Indications for Use
Integrated® Spine System

Manufacturer
Ortho Development® Corporation
12187 South Business Park Drive
Draper, UT 84020
Phone 801-553-9991
Fax 801-553-9993
www.orthodevelopment.com

DESCRIPTION

The Integrated® Spine System consists of rods, polyaxial screws, caps, set screws, and transverse connectors which can be variously assembled to provide immobilization of the lumbar and lumbosacral spine. All components are made from Titanium Alloy (Ti-6Al-4V ELI, ASTM F-136) or Commercially Pure Titanium (CP Ti, ASTM F-67).

INDICATIONS

The Integrated® Spine System is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft and having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion mass.

Use of a rod and ileo-sacral fixation system, T1-S1, the lumbar screws and rods will assist in arthrodesis or fusion of the lumbar spine.

The indications for use are:
1. Spondylolisthesis.
2. Spinal Fractures.
3. Spinal Stenosis.
4. Deformities (Idiopathic Scoliosis, Adult Kyphosis, Lordosis).
5. Psuedoarthrosis or previous fusion.
6. Instability caused by Trauma or Tumors.
7. Revision of previously failed fusion surgery.
8. Degenerative Disc Disease.
9. Stabilization after Osteotomy.

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 Integrated® Spine 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 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.

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 operating 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.

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. 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 will 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 firmly 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. The patient should be warned about the limitation of bending at the point of spinal fusion.
3. After the spinal fusion is complete, the surgeon must 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 Integrated® Spine System will be supplied as a non-sterile implant and **must** be sterilized prior to use. Remove all packaging before sterilization.

All instruments should be thoroughly cleaned prior to sterilization. The following Steam Sterilization Cycles must be followed in order to ensure sterility of the implants and instruments:

Implants:
Prevacuum Cycle: 4 minutes at 132° C (270° F), dry time 45 minutes
Gravity Cycle: 40 minutes at 132° C (270° F), dry time 45 minutes

Instruments:
Prevacuum Cycle: 25 minutes at 132° C (270° F), dry time 30 minutes
Gravity Cycle: 40 minutes at 132° C (270° F), dry time 30 minutes

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

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 does 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.

351-1-10661 01/2013