Spinal System

INSTRUCTIONS FOR USE

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Spinal System consists of a variety of polyaxial screws, rods, hooks, locking nuts, and rod-to-rod connectors. Implant components can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient.

All components are made of titanium alloy, Ti-6Al-4V.

INDICATIONS

When used as a pedicle screw fixation system, the Teslake Spinal 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 posterior thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture
4. Dislocation
5. Scoliosis
6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

The Teslake Spinal System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the Teslake Spinal System is also intended for the following indications:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Spinal stenosis
3. Spondylolisthesis
4. Spinal deformities
5. Fracture
6. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

CONTRAINDICATIONS

The Spinal System should not be implanted in patients with active systemic infection or infection localized to the site of implantation.

Severe osteoporosis may prevent adequate fixation to the bone and those preclude the use of this or any other spinal instrumentation system.

WARNINGS

• Use as indicated. The safety and effectiveness when implanted in the spine for any other indications has not been established.
• Explanted components should not be re-used under any circumstances.
• The Teslake Spinal System should not be used together with the components from any other manufacturer, since the compatibility of the systems has not been established.

PRECAUTIONS

• Use of the Spinal System should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with spinal fusion procedures and spinal fixation; and has had hands-on training in the use of this device.

• One or two Spinal System screws should be implanted at each surgical level.
• The Spinal System should not be implanted in patients with severe osteoporosis or osteopenia.
• The surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
• The Spinal System is supplied non-sterile. It must be sterilized before use.
• Implant components can break when subjected to the increased loading associated with delayed union or nonunion.
• Patients with previous spinal surgery at the level to be treated may have different outcomes compared to those without previous surgery.

The following potential adverse events (singly or in combination) could also result from the implantation of the Spinal System:

1. Bursitis.
2. Decrease in bone density due to stress shielding.
3. Degenerative changes or instability of segments adjacent to fused vertebral levels
4. Fracture of bony structures.
5. Implant material sensitivity, or allergic reaction to a foreign body.
6. Infection, early or late.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Nonunion, delayed union.

9. Discomfort, or abnormal sensations due to the presence of the device.
10. Paralysis.
11. Spinal cord impingement or damage.
12.Vascular damage could result in catastrophic or fatal bleeding
13. Death.

INFORMATION FOR PRESCRIBERS
• Correct selection of the appropriate implant size is important.
• Surgical implants must never be reused or re-implanted. Even though the device appears undamaged, it may have defects and internal stresses that may lead to early breakage.

HOW SUPPLIED
The Spinal System is supplied non-sterile.

RECOMMENDATIONS FOR STEAM STERILIZATION:
The individual products are recommended to be steam sterilized by the hospital in a gravity-displacement autoclave cycle at 270°F (132°C) for a minimum of 3 minutes exposure time with a 1 minute drying time.

When using a prevacuum cycle, an exposure time of 4 minutes at 132°C (270 °F) should be the minimum used, followed by a drying time of at least 20 minutes. Please note that drying times will be variable for different conditions, steam quality, total mass in the sterilizer, and varying cool down time. The user should perform inspections to confirm that products have been appropriately dried, and adjust drying time if required. Only FDA-cleared wraps should be used. Additionally the user should adhere to their standard sterilization validation procedures.

The fully loaded implant and instrument trays are recommended to be steam sterilized by the hospital using an FDA cleared wrap in a gravity-displacement autoclave cycle at 270°F (132°C) for a minimum of 15 minutes of exposure with a 30 minute drying time.

These sterilization recommendations follow the guidelines for sterilization per ANSI/AAMI ST79.

Remove all packaging materials prior to sterilization.

Use only sterile products in the operating field.

CLEANING AND DECONTAMINATION
Any instruments and implants that have been taken into a sterile field must be decontaminated and cleaned before re-sterilizing and re-introducing them into a sterile surgical field.

- Remove all gross visible soil with a damp gauze pad or wipe.
- Prepare an enzymatic cleaning solution per the manufacturer's instructions. Immerse the instruments in the cleaning solution. Instruments composed of multiple separable components should be disassembled prior to cleaning.

- Ultrasonically clean the instruments for while immersed in the cleaning solution for at least 15 minutes.
-Transfer the instruments to fresh enzymatic cleaning solution. Thoroughly scrub the instruments with a soft bristle cleaning brush while immersed in the solution. Scrubbing must also include any lumens with an appropriate sized round brush.
-Thoroughly clean the instruments.
-Rinse all instruments with warm running water and dry with a clean cloth and/or allow to air dry.
-Verify that all instruments are visually clean. If not, repeat the cleaning process from the beginning until they are clean.

Please note that certain cleaning solutions, such as those containing formalin, glutaraldehyde, caustic soda, bleach, or alkaline cleaners may damage some device, particularly some instruments and instrument trays. These solutions should not be used.

MRI COMPATIBILITY:
The Teslake Spinal System has not been evaluated for safety and compatibility in the MR environment. The Teslake Spinal System has not been tested for heating or migration in the MR environment.

PACKAGING:
The implants are delivered in packages. These must be intact at the time of receipt.

The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially-designed storage boxes.

SURGICAL TECHNIQUE MANUAL:
To view or download the surgical technique manual, please visit www.Teslake.com.

MANUFACTURED BY:
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