Surgical Technique Guide

STERILE SPINE

Pedicle Screw System

WishBone Medical

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1 Introduction

1.1 Overview

The STERILE SPINE™ Pedicle Screw System by WishBone Medical is a posterior pedicle screw system manufactured from titanium alloy (Ti-6A1-4V) is designed for temporary stabilization of the spine during the development of spinal fusion. The System is comprised of a variety of pedicle screws, rods, hooks, and connectors and can be used for single or multiple level fixations.

All STERILE SPINE™ Pedicle Screw System implants are pre-packaged sterile. Do not use if package is damaged. For product information, including indications, contraindications, warnings, precautions, and potential adverse effects, visit WishBone Medical's Instructions for Use page online at www.WishBoneMedical.com/IFU.

1.2 Indications

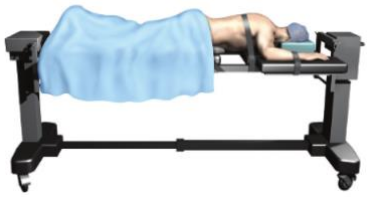
The STERILE SPINE™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1-S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The STERILE SPINE™ Pedicle Screw System is a non-cervical spinal fixation system, used as a Pedicle Spinal System utilized in conjunction with sacral/iliac screw fixation, or anterior-lateral spinal fixation intended to provide stabilization of the spine limited to skeletally mature patients and for use with autogenous graft material. The STERILE SPINE™ Pedicle Screw System is to be utilized in acute and/or chronic instabilities, deformities, or conditions outlined below in the indications section for providing internal spinal stability.

Surgeons implanting this system are expected to be fully versed and trained in the techniques and methods utilized in placement of this spinal fixation system.

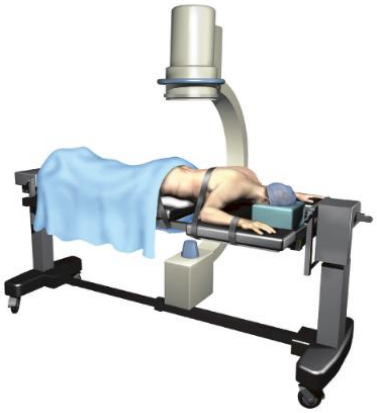
2 Surgical Procedure

2.1 Patient Positioning



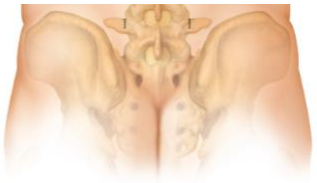
The patient should be positioned prone lying face down on a radiolucent table. Minimize intra-abdominal pressure to avoid venous congestion and excess intra-operative bleeding and allow adequate ventilation under anesthesia in the patient as well. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral junction.

NOTE: It is recommended to use a radiolucent table to assist in achieving the proper patient positioning and an unrestricted fluoroscopic view. Confirm the C-Arm will allow for easy rotation in the lateral, oblique, and A/P positions around the table. Tables that prohibit unobstructed A/P and lateral images should not be used for this procedure.



2.2 Exposure

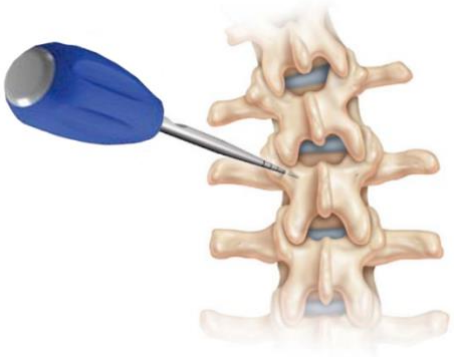
The surgical approach is carried out through a standard midline incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinous process should extend one additional level. The spinal column is then exposed in routine fashion by the surgeon and decompression is carried out as needed.



2.3 Pedicle Entry Point

The pedicle entry point is intersected by the vertical line that connects the lateral edges of bony crest extension of the pars interarticularis, and the horizontal line that bisects the middle of the transverse process. Anatomical variation in individual patients may cause slight differences in the entry site. These differences should be considered carefully and noted on the pre-operative MRI, CT images, and on the intra-operative x-rays.

