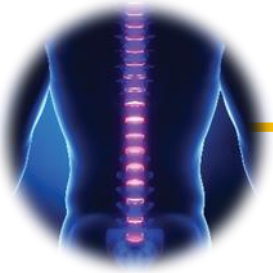
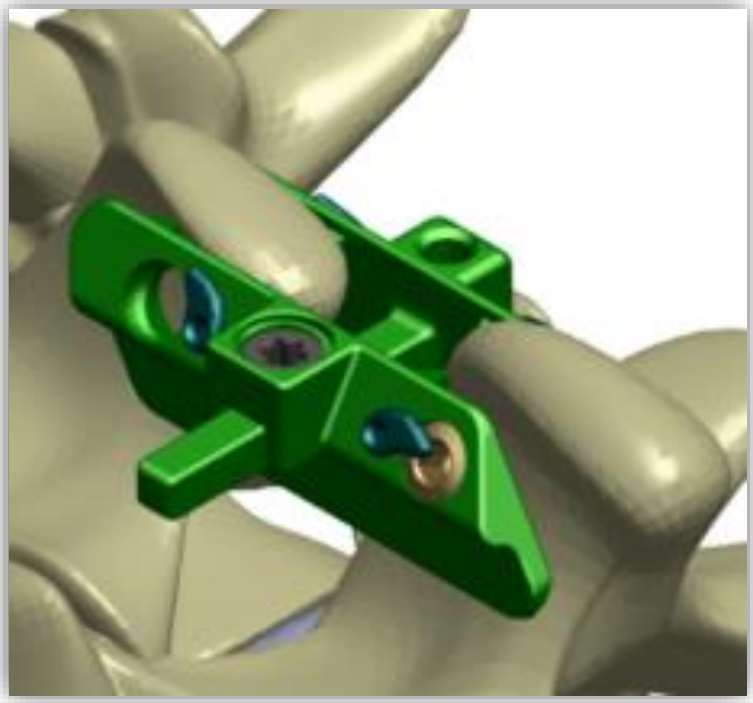


SURGICAL TECHNIQUE

PRECISION SPINE

RELI™ SP PLUS

SPINOUS PLATING SYSTEM



PRECISION SPINE®

Discover the Difference

Made in the USA

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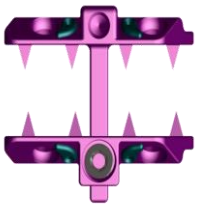
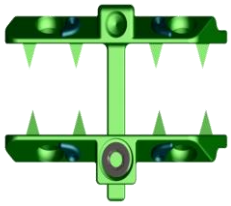
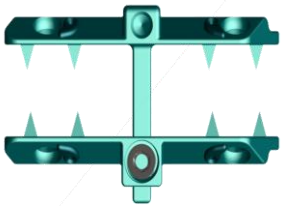
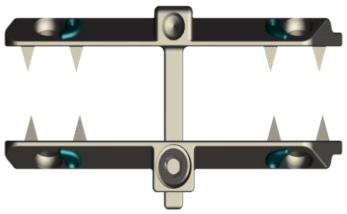




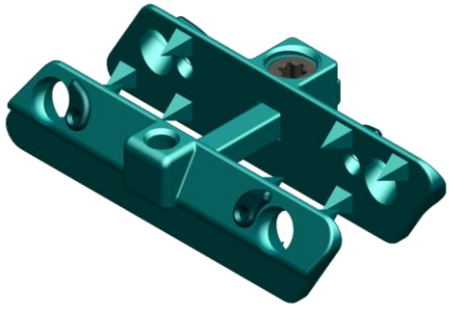




RELI™ *SP* PLUS OVERVIEW

DEVICE DESCRIPTION

The Reli *SP PLUS* Spinous Plating System 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.



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 cross threading
- 28mm, 35mm, 45mm and 55mm plate sizes
- 4.0 and 4.5mm diameter screws
- 10, 12, 14, and 16mm variable angle screws

