Surgical Technique

Inertia® One-Shot Pedicle Screw System

Inertia® Instrument Set

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Introduction

The Inertia® Instrument Set complements the Inertia® One-Shot Pedicle Screw System. The combined systems offer the ability to perform single- and multi-level lumbar fusion procedures in an open, mini-open, or minimally invasive fashion providing unique surgical flexibility for the surgeon and their patients. The system is based on a 5.5mm rod adhered to polyaxial screws of standard sizes of 6.5 and 7.5mm diameter single lead screws. One-Shot screws are single lead to allow optimal direction of the screw through the pedicle during insertion.

For indications, contraindications, precautions and warnings concerning Nexxt Spine's Inertia One-Shot Pedicle Screw System, refer to Essential Product Information at the end of this surgical technique manual or the product Instructions for Use. The procedure contained herein outlines the technique for open placement of the Inertia One-Shot Pedicle Screw System. For additional information please contact Nexxt Spine at (317) 436-7801 or Info@NexxtSpine.com.

Operating Room Setup and Pedicle Preparation

Follow preferred surgical technique for patient positioning, pedicle identification, and targeting. The following 5 steps are OPTIONAL when using the One-Shot Screw:

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

2. 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.

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

4. Select desired screw length based on Probe or Sounder markings.

5. Select Tap that matches preferred Pedicle Screw diameter and assemble to Ratchet Handle. Advance Tap to desired depth as shown on graduated markings of Tap.

NOTE: Taps labeled double lead are identical in size to the corresponding screw.

Taps are labeled to correspond with Screw size. Actual single lead tap diameter is undersized by 0.2mm relative to Screw diameter indicated. Taps labeled double lead are identical in size to the corresponding screw. 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.

Screw Assembly & Insertion

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

Assemble Screw Inserter

- Attach Ratchet Handle and optional screw inserter Sleeve onto the Screw Inserter
- Insert the Screw Inserter into the Housing of the Pedicle Screw (Figure 1)

Figure 1

Load, Deploy, and Release Polyaxial Screw

- Engage torx into Polyaxial Screw. Advance instrument threads into Polyaxial Screw Housing while rotating clockwise.

  NOTE: Torque tight to prevent loosening during insertion

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

Rod Selection and Delivery

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

- Select appropriate length Rod. Use Rod Benders as needed to contour either Straight Rods or Pre-lordosed Rods to desired curvature.
- Deliver selected Rod using the Rod Holder and position in Screw Housings at all levels.
- If additional rod curvature is desired before inserting, use a Rod Bender (Figure 2); or if after inserting, then use In-situ Rod Benders to reshape.
- Screw Housings have a *Snap-in* feature that allows semi-fixation of the rod while positioning (Figure 3). The rod may be removed from the *Snap-in* feature and repositioned.

Figure 2

Figure 3

Locking Set Screw Delivery

Use the Locking Set Screw Inserter (Figure 4) by itself or 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.

Figure 4

- 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 until Locking Set Screw disengages, then turn again clockwise to align threads.

Counter Torque Tube & Locking Set Screw Driver

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

Figure 5

Figure 6

- Place distal tip of Counter Torque Tube over Screw Housing.
- Insert Locking Set Screw down the center of Counter Torque Tube, insure driver is fully buried into the Set Screw which is evident when black line is buried into tube (Figure 6).
- Turn Locking Set Screw clock-wise until Torque Limiting Handle pops.
- Repeat for all Screw Housings.

