PRECISION SPINE®

Instructions for Use

RELI™*SP* PLUS SPINOUS PLATING SYSTEM

LBL-IFU-030 Rev A

RELI *SP* PLUS SPINOUS PLATING 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** or its affiliates, or any directors, officers, employees, or agents of Precision Spine or its affiliates, 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** or its affiliates to any representation or warranty except as specifically set forth herein.

Descriptions or specifications in **Precision Spine** printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties.

DEVICE DESCRIPTION

The **Reli *SP* Plus Spinous Plating System** of **Precision Spine, Inc.** is a posterior, non-pedicle supplemental fixation device to facilitate fusion. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patients. All implants are manufactured from titanium alloy per ASTM F-136. All instrument components are made from medical grade stainless steel, titanium or titanium alloy, and aluminum, which comply with such standards as ASTM F-138, ASTM F-136, ASTM B209, ISO5832-1 or ISO5832-3. All components are supplied clean and "NON STERILE". All implants are intended for single use only and should not be reused under any circumstances.

INDICATIONS

The **Reli *SP* Plus Spinous Plating System** of **Precision Spine, Inc.** is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1) of skeletally mature patients. It is intended for single level plate fixation/attachment to spinous process 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), trauma (i.e. fracture or dislocation), spondylolisthesis, and/or tumor. It is not intended for stand-alone use.

WARNINGS & PRECAUTIONS

The **Reli *SP* Plus Spinous Plating System** should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. Accordingly, strict adherence to the indications, contradictions, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative diseases may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about limitations of the implant, including, but not limited to, the implant of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen, or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic and neurosurgical implants, the **Reli *SP* Plus Spinous Plating System** components should never be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The **Reli *SP* Plus Spinous Plating System** has not been evaluated for safety and compatibility in the MR environment. The **Reli *SP* Plus Spinous Plating System** has not been tested for heating or migration in the MR environment. It must be noted that there are several different manufacturers and generations of MRI systems available, and **Precision Spine** cannot make any claims regarding the safety of **Precision Spine** implants and devices with any specific MR system.

Physician Note: 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. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

CONTRAINDICATIONS: The **Reli *SP* Plus Spinous Plating 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 possible 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.

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. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. Extreme caution should be used around the spinal cord and nerve roots.
3. Breakage, slippage, misuse, or mishandling of the instruments or implant components may cause injury to the patient or hospital personnel.
4. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter.
5. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
6. The implants must be handled and contoured carefully to avoid damage, notching or scratching the surface which may affect their performance.
7. Before closing the soft tissues, all of the locking screws should be tightened firmly according to the operative technique.
8. Implants must never be reused under any circumstances.

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 **Reli™ *SP* Plus Spinous Plating 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.

Note: Flash sterilization is not recommended for the **Reli *SP* Plus Spinous Plating System.**

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 ST79:2010, *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 **Reli *SP* Plus Spinous Plating System** has not been evaluated for safety and compatibility in the Magnetic Resonance environment. The **Reli *SP* Plus Spinous Plating System** has not been tested for heating or migration in the Magnetic Resonance environment.

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 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 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 components are made from medical grade stainless steel, titanium, titanium alloy, aluminum or medical grade plastics described by such standards as ASTM F-138, ASTM F-136, ASTM B209, ASTM D-6394 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 **Reli *SP* Plus Spinous Plating System** is available upon request. If further information is required, please contact the manufacturer.

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