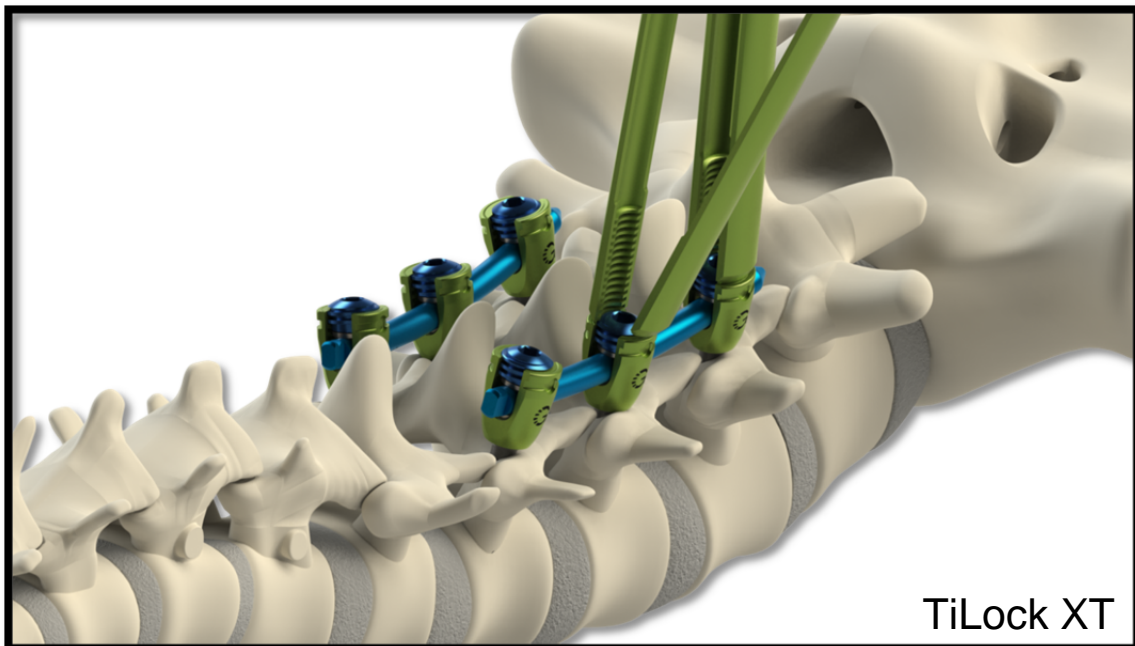


TiLock XT Minimally Invasive Surgery (MIS) Pedicle Screw System

The Genesys Spine TiLock XT Minimally Invasive Surgery (MIS) Pedicle Screw System consists of rods (straight and curved), lock screws, and polyaxial, extended tab, cannulated screws in various lengths and diameters.

The minimally invasive procedure is performed using K-wires and fluoroscopy, which allows the surgeon to employ smaller incisions rather than one long midline incision.

Straight-forward instrumentation, self-tapping screws, and break-away tulip designs help simplify the procedure and reduce operative time.



Surgical Technique Guide

Preoperative Planning

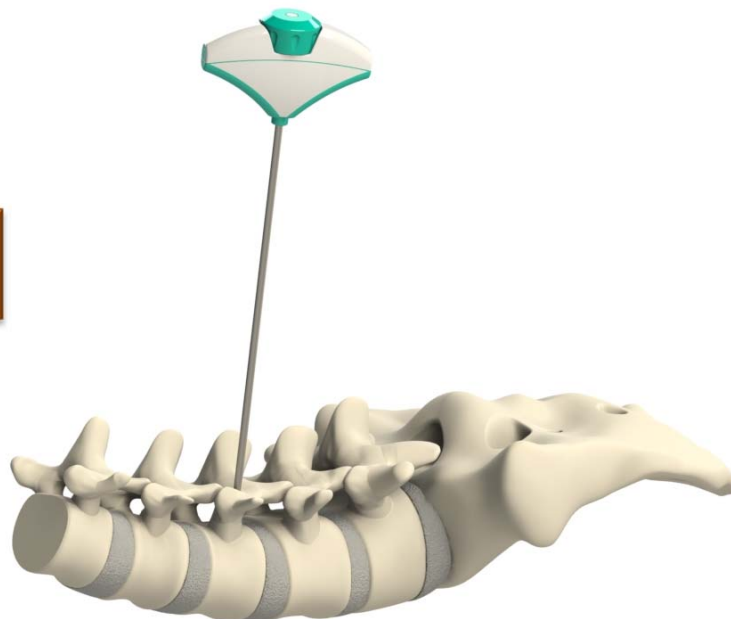
Place the patient in a prone position on a radiolucent table with adequate clearance available for a fluoroscopic C-arm. All other hardware utilized to achieve optimal patient positioning should be checked for radiolucency as well. Surgical tables that place the patient in a knee-chest position should be avoided.

The C-arm should be able to rotate freely through AP, oblique and lateral views in order to obtain the best visualization of the patients' pedicle anatomy. Optimal pedicle visualization will be extremely important to initially locating the pedicle and throughout the pedicle preparation screw placement process of the surgical technique.

Targeting the Pedicle

Locate the lateral border of the appropriate pedicle using fluoroscopy. Obtain an AP fluoro image to confirm the needle location at the lateral, superior margin of the target pedicle. Advance the targeting needle into the pedicle by tapping lightly with a mallet. As the needle advances, it should approach the middle of the pedicle cylinder on an AP image. The position of the targeting needle can be checked with a direct lateral fluoro image to ensure that the trajectory of the advancing needle matches the anatomy the patients' pedicle. After this confirmation, advance the needle to the desired depth within the vertebral body.

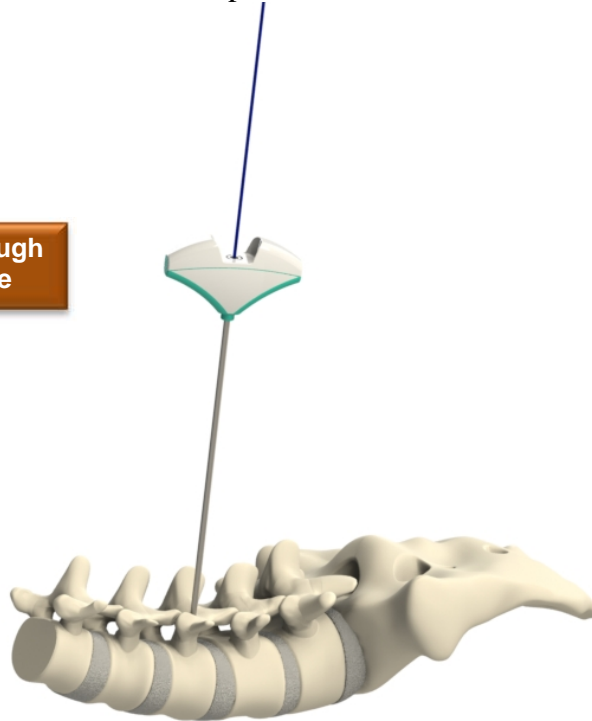
**Insert targeting
needle into the
intended pedicle.**



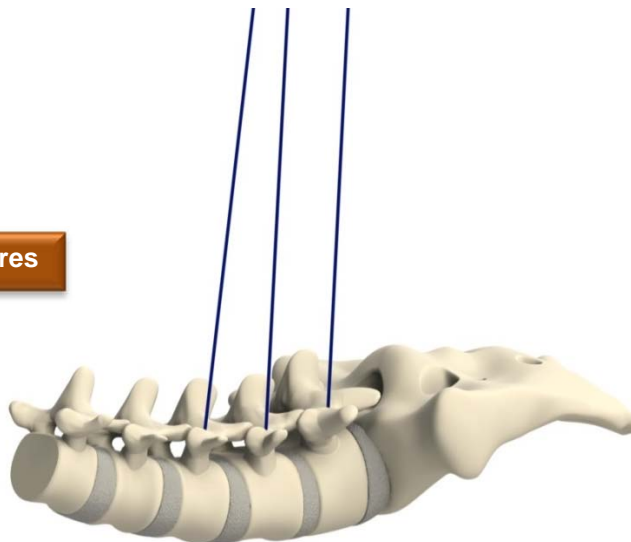
K-Wire Insertion

With the targeting needle docked, remove the sharp stylet from the targeting needle and insert the K-wire through the cannulated needle sheath. Once the K-wire is inserted and firmly docked, remove the targeting needle while taking care not to disturb the K-wire. Repeat these steps for each additional pedicle screws.

