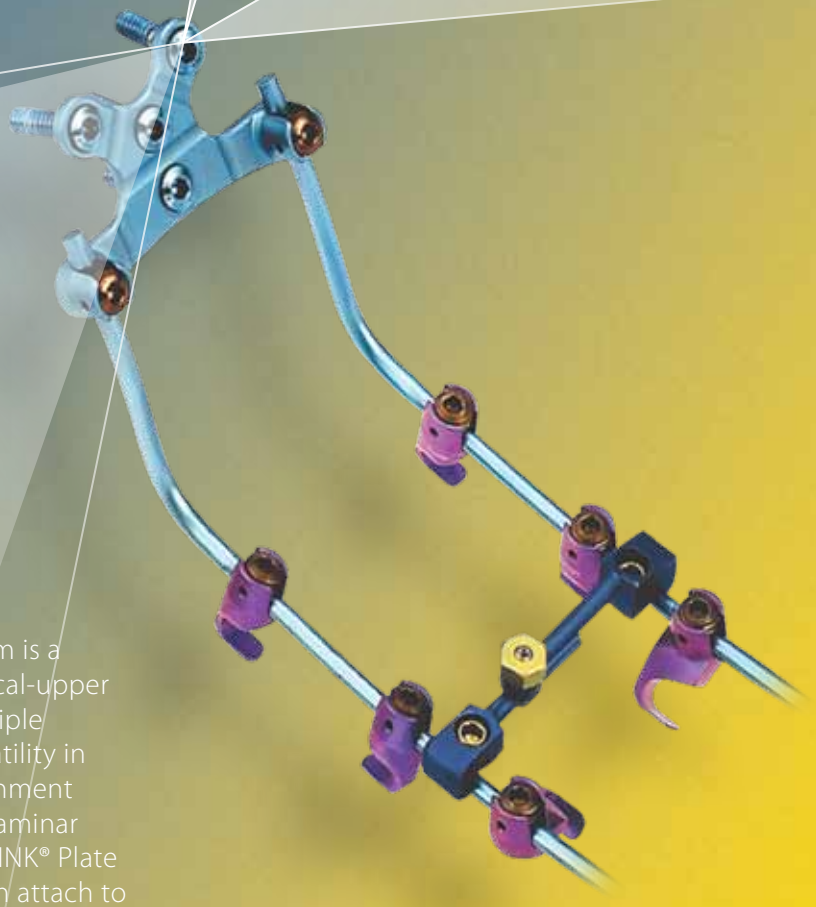
Medtronic

VERTEX MAX®

Reconstruction System

Surgical Technique Demonstrating Occipital Plate Rod and Occipital Keel Plate



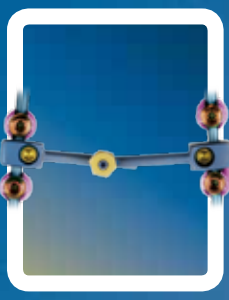
The VERTEX MAX® Reconstruction System is a comprehensive modular posterior cervical-upper thoracic implant system that offers multiple fixation options. The system allows versatility in bony attachment with a variety of attachment mechanisms such as multiaxial screws, laminar hooks, lateral offset connectors, CROSSLINK® Plate connectors, and screw connectors which attach to a rod. Threaded rods allow for a seamless transition from the cervical to the upper thoracic spine.

Cervical/Thoracic Transition Rods

Partially Threaded Screws

Occipital Plate Rod

Increased Angulation Self-Tapping



Adjustable CROSSLINK® Plate

Medtronic

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Reconstruction System

Surgical Technique Demonstrating Occipital Plate Rod and Occipital Keel Plate

Dear Colleague,

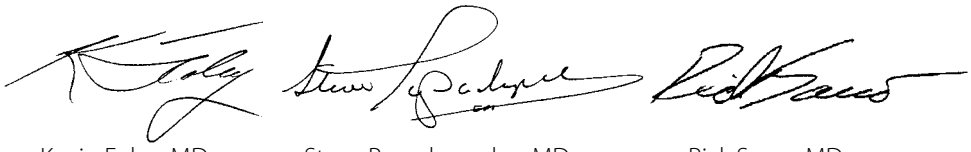
The VERTEX® Reconstruction System pioneered contemporary fixation techniques for the occipitocervical and upper thoracic spine with the advent of multiaxial screws, laminar hooks, and lateral connector attachments to a longitudinal rod. It offered spinal surgeons modular components that addressed different pathologies for spinal fixation. This system provided the opportunity for in situ fixation as well as correction of complex deformities.

Continuous advancements in instrumentation design and technique have allowed further refinements and improved usability and function for fixation of the occipitocervical and upper thoracic spine. Today, to continue meeting the demands of spinal surgeons and the needs of patients, we introduce the next generation, top-loading, multiaxial screw and laminar hook system — the VERTEX MAX® Reconstruction System.

The improved versatility of the VERTEX MAX® Reconstruction System offers you the ability to accommodate a patient's unique anatomical requirements without compromising fixation.

The following monograph presents the VERTEX MAX® Reconstruction System and our personal thoughts reflecting our current clinical practice and operative techniques.

Sincerely,



Kevin Foley, MD Steve Papadopoulos, MD Rick Sasso, MD

Screw Features

VERTEX SELECT™ Multi-Axial Thoracic Screw

- Compatible with 3.2mm and 3.5mm rods
- Up to 45 degrees of angulation
- Index markers on saddles to easily identify the 45° relief notches
- Available in 3.5mm, 4.0mm, and 4.5mm diameter
- Top loading for independent placement
- Self-tapping bone screws
- Rotating saddle reduces rod contouring
- Three angle-relief notches for increased angle flexibility
- Color-coded internal washers help appropriately match drill bits and taps

Top and bottom view of 10mm to 24mm screw relief notches

Bottom and side view of 26mm to 52mm screw relief notches

Partially Threaded Multi-Axial Bone Screws

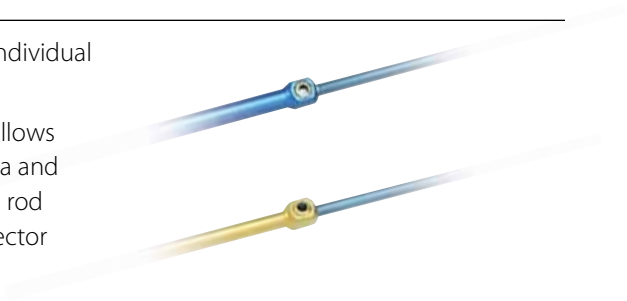
Color Coding Reference

	Screw Size	Color	Drill Bit	Tap
VERTEX SELECT™ Multi-Axial Screws (MAS)	3.5mm × 10mm to 24mm	Green	2.4mm	3.5mm (10mm to 24mm)
	4.0mm × 10mm to 24mm	Blue	2.4mm	4.0mm (10mm to 24mm)
	4.0mm × 26mm to 52mm	Gold	2.9mm	4.0mm (26mm to 52mm)
	4.5mm × 10mm to 42mm	Magenta	2.9mm	4.5mm (10mm to 42mm)
VERTEX SELECT™ Partially Threaded MAS	4.0mm × 26mm to 40mm	Gold	2.9mm	4.0mm (26mm to 40mm)
Occipital Bone Screws	4.0mm × 6mm to 18mm	Light Blue	3.0mm (Cortical)	4.0mm (Cortical)
	4.5mm × 6mm to 18mm	Gray	3.5mm (Cortical)	4.5mm (Cortical)

Implant Features *continued*

Occipital Bone Screws

- Threaded feature allows connection of 3.2mm rod to 4.5mm or 5.5mm rods for cervical to thoracic transition
- Easily contours to meet individual patient anatomy
- Short connection point allows for maximum fixation area and minimizes the run on the rod compared to a rod connector



Laminar Hooks

- Attaches directly to rod
- Optimum sizes for cervical lamina

Offset Laminar Hooks

- Left and right laminar offset hooks

Set Screw

- Buttress thread
- 2.5mm hex internal set screw

Rod Connector

- Connects 3.2mm rod to 4.5mm or 5.5mm rods

Adjustable CROSSLINK® Plate

- Single component
- Increases construct rigidity
- Small footprint for easy placement between screw heads

Lateral Connector

- Accommodates rod attachment of non-linear screws
- Accommodates screw height differences
- Increases screw angulation

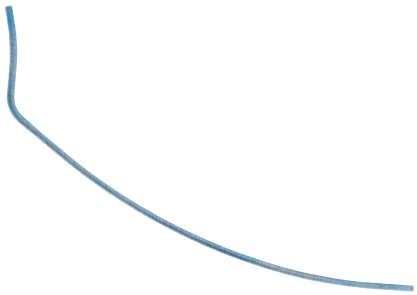
Occipital Fixation

Occipital Bone Screws

- Cortical threads
- 4.0mm and 4.5mm diameters

Pre-Contoured Occipital Rod

- Pre-contoured to match anatomy of occipitocervical junction
- 3.6mm diameter in bend zone
- 100mm and 200mm rod lengths

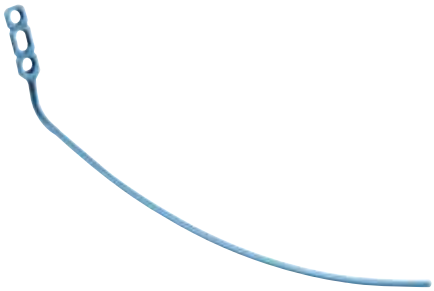


Occipital Keel Plate

- Allows for occipital midline fixation
- Bend zones for contouring
- Accepts 4.0mm and 4.5mm diameter occipital bone screws
- Small, medium and large sizes

Occipital Pre-Contoured Plate Rod

- Pre-contoured to match anatomy of occipitocervical junction
- 3.6mm diameter in bend zone
- 100mm and 200mm rod lengths
- Accepts 4.0mm and 4.5mm diameter occipital bone screws



Instrument Set

Screw Preparation/Placement

Adjustable Drill Guide

Fixed
Drill Guide
(14mm)

Universal Handle

Circular Drill Bit
Adapter

Pedicle Feeler

Pedicle Probe

Awl

Bone Reamer

Depth Gauge

Self-Holding Screwdriver

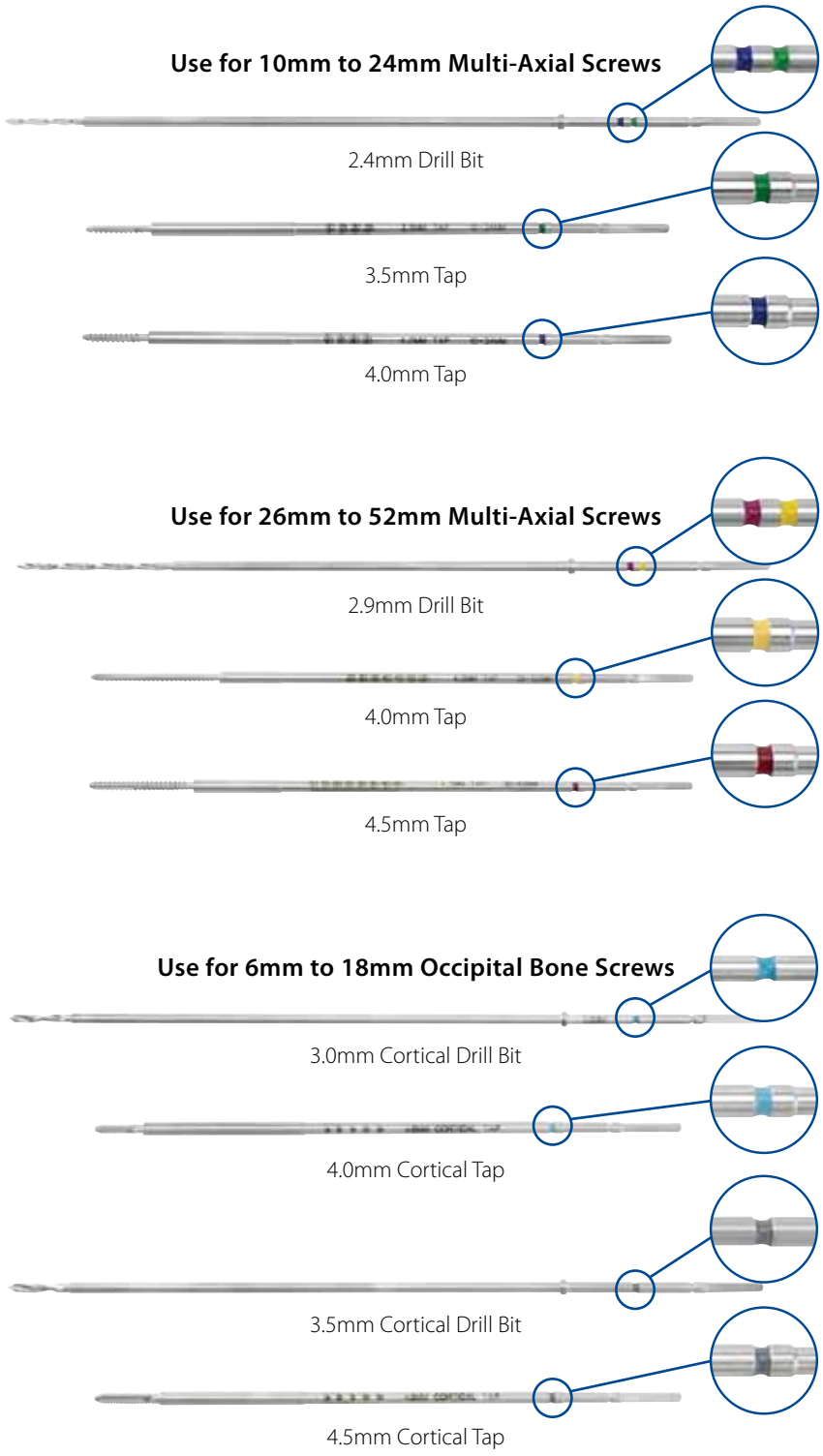
Tap Sleeve

Threaded Screwdriver

Instrument Set *continued*

Screw Preparation/Placement

Color-Coded Drill Bits/Taps



Instrument Set *continued*

Hook Placement

Laminar Elevator

Hook Holder

Rod Preparation

Ratcheting Rod Cutter

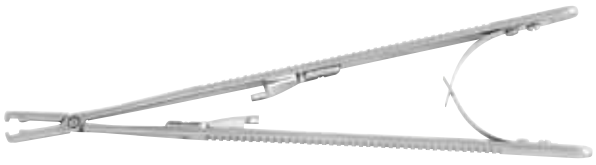
Rod Cutter

Rod Bender

Rod Template

Rod Insertion/Adjustment

Rod Gripper



Rod Holder

Alignment Tool

Instrument Set *continued*

Rod Reduction/Correction

Rod Reducer

Bending Iron Left

Bending Iron Right

Compression/Distraction

Compressor Forceps

Distractor Forceps

Final Tightening

2.5mm Straight Hex Screwdriver

Universal Handle

Straight Hex Torque Driver

Torque Limiting Handle

Rod Pusher/Counter Torque

CROSSLINK® Plate Placement

Lock Nut Driver

Universal Handle

Patient Positioning/Posterior Approach

The following surgical technique describes the application of the VERTEX MAX® Reconstruction System utilizing occipital keel plates and plate rods, laminar hooks, and upper thoracic pedicle screw fixation. 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 paraspinous musculature is elevated in a sub-periosteal 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

