VERTEX®
Reconstruction System Surgical Technique

as described by:

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Dear Colleague:

We believe that there is a need to better address the surgical challenges we face in the posterior cervical and upper thoracic spine. Current instrumentation systems limit the ability to effectively meet all clinical and anatomical requirements. Although we've seen a recent evolution of posterior cervical and upper thoracic systems, they lack the modularity and versatility needed to address the most challenging cases.

After considerable thought, we determined that our design goal was a system with a variety of modular components that offer different options for spinal fixation that attach to a longitudinal rod. The VERTEX® Reconstruction System is comprised of cervical laminar hooks, thoracic multi axial screws, and lateral offset connectors.

The laminar hooks are designed to provide excellent fit and fixation to the sub-axial cervical and upper thoracic spine. The multi axial thoracic screw offers a degree of angulation and independent screw placement that reduces the need to contour the rod. The articulating saddle of the multi axial screw allows for easy rod attachment. A lateral offset connector provides a way to connect non-linear multi axial screws to the rod. This enables us to best fit the anatomy of our patient.

Clinically, the VERTEX® Reconstruction System allows us the ability to effectively treat degenerative disc disease, spondylolisthesis, spinal stenosis, fractures, failed previous fusions, and tumors with more intra-operative options than ever before. The ability to treat a patient’s condition without compromising stabilization due to the constraints of the instrumentation is a new evolution.

The VERTEX® Reconstruction System is a versatile system that is easy to use, and is designed to be effective in treating the more challenging cases in the posterior cervical and upper thoracic spine. The following monograph introduces the VERTEX® Reconstruction System, as well as personal thoughts reflecting our current clinical practice and operative techniques.

Sincerely,

Kevin Foley, MD  Steve Papadopoulos, MD  Rick Sasso, MD
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**Surgical Technique**

**VERTEX® Reconstruction System**

**MEDTRONIC**

**Laminar Hook**
- Attaches directly to rod
- Excellent sizes for cervical lamina

**Titanium Rod**
- Easily contours to meet individual patient anatomy

**Set Screw**
- Buttress threads reduce profile and improves cross-threading resistance
- Internal set screw allows for placement and visualization

**Lateral Connector**
- Accommodates rod attachment of non-linear screws
- Allows for increased angle of screw trajectory
- Accounts for screw height differences

**3.5/4.0mm Diameters Multi Axial Thoracic Screw**
- Allows for 60 degree conical screw angulation, or 30 degrees in any direction
- Top loading allows for independent placement
- Rotating saddle reduces rod contouring

**CROSSLINK® Connector**
- Increases construct rigidity
- Crossbar can be contoured to avoid posterior elements

**Rod Connector**
- Connects 3.2mm rod to 4.5mm or 5.5mm rod
Surgical Technique

**VERTEX® Reconstruction System**

**Instrument Set**

- Drill Guide
- Drill Stop, Cortical Adjustable
- Drill Bit, Cancellous Adjustable
- Drill Bit, Cancellous 4mm
- Circular Drill Bit Adapter
- Alignment Tool
- Pedicle Probe
- Depth Gauge
- Awl
- Straight Hex Screwdriver
- Screwdriver
- 4.0mm Adjustable Cancellous Tap
- 4.0mm Adjustable Cortical Tap
- 3.5mm Adjustable Cancellous Tap
- Drill Bit Handle
- Drill Bit, Cancellous Adjustable
- Drill Bit, Cortical Adjustable
- Drill Bit, Cancellous 14mm
- Screwdriver
- Depth Gauge
The following surgical technique describes the application of the VERTEX® Reconstruction System utilizing upper thoracic pedicle screw fixation for illustrative purposes. Refer to the package insert for a complete list of indications and limitations.

The patient is placed prone in an appropriate manner to avoid specific pressure points. The head may be placed in a padded head holder or secured in three point pins. The back and neck are prepped and draped in a sterile fashion (Figure 1). A midline incision is made and dissection is carried down to the spinous processes of the appropriate vertebrae.

