as described by:

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Six Degrees of Freedom to Connect From ANY Direction, Angle and Height.

INNOVATION THAT ENDURES
Dear Fellow Colleagues,

For the correction of spinal deformities of the lumbar spine, pedicle screws have made a unique contribution towards achieving good clinical results. These positive results have enabled the reclassification of bone screws for use in the pedicles of the sacral, lumbar and thoracic spine (see package insert at the end of this technique for labeling limitations, warnings and indications).

The TSRH® Variable Angle Screws and T-Bolts have become the gold standard by which other systems are compared. The system's ability to conform to the appropriate range of correction in the sagittal and coronal planes has made it the most popular screw system on the market today.

From the pioneering efforts of the TSRH Variable Angle Screws and T-Bolts came the next real advancement in pedicle screw systems: the TSRH-3D™ Spinal Instrumentation. This system offered the next level of deformity correction by allowing a new dimension of dorsal adjustability.

This unique connector design combined medio-lateral and sagittal variability with the ability to adjust the connector’s position dorsally along the smooth shank of the bone screw intraoperatively. With the TSRH-3D Connector, all planes of angulation and placement were addressed; the connector allows for six degrees of freedom for attachment to the pedicle screw (Figure 1).

Now comes the new, low profile TSRH-3D components. Newly designed, this system offers the same features and benefits as the original TSRH-3D; however, the connectors have been significantly reduced in volume, while maintaining the same biomechanical strength. This, along with several other features, such as the addition of a 90˚ Offset connector for facet preservation, pre-cut contoured rods, additional screw sizes and improved instrumentation have made the TSRH-3D System an integral part of spinal surgery.

The following monograph introduces the new TSRH-3D Instrumentation, along with some ideas to maximize procedural efficiency and results.

Sincerely,

J. Kenneth Burkus, M.D.

Figure 1
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**TSRH-3D Connectors:** These reduced volume, ultra-low profile titanium connectors are designed to maximize graft volume while making substantial reductions in operative times. The TSRH-3D connectors allow screw connections from any direction, any angle and any height; this reduces rod contouring; eliminates the need for washers or spacers; and allows for in situ adjustments and anatomical manipulations. With no in situ threading required, the TSRH-3D Spinal Instrumentation further decreases O.R. time by allowing the construct to be pre-assembled while the surgeon places the TSRH-3D screws. The result is a spinal construct with unparalleled simplicity, strength and reduction in size.

These connectors are used with all TSRH-3D screws on 5.5mm or 6.35mm rods.

**Medial-Lateral Offsets:** Available in Small, Medium and Large, these connectors accommodate a variety of screw placements and provide additional options for optimal use in varying patient anatomy.

**90˚ Offset Connectors:** These connectors preserve the superior facet and reduce the overall profile of the construct, thereby improving patient comfort. The offset connector can be used at any level where indicated.

**TSRH-3D Pedicle Screws:** This “Zero Footprint” design maximizes visualization, decortication and graft volume. It also minimizes rod contouring as the TSRH-3D connector secures anywhere along the 26mm smooth shank of the standard screw allowing true in situ dorsal adjustments. The non-aggressive cancellous self-tapping flutes facilitates insertion of the screw.

These titanium screws are offered in 5.5mm, 6.5mm, 7.5mm and 8.5mm diameters and lengths from 20mm to 60mm to accommodate a multitude of patient anatomies.

**Pre-Cut Contoured Rods:** These rods decrease O.R. time by eliminating two steps from most surgeries; rod cutting and rod bending. These rods can accommodate all single level cases and nearly all two level cases. Pre-contoured rods also minimize notch sensitivity, which is inherent in titanium rods.

These 5.5mm and 6.35mm titanium rods are color-coded for easy identification and come in 1cm increments from 3cm to 10cm.
INSTRUMENTS

ROD TEMPLATE (808-572)

ROD GRIPPER (VICE) (815-905)

ROD GRIPPER (RATCHETING)
Available for 5.5mm (820-555) and 6.35mm Rods (808-524)

FRENCH BENDER (808-530)

COMPRESSOR (94632)

DISTRACTOR (94633)

(OPTIONAL)

LEFT RINGED DISTRACTOR (836-990)

RIGHT RINGED DISTRACTOR (836-991)

LOW PROFILE CROSSTALK® PLATES

INSTRUMENTS AND IMPLANTS

HEX HEAD SCREWdriver,
3.5mm (803-900)

PLATE TEMPLATE (810-501)

PLATE HOLDER (810-510)

PLATE BENDERS (810-525)

CROSSTALK® PLATE

CROSSTALK® OFFSET PLATE

CROSSTALK® MULTI-SPAN™ PLATE
The necessary lordotic alignment can be determined through careful review and analysis of the lateral standing plain film. The appropriate TSRH-3D™ Pedicle Screw length can also be estimated at this time.

