Medtronic

VERTEX SELECT®

Reconstruction System Occipitocervical Module

Surgical Technique

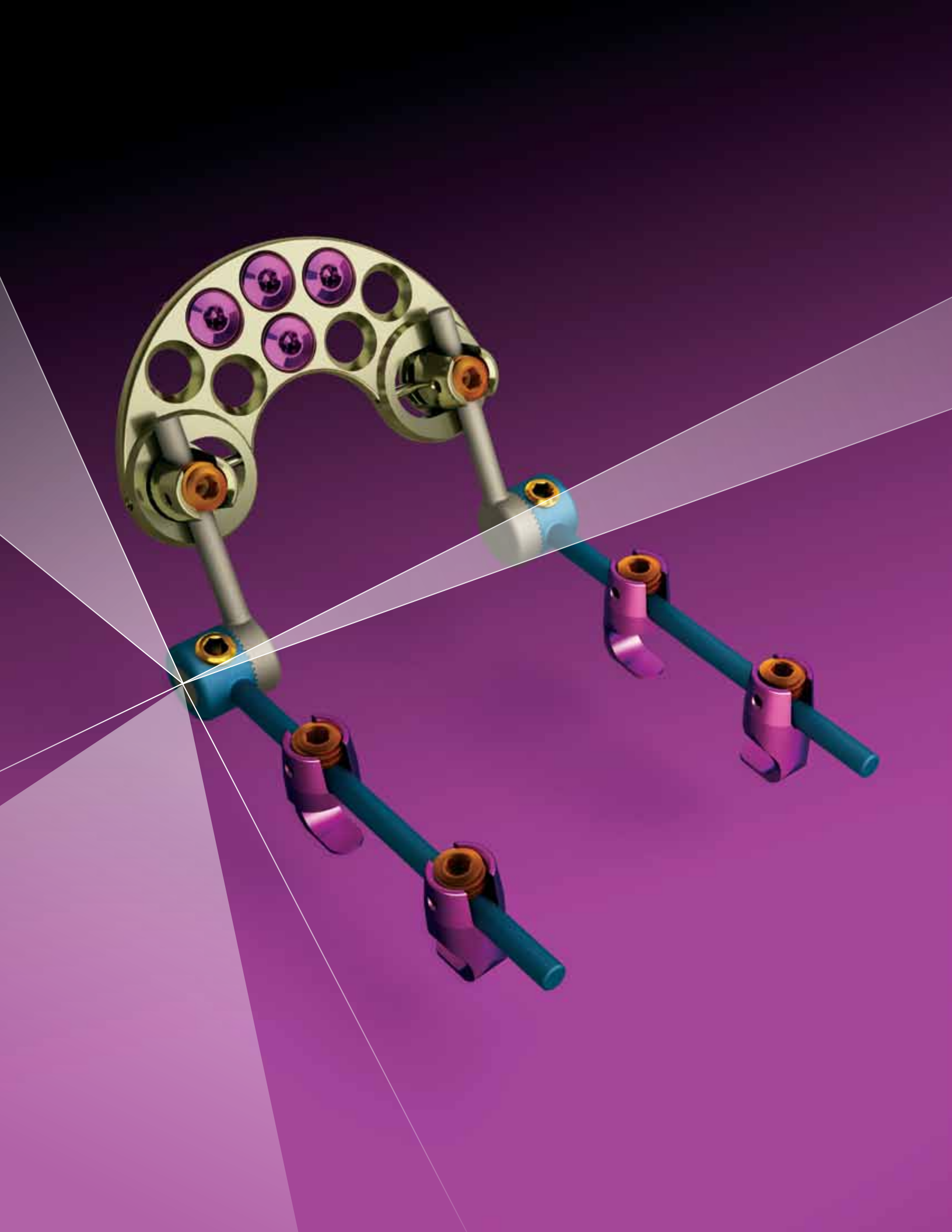
ADJUSTABILITY.
FLEXIBILITY.
ADAPTABILITY.

The module is a "Three-in-One" set of options that provides adjustability, flexibility, and adaptability to accommodate for anatomical challenges within the occipitocervical spine.

1 Providing various occipital fixation solutions with surgeon's choice of an Adjustable OC Plate, fixed midline plates, plate/rods, and screw connectors.

2 Versatile occipitocervical connection options with adjustable and precurved rods.

3 Flexible shaft and alternate angle instruments to address anatomical challenges in the occipitocervical spine.



Medtronic

VERTEX SELECT®

Reconstruction System Occipitocervical Module

Surgical Technique

Occipital Fixation Implant Features

Occipitocervical Bone Screws

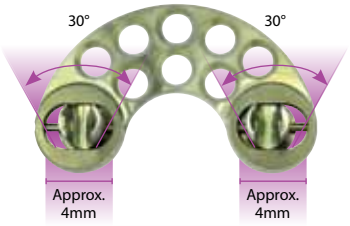
- Increased diameters – 4.5mm and 5.0mm*
- Slightly tapered tip for easier insertion
- Increased thread pitch*

Occipitocervical Screw Connectors

- Allows for six points of occipital midline fixation
- Flexibility in placement on the occiput in the cephalad/caudal directions
- Longer offset connectors for flexibility in the medial/lateral plane
- Dorsal height adjustment capabilities accommodate uneven bone surfaces
- Accepts 4.5mm and 5.0mm diameter occipital bone screws
- Accepts Precontoured Occipital Rod and Occipital Adjustable Rod
- Low profile occipital fixation option

Adjustable OC Plate

- Rotating and translating saddles allow for flexibility in rod placement
- Multiple screw holes for flexible screw placement (must place at least four screws)
- Arched design for increased bone graft volume on the occiput
- Low profile design
- Lateral screw placement for torsional stability
- Easily contoured with the Occipital Plate Bender



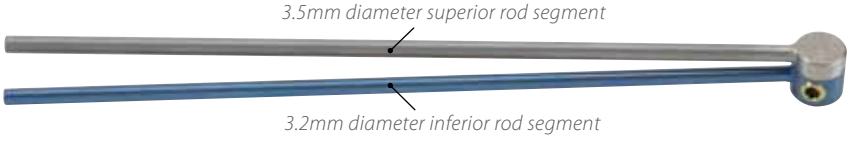
Occipitocervical Midline Fixed Plates

- Allows for occipital midline fixation
- Low profile design
- Lateral screw placement allows for torsional stability
- Multiple sizes available to match patient anatomy
- Accepts 4.5mm and 5.0mm diameter occipital bone screws
- Accepts Occipital Precontoured Rods and Occipital Adjustable Rods
- Easily contoured with the Occipital Plate Bender

"M" shaped design to allow for increased volume of bone graft in the midline of the occiput

Occipitocervical Adjustable Rods

- Hinge portion of rod adjusts to accommodate various anatomical angles in the occipitocervical junction
- Requires less rod bending to fit difficult anatomy
- 360° of rotation
- Angulation can be adjusted intraoperatively
- Diameter of the superior segment of the rod is 3.5mm; inferior rod segment diameter is 3.2mm
- Compatible with Occipital Midline Keel Plates and Occipital Screw Connectors
- Available in 120mm and 220mm lengths



