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

Spineology®
anatomyconservingsurgery™

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Threshold™ V2

Pedicular Fixation System

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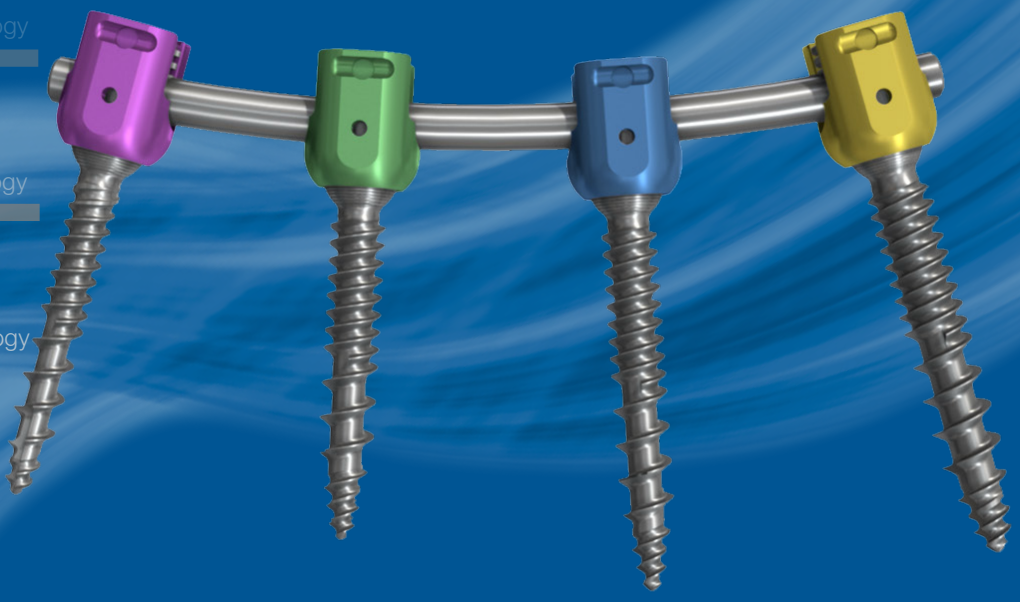

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Table of Contents

A Note for Physicians:

As with any spinal procedure, proper imaging and interpretation of the images is critical to safety. This technique manual is not intended to teach radiographic image interpretation. These instructions are intended as an outline for the use of the Threshold™ V2 Pedicular Fixation System for physicians experienced in spine surgery and interpreting fluoroscopic images of the spine.

Proper aseptic technique, anesthesia and antibiotic use, prone patient positioning, and the ability to obtain proper anterior/posterior (A/P) 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.

Pedicle Preparation

Identify the appropriate anatomical landmarks for creating the entry points for the Screw pilot holes.

The conventional entry site for pedicle Screw placement in the lumbar spine is at the lateral junction of facet and the transverse process (Fig. 1).

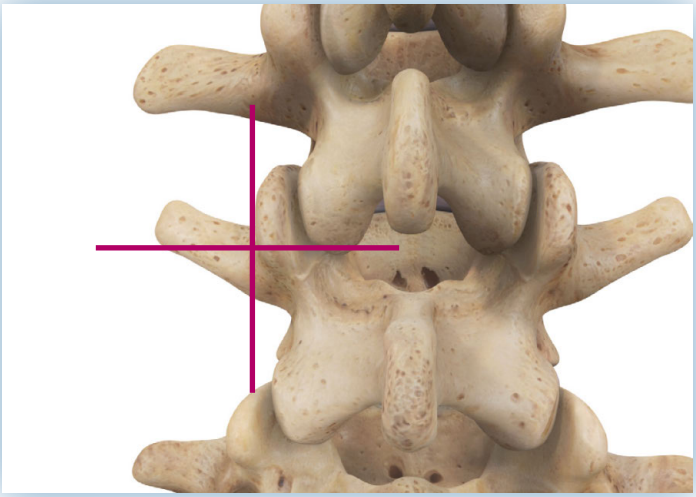

Figure 1

Create the initial pilot hole by lightly tapping the Awl into the pedicle (Fig. 2).

