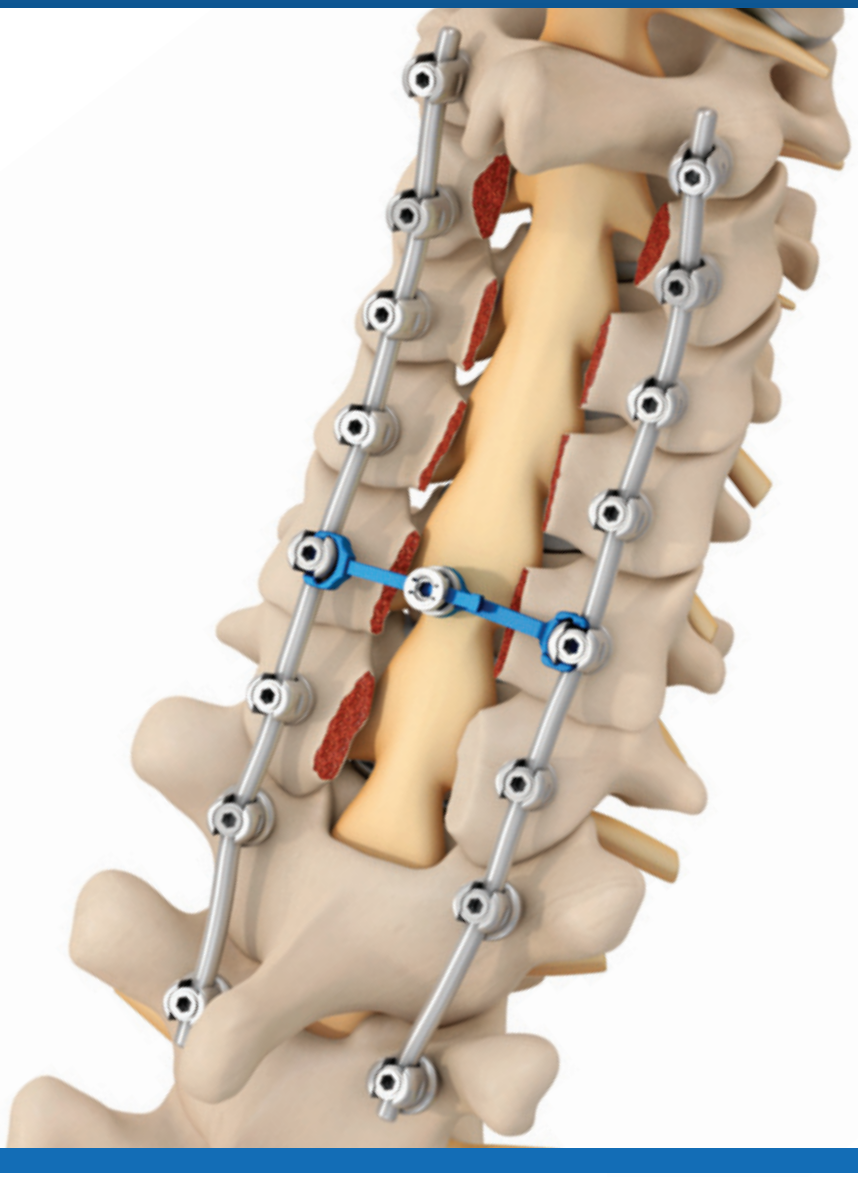
Proficient®

Posterior Cervical Spine System

SURGICAL TECHNIQUE



SpineWave

Table of Contents

SYSTEM OVERVIEW

SCREW DESIGN

Self-Selecting Tri-lobe

- Polyaxial Screw --- allows for 120° of angulation (60° in any direction)
- Tulip design accepts 3.5 or 4.0 mm diameter rods
- Tensioned head
- Size offering:

Diameter	Lengths
3.8 mm	10-34 mm (2 mm inc.)
4.2 mm	10-34 mm (2 mm inc.)
4.6 mm	20-40 mm (4 mm inc.)
5.5 mm	20-40 mm (4 mm inc.)

- Self Tapping
- Extended tab screw offering for muscle sparing approach (offers an additional 3 mm of reduction)
- 4.6 and 5.5 mm screws have a total of 130° of angulation

LOCKING SCREW DESIGN

Truncated Thread

- 2.5 mm hex

ROD OFFERING

Diameter	Material	Length
3.5 mm	Titanium	30-120 mm (curved), 10 mm inc 30, 60, 90, 120, 240 mm (straight)
3.5 mm	Cobalt Chrome	240 mm (straight)
4.0 mm	Cobalt Chrome	240 mm (straight)
Transition Rod (3.5 x 5.5 mm)	Titanium	300 mm

Cross Connector Offering

- Screw-to-screw cross connector
- 4 different sizes (26 - 30 mm, 29 - 36 mm, 35 - 46 mm, 39 - 56 mm)

STEP 1 PATIENT POSITIONING

Place the patient in the prone position with the head and neck held securely in alignment.

STEP 2 SURGICAL APPROACH

Make a mid-line incision, exposing the spinous process and laminae of the vertebrae to be fused. Laterally extend dissection to expose the facets and transverse processes.

STEP 3 SCREW HOLE PREPARATION: AWL

Following exposure, determine the entry point and trajectory of the screw. Using the awl, penetrate the cortical surface of the lateral mass or pedicle (see Figure 1). Repeat for all screw placement landmarks.

