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## **SPARTAN® S<sup>3</sup> FACET SCREW SYSTEM IMPLANTS AND INSTRUMENTATION**

This package insert covers the Spartan® S3 Facet Screw System and Manual Surgical Instruments that are used for the implantation of this system.

### **GENERAL INFORMATION**

The Spartan® S<sup>3</sup> Facet Screw System is designed to stabilize the facet joint for use in conjunction with a legally marketed interbody product. The screws are manufactured from titanium alloy (Ti-6Al-4V ELI) (per ASTM F136). They are offered in 4.3 and 5.0mm diameters and lengths of 20 to 55mm in increments of 5mm (40 to 55mm lengths not available in 4.3mm diameter) in cannulated lag and fully threaded screw varieties.

### **INDICATIONS**

The Spartan® S<sup>3</sup> Facet Screw System is indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels:

- Trauma, including spinal fractures and/or dislocations;
- Spondylolisthesis;
- Pseudarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity;
- Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability.

The Spartan® S<sup>3</sup> Facet Screw System will provide temporary stabilization as an adjunct to spinal fusion.

### **CONTRAINDICATIONS**

1. A case that requires removal of significant portions of the facets or lamina.
2. Active infection or risk of infection due to immunocompromise.
3. Local inflammation.
4. Fever or leukocytosis.
5. Spondylolysis – pars fracture.
6. Morbid obesity.
7. Pregnancy.
8. Mental illness.
9. Significantly distorted anatomy.
10. Presence of tumors.
11. Elevation in White Blood Cell differential count.
12. Elevation in sedimentation rate.
13. Osteoporosis/osteopenia. Osteoporosis is a relative contraindication that may limit the effectiveness of the fixation.
14. Metal allergy or intolerance.
15. Compromised bone integrity in or around the facets or pedicles.

### **WARNING**

Implants provided sterile are sterilized through gamma irradiation. Do not re-sterilize implants provided sterile. Devices provided non-sterile must be cleaned and sterilized before use. Implants may be reprocessed prior to use and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Implantation of devices should be performed only by experienced surgeons with training in the use of spinal devices. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of this device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

### **MAGNETIC RESONANCE ENVIRONMENT**

The Spartan® S<sup>3</sup> Facet Screw 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 the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

### **POSSIBLE ADVERSE EFFECTS**

Possible adverse events or complications associated with the Spartan® S<sup>3</sup> Facet Screw may include, but are not limited to:

1. All of the adverse events associated with general surgery or spinal fusion surgery.
2. Loosening of any or all of the components.
3. Bending and/or breakage of any or all of the components.
4. Foreign body (allergic) reaction to implants, debris, corrosion products including metallosis, staining, tumor formation, and/or auto-immune disease.
5. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
6. Tissue damage caused by improper positioning and placement of implants or instruments.
7. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
8. Infection.
9. Dural tears.
10. Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.

11. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
12. Urinary retention or loss of bladder control or other types of urological system compromise.
13. Scar formation possibly causing neurological compromise around nerves and/or pain.
14. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, spinous process, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
15. Non-union (or pseudarthrosis), delayed union or mal-union.
16. Cessation of any potential growth of the operated portion of the spine.
17. Loss of spinal mobility or function.
18. Inability to perform activities of daily living.
19. Bone loss or decrease in bone density, possibly caused by stress shielding.
20. Herniated nucleus pulposus, disc disruption or degeneration.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
23. Reproductive system compromise such as sterility and sexual dysfunction.
24. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
25. Change in mental status.
26. Death.

Additional surgery may be necessary to correct some of these adverse events.

#### **PREOPERATIVE MANAGEMENT**

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to Spinal Elements.
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. Devices provided non-sterile should be processed and sterilized prior to use.

#### **INTRAOPERATIVE MANAGEMENT**

1. Extreme caution should be used around the spinal cord and nerve roots, especially when inserting the screws. Damage to the nerves will cause loss of neurological function.
2. Breakage, slippage, misuse, or mishandling of the instruments or implant components may cause injury to the patient or hospital personnel.
3. Implants and components should not be bent, reshaped, contoured or otherwise modified.
4. The implants must be handled and contoured carefully to avoid notching or scratching the surface, which maybe reduce the functional strength of the construct.
5. If the construct contains screws, prior to soft tissue closure, recheck all screws to ensure they are tightened. Failure to do so may cause loosening of the other components.
6. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
7. Implants should not be reused under any circumstances.

