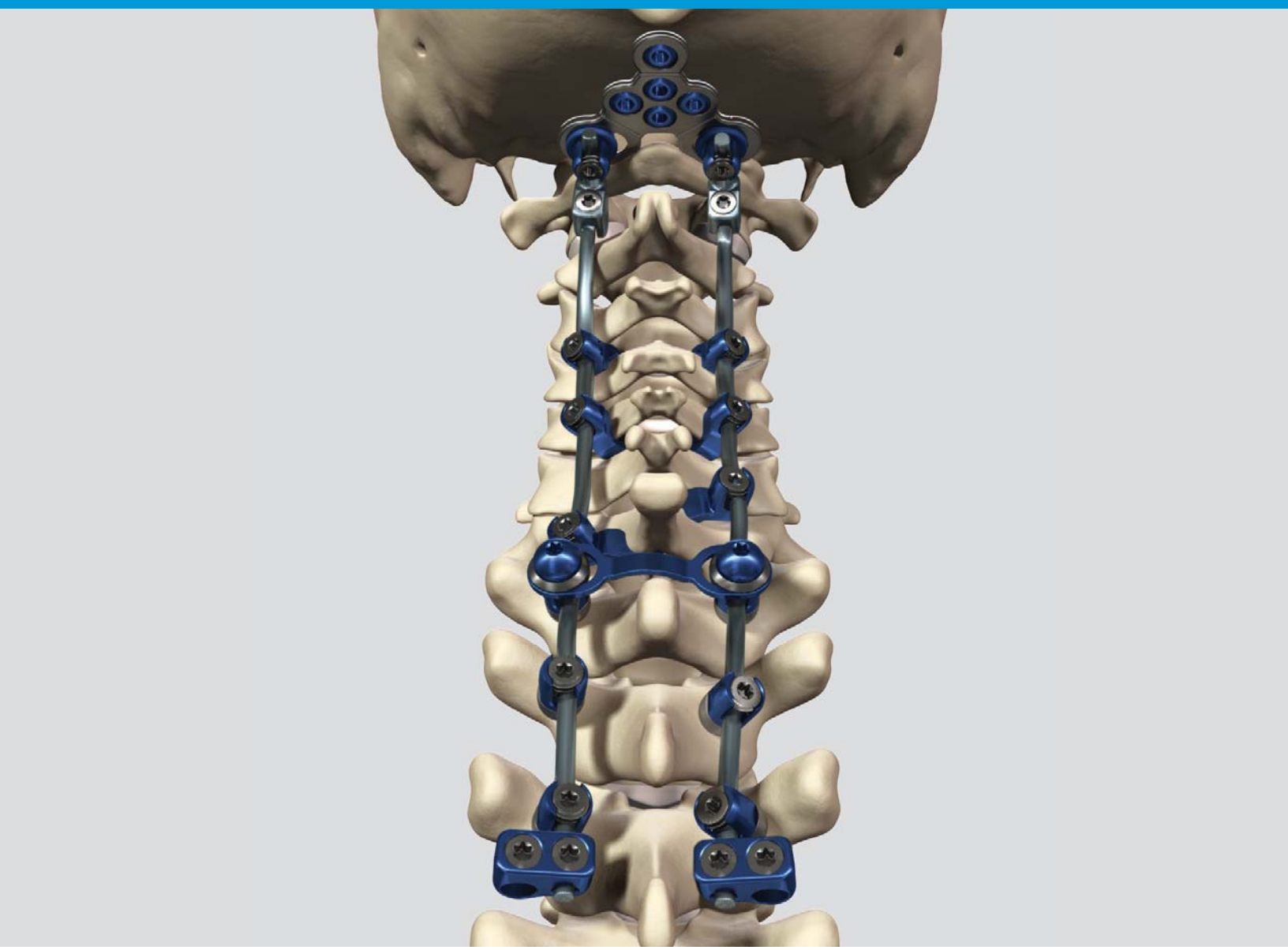
Virage® OCT Spinal Fixation System

Surgical Technique



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Virage OCT Spinal Fixation System
Surgical Technique

Description, Indications & Contraindications

DESCRIPTION
The Zimmer Spine *Virage* OCT Spinal Fixation System is a posterior system intended for the Occipital-Cervical-Thoracic spine (Occiput-T3). The system consists of a variety of rods, anchors, transverse connectors, screws, and polyaxial screws to achieve an implant construct as necessary for the individual case. The system also includes the instruments necessary for inserting and securing the implants. The implant system is intended to be removed after solid fusion has occurred.

The *Virage* System implants are fabricated from medical grade titanium alloy and medical grade cobalt chromium alloy. Implants made from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same construct. All implants are single use only and should not be reused under any circumstances.

MATERIALS
Implants: The *Virage* System implants are fabricated from medical grade titanium alloy per ASTM F136 and medical grade cobalt chromium alloy per ASTM F1537.

Instruments: The *Virage* System instrumentation is generally made from stainless steel, aluminum, titanium, and polymeric materials.

INDICATIONS
When intended to promote fusion of the occipitocervical spine, cervical spine and the thoracic spine, (Occiput -T3), the *Virage* OCT Spinal Fixation System is indicated for the following:

Degenerative disc disease (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 Plate/Rod/Occipital Screws/ Hooks
Occipitocervical plate, 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 occipitocervical and cervical conditions, the occipital screws are limited to occipital fixation only. The occipital screws are not intended for the cervical spine.

Hooks and Rods
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.

Thoracic Screws
The use of thoracic screws is limited to placement in T1-T3 *for anchoring the construct only*. The thoracic screws are not intended to be placed in the cervical spine.

Rod Connectors
The *Virage* OCT Spinal Fixation System can also be linked to the *Instinct*® *Java*® Spinal System and *Sequoia*® Pedicle Screw System offered by Zimmer Spine using rod connectors and transition rods.

The titanium Songer® Spinal Cable System to be used with the *Virage* OCT Spinal Fixation System allows for cable attachment to the posterior cervical or thoracic spine.

CONTRAINDICATIONS
The *Virage* System is not designed or sold for any use except as indicated. DO NOT USE THE *VIRAGE* SYSTEM IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.

Contraindications include, but are not limited to:

1. Overt infection or distant foci of infections.
2. Local inflammation, with or without fever or leukocytosis.
3. Pregnancy.
4. Morbid obesity.
5. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
6. Suspected or documented metal allergy or intolerance.
7. Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
8. Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
9. Use in displaced, non-reduced fractures with bone loss.
10. The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
11. Poor prognosis for good wound healing (e.g., decubitis ulcer, end-stage diabetes, severe protein deficiency, and/or malnutrition).
12. Any case not needing a bone graft or fusion.
13. Any case not described in the indications.

See also the WARNINGS and PRECAUTIONS section at the end of this document.

Implant Overview

The *Virage* OCT Spinal Fixation System provides a comprehensive solution for a rigid posterior fixation of the Occipito-Cervico-Thoracic spine.

The *Virage* System includes multiple polyaxial screw diameters and lengths. All *Virage* System polyaxial screws feature a unique 360° Omnidirectional extreme angle screw design. This unique design simplifies rod alignment and minimizes operating time.

All *Virage* System polyaxial screws have a friction fit head to hold the desired position and facilitate rod placement, maximizing efficiency and safety during the procedure.

The *Virage* System's dual lead screws require fewer revolutions to seat in the pedicle allowing surgeons to insert screws twice as fast compared to a single lead screw.

The *Virage* System offers adjustable head to head transverse connectors that can accommodate up to 20° degrees of freedom in different planes to improve intraoperative surgical flow.

The *Virage* System also offers a variety of implant options including rod to rod transverse connectors, Ø3.5/5.5mm rod connectors, pre-cut and pre-bent Ø3.5mm Ti rods, Ø3.5mm CoCr rods, Ø3.5/5.5mm transition rods, lateral offset connectors, hooks, occipital plates, occipital eyelets, and Ø3.5/3.8mm pre-contoured and adjustable occipital rods.

The *Virage* System instrumentation allows the surgeon the flexibility to build a construct that meets anatomical challenges and handles the pathology being treated.

All implants in the *Virage* System (except the cobalt chrome rods) are manufactured from titanium alloy Ti 6Al-4V ELI. Rods are available in two different materials: titanium alloy and cobalt chrome.

Occipitocervical Surgical Technique Implant Overview:
The *Virage* System offers three adjustable occipital plate sizes to accommodate the patient's anatomy. An occipital strap is available for fixation to the superior midline fixation hole. The *Virage* System offers Ø4.5mm / Ø5.25 occipital bone screws that have cortical threads.

The *Virage* System has many occipital rod options including: adjustable titanium, pre-contoured titanium, and pre-contoured cobalt chrome. Rods transition to a 3.8mm diameter occipital portion to allow for a stronger construct.

The *Virage* System utilizes QuickFlip Guides to allow for plate retention and drill/tap guidance at 2mm increments without changing instrumentation.

Polyaxial Screws:

The *Virage* System polyaxial screws are available in diameters of 3.5mm, 4.0mm, 4.5mm, and 5.0mm. The lengths range from 10mm to 45mm depending on diameter. Refer to the table below:

Color	Diameter	Lengths	Increments
Dark Blue	3.5mm	10-34mm	Every 2mm
Gold	4.0mm	10-34mm	Every 2mm
Magenta	4.5mm	20-45mm	Every 5mm
Green	5.0mm	20-45mm	Every 5mm

Smooth Shank Screws:

The *Virage* System smooth shank polyaxial screws are available in diameters of 3.5mm and 4.0mm. The length of the smooth portion varies with different screw lengths. The caddy will have two numbers associated with each screw size, the first being the length of the smooth portion and the second being the length of threaded portion. The sum of the two numbers will be the total length of the screw.

Diameter	Lengths	Increments
3.5mm	24-34mm	Every 2mm
4.0mm	24-34mm	Every 2mm

NOTE: Lengths of 22mm and 36-40mm can be found in the Deluxe Tray.

Virage OCT Spinal Fixation System

Cervico-Thoracic Surgical Technique

Cervico-Thoracic Surgical Technique:

The following Surgical Technique Guide describes the recommended placement and use of all *Virage* Cervico-Thoracic Spinal System components.

Patient Positioning

Fig. 1 ▲

Step 1

Place the patient on a radiolucent operating table in the prone position with the head and neck held securely in proper alignment. Drape the patient for posterior spinal fusion. (Fig. 1)

Exposure

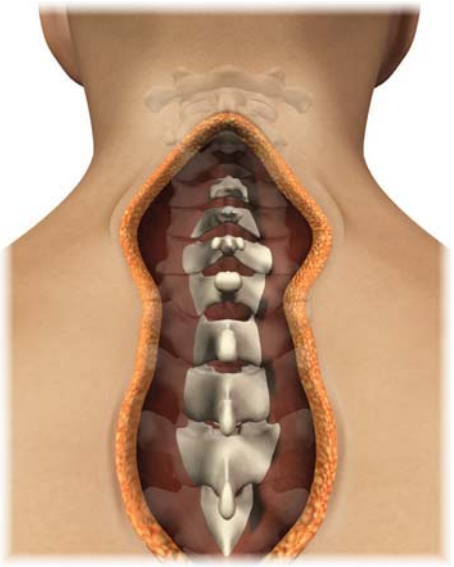


Fig. 2 ▲

Step 2

Complete a midline sub-peroisteal incision and dissection down to the spinous processes of the appropriate vertebrae. Extend dissection laterally to expose the facets and transverse processes. (Fig. 2)

NOTE: *Care must be taken to avoid vital structures including but not limited to the vertebral arteries, nerve roots, and the spinal cord.*

WARNING: *Care should be taken during bone preparation to avoid damage to the pedicle and to the surgical instruments.*

Instruments

Polyaxial Screw Hole Preparation

Fig. 3 ▲

Step 3

Insert the Bone Awl or a burr to break the cortical surface. The Bone Awl has a hard stop that limits insertion to 8 mm. Repeat for all screw placement sites. (Fig. 3)

