

Instructions for Use

Pagoda® Pedicle Screw

Manufacturer

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DESCRIPTION

The Pagoda® Pedicle Screw System consists of rods, polyaxial screws, reduction screws, monoaxial screws, set screws, transverse connectors, and offset connectors which can be variously assembled to provide immobilization of the thoracolumbar and lumbosacral spine. All components are made from Titanium Alloy (Ti6Al4V).

INDICATIONS

The Pagoda Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion using autograft or allograft. This system is intended for posterior, noncervical pedicle fixation of the thoracic, lumbar, and sacral/iliac spine (T1 – S1/Ilium) for the following indications:

1. Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Degenerative Spondylolisthesis with objective evidence of neurologic impairment
3. Trauma (fracture or dislocation)
4. Spinal tumor
5. Failed previous fusion (pseudarthrosis)
6. Spinal stenosis
7. Spinal deformities or curvatures such as scoliosis, kyphosis, or lordosis

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Active or suspected local or systemic infection
2. Any pathological condition that would preclude fixation, appropriate range of motion, or adequate support or fixation of the component
3. Certain systemic or metabolic bone conditions
4. Skeletal immaturity
5. Pregnancy
6. Poor bone quality that cannot provide adequate support or fixation of the implant
7. Any disease, ligamentous or severe muscle laxity or inadequate soft tissue coverage which may compromise the normal healing process or function of the implant
8. Obese or overweight patients who may place undue loads on the orthosis which can result in failure of the device
9. Pathological conditions, neuromuscular disorders, or mental conditions whereby the risks associated with these conditions outweigh the benefits to be derived

ADVERSE EFFECTS

All patients considered candidates for fusion using the Pagoda Pedicle Screw System should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects associated with the procedure. The potential adverse effects include, but are not limited to:

1. Bending, disassembly, loosening fracture, slippage, and/or migration of the components
2. Sensitivity or allergic reaction to the materials used to manufacture the implants

3. Skin or muscle sensitivity
4. Non-union or delayed union
5. Infection
6. Loss of proper spinal curvature, correction, height, and/or reduction
7. Loss of neurological function, dural tear, pain, and/or discomfort
8. Epidural bleeding, hemorrhage of blood vessels, and/or hematomas
9. Loss of bladder and/or bowel control
10. Sterility, impotency, and/or loss of consortium
11. Bone loss and/or bone fracture due to stress shielding
12. Bursitis
13. Bone graft donor site pain
14. Cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, and/or myocardial infarction
15. Death

Adverse effects may necessitate re-operation or revision.

WARNINGS AND PRECAUTIONS

The implantation of spinal pedicle screw systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal pedicle screw system. This is a technically demanding procedure and potentially presents a risk of serious injury to the patient.

Preoperative and operative procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.

Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion. Based on fatigue testing results, the physician/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.

A successful result is not always achieved in every surgical case due to many extenuating circumstances. The safety and effectiveness of spinal pedicle screw 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.

Patients should be informed of the potential risks identified with the use of this device as well as postoperative weight-bearing activity levels, which may require additional surgery. The device is designed as a load-sharing device and is to be used to obtain normal alignment until normal healing and/or fusion occurs. If delayed union or non-union occurs the implant may be subjected to increased loads, which may result in device component fracture.

Pagoda Pedicle Screw System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. Pagoda Pedicle Screw System has not been tested for heating or migration in the MR environment.

PREOPERATIVE

1. Patients who meet the criteria in INDICATIONS FOR USE should be considered for surgery.
2. Patients with conditions such as those addressed in CONTRAINDICATIONS should not be considered for surgery.
3. The surgeon should make sure that all implants and instruments are unpacked, sterilized, and available prior to surgery.
4. Implants and instruments should be inspected for surface flaws and scratches as they can contribute to early

implant failure and should not be used in the presence thereof.

INTRAOPERATIVE

1. The surgical technique manual should be followed.
2. Extreme caution should be used around the spinal cord and nerve root. Damage to the nerves may cause loss of neurological functions.
3. Mishandling of instruments may cause injury to patient and/or operative personnel.
4. Rods should not be reverse bent. If the rods are cut to length, they should be cut perpendicular to the midline of the rod as to create a flat, non-sharp surface.
5. Bone grafts should be used to ensure stability.
6. Notching and scratching of implants should be avoided.
7. All implants are to be tightened to recommended torque and rechecked before closing soft tissue.

POSTOPERATIVE

1. For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol and any other activity that would compromise or delay the healing process.
2. Patients should be warned about the limitation of bending at the point of spinal fusion.
3. After the spinal fusion is complete, the surgeon may consider removing the implant, as this device serves no functional purpose after complete spinal fusion. If the device is not removed, the following complications may occur: implant corrosion, migration, bending, breaking and/or loosening, infection, bone loss, pain, and/or soft tissue reaction.

PACKAGING AND STERILITY

The Pagoda Pedicle Screw System is supplied in sterile or non-sterile packaging. Implants supplied in non-sterile packaging must be sterilized prior to use. Sterile Pagoda implants are sterilized by a minimum of 25kGy gamma irradiation at a sterility assurance level of 10^{-6} . Sterile product packaging should be inspected for flaws before opening. In the presence of a packaging flaw, do not use. Do not re-sterilize. Do not use after expiration date.

All instruments should be thoroughly cleaned prior to sterilization. Cases should be placed in two layers of FDA cleared 1-ply polypropylene wrap, such as Kimguard KC600, using sequential wrapping techniques prior to sterilization.

For non-sterile implants, the following steam sterilization cycles must be followed in order to ensure sterility of the implants and instruments. Remove all packaging before sterilization:

Implants:

Prevacuum Cycle: 4 minutes at 132°C (270°F), dry time 45 minutes

Instruments:

Prevacuum Cycle: 4 minutes at 132°C (270°F), dry time 60 minutes

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).

PRODUCT HANDLING

Implants should be used only if received with packaging intact. Damaged packaging and implants should not be used and should be returned to Ortho Development Corporation. Protect the implants from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage.

PRODUCT COMPLAINTS

Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to Ortho Development® Corporation. If any of the implants or instruments "malfunction" (i.e., do not meet any

of their performance specifications or do not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, Ortho Development® Corporation should be notified immediately by phone, fax, or written correspondence.

When filing a complaint, please provide the product description, product number, lot number, complainant's name and address, and the nature of the complaint.

CAUTION

Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

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