NIDO™

PEDICLE SCREW SYSTEM

Surgical Technique

Kalitec

NIDO Pedicle Screw System

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This surgical technique is for illustrative and demonstrative purposes only. Technique is dependent upon a surgeon's medical judgement to provide the best method of treatment for each patient. Please see Instructions for Use for the complete list of indications for use, warnings, precautions, and other important information concerning the use and guidance of the NIDO Pedicle Screw System.

NIDO PEDICLE SCREW SYSTEM

The NIDO Pedicle Screw System is a modular, comprehensive system for posterior thoracolumbar stabilization, designed to ensure ease of use and intraoperative flexibility through a customizable solution for each unique condition and clinical scenario. The NIDO Pedicle Screw System enhances efficiency and visibility of the operative site with its modular platform and provides a variety of implant and instrument solutions for degenerative, deformity and tumor corrections.

The NIDO Pedicle Screw System has been designed with the assistance of our surgeon development team. Kalitec Medical would like to take the opportunity to thank them for their contributions and efforts to make the NIDO Pedicle Screw System a robust and versatile surgical solution.

NIDO Pedicle Screw System
Implant Overview

Screw Shank

- Dual-lead cortical-cancellous thread forms
- Available in non-cannulated and cannulated-fenestrated
- Screw diameters: 4.75mm and 5.5-8.5mm, in 1mm increments
  - 9.5 and 10.5mm diameters available by special order
  - Screw shanks are color coded by screw diameter
- Screw lengths: 25-115mm, in 5mm increments
  - 4.75mm and 5.5mm diameters – Lengths 25mm to 65mm
  - 6.5mm to 10.5mm diameters – Lengths 25mm to 115mm

Locking Cap

- Universal T30 hexalobe socket
- Interfaces with Split Tip Drivers for self-retention

Polyaxial Tulip

- ± 30° shank angulation (60° spherical angulation) provides intraoperative versatility
- Available in standard and 15mm Extended Tab geometries
- Instrument engagement features for screw insertion and reduction

Rod to Rod Transition Connectors

- Transition and Offset Connectors for construct extension
- All connectors are 5.5 to 5.5mm rod diameter

Rods

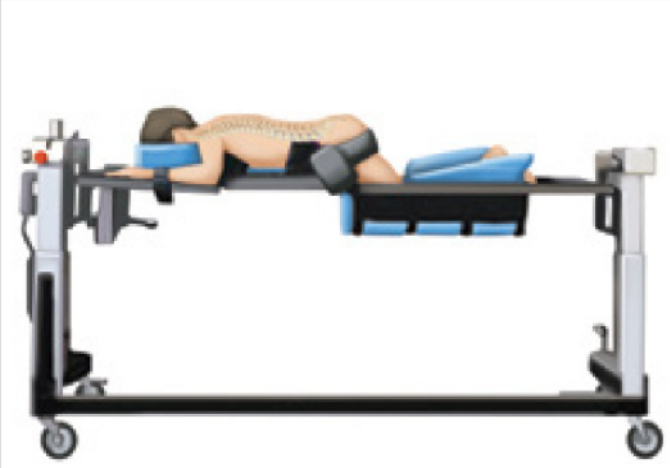
- 5.5mm rod diameters
- Available in Titanium Alloy (Ti-6Al-4V), Cobalt Chrome (CoCr), and Commercially Pure Ti (CP)
- Straight Rods: 35 to 600mm Lengths (CoCr 250-600mm)
- Pre-Bent Rods: 35 to 200mm Lengths

Surgical Technique

Step 1 Patient Positioning and O.R. Setup

Place the patient on the operating table in a prone position. Prepare and drape in a conventional manner. The fluoroscope should have easy access to the surgical field for both A/P and lateral views. Patient's position should be checked radiographically to determine the direction of the pedicles relative to the horizontal plane. There are various techniques for pedicle screw and rod insertion. For the purposes of this technique guide, an open approach and placement of fixation points in the lower lumbar spine will be shown.

NOTE: *If patient is placed on a frame with hips extended, lumbar lordosis will increase.*



