INSTRUCTIONS FOR USE
OrthoCircle Spine Pedicle Screw System

Important Information — Please Read Prior to Use

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

Description:

Pedicle Screw Fixation System is an implant device made from a titanium alloy TI 6Al 4V-ELI. It is to be implanted from the posterior approach. The system consists of rods, poly-axial screws and set screws. The screws are available in diameters of Ø4.50mm, Ø5.50mm, Ø6.50mm, and Ø7.50mm and in lengths of 20mm-60mm. Standard and Reduction Pedicle Screws are both available in these sizes. Titanium rods are available in Ø5.50mm diameter and either straight in lengths from 100mm-300mm or precontoured in lengths from 30mm-125mm. Set screws are used to fasten the rods and poly-axial screws. Implants are provided sterile in individual packaging.
Special instruments are used to implant the pedicle system. Instruments are provided as non-sterile and require sterilization prior to use.

Indications:

The OrthoCircle Spine Pedicle Screw System is a thoracolumbosacral (T1-S1) spinal fixation system containing devices intended for use as a posterior pedicle screw fixation system. Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all the following indications: degenerative disc disease (defined as discogenic back pain 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, and/or failed previous fusion (pseudoarthrosis).

Contraindications:

Contraindications include, but are not limited to:

-Infection, systemic or localized, particularly in or adjacent to the spine or spinal structures
-Poor bone quality or quantity that does not allow adequate fixation of the implant
-Metal sensitivity/allergies to the implant material (titanium alloy)
-Active infectious process or significant risk of infection
-Fever or leukocytosis
-Suspected or documented sensitivity or allergies to the implant materials
-Presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device
-Pregnancy
-Rapid joint disease, bone absorption, and/or severe osteoporosis
-Conditions that preclude successful fusion (i.e. cancer, kidney dialysis, or osteopenia)
-Any patient unwilling to cooperate with post-operative instructions
-Prior fusions at the level(s) to be treated
-Morbid Obesity

Cautions and Precautions

CAUTIONS:

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.
- Do not use components of the Pedicle Screw System with components from any other manufacturer.
- As with all orthopedic implants, none of the Pedicle Screw System components should ever be reused under any circumstances.

Precautions:

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

When used in the following conditions, the surgeon must weigh the risks versus potential benefits.

- History of Smoking
- Morbid obesity
- Mental illness
- Alcoholism or drug abuse
- Pregnancy
- Severe osteopenia
- Any condition having inadequate tissue coverage over the operative site
- Any circumstances not described under Indications for Use
- Patients unwilling or unable to follow post-operative instructions

Preoperative:

Preoperative instructions to the patient are essential.

Care should be used in the handling and storage of the implant components. The implants should not be damaged. Implants should be protected from corrosive elements during storage. The type of construct required for the surgery should be determined prior to beginning the surgery. Implants should be used only if received with packaging and labeling intact. Instruments must be inspected, cleaned and sterilized prior to use in the operative field.

Intraoperative:

Breakage, slippage, misuse, or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel. The implants must be handled and contoured carefully so as to avoid damage to the surface. Before closing the soft tissues, all of the set screws should be tightened firmly according to the operative surgical technique. The tightness of all set screws must be rechecked before wound closure to ensure that no loosening occurred during tightening or manipulation of the other implants. Explanted implants must never be reused.

Post-Operative:

The patient should be instructed in the proper use of crutches, canes, external braces or any other weight bearing or assist devices that may be required, and limit those physical activities which would place excessive stresses on the implants or cause delay of the healing process. The patient should also be instructed in the proper methods to ambulate, climb stairs, get in and out of bed and perform activities of daily living, while minimizing rotational and bending stresses.

MRI Safety Information:

The OrthoCircle Spine Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of The OrthoCircle Pedicle Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

- 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 neurologic impairment, fracture, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.

- Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

Possible Adverse Effects:
Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects:

- Early or late loosening of the components
- Rod migration
- Disassembly, bending, loosening, and/or breakage
- Foreign body reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage over the implant
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Excessive Blood Loss
- Misalignment of anatomical structures or loss of mobility
- Hemorrhage of blood vessels and/or hematomas
- Bone graft, intervertebral body and/or sacral fracture at, above, and/or below the level of surgery
- Non-union or delayed union
- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Fracture, micro fracture, resorption, damage or penetration of any spinal bone (including the vertebral body) and/or bone graft at the operative site
- Damage to neighboring segments
- Bone loss or decrease of the bone density
- Damage to veins/arteries
- Neurovascular compromise including paralysis or other types of serious injuries
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death

Prescription Use Only:
The implant is to be used by prescription only.

Single Use Only:
Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Decontamination, Cleaning, and Sterilization:

All Pedicle Screw implants are delivered sterile and are only for Single Use. Implants are sterilized via gamma irradiation.

Ancillary instruments are delivered non-sterile and therefore, must be decontaminated, cleaned and sterilized prior to surgical use.

Decontamination and cleaning reduces the population of microorganisms and facilitates subsequent sterilization. Strict compliance with instructions pertaining to decontamination, cleaning, and sterilization is mandatory. These processes are validated to AAMI standards TIR 12 and TIR 30.

Once an implant comes in contact with any human tissue or bodily fluid, it should not be resterilized and used.

- **Decontamination and Cleaning**:

All instruments must first be thoroughly cleaned and decontaminated using the following method:

- Clean devices immediately after use to prevent drying of debris or body fluids.
- Remove any debris with a water moistened gauze pad. Substitute a fresh pad if it becomes soiled.
- Cleaning, soak in neutral PH enzymatic cleaner or detergent solution for a minimum of 5 minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. Rinse device thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes.
- Clean disassembled instrument using a pipe cleaner or nylon brush on the accessible surfaces until all visible debris is removed.
- Thoroughly rinse the device using free-flowing warm tap water for a minimum of 15 seconds.
- Drain and wipe dry using a sterile gauze pad.

Visually inspect all instruments to assure there is no visual contamination. If any visual contamination is detected, repeat the cleaning process prior to sterilization.

Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage, particularly instruments; these solutions should not be used. All products should be treated with care; improper use or handling may lead to damage and possible improper functioning of the device

- Sterilization:

It is imperative to steam-sterilize the instrument kits under the following operating conditions:

Steam Sterilization, pre-vacuum, wrapped in an FDA Cleared Wrap

Minimum duration	Minimum temperature	Dry Time
4 minutes	***132*˚C (*270*˚F)**	**40 minutes**

NOTE: Sterilization does not replace decontamination or cleaning. Only a clean product can be correctly sterilized.

NOTE: Do not stack trays – sterilize trays as a single layer/individually

Only sterile implants and instruments may be used for surgery.

It is the end user's responsibility to use only sterilizers and accessories (such as 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 (time and temperature).

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.

Surgical Technique Manual

The Pedicle Screw Fixation System Surgical Technique is available by contacting Customer Service at *888.463.5803*.

PRODUCT COMPLAINTS:

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any Pedicle Screw products should notify OrthoCircle Spine, or, where applicable, their distributor. In the event of serious incident, or risk of serious incident, having resulted in, or may potentially result in, the death or severe deterioration in the state of health of a patient or user, OrthoCircle Spine or the distributor must be notified as soon as possible. When filing a complaint, please provide the component(s) reference number, manufacturing lot number(s), your name and address, and the nature of the complaint in full detail, as well as notification of whether a written report is requested.

Symbols and Definitions

REF	**Catalog Number**			**Consult Instructions for Use.**
LOT	**Lot Number**			**Do not use if package is damaged.**
	**Date of Manufacturer (YYYY-MM-DD)**			**Single use only. Do not re-use.**
	**Use by (YYYY-MM-DD)**		**Rx Only**	**Prescription use only**
STERILE R	**Provided Sterile (gamma sterilized)**		UDI	**Unique Device Identification**
QTY	**Quantity**			**Non-sterile**

For Product Complaints or for additional product information please contact:

(*OrthoCircle Spine– Jack Mathews, 888-463-5803, 15 East Montgomery Crossroads, Suite 3, Savannah, GA 31406*)