# SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

## I. GENERAL INFORMATION

| | |
|---|---|
| Device Generic Name: | Prosthesis, Spinous Process Tension Band Implant |
| Device Trade Name: | LimiFlex Dynamic Sagittal Tether |
| Device Procode: | SGK |
| Applicant's Name and Address: | Empirical Spine<br>18655 Madrone Parkway, Suite 180<br>Morgan Hill, California 95037 |
| Date of Panel Recommendation: | None |
| Premarket Approval Application: (PMA Number) | P220031 |
| Date of FDA Notice of Approval: | February 12, 2026 |

Breakthrough Device: Granted breakthrough device status on March 26, 2021 because the device and proposed indications for use met the program criteria.

## II. 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.

## III. CONTRAINDICATIONS

The Empirical Spine LimiFlex Dynamic Sagittal Tether should not be implanted in patients with the following conditions:

- 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

## IV. Warnings and Precautions

The warnings and precautions can be found in the LimiFlex Dynamic Sagittal Tether labeling.

## V. Device Description

The LimiFlex Dynamic Sagittal Tether is an implant designed to provide dynamic flexion-restricting stabilization of the spine by increasing segmental flexion bending stiffness across the arc of motion through the use of dynamic titanium spring couplers attached to woven straps that wrap around adjacent spinous processes (through the interspinous ligament). The increased flexion bending stiffness is designed to reduce segmental motion within the high flexibility zone where most activities of daily living occur, as well as to maintain the spine in a lordotic posture of relative extension where the facet joints are more engaged and able to resist anterior translation. A complete LimiFlex Dynamic Sagittal Tether consists of two (2) dynamic titanium spring couplers with integrated interconnections (fixed and adjustable) and attached ultra high molecular weight polyethylene (UHMWPE) straps. The LimiFlex Dynamic Sagittal Tether is illustrated in **Figure 1** and **Figure 2**. A single size offering and associated part number is identified in **Table 1.**

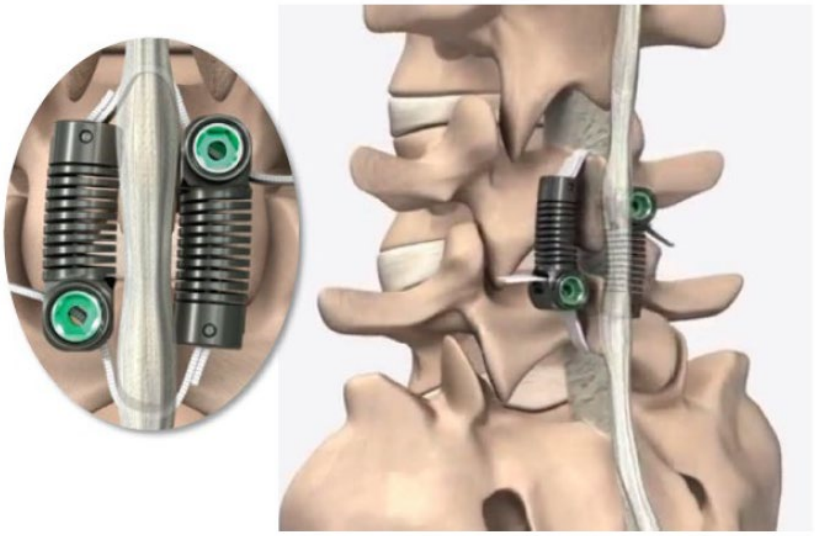

**Figure 1: LimiFlex Dynamic Sagittal Tether**

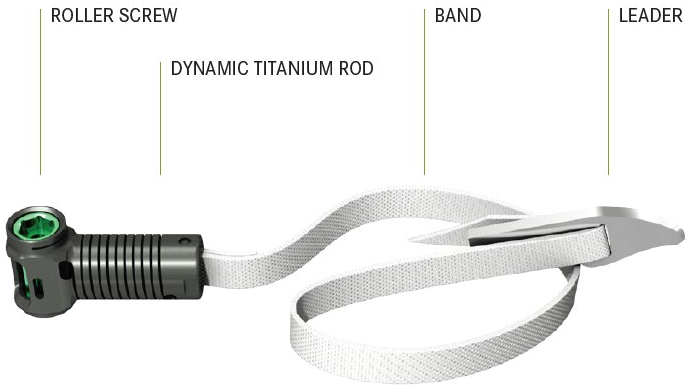


**Figure 2: LimiFlex Dynamic Sagittal Tether Components**

**Table 1: LimiFlex Dynamic Sagittal Tether Catalog Numbers**

| Catalog Number | Description |
|---|---|
| KLF-3001 | LimiFlex Dynamic Sagittal Tether (includes complete packaged subject device and two (2) Leader single-use instruments) |

## VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of lumbar degenerative spondylolisthesis (Grade I per Meyerding classification in a lateral radiograph) with spinal stenosis. Non-surgical alternatives include non-steroidal anti-inflammatory medications, analgesics, oral and epidural steroids, an initial period of rest, physical therapy and bracing. When non-surgical treatments cease to be effective, there are several

surgical alternatives, which include but are not limited to, direct or indirect decompression with or without a device (fusion or non-fusion). Each alternative has its own advantages and disadvantages. A patient should fully discuss the available alternatives with their physician to select the option that best meets their clinical condition, lifestyle and expectations.

## VII. MARKETING HISTORY

The LimiFlex Dynamic Sagittal Tether was marketed by Simpirica Spine in Europe from 2009 through 2014 and was withdrawn from the European market in late 2014 upon the closure of Simpirica Spine due to financial reasons. The LimiFlex Dynamic Sagittal Tether has not been withdrawn from any distribution/ marketing in any country for known safety or effectiveness reasons.

## VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

*Risks Associated with Any Surgery:*
General surgical risks include, but are not limited to:

- Complications from anesthesia such as allergic reaction, anaphylaxis, or other reactions
- Post-surgical pain, bruising, hematoma, swelling, or tenderness at the surgical site
- Complications from medication (e.g., nausea, vomiting, delirium or headache after the surgery)
- Blood loss requiring a blood transfusion
- Blood clots, including pulmonary emboli
- Infection (including urinary tract infection)
- Phlebitis
- Pneumonia
- Poor tissue healing
- Paralysis
- Atelectasis
- Wound complications (such as separation and bruising) and soft tissue damage
- Ileus or intestinal obstruction
- Septicemia
- Myocardial infarction
- Cardiac arrhythmia
- Stroke
- Death

*Risks Associated with Spinal Decompression Surgery:*

Risks associated with spinal decompression surgery include, but are not limited to:

- Dural tear
- Cerebrospinal fluid leak
- Bowel, bladder or sexual dysfunction
- Organ damage
- Disc herniation
- Increased spinal instability requiring additional surgery
- Persistent stenosis requiring additional decompression
- Leg weakness or numbness
- Muscle and tissue injury or damage
- Spinous process fracture
- Cauda Equina damage
- Nerve injury, paralysis or weakness
- Epidural hematoma or bleeding
- Loss of spinal range of motion
- Spontaneous fusion at non-index levels due to heterotopic ossification, development of bridging bone or osteophytes
- Development of new spinal conditions, including but not limited to spinal stenosis and spondylolisthesis

*Risks Associated with Posterior Lumbar Spine Surgery:*

Risks associated with posterior lumbar spine surgery (including the LimiFlex Dynamic Sagittal Tether) include, but are not limited to:

- Sensitivity, allergy or chronic inflammation (e.g., foreign body reaction, bursitis) related to the implant material (titanium, polyethylene)
- Infection related to the device
- Dislocation, malpositioning or lack of fixation of the device after surgery
- Malalignment of anatomic structures
- Mechanical failure of the device, including device breakage, separation or disassembly
- Incomplete healing after the procedure
- Unsatisfactory clinical results that may include increased pain at the device level and exacerbation of symptoms
- Fracture and/or erosion of the spinous processes
- Nerve and/or vascular damage
- Spontaneous fusion due to heterotopic ossification, development of bridging bone or osteophytes
- Additional surgery due to any of the above factors (additional surgery includes revision, removal, reoperation, or supplemental fixation at the treated level)
- Inability to complete the implantation of the device which may require the use of another treatment modality to complete the therapy
- Pain associated and/or attributed to the device

For the specific adverse events (AEs) that occurred in the clinical study, please see **Section X** below.

## IX. SUMMARY OF NON-CLINICAL STUDIES

Non-clinical testing has been performed to characterize the properties and performance of the LimiFlex Dynamic Sagittal Tether and to demonstrate a reasonable assurance of safety and effectiveness to support PMA approval. These non-clinical evaluations included mechanical testing to evaluate safety and performance, as well as biocompatibility testing, sterilization, shelf life and packaging validation, and magnetic resonance (MR) compatibility testing.

### A. Laboratory Studies

The laboratory studies conducted are described in **Table 2** below.

**Table 2: Implant Performance Testing**

| Test | Purpose | Test Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| **Implant** | | | | |
| Biocompatibility | Demonstrate that the LimiFlex Dynamic Sagittal Tether and Leader Accessory are biocompatible for their intended use | Cytotoxicity, sensitization, irritation, systemic toxicity, implantation, pyrogenicity, genotoxicity, chemical characterization and toxicological risk assessment (ISO 10993-1, 3, 5, 6, 10, 11, 17, 18) | ISO 10993 / Biocompatible for intended use | Results of testing in combination with toxicological risk evaluation demonstrated biocompatibility in line with the requirements of ISO 10993-1 for a permanent implant in contact with tissue/bone. |
| Sterilization Validation | Validate that the ethylene oxide (EO) sterilization process terminally sterilizes the packaged LimiFlex Dynamic Sagittal Tether and Leader Accessory per applicable standards. | Comparative resistance study; "over-kill" validation demonstrating the ½ cycle delivers sterility assurance level (SAL) of $10^{-6}$ with acceptably low endotoxin and EO residuals (AAMI TIR 16, EN 556, ISO 11135, 11138, 11737) | Demonstrated biological indicator kill in half-cycle; EO residual, endotoxin and bioburden testing per applicable AAMI and ISO standards for EO sterilization / All required biological indicators killed half-cycle; EO residuals and endotoxin below required thresholds | Full sterilization validation has been conducted per ISO 11135-1 and ISO 11135-2 to establish a Sterility Assurance Level (SAL) of at least $10^{-6}$. |

| Test | Purpose | Test Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| Biomechanical Validation | Demonstrate that the LimiFlex Dynamic Sagittal Tether provides a segmental resistance to flexion | Cadaveric testing of lumbar specimens in flexion/extension, lateral bending and axial rotation, with specimens in the intact, destabilized with LimiFlex Dynamic Sagittal Tether implanted conditions. | The LimiFlex Dynamic Sagittal Tether must provide dynamic flexion-restricting stabilization equivalent to the stability provided by spinal braces commonly used for lumbar fusion, as reported in published literature. | The study showed a 4.3° reduction of flexion-extension ROM (with a follower load) and a 0.57Nm/° increase in flexion stiffness in the lumbar spine after implantation of the LimiFlex Dynamic Sagittal Tether as compared to the intact condition following surgical destabilization. |
| Static Tensile Test | Demonstrate that the LimiFlex Dynamic Sagittal Tether meets performance criteria for static tensile strength and stiffness. | Static tensile testing adapted from ASTM F1717 | 100N min static yield strength; 11-13.5 N/mm stiffness | The acceptance criterion was met. |
| 10-million Cycle Fatigue Test | Demonstrate that the LimiFlex Dynamic Sagittal Tether meets performance criteria for dynamic (10-million cycle) fatigue strength. Initial testing established "F-N" performance. | Dynamic tensile adapted from ASTM F1717 | Fatigue strength 100N at 10M cycles w/o failure and ≤1mm dynamic creep over 10M cycles | The acceptance criterion was met. The dynamic creep was ≤1.3% of the test specimen gauge length. |

| Test | Purpose | Test Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| Leader Static Bending Test | Demonstrate that the Leader Accessory meets performance criteria for its intended use | Static loading of the Leader Accessory simulating worst-case loading during use | >114 N yield strength<br>No component fracture | The acceptance criterion was met. |
| Wear Test | Demonstrate that the LimiFlex Dynamic Sagittal Tether does not generate biologically harmful wear debris during worst-case loading over maximum expected implantation duration | Multi-axial loading per ASTM F2624 with gravimetric assessment and fluid particulate analysis [1]. 10M cycle tensile loading at super-physiologic loads with gravimetric assessment of wear [3]. | No biologically harmful wear debris | The acceptance criterion was met. |
| Packaging and Shelf-Life Validations | Demonstrate that the LimiFlex Dynamic Sagittal Tether and packaging meet performance specifications after simulated transit and storage conditions as well as real-time aging. | Transit simulation followed by accelerated or real-time aging, followed by device and package performance testing | Device and packaging meet performance criteria after simulated transit and aging | Shelf life and transit validation studies, including assessments of packaging seal integrity, real time and accelerated aging testing, were conducted to demonstrate that the device packaging can maintain a sterile barrier over a 48-month shelf life. |
| MRI Compatibility Testing | Demonstrate that the LimiFlex Dynamic Sagittal Tether poses an acceptably low risk to safety or image quality in the MRI environment for | Translational attraction (ASTM F2052), Magnetically induced torque (ASTM F2213), RF-induced heating (ASTM F2182), MR | The LimiFlex Dynamic Sagittal Tether must be found to be at least *MR Conditional* | The nonclinical testing demonstrated that the Limiflex Sagittal Tether is MR Conditional.; see |

| Test | Purpose | Test Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| | 1.5-Tesla and 3-Telsa MRI conditions | image artifacts (ASTM F2119) | | Section IX.A for MR scanning conditions. |
| User Validation | Validate that customer/user requirements for the LimiFlex Dynamic Sagittal Tether, Accessory and Instruments were successfully met | Simulated surgical implantation by qualified users with questionnaire to assess user requirements | All user requirements must be satisfactorily met per use surveys | The acceptance criterion was met. |