Insert K-wire through
targeting needle



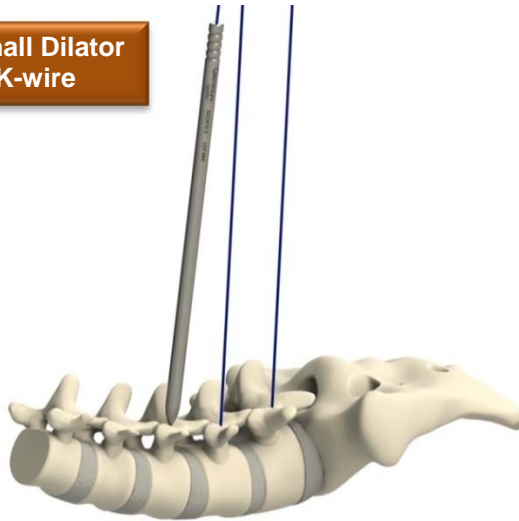
Insert all K-wires



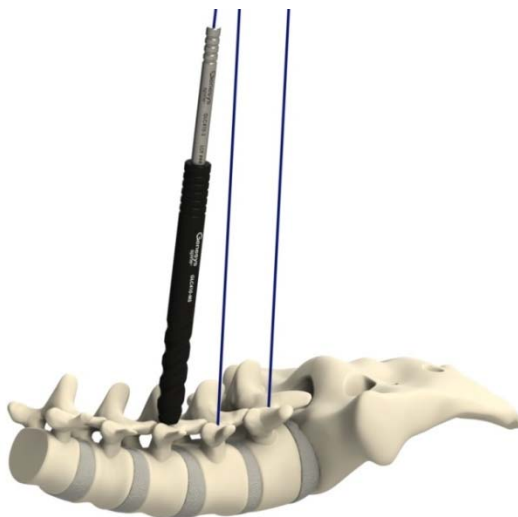
Soft Tissue Dilation

With the K-wire in place, pass the sequential dilators (starting with the smallest) over the wire to create a working portal.

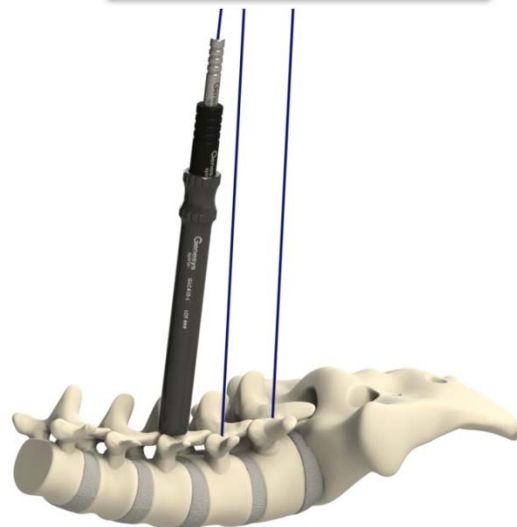
Insert the Small Dilator
over the K-wire



For two dilator approach:
use Small Dilator and
Medium Short Dilator



For three dilator approach:
use Small Dilator, Medium
Dilator, and Large Dilator

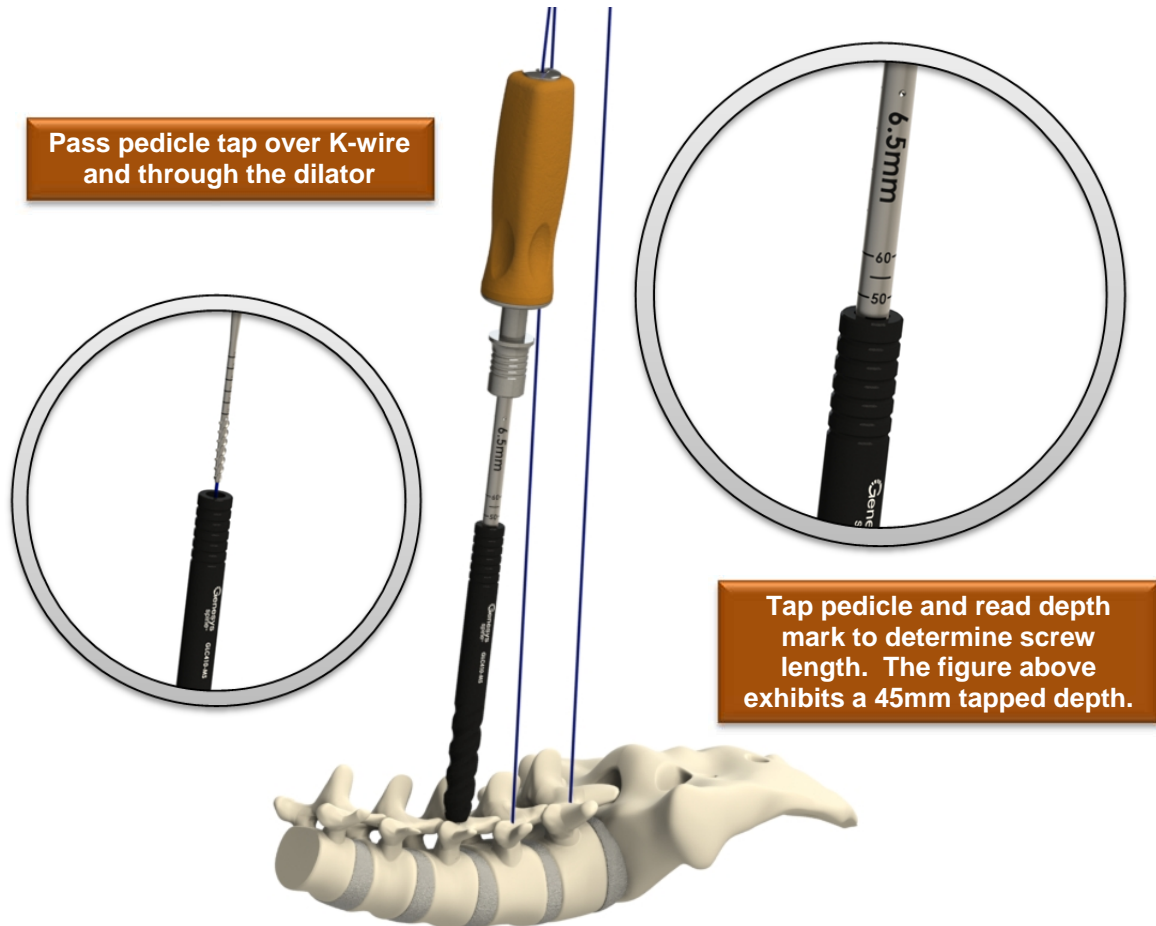


NOTE: Taps can be passed through the medium, medium short and large dilators. The extended pedicle screws can only pass through the large dilators.

Pedicle Preparation

Pass the selected size cannulated pedicle tap over the K-wire. Utilize fluoroscopy to verify the position of the tap in relation to the K-wire. Make sure that the tap does not advance further than the wire and that the K-wire does not advance during tapping.