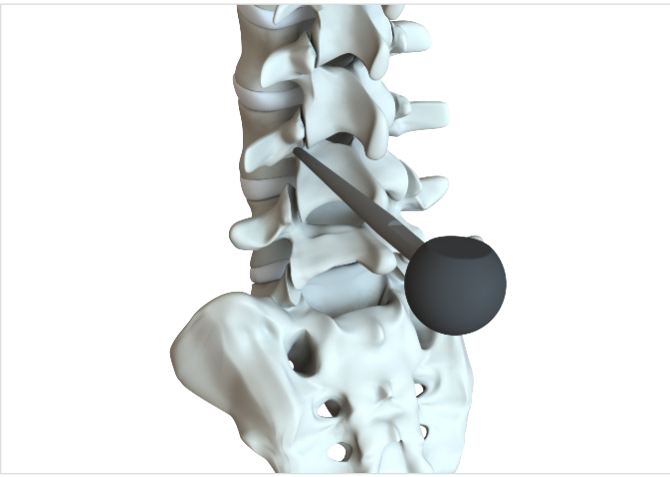
Step 2 Pedicle Preparation

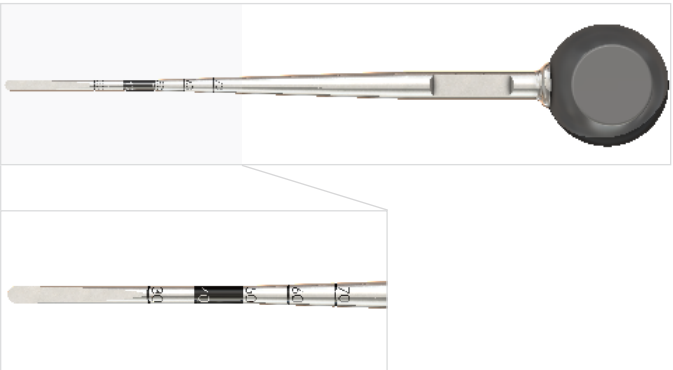
Locate the desired entry point into the pedicle and remove bone and/or soft tissue as needed using standard instruments. Perforate the cortex with a high-speed burr or **Awl**. Create a pilot hole by passing a **Pedicle Probe** through the pedicle and into the vertebral body.

NOTE: *A **Thoracic Step Awl** has been provided to create a pilot hole (a high-speed burr may also be used to break the cortex). The awl diameter is Ø2.25mm with a stop to limit penetration to 10mm.*

NOTE: ***Steffee Style Probes** and **Lenke Style Probes** are also available.*

NOTE: ***Pedicle Probes** are marked with laser lines from 30mm to 70mm in 10mm increments to help visualize depth.*



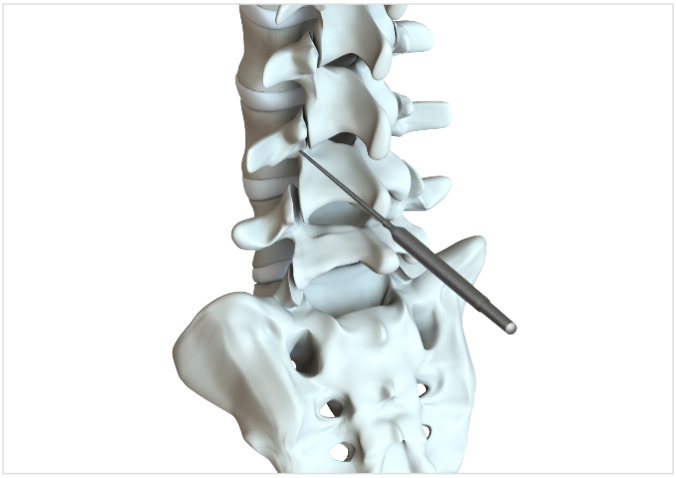


Surgical Technique

Step 2 Pedicle Preparation *(continued)*

Prior to screw insertion, use the **Ball Tip Sounder** inspect the pilot hole and the cortical wall of the pedicle. Palpate the pedicle wall on all sides to determine pedicle integrity.

TIP: *When fully inserted, forceps can be clamped onto the **Ball Tip Sounder** to determine the hole depth/ appropriate screw length.*

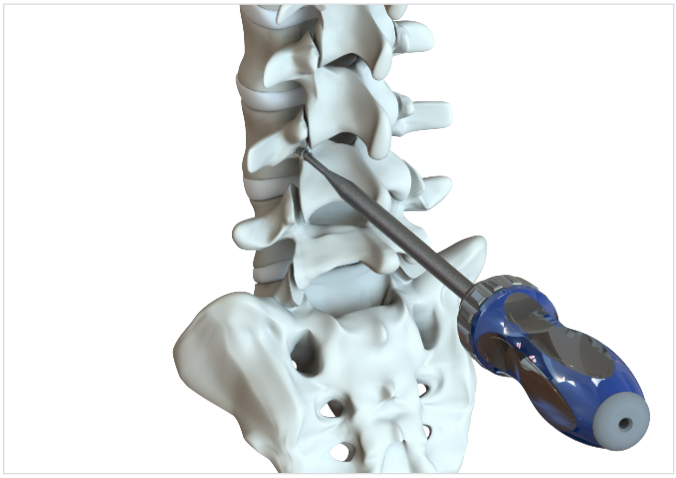


Step 3 Pedicle Tapping

Select the preferred **Ratcheting Handle**, and attach to an appropriately sized **Tap**. Set the ratchet to the preferred drive position and tap through the pedicle into the vertebral body, using the markings on the shaft and fluoroscopy to monitor depth. Prior to screw insertion, inspect the pilot hole again for perforations, using the **Ball Tip Sounder**.

