



INSIGNIA™ ANTERIOR CERVICAL PLATE SYSTEM

INSTRUCTIONS FOR USE (AUSTRALIA)

GENERAL INFORMATION:

The Insignia Anterior Cervical Plate System is intended for anterior fixation to the cervical spine. The Insignia Anterior Cervical Plate System consists of a variety of sizes of plates and screws that are manufactured from titanium alloy conforming to ASTM F136 and are offered non-sterile to be sterilized by the end user. The instruments are made of stainless steel and other materials and are provided either sterile or non-sterile to be cleaned and sterilized by the end user. The instruments in this system are intended for use in surgical procedures.

INDICATIONS FOR USE:

The Insignia Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

CONTRAINDICATIONS:

The system is contraindicated for:

1. Patients with osteopenia, osteoporosis, bone absorption or rapid joint disease.
2. Patients with infection in or adjacent to the spine or spinal structures, fever, leukocytosis.
3. Patients with probable intolerances to titanium, titanium alloy or its components (such as aluminum, titanium, or vanadium).
4. Patients with deficient soft tissue at the wound site or inadequate bone stock or quality.
5. Patients with morbid obesity or gross distorted anatomy due to congenital abnormalities.
6. Pregnant patients or patients with mental illness or other medical conditions which would prohibit beneficial surgical outcome.
7. Patients resistant to following post-operative restrictions on movement.
8. Reuse or multiple uses.

WARNINGS/CAUTIONS/PRECAUTIONS:

1. The following statements apply to single use sterile drills:
 - a. Visually inspect the packaging for signs of damage and breaches of packaging integrity prior to use. Do not use devices if package is opened, damaged, or past the expiry date.
 - b. Do not re-sterilize instruments.
 - c. Do not use scratched or damaged devices.
2. The Insignia Anterior Cervical Plate System is an implant device used only to provide 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 this device.
3. Without solid bone fusion, this device cannot be expected to support the cervical spine indefinitely and may fail due to bone-metal interface, metal, or bone failure.
4. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, compliance of the patient, and other patient conditions which may have an impact on the performance and results of this system. 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, migration and/or disassembly of the device will occur.



5. **The implants are a single use device.** Under no circumstances should it be reused. While the 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. The company accepts no responsibility for implants which have been reused.
6. Potential risks identified with the use of this device, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, and necrosis of bone, neurological injury and vascular or visceral injury.
7. Patients who smoke should be advised of the consequences and of the fact that an increased incidence of non-union has been reported with patients who smoke.
8. Spinal surgery is not recommended for patients with alcohol abuse, morbid obesity, poor bone and muscle quality and/or nerve paralysis.
9. All instruments, except for single use sterile drills, are provided non-sterile and must be cleaned and sterilized before use. All implants are provided non-sterile and must be sterilized before use. Device components should be sterilized using one of the noted validated sterilization cycle parameters. Sterile drills are disposable devices, designed for single use and should not be reused or reprocessed. Reprocessing of single use instruments may lead to instrument damage and possible improper function.
10. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
11. Do not place the plate bender over the blocking mechanism as damage can occur and affect its function. The bend should be applied in the area between the screw holes in order to avoid bending across the screw holes themselves.
12. Drill guides are designed to constrain hole preparation to allow for appropriate bone screw insertion and locking within the plate. Over-angulation of screws may prohibit proper seating of bone screws and result in the inability to lock the screws within the plate.

MRI SAFETY INFORMATION:

The Insignia Anterior Cervical Plate 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 Insignia Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

POSSIBLE ADVERSE EFFECTS:

Possible adverse effects include:

1. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
2. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components.
3. Bone graft fracture, vertebral body fracture or discontinued growth of fused bone at, above and/or below the surgery level.
4. Non-union or pseudoarthrosis.
5. 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.
6. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation.
7. Neurological disorder including paralysis, appearance of radiculopathy and/or abnormal pain development.
8. Displacement of a screw due to incorrect positioning or implant size.



9. Hemorrhaging.
10. Infection.
11. Revision surgery.
12. Death.

PREOPERATIVE MANAGEMENT:

1. The surgeon should only consider utilizing the Insignia Anterior Cervical Plate System with those patients who satisfy the noted indications.
2. The surgeon should avoid utilizing this device with those patients who have contraindicated conditions and/or predispositions.
3. The surgeon should have a complete understanding of the surgical technique, design rationale, indications, and contraindications.
4. The surgeon should have a complete understanding of the function and limitations of the implants and instruments.
5. Careful preoperative planning should include construct strategy and verification of required inventory for the case.
6. Device components should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
7. The condition of all implants & instruments should be checked prior to use. Damaged and/or worn implants and instruments should not be used.
8. Implants and instruments that are provided non-sterile must be cleaned and sterilized before use.

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. Insignia anterior cervical plates are contoured to closely match the anatomical configuration of the spine. If the plate cannot be fitted and additional contouring is necessary, it is recommended that such contouring be minimal and be performed with the instrumentation provided. **The plate must not be contoured in proximity of bone screw pockets or screw retention mechanism.**
3. When contouring the plate, great care should be taken not to scratch, notch or dent the surface as such deformities may compromise the strength of the implant.
4. Single-level plate sizes from 16 – 28 mm should not be contoured.
5. Do not use the awl, 12 mm with the adjustable drill guide as they are not designed to be compatible for use.
6. Proper sizing and positioning of bone graft is essential to obtain successful spinal fusion. The bone graft must extend from the upper to the lower vertebrae to be fused.
7. Bone screws should not be removed more than once to prevent damage to the screw retention mechanism. If necessary, screw removal should only be conducted with instrumentation provided.
8. Single use instruments should be discarded after use.
9. To prevent possible screw back out, visually confirm that the blocking mechanism is fully seated over the screw head.



POSTOPERATIVE MANAGEMENT:

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

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices. The surgeon should instruct the patient on how to compensate for any loss in range of spinal motion due to bone fusion.
2. Additional or revision surgery may be necessary to correct an adverse effect.
3. 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, vibration motion, fall, jolts or other movements preventing proper healing and/or fusion development.
4. In the case of delayed union 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.
5. Postoperative patients should be instructed not to smoke, consume alcohol, or consume non-steroidals and aspirin, as determined by surgeon.
6. Implant devices should be revised or removed immediately, if appropriate, upon a case of a non-union, pseudoarthrosis or if the devices have been bent, dislocated, or broken.
7. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

REPROCESSING OF REUSABLE INSTRUMENTS

General Information for all Reusable 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 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 thoroughly cleaned prior to sterilization.
- Certain instruments of the Insignia Anterior Cervical Plate System may be disassembled for cleaning per instructions provided below.

Locking Driver (137-0001): Press the button on the shaft and turn toward the unlock symbol. Unthread the shaft and slide away from the handle until completely removed.

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 Steps for Instruments

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution, such as <i>Polystica</i> ® 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 <i>Spectrum Surgical code #M-16</i> 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 <i>Prolystica</i> ® 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 <i>Prolystica</i> ® 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 <i>Prolystica</i> ® 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.
- Inspect instruments for any other damage, wear, and/or corrosion.

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 sterilization accessories (containers and filters). 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 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 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 approved 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/Instrument Mixed Set	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes	60 minutes
Instrument Only	Pre-vacuum	270°F (132°C)	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.

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 auscustomerservice@atecspine.com.

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

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



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