Amendia

The Elements of Healing

SPARTAN S3

FACET SCREW SYSTEM

Amendia

4.3
5.0

Sp

SPARTAN
FACET SCREW

SURGICAL TECHNIQUE GUIDE

Spartan S3
Facet Screw System
Table of Contents

Amendia
The Elements of Healing

1755 West Oak Parkway
Marietta, GA 30062
Phone: 877-755-3329
Fax: 877-420-1213
www.Amendia.com
info@amendia.com

Disclaimer:
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon before and during surgery as to the best mode of treatment for each patient. Please reference the 510K or package insert for additional information and a complete list of intended indications, warnings, precautions, and other medical information.

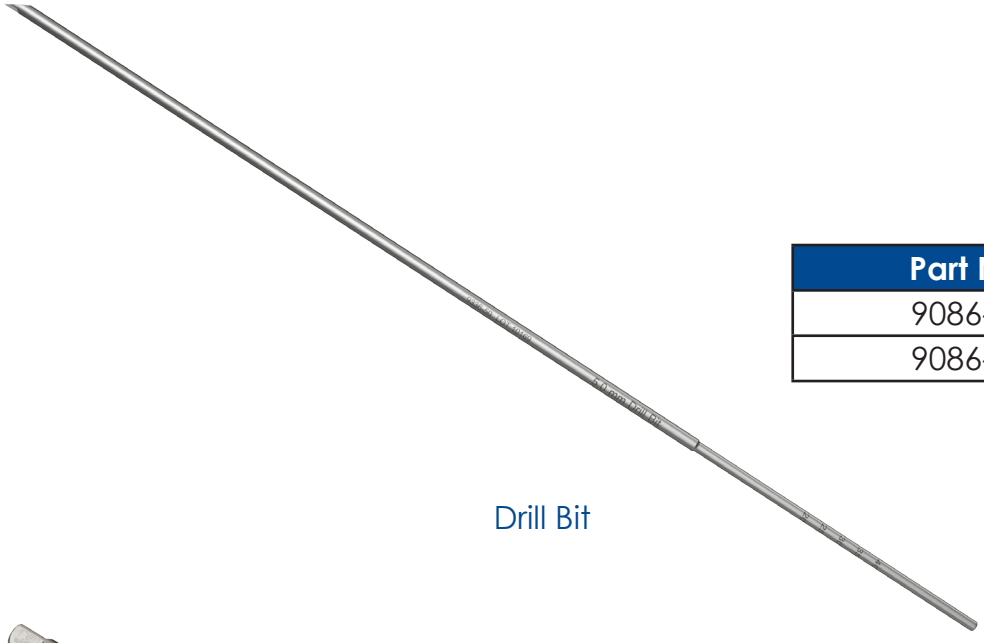
Features & Benefits

- Constructed of implant grade Titanium Alloy (Ti 6Al-4V ELI)
- "Grip Quick" Thread® allows for faster screw delivery
- Spiral self-tapping flutes reduce drive torque and improve integration
- Lag screws have increased shank diameter for stability and strength
- Anti back-out threads under flared head provide rapid change in torque resistance when seated
- Optional skirt provides force distribution to minimize risk of damage to the facet
- Robust 1.4 mm guide wire resists kinking
- Threaded guide wire reduces effort, is easy to control without rapid plunge and anchors into the facet
- Drill marked for depth relation
- Driver retains screw for retraction or revision
- Internal square drive cannot disengage with retainer collar in place
- Ratcheting silicone axial driver handle
- Driver disassembles for thorough decontamination and sterilization

Diameter (mm)	Length (mm)	Skirt Option
4.3	20	No
4.3	25	No
4.3	30	No
4.3	35	No
5.0	25	Yes
5.0	30	Yes
5.0	35	Yes
5.0	40	Yes