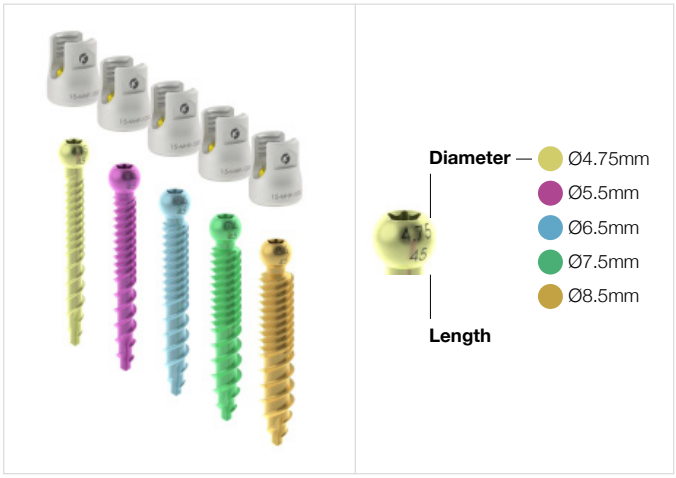
NOTE: ***Taps*** *possess a minimum thread length of 35mm and are marked with laser lines starting at 40mm to help visualize bone depth.*

NOTE: ***Taps*** *are designed to be 0.5mm undersized*



Step 4 Modular Screw Shank Insertion

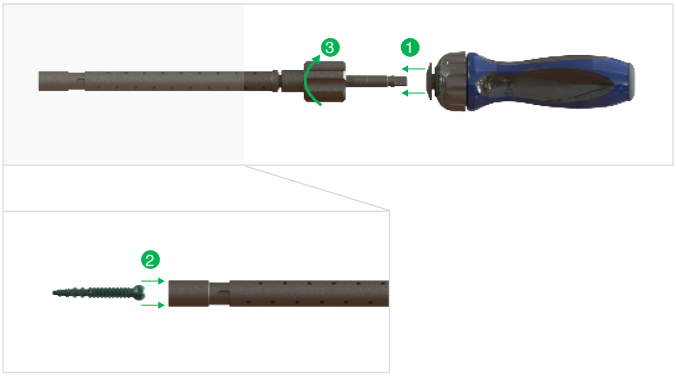
Once the pedicle has been prepared, select the appropriate **Screw Shank** diameter and length. Shank diameters are identified by unique anodization colors, whereas shank length is determined by position within the caddie. Use the integrated **Locking Cap Caddie** measurement features to verify shank diameter and length.



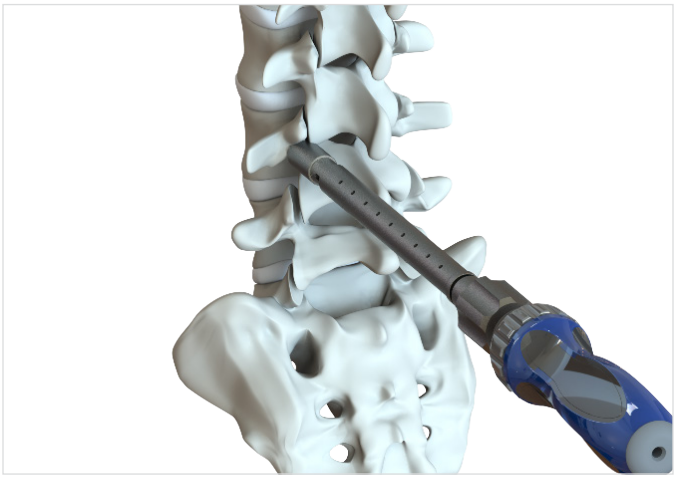
Surgical Technique

Step 4 Modular Screw Shank Insertion *(continued)*

Attach the preferred **Ratcheting Handle** to the **Modular Bone Screw Driver.** Load the **Modular Screw Shank** to the Modular Bone Screw Driver by inserting the T25 hexalobe drive feature into the shank. Secure by turning the proximal knob clockwise; the distal gripping feature will close around the Modular Bone Screw head as the proximal knob is tightened. Verify that the screw and screwdriver interface is rigid, and the shank is aligned straight and coaxial with the Modular Bone Screw Driver.

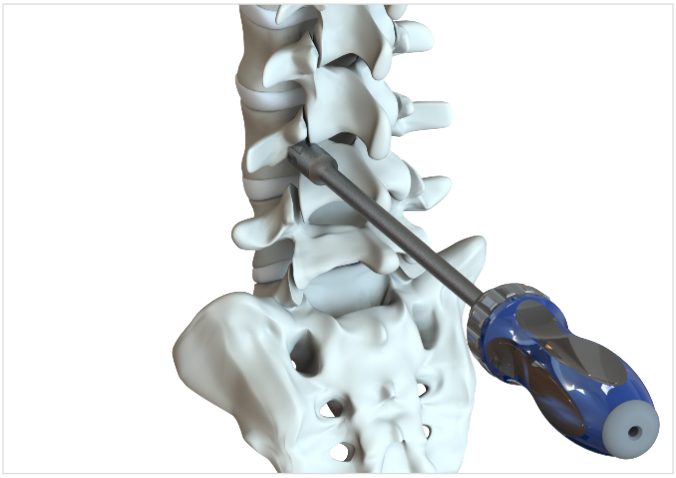


Introduce the **Modular Screw Shank** into the pilot hole and advance until the desired depth is reached. The distal gripping feature of the **Modular Bone Screw Driver** serves as an indicator of screw depth. Do not apply a levering force to the driver during Modular Screw Shank insertion as this can result in an improper trajectory of the Modular Screw Shank or pedicle fractures. When the Modular Screw Shank has been fully seated, disengage the Modular Bone Screw Driver from the screw by rotating the proximal knob counterclockwise until it is fully released.



