NEURO® STRUCTURES

Resolute®

FACET SCREW SYSTEM

SURGICAL TECHNIQUE GUIDE

Made in the USA

neurostructures.com

This is intended as a guide only. There are multiple techniques for the insertion of Facet Screws as with any surgical procedure. A surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warning.

Screws

Full Thread – *Light Blue*
4.5mm

Full Thread – *Blue*
5.0mm

Partial Thread – *Light Green*
4.5mm

Partial Thread – *Green*
5.0mm

Screw Size

		Ø (mm)	Length (mm)				
Self Tapping	Full Thread	4.5	20	25	30	35	40
		5.0	20	25	30	35	40
	Partial Thread	4.5	20	25	30	35	40
		5.0	20	25	30	35	40

1 Guidewire Placement

Insert the Target Needle and guide down. Dock the tip on the bony anatomy of the desired level and confirm placement with A/P fluoroscopy. Adjustments to the entry angle and trajectory should be made until the proper position is attained. Provisionally seat the tip with a gentle mallet tap *(Figure 1)*.

Note: It is recommended that preoperative planning be used to help determine the proper entry point and trajectory. Identify the operative levels using A/P and lateral fluoroscopy.

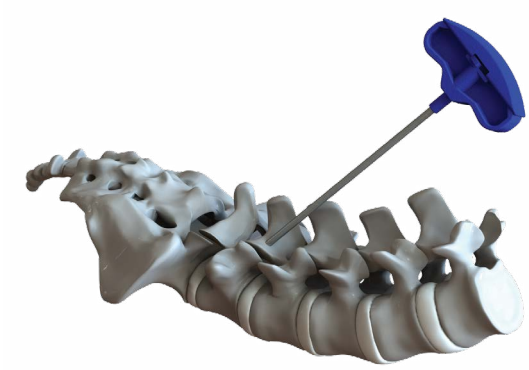

Figure 1

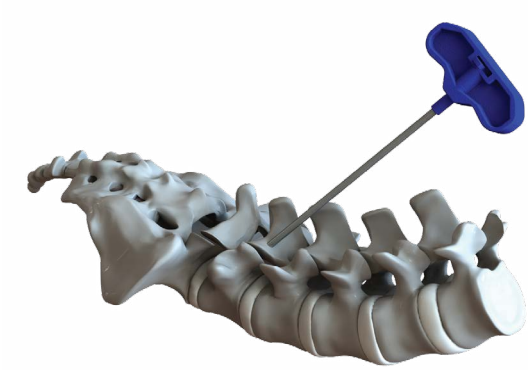

Figure 2

Once proper placement is confirmed, remove the inner stylet of the Target Needle *(Figure 2)*.

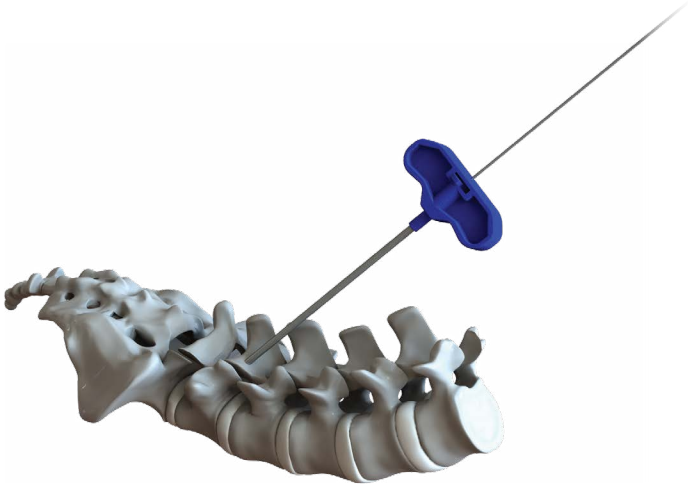

Figure 3

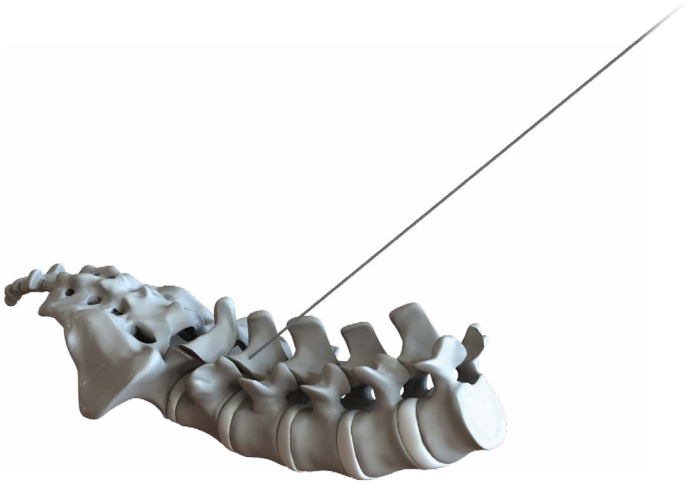

Figure 4

Insert the Guidewire through the cannulated Target Needle sheath and advance to the desired position *(Figure 3)*.

Once the Guidewire is in place, remove the Target Needle and leave the Guidewire in place *(Figure 4)*.

2 Tissue Dilation

Slide Dilator 1 over the Guidewire and advance until fully seated *(Figure 5)*.

