

Syzygy Stabilization System PACKAGE INSERT

CAUTION: Federal law (USA) restricts these devices to the sale by or on the order of a physician. Implants and disposable instruments single use only.

Description:

The Syzygy Stabilization System consists of posted screws, couplers, and associated surgical instruments. **The system is used in conjunction with the Savannah-T pedicle screw and rod system.** The Syzygy posted screws are self-tapping with a cancellous thread design. They are available in cannulated and non-cannulated configurations, in a variety of diameters and lengths. The screws and couplers are manufactured from Ti-6Al-4V (ASTM F136) and are provided non-sterile for single-use.

All implantable components are manufactured from medical grade titanium alloy (Ti-6Al-4V per ASTM F136) and are provided non-sterile for single-use. (NOTE: Titanium and stainless steel implants should not be mixed in patients as corrosion may occur resulting in decreased mechanical performance.) The system is to be used with bone graft material to facilitate spinal fusion.

Indications for Use:

The Syzygy Stabilization System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine, specifically as follows:

- When intended for pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients the Syzygy Stabilization System is indicated for one or more of the following: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and/or failed previous fusion (pseudarthrosis).
- In addition, when used as a pedicle screw fixation system, the Syzygy Stabilization System is indicated for skeletally mature patients having degenerative spondylolisthesis with objective evidence of neurologic impairment and/or severe spondylolisthesis (grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving fusions using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and who are having the device removed after the development of a solid fusion mass.

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. The Syzygy components are not to be used with systems or components of another manufacturer.

Contraindications include, but are not limited to:

- 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.

Precautions:

- Surgical Implants should never be reused.
- Handle carefully to avoid damage to the implants or instruments.
- 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.
- A successful result is not always achieved in every surgical case. Surgeons should not implant the Syzygy spinal implants until receiving adequate training regarding surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events. See the surgical technique manual for more information on proper implantation technique.

The Syzygy Stabilization device 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 the Syzygy Stabilization device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Possible Adverse Effects:

Potential adverse effects may include, but are not limited to the following:

- Bending, disassembly, or fracture of any or all implant components.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on the skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin, seroma or wound dehiscence.
- Dural leak, pseudomeningocele, or fistula requiring surgical repair.
- 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.
- Early or late loosening of spinal fixation implants.
- Peripheral neuropathies, nerve damage, neurovascular compromise, paralysis, loss of bowel or bladder function, or foot-drop. Other neurologic adverse events may include motor or sensory loss, spasms, parasthesia, paraparesis cauda equina syndrome, numbness and decrease or total loss of reflexes and/or muscle tone.
- 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, atelectasis, pneumonia and ARD; bursitis, hemorrhage, seroma, 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.
- Heterotropic bone formation.
- Graft site pain, fracture or wound healing problems.
- Tissue reaction to the implant, debris or corrosion of the implant material.
- Disc herniation and degeneration of adjacent discs.
- Decreased ability to perform activities of daily living.

Adverse effects may necessitate reoperation or revision.

Material Specification: The Syzygy implant components are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. No warranties, expressed or implied, are made.

Packaging: Packages for each of the components should be intact upon receipt. Damaged packages and products should not be used and should be returned to SPINAL ELEMENTS.

Sterilization:

Products not clearly marked as sterile should be assumed non-sterile.

Implants and instruments used in surgery not clearly labeled as sterile must be sterilized by the hospital prior to use.
Remove all packaging materials prior to sterilization where applicable.

Only sterile products should be placed in the operative field.

Surgical Technique Guides: To obtain copies of the Surgical Technique Guides visit WWW.SPINAL ELEMENTS.COM or contact SPINAL ELEMENTS customer service.

Product Complaints: Any health care professional (e.g. customer or user) who has experienced dissatisfaction in the services of SPINAL ELEMENTS 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 sales representative, distributor, or SPINAL ELEMENTS customer service. Further, if any of the devices, instruments or components ever malfunction, (i.e. do not meet any of their performance specifications or otherwise do not perform as intended), or are suspected of doing so, the distributor should be notified immediately. If any SPINAL ELEMENTS product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Manufacturer:

Spinal Elements, Inc. · 3115 Melrose Dr., Suite 200 Carlsbad, CA 92010 · U.S.A. · 760.607.0121

Recommended Sterilization Procedure:

Manufacturer: Spinal Elements Inc.

