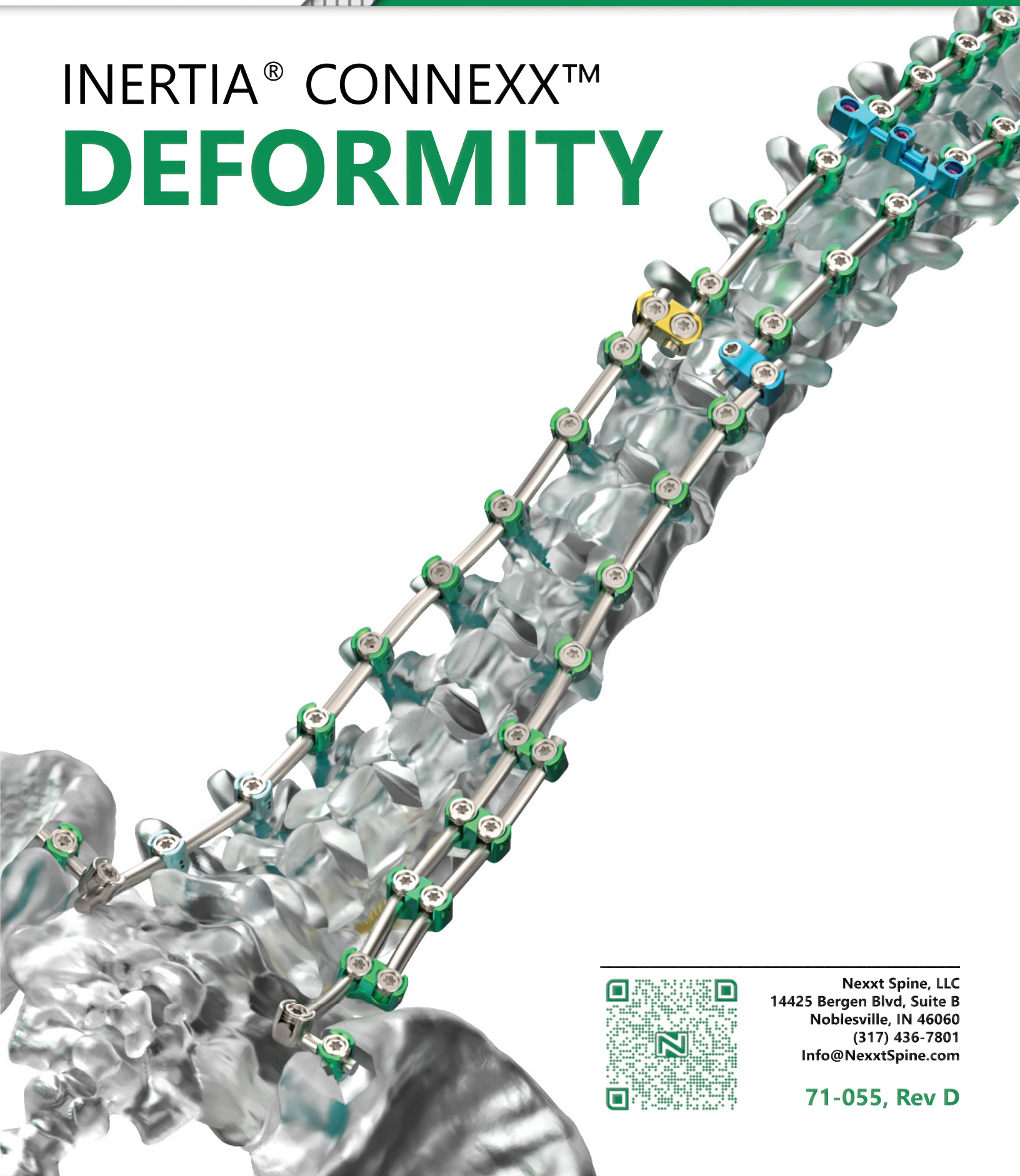
Nexxt Spine

Surgical Technique Guide

INERTIA® CONNEXX™
DEFORMITY



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71-055, Rev D

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INERTIA® CONNEXX™ MODULAR PEDICLE SCREW SYSTEM

The INERTIA® CONNEXX™ 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.

INERTIA® CONNEXX™ enhances efficiency and visibility of the operative site with its modular platform, dual rod diameter capabilities to tailor construct stiffness and provide variable solutions for deformity correction, while providing the surgeon multiple head geometries which can be placed and modified in-situ.

INERTIA® CONNEXX™ has been designed and evolved from valuable feedback from our surgeon development team. Nexxt Spine would like to take the opportunity to thank them for their contributions and efforts to make the INERTIA® CONNEXX™ 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

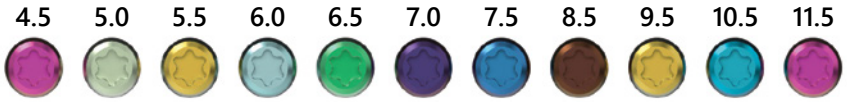
Uniplanar Screws - Ti-6Al-4V ELI per ASTM F136

Reduction

Standard

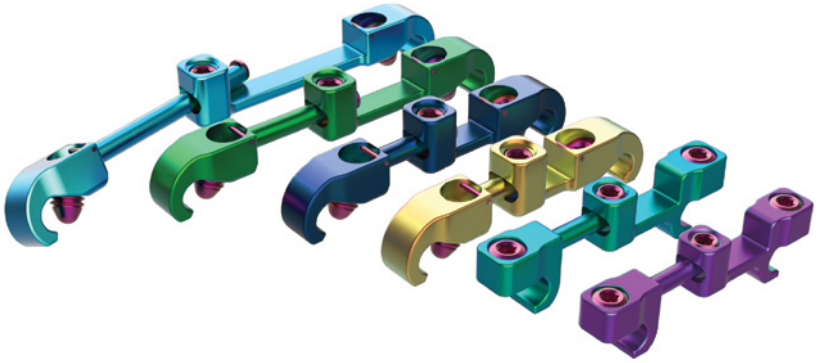
T25 Drive

Ømm Screw by Color



- 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 instruments needed.

CrossLynxx Connectors - Ti-6Al-4V ELI per ASTM F136

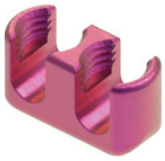


T15 Drive

- Various sizing options to accommodate 23-94mm spans.
- Two-axis flexibility to match patient anatomy.

Rod to Rod Connectors - Ti-6Al-4V ELI per ASTM F136

Single Open Wedding Band



Double Open Wedding Band

Top-Side Load Wedding Band

T25 Drive

Double Closed Wedding Band

Double Closed Domino

Inline 2 Screw

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

T25 Drive

- "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.

Bypass and Z-Rods- Ti-6Al-4V ELI per ASTM F136

T25 Drive

- Monolithic options to strengthen single or multi-rod constructs.
- Ø5.5mm rods compatible with all Housings

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™ Minimally Invasive Modular Pedicle Screw System.

1. UNIPLANAR SCREWS

The Inertia® Connexx Uniplanar and Reduction Uniplanar Screws are designed to provide rotational freedom in the cephalad/caudal plane, but remain fixed in the medial/lateral plane in a preassembled format (Figure 1.1). The movement in the cephalad/caudal plane facilitates easier Rod seating. Prohibiting movement in the medial/lateral plane facilitates direct vertebral rotation, which ultimately helps achieve three dimensional correction of the spine.

Figure 1.1

To insert Uniplanar and Reduction Uniplanar Screws, follow procedure thoroughly detailed in Figure 5.4 of the INERTIA® CONNEXX™ OPEN Surgical Technique Guide (71-050).

NOTE: *Uniplanar and Reduction Uniplanar Screws are compatible with all Inertia® Connexx™ preassembled screw Instrumentation (Figure 1.2).*

Figure 1.2

2. ILIAC SCREW PLACEMENT

The Inertia® Connexx™ System provides a variety of connection options that cater to spinal deformities including neuromuscular or idiopathic scoliosis with pelvic obliquity, or when additional load sharing is needed at the lumbosacral junction.

The iliac crest and posterior superior iliac spine are exposed with the surgeon's preferred method. Care should be taken to expose enough of the iliac crest to allow a proper trajectory of the Modular Shank and ensure the iliac cortex is not compromised during placement of the Modular Shank. It is recommended to notch the iliac crest sufficiently enough around the Modular Shank to recess it to a level reducing or eliminating Modular Housing prominence as much as possible.

1. Use the Iliac Probe to create a pilot hole, aiming for the thick bone approximately 2.5cm above the greater sciatic notch (Figure 2.1). The probe can be used to start the Modular Shank path but does not need to extend the entire length of the chosen Modular Shank. Inspect the pilot hole for cortical wall violations using the Pedicle Sounder.

