NUVASIVE®
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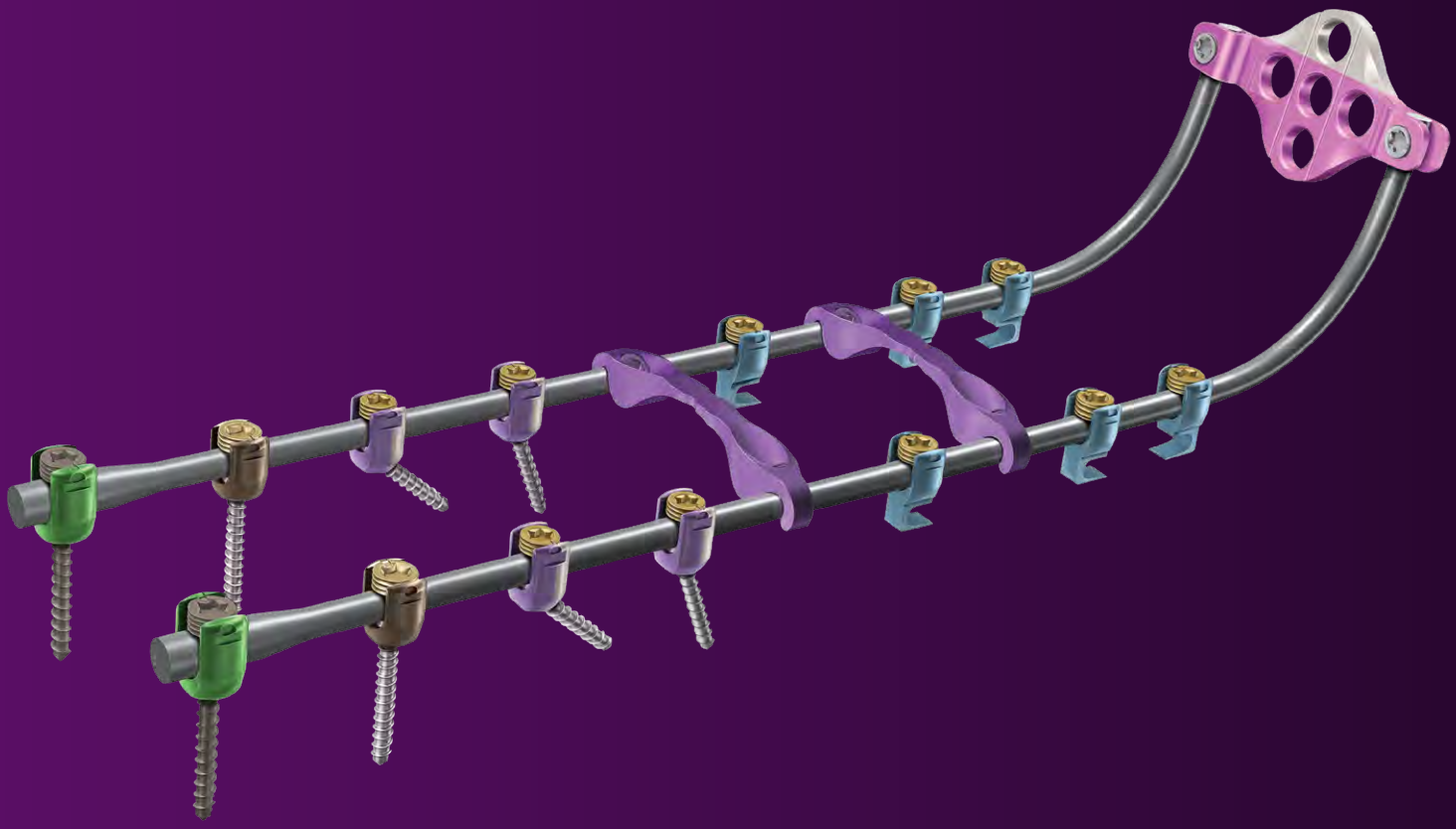
VUEPOINT® OCT

Technique Guide



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PREFACE

Fellow Colleagues:

Over the past decade, surgical techniques have expanded significantly for the posterior occipital, cervical, and thoracic spine. From occipital plates to C1 lateral mass, C2 pedicle, and C2 laminar screws, and from cervical to thoracic pedicle screws, the surgical options have increasingly provided the surgeon with safe and effective treatment options.

From the beginning of the design process of the VuePoint® OCT System, it was our goal to develop an elegant, quality system that allows the surgeon multiple options for instrumenting each area of pathology within the posterior upper spine, whether it be occipitocervical, C1-C2, subaxial cervical, or cervicothoracic. As a result, VuePoint OCT is a complete occipital, cervical, and thoracic system which also seamlessly integrates into thoracolumbar systems to allow applications from skull to sacrum.

Not only is VuePoint OCT a complete system, but we have also endeavored to refine the implants to maximize intraoperative visibility and patient safety and comfort, while minimizing operative time. The entire system is low-profile, including our side-loading Occipital Keel Plate, which makes it especially applicable to thinner patients. Moreover, the VuePoint OCT Favoured Angle Screws offer one of the highest angulations available at 55 degrees. These Favoured Angle Screws also feature the only bi-colored screw head on the market, providing a visual indication of the Favoured Angle orientation. VuePoint OCT is the only system which offers several options of Offset Lateral Connectors, truly giving the surgeon maximal flexibility in designing the most effective construct. The instruments were designed as carefully as our implants; for example, we believe that our positive-lock Drill Guides are the safest on the market.

We also wanted a system that is convenient for the surgeon to use. All Multi Axial Screws have friction-fit heads, enabling the polyaxial heads to stay in whichever orientation the surgeon places them, facilitating Rod placement. All the screws are also color-coded for ease of identification. To maximize ease of use of the instruments, a broad population of surgeons was consulted to optimize the instrument working lengths and to develop handles which are comfortable to hold.

We believe the combined result of all these features is the most complete and thoughtful system on the market today, and trust that your patients will benefit from the numerous clinical advantages of the VuePoint OCT System.

Best regards,

Neill Wright, M.D.
Associate Professor of Neurological
and Orthopaedic Surgery
Washington University School of Medicine
St. Louis, Missouri

Steven Vanni, D.O.
Assistant Professor of Clinical Neurological Surgery
and Orthopaedics and Rehabilitation
University of Miami Hospital
Miami, Florida

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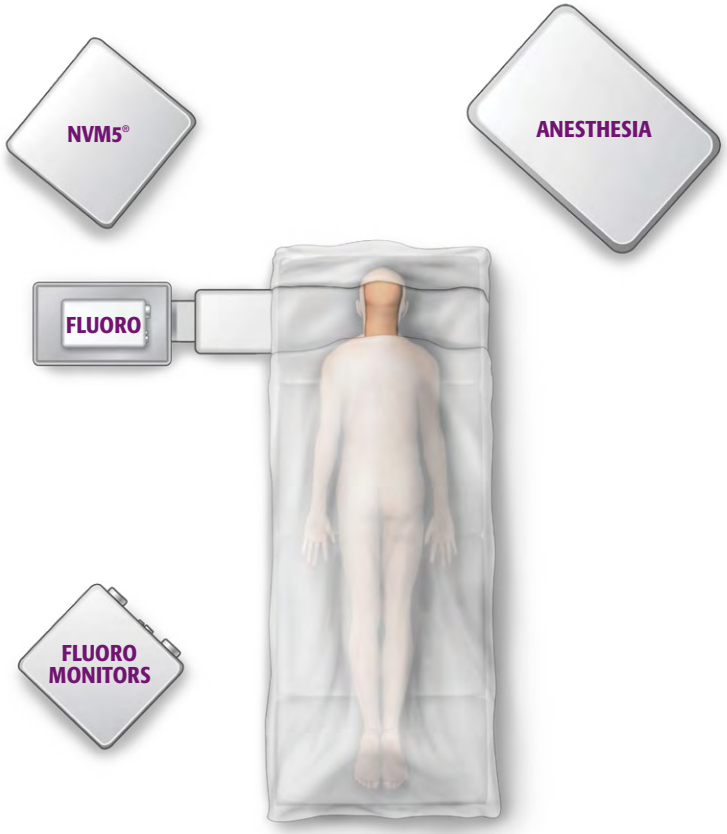
PRE-OP PATIENT POSITIONING AND PREPARATION

Although patient positioning is always up to the discretion of the individual surgeon, care must be taken to position the patient with the neck in an anatomic alignment prior to instrumentation. Most commonly, patients will be positioned prone, with the head in a Mayfield head-holder. Depending on the pathology and surgeon preference, the patient can be log-rolled into the prone position after intubation and line placement, or can be rotated on an OSI table. In any event, precautions should be used to maintain the neck in a neutral alignment during positioning.

Prior to preparation of the operative site, a final positioning check should be done. The extremities should be well padded. The surgeon should verify the anatomic position of the neck relative to the chest such that the patient is not instrumented in unacceptable flexion, extension, translation, or rotation. This is especially important with long-segment fusions or occiput-C1 or C1-C2 cases.

For cases involving the occiput or the upper cervical spine, the skin needs to be prepared up to the level of the inion. For cases involving the lower cervical spine, the skin needs to be prepared low enough for proper access. If intraoperative radiographs or fluoroscopy is going to be used, the shoulders should be tractioned gently to facilitate imaging *(Fig. 1)*. If the patient has redundant or excess skin with neck folds in the operative field, 3-inch surgical tape may be helpful in pulling the skin taut. Tape can be applied in an X-like pattern, starting lateral to the desired operative field and pulled down to the contralateral hip/buttock area.

For a complete list of intended uses, indications, device description, contraindications, warnings, and precautions, please refer to the Instructions for Use (IFU) in the back of this technique guide.



(Fig. 1)

NVM5® – MEP AND SSEP

Use NVM5 to monitor spinal cord health and integrity during VuePoint® OCT surgery. After the patient is fully anesthetized and positioned, use the Motor Evoked Potentials application to apply transcranial stimulation to obtain baseline readings. Subsequent readings should be obtained every 15 minutes at a minimum. Refer to the NVM5 online reference manual for more detailed information on MEP functionality.

STEP 1:
EXPOSURE

The surgical anatomy is then exposed in the standard fashion. Care should be taken not to expose any facet joints that are not in the planned construct, as exposure of the facet may contribute to facet disruption/instability.

STEP 2:
PEDICLE PREPARATION

Locate the desired entry point into the pedicle and perforate the cortex with an Awl *(Fig. 2)*. A pilot hole can also be created, using a Straight Gearshift Probe or Curved Gearshift Probe *(Fig. 3)*.

Alternatively, the starting point can be created with a high-speed burr.

NVM5® – MEP AND SSEP

Continuously monitor nerve proximity with NVM5 dynamic stimulation mode. Connect the Small Dynamic Stimulation Clip to instruments during pedicle preparation.

Real-time, continuous feedback is displayed as easy to interpret, color-coded, numeric threshold responses.

AWL

(Fig. 2)

GEARSHIFT PROBE

(Fig. 3)

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STEP 2:
PEDICLE PREPARATION (CONT.)

