
Kalitec

# CosmoLock®

## Pedicle Screw System

## MIS SURGICAL TECHNIQUE GUIDE


# About Kalitec

At Kalitec, we translate our passion for product development with relentless commitment and attention to detail to create the next successful product. We conduct business to ensure the highest standard for product quality, abidance to ethical conduct, and compliance with government regulations in order to continually improve product and process efficacy, safety, and cost containment objectives currently impacting our industry.

**Kalitec Medical**

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# CosmoLock®
## Pedicle Screw System
# MIS

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# INTRODUCTION

### Description:

The Kalitec CosmoLock Pedicle Screw System is used as a non-cervical spinal fixation device 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: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The CosmoLock Pedicle Screw System is comprised of various types and sizes of screws, rods, and connectors. The implant components are selected for the individual case, being placed in a variety of configurations. The CosmoLock Pedicle Screw System is made from medical implant grade titanium alloy Ti-6Al-4V (ELI) per ASTM F-136, and cobalt chrome alloy per ASTM F-1537.

### Caution:

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

**All implants are intended for single use only. The CosmoLock Pedicle Screw System should not be reused under any circumstances.** Do not use the CosmoLock Pedicle Screw System components in conjunction with components from any other system or manufacturer. These instructions are designed to assist in the use of the CosmoLock Pedicle Screw System and are not a reference for surgical techniques.

### Indications:

The CosmoLock Pedicle Screw System is 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 thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

The CosmoLock Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudarthrosis; and failed previous fusion.

### Contraindications:

- Acute or chronic infectious diseases of any etiology and localization
- Signs of local inflammation
- Open wounds
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Metal/polymer sensitivity/allergies to the implant materials
- Mental illness, alcoholism, drug abuse
- Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis).
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Symptomatic cardiac disease.
- Systemic or terminal illness.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

### Possible Adverse Events:

A listing of possible adverse events includes, but is not limited to:

- Bending, disassembly, or fracture of any or all components of the implant.
- Loosening of the implant.
- Implant material sensitivity, or allergic reaction to a foreign body.
- Infection, early or late.
- Decrease in bone density due to stress shielding.
- Increased biomechanical stress on adjacent levels.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by


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improper positioning and placement of implants or instruments.

- Loss of correction, curvature, height, and/or reduction.
- Dural tear and/or leak.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems (i.e. pulmonary embolism, bronchitis, pneumonia, etc.).
- Non-union (or pseudarthrosis), delayed union and/or mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function.
- Death.

***Note:*** *Re-operation or revision may be necessary to correct some of these anticipated adverse events.*

## Warnings and Precautions:

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

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 degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. The implantation of the CosmoLock Pedicle Screw System should be performed only by experienced spine surgeons with specific training in the use of spinal pedicle screw instrumentation because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, etc. which may impact the performance of the system. The CosmoLock Pedicle Screw System has not been evaluated for safety and compatibility within the MR environment. The CosmoLock MIS Spinal System has not been tested for heating or migration in the MR environment.

***PHYSICIAN NOTE:*** *Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.*

***CAUTION:*** *The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.*

# SURGICAL TECHNIQUE

## Patient Positioning and Skin Marking

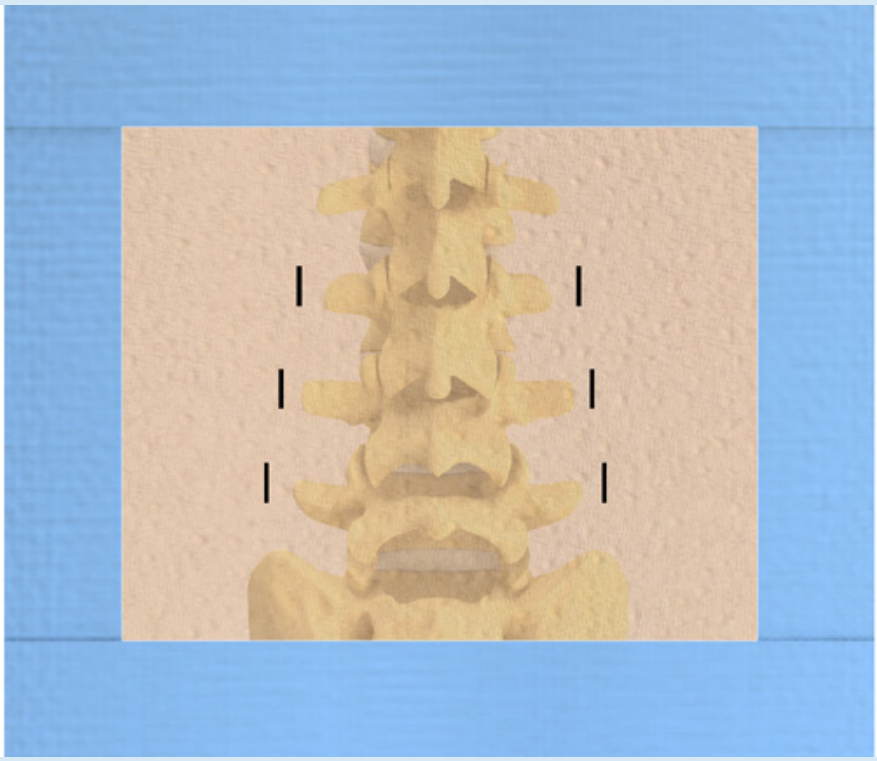

*Figure 1*

***Step 1:***

a. Place patient in the prone position.

b. Identify the appropriate level(s) to be instrumented using intraoperative imaging.

c. Using fluoroscopy, locate and mark the skin incision entry points required for targeting each based on the patients anatomy.

d. Make an incision in the skin (and fascia, if desired) at the markings in the transverse orientation approximately 15mm in length.



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## Pedicle Targeting

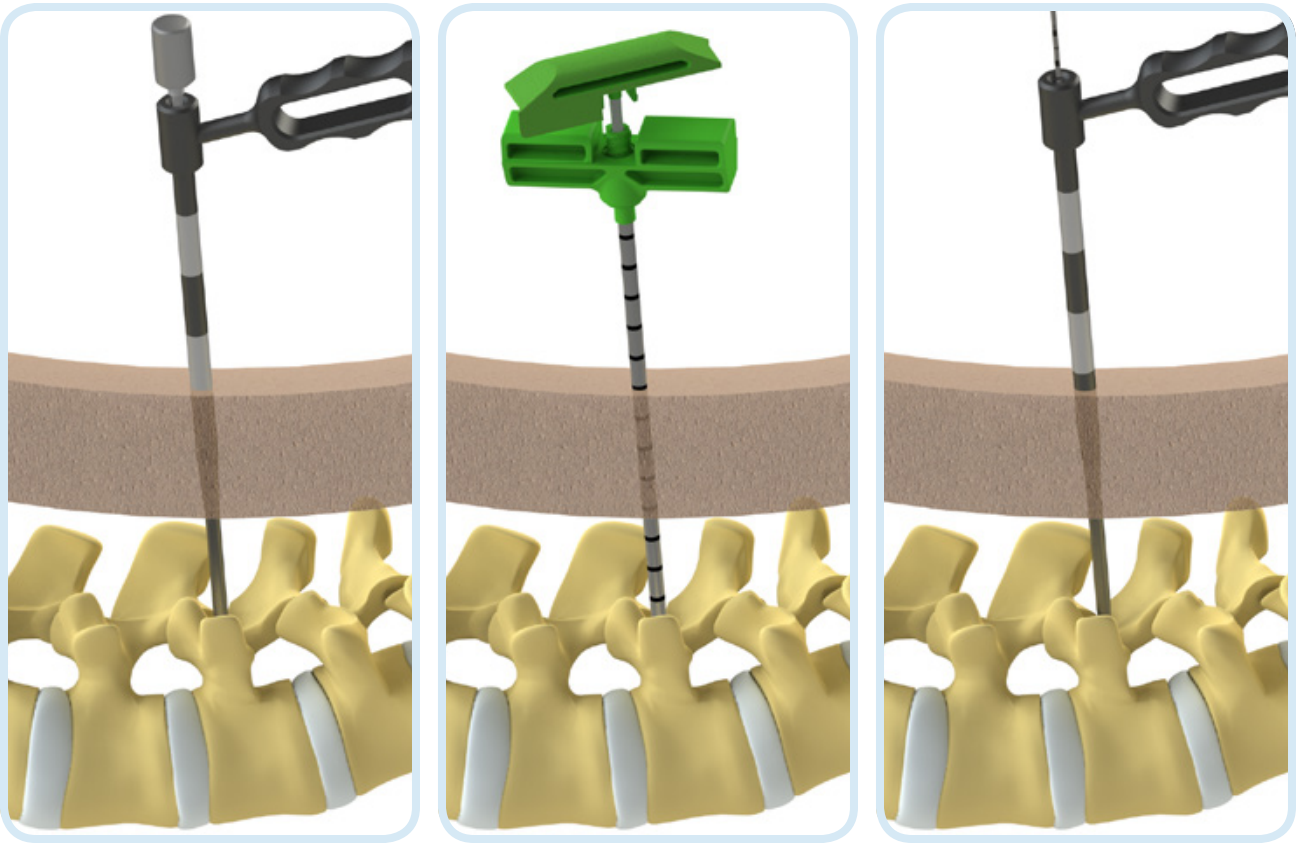


*Figure 2*

***Step 2:***

a. Insert either the Bevel or Diamond Stylet into the Targeting Needle Handle and turn Stylet clockwise until completely seated in the handle.

***Note:*** *You may also use an Aspiration Needle in place of the Targeting Needle.*

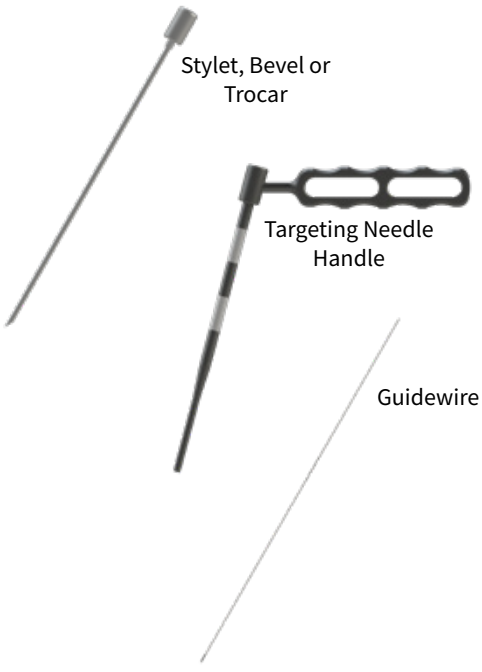
b. Using Fluoroscopy, insert the Targeting Needle through incision and "dock" on bone at the intersection of the facet joint and the transverse process, approximately around the lateral aspect of the pedicle. First verify proper trajectory, then advance the Needle to the desired depth. 20mm bands located along the shaft of the needle can be used as a reference for depth into the pedicle.