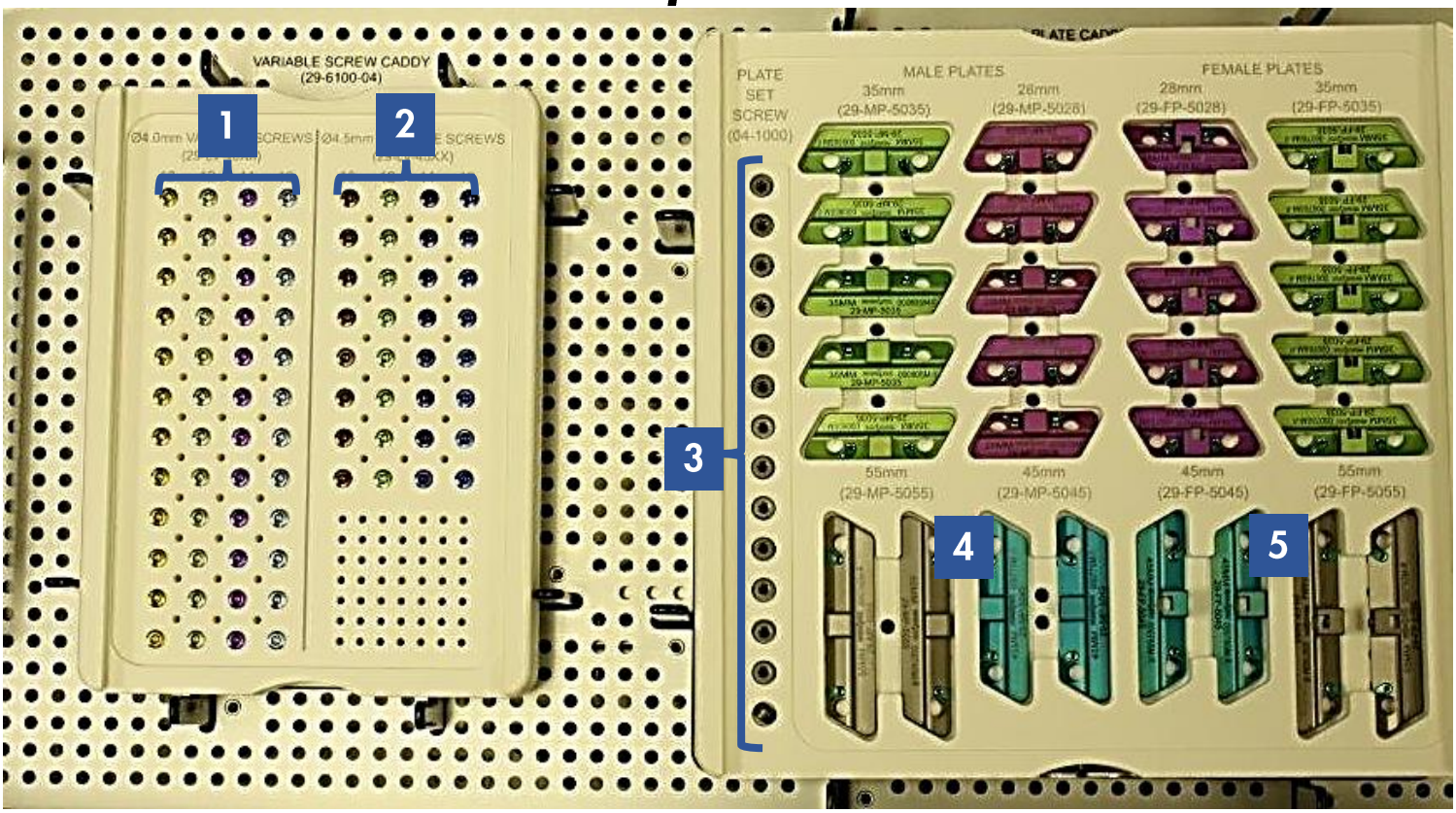
INDICATIONS

The Reli *SP PLUS* Spinous Plating System of Precision Spine 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.

Please refer to package insert (LBL-IFU-030) for complete system description, indications and warnings.