**B. Additional Studies**

MR Compatibility testing was conducted to demonstrate that 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 as summarized in **Table 3** may result in injury:

**Table 3: MRI Conditions for Person with Implanted LimiFlex Dynamic Sagittal Tether Device**

| Parameter | Condition |
|---|---|
| Device Name | Empirical Spine LimiFlex Dynamic Sagittal Tether |
| Static Magnetic Field Strength ($B_0$) | 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. |

## X. 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 4**. Subjects were not permitted to enroll in the LimiFlex Dynamic Sagittal Tether study if they met any of the following exclusion criteria in **Table 4**.

**Table 4: Study Inclusion and Exclusion Criteria**

| Study Inclusion Criteria | Study Exclusion Criteria |
|---|---|
| • Lumbar degenerative spondylolisthesis (Grade I per Meyerding classification), at one level from L1 to S1, with radiographic confirmation using X-ray;<br>  o 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.<br>• 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;<br>  o 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.<br>• Neurogenic claudication or radiculopathy symptoms including leg pain, muscle weakness, and/or sensation abnormality, with or without back pain as evidenced by patient history;<br>• 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;<br>• A pre-operative Visual Analog Scale (VAS) leg pain score of ≥50 on a 100 mm scale; | • A primary and predominate diagnosis of discogenic back pain;<br>• A primary and predominate diagnosis of facet-mediated back pain;<br>• Back or non-radicular leg pain of unknown etiology;<br>• Significant peripheral vascular disease-causing vascular claudication;<br>• Significant peripheral neuropathy caused by conditions other than spinal stenosis;<br>• History of fixed or permanent neurologic deficit related to spinal cord injury;<br>• History of any previous surgery* at any level in the lumbosacral spine except for a discectomy or decompression;<br>• History of any previous surgery* at the level(s) planned for treatment;<br>  *previous surgery includes spinal stimulator placement but does NOT include epidural injections, rhizotomy or nerve ablation<br>• Isthmic spondylolisthesis or spondylolysis (pars fracture) at any level in the lumbar spine;<br>• Clinically significant compromise of vertebrae at L1 to S1 levels due to osteoporotic vertebral compression fracture or any traumatic, neoplastic, metabolic or infectious pathology or congenital abnormality;<br>• 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;<br>• 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 <10 mm from lamina to dorsal tip or other significant deformity due to trauma, or congenital abnormality such as spina bifida occulta at the planned |

| Study Inclusion Criteria | Study Exclusion Criteria |
|---|---|
| *Leg pain includes hip and/or buttock pain on the same side<br>• A pre-operative Oswestry Disability Index (ODI) score ≥35 points on a 100-point scale;<br>• Candidate for surgical decompression at a single level or two contiguous levels, with stabilization at only one level between L1-S1;<br>• 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 >50% of facet joints present following decompression (investigational group only);<br>• ≥25-80 years of age and skeletally mature;<br>• 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<br>• Patient is willing and able to provide Informed Consent for study participation. | instrumented level that would preclude secure fixation of the LimiFlex Dynamic Sagittal Tether Device to the spinous process;<br>• 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 <30mm on pre-operative lateral standing radiographs at the segment to be instrumented;<br>• Degenerative lumbar scoliosis with a Cobb angle >10° at the affected motion segment;<br>• Symptomatic lumbar stenosis that is not amenable to a direct surgical decompression (i.e. patients with stenosis requiring indirect, interbody decompression)<br>• Ankylosed motion segment at the target operative level<br>• Severe osteoporosis, defined as history of fragility fracture and DXA bone mineral density T-score <-2.5 or QCT bone mineral density T-score < 80mg/cubic cm. History of a fragility fracture requires that a DXA scan or QCT scan is completed;<br>• Planned hip or knee replacement surgery, severe osteoarthritis or other musculoskeletal pathology of the hip or leg that could preclude reliable patient self-reporting assessment scales and/or that would likely progress to surgery during study period;<br>• Documented allergy to titanium or polyethylene;<br>• Active local or systemic infection;<br>• Receiving immunosuppressant or long-term steroid-therapy;<br>• Known history of bone metabolic disorder, including Paget's disease, hyperparathyroidism, renal osteodystrophy, and osteomalacia;<br>• Disease or condition that would preclude accurate clinical evaluation of the safety |

| Study Inclusion Criteria | Study Exclusion Criteria |
|---|---|
| | and effectiveness of the study treatment or any significant medical conditions which would place the patient at excessive risk for surgery, such as;<br>o Severe rheumatoid arthritis or other surgery, such as:<br>o Active hepatitis (viral or serum) or HIV positive<br>o Unstable cardiac disease<br>o Uncontrolled diabetes<br>o Renal failure<br>o Severe muscular, neural or vascular diseases that endanger the spinal column<br>o Cauda equina syndrome<br>o Severe neurologic disorders including paralysis<br>• Morbid obesity defined as BMI >40;<br>• Active malignancy or history of metastatic malignancy within the last five years;<br>• Women who are pregnant or are interested in becoming pregnant within the study period;<br>• Currently seeking or receiving worker's compensation for back pain or spinal condition;<br>• Currently involved in spinal litigation that potentially is associated with secondary financial gain;<br>• Current involvement in a study of another investigational product for similar purpose;<br>• Demonstrates three or more Waddell's Signs of Inorganic Behavior;<br>• 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;<br>• Current history (withing 12 months) of substance abuse; including alcohol abuse; or<br>• A prisoner. |

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 5**. Adverse events and complications were recorded at all visits.

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

**Table 5: 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 [R,1] | | | | | | | |
| Informed Consent | X[R,2] | | | | | | | |
| Eligibility Criteria | X[R] | | | | | | | |
| Pregnancy Test (premenopausal women) | X | | | | | | | |
| Radiographs<br><br>*Note: All radiographs are to be obtained in concordance with Radiographic Evaluation Protocol | X[R, 4] | | X[3] | X[5] | X[6] | X[7] | X[4, 7] | 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[R] | | 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:

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

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 6** 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 3** 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 6: 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 |
| **All Evaluated Accounting [Actual[B]] Among Expected Due Procedures** | | | | | | |
| [10] # of procedures with any completed patient reported outcomes | 140 | 123 | 130 | 99 | 125 | 88 |
| **[11] All Evaluated Visit Compliance [%] = [10] / [7a]** | **100%** | **100%** | **97.7%** | **86.1%** | **96.9%** | **82.2%** |
| [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 |
| **[15] Composite clinical success (CCS)** | | | | | **125** | **101** |
| **[16] Actual[B] % Follow-up for CCS [16] = [15] / [9]** | | | | | **89.3%** | **82.1%** |
| **Within Window Accounting [Actual[A]] Among Expected Due** | | | | | | |
| [17] ODI Responder status determined Clinical visit within window | | | | | 109 | 71 |
| [18] Within window compliance [18] =[17]/[7a] | | | | | **84.5%** | **66.4%** |
| [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[A]% 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[B] % 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[A]% 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.