Instrument Guide

Dilator
9083-1



Part No.	Size
9086-43	4.3 mm
9086-50	5.0 mm

Drill Bit

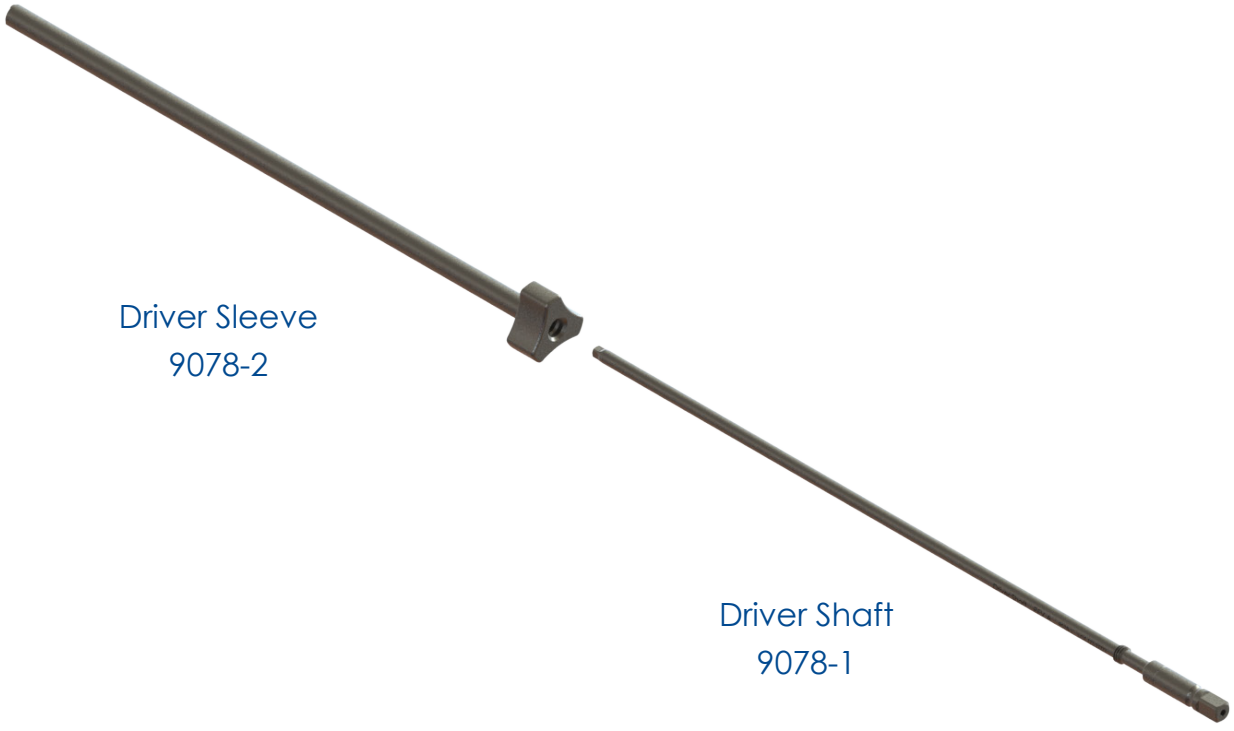
Part No.	Size
9082-39	3.9 mm
9082-46	4.6 mm

Spartan Tap

Instrument Guide

Axial Handle
9094

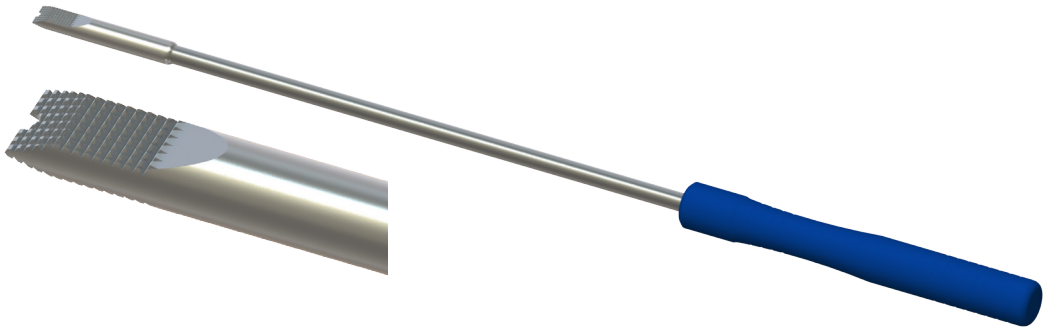
Access Portal
10250



Driver Sleeve
9078-2

Driver Shaft
9078-1

Optional



Part No.	Size
9266-3	3.0 mm
9266-5	5.0 mm

Straight Rasp
(Single Use, Individual Sterile Packaged)

