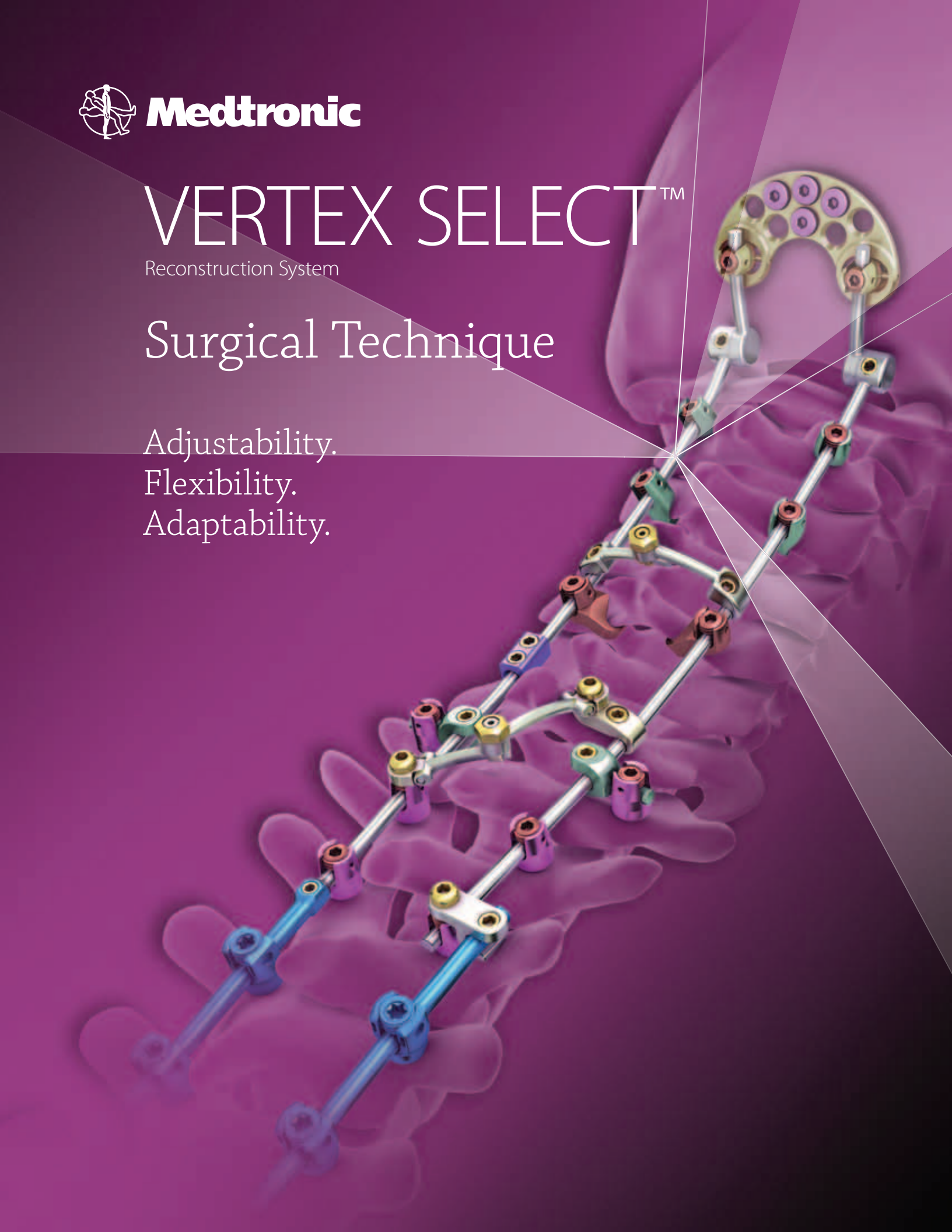
Medtronic

VERTEX SELECT™

Reconstruction System

Surgical Technique

Adjustability.
Flexibility.
Adaptability.



Adjustability. Flexibility. Adaptability.

The VERTEX SELECT™ Reconstruction System is a comprehensive set of options that provides adjustability, flexibility, and adaptability to meet the anatomical challenges of the occipitocervical and upper thoracic spine.

Building upon a strong clinical history... now with even more options.


Adjustability.
Flexibility.
Adaptability.

Medtronic

VERTEX SELECT™

Reconstruction System

Surgical Technique

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Reconstruction System

VERTEX SELECT™

Reconstruction System Occipitocervical (OC) Module

Implant Features

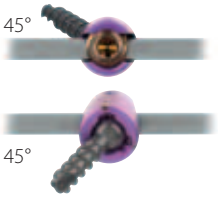
Multi-Axial Screw

- Accepts 3.2mm and 3.5mm rods
- 60° conical angulation
- 30° in any direction
- Up to 45° of angulation in relief notches
- Available in 3.5mm, 4.0mm, and 4.5mm diameters
- Partially threaded options available in 3.5mm and 4.0mm diameters
- Cannulated options available in 4.0mm and 4.5mm diameters

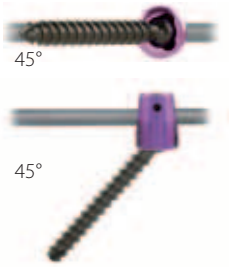
Fully Threaded Multi-Axial Screws (MAS)

Partially Threaded Multi-Axial Screws (MAS)

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



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



Laminar Hooks

- Accept 3.2mm and 3.5mm diameter rods
- Left and right laminar offset hooks

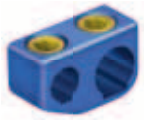
Rods

- Surgeon choice of 3.2mm and 3.5mm rod diameters in various lengths
- Cervical-thoracic threaded rods available in various diameters

Rod Transition Options

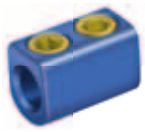
Offset Dominos

- Enable connection from 3.2mm and 3.5mm rod diameters to 3.2mm, 3.5mm, 4.5mm, or 5.5mm rod diameters
- Allow for medial/lateral offset of rods at the transition point



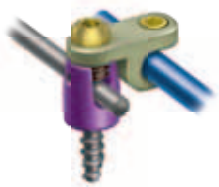
Axial Dominos

- Enable connection from 3.2mm and 3.5mm rod diameters to 4.5mm and 5.5mm rod diameters
- Allow for axial alignment of rods at the transition point



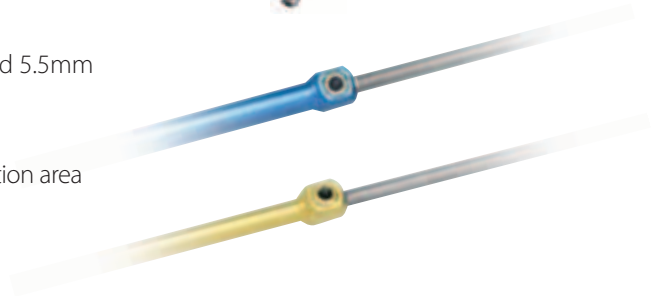
Multi-Axial Screw (MAS) Extension Connectors

- Connect directly to multi-axial screw to allow for extension of adjacent constructs
- Enable connection directly from multi-axial screw to 4.5mm and 5.5mm rod diameters
- "Zero Run on the Rod" transition option to allow for maximum fixation area



Threaded Rods

- Enable connection from 3.2mm and 3.5mm rod diameters to 4.5mm and 5.5mm rod diameters
- Allow for axial alignment of rods at the cervical-thoracic transition point
- Low-profile transition option of the threaded rods allows for maximum fixation area



Implant Features *continued*

Rod Connector Options

Lateral Offset Connectors

- Allow for medial/lateral offset to accommodate nonlinear screws
- Provide additional options for screw placement
- Dorsal height adjustment capabilities to accommodate screw height differences
- Open and closed connector options

Cable Connector

- Allows for connection of ATLAS® Cable to the rod construct

CROSSLINK® Connector Options

CROSSLINK® Connector, MAS to MAS Design

- Connects directly to the top of a multi-axial screw head in cases where adjacent screw heads are in close proximity to one another
- Ability to attach to a different level above or below on each side of construct
- Ability to also connect directly to the rod using the VERTEX SELECT™ System CROSSLINK® Connector Clip
- Arched design allows room for patient anatomy
- Adjustable design and various sizes to accommodate varying distances between rods
- Single-component design for easy placement

CROSSLINK® Connector Clip

- Enables the MAS to MAS CROSSLINK® Connector to attach directly to rod if necessary

CROSSLINK® Connector, Rod to Rod Design

- Adjustable design and various sizes to accommodate varying distances between rods
- Arched design allows room for patient anatomy
- Single-component design for easy placement

Set Screws

- Multi-axial screw and hook standard set screw
- MAS Connector Set Screw enables attachment of a MAS CROSSLINK® Connector or a MAS Extension Connector to a multi-axial screw
- MAS Locking Set Screw locks the MAS CROSSLINK® Connector or the MAS Extension Connector to a multi-axial screw

Instrument Set

Screw Preparation/Placement

Adjustable Drill Guide

Fixed
Drill Guide
(14mm)

Universal Handle

Circular Drill Bit
Adapter

Universal Ratcheting Handle

Pedicle Feeler

Pedicle Probe

Awl

Bone Reamer

Depth Gauge

Quick Release Self-Holding Screwdriver

Tap Sleeve

Threaded Screwdriver

4.0mm External Hex

Instrument Set *continued*

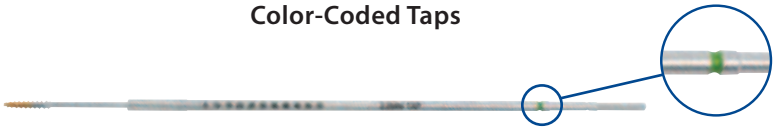
Screw Preparation/Placement *continued*

Color-Coded Drill Bits

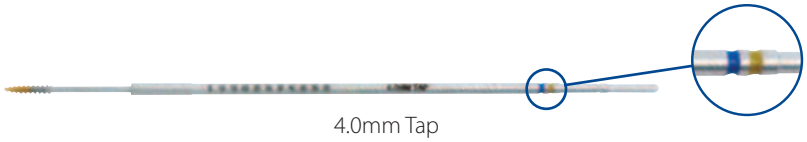
2.4mm Drill Bit

2.9mm Drill Bit

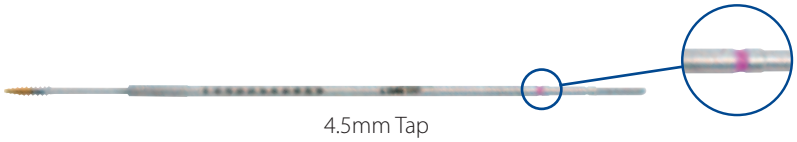
Color-Coded Taps



3.5mm Tap



4.0mm Tap



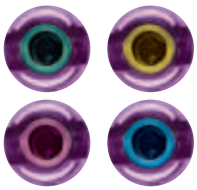
4.5mm Tap

Note

The gold anodized tip of the tap represents the first 10mm of thread.

Color-Coding Reference

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



Instrument Set *continued*

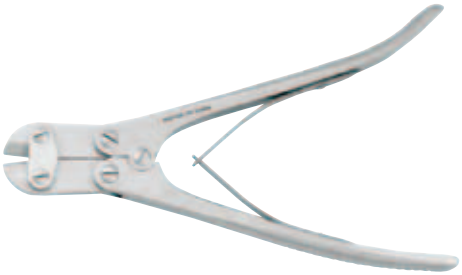
Hook Placement

Laminar Elevator

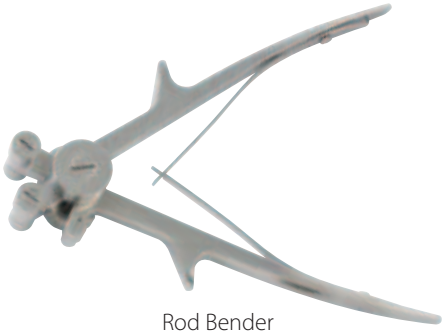
Hook Holder

Rod Preparation

Ratcheting Rod Cutter



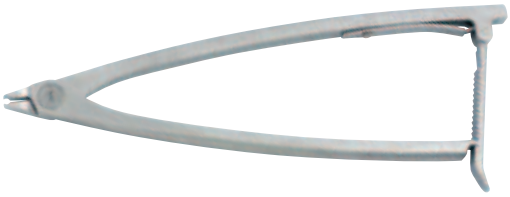
Rod Cutter



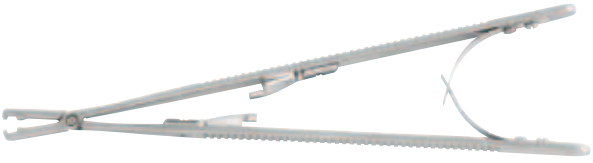
Rod Bender

Rod Template

Rod Insertion/Adjustment



Rod Gripper

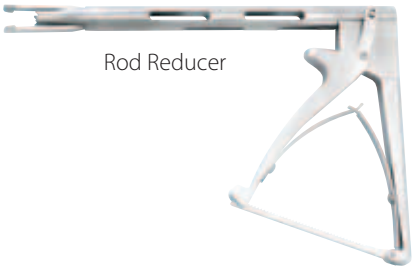


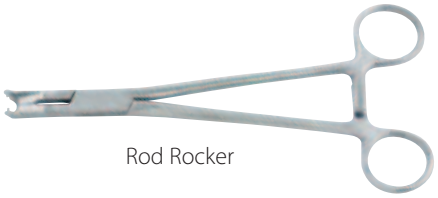
Rod Holder

Alignment Tool

Instrument Set *continued*

Rod Reduction/Correction


Rod Reducer


Rod Rocker

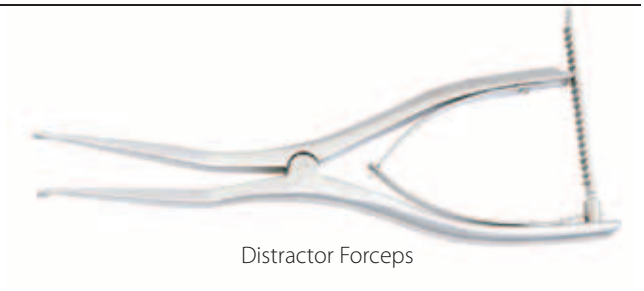

Bending Iron Left

Bending Iron Right


Coronal Benders

Compression/Distraction


Compressor Forceps


Distractor Forceps

Final Tightening


2.5mm Straight Hex Screwdriver

Straight Hex Torque Driver


4.0mm External Hex


4.0mm External Hex Torque Screwdriver


Rod Pusher/Counter Torque


Universal Handle


Torque Limiting Handle


T-Handle

CROSSLINK® Plate Placement


Lock Nut Driver


Universal Handle


Swizzle Stick

Patient Positioning/Posterior Approach

The patient is placed prone in an appropriate manner to avoid specific pressure points.

A midline incision is made, and dissection is carried down to the spinous processes of the appropriate vertebrae.

Dissection is carried laterally to expose the facets and the transverse processes **(Figure 1)**.

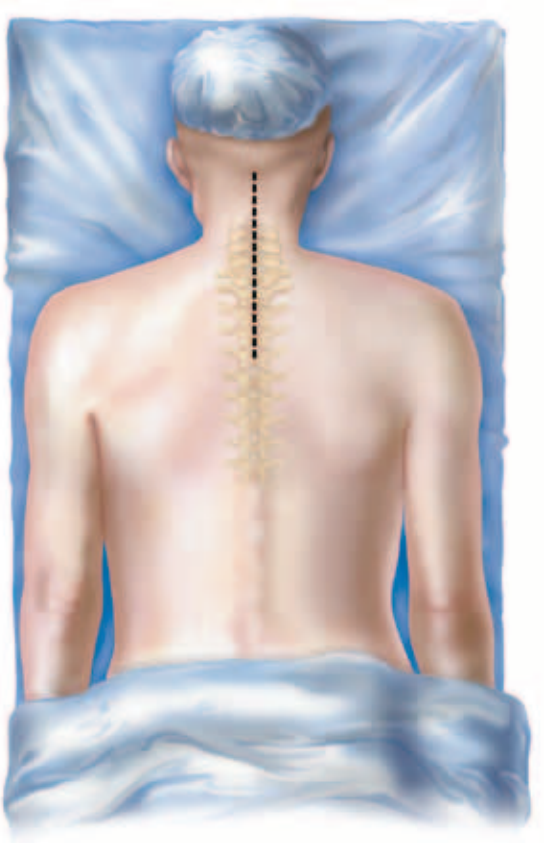


Figure 1

Pedicle Preparation

Anatomical landmarks are identified and carefully reviewed to determine the entry point to the pedicle **(Figure 2)**. An entry hole is made over the pedicle with a burr, drill, or awl **(Figure 3)**.