**Versus the VERTEX MAX® Reconstruction System occipitocervical screws*

Instrument Set

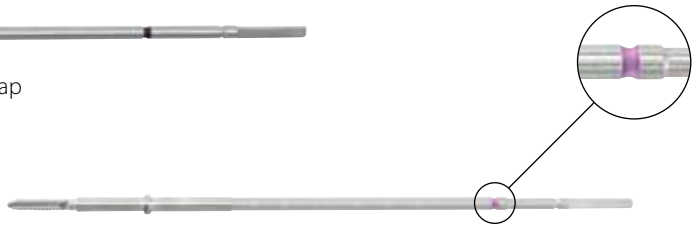
Drill Bits

3.2mm Flexible Drill Bit

3.2mm Straight Drill Bit

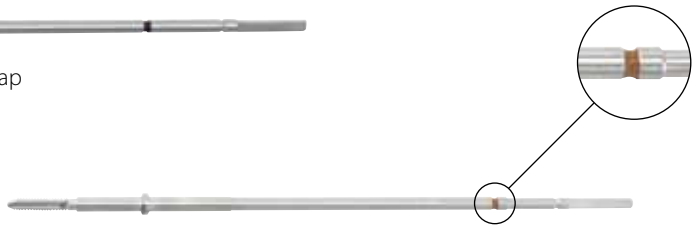
Taps

4.5mm Flexible Tap



4.5mm Straight Tap

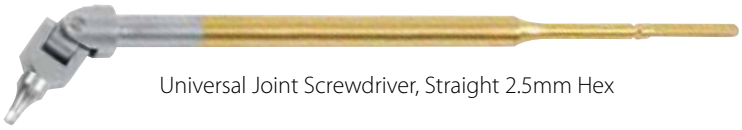
5.0mm Flexible Tap



5.0mm Straight Tap

Screwdrivers

Flexible Screwdriver, Self Holding, 2.5mm Hex



Universal Joint Screwdriver, Straight 2.5mm Hex

Right Angle Screwdriver, Straight 2.5mm Hex

Instrument Set *continued*

Drill-Tap (DT) Screw Guides

Fixed Occipital DT Screw Guide, 6mm/8mm

Fixed Occipital DT Screw Guide, 10mm/12mm

Fixed Occipital DT Screw Guide, 14mm/16mm

18mm Fixed Occipital DT Screw Guide/Screwdriver Guide

Occipital Midline Plate and Rod Benders

Bending Iron, Right

Bending Iron, Left

Occipital Midline Plate Bender/Rod Bender

Note

The surgical techniques described in this document also include the use of instruments from the VERTEX MAX® Reconstruction System instrument set. If an instrument does not appear on page 3 or 4 of this document, it can be found in that instrument set.

VERTEX SELECT®

Reconstruction System

USING THE OCCIPITAL SCREW CONNECTORS AND OCCIPITAL ADJUSTABLE RODS

Rod Placement

For occipitocervical stabilization using the Occipital Screw Connectors, first select and insert the cervical laminar hooks at the desired levels of fixation. Once the laminar hooks are in place, use the Rod Holder to position the Occipital Adjustable Rods to determine the necessary adjustments required to align the rods with the laminar hooks and the most preferable occipital screw position **(Figure 1)**. The appropriate location for placement of occipital 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 in the thickest bone.

The Occipital Adjustable Rod allows the surgeon to preset the angle of the rod to best accommodate the anatomy and minimize the need for bending. The rod is 3.5mm in diameter (grey) superior to the hinge and 3.2mm in diameter (blue) inferior to the hinge. The rod should be oriented so that the 3.5mm diameter segment is positioned on the occiput to be used with the Occipital Screw Connectors. To adjust the angle of the rod, use the Straight Hex Screwdriver to loosen the internal set screw located on the hinge. Adjust the angle as necessary and tighten the internal set screw to secure the rod in a locked position **(Figure 2)**.

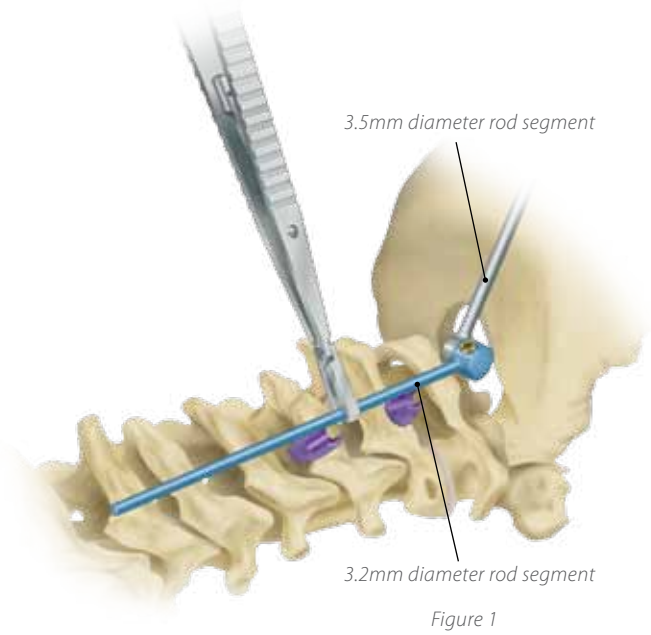


Figure 1

Figure 2

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Rod Contouring

Use the Rod Bender to contour the Occipital Adjustable Rod to best fit the individual patient anatomy **(Figure 3)**. If additional contouring is needed to increase or decrease the bend in the rod, the Left and Right Bending Irons may be used.

Once the angle and position of the Occipital Adjustable Rod has been determined, cut the rod to the required length using the Rod Cutter **(Figure 4)**. The 3.5mm superior portion of the Occipital Adjustable Rod should be cut so that it can be properly positioned on the occiput **(Figure 5)**.

Figure 3

Figure 4

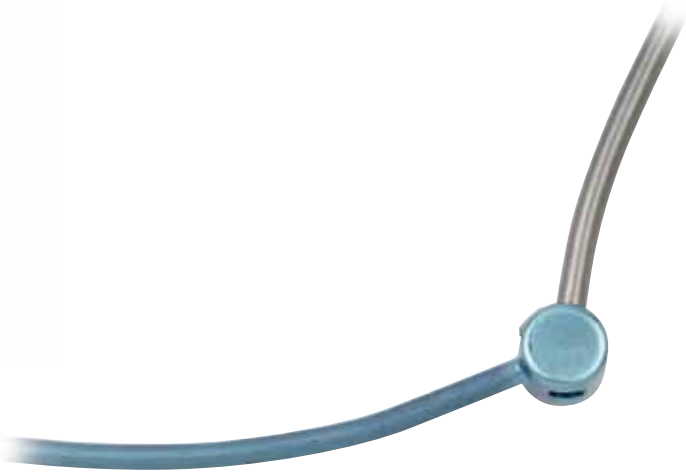


Figure 5

Note

Avoid repeated bending motions to the implants, as excessive bending will decrease the integrity of the implant.

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Screw Connector Placement

Once all of the laminar hooks have been placed and the Occipital Adjustable Rods have been adjusted and contoured to match the patient's anatomy, place three Occipital Screw Connectors on each rod, for a total of six screw fixation points, and provisionally tighten on the rod by tightening the internal gold set screw with the Straight Hex Screwdriver. Generally, the thickest bone in the suboccipital region is the occipital keel (internal occipital protuberance), near the midline. This should be taken into consideration when determining the position of the Occipital Screw Connectors on the rods. The open portion of the connectors should be positioned medially on the rods (i.e., between the rods) so that midline fixation is achieved with the Occipital Bone Screws. Occipital Screw Connectors with longer offsets are available if additional length is needed to maximize screw purchase in the midline.

Once the screw connectors have been provisionally placed on the Occipital Adjustable Rods in the desired position, place the rods in the laminar hooks and provisionally tighten the set screws in each hook to stabilize the rods **(Figure 6a)**.

The Occipital Screw Connectors can be adjusted on the rod in the cephalad/caudal directions, as well as in the AP plane. This dorsal height adjustment capability will help accommodate uneven bone surfaces and facilitate positioning of the connectors so they lie flush with the bone.

NOTE: The Occipital Screw Connectors are compatible with the 3.5mm superior segment (grey) of the Occipital Adjustable Rod, and must not be placed on the 3.2mm inferior segment (blue).

