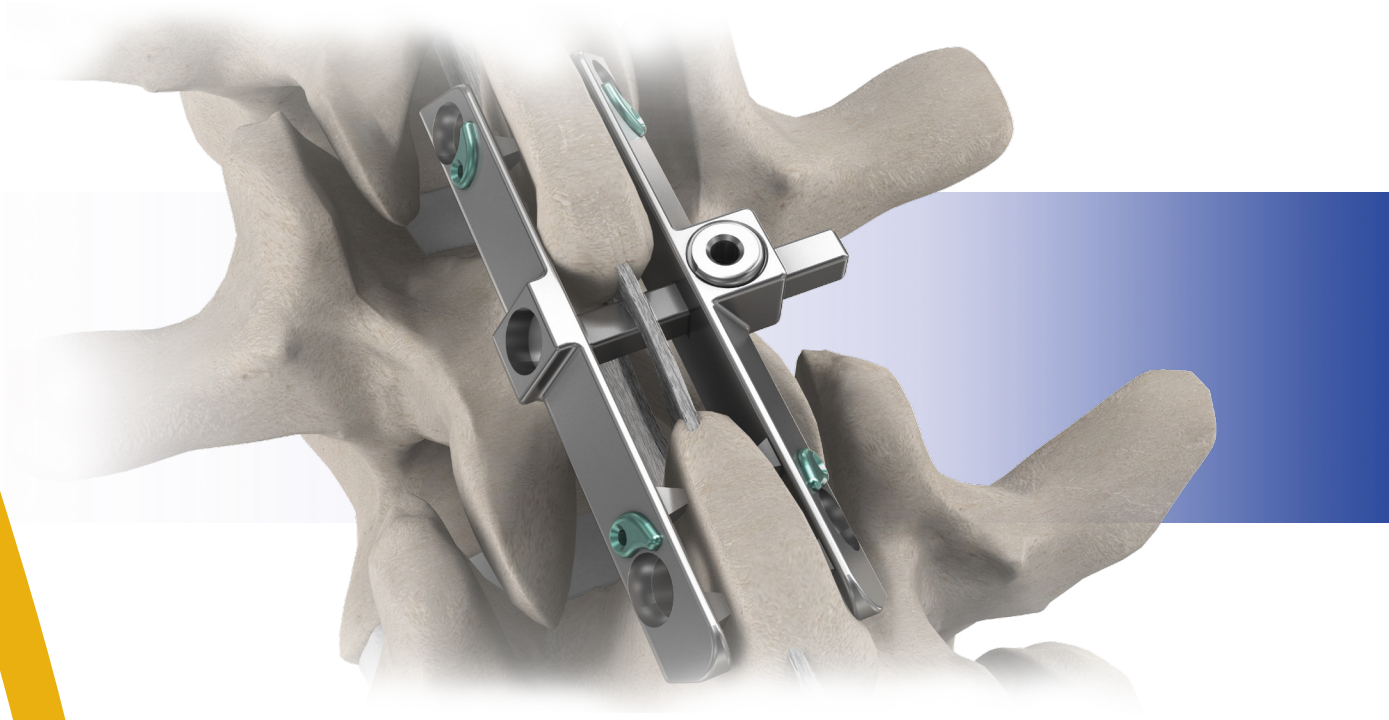
PRECISION SPINE™



PRECISION SPINE™

RELI™ SP

SPINOUS PLATING SYSTEM

Surgical Technique

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Reli™ *SP* System Overview

Device Description:

The Reli™ *SP* 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 B-209, 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.

Implant Features:

- Two-piece design minimizes disruption and keeps the spinous ligament intact
- Each plate has 6 Pyramidal Cleats to increase spinous process fixation
- Square Thread Locking Cap reduces potential for crossthreading
- 28mm, 35mm, 45mm and 55mm plate sizes

Indications:

The Reli *SP* 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 standalone use.

Please refer to package insert (LBL-IFU-019) for complete system description, indications and warnings.

