Boston Scientific

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# Superion™ Indirect Decompression System

## Instructions for Use

℞ ONLY CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

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## Guarantees

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## Warranty

For device warranty information, visit (www.bostonscientific.com/warranty).

## For Further Information

All trademarks are the property of their respective holders.

## Product Model Numbers

| Model Number | Description |
|---|---|
| 101-9808 | Superion Implant, 8 mm |
| 101-9810 | Superion Implant, 10 mm |
| 101-9812 | Superion Implant, 12 mm |
| 101-9814 | Superion Implant, 14 mm |
| 101-9816 | Superion Implant, 16 mm |

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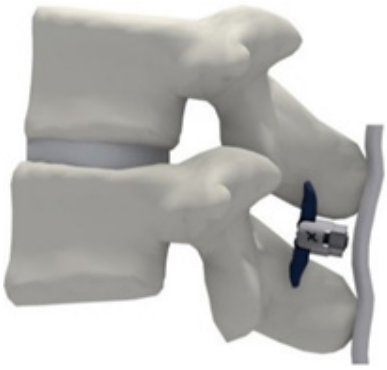
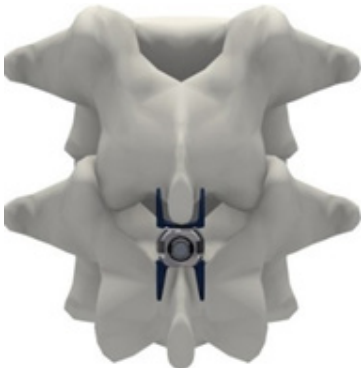
## DEVICE DESCRIPTION

The Superion™ Indirect Decompression System (Superion IDS) is a titanium implant designed to fit between the spinous processes of the lumbar spine. It is composed of titanium 6Al-4V ELI alloy, and consists of a single component with deployable superior and inferior projections that engage the spinous processes to secure it in place dorsal to the lamina. The Superion IDS is provided sterile in sizes of 8 mm, 10 mm, 12 mm, 14 mm, and 16 mm. The Superion IDS is implanted by percutaneous means through a cannula inserted between adjacent spinous processes. Once inserted into the interspinous process space the Superion IDS is deployed, or opened, to provide distraction and restrict extension at the affected spinal segment.



Superion Implant in situ – Lateral View



Superion Implant in situ – A/P View

The Superion IDS system includes a set of proprietary instruments to deliver the Superion Implant minimally invasively. Instruments specifically designed for implanting the Superion Implant are sterile, single-use disposable instruments consisting of a dilator assembly, a cannula assembly, an interspinous gauge, an inserter, a reamer, and a driver. Refer to the Superion Surgical Technique Manual for comprehensive instructions on instrument use.

**CAUTION***: The Superion IDS is manufactured from titanium alloy, which is known to produce MRI artifacts. Patients should be warned to disclose the presence of the Superion IDS prior to an MRI exam. Failure to do so may affect the quality of diagnostic information obtained from the scans.*

## PACKAGE CONTENTS

| Description | Quantity |
|---|---|
| Superion IDS, xx mm<br>xx = length | 1 |

## INDICATIONS FOR USE

The Superion Indirect Decompression System is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superion IDS is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, with or without back pain, who have undergone at least 6 months of non-operative treatment. The Superion IDS may be implanted at one or two adjacent lumbar levels in patients in whom operative treatment is indicated at no more than two levels, from L1 to L5.

For this intended use, Moderate Degenerative Lumbar Spinal Stenosis was defined as follows:

- 25% to 50% reduction in the central canal and/or nerve root canal (subarticular, neuroforaminal) compared to the adjacent levels on radiographic studies, with radiographic confirmation of any one of the following:
  - Evidence of thecal sac and/or *cauda equina* compression
  - Evidence of nerve root impingement (displacement or compression) by either osseous or non-osseous elements
  - Evidence of hypertrophic facets with canal encroachment
- AND Associated with the following clinical signs:
  - Presents with moderately impaired Physical Function (PF) defined as a score of ≥ 2.0 of the Zurich Claudication Questionnaire (ZCQ)
  - Ability to sit for 50 minutes without pain and to walk 50 feet or more.

## CONTRAINDICATIONS

The Superion™IDS is contraindicated in patients with:

- an allergy to titanium or titanium alloy;

- spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as:
  - instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4);
  - an ankylosed segment at the affected level(s);
  - fracture of the spinous process, *pars interarticularis*, or laminae (unilateral or bilateral);
  - scoliosis (Cobb angle >10 degrees);
- *Cauda equina* syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction;
- diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or equivalent method) in the spine or hip that is more than 2.5 S.D. below the mean of adult normals;
- active systemic infection, or infection localized to the site of implantation;
- prior fusion or decompression procedure at the index level;
- morbid obesity defined as a body mass index (BMI) greater than 40.

## WARNINGS

The Superion IDS must be placed in the concavity between the spinous processes. If correct placement of the implant cannot be achieved due to variant anatomy, the physician should consider aborting the procedure because incorrect placement may result in device dislodgement, particularly if the patient experiences a traumatic event postoperatively.

The Superion IDS should only be used by physicians who are experienced and have undergone training in the use of the device. Only physicians who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the Superion IDS should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events.

Data have demonstrated that spinous process fractures can occur with Superion IDS implantation. Potential predictors for spinous process fractures include:

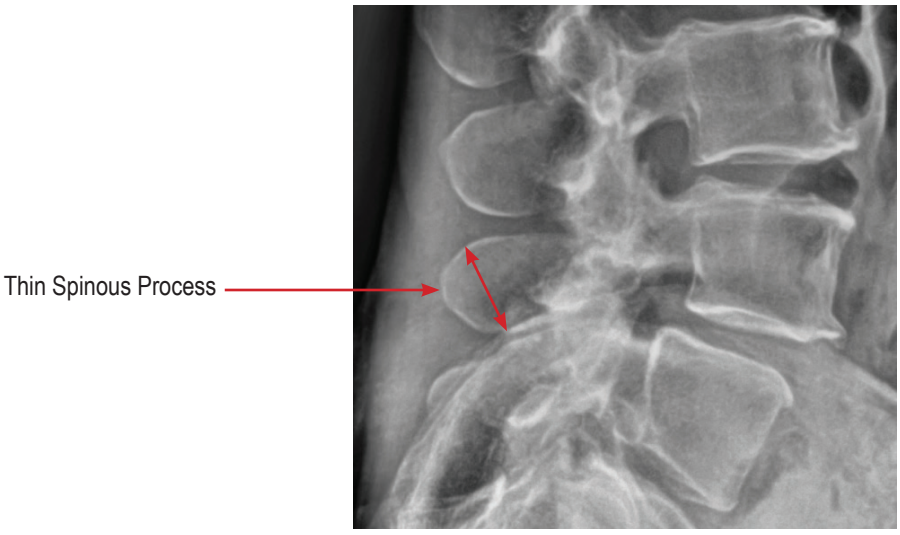
- thin, or “gracile” spinous processes
- kissing” spinous processes
- shallow or more dorsal placement of the device

**Anatomical Considerations**

Certain anatomical characteristics have been associated with an increased risk of spinous process fractures, while others may increase the difficulty of cannula and Implant placement.

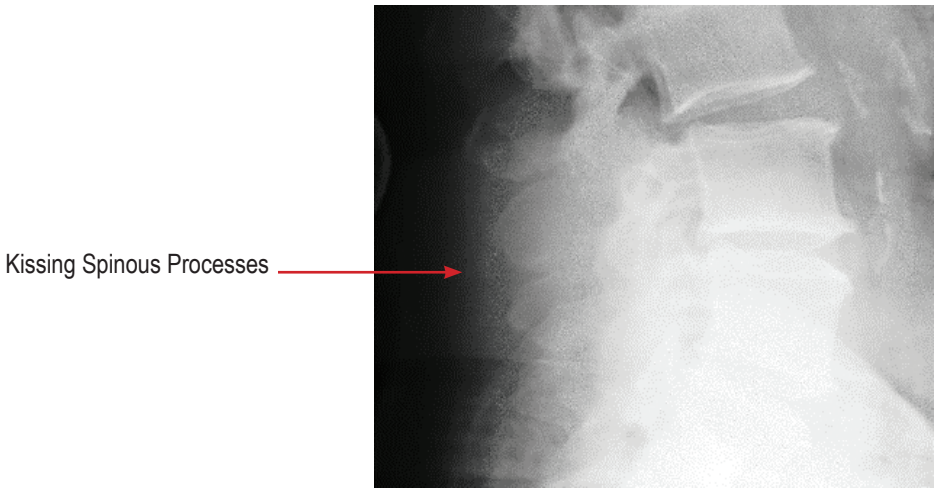
**Thin, or “gracile” Spinous Processes**

Where a spinous process is unusually thin, or measures less than 20 mm in superior-inferior dimension, the likelihood of a post-operative spinous process fracture may be increased.



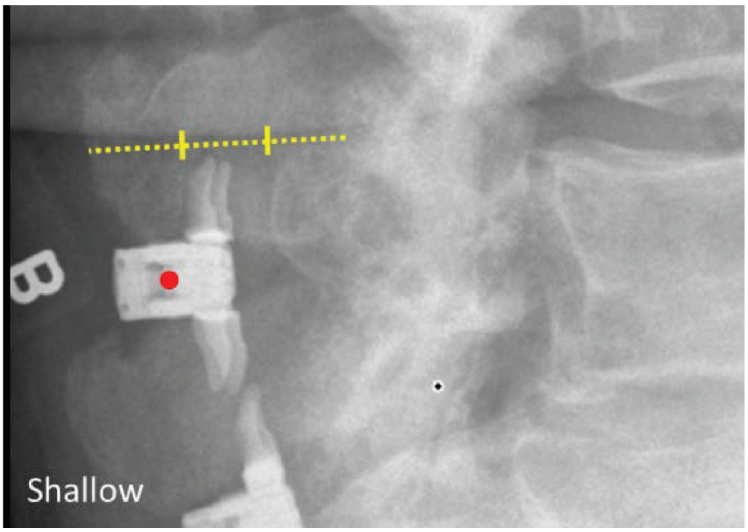
**"Kissing Spine"**

Where spinous processes are in very close approximation, or are in contact (i.e., "kissing"), increased difficulty may be experienced in placement of the cannula. Where spinous processes do not "open up" in flexion, the likelihood of a spinous process fracture may be increased.

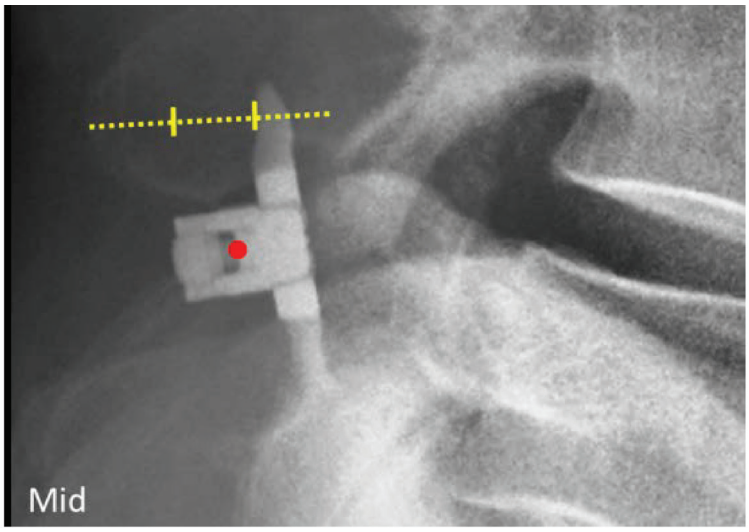



**Implant Placement Location**

Where the Superion™ Implant is placed in a "shallow" or more dorsal position, the likelihood of a post-operative spinous process fracture may increase by a factor >4. To reduce the potential for post-operative fracture, be certain to locate the implant body against the spinolaminar junction, and confirm implant position fluoroscopically.




Incorrect: Shallow Implant Position




Optimal: Implant Position

**PRECAUTIONS**

- Radiological evidence of stenosis must be correlated with the patient's symptoms before the diagnosis can be confirmed.
- If the spinous processes at the affected levels are not distracted in flexion, the Superion™ IDS may not be indicated.
- The safety and effectiveness of the Superion IDS has not been studied in patients with the following conditions: axial back pain without leg, buttock, or groin pain; symptomatic lumbar spinal stenosis at more than two levels; prior lumbar spine surgery; significant peripheral neuropathy; acute denervation secondary to radiculopathy; Paget's disease; vertebral metastases; morbid obesity; pregnancy; a fixed motor deficit; angina; active rheumatoid arthritis; peripheral vascular disease; advanced diabetes; or other systemic disease that may affect the patient's ability to walk.
- Implantation of the Superion IDS should be performed only by qualified and experienced spinal physicians having specific training in the implantation of the device, because this is a technically demanding procedure presenting risk of serious injury to the patient.
- Clinicians should not implant the Superion IDS until receiving adequate training in surgical technique. Inadequate training may result in poor outcomes and/or increased rates of adverse events.

- Spinous process fractures have been reported with this device type. Avoiding strenuous activity in the immediate postoperative period may be advisable.

**Potential Adverse Events**

The following potential adverse events may occur as a result of interspinous process decompression with the Superion IDS:

1. Risks associated with any surgical procedure include: anesthetic medication reactions; blood loss, blood vessel damage, phlebitis or hematoma; blood transfusion which may cause circulatory collapse, blood incompatibility, kidney damage, hepatitis or infection with HIV; myocardial infarction or circulatory problems; deep vein thrombosis, pulmonary embolism or thrombus formation in other vessels; stroke; fever or infection; pneumonia; injury to muscle, soft tissue or nerves; wound swelling, drainage or delayed healing; discomfort and rehabilitation associated with recovery from surgery; inability to perform certain tasks, such as lifting or exercise; and death.
2. Risks associated with lumbar spine surgery include: damage to nerve roots or the spinal cord causing partial or complete sensory or motor loss (paralysis); loss of bladder and/or bowel functions; dural leaks (tears in the tissue surrounding and protecting the spinal cord); instruments used during surgery may break or malfunction which may cause damage to the operative site or adjacent structures; fracture, damage or remodeling of adjacent anatomy, including bony structures or soft tissues during or after surgery; new or worsened back or leg pain; and surgery at the incorrect location or level.
3. Risks associated with lumbar spine implants and associated instruments include: sensitivity or allergy to the implant material; failure of the device/procedure to improve symptoms and/or function; pain and discomfort associated with the operative site or presence of implants; implant malposition or incorrect orientation; spinous process fracture; production of wear debris which may damage surrounding soft tissues including muscle or nerve; formation of scar tissue at implant site; migration or dislodgement of the implant from the original position so that it becomes ineffective or causes damage to adjacent bone or soft tissues including nerves; loosening, fatigue, deformation, breakage or disassembly of the implant, which may require another operation to remove the implant and may require another method treatment.
4. Risks specifically associated with the Superion IDS include deformation, breakage or disassembly of the implant, and spinous process fracture.

**CLINICAL STUDY**

Vertiflex™ performed a clinical study to determine a reasonable assurance of safety and effectiveness of the Superion IDS for the treatment of moderate degenerative lumbar spinal stenosis in the US under IDE #G070118. Data from this clinical study were the basis of the PMA approval decision. A summary of the clinical study is presented below.

***A. Study Design***

Patients were treated between June 2008 and December 2011. The database for this PMA reflected data collected through July 7, 2014 and included 470 patients. There were 31 investigational sites.

The study was a prospective, multi-center, single-blinded, randomized controlled clinical trial comparing the Superion™ IDS to a control group consisting of the X-STOP® IPD, a legally marketed alternative with similar indications for use. The study evaluated use of the Superion IDS in the treatment of subjects aged 45 or older suffering from moderate symptoms of neurogenic intermittent claudication, secondary to a confirmed diagnosis of moderate degenerative lumbar spinal stenosis (LSS) at one or two contiguous levels from L1 to L5, i.e., from the L1-L2 level to the L4-L5 level. A maximum of 35 investigative sites in the U.S. and up to 10 sites outside the U.S. were approved to enroll subjects into the trial using a 1:1 randomization assignment and an adaptively selected sample size ranging from 250 to 350 subjects (125 to 175 enrolled into each group) using a Bayesian adaptive design. Up to an additional 50 subjects (25 per group) could be enrolled to allow for loss to follow-up. In addition, prior to initiating the randomized trial, clinical sites were permitted to enroll up to 2 non-randomized subjects to receive the Superion IDS. A maximum of 70 such additional Superion IDS “training” cases were built into the protocol. Thus, a maximum of 470 subjects were approved to be enrolled into the study. If the study requirements outlined in the Statistical Analysis Plan were met prior to enrolling 470 subjects, the study enrollment could be stopped and the PMA application could subsequently be submitted early.

An investigative site was defined as a facility or facilities in the same general geographic location if they are under the control of a local Institutional Review Board (IRB).

All adverse events (device-related or not) were monitored over the course of the study and radiographic assessments were reviewed by an independent core laboratory. Overall success was determined by data collected during the initial 24 months of follow-up. All device-related adverse events, major procedure-related, and adjacent level-related adverse events and therapeutic failures reported by the clinical investigators were independently adjudicated (for adverse event code, severity and relationship to the device and/or procedure) by a Clinical Events Committee (CEC) composed of three independent spine surgeons. In addition, adverse events reported as having unknown or undetermined relationships to the device by the clinical investigators were to be adjudicated by the CEC.

After implantation of the Superion IDS or the X-STOP IPD device, each investigator provided a postoperative care regimen individualized to the specific needs of each subject. The regimen included but was not limited to: medications, a corset or brace, acupuncture, traction, physical therapy, chiropractic treatment, use of a TENS unit, and massage therapy.

Subjects were required to complete a VAS questionnaire to evaluate pain status at discharge following the index procedure. At each follow-up visit, subjects were interviewed to determine if they had experienced adverse events (AEs) since the previous follow-up visit. A neurological assessment was performed for all subjects at baseline and at all follow-up visits. All subjects were required to complete the Zurich Claudication Questionnaire (ZCQ), Oswestry

Disability Index (ODI), Visual Analog Scale (VAS), SF-12 and the Vertiflex™ Superion Patient Satisfaction questionnaires to evaluate disability, function, pain, quality of life, and satisfaction at each follow-up visit.

This clinical study was designed as a Bayesian adaptive trial with a minimum of 250 evaluable subjects and a maximum of 350 evaluable subjects, with an additional adjustment for loss-to-follow-up of 15%. The final sample size in the randomized mITT population consisted of 190 Superion IDS and 201 X-STOP IPD control subjects (391 total subjects). The primary hypothesis of this randomized controlled trial was that the clinical performance of the Superion IDS is non-inferior to the clinical performance achieved with the active control. The study endpoint was the rate of overall subject success at 24 months. A subject was considered a success if they were a success on each of the four individual primary outcome criteria. The hypotheses tested for this primary study endpoint are as follows: $H_0$: Superion IDS overall success rate is inferior (Superion IDS rate – Control rate < $-\Delta$); $H_A$: Superion IDS overall success rate is non-inferior (Superion IDS rate – Control rate ≥ $-\Delta$).

A Bayesian approach was used to test for non-inferiority. If the posterior probability of the alternative hypothesis was at least 95.8%, using non-informative uniform (Beta [1,1]) priors for each success rate then the claim of non-inferiority would be made. The choice of non-inferiority margin, Δ (i.e., delta) was 10% for the overall subject success rate. The value of 0.958 was selected to control the type I error of this design (type 1 error less than 0.05).

An adaptive sample size approach was used to allow for modifications based on interim results, with a maximum of 350 evaluable subjects and a minimum of 250 subjects. The operating characteristics of the adaptive design demonstrate 86.3% power when the Superion IDS group was superior to the X-STOP IPD control group by 5% and 73.6% power when the advantage is 2.5%. In these calculations, the X-STOP IPD was assumed to have a 65% success rate.

**1. Clinical Inclusion and Exclusion Criteria**

Enrollment in the Superion IDS study was limited to subjects who met the following inclusion criteria:

1. Male or female subjects ≥ 45 years of age.
2. Persistent leg/buttock/groin pain, with or without back pain, that is relieved by flexion activities (example: sitting or bending over a shopping cart)
3. Subjects who have been symptomatic and undergoing conservative care treatment for at least 6 months.
4. Diagnosis of degenerative spinal stenosis of the lumbar spine, defined as the narrowing of the midline sagittal spinal canal (central) and/or narrowing between the facet superior articulating process (SAP), the posterior vertebral margin (lateral recess), and the nerve root canal (foraminal).
5. Radiographic confirmation of at least moderate spinal stenosis which narrows the central, lateral, or foraminal spinal canal at one or two contiguous levels from L1-L5. Moderate spinal stenosis is defined as 25% to 50% reduction in lateral/central foramen compared to the adjacent levels, with radiographic confirmation of any one of the following:
    a. Evidence of thecal sac and/or cauda equina compression
    b. Evidence of nerve root impingement (displacement or compression) by either osseous or non-osseous elements
    c. Evidence of hypertrophic facets with canal encroachment

***Note:*** *All imaging studies used to confirm LSS were completed within 3 months prior to enrollment. Radiographic (imaging) confirmation of LSS included MRI and/or CT. In the case of a transitional L5/L6 segment with a sufficiently prominent L6 spinous process, these subjects were included by a deviation request from Vertiflex.*

6. Must present with moderately impaired Physical Function (PF) defined as a score of ≥ 2.0 of the Zurich Claudication Questionnaire (ZCQ)
7. Must be able to sit for 50 minutes without pain and to walk 50 feet or more
8. Subjects who are able to give voluntary, written informed consent to participate in this clinical investigation and from whom consent has been obtained
9. Subjects, who, in the opinion of the Clinical Investigator, are able to understand this clinical investigation, cooperate with the investigational procedures and are willing to return for all the required post-treatment follow-ups.