---

18 inch Guide Wire
9080-18U
(Single Use, Individual Sterile Packaged)

---

18 inch Threaded Guide Wire
9080-18T
(Single Use, Individual Sterile Packaged)

Available Sizes

Part No.	Size
9152-4320	4.3 mm x 20 mm
9152-4325	4.3 mm x 25 mm
9152-4330	4.3 mm x 30 mm
9152-4335	4.3 mm x 35 mm
9152-5025	5.0 mm x 25 mm
9152-5030	5.0 mm x 30 mm
9152-5035	5.0 mm x 35 mm
9152-5040	5.0 mm x 40 mm

With Washer

Part No.	Size
10313-5025	5.0 mm x 25 mm
10313-5030	5.0 mm x 30 mm
10313-5035	5.0 mm x 35 mm
10313-5040	5.0 mm x 40 mm

Step 1: Exposure

For percutaneous fixation of L3-L4, L4-L5, or L5-S1, make a midline incision approximately over the L3 spinous process. The incision locations may vary due to patient anatomy **(Figure 1)**.

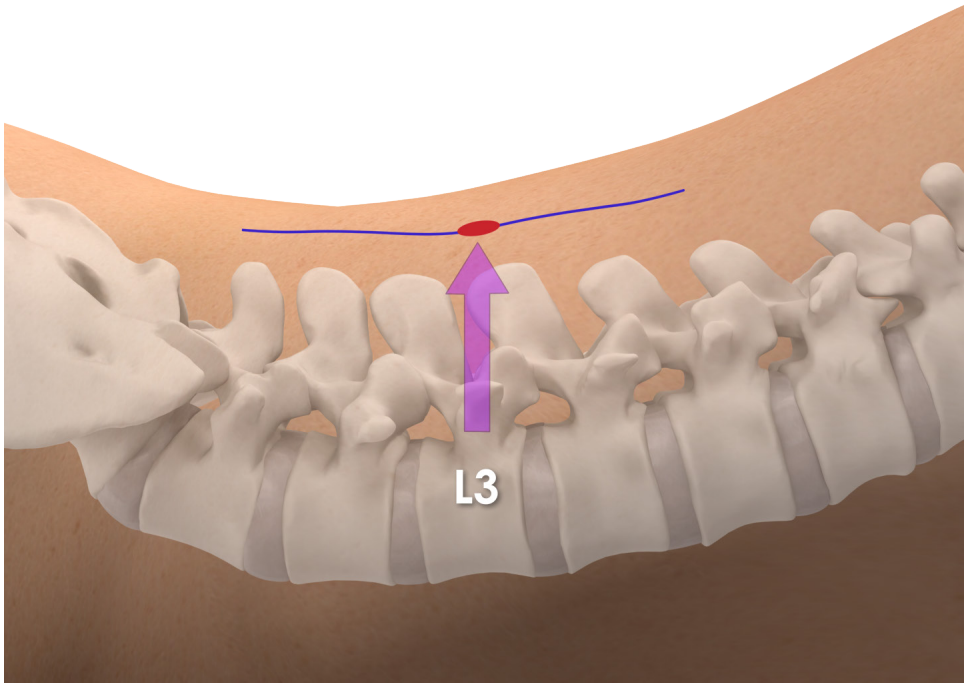


Figure 1

Step 2: Locate Facet

Locate the facet using the **Dilator** attached to the **Axial Ratcheting Handle** and use fluoroscopy to establish the correct angle of approach. Using A/P imaging, engage the tip of the **Dilator** on the medial aspect of the Inferior Articular Process **(Figure 2)**. The tip should be angled laterally so that the **K-wire** can be drilled through the facet joint into the Superior Articular Process and pedicle below **(Figure 3-A, 3-B)**. Using lateral imaging, engage the tip of the **Dilator** on the medial aspect of the Inferior Articular Process. The tip should be angled in the inferior direction so the **K-wire** can be drilled through the facet joint and pedicle below **(Figure 4-A, 4-B)**.