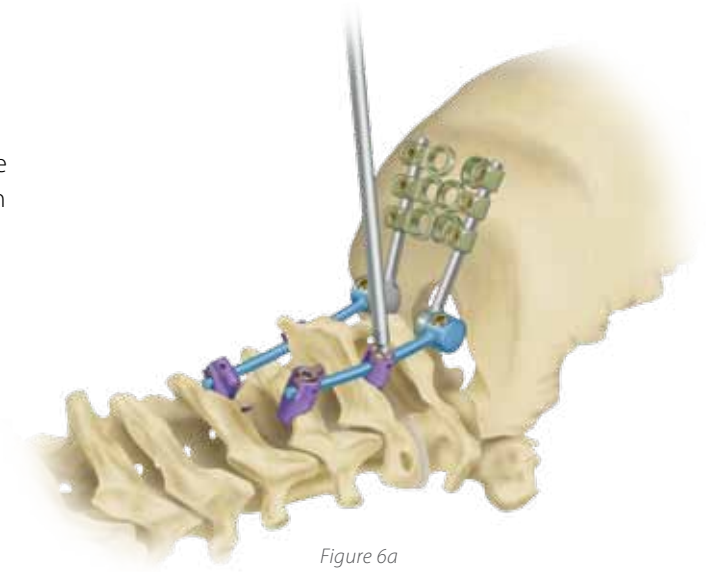


Figure 6a

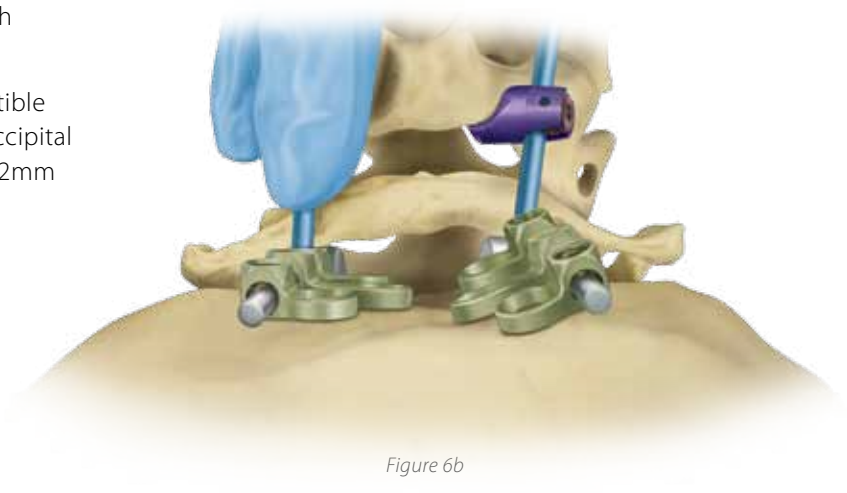


Figure 6b

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Screw Hole Preparation

For occipital fixation, 4.5mm (6mm to 18mm lengths) and 5.0mm (6mm to 18mm lengths) diameter Occipital Bone Screws are available. Select the appropriate drill bit and tap that match the desired screw diameter for occipital fixation (see the Color Coding Reference Chart below).

Occipital Bone Screws — Color Coding Reference

Screw Size	Color	Drill Bit	Tap
4.5mm × 6mm to 18mm	Magenta	3.2mm (Straight Shaft or Flexible Shaft)	4.5mm (Straight Shaft or Flexible Shaft)
5.0mm × 6mm to 18mm	Bronze	3.2mm (Straight Shaft or Flexible Shaft)	5.0mm (Straight Shaft or Flexible Shaft)

The occipital drill bits and taps are available in both straight and flexible shaft designs, based on surgeon preference and anatomical requirements. The straight shaft instruments transfer the energy more efficiently than the flexible shaft instruments, and should be considered the primary instrument choice. The flexible shaft instruments are reserved for use in cases where screw trajectories are difficult to achieve with the straight shaft instruments. For demonstration purposes, the following illustrations depict use of the flexible shaft instruments.

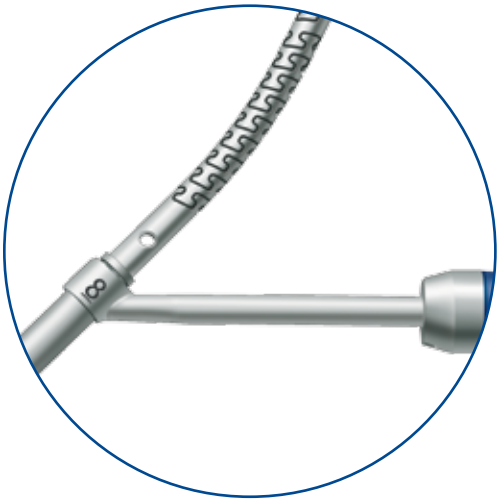


Figure 7

Drilling

Select the appropriate Drill-Tap (DT) Guide based on the desired drilling depth. The DT Guides are available with fixed drilling depths from 6mm to 18mm in 2mm increments. Both the straight and flexible drill bits must be used in conjunction with the DT Guide to achieve a fixed drilling depth **(Figure 7)**. When the flexible drill bit is used, the DT Guide will also prevent excessive motion of the flexible shaft and help direct the drill bit in the proper position. Using the DT Guide to align the drill hole in the Occipital Screw Connector, insert the flexible drill bit through the DT Guide, and drill to the desired depth **(Figure 8)**. Drilling must be done through the Occipital Screw Connectors to ensure proper drilling depth.

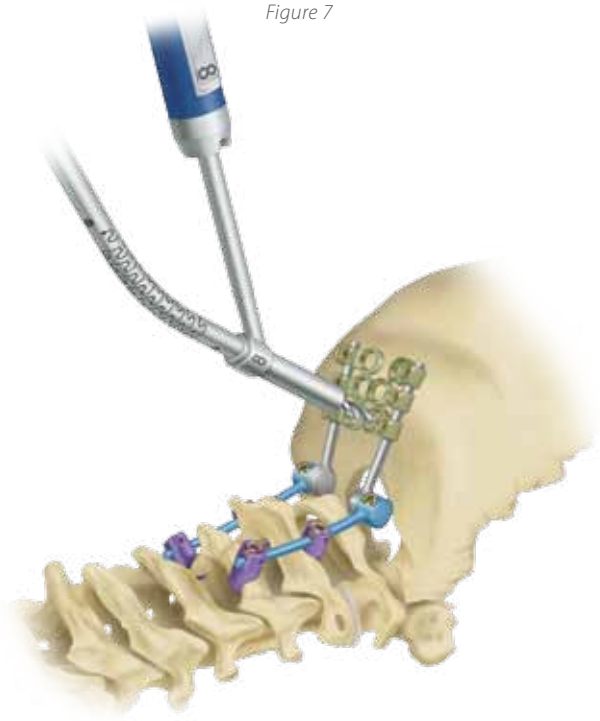


Figure 8

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Screw Hole Preparation *continued*

Screw Measurement

The Depth Gauge should be used to verify the hole depth as well as the occipital bone thickness **(Figure 9)**.

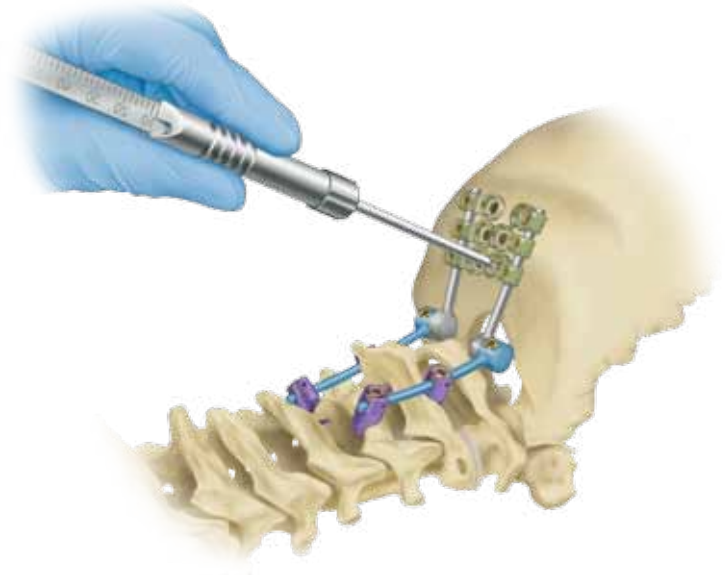


Figure 9

Tapping

Once a satisfactory depth has been achieved, the appropriate straight or flexible tap can be used to prepare the screw hole. Select the appropriate DT Guide based on the desired tapping depth. Both the straight and flexible taps must be used in conjunction with the DT Guide to achieve a fixed tapping depth. When the Flexible Tap is used, the DT Guide will also prevent excessive motion of the flexible shaft and help direct the tap in the proper position. Insert the Flexible Tap attached to the Universal Handle through the DT Guide and tap to the desired depth **(Figure 10)**. The occipital bone is very dense and each hole should be completely tapped.