Probe/Drill

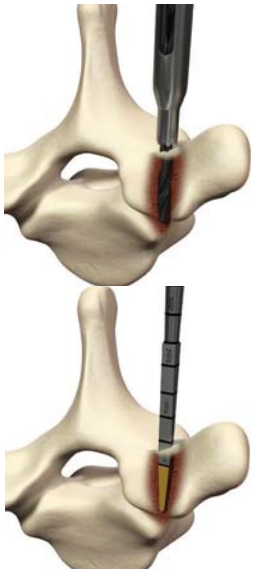


Fig. 4 ▲

Step 4

Determine Drill or Probe penetration depth based on radiographic films or fluoroscopy. K-wires or pedicle markers may be placed into the pedicle throughout the preparation, confirming position on radiographs to manage orientation and trajectory. Caution should be taken to make sure the hole is not prepared too deep. (Fig. 4)

WARNING: *Instrument and implants may cause soft tissue damage. Care should be taken to minimize damage.*

Option A: Probe

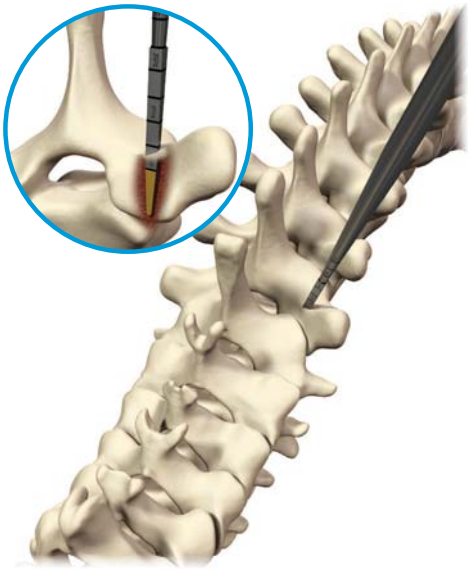


Fig. 5 ▲

Step 4, Option A

Insert the pedicle Probe in the previously prepared entry point while maintaining the appropriate trajectory. Advance the pedicle Probe to the desired depth using the depth markings as a guide. (Fig. 5)

NOTE: *Pedicle Probes are gold up to 10mm.*

Instruments

Bone Awl Ø2.0mm
07.01752.001

Curved Probe
07.01753.001

Straight Probe
07.01754.001

Option B: Drilling

Fig. 6 ▲

Fig. 7 ▲

Verify Hole Integrity and Depth

Fig. 8 ▲

Step 4, Option B

The Drill Guide allows for drilling depth between 8mm-40mm in 2 mm increments.

Drill Guide Adjustable Setup: Hold the Drill Guide handle with the Drill Guide tip oriented vertically so the numbers are upright and readable.

Pull back the knob toward the handle, then lift or lower the rack to the desired depth. Once the desired depth is reached, release the knob to lock the Drill Guide. The depth is set correctly when the silver band is lined up with the numerical marking that matches the desired length of the screw. Press on the top of the rack to be sure it is locked in place. (Fig. 6)

Drill Guide Fixed Setup: The Drill Guide can be utilized as a fixed drill guide by placing in the "FIX" setting or the fully seated position. The depth is set correctly when the silver band is lined up with the FIX marking. (Fig. 6, inset)

The *Virage* System offers four Fixed Drills:

Size	Color
10mm	Gold
12mm	Magenta
14mm	Green
16mm	Light Blue

NOTE: *Fixed Drills have a colored band that matches the tray color for that screw length.*

Attach the Adjustable Drill or Fixed Drills to the A-O Handle with Spin Cap and insert through the Drill Guide.

Orient the Drill Guide and drill at the desired trajectory and drill until reaching the positive stop. The positive stop is reached when the drill stop contacts the top of the Drill Guide. (Fig. 7)

NOTE: *The A-O connection of the Adjustable Drill is gold.*

Step 5

Confirm bone integrity and measure hole depth using the Sounding Probe. (Fig. 8)

NOTE: *The Sounding Probe tip is gold up to 10mm. There are 2mm markings from 10mm to 20mm, then every 5mm from 20mm to 50mm.*

Instruments

Adjustable Drill Guide
07.01755.001

Adjustable Drill (Ø2.3mm)
07.01757.001

A-O Handle with Spin Cap
07.01788.001

Fixed Drills (all Ø2.3mm)
07.01758.001 10mm
07.01758.002 12mm
07.01758.003 14mm
07.01758.004 16mm

Sounding Probe
07.01759.001

Tapping (Optional)

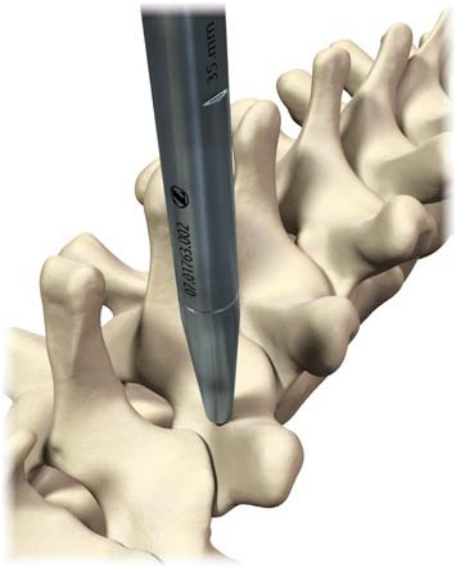


Fig. 9 ▲

Step 6

Virage System polyaxial screws are self-tapping. If tapping is desired, the screw hole may be tapped using the appropriate diameter Tap. (Fig. 9)

The *Virage* System offers taps that are marked true to size:

Small Tap - Ø3.5/4.0mm Screws
Ø3.0mm Tap
Ø3.5mm Tap

NOTE: *Tap threads are colored gold up to 10mm.*

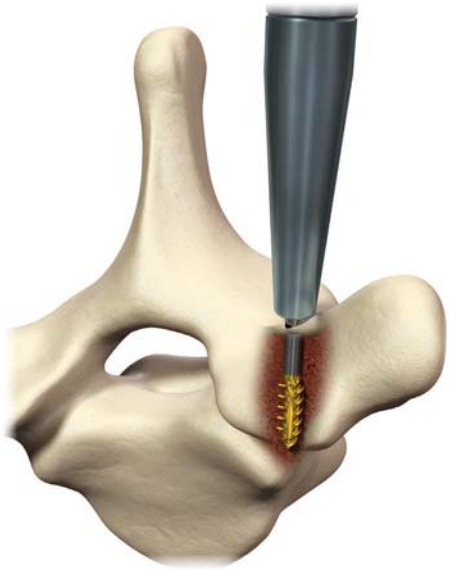


Fig. 10 ▲

Large Tap - Ø4.5/5.0mm Screws
Ø4.0mm Tap
Ø4.5mm Tap

NOTE: *Tap threads are colored black up to 30mm.*

A Tap Sleeve is available if desired. Assemble Tap Sleeve by sliding large opening over the Tap thread. Laser marked lines on proximal end of tap indicate depth of the tap. (Fig. 10)

NOTE: *Tap tips are laser marked every 5mm.*

NOTE: *The 3.5mm Tap Sleeve is compatible with the Ø3.0/Ø3.5mm Taps. The 4.5mm Tap Sleeve is compatible with the Ø4.0/Ø4.5mm Taps.*

Polyaxial Screw Driver Assembly

Fig. 11 ▲

Step 7

Assemble the three piece Screw Driver by sliding the blue Outer Sleeve over the Inner Sleeve until fully engaged on the retaining feature. (Fig. 11, top)

Next, depress button on Inner Sleeve knob and slide the Hex Screw Driver through the Inner Sleeve. Slide until fully seated. Release button and confirm retention. (Fig. 11, bottom)

Connect the Screw Driver to the A-O Handle.

Instruments

Tap
07.01761.001 Ø3.0mm
07.01761.002 Ø3.5mm
07.01762.001 Ø4.0mm
04.01762.002 Ø4.5mm

Tap Sleeve
07.01763.002 Ø3.5mm
07.01763.004 Ø4.5mm

Polyaxial Screw Driver, Inner Sleeve
07.01764.001

Polyaxial Hex Screw Driver, 2.5mm
07.01764.002

Polyaxial Screw Driver, Outer Sleeve
07.01764.003

A-O Handle with Spin Cap
07.01788.001

Polyaxial Screw Loading

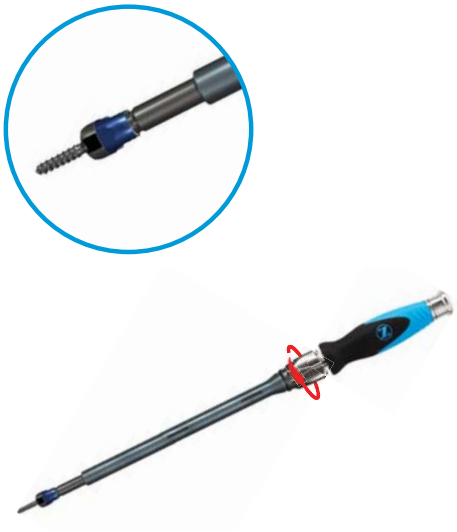


Fig. 12 ▲

Polyaxial Screw Placement

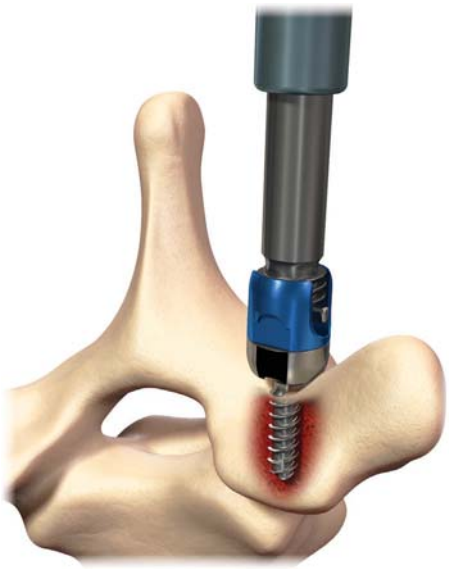


Fig. 13 ▲

Optional: Polyaxial Screw Height Adjustment

Fig. 14 ▲

Step 8

Insert the hex of the Screw Driver into the screw shank. (Fig. 12, top)

Secure the screw by rotating the knob clockwise until tight. (Fig. 12, bottom)

Step 9

Drive the screw to the desired depth where polyaxial movement of the head is maintained.

Remove the Screw Driver by rotating the knob counterclockwise until disengaged from the screw, then pull in the trajectory of the screw shank.

Confirmation of screw position can be made using lateral and A/P radiographs or fluoroscopy. Place the remaining screws using a similar technique. (Fig. 13)

NOTE: *When advancing the screw avoid placing free hand on the knob, thus causing the Screw Driver to disconnect from the screw. To prevent this, place free hand on the blue Outer Sleeve of the Polyaxial Screw Driver.*

NOTE: *The button on the knob of the Driver is for instrument disassembly/cleaning only.*

NOTE: *A smooth shank screw implant option can be used to minimize tissue irritation.*

Step 10

The Tapered Hex Driver may be used to reposition the polyaxial screw. This instrument engages the hex of the screw shank and does not require threading into the tulip head. (Fig. 14)

Instruments

Tapered Hex Driver, 2.5mm
07.01765.001

A-O Handle with Spin Cap
07.01788.001

Polyaxial Screw Head Alignment

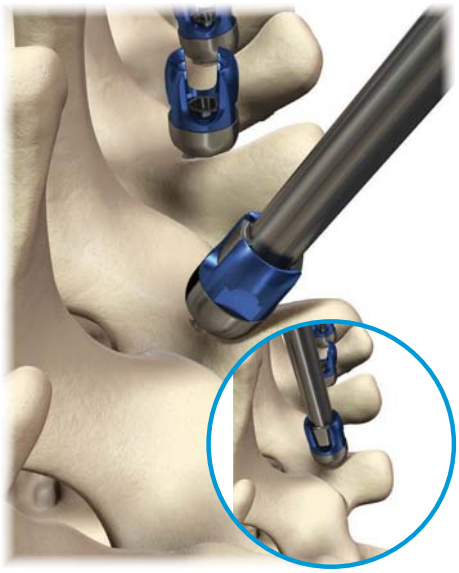


Fig. 15 ▲

Step 11

Align the heads of the screws by engaging the distal end of the Polyaxial Screw Head Turner into the housing head of the screw. Rotate the blue handle until the desired orientation is reached. (Fig. 15)

IMPORTANT: *Use the blue portion of the instrument to rotate the upper housing.*

360° Omnidirectional Extreme Angle Engagement

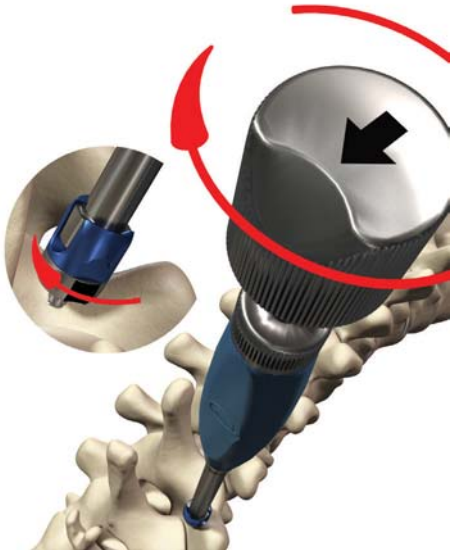


Fig. 16 ▲

Step 12

All *Virage* System polyaxial screws allow for a 360° unconstrained range of motion providing 56° of angulation in all directions.