Pedicle Preparation

Anatomical landmarks are identified and carefully reviewed to determine the entry point to the pedicle **(Figure 2)**. 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 awl **(Figure 3)**.

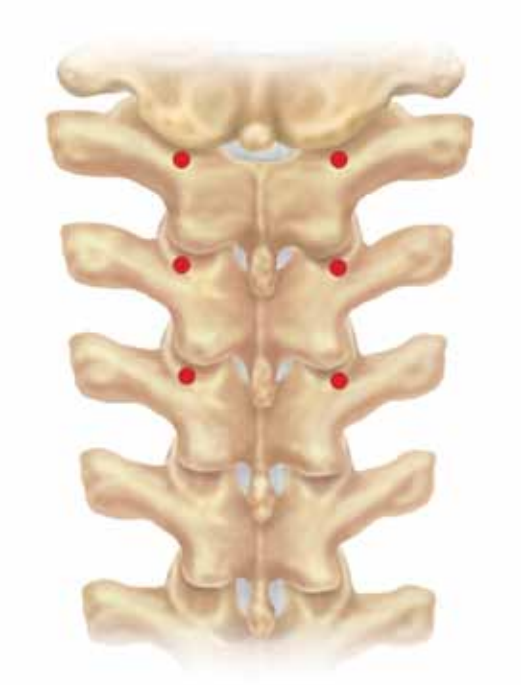


Figure 2

Figure 3

Surgeon Quote

"I routinely use STEALTHSTATION® System guidance for placement of upper thoracic pedicle screws."
– Dr. Kevin Foley

Surgeon Quote

"The anatomical landmarks for entry into the pedicle of the upper thoracic spine are the intersection of a line parallel to the upper one-third of the transverse process and a vertical line through the middle aspect of the upper facet joint. This ends up approximately 3mm to 4mm caudal to the mid-aspect of the upper facet joint."
– Dr. Rick Sasso

Drilling

The drill bits and taps in the Instrument Set are color-coded to facilitate screw insertion. A color code reference chart is shown on Page 3. The Adjustable Drill Guide, with its easy lock and unlock adjustment feature, can be used for drilling depths from 6mm to 52mm. The drilling depth can be adjusted by pressing the slide forward while adjusting the measuring tube to the desired drill depth **(Figure 4)**. Once the slide reaches the desired depth, rotate the slide into the locked position **(Figure 5)** and prepare the pilot hole in the desired trajectory **(Figure 6)**.

Surgeon Quote

"I routinely drill to a depth just beyond the base of the thoracic pedicle and tap into the vertebral body."
– Dr. Steve Papadopoulos

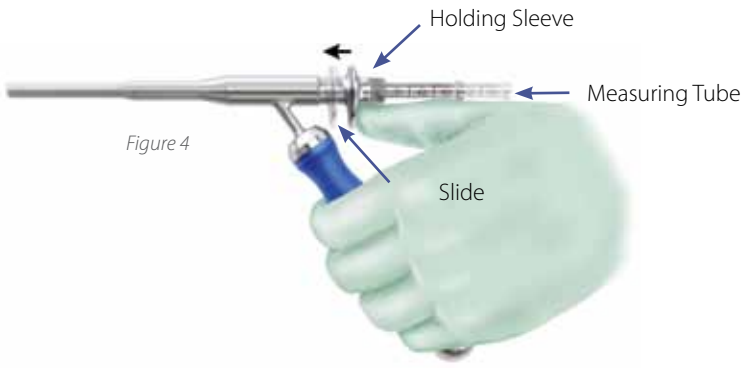


Figure 4

Figure 5

Surgeon Quote

"Instead of a drill, I use a forage technique with a small, straight curette."
– Dr. Rick Sasso

Figure 6

Screw Measurement/Optional Tapping

The Pedicle Feeler is used to gently palpate the cancellous bone of the pedicle, and the Depth Gauge is used to determine the screw length **(Figure 7)**. The VERTEX SELECT™ Multi-Axial Screws are self-tapping to obviate the tapping step. If the surgeon prefers tapping, place the Tap Sleeve over the tri-flat end of the tap and use the gauge on the tap shaft to visualize the depth of the tap in the pedicle **(Figure 8)**.

Figure 7

Figure 8

Optional Reaming

The Bone Reamer may be used to remove uneven bone, if needed, to maximize the multiaxial capabilities of the bone screw **(Figures 9a and 9b)**.

Surgeon Quote

"I typically remove uneven bone with a drill or rongeur just below the saddle of the multiaxial screw so that it will sit flush."
– Dr. Steve Papadopoulos

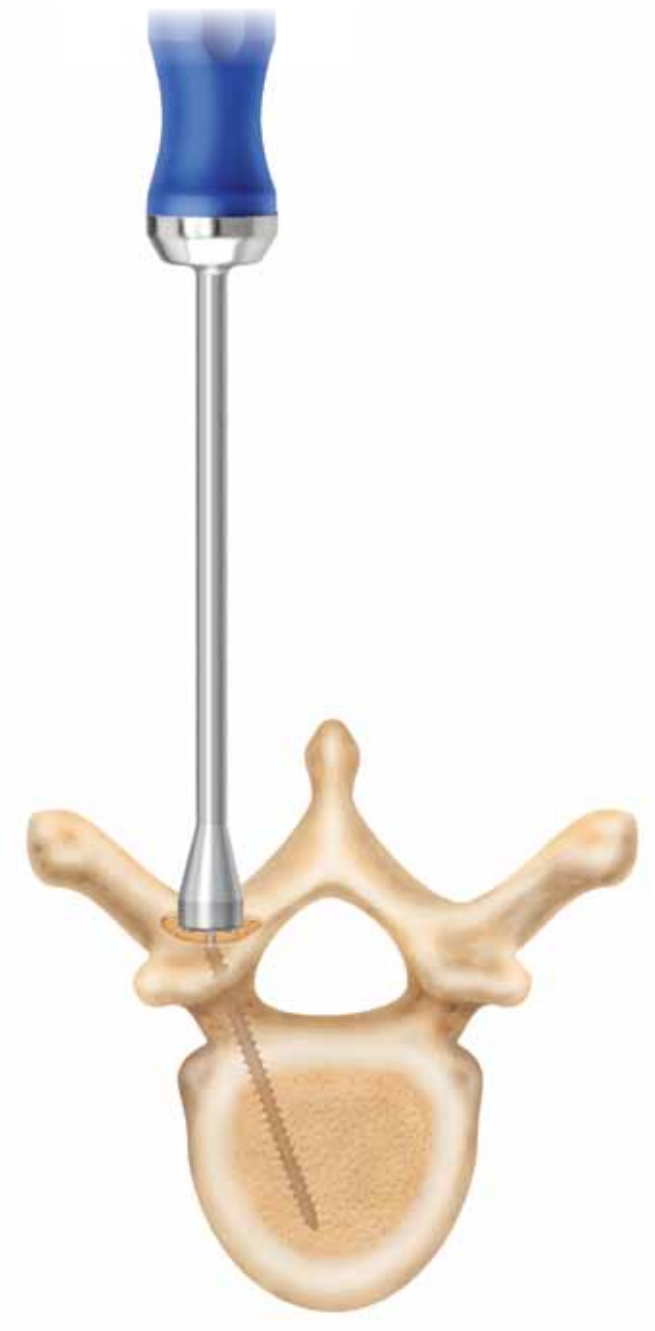


Figure 9a

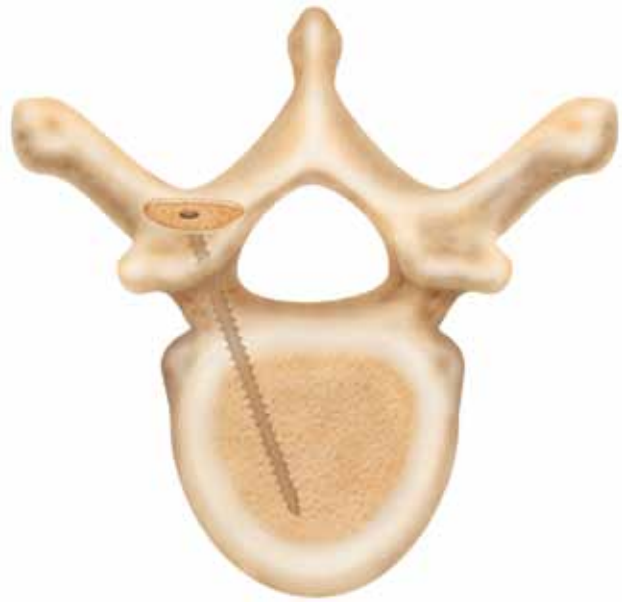


Figure 9b

Screw Placement

Once the desired screw length is selected, the screw is attached to the Self-Holding Screwdriver and inserted into the bone **(Figure 10)**. Confirmation of screw position can be made using radiographs or intraoperative fluoroscopy.

The remaining screws are placed using a similar technique **(Figure 11)**. Prior to rod placement, the Alignment Tool may be used to align the saddles of the VERTEX SELECT™ Multi-Axial Screws **(Figures 12a and 12b)**.

Figure 10

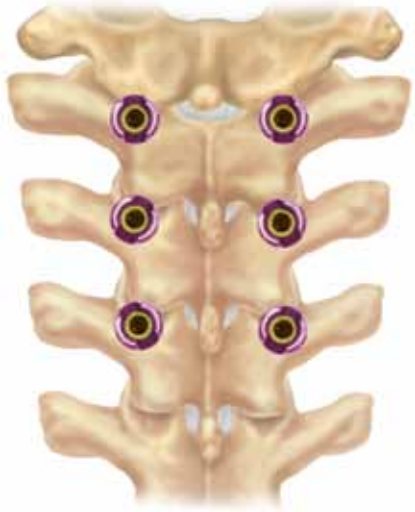


Figure 11

Figure 12a

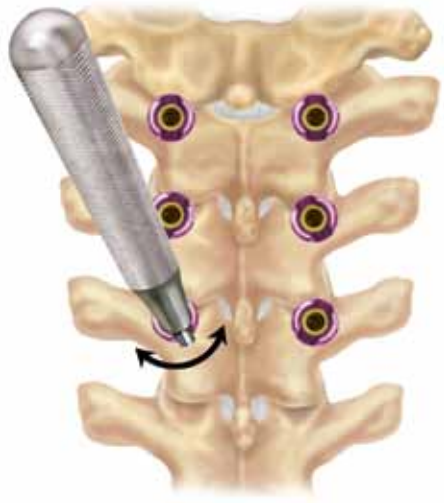


Figure 12b

Hook Placement

When using Laminar Hooks in the cervical and upper thoracic spine, lamina preparation and ligamentum flavum dissection is performed using the Laminar Elevator **(Figure 13)**. If desired, dissection may also be achieved using a hook in the Hook Holder **(Figure 14)**. A limited resection of the caudal lamina of the superior vertebra may be necessary for insertion of the supralaminar 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 placed at the appropriate position **(Figures 15a and 15b)**.