Axial images (CAT scan or MRI) across the vertebral bodies at the level of the pedicle are used preoperatively to assess the medial angle of the pedicle as a guide to screw placement. The entry angle through the pedicle (A) will determine the starting point and the length of the screw (Figure 2).

The diameter of the pedicles is also detailed on the axial scans. The selection of the appropriate length and diameter of the pedicle screws to be implanted can be determined on these preoperative studies. The width of the pedicle is measured at its isthmus. Two measurements are taken: (B) medial cortical wall to lateral cortical wall, and (C) medial to lateral endosteal cortical diameter (Figure 3).

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, when viewed from a lateral x-ray. For L5, the most common TSRH-3D Pedicle Screw used is a 6.5mm diameter by 40mm length.
PATIENT POSITIONING AND ANESTHESIA

The patient is positioned on the operating table in the prone position. A spine surgery frame should be used which will avoid any pressure on the abdomen, thereby avoiding vena caval compression.

The knee-chest position can be utilized; however, this position flexes the hip and reduces lumbosacral lordosis (*Figure 4*). Care must be taken to study preoperative standing lateral radiographs to ensure that normal lumbar lordosis is restored prior to completing the spinal instrumentation.

Placing the patient on a frame with the hips extended will increase lumbar lordosis (*Figure 5*). Positioning the lumbar spine in extension encourages shingling or overlapping of the facet joints. This narrows the neuroforamina and may increase the difficulty of decompression in this area.

*Figure 4*

*Figure 5*
Positioning the lumbar spine in extension may also lead to crowding of the implants at the lumbosacral junction and crossing of the pedicle screw posts inserted into L5 and S1. Inserting the S1 screw in a cephalad trajectory (A) through the large S1 pedicle toward the superior portion of the sacral endplate can eliminate this problem (Figure 6).

Hypotensive anesthesia, autotransfusion and a cellsaver may also be used to reduce intraoperative blood loss. Radiographic guidance and control, either fluoroscopic with image intensifier or quality x-rays, are used intraoperatively. Prior to skin preparation and draping, the patient’s position may be checked radiographically (c-arm or x-ray) to determine the axial direction of the pedicle relative to the horizontal.
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 the levels to be fused. Initially, the positions of the spinous processes are identified through palpation and the lumbar fascia is incised on the sides of each of the spinous processes. The supraspinous and interspinous ligaments should be preserved, particularly above the area of instrumentation, as these are important posterior stabilizers.

Meticulous subperiosteal 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 are 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 dorsal entry point to the medullary canal of the lumbar pedicle is located at the convergent point of three distinct anatomic structures. The middle of the transverse process, the superior facet and the pars interarticularis converge over the dorsal portion of the pedicle (Figure 7). This starting point can also be identified at the intersection of two lines drawn through the middle of the transverse process and the lateral border of the superior articular facet (Figure 8). A burr or ronguer may be used to clear away the hard cortical bone at the junction of the facet and transverse process, thereby exposing the cancellous portion of the pedicle (Figure 9).

The starting point in the sacral pedicles is significantly different due to the lack of transverse processes and the presence of the sacral ala. The size and configuration of the S1 pedicle allow the surgeon more flexibility in positioning the screw within the sacrum. The entrance point to the S1 pedicle is caudal and slightly lateral to the superior articular process. The entry point should be in the most caudal portion of the pedicle.
PREPARATION OF THE PEDICLE CANAL

The central cancellous portion of bone is easily identified in this area. An awl can be used to establish an opening to the pedicle at this site (Figure 10). The use of a pedicle marker can then be used in conjunction with fluoroscopy to ensure the identification of the pedicle.

Having identified the dorsal opening of the pedicle, proper preparation of the pedicle canal requires attention to three key points:

1. Instruments should not be allowed to penetrate the walls of the pedicle. Perforation of the pedicle can cause injury to adjacent neural and vascular structures.

2. The entry angle through the pedicle and into the vertebral body should be varied according to anatomical variation. Superiorly placed screws should be positioned away from unfused facet joints.

3. The anterior cortex of the vertebral body should be violated with great caution and only in cases where additional purchase is necessary.

