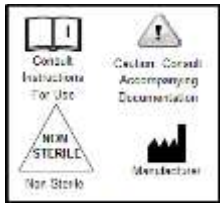
INERTIA® PEDICLE SCREW AND DEFORMITY CORREXXION™ SYSTEM

SYMBOL TRANSLATION



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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 ***Hospital Reprocessing Procedure*** document available at www.NexxtSpine.com/Resources/Indications-For-Use or by calling 317-436-7801 for a copy of the detailed cleaning instructions.

STERILIZATION

The Inertia® Pedicle Screw and Deformity Correxxion™ System implants are supplied non-sterile. 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.

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.