1	
<b>Notes:</b>						
1 N/A = Not currently available						

Lastly, data on disc herniation morphology and location were collected. In the investigational group, 14.3% (19/133) of subjects were reported to have a disc protrusion, and 39.1% (52/133) were reported to have a disc extrusion. In the control group, 4.5% (5/111) of subjects were reported to have a disc protrusion, and 29.7% (33/111) were reported to have a disc extrusion. The location of disc herniation is reported in medial and lateral locations across both treatment groups.

The demographics of the study population are typical for a lumbar spine study performed in the US. A comparison of the treatment and control cohorts revealed no evidence of group differences in key demographic variables. This is expected, as the groups were PS matched to ensure balance across baseline covariates. The PS designed sample showed adequate covariate balance between the Investigational and Control treatment groups.

## **D. Safety and Effectiveness Results**

### **1. Safety Results**

The analysis of safety was based on the investigational cohort of 140 LimiFlex Dynamic Sagittal Tether subjects and 123 PS-selected control subjects available through the Month 24 evaluation. AEs were reportable at any post-operative time as reported or during a scheduled study visit. The key safety outcomes for this study are presented below in **Table 7** through **Table 13**. Adverse effects are reported in **Table 8** through **Table 12**.

Adverse event definitions:

The following safety event definitions were used in this clinical trial:

- Adverse Event (AE) – an untoward medical occurrence in a subject that may or may not be considered device related. All AEs, regardless of relationship to the device, were recorded, as applicable, on the case report forms (CRF) provided. AEs that occurred during this study were treated by established standards of care which will protect the life and safety of the subjects.
- Serious Adverse Events (SAEs) – An AE was considered an SAE if it resulted in death or led to a serious deterioration in the health of the subject that:
  - resulted in a life-threatening illness or injury;
  - resulted in a permanent impairment of a body structure or a body function;
  - required in-patient hospitalization or prolongation of existing hospitalization;
  - resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function.
- Unanticipated Adverse Device Effect (UADE) – an UADE was defined as any serious adverse effect on health or safety, or any life-threatening problem or death, caused by, or associated with, a device, if that effect, problem, or death were not previously identified in nature, severity, or degree of incidence in the investigational plan, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
- AE Device- and Procedure-Relatedness:
  - Definite – The AE is clearly related to the investigational or control device or procedure;
  - Probable – The AE is likely related to the investigational or control device or procedure;
  - Possible – The AE may be related to the investigational or control device or procedure;
  - Not Related – The AE is clearly not related to the investigational or control device or procedure;
  - Unknown – Unable to determine the relationship based on all available information.
- AE Severity – The intensity of AEs was evaluated using the following criteria:
  - Mild – noticeable to the patient but does not interfere with routine activity;
  - Moderate – interferes with the patient’s routine activity but responds to symptomatic therapy or rest;

- Severe – significantly limits the patient's ability to perform routine activities despite symptomatic therapy.

Role of the CEC

The CEC reviewed safety events, including AEs and secondary surgical interventions (SSIs), to allow for uniform resolution of study-related events and evaluations, and to eliminate any site-by-site variations in reporting. The classification of the CEC overrides that of the investigator. CEC adjudications have been applied to data in the following tables.

Adverse Event Summary

**Table 7** summarizes all AEs and rates for the ITT-PS Selected analysis set across both the investigational and control groups at the date of database lock. Overall, similar rates of AEs occurred in the investigational group (86.4% - 121/140) and control group (84.6% - 104/123). SAEs were numerically higher in the investigational group (34.3% - 48/140) as compared to the control group (31.7% - 39/123). The core lab reported 24 spinous process fractures in the investigational group. Lastly, SSIs were numerically lower in the investigational group (7.2% - 10/140) as compared to the control group (10.9% - 13/123).

**Table 7: Adverse Event Summary (ITT-PS Selected analysis set)**

	Investigational			Controls			Investigational - Control <sup>1</sup>		
	(N=140)			(N=123)					
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
<b>Adverse Events</b>									
All	465	121	86.4	436	104	84.6	1.9	-6.7	10.4
Device Related	50	43	30.7	40	32	26.0	4.7	-6.2	15.6
Procedure Related	82	61	43.6	109	63	51.2	-7.6	-19.7	4.4
<b>Serious Adverse Events</b>									
All	60	48	34.3	64	39	31.7	2.6	-8.8	14.0
Device Related	16	16	11.4	16	16	13.0	-1.6	-9.5	6.4
Procedure Related	28	26	18.6	30	23	18.7	-0.1	-9.6	9.3
<b>Spinous Process Fracture</b>		24	17.1	-	-	-	-	-	-
<b>Secondary Surgical Intervention<sup>2</sup></b>		10	7.2		13	10.9	-3.7	-10.8	3.4
<b>Death</b>		0	0.0		1	0.8	-	-	-
<b>Notes:</b>									
<sup>1</sup> 95% binomial confidence interval without PS adjustment.									
<sup>2</sup> Includes secondary surgical interventions occurring on or before 790 days post index surgery. The denominators for the SSI row excludes 2 Investigational not-implanted and 4 Controls not-implanted.									

All Adverse Events

**Table 8** and **Table 9** identifies all AEs reported as of the database lock by AE term, with the number of subjects experiencing the events. Percentages are calculated as the number of subjects experiencing an event divided by the number of subjects treated in the ITT-PS Selected analysis set. The investigational group presented with 465 events occurring in 86.4% (121/140) of subjects, compared to 436 events occurring in 84.6% (104/123) of control subjects.

The most common AEs by rate reported in the investigational group were: new/increased back pain (24.3% – 34/140); new/increased leg pain (21.4% - 30/140); and, other disorders of the musculoskeletal system (21.4% - 30/140). In the control group, the most common AEs by rate were: new/increased back pain (22.0% - 27/123); and, new/increased musculoskeletal pain, other (26.0% - 32/123).

Please note that the following safety tables may include AE codes ‘Spinous process fracture affecting device fixation’ and/or ‘Spinous process fracture, specify displaced or non-displaced.’ These AE codes include spinous process fractures reported by the clinical site only.

**Table 8: All Adverse Events (ITT-PS Selected analysis set)**

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
New/increase back pain	41	34	24.3	29	27	22.0	2.3	-7.9	12.5
New/increased leg pain	37	30	21.4	13	12	9.8	11.7	3.1	20.3
Other disorder of musculoskeletal system	36	30	21.4	23	18	14.6	6.8	-2.4	16.0
Radiculopathy	29	27	19.3	25	23	18.7	0.6	-8.9	10.1
New/increased musculoskeletal pain, other	37	26	18.6	46	32	26.0	-7.4	-17.5	2.6
Other	25	21	15.0	26	19	15.4	-0.4	-9.2	8.3
Numbness/tingling	17	16	11.4	21	16	13.0	-1.6	-9.5	6.4
Osteoarthritis, Hip	11	11	7.9	7	6	4.9	3.0	-2.9	8.8
Fracture	11	10	7.1	2	2	1.6	5.5	0.7	10.3
Bursitis	8	8	5.7	6	5	4.1	1.6	-3.5	6.8
Osteoarthritis, Knee	10	7	5.0	6	6	4.9	0.1	-5.1	5.4
Worsening gait/balance	7	7	5.0	4	4	3.3	1.7	-3.0	6.5
Other nervous system disorder	9	7	5.0	11	11	8.9	-3.9	-10.1	2.3
Other disorder of digestive system	8	7	5.0	10	9	7.3	-2.3	-8.2	3.5
Sensory deficit	11	7	5.0	3	3	2.4	2.6	-2.0	7.1
Leg weakness or numbness	7	6	4.3	12	10	8.1	-3.8	-9.7	2.0
Wound complications dehiscence, bruising-and soft tissue damage	6	6	4.3	4	4	3.3	1.0	-3.6	5.6
Dural tear	6	6	4.3	10	10	8.1	-3.8	-9.7	2.0
Other respiratory disorder; specify	6	6	4.3	11	7	5.7	-1.4	-6.7	3.9
Other cardiac disorder	6	6	4.3	11	11	8.9	-4.7	-10.7	1.4
Urinary Tract Infection	6	6	4.3	3	3	2.4	1.8	-2.5	6.2

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
Spinal stenosis lumbar-requiring additional decompression	4	4	2.9	1	1	0.8	2.0	-1.1	5.2
Medication Reaction	4	4	2.9	3	3	2.4	0.4	-3.5	4.3
Other endocrine or metabolic disorder	4	4	2.9	2	2	1.6	1.2	-2.3	4.8
Spinous process fracture affecting device fixation	4	4	2.9	0	0	0.0	2.9	0.1	5.6
Urinary retention	4	4	2.9	4	4	3.3	-0.4	-4.6	3.8
Other genitourinary disorder	4	4	2.9	3	3	2.4	0.4	-3.5	4.3
Motor deficit	7	4	2.9	13	10	8.1	-5.3	-10.8	0.3
Trauma	4	4	2.9	3	3	2.4	0.4	-3.5	4.3
Nerve injury, paralysis or weakness	3	3	2.1	2	2	1.6	0.5	-2.8	3.8
Spinous process fracture, specify displaced or non-displaced	3	3	2.1	0	0	0.0	2.1	-0.3	4.5
Headache	3	3	2.1	3	3	2.4	-0.3	-3.9	3.3
Other disorders of fluid, electrolyte or acid-base balance	3	3	2.1	0	0	0.0	2.1	-0.3	4.5
Other disorder of skin/subcutaneous tissue	5	3	2.1	5	5	4.1	-1.9	-6.2	2.3
Other renal disorder	3	3	2.1	1	1	0.8	1.3	-1.5	4.2
Mood affective-disorders (e.g. depression)	3	3	2.1	3	3	2.4	-0.3	-3.9	3.3
Cancer	3	3	2.1	1	1	0.8	1.3	-1.5	4.2
Mechanical failure of device (breakage, separation, disassembly)	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Osteoarthritis, other	2	2	1.4	2	2	1.6	-0.2	-3.2	2.8
Disc herniation System	2	2	1.4	2	2	1.6	-0.2	-3.2	2.8
Other lymphovascular disorder	2	2	1.4	3	3	2.4	-1.0	-4.4	2.4
Disorders of ear	2	2	1.4	3	3	2.4	-1.0	-4.4	2.4
Disorders of nose	2	2	1.4	3	3	2.4	-1.0	-4.4	2.4
Disorders of throat	2	2	1.4	1	1	0.8	0.6	-1.9	3.1
Disorder of esophagus, stomach or duodenum	2	2	1.4	1	1	0.8	0.6	-1.9	3.1

**Notes:**  
<sup>1</sup> 95% binomial confidence interval without PS adjustment.

**Table 9: All Adverse Events (ITT-PS Selected analysis set) - continued**

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
Disorder of intestines; specify	2	2	1.4	1	1	0.8	0.6	-1.9	3.1
Device; other, specify	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Sprain; specify site	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Rash vascular	2	2	1.4	2	2	1.6	-0.2	-3.2	2.8
Hematuria	2	2	1.4	1	1	0.8	0.6	-1.9	3.1
Other mental or behavioral disorder; specify	3	2	1.4	4	4	3.3	-1.8	-5.5	1.9
Reflex deficit, specify	3	2	1.4	0	0	0.0	1.4	-0.5	3.4
Lower extremity swelling	2	2	1.4	2	2	1.6	-0.2	-3.2	2.8
Thoracic Stenosis	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Cervical Stenosis	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Pneumonia	1	1	0.7	4	4	3.3	-2.5	-6.0	0.9
Pulmonary Embolism	1	1	0.7	3	3	2.4	-1.7	-4.8	1.3
Hypertension	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Cardiogenic shock	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Dysesthesia	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Loss of bowel/bladder function	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
CSF leak	1	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Sexual dysfunction	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Deep Vein Thrombosis	1	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Bone erosion	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Fever	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Septicemia	1	1	0.7	1	1	0.8	0	-2.2	2.0
Ileus or intestinal obstruction	1	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Allergic Reaction	1	1	0.7	3	3	2.4	-1.7	-4.8	1.3
Dyspnea	1	1	0.7	3	3	2.4	-1.7	-4.8	1.3
Bleeding	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Hematoma	1	1	0.7	3	1	0.8	-0.1	-2.2	2.0
Other access site complications; specify includes pain	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Diabetes mellitus	1	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Thyroid disorder; specify includes hypo- and hyperthyroidism	1	1	0.7	4	4	3.3	-2.5	-6.0	0.9
Disorders of other endocrine glands	1	1	0.7	0	0	0.0	0.7	-0.7	2.1

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
Visual disturbances; specify includes glaucoma, cataract	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Other disorder of eye; specify includes corneal irritation, pain	2	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Compression fracture; specify site	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Coccydynia	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Infection other than surgical wound infection, includes pain	1	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Renal failure	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Anxiety disorders	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Adjacent Segment Disease	1	1	0.7	10	10	8.1	-7.4	-12.4	-2.4
Hypotension	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Arrhythmia	0	0	0.0	5	5	4.1	-4.1	-7.6	-0.6
Congestive Heart Failure	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Implant material reaction	0	0	0.0	2	2	1.6	-1.6	-3.9	0.6
Anemia	0	0	0.0	9	8	6.5	-6.5	-10.9	-2.1
Angina	0	0	0.0	2	2	1.6	-1.6	-3.9	0.6
TIA	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Disorder of gallbladder, biliary tract, or pancreas; specify	0	0	0.0	2	1	0.8	-0.8	-2.4	0.8
Disorder of liver; specify	0	0	0.0	2	2	1.6	-1.6	-3.9	0.6
Infection	0	0	0.0	2	1	0.8	-0.8	-2.4	0.8
Pseudarthrosis	0	0	0.0	3	3	2.4	-2.4	-5.2	0.3
<b>Total counts / subjects with at least 1 AE</b>	<b>465</b>	121		<b>436</b>	104				
<b>Notes:</b> <sup>1</sup> 95% binomial confidence interval without PS adjustment.									

### Device-Related Adverse Events

**Table 10** identifies all device-related AEs in the ITT-PS Selected analysis set. Overall, 30.7% (43/140) of investigational subjects were reported to have experienced a device-related AE, as compared to 26.0% (32/123) of control subjects that were reported to have experienced a device-related AE.

The most common device-related AEs by rate reported in the investigational group were: radiculopathy (12.1% – 17/140); and, new/increased back pain (5.0% - 7/140). Similarly, in the

control group, the most common device-related AEs by rate were: radiculopathy (7.3% – 9/123); and, new/increased back pain (5.7% - 7/123).

**Table 10: Device-Related Adverse Events (ITT-PS Selected analysis set)**

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
Radiculopathy	18	17	12.1	10	9	7.3	4.8	-2.3	11.9
New/increase back pain	7	7	5.0	7	7	5.7	-0.7	-6.1	4.8
Spinal stenosis lumbar-requiring additional decompression	4	4	2.9	0	0	0.0	2.9	0.1	5.6
New/increased leg pain	4	4	2.9	1	1	0.8	2.0	-1.1	5.2
Spinous process fracture affecting device fixation	4	4	2.9	0	0	0.0	2.9	0.1	5.6
Wound complications dehiscence, bruising-and soft tissue damage	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Mechanical failure of device (breakage, separation, disassembly)	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Spinous process fracture, specify displaced or non-displaced	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Device; other, specify	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Surgical wound infection	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Bleeding	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Motor deficit, specify	2	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Adjacent Segment Disease	1	1	0.7	7	7	5.7	-5.0	-9.3	-0.7
CSF leak	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Hematoma	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Osteoarthritis, Hip	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Dural tear	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Numbness/tingling; specify location	0	0	0.0	3	3	2.4	-2.4	-5.2	0.3
Fracture; specify site	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Sensory deficit, specify	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Pseudarthrosis	0	0	0.0	3	3	2.4	-2.4	-5.2	0.3
<b>Total counts</b> / subjects with at least 1 AE	<b>50</b>	43		<b>40</b>	32				

**Notes:**  
<sup>1</sup> 95% binomial confidence interval without PS adjustment.

Procedure-Related Adverse Events

**Table 11** reports all procedure-related AEs in the ITT-PS Selected analysis set. Overall, 43.6% (61/140) of investigational subjects were reported to have experienced a procedure-related AE, as compared to 51.2% (63/123) of control subjects that were reported to have experienced a procedure-related AE.

The most common procedure-related AEs by rate reported in the investigational group were: radiculopathy (14.3% – 20/140); and, new/increased back pain (5.7% - 8/140). Similarly, in the control group, the most common procedure-related AEs by rate were: radiculopathy (15.4% – 19/123); and, new/increased back pain (8.9% - 11/123).

**Table 11: Procedure-Related Adverse Events (ITT-PS Selected analysis set)**

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
Radiculopathy	21	20	14.3	21	19	15.4	-1.2	-9.8	7.5
New/increase back pain	8	8	5.7	11	11	8.9	-3.2	-9.6	3.1
Wound complications dehiscence, bruising- and soft tissue damage	6	6	4.3	2	2	1.6	2.7	-1.4	6.7
Dural tear	6	6	4.3	9	9	7.3	-3.0	-8.7	2.7
Spinal stenosis lumbar-requiring additional decompression	4	4	2.9	1	1	0.8	2.0	-1.1	5.2
New/increased leg pain	4	4	2.9	2	2	1.6	1.2	-2.3	4.8
Spinous process fracture affecting device fixation	4	4	2.9	0	0	0.0	2.9	0.1	5.6
Spinous process fracture, specify displaced or non-displaced	3	3	2.1	0	0	0.0	2.1	-0.3	4.5
Urinary retention	3	3	2.1	2	2	1.6	0.5	-2.8	3.8
Mechanical failure of device (breakage, separation, disassembly)	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
New/increased musculoskeletal pain, other specify location	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Lower extremity swelling	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Pulmonary Embolism	1	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Cardiogenic shock	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Leg weakness or numbness	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Loss of bowel/bladder function	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
CSF leak	1	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Surgical wound infection	1	1	0.7	2	2	1.6	-0.9	-3.5	1.7
Other respiratory disorder; specify	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Encephalopathy, acute	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Worsening gait/balance	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Numbness/tingling; specify location	1	1	0.7	4	4	3.3	-2.5	-6.0	0.9
Bleeding	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Renal failure	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Hematuria	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Urinary Tract Infection	1	1	0.7	1	1	0.8	-0.1	-2.2	2.0
Motor deficit, specify	2	1	0.7	7	5	4.1	-3.4	-7.1	0.4
Adjacent Segment Disease	1	1	0.7	10	10	8.1	-7.4	-12.4	-2.4
Pneumonia	0	0	0.0	2	2	1.6	-1.6	-3.9	0.6
Hypotension	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
Hematoma	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Arrhythmia	0	0	0.0	3	3	2.4	-2.4	-5.2	0.3
Nerve injury, paralysis or weakness	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Deep Vein Thrombosis	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Osteoarthritis, Hip	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Fever	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Ileus or intestinal obstruction	0	0	0.0	2	2	1.6	-1.6	-3.9	0.6
Anemia	0	0	0.0	6	5	4.1	-4.1	-7.6	-0.6
Other lymphovascular disorder; specify	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Other access site complications; specify includes pain	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Fracture; specify site	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Infection other than surgical wound infection, includes pain	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Rash vascular	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Other disorder of skin/subcutaneous tissue; specify	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Mood affective-disorders (e.g. depression)	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Sensory deficit, specify	0	0	0.0	1	1	0.8	-0.8	-2.4	0.8
Pseudarthrosis	0	0	0.0	3	3	2.4	-2.4	-5.2	0.3
<b>Total counts</b> / subjects with at least 1 AE	<b>82</b>	<b>61</b>		<b>109</b>	<b>63</b>				
<b>Notes:</b> <sup>1</sup> 95% binomial confidence interval without PS adjustment.									