RELI™ SP PLUS IMPLANT & INSTRUMENT TRAY 29-6100-CA

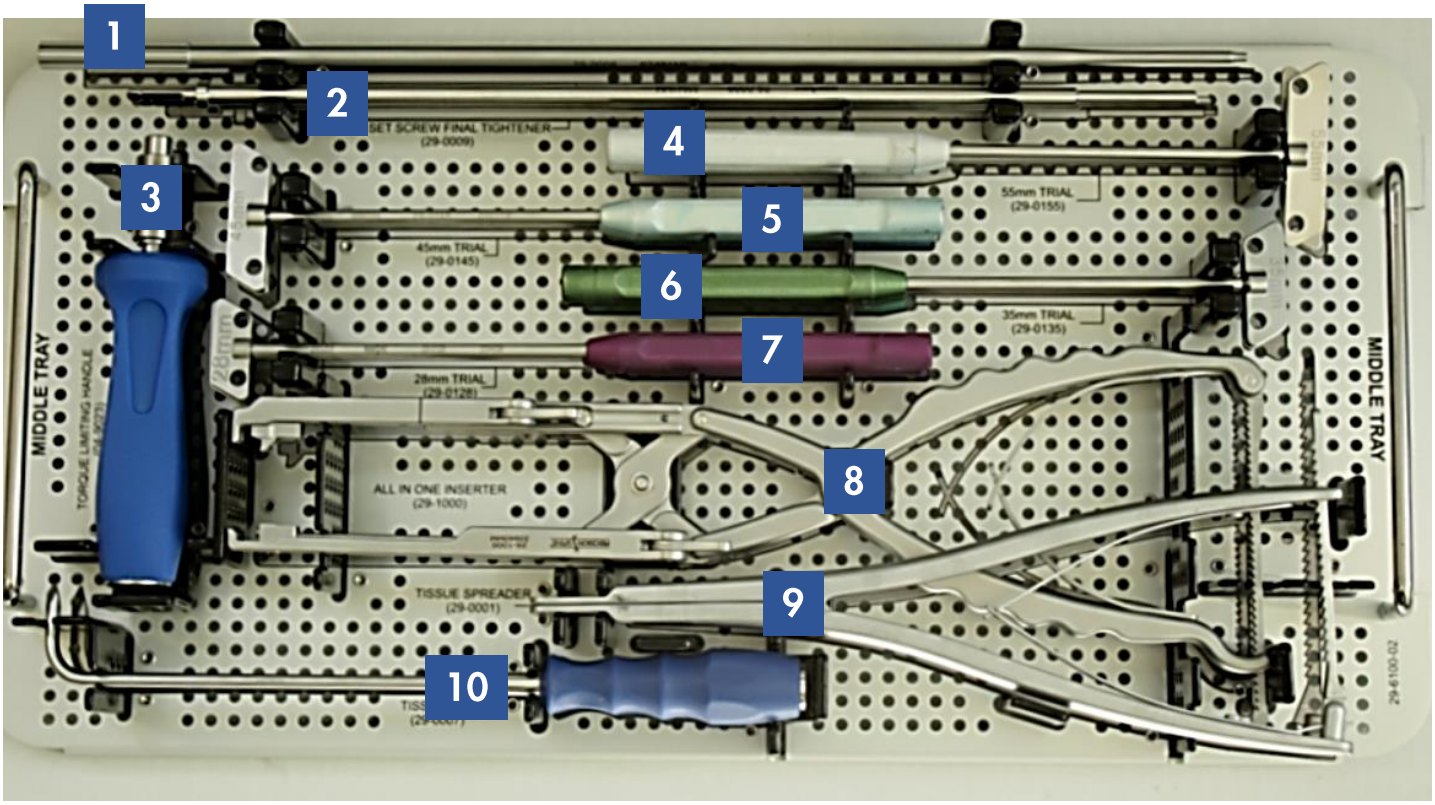
Top Level



#	Part No.	Description	Qty
1	29-LV-4010	4.0mm x 10mm Self Drilling Variable Screw, Reli SP	12
1	29-LV-4012	4.0mm x 12mm Self Drilling Variable Screw, Reli SP	12
1	29-LV-4014	4.0mm x 14mm Self Drilling Variable Screw, Reli SP	12
1	29-LV-4016	4.0mm x 16mm Self Drilling Variable Screw, Reli SP	12
2	29-LV-4510	4.5mm x 10mm Self Drilling Variable Screw, Reli SP	8
2	29-LV-4512	4.5mm x 12mm Self Drilling Variable Screw, Reli SP	8
2	29-LV-4514	4.5mm x 14mm Self Drilling Variable Screw, Reli SP	8
2	29-LV-4516	4.5mm x 16mm Self Drilling Variable Screw, Reli SP	8
3	04-1000	Plate Set Screw	14
4	29-MP-5028	28mm Spinous Male Plate	5
4	29-MP-5035	35mm Spinous Male Plate	5
4	29-MP-5045	45mm Spinous Male Plate	2
4	29-MP-5055	55mm Spinous Male Plate	2
5	29-FP-5028	28mm Spinous Female Plate	5
5	29-FP-5035	35mm Spinous Female Plate	5
5	29-FP-5045	45mm Spinous Female Plate	2
5	29-FP-5055	55mm Spinous Female Plate	2