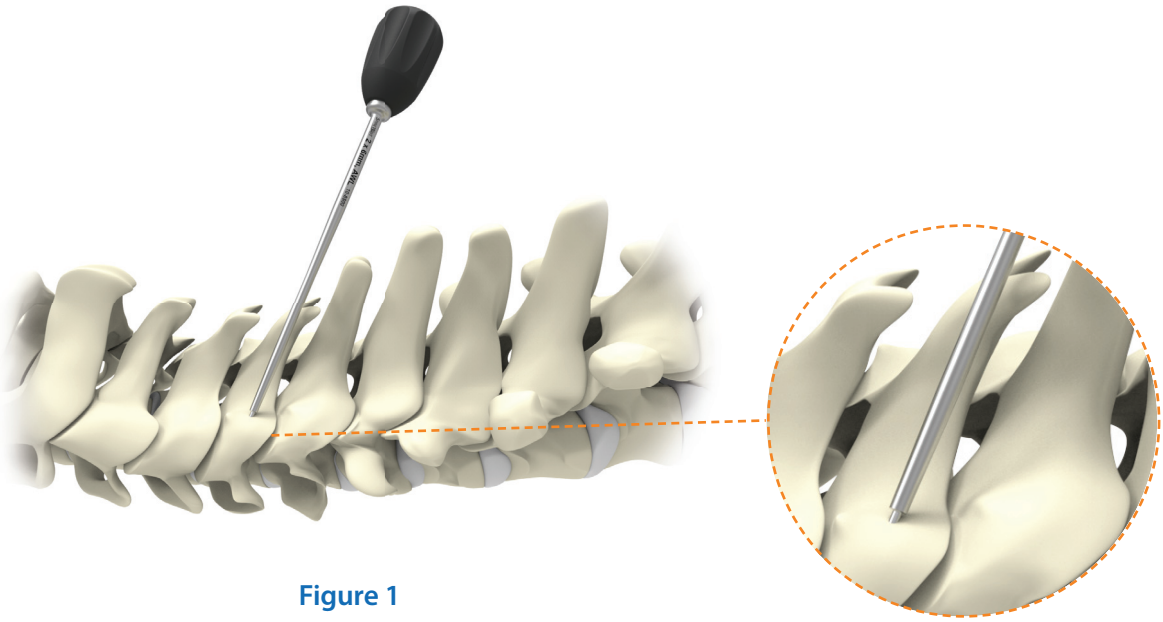


Figure 1

Note: *The awl is designed to mitigate over-penetration with a positive stop 6 mm from the distal tip.*

STEP 4 SCREW HOLE PREPARATION: DRILL

Select the appropriately sized fixed drill and drill guide based on the diameter of the screw to be inserted and patient anatomy. With an in-line handle attached, advance the drill through the guide to the desired depth (see Figure 2).

Note: *Fixed drills in sizes 2.9 mm x 12 mm and 2.9 mm x 14 mm.*

TIP: A numerical marking is on the fixed stop to easily visualize the drill length.

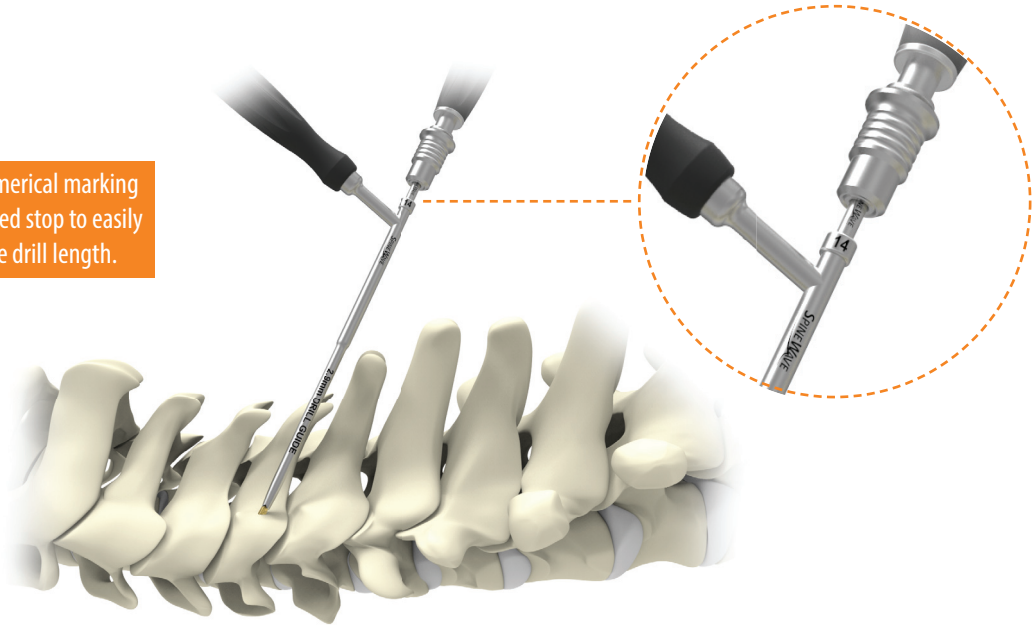


Figure 2

In addition to the fixed drill, an adjustable drill with an adjustable stop is offered. To set the adjustable drill to the desired length, slide the adjustable stop over the proximal shaft of the adjustable drill with the button depressed until the desired depth is legible in the window (see Figure 3). The stop will lock into place when the button is released. Visually confirm the stop is set at the correct depth.

Note: *Adjustable drills and drill guides are offered in diameters of 2.9 mm and 3.3 mm.*

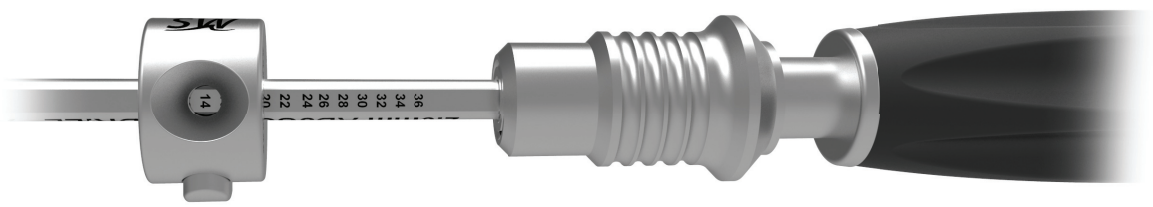


Figure 3

STEP 5 SCREW HOLE PREPARATION: PROBE & SCREW MEASUREMENT

As an alternative, a pedicle probe can be used to prepare the screw trajectory. The length of the screw can be determined by the depth markings on the instrument. To confirm the canal has not been breached, insert the sounding probe into the screw hole to palpate the inner surface (see Figure 4).

