Instructions for Use

ILLICO® FS FACET FIXATION SYSTEM

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 AND 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. ***Refer to Sterilization Section.***
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.

POSSIBLE ADVERSE EFFECTS:

The following complications and adverse reactions have been shown to occur with the use of similar spinal instrumentation. These effects and any other known by the surgeon must be discussed with the patient preoperatively.

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, including instruction and warning and compliance by the patient, of the following is essential:

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.

INSTRUMENT PREPARATION:

1. Cleaning, inspection, lubrication, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
2. Instruments must be cleaned prior to lubrication and sterilization.
3. 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:

All implants and instruments must be free of packaging material and biocontaminants prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Complex devices, such as those with cannulas, hinges, retractable features, mated

surfaces, and textured surface finishes, require special attention during cleaning. Assure devices are in the fully extended, open position throughout cleaning. Certain instruments may require dismantling before cleaning. Operate all equipment and mix all chemicals to concentrations according to manufacturer's recomendations. Handle all products with care. Mishandling may lead to damage and possible improper functioning of the device.

Manual Cleaning Steps

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).

STERILIZATION/RESTERILIZATION:

All instruments are provided non-sterile and must be cleaned and sterilized before use. Implants and instruments should be autoclave sterilized using the following cycle parameter. Alphatec products have been validated to achieve sterility using FDA cleared sterilization accessories (container and filters). FDA cleared filters should be used to achieve and maintain sterility after processing.

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

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, or letter. 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. For additional information regarding the ILLICO FS System or to obtain Surgical Technique, please contact Alphatec Spine, Inc. Order Management at 1(800) 922-1356 or 1(760) 431-9286. **Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.**

Rx Only	**Caution**: Federal law (USA) restricts these devices to sale by or on the order of a physician

CE 0413

CE MARK INFORMATION:

This CE mark applies only to devices affixed with the CE mark.

SYMBOLS:

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

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EC REP

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