NEXXT Spine

INERTIA®

Deformity Correxxion System

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Designed for Simplicity, Reliability and Reproducibility.

The Inertia® Deformity Correxxion System provides surgeons with a wide variety of implant options to address the demands of multi-segmental degenerative and deformity conditions.

The procedure contained herein outlines the technique for open placement of the Inertia® Pedicle Screw System. For additional information, please contact Nexxt Spine at (317) 436-7801 or info@NexxtSpine.com.

Built upon the success of the Inertia® Pedicle Screw System, the Inertia® Deformity Correxxion System includes the addition of the following implant components:

Spinal Hooks
Pedicle Hooks
Transverse Process Hooks
Lamina Hooks

Additional 5.5mm Rod Options
Cobalt Chrome Rods
600mm Ti Alloy Rods
Lined Hex Rods

Additional Screw Options
Uniplanar
Uniplanar Reduction
Monoaxial
Monoaxial Iliac
Polyaxial Iliac
Cortical-Cancellous Screws

Rod to Rod Connectors
Offset Connectors
Inline Connector
Wedding Band Connector
Domino Connector

Cross Connectors
Adjustable CrossLynxx Connector

This Surgical Technique sets forth detailed, recommended procedures for using the Inertia® Deformity Correxxion System. It offers guidance that you should heed but as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when necessary and as required.

Always refer to the package insert, product label and/or instructions before using any Nexxt Spine implant or instrument. Product information is available at www.NexxtSpine.com.

NOTE: Upon the completion of each surgical procedure, use adequate suction and irrigation to ensure the removal of any existing non-implantable materials.

NOTE: This manual is intended as a guide only. There are multiple techniques for the implantation of spinal fixation systems and as with any surgical procedure; the surgeon should be trained and thoroughly familiar with the implant system components before proceeding.

INDICATIONS AND CONTRAINDICATIONS

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION IMPORTANT
This booklet is designed to assist in using the Nexxt Spine Inertia® System. It is not a reference for surgical techniques. .

CAUTION
Federal (or United States) law restricts these devices to sale by or on the order of a physician.

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® Pedicle Screw and Deformity Correxxion 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 the 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.

DESCRIPTION
The Inertia® Pedicle Screw and Deformity Correxxion System consists of rods, pedicle screws, hooks, connectors and set screws. Rods are available in either straight or pre-contoured (curved) forms in a variety of lengths. Pedicle screws are available in monoaxial, polyaxial, uniplanar and double thread versions in a variety of diameter-length combinations. Connectors include rod-rod and rod-anchor. Set screws are used to fasten the rod, pedicle screw and/or connectors. All implant components are manufactured from titanium alloy (Ti-6AL-4V ELI) per ASTM F136 and optional spinal rods from cobalt chromium alloy per ASTM F1537.

INDICATIONS FOR USE
The Inertia® Pedicle Screw and Deformity Correxxion System is intended for pedicle and non-pedicle 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® Pedicle Screw and Deformity Correxxion System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Inertia® Pedicle Screw and Deformity Correxxion System is to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CONTRAINDICATIONS
Use of the Inertia® 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.

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/Nexxt_Spine_Products or by calling 317-436-7801 for a copy of the detailed cleaning instructions.

STERILIZATION
The Inertia® Pedicle Screw and Deformity Correxxion System implants can be supplied sterile or non-sterile. 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 supplied clean but non-sterile and must be cleaned and sterilized prior to surgery.
Non-sterile 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:	Prevacuum
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® 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® System components are available in a variety of sizes to insure 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® System instruments are to be used for implantation of the Inertia® System components. Failure to use the dedicated instruments may compromise the integrity of the implanted device. Care should be taken to insure that the correct component-specific instruments, e.g., single lead versus double lead taps 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® 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® System is available in titanium and cobalt chrome alloys. It is imperative that titanium and stainless steel do not come into contact in vivo with one other. Accelerated corrosion may occur when these two dissimilar metals are in contact within the body environment.

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. Patients should be fully informed of the risk of implant failure.

WARNINGS AND PRECAUTIONS

INSTRUCTIONS:

PREOPERATIVE

1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warning and Precautions should be avoided.

2. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.

3. An adequate inventory of implant sizes should be available at the time of the surgery.

4. All components must be cleaned and sterilized before use.

5. Before the initial experience we recommended that the surgeon critically review all available information and consult with other surgeons having experience with the device.

OPERATIVE

1. Rods may be pre-bent to the degree of correction determined by preoperative testing, however reverse bends should be avoided.

2. To insert a cannulated screw properly, a guide wire should first be used, followed by a tap. Ensure the guide wire is not inserted too deep, becomes bent, and/or breaks. Ensure the guide wire does not advance during pedicle preparation. Remove the guide wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to the underlying tissue.

