INVICTUS® OSSEOSCREW® SYSTEM
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Invictus OsseoScrew is a pedicle screw system that consists of pedicle screws and associated general instruments. Implant components are available in a variety of sizes to suit the individual pathology and anatomical conditions of the patient. The Invictus OsseoScrew is an implantable pedicle screw with a core manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and expandable screw shank that is manufactured from commercially pure titanium (CP Ti Grade 4; unalloyed titanium) conforming to ASTM F67. The instruments in this system are intended for use in surgical procedures.

The Invictus OsseoScrew is designed to be compatible with the Invictus Spinal Fixation System screws, hooks, rods, connectors, and cross-connectors rods for the thoracolumbar spine and Invictus OCT Spinal Fixation System for the cervical (C1 to C7) to thoracic (T1-T3) spine.

INDICATIONS FOR USE:
The Invictus OsseoScrew System (for use with the Invictus Spinal Fixation System and the transition rods from the Invictus OCT Spinal Fixation System) is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

CONTRAINDICATIONS:
Contraindications include but are not limited to the following:
1. Use in the cervical spine
2. Use with bone cement
3. Patients with allergy to titanium or cobalt chrome
4. Patients with joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance
5. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities
6. Commingling of titanium and stainless-steel components within the same construct
7. Reuse or multiple uses
8. Use in bicortical purchase

WARNINGS/CAUTIONS/PRECAUTIONS:
1. The Invictus OsseoScrew System must be used in conjunction with Alphatec Spine's Invictus Spinal Fixation System in order to complete a full spinal construct.
2. The implants and instruments of the Invictus OsseoScrew System are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections in this Instruction for use.
3. The Invictus OsseoScrew 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.
4. The Invictus OsseoScrew Deployment Shafts are single-use devices. Do not reuse. Reuse of the single-use shafts may result in failure due to shearing of the threads or damage to the tip.

5. Once the Invictus OsseoScrew implant has been expanded, it may be difficult to collapse, re-position, or remove; therefore, it is important to confirm proper placement of the Invictus OsseoScrew prior to deploying the expansion feature by use of fluoroscopy or other suitable imaging technique.
6. The Invictus OsseoScrew should not be placed bicortically.
7. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity. 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.
8. 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 affect 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.
9. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
10. 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.
11. The decision of when to use the Invictus OsseoScrew instead of an Invictus screw can only be determined by the surgeon after assessment of the patient's needs, anatomy, and careful analysis of variables such as length and diameter of the pedicle screw required.
12. The un-expanded Invictus OsseoScrew implant may be removed after placement, similar to a typical pedicle screw. However, the implant cannot be reused. Dispose of the used Invictus OsseoScrew per hospital protocol.
13. In the event that the Invictus OsseoScrew implant fails to deploy, the implant may remain in place. Alternatively, the Invictus OsseoScrew may be replaced with a larger diameter screw from the Invictus System.
14. Invictus OsseoScrew trial probes and trial markers should be removed before screw placement.
15. After the Invictus OsseoScrew has been expanded, tension must be relieved by rotating the T-handle one full turn counterclockwise prior to removing the expansion shaft. After the Invictus OsseoScrew has been collapsed, tension must be relieved by rotating the T-handle one full turn clockwise prior to removing the expansion shaft.
16. 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.

MRI SAFETY INFORMATION:

The Invictus OsseoScrew System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Invictus OsseoScrew System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS

Possible adverse effects include:

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, and local tissue reaction
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
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 and/or sacral fracture, and/or discontinued growth of fused bone at, above and/or below the surgery level
7. Neurological injury, disorder, pain and/or abnormal sensations
8. Revision surgery
9. Death

PREOPERATIVE MANAGEMENT:

1. Only those patients meeting the criteria listed in the indication 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.
2. 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.
3. Once the Invictus OsseoScrew implant has been expanded, it cannot be un-expanded, re-expanded, or removed. Therefore, it is critical to confirm proper placement of the Invictus OsseoScrew prior to deploying the expansion feature by use of fluoroscopy or other suitable imaging technique.

POSTOPERATIVE MANAGEMENT:

Postoperative management by the surgeon is essential. This includes instructing, warning, and monitoring the compliance of the patient.

1. The patient should be informed and compliant with the purpose and limitations of the implant devices.
2. The surgeon should instruct the patient regarding the 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. Immobilization should be considered in order to prevent bending, dislocation, or breakage of the implant device in the case of delayed, mal-union, or non-union of bone. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
4. 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.

5. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

REPROCESSING OF REUSABLE 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. All reusable instruments that have been taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into the sterile surgical field.
- 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, 2008.”
- It is recommended to rinse the device components with water that meets specifications for *AAMI TIR34 “Water for the reprocessing of medical devices, 2014”* for example, DI/RO water.
- The validated cleaning and sterilization reprocessing steps provided in these instructions are considered recommended guidelines. The user is ultimately responsible for verifying adequate cleanliness of the devices. Any reprocessing methods used aside from those recommended for Alphatec Spine devices should be validated by the user prior to implementation.
- Equipment, materials, and personnel differ between hospitals; therefore, validation and routine monitoring of the process are normally required at a reprocessing facility.

Instrument Preparation and Disassembly:

- Cleaning, inspection, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be cleaned prior to sterilization.

Cleaning of Instruments, Containers, and Trays:

- Instruments provided in a set must be removed from the set and cleaned prior to sterilization. Instrument trays, containers, and lids must be thoroughly cleaned separately until visually clean.
- Cleaning, maintenance, and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- 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 it to the manufacturer.
- Clean the instruments, trays and inserts using only recommended cleaning solutions. Use of caustic solutions (caustic soda) will damage the instruments.
- All solutions for cleaning must be prepared per the manufacturer’s instructions.