***Note:*** *Use caution to avoid breaching the pedicle and encroaching upon the spinal canal or neural foramen.*

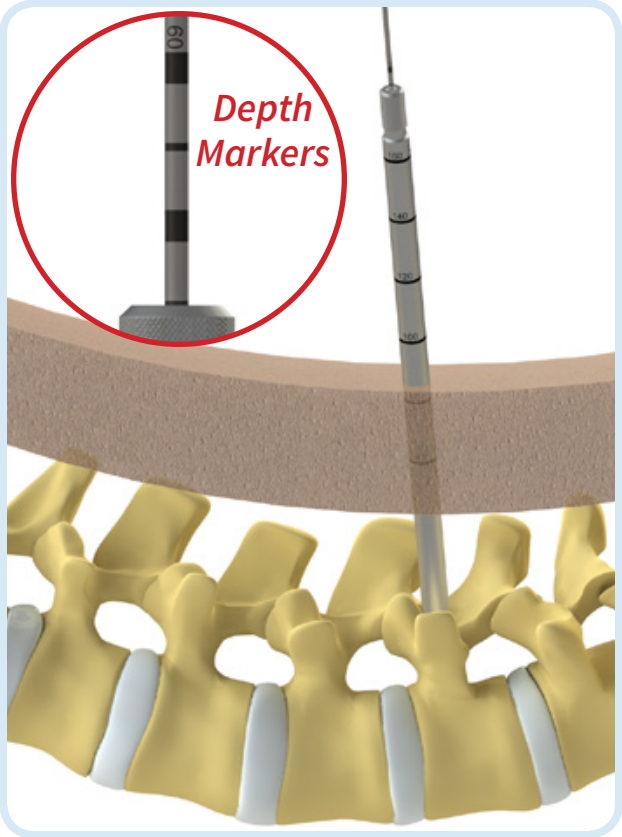
c. Remove the stylet and insert Guidewire to the desired depth.

***Note:*** *Use of instrumentation on patients with very hard bone may lead to damage of the instrument or implant.*

INSTRUMENTS



## Sequential Dilation



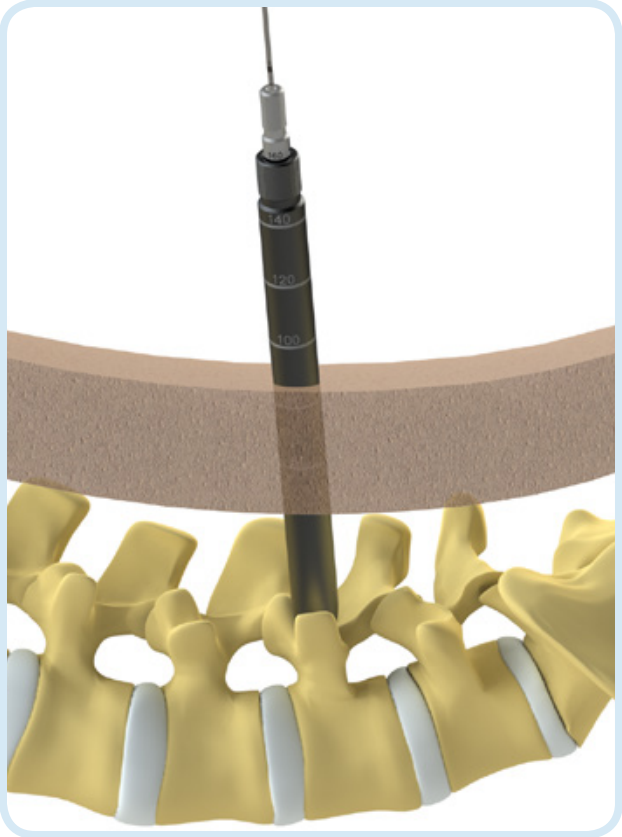



*Figure 3*

***Step 3:***

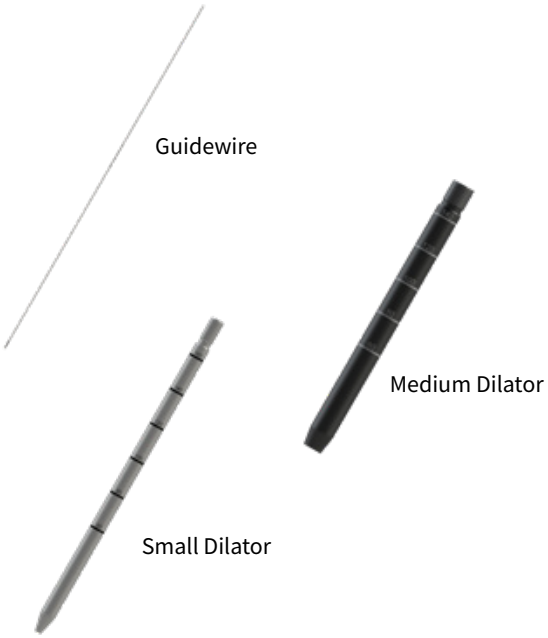
a. Insert the Small Dilator over the Guidewire while holding it steady.

***Note:*** *Guidewire has depth marking that illustrates approximate depth into bone. Reference depth markers while using Small Dilator only.*

b. Verify Guidewire depth fluoroscopically. Use the proximal end of the Targeting Needle Handle and depth markers on the Guidewire to determine Screw length.

c. Insert the Medium Dilator over the Guidewire and Small Dilator. Remove the Small Dilator once the Medium Dilator is positioned.

INSTRUMENTS



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## Tapping

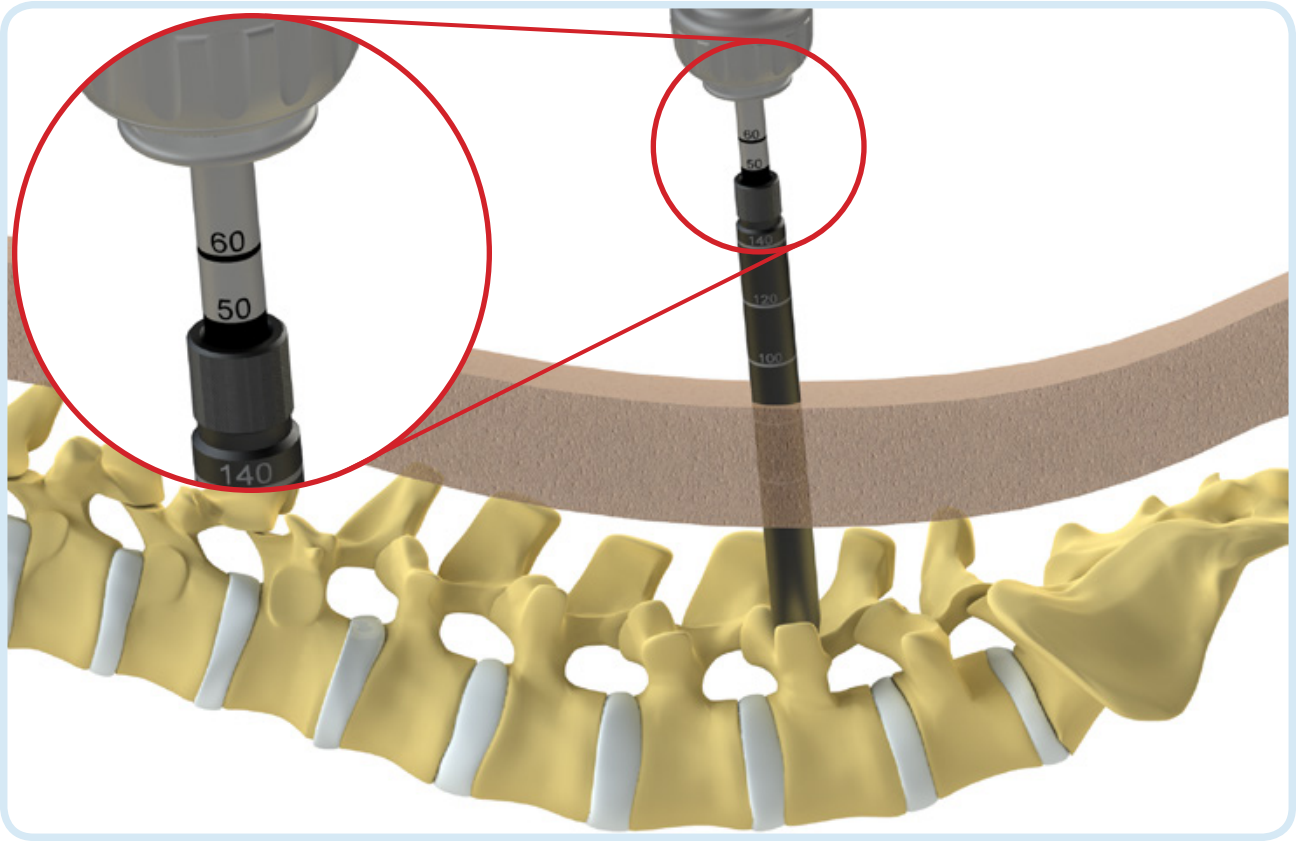



*Figure 4*

***Step 4:***

a. Connect either the Ratcheting Egg or T-Handle to the desired Cannulated Tap. Taps are undersized 0.5mm from the corresponding screw diameter.

b. Insert the Cannulated Tap over the Guidewire and through the Medium Dilator.

c. Tap to the desired depth while maintaining position and depth of Guidewire.

***Note:*** *Use caution to not advance the guidewire further while tapping.*

d. Depth markers on the top relative to the proximal end of the medium dilator indicate depth past the distal end of the dilator.