2.4 Awl

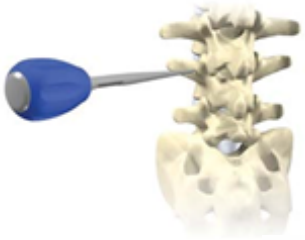


Identify screw entry point and penetrate the cortex using a suitable instrument (awl, rongeur, high speed burr, probe, or equivalent).

The Awl may be used to make an entry hole through the cortex at the pedicle entry point.

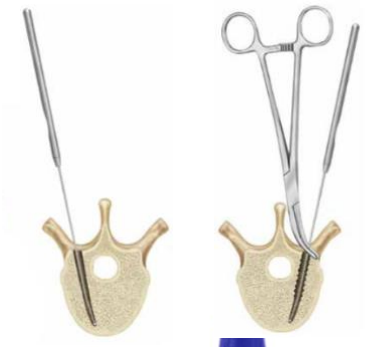
2.5 Pedicle Probe

The Pedicle Gear Shift Probe (Straight or Curved) is inserted through the entry hole and gently pressed into the pedicle canal. The probe is passed through the pedicle canal until the anterior cortex of the vertebral body is reached. Caution should be taken not to violate the anterior wall of the vertebral body or cortical walls.



2.6 Feeler Probe

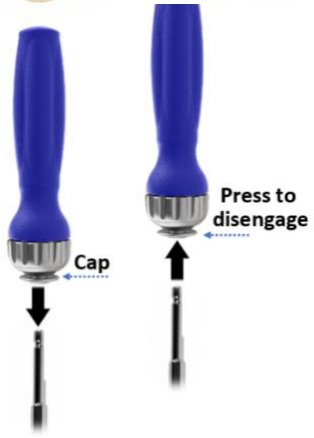
Following the insertion of the probe, the Feeler Probe (Sounder/Ball Tip) is inserted to confirm continuity of the cortical walls of the pedicle. It can also be used to palpate the inner surface of the pedicle canal to check for defects or perforations of the cortical walls.



2.7 Quick Connect Handles

Quick Connect Axial and T-Handles are assembled to the Tap and Polyaxial Screw Inserter by snapping it into place. A slight rotation of the handle may be required to fully engage handles with instrument shafts. To remove the handle, press the cap to disengage the Tap and Polyaxial Screw Inserter.

The position of the ring on the Ratcheting Axial and T-Handles will determine the direction of the Tap and Polyaxial Screw Inserter. Turn the ring clockwise to tap or insert the screw into the pedicle. Turn the ring counterclockwise to remove the tap or screw from the pedicle.



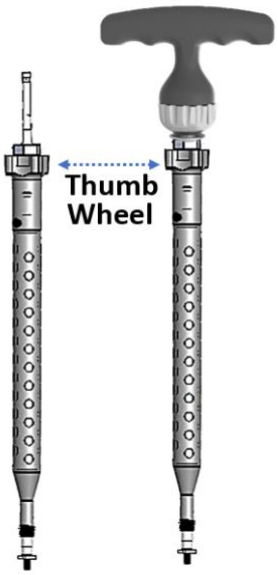
2.8 Tap

Select the Tap that matches preferred Pedicle Screw diameter and attach to handle. Advance Tap to desired depth as shown on graduated markings of Tap.

NOTE: Taps are NOT undersized. They are labeled identical in size to the corresponding screw. Probes and Taps are laser etched with markings to indicate the depth to which the instrument has been inserted and to help the surgeon assess proper screw length.

2.9 Screw Insertion

Select the screw diameter and length appropriate for the pedicle pathway preparation previously performed. The screws are available in diameters of 4.5mm, 5.5mm, 6.5mm, and 7.5mm and lengths of 25 to 90mm.