2. (Optional) Tap the pilot hole using the markings on the shaft of the Tap and fluoroscopy to monitor depth. Re-inspect the pilot hole for perforations.

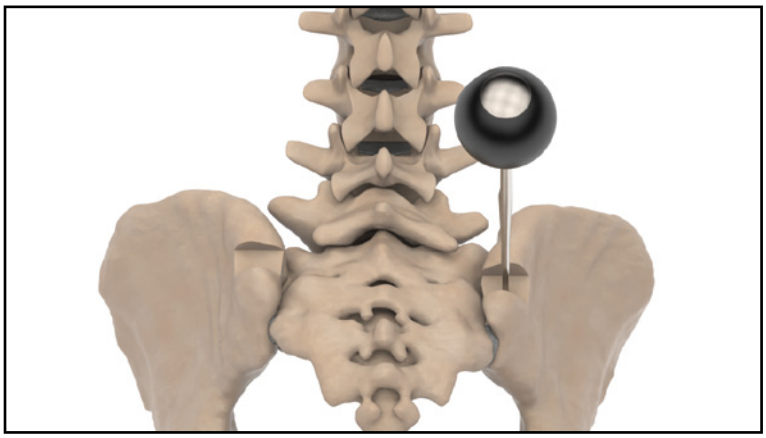


Figure 2.1

NOTE: *Inertia® Connexx Modular Shanks are self-tapping and do not require the use of a tap to facilitate screw insertion.*

2. ILIAC SCREW PLACEMENT (CONT.)

NOTE: *Taps are NOT undersized. They are labeled identical in size to the corresponding screw diameter.*

3. With the ilium prepared, select the preferred diameter of Modular Shank in the appropriate size using the length markings on the Iliac Probe.

4. Insert the Modular Shank into the pilot hole and advance until the desired depth is reached (Figure 2.2). If Modular Shank adjustment is needed, use the Final Driver to adjust screw depth.

5. Complete assembly of the Modular Housing per the Inertia® CONNEXX™ Open Surgical Technique guide (Figure 2.3).

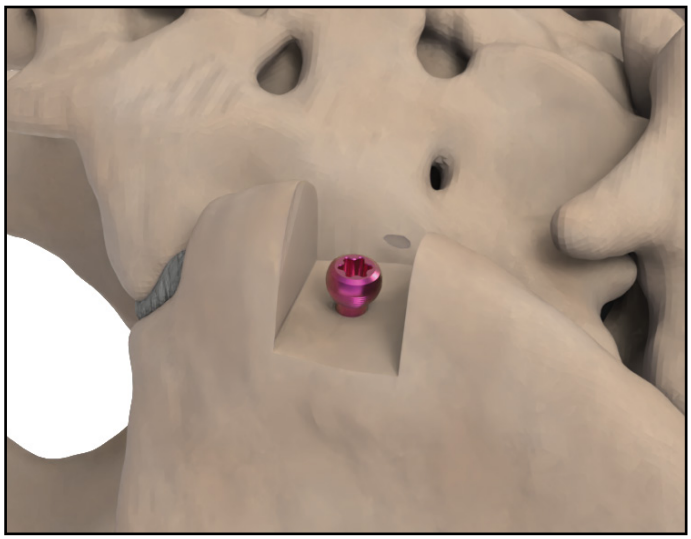


Figure 2.2

Figure 2.3

3. OFFSET CONNECTORS

The Inertia® Connexx™ System Offset Connectors are available in lengths from 25-45mm in 5mm increments. A 60mm connector is provided and may be cut to the desired length by the surgeon prior to implantation (Figure 3.1).

Offset Connectors allow medial / lateral variability in connecting screws to the rod. This is useful when the rod does not line up with the implant.

Use of the Offset Connectors for fixation to the ilium is contraindicated when the sacrum is absent or insufficient for implantation of pedicle screws at the S1 or S2 spinal level.

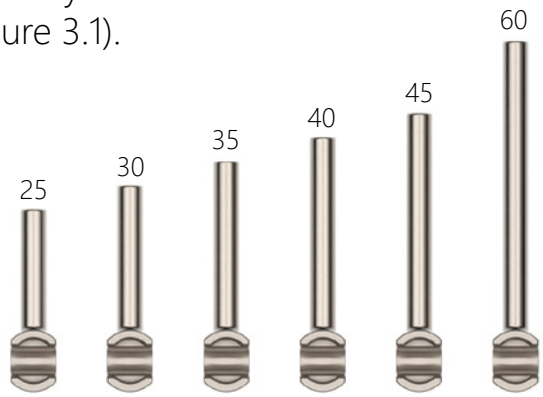


Figure 3.1 - Lengths (mm)

1. The Modular Housing is rotated 90° to accommodate the Offset Connector.

2. The Offset Connector is preloaded onto the rod in the appropriate orientation prior to placement of the adjoining rod into the Modular Housing. Care must be taken to ensure that at least 1.0mm of the Offset Connector rod is extending out of the lateral side of the Modular Housing (Figure 3.2).

3. The Set Screw is then provisionally tightened using the Dual End Set Screw or Tactile Inserter. The final tightening sequence should be completed using the Inertia® Connexx™ Open Degen Surgical Technique (Figure 3.3).

NOTE: *Rod cutters are available by request only.*

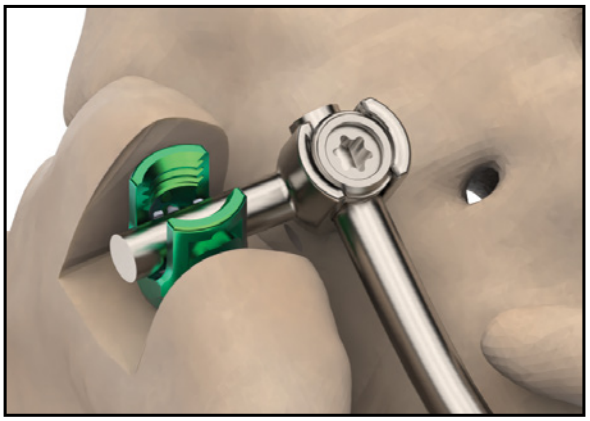


Figure 3.2

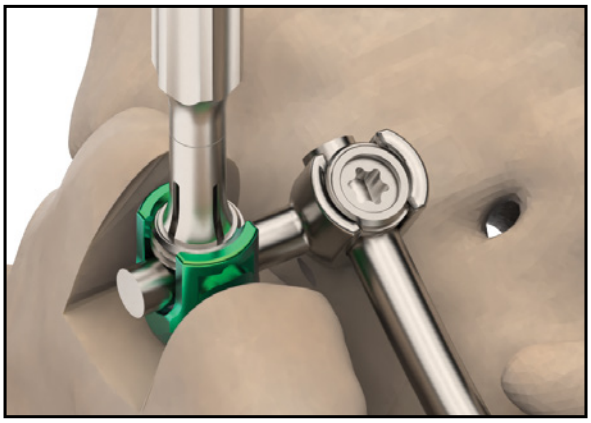


Figure 3.3

4. ALAR-ILIAC (S2A1) SCREW PLACEMENT

The Inertia® Connexx™ System provides implants and instrumentation for S2 Alar-Iliac (S2AI) Modular Shank placement if the surgeon prefers this method of fixation over traditional Iliac Screws.

Place pedicle and S1 screws prior to placement of the Inertia® Connexx™ S2AI Modular Shank. The S1 screw and starting point of the Inertia® Connexx™ Modular Shank should be inline.

Prior to preparing the bone for the Modular Shank, the surgeon should obtain distinct fluoroscopy images. Angle the fluoroscopy unit so that it is perpendicular to the sacrum to find the S1 and S2 dorsal foramina and the starting point. The starting point of the S2AI screw is located at the midpoint between the S1 and S2 foramen and 2 mm medial to the lateral sacral crest (Figure 4.1).

