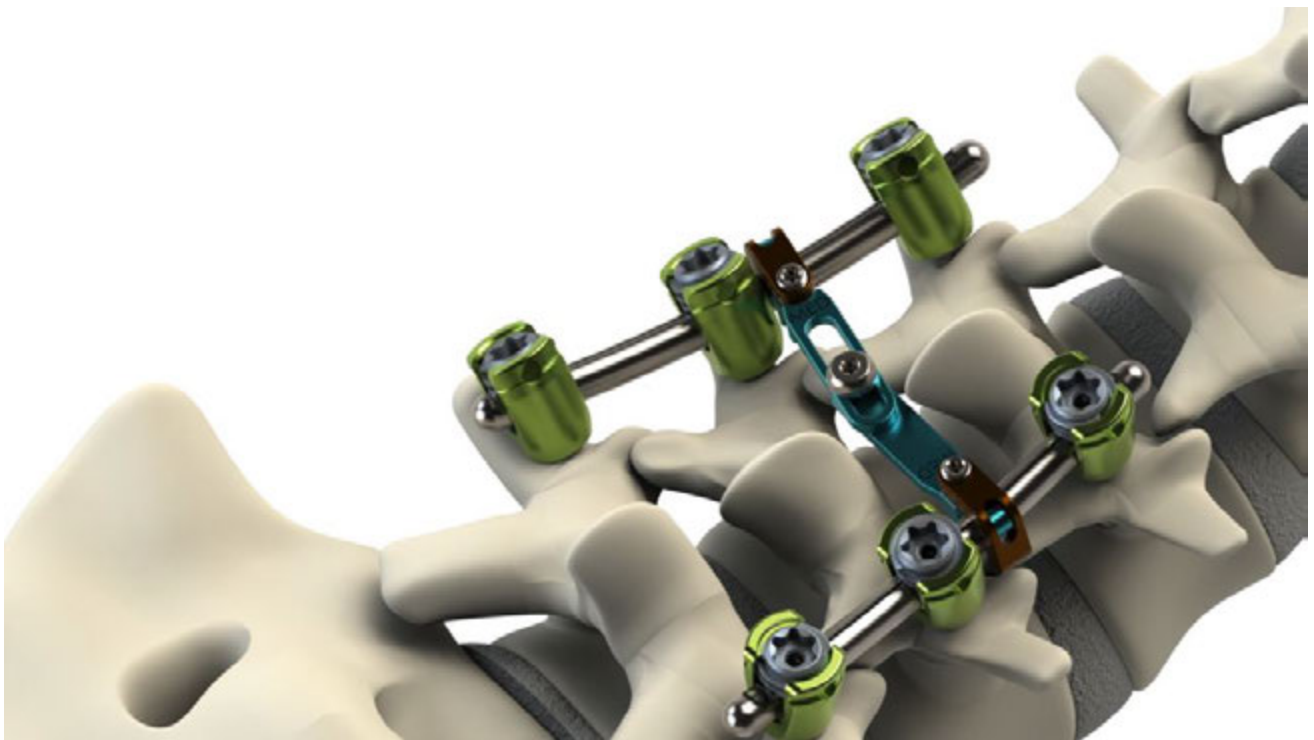




# Surgical Technique



TiLock<sup>2</sup>™ Spinal System

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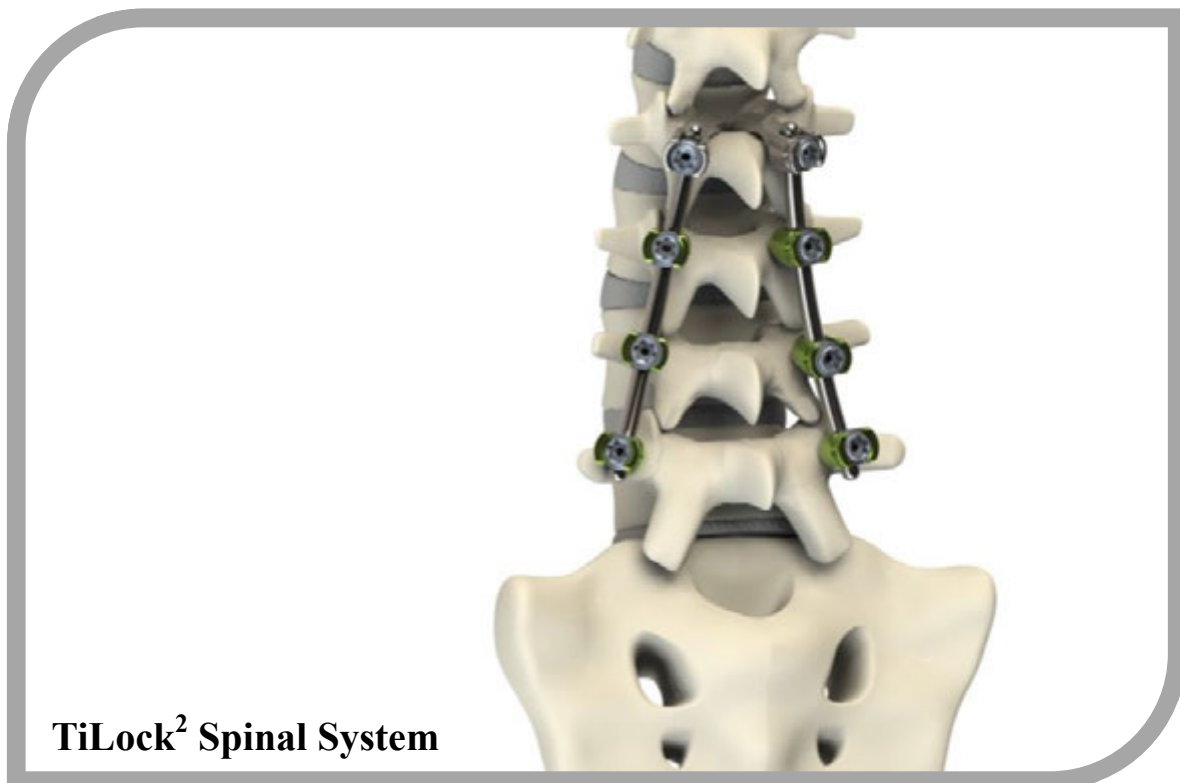
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# TiLock<sup>2</sup>™ Spinal System Surgical Technique

The Genesys Spine TiLock<sup>2</sup> Spinal System consists of rods (straight and curved), lock screws, cross-links, offset connectors, hooks, and several types of polyaxial screws in various lengths and diameters.

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



## 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.

## Pedicle Preparation

After exposing the pedicle screw entry points, a starting hole may be initiated with the Bone Awl. Advance the awl into the pedicle by tapping lightly with a mallet. As the awl advances, it should approach the middle of the pedicle cylinder on an AP image. The position of the awl can be checked with a direct lateral fluoro-image to ensure that the trajectory of the advancing awl matches the anatomy the patients' pedicle. After this confirmation, advance the awl to the desired depth within the vertebral body. The awl inserts to a depth of 20 millimeters.

Insert Awl tip into the intended pedicle



## Probe

Fluoroscopy may be utilized by the surgeon to allow for more accurate placement of pedicle screws. Alternatively, plain x-ray may be utilized to visualize the appropriate trajectory. Enter the pedicle with the pedicle probe. The angled or straight probe may be utilized at the surgeon's discretion. A smaller diameter probe may be made available for smaller or more difficult pedicles. The probe should be rotated with entry to allow for the path of least resistance and to reduce stress on the probe. Calibration on the shaft is utilized to choose the appropriate length screw. Depth should be measured from the initial entry point.