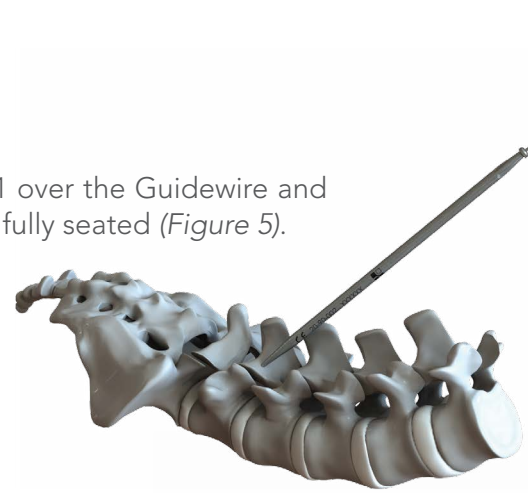

Figure 5

Slide Dilator 2 over Dilator 1 and advance until fully seated *(Figure 6)*.

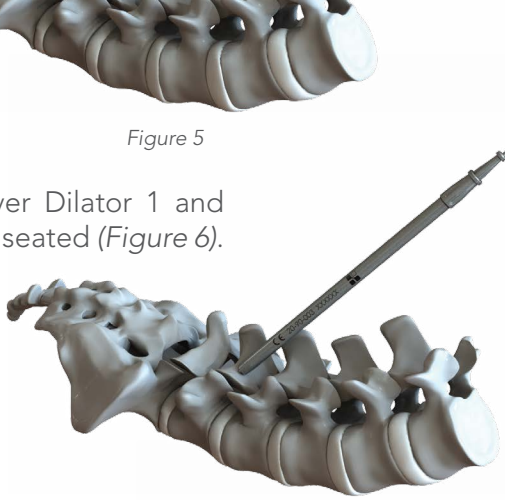

Figure 6

Remove Dilator 1 *(Figure 7)*.

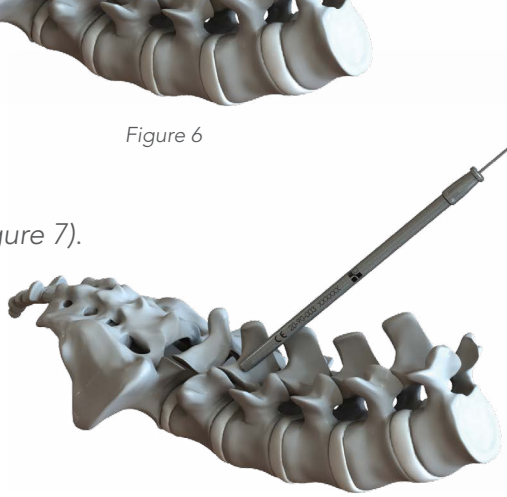

Figure 7

Guidewire Driver can be used as needed *(Figure 8)*.

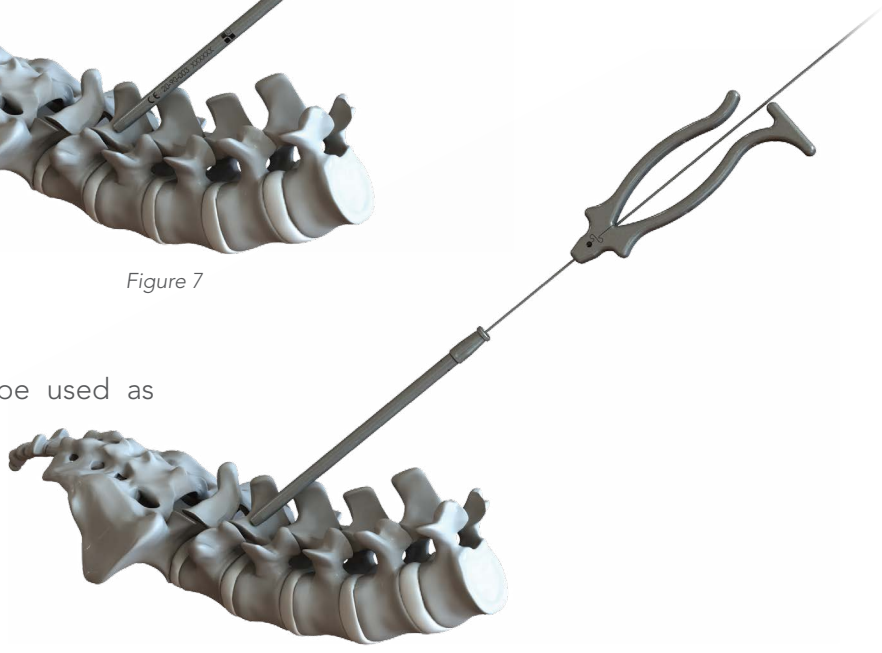

Figure 8

3 Screw Hole Preparation

Attach the Adjustable Drill to the selected handle by pulling up on the quick connect fitting.

Set the Adjustable Drill to the desired depth by turning the knob.

Drill through Dilator 2 using the Adjustable Drill by turning handle clockwise *(Figure 9)*.