### Serious Adverse Events

**Table 12** identifies all events determined to be SAEs in the ITT-PS Selected analysis set. Overall, 34.3% (48/140) of investigational subjects were reported to have experienced an SAE, as compared to 31.7% (39/123) of control subjects that were reported to have experienced an SAE.

The most common SAE by rate reported in the investigational group was radiculopathy (9.3% - 13/140), while in the control group, adjacent segment disease (4.9% - 6/123) was the most common SAE by rate.

**Table 12: Serious Adverse Event (ITT-PS Selected analysis set)**

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
Radiculopathy	13	13	9.3	4	4	3.3	6.6	1.1	12.1
Osteoarthritis, Knee	6	4	2.9	3	3	2.4	0.8	-2.7	4.4

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
Spinal stenosis lumbar-requiring additional decompression	3	3	2.1	1	1	0.8	1.5	-1.3	4.2
Urinary Tract Infection	3	3	2.1	0	0	0.0	2.1	-0.3	4.5
Trauma	3	3	2.1	3	3	2.4	0.1	-3.2	3.4
Osteoarthritis, Hip	2	2	1.4	6	5	4.1	-1.9	-5.5	1.6
Other nervous system disorder; specify	2	2	1.4	2	2	1.6	0.1	-2.6	2.8
Cancer	2	2	1.4	1	1	0.8	0.8	-1.6	3.1
Thoracic Stenosis	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Cervical Stenosis	2	2	1.4	0	0	0.0	1.4	-0.5	3.4
Pulmonary Embolism	1	1	0.7	3	3	2.4	-1.3	-4.0	1.4
Cardiogenic shock	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Leg weakness or numbness	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Hematoma	1	1	0.7	1	1	0.8	0.0	-1.9	2.0
CSF leak	1	1	0.7	2	2	1.6	-0.6	-3.0	1.7
Surgical wound infection	1	1	0.7	1	1	0.8	0.0	-1.9	2.0
Osteoarthritis, other specify location	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Dural tear	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
New/increased leg pain	1	1	0.7	2	2	1.6	-0.6	-3.0	1.7
Ileus or intestinal obstruction	1	1	0.7	1	1	0.8	0.0	-1.9	2.0
Other cardiac disorder; specify	1	1	0.7	5	5	4.1	-2.7	-5.9	0.6
Encephalopathy, acute	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Disorder of esophagus, stomach or duodenum; specify	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Disorder of intestines; specify	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Other disorder of digestive system; specify includes pain	1	1	0.7	1	1	0.8	0.0	-1.9	2.0
Spinous process fracture affecting device fixation	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
New/increased musculoskeletal pain, other specify location	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Renal failure	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Other renal disorder; specify	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Hematuria	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Urinary retention	1	1	0.7	0	0	0.0	0.7	-0.7	2.1
Adjacent Segment Disease	1	1	0.7	6	6	4.9	-3.3	-6.8	0.1
Pneumonia	0	0	0.0	3	3	2.4	-2.0	-4.3	0.2
Hypertension	0	0	0.0	1	1	0.8	-0.7	-2.0	0.6
Arrhythmia	0	0	0.0	3	3	2.4	-2.0	-4.3	0.2
Nerve injury, paralysis or weakness	0	0	0.0	1	1	0.8	-0.7	-2.0	0.6
Deep Vein Thrombosis	0	0	0.0	1	1	0.8	-0.7	-2.0	0.6
Fever	0	0	0.0	1	1	0.8	-0.7	-2.0	0.6
Anemia	0	0	0.0	2	2	1.6	-1.4	-3.2	0.5

Specific Adverse Event	Investigational (I) (N=140)			Controls (C) (N=123)			I vs C <sup>1</sup>		
	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	No. of Events	No. of Pts. (n)	% of Pts. (n/N)	Diff	LB	UB
Angina	0	0	0.0	2	2	1.6	-1.4	-3.2	0.5
TIA	0	0	0.0	1	1	0.8	-0.7	-2.0	0.6
Disorders of nose; specify includes pain	0	0	0.0	1	1	0.8	-0.7	-2.0	0.6
Disorder of gallbladder, biliary tract, or pancreas; specify	0	0	0.0	1	1	0.8	-0.7	-2.0	0.6
Fracture; specify site	0	0	0.0	1	1	0.8	-0.7	-2.0	0.6
Pseudarthrosis	0	0	0.0	3	3	2.4	-2.0	-4.3	0.2
Other	0	0	0.0	1	1	0.8	-0.7	-2.0	0.6
<b>Total counts / subjects with at least 1 AE</b>	<b>60</b>	<b>48</b>		<b>64</b>	<b>39</b>				

**Notes:**

<sup>1</sup> 95% binomial confidence interval without PS adjustment.

Secondary Surgical Intervention

**Table 13** presents the surgical intervention timecourse at index or adjacent levels through post-operative day 790 by treatment type for both the investigational and control groups in the ITT-PS Selected analysis set. There were a total of 12 SSIs in 10 investigational subjects, while 14 SSIs occurred in 13 control subjects.

**Table 13: Secondary Surgical Interventions (ITT-PS Selected analysis set)**

Treatment Group	SSI Type	Event Timecourse (months)					Total (events) *
		<1.5	1.5-3	3-6	6-12	12-24	
<b>LimiFlex Dynamic Sagittal Tether</b>	Removal	1 (0.7%)	-	-	1* (0.7%)	1 (0.7%)	<b>3</b> <b>(2.2%)</b>
	Revision	-	-	-	1* (0.7%)	-	<b>1</b> <b>(0.7%)</b>
	Reoperation	-	1 (0.7%)	-	-	2 (1.4%)	<b>3</b> <b>(2.2%)</b>
	Supplemental Fixation	-	-	2* (1.4%)	1* (0.7%)	2 (1.4%)	<b>5</b> <b>(3.6%)</b>
	<b>Total</b>	<b>1</b> <b>(0.7%)</b>	<b>1</b> <b>(0.7%)</b>	<b>2</b> <b>(1.4%)</b>	<b>3</b> <b>(2.2%)</b>	<b>5</b> <b>(3.6%)</b>	<b>12</b> <b>(8.7%)</b>
<b>TLIF</b>	Removal	-	-	-	-	-	<b>0</b>
	Revision	1 (0.8%)	-	-	-	2 (1.7%)	<b>3</b> <b>(2.5%)</b>
	Reoperation	1 (0.8%)	-	-	-	1 (0.8%)	<b>2</b> <b>(1.7%)</b>

Treatment Group	SSI Type	Event Timecourse (months)					Total (events) *
		<1.5	1.5-3	3-6	6-12	12-24	
	Supplemental Fixation	-	-	-	2 (1.7%)	7* (5.9%)	9 (7.6%)
	<b>Total</b>	<b>2 (1.7%)</b>	<b>0</b>	<b>0</b>	<b>2 (1.7%)</b>	<b>10 (8.4%)</b>	<b>14 (11.8%)</b>

\* Two investigational subjects had two SSI procedures: one underwent one supplemental fixation procedure on Day 148 (3-6mo interval) and one device removal on Day 197 (6-12mo); one underwent one supplemental fixation on Day 218 and one revision on Day 253 (both 6-12mo). One control subject underwent two supplemental fixation SSI procedures, one on post-operative Day 551 and the second on post-operative Day 613 (both 12-24mo). Thus, there are 12 SSIs in 10 Investigational subjects and 14 SSIs in 13 Control subjects.

## 2. Effectiveness Results

The analysis of effectiveness was based on 226 subjects (125 investigational; 101 control) evaluable for primary CCS at Month 24. Key effectiveness outcomes are presented in **Table 14** through **Table 16**.

### Primary Endpoint

A subject was considered a CCS success if the following elements of the primary endpoint were met:

- Improvement of at least 15 points (100-point scale) on ODI at Month 24 compared to baseline
- Absence of a decrease in neurologic status (motor or sensory) at Month 24 compared to baseline, unless attributable to a concurrent medical condition or other cause unrelated to the device and/ or study procedure
- Absence of additional surgical intervention, defined as revision, removal, reoperation or supplemental fixation/fusion\*, in a separate surgery subsequent to the index procedure, at the instrumented level or levels adjacent to the instrumented level, over the initial 24 months post-treatment
- Absence of device integrity failures, defined as device breakage, device separation or disassembly, or device dislocation over the initial 24 months post-treatment

**Table 14** presents the overall success based on the ITT- PS Selected analysis set for subject who had Month 24 data available. Using multiple imputation (MI) methods, the success rate was calculated to be 76.7% for the investigational group as compared to 64.6% for the control group. A completers analysis was also conducted which found the success rate to be 76.8% (98/125) for the investigational group as compared to 59.4% (60/101) for the control group. In both cases, as the lower bound of the 95% confidence interval is higher than the 12.5% non-inferiority margin, the investigational device can be declared a success with respect to non-inferiority as compared to the control treatment in regards to the primary endpoint.

**Table 14: Overall Success (ITT-PS Selected analysis set)**

	Investigational			Controls			Investigational - Controls <sup>4</sup>		
	N	n	%	N	N	%	Diff (%)	LB <sup>11</sup>	UB
<b>(0) Implanted</b>	140	138	98.6%	123	119	96.7%	0.5%	-1.9%	2.9%
<b>(1) No Secondary Surgical Intervention<sup>5</sup></b>	138	128	92.8%	119	106	89.1%	3.2%	-5.4%	11.7%
<b>(2) ODI Responder<sup>6</sup></b>	125	114	91.2%	87	71	81.6%	8.8%	-2.7%	20.2%
<b>(3) Device Integrity<sup>7</sup></b>	114	112	98.2%	88	83	94.3%	1.2%	-2.3%	4.7%
<b>(4) Neurological Success<sup>8</sup></b>	120	115	95.8%	95	90	94.7%	1.7%	-3.5%	7.0%
<b>CCS - Multiple Imputation<sup>9,10</sup></b>	<b>140</b>	<b>---</b>	<b>76.7%</b>	<b>123</b>	<b>---</b>	<b>64.6%</b>	<b>12.2%</b>	<b>-1.2%</b>	<b>25.5%</b>
<b>CCS - Completers<sup>10</sup></b>	125	96	76.8%	101	60	59.4%	12.2%	-1.0%	25.4%

**Notes:**

<sup>1</sup> CCS required no subsequent surgical intervention at the index or adjacent level, an improvement in the Oswestry Disability Index of at least 15 points (decrease), no device integrity failure, and absence of a neurological deficit compared with baseline that is associated with device or procedure as determined by the CEC.

<sup>2</sup> The primary ITT (PS Selected) analysis set includes all Investigational subjects (N=140) and 123 of 140 potential controls selected into a propensity score subclass including 95 prospective controls and 28 retrospective controls. 125 of 140 (89.3%) of Investigational and 101 of 123 (82.1%) were evaluable for Month 24 CCS. 84 of 95 (88.4%) prospective controls, and 17 of 28 (60.7%) retrospective controls were evaluable for CCS.

<sup>3</sup> The average treatment effect on the treated (ATT) was estimated using a PS subclass model that included the following main effects and important interactions: age (yrs), BMI (kg/m<sup>2</sup>), height (cm), ODI, VAS back pain, VAS worst leg/hip pain, OST, angular motion (deg.), translational motion (mm), disc angle (deg.), spondylolisthesis (%), ave. disc ht (mm), white (vs. other), smoking status (current, former, never), Charlson comorbidity index (no age pts) (0, 1, ≥2), diabetes (Yes/No), work status (working, not working [back pain], not working [not back pain]), narcotics use (Yes/No), sensory abnormality at baseline (Yes/No), motor strength deficit (Yes/No), prior lumbar surgery (Yes/No), symptom duration ≥12 Months (Yes/No), treated level L4-L5 (Yes/No), two-level decompression (Yes/No), gender (male vs. female).

<sup>4</sup> The ATT estimated difference is weighted average of the PS subclass differences with  $W_i$  equal to the number of Investigational subjects in that subclass. The standard error used to construct the confidence intervals for the ATT weighted analysis is equal to the square root of  $(1/(\sum W_i)^2) * \sum W_i^2 * \text{var}(\text{diff}_i)$ , where  $\text{var}(\text{diff}_i) = [p_{ii} * (1-p_{ii})/W_i] + [p_{ci} * (1-p_{ci})/N_i]$  and  $p_{ii}$  and  $p_{ci}$  are the observed proportions achieving Month 24 CCS in subclass  $i$  for Investigational and Control respectively.  $W_i$  is the number of subjects in the Investigational arm in subclass  $i$  when estimating ATT and  $N_i$  is the number of control subjects in subclass  $i$ .

<sup>5</sup> Absence of additional surgical intervention, defined as revision, removal, reoperation or supplemental fixation/fusion in a separate surgery subsequent to the index procedure at the instrumented level or levels adjacent to the instrumented level, over the initial 24 months. The denominator for this row is based on subjects with successful implantations. Subjects not successfully implanted are CCS failures.

<sup>6</sup> ODI Responder is censored at SSI.

<sup>7</sup> Absence of device integrity failures, defined as device breakage, device separation or disassembly, or device dislocation over the initial 24 months. This endpoint is censored at SSI. A finding of loose screws at Month 24 is counted as device integrity failure.

<sup>8</sup> Absence of a decrease in neurologic status (motor or sensory) at 24 months compared to baseline unless attributable to a concurrent medical condition or other non-device and/ or procedure-related cause as adjudicated by the CEC.

<sup>9</sup> A fully conditional specification (FCS) approach was used to produce 20 multiply imputed completed data sets. To implement the MI, the simplified CCS endpoints were determined at intermediate timepoints based on freedom from SSI at the index or adjacent level and an ODI improvement of at least 15 points (out of 100). The FCS approach was used to accommodate non-monotonicity in the pattern of missing CCS over time and requires models to be specified for each variable with missing values. All models included PS subclass and treatment group. CCS variables were sequentially added to account for longitudinal temporality. The model for Month 24 included PS subclass, treatment groups, and all intermediate CCS values.

<sup>10</sup> For the MI, the control success rates are ATT weighted for each MI data set and so the difference between mean success rates is equal to the ATT adjusted difference. For the completers analysis, observed (unadjusted) group specific success rates are reported and therefore, the

	Investigational			Controls			Investigational - Controls <sup>4</sup>		
	N	n	%	N	N	%	Diff (%)	LB <sup>11</sup>	UB
difference in crude percentages is not equal to the ATT weighted difference..									
<sup>11</sup> The lower bound (LB) of the 90% CI is equivalent to the LB of the 1-sided 95% non-inferiority CI. The Study Success criterion is a 1-sided 95% CI LB for the CCS that is greater than or equal to -12.5%. <b>Since LB = -1.2% &gt; -12.5% in the MI analysis, the Study Success criterion is achieved based on primary MI analysis.</b>									

To provide greater detail, the primary non-inferiority test was conducted on the primary ITT-PS Selected analysis set by statistically combining within PS subclass comparisons of Month 24 CCS rates between investigational and control groups. The outcomes of each PS subclass are weighted by the number of investigational subjects in each subclass to represent an Average Treatment Effect of the Treated (ATT) analysis. Subjects missing Month 24 CCS data were estimated using MI as described in footnotes 5-6 of the table above such that the primary analysis was performed for the full ITT-PS Selected analysis set. Results of this weighted MI analysis are presented in **Table 15**. To conduct the non-inferiority test, the lower bound of a PS subclass adjusted, one-sided 95% confidence interval for the difference in success rates is determined. If this lower bound is larger than -0.125, it can be concluded that the investigational device is clinically non-inferior to the control treatment in terms of Month 24 CCS.

**Table 15: PS Selected Completers analysis set by PS Subclass and ITT-PS Selected analysis set using Multiple Imputations**

	Investigational			Controls			LimiFlex - Controls		
	W <sup>2</sup>	n	%	N	n	%	Diff (%) <sup>3</sup>	90% LB <sup>4</sup>	95% LB <sup>4</sup>
<b>Subclass 1</b>	10	8	80.0%	31	15	48.4%	31.6%		
<b>Subclass 2</b>	18	9	50.0%	26	16	61.5%	-11.5%		
<b>Subclass 3</b>	24	22	91.7%	21	13	61.9%	29.8%		
<b>Subclass 4</b>	34	25	73.5%	17	12	70.6%	2.9%		
<b>Subclass 5</b>	39	32	82.1%	6	4	66.7%	15.4%		
<b>Crude</b>	125	96	76.8%	101	60	59.4%	<b>17.4%</b>		
<b>ATT Weighted<sup>5</sup></b>	125	96	76.7%	101	65.3	64.6%	<b>12.2%</b>	<b>-1.0%</b>	<b>-3.6%</b>

Notes:  
<sup>1</sup> Includes LimiFlex and Control subjects with non-missing CCS.  
<sup>2</sup> ATT weights (W) are the number of Investigational subjects per PS subclass.  
<sup>3</sup> Fixed effect meta-analysis test for differences across subclasses in LimiFlex minus Control differences chi-square(df=4) = 6.59, p=0.155 (I<sup>2</sup> = 49.9%) indicating no significant subclass by treatment group interaction.  
<sup>4</sup> 90% and 95% lower bounds of normal approximation confidence intervals. The standard error for the weighted analysis is equal to the square root of  $(1/(\sum W_i)^2) * \sum W_i^2 * \text{var}(\text{diff}_i)$ , where  $\text{var}(\text{diff}_i) = [p_i * (1-p_i)]/W_i + [p_{Ci} * (1-p_{Ci})]/N_i$  and  $p_i$  and  $p_{Ci}$  are the observed proportions achieving Month 24 CCS in subclass i for Investigational and Control respectively.  $W_i$  is the number of subjects in the Investigational arm in subclass i when estimating ATT and  $N_i$  is the number of control subjects in subclass i.  
<sup>5</sup> For ATT, the subclasses are weighted according to the number of investigational subjects when determining the PS adjusted treatment group difference and the Control number of subjects achieving Month 24 CCS (n) is what would be expected had the Control subclass specific sample sizes been proportional to those observed in the Investigational sample.