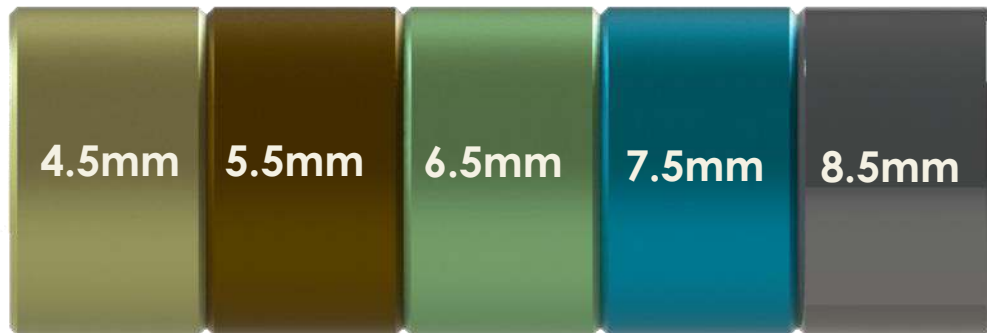
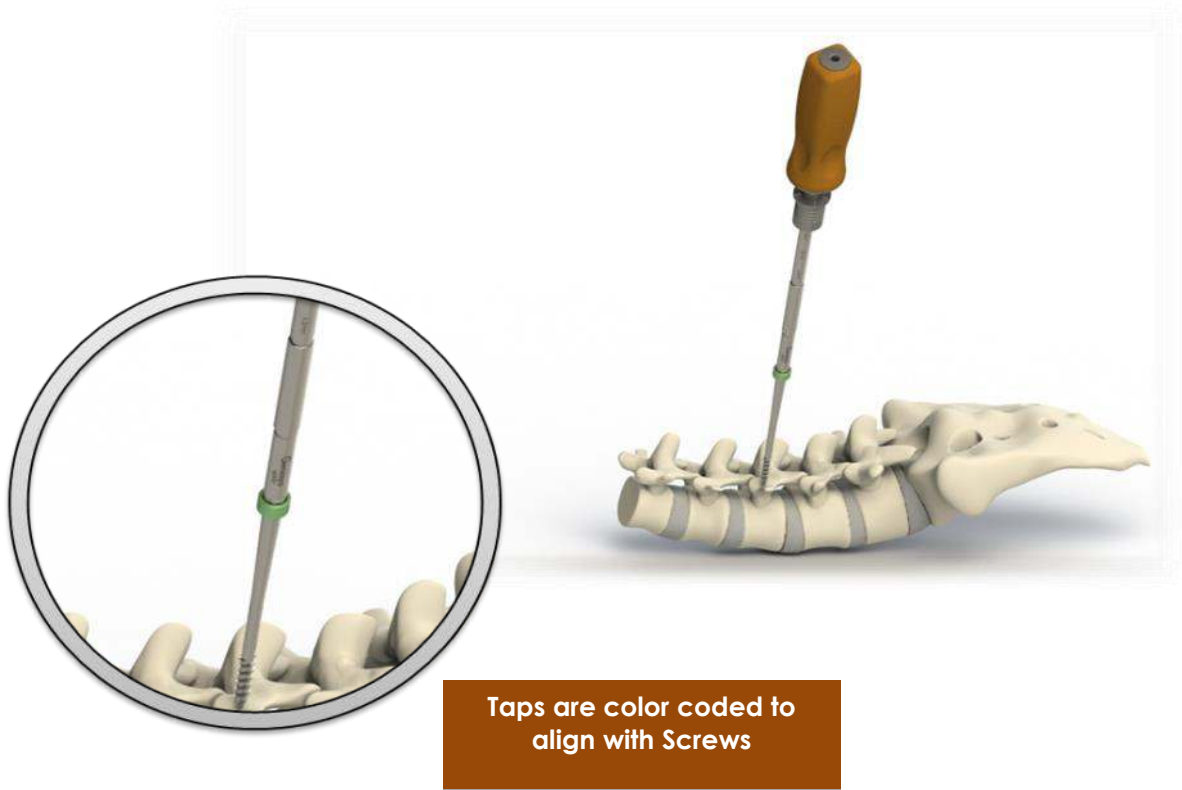
Probe pedicle to the desired depth



## Tap Pedicle

Depending on bone density at the insertion site, a tap may be utilized to ease the insertion of the screw.

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



# Screw Options

Genesys Spine Screws are offered in several formats.

There are four screw types:

- TiLock<sup>2</sup> Screw
- TiLock<sup>2</sup> Cannulated Screw
- TiLock<sup>2</sup> Reduction Screw ("Break-Off Tulip")
- TiLock<sup>2</sup> Cannulated Reduction Screw ("Break-Off Tulip")
- TiLock<sup>2</sup> Cannulated Screw, Extended Tab ("MIS")
- TiLock<sup>2</sup> Monoaxial Screws

The screws have either fixed (Monoaxial) or adjustable (Polyaxial) heads. The available solid screw diameters are 4.5mm, 5.5mm, 6.5mm, 7.5mm, and 8.5mm and current length offerings go from 25mm to 60mm for the 4.5mm through 7.5mm and 25mm through 100mm for the 8.5mm diameter. Tulip color corresponds to the screw diameter (see the color code on the previous page).



## Screw Insertion

Insert the Screwdriver into the screw tulip. The screwdriver should feel snug when the screw is fully seated. Advance the screw into the vertebral body until the tulip head of the screw sits snugly against the base of the facet joint. The Friction-Clip Screwdriver can be removed by pulling it vertically out of the screw tulip. Repeat these steps for each additional screw.