Figure 14

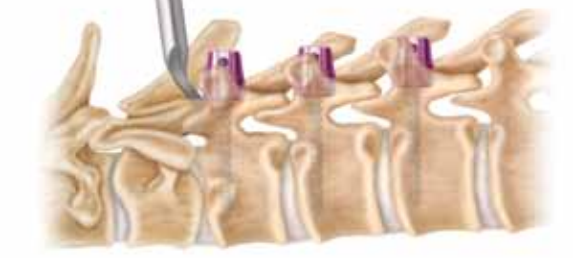


Figure 13

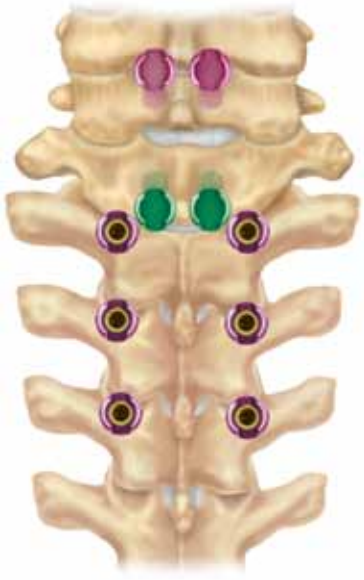


Figure 15a

Figure 15b

Rod Selection

The VERTEX MAX® Reconstruction System has various rod options available to accommodate unique surgical constructs. Threaded Rods can be assembled preoperatively and allow connection of a 3.2mm rod to a 4.5mm or 5.5mm rod for a cervical to thoracic spine transition. When using Threaded Rods, insert the threaded portion of the 3.2mm rod into the receiving end of a 4.5mm or 5.5mm Threaded Rod and turn clockwise until fully tightened. When the rod is correctly positioned, the flat portion of the 3.2mm rod near the locking mechanism will be facing up **(Figure 16)**. Tighten the internal locking mechanism on the Threaded Rod using the Straight Hex Torque Driver and the Torque Limiting Handle **(Figure 17)**.

VERTEX MAX® Rod Connectors can also be used to connect a 3.2mm rod to a 4.5mm or 5.5mm rod. 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 because of anatomical constraints. To link the systems, insert the 3.2mm rod and the 4.5mm 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 18)**. The parallel offset of the Rod Connector will accommodate medial/lateral positioning as well as allow for dorsal adjustment by rotating the connector.

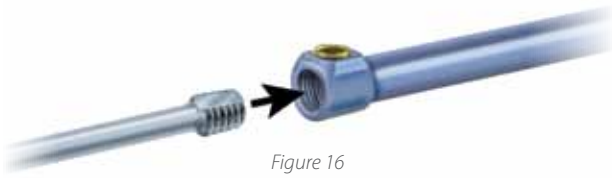


Figure 16

Figure 17

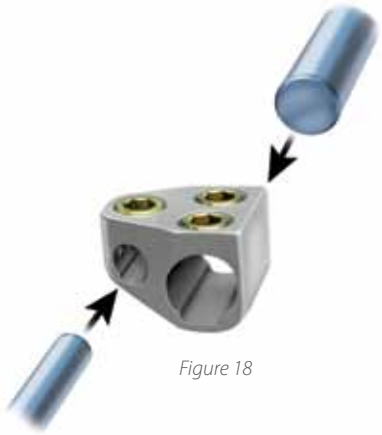


Figure 18

Rod Placement

The rod template is used to determine the curvature and length of the rod needed based on the screw position **(Figure 19)**. Use a marker to mark the rod at the appropriate length and then cut the rod using the Rod Cutter **(Figures 20a and 20b)**. Contour the rod to the sagittal contour of the spine and the medial/lateral orientation of the implants using the Rod Bender **(Figure 21)**.

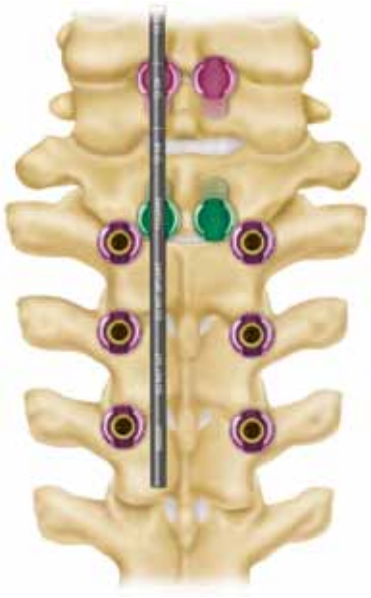


Figure 19

Figure 20a

Figure 20b

Figure 21

Rod Placement/Using Offset Connectors

The relief notches on VERTEX SELECT™ Multi-Axial Screws allow up to 7.5mm of medial/lateral variability* without the need for additional rod contouring **(Figure 22)**. If additional medial/lateral offset is required, Offset Connectors facilitate rod attachment of non-linear screws. The Lateral Offset Connector can also adjust for screw height difference as well as excessive angulation differences, such as medial/lateral angulation in the axial plane or cephalad/caudal in the sagittal plane. Lateral Offset Connectors are side loading to accommodate placement before or after rod insertion **(Figure 23)**.

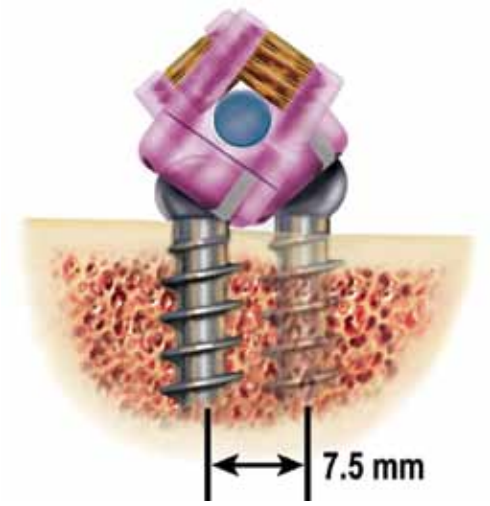


Figure 22

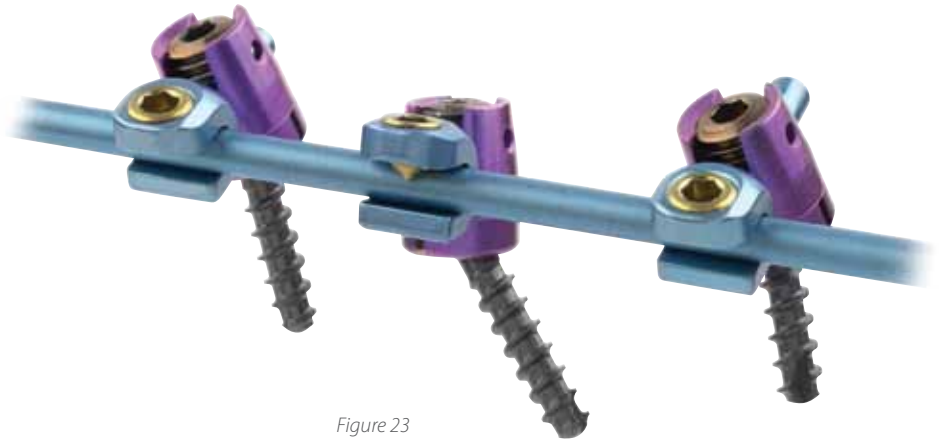


Figure 23

*Data based on Medtronic internal testing. Results available upon request.

Rod Placement/Reduction

Place the rod into the implant heads using the Rod Holder. With the rod fully seated in the screw heads, a set screw can be loaded onto the Self-Holding Screwdriver, placed through the Rod Pusher/Counter Torque, and seated into each screw head **(Figure 24)**. If the rod is not easily captured in the screw head, the Rod Reducer can be used to fully seat the rod and simplify set screw introduction. Place the Rod Reducer over the rod, and grasp the screw head notches from above. As the Rod Reducer handle is gently squeezed, the reducer sleeve will slide down and seat the rod. To secure the rod, load a set screw onto the Self-Holding Screwdriver and pass it through the cannulated portion of the Rod Reducer **(Figure 25)**. Turn the screwdriver clockwise to provisionally tighten.

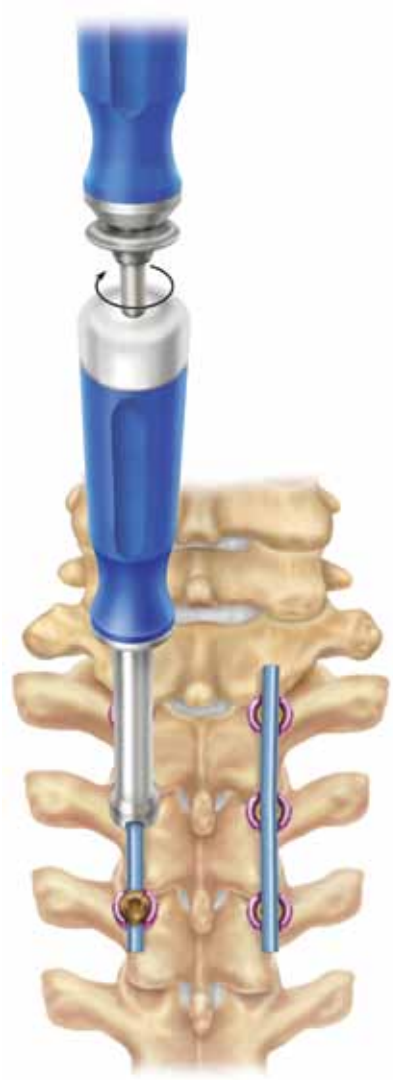


Figure 24

Figure 25

Compression/Distraction and Final Tightening

Once the rod is secured in the implants, in situ bending, distraction, and/or compression may be performed to place the implants in the final position. Compression maneuvers are most often carried out directly on two implants **(Figure 26)**.

After the compression and distraction maneuvers are complete, the set screws should be final tightened using the Straight Hex Torque Driver and Torque Limiting Handle in conjunction with the Rod Pusher/Counter Torque **(Figure 27)**, or the Straight Hex Screwdriver and Universal Handle in conjunction with the Rod Pusher/Counter Torque.

Figure 26

Figure 27

CROSSLINK® Plate Placement/Final Construct

Once decortication is thoroughly performed and allograft and autograft is placed, CROSSLINK® Plates are recommended for the top and bottom one-third of the construct to increase rigidity. Place the CROSSLINK® Plate on one of the rods and tighten the internal set screw using the Straight Hex Screwdriver with the Universal Handle. Repeat this step on the opposite side followed by hand tightening the center nut using the Lock Nut Driver with the Universal Handle. An intraoperative image of the final construct **(Figure 28)** should be made to verify proper correction is achieved prior to wound closure.

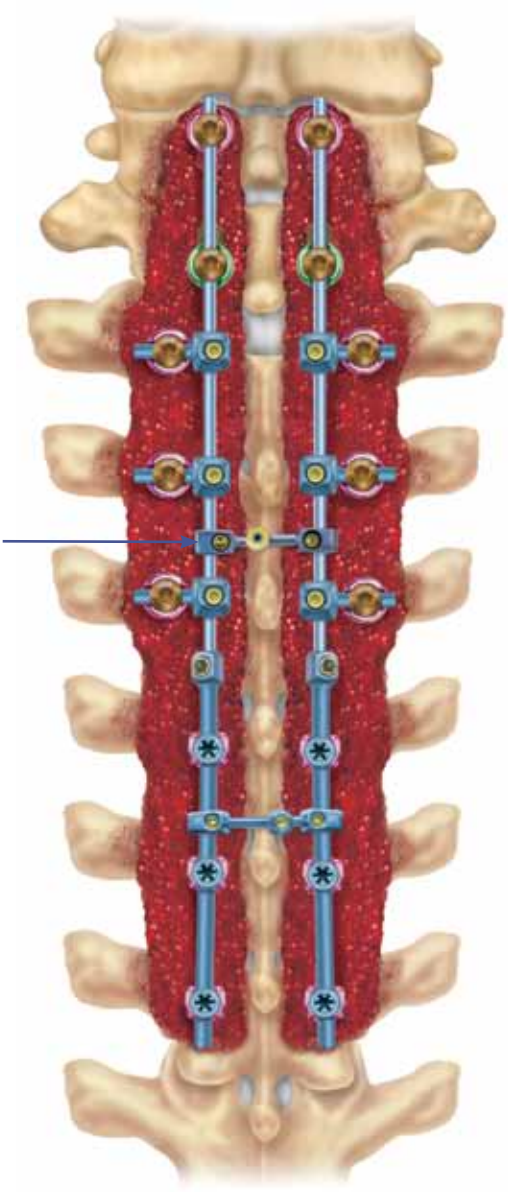


Figure 28

VERTEX MAX®

Reconstruction System

USING THE OCCIPITAL PLATE ROD

Rod Placement

For occipitocervical stabilization with the VERTEX MAX® Reconstruction System, first select and insert the cervical Laminar Hooks at the desired levels of fixation. Once the Laminar Hooks are in place, position the Occipitocervical Plate Rod **(Figure 29)** to determine the necessary adjustments required to align the rod with the Laminar Hooks and the most preferable Occipital Bone Screw position. The appropriate location for placement of Occipital Bone Screws must be determined preoperatively using CT scans or lateral radiographs. Occipital bone thickness varies tremendously and a clear understanding of the anatomy is required for safe screw placement. Anatomical landmarks should be identified and carefully reviewed to determine the entry points for the thickest bone.

