

SURGICAL TECHNIQUE MANUAL



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TRADEMARKS

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INTRODUCTION

Degenerative changes in the spine are a natural occurrence of aging and may result in Lumbar Spinal Stenosis (LSS). If LSS occurs and progresses, the condition may become symptomatic, presenting itself in patients suffering from leg pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication). Diagnosis of LSS is typically made on the basis of clinical presentation, with correlating radiographic findings. Once a diagnosis of degenerative LSS has been made, the first line of treatment is ordinarily non-operative, or conservative, management. Surgical treatment is offered after non-operative treatment fails to provide relief of symptoms for a protracted period (e.g., >6 months).

The Vertiflex™ Procedure uses a small implant, the Superion™ Indirect Decompression System, that creates space for the nerves in the spinal cord to treat those patients who suffer from moderate degenerative LSS. The Superion™ Implant is a device made of titanium alloy, with a straightforward minimally invasive delivery. The Implant is placed between the spinous processes of the symptomatic levels and deployed. The device is designed to limit extension at the symptomatic level(s) while concurrently preserving mobility and structural elements. The superior and inferior projections of the Implant capture the spinous processes, which limits potential for Implant migration. The minimally invasive delivery of the Implant reduces the trauma to surrounding tissues and anatomical structures.



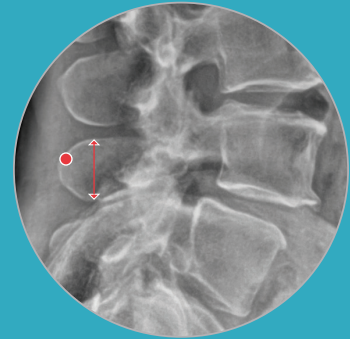
Caution
Federal (USA) law restricts these devices to sale
by, or on the order of, a licensed physician.

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

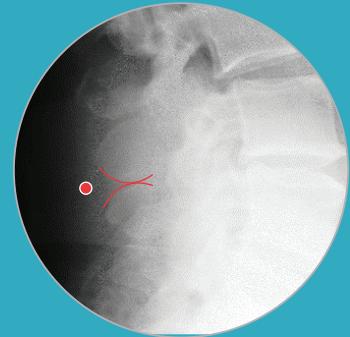
Where a spinous process is unusually thin, or measures less than 20mm in superior-inferior dimension, the likelihood of a postoperative spinous process fracture may be increased.



THIN SPINOUS PROCESSES

“Kissing Spine”

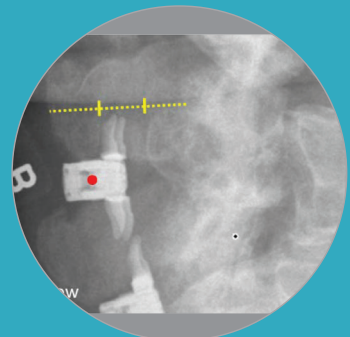
Where spinous processes are in very close approximation or are in contact (i.e., “kissing”), increased difficulty may be experienced in placement of the Cannula. Where spinous processes do not “open up” in flexion, the likelihood of a spinous process fracture may be increased.



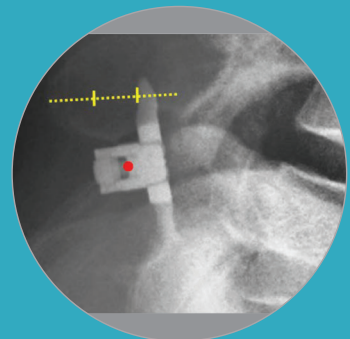
KISSING SPINOUS PROCESSES

Implant Placement Location

Where the Superior™ Implant is placed in a “shallow” or more dorsal position, the likelihood of a postoperative spinous process fracture may increase by a factor >4 . To reduce the potential for postoperative fracture, be certain to locate the implant body sufficiently anterior, 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 Superior™ IDS may not be indicated.
- The safety and effectiveness of the Superior™ 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 diseases that may affect the patient's ability to walk.
- Implantation of the Superior™ 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 Superior™ IDS until receiving adequate training in surgical technique. Inadequate training may result in poor patient 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.

TRAINING

Physicians seeking to use the Superior™ IDS must be trained in the implant components, the manual instruments used in the Vertiflex™ Procedure, clinical applications for the device, its biomechanics, and adverse events and risks associated with the use of the Superior™ IDS. Such training, which consists of both didactic and laboratory work, is offered by Boston Scientific to those interested in using the device.

To arrange for training, please contact your Boston Scientific Sales Representative or Customer Service at (866) 268-6486.

POTENTIAL ADVERSE EVENTS

The following adverse events may occur as a result of interspinous process decompression with the Superior™ 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
- Death

2. Risks associated with lumbar spine surgery include:

- Damage to nerve roots to 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
- 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 of treatment

4. Risks specifically associated with the Superior™ IDS include:

- Deformation, breakage or disassembly of the implant, and spinous process fracture

INDICATIONS

The Superior™ Indirect Decompression System (the Superior™ IDS) 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 moderate degenerative 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 Superior™ IDS 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, who have undergone at least six months of non-operative treatment. The Superior™ IDS may be implanted at one or two adjacent lumbar levels in patients in whom 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 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

IMPORTANT NOTE

This surgical technique manual is intended as a guide only. It is recommended that the physician be thoroughly trained before proceeding. Each physician must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the Superior™ IDS Instructions for Use for complete information on indications, contraindications, adverse reactions, sterilization, and packaging.

CONTRAINDICATIONS

The Superior™ 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 (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 centrally 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 spinous process fracture or 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.

