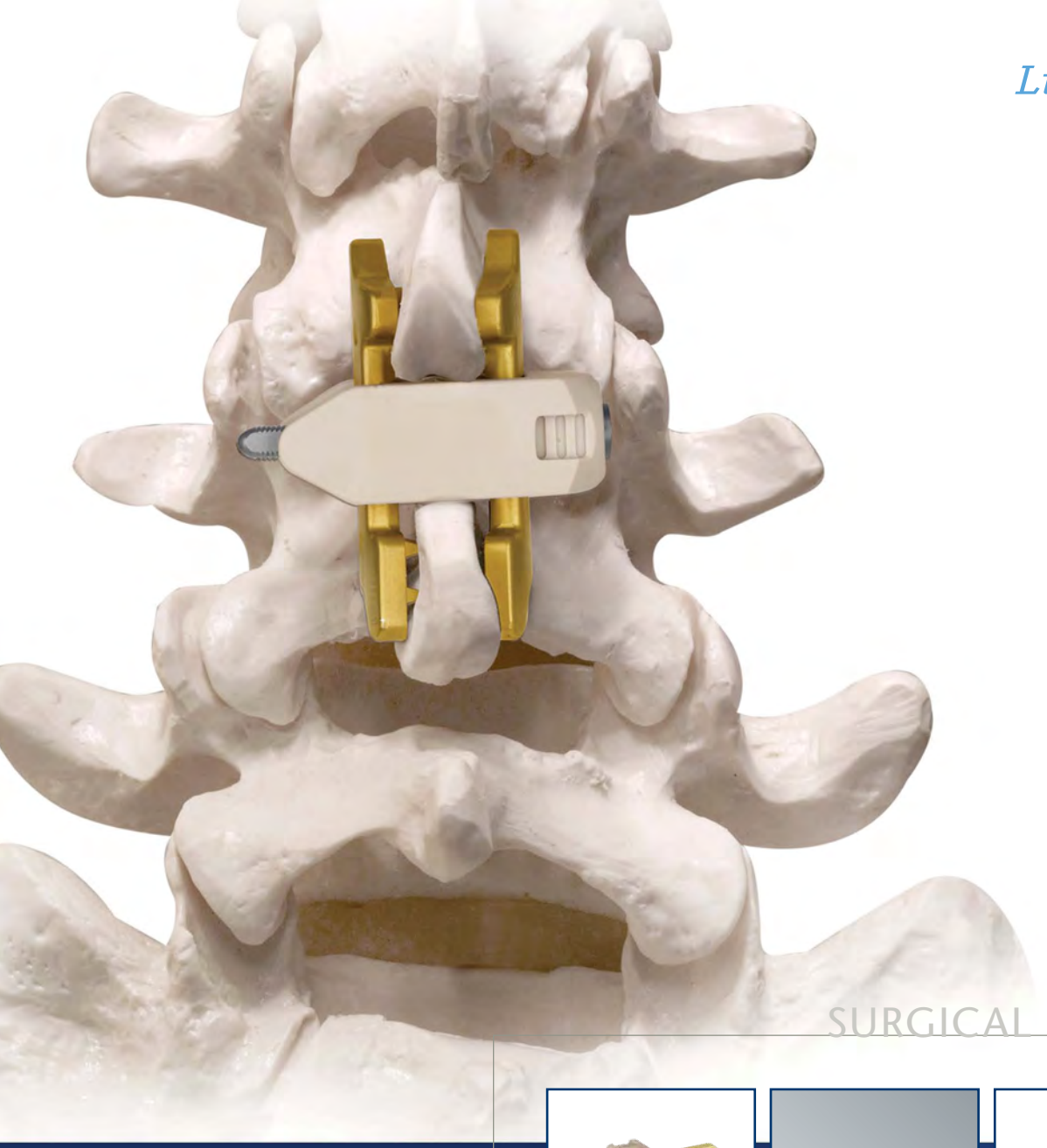
Life moves us



SURGICAL TECHNIQUE

SP-Fix™

Spinous Process Fixation Plate

GLOBUS MEDICAL

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's 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.

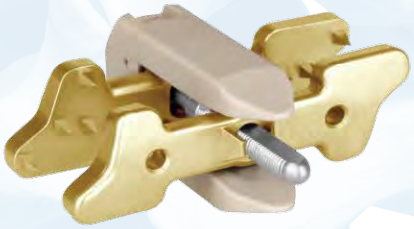
The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

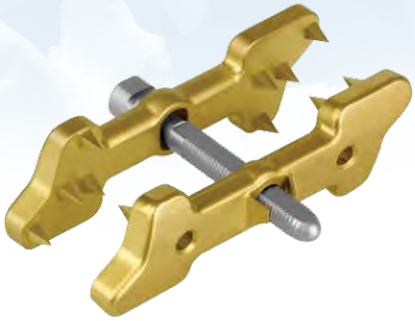
GLOBUS
MEDICAL

www.globusmedical.com

SP-Fix™

Spinous Process Fixation Plate



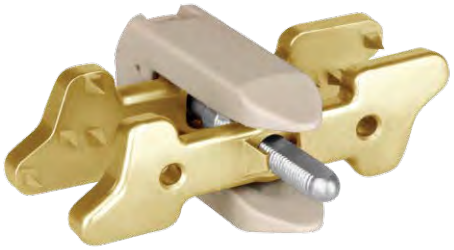


SP-Fix™ is a spinous process fixation device that provides structural stability, indirect decompression and immobilization of the spinous processes of adjacent vertebrae. Supporting a minimally invasive approach, SP-Fix™ preserves the supraspinous ligament and can be placed between spinous processes without fluoroscopic assistance. SP-Fix™ offers surgeons an easy-to-use system that preserves patient anatomy when compared to traditional fixation techniques.

SP-Fix™
DISTINGUISHING CHARACTERISTICS

■ Optimal Fit

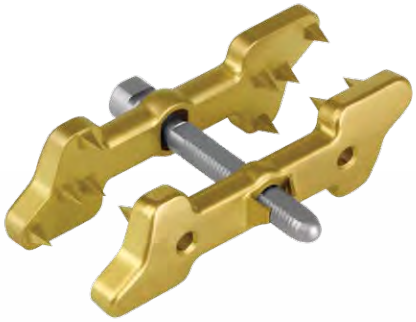
SP-Fix™ implant assemblies are customized before implantation, allowing optimal positioning of the plates for secure and reliable fixation. PEEK Barrels can be sized independently of the plates, adding distraction where necessary.



SP-Fix™ Plate and Barrel Assembly

■ Zero-Step Locking

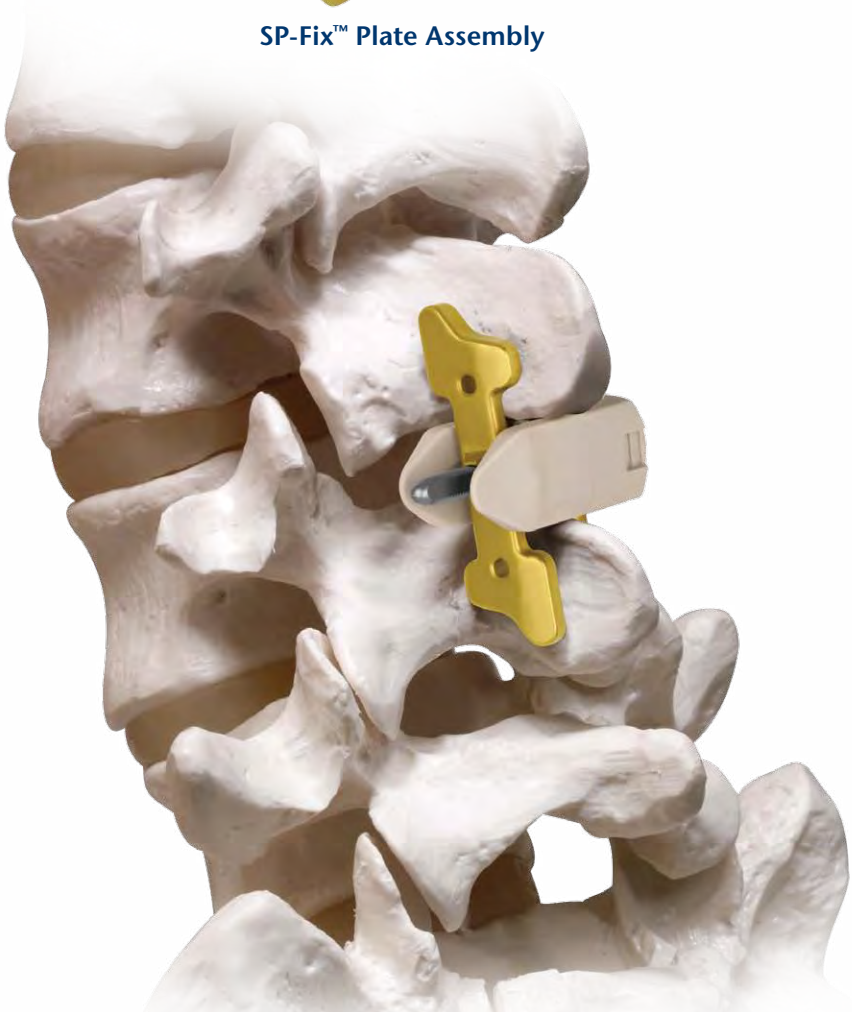
With its ratchet design, SP-Fix™ automatically locks during compression, eliminating extra tightening steps, and reducing complexity.



SP-Fix™ Plate Assembly

■ Absolute Control

SP-Fix™ instruments maintain control of the implant, allowing for precise 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

SP-Fix™ may be customized to the patient's specific anatomy and clinical needs. The system offers the option of either a **Plate and Barrel Assembly** (consisting of a PEEK Barrel with Integrated Central Ratcheting Rod, Pivoting Plate and Locking Plate) or a **Plate Assembly** (consisting of a Central Ratcheting Rod, Pivoting Plate and Locking Plate). Bone graft material may be packed around both assemblies or through the central channel of the PEEK Barrel, promoting bony fusion between spinous processes.