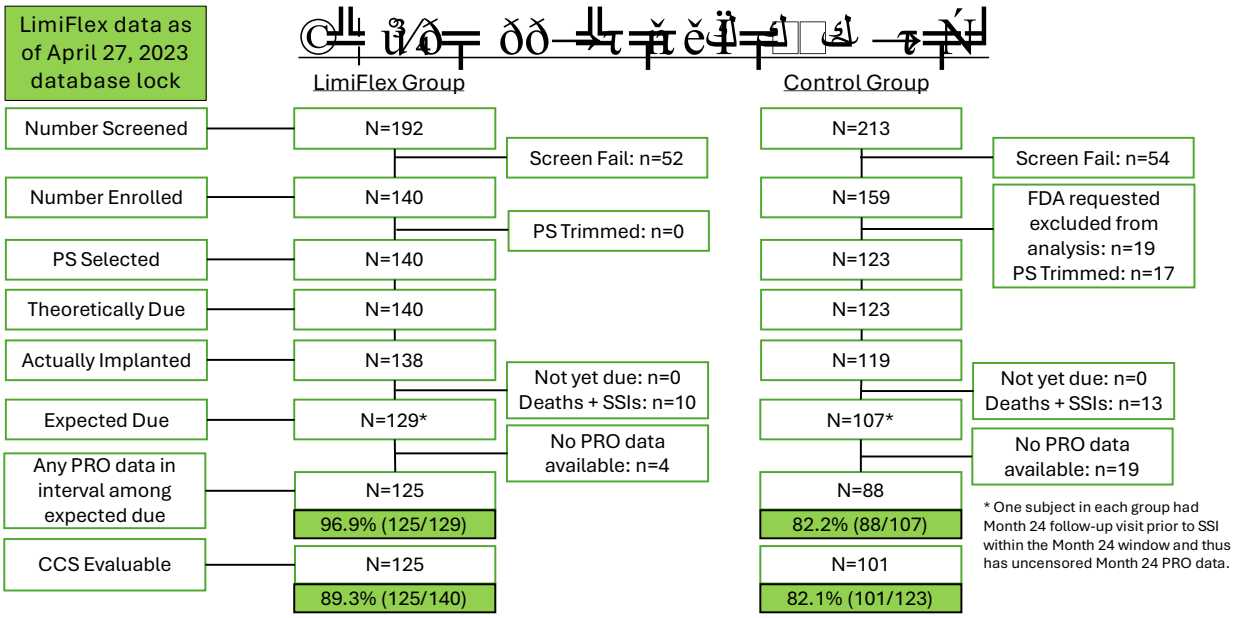


**Figure 3: Subject Accounting Tree**

## 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 7** 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 8** identifies gender, ethnicity and race demographics of investigational and control subjects.

**Table 7: Summary of Baseline and Demographic Continuous Variables ITT-PS Analysis Set**

| | Investigational | | | | | | Controls | | | | | | Investigational - Controls[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Demographics - All** | **N** | **Mean** | **SD** | **Med** | **Min** | **Max** | **N** | **Mean** | **SD** | **Med** | **Min** | **Max** | **Diff** | **LB** | **UB** |
| 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 ($k/m^2$) | 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 |
| **Demographics - Male** | **N** | **Mean** | **SD** | **Med** | **Min** | **Max** | **N** | **Mean** | **SD** | **Med** | **Min** | **Max** | **Diff** | **LB** | **UB** |
| 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 ($k/m^2$) | 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 |
| **Demographic - Female** | **N** | **Mean** | **SD** | **Med** | **Min** | **Max** | **N** | **Mean** | **SD** | **Med** | **Min** | **Max** | **Diff** | **LB** | **UB** |
| 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 ($k/m^2$) | 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 |
| **Baseline Functional Status** | **N** | **Mean** | **SD** | **Med** | **Min** | **Max** | **N** | **Mean** | **SD** | **Med** | **Min** | **Max** | **Diff** | **LB** | **UB** |
| 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 |

**Notes:**

[1] ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.

**Table 8: Summary of Baseline and Demographic Categorical Variables PS Selected Analysis Set**

| | Investigational | | | Controls | | | Investigational - Controls[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| | **N** | **n** | **% (n/N)** | **N** | **n** | **% (n/N)** | **Diff (%)** | **LB** | **UB** |
| **Males** | 140 | 59 | 42.1% | 123 | 37 | 30.1% | 5.3% | -9.9% | 20.6% |
| **Females** | 140 | 81 | 57.9% | 123 | 86 | 69.9% | | | |
| **Ethnicity** | 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% | | | |
| **Race** | 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% | | | |

**Notes:**
[1] 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 9** 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 9: Lumbar Spinal Stenosis Type and Severity**

| | Investigational (N=140) | | | Controls (N=123) | | |
|---|---|---|---|---|---|---|
| **Lumbar Spinal Stenosis Characterization** | | | | | | |
| **Central Canal Stenosis Severity** | **N** | **n** | **% (n/N)** | **N** | **n** | **% (n/N)** |
| 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[1] | | | | | 1 | |
| **Right Lateral Recess Stenosis Severity** | **N** | **n** | **%** | **N** | **n** | **%** |
| 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 | |
| **Left Lateral Recess Stenosis Severity** | **N** | **n** | **%** | **N** | **n** | **%** |
| 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 | |
| **Right Foraminal Stenosis** | **N** | **n** | **%** | **N** | **n** | **%** |
| Yes | 140 | 82 | 58.6 | 122 | 94 | 77.0 |
| No | 140 | 58 | 41.4 | 122 | 28 | 23.0 |
| N/A | | | | | 1 | |
| **Left Foraminal Stenosis** | **N** | **n** | **%** | **N** | **n** | **%** |
| Yes | 140 | 82 | 58.6 | 122 | 90 | 73.8 |
| No | 140 | 58 | 41.4 | 122 | 32 | 26.2 |
| N/A | | | | | 1 | |

**Notes:**
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 10** through **Table 16**. Adverse effects are reported in **Table 11** through **Table 15.**