NOTE: All taps are 0.25mm undersized from their respective screw diameter.



NOTE: The pedicle tap will give accurate depth measurements with the Medium Short and Large Dilators because they are zeroed out. If the tap is passed through the Medium Dilator, the depth reading will be overestimated by 40 millimeters.

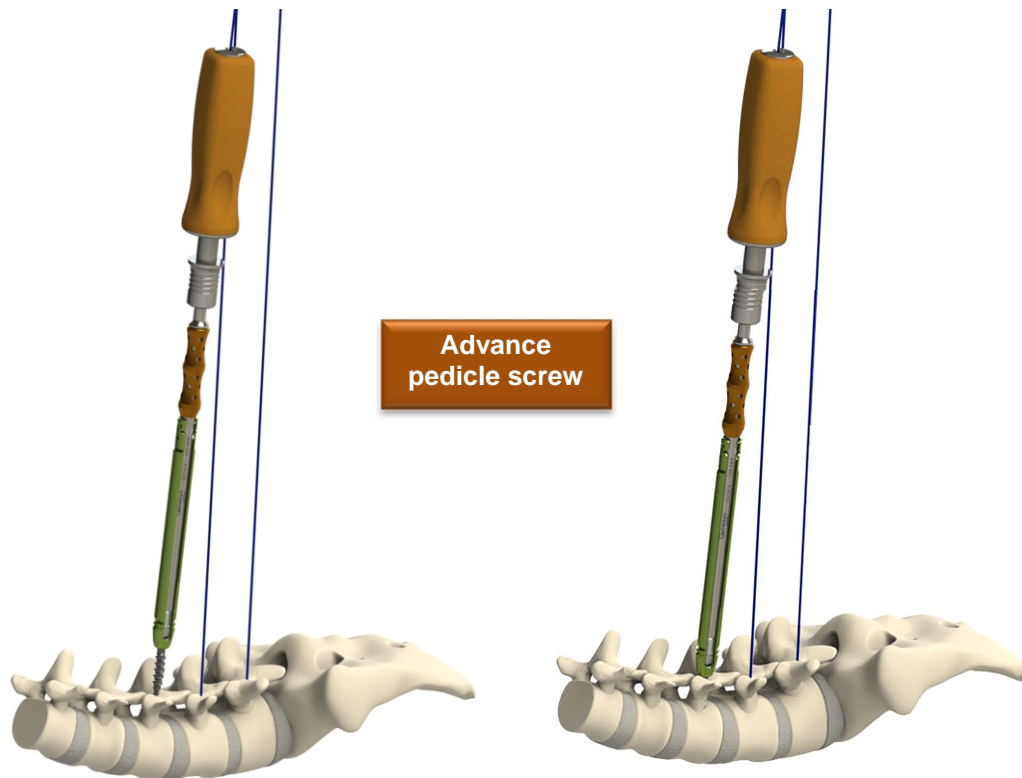
Ensure the lumens (i.e. cannulations) of the cannulated instruments are flushed clear to avoid inadvertently advancing the K-wire.

Pedicle Screw Insertion

Insert the Friction-Clip Screwdriver through the screw tower and into the screw head. The screwdriver should feel snug when the screw is fully seated. With the screw construct properly connected to the screwdriver, pass the screw over the K-wire and down to the pedicle. Advance the screw under fluoroscopic guidance until the screw reaches the posterior wall of the vertebral body. At this point, remove the K-wire and continue advancing the screw until the polyaxial head of the screw sits snugly against the base of the facet joint. The Friction-Clip Screwdriver can be removed by pulling it out of the screw tower. Repeat these steps for each additional pedicle screw.



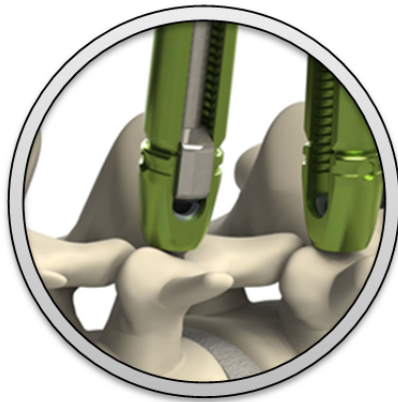
A pedicle screw seated on the Friction-Clip Screwdriver.
NOTE: The extended tulip nearly touches the orange sleeve on the screwdriver.



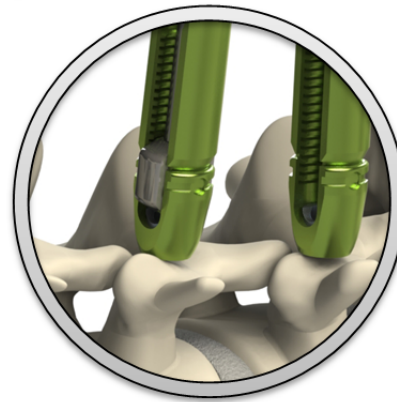
NOTE: All Genesys Spine MIS Pedicle Screws are self-starting.

Aligning the Towers

The windows in the tulips of the pedicle screws must align in order to place the rod. The polyaxial tulips on the pedicle screws may be internally or externally rotated. For internal rotation, use the tulip positioner to rotate the tulips such that the windows are facing the cephalad/caudal directions. It may be necessary to work the tulip in a circular motion to assist with rotation. External rotation of the tulips may be performed by the forked counter-torque instrument.

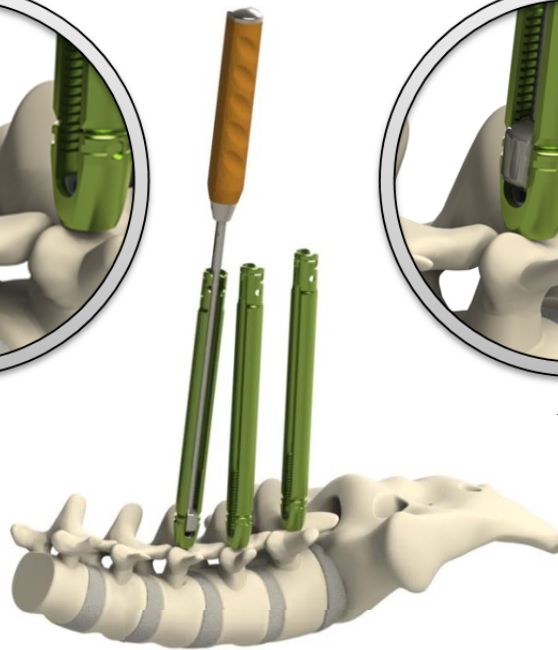


Before



After

Use the tulip positioner instrument to rotate the tulip at its base



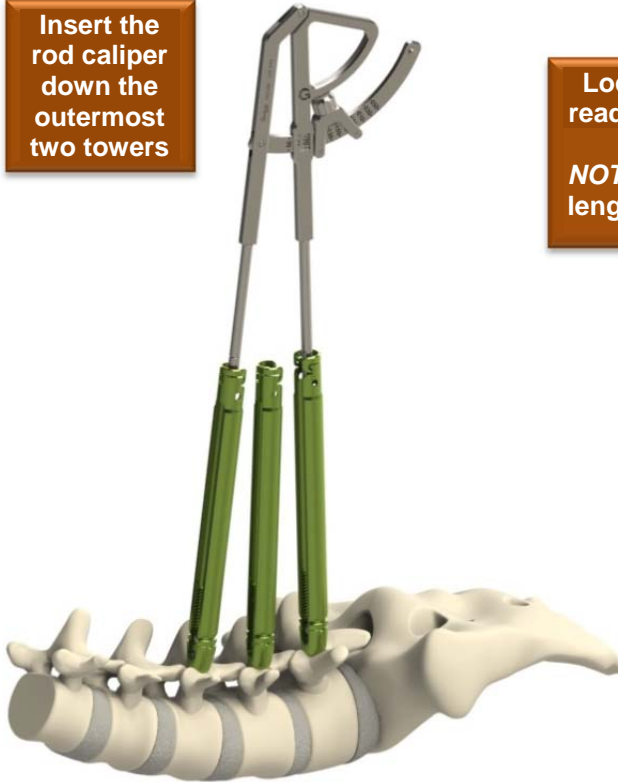
Forked counter-torque may be used for external rotation of the tulips