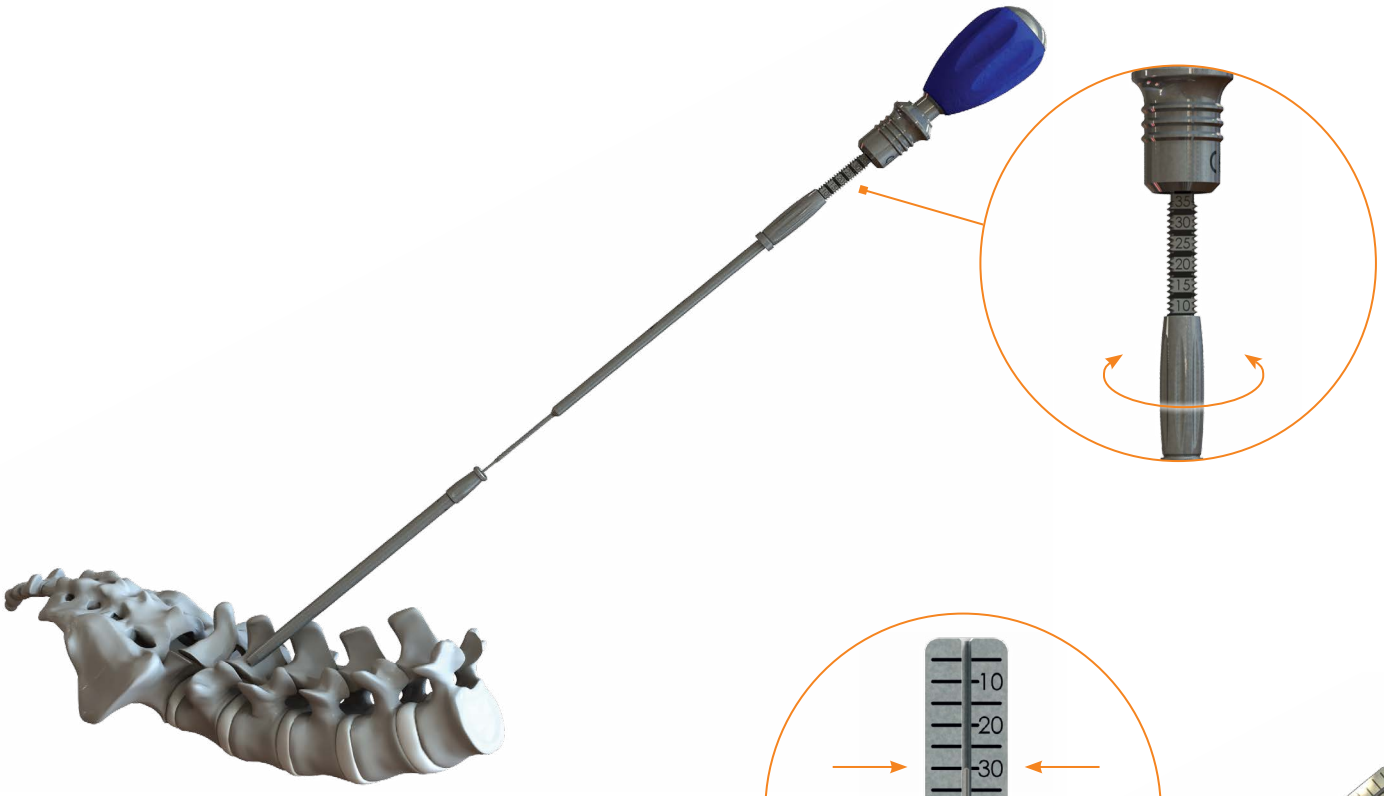

Figure 9

Slide the Guidewire Depth Indicator over the Guidewire and into Dilator 1 *(Figure 10)*.

Use the Guidewire Depth Indicator as needed to verify the depth.

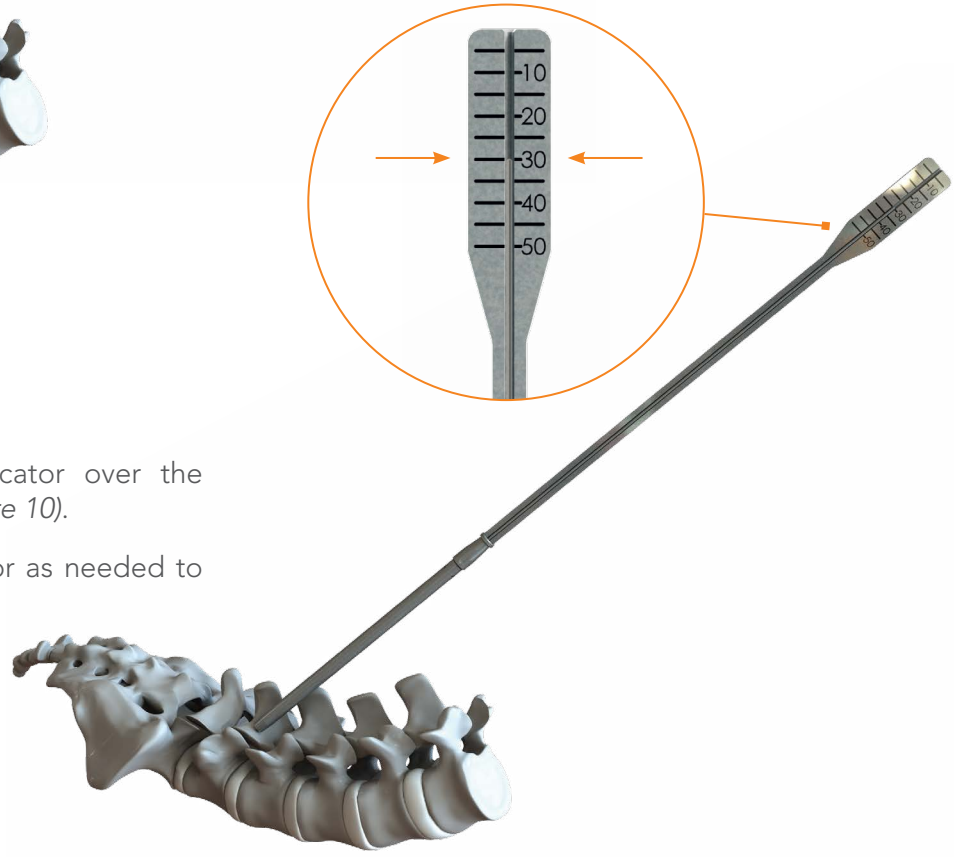

Figure 10

Screw hole can also be prepared by using the Drill Guide and Adjustable Drill.