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:
    a. resulted in a life-threatening illness or injury;
    b. resulted in a permanent impairment of a body structure or a body function;
    c. required in-patient hospitalization or prolongation of existing hospitalization;
    d. 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:
    a. Definite – The AE is clearly related to the investigational or control device or procedure;
    b. Probable – The AE is likely related to the investigational or control device or procedure;
    c. Possible – The AE may be related to the investigational or control device or procedure;
    d. Not Related – The AE is clearly not related to the investigational or control device or procedure;
    e. Unknown – Unable to determine the relationship based on all available information.
- AE Severity – The intensity of AEs was evaluated using the following criteria:
    a. Mild – noticeable to the patient but does not interfere with routine activity;
    b. Moderate – interferes with the patient's routine activity but responds to symptomatic therapy or rest;

c. 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 10** 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 10: Adverse Event Summary (ITT-PS Selected analysis set)**

| | Investigational | | | Controls | | | Investigational - Control[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| | (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 |
| **Adverse Events** | | | | | | | | | |
| 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 |
| **Serious Adverse Events** | | | | | | | | | |
| 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 |
| **Spinous Process Fracture** | | 24 | 17.1 | - | - | - | - | - | - |
| **Secondary Surgical Intervention[2]** | | 10 | 7.2 | | 13 | 10.9 | -3.7 | -10.8 | 3.4 |
| **Death** | | 0 | 0.0 | | 1 | 0.8 | - | - | - |

**Notes:**

[1] 95% binomial confidence interval without PS adjustment.

[2] 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 11** and **Table 12** 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 11: All Adverse Events (ITT-PS Selected analysis set)**

| | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| **Specific Adverse Event** | **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 |

| | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| **Specific Adverse Event** | **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** |
| Urinary Tract Infection | 6 | 6 | 4.3 | 3 | 3 | 2.4 | 1.8 | -2.5 | 6.2 |
| 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:**
[1] 95% binomial confidence interval without PS adjustment.

**Table 12: All Adverse Events (ITT-PS Selected analysis set) - continued**

| | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| **Specific Adverse Event** | **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 |
| Visual disturbances; specify includes glaucoma, cataract | 1 | 1 | 0.7 | 0 | 0 | 0.0 | 0.7 | -0.7 | 2.1 |

| | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| **Specific Adverse Event** | **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** |
| 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 |
| **Total counts** / subjects with at least 1 AE | **465** | 121 | | **436** | 104 | | | | |

**Notes:**
[1] 95% binomial confidence interval without PS adjustment.

Device-Related Adverse Events

**Table 13** 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 13: Device-Related Adverse Events (ITT-PS Selected analysis set)**

| | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| **Specific Adverse Event** | **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 |
| **Total counts** / subjects with at least 1 AE | **50** | 43 | | **40** | 32 | | | | |

**Notes:**
[1] 95% binomial confidence interval without PS adjustment.

Procedure-Related Adverse Events

**Table 14** 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 14: Procedure-Related Adverse Events (ITT-PS Selected analysis set)**

| | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| **Specific Adverse Event** | **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 |
| 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 |

| Specific Adverse Event | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| 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 |
| **Total counts** / subjects with at least 1 AE | **82** | 61 | | **109** | 63 | | | | |

**Notes:**
[1] 95% binomial confidence interval without PS adjustment.

Serious Adverse Events

**Table 15** 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 15: Serious Adverse Event (ITT-PS Selected analysis set)**

| Specific Adverse Event | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| 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 |

| Specific Adverse Event | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| 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 |
| 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 |

| Specific Adverse Event | Investigational (I) (N=140) | | | Controls (C) (N=123) | | | I vs C[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| | 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 |
| 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 |
| **Total counts** / subjects with at least 1 AE | **60** | 48 | | **64** | 39 | | | | |

**Notes:**
[1] 95% binomial confidence interval without PS adjustment.

Secondary Surgical Intervention

**Table 16** 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 16: 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 | |
| **LimiFlex Dynamic Sagittal Tether** | Removal | 1 (0.7%) | - | - | 1* (0.7%) | 1 (0.7%) | **3 (2.2%)** |
| | Revision | - | - | - | 1* (0.7%) | - | **1 (0.7%)** |
| | Reoperation | - | 1 (0.7%) | - | | 2 (1.4%) | **3 (2.2%)** |
| | Supplemental Fixation | - | - | 2* (1.4%) | 1* (0.7%) | 2 (1.4%) | **5 (3.6%)** |
| | **Total** | **1 (0.7%)** | **1 (0.7%)** | **2 (1.4%)** | **3 (2.2%)** | **5 (3.6%)** | **12 (8.7%)** |
| **TLIF** | Removal | - | - | - | - | - | **0** |
| | Revision | 1 (0.8%) | - | - | - | 2 (1.7%) | **3 (2.5%)** |
| | Reoperation | 1 (0.8%) | - | - | - | 1 (0.8%) | **2 (1.7%)** |
| | Supplemental Fixation | - | - | - | 2 (1.7%) | 7* (5.9%) | **9 (7.6%)** |
| | **Total** | **2 (1.7%)** | **0** | **0** | **2 (1.7%)** | **10 (8.4%)** | **14 (11.8 %)** |

* 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 17** through **Table 19.**

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 17** 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 17: Overall Success (ITT-PS Selected analysis set)**

| | Investigational | | | Controls | | | Investigational - Controls[4] | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | n | % | N | N | % | Diff (%) | LB[11] | UB |
| **(0) Implanted** | 140 | 138 | 98.6% | 123 | 119 | 96.7% | 0.5% | -1.9% | 2.9% |
| **(1) No Secondary Surgical Intervention[5]** | 138 | 128 | 92.8% | 119 | 106 | 89.1% | 3.2% | -5.4% | 11.7% |
| **(2) ODI Responder[6]** | 125 | 114 | 91.2% | 87 | 71 | 81.6% | 8.8% | -2.7% | 20.2% |
| **(3) Device Integrity[7]** | 114 | 112 | 98.2% | 88 | 83 | 94.3% | 1.2% | -2.3% | 4.7% |
| **(4) Neurological Success[8]** | 120 | 115 | 95.8% | 95 | 90 | 94.7% | 1.7% | -3.5% | 7.0% |

| | Investigational | | | Controls | | | Investigational - Controls[4] | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | n | % | N | N | % | Diff (%) | LB[11] | UB |
| **CCS - Multiple Imputation[9,10]** | **140** | **---** | **76.7%** | **123** | **---** | **64.6%** | **12.2%** | **-1.2%** | **25.5%** |
| **CCS - Completers[10]** | 125 | 96 | 76.8% | 101 | 60 | 59.4% | 12.2% | -1.0% | 25.4% |

**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 absence of a neurological deficit compared with baseline that is associated with device or procedure as determined by the CEC.

[2] 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.

[3] 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/m2), 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).

