as described by:

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Dear Colleagues,

The new TSRH-3D® Multi Planar Adjusting (MPA™) Screw is unlike any other spinal instrumentation system. It is the result of six years of design work and new thinking, several prototypes, extensive biomechanical testing, and nearly four years of clinical evaluation. The goal has been to develop a single screw system that could solve both degenerative and deformity problems.

In the degenerative spine, the TSRH-3D® MPA™ Screw makes instrumenting the spine easier for the surgeon. The construct can be assembled above the patient and lowered into position out of the way of the paraspinal muscles. Obese patients no longer pose a problem. The pivoting post design also makes multi-level constructs much easier to assemble. With less time and fiddle assembling the construct, both the patient and the surgeon benefit.

The concept of directly translating the deformed spine to the rod was used by such pioneers as Luque and Asher (wires and cables) for scoliosis, and Edwards (threaded connectors) and Steffee (threaded screw posts) for spondylolisthesis. Even early users of the Cotrel-Dubousset DTT envisioned it as a “Device for Transverse Translation” for pulling the deformed spine to the rod, rather than crosslinking. The deformity application of the TSRH-3D® MPA™ System takes advantage of further refinement of these well-known principles. Pulling the spine to the pre-contoured rod via TSRH-3D® MPA™ Screws facilitates simultaneous correction in both the coronal and sagittal planes. The principle of direct vertebral translation to the rod is a powerful tool for deformity correction, including scoliosis, kyphosis, and spondylolisthesis.

The TSRH-3D® PLUS MPA™ System has made me a better surgeon. My instrumentation time is streamlined and my deformity corrections are easier and more effective. TSRH-3D® MPA™ Screws solve problems. It is a nice tool to have in your toolbox, especially when nothing else will do the job quite as well.

Best wishes for solid fusions and 3D alignment,

Dennis G. Crandall, MD
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Short-post TSRH-3D™ MPA™ Screw enhances the simplicity of construct assembly in degenerative cases.

Long-post TSRH-3D™ MPA™ Screw facilitates simultaneous correction in both the coronal and sagittal planes in deformity cases.

Simultaneous three-dimensional correction by Direct Vertebral Translation.

Bend the rod to the desired spinal contour and pull the spine to the rod.

The pivoting post of the Long-post TSRH-3D™ MPA™ Screw applies the precisely directed reduction force.
Quick Connect Screw Driver (8361971)
Flush Break Driver (8361012)
Modular Cutter Wrench, Closed End (8369042)
Modular Cutter Wrench, Open End (8369041)
Modular Flush Cutter Nut (8369044)
Modular Flush Cutter Assembly (8369040)
Modular Obturator (8369043)
Quick Thread Crimp Driver (8361941)
Provisional Reduction Crimp (8361963)
TSRH-3D® MPA™ Driver Shaft and Sleeve
Crimp Removal Tool (8361942)
Reduction Pliers Set Screw (836-062)
VBR Smooth Post Screw Reduction Pliers (836-061)
Reduction Nut (8361961)
VBR Threaded Post Reduction Nut Driver (8361953)
Threaded Post Screw Counter Torque (8361956)
Right-Handed In Situ Bender (84799RH)
Left-Handed In Situ Bender (84799LH)
The following information describes the use of TSRH-3D® PLUS MPA™ Instruments.

**QUICK CONNECT DRIVER—SCREW PLACEMENT OPTION**

Attach the Ratcheting Handle to the Quick Connect Screw Driver and insert a Short-post TSRH-3D® Multi Planar Adjusting (MPA™) Screw into the tip of the driver. The post of the screw should be straight when it is inserted into the tip of the Quick Connect Screw Driver (Figure 1). The screw will make an audible clicking sound and will be held securely in place when it is engaged correctly in the driver. The TSRH-3D® MPA™ Short-post Screw can now be inserted in the pedicle of the vertebral body (Figure 2). Tapping is optional with this screw. To release the Quick Connect Screw Driver from the screw following insertion, a slight pull on the driver will retract it from the post of the screw.

