

Threshold™

Pedicular Fixation System

Surgical Technique

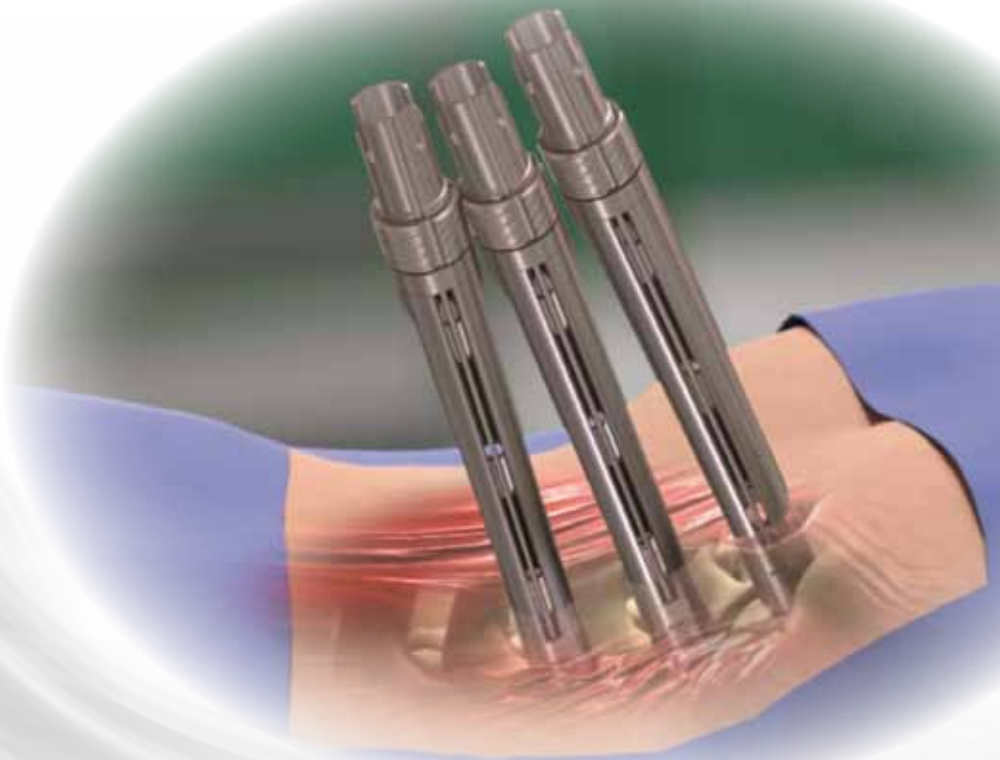


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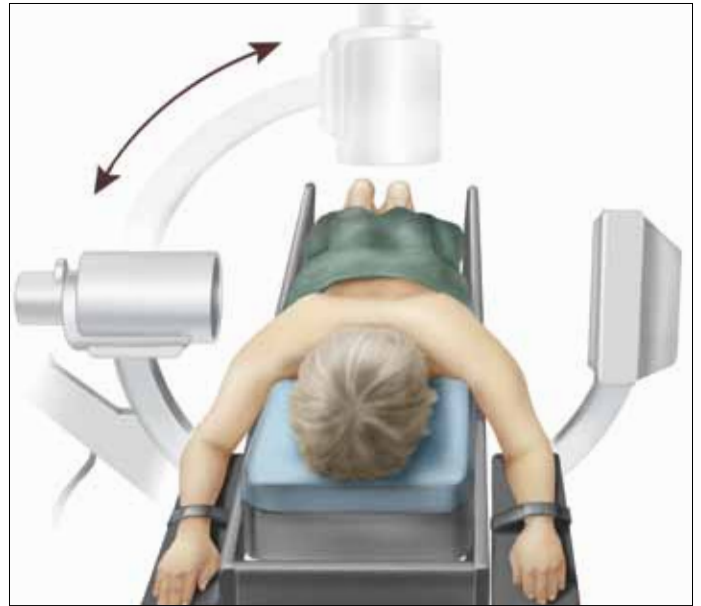
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A Note for Physicians

As with any spinal fusion procedure, proper imaging and interpretation of the images are critical to safety. This technique manual describes the parameters for instrument trajectory selection, but does not purport to teach radiographic image interpretation. These instructions are intended as an outline for the use of the Threshold™ Pedicular Fixation System for physicians experienced in interpreting biplanar fluoroscopic images of the lumbar spine and in image-guided instrument placement.

Patient Preparation and Positioning

- Anesthetize the patient appropriately.
- Position the patient prone on a radiolucent table.
- Prior to surgery, the following recommendations should be followed:
 - Lateral and anterior/posterior (AP) imaging is required for this procedure. If biplane imaging is not being used, swing the image intensifier under the table to ensure that no obstructions are present at the pathologic level in either AP or lateral views.
 - Using the image intensifier, identify the pathologic level.
 - Prep and drape the patient and C-arm image intensifier accordingly.



Determining Incision Location

- Orient the C-arm to provide a true AP image that is coplanar with the endplates of the motion segment(s) to be instrumented.
- Place a Guide Wire on the patient's skin perpendicular to the axis of the spine.
- Using imaging, center the Guide Wire over the cephalad-most pedicles of the motion segment to be instrumented.
- Transfer this line to the patient's skin using a surgical marker. Repeat this process for all other levels to be instrumented.
- Place the Guide Wire on the patient's skin and use imaging to align it with the lateral borders of the pedicles to be instrumented.
- Use a skin marker to transfer this line to the patient's skin. Repeat on both sides.
- Make the incision approximately 1cm lateral to the line intersections. The incision location may need to be slightly more lateral in larger patients. (FIG. 1).

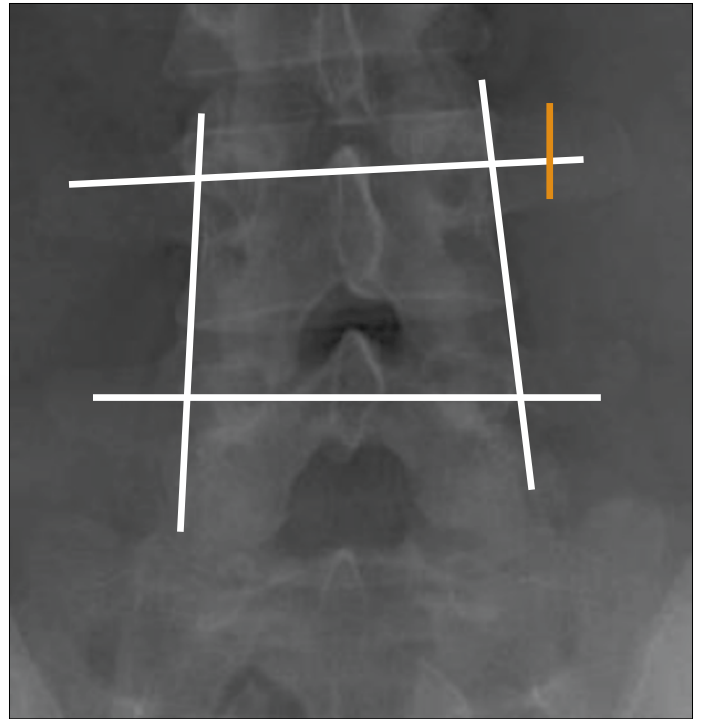


FIG. 1

Assembling the Cannulated Awl

- The Cannulated Awl consists of four parts: Shaft, Stylet, Stylet Cap and Palm Handle.
- Attach the Shaft to the Palm Handle. (FIG. 2)
- Place the Stylet through the Palm Handle and Shaft then rotate until seated. (FIG. 3)
- Screw the Stylet Cap onto the Palm Handle. (FIG. 4)



FIG. 2



FIG. 3



FIG. 4

Guide Wire Placement

The Threshold system utilizes Guide Wires to maintain surgical trajectory reference. In all ensuing steps where the Guide Wire is present, imaging should be used to ensure Guide Wire position is maintained when cannulated instruments and implants are advanced over the Guide Wire.