[4] The ATT estimated difference is weighted average of the PS subclass differences with Wi 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 $(1/(\Sigma W_i)^2) * \Sigma W_i^2 * var(diff_i)$, where $var(diff^i) = [p_{Ii} * (1-p_{Ii})]/W_i + [p_{Ci} * (1-p_{Ci})]/N_i$ and $p_{Ii}$ and $p_{Ci}$ are the observed proportions achieving Month 24 CCS in subclass i for Investigational and Control respectively. Wi is the number of subjects in the Investigational arm in subclass i when estimating ATT and Ni is the number of control subjects in subclass i.

[5] 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.

[6] ODI Responder is censored at SSI.

[7] 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.

[8] 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.

[9] 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.

[10] 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..

[11] 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 LB = -1.2% > -12.5% in the MI analysis, the Study Success criterion is achieved based on primary MI analysis.**

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 18**. 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 18: PS Selected Completers analysis set by PS Subclass and ITT-PS Selected analysis set using Multiple Imputations**

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

Notes:

[1] Includes LimiFlex and Control subjects with non-missing CCS.

[2] ATT weights (W) are the number of Investigational subjects per PS subclass.

[3] Fixed effect meta-analysis test for differences across subclasses in LimiFlex minus Control differences chi-square(df=4) = 6.59, p=0.155 ($I^2$ = 49.9%) indicating no significant subclass by treatment group interaction.

[4] 90% and 95% lower bounds of normal approximation confidence intervals. The standard error for the weighted analysis is equal to the square root of $(1/(\Sigma W_i)^2) * \Sigma W_i^2 * var(diff_i)$, where $var(diff_i) = [p_{Ii} * (1-p_{Ii})]/W_i + [p_{Ci} * (1-p_{Ci})]/N_i$ 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 Ni is the number of control subjects in subclass i.

[5] 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 18** 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 19** 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 19: Month 24 CCS[1] Primary Effectiveness Analysis in Per Protocol Analysis Set and in PP Completers[2] Average Treatment Effect on the Treated (ATT[3]) and CCS with Multiple Imputation**

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

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/m2), 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 Wi 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 $(1/(\sum Wi)2) * \sum Wi2 * var(diffi)$, where $var(diffi) = [pli*(1-pli)]/Wi + [pCi*(1-pCi)]/Ni$, and pli and pCi are the observed proportions achieving Month 24 CCS in subclass i for Investigational and Control respectively. Wi is the number of subjects in the Investigational arm in subclass i when estimating ATT and Ni 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 20**. 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 20: 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 |
|---|---|---|---|---|
| **0 days** | 0.0% | 0.0% | 0.0% | 0.0% |
| **Week 6** | 72.4% | 3.8% | 32.5% | 4.3% |
| **Month 3** | 89.1% | 2.7% | 53.6% | 4.6% |
| **Month 6** | 92.7% | 2.2% | 61.2% | 4.5% |
| **Month 12** | 96.4% | 1.6% | 71.0% | 4.2% |
| **Month 24** | 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 21**. 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 22**, 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 21: Baseline Work History (ITT-PS Selected analysis set)**

| | Investigational (N=140) | | Controls (N=123) | |
|---|---|---|---|---|
| **Current Work Status** | **n** | **% (n/N)** | **n** | **% (n/N)** |
| Working | 70 | 50.0 | 48 | 40.7 |
| Not working | 70 | 50.0 | 70 | 59.3 |
| N/A[1] | | | 5 | |
| **If working, specify:** | **n** | **%** | **n** | **%** |
| Full time | 48 | 68.6 | 34 | 70.8 |
| Part time | 22 | 31.4 | 14 | 29.2 |
| N/A | | | | |
| **If not working, specify:** | **n** | **%** | **n** | **%** |
| 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 |
| **If working, any restrictions due to back pain or neurogenic claudication/radiculopathic symptoms** | **n** | **%** | **n** | **%** |
| 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 | |
| **If working, how much physical activity is required:** | **n** | **%** | **n** | **%** |
| 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 |

**Note:**
[1] N/A = Not currently available.

**Table 22: 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 |
|---|---|---|---|---|
| **0** | 0.0% | 0.0% | 0.0% | 0.0% |
| **Week 6** | 64.3% | 5.7% | 20.8% | 5.8% |
| **Month 3** | 90.0% | 3.6% | 43.8% | 7.1% |
| **Month 6** | 92.9% | 3.1% | 62.5% | 7.0% |
| **Month 12** | 94.3% | 2.8% | 66.7% | 6.8% |
| **Month 24** | 96.2% | 2.4% | 68.9% | 6.7% |

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

**Table 23** 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 23: 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 |
| **Improvement in Leg/Hip Pain VAS**<br>Patients reporting ≥20mm improvement in VAS pain at Month 24 | 86.4%<br>(108/125) | 85.4%<br>(70/82) |
| **Improvement in Back Pain VAS**<br>Patients reporting ≥20mm improvement in VAS pain at Month 24 | 78.4%<br>(98/125) | 71.3%<br>(62/87) |
| **Improvement in Physical Function – ZCQ**<br>Decrease in ZCQ physical function ≥0.5 points at Month 24 | 86.3%<br>(107/124) | 78.6%<br>(55/70) |
| **Improvement in Symptom Severity – ZCQ**<br>Decrease in ZCQ symptom severity ≥0.5 points at Month 24 | 87.9%<br>(109/124) | 74.6%<br>(53/71) |
| **Patient Satisfaction – ZCQ**<br>ZCQ satisfaction score ≤2.5 at Month 24 | 92.0%<br>(115/125) | 88.8%<br>(71/80) |
| **SF-12 Physical Health Survey**<br>Maintenance or improvement of SF-12 physical health at Month 24 | 96.8%<br>(120/124) | 91.7%<br>(66/72) |
| **SF-12 Mental Health Survey**<br>Maintenance or improvement of SF-12 mental health at Month 24 | 68.5%<br>(85/124) | 68.1%<br>(49/72) |
| **Patient Satisfaction with Surgery**<br>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 24**, **Table 25**, and **Table 26** 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 24: Angular Motion in Degrees – Level of Implant (ITT-PS Selected analysis set)**

| | Investigational | | | | | | Control | | | | | | Investigational - Control[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |

**Notes:**
[1] ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.

**Table 25: Angular Motion in Degrees – Below Level of Implant (ITT-PS Selected Analysis Set)**

| | Investigational | | | | | | Control | | | | | | Investigational - Control[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |

**Notes:**
[1] ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.

**Table 26: Angular Motion in Degrees – Above Level of Implant (ITT-PS Selected Analysis Set)**

| | Investigational | | | | | | Control | | | | | | Investigational - Control[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |

**Notes:**
[1] 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 27**, **Table 28,** and **Table 29** 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 27: Translational Motion (mm) – Level of Implant (ITT-PS Selected analysis set)**

| | Investigational | | | | | | Control | | | | | | Investigational - Control[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |

**Notes:**
[1] ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.

**Table 28: Translational Motion (mm) – Below Level of Implant (ITT-PS Selected analysis set)**

| | Investigational | | | | | | Control | | | | | | Investigational - Control[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |

**Notes:**
[1] ATT PS subclass weighted device group differences and 95% confidence intervals (CI) for group differences.