RELI™ SP PLUS IMPLANT & INSTRUMENT TRAY
29-6100-CA

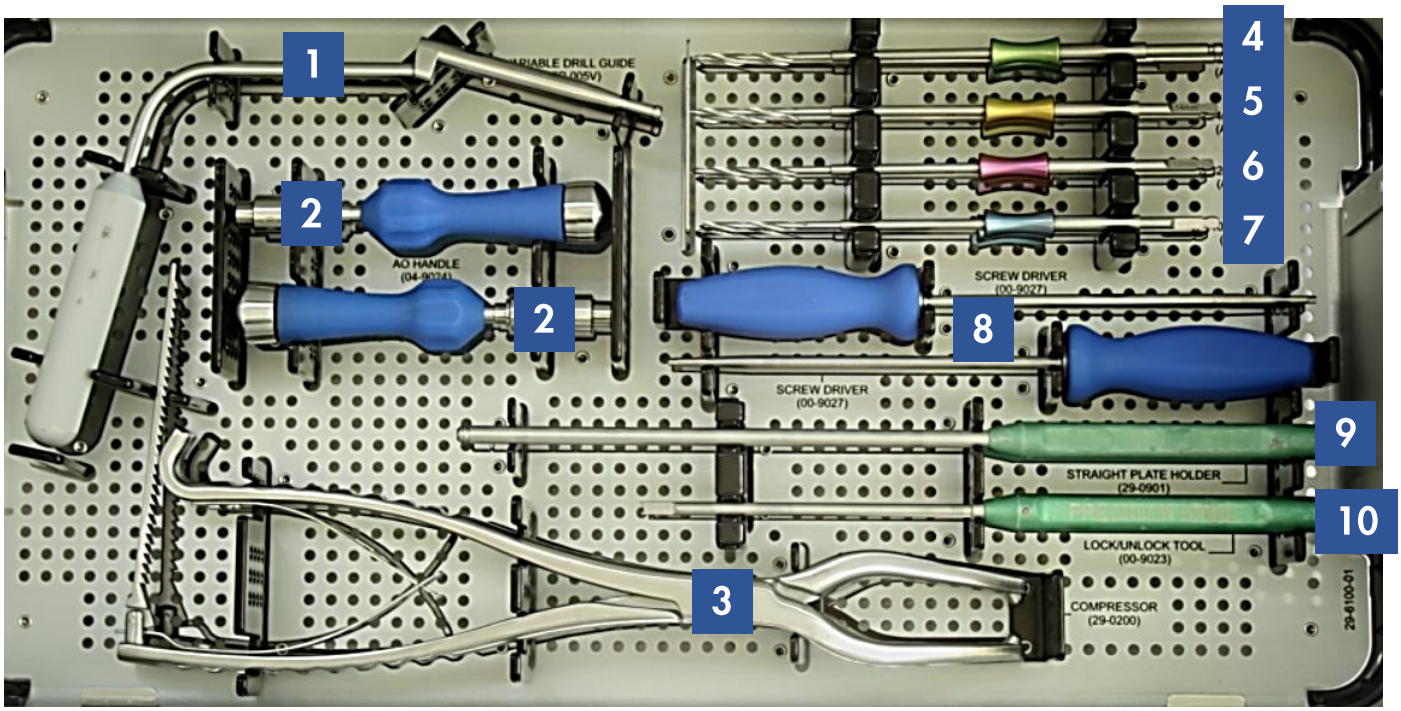
Middle Level



#	Part No.	Description	Qty
1	29-0008	AIO Set Screw Inserter	1
2	29-0009	AIO Set Screw Final Tightener	2
3	04-9023	Torque Limiting Handle	1
4	29-0155	55mm Trial	2
5	29-0145	45mm Trial	2
6	29-0135	35mm Trial	2
7	29-0128	28mm Trial	2
8	29-1000	All in One Inserter	1
9	29-0001	Tissue Spreader	1
10	29-0007	Tissue Awl	1

RELI™ SP PLUS IMPLANT & INSTRUMENT TRAY
29-6100-CA

Bottom Level



#	Part No.	Description	Qty
1	ACP-005V	Variable Drill Guide	1
2	04-9024	AO Straight Handle	2
3	29-0200	Compressor	1
4	ACP-016	Drill 3.0 x 16mm	2
5	ACP-014	Drill 3.0 x 14mm	2
6	ACP-012	Drill 3.0 x 12mm	2
7	29-0610	Drill 3.0 x 10mm	2
8	00-9027	Screw Driver	2
9	29-0901	Straight Plate Holder	1
10	00-9023	Lock/Unlock Tool	1