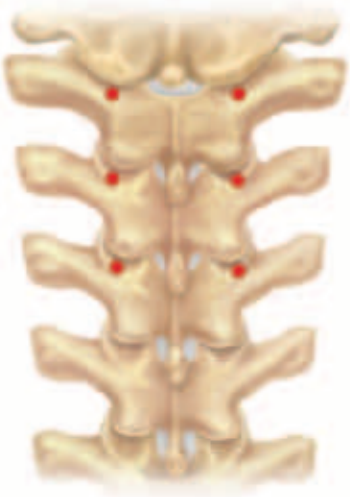


Figure 2

Figure 3

Drilling

The Adjustable Drill Guide, with the lock and unlock adjustment feature, can be used for drilling depths from 6mm to 52mm in 1mm increments.

The drilling depth can be adjusted by pressing the Slide forward while adjusting the Measuring Tube to the desired drill depth **(Figure 4)**.

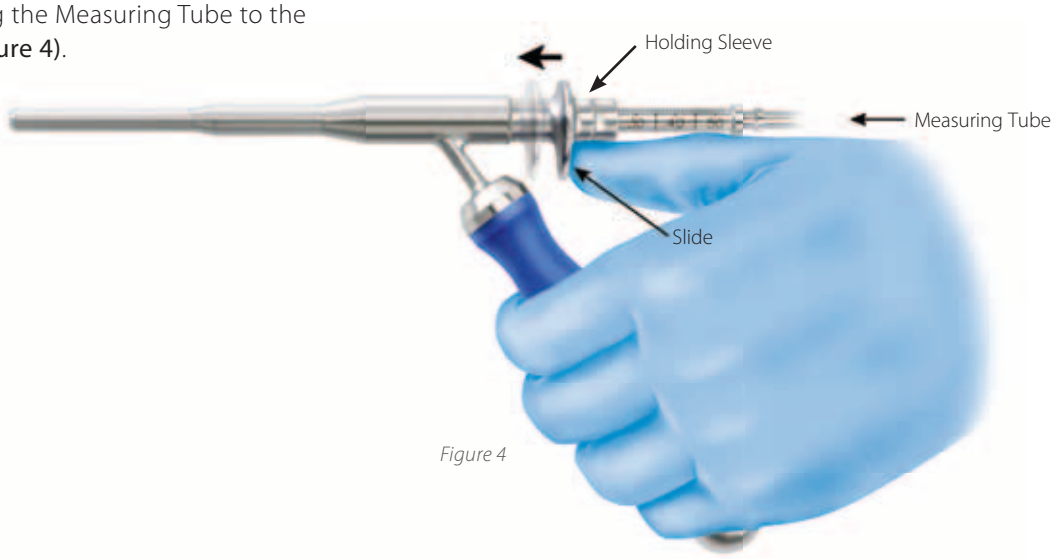


Figure 4

Once the slide reaches the desired depth, rotate the slide into the locked position and prepare the pilot hole in the desired trajectory **(Figures 5 and 6)**.

Figure 5

Figure 6

Screw Measurement

The Pedicle Feeler **(Figure 7)** is used to gently palpate the cancellous bone to the pedicle, and the Depth Gauge is used to determine the screw length **(Figure 8)**.

Figure 7

Figure 8

Optional Tapping

The VERTEX SELECT™ Multi-Axial Screws are self-tapping to eliminate 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 9)**.

Note

The tap may be attached to either the Universal Handle or the Universal Ratcheting Handle.

Note

The gold anodized tip of the tap represents the first 10mm of thread **(Figure 10)**.

Figure 9

Figure 10

Bone Reaming

The Bone Reamer may be used to remove uneven bone, if needed, to maximize the multi-axial capabilities of the bone screw **(Figures 11 and 12).**

Figure 11

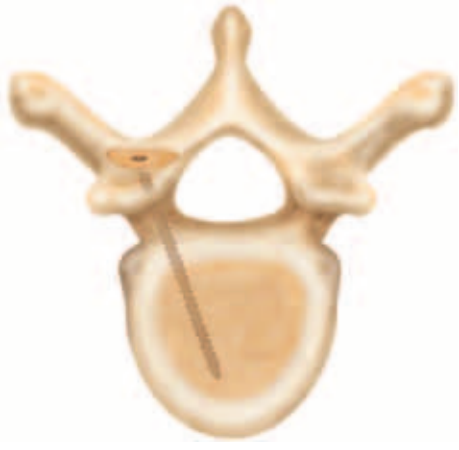


Figure 12

Screw Placement

Once the desired screw length is selected, the screw is attached to either the Quick Release Self-Holding Screwdriver or Threaded Screwdriver, along with the Universal Ratcheting Handle, and inserted into the bone **(Figures 13 and 14)**.

Confirmation of screw position can be made using radiographs or intraoperative fluoroscopy.

The remaining screws are placed using a similar technique.

Note

It is recommended, though not required, that for longer length multi-axial screws (>26mm), you use the threaded screwdriver, as it may help give better handling and control of the screw if needed.

Note

Cannulated multi-axial screws are available.

Figure 13

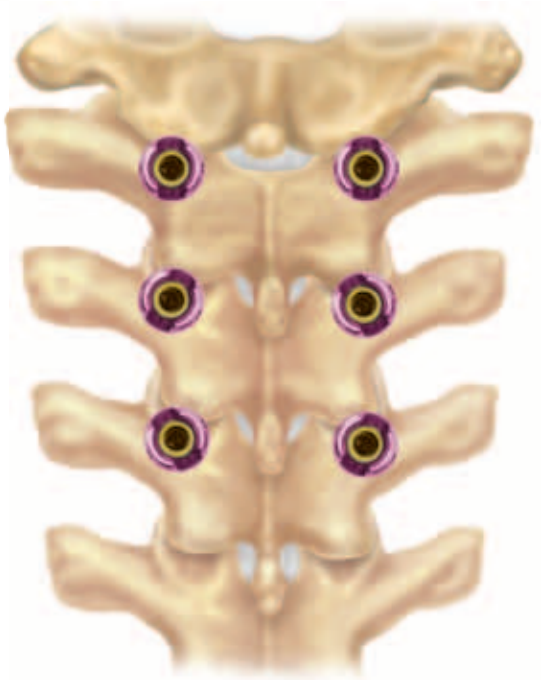
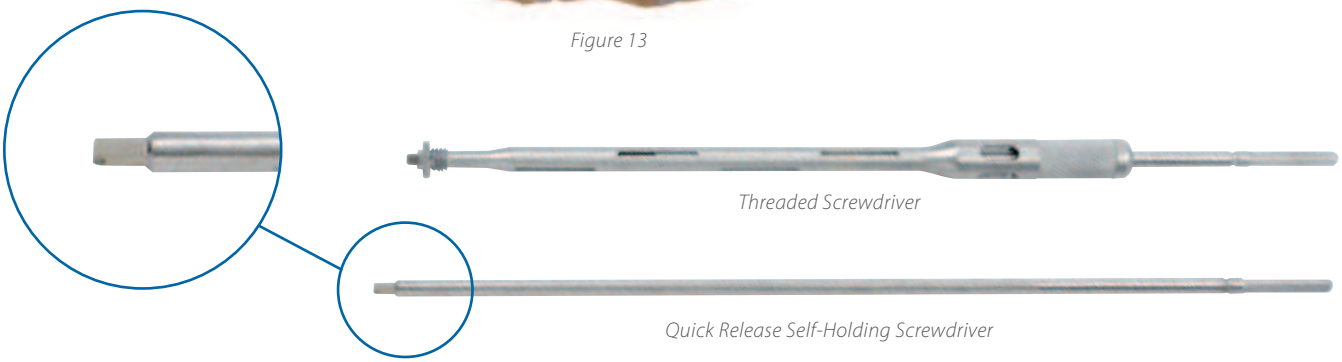


Figure 14

Universal Ratcheting Handle



Threaded Screwdriver

Quick Release Self-Holding Screwdriver

Screw Placement *continued*

Prior to rod placement, the Alignment Tool may be used to align the saddles of the VERTEX SELECT™ Multi-Axial Screws **(Figures 15 and 16)**.

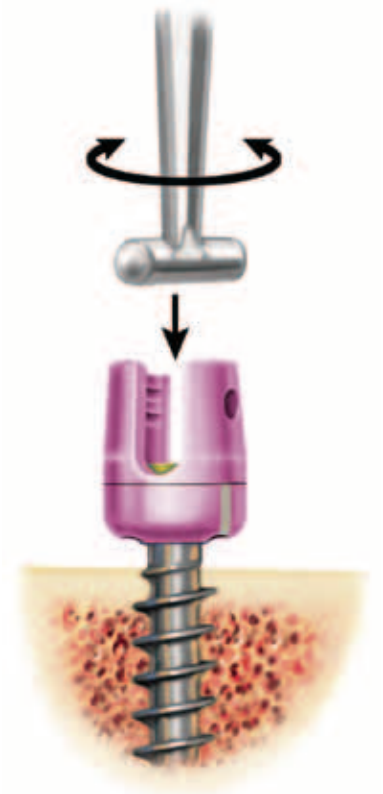


Figure 15

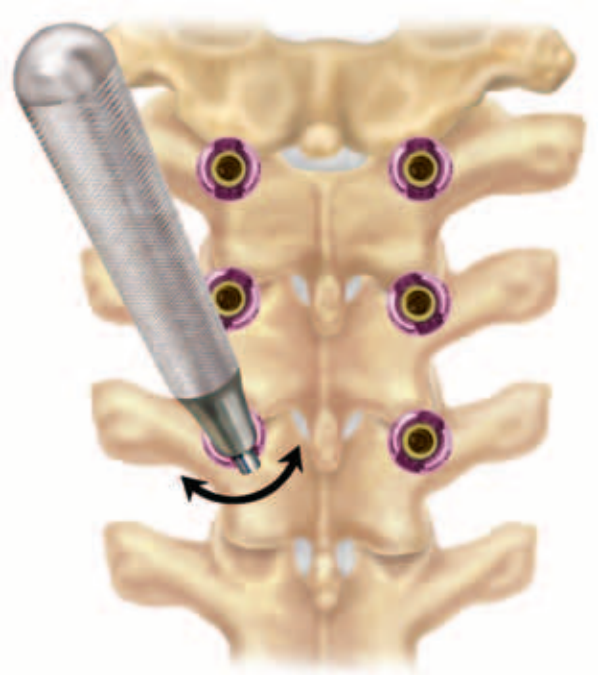


Figure 16

Hook Placement

When using Laminar Hooks in the cervical and upper thoracic spine, lamina preparation and ligamentum flavum dissection are performed using the Laminar Elevator **(Figure 17)**.

If desired, dissection may also be achieved using a hook in the Hook Holder **(Figure 18)**.

The appropriate hook is selected based on the thickness of the lamina and placed at the appropriate position **(Figures 19 and 20)**.

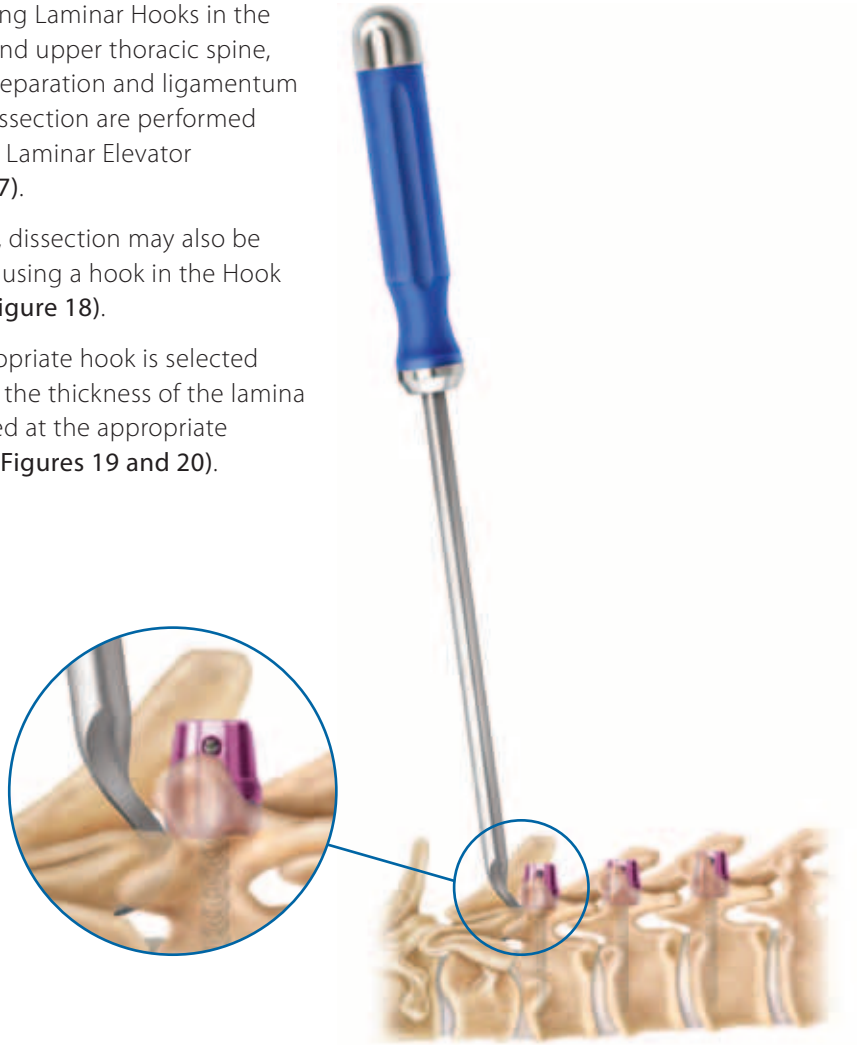


Figure 17

Figure 18

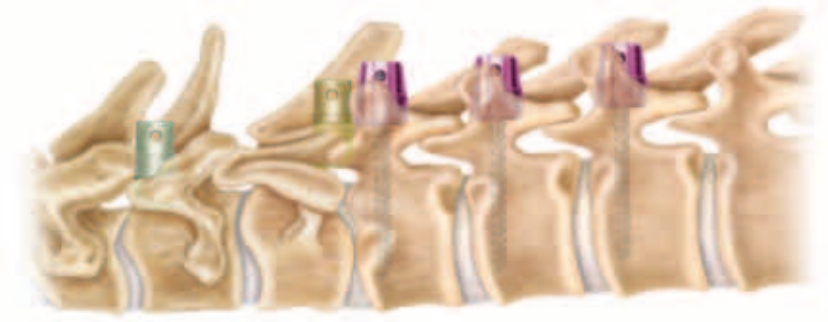


Figure 19

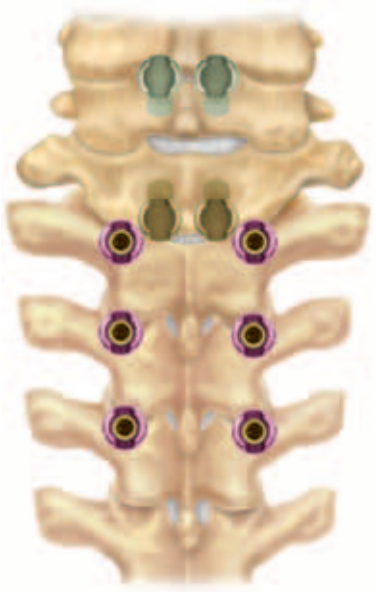


Figure 20

Rod Selection

Straight Rods are available in either 3.2mm or 3.5mm diameters **(Figure 21)**.

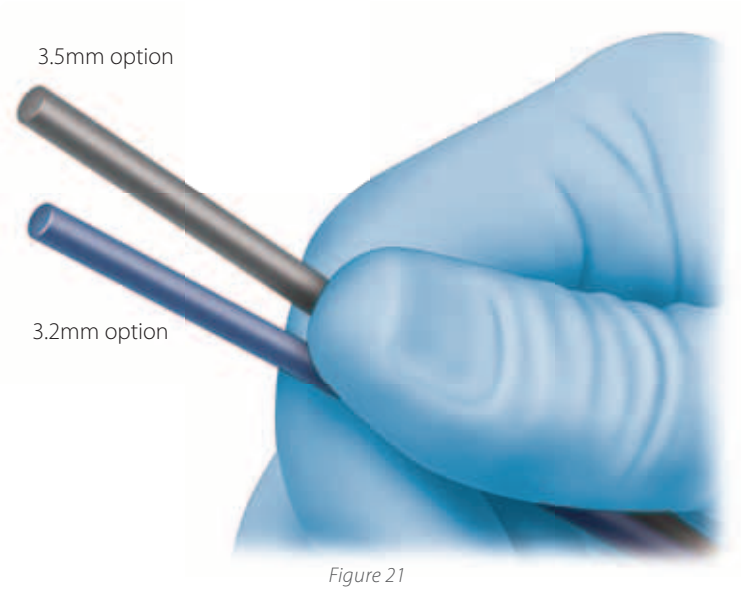


Figure 21

Rod Templating

The Rod Template is used to determine the curvature and length of the rod needed based on the screw or hook positions **(Figure 22)**.

