

INSTRUCTIONS FOR USE

Solanas Posterior Stabilization System

GENERAL INFORMATION:

The Solanas Posterior Stabilization System facilitates the surgical correction of spinal deformities by providing temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. Device implants include a range of sizes of bone screws, hooks, rods and bridge assemblies to provide the versatility required for the specific conditions listed in the Indications for Use section.

The implants are manufactured from surgical grade titanium alloy (Ti-6Al-4V, ASTM F 136). The rods are available in surgical grade titanium alloy (Ti-6Al-4V ELI) and cobalt chrome (Co-28Cr-6Mo). All hooks components are intended for fixation/attachment to the cervical spine only (C1-C7). Pedicle screws and offset connectors are limited to fixation to the upper thoracic spine only (T1-T3) in treating thoracic conditions only. These screws and offset connectors are not intended for placement in the cervical spine.

It is intended that the implants be removed after successful fusion.

In order to achieve additional levels of fixation, the Solanas Posterior Stabilization System may be connected to the Zodiac Spinal Fixation System or the Arsenal Spinal Fixation System offered by Alphatec Spine using the Axial Rod Connectors, Parallel Rod Connectors or Transitional Rods.

INDICATIONS FOR USE

It is intended that this device, in any system configuration, be removed after the development of solid fusion mass. Hook components are indicated for use at C1-C7. Polyaxial screws are limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. These screws are not intended for placement in the cervical spine.

The components in the Solanas® Posterior Stabilization System can be linked to the components in the Zodiac Polyaxial Spinal Fixation System offered by Alphatec Spine using the Axial Rod Connectors, Parallel Rod Connectors or Transitional Rods.

- Degenerative Disc Disease (DDD) defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Atlanto/Axial fracture with instability
- Revision of previous cervical spine surgery
- Tumors.

CONTRAINDICATIONS

The Solanas Posterior Stabilization System is contraindicated for:

1. Use in the thoracic-lumbo-sacral spine below T3.

2. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance.
3. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions, which would prohibit beneficial surgical outcome.
4. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
5. Use with bone cement.
6. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
7. Use with stainless steel components.
8. Reuse, or multiple use.
9. Patients resistant to following post-operative instruction.
10. Patients with allergy to Titanium or Cobalt Chrome.

WARNINGS

1. The implants and instruments of the system are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
2. 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 neurological 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.
3. The system implants are used only to provide temporary internal fixation during the bone fusion process with the assistance of a bone graft. A successful result may not be achieved in every instance of use with these devices. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
4. The implants are designed and intended as temporary fixation devices. The devices should be removed after complete healing has occurred. Devices which are not removed after serving their intended purpose may bend, dislocate, or break and/or cause corrosion, localized tissue reaction, pain, infection, and/or bone loss due to stress shielding. Complete postoperative management to maintain the desired result should also follow implant removal surgery.
5. The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
6. **The product implants are single use devices.** Do not reuse. While an implant may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process.
7. The instruments in the Solanas System are reusable surgical devices except for the Single-Use Rod Template used with the Solanas System, which are single use only. Single use instruments are disposable devices, designed for single use and should not be re-used or re-processed. Reprocessing of Single Use Instruments may lead to instrument damage and possible improper function.

8. The final operative procedure with the system must include tightening of the set screws in order to maintain construct integrity. Each locking mechanism must be rechecked for tightness before closing the soft tissues as noted in the Intraoperative Management section.
9. 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 neurological 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.
10. Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and patient conditions, which may impact the performance of the system when using this device. Use of these systems is significantly affected by the surgeon's proper patient selection, preoperative planning, proper surgical technique, proper selection and placement of implants.
11. Risks identified with the use of these devices, which may require additional surgery, include device component failure, loss of fixation/stabilization, non-union, vertebral fracture, neurological injury, vascular or visceral injury.
12. Risk factors that may affect successful surgical outcomes include: Alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who use tobacco or nicotine products should be advised of the consequences that an increased incidence of non-union has been reported with patients who use tobacco or nicotine products.
13. The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
14. It is critical that Set Screws are final tightened as recommended in the Surgical Technique Guides, using the appropriate instrument(s), *e.g.*, *Torque Handle*. Failure to tighten the Set Screws using the recommended instrument(s) could compromise the mechanical stability of the construct.
15. Without solid bone fusion, this device cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
16. Do not comingle titanium and stainless steel components within the same construct.
17. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.