SURGICAL TECHNIQUE

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

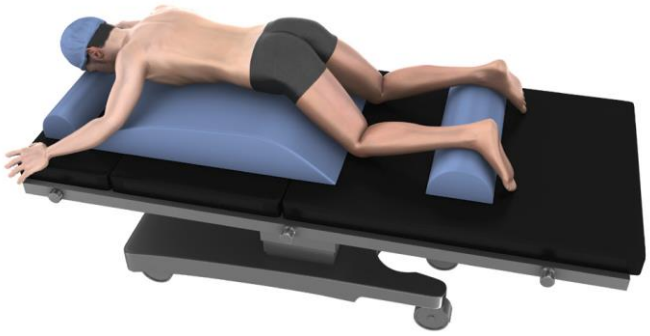
- Keeps the interspinous ligament intact
- Inserts and assembles the implant through the interspinous ligament

INSERTION TECHNIQUE 2

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

1 PATIENT POSITIONING

The patient should be placed in the prone position on the operating table.



2 INCISION

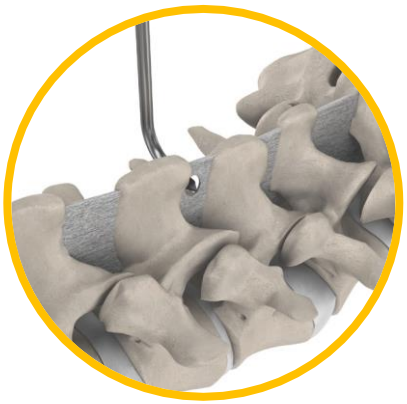
Identify the spinous processes at the level to be instrumented using manual palpation and intraoperative imaging. Make a midline incision (3-5cm in length) to expose the spinous process at the correct level.

SURGICAL TECHNIQUE

3 TRIALING

LIGAMENT PUNCTURE

If the Interspinous Ligament is going to be spared, 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.



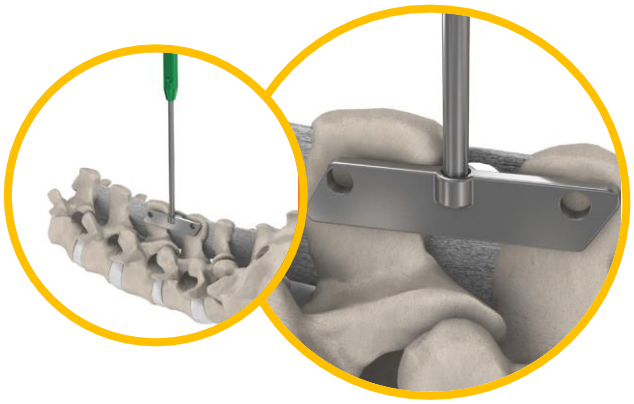
DISTRACTION

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.

TRIALING

Use the appropriate size Trial (29-01XX) along the lateral aspect of the spinous processes and use lateral fluoroscopy to determine the proper size (Fig. 7). Plate size should be based on maximum surface area coverage of both spinous processes (Fig. 8).

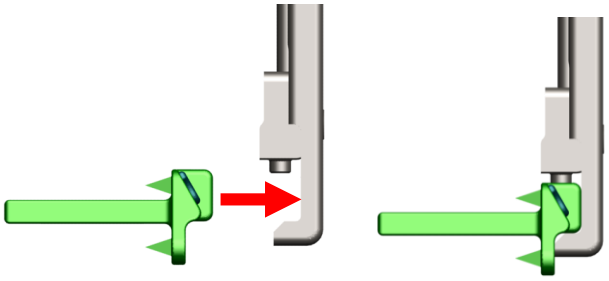
It is important to NOT oversize the plate – avoid plate extension beyond the superior margin of the superior spinous process and the inferior margin of the inferior spinous process.

