LANTERNA MEDICAL TECHNOLOGIES

SANTIS™ Pedicle Screw System
Please read carefully
INSTRUCTIONS FOR USE

Package Insert – Santis™ Pedicle Screw System

IMPORTANT NOTE
The users acknowledge that they have read and agreed on the conditions in this insert, which are considered to be contractual.

CAUTION
Federal Law restricts the device to be sold by, or on the order of a Physician.

BASIC STRUCTURE
The **Santis™ Pedicle Screw System** is comprised of: Rods, Pedicle Screw Assemblies for open and minimally invasive procedures, and Cross Connector Assemblies. Various sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology and anatomy of individual patients.

MATERIAL
Components are made of Ti6Al4V ELI, a titanium based alloy, which complies with ASTM F136. The Cobalt-Chrome rods are made from wrought Co-Cr-Mo alloy, which complies with ASTM F1537.

INDICATION FOR USE
The Santis™ Pedicle Screw System is intended for immobilization and stabilization of the spine. The Santis™ Pedicle Screw System is indicated for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (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, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

PRECAUTION:
The implantation of the Santis™ Pedicle Screw System should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw system; because this is a technically demanding procedure presenting a risk of serious injury to the patient.

LEVEL OF FIXATION
Levels of fixation are for the Thoracic, Lumbar, and Sacral spine.

GENERAL CONDITIONS OF USE
- The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with the surgical and medical indications, the potential risks, and limitations related to this type of surgery; the contraindications, side effects, and precautions defined, and in the knowledge of the nature and metallic, metallurgic and biological characteristics of the implants.
- Detailed surgical technique manuals are made available by Lanterna GmbH and supplied through sales representatives. It is recommended that an extensive review of the surgical technique manual is done before attempting surgery.
- Under no circumstances may the implants be re-used; although the device may appear intact on removal, internal modifications due to the stresses and strains placed on it, or small defect may exist which may lead to failure of the implant.

WARNING:
- "Warning: 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 (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown."
- Benefits of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with an unstable spine;

- There are potential risks associated with the use of this system. These risks, if realized, may require additional surgery; risks include but are not limited to: device component fracture, lose of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury;
- Discard all damaged or mishandled implants;
- Never reuse an implant; even if it appears to be undamaged;
- Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stresses of full weight bearing activities, or implant failure may result;
- Contouring of or bending of a screw, hook, and/or rod may reduce its fatigue strength and cause failure under load. If a spinal screw or hook is bent or otherwise damaged during insertion or adjustment, they must not be implanted and must be replaced. Rods should only be contoured with the proper contouring instrument. Incorrectly contouring rod, or rods that have been repeatedly or excessively contoured must not be implanted;
- Mixing Metals; never mix titanium alloy or cobalt chrome with any stainless steel material.
- The Santis™ Pedicle Screw System should not be used in conjunction with components from any other manufacturer's spinal system.
- Any decision, by a surgeon, to remove the internal fixation device should take into consideration such factors as the risk to the patient by undergoing an additional surgery procedure as well as the difficulty of implant removal;
- Implant removal should be followed by adequate postoperative management to avoid fracture.
- The Santis™ Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment nor tested for heating or migration in the MR environment.

CONTRA-INDICATIONS

- Any active or suspected latent infection in or about the spine;
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complication in post-operative care;
- Bone stock compromised by disease, infection, or prior implantation which cannot provide adequate support, and/or fixation to the device;
- Obesity; an overweight or obese patient can produce loads on the device that exceed maximum load design specification;
- Open wounds;
- Metal sensitivity, documented or suspected;
- Bone resorption, osteopenia and/or osteoporosis;
- Patients having inadequate tissue coverage over the operative site;
- Pregnancy;
- Excessive local inflammation;
- Other medical or surgical conditions which would preclude the potential benefit or spinal implant surgery; such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count;

PRECAUTIONS

- Based on the fatigue testing results; the physician/surgeon should consider the level of implantation, patient weight, patient activity level, or patients condition, etc. which may have an impact on the performance of the system;
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences;
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting or muscle strain) resultant forces can cause failure of the device;
- In some cases, progression of degenerative disease may be so advanced at the time of implantation; the disease may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as delaying technique or to provide temporary relief;
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the spinal fixation device. Spinal fixation systems require detailed knowledge of spinal surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement on implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome;
- The patient should be informed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal healthy bone and may bend, loosen, or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation;
- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implants service life.

- As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indication, contra-indications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risk, the size and shape of human bone presents limitations on the size shape, and strength of the implant.);
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive object. Alterations will produce defects in surfaces finish and internal stresses which may become the focal point for eventual breakage of the implant.

SIDE-EFFECTS

- Late bone grafting or no visible fusion mass and pseudarthrosis;
- Neurological complication, paralysis, soft tissue lesions, and/or migration of the implant;
- Pedicle failure while preparing and inserting the pedicle screws;
- Superficial or deep-set infection and inflammatory phenomena;
- Allergic reaction to the Ti6AL4V ELI alloy or cobalt chrome;
- Reduction in bone density due to different distribution of mechanical stresses;
- Pain and/or abnormal sensations due to hardware bulkiness;
- Neurological and spinal dura mater lesions from surgical trauma;
- Bursitis;
- Presence of micro-particles around the implants;
- Growth of the fused vertebra is altered;
- Partial loss of the degree of correction achieved during surgery;
- Modification of spinal curvature and stiffness of the vertebral column.
- Death

The above list of side-effects is not exhaustive. These side-effects can sometimes necessitate further surgical treatments.