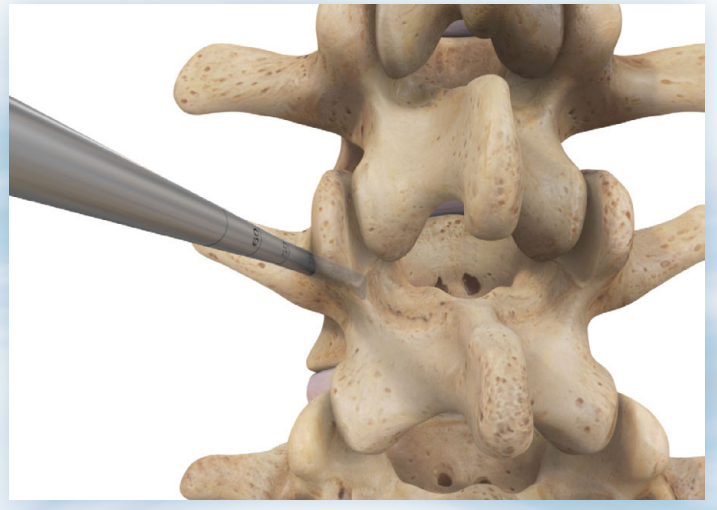

Figure 2

Using the Straight Lumbar Probe, Curved Duckbill Probe or Lenke Probe, extend the pilot hole through the pedicle into the vertebral body (Fig. 3). Fluoroscopic imaging is recommended to ensure the Probe does not breach the walls of the pedicle.

The Curved or Straight Pedicle Feeler can be used to palpate the hole for any perforations in the pedicle walls or base of the hole.

The Threshold V2 Screws include a self-tapping flute feature to obviate the tapping step. The Screws may be inserted immediately following probing of the pedicle if desired.

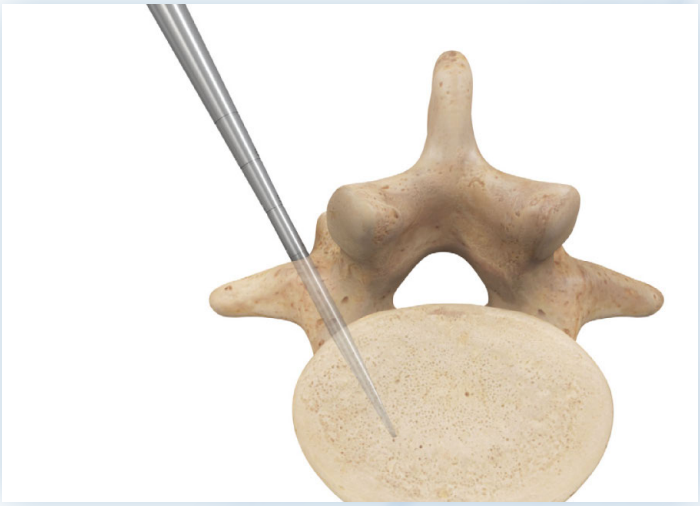

Figure 3

In cases of dense, sclerotic bone, tapping may be performed. The Threshold V2 instrument set contains Taps ranging from 5.0mm to 7.5mm, which correspond to the Screw diameters.

Attach the Axial Ratchet Handle to the desired Tap and tap through the pedicle into the vertebral body until the desired depth is achieved (Fig. 4). Fluoroscopic imaging is recommended to ensure the Tap does not breach the walls of the pedicle. The Taps include length markings and 30mm of thread form to help determine the proper Screw length.

Note: If undersized tapping is desired, select a Tap diameter one size smaller than the diameter of the selected Screw.

The Curved or Straight Pedicle Feeler can be used to palpate the hole for any perforations in the pedicle walls or the base of the hole.

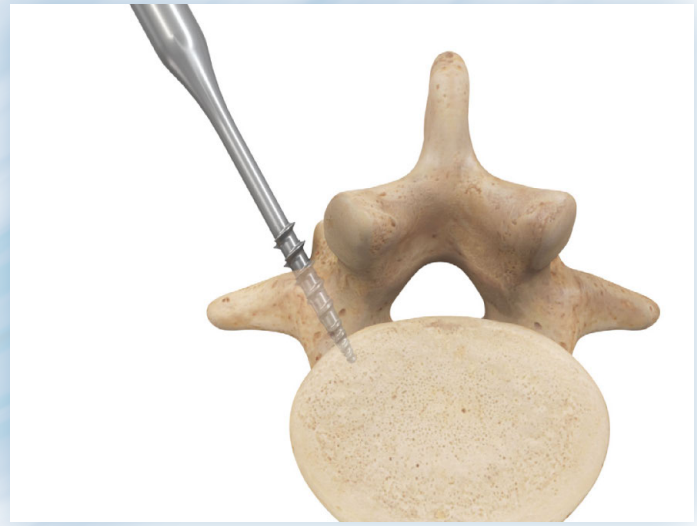

Figure 4

Screw Attachment

Once the proper Screw diameter and length have been determined, attach the Axial Ratchet Handle to the Screwdriver. Ensure the Screwdriver is in the unlocked position by pulling the Screwdriver lock back toward the handle and rotating the lock counter-clockwise (Fig. 5).

