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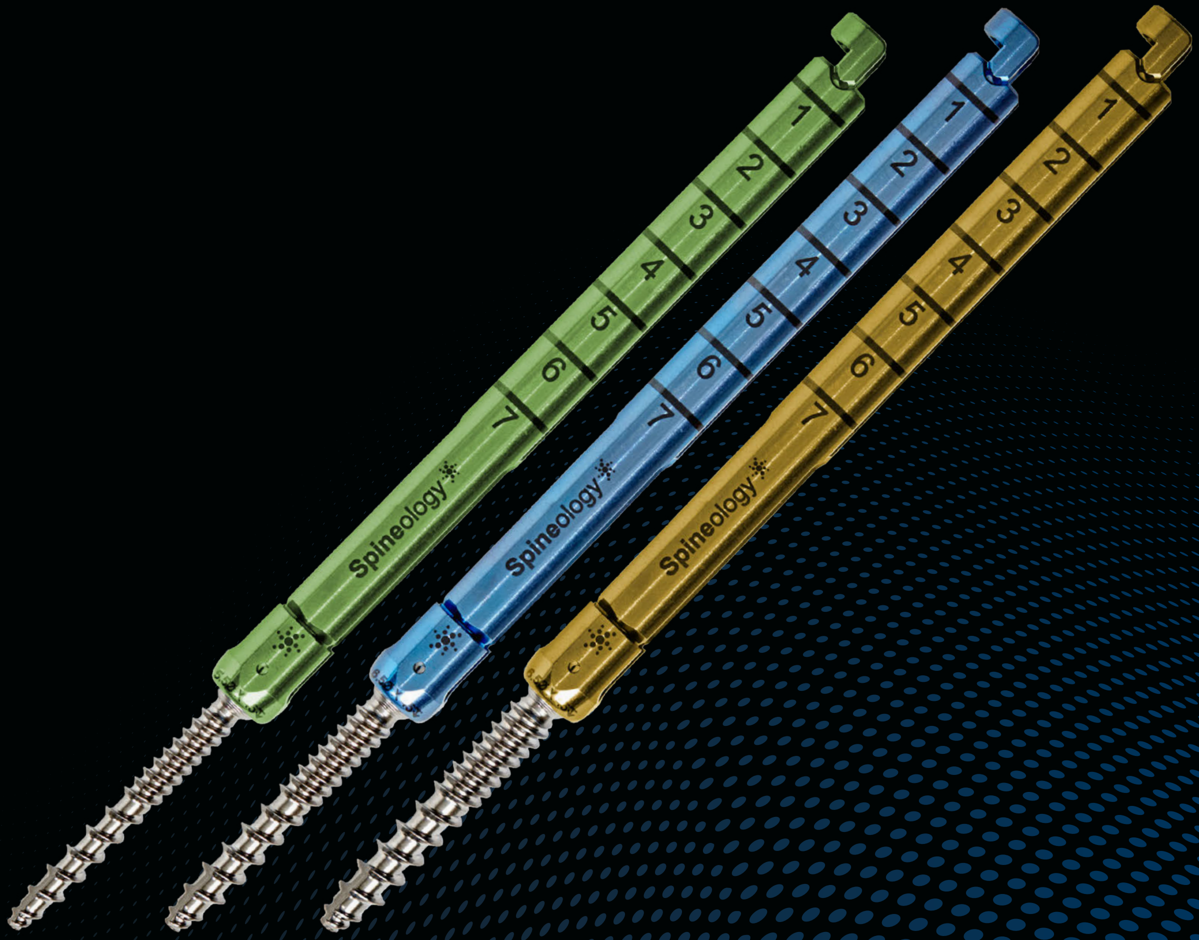

Palisade™

Percutaneous Fixation System

Surgical Technique

Table of Contents

A Note for Physicians:

As with any spinal procedure, proper imaging and interpretation of the images are critical to safety. This technique manual describes the parameters for instrument trajectory selection. It is not intended to teach radiographic image interpretation. These instructions are intended as an outline for the use of the Palisade™ Percutaneous Fixation System for physicians experienced in spine surgery, interpreting fluoroscopic images of the spine, and image guided instrument placement.

