



Battalion[®] Universal Spacer System

INSTRUCTIONS FOR USE

GENERAL INFORMATION:

The Battalion Universal Spacer System (Battalion System) is an intervertebral body fusion device with implants of various lengths, widths, heights, and degrees of lordosis to accommodate individual patient anatomy. The implants are manufactured from PEEK Optima LT1 with/without titanium coated endplates and tantalum markers. All materials are surgical grade conforming to ASTM F2026 (PEEK), ASTM F1580 (titanium coating), and ASTM F560 (tantalum).

Use with supplemental fixation systems from Alphatec Spine such as: Zodiac[®] Polyaxial Spinal Fixation System, Arsenal[®] Spinal Fixation System, Illico[®] MIS Posterior Fixation System, Illico[®] FS Facet Fixation System, BridgePoint[®] Spinous Process Fixation System, or Invictus[®] Spinal Fixation System.

INDICATIONS FOR USE:

The Battalion System is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.

Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain). The lateral approach is limited to levels T5-6 to T11-T12.

Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The Battalion System is intended for use on patients who have had at least six months of non-operative treatment. It is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

LIF Anti-Migration Plate (AMP) may be used with Battalion LLIF interbody spacers to provide integrated fixation.

CONTRAINDICATIONS:

The Battalion 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 PEEK, titanium, or tantalum.
4. Patients resistant to following post-operative 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:

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 commingle dissimilar materials (e.g., titanium and stainless steel) within the same construct.
4. All instruments except the single-use instruments are provided non-sterile and must be cleaned and sterilized prior to surgery. See *CLEANING* and *STERILIZATION* sections in this IFU. Sterile single-use instruments 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.
5. 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. These implants are used only to provide internal fixation, in conjunction with graft and supplemental fixation, during the bone fusion process. A successful result may not be achieved in every instance.
7. 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.
8. 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.
9. AMP™ Anti-Migration Plate is not designed to be used with Battalion LLIF 14 mm wide cages.

PRECAUTIONS:

1. 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.
2. Placement and positional adjustment of implants must only be performed 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.
3. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may affect the performance of this system.
4. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
5. Resection of the anterior longitudinal ligament (ALL) may facilitate insertion of the LLIF implant for greater sagittal correction, when used with AMP™ Anti-Migration Plate and supplemental fixation per the indications, and aid in preventing potential endplate damage.



To minimize risk to surrounding anatomy when resecting the ALL, do not extend the resection past the medial wall of the contralateral pedicle as identified on true AP fluoroscopy.

MRI SAFETY INFORMATION:

The Battalion 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 Battalion 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.

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 the 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:

- Cleaning, inspection, lubrication, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be thoroughly cleaned prior to lubrication and sterilization.
- All instrument hinged, rotating, and articulating parts must be lubricated prior to sterilization with a water soluble and sterilizable lubricant intended for surgical instruments (Hinge-Free®, for example).

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 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.
- Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the step until clean.

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.

Manual Cleaning Steps for Instruments (Required):

Certain instruments of the Battalion System may be disassembled for cleaning per instructions provided below.

PS and PC Straight Inserter: Press the circular button (marked "for cleaning") on the sleeve; slide the sleeve away from the handle and completely over the shaft.

PS and PC Offset Inserter: Press the circular button (marked "for cleaning") on the sleeve; slide the sleeve away from the handle and completely over the shaft. Remove the shaft from the handle by pressing the gold rectangular button; grasp the knurled impact cap at the back; simultaneously twist and pull the cap away from the handle until the shaft releases; pull shaft all the way through the handle.

LLIF Inserter (27412-200, 27412-250, 27412-600, 27412-650): Disassemble the LLIF Angled Inserters into five main components prior to cleaning; disassemble the LLIF Straight Inserter into its four main components, disregarding step b:

- a) Press the circular button on the sleeve subassembly, slide the sleeve away from the handle and completely over the shaft.
- b) Remove the inserter tip from the sleeve.



- c) Remove the shaft from the Driver Subassembly by pressing the angled button on the side of the button housing and pulling on the shaft until it detaches from the Driver Subassembly.
- d) Remove the Handle Subassembly from the Driver Subassembly by pressing the rectangular button on the driver subassembly and pulling on the handle until it detaches from the Driver Subassembly.

LIF Straight Inserter (113-100): Disassemble the Inserter into its main components by pressing the circular button on the sleeve subassembly and sliding the sleeve away from the handle and completely over the shaft.

LLIF Cranial-Caudal Inserter (113-140): Disassemble the Inserter into its main components by pressing the circular button on the sleeve subassembly and sliding the sleeve away from the handle and completely over the shaft.

LLIF Retractor: Disassemble the LLIF Retractor into its six main components prior to cleaning:

- a) Remove the blades from the frame arms by pulling back the golden lever located on the head of each frame arm and pulling up on the blades.
- b) For cleaning, position the retractor body in the closed position by pushing up on the golden lever ring, and pulling the retractor handles apart.
- c) Remove the handles from the retractor by pressing down on the golden buttons and pulling them out of the retractor body.

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 <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 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® 2X Concentrate Enzymatic Presoak & Cleaner</i> 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® 2X Concentrate Alkaline Detergent</i> 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 / RESTERILIZATION OF INSTRUMENTS:

- All instruments are provided non-sterile and must be cleaned and sterilized before use. Instruments must be sterilized using the appropriate cycle parameters in the table below.
- 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.



Sterilization Parameters

Method	Cycle Type	Minimum Temperature	Exposure Time	Minimum Drying Time	Minimum Cool Down Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes	15 minutes

Sterilization Notes:

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

RETURNING INSTRUMENTS TO ALPHATEC SPINE:

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

UDI Construction

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

COMPLAINT HANDLING / REPORTING:

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, e-mail, or letter, per contact information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. You may contact Customer Service directly at customerservice@atecspine.com.

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

R_xonly Caution: Federal law (USA) restricts these instruments to sale by or on the order of a physician.

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



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

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