As shown above in **Table 15** the ATT weighted rate of subjects achieving success was 76.7% in the Investigational completers group and 64.6% in the Control completers group. The PS-

adjusted group difference was 12.2%, in favor of the Investigational group. The lower-bound of the one-sided 95% confidence interval for group differences controlling for PS subclass was -1.2%. Since -1.2% is greater than -12.5%, the results from this comparison demonstrate that the study success criterion for non-inferiority has been achieved.

Additional analyses were conducted as the primary endpoint is pre-specified to be evaluated on the ITT-PS Selected analysis set. Analysis of the outcomes of the full ITT-PS Selected analysis set was conducted using MI. The primary analysis was evaluated using the ITT-PS Selected analysis set with MI of missing values. A fully conditional specification (FCS) approach was used to produce 20 MI completed data sets. To implement the multiple imputation, the simplified CCS endpoints were determined at intermediate timepoints based on freedom from SSI at the index or adjacent level and an ODI improvement of at least 15 points (out of 100). The FCS approach was used to accommodate non-monotonicity in the pattern of missing CCS over time, and requires models to be specified for each variable with missing values. All models included PS subclass and treatment group. CCS variables were sequentially added to account for longitudinal temporality. The model for Month 24 included PS subclass, treatment groups, and all intermediate CCS values. A Completers analysis comprising outcomes of subjects evaluable for Month 24 CCS was also conducted. These outcomes mirror the conclusions of the full ITT-PS Selected analysis set using MI, further supporting demonstration of non-inferiority in this clinical trial.

Considering the PP analysis set (i.e., excluding subjects with major protocol violations), the success rate for the investigational group was calculated to be 78.4% as compared to a success rate of 61.6% in the control group, as shown in **Table 16** below. The lower-bound of the one-sided 95% confidence interval for group differences controlling for PS subclass was 3.7%. Since 3.7% is greater than -12.5%, the results further support non-inferiority of the investigational group as compared to the control group with respect to the PP analysis set.

**Table 16: Month 24 CCS<sup>1</sup> Primary Effectiveness Analysis in Per Protocol Analysis Set and in PP Completers<sup>2</sup> Average Treatment Effect on the Treated (ATT<sup>3</sup>) and CCS with Multiple Imputation**

	Month 24								
	Investigational			Control			Investigational - Control <sup>4</sup>		
	N	n	% (n/N)	N	n	% (n/N)	Diff (%)	LB <sup>5</sup>	UB
(0) Implanted	135	134	99.30%	105	102	97.10%	1.30%	-1.10%	3.70%
(1) No Secondary Surgical Intervention <sup>6</sup>	134	125	93.30%	102	89	87.30%	4.60%	-4.00%	13.30%
(2) ODI Responder <sup>7</sup>	122	112	91.80%	74	60	81.10%	10.30%	-1.30%	21.90%
(3) Device Integrity <sup>8</sup>	111	109	98.20%	74	71	95.90%	1.00%	-2.90%	4.80%
(4) Neurological Success <sup>9</sup>	117	112	95.70%	82	77	93.90%	2.70%	-3.20%	8.60%
<b>CCS - Multiple Imputation<sup>10,11</sup></b>	<b>135</b>	<b>--</b>	<b>78.40%</b>	<b>105</b>	<b>--</b>	<b>61.60%</b>	<b>16.80%</b>	<b>3.70%</b>	<b>30.00%</b>
<b>CCS - Completers<sup>11</sup></b>	<b>120</b>	<b>94</b>	<b>78.30%</b>	<b>87</b>	<b>50</b>	<b>57.50%</b>	<b>16.20%</b>	<b>2.80%</b>	<b>29.60%</b>

**Notes:**

1 CCS required no subsequent surgical intervention at the index or adjacent level, an improvement in the Oswestry Disability Index of at least 15 points (decrease), no device integrity failure, and an absence of a neurological deficit compared with baseline that is associated with device or procedure as determined by the Clinical Events Committee (CEC).

2 The per protocol (PP) analysis set includes 135 of 140 (96.4%) of Investigational subjects and 105 of 123 (85.4%) Control subjects. 120 of 135 (88.9%) of Investigational PP subjects and 87 of 105 (82.9%) of Control PP subjects were evaluable for Month 24 CCS.

3 The ATT was estimated using a PS subclass model that included the following main effects and important interactions: age (yrs), BMI (kg/m<sup>2</sup>), height (cm), ODI, VAS back pain, VAS worst leg/hip pain, OST, angular motion (deg.), translational motion (mm), disc angle (deg.), spondylolisthesis (%), ave disc height (mm), white (vs. other) race, smoking status (current, former, never), Charlson comorbidity index (no age pts) (0, 1, ≥2), diabetes (Yes/No), work status (working, not working [back pain], not working [not back pain]), narcotics use (Yes/No), sensory abnormality at baseline (Yes/No), motor strength deficit at baseline (Yes/No), prior lumbar surgery (Yes/No), symptom duration ≥ 12 months (Yes/No), treated L4-L5 (Yes/No), two-level decompression (Yes/No), gender (male vs. female).

4 The ATT estimated difference is the weighted average of the PS subclass differences with  $W_i$  equal to the number of Investigational subjects in that subclass. The standard error used to construct the confidence intervals for the ATT weighted analysis is equal to the square root of  $(1/(\sum W_i)^2) * \sum W_i^2 * \text{var}(\text{diff}_i)$ , where  $\text{var}(\text{diff}_i) = [p_i^*(1-p_i)]/W_i + [p_{Ci}^*(1-p_{Ci})]/N_i$ , and  $p_i$  and  $p_{Ci}$  are the observed proportions achieving Month 24 CCS in subclass  $i$  for Investigational and Control respectively.  $W_i$  is the number of subjects in the Investigational arm in subclass  $i$  when estimating ATT and  $N_i$  is the number of control subjects in subclass  $i$ .

5 The lower bound (LB) of the 90% CI is equivalent to the LB of the 1-sided 95% non-inferiority CI. The Study Success criterion is a 1-sided 95% CI LB for the CCS that is greater than or equal to -12.5%. Since the LB = 3.70% > -12.5% in the MI analysis, the Study Success criterion is achieved based on the primary MI analysis in the Per Protocol analysis set.

6 Absence of additional surgical intervention, defined as revision, removal, reoperation, or supplemental fixation/fusion in a separate surgery subsequent to the index procedure at the instrumented level or levels adjacent to the instrumented level, over the initial 24 months. The denominator for this row is based on subjects with successful implantations. Subjects not successfully implanted are CCS failures.

7 ODI Responder is censored at SSI.

8 Absence of device integrity failures, defined as device breakage, device separation or disassembly, or device dislocation over the initial 24 months. This endpoint is censored at SSI.

9 Absence of a decrease in neurologic status (motor or sensory) at 24 months compared to baseline unless attributed to a concurrent medical condition or other non-device and/or procedure-related cause as adjudicated by the Clinical Events Committee (CEC).

10 A fully conditional specification (FCS) approach was used to produce 20 multiply imputed (MI) completed data sets. To implement the MI, the simplified CCS endpoints were determined at intermediate timepoints based on freedom from SSI at the index or adjacent level, and an ODI improvement of at least a 15-point decrease compared with baseline. The FCS approach was used to accommodate non-monotonicity in the pattern of missing CCS over time and requires models to be specified for each variable with missing values. All models included PS subclass and treatment group. CCS variables were sequentially added to account for longitudinal temporality. The model for Month 24 included PS subclass, treatment groups, and all intermediate CCS values.

11 For the MI, the control success rates are ATT weighted for each MI data set, and so the difference between mean success rates is equal to the ATT adjusted difference. For the completers analysis, observed (unadjusted) group specific success rates are reported and therefore, the difference in crude percentages is not equal to the ATT weighted difference.

## Secondary Endpoints

A number of secondary endpoints were evaluated in the ITT-PS Selected analysis set, as described below.

### *Oswestry Disability Index*

A CCS subcomponent, ODI, was evaluated in the ITT-PS Selected analysis set. In the investigational group, the number of subjects reported to have improved by a greater than or equal to 15-point decrease (out of 100) in ODI score was 80.3% (106/132) at Week 6, with general trend of improvement to 91.2% (114/125) at Month 24. Similarly, in the control group, the number of subjects reported to have improved by a greater than or equal to 15-point decrease (out of 100) in ODI score was 61.3% (65/106) at Week 6, with general trend of improvement to 81.6% (71/89) at Month 24.

### *Return to Normal Activities of Daily Living*

Kaplan-Meier analysis was performed for subject-reported return to normal activities of daily living (ADL), as summarized in **Table 17**. Kaplan-Meier estimates were calculated using the earliest reported date of return to normal ADL through Month 24. Subjects who exited the study prior to returning to normal ADL were censored at the day of last known follow-up. Additionally, subjects who had an intra-operative deviation were censored at day zero (i.e. the procedure day). The cumulative failure rate reported here is the rate of returning to a normal ADL. At week 6, 72.4% of investigational subjects reported a return to normal ADL as compared to 32.5% of control subjects. By Month 24, 97.1% of investigational subjects reported a return to normal ADL as compared to 73.3% of control subjects.

**Table 17: Kaplan-Meier Analysis of the Cumulative Proportion of Subjects Reporting Return to Normal Activities of Daily Living (ITT-PS Selected analysis set)**

Post-operative Day	Investigational	Standard Error	Control	Standard Error
<b>0 days</b>	0.0%	0.0%	0.0%	0.0%
<b>Week 6</b>	72.4%	3.8%	32.5%	4.3%
<b>Month 3</b>	89.1%	2.7%	53.6%	4.6%
<b>Month 6</b>	92.7%	2.2%	61.2%	4.5%
<b>Month 12</b>	96.4%	1.6%	71.0%	4.2%
<b>Month 24</b>	97.1%	1.4%	73.3%	4.2%

### *Return to Work*

Kaplan-Meier analyses were also performed to compare rates of cumulative return to work (RTW) for subjects working pre-operatively for both the investigational and control groups. For reference, pre-operative baseline work status is provided **Table 18**. For subjects who had been working prior to surgery, the cumulative rate of subjects returning to work by Month 24 was calculated via a Kaplan-Meier time-to-event model. Prior to surgery, 70 investigational subjects and 48 control subjects were working. Subjects who had an SSI or exited prior to returning to work are censored at the time of SSI or study exit. Additionally, subjects who had an intra-operative deviation were censored at day zero (i.e. the procedure day). The cumulative failure rate calculated here is the rate of subjects returning to work. As shown in **Table 19**, of subjects working pre-operatively, at week 6, 64.3% of investigational subjects reported a return to work

as compared to 20.8% of control subjects. By Month 24, 96.2% of these investigational subjects reported a return to work as compared to 68.9% of control subjects.

**Table 18: Baseline Work History (ITT-PS Selected analysis set)**

	Investigational (N=140)		Controls (N=123)	
	n	% (n/N)	n	% (n/N)
<b>Current Work Status</b>				
Working	70	50.0	48	40.7
Not working	70	50.0	70	59.3
N/A <sup>1</sup>			5	
<b>If working, specify:</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
Full time	48	68.6	34	70.8
Part time	22	31.4	14	29.2
N/A				
<b>If not working, specify:</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
Due to patient's spinal condition	10	14.3	11	15.7
Not due to patient's spinal condition	60	85.7	59	84.3
<b>If working, any restrictions due to back pain or neurogenic claudication/radiculopathic symptoms</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
No restrictions	31	44.3	34	72.3
Many restrictions	14	20.0	10	21.3
Few restrictions	25	35.7	3	6.4
Different job w/fewer requirements due to pain	0	0.0	0	0.0
N/A			1	
<b>If working, how much physical activity is required:</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
Heavy	9	12.9	4	8.3
Moderate	13	18.6	13	27.1
Light	27	38.6	12	25.0
None	21	30.0	19	39.6
<b>Note:</b>				
<sup>1</sup> N/A = Not currently available.				

**Table 19: Kaplan-Meier Analysis of the Proportion of Subjects Working Pre-operatively Who Had Returned to Work (ITT-PS Selected analysis set)**

Post-operative Day	Investigational	Standard Error	Control	Standard Error
<b>0</b>	0.0%	0.0%	0.0%	0.0%
<b>Week 6</b>	64.3%	5.7%	20.8%	5.8%
<b>Month 3</b>	90.0%	3.6%	43.8%	7.1%
<b>Month 6</b>	92.9%	3.1%	62.5%	7.0%
<b>Month 12</b>	94.3%	2.8%	66.7%	6.8%
<b>Month 24</b>	96.2%	2.4%	68.9%	6.7%

*Procedure Parameters and Length of Stay, Pain VAS, Zurich Claudication Questionnaire and Patient Satisfaction*

**Table 20** reports the outcomes of a number of secondary endpoints including: average estimated blood loss, average length of procedure; hospital/facility length of stay, VAS leg/hip pain, VAS back pain, ZCQ physical function score, ZCQ symptom function score, ZCQ patient satisfaction score, SF-12 Physical Health Survey, SF-12 Mental Health Survey and patient satisfaction. The

mean results for the investigational subjects were similar or numerically favorable as compared to the control subjects in all of the categories.

**Table 20: Procedure Parameters and Length of Stay, Pain VAS, Zurich Claudication Questionnaire and Patient Satisfaction (ITT-PS Selected analysis set)**

Secondary Endpoint	Investigational	Control
Average Estimated Blood Loss	52 ml	254 ml
Average Length of Procedure	112 minutes	190 minutes
Hospital / Facility Length of Stay	0.64 days	2.95 days
<b>Improvement in Leg/Hip Pain VAS</b> Patients reporting $\geq 20$ mm improvement in VAS pain at Month 24	86.4% (108/125)	85.4% (70/82)
<b>Improvement in Back Pain VAS</b> Patients reporting $\geq 20$ mm improvement in VAS pain at Month 24	78.4% (98/125)	71.3% (62/87)
<b>Improvement in Physical Function – ZCQ</b> Decrease in ZCQ physical function $\geq 0.5$ points at Month 24	86.3% (107/124)	78.6% (55/70)
<b>Improvement in Symptom Severity – ZCQ</b> Decrease in ZCQ symptom severity $\geq 0.5$ points at Month 24	87.9% (109/124)	74.6% (53/71)
<b>Patient Satisfaction – ZCQ</b> ZCQ satisfaction score $\leq 2.5$ at Month 24	92.0% (115/125)	88.8% (71/80)
<b>SF-12 Physical Health Survey</b> Maintenance or improvement of SF-12 physical health at Month 24	96.8% (120/124)	91.7% (66/72)
<b>SF-12 Mental Health Survey</b> Maintenance or improvement of SF-12 mental health at Month 24	68.5% (85/124)	68.1% (49/72)
<b>Patient Satisfaction with Surgery</b> Patient-reported satisfaction at all timepoints	>90%	>90%

### Radiographic Secondary Endpoints

#### *Angular Motion*

Angular motion was measured from lateral flexion-extension radiographs and is the measure of the change in angle between the adjacent endplates of the motion segment. **Table 21**, **Table 22**, and **Table 23** present mean angular motion at the level of the implant, below the level of the implant, and above the level of the implant, respectively. The investigational device is designed to be a motion-sparing technology, and provided a mean of 4.35 degrees of angular motion at the level of the implant at Month 24, while the control treatment which is intended to limit motion for fusion afforded reduced mean angular motion (1.69 degrees) at the level of the implant at Month 24.

**Table 21: Angular Motion in Degrees – Level of Implant (ITT-PS Selected analysis set)**

	Investigational						Control						Investigational - Control <sup>1</sup>		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff	LB	UB
Pre-Op	137	5.75	4.55	4.7	0.1	18.6	104	5.61	3.97	4.8	0.1	15.1	0.48	-0.95	1.90
Month 24	113	4.35	3.74	3.2	0.2	17.0	78	1.69	1.57	1.1	0.0	8.9	2.66	1.89	3.44
<b>Notes:</b>															
<sup>1</sup> ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.															

**Table 22: Angular Motion in Degrees – Below Level of Implant (ITT-PS Selected Analysis Set)**

	Investigational						Control						Investigational - Control <sup>1</sup>		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff	LB	UB
Pre-Op	137	6.96	4.64	6.2	0.0	21.1	97	6.95	3.92	7.1	0.0	15.9	0.37	-0.96	1.70
Month 24	112	7.00	4.23	6.6	0.0	20.7	73	7.32	4.72	7.2	0.1	16.8	-0.71	-2.92	1.49
<b>Notes:</b>															
<sup>1</sup> ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.															

**Table 23: Angular Motion in Degrees – Above Level of Implant (ITT-PS Selected Analysis Set)**

	Investigational						Control						Investigational - Control <sup>1</sup>		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff	LB	UB
Pre-Op	137	5.11	4.31	4.1	0.0	15.9	104	5.65	4.64	4.6	0.1	17.2	-0.06	-1.56	1.44
Month 24	113	4.31	4.68	1.9	0.2	16.8	78	6.59	5.27	5.0	0.0	21.6	-3.04	-5.06	-1.03
<b>Notes:</b>															
<sup>1</sup> ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.															

*Translation Motion*

Translational motion was measured from flexion-extension radiographs and is a measure of the displacement of the posterior-inferior corner of the superior vertebra parallel to the superior endpoint of the inferior vertebra. **Table 24**, **Table 25**, and **Table 26** present mean translational motion at the level of the implant, below the level of the implant, and above the level of the implant, respectively. The investigational device is designed to be a motion-sparing technology, and provided a mean of 0.98 mm of translational motion at the level of the implant at Month 24, while the control treatment which is intended to limit motion for fusion afforded reduced mean translational motion (0.27 mm) at Month 24.

**Table 24: Translational Motion (mm) – Level of Implant (ITT-PS Selected analysis set)**

	Investigational						Control						Investigational - Control <sup>1</sup>		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff	LB	UB
Pre-Op	137	1.30	1.07	1.1	0.0	4.9	104	1.25	0.97	1.0	0.0	5.1	-0.01	-0.40	0.39
Month 24	113	0.98	0.87	0.8	0.0	4.5	78	0.27	0.33	0.2	0.0	1.6	0.71	0.53	0.89
<b>Notes:</b>															
<sup>1</sup> ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.															

**Table 25: Translational Motion (mm) – Below Level of Implant (ITT-PS Selected analysis set)**

	Investigational						Control						Investigational - Control <sup>1</sup>		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff	LB	UB
Pre-Op	137	0.58	0.57	0.4	0.0	2.9	97	0.65	0.54	0.5	0.0	2.7	-0.05	-0.22	0.11
Month 24	112	0.69	0.72	0.5	0.0	5.1	73	0.70	0.64	0.5	0.0	2.6	-0.11	-0.42	0.20
<b>Notes:</b>															
<sup>1</sup> ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.															

