

Spartan® S³ Facet Screw System
PACKAGE INSERT

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

Description:

The Spartan® S³ Facet Screw System is designed to stabilize the facet joint for use in conjunction with a legally marketed interbody product. The screws are made from medical-grade titanium (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 for Use:

The Spartan® S³ 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® S³ Facet Screw System will provide temporary stabilization as an adjunct to spinal fusion.

Contraindications include, but are not limited to:

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

Precautions:

- Surgical Implants should never be reused.
- Handle carefully to avoid damage to the implants or instruments.
- A successful result is not always achieved in every surgical case. Surgeons should not implant the Spartan® S³ Facet Screw until receiving adequate training regarding surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events. See the Spartan® S³ Facet Screw Surgical Technique Manual for more information on proper implantation technique.
- Never reuse an implant under any circumstances. Even when a removed device appears undamaged, it may contain small defects or residual stresses. These defects and stresses may lead to implant failure. Any retrieved devices should be handled in a manner such that they may not be reused in another surgical procedure.

- The Spartan® S³ Facet Screw System has not been evaluated for safety and compatibility in the MR environment. The Spartan® S³ Facet Screw System has not been tested for heating or migration in the MR environment.

Possible Adverse Effects:

Possible adverse events or complications associated with the Spartan® S³ Facet Screw may include, but are not limited to:

- All of the adverse events associated with general surgery or spinal fusion surgery.
- Loosening of any or all of the components.
- Bending and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products including metallosis, staining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
- Tissue damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears.
- 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.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- 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.
- Non-union (or pseudarthrosis), delayed union or mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function.
- Inability to perform activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Herniated nucleus pulposus, disc disruption or degeneration.
- 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.
- Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
- Reproductive system compromise such as sterility and sexual dysfunction.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

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

Material Specification: The Spartan® S³ Facet Screw is 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 AMENDIA.

Sterilization:

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

For Sterile Implants and Instruments:

Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by AMENDIA. The contents are considered sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Implants supplied sterilized from AMENDIA must **not** be re-sterilized.

For Non-Sterile Implants and Instruments:

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.AMENDIA.COM or contact AMENDIA customer service.

Product Complaints: Any health care professional (e.g. customer or user) who has experienced dissatisfaction in the services of AMENDIA or who has any complaints about AMENDIA products referring to quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify this to the sales representative, distributor, or AMENDIA 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 AMENDIA 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: AMENDIA, 1755 West Oak Parkway, Marietta, GA 30062, 877-755-3329 (Toll Free), 770-575-5200 (Main), 877-420-1213 (Fax)

Recommended Sterilization Procedures for Spartan® S³ Facet Screw System Instrumentation and Implants Provided Non-Sterile:

Manufacturer: Amendia, Inc.

Method: Manual Cleaning and Steam Sterilization

Device(s): Trays/Implants/Instruments

CAUTIONS:	<p>The Spartan® S³ Facet Screw system components 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>Spartan® S³ Facet Screw System IMPLANTS are single use. Therefore these guidelines are not intended for USED Spartan® S³ spinal implants or DISPOSABLE, single use instruments.</p> <p>The Spartan® S³ Facet Screw System has not been evaluated for safety and compatibility in</p>
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	the MR environment. The Spartan® S ³ Facet Screw System has not been tested for heating or migration in the MR environment.
Limitations on Reprocessing:	Repeated processing has limited effect on REUSABLE instruments. End of life is normally determined by wear and damage due to use.

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.
Preparation for decontamination:	Disassemble all components to provide maximum exposure for cleaning.
Cleaning -Automated	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.
Cleaning-Manual	<ol style="list-style-type: none"> 1. Disassemble all components before cleaning. 2. Completely submerge instruments in enzyme solution and allow to soak for a minimum of 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, and appropriately sized soft-bristled brush (e.g. pipe cleaner brush). 3. Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas. 4. After manual cleaning, and all visible blood, soft tissue, and bone have been removed ultra-sonic cleaning may be used. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for a minimum of 10 minutes at 45-50kHz. 5. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas. Use de-ionized water for final rinse of all components. 6. Repeat the sonication and rinse steps above until all visible contamination has been removed. 7. Thoroughly and promptly, remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe. Allow the tray and components to dry for a minimum of 15 minutes. The tray and components must be thoroughly dry prior to sterilization cycle.

Disinfection:	Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.
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 Amendia representative for a replacement.
Packaging:	This set of components may be loaded into a dedicated tray, supplied by the manufacturer, for sterilization.
Sterilization:	Visually inspect all components for any remaining debris prior to sterilization. The Spartan® S ³ Facet Screw 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. Sterilize utilizing a pre-vacuum steam autoclave for a <u>minimum of 10 minutes</u> at 270°F (132°C.) The 10 minute, 270° pre-vacuum steam 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).
Drying:	A minimum drying time of 20 minutes, after sterilization, is recommended. Drying times may vary according to load size and should be increased for large loads. Dry, thoroughly and promptly, after both cleaning and sterilization.
Storage:	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.

The instructions provided above have been validated by Amendia 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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