The 2.05mm Drill Bit can be used after perforating the outer cortex. Select the desired depth by pulling back on the knurled segment of the Drill Guide and placing the metal slide into the numbered slot labeled with the appropriate depth *(Figs. 4, 5)*. Attach a Universal Handle to the Drill Bit *(Fig. 6)*, insert the assembly through the barrel of the Drill Guide, and begin drilling *(Fig. 7)*. Once the Drill Bit is advanced to the preselected depth, a positive stop will prohibit the Drill Bit from advancing any farther. Two Drill Guides are available, allowing for 10-24mm and 26-40mm drilling depths.

> ***Note***
>
> *Both Drill Guides have magenta handles to differentiate them from the white-handled Tap Guide.*

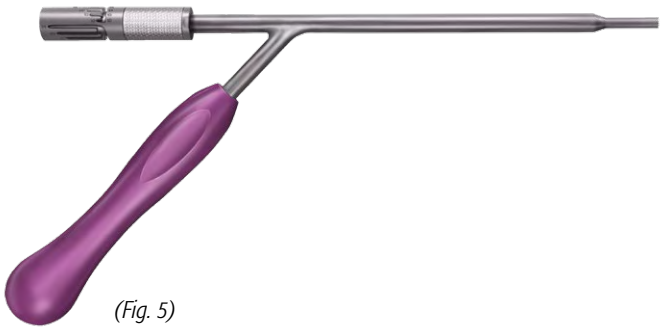
One of the advantages of the VuePoint® OCT System with regard to patient safety is the positive lock on the Drill Guide, ensuring that the drill is not accidentally advanced too deeply.

NVM5® – MEP AND SSEP

Continuously monitor nerve proximity with NVM5 dynamic stimulation mode. Connect the Small Dynamic Stimulation Clip to instruments during pedicle preparation.

14mm SETTING

(Fig. 4)



(Fig. 5)

(Fig. 6)

(Fig. 7)

STEP 2:
PEDICLE PREPARATION (CONT.)

> ***Note***
> *Three options are available if power drilling is preferred:*

1. The AO adaptation segment of the 2.05mm Drill Bit can be attached to the power drill with a matching AO adapter chuck *(Fig. 8)*. However, if the AO adaptation segment does not link up to a power drill, use option 2.
2. Attach the circular segment of the Drill Bit to the power drill utilizing a proper 3-jaw chuck *(Fig. 8)*. If this circular portion does not link up to the power drill, go to option 3.
3. Attach the Jacobs AO Adapter, offered in the set, to the Drill Bit *(Fig. 9)*. This converts the 2.05mm Drill Bit from an AO adaptation into a longer Tri-Flat adaptation, which can then be attached to a power drill with a 3-jaw chuck.

(Fig. 8)

(Fig. 9)

JACOBS AO ADAPTER

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STEP 2:

PEDICLE PREPARATION (CONT.)

Inspect the integrity of the pedicle walls by placing a Ball Tip Probe into the pilot hole and palpating the pedicle wall on all sides *(Fig. 10)*.

All Multi Axial Screws are self-tapping; however, if tapping is preferred, two options are available:

1. One option is to use a Tap Guide. First, select the desired tapping depth on the Tap Guide, which is done similarly to selecting the depth on the Drill Guide. Then attach either a 3.5mm Tap Shaft or 4.0mm Tap Shaft to a Universal Handle, insert the Tap through the barrel of the Tap Guide, and turn the Tap clockwise.

CAUTION
To prevent stripping, stop tapping when the tap bottoms out on the Tap Guide.

Note

Only one Tap Guide is available in the set, and it can tap depths ranging from 10mm to 24mm. This Tap Guide has a white handle to differentiate it from the two Drill Guides with magenta handles.

Note

Tap Shafts have a color-coded band to match the appropriate screw diameter: any 3.5mm magenta Multi Axial Screw Head matches the 3.5mm Tap with a magenta-colored band, and any 4.0mm aqua Multi Axial Screw Head matches the 4.0mm Tap with an aqua-colored band.

Note

A 4.5mm Tap Shaft is not available in the set, although we offer 4.5mm Multi Axial Screws. 4.5mm screws are intended to be rescue screws only.

(Fig. 10)

NVM5® – MEP AND SSEP

Continuously monitor nerve proximity with NVM5 dynamic stimulation mode. Connect the Small Dynamic Stimulation Clip to instruments during pedicle preparation.

STEP 2:

PEDICLE PREPARATION (CONT.)

2. The second option is to use a Tap Sleeve. Slide the Tap Sleeve (slit side first) over the distal part of the Tap *(Fig. 11)* until the distal end of the Tap Sleeve and the distal end of the Tap Shaft are flush *(Fig. 12)*. The slit feature on the Tap Sleeve provides a friction fit, preventing the sleeve from sliding off the Tap Shaft.

   While tapping, the Tap Sleeve slides up the Tap Shaft. Tapping depth is determined by the position of the top of the Tap Sleeve, relative to the measuring marks on the Tap Shaft *(Fig. 13)*.

   Use the Depth Gauge to confirm the depth of the pilot hole and to help determine the appropriate screw length.

Tip

"The Tap Sleeve is particularly useful in patients with soft tissue adjacent to the tap, especially with the lateral trajectory of pedicle screws at T1-T2."

- Dr. Neill Wright, M.D.

(Fig. 11)

STARTING POSITION

(Fig. 12)

SLIDES UP AS THE TAP PENETRATES BONE

(Fig. 13)

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STEP 3:
SCREW INSERTION

With the pedicles prepared and the appropriate screw length determined, attach a Multi Axial Screw to either the Stab-n-Grab Driver or the Threaded Screwdriver.

Stab-n-Grab Driver

Attach a Stab-n-Grab Driver Shaft to a Universal Handle. This driver will engage, pick up, and hold a Multi Axial Screw *(Fig. 14)*.

Alternatively, a Threaded Screwdriver can be used.

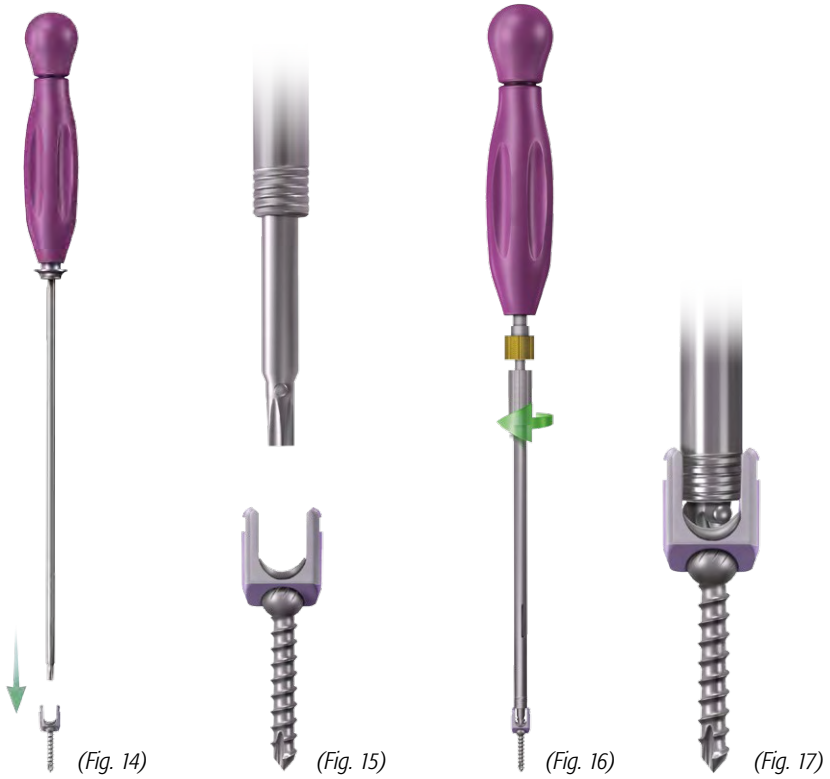
1. Insert the Threaded Screwdriver tip into the Multi Axial Screw Head *(Fig. 15)*. Ensure the driver fits snug into the head and the screw trajectory remains neutral to the driver shaft. Advance the threaded tip to the head of the screw.
2. Secure the engagement of the driver and screw head by turning the long, slim, knurled section of the threaded outer sleeve of the instrument (located below the OPT LOCK) clockwise into the screw head. It is fully seated in the head when resistance is felt *(Figs. 16, 17)*.

Note

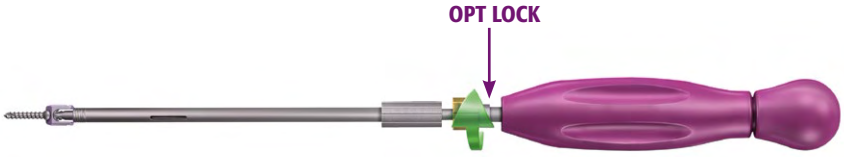
The Optional Lock feature (labeled OPT LOCK on the instrument) ensures the Threaded Driver does not unthread from the screw head while driving any Multi Axial Screw into bone. The OPT LOCK feature can be utilized by turning it clockwise to push down and lock the threaded sleeve of the instrument into the screw head. Continue turning the OPT LOCK feature until resistance is felt. This is only an "optional" feature and is most advantageous if a firm grip is required on the instrument shaft while simultaneously driving the Multi Axial Screw into bone (Figs. 18, 19).

NVM5® – MEP AND SSEP

Continuously monitor nerve proximity with NVM5 dynamic stimulation mode. Connect the Small Dynamic Stimulation Clip to instruments during pedicle preparation.



(Fig. 14) *(Fig. 15)* *(Fig. 16)* *(Fig. 17)*



(Fig. 18)

(Fig. 19)

STEP 3:

SCREW INSERTION (CONT.)

Insert the Multi Axial Screw into the pilot hole until the desired depth is reached *(Figs. 20, 21)*. Disengage the Threaded Driver from the Multi Axial Screw by first turning the OPT LOCK counterclockwise (if this feature was utilized) and then turning the lower knurled section counterclockwise until the outer sleeve is fully unthreaded from the screw head. If the Stab-n-Grab Driver was selected, simply place the screw in the screw hole and pull the driver off the Multi Axial Screw. Repeat these steps for all screw placement sites.

Note

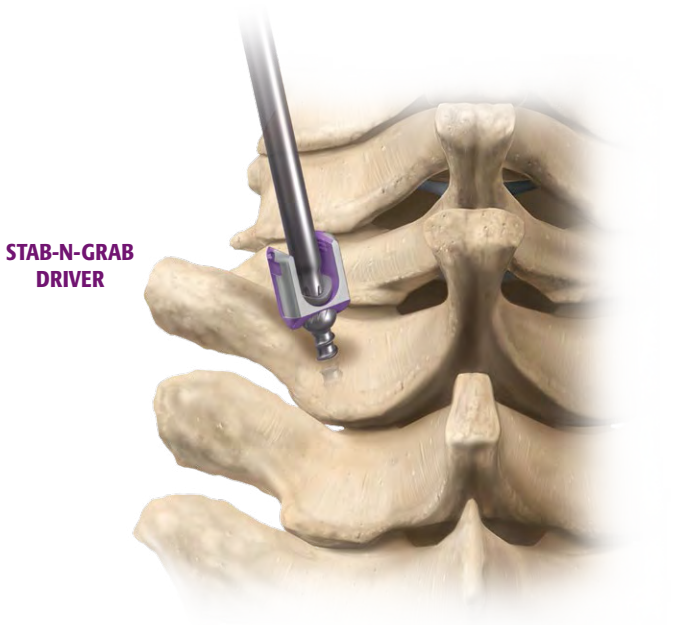
Do not insert the Multi Axial Screws so tightly/deeply that the multi axial feature is lost.