To reach extreme angulation, slowly rotate the silver knob while applying downward pressure until the distal tip engages into the housing of the screw. Tactile/audible feedback confirms engagement. A black stripe on the screw's lower housing indicates extreme angle location. (Fig. 16)

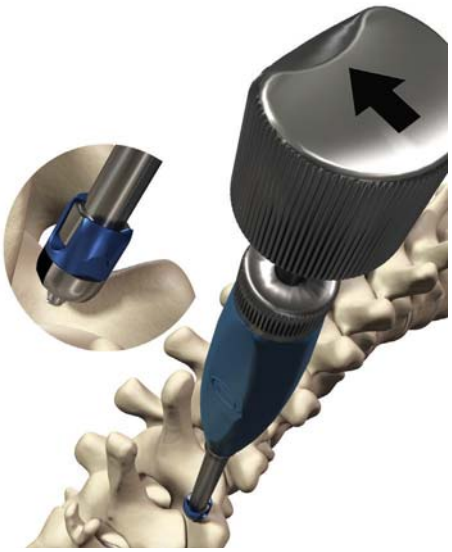


Fig. 17 ▲

To rotate the direction of the extreme angle, turn the silver knob and point the arrow in the desired direction. If needed, align upper housing for rod placement by rotating the blue handle of the Polyaxial Screw Head Turner. (Fig. 17)

NOTE: *If polyaxial screw movement is restricted, adjust the height of the screw.*

Instruments

Polyaxial Screw Head Turner
07.01766.001

Hook Insertion: Hook Trial/Insertion

Fig. 18 ▲

Step 13

Identify which landmarks of the cervical lamina will receive hooks. Remove soft tissue and ligamentous connections sparingly, providing good visualization of the entire lamina and margins of the spinal canal.

Place the Hook Trial on the lamina to identify the appropriate implant size. Prepare the lamina taking care not to remove excess material. When placing both the trial and the implant, take care not to breach the margins of the spinal cord. (Fig. 18)

Hook Attachment

Fig. 19 ▲

Step 14

Attach the Hook Forceps to the proximal body of the hook. Slide the hook underneath the lamina at the previously prepared position.

Secure the hook to the cervical lamina. Place all remaining hooks using the same procedure. (Fig. 19)

NOTE: *The closure top, Closure Top Starter, and Final Driver may be passed through the Hook Forceps.*

Rod Preparation: Template

Fig. 20 ▲

Step 15

A Rod Template may be used to determine the appropriate length and curvature of the rod. (Fig. 20)

WARNING: *Markings on the Rod Template are every 10mm.*

Instruments

8mm Hook Trial
07.01750.001

Hook Forceps
07.01751.001

Rod Template
07.01767.001 100mm
07.01767.002 250mm

Rod Selection/Cutting

Fig. 21 ▲

Step 16

Choose the appropriate rod length and material. The *Virage* System contains pre-cut/pre-bent rods and straight rods. The titanium rods are colored blue and the cobalt chrome rods are silver. Cobalt chrome alloy offers increased strength and stiffness over titanium alloy.

If cutting is needed, use the Rod Cutter. Rotate the knurled wheel until the two arrows are aligned. Insert the rod into appropriate labeled hole of the Rod Cutter to the desired depth. Repeatedly squeeze the handles until the rod is cut. (Fig. 21)

NOTE: *Realigning arrows will assist in removal of the rod.*

NOTE: *The "cutting line" marks the spot where the Rod Cutter will cut the rod. The cutting line is located ~8 mm from the face of the instrument.*

Rod Contouring

Fig. 22 ▲

Step 17

If contouring is needed, use the French Rod Bender. Place the rod within the French Rod Bender and squeeze the handles to achieve the desired curvature.

The French Rod Bender allows three different bend radii. To adjust, pull the center knob and turn to select the desired bend radius.

NOTE: *Reverse bending can weaken the rod and is not recommended.*

If in-situ bending is needed, rods can be contoured in the sagittal plane with the three In-situ Rod Benders. (Fig. 22)

Rod Placement

Fig. 23 ▲

Step 18

Grasp the rod with the Rod Holder and engage the locking mechanism by fully closing the handles. To release, squeeze handles together, disengaging the locking mechanism. (Fig. 23)

Instruments

Rod Cutter
07.01774.001

French Rod Bender
07.01770.001

In-situ Rod Bender
07.01771.002 Left
07.01772.002 Right
07.01773.002 Straight

Rod Holder
07.01768.001

Set Screw Insertion: Closure Top Placement

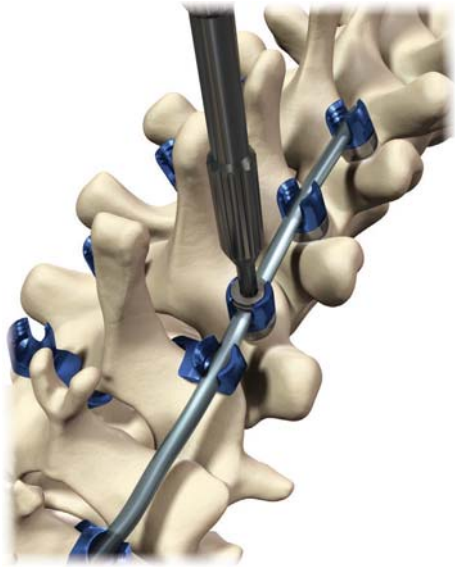


Fig. 24 ▲

Step 19

Insert the closure top using the Closure Top Starter and provisionally tighten into each screw/hook housing. (Fig. 24)

WARNING: *Use care to avoid cross threading.*

Rod Reduction: Rod Rocker

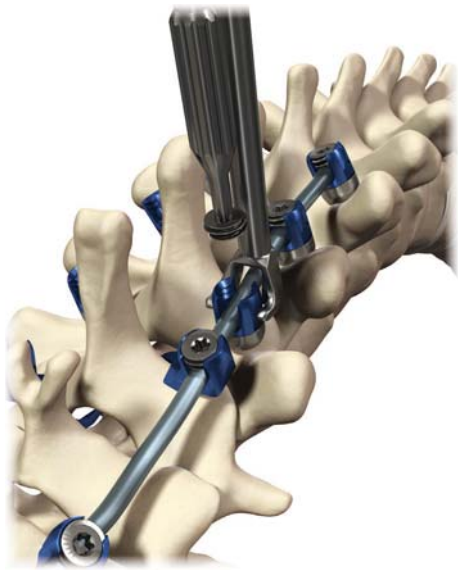


Fig. 25 ▲

Step 20

The Rod Rocker may be used to seat the rod and ease closure top introduction.

Engage the Rod Rocker and gently tilt to lower the rod into the implant housing. Place the closure top with the Closure Top Starter to secure the rod. (Fig. 25)

Kerrison Rod Reducer

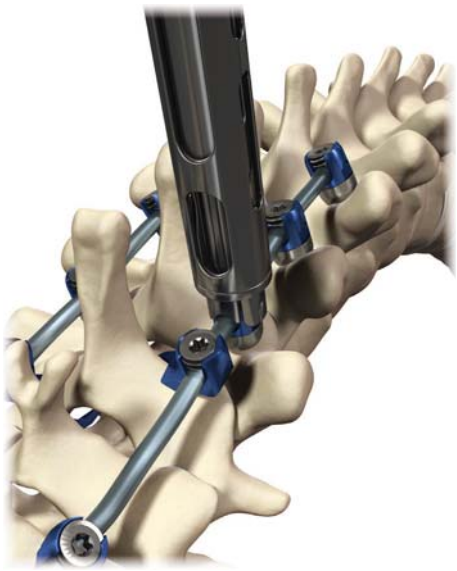


Fig. 26 ▲

Step 21a

Prior to use, open the lock of the Kerrison Rod Reducer and engage onto screw housing by applying a slight downward force until fully seated. Gently squeeze the handle to engage the screw head and seat the rod into screw.

Once seated, insert a closure top using a Closure Top Starter or Final Driver through the Kerrison Rod Reducer. (Fig. 26)

Instruments

Closure Top Starter
07.01782.001

Rod Rocker
07.01775.001

Final Driver
07.01783.001

Kerrison Rod Reducer
07.01777.001

Tower Rod Reducer

Fig. 27 ▲

Fig. 28 ▲

Fig. 29 ▲

Step 21b

To remove the Kerrison Rod Reducer, disengage the lock to allow the handle to open fully; rotate slightly to either side and gently pull. (Fig. 27)

NOTE: *Reduction travel is indicated by laser markings on the side of the Kerrison Rod Reducer.*

Step 22a

Prior to use, ensure the Tower Rod Reducer is fully open by turning the large knob counterclockwise until positive stop is reached.

Engage the Tower Rod Reducer onto the screw housing by applying a slight downward force until fully seated. Turn the large knob to seat the rod into the screw. (Fig. 28)

Step 22b

Once seated, insert a closure top using a Closure Top Starter or Final Driver through the Tower Rod Reducer.

To remove the Tower Rod Reducer, turn the knob counterclockwise until it reaches the positive stop; rotate slightly to either side and gently pull. (Fig. 29)

NOTE: *Reduction travel is indicated by laser markings on the side of the Reducer.*

Instruments

Tower Rod Reducer
07.01776.001

Closure Top Starter
07.01782.001

Final Driver
07.01783.001

Additional Rod Manipulations: Compression/Distraction/Rotation

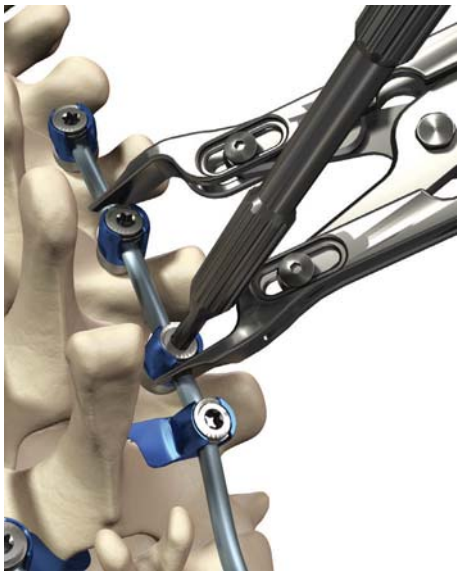


Fig. 30 ▲

Step 23

Once the rod is secured into the implants, distraction and/or compression may be performed to place the implants in their final position. (Fig. 30)

A Rod Gripper is also included for additional rod manipulation.

NOTE: *To disengage the Rod Gripper, press and hold the button until fully disengaged.*

Final Tightening

Fig. 31 ▲

Step 24

When all implants are securely in place and the rods are fully seated, final tightening is performed. Tighten closure tops using the Final Driver, Torque-Limiting Handle, and Inline Counter Torque.