A Low-Top Screw seated on the Friction-Clip Screwdriver

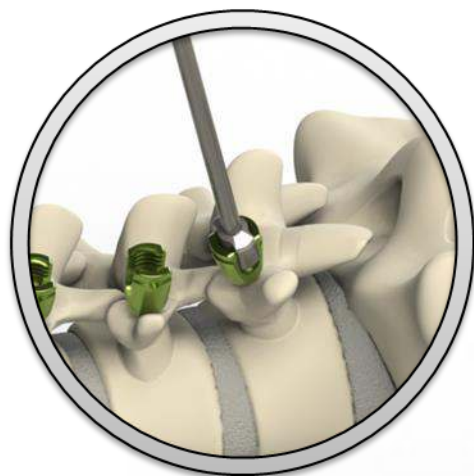
Advance  
screw into  
pedicle



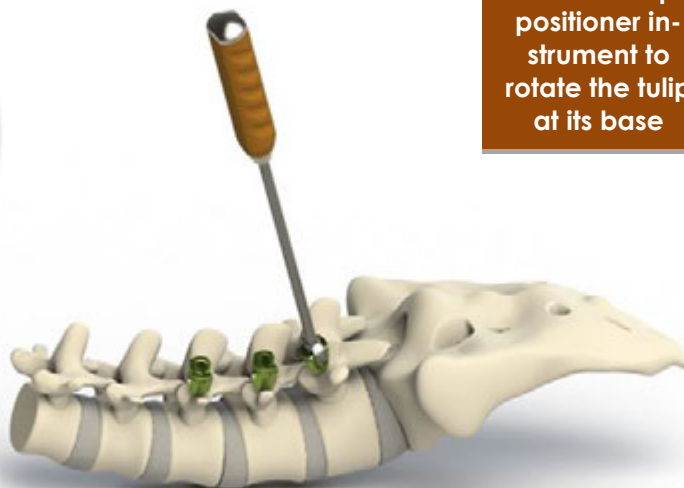


## Aligning the Windows

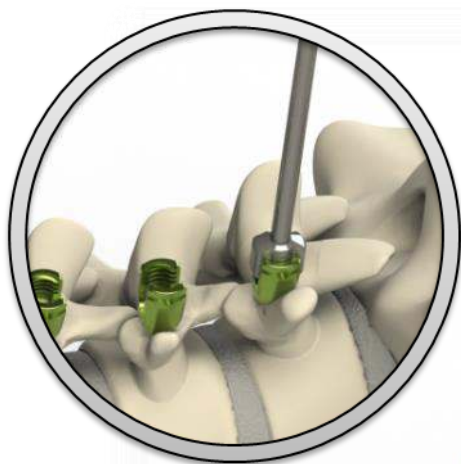
The windows in the tulips of the screws should be aligned in order to place the rod. The polyaxial tulips on the screws may be rotated.