The effects of multiple deployments upon Implant strength have not been determined. In the event that a Superion™ IDS 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.

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

INSTRUMENTS

The Superior™ IDS includes a set of single-use instruments necessary to deliver the Superior™ Implant.

The instruments are manufactured using stainless steel and other industry-standard materials.



DILATOR ASSEMBLY



CANNULA ASSEMBLY



REAMER



INTERSPINOUS (IS) GAUGE



INSERTER



DRIVER

The instruments are provided sterile. Please refer to the instrument Instructions for Use for complete instructions. The Superior™ Implant is also supplied sterile.

1

PATIENT PREPARATION AND POSITIONING

Place the patient on a radiolucent table in the prone position (Fig. 1). The patient should be placed in the prone position with the lumbar spine optimally flexed. A Wilson frame (or equivalent) is recommended to facilitate flexion of the lumbar spine. The surgical field should receive sterile preparation as is standard for the operating physician's surgical environment.

NOTE

Adequate lumbar flexion is important to assure separation of spinous processes and to facilitate ease of introduction of instruments and the Implant.

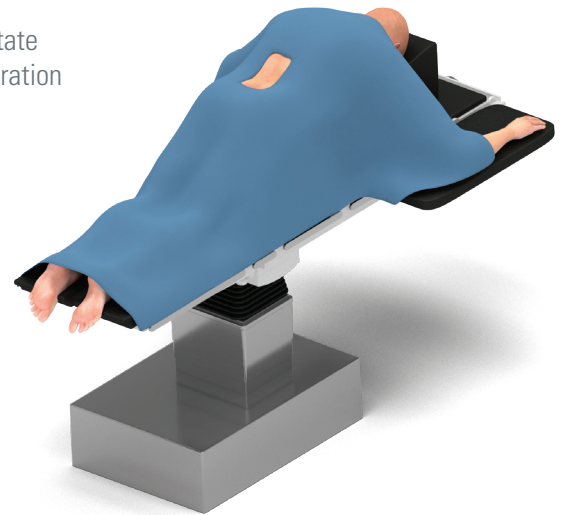


Fig. 1. Patient Positioning - Flexed

2

IDENTIFYING LEVEL TO BE TREATED

Identifying Correct Level

Use Dilator Assembly, hemostat, spinal needle, or K-wire to confirm midline and axial position (Fig. 2).

Single or bi-plane fluoroscopy may be used.

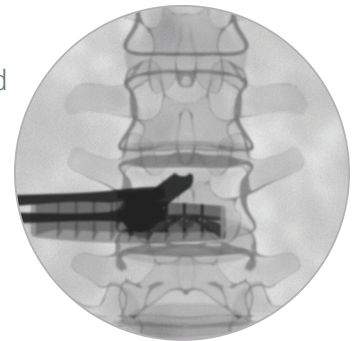


Fig. 2. Confirmation of Midline Position

3

APPROACH

Two surgical approaches can be used to deliver the Superior™ Implant: The fluoroscopically guided technique and the alternative (mini-open) approach offering direct visualization. The optional alternative (mini-open) approach requires the use of a retractor.

APPROACH

Fluoroscopically Guided Technique

1. Identify the appropriate surgical level and accurate midline position using a spinal needle, Dilator Assembly, 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. 3). Dissect to the depth of the supraspinous ligament (SSL). Advance the blade with AP and lateral fluoroscopy to produce a longitudinal split of the SSL at midline (Fig. 3A).

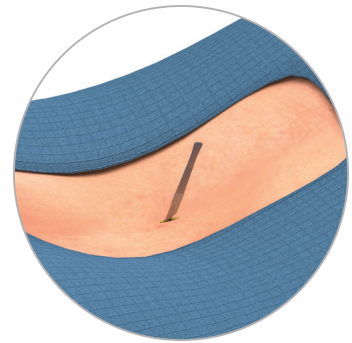


Fig. 3. Skin Incision



Fig. 3A. Longitudinal Split of SSL

ALTERNATIVE APPROACH

Direct Visualization (Mini-Open)

1. Identify the appropriate surgical level and midline using a spinal needle, Dilator Assembly, or scalpel with AP and lateral fluoroscopy.
2. After confirmation of the surgical level, create a 12mm midline incision at the operative level with a scalpel (Fig. 3) and dissect to the depth of the SSL.
3. Insert a retractor to visualize the supraspinous ligament (Fig. 3B).
4. Produce a longitudinal split of the SSL at midline with blade (Fig. 3A).

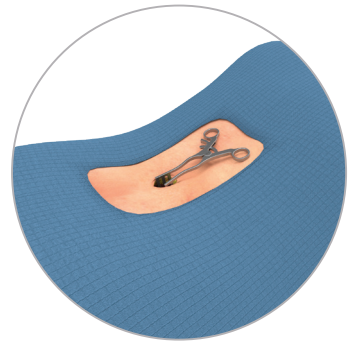



Fig. 3B. Retractor in Position to Visualize Supraspinous Ligament

4

DILATION

Dilator Assembly

Place the Dilator Assembly into the treatment site at midline and confirm position with AP fluoroscopy. Advance the Dilator Assembly manually and with the assistance of a mallet until the distal tip approaches the dorsal aspect of the facet shadow (Fig. 4). Use AP fluoroscopy to confirm midline placement (Fig. 4A). Utilize instrument depth markers and lateral fluoroscopy to verify depth (Fig. 4B). Once midline position and depth are confirmed, unlock and remove the Dilator Assembly handle, leaving only the Dilator. To unlock, turn the collar on the handle counterclockwise in the direction of the  arrow (Fig. 4C).