**TSRH-3D® MPA™ DRIVER WITH SLEEVE—SCREW PLACEMENT OPTION**

Place the Sleeve over the driver shaft and attach the Ratcheting Handle. Turn the driver counterclockwise until it loosens at the end. Once the driver is loose, select the correct TSRH-3D® MPA™ Short-post Screw and insert it into the driver with the pivoting screw post in the upright position. Turn the driver handle clockwise to tighten the screw to the driver. Once the screw is secured into the driver, it can then be inserted into the pedicle (Figure 3). To retract the Driver Shaft and Sleeve from the screw, a slight counterclockwise turn will release the driver from the post of the screw.
FLUSH BREAK DRIVER

Attach the Ratcheting Handle to the Flush Break Driver (8361012) to remove the break off portion of the Break Off Lock Screws. When the Flush Break Lock Screw is in the connector and is ready for final tightening, turn the Flush Break Driver clockwise until the hex top shears off from the lock screw (Figure 4). The sheared off portion will remain in the driver. Finally, remove the sheared off portion of the lock screw from proximal window of the Flush Break Driver.

MODULAR CUTTER ASSEMBLY

The Modular Cutter Assembly consists of two wrenches and the Flush Cutter. It is used to cut and remove the threaded portion of the Long-post TSRH-3D™ MPA™ Screw flush with the connector. Place the Modular Flush Cutter Assembly over the threaded post of the Long-post TSRH-3D™ MPA™ Screw. The slotted end of the cutter should be parallel to the spine. Be sure the Cutter is fully seated on the connectors. To assemble the Modular Flush Cutter, attach the Closed End Wrench to the nut on the top of the Cutter. Be sure to line up the lines on the closed end wrench and the top of the post. Place the assembly over the threaded portion of the post and place the Open End Wrench in the slot just below the top of the Cutter. Push the Open End Wrench Handle and Closed End Wrench Handle together, similar to a bolt cutter, until the long post of the screw is sheared off (Figure 5). The Obturator is used to remove the threaded post from the Cutter (Figure 6).
POSITIONING CLIPS

The Positioning Clips are an option to use to secure the connectors on the rod when loading and manipulating the construct. To use the clips, assemble the connectors, rod, and Flush Break Lock Screws together. Place the Positioning Clips on the back of the connector. When placing the Flush Break Lock Screws, finger tighten just enough so that the lock screw is not pushing against the rod. The ends of the Positioning Clip will snap onto the rod, holding the construct stable (Figure 7). As the Flush Break Lock Screws are tightened, the rod is pushed into the connector forcing the Positioning Clips to come off.

Figure 7
DEGENERATIVE SURGICAL TECHNIQUE

The following technique describes the multi-level fixation of a L2 to S1 degenerative case. Once the pedicle canals have been probed and the proper length Short-post TSRH-3D® MPA™ Screws have been determined, insert the screws into the vertebral bodies using the Quick Connect Driver (Figure 8a) or the Driver with Sleeve option (Figure 8b). The line on the driver indicates that the screw post is positioned medial/lateral. Nitinol Screw Extenders may be preloaded into the hex top of the Short-post TSRH-3D® MPA™ Screw if desired.
The pivoting direction of the screw should be placed in the medial/lateral position. The pivoting direction can vary ±15° (30° total) off of the medial/lateral line without losing strength (Figures 9a and 9b).
A rod template can be used to determine the appropriate rod length and contour needed for the construct. Select the TSRH-3D® System Connectors and preassemble the construct (Figure 10). To facilitate construct placement, attach malleable Nitinol Screw Extenders onto each screw post. Assemble the construct above the incision, pivot the posts medial and out of the way of muscles, then lower the construct into place. The medial/lateral variability of the pivoting posts will facilitate construct assembly despite the presence of multiple screws at different angles (Figure 11).
Final tightening can be performed using the Flush Break Driver. Position the Flush Break Driver on the Flush Break Lock Screw and turn clockwise until the long portion of the set screw is sheared off. The broken off portion will be retained in the shaft of the Flush Break Driver (Figure 12).

An X10 CROSSLINK™ Plate may now be attached to the construct. The correct size plate is determined by using an X10 CROSSLINK™ Measuring Caliper to measure the span between the rods. Once the X10 CROSSLINK™ Plate is in its final position, the X10 CROSSLINK™ Plate set screws can be advanced using the screwdriver. After the set screws are tightened, the midline nut is tightened to secure the final construct (Figure 13). Once the X10 CROSSLINK™ Plate is in place, the TSRH-3D® MPA™ Screw pivoting posts are locked and the TSRH-3D® MPA™ Screw construct is actually stronger than top-loading multi axial type constructs. Refer to white paper literature number LITMPADEFWP5.
The following technique describes the instrumentation for a typical L4 to S1 degenerative case combining standard TSRH-3D® System Screws and TSRH-3D® MPA™ Screws. Once the pedicles are tapped, TSRH-3D® Pedicle Screws could be placed bilaterally at L4 or S1 while Short-post TSRH-3D® MPA™ Screws could be placed bilaterally at L5. This will facilitate loading the preassembled construct (Figure 14).