Plate and Barrel Assembly

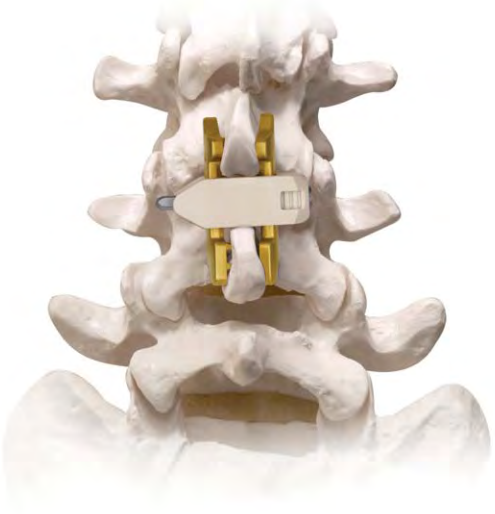
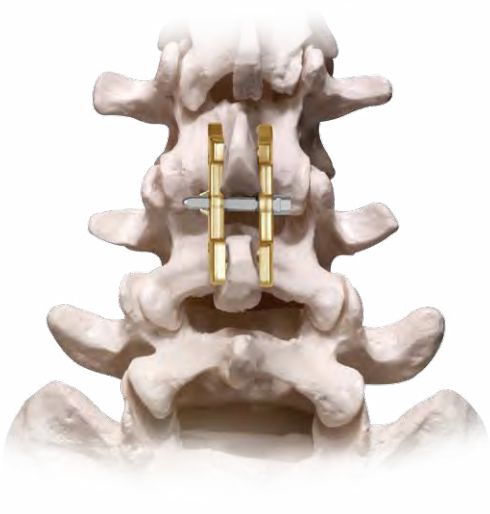


Plate Assembly



PEEK Barrel with Integrated Central Ratcheting Rod

- PEEK Barrel provides interspinous distraction
- PEEK radiolucent material improves post-operative visualization
- Graft packing chamber allows for fusion between adjacent spinous processes
- Distraction heights range from 8–16mm in 2mm increments, with 18mm and 20mm PEEK Barrels additionally available
- Integrated Central Ratcheting Rod (38mm)

Central Ratcheting Rod

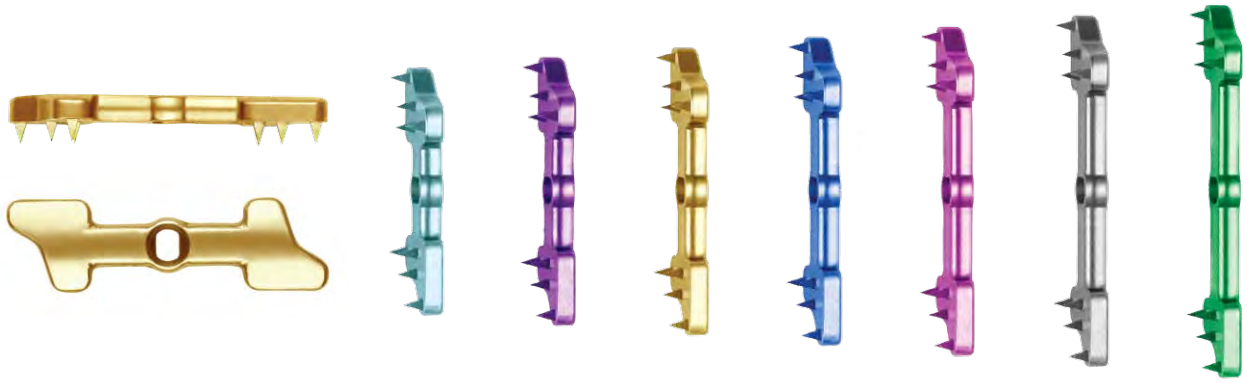
- Titanium-alloy rod features serrations to secure the plates in the desired locked position
- Zero-step locking mechanism allows for intra-operative adjustments
- Available in lengths of 25, 30 and 35mm

IMPLANT OVERVIEW

Plates

- Titanium-alloy plates with spikes designed to maximize fixation to the spinous processes
- Pivoting plates angulate ±15°, which allows for anterior placement on the lamina and sacrum, and conforms to varying bone shapes and sizes
- Available in length of 35–47mm in 3mm increments, with 50mm and 55mm plates additionally available
- Pivoting and Locking Plates are color-coded to match the Plate Trials

Pivoting Plates



Locking Plates

Note: Plates should NOT be ratcheted prior to a case. Ratcheted plates should not be reused.

INSTRUMENT OVERVIEW

Site Preparation Instruments

Interspinous Perforator 646.050

Spinous Process Rake 688.060

Quick Connect Handle 646.960

Rasp 688.075

Rasp with Quick Connect (Assembled)

Sizing Instruments

Distractor 688.300

Trial with Quick Connect (Assembled)

Trials							
Size	8mm	10mm	12mm	14mm	16mm	18mm	20mm
Part No.	688.108	688.110	688.112	688.114	688.116	688.118	688.120

Rod Trial 688.275

Plate Trial

Plate Trials							
Size	35mm	38mm	41mm	44mm	47mm	50mm	55mm
Part No.	688.235	688.238	688.241	688.244	688.247	688.250	688.255

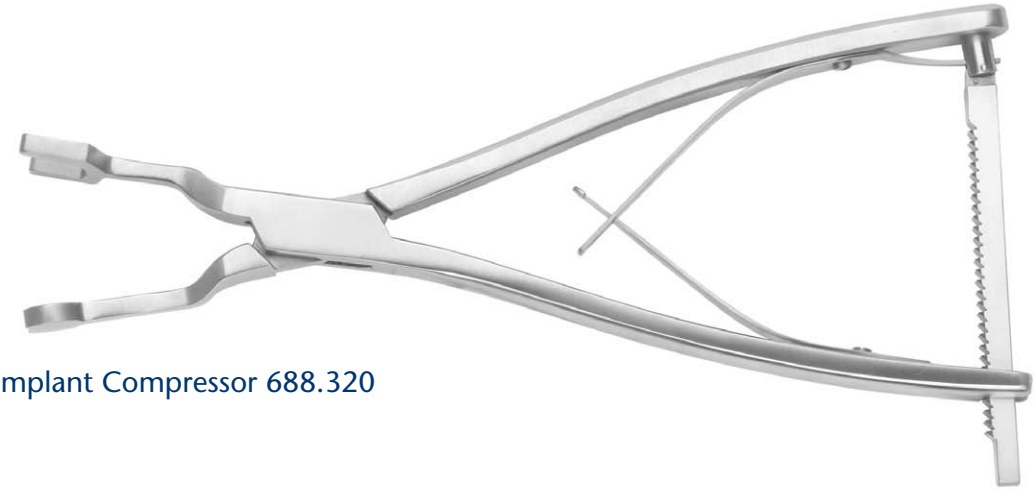
Insertion and Compression Instruments

Plate Holder, 35-41mm 688.310

Plate Holder, 44–55mm 688.311

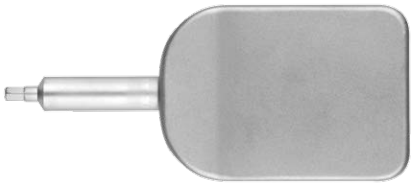
Barrel Holder 688.314

Rod Holder 688.315



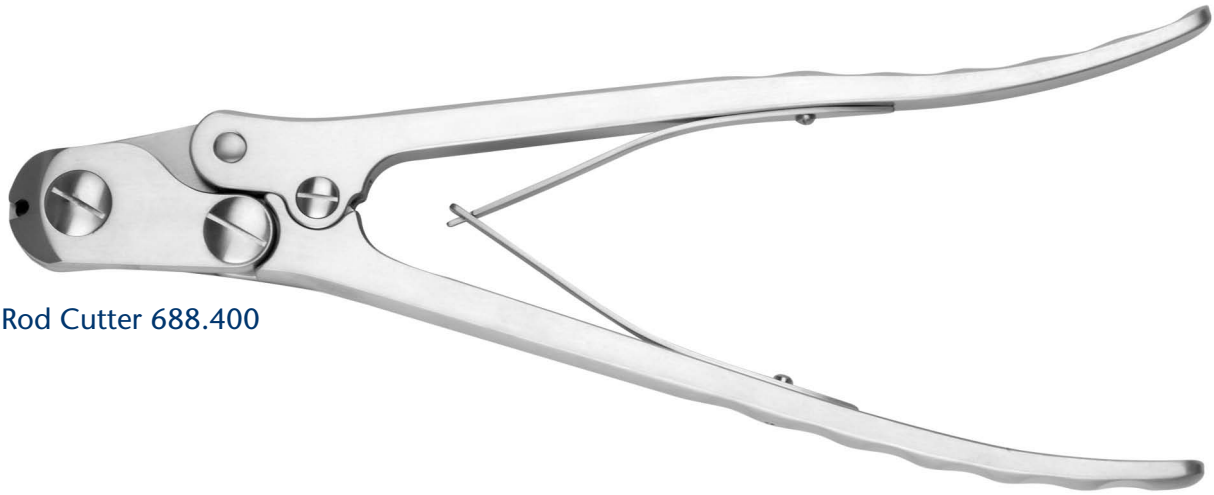
Implant Compressor 688.320

Removal and Customization Instruments



Hex Key 688.330

Removal Driver 688.331



Rod Cutter 688.400

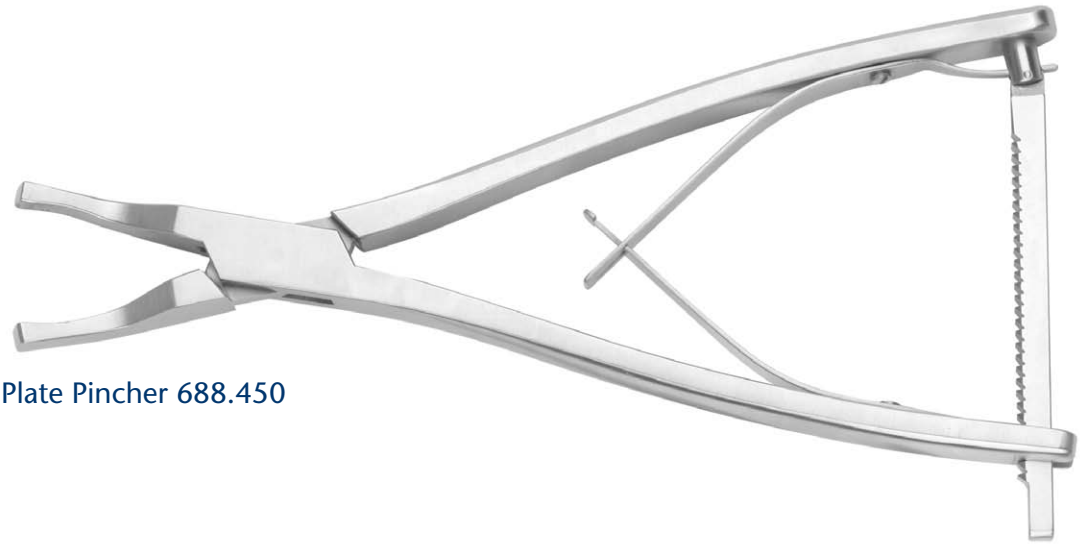


Plate Pincher 688.450

SP-Fix™ SURGICAL TECHNIQUE

Plate and Barrel Assembly

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. The incision is retracted bilaterally, exposing both sides of the spinous process. The supraspinous ligament is kept intact.

