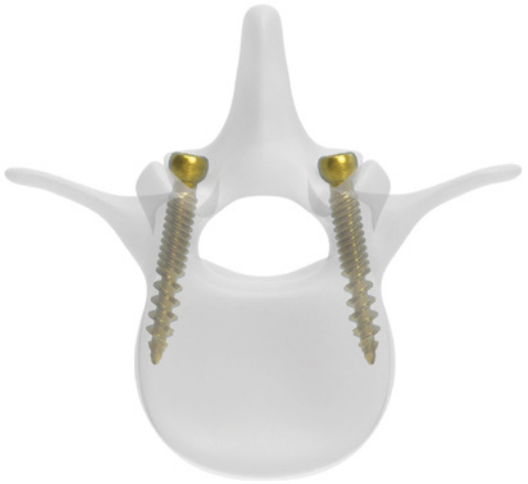
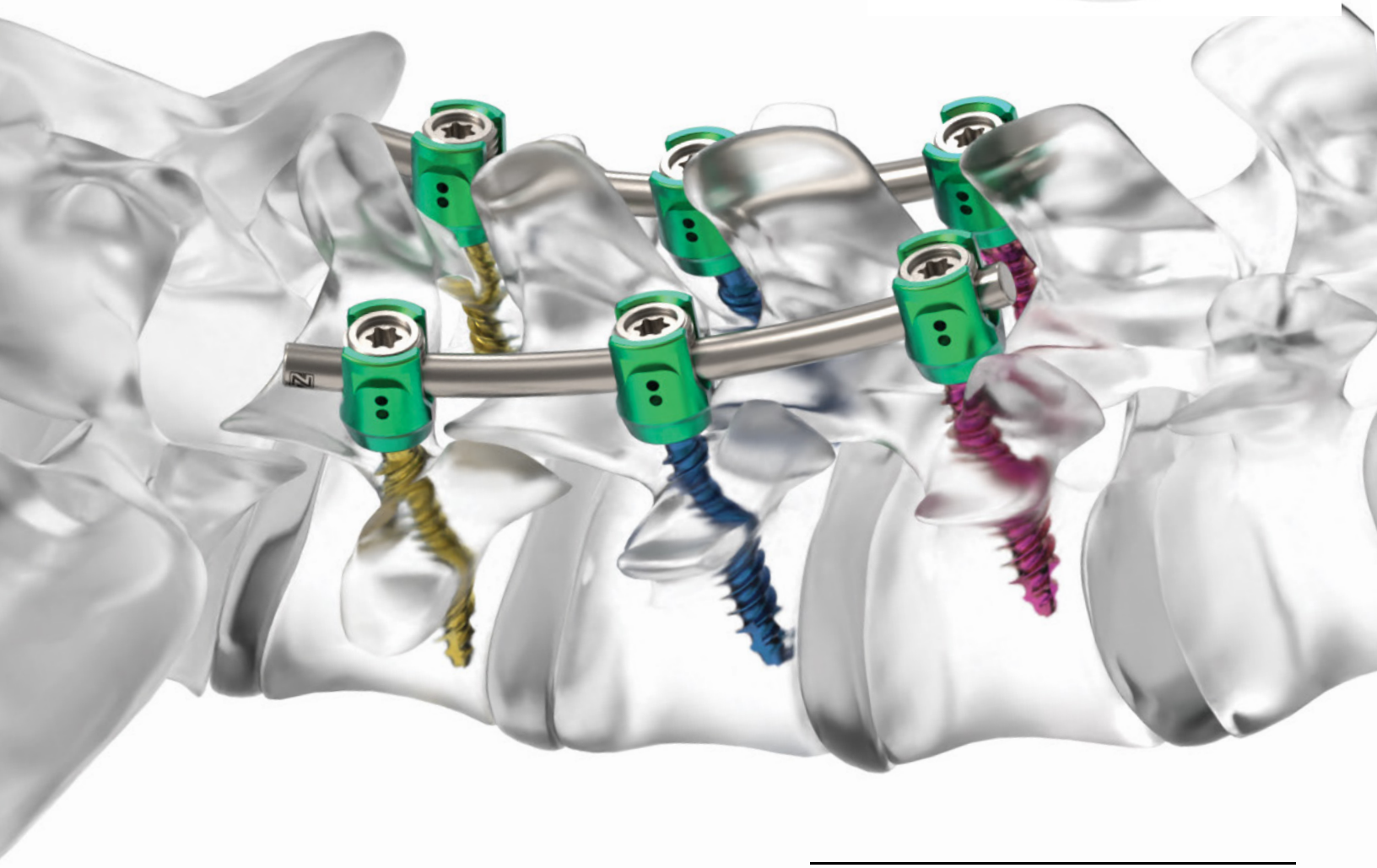
Nexxt Spine

Surgical Technique Guide

INERTIA® CONNEXX™

MIDLINE





Nexxt Spine, LLC
14425 Bergen Blvd, Suite B
Noblesville, IN 46060
(317) 436-7801
Info@NexxtSpine.com

71-056, Rev B

Table of Contents

INERTIA® CONNEXX™ MODULAR PEDICLE SCREW SYSTEM

The INERTIA® CONNEXX™ MIDLINE Modular 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 degenerative, deformity, and tumor/trauma applications via a MidLine mini-open approach using corticocancellous Modular Shanks designed to achieve more cortical bone purchase in the medial to lateral trajectory, Set Screws, and Rod placement.

INERTIA® CONNEXX™ MIDLINE enhances efficiency through a modular platform, intuitive instrumentation, and implant options designed to provide surgeons the ability to stabilize the anatomy through a minimal access, muscle sparing working corridor.

INERTIA® CONNEXX™ has been designed and evolved from valuable feedback from our surgeon development team, and Nexxt Spine would like to take the opportunity to thank them for their contributions and efforts to make the INERTIA® CONNEXX™ MIDLINE Modular Pedicle Screw System one of the most versatile systems for posterior thoracolumbar fixation and stabilization.

Instructions For Use

GENERAL DESCRIPTION
The INERTIA® CONNEXX™ Modular Pedicle Screw System consists of Rods, Pedicle Screws and Set Screws. Rods are available in either straight or pre-contoured (curved) forms in a variety of lengths. Pedicle screws are available in modular polyaxial or non-modular uniplanar designs having double lead standard or cortical/cancellous thread forms in a variety of diameter-length combinations. Set screws are used to fasten the Rod and pedicle screw. All implant components are manufactured from titanium alloy (Ti-6AL-4V ELI) per ASTM F136.

INDICATIONS
The INERTIA® CONNEXX™ Modular Pedicle Screw System is intended for immobilization and stabilization of the posterior non-cervical spine (T1-S2/Ilium) in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (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, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the INERTIA® CONNEXX™ Modular Pedicle Screw System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The INERTIA® CONNEXX™ Pedicle Screw is to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CONTRAINDICATIONS
Use of the INERTIA® CONNEXX™ System and spinal fixation surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Any conditions that preclude the possibility of fusion are relative contraindications. These include but are not limited to: cancer, fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotrophic diseases, obesity, pregnancy and foreign body sensitivity. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation. See also the WARNINGS, PRECAUTIONS AND POTENTIAL RISKS sections of this insert.

IMPORTANT NOTE TO OPERATING SURGEON PRECAUTION
The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The INERTIA® CONNEXX™ Modular Pedicle Screw System is designed to provide biomechanical stabilization as an adjunct to fusion in skeletally mature patients. Spinal fixation should only be undertaken after the surgeon has had hands on training in this method of spinal fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique is available for instructions on the important aspects of this surgical procedure and can be requested from Nexxt Spine LLC at the address or phone number above.

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential adverse effects of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Postoperative evaluation of the fusion and implant status is necessary. The surgeon may remove the implant once a solid fusion is obtained. The patient must be informed of the potential of this secondary surgical procedure and the associated risks.

CLEANING/REPROCESSING OF NEXXT SPINE SURGICAL INSTRUMENTS
All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Refer to the Nexxt Spine Reprocessing Instructions for Reusable Instruments document available at www.NexxtSpine.com/Resources/Indications-For-Use or by calling 317-436-7801 for a copy of the detailed cleaning instructions.

STERILIZATION
The INERTIA® CONNEXX™ Modular Pedicle Screw System implants can be supplied sterile or nonsterile. All sterile products are labeled "STERILE" and supplied in protective sterile barrier packaging. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave sterile implants. If not specifically labeled sterile, components are nonsterile.

Nonsterile components are supplied clean and not sterile. All implants and instruments should be cleaned and sterilized prior to surgery. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). AORN recommended practices for in hospital sterilization should be followed. The use of an FDA cleared sterilization wrap is recommended.

Sterilization testing of components has shown the following recommendations for sterilization are effective to an SAL of 10-6:

Method:	Steam
Cycle:	Prevaccum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Drying Time:	60 minutes

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prior decontamination protocol. Nexxt Spine recommends contacting the Center for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

Warnings and Precautions

1. The safety and effectiveness of this device has not been established for use as part of a growing Rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

2. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.
Other adverse events related to pedicle screw fixation, such as screw or Rod bending, breakage, or loosening, may also occur in pediatric patients, and pediatric patients may be at increased risk for device-related injury because of their smaller stature.

3. The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.
The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

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

5. PATIENT SELECTION Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATIONS section of this document AND who do not have any of the conditions set forth under the CONTRAINDICATIONS section of this document should be considered for spinal fixation surgery using the INERTIA® CONNEXX™ System. In addition, patients who smoke have been shown to have an increased incidence of pseudarthrosis. Based upon the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

6. PATIENT EDUCATION Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

7. HANDLING Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the Rod or screw surfaces as these may induce premature failure of the component. Excessive reverse bending of rods can cause metal stressing resulting in a lower fatigue life for the Rod.

8. IMPLANT SELECTION The INERTIA® CONNEXX™ System components are available in a variety of sizes to ensure proper fit of the implanted device. The potential for the success of the fusion is increased by selecting the correct size of the implant. These devices are not intended to be used as the sole support for the spine.

