InSePtion®
MIS Fixation System
Product Instructions for Use

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Non-Sterile Product ***SINGLE USE***

BEFORE USING THIS PRODUCT READ THE FOLLOWING THOROUGHLY.

Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

Important Information on the Kalitec Medical InSePtion MIS Fixation System

Description:
The Kalitec Medical InSePtion MIS Fixation System is a minimally invasive posterior attachment spinal fixation system manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and designed to be an alternative to pedicle screw fixation for the described indications. The system is composed of spinous process plates, dedicated surgical instruments and sterilization cases. The components are used to build a construct to provide stabilization of spinal segment in the thoracic, lumbar and sacral spine to support fusion.

Indications, Contraindications, and Possible Adverse Effects:

Indications:
The Kalitec Medical InSePtion MIS Fixation System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system is intended for use with autograft or allograft.

The Kalitec Medical InSePtion MIS Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: 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), and/or tumor. The Kalitec Medical InSePtion MIS Fixation System is not intended for standalone use.

Contraindications:
- Acute or chronic infectious diseases of any etiology or localization
- Signs of local inflammation
- Open wounds
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Metal/polymer sensitivity/allergies to the implant materials
- Mental illness, alcoholism, heavy smoking, drug abuse
- Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery
- Incompetent or missing posterior arch (e.g., laminectomy, pars defect severe osteoporosis)
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis)
- Any case not described in the Indications
- Any patient unwilling to cooperate with the post-operative instructions
- Symptomatic cardiac disease
- Systemic or terminal illness
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period
- Any case requiring the mixing of components from other manufacturers systems
- Any case requiring the mixture of stainless steel with titanium or stainless steel with cobalt chrome implant components
- Previous history of infection

Contraindications may be relative or absolute and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

Potential Adverse Events:
A listing of possible adverse events includes, but is not limited to:
- Bending, disassembly, or fracture of any or all components of the implant
- Loosening of the implant
- Implant material sensitivity, or allergic reaction to a foreign body
- Infection, early or late
- Decrease in bone density due to stress shielding
- Increased biomechanical stress on adjacent levels
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by improper positioning and placement of implants or instruments
- Loss of correction, curvature, height, and/or reduction
- Dural tear and/or leak
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis
- Loss of bowel and/or bladder control or other types of urological system compromise
- Scar formation possibly causing neurological compromise around nerves and/or pain
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery
- Interference with radiographic, CT, and/or MR imaging because of the presence of the implants
- Graft donor site complications including pain, fracture, or wound healing problems
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium
- Development of respiratory problems (i.e. pulmonary embolism, bronchitis, pneumonia, etc.)
- Non-union (or pseudarthrosis), delayed union and/or mal-union
- Cessation of any potential growth of the operated portion of the spine
- Loss of spinal mobility or function
- Death

Warnings and Precautions:
The safety and effectiveness of spinal fixation 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 degenerative spondylolisthesis with objective evidence of neurologic 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. The implantation of the Kalitec Medical InSePtion MIS Fixation System should be performed only by experienced spine surgeons with specific training in the use of spinal pedicle screw instrumentation because this is a technically demanding procedure presenting a risk of serious injury to the patient. A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, etc. which may impact the performance of the system.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

If a reusable device is/was used in a patient with, or suspected of having, Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize and eliminate the risk of cross-contamination.

MRI Safety Information:
The Kalitec Medical InSePtion MIS Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Kalitec Medical InSePtion MIS Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Implant Selection:
The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. Overweight patients may be subject to additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery.

Preoperative:
- Only patients that meet the criteria described in the indications should be selected.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery.
- The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The Kalitec Medical InSePtion MIS Fixation System components are not to be combined with the components from another manufacturer.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

All sets should be carefully checked for completeness and all components should be carefully inspected prior to all surgeries.

Intraoperative:
- Any instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Imaging system should be used whenever possible to facilitate surgery.
- Misuse of the instruments or implant components may cause injury to the patient or operative personnel.
- Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.
- Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.
- Before closing the soft tissues, all of the locking screws should be tightened firmly.

Postoperative:
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved Kalitec Medical InSePtion MIS Fixation System components should ever be reused under any circumstances.

Packaging:
Packages for each of the components should be intact upon receipt. All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to Kalitec Medical.

Cleaning and Decontamination:
Implants and instruments of the Kalitec Medical InSePtion MIS Fixation System are supplied clean and NOT STERILE, and must be sterilized prior to use.

All instruments must first be thoroughly cleaned before sterilization and introduction into a sterile surgical field.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment.

Some device materials may develop changes in mechanical, physical or chemical characteristics under conditions of repeated use, cleaning and re-sterilization that may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications.

The instruments should be inspected and checked following a thorough cleaning to make certain they are functioning properly. Visually inspect all devices for any evidence of deterioration, corrosion, and/or discoloration and if found, the instrument should be replaced.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

Precleaning:
Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Blood and bodily fluids are highly corrosive and can produce stains that are difficult to remove.

Manual Cleaning:
Prepare an enzymatic cleaning solution per manufacturer's specifications. Separate dissimilar metal instruments and disassemble all instruments. Fully immerse and soak all instruments in enzymatic cleaner for 15 minutes. Fill all cannulations with enzymatic cleaner. Use a small soft-bristle brush to remove visible soil from all surfaces of the instrument while fully immersed in the solution paying special attention to remove soil from hinges, jaws, tips, box locks, and ratchets. Agitate the instruments in the solution while scrubbing. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Actuate any movable parts to loosen any trapped soil. Rinse instruments under warm (38-49°C) running water until all evidence of detergent is removed. Place the instrument into a bath containing warm (38-49°C) water. Agitate the instruments by hand for at least three minutes. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Prepare an enzymatic cleaning solution to the manufacturer's specifications using distilled water. Ultrasonicate devices for 10 minutes, ensuring the devices are completely submerged. Rinse instruments under warm running water for at least one minute or until all evidence of detergent is removed. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Dry with clean lint-free cloth and/or allow to air dry.

Automated Cleaning:
Automated cleaning should be performed after manual removal of debris using the manual cleaning process identified above.

The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with the approved efficacy (e.g., FDA approval, complying with and validated according to the ISO 15883 series) should be used.

Place the instruments in a suitable washer/disinfector basket and process with the following minimum recommended wash cycle parameters as listed in the following table:

Cycle	Description
1	Prewash- Cold tap water- 2 minutes
2	Enzymatic wash – Hot tap water - 43C min, 5 minutes using enzymatic detergent
3	Detergent wash - Hot tap water – 55C min- 5 minutes using neutral detergent
4	Rinse 1 - Hot tap water - 2 minutes
5	Rinse 2 - Pure water - 90C- 1 minute
6	Dry – Hot air – 90C- 15 minutes

Sterilization:
The Kalitec Medical InSePtion MIS Fixation System instruments and implants are provided non-sterile. These products need to be steam sterilized by the hospital using the following method:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum	270°F(132°C)	4 minutes	40 minutes

Wrap tray with a towel placed between tray and FDA cleared wrap.

The Sterility Assurance Level (SAL) is 1 x 10^{-6}, via the indicated methods. No claims of pyrogenicity are made.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to Kalitec Medical.

Product Complaints:
Any Health Care Professional who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify Kalitec Medical or its representative. Further, if any of the implanted Kalitec Medical InSePtion MIS Fixation System component(s) ever malfunctions, Kalitec Medical or its representative should be notified immediately.

If any Kalitec Medical product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or Kalitec Medical should be notified immediately by telephone, fax or in writing.

For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help Kalitec Medical understand the cause of the complaint.

Further Information:
If further information is needed or required, please contact:

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