INDICATIONS FOR USE

The Sync Medical® Ethos® Spinal System is intended for use in the non-cervical area of the spine.

Indications for use are as follows:

The Ethos Spinal System, when used for pedicle screw fixation is intended only for patients:

- Having severe spondylolisthesis (Grade 3 & 4) at the L5-S1 joint.
- Who are receiving fusion using autogenous bone graft only.
- Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below).
- Who are having the device removed after the development of a solid fusion mass.

The Ethos Spinal System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic deformities of the thoracic, lumbar, and sacral spine:

- Degenerative spondylolisthesis with objective evidence of neurologic impairment
- Fracture
- Dislocation
- Scoliosis
- Kyphosis
- Spinal tumor
- Previous failed fusion (pseudoarthrosis).

The Ethos Spinal System, when used for anterolateral non-pedicle fixation, is intended for the following indications:

- Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies)
- Spinal stenosis
- Spondylolisthesis
- Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis)
- Pseudoarthrosis
- Tumor
- Trauma (i.e. fracture or dislocation)
- Previous failed fusion.

The Ethos Spinal System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

- Degenerative disc disease (defined as back pain of disogenic origin with degenerative disc confirmed by patient history and radiographic studies)
- Spinal stenosis
- Spondylolisthesis
- Spinal deformities (i.e. scoliosis, kyphosis and/or lordosis)
- Pseudoarthrosis
- Tumor
- Trauma (i.e. fracture or dislocation)
- Previous failed fusion.

CONTRAINDICATIONS FOR USE

Contraindications include (but are not limited to) the following:

- Morbid obesity
- Mental illness
- Alcoholism or drug abuse
- Pregnancy
- Metal sensitivity or allergy to implant materials
- Severe osteopenia
- Fever or leukocytosis
- Active infection (systemic, spinal or localized)
- Patients unwilling or unable to follow post-operative care instructions.
- Any circumstance **not** described in the INDICATIONS FOR USE Section above.

WARNING

The safety and effectiveness of pedicle screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechnical 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.

Mixing of different metal types can accelerate the corrosion process. Stainless and titanium implants must not be used together in creating a construct. Components from other manufacturers should never be used with the Ethos Spinal System.

Spinal componenst should never be reused for any reason.

The Ethos Spinal System is not intended as the sole means of spinal support. Its use without a bone graft will not be successful. No spinal implant can withstand the loads of the body without the maturation of a solid fusion mass. Without the development of a solid fusion mass, the spinal implant will eventually bend, loosen or fracture.

Proper implant selection and patient compliance with postoperative precautions will greatly affect the surgical outcome. Patients who smoke have been shown to have an increased level of non-unions. Therefore, these patients should be advised of this fact and warned of the potential consequences.

PRECAUTIONS

General

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. The physician / surgeon should consider the levels of implantation, patient weight, patient activity level and other patient conditions which may impact the performance of the system. The Ethos Spinal System Surgical Technique Guide should be thoroughly reviewed before surgery.

Preoperative

The surgeon must confirm that all necessary implants and instruments are on hand for the planned surgical construct. The implant components should be handled and stored carefully and protected from any damage including corrosive environments. They should be carefully unpacked and examined for damage.

The implants and instruments must be cleaned and sterilized before use.

Intraoperative

Extreme caution must be taken around the spinal cord and nerve roots especially when inserting screws and cross connectors. Breakage, slippage or mishandling of the instruments or implant components, such as sharp edges, may cause injury to the patient or operative personnel.

The implants must be handled and contoured carefully so as to avoid notching or scratching the surface.

Prior to closing the soft tissues, all caps and screws should be tightened firmly according to the operative technique.

Recheck the tightness of all caps and screws after finishing to ensure that none have loosened during the tightening or manipulation of other components.

Postoperative

The patient must be adequately instructed as to the risks and limitations of the implant as well as postoperative care and rehabilitation.

The patient should be instructed in the limitations of physical activities, which would place excessive stresses on the implant or cause delay of the healing process. The patient should also be instructed in the proper use of required weight-bearing or assist devices as well as the proper methods of ambulation, climbing stairs, getting into / out of bed or other daily activities while minimizing rotational and bending stresses.

The surgeon must consider the removal of the implant after healing as the implant can loosen, fracture or corrode even after fusion has occured. The risk and benefits of a second surgery must be carefully evaluated.

PHYSICIAN NOTE

Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

MATERIAL SPECIFICATIONS

Implants are manufactured from implant grade titanium (6AL-4V ELI) which complies with ASTM F-136. The Ethos Spinal System consists of the following:

- Polyaxial screws with locking caps
- Cross Connectors
- Rods
- Instruments
- Sterilizer Case

COMPLICATIONS

Possible adverse effects include, but are not limited to:

- Bending, loosening or fracture of the implants or instruments
- Loss of fixation
- Sensitivity to a metal foreign body (including possible tumor formation)
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which might result in skin breakdown and / or wound complications
- Non-union or delayed union
- Infection
- Nerve or vascular damage due to surgical trauma (including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage).
- Gastrointestinal, urological and / or reproductive system compromise (including sterility, impotency and / or loss of consortium)
- Pain or discomfort
- Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra)
- Hemorrhage of the blood vessels and/or hematomas
- Malalignment of anatomical structures (include loss of proper spinal curvature, correction, reduction and/or height
- Bursitis
- Bone graft donor site pain
- Inability to resume normal daily living activities
- Reoperation
- Death

CLEANING AND DECONTAMINATION

All instruments and implants must be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Sync Medical. Cleaning and decontamination must include the use of neutral cleaners followed by deionized water rinse.

NOTE: Certain cleaning solutions such as those containing formalin, gluteraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should NOT be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION

All components of the ETHOS SPINAL SYSTEM are supplied NON-STERILE and must be sterilized prior to clinical use. All packaging should be sealed and intact upon receipt. If the packaging or product is damaged, it should not be used and should be returned immediately. Sterilization should be achieved by high temperature steam. All packaging materials must be removed prior to sterilization.

The following cycles have been validated:

METHOD	CYCLE	TEMPERATURE	MINIMUM EXPOSURE TIME
Steam	Pre-vacuum (wrapped)	132° C (270° F)	4 minutes
Steam	Gravity Displacement (wrapped)	132° C (270° F)	30 minutes

After sterilization, remove from packaging or sterilization tray using accepted sterile technique with powder-free gloves. Only sterile products should be placed in the operative field. Ensure that the components are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

Manufactured by

INNOVASIS, INC.
614 East 3900 South
Salt Lake City, UT 84107 USA
801.261.2236
info@innovasis.com

Authorized EU Representative

RSQA/RSQR Ltd
Room 402 Ludgate House
107-111 Fleet Street
London EC4A 2AB
United Kingdom
info@rsqa.co.uk
www.rsqa.co.uk

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Sync Medical

ETHOS® SPINAL SYSTEM

Directions for Use