IdentiTi™ ALIF Standalone Interbody System
INSTRUCTIONS FOR USE (AUSTRALIA)

GENERAL INFORMATION:
The IdentiTi ALIF Standalone Interbody System is an integrated intervertebral body fusion device for use in anterior lumbar interbody fusion (ALIF) procedures. The IdentiTi ALIF Standalone Interbody System consists of interbody spacers and bone screws in multiple configurations to accommodate individual patient anatomy. The IdentiTi ALIF Standalone Interbody System interbody spacers are manufactured from a combination of commercially pure porous titanium (CP Ti Grade 2) per ASTM F67 and titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The IdentiTi ALIF Standalone Interbody System interbody spacers are provided in multiple footprints with varying lengths, widths, heights, and angles of lordosis to accommodate individual patient anatomy. The interbody spacers accept three bone screws that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters.

INDICATIONS FOR USE:
The IdentiTi ALIF Standalone Interbody System is indicated for spinal fusion procedures from L2 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the IdentiTi ALIF Standalone Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. However, when used in these patients at multiple levels, and for patients with degenerative spondylolisthesis (>Grade 1) and spinal stenosis at one or two adjacent levels, the IdentiTi ALIF Standalone Interbody System must be used with supplemental spinal fixation systems for use in the lumbar spine. The IdentiTi ALIF Standalone Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended to be used with autograft and/or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate.

The IdentiTi ALIF Standalone Interbody System implants of ≤20° are a standalone system. The IdentiTi ALIF Standalone Interbody System implants of >20° must be used with supplemental spinal fixation systems for use in the lumbar spine.

CONTRAINDICATIONS:
The system is contraindicated for:
1. Patients with bone resorption related disease (e.g., osteopenia), bone and/or joint disease, or deficient soft tissue at the wound site.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness, and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients with allergy or intolerance to titanium.
4. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities.
5. Patients with prior fusion at the level(s) to be treated.
6. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
7. Reuse or multiple uses of the implant.

WARNINGS/CAUTIONS/PRECAUTIONS:

1. Interbody implants and single-use instruments are provided sterile.
    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 implants.
    c. Do not use scratched or damaged devices.
2. Components of this system should not be used with components from other systems or manufacturers.
3. Do not comingle dissimilar materials (e.g., titanium and stainless steel) within the same construct.
4. Bone screws are provided non-sterile and must be sterilized prior to surgery. All instruments are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU.
5. All 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.
6. All instruments in the IdentiTi ALIF Standalone Interbody System are reusable surgical devices except for the Trephine Punch Tips, 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.
7. The system is used to augment the development of a spinal fusion by providing temporary stabilization. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
8. Over-distraction of the disc space can lead to facet over-distraction and spinous process contact.
9. Potential risks identified with the use of these fusion devices, which may require additional surgery, include device component failure, loss of fixation, pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and/or vascular or visceral injury.
10. 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.
11. The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia).
12. Implantation should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
13. Placement and positional adjustment of implants must only be done with system-specific instruments. They must not be used with other instrumentation unless specifically recommended by Alphatec Spine Inc., because the combination with other instrumentation may be incompatible.
14. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of this system.

15. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
16. The IdentiTi ALIF Standalone Interbody System is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation. In the case that fewer than the maximum number of screws accommodated by the device are used, the system should be used with additional supplemental fixation for use in the lumbosacral spine.
17. All components should be final tightened per the specifications in the Surgical Technique. Implants should not be tightened past the locking point, as damage to the implant may occur.
18. When implanted at two contiguous levels, the IdentiTi ALIF Standalone Interbody System must be implanted in the same orientation to prevent screw impingement.
19. Lateral Awls must not be used for Center Screw Hole preparation, as over-insertion into bone may occur.
20. Care should be taken in performing screw hole preparation to facilitate a proper Graft Bolt insertion trajectory and implantation. Confirm under fluoroscopy that the Graft Bolt insertion angle is as close as possible to a 40° trajectory. A shallow or incorrect Graft Bolt trajectory may result in encroachment of the spacer and lead to Graft Bolt breakage.

MRI SAFETY INFORMATION:

The IdentiTi ALIF Standalone Interbody 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 IdentiTi ALIF Standalone Interbody 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, 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. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
4. Infection and/or hemorrhaging.
5. Non-union and/or pseudarthrosis.
6. Neurological disorder, pain and/or abnormal sensations caused by improper placement of the device, and/or instruments.
7. Subsidence of the device into the vertebral body.
8. Revision surgery.
9. Death.

PREOPERATIVE MANAGEMENT:

1. Only patients meeting the criteria listed in the indications for the 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 implantation strategy and a verification of required inventory for the case.
4. The condition of all implants and instruments should be checked prior to use. Damaged and/or worn implants and instruments should not be used.
5. IdentiTi ALIF Standalone interbody implant anterior heights provided on product labels are

theoretical calculations from other geometry (e.g., posterior height, width, lordosis). Anterior heights should be considered reference only. Use trials to assess implant sizing prior to implantation.

INTRAOPERATIVE MANAGEMENT:

1. The surgical technique manual should be followed carefully.
2. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times. Fluoroscopy should be employed where view of device is obstructed.
3. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.

POSTOPERATIVE MANAGEMENT:

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

1. Patient should be informed regarding the purpose and limitations of the implanted 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 implanted devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibratory motion, falls, jolts, or other movements preventing proper healing and/or fusion development.
3. Implanted 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 implanted device in case of delayed, malunion, or nonunion 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.
- The cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.
- It is recommended that all new relevant clinical practice guidelines be followed as per the *CDC guidance, "Guideline for Disinfection and Sterilization in Healthcare Facilities."*
- It is recommended to rinse the device components with water that meets specifications for *AAMI TIR34 "Water for the reprocessing of medical devices,"* for example, DI/RO water.

Instrument Preparation 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.

- Certain instruments of the IdentiTi ALIF Standalone Interbody System may be disassembled for cleaning per instructions provided below.

  Trephine Punch: Press the gold button on the sleeve and remove the shaft from the outer sleeve. Remove tip from shaft.

  Removal Drivers: Rotate draw rod knob clockwise and remove draw rod from the outer sleeve.

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 (Required)

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 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 of 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.
- Inspect instruments for any other damage, wear, and/or corrosion.

STERILIZATION AND RESTERILIZATION:

- All instruments and bone screw implants are provided non-sterile and must be steam sterilized before use in the trays provided, using the validated cycle parameters in the table below.
- Alphatec products have been validated to achieve sterility using sterilization accessories (sterilization wraps and containers).
- Instrument sets have been validated in standard configurations. **No additional items should be added to the set for sterilization.**

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
Implants/Instrument Mixed Set					
Instrument Only Set	Pre-vacuum	132°C (270°F)	4 Minutes	45 Minutes	75 Minutes

Sterilization Notes:

- The cycle conditions in the tables above were validated 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."

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 at auscustomerservice@atecspine.com.

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

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