***Note:*** *Reference depth markers on Tap while using the Medium Dilator only.*

***Note:*** *Extreme under tapping is not recommended due to the potential of screw breakage or instrument damage.*

INSTRUMENTS

## Screw Loading

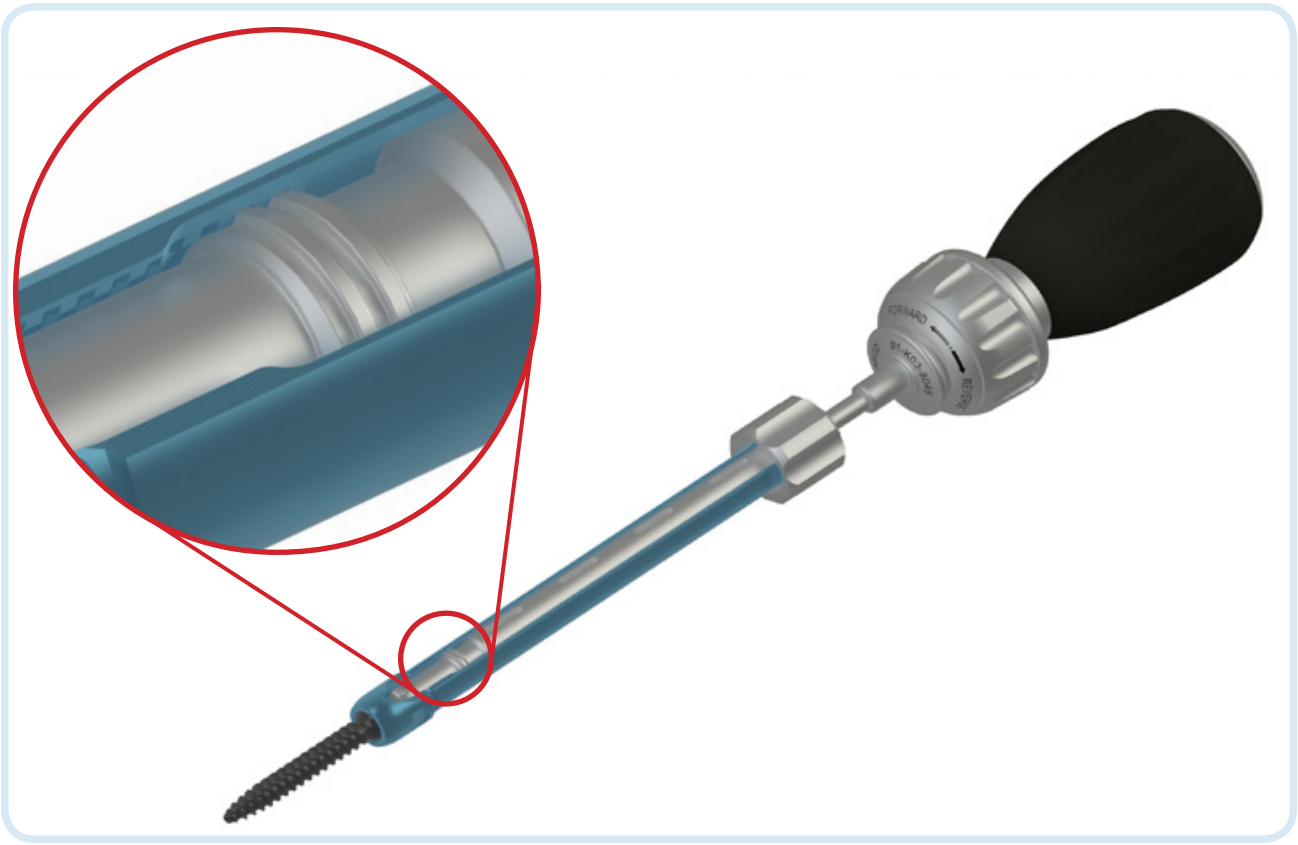


*Figure 5*

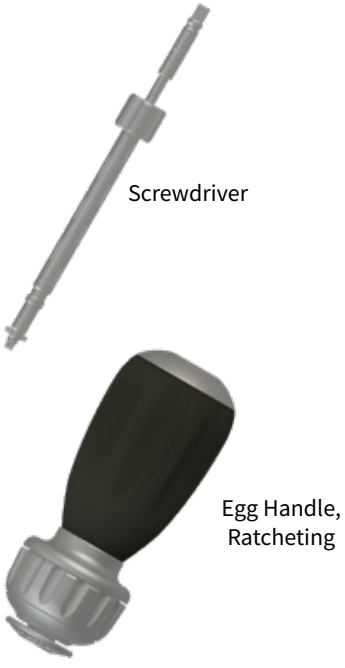
***Step 5:***

a. Assemble the Ratcheting Egg Handle to the Screwdriver. Turn the Handle to the “neutral” or “reverse” position.

b. Place Screwdriver tip into the Screw. Hold the Screw saddle below the break-off point. Push the knob toward the Screw and turn clockwise to engage threads into Screw. When fully tightened, the Screw towers should seat in the hollow portion on the underside of the knob.

c. To ensure the Screw is firmly attached to the Screwdriver, hold the knob and turn the handle counter clockwise.

INSTRUMENTS



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## Screw Insertion

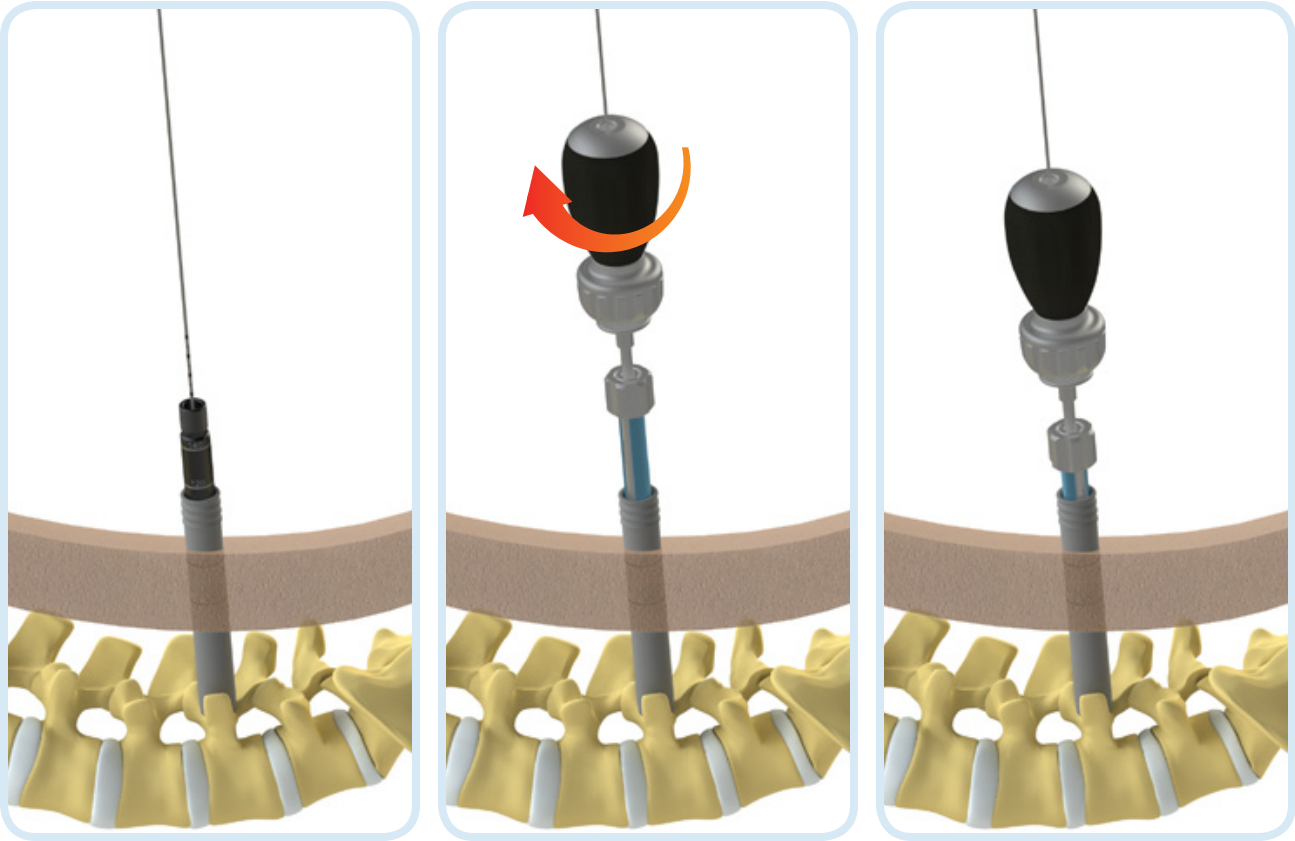


*Figure 6*

***Step 6:***

a. Insert the Large Dilator over the Guidewire and Medium Dilator. Remove the Medium Dilator.

b. Initiate the ratcheting function of the Egg Handle to the "forward" position.

c. Insert the Screw over the Guidewire and through the Large Dilator.

d. To insert the Screw into the pedicle, apply a slight downward pressure and rotate the Egg Handle clockwise until the Screw is seated properly. Periodically use fluoroscopy to verify the Screw is following the desired trajectory.

***Note:*** *Use caution to not advance the Guidewire while inserting the Screw. Advancing the Guidewire may lead to breaching the pedicle and encroaching upon the spinal canal or neural foramen.*

e. Once the Screw is properly placed, remove the Guidewire and disengage the Screw from the Screwdriver. The Larger Dilator can be removed at this point.

f. Place the TTab Slider over the Screw tower and push down to the skin incision.

INSTRUMENTS

## Rod Length Measuring

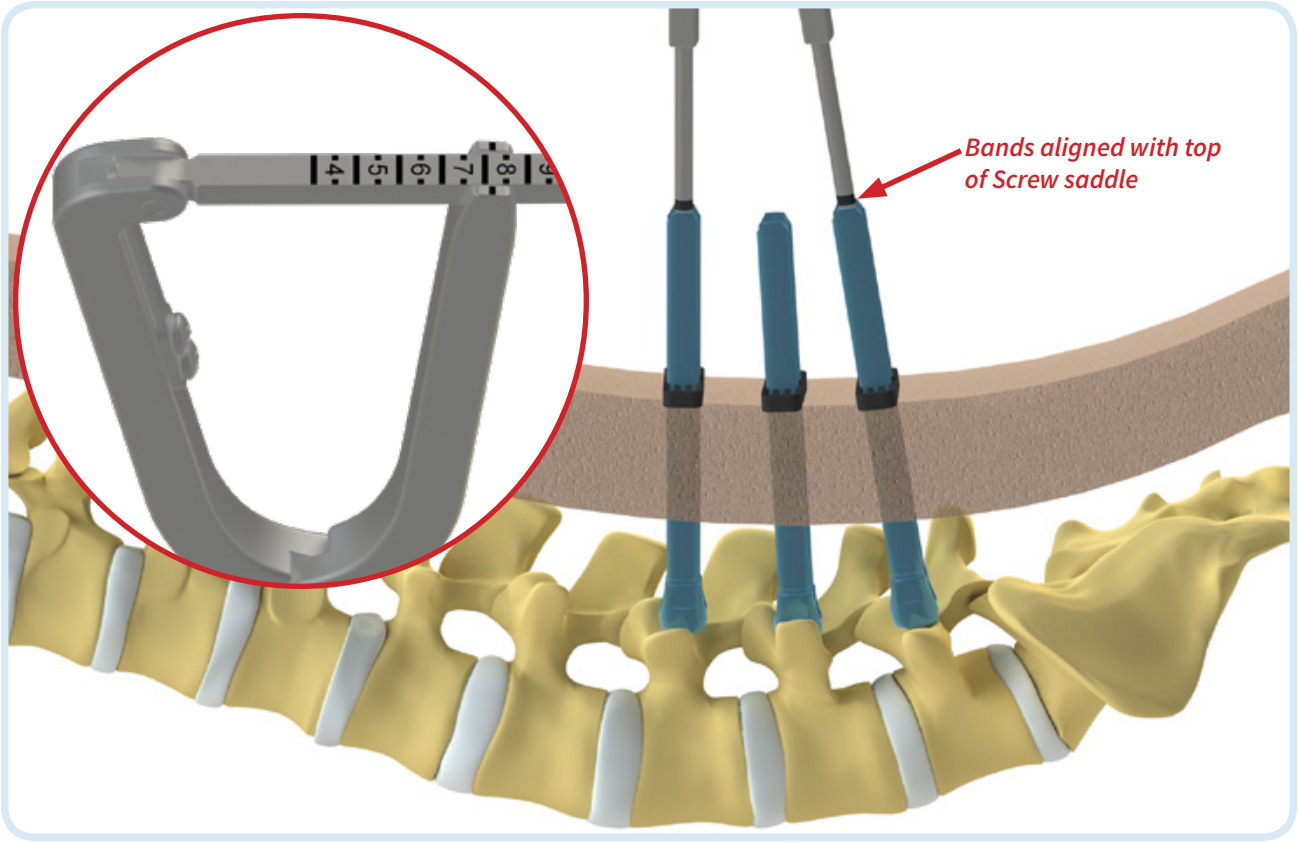


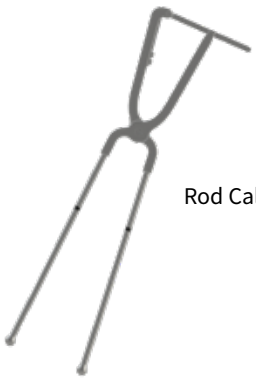

*Figure 7*

***Step 7:***

a. Insert the Rod Calipers into the Screw towers at each end of the construct, so that the Calipers span the length of the intended levels. The Rod Caliper has been sufficiently seated when the black bands on the Caliper shaft are aligned with the top of the Screw towers.

b. Once correctly positioned, reference the rod length measurement indicated at the top of the Caliper.