Proper aseptic technique, anesthesia and antibiotic use, prone 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.

The Palisade system utilizes Guide Wires to maintain surgical trajectory. Good Guide Wire management is essential. When passing instruments, always maintain the position of the Guide Wire by holding the Guide Wire above or below the instrument. Always verify the position of the Guide Wire using imaging for the safety of the patient and to maintain proper trajectory.

Determining Incision Location

Orient the C-arm to provide a true AP image that is coplanar with the superior endplate of a vertebra to be instrumented. Place a Guide Wire on the patient's skin perpendicular to the axis of the spine. Center the Guide Wire over the pedicles of the target vertebra. Transfer this line to the patient's skin using a marker. Repeat this process for all other levels to be instrumented.

Rotate the Guide Wire 90 degrees and mark the skin along the lateral borders of the pedicles on both sides of the spine.

Incise approximately 1cm lateral to the line intersections (Fig. 1).

Note: The incisions may need to be more lateral in larger patients.

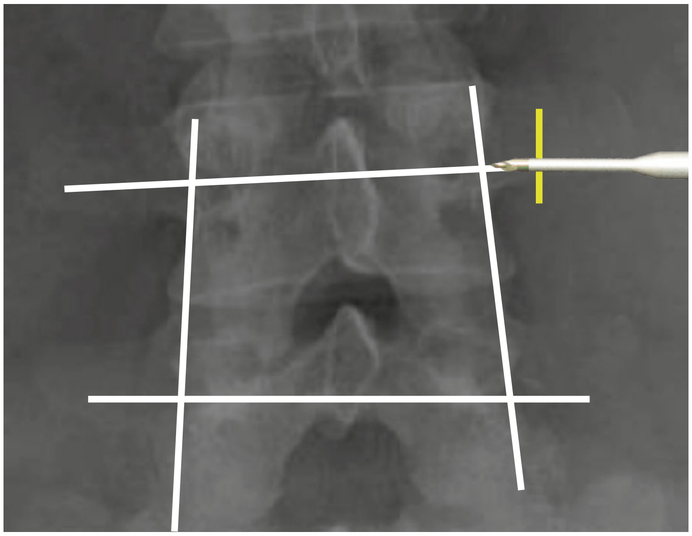

Figure 1 & 2

Guide Wire Placement

Using AP imaging of the level to be instrumented, guide a Pin Introducer to contact bone at the lateral edge and the cephalocaudal center of the pedicle (Fig. 2).

Move to a lateral image and confirm that the Pin Introducer is centered on the dorsal margin of the pedicle and its trajectory is colinear with the axis of the pedicle (Fig. 3).

Note: An optional Direct-to-Screw instrument set is available for placement of the Screw without a Guide Wire. Please refer to the Direct-to-Screw brochure, L477, for further information.

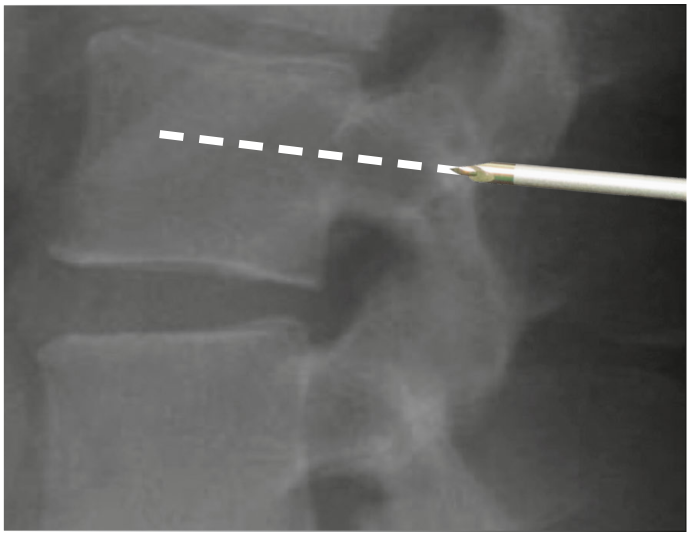

Figure 3

Using AP imaging, advance the Pin Introducer into the pedicle at a slight medial angle. Cease advancement when the tip appears at the midpoint of the pedicle on the image (Fig. 4).