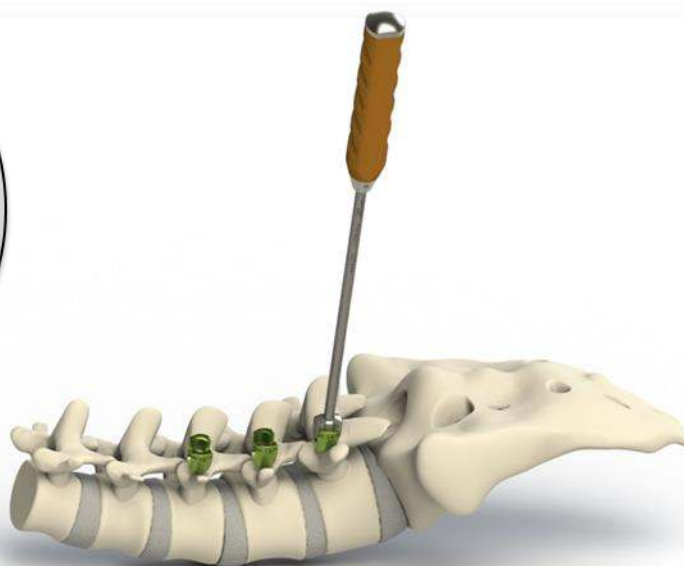
Before



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

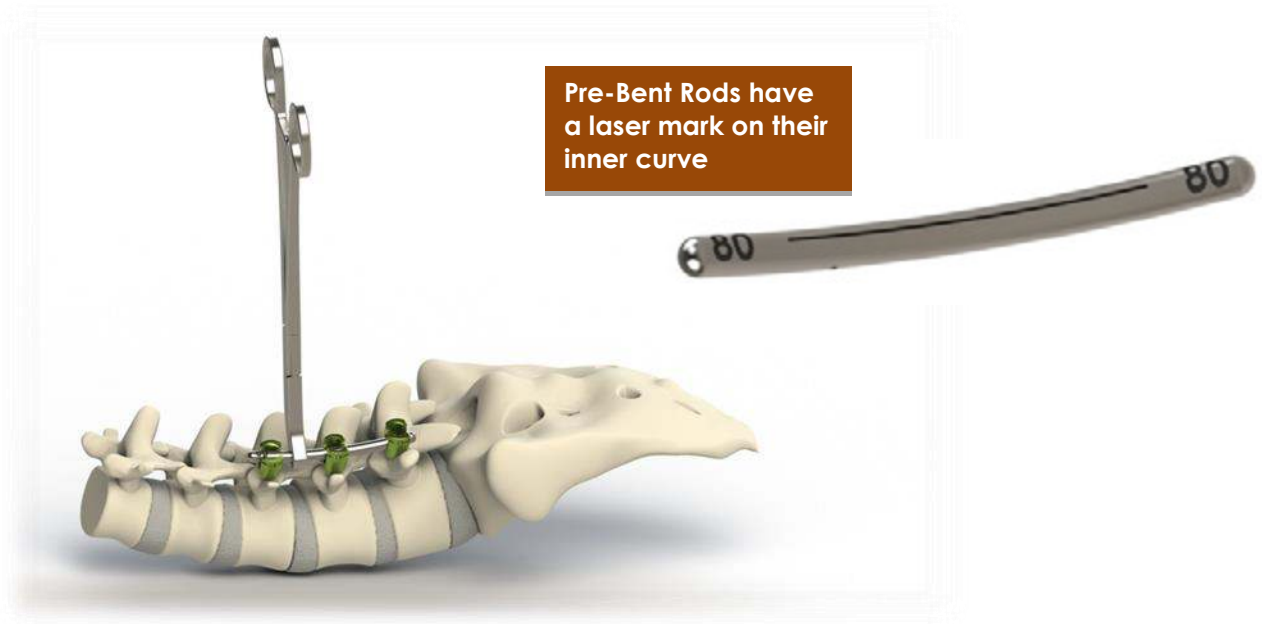


After



## Rod Insertion

The rod is then held by the rod holder and seated into the screw heads



## Reduction

There are several instrument options for reducing the segments. The Rod Rockers, shown below, grasp the screw's tulip while pushing the rod into the screw's saddle



## Lock Screw Selection

When selecting a Lock Screw design there are several options. The primary factor in the Lock Screw design is the instrument interface type that the surgeon desires: both Hex interface (G826) and Torx interface (G827 & G828) are available. Each of these designs can be seen below.



The compatibility of these screws is outlined as follows:

Lock Screw Compatibility Matrix			
Lock Screw	Name	TiLock / TiLock <sup>2</sup> / Hooks / Offset / Dominos	8.5mm TiLock / 8.5mm TiLock <sup>2</sup> / 8.5mm TiLock <sup>2</sup> XT (MIS)
G826	Circular Lock Screw	X	
G826-85	8.5mm Circular Lock Screw		X
G827	Hexalobular Lock Screw	X	
G827-85	8.5mm Hexalobular Lock Screw		X
G828	Circular Star Lock Screw	X	
G828-85	8.5mm Circular Star Lock Screw		X

