DeGen Medical

E³ MIS™ PEDICLE SCREW SYSTEM

Instructions For Use

DESCRIPTION:

The DeGen Medical E³ MIS™ Pedicle Screw System is a versatile rod and screw system. The system consists of rods, screws, head assemblies, pre-assembled polyaxial screws, and set screws which can be assembled in different configurations to provide immobilization of the thoracic, lumbar and sacral spine. All components are either made of Titanium/Titanium Alloy or Cobalt-Chrome Alloy. The head assembly can be placed on the screw head intraoperatively by the surgeon and attached to rod with a set screw. The polyaxial screw (pre-assembled screw body/head assembly) attaches to a rod with a set screw.

The JOUST™ Minimally Invasive Surgery approach is comprised of instrumentation to go with F1 MPS™ Modular Pedicle Screw System and the E³ MIS™ Pedicle Screw System.

INDICATIONS:

The DeGen Medical E³ MIS™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease; spondylolisthesis; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). When used for posterior noncervical pedicle screw fixation in pediatric patients, the DeGen Medical E³ MIS™ Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The DeGen Medical E³ MIS™ Pedicle Screw System is intended to be used with autograft and/ or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

- Active or suspected local or systemic infection
- Fractures and tumors with loss of anterior support
- Pregnancy
- Osteoporosis
- Systemic or metabolic bone conditions
- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices
- Foreign body sensitivity
- Patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during healing and may be at higher risk for implant failure

PRECAUTIONS

- The implantation of spinal fixation devices should be performed only by experienced surgeons with specific training in the use of such devices. This is a technically demanding procedure presenting a risk of serious injury to the patient.
- Patient Selection: In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
  1. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant.
  2. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant.
  3. Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
  4. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
  5. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Size Selection: The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant.
- Implant Failure: Implants can break when subjected to increased loading associated with delayed union or non-union. Internal fixation appliances are load-sharing device that are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of implants.
- Do not reuse surgical implants: An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

WARNINGS:

- 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 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.
- Potential risks identified with the use of this device system, which may require additional surgery, include:
  - Device component fracture
  - Loss of fixation
  - Non-union
  - Fracture of the vertebra
  - Neurological injury
  - Vascular or visceral injury
- Magnetic Resonance (MR) Safety: The DeGen Medical E³ MIS™ Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The system has not been tested for heating or migration in the MR environment.
- E³ MIS™ Pedicle Screw System head assemblies are compatible with screws from the F1 MPS™ Modular Pedicle Screw System, and similarly, F1 MPS™ Modular Pedicle Screw system head assemblies are compatible with screws from the E³ MIS™ Pedicle Screw System. However, the screw threadform and thread pitch of these systems are different, and therefore, each system has its own set of thread taps.
- Do not use the DeGen Medical E³ MIS™ Pedicle Screw System and F1 MPS™ Modular Pedicle Screw System with components of other systems. Unless stated otherwise, DeGen Medical devices are not to be combined with the components of another system. Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage. All components should be final tightened per the specifications in the Surgical Technique. Implants should not be over-tightened, as damage to the implant may occur. Proper placement must take into consideration of anatomy of the patient in and around the surgical site to avoid potential damage.
- Correct handling of implants is important: Contouring of the metal implants should only be done with proper equipment. It is recommended that contouring be gradual and that great care be used to avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- Removing of implant after healing: Metallic implants can possibly increase the risk of infection, loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
- Instructions to the Patient: Postoperative care and the patient's willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and follow the postoperative care regimen as instructed by his or her physician.

Pediatric Specific Warning (in addition to aforementioned)

- The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

POSSIBLE ADVERSE EFFECTS

- Infection, early or late; Pain, discomfort, or abnormal sensations due to the presence of the device; Nerve damage due to surgical trauma or presence of the device; Nonunion, delayed union; Bending or fracture of implant; Loosening of the implant; Screw back out, possibly leading to implant loosening, and/or reoperation for device removal, non-union, delayed union; Metal sensitivity or allergic reaction to a foreign body; Decrease in bone density due to stress shielding; Fracture of bony structures; Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness and paresthesia; Vascular damage could result in catastrophic or fatal bleeding; Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period; Bursitis; Reflex sympathetic dystrophy; Spinal cord impingement or damage, dural tear or leak; Degenerative changes or instability in segments adjacent to fused vertebral levels; Paralysis; Death.