Note: *The pedicle probes are offered in straight or curved options and are marked in 5 mm increments up to 30 mm.*

Note: *The sounding probe is gold up to 10 mm, has 2 mm markings up to 20 mm, and 5 mm markings up to 50 mm.*

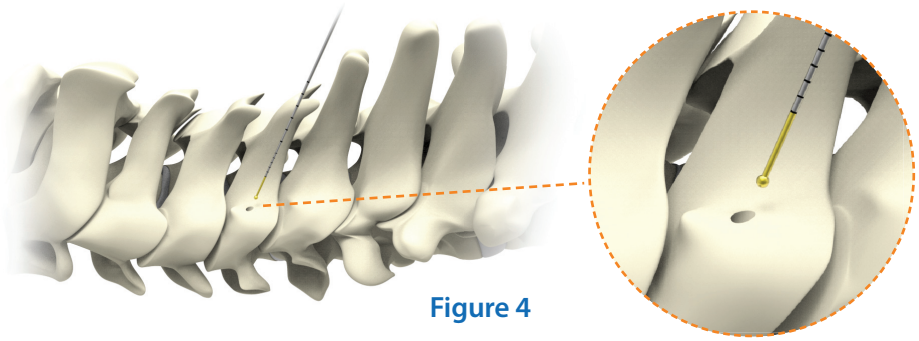


Figure 4

To confirm the screw length, insert the depth gauge into the hole and refer to the depth markings on the proximal part of the instrument.

Note: *The depth gauge length is viewed in the middle of the viewing window.*

STEP 6 SCREW HOLE PREPARATION: TAP

The Proficient® Posterior Cervical Spine System screws are self-tapping. If tapping is desired, attach the appropriate size tap to an in-line handle, insert the tap into the prepared hole, and advance to the desired depth (see Figure 5).

Note: *The taps are true to size and are offered in diameters of 3.3 mm, 3.7 mm, and 4.1 mm in the standard set. The system also includes a 4.5 mm dual lead tap that can be used with the 4.6 mm and 5.5 mm diameter screws.*

Note: *The tap threads are gold up to 10 mm and are marked in 5 mm increments from 20 mm to 30 mm.*

TIP: The 3.3 mm, 3.7 mm, and 4.1 mm tap thread length is 16 mm and can be used as an insertion length reference. To determine the precise screw length, the depth gauge should be used.

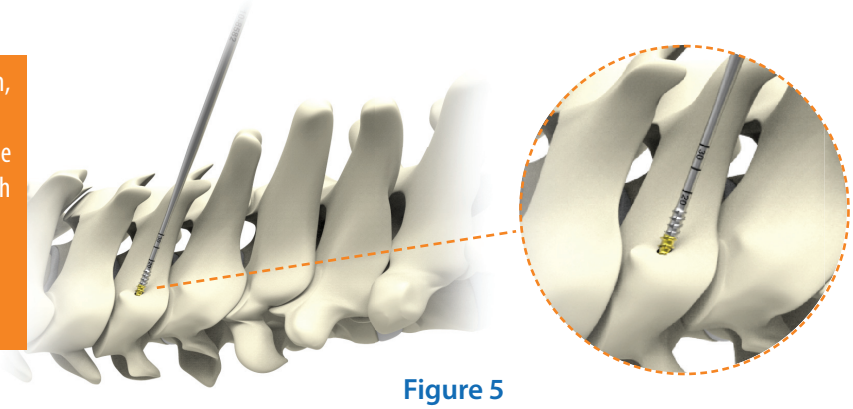


Figure 5

Remove the tap with a counterclockwise motion while maintaining the same trajectory.

STEP 7 SCREW INSERTION

Attach an appropriate size screw to the split tip screwdriver by pressing the driver tip into the hex of the screw (see Figure 6).

Note: *The 3.8 mm and 4.6 mm diameter screws are inserted with a 2.5 mm hex driver, and the 4.6 mm and 5.5 mm diameter screws are inserted with a 3.0 mm hex driver.*

Figure 6

TIP: The split tip screwdriver, 2.5 mm, can be used to insert the screw, locking screw, and provisionally tighten the cross connector. The split tip screwdriver, 2.5 mm, can be easily identified by one black band on the proximal end of the instrument.

With an in-line handle attached, insert the screw to the desired depth (see Figure 7).

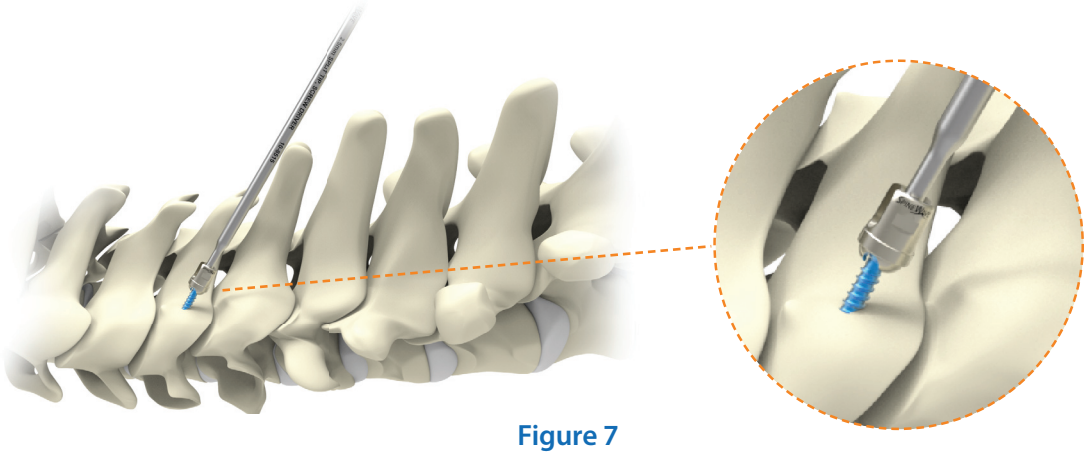


Figure 7

Once the screw is fully inserted, remove the split tip screwdriver from the screw by pulling up on the instrument.