ACCESS INSTRUMENTS

Tissue Awl

- Used to create hole through anterior region of the interspinous ligament
- Part Number: 29-0007

Caspar Pin Driver

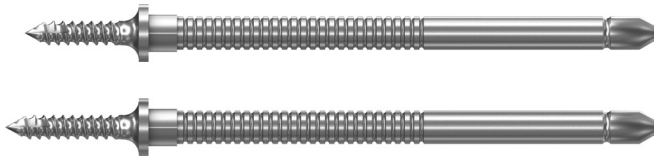
- Used to insert appropriate size Distraction Pins (ACP-P1X) in the appropriate spinous processes
- Part Number: 29-0801

Caspar Pin Sleeves

- Slide over the Distraction Pins (ACP-P1X) to permit application of the Caspar Retractor (29-0800)
- Part Numbers: 29-0960 (60mm, 2x); 29-0975 (75mm, 2x); 29-0990 (90mm, 2x)

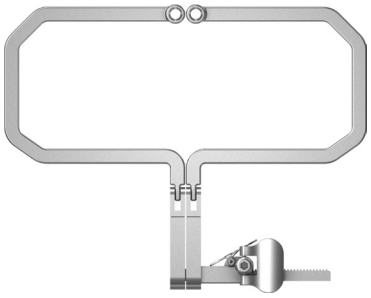
Distraction Pins

- Inserted into the spinous processes
- Part Numbers: ACP-P12 (12mm, 4x); ACP-P16 (16mm, 4x)



Caspar Retractor

- Slides over the Caspar Sleeves (29-09XX) and opened to the desired level of distraction
- Part Number: 29-0800



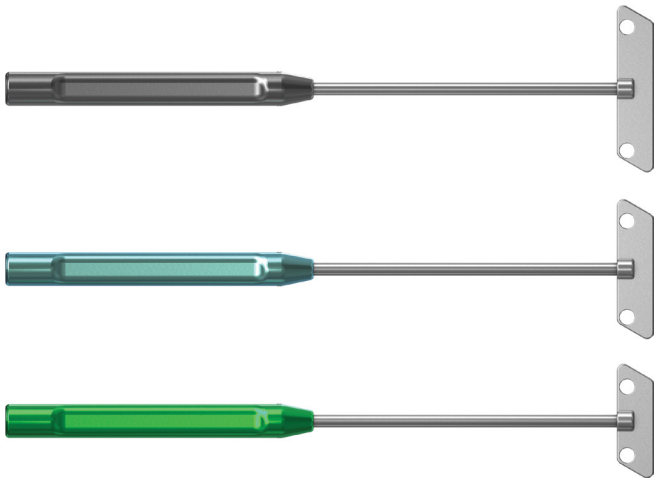
Tissue Spreader

- Inserted into the hole created by the Tissue Awl (29-0007) and used to spread the spinous processes
- Part Number: 29-0001

PREPARATION INSTRUMENTS

Trials

- Used along the lateral aspect of the spinous processes, along with lateral fluoroscopy to determine the proper size of the implant
- Part Numbers: 29-0128 (28mm, 2x); 29-0135 (35mm, 2x); 29-0145 (45mm, 2x); 29-0155 (55mm, 2x)



INSERTION INSTRUMENTS

Plate Holder

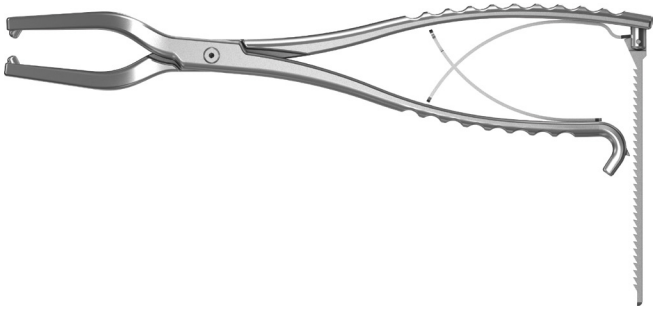
- Can be used on the Interspinous Female Plate (29-00XX-02) and/or the Interspinous Male Plate (29-00XX-01) for assembly
- Part Number: 29-0900 (x2)

Straight Plate Holder

- Threaded to the Interspinous Female Plate (29-00XX-02) so that it can be mated onto the cross bar of the Interspinous Male Plate
- Part Number: 29-0901

Compressor

- Inserted onto plates by aligning distal tips to the holes of the Interspinous Plate
- Part Number: 29-0200 (x2)



LOCKING INSTRUMENTS

Torque Limiting Handle

- Attaches to the Set Screw Final Tightener (04-9097) to assist in tightening the Plate Set Screw to 30 in-lbs
- Part Number: 04-9023

Counter Torque Handle

- Used as a guide to insert the Plate Set Screw (04-1000) and as a counter torque for final tightening
- Part Number: 29-0006

Set Screw Inserter

- Used to thread the Set Screw (04-1000) into the Interspinous Female Plate
- Part Number: 04-9094

Set Screw Final Tightener

- Attaches to the Torque Limiting Handle (04-9023) to tighten the Plate Set Screw until handle clicks at 30 in-lbs
- Part Number: 04-9097 (x2)

1. Implant Insertion:

The technique for using the Reli™ *SP* plate implant includes these basic steps:

1. Loading the implant onto the instrument
2. Inserting it into the surgical site at the appropriate level
3. Compressing
4. Provisional locking
5. Final locking

Two minimally-disruptive instrumentation options are available for tailoring the surgical technique to surgeon preference and the unique characteristics of the patient's anatomy.