3. The placement of screws should be checked radiographically prior to assembly of the rod construct.

4. Care should be taken when positioning the implants to avoid neurological damage.

POSTOPERATIVE

1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.

2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implants could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.

3. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a bone has healed. The surgeon should weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.

4. Periodic X-rays for at least the postoperative first year are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.

5. Surgical implants must never be reused. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

POTENTIAL ADVERSE EFFECTS:

Potential risks identified with the use of this system, which may require additional surgery, include: Bending, fracture or loosening of implant component(s), Nonunion or delayed union, Fracture of the vertebra, Neurological, vascular or visceral injury, Metal sensitivity or allergic reaction to a foreign body, Infection, Decrease in bone density due to stress shielding, Pain, discomfort or abnormal sensations due to the presence of the device, Nerve damage due to surgical trauma, Bursitis, Dural Leak, Paralysis, Death.

Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

Additional potential adverse events for pediatric patients include: inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy), pedicle screw malpositioning with or without neurological or vascular injury, proximal or distal junctional kyphosis and pancreatitis.

INTRODUCTION

The Inertia® Deformity Correxxion System offers a complete array of unique screws, rod connectors, hooks, and rod materials, coupled with innovations in instrumentation to address a greater range of complex spinal pathologies.

HOOK FIXATION

An alternative to the use of pedicle screws for spinal fixation, posterior element hook fixation is still a valuable adjunct in many situations where screws are not possible, desirable, or need to be supplemented.

Hooks are top loading and come in various orientations and sizes. The appropriate hook is chosen by a number of factors including patient anatomy, bone quality, correction technique, and the forces applied.

There are four possible hook placement sites in the spine: pedicle, transverse process, supra-laminar and infra-laminar.

GENERAL HOOK PREPARATION

Site preparation prior to hook placement necessitates meticulous soft tissue debridement in order to define the bony anatomy facilitating proper seating of the hook. Bone preparation depends on the site of application and type of hook used. Proper use of provided instrumentation allows safe placement with optimal stability and minimal risk to adjacent neurovascular structures.

PEDICLE HOOK INSERTION

Pedicle Hooks are placed in the thoracic spine via the facet joint (Figure 1). The direction for the Pedicle Hook is always cephalad and recommended for T10 and above.

The facet of the appropriate level is identified and the capsule is removed with a bovie and/or curette to define the joint. A limited osteotomy at the base of the facet opens the facet joint and exposes the underlying articular cartilage of the superior facet of the caudal vertebra.

The Pedicle Hook Finder is inserted into the facet joint, aiming slightly lateral off the midline to identify the pedicle. Locate the pedicle as an endpoint while avoiding intraosseous penetration of the descending facet often caused by underestimating the kyphotic angulation of the spine in the upper thoracic region. Once the pedicle is localized, the bifid tip of the Pedicle Hook Finder can be utilized to help ensure proper preparation of the pedicle.

Figure 1

Squaring off the caudal edge of the descending facet with an osteotome or drill may facilitate placement of the Pedicle Hook Finder.

The appropriate hook is determined by the patient's anatomy. Once the site is prepared, the selected pedicle hook is loaded onto the Forcep Hook Inserter. The pedicle hook is inserted and seated flush against the facet and the pedicle. The pedicle hook must be within the facet joint and engaging the pedicle as evidenced by medial/lateral stability.

TRANSVERSE PROCESS HOOK INSERTION

Transverse Process Hooks are usually applied in a down going direction over the superior surface, using a Forcep Hook Inserter (Figure 2).

Use a bovie and/or Lamina/Transverse Process Hook Finder to detach the ligament from the superior surface of the transverse process. Ensure the Lamina/Transverse Process Hook Finder and subsequent Transverse Process Hook blade goes around the entire transverse process.

Using the Forcep Hook Inserter to grip the hook, insert the Hook Pusher into the Transverse Process Hook. Slide the Transverse Process Hook into the desired position and gently tamp against the transverse process. Move the hook side to side to ensure the hook is around the transverse process.

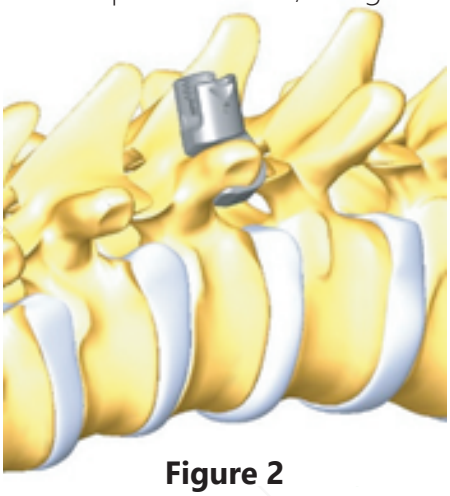

Figure 2

The Hook Pusher may be used in conjunction with the Forcep Hook Inserter to help facilitate full seating of the Transverse Process Hook against the transverse process.