This step can also be done without a Guidewire.

Insert Guidewire into Drill Guide (optional), then insert Adjustable Drill to drill to the desired depth *(Figure 11 & 12)*.

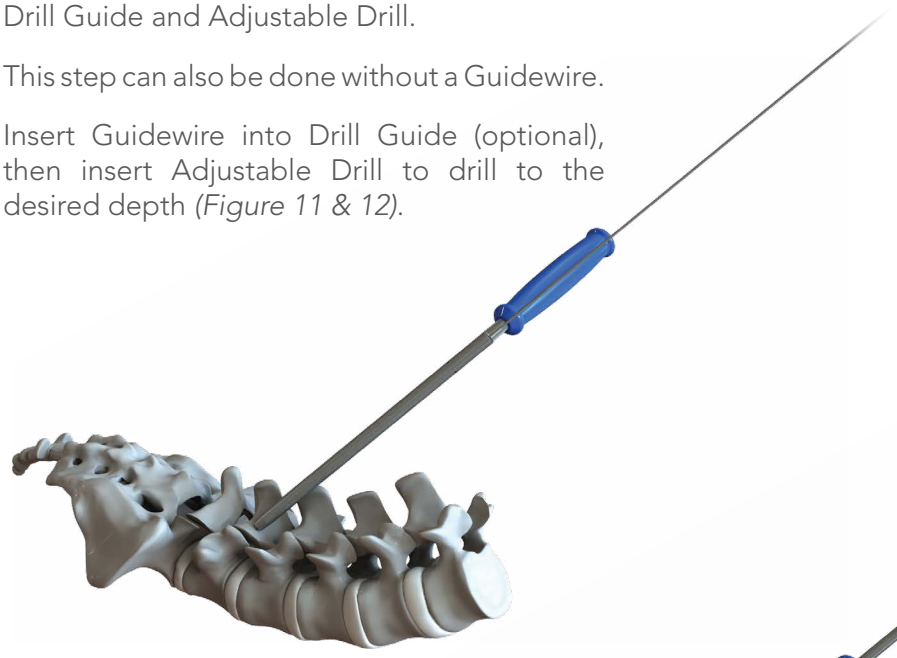

Figure 11

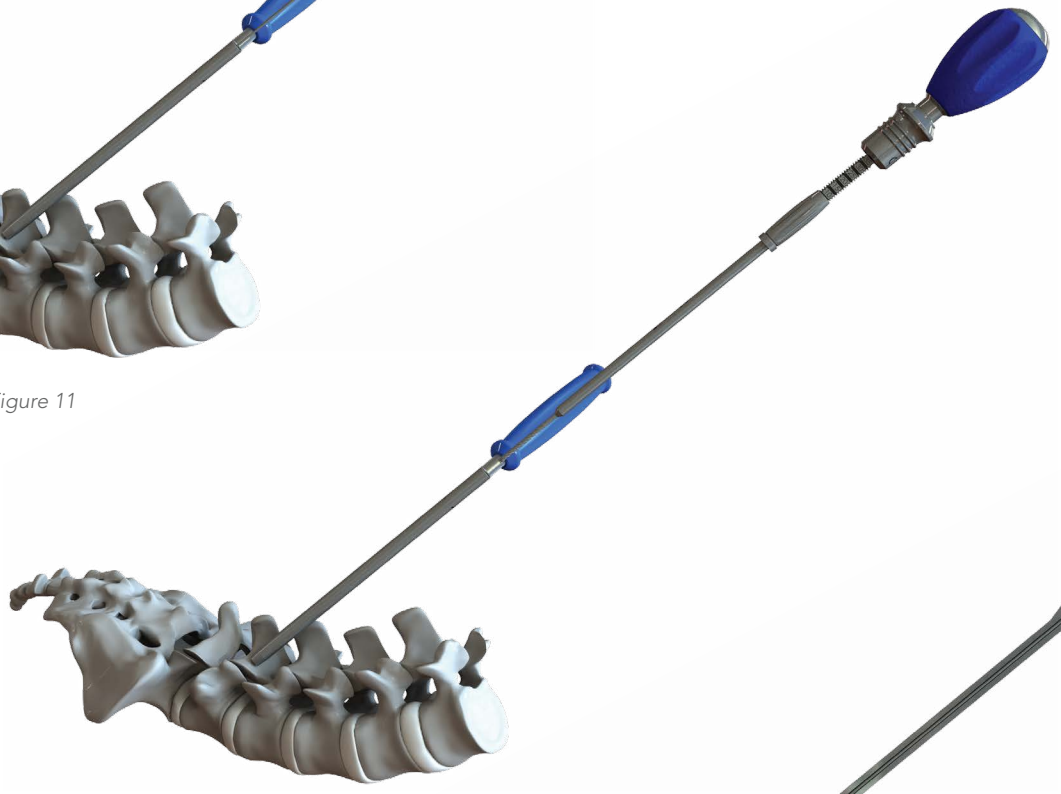

Figure 12

Verify the depth by using the Guidewire Depth Indicator *(Figure 13)*.

