Invictus® Small Stature Spinal Fixation System
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Invictus Small Stature Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The Invictus Small Stature Spinal Fixation System consists of a variety of shapes and sizes of rods, screws, hooks, connectors, and cross connectors that provide internal fixation and stabilization during bone graft healing and/or fusion mass development. The screws, hooks, connectors, and cross connectors are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The rods are available in commercially pure titanium (CP Ti Grade 4) per ASTM F67, titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and cobalt chrome (Co-28Cr-6Mo) per ASTM F1537.

The Invictus Small Stature Transition Connectors accept various rod diameters and are appropriate for use with Alphatec Spine's 5.5 and 6.0 mm diameter rod-based systems, including the Arsenal Spinal Fixation System and the Invictus Spinal Fixation System.

The Invictus Small Stature implants are provided non-sterile. The instruments in this system are intended for use in surgical procedures.

INDICATIONS FOR USE:
The Invictus Small Stature Spinal Fixation System is intended for non-cervical posterior and anterolateral fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.
When used for posterior non-cervical screw fixation in pediatric patients, the Invictus Small Stature Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Invictus Small Stature Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.
The Invictus Small Stature Spinal Fixation System is intended to be used with autograft and/or allograft.

CONTRAINDICATIONS:
The system is contraindicated for:
1. Use in the cervical spine.
2. Patients with allergy to titanium or cobalt chrome.
3. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance.
4. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness, and/or other medical conditions, which would prohibit beneficial surgical outcome.
5. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities.
6. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
7. Reuse or multiple uses.

WARNINGS/CAUTIONS/PRECAUTIONS:

1. The implants and reusable 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. 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 safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
4. 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.
5. 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.
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 Invictus Small Stature Spinal Fixation System are reusable surgical devices except for the Guidewires used with the Invictus Small Stature Spinal Fixation 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 segment, 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. No spinal implant can withstand body loads for an indefinite period of time without the support of bone. In the event that successful fusion is not achieved, bending, breakage, loosening, or disassembly of the device will occur.
11. 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.

12. 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.
13. 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.
14. 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.
15. 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.
16. The Set Screws of the Iliac Side Loading Connector and Side Loading Claw Hook must be final-tightened using the Final Torque Limiting Handle, 70 In-LB and a counter torque.
17. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
18. To prevent Guidewire breakage, do not use a kinked or bent Guidewire.
19. Guidewires should be monitored using fluoroscopic imaging to avoid advancement through the vertebral body and damage to underlying structures.
20. Verify superior and inferior rod overhang. Inadequate overhang may cause improper set screw placement resulting in an unstable construct.
21. Do not final tighten under compression or distraction as the rod may not be normalized to the tulips, resulting in rod slippage.
22. Pedicle screws and rod-to-rod connectors cannot be used on the tapered section of transition rods. If using pedicle screws and rod-to-rod connectors with transition rods, only attach them on constant diameter rod sections.
23. Set Screws must not be final tightened during any derotation, compression/distraction, or in-situ bending maneuvers.

MRI SAFETY INFORMATION:

The Invictus Small Stature Spinal Fixation 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 Invictus Small Stature Spinal Fixation System in the MR environment is unknown. Scanning a patient who has this medical 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, seroma, 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
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. Non-union and/or pseudarthrosis
8. Neurological disorder, pain and/or abnormal sensations
9. Revision surgery
10. 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.
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. 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.
5. Final tightening of Set Screws: All Set Screws must be tightened using the appropriate instruments (e.g., Torque Handle, Final Driver, and Counter Torque) as indicated in the Surgical Technique Guide.
6. During Guidewire placement, it is recommended to frequently use alternate imaging planes. Ideally, an A-P, lateral, and oblique view should be taken at all critical steps during the procedure to confirm proper positioning and alignment, and to prevent kinking or breakage of the devices.

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. Implant devices should be revised or removed if bent, dislocated or broken.
4. 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.
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

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."*
- 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.
- 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:

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

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 removable 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 unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, 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.

Cleaning of Instruments, Container, and Trays:

- All solutions for cleaning must be prepared per the manufacturer's instructions.
- Instruments provided in a set, must be removed from the set for cleaning. Instrument trays, containers, and lids must be thoroughly cleaned separately until visually clean.
- Ensure instruments are in the fully extended, open position throughout cleaning. Disconnect Quick Connect handles from the shafted instruments prior to cleaning.
- Pay special attention during cleaning to complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes.
- Use of water with high mineral content should be avoided.

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 (Required)

Certain instruments of the Invictus Small Stature Spinal Fixation System may be disassembled for cleaning per instructions provided below.

Cannulated Iliac Probes: To disassemble the Cannulated Iliac Probe for cleaning, turn the proximal handle cap counterclockwise and remove the cap with inner cannula.

Manual Cleaning Steps for Instruments (Required):

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution, such as *Polystica*® 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 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 instruments with Deionized / Reverse Osmosis (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 of 15 seconds.
Step 6	Purified water rinse, hot (66°C/150°F minimum), for a minimum of 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 with alkaline detergents.
- Visually inspect for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, and worn components.
- Ensure that the laser markings are legible and verify that all actuating parts move freely.
- When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrument disposal.

STERILIZATION / RESTERILIZATION OF INSTRUMENTS:

- All implants and reusable instruments, and single-use not packaged sterile that are provided non-sterile and must be cleaned and sterilized prior to use in the provided trays using the 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 sterility assurance level (SAL) of 10^{-6} using FDA cleared sterilization accessories (container 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 achieve 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.
- Instrument 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
Implant Only Set	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes	60 Minutes
Implant/Instrument Mixed Set					
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, email, 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 order of a physician.

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

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