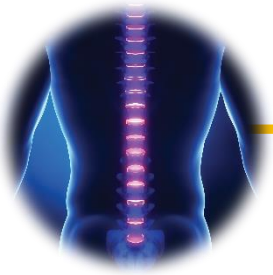

SURGICAL TECHNIQUE

PRECISION SPINE

RCS®

ANTERIOR BUTTRESS PLATE SYSTEM

PRECISION SPINE®

Discover the Difference

Made in the USA

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RCS® Anterior Buttress Plate System

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RCS® ANTERIOR BUTTRESS PLATE SYSTEM OVERVIEW

DESCRIPTION

The Precision Spine RCS Anterior Buttress Plate System is a temporary implant used to prevent allograft or autograft extrusion. The Precision Spine RCS Anterior Buttress Plate System consists of plates and bone screws. The Precision Spine RCS Anterior Buttress Plate System is also intended to provide stabilization and augment development of a solid spinal fusion. The Precision Spine 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. All components are made from medical grade titanium or titanium alloy described by such standards as ASTM F136 or ISO5832-3. The products are supplied clean and "NON-STERILE". SINGLE USE ONLY

INDICATIONS

The Precision Spine 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..

Please refer to package insert (LBL-IFU-003) for complete system description, indications and warnings.

SURGICAL TECHNIQUE

1 PATIENT POSITIONING & APPROACH

The patient is positioned supine with appropriate padding to protect pressure points and peripheral nerves. A bolster or lift may be placed beneath the mid-lumbar spine to increase lordosis, if desired. Fluroscopy may be utilized to identify anatomical landmarks for precise placement of the abdominal incision.

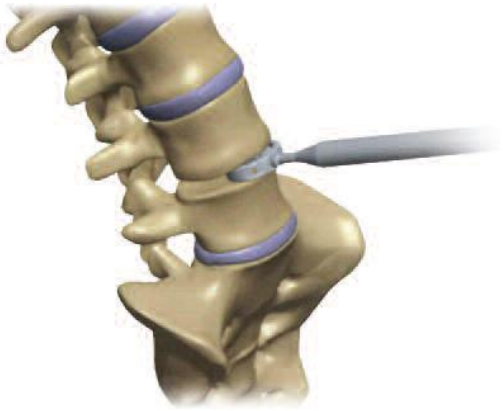

Figure 1

2 INTERVERTEBRAL DEVICE IMPLANTED

Intervertebral device of choice is implanted in disc space. (Figure 1).

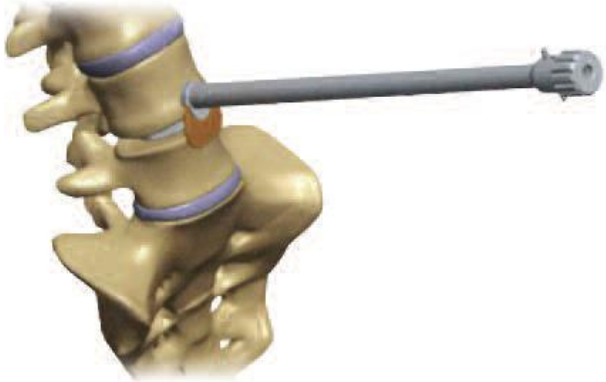

Figure 2

3 BUTTRESS PLATE SELECTION

After discectomy and intervertebral device is implanted, the Buttress Plate height is determined intraoperatively. Once the Buttress Plate height is selected, attach the RCS Buttress Inserter Tool (22-9001) onto the Buttress Plate and insert onto the vertebral body. (Figure 2)

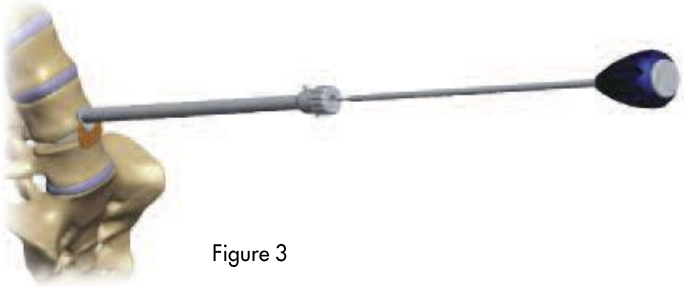

Figure 3

4 AWL INSERTION

The Awl (22-9002) is inserted through the Guide hole until the Awl bottoms out. (Figure 3 and 4)

