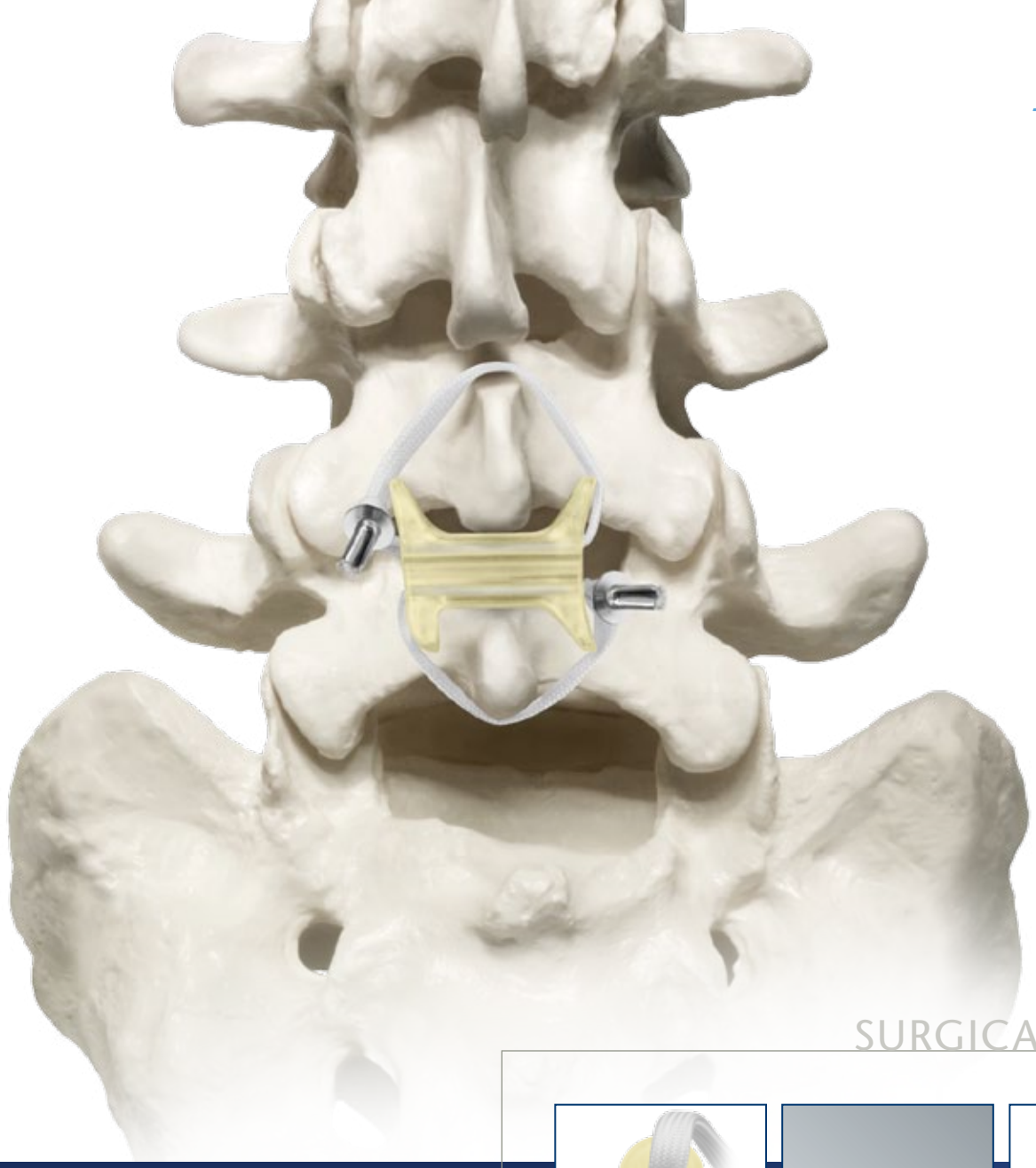
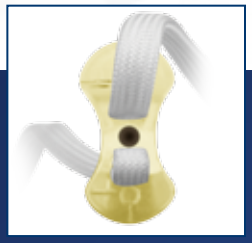
Life moves us



SURGICAL TECHNIQUE



SP-FLEX™

Interspinous Stabilization System

GLOBUS MEDICAL

Outside the US Only

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

SP-FLEX™

Interspinous Stabilization System

SP-FLEX™ is a viscoelastic interspinous spacer that is placed between spinous processes of the lumbosacral spine and is designed to indirectly decompress spinal segments, while aiding in stabilization of the segment.

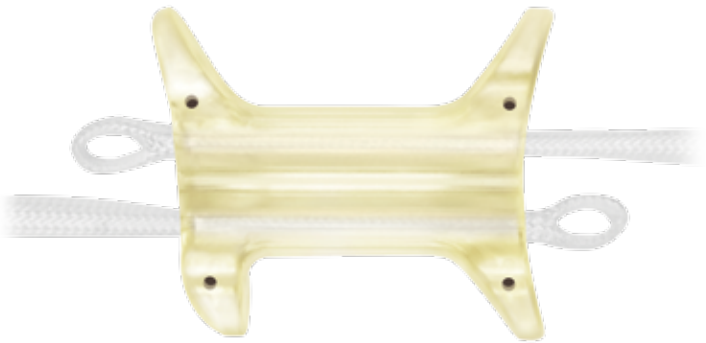
Supporting a less invasive surgical approach, SP-FLEX™ allows preservation of the supraspinous ligament and is an alternative to conservative treatment and decompressive surgery for patients suffering from degenerative disorders of the spine.

SP-FLEX™
DISTINGUISHING CHARACTERISTICS

SP-FLEX™ is a polycarbonate urethane (PCU) based interspinous stabilization device. Designed to be placed between adjacent spinous processes, the device maintains distraction while stabilizing the spinal segment with the attached polyethylene terephthalate (PET) bands. SP-FLEX™ is designed to restore foraminal height and helps to provide relief for patients suffering from degenerative spinal disorders such as lumbar spinal stenosis (LSS) and degenerative disc disease (DDD).

Viscoelasticity

Composed of a viscoelastic core which acts as a cushion in the interspinous space, SP-FLEX™ is designed to maintain foraminal height and dampen loads during extension.



Stabilization

Polyester bands help to maintain the implant position within the interspinous space and stabilize the spine.

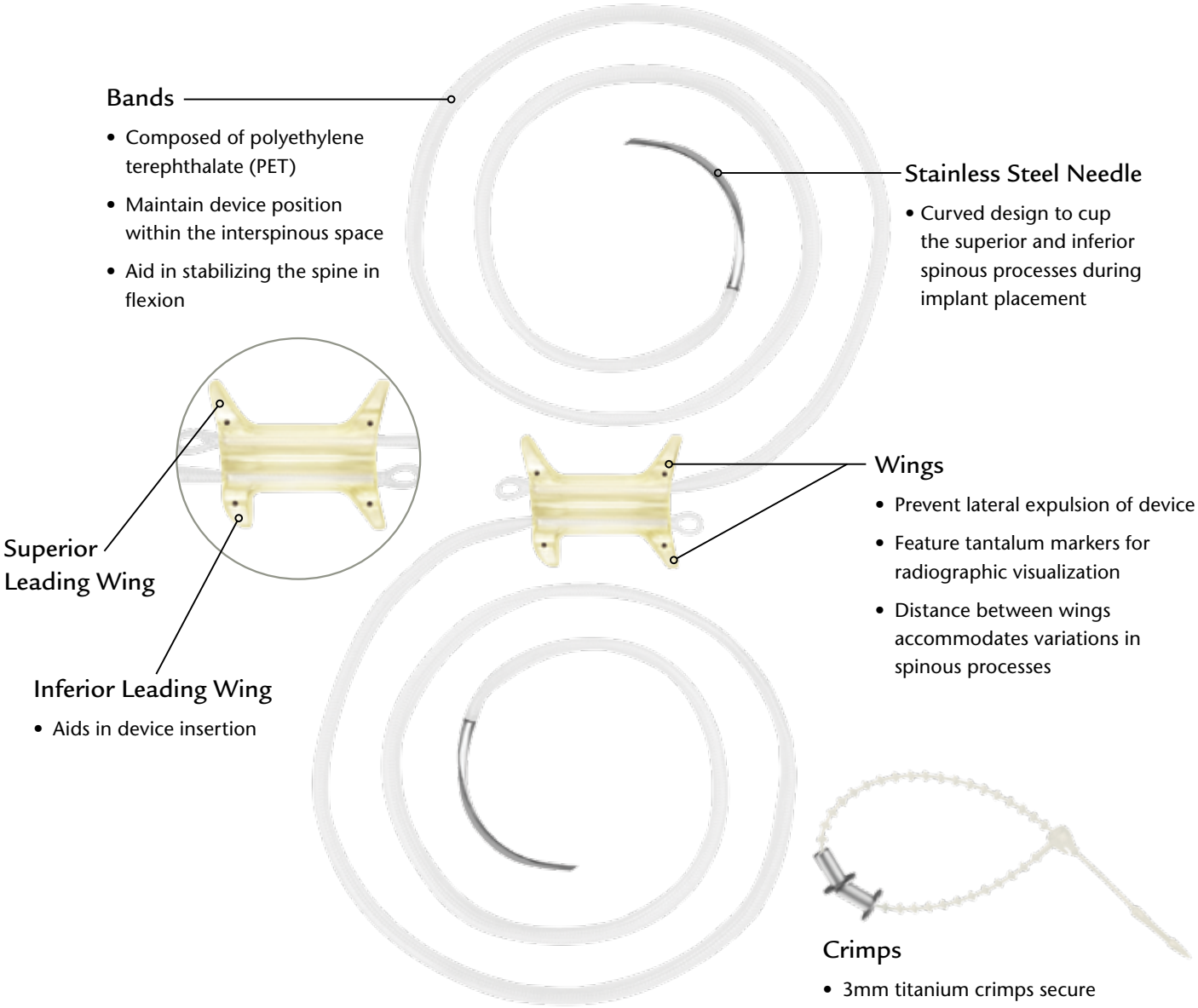
Intuitive Instrumentation

Instruments allow control of the implant for simple implant delivery.