Select the appropriate TSRH-3D® System rod diameter, contour, and length, and the TSRH-3D® Connectors. Preassemble the construct. The Positioning Clips may be used to hold the connectors in place on the rods (Figure 15). Once the set screws are tightened the Positioning Clips will disengage from the construct. The set screw can be attached without compromising the sagittal angulation. Next, the construct may be put onto the posts of the pedicle screws. For easy construct attachment, the use of Nitinol Screw Extenders is recommended. In this scenario, a CROSSLINK® Plate is not needed since there are fixed screws at L4 and S1.
DEFORMITY SURGICAL TECHNIQUE—LOW GRADE SPONDYLOLISTHESIS

The following technique describes correction of a Grade II Isthmic Spondylolisthesis at L5 – S1.

First, a full L5 laminectomy, inferior facetectomy, and nerve root decompression are performed. A discectomy at L5 – S1 will also make L5 mobile for reduction. After the pedicles are prepared and tapped at L5 and S1, Long-post TSRH-3D® MPA™ Screws are placed bilaterally at L5 and TSRH-3D® System Screws should be placed bilaterally at S1 (Figure 16). The screws may be inserted using the Ratcheting Handle attached to either the Quick Connect Driver or the TSRH-3D® MPA™ Driver with Sleeve.
DEFORMITY SURGICAL TECHNIQUE—HIGH GRADE SPONDYLOLISTHESIS

For high-grade Spondylolisthesis, a distal point of fixation is needed to form a strong and stable base from which L5 can be pulled into position. Options include iliac screws (Figure 17a) or S2 alar screws (Figures 17b and 17c). The S2 screws shown in Figure 17b and 17c are multi axial screws aimed laterally into the beak of the sacral ala.

Figure 17a

Figure 17b

Figure 17c
After all screws are placed, select the TSRH-3D® System rod of appropriate length and diameter along with the corresponding TSRH-3D® Connectors. Preassemble the construct. Place Nitinol Screw Extenders on the posts of the S1 screws to ease insertion. Slide the preassembled construct down the Nitinol Screw Extenders at S1 and the Threaded Post of the Long-post TSRH-3D® MPA™ Screw at L5 and into the multi axial screw heads at S2. Repeat the same process on the contralateral side of the spine.

Once the connectors are in place, temporarily secure them at S1 with a Flush Break Lock Screw. When the construct is in place, each rod creates a “diving board” over L5 (Figure 18).
A Low Profile CROSSLINK® Plate or an X10 CROSSLINK™ Plate should be placed between the S1 and S2 levels of the construct. The correct size X10 CROSSLINK™ Plate is determined by using an X10 CROSSLINK™ Measuring Caliper to measure the span between the rods. The X10 CROSSLINK™ Plate should be attached before the reduction is performed to protect the sacral fixation from pull out. Once the plate is in its final position, the set screws on the X10 CROSSLINK™ Plate can be advanced using the Hex Head Screwdriver. After the set screws are tightened, the midline nut is tightened to hold the plate securely in place. (Figure 19).
Place the Provisional Reduction Crimps on both of the Long-post TSRH-3D® MPA™ Screws at L5 (Figure 20). Place the Quick Thread Crimp Driver on the threaded posts of the screws. Squeeze the handles along the Quick Thread Crimp Driver to advance the driver down the threaded post to the Provisional Reduction Crimp. Sequentially tighten the driver by rotating clockwise pushing down on the Reduction Crimps (Figure 21).
By using use of the Provisional Reduction Crimps the spine is brought into its correct anatomic position in a gradual and highly-controlled way. The presence of the pivoting post on the TSRH-3D® MPA™ screws applies the desired and precisely directed reduction force (Figures 22a and 22b).