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

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

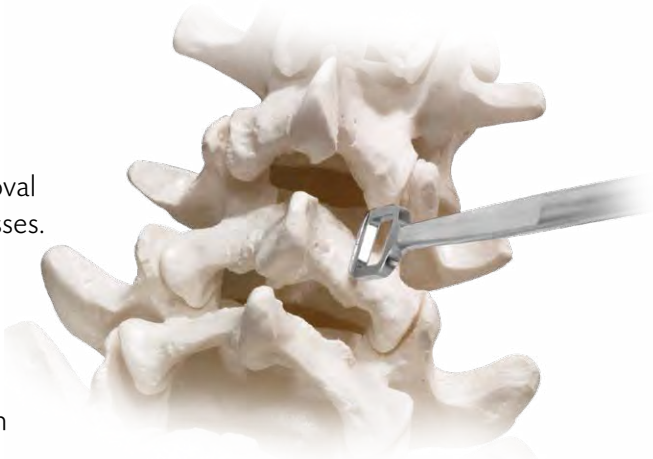
Step 2 Site Preparation

The **Spinous Process Rake** can assist in the removal of soft tissue from the sides of the spinous processes.

Dilate the interspinous ligament by using the **Interspinous Perforator**.

The **Rasp** can be used to gently clear soft tissue from the interspinous space and to create a fusion bed for graft material.

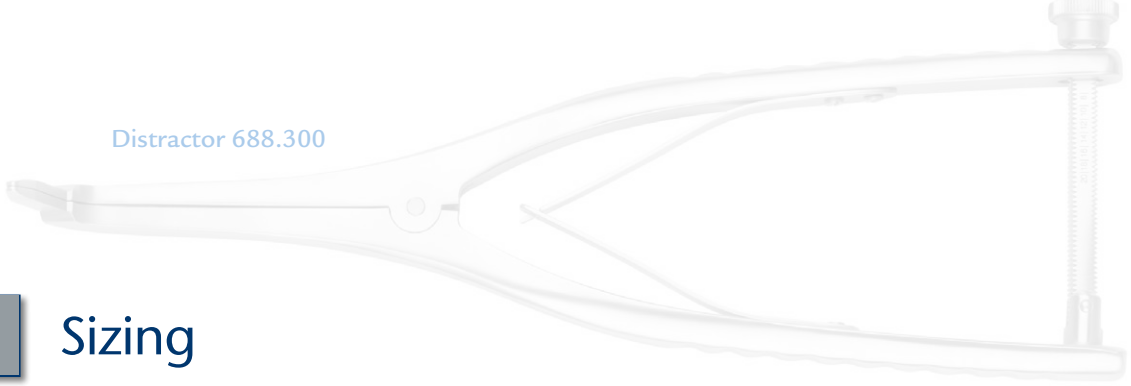
Note: Supraspinous and interspinous ligaments are removed for visibility in the remaining technique images.



Spinous Process Rake removing soft tissue from bone

Using the Interspinous Perforator

Rasp cleaning tissue and decorticating bone in the interspinous space



Step 3 Sizing

Use the sizing instruments to measure the interspinous space to determine the correct implant size, ensuring that the size is appropriate for the individual patient.

Using the Distractor

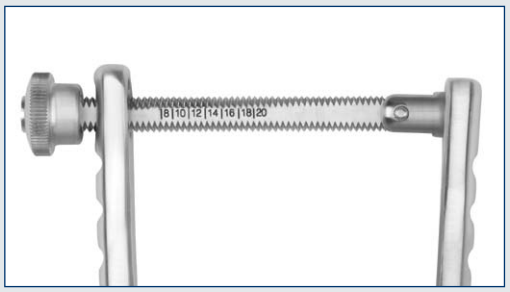
The **Distractor** is used to estimate the height of the interspinous space and to loosen tethered ligaments.

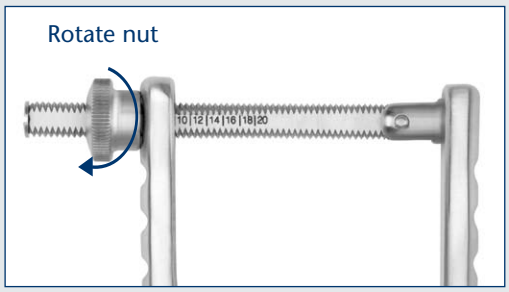
Note: The Trials and PEEK Barrel are designed to be used with the Distractor in place, if desired.

Using the Distractor

Indication Marks on Distractor Spindle

To estimate implant height, read the indicator marks from the inside of the spindle handle. If the reading is between two sizes, select the smaller size. In the image below, trialing would start at 10mm.





Sizing (Cont'd)

Trialing

Trials match the shape of each PEEK Barrel and are used to determine the appropriate PEEK Barrel height, as shown to the right. The correct size will fit tightly into the interspinous space.

Starting with a smaller trial size will help in clearing soft tissue.

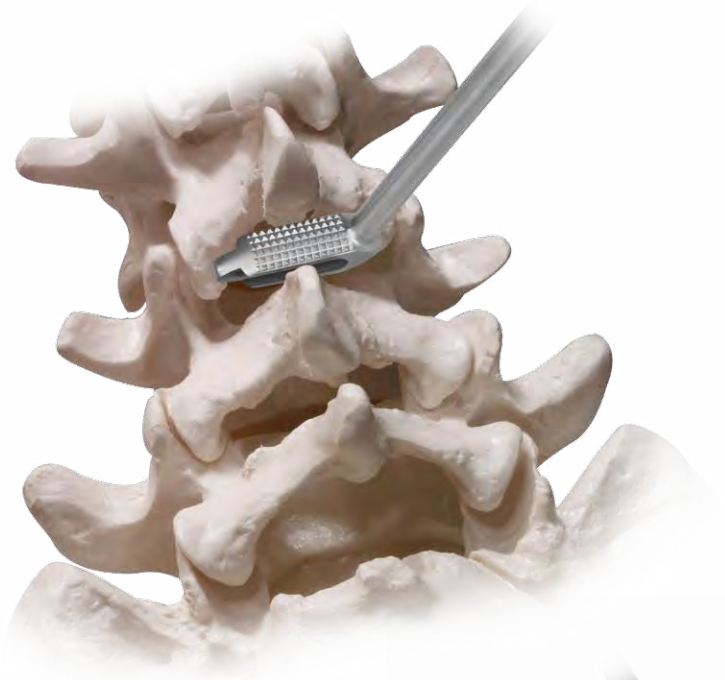
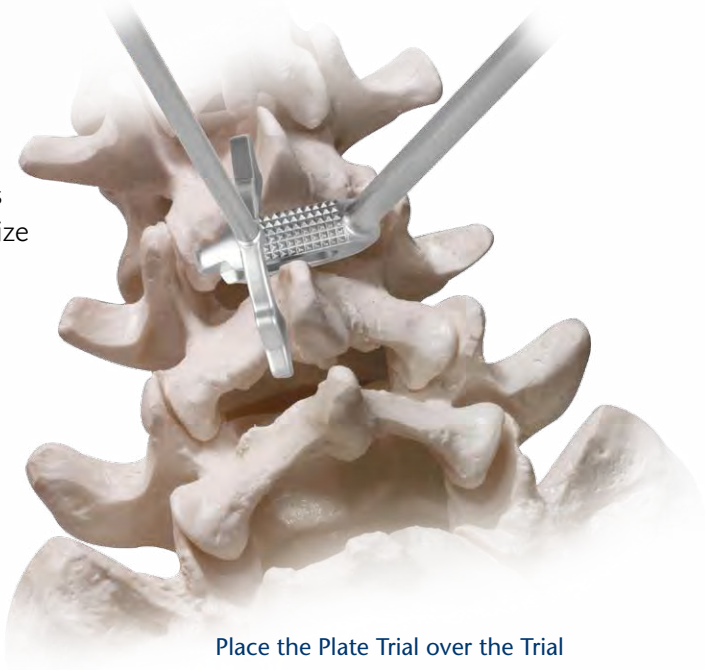


Plate Trials match the shape of the Locking Plates and are used to determine the appropriate plate size used in the final assembly. Plate Trials are color-coded with plate lengths. Select the plate length that maximizes coverage of the spinous process.



Place the Plate Trial over the Trial

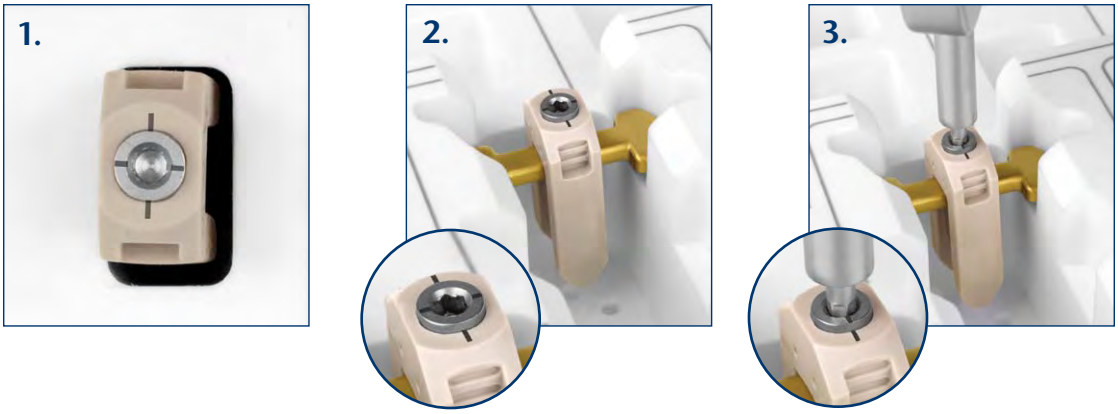
Step 4 Preparing SP-Fix™ Plate and Barrel Assembly

There are three steps required to assemble SP-Fix™:

Step 1: Select the appropriately sized PEEK Barrel from the implant module.