CONTENTS

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

IMPLANT OVERVIEW



Bands

- Composed of polyethylene terephthalate (PET)
- Maintain device position within the interspinous space
- Aid in stabilizing the spine in flexion

Stainless Steel Needle

- Curved design to cup the superior and inferior spinous processes during implant placement

Wings

- Prevent lateral expulsion of device
- Feature tantalum markers for radiographic visualization
- Distance between wings accommodates variations in spinous processes

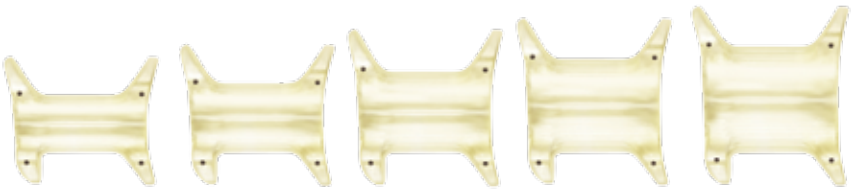
Superior Leading Wing

Inferior Leading Wing

- Aids in device insertion

Crimps

- 3mm titanium crimps secure bands in place



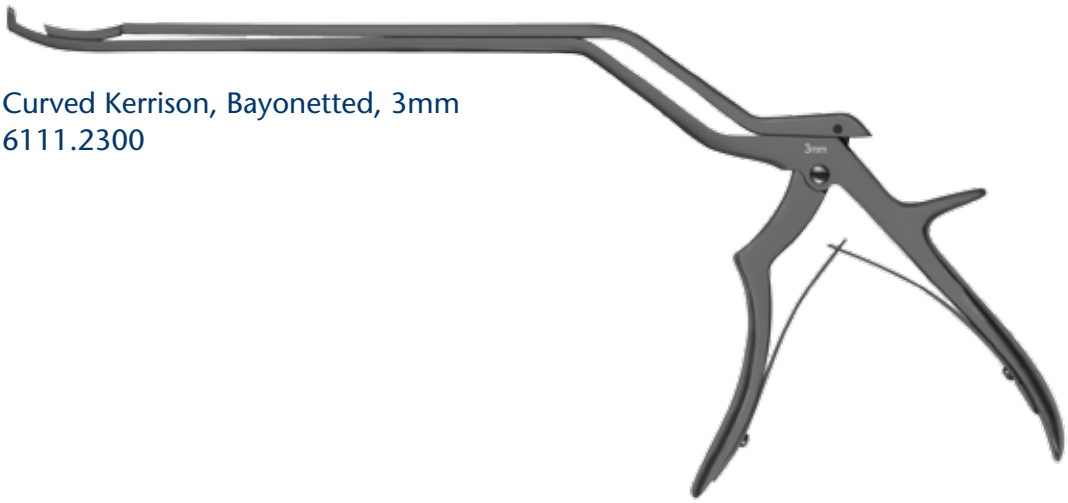
Core

- Composed of polycarbonate urethane (PCU)
- PCU exhibits viscoelastic behavior similar to soft tissue
- PCU is a radiolucent material which allows postoperative visualization
- Distraction heights range from 8–16mm, in 2mm increments

INSTRUMENT OVERVIEW

Site Preparation Instruments

Interspinous Dilator 6111.1200

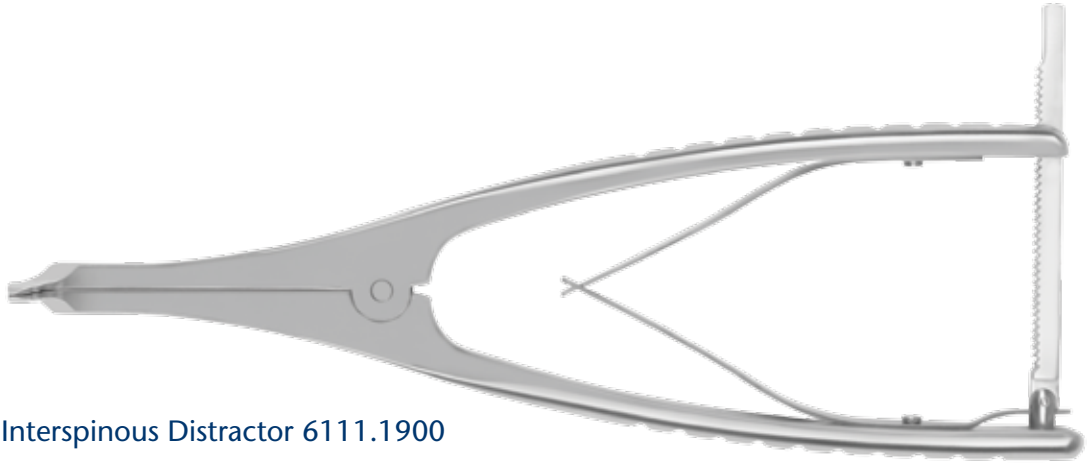


Curved Kerrison, Bayonetted, 3mm
6111.2300

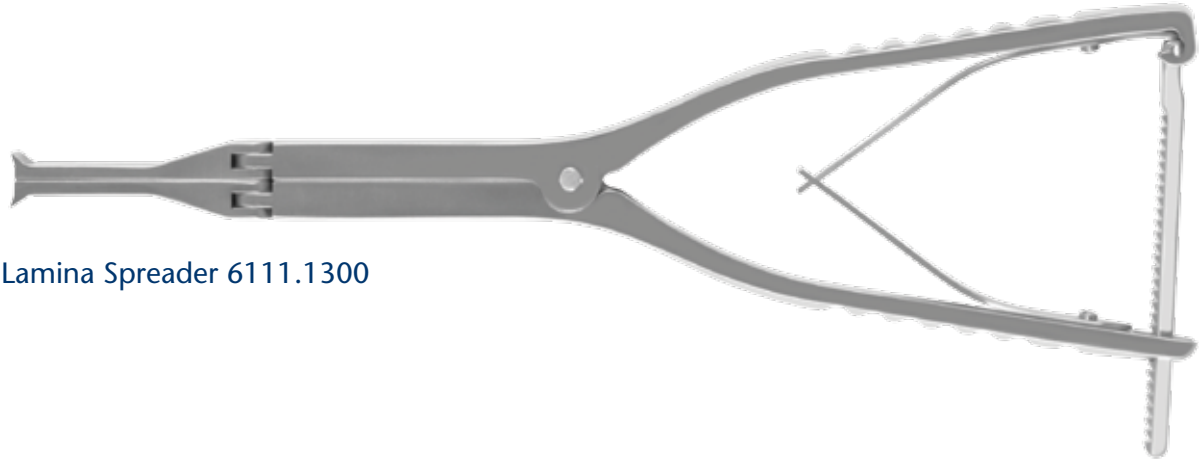
Soft Tissue Dissector, Right 6111.2000

Soft Tissue Dissector, Left 6111.2005

Site Preparation Instruments (cont'd)



Interspinous Distractor 6111.1900



Lamina Spreader 6111.1300

Sizing Instruments

Quick Coupling Handle, Large 646.960

Trial

Trials					
					
Sizes	8mm	10mm	12mm	14mm	16mm
Part No.	6111.1008	6111.1010	6111.1012	6111.1014	6111.1016

Trial, 12mm 6111.1012
Quick Coupling Handle, Large 646.960
(Assembled)

Insertion Instruments

SP-FLEX™ Holder, Slider Clip 6111.1830

SP-FLEX™ Holder, Inner Shaft – R 6111.1800

SP-FLEX™ Holder, Inner Shaft – L 6111.1805

SP-FLEX™ Holder, Outer Shaft – R 6111.1810

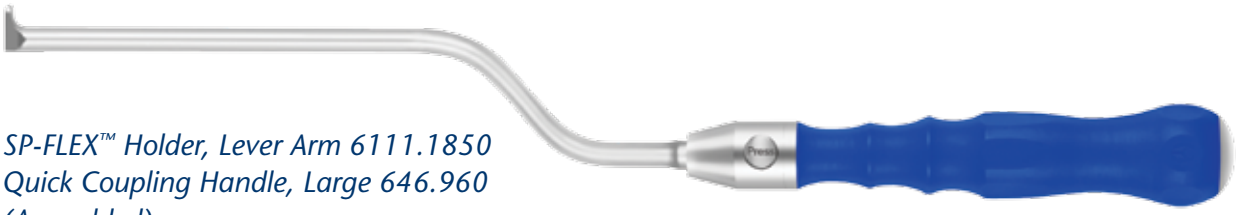
SP-FLEX™ Holder, Outer Shaft – L 6111.1815