FORCEP HOOK INSERTER

The Forcep Hook Inserter attaches securely to each side of the hook housing (Figure 3).

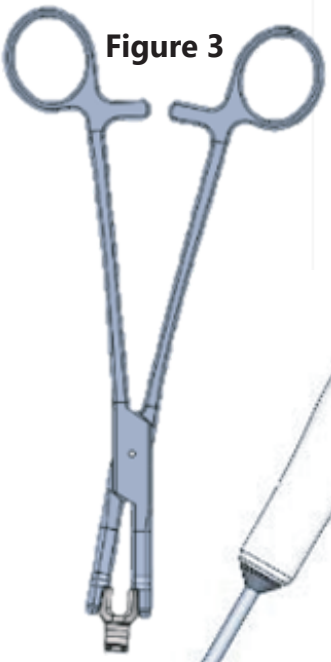

Figure 3

HOOK PUSHER

If necessary, the Hook Pusher may be used to apply a controlled force in the direction of hook application. This is most commonly used with pedicle hooks and occasionally lamina or transverse process hooks. Place distal end of the Hook Pusher inside the hook housing. An impaction cap is provided to allow controlled mallet strikes as necessary for final hook seating (Figure 4).

LOCKING SET SCREW DELIVERY

After placing the rod into the screw housings use the Initial Set Screw Inserter by itself or with the Alignment Tube to deliver Locking Set Screws into each Screw Housing. The Counter Torque can be used interchangeably for Set Screw delivery.

Press fit instrument tip into set screw torx to load implant. Set Screw may be tapped against a table for a tighter fit.

TIP: If Locking Set Screw does not turn smoothly, slowly turn counter-clockwise 180°, then turn again clockwise to align threads.

Figure 4

FINAL TIGHTENING

1. Assemble the T25 Driver Shaft to the Torque Limiting Handle by inserting the square drive connection into the receiving end of the Torque Limiting Handle. A line on the T25 Driver Shaft indicates how deep it must penetrate into the Torque Limiting Wrench to securely attach (Figure 5).

2. Place distal tip of Counter Torque over hook housing.

3. Insert Locking Set Screw down the center of Counter Torque.

4. Turn Locking Set Screw clock-wise until Torque Limiting Handle clicks. Confirm black line on driver shaft is below opening of Counter Torque.

5. Repeat for all hook housings.

HOOK REMOVAL

1. Remove Set Screw and Rod from hook.

2. Attach Forcep Hook Inserter to hook and compress handles to secure. Carefully remove hook from anatomy.

The Hook Pusher can be used to assist in the release of the hook from anatomical structures.

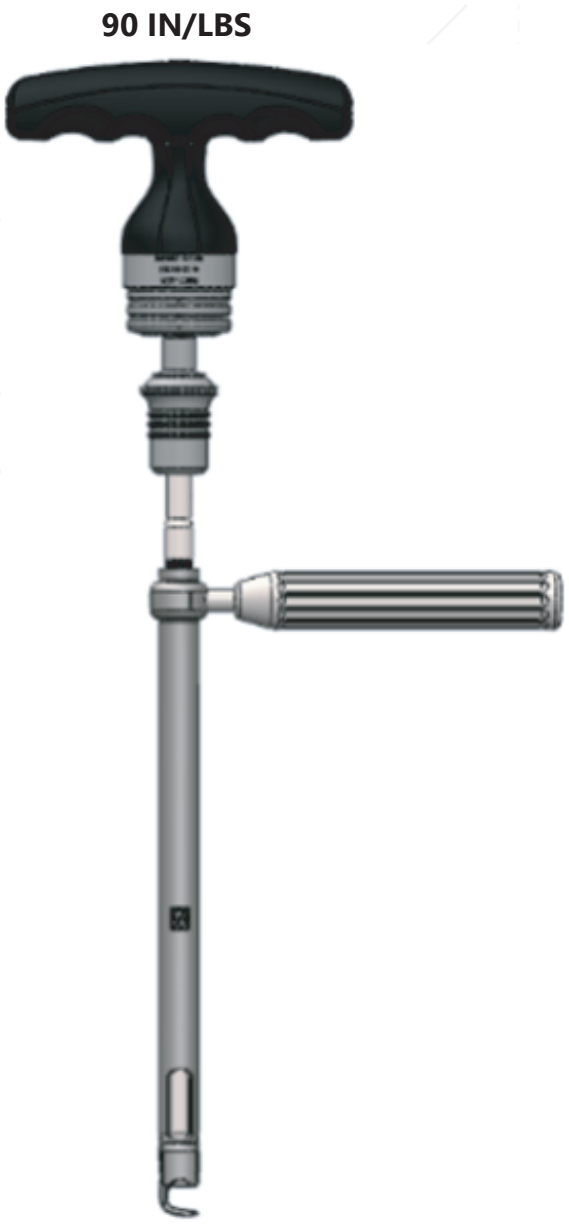

Figure 5

UNIPLANAR SCREWS

The Inertia® Deformity Correxxion Uniplanar Screws are designed to provide polyaxial freedom in the cephalad/caudal plane, but remain fixed in the medial/lateral plane (Figure 6). The polyaxial 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 3 dimensional correction of the spine.