Subjects were not permitted to enroll in the Superion IDS study if they met any of the following exclusion criteria:

1. Axial back pain only
2. Fixed motor deficit
3. Diagnosis of lumbar spinal stenosis which requires any direct neural decompression or surgical intervention other than those required to implant the control or investigational device
4. Unremitting pain in any spinal position
5. Significant peripheral neuropathy or acute denervation secondary to radiculopathy
6. Lumbar spinal stenosis at more than two levels determined pre-operatively to require surgical intervention
7. Significant instability of the lumbar spine as defined by ≥ 3mm translation or ≥ 5° angulation
8. Sustained pathologic fractures of the vertebrae or multiple fractures of the vertebrae and/or hips
9. Spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4)
10. Spondylolysis (pars fracture)
11. Degenerative lumbar scoliosis with a Cobb angle of > 10° at treatment level

12. Osteopenia or osteoporosis. To confirm eligibility, at the Clinical Investigator's discretion, the following subjects may have a DEXA scan performed:
    - Women 65 or older
    - Postmenopausal women < age 65
    - Subjects with major risk factors for or diagnosed with osteoporosis or osteopenia
        - If DEXA is required, exclusion is defined as a DEXA bone density measurement T score ≤ -2.5
13. Morbid obesity, defined as Body Mass Index (BMI) greater than 40kg/$m^2$
14. Insulin-dependent diabetes mellitus
15. Significant peripheral vascular disease (diminished dorsalis pedis or tibial pulses)
16. Prior surgery of the lumbar spine
17. *Cauda equina* syndrome (defined as neural compression causing neurogenic bowel or bladder dysfunction)
18. Infection in the disc or spine, past or present
19. Evidence of active (systemic or local) infection at time of surgery
20. Active systemic disease such as AIDS, HIV, hepatitis, etc.
21. Paget's disease at involved segment or metastasis to the vertebra, osteomalacia, or other metabolic bone disease
22. Currently undergoing immunosuppressive therapy or long-term steroid use
23. Known allergy to titanium or titanium alloys
24. Tumor in the spine or a malignant tumor except for basal cell carcinoma
25. Known or suspected history of alcohol and/or drug abuse
26. Prisoner or transient
27. Life expectancy less than two years
28. Angina, active rheumatoid arthritis, or any other systemic disease that would affect the subject's welfare or outcome of the clinical investigation
29. Any significant mental illness (e.g., major depression, schizophrenia, bipolar disorder, etc.) that could impair the consent process or ability to complete subject self-report questionnaires
30. Involved in pending litigation of the spine or worker's compensation related to the back
31. Enrolled in the treatment phase of another drug or device clinical investigation (currently or within past 30 days)
32. Congenital defect of the spine
33. Pregnant or lactating

**2. Follow-up Schedule**

All subjects were scheduled to return for follow-up examinations at 6 weeks (± 2 weeks), 3 months (± 2 weeks), 6 months (± 1 month), 12 months (± 2 months), 18 months (± 2 months), 24 months (± 2 months) post-treatment and annually thereafter to collect data for the primary evaluation of safety and effectiveness.

The evaluations performed in relation to the index procedure pre-operatively, as well as the assessments performed which were used to assess the endpoints post-operatively, are shown in Table 1. To reflect extended follow-up associated with post-market requirements, the Table has been revised to reflect the visit schedule through 60 months. Adverse events were recorded at all visits.

**Table 1: Follow-Up Visit Schedule**

| | Screening Baseline | Surgical Treatment | Discharge (±0-7 days) | 6-week (±2 weeks) | 3-month (±2 weeks) | 6-month (±1 month) | 12-month (±2 months) | 18-month (±2 months) | 24-month[c] (±2 months) | 36-month[c] (±2 months) | 48-month[c] (±2 months) | 60-month[c] (±2 months) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Study Visit Window** | | Day 0 | 0-7 days | 4-8 wks | 10-14 wks | 5-7 mos | 10-14 mos | 16-20 mos | 22-26 mos | 22-26 mos | 22-26 mos | 22-26 mos |
| Signed Informed Consent | X | | | | | | | | | | | |
| Demographic Information | X | | | | | | | | | | | |
| Complete History & Physical | X | | | | | | | | | | | |
| Randomization | X | | | | | | | | | | | |
| Standing AP & Lateral Lumbar Spine X-rays | X[a] | | X | X | X | X | X | X | X | X | X | X |
| Flexion / Extension Lateral Lumbar Spine X-rays | X[a] | | | X | X | X | X | X | X | X | X | X |

**Table 1: Follow-Up Visit Schedule**

| | Screening Baseline | Surgical Treatment | Discharge (±0-7 days) | 6-week (±2 weeks) | 3-month (±2 weeks) | 6-month (±1 month) | 12-month (±2 months) | 18-month (±2 months) | 24-month[c] (±2 months) | 36-month[c] (±2 months) | 48-month[c] (±2 months) | 60-month[c] (±2 months) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Study Visit Window** | | Day 0 | 0-7 days | 4-8 wks | 10-14 wks | 5-7 mos | 10-14 mos | 16-20 mos | 22-26 mos | 22-26 mos | 22-26 mos | 22-26 mos |
| Lumbar Spine MRI/ CT Scan | X[a] | | | | | | | | | | | |
| DEXA Scan[b] | As needed | | | | | | | | | | | |
| SF-12 –Health Survey (v2) | X | | | X | X | X | X | X | X | X | X | X |
| Zurich Claudication Questionnaire (ZCQ) | X | | | X | X | X | X | X | X | X | X | X |
| Oswestry Disability Index (v2) | X | | | X | X | X | X | X | X | X | X | X |
| Neurological Status | X | | X | X | X | X | X | X | X | X | X | X |
| Visual Analogue Scale | X | | X | X | X | X | X | X | X | X | X | X |
| VertiFlex Patient Satisfaction Questionnaire | | | | X | X | X | X | X | X | X | X | X |
| Assess Adverse Events | | X | X | X | X | X | X | X | X | X | X | X |

[a]Lumbar spine x-rays and MRI/CT taken within 3 months of enrollment can be used to confirm eligibility.

[b]In order to confirm eligibility, at the Investigator's discretion, subjects previously diagnosed with osteoporosis, osteopenia, osteomalacia, female subjects over the age of 65, and post-menopausal female subjects under the age of 65 with any of the risk factors for osteoporosis, will have DEXA scans performed prior to study entry.

[c]Subjects may be required to return for additional follow-up visits annually (±2 months) for up to ten (10) years, or until Vertiflex notifies Investigator of study conclusion at an earlier time.

**3. Clinical Endpoints**

The effectiveness of the Superion™ IDS was assessed using a composite definition of study success as compared to the X-STOP® IPD control group.

The safety of the Superion IDS was assessed by comparison to the X-STOP IPD control group with respect to the nature and frequency of adverse events (overall and in terms of seriousness and relationship to the implant), secondary surgical procedures as well as maintenance or improvement in neurological status.

The primary endpoint of the investigation was individual patient success, which required the patient to meet all of the following criteria at 24 months:

- Clinically significant improvement in outcomes compared to baseline, as determined by meeting the criterion for at least two of three domains of ZCQ
  - ≥ 0.5 point improvement in physical function
  - ≥ 0.5 point improvement in symptom severity
  - score of ≤ 2.5 points on patient satisfaction domain
- No reoperations, removals, revisions, or supplemental fixation at the index level(s)
- No major implant or procedure-related complications
  - no dislodgement, migration, or deformation
  - no new or persistent worsened neurological deficit at the index level
  - no spinous process fractures
  - no deep infection, death, or other permanent device attributed disability
- No clinically significant confounding treatments:
  - no epidural injections, nerve block procedures at index level, spinal cord stimulators or rhizotomies

***B. Extended Follow-up of Premarket Cohort***

As a condition of approval, the FDA asked Vertiflex™ to conduct a Post-Approval Study to provide long-term device performance, wherein Vertiflex was asked to perform a 60-month post-approval study (PAS) to evaluate the longer term safety and effectiveness of the Superion IDS as compared to the

X-STOP IPD by following all patients from the pivotal investigational device exemption (IDE) study G070118 with device survival to 24 months (137 Superion and 144 X-STOP randomized patients had not died or terminally failed as of the 24 month visit) annually through 60 months at 25 study sites.

At each annual (±2 month) visit after 24 months, Vertiflex was asked to collect the following data: Zurich Claudication Questionnaire (ZCQ); neurological status as determined by physical exam; radiographic information; maintenance of distraction; all adverse events regardless of cause; incidence of epidural injections regardless of the cause and spinal level injected; incidence of analgesic narcotics usage; reoperations, revisions, removals or supplemental fixation at the index levels; SF-12 Short Form Health Survey, Version 2; VertiFlex Patient Satisfaction Survey; Visual Analog Scale (VAS); Oswestry Disability Index (ODI), return to work and to activities of daily living, and rehabilitation utilization.

Radiographic information collected included standing anteroposterior and lateral lumbar radiographs, range of motion on lateral standing flexion/extension films (at implanted and adjacent level(s)), radiolucency, device displacement or migration, and radiographic observations such as incidence of total and per patient spinous process fractures or heterotopic ossification. Adverse events were to be evaluated by the Medical Monitor. Data were to be evaluated for safety endpoints by an independent Clinical Events Committee (CEC).

The primary hypothesis of this extended follow-up post approval study was that performance of the Superion IDS remained clinically non-inferior to X-STOP IPD at 60 months post-surgery using the same non-inferiority margin ($\delta$= -0.10) as was used at 24 Months. An individual subject would be considered a success if they met all of the following conditions at the 60-month follow-up:

Clinically significant improvement in outcomes compared to baseline, as determined by meeting the following:

- At least two of three domains of the Zurich Claudication Questionnaire (ZCQ),
  - Improvement in physical function by ≥ 0.5 points
  - Improvement in symptom severity by ≥ 0.5 points
  - "Satisfied" or "somewhat satisfied" as defined by a score of ≤ 2.5 points on the patient satisfaction domain
- No re-operations, revisions, removals, or supplemental fixation at the index level(s)
- No major implant-or procedure-related complications:
  - No dislodgement, migration, or deformation
  - No new or persistent worsened neurological deficit at the index level
  - No spinous process fractures
  - No deep infection, death, or other permanent device attributed disability
- No clinically significant confounding treatments:
  - No epidural injections or nerve block procedures at index level, spinal cord stimulators or rhizotomies

The secondary study objective was to demonstrate the superiority of Superion™ IDS to X-STOP® IPD in effectively treating moderately impaired LSS patients as measured by 60 months postoperative overall success rates.

To the extent possible, all tables provided hereafter have been updated to reflect both the 24-month results, and the longer-term results through 60 months.

***C. Accountability of PMA Cohort***

At the time of database lock (July 7, 2014), of 391 per protocol patients (190 Superion IDS and 201 X-STOP IPD) enrolled in the PMA study. Overall, 94.6% (183 Superion IDS and 187 X-STOP IPD) of patients enrolled in the study were available for analysis at the study completion (24-month post-operative visit). The Superion IDS cohort had a follow-up rate of 97.3% and the X-STOP IPD cohort had a follow-up rate of 94.9% through 24 months (Line 14, Table 2). At 60 months the Superion IDS cohort had a follow-up rate of 85.8%, and the X-STOP IPD cohort had a follow-up rate of 82.1%.

The primary analysis cohort for this study was the Modified Intent-to-Treat Cohort, defined as:

Modified Intent-to-treat patient population (mITT): The mITT patient population will include all patients randomized and having an anesthesia start time, where patients will be classified by the group in which they are randomized. Subjects with an anesthesia start time, but that do not receive a device, or receive the wrong device, will be failures.

Confirmatory analysis was performed in the Per Protocol Cohort, defined as:

Per protocol (PP) Population: The PP patient population will include all subjects with 24-month follow-up data and no major protocol deviations and subjects that failed before 24 months.

Patient accounting and follow-up through 60 months (Table 2), a patient accounting tree (Figure 1), and a summary of patient and data accounting through 60 months months (Table 3) are provided below.

**Table 2: Patient Accounting and Follow-up Compliance Table**

**Superion and X-STOP ITT Analysis Sets**

| Date of data transfer 06FEB2017 | Pre-op | | Week 6 | | Month 3 | | Month 6 | | Month 12 | | Month 18 | | Month 24 | | Month 36 | | Month 48 | | Month 60 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | I | C | I | C | I | C | I | C | I | C | I | C | I | C | I | C | I | C | I | C |
| (1) Theoretical follow-up | 190 | 201 | 190 | 201 | 190 | 201 | 190 | 201 | 190 | 201 | 190 | 201 | 190 | 201 | 190 | 201 | 190 | 201 | 190 | 201 |
| (2) Cumulative deaths | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 2 | 2 | 2 | 3 | 2 | 5* | 6 | 5 | 6 | 6 | 7 | 6 |
| (3) Cum. 'Terminal Failures' (Reops/LI) | 0 | 0 | 3 | 3 | 8 | 11 | 20 | 19 | 40 | 32 | 46 | 48 | 51 | 53 | 58 | 63 | 63 | 68 | 66 | 72 |
| (4) Not Yet Overdue | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| (5) Deaths+term failures among theor. due | 0 | 0 | 3 | 3 | 9 | 11 | 21 | 19 | 42 | 34 | 48 | 51 | 53 | 57 | 64 | 67 | 69 | 73 | 73 | 77 |
| (6) Expected due for clinic visit | 190 | 201 | 187 | 198 | 181 | 190 | 169 | 182 | 148 | 167 | 142 | 150 | 137 | 144 | 126 | 134 | 121 | 128 | 117 | 124 |
| (7) Failures among theoretical due | 0 | 0 | 3 | 3 | 8 | 11 | 20 | 19 | 40 | 32 | 46 | 48 | 51 | 53 | 58 | 63 | 63 | 68 | 66 | 72 |
| (8) Expected due+failures among theor. due | 190 | 201 | 190 | 201 | 189 | 201 | 189 | 201 | 188 | 199 | 188 | 198 | 188 | 197 | 184 | 197 | 184 | 196 | 183 | 196 |
| **All Evaluated Accounting (Actual[B]) Among Expected Due Procedures** | | | | | | | | | | | | | | | | | | | | |
| (9) # of procedures with any clinical data in interval | 190 | 201 | 182 | 193 | 171 | 182 | 164 | 177 | 145 | 162 | 132 | 137 | 131 | 133 | 108 | 109 | 90 | 81 | 88 | 82 |
| 10) All Evaluated Visit Compliance (%) | 100% | 100% | 97.3% | 97.5% | 94.5% | 95.8% | 97.0% | 97.3% | 98.0% | 97.0% | 93.0% | 91.3% | 95.6% | 92.4% | 85.7% | 81.3% | 74.4% | 63.3% | 75.2% | 66.1% |
| (11) ZCQ Responder status determined | 190 | 201 | 181 | 193 | 171 | 182 | 164 | 177 | 145 | 162 | 132 | 137 | 131 | 133 | 108 | 109 | 90 | 81 | 88 | 82 |
| (12) Radiographic evaluation | 184 | 194 | 175 | 178 | 165 | 187 | 170 | 182 | 162 | 175 | 147 | 161 | 145 | 150 | 126 | 127 | 106 | 93 | 101 | 91 |
| (13) Composite clincal success | 190 | 201 | 184 | 196 | 179 | 193 | 184 | 197 | 185 | 195 | 179 | 187 | 183 | 187 | 167 | 176 | 155 | 156 | 157 | 161 |
| 14) Actual[B] % Follow-up for CCS | 100% | 100% | 96.8% | 97.5% | 94.5% | 95.8% | 97.0% | 97.3% | 98.0% | 97.0% | 93.0% | 91.3% | 97.3% | 94.9% | 90.8% | 89.3% | 84.2% | 79.6% | 85.8% | 82.1% |
| **Within Window Accounting (Actual[A]) Among Expected Due** | | | | | | | | | | | | | | | | | | | | |
| | I | C | I | C | I | C | I | C | I | C | I | C | I | C | I | C | I | C | I | C |
| (15) ZCQ Responder status determined | 190 | 201 | 168 | 179 | 169 | 180 | 152 | 167 | 111 | 122 | 129 | 131 | 115 | 113 | 100 | 100 | 81 | 74 | 75 | 70 |
| (16) Radiographic evaluation | 184 | 194 | 162 | 162 | 162 | 186 | 154 | 169 | 123 | 131 | 138 | 152 | 127 | 128 | 116 | 118 | 97 | 86 | 89 | 82 |
| (17) Composite clinical success | 190 | 201 | 171 | 182 | 177 | 191 | 172 | 186 | 151 | 154 | 175 | 179 | 166 | 166 | 158 | 163 | 144 | 142 | 141 | 142 |
| (18) Actual[A]% Follow-up for CCS | 100% | 100% | 89.8% | 90.4% | 93.4% | 94.7% | 89.8% | 91.8% | 75.0% | 73.1% | 90.8% | 87.3% | 88.3% | 84.3% | 85.9% | 82.7% | 78.3% | 72.4% | 77.0% | 72.4% |

I[1] = Superion™ IDS, C[2] = X-STOP® IPD

*One (1) death in the X-STOP IPD arm occurred after terminal failure, and hence, the sum of terminal failures + deaths is one less than would be expected.

The patient accounting tree for the Superion™ IDS IDE is depicted below in Figure 1.

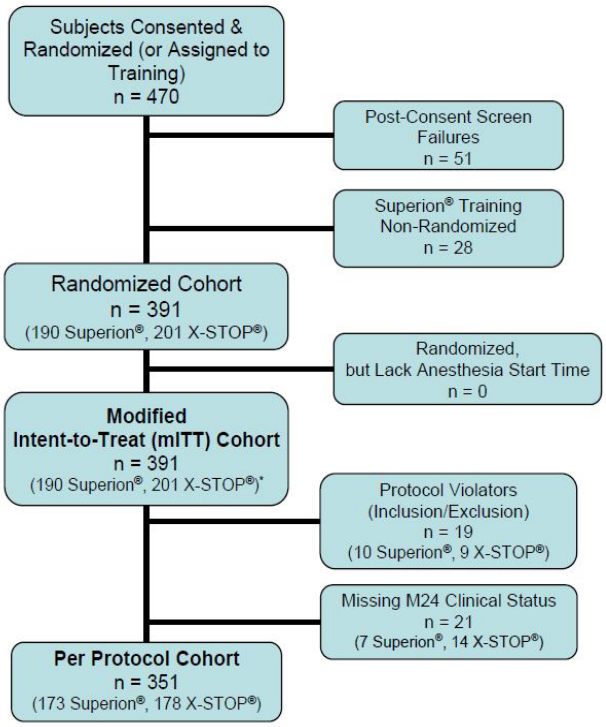



**Figure 1: Patient Accounting Tree**

There were no subjects with misallocations of randomization, meaning all subjects received the device to which they were randomized. As such, the mITT cohort is identical to the "As-Treated" patient cohort.

Of the 51 post-consent screen failures, there were 2 subjects in the training group and 49 that were randomized for the pivotal cohort that did not proceed to treatment. The 49 post-consent screen failures included 28 in the Superion IDS arm and 21 in the X-STOP® IPD arm. The subjects that were post-consent screen failures were blinded to treatment group to mitigate bias.

Subjects were expected due at 24 months, and annually thereafter through 60 months, if they had not terminally failed due to clinical failure defined as reoperation, revision or additional treatment, and had not died. Data were missing for 7 Superion IDS and 14 X-STOP IPD subjects at 24 months, and for 33 Superion IDS and 40 X-STOP IPD subjects at 60 months.