Fit the Template into the desired area and mold into proper shape. Remove the Template and use to shape either your straight or threaded rod to match.

Note

The Rod Template has markings that can help determine the appropriate length of the entire construct **(Figure 23)**.

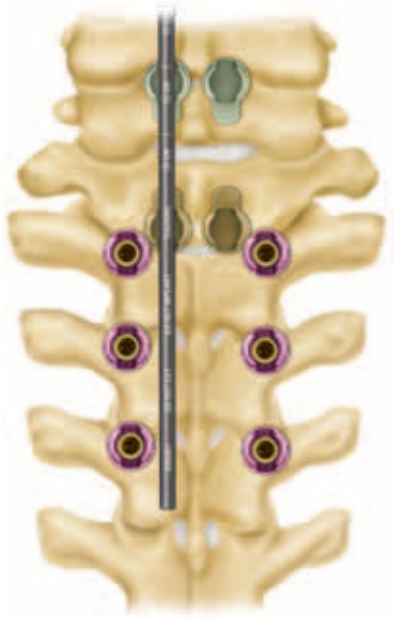


Figure 22

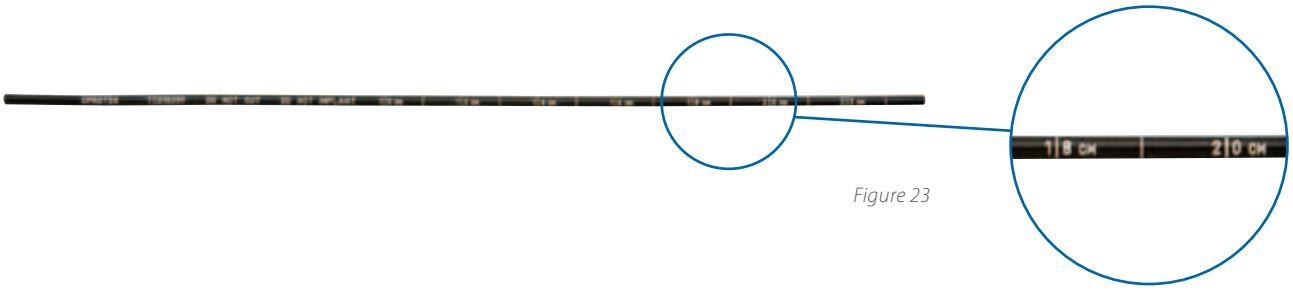


Figure 23

Rod Cutting

Use a marker to mark the rod at the appropriate length as determined by the Rod Template, and then cut the rod using the Rod Cutter **(Figure 24)**.

The Rod Cutter can also be used as an alternate for rod cutting **(Figure 25)**.

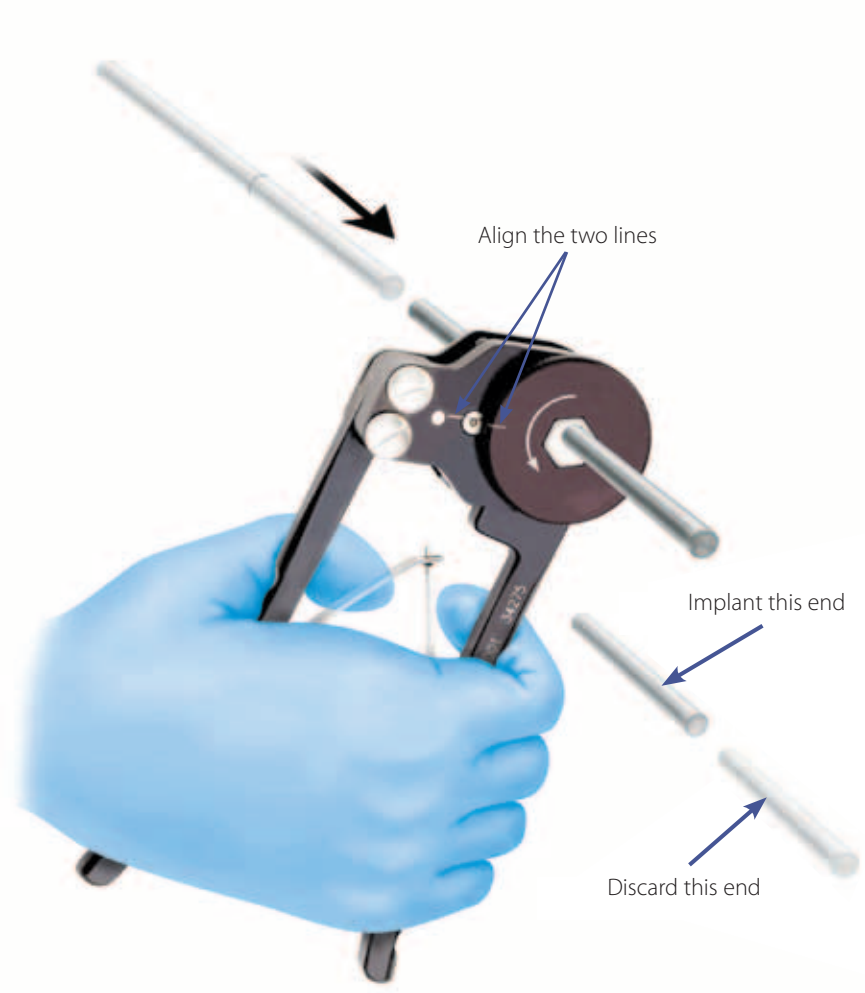


Figure 24

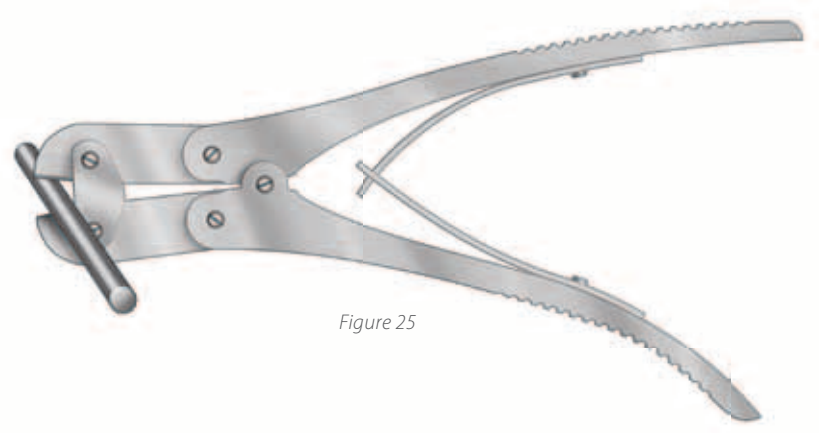


Figure 25

Rod Bending

Contour the rod to the sagittal contour of the spine and the medial/lateral orientation of the implants using the Rod Bender **(Figure 26)**.

If *in situ* bending is needed, the rod can be contoured in the sagittal plane with the Bending Irons **(Figure 27)** and in the medial/lateral plane with the Coronal Benders **(Figure 28)**.

Figure 26

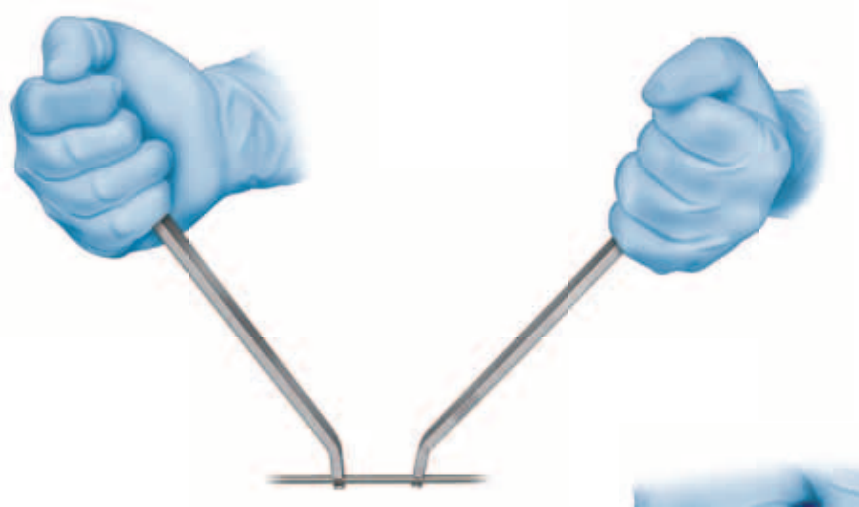


Figure 27

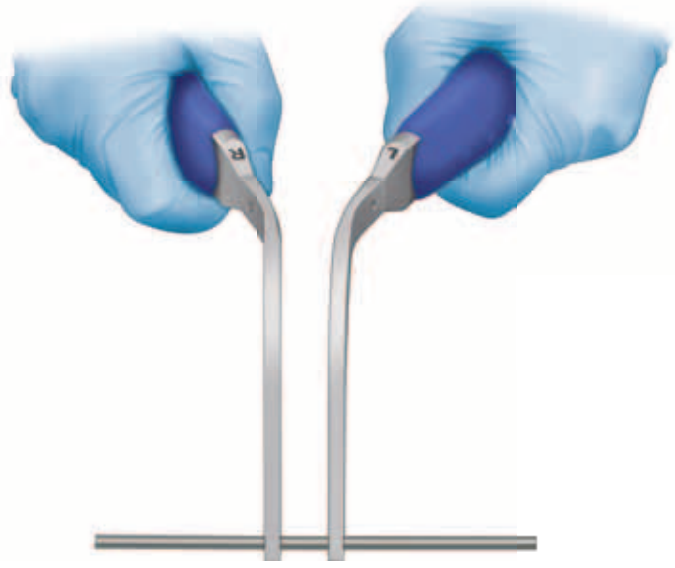


Figure 28

Using Lateral Offset Connectors

The relief notches on the VERTEX SELECT™ Multi-Axial Screw (MAS) allow up to 7.5mm of medial/lateral variability **(Figure 29)**. If additional medial/lateral offset is required, Lateral Connectors can facilitate rod attachment of the non-linear screws and can adjust for screw height difference and excessive angulations.

Closed-Ended Lateral Connectors are provided for placement before rod insertion **(Figure 30)**, and Open-Ended Lateral Connectors are side loading to accommodate placement before or after rod insertion **(Figure 31)**.

Provisionally tighten the set screw on the lateral connector to prevent migration on the rod by using the Quick Release Self-Holding Screwdriver with the Universal Handle.

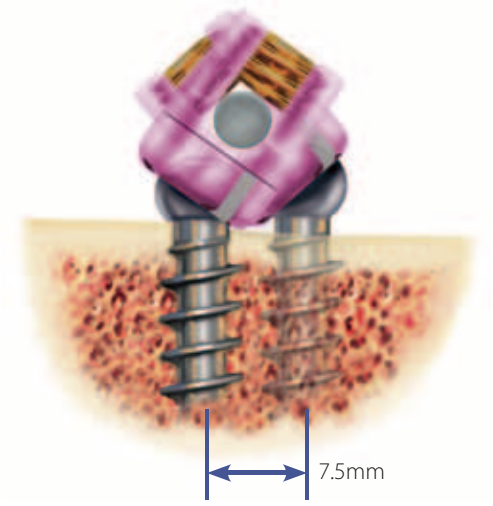


Figure 29

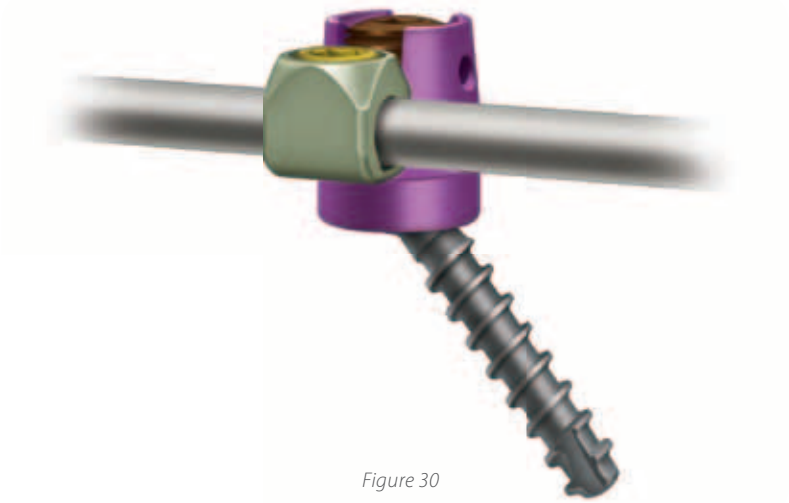


Figure 30

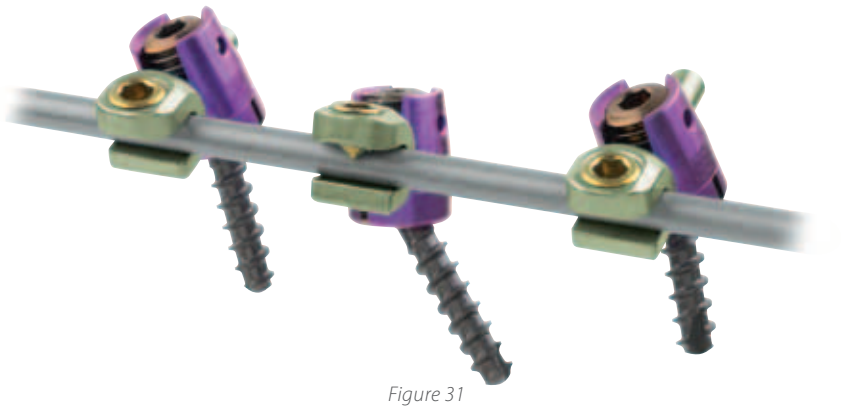


Figure 31

Rod Placement

Place the rod into the implant heads using the Rod Holder **(Figure 32)**.

With the rod fully seated in the screw heads, a set screw can be loaded onto the Quick Release Self-Holding Screwdriver, placed through the Rod Pusher/Counter Torque, and seated into each screw head **(Figure 33)**.

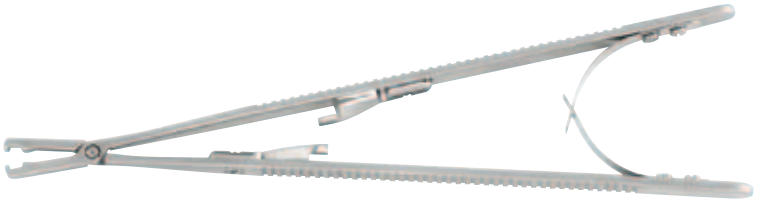


Figure 32

Note

If a MAS CROSSLINK® Connector will be used, a separate set screw is required. Refer to the MAS CROSSLINK® Connector section for more information.

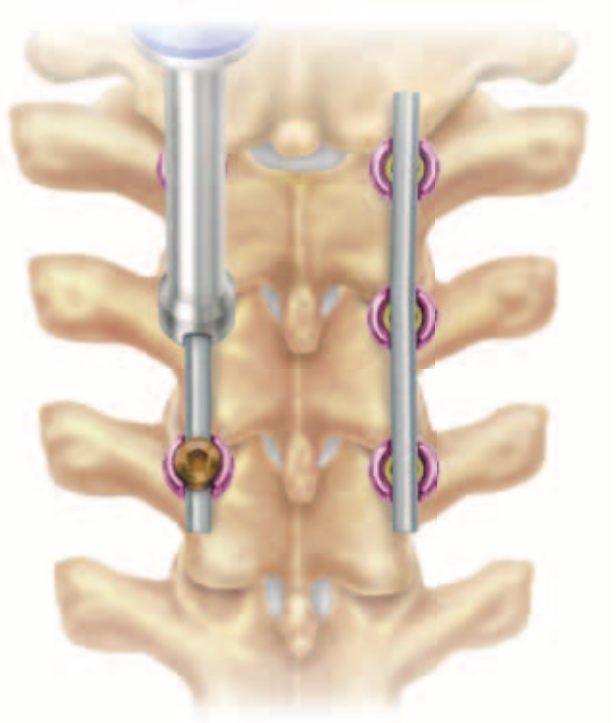


Figure 33

Rod Reduction

If the rod is not easily captured in the screw head, the Rod Reducer or Rod Rocker can be used to fully seat the rod and simplify set screw introduction.