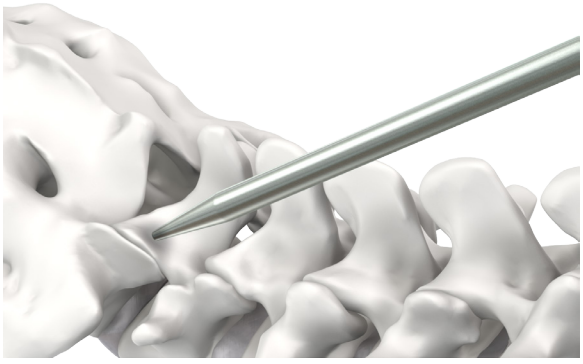


Figure 2

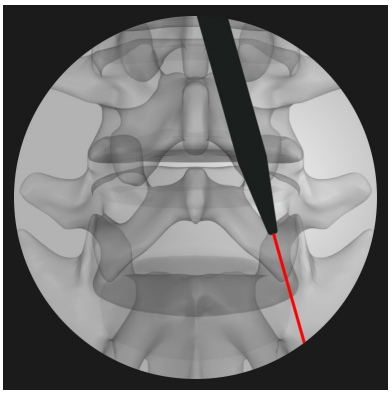


Figure 3-A

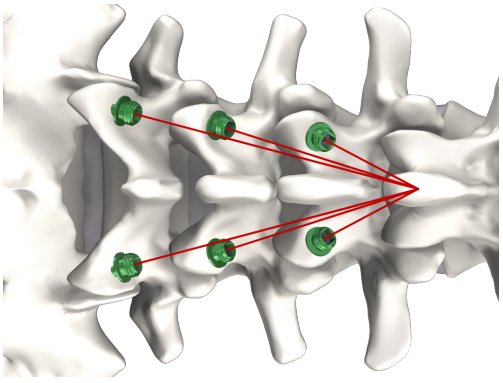


Figure 3-B

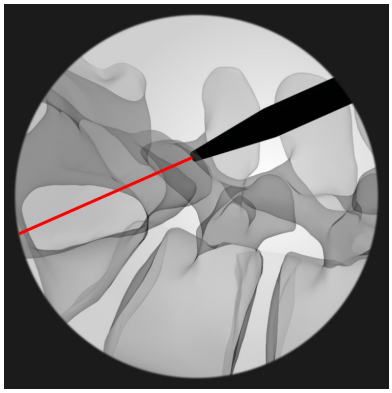


Figure 4-A

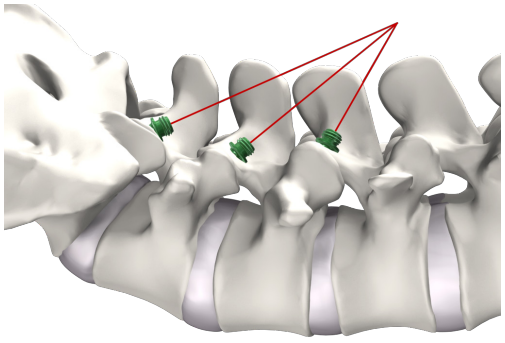


Figure 4-B

Step 3: Drill K-Wire in Facet

With the **Dilator** in place, drill the trocar tip of the [Threaded] **K-Wire** to the desired depth, into the Superior Articular Process **(Figure 5)**.

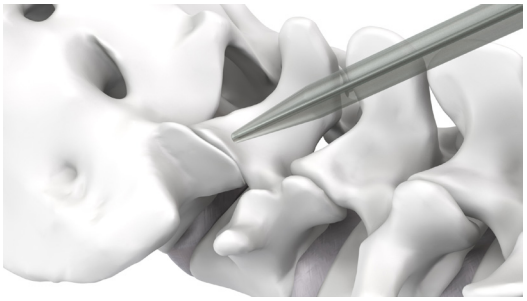


Figure 5

Step 4: Install Access Portal

Remove the **Axial Ratcheting Handle** and slide the **Access Portal** over the **Dilator (Figure 6)**. Be sure the **Access Portal** docks flush with the Inferior Articular Process. Once the **Access Portal** is in place, remove the **Dilator** leaving behind the **K-Wire** and **Access Portal (Figure 7)**.