The next factor in selecting a Lock Screw is the size of pedicle screw being used. 8.5mm Pedicle Screws require the -85 Lock Screws: G825-85, G826-85, G827-85, or G828-85

NOTE: The 8.5mm Set caps can only be used with the 8.5mm Screws.

# Lock Screw Placement

After fluoroscopic verification of the rod position, place a Lock Screw on the distal end of the Lock Screw Starter. Maintain control of the rod with the Rod Inserter and advance the Lock Screw down one of the screws' tulip. 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.



There are two Lock Screw Starter Designs: a "stab-and-grab" style as shown above and a locking style which is exhibited below. In addition, each style lock screw starter is offered in a design compatible with hex interface lock screws and the torx interface lock screws. The table below outlines the styles that are offered.

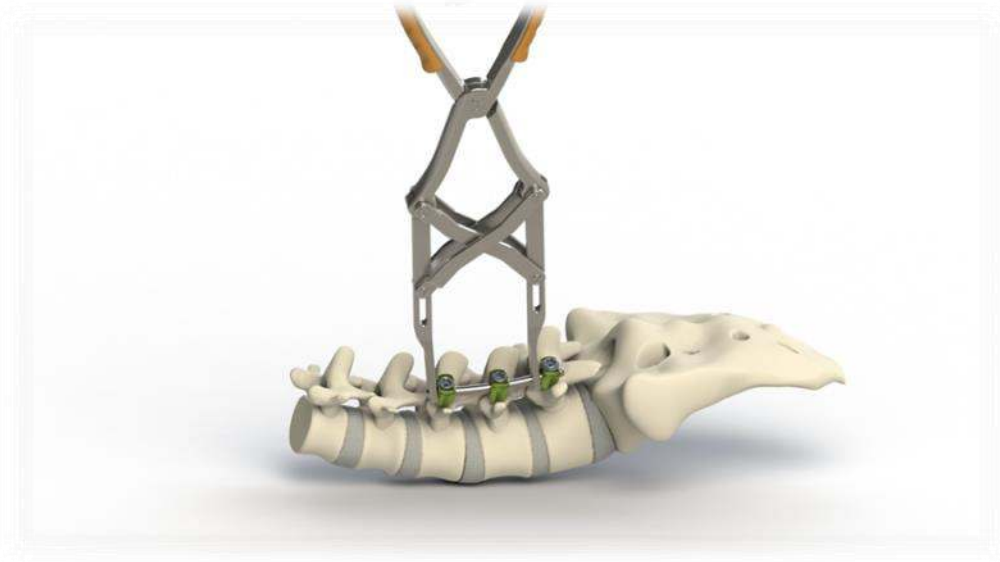
Lock Screw Starter Designs		
Lock Screw Starter Type	Hex Interface Screw G826	Torx Interface Screws G827, 828
Stab-and-Grab	GL306 Cap Screw Starter Shaft	GLC403 MIS Star Friction Setcap Starter
Locking Style	GLC421 MIS Locking Lock Screw Starter	GLC429-X MIS Locking Star Setcap Starter