Turn the Torque-Limiting Handle clockwise to advance the closure top until two clicks are heard (torque set at 23in-lbs). (Fig. 31)

NOTE: *Ensure the Final Driver is fully seated into the Torque-Limiting Handle.*

Transverse Connector Placement

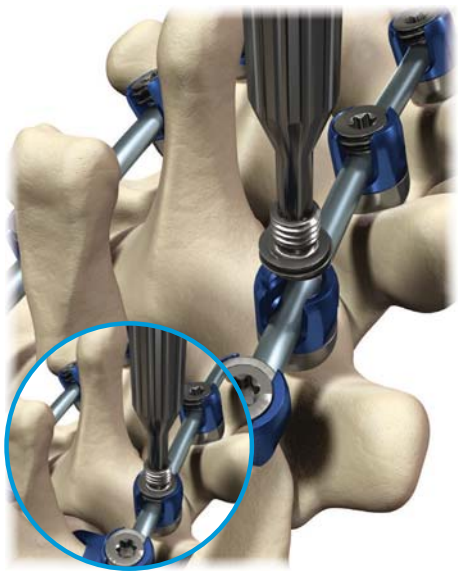


Fig. 32 ▲

Step 25a

The *Virage* System includes head to head transverse connectors (HHTC) from 27mm to 53mm. The HHTC is composed of three components: HHTC closure top, arm, and dome nut.

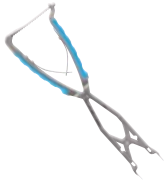
The HHTC can accommodate housing tilt up to 20° (10° each side) requiring less bending of the HHTC arm and allowing off axis screw head position.

Insert an HHTC closure top (07.01719.001) into the head of the applicable polyaxial screw using a Closure Top Starter. (Fig. 32)

Final tighten the HHTC closure top using the Final Driver, Torque-Limiting Handle, and Inline Counter Torque. Repeat on the contralateral side.

Turn the Torque Limiting Handle clockwise to advance the closure top until two clicks are heard.

Instruments



Compressor
07.01778.001

Distractor
07.01779.001

Rod Gripper
07.01769.001

Torque-Limiting Handle, 3/16"
07.01792.001

Final Driver
07.01783.001

Closure Top Starter
07.01782.001

Inline Counter Torque
07.01785.001

Fig. 33 ▲

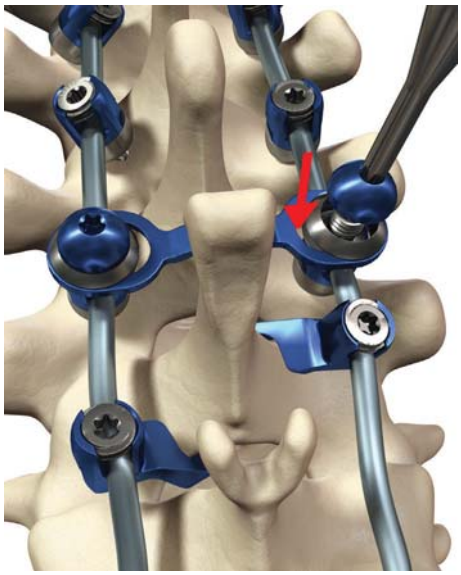


Fig. 34 ▲

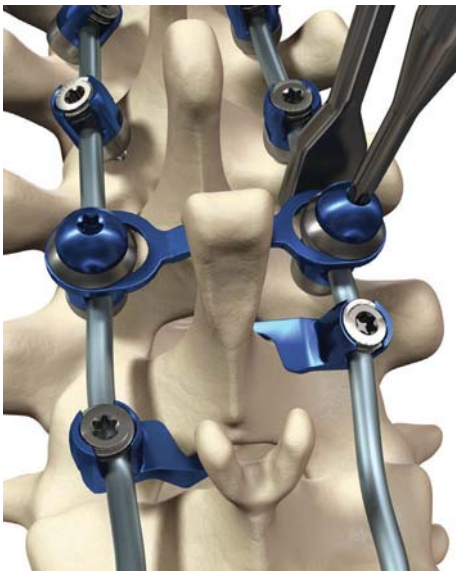


Fig. 35 ▲

Step 25b

Determine the appropriate size HHTC arm using the Transverse Connector Caliper. Place both tips of the Caliper into the HHTC closure top. Read the length and/or color coding on the Caliper to determine appropriate HHTC size. (Fig. 33)

HHTC arms are adjustable and available in multiple sizes:

Size	Lengths	Tray Color
Extra Small	27-33mm	Gold
Small	32-38mm	Magenta
Medium	37-43mm	Green
Large	42-48mm	Light Blue
Extra Large	47-53mm	Orange

NOTE: *There is a 1mm overlap between sizes.*

Step 26

Place the HHTC arm over the HHTC closure tops and around the tops of the polyaxial screws.

Once the HHTC arm is in position, insert the HHTC dome nut (07.01720.001) with the Closure Top Starter; provisionally tighten. Repeat on the contralateral side. (Fig. 34)

Step 27

Perform final tightening using the Final Driver and Torque-Limiting Handle until two clicks are heard. Repeat on the contralateral side. (Fig. 35)

NOTE: *The Rod Pusher is available to provide counter torque to the Ø3.5mm rod.*

Instruments

Transverse Connector Caliper
07.01780.001

Closure Top Starter
07.01782.001

Final Driver
07.01783.001

Torque-Limiting Handle, 3/16"
07.01792.001

Rod Pusher
07.01784.001

A-O Handle with Spin Cap
07.01788.001

Rod to Rod Transverse Connector

Fig. 36 ▲

Fig. 37 ▲

Transition Rod Placement Ø3.5mm/5.5mm Transition Rods

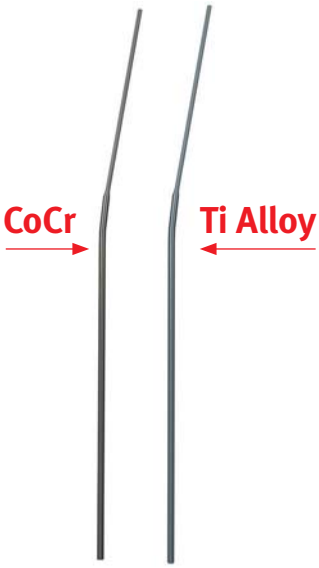


Fig. 38 ▲

Step 28

Rod to rod transverse connectors (RRTC) are adjustable and available in multiple sizes:

Size	Lengths	Tray Color
Extra Small	27-33mm	Gold
Small	32-38mm	Magenta
Medium	37-43mm	Green
Large	42-48mm	Light Blue
Extra Large	47-53mm	Orange

NOTE: *There is a 1mm overlap between sizes.*

Determine the appropriate size RRTC by using the Transverse Connector Caliper. Place both tips of the Caliper around lateral side of rods. Read the length and/or color coding on the Caliper to determine appropriate RRTC size (see table above). (Fig. 36)

Step 29

Engage the RRTC Driver onto the RRTC hex nut. Position the RRTC onto the construct and snap it onto the rods using slight downward pressure. Repeat on the contralateral side.

Attach the Torque-Limiting Handle to the RRTC Driver and final tighten by rotating clockwise until two clicks are heard. (Fig. 37)

NOTE: *The Rod Pusher is available to provide counter torque to the Ø3.5mm rod.*

Step 30

Transition rods allow for a transition from the cervical to the thoracic spine or at any location where it is necessary to move from a Ø3.5mm rod to a Ø5.5mm rod. (Fig. 38)

Titanium and cobalt chrome transition rods are offered pre-bent at the transition. Additional rod contouring and rod cutting may be accomplished using the French Rod Bender and/or Rod Cutter.

CAUTION: *The start of the transition zone is indicated by a dark band. Do not connect implants within this transition zone.*

NOTE: *A Ø5.5mm Rod Cutter and Bender will need to be ordered for the Ø5.5mm rod.*

NOTE: *Reverse bending can weaken the rod and is not recommended.*

Instruments

Transverse Connector Caliper
07.01780.001

Transverse Connector Driver
07.01781.001

Torque-Limiting Handle, 3/16"
07.01792.001

A-O Handle with Spin Cap
07.01788.001

Rod Pusher
07.01784.001

Rod Cutter
07.01774.001

French Rod Bender
07.01770.001

Ø3.5mm/5.5mm Rod Connectors

Fig. 39 ▲

Step 31

The *Virage* System offers closed rod connectors to connect a Ø3.5mm rod to a Ø5.5mm titanium rod of the Zimmer *Instinct*® *Java*® Spinal Fixation System or *Sequoia*® Pedicle Screw System. (Fig. 39)

Fig. 40 ▲

The closed rod connector contains two internal set screws that require locking using the Final Driver connected to the Torque-Limiting Handle. (Fig. 40)

NOTE: *A Rod Pusher is available to provide counter torque to the Ø3.5mm rod.*

Lateral Offset Connector Placement

Fig. 41 ▲

Step 33

Lateral offset connectors offer medial-lateral flexibility in challenging rod/screw alignment situations.

The *Virage* System offers two lengths of lateral offset connectors: 10mm and 25mm.

Final tighten the closure top and set screw using the Final Driver connected to the Torque-Limiting Handle. (Fig. 41)

NOTE: *A Rod Pusher is available to provide counter torque to the Ø3.5mm rod.*

CAUTION: *Ensure the closure top is secured against the flat of the lateral offset connector arm.*

NOTE: *The lateral offset connector can either be bent or cut using the In-situ Benders or Rod Cutter (use Ø3.8 opening).*

Instruments

Final Driver
07.01783.001

Torque-Limiting Handle, 3/16"
07.01792.001

Rod Pusher
07.01784.001

A-O Handle with Spin Cap
07.01788.001

Final Construct

Fig. 42 ▲

Step 34

Recheck all connections of the final construct. An intraoperative radiographic image of the final construct should be made to confirm the desired construct is achieved prior to wound closure. (Fig. 42)

Virage OCT Occipitocervical

Surgical Technique

Occipitocervical Surgical Technique:

The following Surgical Technique describes the recommended placement and use of *Virage* Occipitocervical Spinal System components.

Occipital Landmarks

Fig. 43 ▲

Step 1

In general, the thickest bone in the sub occipital region is the occipital keel (internal occipital protuberance), near the midline. When positioning the occipital plate, it should be centered on the midline between the External Occipital Protuberance (EOP) and the posterior border of the foramen magnum. The goal is to maximize bone purchase (closer to EOP) while achieving a low profile. (Fig. 43)

WARNING: *Care should be taken during bone preparation to avoid damage to the occiput and to the surgical instruments.*

Occipital Fixation Plate Fixation

Fig. 44 ▲

Step 2

The *Virage* System offers three occipital plates to accommodate patient anatomy:

Size	Widths
Small	24-33mm
Medium	32-41mm
Large	40-49mm

NOTE: *There is a 1mm overlap between sizes.*

Each plate size has three midline holes and two lateral holes for occipital fixation. Placement of as many screws as possible is recommended. A minimum of two screws must be used; a minimum of three screws must be used if the plate is bent, including one screw in the superior hole. The occipital plates include rod connector housings that rotate up to 40° to ease rod placement. (Fig. 44)

Fig. 45 ▲

Occipital Plate Contouring

Fig. 46 ▲

Occipital Screw Hole Preparation Drilling

Fig. 47 ▲

Step 2, continued

The *Virage* System occipital screws are available in diameters of 4.5mm and 5.25mm. (Fig. 45) Refer to the table below:

Diameter	Length	Increments	Color
Ø4.5mm	6mm-16mm	Every 2mm	
Ø5.25mm	6mm-16mm	Every 2mm	

Step 3

The *Virage* System occipital plate can be contoured to fit a patient's anatomy using the Occipital Plate Bender at the plate's one bend zone at the superior hole. Reference the bend direction on the distal end of the Plate Bender. Ensure the Plate Bender is aligned with bend zone features by positioning the entire length of the plate's groove in the Plate Bender's center tip feature. Prior to bending, verify positive engagement visually and confirm by attempting to manipulate the plate in an alternating clockwise and counterclockwise fashion. A properly aligned plate/Plate Bender will not allow for any relative motion between the two devices. (Fig. 46)

Step 4

Three Occipital Drill/Tap Guides are available and each has a 2mm depth adjustment feature (6/8mm, 10/12mm, and 14/16mm).

Select the appropriate Occipital Drill/Tap Guide and connect to the 3/16" Handle. Engage the distal tip of the Occipital Drill/Tap Guide into the desired plate screw hole by pressing down until fully seated.