Holding the shank of the Screw, insert the distal tip of the Screwdriver into the Screw head. Gently rotate the Screw shank to seat the Screw if necessary.

Once engaged, rotate the engagement knob clockwise until fully tightened to secure the Screw onto the Screwdriver (Fig. 5).

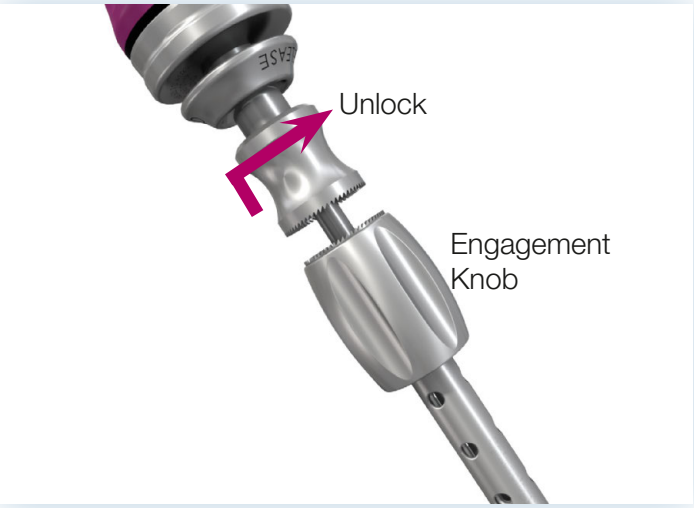

Figure 5

Rotate the Screwdriver lock clockwise into the lock position to prevent inadvertent disengagement of the Screw from the Screwdriver (Fig. 6). The Screw is now ready for insertion.

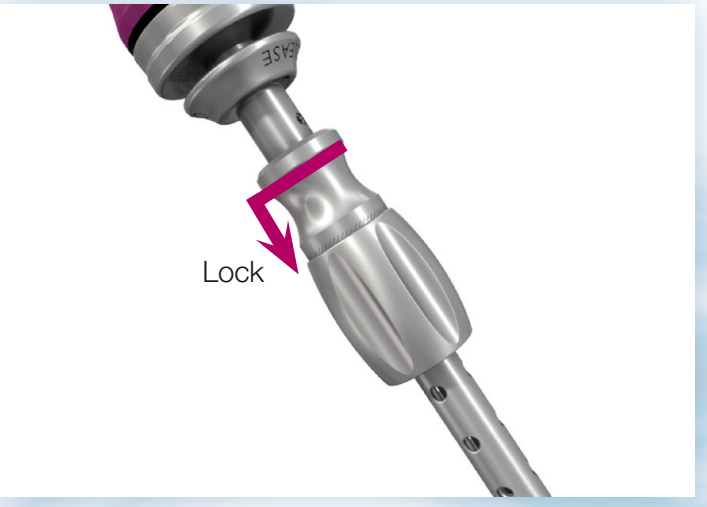

Figure 6

Screw Insertion

Insert and advance the Screw through the previously prepared pathway using A/P and lateral fluoroscopic imaging to confirm proper Screw position (Fig. 7).

To remove the Screwdriver from the Screw, pull up on the Screwdriver lock and rotate counterclockwise to unlock the Screwdriver. Turn the engagement knob counterclockwise until the Screwdriver releases from the Screw. Pull the Screwdriver straight up from the Screw to fully disengage.

Repeat these steps for all additional Screws.

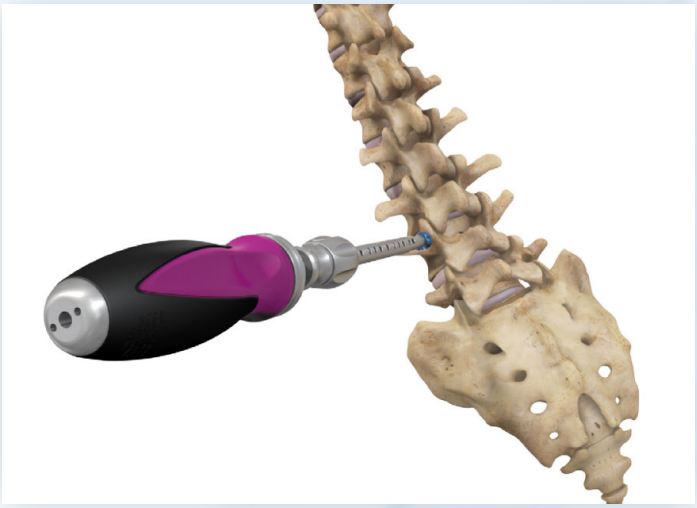

Figure 7

Rod and Set Screw Insertion

Place the distal tips of the Rod Caliper into the Screw heads to determine the correct Rod length (Fig. 8). The indicated Rod Caliper measurement includes a 4mm Rod overhang on each end.