For the stab-and-grab style, align the driver's tip with the lock screw and simply push down. For the locking style, mate the driver's tip with the lock screw and then slide the sleeve down and twist into the locking position as shown below. Be sure to unlock the instrument from the lock screw before instrument removal.



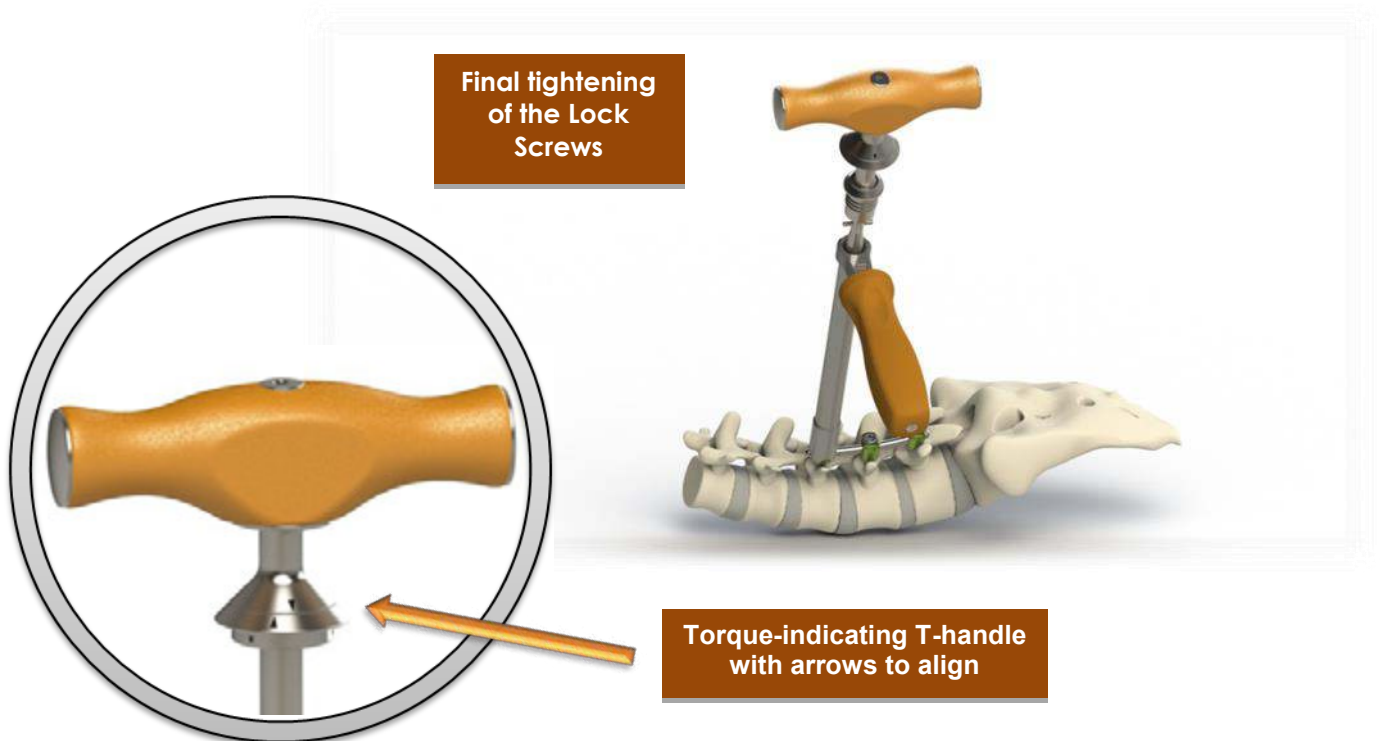
## Compression/Distraktion (Optional)

Compression and distraction can occur after final tightening of at least one Lock Screw to the rod.



