Nexxt Spine

Surgical Technique Guide

INERTIA® CONNEXX™

OPEN

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INERTIA® CONNEXX™ OPEN MODULAR PEDICLE SCREW SYSTEM

The INERTIA® CONNEXX™ Open 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.

INERTIA® CONNEXX™ enhances efficiency through a modular platform and provides the surgeon multiple reduction options to assist in implant accessibility and limit bulk in the 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™ Open Pedicle Screw System one of the most versatile systems for posterior thoracolumbar fixation and stabilization.

Indications 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.

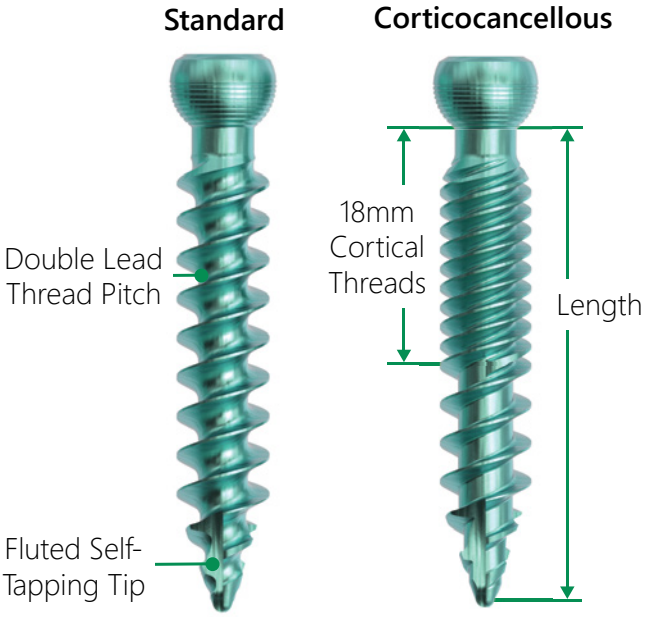
11. MIXED METALS. The INERTIA® CONNEXX™ System is available in titanium alloy. It is imperative that this metal does not come into contact in vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are used together when building a construct.

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® CONNEXX™ 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 & 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.

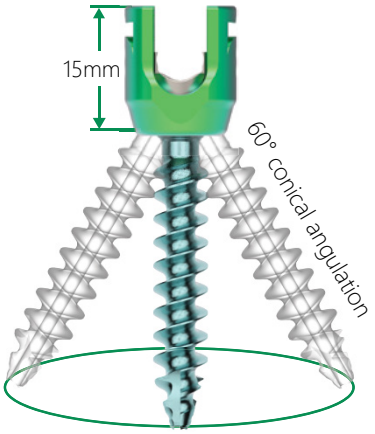
Modular Shank Sizing

Ø4.5-11.5mm x 20-120mm

Solid Standard | Cannulated Standard | Solid Corticocancellous | Cannulated Corticocancellous

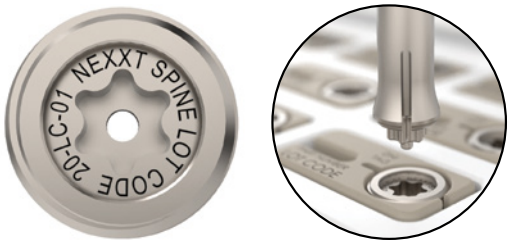
Modular Housings - Ti-6Al-4V ELI per ASTM F136

- 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

Ø5.5mm

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

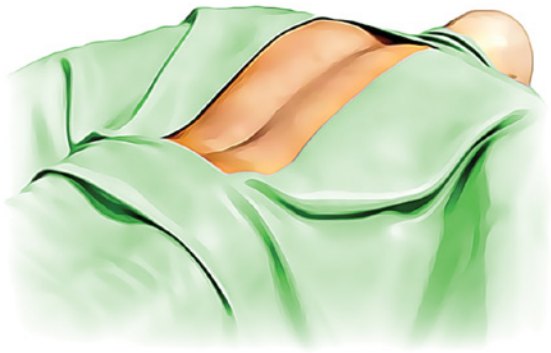


Figure 1.1
Position patient in a traditional manner as deemed by the surgeon

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.

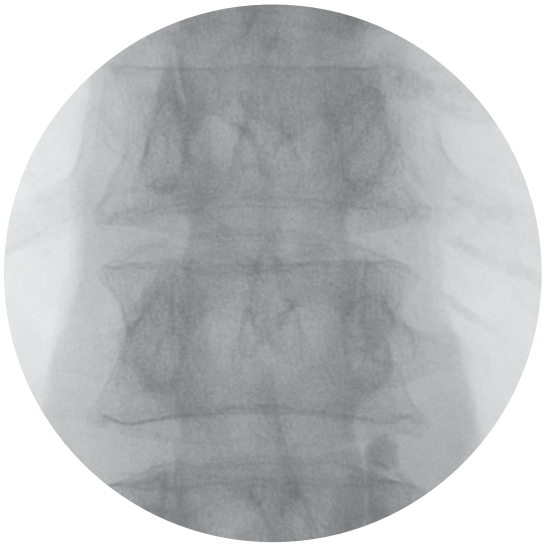


Figure 1.2
Symmetrical pedicles and centered spinous process

There are various techniques for pedicle screw and Rod insertion. For the purpose of this guide, a Wiltse paramedial approach from L4 to S1 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.

2. PEDICLE PREP

Locate the desired entry point into the pedicle and remove bone and/or soft tissue as needed using standard instruments. Perforate the cortex at the pedicle entry with a high-speed burr or 9mm long Bone Awl.

Open the pedicle pathway by passing a Lenke Probe through the pedicle and into the vertebral body (Figure 2.1). Laser reference lines every 10mm on the probe indicate the depth of the pathway, and can be used to determine proper Shank length (Figure 2.2).

Figure 2.1
Lenke Probe creating pilot hole in vertebral body

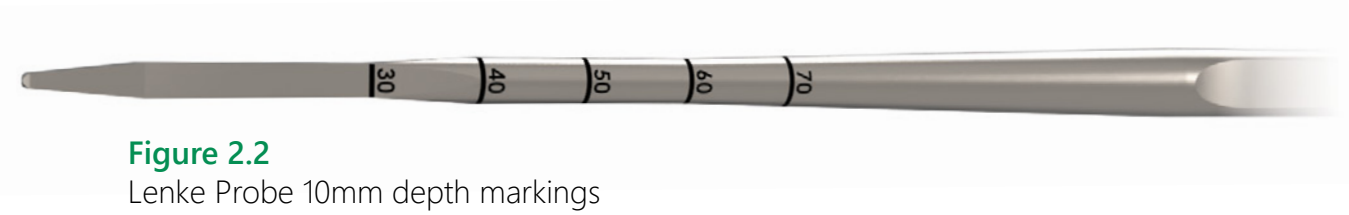


Figure 2.2
Lenke Probe 10mm depth markings

Prior to screw insertion, inspect the pilot hole for perforations and pedicle integrity, using the Ball Tip Sounder. Inspect the cortical wall of the pedicle for perforations with the Ball Tip Sounder by palpating the pedicle wall on all sides.

TIP: *When fully inserted, forceps can be clamped onto the Ball Tip Probe to determine the hole depth for choosing the screw length.*

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

NOTE: *Lenke Style Probes are standard in the CONNEXX™ system, with Steffee Style Probes available upon request, as well as options for both lumbar and thoracic geometries.*

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. Tap thread geometry is designed to provide a line to line fit with the Shanks. Prior to screw insertion, inspect the pilot hole again for perforations using the Ball Tip Sounder.

NOTE: *Tap sleeves are color coded to match the corresponding Shank (Figure 3.1)*

NOTE: *All Taps provide 30mm of thread length. Taps up to Ø7.5mm are marked with laser lines from 30-60mm. Taps Ø8.5mm and larger are marked 30-90mm. (Figure 3.2)*

Figure 3.1
Tap with Ratcheting T-Handle and Ø4.5mm color stripe

Figure 3.2
Ø9.5mm Tap marked with 30-90mm of laser lines and Ø6.5mm Tap marked with 30-60mm of laser lines.

4. 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 4.1).