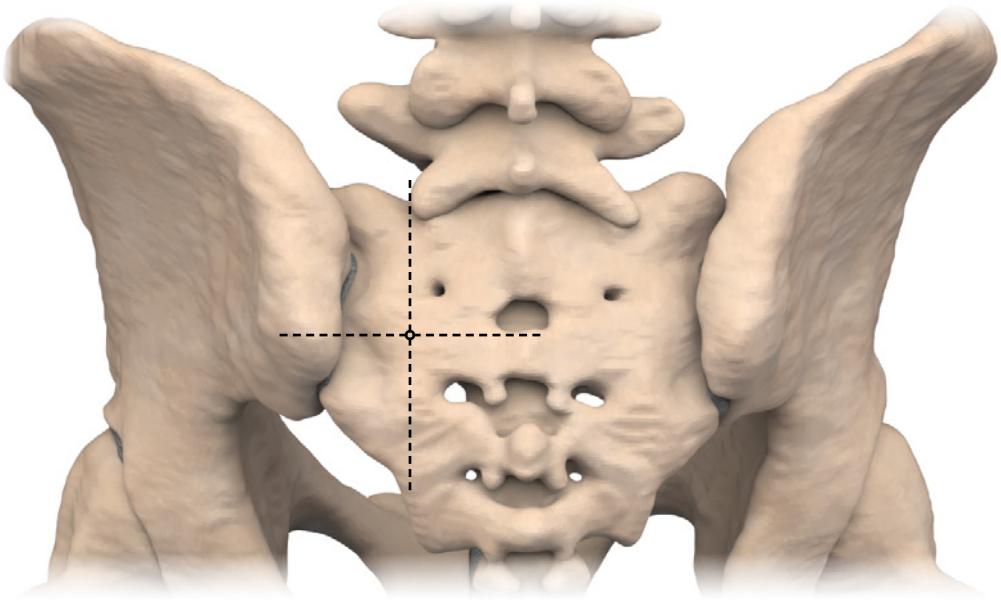


Figure 4.1

1. Use a Pedicle Probe to penetrate the cortex at the starting point, then angle the Pedicle Probe towards the anterior inferior iliac spine (AIIS) (Figure 4.2). Palpating the greater trochanter can be a useful landmark.

NOTE: *Pedicle Probes should be pointed dorsally to avoid penetration of the anterior sacrum.*

4. ALAR-ILIAC (S2A1) SCREW PLACEMENT (CONT.)

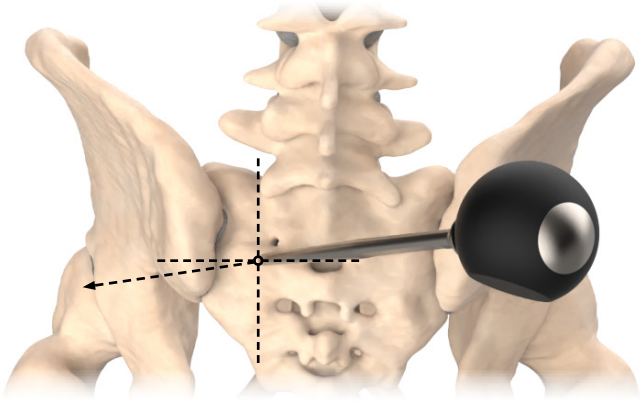


Figure 4.2

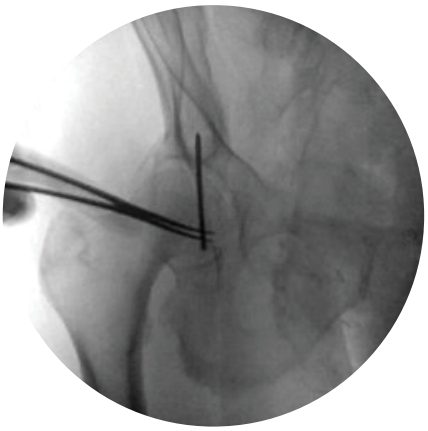


Figure 4.3

2. Advance the Pedicle Probe from the starting point described above into the sacral alar. Next, take a fluoroscopic image to confirm that the trajectory is within the "teardrop" (Figure 4.3). The image of a teardrop is produced by an overlap of the anterior inferior iliac spine and posterior superior iliac spine.

The C-Arm angle can vary by patient, see Figure 4.4 and 4.5 for imaging guidance.

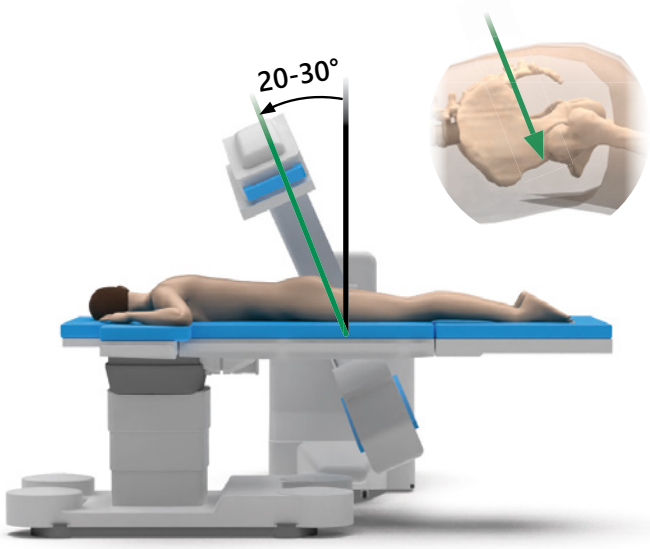


Figure 4.4

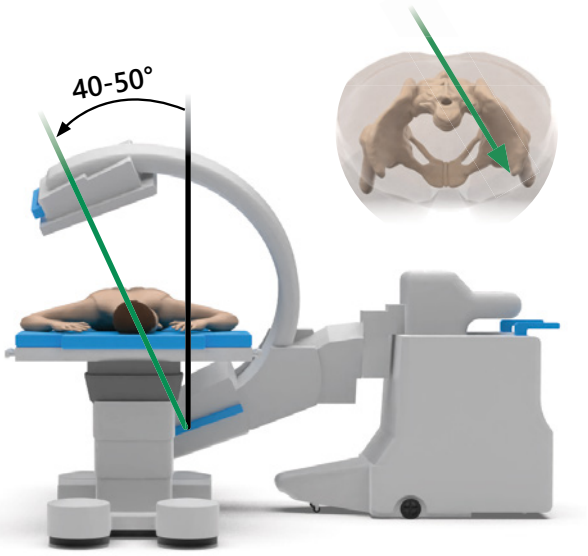


Figure 4.5

4. ALAR-ILIAC (S2A1) SCREW PLACEMENT (CONT.)

3. Pedicle Probe is advanced from the desired starting point toward the sacroiliac joint directing approximately 20° angulation caudally in the sagittal plane and 30° angulation horizontally in the coronal plane connecting the posterior superior iliac spine (PSIS). After inserting the Pedicle Probe approximately 3–4 cm until reaching the SI joint.

4. Advance the Pedicle Probe by lightly malleting the Pedicle Probe with the mallet until it passes through the cortical wall of the SI joint (Figure 4.6) Continue insertion of the Pedicle Probe through the cancellous channel of the ilium heading above the superior rim of the sciatic notch. Length of the Modular Shank can be determined by depth markings on the side of the Iliac Probe.

5. A Pedicle Sounder should be used to palpate the 5 bony borders ensuring that the screw would be located intraosseously.

6. It is imperative that the surgeon document Pedicle Probe positioning via fluoroscopy. On the lateral and coronal image, the S2AI screws should be placed above the superior rim of the sciatic notch (Figure 4.7). The ideal trajectory of the S2AI Modular Shank is situated immediately above the notch so that the bottom threads of the screw will be in contact with the cortical bone forming the upper limit of the notch, providing a better pull-out strength

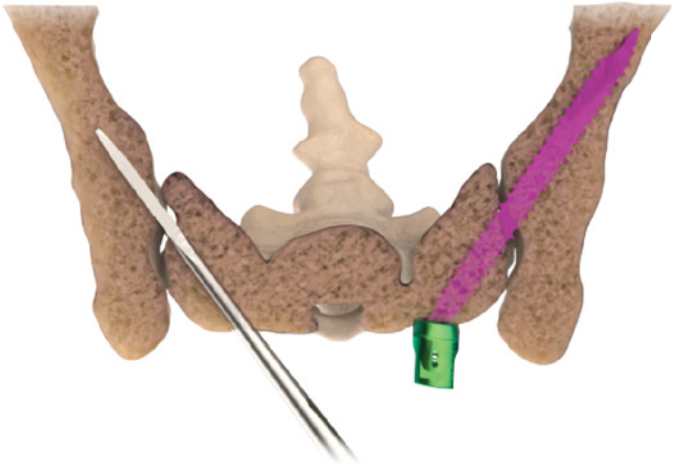


Figure 4.6

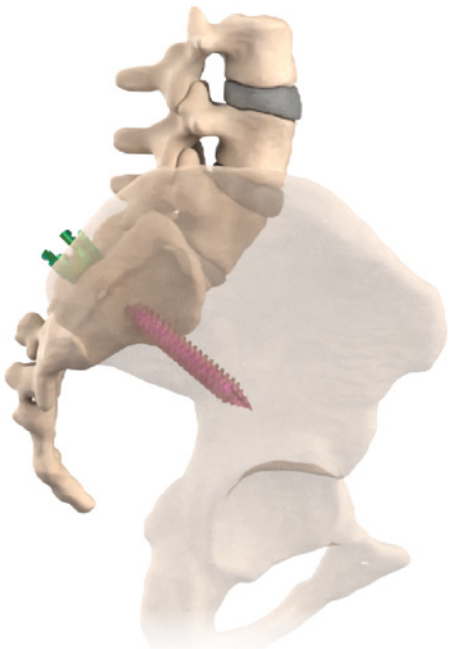


Figure 4.7

5. CROSSLYNXX TRANSVERSE CONNECTORS

INERTIA® CONNEXX™ CrossLynxx Connectors are designed to transversely connect two rods upon the completion of posterior spinal instrumentation constructs. Cross connectors increase the torsional stability of posterior constructs to aid in spinal fusion. In long constructs, the CrossLynxx Connectors should be placed on the upper one-third of the construct and an additional implant in the lower one-third of the construct.