To use the Rod Rocker, place over the rod and grasp the screw head notches **(Figure 34a)**. Gently squeeze and tilt the Rod Rocker to reduce the rod into the screw saddle **(Figure 34b)**.

To use the Rod Reducer, place it over the rod and grasp the screw head notches from above. As the Reducer handle is squeezed, the Rod Reducer sleeve will slide down and seat the rod **(Figure 34c)**.

To secure the rod, load a set screw into the multi-axial screw saddle with the Quick Release Self-Holding Screwdriver, as the Rod Reducer or Rod Rocker continues to hold the rod in place **(Figure 34d)**.

Figure 34a

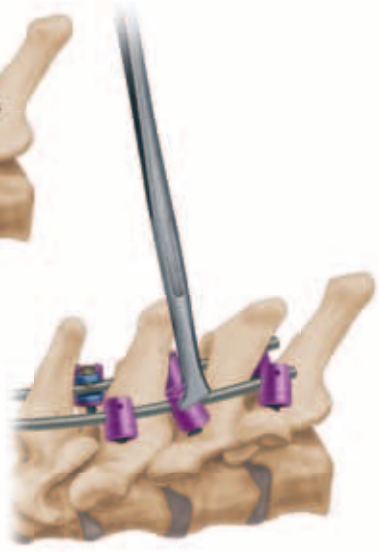


Figure 34b

Figure 34c

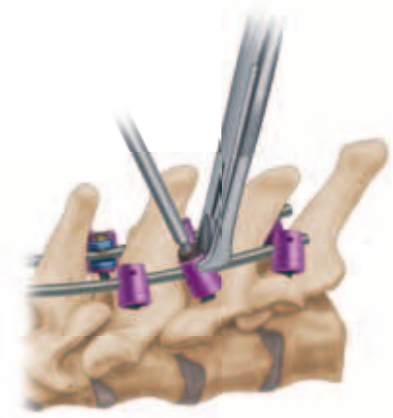


Figure 34d

Compression and Distraction

Once the rod is secured into 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 35)**.

A Rod Gripper is also included for additional rod manipulation **(Figure 36)**.

Figure 35

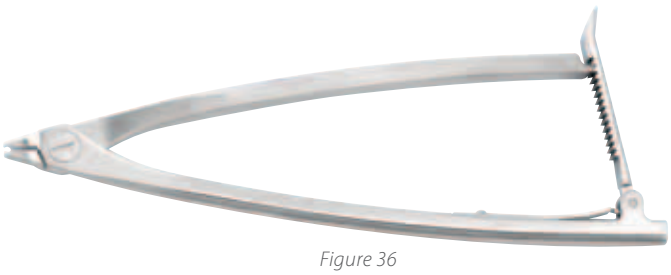


Figure 36

Final Tightening

After the compression and distraction maneuvers are complete, the set screws should be final tightened using the Straight Hex Torque Driver and Torque Limiting T-Handle in conjunction with the Rod Pusher/Counter Torque (Figure 37).

Figure 37

Torque Limiting T-Handle

Rod Transition Options

Rod transition options allow for a transition from the cervical to the thoracic spine or at any location where it is necessary to move from a smaller rod diameter to a large rod diameter.

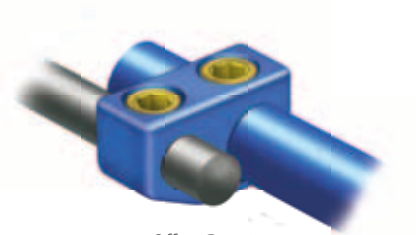
All VERTEX SELECT™ Rod Connectors can be used to connect 3.2mm or 3.5mm rods to 3.2mm, 3.5mm, 4.5mm, or 5.5mm rods.

Various designs are available depending on the alignment and anatomical requirements.

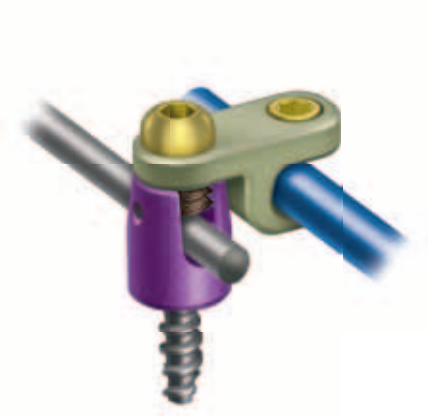
If choosing the threaded rods, insert the threaded portion of the 3.2mm or 3.5mm rod into the receiving end of a 4.5mm or 5.5mm rod and rotate clockwise until fully tightened.

All set screws of the rod transition options utilize a Torque Limiting Driver for final tightening.

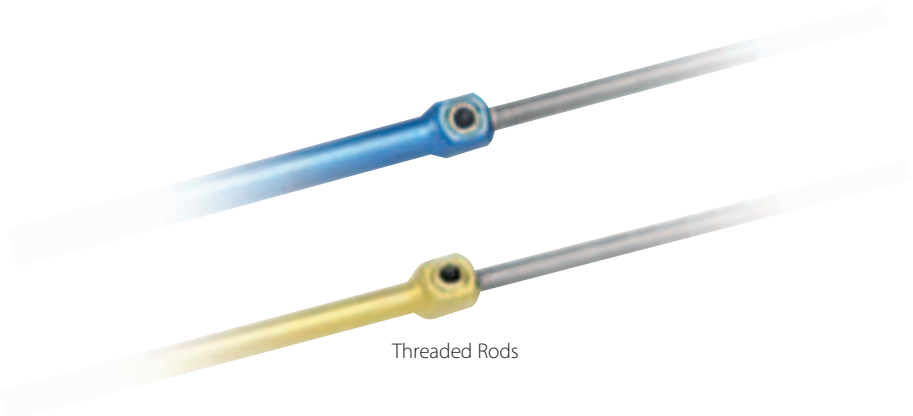
Axial Domino



Offset Domino



Multi-Axial Screw (MAS)
Extension Connector



Threaded Rods

Using Multi-Axial Screw (MAS) Extension Connector Option

The MAS Extension Connector will allow for a "zero run on the rod" connection between dual rods by connecting directly to the head of a multi-axial screw. It also will allow extension of a previous construct directly from a multi-axial screw head.

Place a MAS Connector Set Screw in the head of the multi-axial screw using the Self Holding External 4.0mm Hex Screwdriver **(Figure 38)**.

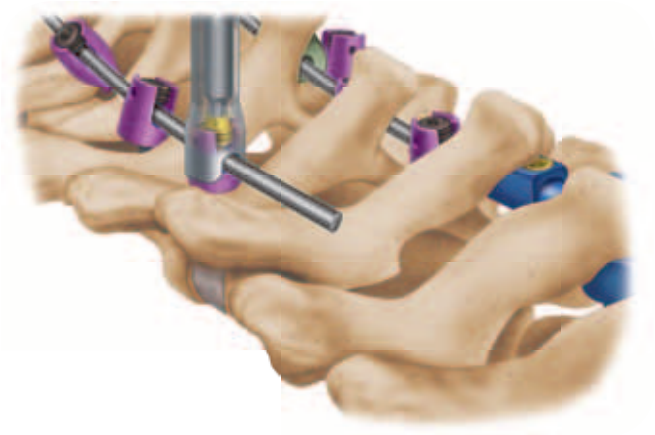


Figure 38

Insert preferred size MAS Extension Connector over the MAS Connector Set Screw, with open end facing lateral.

Place a MAS CROSSLINK® Locking Screw over the MAS Extension Connector **(Figure 39)** and tighten using the Straight Hex Torque Driver and the Torque Limiting T-Handle.

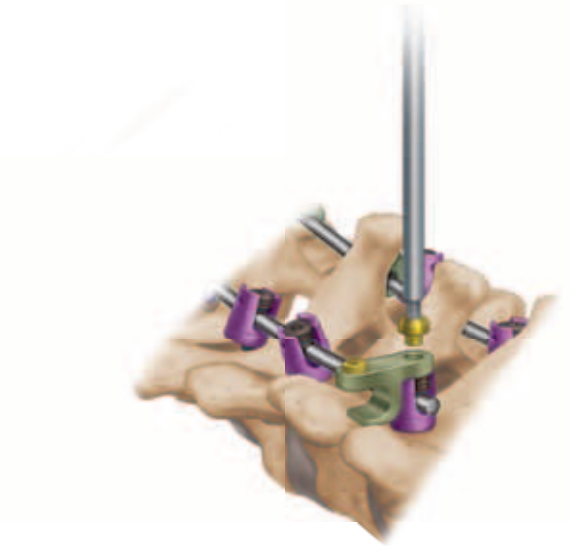


Figure 39

Place the adjoining rod in the open-end portion of the connector and tighten set screw into position using the Straight Hex Torque Driver and the Torque Limiting T-Handle **(Figure 40)**.

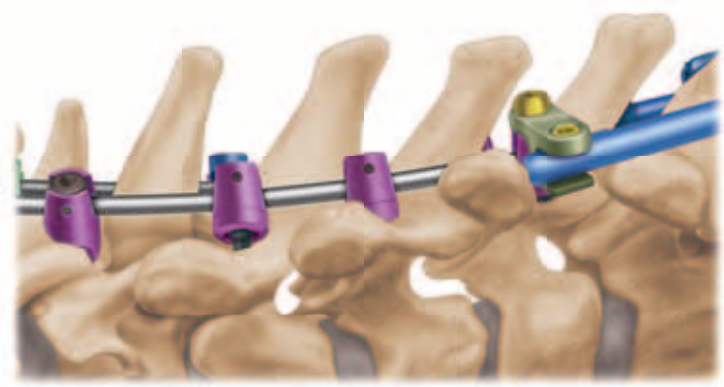
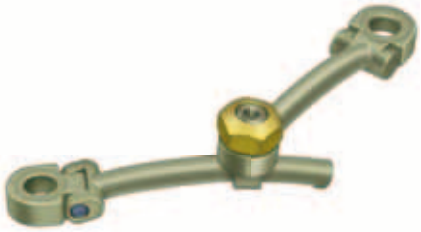


Figure 40

CROSSLINK® Connector Placement

Once decortication is thoroughly performed and bone graft material is placed, CROSSLINK® Connectors are recommended for the top and bottom thirds of the construct to increase rigidity. Two CROSSLINK® Connector designs are available, the MAS CROSSLINK® Connector and the Rod CROSSLINK® Connector.

Optional MAS Connector Clip is available to attach a MAS CROSSLINK® Connector to a rod, if needed.



MAS CROSSLINK® Connector

Rod CROSSLINK® Connector

MAS/Rod Connector Clip

Note

The CROSSLINK® Swizzle Stick can be used for positioning the CROSSLINK® Connectors by threading the Swizzle Stick into the center nut, then removed after final tightening (Figure 41). It may also help to align the center nut driver.

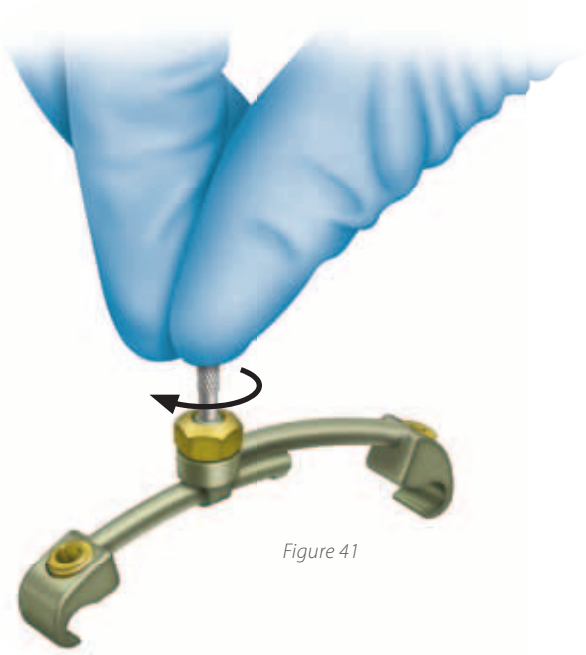


Figure 41

Multi-Axial Screw (MAS) CROSSLINK® Connector Placement

The MAS CROSSLINK® Connector has the ability to connect directly to the head of two multi-axial screws in cases where adjacent screw heads are in close proximity to one another, as well as the ability to span various levels.

To use the MAS CROSSLINK® Connector, first place the MAS Connector set screw in the head of the multi-axial screw (MAS) using the Self-Holding 4.0mm Hex Screwdriver **(Figure 42)**. Attach the MAS CROSSLINK® Connector, then place a MAS CROSSLINK® Locking Screw over the MAS CROSSLINK® Connector and provisionally tighten using the Quick Release Self-Holding Screwdriver **(Figure 43)**.

Also, the MAS CROSSLINK® Connector has the ability to connect directly to the rod if necessary by using the MAS/Rod CROSSLINK® Connector Clip. Place the CROSSLINK® Connector over the clip, attach a MAS CROSSLINK® Locking Screw over the CROSSLINK® Connector, and provisionally tighten using the Quick Release Self-Holding Screwdriver. The MAS CROSSLINK® Locking Screws should be tightened using the Straight Hex Torque Driver and Torque Limiting Handle.

Once the CROSSLINK® Connector is in position, hand tighten the center nut using the Lock Nut Driver **(Figure 44)**.

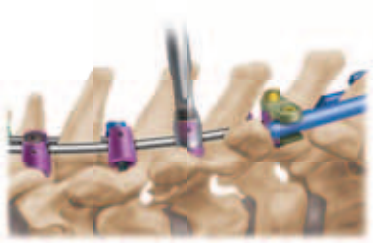


Figure 42

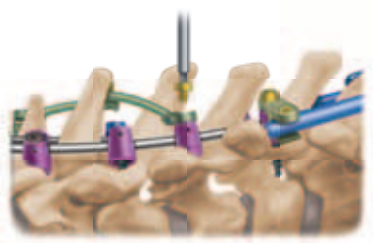


Figure 43

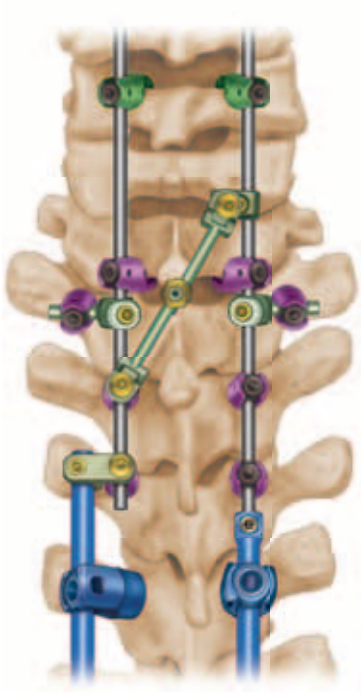


Figure 44

Note

The center nut is not intended for break-off and should be hand tightened only.

Final Construct

An intraoperative image of the final construct should be made to verify proper connection is achieved prior to wound closure **(Figure 45)**.

Note

Cable Connectors are included in the set to allow for additional fixation using the ATLAS® Cable System. Cable Connectors are open-ended connectors and can be placed either medially or laterally on the rod. Once placed, the cable can simply be threaded through the hole and fixated according to the ATLAS® Cable technique **(Figure 46)**.