NVM5® – MEP AND SSEP

Continuously monitor nerve proximity with NVM5 dynamic stimulation mode. Connect the Small Dynamic Stimulation Clip to instruments during pedicle preparation.

NVM5 – MEP AND SSEP

Use NVM5 to monitor spinal cord health and integrity during VuePoint OCT surgery. After screws are inserted, a subsequent MEP reading may be taken to verify that there has been no compromise of the motor pathways of the spinal cord.



(Fig. 20)

(Fig. 21)

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STEP 3:
SCREW INSERTION (CONT.)

> ***Note***
> *Three Multi Axial Screw options are available:*

1. **Multi Axial Screw** = 40/40° of Angulation *(Fig. 22)*
   a. Offers an 80° conical sweep.
   b. Offered in 3.5mm, 4.0mm, and 4.5mm diameters.

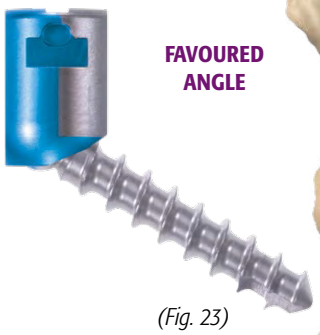
2. **Favoured Angle Multi Axial Screw** = 55/10° of Angulation *(Fig. 23)*
   a. Up to 55° of favoured angulation.
   b. The silver half of the bi-colored screw head provides a visual indication of the favoured angle orientation.
   c. Offered in 3.5mm and 4.0mm diameters.

3. **Favoured Angle Partially Threaded Screw** = 55/10° of Angulation *(Fig. 24)*
   a. Smooth portion helps protect nerve roots.
   b. 50/50 ratio: smooth to threaded.
   c. The silver half of the bi-colored screw head provides a visual indication of the favoured angle orientation.
   d. Offered in 3.5mm diameter.

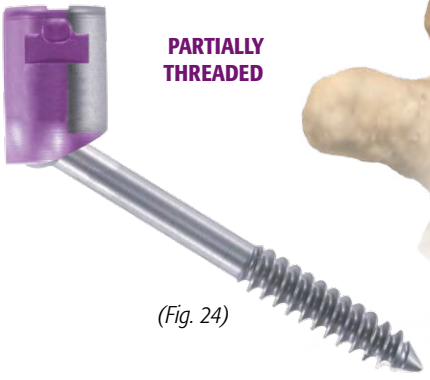
All three Multi Axial Screw types offer friction fit screw heads to provide superior alignment control *(Fig. 25)*, facilitating Rod placement. The Multi Axial Screws are also color-coded: 3.5mm are magenta, 4.0mm are aqua, and 4.5mm are bronze.

> ***Note***
> *Although the Favoured Angle Screws have greater angulation compared to traditional Multi Axial Screws (55° compared to 40°), this is in one direction only. The opposite direction provides less angulation (10° compared to 40°). Make sure that the Favoured Angle Screws are appropriate for the indication.*

(Fig. 22)



(Fig. 23)



(Fig. 24)

(Fig. 25)

STEP 4:

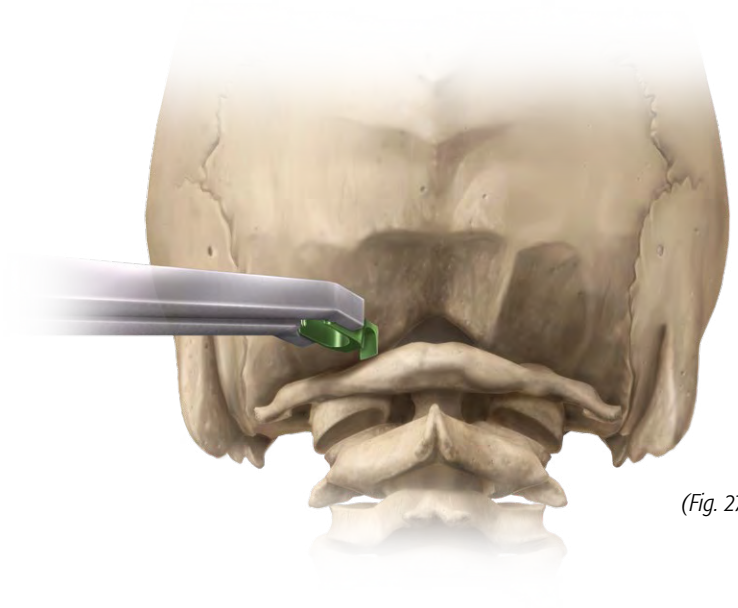
HOOK INSERTION

Select the appropriate Hook size, based on the claw length required.

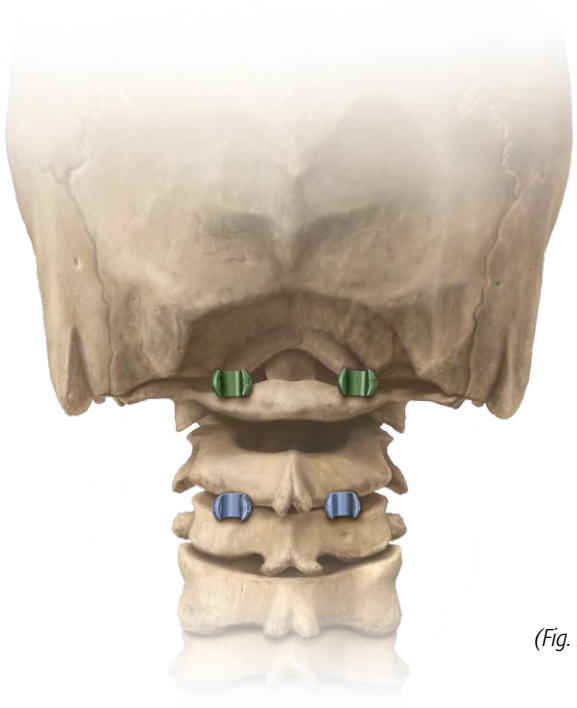
> ***Note***
> *Hooks are available in 5.0mm and 7.0mm sizes.*

Engage the Hook with the Hook Holder *(Fig. 26)* by squeezing the Holder on the Hook Head, and then place the Hook onto the lamina *(Fig. 27)*. Repeat these steps for all Hook placement sites *(Fig. 28)*.

(Fig. 26)



(Fig. 27)



(Fig. 28)

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STEP 5:
OCCIPITAL PREPARATION

Two fixation options are available to address the occiput: Occipital Keel Plates and Eyelet Connectors.

Keel Plates

Each Occipital Keel Plate offers five screw placement options, three in the midline and two lateral. The plate's low profile is maintained through two side-loading Rod slots. The unique magenta/silver bi-color feature indicates that the silver side of the plate should face superior *(Fig. 29)* to orient the 20° locking mechanism toward the surgeon *(Fig. 30)*.

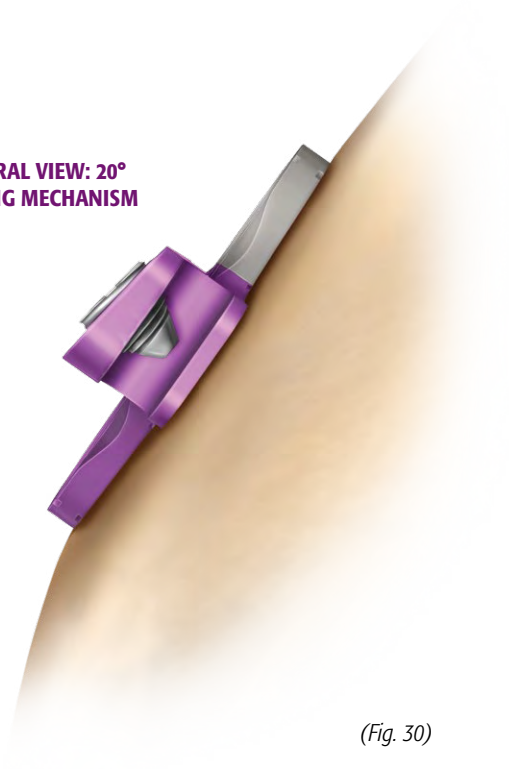
Select the Occipital Keel Plate size which best matches the patient's anatomy. After burring down any bony protuberances (while still maintaining the integrity of the cortical bone), the plate can be bent to best match the contour of the patient's occiput.

> ***Note***
> *Occipital Keel Plates are available in 35mm, 40mm, and 45mm widths. The Plate is measured from the center of the Rod on one side to the center of the Rod on the other side.*

SILVER SIDE SUPERIOR

(Fig. 29)

LATERAL VIEW: 20° LOCKING MECHANISM



(Fig. 30)

STEP 6:

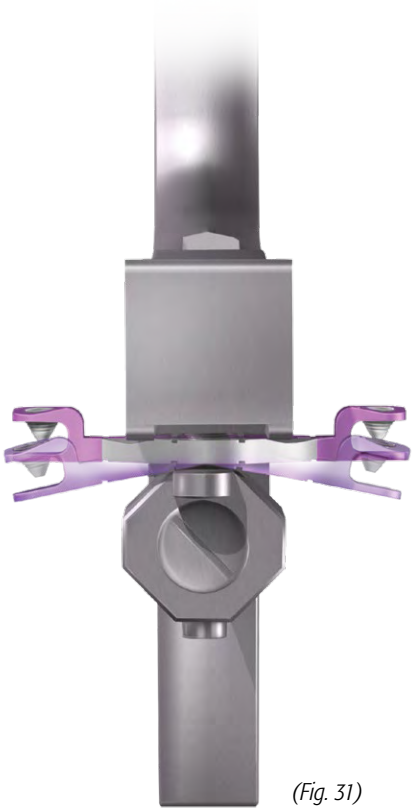
PLATE BENDING

After evaluating the contour of the occiput, the plate can be bent (1) medially, (2) laterally, or (3) in a combination of both.

1. A medial bend can be achieved by placing a Keel Plate in the Midline Keel Plate Bender. The three midline Keel Plate holes will rest on the three pegs within the bending instrument. Once in place, begin lightly squeezing the handles until the desired contour is achieved *(Fig. 31)*.

2. An arching bend can be achieved by bending the plate from the lateral ends. Place the preselected plate into the 4-in-1 Bender, inserting the silver side first. Then hold the Left 4-in-1 Bender in the left hand and the Right 4-in-1 Bender in the right hand, and gently bend down and inward *(Fig. 32)*.

CAUTION
To maintain the mechanical integrity of the plate, once the plate is bent in one direction with either tool, further bending only in that same direction should be attempted. Unbending of the plate may cause mechanical compromise.



(Fig. 31)

(Fig. 32)

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STEP 7:

EYELET CONNECTORS

Alternatively, Occipital Eyelet Connectors can be placed for fixation of the occiput. Eyelet Connectors allow for increased flexibility of bone screw placement because they are placed independent of each other.