Verify drill/tap depth by reading the depth markings on the top surface of the Occipital Drill/Tap Guide. (Fig. 47)

WARNING: *Bending the plate outside of the bend zone groove may result in cracking of the plate. The surgeon should always inspect the plate before implanting.*

WARNING: *Do not reverse bend the plate. Reverse bending may result in a projectile fracture of the plate.*

NOTE: *The plate may be bent up to 12˚ in either direction.*

Instruments

Plate Bender
07.01803.001

Occipital Drill/Tap Guide
07.01793.001 6/8mm
07.01793.002 10/12mm
07.01793.003 14/16mm

Handle, 3/16"
07.01790.001

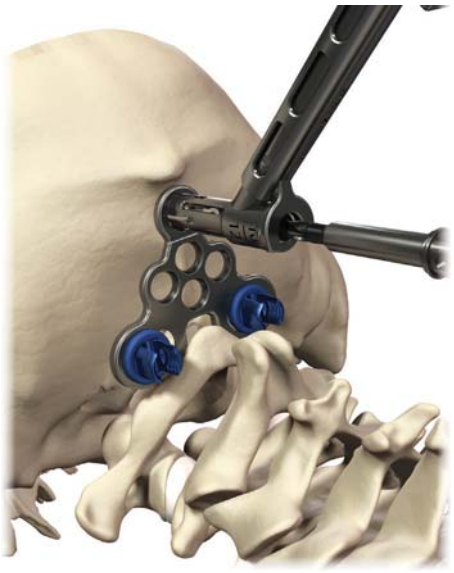


Fig. 48 ▲

Step 5

Attach the Ø3.5mm Flexible or Rigid Occipital Drill to the A-O Handle and place through the Occipital Drill/Tap Guide; drill to the desired depth. (Fig. 48)

WARNING: *Care should be taken during bone preparation to avoid penetrating too deep.*

Verify Hole Integrity and Depth

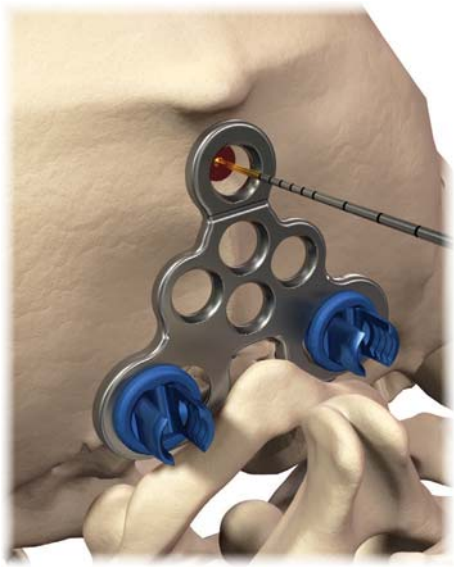


Fig. 49 ▲

Step 6

Confirm bone integrity and measure hole depth using the Sounding Probe. (Fig. 49)

Tapping

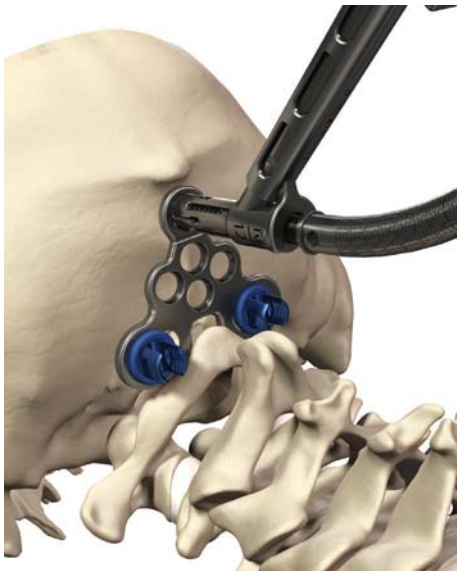


Fig. 50 ▲

Step 7

Attach the Ø3.5mm Flexible or Rigid Occipital Tap to the A-O Handle and place through the appropriate Occipital Drill/Tap Guide; tap to the desired depth. (Fig. 50)

NOTE: *Both the Flexible and Rigid Taps must be used in conjunction with the Guide to achieve the desired depth.*

NOTE: *Tapping is required as the occipital bone screws are not self-tapping.*

Instruments

Occipital Drill/Tap Guide
07.01793.001 6/8mm
07.01793.002 10/12mm
07.01793.003 14/16mm

Handle, 3/16"
07.01790.001

Occipital Drill, Rigid
07.01794.001

Occipital Drill, Flexible
07.01795.001

A-O Handle with Spin Cap
07.01788.001

Sounding Probe
07.01759.001

Occipital Taps
Rigid
07.01796.001 Ø4.5mm
07.01796.002 Ø5.25mm
Flexible
07.01797.001 Ø4.5mm
07.01797.002 Ø5.25mm

Screw Placement

Fig. 51 ▲

Step 8

Select and verify the appropriate diameter and length of the occipital screw. Insert the screw using either the Rigid or Flexible Hex Driver.

WARNING: *Care should be taken to ensure the occipital screw is not driven in too deep.*

Ensure all screws are fully seated once the construct is assembled. An Allen Hex Wrench is available if the patient's anatomy does not accommodate a Rigid or Flexible Driver. (Fig. 51)

NOTE: *When using the Flexible Driver, the Occipital Counter Torque may be used to maintain Driver/screw alignment during Driver insertion and removal.*

Occipital Strap Option

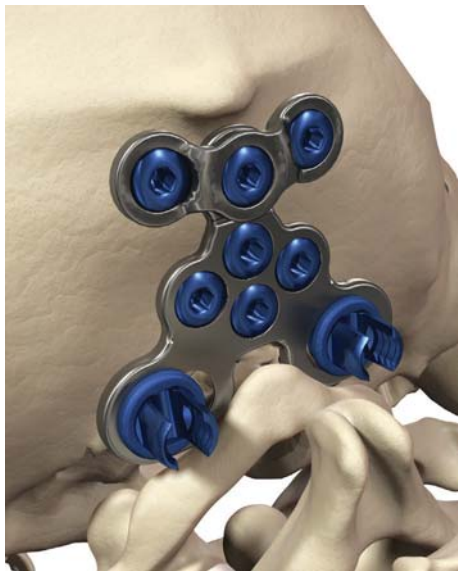


Fig. 52 ▲

Step 9 (optional)

Prepare lateral holes of the occipital strap in the same manner as occipital plate holes (i.e., drill depth equals bone screw length).

For the center hole, select an occipital bone screw that is 2mm longer than the drill and tap depth previously prepared before occipital strap placement (i.e., drill depth plus 2mm equals bone screw length). A minimum of two screws must be placed in the lower portion of the plate if the strap is used. (Fig. 52)

NOTE: *Do not drill the superior midline hole through the occipital plate and strap.*

Rod Selection/Rod Cutting

Fig. 53 ▲

Step 10

A Rod Template may be used to determine the appropriate length and curvature of the rod.

NOTE: *Markings on the Rod Template are every 10mm.*

The *Virage* System includes occipital rods in different configurations and materials: pre-contoured titanium, pre-contoured cobalt chrome, and adjustable titanium. Cut to length using the Rod Cutter. (Fig. 53)

Instruments

Hex Drivers, 3.0mm
07.01798.001 Rigid
07.01799.001 Flexible

A-O Handle with Spin Cap
07.01788.001

Occipital Counter Torque
07.01802.001

Allen Hex Wrench, 3.0mm
07.01801.001

Rod Template
07.01767.001 100mm
07.01767.002 250mm

Rod Cutter
07.01774.001

Rod Contouring

Fig. 54 ▲

Step 11

Contour the rod into the desired shape using the French Rod Bender, In-situ Rod Benders, and/or tube bending features of the In-situ Rod Benders. (Fig. 54)

NOTE: *Reverse bending can weaken the rod and is not recommended.*

Rod Placement

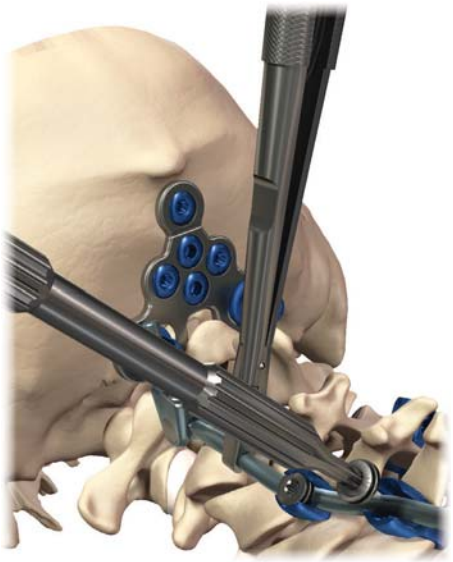


Fig. 55 ▲

Step 12

Grasp the rod with the Rod Holder and engage the locking mechanism by fully closing the handles. To release, squeeze the handles together, disengaging the locking mechanism.

Provisionally tighten closure tops using the Closure Top Starter or Occipital Final Drivers. (Fig. 55)

CAUTION: *Pre-contoured* Virage *System occipital rods transition from Ø3.5mm to Ø3.8mm. The start of the transition zone is indicated by a dark band. Do not connect implants within this transition zone.*

Final Tightening

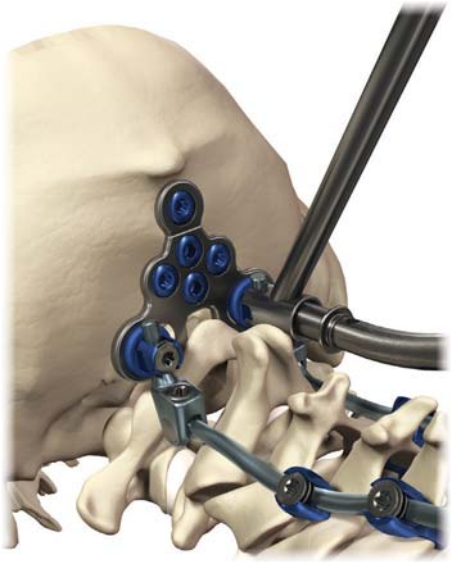


Fig. 56 ▲

Step 13

Once all of the occipital screws have been secured, final tighten all closure tops and set screws using a Final Driver or Occipital Final Driver (Flexible or Rigid), Torque-Limiting Handle, and Counter Torque/Rod Pusher until two clicks are heard (Fig. 56)

NOTE: *Use the Occipital Counter Torque when final tightening closure tops into the occipital plate housings.*

CAUTION: *Ensure the set screw of the adjustable occipital rod is final tightened.*

Instruments

Rod Holder **07.01768.001**

French Rod Bender **07.01770.001**

In-situ Rod Bender
07.01771.002 Left
07.01772.002 Right
07.01773.002 Straight

Torque-Limiting Handle, 3/16" **07.01792.001**

A-O Handle with Spin Cap **07.01788.001**

Occipital Final Drivers
07.01804.001 Flexible
07.01805.001 Rigid

Occipital Counter Torque **07.01802.001**

Inline Counter Torque **07.01785.001**

Rod Pusher **07.01784.001**

Closure Top Starter **07.01782.001**

Occipital Eyelet (Optional)

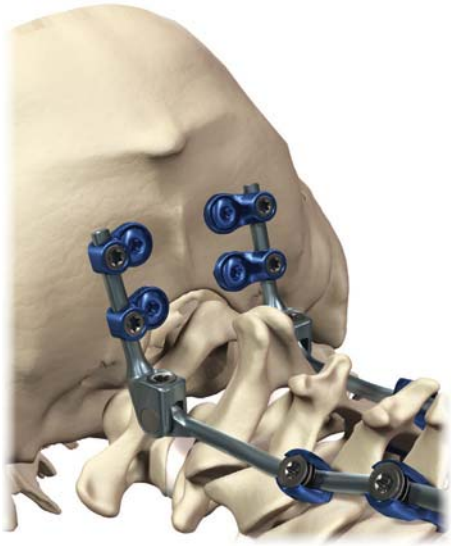


Fig. 57 ▲

Step 14

When occipital plate use is not possible or preferred, occipital eyelets are available as an alternative method of fixation. A minimum of two eyelets should be used on each rod. Slide eyelets over the rod and determine the desired bone screw location. Complete Drill, Tap, and Screw Placement steps as indicated for occipital plates. Once all of the occipital screws have been secured, final tighten set screws using an Occipital Final Driver (Flexible or Rigid), Torque-Limiting Handle, and Occipital Counter Torque until two clicks are heard. (Fig. 57)

NOTE: *The Occipital Counter Torque does not fit over the occipital eyelets and must be used next to occipital eyelets along the Ø3.8mm rod segment.*

Cable Connectors (Optional)

Fig. 58 ▲

Step 15

Virage System cable connectors are available for connection to the titanium Songer® Spinal Cable System. Final tighten the set screw using the Final Driver and Torque-Limiting Handle in conjunction with the Rod Pusher. (Fig. 58)

Final Construct

Fig. 59 ▲

Step 16

Recheck all connections of the final construct. An intraoperative radiographic image of the final construct should be made to confirm the desired construct is achieved prior to wound closure. (Fig. 59)

Instruments

Occipital Counter Torque
07.01802.001

Occipital Final Drivers
07.01804.001 Flexible
07.01805.001 Rigid

Torque-Limiting Handle, 3/16"
07.01792.001

Final Driver
07.01783.001

Rod Pusher
07.01784.001

A-O Handle with Spin Cap
07.01788.001

Virage OCT Instrument Disassembly for Cleaning

Surgical Technique

After cleaning, reassemble by reversing instructions.