PRECAUTIONS

1. 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.
2. Device components should be received and accepted only in packages that have not been damaged. Damaged implants and damaged or worn instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
3. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may have an impact on the performance of the system.

MRI SAFETY INFORMATION

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

POSSIBLE ADVERSE EFFECTS

The following complications and adverse reactions have been shown to occur with the use of similar spinal instrumentation. These effects and any other known by the surgeon must be discussed with the patient preoperatively.

1. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation
3. In the case of insufficient soft tissue at and around the wound site to cover devices, skin impingement and possible protrusion through the skin may occur
4. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height
5. Infection and/or hemorrhaging
6. Bone graft, vertebral body fracture, and/or discontinued growth of fused bone at, above and/or below the surgery level
7. Non-union and/or pseudarthrosis
8. Neurological disorder, pain and/or abnormal sensations
9. Inability to perform routine activities
10. Revision surgery
11. Death

PREOPERATIVE MANAGEMENT

1. Only patients meeting the criteria listed in the indications for use section should be selected.
2. Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.
3. Careful preoperative planning should include construct strategy, pre-assembly of component parts (if required), and verification of required inventory for the case.

INTRAOPERATIVE MANAGEMENT

1. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times, especially upon insertion of spinal hooks.
2. Rods should be contoured in only one direction, one time. Avoid notching, scratching or reverse bending of the devices because these alterations will produce defects in the surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
3. If it is mandatory to cut the rods to a more specific length, rod cutting should be done at a distance from the operative range, and such that a non-sharp edge remains on the rod.
4. A new bone tap should be used each time to ensure a sharp cutting edge and the absence of clogging bone debris. Use of the improper length or diameter of bone tap or bone screw may allow loosening of implants, nerve damage, and undesirable fusion.

5. The final operative procedure with the Solanas System must include tightening of all setscrews to the torque values indicated by the surgical technique with the instruments provided. Each locking mechanism must be rechecked for tightness before closing the soft tissues.
6. Final Set Screw Tightening: All Set Screws must be tightened using the appropriate instrument (*e.g., Torque Handle*) as indicated in the Surgical Technique Guide.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning and compliance by the patient, of the following is essential:

1. Patient should be informed and compliant with the purpose and limitations of the implant devices.
2. The surgeon should instruct the patient regarding amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibratory motion, fall, jolts or other movements preventing proper healing and/or fusion development.
3. In the case of delayed, mal-, or non-union of bone, the patient must continue to be immobilized in order to prevent bending, dislocation, or breakage of the implant devices. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
4. Postoperative patients should be instructed not to smoke, consume alcohol, or consume non-steroidals and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.
5. Postoperative patients should be instructed not to use tobacco or nicotine products, consume alcohol, or use non-steroidal anti-inflammatory drugs and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.
6. The implants are designed and intended as temporary fixation devices. The devices should be removed after complete healing has occurred. Devices which are not removed after serving their intended purpose may bend, dislocate, or break and/or cause corrosion, localized tissue reaction, pain, infection, and/or bone loss due to stress shielding. Complete postoperative management to maintain the desired result should also follow implant removal surgery.

REPROCESSING OF REUSABLE INSTRUMENTS – Important information for instruments

General Information for all Instruments:

- **Point-of-Use Processing:** To facilitate cleaning, instruments should be cleaned initially directly after use in order to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
- The cleaning process is the first step in effectively reprocessing reusable instruments. Adequate sterilization depends on thoroughness of cleaning.
- The cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.

- It is recommended that all new relevant clinical practice guidelines be followed as per the *CDC guidance, “Guideline for Disinfection and Sterilization in Healthcare Facilities”*.
- It is recommended to rinse the device components with water that meets specifications for *AAMI TIR34 “Water for the reprocessing of medical devices”* for example, DI/RO water.