Rod Measurement

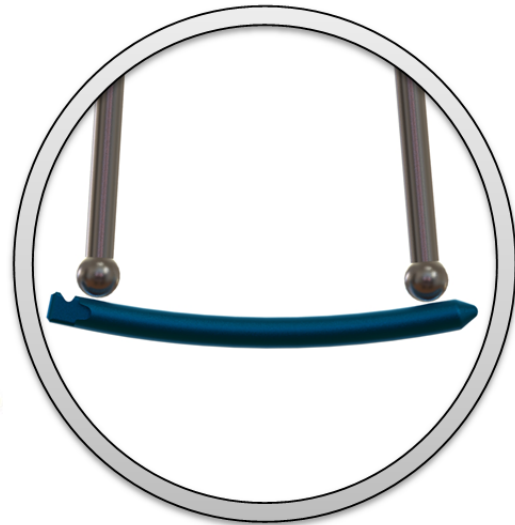
Slide the Rod Caliper tool down the outermost towers until each leg reaches the screw head then tighten the set-screw on the slide to mark the position. Remove the Rod Caliper from the extended tulips and read the size indicated on the Rod Caliper slide to determine the optimal rod length. Additionally, the caliper can be compared to the indicated rod to visually confirm proper sizing.

Insert the rod caliper down the outermost two towers



Lock caliper in place with set-screw and read suggested rod size on caliper's slide.

NOTE: The best practice is to round-up in length and add 5mm when selecting a rod.



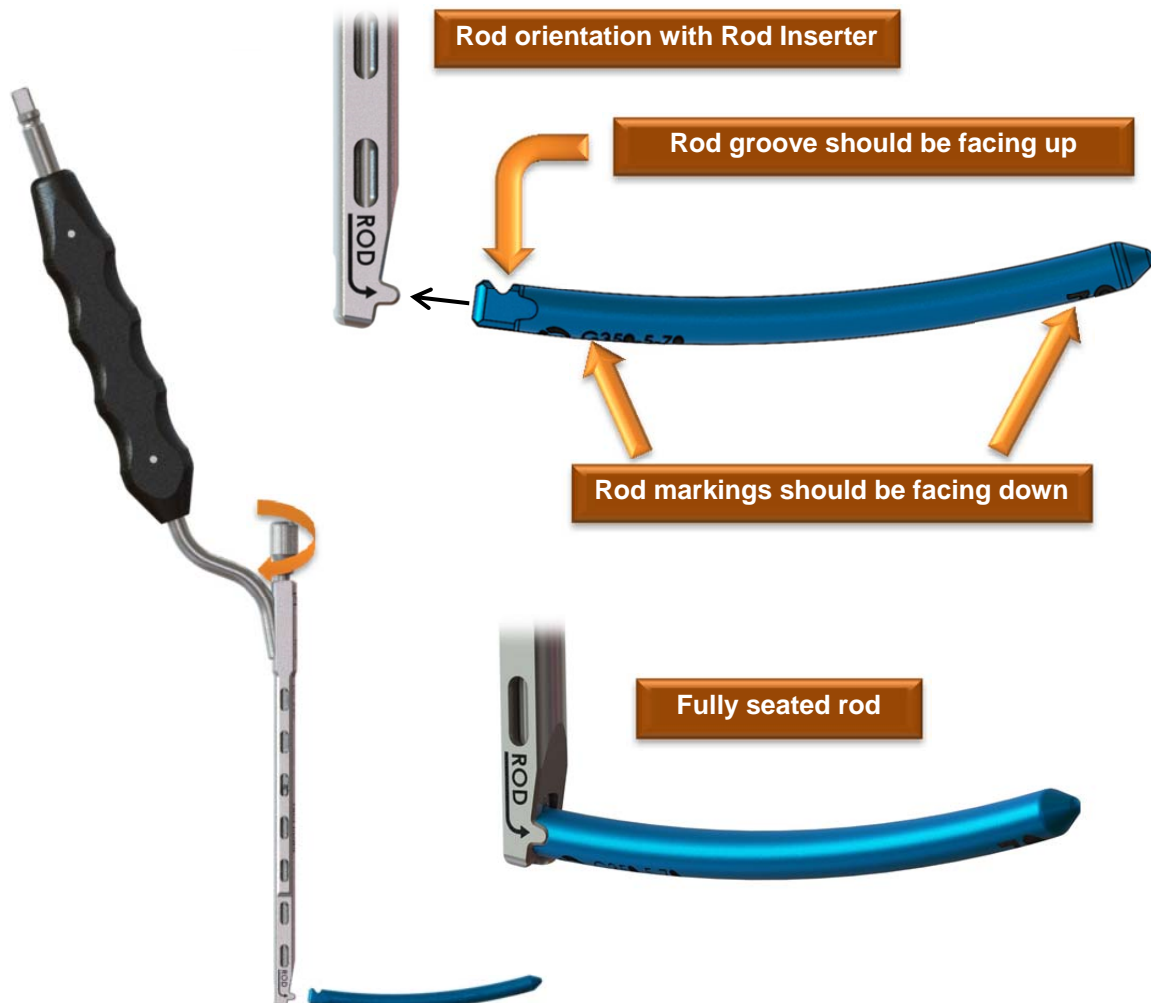
Extended rod calipers have measurements on both the front and back of the slide to provide a more accurate rod size estimate.



Rod Attachment & Approach

Loosen the piston on the Rod Inserter and insert the rod into the Rod Inserter's window. The rounded teeth on the Rod Inserter must mate with the round recesses in the rod. The piston must be tightened down on the rod such that the piston engages with the groove on the top side of the rod.