- Using AP imaging, advance the Cannulated Awl through the incision point until bony contact is made. (FIG. 5)
- Alter the tip position until it appears to be on the lateral edge of the pedicle. (FIG. 6)

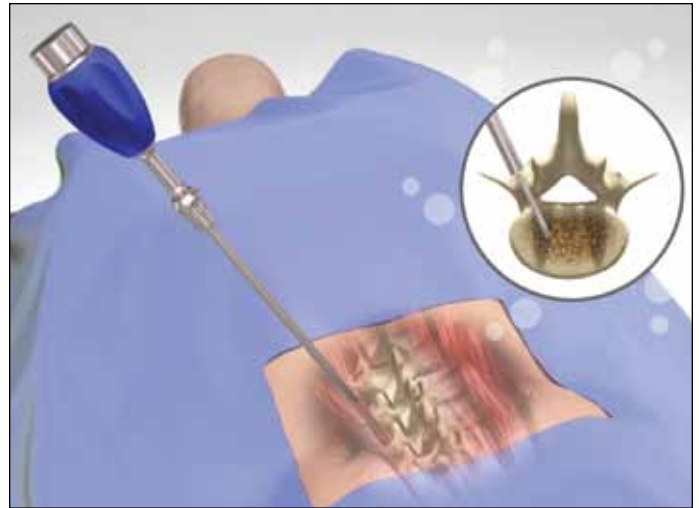


FIG. 5

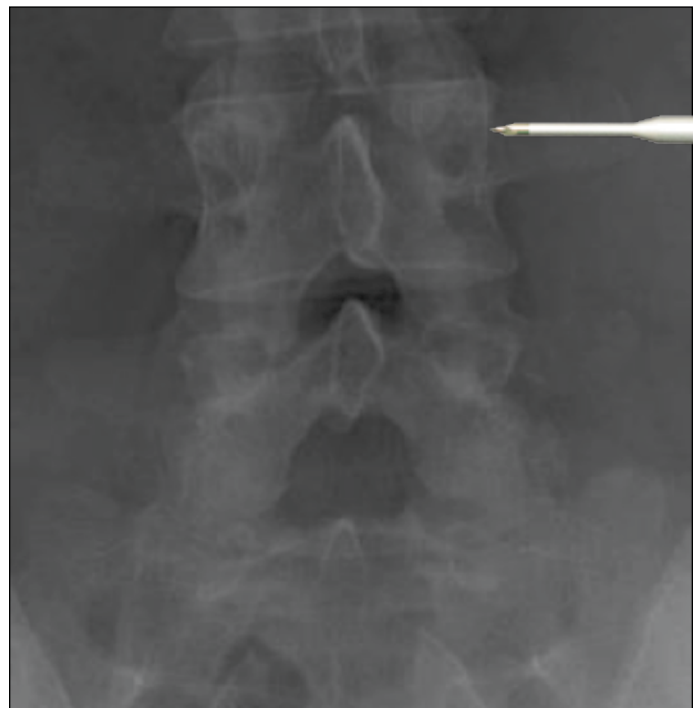


FIG. 6

Guide Wire Placement (continued)

- Revert to a lateral image and confirm that the Cannulated Awl is centered on the pedicle and the trajectory is coplanar with the pedicle axis. (FIG. 7)
- Using AP imaging, advance the Cannulated Awl into the pedicle with a slight medially directed angle. Cease advancement when the tip appears at the midpoint of the pedicle on the image. (FIG. 8)

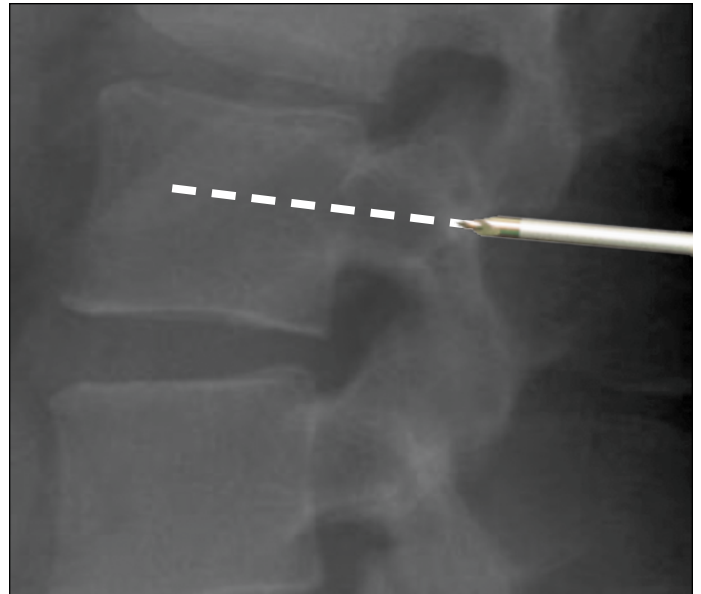


FIG. 7

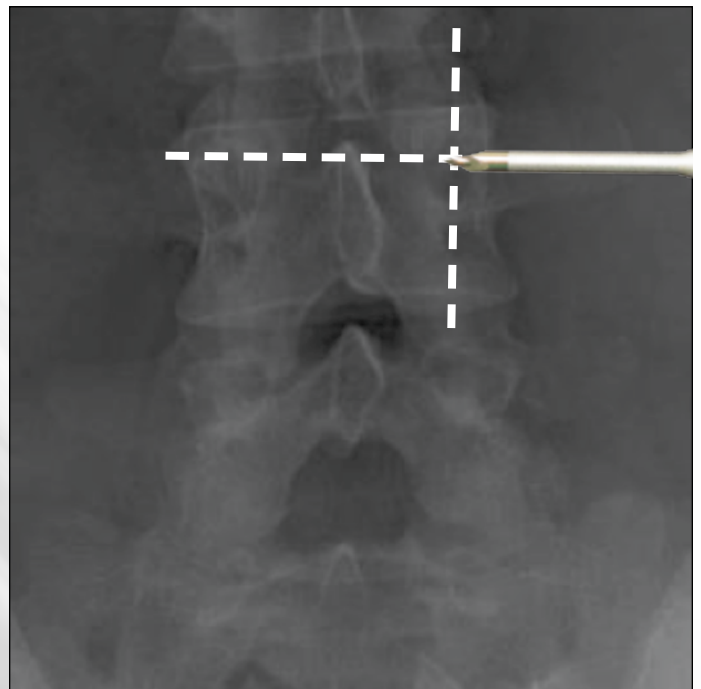


FIG. 8

- Revert to lateral imaging. If the image shows penetration into the vertebral body, the procedure can continue. If the image does not show penetration into the vertebral body, revert back to AP imaging. Extract the Cannulated Awl back to the bony entrance and re-advance with a corrected angle. Revert to lateral imaging and inspect the position again. (FIG. 9)
- Remove the inner Stylet from the Cannulated Awl and replace it with the Guide Wire. (FIG. 10)
- Advance the Guide Wire until the tip is positioned approximately two-thirds of the way across the vertebral body on the lateral image.
- Remove the Palm Handle. The Shaft is left in place and used as the 1st Dilator. (FIG. 11)

Note: *If desired, a disposable Pin Introducer is available for Guide Wire placement. In the event this is preferred, the technique for Guide Wire placement is the same with the exception that the Pin Introducer is removed following introduction of the Guide Wire.*