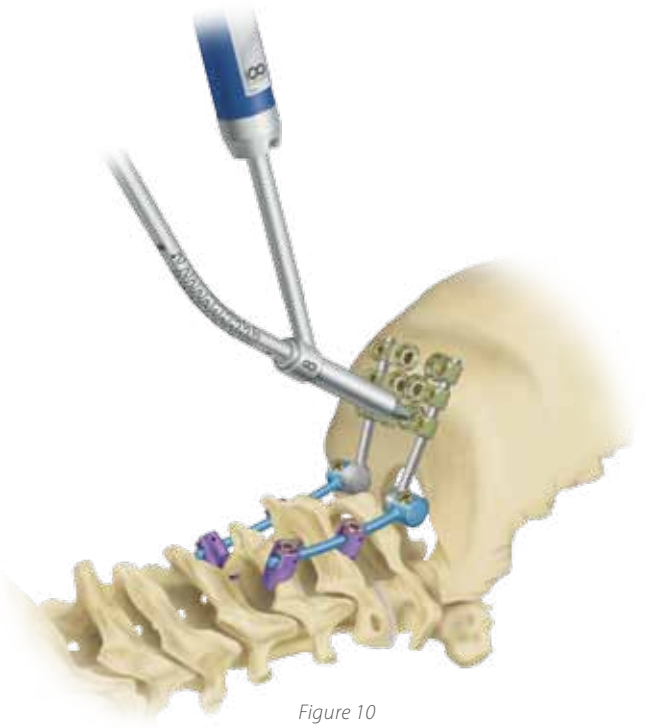


Figure 10

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Bone Screw Insertion

Choose the appropriate diameter and length screw for each screw location and verify the diameter and length before placement.

Use the 2.5mm Self-Holding Screwdriver to engage the bone screw, insert it into the occipital bone, and provisionally tighten. If the patient's anatomical position requires use of the flexible instruments, the 2.5mm Self-Holding Flexible Screwdriver may be used for screw insertion **(Figure 11)**.

NOTE: To prevent excessive motion of the flexible shaft and to direct the screwdriver in the proper position, the Flexible Screwdriver must be used in conjunction with the Screwdriver Guide, located on the opposite end of the 18mm guide.

The remaining screws can be placed using the same technique. Once all of the screws have been placed, use the 2.5mm Straight Hex Screwdriver to hand tighten the screws in their final position. If the patient's anatomical position requires use of the flexible instruments, the Universal Joint Screwdriver or the Right Angled Screwdriver may be used for final tightening **(Figure 12)**.

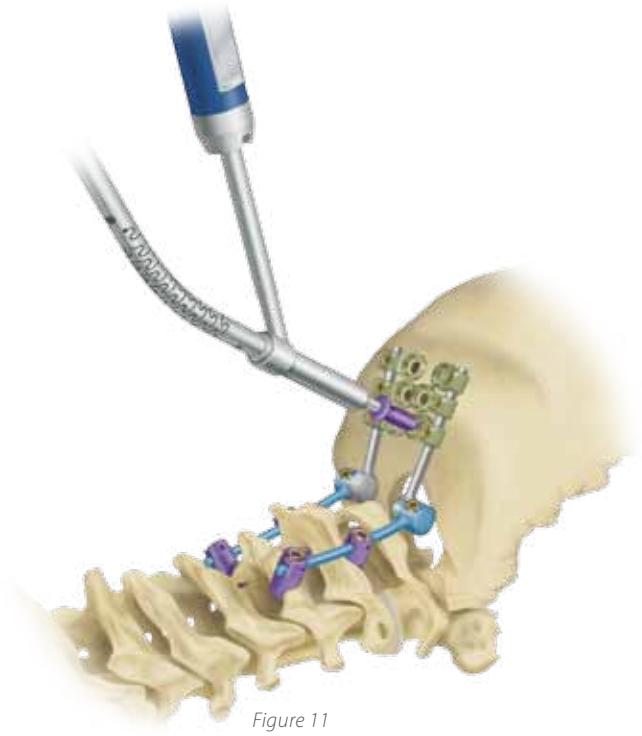


Figure 11

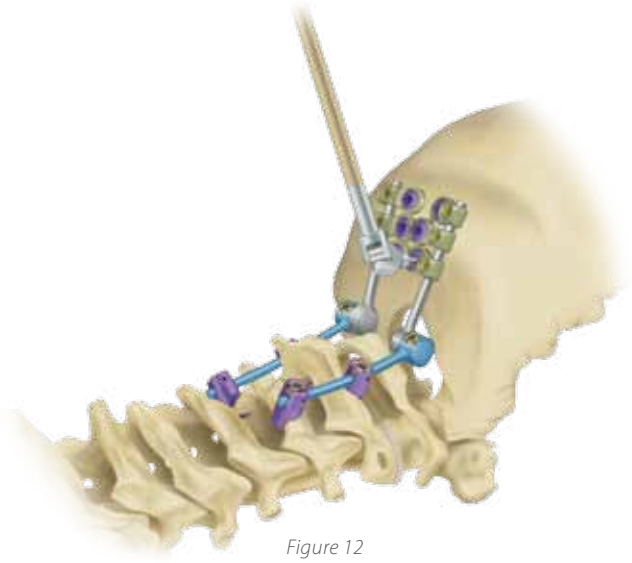


Figure 12

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Final Tightening of Construct

Once all of the Occipital Bone Screws have been final tightened, all set screws in the laminar hooks should be final tightened using the Straight Hex Torque Driver and Torque Limiting Handle in conjunction with the Rod Pusher/Counter Torque **(Figure 13)**.

Securely tighten the Occipital Screw Connectors on the rod using the Straight Hex Screwdriver **(Figure 14)**.

Figure 13

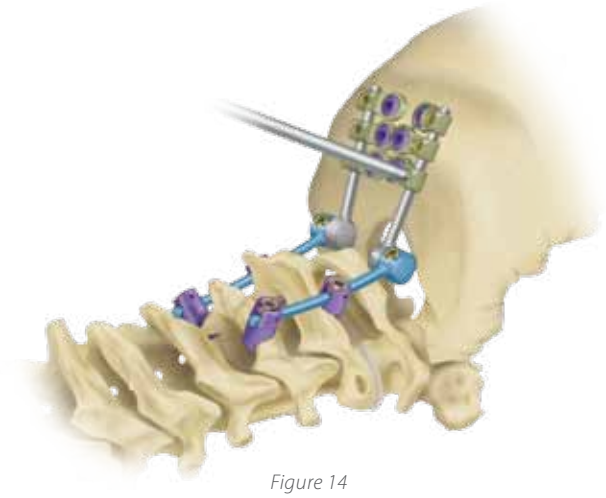


Figure 14

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Final Construct

Recheck all connections of the final construct prior to wound closure **(Figure 15)**.

