Superion®

INTRODUCTION
One of the natural processes of the degeneration of the spine results in Lumbar Spinal Stenosis (LSS). As human life expectancies continue to grow this condition becomes symptomatic, presenting itself in patients suffering from leg pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication). Accordingly, once a positive diagnosis has been made, the process of treating lumbar spinal stenosis can take different paths. Non-surgical medical management is an option or surgical intervention.

The Superion® Interspinous Spacer was developed to treat those patients who suffer from LSS. The Superion® device is an implant made of titanium with a straightforward percutaneous delivery. The implant is placed between the spinous processes of the symptomatic disc levels and deployed. The device is designed to limit extension at the symptomatic levels while concurrently preserving mobility, structural elements, and alignment. The superior and inferior projections capture the spinous processes, which limits any implant migration. The percutaneous delivery of the implant minimizes the trauma to surrounding tissues and anatomical structures.

INDICATIONS
The Superion® Interspinous Spacer (the Superion® ISS) is intended to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of 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® ISS is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain. The Superion® ISS may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels.

IMPORTANT NOTE:
This surgical technique is intended as a guide only. It is recommended that the surgeon be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the Superion® insert for complete information on indications, contraindications, adverse reactions, sterilization, and packaging.
CONTRAINDICATIONS

The Superion® Interspinous Spacer 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:
  - significant 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);
  - acute fracture of the spinous process, pars interarticularis, or laminae fracture (unilateral or bilateral);
  - significant 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 in the presence of one or more fragility fractures;
- active systemic infection, or infection localized to the site of implantation.

CAUTION

Federal (USA) law restricts these devices to sale by, or on the order of, a licensed physician.

WARNINGS

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

The effects of multiple deployments upon implant strength have not been determined. In the event that a Superion® Interspinous Spacer must be deployed, closed, and redeployed for repositioning more than three times during a procedure, the Spacer should be discarded, and a new device used.

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® Interspinous Spacer may not be indicated.
- The safety and effectiveness of the Superion® Interspinous Spacer 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® Interspinous Spacer should be performed only by qualified and experienced spinal surgeons having specific training in the implantation of the device, because this is a technically demanding procedure presenting risk of serious injury to the patient.
- Surgeons should not implant the Superion® Interspinous Spacer until receiving adequate training in surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events.
- A stress fracture of the spinous may occur if strenuous activity is resumed too soon postoperatively.
The Superion® Interspinous Spacer System includes a set of instruments necessary to deliver the Superion® Implant percutaneously. The instruments are manufactured of titanium, stainless steel and other industry standard materials.

NOTE: The instruments must be properly cleaned and sterilized prior to each surgery. Please refer to the package insert for complete cleaning instructions. The Superion® Implant is supplied sterile.
Place the patient on a radiolucent table in the prone position with the lumbar spine flexed. Two surgical approaches can be used to deliver the Superion® Implant. The optional approach requires the use of the Retractor.

**APPROACH:** Fluoroscopically Guided Technique

1. Identify the appropriate surgical level and accurate midline position using a spinal needle, Dilator 1, or scalpel with AP and lateral fluoroscopy.

2. After confirmation of the surgical level, create a 12-15mm midline incision at the operable level with a scalpel (Fig. 1).

**OPTIONAL APPROACH:** Direct Visualization

1. Identify the appropriate surgical level and midline using a spinal needle, Dilator 1, or scalpel with an AP and lateral fluoroscopy view.

2. After confirmation of the surgical level, create a 12-15mm midline incision at the operable level with a scalpel (Fig. 1).

3. Insert the Retractor to visualize the supraspinous ligament (Fig. 2).

4. Produce longitudinal split of supraspinous ligament (SSL) at midline with blade.
Begin dilating the supraspinous ligament by inserting Dilator 1 through the supraspinous ligament (Fig. 3). Ensure correct placement of Dilator 1 by aligning the channels on the distal end cranially and caudally. Under fluoroscopy confirm trajectory and alignment to the midline.

Utilize the distal tip taper and shaft diameter intersection as a depth stop marker to the anterior side of the supraspinous ligament; or insert Dilator 1 until tapered portion of the instrument is just ventral to the SSL. Limiting the depth of Dilator 1 during insertion ensures the maximum amount of working space within the interspinous space.

Note: If the Optional Approach is preferred use Dilator 1 – Blunt for Step 2a.

Insert Dilator 2 over Dilator 1 (Fig. 4). Ensure alignment of Dilator 2 to the midline axis.

DEPTH OF INSERTION OF DILATOR 2:
1. Align the proximal surface of Dilator 2 with the depth marker on Dilator 1 (circumferential groove).

2. Confirm under fluoroscopy the depth of insertion of Dilator 2 through the supraspinous ligament. Utilize the intersection of the distal tip taper as a depth stop marker to the anterior side of the supraspinous ligament. Remove Dilator 1.
Insert the Cannula over Dilator 2 (Fig. 5) and through the supraspinous ligament. Ensure proper Cannula orientation via the cephalad indicator on the Cannula. The channels of the Cannula should be orientated with the spinous processes.

**DEPTH OF INSERTION OF CANNULA:**

1. Under fluoroscopy confirm depth of insertion of the Cannula through the supraspinous ligament.

2. Remove Dilator 2.

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**DILATION – OPTIONAL**

The Handle and Mallet can be used to further advance Dilator 2 and/or the Cannula. The Handle can also be used to hold the Dilators and Cannula in place while taking fluoroscopic images of the orientation. To use, place the Handle over the Dilator or Cannula and orient the distal end of the Handle in the caudal position. To further advance, use the Mallet at the indicated position to gently tap on the Handle (Fig. 6).

