

INERTIA®
Pedicle Screw System

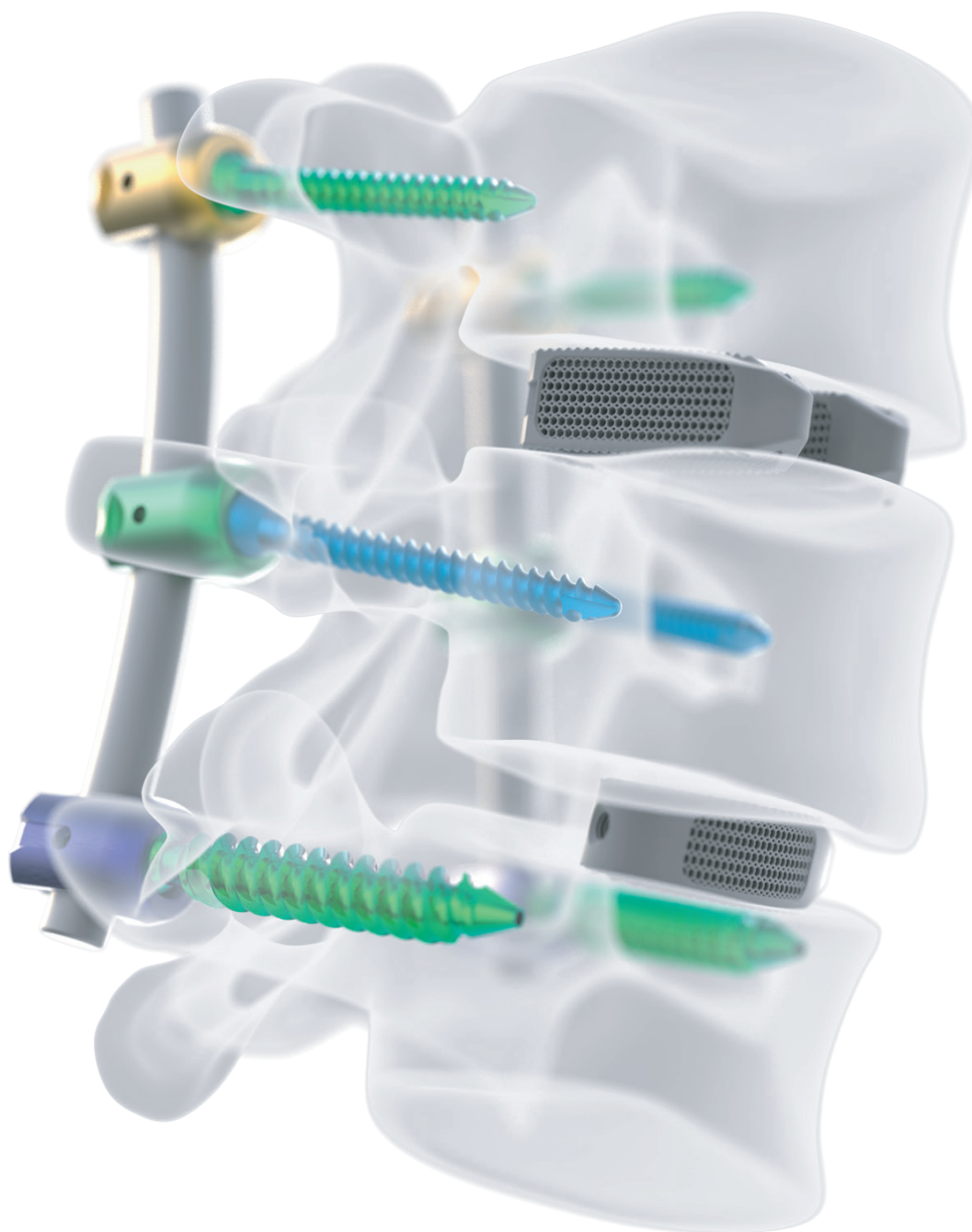


TABLE OF CONTENTS

Inertia® Pedicle Screw System Introduction	pg. 3
Indications and Contraindications	pg. 4
Warnings and Precautions	pg. 5-6