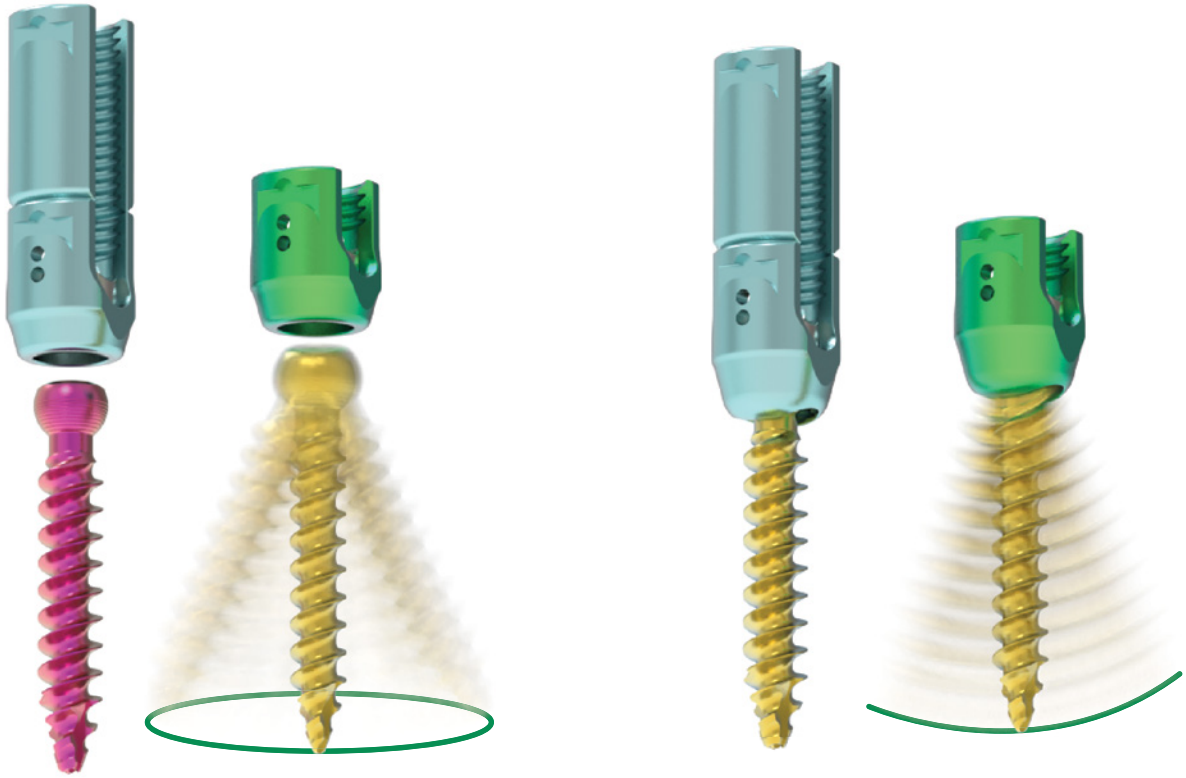


Figure 4.1
Modular 60° Polyaxial vs 60° Uniplanar Angulation

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

Modular Reduction Housings are employed for instrument-free reduction up to 20mm 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.

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

4. SHANK INSERTION (cont.)

Once the pedicle 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 4.2), whereas the Shank length may be determined by position in the caddy.

To verify Modular Shank diameter and length, use the measurement features integrated into the Shank caddies (Figure 4.5). Measurement of Modular Shanks must be completed with the Tracking Tag attached to the Modular Shank.

Figure 4.2 - Ømm by Anodization Color

Attach the Ratcheting Handle of choice to the Low Profile Shank Inserter and load the chosen Modular Shank. To load the Low Profile Shank Inserter, insert the hexalobe drive feature into the Modular Shank and secure by turning the proximal knob clockwise. Verify that the Modular Shank and screwdriver interface is rigid, and the Modular Shank is aligned straight and coaxial with the Low Profile Shank Inserter (Figure 4.3).

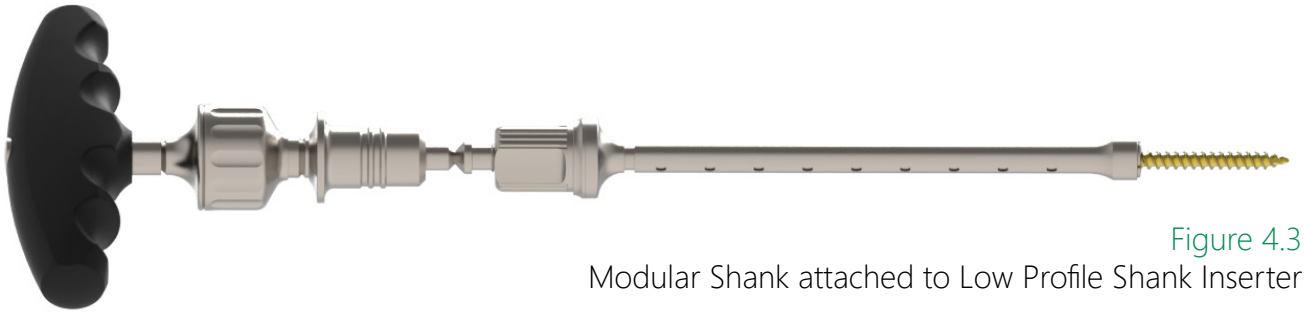


Figure 4.3
Modular Shank attached to Low Profile Shank Inserter

Introduce the Modular Shank into the pilot hole and advance until the desired depth is reached. The Shank Driver's distal locking feature serves as an indicator that the Modular Shank has been implanted to the desired depth. The distal geometry of the driver has been designed to mimic the shape of the Housing and will ensure that the Modular Shank is placed to the appropriate depth.

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

4. 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.

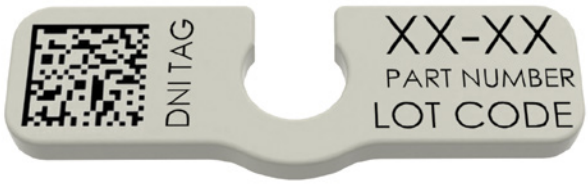


Figure 4.4
Shank Tracking Tag

Figure 4.5
Integrated Shank measurement tools

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 4.4).

NOTE: *The Modular Shank can be removed or repositioned with the Low Profile 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. (Figure 4.6) 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.

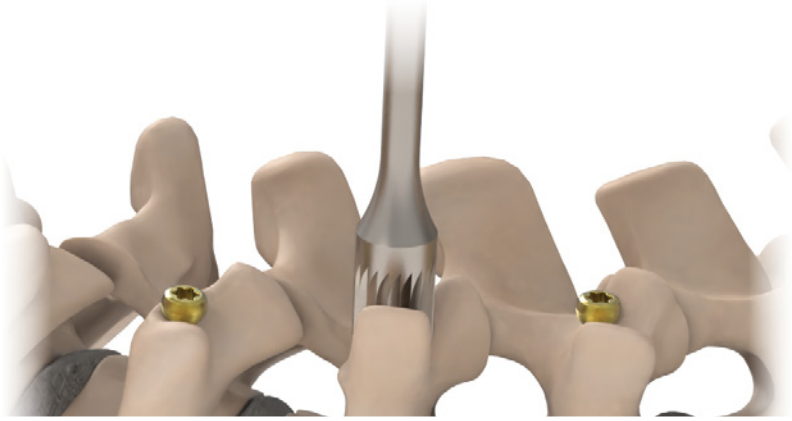


Figure 4.6
Decorticating tool removing tissue around screw head

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

5. HOUSING ATTACHMENT

After placement of the Shank, utilize the appropriate Housing Inserter to facilitate introduction and connection of a Housing to the Shank. 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 Housing Inserter from the Housing.