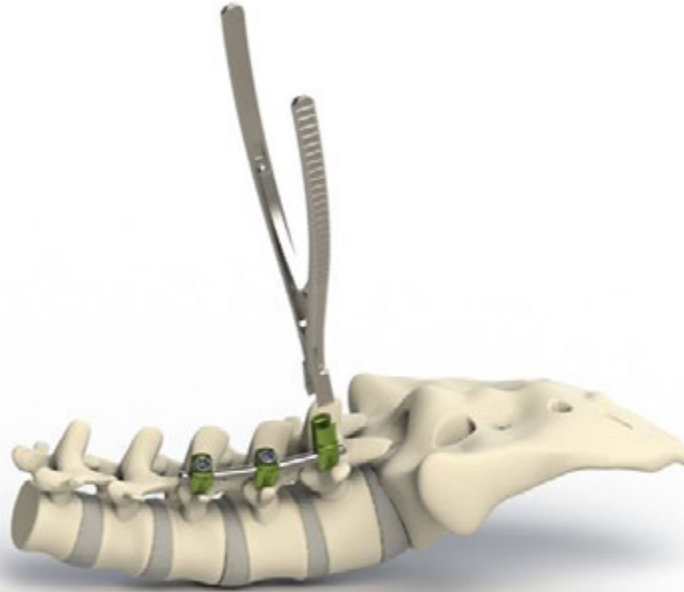
### Final Tightening

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



## Reduction Tab Removal (Only for Reduction Screws)

To remove the Reduction Screw's tabs, use the Tab Breaker Pliers, forceps, or a hemostat to grip onto one of the tulip tabs. Rock back and forth until the tab breaks away from the rest of the construct. Repeat on the other tab and dispose of both tabs.