Note: A flexible Rod Template is also available to determine Rod length.

Select the appropriate size Rod and secure it into the Rod Holder. Seat the Rod into the Screw heads.

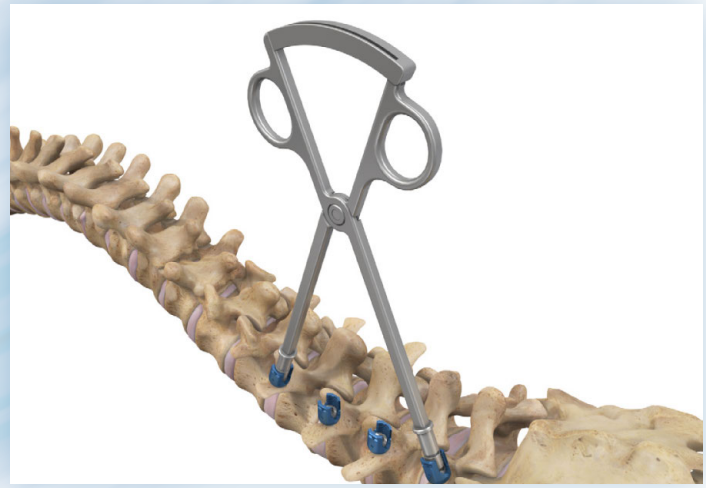

Figure 8

Rod and Set Screw Insertion (continued)

Note: A Screw Height Adjuster is available to adjust the height of the Screw if needed, and a Tulip Head Adjuster is available to align the Screw head orientation and ease Rod placement.

Once the Rod is properly placed, insert the Set Screw Placer into the Set Screw and advance the Set Screw into a Screw head until it is provisionally tightened (Fig. 9). Repeat for each Screw in the construct.

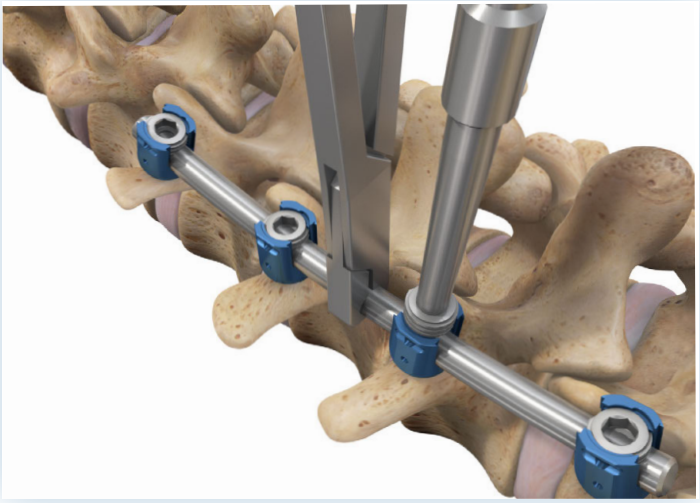

Figure 9

Rod Reduction Options

If the Rod is not fully seated into the bottom of the Screw head, the Rod Reducer, Rod Rocker, or Rod Pusher can be used to fully seat the Rod.

Caution: Care should be taken with any Rod reduction maneuver. Improper instrument use may dislodge the implants or damage the bony anatomy.

To use the Rod Reducer, position the Rod Reducer so the body of the Reducer is perpendicular to the Rod. Place the Rod Reducer over the Screw head until the Screw head is fully seated. Squeeze the handle to engage the Screw head and reduce the Rod. Continue to squeeze the handle until the Rod is fully seated in the Screw head (Fig. 10).