Figure 46

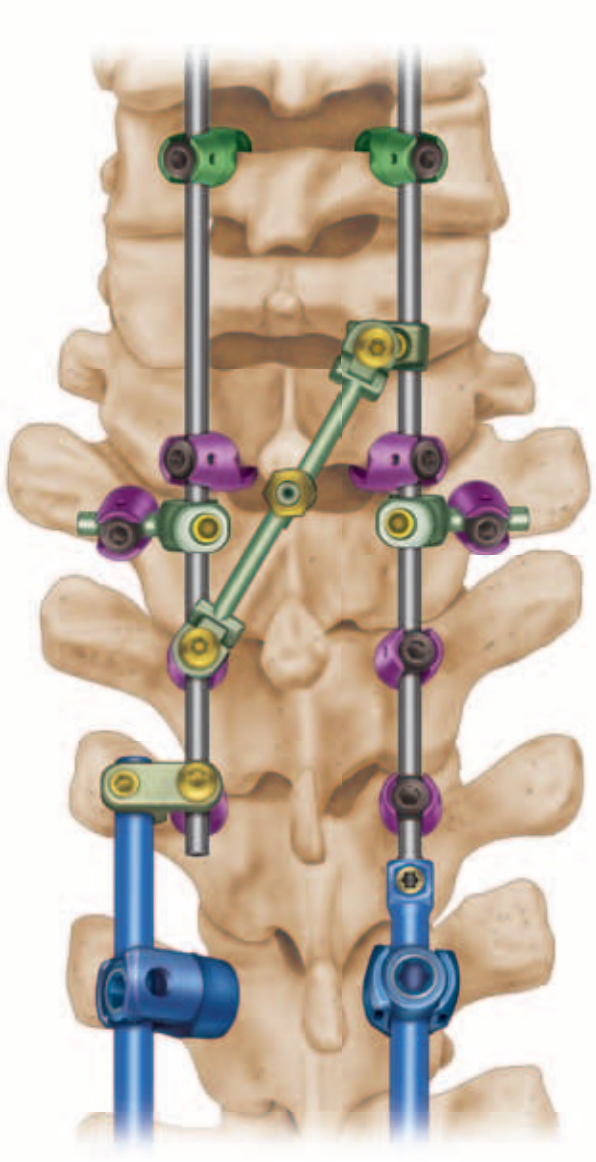


Figure 45

Explantation

To remove any of the VERTEX SELECT™ Reconstruction System implants described throughout this technique, engage the set screw and multi-axial screw with a 2.5mm Hex Screwdriver and turn counterclockwise until the set screw is disengaged from the implant and the bone screw is disengaged from the bone.

VERTEX SELECT™

Reconstruction System Occipitocervical (OC) Module

USING THE OCCIPITAL SCREW CONNECTORS AND OCCIPITAL ADJUSTABLE RODS

and

USING THE OCCIPITAL MIDLINE PLATES AND OCCIPITAL ADJUSTABLE RODS

The VERTEX SELECT™ Reconstruction System Occipitocervical Module must be ordered separately from the standard VERTEX SELECT™ Implants and Instrument Set.

Occipital Fixation Implant Features

Occipitocervical Bone Screws

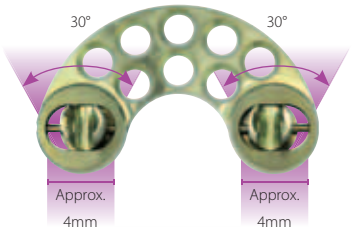
- Increased diameters—4.5mm and 5.0mm*
- Slightly tapered tip for easier insertion*
- Increased thread pitch*

Occipitocervical Screw Connectors

- Allow 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
- Accept 4.5mm and 5.0mm diameter occipital bone screws
- Accept Pre-Contoured Occipital Rod and Occipital Adjustable Rod
- Low-profile occipital fixation option

Adjustable Occipital (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
- Contoured with the Occipital Plate Bender



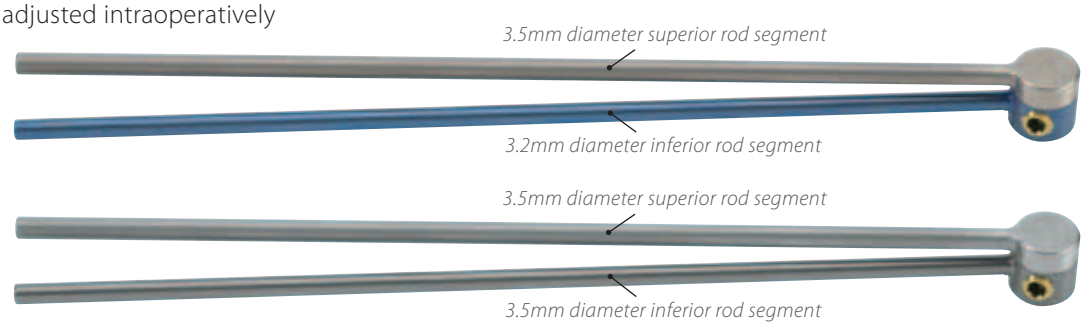
Occipitocervical Midline Fixed Plates

- Allows for occipital midline fixation
- Low-profile design
- Lateral screw placement allows for torsional stability
- Multiple sizes available to match patient anatomy
- Accept 4.5mm and 5.0mm diameter occipital bone screws
- Accept Occipital Pre-Contoured Rods and Occipital Adjustable Rods
- 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
- Available in 3.2mm/3.5mm diameter or 3.5mm/3.5mm diameter
- Available in 120mm and 220mm lengths



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

Occipital Fixation Implant Features *continued*

Occipitocervical Pre-curved Rods

- Pre-contoured to match anatomy of the occipitocervical junction
- Available in 3.2mm/3.6mm or 3.5mm diameters
- Available in 100mm and 200mm lengths

Occipitocervical Plate/Rods

- Pre-contoured to match anatomy of the occipitocervical junction
- Available in 3.5mm diameters
- Available in 100mm and 200mm lengths

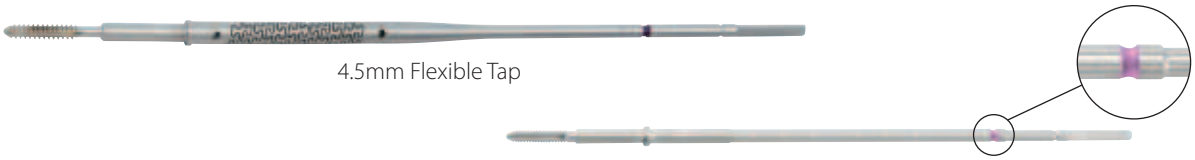
Instrument Set

Drill Bits

3.2mm Flexible Drill Bit

3.2mm Straight Drill Bit

Taps



4.5mm Flexible Tap

4.5mm Straight Tap

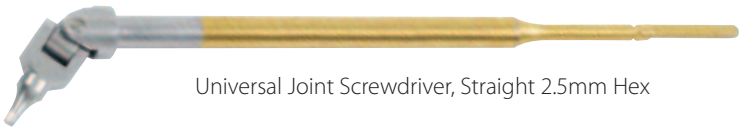
5.0mm Flexible Tap

5.0mm Straight Tap

Screwdrivers

Flexible Screwdriver, Self Holding, 2.5mm Hex

Right Angle Screwdriver, Straight 2.5mm Hex



Universal Joint Screwdriver, Straight 2.5mm Hex

Instrument Set *continued*

Drill-Tap (DT) Screw Guides

Fixed Occipital DT Guide, 6mm/8mm

Fixed Occipital DT Guide, 10mm/12mm

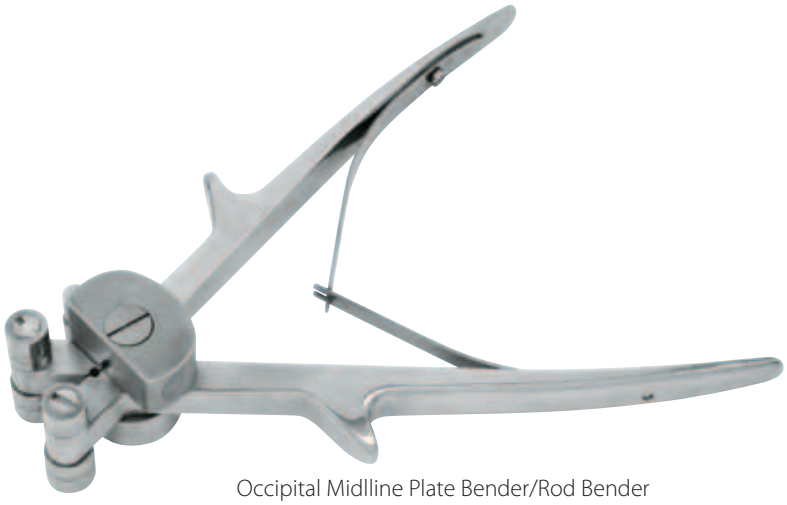
Fixed Occipital DT Guide, 14mm/16mm

18mm Fixed Occipital DT Guide/Screwdriver Guide

Occipital Midline Plate and Rod Benders

Bending Iron, Right

Bending Iron, Left



Occipital Midlline Plate Bender/Rod Bender

Note

The surgical techniques described in this document also include the use of instruments from the VERTEX SELECT™ Reconstruction instrument set. If an instrument does not appear on page 31 or 32 of this document, it can be found in that instrument set.

VERTEX SELECT™

Reconstruction System Occipitocervical Module

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 47)**. 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. 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 48)**.

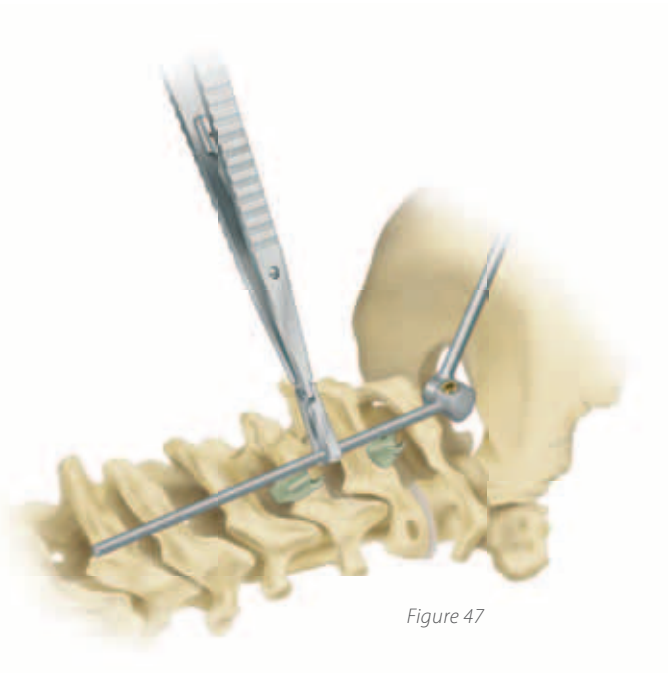


Figure 47

Figure 48

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 49)**. 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 have been determined, cut both ends of the rod to the required lengths using the Ratcheting Rod Cutter **(Figure 50)**.

Figure 49

Figure 50

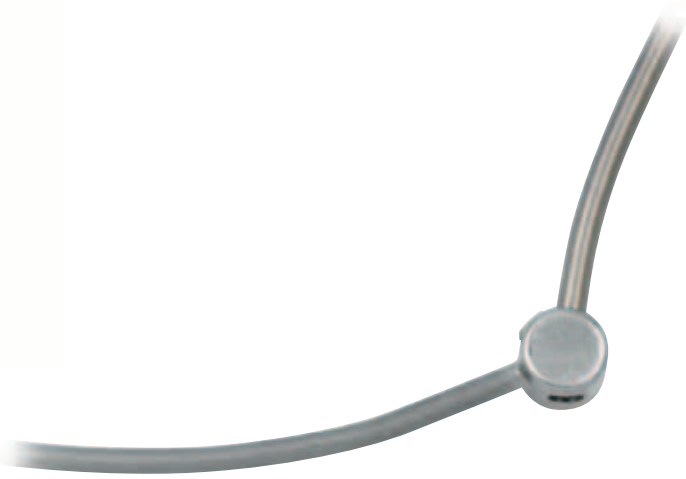


Figure 51

Note

Avoid repeated bending motions to the implants, as excessive bending will decrease the integrity of the implant (Figure 51).

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 **(Figure 52)**. 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.

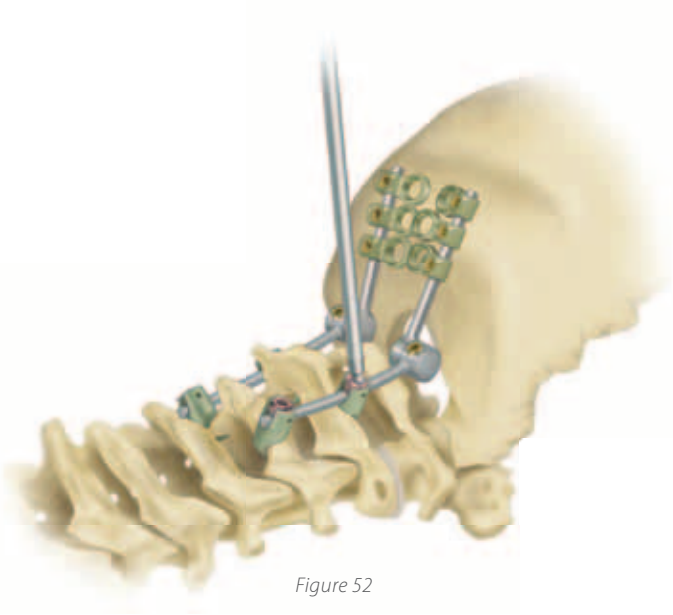


Figure 52

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 53)**.

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.

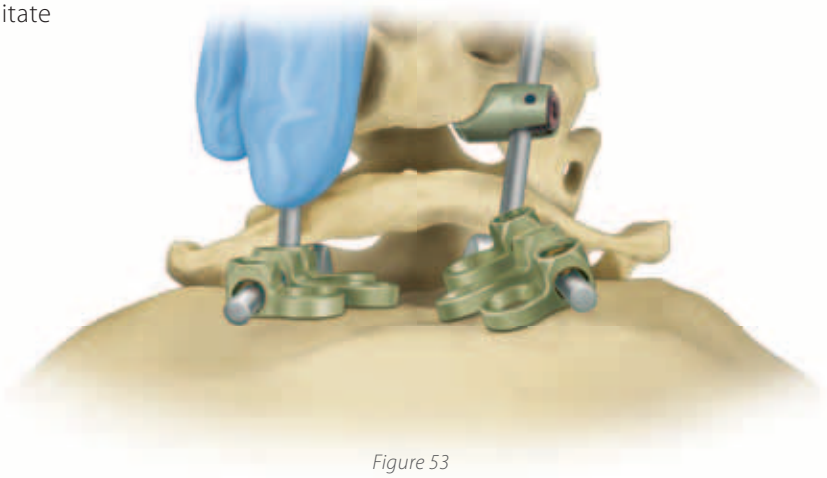


Figure 53

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.

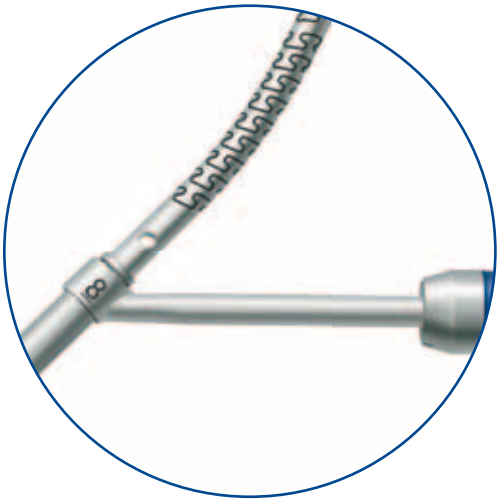


Figure 54

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 54)**. When the flexible drill bit is used, the DT Guide will help stabilize the flexible shaft and 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 55)**. Drilling must be done through the Occipital Screw Connectors to ensure proper drilling depth.

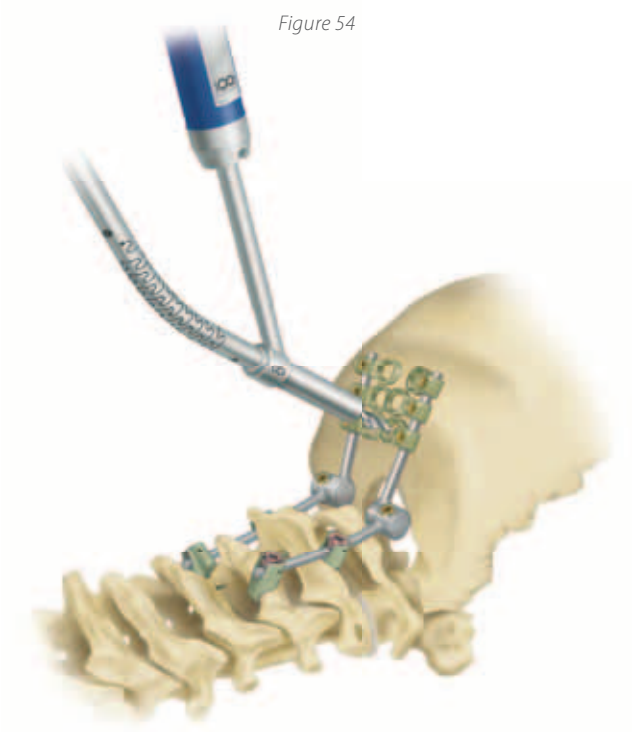


Figure 55

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 56)**.

