PRECISION SPINE™

Instructions For Use

PRECISION SPINE™ FACET SCREW SYSTEM

LBL-IFU-012 Rev B

FACET 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

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DEVICE DESCRIPTION

The **Facet Screw System** is composed of Facet Screws in two diameter sizes in varying lengths. The implant with the associated instruments are used to provide stabilization to the spine with minimal invasion and offered as an alternative to pedicle screw fixation. All components are made from medical grade titanium or titanium alloy described by standard ASTM F136 and/or ISO 5832-3. The products are supplied clean and "NON-STERILE".

INDICATIONS

The **Facet Screw System** is intended to stabilize the spine as an aid to fusion by transfacet fixation. The device is indicated for posterior surgical treatment with or without bone graft, at single or multiple levels, of any or all of the following spinal levels L1 to S1 (inclusive): Spondylolisthesis, Spondylolysis, Pseudoarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

PRECAUTIONS

1. The success of any spinal fusion is dependent upon many factors that include, but are not limited to, the health and metabolism of the patient. Medical conditions or disease states that alter a patient's normal metabolism may interfere with bone healing.
2. Any fusion that relies on a metal construct for stabilization during the bone healing phase presupposes that bony fusion will ultimately occur. If the bone does not heal and a non-union develops, the metal construct will eventually fail. The **Facet Screw System** relies upon load-sharing with an anterior interbody construct to aid in successful fusion.
3. This device is intended for bilateral placement, with or without bone graft.
4. It is important to choose the correct implant size. Surgeons should be fully trained and familiar with use of the instruments and proper placement of the facet screw implant.
5. Pedicle screw systems, not facet screws, should be considered when there is degenerative disease of the facet joints with instability.
6. As with any percutaneous spinal procedure, good imaging and interpretation of the images are critical to safety.
7. Physicians should be experienced in interpreting biplanar fluoroscopic images of the thoracolumbar spine and experienced in image guided instrument placement.
8. Safety and effectiveness have not been established in patients with the following conditions: greater than grade 2 spondylolisthesis, two or more levels to be fused, morbid obesity (BMI >40), pregnancy.
9. Patients who are taking medications that may interfere with bone or soft tissue healing (e.g. long-term steroid use) may not be suitable candidates as these medications may interfere with bone growth and graft incorporation.
10. As with any permanent implant, a perioperative antibiotic protocol is recommended.
11. Metallic implants can corrode, loosen, migrate, cause pain, bend or fracture, even after a fusion has occurred.
12. An implant should never be reused.
13. The Bone Needle (part number RAN-1315N) and Kirshner Wire (part number KM71164) are Single-Use and are not to be reused.
14. Prior to use, ensure that the expiration date on the Bone Needle (part number RAN-1315N) package is not beyond the use date.

CONTRAINDICATIONS

The **Facet Screw System** contraindications include, but are not limited to:

1. Sepsis, local or systemic
2. Osteomyelitis at the surgical site
3. Absence or destruction of any portion of the facet joint, or procedures which will require removal of any portion of the facet joint
4. Known or suspected sensitivity to implant materials
5. Significant metabolic bone disease (e.g. osteoporosis or osteomalacia) to a degree that posterior spinal instrumentation is contraindicated
6. Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery

ADVERSE EFFECTS/SURGICAL RISKS

Possible adverse effects or risks include, but are not limited to, the following, which may require additional surgery.

1. Infection of soft tissue and/or bone (osteomyelitis); fever
2. Implant loosening
3. Bending or breakage of the device
4. Incomplete relief of symptoms
5. Incomplete fusion, delayed union or non-union
6. Fracture of the pedicle or bone of the facet joint
7. Soft tissue injury
8. Edema
9. Skin irritation, wound dehiscence
10. Dural injury, with or without CSF leakage
11. Neurologic injury, transient or permanent
12. Pain and loss of function
13. Hemorrhage, hematoma
14. Device migration

WARNINGS

The following are warnings for this device.

1 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.
2. Single use only.
3. 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. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
4. Non-sterile; the screws and instruments are sold non-sterile, and therefore must be sterilized before use.
5. The components of this system should not be used with components of any other system or manufacturer.
6. Titanium components should not be used with stainless steel components within the same system.

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. 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 are dull, they will not function optimally and should be returned to **Precision Spine** for replacement.

INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots, especially when inserting the screws.
2. Breakage, slippage, misuse, or mishandling of the instruments or implant components may cause injury to the patient or hospital personnel.
3. The implants must be handled and contoured carefully to avoid notching or scratching the surface.
4. Implants must never be reused.
5. The placement of screws should be confirmed radiographically.

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 **Facet Screw System** is supplied non-sterile and must be sterilized prior to use. Remove all packaging before sterilization. Implants and instruments should be autoclave sterilized using one of the following validated cycle parameters.

Note: Flash sterilization is not recommended for the **Facet Screw System.**

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

To assure maintenance of sterility we recommend:

- Utilization of a minimum drying time of 30 minutes in accordance with ANSI/AAMI ST79:2010, *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 **Facet Screw System** has not been evaluated for safety and compatibility in the MR environment. The **Facet Screw System** has not been tested for heating or migration in the MR environment. Components may interfere with the quality of the imaging obtained using MRI.

STORAGE INSTRUCTIONS

All products should be stored in a cool, dry place.

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 be used only 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, and inspected for visible soils and must be cleaned.
- **WARNING:** The following Cleaning 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 (e.g. 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. 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. Do not allow organic debris to dry.
  - Prepare a 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 10 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, relubrication 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 only applies 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

Implant material is Titanium Ti-6Al-4V ELI per ASTM F-136.

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, the name and address of the person filing the complaint, and the nature of the complaint.

ADDITIONAL INFORMATION

The surgical technique guide for the implantation of the **Facet Screw System** is available upon request. If further information is required, please contact the manufacturer.

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