PEDICLE SCREW TECHNIQUE

Operating Room Set up and Pedicle Preparation	pg. 7
Screw Assembly and Insertion	pg. 8
Rod Selection and Delivery	pg. 9
Locking Set Screw Delivery	pg. 9
Counter Torque Tube and Final Set Screw Locking	pg. 10
Reduction Screw Assembly and Insertion (Optional)	pg. 11-12
Reduction Methods (Optional)	pg. 13-14
“Turbo” Tower Reducer (Optional)	pg. 13
Pistol Grip Reducer (Optional)	pg. 13
Rod Rocker (Optional)	pg. 14
Compression and Distraction (Optional)	pg. 14

PRODUCT INFORMATION

Implant Product Numbers	pg. 15
Instrument Product Numbers	pg. 16



INERTIA®

Pedicle Screw System

Designed for Simplicity, Reliability and Reproducibility.

The Inertia® Pedicle Screw System is a comprehensive system intended to address numerous pathologies for the thoracic and lumbar spine.

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.

SYSTEM FEATURES INCLUDED:

- Screw diameters: \varnothing 4.5, 5.5, 6.5, 7.0, 7.5, 8.5, 9.0, 9.5, and 10.5mm
- Screw lengths: 20-80mm in 5mm increments (4.5 & 5.5)
20-100mm in 5mm increments (6.5, 7.0, 7.5)
20-120mm in 5mm increments (8.5, 9.0, 9.5, 10.5)
- Double helical thread design reduces insertion time and effort 50%.
- Rod Capture Mechanism prevents migration during rod insertion.



INERTIA®

Pedicle Screw System



INDICATIONS AND CONTRAINDICATIONS

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 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.

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 System consists of rods, polyaxial screws and set screws. Rods are available in either straight or pre-contoured (curved) forms and in a variety of lengths. Polyaxial screws are available in a variety of diameter-length combinations. Set screws are used to fasten the rod and polyaxial screw. All implant components are manufactured from Titanium alloy (Ti-6Al-4V ELI) per MAST F136 and optional spinal rods from cobalt chromium alloy per ASTM F1537.

INDICATIONS:

The Inertia® Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1 to S2): severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; spinal stenosis; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

CONTRAINDICATIONS:

Use of the Inertia® Pedicle Screw 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.

Also see the **WARNINGS, PRECAUTIONS AND POTENTIAL RISKS** sections of this insert.

CLEANING/REPROCESSING OF NEXXT SPINE SURGICAL INSTRUMENTS:

Nexxt Spine surgical instruments are supplied non-sterile. While it is recommended that the following steps are included in a decontamination/reprocessing protocol, the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for Nexxt Spine implants or disposable surgical instruments.

Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed with a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean Nexxt Spine surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solution may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of one minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles.

STERILIZATION:

The Inertia® Pedicle Screw System 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:	30 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 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.

2. 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.

3. 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.

4. 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 Titanium Rods can cause metal stressing resulting in a lower fatigue life for the rod.

5. 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.

6. 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.

7. 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 or migration in the MR environment.

8. MIXED METALS: The Inertia® 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 in contact within the body environment.

9. 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.

10. 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.

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 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.

WARNINGS AND PRECAUTIONS

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.

PRODUCT COMPLAINTS:

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Nexxt Spine immediately. Nexxt Spine should be notified immediately of any product malfunction by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

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OPERATION ROOM SETUP AND PEDICLE PREPARATION

Follow preferred surgical technique for patient positioning, pedicle identification, and targeting.

Insert the Awl into pedicle canal. Push down and rotate back and forth to penetrate hard cortical bone.

Insert bone Probe (Straight or Curved) into entry site and gently guide Probe through pedicle canal. Graduated markings on the bone Probe identify total depth.

Insert the Pedicle Sounder (Straight or Curved) into the pedicle to palpate and confirm pedicle wall integrity.

Select desired screw length based on Probe or Sounder markings.

Select the Tap that matches preferred Pedicle Screw diameter and attach to handle. Advance Tap to desired depth as shown on graduated markings of Tap.