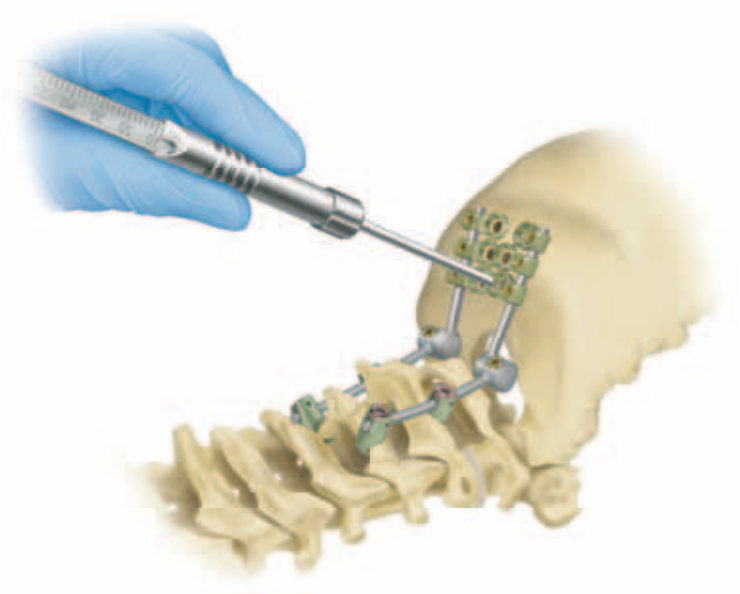


Figure 56

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 57)**. The occipital bone is very dense, and each hole should be completely tapped.

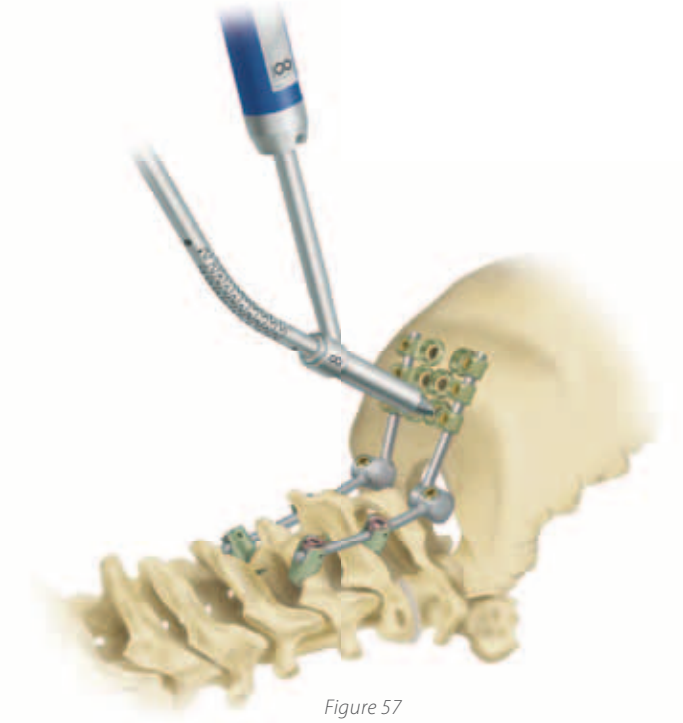


Figure 57

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 58)**.

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 DT 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 59)**.

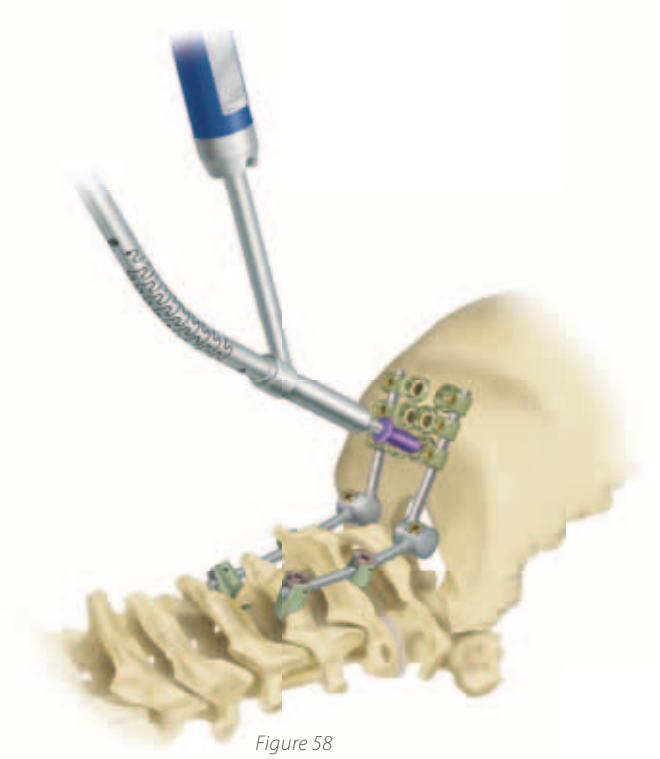


Figure 58

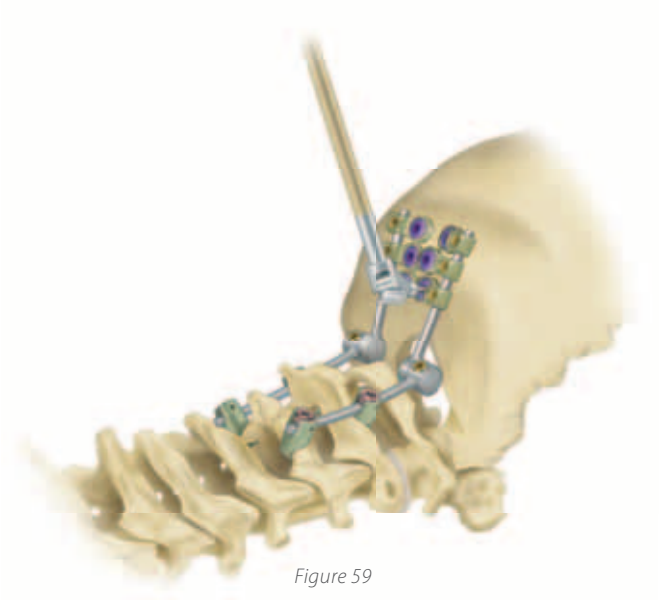


Figure 59

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 60)**.

Securely tighten the Occipital Screw Connectors on the rod using the Straight Hex Screwdriver **(Figure 61)**.

Figure 60

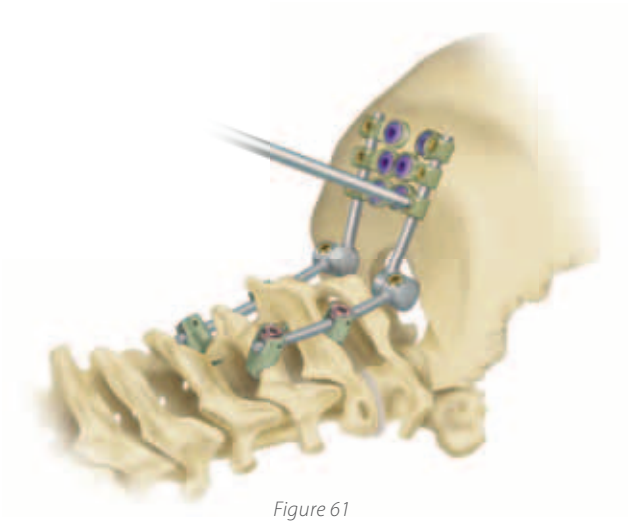


Figure 61

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 62)**.

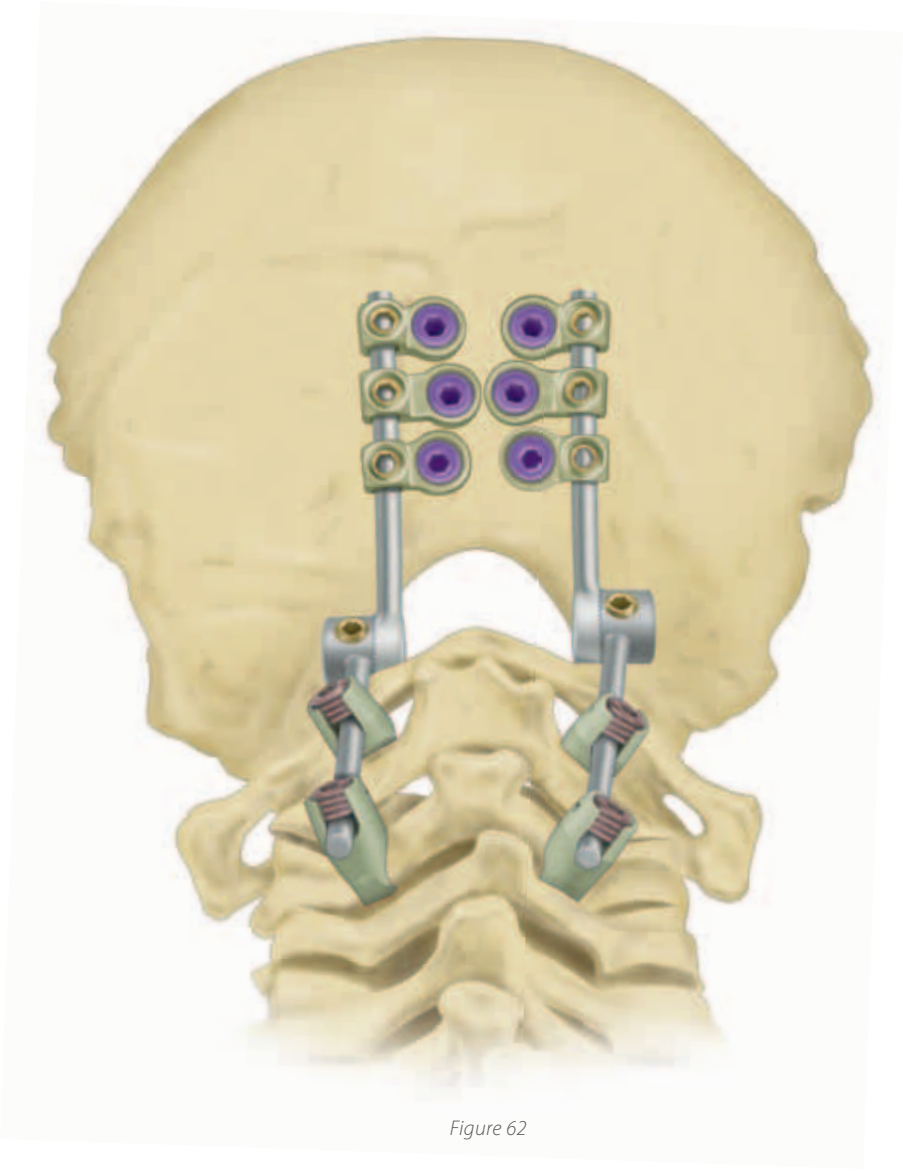


Figure 62

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 Occipitocervical (OC) Module

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 63)**.

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

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

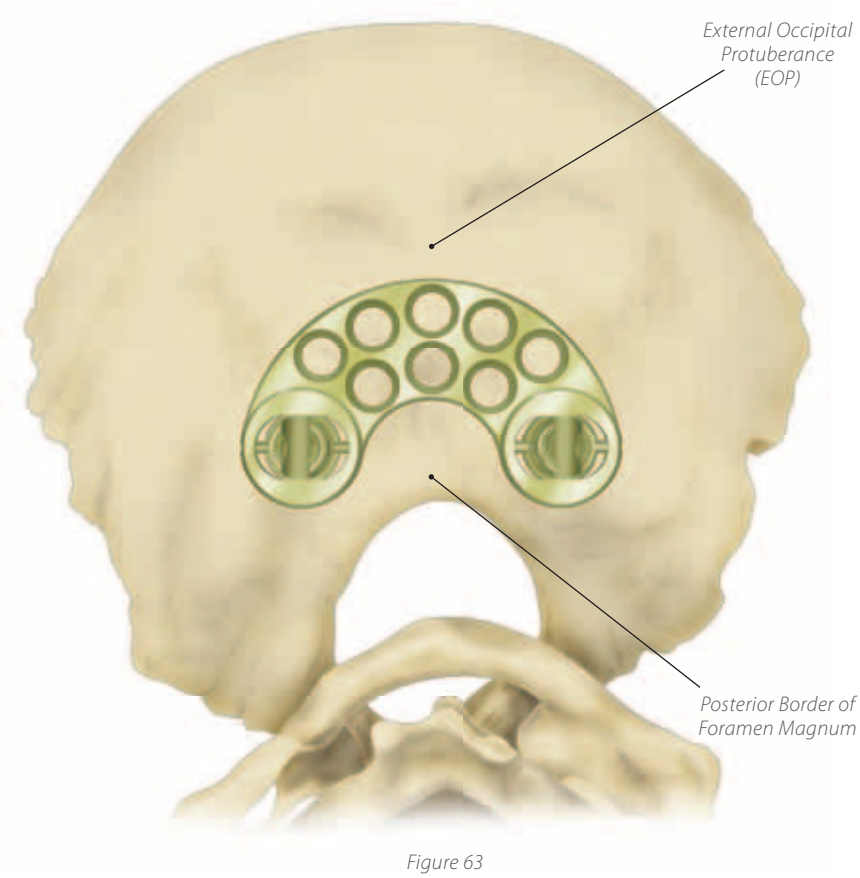


Figure 63

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 64)**. Instructions for use of the Occipital Adjustable Rod are described on page 34.

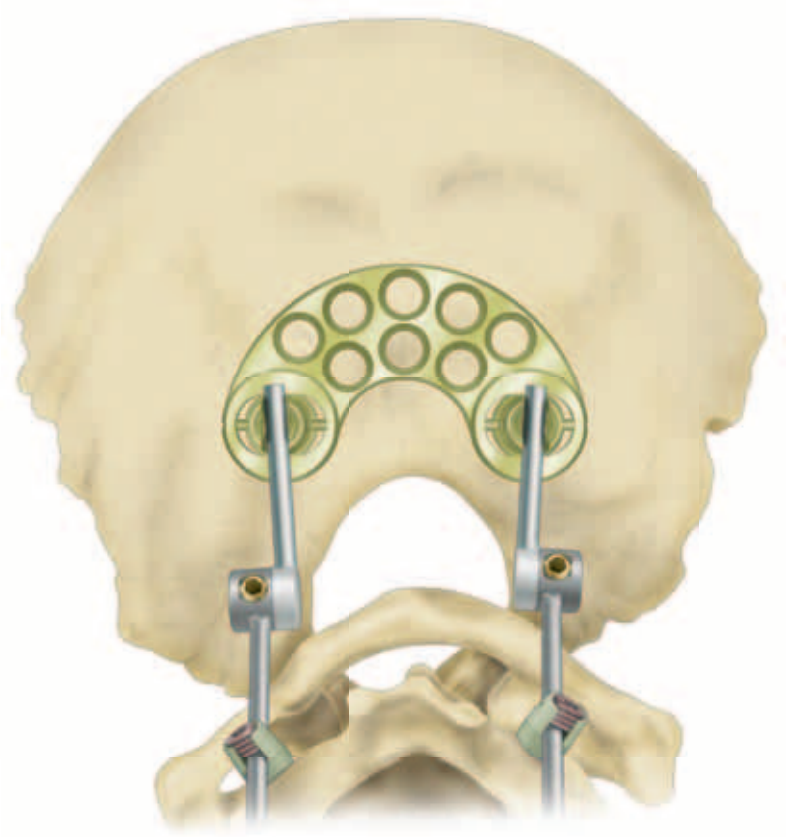


Figure 64

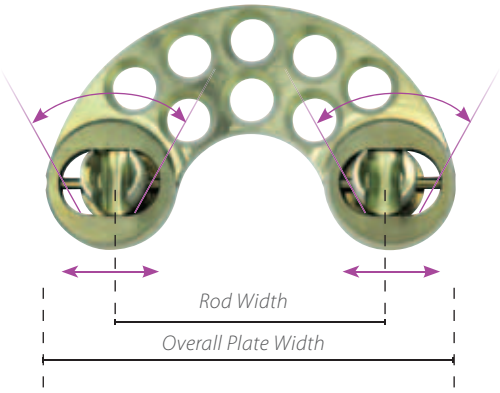


Plate Sizes

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

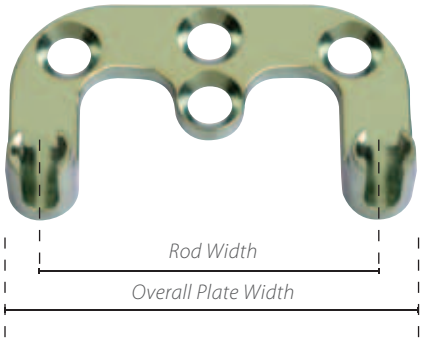


Plate Sizes

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

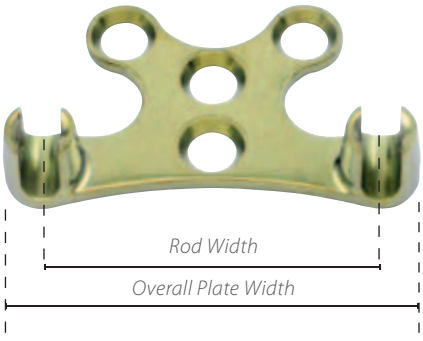


Plate Sizes

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 65)**. The Left and Right Bending Irons may also be used as additional tools to contour the plate **(Figure 66)**. 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.