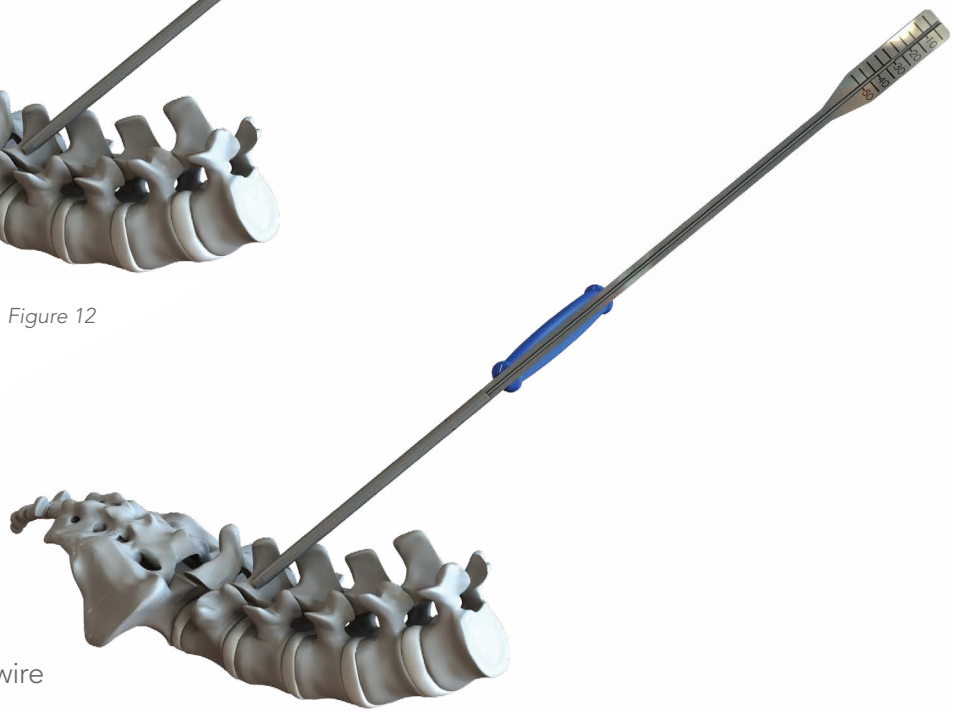

Figure 13

If no Guidewire is used, depth verification needs to be assessed using the Depth Gauge *(Figure 14)*. Check lateral fluoroscopy for the tip position.

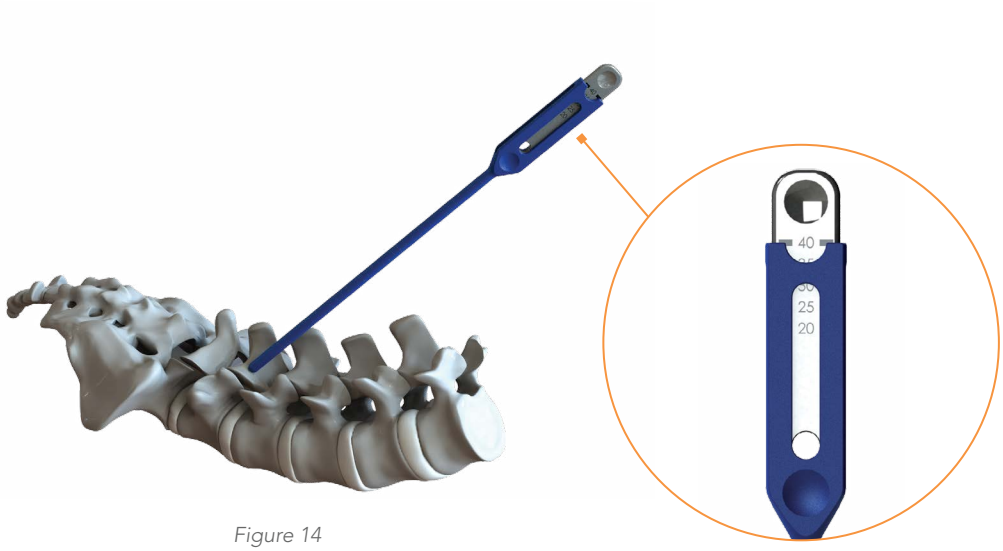

Figure 14

4 Screw Insertion

Attach the Screw Driver to the quick connect handle.

Verify screw length and load the screw onto the Screw Driver. Lock the screw by turning the locking sleeve clockwise *(Figure 15)*.

Pass the Facet Screw Driver assembly over the Guidewire, apply a small amount of downward pressure, and rotate the assembly clockwise to advance the screw *(Figure 16)*.

Advance the screw to the desired depth and verify placement under fluoroscopy. After screw placement remove the Guidewire from the surgical field. Advance the screw to its final position *(Figure 17)*.

Caution: Use fluoroscopy to maintain Guidewire advancement during screw delivery.