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

NOTE: Probes, Sounders, and Taps are laser etched at 10mm increments, indicating the depth to which the instrument has been inserted and to help the surgeon assess proper screw length (Figure 1).



Figure 1

SCREW ASSEMBLY & INSERTION

With pedicle prepared, determine Screw length and diameter via preferred methods.

ASSEMBLE SCREW INSERTER

1. Attach Ratchet Handle onto the Auto-Locking Screw Inserter.
2. Insert the Screw Inserter into the Housing of the Pedicle Screw (Figure 2).

LOAD, DEPLOY, AND RELEASE POLYAXIAL SCREW

1. Engage hexalobe into Polyaxial Screw. Advance instrument threads into Polyaxial Screw Housing while rotating clockwise.

NOTES:

-If the Auto-Locking Screw Inserter does not engage hexalobe, gently rotate the Screw Shank until the Screw Inserter fully seats into the Screw Housing (Figure 3).

-Torque tight to prevent loosening during insertion.

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

3. Remove Screw Driver: Rotate thumb wheel counter-clockwise while holding handle fixed to disengage from Pedicle Screw. Lift instrument out of surgical area.

4. A Provisional Screw Driver may be used to further advance screws.

5. Repeat Screw selection for desired levels and on contralateral side as desired.



Figure 2

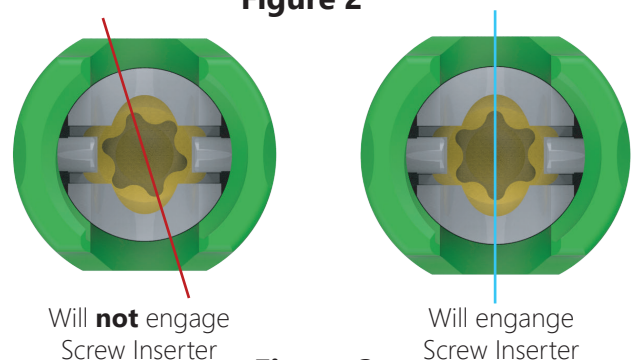


Figure 3

ROD SELECTION AND DELIVERY

Utilize Trial Rods or other methods to determine appropriate Rod length and contour.

1. Select appropriate length Rod. Use Rod Benders as needed to contour either Straight Rods or Pre-lordosed Rods to desired curvature (Figure 4).
2. Deliver selected Rod using the Rod Holder and position in Screw Housings at all levels.
3. If additional Rod curvature is desired after inserting, then use In-situ Rod Benders to reshape.
4. Screw Housings have a patented Rod Snap-In feature (US. #10,172,647) which allows semi-fixation of the Rod while positioning (Figure 5). The Rod may be removed from the Snap-In feature and repositioned.



Figure 4

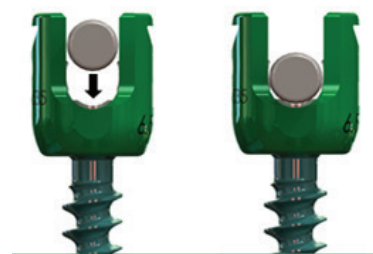


Figure 5

LOCKING SET SCREW DELIVERY

Use the Initial Set Screw Inserter (Figure 6) with the Alignment Tube to deliver Locking Set Screws into each Screw Housing. The Counter Torque Tube can be used interchangeably for Set Screw delivery.

1. Press fit instrument tip into Set Screw hexalobe to load implant. Set Screw may be tapped against a table for a tighter fit.
2. Insert into the Alignment Tube and engage threads of the Set Screw into the Screw Housing and provisionally tighten.

NOTE:

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



Figure 6

COUNTER TORQUE TUBE & LOCKING SCREW DRIVER

1. Assemble the T25 Driver 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 indicates how deep it must penetrate into the Torque Limiting Handle to securely attach (Figure 7.)
2. Place distal tip of Counter Torque Tube over Screw Housing.
3. Ensure driver is fully buried into the Set Screw which is evident when black line is no longer visible. (Figures 8 & 9).
4. Turn Locking Set Screw clock-wise until Torque Limiting Handle clicks once. Repeated clicks are not necessary.
5. Repeat for all Screw Housings.