Use any type of forceps readily available to offset the user's hand from instruments during use of intraoperative fluoroscopy.

CAUTION

Dural injury may result if the Dilator Assembly is advanced too deeply, i.e., beyond (or past) the facet shadow ventrally. Monitor its depth using lateral fluoroscopy.

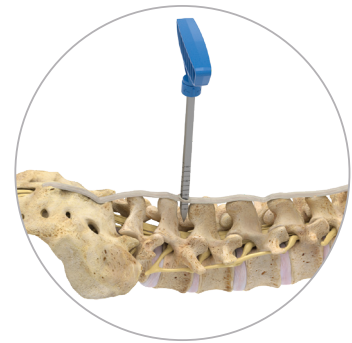


Fig. 4. Dilator Assembly Placement

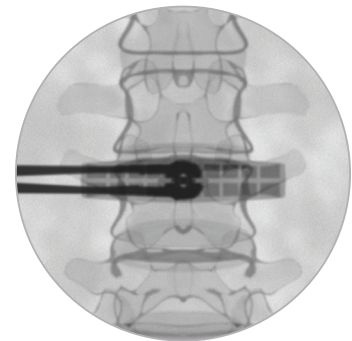


Fig. 4A. AP View: Dilator Assembly Position

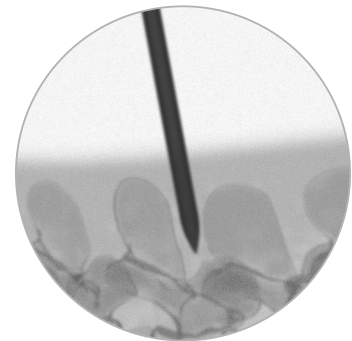


Fig. 4B. Lateral View: Dilator Assembly Position

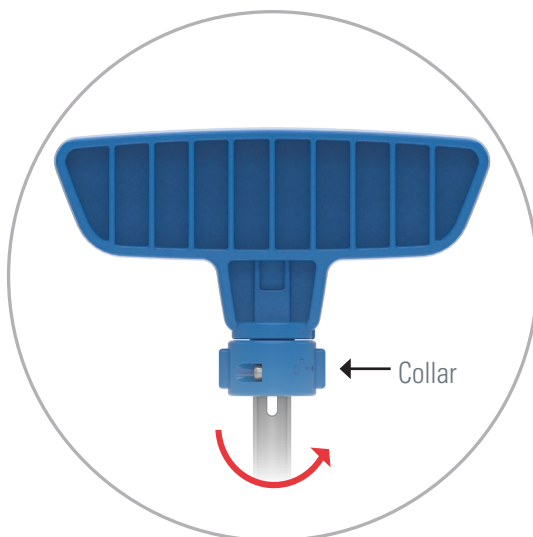


Fig. 4C. Dilator Assembly Handle


4

DILATION (CONTINUED)

Cannula Assembly

Insert the Cannula Assembly over the Dilator and through the supraspinous ligament (Fig. 4D). Ensure the distal channels of the Cannula Assembly are orientated with the spinous processes. Use direct visualization and fluoroscopy to confirm trajectory and alignment to the midline are maintained.

Depth of Insertion of Cannula Assembly

1. Advance the Cannula Assembly manually or using a mallet, taking care to ensure the Dilator does not advance further.
2. Advance the Cannula Assembly until the distal tip reaches the dorsal aspect of the facet shadow and is firmly seated between the adjacent spinous processes (Fig. 4E). Use lateral fluoroscopy to monitor depth of insertion. When position is confirmed, remove Dilator. Unlock and remove the Cannula Assembly handle, ultimately leaving only the outer Cannula (hereinafter referred to as Cannula). To unlock the Cannula Assembly, turn the collar on the handle counterclockwise in the direction of the  arrow (Fig. 4F).

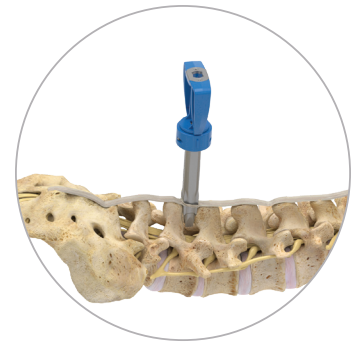


Fig. 4D. Cannula Assembly Placement

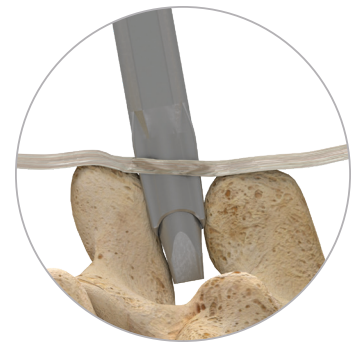


Fig. 4E. Cannula Position Detail

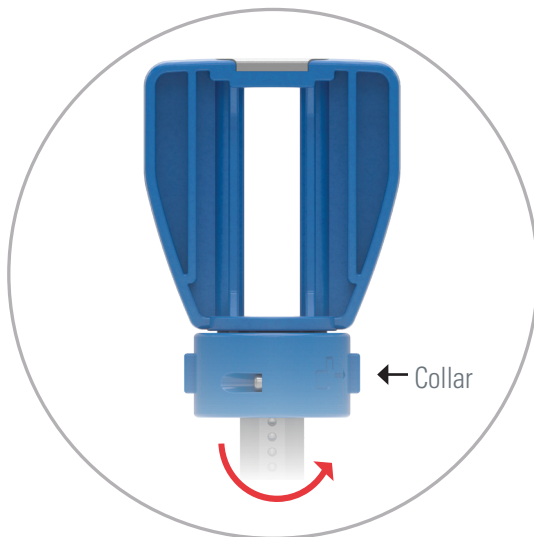


Fig. 4F. Cannula Assembly Handle

CAUTION

Dural injury may result if the Dilator Assembly is advanced too deeply, i.e., beyond (or past) the facet shadow ventrally. Monitor its depth using lateral fluoroscopy.