INSTRUMENTS



Rod Caliper

## Tissue Dissection (Optional)

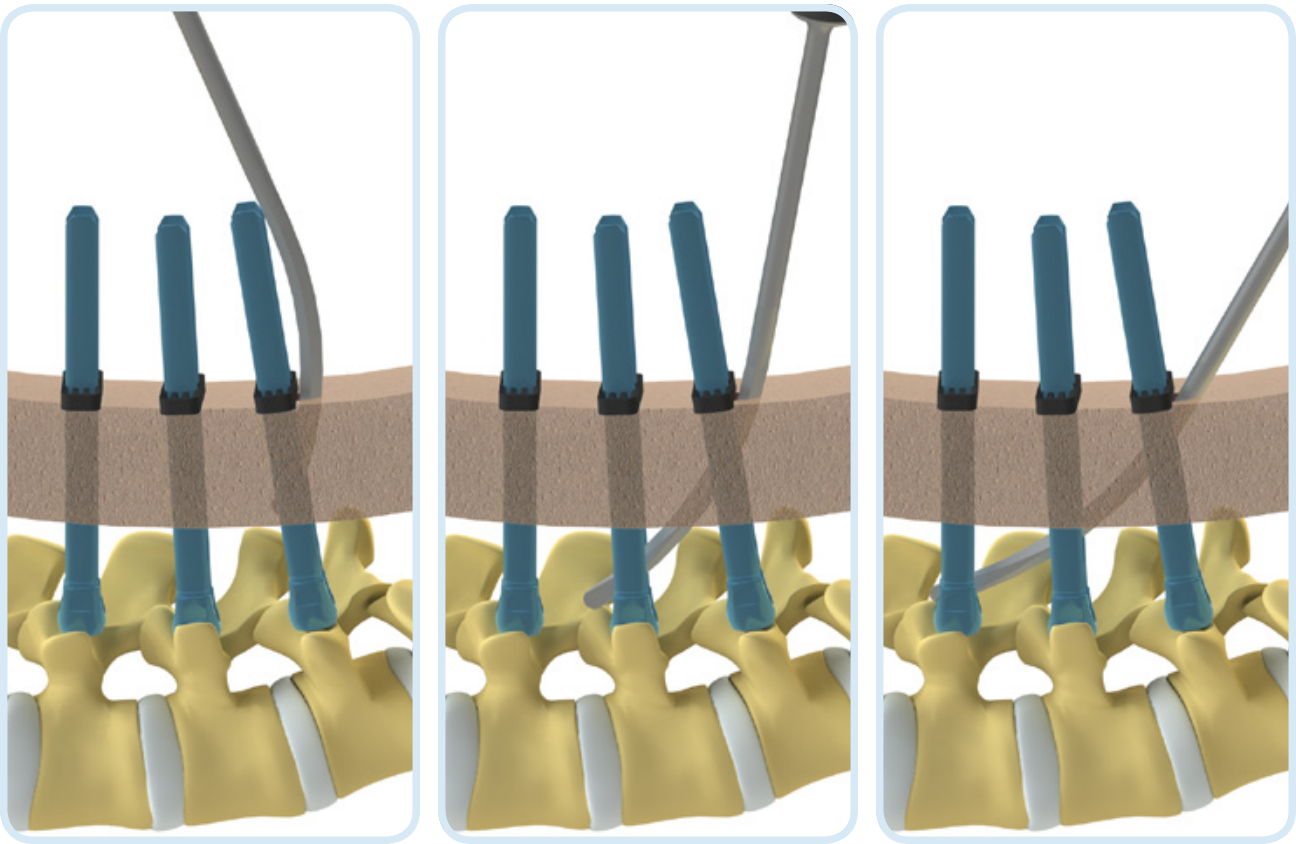


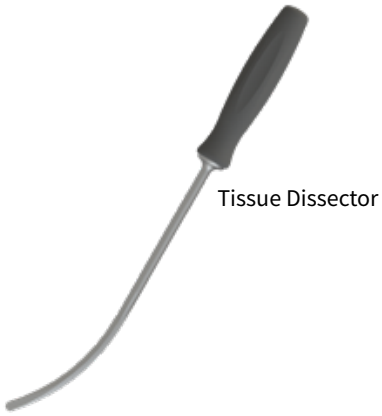
*Figure 8*

***Step 8:***

a. Prior to Rod insertion, the Tissue Dissector may be utilized to create a pathway between the Screw saddles to facilitate Rod insertion.

b. Align the adjacent Screw saddles such that the full open slots are facing each other. This position will allow for the Rod to be inserted and guided into place.

INSTRUMENTS



Tissue Dissector

## Rod Insertion - Fixed 90° Inserter

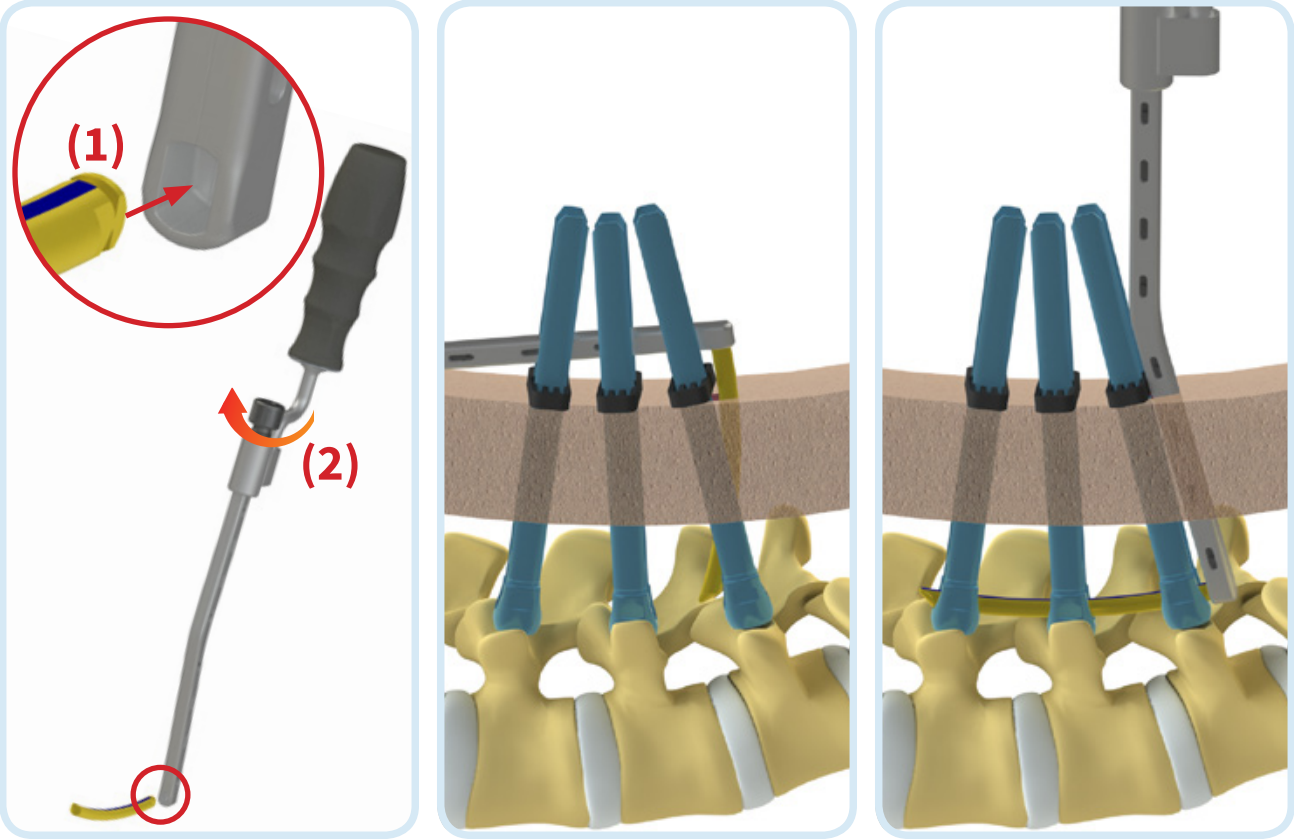



*Figure 9 - Option 1*

***Step 9 - Option 1:***

a. Attach the Rod to the Fixed Rod Inserter by (1) inserting the flat end of the Rod into the distal end of the Fixed Rod Inserter, then (2) turning the knob to lock the Rod in place. The T30 Locking Cap Adjuster should be utilized on the back end of the knob to ensure Rod is fully secured.

b. Position the Fixed Rod Inserter parallel to the skin surface with the leading tip of the Rod facing downward. Advance the Rod down the outside of the Screw tower into the incision, ensuring you have passed the fascia.

c. Rotate the Fixed Rod Inserter up 90° capturing each Screw tower as you rotate. Verify the Rod is seated properly by using fingers to rotate each Screw tower head - if unable to rotate each Screw head, the Rod has successfully been passed.

INSTRUMENTS

Fixed Rod Inserter



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## Rod Insertion - Articulating Inserter

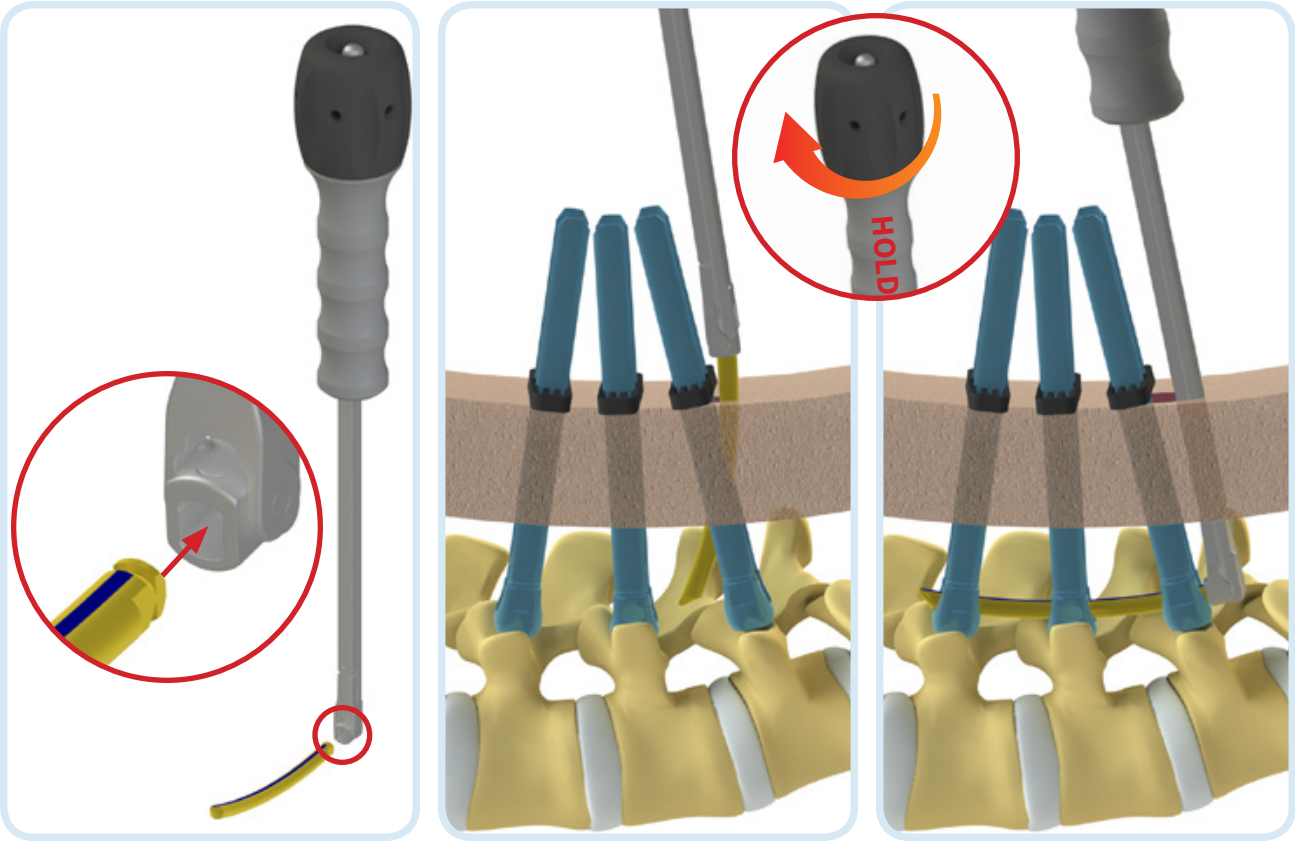


*Figure 9 - Option 2*

***Step 9 - Option 2:***

a. Attach the Rod to the Articulating Rod Inserter by inserting the flat end of the Rod into the distal slot of the Inserter. A tactile click indicates the Rod has been properly seated into the slot.

b. While holding the distal portion of the Inserter handle stationary, turn the proximal end of the handle counter clockwise to ensure the Rod is in-line with the Inserter shaft.

c. With the leading tip of the Rod facing downward, advance the Rod down the outside of the Screw into the incision, ensuring the tip of the Rod is below the fascia.

d. Once below the fascia, hold the distal end of the handle stationary while turning the proximal end clockwise to articulate the rod up to 90°, capturing each Screw tower as you rotate. Verify Rod is seated properly by using fingers to rotate each Screw tower head - If unable to rotate each Screw head, the Rod has successfully been passed.