9.INSTRUMENT USAGE INERTIA® CONNEXX™ System instruments are to be used for implantation of the INERTIA® CONNEXX™ System components. Failure to use the dedicated instruments may compromise the integrity of the implanted device. Care should be taken to ensure that the correct component-specific instruments are used properly. Failure to do so may compromise the integrity of the implanted device and lead to premature device failure and subsequent patient injury.

10. MR ENVIRONMENT The INERTIA® CONNEXX™ System has not been evaluated for safety and compatibility in the MR environment. The INERTIA® System has not been tested for heating migration or image artifact in the MR environment. The safety of the INERTIA® System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

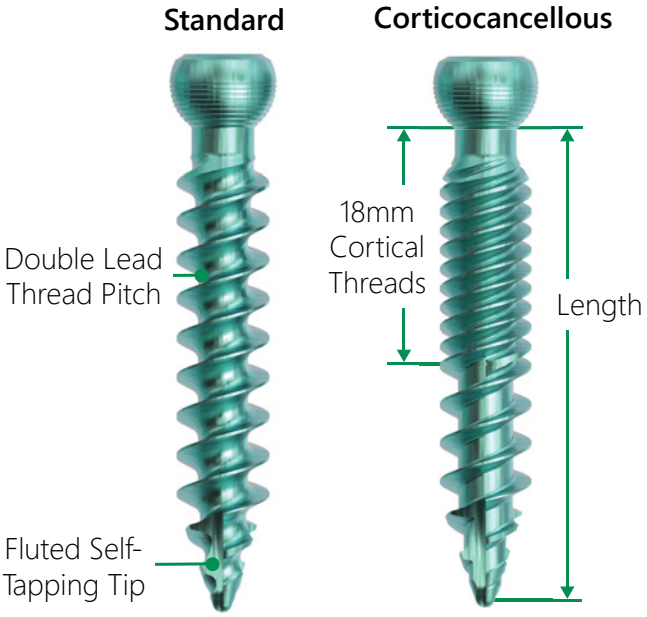
11. MIXED METALS. The INERTIA® CONNEXX™ System is available in titanium alloy. It is imperative that this metal does not come into contact in vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are used together when building a construct.

12. SINGLE USE ONLY These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.

13. DELAYED UNION OR NONUNION The INERTIA® System is designed to assist in providing an adequate biomechanical environment for fusion. It is not intended to be and must not be used as the sole support for the spine. If a delayed union or nonunion occurs the implant may fail due to metal fatigue. Patients should be fully informed of the risk of implant failure.

PRODUCT SPECS AND FEATURES

Modular Shanks - Ti-6Al-4V ELI per ASTM F136



- Fully compatible with INERTIA® CONNEXX™ product portfolio to accommodate a variety of minimally invasive, open, mid-line, and hybrid techniques.
- Standardized T25 drive feature for all Shanks and Set Screws to reduce instrument need.

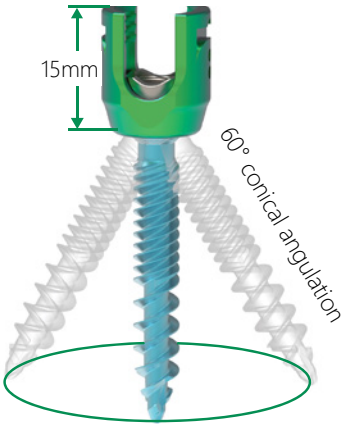
Modular Shank Sizing

Ø4.5-11.5mm x 20-140mm

Solid Corticocancellous | Cannulated Corticocancellous | Solid Standard | Cannulated Standard

Modular Housings - Ti-6Al-4V ELI per ASTM F136

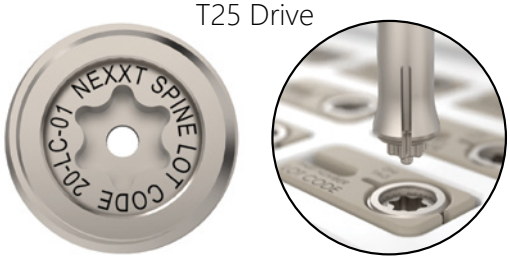
- All Modular housings are compatible with all Shanks.
- Patented Rod Retention tabs securely hold rod during preliminary placement with audible click.
- Modular Housing allows both OPEN and MIS instrumentation for primary and revision procedures.
- Modular Housings available in Standard, Reduction, and a wide variety of Pre-Assembled Uniplanar.



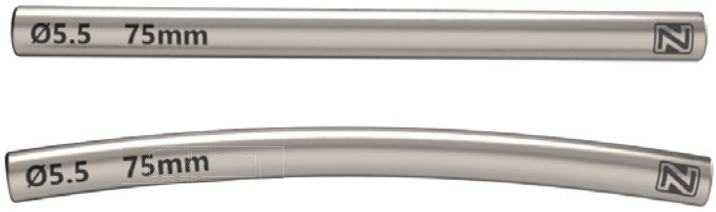
Set Screws - Ti-6Al-4V ELI per ASTM F136

- "Click on" attachment feature securely mates driver to Set Screw.
- Set Screw will automatically disengage from driver when locked at correct depth and compressing on Rod.

T25 Drive



Spine Rods - Ti-6Al-4V ELI per ASTM F136



- Rods provided straight, pre-bent, or pre-cut for surgeon needs.
- Available in lengths 35-175mm pre-bent and 25-600mm straight.

Implant Traceability

- All Shanks, Set Screws, and Modular Standard and Reduction Housings include a Removable Tracking Tag marked with lot code information and UDI to simplify tracking of implants
- Modular Extended Tabs also include a UDI, part number, and lot code etched onto the surface.

NOTE:
Removable Tracking Tag is not an implant and should be disposed or provided to hospital materials management for tracking purposes if appropriate.

Some implant dimensions may be only available By Request.
Contact **Info@NexxtSpine.com** for full implant availability.

SURGICAL STEPS

The surgical technique shown in this document is for illustrative and demonstrative purposes only. The technique actually employed will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, and other important information concerning the use and guidance of the INERTIA® CONNEXX™ Open Modular Pedicle Screw System.

1. PATIENT POSITIONING

Place the patient on the operating table in a prone position (Figure 1.1). Prepare and drape in a conventional manner that will allow for implant placement and anatomical marking. The fluoroscope should have easy access to the surgical field for both A/P and lateral views.

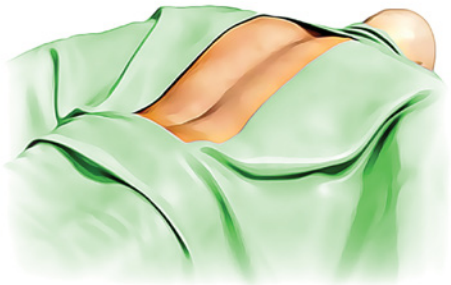


Figure 1.1
Position patient in a traditional manner as deemed by the surgeon.

Patient's position should be checked radiographically to determine the direction of the pedicles relative to the horizontal plane, as well verifying that the pedicles are symmetrical to each other with the spinous process centered between them (Figure 1.2). The superior endplate should be parallel and be visualized as a crisp solid line with no obliquity.

There are various techniques for midline Screw and Rod insertion. For the purpose of this guide, a mid-line approach from L3 to L5 will be shown. Please refer to the Indications for Use (IFU) at the front of this technique guide for complete description, indications, contraindications, warnings, and precautions.

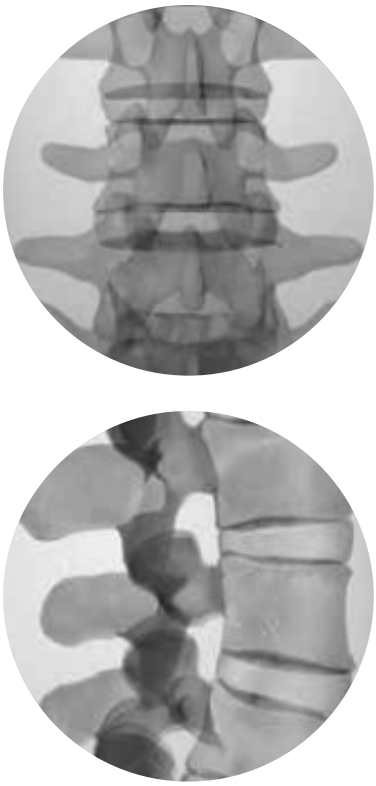


Figure 1.2
Symmetrical pedicles and centered spinous process.

2. ACCESS

Locate the affected level by using fluoroscopy in the A/P and lateral views. Using a Guidewire or skin marker, obtain a true A/P image to identify and mark the starting location (Figures 2.1 and 2.2). A medial line should be marked on patient from the inferior 1/3 of the cranial spinous process down to the middle of the caudal spinous process, as defined by the Guidewire or skin marker.

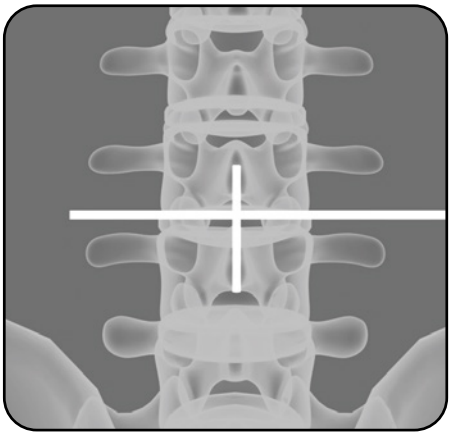


Figure 2.1
Skin marker under fluoro.

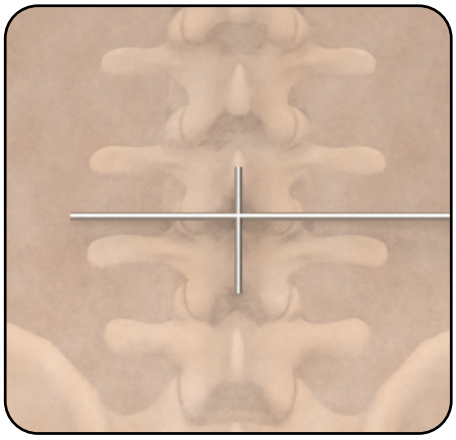


Figure 2.2
Skin marker marking starting location.