4

DILATION (CONTINUED)

3. The distal end of the Cannula will be positioned approximately 10mm dorsal to the spinolaminar junction and beyond the apices of the spinous processes (Fig. 4G). Position may be reconfirmed with AP and lateral fluoroscopy (Fig. 4H, 4I).

CAUTION

Dural injury may result if the Cannula Assembly is advanced too deeply, i.e., beyond (or past) the facet shadow ventrally. Monitor its depth using lateral fluoroscopy.

Avoid further advancing the Dilator when advancing the Cannula Assembly or dural injury may result.



Fig. 4G. Cannula Final Placement

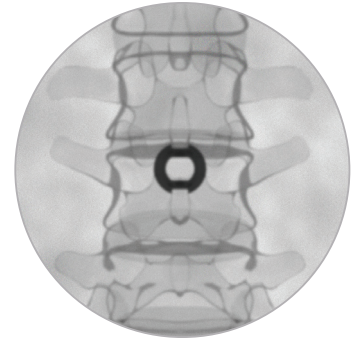


Fig. 4H. AP Confirmation of Cannula Placement and Midline Trajectory

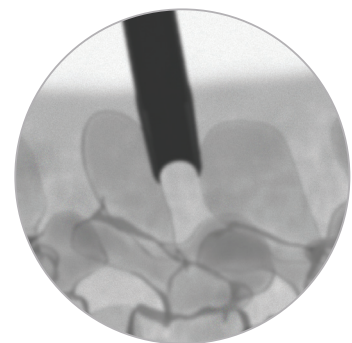


Fig. 4I. Lateral Confirmation of Cannula Depth

5 PREPARATION (OPTIONAL)

Interspinous Reamer

The Reamer can be used to further prepare the interspinous space for delivery of the Implant. Insert the Reamer through the Cannula into the interspinous space (Fig. 5), no further than the facet shadow or spinolaminar junction.

Monitor depth of insertion with the use of lateral fluoroscopy (Fig. 5A). To use, articulate clockwise and counterclockwise. The depth of cut is 15mm beyond the distal end of the Cannula when the Reamer is fully seated.

CAUTION

Dural injury may result if the Reamer is advanced too deeply, i.e., beyond (or past) the facet shadow ventrally. Monitor Reamer depth using lateral fluoroscopy.

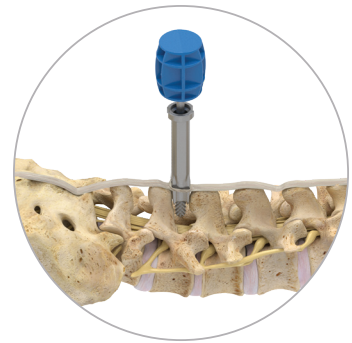


Fig. 5. Use of Interspinous Reamer

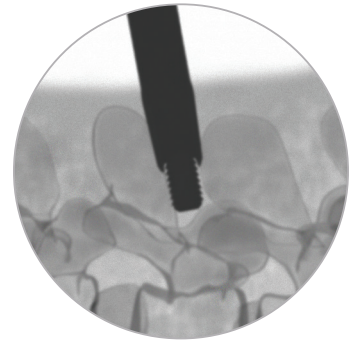


Fig. 5A. Closely Monitor Reamer Depth Using Lateral Fluoroscopy

6

IMPLANT GAUGING

Insert the Interspinous Gauge through the Cannula to determine proper Implant size selection (Fig. 6). Proper orientation of the Interspinous Gauge is ensured via the flats on the barrel. The fingers should rest on the lever to facilitate actuation of the Interspinous Gauge. Confirm the depth of insertion under lateral fluoroscopy (Fig. 6A). The distal tips of the Interspinous Gauge should contact the spinous process dorsal to the spinolaminar junction of the superior lamina. Measurement of the interspinous space is obtained by firmly actuating the trigger until resistance is detected at the distal tips (Fig. 6B) and is read on the Interspinous Gauge scale (Fig. 6C).

CAUTION

Do not over-distract. Boston Scientific does not recommend over-sizing, as the device is not intended to distract the motion segment beyond the allowed physiological range of motion, but rather, to prevent extension from the flexed state.



