Degenerative Spondylolisthesis
CONTENTS

Preface ................................................................. 2

Implants ........................................................................ 3

Instruments .................................................................... 4

Preliminary Steps
Radiological Study .......................................................... 6
Preoperative Planning ..................................................... 8
Patient Positioning/Anesthesia ....................................... 9
Surgical Approach ....................................................... 10

Surgical Technique Steps
Identification of The Pedicles .......................................... 11
Preparation of The Pedicle Canal ..................................... 12
Tapping The Pedicles .................................................... 13
Determining Screw Length/Screw Insertion ....................... 14
TSRH Variable Angle Screw Insertion .............................. 15
Developing The Fusion Bed ............................................ 16
Construct Assembly:
Spondylolisthesis at L5-S1 ........................................... 17
Rod Selection, Cutting, Bending ..................................... 18
Construct Assembly .................................................... 19
Low Profile CROSSLINK® Plate Assembly ....................... 24
Postoperative Care and Mobilization .............................. 26
Dear Fellow Surgeon:

Historically, severe disability from major deformity of degenerative spondylolisthesis has presented a major challenge for the surgeon and difficult courses of treatment for the patient. The aims have been to obtain solid arthrodesis and where possible to effect reduction to at least improve the “slip angle”, so that the mobile spine above has a more normal angle of support in relation to the horizontal. Attempts at closed reduction have been difficult, relatively unsuccessful and disabling. Prolonged immobilization has been up to 3 months on a Stryker frame or in a plaster bed to allow successful maturation of the fusion mass. In an effort to allow some degree of mobilization while fusion occurred, plaster body casts of the hip spica type were used and finally braces including the thigh. Despite the magnitude of these treatments for the patient, there was still an unfortunately high rate of failure.

The use of internal fixation with pedicle screws has provided an excellent internal splint to stabilize the spine, dramatically improving the fusion rate and at the same time offering a reasonable degree of effective reduction with improvement of the “slip angle”.

The TSRH Pedicle Screw Spinal System provides the opportunity of effectively immobilizing the spine along with a reasonable degree of correction and at the same time allowing the most important part of the operation to be carried out, namely a very effective, meticulous spinal fusion with ample autogenous bone.

The TSRH Pedicle Screw Spinal System allows the application of bone graft to the spine. It allows easy contouring of the fixation system to improve and maintain the patient’s spinal alignment.

TSRH Variable Angle T-bolts now allow easier insertion of the rods if the pedicle screws are not in perfect alignment, decreasing operative time and increasing the ease of the operation.

The system allows fulfillment of the aims of the operative procedure, namely to provide effective immobilization of the involved segments while fusion occurs and to provide reasonable reduction where indicated.

Sincerely,

Edward H. Simmons, MD

Edward D. Simmons, Jr. MD
IMPLANTS

TSRH® PEDIACLE SCREW
SPINAL SYSTEM IMPLANTS

Available in Stainless Steel or Titanium, 5.5mm and 6.35mm (1/4") Rod Diameters

Rod
Actual Length: 20"

Variable Angle T-Bolt
Small

Variable Angle T-Bolt
Medium

Variable Angle T-Bolt
Large

Double Hex Locking Screw

Standard Break Lock Screw

Flush Break Lock Screw

WARNING: Do not intermix Stainless Steel with Titanium

TSRH CROSSLINK® SYSTEM IMPLANTS

Plate

Locknut

Eyebolt

CROSSLINK Plate

CROSSLINK Multi-Span Plate

CROSSLINK Offset Plate

LOW PROFILE CROSSLINK® SYSTEM IMPLANTS
TSRH® PEDICLE SCREW
SPINAL SYSTEM INSTRUMENTS

- Pedicle Probe
- Straight Holt Probe
- Round Holt Probe
- Screw Gauge
- QC Ratcheting Handle
- Fixed QC Egg Handle
- Dual Screw Driver Shaft
- QC Cannulated Tap
- QC Awl Shaft
- Rod Template
- T-Bolt Positioner
- Positioning Clip
- French Rod Bender
- Offset Mini-Corkscrew
- Central Post Hook Holder
TSRH® PEDICLE SCREW
SPINAL SYSTEM INSTRUMENTS

NOTE: For a complete listing of sizes and catalog numbers for the TSRH Pedicle Screw Spinal System implants and instruments, please refer to the Medtronic Sofamor Danek Product Catalog.
Comprehensive radiological studies, including plain radiographs (A/P and lateral standing), CT and MRI scans, are essential to determine the existence and extent of neural compression subsequent to severe cases of spondylolisthesis (grades 3 & 4) at L5-S1.

