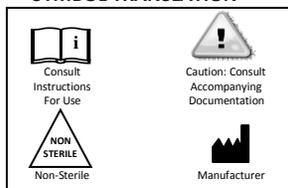


NEXT Spine

INERTIA® PEDICLE SCREW SYSTEM

SYMBOL TRANSLATION



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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION IMPORTANT

This booklet is designed to assist in using the Next Spine Inertia™ Spinal 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 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 Next 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. All implant components are manufactured from Titanium alloy (Ti-6Al-4V ELI) per ASTM F-136.

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

Cleaning/Reprocessing of NEXXT Spine Surgical Instruments

Next 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 Next 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 Next 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. Next 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

- 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.
- 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.
- 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.
- 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.
- 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.
- 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.

- 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.
- 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.
- 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.
- 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

- Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warning and Precautions should be avoided.
- Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
- An adequate inventory of implant sizes should be available at the time of the surgery.
- All components must be cleaned and sterilized before use.
- 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

- Rods may be pre-bent to the degree of correction determined by preoperative testing, however reverse bends should be avoided.
- The placement of screws should be checked radiographically prior to assembly of the rod construct.
- Care should be taken when positioning the implants to avoid neurological damage.

POSTOPERATIVE

- 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.
- 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.
- 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.
- 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.
- 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.