



ISSYS LP Spinal Fixation Systems Package Insert

SPINAL ELEMENTS
ISSYS LP Spinal Fixation System
ISSYS LP Polyaxial Pedicle Screw System - ISSYS LP Monoaxial Screw System

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

NON STERILE PRODUCT
MUST BE STERILIZED PRIOR TO USE
SINGLE USE ONLY

“THE ISSYS LP SPINAL FIXATION SYSTEM HAS NOT BEEN EVALUATED FOR SAFETY AND COMPATABILITY IN THE MR ENVIRONMENT. THE ISSYS LP SPINAL FIXATION SYSTEM HAS NOT BEEN TESTED FOR HEATING OR MIGRATION IN THE MR ENVIRONMENT.”

The ISSYS LP Spinal Fixation Systems are comprised of spinal implants for fixation of the non cervical spine. They include rods, screws (Monoaxial and Polyaxial), blockers, staples, and cross connectors. The components are manufactured from Titanium alloy. The screws are available in various sizes from 4.5mm to 10mm diameters with lengths ranging from 25mm to 100mm.

MATERIALS

Titanium alloy: Ti6Al4V according to ISO 5832-3, ASTM F-136

(NOTE: Titanium and stainless steel implants should not be mixed in patients as corrosion may occur resulting in decreased mechanical performance.)

INDICATIONS

The ISSYS LP Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine, specifically as follows:

For pedicular use: When used as pedicle screw fixation system of the non cervical posterior spine in skeletally mature patients, these systems are indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, this system is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (grade 3 & 4) at the L5-S1 joint having fusion with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass.

The ISSYS LP Spinal Fixation System is also intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.

When used as non pedicular fixation system:

The ISSYS LP Spinal Fixation Systems, when used as an anterior screw fixation system and posterior sacral/iliac screw fixation system are indicated for the following:

- Degenerative disc disease of the thoracic and lumbar spine (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Spondylolisthesis
- Fracture
- Spinal deformities such as scoliosis, kyphosis, lordosis
- Tumor
- Revision of failed fusion attempts



- Pseudarthrosis
- Spinal stenosis

When used in the anterior indication the ISSYS LP Spinal Fixation Systems are indicated for use in the thoracic and lumbar spine.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal; implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

GENERAL CONDITIONS OF USE

Warning: 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, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill, and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

INFORMATION FOR PATIENTS

The surgeon should discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels,



and the necessity for periodic medical follow-up. The patient should be warned of the surgical risks and made aware of possible adverse effects. The patient should be warned that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.

INFECTION

Transient bacteria can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteria. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

INSTRUMENTS

Specialized instruments are provided by SPINAL ELEMENTS and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments should be examined for wear or damage prior to surgery.

REUSE

An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.

It is recommended to verify that the instruments are in good condition and operating order prior to use during surgery.

HANDLING

Correct handling of the implant is extremely important. The operating surgeon should avoid notching or scratching the device.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES

When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the material that make up the implants be checked before they are implanted.

IMPLANT SELECTION AND USE

The choice of proper shape, size, and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.

Patient's overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape, and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates only is recommended if necessary according to the surgical technique of each system. Rods or plates should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the device's surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.



METAL COMPONENTS

Some of the alloys utilized to produce orthopedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such phenomena.

SYSTEM COMPATIBILITY

While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system should not be used in conjunction with components from any other manufacturer's spinal system. Any such use will negate the responsibility of SPINAL ELEMENTS for the performance of the resulting mixed component implant.

The ISSYS LP Spinal Fixation System components (Pedicule Screws, Monoaxial Screws and Staples, Blocker, Rods, Polyaxial Cross Connectors, Monoblock Cross Connectors) have been specifically designed for use with this system. DO NOT use the ISSYS LP Spinal Fixation System with any components not specifically recommended.

Warning: Do Not Use The 5.5 mm Diameter Rods With Any Of The Current Cross Connectors.

POSTOPERATIVE CARE

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass, external immobilization by bracing or casting be employed. The patient should be instructed regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. The patient should also be instructed to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result



- from trauma, infection, biological complications or mechanical problems, with the substantial possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
 - Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders; including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
 - Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
 - Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
 - Decrease in bone density due to stress shielding.
 - Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of the bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.

REMOVAL OF IMPLANTS

These implants are temporarily internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains
- Bone growth restraint due to the presence of the implants (in pediatric use)
- Failure or mobilization of the implant

Standard ancillaries provided by SPINAL ELEMENTS can be used to remove the implants. Any decision by a physician to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended.

Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

PACKAGING

- The implants are delivered in packages; these must be intact at the time of receipt.
- The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

RECOMMENDED CLEANING PROCEDURES FOR MEDICAL DEVICES PROVIDED NON STERILE

- Cleaning should be performed manually, ultrasonically, and in accordance with the specifications designated by the manufacturer of the hospital's equipment. This includes the use of neutral cleaners followed by deionized water rinses and a final sterile water rinse.
- Corrosive products or instruments should be avoided (abrasive sponges and metal brushes).
- Cleaning before sterilization: machine cleaning using a wide spectrum bactericide and fungicide.
- Cleaning products prohibited: Strong mineral acids (sulfuric, nitric, hydrochloric, etc...) or strong Lewis acids such as Zinc chloride or boron trifluoride and strong oxidizing agents such as aqueous solutions containing sodium hypochlorite and NaOH (soda) or a high concentration of hypochlorite or permanganate ions.

DO NOT USE SODA TO CLEAN DEVICES MADE OF ALUMINUM.

DO NOT USE SODIUM CHLORITE TO CLEAN DEVICES MADE OF STAINLESS STEEL.



Prolonged exposure to high temperatures and to most aggressive solvents (such as ethylene dichloride, phenolic and aniline solutions) must be avoided.

- It is recommended to use aqueous solutions that have a pH above 4.0.
- Before using a cleaning product it is recommended to perform oxidation test.

RECOMMENDED DECONTAMINATION PROCEDURE FOR MEDICAL DEVICES PROVIDED NON STERILE

- The instruments should be carefully cleaned before any decontamination. Cleaning should remove all dried infectious residual matter.
- For patients with no risk of transmittable subacute spongiform encephalopathy, the standard recommendations include the following methods of decontamination:
 - For devices made in Stainless Steel or in Titanium: soak in 1M soda for 1 hour.

Note: this procedure is not appropriate for devices made in Aluminum as it will generate dangerous chemical reaction.

- For devices made in Aluminum or in Titanium: soak in sodium chlorite, at 2% active chlorine, for 1 hour.

Note: this procedure is not appropriate for devices made in Stainless Steel as it will generate corrosion.

- Or, autoclave treatment at 134°C (273°F) for 18 minutes in a porous load autoclave.
- For devices made in Stainless Steel or in Titanium: autoclave treatment with soda, at a concentration 1M, at 121°C (250°F) for 30 minutes in a gravity displacement autoclave, or soaking in a 1M concentrate soda.

Note: this procedure is not recommended for devices made in Aluminum as it will generate dangerous chemical reaction.

- For devices made in Aluminum or in Titanium: sodium chlorite at 2% active chlorine, for 1 hour, followed by autoclave treatment at 121°C (250°F) for 1 hour in a gravity displacement autoclave or by autoclave treatment at 134°C (273°F) for 1 hour in a porous load autoclave.

Note: this procedure is not appropriate for devices made in Stainless Steel as it will generate corrosion.

N.B.: To sterilize the material, it must then undergo the required sterilization process.

RECOMMENDED STERILIZATION PROCEDURES FOR MEDICAL DEVICES PROVIDED NON STERILE

- This device is provided not sterile, so all parts must be cleaned and sterilized before use.
- Remove all devices from their packaging prior to sterilization.
- Sterilize the devices by steam autoclaving procedure regularly used in the hospital.

Recommendation: The system should be sterilized using an FDA CLEARED WRAP.

Method: Steam

Cycle Type	Temperature	Exposure Time Min (Minimum)	Dry Time Minutes (Minimum)
Pre-Vacuum	132 °C (270°F)	4	45

Other alternative sterilization methods and cycles are possible but must be validated.

- Autoclave must be validated to guarantee the recommended sterilization temperature is reached all along the exposure time.
- EtO sterilization, cold sterilization, irradiation, plasma techniques are not recommended for the inactivation of prions.
- If paper-filter sterilization boxes are used, it is advisable to verify whether the filters are intact before sterilization. If after sterilization it remains water in the sterilization boxes, sterilization cannot be considered as efficient.

NOTE: These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing test must be performed to confirm inactivation of all forms of viable microorganisms.



FURTHER INFORMATION

A surgical technique brochure is available on request through your SPINAL ELEMENTS agent or directly from SPINAL ELEMENTS. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

COMPLAINTS

Any professional (e.g. Customer or user) who has experienced dissatisfaction in the services or who has any complaints about SPINAL ELEMENTS products referring to quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify this to the representative or distributor. If the malfunction or deterioration of the device, or any inadequacy in instructions for use has led, or might lead, to the death or serious injury of a patient or user, please notify immediately by telephone or fax.

When filing a complaint form, please provide maximum information such as the identification of the product (name, reference, lot number), the nature of the complaint or the description of the incident, the consequences, and all technical elements that could be helpful in the future investigation, such as: the device, x-rays, etc... should be addressed.

For further information or complaint, please contact:

	<p>FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN</p>	<p>SINGLE USE DEVICE, DO NOT REUSE</p>
	<p>CONSULT ACCOMPANYING PACKAGE INSERT FOR LABELING INDICATIONS</p>	<p>DEVICES ARE SUPPLIED NON-STERILE</p>
	<p>SPINAL ELEMENTS 3115 Melrose Dr., Suite 200 Carlsbad, CA 92010 · U.S.A. · 760.607.0121</p>	<p>CONSULT INSTRUCTIONS FOR USE</p>