English
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STERILE
IMPLANTS

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CE 0088 (Implants) STERILE R CE (Instruments)

1.0 Description:

SANTIS™ Polyaxial Pedicle Screw Implant:

The SANTIS™ Polyaxial Pedicle Screw Implant is intended for posterior approach. It consists of two components comprised wholly of Titanium Alloy.
Typically, eight components are used to treat a single level. It is offered in a variety of diameter sizes and lengths. The length is measured between the tip of the distal aspect and top of the proximal aspect of the body of the screw.

2.0 Indications:

The devices are intended for use in patients with degenerative or otherwise diseased spine that is unresponsive to conservative treatment. These patients may also have up to Grade II Spondylolisthesis at the involved levels.

3.0 Contraindications:

Contraindications include but are not limited to:

- Active infections that may spread to the surgical level(s) Hematogenously
- Osteopenia or osteoporosis to a degree that would contraindicate spinal instrumentation,
- Inadequate bone stock to fix the component
- Patients unwilling to follow postoperative instructions
- Mental illness or substance abuse
- Systemic disease that requires the chronic administration of nonsteroidal anti-inflammatory or steroidal drugs
- Spinal conditions other than those indicated
- Morbid obesity
- Grossly distorted anatomy or
- Known or suspected sensitivity to metal

4.0 Warnings and Precautions

Spine surgery is not always successful. Preoperative symptoms may not be relieved or may worsen. Surgical knowledge of the procedure and the device are important, as is patient selection. Patient compliance is also important. Tobacco and alcohol abuse may lead to unsuccessful results.

Results may be worse with multilevel disease. Supplemental fixation may be required in certain cases. The surgeon should be familiar with fixation techniques and appropriate hardware.
Only SANTIS™ Polyaxial Pedicle Screw instrumentation should be used with SANTIS™ implant components, do not use implants or instruments from other systems or manufacturers in combination.

Other warnings include:

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. The implants are provided non-sterile and for single use only and may be re-sterilized but NOT re-used.
3. The packaging and implant should be inspected for damage prior to surgery.
4. The surgeon should be familiar with the various devices and instruments and verify that all are available before beginning surgery.
5. All instruments should be cleaned and sterilized before use.

Intraoperative:

1. Instruction manuals should be followed.
2. Extreme caution should be used around the spinal cord, nerve roots and blood vessels.
3. Ensure that the implant is properly placed and seated prior to closing the soft tissue.

Postoperative:

1. The patient should limit activities that result in overhead lifting, repetitive bending or heavy lifting until solid bony fusion is achieved.
2. Non steroidal anti-inflammatory and steroidal drugs should be avoided for at least 90 days postoperatively.

3. Although the implanted devices have not been tested for MRI and/or CT safety, research shows that similar devices are considered safe for post-op evaluation using MRI / CT equipment. [1]

5.0 Possible Adverse Effects

As with any surgical lumbar procedure, complications may occur. Potential risks include:

- Pseudoarthrosis
- Dural tears or leaking; spinal cord or nerve root trauma
- Reoperation
- Leg pain, tingling or warmth
- Back pain
- Vessel damage or bleeding
- Hematoma
- Ileus
- Postoperative infection
- Atelectasis, pneumonia
- Scarring, herniation or degeneration of adjacent discs
- Breakage of any or all of the components, implant migration, loss of purchase, implant fracture, and bone fracture
- Foreign body reactions to the implant including infection
- Death
- Additional complications which are not anticipated may also occur.

6.0 Cleaning and Sterility

The SANTIS™ Polyaxial Pedicle Screw **Implants** are provided sterile. Before use, they should be carefully inspected to ensure that the package is intact and free from damage. If damaged in any way, the implants should not be used but should be returned to LANTERNA.
SANTIS instruments are provided NON STERILE. They should be washed in an automatic washer disinfector machine and steam sterilized in accordance with institution's sterilization protocols and procedures prior to use.
The **instruments** in cases should be wrapped and steam sterilized in an autoclave on a pre-vacuum cycle at >132°C for a period of >4 minutes, with a minimum drying time of 40 to 50 minutes.
The instruments are re-usable and should be re-cleaned prior to steam re-sterilization as described above.
The implants are single use,
The recommended standard for steam sterilization is ISO 17665-1 2006.

Reference:
1 Shellock, F.G. "Reference Manual for Magnetic Resonance Safety, Implants, and Devices", 2008 edition.