**Table 3: Data Accounting for Superion IDS IDE**

| Parameter | Superion IDS | | | | X-STOP IPD | | | |
|---|---|---|---|---|---|---|---|---|
| | 24 Mos | 36 Mos | 48 Mos | 60 Mos | 24 Mos | 36 Mos | 48 Mos | 60 Mos |
| Randomized or Assigned to Training | 248 | | | | 222 | | | |
| Withdrawn Prior to Treatment | 30 | | | | 21 | | | |
| Training Patients | 28 | | | | 0 | | | |
| Subjects Treated (mITT) | 190 | | | | 201 | | | |
| Composite Clinical Success Evaluable | 183 | 167 | 155 | 157 | 187 | 176 | 156 | 161 |
| Deaths + Clinical Failures Among Implanted[1] | 53 | 64 | 69 | 73 | 57 | 67 | 73 | 77 |
| Expected (mITT) | 137 | 126 | 121 | 117 | 144 | 134 | 128 | 124 |
| ZCQ | 131 | 108 | 90 | 88 | 133 | 109 | 81 | 82 |
| VAS Leg and Back Pain | 131 | 107 | 87 | 85 | 133 | 106 | 80 | 82 |
| ODI | 131 | 108 | 90 | 88 | 133 | 109 | 81 | 82 |
| SF-12 | 128 | 96 | 55 | 68 | 133 | 92 | 47 | 73 |
| Neurological Evaluation | 150 | 125 | 108 | 94 | 157 | 131 | 95 | 84 |

| Table 3: Data Accounting for Superion IDS IDE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Parameter** | **Superion IDS** | | | | **X-STOP IPD** | | | |
| | 24 Mos | 36 Mos | 48 Mos | 60 Mos | 24 Mos | 36 Mos | 48 Mos | 60 Mos |
| Radiographic Evaluation | 145 | 126 | 106 | 101 | 150 | 127 | 93 | 91 |
| Patient Satisfaction Evaluation | 152 | 127 | 110 | 111 | 157 | 130 | 99 | 99 |

[1]Patients with reoperations, revisions, and epidural steroid injection

***D. Study Population Demographics and Baseline Parameters***

The demographics of the study population are typical for a lumbar interspinous spacer study performed in the US. Baseline demographic information and operative variables are presented in Table 4, Table 5, and Table 6.

| Table 4: Summary of Baseline and Demographic Categorical Variables Superion™ IDS and X-STOP® IPD Control mITT Analysis Sets | | | | |
|---|---|---|---|---|
| | **Superion IDS** | | **X-STOP IPD** | |
| | **N** | **%** | **N** | **%** |
| **Number of subjects** | 190 | - | 201 | - |
| **Males** | 110 | 57.9 | 129 | 64.2 |
| **Females** | 80 | 42.1 | 72 | 35.8 |
| **Race** | **N** | **%** | **N** | **%** |
| White | 177 | 93.2 | 196 | 97.5 |
| Asian | 0 | 0.0 | 1 | 0.5 |
| African American | 8 | 4.2 | 1 | 0.5 |
| American Indian or Alaska Native | 0 | 0.0 | 0 | 0.0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0.0 | 1 | 0.5 |
| Other | 5 | 2.6 | 2 | 1.0 |
| **Ethnicity** | **N** | **%** | **N** | **%** |
| Hispanic or Latino | 5 | 2.6 | 11 | 5.5 |
| Not Hispanic or Latino | 185 | 97.4 | 190 | 94.5 |
| **Use of nicotine products** | **N** | **%** | **N** | **%** |
| No | 89 | 46.8 | 101 | 50.2 |
| Current Use | 24 | 12.6 | 24 | 11.9 |
| Previous Use | 77 | 40.5 | 76 | 37.8 |

Statistical analysis of baseline demographics did not show any significant differences between subjects randomized into the Superion IDS group compared to those randomized into the X-STOP® IPD control group.

| Table 5: Summary of Baseline and Demographic Continuous Variables Superion IDS and X-STOP IPD mITT Analysis Set | | | | | | |
|---|---|---|---|---|---|---|
| | **Superion IDS** | | | **X-STOP IPD** | | |
| **Demographics – All** | **N** | **Mean** | **SD** | **N** | **Mean** | **SD** |
| Age at surgery (yrs) | 190 | 66.9 | 9.4 | 201 | 66.2 | 10.2 |
| Height (inches) | 190 | 67.2 | 4.2 | 201 | 67.9 | 3.8 |
| Weight (lbs) | 190 | 189.7 | 36.5 | 201 | 195.8 | 36.9 |
| BMI ($k/m^2$) | 190 | 29.5 | 4.6 | 201 | 29.7 | 4.6 |
| **Demographics – Male** | **N** | **Mean** | **SD** | **N** | **Mean** | **SD** |
| Age at surgery (yrs) | 110 | 68.0 | 9.0 | 129 | 66.4 | 10.2 |
| Height (inches) | 110 | 69.9 | 2.6 | 129 | 70.0 | 2.8 |
| Weight (lbs) | 110 | 204.9 | 32.6 | 129 | 207.2 | 32.0 |
| BMI ($k/m^2$) | 110 | 29.5 | 4.3 | 129 | 29.7 | 4.0 |
| **Demographics – Female** | **N** | **Mean** | **SD** | **N** | **Mean** | **SD** |
| Age at surgery (yrs) | 80 | 65.3 | 9.7 | 72 | 65.8 | 10.3 |
| Height (inches) | 80 | 63.4 | 2.8 | 72 | 64.2 | 2.5 |
| Weight (lbs) | 80 | 168.8 | 31.0 | 72 | 175.4 | 36.3 |

| Table 5: Summary of Baseline and Demographic Continuous Variables Superion IDS and X-STOP IPD mITT Analysis Set | | | | | | |
|---|---|---|---|---|---|---|
| | Superion IDS | | | X-STOP IPD | | |
| BMI (k/m$^2$) | 80 | 29.5 | 5.0 | 72 | 29.8 | 5.4 |
| **Baseline Functional Status** | **N** | **Mean** | **SD** | **N** | **Mean** | **SD** |
| Oswestry (ODI) | 190 | 39.1 | 13.4 | 201 | 39.9 | 11.6 |
| Zurich Claudication Qx Severity | 190 | 3.33 | 0.64 | 201 | 3.37 | 0.61 |
| Zurich Claudication Qx Physical | 190 | 2.63 | 0.43 | 201 | 2.72 | 0.43 |
| SF-12 PCS (Physical) | 189 | 29.4 | 8.1 | 201 | 28.5 | 6.9 |
| SF-12 MCS (Mental Health) | 189 | 50.0 | 12.7 | 201 | 48.9 | 12.2 |
| VAS Back pain | 190 | 55.4 | 27.9 | 201 | 55.1 | 27.4 |
| VAS Leg pain (right leg) | 190 | 55.0 | 31.3 | 201 | 52.9 | 32.5 |
| VAS Leg pain (left leg) | 190 | 49.6 | 31.8 | 201 | 50.8 | 31.7 |

Descriptive comparisons of device group mean differences at baseline, device group differences over time, and change from baseline over time were facilitated using Cohen's standardized effect size. While there were small statistical differences in Race and ZCQ – Physical Function baseline parameters, it was determined that these differences were not clinically important for the investigational and control groups.

| Table 6: Operative Variables and Types of Stenosis Superion IDS and X-STOP® IPD mITT Analysis Set | | | | |
|---|---|---|---|---|
| | Superion IDS | | X-STOP IPD | |
| | n | % | n | % |
| **Number of Subjects Treated** | 189 | 99.5 | 199 | 99.0 |
| **Subjects Attempted / Not Implanted** | 1 | 0.5 | 2 | 1.0 |
| **Number of Levels Treated** | **n** | **%** | **n** | **%** |
| 1 | 99 | 52.4 | 99 | 49.7 |
| 2 | 90 | 47.6 | 100 | 50.3. |
| **Stenosis Type** | **n** | **%** | **n** | **%** |
| Central Only | 66 | 34.7 | 60 | 29.9 |
| Lateral Only | 16 | 8.4 | 15 | 7.5 |
| Central and Lateral Stenosis | 100 | 52.6 | 118 | 58.7 |
| Foraminal Stenosis | 8 | 4.2 | 8 | 4.0 |

Baseline differences in operative covariates such as treated levels or stenosis type did not have an overall impact on the clinical success of subjects receiving either Superion™ IDS or X-STOP® IPD.

***E. Safety and Effectiveness Results***

**4. Safety Results**

The analysis of safety was based on the mITT cohort of 391 subjects (190 Superion IDS subjects and 201 X-STOP IPD subjects) available for the 24 month evaluation, and longer-term results available through 60 months.. When making an assessment of safety, an Adverse Event (AE) was considered as: any undesired clinical response or complication experienced by a subject. All operative and postoperative AEs, whether device-related or not, were recorded on the AE Case Report Forms. Safety outcomes were determined by evaluating the type, frequency, seriousness, and relationship to device of AEs through the 24-month time point for all subjects. AEs were categorized as device-related, procedure-related, adjacent-level-related, or systemic.

**AE Device/Procedure-Relatedness**

The clinical investigator, on the basis of his or her clinical judgment and the following definitions, determined the severity and relationship of the AE to the device and/or procedure:

- Not related: The AE is clearly not related
- Unknown/Undetermined: The AE is unknown or undetermined to be related
- Related: The AE is clearly related
- Device-related: The AE is related to the Study device or the control device
- Procedure-related: The AE is related to the procedure to implant the investigational or control device.

**AE Severity**

The severity of an AE was categorized as mild, moderate or severe. Severity was determined by the clinical investigator, using the following definitions:

- Mild: The AE is transient or causes mild discomfort. There usually is no intervention/therapy required and the AE does not interfere with the subject's normal activities.
- Moderate: The AE causes some limitation in activity and some assistance may be needed. There is no or minimal medical intervention/therapy required.
- Severe: The AE causes marked limitation in activity. The subject's usual daily activity is interrupted. The subject may require medical intervention/therapy, hospitalization is possible.

**Serious AEs**

The AE was regarded as a Serious Adverse Event (SAE) if the injury or illness:

- Results in death
- Is life-threatening,
- Results in or prolongs hospitalization
- Results in permanent impairment of a body function or permanent damage to a body structure, or
- Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

**Serious Adverse Device Effect**

A Serious Adverse Device Effect (SADE) is a device-related adverse event that has resulted in any of the consequences characteristic of a serious AE or that might have led to any of these consequences if suitable action had not been taken or intervention had not been made.

**Unanticipated Adverse Device Effect**

An Unanticipated Adverse Device Effect (UADE) is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the risks identified for the investigational or control device; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

**Role of the CEC**

Adverse events were evaluated by the Medical Monitor. Data were evaluated for safety endpoints by an independent CEC. The CEC had predetermined stopping rules, one of which was greater than 10% postoperative observation of in situ study device unlocking with full or partial collapse of the cam lobes at annual review. The first stopping review occurred after a minimum of 30 subjects in the study group had been accrued. This observation was monitored annually throughout the study. Additionally, all device-related events, major procedure-related, and adjacent level-related events and therapeutic failures reported by the clinical investigators were adjudicated by the independent CEC. In addition, events reported as having unknown or undetermined relationships to the device by the clinical investigators were to be adjudicated by the CEC.

The key safety outcomes for this study are presented below in Table 7 through Table 28, wherein are presented cumulative data collected through 60 months.

### Adverse Events that Occurred in the PMA Clinical Study

**Overall Adverse Events**

A summary of the total number of adverse events, adverse events related to the device or procedure, serious adverse events, and serious adverse events that were related to the device or procedure is shown below in Table 7.

The safety profile of the Superion™ IDS device is similar to the X-STOP® IPD device when considering adverse event incidence. The overall incidence of any adverse event (Superion IDS: 94.7% vs. X-STOP IPD: 91.5%), device-related adverse events (Superion IDS: 11.6% vs. X-STOP IPD: 7.5%), procedure-related adverse events (Superion IDS: 14.2% vs. X-STOP IPD: 15.9%), serious adverse events (Superion IDS: 46.3% vs. X-STOP IPD: 45.8%), and device- or procedure-related serious adverse events (Superion IDS: 8.4% vs. X-STOP IPD: 9.5%) were similar between both groups at 24 months. No device-related or procedure-related deaths were reported during follow-up in either the Superion IDS or X-STOP IPD control groups.

The results obtained through 60 months proved similar. The overall incidence of any adverse event (Superion IDS: 96.3% vs. X-STOP IPD: 95.0%), device-related adverse events (Superion IDS: 12.6% vs. X-STOP IPD: 9.0%), procedure-related adverse events (Superion IDS: 14.7% vs. X-STOP IPD: 15.9%), serious adverse events (Superion IDS: 59.5% vs. X-STOP IPD: 57.7%), and device- or procedure-related serious adverse events (Superion IDS: 8.9% vs. X-STOP IPD: 10.9%), remain similar between both groups at 60 months.

**Table 7: Comparisons of Summary Adverse Event Rates between Superion™ IDS and X-STOP® IPD mITT Analysis Sets at 60 Months**

| | Superion IDS (N=190) | | X-STOP IPD (N=201) | | X-STOP minus Superion[1] | | |
|---|---|---|---|---|---|---|---|
| | n | % | n | % | DIFF | LB | UB |
| Any adverse event (per patient) | 183 | 96.3 | 191 | 95.0 | -1.3 | -11.2 | 8.6 |
| Any device-related AE | 24 | 12.6 | 18 | 9.0 | -3.7 | -13.5 | 6.3 |
| Any procedure-related AE | 28 | 14.7 | 32 | 15.9 | 1.2 | -8.8 | 11.1 |
| Any serious AE | 113 | 59.5 | 116 | 57.7 | -1.8 | -11.7 | 8.2 |
| Serious AE that is either device-related or procedure-related | 17 | 8.9 | 22 | 10.9 | 2.0 | -7.9 | 11.9 |
| Deaths | 7 | 3.7 | 6 | 3.0 | -0.7 | -10.6 | 9.2 |

***Notes:*** *[1] Exact 95% confidence interval for the group difference. Diff signifies difference between percentages of groups. LB signifies lower bound of 95% confidence interval. UB signifies upper bound of 95% confidence interval.*

As described above, during the clinical study, adverse events were classified as device-related or procedure-related, not device-related or procedure-related, or as having an "unknown/undetermined" relationship. At FDA's request, an additional analysis was performed that grouped adverse events with an "unknown/undetermined" assessment for device and procedure relation with those events deemed to have a definite device or procedure relation as a "worst case" assessment. These results are presented below in Table 8, updated to reflect data acquired through 60 months.

Under these "worst case" conditions, the overall incidence of any adverse event (Superion IDS: 96.3% vs. X-STOP IPD: 95.0%), device-related adverse events (Superion IDS: 44.7% vs. X-STOP IPD: 43.8%), procedure-related adverse events (Superion IDS: 40.5% vs. X-STOP IPD: 51.7%), serious adverse events (Superion IDS: 59.5% vs. X-STOP IPD: 58.2%), and device- or procedure-related serious adverse events (Superion IDS: 23.2% vs. X-STOP IPD: 26.4%) remain similar between both groups at 60 months, with the exception of procedure-related events, where there was an 11.3% higher rate in the X-STOP IPD arm.

**Table 8: Worst Case Comparisons of Summary Adverse Event Rates between Superion IDS and X-STOP IPD mITT Analysis Sets with Unknown/Undetermined Events Grouped with Related Events at 60 Months**

| | Superion IDS (N=190) | | X-STOP IPD (N=201) | | X-STOP minus Superion[1] | | |
|---|---|---|---|---|---|---|---|
| | n | % | n | % | DIFF | LB | UB |
| Any adverse event (per patient) | 183 | 96.3 | 191 | 95.0 | -1.3 | -11.2 | 8.6 |
| Any device-related AE[2] | 85 | 44.7 | 88 | 43.8 | -1.0 | -10.9 | 9.0 |
| Any procedure-related AE[2] | 77 | 40.5 | 104 | 51.7 | 11.2 | 1.3 | 21.0 |
| Any serious AE | 113 | 59.5 | 117 | 58.2 | -1.3 | -11.2 | 8.7 |
| Serious AE that is either device-related or procedure-related | 44 | 23.2 | 53 | 26.4 | 3.2 | -6.7 | 13.1 |
| Deaths | 7 | 3.7 | 6 | 3.0 | -0.7 | -10.6 | 9.2 |

***Note:*** *[1] Exact 95% confidence interval for the group difference.*

***Note:*** *[2] Includes "Yes" and "Unknown/Undetermined" relationships*

Specific adverse events are listed in alphabetical order according to adverse event categories in Table 9. These events are reflective of all data acquired through 60 months, in accordance with post-approval requirements. Adverse event rates are based on the number of subjects having at least one occurrence of an adverse event, and divided by the number of subjects in that treatment group. Events per subject are based on the number of adverse events, divided by the total number of subjects in each cohort. Subjects experiencing adverse events in more than one category are represented in each category in which they experienced an adverse event. Regarding specific adverse events, the most common adverse events observed in the Superion IDS group and X-STOP IPD group were Pain - Back, Pain - Leg, Pain - Buttock & Groin, Spinal stenosis symptoms at index level, and Spinous process fracture.

As shown in the detailed overall adverse event table (Table 9), pain-related adverse events were distributed differently between the Superion IDS and X-STOP IPD groups. X-STOP IPD patients were more likely to have Pain - Back or Pain - Leg adverse events, while Superion IDS patients were more

likely to have Pain – Buttock & Groin adverse events. Overall, X-STOP IPD patients were more likely to have a back, leg, buttock, or groin adverse event compared with Superion IDS patients. In addition, X-STOP IPD patients were more likely to have events related to soft tissue damage or fever. In contrast, Superion IDS patients were more likely to have an adverse event related to spinous process fracture. Since none of the 95% confidence intervals exclude zero, there are no statistically significant device group differences in specific adverse rates.

**Table 9: Specific Adverse Events in Superion™ IDS IDE up to 60 months (mITT cohort)**

| Adverse Event Type | Superion IDS (I) (N = 190) | | | X-STOP® IPD (C) (N = 201) | | | X-STOP minus Superion[1] | | |
|---|---|---|---|---|---|---|---|---|---|
| | No. of Events | No. of Pts. | % of Pts. | No. of Events | No. of Pts. | % of Pts | Diff | LB | UB |
| Abdominal pain | 2 | 2 | 1.1 | 0 | 0 | 0.0 | -1.1 | -11.0 | 8.9 |
| Accidental injury | 21 | 16 | 8.4 | 21 | 18 | 8.0 | 0.1 | -9.9 | 10.0 |
| Adjacent level DDD | 1 | 1 | 0.5 | 4 | 2 | 1.0 | 0.5 | -9.4 | 10.4 |
| Adjacent level stenosis | 1 | 1 | 0.5 | 4 | 2 | 1.0 | 0.5 | -9.4 | 10.4 |
| Allergic reaction | 6 | 4 | 2.1 | 6 | 6 | 3.0 | 0.9 | -9.0 | 10.8 |
| Anemia | 4 | 3 | 1.6 | 1 | 1 | 0.5 | -1.1 | -11.0 | 8.8 |
| Angina | 4 | 4 | 2.1 | 0 | 0 | 0.0 | -2.1 | -12.0 | 7.8 |
| Bronchitis | 3 | 3 | 1.6 | 6 | 5 | 2.5 | 0.9 | -9.0 | 10.8 |
| Cancer/Neoplasm | 13 | 11 | 5.8 | 14 | 13 | 6.5 | 0.7 | -9.3 | 10.6 |
| Cardiovascular | 25 | 20 | 10.5 | 20 | 16 | 8.0 | -2.6 | -12.5 | 7.4 |
| Cerebrovascular accident (CVA) | 2 | 2 | 1.1 | 1 | 1 | 0.5 | -0.6 | -10.5 | 9.4 |
| Chronic obstructive pulmonary disease (COPD) | 1 | 1 | 0.5 | 1 | 1 | 0.5 | 0.0 | -9.9 | 9.9 |
| Coronary episode, ischemic | 3 | 2 | 1.1 | 5 | 2 | 1.0 | -0.1 | -10.0 | 9.9 |
| Deep infection at the operative site | 0 | 0 | 0.0 | 3 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Deep vein thrombosis | 2 | 2 | 1.1 | 1 | 1 | 0.5 | -0.6 | -10.5 | 9.4 |
| Dental | 0 | 0 | 0.0 | 2 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Device breakage | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Device breakage preventing device placement | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Device deformation preventing device placement | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Device dislodgement | 1 | 1 | 0.5 | 2 | 2 | 1.0 | 0.5 | -9.4 | 10.4 |
| Device erosion | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Device migration | 1 | 1 | 0.5 | 8 | 7 | 3.5 | 3.0 | -7.0 | 12.9 |
| Device subsidence | 4 | 4 | 2.1 | 0 | 0 | 0.0 | -2.1 | -1.0 | 7.8 |
| Dextroscoliosis | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Diabetes mellitus | 0 | 0 | 0.0 | 5 | 5 | 2.5 | 2.5 | -7.4 | 12.4 |
| Diabetes mellitus inadequate control | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Disc bulge | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Dizziness | 6 | 6 | 3.2 | 1 | 1 | 0.5 | -2.7 | -12.5 | 7.3 |

| Table 9: Specific Adverse Events in Superion™ IDS IDE up to 60 months (mITT cohort) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Adverse Event Type | Superion IDS (I) (N = 190) | | | X-STOP® IPD (C) (N = 201) | | | X-STOP minus Superion[1] | | |
| | No. of Events | No. of Pts. | % of Pts. | No. of Events | No. of Pts. | % of Pts | Diff | LB | UB |
| Dural leaks | 6 | 6 | 3.2 | 3 | 3 | 1.5 | -1.7 | -11.6 | 8.3 |
| Dyspnea | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Edema | 2 | 2 | 1.1 | 4 | 4 | 2.0 | 0.9 | -9.0 | 10.8 |
| EENT | 2 | 2 | 1.1 | 0 | 0 | 0.0 | -1.1 | -11.0 | 8.9 |
| Endocrine/Metabolic | 11 | 11 | 5.8 | 13 | 11 | 5.5 | -0.3 | -10.2 | 9.6 |
| Facet Cyst | 4 | 3 | 1.6 | 0 | 0 | 0.0 | -1.6 | -11.5 | 8.3 |
| Fever | 0 | 0 | 0.0 | 4 | 4 | 2.0 | 2.0 | -7.9 | 11.9 |
| Gallstones | 0 | 0 | 0.0 | 2 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Gastroesophageal reflux disease (GERD) | 2 | 2 | 1.1 | 0 | 0 | 0.0 | -1.1 | -11.0 | 8.9 |
| Gastrointestinal | 9 | 7 | 3.7 | 10 | 9 | 4.5 | 0.8 | -9.1 | 10.7 |
| Gastrointestinal (GI) bleed | 2 | 2 | 1.1 | 2 | 2 | 1.0 | -0.1 | -10.0 | 9.9 |
| Genitourinary | 27 | 23 | 12.1 | 17 | 17 | 8.5 | -3.6 | -13.5 | 6.3 |
| Headache | 1 | 1 | 0.5 | 5 | 5 | 2.5 | 2.0 | -7.9 | 11.9 |
| Hematologic | 0 | 0 | 0.0 | 2 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Hematoma | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Immune | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Infection* | 16 | 15 | 7.9 | 18 | 16 | 8.0 | 0.1 | -9.9 | 10.0 |
| Instruments breakage or malfunction preventing device placement | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Loss of bladder control | 0 | 0 | 0.0 | 2 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Loss of bowel control | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Multi-level DDD | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Muscle damage | 2 | 2 | 1.1 | 1 | 1 | 0.5 | -0.6 | -10.5 | 9.4 |
| Musculoskeletal** | 109 | 78 | 41.1 | 101 | 69 | 34.8 | -6.2 | -16.1 | 3.7 |
| Myocardial infarction | 5 | 5 | 2.6 | 3 | 3 | 1.5 | -1.1 | -11.0 | 8.8 |
| Nausea | 0 | 0 | 0.0 | 4 | 4 | 2.0 | 2.0 | -7.9 | 11.9 |
| Nerve root damage | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Neurological disorder | 27 | 22 | 11.6 | 13 | 13 | 6.5 | -5.1 | -15.0 | 4.8 |
| Ophthalmic | 10 | 8 | 4.2 | 6 | 6 | 3.0 | -1.2 | -11.1 | 8.7 |
| Osteolysis | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Other, specify*** | 141 | 73 | 38.4 | 167 | 82 | 40.8 | 2.4 | -7.6 | 2.3 |
| Pain – Back | 68 | 60 | 31.6 | 91 | 80 | 39.8 | 8.2 | -1.7 | 18.0 |
| Pain – Back & Buttock | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |

| Table 9: Specific Adverse Events in Superion™ IDS IDE up to 60 months (mITT cohort) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Adverse Event Type | Superion IDS (I) (N = 190) | | | X-STOP® IPD (C) (N = 201) | | | X-STOP minus Superion[1] | | |
| | No. of Events | No. of Pts. | % of Pts. | No. of Events | No. of Pts. | % of Pts | Diff | LB | UB |
| Pain – Back & Hip | 1 | 1 | 0.5 | 0 | 0 | 0 | -0.5 | -10.4 | 9.4 |
| Pain – Back & Leg | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Pain – Buttock | 1 | 1 | 0.5 | 2 | 2 | 1.0 | 0.5 | -9.4 | 10.4 |
| Pain – Buttock & Groin | 27 | 25 | 13.2 | 21 | 18 | 9.0 | -4.2 | -14.1 | 5.7 |
| Pain – Buttock & Hip | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Pain – Hip | 2 | 2 | 1.1 | 3 | 3 | 1.5 | 0.4 | -9.5 | 10.4 |
| Pain – Leg | 51 | 46 | 24.2 | 79 | 55 | 27.4 | 3.2 | -6.8 | 13.0 |
| Peripheral Vascular Disorder | 0 | 0 | 0.0 | 3 | 3 | 1.5 | 1.5 | -8.4 | 11.4 |
| Pneumonia | 10 | 7 | 3.7 | 6 | 6 | 3.0 | -0.7 | -10.6 | 9.2 |
| Presence of osteophyte formation associated with severe disc or facet degeneration | 1 | 1 | 0.5 | 2 | 2 | 1.0 | 0.5 | -9.4 | 10.4 |
| Progression of underlying disease | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Psychiatric/Substance abuse | 1 | 1 | 0.5 | 4 | 4 | 2.0 | 1.5 | -8.4 | 11.4 |
| Pulmonary edema | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Pulmonary embolism | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Renal failure | 3 | 3 | 1.6 | 1 | 1 | 0.5 | -1.1 | -11 | 8.8 |
| Renal insufficiency | 3 | 3 | 1.6 | 2 | 2 | 1.0 | -0.6 | -10.5 | 9.3 |
| Respiratory disorder | 4 | 3 | 1.6 | 4 | 4 | 2.0 | 0.4 | -9.5 | 10.3 |
| Respiratory distress | 2 | 2 | 1.1 | 0 | 0 | 0.0 | -1.1 | -11 | 8.9 |
| Respiratory infection | 0 | 0 | 0.0 | 3 | 3 | 1.5 | 1.5 | -8.4 | 11.4 |
| Rheumatoid arthritis | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Sensory loss | 4 | 3 | 1.6 | 6 | 6 | 3.0 | 1.4 | -8.5 | 11.3 |
| Shortness of breath | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Skin and subcutaneous tissue | 4 | 4 | 2.1 | 10 | 8 | 4.0 | 1.9 | -8.0 | 11.8 |
| Soft tissue damage | 1 | 1 | 0.5 | 9 | 8 | 4.0 | 3.5 | -6.5 | 13.3 |
| Spinal stenosis symptoms at index level | 41 | 39 | 20.5 | 40 | 35 | 17.4 | -3.1 | -13.0 | 6.8 |
| Spinal stenosis symptoms associated with non-index condition | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Spinous process fracture | 25 | 22 | 11.6 | 14 | 13 | 6.5 | -5.1 | -15.0 | 4.8 |
| Stroke | 4 | 4 | 2.1 | 1 | 1 | 0.5 | -1.6 | -11.5 | 8.3 |

| Table 9: Specific Adverse Events in Superion™ IDS IDE up to 60 months (mITT cohort) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Adverse Event Type | Superion IDS (I) (N = 190) | | | X-STOP® IPD (C) (N = 201) | | | X-STOP minus Superion[1] | | |
| | No. of Events | No. of Pts. | % of Pts. | No. of Events | No. of Pts. | % of Pts | Diff | LB | UB |
| Syncope | 1 | 1 | 0.5 | 2 | 2 | 1.0 | 0.5 | -9.4 | 10.4 |
| Synovial cyst | 0 | 0 | 0.0 | 0 | 0 | 0.0 | . | . | . |
| Transient ischemic attack (TIA) | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Urinary tract infection | 10 | 9 | 4.7 | 6 | 6 | 3.0 | -1.8 | -11.7 | 8.2 |
| Vertebral compression fractures | 1 | 1 | 0.5 | 3 | 3 | 1.5 | 1.0 | -8.9 | 10.9 |
| Wound dehiscence or delayed healing | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Wound drainage | 1 | 1 | 0.5 | 4 | 4 | 2 | 1.5 | -8.4 | 11.4 |

[1] Exact 95% confidence interval for the group difference (X-STOP minus Superion).
*Infection AEs are defined as: including superficial infections and seroma at the surgical site, as well as infections at remote sites (e.g., sinus or throat infection)
**Musculoskeletal AEs are defined as: including weakness, cramping, joint pain, joint surgery or replacement, and other disorders in non-lumbar spinal tissues
***Other adverse events includes events not fitting a specific existing adverse event category, including insomnia, psychological disorder, weight loss, general weakness, ganglion cyst, and drug withdrawal.

Table 10 provides the actual counts of specific events by time of onset. Most adverse events were evenly distributed throughout the course of the study up to 60 months. The exception is the occurrence of spinous process fracture. The majority of these fractures occurred within the first 6 months post-operatively in both cohorts. No other clinically important trends in adverse event occurrence were demonstrated by the data.

| Table 10: Counts of Specific Adverse Events by Time of Occurrence up to 60 Months (mITT cohort) | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Day of Surgery | | Immed. Post-Op to Month 3 (Day 1-90) | | > Mo. 3 to Mo. 6 (Day 91-180) | | > Mo. 6 to Mo. 12 (Day 181-365) | | > Mo. 12 to Mo. 24 (Day 365-730) | | Post Month 24 (Day >730) | | Totals | |
| | I[1] | C[2] | I | C | I | C | I | C | I | C | I | C | I | C |
| Abdominal Pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 2 | 0 |
| Accidental injury | 1 | 0 | 2 | 5 | 2 | 3 | 7 | 3 | 6 | 8 | 3 | 2 | 21 | 21 |
| Adjacent level DDD | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 |
| Adjacent level stenosis | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 1 | 4 |
| Allergic reaction | 0 | 1 | 1 | 1 | 0 | 1 | 1 | 2 | 2 | 1 | 2 | 0 | 6 | 6 |
| Anemia | 0 | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 4 | 1 |
| Angina | 0 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 4 | 0 |
| Bronchitis | 0 | 0 | 0 | 2 | 0 | 1 | 0 | 2 | 2 | 1 | 1 | 0 | 3 | 6 |
| Cancer/Neoplasm | 0 | 0 | 2 | 2 | 2 | 2 | 3 | 5 | 4 | 4 | 2 | 1 | 13 | 14 |
| Cardiovascular | 1 | 0 | 2 | 2 | 5 | 3 | 3 | 0 | 12 | 10 | 2 | 5 | 25 | 20 |
| Cerebrovascular accident (CVA) | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 1 | 0 | 2 | 1 |
| Chronic obstructive pulmonary disease (COPD) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| Coronary episode, ischemic | 0 | 0 | 1 | 4 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 3 | 5 |
| Deep infection at the operative site | 0 | 0 | 0 | 2 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| Deep vein thrombosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 0 | 2 | 1 |
| Dental | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| Device breakage | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Device breakage preventing device placement | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device deformation preventing device placement | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |

| Table 10: Counts of Specific Adverse Events by Time of Occurrence up to 60 Months (mITT cohort) | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Day of Surgery | | Immed. Post-Op to Month 3 (Day 1-90) | | > Mo. 3 to Mo. 6 (Day 91-180) | | > Mo. 6 to Mo. 12 (Day 181-365) | | > Mo. 12 to Mo. 24 (Day 365-730) | | Post Month 24 (Day >730) | | Totals | |
| | I[1] | C[2] | I | C | I | C | I | C | I | C | I | C | I | C |
| Device dislodgement | 0 | 0 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 |
| Device erosion | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device migration | 0 | 0 | 1 | 4 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 1 | 8 |
| Device subsidence | 0 | 0 | 0 | 0 | 2 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 4 | 0 |
| Dextroscoliosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Diabetes mellitus | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 3 | 0 | 5 |
| Diabetes mellitus inadequate control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Disc bulge | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dizziness | 0 | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 6 | 1 |
| Dural leaks | 2 | 0 | 0 | 0 | 0 | 1 | 2 | 0 | 2 | 1 | 0 | 1 | 6 | 3 |
| Dyspnea | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Edema | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 2 | 0 | 2 | 0 | 0 | 2 | 4 |
| EENT | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 |
| Endocrine/Metabolic | 0 | 3 | 2 | 2 | 1 | 2 | 3 | 1 | 2 | 4 | 3 | 1 | 11 | 13 |
| Facet Cyst | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 2 | 0 | 0 | 0 | 4 | 0 |
| Fever | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 4 |
| Gallstones | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 2 |
| Gastroesophageal reflux disease (GERD) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 2 | 0 |
| Gastrointestinal | 0 | 0 | 1 | 2 | 1 | 2 | 2 | 2 | 1 | 2 | 4 | 2 | 9 | 10 |
| Gastrointestinal (GI) bleed | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 2 | 2 |
| Genitourinary | 6 | 1 | 10 | 7 | 2 | 2 | 4 | 2 | 3 | 3 | 2 | 2 | 27 | 17 |
| Headache | 0 | 0 | 1 | 3 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 1 | 5 |
| Hematologic | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 |
| Hematoma | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Immune | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Infection* | 0 | 0 | 4 | 4 | 3 | 2 | 5 | 3 | 3 | 6 | 1 | 3 | 16 | 18 |
| Instruments breakage or malfunction preventing device placement | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Loss of bladder control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 |
| Loss of bowel control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| Multi-level DDD | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 |
| Muscle damage | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 2 | 1 |
| Musculoskeletal** | 1 | 0 | 30 | 24 | 12 | 15 | 20 | 12 | 32 | 37 | 14 | 13 | 9 | 101 |
| Myocardial infarction | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 2 | 1 | 1 | 1 | 0 | 5 | 3 |
| Nausea | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 4 |
| Nerve root damage | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Neurological disorder | 0 | 2 | 6 | 4 | 2 | 1 | 6 | 2 | 10 | 3 | 3 | 1 | 27 | 13 |
| Ophthalmic | 2 | 0 | 3 | 0 | 0 | 0 | 3 | 2 | 1 | 4 | 1 | 0 | 10 | 6 |
| Osteolysis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| Other*** | 1 | 0 | 5 | 8 | 3 | 2 | 3 | 6 | 15 | 9 | 114 | 142 | 141 | 167 |
| Pain – Back | 0 | 1 | 15 | 24 | 11 | 7 | 9 | 19 | 13 | 14 | 20 | 26 | 68 | 91 |
| Pain – Back & Buttock | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 |
| Pain – Back & Hip | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 |
| Pain – Back & Leg | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

| Table 10: Counts of Specific Adverse Events by Time of Occurrence up to 60 Months (mITT cohort) | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Day of Surgery | | Immed. Post-Op to Month 3 (Day 1-90) | | > Mo. 3 to Mo. 6 (Day 91-180) | | > Mo. 6 to Mo. 12 (Day 181-365) | | > Mo. 12 to Mo. 24 (Day 365-730) | | Post Month 24 (Day >730) | | Totals | |
| | I[1] | C[2] | I | C | I | C | I | C | I | C | I | C | I | C |
| Pain – Buttock | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 2 |
| Pain – Buttock & Groin | 0 | 0 | 6 | 5 | 3 | 2 | 4 | 3 | 8 | 4 | 6 | 7 | 27 | 21 |
| Pain – Buttock & Hip | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pain – Hip | 0 | 0 | 1 | 2 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 2 | 3 |
| Pain – Leg | 1 | 0 | 11 | 18 | 6 | 9 | 6 | 13 | 14 | 11 | 13 | 19 | 51 | 70 |
| Peripheral Vascular Disorder | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 3 |
| Pneumonia | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 2 | 2 | 6 | 2 | 10 | 6 |
| Presence of osteophyte formation associated with severe disc or facet degeneration | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 1 | 2 |
| Progression of underlying disease | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Psychiatric/Substance abuse | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 1 | 1 | 4 |
| Pulmonary edema | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Pulmonary embolism | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Renal failure | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 3 | 1 |
| Renal insufficiency | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 2 | 0 | 3 | 2 |
| Respiratory disorder | 0 | 3 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 0 | 2 | 0 | 4 | 4 |
| Respiratory distress | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 2 | 0 |
| Respiratory infection | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 2 | 0 | 3 |
| Rheumatoid arthritis | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Sensory loss | 0 | 0 | 1 | 2 | 1 | 0 | 2 | 1 | 0 | 1 | 0 | 2 | 4 | 6 |
| Shortness of breath | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Skin and subcutaneous tissue | 0 | 0 | 2 | 4 | 0 | 2 | 0 | 0 | 1 | 4 | 1 | 0 | 4 | 10 |
| Soft tissue damage | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 1 | 1 | 3 | 0 | 3 | 1 | 9 |
| Spinal stenosis symptoms associated with non-index condition | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Spinal stenosis symptoms at index level | 0 | 0 | 12 | 11 | 8 | 4 | 13 | 7 | 4 | 12 | 4 | 6 | 41 | 40 |
| Spinous process fracture | 4 | 2 | 13 | 9 | 3 | 1 | 3 | 1 | 1 | 1 | 1 | 0 | 25 | 14 |
| Stroke | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 3 | 0 | 4 | 1 |
| Syncope | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 2 |
| Synovial cyst | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transient ischemic attack (TIA) | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Urinary tract infection | 1 | 1 | 3 | 1 | 3 | 0 | 1 | 1 | 1 | 3 | 1 | 0 | 10 | 6 |
| Vertebral compression fractures | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 1 | 1 | 3 |
| Wound dehiscence or delayed healing | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Wound drainage | 0 | 0 | 0 | 3 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 4 |

I[1] = Superion™ IDS, C[2] = X-STOP® IPD
*Infection AEs are defined as: including superficial infections and seroma at the surgical site, as well as infections at remote sites (e.g., sinus or throat infection)
**Musculoskeletal AEs are defined as: including weakness, cramping, joint pain, joint surgery or replacement, and other disorders in non-lumbar spinal tissues
***Other adverse events includes events not fitting a specific existing adverse event category, including insomnia, psychological disorder, weight loss, general weakness, ganglion cyst, and drug withdrawal.

## Device-Related Adverse Events

The most frequent device-related adverse events were spinous process fractures, as noted in Table 11 below, which occurred in 7.9% of Superion IDS patients and 2.5% of X-STOP IPD patients through 60 months. There were no large numerical differences in the number of device-related adverse events, with the exception of Deep infection at the operative site, Device migration, Device subsidence, Spinal stenosis symptoms at index level, and Spinous process fractures. However, given the low incidences of the aforementioned device-related adverse events, it is difficult to draw conclusions regarding the clinical importance of these differences.

**Table 11: Specific Device-Related Adverse Events in Superion™ IDS IDE up to 60 months (mITT cohort)**

| | Superion IDS (N = 190) | | | X-STOP® IPD (N = 201) | | |
|---|---|---|---|---|---|---|
| **Adverse Event Type** | **No. of Events** | **No of Pts.** | **% of Pts.** | **No. of Events** | **No. of Pts.** | **% of Pts.** |
| Deep infection at the operative site | 0 | 0 | 0.0 | 2 | 1 | 0.5 |
| Device breakage | 0 | 0 | 0.0 | 1 | 1 | 0.5 |
| Device deformation preventing device placement | 1 | 1 | 0.5 | 0 | 0 | 0.0 |
| Device dislodgement | 1 | 1 | 0.5 | 2 | 2 | 1.0 |
| Device migration | 1 | 1 | 0.5 | 5 | 5 | 2.5 |
| Device subsidence | 4 | 4 | 2.1 | 0 | 0 | 0.0 |
| Dural leaks | 1 | 1 | 0.5 | 0 | 0 | 0.0 |
| Loss of bowel control | 0 | 0 | 0.0 | 1 | 1 | 0.5 |
| Pain – Back | 1 | 1 | 0.5 | 1 | 1 | 0.5 |
| Pain - Leg | 1 | 1 | 0.5 | 1 | 1 | 0.5 |
| Spinal stenosis symptoms at index level | 0 | 0 | 0.0 | 4 | 4 | 2.0 |
| Spinous process fracture | 16 | 15 | 7.9 | 5 | 5 | 2.5 |
| Other | 2 | 2 | 1.1 | 1 | 1 | 0.5 |

## Procedure-Related Adverse Events

The most frequent procedure-related adverse events, as noted in Table 12 below, were spinous process fractures, which occurred in 8.9% of Superion IDS patients and 3.5% of X-STOP IPD patients. There were no large numerical differences in the number of procedure-related adverse events, with the exception of coronary episode, ischemic, deep infection at the operative site, device migration, device subsidence, dural leaks, spinal stenosis symptoms at index level, spinous process fracture and wound drainage. However, given the low incidences of the aforementioned procedure-related adverse events, it is difficult to draw conclusions regarding the clinical importance of these differences.

**Table 12: Specific Procedure- Related Adverse Events in Superion IDS IDE up to 60 months (mITT cohort)**

| | Superion IDS (N=190) | | | X-STOP IPD (N=201) | | |
|---|---|---|---|---|---|---|
| **Adverse Event Type** | **No. of Events** | **No of Pts.** | **% of Pts.** | **No. of Events** | **No. of Pts.** | **% of Pts.** |
| Coronary episode, ischemic | 0 | 0 | 0.0 | 4 | 1 | 0.5 |
| Deep infection at the operative site | 0 | 0 | 0.0 | 3 | 2 | 1.0 |
| Device deformation preventing device placement | 1 | 1 | 0.5 | 0 | 0 | 0.0 |
| Device dislodgement | 1 | 1 | 0.5 | 1 | 1 | 0.5 |
| Device migration | 1 | 1 | 0.5 | 4 | 4 | 2.0 |
| Device subsidence | 2 | 2 | 1.1 | 0 | 0 | 0.0 |
| Dural leaks | 3 | 3 | 1.6 | 0 | 0 | 0.0 |
| Fever | 0 | 0 | 0.0 | 1 | 1 | 0.5 |
| Genitourinary | 1 | 1 | 0.5 | 2 | 2 | 1.0 |
| Hematoma | 0 | 0 | 0.0 | 1 | 1 | 0.5 |
| Infection* | 2 | 2 | 1.1 | 2 | 1 | 0.5 |
| Nausea | 0 | 0 | 0.0 | 1 | 1 | 0.5 |
| Neurological disorder | 0 | 0 | 0.0 | 1 | 1 | 0.5 |
| Pain – Back | 1 | 1 | 0.5 | 1 | 1 | 0.5 |
| Pain – Leg | 1 | 1 | 0.5 | 0 | 0 | 0.0 |
| Renal insufficiency | 0 | 0 | 0.0 | 1 | 1 | 0.5 |

| Table 12: Specific Procedure- Related Adverse Events in Superion IDS IDE up to 60 months (mITT cohort) | | | | | | |
|---|---|---|---|---|---|---|
| | Superion IDS (N=190) | | | X-STOP IPD (N=201) | | |
| Adverse Event Type | No. of Events | No of Pts. | % of Pts. | No. of Events | No. of Pts. | % of Pts. |
| Respiratory disorder | 0 | 0 | 0.0 | 2 | 2 | 1.0 |
| Skin and subcutaneous tissue | 0 | 0 | 0.0 | 2 | 2 | 1.0 |
| Spinal stenosis symptoms at index level | 0 | 0 | 0.0 | 3 | 3 | 1.5 |
| Spinous process fracture | 18 | 17 | 8.9 | 7 | 7 | 3.5 |
| Wound drainage | 0 | 0 | 0.0 | 4 | 4 | 2.0 |
| Other, specify** | 1 | 1 | 0.5 | 0 | 0 | 0.0 |
| *Infection AEs are defined as: including superficial infections and seroma at the surgical site, as well as infections at remote sites (e.g., sinus or throat infection).<br>**Other adverse events includes events not fitting a specific existing adverse event category, including insomnia, psychological disorder, weight loss, general weakness, ganglion cyst, and drug withdrawal. | | | | | | |

As noted in Tables 11 and 12 above, the adverse events as determined by the CEC demonstrated that the Superion™ IDS patients experienced more device-related adverse events (Superion IDS, 11.6%; X-STOP® IPD, 7.5%), while X-STOP IPD patients experienced more procedure-related adverse events (Superion IDS, 14.2%; X-STOP IPD, 15.9%) through 24 months. At 60 months, the relationships were largely unchanged, with Superion IDS patients experiencing more device-related adverse events (Superion IDS 14.2%, X-STOP IPD 10.9%), while X-STOP IPD subjects experienced more procedure-related adverse events (Superion IDS 16.3%, X-STOP IPD 17.4%).