The paraspinal musculature is elevated in a subperiosteal plane. Dissection is carried laterally to expose the facets and the transverse processes. Attention is given to the preservation of the most cephalad facet capsule while all other soft tissue is removed from the facets to be included in the fusion. Attention is now directed toward instrumentation of the spine.

Figure 1
The following technique describes the placement of VERTEX® Screws within the pedicle at T1 – T3. Anatomical landmarks are identified and carefully reviewed to determine the entry point to the pedicle. Anatomical variations should be noted on inspection of preoperative CT scans and AP radiographs. The surgeon may choose to utilize an image-guided surgical navigation system such as the STEALTHSTATION® Treatment Guidance Platform® or the FLUORONAV® Virtual Fluoroscopy System®. Additionally, intraoperative imaging may be utilized to facilitate thoracic pedicle screw placement. If a laminectomy or laminotomy is performed the pedicle may be directly visualized and/or palpated. An entry hole is made over the pedicle with a burr, drill, or sharp trocar (Figure 2).

“The anatomical landmarks for entry into the pedicle of the upper thoracic spine are the intersection of a line parallel to the upper 1/3 of the transverse process and a vertical line through the middle aspect of the upper facet joint. This ends up approximately 3 to 4 mm caudal to the mid aspect of the upper facet joint.”

Dr. Rick Sasso

“I routinely use StealthStation guidance for placement of upper thoracic pedicle screws.”

Dr. Kevin Foley

*Please see your sales representative for technical information and/or the package insert for STEALTHSTATION® Treatment and Guidance platform FLUORONAV® Virtual Fluoroscopy.*
The drill guide is used to align either the 14mm fixed cancellous drill bit (Figure 3), an adjustable depth cancellous drill bit or an adjustable depth cortical drill bit (Figure 4). A pilot hole is then drilled to the desired depth and trajectory. The drill bit may be attached to the drill bit handle for manual drilling or attached to a power drill with or without the use of the circular drill bit adapter.

“Instead of a drill, I use a forage technique with a small straight curette.”

Dr. Rick Sasso

“I routinely drill to a depth just beyond the base of the thoracic pedicle and tap into the vertebral body.”

Dr. Steve Papadopoulos
The depth gauge is then used to gently palpate the cancellous bone of the pedicle and to determine screw length (Figure 5). If the canal is exposed via a laminotomy, the medial and inferior walls of the pedicle may be visualized and monitored while tapping and placing the screw.
A tap may now be placed down the pedicle to the appropriate depth (Figure 6). The surgeon may choose to only partially tap the pedicle screw hole rather than the entire depth. The gauge on the tap shaft will indicate the depth of the tap in the pedicle.

The appropriate length screw is then applied to the screwdriver and inserted into the bone (Figure 7). Confirmation of screw position may be made by radiographs or intraoperative fluoroscopy.

“I typically remove uneven bone with a drill or rongeur just below the saddle of the multi axial screw so that it will sit flush.”

Dr. Steve Papadopoulos
The remaining screws are placed using a similar technique (Figure 8). Prior to rod placement, the alignment tool may be used to align the saddles of the VERTEX® Multi Axial Screws (Figure 9).
A rod template may now be used to determine the curvature and length of the rod needed based on the screw position (Figure 10). The rod is cut to length (Figure 11) and contoured to conform to the sagittal contour of the spine and medial-lateral orientation of the screws (Figure 12).
The VERTEX® Multi Axial Screw can allow up to 5mm of medial-lateral variability without the need for additional rod contouring (Figure 13). Offset connectors may also be used to facilitate coupling the screws to the rod if further medial-lateral offset is required (See page 14). The rod is introduced with the rod holder (Figure 14). Autogenous corticocancellous bone graft may be placed either before or after rod implantation.
If medial or lateral offset is needed that is beyond the offset capabilities of the VERTEX® Multi Axial Screw, a lateral connector (Figure 15) may be utilized to accommodate a variable degree of offset (Figure 16). This lateral offset connector can also adjust for small height variances between the multi axial screws, as well as excessive angulation differences (medial-lateral angulation in the axial plane or cephalad-caudal in the sagittal plane).
With the rod fully seated in the screw heads, a set screw can be loaded onto the tapered hex screwdriver and seated into each screw head. To minimize cross-threading of the set screw, index the threads by rotating the set screw counter-clockwise until a click is felt or heard. When the rod is not fully seated in the screw head, a set screw can be loaded onto the tapered hex screwdriver and placed through the rod pusher/counter torque (Figure 17a). The set screw can temporarily be docked in the inner threads of the rod pusher/counter torque for aligning the set screw with the threads of the screw (Figure 17b). The rod pusher/counter torque will assist in seating the rod prior to introducing the set screw (Figure 18).

