NIDO™ Pedicle Screw System

Product Instructions for Use

Kalitec Medical
618 E. South Street, Suite 500
Orlando, FL 32801
(407) 545-2063

Non-Sterile Product ***SINGLE USE***

BEFORE USING THIS PRODUCT, READ THE FOLLOWING THOROUGHLY.

Important Information on the NIDO Pedicle Screw System

Description:
The Kalitec Medical NIDO Pedicle Screw System is used as a non-cervical spinal fixation device 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: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The NIDO Pedicle Screw System is comprised of various types and sizes of screws, rods, and connectors. The implant components are selected for the individual case, being placed in a variety of configurations. The NIDO Pedicle Screw System implants are made from medical implant grade titanium alloy Ti-6Al-4V (ELI) per ASTM F-136.

Caution:
Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

All implants are intended for single use only. The NIDO Pedicle Screw System components should not be reused under any circumstances. Do not use the NIDO Pedicle Screw System components in conjunction with components from any other system or manufacturer other than the Kalitec Medical Cosmolock Pedicle Screw System. These instructions are designed to assist in the use of the NIDO Pedicle Screw System and are not a reference for surgical techniques.

Indications for Use:
The NIDO 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 thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

The NIDO Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudarthrosis; and failed previous fusion.

The NIDO™ Pedicle Screw System Cannulated/Fenestrated Screws are intended to be used with saline and radiopaque dye.

Contraindications:
- Acute or chronic infectious diseases of any etiology and localization
- Signs of local inflammation
- Open wounds
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Metal/polymer sensitivity/allergies to the implant materials
- Mental illness, alcoholism, drug abuse
- Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis).
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Symptomatic cardiac disease.
- Systemic or terminal illness.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

Possible Adverse Events:
A listing of possible adverse events includes, but is not limited to:
- Bending, disassembly, or fracture of any or all components of the implant.
- Loosening of the implant.
- Implant material sensitivity, or allergic reaction to a foreign body.
- Infection, early or late.
- Decrease in bone density due to stress shielding.
- Increased biomechanical stress on adjacent levels.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by improper positioning and placement of implants or instruments.
- Loss of correction, curvature, height, and/or reduction.
- Dural tear and/or leak.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems (i.e. pulmonary embolism, bronchitis, pneumonia, etc.).
- Non-union (or pseudarthrosis), delayed union and/or mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function.
- Death.

Note: Re-operation or revision may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions:
Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

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 degenerative spondylolisthesis with objective evidence of neurologic 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. The implantation of the NIDO Pedicle Screw System should be performed only by experienced spine surgeons with specific training in the use of spinal pedicle screw instrumentation because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, etc. which may impact the performance of the system.

The safety and effectiveness of the NIDO Pedicle Screw System devices have not been established when used in conjunction with bone cement or for use on patients with poor bone quality (e.g., osteoporosis, osteopenia). The NIDO Pedicle Screw System fenestrated screws are intended only to be used with saline or radiopaque dye.

When utilizing parallel domino or tulip rod connectors to join segments of rod, a minimum of two connectors per union are required for construct stability.

The NIDO Pedicle Screw System has not been evaluated for safety and compatibility within the MR environment. The NIDO Pedicle Screw System has not been tested for heating or migration in the MR environment.

If a reusable device is/was used in a patient with, or suspected of having, Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize and eliminate the risk of cross-contamination.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Implant Selection:
The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. When used the system connectors must be deployed in pairs and never singly to ensure proper immobilization and stabilization of spinal segments. Contouring or bending of rods only is recommended if necessary according to the surgical technique of each system. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods, which have been repeatedly or excessively contoured, must not be implanted. Overweight patients may be subject to additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or

failure of the implants. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery.

Preoperative:

- Only patients that meet the criteria described in the indications should be selected.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery.
- The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The NIDO™ Pedicle Screw System components are not to be combined with the components from another manufacturer
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
- All sets should be carefully checked for completeness and all components should be carefully inspected prior to all surgeries.

Intraoperative:

- Any instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Cut the rods outside the operative field.
- Imaging system should be used whenever possible to facilitate surgery.
- Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.
- Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.
- Before closing the soft tissues, all of the locking screws should be tightened firmly.