INSTRUMENTS

Articulating Rod Inserter

## Locking Cap Insertion

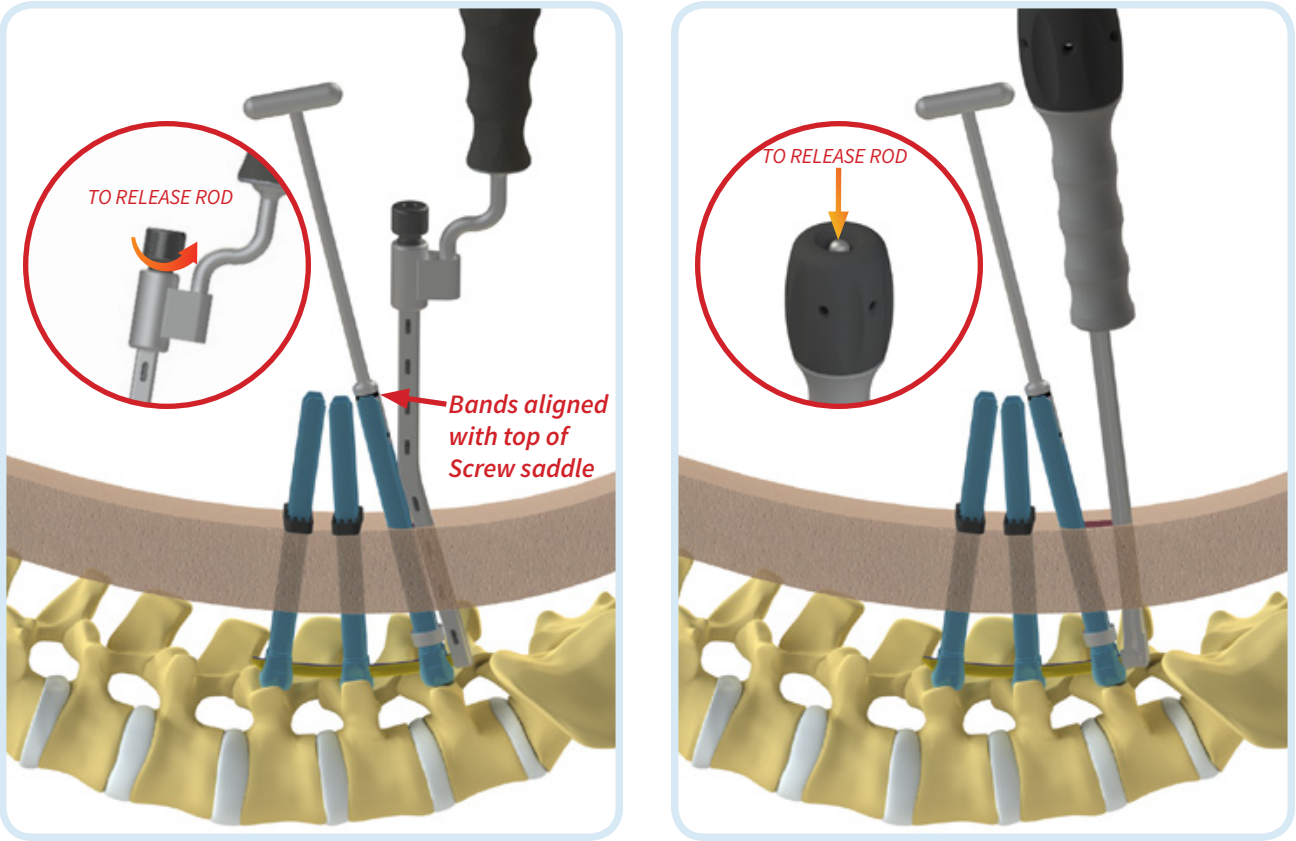


*Figure 10*

***Step 10:***

a. Insert the split tip of the Cap Starter into a Locking Cap and press down firmly to engage.

b. Prior to Cap insertion, remove the Tower Tab Slider.

c. Align the self-centering collar of the Cap starter with the Screw tower. Once the Locking Cap has reached the Screw threads, apply a gentle downward pressure and turn the Cap Starter clockwise until the Locking Cap is secured.

***Note:*** *There is 15mm of threading above the break off portion of the Screw saddle if Rod reduction is needed.*

INSTRUMENTS




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## Final Tightening

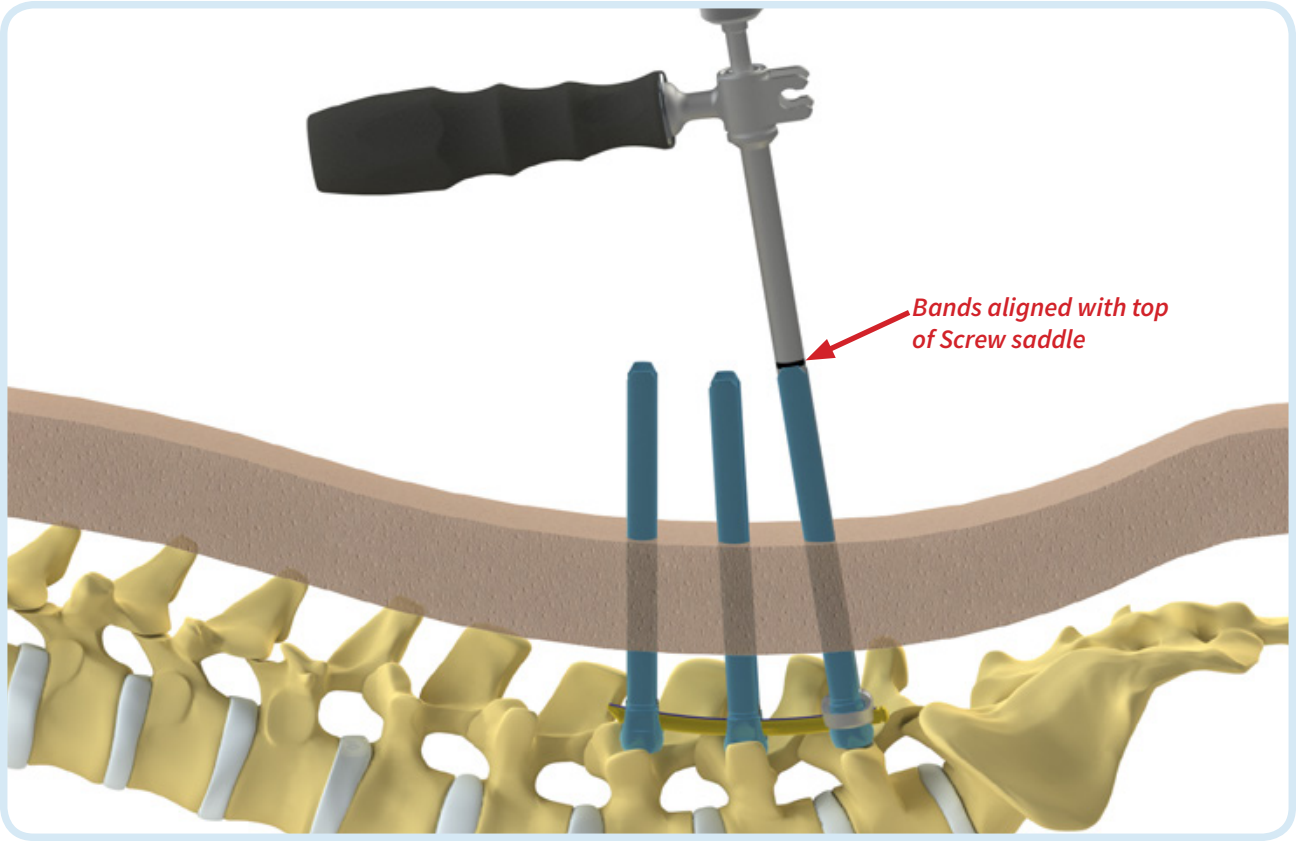



*Figure 11*

***Step 11:***

a. Attach the Torque Limiting T-Handle (90in-lbs) to the Final Cap Driver Shaft.

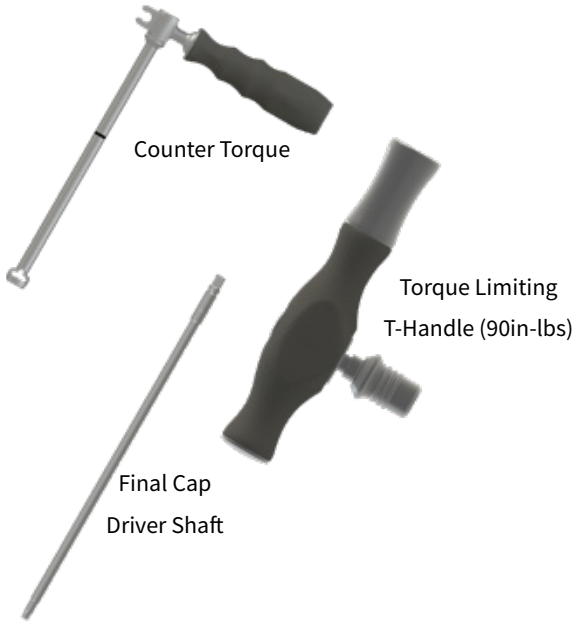
b. Slide the Counter Torque over the Screw tower until seated over the Rod. Insert the Final Driver into the Counter Torque tube and engage the Locking Cap.

c. Hold the Counter Torque firmly, and turn the Torque Limiting T-Handle clockwise until a tactile click occurs, indicating 90in-lbs of torsion has been achieved.