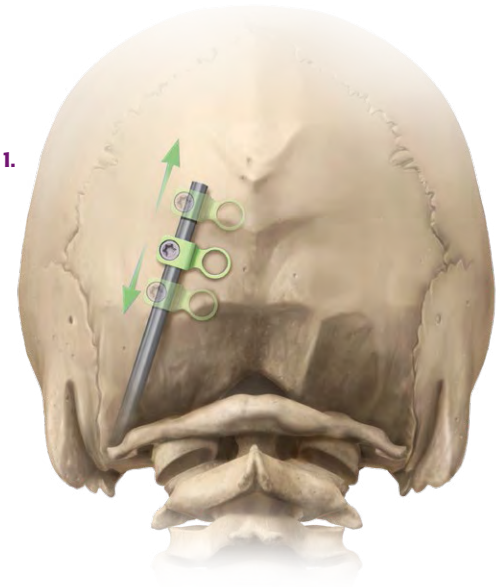
After bending the Rod to match the occipital anatomy, pre-load the Eyelet Connector to the Rod and provisionally tighten. Connect the desired number of Eyelets to each Rod *(Fig. 35)*. Once placed on the Rod, each Eyelet Connector offers 3° of freedom to best accommodate Eyelet placement:

1. Translate the Eyelet up and down the Rod *(Fig. 33)*
2. Pivot the Eyelet dorsally *(Fig. 34)*
3. Pivot the Eyelet ventrally *(Fig. 34)*

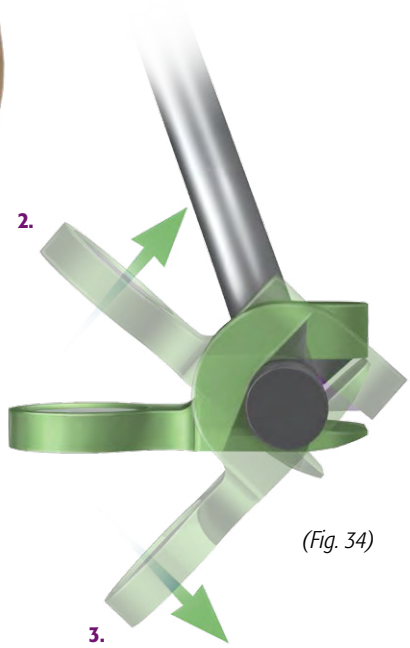
Tip

"Back out the Eyelet Connector Set Screw a few counterclockwise turns to allow room for the Rod to attach, if required. Also, once the Eyelet is connected to the Rod, the Set Screw can be slightly loosened to accommodate the 3° of freedom."

- Dr. Steven Vanni, D.O.



(Fig. 33)



(Fig. 34)

(Fig. 35)

STEP 8:

DRILLING AND TAPPING

First, select the desired drilling depth by pulling the distal part of the Occipital Drill/Tap Guide forward and away from the handle and turning the instrument to the desired depth, noted by the small metal slide which sits in the numbered slot *(Fig. 36)*.

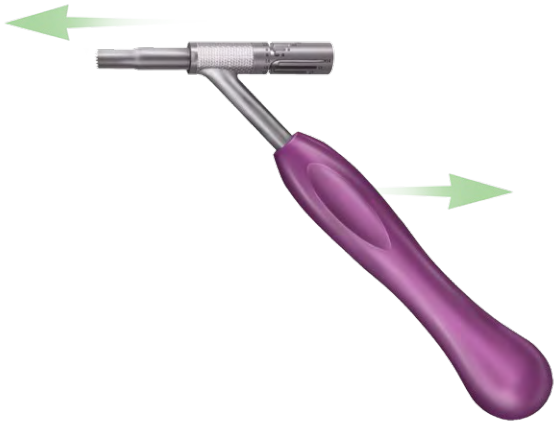
Second, attach the 3.35mm Straight Occipital Drill Bit Shaft onto the Universal Handle *(Fig. 37)* or power drill.

Third, use the Keel Plate Holder to secure the Keel Plate and position it on the occiput before drilling, tapping, and screwing. Attach the Keel Plate Holder's feet to the lateral ends of the Keel Plate and squeeze the handle to tighten and ensure a firm grip on the Keel Plate *(Fig. 38)*.

Tip

"The Keel Plate Set Screw on the lateral ends of the plate can prohibit the Keel Plate Holder's feet from attaching onto the plate. However, by simply backing the Set Screw a few counterclockwise turns using the Stab-n-Grab Driver, the Keel Plate Holder's feet will easily grip into place."

- Dr. Steven Vanni, D.O.



(Fig. 36)

(Fig. 37)

(Fig. 38)

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STEP 8:

DRILLING AND TAPPING (CONT.)

The correct orientation of the Keel Plate is determined by facing the silver side of the plate superior. This orientation is necessary due to a unique 20° Keel Plate locking feature that offers full visibility and increased access to the locking mechanism from the surgeon's VuePoint when performing final tightening of the Rod to the Keel Plate.

Place the 3.35mm Occipital Drill Bit through the Drill/Tap Guide and then place it through the desired fixation hole in the Keel Plate *(Fig. 39)*. The Keel Plate should be placed on the midline of the occiput. Begin drilling to the preselected depth. A positive stop will prohibit the drill from advancing any farther.

> ***Note***
>
> *There is also the option of drilling directly into the occiput through the Drill/Tap Guide, if desired. Both drilling options (i.e., through the plate or directly on the occiput), will drill the same depth because the distal tip of the Occipital Drill/Tap Guide slides through the Keel Plate fixation hole to sit flush with the surface of the occiput.*

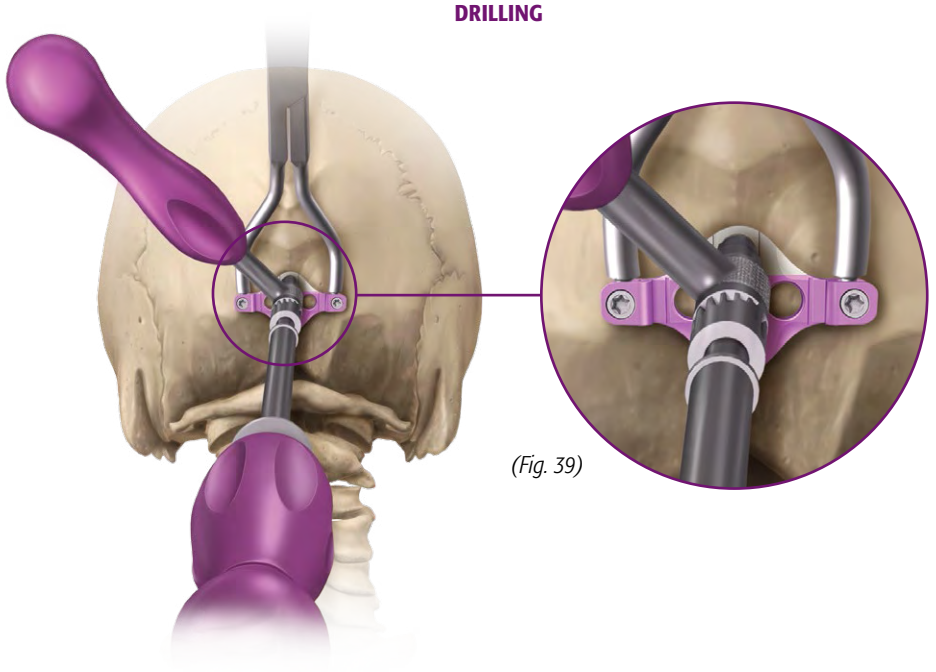
Repeat the aforementioned steps using a 4.5mm Tap when tapping the occipital bone through the Occipital Drill/Tap Guide *(Fig. 40)*.

> ***Note***
>
> *The Cortical Occipital Screws are not self-tapping. Tapping to the desired depth is required. Also, a 5.0mm Tap is not available in the set because 5.0mm screws are intended to be rescue screws.*

> ***Note***
>
> *Drill and screw depths are line-to-line; that is to say, drilling 10mm will equate to placing a 10mm screw.*

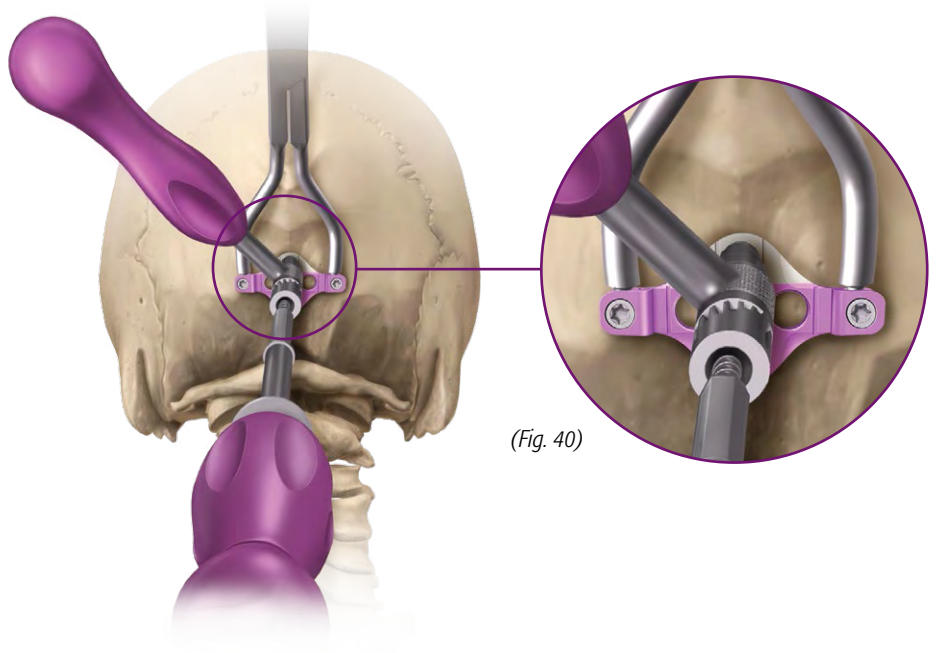
> ***Tip***
>
> *"The power drill is especially useful when drilling the occiput. The safety advantage of the VuePoint® OCT System is the positive lock on both the Drill Guide and the Tap Guide."*
>
> *- Dr. Neill Wright, M.D.*

DRILLING



(Fig. 39)

TAPPING



(Fig. 40)

STEP 9:

SCREW PLACEMENT

With the occipital bone holes prepared and the appropriate screw length determined, pick up a Cortical Occipital Bone Screw with the Stab-n-Grab Driver *(Fig. 41)* and drive the bone screw into the occiput until the screw is flush with the plate. Follow up with the black Final Tightening Shaft and Universal Handle if additional torque is needed to place the screw flush within the Keel Plate screw hole.

> ***Note***
>
> *Occipital Bone Screws come in 4.5mm and 5.0mm diameters, ranging from 6mm to 14mm lengths. The 4.5mm screws are recommended for primary screw placement. The 5.0mm screws are recommended for the rescue screw option.*

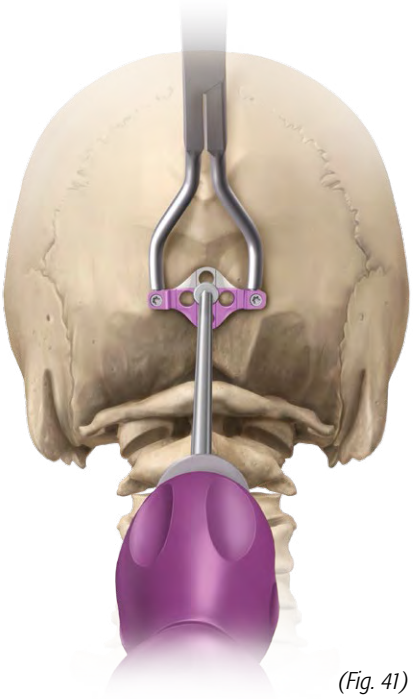
Repeat these steps for all screw placement sites *(Fig. 42)*.

