



QuikStep™

Palisade™ All-In-One Screwdriver

Surgical Technique

Table of Contents

QuikStep™

Palisade All-In-One Screwdriver Procedure

Step 1: QuikStep Assembly

Screwdriver3

Carrier..... 4

Step 2: Screw Placement

Pedicle Docking..... 5

Screw Advancements6

Product Catalog7

A Note for Physicians:

As with any spinal fusion procedure, proper imaging and preoperative planning are critical to safety. This technique manual does not purport to teach radiographic image interpretation. These instructions are intended as an outline for the use of the QuikStep All-In-One Palisade Screwdriver system and is for physicians experienced in the interpretation of fluoroscopic imaging of the lumbar spine and image guided instrument placement.

Physicians should always use their best medical judgment. Proper aseptic technique, anesthesia and antibiotic use, patient positioning, and the ability to obtain proper anterior-posterior (AP) and lateral images are assumed. It is always good practice to verify the ability to obtain useable AP and lateral images before preparing the sterile field.

About the QuikStep All-In-One Palisade Screwdriver System:

The QuikStep All-In-One Palisade Screwdriver system is used with the Palisade Pedicular Fixation System to facilitate placement of a Palisade Screw into a pedicle without the need for a Pin Introducer and Guidewire.

About this Guide:

This guide provides instruction on the use of the QuikStep All-In-One Palisade Screwdriver system when used in conjunction with Palisade™ Pedicular Fixation System. Detailed instructions on the use of the Palisade Pedicular Fixation System is not covered within this guide, but is available via the Palisade Surgical Technique Guide, L427.

QuikStep™ All-In-One Screwdriver

QuikStep Assembly | Screwdriver

The QuikStep All-In-One Screwdriver may be used for the placement of Palisade Screws without the use of Guidewires.

The QuikStep Screwdriver system is comprised of 4 main components: the Ratcheting Axial Handle, a Palisade Screwdriver, the Stylet Carrier, and the appropriate Stylet.

Assemble the Ratcheting Axial Handle with the preferred Palisade Screwdriver (Fig. 1).

Grasp the Screw shank and slowly rotate the Screwdriver until the driver tip is fully engaged with the Screw.

While holding the Screw shank, turn the knob on the Screwdriver clockwise to engage the threads in the Screw extended tabs. Tighten the knob to secure the Screw to the Screwdriver (Fig. 2).

Note: The Extra-Short Palisade Screwdriver and Palisade Navigation Screwdrivers both use a friction fit to secure the Screw. The standard length Palisade Screwdriver has an added locking mechanism to prevent premature release during Screw advancement.

Ratcheting Axial Handle



Carrier



Stylets

Long



Short



Extra-Short



Instruments from Standard Palisade Trays

Standard Palisade Screwdriver



Palisade Navigation Screwdriver



Extra-Short Palisade Screwdriver



Palisade Screw

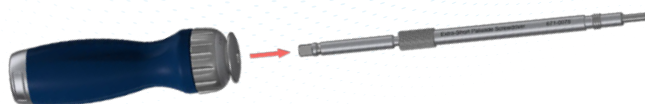
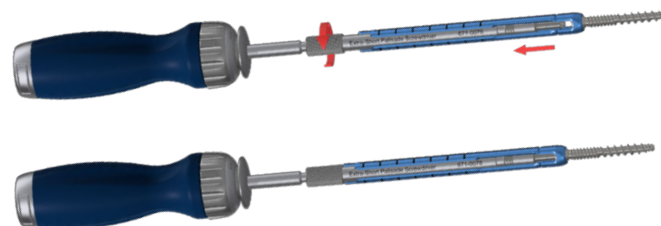


Figure 1



Figure 2



QuikStep Procedure

QuikStep Assembly | Carrier

IMPORTANT: The Extra-Short Palisade Screwdriver must be used with the Extra-Short Stylet, the Short Stylet must be used with the Standard Palisade Screwdriver, and the Long Stylet must be used with the Palisade Navigation Screwdriver.

Failure to use the correct Stylet with the selected Palisade Screwdriver could result in patient injury.

Insert the Short Stylet into the distal end of the Carrier assembly and position the Stylet Hub within the slot correlating to the selected Screw length (Fig. 3).

Depress the button on the proximal end of Ratcheting Axial Handle and insert the Carrier assembly through the proximal end of the Handle (Fig. 4).

Note: Ensure that the Stylet Hub remains in position during assembly of the Carrier to the Ratcheting Axial Handle.

Turn the Knob on the Carrier counterclockwise until it stops, and the Stylet is set to the "00" position. This sets the distal tip of the Stylet flush with the distal tip of the Screw.

