Instructions for Use

SureLOK™ MIS 3L Percutaneous Screw System

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

There is no express or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on **Precision Spine®** product(s) described in this publication. Under no circumstances shall **Precision Spine** be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has the authority to bind **Precision Spine** to any representation or warranty except as specifically set forth herein.

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DEVICE DESCRIPTION:

The **SureLOK MIS 3L** Percutaneous Screw System is a top-loading, multiple component, posterior spinal fixation system which consists of cannulated pedicle screws, straight and pre-curved rods, and locking cap screws. All of the components are available in a variety of sizes to match more closely the patient's anatomy. The **SureLOK MIS 3L** Percutaneous Screw System is suitable for the following procedures: open, mini-open, percutaneous MIS approach, or a combination of any during the same procedure. All implantable components are made from medical grade titanium or titanium alloy described by such standards as ASTM F136 or ISO 5832-3. All components are supplied clean and "NON-STERILE".

INDICATIONS:

The **SureLOK MIS 3L** Percutaneous 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 spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The **SureLOK MIS 3L** Percutaneous Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4 of the L5-S1 vertebra) in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudarthrosis; and failed previous fusion.

PRECAUTIONS:

The **SureLOK MIS 3L** Percutaneous Screw System should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. All system implants are single-use only. Reuse of the device may result in the following:

1. Infection
2. Loosening
3. Fracture / mechanical failure of the device
4. Inability to properly engage surgical instrumentation
5. Pyrogenic reaction

CONTRAINDICATIONS:

The **SureLOK MIS 3L** Percutaneous Screw System contraindications include, but are not limited to:

1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Patients unwilling or unable to follow post-operative care instructions
9. Active infectious process or significant risk of infection
10. Any circumstances not listed in the indication of the device

POTENTIAL ADVERSE EFFECTS:
All of the possible adverse effects associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Non-Union
2. Fracture of the vertebra
3. Neurological injury
4. Vascular or visceral injury
5. Early or late loosening of any or all of the components
6. Loss of fixation
7. Device component fracture
8. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or autoimmune disease
9. Disassembly and/or bending of any or all of the components
10. Infection
11. Hemorrhage
12. Change in mental status
13. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
14. Pain, discomfort, or abnormal sensations due to the presence of the device
15. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
16. Cessation of any potential growth of the operated portion of the spine
17. Loss of or increase spinal mobility or function
18. Death

Note: Additional surgery may be required to correct some of these potential adverse events.

WARNINGS:
The following are warnings for this device.

1. 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 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 condition is unknown.
2. When used as a pedicle screw system, this system is intended for Grade 3 or 4 spondylolisthesis at the fifth lumbar/first sacral (L5-S1) vertebral joint.
3. 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 vertebrae, neurological injury, and vascular or visceral injury.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
5. Single use only.
6. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
7. To facilitate fusion, a sufficient quantity of autograft bone should be used.
8. Do not reuse implants. Discard used, damaged, or otherwise suspect implants.
9. The implantation of the pedicle screw system should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
10. Based on the fatigue testing results, 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.
11. Non-sterile; the screws, rods, locking cap screws, cross-links, connectors, hooks, and instruments are sold non-sterile, and therefore must be sterilized before use.
12. The components of this system should not be used with components of any other system or manufacturer.
13. Titanium components should not be used with stainless steel components within the same system.
14. Do not reuse implants. Discard used, damaged, or otherwise suspect implants. **AN IMPLANT SHOULD NEVER BE RE-USED**. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise device performance and patient safety.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. The implant components should be handled and stored carefully, protected from any damage, including corrosive environments.
4. Correct selection of the implant is very important.
5. An adequate inventory of implant sizes should be available at the time of surgery.
6. All implants and instruments must be unpacked, inspected for damage, cleaned and sterilized prior to use in the operative field. Instruments requiring sharp tips and/or edges to function should be inspected prior to use. If such instruments have dulled and will not function optimally, they should be returned to **Precision Spine®** for replacement.