Uniplanar Screws are available in the following sizes:

Ø4.5mm x 20-80mm
Ø5.5mm x 20-80mm
Ø6.5mm x 20-100mm
Ø7.5mm x 20-100mm

Figure 6

To insert Uniplanar Screws, follow the same procedure thoroughly detailed on pages 7 - 12 of the Inertia® Pedicle Screw System Surgical Technique Guide.

NOTE: Uniplanar Screws are compatible with all Inertia Instrumentation.

MAC REDUCTION AND UNIPLANAR REDUCTION SCREWS

Screw Sizes:

MAC Reduction	Uniplanar Reduction
Ø4.5mm x 20-80mm	Ø4.5mm x 20-80mm
Ø5.5mm x 20-80mm	Ø5.5mm x 20-80mm
Ø6.5mm x 20-100mm	Ø6.5mm x 20-100mm
Ø7.5mm x 20-100mm	Ø7.5mm x 20-100mm

Attach Ratchet Handle and optional Screw Inserter Sleeve onto the Reduction Screw Inserter (Figure 7).

Insert the tip of the Reduction Screw Inserter into the Housing of the Uniplanar Reduction Screw.

Advance instrument threads into the Uniplanar Reduction Screw housing while rotating clockwise.

NOTE: Torque tight to prevent screw loosening during insertion.

Thread Pedicle Screw into prepared pedicle canal to the desired depth.

The In-situ Driver may be used to adjust height of screws.

Figure 7

After placing the Rod into the screw housings use the Initial Set Screw Inserter by itself or with the Alignment Tube to deliver Set Screws into each screw housing. The Counter Torque can be used interchangeably for Set Screw delivery.

Press fit inserter tip into set screw torx to load implant. Set Screw may be tapped against a table for a tighter fit.

TIP: If Set Screw does not turn smoothly, slowly turn counter-clockwise until Locking Set Screw disengages, then turn again clockwise to align threads.

To remove reduction tabs, place the Reduction Tab Remover over either tab for removal (Figure 8). Lever the tab away from the axis of the screw housing. The Reduction Tab Remover will retain the tab remnant for controlled removal from the incision site.

After removal of each tab, remove remnant from Reduction Tab Remover.

Figure 8

Remove remaining tabs in the same manner.

FINAL TIGHTENING

1. Assemble the T25 Driver Shaft to the Torque Limiting Handle by inserting the square drive connection into the receiving end of the Torque Limiting Handle. A line on the T25 Driver Shaft indicates how deep it must penetrate into the Torque Limiting Handle to securely attach.

2. Place distal tip of Counter Torque over screw housing.

3. Insert Locking Set Screw down the center of Counter Torque.

4. Turn Locking Set Screw clock-wise until Torque Limiting Handle clicks. Confirm black line on driver shaft is below opening of Counter Torque.

5. Repeat for all screw housings.

Optional: Slide Reduction Crown down each screw housing and allow them to rest on the Rod throughout both the reduction maneuver and the tab removal (Figure 9).

Deliver a Locking Set Screw into each reduction housing. Advance the Locking Set Screws in unison or back-and-forth from one Set Screw to the other. The Reduction Crowns will ride down the reduction housing with the Rod as the Set Screw is advanced.

NOTE: Do not remove the Reduction Crowns until all tabs are removed. Make sure the Reduction Crown is not obstructing tab removal.

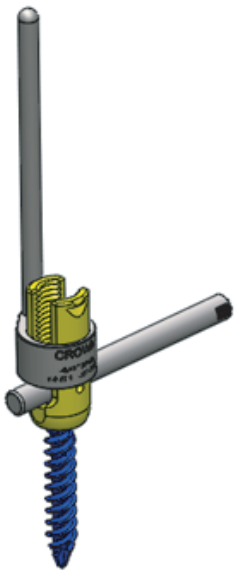

Figure 9

MONOAXIAL SCREWS

Monoaxial Screws (Figure 10) are available in the following sizes:

Ø4.5mm x 20-80mm
Ø5.5mm x 20-80mm
Ø6.5mm x 20-100mm
Ø7.5mm x 20-100mm
Ø8.5mm x 20-120mm
Ø9.5mm x 20-120mm
Ø10.5mm x 20-120mm

Figure 10

To insert Monoaxial Screws, follow the same procedure thoroughly detailed on pages 7 - 12 of the Inertia® Surgical Technique Guide.

NOTE: Monoaxial Screws are compatible with all Inertia Instrumentation.