Securely attach Ratcheting Axial or T-Handle onto the Polyaxial Screw Inserter by snapping it into place. A slight rotation of the handle may be required to fully engage with the inserter. To remove the handle from the inserter, press the cap on the handle to disengage the driver

The ring on the Ratcheting Axial or T-Handle determines the direction the screw will be driven by the Polyaxial Screw Inserter. Turn the ring clockwise to insert the screw into the pedicle. Turn the ring counterclockwise to remove the screw from the pedicle.

Fully seat the tip of the hexalobe inserter into the corresponding feature of the screw. If the hexalobe feature of the screw and inserter do not fully engage or align, rotate the screw shank until the tip of the inserter fully seats into the hexalobe of the screw.

Once the hexalobe tip of the inserter is fully seated, load the screw to the inserter by rotating the thumb wheel clockwise, advancing the threads of the inserter sleeve into the tulip housing. Torque tight to prevent loosening during insertion.

Confirm axis of screw shank is in alignment with inserter shaft and screw is securely attached to inserter (no wobble) prior to insertion.

Note: Avoid contact with thumb wheel on Polyaxial Screw Inserter during screw insertion to prevent unintended disengagement of implant from instrument.

Slowly advance the screw down the pedicle to ensure proper tracking.

The pedicle screw should parallel the endplates and extend 50% to 80% into the vertebral body when fully seated.

Rotate the thumb wheel counter-clockwise to disengage the inserter from the tulip housing.

Verify polyaxial capability by rotating the tulip head in multiple directions.

The Tulip Head Positioner may be used to make adjustments to the position of the tulip head(s).

The Screw Height Adjuster may be used to make adjustments to the height of the screw.

2.10 Rod Selection

Select appropriate length straight or curved Rod. Depending on desired length, curved rods are available from 35mm to 120mm in 5 or 10mm length increments and straight rods from 100mm to 400mm in 50mm increments. The rod should extend approximately 5 millimeters beyond the outer edges of screw tulip head.

2.11 Rod Templating

The Rod Template may be utilized to determine appropriate Rod length and contour.

2.12 Rod Bending

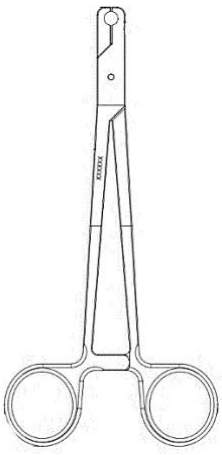
A standard feature of the system is pre-lordosed rods. In select circumstances requiring customized bends based on rod templating, the rod can be shaped utilizing the Rod Bender. The polyaxial adjustability of the system eliminates the need for precision bending of the rod. A simple lordotic bend is sufficient and the amount of curvature is based on the patient's anatomy and the amount of reduction to be achieved.

2.13 Rod Insertion

The rod is then placed into the Pedicle Screw housing.

The screw allows up to 50° of angulation which should be sufficient to adjust to the position of the rod which can also be done by the Rod Benders. The Vertebral Rod Aligner and the Rod Holders can be used to stabilize the housing while inserting Set Screws.

Note: The Tulip Head Positioner can be used to align tulip heads prior to Rod placement.



2.14 Set Screw Insertion

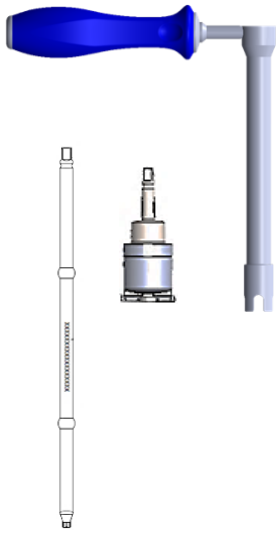
Use the Initial Set Screw Inserter to deliver Set Screws into each tulip head at all levels. Load Set Screw by pressing downward on the tapered tip of Initial Set Screw Inserter to retain Set Screw. Engage threads of the Set Screw into the tulip head and provisionally tighten.

NOTE: If Set Screw does not turn smoothly in tulip head, slowly turn Initial Set Screw Inserter counter-clockwise until Set Screw disengages, then turn again clockwise to align threads.