Fig. 6. Insertion of Gauge

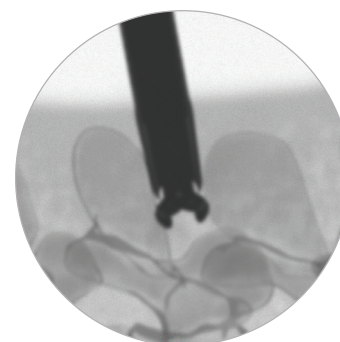


Fig. 6A. Confirm Depth Under Lateral Fluoroscopy

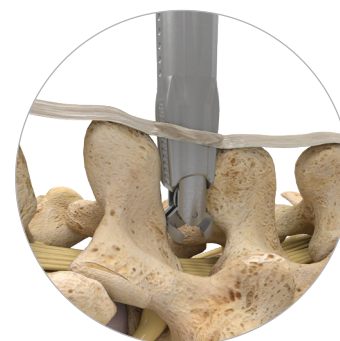


Fig. 6B. Measurement

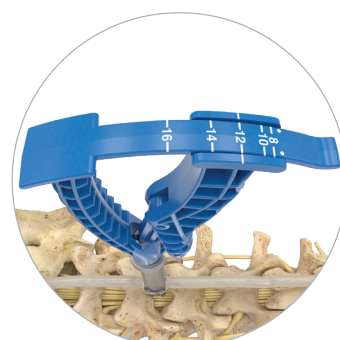


Fig. 6C. Size Scale on Gauge

6 IMPLANT GAUGING (CONTINUED)

Under an AP Ferguson fluoroscopic view, confirm the midline positioning so that the distal tips of the Interspinous Gauge contain the spinous processes (Fig. 6D, 6E). Once position and measurement are confirmed, the Interspinous Gauge may be removed. Release of the Interspinous Gauge is achieved with a finger release of the size scale tab.

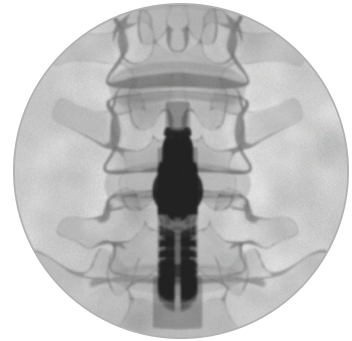


Fig. 6D. Interspinous Gauge
AP Ferguson Superior Aspect

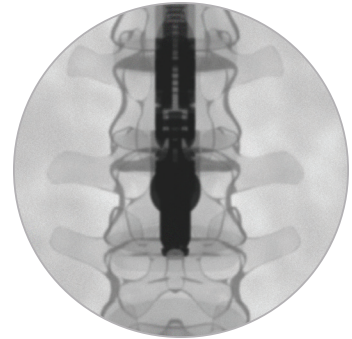


Fig. 6E. Interspinous Gauge
AP Ferguson Inferior Aspect

7 LOADING THE IMPLANT

Select the appropriate size Implant as determined by the Interspinous Gauge. The Inserter is a multi-function instrument utilized to deliver all sizes of the Implant through the Cannula. The Inserter 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. 7).
2. Flip the lever so the bottom of the lever aligns with the bottom of the handle, pulling the proximal third of the Implant into the shaft of the Inserter (Fig. 7A). The Implant is now locked on to the Inserter.

NOTE

Before loading the Implant, ensure the lever is rotated up and the clamp prongs extend out beyond the distal end of the outer shaft.

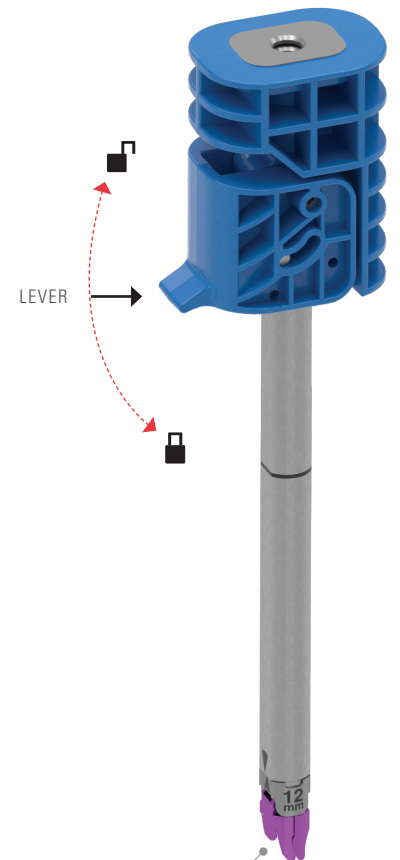


Fig. 7A. Implant Loaded onto Inserter

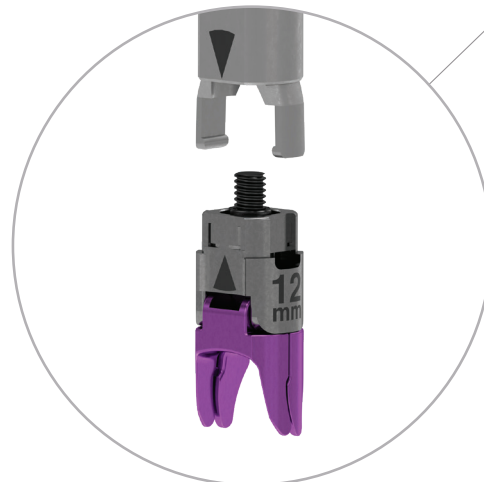


Fig. 7.
Implant Detail

8

DELIVERING THE IMPLANT

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 (Fig. 8). The notch on the lever and the laser-etched arrow on the distal end of the Inserter point cranially. Under lateral fluoroscopy, introduce the Inserter into the Cannula to minimum insertion depth (Fig. 8A). Ensure proper depth under lateral fluoroscopy. The heavy etch band on the barrel of the Inserter should align with the proximal surface of the Cannula. Partially deploy the Implant under lateral fluoroscopy (Fig. 8B) by turning the Driver clockwise. When the Implant has been deployed approximately 30%, utilize AP fluoroscopy (Ferguson View, Fig. 8C) toward the superior aspect, first to ensure bilateral containment of the superior spinous process, and then check inferior.

NOTE

Evidence of poor bone density may suggest increased potential for spinous process fracture.

