ZODIAC® SPINAL FIXATION SYSTEM
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Zodiac Spinal Fixation System (Zodiac System/Zodiac Polyaxial/Zodiac Lumbar Spinal Fixation System) facilitates the surgical correction of spinal deformities by providing internal fixation and stabilization during bone graft healing and/or fusion mass development. The implants are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI or Ti-6Al-4V) or stainless steel (SS 316L). Implant rods are also available in commercially pure titanium (Ti Grade 4), titanium alloy (Ti 6Al 4V ELI), stainless steel and cobalt chrome (Co-28Cr-6Mo). All hooks are made from stainless steel (SS 316L) and titanium alloy (Ti 6Al 4V ELI). The Zodiac System is intended for fixation/attachment to the posterior thoracic and lumbar spine only.

The Zodiac System may be used in connection with Alphatec Spine's Solanas® Posterior System, which in turn connects with Avalon® Occipital Plate System creating additional levels of fixation.

The Zodiac System does not include cannulated screws; if cannulated screws are preferred, please use the Alphatec Spine Illico® MIS System.

INDICATIONS FOR USE:
The Zodiac Spinal Fixation System is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the Zodiac System are dependent in part on the configuration of the assembled device and the method of attachment to the spine.

It is intended that this device, in any system configuration, be removed after development of solid fusion mass. Hook component indications are limited to T7-L5. Sacral-Iliac screw indications are limited to the sacrum-iliac crest only.

1. The Zodiac System, when used as a hook and sacral iliac screw fixation system (non-pedicle screw) is intended for:
    a. Patients having fractures of the thoracic and lumbar spine.
    b. Patients having deformity (i.e., idiopathic scoliosis, neuromuscular scoliosis, or kyphoscoliosis with associated paralysis or spasticity).
    c. Patient having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).
2. The Zodiac System, when used as a pedicle screw system in the thoraco-lumbo-sacral iliac region of the spine is intended for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).
3. In addition, the Zodiac System, when used as a pedicle screw fixation system is intended for:
    a. Patients receiving autograft or allograft bone graft.
    b. Patients having the device fixed or attached to the lumbar and sacral iliac spine and having severe spondylolisthesis, grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.
4. The Zodiac System, when used as a laminar hook and bone screw system is intended for:
    a. Patients having fractures of thoracic and lumbar spine.

b. Patients having thoracolumbar deformity (i.e., idiopathic scoliosis, neuromuscular scoliosis, or kyphoscoliosis with associated paralysis or spasticity).
c. Patients having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).

CONTRAINDICATIONS:

The system is contraindicated for:

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

WARNINGS/CAUTIONS/PRECAUTIONS:

1. The implants and instruments of the System are provided non-sterile. Implants must be sterilized and instruments must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
2. The Zodiac System Implants are used 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.
3. **The Implants and the Rod Template are single use devices.** Under no circumstances should they be reused. While a device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated so as to allow for 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 Zodiac System instruments are reusable surgical devices, except for the Rod Template.
5. Do not comingle titanium and stainless steel components within the same construct.
6. The final operative procedure with the Zodiac System must include tightening 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.
7. 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.

8. Potential 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.
9. 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.
10. 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.
11. It is critical that set screws are torqued to the proper values as recommended in this IFU and the Surgical Technique Guides, using the instruments provided. Failure to tighten the set screw to the recommended torque could compromise the mechanical stability of the connector.
12. The system implants and instruments of the Alphatec Spine product lines should not be used with any other company's spinal systems.
13. 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.
14. 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.
15. 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.
16. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

MRI SAFETY INFORMATION:

The Zodiac Spinal Fixation System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Zodiac Spinal Fixation System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

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, 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 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 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 rod to a more specific length, rod cutting should be done at a distance from the operative field, 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. The torque values for specific Set Screws are listed below for the Zodiac System implants.

   Refer to the Surgical Technique Guide for appropriate instrument(s) use:
   - Bridge screws must be tightened to 40in-lb.
   - All Rod Connectors must be tightened to 40in-lb with the following exception:
     - Open Offset Rod Connectors must be tightened to 100in-lb.
   - Iliac Bolts must be tightened to 80in-lb.
   - Monoaxial, Polyaxial, Uniplanar screws and Hooks must be tightened to 100 in-lb.