In addition flexion and extension lateral radiographs can indicate the degree of mobility of the listhesis, indicating the least amount of reduction that may be readily obtained and maintained with the instrumentation.

CT scan or MRI scan evaluations have proven to be a very effective diagnostic and preoperative planning tool.
STEP 1

MRI: Lateral Recess Stenosis

CT Scan: Area of Spondylolysis

Postoperative A/P Radiograph

Postoperative Lateral Radiograph
Preoperative Planning

The necessary lordotic alignment can be determined through careful review and analysis of the lateral standing plain film. The appropriate TSRH Variable Angle Pedicle Screw can also be determined at this time.

CT scans (axial images) can be used preoperatively to measure the diameter of the pedicles and select the appropriate length and diameter of the pedicle screws to be implanted (Fig. 1). The width of the pedicle is measured at its isthmus. Two measurements are taken: (a) medial cortical wall to lateral cortical wall, and (b) medial to lateral endosteal cortical diameter.

The medial angle of the pedicles should also be assessed as a guide to screw placement.

The appropriate screw diameter is one that completely fills the endosteal cortical canal of the pedicle. The screw length should extend 50-80% into the vertebral body. For L5, the most common TSRH Pedicle Screw used is a 6.5mm diameter by 45mm length.

NOTE: Remember to account for the Xray, CT or MRI magnification factor when taking these measurements.
Patient Positioning / Anesthesia

The patient is positioned on the operating table in the prone position (Fig. 2). A spine surgery frame should be used which will avoid any pressure on the abdomen, thereby avoiding vena caval compression. Hypotensive anesthesia, autotransfusion and a cell-saver may also be used to reduce intraoperative blood loss. Radiographic guidance and control, either fluoroscopic with image intensifier or quality Xrays are used intraoperatively. Prior to skin prep and draping, the patient’s position may be checked radiographically (C-arm or Xray) to determine the axial direction of the pedicles to the horizontal.
Surgical Approach

The surgical approach is carried out through a standard midline incision to the spinal column over the anatomic position of the spinous processes. The incision should be long enough to ensure exposure of L3 through S1. Initially, the positions of the spinous processes are identified through palpation and the lumbar facia is incised on the sides of each of the spinous process. The supraspinous and interspinous ligaments should be preserved particularly above the area of instrumentation, as these are important posterior stabilizers.

Meticulous sub-periosteal exposure of the posterior elements is performed. The paraspinal musculature is detached to the outer margins of the transverse processes.

When indicated, soft tissue and bony decompression is performed to relieve neurological compression. The capsule and articular cartilage of the facet joints to be included in the fusion are excised. When necessary, decompressive laminectomies are performed to correct any stenosis in the central canal along with lateral recess and neural foraminal decompressions.

Decompression can now be carried out as needed.
Identification of the Pedicles

The entrance to the intramedullary canal of the pedicle is located at the point where the middle of the transverse process, superior facet and pars interarticularis converge (Fig. 3).

The entrance to the S1 pedicle is caudal and just slightly lateral to the superior articular process.

The pedicle canals of L4, L5 and S1 are entered with a power burr or rongeur at the junction of the facet and transverse process (Fig. 4).

With the use of radiographic guidance, the pedicle is probed with a blunt pedicle probe (823-365) orienting inwards according to the pre-operative imaging studies. Proper cranio-caudad orientation is also important and is assisted by the pre-operative standing lateral and intraoperative lateral radiographs. The probe should have good contact with the bone at all times within the pedicle. A 5\(^*\) x 1mm diameter K-wire (803-043) can be inserted into the canal prepared in the pedicle and the positions checked radiographically with AP and lateral Xrays or image intensifier views.