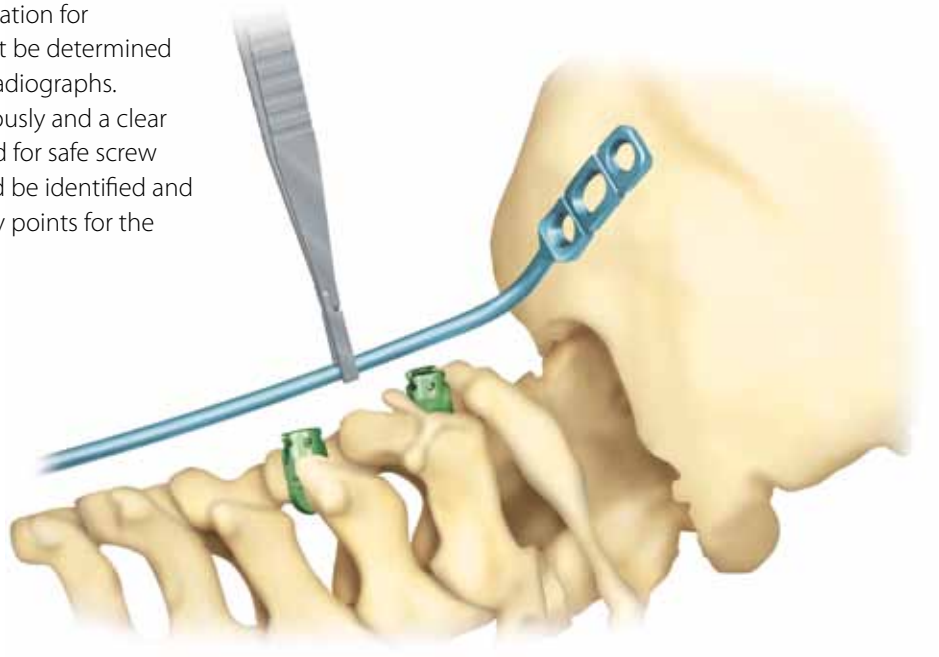


Figure 29

Rod Contouring

Cut the rod to the appropriate length using the Rod Cutter **(Figure 30)**. The Occipitocervical Plate Rods have been pre-contoured to minimize the need for bending. However, if necessary, use the Rod Bender **(Figure 31)** to contour the rod to best fit the individual patient anatomy. Contour the plate portion to conform with the occipital bone **(Figure 32)**.

Figure 30

Figure 31

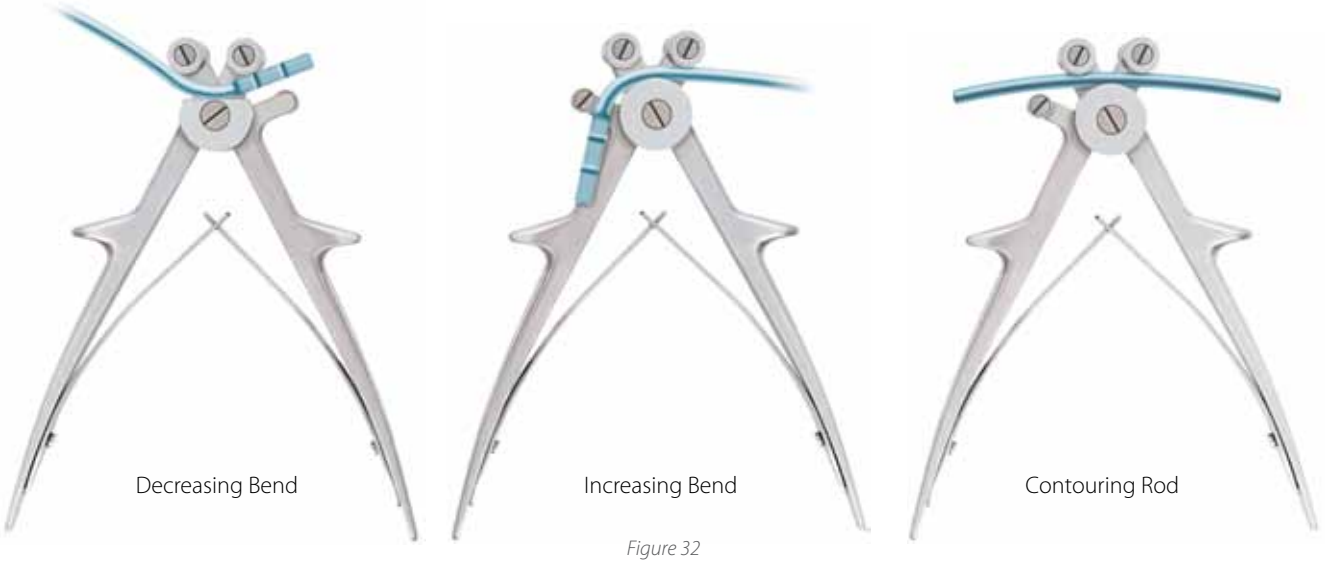


Figure 32

Rod Contouring *continued*

Once all of the hooks have been placed and the Occipital Plate Rods have been contoured to match the patient's anatomy **(Figure 33)**, provisionally tighten set screws in each hook to stabilize the rods.

In general, the thickest bone in the suboccipital region is the occipital keel (internal occipital protuberance), near the midline. When positioning the Plate Rods, it is, therefore, helpful to place them such that the occipital plate portion is directed medially.

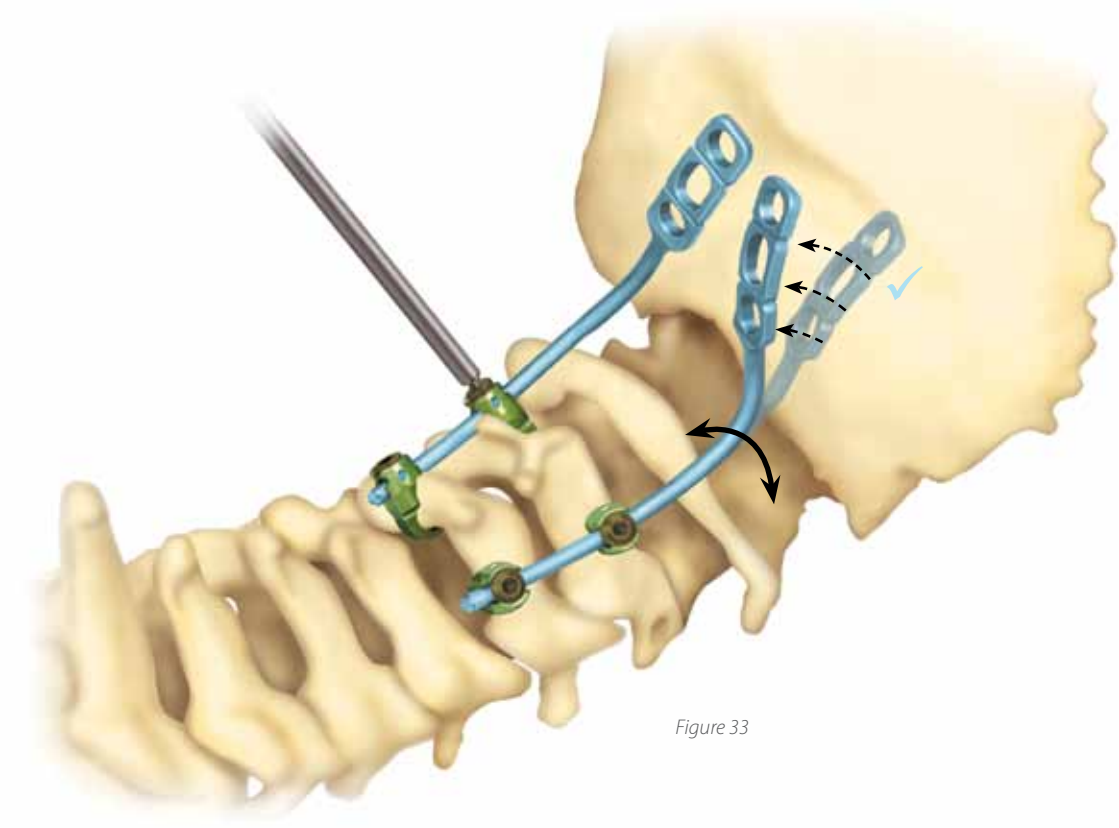


Figure 33

Surgeon Quote

"I allow the rod to roll at the apex portion of the bend to allow the cephalad portion of the rod to point medially."
– Dr. Rick Sasso

Drilling

For occipital fixation, 4.0mm (6mm to 18mm lengths) and 4.5mm (6mm to 18mm lengths) diameter Occipital Bone Screws are available. Separate drill bits and taps are required for each diameter screw. Select the appropriate drill bit and tap that match the desired screw diameter for occipital fixation **(Figure 34)**.

Occipital Bone Screws — Color Coding Reference

Screw Size	Color	Drill Bit	Tap
4.0mm × 6mm to 18mm	Light Blue	3.0mm (Cortical)	4.0mm (Cortical)
4.5mm × 6mm to 18mm	Gray	3.5mm (Cortical)	4.5mm (Cortical)

Use the Drill Guide to align the drill hole with the occipital component of the Plate Rod and drill to the desired depth. The desired depth is set prior to drilling by using the Adjustable Drill Guide **(Figure 35)**.

Surgeon Quote

"Using a high-speed drill, I set the Adjustable Drill Guide at the 10mm depth stop. I apply low force to the drill and feel as it goes through the far cortex. I then look to determine how much drill remains to select the appropriate length screw."

– Dr. Rick Sasso

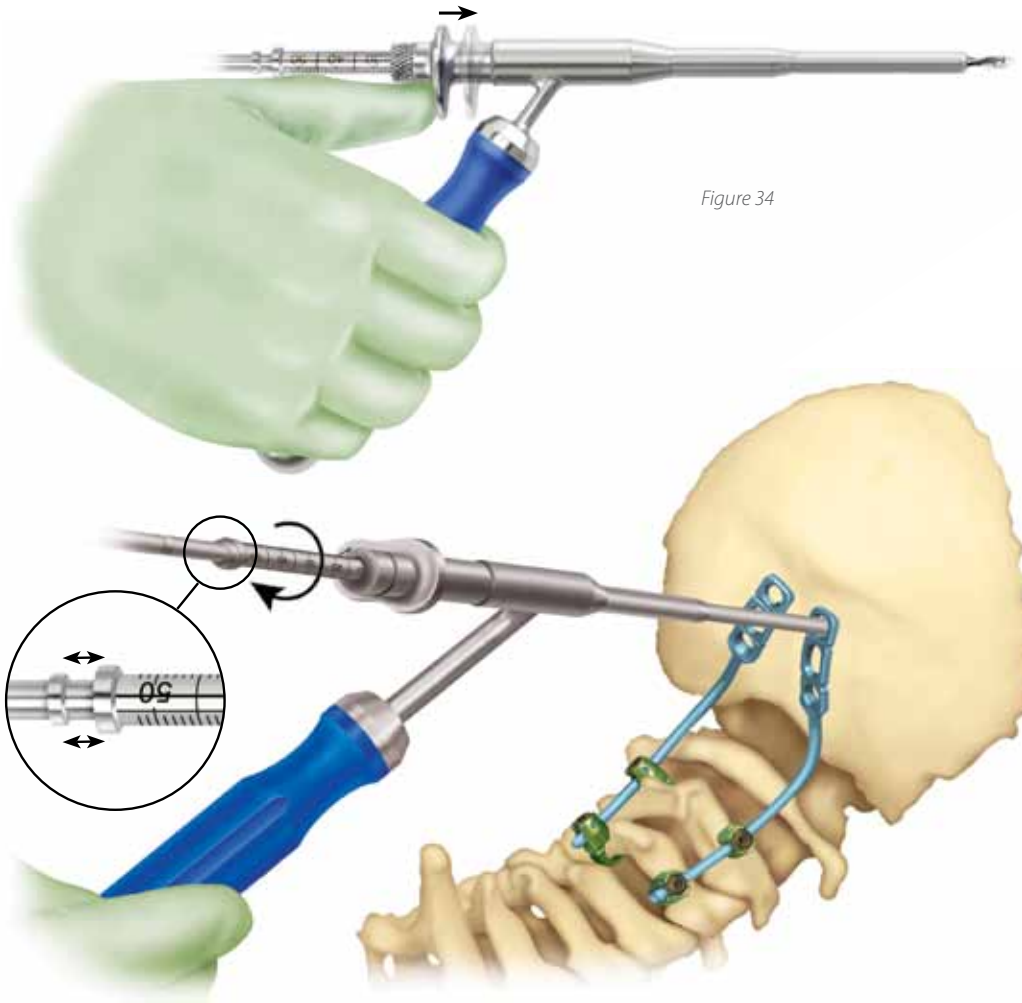


Figure 34

Figure 35

Screw Measurement/Tapping

The Depth Gauge should be used to verify the hole depth as well as the occipital bone thickness **(Figure 36)**. Once a satisfactory depth has been achieved, the appropriate tap can be used to prepare the screw hole **(Figure 37)**.