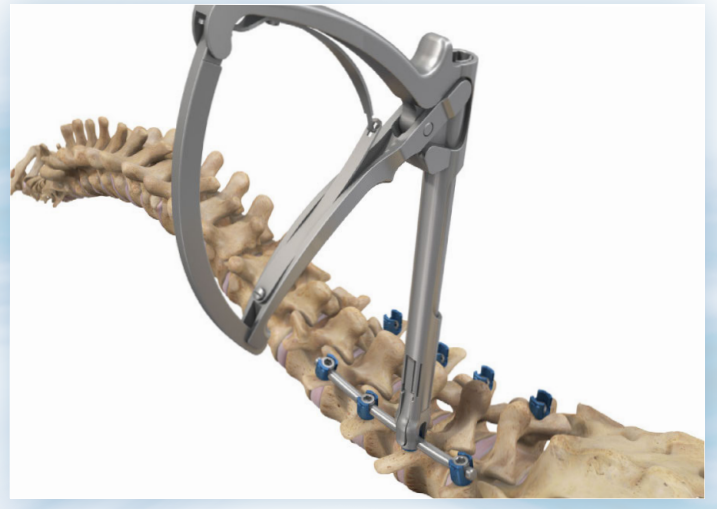

Figure 10

If using the Rod Rocker, place the prongs at the distal tip of the Rod Rocker into the dimples in the Screw head and lock into place by squeezing the finger holes together. Move the Rod Rocker towards the Rod until the Rod is fully seated in the Screw head (Fig. 11).

If using the Rod Pusher, place the Rod Pusher over the Rod and push the Rod into the Screw head until the Rod is fully seated.

While maintaining the Rod reduction, insert and advance the Set Screws as previously described.

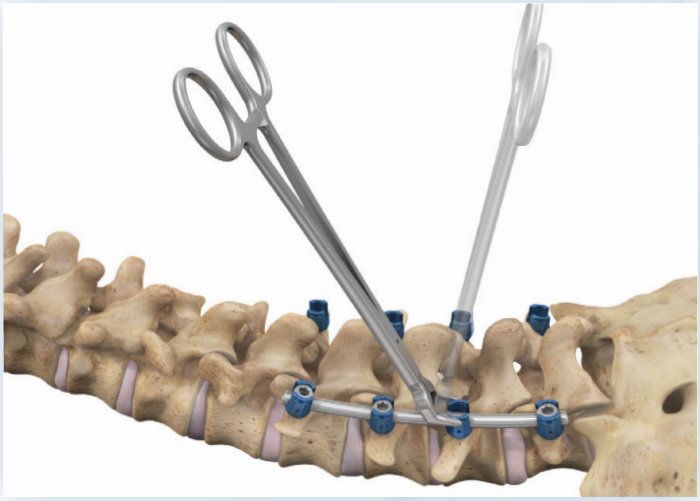

Figure 11

Final Tightening

Place the Final Driver through the Counter Torque outside of the wound.

Seat the distal tip of the Final Driver into a Set Screw and lower the Counter Torque onto the Screw until fully seated (Fig. 12).

Hold the Counter Torque and rotate the Final Driver clockwise until torque is achieved - as indicated by an audible snap within the Final Driver.

Repeat for each Set Screw.

Note: The position of the Counter Torque handle, as it relates to the Rod direction, can be changed by pressing the rotation button at the top of the Counter Torque and rotating the handle to the desired location.

Figure 12

Compression/Distraction

If compression or distraction is desired, use the Counter Torque and Final Driver to lock the Screw on one end of the motion segment. Compression or distraction will occur against the fully tightened Screw.

Place the distal tips of the Compressor or Distractor securely against the Screw heads (Fig. 13). When secure, squeeze the handle of the Compressor/Distractor to manipulate the motion segment. Once satisfactory compression or distraction has been achieved, provisionally tighten the Set Screw of the distracted/ compressed Screw using the Set Screw Placer.

Final tighten all Set Screws using the Counter Torque and Final Driver.

Figure 13

Optional Surgical Technique Reduction Screw

If using Threshold V2 Reduction Screws, follow the standard surgical technique through Rod Placement.

Place and provisionally tighten Set Screws in all standard Screws following the standard Surgical Technique. Insert the Set Screw Placer into the Set Screw and advance the Set Screw into the Reduction Screw head until it becomes difficult to turn. Remove the Set Screw Placer.

Place the Final Driver through the Counter Torque outside of the wound and seat the distal tip of the Final Driver into the Set Screw. Lower the Counter Torque onto the Reduction Screw until fully seated (Fig. 14).

Figure 14

Hold the Counter Torque and rotate the Final Driver clockwise to achieve full reduction. Proceed to final tightening of the Set Screw following the standard surgical technique.

Repeat steps for additional Reduction Screws as needed. Final tighten all Set Screws.

Place the Tab Breaker over the Tab of the Reduction Screw and gently rock back and forth in a medial – lateral direction to break off and remove the Tab. Repeat step on opposite side (Fig, 15).