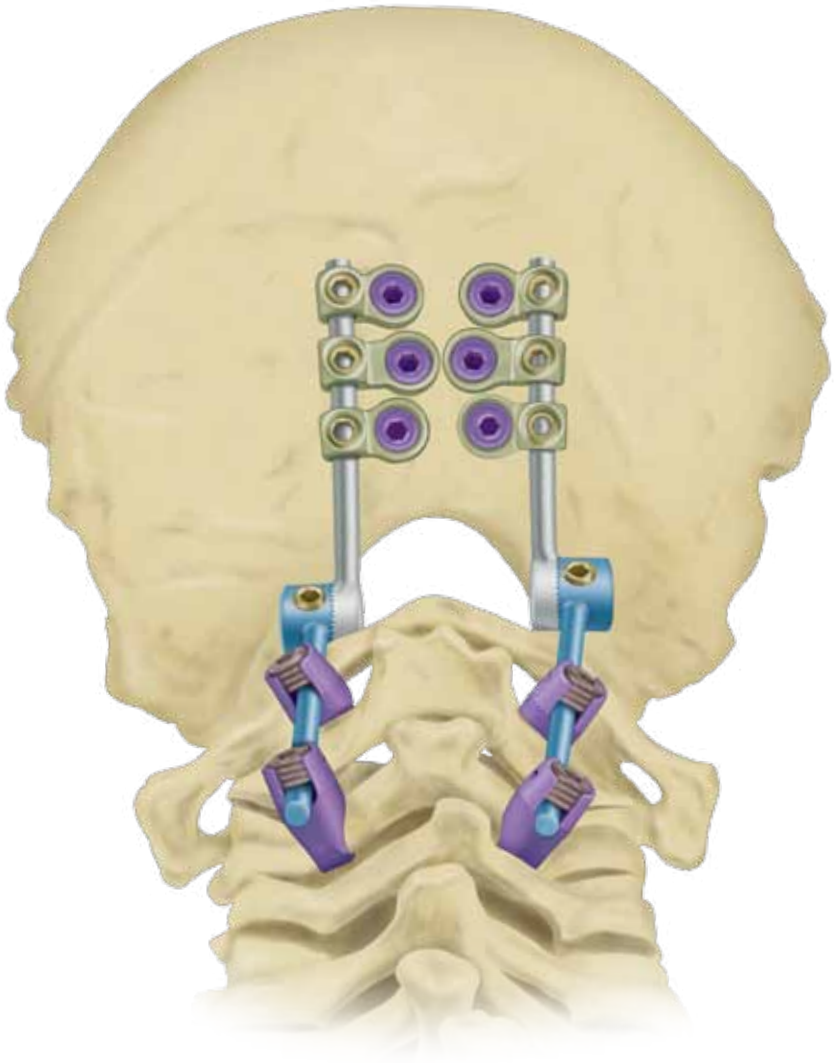


Figure 15

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Explantation

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

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

VERTEX SELECT®

Reconstruction System

USING THE OCCIPITAL MIDLINE
PLATES AND OCCIPITAL
ADJUSTABLE RODS

Occipital Midline 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 Midline Plate it should be centered in the midline between the external occipital protuberance (EOP) and the posterior border of the foramen magnum **(Figure 16)**.

There are three midline plate designs available in the OC Module set. Any geometry of plate may be used. The following illustrations depict the use of the Adjustable OC Plate.

The goal is to maximize bone purchase (closer to EOP) while achieving a low profile. The geometry of the Adjustable OC Plate and the "M" plate are designed to maximize bone graft placement in the midline.

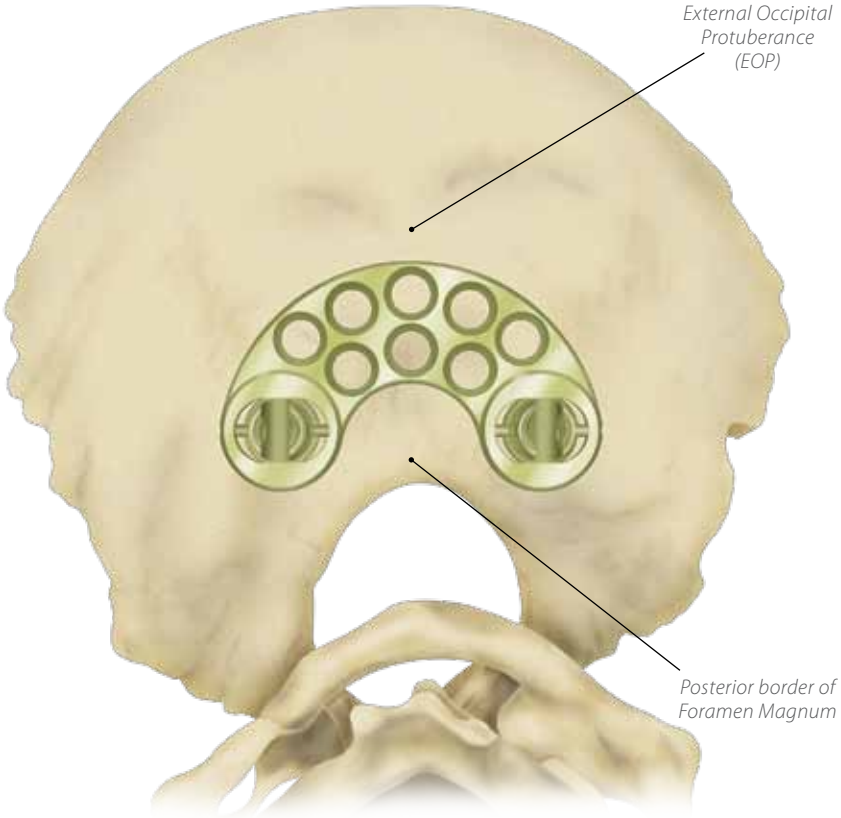


Figure 16

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Midline Plate Placement *continued*

Once all of the laminar hooks have been placed, position the Occipital Adjustable Rod in the laminar hooks to determine the proper plate size, as well as any adjustments to align the rod properly **(Figure 17)**. Instructions for use of the Occipital Adjustable Rod are described on page 6.

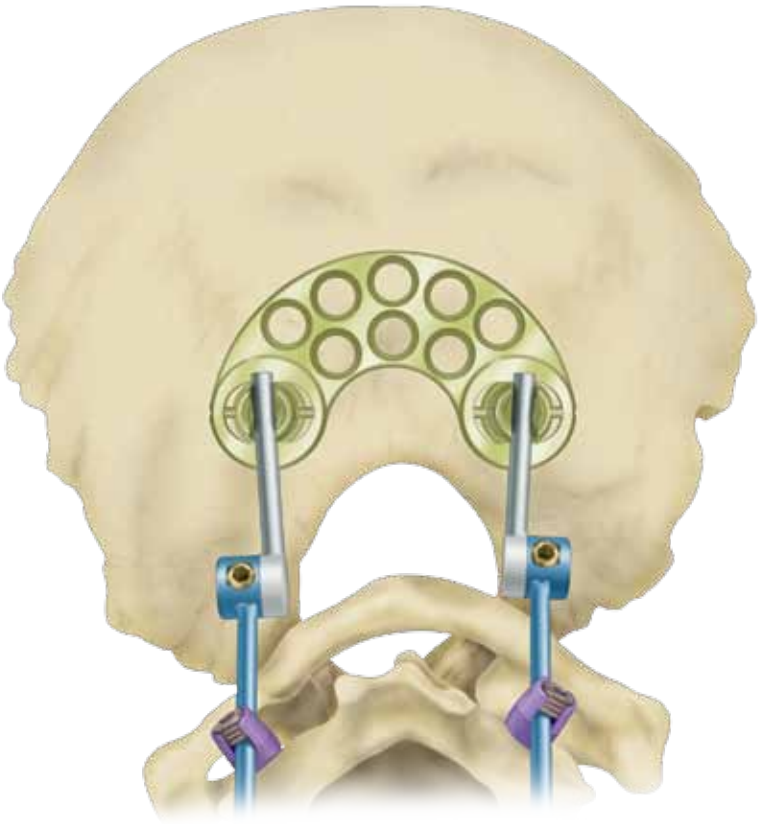


Figure 17

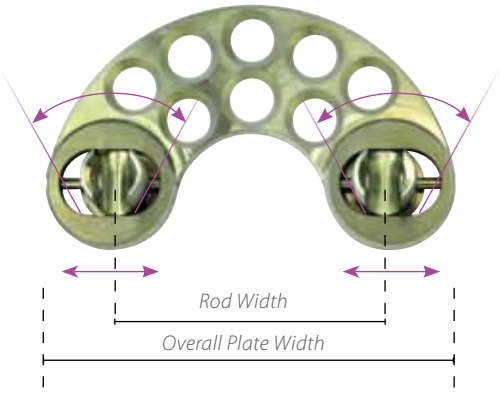


Plate Sizes

Min Rod Width	Max Rod Width	Overall Plate Width
30.3mm	37.7mm	50mm

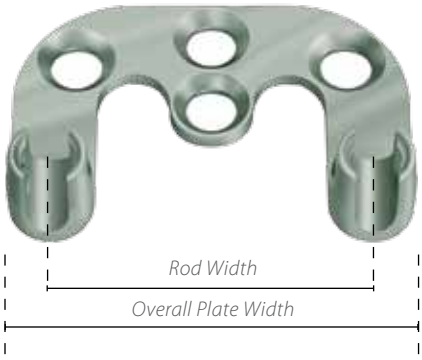


Plate Sizes

Sizes	Rod Width	Overall Width
Small	25.5mm	34mm
Medium	31.5mm	40mm
Large	39.5mm	48mm

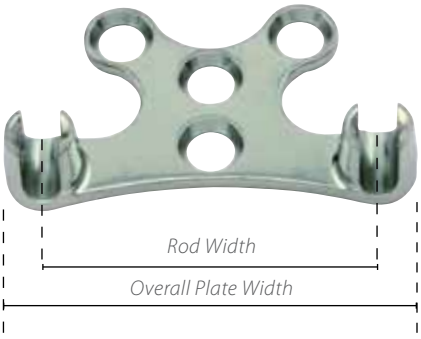


Plate Sizes

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

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Midline Plate Contouring

If necessary, the plate can be contoured using the Occipital Plate Bender for a more anatomic fit against the occiput **(Figure 18)**. The left and right bending irons may also be used as an additional tool to contour the plate **(Figure 19)**. Repeated bending should be avoided as it 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.