Instrument Preparation:

- Cleaning, inspection, lubrication, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be cleaned prior to lubrication and sterilization.
- All instrument hinged, rotating, and articulating parts must be lubricated prior to sterilization with a water soluble and sterilizable lubricant intended for surgical instruments (*Hinge-Free® for example*).

Cleaning Instructions for all Instruments:

- Instruments must be cleaned prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Disconnect all handles/knobs prior to cleaning.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
- Ensure all moving parts of instruments are cleaned at both extents of travel.
- Handle all products with care. Mishandling may lead to damage and possible improper functioning.
- Clean the instruments, trays and inserts using only recommended cleaning solutions. Use of caustic solutions (caustic soda) will damage the instruments.
- Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible and verify that all actuating parts move freely. Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.

Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the step until clean.

Manual Cleaning Steps

Step 1	Rinse devices in deionized (DI) or reverse osmosis (RO) water to remove excess soil.
Step 2	Submerge device in enzyme solution and allow to soak for 5 minutes.
Step 3	Scrub device using a soft bristled brush until all visible soil has been removed. Use of a syringe or water jet is recommended for hard to reach areas.
Step 4	Rinse devices in lukewarm tap water for a minimum of 1 minute.
Step 5	Submerge devices in cleaning solution such as CritiKlenz® and sonicate for a minimum of 10 minutes
Step 6	Thoroughly rinse devices with DI/RO water to remove all detergent residues.
Step 7	Dry devices with a clean soft cloth.

Automatic Washer Cleaning

Step 1	Rinse devices in deionized DI/RO water to remove excess soil.
Step 2	Submerge device in enzyme solution and allow to soak for 5 minutes.
Step 3	Rinse devices in lukewarm tap water to remove detergent residuals.
Step 4	Place devices in fully extended open position into washer and process through a standard washer/disinfector instrument cycle.

Automatic Washer/Disinfector Cycle Steps

Step 1	Pre Wash, cold tap water, 2 minutes.
Step 2	Enzyme wash, hot tap water, 1 minute.
Step 3	Detergent wash, Hot tap water (66°C/150°F), 2 minutes.
Step 4	Rinse 2x, hot tap water, 15 seconds.
Step 5	Purified Water rinse, Hot tap water (66°C/150°F), 10 seconds.
Step 6	Hot Air Dry, (116°C/240°F), 7- 30 minutes.

STERILIZATION/RESTERILIZATION:

All implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Implants and instruments should be autoclave sterilized using the following validated cycle parameters. Alphatec products have been validated to achieve sterility using a double layer of single ply sterilization wrap.

Sterilization Parameters for the Solanas System Sets

System	Cycle Type	Temperature	Minimum Exposure Time	Minimum Drying Time
Solanas Sets	Pre-vacuum	270°F (132°C)	8 minutes	50 minutes

Sterilization Notes:

- The 8 minute sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) 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 US FDA for the selected sterilization cycle specifications (time and temperature).
- The cycle conditions in the tables above were validated and are considered adequate to achieve a SAL of 10⁻⁶.

MAINTENANCE OF TORQUE WRENCH

CALIBRATION: Regular calibration ensures the Torque Wrench performs according to its specifications. To ensure that the Torque Wrench operates properly and safely at all times, Alphatec recommends that the Torque Wrench be calibrated every six (6) months. Heavy use applications may necessitate much more frequent calibration. **If at any time a torque wrench appears to be malfunctioning, remove it from service and return it to Alphatec for recalibration or replacement immediately.** For any questions regarding calibration, please contact Alphatec Customer Service.

COMPLAINT HANDLING/REPORTING

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, fax, e-mail, or letter, per contact

information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible.

You may contact Customer Service directly at:

Phone (800) 922-1356

Phone (760) 431-9286

Fax (760) 431-7083

customerservice@alphatecspine.com

SYMBOLS

For a listing of Symbols and Explanations, see alphatecspine.com/eifu

R_xonly

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.