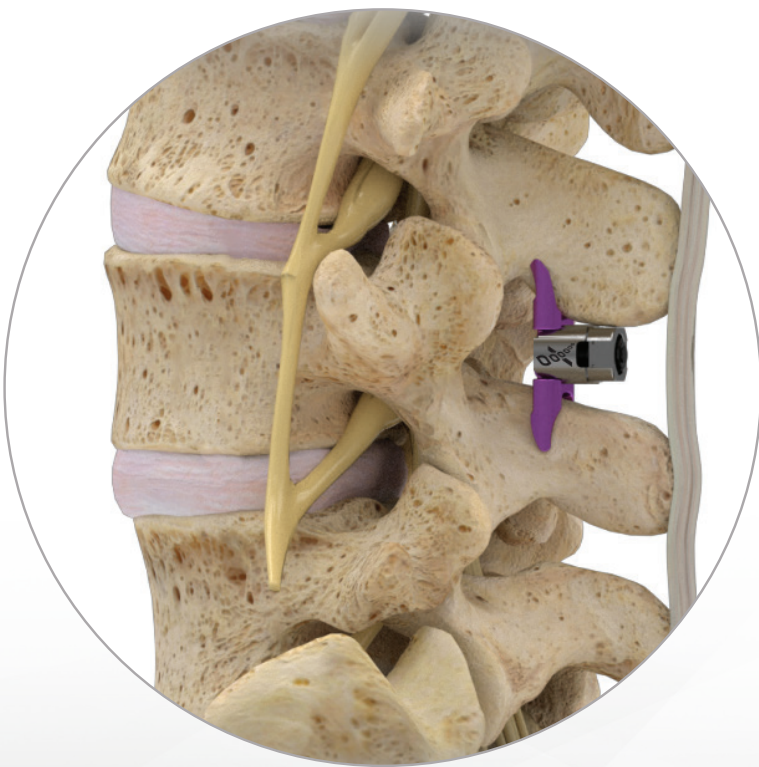


superion[®]
Indirect Decompression System

Surgical Technique Manual



vertiflex[®]

Surgical Technique Manual

Caution

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

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 Superior® Indirect Decompression System was developed to treat those patients who suffer from moderate degenerative LSS. The Superior® Implant is a device made of titanium, 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 levels 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.

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 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 package insert 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) of greater than 40

Warnings

The Superior® 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 Superior® 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 Superior® 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 Superior® 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 Superior® IDS implantation. Potential predictors for spinous process fractures include:

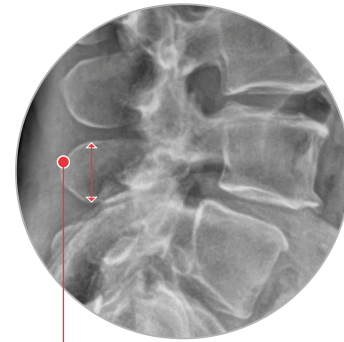
- Thin, or "gracile" spinous processes
- "Kissing" spinous processes
- "Shallow" or more dorsal placement of the device

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

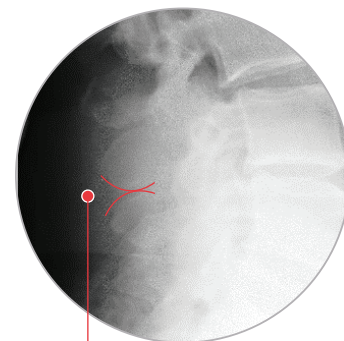
Where a spinous process is unusually thin, or measures less than 20mm in superior-inferior dimension, the likelihood of a post-operative spinous process fracture may be increased.



THIN SPINOUS PROCESS

“Kissing Spine”

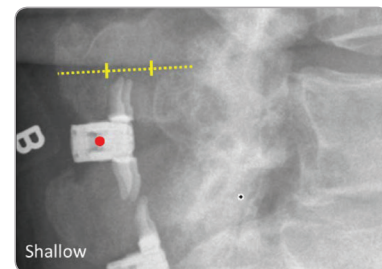
Where spinous processes are in very close approximation, or are in contact (i.e., “kissing”), increased difficulty may be experienced in placement of the Cannula. Where spinous processes do not “open up” in flexion, the likelihood of a spinous process fracture may be increased.



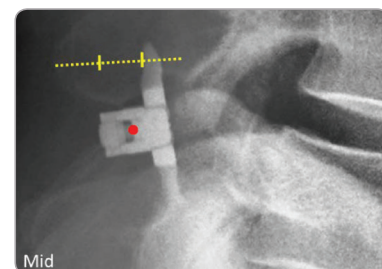
KISSING SPINOUS PROCESSES

Implant Placement Location

Where the Superior® Implant is placed in a “shallow” or more dorsal position, the likelihood of a 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 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 disease 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 to implant the Superior® IDS, the implantation 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 Vertiflex® to those interested in using the device.