Figure 4

Move to lateral imaging. If the image shows penetration into the vertebral body, the procedure can continue. If the image does not show penetration into the vertebral body, revert back to AP imaging, extract the Pin Introducer back to the bony entrance and re-advance with a corrected angle. Revert to lateral imaging and inspect the position again (Fig. 5).

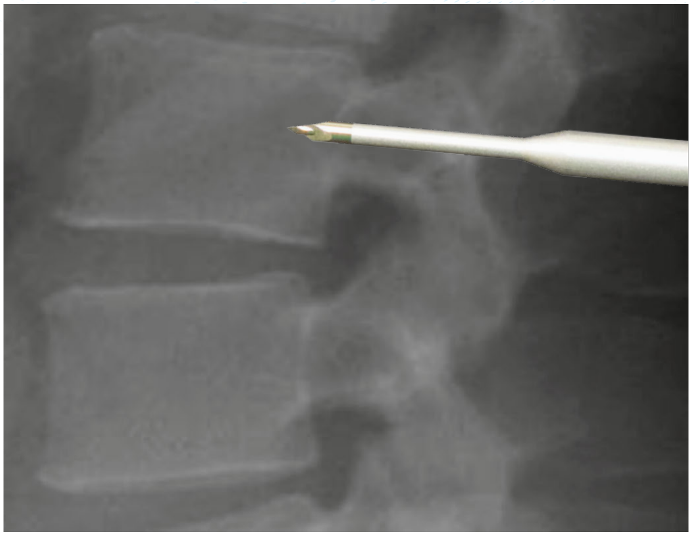

Figure 5

When imaging indicates penetration into the vertebral body has been achieved, remove the Stylet from the Pin Introducer and replace it with the Guide Wire.

Advance the Guide Wire until the tip is approximately two-thirds of the way across the vertebral body on the lateral image.

Remove the Pin Introducer.

Dilator Placement and Soft Tissue Dilation

Sequentially place Dilators, 1 through 3 (smallest to largest), over the Guide Wire and advance each until bony contact is made (Fig. 6).

Remove Dilator 1. Leave Dilators 2 and 3 in place to act as a tissue shield for the Tap and Screw.

Note: Dilators 2 and 3 are constructed of plastic. This will insulate the Tap and/or Screwdriver assembly from surrounding tissues in the event EMG stimulation is desired.

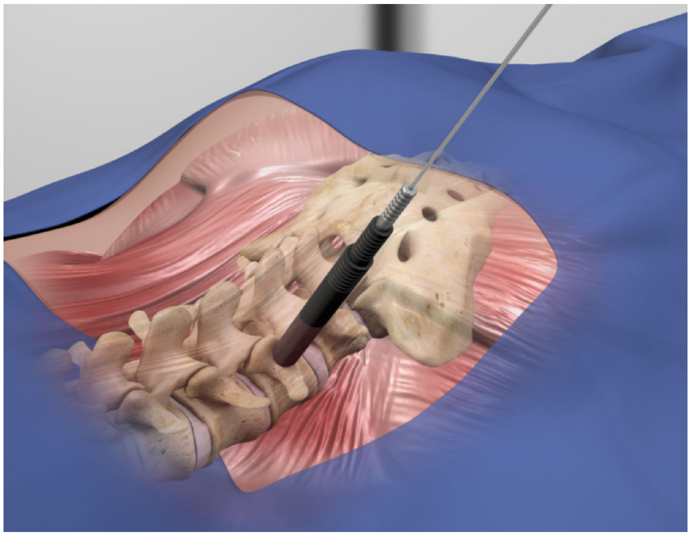

Figure 6

Tapping

Advance the Tap over the Guide Wire and through Dilator 2 until bony contact is made. Use lateral imaging to ensure the Tap and Guide Wire are aligned.