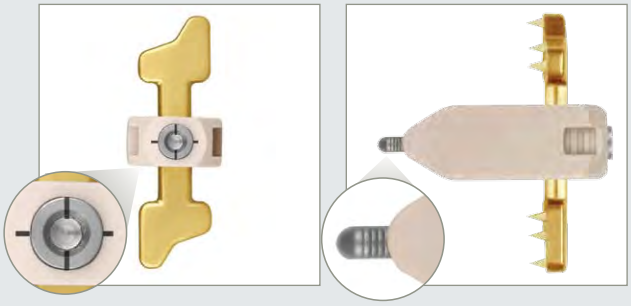
Step 2: Slide the PEEK Barrel over the Pivoting Plate.

Step 3: Turn the hex located on the rear of the PEEK Barrel 90° with the Hex Key to capture the Pivoting Plate.



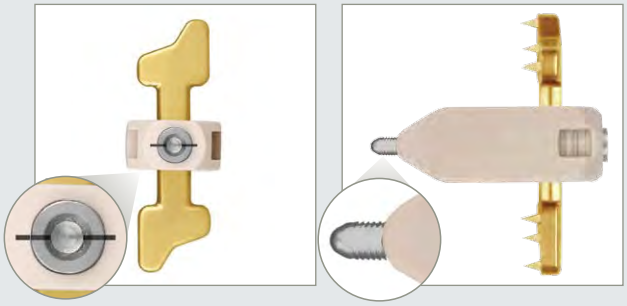
Capturing the Plate

Not Captured



Note: When the etchings do not line up, the Pivoting Plate is not captured. When the serrations face posterior, the Pivoting Plate is not captured.

Captured

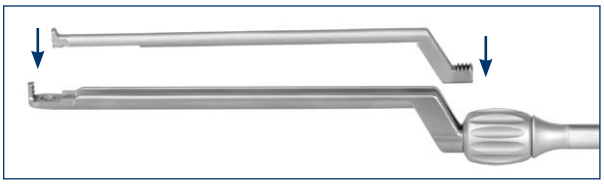


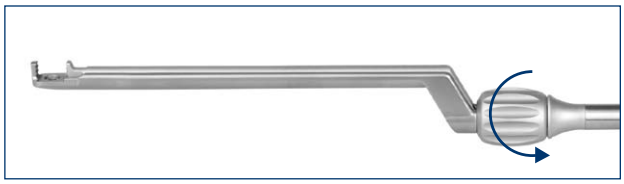
Note: When the etchings line up, the Pivoting Plate is captured. When flats face posterior, the Pivoting Plate is captured.

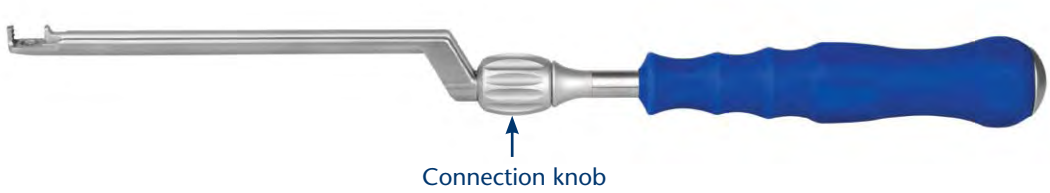
Preparing SP-Fix™ Plate and Barrel Assembly (Cont'd)

Assembling the Holders

To assemble the holders, place the insert into the main body of the holder and rotate the connection knob counter-clockwise. Be sure to disassemble the holders prior to cleaning.

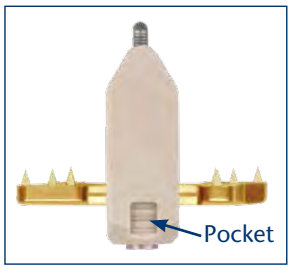


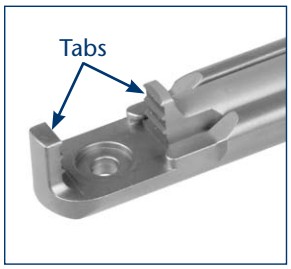


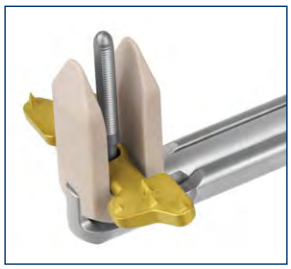


Using the Barrel Holder

Place the PEEK Barrel into the **Barrel Holder**, orienting the pocket at the rear of the barrel to the tabs on the holder. Once engaged, rotate the connection knob clockwise until there is a firm connection between the PEEK Barrel and the Barrel Holder.

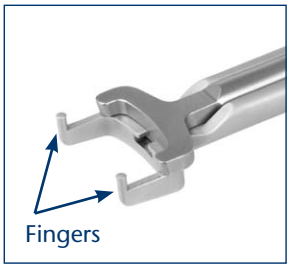


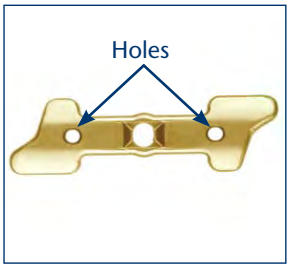


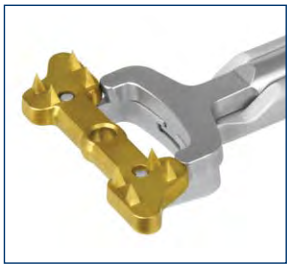


Using the Plate Holder

Insert the fingers on the **Plate Holder** into the corresponding holes on the back of the Locking Plate. Once engaged, rotate the connection knob clockwise until there is a firm connection between the Locking Plate and the Plate Holder.



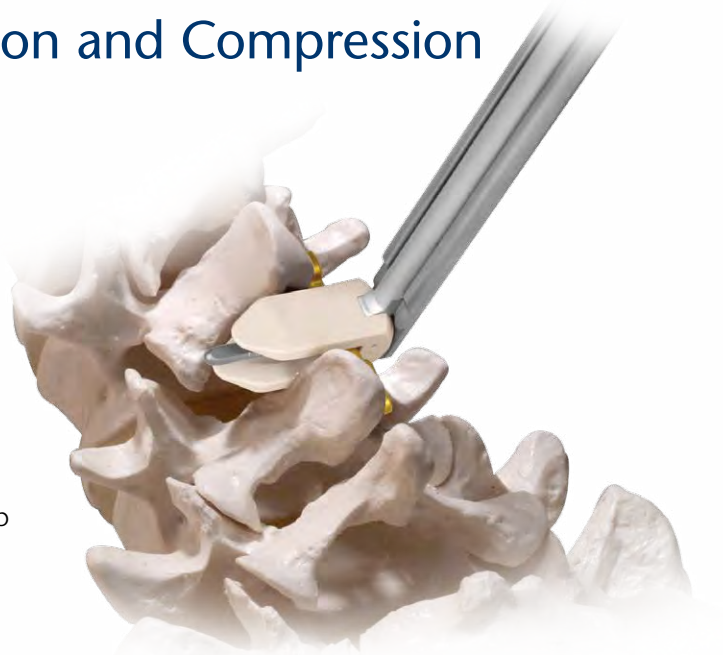




Step 5 Implant Insertion and Compression

Implant Insertion

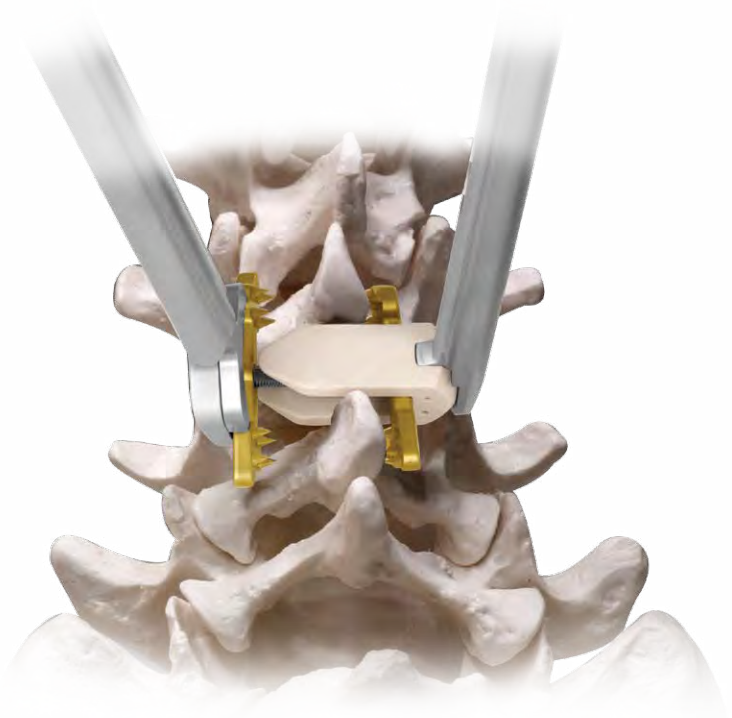
Introduce the tip of the PEEK Barrel Assembly into the interspinous space and advance until the spikes of the Pivoting Plate are touching the spinous processes.



PEEK Barrel Assembly inserted into the interspinous space

Using the Plate Holder, align the Locking Plate with the Central Ratcheting Rod. Grasp the holders as shown and compress the handles together, keeping one hand close to the implant. Compress until the first ratchet has been captured. The implant will click as the ratchet is advanced, indicating the locking plate is captured. The holders should now be removed from the PEEK Barrel and Locking Plate.

Note: Implants should only be compressed during surgery.