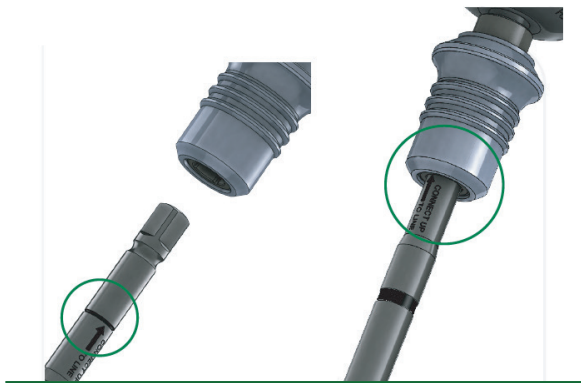


Figure 7



Figure 8

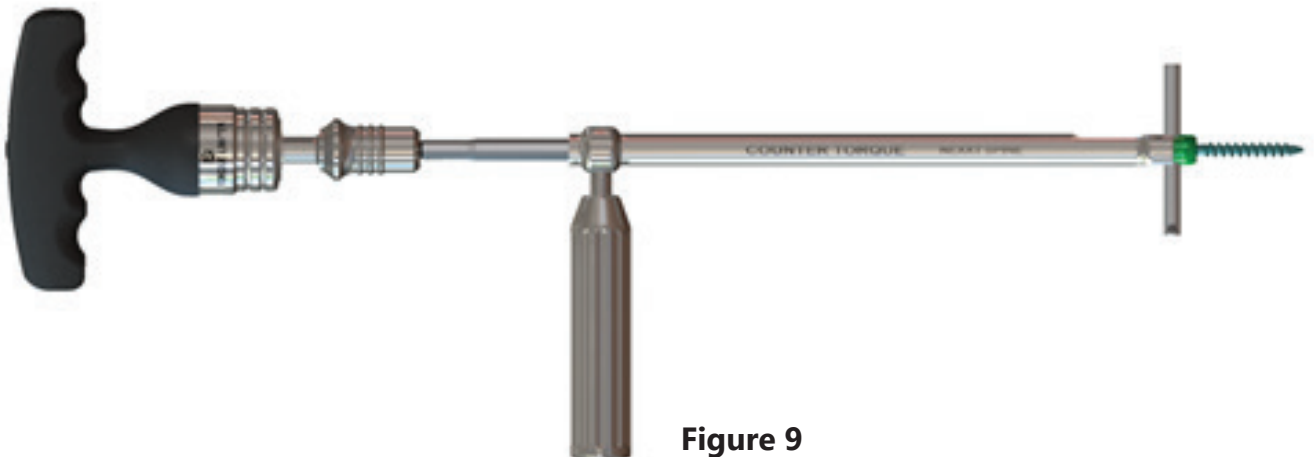


Figure 9

NOTE:

-Locking Torque is directly marked on all Torque Limiters. Use the required Torque Limiter as follows:
4.5mm - 9.0mm require 90 IN/LBS Final Locking Torque.
9.5mm & 10.5mm require 110 IN/LBS Final Locking Torque.

REDUCTION SCREW ASSEMBLY & INSERTION (OPTIONAL)

ASSEMBLE SCREW INSERTER

1. Attach Ratchet Handle onto the Auto-Locking Reduction Screw Inserter (Figure 10).
2. Insert the tip of the Auto-Locking Reduction Screw Inserter into the Housing of the Reduction Screw.

LOAD, DEPLOY, AND RELEASE POLYAXIAL SCREW

1. Engage hexalobe into Reduction Screw. Advance instrument threads into Reduction Screw Housing while rotating clockwise.

NOTES:

-If the Auto-Locking Reduction Screw Inserter does not engage hexalobe, gently rotate the Screw Shank until the Screw Inserter fully seats into the Screw Housing (Figure 3).

-Torque tight to prevent screw loosening during insertion.

2. Thread Pedicle Screw into pedicle canal to the desired depth.
3. Remove Screw Driver: Rotate thumb wheel counter-clockwise while holding handle fixed to disengage from Reduction Screw. Lift instrument out of surgical area.
4. A Provisional Screw Driver may be used to further advance screws.
5. Repeat Screw selection for desired levels and on contralateral side as desired.