**NOTE:** The K-wire is correctly positioned in the center of the pedicle canal when, in an A/P view, only the diameter of the wire is seen and the pedicle canal completely surrounds the image of the wire.
Preparation of the Pedicle Canal

The preparation of the pedicle canal requires that attention be given to three key aspects (Fig. 5):

1. Instruments should not be allowed to penetrate the walls of the pedicle. Such penetration can cause damage to neural and vascular structures.

2. The angle of entry to the pedicle canal should be considered in relation to the position of superiorly placed screws and the individual anatomy.

3. The anterior cortex of the vertebral body should not be violated.

As each K-wire is removed, an awl (836.022) is used to open the proximal pedicle canal. A pedicle probe is then used to deepen the hole to the desired length. As the pedicle probe is gently worked down the pedicle canal, the surgeon should feel the sensation of the soft cancellous bone (Fig. 6). If resistance is felt during this process, the position should be checked radiographically. A change in the feel of the probe, i.e., resistance or change in bone density, is a warning that caution should be exercised.
Tapping the Pedicles

Tapping of the pedicles is usually not required, however, in patients with hard bone and relatively “narrow” pedicles, tapping is recommended and will make subsequent screw insertion easier.

It is not necessary to tap more than a partial length of the pedicle as this will provide enough of a prepared track for the screw to follow.

**NOTE:** Two hand control of pedicle instruments, including the probe, tap and screwdriver, is essential at all times for the surgeon to have control of direction and force.

Taps correspond with their respective screw diameter. TSRH Pedicle Screws come in 5.5mm, 6.5mm and 7.5mm diameters in lengths ranging from 25mm to 75mm. Each diameter has a corresponding tap (5.5mm 8231330, 6.5mm 8231331, 7.5mm 8231333).

The tap is inserted into a ratcheting (836-011) or non-ratcheting (836-012) handle. The pedicle is then tapped (Fig. 7).

After tapping, curved (803-291) and straight ball tip (803-292) Holt probes may be used to follow the tap threads and check for violation of the pedicle walls. (Fig. 8).
Determining Screw Length / Screw Insertion

Once the pedicle has been tapped and the walls checked with probes, the straight ball tip probe, calibrated at 10mm intervals (Fig. 9), may be used to determine screw length.

NOTE: For maximum construct biomechanical strength, the screw length selected should allow the screw to be inserted 50-80% into the vertebral body.
TSRH Variable ANGLE Screw Insertion

With the pedicle canals prepared and the screw length determined, the TSRH Variable Angle Screws are sequentially inserted from S1 to L4, bilaterally, using the TSRH Universal Screwdriver shaft/ratcheting handle assembly (8081533, 836.011).

The Variable Angle Screws are inserted into the pedicle until all of the threads are engaged. A tapered thread run out and tapered root diameter provide maximum resistance to fatigue at the bone-screw interface just below the Variable Angle Screw posts. When fully inserted, the screws should extend 50-80% into the vertebral body and be parallel to the vertebral body end plate. The splined face of the Variable Angle Screw should be directed medially. (Fig. 10)
Developing the Fusion Bed

The transverse processes, lateral gutter and sacral alae are carefully dissected free of all covering periosteal tissues and are decorticated. Removal of facet joint articular surfaces and decortication of the pars, facet wall and laminae is also carried out. Meticulous development of the fusion bed enhances the potential for achieving solid fusion.

Cortico-cancellous bone graft obtained from the iliac crest along with any fragments of bone taken during decompression (i.e. laminae, spinous process) are firmly pressed onto the bone fusion bed. The iliac crest bone graft is taken through the same incision by raising a flap along the dorso-lumbar facia to the rim of the iliac crest and then carrying out sub-periosteal exposure of the outer table of the crest, or by making a trap-door into the posterior margin of the crest.
Construct Assembly: Spondylolisthesis at L5-S1

When necessary, decompression laminectomies are performed to correct any stenosis in the central canal, lateral recess and neural foramina. After decompression, the bone graft is applied and the TSRH Pedicle Screw System can be used to accomplish both reduction of the pre-existing deformities and rigid fixation.

Variable Angle Screws of the appropriate length and diameter are inserted into the pedicles of S1, L5 and L4 (Fig. 11).
Rod Selection, Cutting AND Bending

Rods are available in 5.5mm and 6.35mm (1/4”) diameters. The rods can be selected according to their degree of rigidity: Rigid, Flex and Super Flex.