**Table 26: Translational Motion (mm) – Above Level of Implant (ITT-PS Selected analysis set)**

	Investigational						Control						Investigational - Control <sup>1</sup>		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff	LB	UB
Pre-Op	137	1.04	0.94	0.7	0.0	4.2	104	1.16	0.96	0.9	0.0	3.6	-0.08	-0.36	0.20
Month 24	113	0.87	1.02	0.4	0.0	4.3	78	1.28	1.15	1.0	0.0	5.2	-0.56	-0.97	-0.15
<b>Notes:</b>															
<sup>1</sup> ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.															

### Disc Angle

Disc angle is the angle formed between the endplates of adjacent vertebrae and was measured on neutral lateral radiographs to assess local segmental lordosis. As shown below in **Table 27**, mean disc angle (i.e., segmental lordosis) numerically increased, but was relatively maintained, in both the investigational and control subjects when comparing pre-operative calculations to those at Month 24.

**Table 27: Disc Angle in Degrees (ITT-PS Selected analysis set)**

	Investigational						Control						Investigational - Control <sup>1</sup>		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff	LB	UB
Pre-Op	140	7.96	4.64	8.4	-4.1	19.9	119	8.13	4.82	8.8	-5.3	19.2	-0.47	-2.27	1.33
Month 24	112	8.83	4.64	8.7	-2.8	21.6	88	8.26	4.11	8.9	-0.9	21.1	0.43	-1.15	2.00
<b>Notes:</b>															
<sup>1</sup> ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.															

### Spinous Process Fracture Secondary Endpoints

The independent radiographic core lab (MMI) reported spinous process fractures in a total of 24 investigational subjects at any time through Month 24 for a total incidence rate of 17.1% (24/140). Control subjects were not assessed for spinous process fracture, as traditional lumbar fusion does not depend on maintenance of intact spinous processes without fractures.

**Table 28** identifies the presence and timecourse of spinous process fractures for the investigational group. These data are censored following intra-operative deviation or SSI. At Month 6, 9.2% (12/118) of subjects were identified as having spinous process fractures present, with 18.3% of subjects (21/91) identified as having spinous process fractures present by Month 24. With respect to location, at Month 24, it could be determined that 3.5% of subjects (4/91) had radiographically identified spinous process fractures that were posterior at the dorsal tip, 12.2% of subjects (14/91) had spinous process fractures that were coincident with the implant, 1.7% of

subjects (2/91) had spinous process fractures that were anterior to the implant, 2.6% of subjects (3/91) had spinous process fractures that were indeterminate, and one was unable to be assessed. Regarding displacement status, at Month 24, it could be determined that 11.3% of subjects (13/91) had displaced spinous process fractures, 6.1% of subjects (7/91) had non-displaced spinous process fractures, 2.6% of subjects (3/91) had indeterminate spinous process fractures, and one was unable to be assessed.

**Table 28: MMI Qualitative Assessment of Spinous Process Fractures in the Investigational Group (ITT-PS Selected analysis set)**

At Level of Implant	Post Operative		Week 6		Month 3		Month 6		Month 12		Month 24	
	n	% (n/N)	n	% (n/N)	n	% (n/N)	n	% (n/N)	n	% (n/N)	n	% (n/N)
Absent	103	76.9	122	92.4	115	89.1	118	90.1	106	87.6	91	79.1
Present	3	2.2	9	6.8	13	10.1	12	9.2	13	10.7	21	18.3
Indeterminate	26	19.4	1	0.8	1	0.8	1	0.8	2	1.7	2	1.7
Unable to assess	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9

The independent CEC did not consider one of the core lab reported fractures to be a spinous process fracture. Of the remaining 23 spinous process fractures, the CEC classified 91.3% (21/23) as mild in severity. The majority were classified as device- and procedure-related (78.3%, 18/23), and the remaining 5 (21.7%, 5/23) were attributed to the investigational device only.

**Table** below presents a sensitivity analysis where all spinous process fractures identified by the radiographic core lab are considered to be CCS failures. Under this scenario, the success rate of the investigational group is 60.8% (76/125) which is still supportive of the study non-inferiority hypothesis.

**Table 29: Primary Endpoint Sensitivity Analysis Considering All Spinous Process Fractures Identified by the Radiographic Core Lab as CCS Failures (ITT-PS Selected analysis set)**

	Investigational			95% CI <sup>1</sup>	
	N	n	% (n/N)	LB	UB
<b>Composite Clinical Success</b>	125	76	60.8%	52.2%	69.4%
<b>(0) Implanted</b>	140	138	98.6%	94.9%	99.8%
<b>(1) No Secondary Surgical Intervention<sup>2</sup></b>	138	128	92.8%	88.4%	97.1%
<b>(2) ODI Responder<sup>3</sup></b>	125	114	91.2%	86.2%	96.2%
<b>(3) Device Integrity<sup>4</sup></b>	114	112	98.2%	93.8%	99.8%
<b>(4) Neurological Success<sup>5</sup></b>	120	115	95.8%	92.3%	99.4%
<b>(5) Absence of Spinous Process Fracture</b>	140	116	82.9%	76.6%	89.1%

**Notes:**

1 95% unadjusted normal approximation confidence interval (CI) except for (0) Implanted and (3) Device integrity. For these 95% exact binomial CIs are provided.

2 Absence of additional surgical intervention, defined as revision, removal, reoperation or supplemental fixation/fusion in a separate surgery subsequent to the index procedure at the instrumented level or levels adjacent to the instrumented level, over the initial 24 months. The denominator for this row is based on subjects with successful implantations. Subjects not successfully implanted are CCS failures.

3 ODI Responder is censored at SSI.

4 Absence of device integrity failures, defined as device breakage, device separation or disassembly, or device dislocation over the initial 24 months. This endpoint is censored at SSI.

5 Absence of a decrease in neurologic status (motor or sensory) at 24 months compared to baseline unless attributable to a concurrent medical condition or other non-device and/ or procedure-related cause as adjudicated by the clinical events committee.

Clinical outcomes were also correlated with the presence of spinous process fractures identified by the independent radiographic core lab, as reported in **Table 30** below. When reviewing the possible clinical sequelae of spinous process fractures, there were no notable differences demonstrated in the primary endpoint CCS or its components, as compared to subjects that did not have a radiographically identified spinous process fracture. These results are shown in **Table 30** below.

**Table 30: Primary Endpoint and Patient Reported Outcome Component Success Stratified by Presence or Absence of Process Fractures Identified by the Radiographic Core Lab at Any Time Point, Month 24 (ITT-PS Selected analysis set)**

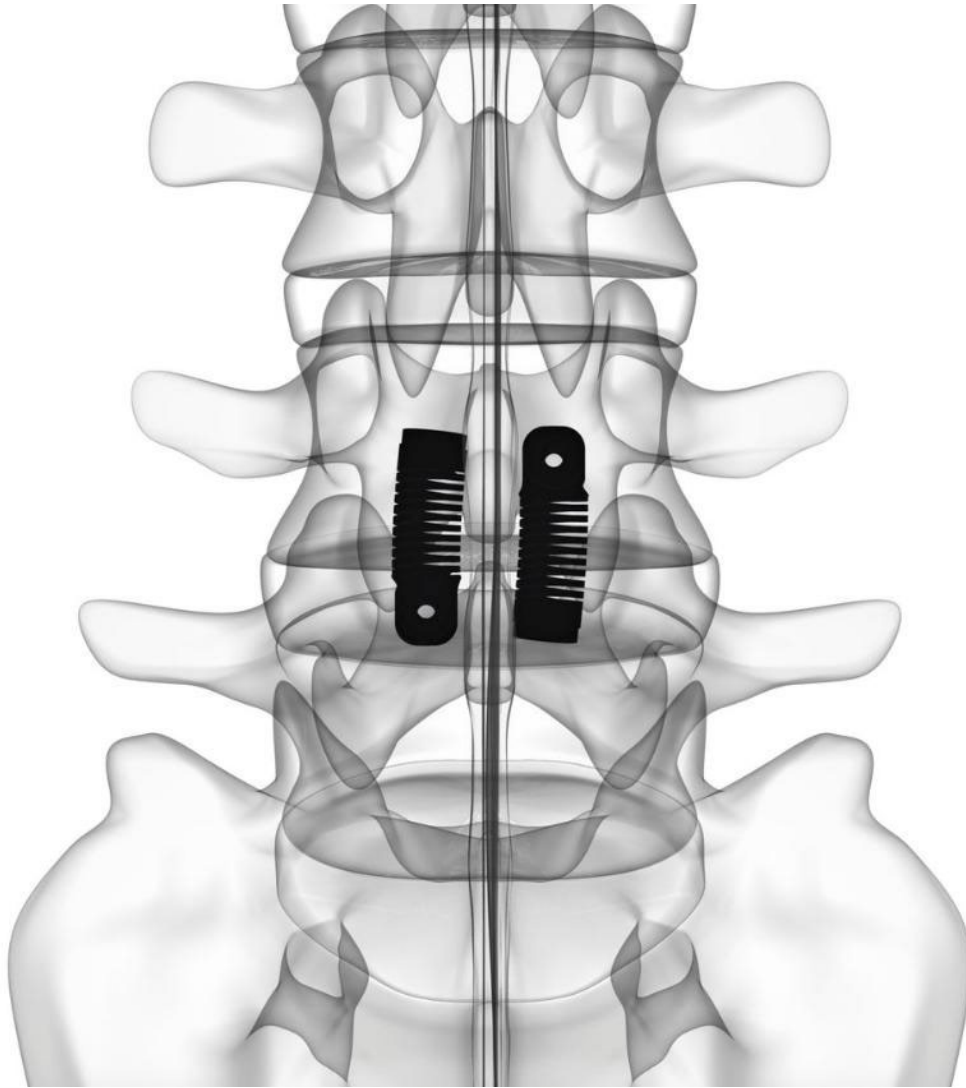
	Fracture			No Fracture			Difference		
	N	n	%	N	n	%	Diff (%)	LB <sup>1</sup>	UB <sup>1</sup>
<b>Composite Clinical Success</b>	24	20	83.3	101	76	75.2	8.1	-6.3	22.5
(0) Implanted	24	23	95.8	116	115	99.1	-3.3		
(1) No SSI <sup>2</sup>	23	22	95.7	115	106	92.2	3.5	-4.6	11.6
(2) ODI Responder <sup>3</sup>	22	20	90.9	103	94	91.3	-0.4	-11.4	10.7
(3) Device Integrity <sup>4</sup>	21	21	100.0	93	91	97.8	2.2		
(4) Neurological Success <sup>5</sup>	22	21	95.5	98	94	95.9	-0.5	-8.5	7.5
<b>Pain</b>									
VAS Back: $\geq 20$ mm decrease <sup>3</sup>	22	18	81.8	103	80	77.7			
VAS Leg (Worst Side): $\geq 20$ mm decrease	22	21	95.5	103	87	84.5			
<b>Back and Stenosis-Related Outcomes</b>									
ZCQ Physical Function: $\geq 0.5$ point decrease <sup>3</sup>	22	20	90.9	102	87	85.3			
ZCQ Patient Satisfaction: $\leq 2.5$ points <sup>3</sup>	22	22	100.0	103	93	90.3			
ZCQ Symptom Severity: $\geq 0.5$ point decrease <sup>3</sup>	22	19	86.4	102	90	88.2			
<b>Disability</b>									
ODI: $\geq 15$ point decrease <sup>3</sup>	22	20	90.9	103	94	91.3			
<b>Notes:</b> 1 LB, UB are lower and upper bounds of 90% confidence intervals. These are provided for endpoints where success rates permit meaningful comparisons. 2 Absence of additional surgical intervention, defined as revision, removal, reoperation or supplemental fixation/fusion in a separate surgery subsequent to the index procedure at the instrumented level or levels adjacent to the instrumented level, over the initial 24 months. The denominator for this row is based on subjects with successful implantations. Subjects not successfully implanted are CCS failures. 3 ODI, VAS and ZCQ censored at implantation failure and SSI. 4 Absence of device integrity failures, defined as device breakage, device separation or disassembly, or device dislocation over the initial 24 months. This endpoint is censored at SSI. 5 Absence of a decrease in neurologic status (motor or sensory) at 24 months compared to baseline unless attributable to a concurrent medical condition or other non-device and/or procedure-related cause as adjudicated by the clinical events committee.									

### *Radiographic Fusion Status Secondary Endpoints*

An assessment of fusion status was performed for the control group using fusion status evaluation methodologies discussed in the FDA Guidance Document for the Preparation of IDEs for Spinal Systems (<https://www.fda.gov/media/71777/download>), which also contains general recommendations on the bridging bone (at left posterolateral, right posterolateral or intervertebral space), angular motion less than 5 degrees, and translational motion less than 3mm. It is also important to note that the aforementioned guidance acknowledges that the radiographic assessment of many metallic spinal systems can be confounded by presence of opacifying hardware. When assessed against the fusion status evaluation methodologies discussed in the aforementioned guidance, 49.4% (41/83) of control subjects were confirmed to meet these criteria at Month 24.



## SURGICAL TECHNIQUE MANUAL



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*Prescription device: Federal U.S. law restricts this device to sale by, or on the order of, a physician.*

## INDICATIONS FOR USE

The LimiFlex™ Dynamic Sagittal Tether is a motion-preserving spinal implant that is intended to provide dynamic flexion-restricting stabilization of the spine following a lumbar decompression. The LimiFlex Dynamic Sagittal Tether is indicated for use at one level from L3-L5, in skeletally mature patients following surgical decompression for treatment of lumbar degenerative spondylolisthesis (Grade I per Meyerding classification) with spinal stenosis. Patients consist of those with neurogenic claudication or radiculopathic symptoms, including leg pain, muscle weakness, and/or sensation abnormality, with or without back pain, who have been unresponsive for a minimum of three months of non-operative treatment and have confirmed diagnosis through patient history and diagnostic studies using X-ray, MRI and/or CT.

## CONTRAINDICATIONS

- Posterior element anatomy inappropriate for interspinous fixation, including
  - Absence or fracture of spinous processes or posterior elements, or deformity that precludes secure device fixation,
  - Facet joint incompetence,
  - Prediction of resection of greater than 50% of spinous processes or facet joints during decompression of the instrumented segment;
  - Spondylolysis or isthmic spondylolisthesis at the instrumented level;
  - The estimated distance between the LimiFlex Dynamic Sagittal Tether strap attachment points (midpoint of the cranial edge of the cranial spinous process and the midpoint of the caudal edge of the caudal spinous process) is less than 30mm on pre-operative lateral standing radiographs at the segment to be instrumented;
  - Posterior element tumor
  - Severe osteoporosis
- A primary diagnosis of facet-mediated back pain;
- Symptomatic lumbar stenosis at the instrumented level that is not amenable to a direct decompression;
- Documented allergy to implant materials, including titanium or polyethylene;
- Active systemic or local infection

## WARNINGS

- **It is important to read the Instructions for Use and Surgical Technique Manual prior to use of the LimiFlex Dynamic Sagittal Tether.**
- Do not use this product if you have not been properly trained in its use. Physicians using the LimiFlex Dynamic Sagittal Tether should be thoroughly familiar with the physiology and pathology of the selected anatomy and be trained in the performance of the LimiFlex Dynamic Sagittal Tether and the accompanying surgical technique.
- Do not alter the pre-assembled device, accessory or instruments prior to use of the devices.
- Use the LimiFlex Dynamic Sagittal Tether Instruments and Leaders (accessory) to implant the LimiFlex Dynamic Sagittal Tether.
- Appropriate surgical decompression is critical to the effectiveness of the LimiFlex Dynamic Sagittal Tether procedure. To the extent possible, the surgeon should preserve soft tissue structures during the posterior lumbar decompression stage with use of the LimiFlex Dynamic Sagittal Tether while ensuring thorough neural decompression. Please refer to the Surgical Technique Manual for specific considerations regarding the decompression.

## PRECAUTIONS

- Note that the LimiFlex Dynamic Sagittal Tether is not intended for pediatric use or correction of scoliosis.
- The effectiveness of the subject device has not been compared to decompression alone.
- The use of the subject device at a spinal segment treated with total disc replacement has not been studied.
- The safety and effectiveness of the LimiFlex Dynamic Sagittal Tether has not been established in patients with the following conditions:
  - o More than one spinal level requiring surgical intervention, other than adjacent level decompression.
  - o More than one surgical procedure at any combination of lumbar levels other than adjacent level decompression.
  - o Prior surgery at any lumbar vertebral level with instrumentation.
  - o Prior surgery at the index lumbar vertebral level without instrumentation.
  - o History of Paget's disease, osteomalacia, or other metabolic bone disease.
  - o History of an autoimmune disease.
  - o Psychiatric or cognitive impairment.
  - o Current or recent history of illicit drug or alcohol abuse, or dependence as defined as the continued use of alcohol despite the development of social, legal, or health problems.

## OVERVIEW: IMPLANT AND INSTRUMENT SET

### ***KLF-3001: LimiFlex Dynamic Sagittal Tether***

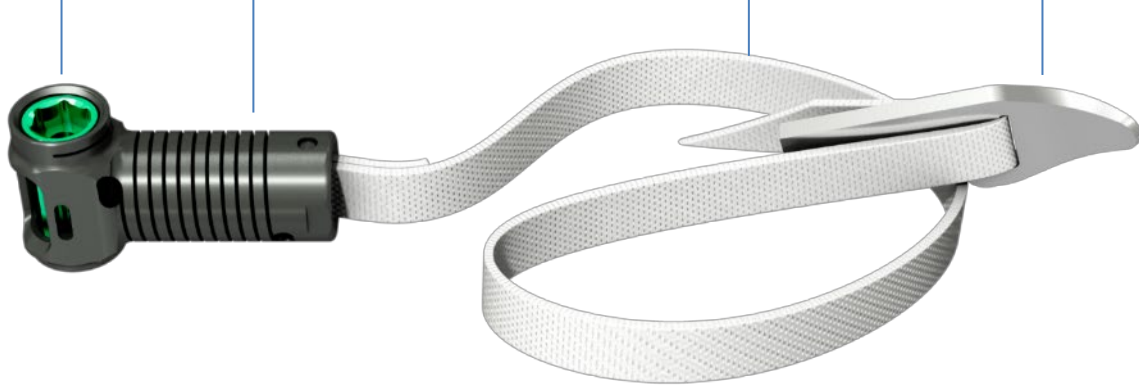
One (1) LimiFlex Dynamic Sagittal Tether consists of two (2) dynamic titanium spring couplers each with a roller screw and a pre-attached ultra-high molecular weight (UHMW) polyethylene textile band. The LimiFlex Dynamic Sagittal Tether is packaged sterile with two (2) Leaders (single-use instruments) designed to facilitate placement of the bands around the spinous processes.