SP-FLEX™ Holder, Threaded Shaft 6111.1820

SP-FLEX™ Holder Assembly

Insertion Instruments (cont'd)

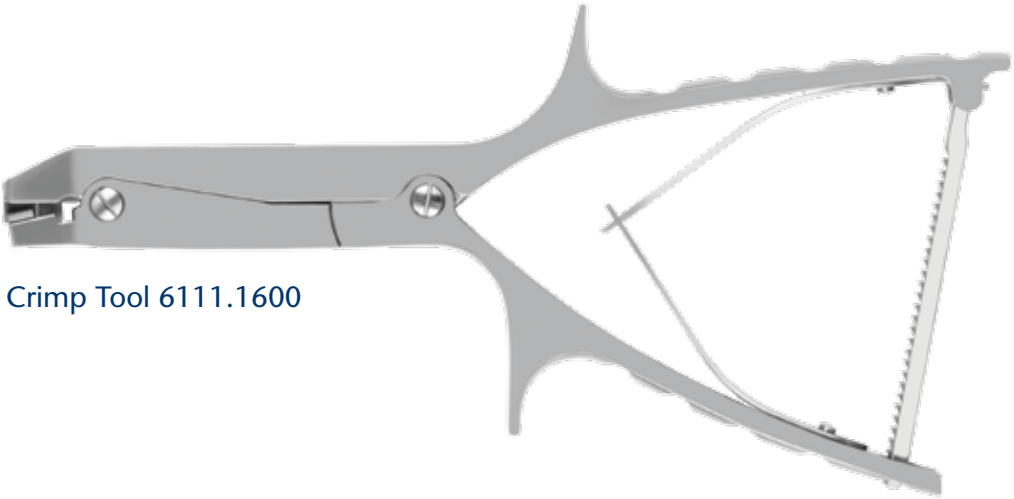
SP-FLEX™ Holder, Lever Arm 6111.1850



SP-FLEX™ Holder, Lever Arm 6111.1850
Quick Coupling Handle, Large 646.960
(Assembled)

Implant Tamp 6111.2200

Implant Tamp 6111.2200
Quick Coupling Handle, Large 646.960
(Assembled)



Crimp Tool 6111.1600

SP-FLEX™ SURGICAL TECHNIQUE

Step 1 Approach

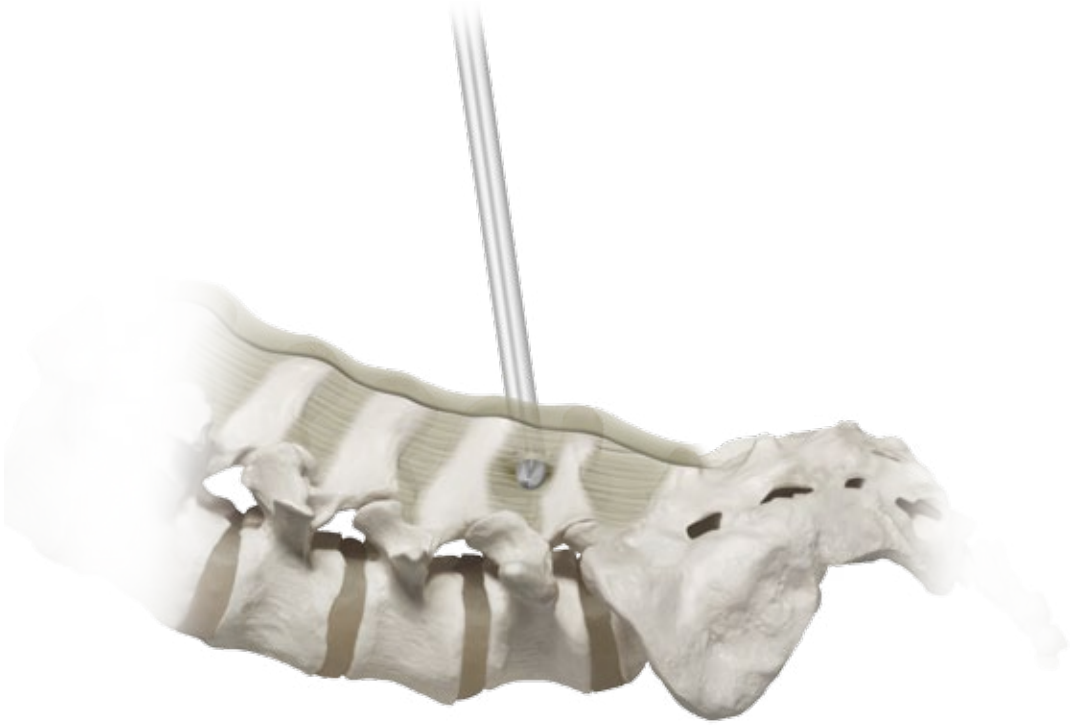
The patient is placed under anesthesia, positioned prone and in flexion. The operative area is carefully cleaned and a midline 3-5cm incision is made at the desired level. Bilateral dissection is performed, exposing both sides of the spinous processes.

Lateral C-arm fluoroscopy or other radiographic methods should be utilized throughout surgery to ensure correct placement of SP-FLEX™.

Please refer to the product insert for complete description, indications, contraindications, precautions and warnings.

Step 2 Site Preparation

Prepare the interspinous space by dilating the interspinous ligament with the **Interspinous Dilator**.

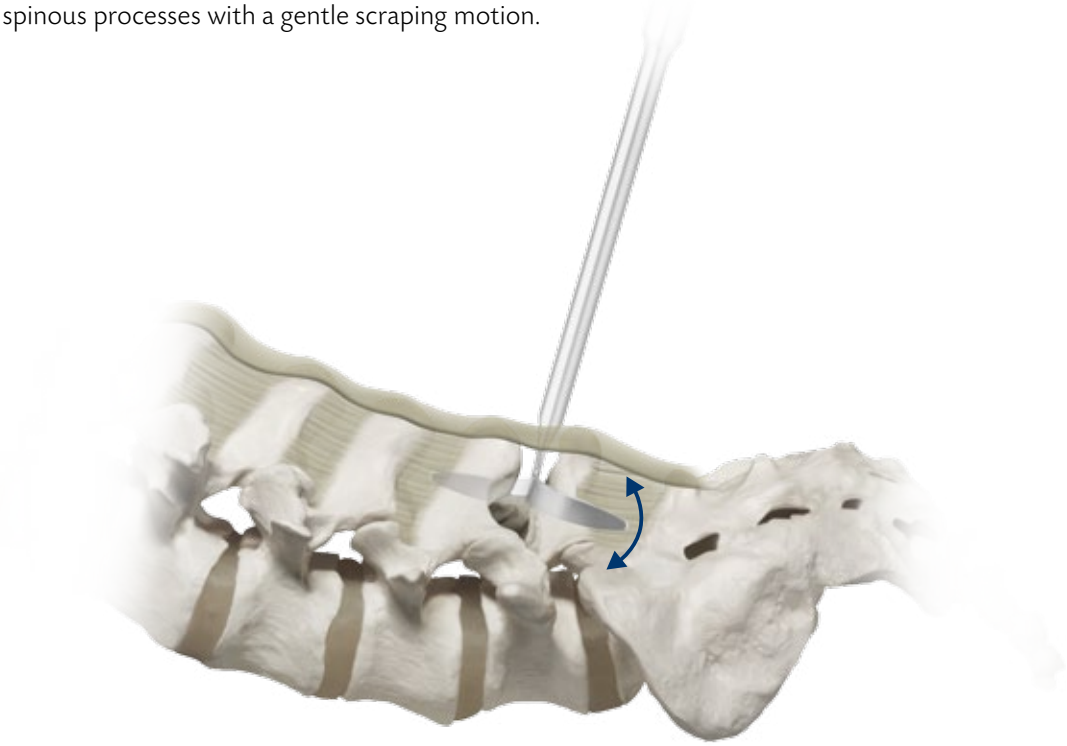


Interspinous space perforated to create a working hole

Remove the interspinous ligament and any excess bone from the interspinous space using the **Curved Kerrison**, leaving the supraspinous ligament intact.

Removing interspinous ligament and excess bone

The **Soft Tissue Dissector (Right or Left)** should be used to clear away any excess soft tissue on the inferior and superior spinous processes with a gentle scraping motion.