Attach the Locking Plate to the PEEK Barrel Assembly

Compress the handles as shown

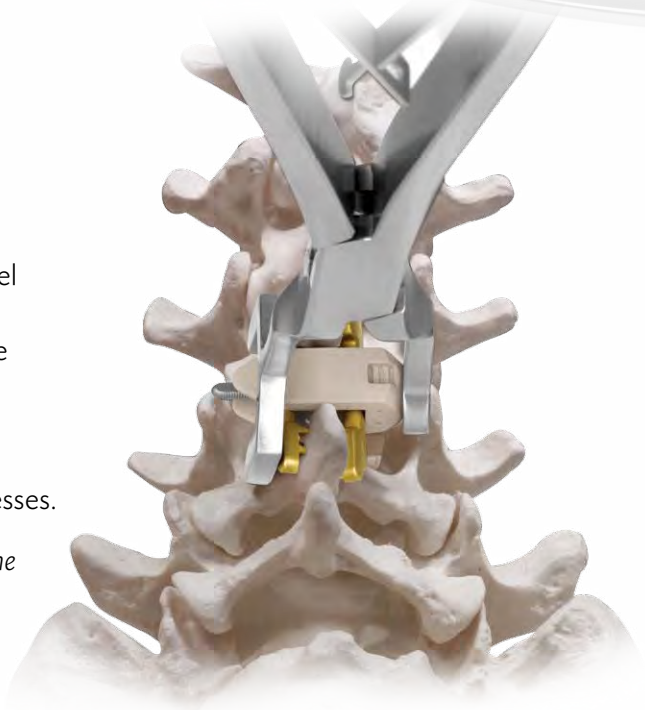
Implant Compressor 688.320

Implant Insertion and Compression (Cont'd)

Compression

Place the **Compressor** over both the PEEK Barrel and Locking Plate and compress until the spikes are firmly seated into the spinous processes. The implant is now locked. For additional purchase, or to accomodate for varying spinous process thicknesses, the **Plate Pincher** can be used to engage the spikes deeper into the spinous processes.

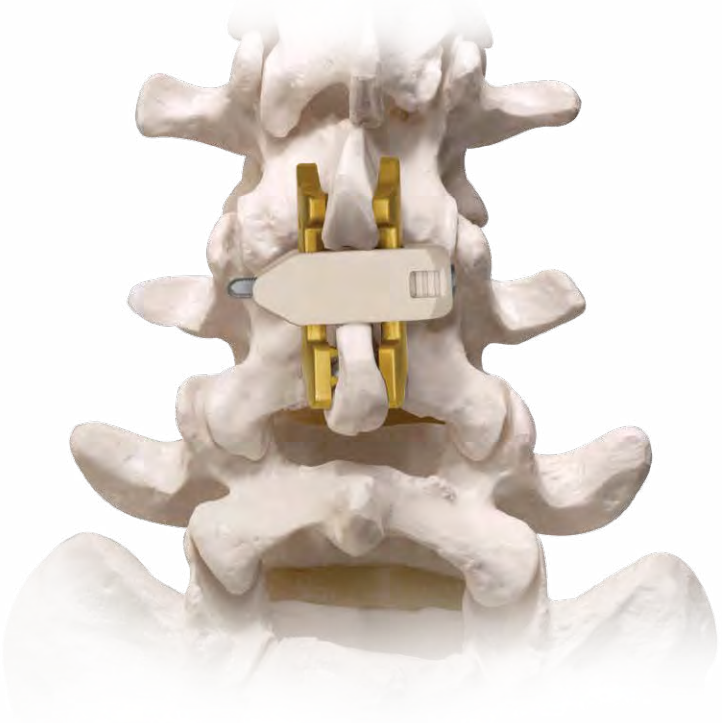
Note: The Compressor should always be used after the Plate Pincher to ensure the plates are locked.



Compressing the assembly

Final Construct

Plate and Barrel Assembly



SP-Fix™ SURGICAL TECHNIQUE

Plate Assembly

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. The incision is retracted bilaterally, exposing both sides of the spinous process.

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

Note: Please refer to the product insert, printed at the end of this surgical technique for complete description, indications, contraindications and warnings.

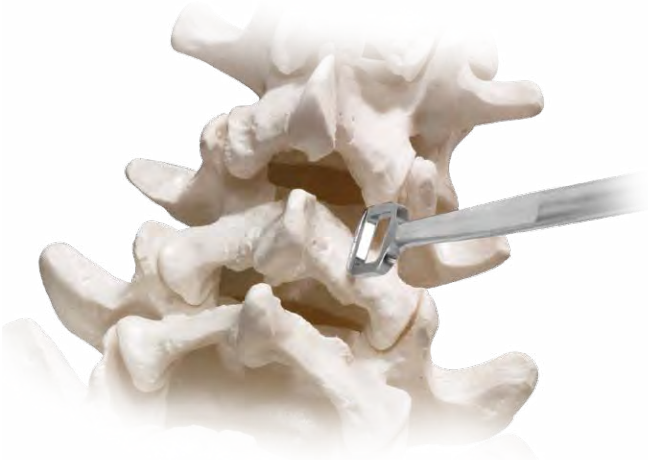
Step 2 Site Preparation

The **Spinous Process Rake** can assist in the removal of soft tissue from the sides of the spinous processes.

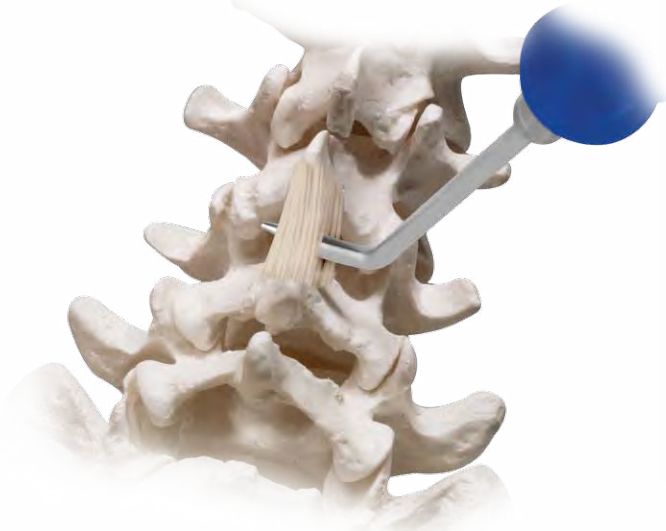
Dilate the interspinous ligament by using the **Interspinous Perforator**.

The **Rasp** can be used to gently clear soft tissue from the interspinous space and create a fusion bed for graft material.

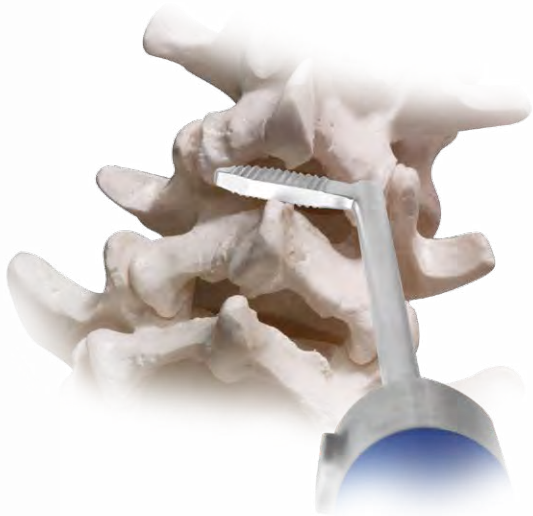
Note: Supraspinous and interspinous ligaments are removed for visibility in the remaining technique images.



Spinous Process Rake removing soft tissue from bone



Using the Interspinous Perforator

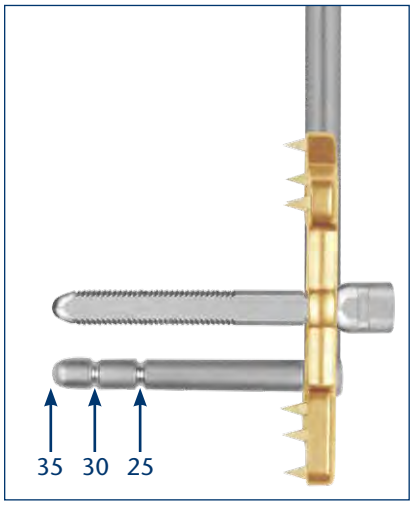


Rasp cleaning tissue and decorticating bone in the interspinous space

Step 3 Sizing

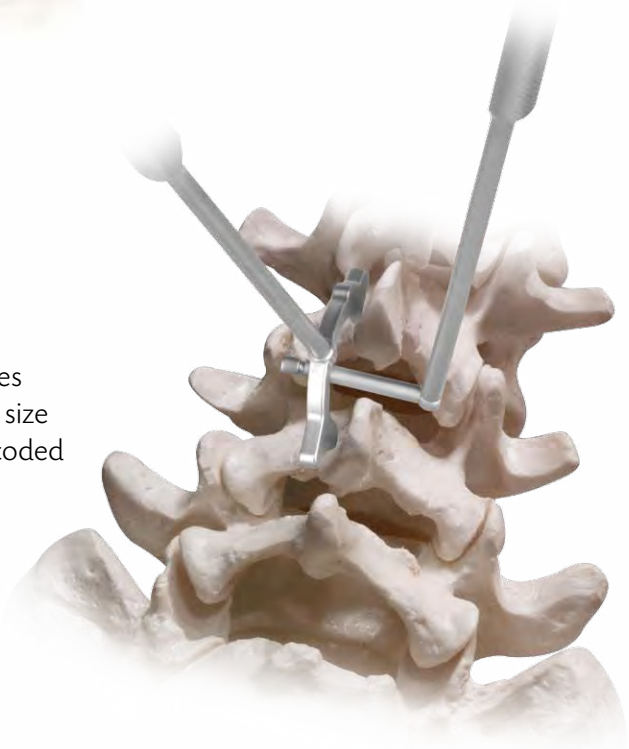
Trialing

The **Rod Trial** is used to determine the appropriate rod length. Place the rod through the interspinous space, ensuring the trial is flush against the interspinous ligament. Rod Trial grooves help to determine the appropriate length of the Central Ratcheting Rod and are visible on fluoroscopy.



Use the Rod Trial to determine rod length

Plate Trials match the shape of the Locking Plates and are used to determine the appropriate plate size used in the final assembly. Plate Trials are color-coded with plate lengths. Select the plate length that maximizes coverage of the spinous process.



Place the Plate Trial over the Rod Trial

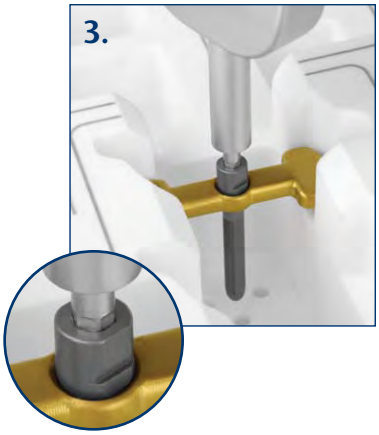
Step 4 Preparing SP-Fix™ Plate Assembly

There are three steps required to assemble SP-Fix™:

Step 1: Select the appropriately sized Central Ratcheting Rod from the implant module.