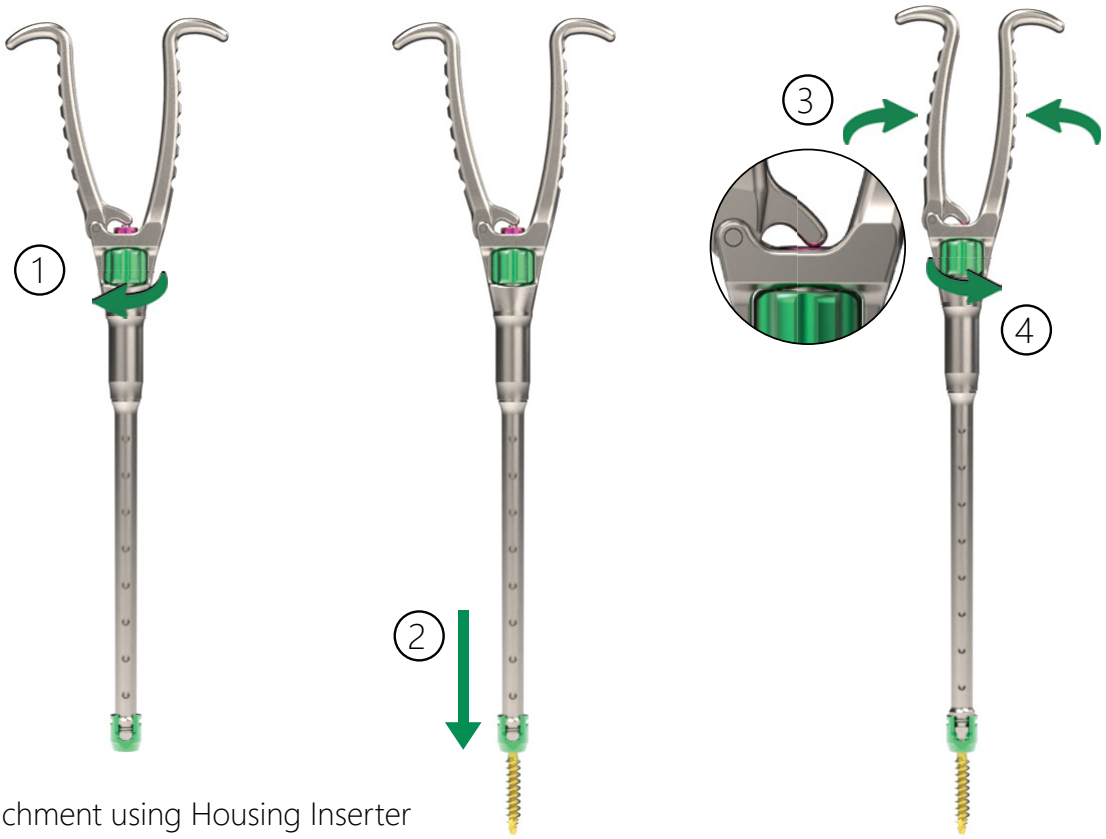


Figure 5.1
Housing attachment using Housing Inserter

5. 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 5.2).*

Figure 5.2
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 5.3).

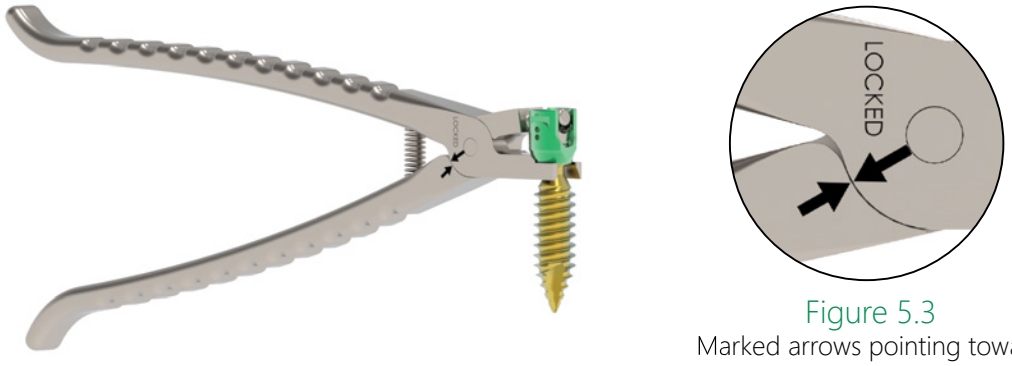


Figure 5.3
Marked arrows pointing toward each other indicate secure lock

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 prevent adequate attachment.*

5. HOUSING ATTACHMENT (cont.)

The Screw Inserter can be used to implant the assembled Housing and Shank by following the steps as shown (Figure 5.4).

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.

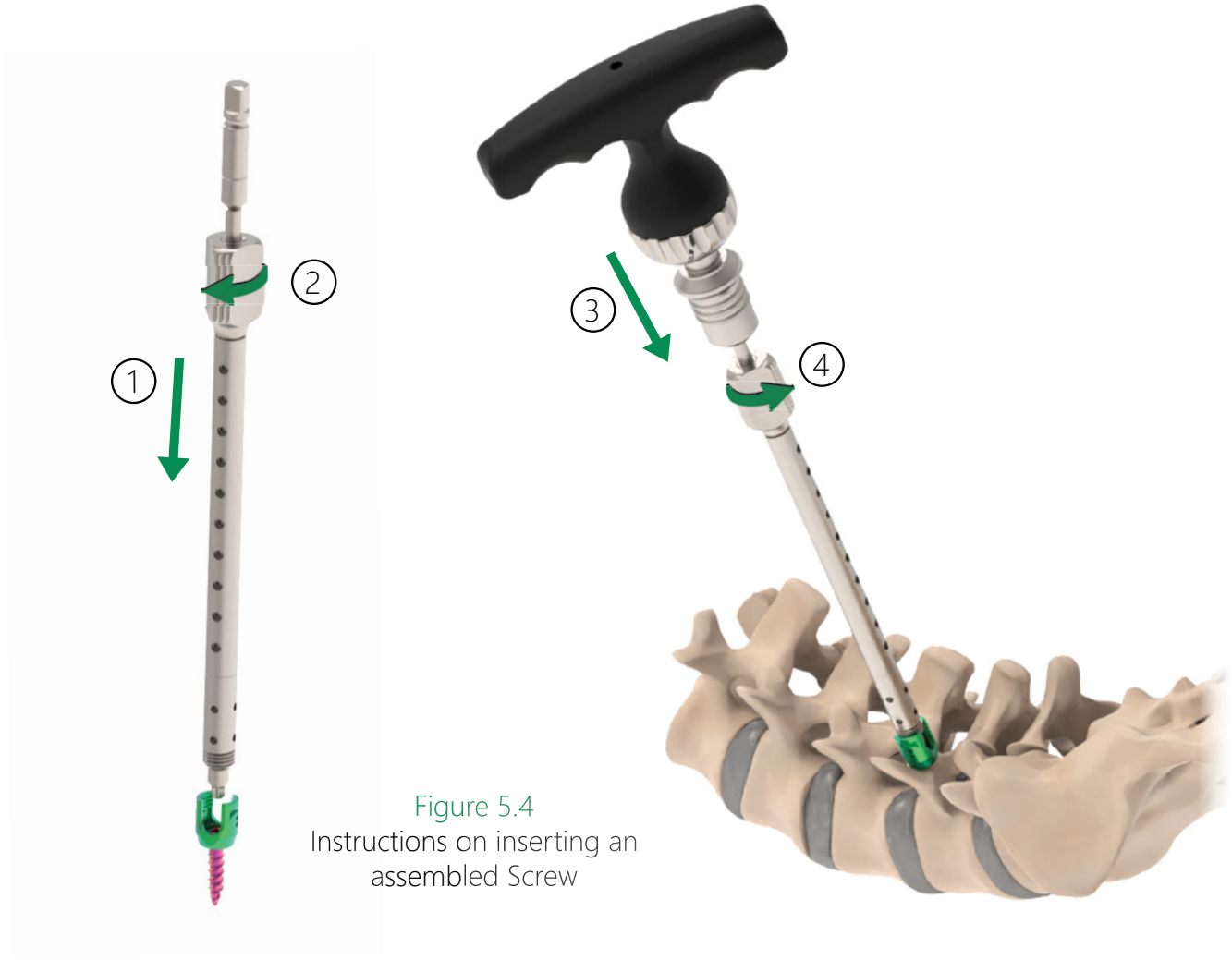


Figure 5.4
Instructions on inserting an assembled Screw

6. ROD SELECTION AND CONTOURING

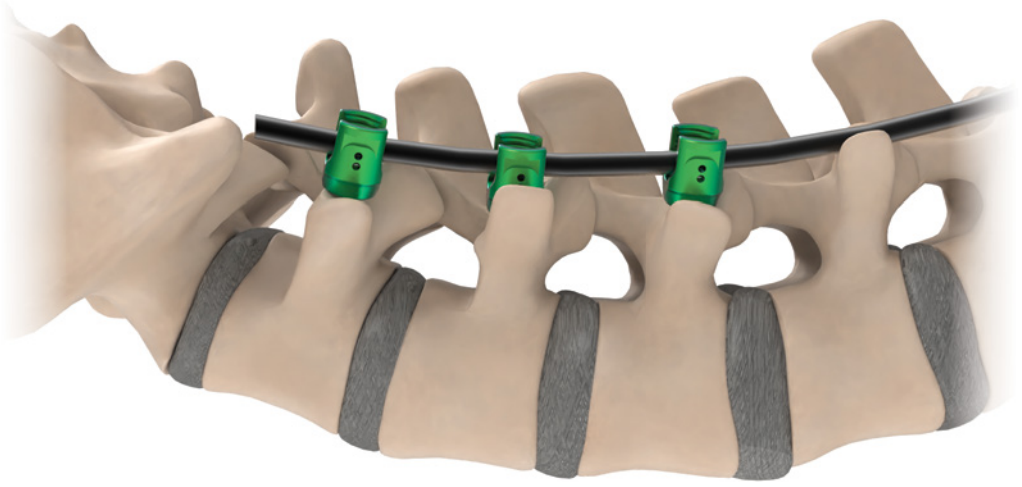


Figure 6.1
Rod Template being used to determine Rod length and contour

The INERTIA® CONNEXX™ 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 6.1).