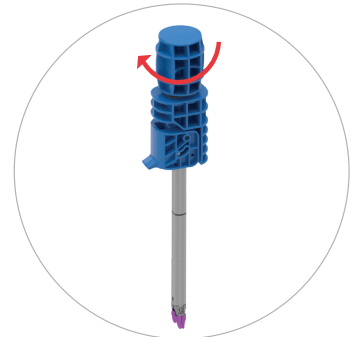


Fig. 8. Driver

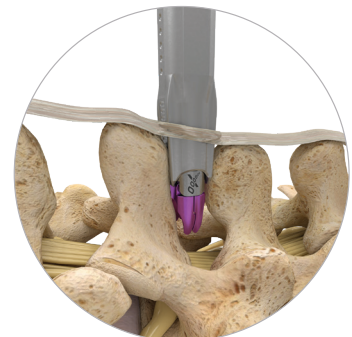


Fig. 8A. Minimum Insertion Depth

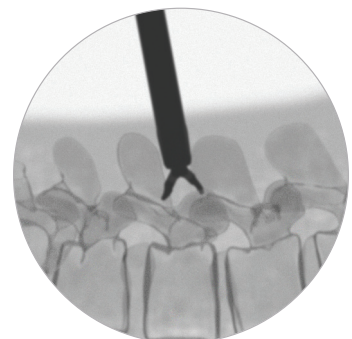


Fig. 8B. Verify Depth Under Lateral Fluoroscopy

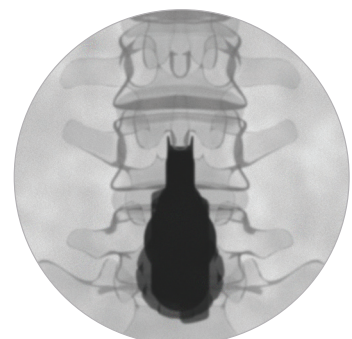


Fig. 8C. Verify Containment of Spinous Processes

8

DELIVERING THE IMPLANT (CONTINUED)

When the spinous process containment is confirmed, continue rotating the Driver clockwise until the Implant's superior and inferior cam lobes have been completely deployed and the Driver can no longer be rotated (Fig. 8D). Final tighten with two or three fingers.

If resistance to deployment is encountered, and repositioning of the Implant is required, rotate the Driver counterclockwise until a positive stop is reached and withdraw dorsally to collapse the cam lobes. Reposition the Implant to an optimal depth, using lateral fluoroscopy to verify placement. After confirming optimal placement, rotate Driver clockwise to redeploy the Implant.

CAUTION

Do not force deployment or Implant breakage or damage to bony structures may result.

Caution:

Certain anatomical characteristics have been associated with an increased risk of spinous process fractures. These risk factors include the use of a Superion™ Implant where the spinous process(es) is (are) too thin, or gracile, to accept the load, or placement of the Implant in too shallow, or dorsal, a position.

Spinous processes having a superior/inferior dimension of <20mm have been shown to increase the potential for fracture (Fig. 8E). Evidence of poor bone density may suggest increased potential for spinous process fracture.

Shallow/dorsal placement (i.e., in the posterior 1/3 of the interspinous process space) should be avoided, as this position has been shown to increase the potential for spinous process fracture (Fig. 8F, 8G).

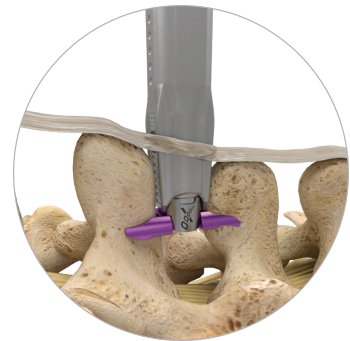


Fig. 8D. Implant Expanded

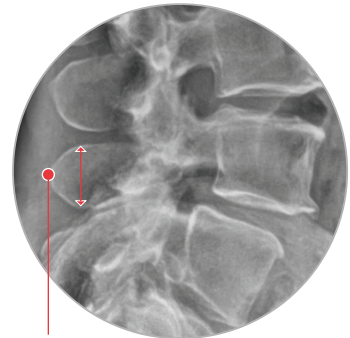


Fig. 8E Thin Spinous Process

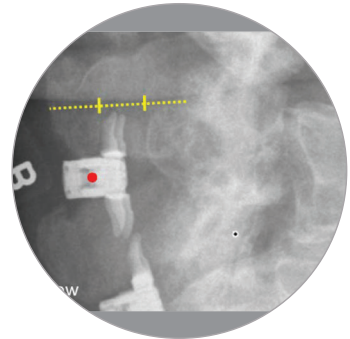


Fig. 8F. Incorrect: Shallow Placement in Posterior 1/3 of Interspinous Process Space

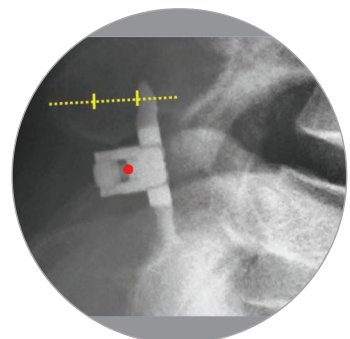


Fig. 8G. Optimal Placement in the Interspinous Process Space

8

DELIVERING THE IMPLANT (CONTINUED)

Caution:

Should any resistance be encountered during deployment of the Superior™ Implant, it may be suggestive of interference between the Implant and bony anatomy (e.g., lamina, hypertrophic spinous process, etc.), and/or suboptimal Implant positioning.

