Instructions for Use

RCS® Anterior Buttress Plate 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 **RCS** Anterior Buttress Plate System is a temporary implant used to prevent allograft or autograft extrusion. The **RCS** Anterior Buttress Plate System consists of plates and bone screws. The **RCS** Buttress Plate System is also intended to provide stabilization and augment development of a solid spinal fusion. The **RCS** Anterior Buttress Plate System fixates to the anterior portion of the thoracolumbar vertebral body. The construct may be employed alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. The components will be provided non-sterile.

INDICATIONS:

The **RCS** Anterior Buttress Plate System is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

PRECAUTIONS:

The **RCS** Anterior Buttress Plate System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized 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 **RCS** Anterior Buttress Plate System contraindications include, but not limited to:

1. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance
2. Patients with fever, tumors, elevated white blood count and other medical conditions, which would prohibit beneficial surgical outcomes
3. Obesity
4. Mental illness
5. Pregnancy
6. Local infection or inflammation
7. Any case needing to mix metals from different components
8. Any patient unwilling to cooperate with postoperative instructions
9. All cases not stated in the indications
10. Reuse, or multiple uses

POTENTIAL ADVERSE AFFECTS:

The following potential adverse effects associated with the procedure have been shown to occur with the use of similar spinal systems. All patients considered candidates for fusion should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects. The following are potential adverse effects, but not limited to:

1. Loss of proper spinal curvature, correction, height, and/or reduction
2. Infection
3. Non-Union or delayed union
4. Foreign body reaction to the implants
5. Hemorrhaging
6. Loss of neurological function, dural tear, pain, and/or discomfort
7. Bone graft fracture, vertebral body fracture or discontinued growth of fused at, above and/or below the surgery level
8. Bending, loosening, fracture, disassembly, slippage and/or migration of the components
9. Pain or discomfort
10. Change in mental status
11. Bursitis
12. Bone loss and/or bone fracture due to stress shielding
13. Inability to resume activities of normal daily activities
14. Revision surgery
15. Death

WARNINGS:

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. 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.
3. The components of this system should not be used with components of any other system or manufacturer.

PREOPERATIVE:

1. The surgeon should for surgery only those patients indicated for use with the **RCS®** Anterior Buttress Plate System.
2. The surgeon should not consider for surgery those patients contraindicated for the use of the **RCS** Anterior Buttress Plate System.
3. The surgeon should have a complete understanding of the surgical technique and of the system's design rationale, indications, contraindications and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.

INTRAOPERATIVE:

1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. Damage to the nerves will cause loss of neurological functions. Extreme caution should be taken to avoid the spinal cord and nerve roots at all times.
3. Careful use of the implants and instruments should be taken. Misuse of the components may cause injury to the patient or operative personnel.
4. Notching and scratching of implants should be avoided.
5. The **RCS** Anterior Buttress Plate System should be supported by anterior and/or posterior stabilization devices.

POSTOPERATIVE:

1. The physician's postoperative directions, warnings to the patient and the corresponding patient's compliance are extremely important.
2. For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol, and any other activity that would compromise or delay the healing process.
3. The patient should be warned about the limitation of bending at the point of spinal fusion.
4. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibration motion, fall, jolts, or other movements preventing proper healing and/or fusion.
5. The removal of implants should be properly disposed of and are not to be reused under any circumstance.

PACKAGING AND STERILIZATION:
The **RCS®** Anterior Buttress Plate System will be supplied clean and 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.

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: Only use FDA cleared sterilization wraps to enclose the sterilization tray.

MAGNETIC RESONANCE ENVIRONMENT:
The **RCS** Anterior Buttress Plate System has not been evaluated for safety and compatibility in the Magnetic Resonance environment. The **RCS** Anterior Buttress Plate 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 all 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. 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 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 3,000 actuations (Clicks), whichever comes first.

MATERIAL SPECIFICATION:
All components are manufactured from medical grade titanium or titanium alloy described by such standards as ASTM F-136 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, the name and address of the person issuing the complaint, and the nature of the complaint.

ADDITIONAL INFORMATION:
The surgical technique guide for the implantation of the **RCS®** Anterior Buttress Plate 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
			
MANUFACTURED BY			