ILLICO® FS FACET FIXATION SYSTEM
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Illico FS System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The system is comprised of the Facet Screw and Facet Lag Screw with Washer offered in two diameters (4.5mm and 5.0mm) and instrumentation. The implant provides bilateral facet fixation, with or without bone graft, at single or multiple levels and can be used in conventional or percutaneous surgical procedures. The implants are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI).

INDICATIONS FOR USE:
The Illico FS System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The Illico FS System is intended for bilateral facet fixation, with or without bone graft, at single or multiple levels from L1 to S1 inclusive. The Illico FS System is indicated for treatment of any or all of the following:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origins confirmed by history and radiographic studies.
- Degenerative disease of the facets with instability.
- Trauma (i.e. fracture or dislocation).
- Spondylolisthesis.
- Spondylolysis.
- Pseudoarthrosis and failed previous fusion which are symptomatic or which may cause secondary instability or deformity.

CONTRAINDICATIONS:
The Illico FS System is contraindicated for:

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

WARNINGS/CAUTIONS/PRECAUTIONS:
1. The safety and effectiveness of the Illico FS System has been established only for those spinal conditions listed in the Indications For Use section. The safety and effectiveness of these devices for any other conditions are unknown.
2. The Illico FS System implants are used only to provide temporary internal fixation during the bone fusion process with or without the assistance of a bone graft. A successful result may not be achieved in every instance of use with these devices.
3. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, or bone failure.

4. The benefit of spinal fusions utilizing any facet screw fixation system has not been adequately established in patients with stable spines.
5. The implants are provided non-sterile and must be cleaned and sterilized before use.
6. These implants are for SINGLE USE ONLY. 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 a 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 products which have been reused.
7. Based on testing results, 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, proper reduction, and complete compliance of the patient.
8. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level and patient condition, which may impact the performance of the system when using this device.
9. Potential risks identified with the use of these devices, which may require additional surgery, include device component fracture, loss of fixation, nonunion, fracture of the vertebra, neurological injury, vascular or visceral injury.
10. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
11. Other significant risks to spinal surgery include alcohol abuse, obesity, and/or patients with poor bone, muscle and/or nerve quality.
12. It is recommended that the implants of the Alphatec Spine product lines should not be used with any other company's spinal systems.
13. Titanium and stainless steel components must not be used within the same construct.
14. To prevent guidewire breakage, do not use a kinked or bent guidewire.
15. The implantation of the Illico FS System should be performed only by experienced spinal surgeons with specific training in the use of this facet screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
16. The Illico FS System has not been evaluated for safety and compatibility in the MR environment. The Illico FS System has not been tested for heating or migration in the MR environment.

MRI SAFETY INFORMATION:

The Illico FS 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 Illico FS 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, 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, 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. Scar tissue formation possibly causing neurological and/or vascular compromise.
10. Revision surgery.
11. Death.

PREOPERATIVE MANAGEMENT:

1. The surgeon should consider for surgery only those patients indicated for the use of the Illico FS System.
2. The surgeon should not consider for surgery those patients contraindicated for the use of the Illico FS System.
3. The surgeon should have a complete understanding of the surgical technique and of the system design rationale, indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of the implant and each instrument.
5. Careful preoperative planning should include verification of required inventory for the case.
6. Damaged implants should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.

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. During guidewire placement, it is recommended to frequently use alternate imaging planes. Ideally, an A-P, lateral, and oblique view should be taken at all critical steps during the procedure to ensure proper positioning and alignment, and to prevent kinking or breakage of the devices.
3. Surgical Technique provided for the Illico FS System should be followed to ensure proper implant placement.

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. 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.
3. In the case of delayed, mal-, 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.
4. Postoperative patients should be instructed not to smoke, consume alcohol, or consume non-steroidals and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.

5. 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.
6. The Illico FS System implants are designed and intended as temporary fixation devices. The devices should be removed after complete healing has occurred. Devices which are not removed after serving their intended purpose may bend, dislocate, or break and/or cause corrosion, localized tissue reaction, pain, infection, and/or bone loss due to stress shielding. Complete postoperative management to maintain the desired result should also follow implant removal surgery.
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 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 Steps for Instruments

Step 1	Rinse devices in deionized (DI) or reverse osmosis (RO) water to remove excess soil.
Step 2	Submerge device in warm enzymatic solution, such as Enzycare2®, and allow to soak for a minimum of 5 minutes. Prepare a new solution if it becomes grossly contaminated.
Step 3	Scrub device using a soft bristled brush until all visible soil has been removed. Use a syringe (minimum 50mL) or water jet for hard-to-reach areas.
Step 4	Rinse devices in running lukewarm tap water for a minimum of 1 minute to remove any residual detergent. Flush hard-to-reach areas thoroughly with lukewarm tap water.
Step 5	Prepare a cleaning solution, such as CritiKlenz®, in an ultrasonic bath. Fully submerge devices in cleaning solution and sonicate for a minimum of 10 minutes.
Step 6	Thoroughly rinse devices with RO/DI water to remove all detergent residues.
Step 7	Dry devices with a clean, soft cloth and clean pressurized (minimum 30psi) air.

Automatic Washer Cleaning Steps Pre-cleaning

Step 1	Rinse devices in deionized (DI) or reverse osmosis (RO) water to remove excess soil, paying particular attention to cannula of devices and hard-to-reach areas.
Step 2	Prepare a warm enzymatic solution, such as Enzycare2®. Flush cannula of devices and hard-to-reach areas with solution prior to immersion. Submerge device in solution and allow to soak for a minimum of 5 minutes.
Step 3	Rinse devices in lukewarm tap water to remove detergent residuals.
Step 4	Place devices in fully extended open position into washer and process through a standard washer/disinfector instrument cycle.

Disinfector Cycle Steps

Step 1	Pre Wash, cold tap water, 2 minutes.
Step 2	Enzyme wash (such as Enzycare2®), hot tap water, 1 minute.
Step 3	Detergent wash (such as CritiKlenz®), Hot tap water (66°C/150°F), 2 minutes.
Step 4	Rinse 2x, hot tap water, 15 seconds.
Step 5	Thermal Rinse, Hot tap water (80-93°C/176-200°F), 2 minutes.
Step 6	Purified Water rinse, (66°C/150°F), 10 seconds.
Step 7	Dry using a clean, soft cloth and pressurized air (minimum 30psi).

INSPECTION:

- Inspect each instrument 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.
- When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrument disposal.

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 Parameters

Set Type	Cycle Type	Temperature	Exposure Time	Minimum Dry Time	Minimum Cool Down Time
Mixed Implants/Instruments	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes	60 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."

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.

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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