A blunt probe is inserted through the pedicle and into the vertebral body (Figure 11). The probe should contact bone at all times. The probe should pass through the pedicle without excessive force. As the pedicle probe is gently worked down the pedicle canal, the surgeon should feel the sensation of creating a channel through soft cancellous bone. If resistance is felt during this process, the entry position and entry angle should be re-evaluated. If resistance or change in bone density continues during the opening of the pedicle, a radiographic marker can be placed and its position within the pedicle confirmed.
The sagittal plane inclination of the probe should be parallel to the adjacent vertebral endplate (A) (Figure 12). At the most cephalad vertebrae included in the construct, the starting point should be at the caudal portion of the pedicle and the probe should be angled in a cephalad direction (B) (Figure 12). This maneuver will place the pedicle screw entry hole below and away from the unfused superior facet joint.

Similarly, the S1 sacral entry point should be placed at the caudal portion of the large S1 pedicle. From this starting point on the facet, the probe is angled medially by approximately 25 to 30 degrees and angled cephalad so as to direct the probe tip toward the sacral endplate (C) (Figure 13). The caudal entry point and the cephalad angulation of the probe will ensure that the S1 screw will not interfere with the placement of the adjacent L5 screw.

Note: Because the target zone for L5 is smaller than the target zone for S1, the surgeon should place the L5 screw first. This allows the surgeon to evaluate the probes trajectory at S1 to minimize the potential for the S1 screw to cross at L5. The surgeon can then redirect the S1 screw before committing to the screw path, and ensure proper screw placement at S1 (see Figure 31a and 31b).
Having opened the channel of the pedicle, all four walls of the pedicle can be palpated with a curved ball-tipped probe to ensure that the walls of the pedicle have not been violated. A straight ball-tipped probe calibrated at 10mm intervals can then be inserted into the vertebral body and the length of the pedicle and vertebral body measured to determine appropriate screw length (Figure 14).

Utilization of an image-guided system, such as the StealthStation® Treatment Guidance Platform, may be used to ensure the pedicle is prepared at the appropriate starting point, and to maintain precise angulation during pedicle screw placement. Screw lengths can also be determined by preoperatively planning on a system such as the StealthStation System.

A radiographic marker is placed through the pedicle and into the vertebral body, and its position within the confines of the pedicle is confirmed with plain radiographs or fluoroscopy. The appropriate length of the screw can also be confirmed on lateral radiographs by referring to the marker.

If the situation arises where you can choose between two lengths of screws, choose a shorter screw. The unique feature of the TSRH-3D pedicle screw allows for in situ dorsal adjustment of the connector and rod construct.

Figure 14
The TSRH-3D™ pedicle screws have a self-tapping flute and do not require tapping. They may be inserted following the preparation and probing of the pedicle. If tapping is preferred, the TSRH-3D Spinal Instrumentation offers four taps (4.5mm, 5.5mm, 6.5mm and 7.5mm) which correspond to the screw diameters.

The appropriate diameter tap is inserted through the pedicle and into the vertebral body (Figure 15).

Following this final preparation of the pedicle, a probe can be used to follow the tap threads through the cancellous bone and palpate for any perforations in the pedicle walls (Figure 16).
With the pedicle canals prepared and the screw length determined, the TSRH-3D screws are sequentially inserted using the 3.2mm Screwdriver Shaft with Sleeve and Ratcheting Handle Assembly. The post of the screw is attached to the hex end of the 3.2mm Screwdriver Shaft (Figure 17a). The screw is held to the screwdriver shaft by advancing the screwdriver sleeve over the screw until the shaded area on the proximal end of the screw is fully covered (Figure 17b).

When fully inserted, the screws should extend 50 - 80% into the vertebral body and be parallel to the endplates. The TSRH-3D pedicle screws should be inserted until the last thread is approximately flush with the bony surface (Figure 18); final screw positioning may be adjusted after rods and connectors have been applied. Once the screw is inserted, the sleeve is retracted and the 3.2mm Screwdriver is disengaged from the screw.
Meticulous development of the fusion bed enhances the potential for achieving solid fusion. First, the facet joint capsules are removed. The articular cartilage of the facet joints is removed and cancellous bone is exposed by removal of the articular bony endplates with a high-speed burr. Cancellous bone graft is packed into each facet joint.

The transverse processes, sacral alae and the lateral walls of the facet joints are decorticated with high-speed burrs and curettes (Figure 19). The pars interarticularis and any remaining portion of the lamina are finally decorticated with gouges or burrs.