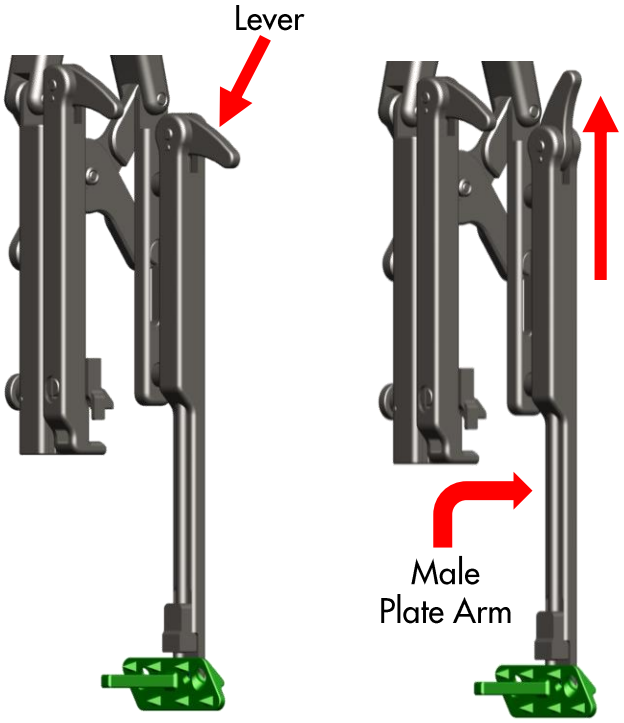


SURGICAL TECHNIQUE

4 MALE PLATE ATTACHMENT

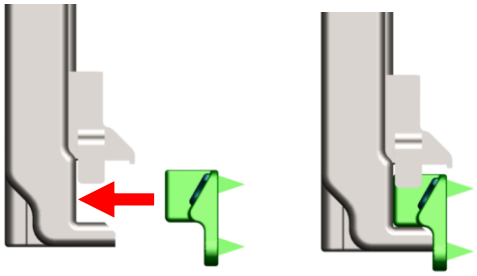
Assemble the All in One Inserter (AIO) (29-1000) Male Plate Arm onto the Reli SP PLUS Male Plate (29-MP-50XX). Rotate the Male Plate Arm Lever 90^0 to the up position to lock the plate onto the arm.

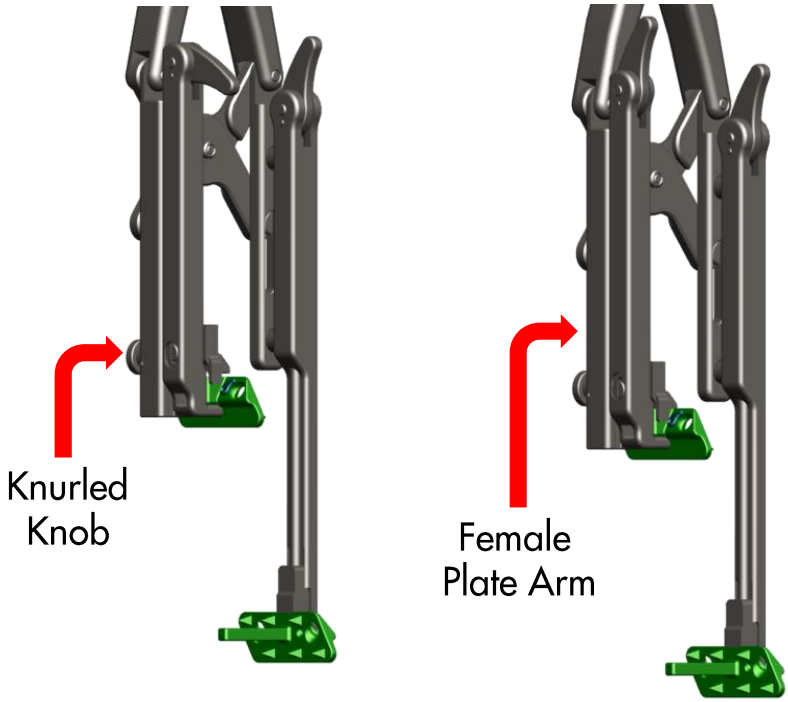




5 FEMALE PLATE ATTACHMENT

Assemble the Female Plate (29-FP-50XX) onto the Female Plate Arm. Rotate the Female Plate Arm Lever 90^0 to the up position to lock the plate onto the arm. Loosen the Female Plate Arm by turning the knurled knob Counter Clockwise. Raise the AIO Female Plate Arm proximally and turn the Knurled Knob Clockwise to lock the arm in position.





SURGICAL TECHNIQUE

6 PLATE INSERTION

If the Interspinous Ligament is being spared, with the Female Arm in the raised position, insert the Male Plate Cross Arm through the Interspinous Process Ligament.

Loosen the Knurled Knob to release the Female Plate Arm. Lower the Female Arm until the proximal portion of the arm is aligned with the laser etch line on the AIO body.

Turn the Knurled Knob Counter Clockwise to lock the female plate arm in place.

Compress the All-In-One Inserter to fully engage the two plates.

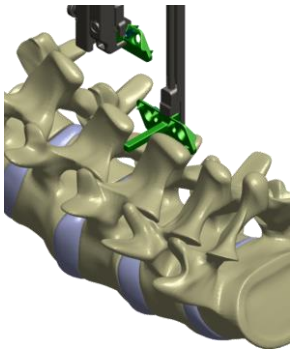
If the Interspinous Ligament is being sacrificed, release the Female Plate Arm by turning the Knurled Knob Counter Clockwise.