To arrange for training, please contact your Vertiflex® 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

Instruments

The Superior® IDS includes a set of instruments necessary to deliver the Superior® Implant. 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 instrument package insert for complete cleaning instructions. The Superior® Implant is supplied sterile.



DILATOR 1



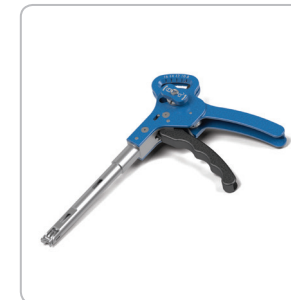
DILATOR 1 BLUNT



DILATOR 2



CANNULA



INTERSPINOUS GAUGE



INSERTER



DRIVER



HANDLE



INTERSPINOUS REAMER



RETRACTOR



MALLET



GRASPING FORCEPS

1. Patient Preparation & 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.

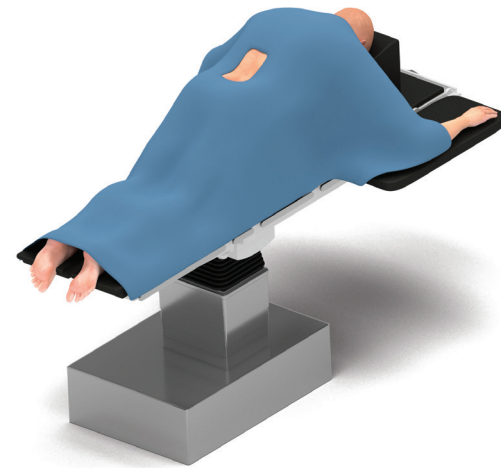


FIG. 1. PATIENT POSITIONING - FLEXED

Note

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

2. Identifying Level to be Treated

Identifying Correct Level

Use Dilator 1, Dilator 1 Blunt, hemostat, spinal needle, or K-wire to confirm midline and axial position.

Single or bi-plane fluoroscopy may be used.

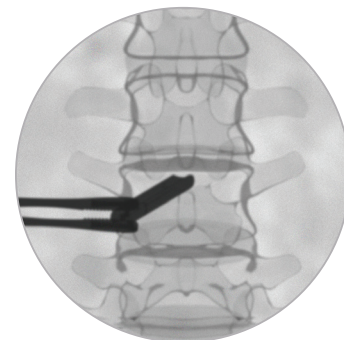


FIG. 2. CONFIRMATION OF MIDLINE POSITION

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 the Retractor.

APPROACH

Fluoroscopically Guided Technique

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

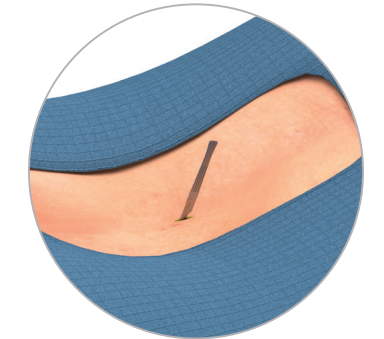


FIG. 3. SKIN INCISION

ALTERNATIVE APPROACH

Direct Visualization (Mini-Open)

1. Identify the appropriate surgical level and midline using a spinal needle, Dilator 1, Dilator 1 Blunt, 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. 3).
3. Insert the Retractor to visualize the supraspinous ligament (Fig. 3B).
4. Produce a longitudinal split of the supraspinous ligament (SSL) at midline with blade (Fig. 3A).

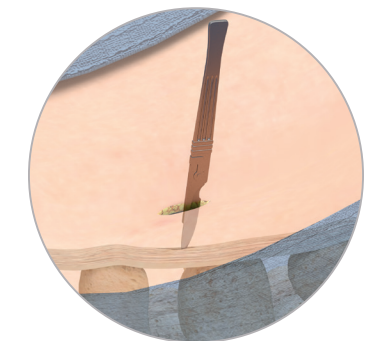


FIG. 3A. LONGITUDINAL SPLIT OF SSL

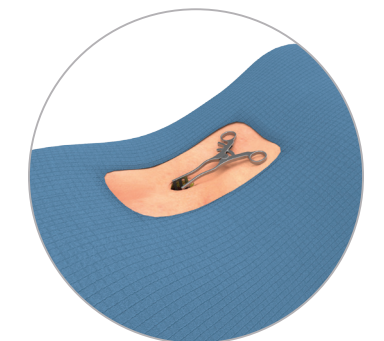


FIG. 3B. RETRACTOR IN POSITION TO VISUALIZE SUPRASPINOUS LIGAMENT

4. Dilation

Dilator 1

Place Dilator 1 or Dilator 1 Blunt (hereinafter referred to as Dilator 1) into the treatment site at midline and advance manually, or with the assistance of the optional Mallet, until the distal tip approaches the dorsal aspect of the facet shadow as verified by lateral fluoroscopy (Fig. 4). Use AP fluoroscopy to confirm midline placement and the Dilator 1 depth markers and lateral fluoroscopy to verify depth.