> ***Note***
>
> *A Rod or Pre-Bent Rod can be provisionally tightened down when all Bone Screws, Hooks, and Multi Axial Screws are in place. There are two ways to perform the final tightening of the Keel Plate Set Screw onto the Rod:*

1. Attach the black-colored Final Tightening Shaft to the Torque Limiting Handle. A tactile and audible "click" indicates the Set Screw is locked at the recommended 26 in.-lbs.
2. Attach the black-colored Final Tightening Shaft to a Universal Handle (white-knuckle tighten).

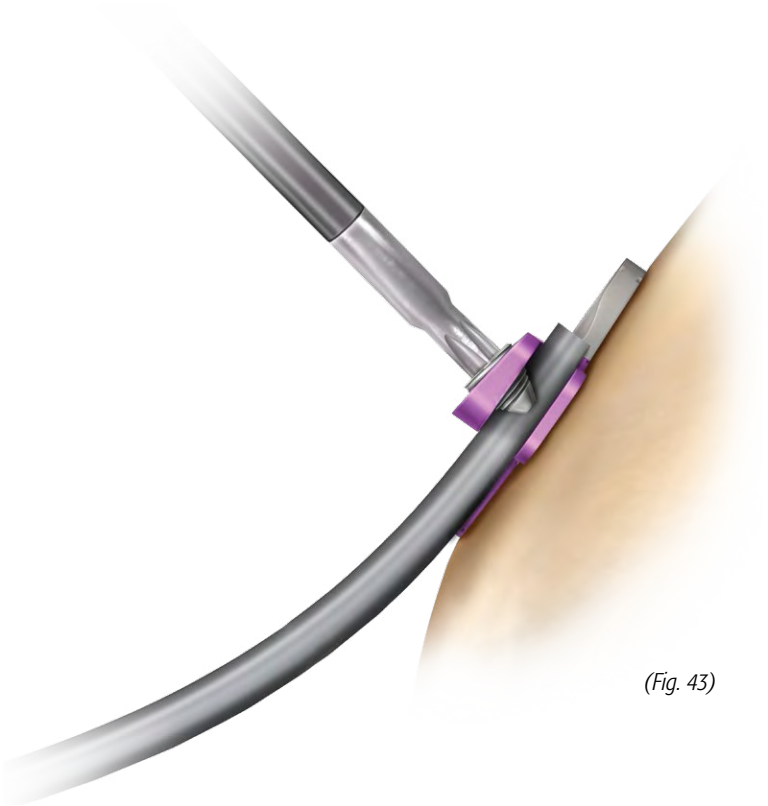
> ***Tip***
>
> *If needed, the Rod can be persuaded into the Keel Plate with use of the Rod Compressor (one end on the inside of the Rod connection portion of the plate, the other on the outside of the Rod, compressing the Rod lateral to medial). A Rod Pusher can also persuade the Rod into the Keel Plate by pushing the Rod medially into the Keel Plate.*

> ***Note***
>
> *The 20° locking mechanism on the Keel Plate allows a direct line of sight to the Set Screw, from the surgeon's VuePoint, which facilitates the final tightening step (Fig. 43).*



(Fig. 41)

(Fig. 42)



(Fig. 43)

VUEPOINT® OCT TECHNIQUE GUIDE

STEP 10:

ROD PREPARATION

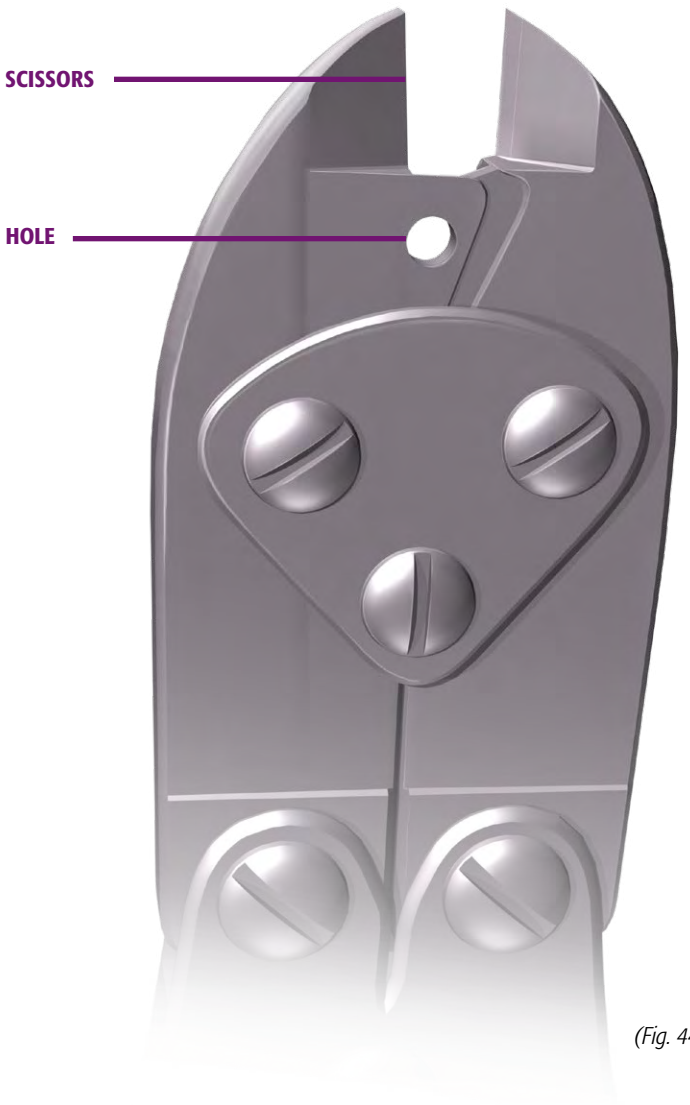
Rod Template lengths of 120mm and 240mm may be used to determine the length and overall curvature of the Rod.

Cutting the Rod

Use the Rod Cutter to cut the Rod to the appropriate length.

> ***Note***
> *The Rod Cutter offers 2 cutting locations:*

1. The hole in the cutter is recommended for primary cuts to create a clean, shear cut *(Fig. 44)*.
2. The scissors portion of the cutter is recommended for secondary cuts to help address in situ cutting requirements *(Fig. 44)*.



(Fig. 44)

STEP 11:

ROD BENDING

The Rod Bender can be used to contour the 3.5mm Rod to best match the desired curvature of the spine. The most lateral pivot wheel allows for a greater degree of bending angulation to be achieved, typically utilized when addressing an occipitocervical bend.

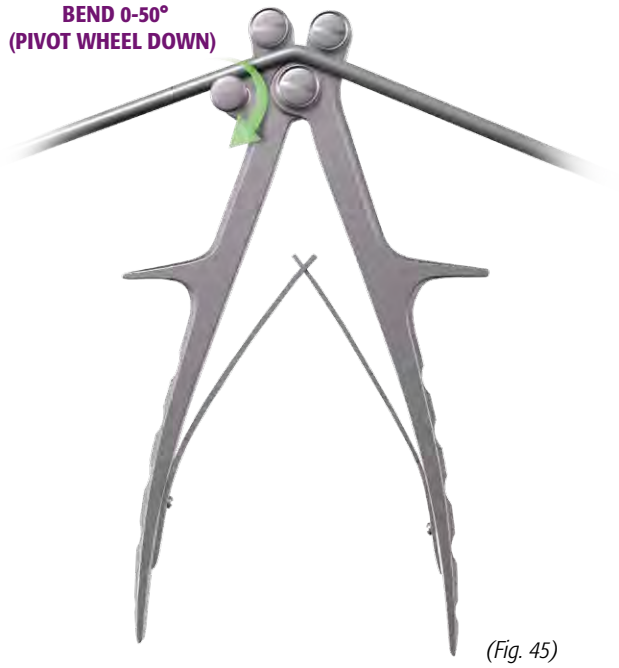
Three bending degree ranges can be achieved with the Rod Bender:

1. 0-50° - Pivot the wheel down toward 90° and place the Rod superior to the pivot wheel *(Fig. 45)*.

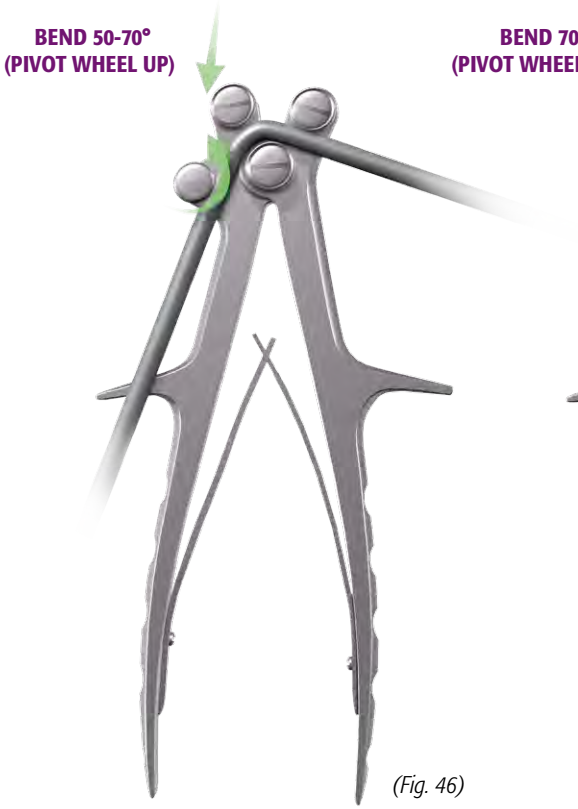
> ***Note***
> *The pivot wheel's starting position must be facing downward and positioned at 90.°*

2. 50-70° - Rotate the pivot wheel up toward 70° and place the Rod inferior to the pivot wheel *(Fig. 46)*.
3. 70-90° - Rotate the pivot wheel down toward 90° and place the Rod inferior to the pivot wheel *(Fig. 47)*.

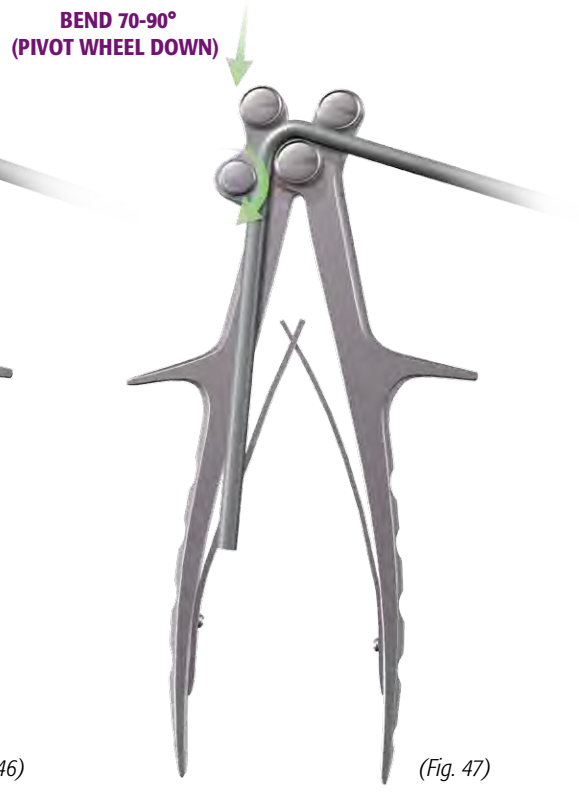
> ***Note***
> *The pivot wheel is laser-etched 70° & 90° to denote the pivot up or down, respectively.*



(Fig. 45)



(Fig. 46)



(Fig. 47)

STEP 12:
SCREW HEAD ALIGNMENT

Alignment Tool

To ensure proper alignment of the Multi Axial Screw Heads, the Alignment Tool is used to adjust the head orientation before the Rod is inserted *(Figs. 48, 49)*. All Multi Axial Screw Heads offer a Friction Fit feature which eliminates the head flop sometimes encountered with competitive systems. Head flop is potentially troublesome when aligning a multi-level construct.