ADJUSTABLE CROSSLYNXX CONNECTOR

Inertia® 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 another one in the lower one-third of the construct.

Step 1

Measuring

To determine the appropriate length CrossLynxx Connector use the CrossLynxx Measuring Caliper (Figure 11).

CrossLynxx Connectors are available in 6 sizes:

23-29mm
29-39mm
39-44mm
42-50mm
49-64mm
64-94mm

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

If implant contouring is necessary to accommodate non-parallel, non-planar rods, or increased clearance, proceed to Step 2. If no contouring is needed, proceed to Step 3.

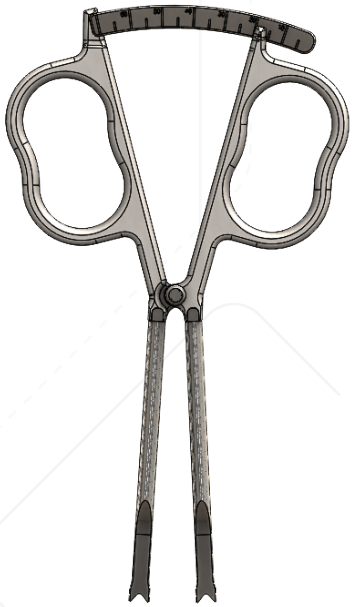

Figure 11

Step 2
Contouring

To contour the CrossLynxx 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 12). The other bender fits over the middle segment of the implant.

NOTE: Only the female end of the implant fits into the Implant Benders (Figure 13).

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

NOTE: The 23-29mm & 29-39mm CrossLynxx connectors have unique benders, labeled "short x-link bender left" and "short x-link bender right."

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

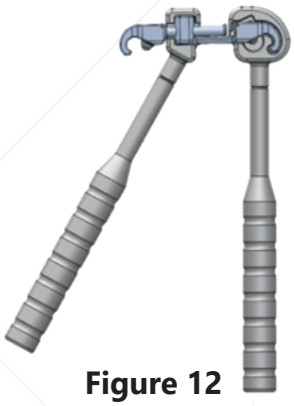

Figure 12

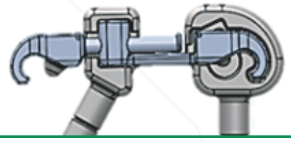

Figure 13

Step 3
Insertion

Connect the Torque Limiting 40 in-lb. Handle to the CrossLynxx Driver shaft (Figure 14).

The rod set screws must be backed out with the CrossLynxx Driver such that they do not obstruct placement of the connector on rod.

Place the connector on the rods and provisionally tighten the rod set screws and midline screw.

Figure 14

Step 4
Final Tightening

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 15).

Removal
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 15

OFFSET CONNECTORS

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. Please note: Rod cutters are available by request only.

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.

The screw housing (tulip) is rotated 90° to accommodate the Offset Connector.

The Offset Connector is preloaded onto the rod in the appropriate orientation prior to placement of the adjoining rod into the screw housing (tulip). Care must be taken to ensure that at least 1.0mm of the Offset Connector rod is extending out of the screw housing (tulip).

The Locking Set Screw is then provisionally tightened using the Initial Set Screw Inserter. The final tightening sequence for the Offset Connector is identical to that for the Inertia pedicle screws and hooks.

Tip: Offset Connectors are particularly useful for pelvic fixation. Please refer to the Iliac Fixation section (Figure 16).

NOTE: Ensure that the Screw Offset is perpendicular to the screw head.

NOTE: When used for fixation to the ilium, the Offset Connectors of the Inertia® Deformity Correxxion System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level. Use of the Inertia 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.

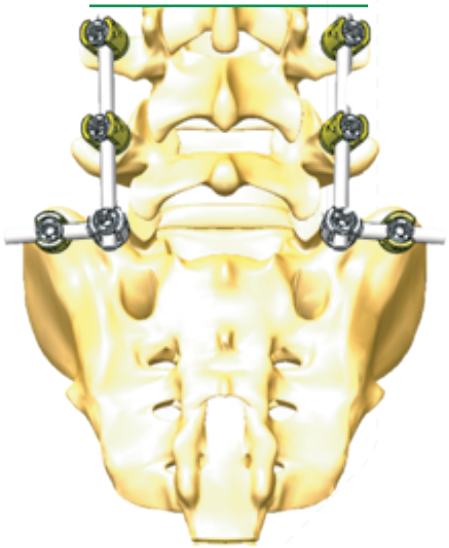

Figure 16

ILIAC FIXATION OPERATIVE TECHNIQUE

The Inertia® Deformity Correxxion 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.

APPROACH TO THE ILIAC CREST

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 bone screw and ensure the iliac cortex is not compromised during placement of the screw.

PREPARATION OF THE ILIAC CREST

It is recommended to notch the iliac crest sufficiently enough around the screw housing (tulip) to recess it to a level reducing or eliminating implant prominence as much as possible.