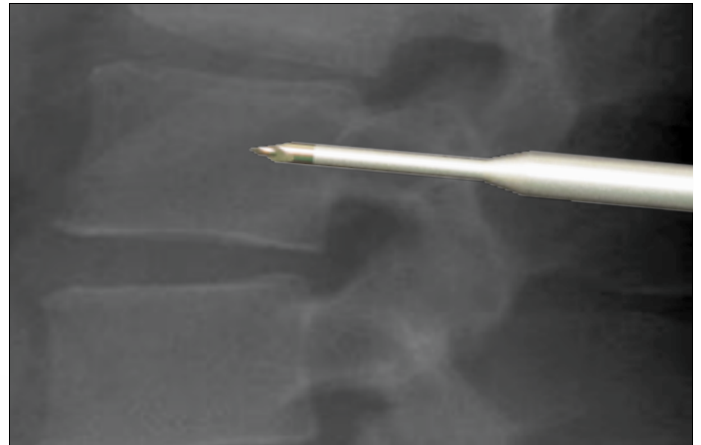


FIG. 9

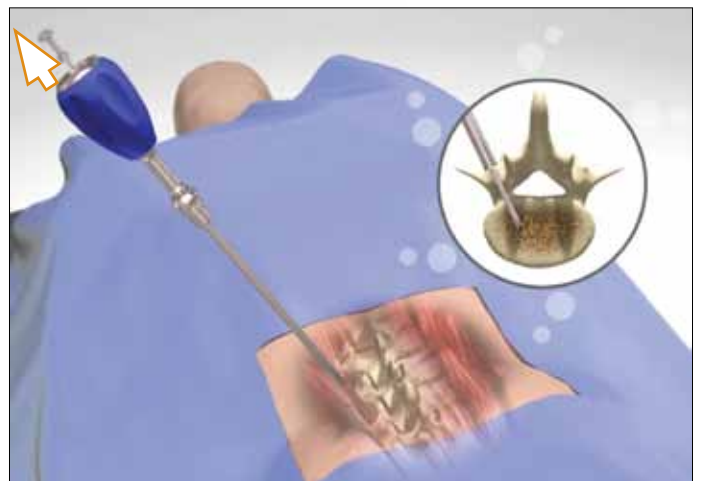


FIG. 10

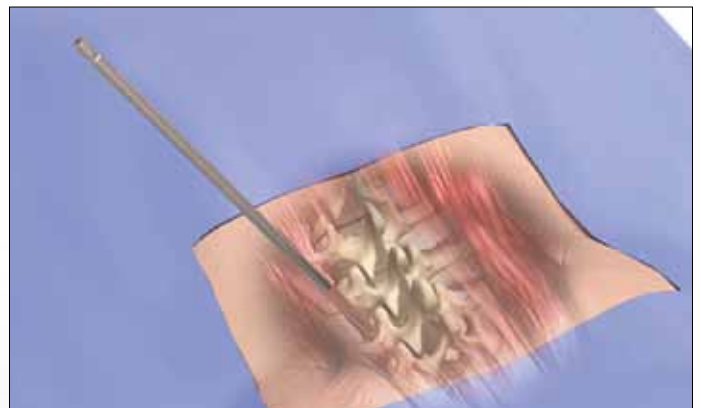


FIG. 11

Dilator Placement and Soft Tissue Dilation

- Sequentially place Dilators 2, 3 and 4, smallest to largest, over the Guide Wire and advance until bony contact is made. (FIG.12)

Note: *In the event the Pin Introducer was used for Guide Wire placement, use Dilator 1 to initiate the tissue dilation process.*

- Remove Dilators 1 and 2. Leave Dilators 3 and 4 in place to act as a tissue shield for the Tap.

Note: *Dilators 3 and 4 are constructed of plastic. This will insulate the operative site from surrounding tissues in the event EMG stimulation of the Tap and/or Pedicle Screws is desired.*

Note: *Threaded versions of Dilators 3 and 4 are available.*

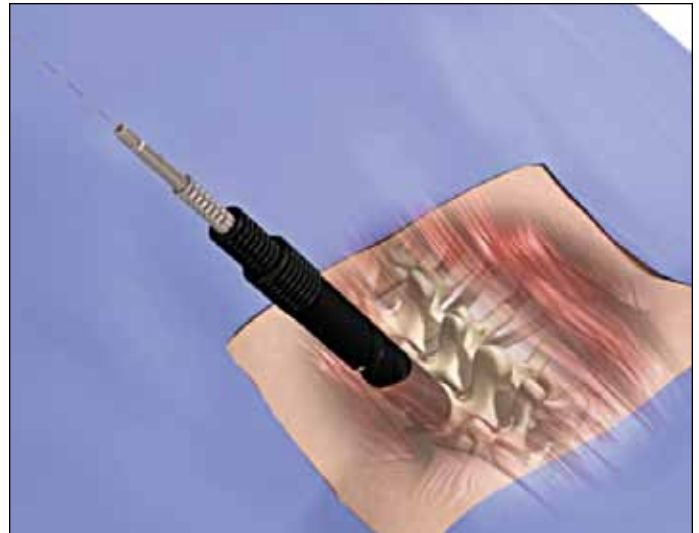


FIG. 12

Tapping

- Taps are color-coded to screw diameter.
- Select the appropriately sized Tap: 5.0, 6.0 or 7.0 mm. Advance it over the Guide Wire and through the Dilator until bony contact is made. Continue to advance the Tap to the desired depth by rotating clockwise. (FIG.13)
- Screw length can be determined by reading the etched lines and numbers on the Tap in relation to Dilator 3. (FIG. 14)
- Ensure Dilator 3 is in place, as it will insulate the Tap shaft from the surrounding tissue. Stimulate the Tap to inspect pedicle wall integrity.
- Remove the Tap and Dilator 3, leaving the Guide Wire and Dilator 4 in place.

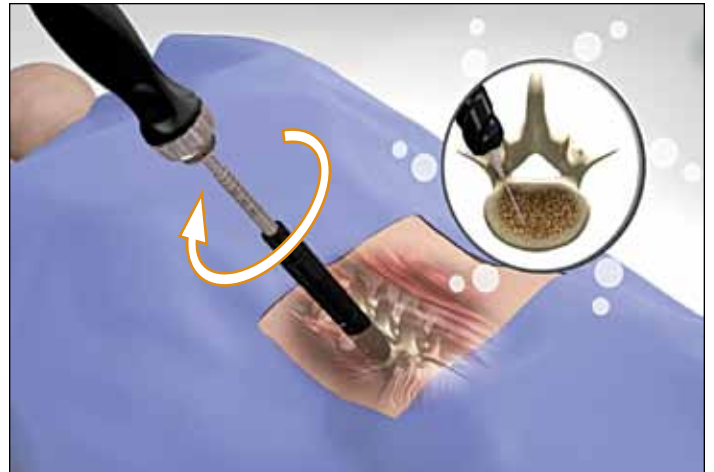


FIG. 13



FIG. 14

Screw Extension Attachment

- Both Open and Closed Screw Extensions are available to facilitate pedicle screw insertion and rod delivery.
- Insert the Extension Assembly Tool into the proximal end of the desired Screw Extension. Advance the Extension Assembly Tool until seated into the Screw Extension. (FIG. 15)
- Place the tulip head of the screw into the distal tip of the Screw Extension and push the two together. The two doors on the Screw Extension will remain open until properly inserted. (FIG. 16)
- Figure 17 shows the implant fully seated. (FIG. 17)
- Once the screw is fully seated, firmly tighten the knob at the proximal end of the Screw Extension clockwise to lock the screw to the Screw Extension. (FIG. 18)
- Remove the Extension Assembly Tool.