The surgeon may prefer to perform the decortication process prior to the insertion of the pedicle screws. However, in most cases, the reduced profile of the pedicle screw posts allows the surgeon to adequately visualize and decorticate the bony elements in the lateral gutter with the screws in place. During the decortication process, great care is taken not to score the implant.

Corticocancellous 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 prior to the placement of the connectors and rod construct. This allows for graft fusion volume, and a graft that is uninterrupted by the metal. The screw post and connector will accommodate the fusion bed regardless of its size or height. The iliac crest bone graft is taken through the same incision by raising a flap along the dorsolumbar fascia to the rim of the iliac crest, and then carrying out subperiosteal exposure of the outer table of the crest.

“...the zero footprint of the TSRH-3D pedicle screw posts allows the surgeon to adequately visualize and decorticate the bony elements...”
There are two styles of rods available; pre-cut contoured rods, which have a pre-lordotic bend, and a 25cm straight rod. Both styles of titanium rods are available in 5.5mm and 6.35mm (1/4") diameters.

The use of the pre-cut contoured rods facilitate the surgery by minimizing the time necessary to measure, cut, and bend rods, especially when performing one and two-level fusions.

If a 25cm rod is selected, a rod template may be used to determine the rod length and contour needed for construct assembly (Figure 20). A sterile marking pen may be used to mark the rod at the point to be cut. The table top rod cutter 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 the French Bender (Figure 21). The rod does not have to be precisely bent for attachment to the screws, especially for a single-level fusion. However, bending the rod to an appropriate lordotic curvature lowers the profile of the implants and improves the biomechanics of the construct by reducing the bending moment and thus reducing the stresses on the pedicle screws. A lordotic bend in the rod also allows an element of mediolateral adjustment on a multi-level construct.

**Tips for Rod Bending:**

**For One Level:**
- No bending is required (use pre-cut contoured rods).

**For Two Levels:**
- Virtually any bend will work (use pre-cut contoured rods).

**For Multi-Level Bends:**
Rod contouring requires more planning. To accommodate additional segments, the various sized offset connectors can be helpful by allowing the rod to maintain its medial-lateral orientation.
Due to the differences in the angle of the pedicles, the screw posts may not be aligned in a uniform distance from the midline posterior spinous processes (Figure 22). Lateral bending of rods to compensate for lateral placement of screws is greatly reduced due to the small, medium, large, and 90° offset TSRH-3D™ Connectors (Figure 23). The variable sized washers of the small, medium and large connectors provide medial-lateral adjustment to engage laterally placed screws in multi-level constructs. Contouring the rod may also help capture laterally placed screws as with the TSRH-3D Connectors, the rod will always find its natural placement when implanted. Also, with the use of the 90° offset connector, facet preservation is achieved.
Radial splines on the TSRH-3D Connector allow sagittal alignment greater than 90 degrees (Figure 24). This variable angle interface combined with the various connector offerings and the smooth screw post allows for anatomic placement of pedicle screws with minimal rod contouring. This will also minimize any forced preloading or stressing of the screw rod interface.

After the degree of offset between the screws has been determined, the TSRH-3D Connectors with appropriate rod diameter and washer width are selected and preloaded on the rod. Finger tightening the lock screw holds the TSRH-3D connector in position on the rod while allowing the connector to swivel and line up with the screw post (Figure 25).

“This variable angle interface combined with the lateral offset washers and the smooth screw post allows for anatomic placement of pedicle screws with minimal rod contouring.”
Bone graft for the fusion is now inserted just prior to the rod/connector insertion. It is 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 rod/connector construct as this allows for graft fusion volume and a graft that is uninterrupted by metal (Figure 26). The screw posts and connector will accommodate the fusion bed regardless of its size or height (Figure 27).
To facilitate the loading of the rod/connector construct onto the screws, malleable screw extenders may be inserted into the internal hex of the screw posts (Figure 28). The extenders help “guide” the connectors to their proper alignment and allow engagement with the screws (Figure 29 and Figure 30).