NOTE: *The **Modular Bone Screw Driver** is designed to limit the depth at which a screw shank is implanted so that the spherical head of the screw shank can accept a corresponding tulip.*

Use the **Decorticating Planer** over the top of the **Modular Screw Shank** to decorticate the bone surrounding the spherical head of the screw.



NOTE: *The **Modular Screw Shank** can be removed or repositioned with the **Modular Bone Screw Driver** or the **T25 Screw Height Adjuster** as all implants feature a common T25 hexalobe socket.*

Surgical Technique

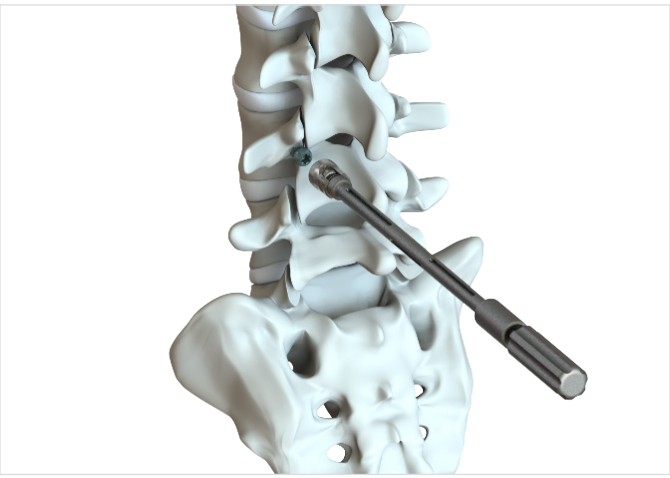
Step 5 Modular Housing Attachment

The NIDO Pedicle Screw System provides two screw tulip options based on the need for reduction.

- **Polyaxial (Standard Tulips)** are the most commonly utilized tulip, and are used with the **Modular Screw Shank**.
- **Extended Tab Tulips** are used for up to 15mm of instrument free reduction, and are used with the **Modular Screw Shank**.

After placement of the **Modular Screw Shank**, use the appropriate **Tulip Inserter** to introduce and connect a **Modular Tulip** to the Modular Screw Shank.

1. Rotate the distal threads of the **Tulip Inserter** into the threads of the **Modular Tulip** by rotating the knurled section of the instrument clockwise. The distal foot of the Tulip Inserter will prevent the Modular Tulip from rotating while being loaded. ***Caution: Do not prematurely lock the Tulip onto a Screw Shank. Once attached, Modular Tulips can not be disassembled.***
2. Slide the **Modular Tulip** onto the screw shank by applying a downward force to connect the two components.
3. Depress the back handle of the **Tulip Inserter** to attach the **Modular Tulip** to the **Modular Screw Shank**. There should be an audible "click."
4. Verify the **Modular Tulip/Screw Shank** connection by pulling the **Tulip Inserter** proximally.
5. Unthread the **Tulip Inserter** from the **Modular Tulip** by rotating the knurled section of the instrument counterclockwise.



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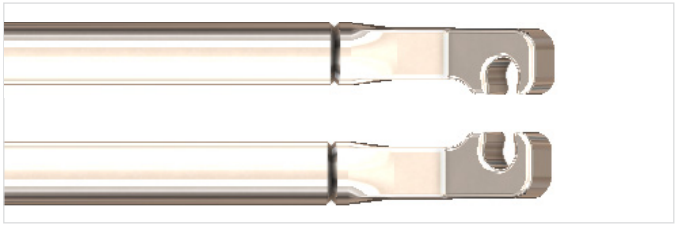
Step 6 Rod Selection and Contouring

The NIDO Pedicle Screw System offers a variety of **Rod** diameters, lengths, and materials. Rods are offered in both straight and curved options, and may be cut to length using a **Rod Cutter**.

Use the **3-Position Rod Bender** to prepare and contour the **Rods** with progressive bends until desired curvature is achieved. Pre-contoured Rods provide an initial curvature approximation without inducing additional stress onto the rod. **Sagittal and Coronal Rod Benders** are also offered.