PACKAGING, LABELING AND STORAGE

- The implants are provided in both STERILE and NON STERILE formats. NON STERILE implants must be cleaned and sterilized before use: (see below)
- The instruments are supplied NON-STERILE**.** They must be cleaned and sterilized before use; (see below)
- In the case of STERILE implants, the packages must be intact at the time of receipt. All legal information required for this type of implant is given on the label and insert of each package;
- Use care in handling and storage of implants component. Cutting, sharply bending, or scratching the surface of the implants can significantly reduce the strength and fatigue resistance of the implant components.

CLEANING AND DISINFECTING PROCEDURES

- All reusable instruments should be cleaned and disinfected between uses. Follow the directions below to properly clean and disinfect reusable instruments prior to sterilization.
    - Disassembly – Where possible, disassemble all instruments prior to cleaning, disinfection and sterilization.
    - Clean instruments immediately after use to prevent tissue or bodily fluids from drying on the instruments.
- Decontamination – Saturate the entire surface with full strength disinfectant/cleaner and allow it to remain in contact for 5 minutes. Do not use high acidic (pH <4) or high alkaline (pH >10) products.
    - Cleaning Instructions

Pre-Cleaning	Remove gross contaminants by immersing devices in a neutral pH enzymatic cleaner.
	Rinse under warm, running, potable tap water for two(2) minutes
	Scrub with an appropriate soft-bristle brush until clean.
	Thoroughly clean the instruments.
Washing	Wash in an ultrasonic cleaning bath filled with neutral enzymatic detergent solution (e.g. Miltex EZ-Zyme) prepared according to the manufacturer's instructions
	Ultrasonicate for 10 minutes or per manufacturer's instructions
Rinsing	Disassemble the Extension Tower as described below.
	Rinse under warm, running, potable tap water for two(2) minutes.
Inspection	Visually inspect the instruments to confirm there is no visual contamination. If this end point cannot be met. Dispose of the instrument.
Drying	Dry devices using an absorbant, non-shedding cloth or industrial hot dryer, or place into a drying cabinet until all moisture is removed.

- Preparation and Assembly – Assemble all instruments that were previously disassembled. Perform a visual and functional inspection of all instruments to verify that they are in working order. Replace any reusable instruments that are cracked or damaged or do not function.
- Return the instruments to the instrument trays for sterilization.

STERILIZATION PROCEDURES

- The instruments are supplied NON-STERILE
- Implants are provided in both STERILE and NON STERILE formats. In the case of NON STERILE implants and all instruments, please follow these instructions
- ANSI/AAMI ST79 guidelines for in-hospital sterilization should be followed for all implants and instruments. Implants and instruments should be sterilized in the sterilization case provided. Sterilization cases should be wrapped with two layers of FDA-Cleared wrap, with a surgical towel placed between the bottom of the tray and the wraps. Using a properly functioning and calibrated steam sterilizer, the following parameters may be used for effective sterilization:
  - Pre-Vacuum Steam Sterilization
  - 132°C (270°F) Sterilization Temperature
  - 4 Minute Sterilization Time
  - 40 to 50 Minute Dry Time

USEFUL LIFE OF INSTRUMENTS

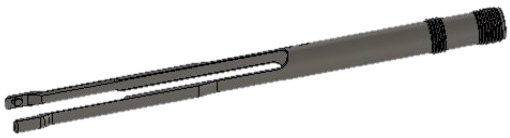
Routinely inspect devices for wear and tear. If evidence of wear such as corrosion, pitting, or discoloration is observed, dispose of the instrument and obtain a new instrument from the manufacturer. If any cutting instruments become dull and do not function properly, obtain a new instrument from the manufacturer.

Disassembly, assembly and Cleaning Instructions
SANTIS™ Screw Extension Tower- Article # MIS 7902
Quick Reference Guide

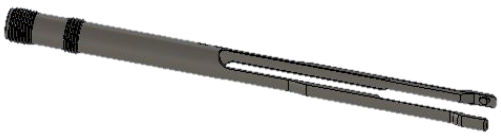
LANTERNA MEDICAL TECHNOLOGIES RECOMMENDS THE FOLLOWING DISASSEMBLY, ASSEMBLY AND CLEANING SEQUENCE:

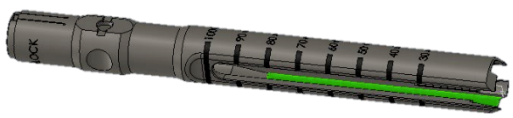
1. After use or surgery, turn the collar in a clockwise direction while applying gentle upward pressure on the internal component.

2. Remove the internal component by pulling it out of the tower. – Clean both parts thoroughly. (Refer to Cleaning and Disinfecting Procedures).



3. After cleaning, Insert the inner sleeve into the top of the TOWER and align the two prongs with the internal tracks.





4. Insert DILATOR 2 from the opposite end of the TOWER. This will properly set the prongs into the tracks of the TOWER. Advance the inner sleeve until it is fully seated in the TOWER.

5. Turn the collar counter clockwise to properly secure the inner sleeve with the TOWER.

GUARANTEE
The guarantee is only applicable if the device is used in accordance with normal conditions as defined in this instruction insert and in conformity with the recommended surgical technique.

The surgical technique may be obtained by contacting Lanterna at the address below.

Manufacturer:

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