Specific Adverse Events with More than a 2% Difference Between Treatment Groups

For additional clarity, specific adverse events where the difference between Superion IDS and X-STOP IPD were more than 2% are shown in Table 13.

| Table 13: Specific Adverse Events in Superion IDE with > 2% Difference | | | | | | |
|---|---|---|---|---|---|---|
| | Superion IDS (N=190) | | | X-STOP IPD (N=201) | | |
| Adverse Event Type | No. of Events | No of Pts. | % of Pts. | No. of Events | No. of Pts. | % of Pts. |
| Angina | 4 | 4 | 2.1 | 0 | 0 | 0.0 |
| Cardiovascular | 25 | 20 | 10.5 | 20 | 16 | 8.0 |
| Device migration | 1 | 1 | 0.5 | 8 | 7 | 3.5 |
| Device subsidence | 4 | 4 | 2.1 | 0 | 0 | 0.0 |
| Diabetes mellitus | 0 | 0 | 0.0 | 5 | 5 | 2.5 |
| Dizziness | 6 | 6 | 3.2 | 1 | 1 | 0.5 |
| Genitourinary | 27 | 23 | 12.1 | 17 | 17 | 8.5 |
| Musculoskeletal* | 109 | 78 | 41.1 | 101 | 70 | 34.8 |
| Neurological disorder | 27 | 22 | 11.6 | 13 | 13 | 6.5 |
| Other** | 141 | 73 | 38.4 | 168 | 82 | 40.8 |
| Pain - Back | 68 | 60 | 31.6 | 91 | 80 | 39.8 |
| Pain - Buttock & Groin | 27 | 25 | 13.2 | 21 | 18 | 9.0 |
| Pain - Leg | 51 | 46 | 24.2 | 70 | 55 | 27.4 |
| Soft tissue damage | 1 | 1 | 0.5 | 9 | 8 | 4.0 |
| Spinal stenosis symptoms at index level | 41 | 39 | 20.5 | 40 | 35 | 17.4 |
| Spinous process fracture | 25 | 22 | 11.6 | 14 | 13 | 6.5 |
| *Musculoskeletal AEs are defined as: including weakness, cramping, joint pain, joint surgery or replacement, and other disorders in non-lumbar spinal tissues<br>**Other adverse events includes events not fitting a specific existing adverse event category, including insomnia, psychological disorder, weight loss, general weakness, ganglion cyst, and drug withdrawal. | | | | | | |

Serious Adverse Events

Serious adverse events occurred in 59.5% (113/190) of Superion IDS patients compared with 57.7% (116/201) of X-STOP IPD patients though 60 months. A listing of the specific serious adverse events which occurred during this study is shown in Table 14 below. (Some patients may have experienced more than one adverse event.)

| Table 14: Specific Serious Adverse Events in Superion IDS IDE up to 60 months (mITT cohort) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Superion (I) (N=190) | | | X-STOP IPD (C) N=201) | | | X-STOP minus Superion[1] | | |
| **Adverse Event Type** | **No. of Events** | **No of Pts.** | **% of Pts.** | **No. of Events** | **No. of Pts.** | **% of Pts.** | **Diff** | **LB** | **UB** |
| Abdominal pain | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Accidental injury | 6 | 5 | 2.6 | 6 | 5 | 2.5 | -0.1 | -1.0. | 9.8 |
| Adjacent level DDD | 1 | 1 | 0.5 | 1 | 1 | 0.5 | 0.0 | -9.9 | 9.9 |
| Adjacent level stenosis | 0 | 0 | 0.0 | 3 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Allergic reaction | 2 | 2 | 1.1 | 1 | 1 | 0.5 | -0.6 | -10.5 | 9.4 |
| Anemia | 3 | 2 | 1.1 | 0 | 0 | 0.0 | -1.1 | -11.0 | 8.9 |
| Angina | 2 | 2 | 1.1 | 0 | 0 | 0.0 | -1.1 | -11.0 | 8.9 |
| Cancer/Neoplasm | 8 | 7 | 3.7 | 6 | 6 | 3.0 | -0.7 | -10.6 | 9.2 |
| Cardiovascular | 11 | 8 | 4.2 | 9 | 7 | 3.5 | -0.7 | -10.6 | 9.2 |
| Cerebrovascular accident (CVA) | 2 | 2 | 1.1 | 1 | 1 | 0.5 | -0.6 | -10.5 | 9.4 |
| Chronic obstructive pulmonary disease (COPD) | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Coronary episode, ischemic | 0 | 0 | 0.0 | 5 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Deep infection at the operative site | 0 | 0 | 0.0 | 3 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Deep vein thrombosis | 1 | 1 | 0.5 | 1 | 1 | 0.5 | 0 | -9.9 | 9.9 |
| Device Dislodgement | 0 | 0 | 0.0 | 2 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Device Migration | 1 | 1 | 0.5 | 4 | 3 | 1.5 | 1.0 | -8.9 | 10.9 |
| Device Subsidence | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Dizziness | 2 | 2 | 1.1 | 0 | 0 | 0.0 | -1.1 | -11.0 | 8.9 |
| Dural leaks | 6 | 6 | 3.2 | 2 | 2 | 1.0 | -2.2 | -12.0 | 7.8 |
| Dyspnea | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Edema | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Fever | 0 | 0 | 0.0 | 2 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Gallstones | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Gastrointestinal | 4 | 4 | 2.1 | 3 | 3 | 1.5 | -0.6 | -10.5 | 9.3 |
| Gastrointestinal (GI) bleed | 1 | 1 | 0.5 | 1 | 1 | 0.5 | 0.0 | -9.9 | 9.9 |
| Genitourinary | 9 | 8 | 4.2 | 4 | 4 | 2.0 | -2.2 | -12.1 | 7.7 |
| Hematoma | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Infection* | 2 | 2 | 1.1 | 1 | 1 | 0.5 | -0.6 | -10.5 | 9.4 |
| Loss of bowel control | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Musculoskeletal** | 16 | 15 | 7.9 | 24 | 21 | 10.4 | 2.6 | -7.4 | 12.4 |
| Myocardial infarction | 5 | 5 | 2.6 | 3 | 3 | 1.5 | -1.1 | -11 | 8.8 |
| Nausea | 0 | 0 | 0.0 | 2 | 2 | 1.0 | 1 | -8.9 | 10.9 |
| Neurological disorder | 3 | 3 | 1.6 | 3 | 3 | 1.5 | -0.1 | -10 | 9.8 |
| Other*** | 38 | 29 | 15.3 | 29 | 23 | 11.4 | -3.8 | -13.7 | 6.1 |
| Pain - Back | 11 | 11 | 5.8 | 15 | 15 | 7.5 | 1.7 | -8.3 | 11.6 |
| Pain - Buttock | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Pain - Buttock & Groin | 3 | 3 | 1.6 | 6 | 5 | 2.5 | -0.9 | -9.0 | 10.8 |
| Pain - Hip | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Pain - Leg | 12 | 11 | 5.8 | 15 | 14 | 7.0 | 1.2 | -8.8 | 11.1 |
| Peripheral Vascular Disorder | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Pneumonia | 7 | 6 | 3.2 | 2 | 2 | 1.0 | -2.2 | -12.0 | 7.8 |
| Presence of osteophyte formation associated with severe disc or facet degeneration | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |

| Table 14: Specific Serious Adverse Events in Superion IDS IDE up to 60 months (mITT cohort) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Superion (I) (N=190) | | | X-STOP IPD (C) N=201) | | | X-STOP minus Superion[1] | | |
| Adverse Event Type | No. of Events | No of Pts. | % of Pts. | No. of Events | No. of Pts. | % of Pts. | Diff | LB | UB |
| Pulmonary edema | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Pulmonary embolism | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |
| Renal failure | 3 | 3 | 1.6 | 1 | 1 | 0.5 | -1.1 | -11 | 8.8 |
| Respiratory disorder | 2 | 2 | 1.1 | 1 | 1 | 0.5 | -0.6 | -10.5 | 9.4 |
| Respiratory distress | 2 | 2 | 1.1 | 0 | 0 | 0.0 | -1.1 | -11 | 8.9 |
| Respiratory infection | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Sensory loss | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Soft tissue damage | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Spinal stenosis symptoms at index level | 24 | 23 | 102.1 | 19 | 17 | 8.5 | -3.6 | -13.5 | 6.3 |
| spinous process fracture | 11 | 10 | 5.3 | 5 | 5 | 2.5 | -2.8 | -12.7 | 7.2 |
| stroke | 4 | 4 | 2.1 | 0 | 0 | 0.0 | -2.1 | -12.0 | 7.8 |
| Transient ischemic attack (TIA) | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Urinary tract infection | 0 | 0 | 0.0 | 2 | 2 | 1.0 | 1.0 | -8.9 | 10.9 |
| Vertebral compression fracture | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Wound dehiscence or delayed healing | 0 | 0 | 0.0 | 1 | 1 | 0.5 | 0.5 | -9.4 | 10.4 |
| Wound drainage | 1 | 1 | 0.5 | 0 | 0 | 0.0 | -0.5 | -10.4 | 9.4 |

[1] Exact 95% confidence interval for the group difference (X-STOP® minus Superion).
*Infection AEs are defined as: including superficial infections and seroma at the surgical site, as well as infections at remote sites (e.g., sinus or throat infection)
**Musculoskeletal AEs are defined as: including weakness, cramping, joint pain, joint surgery or replacement, and other disorders in non-lumbar spinal tissues
***Other adverse events includes events not fitting a specific existing adverse event category, including insomnia, psychological disorder, weight loss, general weakness, ganglion cyst, and drug withdrawal.

Device- or Procedure-Related Serious Adverse Events

In regards to serious adverse events which were device- or procedure-related, X-STOP® IPD patients exhibited a slightly higher rate of serious adverse events that were device- or procedure-related (X-STOP IPD: 10.9% (22/201), Superion™ IDS: 8.9% (17/190)) through 60 months. These device- or procedure-related serious adverse events primarily occur the day of surgery through Month 3 postoperatively. (Some patients may have experienced more than one adverse event.)

| Table 15: Counts and Percentages of Serious Device or Procedure-Related Adverse Events in Superion IDS IDE up to 60 months (mITT cohort) | | | | | | |
|---|---|---|---|---|---|---|
| | Superion (I) (N=190) | | | X-STOP (C) (N=201) | | |
| Adverse Event Type | No. of Events | No of Pts. | % of Pts. | No. of Events | No. of Pts. | % of Pts. |
| Coronary episode, ischemic | 0 | 0 | 0.0 | 4 | 1 | 0.5 |
| Deep infection at the operative site | 0 | 0 | 0.0 | 3 | 2 | 1.0 |
| Device dislodgement | 0 | 0 | 0.0 | 2 | 2 | 1.0 |
| Device migration | 1 | 1 | 0.5 | 2 | 2 | 1.0 |
| Device subsidence | 1 | 1 | 0.5 | 0 | 0 | 0.0 |
| Dural leaks | 3 | 3 | 1.6 | 0 | 0 | 0.0 |
| Genitourinary | 1 | 1 | 0.5 | 2 | 2 | 1.0 |
| Hematoma | 0 | 0 | 0.0 | 1 | 1 | 0.5 |
| Infection* | 1 | 1 | 0.5 | 0 | 0 | 0.0 |
| Nausea | 0 | 0 | 0.0 | 1 | 1 | 0.5 |
| Pain – Back | 1 | 1 | 0.5 | 1 | 1 | 0.5 |
| Pain – Leg | 1 | 1 | 0.5 | 0 | 0 | 0.0 |
| Respiratory disorder | 0 | 0 | 0.0 | 1 | 1 | 0.5 |
| Spinal stenosis symptoms at index level | 0 | 0 | 0.0 | 5 | 5 | 2.5 |

| Table 15: Counts and Percentages of Serious Device or Procedure-Related Adverse Events in Superion IDS IDE up to 60 months (mITT cohort) | | | | | | |
|---|---|---|---|---|---|---|
| | Superion (I) (N=190) | | | X-STOP (C) (N=201) | | |
| Adverse Event Type | No. of Events | No of Pts. | % of Pts. | No. of Events | No. of Pts. | % of Pts. |
| Spinous process fracture | 11 | 10 | 5.3 | 5 | 5 | 2.5 |
| Other, specify** | 1 | 1 | 0.5 | 1 | 1 | 0.5 |

*Infection AEs are defined as: including superficial infections and seroma at the surgical site, as well as infections at remote sites (e.g., sinus or throat infection)

Overall Conclusions from Review of Adverse Events

The overall adverse event rates of the Superion IDS and X-STOP IPD cohorts subjects were similar, but there were differences in the types of adverse events. While the devices each had different associated adverse event rates associated with individual types of events (e.g., spinous process fracture or migration/dislodgement), the balance of these events, either severe or non-severe, and overall adverse event rate, were not preferential to one device or another. More specifically, Superion™ IDS subjects experienced more device-related adverse events; as compared with X-STOP® IPD subjects who numerically experienced more procedure-related adverse events, although the differences were similar between the two groups. The data presented demonstrates a reasonable assurance of the safety of the Superion IDS device compared to an approved device (X-STOP IPD) for the same intended patient population of moderate degenerative lumbar spinal stenosis.

**Subsequent Surgical Interventions**

A time course listing of subsequent surgical interventions is provided in Table 16 (Superion IDS) and Table 17 (X-STOP IPD). In the modified intent-to-treat patient population (mITT) through 24 months (as part of the primary endpoint), there were a total of 38 reoperations or revisions in the Superion IDS group (38/190, 20.0%) compared with 29 reoperations or revisions in the X-STOP IPD group (29/201, 14.4%). Reoperations and revisions in subjects prior to 24 months of treatment were considered to be failures in the primary endpoint.

In the modified intent-to-treat patient population (mITT) through the last available follow-up (included some time points past 24 months) at the time of PMA submission, there were a total of 49 reoperations or revisions in the Superion IDS group (49/190, 25.8%) compared with 44 reoperations or revisions in the X-STOP IPD group (44/201, 21.9%). The majority of reoperations and revisions were performed for pain adverse events (either back pain or leg pain, or combined back and leg pain).

Through 60 months, there were a total of 55 reoperations or revisions in the Superion IDS group (55/190, 28.9%) compared with 56 reoperations or revisions in the X-STOP IPD group (56/201, 27.8%). Here also, the majority of reoperations and revisions were performed for pain adverse events (either back pain or leg pain, or combined back and leg pain).

At 60 months, similar numbers of subjects had decompression and device removal (Superion IDS [14.2% (27/190)]; X-STOP IPD [13.4% (27/201)]), device removal and fusion (Superion IDS [9.5% (13/190)]; X-STOP IPD [10.0% (20/201)]) and device removal (Superion IDS [0.5% (1/190)]; X-STOP IPD [1.0% (2/201)]) between the 2 groups.

A higher percentage of Superion IDS subjects had supplemental decompression (Superion IDS [2.1% (4/190)]; X-STOP IPD [0.0% (0/201)]). Two (2) X-STOP IPD subjects had an intraoperative complication preventing implantation (1.0% - 2/201), compared with one (1) Superion IDS patient (0.5% - 1/190). The primary reason for reoperation or revision in both Superion IDS and X-STOP IPD subjects was related to continued pain.

| Table 16: Reoperation and Revision Events in the Superion IDS Arm – (mITT) Population | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Superion IDS n=190 | | | | | | | | | | |
| Reoperation or Revision Type* | Event Time Course (months) | | | | | | | | Total (events) | Reasons |
| | <1.5 | 1.5-3 | 3-6 | 6-12 | 12-24 | 24-36 | 36-48 | 48-60 | | |
| Decompression and Device Removal | - | 3 (1.6%) | 4 (2.1%) | 8 (4.2%) | 4 (2.1%) | 5 (2.6%) | 2 (1.1%) | 1 (0.5%) | 27 (14.2%) | 21 leg and/or low back pain, 2 bone-related fracture, 2 neurological decline, 1 device deployment issue, 1 facet cyst |
| Device Removal and Fusion | 1 (0.5%) | - | - | 4 (2.1%) | 5 (2.6%) | 3 (1.6%) | 4 (2.1%) | - | 18 (9.5%) | 12 leg and/or low back pain, 2 bone-related fracture, 1 neurological decline, 3 unknown |
| Device Removal | - | - | - | 1 (0.5%) | - | - | - | - | 1 (0.5%) | 1 leg and/or low back pain |
| Fusion (no device removal) | - | - | - | 1 (0.5%) | 1 (0.5%) | 1 (0.5%) | - | - | 3 (1.6%) | 2 leg and/or low back pain, 1 synovial cyst |
| Supplemental Decompression | - | - | 2 (1.1%) | 1 (0.5%) | 1 (0.5%) | - | - | - | 4 (2.1%) | 3 leg and/or low back pain, 1 synovial cyst |
| I&D and Device Removal | 1 (0.5%) | - | - | - | - | - | - | - | 1 (0.5%) | 1 dural tear |
| Intraoperative Failure | 1 (0.5%) | - | - | - | - | - | - | - | 1 (0.5%) | 1 dural tear |
| Subtotal Events | 3 (1.6%) | 3 (1.6%) | 6 (3.2%) | 15 (7.9%) | 11 (5.8%) | 9 (4.7%) | 6 (3.2%) | 2 (1.1%) | 55 (28.9%) | |

*Single patients may be listed in more than one category

| Table 17: Reoperation and Revision Events in the X-STOP® IPD Arm - (mITT) Population | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| X-STOP IPD, n=201 | | | | | | | | | | |
| Reoperation or Revision Type* | Event Time Course (months) | | | | | | | | Total (events) | Reasons |
| | <1.5 | 1.5-3 | 3-6 | 6-12 | 12-24 | 24-36 | 36-48 | 48-60 | | |
| Decompression and Device Removal | 1 (0.5%) | 1 (0.5%) | 3 (1.5%) | 3 (1.5%) | 8 (4.0%) | 4 (2.0%) | 3 (1.5%) | 1 (2.0%) | 27 (13.4%) | 22 leg and/or low back pain, 3 device dislodgement, 1 neurological decline, 1 herniated disc |
| Device Removal and Fusion | - | - | - | 2 (0.5%) | 5 (2.5%) | 5 (2.5%) | 5 (2.5%) | 3 (1.5%) | 20 (10.0%) | 19 leg and/or low back pain, 1 bone-related fracture |
| Device Removal | - | - | - | 1 (0.5%) | - | 1 (0.5%) | - | - | 2 (1.0%) | 1 leg and/or low back pain, 1 bone-related fracture |
| Device Replacement | - | 1 (0.5%) | - | 1 (0.5%) | - | 1 (0.5%) | - | - | 3 (1.5%) | 2 leg and/or low back pain |
| Intraoperative Failure | 2 (1.0%) | - | - | - | - | - | - | - | 2 (1.0%) | 2 bone-related fracture |
| Irrigation and Debridgement | 2 (1.0%) | - | - | - | - | - | - | - | 2 (1.0%) | 2 deep infection |
| Subtotal Events | 5 (2.5%) | 2 (1.0%) | 3 (1.5%) | 7 (3.5%) | 13 (6.5%) | 11 (5.5%) | 8 (4.0%) | 7 (3.5%) | 56 (27.9%) | |
| *Single patients may be listed in more than one category | | | | | | | | | | |

**Additional Treatments (Epidurals, Rhizotomies and Spinal Cord Stimulators)**

Following index surgery, 25 of the 190 (13.2%) Superion™ ISDS mITT subjects received an epidural steroid injection or nerve block at the level(s) of surgery prior to Month 24. In contrast, 33 of the 201 (16.4%) X-STOP® IPD mITT subjects received an epidural steroid injection or nerve block at the level(s) of surgery prior to Month 24. All subjects who received an epidural steroid injection or nerve block at the level(s) of surgery prior to Month 24 were considered study failures. Through 60 months, 33 Superion IDS patients (17.4%) and 40 X-STOP IPD patients (20.0%) had such an injection.

Following index surgery, 0 of the 190 (0.0%) Superion IDS mITT subjects received a rhizotomy at the level(s) of surgery prior to Month 24. One (1) of the 201 (0.5%) X-STOP IPD mITT subjects received a rhizotomy and was therefore considered a study failure. No subject in either group received a spinal cord stimulator at the level(s) of surgery through 24 months.

As shown in Table 18, 49.5% of Superion IDS subjects, and 31,8% of X-STOP IPD subjects were taking opioid narcotic medications pre-operatively, at the time of enrollment. The percentage increased in the immediate post-operative period to 64.1% for Superion IDS subjects, and 35.8% for X-STOP IPD subjects, but decreased markedly thereafter to 13.3% in Superion IDS subjects and 7.1% in X-STOP IPD subjects at 24 months, and to 7.5% in Superion IDS subjects and 6.2% in X-STOP IPD subjects at 60 months. This represents a 73.1% decrease from pre-operative opioid use among Superion IDS patients at 24 months, and an 84.8% decrease from pre-operative opioid use at 60 months. X-STOP IPD opioid use decreased 77.7% from pre-operative use at 24 months, and 80.5% from pre-operative use at 60 months.Narcotic use was not a study failure criterion.

**Table 18: Narcotic Use – Percent of Subjects at Each Follow-Up**

| | Preop | 6 Wks | 3 Mos | 6 Mos | 12 Mos | 18 Mos | 24 Mos | 36 Mos | 48 Mos | 60 Mos |
|---|---|---|---|---|---|---|---|---|---|---|
| Superion | 49.5% | 64.1% | 29.5% | 27.6 | 25.2% | 17.3% | 13.3% | 11.2% | 8.5% | 7.5% |
| X-STOP | 31.8% | 35.8% | 8.5% | 8.6% | 7.3% | 5.1% | 7.1% | 7.0% | 6.2% | 6.2% |

**Surgery and Hospitalization Data**

The operative details from the IDE subjects are shown in Table 19 and Table 20. The Superion IDS was implanted via a minimally-invasive or “mini-open” approach, compared to X-STOP IPD which was implanted via an open approach. As expected, Table 19 shows that mean blood loss was numerically greater with the X-STOP IPD device, likely due to the surgical approach. Operative time, however, was numerically greater in the Superion IDS group

**Table 19: Perioperative Results from Superion IDS IDE (mean ± SD)**

| Operative Detail | Superion IDS (n=190) | X-STOP IPD (n=200) |
|---|---|---|
| Blood Loss (cc) | 13.5 ± 15.9 | 38.7 ± 43.8 |
| Hospital Length of Stay (days) | 1.80 ± 1.5 | 1.90 ± 1.5 |
| Operative Time (min) | 56.3 ± 26.8 | 47.2 ± 18.8 |

Repair of the supraspinous ligament was performed in approximately half of the Superion IDS group. This procedure was not performed in any of the X-STOP IPD group. As shown in Table 20, additional procedures which could be interpreted as decompression procedures (e.g., facet debulking, osteophyte removal, soft tissue removal), were performed in 11 levels in 9 Superion IDS subjects and 16 levels in 12 X-STOP IPD subjects.