Note

Avoid repeated bending motions to the implants, as excessive bending will decrease the integrity of the implant.

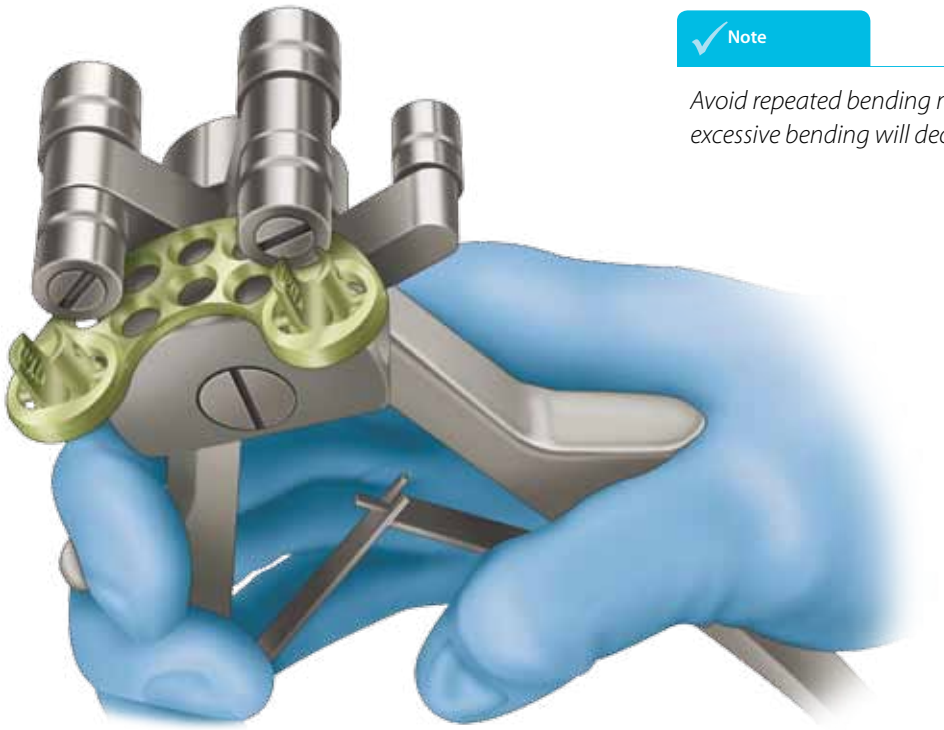


Figure 18

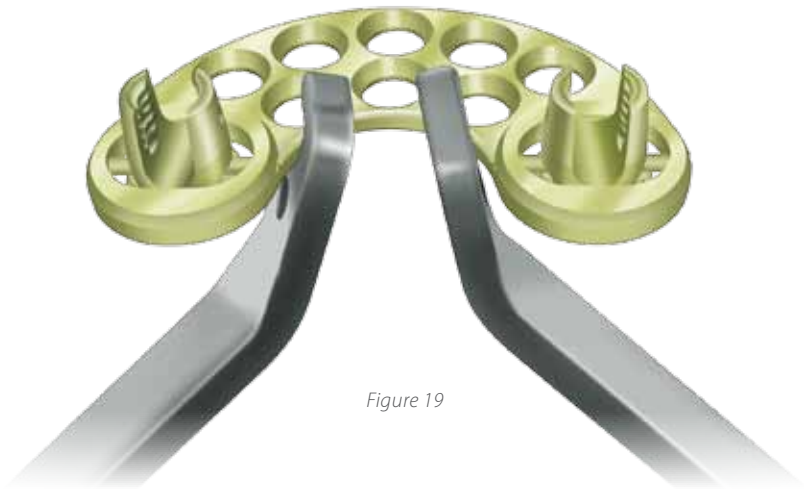


Figure 19

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Screw Hole Preparation

For occipital fixation, 4.5mm (6mm to 18mm lengths) and 5.0mm (6mm to 18mm lengths) diameter Occipital Bone Screws are available. Select the appropriate drill bit and tap that match the desired screw diameter for occipital fixation (see the Color Coding Reference Chart below).

Occipital Bone Screws — Color Coding Reference

Screw Size	Color	Drill Bit	Tap
4.5mm × 6mm to 18mm	Magenta	3.2mm (Straight Shaft or Flexible Shaft)	4.5mm (Straight Shaft or Flexible Shaft)
5.0mm × 6mm to 18mm	Bronze	3.2mm (Straight Shaft or Flexible Shaft)	5.0mm (Straight Shaft or Flexible Shaft)

The occipital drill bits and taps are available in both straight and flexible shaft designs, based on surgeon preference and anatomical requirements. The straight shaft instruments transfer the energy more efficiently than the flexible shaft instruments, and should be considered the primary instrument choice. The flexible shaft instruments are reserved for use in cases where screw trajectories are difficult to achieve with the straight shaft instruments. For demonstration purposes, the following illustrations depict use of the flexible shaft instruments.

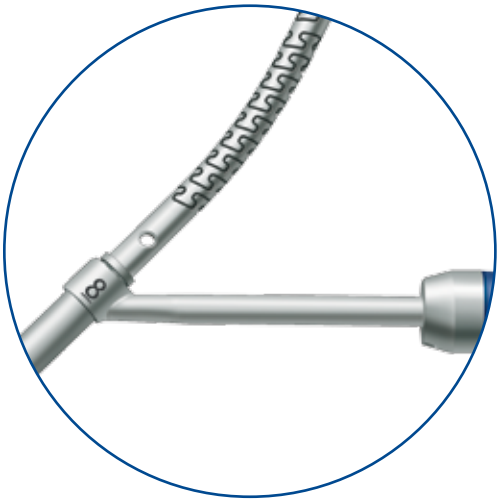


Figure 20

Drilling

Select the appropriate Drill-Tap (DT) Guide based on the desired drilling depth. The DT Guides are available with fixed drilling depths from 6mm to 18mm in 2mm increments. Both the straight and flexible drill bits must be used in conjunction with the DT Guide to achieve a fixed drilling depth **(Figure 20)**. When the flexible drill bit is used, the DT Guide will also prevent excessive motion of the flexible shaft and help direct the drill bit in the proper position. Using the DT Guide to align the drill hole in the Occipital Midline Plate, insert the flexible drill bit through the DT Guide, and drill to the desired depth **(Figure 21)**. Drilling must be done through the Occipital Midline Plate to ensure proper drilling depth.

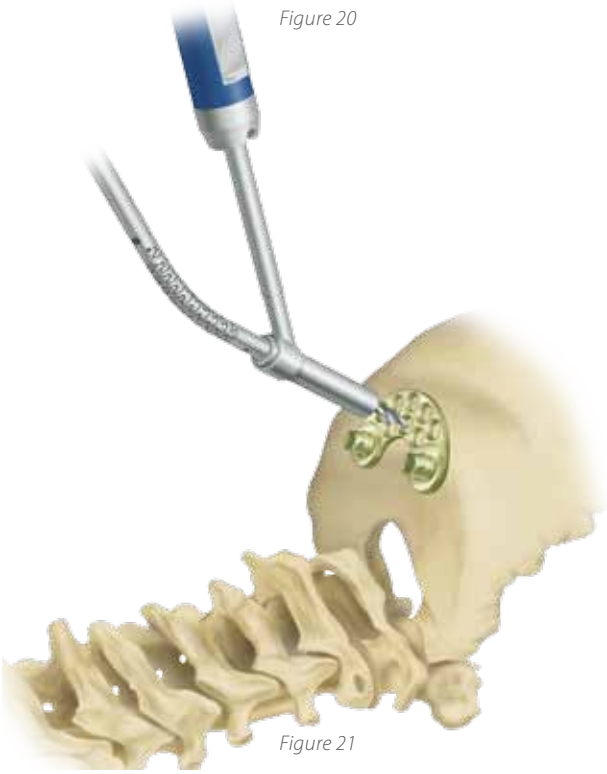


Figure 21

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Occcipital Screw Hole Preparation *continued*

Screw Measurement

The Depth Gauge should be used to verify the hole depth as well as the occipital bone thickness **(Figure 22)**.

