Instructions for Use
STERILE SPINE™ Pedicle Screw System

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

Manufacturer:

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Rx only	• **Caution: Federal law restricts this device to sale by or on the order of a physician.**
5.4.2	• **Single-use**
REF 5.1.6	• **Catalog number**
LOT 5.1.5	• **Lot number**
5.4.4	• **Caution: See instructions for use**
STERILE R 5.2.4	• **Sterile – Irradiation**
STERILE EO 5.2.3	• **Sterile – ethylene oxide**
5.1.4	• **Use by date**
5.2.6	• **Do not resterilize**
LATEX	• **Not made with Natural Rubber Latex**
5.2.8	• **Do Not Use If Package is Damaged**
NON STERILE 5.2.7	• **Non-Sterile**

Symbols: ISO-15223

DESCRIPTION
The STERILE SPINE Pedicle Screw System is a non-cervical spinal fixation system designed to provide immobilization and stabilization as an adjunct to spinal fusion. The STERILE SPINE Pedicle Screw System allows for correction and stabilization of spinal disorders, allowing for the biologic healing process to occur. The STERILE SPINE Pedicle Screw System includes polyaxial screws of varying heights and diameters, rods, caps, set screws, hooks, and transverse cross connectors.

Various instrumentation is specifically manufactured as part of the STERILE SPINE Pedicle Screw System and is available to aide and facilitates the implantation. All components are made to facilitate fixation to the thoracic, lumbar and/or sacral spine, and are not to be used with other spinal systems.

MATERIAL
The STERILE SPINE Pedicle Screw System implants are manufactured from titanium alloy (Ti-6Al-4V).

MR SAFETY INFORMATION
The STERILE SPINE Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The STERILE SPINE Pedicle Screw System has not been tested for heating or migration in the MR environment.

INTENDED USE
The STERILE SPINE Pedicle Screw System is a non-cervical spinal fixation system, used as a Pedicle Spinal System utilized in conjunction with sacral/iliac screw fixation, or anterior - lateral spinal fixation intended to provide stabilization of the spine limited to skeletally mature patients and for use with autogenous graft material. The STERILE SPINE Pedicle Screw System is to be utilized in acute and/or chronic instabilities, deformities, or conditions outlined below in the indications section for providing internal spinal stability.

Surgeons implanting this system are expected to be fully versed and trained in the techniques and methods utilized in placement of this spinal fixation system.

INDICATION FOR USE
The STERILE SPINE 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/iliac spine (T1 – S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

CONTRAINDICATION
The contraindications for this system are similar to other systems available with a similar design for spinal fixation.

Absolute Contraindications:
1. Infection or inflammation
2. Allergy to implant components (titanium alloy)
3. Morbid Obesity
4. Metal Sensitivity/foreign body sensitivity
5. Inadequate tissue coverage at the operative site
6. Open wounds exposing the local operative site

Relative Contraindications:
1. Fever
2. Pregnancy unless indicated for emergent spinal fixation (unstable fracture)
3. Signs of infection where implant may be implanted
4. Patient non-compliance or unable to follow post-operative instructions
5. Any condition not specifically prescribed in the indications section

POSSIBLE ADVERSE EFFECTS
1. Bending, fracture, loosening or migration of the implant.
2. Non-union (pseudarthrosis) or delayed union.
3. Metal sensitivity or foreign body reaction.
4. Decrease in bone density due to stress shielding.
5. Fracture of bony structures.
6. Pain, discomfort, or abnormal sensations due to presence of implant.
7. Nerve, soft tissue, or blood vessel damage due to surgical trauma.
8. Nerve root or spinal cord impingement or injury.
9. Dural leak
10. Bursitis
11. Necrosis of bone
12. Hemorrhage
13. Infections
14. Death

SURGICAL TECHNIQUES
Surgical techniques are available describing the uses of this system. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use. Surgical techniques can be found on the WishBone Medical website: www.wishbonemedical.com.