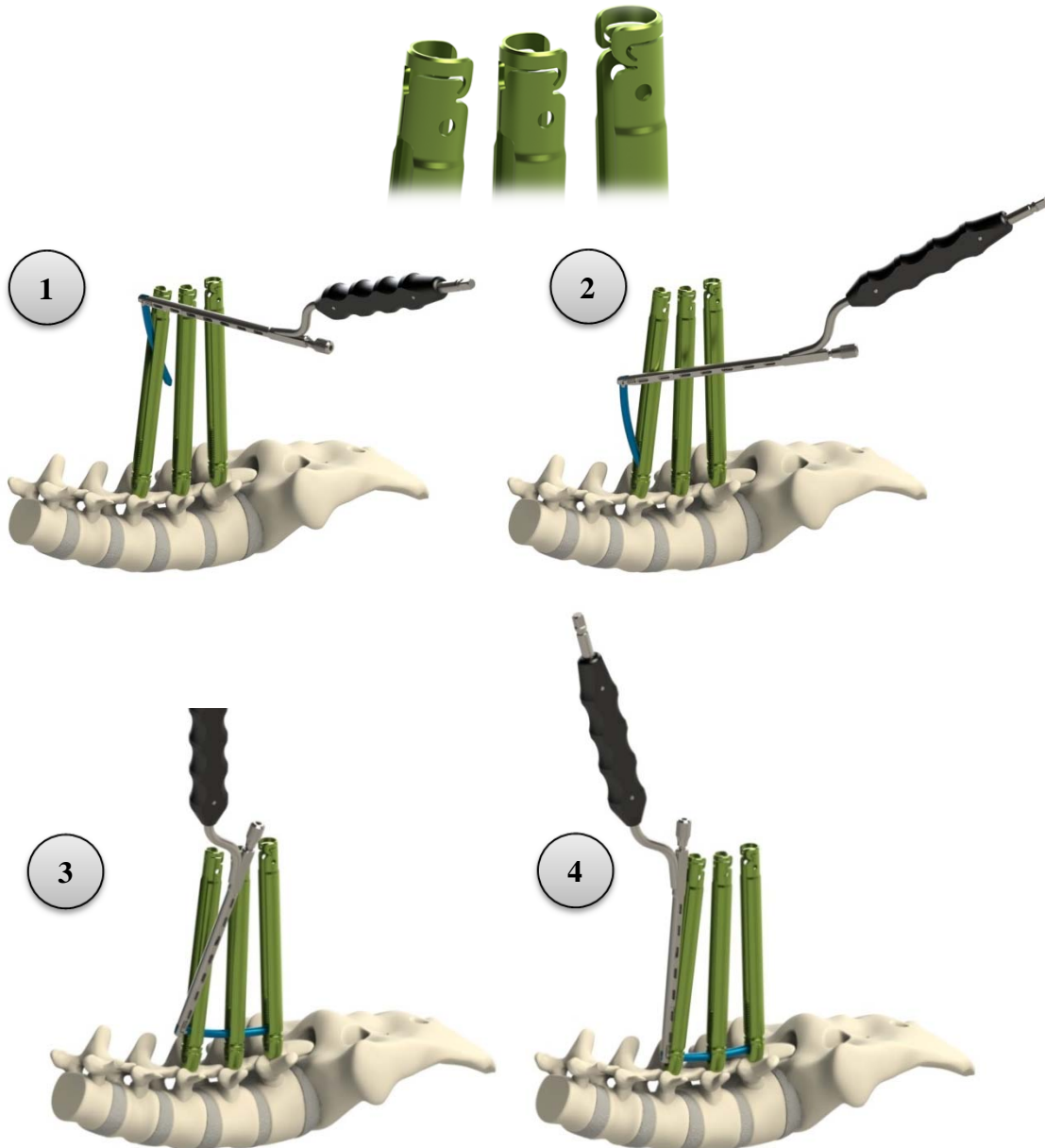
Use the Rod Inserter to guide the rod down the extended tabs on the pedicle screws and into the base of each screw. After the rod is seated, use fluoroscopy to confirm the rod is in the correct position prior to tightening. The Rod Inserter can be used to adjust the cephalad/caudal position of the rod within the screws. The Genesys Spine TiLock XT system may be used for most common rod-insertion techniques.



Rod Placement (Approach #1)

Percutaneous Tunneling Approach

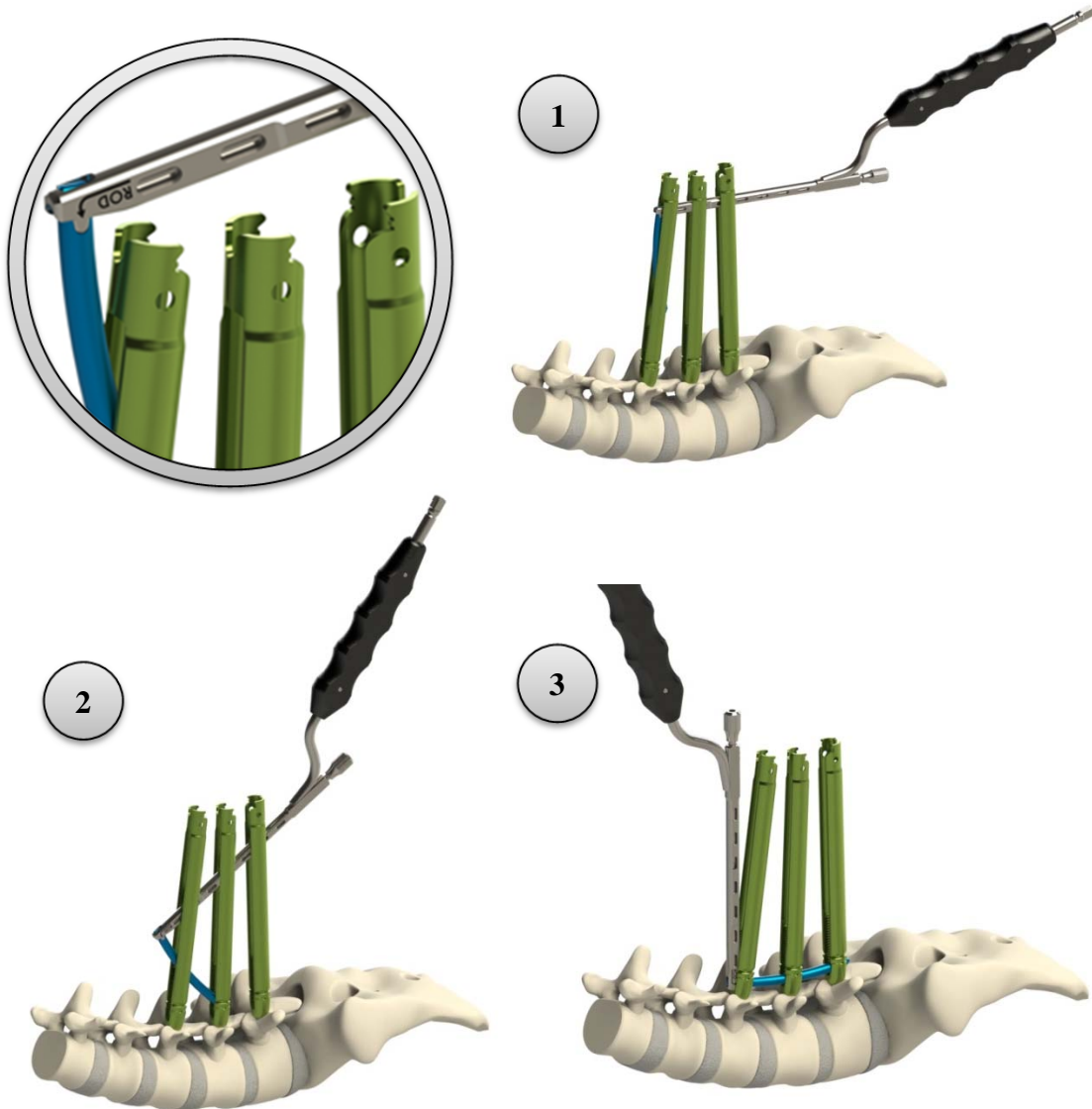
Users of this technique generally retain the Connection Rings at the tower openings in order to keep the rigidity of the tower assembly.