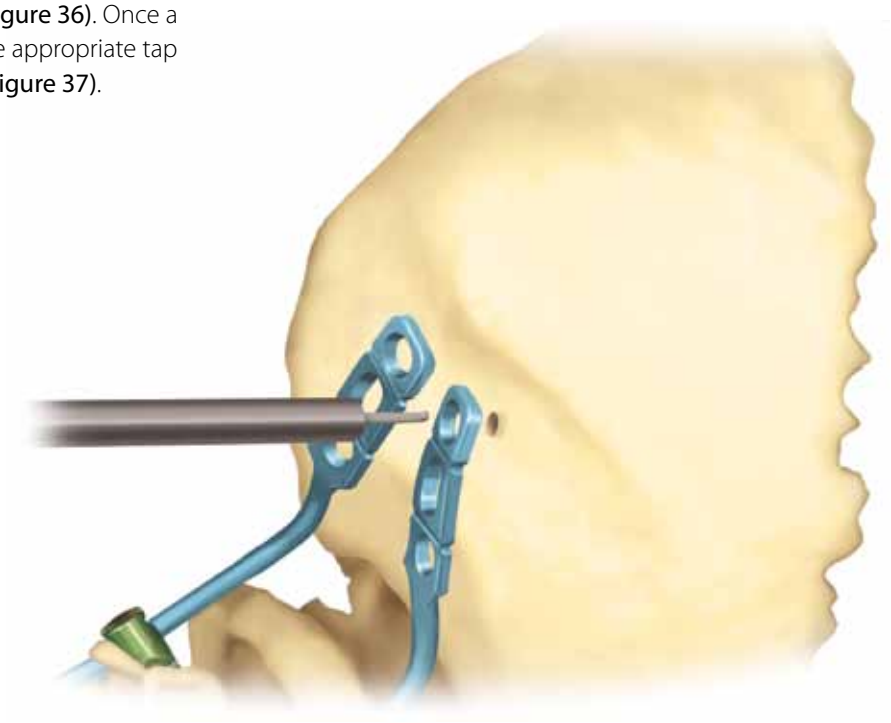


Figure 36

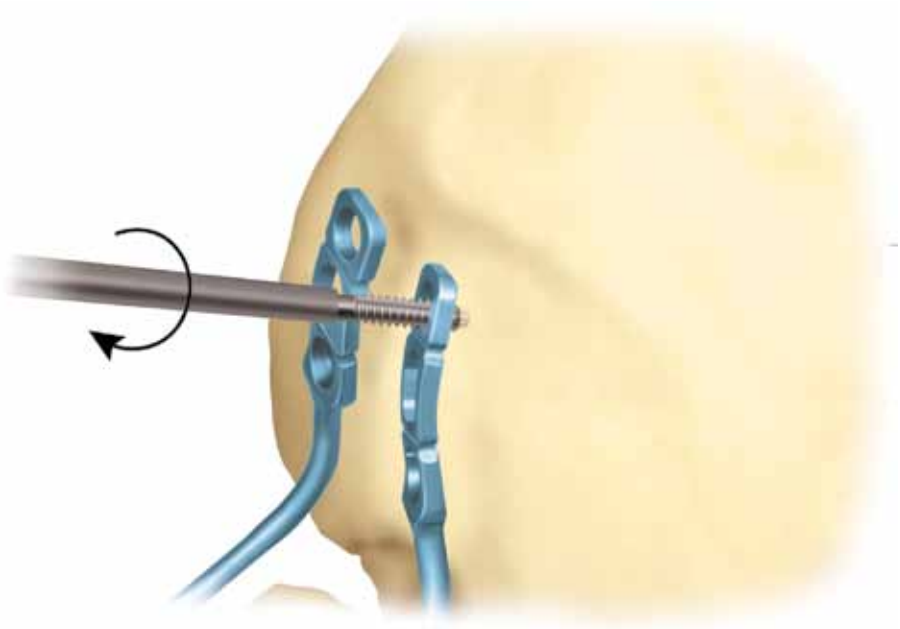


Figure 37

Screw Placement

Choose the appropriate diameter and length screw for each screw location and verify the diameter and length before placement. Use the Self-Holding Screwdriver to insert the appropriate diameter and length screw and provisionally tighten **(Figure 38)**.The remaining screws can be placed using the same technique. Once all of the screws have been placed, securely hand tighten to the final position **(Figure 39)**.

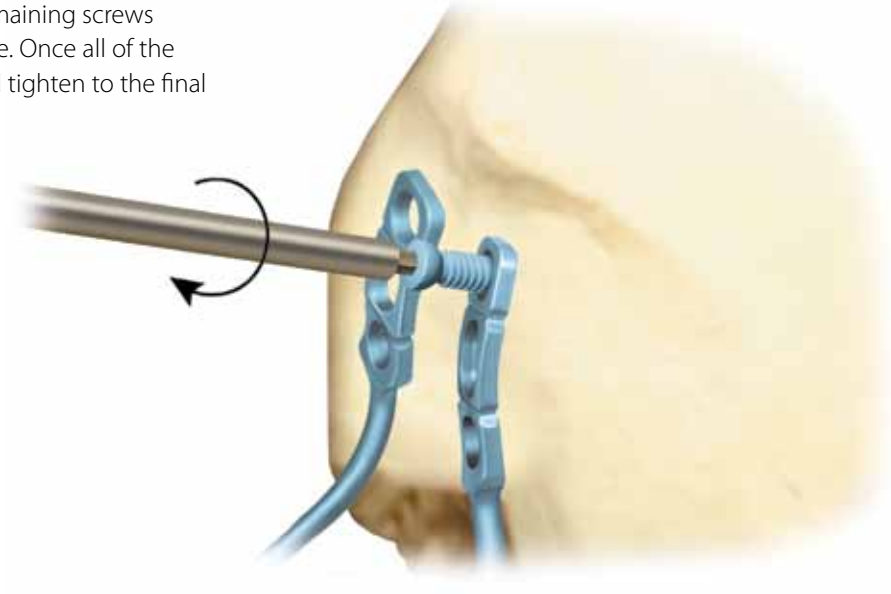


Figure 38

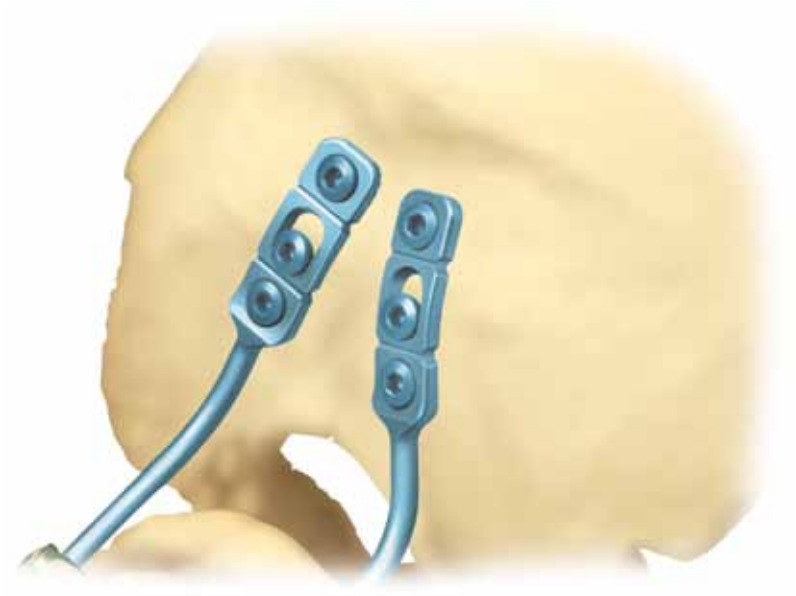


Figure 39

Final Tightening

Once all of the Occipital Bone Screws have been placed, all of the set screws in the hooks should be final tightened using the Straight Hex Torque Driver and Torque Limiting Handle in conjunction with the Rod Pusher/Counter Torque **(Figure 40)**.

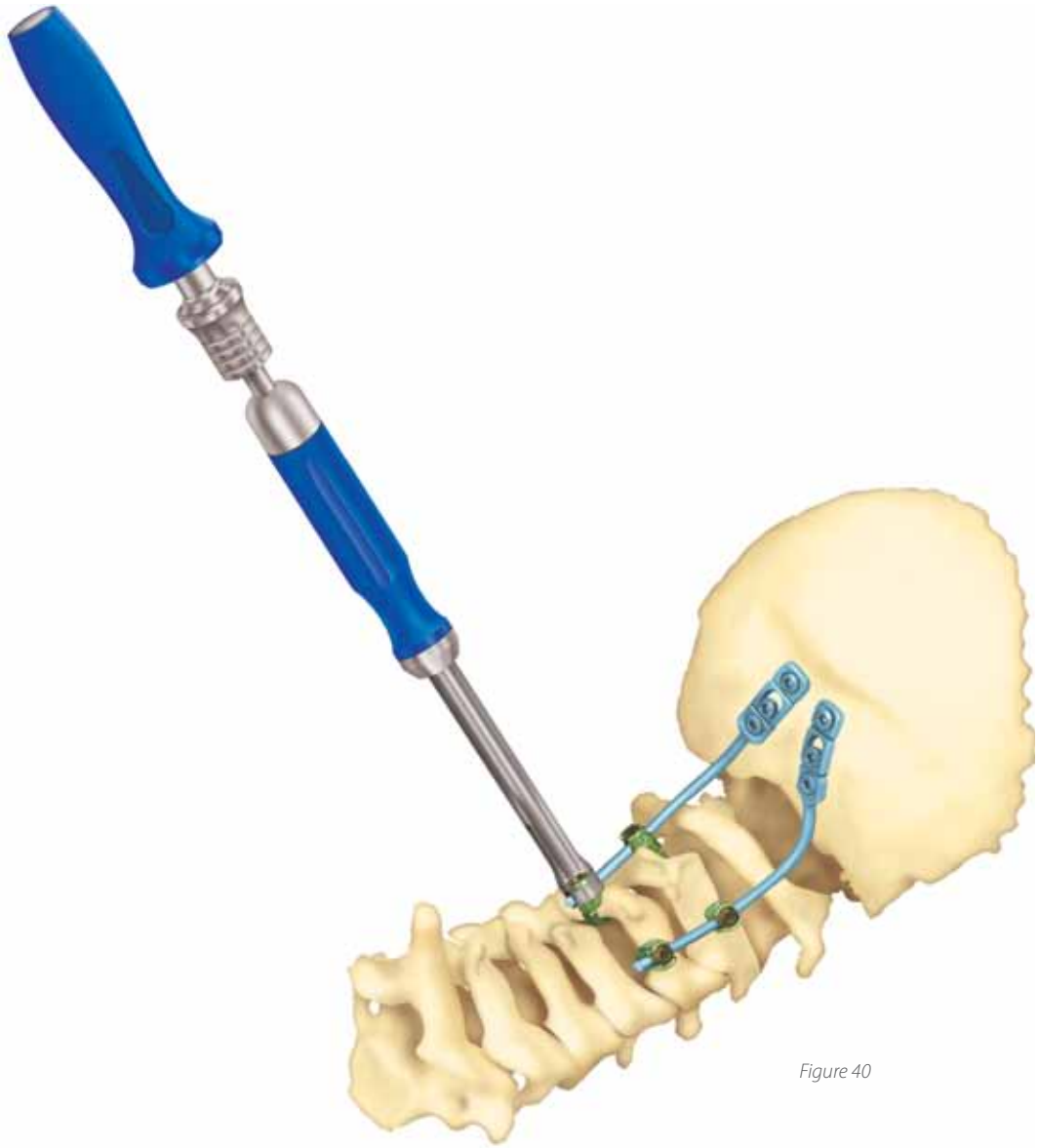


Figure 40

Final Construct

CROSSLINK® Plates are recommended for the top and bottom one-third of the construct to increase rigidity. Recheck all of the final construct **(Figure 41)** connections prior to wound closure.

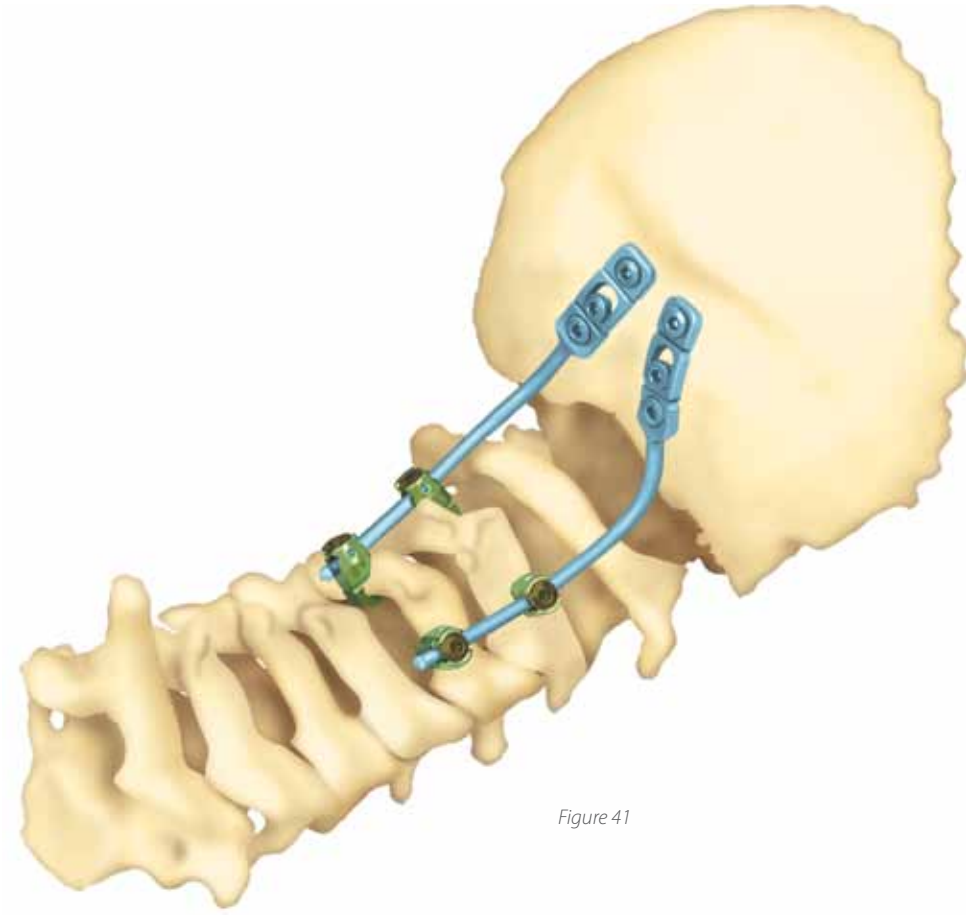


Figure 41

VERTEX MAX®

Reconstruction System

USING THE OCCIPITAL KEEL PLATE

Keel Plate Placement

In general, the thickest bone in the suboccipital region is the occipital keel (internal occipital protuberance), near the midline. When positioning the Occipital Keel Plate it should be centered in the midline between the external occipital protuberance (EOP) and the posterior border of the foramen magnum **(Figure 42)**.