A posterior midline incision down the medial line is made followed by a standard posterior approach (Figure 2.3). Elevate muscles to the lateral border facet capsule and lateral edge of the pars, followed by placement of retractors to maintain exposure (Figure 2.4).

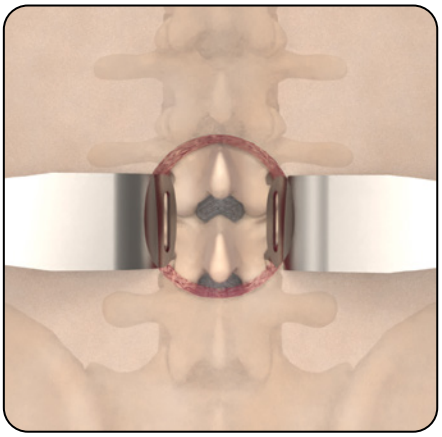


Figure 2.3
Retractors used to gain access.

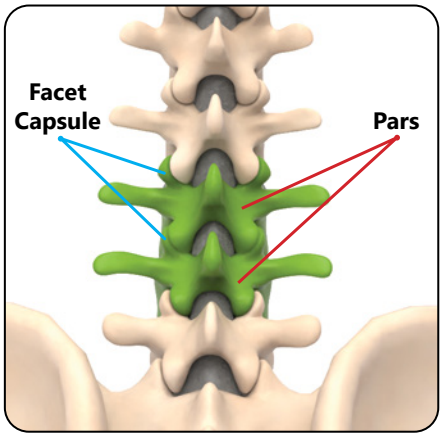


Figure 2.4
Positioning of Pars and Facet Capsules.

NOTE: *Care should be taken to secure and isolate the multifudus muscle segments to allow for maintenance of trunk strength post-operatively.*

3. IDENTIFICATION OF MODULAR SHANK ENTRY POINT

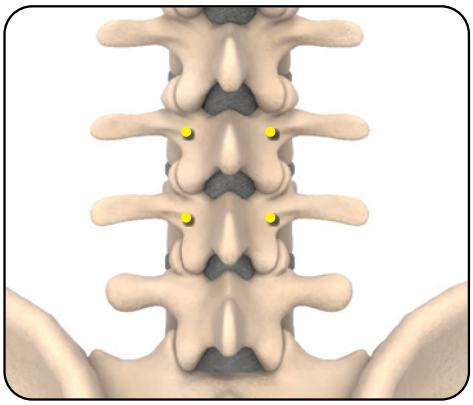


Figure 3.1
Entry points at multiple levels.

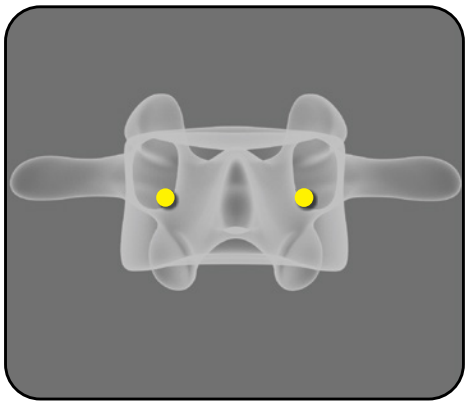


Figure 3.2
7 and 5 o'clock position for pedicles.

Using a Penfield, visualize and palpate the superior most lateral edge of the pars. Move 3-5mm medial and mark the entry point for the Modular Shank or Screw with a high speed burr or Drill (Figure 3.1).

NOTE: *Entry point is approximately the midpoint of the inferior facet capsule of the level above. This position allows for the entry point to be superior to the neuroforamin.*

Obtain an AP image to confirm the entry point is the medial border of the pedicle at a 7 o'clock position for the right pedicle and a 5 o'clock position for the left pedicle (Figure 3.2)[1,2].

TIP: *For the cephalad shank, it is important to avoid the adjacent facet capsule and make entry point slightly inferior (Figures 3.3, 3.4, 3.5).*

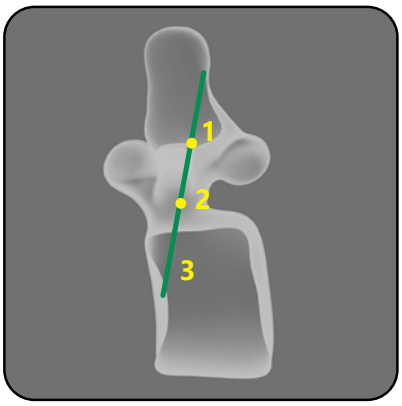


Figure 3.3
Entry point 3-5mm medial.

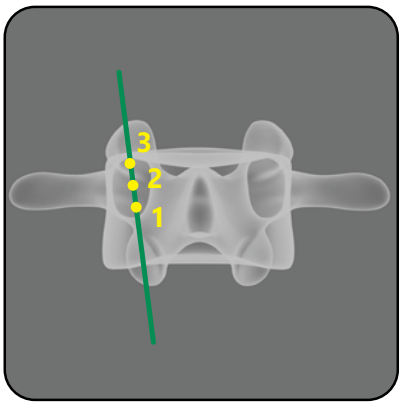


Figure 3.4
A/P view of projected path.

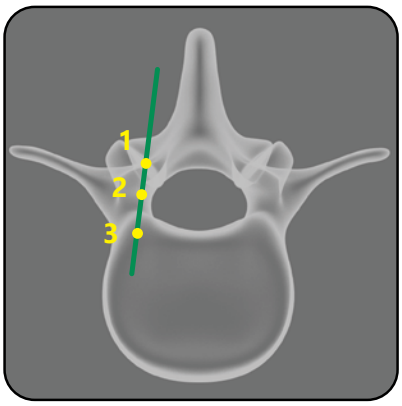


Figure 3.5
15-20° medial to lateral.

1. Matsukawa K, Yato Y. Lumbar pedicle screw fixation with cortical bone trajectory: A review from anatomical and biomechanical standpoints. Spine Surg Relat Res. 2017 Nov 27;1(4):164-173. doi: 10.22603/ssrr.1.2017-0006. PMID: 31440629; PMCID: PMC6698564.
2. Kaye ID, Prasad SK, Vaccaro AR, Hilibrand AS. The Cortical Bone Trajectory for Pedicle Screw Insertion. JBJS Rev. 2017 Aug;5(8):e13. doi: 10.2106/JBJS.RVW.16.00120. PMID: 28857932.

3. IDENTIFICATION OF MODULAR SHANK ENTRY POINT (CONT.)

The starting point of S1 screws will be superior and medial to the S1 foramen (Figure 3.6). The trajectory will be parallel to the sacral endplate at a slight 10° medial to lateral trajectory (Figure 3.7).

TIP: *For S1 screws, it is advised to tap with the 5.5mm tap and utilize 6.5mm diameter screws.*

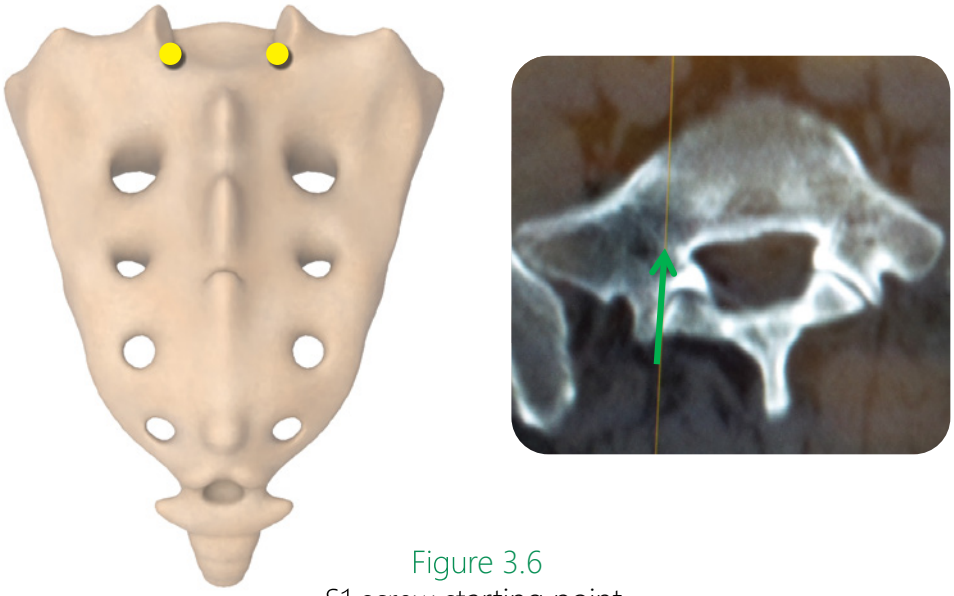


Figure 3.6
S1 screw starting point.

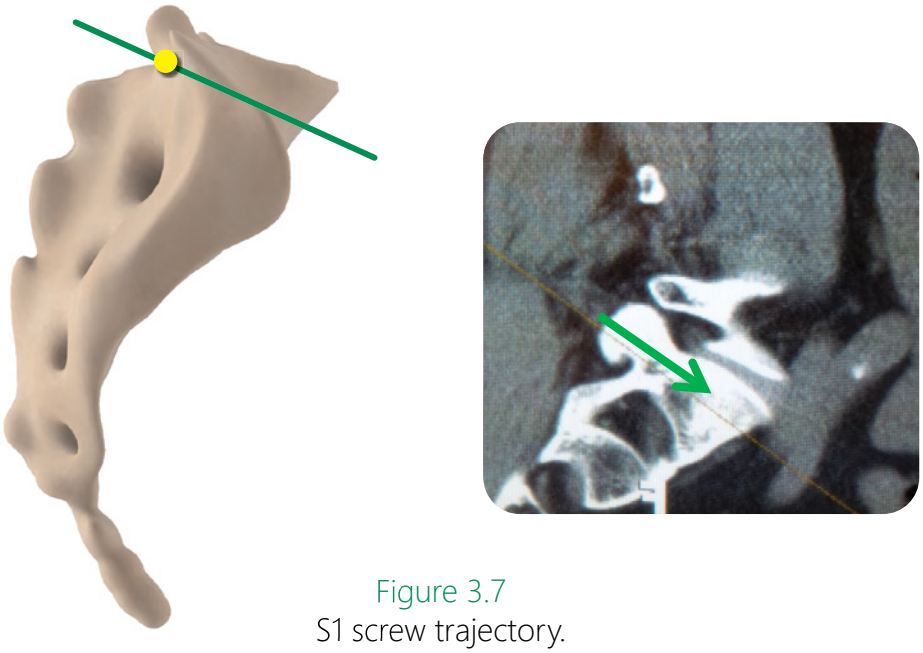


Figure 3.7
S1 screw trajectory.