> ***Note***
>
> *A key advantage of the VuePoint® OCT System is providing the surgeon a continuous visualization of the direction of the Favoured Angle Screw from his/her VuePoint, or top-down (Fig. 50). When using a Favoured Angle Multi Axial Screw, denoted by the bi-colored screw head, always face the silver half of the screw head in the direction which necessitates the most angulation. Favoured Angle Multi Axial Screws offer up to 55° of angulation.*

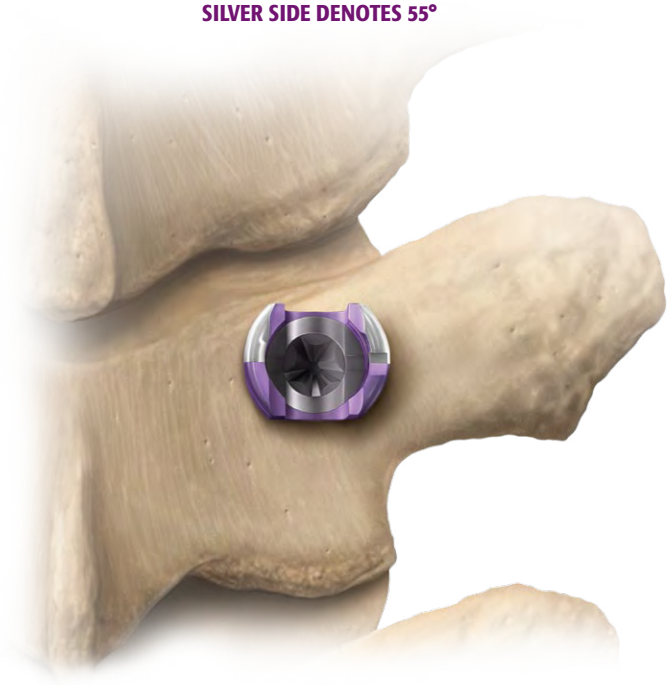
NON-ALIGNED SCREWS AT T1-T3

(Fig. 48)

ALIGNED SCREWS AT T1-T3

(Fig. 49)

SILVER SIDE DENOTES 55°

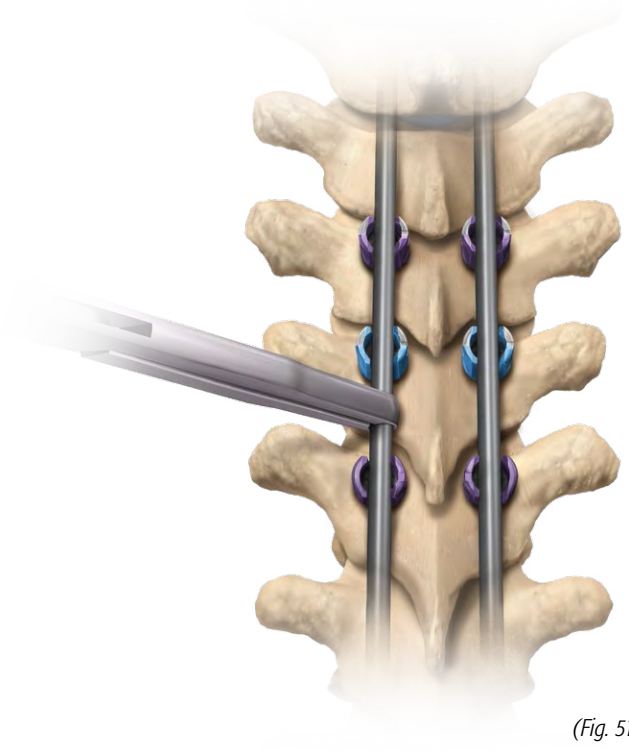


(Fig. 50)

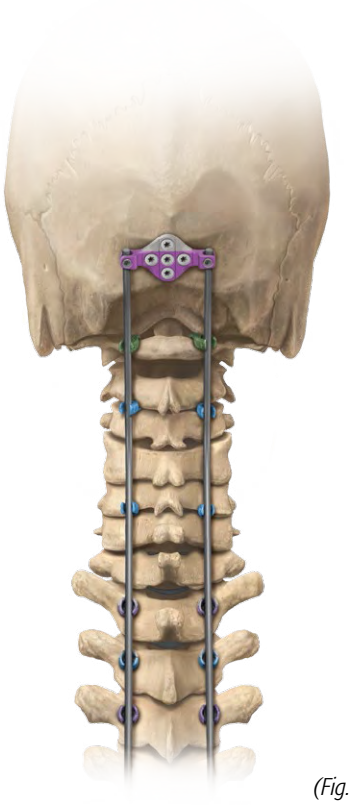
STEP 13:

ROD PLACEMENT

Insert the Rod into the Multi Axial Screw Heads, Hook Heads, and Occipital Keel Plate using the Rod Holder *(Figs. 51, 52)*.



(Fig. 51)



(Fig. 52)

VUEPOINT® OCT TECHNIQUE GUIDE

STEP 14:

SET SCREW SEATING AND PROVISIONAL TIGHTENING

Once the Rod is positioned, the construct can be secured using Set Screws. Engage a Set Screw using the Stab-n-Grab Driver or Tactile Set Screw Driver *(Fig. 53)*. Then thread the Set Screw into the Multi Axial Screw or Hook Head and provisionally tighten down.

Note

If required, align the "timing marks" on the Set Screw and the Tulip Head prior to insertion to position the mating threads in their proper orientation in order to thread the Set Screw more easily (Fig. 54).

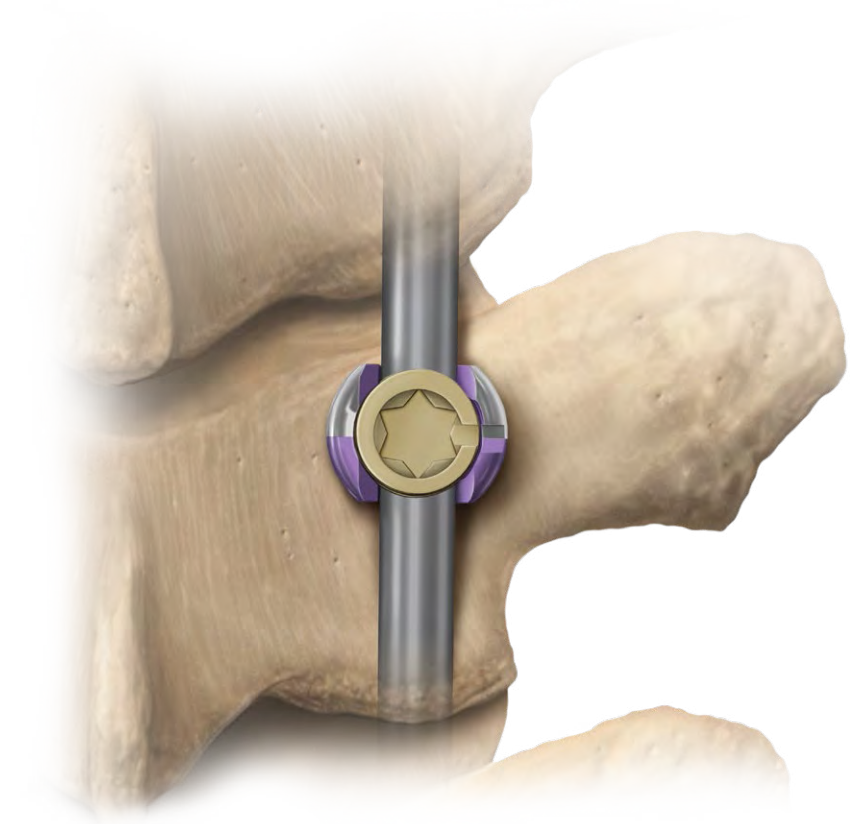
Tip

"I recommend the Tactile Set Screw Driver because I get audible and tactile verification that the Set Screw is lined up after doing a counterclockwise turn of the Set Screw on the Tulip Head."

- Dr. Steven Vanni, D.O.

(Fig. 53)

SURGEON'S VUEPOINT



(Fig. 54)

STEP 15:
ROD REDUCTION

If Rod reduction is required before placing the Set Screw, the Rod can be reduced to the bottom of the Multi Axial Screw or Hook Head by employing either a Persuader, Rocker, or Rod Pusher.

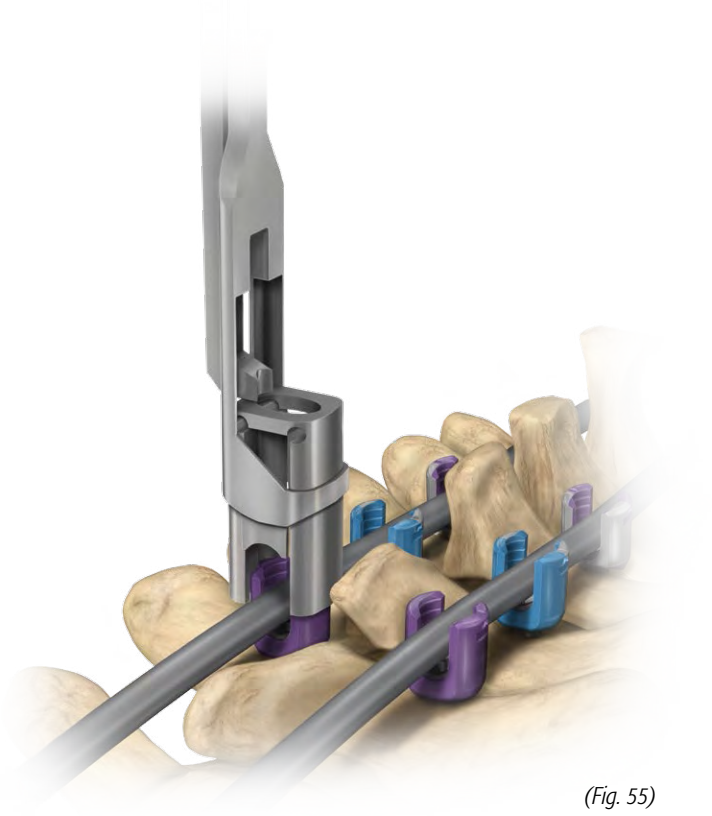
Persuader

1. Engage and fully seat the Persuader onto any Multi Axial Screw or Laminar Hook Head and squeeze the handle, thereby pushing the Rod down to the bottom of the saddle *(Fig. 55)*.
2. Once the Rod is reduced, engage a Set Screw using the Tactile Set Screw Driver.
3. Insert the Tactile Set Screw Driver with the attached Set Screw into and through the Persuader. Hold the Persuader in position and provisionally tighten down the Set Screw *(Fig. 56)*.
4. Finally, disengage the Persuader from the Multi Axial Screw or Hook Head by pulling the Ratchet off the handle.