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 6.2). Pre-contoured Rods simplify the initial approximation without inducing addition stress into the Rod.

Figure 6.2
Rod Bender

7. ROD & 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 7.1
Tactile Set Screw Inserter

Insert the distal end of the Tactile Set Screw Inserter into the Set Screw. 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 7.1, 7.2).

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 7.2
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.*

8. ROD REDUCTION

Multiple options are available to achieve varying amounts of Rod reduction, as well as medial persuasion of rods. The INERTIA® CONNEXX system provides four (4) distinct options for Rod reduction:

1. Rod Rocker – 10mm
2. Reduction Housings – 20mm
3. Pistol Grip Reducer – 20mm
4. Inline Reducer – 30mm

Figure 8.1
Reduction Housing

OPTION 1: REDUCTION HOUSINGS
For planned need for reduction due to anatomy or deformity correction, INERTIA® CONNEXX™ provides reduction implants in both the Housing (Figure 8.1) and pre-assembled Uniplanar Screw options. The extended design allows for up to 20mm of instrument free reduction. See OPTIONAL TECHNIQUE: REDUCTION SCREW INSERTION for surgical technique overview.

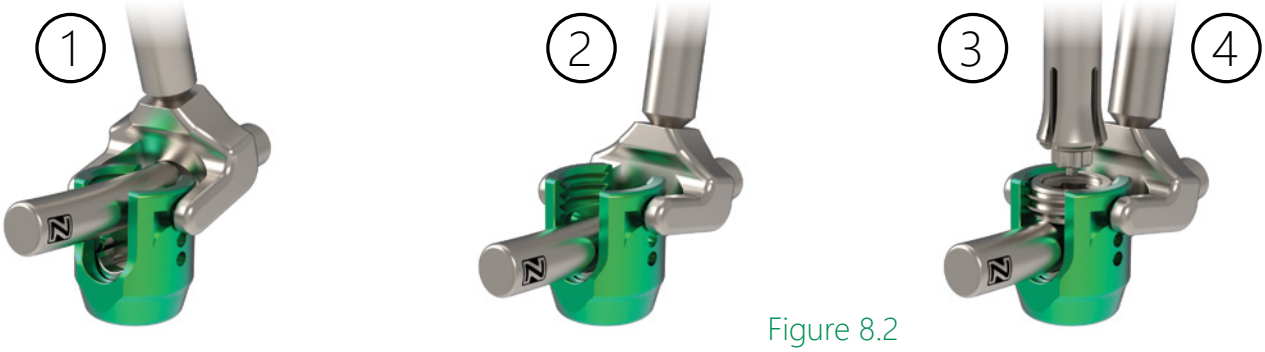


Figure 8.2
Rod Rocker reduction steps

OPTION 2: ROD ROCKER
For reduction less than 10mm , the Rod Rocker may be used to seat the Rod (Figure 8.2).

1. Align the prongs of the Rod Rocker in the medial and lateral slots on the Housing.
2. Use the Rod Rocker as a lever to introduce the Rod into the screw head.
3. Once the Rod is fully reduced into the Housing use the Tactile Set Screw Inserter to introduce the Set Screw into the Housing.
4. Turn the Set Screw until it comes into contact with the Rod. Do not final tighten.

NOTE: *The Rod Rocker can be used to reduce rods into Polyaxial or Uniplanar Assemblies.*

8. ROD REDUCTION (CONT.)

OPTION 3: INLINE REDUCER

1. The Inline Reducer provides up to 30mm of continuous gradual reduction (Figure 8.3).
2. Ensure the Inline Reducer is in the starting position by fully backing up the proximal knob counterclockwise. The Universal T-Handle can be assembled to the proximal knob to assist with the drive mechanism.
3. Assemble Inline Reducer to screw by placing the Inline Reducer squarely over the Housing and pushing it down until it is completely over the Housing. Align the distal open slot with the slot in the Housing.

NOTE: *The distal mating geometry of the Inline Reducer has been designed to only allow seating of the instrument when aligned with the outer geometry of the Housing.*

4. Verify proper engagement by pulling up on the Inline Reducer. Do not pull gold sleeve as this will prematurely detach the assembly.
5. Place the Reduction Handle onto the proximal knob and turn clockwise.
6. Once the Rod is fully reduced into the screw head use the Tactile Set Screw Inserter to introduce the Set Screw into the Housing.
7. Turn the Set Screw until it comes into contact with the Rod. Do not final tighten.
8. Pull gold sleeve proximally to release the Inline Reducer from the screw assembly.

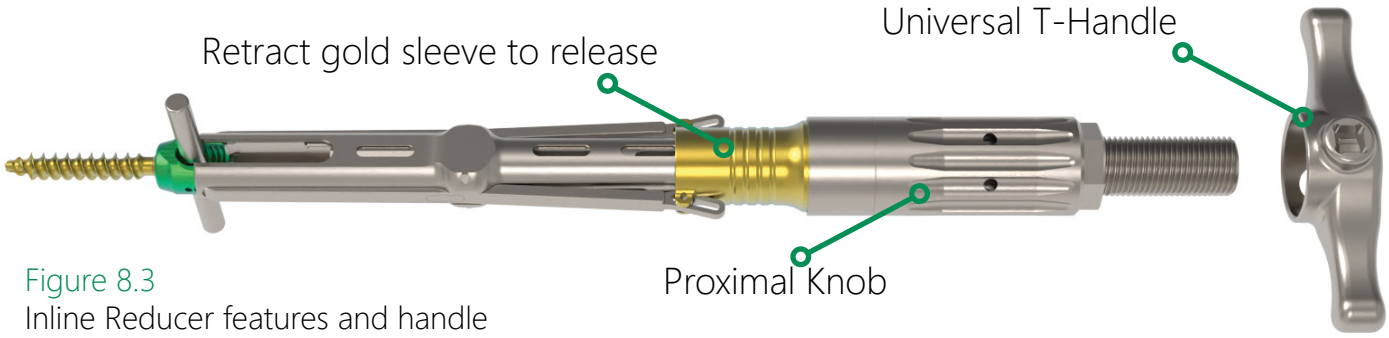


Figure 8.3
Inline Reducer features and handle

NOTE: *If reducing over multiple levels, use the Reducer Socket attachment on a Straight Ratcheting Handle to minimize interference with adjacent reducers.*

8. ROD REDUCTION (CONT.)

OPTION 4: PISTOL GRIP REDUCER

1. The Pistol Grip Reducer provides up to 20mm of continuous gradual reduction.
2. Ensure the Pistol Grip Reducer is in the fully open position and that the instrument's handles have not been prematurely compressed.
3. Assemble Pistol Grip Reducer to screw by placing the reducer squarely over the Housing and pushing it down until it is completely over the Housing. Align the distal open slot with the slot in the Housing (Figure 8.4).
4. Compress the handles to engage the screw and reduce the Rod.
5. The Tactile Set Screw Inserter is inserted through the reducer to lock the Rod into place.