Advance the Tap into the bone to the desired depth by rotating clockwise. To determine Screw length read the etched lines and numbers on the Tap in relation to the fully seated Dilator 2 (Fig. 7).

Remove the Tap and Dilator 2, leaving the Guide Wire and Dilator 3 in place.

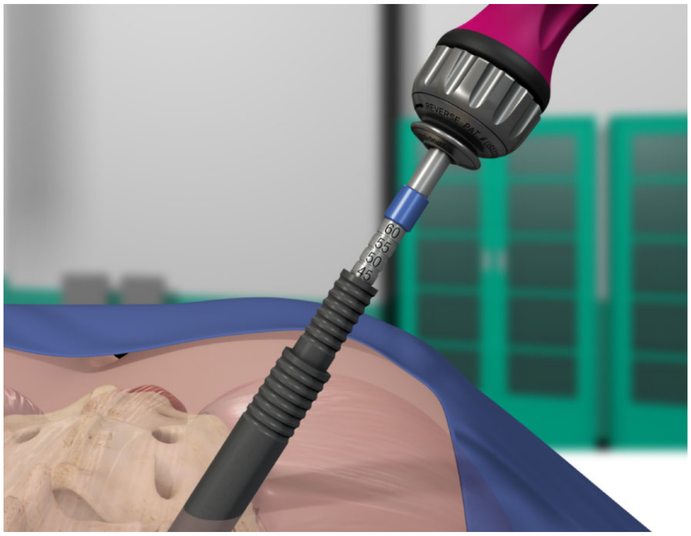

Figure 7

Pedicle Screw Placement continued

Advance the Screwdriver assembly over the Guide Wire. Use lateral imaging to ensure the Screwdriver assembly and Guide Wire are aligned.

Advance the Screw into the pedicle by turning the Screwdriver handle clockwise. When the Screw tip crosses the posterior wall of the vertebral body, remove the Guide Wire.

Advance the Screw until the desired depth is achieved.

Note: Numbered lines 1cm apart on the Screw extension allow observation of Screw advancement. When the top line on the extension reaches Dilator 3, the distal edge of the Screw head is flush with the distal end of the Dilator (Fig. 10).

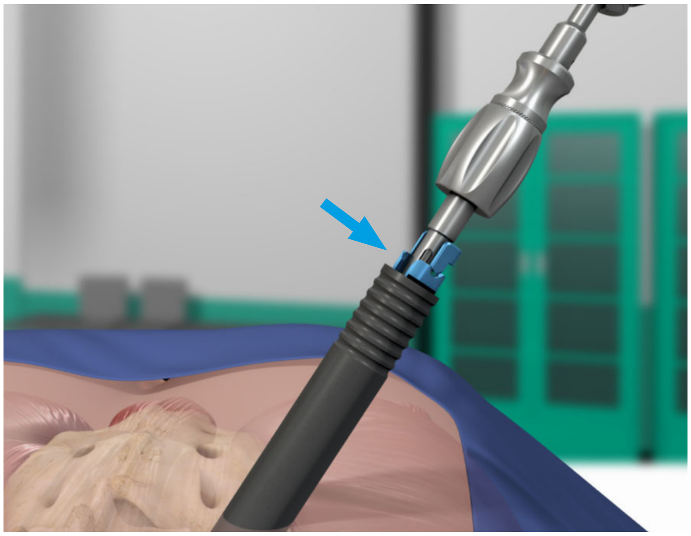

Figure 10

Pull back and turn the Screwdriver lock counterclockwise to the unlocked position (Fig. 8). Rotate the knob at the proximal end of the Screwdriver counterclockwise to remove the Screwdriver from the Screw.