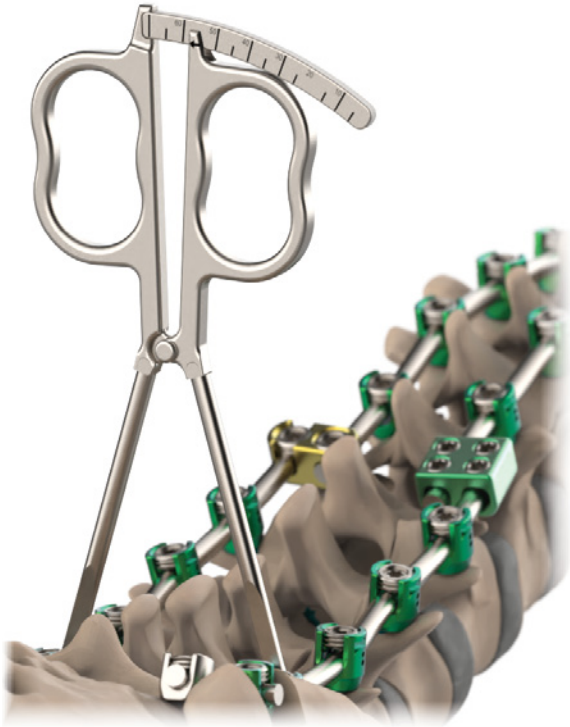


Figure 5.1

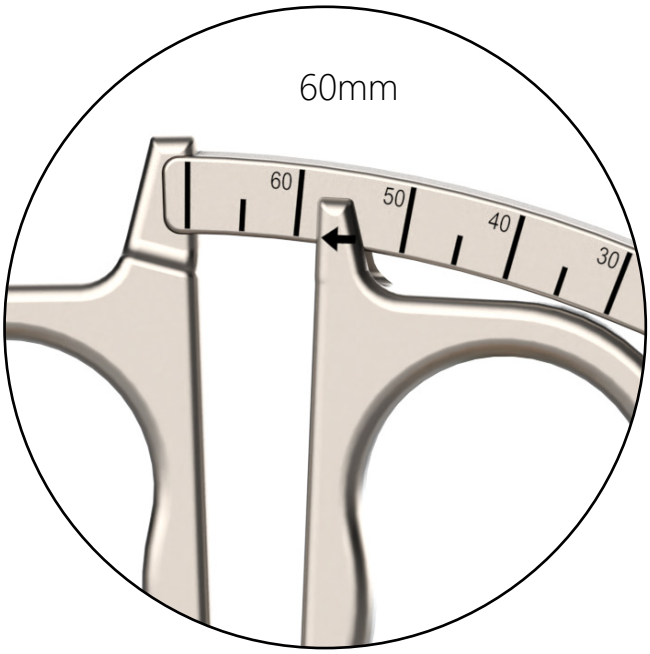


Figure 5.2

1. To determine the appropriate length CrossLynxx Connector, utilize the Crosslynxx Measuring Caliper by placing the distal tips of the instrument on the left and right Spinal Rods at the appropriate levels (Figure 5.1). Care should be taken to ensure that the available exposed rod provides enough spacing for the width of the implant.

NOTE: *If the measurement indicated is at the transition between two sizes, it is recommended to choose the larger of the two sizes (Figure 5.2).*

NOTE: *If implant contouring is necessary to accommodate non-parallel, non-planar rods, or increased clearance, proceed to next step. If no contouring is needed, proceed to Step 3 for the Crosslynxx Transverse Connector.*

5. CROSSLYNXX TRANSVERSE CONNECTORS (CONT.)

2. To contour the CrossLynxx Cross Connector, place the female end of the implant into the end of the CrossLynxx Bender as shown. Only the female side of the connector is placed into the bender (Figure 5.3). The other bender fits over the middle segment of the implant.

NOTE: *Use only the benders included in the Inertia CrossLynxx set to prevent damage to the implant during contouring.*

NOTE: *The 23-29mm and 29-39mm CrossLynxx connectors have unique benders, labeled "SHORT X-LINK BENDER LEFT" and "SHORT X-LINK BENDER RIGHT" (Figure 5.4).*

NOTE: *It is not recommended to bend or twist more than 20° in any direction.*

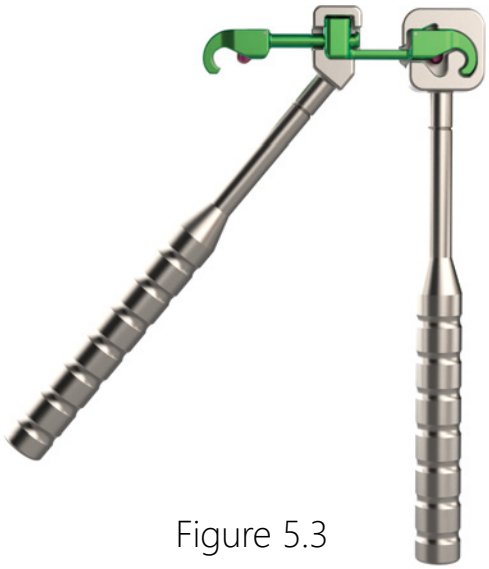


Figure 5.3

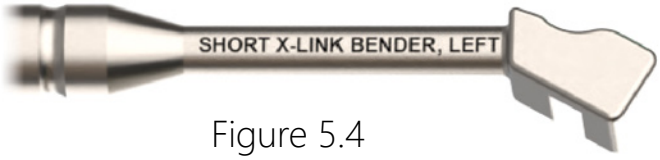


Figure 5.4

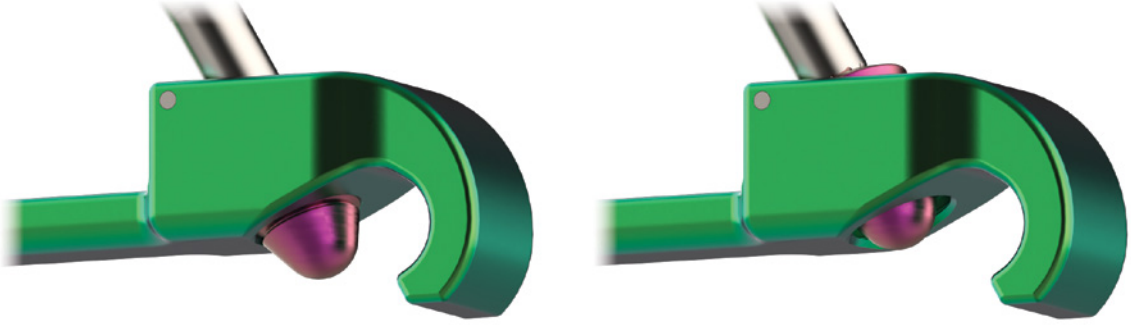


Figure 5.5

3. Connect the Torque Limiting 40 in-lb. Handle to the CrossLynxx Driver shaft. The rod set screws must be backed out with the CrossLynxx Driver such that they do not obstruct placement of the connector on rod (Figure 5.5).

5. CROSSLYNXX TRANSVERSE CONNECTORS (CONT.)

4. Place the connector flush on the Rods and provisionally tighten the Set Screws and midline Screw.

5. Once the correct position of the connector is established on the rods, perform final tightening on both sets screws and midline screw using the same Torque Limiting 40 in-lb. Handle and CrossLynxx Driver. Tighten by turning the handle clockwise until it clicks (Figure 5.6).