“I prefer to load the set screw freehand and use the rod pusher/counter torque for final tightening.”

Dr. Kevin Foley
Once all of the set screws have been placed (Figure 19), tighten each set screw starting at one end of the rod and sequentially working to the other end. Securely tighten each set screw by using the screwdriver in conjunction with the rod pusher/counter torque instrument (Figure 20).
The following technique describes the placement of VERTEX® Laminar Hooks within the cervical and upper thoracic spine. Lamina preparation and ligamentum flavum dissection may be achieved by using the laminar elevator (Figure 21). Note: Dissection may also be achieved by the hook itself using the hook holder. A limited resection of the caudal lamina of the superior vertebra may be necessary for insertion of the supra laminar hooks. If the ligamentum flavum is calcified or the lamina are overlapping, a high speed drill may be used. The appropriate hook is selected based on the thickness of the lamina and loaded onto the hook holder (Figure 22).

A rod template can now be used to determine the curvature and length of the rod needed based on the hook position. The rod is cut to length and contoured to conform to the spine (See page 12) and introduced using the rod holder (Figure 23).
The set screw is inserted, but not tightened, using the screwdriver (Figure 24). If needed, the guide on the hook holder allows for proper positioning of the screwdriver to insert the set screw (Figure 25).
Compression may be applied by using the compressor in order to achieve the laminar claw (Figure 26). Set screws are then securely tightened into the saddles of the hooks using the screwdriver. Note: If distraction is needed, place hooks in the opposite direction and apply distraction with the distractor. This process is then repeated for the contralateral side with pedicle screw placement into the thoracic spine as needed (Figure 27).
CROSSLINK® Connectors are recommended for the top and bottom one-third of the construct to increase rigidity. The connector consists of two clips and one bar. The clips can be held and inserted with the hook holder or inserted by hand bilaterally onto the rods at the appropriate level of fixation (Figure 28). The bar forms the transverse element of the assembly and can be contoured to conform to variations in rod position and cut to length prior to insertion into the clip body (Figure 29). After the bar is positioned in the clip bodies, the final assembly is secured with two VERTEX® Reconstruction System set screws. In some cases, the inter-spinous ligament and portions of the spinous processes can be removed for proper seating of the CROSSLINK® Connector.
With the use of Rod Connectors, additional levels of fixation may be achieved by connecting the VERTEX® Reconstruction System to the CD HORIZON® LEGACY™ Spinal System 4.5 or 5.5mm rods. This is of particular importance when extension of a previously implanted construct is required or when it is preferable to utilize smaller or larger implant components due to anatomical constraints. To link the systems, insert the 3.2mm and 4.5 or 5.5mm rod segment through the opposing sides of the rod connector and tighten into position to form a contiguous segment of rod (Figure 30). Position the rod into the appropriate fixation components and secure with set screws. The parallel offset of the rod connector will accommodate medial/lateral positioning as well as allowing for dorsal adjustment by rotating the rods.
### Implants

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**Titanium Multi Axial Cancellous Thoracic Bone Screws**