An optional Grasping Forceps is available to offset the user's hand from instruments during use of intraoperative fluoroscopy.

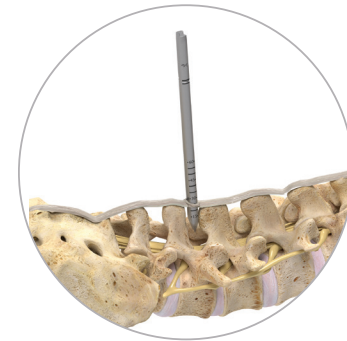
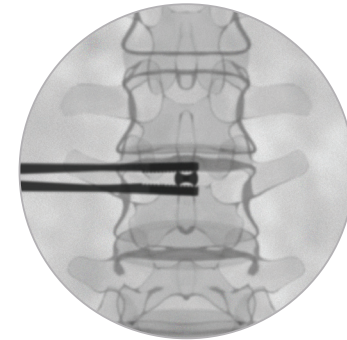
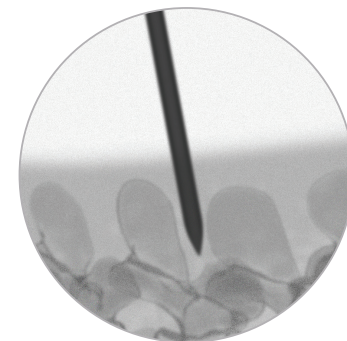


FIG. 4. DILATOR 1 PLACEMENT



A/P VIEW: DILATOR 1 POSITION



LATERAL VIEW: DILATOR 1 POSITION



Caution

Dural injury may result if Dilator 1 is advanced too deeply. Control Dilator 1 depth using lateral fluoroscopy.

4. Dilation (continued)

Dilator 2

Insert Dilator 2 over Dilator 1 (Fig. 4A) to the previously indicated depth, and ensure the Dilator channels are aligned with the superior and inferior spinous processes. Use direct visualization and lateral fluoroscopy to verify depth, and AP fluoroscopy to confirm midline placement, and to confirm trajectory and alignment to the midline are maintained.

Depth of Insertion of Dilator 2

1. Advance Dilator 2 manually, or using the optional Handle and Mallet, **taking care to ensure Dilator 1 does not advance further.**
2. Advance Dilator 2 until the distal tip approaches the dorsal aspect of the facet shadow (Fig. 4B). Use direct visualization and lateral fluoroscopy to control depth of insertion. Remove Dilator 1.



Caution

Dural injury may result if Dilator 2 is advanced too deeply. Control Dilator 2 depth using lateral fluoroscopy.

Avoid further advancing Dilator 1 when advancing Dilator 2, or dural injury may result.

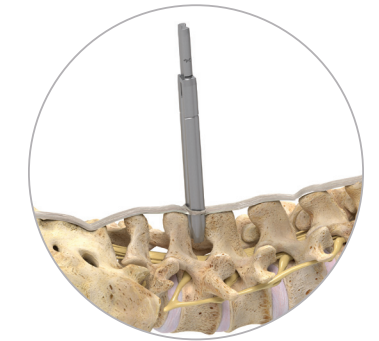


FIG. 4A. DILATOR 2 PLACEMENT



FIG. 4B. DILATOR 2 POSITION DETAIL

4. Dilation (continued)

Cannula

Insert the Cannula over Dilator 2 (Fig. 4C) 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. Use direct visualization and fluoroscopy to confirm trajectory and alignment to the midline are maintained (Fig. 4D).

Depth of Insertion of Cannula

1. Advance the Cannula manually, or using the optional Handle and Mallet, taking care to ensure Dilator 2 does not advance further.
2. Advance the Cannula until the distal tip is firmly seated between the adjacent spinous processes and positioned beyond the apices of the spinous processes (Fig. 4E). Verify position with lateral fluoroscopy and remove Dilator 2 (Fig. 4F).