FIG. 15

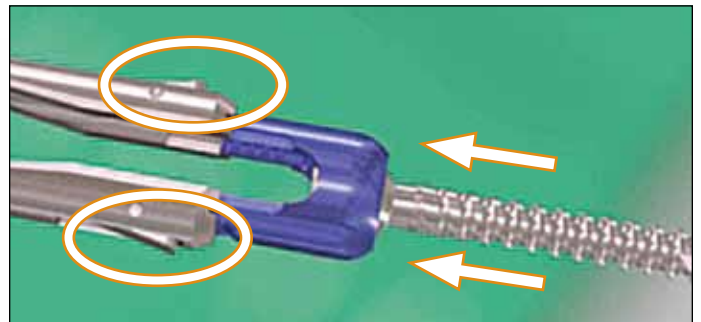


FIG. 16

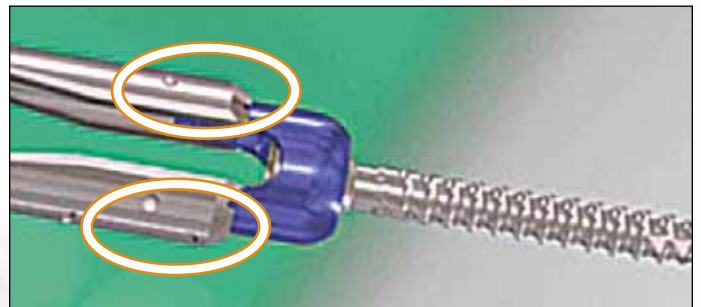


FIG. 17



FIG. 18

Pedicle Screw Placement

- Connect the Ratcheting Axial Handle to the Screw Driver.
- Place the Screw Driver into the Screw Extension. Secure the Screw Driver to the screw by seating the hex on the distal tip of the Screw Driver into the screw. Then press down and rotate the wheel on the proximal end of the Screw Driver clockwise until tight. (FIG. 19)
- Advance the assembled Screw Driver over the Guide Wire. Screw it into the pedicle by turning the Screw Driver handle clockwise. Advance the screw until the tip reaches the posterior wall of the vertebral body. (FIG. 20)
- Once the posterior wall of the vertebral body has been crossed, remove the Guide Wire to prevent it from being entrapped by the advancing screw. Advance the screw until the desired depth is achieved.
- Ensure Dilator 4 is in place to insulate the Screw Extension from surrounding tissue. Stimulate to inspect pedicle integrity.

Note: When the locking rings reach the top of Dilator 4, the distal edge of the screw head is flush with the distal end of the Dilator.

Note: Do not grasp the Screw Driver wheel during insertion. Doing so causes the Screw Driver to loosen its grip on the screw.

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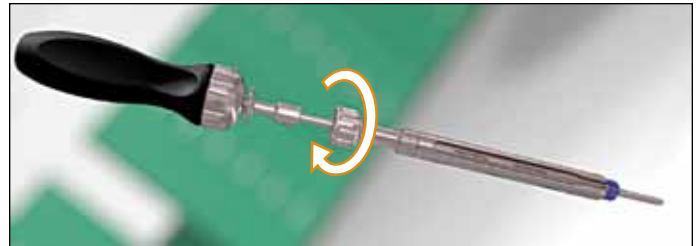


FIG. 19

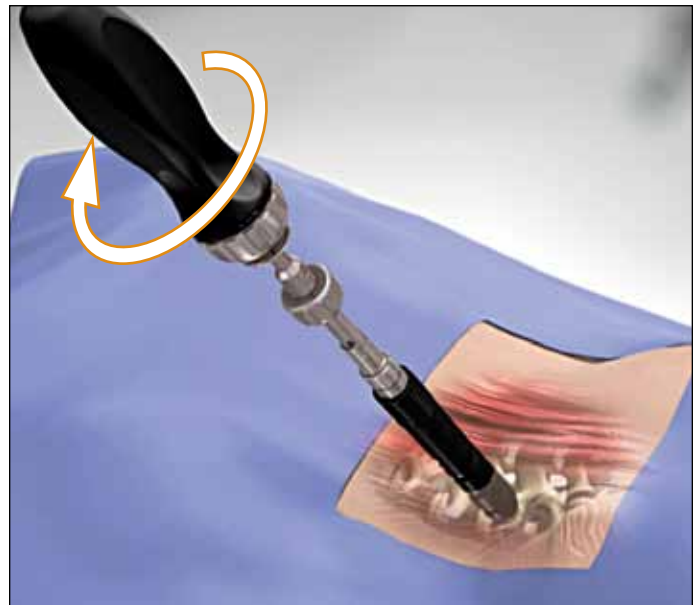


FIG. 20

Pedicle Screw Placement (continued)

- Disengage the Screw Driver from the pedicle screw and Screw Extension by rotating the wheel at the proximal end of the Screw Driver counterclockwise.
- Remove the Screw Driver and Dilator 4.
- Repeat pedicle screw placement steps for each desired location.
- When placing subsequent screws, insert them to a depth comparable to the first screw. This simplifies rod insertion and set screw placement. This can be observed either on imaging or by observing the position of the proximal ends of the Screw Extensions. When the Screw Extension ends are aligned, the screw depths are well positioned. (Fig 21)
- Minor adjustments to screw depths can be made with the Screw Adjuster.

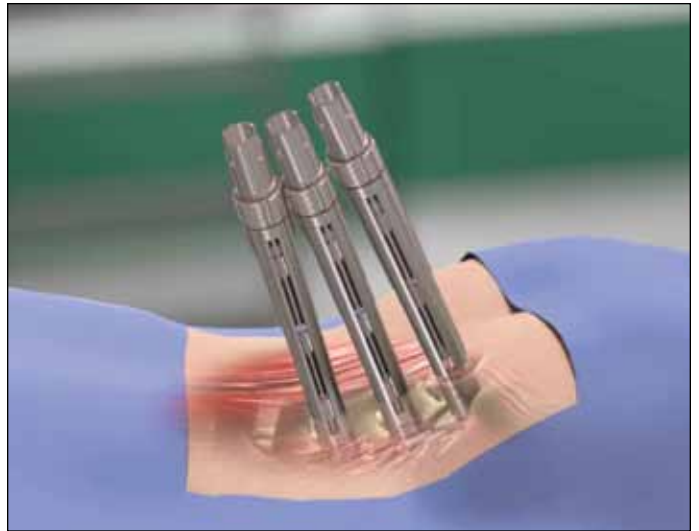


FIG. 21

Muscle Plane Spreading

- Align the Screw Extensions.
- Place the Tissue Dissector down the slot of one Screw Extension until it contacts the tulip head.
- Move the distal tip of the Tissue Dissector toward the adjacent level tulip head and angle it such that it contacts the adjacent screw head. This dissects a tissue plane and creates a pathway for rod placement. (FIG. 22)
- Repeat between each of the screws.

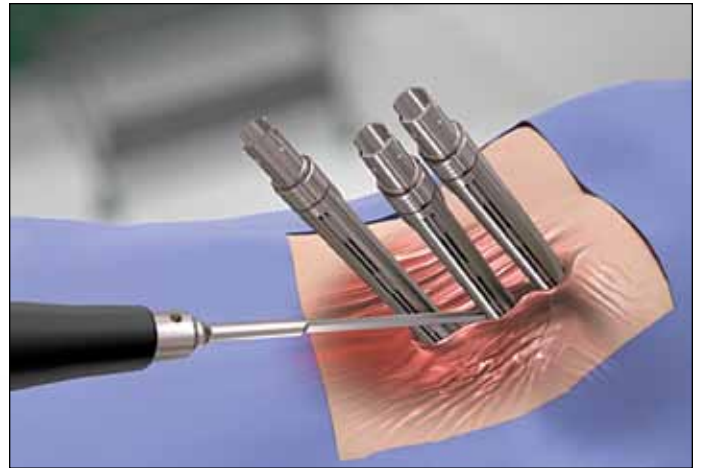


FIG. 22

Rod Measuring

- Place the Rod Measuring Caliper down the two outermost Screw Extensions. Ensure that the distal ends of the Rod Measuring Caliper are fully seated into the Screw Extensions. (FIG. 23)
- Select the appropriate rod length by reading the scale on the top of the Rod Measuring Caliper. (FIG. 24)

Note: The length indicated includes 4 mm of overhang on each end beyond the outermost screws of the construct.