4. MODULAR SHANK PLACEMENT - PERFORATE CORTEX

Initiate implant placement by perforating the proximal cortex using a high speed burr or Drill. It is recommended that the cephalad shanks should be placed in a medial to lateral, and inferior to superior trajectory (Figure 4.1).

TIP: *An average angle of 15° medial to lateral should be taken and lateral fluoro should be used, aiming for the posterior, superior most aspect of the targeted vertebral body.*

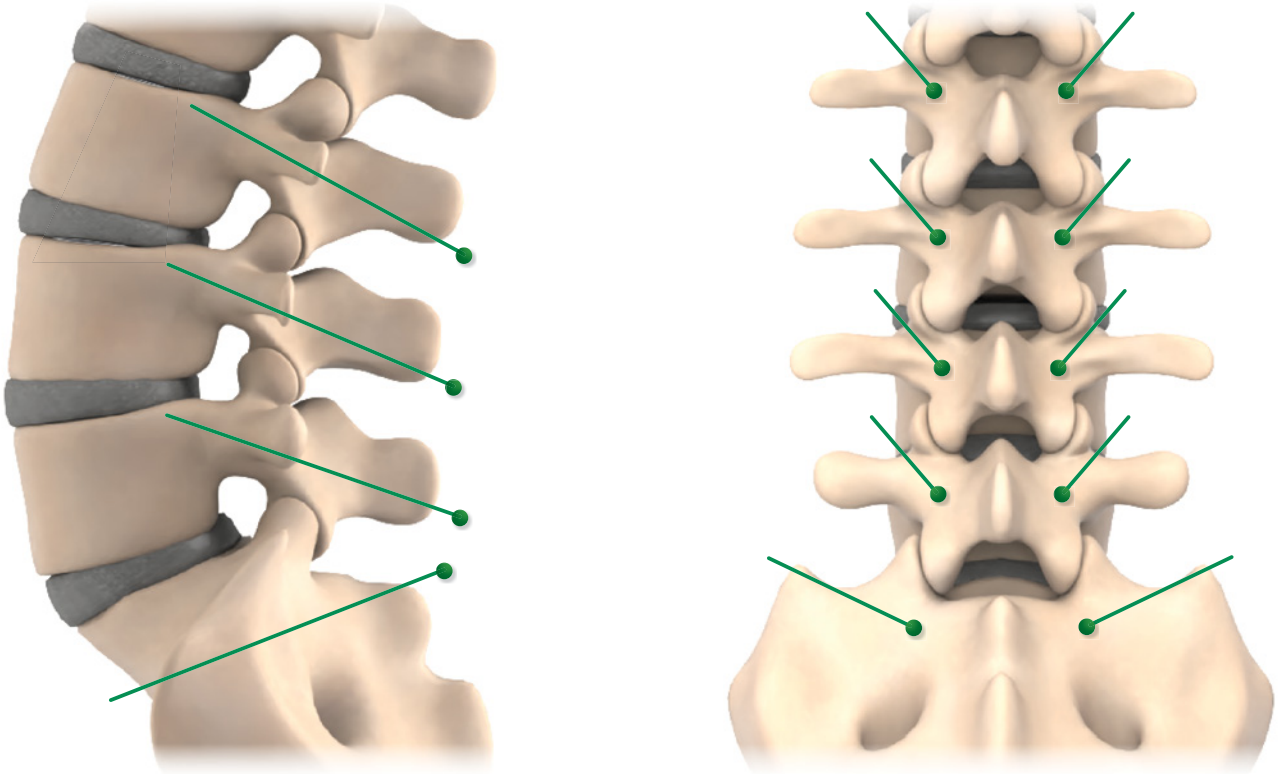


Figure 4.1
Example implant placement trajectory for multiple levels.

5. MODULAR SHANK PLACEMENT - PILOT HOLE PREPARATION

Adjust depth stop of Adjustable Drill Guide to desired depth by depressing the PRESS button and sliding the barrel of the instrument until the desired depth marking is displayed (Figure 5.1).

NOTE: *It is recommended to set the initial drill depth to 25mm, if preoperative measurements have not been determined.*

NOTE: *The Corticocancellous Modular Shanks have been designed to be used with a single Drill diameter. The Taps create the pathway for the Modular Shank threads, allowing for intimate contact with the minor diameter of the Modular Shank.*

Assemble the Ratcheting Handle of preference to the Drill and insert Drill into Drill Guide. Ensure that the distal tip of the drill is in the pilot hole previously created before advancing drill (Figure 5.2).

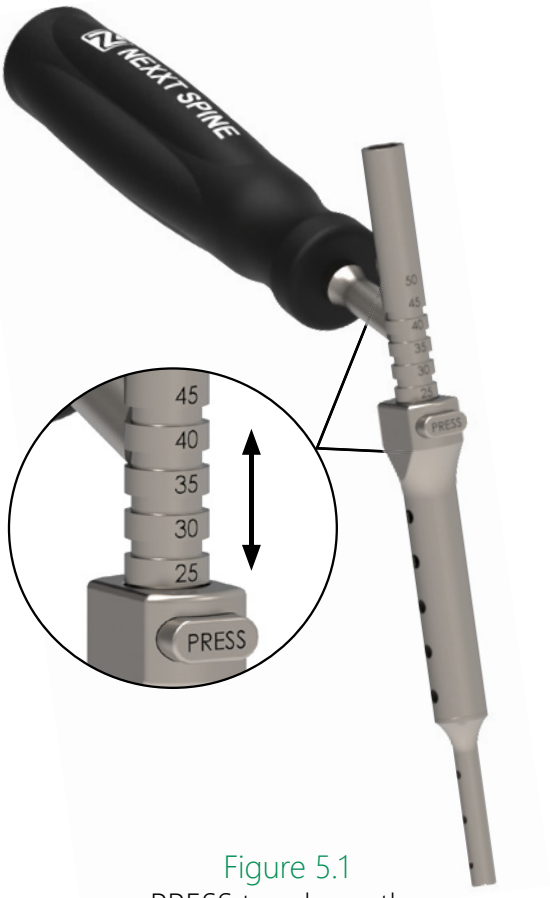


Figure 5.1
PRESS to release the depth guide channel.

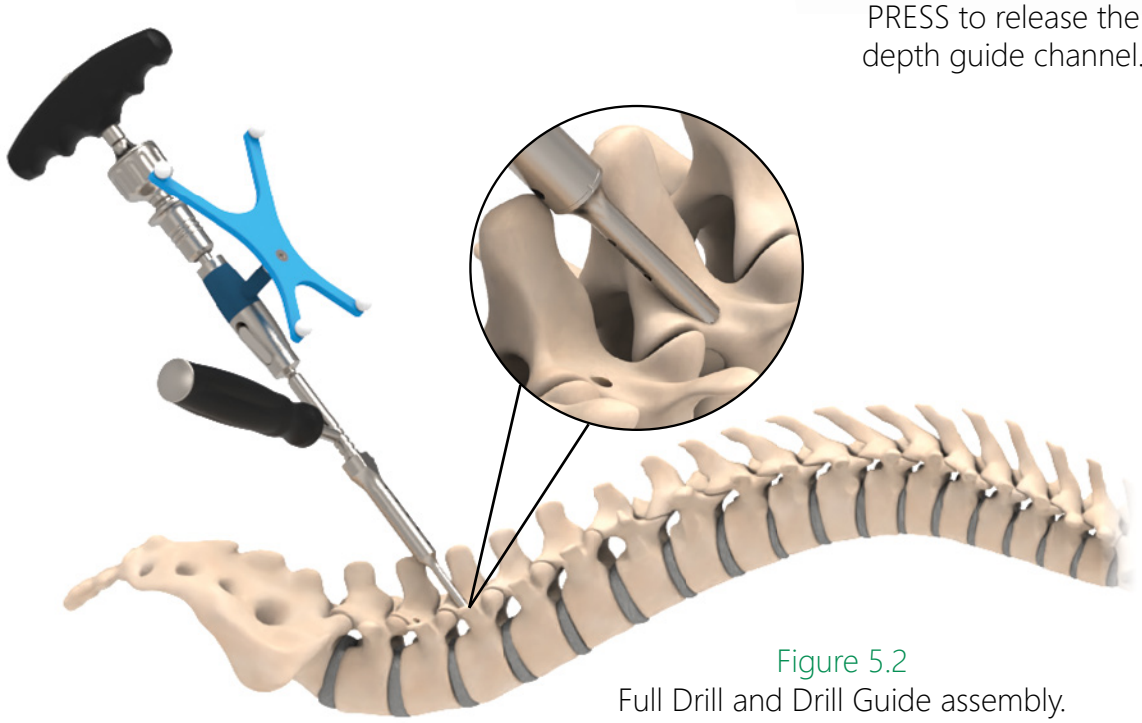


Figure 5.2
Full Drill and Drill Guide assembly. Navigated Drill shown.

5. MODULAR SHANK PLACEMENT - PILOT HOLE PREPARATION (CONT.)

Under lateral fluoro, drill through the pedicle in a medial to lateral and inferior to superior trajectory to the posterior, superior most aspect of the vertebral body, using the Drill Guide to hold trajectory and limit depth (Figure 5.3).