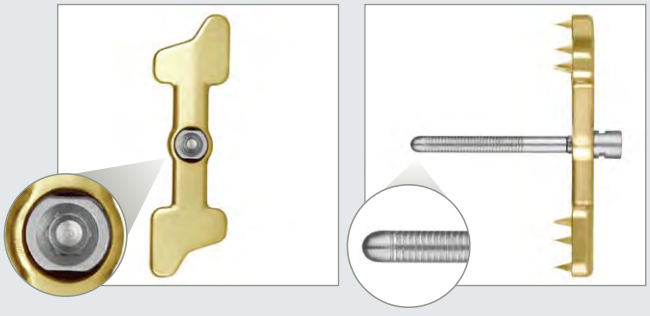
Step 2: Slide the Central Ratcheting Rod into the Pivoting Plate.

Step 3: Turn the hex located on the Central Ratcheting Rod 90° with the Hex Key to capture the Pivoting Plate.



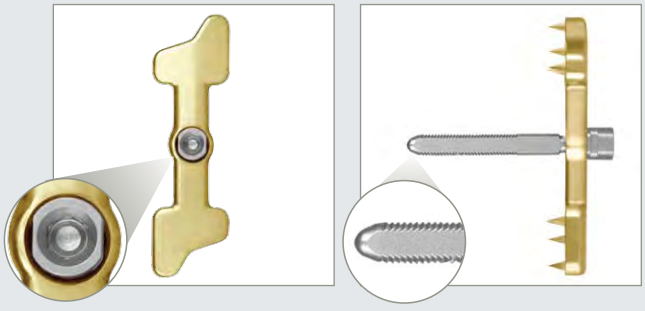
Capturing the Plate

Not Captured



Note: When the serrations face posterior, the Pivoting Plate is not captured.

Captured

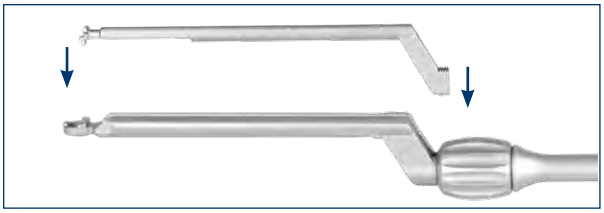


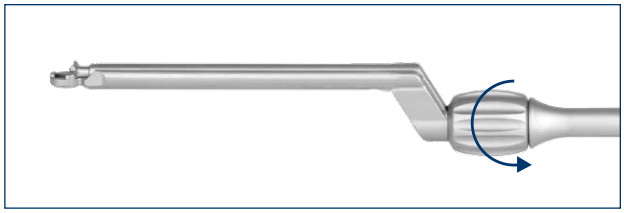
Note: When flats face posterior, the Pivoting Plate is captured.

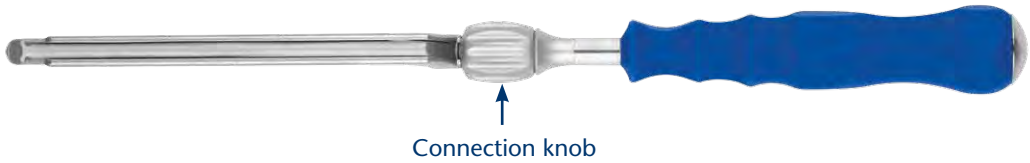
Preparing SP-Fix™ Plate Assembly (Cont'd)

Assembling the Holders

To assemble the holders, place the insert into the main body of the holder and rotate the connection knob counter-clockwise. Be sure to disassemble the holders prior to cleaning.

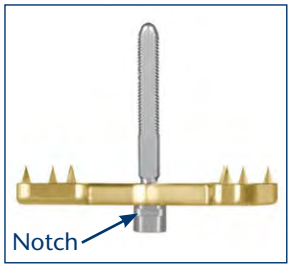


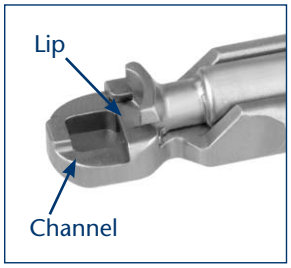


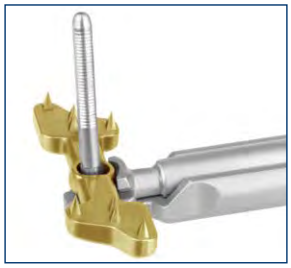


Using the Rod Holder

Place the Central Ratcheting Rod into the channel on the **Rod Holder**, orienting the notch in the rod to the lip on the holder. Once engaged, rotate the connection knob clockwise until there is a firm connection between the Central Ratcheting Rod and the Rod Holder.

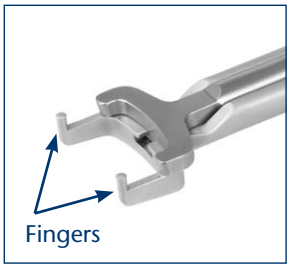


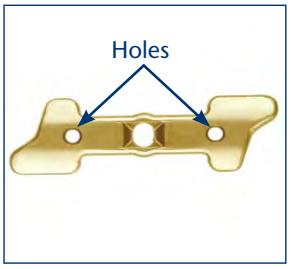


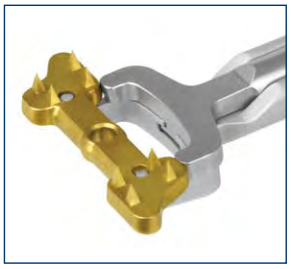


Using the Plate Holder

Insert the fingers on the **Plate Holder** into the corresponding holes on the back of the Locking Plate. Once engaged, rotate the connection knob clockwise until there is a firm connection between the Locking Plate and the Plate Holder.



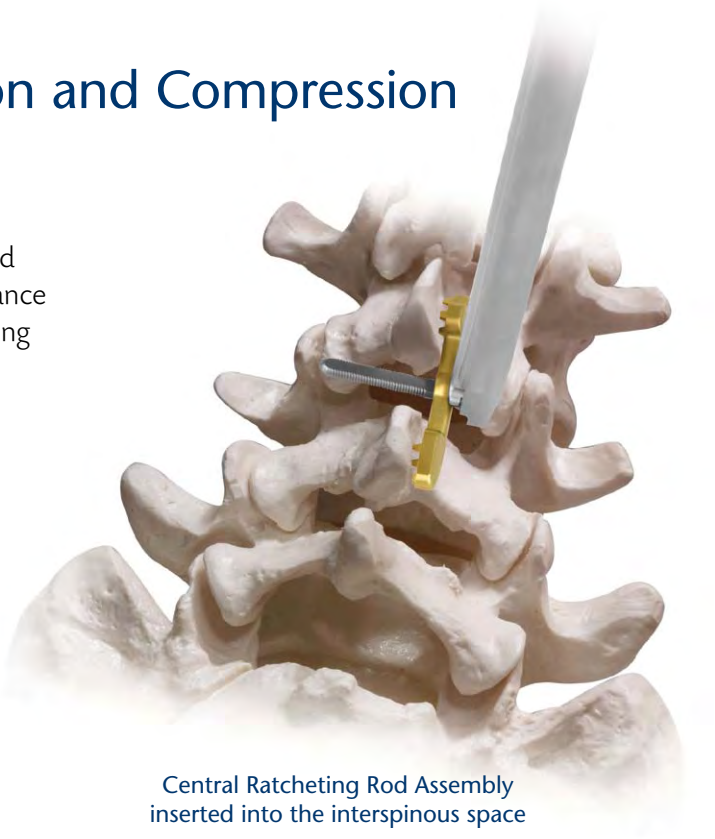




Step 5 Implant Insertion and Compression

Implant Insertion

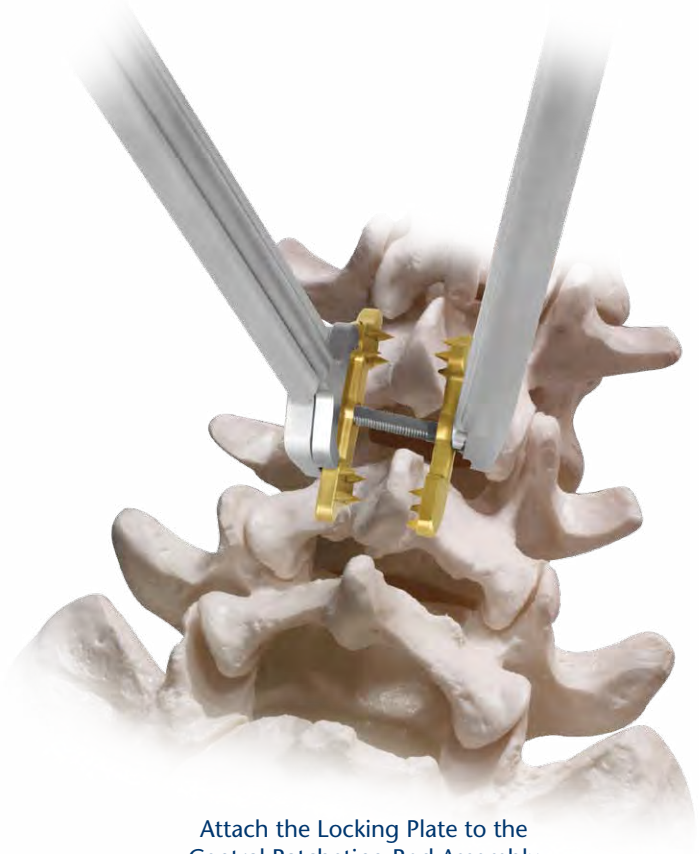
Introduce the tip of the Central Ratcheting Rod Assembly into the interspinous space and advance until the spikes of the Pivoting Plate are touching the spinous processes.



Central Ratcheting Rod Assembly inserted into the interspinous space

Using the Plate Holder, align the Locking Plate with the Central Ratcheting Rod. Grasp the holders as shown and compress the handles together, keeping one hand close to the implant. Compress until the first ratchet has been captured. The implant will click as the ratchet is advanced, indicating the locking plate is captured. The holders should now be removed from the Central Ratcheting Rod and Locking Plate.

Note: Implants should only be compressed during surgery.