- Use of water with high mineral content should be avoided.
- 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 instruments are in the fully extended, open position throughout cleaning. Disconnect Quick Connect handles/knobs from the shafted instruments prior to cleaning.
- 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 function.

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 for Instruments

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution, such as *Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner* or equivalent, per manufacturer's recommendations and submerge device in enzyme solution. Actuate the device while it is submerged and soak for a minimum of 10 minutes.
Step 3	Actuate and scrub the device using an appropriately sized soft bristled brush, such as a *Spectrum Surgical code #M-16* or 45-542 (or equivalent), to brush any lumens for a minimum of 2 minutes. If needed, actuate at several locations to access all surfaces. Use of a syringe (minimum of 50 ml) or water jet is recommended for the hard-to-reach areas and repeat 3 times.
Step 4	Rinse devices in Deionized / Reverse Osmosis (DI/RO) water for a minimum of 1 minute.
Step 5	Prepare cleaning solution, such as *Prolystica® 2X Concentrate Alkaline Detergent,* per manufacturer's recommendations and submerge and actuate devices in cleaning solution 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, lint free cloth or filtered compressed air.

Automatic Washer Cleaning Steps for Instruments

Step 1	Complex instruments, such as those with cannulations, lumens, 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 with ambient temperature tap water where debris could become trapped. Place them into the Washer/Disinfector and process through a standard surgical instrument cycle.
Step 2	Prewash with cold tap water for 2 minutes.
Step 3	Enzyme wash using cleaner such as *Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner* or equivalent, per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum of 1 minute.
Step 4	Detergent wash using detergent such as *Prolystica® 2X Concentrate Alkaline Detergent* or equivalent, per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum 2 minutes.
Step 5	Rinse 2 times, hot tap water (66°C/150°F minimum), for a minimum 15 seconds.
Step 6	Purified water rinse, hot (66°C/150°F minimum), for a minimum 10 seconds.
Step 7	Hot air dry (115°C/239°F minimum), for a minimum of 10 minutes.

INSPECTION:

- Inspect each instrument, container, and tray to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Drill bits, reamers, rasps and other cutting instruments should be inspected after processing.
- Inspect instruments for any other damage, wear, and/or corrosion.
- When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrument disposal.

STERILIZATION AND RESTERILIZATION:

- All implants and reusable instruments are provided non-sterile and must be steam sterilized prior to use using validated cycle parameters in the table below. Each facility should ensure its processing system can effectively apply validated cycle parameters such that equivalent sterility assurance levels are achieved. It is the responsibility of the healthcare facility to qualify their sterilizers' maximum load capacity and determine what effect the loading pattern of the sterilizer has on the sterilization of the devices.
- Alphatec perforated trays have been validated to achieve a sterility assurance level (SAL) of 10^{-6} using FDA cleared sterilization accessories (containers and filters). FDA-cleared reusable or paper filters should be used to achieve and maintain sterility after processing.
- Alphatec perforated container/tray configurations have also been validated to a sterility assurance level (SAL) of 10^{-6} using FDA-cleared sterilization wrap. Perforated container/tray configurations must be double wrapped to allow steam to penetrate and make direct contact with all surfaces.

- Do not stack trays during sterilization.
- Sets have been validated in standard configurations. No additional items should be added to the set for sterilization.
- Certain devices are packaged non-sterile as a single device to be steam sterilized by the end user. Without stacking, place the device in a container basket or use hospital-provided FDA-cleared sterilizers and accessories (e.g., sterilization wraps, sterilization pouches, sterilization trays). Confirm the container basket or sterilizer/accessories are acceptable for use with the ATEC device by referring to the specifications outlined in basket/sterilizer/accessory instructions for use. Verify sterilization can be achieved following the recommended sterilization cycle specifications (time and temperature).
- 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 FDA for the selected sterilization cycle specifications (time and temperature). Recommended sterilization parameters are provided below.

Sterilization Parameters

Set Type	Cycle Type	Temperature	Exposure Time	Minimum Drying Time	Minimum Cool Down Time
Invictus OsseoScrew Implant Only Set	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes	60 minutes
Invictus OsseoScrew Mixed Set	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes	60 Minutes
Invictus OsseoScrew Instrument Only Set	Pre-vacuum	132°C (270°F)	4 Minutes	45 Minutes	75 Minutes

Sterilization Notes:

- These parameters are consistent with the appropriate version of *ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."*

RETURNING INSTRUMENTS TO ALPHATEC SPINE:

All used products returning to Alphatec Spine must undergo all steps of cleaning, inspection, and terminal sterilization before being returned to Alphatec Spine. Documentation of decontamination should be included.

UDI CONSTRUCTION:

To compile a unique device identifier (UDI) for reusable, reprocessed devices, the device identifier (GTIN) may be ascertained by searching for the part number in the FDA GUDID at https://accessgudid.nlm.nih.gov/. The production identifier(s) (e.g., lot number, serial number) may be found directly marked on the device.

COMPLAINT HANDLING / REPORTING:

All product complaints relating to safety, efficacy, or performance of the product should be reported immediately to Alphatec Spine by telephone, 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 customerservice@atecspine.com.

For Surgical Technique Guides or additional information regarding the products, please contact your local representative or Alphatec Spine, Inc. Customer Service directly at customerservice@atecspine.com.

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

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

ALPHATEC SPINE, INC
1950 Camino Vida Roble
Carlsbad, CA 92008, USA
(760) 431-9286
(800) 922-1356
www.atecspine.com