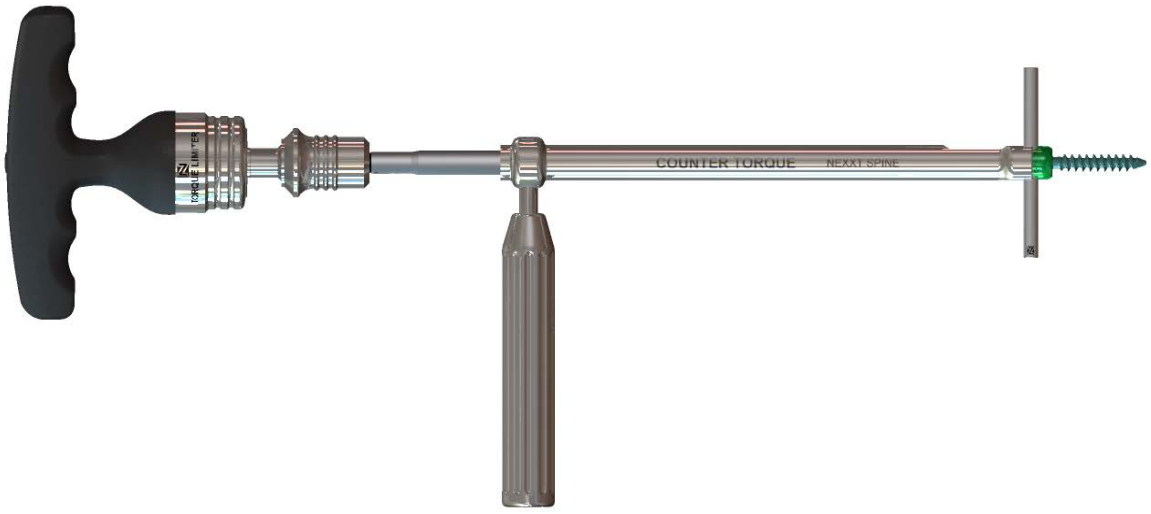

Figure 6

Levered Rod Reducer for Reduction (optional)

If the rod is up to 25 mm proud, then use the Levered Rod Reducer to achieve the final position of the Rod into the Screw Housing.

- Press down and snap the Reducer's legs straight down over the Screw Housing until it clicks into the side grooves (Figure 7). The handle must be in the open position to connect to the Screw Housing.
- Squeeze the handle towards the instrument to draw the Rod down into the Screw Housing (Figure 7).
- Insert Locking Set Screw hand-tight into Screw Housing to secure the Rod.
- After initially tightening the Locking Set Screw, the instrument can be removed. Open the Rod Reducer's Handle and rotate the instrument to snap the instrument legs off the Screw Housing (Figure 8).

Figure 7

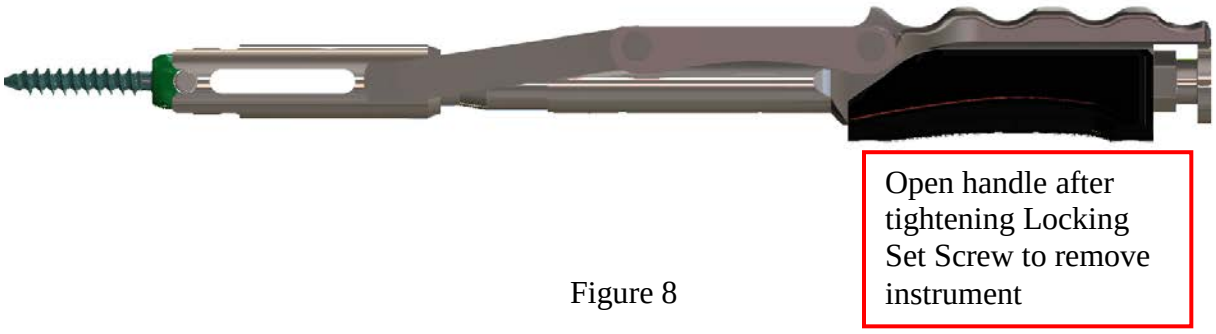

Figure 8

Rod Fork Reducer (optional)

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

- Insert tips of Rod Fork Reducer into holes along the sides of the Screw Housing (Figure 9).
- Squeeze and lock tips into holes and pivot handle downward levering Rod down into Housing.
- Insert Locking Set Screw with the Set Screw Inserter. Torque until hand-tight.
- Open Forcep Handles and remove instrument.

Figure 9

Compression & Distraction (optional)

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

- After determining the level from which to compress or distract, temporarily secure a Locking Set Screw hand tight and ensure all other Locking Set Screws are loosely engaged.
- Position the feet of the Compressor or Distractor 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.
- Compress toward or distract away from secured Screw Housing until desired effect is achieved.
- Engage ratchet handle on instrument to maintain compression or distraction.
- Tighten Locking Set Screws hand-tight.
- Release and remove Compressor or Distractor.
- Complete final tightening of all Locking Set Screws as explained on page 8.