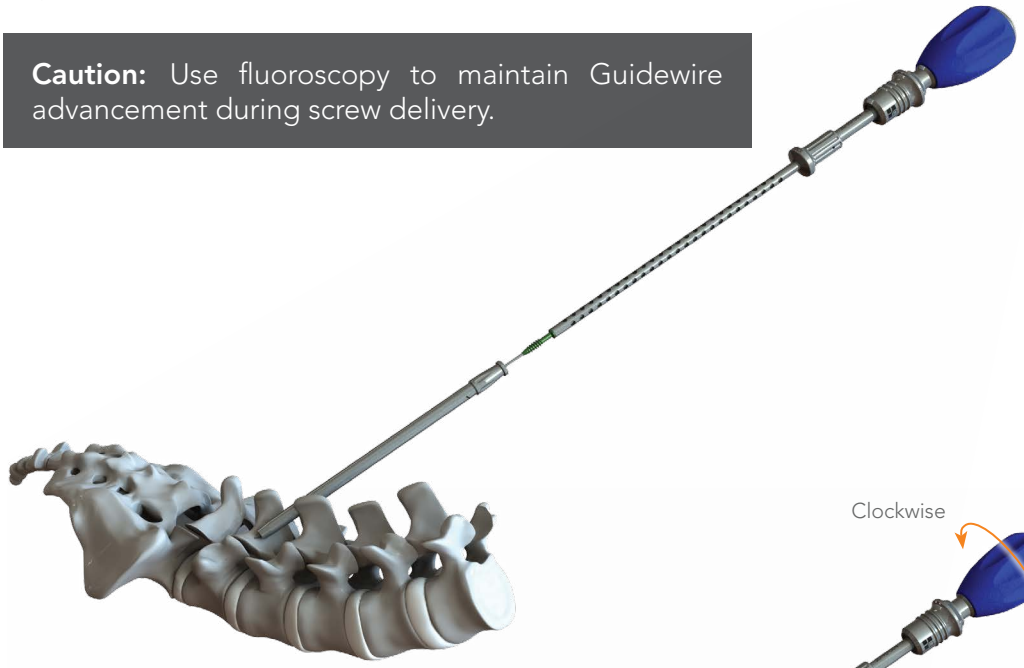

Figure 15

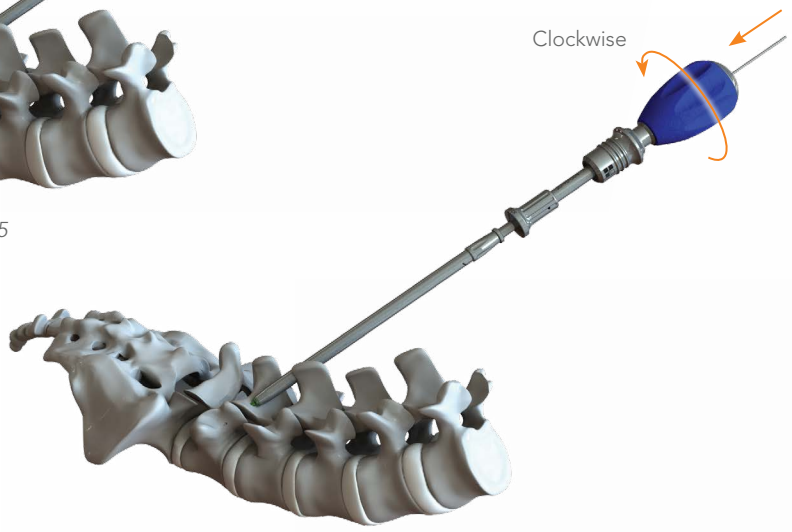

Figure 16

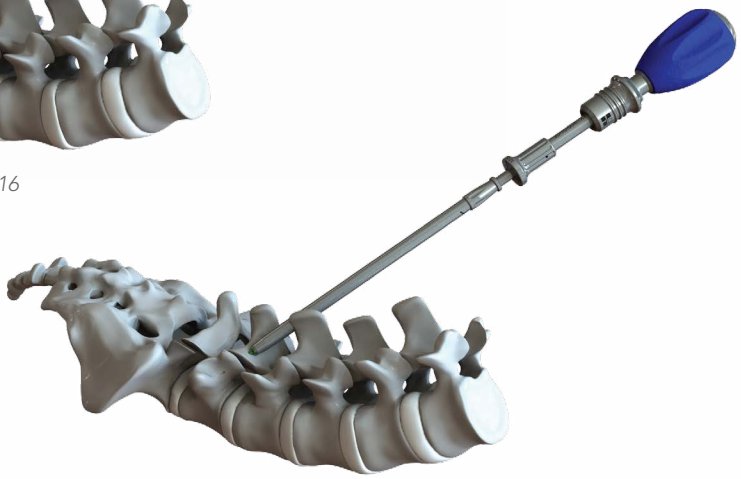

Figure 17

Note: If no Guidewire was used, screw can be advanced in a similar fashion without the use of Dilator 2. Use fluroscopy as needed to confirm screw placement.