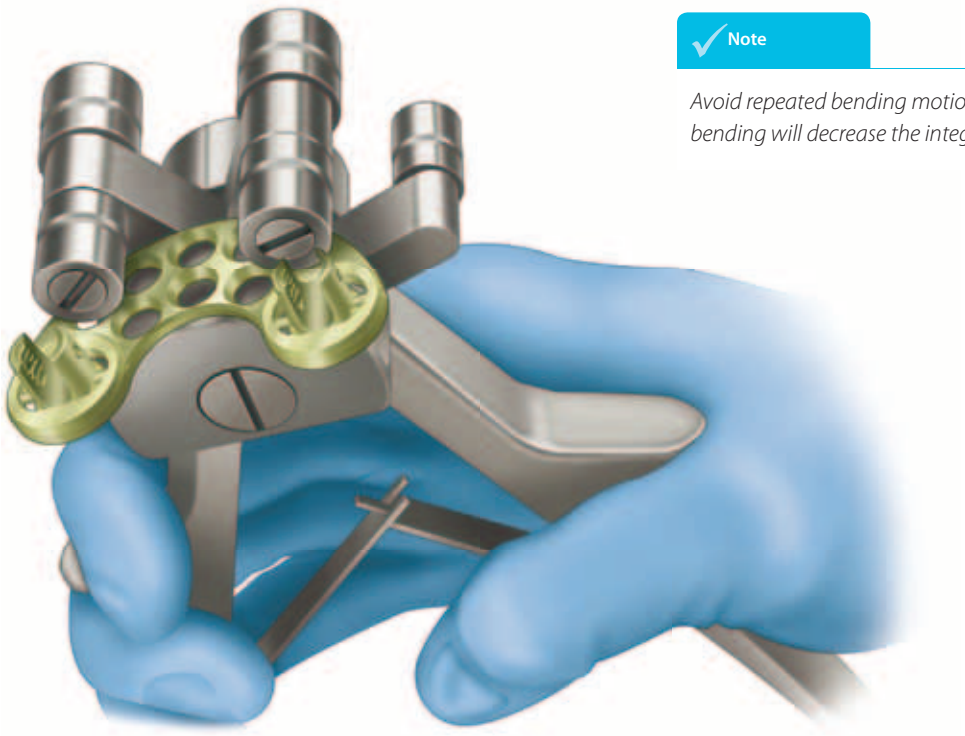


Figure 65

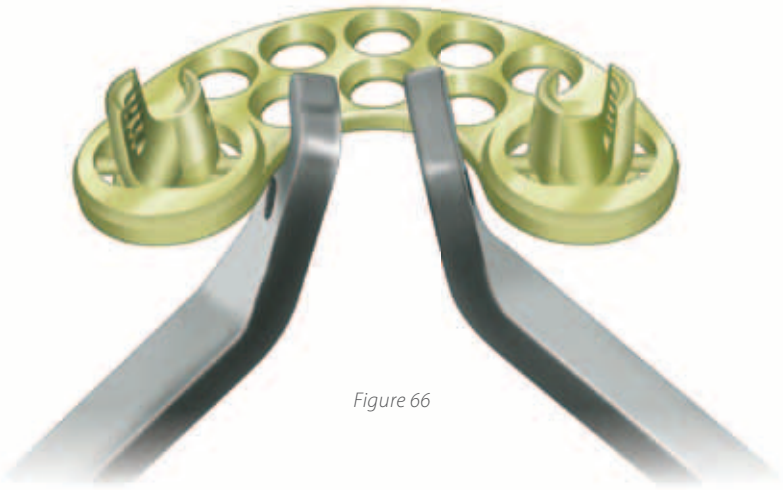


Figure 66

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.

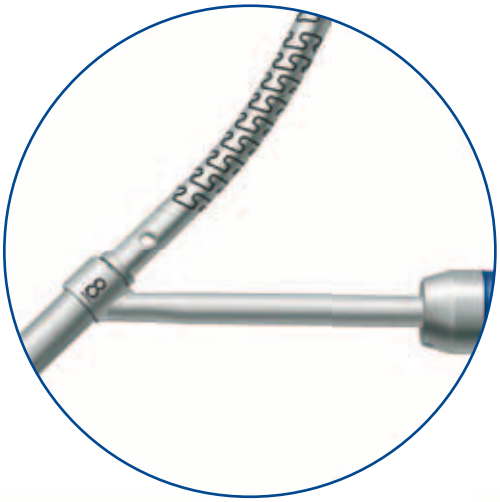


Figure 67

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 67)**. When the flexible drill bit is used, the DT Guide will help stabilize the flexible shaft and 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 68)**. Drilling must be done through the Occipital Midline Plate to ensure proper drilling depth.

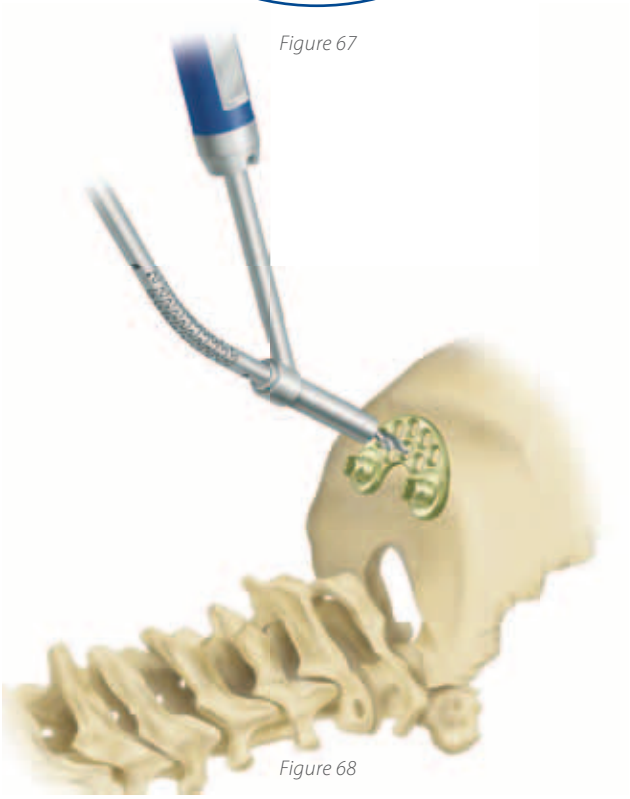


Figure 68

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 69)**.

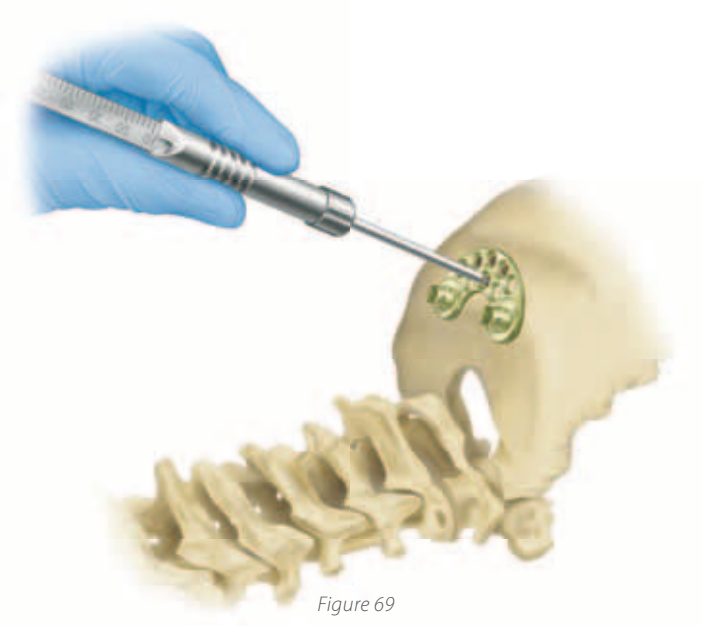


Figure 69

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 70)**. The occipital bone is very dense, and each hole should be completely tapped.

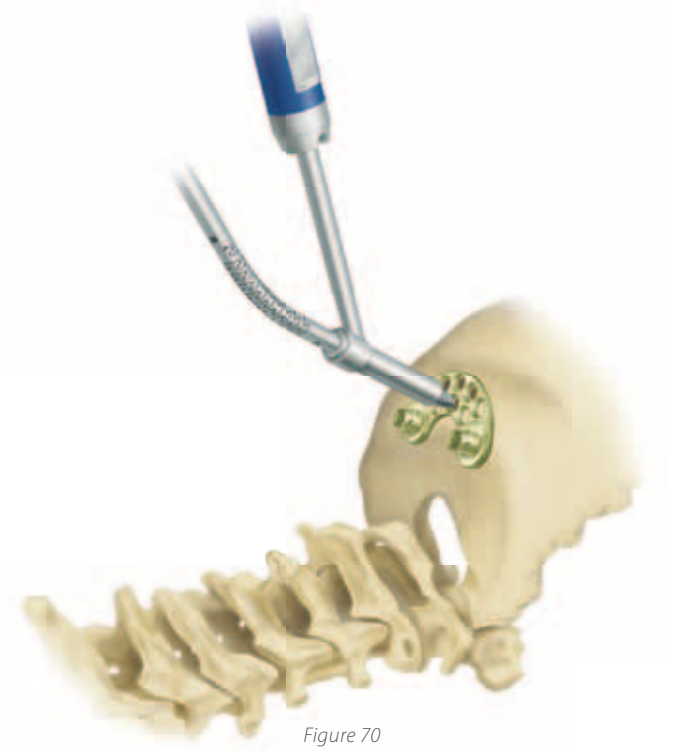


Figure 70

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 Occipitocervical (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 71)**.

Note

When the flexible screwdriver is used the DT Guide will help stabilize the flexible shaft and direct the screwdriver.

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 72)**.

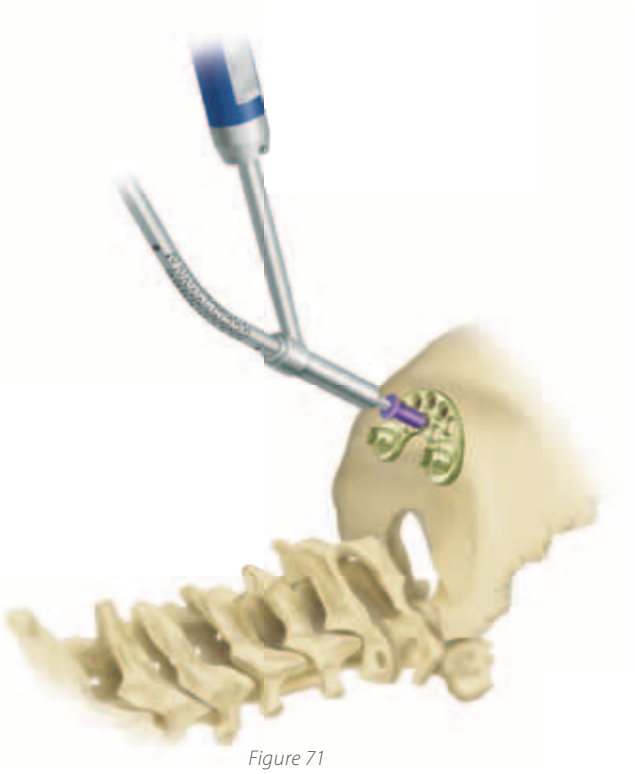


Figure 71

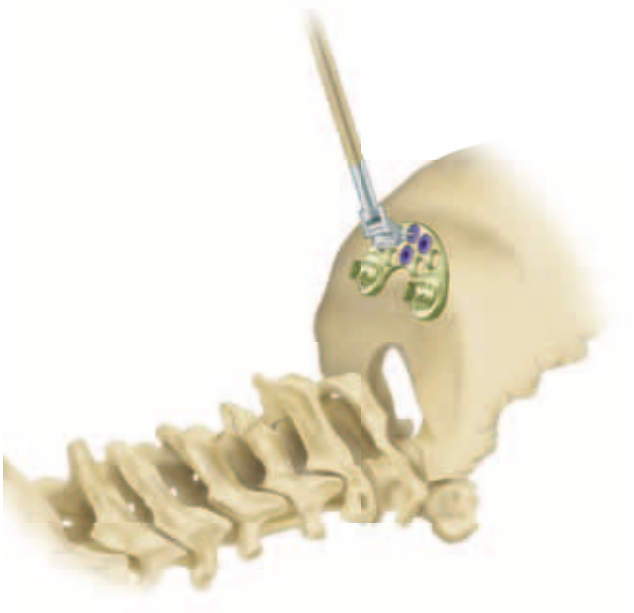


Figure 72

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 73)** 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 74)**. 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.

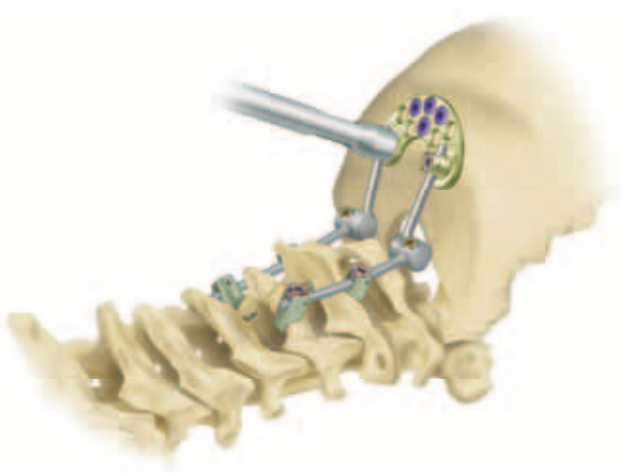


Figure 73

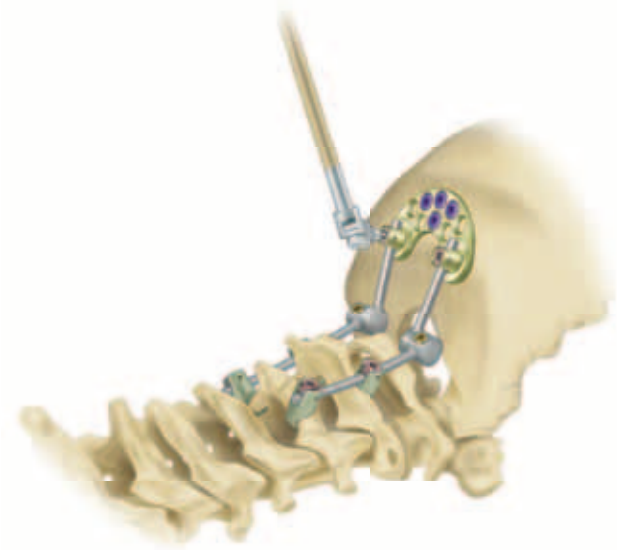
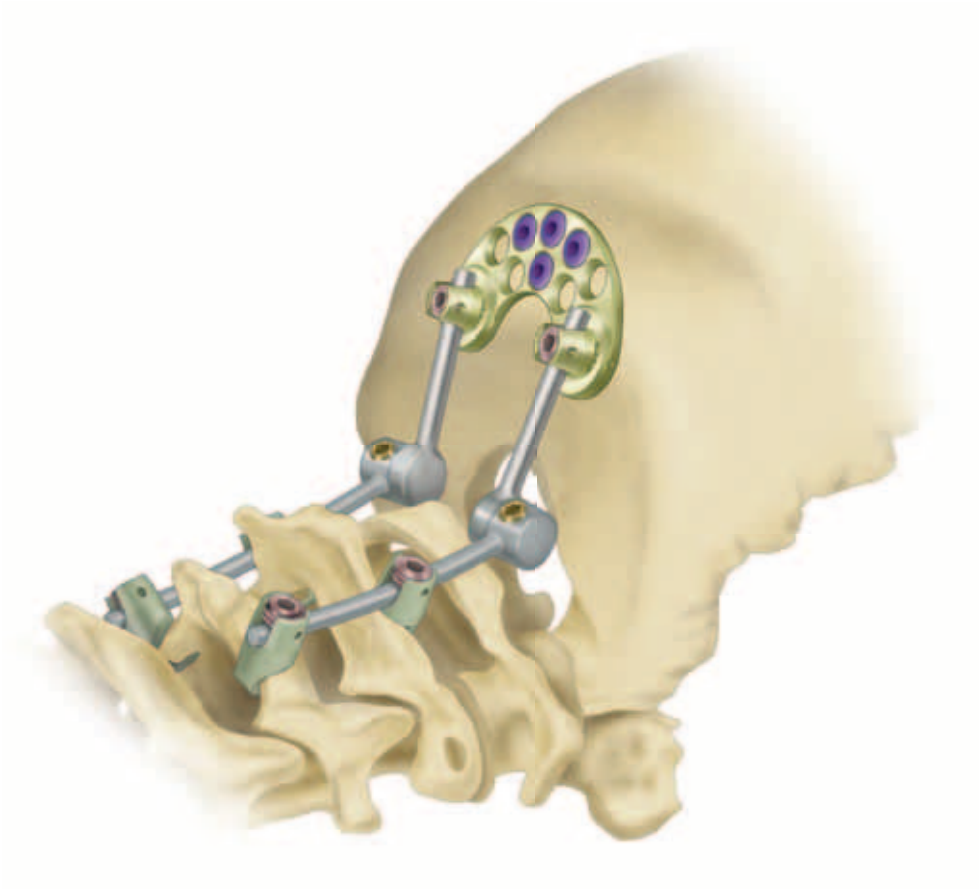


Figure 74

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.