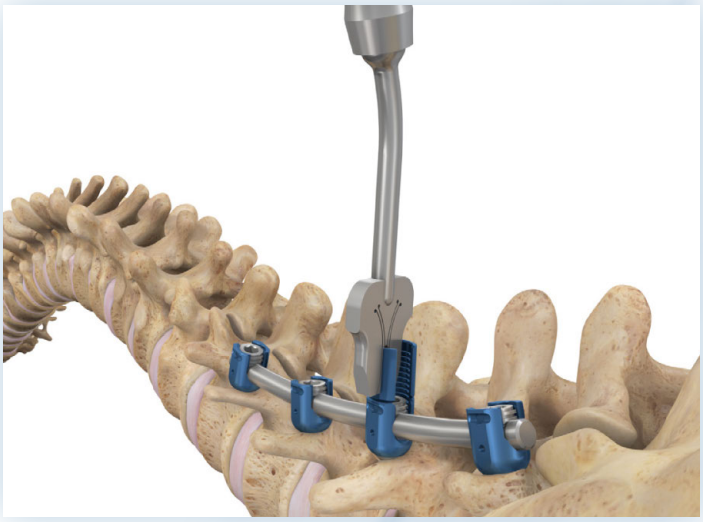

Figure 15

Connector Options

The ConneX™ Cross Connector and Rod Connectors offer a variety of compatible Connector options for use with Threshold V2 Pedicular Fixation System. Please refer to the ConneX Cross Connector/Rod Connector Surgical Technique, L462, for further information.

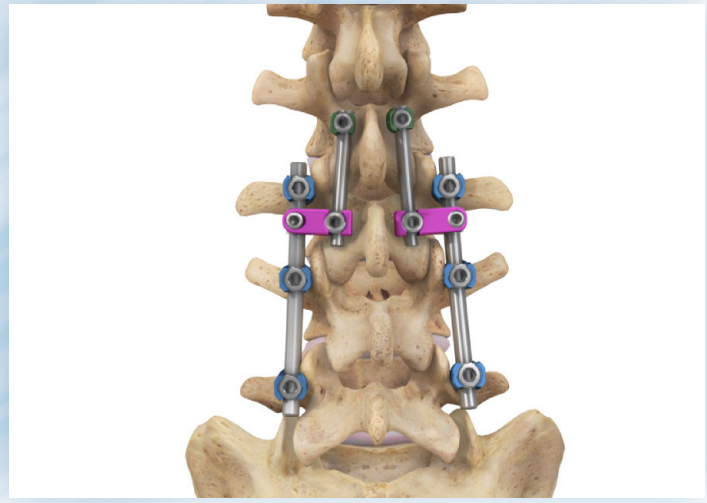

Figure 16

Appendix A: Threshold™ V2 Pedicular Fixation System

Implants

CATALOG #	DESCRIPTION
550-5030	Threshold V2 Polyaxial Screw, 5.0 x 30mm
550-5035	Threshold V2 Polyaxial Screw, 5.0 x 35mm
550-5040	Threshold V2 Polyaxial Screw, 5.0 x 40mm
550-5045	Threshold V2 Polyaxial Screw, 5.0 x 45mm
550-5050	Threshold V2 Polyaxial Screw, 5.0 x 50mm
550-5530	Threshold V2 Polyaxial Screw, 5.5 x 30mm
550-5535	Threshold V2 Polyaxial Screw, 5.5 x 35mm
550-5540	Threshold V2 Polyaxial Screw, 5.5 x 40mm
550-5545	Threshold V2 Polyaxial Screw, 5.5 x 45mm
550-5550	Threshold V2 Polyaxial Screw, 5.5 x 50mm
550-5555	Threshold V2 Polyaxial Screw, 5.5 x 55mm
550-5560	Threshold V2 Polyaxial Screw, 5.5 x 60mm
550-6530	Threshold V2 Polyaxial Screw, 6.5 x 30mm
550-6535	Threshold V2 Polyaxial Screw, 6.5 x 35mm
550-6540	Threshold V2 Polyaxial Screw, 6.5 x 40mm
550-6545	Threshold V2 Polyaxial Screw, 6.5 x 45mm
550-6550	Threshold V2 Polyaxial Screw, 6.5 x 50mm
550-6555	Threshold V2 Polyaxial Screw, 6.5 x 55mm
550-6560	Threshold V2 Polyaxial Screw, 6.5 x 60mm
550-6565	Threshold V2 Polyaxial Screw, 6.5 x 65mm
550-7530	Threshold V2 Polyaxial Screw, 7.5 x 30mm
550-7535	Threshold V2 Polyaxial Screw, 7.5 x 35mm
550-7540	Threshold V2 Polyaxial Screw, 7.5 x 40mm
550-7545	Threshold V2 Polyaxial Screw, 7.5 x 45mm
550-7550	Threshold V2 Polyaxial Screw, 7.5 x 50mm
550-7555	Threshold V2 Polyaxial Screw, 7.5 x 55mm
550-7560	Threshold V2 Polyaxial Screw, 7.5 x 60mm
550-7565	Threshold V2 Polyaxial Screw, 7.5 x 65mm
550-8530	Threshold V2 Polyaxial Screw, 8.5 x 30mm
550-8535	Threshold V2 Polyaxial Screw, 8.5 x 35mm
550-8540	Threshold V2 Polyaxial Screw, 8.5 x 40mm
550-8545	Threshold V2 Polyaxial Screw, 8.5 x 45mm
550-8550	Threshold V2 Polyaxial Screw, 8.5 x 50mm
550-8555	Threshold V2 Polyaxial Screw, 8.5 x 55mm
550-8560	Threshold V2 Polyaxial Screw, 8.5 x 60mm
550-8565	Threshold V2 Polyaxial Screw, 8.5 x 65mm
550-8570	Threshold V2 Polyaxial Screw, 8.5 x 70mm
550-8580	Threshold V2 Polyaxial Screw, 8.5 x 80mm
550-8590	Threshold V2 Polyaxial Screw, 8.5 x 90mm
550-8599	Threshold V2 Polyaxial Screw, 8.5 x 100mm