*Note: For the **Spartan Skirt Washer**, a larger access portal is required but is not provided in the instrumentation.*

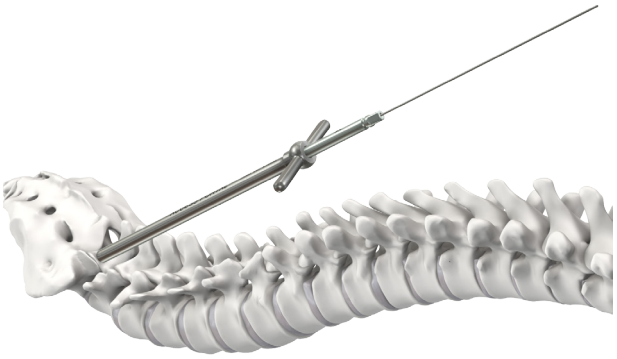


Figure 6

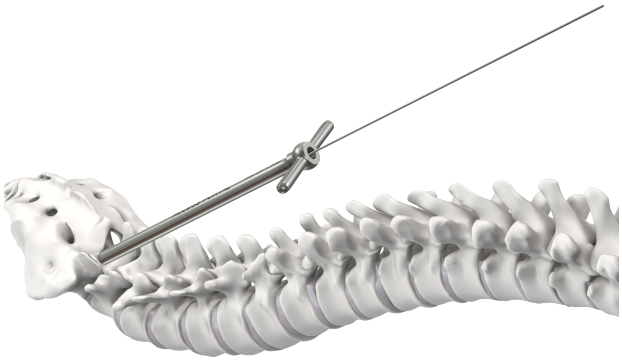


Figure 7

Step 5: Pre-Drill Hole

Slide the appropriate sized **Drill Bit** down the **K-Wire** until it contacts the Inferior Anterior Process. Drill to the desired depth using flouro imaging and the depth markings on the drill bit for indications **(Figure 8)**.

Figure 8

Step 6: Optional Tap

Tap the drilled hole using the appropriate sized **Tap** with the **Axial Ratcheting Handle**. The threaded length of the **Tap** is 20 mm **(Figure 9)**.

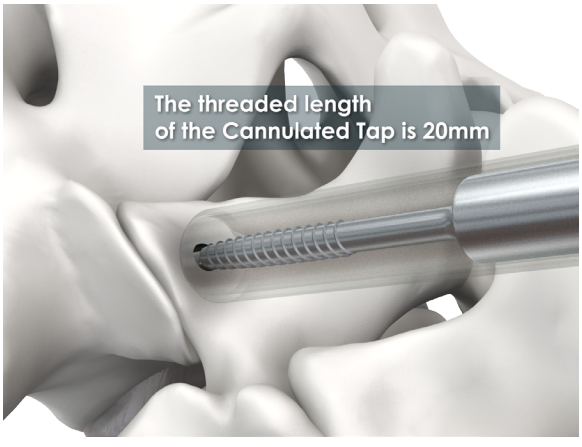


Figure 9

Step 7: Install Screw on Driver

Slide the **Driver Shaft** through the **Driver Sleeve (Figure 10)** and thread into place **(Figure 11)**. The **Driver Sleeve** will be able to slide a few millimeters along the **Driver Shaft**- this is normal. Place the **Spartan Facet Screw** on the square drive **(Figure 12)**, slide the **Driver Sleeve** down to engage the **Spartan Facet Screw (Figure 13)** and thread it on extra-tight **(Figure 14)**. This will effectively retain the screw on the **Driver**.