Rod Placement (Approach #2)

In-Line Tower Sweep Approach

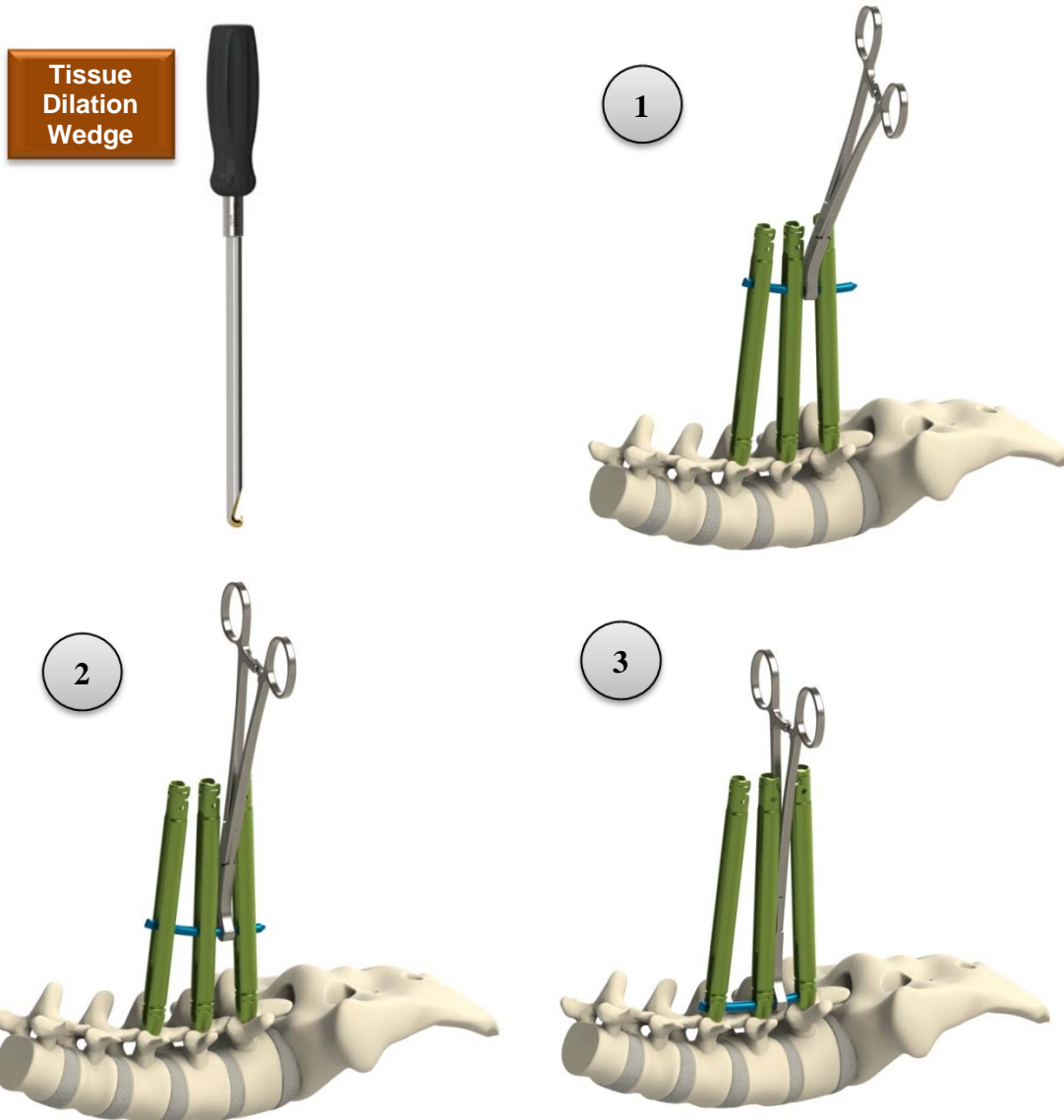
Users of this technique generally remove the Connection Ring at the tower opening in order to allow the rod inserter to pass easier. Please refer to the *Tower Removal* section for more details on this step.



Rod Placement (Approach #3)

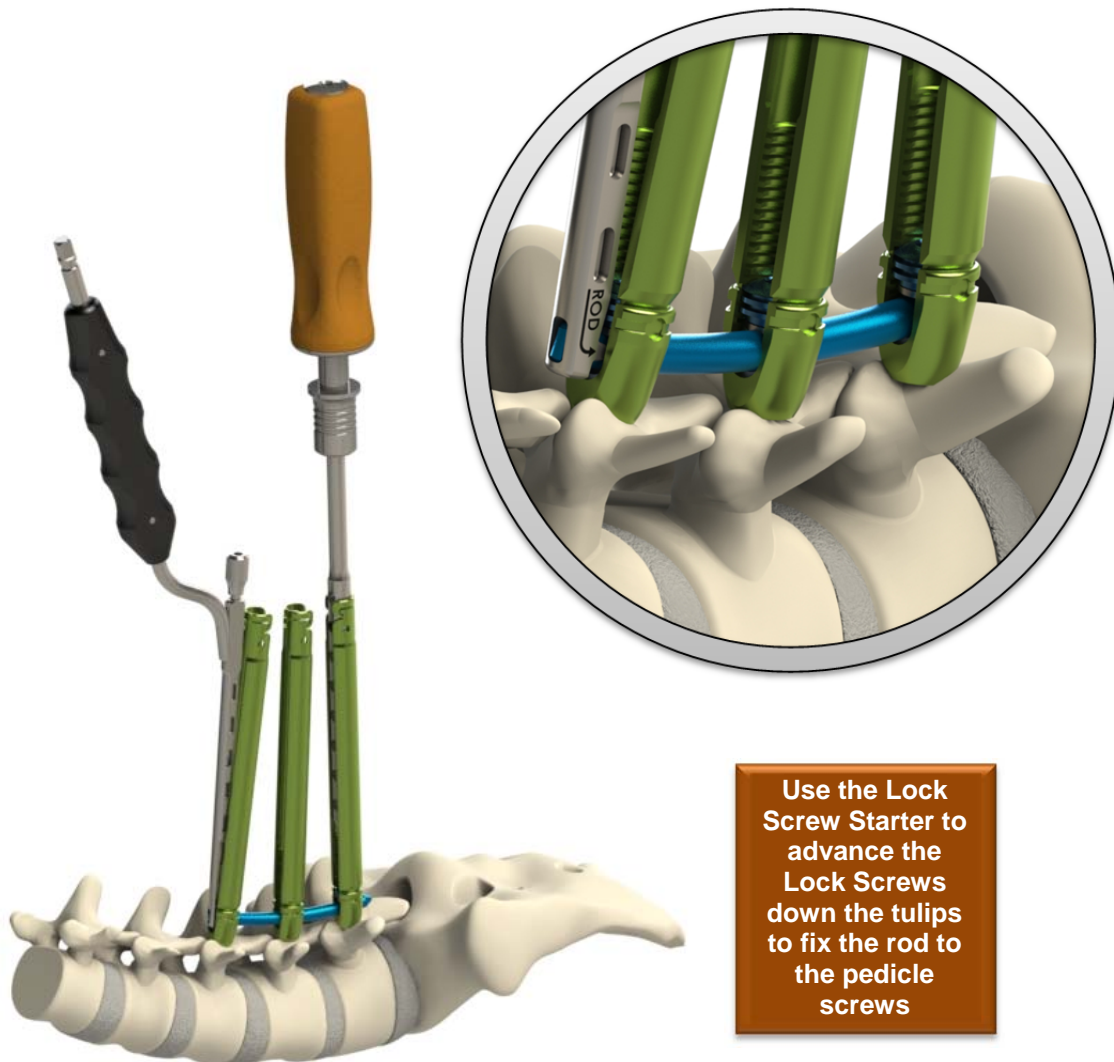
Wiltse Approach

Users of this technique should consider clearing the tissue between the towers with a Tissue Dilation Wedge. This method also requires Rod Gripping Forceps instead of a standard rod inserter. The Rod Gripping Forceps are used to walk the rod down to the screw heads.



Lock Screw Placement

After fluoroscopic verification of the rod position, place a Lock Screw on the distal end of the MIS Lock Screw Starter. Maintain control of the rod with the Rod Inserter and advance the Lock Screw down one of the extended tab pedicle screws. There are 20mm of reduction threads built into the tulip walls. Provisionally tighten the Lock Screw against the rod. Repeat this step with all other pedicle screws before obtaining a final fluoroscopic confirmation of the rod position.