Attach the Locking Plate to the Central Ratcheting Rod Assembly

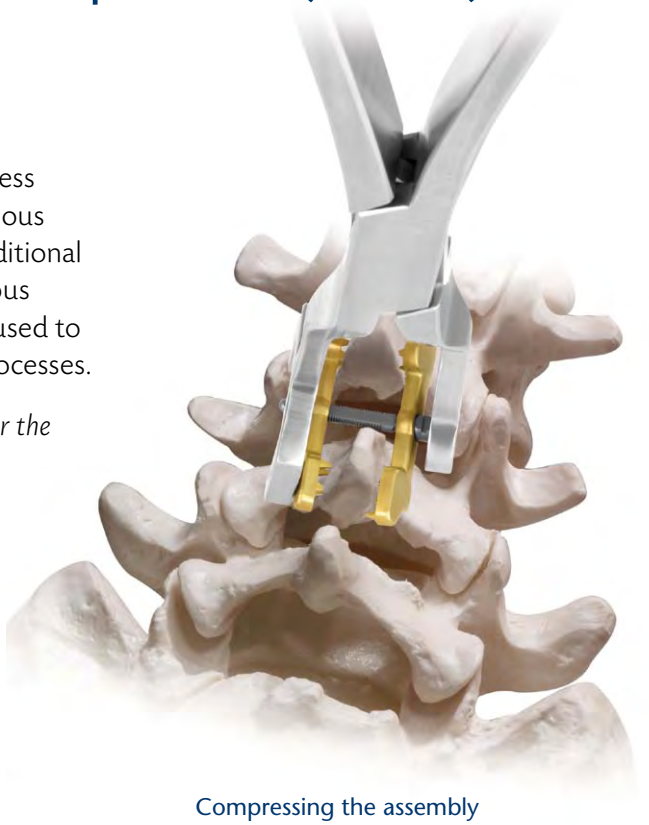
Compress the handles as shown

Implant Insertion and Compression (Cont'd)

Compression

Place the **Compressor** over both the Central Ratcheting Rod and Locking Plate and compress until the spikes are firmly seated into the spinous processes. The implant is now locked. For additional purchase, or to accomodate for varying spinous process thickness, the **Plate Pincher** can be used to engage the spikes deeper into the spinous processes.

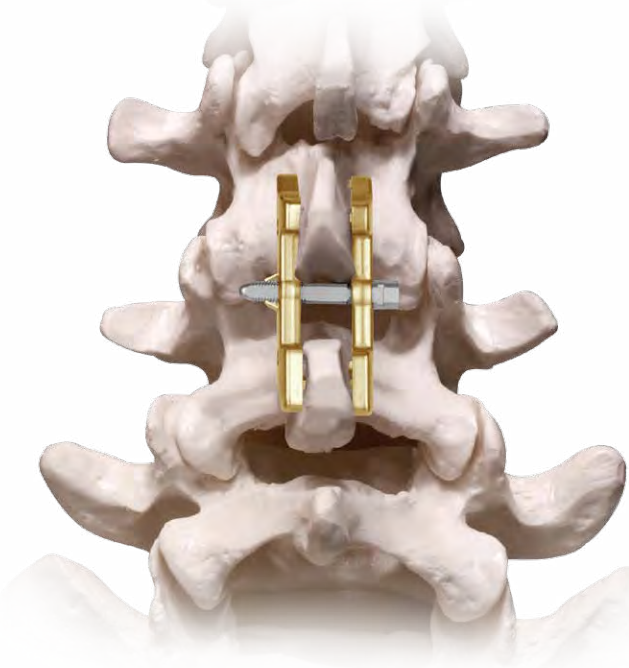
Note: The Compressor should always be used after the Plate Pincher to ensure the plates are locked.



Compressing the assembly

Final Construct

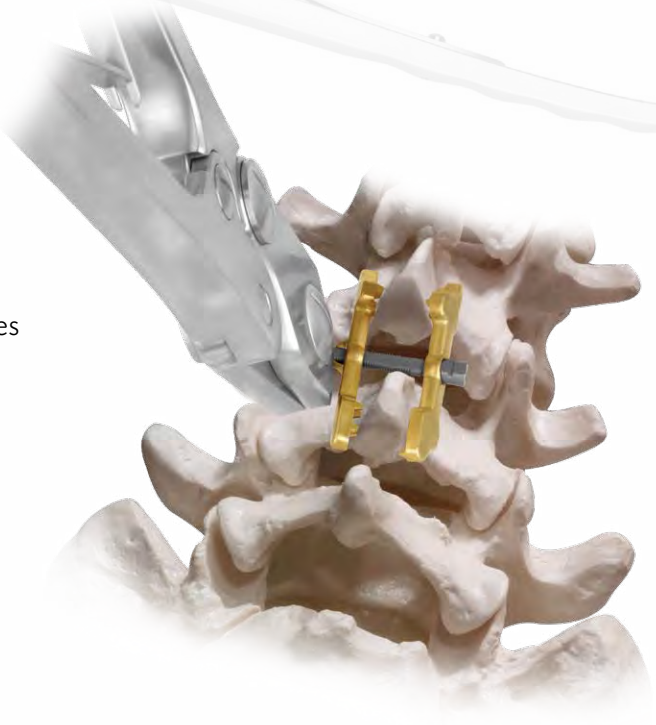
Plate Assembly



OPTIONAL TECHNIQUES

Rod Cutter

The **Rod Cutter** may be used to remove excess Central Ratcheting Rod. Once desired length is determined, compress the handles on the Rod Cutter to remove any excess rod. Keep the handles closed to contain the excess rod.



Removing excess rod

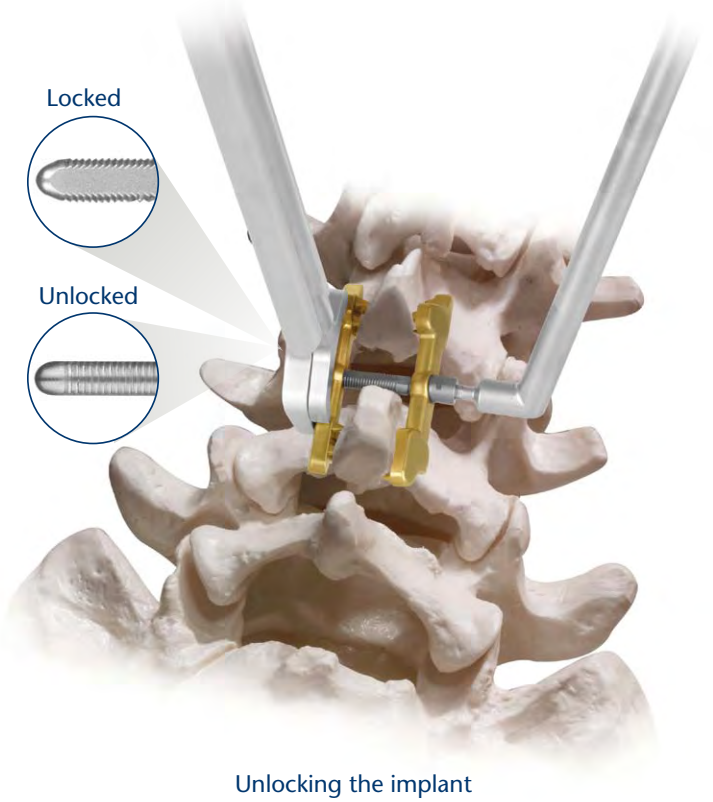
Implant Removal

To remove SP-Fix™, attach the Plate Holder onto the Locking Plate before rotating the **Removal Driver**. Insert the Removal Driver into the hex located on the rear of the implant and rotate 90° in either direction. Use the **Plate Holder** to gently rock the Locking Plate as the Removal Driver is rotated until the spikes disengage from the spinous processes, and the plate loosens. As the hex is rotated, feel the construct for the unlocked position and confirm its position visually. Use the same rocking motion to loosen the Pivoting Plate from the spinous processes. Gently pull to remove SP-Fix™ from the interspinous space.

Note: From a direct posterior view, the tip of the Central Ratcheting Rod can be verified for the locked or unlocked position.