As an alternative screwdriver, the threaded screwdriver may be used to insert screws (see Figure 8). To use the threaded screwdriver, insert the hex tip into the selected screw. Using the proximal knob, tighten the inner sleeve into the tulip of the screw to secure the connection. The outer sleeve can be used to stabilize the instrument during screw insertion.

Figure 8

To remove the threaded screwdriver, unthread the inner sleeve using the proximal knob. For minor screw adjustment following screw placement, use the screw adjuster (2.5 mm or 3.0 mm).

STEP 8 ROD PREPARATION

Using the screw head positioner, align the screws into the desired orientation. To efficiently align the screw heads, rotate the screw base to find a tri-lobe (see Figure 9,10) then turn the tulip into alignment (see Figure 11). Complete alignment for all screws in construct (see Figure 12).

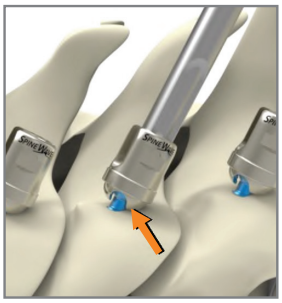


Figure 9

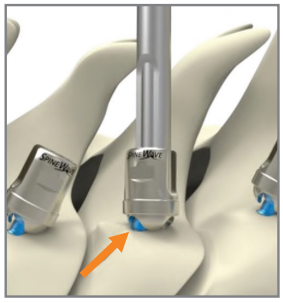


Figure 10

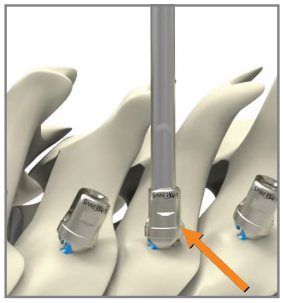


Figure 11

The rod template may be used to determine the length and curvature of the rod. Choose the appropriate rod material, diameter, and length.

Note: *Rods are offered in straight and curved styles, and range in lengths from 30 mm- 240 mm. Transition rods are available up to 600 mm.*

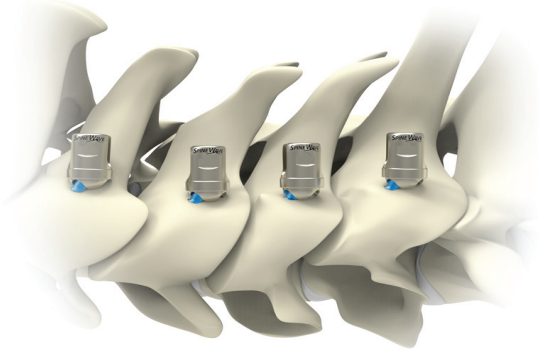


Figure 12

Note: *Rods are offered in titanium and cobalt chrome in diameters of 3.5 mm and 4.0 mm.*

To cut the rod, insert the rod into the appropriate diameter hole, and squeeze the handles to cut the rod (see Figure 13). Contour the rod using the rod bender. The instrument allows for three different radii of curvature. To adjust, turn the knob to the desired curvature (see Figure 14).

Note: *The rod cutter offers an open and closed hole for both 3.5 mm and 4.0 mm rod sizes.*

Note: *The cutting blade is located 6.5 mm from the face of the instrument.*

Figure 13

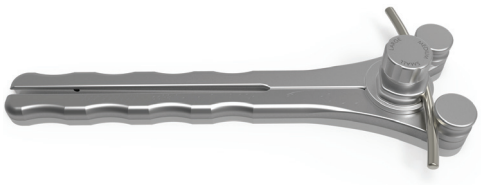


Figure 14

The in situ benders can then be used to achieve final incremental contouring of the rod.
Caution: *To avoid stress concentration and notching of the rod, care should be taken not to make extreme bends.*

STEP 9 ROD INSERTION

Using the rod holder, place the rod into the heads of the screws (see Figure 15).

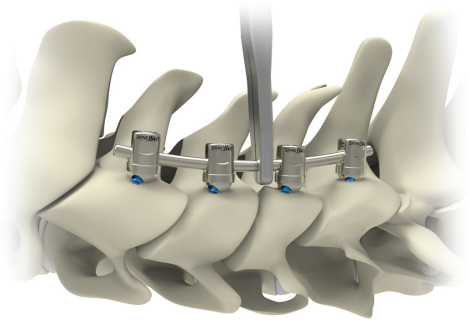


Figure 15

STEP 10 LOCKING SCREW INSERTION

Assemble the locking screw to the split tip screwdriver by firmly pressing the instrument into the locking screw hex. Insert the locking screw into the tulip and provisionally tighten.

Optional: Rod Reduction

If the rod is not easily captured in the screw head, there are several ways to fully seat the rod. For minimal reduction, use the counter torque as a rod pusher by placing it over the rod and applying downward pressure to seat the rod.

For moderate reduction, use the rod rocker by placing the instrument over the rod and aligning it with the notches on the screw head (see Figure 16). Once engaged, tilt the rod rocker back to seat the rod (see Figure 17).