Roller screw Dynamic Titanium Spring Coupler

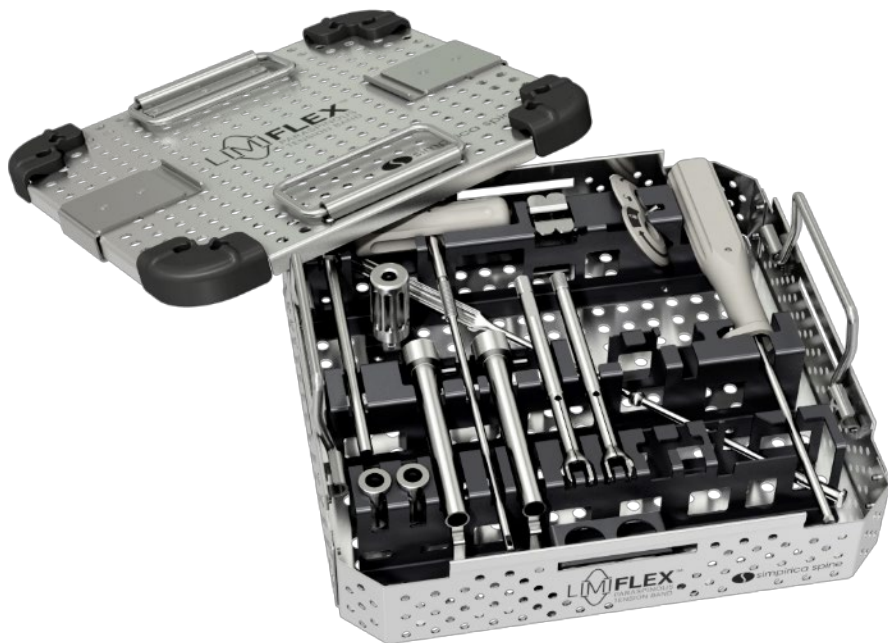
Band

Leader



***KLI-3002: LimiFlex Dynamic Sagittal Tether Instrument Set***

Illustrations and descriptions of the LimiFlex Instrument Set are provided for reference. Refer to the LimiFlex Instrument Set Instructions for Use and Manual for instructions specific to the instrument set including assembly, disassembly and reprocessing.



LI-3001: Passer



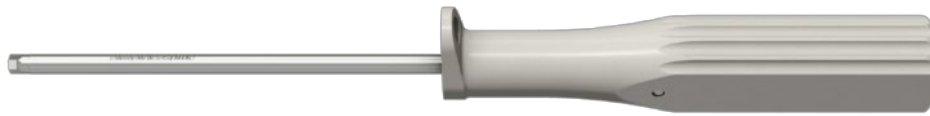
LI-3002: Holder (2x)



LI-3003: Symbol Plate



LI-3004: Driver



LI-3005: Tensioner Clip (2x)



LI-3006: Tensioner



LI-3007: LimiFlex Instrument Tray

## SURGICAL PLANNING

It is important to read the Instructions for Use (IFU) prior to use of the LimiFlex™ Dynamic Sagittal Tether. The surgical procedure described in this Surgical Technique Manual is supplementary to the IFU.

- Preoperative planning and familiarity with the LimiFlex™ Dynamic Sagittal Tether surgical technique are essential, and are based on principles that provide the foundations for sound surgical handling. Do not use this product if you have not been properly trained in its use.
- Do not re-use / Do not re-sterilize. Reuse, reprocessing or re-sterilization of the device may compromise the structural integrity of the device and / or create a risk of contamination of the device, which could result in patient injury, illness, or death. Resue of an implant or implant component that was already implanted in the body of the patient or of another person or of an implant that has come into contact with the body fluids or tissues of another person is forbidden.
- Although allergies and other reactions to materials used in the LimiFlex Dynamic Sagittal Tether are unusual, they should be taken into consideration in preoperative planning.
- The rules of asepsis are to be observed during the implantation.
- The LimiFlex Dynamic Sagittal Tether and Leaders are sterilized with ethylene oxide. They are provided sterile unless the package is opened or damaged or if the “Use By” date noted on the product label has passed. Inspect the LimiFlex Dynamic Sagittal Tether, Leaders and packaging before use to verify that no damage has occurred to the sterile packaging and that all product remains properly positioned in the packaging. Product sterility is only guaranteed if the sterile packaging is intact and has no traces of deterioration.
- Verify the expiration date before using. Use before the “Use By” date noted on the product label.
- The device consists of two (2) titanium tension spring couplers with attached UHMW polyethylene textile bands. Both spring couplers and bands must be used to provide adequate stabilization.
- Do not implant the device such that it is in contact with any non-titanium metal implants including stainless steel.
- Throughout the entire procedure, DO NOT engage the Driver with the LimiFlex™ Dynamic Sagittal Tether unless both couplers are loaded onto Holders and the Symbol Plate is in place on top of Holders. Do not engage the Driver with the implant before the procedure: doing so could impede proper implantation. The LimiFlex™ Dynamic Sagittal Tether is provided pre-aligned in its packaging to facilitate proper band threading.
- The device must be appropriately adjusted for the individual patient, taking anatomical and biomechanical factors into account.
- The LimiFlex™ Dynamic Sagittal Tether should be implanted only while using radiographic visualization; imaging should be utilized during implantation to ensure that the dynamic titanium spring couplers are appropriately positioned and tensioned. Use the LimiFlex™ Instruments and Leaders (accessory) to implant the LimiFlex™ Dynamic Sagittal Tether.
- The use of one or more LimiFlex Dynamic Sagittal Tether(s) to treat multiple segments in the same patient has not been studied.

- Do not use a single LimiFlex™ Dynamic Sagittal Tether to treat multiple segments or attach a single LimiFlex™ Dynamic Sagittal Tether to two non-adjacent spinous processes.
- The use of the LimiFlex Dynamic Sagittal Tether at a spinal segment treated with total disc replacement has not been studied.
- Immediate postoperative care must be carefully planned.

## PRE-OPERATIVE PLANNING

### General Tips:

- Identify the level to be decompressed.
- Note morphology of facets and spinous processes.
- Identify the reference for the patient's normal standing lordosis (e.g. in a standing lateral x-ray). Specifically, look at disc angle and distance between the spinous processes.
- Determine and agree on plan to re-position patient, if required post decompression, into normal lordosis prior to LimiFlex implantation.

### Decompression

- When decompression is performed, ensure a thorough, adequate decompression. (LimiFlex Dynamic Sagittal Tether restricts flexion, but does not provide mechanical decompression.)

### Patient Position for Implantation

- The patient should be in a neutral position (approximating a standing posture) for optimal device tensioning.
- If decompression is performed in a flexed position, the patient will need to be re-positioned prior to tensioning the implant.
- Do not implant LimiFlex Dynamic Sagittal Tether with the patient in a hyperextended position as this may result in excessive tension.

### Ligaments and Soft Tissue

- The interspinous and supraspinous ligaments (ISL/SSL) at the implantation level may be resected if required and LimiFlex Dynamic Sagittal Tether will still restrict flexion. If possible, leave the ISL/SSL at the adjacent segments intact.
- To the extent possible, the surgeon should preserve soft tissue structures during the posterior lumbar decompression stage with use of the LimiFlex Dynamic Sagittal Tether.

### Facets

- Facet incompetence is contraindicated because the LimiFlex Dynamic Sagittal Tether requires facets that can resist shear loads.
- Partial, undercutting facetectomy laterally to the medial border of the pedicle may be performed; foraminotomy may be performed as indicated. Ensure that 50% of the articular surface of the facet is preserved.

### Spinous Processes

- Manually confirm the competence of the spinous processes after decompression, prior to implantation.
- Up to ½ of each spinous process (cranial-caudal, in the plane parallel to the slope of the spinous process) may be resected.

### Bone Quality

- LimiFlex Dynamic Sagittal Tether may be implanted in patients with osteopenia or osteoporosis, however LimiFlex Dynamic Sagittal Tether should not be used in patients with severe osteoporosis (T-score  $\leq$  -2.5 with fragility fracture<sup>1</sup>).

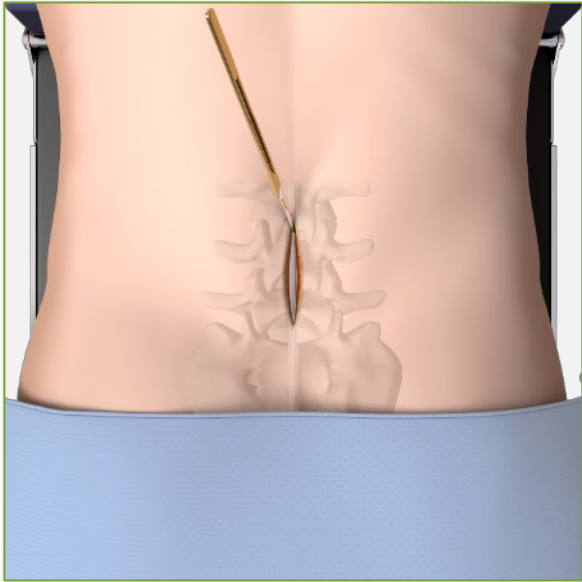
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<sup>1</sup> Assessment of fracture risk and its application to screening for postmenopausal osteoporosis. Report of a WHO Study Group.

Note: Please reference the Instructions for Use for Warnings, and Precautions

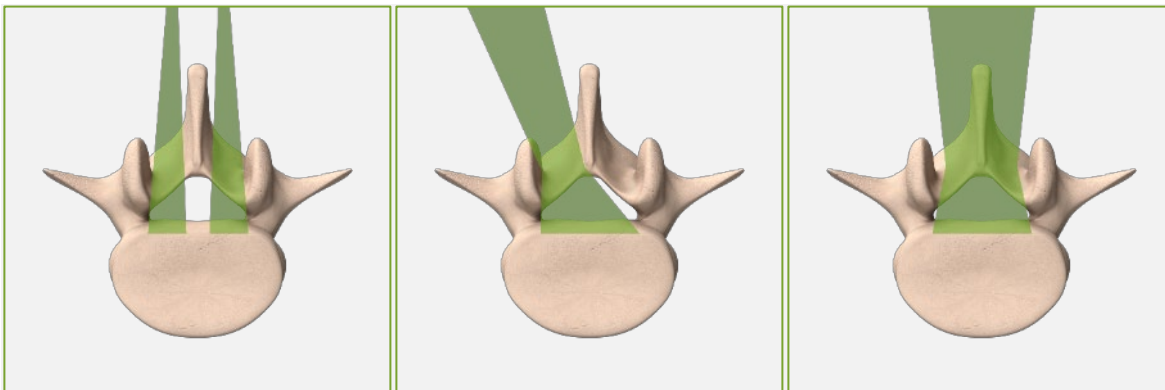
## INCISION, DECOMPRESSION, AND PATIENT POSITIONING

### *Midline incision with bilateral fascial incisions*



Create a midline longitudinal incision at the affected level, followed by parallel bilateral fascial incisions adjacent to the spinous processes. Elevate the paraspinal musculature off of the spinous processes and laminae bilaterally. After decompression, if performed with the patient in flexion, reposition the patient if necessary to create the appropriate segmental alignment.

### *Decompression*



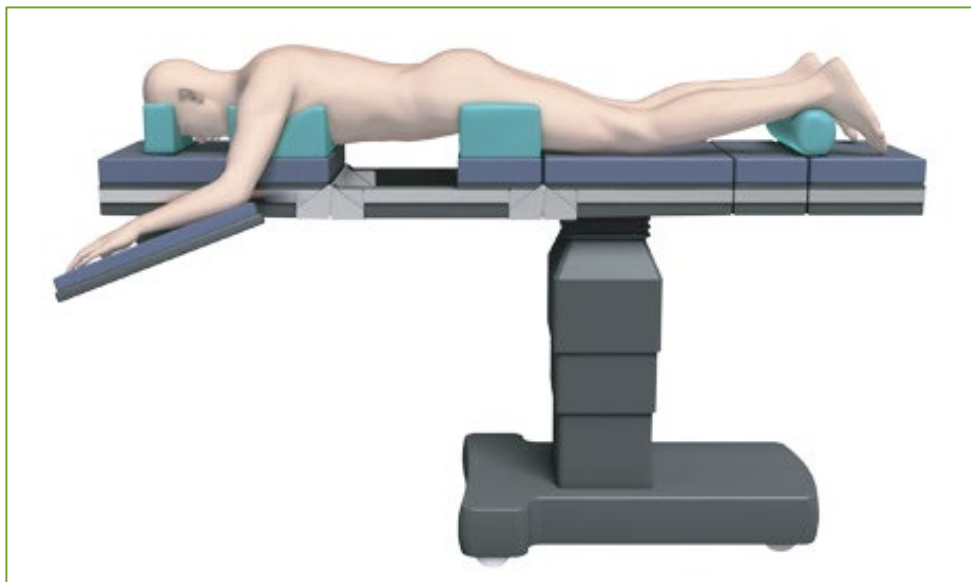
Decompression should be performed per standard technique (e.g., bilateral/midline-sparing, unilateral, midline, etc.)

Tip: Use of a high-speed surgical burr (e.g. as opposed to rongeurs) for bone resection during decompression may help avoid compromising the integrity of the spinous processes during the decompression.

Note: Operating surgeon is encouraged to limit the amount of tissue removal (including bone and soft tissue) during the stage of posterior lumbar decompression

- The interspinous and supraspinous ligaments (ISL/SSL) at the implantation level may be resected if required and LimiFlex Dynamic Sagittal Tether will still restrict flexion. If possible, leave the ISL/SSL at the adjacent segments intact.
- Partial, undercutting facetectomy laterally to the medial border of the pedicle may be performed; foraminotomy may be performed as indicated. Ensure that 50% of the articular surface of the facet is preserved.
- Up to ½ of each spinous process (cranial-caudal in the plane parallel to the slope of the spinous process) may be resected.

### *Patient positioning*



After decompression, reposition the patient if necessary to create the appropriate segmental alignment.

Note: Patient positioning should be confirmed prior to tensioning LimiFlex Dynamic Sagittal Tether. The patient should be in a neutral or slightly extended position (approximating a standing posture) for optimal device tensioning. If decompression is performed in a flexed position, the patient should be repositioned prior to tensioning the LimiFlex. Do not implant LimiFlex Dynamic Sagittal Tether with the patient in a hyperextended position as this may result in excessive tension and risk of possible damage to the device or spinal anatomy.

Tip: Prior to LimiFlex placement:

- Remove gelfoam, etc., from canal
- Confirm adequate decompression of the neural elements is achieved (bilaterally, as required)
- Confirm the competence of the facets and spinous processes

## SURGICAL PROCEDURE

### LOAD COUPLERS ONTO HOLDERS

#### *Load couplers*



- Insert green face of the roller screw into the Holder

#### *Tighten knob*



- Press the coupler into the Holder
- **Take care to avoid pinching gloves in the coupler/Holder interface**
- Tighten the knob by turning clockwise
- Ensure that the Holder is clamped flush onto the coupler

### ***Check band orientation***



- Check that the band is against the flat side of the Holder footplate

### **LOAD LEADER ONTO PASSER**

#### ***Load Leader***



- The Leader fits into the Passer in only one orientation

### ***Tighten knob***



- Rotate the knob clockwise to secure the Leader to the Passer

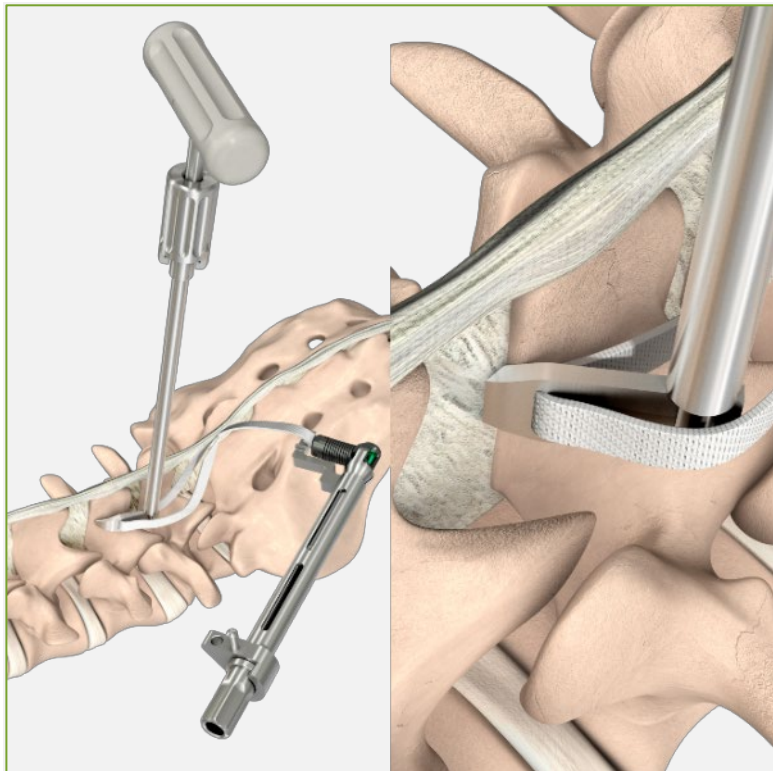
### ***Check band orientation***



- The Leader curves clockwise to facilitate passing the band around the spinous processes
- Ensure Leader is secure

## PASS FIRST BAND AROUND SPINOUS PROCESS

### *Position Leader*



- The Leaders are used to pass the bands around the spinous processes in the clockwise direction.
- Use the Leader to locate the edge of the spinous process
- Pierce the anterior half of the interspinous ligament as close to the spinous process as possible
- **Ensure the band is not twisted. The beveled edge faces up**