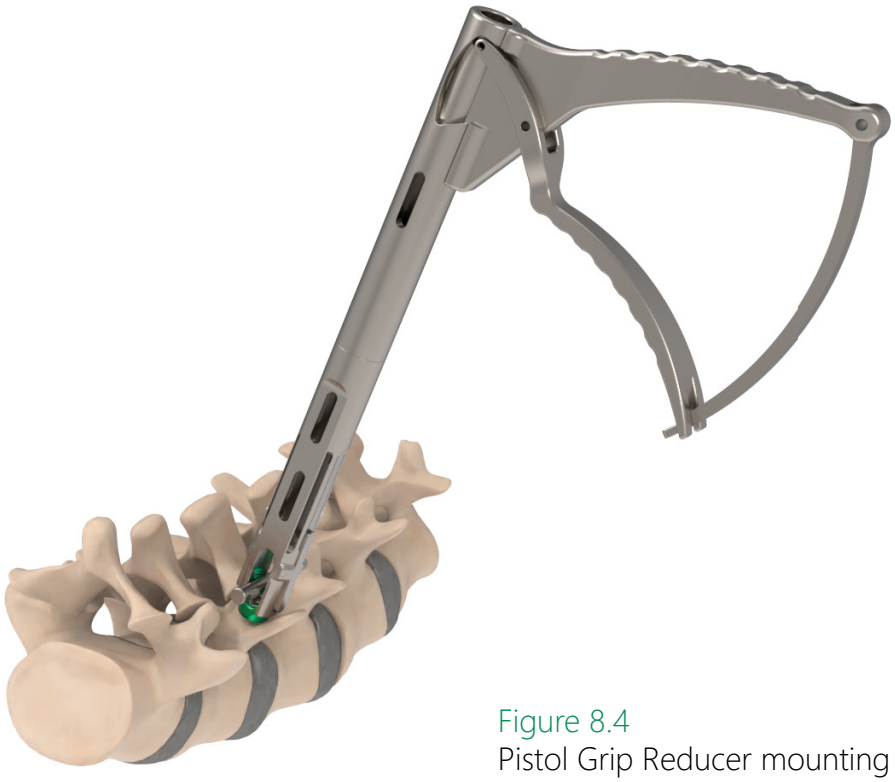


Figure 8.4
Pistol Grip Reducer mounting onto Housing

9. ILIAC SCREWS

Iliac Screws provide additional stabilization of long construct spinal fusions, or where caudal fixation is required to maintain or restore lumbar lordosis.

If Iliac Screw fixation is desired, expose the posterior superior iliac spine (PSIS) and decorticate/resect the entry point to allow the Iliac Screw head to be recessed below the iliac crest (Figure 9.1)

Use the Lenke Probe to create a pilot hole, aiming for the thick bone just above the greater sciatic notch with screw angulations of 25° lateral and 30° caudal.

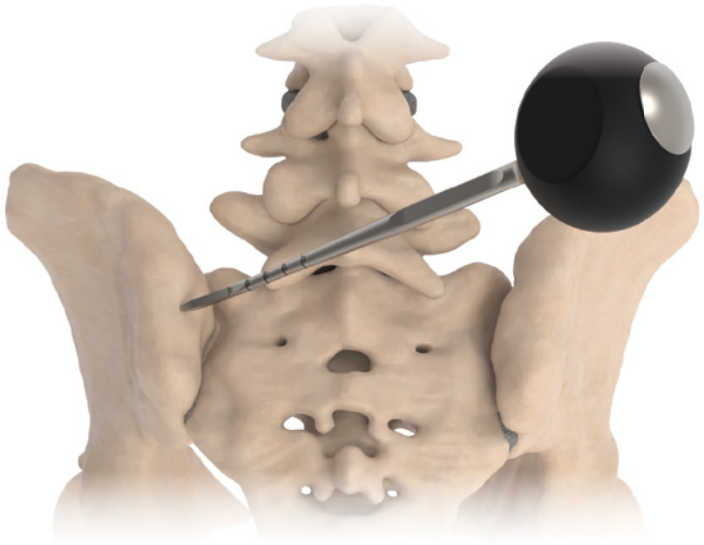


Figure 9.1
Lenke Probe creating pilot hole

Inspect the pilot hole for cortical wall violations using the Ball Tip Sounder.

Tap the pilot hole using the markings on the shaft of the Iliac Taps and fluoroscopy to monitor depth. Re-inspect the pilot hole for perforations.

Assemble to Shank Driver as demonstrated on STEP 4: Shank Insertion and insert the Iliac Shank (Shanks which are typically larger than Ø7.0mm and greater than 55mm in length) into the pilot hole and advance until the desired depth is reached.

Ensure that when fully seated, the Iliac Shank is below the ridge of the iliac crest to minimize hardware prominence. If Iliac Shank adjustment is needed, use the In-Situ Driver to adjust Iliac Shank depth.

Assemble Housing as demonstrated on STEP 5 Housing Attachment.

10. IN-SITU ROD BENDING

In-Situ Rod Benders may be used to modify the curvature to the spinal rods to assist with the correction in the sagittal and coronal planes. Rod contouring may be performed after the Rod has been fully seated into the implants and Set Screws inserted (Figure 10.1).

For sagittal correction, slide either the angled or straight ends of the In-Situ Benders around the Rod so that the Rod sits flush within the Rod slot.

Compress the In-situ benders toward each other to achieve lordosis, or bend away from each other to produce kyphosis. The In-Situ Benders have two distinct (left and right) instruments to achieve the correction.

NOTE: *In-Situ Benders are powerful instruments, so careful bending is recommended , and ensure that implant fixation has not been compromised.*

Figure 10.1
In-Situ Benders in position for bending

11. REDUCTION HOUSINGS

Figure 11.1
Reduction Housings feature 20mm of internal reduction

Reduction Housings provide an alternative, low-profile Rod reduction method. Each Reduction Housing provides 20mm of internal Rod reduction without the need for additional instrumentation (Figure 11.1).

NOTE: *All reduction instrumentation options will work with the Extended Tabs of the Reduction Housing.*

Follow the INERTIA® CONNEXX™ Pedicle Preparation and Screw Insertion surgical steps noted in STEPS 4 and 5. A Reduction Housing Assembly Tool is required for mating to the Shank.

With the Reduction Screw assembly and Rod in place, slide the Reduction Housing Counter-torque over the screw head until it seats flush on the Rod. These steps are similar for all reduction implant configurations.

Using the Tactile Set Screw Inserter, reduce the Rod by threading a Set Screw down the Reduction Housing. Be sure to apply downward force on the Counter-torque so the slot remains fully seated on the Rod during reduction. The Rod is fully reduced when the top of the Set Screw sits below the break-off groove at the base of the Reduction Housing.

NOTE: *Final tightening should not be completed until all compression or distraction maneuvers have been completed.*

With the Rod fully reduced, remove the Counter-torque, and slide the Reduction Tab Breaker over the Reduction Tab of the Reduction Housing. Rock the Reduction Tab Breaker in a medial/lateral direction until it breaks free from the screw head. Repeat this process on the opposite Reduction Tab (Figure 11.2).

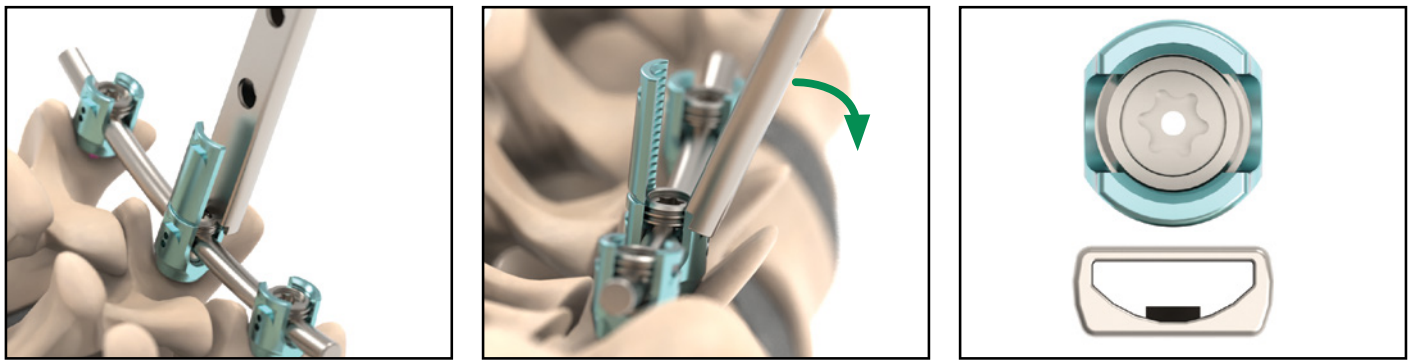


Figure 11.2
Steps and alignment for the Reduction Tab Breaker

12. COMPRESSION AND DISTRACTION

Choose the Distractor (Figure 12.1) or Compressor (Figure 12.2), and place slotted distal tips over the Rod, against the Housing of the targeted screws.

Provisionally tighten the Set Screw on one side of the motion segment, and leave the Set Screw loose in the adjacent segment to be compressed or distracted.