Method: Manual Cleaning and Steam Sterilization

Device(s): Trays/Implants/Instruments

CAUTIONS:	<p>The Syzygy System is provided NON-STERILE should be cleaned and sterilized before use.</p> <p>Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.</p> <p>Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used.</p> <p>Saline solution has a corrosive effect on stainless steel and should not be used.</p> <p>Use only neutral pH cleaning agents and detergents.</p> <p>Syzygy implants are single use. Therefore these guidelines are not intended for USED Savannah® and Savannah-T® spinal implants or DISPOSABLE, single use instruments.</p> <p>The Syzygy Stabilization device 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 the Syzygy Stabilization device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.</p>
Limitations on Reprocessing:	<p>Repeated processing has limited effect on REUSABLE instruments.</p> <p>End of life is normally determined by wear and damage due to use.</p>

INSTRUCTIONS	
Point of use:	Use clean flowing water and disposable wipes to remove excess soil. Reprocess instruments as soon as possible to prevent body fluid and tissue from drying on instruments prior to cleaning.
	A manual cleaning method can be used, or manual with an additional automated cycle. It is preferred to use both manual and automatic cleaning methods, however, due to the somewhat limited availability of automated cleaning equipment it is possible to use just the manual cleaning procedures.
CLEANING AGENT	Endozime AW Plus is to be prepared as follows: Add ½ ounce of Endozime® AW plus to 1 gallon of warm tap water (17mL/4liter, 27°-44°C)
Cleaning -Automated	<p>1) Manually pre-clean the instruments</p> <p>(1.1) Immerse and soak for a minimum of 5 minutes in enzymatic detergent at <43°C.</p> <p>(1.2) Immerse in enzymatic detergent and clean thoroughly for 14 minutes at <43°C.</p> <p>(1.2.1) Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.</p> <p>(1.3) Rinse thoroughly for 2 minutes with warm demineralized water. (Purified water at 27°-44°C)</p>

(2) Place instruments in an automated washer. Ensure the instruments stay in place and do not touch or overlap so that the design features are accessible for cleaning and do not retain liquid.

(3) Run the washer per the parameters below:

Washer Parameters

Cycle	Time	Parameters	Temperature
Pre-Wash	300 seconds		Cold ¹
Wash 1	300 seconds	½ Oz Endozime AW Plus per 1 Gallon Tap Water	65.5° C
Wash 2	300 seconds	½ Oz Endozime AW Plus per 1 Gallon Tap Water	65.5° C
Purified Water Rinse	10 seconds	Non-Recirculated Purified Water	82.2° C ²
Dry Time	7 minutes	N/A	115.5° C

¹Cold tap water line

²Purified water tank temperature set at 82.2° C/180° F

Cleaning-Manual

- (1) Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at <43°C.
- (2) Immerse in enzymatic detergent and clean thoroughly for at least 14 minutes at <43°C.
 - (2.1) Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.
- (3) Rinse thoroughly for 2 minutes with warm demineralized water. (Purified water at 27°-44°C)
- (4) Allow instrument to air dry in a clean area. Blow lumens with clean air using filtered air source or syringe.

Maintenance, inspection, and testing;

Carefully inspect each device to ensure that all visible blood and soil have been removed.
 Inspect lumens to confirm that all foreign material has been removed.
 Visually inspect for damage and/or wear.
 Note: If any damage or wear is noted that impairs the function of the instrument, contact your Spinal Elements representative for a replacement.

Packaging:

This set of components may be loaded into a dedicated tray, supplied by the manufacturer, for sterilization. The tray should be wrapped using FDA-cleared sterilization wrap or other FDA-cleared accessory that has been validated to allow sterilant penetration and subsequently maintain sterility.

Sterilization:	<p>Visually inspect all components for any remaining debris prior to sterilization.</p> <p>The Syzygy system components provided NON-STERILE should be autoclave sterilized using the sterilizer manufacturer's instructions and the institution's procedures for ensuring sterility. The sterilization cycle should occur in a calibrated autoclave.</p> <p>Syzygy[®] components should be sterilized utilizing a pre-vacuum steam autoclave for a minimum of 10 minutes at 270°F (132°C.)</p> <p>The 10 minute, 270° pre-vacuum steam sterilization cycles are not considered by the Food and Drug Administration to be a standard sterilization cycle. 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).</p>
Drying:	<p>A minimum drying time of 20 minutes, after sterilization, is recommended.</p> <p>Drying times may vary according to load size and should be increased for large loads.</p> <p>Dry, thoroughly and promptly, after both cleaning and sterilization.</p>
Storage:	<p>Store components in a clean, dry, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes in humidity and temperature.</p>

The instructions provided above have been validated by Spinal Elements as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.



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