Battalion™ Universal Spacer System

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, and BridgePoint Spinous Process Fixation System.

INDICATIONS:

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. The Battalion System is intended for use with autograft or allograft (eg. Allogenic bone graft composed of cancellous and/or corticocancellous bone graft) and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

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:

1. The implants and Single-Use instruments are provided sterile
   a. Do not re-sterilize implants
   b. Do not use implants if package is opened or damaged or if expiration date has passed.
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. 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. The benefit of spinal fusions utilizing any vertebral body replacement has not been adequately established in patients with stable spines.
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.

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. These implants have not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating or migration 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.
3. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Alphatec Spine Inc., because the combination with other instrumentation may be incompatible.
4. Based on dynamic testing results, 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
5. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

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 vision 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.

Instrument Preparation:

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

Battalion Inserter: Disassemble the Axial Straight and Curved Inserters per step a) to disassemble into two components prior to cleaning; disassemble Offset Straight Inserters into its 3 components per steps a) and b) prior to cleaning:

a) Press the circular button (marked "for cleaning") on the sleeve subassembly, slide the sleeve away from the handle and completely over the shaft.

b) Remove the Shaft Subassembly from the Handle Subassembly 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: Disassemble the LLIF Angled Inserters into five main components prior to cleaning; disassemble the LLIF Straight Inserter into its four main components, disregard 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.

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.

Step 1	Rinse devices in ambient temperature tap water to remove excess soil.
Step 2	Submerge instrument in enzyme solution such as *Polystica*® 2X Enzymatic or equivalent. Actuate the instrument while it is submerged and soak for a minimum of 10 minutes.
Step 3	Actuate and scrub the instrument using a 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 instruments in Deionized / Reverse Osmosis water for a minimum of 1 minute.
Step 5	Submerge and actuate instruments in a cleaning solution such as *Prolystica*® 2X Alkaline (pH 11.2) or equivalent, and sonicate for a minimum of 10 minutes.
Step 6	Thoroughly rinse instruments with Deionized / Reverse Osmosis water to remove all detergent residues.
Step 7	Dry instruments with clean, lint free cloth or filtered compressed air.

Automatic Washer Cleaning Steps for Instruments

Important - Manual Cleaning Steps 1 and 2 are required before performing the Automated Washer / Disinfector Cycle Steps.

Step 1	Follow steps 1 and 2 of the Manual Cleaning Steps for Instruments.
Step 2	Thoroughly rinse instruments in ambient temperature tap water to remove detergent residuals.
Step 3	Place instruments in fully extended open position into washer and process through a standard washer/disinfector instrument cycle.
Step 4	PreWash, cold tap water, for a minimum of 2 minutes.

Step 5	Enzyme wash (such as *Prolystica*® 2X enzymatic or equivalent), hot tap water, for a minimum of 1 minute.
Step 6	Detergent wash (such as *Prolystica*® 2X Alkaline (pH11.2) or equivalent), Hot tap water (66°C/150°F minimum), for a minimum of 2 minutes.
Step 7	Rinse 2x, hot tap water, for a minimum of 15 seconds.
Step 8	Purified Water rinse, Hot (66°C/150°F minimum), for a minimum of 10 seconds.
Step 9	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 tables below.
- Alphatec perforated trays have been validated to achieve sterility 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 sterility using FDA cleared sterilization wrap. Perforated container/tray configurations must be double wrapped in sterilization wrap to allow steam to penetrate and make direct contract with all surfaces.
- Do not stack trays during sterilization.

Table 1 – Sterilization Parameters

Method	Cycle Type	Minimum Temperature	Minimum Exposure Time	Minimum Drying Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes (followed by a 15 minutes cool down period)*

* Battalion Lateral Instruments

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, fax, 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@alphatecSpine.com

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

℞only **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 alphatecspine.com/eifu

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