Direction of the Reduction Force with Rigid Screws

Figure 22a

Force Direction with TSRH-3D® MPA™ Screws

Figure 22b
If the L5 Connector “bottoms out” onto the L5 TSRH-3D® MPA™ Screw head before full reduction is achieved (Figure 23a), there are two options for getting the last few millimeters of correction. The rod can be contoured with more lordosis at L5 to increase the reduction distance for L5 to be pulled back (Figure 23b), or the Connector on S1 can be placed at the top of the post to create more reduction distance (Figure 23c).
Once the Spondylolisthesis is fully corrected, compress L5 to S1 with the Compressor to make the new alignment as stable as possible. My experience has shown that the correction is more likely to be maintained if bone or a small cage is placed into the disc space via PLIF/TLIF before L5 is compressed to S1. Place Flush Break Lock Screws in the TSRH-3D® Connectors at L5 and S1 (Figure 24). Using the Flush Break Driver, tighten all four Flush Break Lock Screws at L5 and S1 by turning clockwise. As tightening occurs, the break off portion of the set screw will shear off and remain in the sleeve of the Flush Break Driver.
To cut the post from the Long-post TSRH-3D® MPA™ Screws, use the Modular Flush Cutter, which consists of the Open End Wrench, the Closed End Wrench, and the Cutter Assembly (Figure 25). The final construct (Figure 26) should be verified with an x-ray.
DEFORMITY SURGICAL TECHNIQUE—KYPHOSIS

The following technique describes thoracic Kyphosis (e.g., Scheuermann’s) correction from T2 to L2. Before surgery, MRI the spine to be certain there is no canal stenosis. Kyphosis correction may be done after laminectomies, if required. Next, all structures resisting reduction must be addressed. This usually requires anterior release and thorough facet debridement. Occasionally, anterior or posterior osteotomies are required.

The surgeon can use the standard TSRH-3D® System to instrument the posterior thoracic region for spinal fusion from T2 to T10. Since the top of the construct will stress the spine most during reduction, down-going laminar hooks are preferred from T2 to T4 instead of screws. Screws or hooks can be used T4 to T10 or T12 to keep the construct profile as low as possible.
After placing the appropriate implants from T2 to T10, insert Long-post TSRH-3D® MPA™ Screws from T10 or T11 to L2. Be sure to fully seat the Long-post TSRH-3D® MPA™ Screws to keep the construct profile low. Using the TSRH-3D® MPA™ Driver or Quick Connect Driver, insert Long-post TSRH-3D® MPA™ Screws into the prepared pedicles bilaterally.

From T10 to T12, either multi axial screws or TSRH-3D® MPA™ Screws can be used depending on the depth of the soft tissues. For ease of rod assembly, skip one level between the multi axial and TSRH-3D® MPA™ Screws (Figures 27a and 27b).
Full length uncut rods are used. The rods should be bent to the normal contour of the spine above the Kyphosis apex. The portion of each rod distal to the Gibbus is left unkontoured. Begin rod placement above the Gibbus and lock both rods onto all screws or hooks above the apex (T2 to T7) (Figure 28).

Slide a TSRH-3D® Connector for each TSRH-3D® MPA™ Screw onto the caudal end of each rod. Attach the connectors sequentially to the long reduction posts of the screws. Keep the set screws loose (Figure 29). **IMPORTANT: A CROSSLINK® Plate must be applied to the proximal rod before any reduction forces are applied.** This spreads the stress of reduction more evenly over all of the proximal points of fixation.
Once the connectors are secured to the screw posts, slide Provisional Reduction Crimps over the threaded screw posts. Attach the Quick Thread Crimp Driver onto the threaded post so that it is flush with the Reduction Crimp. Turn the Quick Thread Crimp Driver clockwise to advance the Reduction Crimps clockwise and pull the spine to the rod. Depending on the severity of the Kyphosis, it may be necessary to reduce the T10 or T11 Reduction Crimps before it is possible to place the Provisional Reduction Crimps on the distal posts (Figure 30). The reduction process should be performed simultaneously on both sides of the spine, alternating from post to post in order to more evenly spread the stress of the reduction to multiple screws. Reduction should proceed slowly, with only a few turns on each Reduction Crimp at a time.
Repeat the reduction process at 3 to 5 minute intervals to allow the spine and the fixation to distribute the reduction stress (Figure 31). Be sure to compress the entire construct (posterior column) toward the midpoint, or apex, as the reduction proceeds. This prevents the spinal cord from being lengthened during the procedure. Spinal cord monitoring, such as the NIM-SPINE™ System Neural Integrity Monitor, should be used.