FIG. 23



FIG. 24

Rod Insertion (Wiltse)

- Secure the rod in the Rod Holder.
- Advance the rod down the Screw Extensions until the rod is fully seated in the screw heads. (FIG. 25)
- Confirm desired rod position using imaging.

Note: *If an inordinate amount of pressure was required to seat the rod, remove the rod to ensure a complete dissection of the muscle has occurred and the muscle is not entrapped.*

Note: *The Screw Adjuster can be used to confirm that the rod is present in the Screw Extension. To do so, pass the Screw Adjuster through the Screw Extension. If the etch line on the Screw Adjuster shaft is seen, the rod is present within the Screw Extension.*

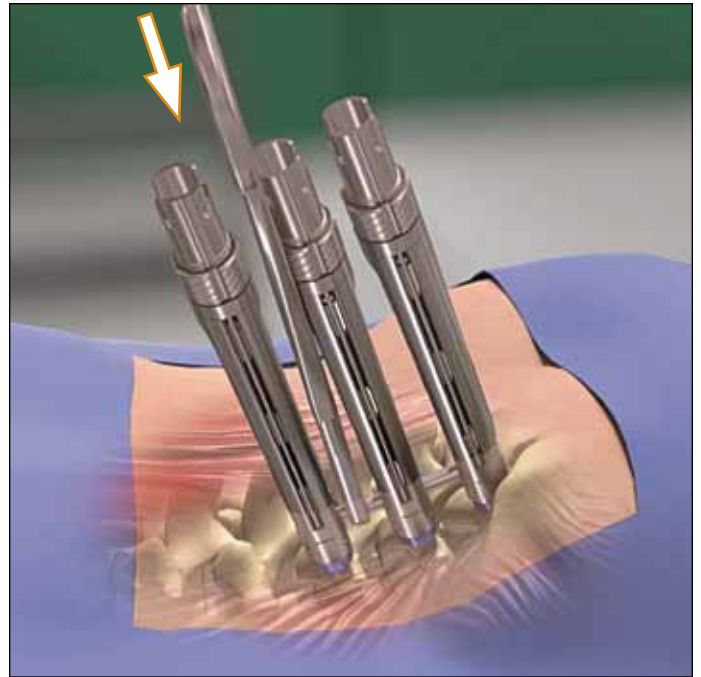


FIG. 25

Set Screw Placement

- Press a Set Screw onto the distal tip of the Set Screw Placer.
- Rotate the proximal knob to capture the Set Screw.
- Pass the Set Screw Placer through the Screw Extension. Rotate the Set Screw Placer clockwise to seat the set screw. When the etch line on the shaft of the Set Screw Placer advances below the proximal end of the Screw Extension, the Set Screw is fully seated. (FIG. 26)
- Unthread the knob to release the Set Screw and remove the Set Screw Placer.
- Repeat for all screws.

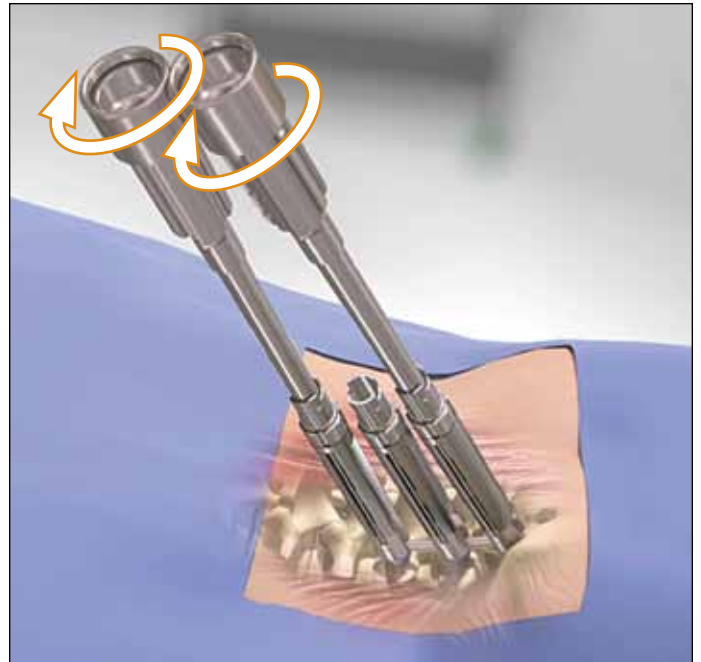


FIG. 26

Rod Reduction (optional)

There are three different instruments available for rod reduction: the External Rod Reducer, Internal Rod Reducer and Cannulated Rod Pusher.

External Rod Reducer

- Ensure the External Rod Reducer is in the start position. This is done by turning the black knob counterclockwise.
- Place the External Rod Reducer over the Screw Extension.
- Rotate the External Rod Reducer counterclockwise while pushing down until it seats in the slots on the proximal end of the Screw Extension.
- Rotate the black knob of the External Rod Reducer clockwise until the rod is fully seated. (FIG. 27)
- Use imaging to confirm the desired rod overhang is achieved at both ends.
- Load a Set Screw on the Set Screw Placer. Pass the assembly through the External Rod Reducer.
- Provisionally tighten the Set Screw. (FIG. 28)
- Release the Set Screw Placer from the Set Screw.
- Remove the External Rod Reducer by rotating the black knob counterclockwise until it is again in the start position. Remove.

Note: The External Rod Reducer offers 32 mm of reduction capability.

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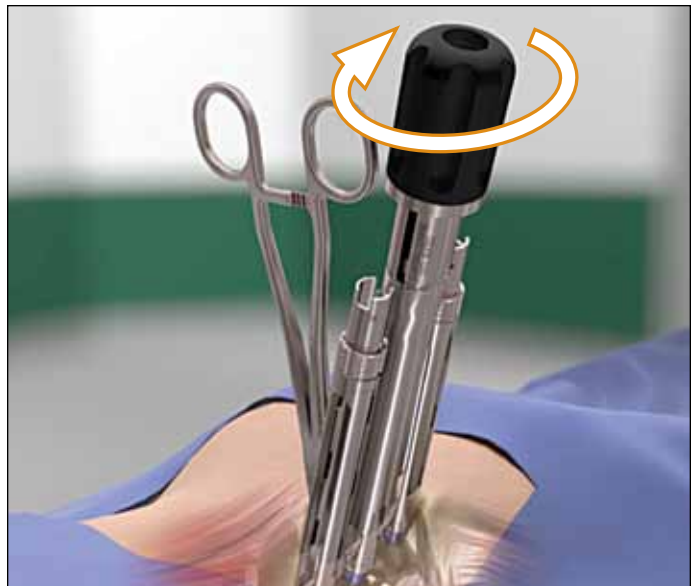


FIG. 27

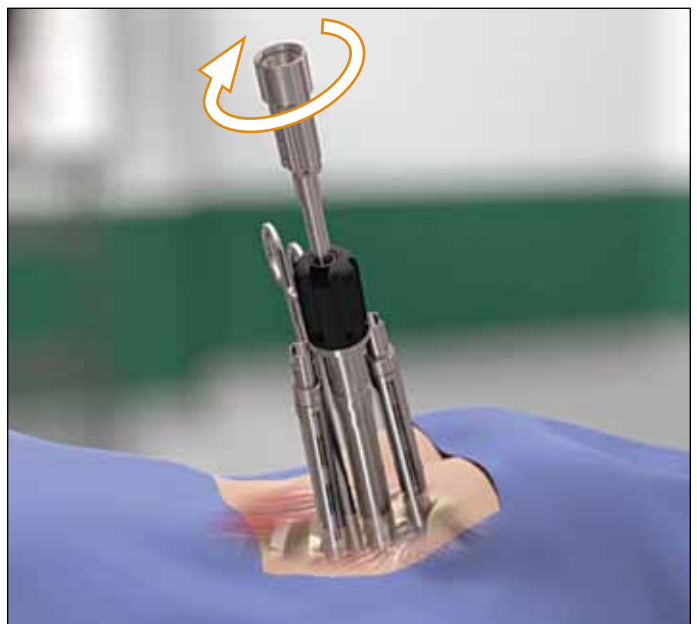


FIG. 28

Rod Reduction (optional) (continued)