**Table 20: Operative Variables from the Superion IDS Clinical Trial (mITT cohort)**

| | Superion IDS | | X-STOP IPD | |
|---|---|---|---|---|
| | **n** | **%** | **n** | **%** |
| Number of Subjects Treated | 189 | | 199 | |
| Subjects Attempted / Not Implanted | 1 | 8.4 | 2 | 3.7 |
| **Number of Levels Treated** | **n** | **%** | **n** | **%** |
| 1 | 99 | 52.4 | 99 | 49.7 |
| 2 | 90 | 47.6 | 100 | 50.3 |
| **One Level Treated** | **n** | **%** | **n** | **%** |
| L1-L2 | 1 | 1.0 | 0 | 0.0 |
| L2-L3 | 0 | 0.0 | 5 | 5.1 |
| L3-L4 | 7 | 7.1 | 9 | 9.1 |
| L4-L5 | 91 | 91.9 | 85 | 85.9 |
| **Two Levels Treated** | **n** | **%** | **n** | **%** |

| Table 20: Operative Variables from the Superion IDS Clinical Trial (mITT cohort) | | | | |
|---|---|---|---|---|
| L1-L2/L2-L3 | 2 | 2.2 | 1 | 1.0 |
| L2-L3/L3-L4 | 8 | 8.9 | 7 | 7.0 |
| L2-L3/L4-L5 | 0 | 0.0 | 1 | 1.0 |
| L3-L4/L4-L5 | 80 | 88.9 | 91 | 91.0 |
| L4-L5/L5-S1 | 0 | 0.0 | 0 | 0.0 |
| **Anesthesia Type (all patients)** | **n** | **%** | **n** | **%** |
| General | 156 | 82.1 | 179 | 89.1 |
| Conscious IV Sedation | 25 | 13.2 | 18 | 9.0 |
| Local | 14 | 7.4 | 11 | 5.5 |
| **Surgical Approach (as treated patients by level)** | **n** | **%** | **n** | **%** |
| Percutaneous | 131 | 46.8 | 0 | 0.0 |
| Mini-Open | 149 | 53.2 | 0 | 0.0 |
| Open | 0 | 0.0 | 299 | 100.00 |
| **Device Size (as treated patients by level)** | **n** | **%** | **n** | **%** |
| 6 mm (X-STOP IPD only) | N/A | N/A | 2 | 0.7 |
| 8 mm | 2 | 0.7 | 9 | 3.0 |
| 10 mm | 36 | 12.9 | 71 | 23.8 |
| 12 mm | 95 | 33.9 | 131 | 43.8 |
| 14 mm | 117 | 41.8 | 79 | 26.4 |
| 16 mm (Superion) | 30 | 10.7 | 7 | 2.3 |
| **Supraspinous Ligament sutured (A T by level)** | **n** | **%** | **n** | **%** |
| Yes | 130 | 46.4 | N/A | N/A |
| No | 150 | 53.6 | N/A | N/A |
| **Additional Procedure (as treated by patients by level)** | **n** | **%** | **n** | **%** |
| Any additional procedures | 11 | 3.9 | 16 | 5.4 |
| Facet(s) debulking | 0 | 0.0 | 2 | 0.7 |
| Osteophyte removal | 3 | 1.1 | 3 | 1.0 |
| Soft tissue removal | 6 | 2.1 | 13 | 4.4 |
| Laminectomy / wide decompression | 0 | 0.0 | 1 | 0.3 |
| Other | 2 | 0.7 | 1 | 0.3 |

**Radiographic Data Potentially Related to Safety**

Radiographic observations were reported in the Superion IDS IDE based on independent radiographic review of all radiographs. The overall incidence of radiographic observations is presented in Table 21.

Following index surgery through 24 months, 31 of the 190 (16.3%) Superion IDS mITT subjects had a spinous process fracture identified by the radiographic core lab. In contrast, 17 of the 201 (8.5%) X-STOP® IPD mITT subjects had a spinous process fracture through 24 months. No Superion IDS patient incurred a fracture after 24 months, while in one X-STOP IPD patient a fracture was detected at the 60 month visit. By 24 months, healed fractures were noted (as determined by independent radiographic review) in 10 of the 31 Superion IDS subjects (32.3%) and 7 of the X-STOP IPD subjects (41.2%). By 60 months, 14 of the fractures detected in Superion IDS patients remained unhealed (45%), while 6 fractures in X-STOP IPD patients remained unhealed (35%) In addition, 24 of the 201 (11.9%) X-STOP IPD subjects had a device dislodgement or migration, as reported by independent radiographic assessment. These results are outlined in Table 21. In contrast, none of the Superion IDS subjects exhibited device dislodgement or migration, using the same assessment standards. In contrast to the X-STOP IPD, once placed, the Superion IDS appeared to retain its postoperative position between the spinous processes.

| Table 21: Subjects with Radiographic Observations in the Superion IDE | | | | |
|---|---|---|---|---|
| Radiographic Observation | Superion™ IDS (n=190) | | X-STOP® IPD (n=201) | |
| | n | % | n | % |
| Spinous Process Fracture (any time) | 31 | 16.3% | 17 | 8.5% |
| Spinous Process Fracture (non-healed at 24 months) | 21 | 11.1% | 10 | 5.0% |
| Spinous Process Fracture (non-healed at 60 months) | 14 | 7.3% | 7 | 3.0% |
| Device Migration (> 5mm) | 0 | 0.0% | 13 | 6.5% |
| Device Dislodgement | 0 | 0.0% | 20 | 10.0% |
| Any Radiographic Observation (any time) | 31 | 16.3% | 34* | 16.9% |
| Any Radiographic Observation (24 months) | 21 | 11.1% | 28 | 13.9% |
| Any Radiographic Observation (60 months) | 14 | 7.3% | 25 | 12.4% |

*Significant overlap was present in X-STOP IPD subjects having spinous process fractures, device migration, and device dislodgement.

It should be noted that the study demonstrated a discrepancy between spinous process fractures as determined by the investigators (investigational group - 13; control group - 10), by the radiographic core lab (investigational group - 31; control group - 17), and by the CEC (investigational group - 24; control group - 14) as shown below in Table 22. The results from independent radiographic review were used in the final Clinical Composite Success (CCS) analysis and are also shown in Table 22 below. Vertiflex™ has explained the discrepancy between site reported observations, observations by the CEC, and observations by the radiographic core lab by stating that the radiographic core lab was equipped with more sensitive imaging equipment and some of the fractures were asymptomatic. Vertiflex has provided an analysis of ZCQ, ODI, and VAS (Leg and Back) scores at 24 months in support of this statement (see Table 26 below). as indicated above, the core laboratory determined that 21 investigational and 10 control fractures remained unhealed at 24 months, and 14 investigational arm and 7 control arm fractures remained unhealed at 60 months, one of the latter having been detected at the 60 month visit.

| Table 22: Fracture Identification and Reporting in the Superion IDE | | | | | | |
|---|---|---|---|---|---|---|
| Number of Spinous Process Fractures According to Reporting Method | Training Cohort | | Superion IDS mITT Cohort | | X-STOP IPD mITT Cohort | |
| | Events | Subjects | Events | Subjects | Events | Subjects |
| **Adverse Events** | | | | | | |
| Site Reported* | 0 | 0 | 13 | 11 | 10 | 9 |
| CEC Adjudicated** | 3 | 3 | 24 | 22 | 14 | 13 |
| Independent Radiographic Review | 6 | 6 | 31 | 31 | 17 | 17 |
| Non-Healed Fractures (M24)*** | 2 | 2 | 21 | 21 | 10 | 10 |
| Non-Healed Fractures (M60) | 2 | 2 | 14 | 14 | 7**** | 7 |

*Site reported fractures are those adverse events originally placed in the “spinous process fracture” category by the investigators.
**Note that the CEC had access to the results of the independent radiographic review as reported by the Radiology Core Laboratory and re-categorized several adverse events as spinous process fractures.
***Incidences of non-healed fractures at 24 months post index procedure as determined by the Radiology Core Laboratory.
****One (1) additional fracture observed at 60 months.

Spinous process fractures observed via independent radiographic review were further characterized by the timing of fracture diagnosis on imaging studies. The time course of spinous process fractures in both treatment groups is shown in Table 23. As demonstrated in Table 23 below, the majority of spinous process fractures in both treatment groups were observed within 6 weeks of device implantation. In addition, 4/31 (12.9%) of Superion IDS subjects and 1/17 (5.9%) X-STOP IPD subjects with fractures had an observation of fracture in the immediate post-operative x-ray.

| Table 23: Time Course of Spinous Process Fractures in Superion™ IDS & X-STOP® IPD Patients | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Post-op | Week 6 | Month 3 | Month 6 | Month 12 | Month 18 | Month 24 | > Month 24 | Total |
| Superion IDS | 4 | 23 | 3 | - | 1 | - | - | - | 31 |
| X-STOP IPD | 1 | 13 | 2 | 1 | - | - | - | 1 | 18 |
| Superion IDS | 30/31 (96.7%) btw 0-3 months | | | 1/31 (3.2%) btw 6-24 months | | | | | |
| X-STOP® IPD | 16/18 (88.9%) btw 0-3 months | | | 1/18 (5.5 %) btw 6-24 months | | | | 1/18 (5.5%) @ 60 Months | |

Table 24 and Table 25 provide additional details regarding the characteristics of the spinous process fractures. The majority of fractures in the Superion IDS group were located in continuity with the device, while those in the X-STOP IPD group were located anterior to the device. Specifically, in the Superion IDS group, a majority of the fractures (80.6%) present were coincident or in contact with the device, while in the X-STOP IPD group, a majority of the fractures (70.6%) were present anterior to the location of the device. Healing (Table 24) was observed at 24 months at a higher rate in fractures that were anterior to the device (Superion IDS [50.0% (2/4)]; X-STOP IPD [50.0% (6/12)]) compared with those fractures coincident with the device (Superion IDS [28.0% (7/25)]; X-STOP IPD [20.0% (1/5)]).

| Table 24: Fracture Healing by Location | | | | | | |
|---|---|---|---|---|---|---|
| Device | Coincident with Device | | | Anterior to Device | | |
| | n | % of Fractures | % Healed by 24M | n | % of Fractures | % Healed by 24M |
| Superion IDS[1] | 25 | 80.6% | 28.0% (7/25) | 4 | 12.9% | 50.0% (2/4) |
| X-STOP IPD | 5 | 29.4% | 20.0% (1/5) | 12 | 70.6% | 50.0% (6/12) |

[1] Location of spinous process fracture information was not available for 2 Superion IDS subjects with fractures

The majority of fractures in both Superion IDS [83.9% (26/31)] and X-STOP IPD [88.2% (15/17)] groups were displaced fractures (Table 25). A displaced fracture was defined by Vertiflex™ as no contact between the fragment and the remaining vertebra with at least a 2mm wide gap at some point along the fracture gap. However, Vertiflex notes that healing of the displaced fractures was observed in a subset of patients. Healing of displaced spinous process fractures was noted in 23.1% (6/26) of Superion IDS subjects and 40.0% (6/15) of X-STOP IPD subjects.

| Table 25: Fracture Healing in Subjects with Displaced and Non-displaced Fractures | | | | | | |
|---|---|---|---|---|---|---|
| Device | Displaced Fractures | | | Non-Displaced Fractures | | |
| | n | % of Fractures | % Healed by 24M | n | % of Fractures | % Healed by 24M |
| Superion IDS[1] | 26 | 83.9% | 23.1% (6/26) | 3 | 9.6% | 100.0% (3/3) |
| X-STOP IPD | 15 | 88.2% | 40.0% (6/15) | 2 | 11.8% | 50.0% (1/2) |

[1] Displacement of spinous process fracture information was not available for 2 Superion IDS subjects with fractures, nor were analyses performed beyond the 24 month imaging.

Clinical outcomes were also correlated with the presence of spinous process fractures identified by the independent radiographic core lab, as reported in Table 26 below. When reviewing the possible clinical sequelae of spinous process fractures, there were no notable differences demonstrated in ZCQ, ODI, VAS Back pain, VAS Leg pain, and SF-12 in either the Superion IDS or X-STOP IPD groups, as compared to patients in each group that were not diagnosed with a spinous process fracture. The 24 month results are shown in Table 26a below, and the 60 month results are shown in Table 26b belo

| Table 26a: Clinical Outcome Measurements Stratified by Presence or Absence of Spinous Process Fracture at Any Time Point, 24 Months (mITT cohort) | | | | |
|---|---|---|---|---|
| **24 Month Clinical Outcomes** | **Superion™ IDS** | | **X-STOP® IPD** | |
| | **Fracture** | **No Fracture** | **Fracture[1]** | **No Fracture** |
| **Pain** | | | | |
| VAS Back: ≥20mm decrease | 78.3% (18/23) | 64.8% (70/108) | 46.2% (6/13) | 70.8% (85/120) |
| VAS Leg (Worse): ≥20mm decrease | 73.9% (17/23) | 75.9% (82/108) | 69.2% (9/13) | 78.3% (94/120) |
| **Back & Stenosis-Related Outcomes** | | | | |
| ZCQ Physical Function: ≥0.5 point decrease | 73.9% (17/23) | 72.2% (78/108) | 76.9% (10/13) | 80.8% (97/120) |
| ZCQ Symptom Severity: ≥0.5 point decrease | 78.3% (18/23) | 76.9% (83/108) | 69.2% (9/13) | 81.7% (98/120) |
| ZCQ Patient Satisfaction ≤2.5 points | 73.9% (17/23) | 86.1% (93/108) | 84.6% (11/13) | 92.5% (111/120) |
| ODI: ≥15 point decrease | 65.2% (15/23) | 63.0% (68/108) | 61.5% (8/13) | 67.5% (81/120) |

[1] Subjects in the fracture group for X-STOP include those subjects who had an incidence of both spinous process fracture and migration and/or dislodgement.

| Table 26b: Clinical Outcome Measurements Stratified by Presence or Absence of Spinous Process Fracture at Any Time Point, at 60 months Months (mITT cohort) | | | | |
|---|---|---|---|---|
| **60 Month Clinical Outcomes** | **Superion IDS** | | **X-STOP IPD** | |
| | **Fracture** | **No Fracture** | **Fracture[1]** | **No Fracture** |
| **Pain** | | | | |
| VAS Back: ≥20mm decrease | 63.6% (7/11) | 63.3% (31/49) | 50.0% (5/10) | 75.0% (54/72) |
| VAS Leg (Worse): ≥20mm decrease | 81.8% (9/11) | 75.5% (37/49) | 50.0% (5/10) | 79.2% (57/72) |
| **Back & Stenosis-Related Outcomes** | | | | |
| ZCQ Physical Function: ≥0.5 point decrease | 63.6% (7/11) | 80.4% (41/51) | 60.0% (6/10) | 83.3% (60/72) |
| ZCQ Symptom Severity: ≥0.5 point decrease | 63.6% (7/11) | 76.5% (39/51) | 60.0% (6/10) | 86.1% (62/72) |
| ZCQ Patient Satisfaction ≤2.5 points | 72.7% (8/11) | 92.2% (47/51) | 80.0% (8/10) | 95.8% (69/72) |
| ODI: ≥15 point decrease | 54.5% (6/11) | 64.7% (33/51) | 40.0% (4/10) | 72.2% (52/72) |

[1]Subjects in the fracture group for X-STOP include those subjects who had an incidence of both spinous process fracture and migration and/or dislodgement..

Additional treatments were also assessed for subjects with and without spinous process fractures (Table 27). Superion IDS subjects and X-STOP IPD subjects presenting with spinous process fractures had lower re-operation and epidural injection rates compared to subjects without fractures. These data demonstrate that subjects observed to have a spinous process fracture by the independent radiographic lab required an additional treatment at a lower rate than study subjects without spinous fractures. These results, coupled with the clinical outcomes presented in Table 26, suggest that some of these spinous process fractures may have been asymptomatic.

| Table 27: Additional Treatments Stratified by Presence or Absence of Spinous Process Fracture at Any Time Point, 60 Months | | | | |
|---|---|---|---|---|
| **Treatment Type** | **Superion™ IDS** | | **X-STOP® IPD** | |
| | **Fracture** | **No Fracture** | **Fracture** | **No Fracture** |
| Reoperation or Revision | 19.4% (6/31) | 26.4%% (42/159) | 23.5% (4/17) | 23.4% (43/184) |
| Epidural Steroid Injection or Nerve Root Block | 12.9% (4/31) | 18.2% (29/159) | 23.5% (4/17) | 19.6% (36/184) |
| **Overall Additional Treatment*** | **25.8% (8/31)** | **36.5% (58/159)** | **23.5% (4/17)** | **23.4% (43/184)** |
| *Subjects could have both a reoperation and injection during follow-up. | | | | |

**Neurologic Status Outcomes**

Neurologic success was defined as maintenance or improvement in neurological status as assessed by motor, sensory and deep tendon reflex examination. The rate of neurologic failures was similar for both Superion IDS and X-STOP IPD groups. The Superion IDS patient population had seven (7) patients (3.7%) that developed new or worsening persistent motor or sensory neurologic assessments at 24 months, while the X-STOP IPD population had five (5) failures (2.5%) as shown in Table 28 below. By 60 months, an additional 3 Superion IDS patients had a neurological failure, for a total of ten (10). Vertiflex™ also provided an analysis of ZCQ scores at 24 months for these patients. Only one Superion IDS patient that was a neurologic failure was also a ZCQ failure.

| Table 28: Neurological Outcome Failures in the Superion IDE Trial (mITT Patient Population) | | | | |
|---|---|---|---|---|
| **Type of Neurological Failure** | **Superion IDS** | | **X-STOP IPD** | |
| | **n** | **%** | **n** | **%** |
| Motor Failure | 5 | 3.6 | 3 | 1.5 |
| Sensory Failure | 4 | 2.1 | 1 | 0.5 |
| Motor & Sensory Failure | 1 | 0.5 | 1 | 0.5 |

**5. Effectiveness Results**

The analysis of effectiveness was based on the 391 evaluable subjects at the 24-month time point. Key effectiveness outcomes are presented in Tables 29 to 35.

**Primary Effectiveness Analysis**

The primary composite endpoint, termed Composite Clinical Success (CCS), was developed to measure the safety and effectiveness of the Superion IDS when compared to X-STOP IPD for the treatment of moderate degenerative lumbar spinal stenosis. This primary composite success measurement at 24 months included measurements of clinical efficacy (ZCQ Success), absence of subsequent treatments (e.g., epidurals, rhizotomy, and spinal cord stimulators), neurological success, safety (absence of device revision or removal), and absence of implant or procedure-related complications (absence of dislodgement, migration, spinous process fracture, or serious device-related adverse events).

As demonstrated in Table 29, non-inferiority of Superion IDS was established in the primary effectiveness cohort with a Bayesian Posterior Probability > 0.958 (as described in the Statistical Analysis Plan), in the mITT cohort that included all subjects with an anesthesia start time in the Superion IDS IDE. Further, the demonstration of non-inferiority in the Per Protocol cohort provides confirmation of the non-inferiority result of the Superion IDS IDE and demonstrates the robustness of the overall statistical determination. Similarly, Table 29 also shows that non-inferiority of the Superion IDS vs the X-STOP IPD was maintained at 60 months, with Bayesian Posterior Probability of >0.958. This establishes the durability of composite success, versus the control device, through 5 years.

| Table 29: Composite Clinical Success in Superion™ IDS IDE at 24 months | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Number and Percentage Achieving Overall Success | | | | | | Posterior Probability of Non-Inferiority |
| | Superion IDS | | | X-STOP® IPD | | | |
| 24 Months | | | | | | | |
| Analysis Cohort | N | n | % | N | n | % | |
| mITT[1] | 183 | 95 | 52.7% | 187 | 93 | 50.2% | 0.9927 |
| Per Protocol | 173 | 92 | 53.1% | 178 | 88 | 49.4% | 0.9944 |
| 60 Months | | | | | | | Posterior Probability of Non-Inferiority |
| | N | n | % | N | n | % | |
| mITT | 157 | 67 | 42.7 | 161 | 63 | 39.1 | 0.9933 |
| Per Protocol | 146 | 54 | 43.8 | 151 | 60 | 39.7 | 0.9934 |

[1]As described in the statistical analysis plan, missing data for the posterior probability at Month 24 were handled using Bayesian multiple imputation methodologies. All 190 Superion IDS and 201 X-STOP IPD patients were included in the primary Month 24 analysis using Bayesian multiple imputation. The %'s, as well as the posterior probability reported for the Bayesian multiple imputation (MI) are based on the mean over 5000 multiple imputations. The (SD's) over multiple imputations for these estimates were 52.7% (0.6%), 50.2% (0.9%), and 0.9927 (0.4%), respectively, at 24 months. The reported N and n values for these rows reflect only the numbers of patients with complete Month 24 and Month 60 CCS.