Remove the Screwdriver and Dilator 3. Repeat Screw placement steps for the other pedicles to be instrumented.

Note: When placing subsequent Screws, insert them to a depth comparable to the adjacent Screws. This can be observed on lateral imaging or by observing the position of the proximal ends of the Screw extensions (Fig. 11).

Adjustments to Screw depths can be made with the Screw Adjuster.

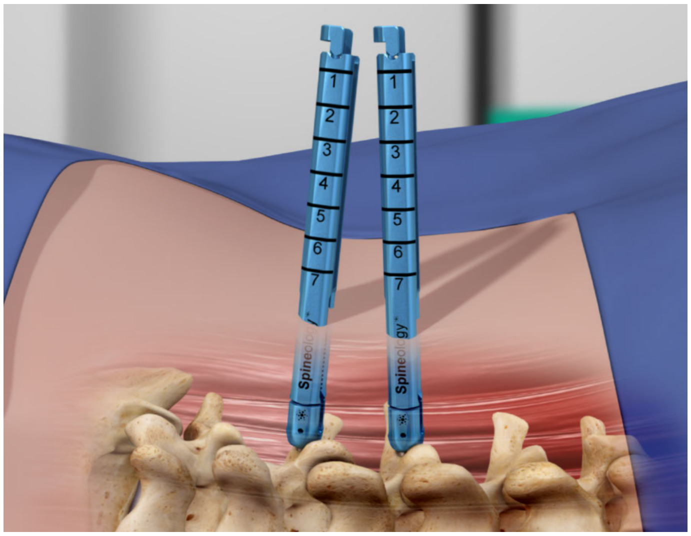

Figure 11

Rod Release

Rod Holder
Unclip the ratcheting bar. Remove the Rod Holder.

Straight Rod Holder
Push the button to unlock the Rod Holder and pull the trigger to release the Rod. Back the Rod Holder off of the end of the Rod.

Final Tightening

Connect the Short Final Driver to the Torque Handle. Place the Final Driver through the Counter Torque and place over the Screw extension. Engage the Set Screw with the Final Driver. Rotate the Counter Torque until it seats on the Rod (Fig. 20).

While holding the Counter Torque in one position, rotate the Final Driver Torque Handle until an audible click is heard. Remove the Counter Torque and Final Driver. Repeat for each Screw.

Note: The handle location of the Counter Torque can be changed with respect to the Screw extension by pulling the handle up and moving it to the desired location.

Note: The Final Driver Torque Handle is marked "10 NM" on the shaft.

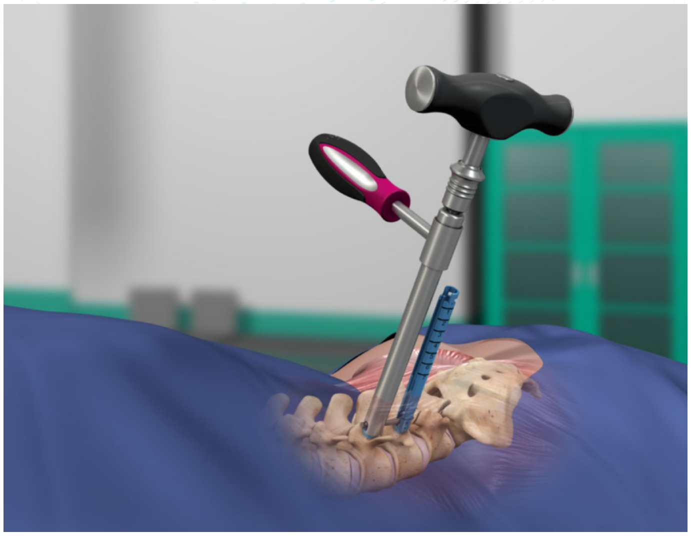

Figure 20

Compression/Distraction

Place Set Screws in all Screw heads. Final tighten one of the Set Screws. Connect the Long Final Driver to the Torque Handle.