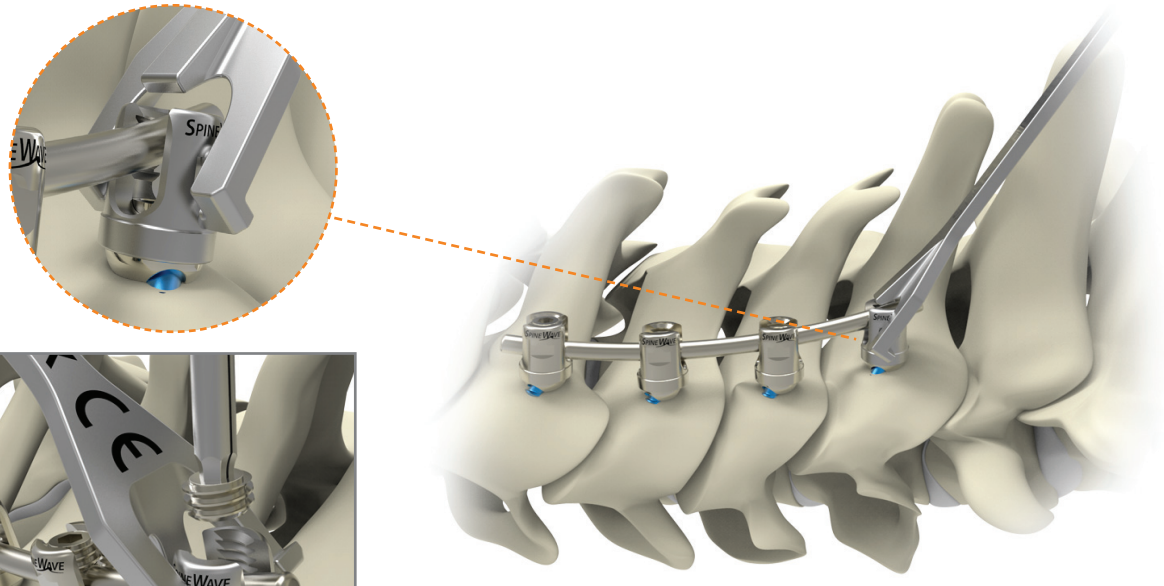


Figure 16

Figure 17

STEP 10 LOCKING SCREW INSERTION (CONTINUED)

If additional reduction is required to fully seat the rod, use the persuader. After assembling the inner and outer sleeve of the persuader, dock the persuader onto the screw head with the lever in the upward position (see Figure 18). Depress the lever to its fully closed position (see Figure 19). The locking screw can then be passed down the internal shaft of the persuader to engage the screw.

TIP: The persuader reduces the rod up to 20 mm.

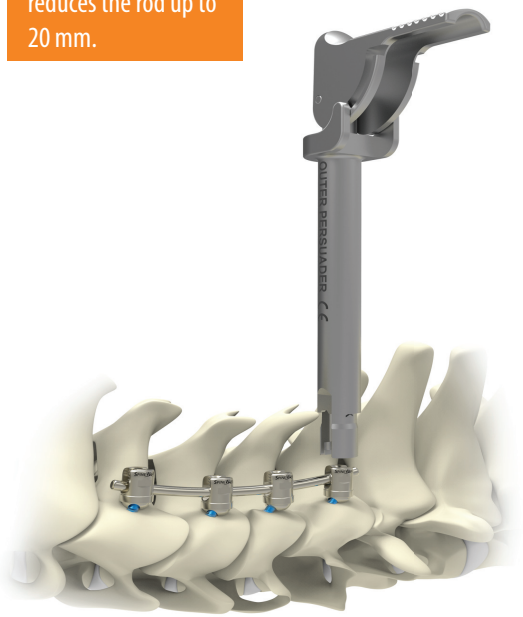


Figure 18

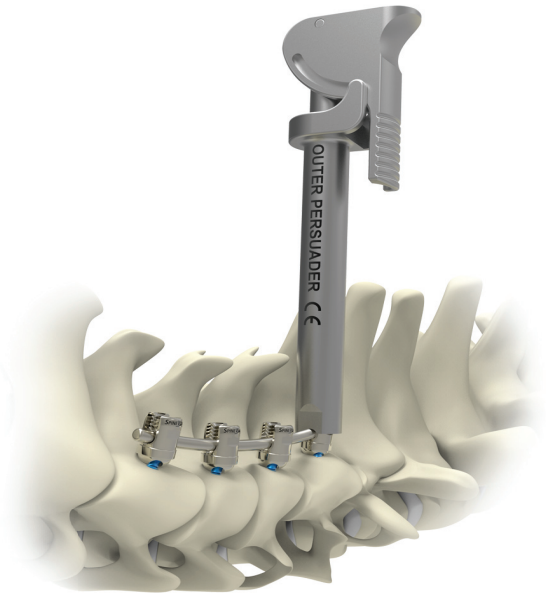


Figure 19

Optional: Compression/Distraction

Provisionally tighten the locking screw on one side of the construct and leave the adjacent locking screw loose.

Perform compression or distraction by seating the distal openings of the instrument over the rod and compressing the handles. Tighten the locking screw when desired position is achieved.

STEP 11 FINAL TIGHTENING

Assembling the locking screwdriver, torque handle, and counter torque handle.

TIP: The locking screwdriver can be easily identified by two black bands at the proximal end of the instrument.

Position the counter torque handle over the screw head and onto the rod to provide leverage.

Pass the locking screwdriver through the inner shaft of the counter torque handle. Engage the locking screw and turn in a clockwise direction until audible click is heard.

Note: *The torque handle is preset to a limit of 20 in/lbs in order to achieve proper locking.*

Optional: Cross Connector Placement

The Proficient® Posterior Cervical Spine System offers screw-to-screw cross connectors. After selecting the appropriate size implant, grasp the body of the implant with the introducer. Starting with the telescoping end, place the ends of the cross connector into the screw heads directly over the rod (see Figure 20).