CATALOG #	DESCRIPTION
570-5540	Threshold V2 Reduction Screw, 5.5 x 40mm
570-5545	Threshold V2 Reduction Screw, 5.5 x 45mm
570-5550	Threshold V2 Reduction Screw, 5.5 x 50mm
570-6540	Threshold V2 Reduction Screw, 6.5 x 40mm
570-6545	Threshold V2 Reduction Screw, 6.5 x 45mm
570-6550	Threshold V2 Reduction Screw, 6.5 x 50mm
570-7540	Threshold V2 Reduction Screw, 7.5 x 40mm
570-7545	Threshold V2 Reduction Screw, 7.5 x 45mm
570-7550	Threshold V2 Reduction Screw, 7.5 x 50mm
530-2055	Curved Rod, 55mm
530-2060	Curved Rod, 60mm
530-2065	Curved Rod, 65mm
530-2070	Curved Rod, 70mm
530-2075	Curved Rod, 75mm
530-2080	Curved Rod, 80mm
530-2090	Curved Rod, 90mm
530-2100	Curved Rod, 100mm
530-2110	Curved Rod, 110mm
530-2120	Curved Rod, 120mm
530-0001	Set Screw (Sterile Packed with Screw)
530-0007	Set Screw (Sterile Packaged Individually)
550-0100	Straight Rod, 100mm
550-0120	Straight Rod, 120mm
550-0140	Straight Rod, 140mm
550-0200	Straight Rod, 200mm
550-1400	Straight Rod, 400mm w/Hex

Appendix A: Threshold™ V2 Pedicular Fixation System

Instrument Set 1

CATALOG #	DESCRIPTION
553-0020	Awl
553-0003	Curved Duckbill Probe
553-0004	Straight Lumbar Probe
553-0005	Straight Lenke Probe
552-0050	5.0 Tap
552-0055	5.5 Tap
552-0065	6.5 Tap
552-0075	7.5 Tap
553-0001	Screwdriver
553-0001	Screwdriver
900-0007	Axial Ratchet Handle
900-0007	Axial Ratchet Handle
553-0006	Pedicle Feeler - Straight
553-0007	Pedicle Feeler - Curved
553-0022	Screw Removal Tool
553-0021	Rod Caliper
553-0009	Rod Template
553-0011	Set Screw Placer
553-0011	Set Screw Placer
553-0013	Tulip Head Adjuster
553-0037	Tab Breaker
554-0042	In-situ Bender
554-0043	In-situ Bender
553-0017	Rod Pusher

Instrument Set 2

CATALOG #	DESCRIPTION
553-0012	Counter Torque
530-0043	Final Torque Driver
530-0045	Rod Bender
553-0008	Rod Holder
530-0042	T-Handle - Ratcheting
553-0018	Rod Gripper
553-0002	Rod Rocker
553-0033	Rod Hex Wrench
553-0016	Rod Reducer
553-0016	Rod Reducer
553-0014	Compressor
553-0015	Distractor

Pedicle Marker Instrument Set

CATALOG #	DESCRIPTION
521-0001	Pedicle Marker Inserter
521-0002	Pedicle Markers, Non-Threaded, Single Ring (Qty 3)
521-0003	Pedicle Markers, Non-Threaded, Double Ring (Qty 3)
521-0004	Pedicle Markers, Threaded, Single Ring (Qty 3)
521-0005	Pedicle Markers, Threaded, Double Ring (Qty 3)

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.