NOTE: *In order to increase bone engagement on larger diameter screws, the difference between the major and minor diameter increases with screw size, resulting in a larger volume of material gripped by the threads. As a result of this, the minor diameter changes size minimally, which allows for the use of a single drill to cover all screw sizes.*

NOTE: *Aim for the posterior 1/3 or mid portion of the superior endplate in the sagittal view, while maintaining a 15 – 20° medial to lateral trajectory. Do not breach the endplate while drilling.*

Use a Lenke Probe or Sounder to inspect the pilot hole for perforations by palpating the walls of the prepared hole (Figure 5.4).

NOTE: *Care should be taken while drilling across the various cortical walls, as the surgeon may feel a "plunging" sensation while traversing the various cortices.*

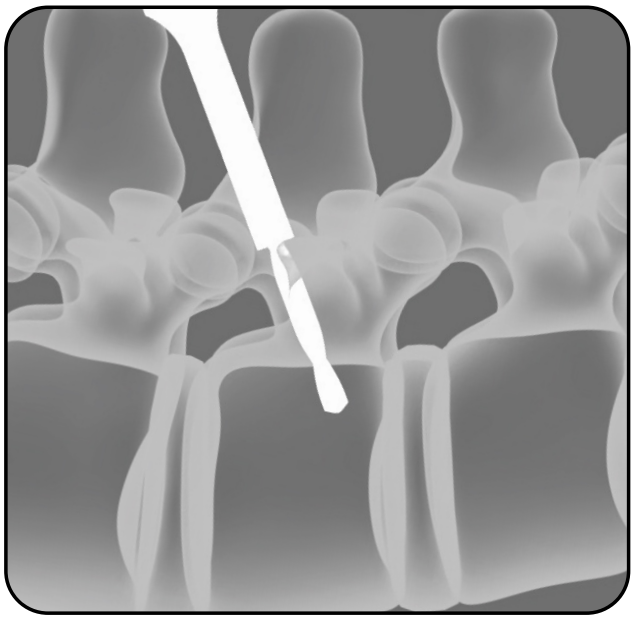


Figure 5.3
Use fluoro to help prevent endplate breaches.

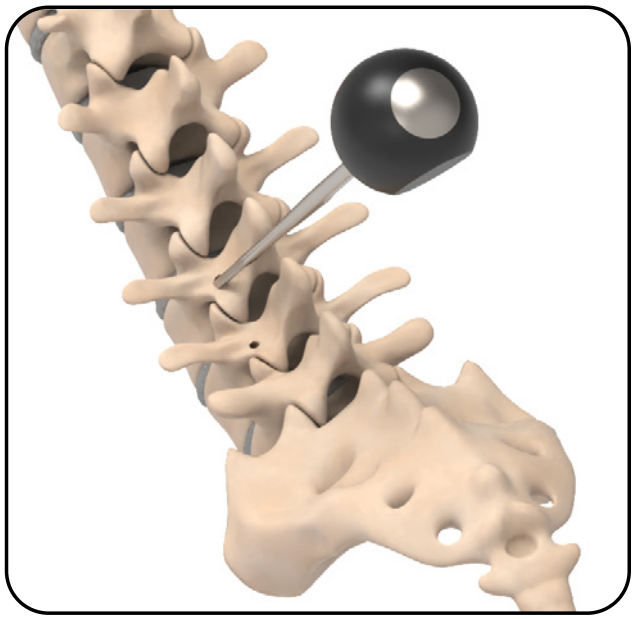


Figure 5.4
Use the Lenke Probe to inspect holes post drilling.

6. MODULAR SHANK PLACEMENT - PILOT HOLE TAPPING

Select the preferred Ratcheting Handle, and attach to an appropriately sized Tap. Set the ratchet to the preferred drive position.

Tap the pilot hole with the same diameter Tap as the final screw diameter and advance to the superior endplate without violating the endplate (Figure 6.1).

Final Modular Shank length can be determined off the markings on the tap, with the thread length being 30mm, and markings every 10mm (Figure 6.2).

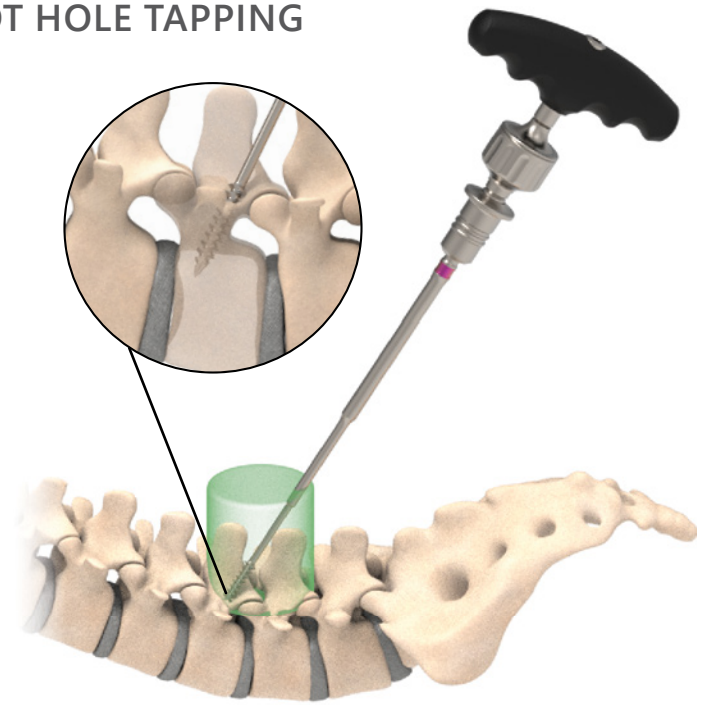


Figure 6.1
Tap assembly tapping down pilot hole.

Figure 6.2
Laser etching on tap indicates Ømm and depth.

Prior to screw insertion, inspect the pilot hole again for perforations using the Ball Tip Sounder (Figure 6.3).

TIP: *It is important to tap line-to-line to prevent the creation of micro fractures, which can occur when the pilot hole is under-tapped.*

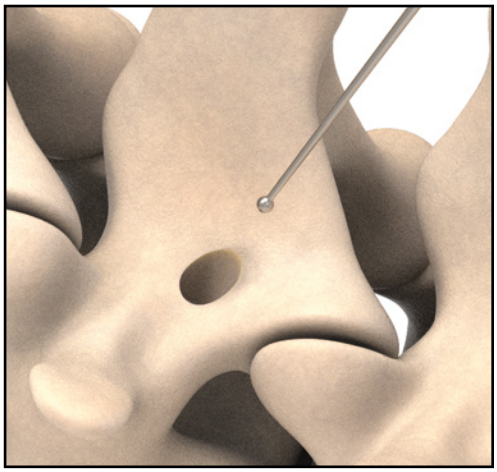


Figure 6.3
Inspect with Ball-Tip Sounder after tapping.

7. SHANK INSERTION

Depending on the spinal pathology being treated, a surgeon may choose to utilize different types of pedicle screws. The INERTIA® CONNEXX™ Modular Screw design allows the surgeon to tailor the appropriate Housing or preassembled Screw assembly depending on the need for reduction or standard geometries (Figure 7.1).

Refer to Figure 5.4 of the INERTIA® CONNEXX™ OPEN Surgical Technique Guide (71-050) for placement of optional, pre-assembled screws (Figure 7.2).

Figure 7.1
Modular 60° Polyaxial Housings.

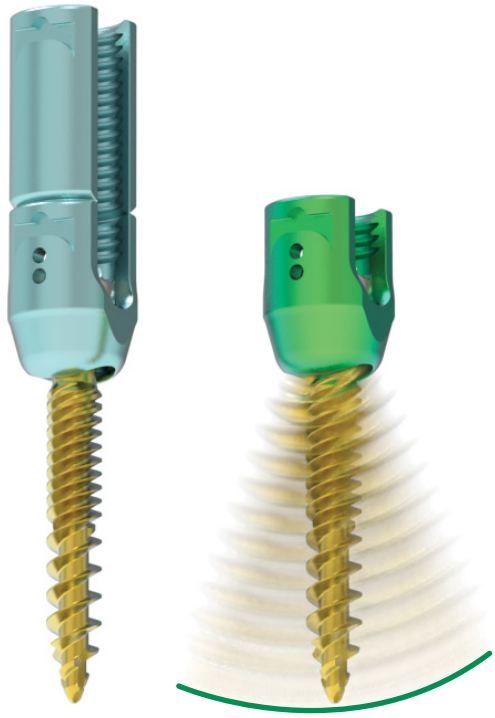


Figure 7.2
Uniplanar 60° Angulation Housings.

Modular Standard Housings are commonly used and can be paired with the Modular Shank.

Modular Reduction Housings have 20mm of internal reduction and can be combined with the Modular Shank.

Uniplanar Screws are commonly used at the apex of a scoliotic curve due to their fixation in the medial-lateral plane.

Uniplanar Screws are supplied pre-assembled and cannot be used with the Modular Shank.

7. SHANK INSERTION (CONT.)

Once the Midline screw corridor has been prepared, select the preferred Modular Shank diameter and length per the pathology's requirements.

Shank diameters may be determined by the caddy in which they reside, and via the unique anodization colors (Figure 7.3), whereas the Shank length may be determined by position in the caddy.