POSTOPERATIVE MANAGEMENT:

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

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.

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 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 (Required)

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution 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 to brush any lumens for a minimum of 2 minutes. If present, actuate at actuating 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. If needed, actuate at actuating locations to access all surfaces. Use a syringe (minimum of 50 ml) or water jet to flush hard-to-reach areas (e.g., lumens) from each end of the devices. Ensure to flush out lumens, blind holes, cracks, or cavities while rinsing.
Step 5	Prepare pH neutral or alkaline cleaning solution 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. If present, actuate at actuating locations to access all surfaces. Use a syringe (minimum of 50 ml) or water jet to flush hard-to-reach areas (e.g., lumens) from each end of the devices and repeat 3 times. Ensure to flush out lumens, blind holes, cracks, or cavities while rinsing.
Step 7	Dry devices with a clean, lint free cloth or filtered compressed air.

Automatic Washer Cleaning

It is recommended based on validations to conduct all manual cleaning steps before automated cleaning steps when using alkaline detergent.

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.

Step 2	Prepare enzymatic solution 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 to brush any lumens for a minimum of 2 minutes. If present, actuate at actuating 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. If needed, actuate at actuating locations to access all surfaces. Use a syringe (minimum of 50 ml) or water jet to flush hard-to-reach areas (e.g., lumens) from each end of the devices and repeat 3 times. Ensure to flush out lumens, blind holes, cracks, or cavities while rinsing.
Step 5	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 6	Prewash with cold tap water for 2 minutes.
Step 7	Enzyme wash using cleaner per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum of 1 minute.
Step 8	Detergent wash using pH neutral or alkaline detergent per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum 2 minutes.
Step 9	Rinse 2 times, hot tap water (66°C/150°F minimum), for a minimum 2 minutes.
Step 10	Purified water rinse, hot (66°C/150°F minimum), for a minimum 2 minutes.
Step 11	Hot air dry (115°C/239°F minimum), for a minimum of 10 minutes.
Step 12	Dry devices with a clean, lint free cloth or filtered compressed air.

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 Parameter Tables

Table 1: The DVR Instrument Tray set has been validated to achieve sterility using FDA cleared sterilization accessories (container and filters). FDA cleared filters should be used to achieve and maintain sterility after processing.

Set Type	Cycle Type	Temperature	Exposure Time	Minimum Drying Time
DVR Instrument Tray	Pre-vacuum	270 °F (132 °C)	4 Minutes	30 Minutes

Table 2: All other Zodiac sets have been validated to achieve sterility using a double layer of single ply sterilization wrap.

Set Type	Cycle Type	Temperature	Exposure Time	Minimum Drying Time
Degenerative Implant Case	Pre-vacuum	270°F (132°C)	4 Minutes	30 Minutes
8.5 mm Screw Set	Pre-vacuum	270°F (132°C)	4 Minutes	45 Minutes
Spinal Fixation System	Pre vacuum	270°F (132°C)	4 Minutes	30 Minutes
Deformity Implant, Instrument Case	Pre-vacuum	270°F (132°C)	4 Minutes	45 Minutes
Pelvic Fixation System	Pre-vacuum	270°F (132°C)	4 Minutes	80 Minutes
Degenerative Implant, Instrument Case 1	Pre-vacuum	270°F (132°C)	4 Minutes	60 Minutes
Degenerative Implant, Instrument Case 2	Pre-vacuum	270°F (132°C)	4 Minutes	45 Minutes
Derotation Tube Instrument Set	Pre-vacuum	270°F (132°C)	4 Minutes	45 Minutes
Table Top Rod Cutter Instrument	Pre-vacuum	270°F (132°C)	10 Minutes	20 Minutes

Table 2 above specifies sterilization cycles that are not considered by the United States Food and Drug Administration (US FDA) to be standard sterilization cycles. 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).

Sterilization Notes:

- The cycle conditions in the tables above were validated and are considered adequate to achieve a SAL of 10^{-6}.
- These parameters are consistent with the appropriate version of *ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

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 device seems 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.

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.

℞only 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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