Table 30 shows the success rates for each of the individual components of the CCS for the mITT patient population at 24 months through 60 months. As seen in Table 30, with the exception of reoperations and revisions, which continued to occur at low rates, in all other components of the CCS the Superion IDS continued to exceed 80% through 60 months post-treatment, establishing the durability of outcomes.

| Table 30: Primary Endpoint Component Success (mITT Patient Population) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Component Success | | | | | | | |
| | Superion IDS | | | | X-STOP IPD | | | |
| | 24 Mos | 36 Mos | 48 Mos | 60 Mos | 24 Mos | 36 Mos | 48 Mos | 60 Mos |
| Clinical Success (2/3 ZCQ Domains) | 81.7% (107/131) | 88.0% (95/108) | 85.6% (77/90) | 84.1% (74/88) | 87.2% (116/133) | 89.0% (97/109) | 90.1% (73/81) | 87.8% (72/82) |
| No Re-operations & Revisions | 80.0% (152/190) | 78.4% (149/190) | 75.3% (143/190) | 74.7% (142/190) | 86.6% (174/201) | 81.6% (164/201) | 78.6% (158/201) | 76.6% (154/201) |
| No Major Related Complications | 86.3% (164/190) | 87.4% (166/190) | 85.8% (163/190) | 86.8% (165/190) | 82.6% (166/201) | 84.1% (169/201) | 85.6% (172/201) | 84.1% (169/201) |
| No Confounding Additional Treatments | 86.8% (165/190) | 84.2% (160/190) | 83.7% (159/190) | 82.6% (157/190) | 83.1% (167/201) | (82.1% (165/201) | 81.1% (163/201) | 79.6% (160/201) |

Table 31 lists the specific elements of the individual component results of the CCS at 24 through 60 months, resulting in an overall success rate of 51.9% for Superion IDS and 49.7% for X-STOP IPD in the "completers" population at 24 months, 49.1% Superion IDS and 46% X-STOP IPD at 36 months, 42.6% Superion IDS and 39.1% X-STOP IPD at 48 months, and 42.7% Superion IDS and 39.1% X-STOP IPD at 60 months. In this detail, which provides data from all elements of the CCS through 60 months, there is little difference between Superion IDS and X-STOP IPD, with the exception of spinous process fractures, for which there is a higher percentage in the Superion IPD arm, and migrations and dislodgements, for which there is a higher percentage in the X-STOP IPD arm. In general, however, the trends seen at 24 months remain constant at 60 months.

| Table 31: Superion™ IDS and X-STOP® IPD mITT Analysis Set - Descriptive Comparisons of the Percentages of Subjects Achieving CCS Component Success | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number and Percentage Meeting Criteria | | | | | | | | | | | | | | | | | | | | | | | |
| | Superion IDS | | | X-STOP IPD | | | Superion IDS | | | X-STOP IPD | | | Superion IDS | | | X-STOP IPD | | | Superion IDS | | | X-STOP IPD | | |
| | N | n | % | N | n | % | N | n | % | N | n | % | N | n | % | N | n | % | N | n | % | N | n | % |
| | 24 Mos. | | | | | | 36 Mos. | | | | | | 48 Mos. | | | | | | 60 Mos. | | | | | |
| **(1) ZCQ Responder (at least two of three ZCQ domains)** | **131** | **107** | **81.7** | **133** | **116** | **87.2** | **108** | **95** | **88.0** | **109** | **97** | **89.0** | **90** | **77** | **85.6** | **81** | **73** | **90.1** | **88** | **74** | **84.1** | **82** | **72** | **87.8** |
| Improvement in physical function by ≥0.5 points | 131 | 95 | 72.5 | 133 | 107 | 80.5 | 108 | 86 | 79.6 | 109 | 90 | 82.6 | 90 | 72 | 80.0 | 81 | 69 | 85.2 | 88 | 71 | 80.7 | 82 | 66 | 80.5 |
| Improvement in symptom severity by ≥0.5 points | 131 | 101 | 77.1 | 133 | 107 | 80.5 | 108 | 91 | 84.3 | 109 | 87 | 79.8 | 90 | 76 | 84.4 | 81 | 69 | 85.2 | 88 | 66 | 75.0 | 82 | 68 | 82.9 |
| Mean satisfaction ≤ 2.5 points (1=very sat., 2=somewhat sat., 3=somewhat dis, 4=very dis.) | 131 | 110 | 84.0 | 133 | 122 | 91.7 | 108 | 99 | 91.7 | 109 | 98 | 89.9 | 90 | 78 | 86.7 | 81 | 75 | 92.6 | 88 | 79 | 89.8 | 82 | 77 | 93.9 |
| **(2) No re-operations, revisions, removals or supplemental fixation at the index level(s)** | **190** | **152** | **80.0** | **201** | **174** | **86.6** | **190** | **149** | **78.4** | **201** | **164** | **81.6** | **190** | **143** | **75.3** | **201** | **158** | **78.6** | **190** | **142** | **74.7** | **201** | **154** | **76.6** |
| **(3) No major device- or procedure-related complications defined as:** | **190** | **164** | **86.3** | **201** | **166** | **82.6** | **190** | **166** | **87.4** | **201** | **169** | **84.1** | **190** | **163** | **85.8** | **201** | **172** | **85.6** | **190** | **165** | **86.8** | **201** | **169** | **84.1** |
| Failure from dislodgement or migration at any time | 190 | 190 | 100 | 201 | 177 | 88.1 | 190 | 190 | 100 | 201 | 177 | 88.1 | 190 | 190 | 100 | 201 | 177 | 88.1 | 190 | 190 | 100 | 201 | 177 | 88.1 |
| New or persistent worsened neurological deficit at the index level | 150 | 143 | 95.3 | 157 | 152 | 96.8 | 125 | 116 | 92.8 | 131 | 127 | 96.9 | 108 | 97 | 89.8 | 95 | 93 | 97.9 | 94 | 84 | 89.4 | 84 | 79 | 94.0 |

| Table 31: Superion™ IDS and X-STOP® IPD mITT Analysis Set - Descriptive Comparisons of the Percentages of Subjects Achieving CCS Component Success | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number and Percentage Meeting Criteria | | | | | | | | | | | | | | | | | | | | | | | |
| | Superion IDS | | | X-STOP IPD | | | Superion IDS | | | X-STOP IPD | | | Superion IDS | | | X-STOP IPD | | | Superion IDS | | | X-STOP IPD | | |
| | N | n | % | N | n | % | N | n | % | N | n | % | N | n | % | N | n | % | N | n | % | N | n | % |
| | 24 Mos. | | | | | | 36 Mos. | | | | | | 48 Mos. | | | | | | 60 Mos. | | | | | |
| Spinous process fractures at the index level(s) | 190 | 169 | 88.9 | 201 | 191 | 95.0 | 190 | 173 | 91.1 | 201 | 194 | 96.5 | 190 | 173 | 91.1 | 201 | 195 | 97.0 | 190 | 174 | 91.6 | 201 | 194 | 96.5 |
| Deep infection at the operative site requiring hospitalization, surgical draining, or IV antibiotics | 190 | 190 | 100 | 201 | 199 | 99.0 | 190 | 190 | 100 | 201 | 199 | 99.0 | 190 | 190 | 100 | 201 | 199 | 99.0 | 190 | 190 | 100 | 201 | 199 | 99.0 |
| Death or other permanent disability attributed to the device | 190 | 190 | 100 | 201 | 201 | 100 | 190 | 190 | 100 | 201 | 201 | 100 | 190 | 190 | 100 | 201 | 201 | 100 | 190 | 190 | 100 | 201 | 201 | 100 |
| **(4) No clinically significant confounding treatments:** | **190** | **165** | **86.8** | **201** | **167** | **83.1** | **190** | **160** | **84.2** | **201** | **165** | **82.1** | **190** | **159** | **83.7** | **201** | **163** | **81.1** | **190** | **157** | **82.6** | **201** | **160** | **79.6** |
| No epidural injections or nerve block procedures to treat spinal stenosis symptoms at the index level(s) at any time | 190 | 165 | 86.8 | 201 | 168 | 83.6 | 190 | 160 | 84.2 | 201 | 166 | 82.6 | 190 | 159 | 83.7 | 201 | 164 | 81.6 | 190 | 157 | 82.6 | 201 | 161 | 80.1 |
| No spinal cord stimulators or rhizotomies | 190 | 190 | 100 | 201 | 200 | 99.5 | 190 | 190 | 100 | 201 | 200 | 99.5 | 190 | 190 | 100 | 201 | 200 | 99.5 | 190 | 190 | 100 | 201 | 200 | 99.5 |
| **Composite Clinical Success** | **183** | **95** | **51.9** | **187** | **93** | **49.7** | **167** | **82** | **49.1** | **176** | **81** | **46.0** | **155** | **66** | **42.6** | **156** | **61** | **39.1** | **157** | **67** | **42.7** | **161** | **63** | **39.1** |

**Zurich Claudication Questionnaire**

For the components of ZCQ, both treatments improved symptoms; however, the Superion™ IDS device demonstrated slightly less improvement compared to the X-STOP® IPD. Immediate relief of clinical symptoms was seen in the three ZCQ domains with improvement maintained through 24 months. The relationship remained relatively constant through 60 months. These findings were not nominally significant.

**Reoperations, Removals, Revisions, or Supplemental Fixation**

For the component of "no re-operations, removals, revisions, or supplemental fixation at the index level(s)," in the modified intent-to-treat patient population, through 24 months (as part of the primary endpoint), there were a total of 38 reoperations or revisions in the Superion IDS group (38/190, 20.0%) compared with 29 reoperations or revisions in the X-STOP IPD group (29/201, 14.4%). By 60 months, the minor difference between the two arms had narrowed, with 74.7% of Superion IDS subjects having had a surgical reintervention, and 76.6% of X-STOP IPD subjects having had a reoperation or revision. Between 24 and 60 months, an additional 5.3% of Superion IDS subjects had a reoperation or revision, while 10.0% of X-STOP IPD subjects had a surgical reintervention.

**Implant-and Procedure-Related Complications**

For the component of dislodgement, migration or deformation, 24 of the 201 (11.9%) X-STOP IPD mITT subjects had a device dislodgement or migration, and none of the Superion IDS subjects experienced this type of event. In terms of spinous process fractures that were considered CCS failures, 21 of the 190 (11.1%) Superion IDS mITT subjects had a spinous process fracture that did not heal by Month 24. In contrast, 10 of the 201 (5.0%) X-STOP IPD mITT subjects had a spinous process fracture that did not heal by the 24-month time point. Between 24 an 60 monhs, healing of spious process fractures continued in both arms, with 14 Superion IDS fractures (7.3%) and 7 X-STOP IPD fractures (3.0%) remaining unhealed according to core lab assessment.

The rate of neurologic failures was similar for both Superion IDS and X-STOP IPD groups. The Superion IDS patient population had seven (7) failures (3.7%) that had new or worsening persistent motor or sensory neurologic assessments, while the X-STOP IPD population had five (5) failures (2.5%) of these criteria. At 60 months, there were an additional 5 Superion IDS neurological failures.

**Clinically Significant Confounding Treatments**

Following index surgery, 0 of the 190 (0.0%) Superion IDS mITT subjects received a rhizotomy at the level(s) of surgery prior to Month 24. In contrast, 1 of the 201 (0.5%) X-STOP IPD mITT subjects received a rhizotomy and was therefore considered a study failure. No subject in either group received a spinal cord stimulator at the level(s) of surgery prior to Month 24. Following index surgery, 25 of the 190 (13.2%) Superion IDS mITT subjects received an epidural steroid injection or nerve block at the level(s) of surgery prior to month 24 and were considered study failures as a result. In contrast, 33 of the 201 (16.4%) X-STOP IPD mITT subjects received an epidural steroid injection or nerve block at the level(s) of surgery prior to Month 24. At 60 months, there were 33 Superion IDS subjects (17.4%) who had a confounding treatment, while 40 X-STOP IPD subjects (19.9%) had such a treatment.

**Additional Stratified Outcomes**

As the device was indicated for one- or two-level treatments, additional analyses were performed stratifying CCS results by level implanted and number of levels. Although the study was not powered for these stratified analyses, definitive evidence of non-inferiority of the Superion IDS device was also demonstrated for one-level procedures alone with posterior probabilities of 0.9902 and 0.9940 at Months 24 and 60, respectively. There were fewer two-level procedures. For two-level procedures, the posterior probabilities of non-inferiority of the Superion IDS device at Month 24 and 60 are 0.8176 and 0.8013, respectively. Therefore, the analyses stratified by number of levels treated support non-inferiority for both one- and two-level procedures.

## Secondary Effectiveness Analysis

Secondary endpoints included ODI, VAS (Back and Leg), SF-12 Short Form Survey (Physical Function and Mental Health), and a Vertiflex-derived patient satisfaction survey (Vertiflex Patient Satisfaction Survey).

Analysis of secondary clinical endpoints demonstrated similar trends in both the Superion IDS and X-STOP IPD cohorts (Table 32). In general, the Superion IDS demonstrated improvement in pain and function as measured with ODI, and less pain as measured through VAS. The similarities in clinical endpoint outcomes between groups further demonstrate the similar effectiveness of the Superion IDS device to the control X-STOP IPD device. Even when investigating each demographic population, no substantial trends could be found that would demonstrate greater effectiveness of one device over the other. These results proved consistent and durable through 60 months for both treatment groups.

| Table 32: Superion™ IDS and X-STOP® IPD Control mITT Analysis Set- Secondary Endpoint Successes at 24 Through 60 Months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Superion IDS | | | | X-STOP IPD | | | |
| | 24 Mos | 36 Mos | 48 Mos | 60 Mos | 24 Mos | 36 Mos | 48 Mos | 60 Mos |
| Improvement of at least 15 pts in ODI | 63.4% (83/131) | 67.6% (73/108) | 61.1% (55/90) | 64.8% (57.88) | 66.9% (89/133) | 71.6% (78/109) | 67.9% (55/81) | 68.3% (56/82) |
| Improvement of at least 20mm on leg pain (worst) VAS | 75.6% (99/131) | 82.2% (88/107) | 78.2% (68/87) | 80.0% (68.85) | 77.4% (103/133) | 76.4% (81/106) | 75.0% (60/80) | 75.6% (62/82) |
| Improvement of at least 20mm on back pain VAS | 67.2% (88/131) | 76.6% (82/107) | 66.7% (58/87) | 64.7% (55/85) | 68.4% (91/133) | 72.6% (77/106) | 66.3% (53.80) | 72.0% (59/82) |
| Maintenance or improvement of SF-12 PCS | 80.5% (102/128) | 88.5% (85/96) | 83.6% (46/55) | 86.8% (59/68) | 89.5% (119/133) | 88.0% (81/92) | 83.0% (39/47) | 86.3% (63/73) |
| Maintenance or improvement of SF-12 MCS | 60.2% (77/128) | 62.5% (60/96) | 54.5% (30/55) | 57.4% (39/68) | 66.9% (89/133) | 63.0% (58/92) | 63.8% (30/47) | 65.8% (48/73) |

ODI mean scores demonstrated an improvement in ODI of at least 15 points in both the Superion IDS and X-STOP IPD by 3 months. This improvement was maintained through 24, 36, 48, and 60 months. Improvement in mean VAS Back pain score was demonstrated at 6 weeks, and the results also remained durable through 60 months. Similarly mean VAS leg (worse) scores also improved by 3 months and maintenance of this improvement was maintained through 60 months. These improvements in pain and function are considered clinically meaningful. In particular, the improvement in leg pain may be significant to patients and their treating physicians as this symptom is a primary menifestation of intermittent neurogenic claudication.

As shown in Tables 33 and 34 below, both the SF-12 Physical Component Summary scores and Mental Health Component Summary scores increased by 3 months, and improvement was maintained through 60 months.

| Table 33: Time Course of Percentage of Subjects Maintaining or Improving SF-12 Physical Function Component (mITT Patient Population) | | | | | | |
|---|---|---|---|---|---|---|
| | Number and Percentage Meeting Criteria | | | | | |
| | Superion | | | X-STOP | | |
| | N | n | % | N | n | % |
| Week 6 | 180 | 143 | 79.4% | 193 | 163 | 84.5% |
| Month 3 | 169 | 140 | 82.8% | 180 | 155 | 86.1% |
| Month 6 | 164 | 131 | 79.9% | 177 | 153 | 86.4% |
| Month 12 | 143 | 121 | 84.6% | 161 | 141 | 87.6% |
| Month 18 | 130 | 110 | 84.6% | 137 | 124 | 90.5% |
| Month 24 | 128 | 103 | 80.5% | 133 | 119 | 89.5% |
| Month 36 | 96 | 85 | 88.5% | 92 | 81 | 88.0% |
| Month 48 | 55 | 46 | 83.6% | 47 | 39 | 83.0% |
| Month 60 | 68 | 59 | 86.8% | 73 | 63 | 86.3% |

| Table 34: Time Course of Percentage of Subjects Maintaining or Improving SF-12 Physical Function Component (mITT Patient Population) | | | | | | |
|---|---|---|---|---|---|---|
| | Number and Percentage Meeting Criteria | | | | | |
| | Superion™ | | | X-STOP® | | |
| | N | n | % | N | n | % |
| Week 6 | 180 | 102 | 56.7% | 193 | 134 | 69.4% |
| Month 3 | 169 | 101 | 59.8% | 180 | 120 | 66.7% |
| Month 6 | 164 | 89 | 54.3% | 177 | 116 | 65.5% |
| Month 12 | 143 | 86 | 60.1% | 161 | 108 | 67.1% |
| Month 18 | 130 | 68 | 52.3% | 137 | 96 | 70.1% |
| Month 24 | 128 | 77 | 60.2% | 133 | 89 | 66.9% |
| Month 36 | 96 | 60 | 62.5% | 92 | 81 | 63.0% |
| Month 48 | 55 | 30 | 54.5% | 47 | 39 | 63.8% |
| Month 60 | 68 | 39 | 57.4% | 73 | 63 | 65.8% |

Patient satisfaction was measured using a questionnaire (Table 35). At 24 months, 86.2% of subjects in the Superion IDS group and 88.5% of subjects in the X-STOP IPD group were “Satisfied” or “Somewhat Satisfied.” By 60 months, these percentages had increased modestly to 90.1% for the Superion IDS arm, and 92.9% for the X-STOP IPD arm. Also, 82.9% of Superion IDS patients vs. 84.1% of X-STOP IPD patients answered “Definitely Yes” or “Probably Yes” to whether they would have the same treatment again. Here also, the percentages for each arm increased modestly through 60 months to 88.3% for the Superion IDS group, and 88.9% for X-STOP IPD arm, although differences between groups remained non-significant statistically at all follow-up points.

| Table 35: Patient Satisfaction at Month 24 by Treatment Group - mITT Analysis Set | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Superion IDS | | | | X-STOP IPD | | | |
| **How satisfied were you with your treatment?** | **24 Mos** | **36 Mos** | **48 Mos** | **60 Mos** | **24 Mos** | **36 Mos** | **48 Mos** | **60 Mos** |
| Satisfied | 75% (144) | 80.3% (102) | 72.7% (80) | 76.6% (85) | 78.3% (123) | 80.0% (104) | 78.8% (78) | 79.8% (79) |
| Somewhat Satisfied | 11.2% (17) | 9.4% (12) | 17.3% (19) | 13.5% (15) | 10.2% (16) | 7.7% (10) | 11.1% (11) | 13.1% (13) |
| Somewhat Dissatisfied | 0.0% (0) | 0.0% (0) | 0.0% (0) | 0.0% (0) | 0.0% (0) | 0.0% (0) | 0.0% (0) | 0.0% (0) |
| Dissatisfied | 13.8% (21) | 10.2% (13) | 10.0% (11) | 9.9% (11) | 11.5% (18) | 12.3% (16) | 10.1% (10) | 7.1% (7) |
| **Would you have the same treatment again?** | **24 Mos** | **36 Mos** | **48 Mos** | **60 Mos** | **24 Mos** | **36 Mos** | **48 Mos** | **60 Mos** |
| Definitely yes | 63.2% (96) | 69.3% (88) | 68.2% (75) | 68.5% (76) | 68.8% (108) | 70.8% (92) | 71.7% (71) | 74.7% (74) |
| Probably yes | 19.7% (30) | 17.3% (22) | 20.9% (23) | 19.8% (22) | 15.3% (24) | 12.3% (16) | 16.2% (16) | 15.2% (15) |
| Probably no | 9.2% (14) | 6.3% (8) | 6.4% (7) | 6.3% (7) | 10.2% (16) | 13.1% (17) | 10.2% (10) | 6.1% (6) |
| Definitely no | 7.9% (12) | 7.1% (9) | 4.5% (5) | 5.4% (6) | 5.7% (9) | 3.8% (5) | 2.0% (2) | 4.0% (4) |

Overall, there was a trend toward slightly better effectiveness outcomes for the X-STOP IPD in the secondary endpoints at 24 months; but the results remained comparable between the two groups.

**Radiographic Analysis**

Additional Radiographic Assessments

The additional radiographic effectiveness assessments measured by the radiographic core lab were:

- Range of Motion

- Translation
- Disc Angle
- Anterior Disc Height
- Posterior Disc Height
- Spinous Process Distance
- Foraminal Height
- Spondylolisthesis Progression

Range of Motion

Vertiflex™ presented data regarding the range of motion (ROM) arc over time. The quantitative ROM data are presented below in Table 36. The ranges of motion between the 2 study arms are comparable. There is minimal change in ROM over time in either treatment group, and Vertiflex characterizes the data as maintenance of motion. Vertiflex states that the investigational device functions by extension blockage; however, data separating flexion from extension was not captured in the study, thus the data are not clear in determining if this was achieved.

**Table 36: Flexion Extension - Rotation (F to E) (deg), Superion™ and X-STOP® mITT Analysis Sets**

| | Superion IDS | | | X-STOP IPD | | |
|---|---|---|---|---|---|---|
| | At level(s) of Implant (per level) | | | | | |
| | N | Mean | SD | N | Mean | SD |
| Pre-Op | 272 | 4.37 | 3.7 | 288 | 4.61 | 3.40 |
| Month 24 | 223 | 3.33 | 3.06 | 230 | 3.82 | 3.11 |
| Month 36 | 187 | 2.81 | 2.91 | 191 | 3.53 | 2.89 |
| Month 48 | 157 | 2.70 | 2.63 | 136 | 2.70 | 2.58 |
| Month 60 | 149 | 2.81 | 2.85 | 135 | 2.91 | 2.76 |

Translation

Vertiflex presented data regarding the translational motion (flexion to extension) over time. The quantitative translational motion data are presented below in Table 37. The ranges of motion between the 2 study arms are comparable. There is minimal change in translational motion over time in either treatment group, and Vertiflex characterizes the data as maintenance of motion. Data separating flexion from extension were not captured in the study.