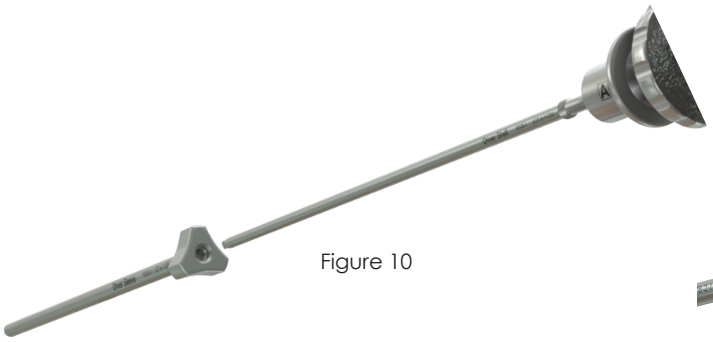


Figure 10

Figure 11

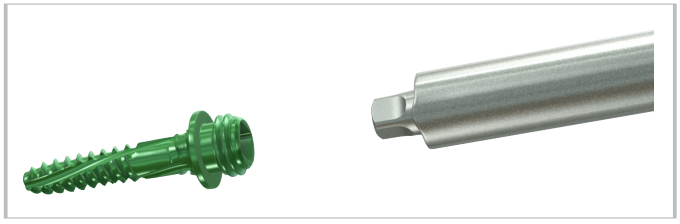


Figure 12

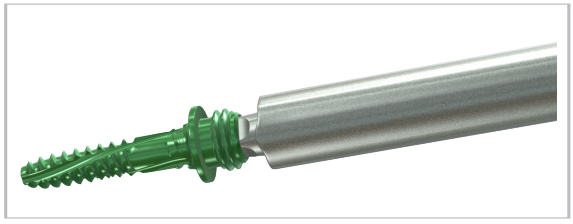


Figure 13

Figure 14

Step 8: Deliver Screw through Facet

*Note: The installation procedure of the **Facet Screw** is the same regardless of whether it is part number 9152-DDLL or 101313-DDLL.*

Slide the **Facet Screw/Driver** down the **K-Wire** inside the **Access Portal (Figure 15-A)** until the **Screw** contacts the Inferior Articular Process **(Figure 15-B)**. Screw the **Spartan Facet Screw** into the facet. Once the tip is threaded into the Superior Articular Process, remove the **K-Wire** to avoid driving it forward with the **Screw**. As the lag engages, the facet joint **(Figure 16)** contracts and the flange of the **Screw** will seat on the Inferior Anterior Process offering resistance, indicating the **Screw** is properly seated. Unthread the **Driver Sleeve** from the **Screw** by rotating the triangular knob counter-clockwise **(Figure 17)**. Remove the **Driver** and **Access Portal**.

*Note: Over tightening of the **Facet Screw** in the Facet may fracture the inferior articular process of the superior vertbral body.*