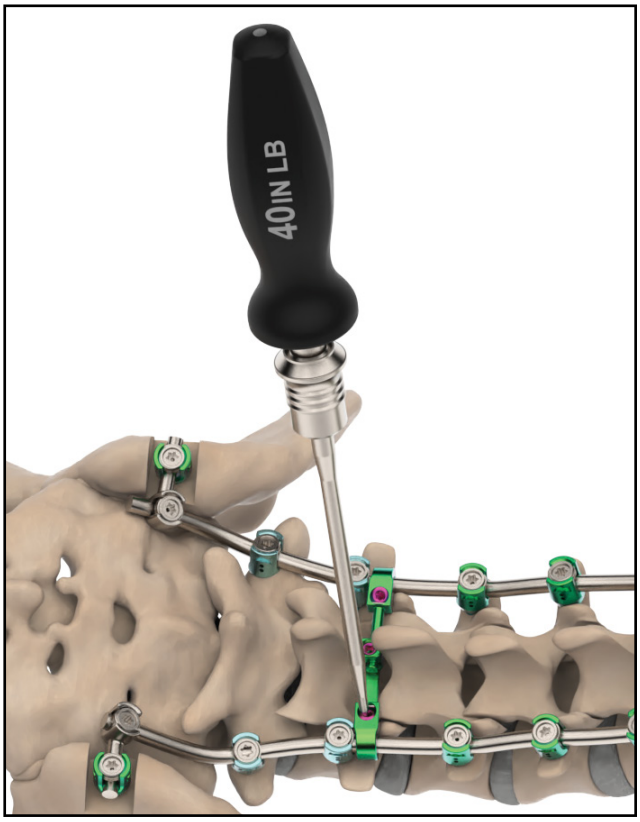


Figure 5.6

6. To remove the Inertia® CrossLynxx Connector, insert the CrossLynxx Driver into the midline screw and rotate counterclockwise. Repeat for the set screws on the rods. Remove the connector by hand or with forceps (Figure 5.7).

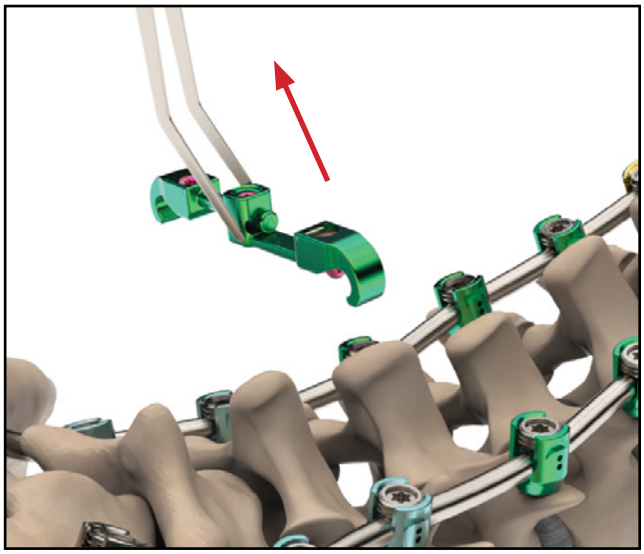


Figure 5.7

6. 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 surgical steps in the INERTIA® CONNEXX™ OPEN Surgical Technique Guide (71-050) STEPS 4 and 5 for placement of the housing. 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 6.2).

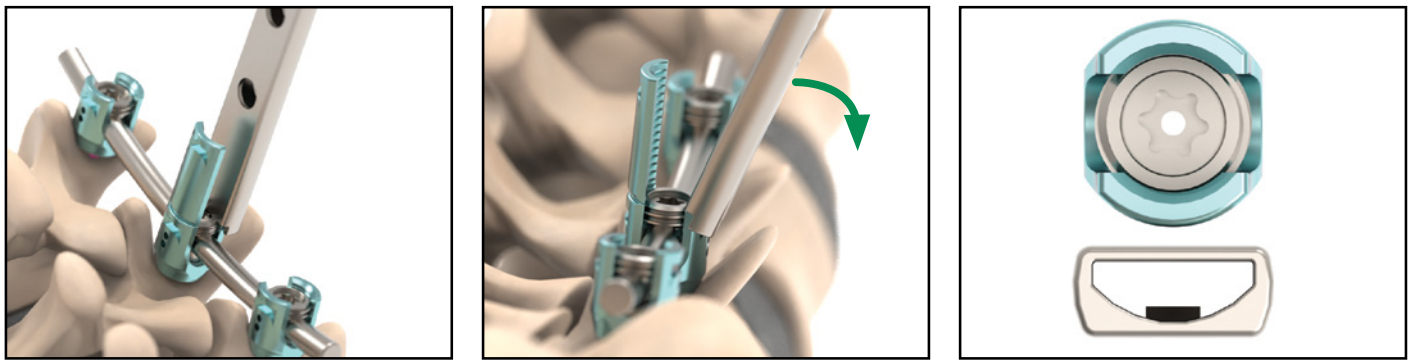


Figure 6.2
Steps and alignment for the Reduction Tab Breaker

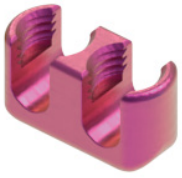
7. ROD TO ROD CONNECTORS

INERTIA® CONNEXX™ Rod to Rod Connectors will accept rod diameters ranging from 5.5mm up to 6.0mm.

Eight distinct designs are available to accommodate alignment and anatomical requirements, as well as access to existing rod length during revision or adjacent segment disease procedures.

Bypass Rods (L/R)

Single Open Wedding Band



Double Open Wedding Band

Side Load Wedding Band

Double Closed Wedding Band

Double Closed Domino

Inline 2 Screw

7. ROD TO ROD CONNECTORS (CONT.)

The following surgical technique demonstrates the assembly of the Rod to Rod Connectors.

1. Slide the rod to rod connector to the desired position on the rod and provisionally tighten the Set Screws with the Tactile Set Screw Inserter (Figure 7.1).

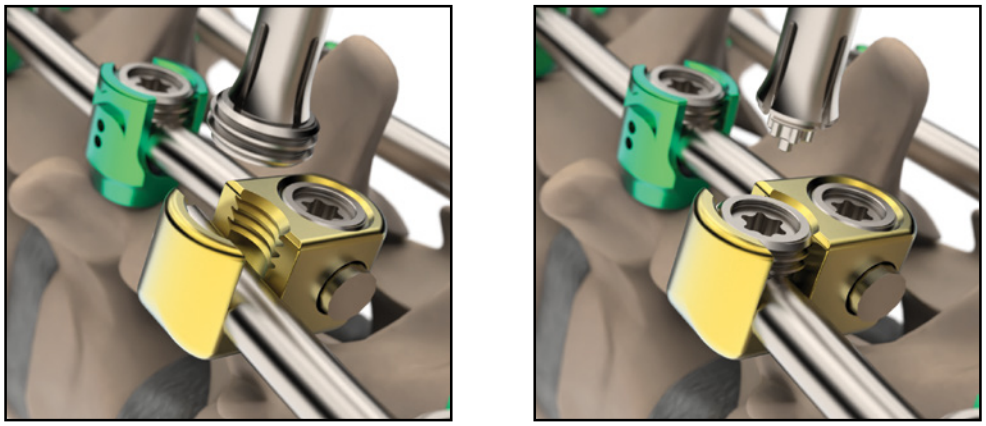


Figure 7.1

2. Perform final tightening by attaching the Final Driver to the same 90 in-lb Torque Limiting Handle utilized for the Set Screws and rotate clockwise until an audible "click" is heard and tension is released within the handle (Figure 7.2).

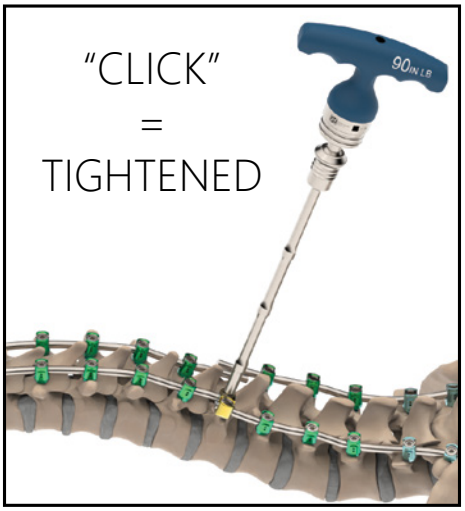


Figure 7.2

8. BYPASS AND OFFSET Z RODS

The following surgical technique demonstrates the assembly of the Bypass and Offset Z rods. Rod extensions are provided to avoid the need to remove old instrumentation during revision or adjacent segment procedures.