PROBING THE ILIUM

Place the Iliac Probe in such a way that the path is approximately 1.0mm to 1.5mm above the greater sciatic notch. The probe can be used to start the screw path but does not need to extend the entire length of the chosen screw. When choosing a screw size, it is generally considered best to use the largest diameter possible.

Inertia® Polyaxial Iliac Screws are available in the following sizes:

Ø5.5mm x 60-80mm
Ø6.5mm x 60-100mm
Ø7.5mm x 60-100mm
Ø8.5mm x 60-120mm
Ø9.0mm x 60-120mm
Ø9.5mm x 60-120mm
Ø10.5mm x 60-120mm

NOTE: Longer length Iliac Probes are available by request.

(OPTIONAL) TAPPING THE ILIUM

Tap to the desired depth based on the length of the screw to be implanted.

NOTE: Inertia® pedicle screws are self-tapping and do not require the use of a tap to facilitate screw insertion.

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

SCREW INSERTION

Determine screw length and diameter via preferred methods.

Attach Ratchet Handle and optional Screw Inserter Sleeve onto the Screw Inserter.

Insert the tip of the Screw Inserter into the screw housing (tulip).

Advance instrument threads into screw housing while rotating clockwise.

NOTE: Torque tight to prevent screw loosening during insertion.

Insert the selected screw into the prepared ilium. The screw housing (tulip) should be positioned far enough above the iliac crest to allow for insertion of the Rod or Offset Connector; however, it should be recessed as much as possible to reduce or eliminate implant prominence.

To disengage the screw from the screw driver tip, turn the knob counter-clockwise until the instrument disengages from the screw.

Repeat above steps for remaining screws.

NOTE: When used for fixation to the ilium, the Offset Connectors of the Inertia® Deformity Correxxion System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level. Use of the Inertia® 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.

ROD TO ROD CONNECTORS

Rod to rod connectors will accept rod diameters ranging from 5.5mm up to 6.5mm.

Five designs are available to accommodate alignment and anatomical requirements.

1. Inline
2. Domino
3. Wedding Bands
4. Single Open Wedding
5. Double Open Wedding

Slightly loosen the Set Screws in the rod to rod connectors by inserting the Initial T25 Set Screw Inserter and rotating them counterclockwise (Figure 17). The Set Screws are loose when the spinal rods slide easily into the connector.

Figure 17

Slide the rod to rod connector to the desired position on the rod and provisionally tighten the Set Screws with the Initial T25 Set Screw Inserter (Figure 18).

Perform final tightening by attaching the Final T25 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 19).

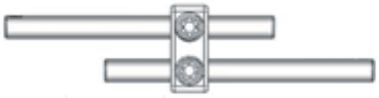

Figure 18

Figure 19

ROD TEMPLATE

A malleable 400mm Rod Template is provided. Manually contour the Rod Template to represent the desired rod configuration. Use the contoured Rod Template as a guide during the rod contouring process.

PISTOL ROD REDUCER

The Pistol Rod Reducer can provide up to 20mm of rod reduction to enable insertion of the Set Screw (Figure 20).

1. Press straight down and snap the distal tip of the reducer over the screw housing (tulip) until it clicks into the side grooves. The ratcheting handle must be in the open position to connect to the screw housing (tulip).

2. Squeeze the handle of the reducer to draw the Rod down into the screw housing (tulip).

3. Insert Set Screw into the screw housing (tulip) and provisionally tighten to secure the Rod.

4. After provisionally tightening the Set Screw, the reducer can be removed. Disengage the reducer by lifting up the ratchet lever and separating handle (tulip).