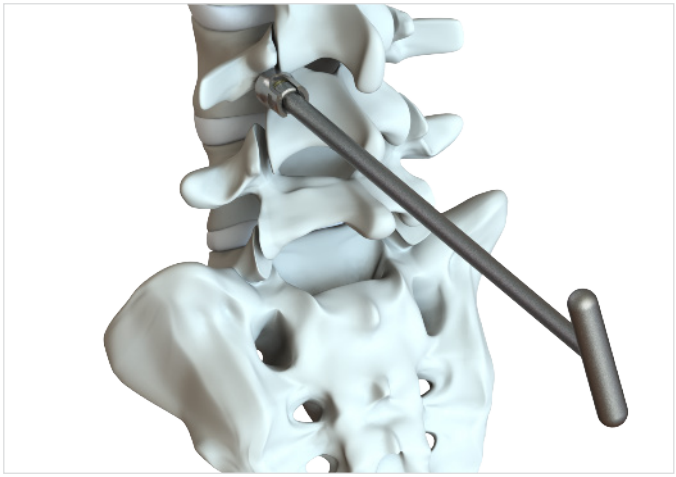
Step 7 Rod and Lock Screw Insertion

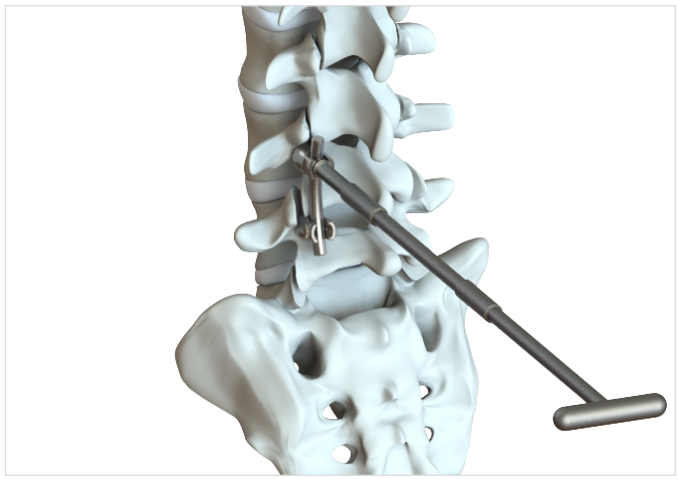
If required, adjust screw height by fully inserting the **T25 Screw Height Adjuster** into the **Modular Screw Shank** and turn to the desired height. To adjust rod housing orientation, insert the **T-Handle Head Persuader** into the **Modular Tulip** and adjust Modular Tulips to ensure proper orientation for **Rod** insertion.

Attach the **Locking Cap** to the distal end of the **T30 Split Tip Cap Starter**. Align the Cap Starter with the **Modular Tulip** and introduce the Locking Cap. Turn the Locking Cap until it makes contact with the **Rod**. Do not final tighten. Repeat this procedure for inserting all Locking Caps.

NOTE: *Load the **Locking Cap** to the **T30 Split Tip Cap Starter** directly from the **Locking Cap Caddie** to hold the implant in place.*

NOTE: *Seating the **Locking Cap** into the **Modular Tulip** requires minimal effort. Do not force placement as this may damage the threads of the Locking Cap or Modular Tulip. If the Locking Cap is difficult to rotate, the **Rod** may not be seated properly and Rod reduction or contouring may be required. Rotate the Locking Cap counterclockwise by a half turn prior to advancing the Locking Cap clockwise to assist with thread alignment.*





Surgical Technique

Step 8 Rod Reduction

The NIDO Pedicle Screw System provides three (3) **Rod** reduction options:

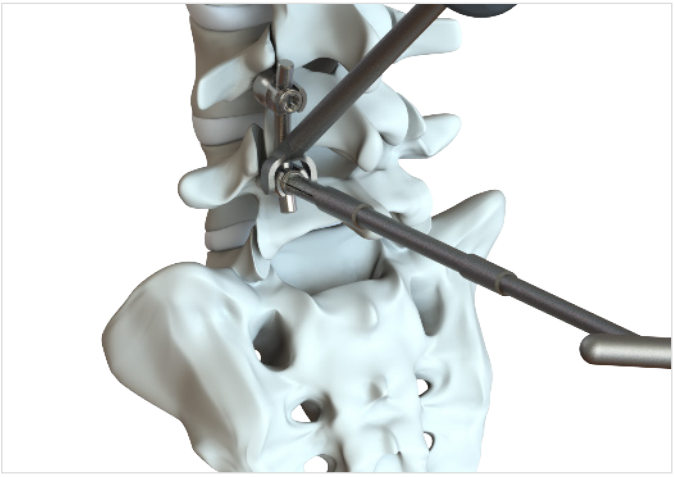
1. **Extended Tab Tulip** – 15mm
2. **Hinged Rocker** or **One-Piece Rocker** – 10mm
3. **Axial Reducer** – 30mm

Option 1: Extended Tab Tulip

The extended tulip design allows for up to 15mm of instrument free reduction to accommodate anatomy or deformity correction.