Potential causes for such resistance include:

- Implant and Driver are not completely inserted through Cannula
- Soft tissue obstruction of Implant
- Cam lobes breaching, or obstructed by, a spinous process
- Cam lobes deploying outside (lateral to) the spinous processes
- Implant is too far ventral and is engaging the lamina

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, Fig. 8H), 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, completely reverse-deploy (close) the Implant before repositioning and redeployment. Confirm correct position via fluoroscopy before completing deployment to the open and locked position.

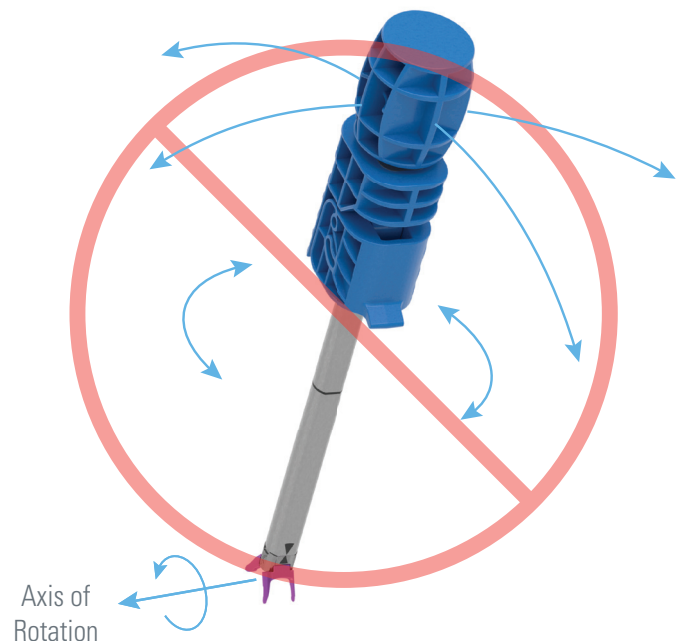


Fig. 8H.

8

DELIVERING THE IMPLANT (CONTINUED)

Remove Driver from Inserter

Ensure proper Implant depth position prior to removal of the Driver and Inserter. Shallow, or dorsal, placement of the Implant in the posterior 1/3 of the interspinous process space may increase the likelihood of spinous process fracture. It is very important that the superior cam lobes rest ventrally, against the superior segment's lamina. After Implant deployment, the Implant should be driven ventrally by removing the Driver and gently tapping on the Inserter. The final and proper placement of the device should be verified via lateral fluoroscopy (Fig. 8I).

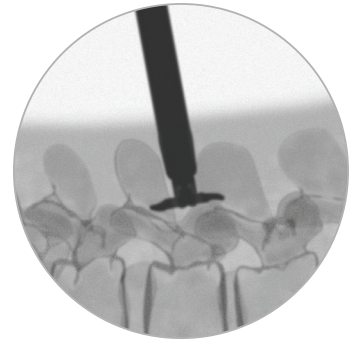


Fig. 8I. Verify Proper Implant Position

9

REMOVAL OF THE INSERTER

To Detach the Inserter

1. Once final positioning of the Implant has been confirmed via AP and lateral fluoroscopy, the Inserter may be removed (Fig. 9).
2. Rotate the lever upward to disengage.
3. Withdraw the Inserter and the Cannula.
4. Close the incision in routine fashion. At the physician's discretion, the split supraspinous ligament may also be closed.

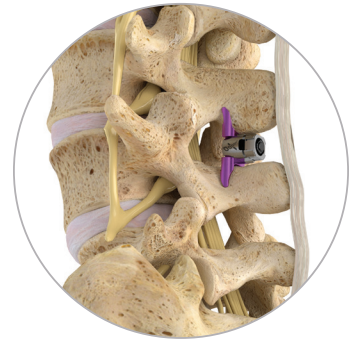


Fig. 9. Inserter Removed

10 FINAL IMPLANT POSITION

Optimal Superion™ Implant Placement

Final imaging may be taken after all instrumentation has been removed (Fig. 10, 10A).

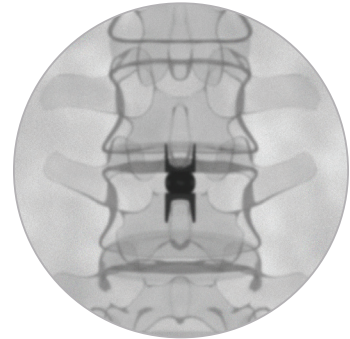


Fig. 10. AP Verification of Implant Position

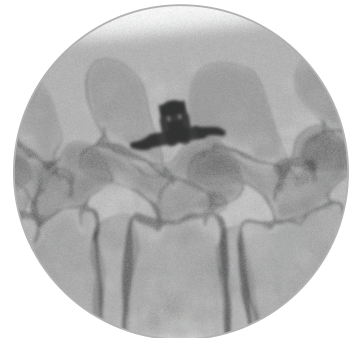


Fig. 10A. Lateral Verification of Implant Position

11 TWO-LEVEL PROCEDURE

Prioritize the level to instrument first with consideration of the following:

- The most symptomatic level may be done first to ensure adequate neural decompression
- A relatively short spinous process height may cause cam lobes to overlap
- A grade-1 spondylolisthesis may cause one Implant to seat more dorsal than the other

Utilize the same instrumentation sequence as a 1-level technique with a 12-15mm skin incision at each level to be treated. Alternatively, a single 22-25mm incision can be utilized to access two contiguous levels. After placement of the first Implant, repeat all access, gauging and Implant delivery steps to complete the second level procedure (Fig. 11, 11A).

NOTE

Indications for use limit 2-level procedures to contiguous levels. The Implant has been designed to allow for some overlap of contiguous Implants.