Appendix B: Threshold™ V2 Implant Removal

If the Implants are to be removed after a solid fusion occurs, proceed as follows:

1. Surgically expose the implant site.
2. Clean tissue away from the Set Screw.
3. Loosen the Set Screw using the Final Driver and remove it.
4. Remove the rod to expose the head of the Screw.
5. Insert the Screw Height Adjuster into the head of the Screw and proceed to back the Screw out of the pedicle.

Repeat these steps as necessary for removal of each Screw.

DEVICE DESCRIPTION

Pedicular Fixation Systems

Spineology Fortress, Threshold, Threshold V2, and Palisade Pedicular Fixation System consist of screws (titanium alloy), curved and straight rods (see table below for diameters and material), and ConneX Connector (see table below for configurations and materials) devices to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. All screws are available with or without a hydroxyapatite coating. These systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine. The screws can be placed in the pedicles in a variety of trajectories ranging from the standard anatomic transpedicular path projected medially toward the ventral vertebral body, to a caudocephalad path sagittally and a laterally directed path in the transverse plane.

INDICATIONS

Spineology Fortress, Threshold, Threshold V2, and Palisade Pedicular Fixation Systems are 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.

CONTRAINDICATIONS

Contraindications include, but are not limited to:
1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Suspected or documented metal allergy or intolerance.
10. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
11. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
12. Any patient unwilling to follow postoperative instructions.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:
1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. Retropulsed graft, cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including but not limited to the sacrum, pedicles, lamina, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stress shielding.
18. Graft donor site complications including pain, fracture, or wound healing problems.
19. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
20. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

NOTE: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses.

In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend or fracture as a result of exposure to every day mechanical stresses.

PRECAUTION

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this type of system, because this is a technically demanding procedure presenting a risk of serious injury to the patient.
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.
Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/ or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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

MRI WARNING

Spineology Pedicular Fixation Systems, including ConneX Connector devices, have not been evaluated for safety, heating, migration, or and compatibility in the MR environment.

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre dispositions such as those addressed in the contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The device components are not to be combined with the components from another manufacturer.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Utilize an imaging system to facilitate surgery.
5. To insert a screw properly, a sharp tap should first be used.
6. **CAUTION:** Do not overtap or use a screw that is either too long or too large. Overtapping, using an incorrectly sized screw, or accidentally advancing the tap or screw/bolt insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter as will fit into each pedicle.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws. Once this is completed go back and firmly tighten all of the screws and nuts. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.
1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of nonunion persists or if the components loosen, bend, and/or break, the device(s) should be revised and/ or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
6. The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection;
(7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the device components should never be reused under any circumstances.

PACKAGING

Sterile product packaging should be inspected for continuity. Packages for each of the sterile components should be intact upon receipt. Do not use sterile product if the packaging has been damaged or the shelf life has been exceeded. Devices must be handled properly to maintain sterility. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Spineology.

CLEANING AND DECONTAMINATION SUMMARY

Thoroughly clean the instruments. Cleaning and decontamination of surgical instruments are required before introduction into the sterile field. Following use, preventing drying will facilitate later cleaning.
- Soak in enzymatic detergent (mixed per manufacturer's recommendations) for five (5) minutes or longer.
- Use a soft brush for manual cleaning and a soft bottle brush to clean tubes. Pay special attention to inner diameters and crevices during cleaning. Ultrasonic cleaning is recommended.
- A final rinse with purified water will help to prevent mineral deposits on the instruments. Rinse each part thoroughly under running water for one (1) minute or longer.

All surgical instruments should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device. Please contact your local Spineology representative for complete reprocessing instructions.

STERILIZATION

Only sterile products should be placed in the operative field. Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the process parameters below and in their respective cleaning and reprocessing instructions:

Method: Steam
Exposure Time: Minimum 4 Minutes
Cycle: Pre-Vacuum
Temperature: 270°F 132°C)
Drying Time: Minimum 30 Minutes

*Threshold V2 System Instruments: L442

Only FDA-cleared wraps are recommended for use with the sterilization tray. Deviations from the recommended methods of cleaning and decontamination are not advised. It is the sole responsibility of the user to qualify such deviations.

FURTHER INFORMATION OR PRODUCT COMPLAINTS CONTACT SPINEOLOGY AT:

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