Internal Rod Reducer

- Connect the Internal Rod Reducer to an Axial Handle.
- With the locking cap in the unlocked position and the threaded rod in its proximal location, insert the Internal Rod Reducer through the Screw Extension adjacent to where the Set Screw is to be placed.
- Rotate the Internal Rod Reducer until it engages the slots in the Screw Extension.
- To secure the locking cap of the Internal Rod Reducer onto the Screw Extension, push down and rotate the cap clockwise to the “lock” position. (FIG. 29)
- Rotate the threaded rod clockwise to drive the rod until it is fully seated. (FIG. 30)

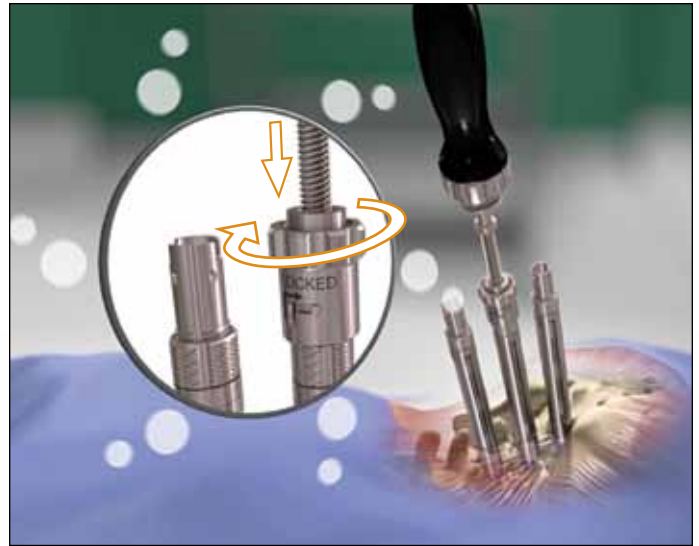


FIG. 29

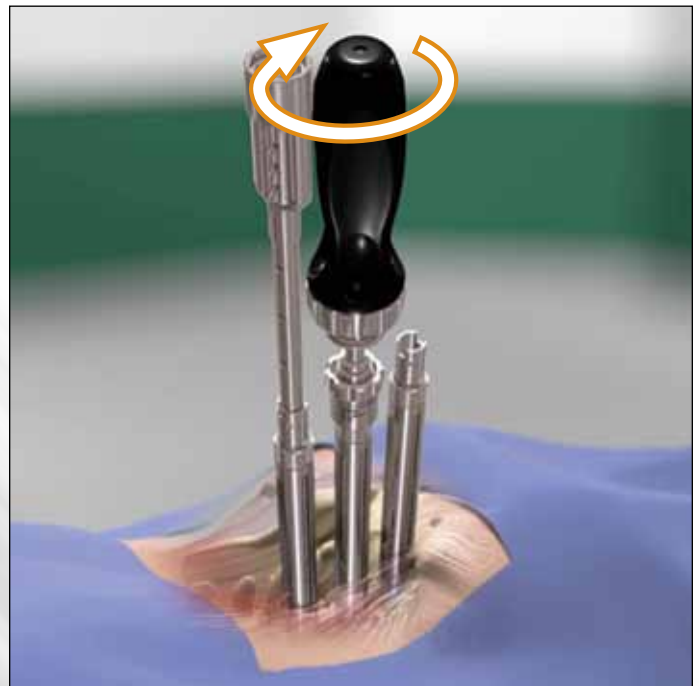


FIG. 30

- Use imaging to confirm the desired rod overhang is achieved at both ends.
- Place Set Screw in the adjacent screw. **(FIG. 31)**
- Remove Set Screw Placer and Internal Rod Reducer.

Note: *If operating at more than one level, place set screws on either side of Internal Rod Reducer prior to removal.*

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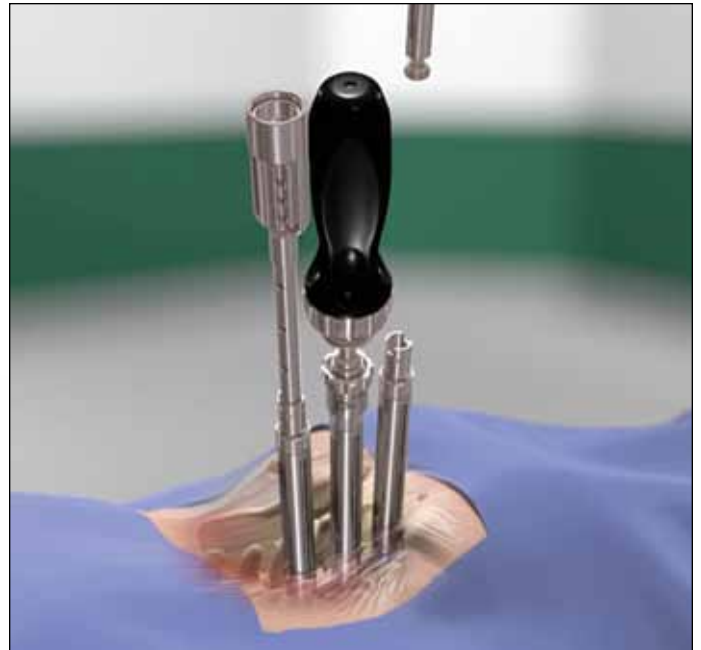


FIG. 31

Rod Reduction (optional) (continued)

Cannulated Rod Pusher

- Pass the Cannulated Rod Pusher over the Screw Extension until it contacts the rod and then push down.
- Load a Set Screw on the Set Screw Placer. Pass the assembly through the Screw Extension.
- Use imaging to confirm the desired rod overhang is achieved at both ends.
- Provisionally tighten the Set Screw. **(FIG. 32)**
- Release the Set Screw Placer from the Set Screw.
- Remove the Set Screw Placer and Cannulated Rod Pusher.

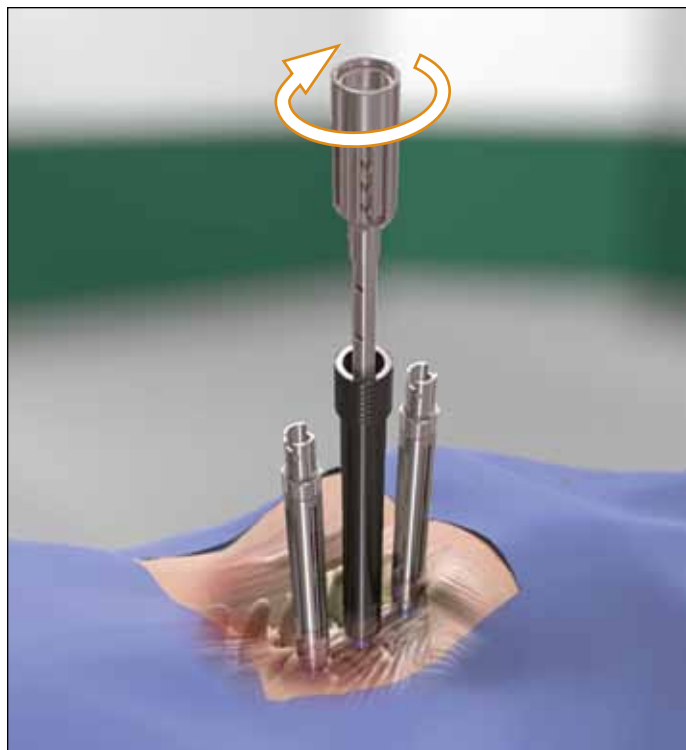


FIG. 32

Compression/Distraction (optional)

Compression

- Fully tighten one of the Set Screws with the Final Driver and Counter Torque (see page 24 for instructions on Final Tightening). This will provide a solid location for compression or distraction. **(FIG. 33)**
- Place the Extension Pivot shaft into the Screw Extension that has the final tightened Set Screw.
- Rotate the adjustment nut to accommodate the positions of the Screw Extensions.
- Seat the Extension Pivot locking cap onto the other Screw Extension.
- Rotate the Extension Pivot until it engages the slots in the Screw Extension.
- To secure the locking cap onto the Screw Extension, push down and rotate the cap clockwise to the “lock” position. **(FIG. 34)**

(Continued on the next page.)