Insertion Technique 1

- Keeps the interspinous ligament intact
- Inserts and assembles the implant through the interspinous ligament

Insertion Technique 2

- Removes the interspinous ligament
- Inserts a preassembled plate construct with an instrument

2. Patient Positioning:

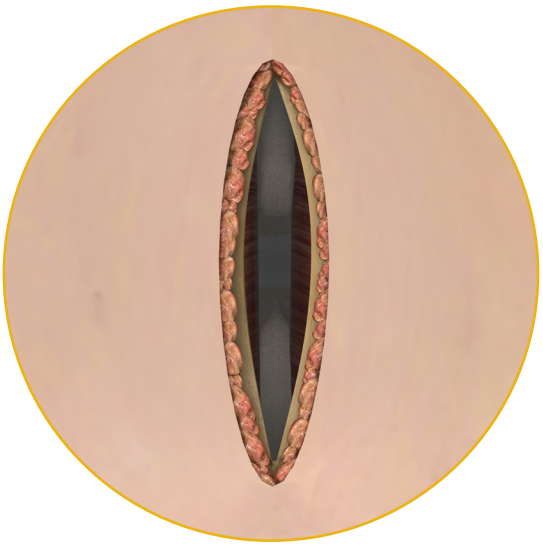
The patient should be placed in the prone position on the operating table (Fig. 1).

Figure 1

3. Site Identification and Incision:

Identify the spinous processes at the level to be instrumented using manual palpation and intraoperative imaging. Make a midline incision (3-5cm in length) to expose the spinous process at the correct level (Fig. 2).

Figure 2



4. Insertion Technique 1

1. Ligament Puncture

Using the Tissue Awl (29-0007), create a hole though the anterior region of the interspinous ligament. Make sure the hooked awl is placed at the midpoint between the adjacent spinous processes (Fig. 3).

2. Distraction

Two different types of spinous process distraction instruments are offered.

Option 1:
Insert the Tissue Spreader (29-0001) into the hole created by the hooked awl and spread the spinous processes. Begin to distract adjacent spinous processes (Fig. 4).

Option 2:
Insert the appropriate size Distraction Pins (ACP-P1X) in the appropriate spinous processes using the Caspar Pin Driver (29-0801) (Fig. 5).

Slide the appropriate length Caspar Sleeves (29-09XX) over the Distraction Pins. Slide the Caspar Retractor (29-0800) over the Caspar Sleeves and then open to the desired level of distraction (Fig. 6).

3. Trialing

Use the appropriate size Trial (29-01XX) along the lateral aspect of the spinous processes and use lateral flouroscopy to determine the proper size (Fig. 7). Plate size should be based on maximum surface area coverage of both spinous processes (Fig. 8). It is important to NOT oversize the plate – avoid plate extension beyond the superior margin of the superior spinous process and the inferior margin of the inferior spinous process.

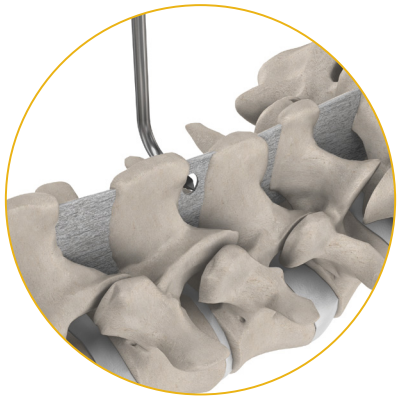
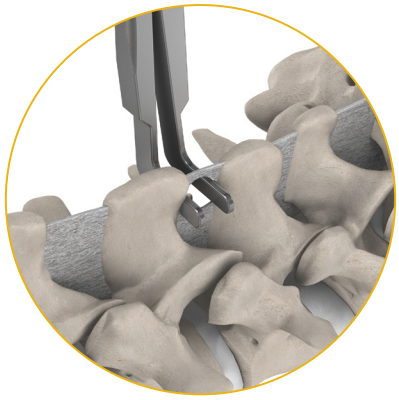