Alternate dilation instruments: Dilator 1 NG, Dilator 1 - Blunt NG, Dilator 2 NG, Cannula NG and Handle NG can also be used to complete the dilation process as laid out in section 2.

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**PREPARATION – OPTIONAL**

The Interspinous Reamer can be used to further prepare the interspinous space for delivery of the Implant. Insert the Interspinous Reamer through the Cannula into the interspinous space (Fig. 7). To use, articulate clockwise and counter clockwise. The depth of cut is 15mm when the Interspinous Reamer flange mates the proximal surface of the Cannula.

» **CAUTION:**
Closely monitor depth to avoid close proximity to spinal canal.
Insert the Interspinous Gauge through the Cannula to determine proper implant size selection. Proper orientation of the Interspinous Gauge is ensured via the orientation flat on the barrel. Confirm the depth of insertion under lateral fluoroscopy. The distal tips of the Interspinous Gauge should contact the spinous process dorsal to the spinolaminar junction of the superior aspect. Measurement of the interspinous space is obtained by firmly actuating the trigger until resistance is detected at the distal tips (Fig. 8a, 8b, 8c, 8d).

» CAUTION: Do not over-distract. VertiFlex Inc. does not recommend over-sizing.
3. PREPARATION (cont.)

Under an AP Ferguson fluoroscopic view, confirm the midline positioning so that the distal tips of the Interspinous Gauge contain the spinous processes (Fig. 8e, 8f).
DELIVERY – LOADING THE IMPLANT

Select the appropriate size implant as determined by the Interspinous Gauge. The Inserter instrument is a multi-function instrument utilized to deliver all sizes of the Implant through the Cannula. The instrument loads the Implant, inserts it into the interspinous space via the Cannula, and is utilized to deploy the Implant. The following steps must be closely followed to ensure proper placement and deployment of the Implant.

**LOADING THE IMPLANT ONTO THE INSERTER:**

1. Align the arrow on the body of the implant with the arrow on the distal end of the Inserter (Fig. 9a).

2. Turn the dial towards the locked position until the arrow on the dial aligns with the handle end on the body of the inserter (Fig. 9b).

Note: Before loading the Implant ensure that Dial is turned completely to the unlocked position.
Insert the Driver through the proximal entry point on the Inserter and gently rotate until the distal end of the Driver has engaged the Implant. Load the Inserter into the Cannula to minimum insertion depth (alignment of heavy etch band on the barrel of the Inserter with the proximal surface of the Cannula). Ensure proper depth under lateral fluoroscopy. Now, partially deploy the Implant under lateral fluoroscopy (Fig. 10a) by turning the Driver clockwise. When the Implant has been deployed approximately 30% to 50%, utilize A/P fluoroscopy (Ferguson View, Fig. 10b) toward the superior aspect first to ensure bilateral containment of the superior spinous process then check inferior. When the spinous process containment is confirmed, continue rotating the Driver until the Implant’s superior and inferior projections have been completely deployed and the Driver can no longer be rotated. Final tighten with two or three fingers.

» CAUTION:
Do not force deployment or implant breakage or damage to bony structures may result. If resistance to deployment is encountered and re-positioning of the Implant is required intraoperatively, rotate the Driver counterclockwise and slightly withdraw dorsally to collapse the superior and inferior projections. Reposition the Implant to an optimal position; utilize lateral fluoroscopy to check position. After confirmation of an optimal position, rotate the Driver clockwise to re-deploy the Implant.

Load the Inserter through the Cannula. Ensure proper orientation via the flat on the barrel of the Inserter.
CAUTION:
Should any resistance be encountered during deployment of the Superion® device, it may be suggestive of interference between the implant and bony anatomy (e.g., lamina, hypertrophic spinous process, etc.), and/or suboptimal implant positioning. Under such circumstances, DO NOT attempt to manipulate the position of the device by “Gear-Shifting” the Inserter (i.e., gross cranial/caudal/lateral articulation), as the mechanical advantage/leverage provided by the length of the inserter may be sufficient to damage the implant or surrounding anatomy. If resistance is encountered, or if device position is suboptimal, reverse deploy the implant before repositioning and redeployment. Confirm correct position via fluoroscopy before completing deployment to the open and locked position.
1. Remove Driver.

2. Ensure proper Implant placement via fluoroscopy. Ensure proper implant depth position prior to removal of insertion.

Note: The effects of multiple deployments upon implant strength have not been determined. In the event that a Superion® implant must be deployed, closed, and redeployed for repositioning more than three times during a procedure, the implant should be discarded and a new device used.
REMOVAL OF THE INserter

TO DETACH THE INserter:
1. Turn the dial towards the unlocked position until the dials come to a halt.
2. Withdraw the Inserter and the Cannula.

Suture the incision in routine fashion.

DEVICE REMOVAL:
In the event that a Superion® implant must later be removed:
1. Locate the Cannula at the level of implantation following steps 1 through 2c.
2. Place the Inserter instrument through the Cannula and engage and lock the proximal end of the implant to the Inserter, following step 4a.
3. Insert the Driver instrument through the Inserter and gently rotate until it has engaged the implant. Fluoroscopy may be employed to assist in positioning the Inserter relative to the implant.
4. Rotate the Driver counter-clockwise until the implant is closed. A positive stop will be felt.
5. Withdraw the inserter with attached implant from the Cannula, and withdraw the Cannula.
## ORDERING INFORMATION

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