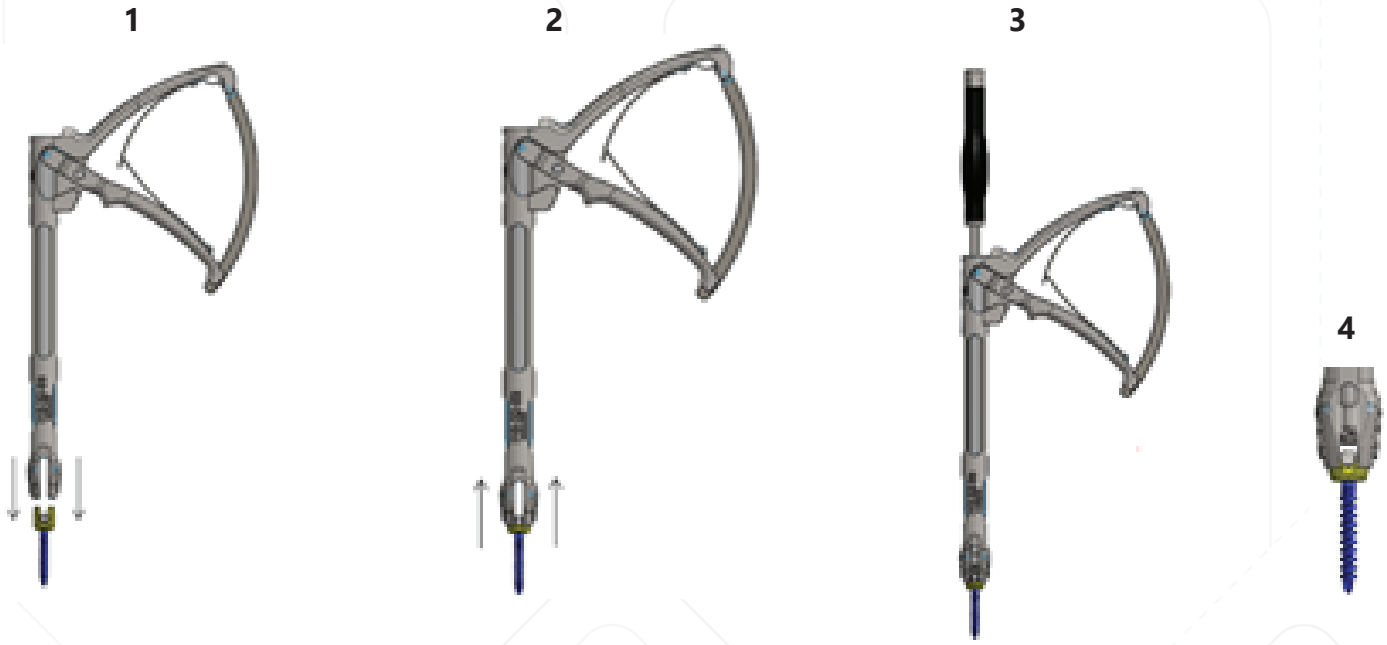

Figure 20

"TURBO" TOWER REDUCERS

Turbo Towers provide simultaneous translational correction of the spine and sequential reduction of the Rods at each vertebral level lessening the chance of screw pull-out and loss of fixation (Figure 21). A benefit of this approach is less stress is applied to the instrumentation and bone, as rod reduction is gradual and controlled. Reduction range is 25mm.

1. Turn reducer knob counterclockwise as far as possible to allow distal tips of the tower to be positioned outside of the reducer body.

2. Press instrument straight down on the screw housing (tulip) to splay the distal tips of the tower over the screw housing until they click into the side grooves.

3. To begin rod reduction, rotate the reducer knob clockwise. The outer sleeve of the tower will move downward to contact the rod.

4. An optional Tower Reducer Wheel (provided) can be attached to the top of the tower to assist with reducer knob rotation.

5. Continue to rotate reducer knob clockwise until a positive stop is felt indicating the Rod is now in the screw housing (tulip). Verification that the rod is seated can be determined when the inner and outer shaft's top surfaces are flush.

6. Insert Set Screw into the screw housing (tulip) and provisionally tighten to secure the Rod.

7. After provisionally tightening the Set Screw, remove tower by rotating reducer knob counterclockwise as far as possible to allow distal tips of the tower to be positioned outside of the reducer body, then rotate the entire tower 90° counterclockwise to detach from the Screw Housing (tulip).

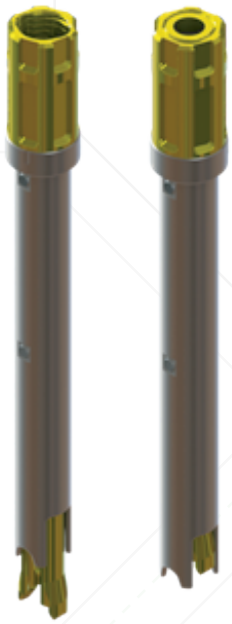

Figure 21

IMPLANT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Rods	10-51-55400	Straight Rod, COCR, Hex, Line, Ø5.5x400 mm
	10-8-55200/600*	Straight Rod, Titanium, Hex, Line, Ø5.5x200/600 mm
	10-51-55200/600*	Straight Rod, COCR, Hex, Line, Ø5.5x200/600 mm
Screws	10-30-10520/120*	Monoaxial Screw, Ø10.5x20/120 mm
	10-30-4520/80*	Monoaxial Screw, Ø4.5x20/80 mm
	10-30-5520/80*	Monoaxial Screw, Ø5.5x20/80 mm
	10-30-6520/100*	Monoaxial Screw, Ø6.5x20/100 mm
	10-30-7520/100*	Monoaxial Screw, Ø7.5x20/100 mm
	10-30-8520/120*	Monoaxial Screw, Ø8.5x20/120 mm
	10-30-9520/120*	Monoaxial Screw, Ø9.5x20/120 mm
	10-40-4520/80*	Uniplanar Screw, Ø4.5x20/80 mm
	10-40-5520/80*	Uniplanar Screw, Ø5.5x20/80 mm
	10-40-6520/100*	Uniplanar Screw, Ø6.5x20/100 mm
	10-40-7520/100*	Uniplanar Screw, Ø7.5x20/100 mm
	10-45-4520/80*	MAC Reduction Screw, Ø4.5x20/80 mm
	10-45-5520/80*	MAC Reduction Screw, Ø5.5x20/80 mm
	10-45-6520/100*	MAC Reduction Screw, Ø6.5x20/100 mm
	10-45-7520/100*	MAC Reduction Screw, Ø7.5x20/100 mm