Place the Compressor/Distractor Tubes over the Screw extensions and push down to the Rod. Place the Compressor/Distractor Link into the pivot holes in the Compressor/Distractor Tubes for the desired action. Holes marked “D” are for distraction and holes marked “C” are for compression (Fig. 21).

Place the pins on the Compressor/Distractor Handle in the other set of holes in the Compressor/Distractor Tubes from the opposite side of the Compressor/Distractor Link.

Place the Final Driver through the Tube on the Screw which has not been tightened. Squeeze the Compressor/Distractor Handles to compress or distract to the desired position.

Tighten the Set Screw sufficiently to hold the position. Remove the Final Driver and the Compressor/Distractor assembly. Use the Counter Torque and the Final Driver to tighten the Set Screw to the final torque.

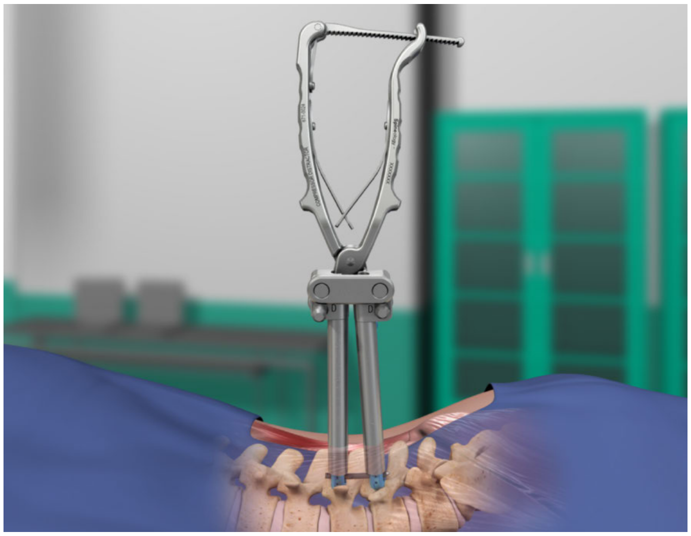

Figure 21

Screw Extension Removal

Hook the top ring with the Top Ring Breaker. Lever the handle to remove the top ring (Fig. 22).

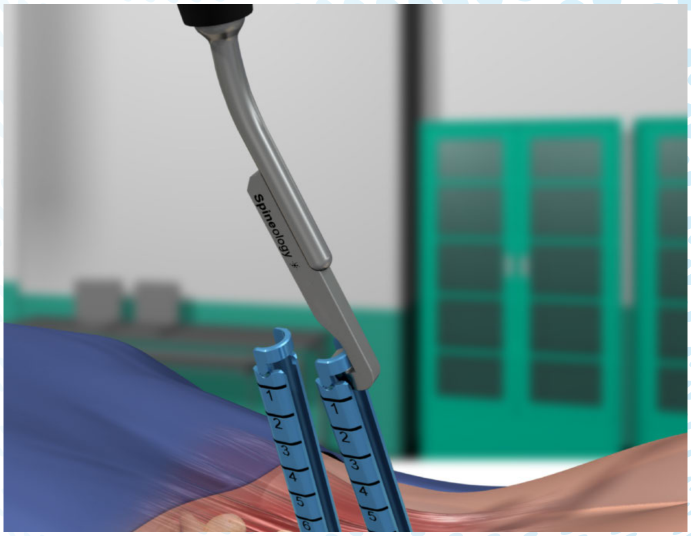

Figure 12

Slide the Tab Breaker over an extension tab until it stops. Lever the tab side to side to break the tab and remove it from the Screw head. Repeat for the other side (Fig. 23).