Option 2: Rod Rocker

1. For moderate reduction less than 10mm, the **Hinged Rod Rocker** may be used to persuade the rod.
2. Align the lateral posts of the **Hinged Rod Rocker** to the lateral slots on the **Modular Tulip**.
3. Use the **Hinged Rod Rocker** as a lever to persuade the **Rod** into the **Modular Tulip**.
4. Once the **Rod** is fully reduced into the **Modular Tulip**, use the **T30 Split Tip Cap Starter** to introduce the **Locking Cap** into the Modular Tulip.
5. Turn the **Locking Cap** until it comes into contact with the **Rod**. Do not final tighten.



Option 3: Axial Reducer

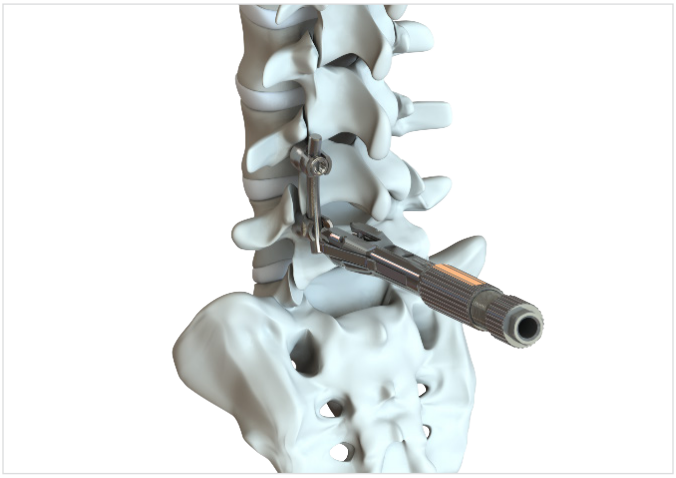
1. The **Axial Reducer** provides up to 30mm of continuous, gradual reduction.
2. Ensure the **Axial Reducer** is in the starting position by fully loosening the proximal knob counterclockwise. An interfacing **Hex Socket** and **Ratcheting Handle** can be assembled to the proximal knob of the Axial Reducer to assist with the drive mechanism.
3. Attach the **Axial Reducer** squarely over the **Modular Tulip** and push down until it is completely over the Modular Tulip. Align the distal open slot of the Modular Tulip to the open slot of the Axial Reducer.
4. Rotate the proximal knob of the **Axial Reducer** clockwise to secure it to the **Modular Tulip**.

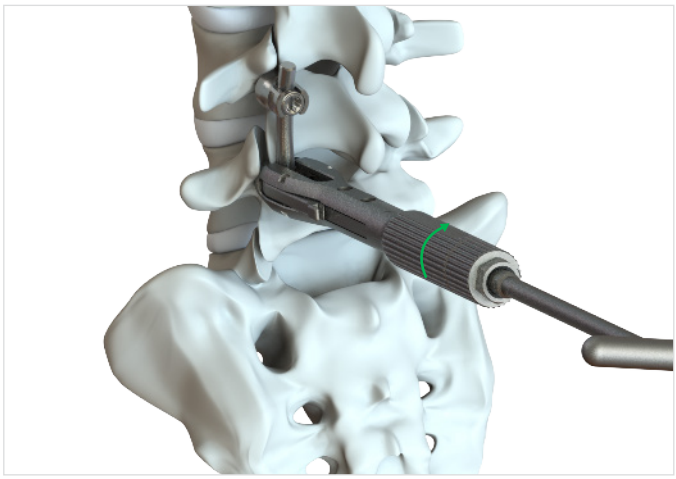
Surgical Technique

Step 8 Rod Reduction *(continued)*

5. Continue rotating the proximal knob until the **Rod** is fully reduced into the **Modular Tulip**.
6. Once the **Rod** is fully reduced into the **Modular Tulip**, use the **T30 Split Tip Cap Starter** to introduce the **Locking Cap** into the Modular Tulip. Turn the Locking Cap until it comes into contact with the Rod. Do not final tighten.
7. Rotate the proximal knob fully counterclockwise to disconnect the **Axial Reducer** from the **Modular Tulip**.

NOTE: *Full reduction of the **Rod** can be verified when the proximal knob is flush with the main body of the **Axial Reducer**.*





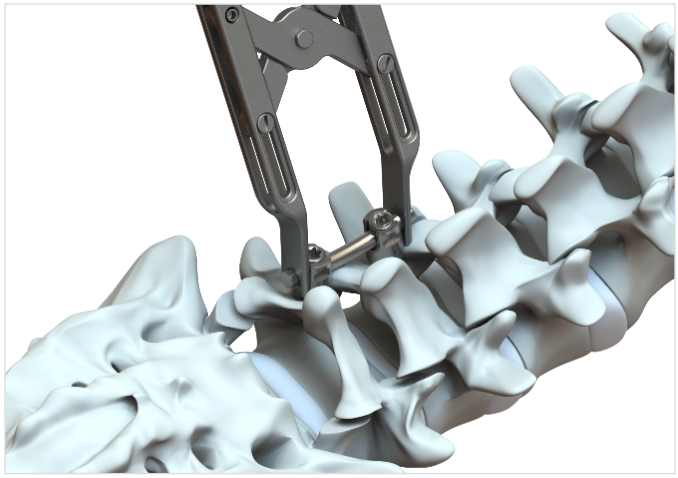
Surgical Technique

Step 9 Compression and Distraction

If compression or distraction is desired, provisionally tighten a **Locking Cap** on one side of the motion segment, leaving the adjacent Locking Cap loose to allow movement along the Rod.