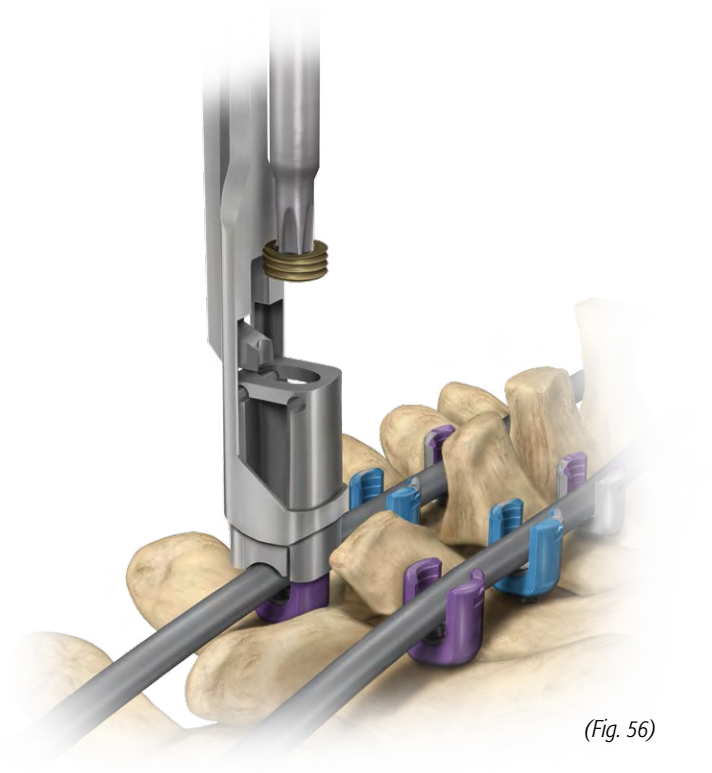
CAUTION
It is possible to pull out the screw if too much force is applied with the Persuader.

Note

The Persuader is bayonetted by design. It provides the surgeon added visibility when addressing the Set Screw.



(Fig. 55)



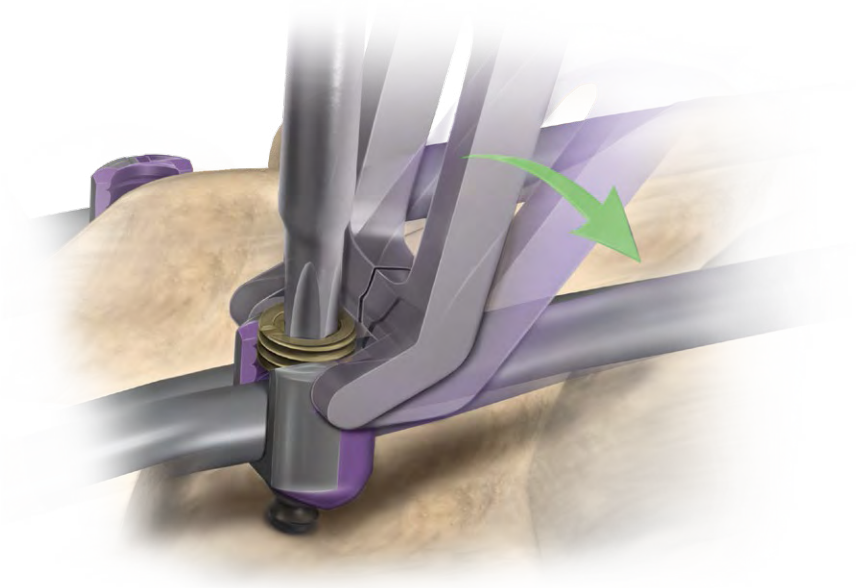
(Fig. 56)

STEP 15:
ROD REDUCTION (CONT.)

Rocker

1. Engage any Multi Axial Screw or Laminar Hook Head by placing the Rocker over the lateral part of the Tulip Screw and squeezing the handles. The Rocker will engage into the two small dimples on the sides of the Tulip Screw Head.
2. Once engaged, tilt the Rocker to reduce the Rod to the bottom of the saddle *(Fig. 57)*.
3. Insert the Tactile Set Screw Driver with the attached Set Screw onto the Tulip Head, hold the Rocker in position, and provisionally tighten down the Set Screw *(Fig. 57)*.

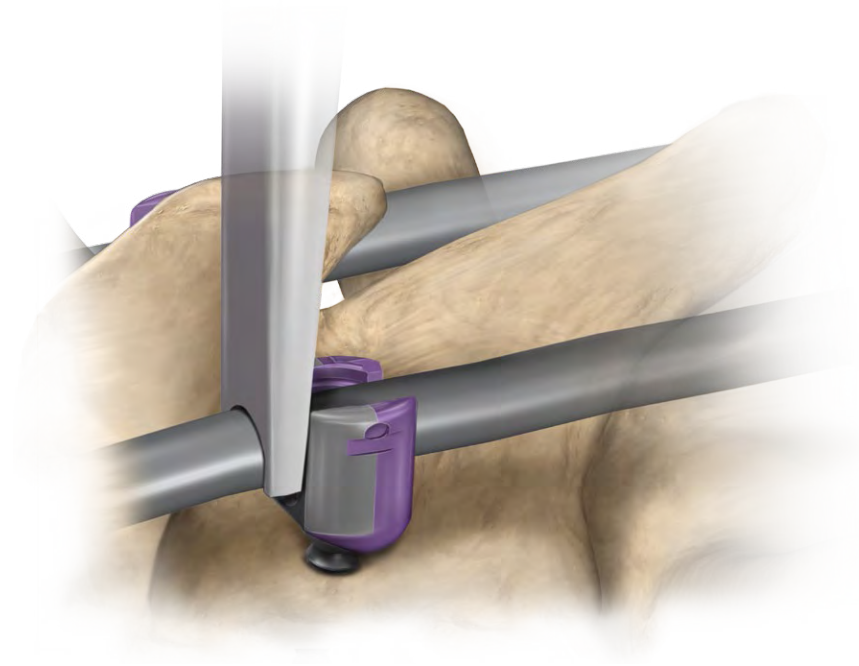
> ***Note***
> *The Rocker offers an angled distal tip by design, providing the surgeon with greater visibility when addressing the Set Screw.*



(Fig. 57)

Rod Pusher

1. Place the Rod Pusher adjacent to the Multi Axial Screw or Laminar Hook Head and gently press downward to reduce the Rod to the bottom of the saddle *(Fig. 58)*.
2. Insert the Tactile Set Screw Driver with the attached Set Screw onto the Tulip Head, hold the Rod Pusher in position, and provisionally tighten down the Set Screw.



(Fig. 58)

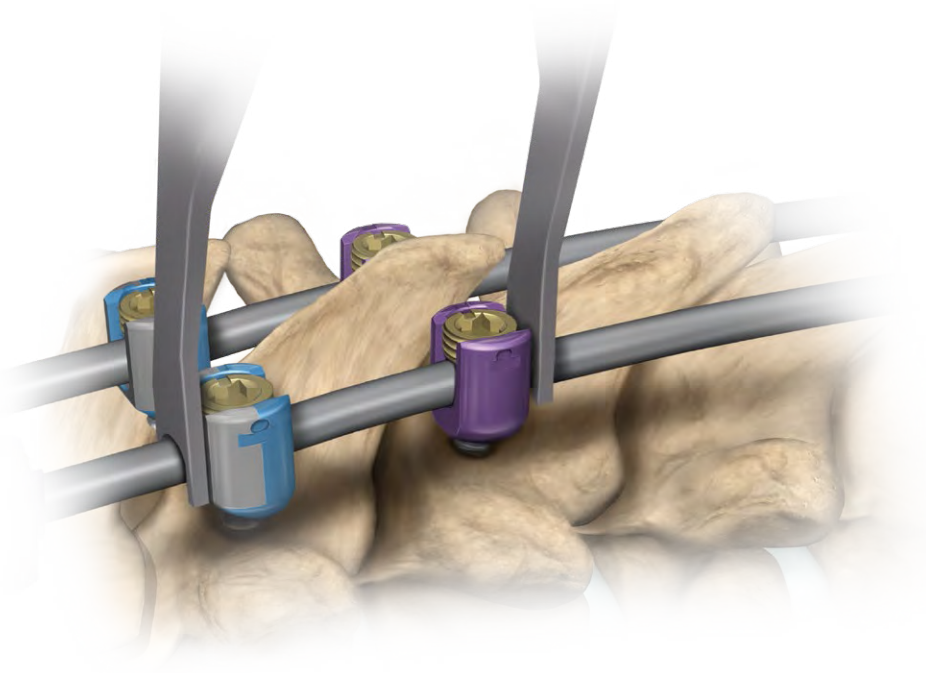
STEP 16:
ROD ADJUSTMENT

In Situ Rod Bender

In Situ Rod contouring may be performed with In Situ Benders prior to final Set Screw tightening. The In Situ Benders are used to improve or adjust kyphosis and lordosis.

Compressor

If compression is required, provisionally tighten the Set Screw on one side of the motion segment, leaving the other Set Screw loose to allow movement along the Rod. Place the Compressor on the outermost part of both Multi Axial Screws, relative to the construct. With the instrument properly engaged, deliver the appropriate amount of compression by squeezing the instrument handles and then provisionally tighten the loose Set Screw to hold the construct in position prior to final tightening *(Fig. 59)*.



(Fig. 59)

NVM5® – MEP AND SSEP

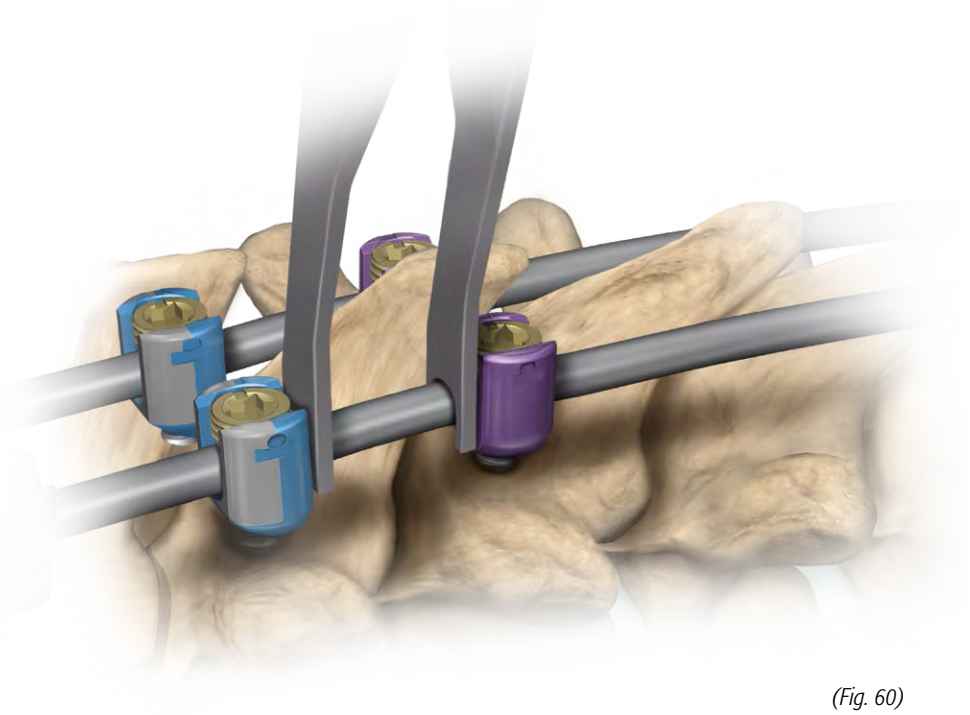
Use NVM5 to monitor spinal cord health and integrity during VuePoint OCT surgery. After any Rod adjustment, a subsequent MEP reading may be taken to verify that there has been no compromise of the motor pathways of the spinal cord.