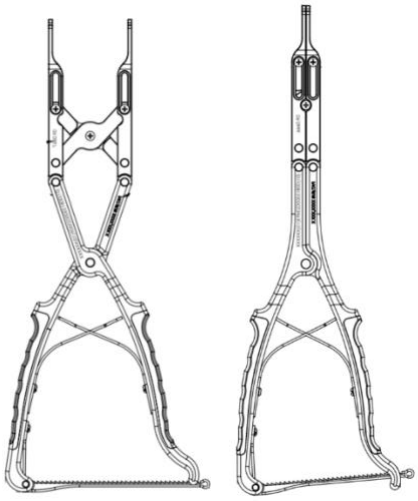
2.15 Final Set Screw Tightening

Assemble the Torque Limiting Adaptor to the Set Screw Final Tightening Shaft and Non-Ratcheting ¼" sq. Axial or T-Handle.

Place Counter Torque over tulip head. Insert Set Screw Final Tightening Shaft into Counter Torque until tip is fully Seated in Set Screw. Tighten Set Screw in a clockwise direction until Torque Limiting Adaptor clicks once. Repeat for all Set Screws.



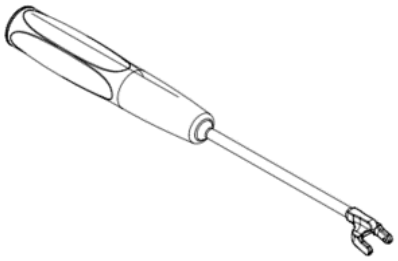
2.16 Compression & Distraction



Compression or Distraction may be performed at the surgeon's discretion.

Compression is accomplished using the Parallel Compressor. The compressor fits onto the rod on the outside of the tulip heads to be compressed. One of the Set Screws should be provisionally (not final) tightened. As the compressor handle is closed, the provisionally tightened screw is drawn toward the other accomplishing compression of the desired segment. Once desired compression has been achieved, the provisionally tightened set screw is further tightened using the Initial Set Screw Inserter while being held in place with the compressor. Once compressor is released, Set Screws must be final tightened as described in the previous step.

Distraction is accomplished using the Parallel Distractor. The distractor fits onto the rod on the inside of the tulip heads to be distracted. One of the Set Screws should be provisionally (not final) tightened. As the distractor handle is closed, the provisionally tightened screw is drawn away from the other accomplishing distraction of the desired segment. Once desired distraction has been achieved, the provisionally tightened set screw is further tightened using the Initial Set Screw Inserter while being held in place with the distractor. Once the distractor is released, Set Screws must be final tightened as described in the previous step.



2.17 Rod Rocker & Tower Reducer

If the Rod is slightly proud above the Screw Housing, then use the Rod Rocker or Tower Reducer to achieve the fully seated position of the Rod into the Screw Housing.

ROD ROCKER

Insert tips of Rod Rocker into holes along the sides of the tulip head of screw. Pivot handle downward levering Rod down into tulip head of screw. Insert Set Screw with the Initial Set Screw Inserter. Torque until hand-tight.

TOWER REDUCER:

Attachment:

Turn Tower Reducer knob counterclockwise until hard stop is reached to allow distal tips of the tower to be positioned outside of the reducer body. Press instrument straight down on the tulip head to splay the distal tips of the tower over the screw housing until they click into the side grooves.

Reduction:

Rotate the reducer knob clockwise. The outer sleeve of the tower will move downward to contact the rod and drive Rod down into housing. An optional Tower Reducer Adaptor (provided) can be attached to the top of the tower to assist with reducer knob rotation if additional leverage is desired. Continue to rotate reducer knob clockwise until a positive stop is felt indicating the Rod is now in the tulip head. Insert Set Screw into the screw housing (tulip) and provisionally tighten to secure the Rod.

Removal:
Turn reducer knob counterclockwise until hard stop is reached to allow distal tips of the tower to be positioned outside of the reducer body, then rotate the tower and pull upward to detach from the tulip head of the screw.