Figure 10

REDUCTION SCREW INSERTION (CONTINUED)

LOCKING SET SCREW DELIVERY

After placing the Rod into the screw housings (refer to ROD SELECTION & DELIVERY), use the Initial Set Screw Inserter with the Alignment Tube to deliver Set Screws into each screw housing. The Reduction Counter Torque can be used for Set Screw delivery.

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

To remove reduction tabs, place the Reduction Tab Remover over either tab for removal (Figure 11). 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.

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 12).

NOTE:

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

Once the ring of the Reduction Crown is below the break line the Reduction Tab Remover can be used to remove tabs.

FINAL TIGHTENING

Refer to COUNTER TORQUE TUBE & LOCKING SCREW DRIVER step above.



Figure 11

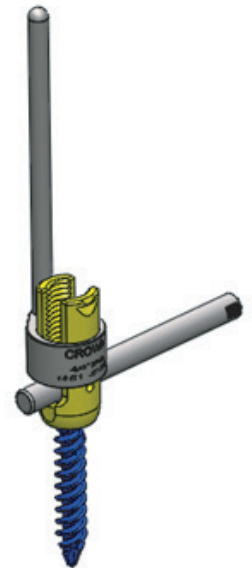


Figure 12

REDUCTION METHODS (OPTIONAL)

"TURBO" TOWER REDUCERS

Turbo Towers (Figure 13) 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. 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.

Attachment:

1. Turn reducer knob counterclockwise until hard stop is reached to allow distal tips of the tower to be positioned outside of the reducer body (Figure 13 A).
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.

Reduction:

3. Rotate the reducer knob clockwise. The outer sleeve of the tower will move downward to contact the rod and drive Rod down into housing.
4. An optional Tower Reducer Wheel (provided) can be attached to the top of the tower to assist with reducer knob rotation if additional leverage is desired.
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 (Figure 13 B).
6. Insert Set Screw into the screw housing (tulip) and provisionally tighten to secure the Rod.

Removal:

7. Turn reducer knob counterclockwise until hard stop is reached to allow distal tips of the tower to be positioned outside of the reducer body (Figure 13 A), then rotate the entire tower 90° counterclockwise to detach from the Screw Housing (tulip).

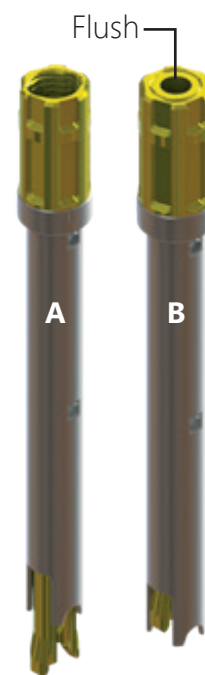


Figure 13

PISTOL ROD REDUCER

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

1. Press straight down over the screw housing (tulip) and engage the ratcheting handle to ensure a locked connection. 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 handles, then Pistol Rod Reducer is free to lift up.

ROD ROCKER REDUCTION

If the Rod is slightly proud above the Screw Housing, then use the Rod Rocker to achieve the fully seated position of the Rod into the Screw Housing.

1. Insert tips of Rod Rocker into holes along the insides of the Screw Housing (Figure 14).
2. Squeeze and lock tips into holes and pivot handle downward levering Rod down into Housing.
3. Insert Locking Set Screw with the Set Screw Inserter. Torque until hand-tight.
4. Open Forcep Handles to remove instrument.

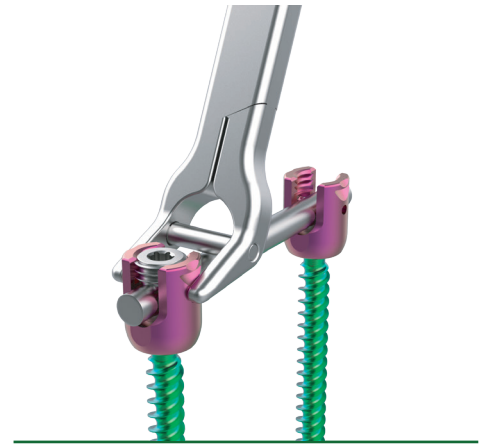


Figure 14

COMPRESSION & DISTRACTION

Once construct has been assembled, it is possible to perform segmental compression or distraction.