Pediatric Specific Adverse Events (in addition to above mentioned)

- Spinal stenosis; Loss or limitation of growth, short stature; Deformity progression, deformity recurrence, or new deformity formation due to crankshaft phenomenon; Implant malfunction or breakage (not limited to rod or screw breakage); Pedicle expansion, pedicle cut out by screw threads, or pedicular fracture.

CLEANING

- Unless just removed from an unopened package, all instruments and implants must be disassembled (if applicable) and cleaned before sterilization
- Cleaning Precautions: Avoid excessively acidic or alkaline solutions. Do not exceed two hours soaking in any solution. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

A. PRE-CLEANING

- Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. Remove gross contaminants with a steady stream of lukewarm/cool water (below 110° F/43° C). Disassemble the devices where possible to expose all surfaces and clean separately.

B. MANUAL CLEANING

- Immerse the devices in solution of tap water and enzymatic cleaner. Follow manufacturers' directions regarding concentration, temperature, and contact time. Use a syringe to ensure that solution reaches all parts of cannulations and close mating surfaces where necessary. Ensure that air is not trapped within features of the device when immersing in the solution.
- After soaking is completed use nylon brushes to clean the devices thoroughly paying particular attention to features where soil may be shielded from the brushing. Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes, teeth of broaches, etc. Use a bottle brush of appropriate diameter for cannulations. Ensure that the brush passes the whole length of each cannulation at least three times.
- If a device may not be disassembled, or has a long cannula, use an ultrasonic bath and process at the frequency, temperature, contact time, and concentration recommended by the enzymatic agent manufacturer. Immerse the device completely in solution of tap water and enzymatic agent and activate the ultrasonic bath.
- Remove the instruments from the cleaning solution and transfer to a purified water bath and soak for 1 minute.
- Thoroughly rinse with purified water for a minimum of 1 minute paying attention to flush lumens, blind holes and difficult to reach areas.
- Carefully inspect each device to ensure that all visible contamination has been removed and thoroughly clean. If contamination is noted repeat the cleaning process.

C. AUTOMATED CLEANING (OPTIONAL)

- Automated is in addition to manual cleaning [step B.] and automated cleaning does not replace manual cleaning.
- If automated cleaning equipment is used, ensure the washer meets approved efficacy (Validated according to ISO 15883).
- Load the medical devices into the washer. Ensure cannulations and blind holes are not horizontal. Articulating devices should be in the open position. Connect cannulations to the rinsing ports of the washer where possible. Make sure all instruments stay in place and do not touch or overlap each other.
- Operate the washer-disinfector cycle.
- Carefully inspect each device to ensure that all visible contamination has been removed and thoroughly clean. If contamination is noted repeat the cleaning process.

D. DRYING

- Place on drying rack and allow to air dry until no water remains. Drying may be expedited by use of lint free cloth or clean compressed air.

INSPECTION

- Inspect all devices before sterilization or storage to ensure the complete removal of soil from surfaces, lumens, holes and movable parts.
- If damage or biological residue is observed, the implant or instrument must be discarded. Return damaged items to DeGen Medical.
- Do not use if damage or wear is noted that may compromise the proper function of the instrument or instrument case. Contact customer service or your DeGen Medical representative for a replacement.
- If corrosion is noted, do not use and contact customer service or your DeGen Medical representative for a replacement.

STERILIZATION:

All implants and instruments used in surgery must be sterilized prior to use. Remove all packaging materials prior to sterilization. All implants and instruments should be cleaned and sterilized prior to surgery. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled within the instrument tray(s). Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. Do not stack trays during sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be wrapped in a FDA cleared sterilization wrap and steam sterilized.

The following is the recommended sterilization cycle:

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

WARRANTY:

The DeGen Medical products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties are hereby disclaimed.

CAUTION:

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

INFORMATION

To view Surgical Technique Guide or for further information, please contact customer service via phone or mail at:

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