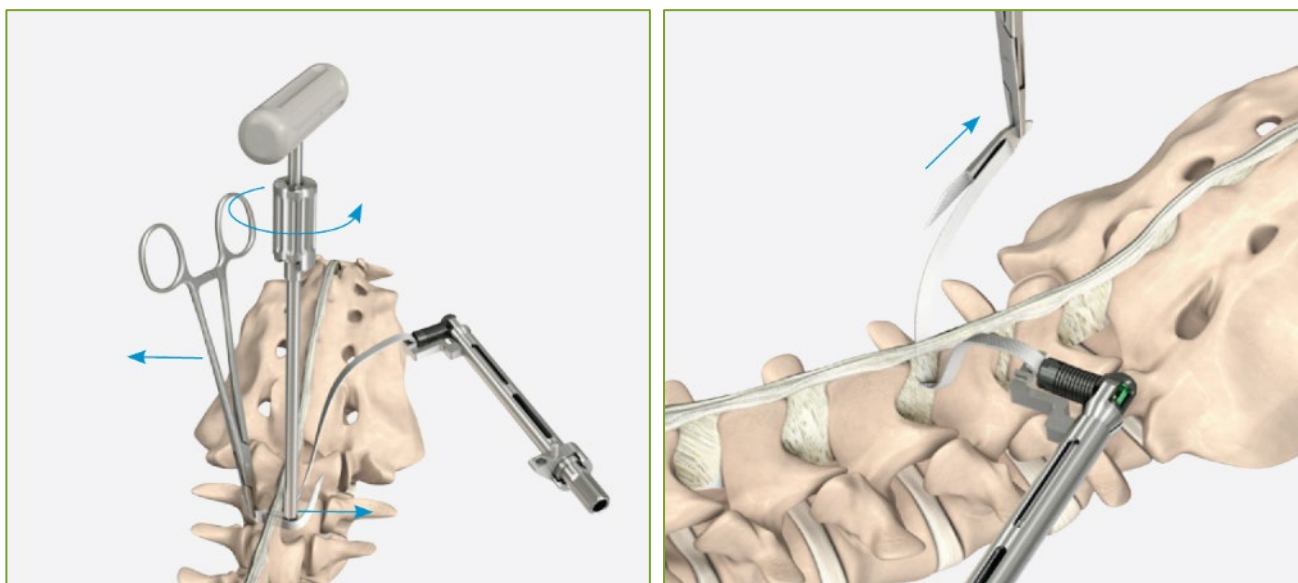
### *Pierce ligament*

- Rotate the T-handle 90° clockwise while pressing the Leader against the interspinous ligament to pierce the interspinous ligament

*Tip: If Bands are difficult to pass around spinous processes, e.g. Baastrup's / kissing spinous processes, or bone quality difficult to palpate with leader, the following may facilitate passing the bands:*

- *Flexing the table (Jackson Axis or Wilson Frame) to open up interspinous space. After passing the Bands, the table will need to be repositioned to achieve neutral alignment as described above.*
- *Locate interspinous space with blunt instrument e.g. right-angle clamps.*

## Retrieve Leader with clamps

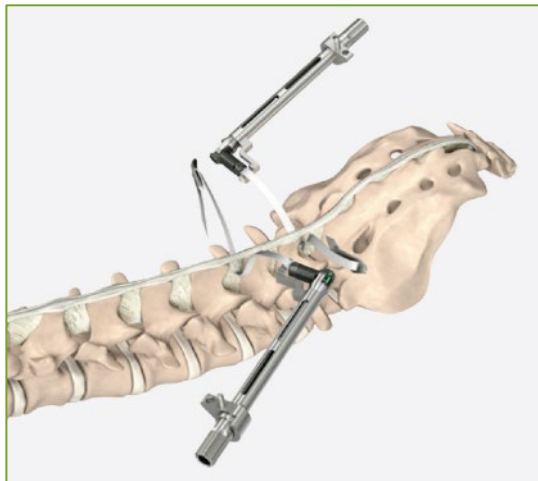


- Use needle-holder clamps to firmly grasp the Leader on the contra-lateral side of the interspinous ligament
- Turn knob counter-clockwise to release Leader from Passer
- Pull distal end of Passer laterally to disengage from Leader
- Pull Leader and band through ligament with clamps

*Tip: To facilitate disengagement of Passer from Leader (after loosening the knob), apply mild finger pressure laterally against the distal tip of the Passer while pulling the leader and band through the ISL on the contralateral side.*

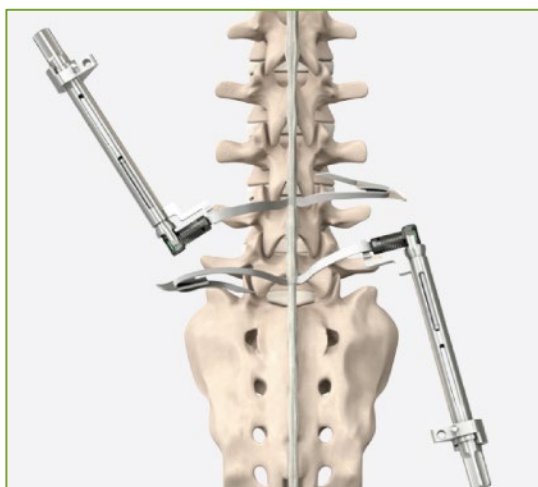
## PASS SECOND BAND AND CONFIRM LEVEL

### *Pass second band*



- Pass the second band using the Passer and the same technique as for the first band
- Check that both bands are against the spinous processes

### *Verify correct level and that band is not twisted*



- Verify that bands are at the correct level, around the correct spinous processes (fluoroscopy recommended)
- Verify that the bands are not twisted and that the beveled edges face dorsally

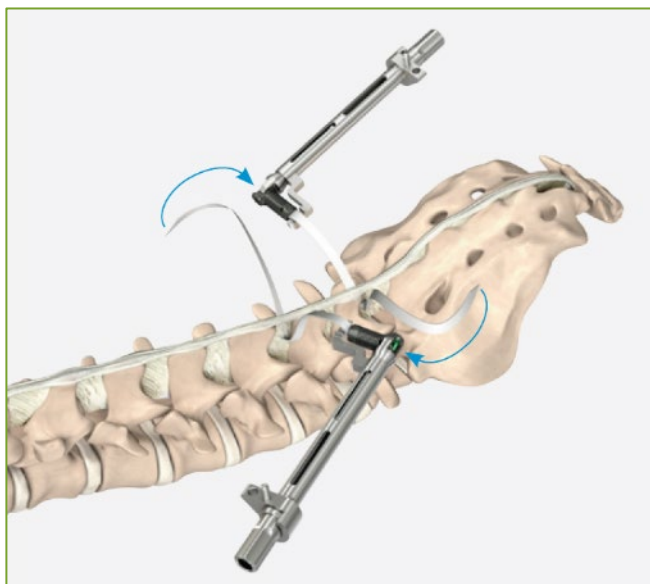
### *Remove Leaders*



- Remove Leaders from the ends of the bands

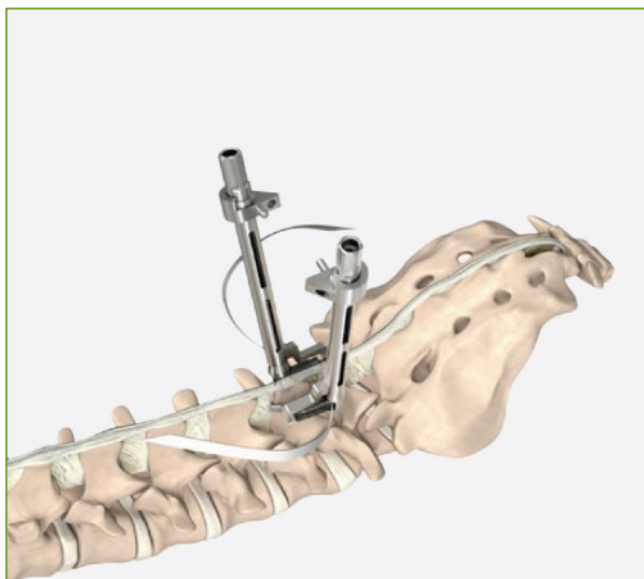
## THREAD BANDS THROUGH RODS

### *Thread bands through rods*



- Insert the tip of the band on the left side through the slot in the locking mechanism of the rod on the left side
- Insert the tip of the band on the right side through the slot in the locking mechanism of the rod on the right side
- Ensure the bands are not twisted, and the beveled edge is oriented dorsally

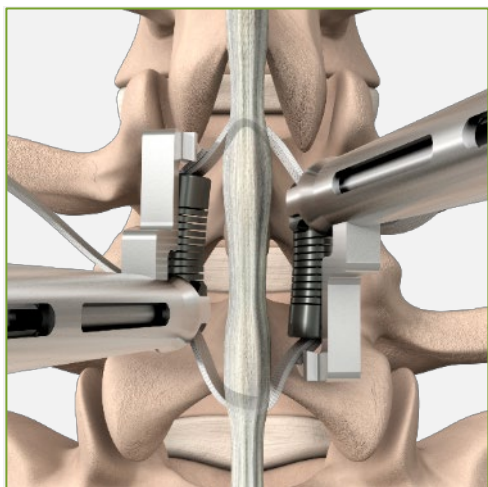
### *Remove slack from bands*



- Manually remove slack from the bands as the rods are placed into the incision

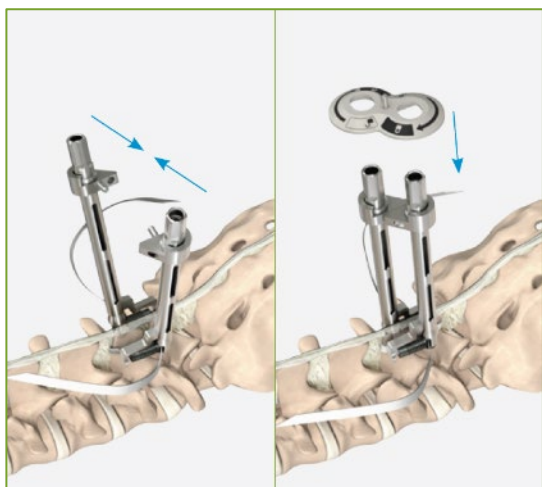
## CONNECT HOLDERS AND PREPARE TO LOCK FIRST BAND

### *Place dynamic titanium spring couplers*



Place couplers medial to the paraspinal musculature. Ensure couplers are flush against the spinous processes and that both Bands are against the flat, medial side of the Holder footplates.

### *Mate Holders*



### *Connect Holders.*

Remove slack from both bands by pulling on the end of each band.

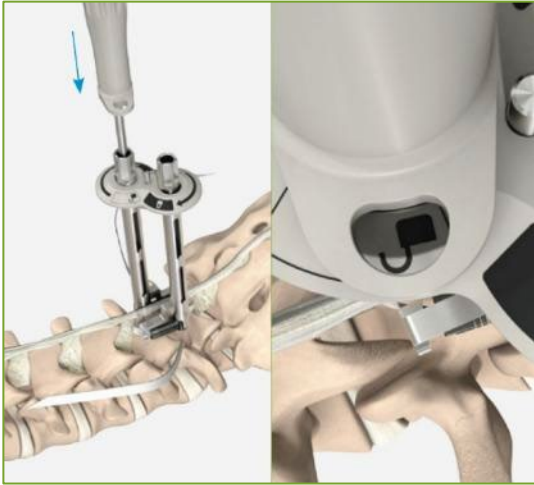
Tip: When the slack is removed, compare the Band tails to each other. When they are the same length, the titanium spring couplers are centered cranial/caudal on both sides of the spinous processes. Adjust accordingly if needed.

### *Place Symbol Plate*

Place Symbol Plate onto top of Holders so that Holder knobs extend through holes in Symbol Plate.

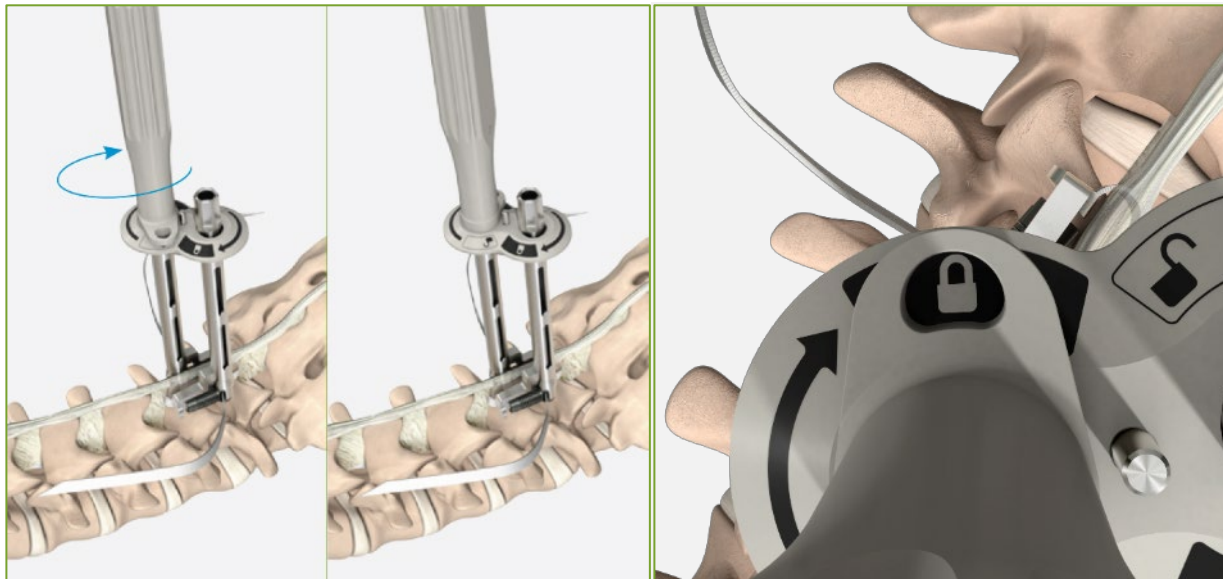
### ***Insert Driver***

Insert Driver into first Holder cannula with the flag in the unlock zone on the Symbol Plate. A tactile and audible “click” will be felt and heard when the Driver correctly mates with implant.



## LOCK FIRST BAND

### *Lock band*



Secure and lock band by turning Driver handle clockwise until the lock symbol on the Symbol Plate is completely visible within the window of the Driver flag.

### **CAUTION:**

- Do not overtighten Driver while securing first band. Overtightening could make later re-adjustment difficult.
- After Driver is turned clockwise until the lock symbol on the Symbol Plate is completely visible within the window of the Driver flag, to ensure the device is properly locked, the flag window must remain entirely within lock zone.

*Note: Confirm that band is securely locked before proceeding to next step.*

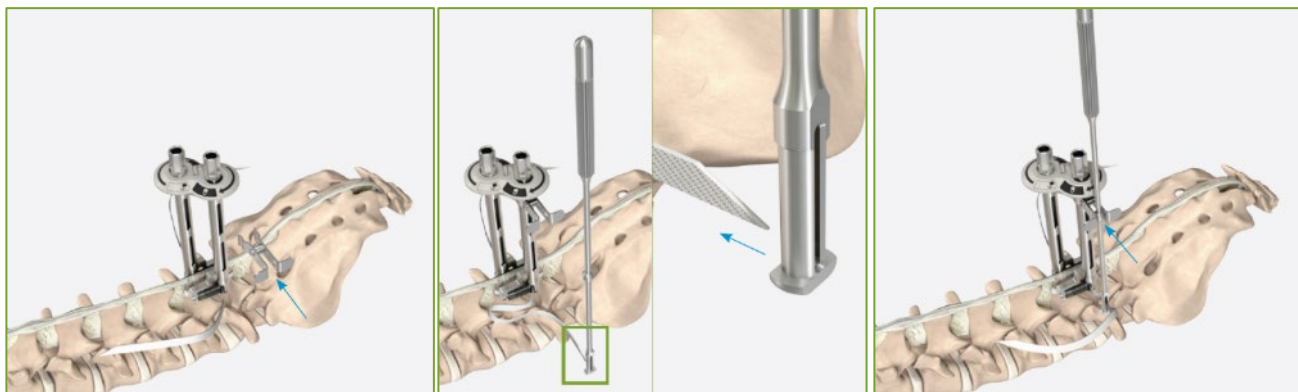
## REMINDER: CHECK PATIENT POSITION

*Note: Prior to tensioning LimiFlex Dynamic Sagittal Tether, confirm that the patient positioning is correct.*



- The patient should be in a neutral or slightly extended position (approximating a standing posture) for optimal device tensioning
- If decompression is performed in a flexed position, the patient will need to be re-positioned prior to tensioning the LimiFlex Dynamic Sagittal Tether
- Do not implant LimiFlex Dynamic Sagittal Tether with the patient in a hyperextended position as this may result in excessive tension as this may result in excessive tension and risk of possible damage to the device or spinal anatomy.
- The icon on the top of the Driver provides a reminder to check patient position and alignment
- Verify a thorough neural decompression including foraminal patency and exiting nerve roots free

## PLACE TENSIONER CLIP AND TENSIONER



### ***Attach Tensioner Clip***

- Attach circular end of Tensioner Clip to Holder
- Ensure that Tensioner Clip is moved all the way up under the Holder head and Symbol Plate

### ***Position Tensioner***

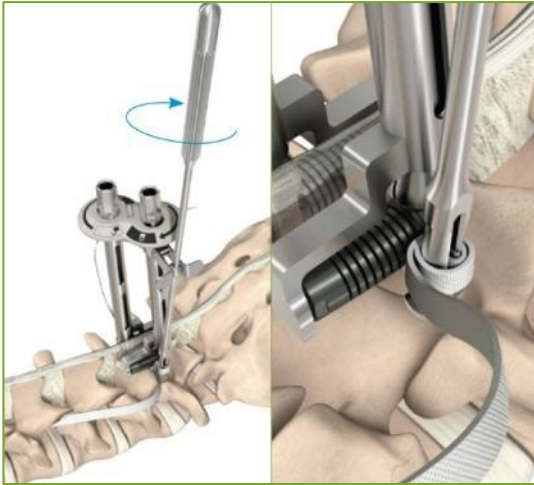
Thread Tensioner onto second band and slide into incision until distal end is next to rod

- Ensure that band is not twisted and that beveled edge faces dorsally

### ***Mate ball of Tensioner with Tensioner Clip***

## TENSION DEVICE

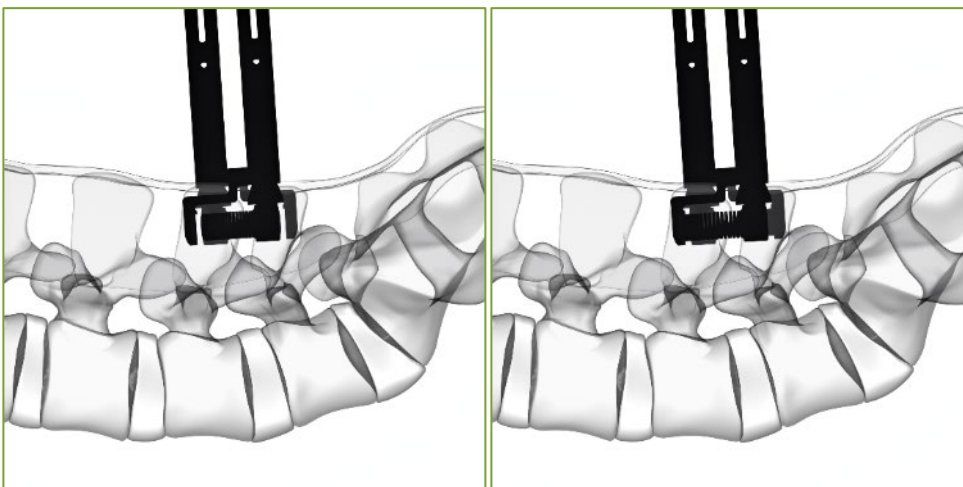
### *Tension Implant*



Rotate Tensioner clockwise until both rods extend to Holder arms

- While tensioning, check that the rods are even and that the device is centered at the target level
- Tensioning is controlled:
  - o Over-tensioning is prevented by the Holder footplates
  - o Under-tensioning is seen as a significant gap between the Holder arms and the rods (lateral fluoroscopy image recommended to verify implant tension)

Patient positioning should be confirmed prior to tensioning LimiFlex. The patient should be in a neutral or slightly extended position (approximating a standing posture) for optimal device tensioning. If decompression is performed in a flexed position, the patient should be repositioned prior to tensioning the LimiFlex. Do not implant LimiFlex with the patient in a hyperextended position as this may result in excessive tension and risk of possible damage to the device or spinal anatomy.