1. After determining the level from which to compress or distract, temporarily secure a Locking Set Screw. Hand-tighten and ensure all other Locking Set Screws are loosely engaged.
2. Position the feet of the Compressor (Figure 15) or Distractor (Figure 16) against the Screw Housing. For distraction, position the Distractor inside the Screw Housings to be distracted. For compression, position the Compressor outside the Screw Housings to be compressed.
3. Compress toward or distract away from secured Screw Housing until desired effect is achieved.
4. Engage ratchet handle on instrument to maintain compression or distraction.
5. Hand-tighten the Locking Set Screws.
6. Release and remove the Compressor or Distractor.
7. Complete final tightening of all Locking Set Screws as explained in FINAL TIGHTENING.



Figure 16

IMPLANT PRODUCT NUMBERS AND DESCRIPTIONS

Double Lead Screws



Product Code	Double Lead
10-22-4535	4.5mm x 35
10-22-4540	4.5mm x 40
10-22-4545	4.5mm x 45
10-22-4550	4.5mm x 50
10-22-4555	4.5mm x 55
10-22-5535	5.5mm x 35
10-22-5540	5.5mm x 40
10-22-5545	5.5mm x 45
10-22-5550	5.5mm x 50
10-22-5555	5.5mm x 55
10-22-6535	6.5mm x 35
10-22-6540	6.5mm x 40
10-22-6545	6.5mm x 45
10-22-6550	6.5mm x 50
10-22-6555	6.5mm x 55
10-22-7035	7.0mm x 35
10-22-7040	7.0mm x 40
10-22-7045	7.0mm x 45
10-22-7050	7.0mm x 50
10-22-7055	7.0mm x 55
10-22-7535	7.5mm x 35
10-22-7540	7.5mm x 40
10-22-7545	7.5mm x 45
10-22-7550	7.5mm x 50
10-22-7555	7.5mm x 55
10-22-8535	8.5mm x 35
10-22-8540	8.5mm x 40
10-22-8545	8.5mm x 45
10-22-8550	8.5mm x 50
10-22-8555	8.5mm x 55
10-22-9035	9.0mm x 35
10-22-9040	9.0mm x 40
10-22-9045	9.0mm x 45
10-22-9050	9.0mm x 50
10-22-9055	9.0mm x 55
10-22-9540	9.5mm x 40
10-22-9545	9.5mm x 45
10-22-9550	9.5mm x 50
10-22-9555	9.5mm x 55
10-22-9570	9.5mm x 70
10-22-9575	9.5mm x 75
10-22-9580	9.5mm x 80
10-22-9585	9.5mm x 85
10-22-9590	9.5mm x 90
10-22-10540	10.5mm x 40
10-22-10545	10.5mm x 45
10-22-10550	10.5mm x 50
10-22-10555	10.5mm x 55
10-22-10570	10.5mm x 70
10-22-10575	10.5mm x 75
10-22-10580	10.5mm x 80
10-22-10585	10.5mm x 85
10-22-10590	10.5mm x 90

Lordotic Rods 5.5mm



Product Code	Length
10-6-5530	30
10-6-5535	35
10-6-5540	40
10-6-5545	45
10-6-5550	50
10-6-5555	55
10-6-5560	60
10-6-5565	65
10-6-5570	70
10-6-5575	75
10-6-5580	80
10-6-5585	85
10-6-5590	90
10-6-5595	95
10-6-55100	100
10-6-55110	110