Choose the **Compressor** or **Distractor**, and place the slotted distal tips over the **Rod**, against the tulip heads of the targeted screws. With the instrument properly engaged over the Rod, deliver the desired level of compression or distraction. Provisionally tighten the loose **Locking Cap** to hold the construct in position prior to final tightening.

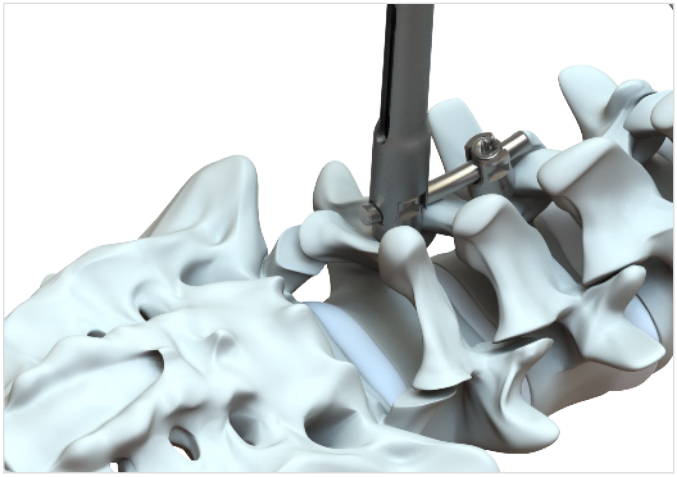
NOTE: *It is NOT recommended to final tighten the **Locking Cap** while it is under the force of compression or distraction.*



Step 10 Final Tightening

All **Locking Caps** must be tightened to a torque of 90 in-lbs.

Attach the **90 in-lbs. Black Torque Limiting T-Handle** to the **Final Cap Driver**. Slide the **Counter-Torque** over the **Modular Tulip** until the instrument bottoms out and rests on the **Rod**. Insert the Final Cap Driver through the Counter-Torque and seat securely into the **Locking Cap**. Turn the Torque Limiting Handle clockwise until the breakaway torque is reached. Final tightening is achieved when the Handle audibly clicks. Repeat on each screw assembly.



Step 11 Revision/Removal

The NIDO Pedicle Screw System **Tulip and Screw Shank Assembly** can be removed intraoperatively from the site using the **Locking Cap Adjuster** and **Screw Height Adjuster**.

1. Using the **Locking Cap Adjuster**, loosen and then remove the **Locking Caps**.
2. Once all the **Locking Caps** have been removed use a **Rod Holder** to grasp the **Rod** and remove.
3. Insert the **Screw Height Adjuster** into the hexalobe socket of the **Screw Shank**.
4. Rotate the **Modular Screw Assembly** counterclockwise until the screw is explanted.

Surgical Technique

Insertion of Domino Rod Connectors

Step 1 Attach Inserter

Using the proximal handle of the **Domino Inserter**, carefully thread the distal tip into a **Domino Rod Connector** set screw hole until it is about to enter the rod slot. Rotate the knurled knob clockwise until the outer shaft makes contact with the top surface of the connector.

Insert the **Domino Rod Connector** by sliding onto an implanted **Rod**. Once in desired position, rotate the knurled knob counterclockwise to loosen the outer sleeve. Then turn the proximal knob clockwise to drive the tip onto the Rod and temporarily fix the Domino Rod Connector in place.

Step 2 Set Screw Insertion

Once the secondary **Rod** has been inserted into the **Domino Rod Connector**, insert a **Domino Set Screw** into the set screw hole using the **Domino Set Screw Inserter**.
Remove the **Domino Inserter** and repeat process with additional set screw holes.

NOTE: *The **Domino Set Screw Inserter** is not to be used for final tightening. Damage to instrument or implant may occur if over-torqued.*

Step 3 Final Tightening

Utilizing the **Domino Counter Torque**, **T20 Domino Final Driver**, and the **Aqua 60 in-lb Torque Limiting Handle**, final tighten each of the **Domino Set Screws**. Final tightening is achieved when the Handle audibly clicks.

The same implantation procedure applies to all **Aqua-Colored Rod to Rod Transition Connectors**.

NOTE: *When utilizing **Parallel Domino Connectors** to join segments of rod, a minimum of two connectors per union are required for construct stability.*

Surgical Technique

Insertion of Tulip Rod Connectors

Step 1 Attach Inserter

Using the same technique as the **Modular Tulips**, attach the **Tulip Inserter** to a **Tulip-style Rod Connector** by rotating the knurled knob clockwise.