Note: *There should be no locking screw between the head-to-head cross connector and the rod upon insertion.*

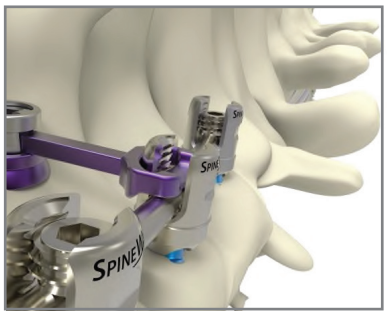


Figure 20

Provisionally tighten the locking screws onto the rods.

Attach the torque handle to the locking screwdriver, and final tighten locking screws and the center locking screw.

Removal

The Proficient® Posterior Cervical Spine System locking screw and Proficient® screw can be explanted using the split tip, 2.5 mm screwdriver, screw adjuster, or the locking screwdriver.

SCREWS

Cat #	Description
21-8318	Polyaxial Screw, Cervical, 3.8 mm X 10 mm
21-8319	Polyaxial Screw, Cervical, 3.8 mm X 12 mm
21-8320	Polyaxial Screw, Cervical, 3.8 mm X 14 mm
21-8321	Polyaxial Screw, Cervical, 3.8 mm X 16 mm
21-8322	Polyaxial Screw, Cervical, 3.8 mm X 18 mm
21-8323	Polyaxial Screw, Cervical, 3.8 mm X 20 mm
21-8324	Polyaxial Screw, Cervical, 3.8 mm X 22 mm
21-8325	Polyaxial Screw, Cervical, 3.8 mm X 24 mm
21-8326	Polyaxial Screw, Cervical, 3.8 mm X 26 mm
21-8327	Polyaxial Screw, Cervical, 3.8 mm X 28 mm
21-8328	Polyaxial Screw, Cervical, 3.8 mm X 30 mm
21-8329	Polyaxial Screw, Cervical, 3.8 mm X 32 mm
21-8330	Polyaxial Screw, Cervical, 3.8 mm X 34 mm
21-8364	Polyaxial Screw, Cervical, 4.2 mm X 10 mm
21-8365	Polyaxial Screw, Cervical, 4.2 mm X 12 mm
21-8366	Polyaxial Screw, Cervical, 4.2 mm X 14 mm
21-8367	Polyaxial Screw, Cervical, 4.2 mm X 16 mm
21-8368	Polyaxial Screw, Cervical, 4.2 mm X 18 mm
21-8369	Polyaxial Screw, Cervical, 4.2 mm X 20 mm
21-8370	Polyaxial Screw, Cervical, 4.2 mm X 22 mm
21-8371	Polyaxial Screw, Cervical, 4.2 mm X 24 mm
21-8372	Polyaxial Screw, Cervical, 4.2 mm X 26 mm
21-8373	Polyaxial Screw, Cervical, 4.2 mm X 28 mm
21-8374	Polyaxial Screw, Cervical, 4.2 mm X 30 mm
21-8375	Polyaxial Screw, Cervical, 4.2 mm X 32 mm
21-8376	Polyaxial Screw, Cervical, 4.2 mm X 34 mm
11-8053	Polyaxial Screw, Cervical, 4.6 mm X 20 mm
11-8055	Polyaxial Screw, Cervical, 4.6 mm X 24 mm
11-8057	Polyaxial Screw, Cervical, 4.6 mm X 28 mm
11-8059	Polyaxial Screw, Cervical, 4.6 mm X 32 mm
11-8061	Polyaxial Screw, Cervical, 4.6 mm X 36 mm
11-8063	Polyaxial Screw, Cervical, 4.6 mm X 40 mm
11-8076	Polyaxial Screw, Cervical, 5.5 mm X 20 mm
11-8078	Polyaxial Screw, Cervical, 5.5 mm X 24 mm
11-8080	Polyaxial Screw, Cervical, 5.5 mm X 28 mm
11-8082	Polyaxial Screw, Cervical, 5.5 mm X 32 mm
11-8084	Polyaxial Screw, Cervical, 5.5 mm X 36 mm
11-8086	Polyaxial Screw, Cervical, 5.5 mm X 40 mm
11-8999	Locking Screw

RODS

Cat #	Description
11-8650	Curved Rod, Ti, 3.5 mm X 30 mm
11-8652	Curved Rod, Ti, 3.5 mm X 40 mm
11 -8654	Curved Rod, Ti, 3.5 mm X 50 mm
11 -8656	Curved Rod, Ti, 3.5 mm X 60 mm
11 -8658	Curved Rod, Ti, 3.5 mm X 70 mm
11 -8660	Curved Rod, Ti, 3.5 mm X 80 mm
11 -8662	Curved Rod, Ti, 3.5 mm X 90 mm
11 -8664	Curved Rod, Ti, 3.5 mm X 100 mm
11 -8666	Curved Rod, Ti, 3.5 mm X 110 mm
11 -8668	Curved Rod, Ti, 3.5 mm X 120 mm
11 -8684	Straight Rod, Ti, 3.5 mm X 30 mm
11 -8690	Straight Rod, Ti, 3.5 mm X 60 mm
11 -8696	Straight Rod, Ti, 3.5 mm X 90 mm
11-8702	Straight Rod, Ti, 3.5 mm X 120 mm
11-8714	Straight Rod, Ti, 3.5 mm X 240 mm
11-8788	Straight Rod, CoCr, 3.5 mm X 240 mm
11-8991	Straight Rod, CoCr, 4.0 mm X 240 mm
11-8528	Transition Rod, Ti, 3.5x 5.5 X 300 mm