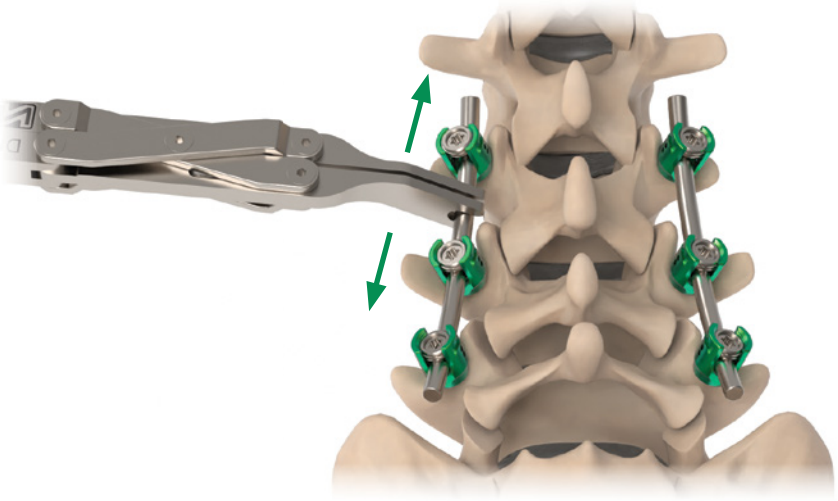


Figure 12.1
Distractor mounted between desired Housings

With the instrument properly engaged over the Rod, deliver the desired level of compression or distraction. Provisionally tighten the loose Set Screw to hold the construct in position prior to final tightening.

NOTE: *It is not recommended to final tighten the Set Screw while it is under the force of compression or distraction.*

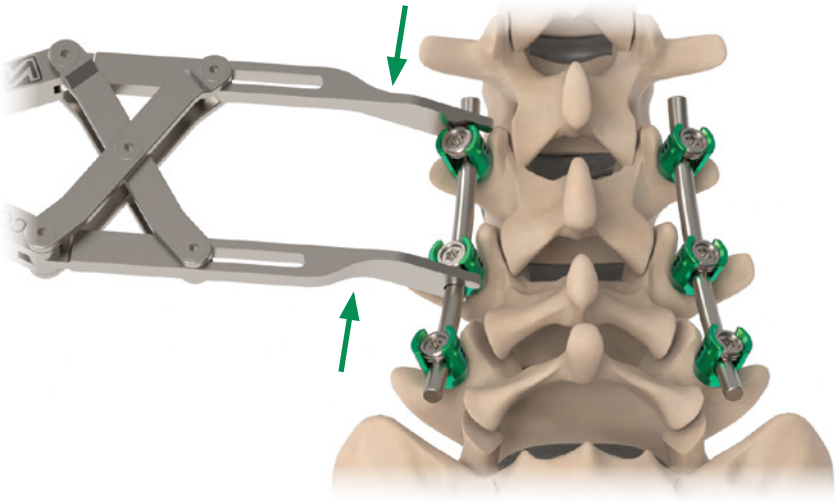


Figure 12.2
Compressor mounted on the outside of desired Housings

13. FINAL TIGHTENING

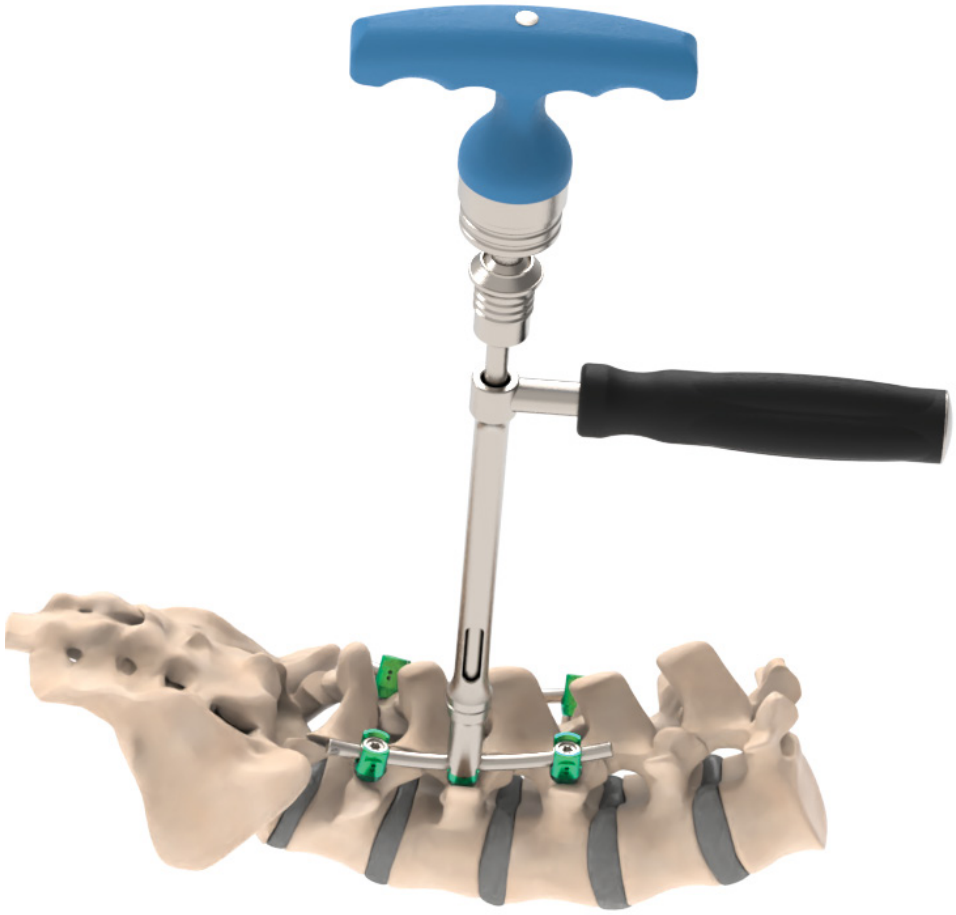


Figure 13.1
90 in-lbs Torque Limiting Handle assembled with Final Open Driver and Counter Torque

All Set Screws must be tightened to a torque of 90 in-lbs. to affect a secure construct.

Attach the 90 in-lbs. Torque Limiting Handle to the Final Open Driver (Figure 13.1). Slide the Counter-torque over the Housing until the instrument bottoms out and rests on the Rod. Insert the Final Open Driver through the Counter-torque and seat securely into the Set Screw. Turn the Torque Limiting Handle clockwise until the breakaway torque is reached. Final tightening is achieved when the Torque Limiting Handle audibly clicks. Repeat on each screw.

14. REVISION/REMOVAL

The INERTIA® CONNEXX™ Housing can be removed intraoperatively from the Shank if required using the Housing Removal Tool as seen on the next page.

1. Remove the Set Screw and Rod by loosening and removing all the Set Screws using the Final Open Driver (Figure 14.1). The Counter Torque wrench can be used to reduce load on the construct.

2. Once all the Set Screws have been removed, use a Rod Holder to grasp the Rod to extract (Figure 14.2).

3. Attach the appropriate Tulip Removal instrument to the appropriate Housing by placing the instrument's distal tip over the Housing (Figure 14.3).

NOTE: *If the entire construct is to be removed, the Final Open Driver can be utilized to remove the entire assembled implant.*