- 6900430: 3.5mm x 0mm
- 690043: 3.5mm x 40mm
- 690044: 4.0mm x 6mm
- 6900440: 4.0mm x 0mm
- 6900444: 4.0mm x 4mm
- 6900446: 4.0mm x 6mm
- 6900448: 4.0mm x 8mm
- 6900440: 4.0mm x 4mm
- 6900444: 4.0mm x 4mm
- 69004444: 4.0mm x 4mm
- 69004446: 4.0mm x 4mm
- 69004448: 4.0mm x 4mm
- 69004450: 4.0mm x 50mm
- 69004452: 4.0mm x 52mm

**Titanium Multi Axial Cortical Thoracic Bone Screws**

- 69004426: 4.0mm x 26mm
- 69004428: 4.0mm x 28mm
- 69004430: 4.0mm x 30mm
- 69004432: 4.0mm x 32mm
- 69004434: 4.0mm x 34mm
- 69004436: 4.0mm x 36mm
- 69004438: 4.0mm x 38mm
- 69004440: 4.0mm x 40mm
- 69004442: 4.0mm x 42mm
- 69004444: 4.0mm x 44mm
- 69004446: 4.0mm x 46mm
- 69004448: 4.0mm x 48mm
- 69004450: 4.0mm x 50mm
- 69004452: 4.0mm x 52mm

**Set Screws**

- 6900300: Set Screw

**Rods**

- 69000: 3.5mm Rod, 0mm
- 690040: 3.5mm Rod, 40mm

**hooks**

- 6904045: 4.5mm Laminar Hook (purple)
- 6904060: 6.0mm Laminar Hook (green)

**Connectors**

- 6901000: Screw Connector

**Instrument Set**

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Method: Steam

Cycle: Gravity

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose are excluded. Never use stainless steel and titanium implant components in the same surgical field.

To achieve best results, do not use any of the VERTEX Reconstruction System implant components with components from any other system or manufacturer unless specifically labeled to be compatible. Ask Medtronic Sofamor Danek, Inc. for confirmation of compatibility. The VERTEX Reconstruction System is fabricated from grade medical titanium or titanium alloy. The VERTEX Reconstruction System also includes a retaining ring for the multi-axis screws. The VERTEX Reconstruction System is compatible with titanium or titanium alloy implants only. Do not use with stainless steel, niobium, or vanadium implants. The VERTEX Reconstruction System is intended for use with a partial or total laminar or facet use or are specifically excluded. Never use stainless steel and titanium implant components in the same surgical field.

1. Active infectious process or significant risk of infection (immunocompromise).  
2. Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications.  
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion.  
4. The patient should be adequately warned of these hazards and closely supervised to ensure cooperation until the fusion(s) have achieved a reasonable degree of stability.  
5. As a precaution, before patients with implants receive any subsequent surgery (such as aspirin during the bone graft healing process).

Important Information on the VERTEX Reconstruction System

Purpose: The VERTEX Reconstruction System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the occipital, cervical, and/or thoracic spine.

Description: The VERTEX Reconstruction System is a posterior system, which consists of a variety of components and their corresponding product identifiers. The system includes surgical components, which can be rigidly locked to the rod in a variety of configurations, with each component being interchangeable with other components in the system. If the patient cannot be safely treated with the system described in this surgeon’s kit, another system should be selected. If the system is not used in accordance with the directions provided, the patient may sustain injury. The surgeon should be advised of the potential for complications associated with the use of this system at the surgeon’s discretion. See the package inserts of both of these systems for labeling information.

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Surgical Technique

**POtENtIAl ADvErSE EvENTs**

1. Severe bone resorption.


3. Screw loosening, bending or breakage

4. Infection.

5. Post-operative change in surgical scar, loss of correction, height, and/or reduction.

6. Infection.

7. Grossly distorted anatomy caused by congenital abnormalities.

8. Screw breakage, loosening or failure

9. Suspected or documented metal allergy or intolerance.

10. Overtapping, using an incorrectly sized screw/bolt, or accidentally advancing the screw/bolt beyond the head part of the screw, or burs used on the threads or heads of the device(s). It is important to check the device(s) before using the equipment and should personally assemble the devices after use per the surgeon and patient, in most patients, removal is indicated because the implants and/or screws after finishing to make sure that none loosened during the tightening of the other rods or screws. Failure to do so may cause loosening of the other components.