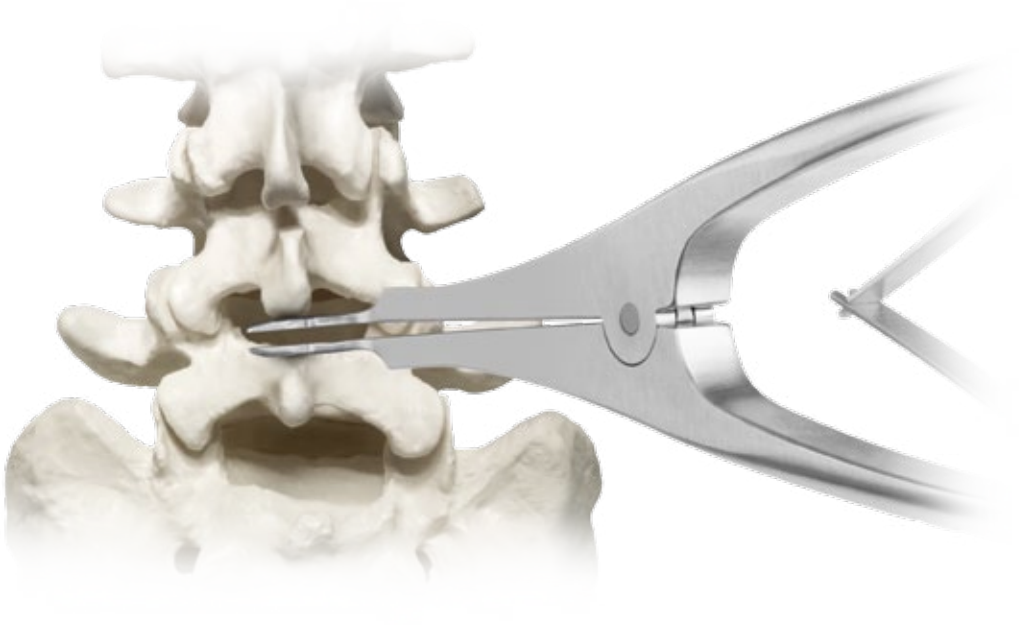
Soft Tissue Dissector removing excess soft tissue from spinous processes

Step 3 Distraction

Distraction of the interspinous space is necessary prior to trialing and implant insertion. There are two options available for distraction of the interspinous space: the **Interspinous Distractor** and/or the **Lamina Spreader.**

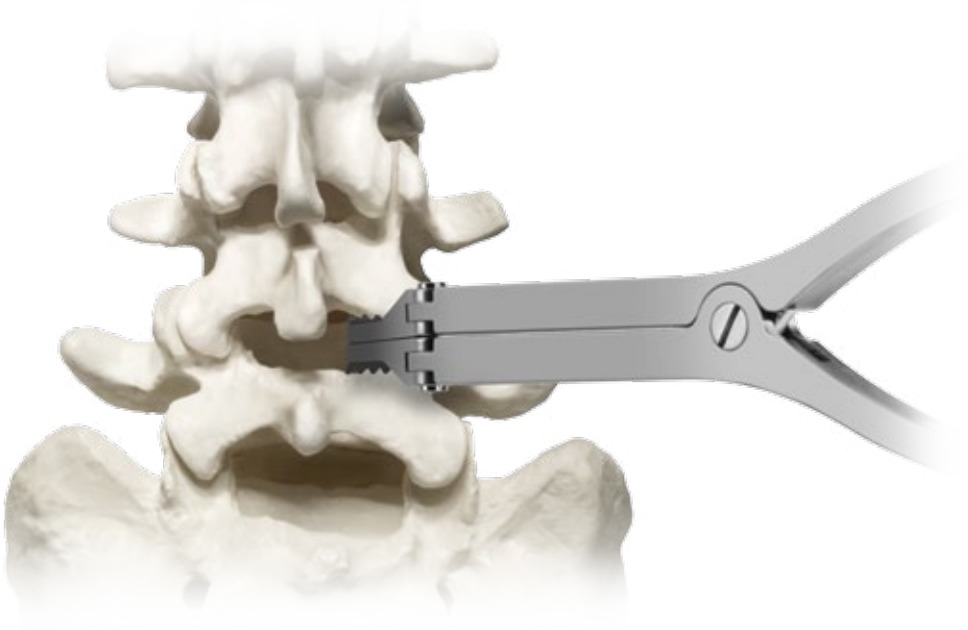
Using the Interspinous Distractor

Insert the tips of the distractor into the interspinous space close to the lamina. Ensure that the ratchet is engaged at the top of the distractor. Compress until appropriate distraction has been achieved and the endplates are parallel.



Using the Lamina Spreader

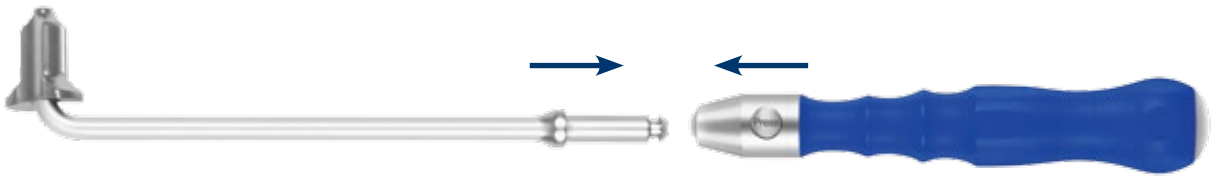
Insert the tips of the spreader between the superior and inferior lamina. Ensure that the ratchet is engaged at the top of the spreader. Compress until the appropriate distraction has been achieved and the endplates are parallel.



Step 4 Trialing

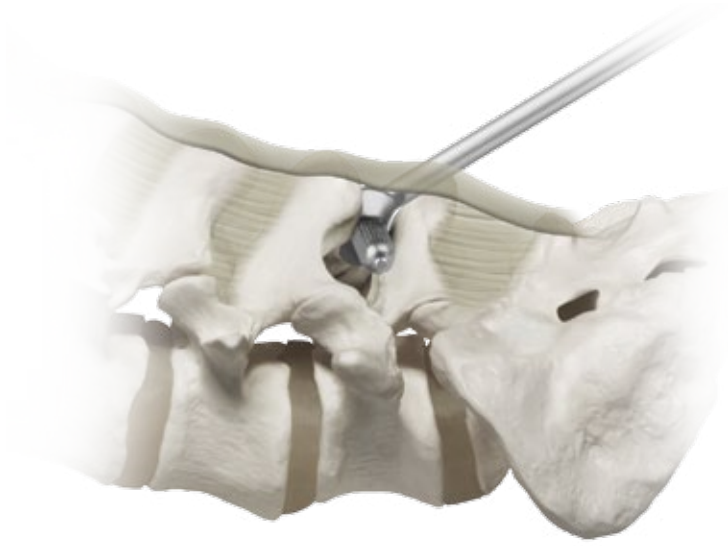
Trials are used to size the interspinous space. Beginning with 8mm, trial sequentially until the desired height is achieved.

Attach the **Quick Coupling Handle, Large** to the desired trial, as shown below.

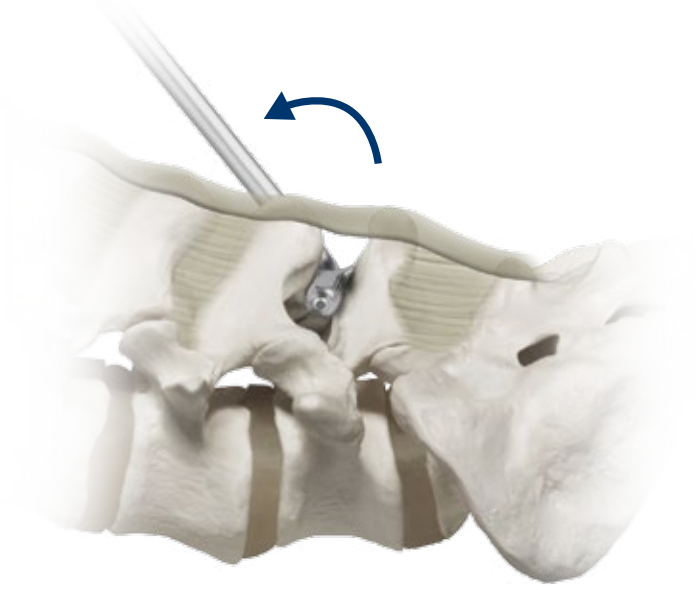


Assembling the Trial

Introduce the trial's dilating tip through the interspinous space, ensuring anterior placement between adjacent spinous processes. Ensure that the tip of the trial is aligned with the angulation of the spinous processes. Once the trial is through the interspinous space, gently rotate the trial 90° cephalad.

