ILLICO® MIS POSTERIOR FIXATION SYSTEM
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Illico MIS Posterior Fixation System is intended to facilitate the surgical correction of noncervical spinal deformities by providing temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. When used for a minimally invasive posterior approach Illico MIS Instrumentation is used in conjunction with polyaxial screw components. The implants are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI or Ti-6Al-4V). The rods are available in commercially pure (CP) titanium and/or cobalt chrome.

INDICATIONS FOR USE:
The Illico MIS Posterior Fixation System is intended for posterior, non-cervical, spinal fixation device in skeletally mature patents as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion. It is intended to provide stabilization during the development of fusion utilizing autograft or allograft bone graft. It is intended that this device, in any system configuration, be removed after development of solid fusion mass.

CONTRAINDICATIONS:
The system is contraindicated for:
1. Use in the cervical 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. Comingling of titanium and stainless steel components within the same construct.
8. Reuse, or multiple use.

WARNINGS/CAUTIONS/PRECAUTIONS:
1. The implants and instruments of the Illico System are provided non-sterile. Refer to the CLEANING and STERILIZATION sections for directions on cleaning and sterilization.
2. The Illico MIS Posterior Fixation System implants are used only to provide temporary internal fixation during the bone fusion process with the assistance of a bone graft. A successful result may not be achieved in every instance of use with these devices. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
3. The product implants are single use devices. Do not reuse.
4. The instruments are reusable surgical devices with the exception of the guide wires which are designed for single use.
5. To prevent guide wire breakage, do not use a kinked or bent guide wire.
6. 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. 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.

7. Potential risks identified with the use of these devices, which may require additional surgery, include device component failure, loss of fixation/stabilization, non-union, vertebral fracture, neurological injury, vascular or visceral injury.
8. Other significant risks to spinal surgery include alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who smoke should be advised of the consequences that an increased incidence of non-union has been reported with patients who smoke.
9. It is critical that set screws are turned to the proper torque values as recommended in the surgical techniques, using the instruments provided.
10. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
11. It is recommended that the implants of the Alphatec Spine product lines should not be used with any other company's spinal systems.
12. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
13. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
14. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

MRI SAFETY INFORMATION:

The Illico MIS 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 MIS 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. Revision surgery.
10. Death.

PREOPERATIVE MANAGEMENT:

1. Only those patients meeting the criteria listed in the indications for 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 construct strategy, pre-assembly of component parts (if required), and verification of required inventory for the case.

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 guide wire 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. Rods should be bent in only one direction, one time, at an angle no greater than 15° at the same point of location. If it is mandatory to cut the rods to a more specific length, rod cutting should be done at a distance from the operative range, and such that a non-sharp edge remains on the rod.
4. Only one single continuous rod should be used on the same side of the spine whenever possible. Connecting two parallel or axially aligned rods is not recommended.
5. 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.
6. The final operative procedure with polyaxial screws must include tightening of set screws to 100in-lb torque value with the instruments provided.

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 and compliant with the purpose and limitations of the implant devices.
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, vibratory motion, fall, jolts or other movements preventing proper healing and/or fusion development.
3. In the case of delayed, mal-union, or non-union of bone, immobilization should be considered 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-steroidal anti-inflammatory drugs and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.

5. The Illico MIS Posterior Fixation 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.
6. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

STERILIZATION TRAYS CONTAINING SMADE TRACKERS

General Information

- Certain sterilization trays contain a black location tracking device (SMADE). This tracker contains a non-replaceable lithium-metal battery.
- SMADE tracker operating temperatures range from -20°C to +140°C and operating pressures up to 3.0 bar.
- WARNING: Failure to follow any and all of the safety precautions listed below may result in the device and batteries overheating, igniting, or exploding, and may cause serious injury or damage to humans, animals, and property.
    - Do not expose the device or batteries to excessive heat (over +150°C) or open flame.
    - Do not puncture or cut the device or batteries within.
    - Do not attempt to make any modifications to the device or batteries.
    - Do not attempt to disassemble the device or batteries.

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 enzyme solution and soak for 5 minutes.
Step 3	Scrub device using a soft bristled brush until all visible soil has been removed. Use of a syringe or water jet is recommended for hard-to-reach areas.
Step 4	Rinse devices in lukewarm tap water for a minimum of 1 minute.
Step 5	Submerge devices in cleaning solution such as CritiKlenz 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. Pressurized air (30 psi) may be used to assist in drying.

Automatic Pre-Wash Steps

Step 1	Rinse devices in deionized (DI) or reverse osmosis (RO) water, paying particular attention to hard-to-reach areas, to remove excess soil.
Step 2	Submerge device in enzyme solution and soak for 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.

Automatic Washer Cleaning Steps for Instruments

Step 1	Pre Wash, cold tap water, 2 minutes.
Step 2	Enzyme wash, hot tap water, 1 minute.
Step 3	Detergent wash, Hot tap water (66 °C/150 °F), 2 minutes.
Step 4	Rinse 2x, hot tap water, 15 seconds.
Step 5	Purified Water rinse (66 °C/150 °F), 10 seconds.
Step 6	Dry devices with a clean, soft cloth. Pressurized air can be used to assist drying.

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.
- 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

System	Cycle Type	Temperature	Exposure Time	Minimum Drying Time
Illico MIS Posterior Fixation System Implants				
Non-Cannulated Screws and Rods Implants SKIF-73700-01	Pre-vacuum	270°F (132°C)	8 minutes	60 minutes
Cannulated Screws and Rods Implants SKIF-73700-02	Pre-vacuum	270°F (132°C)	8 minutes	60 minutes
Cobalt Chrome Rod Caddy SKIF-73700-05	Pre-vacuum	270°F (132°C)	8 minutes	60 minutes
Illico MIS Posterior Fixation System Instruments				
Retractor Instruments SKIF-73500	Pre-vacuum	270°F (132°C)	10 minutes	60 minutes
Posterior Disc Prep minutes Instruments SKIF-73501	Pre-vacuum	270°F (132°C)	10 minutes	60 minutes
Screw Extender Posterior Fixation Instruments SKIF-73700-03	Pre-vacuum	270°F (132°C)	8 minutes	10 minutes
Screw System Instruments SKIF-73700-04	Pre-vacuum	270°F (132°C)	8 minutes	10 minutes
Standard Screw Extender Multi-level Instruments SKIF-73700-06	Pre-vacuum	270°F (132°C)	8 minutes	10 minutes
Wide Screw Extender Multi-level Instruments SKIF-73700-07	Pre-vacuum	270°F (132°C)	8 minutes	10 minutes

The table above specifies sterilization cycles that are not considered by the United States Food and Drug Administration (US FDA). to be standard sterilization cycles. 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 US FDA for the selected sterilization cycle specifications (time and temperature).

MAINTENANCE OF TORQUE WRENCH:

CALIBRATION: Regular calibration ensures the Torque Wrench performs according to its specifications. To ensure that the Torque Wrench operates properly and safely at all times, Alphatec recommends that the Torque Wrench be calibrated every six (6) months, after 200 autoclave cycles, or approximately 3000 actuations (clicks), whichever comes first. Heavy use applications may necessitate much more frequent calibration. **If at any time a torque wrench appears to be malfunctioning, remove it from service and return it to Alphatec for recalibration or replacement immediately.** For any questions regarding calibration, please contact Alphatec Customer Service at (800) 922-1356.

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 customerservice@atecspine.com.

℞only 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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