Prior to utilizing the Bypass or Offset Z Rod, ensure the Rod distance between the heads of the original procedure will allow for the attaching geometry of the Bypass Rod.

1. Determine the desired location for the rod to rod connector, and remove any fusion mass at that site with the osteotome or high speed burr.

2. Measure desired rod length of the Bypass Rod and utilize the appropriate length implant or utilize Rod Cutter and modify length.

3. Rod contouring can be accomplished prior to final tightening of the construct.

4. Slightly loosen the Set Screw in the Bypass Rod, or Rod to Rod connector, by inserting the Final Driver and rotating counterclockwise. The Set Screws are loose when the spinal rods slide easily into the connector (Figure 8.1).

5. Slide the Bypass or Offset Z Rod to the desired position on the rod and provisionally tighten the Set Screws with the Final Driver (Figure 8.2).

6. Perform final tightening by attaching the Final Driver to the same Torque Limiting Handle utilized for the Set Screws and rotate clockwise until an audible "click" is heard and tension is released within the handle (Figure 8.3).

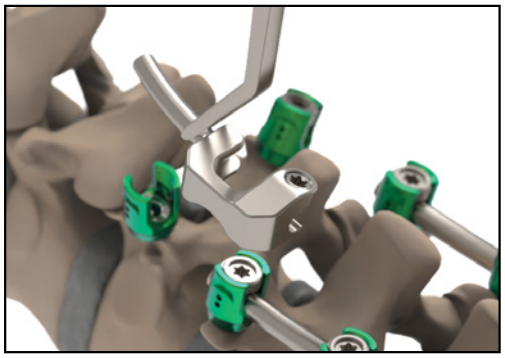


Figure 8.1

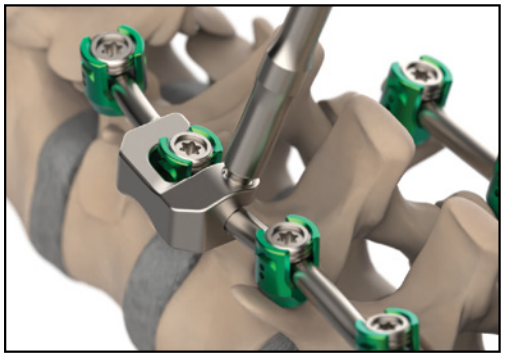


Figure 8.2

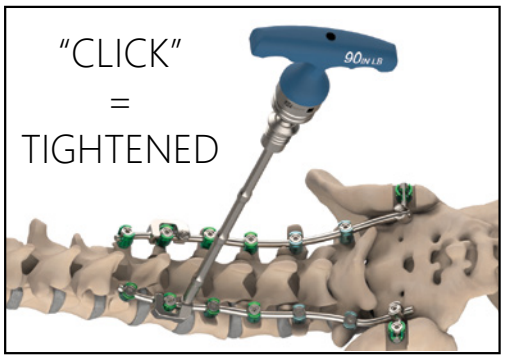


Figure 8.3

9. SECONDARY ROD CONSTRUCTS

The surgeon should ensure that all implant options are available and that preoperative resection or deformity planning has been determined. The Modular Dual Rod Housing allows the surgeon to place additional rods for three and four-rod constructs.

For Modular Shank placement and technique, please refer to the INERTIA® CONNEXX™ Open Surgical Technique. Modular Shanks provide the surgeon with visual confirmation of stabilizing bone when advanced boney resection is required for deformity correction.

After placement of the Shank, utilize the appropriate Housing Inserter to facilitate the introduction and connection of 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 end of the Housing Inserter into the threads of the Modular Dual Rod Housing side, noted by the internal locking feature to the Modular Shank (Figure 9.1).

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

NOTE: *Preassembly of the Dual Rod Housing and Shank before placement may cause the elongated geometry of the Dual Rod Housing to impact the medial anatomy. If this occurs, the Final Driver can be used for the assembled construct.*

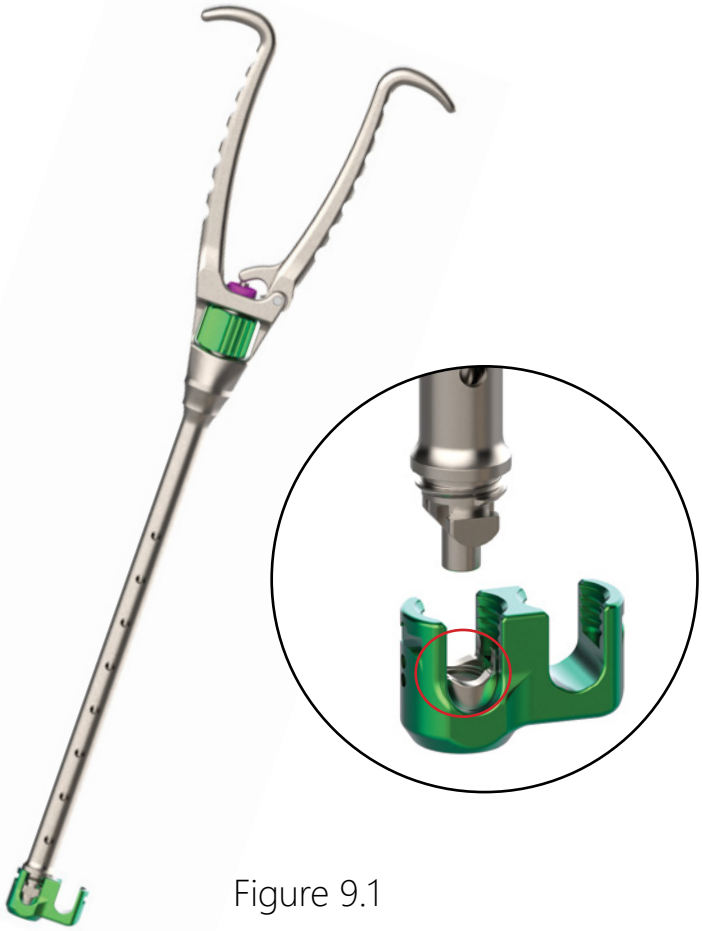


Figure 9.1

9. SECONDARY ROD CONSTRUCTS (CONT.)

2. Slide the Dual Rod Housing onto the Shank by applying a downward force to connect the two components (Figure 9.2). The distal pin of the Housing Inserter will interface with the Housing, allowing the Assembly Tool's proximal grips to move freely.

3. Squeeze the handles of the Housing Inserter together to deploy and lock the Dual Rod Housing to the Shank. If done correctly, the magenta indicator at the proximal end of the instrument should sit flush with the handle casing (Figure 9.3).

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

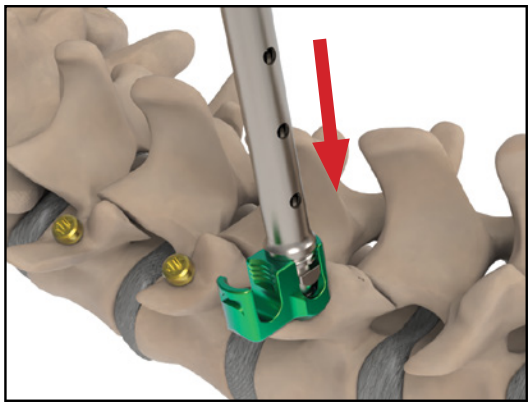


Figure 9.2

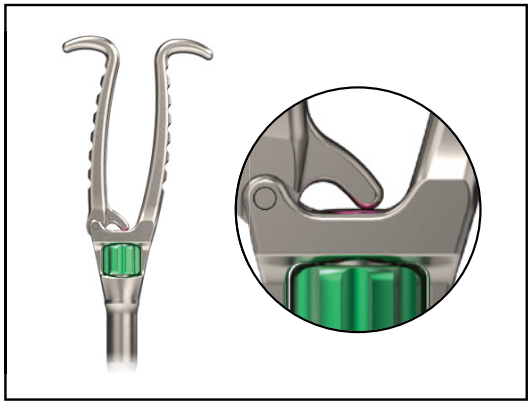


Figure 9.3

TIP: *After locking the components, the surgeon should pull the instrument upward and rotate slightly to confirm that the 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 9.4).*

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.*

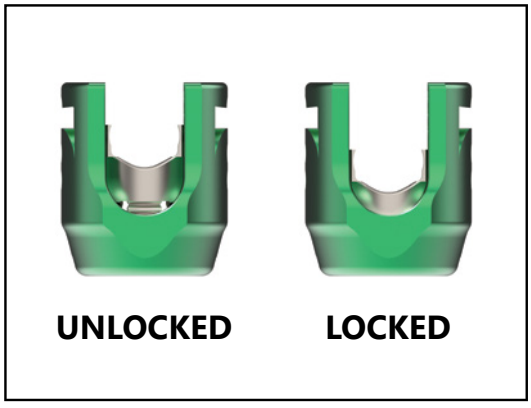


Figure 9.4

9. SECONDARY ROD CONSTRUCTS (CONT.)

For back table assembly, place the provisionally assembled Shank and Dual Rod Housing into the Housing Assembly Tool. The elongated rod of the instrument should sit in the saddle of the Housing, while the distal portion 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 9.5).