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved NIDO Pedicle Screw System components should ever be reused under any circumstances.

Packaging:

Packages for each of the components should be intact upon receipt. All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to Kalitec Medical.

Cleaning and Decontamination:

Implants and instruments of the Nido Pedicle Screw System are supplied clean and NOT STERILE, and must be sterilized prior to use.

Cleaning:

All instruments must first be cleaned before sterilization and introduction into a sterile surgical field.

Manual Cleaning:

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment.

Prepare an enzymatic cleaning solution per manufacturer's specifications. Separate dissimilar metal instruments and disassemble all instruments. Fully immerse and soak all instruments in enzymatic cleaner for 15 minutes. Use a small soft-bristle brush to remove visible soil from all surfaces of the instrument while fully immersed in the solution paying special attention to remove soil from hinges, jaws, tips, box locks, and ratchets. Agitate the instruments in the solution while scrubbing. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Actuate any movable parts to loosen any trapped soil. Rinse instruments under warm (38-49°C) running water until all evidence of detergent is removed. Place the instrument into a bath containing warm (38-49°C) water. Agitate the instruments by hand for at least three minutes. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Prepare an enzymatic cleaning solution to the manufacturer's specifications using distilled water. Ultrasonicate devices for 10 minutes, ensuring the devices are completely submerged. Rinse instruments under warm running water for at least one minute or until all evidence of detergent is removed. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Dry with clean lint-free cloth and/or allow to air dry.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The instruments should be inspected and checked to make certain they are functioning properly. Visually inspect all devices for any evidence of deterioration, corrosion, and/or discoloration and if found, the instrument should be replaced.

Automated Cleaning:

Rinse devices under running tap water to remove gross soils. Particular attention must be given to crevices, lumens, mated surfaces and other hard to clean areas. Use a syringe or jetted water to flush difficult to reach areas.

Place instruments in a suitable washer basket or system tray and process through a standard instrument washer. The table below represents the minimum parameters required for proper cleaning and disinfection:

Step	Description
1	2 minute Cold Water Prewash, temperature as supplied
2	5 minute Enzymatic Wash, 43ºC minimum
3	5 minute Hot Tap Neutral Detergent Wash 55ºC minimum
4	2 minute Hot Tap Water Rinse, temperature as supplied
5	1 minute Pure Water Rinse, 90ºC minimum
6	15 minute Hot Air Dry, 90ºC minimum

Notes:

- The washer manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector.
- A washer/disinfector with approved efficacy (e.g., CE mark, FDA clearance, and validation according to ISO 15883) should be used.
- Avoid impact, scratching, bending, or surface contact with any material that might affect the implant or instrument surface or configuration.
- Pay particular attention to recesses as chemicals and rinse water may be entrapped in the recess after rinsing.
- Visually inspect all devices after cleaning to ensure cleanliness and function.

Sterilization:

The NIDO Pedicle Screw System instruments and implants are provided non-sterile. All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the process parameters below:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum	270°F(132°C)	4 minutes	60 minutes

Wrap tray with a towel placed between tray and FDA cleared wrap. The provided containment devices are not self-contained and require a sterilization wrap to maintain sterile integrity once the containment device and its contents are sterilized.

Do not stack trays during sterilization. Trays should only be loaded utilizing the provided brackets and as indicated by the device shadow outlines on the tray inserts to ensure proper sterilization of the contents and that maximum tray weight of 25 pounds is not exceeded.

The Sterility Assurance Level (SAL) is 1×10^{-6}, via the indicated methods. No claims of pyrogenicity are made.

Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to Kalitec Medical.

It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.

Product Complaints:

Any Health Care Professional, who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify Kalitec Medical or its representative. Further, if any of the implanted NIDO Pedicle Screw System component(s) ever malfunctions, Kalitec Medical or its representative should be notified immediately.

If any Kalitec Medical product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or Kalitec Medical should be notified immediately by telephone, fax or in writing.

For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help Kalitec Medical understand the cause of the complaint.

If further information is needed or required, please contact:

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