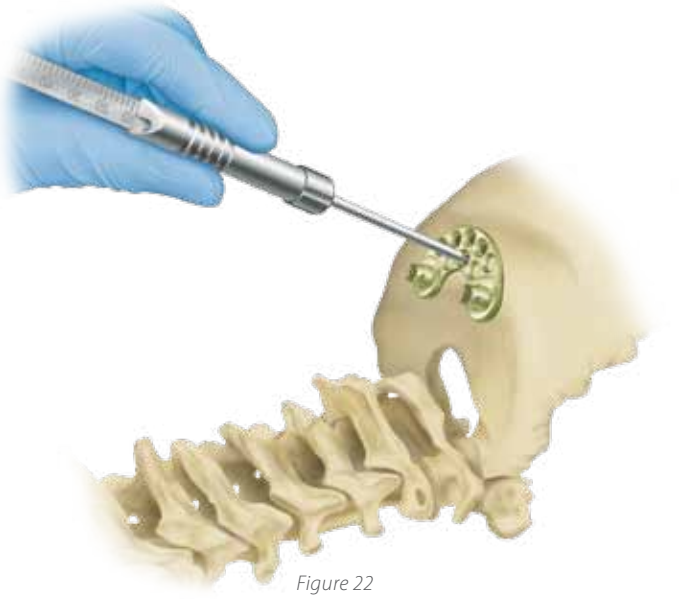


Figure 22

Tapping

Once a satisfactory depth has been achieved, the appropriate Flexible Tap can be used to prepare the screw hole. Select the appropriate DT Guide based on the desired tapping depth. Both the straight and flexible taps must be used in conjunction with the DT Guide to achieve a fixed tapping depth. When the Flexible Tap is used, the DT Guide will also prevent excessive motion of the flexible shaft and help direct the tap in the proper position. Insert the Flexible Tap attached to the Universal Handle through the DT Guide and tap to the desired depth **(Figure 23)**. The occipital bone is very dense and each hole should be completely tapped.

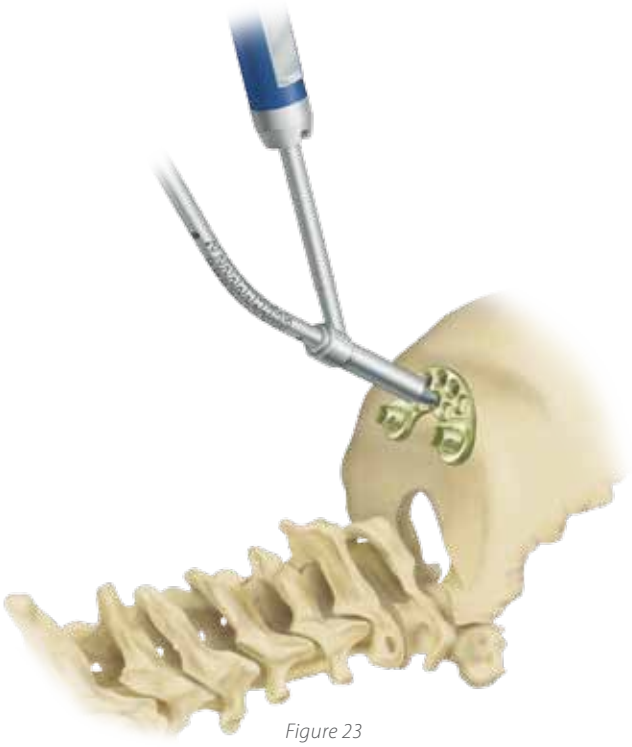


Figure 23

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Bone Screw Insertion

Choose the appropriate diameter and length screw for each screw location and verify the diameter and length before placement.

NOTE: For the Adjustable OC Plate, place at least four screws.

Use the 2.5mm Self-Holding Screwdriver to engage the bone screw, insert it into the occipital bone, and provisionally tighten. If the patient's anatomical position requires use of the flexible instruments, the 2.5mm Self-Holding Flexible Screwdriver may be used for screw insertion **(Figure 24)**.

NOTE: To prevent excessive motion of the flexible shaft and to direct the screwdriver in the proper position, the Flexible Screwdriver must be used in conjunction with the Screwdriver Guide.

The remaining screws can be placed using the same technique. Once all of the screws have been placed, use the 2.5mm Straight Hex Screwdriver to hand tighten the screws in their final position. If the patient's anatomical position requires use of the flexible instruments, the Universal Joint Screwdriver or the Right Angled Screwdriver may be used for final tightening **(Figure 25)**.

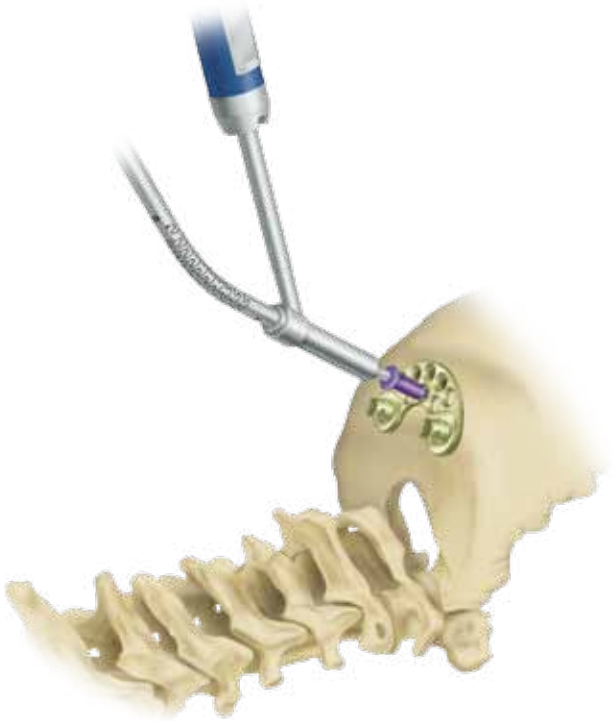


Figure 24

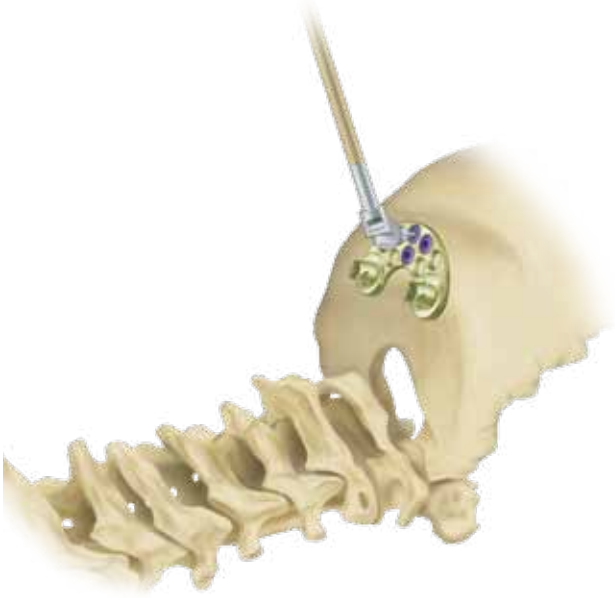


Figure 25

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Final Tightening of Construct

Once all of the Occipital Bone Screws have been final tightened and the rods have been adjusted to match the patient's anatomy and placed into the laminar hooks and saddles of the Occipital Midline Plate, use the 2.5mm Self-Holding Screwdriver to provisionally tighten the set screws in the saddles of the Occipital Midline Plate to stabilize the rod. If the patient's anatomical position requires use of the flexible instruments, the 2.5mm Self-Holding Flexible Screwdriver may be used to insert the set screw. Use the 2.5mm Self-Holding Screwdriver to provisionally tighten the set screws in the laminar hooks.

