



Fortress™ Pedicular Fixation System
Threshold™ Pedicular Fixation System
Threshold™ V2 Pedicular Fixation System
Palisade™ Pedicular Fixation System

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. Screw preparation and placement may be accomplished manually or attached to a powered drill using Spineology's Power Adapter instrument accessory.

ConneX™ Cross Connector

Spineology ConneX Cross Connector devices are transversely-placed titanium alloy implants that are intended to connect the rod on one side of a spinal construct to the rod on the other side. These devices are manufactured from titanium alloy and are adjustable to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. ConneX Cross Connector devices 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.

ConneX™ Rod Connector

Spineology ConneX Rod Connector devices are titanium alloy implants that are intended to connect two rods in a spinal construct. These devices are manufactured from titanium alloy and the components allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. ConneX Rod Connector devices 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.

Component	Fortress	Threshold	Threshold V2	Palisade
5.5mm Curved Rod (titanium alloy)		X	X	
5.5mm Straight Rod, (titanium alloy)		X	X	
4.75mm Curved Rod (cobalt chrome)	X	X	X	X
4.75mm Straight Rod, (cobalt chrome)	X	X	X	X
ConneX Cross Connectors (titanium alloy)	X	X	X	X
ConneX Rod Connector, Off-set (titanium alloy)	X	X	X	X
ConneX Rod Connector, Axial (titanium alloy)		X	X	
ConneX Rod Connector, Parallel (titanium alloy)		X	X	

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.

MRI WARNING

Spineology Pedicular Fixation Systems, including ConneX Connector devices, have not been evaluated for safety and compatibility in the MR environment. These implantable devices have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Fortress, Threshold, Threshold V2, and Palisade implantable devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 overlap 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.

IMPLANT HANDLING

Exercise care in handling implants. Protect the implants from contact with objects that may damage the surface. Inspect each implant prior to use and do not use if any damage is suspected.

STERILE PRODUCT PACKAGING

Implants and instruments provided sterile should be inspected for package continuity. Packages for each of the sterile products 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.

- **Note that products provided sterile are for single use only.**
- **Do not re-sterilize products provided sterile.**

STORAGE

Store the implants and instruments provided sterile at room temperature conditions.

DISPOSAL

Dispose of excess or unused bone tissue, and all packaging that has been in contact with the tissue, in accordance with recognized procedures for discarding regulated medical waste materials.

DEVICE REMOVAL / REVISION

Please refer to the applicable Pedicular Fixation System Surgical Technique Guide document as listed below for instructions.

- L290, Fortress
- L427, Palisade

- L238, Threshold
- L459, Threshold V2
- L462, ConneX

Please contact your Spineology representative if you need a replacement document.

INSTRUMENT HANDLING

Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments which exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned, decontaminated, and re-sterilized immediately after use.

INSTRUMENT CLEANING, DECONTAMINATION, AND STERILIZATION

All instruments provided non-sterile must be cleaned, decontaminated, and sterilized by the hospital before use. Please refer to the applicable Pedicular Fixation System Reprocessing Instructions for Spineology Surgical Instruments document as listed below for instructions.

- L287, Fortress
- L428, Palisade
- L254, Threshold
- L442, Threshold V2
- L439, ConneX

Please contact your Spineology representative if you need a replacement document.

FURTHER INFORMATION OR PRODUCT COMPLAINTS

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