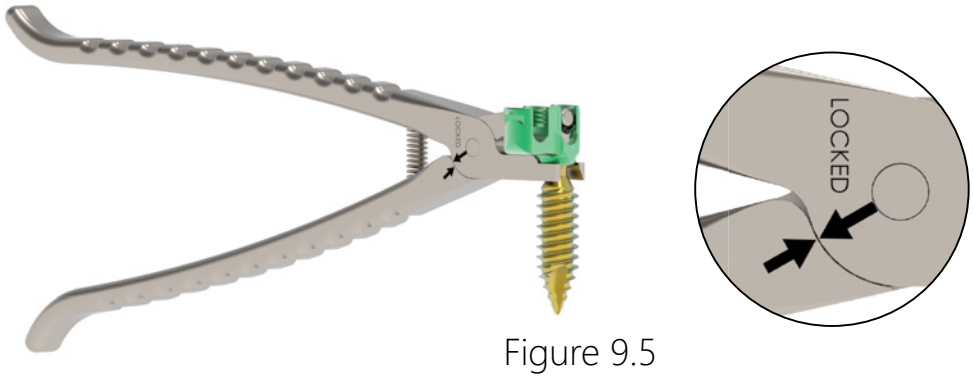


Figure 9.5

The Screw Inserter can be used to implant the assembled Housing and Shank by following the steps as shown (Figure 9.6).

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

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

Figure 9.6

9. SECONDARY ROD CONSTRUCTS (CONT.)

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

3. Using a ¼ Square Handle, insert the assembly into the prepared pedicle until desired depth is reached (Figure 9.7).

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

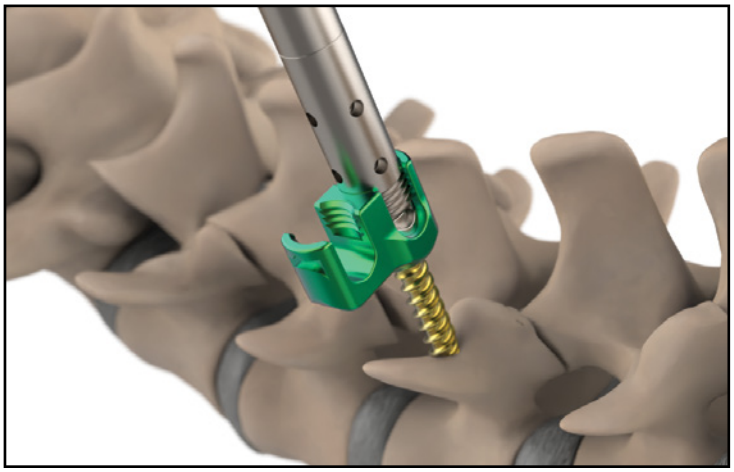


Figure 9.7

Refer to the INERTIA® CONNEXX™ Open Surgical Technique for Rod and Set Screw placement. The Dual Rod Counter Torque Wrench should stabilize the Dual Rod Housing for final tightening.

If Rod reduction is required, the Dual Rod Rocker can be utilized. The distal geometry of the Rocker will allow for the reduction of the primary or the secondary rod (Figure 8.7).

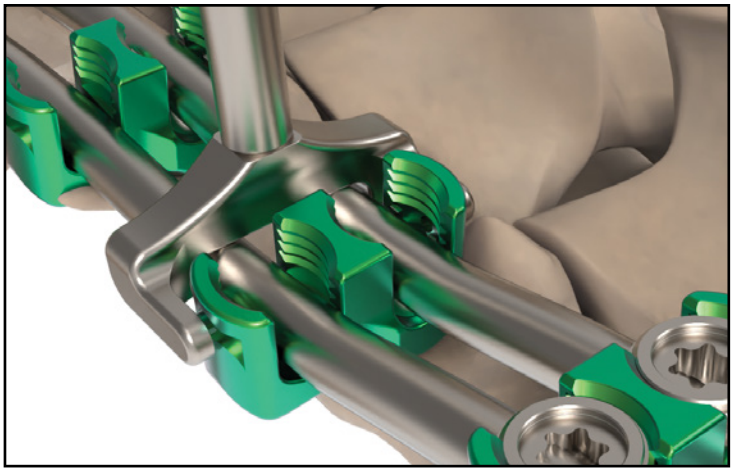


Figure 9.8

10. IN SITU BENDING AND ROD MANIPULATION

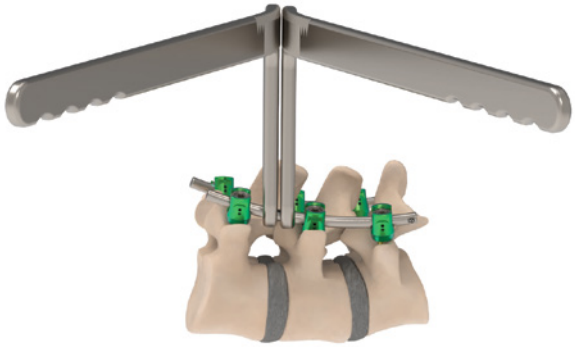
The Inertia® Connexx™ System offers multiple in situ options for rod manipulation and assist with deformity correction or maintenance/restoration of spinopelvic parameters (Figure 10.1).

Start by provisionally placing and tightening Set Screws.

Sagittal Bending

Slide the angled or straight ends around the rod so that the rod sits flush within the rod slot. Compress the Sagittal Benders for lordosis or bend them apart for kyphosis.

Coronal Bending



Place both In situ Coronal Benders over the rod until the slots sit flush. Align the ridges at the 90° bends and compress the arms of the Coronal Benders toward each other.

Figure 10.1

Rod Derotation - A Dual Action Rod Gripper can be used to rotate the rod into the correct orientation and ensure proper position within the Modular Housings.

NOTE: *If using a Rod with a hex end, the Rod Rotation Hex Wrench Tool can be used to assist with rod derotation.*

Once rod reduction, compression/distraction, and manipulation maneuvers have been completed, all of the Set Screws must be final tightened.

11. REVISION/REMOVAL

The INERTIA® CONNEXX™ Housing can be removed intraoperatively from the Shank if required using the Housing Removal Tool (Fig 11.4).

1. Remove the Set Screw and Rod by loosening and removing all the Set Screws using the Final Open Driver (Figure 11.1). 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 11.2).

3. Attach the appropriate Tulip Removal instrument to the appropriate Housing by placing the instrument's distal tip over the Housing (Figure 11.3).