Polyaxial Screw Driver

Fig. 60 ▲

Step 1
Pull back the collar on the A-O Handle and disconnect it from the Screw Driver. (Fig. 60)

Fig. 61 ▲

Step 2
Depress the button and remove the Screw Driver Shaft. (Fig. 61)

Instruments

Polyaxial Screw Driver, Inner Sleeve
07.01764.001

Polyaxial Hex Screw Driver, 2.5mm
07.01764.002

Polyaxial Screw Driver, Outer Sleeve
07.01764.003

A-O Handle with Spin Cap
07.01788.001

Polyaxial Screw Head Turner

Fig. 62 ▲

Step 3

Pull the outer sleeve off of the Screw Driver. (Fig. 62)

Flush all holes near the button. (Fig. 62, inset)

NOTE: *After cleaning, reassemble the Screw Driver prior to sterilization. See assembly instructions in the Surgical Technique.*

Fig. 63 ▲

Step 4

Turn the knob counterclockwise to disassemble. (Fig. 63)

Fig. 64 ▲

Step 5

Pull the inner shaft out of the outer shaft and separate. (Fig. 64)

NOTE: *After cleaning, reassemble the Polyaxial Screw Head Turner prior to sterilization.*

Instruments

Polyaxial Screw
Head Turner
07.01766.001

Tower Rod Reducer

Fig. 65 ▲

Step 7

To disassemble, turn the knob clockwise until the inside shaft is free.
(Fig. 65)

Fig. 66 ▲

Step 8

Pull the inside shaft to separate. (Fig. 66)

Fig. 67 ▲

Step 9

Turn the top knob and flush. (Fig. 67)

NOTE: *After cleaning, reassemble the Tower Rod Reducer prior to sterilization.*

Instruments

Tower Rod Reducer
07.01776.001

Virage OCT Revision and Removal Steps

Surgical Technique

Removal - Cervico-Thoracic

Removal - Occipitocervical

Fig. 68 ▲

Cervico-Thoracic System Construct Removal

Remove all closure tops and loosen set screws using the Final Driver, Torque-Limiting Handle and Inline Counter Torque/Rod Pusher. Remove rods from construct. Remove pedicle screws by fully engaging the Screw Driver and turning counterclockwise.

If the hex portion of the screw cannot be re-engaged, utilize the Polyaxial Screw Remover. To use, remove the Polyaxial Hex Driver from Polyaxial Screw Driver and replace with the Polyaxial Screw Remover. Insert and tighten into the pedicle screw and rotate counterclockwise about the pedicle screw shank axis. (Fig. 68)

Occipitocervical System Construct Removal

Remove all closure tops and loosen all set screws using a Final Driver or Occipital Final Driver (Rigid or Flexible). Remove all occipital bone screws using the 3mm Hex Driver. Remove rods and occipital plate / eyelets from the construct.

Instruments

Final Driver
07.01783.001

Torque-Limiting Handle, 3/16"
07.01792.001

Inline Counter Torque
07.01785.001

Rod Pusher
07.01784.001

A-O Handle with Spin Cap
07.01788.001

Polyaxial Screw Remover
07.01786.002

Polyaxial Screw Driver, Inner Sleeve
07.01764.001

Occipital Final Drivers
07.01804.001
07.01805.001

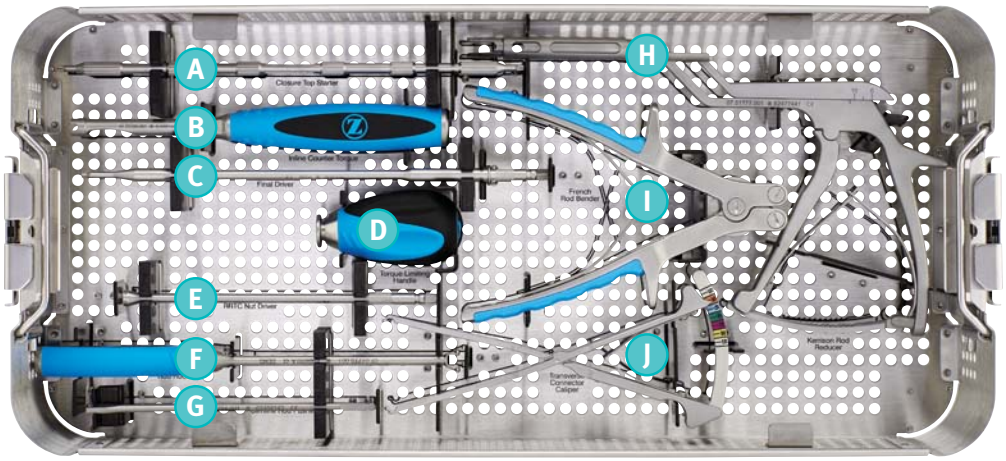
Hex Drivers, 3.0mm
07.01798.001 Rigid
07.01799.001 Flexible

Occipital Counter Torque
07.01802.001

Tray Layouts

Virage OCT Standard Implant and Instrument Set – Module 07.01973.410

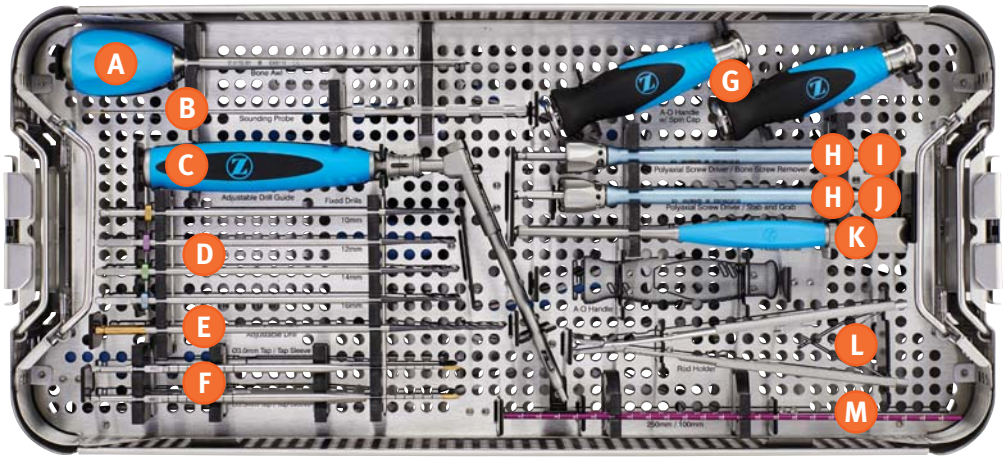
Instrument Set – Lower Tray



Part Number	Description	Quantity	Reference
07.01770.001	French Rod Bender	1	I
07.01775.001	Rod Rocker	1	F
07.01777.001	Kerrison Rod Reducer	1	H
07.01780.001	Transverse Connector Caliper	1	J
07.01781.001	Transverse Connector Driver – Rod to Rod	2	E
07.01782.001	Closure Top Starter	2	A
07.01783.001	Closure Top Final Driver	2	C
07.01784.001	Rod Pusher	1	G
07.01785.001	Inline Counter Torque	1	B
07.01792.001	Torque-Limiting Handle - 3/16"	1	D
07.01810.001	Standard Instrument Tray	1	–
07.01260.001	Generic Stackable Lid Tray	1	–

Virage OCT Standard Implant and Instrument Set – Module 07.01973.410

Instrument Set – Upper Tray



Part Number	Description	Quantity	Reference
07.01752.001	Bone Awl	1	A
07.01755.001	Drill Guide	1	C
07.01757.001	Adjustable Drill – Ø2.3mm	2	E
07.01758.001	Fixed Drill - Ø2.3mm X 10mm	1	D
07.01758.002	Fixed Drill - Ø2.3mm X 12mm	1	D
07.01758.003	Fixed Drill - Ø2.3mm X 14mm	1	D
07.01758.004	Fixed Drill - Ø2.3mm X 16mm	1	D
07.01759.001	Sounding Probe	1	B
07.01761.001	Tap, Small – Ø3.0mm	1	F
07.01761.002	Tap, Small – Ø3.5mm	1	F
07.01763.002	Tap Sleeve – Ø3.5mm	1	F
07.01764.001	Polyaxial Screw Driver, Inner Sleeve	2	H (assembled)
07.01764.002	Polyaxial Hex Screw Driver, 2.5mm	2	H (assembled)
07.01764.003	Polyaxial Screw Driver, Outer Sleeve	2	H (assembled)
07.01765.001	Tapered Hex Driver, 2.5mm	1	J (under H)
07.01766.001	Polyaxial Screw Head Turner	1	K
07.01767.001	Rod Template-100mm	1	M
07.01767.002	Rod Template-250mm	1	M
07.01768.001	Rod Holder	1	L
07.01786.002	Polyaxial Screw Remover	1	I (under H)
07.01788.001	A-O Handle with Spin Cap	2	G
07.01810.002	Standard Instrument Top Tray	1	–

Virage OCT Standard Implant and Instrument Set – Module 07.01973.410

Implant Set

Implant Tray			
Part Number	Description	Quantity	Reference
07.01811.001	Standard Implant Tray	1	–
07.01260.001	Generic Stackable Lid Assembly	1	–