Figure 3



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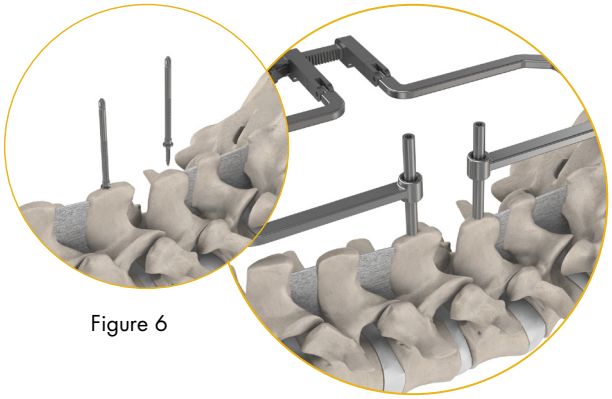


Figure 5

Figure 6

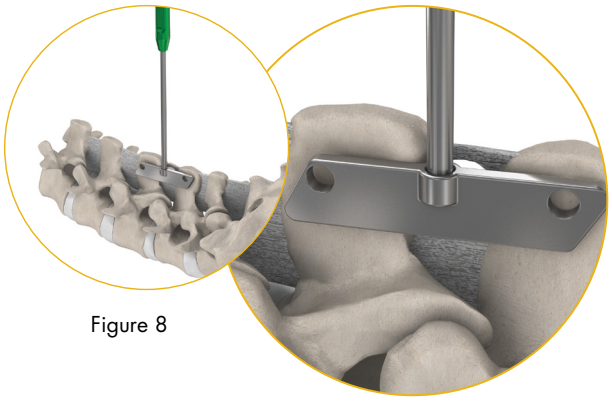


Figure 7

Figure 8

4. Male Plate Insertion

Assemble Plate Holder (29-0900) onto the Interspinous Male Plate (29-00XX-01) (Fig. 9). Using the plate holder, insert the cross bar of the Interspinous Male Plate through the interspinous ligament (Fig. 10).

Figure 9

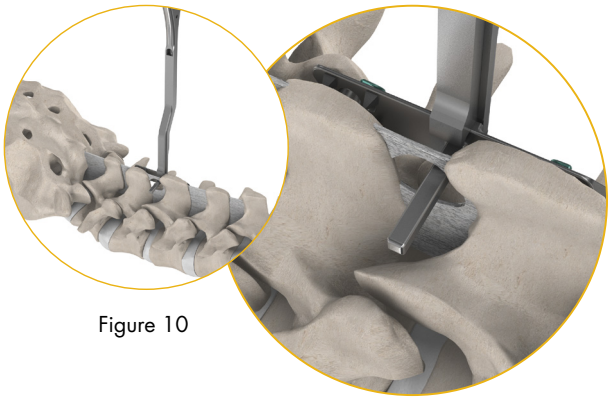


Figure 10

5. Female Plate Insertion

Thread Straight Plate Holder (29-0901) to the Interspinous Female Plate (29-00XX-02) (Fig. 11). Mate the Interspinous Female Plate onto the cross bar of the Interspinous Male Plate (Fig. 12). After plates are in the desired position, remove the plate holders.

Alternately, a second Plate Holder (29-0900) can be used on the Interspinous Female Plate to assemble it to the Interspinous Male Plate.