INSTRUMENT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Rod Instruments	I10-08-10	Rod Hex Wrench
	I10-30-07	Rod Bender, Coronal, Left & Right Set
	I10-30-10	Rod Template, 400mm
	I10-30-08*	Rod Cutter
	I10-30-09*	Dual Action Rod Gripper
Reducers	I10-32-03	Pistol Rod Reducer
	I10-32-04	Tower Reducer Wheel
	I10-32-06	Tower Reducer
	I10-32-07*	Tower Reducer, Adapter
Probes	I10-05-13*	Iliac Probe, Lenke, Straight
	I10-05-14*	Iliac Probe, Lenke, Curved
	I10-05-17*	Iliac Probe, Lenke, Straight, Palm Grip
	I10-05-18*	Iliac Probe, Lenke, Curved, Palm Grip

***Optional implants and instruments by request.**

HOOK IMPLANT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Hooks	10-23-PHSM	Pedicle Hook, Sm
	10-23-PHLG	Pedicle Hook, Lg
	10-23-PHMD*	Pedicle Hook, Md
	10-23-TLLG	Transverse Hook, Left, Lg
	10-23-TLSM	Transverse Hook, Left, Sm
	10-23-TLMD*	Transverse Hook, Left, Md
	10-23-TRLG	Transverse Hook, Right, Lg
	10-23-TRSM	Transverse Hook, Right, Sm
	10-23-TRMD*	Transverse Hook, Right, Md
	10-24-LLLG	Lamina Hook, Offset Left, Lg
	10-24-LLSM	Lamina Hook, Offset Left, Sm
	10-24-LLMD*	Lamina Hook, Offset Left, Md
	10-24-LRLG	Lamina Hook, Offset Right, Lg
	10-24-LRSM	Lamina Hook, Offset Right, Sm
	10-24-LRMD*	Lamina Hook, Offset Right, Md
	10-24-LSLG	Lamina Hook, Straight, Lg
	10-24-LSSM	Lamina Hook, Straight, Sm
	10-24-LSMD*	Lamina Hook, Straight, Md

HOOK INSTRUMENT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Hooks	I10-23-01-NS	Pedicle Hook, Finder, No Stop
	I10-23-02	Lamina/Transverse Hook, Finder
	I10-23-05	Hook Pusher
	I10-23-06	Hook Inserter, Forcep

CROSS CONNECTOR IMPLANT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Cross Connectors	10-28-CC2639*	Adj Cross Connector, 26-39 mm
	10-28-CC2329	Adj Cross Connector, LP 23-29mm
	10-28-CC2939	Adj Cross Connector, LP 29-39mm
	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

***Optional implants and instruments by request.**

CROSS CONNECTOR INSTRUMENT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Cross Connectors	I10-01-48	Handle-Axial, SQR, Torque Limiting, 40 in-lb
	I10-28-01	Crosslynxx, Bender, Right
	I10-28-02	Crosslynxx, Bender, Left
	I10-28-04	Crosslynxx Driver, SQR
	I10-28-05	Crosslynxx Measuring Calipers
	I10-28-03*	Crosslynxx Measuring Template

OFFSET CONNECTOR IMPLANT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Offset Connectors	10-25-C25	5.5/5.5 Offset Connector, 25 mm
	10-25-C30	5.5/5.5 Offset Connector, 30 mm
	10-25-C35	5.5/5.5 Offset Connector, 35 mm
	10-25-C40*	5.5/5.5 Offset Connector, 40 mm
	10-25-C45*	5.5/5.5 Offset Connector, 45 mm
	10-25-C60	5.5/5.5 Offset Connector, 60 mm

ROD TO ROD CONNECTOR IMPLANT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Rod to Rod Connectors	10-26-EE5555	Ø5.5/5.5 Connector, Inline
	10-26-DM5555	Ø5.5/5.5 Connector, Domino
	10-26-WD5555	Ø5.5/5.5 Connector, Wedding
	10-26-DW	Ø5.5/5.5 Connector, Double Open Wedding
	10-26-SW	Ø5.5/5.5 Connector, Single Open Wedding

ROD TO ROD CONNECTOR INSTRUMENT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Rod to Rod Connectors	I10-26-02	Inertia Correxxion, Open Wedding Band, Inserter

***Optional implants and instruments by request.**

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