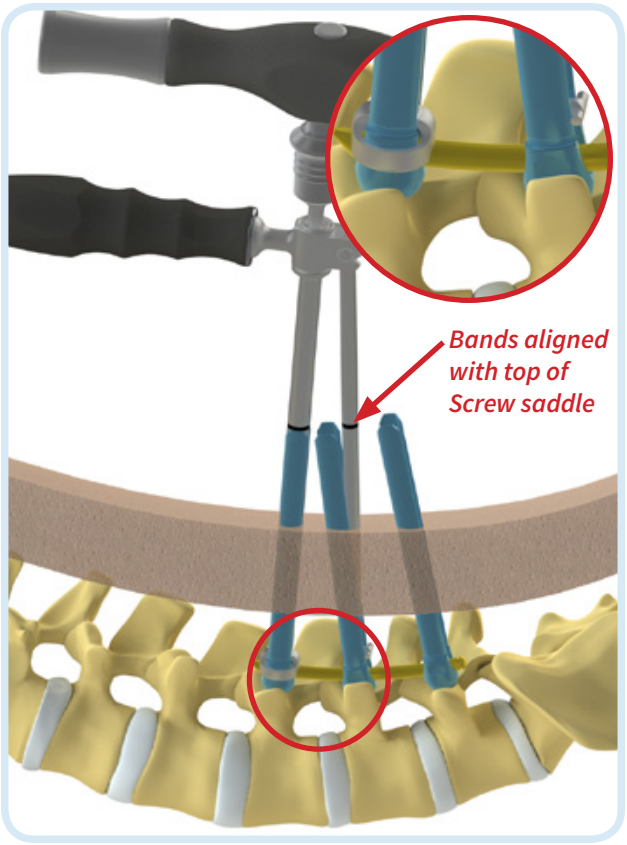
d. Repeat for remaining Screws.

***Note:*** *Cross-threading may lead to damage to the Locking Cap and/or Screw head that may go unnoticed and could compromise the final locking functionality.*

INSTRUMENTS



## Compression (Optional)



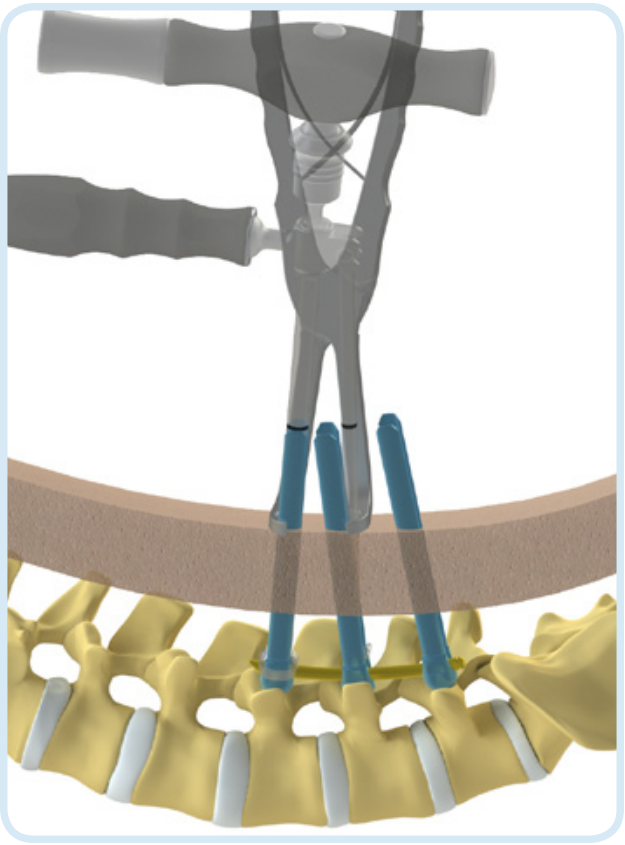



Figure 12

***Step 12:***

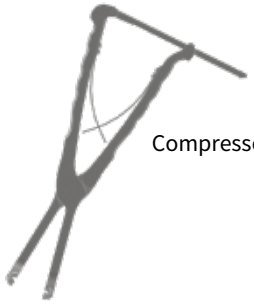
a. After final tightening one of the Locking Caps, insert the Counter Torque over the Screw tower where compression is needed.

b. Insert the Compressor-Distractor Lever into the Screw saddle with the distal post positioned on the outside of the level being compressed. The proximal end of the Lever should engage the cup section of the Counter Torque, providing a lever for compression at the skin.

c. Place the Compressor around the Screw towers and squeeze handle to achieve desired compression.

d. While holding the Compressor stationary, insert the Final Driver Shaft and turn the Torque Limiting T-Handle clockwise until a tactile click occurs, indicating 90in-lbs of torsion has been achieved.

INSTRUMENTS




## Distraction (Optional)

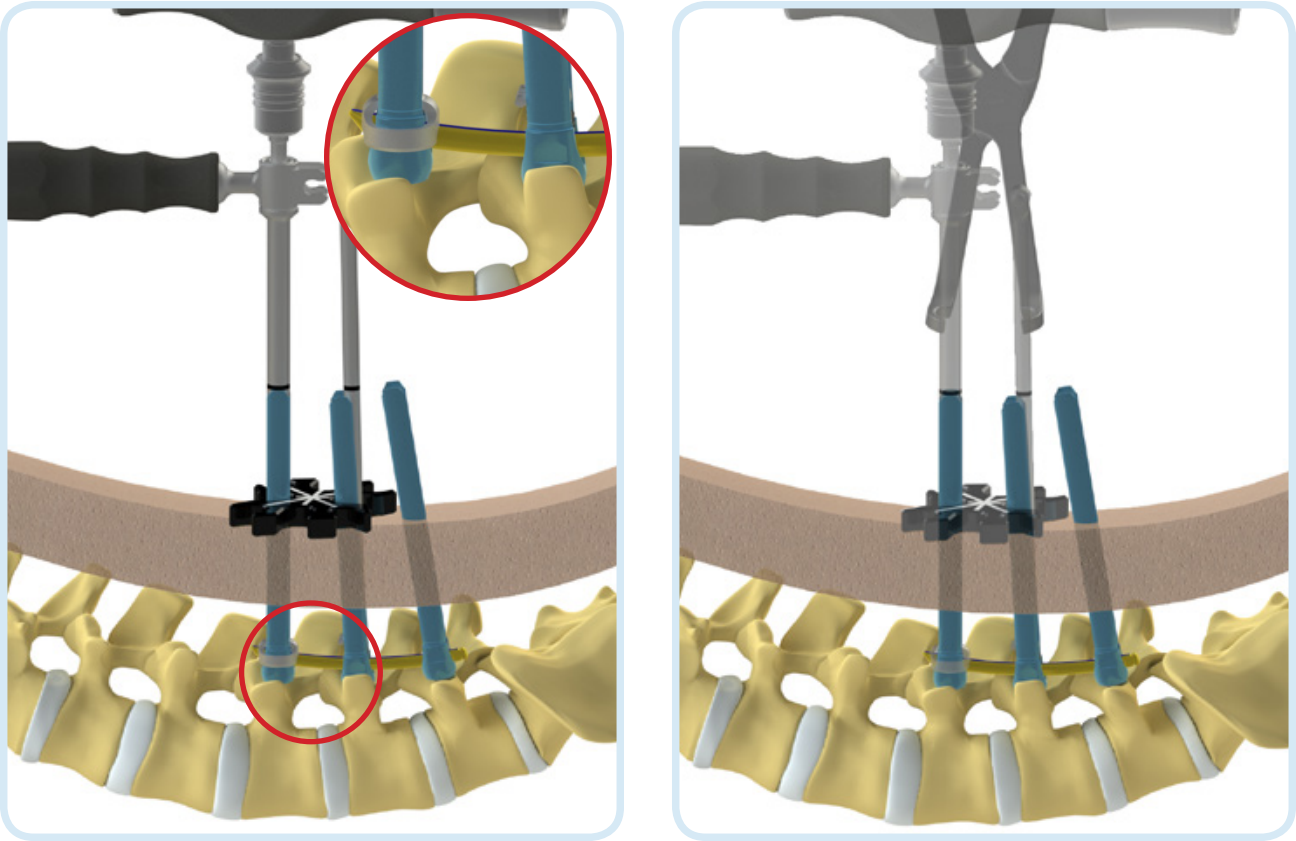


*Figure 13*

***Step 13:***

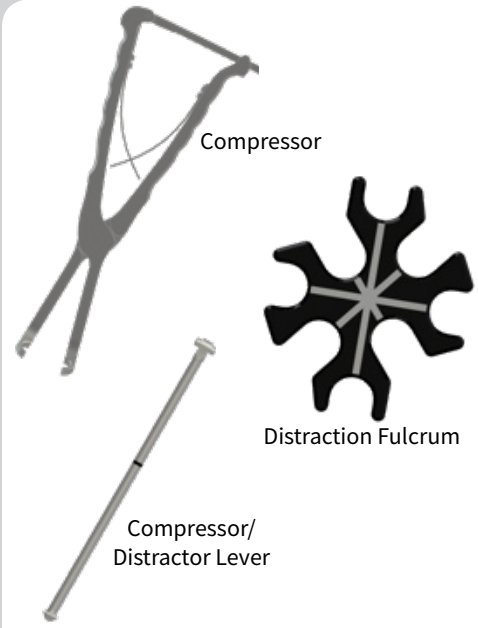
a. If desired, the Distraction Fulcrum may be utilized to achieve distraction. After final tightening one of the Locking caps, insert the Counter Torque over the Screw tower where distraction is needed.

b. Insert the Compressor/Distractor Lever into the Screw saddle with the distal post positioned on the inside of the level being distracted. The proximal end of the Lever should **not** engage the cup section of the Counter Torque, thus allowing the Distraction Fulcrum to provide distraction leverage.

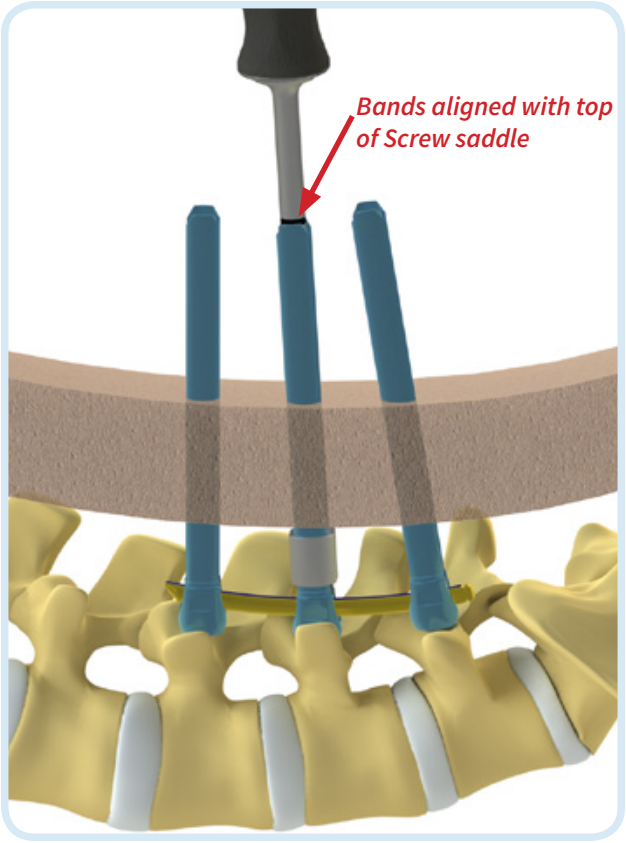
c. Place the Compressor around the Screw towers above the Distraction Fulcrum and squeeze handle to achieve desired distraction.

d. While holding the Compressor stationary, insert the Final Driver Shaft and turn the Torque Limiting T-Handle clockwise until a tactile click occurs, indicating 90in-lbs of torsion has been achieved.