Once the appropriate rod is selected, a rod template may be used to determine the rod length and contour needed for construct assembly (Fig.12). A sterile marking pen may be used to mark the rod at the point to be cut. The table top rod cutter (808-527) is used to cut the rods to the appropriate length outside the operative field.

The cut sections of rod may now be bent into lordosis using "French Benders" (808-530) (Fig. 13). The amount of lordosis bent into the rod is based on the amount of reduction to be performed or if the patient is being fused in-situ.
Construct Assembly

Prior to inserting the rods, the lordotic alignment of the spine should be checked with the intraoperative lateral X-ray or image view and compared to the preoperative lateral standing view. Maintenance of lordosis over the instrumented levels is very important. Extension of the hips can be carried out with an adjustable table to increase lordosis as needed.

Due to the differences in the angle of the pedicles as measured from the midline (spinous processes), screw alignment as viewed posteriorly may be off-line (Fig. 14). Traditional fixation methods required lateral bending of rods to compensate for this; however, the TSRH Pedicle Screw System incorporates offset Variable Angle T-Bolts that compensate for lateral placement of pedicle screws.

Top Tightening Variable Angle T-Bolts, in three sizes (small, medium and large), come in 5.5mm and 6.35mm diameters, stainless steel and titanium, to correspond with the use of 5.5mm and 6.35mm rods in either material. The small, medium and large offset washers are incorporated to interface with laterally placed screws (Fig. 15). Small Variable Angle T-Bolts provide 3mm of lateral offset, medium Variable Angle T-Bolts provide 6mm lateral offset and large Variable Angle T-Bolts provide 9mm of lateral offset.
Radial splines allow the Variable T-Bolt and the Variable Angle Screw to interface in six degree increments. This variable angle interface combined with the lateral offset washers allows for anatomic placement of pedicle screws with minimal rod contouring (Fig. 16). This will also minimize any forced pre-loading or stressing of the screw rod interface.

After the degree of offset between the pedicle screws has been analyzed, the Variable Angle T-Bolts with appropriate diameter and washer width are selected. These can be loaded on the rod and held in place with “Positioning Clips” (845-188 for 5.5mm diameter rods or 808-188 for 6.35mm diameter rods). The Positioning Clips prevent the Variable Angle T-Bolts from spinning around on the rod as well as sliding off the rod during insertion (Fig. 17). Remove the clip prior to wound closure.

Bone graft for the L5-S1 fusion is now inserted just prior to rod insertion. It is extremely important to have proper localization and packing of the bone graft into the decorticated “fusion bed”. It is easier to accomplish this before inserting the rods.
After all T-Bolts have been selected and loaded in their appropriate location on the two rods, each rod assembly is lowered into the wound sequentially and the Variable Angle T-Bolt/Variable Angle Screw interface is facilitated manually or with the assistance of a T-Bolt Positioner (808-545) (Fig. 18).

Once the rod is in place, it is essential that each Variable Angle Washer be flush with the top of each Variable Angle Screw. If they are not flush the rod may be removed and more lordosis bent into the rod.
If the distance between the Variable Angle T-Bolt and Variable Angle Screw is minimal or if spondylolisthesis reduction is desired, a Mini-Corkscrew (808-543) may be used to facilitate alignment of the Variable Angle T-Bolt/Variable Angle Screw interface by:

1) placing a Hook/Screw Holder (808-180) on the Variable Angle Screw (Fig. 19a)

2) placing the Mini Corkscrew foot onto the rod over the Variable Angle T-Bolt (Fig. 19b),

3) spinning the Mini Corkscrew hook in the appropriate direction until it contacts the ratcheting lock of the Hook/Screw Holder (Fig. 19c),

4) once the Mini Corkscrew is in place, turning the T-handle clockwise to push the Variable Angle T-Bolt into the posts of the Variable Angle Screw, achieving a perfect interface (Fig. 19c).
Once all the Variable Angle T-Bolts are flush with the tops of the Variable Angle Screws, each T-Bolt is provisionally tightened using the 7/32" Socket Driver (836.023). Review the final construct. Final tightening to 80-120 inch-pounds is achieved using the T-Handle Wrench, Counter Torque Wrench (808-546) and Deflection Beam Torque Wrench (836.050).