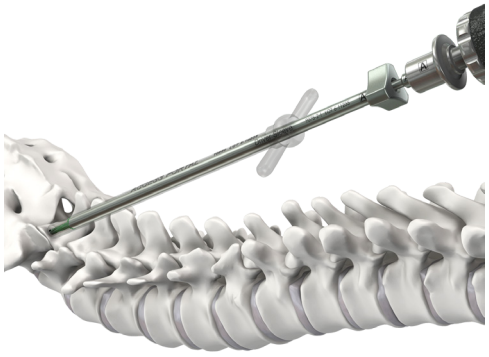


Figure 15-A

Figure 15-B

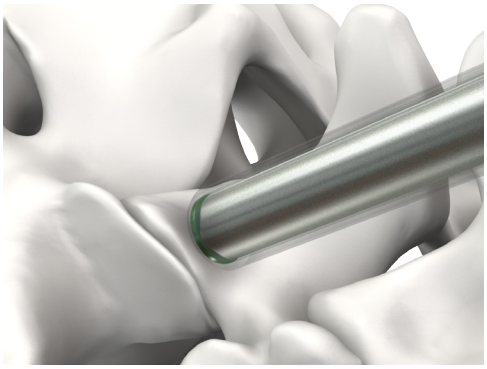


Figure 16

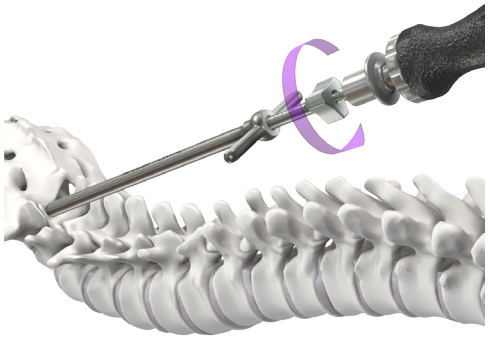


Figure 17

Figures 18 and 19: Post Operative Fluoro Images

Figures 20-22: Implant Images

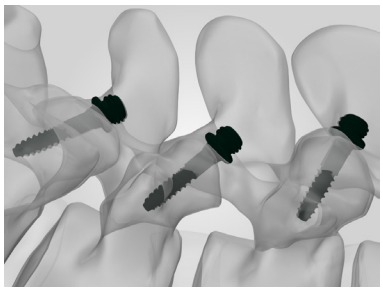


Figure 18

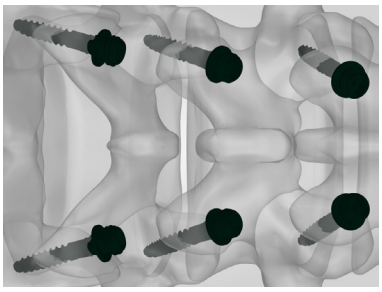


Figure 19

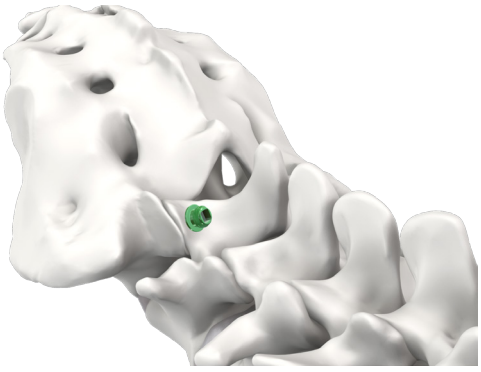


Figure 20

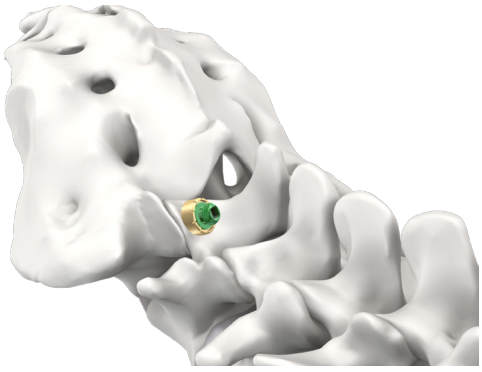


Figure 21

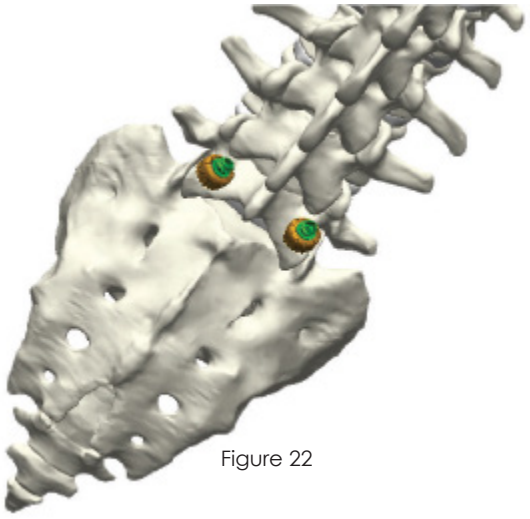


Figure 22

Removal Procedure

Using the **Dilator**, locate a path to the **Spartan Facet Screw**. Deliver the **Access Portal** over the **Dilator** and locate the distal opening around the **Spartan Facet Screw**. Slide the **Driver Shaft** through the **Driver Sleeve** and thread into place. Place the square drive inside the head of the **Spartan Facet Screw**, slide the **Driver Sleeve** down to engage the retaining threads of the **Facet Screw** and thread the **Driver Sleeve** onto the head of the screw. This will effectively retain the screw on the **Driver**. Unscrew the **Spartan Facet Screw** from the facet.

Important Product Information

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 40mm in increments of 5mm (40mm length 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.

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.

Important Product Information

Possible Adverse Effects Continued:

- 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.

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)

Important Product Information

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:	The Spartan® S3 Facet Screw system components provided NON-STERILE should be cleaned and sterilized before use. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended. 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. 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. 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.
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	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.

Important Product Information

Cleaning-Manual Continued...	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® S3 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 minimum of 10 minutes 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.

Amendia

The Elements of Healing

1755 West Oak Parkway
Marietta, GA 30062
Phone: 877-755-3329
Fax: 877-420-1213
www.Amendia.com
info@amendia.com

510(k) Number: K113011
MM-005, Rev. 2