INSTRUMENTS



## Tower Removal



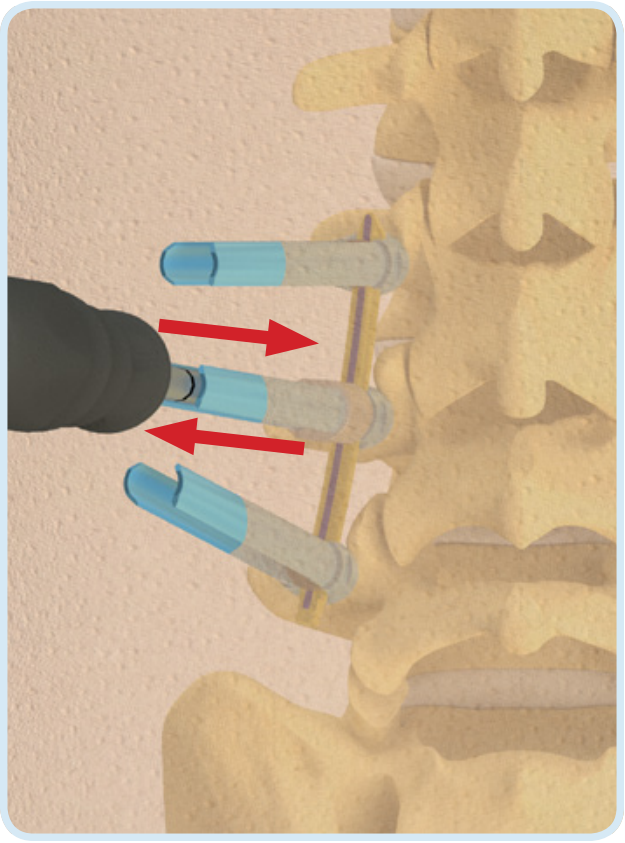



Figure 14

***Step 14:***

a. Insert the Tab Breaker over the Screw saddle and until it reaches the Screw head and can no longer advance.

b. Rock the Tab Breaker in the medial or lateral direction until the towers break away from the Screw head.

***Note:*** *Do not twist the Tab Breaker in an attempt to break off the towers*

c. Remove Screw towers and repeat for remaining Screws.

INSTRUMENTS

Tab Breaker



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## Implant Removal Instructions

***Removal:***

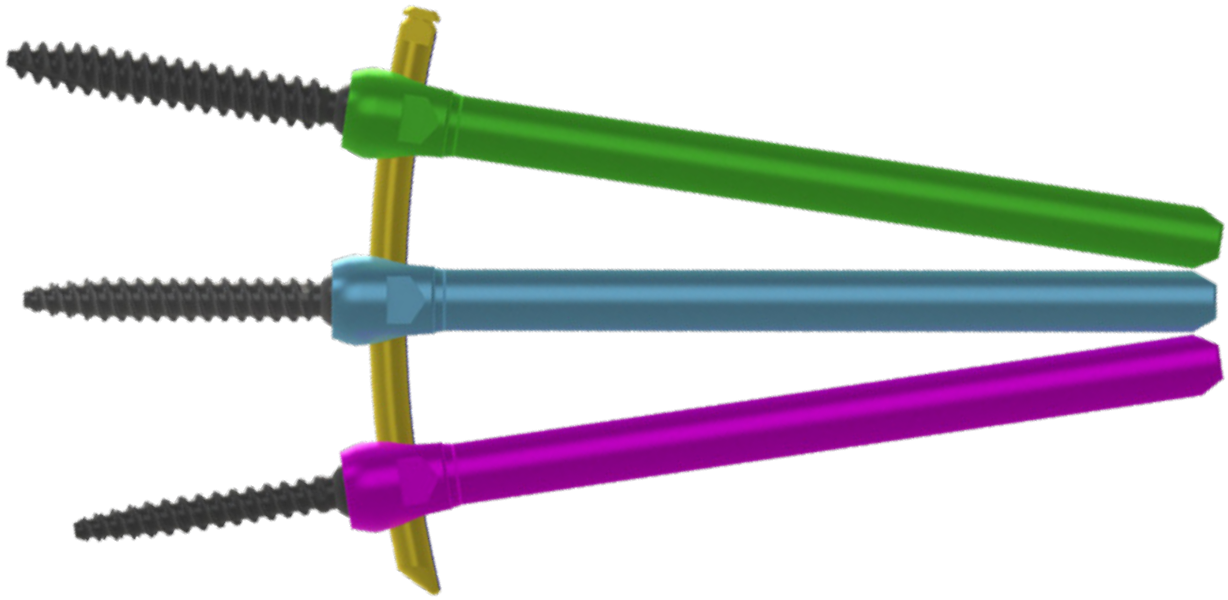
a. Expose the operative site to visualize the Implants to be removed.

b. Remove the Locking Caps (T30) from each Pedicle Screw using the T-Handle Locking Cap Adjuster. Remove Rods with the Rod Holder.

c. Remove Pedicle Screws (T25) using the installation steps as outlines in this surgical technique in reverse.

# SYSTEM CONFIGURATION

## IMPLANTS



| Catalog # | Description |
|---|---|
| 10-SCT-4725 to 10-SCT-4745 | Screw, Cann TTab, 4.75 x 25 - 45mm |
| 10-SCT-5530 to 10-SCT-5555 | Screw, Cann TTab, 5.5 x 30 - 55mm |
| 10-SCT-6535 to 10-SCT-6555 | Screw, Cann TTab, 6.5 x 35 - 55mm |
| 10-SCT-7535 to 10-SCT-7555 | Screw, Cann TTab, 7.5 x 35 - 55mm |
| 10-SCT-8535 to 10-SCT-8555 | Screw, Cann TTab, 8.5 x 35 - 55mm |
| 10-BRC-0035 to 10-BRC-0130 | Rod, Crv Bulleted, 5.5 x 35 - 130mm |
| 10-BRS-0130 to 10-BRS-250 | Rod, Str Bulleted, 5.5 x 130 - 250mm (20mm increments) |
| 11-LCL-0000 | Locking Cap |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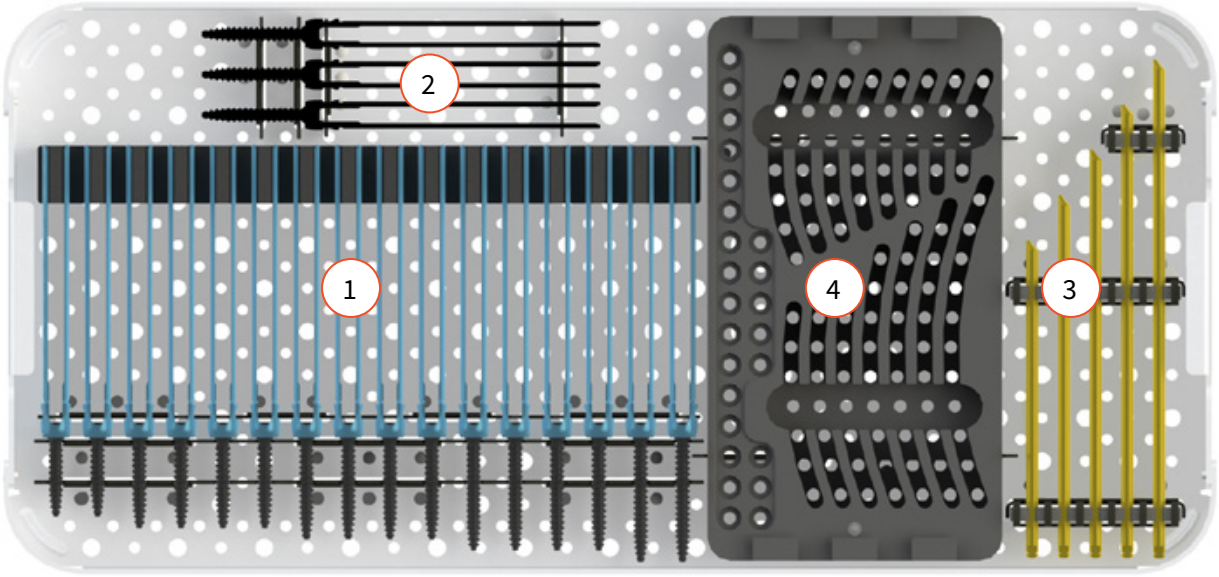
# SYSTEM CONFIGURATION

## IMPLANT TRAY - INSERT LEVEL 1

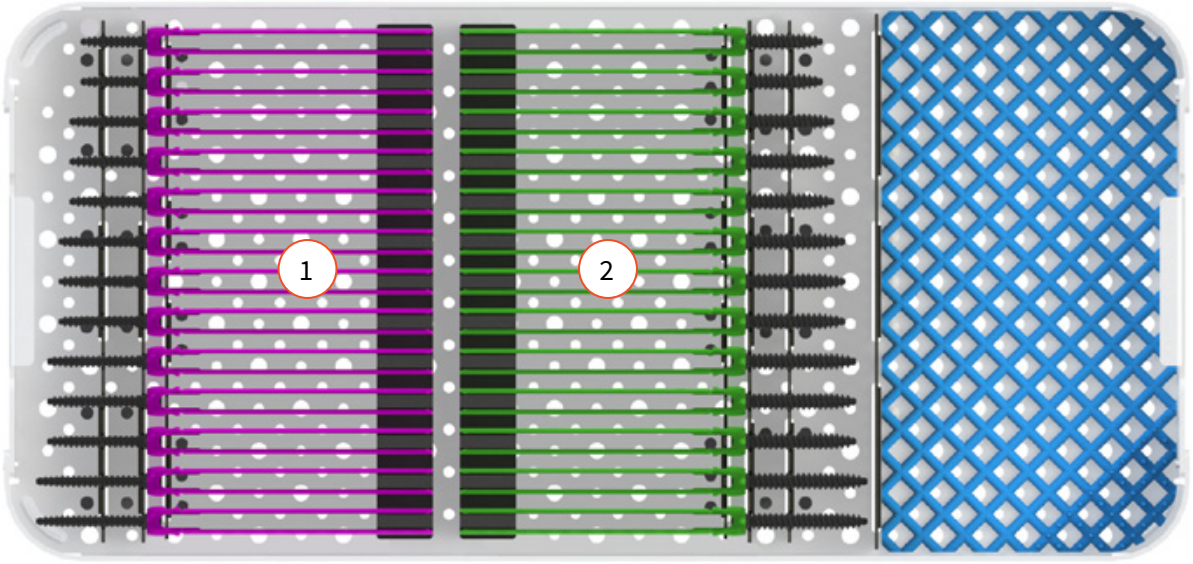



| Item # | Description | *Qty/Set |
|---|---|---|
| 1 | Screw, Cann TTab, 6.5 x 35 - 55mm | 4 - 8 ea. |
| 2 | Extra Screws | Up to 6 |
| 3 | Rod, Str Bulleted, 130 - 210mm (20mm increments) | 1 - 3 ea. |
| 4 | Caddie, MIS Rods & Caps | 1 |
| 5 | Caddie Lid, MIS Rods & Caps (not shown) | 1 |

**Qty/Set may vary depending surgeon/distributor request.*

# SYSTEM CONFIGURATION

## IMPLANT TRAY - INSERT LEVEL 2




| Item # | Description | *Qty/Set |
|---|---|---|
| 1 | Screw, Cann TTab, 5.5 x 30 - 50mm | 2 - 6 ea. |
| 2 | Screw, Cann TTab, 7.5 x 35 - 55mm | 2 - 6 ea |