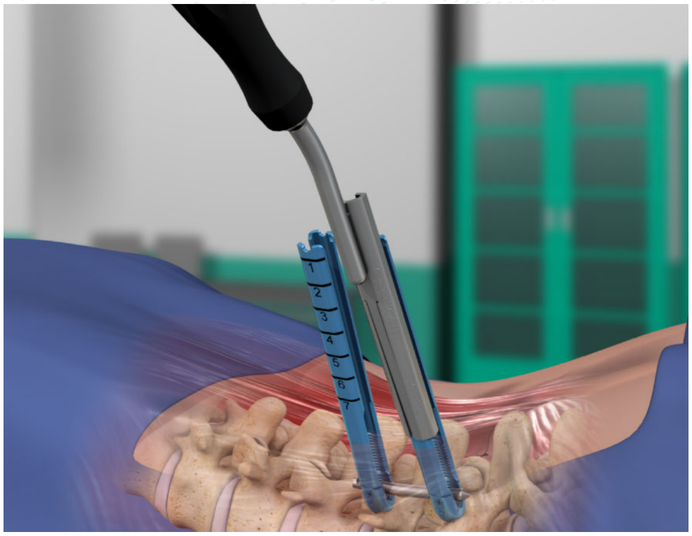

Figure 23

Connector Options

The ConneX™ Cross Connector and Rod Connectors offer a variety of compatible Connector options for use with the Palisade™ Percutaneous Fixation System. Please refer to the ConneX Cross Connector/Rod Connector Surgical Technique, L462, for further information.

Appendix A: Revision and Removal

Insert the star portion of the Set Screw Placer shaft into the Set Screw(s) of the pedicle Screw(s) to be removed. Attach the Ratcheting Handle to the opposite end of the Set Screw Placer shaft and adjust the handle to permit the counterclockwise rotation of the Set Screw(s). Fully extract the Set Screw(s) by turning in a counterclockwise direction. Using the Rod Gripper, lift out the Rod from the Screw heads of all pedicle Screws to be removed. Use the Screwdriver or Screw Height Adjuster to remove all Screws. Take post-procedure radiographs to ensure that all hardware has been removed. Explanted components should be properly discarded and not re-used.

Appendix B:
Palisade™ Percutaneous Fixation System

Instruments

CATALOG #	DESCRIPTION
530-0042	Ratcheting T-Handle
530-0045	Rod Bender
530-0048	Tissue Dissector
642-0001	Rod Holder
671-0002	Locking Set Screw Placer
671-0048	Rod Caliper
671-0004	Ring Breaker
671-0052	Dilator One
671-0007	Dilator Two
671-0008	Dilator Three
671-0012	4.5mm Tap
671-0013	5.5mm Tap
671-0014	6.5mm Tap
671-0015	7.5mm Tap
671-0016	Screw Driver
671-0050	Palm Handle Set Screw Placer

CATALOG #	DESCRIPTION
671-0024	Compressor/Distractor Handle
671-0025	Compressor/Distractor Tube (L&R)
671-0026	Tab Breaker
671-0027	Compressor/Distractor Link
671-0051	Rescue Sleeve
671-0030	Straight Fixed Rod Holder
900-0007	Ratcheting Axial Handle
671-0049	Tulip Head Turner
671-0035	Counter Torque
671-0055	Short ¼” Final Driver
671-0056	Long ¼” Final Driver
671-0040	Double Ended Set Screw Placer
671-0042	Instrument Case 1
671-0046	Instrument Case 2
900-0005	Torque Limiting Handle
671-0053	Screw Height Adjuster