2.18 Multi-axial Transverse Connector Insertion (optional)

Select the desired Multi-axial Transverse Connector: Small 40-50mm, Medium 50-60mm, Large 60-70mm. The Multi-axial Transverse Connector is designed to translate and rotate about its longitudinal axis and pivot about its midpoint allowing it to fit most screw/rod constructs without the need for bending. The rods are placed on each side into the transverse connector adding significant stability-rigidity, particularly torsional stability to the construct, the Multi-Axial Transverse Connector is adjustable should the width / distance vary. Select the appropriate Multi-axial Transverse Connector. Check that the center set screw is loose to allow the Multi-axial Transverse Connector to pivot about its midpoint. Ensure that the clamping screws at each end are in the open (down) position. Place the clamps over each rod, tighten the clamping screws and finish by tightening the center set screw with the Cross bar driver.

2.19 Wound Closure

Wound closure is performed in the customary manner.

2.20 Revision/Removal

Implants may be explanted or revised. The original instrumentation set contains all imperative instruments to perform these procedures.
Remove Multi-axial Transverse Connectors with the Torque Limiting Cross Connector Driver.

All locking caps must first be removed. To remove Set Screws assemble the Set Screw Final Tightening Shaft to the Non-Ratcheting ¼" sq. Axial or T-Handle. DO NOT USE THE INITIAL SET SCREW INSERTER FOR SET SCREW REMOVAL. Place Counter Torque over tulip head. Insert Set Screw Final Tightening Shaft into Counter Torque until tip is fully Seated in Set Screw. Turn Set Screw in a counter-clockwise direction. Repeat for all Set Screws.

Using the Forcep Style Rod Holder, disengage the rod from the pedicle screws and remove.

To remove polyaxial screws, assemble Ratcheting Axial or T-Handle to the Polyaxial Screw Inserter. Set ratcheting wheel to counter-clockwise position. Re-attached inserter to screw to remove.

3 Important Information

3.1 Warnings

The warnings discussed within this manual do not include all possible adverse surgical events, but are inherent to metallic internal fixation devices of the spine. The surgeon is instructed to thoroughly explain the general surgical risks to the patient before surgical treatment is initiated. The safety and effectiveness for spinal pedicle screw systems has been established only for spinal conditions with spinal deformity or mechanical instability of the thoracic, lumbar, or sacral spine requiring spinal fusion and instrumentation. These spinal conditions also include those with, or the potential for significant mechanical instability including spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous attempted fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown. Modes of failure of these devices have been established. This device is not intended to be the sole mechanism of support of the spine. Without adjunctive biologic support for any spinal fixation and fusion condition for which it has been designed and used, the device cannot be expected to support the spine indefinitely and will fail in any number of proven modes. The potential for multiple risks associated with the use of this device that may require additional surgery have been documented and described including:

- Device component fracture
- Loss of fixation
- Fracture of the vertebra or pedicle
- Neurological injury
- Vascular or visceral injury

The STERILE SPINE Pedicle Screw System is intended to provide structural support and assist spinal fusion healing and is not intended to replace normal bony structures.

Multiple factors including patient size, weight, activity levels, and injuries will dictate implant longevity, especially during the biologic healing phase following implantation. If ultimate healing is delayed or does not occur, metal fatigue, and/or failure can occur. Adjunctive spinal immobilization during the biologic healing phase is to be maintained until there is clinical and radiographic evidence of healing.

Surgeons implanting The STERILE SPINE Pedicle Screw System must be thoroughly trained and knowledgeable with the surgical, medical, metallurgical and mechanical aspects of the system.

The patient bears responsibility with regards to following the surgeons' postoperative instructions and limitations, and should be warned that noncompliance with this aspect of their care could lead to implant breakage, loosening, migration, and the possibility of the necessity for revision surgery to alter or remove the implant.

All implanted devices are intended and designed to be single use only. Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those patients without previous spinal surgery.