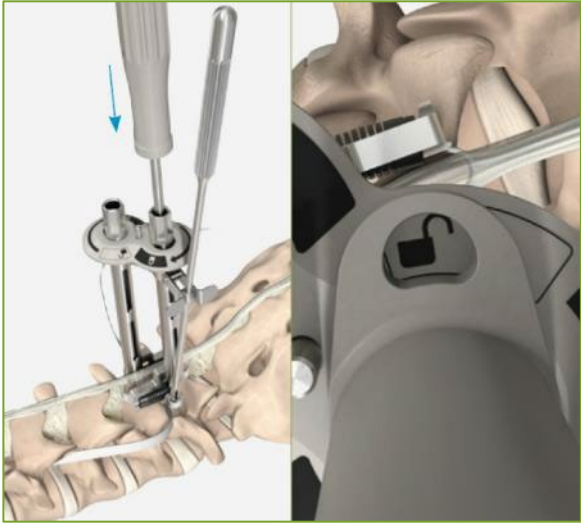
Un-tensioned

Tensioned

*Tip - Great care should be taken during tensioning. The mated Holders with couplers contacting the footplates become a long, rigid lever arm that can, with small input, generate high stresses and loads that may compromise the integrity of the spinous processes.*

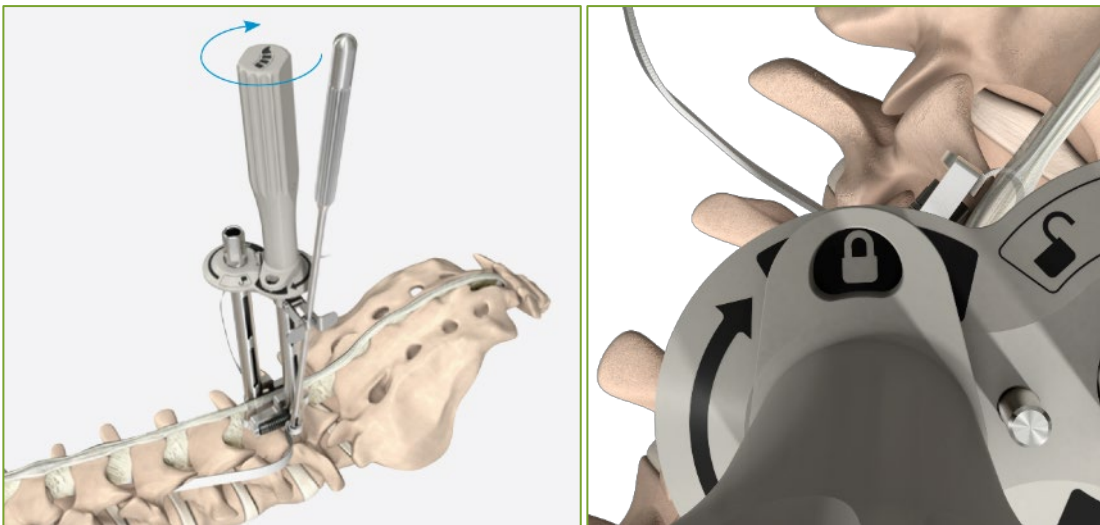
## LOCK SECOND BAND

### *Insert Driver*



Insert Driver into cannula of second Holder with flag in the unlock zone on the Symbol Plate  
A tactile and audible “click” will be felt and heard when the Driver correctly mates with the implant

### *Lock Band*



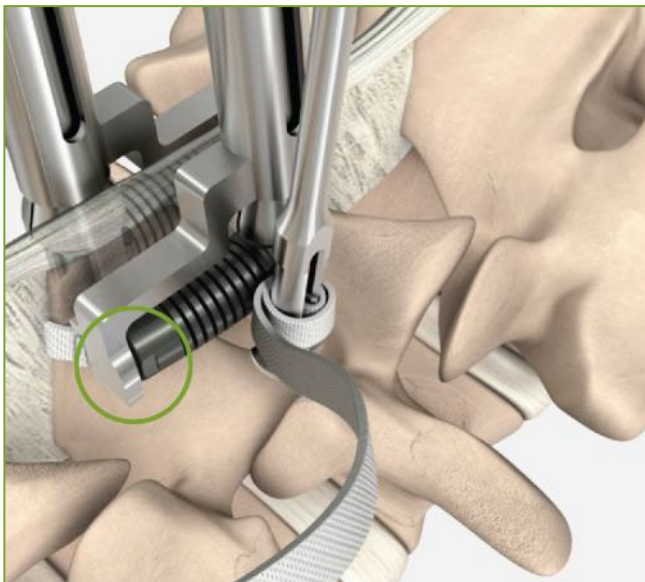
Secure and lock band by turning Driver handle clockwise until the lock symbol on the Symbol Plate is completely visible within the window of the Driver flag. Confirm that flag window remains entirely within the lock zone.

*NOTE: During final locking of the LimiFlex Dynamic Sagittal Tether, the bands are incrementally retracted into the attachment mechanism, increasing device tension. Ensure that the spinous processes and associated anatomy are able to withstand the additional tension.*

*CAUTION: After Driver is turned clockwise until the lock symbol on the Symbol Plate is completely visible within the window of the Driver flag, to ensure the device is properly locked, the flag window must remain entirely within the lock zone. Confirm that flag window remains entirely within the lock zone.*

## CONFIRM TENSIONING AND THAT NERVE ROOTS ARE FREE

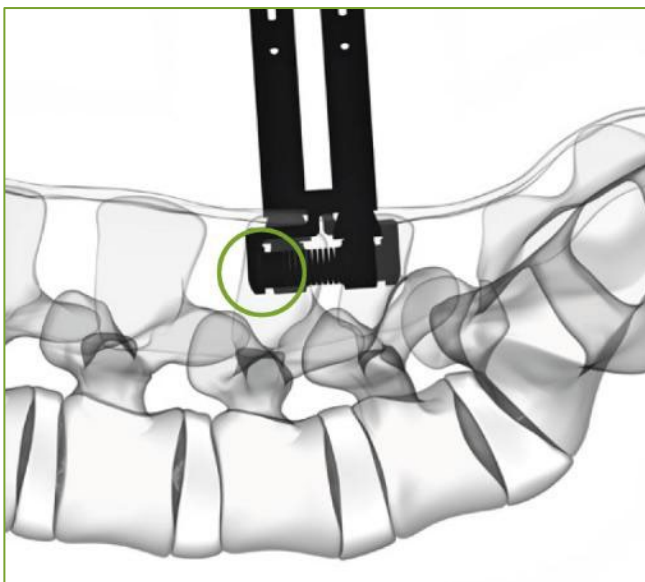
### *Check device tension and positioning*



#### Check:

- Rods extended to touch Holder arms
- Device centered on interspinous interval
- Segmental extension / lordosis is correct (i.e. neutral)

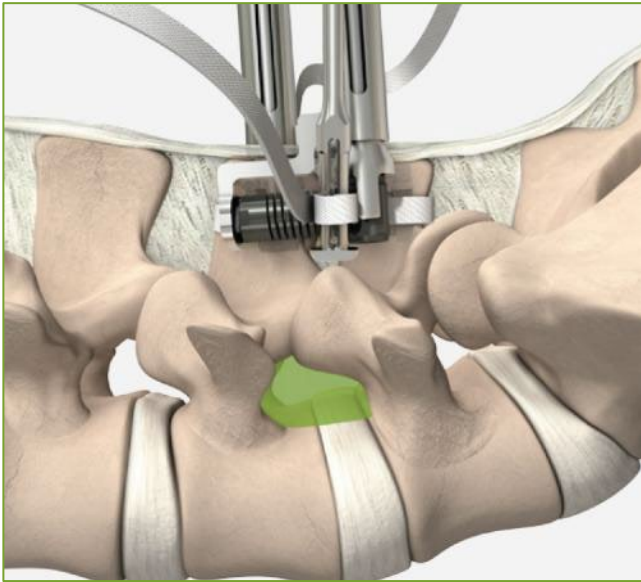
### *Confirm tensioning with fluoroscopy*



On a lateral fluoroscopic image it can be confirmed that couplers are tensioned:

Couplers extend to Holder footplates without significant gaps between couplers and Holder footplates

***Confirm nerve roots are free***



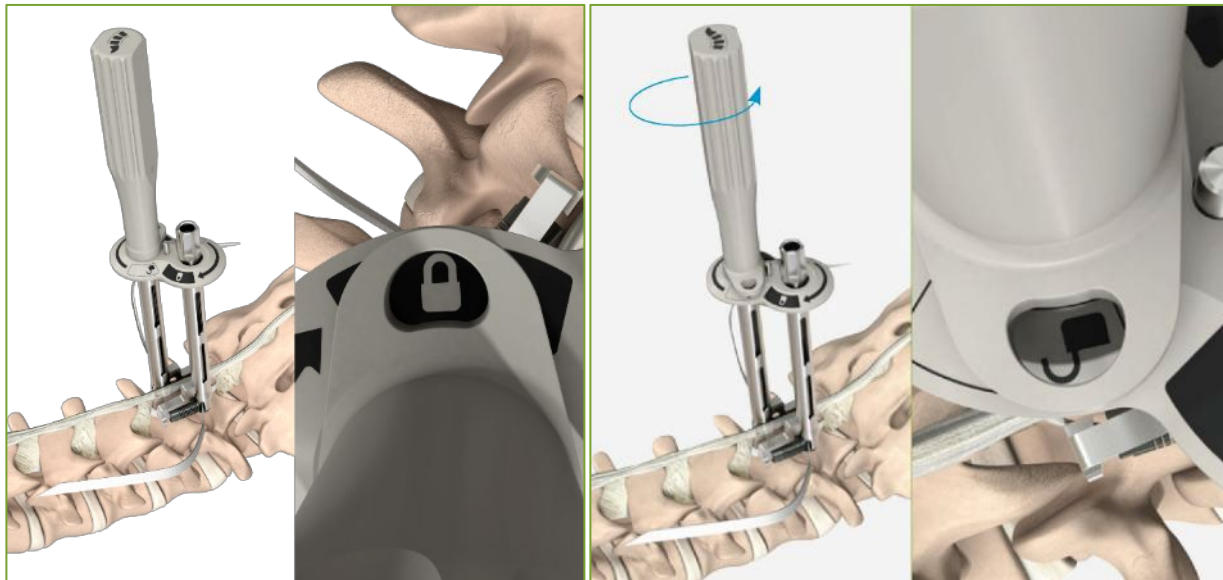
**Check:**

- Nerve roots free (lateral recess, foramen, etc.), e.g. with a probe to ensure foraminal patency and that exiting nerve roots are free bilaterally as required

## READJUSTMENT & UNLOCKING THE BAND (IF REQUIRED)

Note: The band is only to be unlocked if readjustment of the LimiFlex Dynamic Sagittal Tether is desired, for example if the patient positioning or device cranial-caudal location is unsatisfactory

### *Unlock band*



Turn Driver counter-clockwise until flag is in unlock zone on Symbol Plate

If both sides require re-adjustment, repeat this step for the second side

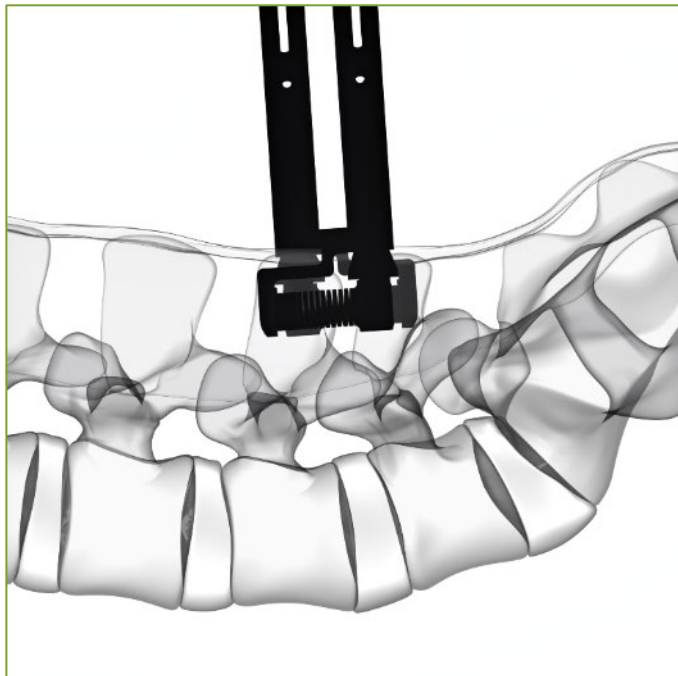
Repeat procedure starting from page 23 with locking of first band in order to tension, secure, and lock bands

### **CAUTION:**

- Attempting to lock, unlock or adjust the device without the appropriate instrument may damage the device.
- If the Holders have already been removed prior to re-adjustment, do not engage the Driver alone with the LimiFlex Dynamic Sagittal Tether. Instead, ensure that both rods are loaded onto Holders and that Symbol Plate is in place on top of Holders prior to re-adjustment.
- If re-adjustment is deemed necessary after Holder removal, re-apply Holders and Symbol Plate, re-insert Driver into same position in which it was prior to removal, and proceed to appropriate steps to re-adjust.
- If Holders cannot be re-applied for re-adjustment, cut bands if necessary, remove both rods and bands, and use another LimiFlex Dynamic Sagittal Tether.

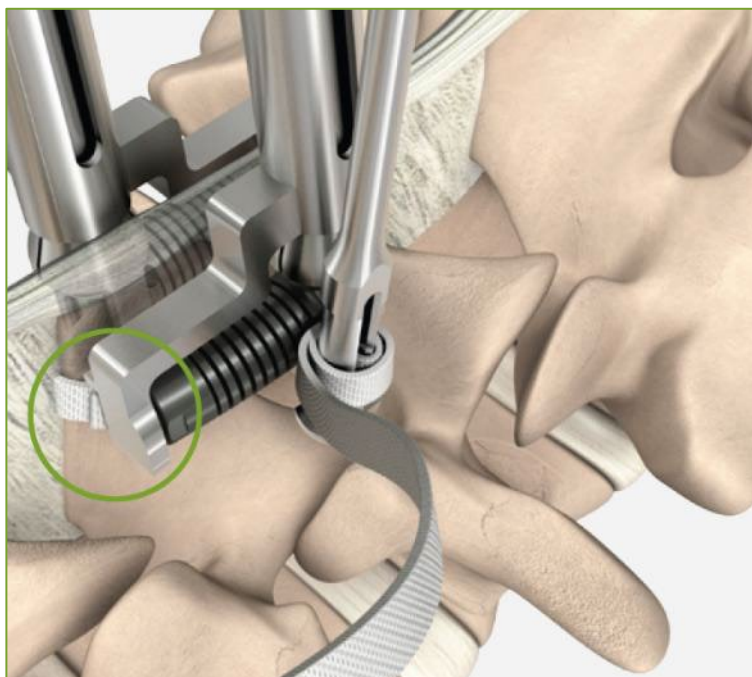
## FINAL CHECK BEFORE INSTRUMENT REMOVAL

### 1. Lordosis



Check: Treated segmental angle similar to that of a neutral to slightly extended position