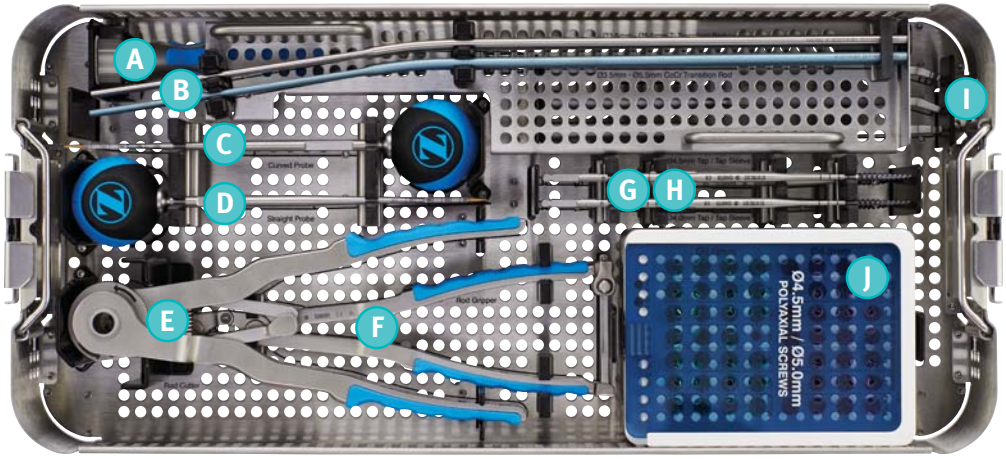
Ø3.5 Polyaxial Screw Caddy				Ø4.0 Polyaxial Screw Caddy			
Part Number	Description	Quantity	Ref.	Part Number	Description	Quantity	Ref.
07.01811.002	Ø3.5mm Polyaxial Screw Caddy	1	A	07.01811.004	Ø4.0mm Polyaxial Screw Caddy	1	G
07.01811.003	Ø3.5mm Polyaxial Screw Caddy Lid	1	A	07.01811.005	Ø4.0mm Polyaxial Screw Caddy Lid	1	G
07.01702.003	Ø3.5mm X 10mm	10	A	07.01702.046	Ø4.0mm X 10mm	4	G
07.01702.005	Ø3.5mm X 12mm	12	A	07.01702.048	Ø4.0mm X 12mm	4	G
07.01702.007	Ø3.5mm X 14mm	12	A	07.01702.050	Ø4.0mm X 14mm	4	G
07.01702.009	Ø3.5mm X 16mm	8	A	07.01702.052	Ø4.0mm X 16mm	4	G
07.01702.011	Ø3.5mm X 18mm	4	A	07.01702.054	Ø4.0mm X 18mm	2	G
07.01702.013	Ø3.5mm X 20mm	4	A	07.01702.056	Ø4.0mm X 20mm	2	G
07.01702.015	Ø3.5mm X 22mm	4	A	07.01702.058	Ø4.0mm X 22mm	2	G
07.01702.017	Ø3.5mm X 24mm	2	A	07.01702.060	Ø4.0mm X 24mm	2	G
07.01702.019	Ø3.5mm X 26mm	2	A	07.01702.062	Ø4.0mm X 26mm	2	G
07.01702.021	Ø3.5mm X 28mm	2	A	07.01702.064	Ø4.0mm X 28mm	2	G
07.01702.023	Ø3.5mm X 30mm	2	A	07.01702.066	Ø4.0mm X 30mm	2	G
07.01702.025	Ø3.5mm X 32mm	2	A	07.01702.068	Ø4.0mm X 32mm	2	G
07.01702.027	Ø3.5mm X 34mm	2	A	07.01702.070	Ø4.0mm X 34mm	2	G
Polyaxial Smooth Shank Screw Caddy							
07.01811.006	24-34mm Smooth Shank Polyaxial Screw Caddy	1	I	07.01811.007	24-34mm Smooth Shank Polyaxial Screw Caddy Lid	1	I
07.01707.003	Ø3.5mm X 24mm	2	I	07.01707.022	Ø4.0mm X 24mm	2	I
07.01707.005	Ø3.5mm X 26mm	2	I	07.01707.024	Ø4.0mm X 26mm	2	I
07.01707.007	Ø3.5mm X 28mm	2	I	07.01707.026	Ø4.0mm X 28mm	2	I
07.01707.009	Ø3.5mm X 30mm	2	I	07.01707.028	Ø4.0mm X 30mm	2	I
07.01707.011	Ø3.5mm X 32mm	2	I	07.01707.030	Ø4.0mm X 32mm	2	I
07.01707.013	Ø3.5mm X 34mm	2	I	07.01707.032	Ø4.0mm X 34mm	2	I

Virage OCT Standard Implant and Instrument Set – Module 07.01973.410

Implant Set, continued

Part Number	Description	Quantity	Ref.		Part Number	Description	Quantity	Ref.
Straight Rods					**Curved Rods**			
07.01811.014	Rod Caddy						1	
07.01709.002	Ti, Ø3.5mm X 25mm	2	H		07.01710.001	Ti, Ø3.5mm X 40mm	2	H
07.01709.003	Ti, Ø3.5mm X 30mm	2	H		07.01710.002	Ti, Ø3.5mm X 45mm	2	H
07.01709.004	Ti, Ø3.5mm X 35mm	2	H		07.01710.003	Ti, Ø3.5mm X 50mm	2	H
07.01709.006	Ti, Ø3.5mm X 400mm	2	E		07.01710.005	Ti, Ø3.5mm X 60mm	2	H
07.01715.002	CoCr, Ø3.5mm X 400mm	2	E		07.01710.007	Ti, Ø3.5mm X 70mm	2	H
					07.01710.009	Ti, Ø3.5mm X 80mm	2	H
					07.01710.011	Ti, Ø3.5mm X 90mm	2	H
					07.01710.012	Ti, Ø3.5mm X 100mm	2	H
					07.01710.013	Ti, Ø3.5mm X 110mm	2	H
					07.01710.014	Ti, Ø3.5mm X 120mm	2	H
Lateral Offset and Transverse Connector Caddy								
07.01811.010	Lateral Offset and Transverse Connectors Caddy						1	
07.01717.002	Head to Head Transverse Connector, 30mm	1	C		07.01721.002	Rod to Rod Transverse Connector, 30mm	1	B
07.01717.003	Head to Head Transverse Connector, 35mm	1	C		07.01721.003	Rod to Rod Transverse Connector, 35mm	1	B
07.01717.004	Head to Head Transverse Connector, 40mm	1	C		07.01721.004	Rod to Rod Transverse Connector, 40mm	1	B
07.01717.005	Head to Head Transverse Connector, 45mm	1	C		07.01721.005	Rod to Rod Transverse Connector, 45mm	1	B
07.01717.006	Head to Head Transverse Connector, 50mm	1	C		07.01721.006	Rod to Rod Transverse Connector, 50mm	1	B
07.01719.001	Head to Head Transverse Connector Closure Top	6	C		07.01811.011	Rod to Rod Transverse Connectors Lid	1	B
07.01720.001	Head to Head Transverse Connector Dome Nut	6	C					
07.01811.012	Head to Head Transverse Connectors Caddy Lid	1	C					
07.01727.001	Lateral Offset Connector – 10mm	2	D		07.01727.002	Lateral Offset Connector – 25mm	2	D
07.01811.013	Lateral Offset Connectors Lid	1	D					
Closure Top Caddy								
07.01811.008	Closure Top Caddy	1	F		07.01811.009	Closure Top Caddy Lid	1	F
07.01728.001	Standard Closure Top	24	F					

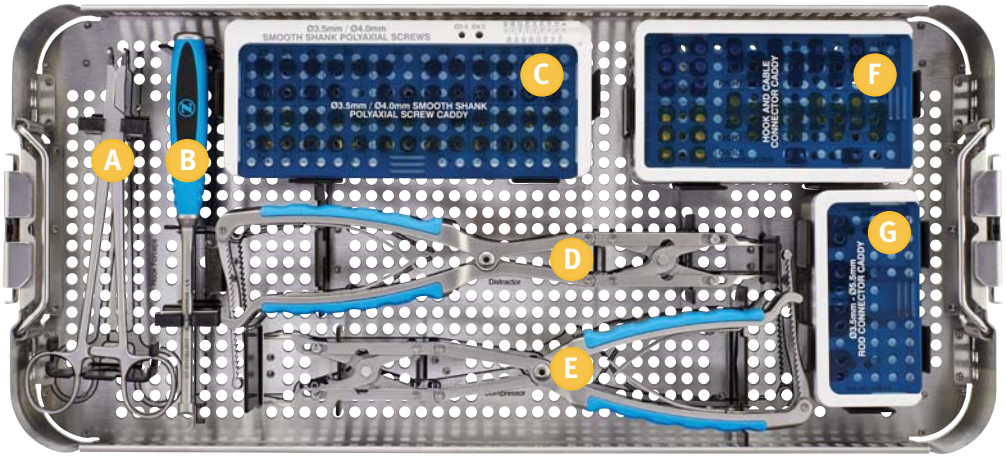
Virage OCT CT Junction Implant and Instrument Set - Module 07.01973.430



Part Number	Description	Quantity	Reference
07.01814.001	CT Junction Tray	1	–
07.01260.001	Lid, Generic	1	–
07.01753.001	Curved Probe	1	C
07.01754.001	Straight Probe	1	D
07.01762.001	Tap, Large – Ø4.0mm	1	G
07.01762.002	Tap, Large – Ø4.5mm	1	G
07.01763.004	Ø4.5mm Tap Sleeve	1	H
07.01769.001	Rod Gripper	1	F
07.01771.002	In-situ Rod Bender - Left	1	I
07.01772.002	In-situ Rod Bender - Right	1	I
07.01773.002	In-situ Rod Bender - Straight	1	I
07.01774.001	Rod Cutter - Ratcheting	1	E
07.01776.001	Tower Rod Reducer	1	A
Transition Rod Caddy			
07.01714.001	Transition Ti Rod - Ø3.5mm / Ø5.5mm X 450mm	3	B
07.01716.001	Transition CoCr Rod - Ø3.5mm / Ø5.5mm X 450mm	3	B
07.01814.004	Transition Rod Caddy	1	–

Polyaxial Screw Caddy								
Part Number	Description	Quantity		Ref.	Part Number	Description	Quantity	Ref.
07.01814.002	Ø4.5/5.0 Polyaxial Screw and Rod Connector Caddy	1		J	07.01814.003	Ø4.5/5.0 Polyaxial Screws Lid	1	J
07.01708.002	Ø4.5mm X 20mm	4		J	07.01708.010	Ø5.0mm X 20mm	2	J
07.01708.003	Ø4.5mm X 25mm	4		J	07.01708.011	Ø5.0mm X 25mm	4	J
07.01708.004	Ø4.5mm X 30mm	4		J	07.01708.012	Ø5.0mm X 30mm	4	J
07.01708.005	Ø4.5mm X 35mm	4		J	07.01708.013	Ø5.0mm X 35mm	4	J
07.01708.006	Ø4.5mm X 40mm	2		J	07.01708.014	Ø5.0mm X 40mm	2	J
07.01708.007	Ø4.5mm X 45mm	2		J	07.01708.015	Ø5.0mm X 45mm	2	J

Virage OCT Deluxe Implant and Instrument Set - Module 07.01973.440

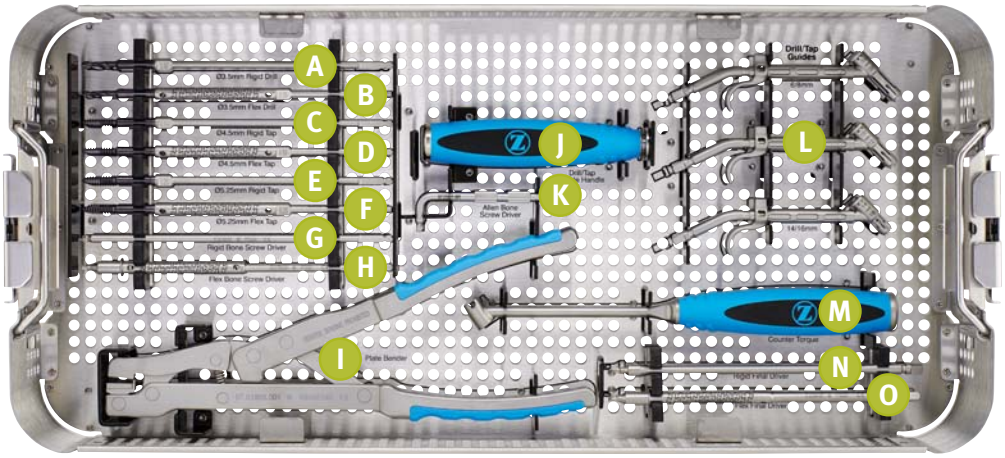


Part Number	Description	Quantity	Reference
07.01750.001	Hook Trial - 8mm	1	B
07.01751.001	Hook Forceps	1	A
07.01778.001	Compressor	1	E
07.01779.001	Distractor	1	D
07.01813.001	Deluxe Tray	1	–
07.01260.001	Generic Stackable Lid Assembly	1	–