3.2 Cautions

The contraindications for this system are similar to other systems with a similar design for spinal fixation.
Absolute Contraindications:

1. Infection or inflammation
2. Allergy to implant components (titanium alloy)
3. Morbid Obesity
4. Metal Sensitivity/foreign body sensitivity
5. Inadequate tissue coverage at the operative site
6. Open wounds exposing the local operative site

Relative Contraindications:

1. Fever
2. Pregnancy unless indicated for emergent spinal fixation (unstable fracture)
3. Signs of infection where implant may be implanted
4. Patient non-compliance or unable to follow post-operative instructions.
5. Any condition not specifically prescribed in the indications section.

Only experienced spinal surgeons with specific training in the use of the STERILE SPINE Pedicle Screw System should implant this system for lumbar fusion procedures. Spinal instrumentation using the STERILE SPINE Pedicle Screw System is a technically demanding procedure with potential risks of serious injury to the patient if not properly utilized.

1. **Surgical implants and may never be reused.** Small defects and internal stress patterns may be present with previously re-used implants and may lead to early breakage even though the device may appear undamaged.
2. Correct implant handling is of vital importance. Avoidance of any metallic notching, scratching, or reverse bending of the devices is imperative! Alterations will produce defects in surface finish in internal stresses that may become a focal point for eventual implant breakage. Do not use the implant if damage is suspected. Proper contouring of metallic implants with proper equipment is essential.
3. Bending the construct. Titanium alloy component should never be bent sharply or reverse bending applied. If a construct is over contoured please select a new construct for proper contouring rather than reverse bending or over contouring of the implant.
4. Implant removal after healing is recommended. Any number of complications can occur if the device is not removed after its intended use has been fulfilled.
    a. Corrosion with localized tissue reaction or pain.
    b. Implant migration resulting in injury.
    c. Risk of additional injury from postoperative injury or trauma.
    d. Loosening, bending or breakage, which could make implant removal impractical or significantly difficult.
    e. Local pain, discomfort, or abnormal sensation due to device presence.
    f. Possible increased risk of infection.
    g. Bone loss due to stress shielding. The surgeon must carefully weigh the risks versus benefits, when deciding whether to remove the implant and at what point in time implant removal should occur.
    h. Implant removal should be followed by adequate postoperative management to avoid re-fracture or deformity such as bracing. If the patient is older and has a low activity level, the surgeon may choose avoid implant removal thus eliminating the risks involved with secondary surgery.
5. Patient instruction is imperative following surgery. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful spinal fusion and bone healing. The patient should be informed about their procedure and implant limitations, strict limitation of physical activity, especially lifting and twisting during healing phases, as well as participation in any active sports during the healing phase. The patient should be instructed that the metallic implant is not as strong as normal healthy bone and could loosen, bend, or fail if excessive demands are placed on it, especially in the absence of complete bony healing. Active, debilitated, or psychology impaired patients who are not able to follow instructions or those who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation following spinal fusion. Failure to follow proper instructions and activity restrictions may lead to implant migration, damage to nerves, or blood vessels in addition to loss of bone fixation.

Possible adverse Effects:

1. Bending, fracture, loosening or migration of the implant.
2. Non-union (pseudarthrosis) or delayed union.
3. Metal sensitivity or foreign body reaction.
4. Decrease in bone density due to stress shielding.
5. Fracture of bony structures.
6. Pain, discomfort, or abnormal sensations due to presence of implant.
7. Nerve, soft tissue, or blood vessel damage due to surgical trauma.
8. Nerve root or spinal cord impingement or injury.9999
9. Dural leak
10. Bursitis
11. Necrosis of bone
12. Hemorrhage
13. Infections
14. Death

Only the included instrumentation and implants (manufactured with Ti-6Al-4V), specifically manufactured for the STERILE SPINE Pedicle Screw System, are to be utilized in the preparation and implantation of the spinal construct.

For product information, including indications, contraindications, warnings, precautions, and potential adverse effects, visit WishBone Medical's Instructions for Use page online at www.WishBoneMedical.com/IFU.

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