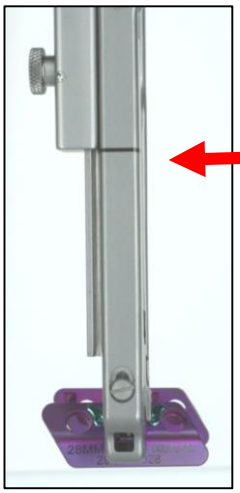
Lower the Female Arm until the proximal portion of the arm is aligned with the laser etch line on the AIO body.

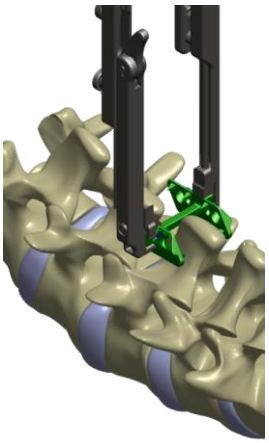
Turn the Knurled Knob Counter Clockwise to lock the female plate arm in place.

Compress the All-In-One Inserter to initially engage the two plates.

Lower the All-In-One Guide Assembly between the spinous processes and fully compress the AIO Inserter.







SURGICAL TECHNIQUE

7 ADJUNCT SCREW INSERTION

The Variable Drill Guide (ACP-005V) and Drill (ACP-012, 014 or 016) can be used to create the screw hole.

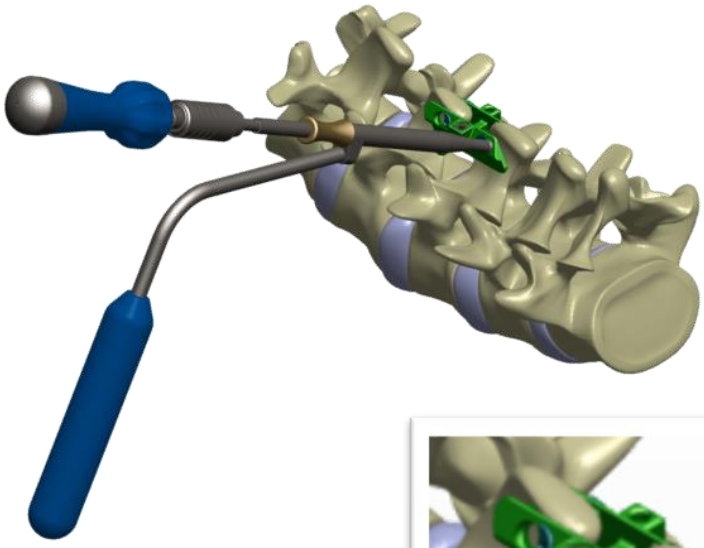
Attach the Drill Guide to the Plate and drill the screw hole.

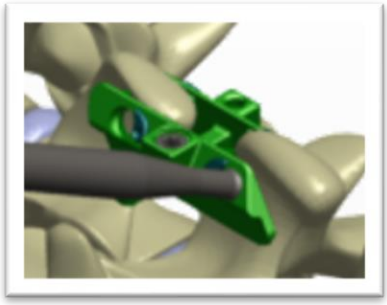
The self-tapping, self-drilling Bone Screws are available in 12, 14, 16mm lengths in both 4.0 and 4.5mm diameters.

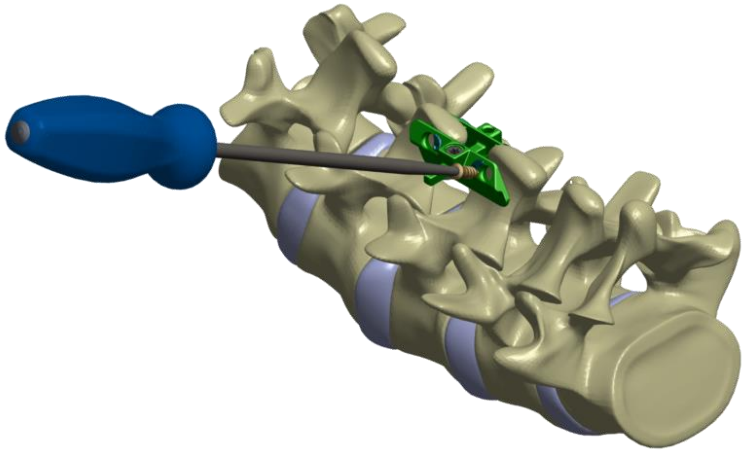
The Bone Screws selected for implantation are inserted using the Bone Screw Driver.