The goal is to maximize bone purchase (closer to EOP) while achieving a low profile.

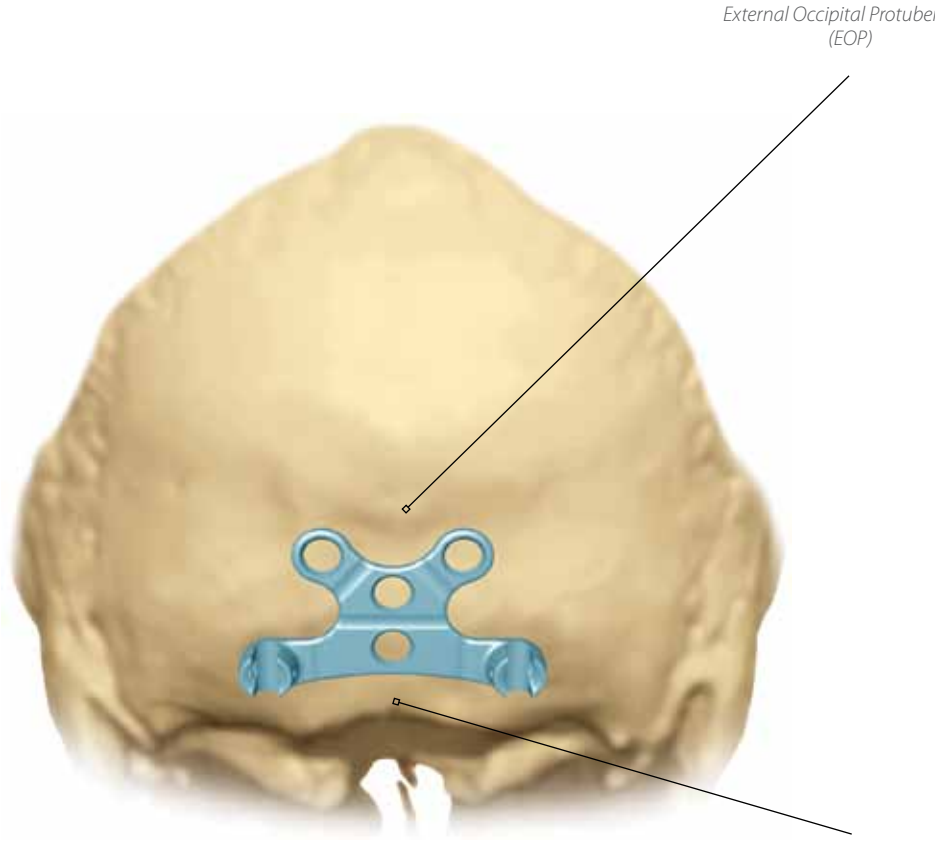


Figure 42

Keel Plate Placement *continued*

Once all of the Laminar Hooks have been placed, the proper plate size is determined by using the rod alignment of the cervical Laminar Hooks **(Figure 43)**.

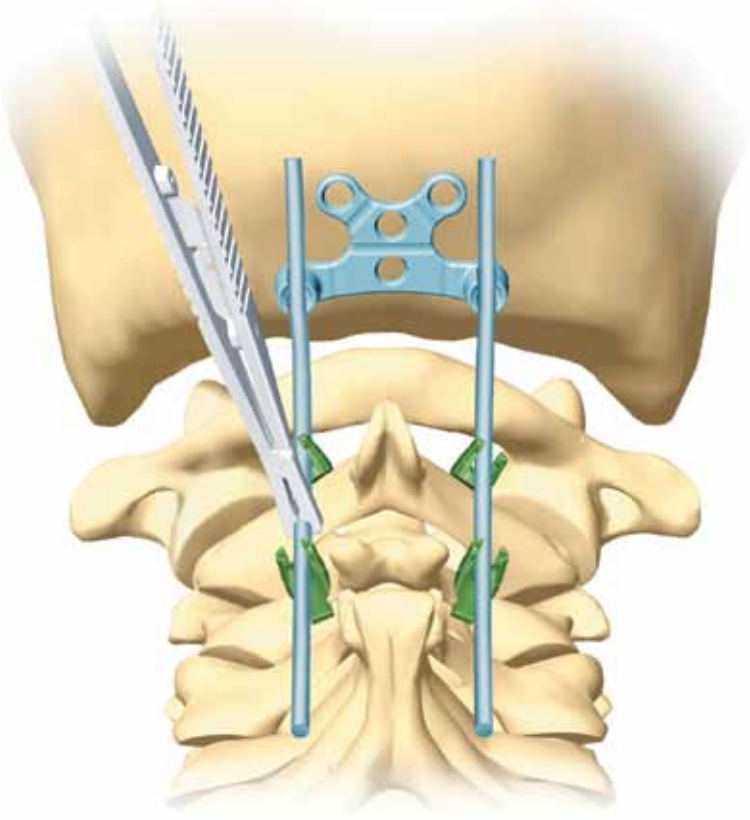


Figure 43

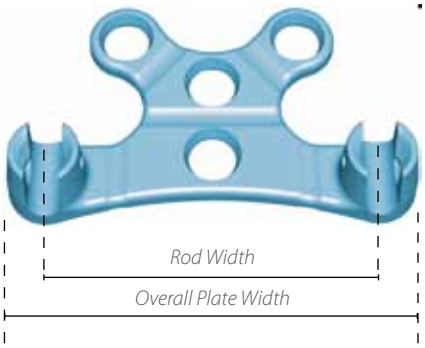


Plate Sizes

Sizes	Rod Width	Overall Width
Small	24mm	32.6mm
Medium	36mm	44.6mm
Large	40mm	48.6mm

Surgeon Quote

"I like to place the set screws in the laminar hooks at this point but not tighten them to the rods. I then slide the appropriate size occipital plate under the rod (from the cephalad direction) into position. If any plate contouring is necessary, I can easily remove the plate, contour it, and reposition. I then fix the plate to the occipital bone with bone screws."

– Dr. Kevin Foley

Keel Plate Contouring

If necessary, the plate can be contoured along the bend zones **(Figure 44)** utilizing the Left and Right Bending Irons to allow for a more anatomic fit against the occiput **(Figure 45)**. Repeated bending may compromise the integrity of the implant. It may be necessary to contour a small portion of uneven occipital bone with a high-speed drill to allow the plate to lie flush.

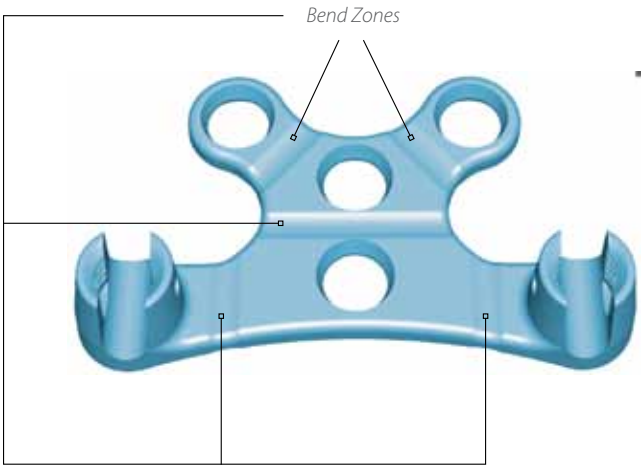


Figure 44

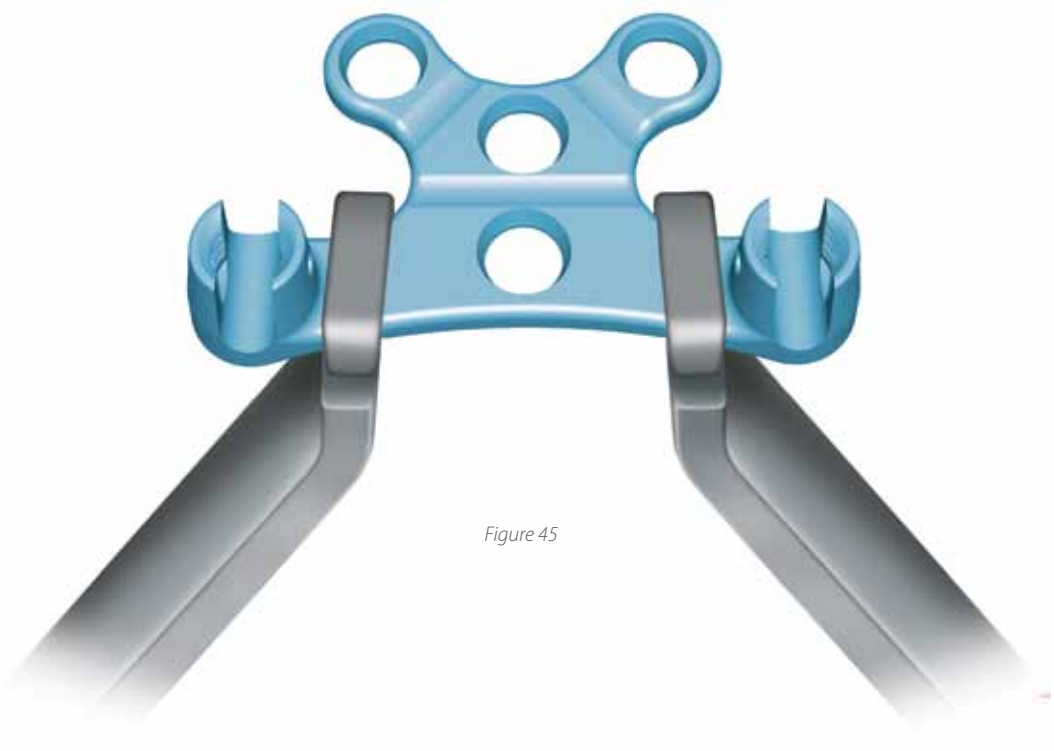


Figure 45

Drilling

For occipital fixation, 4.0mm (6mm to 18mm lengths) and 4.5mm (6mm to 18mm lengths) diameter screws are available. Separate drill bits and taps are required for each diameter screw. Select the appropriate drill bit and tap that match the desired screw diameter for occipital fixation **(Figure 46)**.

Occipital Bone Screws — Color Coding Reference

Screw Size	Color	Drill Bit	Tap
4.0mm × 6mm to 18mm	Light Blue	3.0mm (Cortical)	4.0mm (Cortical)
4.5mm × 6mm to 18mm	Gray	3.5mm (Cortical)	4.5mm (Cortical)

Use the Drill Guide to align the drill hole with the midline plate and drill to the desired depth. The desired depth is set prior to drilling by using the Adjustable Drill Guide **(Figure 47)**.

Surgeon Quote

"Using a high-speed drill, I set the Adjustable Drill Guide at the 10mm depth stop. I apply low force to the drill and feel as it goes through the far cortex. I then look to determine how much drill remains to select the appropriate length screw."

– Dr. Rick Sasso

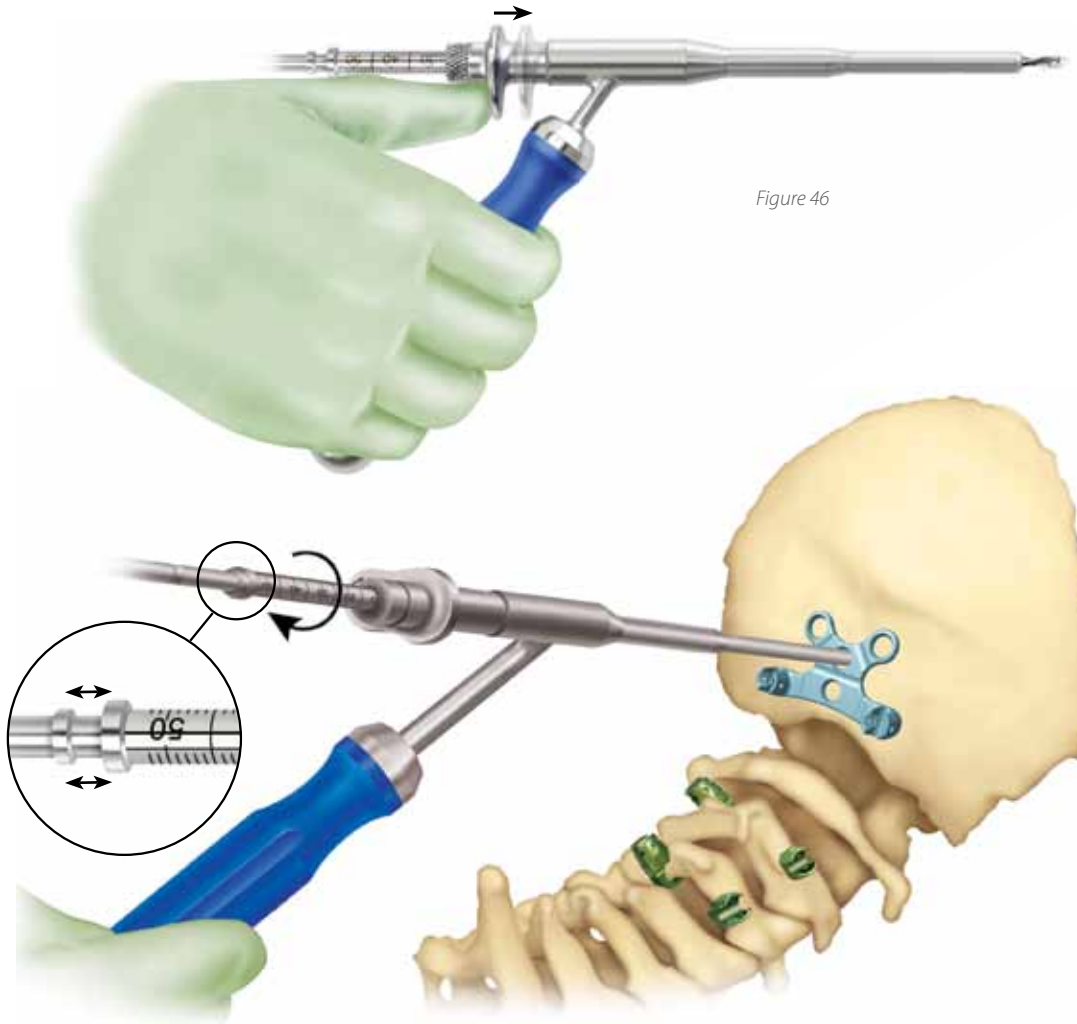


Figure 46

Figure 47

Screw Measurement/Tapping

The Depth Gauge should be used to verify the hole depth as well as the occipital bone thickness **(Figure 48)**. Once a satisfactory depth has been achieved, the appropriate tap can be used to prepare the screw hole **(Figure 49)**.