NOTE: If Flush Break Lock Screws (845-066 for 5.5mm rods, Stainless Steel; 855-066 for 5.5mm rods, Titanium; 808-145 for 6.35mm rods, Stainless Steel or 828-145 for 6.35mm rods, Titanium), or Double Hex Head Lock Screws (808.105 for 5.5mm rods, Stainless Steel; 828.105 for 5.5mm rods, Titanium; 808.105 for 6.35mm rods, Stainless Steel; or 828.105 for 6.35mm rods, Titanium) are used in the construct, the Deflection Beam Torque Wrench is not required. Final torque is reached when the top of the Flush Break Lock Screws have sheared off.
Decortication, if delayed, and bone grafting can now take place.

A Low Profile CROSSLINK® Plate or Low Profile CROSSLINK Multi-Span™ Plate may now be applied.

The appropriate size Low Profile CROSSLINK Plate or Low Profile CROSSLINK Multi-Span Plate is determined with the measuring template (Fig. 20). Rods may be spread or compressed as necessary to facilitate insertion of the plate.

With the use of the Plate Holder (810-510), the appropriate Low Profile CROSSLINK Plate or Low Profile CROSSLINK Multi-Span Plate is selected and pressed down onto the rods (Fig. 21).

Plate benders should be used to contour the Low Profile CROSSLINK Plates or the CROSSLINK Multi-Span Plates. When bending the Low Profile CROSSLINK and Multi-Span Plates, do not exceed 20° in any single plane.

The set screws are advanced using the screwdriver to a torque of approximately 60 in-lbs., alternating tightening from side to side to ensure uniform closure (if using a CROSSLINK Multi-Span Plate, the midline screw is tightened after the set screws are secured). Two screwdrivers may be used simultaneously to advance the set screws for uniform closure.
If it is necessary to contour the Low Profile CROSSLINK Multi-Span Plate, follow these steps:

- Shorten the telescopic mechanism slightly less than the span between the rods and provisionally tighten the midline set screw.

- Bend the plate as required using the plate benders. However, do not exceed 20° in any single plane.

- Loosen the midline set screw and apply the CROSSLINK Plate as stated above.

Wound closure is then performed in the customary manner.
Patients must be warned to avoid physical activities that would place excessive stress upon the implant or bone graft, which could delay or prevent healing. However, regular graduated mild to moderate activity is beneficial to bone formation particularly when the vertebrae have been adequately stabilized internally. Patients should use adequate external support until bony fusion has been established. They should be instructed in the proper methods of getting in and out of bed, from a sitting position, etc.

Please see the package insert for Warnings, Precautions and Possible Adverse Events.
The TSRH® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

**DESCRIPTION:**

The TSRH® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, and connecting components. In addition, CDLP® rods, DYNALOK PLUS™ bolts, CD KHORIZON® Low Profile MULTI-SPIKE® CROSSLINK Plates, CD LH® locked connectors, CD VARIO Flange Bolts, and CD LH® and CD KHORIZON® set screws and locking screws may be used with the TSRH® Spinal System.

The TSRH® Spinal System implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The hooks are intended for posterior use only and the staples are for anterior use only. The TSRH® and CD KHORIZON® screws are intended for posterior use only.

All CROSSLINK® Plates are for posterior use and the CROSSLINK Avial and Offset Plates may be used anteriorly as well.

The TSRH® Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ISO 5822-1. Alternatively, the entire system may be made out of medical grade titanium alloy described by such standards as ASTM F136 or ISO 5822-3. Never use stainless steel and titanium implant components in the same construct.

MEDITRONIC STERI PLUS® expressly warrants that these devices are fabricated from one or more of the foregoing materials. No other warranties, express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

To achieve best results, do not use any of the TSRH® Spinal System implant components from any other system, except those components listed above, or any other manufacture. As with all orthopaedic and neurological implants, none of the TSRH® Spinal System components should ever be reused under any circumstances.

**INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:**

**INDICATIONS:**

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the TSRH® Spinal System is indicated for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral column, (2) having spinal deformity of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies, (3) spondylolisthesis, (4) fracture, (5) dislocation, (6) scoliosis, (7) kyphosis, (8) spinal tumor, and/or (9) failed previous fusion (pseudarthrosis).