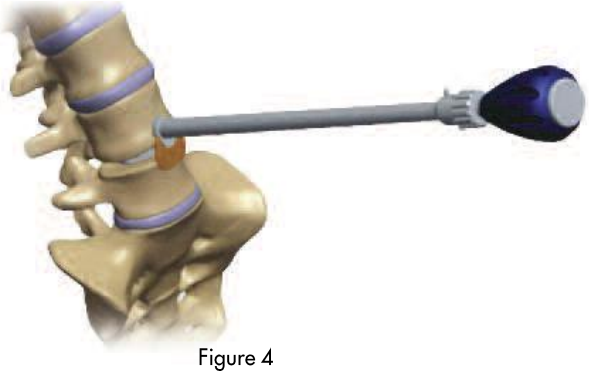

Figure 4

SURGICAL TECHNIQUE

5 SCREW INSERTION

Attach Screw onto Screwdriver (22-9003) and insert the Screw through the Guide hole until the Screw is fully seated. (Figure 5 and 6)

Figure 5

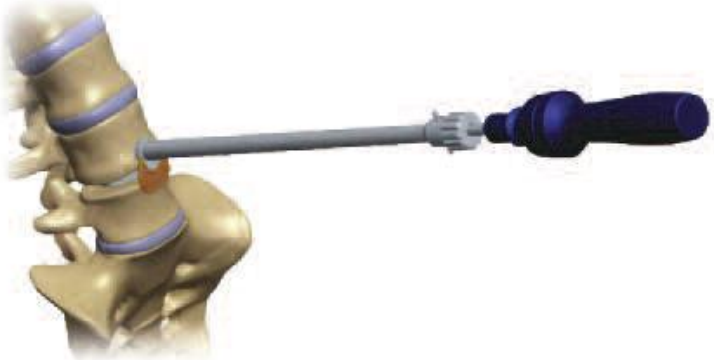

Figure 6

6 FINAL POSITION

See correct final positioning (Figure 7)

7 PLATE REMOVAL

Attach Guide to Buttress Plate and insert Screwdriver (22-9003) through the Guide and back out Screw. Then pull Guide back and it will pull Plate out. (Figure 8)

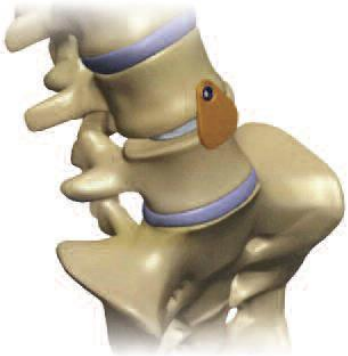

Figure 7

Figure 8

IMPLANT & INSTRUMENT PART NUMBERS

IMPLANTS

Part No.	Description
22-1001-25	RCS Buttress Plate 25mm
22-1001-30	RCS Buttress Plate 30mm
22-5520	Self Drilling Screw 5.5mm x 20mm
22-5525	Self Drilling Screw 5.5mm x 25mm
22-5530	Self Drilling Screw 5.5mm x 30mm
22-5535	Self Drilling Screw 5.5mm x 35mm

INSTRUMENTS

Part No.	Description
21-1050	Sterilization Tray
22-9001	RCS Buttress Inserter Tool
22-9002	RCS Buttress Awl
22-9003	RCS Buttress Screwdriver Straight
PSSRS	Ratchet Straight (used with 22-9003)

INDICATIONS

CONTRAINDICATIONS

The RCS® Anterior Buttress Plate System contraindications include, but are not limited to:

1. Loss of proper spinal curvature, correction, height, and/or reduction
2. Infection
3. Nonunion 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 fusion 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 normal daily activities
14. Revision surgery
15. Death

POTENTIAL ADVERSE EFFECTS

The following potential adverse affects 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 instrument-tation, and the potential adverse affects. The following are potential adverse affects, but not limited to:

1. Loss of proper spinal curvature, correction, height, and/or reduction
2. Infection
3. Nonunion 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 fusion 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 normal daily activities
14. Revision surgery
15. Death

WARNINGS

The implantation of the Precision Spine RCS Anterior Buttress Plate System should be performed only be experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient. The Precision Spine RCS Anterior Buttress Plate has not been evaluated for safety and compati-bility in the MR environment. The Precision Spine RCS Anterior Buttress Plate has not been tested for heating or migrations in the MR environment.

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