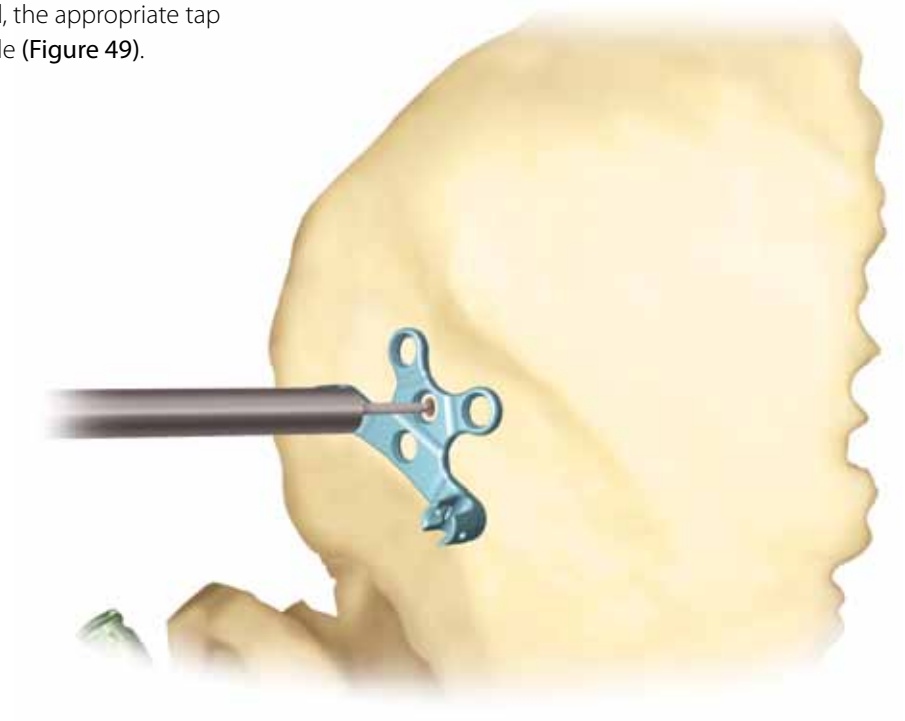


Figure 48

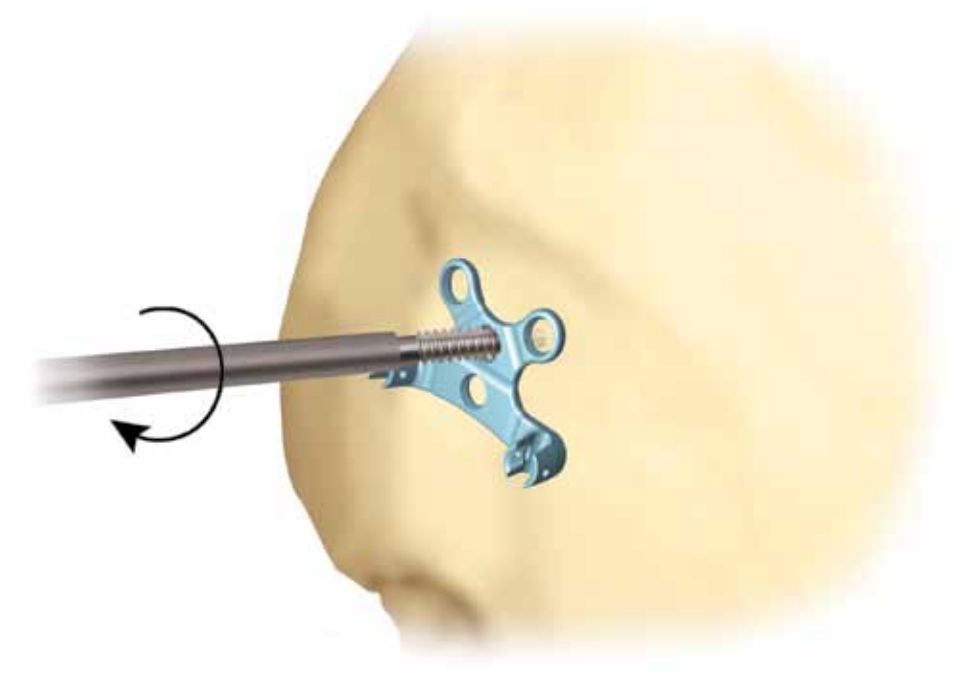


Figure 49

Screw Placement

Choose the appropriate diameter and length screw for each Occipital Bone Screw location and verify the diameter and length before placement. Use the Self-Holding Screwdriver to insert the appropriate diameter and length screw and provisionally tighten **(Figure 50)**.

The remaining screws can be placed using the same technique. Once all of the screws have been placed, securely hand tighten to the final position **(Figure 51)**.

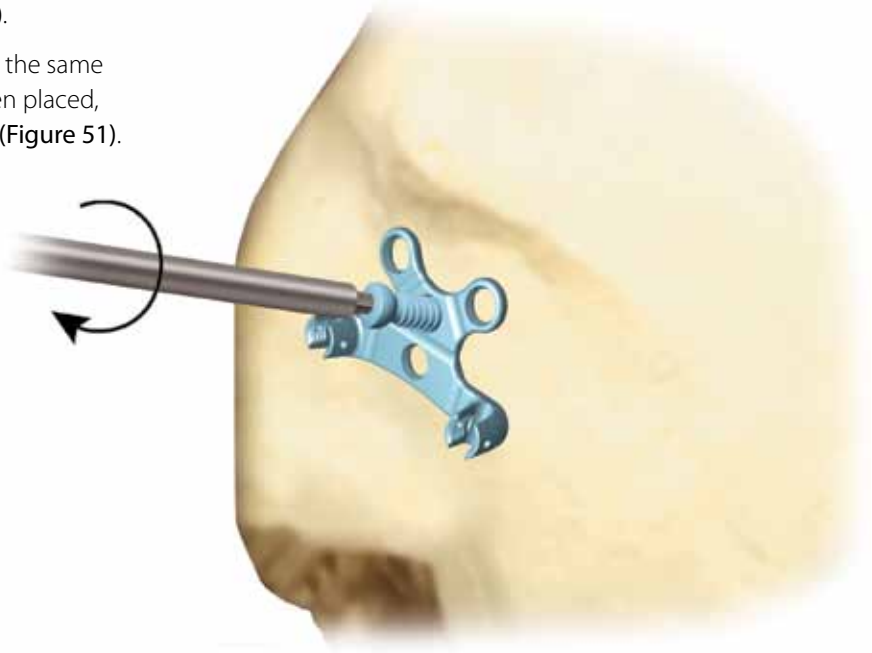


Figure 50

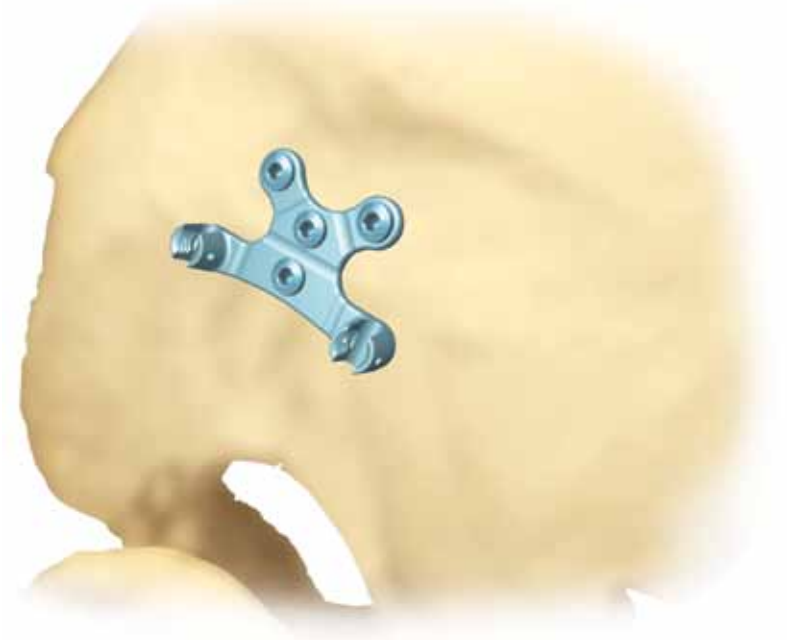


Figure 51

Rod Contouring

Cut the rod to the appropriate length using the Rod Cutter **(Figure 52)**.

The Occipital Rod has been precontoured **(Figure 53)** to minimize the need for bending. However, if needed, use the Rod Bender to contour the rod **(Figure 54)** to best fit the individual patient anatomy.

Figure 52

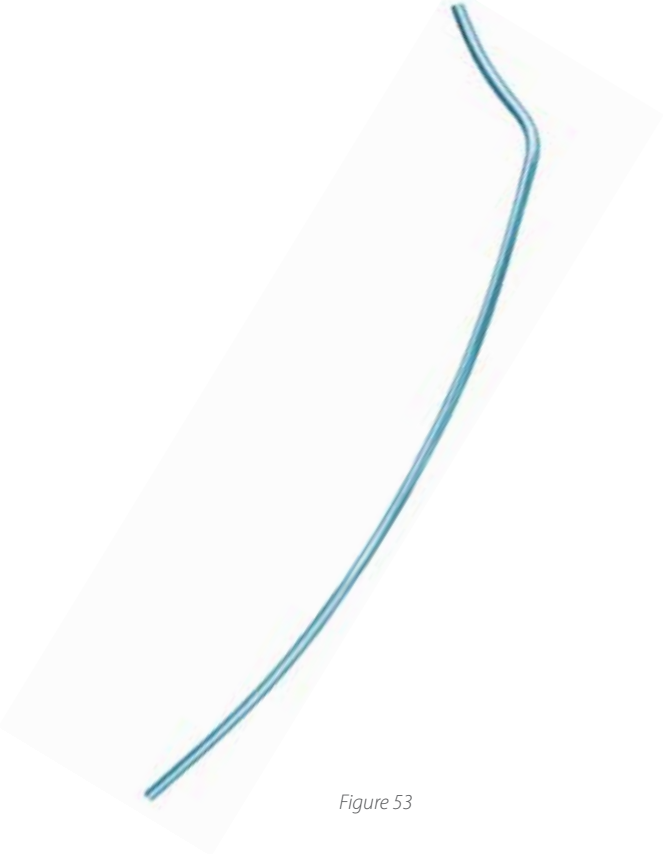


Figure 53

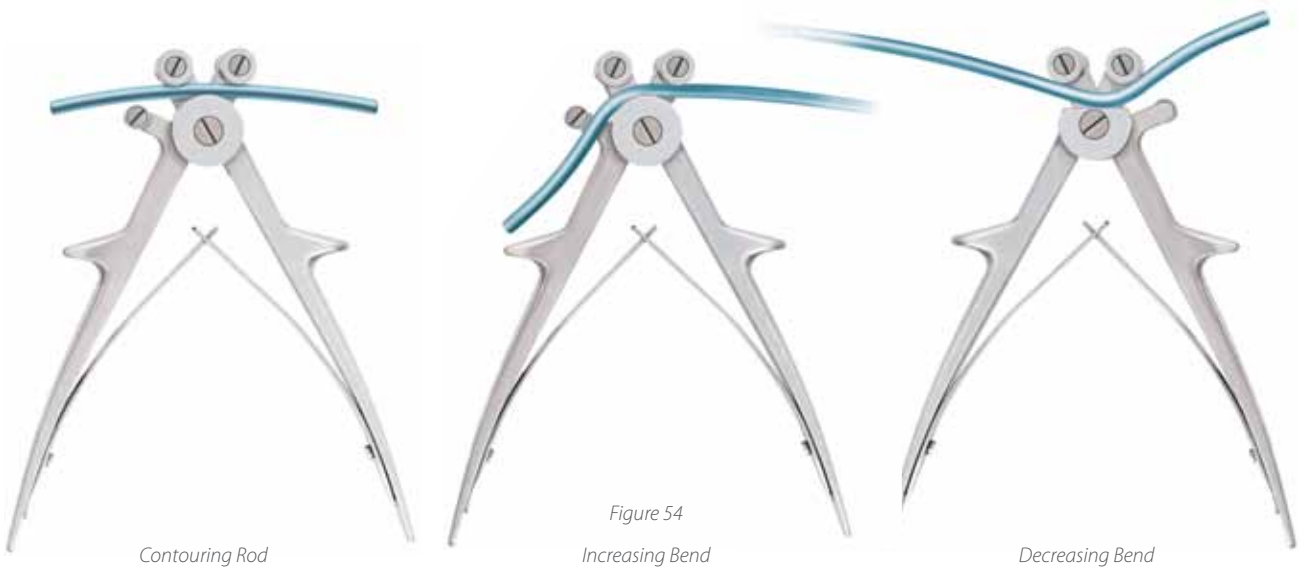


Figure 54

Contouring Rod *Increasing Bend* *Decreasing Bend*

Final Tightening/Final Construct

Once the rods have been contoured to match the patient's anatomy, provisionally tighten set screws in each Laminar Hook and in the Occipital Keel Plate to stabilize the rods.