Once all of the set screws have been placed and the rods are secured in the implants, use the Straight Hex Screwdriver and the Torque-Limiting Handle in conjunction with the Rod Pusher/Counter Torque **(Figure 26)** to final tighten the set screws in the saddles of the plate. If the patient's anatomical position requires use of the flexible instruments, the Universal Joint Screwdriver or the Right Angled Screwdriver may be used for final tightening of the set screws **(Figure 27)**. Set screws in the laminar hooks should also be final tightened using the Straight Hex Torque Driver and Torque-Limiting Handle in conjunction with the Rod Pusher/Counter Torque.

Recheck all connections of the final construct prior to wound closure.

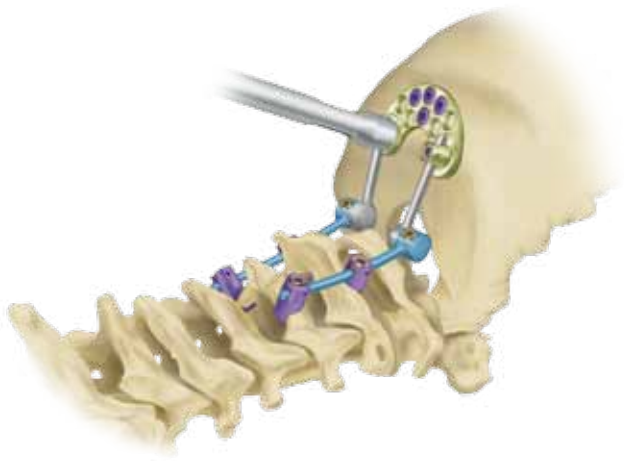


Figure 26

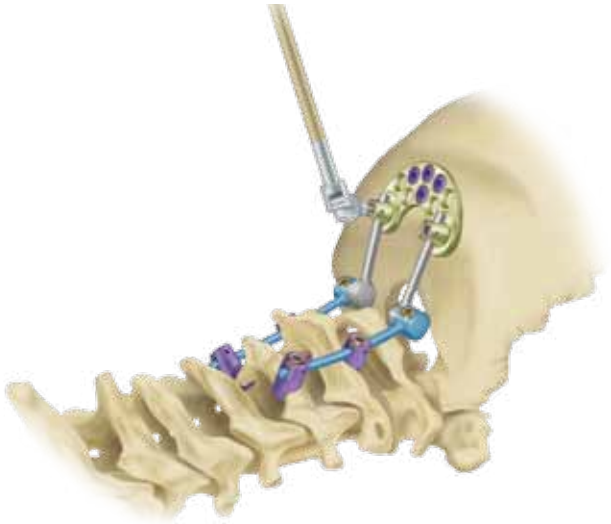
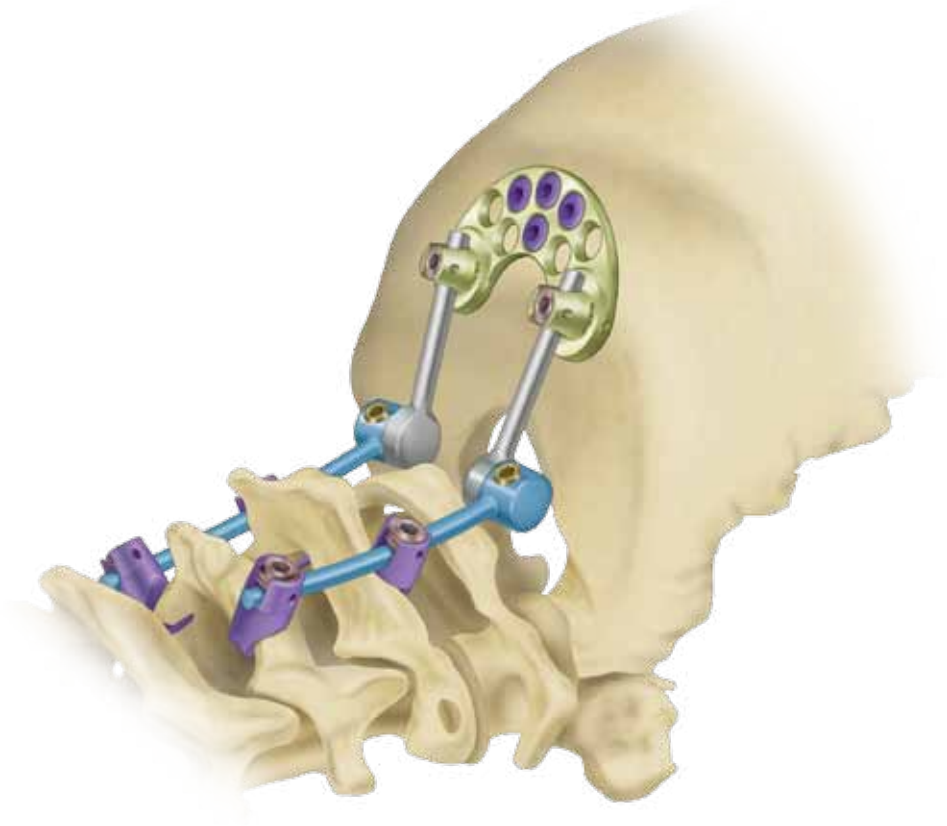


Figure 27

The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Explantation

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



The VERTEX SELECT® Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter, therefore the occipital components between the two systems are not compatible and must not be used interchangeably.

Product Ordering Information

Occipital Midline Plates

Item #	Description
7755278	Adjustable OC Plate
7759970	Occipitocervical Midline Plate, S
7759971	Occipitocervical Midline Plate, M
7759972	Occipitocervical Midline Plate, L
6959970	Occipital Midline Keel Plate, S
6959971	Occipital Midline Keel Plate, M
6959972	Occipital Midline Keel Plate, L

Occipital Screw Connectors

Item #	Description
7755325	Occipital Screw Connector
7755327	Occipital Screw Connector, Offset

Occipitocervical Rods

Item #	Description
7755122	3.2/3.5mm × 120mm Occipitocervical Adjustable Rod
7755123	3.2/3.5mm × 220mm Occipitocervical Adjustable Rod
6955270	3.2mm × 200mm Precurved Occipitocervical Rod

Occipital Bone Screws

Item #	Description
7750506	4.5 × 6mm Occipital Bone Screw
7750508	4.5 × 8mm Occipital Bone Screw
7750510	4.5 × 10mm Occipital Bone Screw
7750512	4.5 × 12mm Occipital Bone Screw
7750514	4.5 × 14mm Occipital Bone Screw
7750516	4.5 × 16mm Occipital Bone Screw
7750518	4.5 × 18mm Occipital Bone Screw
7750606	5.0 × 6mm Occipital Bone Screw
7750608	5.0 × 8mm Occipital Bone Screw
7750610	5.0 × 10mm Occipital Bone Screw
7750612	5.0 × 12mm Occipital Bone Screw
7750614	5.0 × 14mm Occipital Bone Screw
7750616	5.0 × 16mm Occipital Bone Screw
7750618	5.0 × 18mm Occipital Bone Screw

Occipitocervical Instruments

Item #	Description
7756334	4.5mm Occipital Tap
7756383	4.5mm Occipital Flexible Tap
7756337	5.0mm Occipital Tap
7756384	5.0mm Occipital Flexible Tap
7759978	Fixed Occipital DT Screw Guide, 6mm/8mm
7759979	Fixed Occipital DT Screw Guide, 10mm/12mm
7759980	Fixed Occipital DT Screw Guide, 14mm/16mm
7759982	Fixed Occipital DT Screw Guide, 18mm Screwdriver Guide
7756286	Flexible Screwdriver, Self Holding, 2.5mm Hex
7756187	Universal Joint, Screwdriver, Straight 2.5mm Hex
7756188	Screwdriver, Right Angle 2.5mm Hex
7756290	Bending Iron, Left
7756291	Bending Iron, Right
7756230	Occipital Midline Plate Bender/Rod Bender

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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Notes

Notes

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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.