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

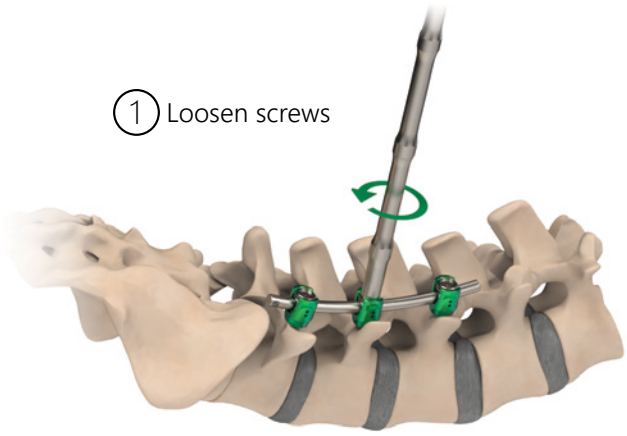


Figure 11.1
Removing Set Screws with Final Open Driver

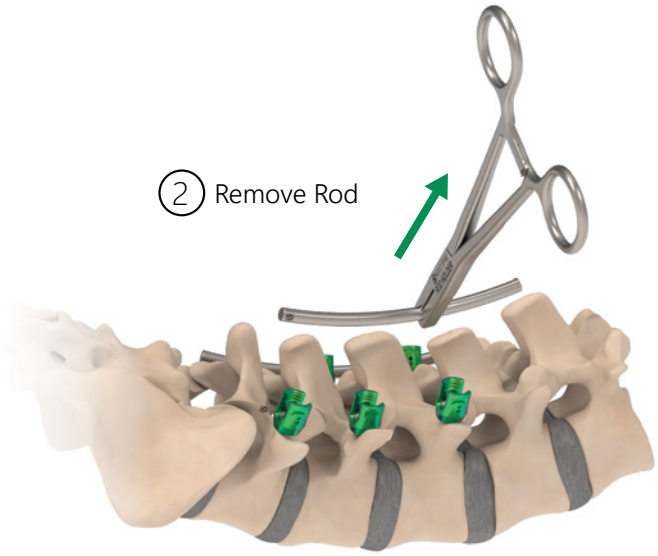


Figure 11.2
Removing Rods with Rod holder

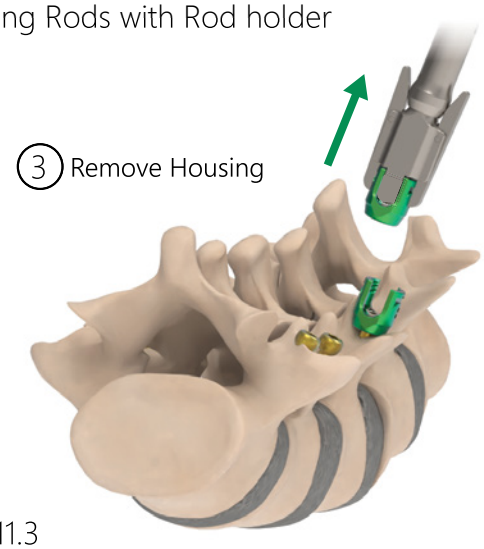


Figure 11.3
Removing Housing with Tulip Removal Tool

11. 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.

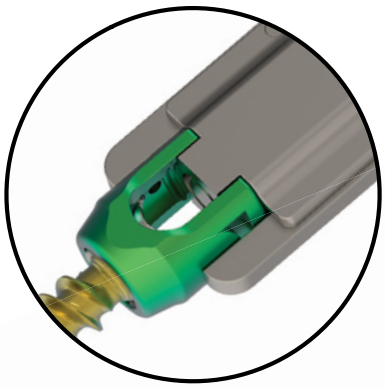


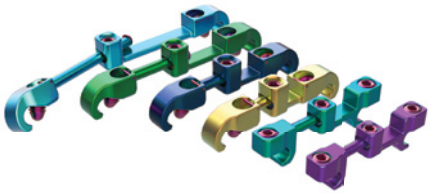
Figure 11.4a
Close up after instrument engaging

Figure 11.4b
Instructions on how to attach and use Housing Removal Tool

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

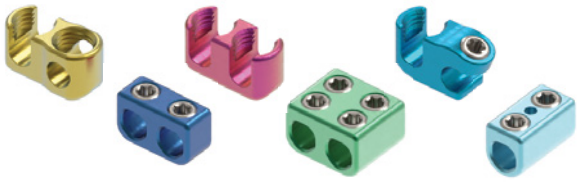
IMPLANT PART NUMBERS

Adjustable CrossLynxx Connectors



Standard P/N	Description
10-28-CC2639*	Adj Cross Connector, 26-39 mm
10-28-CC2329	Adj Cross Connector, 23-29mm LP
10-28-CC2939	Adj Cross Connector, 29-39mm LP
10-28-CC3944	Adj Cross Connector, 39-44 mm
10-28-CC4250	Adj Cross Connector, 42-50 mm
10-28-CC4964	Adj Cross Connector, 49-64 mm
10-28-CC6494*	Adj Cross Connector, 64-94 mm

Rod to Rod Connectors



Standard P/N	Description
20-26-DW	R2R Connector, Double Open
20-26-DW65*	R2R Connector, Double Open, 6.5/5.5
20-26-SL	R2R Connector, Side Load
20-26-SW	R2R Connector, Single Open
10-26-EE5555*	5.5-5.5 R2R Connector, Inline
10-26-WD5555	5.5-5.5 R2R Connector, WB
10-26-DM5555*	5.5-5.5 R2R Connector, Domino

Offset Connectors

Standard P/N	Description
20-25-25	Offset connector, 25mm
20-25-30	Offset connector, 30mm
20-25-35	Offset connector, 35mm
20-25-40*	Offset connector, 40mm
20-25-45*	Offset connector, 45mm
20-25-60	Offset connector, 60mm

Bypass Rods

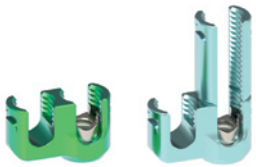
Standard P/N	Description
20-27X-45	Bypass Rod L/R 45mm
20-27X-150	Bypass Rod L/R 150mm
20-27X-40:150*	Bypass Rod L/R 40-150mm

Green rows indicate Standard Order.

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

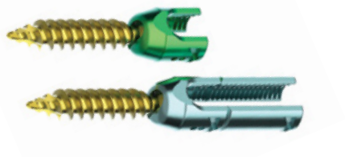
IMPLANT PART NUMBERS (CONT.)

Dual Rod Housings



Standard P/N	Description
20-HD-01	Housing, Dual Rod
20-HD-02	Reduction Housing, Dual Rod

Uniplanar Bone Screws



Standard P/N	Description
20-UDR-XXXX-XX*	Uniplanar Screws: Ø4.5-7.5 x 20-100mm
20-UDS-XXXX-XX*	Uniplanar Reduction Screws: Ø4.5-7.5 x 20-100mm

Offset Z-Rod

Standard P/N	Description
20-RZ-100200	Ø5.5mm, 100mm x 200mm

Set Screws

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

Straight Rods

Standard P/N	Description
10-7-55120	Straight Rod Ø5.5mm x 120mm
10-7-55130	Straight Rod Ø5.5mm x 130mm
10-7-55140	Straight Rod Ø5.5mm x 140mm
10-7-55150	Straight Rod Ø5.5mm x 150mm
10-7-55200	Straight Rod Ø5.5mm x 200mm
10-7-55400	Straight Rod Ø5.5mm x 400mm
10-7-55XXX*	Straight Rod Ø5.5mm x 25-175mm

Optional Rods

Standard P/N	Description
10-8-55XXX*	Hex, Line, Ø5.5 x 25-600mm
10-38-55XXX*	Double Prebent Rod, Ø5.5 x 30-120mm
10-51-55XXX*	CoCr, Hex, Lined, Ø5.5 x 25-600mm
10-53-55XXX*	CoCr, Lined, Ø5.5 x 25-600mm

Green rows indicate Standard Order.

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

INSTRUMENT PART NUMBERS

Sagittal Rod Benders

Standard P/N	Description
I10-30-05L	Sagittal Bender, Ø5.5mm Left
I10-30-05R	Sagittal Bender, Ø5.5mm Right

Coronal Rod Benders

Standard P/N	Description
I10-30-07L	Coronal Bender, Ø5.5mm Left
I10-30-07R	Coronal Bender, Ø5.5mm Right

Inline Rod Reducer

Standard P/N	Description
I20-10-05	Connexx Inline Reducer

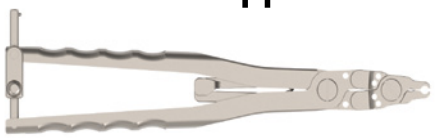
Connector Inserter

Standard P/N	Description
I20-26-01	Connector Inserter

Dual Rod Counter Torque

Standard P/N	Description
I20-26-03*	Dual Rod Housing Counter Torque

Rod Gripper



Standard P/N	Description
I10-30-09*	Rod Gripper, Dual Action (Derotation Clamp)

Reduction Tab Breaker

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

Rod Template

Standard P/N	Description
I10-30-10	Rod Template, 400mm

Green rows indicate Standard Order.

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

INSTRUMENT PART NUMBERS (CONT)

Axial Handle, 40 in-lb.

Standard P/N	Description
I10-01-48	Handle-Axial, SQR, Torque Limiting, 40 in-lb

Crosslynxx Benders

Standard P/N	Description
I10-28-01	Crosslynxx, Bender, Right
I10-28-02	Crosslynxx, Bender, Left

Crosslynxx Driver

Standard P/N	Description
I10-28-04	Crosslynxx Driver, SQR

Crosslynxx Calipers

Standard P/N	Description
I10-28-05	Crosslynxx Measuring Calipers
I10-28-03*	Crosslynxx Measuring Template

Dual Housing Rod Rocker

Standard P/N	Description
I20-26-02*	Dual Housing Rod Rocker

Hex Wrench

Standard P/N	Description
I10-08-10*	Hex Wrench, Rod Rotation

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

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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.

71-055, Rev D