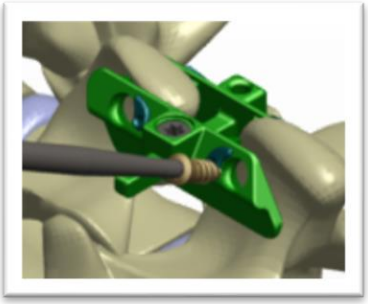
Insert the Bone Screw until it rests firmly inside the plate screw hole. This will enable the Locking Mechanism to be engaged.

Note: Only one screw per spinous process is indicated.







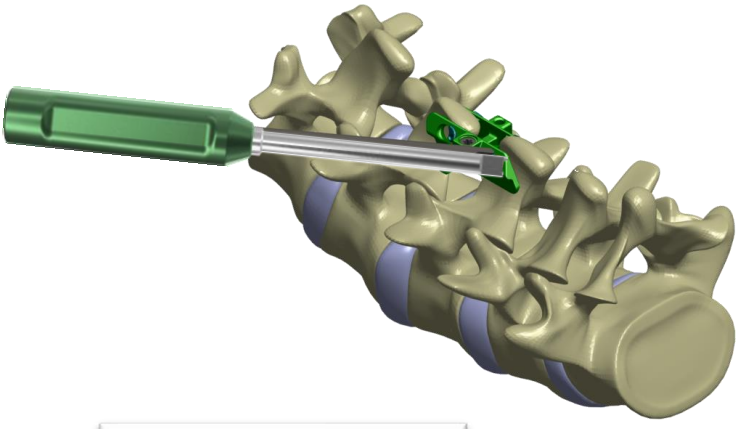


SURGICAL TECHNIQUE

8 SCREW LOCKING

Once the Bone Screws have been properly seated, positioned, and tightened, the Locking Mechanism can be rotated to secure the seated Bone Screw.

Insert the ACP Unlock/Lock Tool (00-9023) into the green rivet and rotate until the rivet covers the screw head.



SURGICAL TECHNIQUE

9 SET SCREW INSERTION

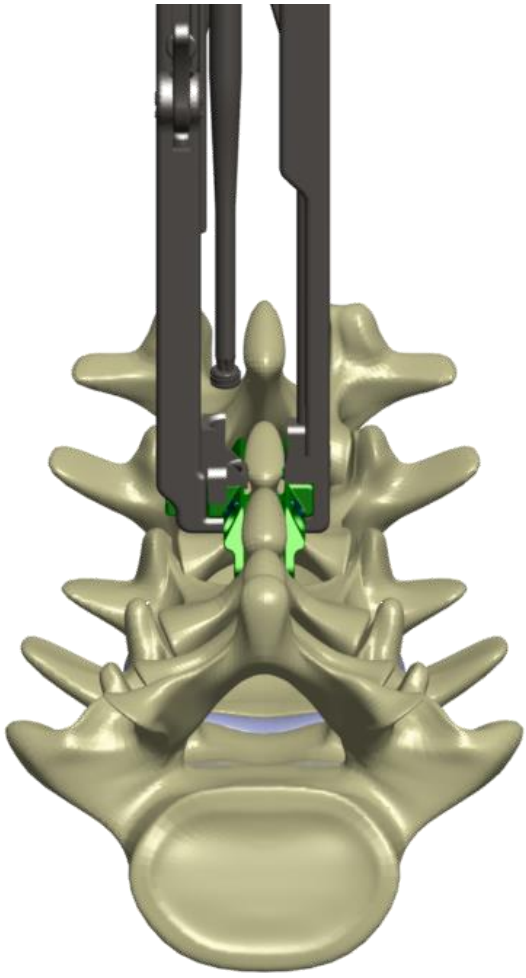
Insert the Plate Set Screw (04-1000) using the Set Screw Inserter (29-0008) and thread into Female Plate. Hand tighten once desired position is confirmed.

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.

10 IMPLANT REMOVAL

Insert the Set Screw Final Tightener, coupled with the Torque Limiting Handle, into the head of the set screw. Turn counterclockwise to remove the set screw from the plate. Remove plate with pickups

If needed, the Bone Screws can be removed using the ACP Lock/Unlock Tool (00-9023). The Locking Mechanism is rotated back to its unlocked position. Once the rivet has been rotated the Screws can be removed from the construct.



INDICATIONS

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
9. care instructions
10. Active infectious process or significant risk of infection
11. 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 effects.

WARNINGS:

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 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* PLUS 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.

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.

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