Use the Lock Screw Starter to advance the Lock Screws down the tulips to fix the rod to the pedicle screws

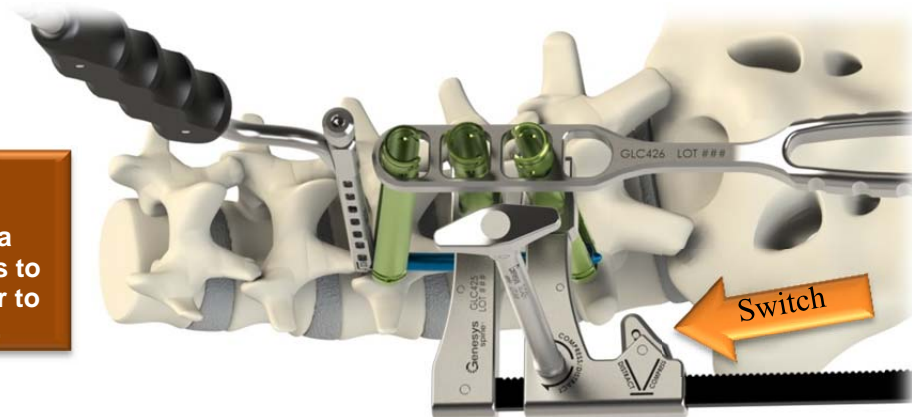
Compression / Distraction (Optional)

Compression and distraction occurs after tightening of at least one Lock Screw. Using the MIS Tower Ring instrument create a fulcrum point near the tower openings. Compression or distraction can be completed using a single rail instrument. Place the two mouths of MIS Disc Space Adjuster around the two screw towers. Set the rail instrument's switch to 'Compression' or 'Distraction' and turn the key in the direction of the intended action as exhibited by the instrument's marks (see figure below). Alternatively, the Tower Ring can be used as a fulcrum point for standard hand-held compressing and distracting instruments as well.

**Compression /
Distraction
Assembly**

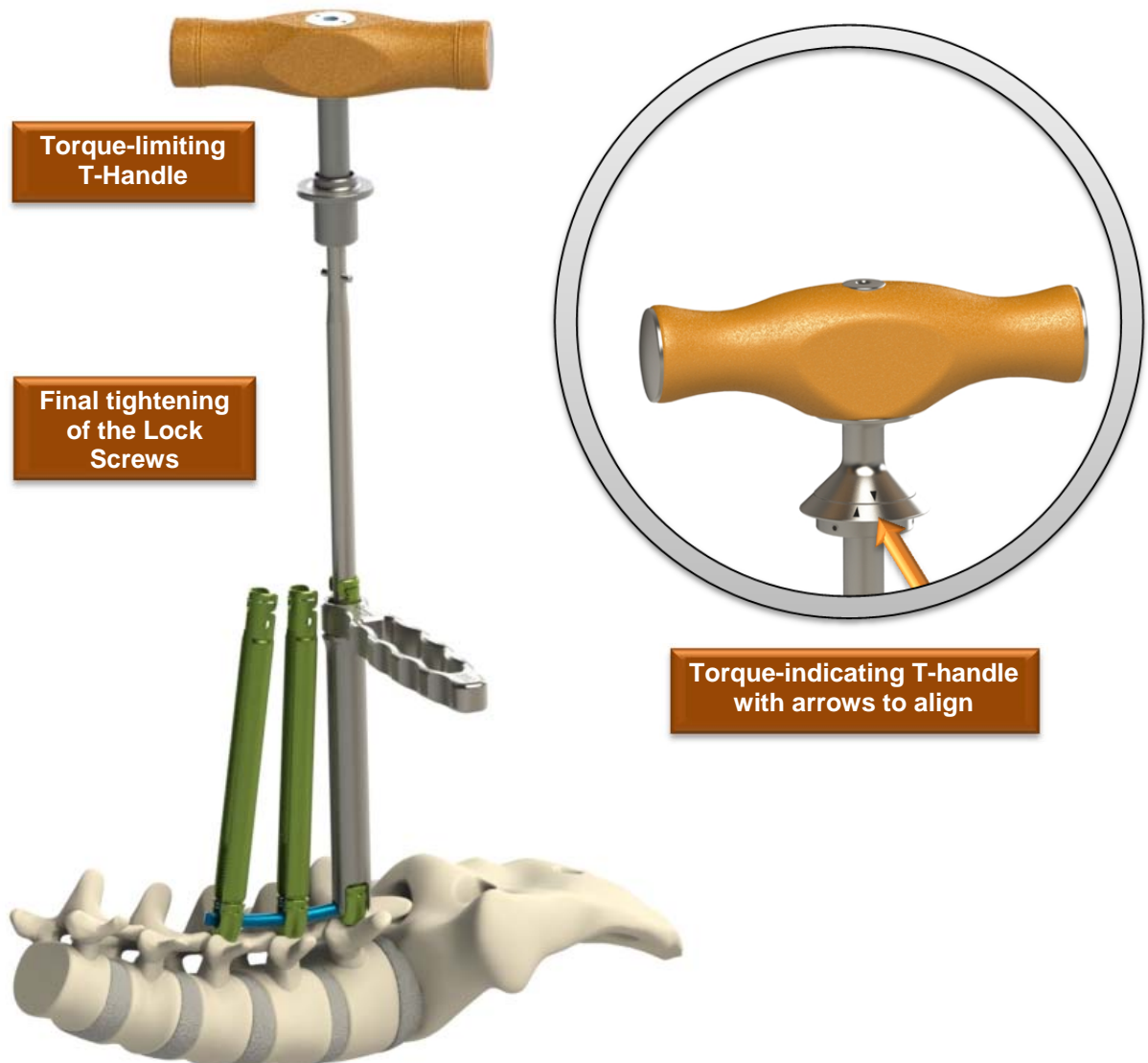


**The rail style
compressor/
distractor has a
switch that needs to
be activated prior to
advancement.**



Final Tightening

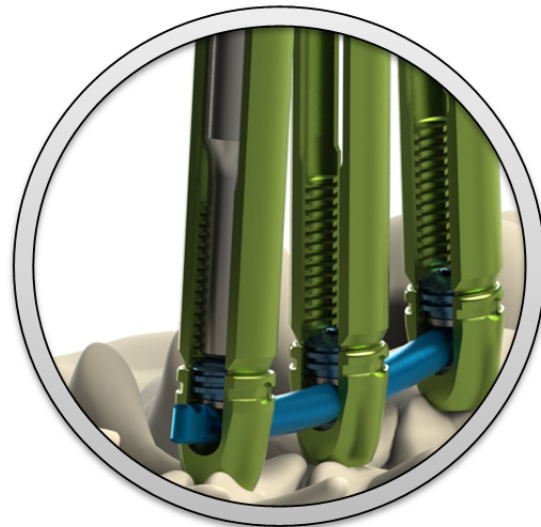
Final tighten each Lock Screw to 110 Nm using the MIS Final Torque Shaft, a Torque-Limiting T-handle or Torque-Indicating T-handle, and an MIS Counter Torque. The MIS Counter Torque is used to prevent the tightening torque from being transmitted into the pedicle. Tighten the Lock Screw to the rod until the Torque-Limiting T-handle "Pops" or the arrows align on the Torque-Indicating T-handle.



Tower Removal

To remove the screw towers, start by breaking the Connection Ring from each tower using the Tab Breaker Pliers, forceps, or a hemostat. The extended tabs that make up the tower (or “tulip assembly”) may now be removed with a Tower Breaker or the Double Tab Breaker (shown below). Fully seat the Tower Breaker onto the Lock Screw before dislocating the extended tabs.