#### **POSTOPERATIVE MANAGEMENT**

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the

following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
4. Contaminated instruments must be cleaned promptly after use per instructions noted in the Cleaning Instruction section of this insert in order to prevent drying and ensure an effective cleaning.

#### **SINGLE USE**

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death. All implants are single use.

#### **STERILITY**

All devices provided sterile have been gamma irradiation sterilized and are for single use only. Do not re-sterilize sterile devices. All devices provided non-sterile must be sterilized prior to use. Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by Spinal Elements.

#### **SHELF LIFE**

The product expiration date is indicated by the hourglass symbol on the product label. **Caution:** Do not use sterile devices if the packaging providing the sterile barrier has been compromised. 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.

### **CLEANING AND MAINTENANCE**

#### **GENERAL INFORMATION**

Spinal Elements' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments. All devices provided non-sterile must be cleaned and sterilized prior to use. Do not clean devices provided sterile.

#### **CLEANING AND MAINTENANCE**

Devices must be free of packaging material prior to cleaning. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

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.

Disassemble all components to provide maximum exposure for cleaning.

Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used. Saline solution has a corrosive effect on stainless steel and should not be used. Use only neutral pH cleaning agents and detergents.

**Caution:** Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used as a follow-up method to manual cleaning. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.

## AUTOMATED CLEANING INSTRUCTIONS

All devices must be processed manually prior to automated cleaning. Follow the instructions below for the manual and automated washing.

### PRE-AUTOMATED WASHER: MANUAL CLEANING

1. Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at <43°C.
2. Immerse in Endozime® AW Plus enzymatic detergent (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations and clean thoroughly for at least 14 minutes at <43°C. 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)

### AUTOMATED CLEANING

4. Transfer the instruments into the automated washer for processing. Position the instruments to allow for proper drainage. 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. Process per the cycle below. These are minimum validated parameters:

Phase	Recirculation Time	Water Temp	Detergent Type (if applicable)
Pre-wash	300 seconds	Cold tap water	N/A
Wash 1	300 seconds	65.5°C	Endozime AW Plus or equivalent per manufacturer's instructions
Wash 2	300 seconds	65.5°C	Endozime AW Plus or equivalent per manufacturer's instructions
PURW Rinse	10 seconds	82.2°C	N/A
Drying	7 minutes	115.5°C	N/A

5. If needed, dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
6. Visually examine devices to ensure all visible soil has been removed.
7. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.

## MANUAL CLEANING INSTRUCTIONS

Follow the instructions listed below for manual cleaning prior to sterilization.

1. Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at <43°C.
2. Immerse in Endozime® AW Plus enzymatic detergent (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations and clean thoroughly for at least 14 minutes at <43°C. 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 distilled, de-ionized, or reverse osmosis water. (27°-44°C)
4. Allow instrument to air dry in a clean area. Blow lumens with clean air using filtered air source or syringe.

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.











## STERILIZATION

Devices provided non-sterile and must be sterilized before use. Non-sterile devices should be autoclave sterilized using one of the following validated cycle parameters.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Pre-vacuum	273°F (134°C)	4 minutes	30 minutes

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665-1: 2006. Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and *ANSI-AAM ST 79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. These parameters were validated to a sterility assurance level (SAL) of 10<sup>-6</sup>. The Pre-Vacuum, 270°F (132°C), 10-minute sterilization cycle is 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).

**Information**

-  REF Catalog Number
-  MAT Material
-  LOT Batch Code
-  QTY Packaged Quantity
-  Manufacturer
-  Date of Manufacture
-  Caution, Consult Accompanying Documents
-  Do Not Re-Use
-  STERILE R Sterilized using irradiation
-  Use-by date

 NON-STERILE Device Not Sterile

 Rx Only Prescription Only

 Instruction for Use are provided electronically at [ifu.spinalelements.com](http://ifu.spinalelements.com)

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**CAUTION: Federal Law (USA) restricts these devices for sale by or on the order of a physician.**