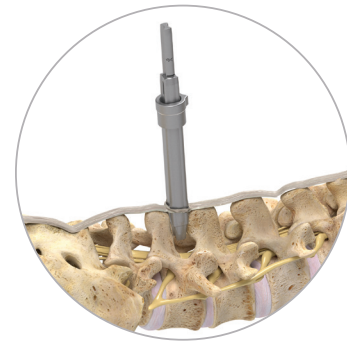


FIG. 4C. CANNULA PLACEMENT

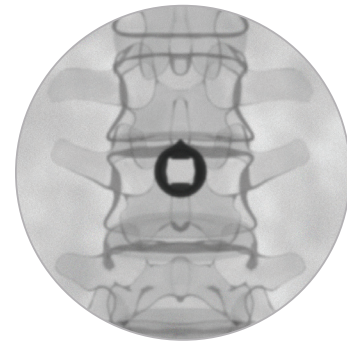


FIG. 4D. A/P CONFIRMATION OF CANNULA PLACEMENT AND MIDLINE TRAJECTORY



FIG. 4E. CANNULA POSITION DETAIL

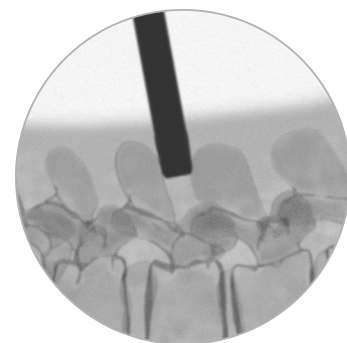


FIG. 4F. LATERAL CONFIRMATION OF CANNULA DEPTH



Caution

Dural injury may result if Cannula is advanced too deeply. Control Cannula depth using lateral fluoroscopy.

Avoid further advancing Dilator 2 when advancing Cannula, or dural injury may result.

4. 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 and Cannula and orient the distal end of the Handle perpendicular to the patient. To further advance, use the Mallet to gently tap on the target-shaped feature of the Handle (Fig. 4G).



Caution

Do not tap on the proximal tip of Dilator 2 or the Cannula to avoid advancing either instrument too deeply or dural injury may result.



FIG. 4G. USE OF HANDLE AND MALLET

Preparation (optional)

Interspinous Reamer

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. 4H). To use, articulate clockwise and counter clockwise. The depth of cut is 15mm beyond the distal end of the Cannula is fully seated.

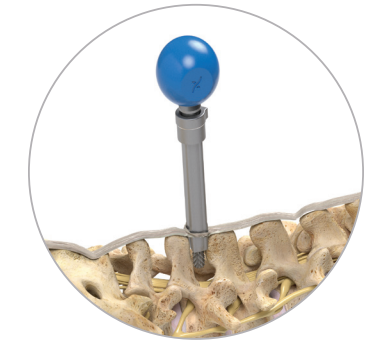
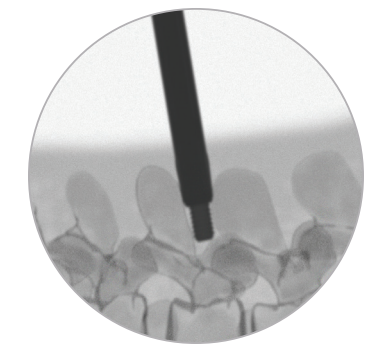


FIG. 4H. USE OF INTERSPINOUS REAMER



Caution

Dural injury may result if Reamer is advanced too deeply. Control Reamer depth using lateral fluoroscopy.



CLOSELY MONITOR REAMER DEPTH USING LATERAL FLUOROSCOPY

5. Implant Gauging

Insert the Interspinous Gauge through the Cannula to determine proper Implant size selection (Fig. 5). Proper orientation of the Interspinous Gauge is ensured via the orientation flat on the barrel. Confirm the depth of insertion under lateral fluoroscopy (Fig. 5A). 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. 5B), and is read on the Interspinous Gauge scale (Fig. 5C).

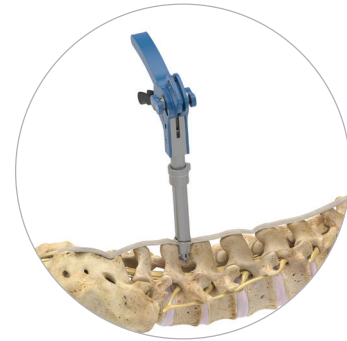


FIG. 5. INSERTION OF GAUGE

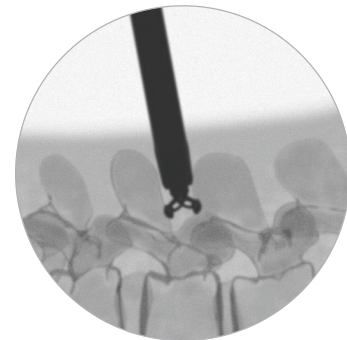


FIG. 5A. CONFIRM DEPTH UNDER LATERAL FLUOROSCOPY

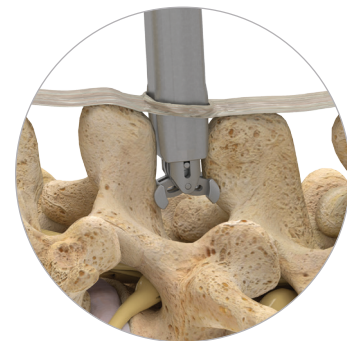


FIG. 5B. MEASUREMENT



FIG. 5C. SIZE SCALE ON GAUGE



Caution

Do not over-distract. Vertiflex® 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.