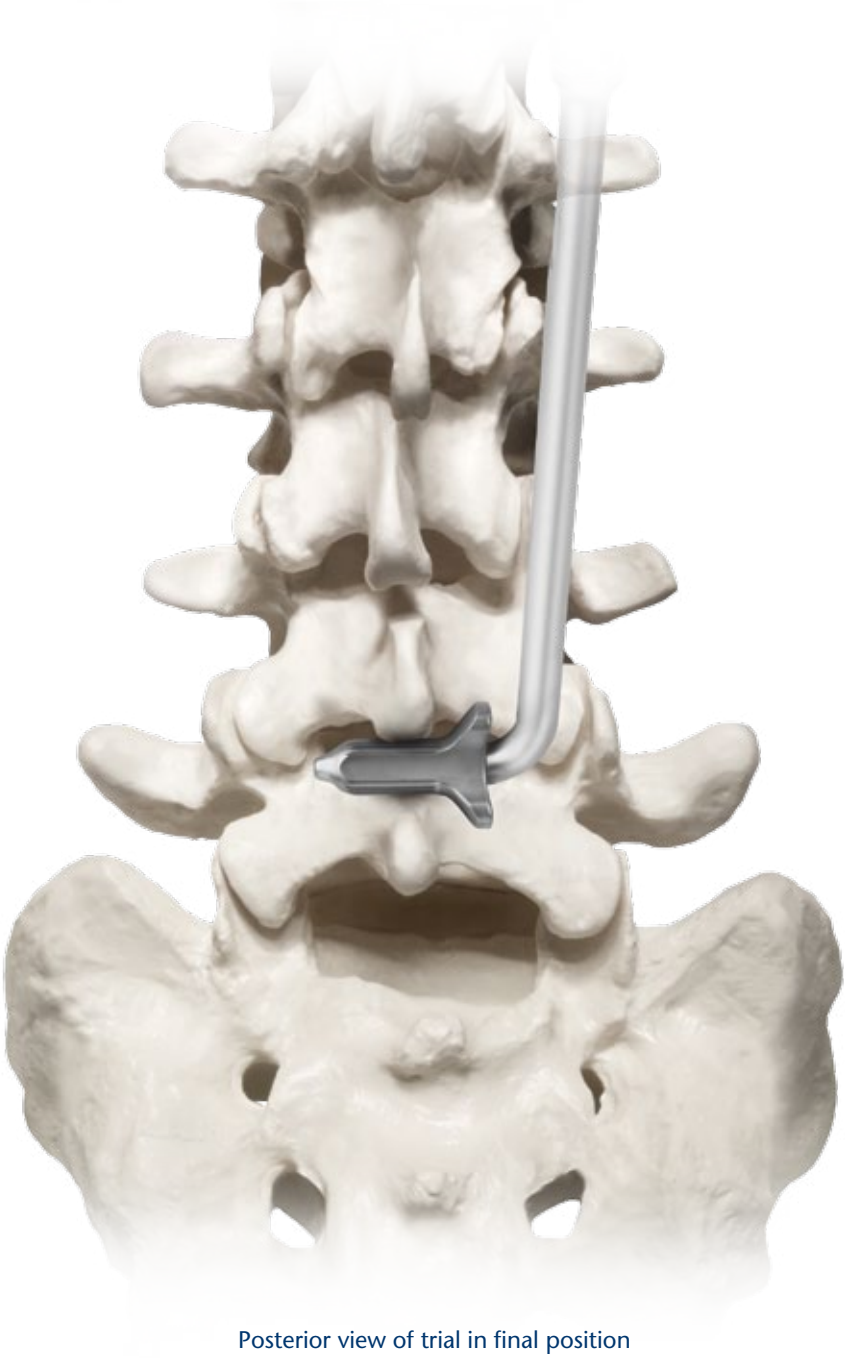


Inserting the dilating tip of the trial into the interspinous space



Achieving final position by rotating the trial 90°

Trialing (cont'd)

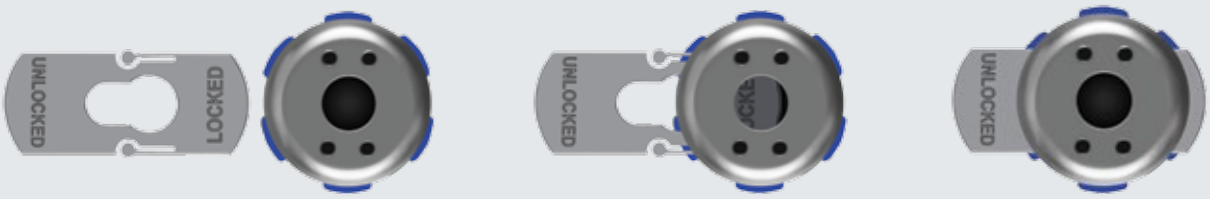


Posterior view of trial in final position

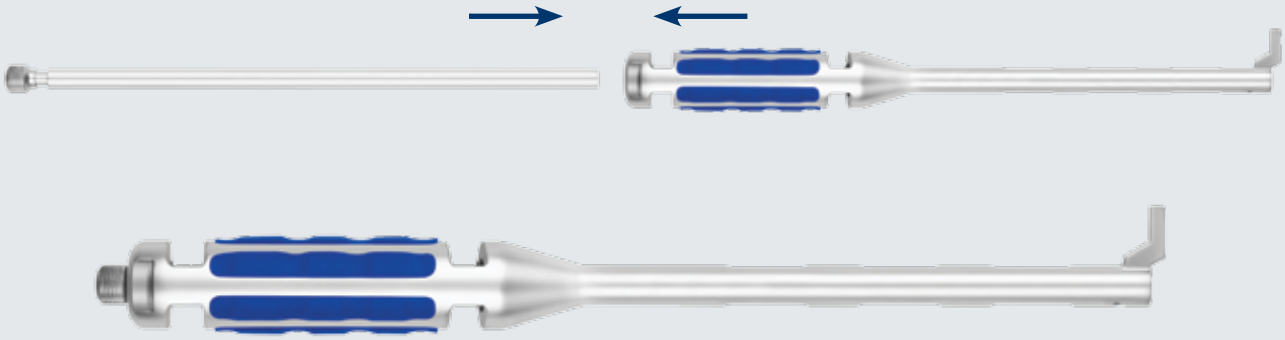
Assembling the Holder

The **SP-FLEX™ Holder Assembly** is comprised of four separate components that are assembled to create a holder for either a right or left sided approach.

Insert the **Slider Clip** into the top of the **SP-FLEX™ Holder, Outer Shaft**. Once inserted, the clip will be in the unlocked position.



Slide the **SP-FLEX™ Holder, Threaded Shaft** into the outer shaft, ensuring that the right or left handed components are selected for the desired holder assembly. In this example, the SP-FLEX™ Holder, Outer Shaft, Right is shown.

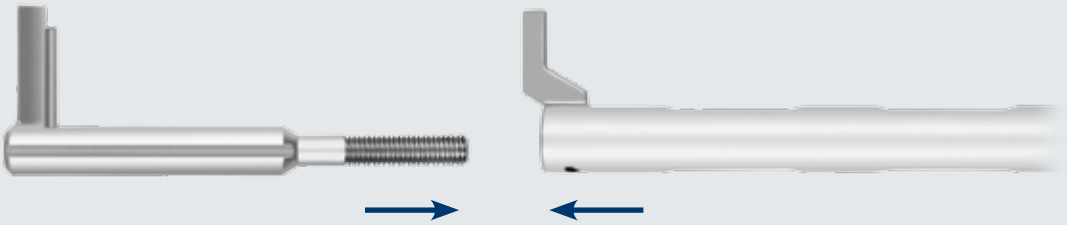


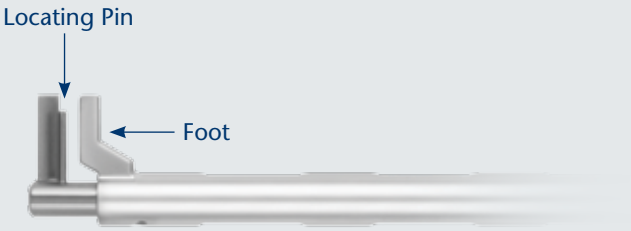
Once the threaded shaft is fully engaged with the outer shaft, push the clip to the locked position.

Assembling the Holder (cont'd)

Insert the **SP-FLEX™ Holder, Inner Shaft** into the holder assembly. Once inserted, rotate the knurled knob at the top of the holder assembly clockwise until the two components are engaged.

Note: The foot of the inner shaft will move upwards towards the outer shaft. Leave space for implant placement on the locating pin of the outer shaft before final tightening of the SP-FLEX™ Holder Assembly.





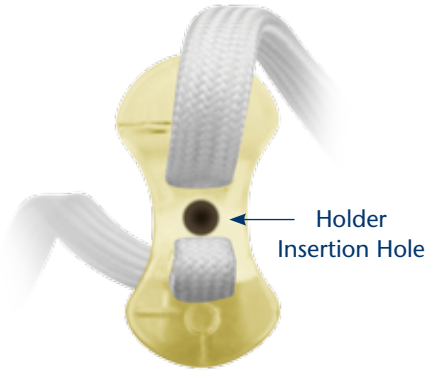
Final Assembly

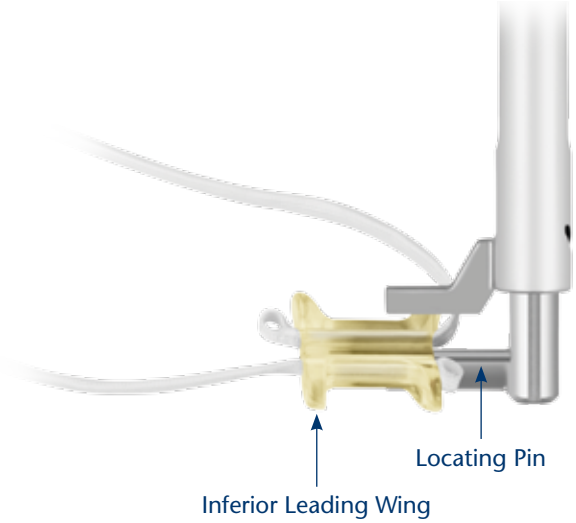
Step 5 Implant Insertion

Assemble the SP-FLEX™ Holder Assembly as described on the previous pages.