**Table 29: Translational Motion (mm) – Above Level of Implant (ITT-PS Selected analysis set)**

| | Investigational | | | | | | Control | | | | | | Investigational - Control[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |

**Notes:**
[1] 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 30**, 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 30: Disc Angle in Degrees (ITT-PS Selected analysis set)**

| | Investigational | | | | | | Control | | | | | | Investigational - Control[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 |

**Notes:**
[1] 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 31** 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 31: MMI Qualitative Assessment of Spinous Process Fractures in the Investigational Group (ITT-PS Selected analysis set)**

| | Post Operative | | Week 6 | | Month 3 | | Month 6 | | Month 12 | | Month 24 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| At Level of Implant | 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 32: 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[1] | |
|---|---|---|---|---|---|
| | N | n | % (n/N) | LB | UB |
| **Composite Clinical Success** | 125 | 76 | 60.8% | 52.2% | 69.4% |
| **(0) Implanted** | 140 | 138 | 98.6% | 94.9% | 99.8% |
| **(1) No Secondary Surgical Intervention[2]** | 138 | 128 | 92.8% | 88.4% | 97.1% |
| **(2) ODI Responder[3]** | 125 | 114 | 91.2% | 86.2% | 96.2% |
| **(3) Device Integrity[4]** | 114 | 112 | 98.2% | 93.8% | 99.8% |
| **(4) Neurological Success[5]** | 120 | 115 | 95.8% | 92.3% | 99.4% |
| **(5) Absence of Spinous Process Fracture** | 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 33** 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 33** below.

**Table 33: Primary Endpoint and Patient Reported Outcome Component Success Stratified by Presence or Absence of Spinous 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[1] | UB[1] |
| **Composite Clinical Success** | 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[2] | 23 | 22 | 95.7 | 115 | 106 | 92.2 | 3.5 | -4.6 | 11.6 |
| (2) ODI Responder[3] | 22 | 20 | 90.9 | 103 | 94 | 91.3 | -0.4 | -11.4 | 10.7 |
| (3) Device Integrity[4] | 21 | 21 | 100.0 | 93 | 91 | 97.8 | 2.2 | | |
| (4) Neurological Success[5] | 22 | 21 | 95.5 | 98 | 94 | 95.9 | -0.5 | -8.5 | 7.5 |
| **Pain** | | | | | | | | | |
| VAS Back: ≥ 20mm decrease[3] | 22 | 18 | 81.8 | 103 | 80 | 77.7 | | | |
| VAS Leg (Worst Side): ≥ 20mm decrease | 22 | 21 | 95.5 | 103 | 87 | 84.5 | | | |
| **Back and Stenosis-Related Outcomes** | | | | | | | | | |
| ZCQ Physical Function: ≥ 0.5 point decrease[3] | 22 | 20 | 90.9 | 102 | 87 | 85.3 | | | |
| ZCQ Patient Satisfaction: ≤ 2.5 points[3] | 22 | 22 | 100.0 | 103 | 93 | 90.3 | | | |
| ZCQ Symptom Severity: ≥ 0.5 point decrease[3] | 22 | 19 | 86.4 | 102 | 90 | 88.2 | | | |
| **Disability** | | | | | | | | | |
| ODI: ≥ 15 point decrease[3] | 22 | 20 | 90.9 | 103 | 94 | 91.3 | | | |

**Notes:**
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.

3. Subgroup Analyses

The study was not specifically powered for any subgroup analyses.

4. Pediatric Extrapolation

In this premarket application, existing clinical data were not leveraged to support approval of a pediatric patient population.

## XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included investigators of which none were full-time or part-time employees of the sponsor and two had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: None
- Significant payment of other sorts: None
- Proprietary interest in the product tested held by the investigator: 1 sub-investigator
- Significant equity interest held by investigator in sponsor of covered study: 1 sub-investigator

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. None of the principal investigators had financial conflicts of interest to report. Only one sub-investigator had a conflict of interest. The information provided does not raise any questions about the reliability of the data.

## XII. PANEL MEETING RECOMMENDATION AND POST-PANEL ACTION

In accordance with the provisions of section 515(c)(2) of the Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Orthopaedic and Rehabilitation Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

## XIII. CONCLUSIONS DRAWN FROM THE PRE-CLINICAL AND CLINICAL STUDIES

### A. Effectiveness Conclusions

A total of 140 investigational subjects and 159 control subjects were enrolled in this clinical trial. Per FDA feedback, data from one control site was excluded from analysis (19 control subjects), resulting in 280 subjects (140 investigational; 140 control) that were assessed via the PS sub-classification process. The ITT-PS Selected analysis set consisted of 140 investigational subjects and 123 control subjects that were PS-selected.

The ITT-PS Selected analysis set was used to test the non-inferiority hypothesis in this study.

Overall success was defined based on a primary composite endpoint which included the following components: 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; and, absence of device integrity failures, defined as device breakage, device separation or disassembly, or device dislocation over the initial 24 months post-treatment.

The overall success rate for the investigational group was 76.7% as compared to a success rate of 64.6% for the control group at Month 24, using MI. Based upon the 95% confidence interval, the results achieved study success in demonstrating non-inferiority. Considering the PP analysis set (i.e. excluding subjects with major protocol violations), the success rate for the investigational group was 78.4% as compared to the success rate of 61.6% in the control group at Month 24, further supporting the non-inferiority claim.

In conclusion, the study data suggests that at Month 24, the LimiFlex Dynamic Sagittal Tether is at least as effective as the fusion control, for the patient population and indications studied in this investigation, in terms of overall success according to the primary composite endpoint and provides a reasonable assurance of effectiveness.

## B. Safety Conclusions

In the ITT-PS Selected analysis set, 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).

In conclusion, the clinical study results demonstrate that the Limiflex Dynamic Sagittal Tether is at least as safe as the fusion control, for the patient population and indications studied, and provides a reasonable assurance of safety.

## C. Benefit-Risk Determination

The probable benefits and risks of the LimiFlex Dynamic Sagittal Tether are also based on data collected in the clinical study conducted to support PMA approval. The clinical

study results demonstrated several benefits and risks of the investigational device through Month 24 as described in **Table 34** below.