Appendix B:
Palisade™ Percutaneous Fixation System

Implants

CATALOG #	DESCRIPTION
670-5030	Cannulated Poly Axial Screw 5.0x30mm Break-off Extension
670-5035	Cannulated Poly Axial Screw 5.0x35mm Break-off Extension
670-5040	Cannulated Poly Axial Screw 5.0x40mm Break-off Extension
670-5045	Cannulated Poly Axial Screw 5.0x45mm Break-off Extension
670-5050	Cannulated Poly Axial Screw 5.0x50mm Break-off Extension
670-5535	Cannulated Poly Axial Screw 5.5x35mm Break-off Extension
670-5540	Cannulated Poly Axial Screw 5.5x40mm Break-off Extension
670-5545	Cannulated Poly Axial Screw 5.5x45mm Break-off Extension
670-5550	Cannulated Poly Axial Screw 5.5x50mm Break-off Extension
670-5555	Cannulated Poly Axial Screw 5.5x55mm Break-off Extension
670-6530	Cannulated Poly Axial Screw 6.5x30mm Break-off Extension
670-6535	Cannulated Poly Axial Screw 6.5x35mm Break-off Extension
670-6540	Cannulated Poly Axial Screw 6.5x40mm Break-off Extension
670-6545	Cannulated Poly Axial Screw 6.5x45mm Break-off Extension
670-6550	Cannulated Poly Axial Screw 6.5x50mm Break-off Extension
670-6555	Cannulated Poly Axial Screw 6.5x55mm Break-off Extension
670-7535	Cannulated Poly Axial Screw 7.5x35mm Break-off Extension
670-7540	Cannulated Poly Axial Screw 7.5x40mm Break-off Extension
670-7545	Cannulated Poly Axial Screw 7.5x45mm Break-off Extension
670-7550	Cannulated Poly Axial Screw 7.5x50mm Break-off Extension
670-7555	Cannulated Poly Axial Screw 7.5x55mm Break-off Extension

Optional Articulating Rod Holder Case

CATALOG #	DESCRIPTION
530-0092	Articulating Dissector
530-0086	Extension Tower Guide
530-0085	Articulating Rod Holder
671-0005	Articulating Rod Holder Guide

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.

CATALOG #	DESCRIPTION
670-4030	30mm Fixed Percutaneous Palisade Rod
670-4035	35mm Fixed Percutaneous Palisade Rod
670-4040	40mm Fixed Percutaneous Palisade Rod
670-4045	45mm Fixed Percutaneous Palisade Rod
670-4050	50mm Fixed Percutaneous Palisade Rod
670-4055	55mm Fixed Percutaneous Palisade Rod
670-4060	60mm Fixed Percutaneous Palisade Rod
670-4065	65mm Fixed Percutaneous Palisade Rod
670-4070	70mm Fixed Percutaneous Palisade Rod
670-4075	75mm Fixed Percutaneous Palisade Rod
670-4080	80mm Fixed Percutaneous Palisade Rod
670-4090	90mm Fixed Percutaneous Palisade Rod
670-4100	100mm Fixed Percutaneous Palisade Rod
670-4110	110mm Fixed Percutaneous Palisade Rod
670-4120	120mm Fixed Percutaneous Palisade Rod
670-4200	200mm Fixed Percutaneous Palisade Rod
670-6030	30mm Articulating Percutaneous Palisade Rod
670-6035	35mm Articulating Percutaneous Palisade Rod
670-6040	40mm Articulating Percutaneous Palisade Rod
670-6045	45mm Articulating Percutaneous Palisade Rod
670-6050	50mm Articulating Percutaneous Palisade Rod
670-6055	55mm Articulating Percutaneous Palisade Rod
670-6060	60mm Articulating Percutaneous Palisade Rod
670-6065	65mm Articulating Percutaneous Palisade Rod
670-6070	70mm Articulating Percutaneous Palisade Rod
670-6075	75mm Articulating Percutaneous Palisade Rod
670-6080	80mm Articulating Percutaneous Palisade Rod
670-6090	90mm Articulating Percutaneous Palisade Rod
670-6100	100mm Articulating Percutaneous Palisade Rod
670-6110	110mm Articulating Percutaneous Palisade Rod
670-6120	120mm Articulating Percutaneous Palisade Rod
670-0001	Palisade Set Screw (Individually sterile packed)
670-0007	Palisade Set Screw (Sterile packed with Palisade Screws)

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Palisade™

Percutaneous Fixation System

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

Spineology's Palisade Percutaneous 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).