WARNINGS & SAFETY PRECAUTIONS
The safety and effectiveness for spinal pedicle screw systems has been established only for spinal conditions with spinal deformity or mechanical instability of the thoracic, lumbar, or sacral spine requiring spinal fusion and instrumentation. These spinal conditions also include those with, or the potential for significant mechanical instability including spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous attempted fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown. Modes of failure of these devices have been established. This device is not intended to be the sole mechanism of support of the spine. Without adjunctive biologic support for any spinal fixation and fusion condition for which it has been designed and used, the device cannot be expected to support the spine indefinitely and will fail in any number of proven modes.

The STERILE SPINE Pedicle Screw System is intended to provide structural support and assist spinal fusion healing and is not intended to replace normal bony structures.

Multiple factors including patient size, weight, activity levels, and injuries will dictate implant longevity, especially during the biologic healing phase following implantation. If ultimate healing is delayed or does not occur, metal fatigue, and/or failure can occur. Adjunctive spinal immobilization during the biologic healing phase is to be maintained until there is clinical and radiographic evidence of healing.

Surgeons implanting The STERILE SPINE Pedicle Screw System must be thoroughly trained and knowledgeable with the surgical, medical, metallurgical and mechanical aspects of the system.

The patient bears responsibility with regards to following the surgeons' postoperative instructions and limitations, and should be warned that noncompliance with this aspect of their care could lead to implant breakage, loosening, migration, and the possibility of the necessity for revision surgery to alter or remove the implant.

All implanted devices are intended and designed to be single use only. Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those patients without previous spinal surgery.

a) 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.

b) IMPLANT STRENGTH AND LOADING
The STERILE SPINE Pedicle Screw System in intended to assist healing and is not intended to replace normal bony structures. Mechanical testing and clinical use indicates that the majority of the axial and compressive loads are carried in the anterior column of the spine. When posterior spinal implants are utilized for spinal stability, adequate construct planning to

account for anterior column support is necessary, either by existing anatomy or by surgical planning.

c) SELECTION OF IMPLANTS
Based on the fatigue testing results, the surgeon should consider the levels of implantation, patient size and weight, expected activity levels, and other patient conditions that may affect the performance of the systems.

Surgical technique manual review and proper inspection of implants and instruments prior to surgery is crucial for adequate surgical handling and implantation.

Surgeon selection of the proper size, shape, configuration and design of the implant increases the potential for surgical success. While proper selection and implantation can help minimize the risks associated with spinal fixation, the size and shape of the patients' individual anatomy can represent limitations on the size and strength of implants.

Proper surgical technique and extreme caution is to be utilized by the surgeon in handling and implantation of these devices.

d) INTRAOPERATIVE CONSIDERATIONS
The surgeon is expected to have reviewed available implant materials and obtained appropriate radiographic imaging to allow for optimal implantation of this device.

Appropriate preoperative templating can assist in the selection of implant size, diameter, and construct parameters. Surgeons should inspect available implants and instrumentation prior to surgery to ensure adequate component availability.

Radiographic or advanced intraoperative imaging should be utilized if there is any question as to the implant size, location or placement of the spinal device. This device and its components are to be utilized with this system alone, and not to be used with those from any other system.

Standard principles of rod contouring and preparation remain constant for all implants including The STERILE SPINE Pedicle Screw System. Strict avoidance of sharp bends and/or recontouring should be to prevent stress risers and may lead to early rod fracture.

e) **CORROSION**
The STERILE SPINE Pedicle Screw System should be used only with its intended components, as contact with dissimilar metals will accelerate the corrosion process, thereby potentially increasing the fatigue fracture of the components. Only the included instrumentation and implants (manufactured with Ti-6Al-4V), specifically manufactured for the STERILE SPINE Pedicle Screw System, are to be utilized in the preparation and implantation of the spinal construct.

INSTRUMENT CLEANING
The following recommendation is for the manual cleaning and decontamination of the STERILE SPINE Pedicle Screw System instrumentation. These recommendations are considered general guidelines with the ultimate responsibility for verifying the adequate cleaning and eventual sterilization to the user. Hard to reach areas such as lumens and tubular structures must be qualified by the hospital.

Prior to onsite cleaning and sterilization, medical devices must be inspected to ensure the system's devices are present and in good condition to function properly. Devices are inspected prior to cleaning, decontamination, and sterilization. If any damage, deformation, wear, or other lack of function, especially those identified below, the device is to be discarded and not used.