Central Ratcheting Rod Locked

Central Ratcheting Rod Unlocked



Unlocking the implant

SP-Fix™ IMPLANT SET

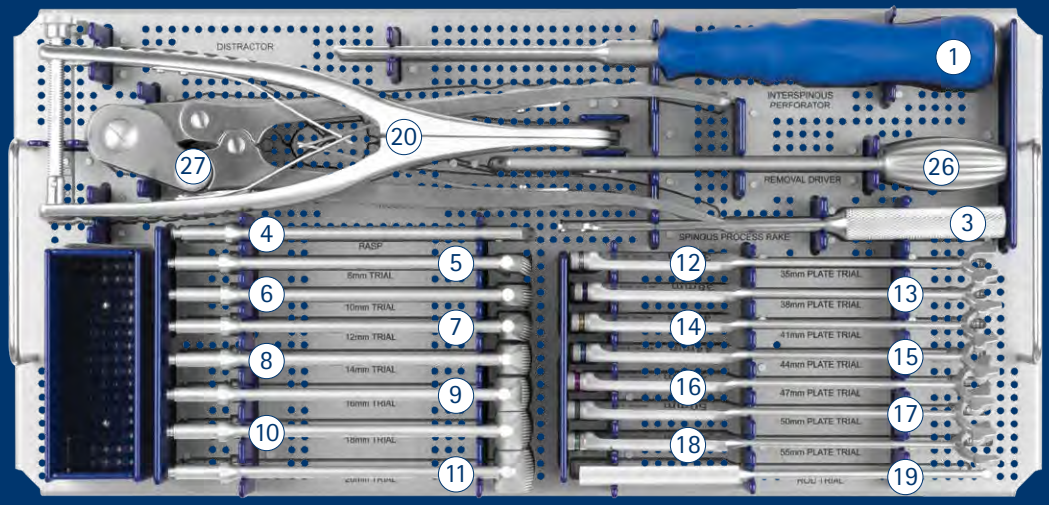
SP-Fix™ Implant Set List 988.901

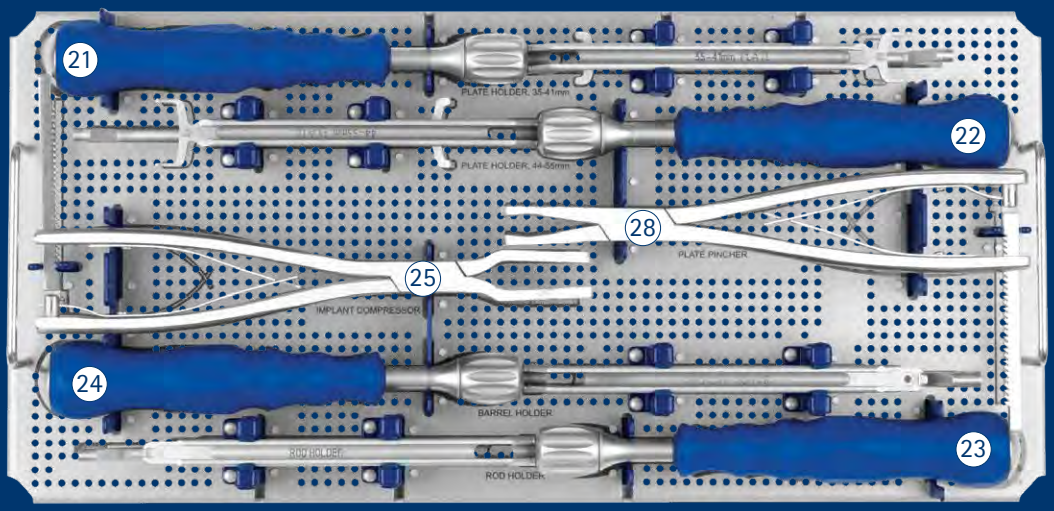
Description	Height	Part No.	Qty
SP-Fix™ Barrel Assembly	8mm	388.308	2
SP-Fix™ Barrel Assembly	10mm	388.310	2
SP-Fix™ Barrel Assembly	12mm	388.312	2
SP-Fix™ Barrel Assembly	14mm	388.314	2
SP-Fix™ Barrel Assembly	16mm	388.316	2
SP-Fix™ Barrel Assembly	18mm	388.318	0*
SP-Fix™ Barrel Assembly	20mm	388.320	0*
SP-Fix™ Ratcheting Rod	25mm	188.525	2
SP-Fix™ Ratcheting Rod	30mm	188.530	2
SP-Fix™ Ratcheting Rod	35mm	188.535	2
SP-Fix™ Pivoting Plate	35mm	188.135	2
SP-Fix™ Pivoting Plate	38mm	188.138	2
SP-Fix™ Pivoting Plate	41mm	188.141	2
SP-Fix™ Pivoting Plate	44mm	188.144	2
SP-Fix™ Pivoting Plate	47mm	188.147	2
SP-Fix™ Pivoting Plate	50mm	188.150	0*
SP-Fix™ Pivoting Plate	55mm	188.155	0*
SP-Fix™ Locking Plate	35mm	188.035	2
SP-Fix™ Locking Plate	38mm	188.038	2
SP-Fix™ Locking Plate	41mm	188.041	2
SP-Fix™ Locking Plate	44mm	188.044	2
SP-Fix™ Locking Plate	47mm	188.047	2
SP-Fix™ Locking Plate	50mm	188.050	0*
SP-Fix™ Locking Plate	55mm	188.055	0*
Hex Key		688.330	1
SP-Fix™ Implant Module		988.001	1

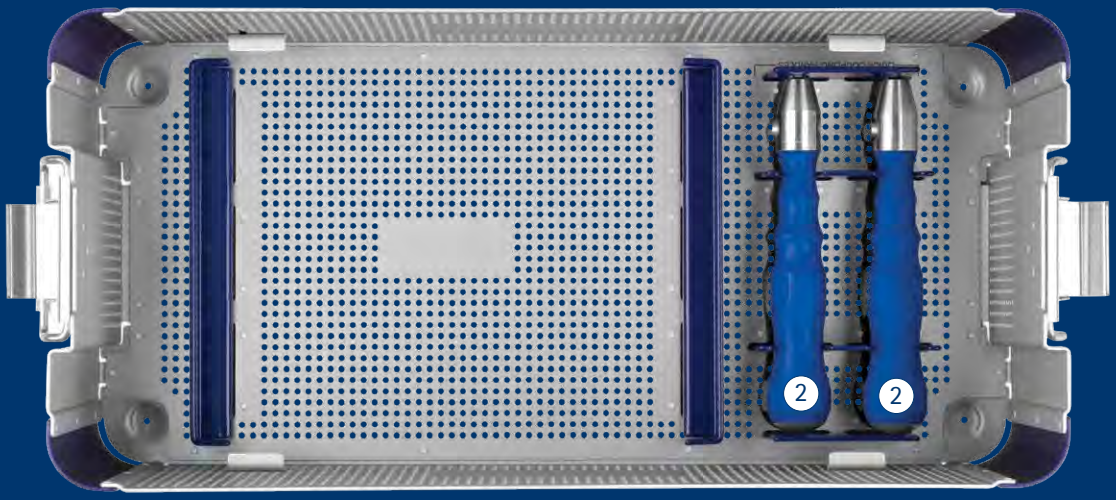
Items highlighted in gray are additionally available.

** Note: One of each of the additionally available items above are included in each Loaner Set. If you have a Consigned Set and require these items, please request these additionally available items through Customer Service.*

SP-Fix™ INSTRUMENT SET







SP-Fix™ Instrument Set List 988.902

	Description		Qty
1	646.050	Interspinous Perforator	1
2	646.960	Quick Connect Handle	2
3	688.060	Spinous Process Rake	1
4	688.075	Rasp	1
5	688.108	Trial, 8mm	1
6	688.110	Trial, 10mm	1
7	688.112	Trial, 12mm	1
8	688.114	Trial, 14mm	1
9	688.116	Trial, 16mm	1
10	688.118	Trial, 18mm	1
11	688.120	Trial, 20mm	1
12	688.235	Plate Trials, 35mm	1
13	688.238	Plate Trials, 38mm	1
14	688.241	Plate Trials, 41mm	1
15	688.244	Plate Trials, 44mm	1
16	688.247	Plate Trials, 47mm	1
17	688.250	Plate Trials, 50mm	1
18	688.255	Plate Trials, 55mm	1
19	688.275	Rod Trial	1
20	688.300	Distractor	1
21	688.310	Plate Holder, 35–41mm	1
22	688.311	Plate Holder, 44–55mm	1
23	688.314	Rod Holder	1
24	688.315	Barrel Holder	1
25	688.320	Implant Compressor	1
26	688.331	Removal Driver	1
27	688.400	Rod Cutter	1
28	688.450	Plate Pincher	1
	988.002	SP-Fix™ Instrument Graphic Case	

IMPORTANT INFORMATION ON THE SP-FIX™ SPINOUS PROCESS FIXATION PLATE

DESCRIPTION

The SP-Fix™ Spinous Process Fixation Plate consists of plates, rods and barrels that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The components are available in a range of sizes to fit the anatomical needs of a variety of patients. SP-Fix™ implants are composed of titanium alloy (per ASTM F136) and PEEK radiolucent polymer (per ASTM F2026).

INDICATIONS

The SP-Fix™ Spinous Process Fixation Plate is a posterior non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1–S1). It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The SP-Fix™ Spinous Process Fixation Plate is intended for use with bone graft material and is not intended for stand-alone use.

WARNINGS

Possible adverse effects which may occur include, but are not limited to: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials including metallosis, staining, tumor formation and/or autoimmune disease; infection; device fracture or failure; device migration or loosening; decrease in bone density; loss of spinal mobility or function; inability to perform activities of daily living; fracture of any spinal bone including the pedicles, spinous process, pars interarticularis, vertebral body, or sacrum; change in spinal curvature or disc height; herniated nucleus pulposus, disc degeneration or disruption; graft donor site complications including pain, fracture and wound healing problems; tissue damage, pain, discomfort, or abnormal sensations due to the presence of the device or implantation surgery; scar formation causing neurologic compromise or pain; injury to nerves including loss or decrease of neurologic function, paralysis, dural tears, development of radiculopathy, numbness or tingling; cauda equina syndrome; injury to vessels, hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, or other types of cardiovascular system compromise; injury to organs including urinary retention, loss of bladder control, or other types of urologic system compromise; gastrointestinal system compromise; reproductive system compromise including sterility, sexual dysfunction; development of respiratory problems including pulmonary embolism; venous thrombosis, lung embolism and cardiac arrest; and death. Additional surgery may be necessary to correct some of these effects.

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.

This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PRECAUTIONS

Implantation of these devices should be performed only by experienced spinal surgeons with specific training in the use of the system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implants.

Surgical implants must never be reused. An explanted implant must never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.

Correct handling of the implant is extremely important. The operating surgeon should avoid any notching or scratching of the device. The implants should not be contoured as this may create stress patterns which could lead to breakage or may disrupt implant function.

Implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after fusion occurs, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Correct selection of the implant is extremely important. The potential for surgical success is increased by the selection of the proper size, shape and design of the implant. While proper selection can minimize risks, size and shape of human bones present limitations on the size and strength of implants. Internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load-bearing.

Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be used in conjunction with titanium or titanium alloy implants. SP-Fix™ implants should not be connected to components of other systems or manufacturer.

SP-Fix™ has not been evaluated for safety and compatibility in the MR environment. SP-Fix™ has not been tested for heating or migration in the MR environment.

CONTRAINDICATIONS

The contraindications include, but are not limited to: Active infectious process or significant risk of infection (immunocompromise); local inflammation, fever, or leukocytosis, morbid obesity; pregnancy; mental illness; distorted anatomy caused by congenital abnormalities; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities; rapid joint disease, bone absorption osteopenia, and/or osteoporosis; suspected or documented material allergy or intolerance; incompetent or missing posterior arch (e.g. laminectomy, pars defect, severe osteoporosis); any case where metals must be mixed from different components; any case where the implant components selected for use would be too large or too small to achieve a successful result; any case where fracture healing is not required; any patient in which implant utilization would interfere with

anatomical structures or expected physiological performance; any patient unwilling to follow post-operative instructions; any case not described in the indications.

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

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

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

CLEANING

Cleaning instruments by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

1. Clear any corners or recesses of all debris. (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
2. Remove all traces of blood and other such residues immediately. Do not allow these to dry.
3. The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Instraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
6. Dry instruments immediately after cleaning.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

SP-Fix™ implants and instruments have been validated to assure a Sterility Assurance Level (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.*

Implants:
These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132° C (270° F)	28 Minutes	15 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132° C (270° F)	4 Minutes	15 Minutes

Instruments:
These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132° C (270° F)	25 Minutes	45 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	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.

CAUTION: Federal (USA) Law restricts this Device to Sale by or on the order of a Physician.

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www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
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