Once all of the screws have been placed, they should be final tightened using the Straight Hex Torque Driver and Torque Limiting Handle in conjunction with the Rod Pusher/Counter Torque.

CROSSLINK® Plates are recommended for the top and bottom one-third of the construct to increase rigidity.

Recheck all of the final construct **(Figure 55)** connections prior to wound closure.

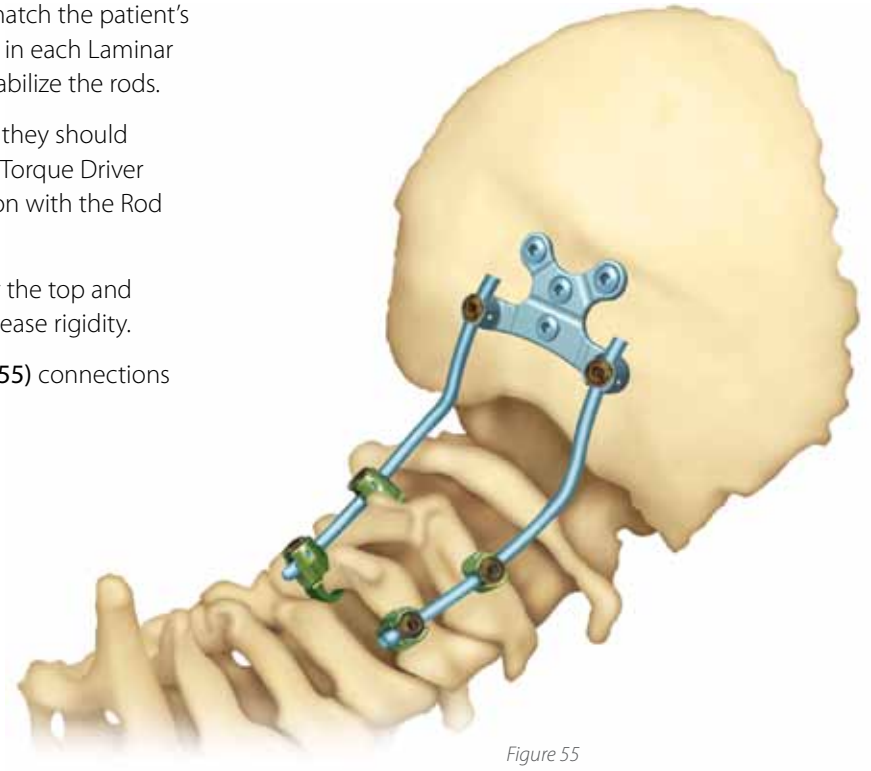


Figure 55

Explantation

To remove any of the VERTEX MAX® Reconstruction System implants described throughout this technique, engage the set screw, multiaxial screw, and the occipital bone screw with a 2.5mm Hex Screwdriver and turn counter- clockwise until the set screw is disengaged from the implant, and the bone screw until it is disengaged from the bone. The implant can then be removed from the bone.

Product Ordering Information

Titanium Rods

Item #	Description
6900120	3.2mm × 120mm
6900240	3.2mm × 240mm
6955240	3.2mm × 240mm, Threaded
6955245	4.5mm × 360mm, Threaded
6955255	5.5mm × 360mm, Threaded
6955260	3.2mm × 100mm, Precurved Occipital Rod
6955270	3.2mm × 200mm, Precurved Occipital Rod

Occipital Plate Rods

Item #	Description
6900270	3.2mm × 100mm, Precurved Occipital Plate Rod
6900280	3.2mm × 200mm, Precurved Occipital Plate Rod

Occipital Keel Plates

Item #	Description
6955273	Occipital Keel Plate, Small
6955274	Occipital Keel Plate, Medium
6955275	Occipital Keel Plate, Large

Set Screw

Item #	Description
6950315	Set Screw

Occipital Bone Screws

Item #	Description
6955406	4.0mm × 6mm
6955408	4.0mm × 8mm
6955410	4.0mm × 10mm
6955412	4.0mm × 12mm
6955414	4.0mm × 14mm
6955416	4.0mm × 16mm
6955418	4.0mm × 18mm
6955506	4.5mm × 6mm
6955508	4.5mm × 8mm
6955510	4.5mm × 10mm
6955512	4.5mm × 12mm
6955514	4.5mm × 14mm
6955516	4.5mm × 16mm
6955518	4.5mm × 18mm

Multi-Axial Screws

Item #	Description
6958710	3.5mm × 10mm
6958712	3.5mm × 12mm
6958714	3.5mm × 14mm
6958716	3.5mm × 16mm
6958718	3.5mm × 18mm
6958720	3.5mm × 20mm
6958722	3.5mm × 22mm
6958724	3.5mm × 24mm
6958810	4.0mm × 10mm
6958812	4.0mm × 12mm
6958814	4.0mm × 14mm
6958816	4.0mm × 16mm
6958818	4.0mm × 18mm
6958820	4.0mm × 20mm
6958822	4.0mm × 22mm
6958824	4.0mm × 24mm
6958826	4.0mm × 26mm
6958828	4.0mm × 28mm
6958830	4.0mm × 30mm
6958832	4.0mm × 32mm
6958834	4.0mm × 34mm
6958836	4.0mm × 36mm
6958838	4.0mm × 38mm
6958840	4.0mm × 40mm
6958842	4.0mm × 42mm
6958844	4.0mm × 44mm
6958846	4.0mm × 46mm
6958848	4.0mm × 48mm
6958850	4.0mm × 50mm
6958852	4.0mm × 52mm
6958910	4.5mm × 10mm
6958912	4.5mm × 12mm
6958914	4.5mm × 14mm
6958916	4.5mm × 16mm
6958918	4.5mm × 18mm
6958920	4.5mm × 20mm
6958922	4.5mm × 22mm
6958924	4.5mm × 24mm
6958926	4.5mm × 26mm
6958928	4.5mm × 28mm
6958930	4.5mm × 30mm
6958932	4.5mm × 32mm
6958934	4.5mm × 34mm
6958936	4.5mm × 36mm
6958938	4.5mm × 38mm
6958940	4.5mm × 40mm
6958942	4.5mm × 42mm

Product Ordering Information *continued*

Partially Threaded Multi-Axial Screws

Item #	Description
6958826PT	4.0mm × 26mm, 13mm Threads
6958828PT	4.0mm × 28mm, 14mm Threads
6958830PT	4.0mm × 30mm, 15mm Threads
6958832PT	4.0mm × 32mm, 16mm Threads
6958834PT	4.0mm × 34mm, 17mm Threads
6958836PT	4.0mm × 36mm, 18mm Threads
6958838PT	4.0mm × 38mm, 19mm Threads
6958840PT	4.0mm × 40mm, 20mm Threads

Screw Connector

Item #	Description
6901000	Screw Connector

Lateral Connectors

Item #	Description
6955960	10mm Lateral Offset Connector, Open
6955965	13mm Lateral Offset Connector, Open

Rod Connectors

Item #	Description
6902200	3.2mm to 5.5mm
6902220	3.2mm to 4.5mm

CROSSLINK® Plate Connectors

Item #	Description
7002525	Small
7002526	Medium
7002527	Large

Laminar Hooks

Item #	Description
6955973	4.5mm Laminar Hook
6955974	6.0mm Laminar Hook
6955975R	4.5mm Laminar Hook, Right Offset
6955975L	4.5mm Laminar Hook, Left Offset
6955977R	6.0mm Laminar Hook, Right Offset
6955977L	6.0mm Laminar Hook, Left Offset

Instrument Set

Item #	Description
Item	Description
6956001	Awl Shaft
6956003	Pedicle Probe
6956005	Adjustable Drill Guide
6956006	14mm Drill Guide
6905715	Circular Drill Bit Adapter
6956016	Universal Handle
6956020	Depth Gauge
8572102	Pedicle Feeler
6956030	Tap Sleeve
6956035	3.5mm Tap (10 – 24mm)
6956040	4.0mm Tap (10 – 24mm)
6956041	4.0mm Tap (26 – 52mm)
6956045	4.5mm Tap (10 – 42mm)
6956140	4.0mm Cortical Tap (6 – 18mm)
6956145	4.5mm Cortical Tap (6 – 18mm)
6956148	Bone Reamer
6956155	Self-Holding Screwdriver Shaft
6956195	Threaded Screwdriver
6905785	Alignment Tool
6956158	Laminar Elevator
6956160	Hook Holder
6900241	3.2mm × 240mm Rod Template
6956163	Rod Gripper
6905782	Rod Bender
6905784	Rod Cutter
6956165	Ratcheting Rod Cutter
6956170	Rod Pusher/Counter Torque
6905787	Compression Forceps
6905788	Distractor Forceps
6956175	Rod Reducer
6956190L	Bending Irons, Left
6956190R	Bending Irons, Right
6956193	Straight Hex Screwdriver
6956200	Torque Limiting Handle
6956201	Straight Hex Torque Driver 3/8" End
6956164	Rod Holder
7005776	Lock Nut Driver

Disposable Drill Bits

Item #	Description
6956010	Sterile 2.4mm Drill Bit (10 – 24mm)
6956011	Sterile 2.9mm Drill Bit (26 – 52mm)
6956012	Sterile 3.0mm Cortical Drill Bit (6 – 18mm)
6956013	Sterile 3.5mm Cortical Drill Bit (6 – 18mm)
6956007	Non Sterile 2.4mm Drill Bit (10 – 24mm)
6956008	Non Sterile 2.9mm Drill Bit (26 – 52mm)
6956017	Non Sterile 3.0mm Cortical Drill Bit (6 – 18mm)
6956018	Non Sterile 3.5mm Cortical Drill Bit (6 – 18mm)

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 upper thoracic spine.

DESCRIPTION

The VERTEX® Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® cable may be used with this system at the surgeon's discretion. See the package inserts of both of those systems for labeling limitations.

The VERTEX® Reconstruction System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium, medical grade titanium alloy, and/or medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and or/cobalt chromium with stainless steel in the same construct. The VERTEX® Reconstruction System includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt chromium implants only. The posted screw connectors and some multi-axial screws contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability.

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 do so in this or another MEDTRONIC document. As with all orthopedic and neurosurgical implants, none of the VERTEX® Reconstruction System components should ever be reused under any circumstances.

INDICATIONS

When intended as an adjunct to fusion of the occipitocervical spine, cervical spine, and the thoracic spine, (Occiput-T3), the VERTEX® Reconstruction System is indicated for skeletally mature patients using allograft and/or autograft for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Occipitocervical Components: Plate Rod/Plates/Rods/Occipital Screws/Hooks

The occipitocervical plate rods, plates, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, these screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine.

Occipitocervical constructs require bilateral fixation to C2 and below.

Note: Segmental fixation is recommended for these constructs.

Hooks and Rods

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Multi-axial Screws/Connectors

The use of multi-axial screws are limited to placement in T1-T3. The screws are not intended to be placed in the cervical spine.

Titanium ATLAS® Cable System to be used with the VERTEX® Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

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. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
14. Any patient unwilling to follow postoperative instructions.
15. Any case not described in the indications.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. **Severe bone resorption.**
2. **Osteomalacia.**
3. **Severe osteoporosis.**

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, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. 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. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stresses shielding.
18. Graft donor site complications including pain, fracture, or wound healing problems.
19. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
20. 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.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

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

WARNINGS AND PRECAUTION

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.

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 severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices 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.

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.

!USA **FOR US AUDIENCES ONLY**

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Important Information on the VERTEX® Reconstruction System *continued*

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 pre-dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. 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 VERTEX® RECONSTRUCTION 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. 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, use pre-cut rods of the length needed.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. To insert a screw properly, drill a pilot hole corresponding to selected screw size and prepare screw site with a sharp tap.
6. **Caution:** Do not overtap or use a screw that is either too long or too large. Overtapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.
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. Before closing the soft tissues, all of the screws or set screws should be tightened firmly. Recheck the tightness of all screws or set screws after finishing to make sure that none loosened during the tightening of the other screws or set 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. 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-steroidals 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 VERTEX® Reconstruction 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 should 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 VERTEX® Reconstruction 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.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened MEDTRONIC 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. 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. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum *	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

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 or 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.

Contact Customer Service or your Sales Representative for the most up-to-date version of the package insert.

EC REP

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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 judgment 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 important medical information.

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