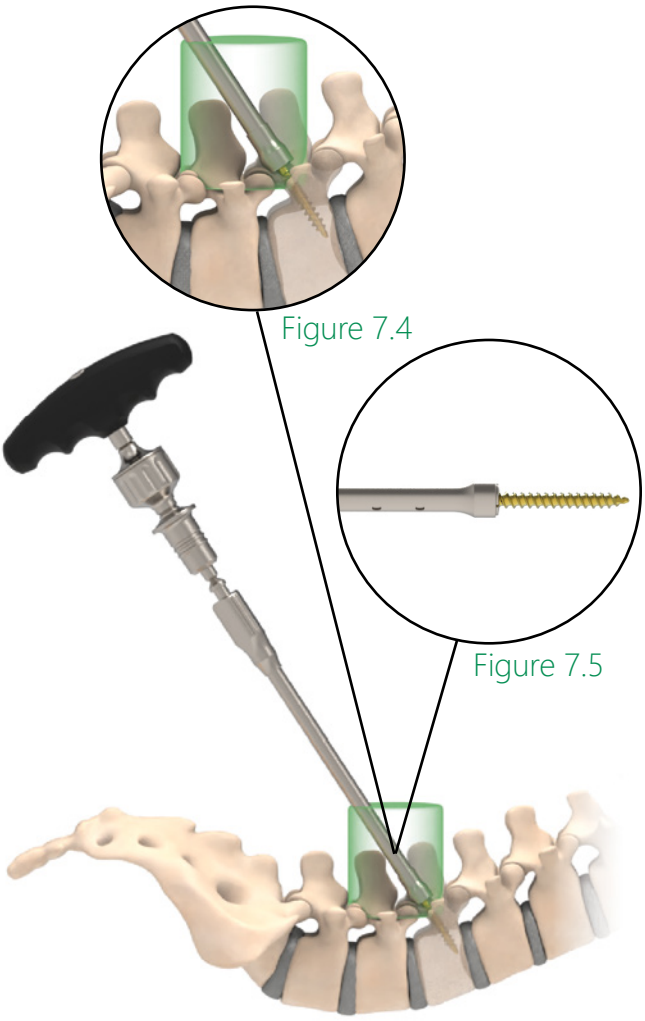
Figure 7.3 - Ømm by Anodization Color

Introduce the Modular Shank into the pilot hole and advance until the distal end of the Shank Driver meets bone and the distal end of the shank tip reaches the posterior, superior most aspect of the vertebral body (Figure 7.4).

The Shank Driver's distal locking feature serves as an indicator that the Modular Shank has been implanted to the desired depth (Figure 7.5). Release the Shank Driver from the screw shank by turning the thumbwheel counterclockwise.

NOTE: *Do not apply a levering force to driver during Modular Shank insertion as this can result in an improper trajectory or pedicle fractures.*

NOTE: *It is recommended to leave the Modular Shank proud to allow for assembly of the Modular Housing. Final height of the construct can be achieved with the Final Driver.*



7. SHANK INSERTION (CONT.)

Repeat pilot hole preparation and screw placement for all contralateral and ipsilateral levels.

Surgeons may desire to utilize an alternate screw trajectory which can assist with Modular Shank placement (Figure 7.6) and minimize exposure requirements (Figure 7.7).

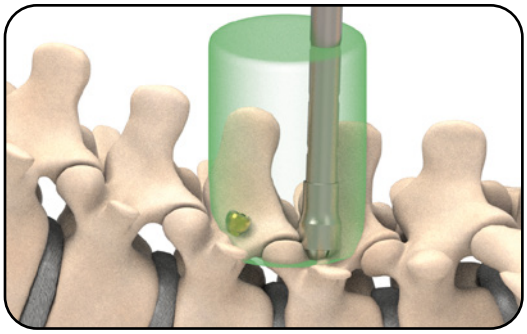


Figure 7.6
Alternate angle Shank trajectory.

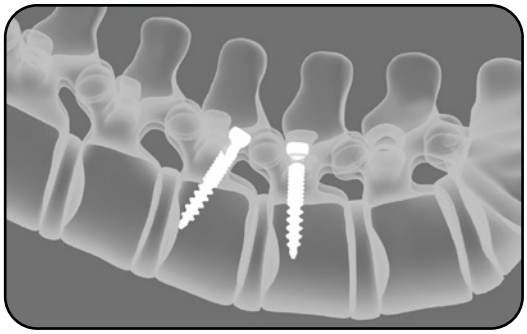


Figure 7.7
Alternate Shank placement.

Burr hole preparation should now follow an entry point that is the medial border of the pedicle at 9 o'clock position for the right pedicle, and a 3 o'clock position for the left pedicle. Verification with AP fluoro imaging should be used (Figure 7.9).

Drill hole preparation should aim for the posterior 1/3 or mid portion of the superior endplate in the sagittal view (Figure 7.8), while maintaining a 15 – 20° medial to lateral trajectory (Figure 7.10)[1,2]. Do not breach the endplate while drilling.

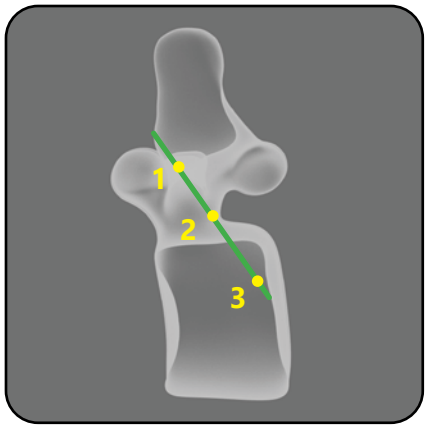


Figure 7.8
Aim for the upper 1/3 or mid portion of superior endplate.

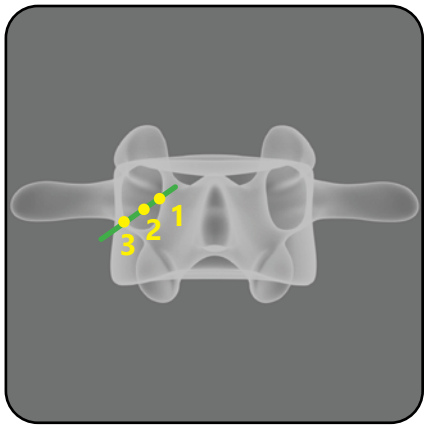


Figure 7.9
Start left pedicle entry at a 3 o'clock position.

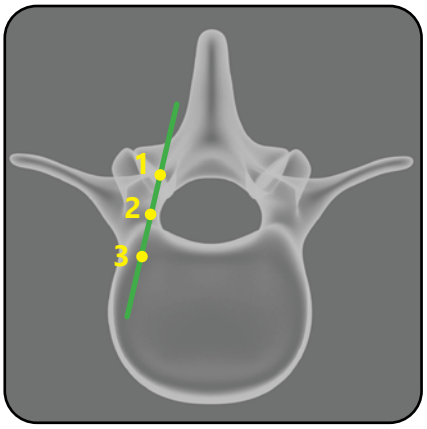


Figure 7.10
Maintain 15-20° medial to lateral angulation.

1. Matsukawa K, Yato Y. Lumbar pedicle screw fixation with cortical bone trajectory: A review from anatomical and biomechanical standpoints. Spine Surg Relat Res. 2017 Nov 27;1(4):164-173. doi: 10.22603/ssrr.1.2017-0006. PMID: 31440629; PMCID: PMC6698564.
2. Kaye ID, Prasad SK, Vaccaro AR, Hilibrand AS. The Cortical Bone Trajectory for Pedicle Screw Insertion. JBJS Rev. 2017 Aug;5(8):e13. doi: 10.2106/JBJS.RVW.16.00120. PMID: 28857932.

7. SHANK INSERTION (CONT.)

When the Modular Shank has been fully seated, disengage the Low Profile Shank Inserter from the Shank by rotating the lock knob counterclockwise until fully released. Alternatively, the Open Final Driver may be used to place the Modular Shanks.

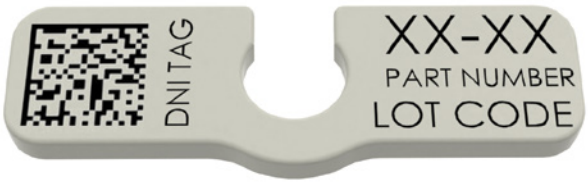


Figure 7.11
The Shank Tracking Tag.

IMPORTANT: All Modular Shanks are provided with lot traceable tags which should be removed and secured prior to assembly to the Low Profile Shank Inserter. Lot traceability tags should be cleaned, decontaminated and provided to the facility to assist with the verification of implants utilized (Figure 7.11).

NOTE: *The Modular Shank can be removed or repositioned with the Think Shank Inserter or Open Final Driver as all implants utilize a common T25 hexalobe drive feature.*

To ensure optimal clearance for the Housing after placement utilize the Decorticating Tool and any of the ¼" Square handles. The Decorticating Tool is designed to remove any surrounding tissue and bone that is immediately adjacent to the spherical head of the screw post, ensuring full polyaxiality of the final screw construct (Figure 7.12).

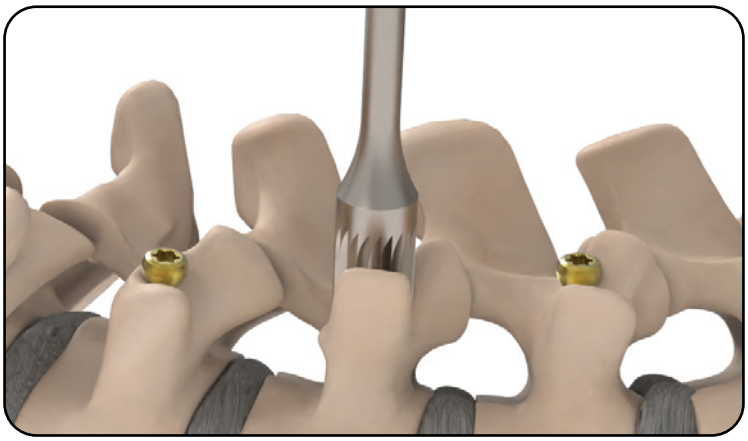


Figure 7.12
Decorticating tool removing tissue around screw head.

NOTE: *It is **not** recommended to utilize this instrument with power.*

8. HOUSING ATTACHMENT

After placement of the Shank, utilize the appropriate Housing Inserter to facilitate introduction and connection of a Housing to the Shank (Figure 8.1). Ensure that the correct Housing Tool is utilized as the instrument for Standard Housings cannot be used for Reduction Housings.

1. Thread the distal threads of the instrument into the threads of the Housing. The distal foot of the Housing Inserter will prevent the Housing from rotating when threading into the implant.