“The extenders help ‘guide’ the connectors to their proper alignment and allow engagement with the screws.”
At the lumbosacral junction, the screw posts may impinge or cross (Figure 31a). This can be avoided by proper sagittal plane alignment of the screws and by placing the L5 screw first due to its smaller target zone. This allows the surgeon to evaluate the probes trajectory at S1 and minimize the potential for the screw to cross at L5. By starting the S1 sacral pedicle screw in the caudal portion of the pedicle and inserting the screw in a cephalad direction (toward the sacral endplate), the S1 screw shanks will be adequately separated after the L5 screws are inserted parallel to the adjacent endplate (Figure 31b). In those cases where the proximity of the screw posts do not allow the top loading of the preassembled construct (rod and connectors), the connectors can be individually placed over the screw shanks. The contoured rod can then be sequentially advanced through each connector (Figure 32).
Once the rods are inserted, 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 important.

After the construct has been assembled, segmental distraction and compression may be carried out to reduce frontal plane (scoliosis, lateral listhesis) or sagittal plane deformities (flatback, hypolordosis) (Figure 33). The screw and connector glide up and down the rod and can be provisionally tightened and retightened as final adjustments are carried out. Each set screw is provisionally tightened using either the 3.2mm Screwdriver Shaft in the internal hex of the lock screw, or the T-handle and socket wrench assembly (Figure 34).
If the patient has been positioned in the knee-chest position (Figure 35), the lumbosacral lordosis is often reduced. With the implants in place but not tightened, the foot end of the table can be raised to improve the lumbosacral lordosis (Figure 36). Further changes in segmental lordosis can be affected by compression of the screw and connector assembly along the rod. With this maneuver, a precise amount of lordosis may be achieved prior to the final tightening of the construct. A lateral radiograph or fluoroscopy can be used to determine the sagittal contour obtained at surgery. The depth of the screws can also be checked on the lateral radiograph.

Before final tightening of the lock screws, the TSRH-3D™ pedicle screws can be advanced into the vertebral body, leaving the shaded top post visible above the connector. This can be done without loosening the lock screw, thereby maintaining previous correction or position. Advancing the screw will help reduce any dorsal prominence above the connector (Figure 37).

Note: If the situation arises where you can choose between two lengths of pedicle screws, choose the shorter screw. The unique feature of the TSRH-3D pedicle screw allows for in situ dorsal adjustment of the connector and rod construct.
Once all of the pedicle screws are at the optimal height, review the final construct (Figure 38). Final tightening to approximately 80-90 inch-pounds is achieved using the T-handle with Socket Wrench assembly and the Counter Torque. Final torque is reached when the tops of the double hex breakoff lock screws have sheared off (Figure 39). If needed, the same instrument can be used for removal.

*Note: The 90° Offset connector helps to preserve the superior facet, while reducing the height of the construct.*
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 (Figure 40). Rods may be slightly spread or compressed as necessary to facilitate insertion of the plate.

With the use of the Plate Holder, the appropriate Low Profile CROSSLINK Plate or Low Profile CROSSLINK Multi-Span Plate is selected and pressed down onto the rods.

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 degrees in any single plane (Figure 41).

The set screws are advanced using the screwdriver to a torque of approximately 60 inch-pounds, 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.
POSTOPERATIVE CARE AND MOBILIZATION

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 Warning, Precautions and Possible Adverse Events.

NOTE: Implant Explantation
The TSRH-3D Connectors may be removed by applying the 7/32 socket driver from the TSRH-3D instrument set to the Connector Lock Screw and turning counter-clockwise until the Lock Screw is removed (see figure 39, page 25). The TSRH-3D Pedicle Screws may be removed by applying the 3.2mm hex driver from the TSRH-3D instrument set to the screw and turning counter-clockwise until the screw is removed from the pedicle (see figure 18, page 15).
# PRODUCT INFORMATION

## TITANIUM CONNECTORS & LOCK SCREW

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## STRAIGHT TITANIUM RODS

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IMPORTANT INFORMATION ON THE TSRH® SPINAL SYSTEM

PURPOSE:
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, G2D® rods, DYNALOX PLUS® bolts, G2D® HORIZON Low Profile MULTI-Spine CROSSLINK® Plates, G2D® rod bolt connectors, G2D® Variable Angle T-Bolts, and G2D® and G2D® HORIZON® 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®-ID connectors and TSRH®-ID screws are intended for posterior use only. All CROSSLINK® Plates are for posterior use and the CROSSLINK Axial 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 F136 or ISO 5832-1 or ISO 5832-2. Alternatively, the entire system may be made out of medical grade titanium alloy described by such standards as ASTM F136 or ISO 5832-3. Never use stainless steel and medical grade titanium implant components in the same construct.