Polyaxial Smooth Shank Screw Caddy								
Part Number	Description	Quantity	Ref.		Part Number	Description	Quantity	
07.01813.002	22-40mm Smooth Shank Polyaxial Screw Caddy	1	C		07.01813.003	22-40mm Smooth Shank Polyaxial Screw Caddy Lid	1	C
07.01707.001	Ø3.5mm X 22mm	2	C		07.01707.020	Ø4.0mm X 22mm	2	C
07.01707.003	Ø3.5mm X 24mm	2	C		07.01707.022	Ø4.0mm X 24mm	2	C
07.01707.005	Ø3.5mm X 26mm	2	C		07.01707.024	Ø4.0mm X 26mm	2	C
07.01707.007	Ø3.5mm X 28mm	2	C		07.01707.026	Ø4.0mm X 28mm	2	C
07.01707.009	Ø3.5mm X 30mm	2	C		07.01707.028	Ø4.0mm X 30mm	2	C
07.01707.011	Ø3.5mm X 32mm	2	C		07.01707.030	Ø4.0mm X 32mm	2	C
07.01707.013	Ø3.5mm X 34mm	2	C		07.01707.032	Ø4.0mm X 34mm	2	C
07.01707.015	Ø3.5mm X 36mm	2	C		07.01707.034	Ø4.0mm X 36mm	2	C
07.01707.017	Ø3.5mm X 38mm	2	C		07.01707.036	Ø4.0mm X 38mm	2	C
07.01707.019	Ø3.5mm X 40mm	2	C		07.01707.038	Ø4.0mm X 40mm	2	C
Hook and Cable Connector Caddy								
07.01813.004	Hook and Cable Connector Caddy	1	F		07.01813.005	Hook and Cable Connector Caddy Lid	1	F
07.01697.002	Laminar Hook - 6mm	4	F		07.01698.002	Offset Laminar Hook, Left - 6mm	2	F
07.01697.004	Laminar Hook - 8mm	4	F		07.01698.004	Offset Laminar Hook, Left - 8mm	2	F
07.01700.001	Cable Connector	2	F		07.01699.002	Offset Laminar Hook, Right - 6mm	2	F
					07.01699.004	Offset Laminar Hook, Right - 8mm	2	F
Rod Connector Caddy								
07.01813.006	Ø3.5-5.5mm Rod Connector Caddy	1	G		07.01813.007	Ø3.5-5.5mm Rod Connector Caddy Lid	1	G
07.01739.001	Rod Connector, Closed 3.5 to 5.5	4	G					

Virage OCT Occipital Implant and Instrument Set - Module 07.01973.450

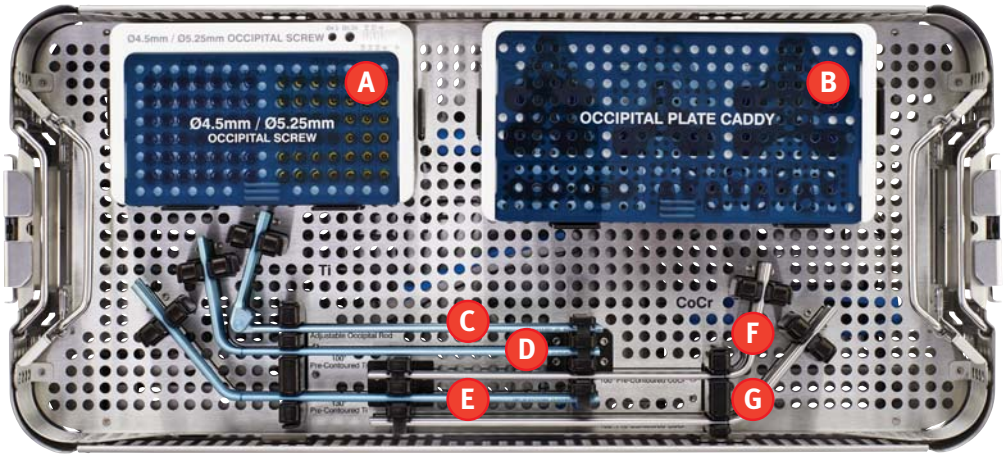
Lower Tray



Part Number	Description	Quantity	Reference
07.01790.001	Handle, 3/16"	1	J
07.01793.001	Occipital Drill/Tap Guide – 6mm/8mm	1	L
07.01793.002	Occipital Drill/Tap Guide - 10mm/12mm	1	L
07.01793.003	Occipital Drill/Tap Guide - 14mm/16mm	1	L
07.01794.001	Occipital Drill, Rigid - Ø3.5mm	1	A
07.01795.001	Occipital Drill, Flexible - Ø3.5mm	1	B
07.01796.001	Occipital Tap , Rigid - Ø4.5mm	1	C
07.01796.002	Occipital Tap, Rigid - Ø5.25mm	1	E
07.01797.001	Occipital Tap, Flexible - Ø4.5mm	1	D
07.01797.002	Occipital Tap , Flexible - Ø5.25mm	1	F
07.01798.001	Hex Driver, Rigid, 3.0mm	1	G
07.01799.001	Hex Driver, Flexible, 3.0mm	1	H
07.01801.001	Allen Hex Wrench, 3.0mm	1	K
07.01802.001	Occipital Counter Torque	1	M
07.01803.001	Plate Bender	1	I
07.01804.001	Occipital Final Driver, Flexible	1	O
07.01805.001	Occipital Final Driver, Rigid	1	N
07.01812.001	Occipital Tray	1	–
07.01260.001	Generic Stackable Lid Assembly	1	–

Virage OCT Occipital Implant and Instrument Set - Module 07.01973.450

Upper Tray



Part Number	Description	Quantity	Reference
07.01711.001	Ti Occipital Rod - Adjustable	3	C
07.01712.001	Pre-Contoured Occipital Rod, Ti - 100deg	2	D
07.01712.003	Pre-Contoured Occipital Rod, TI - 130deg	2	E
07.01713.001	Pre-Contoured Occipital Rod, CoCr - 100deg	2	F
07.01713.003	Pre-Contoured Occipital Rod, CoCr - 130deg	2	G
07.01812.002	Occipital Top Tray	1	–

Occipital Plate Caddy								
Part Number	Description	Quantity	Ref.		Part Number	Description	Quantity	Ref.
07.01812.005	Occipital Plate Caddy	1	B		07.01812.006	Occipital Plate Caddy Lid	1	B
07.01693.004	Occipital Plate - Small	1	B		07.01694.001	Occipital Strap	2	B
07.01693.005	Occipital Plate - Medium	2	B		07.01738.001	Occipital Eyelet	6	B
07.01693.006	Occipital Plate - Large	1	B					

Occipital Screw Caddy								
Part Number	Description	Quantity	Ref.		Part Number	Description	Quantity	Ref.
07.01812.003	Ø4.5mm / Ø5.25mm Occipital Bone Screw Caddy	1	A		07.01812.004	Ø4.5mm / Ø5.25mm Occipital Bone Screw Caddy Lid	1	A
07.01696.001	Ø4.5mm X 6mm	5	A		07.01696.014	Ø5.25mm X 6mm	2	A
07.01696.003	Ø4.5mm X 8mm	5	A		07.01696.016	Ø5.25mm X 8mm	2	A
07.01696.005	Ø4.5mm X 10mm	5	A		07.01696.018	Ø5.25mm X 10mm	2	A
07.01696.007	Ø4.5mm X 12mm	5	A		07.01696.020	Ø5.25mm X 12mm	2	A
07.01696.009	Ø4.5mm X 14mm	5	A		07.01696.022	Ø5.25mm X 14mm	2	A
07.01696.011	Ø4.5mm X 16mm	5	A		07.01696.024	Ø5.25mm X 16mm	2	A

Instrument Visual Guide

Virage OCT Standard System Instruments

Bone Awl
07.01752.001

Drill Guide
07.01755.001

Adjustable Drill – Ø2.3mm
07.01757.001

Fixed Drill
07.01758.001 Ø2.3mm X 10mm
07.01758.002 Ø2.3mm X 12mm
07.01758.003 Ø2.3mm X 14mm
07.01758.004 Ø2.3mm X 16mm

Sounding Probe
07.01759.001

Tap, Small
07.01761.001 Ø3.0mm
07.01761.002 Ø3.5mm

Tap Sleeve – Ø3.5mm
07.01763.002

Assembled Polyaxial Screw Driver
07.01764.001
07.01764.002
07.01764.003

Tapered Hex Driver, 2.5mm
07.01765.001

Polyaxial Screw Head Turner
07.01766.001

Rod Template – 100mm
07.01767.001

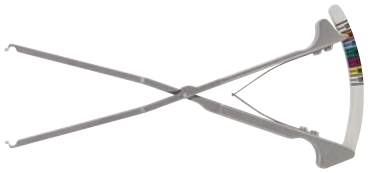
Rod Template – 250mm
07.01767.002

Rod Holder
07.01768.001

French Rod Bender
07.01770.001

Rod Rocker
07.01775.001

Kerrison Rod Reducer
07.01777.001



Transverse Connector Caliper
07.01780.001

Transverse Connector Driver – Rod to Rod
07.01781.001

Closure Top Starter
07.01782.001

Closure Top Final Driver
07.01783.001

Rod Pusher
07.01784.001

Inline Counter Torque
07.01785.001

Polyaxial Screw Remover
07.01786.002

A-O Handle with Spin Cap
07.01788.001

Torque-Limiting Handle - 3/16"
07.01792.001

Instrument Visual Guide

Virage OCT CT Junction System Instruments

Curved Probe
07.01753.001

Straight Probe
07.01754.001

Tap, Large
07.01762.001 Ø4.0mm
07.01762.002 Ø4.5mm

Ø4.5mm Tap Sleeve
07.01763.004

Rod Gripper
07.01769.001

In-situ Rod Bender - Left
07.01771.002

In-situ Rod Bender - Right
07.01772.002

In-situ Rod Bender - Straight
07.01773.002

Rod Cutter
07.01774.001

Tower Rod Reducer
07.01776.001

Instrument Visual Guide

Virage OCT Deluxe System Instruments

Hook Trial - 8mm
07.01750.001

Hook Forceps
07.01751.001

Compressor
07.01778.001

Distractor
07.01779.001

Instrument Visual Guide

Virage OCT Occipital System Instruments

Handle, 3/16"
07.01790.001

Occipital Drill/Tap Guide
07.01793.001 6mm/8mm
07.01793.002 10mm/12mm
07.01793.003 14mm/16mm

Occipital Drill, Ø3.5mm
07.01794.001 Rigid
07.01795.001 Flexible

Occipital Tap
07.01796.001 Rigid - Ø4.5mm
07.01796.002 Rigid - Ø5.25mm
07.01797.001 Flexible - Ø4.5mm
07.01797.002 Flexible - Ø5.25mm

Hex Driver, 3.0mm
07.01798.001 Rigid
07.01799.001 Flexible

Allen Hex Wrench, 3.0mm
07.01801.001

Occipital Counter Torque
07.01802.001

Plate Bender
07.01803.001

Occipital Final Driver
07.01804.001 Flexible
07.01805.001 Rigid

Warnings and Precautions

WARNINGS

Following are specific warnings, precautions, and adverse effects associated with use of the *Virage* System that should be understood by the surgeon and explained to the patients. General surgical risk should be explained to the patients prior to surgery.

- Implantation of the *Virage* System should be performed only by experienced spinal surgeons
- All implants are intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single-use devices include:
  - Mechanical malfunction
  - Transmission of infectious agents
- Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.
- The *Virage* System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture.
- Universal precautions should be observed by all end users that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges to prevent injuries during and after surgical procedures and reprocessing.
- **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.

Additional preoperative, intraoperative, and postoperative warnings and precautions:

PREOPERATIVE

- Usage of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments.
- Proper handling, decontamination (including pre-rinsing, washing, rinsing and sterilization), storage and utilization are important for the long and useful life of all surgical instruments. Even with correct use, care and maintenance, they should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., bone awls/drills) and driving instruments (e.g., drivers). These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.
- Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct; otherwise, galvanic corrosion may occur. See DESCRIPTION section for *Virage* System materials and compatibility information.

INTRAOPERATIVE

- If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant surface. Do not repeatedly or excessively bend the implant. Do not reverse bend the plate or rods.
- Bending plate outside of bend zone groove may result in cracking of plate. Surgeon should always inspect plate before implanting.
- Occiput and pedicle bone integrity should be verified
- Care should be taken during occiput and pedicle preparation to avoid penetrating too deep.
- Care should be taken to ensure occipital screw is not driven in too deep
- Care should be taken during bone preparation to avoid damage to the pedicle and to the surgical instruments.
- Care should be taken to minimize soft tissue damage during surgery.
- Care should be taken to avoid removing excess material from the Lamina.
- Care should be taken to avoid cross-threading screws and closure tops.
- If any implant or instrument comes in contact with a non-sterile surface it should not be used.

POSTOPERATIVE

- Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in fracture. The patient should understand that an implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
- The *Virage* System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture.

Disclaimer:

This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects.

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EC REP

Zimmer Limited
SN3 4FP, U.K.
+44.1793.58.4500

Manufactured by:

Zimmer Spine
7375 Bush Lake Road
Minneapolis, MN 55439
800.655.2614

zimmerspine.com

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