**Table 34: LimiFlex Dynamic Sagittal Tether Observed Benefits and Risks**

| | Specific Benefit / Risk | Data Supporting Benefit / Risk |
|---|---|---|
| **Design Benefits** | Dynamic Flexion-restricting Stabilization and Maintenance / Restoration of Motion | Mean pre-op angular motion at the level of implant for the investigational and control groups were 5.75˚ and 5.61˚, respectively. At Month 24, mean angular motion for the investigational and control groups were 4.35˚ and 1.69˚, respectively. |
| | | Mean pre-op translational motion for the investigational and control groups was 1.3mm, and 1.25mm, respectively. At Month 24, the mean translational motion for the investigational and control groups was 0.98 mm, and 0.27 mm, respectively. |
| **Treatment Benefits** | Maintenance of Improvement in Pain and Function | 91.2% of investigational subjects experienced a clinically meaningful improvement from baseline (defined as a ≥15-point decrease in ODI) at Month 24, compared to 81.6% of control subjects. |
| | | 78.4% of investigational subjects experienced a clinically meaningful improvement in back pain from baseline (defined as a ≥20 mm decrease in VAS Back) at Month 24, compared to 71.3% of control subjects. |
| | | 86.4% of investigational subjects experienced a clinically significant improvement in leg/hip pain from baseline (defined as a ≥20 mm decrease in VAS worst leg) at Month 24, compared to 85.4% of control subjects. |
| | Improved Quality of Life | 86.3% of investigational subjects experienced a decrease in ZCQ Physical Function of at least 0.5 points at Month 24, compared to 78.6% of control subjects.<br><br>87.9% of investigational subjects experienced a decrease in ZCQ Symptom Severity of at least 0.5 points at Month 24, compared to 74.6% of control subjects.<br><br>92.0% of investigational subjects experienced a ZCQ Satisfaction score less than or equal to |

| | Specific Benefit / Risk | Data Supporting Benefit / Risk |
|---|---|---|
| | | 2.5 at Month 24, compared to 88.8% of control subjects. |
| | | 96.8% of investigational subjects experienced maintained or improved physical health via SF-12 Physical Health Survey at Month 24, compared to 91.7% of control subjects.<br><br>68.5% of investigational subjects experienced maintained or improved mental health via SF-12 Mental Health Survey at Month 24, compared to 68.1% of control subjects. |
| | | >90% of investigational and control subjects reported satisfaction with surgery at all timepoints when asked "Are you satisfied with your surgery?" |
| **Risks** | Removal, Revision, Reoperation, Supplemental Fixation | A total of 10 subjects (7.2%, 10/138) had SSIs in the Investigational group, while thirteen subjects (10.9%, 13/119) had SSIs in the control group through Month 24. |
| | Device Breakage, separation, disassembly, dislocation | At Month 24, 112 out of 114 (98.2%) of investigational devices did not have device integrity failures, compared to 83 out of 88 (94.3%) of devices in the control group. |
| | Device-Related Adverse Events | Investigational subjects were assessed to have a 30.7% rate of device-related AEs (50 events in 43/140 subjects) as compared to 26.0% of control subjects (40 events in 32/123 subjects).<br><br>Investigational subjects were assessed to have a 11.4% rate of device-related SAEs (16 events in 16/140 subjects) as compared to 13.0% of control subjects (16 events in 16/123 subjects). |
| | Neurological Deterioration | At Month 24, 95.8% (115/120) of Investigational subjects were determined to have neurological status success compared to 94.7% (90/95) of control subjects. |
| | Spinous Process Fractures | The core lab identified a total of 24 spinous process fractures through Month 24 for a rate of 17.1% (24/140) of subjects with spinous process fractures identified at any time through Month 24. |

In conclusion, given the available information above, the data support that, 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 where 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, the probable benefits of the LimiFlex Dynamic Sagittal Tether outweigh the probable risks to health through Month 24.

1. Patient Perspective

   Patient perspectives considered for the LimiFlex Dynamic Sagittal Tether included results from ODI, VAS, ZCQ, SF-12 PCS, and SF-12 MCS questionnaires and patient-reported return to ADL and RTW as described above. These patient-reported outcomes were considered as part of the benefit-risk assessment for the subject device, and as noted above, a greater proportion of subjects in the investigational group reported improved pain, function, disability, return to ADL and RTW post-treatment as compared to subjects in the fusion control group.

## D. Overall Conclusions

The non-clinical and clinical data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. Based on the clinical study results, it is reasonable to conclude that the clinical benefits associated with the use of the LimiFlex Dynamic Sagittal Tether in terms of improvement of pain and disability, outweigh the risks, both in terms of the device and surgical procedure when used in the indicated population in accordance with the instructions for use, and as compared to the fusion control treatment in the same indicated population.

# XIV. CDRH Decision

CDRH issued an approval order on February 12, 2026. The final clinical conditions of approval are described below.

*The LimiFlex Dynamic Sagittal Tether™ Continued Follow-Up Study*: Based on the protocol outline received October 21, 2025, this PAS is intended to evaluate the longer-term device integrity and survival of the LimiFlex Dynamic Sagittal Tether™, the maintained success in prevention or delay of adjacent level degenerative disease, the stability of the degenerative spondylolisthesis, analysis of further occurrence and significance of spinous process fractures, and the reduction of spinal stenosis symptoms in n=124 LimiFlex Dynamic Sagittal Tether™ subjects in the Intent-to-Treat, Propensity Score Selected (ITT-PS Selected) analysis population who were enrolled in the pivotal study. Subjects will

be followed 60 months from the time of each subject's index surgery (Month 60).

The primary safety endpoints are serious adverse events (SAEs), and device- or procedure-related Adverse Events (AEs). Additional safety analyses will include the rate of AEs, including by relatedness to device or procedure and severity (mild, moderate, or severe), time-to-event, including mean and ranges if applicable, and Subsequent Surgical Intervention (SSI) by rate and type.

The primary effectiveness endpoint is a composite clinical success (CCS) responder endpoint based on clinical status at Month 60. An individual subject will be regarded as achieving Month 60 CCS only if they meet all of the following criteria at Month 60 compared to baseline:

1. Improvement of at least 15 points (100-point scale) on the Oswestry Disability Index (ODI) from baseline compared to Month 60.

2. Absence of a decrease in neurologic status (motor or sensory) at Month 60 compared to baseline unless attributable to a concurrent medical condition or other cause unrelated to the device and/ or study procedure.

3. 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, through Month 60.

4. Absence of device integrity failures, defined as device breakage, device separation or disassembly, or device dislocation, through Month.

In addition, at Month 60, individual subjects will be assessed for the following endpoints:

1. No occurrence of any spinous process fractures through Month 60.

2. No occurrence of a major device-related adverse event through Month 60.

The data presentation and statistical analyses will be conducted using observed data on a minimum of 85% follow-up of the pivotal study cohort at 36-months, 48-months, and 60-months post-implantation.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820), which

was in effect at the time of the inspection. As of February 2, 2026, the revised part 820, referred to as the Quality Management System Regulation (QMSR), is effective.

## XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.