2. Slide the Housing onto the Shank by applying a downward force to connect the two components. The distal pin of the Housing Inserter will interface with the Housing allowing the proximal grips of the Assembly Tool to move freely.

3. Squeeze the handles of the Housing Inserter together to deploy and lock the Housing to the Shank. If done correctly, the magenta indicator at the proximal end of the instrument should sit flush with the handle casing.

4. Rotate the knob counterclockwise to disconnect the Tulip Inserter from the Housing.

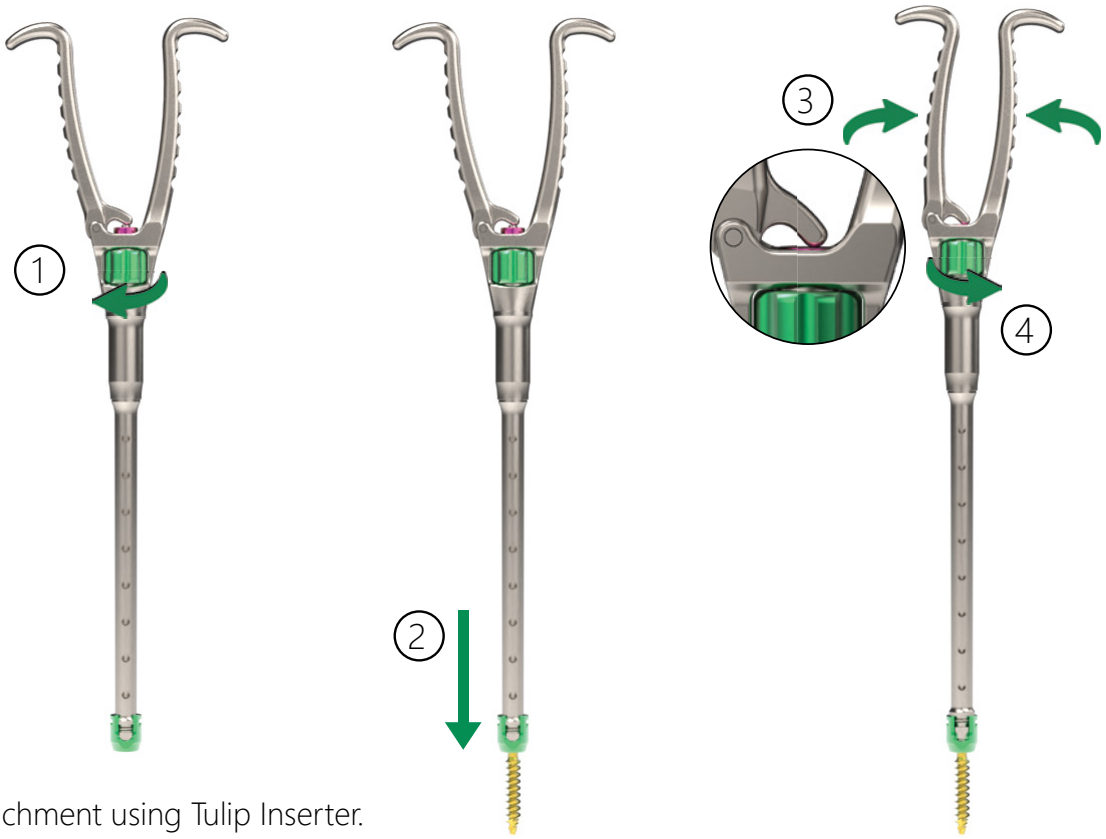


Figure 8.1
Housing attachment using Tulip Inserter.

8. HOUSING ATTACHMENT (CONT.)

TIP: *After locking the components, surgeon should pull instrument upward and rotate slightly to confirm that components have been securely connected. The surgeon can also verify the implant has been appropriately locked by visualizing the silver cap position within the Housing (Figure 8.2).*

Figure 8.2
Unlocked and locked cap positions of Housings.

For back table assembly, place the provisionally assembled Shank and Housing into the Housing Assembly Tool. The elongated rod of the instrument should sit in the saddle of the housing, while the distal portion of the Housing is seated in the mating "cup". Ensure that the Shank is not captured, and is free to rotate and toggle before final seating. Compress the handles of the instrument until the alignment arrows are fully pointing toward each other to fully seat and secure the components together (Figure 8.3).

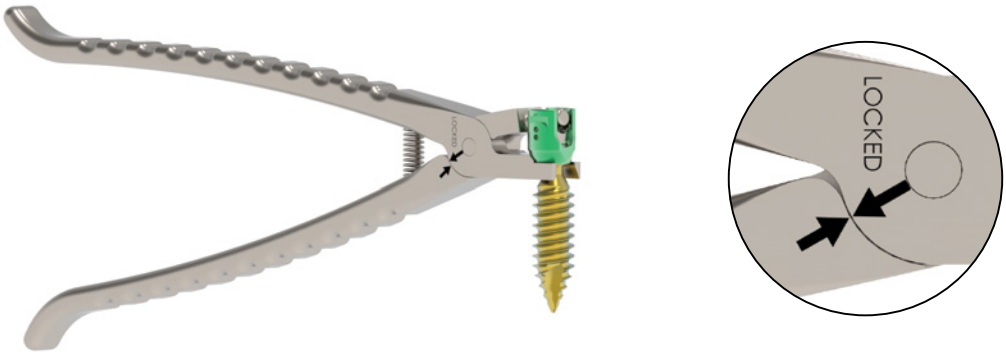


Figure 8.3
Marked arrows pointing toward each other indicate secure lock.

NOTE: *Improper assembly of the Housing to the Shank can cause separation in subsequent steps such as Rod reduction. The presence of soft tissue trapped between the components could hinder achieving adequate attachment.*

8. HOUSING ATTACHMENT (CONT.)

The Screw Inserter can be used to implant the assembled Housing and Shank by following the steps as shown (Figure 8.4).

1. Insert the hexalobe tip into the Shank until bottomed out.

2. Turn proximal knob clockwise to thread outer sleeve into Housing until tight.

3. Using a ¼ Square Handle, insert the assembly into the prepared pedicle until desired depth is reached.

4. Turn proximal knob counter clockwise and pull the instrument upwards to disengage from the implant. Head orientation may need to be adjusted at this time.

CAUTION: Do not utilize the Screw Inserter to assemble the Housing to the Shank as this will prematurely set the locking feature of the housing and inhibit proper assembly.

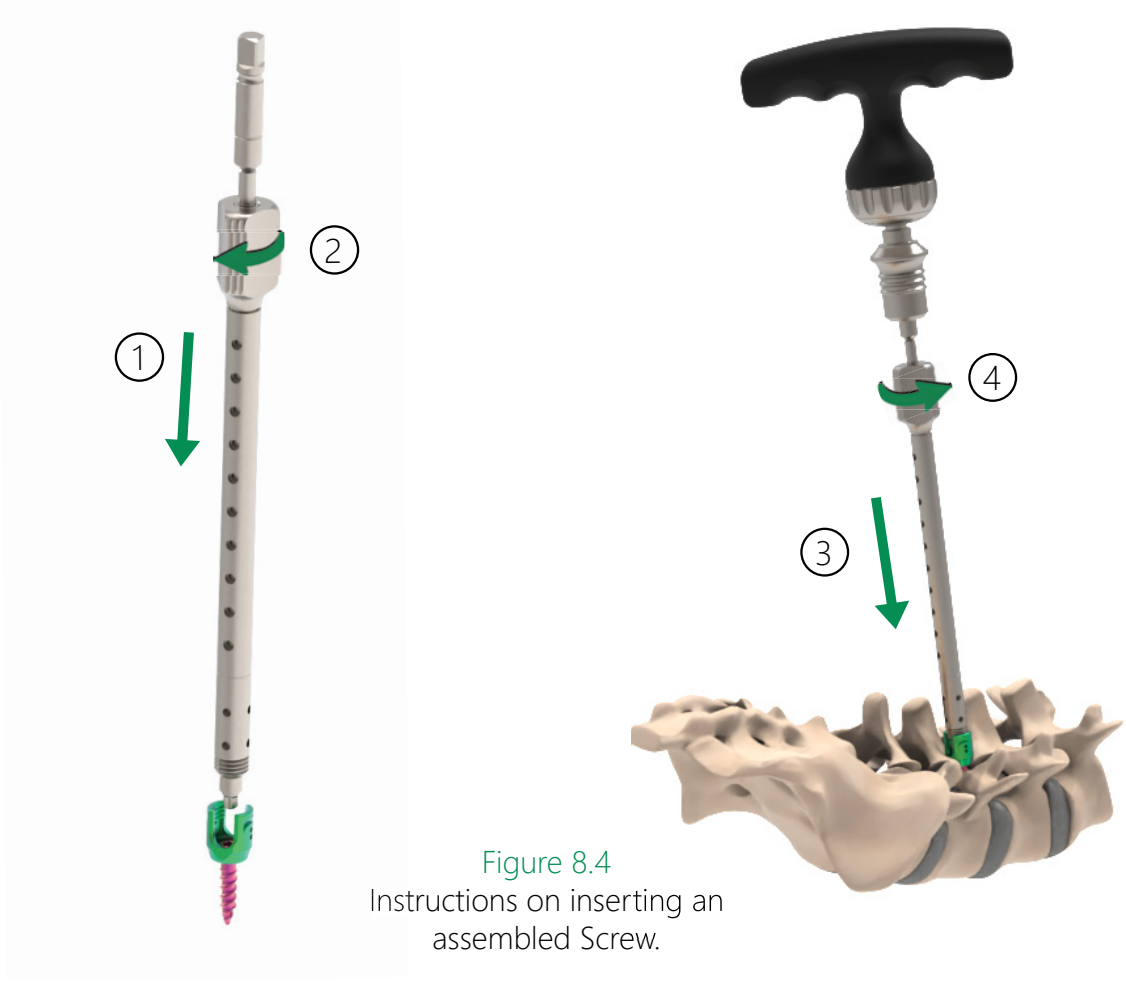


Figure 8.4
Instructions on inserting an assembled Screw.