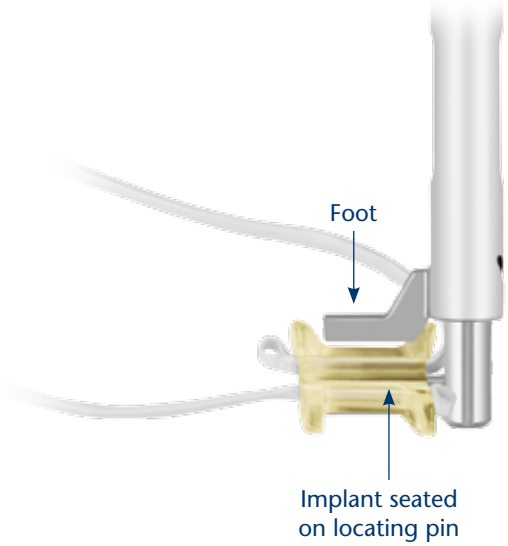
Loading the Implant

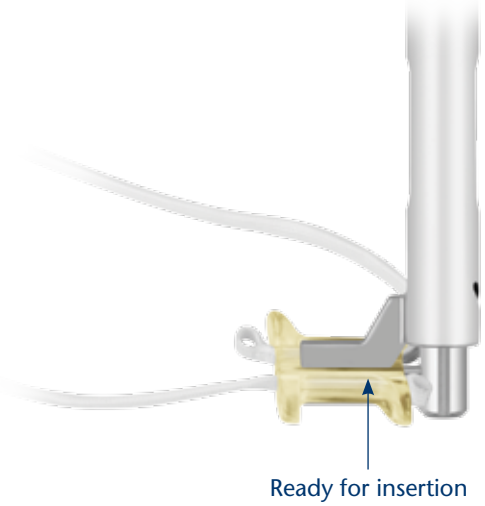
Load the implant onto the holder assembly with the inferior leading wing away from the holder. Locate the holder insertion hole in the middle of the implant. Line up the hole to the locating pin on the SP-FLEX™ Holder, Inner Shaft, Right.





Position the implant so that it is fully seated onto the locating pin. Continue to rotate the knurled knob on the holder assembly until the foot is fully seated on the implant. The implant is now ready for insertion.





Implant Insertion (cont'd)

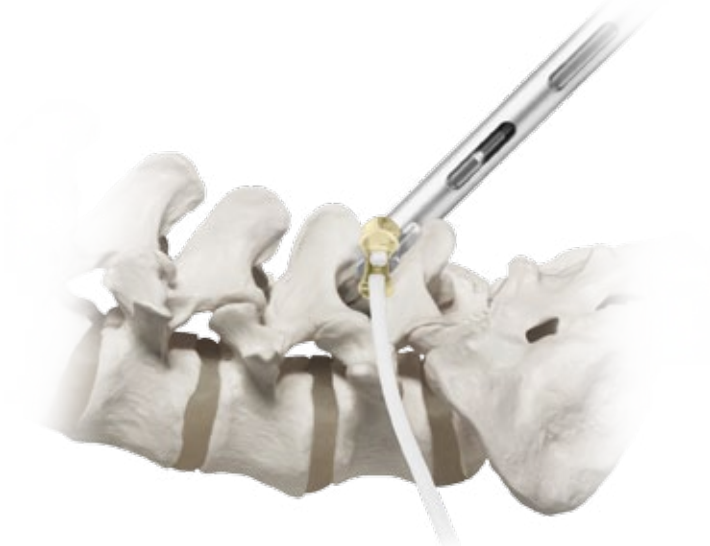
Inserting the Implant

Prior to implant insertion, feed the contralateral band of the implant through the interspinous space of the level to be distracted. Insert the superior leading wing of the implant into the interspinous space and hook it under the supraspinous ligament. Rotate the inferior leading wing of the implant past midline through the interspinous space. Rotate the implant 90° cephalad for final positioning.

The **SP-FLEX™ Holder, Lever Arm** may also be used to apply lateral force at the base of the holder assembly, to pass the wings through the interspinous space.

The wings should rest on the lamina-spinous process junction. The **Implant Tamp** may be used to seat the implant more anterior towards the lamina-spinous process junction. Remove the holder assembly by rotating the knurled knob counterclockwise, disengaging the foot of the holder assembly from the implant. Gently rock the holder assembly until the implant is released.

Passing the PET band through the interspinous space

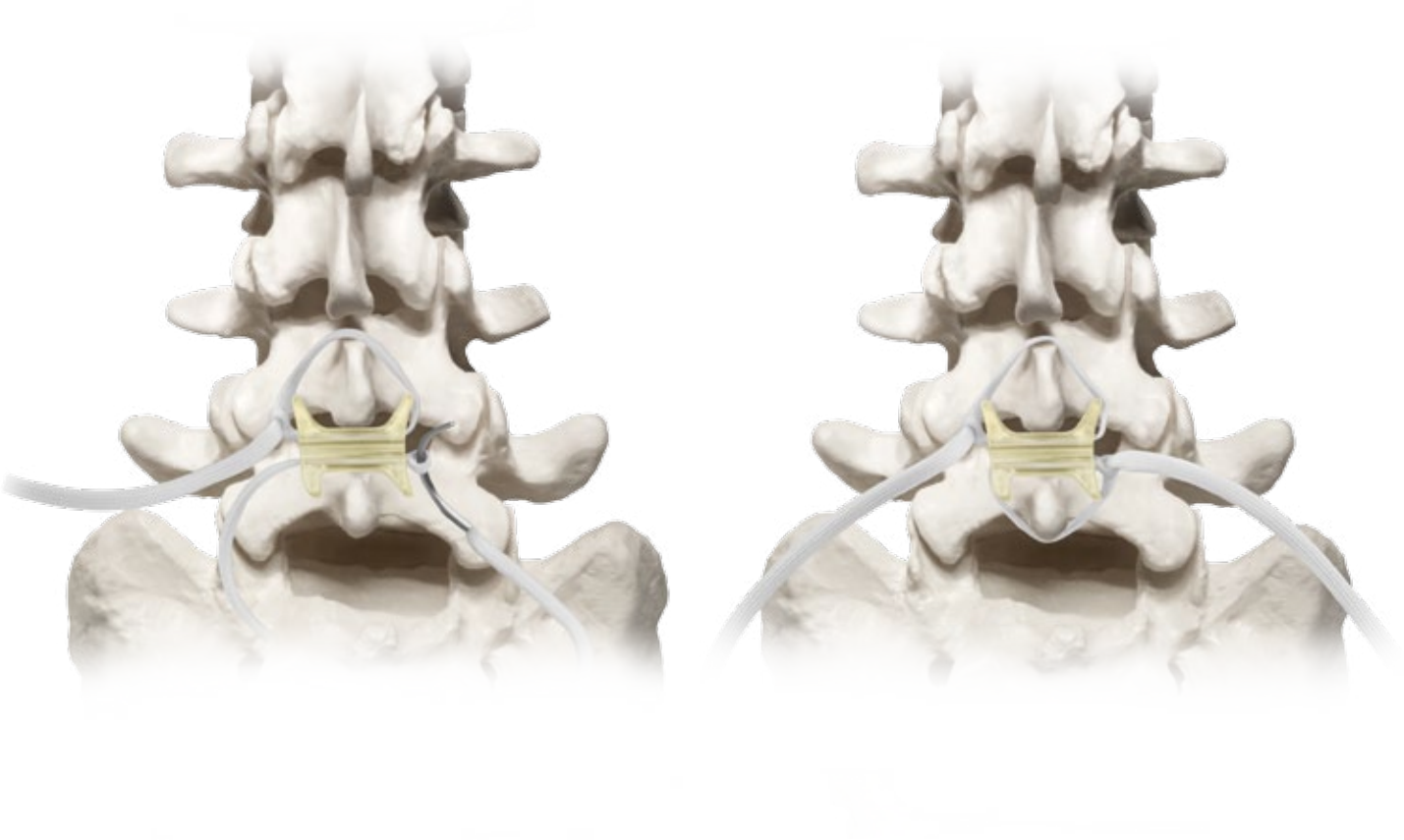


Inserting implant through the interspinous space past midline

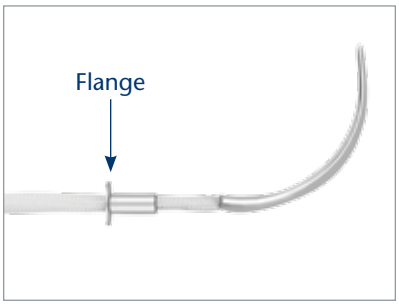
Rotating the implant 90° into final position

Securing the Implant

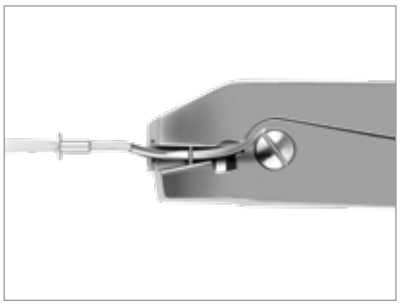
Feed the superior and inferior needle around the respective spinous processes, and pass the needles through the loop located on the contralateral side.