MEDTRONIC SOFAMOR DANEK expressly warrants that these devices are fabricated from one or more of the foregoing material specifications. 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 with components from any other system, except those components listed above, or any other manufacturer. As with all orthopaedic and neurosurgical 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) vertebra 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 (L5 and below); and (4) who are having the device removed after the development of a solid fusion mass.

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).

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. 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), dysesthesias, hyposthesia, anesthesia, areflexia, alteration of radiculopathy, and/or the development or continuation of pain, numbness, neurama, spams, 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, and/or below the level of surgery. Retropulsed graft.
13. Hemorrhage, hematoma, occlusion, seroma, edema, hyperemia, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
14. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
15. Development of any 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. Illex, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hyperemia, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, 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/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 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.

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

CAUTION: 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 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 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 surgical procedure. The TSRH® Spinal System components (described in the DESCRIPTION section are not to be combined with the components from another manufacturer. Different metal 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 reverse bent in the same location. Use great care to ensure 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, pre-cut rods of the length needed.

4. Do not use the TSRH® hook trials in any type of preoperative trial. 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 utilized to facilitate surgery.

6. To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Do not overtap or use a screw/bolt that is either too long or too large. Overtapping or using an incorrectly sized screw/bolt may cause damage, hemorrhage, or 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 vertebral body being fused.

8. To assure maximum stability, two or more CROSOLINK™ plates on two bilaterally placed, continuous rods should be used whenever possible.

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 tissues, provisionally tighten (finger tighter) all of the nuts or screws, especially if screws or nuts that have a break-off feature. Once this has been completed, go back and firmly tighten all of the screws and nuts. Recheck the tightness of the other 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. Thrombus 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 subjected to mechanical vibrations or shocks 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 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 procedure), prophylactic antibiotics may be considered, especially for high risk patients.

6. The TSRH® 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 or their 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 Service. If further information is needed or required, please contact:

IN THE USA

Customer Service Division
MEDTRONIC SOFAMOR DANEK, USA, INC.
180 Pyramid Place
Memphis, Tennessee 38112 USA
Telephone: 800-876-3133 or 901-396-3133

IN EUROPE

MEDTRONIC SOFAMOR DANEK International
13, rue de la Redon
e 92290 TREMILAY EN FRANCE

**authorized EC representative

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PACKAGING:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be returned to MEDTRONIC SOFAMOR DANEK. 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 reintroduction into a sterile surgical field. Cleaning and disinfecting of instruments can be performed with alcohols, aldehyde-free solvents at higher temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

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

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

STERILIZATION:

Unless marked sterile and clearly labeled as such, the TSRH® Spinal System components, as well as those implants from other MEDTRONIC SOFAMOR DANEK spinal systems specifically indicated for use with the TSRH® 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 a hospital in a tray or case, it should be sterilized in a tray or case provided by Medtronic Sofamor Danek. 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 ** symbol: 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 risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

METHOD CYCLE TEMPERATURE EXPOSURE TIME
Steam Gravity 250°F (121°C) 30 Minutes
Steam Gravity 273°F (134°C) 20 Minutes**
Steam Pre-Vacuum 270°F (132°C) 4 Minutes

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 TSRH® Spinal System component(s) have “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 has 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.

In the event that the TSRH® Spinal System implants are not to be used, they should be disposed of as medical waste.

FOR ORDERING INFORMATION:

Telephone: (800) 876-3133
Fax: (866) 762-3133

MEDTRONIC SOFAMOR DANEK International
93290 TREMILAY EN FRANCE
FRANCE

**authorized EC representative

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**TSRH®**
A universal screw, rod and hook system with applications in degenerative spondylolisthesis, deformity, tumor and trauma procedures.

**TSRH-3D™**
Unique connectors and pedicle screws that deliver unequalled medial-lateral and sagittal angulation with true in situ dorsal adjustability.

**Vertebral Body Reduction**
A complementary module to the TSRH-3D implants and instruments that addresses degenerative spondylolisthesis reduction and tumor/trauma indications. The module has two styles of extended post screws and associated instrumentation.

**Pediatric**
A universal rod and hook system with less volume than other TSRH implants to aid in addressing the spinal concerns in children.

**Low Profile CROSSLINK® Plates**
A plate intended to help prevent rod migration and to help increase the overall construct rigidity by increasing the axial and torsional stiffness. The plates are offered in many sizes and may be contoured to increase the intraoperative solutions.

**TACOMA Sacral Plates**
A variable angle plate that conforms to the sacral inclination without contouring the rod. The plate is used as a means of fixation for constructs requiring rigid sacral fixation.