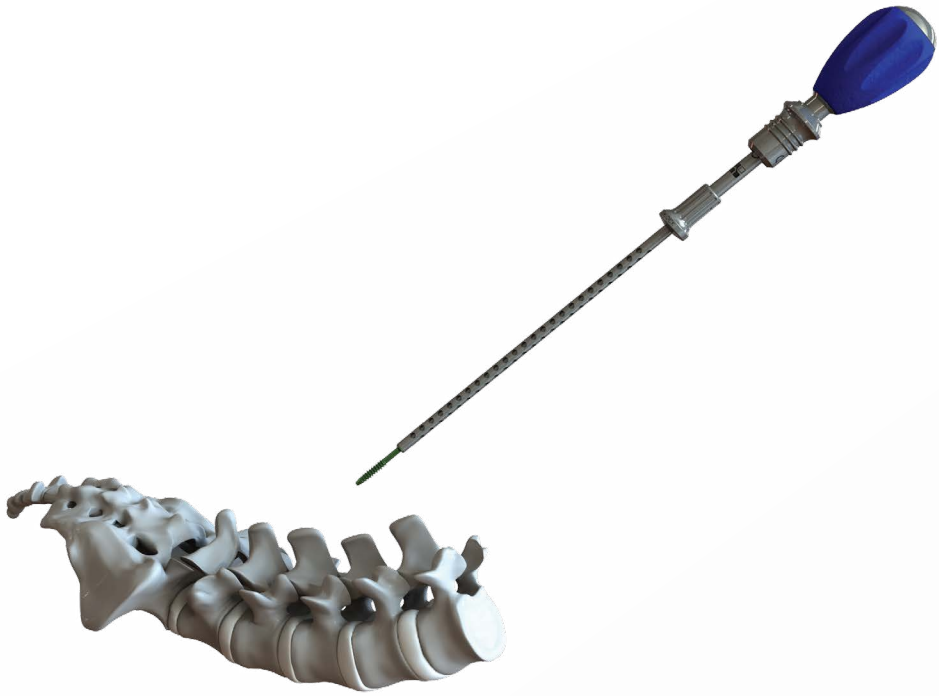

Figure 18

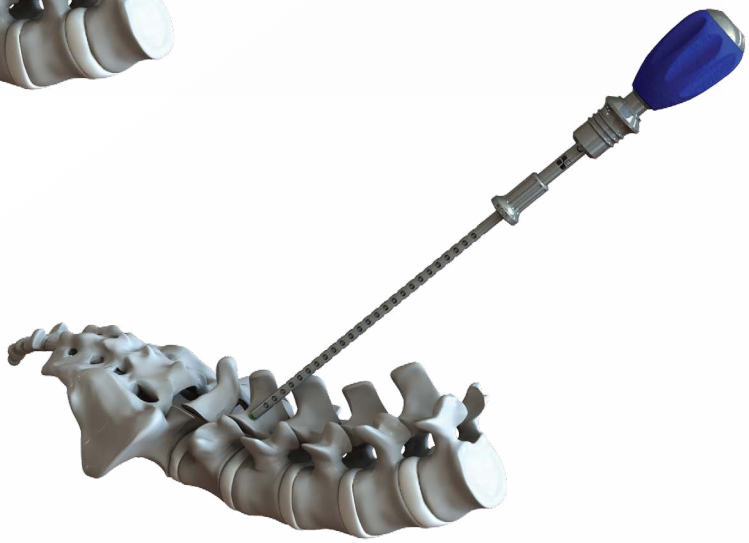

Figure 19

5 Instrument Removal

Gently turn the Screw Driver locking sleeve counterclockwise while holding the handle. Pull the sleeve and remove the driver from the surgical field. Remove Dilator 2 from the surgical field.

Caution: Confirm final screw placement before removing the instruments.

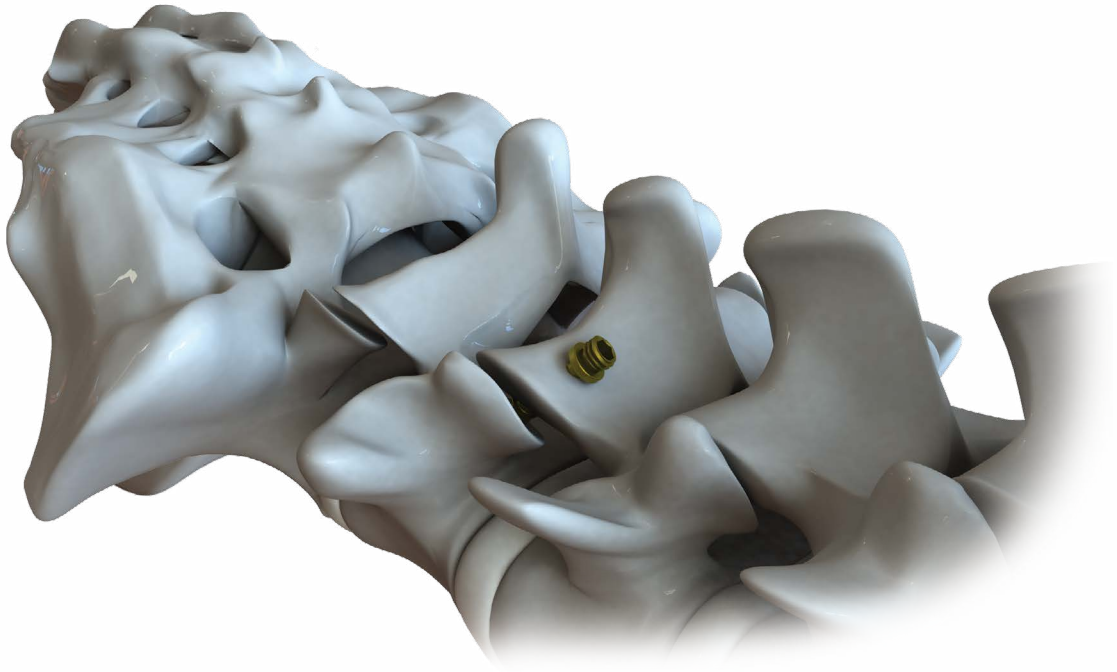

Figure 20

20-90-001
Non-Ratcheting
Palm Handle

20-90-014
Ratcheting T-Handle

20-90-015
Ratcheting Axial
Handle

20-90-002
Dilator 1

20-90-003
Dilator 2

20-90-004
Screw Driver

20-90-011
Drill Guide

20-90-012
Adjustable Drill

20-90-013
Guidewire Depth
Indicator

20-90-016
Depth Gauge

20-90-006
Guidewire Driver
(with Strike Plate)

TNL0815
Target Needle

20-90-007
Guidewire Sharp

Description:

The Resolute Facet Screw System is designed to stabilize the facet joint as an aid to fusion in the lumbar spine. The screws are offered in lengths varying from 20mm to 40mm and diameters of 4.5mm to 5.0mm. There are two designs, full and partial thread. All screws are made of titanium alloy per ASTM F136.