**Qty/Set may vary depending surgeon/distributor request.*



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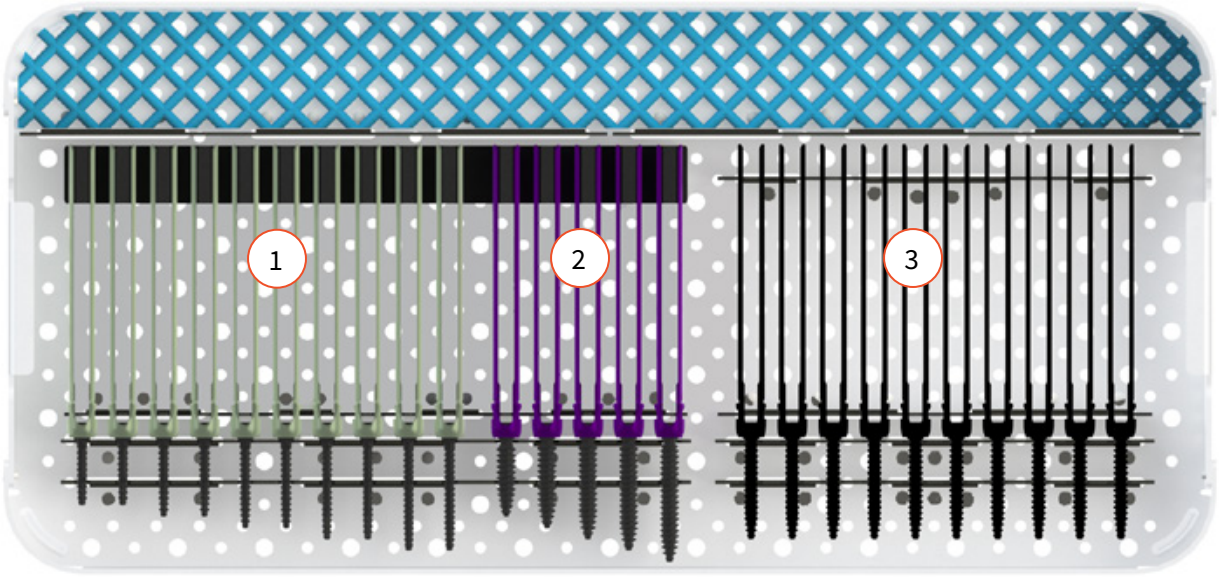
# SYSTEM CONFIGURATION

## IMPLANT TRAY - INSERT LEVEL 3

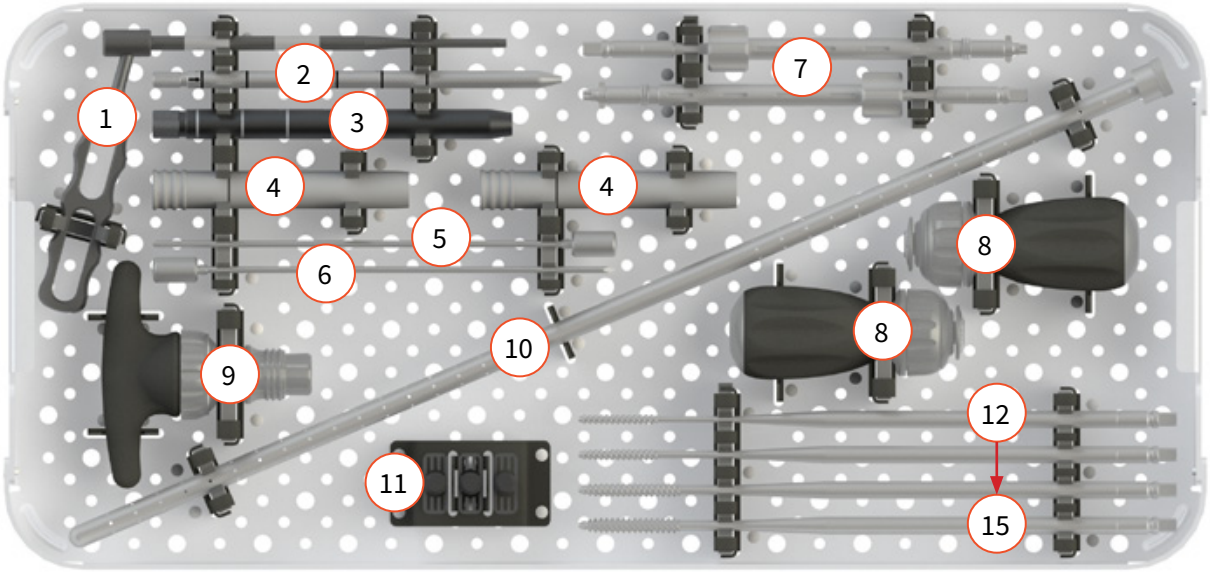



| Item # | Description | *Qty/Set |
|---|---|---|
| 1 | Screw, Cann TTab, 4.75 x 30 - 50mm | 2 - 4 ea. |
| 13 | Screw, Cann TTab, 8.5 x 35 - 55mm | 2 ea. |
| 14 | Extra Screws | Up to 20 |

**Qty/Set may vary depending surgeon/distributor request.*

# SYSTEM CONFIGURATION

## INSTRUMENT TRAY A - INSERT LEVEL 1




| Item # | Description | Qty/Set |
|---|---|---|
| 1 | Targeting Needle Handle | 1 |
| 2 | Dilator, Small | 2 |
| 3 | Dilator, Medium | 2 |
| 4 | Dilator, Large | 2 |
| 5 | Needle, Bevel Stylet, Disposable | 2 |
| 6 | Needle, Diamond Stylet, Disposable | 2 |
| 7 | Screwdriver | 2 |
| 8 | Egg Handle, Ratcheting | 2 |
| 9 | T-Handle, Ratcheting | 1 |
| 10 | Guidewire Tube | 1 |
| 11 | TTab Slider | 12 |
| 12 | Cannulated Tap, 4.75mm | 1 |
| 13 | Cannulated Tap, 5.5mm | 1 |
| 14 | Cannulated Tap, 6.5mm | 1 |
| 15 | Cannulated Tap, 7.5mm | 1 |



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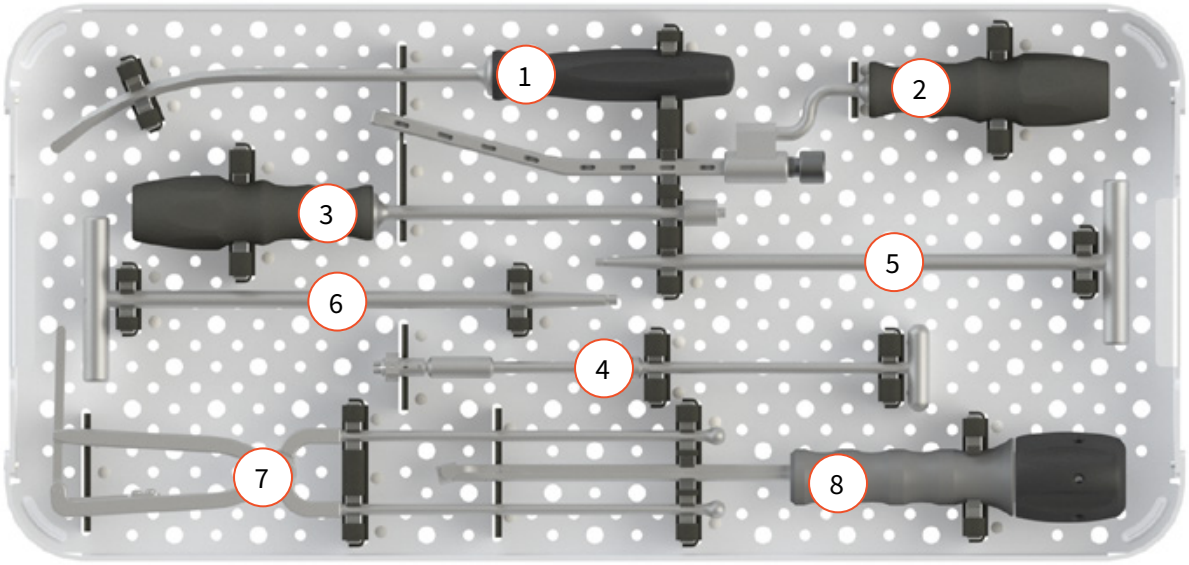
# SYSTEM CONFIGURATION

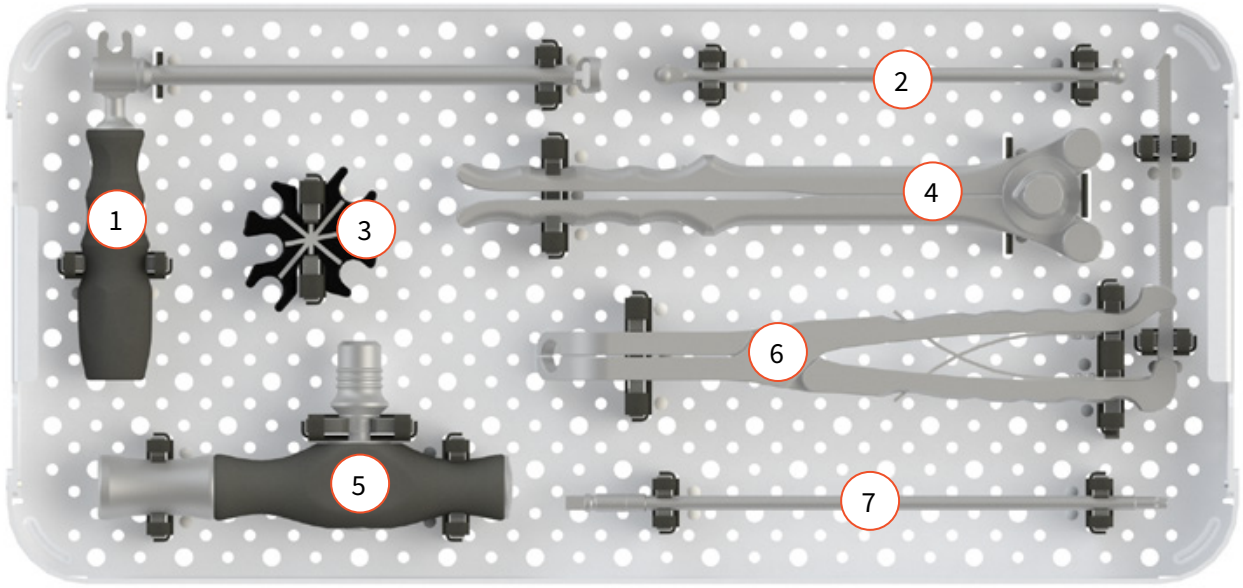
## INSTRUMENT TRAY A - INSERT LEVEL 2




| Item # | Description | Qty/Set |
|---|---|---|
| 1 | Tissue Dissector | 1 |
| 2 | Rod Inserter, Fixed 90° | 1 |
| 3 | Tab Breaker | 1 |
| 4 | T-Handle, T30 Split-Tip Cap Starter | 3 |
| 5 | T-Handle, T30 Locking Cap Adjuster | 1 |
| 6 | T-Handle, T25 Screw Height Adjuster | 1 |
| 7 | Rod Caliper | 1 |
| 8 | Rod Inserter, Articulating | 1 |

# SYSTEM CONFIGURATION

## INSTRUMENT TRAY B - INSERT LEVEL 1




| Item # | Description | Qty/Set |
|---|---|---|
| 1 | Counter Torque, TTab | 1 |
| 2 | Compressor/Distractor Lever | 1 |
| 3 | Distraction Fulcrum | 1 |
| 4 | Rod Bender, 5.5mm | 1 |
| 5 | T-Handle, Torque Limiting (90in-lbs) | 1 |
| 6 | Compressor, MIS | 1 |
| 7 | Final Cap Driver Shaft, T30 | 1 |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NOTES:

## NOTES:



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For instrument part numbers, please contact
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