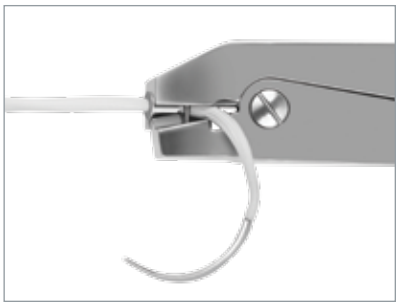


Insert a crimp over the needle on each band, ensuring that the flange side of the crimp is facing away from the needle and towards the implant. Pass the needle through the **Crimp Tool**, as shown below.



Inserting crimp over the needle



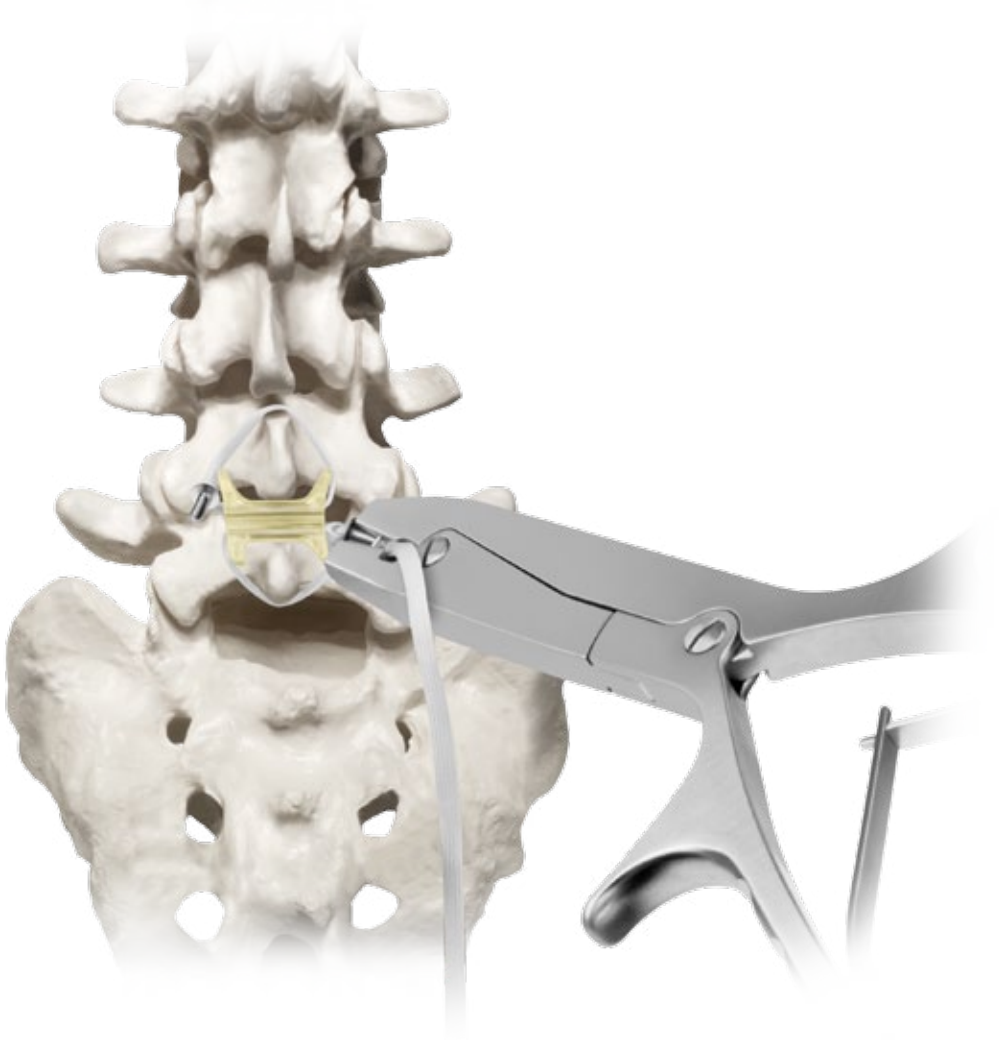


Passing needle through the Crimp Tool

Implant Insertion (cont'd)

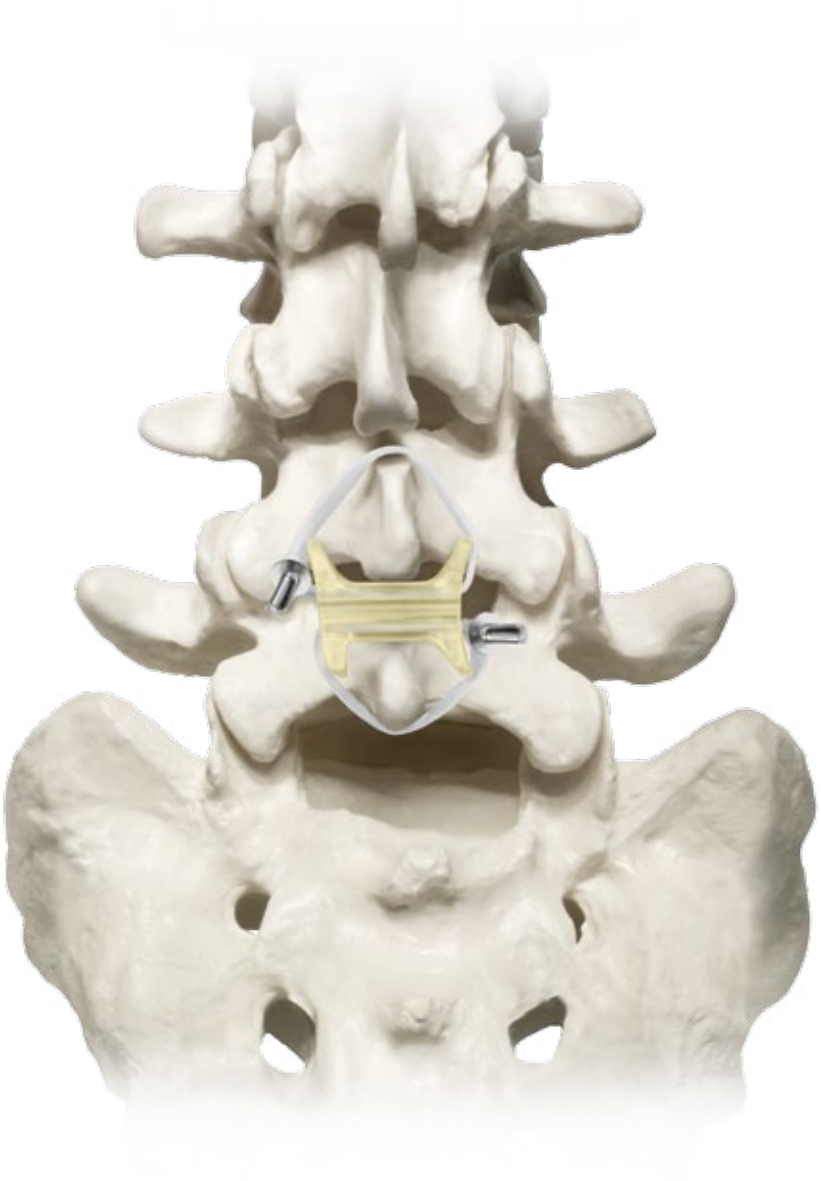
Securing the Implant (cont'd)

Pull the band through the tool and slide the tool over the crimp, tensioning against the loop on the band. Ensure that the band is tight against the spinous processes. Compress the handles on the tool as shown below. Use a bovie to cut the excess band material and discard. Repeat the steps above for the contralateral side to create a uniform construct.



Tensioning the crimp against the loop

Final Construct



OPTIONAL: Implant Removal

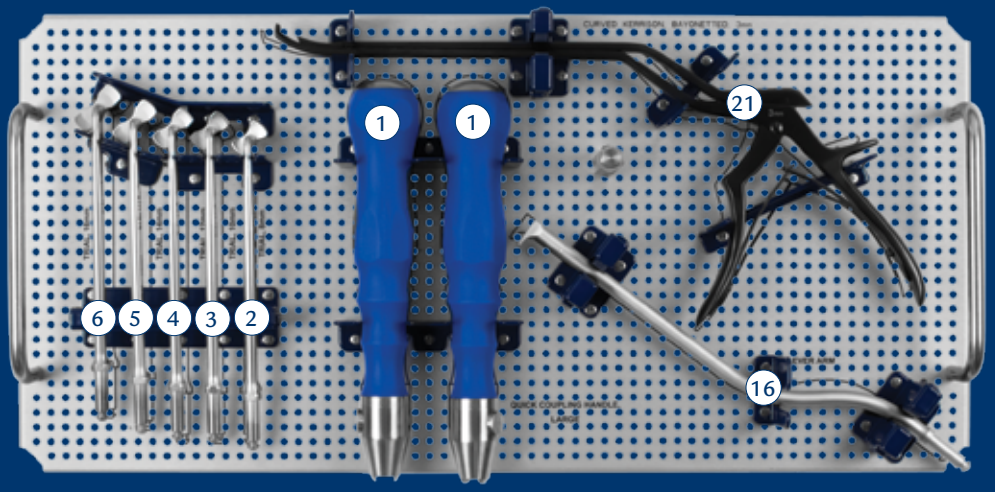
To remove SP-FLEX™, create a midline incision at the desired level. Cut the bands and remove the core using an interspinous distractor and/or manual instruments such as rongeurs, etc.