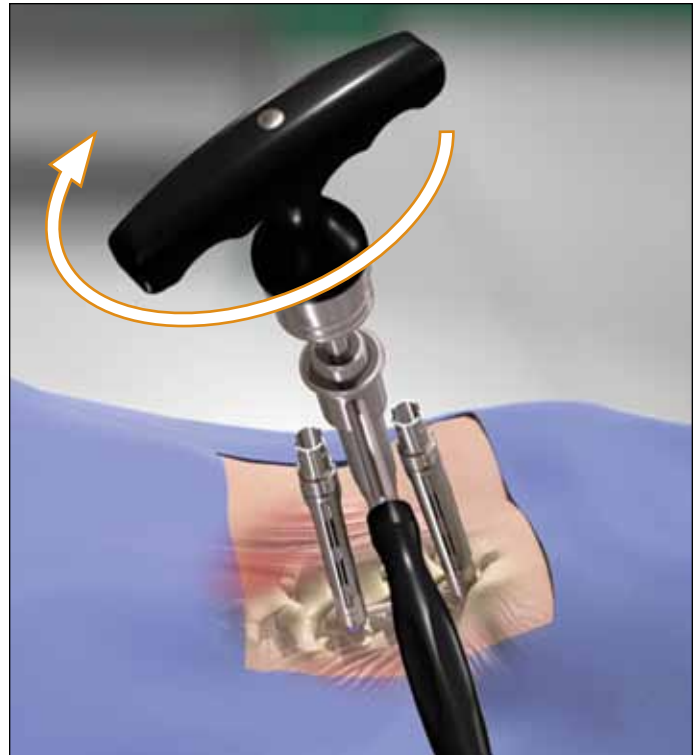


FIG. 33

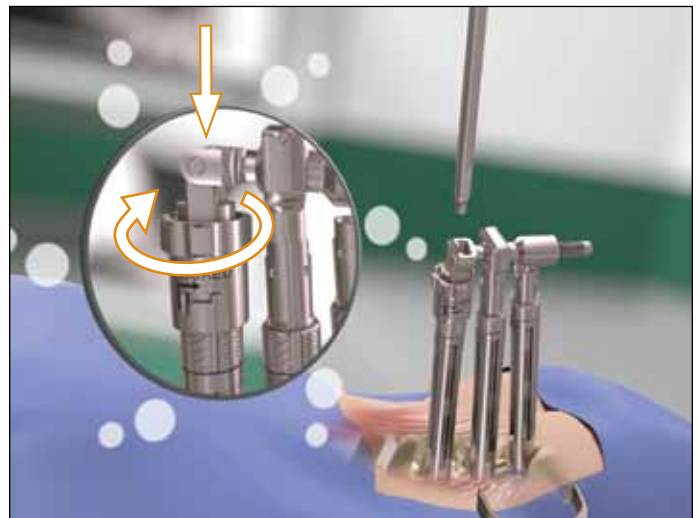


FIG. 34

Compression/Distraction (optional) (continued)

- Place the Compressor around the Screw Extensions as close to the skin as possible.
- Insert the Final Driver through the Screw Extension with the Pivot Locking Cap and into the Set Screw to be tightened.
- Compress the extensions to the desired level.
(FIG. 35)
- Provisionally tighten the Set Screw with the Final Driver but do not apply final torque.
- Remove the Extension Pivot and perform final tightening with the Counter Torque.



FIG. 35

Distraction

- Follow the steps above relative to attachment and use of the Extension Pivot.
- Place the Distractor between the Screw Extensions as close to the skin as possible.
- Insert the Final Driver through the Screw Extension with the locking cap and into the Set Screw to be tightened.
- Distract the extensions to the desired level. (FIG. 36)
- Provisionally tighten the Set Screw with the Final Driver but do not apply final torque.
- Remove the Extension Pivot and perform final tightening with the Counter Torque (see page 21 for instructions on final tightening).

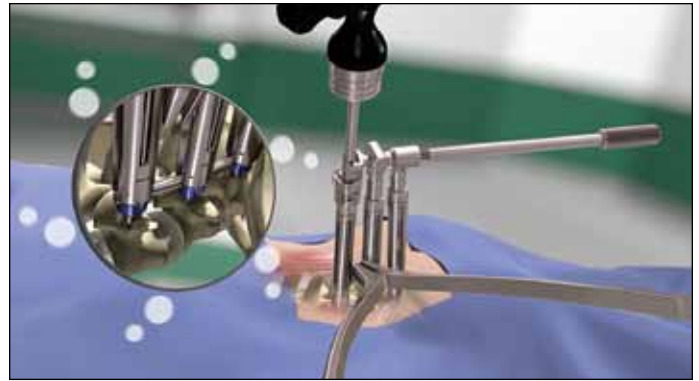


FIG. 36

Final Tightening

- Place the Counter Torque on a Screw Extension. The Counter Torque is fully seated when it will no longer rotate. (FIG. 37)

Note: It is possible to change the handle location of the Counter Torque by pulling up on the handle and moving it to the desired location.

- Insert the Final Driver through the Counter Torque and into the Set Screw.
- Hold the Counter Torque and rotate the Final Driver until an audible click is heard. (FIG. 38)
- Remove the Final Driver and the Counter Torque. Repeat for each screw.

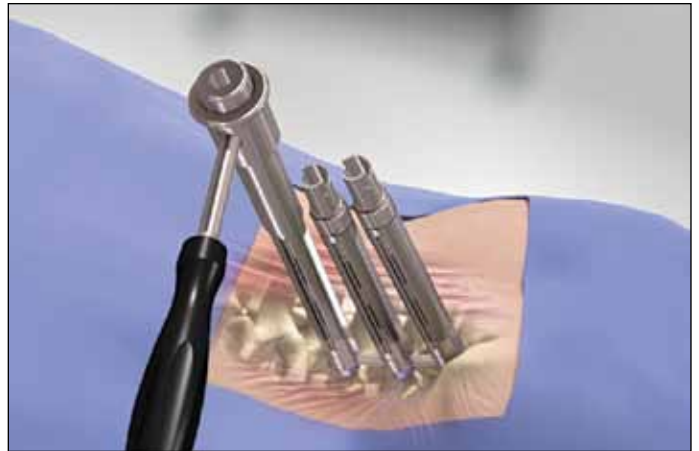


FIG. 37

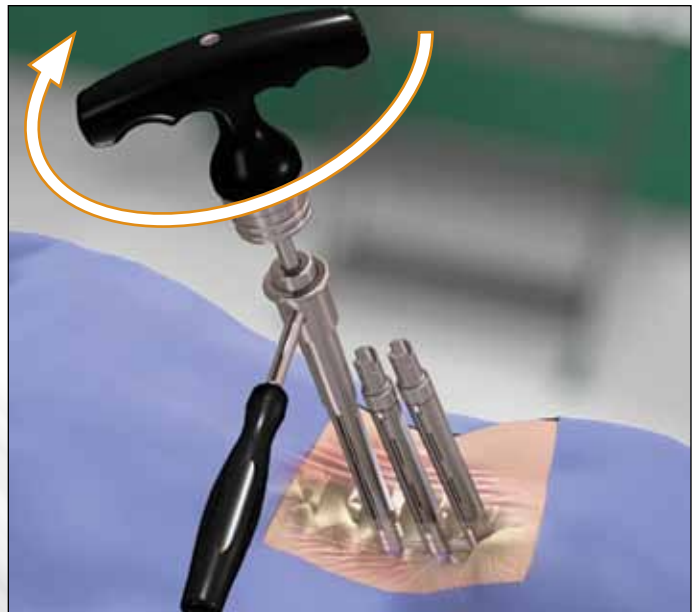


FIG. 38

Screw Extension Removal

- Rotate the knob at the proximal end of the Screw Extension counterclockwise until it stops. Remove the Screw Extension, leaving the final construct in place. (FIG. 39)