9. ROD SELECTION AND CONTOURING

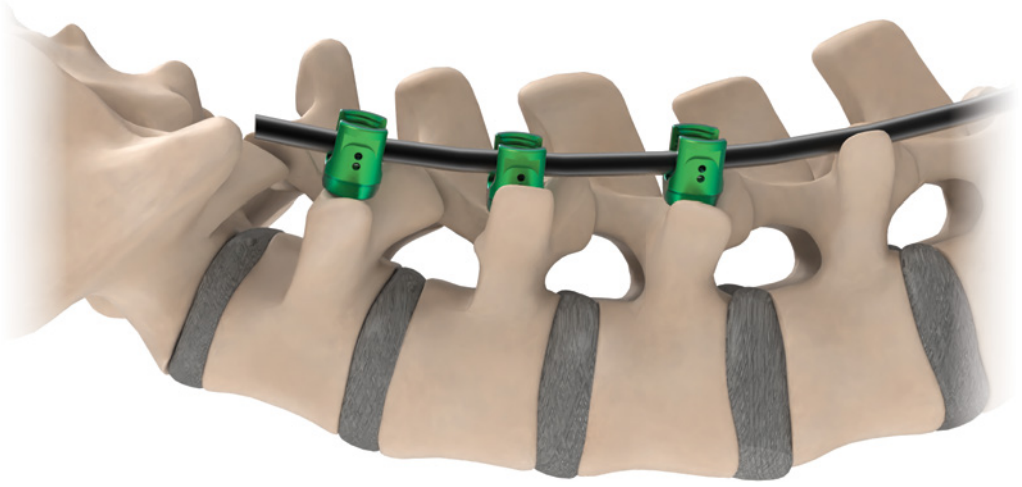


Figure 9.1
Rod Template being used to determine Rod length and contour.

The INERTIA® CONNEXX™ MIDLINE Modular Pedicle Screw System offers multiple Rod lengths and material choices with both straight and curved options. Alternatively, Rods may be cut to length using a Rod Cutter. Surgeons should select the Rod that is appropriate for their patient's needs.

The system includes a Rod Template that can be used to determine Rod length and desired contour. The Rod Template should be inserted into Housings and contoured to fully seat within the Housing. Appropriate length can be determined using the length markings on the Rod Template (Figure 9.1).

Use the Rod Bender to prepare and contour the Rods with progressive bends until obtaining a shape similar to that defined by the Rod Template (Figure 9.2). Pre-contoured Rods simplify the initial approximation without inducing additional stress into the Rod.

Figure 9.2
The Rod Bender.

10. ROD AND SET SCREW INSERTION

For rod positioning, moving some Housings may be required. Adjust assembled Screw height by fully inserting the Open Final Driver into the Shank and turn to the desired height. To adjust housing orientation, insert the Head Adjuster into the Housing and turn to ensure Housings are in proper orientation for Rod insertion.

The Rod Holder may be used to assist in placing the Rod depending on surgeon preference.

Figure 10.1
The Tactile Set Screw Inserter.

Insert the distal end of the Tactile Set Screw Inserter into the Set Screw (Figure 10.1). The Tactile Set Screw Inserter has been designed to capture the Set Screw and release once it has been fully seated onto the Rod (Figure 10.2).

Align the Tactile Set Screw Inserter with the assembled Modular Housing and introduce the Set Screw. Turn the Set Screw until it comes into contact with the Rod. Do not final tighten. Repeat this procedure for inserting all Set Screws.

Figure 10.2
Tactile Set Screw Inserter automatically dissociates when securely tightened.

NOTE: *The Set Screw can be loaded directly from the Set Screw Caddy so as to hold the implant in place while assembling to the Tactile Set Screw* Inserter.

NOTE: *Set Screw insertion requires minimal effort to seat within the Modular Housing. Do not force placement as this may damage the threads of the Set Screw. If the Set Screw is difficult to rotate, the Rod may not be seated properly and Rod reduction or contouring may be required.*

IMPLANT PART NUMBERS

Standard P/N	Description
Ø4.5mm x XXmm CC. Shanks	
20-SDC-4525	Ø4.5mm x 25mm
20-SDC-4530	Ø4.5mm x 30mm
20-SDC-4535	Ø4.5mm x 35mm
20-SDC-4540	Ø4.5mm x 40mm
20-SDC-4545	Ø4.5mm x 45mm
20-SDC-4550*	Ø4.5mm x 50mm
20-SDC-4555*	Ø4.5mm x 55mm
20-SDC-4560*	Ø4.5mm x 60mm
20-SDC-4565*	Ø4.5mm x 65mm
20-SDC-4570*	Ø4.5mm x 70mm
20-SDC-4575*	Ø4.5mm x 75mm
20-SDC-4580*	Ø4.5mm x 80mm

Standard P/N	Description
Ø5.0mm x XXmm CC. Shanks	
20-SDC-5025	Ø5.0mm x 25mm
20-SDC-5030	Ø5.0mm x 30mm
20-SDC-5035	Ø5.0mm x 35mm
20-SDC-5040	Ø5.0mm x 40mm
20-SDC-5045	Ø5.0mm x 45mm
20-SDC-5050*	Ø5.0mm x 50mm
20-SDC-5055*	Ø5.0mm x 55mm
20-SDC-5060*	Ø5.0mm x 60mm
20-SDC-5065*	Ø5.0mm x 65mm
20-SDC-5070*	Ø5.0mm x 70mm
20-SDC-5075*	Ø5.0mm x 75mm
20-SDC-5080*	Ø5.0mm x 80mm

Standard P/N	Description
Ø5.5mm x XXmm CC. Shanks	
20-SDC-5525	Ø5.0mm x 25mm
20-SDC-5530	Ø5.0mm x 30mm
20-SDC-5535	Ø5.0mm x 35mm
20-SDC-5540	Ø5.0mm x 40mm
20-SDC-5545	Ø5.0mm x 45mm
20-SDC-5550*	Ø5.0mm x 50mm
20-SDC-5555*	Ø5.0mm x 55mm
20-SDC-5560*	Ø5.0mm x 60mm
20-SDC-5565*	Ø5.0mm x 65mm
20-SDC-5570*	Ø5.0mm x 70mm
20-SDC-5575*	Ø5.0mm x 75mm
20-SDC-5580*	Ø5.0mm x 80mm

Standard P/N	Description
Ø6.5mm x XXmm CC. Shanks	
20-SDC-6525	Ø6.5mm x 25mm
20-SDC-6530	Ø6.5mm x 30mm
20-SDC-6535	Ø6.5mm x 35mm
20-SDC-6540	Ø6.5mm x 40mm
20-SDC-6545	Ø6.5mm x 45mm
20-SDC-6550*	Ø6.5mm x 50mm
20-SDC-6555*	Ø6.5mm x 55mm
20-SDC-6560*	Ø6.5mm x 60mm
20-SDC-6565*	Ø6.5mm x 65mm
20-SDC-6570*	Ø6.5mm x 70mm
20-SDC-6575*	Ø6.5mm x 75mm
20-SDC-6580*	Ø6.5mm x 80mm
20-SDC-6585*	Ø6.5mm x 85mm
20-SDC-6590*	Ø6.5mm x 90mm
20-SDC-6595*	Ø6.5mm x 95mm
20-SDC-65100*	Ø6.5mm x 100mm

Additional shank sizes available by request in combinations of cannulated, solid, corticocancellous, double-lead, and uniplanar.*

Green rows indicate Standard Order.

*By Request, contact Info@NexxtSpine.com for full SKU offering.

INSTRUMENT PART NUMBERS

Shank Inserter

Standard P/N	Description
I20-08-14	Low Profile Shank Inserter
I20-08-01*	CONNEXX Shank Inserter

Ball Tip Sounders

Standard P/N	Description
I10-05-01L	Inertia, Sounder, Straight
I10-05-06	Inertia, Sounder, Curved

Housing Inserter

Standard P/N	Description
I20-08-10	Housing Inserter

Adjustable Drill Guide

Standard P/N	Description
I20-22-01	Drill Guide

Lenke Probes

Standard P/N	Description
I20-05-06*	Thoracic Pedicle Probe, Lenke Straight
I20-05-07	Thoracic Pedicle Probe, Lenke Curved
I20-05-08	Lumbar Pedicle Probe, Lenke Straight
I20-05-09	Lumbar Pedicle Probe, Lenke Curved

Drill

Standard P/N	Description
I20-22-35	Drill, Ø3.5mm
I20NAV-22-35*	Navigated Drill, Ø3.5mm

Green rows indicate Standard Order.

*By Request, contact Info@NexxtSpine.com for full SKU offering.

INSTRUMENT PART NUMBERS (CONT)

Awl

Standard P/N	Description
I10-13-01*	Inertia, Awl, 9mm

Screw Inserter

Standard P/N	Description
I20-08-05	CONNEXX Screw Inserter

Decorticating Tool

Standard P/N	Description
I20-08-20	CONNEXX Decorticating Tool

Tulip Removal Tool

Standard P/N	Description
I20-12-50	CONNEXX Tulip Removal Tool

Taps

Standard P/N	Description
I20-05-45	Ø4.5mm Tap
I20-05-55	Ø5.5mm Tap
I20-05-65	Ø6.5mm Tap
I20-05-75	Ø7.7.5mm Tap
I20-05-40:115*	Ø4.0-11.5mm Tap

Green rows indicate Standard Order.

*By Request, contact Info@NexxtSpine.com for full SKU offering.

COMPATIBLE NEXXT MATRIXX® SYSTEMS

Lateral + STRUXXURE® L

ALIF + STRUXXURE® A

SA ALIF

Corpectomy

TLIF

TLIF Oblique

Nexxt Spine, LLC
14425 Bergen Blvd, Suite B
Noblesville, IN 46060
(317) 436-7801
Info@NexxtSpine.com
NexxtSpine.com

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit NexxtSpine.com for additional product information.

71-056, Rev B