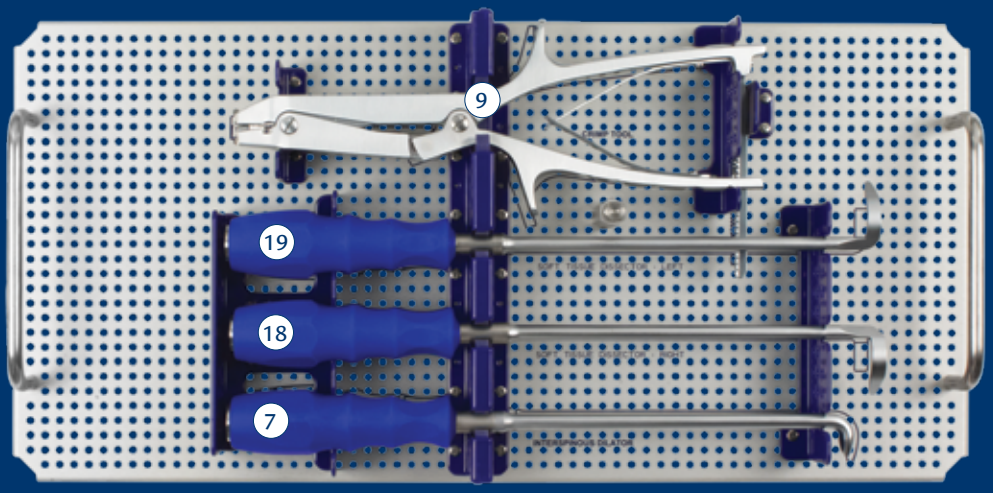
SP-FLEX™ IMPLANT SET

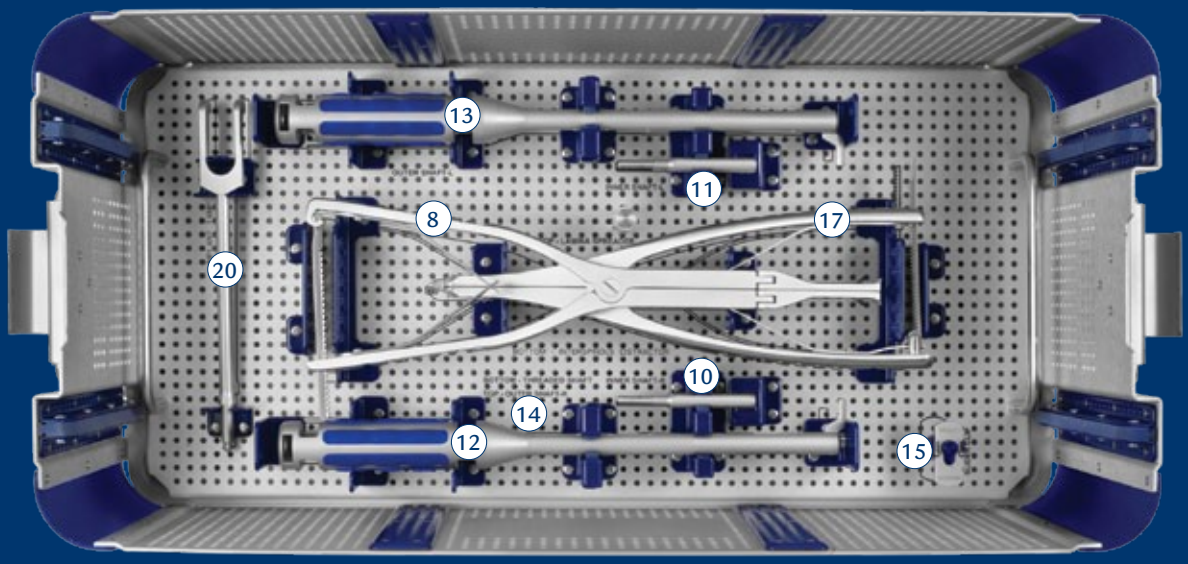
SP-FLEX™ Implant Set 9111.9002

Implants		Qty
4111.0008S	SP-FLEX™ , 8mm	2
4111.0010S	SP-FLEX™ , 10mm	2
4111.0012S	SP-FLEX™ , 12mm	2
4111.0014S	SP-FLEX™ , 14mm	2
4111.0016S	SP-FLEX™, 16mm	2
1111.3000S	SP-FLEX™ Crimp	2
9111.0002	SP-FLEX™ Implant Soft Case	

SP-FLEX™ INSTRUMENT SET







SP-FLEX™ Instrument Set 9111.9001

	Instruments		Qty
1	646.960	Quick Coupling Handle, Large	2
2	6111.1008	Trial, 8mm	1
3	6111.1010	Trial, 10mm	1
4	6111.1012	Trial, 12mm	1
5	6111.1014	Trial, 14mm	1
6	6111.1016	Trial, 16mm	1
7	6111.1200	Interspinous Dilator	1
8	6111.1300	Lamina Spreader	1
9	6111.1600	Crimp Tool	1
10	6111.1800	SP-FLEX™ HOLDER, Inner Shaft – R	1
11	6111.1805	SP-FLEX™ HOLDER, Inner Shaft – L	1
12	6111.1810	SP-FLEX™ HOLDER, Outer Shaft – R	1
13	6111.1815	SP-FLEX™ HOLDER, Outer Shaft – L	1
14	6111.1820	SP-FLEX™ HOLDER, Threaded Shaft	1
15	6111.1830	SP-FLEX™ HOLDER, Slider Clip	1
16	6111.1850	SP-FLEX™ HOLDER, Lever Arm	1
17	6111.1900	Interspinous Distractor	1
18	6111.2000	Soft Tissue Dissector – Right	1
19	6111.2005	Soft Tissue Dissector – Left	1
20	6111.2200	Implant Tamp	1
21	6111.2300	Curved Kerrison, Bayonetted, 3mm	1
	9111.0001	SP-FLEX™ Instrument Set	

IMPORTANT INFORMATION ON SP-FLEX™ INTERSPINOUS STABILIZATION SYSTEM

DESCRIPTION

SP-FLEX™ Interspinous Stabilization System is a posterior, interspinous stabilization device that fits between the spinous processes of the lumbosacral (L1-S1) spine. SP-FLEX™ is a cushioning spacer designed to help decompress the spinal segment while aiding in stabilization of the segment. The SP-FLEX™ implant consists of a polycarbonate urethane (PCU) core with two polyethylene terephthalate (PET) bands, and two commercially pure titanium (ASTM F67) crimps. The core also has titanium alloy (ASTM F1295 or ASTM F136) or tantalum (ASTM F560) markers for radiographic visualization. The implant is provided with two stainless steel

(ASTM F138) needles to feed the bands around the spinous processes; once the bands are crimped, the needles are detached and are not intended to be implanted.

INDICATIONS

SP-FLEX™ Interspinous Stabilization System is a posterior non-pedicle interspinous stabilization device for use in the lumbosacral (L1-S1) spine. SP-FLEX™ is indicated for the treatment of patients suffering from the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), retrolisthesis, spondylolisthesis, facet syndrome, and/or lumbar spinal stenosis (defined as a narrowing of the canal, characterized by back, buttock or leg pain producing nerve compression and ischemia, which is relieved by lying supine or flexing the spine).

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- injury to nerves, vessels, and organs,
- allergic or tissue reaction to implant materials,
- hematoma and impaired wound healing,
- migration or loosening of the device,
- fracture of the device,
- pain, discomfort, or abnormal sensations due to presence of the device,
- heterotopic ossification and fusion,
- venous thrombosis, lung embolism, and cardiac arrest.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Components of this system should not be used with components of any other system or manufacturer.

PRECAUTIONS

The implantation of this device should be performed only by experienced spinal surgeons because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

The implants are provided sterile and for single use only. Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the physicians/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

CONTRAINDICATIONS

Use of SP-FLEX™ Interspinous Stabilization system is contraindicated in patients with the following conditions:

1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis, which may prevent adequate fixation
4. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
5. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
6. Any condition not described in the indications for use.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.

IMPORTANT INFORMATION ON SP-FLEX™ INTERSPINOUS STABILIZATION SYSTEM

8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (466-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

The SP-FLEX™ Interspinous Stabilization implants are provided STERILE, and the surgical instruments are provided NON-STERILE.

The SP-FLEX™ Interspinous Stabilization implants are sterilized by gamma radiation using a standard medical device sterilization dose of 25-40kGy. This sterilization dose is validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile implants are packaged in a heat sealed, double foil pouch. Shelf life was determined to be 5 years. The expiration date is provided on the package label. Implants are considered sterile unless the packaging has been opened or damaged.

Non-sterile SP-FLEX™ instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.*

Instruments:
These instruments are provided NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	25 Minutes	30 Minutes
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	15 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		Use by (YYYY-MM)

REV A

Notes

Notes

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www.globusmedical.com

Customer Service:
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