After the Kyphosis has been partially reduced, cut the rod to more closely reflect the length of rod ultimately needed (Figure 32).
As the intermediate points of fixation come in contact with the rod, they are locked onto the rod and compressed toward the apex. To initiate lordosis at the distal instrumented vertebra, in situ bend the distal end of the rod into slight lordosis. After correction is achieved, tighten all of the Flush Break Lock Screws using the Flush Break Driver (Figure 33). As tightening occurs, the break off portion of the set screw will be sheared off and retained in the sleeve of the Flush Break Driver.

Use the Modular Flush Cutter Assembly to cut and remove the threaded posts from all of the Long-post TSRH-3D® MPA™ Screws (Figure 34).
An X10 CROSSLINK™ Plate should now be attached between T10 – L2. The correct size plate is determined by using the X10 CROSSLINK™ Measuring Caliper, which measures the span between the rods. Once the plate is in its final position, the set screws on the X10 CROSSLINK™ Plate can be advanced using the Hex End Screwdriver. After the set screws are tightened, the midline nut is tightened to secure the plate.

The final construct (Figures 35a and 35b) should be verified using fluoroscopy before closure is performed in the customary manner.
DEFORMITY SURGICAL TECHNIQUE—SCOLIOSIS

The following technique describes a typical degenerative Scoliosis correction from T11 to S1. Full nerve root decompression must be performed in cases with stenosis. All structures preventing reduction must be addressed. Thorough facet debridement, and often TLIF/PLIF or anterior release are required. Osteotomies are rarely required. Once all pedicles are tapped (tapping is optional with TSRH-3D® MPA™ Screws) from T11 to S1, select the appropriate Long-post TSRH-3D® MPA™ Screws. Insert the Long-post TSRH-3D® MPA™ Screws bilaterally from T11 to S1. For long fusions such as T11 to S1, structural interbody support is recommended from at least L3 or L4 to S1 via ALIF/PLIF or TLIF (Figures 36a and 36b).
Next, bend the rod to the desired or “ideal” spinal contour. Be sure to include adequate lumbar lordosis on the bend. Preassemble the TSRH-3D® Connectors onto the contoured rod and load the connectors onto the threaded posts of the screws. Insert Flush Break Lock Screws into the connectors loosely. Place the concave rod first (Figures 37a and 37b).
Rotate the rod into the correct sagittal orientation and lock it into place at either the top (Figures 38a and 38b) or bottom (Figures 38c and 38d) of the construct. Place the Provisional Reduction Crimps onto the threaded posts of the screws.
Take the Quick Thread Crimp Driver, squeeze the handle, and insert it onto the threaded post until it is flush with the Provisional Reduction Crimp (Figure 39a). Sequentially rotate the Quick Thread Crimp Driver clockwise to tighten all the Reduction Crimps from T11 to S1 (Figure 39b). **As the Reduction Crimps are tightened, simultaneous correction occurs in both the coronal and sagittal planes as the spine is pulled to the rods.** Repeat the process on the convex side of the spine until the desired correction is achieved. Additional correction can be achieved with the convex rod if the rod is contoured to the ideal posture rather than to the existing spinal curvature.
After the Scoliosis has been corrected, use the Flush Break Driver to tighten all the Flush Break Lock Screws. As clockwise tightening occurs, the break off portion of the lock screws will be sheared off and retained in the sleeve of the Flush Break Driver.

An X10 CROSSLINK™ Plate should be placed at the top and bottom of the construct to increase construct rigidity. The correct size plate is determined by using the X10 CROSSLINK™ Measuring Caliper to measure the span between the rods. Once the plates are in final position (Figure 40), the long post of the Long-post TSRH-3D® MPA™ Screws are sheared off using the Modular Flush Cutter Assembly (Figure 41).
The final construct (Figure 42) should be verified by x-ray or fluoroscopy prior to closing.
# Deformity Implants

## Long Post Screws

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<td>TSRH-3D® MPA™ Driver Shaft</td>
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<td>8369041</td>
<td>Modular Cutter Wrench, Open End</td>
<td>8361973</td>
<td>TSRH-3D® MPA™ Driver Sleeve</td>
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<tr>
<td>8369042</td>
<td>Modular Cutter Wrench, Closed End</td>
<td>8361953</td>
<td>VBR Reduction Nut Driver</td>
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<tr>
<td>8369043</td>
<td>Modular Cutter Obturator</td>
<td>8361956</td>
<td>VBR Counter Torque</td>
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<td>8369044</td>
<td>Modular Cutter Nut</td>
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<td>VBR Driver</td>
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<td>847999RH</td>
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### DEGENERATIVE IMPLANTS

**SHORT-POST TSRH-3D® MPA™ SCREWS**

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**DEGENERATIVE INSTRUMENTS**

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<td>8361971</td>
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**TSRH-3D® System Flush Break Lock Screw Set**

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<tr>
<td>8281248</td>
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<td>8361012</td>
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<tr>
<td>8361014</td>
<td>7/32&quot; to 3.5mm Hex Bit</td>
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The NIM-SPINE™ System is a powerful, multi-modality neural integrity monitor that includes both the technical capabilities demanded by monitoring professionals, and the ease-of-use features necessary to allow surgeons to directly monitor the patient’s nerve root and spinal cord function.