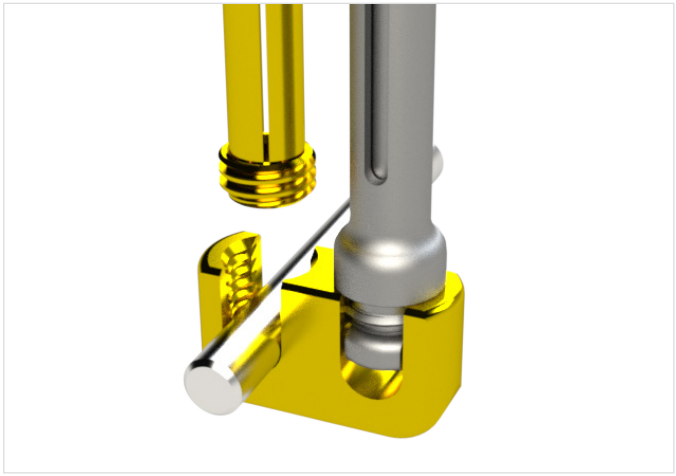
If using a **Modular Parallel Tulip Connector**, attach the **Tulip Inserter** to the side of the connector that will be attched to the **Modular Screw Shank**. Then connect to the **Screw Shank** using the same technique as **Modular Tulips**.

Step 2 Rod Attachment

Once the implanted **Rod** has been inserted into the **Tulip Rod Connector**, insert a **Locking Cap** using the **T30 Split Tip Cap Starter**. Remove the **Tulip Inserter** and repeat the process with additional connections.

Lateral Rod Connectors have an integrated rod that should be placed into a **Modular Screw Tulip** and therefore only have one rod connection point.

NOTE: *The **T30 Split Tip Cap Starter** is not to be used for final tightening. Damage to instrument or implant may occur if over-torqued.*



Step 3 Final Tightening

Utilizing the **Gold Counter Torque**, **Final Cap Driver**, and the **Black 90 in-lb Torque Limiting Handle**, final tighten each of the **Locking Caps**. Final tightening is achieved when the Handle audibly clicks.

The same implantation procedure applies to all **Gold-Colored Rod to Rod Transition Connectors**.

NOTE: *When utilizing **Parallel Tulip Connectors** to join segments of rod, a minimum of two connectors per union are required for construct stability.*

Instructions For Use

Description
The Kalitec Medical NIDO 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 NIDO 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 NIDO Pedicle Screw System implants are made from medical implant grade titanium alloy Ti-6Al-4V (ELI) per ASTM F-136.

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 NIDO Pedicle Screw System should not be reused under any circumstances. Do not use the NIDO Pedicle Screw System components in conjunction with components from any other system or manufacturer other than the Kalitec Medical Cosmolock Pedicle Screw System. These instructions are designed to assist in the use of the NIDO Pedicle Screw System and are not a reference for surgical techniques.

Indications For Use:
The NIDO 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 NIDO 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.

The NIDO Pedicle Screw System Cannulated/Fenestrated Screws are intended to be used with saline and radiopaque dye.

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 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 NIDO 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.

Instructions For Use

When utilizing parallel domino or tulip rod connectors to join segments of rod, a minimum of two connectors per union are required for construct stability.

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

The safety and effectiveness of the NIDO Pedical Screw System devices have not been established when used in conjunction with bone cement or for use on patients with poor bone quality (e.g. osteoporosis, osteopenia). The NIDO Pedicle Screw System fenestrated screws are intended only to be used with saline or radiopaque dye.

If a reusable device is/was used in a patient with, or suspected of having, Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize and eliminate the risk of cross-contamination.

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.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Implant Selection

The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. When used, the system connectors must be deployed in pairs and never singly to ensure proper immobilization and stabilization of spinal segments. Contouring or bending of rods only is recommended if necessary according to the surgical technique of each system. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods, which have been repeatedly or excessively contoured, must not be implanted. Overweight patients may be subject to additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery.

Preoperative

- Only patients that meet the criteria described in the indications should be selected.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery.
- The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The NIDO Pedicle Screw System components are not to be combined with the components from another manufacturer
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
- All sets should be carefully checked for completeness and all components should be carefully inspected prior to all surgeries.

Intraoperative

- Any instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Cut the rods outside the operative field.
- Imaging system should be used whenever possible to facilitate surgery.
- Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.
- Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.
- Before closing the soft tissues, all of the locking screws should be tightened firmly.

Postoperative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved NIDO Pedicle Screw System components should ever be reused under any circumstances.

Packaging

Packages for each of the components should be intact upon receipt. All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to Kalitec Medical.

Cleaning and Decontamination

Implants and instruments of the NIDO Pedicle Screw System are supplied clean and NOT STERILE, and must be sterilized prior to use.

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Kalitec Medical
618 E. South Street Suite 500
Orlando, FL 32801
407-545-2063

KalitecMed.com