Instruments are provided to facilitate proper introduction and placement of the screws.

NeuroStructures, Inc. disclaims all warranties, express or implied, including but not limited to any implied warranty of merchantability or fitness for a particular use.

Intended Use/Indications for Use:

The Resolute Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: Spondylolisthesis, Pseudoarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DOD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

Contraindications:

Contraindications include, but are not limited to, the following conditions:

- Sepsis, local or systemic
- Osteomyelitis at the surgical site
- Absence or destruction of any portion of the facet joint, or procedures which will require removal of any portion of the facet joint
- Known or suspected sensitivity to implant materials
- Significant metabolic bone disease (e.g. osteoporosis or osteomalacia) to a degree that posterior spinal instrumentation is contraindicated
- Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery

Precaution:

- The success of any spinal fusion is dependent upon many factors that include, but are not limited to, the health and metabolism of the patient. Medical conditions or disease states that alter a patient's normal metabolism may interfere with bone healing.
- Any fusion that relies on a metal construct for stabilization during the bone healing phase presupposes that bony fusion will ultimately occur. If the bone does not heal and a non-union develops, the metal construct will eventually fail. The Resolute Facet Screw System relies upon load sharing with an anterior interbody construct to aid in successful fusion.
- This device is intended for bilateral placement, with or without bone graft.
- It is important to choose the correct implant size. Surgeons should be fully trained and familiar with use of the instruments and proper placement of the facet screw implant.
- Pedicle screw systems, not facet screws, should be considered when there is degenerative disease of the facet joints with instability.
- As with any percutaneous spinal procedure, good imaging and interpretation of the images are critical to safety. Physicians should be experienced in interpreting biplanar fluoroscopic images of the thoracolumbar spine and experienced in image-guided instrument placement.
- Safety and effectiveness have not been established in patients with the following conditions: greater than grade 2 spondylolisthesis, two or more levels to be fused, morbid obesity (BMI >40), pregnancy.
- Patients who are taking medications that may interfere with bone or soft tissue healing (e.g. long-term steroid use) may not be suitable candidates as these medications may interfere with bone growth and graft incorporation.
- As with any permanent implant, a perioperative antibiotic protocol is recommended.
- Metallic implants can corrode, loosen, migrate, cause pain, bend or fracture, even after a fusion has occurred.
- An implant should never be reused.
- The implant should not be used with components from another device or manufacturer.

Adverse Effects/Surgical Risks:

POSSIBLE ADVERSE EFFECTS OR RISKS INCLUDE, BUT ARE NOT LIMITED TO, THE FOLLOWING, WHICH MAY REQUIRE ADDITIONAL SURGERY:

- Infection of soft tissue and/or bone (osteomyelitis); fever
- Implant loosening
- Bending or breakage of the device
- Incomplete relief of symptoms
- Incomplete fusion, delayed union or non-union
- Fracture of the pedicle or bone of the facet joint
- Soft tissue injury
- Edema

- Skin irritation, wound dehiscence
- Dural injury, with or without CSF leakage
- Neurologic injury, transient or permanent
- Pain and loss of function
- Hemorrhage, hematoma
- Device migration
- Death

MRI Warning:

The Resolute Facet Screw System has not been evaluated for safety and compatibility in the MR environment. The Resolute Facet Screw System has not been tested for heating or migration in the MR environment.

Implant Handling:

Exercise care in handling implants. Protect the implants from contact with objects that may damage the surface. Inspect each implant prior to use and do not use if any damage is suspected.

Instruments:

Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments which exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned and resterilized immediately after use.

Cleaning and Decontamination:

Cleaning and decontamination of surgical instruments are required before introduction into the sterile field.

Following use, disassemble devices as instructed for thorough cleaning. Preventing drying will facilitate later cleaning.

- Soak in enzymatic detergent (mixed per manufacturer's recommendations) for one (1) minute or longer.
- Use a soft brush for manual cleaning and a soft bottle brush to clean tubes. Pay special attention to inner diameters and crevices during cleaning. Ultrasonic cleaning is acceptable.
- Rinse each part thoroughly under running water for one (1) minute or longer.
- Visually inspect all devices to ensure there is no visual contamination. If devices are not visually clean, repeat the cleaning steps.

Sterilization:

Note that these implants and instruments are non-sterile

All implants and instruments must be cleaned and sterilized by the hospital before use as described below.

Instrument trays are provided for storing and sterilizing the instruments. Instrument trays do not provide a sterile barrier. Trays must be used with a sterilization wrap. Sterilization can be performed on wrapped trays with the following cycle parameters:

Steam Sterilization Cycle Type	Exposure time at 132 °C (270 °F)	Drying Times
Prevacuum	4 min	30 min

Deviations from the recommended methods of cleaning and decontamination are not advised. It is the sole responsibility of the user to qualify such deviations.

Device Retrieval:

Contact NeuroStructures, Inc. to discuss Revision/Retrieval.

Further Information or Product Complaints:

Contact NeuroStructures, Inc. at:

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