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (2) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

**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. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis, Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
10. Suspected or documented metal allergy or intolerance.
11. Any case not needing a bone graft and fusion.
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
13. Any case that requires the mixing of metals from two different components or systems.
14. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
15. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
16. Any patient unwilling to follow postoperative instructions.

**POSSIBLE 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, necrosis, 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), dysphasia, hypotension, anesthesia, paresthesia, appearance of radiopaque swelling, and/or the development or continuation of pain, numbness, paraesthesia, sensory loss, tingling sensation, and/or visual deficits.
9. 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 the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, or below the level of surgery. Retropulsed graft.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
15. Osteomyelitis or other potential growth of the operated portion of the spine.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stress shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Iliac, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound infection, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

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

**WARNING AND PRECAUTIONS:**

**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/or failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown.

**PRECAUTION:** The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal 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 existing 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 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.

**PHYSICIAN NOTE:** Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

**CAUTION:** For maximum strength, whenever possible, use a continuous rod instead of connecting two rods in a series with a connector.

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

**FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.**

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

**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 can cause metal fatigue and component 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.

**PROPRIETARY:**

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant component. 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 TSPH Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer. Different metallic types should never be used together.

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. This admonition is especially true when inserting hooks and screws. 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 reversed bent in the same location. Use great care to ensure 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, pre-cut rods of the length needed.

4. Do not use the TSPH hook trials in any type of pyrexing action. The trial may bend or break, especially at the tip. Also, the trial or other nearby hardware may suddenly change position, possibly causing damage or injury.

5. Whenever possible or necessary, an imaging system should be used to facilitate surgery.

6. To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Do not overlap or use a screw/stock that is either too long or too large. Overlapping or using an incorrectly sized screw/bolt may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screwed bolts are inserted into spinal pedicles, use a large screw/stock 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. To assure maximum stability, two or more CROSSLINK® plates on two bilaterally placed, continuous rods should be used whenever possible.

BONE CEMENT:

9. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

10. Before closing the soft tissue, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a break-off feature. 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 or 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 cause a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation system 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-steroidal 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 non-union persists or if the component loosens, bent, and/or breaks, 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 TSPH Spinal System 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 since 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 local 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 may cause 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 TSPH Spinal System components should never be reused under any circumstances.

PACKAGING:

Packages for each of the components should be intact upon receipt. 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 MEDTRONIC-SOFAMOR DANEK.

CLEANING AND DECONTAMINATION:

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Cleaning and disinfecting of instruments can be performed with alkali-aldehyde-free solvents at higher temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deodorized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkali-alkaline cleansers may damage some devices, particularly instruments; these solutions should not be used. Additionally, certain instruments may require dismantling before cleaning.

STERILIZATION:

Unlike marked sterile and clearly labeled as such, the TSPH Spinal System components, as well as those implants from other MEDTRONIC SOFAMOR DANEK spinal systems specifically indicated for use with the TSPH Spinal System, described in this insert are provided non-sterile and must be sterilized prior to use. If the product described in this document is sterilized by the hospital in a tray or case, it should be sterilized in a tray or case provided by Medtronic Sofamor Danek, if available. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

NOTE: The following note applies to the process parameter identified with the * below. For use of this product and instruments outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

<table>
<thead>
<tr>
<th>METHOD</th>
<th>CYCLE</th>
<th>TEMPERATURE</th>
<th>EXPOSURE TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>250°F (121°C)</td>
<td>30 Minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>275°F (135°C)</td>
<td>20 Minutes*</td>
</tr>
<tr>
<td>Steam Pre-Vacuum</td>
<td>270°F (132°C)</td>
<td>4 Minutes</td>
<td>4 Minutes</td>
</tr>
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Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or (if applicable) returning to MEDTRONIC SOFAMOR DANEK.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK at the addresses below. Further, if any of the implanted TSPH Spinal System component(s) ever "malfunctions" (i.e., does not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so), the distributor should be notified immediately. If any MEDTRONIC SOFAMOR DANEK product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

FURTHER INFORMATION:

If further directions for use of this system are needed, please check with MEDTRONIC SOFAMOR DANEK Customer Services. If further information is needed or required, please contact:

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