CROSS CONNECTORS

Cat #	Description
11-8240	Cross Connector, screw-to-screw, 26-30 mm
11-8241	Cross Connector, screw-to-screw, 29-36 mm
11-8242	Cross Connector, screw-to-screw, 35-46 mm
11-8243	Cross Connector, screw-to-screw, 39-56 mm

INSTRUMENT OVERVIEW

10-8500 Awl

10-8576 Drill Guide, 2.9 mm
10-8577 Drill Guide, 3.5 mm

10-8538 Handle, In-line

10-8571 Drill, Fixed 2.9 x 12 mm
10-8572 Drill, Fixed 2.9 x 14 mm

10-8574 Drill, Adjustable, 2.9 x 36 mm
10-8575 Drill, Adjustable, 3.5 x 48 mm

10-8579 Drill Stop, Adjustable

10-8580 Probe, Straight
10-8581 Probe, Curved

10-8510 Sounding Probe

10-8511 Depth Gauge

10-8582 Tap, 3.3 mm
10-8583 Tap, 3.7 mm
10-8584 Tap, 4.1 mm

10-8585 Tap, DL 4.5 mm

10-8515 Screwdriver, split tip 2.5 mm
10-8540 Screwdriver, split tip 3.0 mm

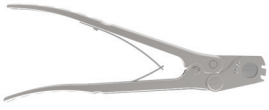
10-8518 Screw Head Positioner

10-8517 Screw Adjuster, 2.5 mm
10-8543 Screw Adjuster, 3.0 mm

10-8588 Rod Rocker, 240 mm

10-8586 Screwdriver, threaded 2.5 mm
10-8587 Screwdriver, threaded 3.0 mm

10-8533 Rod Template, 240 mm



10-8520 Rod Cutter

10-8522 Rod Bender

INSTRUMENT OVERVIEW (CONTINUED)

10-8544 Rod Holder

10-8523.1 Rod Bender
In Situ, Left

10-8523.2 Rod Bender
In Situ, Right

10-8589 Counter Torque
Handle, In-line

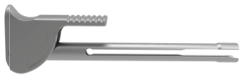
10-8660 Locking Screwdriver

10-8530 Distractor

10-8529 Compressor

10-8591 Counter Torque Handle, Connector

10-8527 Handle, Torque Limiting



10-8524.1 Persuader, Inner Sleeve

10-8524.2 Persuader, Outer Sleeve

10-8534 Introducer, Connector

PRODUCT DESCRIPTION

The Proficient® Posterior Cervical Spine System consists of a selection of non-sterile, single use polyaxial screws, set screws, rods, and cross connector components manufactured from titanium (ASTM FI36 and ASTM F67), cobalt chrome alloy (ASTM F1537), and Elgiloy (ASTM FI058). The surgeon attaches the rod, screw, and cross connectors to the cervico-thoracic region of the spine in order to stabilize the spine during fusion of vertebral bodies.

INTENDED USE

The Proficient® Posterior Cervical Spine System is intended to immobilize and stabilize the spine as an adjunct to fusion for cervical (C2-C7) and thoracic (T1-T3) spinal segments that have been affected by the following acute or chronic instabilities: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative diseases, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies and degenerative disease of the facets with instability. The Proficient® Posterior Cervical Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical spine whose life expectancy is insufficient to permit achievement of fusion. In order to achieve additional levels of fixation, the Proficient® Posterior Cervical Spine System may be connected to the CapSure® Spine System or the Sniper® Spine System using the Proficient® transition rods.

CONTRAINDICATIONS

The Proficient® Posterior Cervical Spine System is contraindicated for:

- Use in spinal regions below T3 (i.e., T4-T12 thoracic, lumbar, sacral)
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- Any case where the implants or components selected would be either too large or too small to achieve a successful result
- Any patient unwilling or unable to follow postoperative instructions

The Proficient® Posterior Cervical Spine System is also contraindicated for patients with:

- Active infection
- Pregnancy
- Severe osteoporosis or osteopenia
- Morbid obesity
- Anatomy or other factors that prohibit safe surgical access to the surgical site
- Allergy or sensitivity to any component of the treatment procedure
- Inadequate tissue coverage over the operative site
- Inadequate bone stock or bone quality
- Fever or leukocytosis
- Uncorrectable coagulopathy or hemorrhagic diathesis
- Cardiopulmonary conditions that present prohibitive anesthesia risk
- Neuromuscular disease or disorder
- Mental illness
- Congenital abnormalities, tumor, or other conditions that would prevent secure fixation that can decrease the useful life of the device
- All cases not stated in the indications for use

HOW SUPPLIED

The Proficient® Posterior Cervical Spine System is supplied NON-STERILE and must be sterilized prior to use. SINGLE USE ONLY. Packaging for device should be intact upon receipt. All components should be carefully checked for signs of damage prior to use. Damaged packages or products should not be used and should be returned to Spine Wave.

CLEANING

All implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. The recommended manual cleaning instructions are described below. Other cleaning methods must be validated by the user.

- Rinse components thoroughly with running warm (35-40°C) tap water for approximately one (1) minute. While rinsing, use a soft bristle brush to loosen and remove as much visible soil as possible from components.
- Soak components in a hospital approved neutral pH enzymatic cleaner for a minimum often (10) minutes. Components must be fully immersed in the cleaner. Follow the cleaner manufacturer's instructions for cleaner preparation and exposure time. These cleaning instructions were validated using Enzol® manufactured by Johnson and Johnson.
- Thoroughly rinse the components with running warm (35-40°C) tap water. While rinsing, use soft bristle brushes, pipettes or a water jet to clean out lumens, holes, and other challenging features.
- Manually scrub the components thoroughly in freshly prepared, clean, neutral pH enzymatic cleaner using soft bristle brushes or pipettes. All lumens, holes, hinged components, mating surfaces, crevices, and challenging components should be thoroughly scrubbed. Actuate all moveable features and expose all areas to cleaner and to the brush or pipette.