- Lack of hinged/articulated motion, excessive motion, unsuccessful locking/unlocking
- Cutting features without continuous smooth edge; nicks, cracks, or visual imperfections.
- Missing devices or missing components of assembled devices
- Components with mating interfaces that do not assemble properly
- Visually apparent corrosion, distortion, cracks, large nicks or burrs

It is imperative to remove all labels and packaging materials from instruments. Disassemble all instruments as appropriate and submerge the products in a hospital grade enzymatic detergent for a minimum of five minutes at 95 to 113°F (35 to 45°C). Thoroughly scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that the flutes are effectively cleaned. Use a small diameter brush or pipe cleaner to clean cannulated holes. Inspect for visible soil on exposed surfaces. Each product should then be rinsed thoroughly for a minimum of two minutes with warm (as delivered from the tap) de-ionized water. Sonicate instruments in fully opened positions in a hospital grade enzymatic ultrasonic cleaner for a minimum of 10 minutes at 95 to 113°F (35 to 45°C). Allow to air dry blowing lumens with clean filtered or a syringe. Inspect device for visible soil and repeat cleaning if any visible soil is found.

The following recommendation is for automated cleaning and decontamination of the STERILE SPINE Pedicle Screw System instrumentation. It is imperative to remove all labels and packaging materials from instruments. Disassemble all instruments as appropriate and submerge the products in a standard hospital grade enzymatic detergent for a minimum of five minutes at 95 to 113°F (35 to 45°C). Thoroughly scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that the flutes are effectively cleaned. Use a small diameter brush or pipe cleaner to clean cannulated holes. Inspect for visible soil on exposed surfaces. Each product should then be rinsed thoroughly for a minimum of two minutes with warm (as delivered from the tap) de-ionized water. Sonicate instruments in fully opened positions in a hospital grade enzymatic ultrasonic cleaner for a minimum of 10 minutes at 95 to 113°F (35 to 45°C). Allow to air dry blowing lumens with clean filtered or a syringe. Place instrument into cleaning tray and place tray in the washer.

The following washer parameters are recommended:

Cycle	Solution	Time (seconds)	Temperature
Wash	Hospital Grade Enzymatic Detergent Wash	480	131-150°F
Rinse	Potable Tap Water	120	104-113°F

Inspect device for visible soil and repeat cleaning if any visible soil is found. Instrument

STERILIZATION
The STERILE SPINE Pedicle Screw System implants are supplied sterile and packaged according to standard sterilization protocols and are single use only. Do not re-sterilize or reuse. Do not use if package is open or damaged. This is a single-use device. Re-use of single-use sterile devices can result in the transfer of materials not limited to bone, tissue, blood or infectious disease. This device is provided sterile, and re-sterilization of the device has not been validated. Sterile packaging includes implant identification including lot number and expiration date.

Instrumentation essential to the implantation are supplied non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam parameters are recommended and should be conducted with an FDA cleared-wrap. These recommendations are in accordance with ANSI/AAMI ST79 and will provide a sterility assurance level (SAL) of 10-6.

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 minutes	30 minutes

HOW SUPPLIED/STORAGE:
The devices are packed in protective packaging that is labeled to its contents.
The majority of the implants are provided sterile, and instruments are provided in reusable sterilization case and trays.
• Always store the implants in the original protective packaging and store the instruments in their provided sterilization cases and trays.
• Store the devices in a dry and dust-free place (standard hospital environment).

ADDITIONAL INFORMATION
Note: Strict adherence to postoperative surgical instructions to patients and appropriate nursing care are critical for optimal outcomes. A successful outcome and result will not be achieved in every instance of the use the use of this device. Several known conditions have been established to be associated with less than optimal outcomes that include, but are not limited to: cigarette smoking, obesity, inadequate nutritional state, and alcohol use.

Implant Removal after Healing: It is intended that the implants are to be removed after bony healing has occurred. Since it is no longer necessary after healing, implants are to be removed to avoid potential complications such as: implant loosening, fracture, corrosion, migration, stress shielding of bone or pain, particularly in young active patients. Implant removal should be accompanied by adequate postoperative instructions, immobilization, and management.

FOR FURTHER INFORMATION
Please contact WishBone Medical, Inc. or your authorized representative for further information about this product.

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