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 top of 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. Infection.


15. Overtapping, using an incorrectly sized screw/bolt, or accidentally advancing the screw/bolt beyond the head part of the screw, or burs used on the threads or heads of the device(s). It is important to check the device(s) before using the equipment and should personally assemble the devices after use per the surgeon and patient, in most patients, removal is indicated because the implants and/or screws after finishing to make sure that none loosened during the tightening of the other rods or screws. Failure to do so may cause loosening of the other components.

16. Loss of or increase in spinal mobility or function.

17. Bow loss or decrease in bone density, possibly caused by stresses shielding.

18. Graft donor site complications including pain, fracture, or wound healing problems.

19. Lesions, gastritis, obstruction or loss of bowel control or other types of gastrointestinal system complications.

20. Hemorrhage, hemoptysis, occlusion, sepsis, sepsis, peritonitis, obstruction, stroke, excessive bleeding, pleural, wound, wound, wound, damage, delayed bleeding, or other types of cardiovascular system complications.

21. Reproductive system complications, including infertility, loss of sexual function, and sexual dysfunction.

22. Reproductive system complications, including infertility, loss of sexual function, and sexual dysfunction.

23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchiolitis obliterans, etc.

24. Change in mental status.

25. Death.

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

**WARNING**

The implantation of pedicle screw spinal systems should be performed only by experienced physicians and should be limited to those patients with extreme spinal deformities or instability of the thoracic, lumbar, and or sacral spines or instability of the thoracic, lumbar, and or sacral spines or instability of the thoracic, lumbar, and or sacral spines.

PRECAUTIONS

The indications of use.

In order to achieve additional levels of fixation, the CD HORIZON Spinal System may also be used for the same indications.

PRESERVATIVE

The medical grade titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy used in the CD HORIZON Spinal System with or without CD HORIZON SPECTRA® instrumentation is intended for posterior, -non-cervical fixation for the following indications: degenerative or traumatic disc disease as defined and confirmed by history and radiographic studies; spondylolisthesis; trauma (i.e., fracture or dislocation); and the treatment of spinal stenosis. The system includes 2.5mm, 3.5mm, and 4.5mm screws, CROSSLINK rod connector.

Infection.

Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON Spinal System. These components include TSRH rods, hooks, plates, connectors, washers, and/or screw heads, hooks, connectors and CROSSLINK for anterior and posterior fusion, and DYNALOK PLUS and DYNALOK SLANTED hooks with rod connectors, and Medtronic Multi-Axis rod systems and screws. Please note that certain compatible and components are specifically designed to connect to CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation, CD HORIZON™ Spinal System instrumentation.

In order to achieve additional levels of fixation, the CD HORIZON Spinal System may also be used for the same indications. The rods should not be repeatedly or excessively bent. The rods should not be reverse threaded.

The manufacturer of pedicle screw spinal systems is an extremely poor candidate for spine fusion. Patients with poor muscle and bone quality and/or poor bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality and bone quality.
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. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270°F (132°C)</td>
<td>4 Minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>250°F (121°C)</td>
<td>60 Minutes</td>
</tr>
<tr>
<td>Steam*</td>
<td>Pre-Vacuum*</td>
<td>273°F (134°C)*</td>
<td>20 Minutes*</td>
</tr>
<tr>
<td>Steam*</td>
<td>Gravity*</td>
<td>273°F (134°C)*</td>
<td>20 Minutes*</td>
</tr>
</tbody>
</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.

PRODUCT COMPLAINTS

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

Further Information: Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact MEDTRONIC SOFAMOR DANEK.

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Contact Customer Service or your Sales Representative for the most up-to-date revision of the package insert.
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. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.