- Prepare an ultrasonic bath and sonicate the devices while immersed in the hospital approved cleaning solution for ten (10) minutes. Follow the cleaner manufacturer's instructions for cleaner preparation and exposure time.
- Rinse components thoroughly with deionized or purified water; use pipettes or a water jet to clean out lumens, holes, and other challenging features. Actuate all movable features to fully irrigate all areas.
- Visually inspect components for soil. Repeat the cleaning procedure if necessary until no visible soil remains on the components.
- Perform a final rinse on the components using deionized water or purified water.
- Dry the components using clean compressed air or a soft, lint free, clean cloth.

STERILIZATION

The Proficient® Posterior Cervical Spine System is supplied NONSTERILE and must be sterilized prior to use. Remove all packaging materials prior to sterilization, pre-clean, wrap in an FDA cleared wrap, and sterilize by steam sterilization using one of the following parameters:

Method	Cycle	Temperature	Exposure	Drying
Steam	Gravity	270°F (132°C)	15 Minutes	15 Min
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	20 Min

If components of the Proficient® Posterior Cervical Spine System are sterilized by the hospital in a tray or case, it should be a tray or case provided by SPINE WAVE, INC.

WARNINGS AND PRECAUTIONS

- Use of cross sectional imaging (e.g., CT) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.
- The implantation of the cervicothoracic spinal system screw should be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of this cervico-thoracic screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Pre-operative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal systems should include review of cross sectional imaging studies (e.g., CT) to evaluate the patient's cervical anatomy including the transverse foramen and the course of the vertebral arteries. If any findings would compromise the placement of lateral mass or pedicle screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.
- Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.
- SINGLE-USE ONLY. Surgical implants must never be reused. 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.
- Non-sterile; all components of the Proficient® Posterior Cervical Spine System are provided non-sterile and must therefore be sterilized before use.
- A successful result is not achieved in every surgical case. This is especially true in spinal surgery where other patient conditions may compromise the results.
- Preoperative and operative procedures, including thorough knowledge of surgical techniques, and proper selection and placement of the implant, are important considerations in the success of the surgery.
- Correct handling of the implant is extremely important. The surgeon should avoid any notching, scratching, or reverse bending of the rods when contouring. Alterations will produce defects in surface finish and internal stresses which may cause breakage of the implant. Bending of screws will decrease the fatigue life and may cause failure.
- While some corrosion is present on all implanted metals and alloys, the mixing of dissimilar metals may accelerate this corrosion process. Internal fixation devices, such as rods, hooks, etc., that come into contact with components of the Proficient® Posterior Cervical Spine System must be made from like or compatible metals.
- Potential risks identified with the use of this 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.
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device.
- Based on the fatigue testing results, the surgeon should consider the levels of implantation, patient weight, patient activity level and other patient conditions that may impact the performance of the system.

- Postoperative procedures, including patient instruction on the physical limits and restrictions associated with spinal fixation, are important considerations in the success of the surgery. The patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend, and/or break if excessive demands are placed on them in the absence of complete bone healing. The patient must be made aware that implants displaced or damaged by improper activities may experience migration and cause damage to nerves or blood vessels.
- The spinal fixation system is only intended to support the spine during the period required to achieve spinal fusion. There is a risk of failure of the implant if fusion does not occur, in which case additional surgeries may be required.
- The Proficient® Posterior Cervical Spine System has not been evaluated for safety and compatibility in the MR environment. The Proficient® Posterior Cervical Spine System has not been tested for heating or migration in the MR environment.
- Components of this system should not be used with the components of any other system or manufacturer.

POSSIBLE ADVERSE EFFECTS

All of the potential adverse events or complications associated with spinal fixation procedures are possible. Potential risks associated with the use of spinal fixation include, but are not limited to the following:

- Loosening, bending, fracturing, or disassembling of the implant components
- Implant migration
- Infection
- Pain, discomfort, or abnormal sensations caused by the implant
- Tissue sensitivity to the implant material
- Pressure on the skin and potential for skin breakdown and/or wound complications
- Scar formation possibly causing neurological compromise around nerves and/or pain
- Nonunion or delayed union
- Loss of neurological function, dural tear, pain, and/or discomfort.
- Change in normal spinal curvature, correction, height, and/or reduction
- Complications associated with spinal surgery, including, but not limited to, gastrointestinal disorders, urological disorders, reproductive system compromise, vascular disorders, bronchopulmonary disorders, bursitis, hemorrhage, stroke, hematoma, occlusion, edema, embolism, myocardial infarction, cardiovascular system compromise, infection, paralysis, and death
- Bone graft fracture, vertebral body fracture or discontinued growth of fused bone above and/or below the surgery level
- Bone loss or fractures due to stress shielding
- Change in mental status
- Decrease in bone density due to stress shielding
- Cessation of any potential growth of the portion of the spine with the implant
- Loss of fixation
- Wound necrosis or wound dehiscence
- Loss of spinal mobility or function resulting in the inability to perform the activities of daily living.
- Revision surgery

If such events occur, the intended clinical outcome may not be achieved.

SURGICAL TECHNIQUE

Surgical technique manual for the Proficient® Posterior Cervical Spine System is available by contacting Spine Wave, Inc.

PRODUCT COMPLAINTS

Any health care professional who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance of this device, should notify Spine Wave, Inc. If any Spine Wave, Inc. product "malfunctions" and may have caused or contributed to the death or serious injury of a patient, Spine Wave, Inc. should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, please provide the component(s) name(s), catalog number(s), lot number(s), your name and address, the nature of the complaint, and notification of whether a written report is requested.

PATENT INFORMATION

Covered by one or more U.S. patents or patent applications. See www.spinewave.com/contact_legal.html for details.

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