The NIM-SPINE™ System Pedicle Probe can be used to gain access to the pedicle. EMG monitoring can be performed during advancement of the probe into the pedicle to ensure proper placement. Further evaluation can be performed after screw placement by utilizing the NIM-SPINE™ System Stim-Controlled Ball Tip Probe to stimulate the screw. Free-running EMG will monitor any nerve root irritation during this procedure.

<table>
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<tr>
<th>Item</th>
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<tr>
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<td>9450051</td>
<td>2.3mm Ball Tip Probe</td>
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<tr>
<td>9450020</td>
<td>Pedicle Needle</td>
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<tr>
<td>9450057</td>
<td>Stim-Controlled Ball Tip Probe</td>
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<td>9450059</td>
<td>Straight Pedicle Probe</td>
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<td>Thoracic Pedicle Probe</td>
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<td>9450047</td>
<td>Lumbar Pedicle Probe</td>
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NIM-SPINE™ System Touch Screen Monitor

NIM-SPINE™ System Pedicle Probe

NIM-SPINE™ System Stim-Controlled Ball Tip Probe
PURPOSE:
The TSRHi 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 TSRHi Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, and connecting components. In addition, GDHi rods, DYNALOK PLUS™ bolts, CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK™ Plates, GDHi rod/bolt connectors, GDHi Variable Angle T-Bolts, and GDHi™ and CD HORIZON™ set screws and locking screws may be used with the TSRHi Spinal System.

The TSRHi 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 TSR3-D™ connectors and TSRHi 3-D™ screws are intended for posterior use only. All CROSSLINK™ Plates are for posterior use and the CROSSLINK Axial and Offset Plates may be posteriorly used as well.

The TSRHi Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ISO 5832-1 or ISO 5832-9. 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 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 TSRHi 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 TSRHi 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 TSRHi 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 TSRHi 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.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRHi 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) spondylolisthesis, (3) fracture, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) pseudarthrosis, (7) tumor resection, and/or (8) unsuccessful previous attempts at spinal fusion.

For anterior use only the TSRHi Spinal System has the additional indications of: (1) spinal stenosis and/or (2) spondylosis.

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.

Potential Adverse Events
All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, 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, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neura, spasms, 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 harvest site at, above, and/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. Cessation 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. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
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: 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.

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 may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or 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 TSH® 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 insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, pre-cut rods of the length needed.
4. Do not use the TSH® hook trials in any type of prying 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 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 over-tap or use a screwdriver. The diameter and/or length of the screw should be no larger than the screw/bolt diameter as will fit into each pedicle.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. To assure maximum stability, two or more GROSSLINK® 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 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 is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) is complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions, and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-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 procedures), 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 serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the TSRH® 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:

Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic Sofamor Danek. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must 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, many instruments require disassembly before cleaning.

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

STERILIZATION:

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

<table>
<thead>
<tr>
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<th>CYCLE</th>
<th>TEMPERATURE</th>
<th>EXPOSURE TIME</th>
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<td>Steam</td>
<td>Gravity</td>
<td>250°F (121°C)</td>
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<td>Steam*</td>
<td>Gravity*</td>
<td>273°F (134°C)*</td>
<td>20 Minutes*</td>
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</table>

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment. *For 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.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

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) 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.

IN THE USA

MEDTRONIC SOFAMOR DANEK USA, INC.
1800 Pyramid Place
Memphis, Tennessee 38132 USA
Telephone: 800-876-3133 or 901-396-3133
Fax: 901-547-2272

MEDTRONIC SOFAMOR DANEK EUROPE
SOFAMOR S.N.C.*
13, rue de la Perdrix
92390 TREMBLAY
FRANCE
Telephone: (33) 3.21.89.50.00
Fax: (33) 3.21.99.50.09

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgement of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.