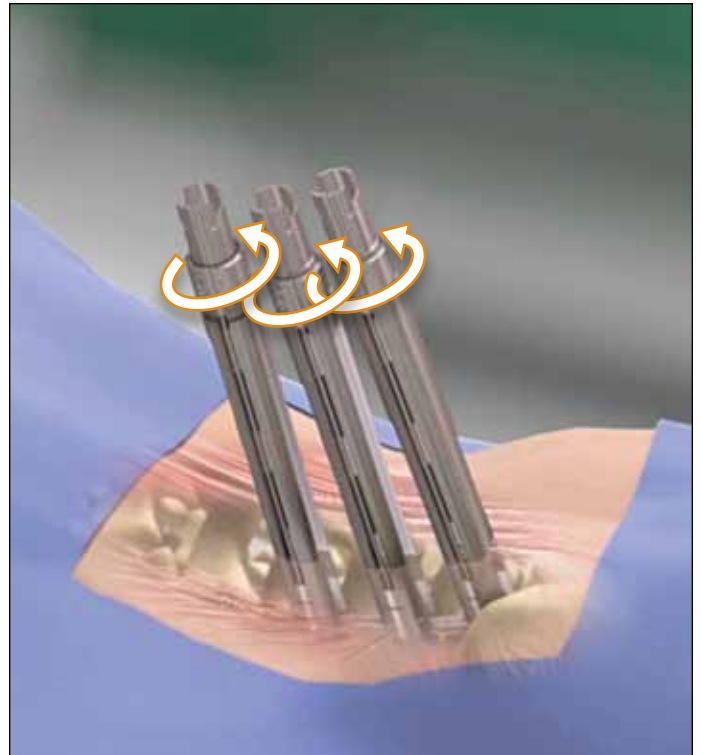


FIG. 39

Appendix A:

Screw Extension Reattachment

In the event a Screw Extension has been removed and reattachment is desired, a Reattachment Tool is provided.

Reattachment Prior to Rod Insertion:

- Pass the “Screw” end through the tissue and into the screw head. Ensure the small hex engages into the screw.
- Slide the Screw Extension over the Reattachment Tool until it contacts the screw head.
- Pass the largest Dilator over the Screw Extension and screw head until it contacts bone.
- Apply slight downward pressure to the Screw Extension and Reattachment Tool.
- Rotate the Screw Extension until it provisionally seats.
- Continue to push down on the Screw Extension and pull up on the Dilator. This allows the Screw Extension to fully seat and the locking tabs to engage into the screw head.
- Re-lock the Screw Extension.

Note: *If the Screw Extension was removed after rod insertion and prior to Set Screw placement, it is necessary to remove the rod and utilize the above instructions to reattach the Screw Extension.*

Reattachment with Rod and Set Screw Inserted:

- Pass the “Set Screw” end through the tissue and into the Set Screw.
- Repeat the steps as described above.

Appendix B: Revision and Removal

Insert the hex portion of the Set Screw Driver shaft into the Set Screw(s) of the pedicle screw(s) to be removed. Attach the Ratcheting Handle to the opposite end of the Set Screw Driver shaft and adjust the handle to permit the counterclockwise rotation of the Set Screw(s). Fully extract the Set Screw(s) by turning in a counterclockwise direction. Using the Rod Gripper, lift out the rod from the screw heads of all pedicle screws to be removed. Be certain to fully seat the Hex Handle to the opposite end of the Hex Screw Driver shaft and adjust the handle to permit the counterclockwise rotation of the pedicle screw(s). Fully extract each pedicle screw from the vertebral body by turning in a counterclockwise direction. Take post-procedure radiographs to assure that all hardware has been removed. Explanted components should be properly discarded and not used for re-implantation.

Appendix C:

Threshold™ Pedicular Fixation System

Instrument Case 1

CATALOG #	DESCRIPTION
530-0002	Cannulated Awl Shaft
530-0003	Awl Stylet
530-0004	Awl Stylet Cap
530-0005	Awl Handle
530-0020	Open Extension
530-0019	Extension Assembly Tool
530-0021	Closed Extension
530-0042	Ratcheting T-Handle
530-0012	Dilator 1
530-0013	Dilator 2
530-0014	Dilator 3 (threaded)
530-0015	Dilator 3
530-0016	Dilator 4
530-0017	Dilator 4 (threaded)
530-0027	Rod Holder
530-0032	Rod Caliper
530-0025	Tissue Dissector
530-0010	Guide Wire (threaded)
530-0009	Guide Wire (non-threaded)
530-0011	Guide Wire Dispenser

Instrument Case 2

CATALOG #	DESCRIPTION
530-0050	5.0 mm Tap
530-0060	6.0 mm Tap
530-0070	7.0 mm Tap
530-0041	Ratcheting Axial Handle
530-0023	Screw Driver
530-0026	Tower Alignment Tool
530-0024	Screw Adjuster
530-0033	Extension Pivot
530-0044	Counter Torque
530-0045	Rod Bender
530-0046	Compressor
530-0031	Reducer
530-0047	Distractor
530-0043	Final Driver
530-0040	Internal Rod Reducer
530-0037	Set Screw Placer
530-0006	Cannulated Rod Pusher
530-0036	Extension Reattachment
530-0034	Counter Torque

Indications for Use/Intended Use

The Spinal System is a posterior, non-cervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the Spinal System is intended for skeletally mature patients with severe spondylolisthesis (grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebra, who are receiving fusion by autogenous bone graft only, who are having the device attached to the lumbar and sacral spine (levels may be from L3 to the sacrum/ilium), or who are having the device removed after the attainment of a solid fusion.

Contraindications

Contraindications for the Spinal System are similar to those of other systems of similar design and

include, but are not limited to:

- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Morbid obesity
- Pregnancy
- Grossly distorted anatomy (e.g., congenital abnormalities) and bone abnormalities (e.g., bone absorption, osteopenia, or osteoporosis)
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- Suspected or documented metal allergy or intolerance

Warnings

- The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation scoliosis, kyphosis, spinal tumor and failed previous

fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

- Some degree of corrosion occurs on all implanted metal and alloys. Mixing of dissimilar metals can accelerate the corrosion process. Different manufacturers use different materials, varying tolerances and design configurations. Components of the Spinal System should not be used with components from any other system or manufacturer. Instruments may be used until they become dull or there is an unacceptable level of pitting, corrosion, discoloration or other deterioration.

Precautions

The Spinal System should only be implanted by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. In addition, based on the fatigue test results, the surgeon should consider the levels of implantation, patient weight, patient activity level and other patient conditions (e.g., smoking, occupation) which may impact on the performance of the system.

Federal law (USA) restricts this device to sale by or on order of a physician.

Threshold™ implants and instruments for this procedure are patent pending.

Spineology, the innovator in anatomy-conserving spine surgery, develops surgical techniques, instruments and implants that conserve spinal bone, nerve and muscle tissues. Spineology is committed to increasing procedural efficiency, reducing surgical morbidity and accelerating patient recovery. Learn more at spineology.com.



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