INTRAOPERATIVE:

1. The primary goal of this surgery is to arthrodese selected vertebrae.
2. Adequate exposure, bony preparation and grafting are essential to achieving this result.
3. Extreme caution should be used around the spinal cord and nerve roots, especially when inserting the screws.
4. Breakage, slippage, misuse, or mishandling of the instruments or implant components may cause injury to the patient or hospital personnel.
5. The implants must be handled and contoured carefully to avoid notching or scratching the surface.
6. Before closing the soft tissues, all of the locking cap screws should be tightened firmly according to the operative technique.
7. Implants must never be reused.
8. The placement of screws should be checked radiographically prior to assembly of the rod construct.
9. During construct assembly do not cross-thread locking cap screws. Rotate locking cap screws counter clock wise for 1 to 2 revolutions in screw head before attempting to thread locking cap screw into screw head.

POSTOPERATIVE:

1. Detailed instructions on the use and limitations of the implant should be given to the patient. The patient must be made aware of the limitations of the implant. Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation devices.
2. Surgical implants must never be reused. Any retrieved devices should never be reused in another surgical procedure. The retrieved parts should be handled and disposed of in such a manner as to ensure that reuse is not possible.
3. Adequate postoperative management to avoid fracture, re-fracture or other complications should follow implant removal.

STERILIZATION

The **SureLOK™ MIS 3L** Percutaneous Screw System is supplied non-sterile and must be cleaned and sterilized prior to use. Remove all packaging before sterilization. Implants and instruments should be autoclave sterilized using one of the following validated cycle parameters.

Method	Cycle Type	Sterilization Temperature	Minimum Exposure Time
Steam	Gravity Displacement	270°F (132°C)	15 minutes
Steam	Pre-vacuum	270°F (132°C)	4 minutes

To assure maintenance of sterility we recommend:

- Utilization of a minimum drying time of 20 minutes in accordance with ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health facilities.*
- For USA: Use only FDA cleared sterilization wraps to enclose the sterilization tray.

MAGNETIC RESONANCE ENVIRONMENT

The **SureLOK MIS 3L** Percutaneous Screw System has not been evaluated for safety and compatibility in the Magnetic Resonance environment. The **SureLOK MIS 3L** Percutaneous Screw System has not been tested for heating, migration, or image artifact in the MR environment. The safety of **SureLOK MIS 3L** Percutaneous Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

STORAGE INSTRUCTIONS

All products should be stored in a cool dry place.

HOW SUPPLIED

The required components and specialized instruments are supplied non-sterile in a container suitable for steam sterilization or

individually packaged as replacement product. All components and instruments may be purchased independently.

CARE AND HANDLING

- All torque handles should be returned to the manufacturer for recalibration every six months.
- Please refer to ASTM standards such as F1744-96, “Standard Guide for Care and Handling of Stainless Steel Surgical Instruments” for additional information.
- Surgical instruments are subject to wear with normal usage. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose.
- **Precision Spine®** recommends that all instruments be visually inspected for wear and disfigurement, as well as tested to ensure instruments are functioning properly prior to use. If instruments are discolored, have loose screws/pins, are out of alignment, are cracked or have other irregularities, **DO NOT USE**.