Figure 11

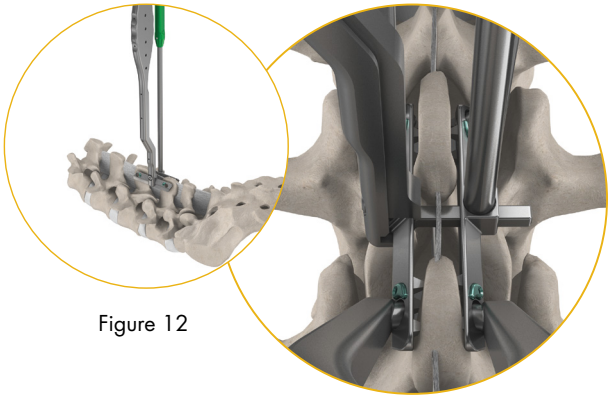


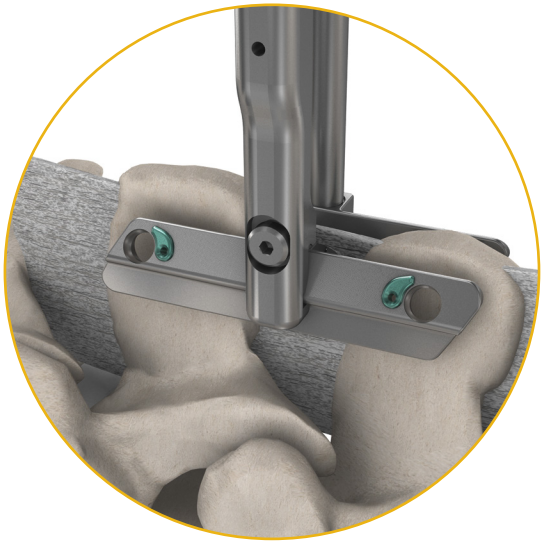
Figure 12

5. Insertion Technique 2

1. Pre-assembled Plate

Assemble appropriate size Interspinous Male and Female Plate and lock into desired position with Straight Plate Holder (29-0901). With interspinous ligament removed, insert plate assembly into desired position (Fig. 13). Distance between the plates can be adjusted by loosening the plate holder and sliding the plates away from each other. Once proper placement is achieved, remove plate holder.

Figure 13



6. Compression

After implant is in desired position, insert Compressors (29-0200) onto plates by aligning distal tips of the Compressor to the holes of the Interspinous Plate (Fig. 14).

Begin compression by either squeezing both Compressors simultaneously or alternating back and forth, to ensure the spikes seat properly in both the inferior and superior spinous processes. Remove Compressors once desired position and compression is achieved.

7. Set Screw Insertion

Using the Counter-Torque handle (29-0006) as a guide, insert the Plate Set Screw (04-1000) (Fig. 15) using the Set Screw Inserter (04-9094) (Fig. 16) and thread into Interspinous Female Plate. Hand tighten once desired position is confirmed.

8. Final Tightening

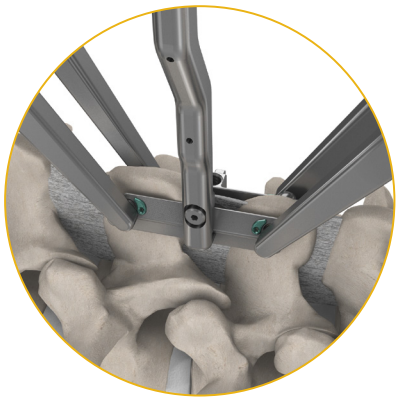
With the Counter-Torque handle still in place, use the Set Screw Final Tightener (04-9097) attached to the 30 in-lb Torque Limiting Handle (04-9023) to tighten the Plate Set Screw until handle clicks (Fig. 17). For additional counter torque, the Counter-Torque handle may be used alone or with the Compressors still in place. Or, as an alternative to using the Counter Torque handle, the compressors may be used alone to provide counter torque during final tightening.

9. Implant Removal

Using the Counter-Torque handle as a guide, insert the Set Screw Final Tightener, coupled with the Torque Limiting Handle (Fig. 18), into the head of the set screw (Fig. 19). Turn counterclockwise to remove the set screw from the plate.

Thread Straight Plate Holder into Interspinous Female Plate (Fig. 20). Grab Interspinous Male Plate with Plate Holder. Move Plate Holders laterally until the male plate rod has disengaged from the female plate (Fig. 21). Remove plate from patient.

Figure 14



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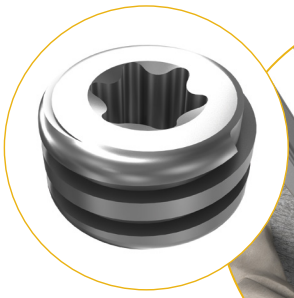

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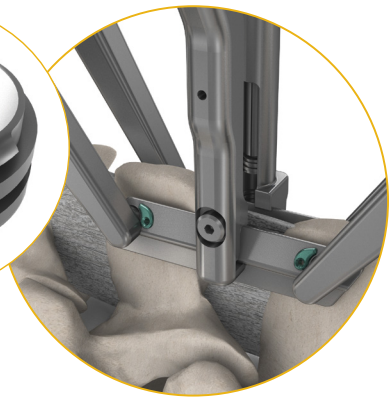