Set Screws

Product Code	Length
10-4-000	4.5-7.5mm
10-4-001	8.5-9.0mm
10-4-002	9.5-10.5mm

Straight Rods 5.5mm



Product Code	Length
10-7-5535	35
10-7-5540	40
10-7-5545	45
10-7-5550	50
10-7-5555	55
10-7-5560	60
10-7-5565	65
10-7-5570	70
10-7-5575	75
10-7-5580	80
10-7-5585	85
10-7-5590	90
10-7-5595	95
10-7-55100	100
10-7-55110	110
10-7-55120	120
10-7-55130	130
10-7-55140	140
10-7-55150	150
10-7-55200	200
10-7-55400	400

INSTRUMENT PRODUCT NUMBERS AND DESCRIPTIONS

Type	Part Number	Description
Handles	I10-01-25	Ratchet T Handle
	I10-01-26	Axial Ratchet Handle 1/4" Square Connect*
	I10-01-27	Palm Ratchet Handle 1/4" Square Connect*
	I10-01-07	Ratchet Straight Handle*
	I10-01-08	Ratchet Palm Handle*
Double Lead Taps	I10-06-35S	Tap, double lead, shallow, Ø3.5mm*
	I10-06-45S	Tap, double lead, shallow Ø4.5mm*
	I10-06-45	Tap, double lead, Ø4.5mm
	I10-06-55	Tap, double lead, Ø5.5mm
	I10-06-65	Tap, double lead, Ø6.5mm
	I10-06-70	Tap, double lead, Ø7.0mm*
	I10-06-70	Tap, double lead, Ø7.5mm*
	I10-06-85	Tap, double lead, Ø8.5mm*
	I10-06-95	Tap, double lead, Ø9.5mm*
	I10-06-105	Tap, double lead, Ø10.5mm*
Probes	I10-05-02	Duckbill Straight Probe (pear) (lumbar)*
	I10-05-03	Duckbill Curved Probe (pear) (lumbar)*
	I10-05-04	Lenke Straight Probe (pear) (thoracic)
	I10-05-05	Lenke Curved Probe (pear) (thoracic)
	I10-05-07	Lenke Straight Probe (pear) (lumbar)*
	I10-05-08	Lenke Curved Probe (pear) (lumbar)*
	I10-05-09	Lenke Straight Probe (gear) (lumbar)*
	I10-05-10	Lenke Curved Probe (gear) (lumbar)*
	I10-05-11	Duckbill Straight Probe (gear) (lumbar)*
	I10-05-12	Duckbill Curved Probe (gear) (lumbar)*
Sounders	I10-05-01	Ball Tip Sounder - Straight
	I10-05-06	Ball Tip Sounder - Curved
Screw & Cap Inserters	I10-33-07	Polyaxial Screw Inserter*
	I10-33-19	Polyaxial Screw Inserter
	I10-33-08	Screw Inserter Sleeve
	I10-33-24	Screw Inserter, Auto-Locking*
	I10-04-25	Set Screw Inserter T25
Final Tighten	I10-01-11	Torque T Handle 1/4 Sq. 90inlb
	I10-02-25	Final Driver T25, 1/4 Sq. Adapter
	I10-15-05	Alignment Tube
	I10-15-06	Anti-Torque Tube/Handle
Rod Holder, Pusher Reducers	I10-08-06	Thin Rod Holder
	I10-09-02	Thin Rod Pusher*
	I10-31-02	Forcep Reducer
Other	I10-32-02	Linked Reducer*
	I10-32-06	Tower Reducer
	I10-32-07	Tower Reducer, Adapter
	I10-02-18	In-Situ Driver, T15, X15TN
	I10-02-20	Head Positioner
	I10-10-04	Distractor - parallel
	I10-11-04	Compressor - parallel
	I10-30-06	French Rod Bender
	I10-30-05L&R	In-Situ Rod Bender
	I10-13-01	Awl
	I10-15-07	Alignment Tube
8.5 & 9.0 Revision Instruments	I10-15-08	Anti-Torque Tube/Handle
	I10-33-05	Polyaxial Screw Inserter Revision
	I10-33-06	Screw Inserter Sleeve Revision
9.5 & 10.5 Revision Instruments	I10-15-11	95105 Counter Torque
	I10-33-26	95105 Polyaxial Screw Inserter
	I10-01-58	Torque Limiting Handle 110 IN/LBS

*Optional instruments by request.





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70-001, Rev. I