If desired, the Stylet may be predeployed beyond Screw Tip to allow for positive bone contact. If this is preferred, rotate the knob clockwise until the Stylet reaches desired position. It is not recommended to allow more than 2mm of deployment as this can increase risk of bending during impaction.

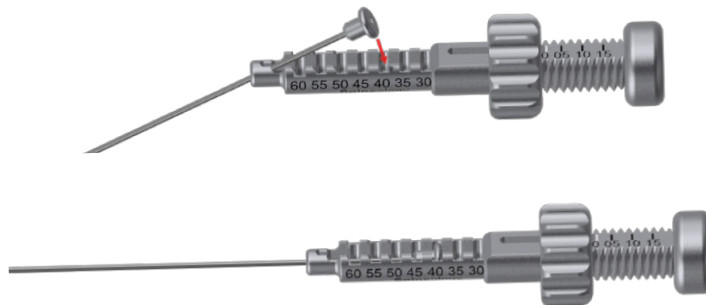


Figure 3

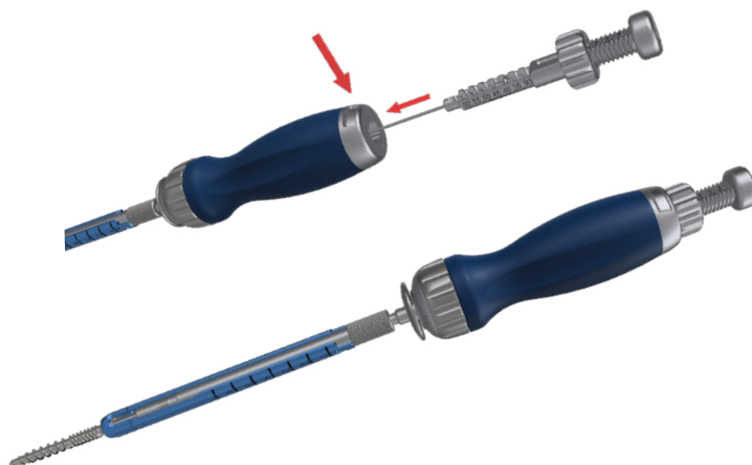


Figure 4

Screw Placement | Pedicle Docking

Using AP imaging, guide the distal tip of the Screw and/or Stylet to dock on the lateral edge and the cephalocaudal center of the pedicle (Fig. 5).

Move to a lateral image and confirm that the distal tip of the Screw and/or Stylet is centered on the dorsal margin of the pedicle and confirm the trajectory is colinear with the axis of the pedicle (Fig. 6).

Note: The Stylet may be extended further if desired to dock on posterior anatomy. Confirm positioning using fluoroscopy.

Rotate the knob on the Carrier clockwise until the top of the knob is aligned with the 5 mm laser etched line, then use the Mallet to gently strike the proximal end of the Carrier to advance the Stylet into the pedicle (Fig. 7). Use fluoroscopy to confirm the Stylet tip advances on the trajectory coaxial to the pedicle.

Note: It is important to monitor the trajectory of the Stylet under fluoroscopic imaging to avoid the potential of pedicle/medial wall breach, which may result patient injury.

Continue to advance the Stylet by no more than 5 mm increments, until it is fully advanced through the pedicle, or a maximum distance of 20 mm.

Using lateral imaging, confirm the Stylet has passed the posterior border of the vertebral body, or a maximum depth of 20 mm, and continue the procedure (Fig. 8).

Note: If the Stylet has not passed the posterior border of the vertebral body, move to AP fluoroscopy and extract the Stylet to the minimum depth – the “00” position – by rotating the knob on the Carrier counterclockwise. Next correct the trajectory and readvance the Stylet, repeating the steps previously described in this section (Screw Placement | Pedicle Docking).