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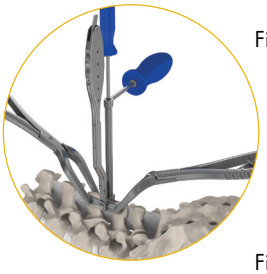
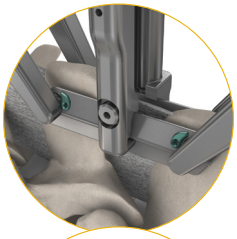


Figure 18



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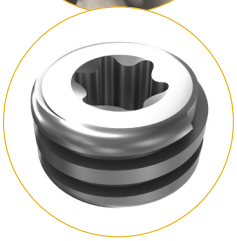
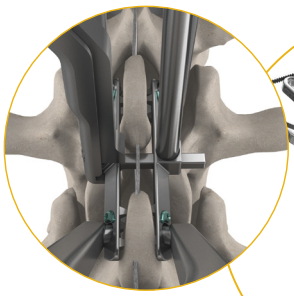


Figure 20



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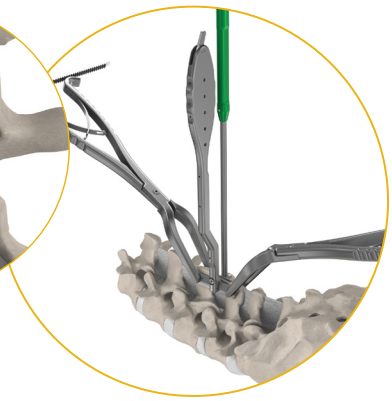
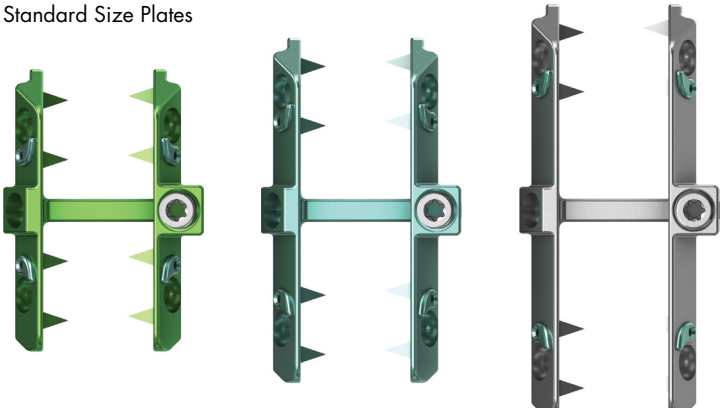


Implants & Instruments

Implants

Item No.	Description
04-1000	Plate Set Screw
29-0028-01	**28mm Interspinous Male Plate ***
29-0035-01	35mm Interspinous Male Plate
29-0045-01	45mm Interspinous Male Plate
29-0055-01	55mm Interspinous Male Plate
29-0028-02	**28mm Interspinous Female Plate ***
29-0035-02	35mm Interspinous Female Plate
29-0045-02	45mm Interspinous Female Plate
29-0055-02	55mm Interspinous Female Plate

Standard Size Plates



35mm 45mm 55mm

Instruments

Item No.	Description
29-6000-CA	**IMPLANT & INSTRUMENT KIT**
04-9023	Torque Limiting Handle
04-9094	Set Screw Inserter
04-9097	Set Screw Final Tightener
29-0001	Tissue Spreader
29-0006	Counter Torque
29-0007	Tissue Awl
29-0128	**28mm Trial ***
29-0135	35mm Trial
29-0145	45mm Trial
29-0155	55mm Trial
29-0200	Compressor
29-0900	Plate Holder
29-0901	Straight Plate Holder

Item No.	Description
29-6001-CA	**RETRACTOR KIT**
29-0800	Caspar Retractor
29-0801	Caspar Pin Driver
29-0960	60mm Caspar Sleeve
29-0975	75mm Caspar Sleeve
29-0990	90mm Caspar Sleeve
ACP-P12	12mm Distraction Pin
ACP-P16	16mm Distraction Pin

*** Special Order**

Indications

Contraindications:

The Reli™ *SP* 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 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.

Precautions & Warnings:

The Reli™ *SP* 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 postoperative 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, contraindications, 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, none of the Reli™ *SP* Spinous Plating System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death. **(continued on next page)**

Precautions & Warnings:

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The Reli *SP* Spinous Plating System has not been evaluated for safety and compatibility in the MR environment. The Reli *SP* 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.

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Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician.

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