Figure 10 Compressor

Figure 11 Distractor

Implant & Instrument Catalog Numbers & Description

Standard Implant Catalog Numbers and Descriptions

Inertia One-Shot Pedicle Screw System

Screws	Product Code
6.5mm x 30	10-20-6530
6.5mm x 35	10-20-6535
6.5mm x 40	10-20-6540
6.5mm x 45	10-20-6545
6.5mm x 50	10-20-6550
6.5mm x 55	10-20-6555
6.5mm x 60	10-20-6560
7.0mm x 30	10-20-7030
7.0mm x 35	10-20-7035
7.0mm x 40	10-20-7040
7.0mm x 45	10-20-7045
7.0mm x 50	10-20-7050
7.0mm x 55	10-20-7055
7.0mm x 60	10-20-7060
7.5mm x 30	10-20-7530
7.5mm x 35	10-20-7535
7.5mm x 40	10-20-7540
7.5mm x 45	10-20-7545
7.5mm x 50	10-20-7550
7.5mm x 55	10-20-7555
7.5mm x 60	10-20-7560
Set Screws	
4.5-7.5	10-4-000

Lordotic Rods 5.5mm

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

Straight Rods 5.5mm

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

Instrument Catalog Numbers and Descriptions

Type	Part Number	Description
Handles	I10-01-06	Ratchet T Handle Pull
	I10-01-07	Ratchet Straight Hand Pull
	I10-01-08	Ratchet Palm Handle Pull
Single Lead Taps	I10-03-55	Tap, single lead, 5.5 Dia
	I10-03-551	Tap, single lead, 5.5 Dia - Cancellous
	I10-03-65	Tap, single lead, 6.5 Dia
	I10-03-75	Tap, single lead, 7.5 Dia
Double Lead Taps	I10-06-55	Tap, double lead, 5.5 Dia
	I10-06-65	Tap, double lead, 6.5 Dia
	I10-06-75	Tap, double lead, 7.5 Dia
Probes	I10-05-02	Straight Probe
	I10-05-03	Curved Probe
Feelers	I10-05-01	Ball Tip Feeler
	I10-05-06	Ball Tip Feeler Curved
Screw & Cap Inserters	I10-33-02	Polyaxial Screw Inserter
	I10-33-08	Screw Inserter Sleeve
	I10-04-25	Set Screw Inserter T25
Final Tighten	I10-01-11	Torque T Handle 1/4 Sqr - 90inlb
	I10-02-25	Torque Shaft T25, 1/4 Adapter
	I10-15-05	Alignment Tube
	I10-15-06	Anti-Torque Tube/Handle
Rod Holder & Pusher	I10-08-06	Thin Rod Holder
	I10-09-02	Thin Rod Pusher
Reducers	I10-31-02	Forcep Reducer
	I10-32-02	Linked Reducer
Other	I10-02-15	T15 Insitu Driver
	I10-10-02	Distractor-parallel
	I10-11-02	Compressor- parallel
	I10-30-04	French Rod Bender
	I10-30-05L&R	In-Situ Rod Bender
	I10-13-01	Awl
8.5 & 9.0 Revision Instruments	I10-15-07	Alignment Tube
	I10-15-08	Anti-Torque Tube/Handle
	I10-33-05	Polyaxial Screw Inserter Revn
	I10-33-06	Screw Inserter Sleeve Revn

Essential Product Information

Nexxt Spine LLC, 14425 Bergen Blvd, Suite B, Noblesville, IN 46060
Phone: (317) 436.7801 Fax: (317) 245.2518

Inertia™ Pedicle Screw System Package Insert

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

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.

IMPORTANT NOTE TO OPERATING SURGEON

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. 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 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.

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. Verify that all instruments are in their open and unlocked position prior to sterilization. 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

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. See also the WARNINGS, PRECAUTIONS AND POTENTIAL RISKS sections of this insert.

WARNINGS

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. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

See the Potential Risks section of the package insert for a complete list of potential risks.

PRECAUTIONS

1. **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.
2. **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.
3. **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.
4. **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 <u>not</u> intended to be used as the sole support for the spine.
5. **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.
6. **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.
7. **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.
8. **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.
9. **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.

POTENTIAL RISKS

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.

Nexxt Spine LLC
14425 Bergen Blvd, Suite B
Noblesville, IN 46060
T 317-436-7801
F 317-245-2518
www.NexxtSpine.com