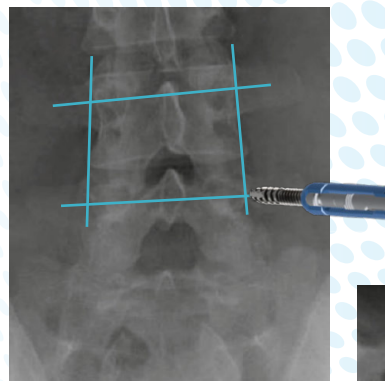


Figure 5

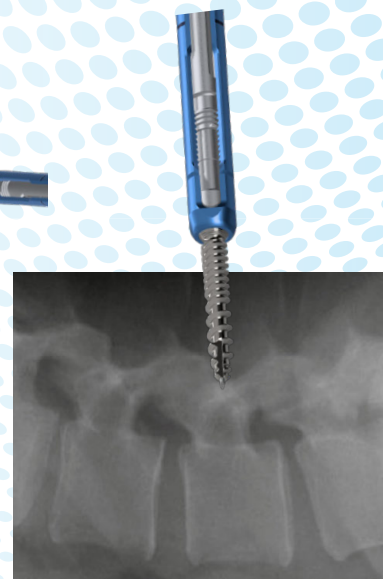


Figure 6

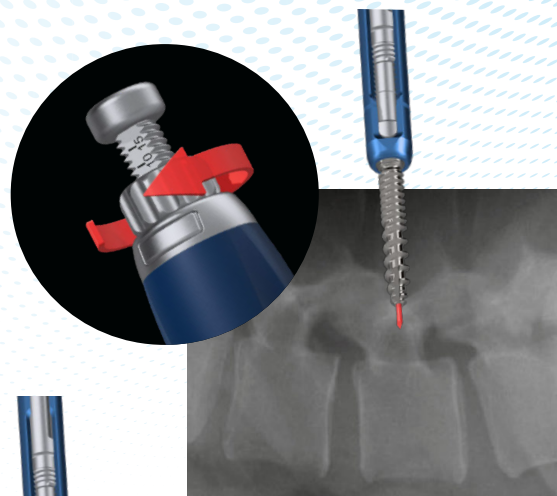


Figure 7

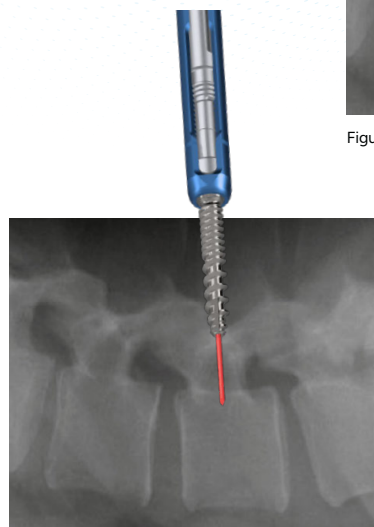


Figure 8

QuikStep Procedure

Screw Placement | Screw Advancement

Once the Stylet and Screw are docked, the Screw may be advanced.

Turn the Ratcheting Axial Handle clockwise to advance the Screw over the Stylet and into the pedicle. The Stylet and Carrier will auto-retract as the Screw is advanced into the pedicle. Confirm the Stylet is retracting during Screw advancement through a combination of direct visualization of the Carrier assembly and lateral fluoroscopy.

Note: If the Stylet does not retract automatically as the Screw is advanced, turn the threaded knob counterclockwise as the Screw is advanced to retract the Stylet manually. If necessary, the Wrench may be used to apply additional force to the knob to ease Stylet extraction from sclerotic bone and/or if the Stylet is bent.

Warning: Failure to ensure successful retraction of the Stylet may lead to unintentional Stylet advancement, which may lead to a breach of the anterior wall of the vertebral body, neurologic damage, or vascular damage.

Advance the Screw until the desired depth is achieved. Ensure the Stylet has fully retracted by turning the knob on the Carrier counterclockwise until at the minimum depth – the “00” position.

Repeat for each pedicle to be instrumented. For a complete overview of the Palisade procedure and instrumentation, please refer to the Palisade Surgical Technique, L427.



Figure 9

QuikStep Screwdriver Instrumentation & Disposables

Product Catalog



Ratcheting Axial Handle



Carrier



Wrench



Extra-Short Screwdriver



Extra-Short Stylet



Short Stylet



Long Stylet

Instruments

CATALOG #	DESCRIPTION
671-0068	Ratcheting Axial Handle
671-0067	Carrier
671-0078	Extra-Short Palisade Screwdriver

Disposables

CATALOG #	DESCRIPTION
670-0075	All-In-One Stylet, Short, Sterile
670-0074	All-In-One Stylet, Long, Sterile
670-0076	All-In-One Stylet, Extra-Short, Sterile

Unique Device Identification (UDI)

All Spineology devices are labeled with UDI in human readable and/or Automatic Identification and Data Capture (AIDC) format. The human readable UDI is formatted starting with M740 and followed by device identifying characters.

The UDI of single use devices is found on the package label in both formats.

The UDI of reusable devices is directly marked on the device in human readable format or can be derived from the catalog number directly marked on the device. For example, a device with catalog number 123-4567 would have a UDI of M74012345670.



Spineology Inc.

7800 Third Street North, Suite 600

Saint Paul, MN 55128-5455

p: 888.377.4633 or 651.256.8500

f: 651.256.8505

spineology.com

QuikStep™

Palisade™ All-In-One Screwdriver

Surgical Technique

Federal law (USA) restricts this device to sale by or on the order of a physician.

Spineology's Palisade Pedicular Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion.

For a complete list of contraindications, precautions, and warnings please refer to the package insert (10-15-45).