**Table 37: Translation (F to E) (mm), Superion and X-STOP mITT Analysis Sets**

| | Superion IDS | | | X-STOP IPD | | |
|---|---|---|---|---|---|---|
| | At level(s) of Implant (per level) | | | | | |
| | N | Mean | SD | N | Mean | SD |
| Pre-Op | 272 | 1.00 | 0.86 | 288 | 1.05 | 0.90 |
| Month 24 | 223 | 0.97 | 0.89 | 230 | 1.023 | 0.86 |
| Month 36 | 187 | 0.77 | 0.81 | 191 | 0.97 | 0.85 |
| Month 48 | 157 | 0.71 | 0.87 | 136 | 0.77 | 0.72 |
| Month 60 | 149 | 0.86 | 0.86 | 135 | 0.92 | 0.82 |

Disc Angle

In terms of disc angle, the changes from the pre-operative disc angle measurements are nominally significant at every time point from post-operative through 60 months, as shown in Table 38. At every time point, the changes were smaller in the Superion IDS group. This is consistent with other radiographic data that suggest the X-STOP IPD devices are designed with an oval shape; thereby affecting distraction. Vertiflex states that the radiographic data suggests the larger distraction caused by the X-STOP IPD devices reduces the disc angle. In other words, the natural lordosis present at the pre-operative evaluation decreases when the spinous process distance increases.

| Table 38: Static Alignment Disc Angle (deg) - Superion™ IDS and X-STOP® IPD mITT Analysis Sets | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Superion IDS | | | | | | X-STOP IPD | | | | | |
| | At level(s) of Implant (per level) | | | | | | | | | | | |
| | N | Mean | SD | Med | Min | Max | N | Mean | SD | Med | Min | Max |
| Pre-Op | 277 | 9.22 | 4.59 | 9.3 | -4.7 | 21.8 | 296 | 9.48 | 4.32 | 9.3 | -2.9 | 21.4 |
| Post-Op | 270 | 5.07 | 4.25 | 5.1 | -5.5 | 19.1 | 289 | 4.40 | 3.91 | 4.1 | -5.9 | 14.3 |
| Week 6 | 269 | 8.08 | 4.43 | 8.3 | -3.8 | 19.6 | 293 | 6.92 | 4.52 | 6.7 | -6.2 | 20.7 |
| Month 3 | 251 | 8.16 | 4.44 | 8.3 | -4.4 | 19 | 287 | 7.42 | 4.48 | 7.2 | -5.3 | 21.2 |
| Month 6 | 257 | 8.56 | 4.46 | 8.9 | -6.4 | 19.7 | 279 | 7.65 | 4.40 | 7.2 | -4.8 | 20.9 |
| Month 12 | 242 | 8.67 | 4.43 | 8.9 | -8.4 | 20.7 | 266 | 7.69 | 4.58 | 7.7 | -4.2 | 21.4 |
| Month 18 | 221 | 8.59 | 4.55 | 8.8 | -5.4 | 20.2 | 244 | 7.88 | 4.59 | 7.7 | -4.8 | 21.3 |
| Month 24 | 225 | 8.45 | 4.50 | 8.5 | -4.9 | 19.6 | 231 | 7.73 | 4.65 | 7.6 | -5.1 | 20.7 |
| Month 36 | 186 | 8.6 | 4.43 | 8.6 | -5.1 | 20.1 | 192 | 7.8 | 4.63 | 7.7 | -5.3 | 19.5 |
| Month 48 | 161 | 8.5 | 4.45 | 8.7 | -5.1 | 19.6 | 138 | 7.7 | 4.77 | 7.6 | -5.2 | 19.6 |
| Month 60 | 151 | 8.6 | 4.40 | 8.6 | -5.2 | 18.7 | 137 | 7.6 | 4.77 | 7.5 | -4.3 | 21.6 |

Anterior Disc Height

Vertiflex™ presented data regarding the anterior disc height over time. The quantitative anterior disc height data are presented below in Table 39. Anterior disc height changes from the pre-operative measurements at the index level are nominally different at 6 weeks through 60 months in both treatment groups. At each time point, the X-STOP IPD group had a larger decrease in anterior disc height.

| Table 39: Anterior Disc Height (mm) - Superion IDS and X-STOP IPD mITT Analysis Sets | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Superion IDS | | | | | | X-STOP IPD | | | | | |
| | At level(s) of Implant (per level) | | | | | | | | | | | |
| | N | Mean | SD | Med | Min | Max | N | Mean | SD | Med | Min | Max |
| Pre-Op | 277 | 10.6 | 3.24 | 10.8 | 1.1 | 19.8 | 296 | 10.6 | 3.03 | 11 | 2.7 | 18.1 |
| Post-Op | 270 | 9.7 | 3.10 | 9.6 | 1.8 | 19.4 | 289 | 9.5 | 2.9 | 9.7 | 1.4 | 16 |
| Week 6 | 269 | 10.2 | 3.16 | 10.3 | 1.6 | 18.5 | 293 | 9.8 | 3.1 | 10 | 0.8 | 17.2 |
| Month 3 | 251 | 10.0 | 3.14 | 10.2 | 1.6 | 18.4 | 287 | 9.8 | 3.13 | 10.2 | 0.4 | 17.3 |
| Month 6 | 257 | 10.1 | 3.10 | 10.4 | 0.7 | 18 | 279 | 9.9 | 3.14 | 10.1 | 0.6 | 17.5 |
| Month 12 | 244 | 10.0 | 3.13 | 10.3 | 0.1 | 16.4 | 268 | 9.7 | 3.23 | 10.1 | 0.1 | 16.4 |
| Month 18 | 221 | 9.8 | 3.20 | 10 | 0.8 | 16.9 | 244 | 9.7 | 3.29 | 9.9 | 0 | 16.1 |
| Month 24 | 225 | 9.6 | 3.25 | 9.7 | 0.5 | 16.6 | 231 | 9.6 | 3.29 | 9.9 | 0 | 16.2 |
| Month 36 | 186 | 9.6 | 3.13 | 9.7 | 0.3 | 16.3 | 192 | 9.4 | 3.23 | 9.7 | 1.1 | 16.0 |
| Month 48 | 161 | 9.4 | 3.11 | 9.4 | 0.3 | 16.0 | 138 | 9.3 | 3.39 | 9.8 | 1.1 | 16.1 |
| Month 60 | 151 | 9.3 | 3.11 | 9.3 | 0.3 | 15.9 | 137 | 9.3 | 3.35 | 9.9 | 1.1 | 15.9 |

Posterior Disc Height

Vertiflex presented data regarding the posterior disc height over time. Quantitative posterior disc height data are presented below in Table 40. Posterior disc height increases following surgery in both treatment groups. However, there is a decrease in posterior disc height over time compared to the post-operative measurements, with the decrease more pronounced in the Superion IDS group. At 24 months, and subsequently through 60 months, the mean posterior disc height is lower than the pre-operative measurements in both trial arms.

| Table 40: Posterior Disc Height (mm) - Superion™ IDS and X-STOP® IPD mITT Analysis Sets | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Superion IDS | | | | | | X-STOP IPD | | | | | |
| | At level(s) of Implant (per level) | | | | | | | | | | | |
| | N | Mean | SD | Med | Min | Max | N | Mean | SD | Med | Min | Max |
| Pre-Op | 277 | 5.0 | 1.68 | 4.9 | 1.1 | 9.5 | 296 | 4.9 | 1.73 | 5.0 | 0.5 | 10.2 |
| Post-Op | 270 | 6.6 | 2.07 | 6.4 | 1.6 | 12.7 | 289 | 6.8 | 2.0 | 6.9 | 1.4 | 12.3 |
| Week 6 | 269 | 5.3 | 1.83 | 5.2 | 1.0 | 11.0 | 293 | 5.5 | 1.79 | 5.6 | 1.2 | 10.2 |
| Month 3 | 251 | 5.1 | 1.77 | 5.0 | 1.1 | 10.7 | 287 | 5.3 | 1.75 | 5.3 | 1.5 | 10.2 |
| Month 6 | 257 | 4.9 | 1.75 | 4.9 | 1.1 | 9.9 | 279 | 5.2 | 1.75 | 5.2 | 1.4 | 10.4 |
| Month 12 | 244 | 4.7 | 1.78 | 4.6 | 0.7 | 9.3 | 268 | 5 | 1.79 | 5.1 | 1.2 | 10 |
| Month 18 | 221 | 4.6 | 1.78 | 4.6 | 0.4 | 9.1 | 244 | 4.9 | 1.74 | 5.1 | 1.2 | 9.3 |
| Month 24 | 225 | 4.6 | 1.81 | 4.5 | 0.4 | 9.1 | 231 | 4.8 | 1.80 | 4.8 | 1.0 | 10.4 |
| Month 36 | 186 | 4.5 | 1.86 | 4.5 | 0.3 | 9.1 | 192 | 4.7 | 1.85 | 4.7 | 0.2 | 9.3 |
| Month 48 | 161 | 4.4 | 1.83 | 4.4 | 0.4 | 9.3 | 138 | 4.7 | 1.91 | 4.7 | 0.7 | 8.9 |
| Month 60 | 151 | 4.1 | 1.90 | 4.1 | 0.2 | 8.9 | 137 | 4.7 | 1.92 | 4.9 | 0.0 | 9.1 |

Spinous Process Distance

In regards to spinous process distance, there are no statistically significant differences between the Superion IDS and X-STOP IPD groups as shown below in Table 41. In both groups, there is an immediate increase in the post-op measurements, followed by a slight decrease that can be attributed to patient mobility and device settling. At 24 months, and subsequent follow-ups through 60 months, the spinous process distance is greater than the pre-operative condition for both groups.

| Table 41: Spinous Process Distance (mm) - Superion IDS and X-STOP IPD mITT Analysis Sets | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Superion IDS | | | | | | X-STOP IPD | | | | | |
| | At level(s) of Implant (per level) | | | | | | | | | | | |
| | N | Mean | SD | Med | Min | Max | N | Mean | SD | Med | Min | Max |
| Pre-Op | 176 | 45.3 | 7.5 | 44.7 | 29.9 | 67.8 | 190 | 45.1 | 7.1 | 45 | 30.7 | 66.6 |
| Post-Op | 146 | 51.1 | 7 | 50.9 | 35.8 | 67.6 | 149 | 51.9 | 7 | 51.9 | 34.3 | 70.6 |
| Week 6 | 116 | 48.7 | 6.9 | 49.2 | 31.9 | 64.3 | 154 | 48.7 | 6.7 | 48.1 | 34 | 67 |
| Month 3 | 104 | 48.5 | 6.7 | 48.7 | 33.8 | 62.8 | 145 | 47.8 | 6.7 | 47.4 | 33.7 | 67.4 |
| Month 6 | 111 | 47.9 | 6.8 | 48.1 | 34.1 | 63 | 137 | 47.8 | 6.7 | 47.1 | 34.4 | 67.5 |
| Month 12 | 100 | 47.2 | 6.9 | 46.4 | 33.7 | 62.8 | 128 | 48 | 7 | 47.2 | 34.4 | 68 |
| Month 18 | 89 | 47.6 | 7.2 | 47.7 | 33.9 | 62.8 | 118 | 47.5 | 7 | 47 | 33.9 | 68.1 |
| Month 24 | 82 | 47.2 | 6.9 | 46.1 | 33.8 | 62.2 | 104 | 48 | 6.5 | 47.2 | 35.6 | 64.4 |
| Month 36 | 71 | 46.2 | 6.9 | 45.7 | 33.8 | 58.9 | 101 | 47.5 | 6.9 | 47.1 | 35.0 | 68.3 |
| Month 48 | 57 | 46.8 | 6.9 | 47.7 | 33.8 | 62.6 | 64 | 47.6 | 7.3 | 46.8 | 35.1 | 68.5 |
| Month 60 | 58 | 46.9 | 6.3 | 47.4 | 34.0 | 58.6 | 64 | 47.8 | 6.6 | 47.2 | 36.8 | 67.9 |

Foraminal Height

Vertiflex™ presented data regarding the foraminal height over time. The quantitative foraminal height data are presented below in Table 42. Foraminal height increases following surgery in both treatment groups. However, there is a decrease in foraminal height over time compared to the post-operative measurements, with the decrease more pronounced in the Superion IDS group. At 24 through 60 months, the mean foraminal height is nominally lower than the pre-operative measurements in the Superion IDS group. The foraminal height measurement is the same as pre-operative height at 24 months, lower at 36 months, again the same as pre-op at 48 months, and lower at 60 months in the X-STOP IPD group. In general, however, foraminal height was

seen to increase immediately after treatment in both arms, but return to at or near baseline before 12 months. Foraminal height remained at or slightly lower than baseline thereafter in both arms, through 60 months.

**Table 42: Foraminal Height (mm) - Superion™ IDS and X-STOP® IPD mITT Analysis Sets**

| | Superion IDS | | | | | | X-STOP IPD | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | At level(s) of Implant (per level) | | | | | | | | | | | |
| | N | Mean | SD | Med | Min | Max | N | Mean | SD | Med | Min | Max |
| Pre-Op | 275 | 16.6 | 2.8 | 16.7 | 9.8 | 24.9 | 294 | 16.6 | 2.7 | 16.6 | 9.3 | 27.8 |
| Post-Op | 266 | 18.5 | 3.2 | 18.8 | 9.2 | 27.6 | 287 | 18.9 | 2.9 | 18.8 | 10.7 | 29.5 |
| Week 6 | 267 | 17.0 | 2.9 | 17.1 | 9.4 | 25.9 | 293 | 17.5 | 2.8 | 17.4 | 9.5 | 27.6 |
| Month 3 | 249 | 16.8 | 2.8 | 16.9 | 9.6 | 25.9 | 285 | 17.2 | 2.8 | 17.2 | 9.4 | 27.5 |
| Month 6 | 256 | 16.7 | 2.8 | 16.9 | 9.2 | 25.5 | 277 | 17.1 | 2.7 | 17.1 | 11 | 27.5 |
| Month 12 | 241 | 16.4 | 2.8 | 16.8 | 8.9 | 25.2 | 264 | 16.9 | 2.7 | 16.9 | 10.8 | 27.3 |
| Month 18 | 220 | 16.4 | 2.9 | 16.4 | 9 | 25.2 | 241 | 16.8 | 2.8 | 16.7 | 8.9 | 26.9 |
| Month 24 | 217 | 16.3 | 2.9 | 16.5 | 7.9 | 25.4 | 220 | 16.6 | 2.9 | 16.6 | 8.9 | 27 |
| Month 36 | 186 | 16.4 | 2.8 | 16.7 | 9.6 | 24.0 | 101 | 16.5 | 2.9 | 16.4 | 9.1 | 27.5 |
| Month 48 | 161 | 16.4 | 2.9 | 16.5 | 10.2 | 24.3 | 64 | 16.6 | 3.1 | 16.8 | 8.4 | 27.2 |
| Month 60 | 151 | 16.2 | 2.9 | 16.6 | 10.0 | 24.3 | 64 | 16.4 | 2.9 | 16.7 | 8.4 | 22.0 |

Spondylolisthesis Progression

For spondylolisthesis progression, there were no notable differences between Superion IDS and X-STOP IPD at the index levels as shown in Table 43. In all cases, spondylolisthesis was slightly decreased at all time points from 24 through 60 months. The values suggest spondylolisthesis measurements were maintained from pre-op to month 24. These results are expected since the devices are not intended to reduce the presence of spondylolisthesis. The data also demonstrate the investigational and control devices do not encourage greater spondylolisthesis.

**Table 43: Spondylolisthesis (mm) - Superion IDS and X-STOP IPD mITT Analysis Sets**

| | Superion IDS | | | | | | X-STOP IPD | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | At level(s) of Implant (per level) | | | | | | | | | | | |
| | N | Mean | SD | Med | Min | Max | N | Mean | SD | Med | Min | Max |
| Pre-Op | 275 | -0.4 | 3.14 | 0.4 | -10.2 | 5.7 | 296 | -0.2 | 3 | 0.5 | -9.1 | 5.7 |
| Post-Op | 266 | -0.45 | 2.77 | 0.2 | -9.4 | 4.7 | 287 | -0.24 | 2.8 | 0.3 | -8.6 | 5.5 |
| Week 6 | 267 | -0.58 | 3.16 | 0.2 | -9.7 | 5.5 | 293 | -0.46 | 3.08 | 0.3 | -9.4 | 5.7 |
| Month 3 | 249 | -0.58 | 3.2 | 0.2 | -9.8 | 5.5 | 285 | -0.39 | 3.08 | 0.4 | -9.5 | 5.8 |
| Month 6 | 256 | -0.58 | 3.2 | 0.1 | -9.8 | 4.8 | 277 | -0.45 | 3.08 | 0.3 | -11 | 5.9 |
| Month 12 | 241 | -0.58 | 3.22 | 0 | -10.2 | 5.2 | 264 | -0.4 | 3.11 | 0.4 | -11.7 | 6.2 |
| Month 18 | 220 | -0.58 | 3.21 | 0.2 | -10.4 | 6.8 | 241 | -0.51 | 3.05 | 0.3 | -12.3 | 5.4 |
| Month 24 | 217 | -0.66 | 3.22 | 0.1 | -10.3 | 4.6 | 220 | -0.51 | 3.05 | 0.2 | -9.5 | 6.1 |
| Month 36 | 186 | -0.72 | 3.16 | -0.2 | -10.0 | 4.6 | 192 | -0.42 | 2.99 | 0.2 | -9.5 | 6.4 |
| Month 48 | 161 | -0.78 | 3.17 | -0.1 | -9.7 | 4.8 | 138 | -0.53 | 3.07 | 0.2 | -9.1 | 6.5 |
| Month 60 | 151 | -0.92 | 3.34 | -0.4 | -9.6 | 5.3 | 137 | -0.51 | 2.96 | 0.2 | -9.3 | 5.2 |

**6. Subgroup Analyses**

A number of other exploratory analyses were performed to determine if various baseline pre-existing spinal conditions or surgical effects had an effect on poolability, treatment success, and Superion IDS safety and effectiveness. In addition, several exploratory analyses were performed on subjects who were observed to have spinous process fractures at any time point based upon independent radiographic review.

These exploratory analyses included migrations/dislodgements, level poolability, stenosis locations, smoking status, presence or absence of spondylolisthesis, supraspinous ligament repair, spinous process fractures, instrumentation sets, anesthesia types, learning curves, device sizes, comorbidity analyses, and presence or absence of bone-implant interface changes.

The exploratory analyses suggest that subjects treated with the Superion™ IDS exhibit comparable clinical outcomes regardless of pre-existing conditions, such as 1- or 2-level disease, various types of stenosis, up to Grade I spondylolisthesis, and smoking status. In addition, intra-operative details, such as supraspinous ligament repair and instrumentation set versions, do not appear to have an effect on the clinical outcomes produced following implantation with the Superion IDS. Furthermore, the presence of radiographic findings, such as spinous process fractures and bone-implant interface changes, did not affect the clinical outcomes observed with the Superion IDS.

There were no pre-specified analyses related to weight, age, or gender. Post-hoc analyses were performed for weight, age, and gender, and there were no notable differences between groups.

**7. Conclusions Drawn**

The clinical results from the use of the investigational device, the Superion IDS, were shown to be statistically non-inferior to the control group results at 24 months. Importantly, these results were shown to be durable through 60 months post-treatment. The scientific evidence that has been presented here supports the safety and effectiveness of the Superion IDS in the treatment of moderate degenerative lumbar spinal stenosis at one or two levels from L1 to L5. The study demonstrated that treatment of moderate degenerative lumbar spinal stenosis with the Superion IDS was as effective as the control treatment (X-STOP® IPD), and proved as durable. The results for the primary effectiveness outcome parameters for the investigational group were non-inferior to the control group through 5 years follow-up.

Additionally, there were no major differences in safety outcomes between the two treatment arms. While the incidence of spinous process fractures was higher in the Superion IDS arm, data suggested that (a) these fractures have a tendency to heal over time, and (b) the clinical outcomes of subjects incurring a fracture are not significantly different from those in whom no fracture was detected. In contrast, X-STOP IPD subjects were more likely to have a device migration or dislodgement, while there were no migrations or dislodgements in the Superion IDS arm. In terms of device- or procedure-related adverse events, Superion IDS subjects experienced more device-related adverse events (11.6%) through 60 months than did X-STOP IPD subjects (7.5%), while the latter had more procedure-related adverse events (15.9%) than did the Superion IDS subjects (14.2%).

The overall adverse events rates in the Superion IDS and X-STOP IPD cohorts were similar, but there were differences in the types of events. While the devices had different adverse event rates associated with individual types of events (e.g., spinous process fracture or migration/dislodgement), on balance, these events, either severe or non-severe, and overall adverse event rate, were not preferential to one treatment arm or another, at 24 months, or through 60 months.

## PACKAGING

All packages containing implants should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the product packaging is damaged, the product should not be used and should be returned.

The Superion IDS components must be stored, opened and handled in such a way that they are protected from inadvertent damage or contamination.

## STERILITY

Superion IDS devices are sterilized with gamma radiation (25 kGy minimum), and are supplied "**STERILE**" and intended for single patient use only. DO NOT RESTERILIZE THESE PRODUCTS. The sterility can only be assured if the packaging is intact. Do not use these devices if the STERILE packaging has been opened or damaged. Contact your Boston Scientific representative for replacement. Remove all packaging material prior to use. Only sterile implants should be used in surgery.

**Radiation Sterilized**

**Do Not Resterilize**


**FOR SINGLE USE ONLY**

## STORAGE

The Superion IDS implants and instruments should be stored in a clean and dry area until ready for use.

## INSTRUCTIONS FOR USE

The physician implanting the Superion IDS is expected to be fully educated and trained in the techniques necessary to implant the device.The Superion IDS may be implanted only using the applicable Superion manual instrumentation provided by Vertiflex.Refer to the Superion IDS *Surgical Technique Manual* for recommended implantation procedures. The techniques for implanting the Superion™ IDS should be reviewed by the physician prior to use of the system. Proper selection of patients, and good compliance of patients with instructions for postoperative care and behavior, are critical to the realization

of a successful procedure. All patients contemplating implantation of this device should be apprised of the risks associated with the procedure, as well as the limitation of activities the patient will face following surgery. The physician is expected to provide detailed instructions to the patient regarding postoperative activities.The physician should inspect the components and instruments of the Superion IDS system before surgery to assure that all necessary components are present.

### MRI Compatibility 


Non-clinical testing has demonstrated that the Superion IDS is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3.0-Tesla (3.0 T).
- Spatial gradient field of up to:
  - 7,480 G/cm (74.80 T/m) for 1.5 T systems.
  - 3,740 G/cm (37.40 T/m) for 3.0 T systems.
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

#### 1.5T RF heating

In non-clinical testing with body coil excitation, the Superion IDS produced a temperature rise of less than 4.0 ºC at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 1.5 T Siemens Espree (MRC30732) MR scanner with SYNGO MR B17 software.

#### 3.0T RF heating

In non-clinical testing with body coil excitation, the Superion IDS produced a temperature rise of less than 5.0 ºC at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 3.0 T Siemens Trio (MRC20587) MR scanner with SYNGO MR A30 4VA30A software.

**Caution***: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.*

#### MR Artifact

In testing with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 2.6 cm from the implant.

## PRODUCT COMPLAINTS

Any healthcare professional (e.g, customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify the distributor or Boston Scientific Neuromodulation Corporation. Further, if any of the implanted spinal system component(s) ever “malfunctions” (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether or not a written report from the distributor is requested.

DESCRIPTION OF LABELING SYMBOLS

| | |
|---|---|
|  | Batch code |
|  | Catalog number |
|  | CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician |
|  | Consult instructions for use |
|  | Single-use only |
|  | Do not resterilize |
|  | Manufacturer |
|  | MR conditional |
|  | Sterilized using irradiation |
|  | Use-by date |
|  | Caution, consult accompanying documents |
|  | Do not use if package is damaged |
|  | Date of Manufacturer |
|  | Contents |
|  | EU Authorized Representative Address |
|  | Australian Sponsor Address |
|  | Double Barrier System |

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