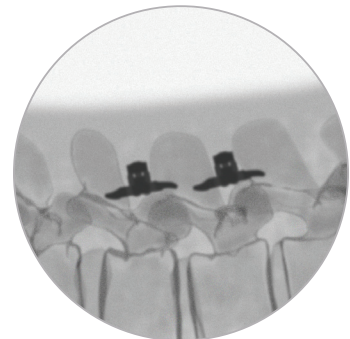


Fig. 11. Lateral View – Completed 2-Level Procedure

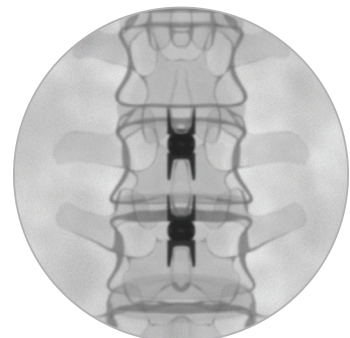


Fig. 11A. AP View – Completed 2-Level Procedure

12 REMOVAL OF AN IMPLANT

Implant Removal

In the event that a Superior™ Implant must later be removed:

1. Sequentially dilate the skin and supraspinous ligament over the site of the original implantation, following the access step described in Steps 3 (Approach) and 4 (Dilation) above. Position the Cannula immediately dorsal to the Implant, using AP and lateral fluoroscopy for targeting.
2. Place the Inserter through the Cannula. Engage and lock the proximal end of the Implant to the Inserter, following Step 7 (Loading the Implant) above. Fluoroscopy may be employed to assist in positioning the Inserter relative to the Implant (Fig. 12).
3. Insert the Driver through the Inserter and gently rotate until it has engaged the Implant.
4. Rotate the Driver counterclockwise until the Implant is closed (Fig. 12A). A positive stop will be felt when the Implant is completely closed. Withdraw the Inserter with attached Implant from the Cannula, and withdraw the Cannula.

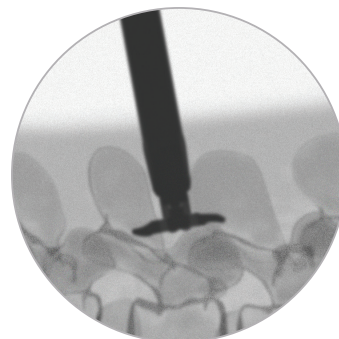


Fig. 12. Inserter Engaged with Proximal End of Implant

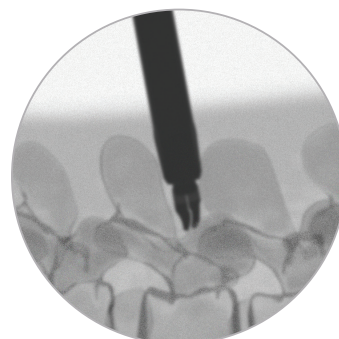


Fig. 12A. Implant Completely Closed and Ready for Removal

ORDERING INFORMATION

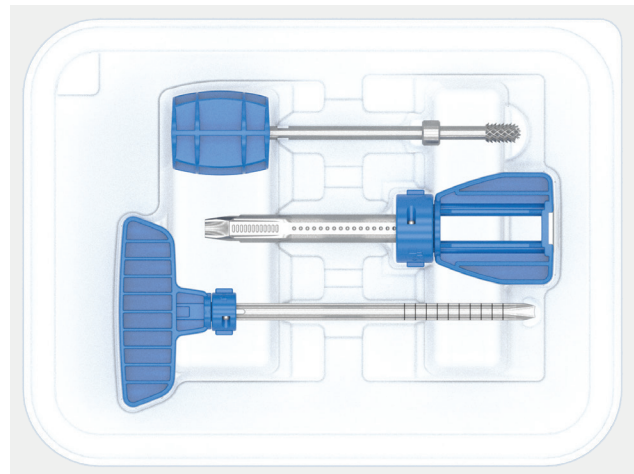
Superion™ Implants

CATALOG #	ITEM DESCRIPTION	
101-9808	8mm	Gold
101-9810	10mm	Blue
101-9812	12mm	Magenta
101-9814	14mm	Bronze
101-9816	16mm	Green



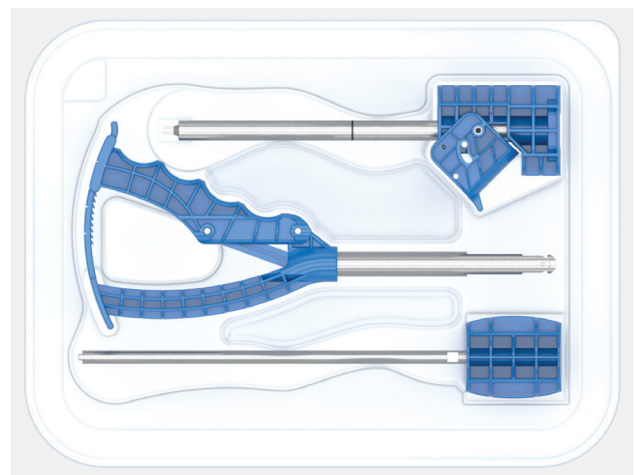
Instruments

CATALOG #	ITEM DESCRIPTION
140-9800	Vertiflex™ Instrument Platform Kit
	Dilator Assembly
	Cannula Assembly
	Reamer



140-9800

CATALOG #	ITEM DESCRIPTION
102-9800	Superion™ IDS Kit
	Driver
	Insertter
	IS Gauge



102-9800

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



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