Set Configuration

Multi-Axial Screw

Multi-Axial Screws

Part Number	Description	Qty In Standard Set	Loose Goods
6958710	3.5mm × 10mm MAS	6	
6958712	3.5mm × 12mm MAS	10	
6958714	3.5mm × 14mm MAS	14	
6958716	3.5mm × 16mm MAS	8	
6958718	3.5mm × 18mm MAS	6	
6958720	3.5mm × 20mm MAS	4	
6958722	3.5mm × 22mm MAS	2	
6958724	3.5mm × 24mm MAS	2	
6958726	3.5mm × 26mm MAS	2	
6958728	3.5mm × 28mm MAS	2	
6958730	3.5mm × 30mm MAS	2	
6958732	3.5mm × 32mm MAS	2	
6958734	3.5mm × 34mm MAS	2	
6958736	3.5mm × 36mm MAS	0	×
6958738	3.5mm × 38mm MAS	0	×
6958740	3.5mm × 40mm MAS	0	×
6958810	4.0mm × 10mm MAS	2	
6958812	4.0mm × 12mm MAS	4	
6958814	4.0mm × 14mm MAS	6	
6958816	4.0mm × 16mm MAS	4	
6958818	4.0mm × 18mm MAS	2	
6958820	4.0mm × 20mm MAS	2	
6958822	4.0mm × 22mm MAS	2	
6958824	4.0mm × 24mm MAS	2	
6958826	4.0mm × 26mm MAS	2	
6958828	4.0mm × 28mm MAS	2	
6958830	4.0mm × 30mm MAS	2	
6958832	4.0mm × 32mm MAS	2	
6958834	4.0mm × 34mm MAS	2	
6958836	4.0mm × 36mm MAS	0	×
6958838	4.0mm × 38mm MAS	0	×
6958840	4.0mm × 40mm MAS	0	×
6958842	4.0mm × 42mm MAS	0	×
6958844	4.0mm × 44mm MAS	0	×
6958846	4.0mm × 46mm MAS	0	×
6958848	4.0mm × 48mm MAS	0	×
6958850	4.0mm × 50mm MAS	0	×
6958852	4.0mm × 52mm MAS	0	×
6958910	4.5mm × 10mm MAS	0	×
6958912	4.5mm × 12mm MAS	0	×
6958914	4.5mm × 14mm MAS	0	×
6958916	4.5mm × 16mm MAS	0	×
6958918	4.5mm × 18mm MAS	0	×
6958920	4.5mm × 20mm MAS	0	×
6958922	4.5mm × 22mm MAS	0	×
6958924	4.5mm × 24mm MAS	2	
6958926	4.5mm × 26mm MAS	2	
6958928	4.5mm × 28mm MAS	2	

Set Configuration *continued*

Partially Threaded
Multi-Axial Screw

Multi-Axial Screws *continued*

Part Number	Description	Qty In Standard Set	Loose Goods
6958930	4.5mm × 30mm MAS	2	
6958932	4.5mm × 32mm MAS	2	
6958934	4.5mm × 34mm MAS	2	
6958936	4.5mm X 36mm MAS	0	×
6958938	4.5mm × 38mm MAS	0	×
6958940	4.5mm × 40mm MAS	0	×
6958942	4.5mm × 42mm MAS	0	×
6958944	4.5mm × 44mm MAS	0	×
6958946	4.5mm × 46mm MAS	0	×
6958948	4.5mm × 48mm MAS	0	×
6958950	4.5mm × 50mm MAS	0	×
6958952	4.5mm × 52mm MAS	0	×
6958718PT	3.5mm × 18mm PT MAS	0	×
6958720PT	3.5mm × 20mm PT MAS	0	×
6958722PT	3.5mm × 22mm PT MAS	0	×
6958724PT	3.5mm × 24mm PT MAS	2	
6958726PT	3.5mm × 26mm PT MAS	2	
6958728PT	3.5mm × 28mm PT MAS	2	
6958730PT	3.5mm × 30mm PT MAS	2	
6958732PT	3.5mm × 32mm PT MAS	2	
6958734PT	3.5mm × 34mm PT MAS	2	
6958736PT	3.5mm × 36mm PT MAS	0	×
6958738PT	3.5mm × 38mm PT MAS	0	×
6958740PT	3.5mm × 40mm PT MAS	0	×
6958818PT	4.0mm × 18mm PT MAS	0	×
6958820PT	4.0mm × 20mm PT MAS	0	×
6958822PT	4.0mm × 22mm PT MAS	0	×
6958824PT	4.0mm × 24mm PT MAS	2	
6958826PT	4.0mm × 26mm PT MAS	2	
6958828PT	4.0mm × 28mm PT MAS	2	
6958830PT	4.0mm × 30mm PT MAS	2	
6958832PT	4.0mm × 32mm PT MAS	2	
6958834PT	4.0mm × 34mm PT MAS	2	
6958836PT	4.0mm × 36mm PT MAS	0	×
6958838PT	4.0mm × 38mm PT MAS	0	×
6958840PT	4.0mm × 40mm PT MAS	0	×

Laminar Hook

Offset
Laminar Hook

Hooks

Part Number	Description	Qty In Standard Set	Loose Goods
7756073	4.5mm Laminar Hook	2	
7756074	6.0mm Laminar Hook	2	
7756073R	4.5mm Offset Laminar Hook, Right	2	
7756073L	4.5mm Offset Laminar Hook, Left	2	
7756074R	6.0mm Offset Laminar Hook, Right	2	
7756074L	6.0mm Offset Laminar Hook, Left	2	

Set Configuration *continued*

Set Screws

Rods

MAS CROSSLINK® Connector

MAS/Rod CROSSLINK® Connector Clip

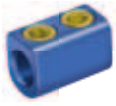
Open-End Lateral Connector

Rod CROSSLINK® Connector

Cable Connector

MAS Extension Connector

Offset Domino



Axial Domino

Set Screws

Part Number	Description	Qty In Standard Set	Loose Goods
6950315	Set Screw	26	
7753500	MAS Connector Set Screw	8	
7752529	MAS CROSSLINK®/MAS Extension Connector Locking Screw	8	

Rods

Part Number	Description	Qty In Standard Set	Loose Goods
7750010	3.5mm × 120mm Titanium Rod	0	×
6900240	3.2mm × 240mm Titanium Rod	3	
7750015	3.5mm × 240mm Titanium Rod	3	
7750020	3.5mm × 300mm Titanium Rod	0	×
6955240	3.2mm × 240mm Threaded Rod	3	
7755240	3.5mm × 240mm Threaded Rod	3	
7755245	4.5mm × 360mm Threaded Rod	3	
7755247	5.5mm × 360mm Threaded Rod	3	

Rod Connectors

Part Number	Description	Qty In Standard Set	Loose Goods
7756064	Open-End Lateral Connector, 10mm	4	
7756066	Open-End Lateral Connector, 13mm	4	
7756067	Closed-End Lateral Connector, 10mm	4	
7756068	Closed-End Lateral Connector, 13mm	4	
7751110	Cable Connector	4	
7752525	MAS CROSSLINK® Connector, S	1	
7752526	MAS CROSSLINK® Connector, M	1	
7752527	MAS CROSSLINK® Connector, L	1	
7752528	MAS/Rod CROSSLINK® Connector Clip	2	
7752535	Rod CROSSLINK® Connector, S	1	
7752536	Rod CROSSLINK® Connector, M	1	
7752537	Rod CROSSLINK® Connector, L	1	

Transition Connectors

Part Number	Description	Qty In Standard Set	Loose Goods
7756069	MAS Extension Connector, 3.2mm/3.5mm	3	
7756071	MAS Extension Connector, 4.5mm	3	
7756072	MAS Extension Connector, 5.5mm	3	
7750443	Offset Domino, 3.2mm/3.5mm to 3.2mm/3.5mm	3	
7750444	Offset Domino, 3.2mm/3.5mm to 4.5mm	3	
7750445	Offset Domino, 3.2mm/3.5mm to 5.5mm	3	
7750346	Axial Domino, 3.2mm/3.5mm to 3.2mm/3.5mm	3	
7750347	Axial Domino, 3.2mm/3.5mm to 4.5mm	3	
7750348	Axial Domino, 3.2mm/3.5mm to 5.5mm	3	

Set Configuration *continued*

Sterile Drill Bits

Part Number	Description	Qty In Standard Set	Loose Goods
6956011	2.9mm Sterile Drill Bit	1	
7756010	2.4mm Sterile Drill Bit	1	

Instruments

Part Number	Description	Qty In Standard Set	Loose Goods
6956016	Universal Handle	3	
7756005	Adjustable Drill Guide	1	
6956006	14mm Drill Guide	1	
7756035	3.5mm Tap	1	
7756040	4.0mm Tap	1	
7756045	4.5mm Tap	1	
6956030	Tap Sleeve	1	
6956193	Screwdriver Shaft, Straight Hex	1	
7756203	CROSSLINK® Lock Nut Driver	1	
7756195	Threaded Screwdriver, 2.5mm Hex	1	
6956001	Awl Shaft	1	
6956003	Pedicle Probe	1	
8572102	Pedicle Feeler	1	
6956020	Depth Gauge	1	
6956148	Bone Reamer	1	
6956158	Laminar Elevator	1	
7756160	Hook Holder/Inserter	1	
7756170	Rod Pusher Counter Torque, Straight, MAS	1	
7756200	Torque Limiting Handle, T-Handle	1	
6956200R	Torque Limiting Handle, Straight Handle	1	
6956201	Straight Hex Torque Shaft, 2.5mm	2	
7756205	CROSSLINK® Swizzle Stick	1	
7756165	Screwdriver Shaft, Self Holding External Hex, 4.0mm	1	
7756202	Straight Hex Torque Shaft, External, 4.0mm	1	
7756154	Universal Rachet Handle	2	
6959993	Quick Release Self Holding Screwdriver	2	
6956163	Rod Gripper	1	
6956164	Rod Holder	1	
6905784	Insitu Rod Cutter	1	
7756167	Rod Rocker	1	
6956175	Rod Reducer	1	
7756290	Bending Iron, Left	1	
7756291	Bending Iron, Right	1	
7756197	Coronal Bender, Left	1	
7756198	Coronal Bender, Right	1	
6905787	Compression Forceps	1	
6905788	Distractor Forceps	1	
6900241	Rod Template	1	
6905785	Alignment Tool	1	
6956165	Rachet Rod Cutter	1	
6905782	Rod Bender	1	

Set Configuration *continued*

Adjustable OC Plate

Occipital Midline Plates

Occipital Screw Connectors

Occipitocervical Adjustable Rods

Occipitocervical Pre-Curved Rod

Occipital Plate/Rod

Occipitocervical Module

Occipital Midline Plates

Part Number	Description	Qty In Standard Set	Loose Goods
7755278	Adjustable OC Plate	2	
7759970	Occipitocervical Midline Plate, S	1	
7759971	Occipitocervical Midline Plate, M	1	
7759972	Occipitocervical Midline Plate, L	1	
6959970	Occipital Midline Keel Plate, S	1	
6959971	Occipital Midline Keel Plate, M	1	
6959972	Occipital Midline Keel Plate, L	1	

Occipital Screw Connectors

Part Number	Description	Qty In Standard Set	Loose Goods
7755325	Occipital Screw Connector	8	
7755327	Occipital Screw Connector, Offset	4	

Occipitocervical Rods

Part Number	Description	Qty In Standard Set	Loose Goods
7755122	3.2mm/3.5mm × 120mm Occipitocervical Adjustable Rod		×
7755123	3.2mm/3.5mm × 220mm Occipitocervical Adjustable Rod	3	
7755120	3.5mm × 120mm Occipitocervical Adjustable Rod		×
7755124	3.5mm × 220mm Occipitocervical Adjustable Rod		×
6955270	3.2mm × 200mm Pre-Curved Occipitocervical Rod	3	
7755271	3.5mm × 200mm Pre-Curved Occipitocervical Rod		×
7755231	3.5mm × 100mm Occipitocervical Pre-Contoured Plate/Rod		×
7755232	3.5mm × 200mm Occipitocervical Plate/Rod		×

Set Configuration *continued*

Occipital Bone Screws

Occipital Bone Screws

Part Number	Description	Qty In Standard Set	Loose Goods
7750506	4.5mm × 6mm Occipital Bone Screw	6	
7750508	4.5mm × 8mm Occipital Bone Screw	6	
7750510	4.5mm × 10mm Occipital Bone Screw	6	
7750512	4.5mm × 12mm Occipital Bone Screw	6	
7750514	4.5mm × 14mm Occipital Bone Screw	4	
7750516	4.5mm × 16mm Occipital Bone Screw		×
7750518	4.5mm × 18mm Occipital Bone Screw		×
7750606	5.0mm × 6mm Occipital Bone Screw	4	
7750608	5.0mm × 8mm Occipital Bone Screw	4	
7750610	5.0mm × 10mm Occipital Bone Screw	4	
7750612	5.0mm × 12mm Occipital Bone Screw	4	
7750614	5.0mm × 14mm Occipital Bone Screw	2	
7750616	5.0mm × 16mm Occipital Bone Screw		×
7750618	5.0mm × 18mm Occipital Bone Screw		×

Occipitocervical Instruments

Part Number	Description	Qty In Standard Set	Loose Goods
7756334	4.5mm Occipital Tap	1	
7756383	4.5mm Occipital Flexible Tap	1	
7756337	5.0mm Occipital Tap	1	
7756384	5.0mm Occipital Flexible Tap	1	
7759978	Fixed Occipital DT Guide, 6mm/8mm	1	
7759979	Fixed Occipital DT Guide, 10mm/12mm	1	
7759980	Fixed Occipital DT Guide, 14mm/16mm	1	
7759982	Fixed Occipital DT Guide, 18mm Screwdriver Guide	1	
7756286	Flexible Screwdriver, Self Holding, 2.5mm Hex	1	
7756187	Universal Joint, Screwdriver, Straight 2.5mm Hex	1	
7756188	Screwdriver, Right Angle 2.5mm Hex	1	
7756290	Bending Iron, Left	1	
7756291	Bending Iron, Right	1	
7756230	Occipital Midline Plate Bender/ Rod Bender	1	

Sterile Drill Bits

Part Number	Description	Qty In Standard Set	Loose Goods
7756131	3.2mm Occipital Drill Bit, Sterile	1	
7756281S	3.2mm Occipitocervical Flexible Drill Bit, Sterile	1	

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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0381090 Rev B

Notes

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For more information visit
www.myspinetools.com

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.

Medtronic