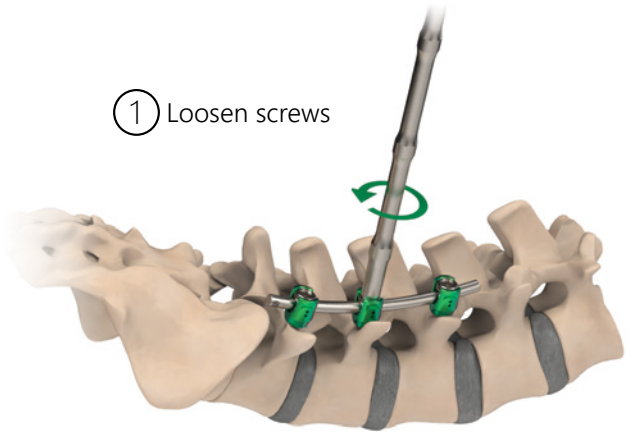


Figure 14.1
Removing Set Screws with Final Open Driver

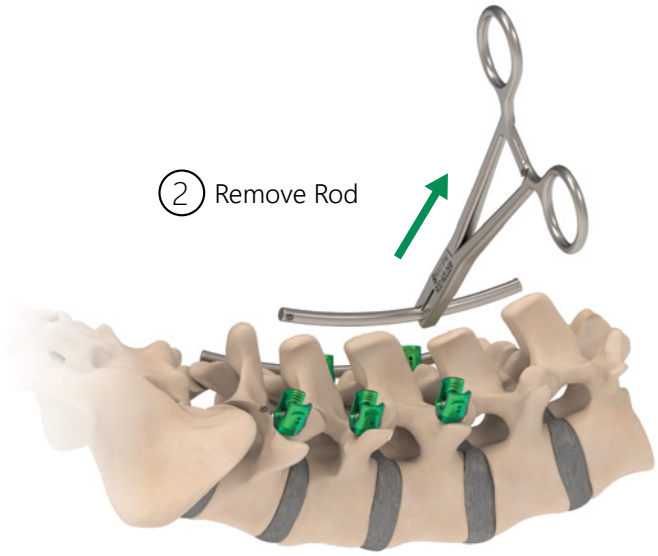


Figure 14.2
Removing Rods with Rod holder

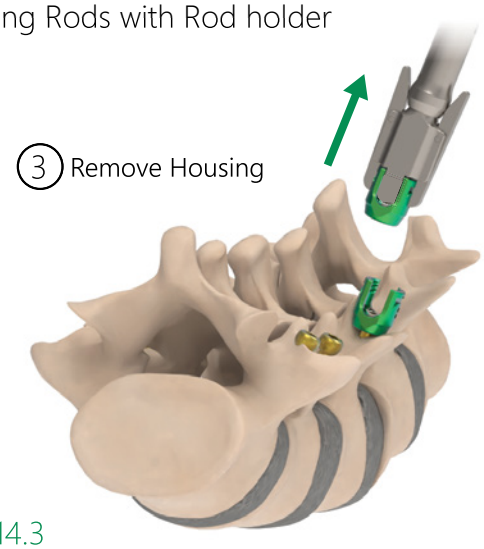


Figure 14.3
Removing Housing with Tulip Removal Tool

14. REVISION/REMOVAL (cont.)

NOTE: Ensure that the distal tip is fully seated and flush with the top of the Housing. The engagement pins on the distal jaws of the Housing Removal Tool should engage with the noted lower Housing apertures

1. Squeeze the handles of the instrument to engage the Housing.
2. Rotate the proximal knob on the instrument clockwise to disengage the Housing from the Shank.
3. Pull the instrument proximally to disassemble the Housing from the Shank.
4. Replace with appropriate Housing.

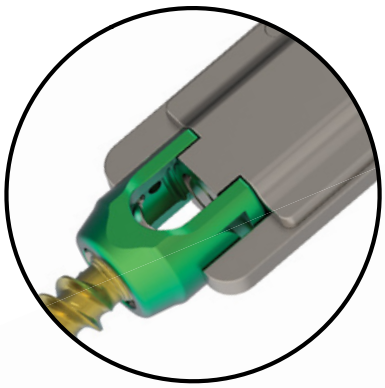


Figure 14.3b
Close up after instrument engaging

Figure 14.3a
Instructions on how to attach and use Housing Removal Tool

NOTE: *Housings are single use.*
After Housing removal, discard the Housing.

IMPLANT PART NUMBERS

Pre-Bent Rods

Standard P/N	Description
Ø5.5mm x XXXmm Pre-Bent Rod	
10-6-5525*	Ø5.5mm x 25mm
10-6-5530*	Ø5.5mm x 30mm
10-6-5535	Ø5.5mm x 35mm
10-6-5540	Ø5.5mm x 40mm
10-6-5545	Ø5.5mm x 45mm
10-6-5550	Ø5.5mm x 50mm
10-6-5555	Ø5.5mm x 55mm
10-6-5560	Ø5.5mm x 60mm
10-6-5565	Ø5.5mm x 65mm
10-6-5570	Ø5.5mm x 70mm
10-6-5575	Ø5.5mm x 75mm
10-6-5580	Ø5.5mm x 80mm
10-6-5585*	Ø5.5mm x 85mm
10-6-5590	Ø5.5mm x 90mm
10-6-5595*	Ø5.5mm x 95mm
10-6-55100	Ø5.5mm x 100mm
10-6-55105*	Ø5.5mm x 105mm
10-6-55110	Ø5.5mm x 110mm
10-6-55115*	Ø5.5mm x 115mm
10-6-55120*	Ø5.5mm x 120mm
10-6-55125*	Ø5.5mm x 125mm
10-6-55130*	Ø5.5mm x 130mm
10-6-55135*	Ø5.5mm x 135mm
10-6-55140*	Ø5.5mm x 140mm
10-6-55145*	Ø5.5mm x 145mm
10-6-55150*	Ø5.5mm x 150mm
10-6-55175*	Ø5.5mm x 175mm

Straight Rods

Standard P/N	Description
Ø5.5mm x XXXmm Straight Rod	
10-7-5525*	Ø5.5mm x 25mm
10-7-5530*	Ø5.5mm x 30mm
10-7-5535*	Ø5.5mm x 35mm
10-7-5540*	Ø5.5mm x 40mm
10-7-5545*	Ø5.5mm x 45mm
10-7-5550*	Ø5.5mm x 50mm
10-7-5555*	Ø5.5mm x 55mm
10-7-5560*	Ø5.5mm x 60mm
10-7-5565*	Ø5.5mm x 65mm
10-7-5570*	Ø5.5mm x 70mm
10-7-5575*	Ø5.5mm x 75mm
10-7-5580*	Ø5.5mm x 80mm
10-7-5585*	Ø5.5mm x 85mm
10-7-5590*	Ø5.5mm x 90mm
10-7-5595*	Ø5.5mm x 95mm
10-7-55100*	Ø5.5mm x 100mm
10-7-55105*	Ø5.5mm x 105mm
10-7-55110*	Ø5.5mm x 110mm
10-7-55115*	Ø5.5mm x 115mm
10-7-55120*	Ø5.5mm x 120mm
10-7-55125*	Ø5.5mm x 125mm
10-7-55130*	Ø5.5mm x 130mm
10-7-55135*	Ø5.5mm x 135mm
10-7-55140*	Ø5.5mm x 140mm
10-7-55145*	Ø5.5mm x 145mm
10-7-55150*	Ø5.5mm x 150mm
10-7-55175*	Ø5.5mm x 175mm
10-7-55200*	Ø5.5mm x 200mm
10-7-55250*	Ø5.5mm x 250mm
10-7-55300*	Ø5.5mm x 300mm
10-7-55350*	Ø5.5mm x 350mm
10-7-55400*	Ø5.5mm x 400mm
10-7-55500*	Ø5.5mm x 500mm
10-7-55600*	Ø5.5mm x 600mm

Set Screw

Standard P/N	Description
20-LC-01	Set Screw

Standard Housing

Standard P/N	Description
20-HS-01	Housing, Standard

Reduction Housing

Standard P/N	Description
20-HR-01*	Housing, Reduction

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

Green rows indicate Standard Order

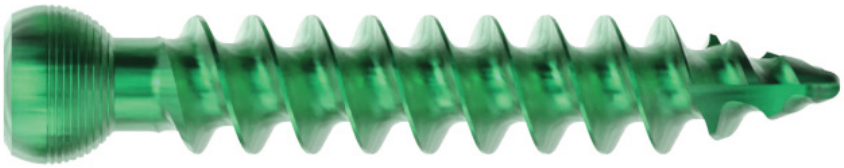
Solid Shanks

Standard P/N	Description
Ø5.5mm x XXmm Shanks	
20-SDS-5520*	Ø5.5mm x 20mm
20-SDS-5525*	Ø5.5mm x 25mm
20-SDS-5530	Ø5.5mm x 30mm
20-SDS-5535	Ø5.5mm x 35mm
20-SDS-5540	Ø5.5mm x 40mm
20-SDS-5545	Ø5.5mm x 45mm
20-SDS-5550	Ø5.5mm x 50mm
20-SDS-5555*	Ø5.5mm x 55mm
20-SDS-5560*	Ø5.5mm x 60mm
20-SDS-5565*	Ø5.5mm x 65mm
20-SDS-5570*	Ø5.5mm x 70mm
20-SDS-5575*	Ø5.5mm x 75mm
20-SDS-5580*	Ø5.5mm x 80mm