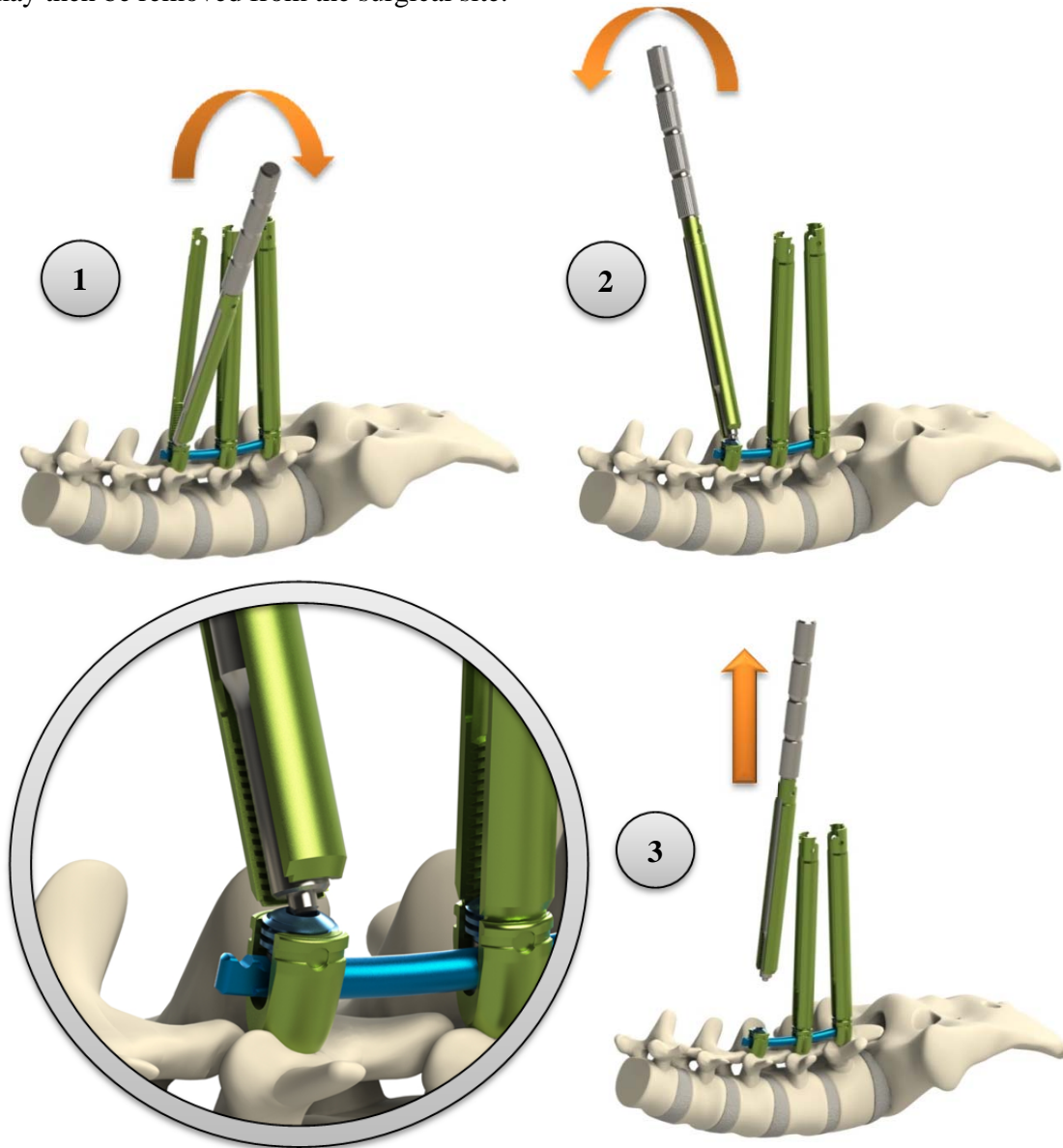
Insert tool into retention clip window (denoted by arrow) and break the retention clip from the tower assembly.



Insert the Double Tab Breaker into the tower until it bottoms out in Circular Lock Screw.

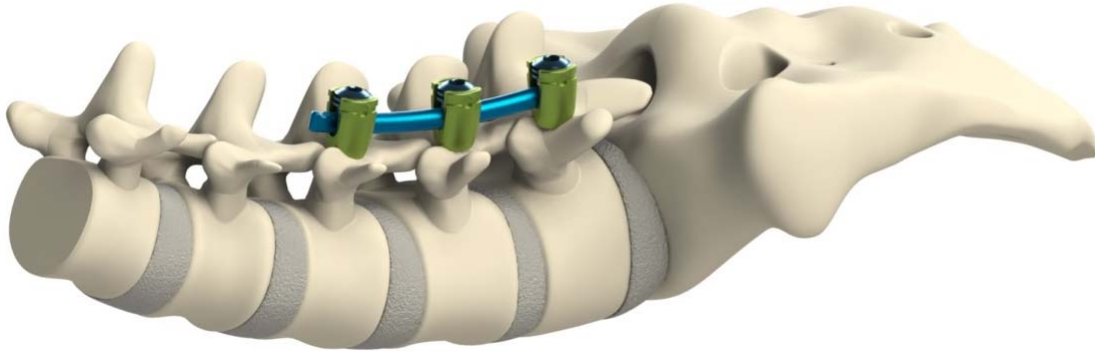
Tower Removal (Continued)

Holding both sides of the screw tower in one hand and the tower breaking instrument in the other, rock the tower medially and laterally until both tabs have been dislocated. The tabs may then be removed from the surgical site.



NOTE: The surgical technician can verify that all removed tabs have the 20mm of reduction thread on them.

Final Construct



Repeat the steps for the Contralateral Side

Removal / Revision

Remove the Lock Screws using the Counter-Torque instrument and a MIS Final Torque Shaft by turning the lock screw in a counterclockwise direction. Once all lock screws are removed, the rod may be removed manually or using the Rod Gripper Forceps. Remove the implanted screws using the Friction-Clip Screwdriver by turning in a counterclockwise direction to back out the screws.

Indications

The TiLock 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 disc disease (DDD) (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); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Contraindications

1. Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
2. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
3. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.
4. Any entity or condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis or osteopenia, is a relative contraindication. Other relative contraindications include obesity, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.

Warnings

Following are specific warnings and precautions that should be understood by the surgeon and explained to the patient.

General surgical risks should be explained to the patient prior to surgery.

1. IN THE U.S.A., THIS PRODUCT HAS LABELING LIMITATIONS.
2. 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 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 is unknown.
3. BENEFIT OF SPINAL FUSIONS UTILIZING ANY PEDICLE SCREW FIXATION SYSTEM HAS NOT BEEN ADEQUATELY ESTABLISHED IN PATIENTS WITH STABLE SPINES.
Potential risks identified with the use of this device system, which may require additional surgery, include:
 - a) Device component fracture.
 - b) Loss of fixation.
 - c) Non-union.
 - d) Fracture of the vertebra.
 - e) Neurological injury.
 - f) Vascular or visceral injury
4. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to

those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

5. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

6. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with other metal objects, must be made from like or compatible metals.

7. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

- a) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
- b) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the device.
- c) A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- d) Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary relief.
- e) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- f) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

Precautions

1. THE IMPLANTATION OF PEDICLE SCREW SPINAL SYSTEMS SHOULD BE PERFORMED ONLY BY EXPERIENCED 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.
2. SURGEONS SHOULD HAVE KNOWLEDGE OF HOW TO TARGET PEDICLE SCREWS USING FLUOROSCOPY AND K-WIRE WHEN UTILIZING A MINIMALLY INVASIVE SURGICAL TECHNIQUE.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of the metal implants should only be performed with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease fatigue life and may cause failure.
5. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can loosen, fracture, corrode, migrate, and possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
6. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative Rehabilitation.
7. MAGNETIC RESONANCE (MR) ENVIRONMENT. The TiLock System has not been evaluated for safety and compatibility in the MR environment. The TiLock System has not been tested for heating or migration in the MR environment.
8. PATIENT SELECTION. Based on fatigue testing results, when using the Genesys Spine TiLock Pedicle Screw System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.



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