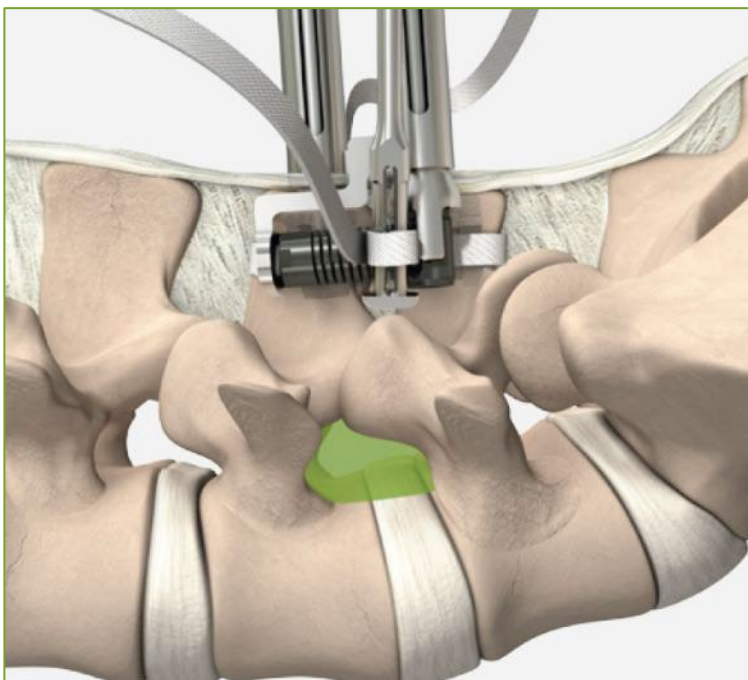
### 2. Tension



Check: Rods both extended to touch the Holder arms

Check: Bands routing along flat, medial sides of Holder arms

### 3. Nerve roots free

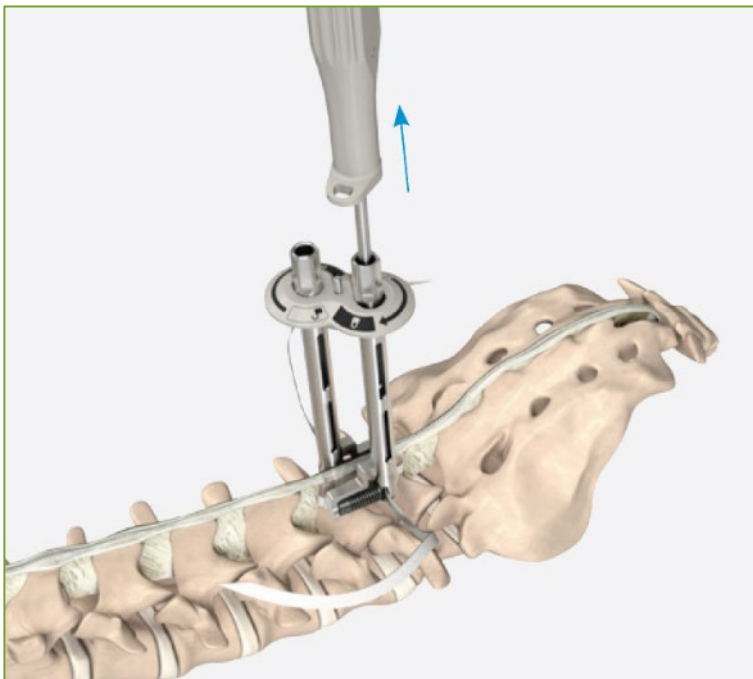


Check: Foraminae patent and exiting nerve roots free, bilaterally as required

Check: Central thecal sac and traversing nerve roots free after tensioning

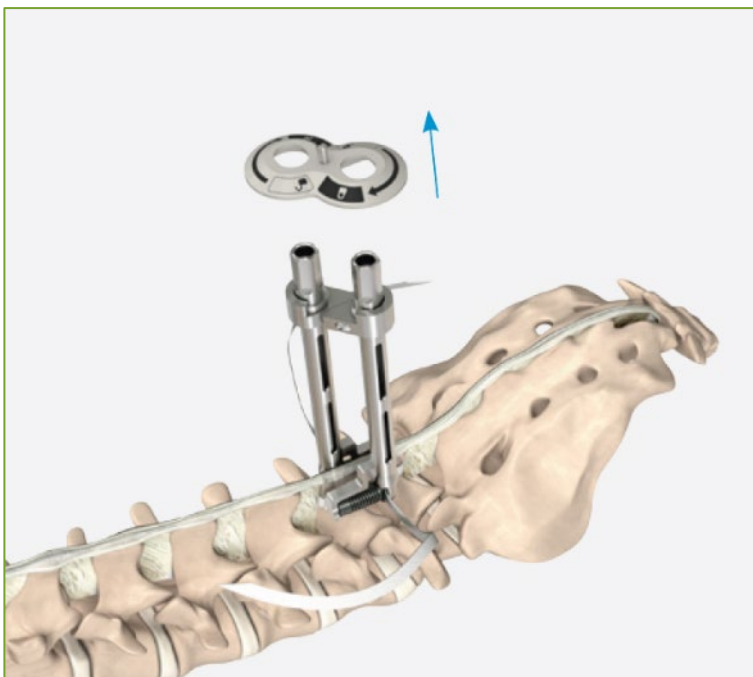
## REMOVE INSTRUMENTS

### *Remove Driver*



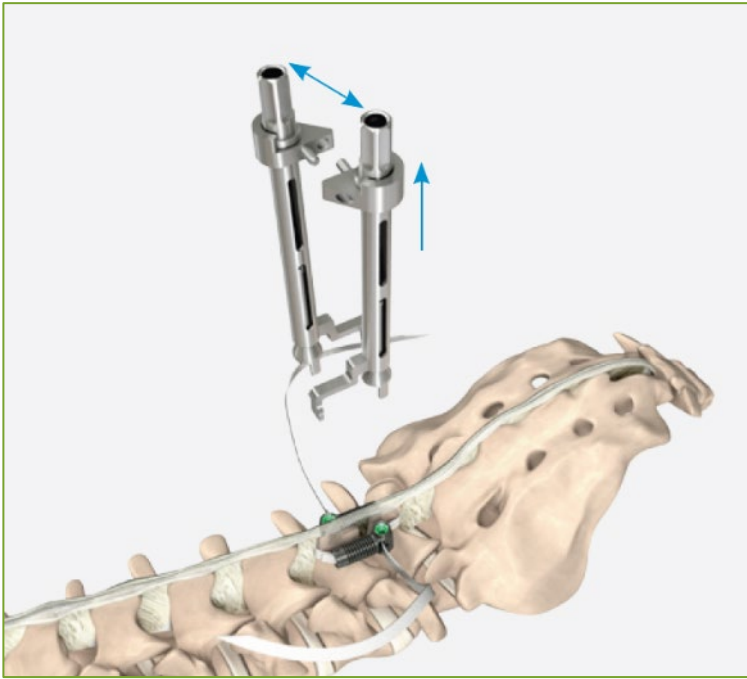
- Lift Driver straight out of Holder
- Do not turn Driver as it is removed

### *Remove Symbol Plate*



- Lift Symbol Plate off Holders

## Remove Holders

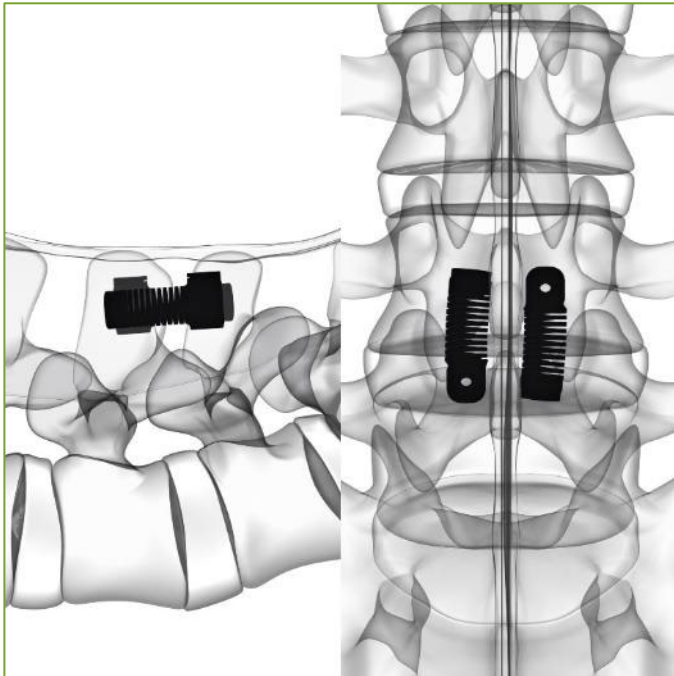


- Turn knobs counter-clockwise (approximately 6 turns) to release Holders from couplers
- Gently shake Holders to release from implant
- Manually inspect device in situ to confirm band tension and position

Remove any other remaining instruments from incision

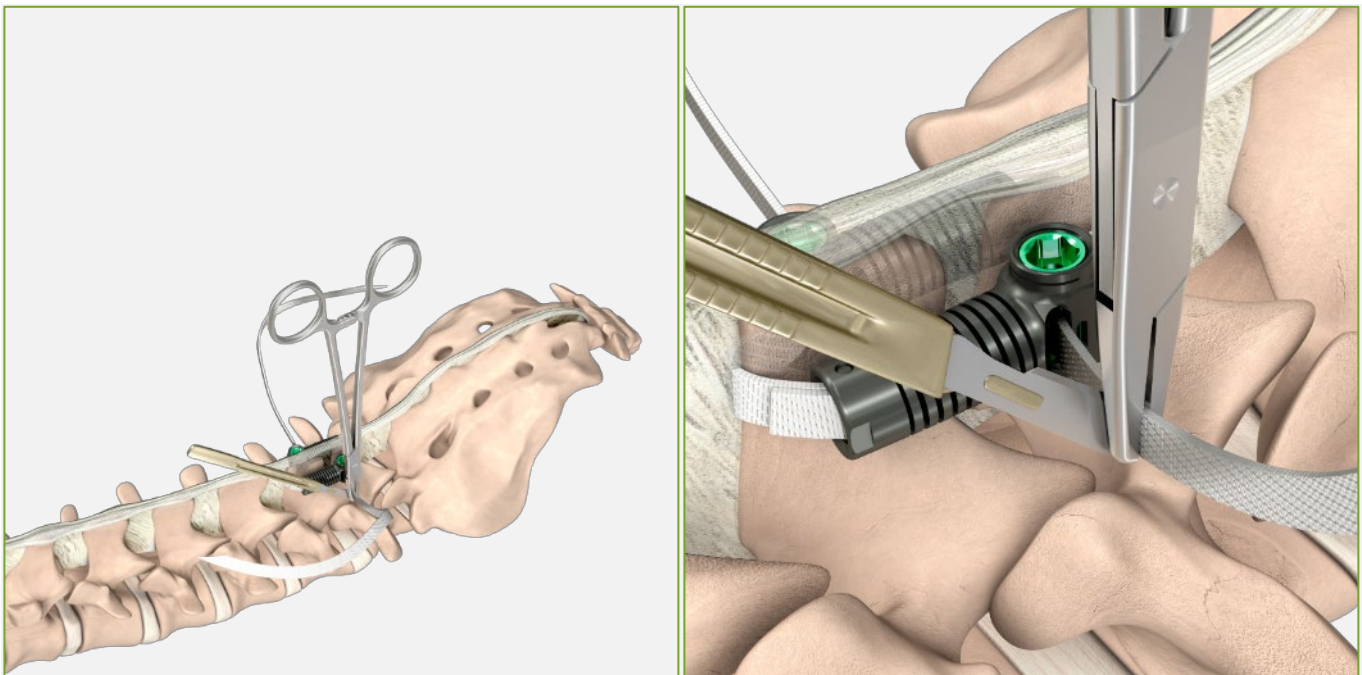
## VERIFY TENSION AND POSITION

*Take fluoroscopic images*



Final AP and lateral fluoroscopic images should be taken to verify device tension and position.

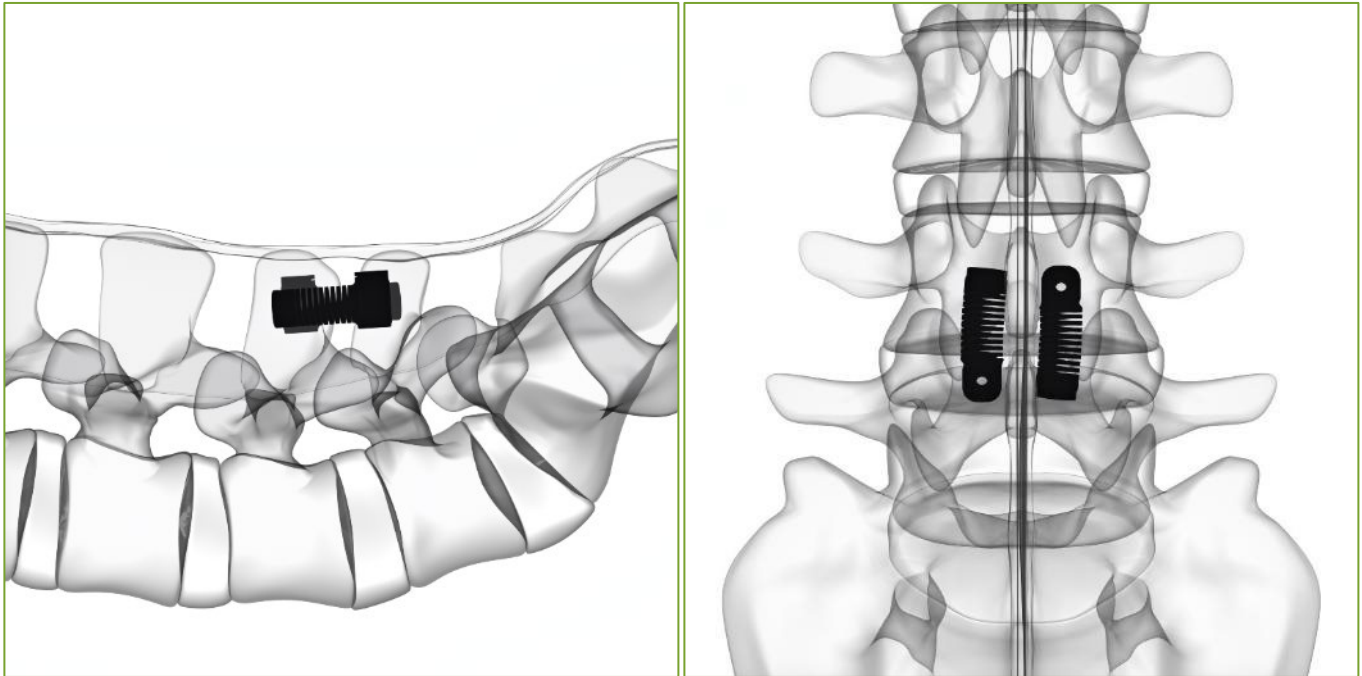
## *Cut bands*



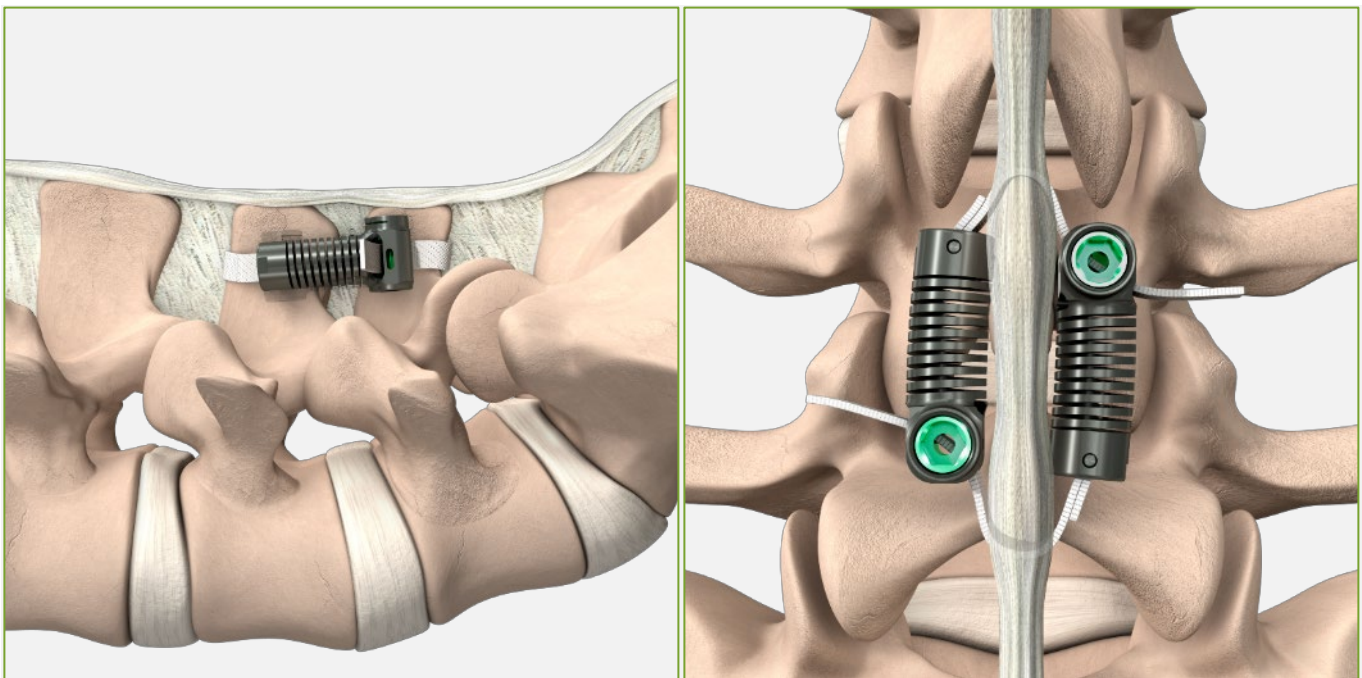
Cut excess bands on both sides using a sharp scalpel. Leave 10 - 20 mm of band on each side of implant

Discard the excess bands and Leaders.

## FINAL RESULT



- On an AP fluoroscopic image, rods may be seen conforming to the anatomy and the ends may curve slightly medially along the spinous processes when under tension. This is normal.



Close incision using standard technique.

## MRI INFORMATION



**MR Conditional** (Contact Empirical Spine for additional information)

A person with an Empirical Spine LimiFlex Dynamic Sagittal Tether device may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Empirical Spine LimiFlex Dynamic Sagittal Tether
Static Magnetic Field Strength (B0)	1.5T and 3.0T
Maximum Spatial Field Gradient	20 T/m (2000 G/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	First level Controlled Operating Mode
Scan Duration	1 hour of continuous scanning in Normal Operating Mode without a cooling period
MR Image Artifact	The presence of LimiFlex Dynamic Sagittal Tether may produce an image artifact of 10mm. Some manipulation of scan parameters may be needed to compensate for the artifact.

Patients who have other MR Conditional Devices can be scanned as long as all the MR Conditional Scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met. If information about a specific parameter is not included, there are no conditions associated with that parameter.



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18655 Madrone Parkway  
Morgan Hill, CA 95037 USA  
Tel: +1 650-585-6307  
Fax: +1 650-585-6307

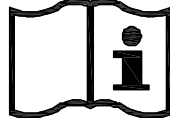
[www.limiflex.com](http://www.limiflex.com)

**Revision History:**

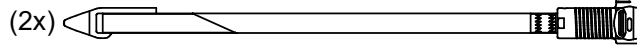
<b>Rev</b>	<b>Effective Date</b>	<b>DCR #</b>	<b>Author</b>	<b>Describe changes:</b>
A			L Fielding	Initial release

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Morgan Hill, CA 95037 USA  
Tel: +1 650-585-6307  
Fax: +1 650-585-6307

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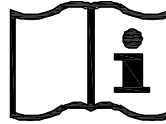


(01)00859373004005(17)261231(10)NNNNN

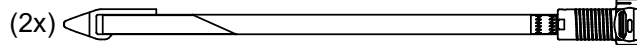
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18655 Madrone Pkwy  
Morgan Hill, CA 95037 USA  
Tel: +1 650-585-6307  
Fax: +1 650-585-6307

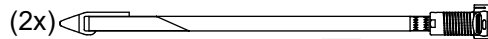
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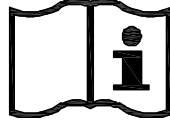
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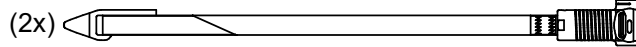
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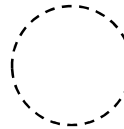


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Morgan Hill, CA 95037 USA  
Tel: +1 650-585-6307  
Fax: +1 650-585-6307

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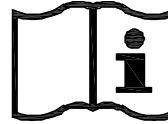


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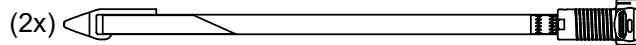
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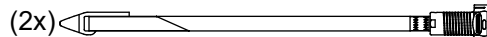
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18655 Madrone Pkwy  
Morgan Hill, CA 95037 USA  
Tel: +1 650-585-6307  
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