Standard P/N	Description
Ø6.5mm x XXmm Shanks	
20-SDS-6520*	Ø6.5mm x 20mm
20-SDS-6525*	Ø6.5mm x 25mm
20-SDS-6530*	Ø6.5mm x 30mm
20-SDS-6535	Ø6.5mm x 35mm
20-SDS-6540	Ø6.5mm x 40mm
20-SDS-6545	Ø6.5mm x 45mm
20-SDS-6550	Ø6.5mm x 50mm
20-SDS-6555	Ø6.5mm x 55mm
20-SDS-6560*	Ø6.5mm x 60mm
20-SDS-6565*	Ø6.5mm x 65mm
20-SDS-6570*	Ø6.5mm x 70mm
20-SDS-6575*	Ø6.5mm x 75mm
20-SDS-6580*	Ø6.5mm x 80mm
20-SDS-6585*	Ø6.5mm x 85mm
20-SDS-6590*	Ø6.5mm x 90mm
20-SDS-6595*	Ø6.5mm x 95mm
20-SDS-65100*	Ø6.5mm x 100mm

Standard P/N	Description
Ø7.5mm x XXmm Shanks	
20-SDS-7520*	Ø7.5mm x 20mm
20-SDS-7525*	Ø7.5mm x 25mm
20-SDS-7530*	Ø7.5mm x 30mm
20-SDS-7535	Ø7.5mm x 35mm
20-SDS-7540	Ø7.5mm x 40mm
20-SDS-7545	Ø7.5mm x 45mm
20-SDS-7550	Ø7.5mm x 50mm
20-SDS-7555	Ø7.5mm x 55mm
20-SDS-7560*	Ø7.5mm x 60mm
20-SDS-7565*	Ø7.5mm x 65mm
20-SDS-7570*	Ø7.5mm x 70mm
20-SDS-7575*	Ø7.5mm x 75mm
20-SDS-7580*	Ø7.5mm x 80mm
20-SDS-7585*	Ø7.5mm x 85mm
20-SDS-7590*	Ø7.5mm x 90mm
20-SDS-7595*	Ø7.5mm x 95mm
20-SDS-75100*	Ø7.5mm x 100mm

Standard P/N	Description
Ø4.5mm-11.5mm x XXmm Solid Shanks	
20-SDS-4520:80*	Ø4.5mm x 20:80mm
20-SDS-5020:80*	Ø5.0mm x 20:80mm
20-SDS-5520:80*	Ø5.5mm x 20:80mm
20-SDS-6020:80*	Ø6.0mm x 20:80mm
20-SDS-6520:100*	Ø6.5mm x 20:100mm
20-SDS-7020:100*	Ø7.0mm x 20:100mm
20-SDS-7520:100*	Ø7.5mm x 20:100mm
20-SDS-8530:120*	Ø8.5mm x 30:120mm
20-SDS-9540:120*	Ø9.5mm x 40:120mm
20-SDS-10540:120*	Ø10.5mm x 40:120mm
20-SDS-11540:120*	Ø11.5mm x 40:120mm

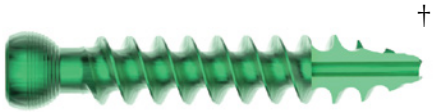


Special Order Shanks

Standard P/N	Description
Solid Corticocancellous Shanks	
20-SDC-4525:80*	Ø4.5mm x 25:80mm
20-SDC-5025:80*	Ø5.0mm x 25:80mm
20-SDC-5525:80*	Ø5.5mm x 25:80mm
20-SDC-6025:80*	Ø6.0mm x 25:80mm
20-SDC-6525:100*	Ø6.5mm x 25:100mm
20-SDC-7025:100*	Ø7.0mm x 25:100mm
20-SDC-7525:100*	Ø7.5mm x 25:100mm
20-SDC-8540:120*	Ø8.5mm x 40:120mm

Standard P/N	Description
Cannulated Shanks	
20-SCS-5020:80*	Ø5.0mm x 20:80mm
20-SCS-5520:80*	Ø5.5mm x 20:80mm
20-SCS-6020:80*	Ø6.0mm x 20:80mm
20-SCS-6520:100*	Ø6.5mm x 20:100mm
20-SCS-7020:100*	Ø7.0mm x 20:100mm
20-SCS-7520:100*	Ø7.5mm x 20:100mm
20-SCS-8540:120*	Ø8.5mm x 40:120mm

Standard P/N	Description
Cannulated Corticocancellous Shanks	
20-SCC-5025:80*	Ø5.0mm x 25:80mm
20-SCC-5525:80*	Ø5.5mm x 25:80mm
20-SCC-6025:80*	Ø6.0mm x 25:80mm
20-SCC-6525:100*	Ø6.5mm x 25:100mm
20-SCC-7025:100*	Ø7.0mm x 25:100mm
20-SCC-7525:100*	Ø7.5mm x 25:100mm
20-SCC-8540:120*	Ø8.5mm x 40:120mm

† 

† 

† Shanks shown in partial cross section to illustrate cannula

INSTRUMENT PART NUMBERS

Tactile Set Screw Inserter

Standard P/N	Description
I20-10-13	Tactile Set Screw Inserter
I20-10-12*	Dual End Set Screw Inserter

Inline Reducer

Standard P/N	Description
I20-10-05	Inline Reducer
I20-10-08*	Pistol Grip Reducer

Open Decorticating Tool

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

9mm Awl

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

Housing Assembly Tool

Standard P/N	Description
I20-16-08	Housing Assembly Tool

Rod Holder

Standard P/N	Description
I10-08-06	Rod Holder

Shank Inserter

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

Alignment Tube

Standard P/N	Description
I20-12-03	Alignment Tube

Rod Bender

Standard P/N	Description
I10-30-15	Rod Bender

Housing Inserters

Standard P/N	Description
I20-08-10	Housing Inserter
I20-08-11*	Housing Inserter, Reduction

Screw Inserter

Standard P/N	Description
I20-08-05	Screw Inserter
I20-08-07*	Screw Inserter, Reduction

Final Driver

Standard P/N	Description
I20-10-11*	Final Driver Long
I20-10-15	Final Driver

Pear Handle 1/4" Square

Standard P/N	Description
I10-14-37	Quick 1/4" SQ Pear

90LB Square Handle

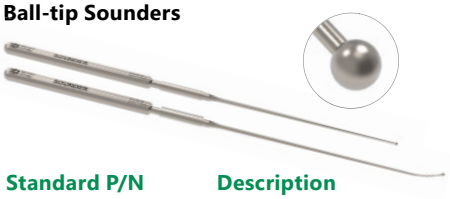
Standard P/N	Description
I10-01-11	Torque Limiting, 90lb, 1/4" Square

Ratcheting T-Handle

Standard P/N	Description
I10-01-77	Cannulated Ratcheting T-Handle, 1/4" Square

INSTRUMENT PART NUMBERS (cont)

Ball-tip Sounders



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

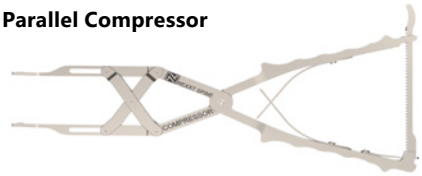
In-Situ Rod Benders

Standard P/N	Description
I10-30-05L	Rod Bender Left
I10-30-05R	Rod Bender Right

Universal T Handle

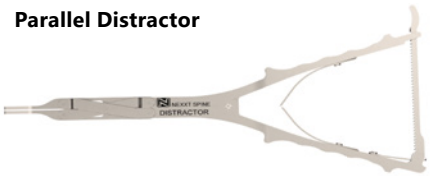
Standard P/N	Description
I20-10-07*	Universal T-Handle

Parallel Compressor



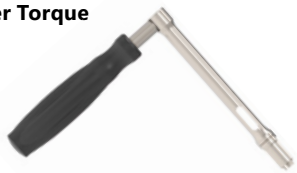
Standard P/N	Description
I10-11-04	Titanium Compressor

Parallel Distractor



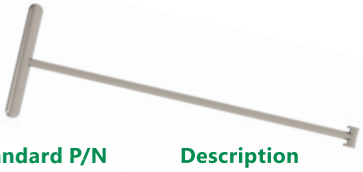
Standard P/N	Description
I10-10-04	Titanium Distractor

Counter Torque



Standard P/N	Description
I20-12-04	Counter Torque

Inertia Head Positioner



Standard P/N	Description
I10-02-20	Head Positioner

Rod Rocker

Standard P/N	Description
I20-10-04	Rod Rocker

Tulip Removal Tool

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

Double-Lead 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	Ø7.5mm Tap
I20-05-XX*	Ø4.0-11.5mm Tap

Lenke Probes

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

Reduction Tab Breaker

Standard P/N	Description
I20-12-20*	Reduction Tab Breaker

COMPATIBLE NEXXT MATRIXX® SYSTEMS

Lateral + STRUXXURE® L

ALIF + STRUXXURE® A

SA ALIF

Corpectomy

TLIF

TLIF Oblique

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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.