CLEANING AND DECONTAMINATION

- These instructions are to be followed prior to initial use and reprocessing of the instruments.
- Reprocessing the instruments using the methods described herein, will not limit the useful life of the instruments. The useful life of the product is typically determined by wear and damage due to use.
- Transport trays should be considered reusable devices, inspected for visible soils and must be cleaned.
- **WARNING:** The following Cleaning and Sterilization instructions have been validated. Failure to follow all steps may result in an improperly cleaned and sterilized instrument (Non-Sterile).
- **CAUTION:** In order to preserve optimal efficiency and safety of the instruments, the following instructions must be followed.
    - The use of metallic brushes, scrub pads or other articles that are likely to damage the instrument must be avoided.
    - Chemicals, such as chlorine or soda, as well as organic or ammoniated acids or solvents (ex. Acetone) that are likely to damage the instrument, must not be used.
    - Mercurial solutions are not recommended, as they corrode metal parts.
    - If applicable, disassemble instruments prior to Cleaning and Sterilization. Articulated instruments must be opened in order to allow the cleaning of all interstices.
    - Immediately after the surgical procedure, disallowing organic debris to dry on the instruments, remove as much debris as possible from each instrument using a water moistened gauze pad or wipe, exchanging the gauze pad or wipe as it becomes soiled.
    - Prepare a neutral or near-neutral pH enzymatic cleaning solution per the manufacturer’s instructions with warm tap water (35-40°C).
    - Immerse the instruments in the cleaning solution for a minimum of 30 minutes, activating any mechanisms 5X, so the enzymatic cleaner contacts all mated surfaces. Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solutions. Be sure that thorough scrubbing also includes any lumens with an appropriately sized brush that contacts all surfaces. Change the soak solution after each utilization or if grossly soiled.
    - Rinse the instruments in warm tap water (35-40°C) for at least one minute.
    - Transfer the instruments into fresh enzymatic cleaning solution. Sonicate the instruments while immersed in the cleaning solution for a minimum of 15 minutes.
    - Thoroughly rinse all instruments and lumens with warm running water (35-40°C), for at least one minute each until flushing water runs clear. Use a hose or water jet to rinse any lumens, holes, or complex interfaces. Perform a second rinse with DI water, again using a hose or water jet to rinse any lumens, holes, or complex interfaces.
    - Dry with a sterile gauze, clean cloth and/or clean compressed air. Inspect instruments for cleanliness, function, and residual moisture. Any device that is not visually clean must be reprocessed.

LUBRICATION

To protect instruments from staining and rusting during sterilization and storage, they should be lubricated with a water-soluble, preserved lubricant after each cleaning. Since effective ultrasonic cleaning removes all lubricant, re-lubrication is important. The lubricant should contain a chemical preservative to prevent bacterial growth in the lubricant bath. The bath solution should be made with demineralized water. A lubricant containing a rust inhibitor helps prevent electrolytic corrosion of points and edges. Immediately after cleaning, instrument should be immersed for 30 seconds and allowed to drain off, not wiped off. A lubricant film will remain through the sterilization to protect them during storage.

SPECIAL NOTE FOR TORQUE LIMITING HANDLES

(This note applies only to customers who purchase Torque Limiting Handles.)

The following are suggested guidelines for calibration cycles of Torque Limiting Handles. Note that these are general recommendations only and users are encouraged to determine specific calibration cycles for each product depending on their

particular situation or usage. Return product after six months of use, or after 150 autoclave cycles, or after approximately 3000 actuations (Clicks), whichever comes first.

MATERIAL SPECIFICATION
All implantable components are made from medical grade titanium or titanium alloy, which comply with such standards as ASTM F136 or ISO 5832-3. The products are supplied clean and "NON-STERILE".

CLINICAL HISTORY
These instructions for use are based upon current experience. The physician may wish to vary the procedure in accordance with clinical judgment.

PRODUCT COMPLAINTS
Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to **Precision Spine®** If any of the implants or instruments "malfunction" (i.e., do not meet any of their performance specifications or do not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, **Precision Spine** should be notified immediately by phone, fax or written correspondence. When filing a complaint, please provide the product description, product number, lot number, your name and address, and the nature of the complaint.

ADDITIONAL INFORMATION:
The surgical technique guide for the implantation of the **SureLOK™ MIS 3L** Percutaneous Screw System is available upon request. If further information is required, please contact the manufacturer.

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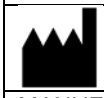
			**RX only**
SEE PACKAGE INSERT FOR LABELING LIMITATIONS	NOT STERILE	SINGLE USE ONLY	SALE BY PHYSICIAN PRESCRIPTION FOR USA ONLY
			
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