Instructions for Use
Pisces Spinal System
Manufacturer
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DESCRIPTION

The Pisces Spinal System is an implantable system intended to provide immobilization and stabilization of spine segments. The device is a modular assembly that consists of solid/cannulated pedicle screws, standard/reduction/extended tab tulips, spinal rods, set screws, and transverse connectors, all of which are made of implantable-grade titanium (Ti6Al4V). The tulip assembly consists of a tulip body which holds a saddle piece for a 5.5mm or 6.0mm rod to mate with a bottom bore for a locking ring to insert into, and a top threaded feature used to retain a locking set screw. The pedicle screw has a spherical head which the tulip assembly snaps onto either before or after surgical insertion. The 5.5mm or 6.0mm rod is inserted into the tulip assembly. After assembly of multiple pedicle screws, a set screw is inserted into the tulip and locked to a predetermined locking torque, immobilizing the construct. For the 20mm reduction and 90mm extended tab tulips, the guide tabs are removed from the construct following final lock. 20mm reduction tabs can be used to provide length for rod reduction while 90mm tab tulips facilitate minimally invasive surgeries (MIS). All implants are provided sterile for single use only; the implant shall not be re-used.

INDICATIONS

The Pisces Spinal 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 Pisces Spinal 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 levels, other patient conditions, etc., which may impact on the performance of the system.

Pisces Spinal System is intended to be used with 5.5mm and 6.0mm titanium spinal rods manufactured by Ortho Development Corporation. Failure to use appropriate rods may cause intra – and / or post – operative mechanical failure of the Pisces Spinal 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.

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. Ensure 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 65 in-lbs for screws and 15 in-lbs for transverse connectors 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.

MAGNETIC RESONANCE (MR)

The Pisces Spinal 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 Pisces Spinal System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING AND STERILITY
All implants have been sterilized by a minimum of 25 kGy gamma irradiation at a sterility assurance level of 10^{-6}. Sterile product packaging should be inspected for flaws before and after opening. In the presence of a flaw or if implant sterility has been compromised the product must be considered non-sterile and should not be implanted. Implants shall not be re-sterilized for patient use even if it appears undamaged.

INSTRUMENT STERILITY
All instruments should be thoroughly cleaned prior to sterilization. Cleaning instructions for reusable instruments are provided in the Ortho Development Corporation Pisces Reusable Instrument Care and Cleaning Manual. The following Steam Sterilization Cycles must be followed in order to ensure sterility:

Cycle Type	Minimum Sterilization Exposure Temperature	Sterilization Exposure Time (minutes)	Minimum Dry Time (minutes)
Prevacuum	**132°C (270°F)**	**4**	**60**

NOTE: Refer to the Reusable Instrument care manual for Pisces Spinal System (351-1-10829) for more detail.

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).

Cases should be placed in two layers of FDA cleared 1-ply polypropylene wrap, such as Kimgaurd KC600, using sequential wrapping technique prior to sterilization.

PRODUCT HANDLING
Implants should always be stored unopened in their respective protective packages. Prior to use, inspect packaging for damage which may compromise sterility. When removing the implant from its packaging, the relevant aseptic techniques must be observed. Protect the implant from contact with objects which may damage the surface finish. Inspect each implant prior to use for visual damage. Do not implant this or any device that has been used, even if it appears undamaged.

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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