5. Implant Gauging (continued)

Once resistance is detected at the distal tips, lock the gauge (Fig. 5D, 5E).

Under an AP Ferguson fluoroscopic view, confirm the midline positioning so that the distal tips of the Interspinous Gauge contain the spinous processes (Fig. 5F, 5G).



FIG. 5D. PLACEMENT OF INTERSPINOUS GAUGE UNLOCKED



FIG. 5E. PLACEMENT OF INTERSPINOUS GAUGE LOCKED

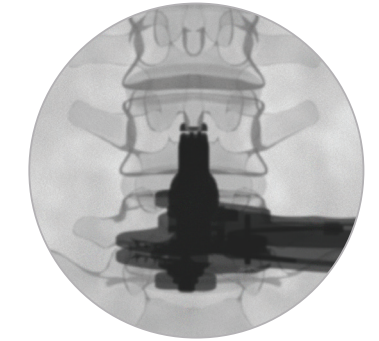


FIG. 5F. INTERSPINOUS GAUGE - AP FERGUSON SUPERIOR ASPECT

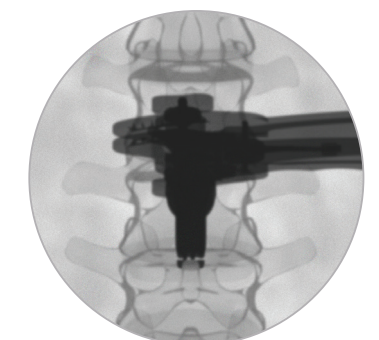



FIG. 5G. INTERSPINOUS GAUGE - AP FERGUSON INFERIOR ASPECT

6. 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 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. 6).
2. Turn the dial towards the locked  position until the arrow on the dial aligns with the arrow on the body of the inserter (Fig. 6A).

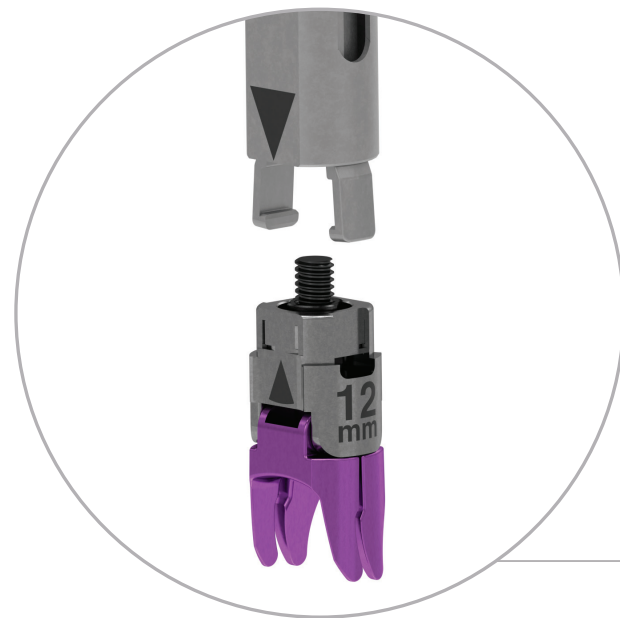


FIG. 6.



FIG. 6A.

Note

Before loading the Implant, ensure that Dial is turned completely to the unlocked  position.

7. 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. 7). Load the Inserter into the Cannula to minimum insertion depth (Fig. 7A). The heavy etch band on the barrel of the Inserter should align with the proximal surface of the Cannula. Ensure proper depth under lateral fluoroscopy. Partially deploy the Implant under lateral fluoroscopy (Fig. 7B) by turning the Driver clockwise. When the Implant has been deployed approximately 30% to 50%, utilize A/P fluoroscopy (Ferguson View, Fig. 7C) 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 (Fig. 7D). Final tighten with two or three fingers.

If resistance to deployment is encountered, and repositioning of the Implant is required, rotate the Driver counter-clockwise and slightly withdraw dorsally to collapse the cam lobes. Reposition the Implant to an optimal position, using lateral fluoroscopy to verify position. After confirming optimal position, rotate Driver clockwise to re-deploy the Implant.