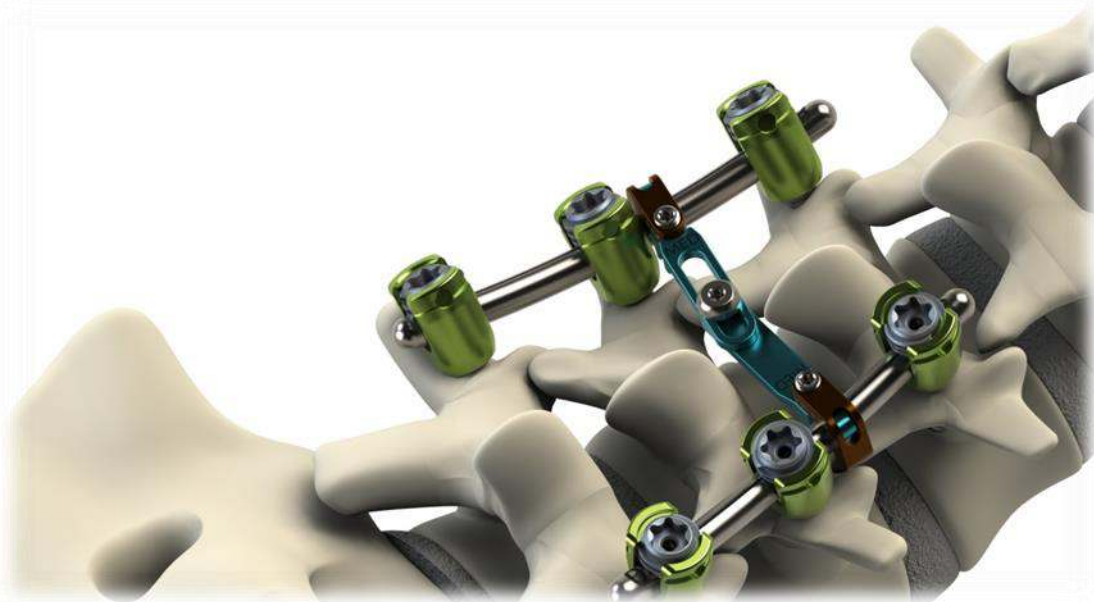
### Final Construct



Repeat the steps for the Contralateral Side

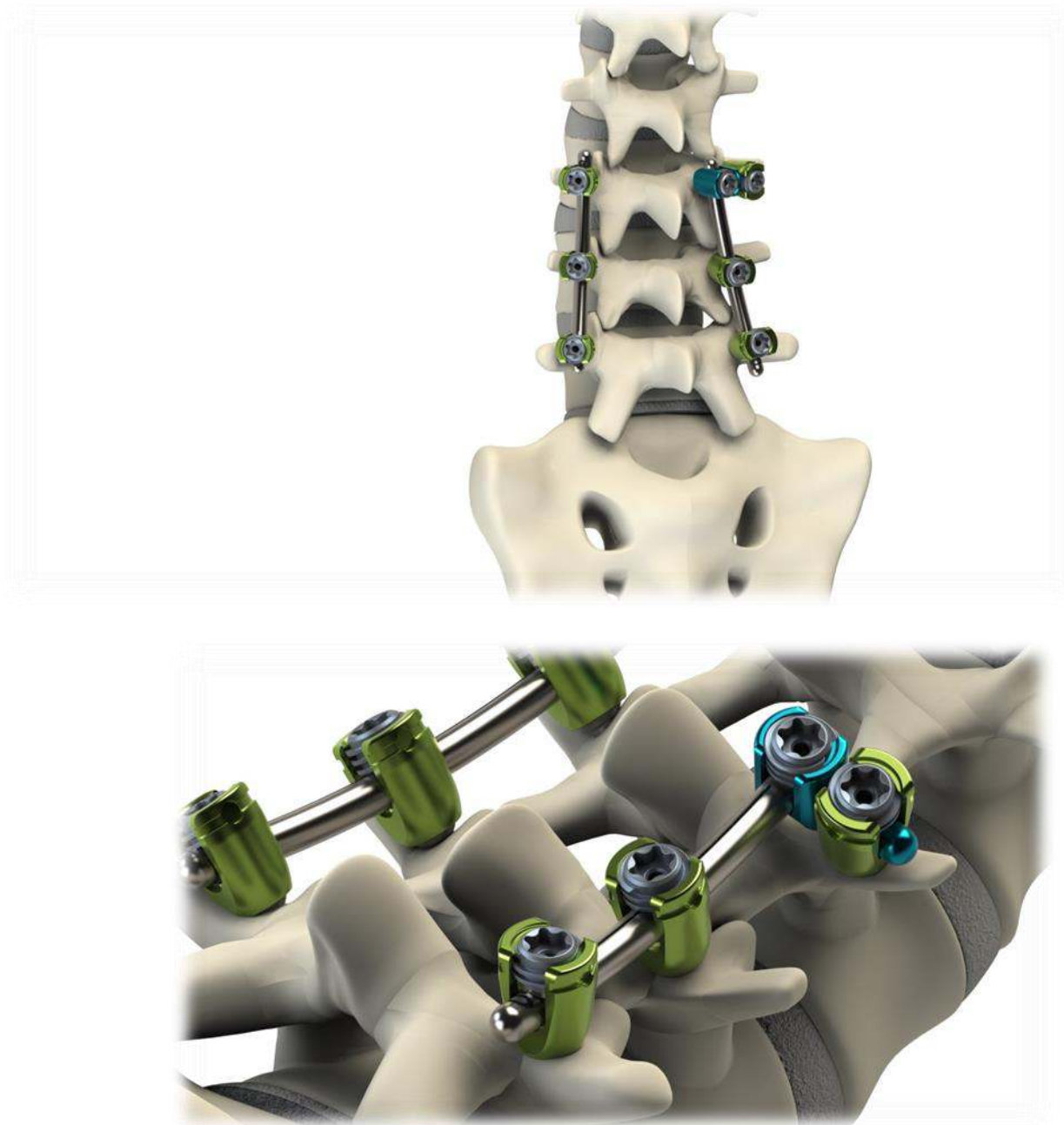
## Optional Addition #1: Cross Link

Cross-links are available to provide additional stiffness and reduce rotation of construct.



## Optional Addition #2: Offset Connector

Offset connectors are available to better accommodate the patient's anatomy when required.





## Optional Addition #3: Hook

Hooks are available to help stabilize the construct and prevent bending.



## Optional Addition #4: Connectors

Connectors are available to connect multiple rod constructs.



### Removal/Revision

Remove the Lock Screws using the Counter-Torque instrument and a 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/Contraindications/Warnings

## Indications

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The TiLock<sup>2</sup> Spinal 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

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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

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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) Device component fracture.
- c) Loss of fixation.
- d) Non-union.
- e) Fracture of the vertebra.
- f) Neurological injury.
- g) 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

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## Indications/Contraindications/Warnings Continued

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.

### 8. REUSE OF IMPLANTS.

The risk of reusing implants includes infection and tissue irritation. In addition, exposure to the chemicals used for cleaning can induce physical changes to the materials; the result can be sudden mechanical failure or device malfunction. Genesys Spine accepts no responsibility for a re-used implant.

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# Precautions

## Precautions

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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.
9. Instruments should not be used in any capacity other than their intended use.

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







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