Caution

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

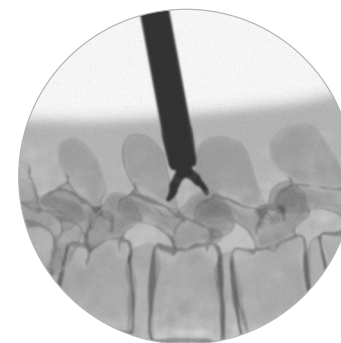


FIG. 7B. VERIFY DEPTH UNDER LATERAL FLUOROSCOPY

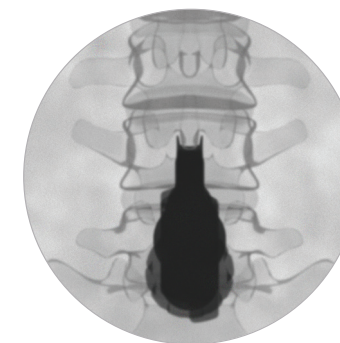


FIG. 7C. VERIFY CONTAINMENT OF SPINOUS PROCESSES

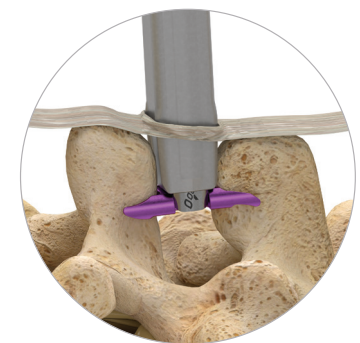


FIG. 7D. IMPLANT EXPANDED



FIG. 7. DRIVER

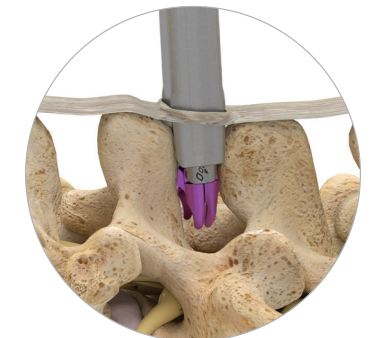


FIG. 7A. MINIMUM INSERTION DEPTH

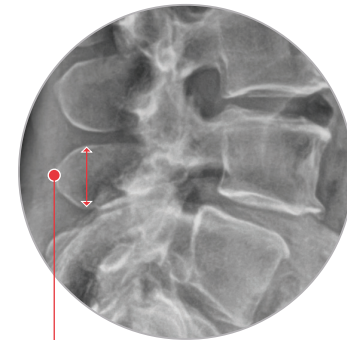
7. Delivering the Implant (continued)

Caution:

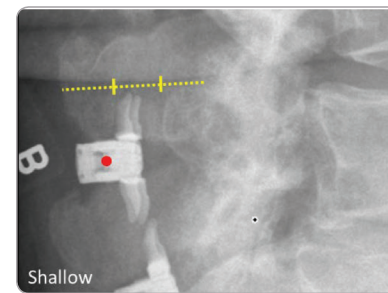
Certain anatomical characteristics have been associated with an increased risk of spinous process fractures. These risk factors include the use of a Superior® Implant where the spinous process(es) is(are) too thin, or gracile, to accept the load, or placement of the Implant in too shallow, or dorsal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

Spinous processes having a superior/inferior dimension of <20mm have been shown to increase the potential for post-operative fracture.

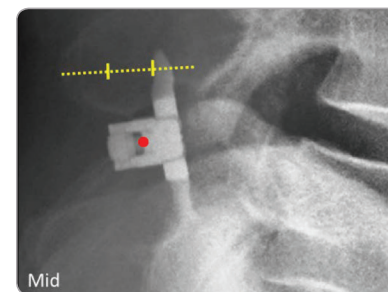
Shallow/dorsal placement (i.e., in the posterior 1/3 of the interspinous process space) should be avoided, as this position has been shown to increase the potential for spinous process fracture.



THIN SPINOUS PROCESS



INCORRECT: SHALLOW PLACEMENT IN POSTERIOR 1/3 OF INTERSPINOUS PROCESS SPACE



OPTIMAL PLACEMENT IN THE INTERSPINOUS PROCESS SPACE

7. 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. 7E), 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 (close) the Implant before repositioning and redeployment. Confirm correct position via fluoroscopy before completing deployment to the open and locked position.

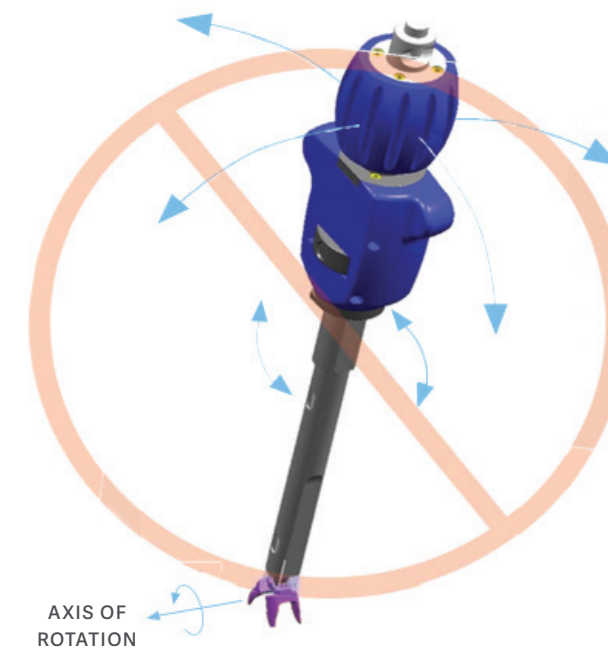


FIG. 7E.

Note

The effects of multiple deployments upon Implant strength have not been determined. In the event that a Superior® 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.

7. Delivering the Implant (continued)

Remove Driver from Inserter

Ensure proper Implant placement via fluoroscopy (Fig. 7F). Ensure proper Implant depth position prior to removal of the 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 may be driven ventrally by removing the Driver and gently tapping on the Inserter.

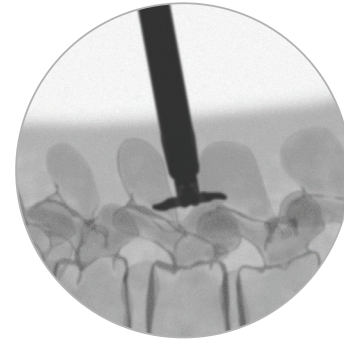


FIG. 7F. VERIFY PROPER IMPLANT POSITION

8. Final Implant Position

Optimal Superior® Implant Placement

Final implant placement should be confirmed under AP (Fig. 8) and lateral fluoroscopy (Fig. 8A).

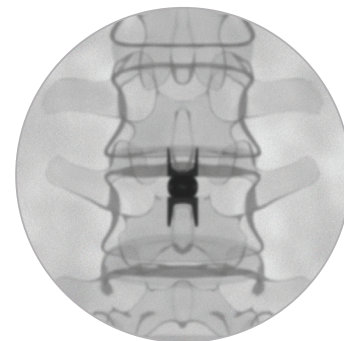
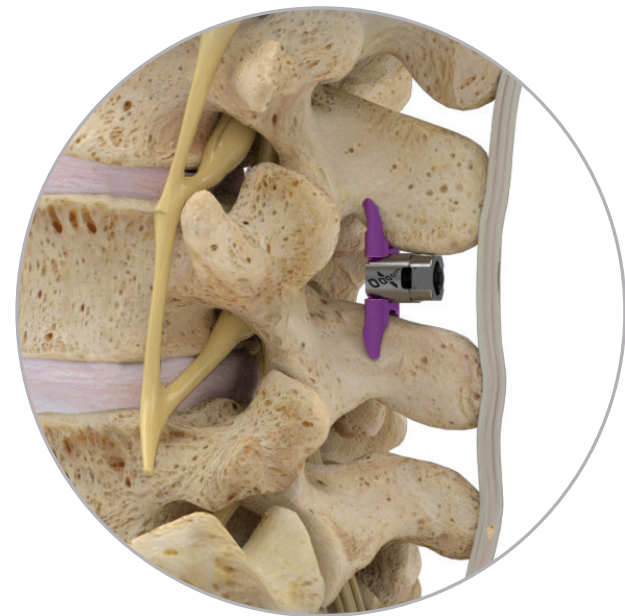


FIG. 8. A/P VERIFICATION OF IMPLANT POSITION

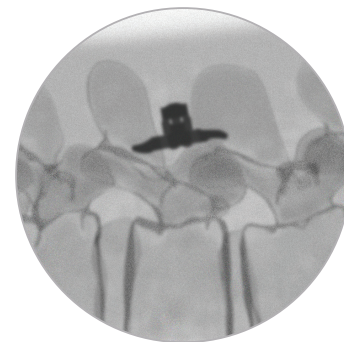


FIG. 8A. LATERAL VERIFICATION OF IMPLANT POSITION

9. 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 22-25 mm 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. 9, 9A).

Note

A two-level procedure **must** be at contiguous levels.

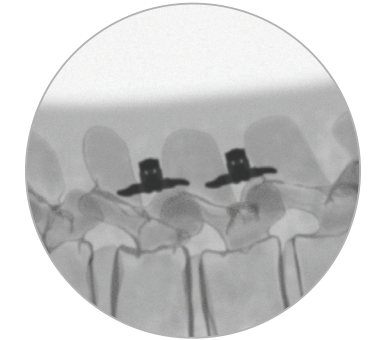


FIG. 9. LATERAL VIEW – COMPLETED 2-LEVEL PROCEDURE

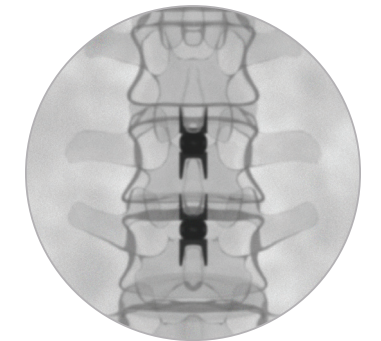



FIG. 9A. A/P VIEW – COMPLETED 2-LEVEL PROCEDURE

10. Removal of the Inserter

To Detach the Inserter

1. Turn the Inserter dial towards the unlocked  position until the dial comes to a halt to disengage the Inserter from the Implant.
2. Withdraw the Inserter and the Cannula.

Suture the incision in routine fashion. At the physician's discretion, the split supraspinous ligament may also be closed.

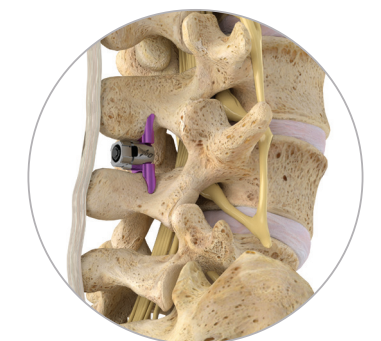


FIG. 10. COMPLETED PROCEDURE

11. 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 A/P and lateral fluoroscopy for targeting.
2. Place the Inserter instrument through the Cannula. Engage and lock the proximal end of the Implant to the Inserter, following Step 6 (Loading the Implant) above.
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 (Fig. 11).
4. Rotate the Driver counter-clockwise until the Implant is closed (Fig. 11A). 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.

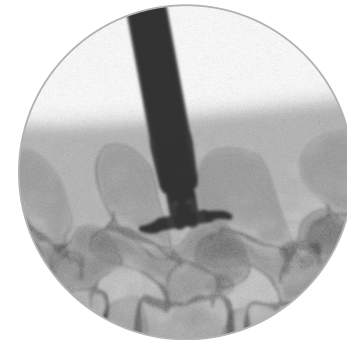


FIG. 11. INSERTER ENGAGED WITH PROXIMAL END OF IMPLANT

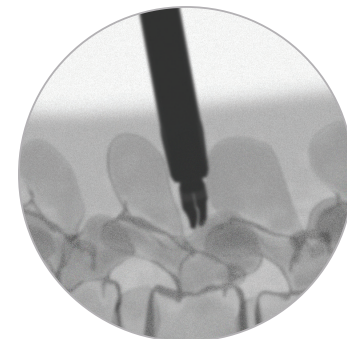


FIG. 11A. IMPLANT COMPLETELY CLOSED AND READY FOR REMOVAL

Ordering Information

CATALOG # ITEM DESCRIPTION

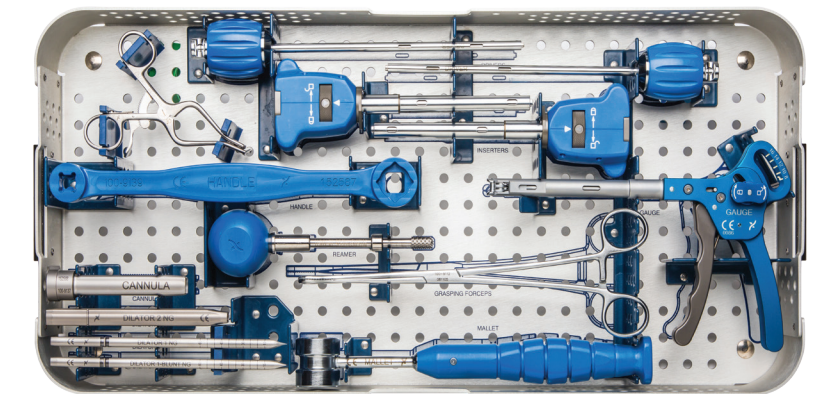
Superior® Implants

100-9808	8mm	Gold
100-9810	10mm	Blue
100-9812	12mm	Magenta
100-9814	14mm	Bronze
100-9816	16mm	Green



Instruments

100-9146	Dilator 1
100-9135	Dilator 1 - Blunt
100-9136	Dilator 2
100-9137	Cannula
100-9108	Driver
100-9110	Inserter
100-9112	Grasping Forceps
100-9115	Interspinous Gauge
100-9117	Interspinous Reamer
100-9126	Retractor
100-9127	Mallet
100-9139	Handle
100-9119	Sterilization Tray





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