VUEPOINT® OCT TECHNIQUE GUIDE

STEP 16:
ROD ADJUSTMENT (CONT.)

Distractor

If distraction is required, provisionally tighten the Set Screw on one side of the motion segment, leaving the other Set Screw loose to allow movement along the Rod. Place the Distractor on the innermost part of the Multi Axial Screws, relative to the construct. With the instrument properly engaged, deliver the appropriate amount of distraction by squeezing the instrument handles, and then provisionally tighten the loose Set Screw to hold the construct in position prior to final tightening *(Fig. 60)*.



(Fig. 60)

STEP 17:
FINAL TIGHTENING

(Fig. 61)

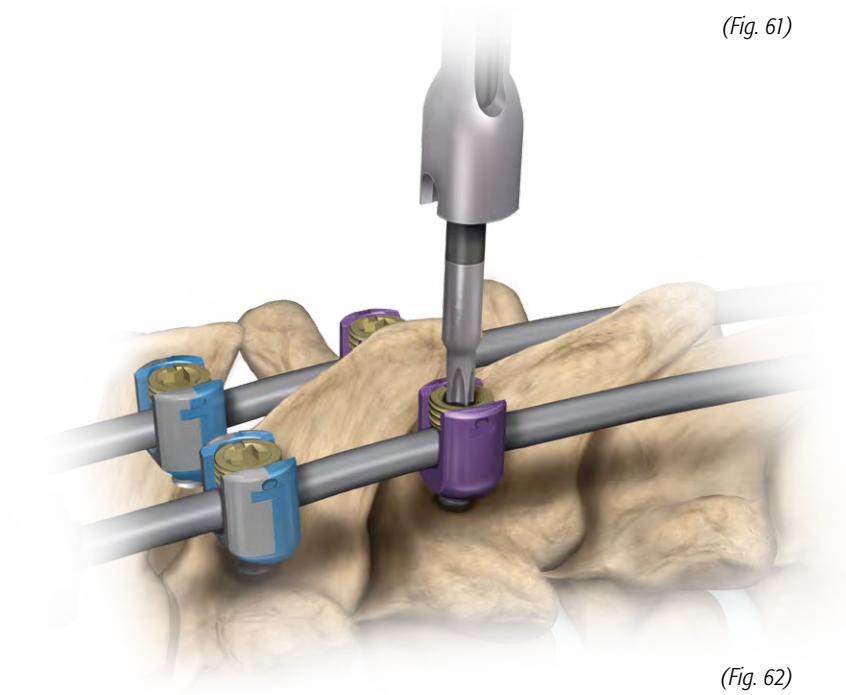
Two options are available to perform final tightening of Set Screws

Option 1:

Attach the Final Tightening Shaft, which is colored black, to the Torque Limiting Handle *(Fig. 61)*. Seat the Counter Torque over a Multi Axial Screw or Hook Head and slide the Torque Limiting Handle and Final Tightening Shaft assembly through the canal of the Counter Torque *(Fig. 62)*. Engage the driver into the provisionally tightened Set Screw and begin turning the Set Screw clockwise until the Torque Limiting Handle torques out. A tactile and audible "click" validates that the Set Screw is locked at the recommended 26 in.-lbs. *(Fig. 63)*.

Option 2:

Attach the Final Tightening Shaft to a Universal Handle. Seat the Counter Torque over a Multi Axial Screw or Hook Head and slide the Universal Handle and Final Tightening Shaft assembly through the canal of the Counter Torque. Engage the driver into the provisionally tightened Set Screw and white-knuckle tighten



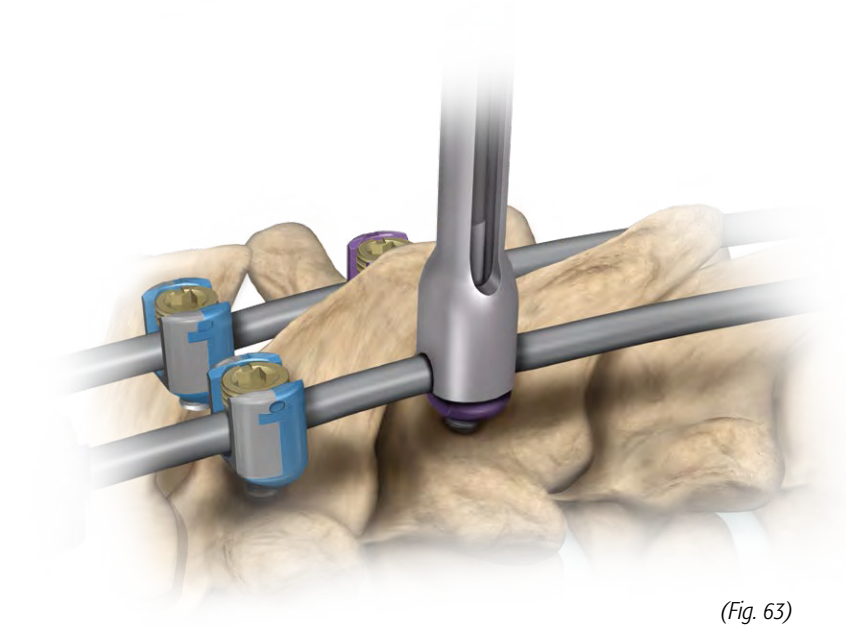
(Fig. 62)

Note

An audible titanium squeak may occur, which also indicates the Set Screw is locked.

NVM5® – MEP AND SSEP

Use NVM5 to monitor spinal cord health and integrity during VuePoint OCT surgery. After final tightening, a subsequent MEP reading may be taken to verify that there has been no compromise of the motor pathways of the spinal cord.



(Fig. 63)

VUEPOINT® OCT TECHNIQUE GUIDE

STEP 18:
SUPPLEMENTAL INSTRUMENTATION

Cross Connector Placement

Once all Multi Axial Screws, Rods, Hooks, Keel Plate, and Occipital Bone Screws have had final tightening performed, further torsional support may be added to the construct with the placement of Cross Connectors.

First, use the Cross Connector Calipers to decide the appropriate Cross Connector size *(Fig. 64)*. Second, attach the Cross Connector Holder to the middle portion of the Cross Connector, and then place the Cross Connector over the Rods at the desired level. Finally, place the Universal Handle and black-colored Final Tightening Shaft assembly through the Cross Connector Holder opening *(Fig. 65)*, sliding the driver tip into the Cross Connector Set Screw, and white-knuckle tighten down the Set Screws.

Note

An audible titanium squeak may occur, which also indicates the Set Screws are locked.

Note

Cross Connectors range from 26mm to 50mm and are offered in 2mm increments.

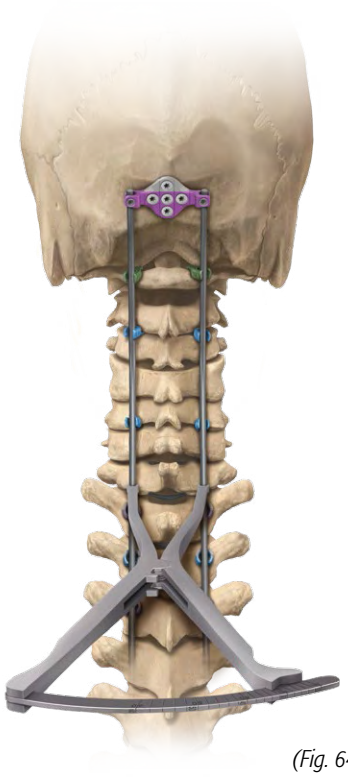
Note

The Cross Connector offers a 45º lateralized locking mechanism, which safely directs the Final Tightening Shaft away from the spinal cord.

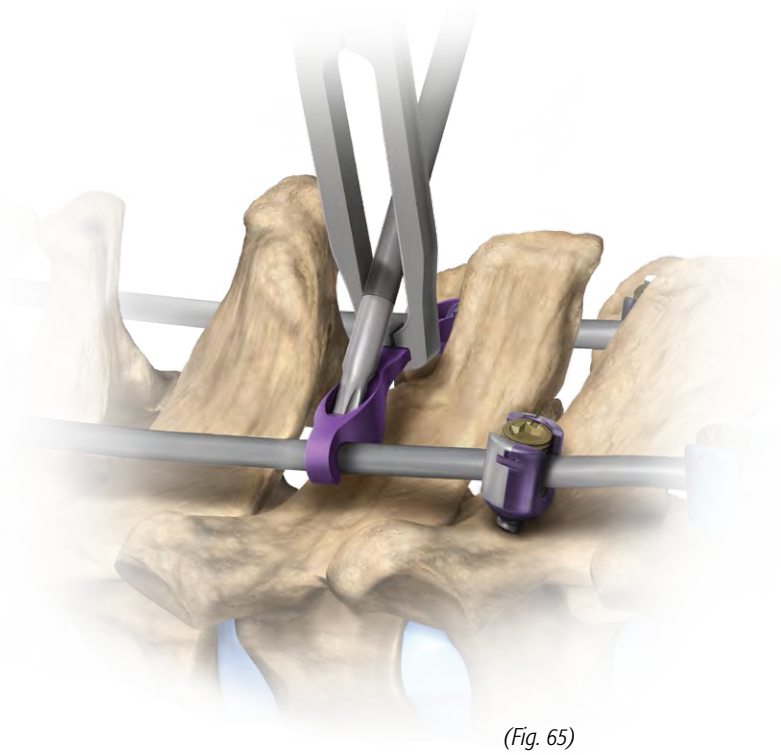
Tip

"If the Cross Connector does not initially attach to the Rod, try backing out the Cross Connector Set Screw with counterclockwise turns, using the Final Tightening Shaft. This allows the Cross Connector ample room to easily reattach onto the Rod."

- Dr. Neill Wright, M.D.



(Fig. 64)



(Fig. 65)

STEP 18:
SUPPLEMENTAL INSTRUMENTATION (CONT.)

Cross Connector Placement (cont.)

The Cross Connector may require additional bending to accommodate anatomical requirements. Both Right and Left 4-in-1 Benders can bend a Cross Connector in two orientations:

1. Arch Bend

a. An arch bend is useful to increase the space between the spinal cord and the apex of the Cross Connector.

b. An arch bend is also advantageous when the Cross Connector Calipers measure between sizes. For instance, if 31mm is measured, but only 30mm and 32mm Cross Connectors are available in the set, select the 32mm Cross Connector and bend it to accommodate the 31mm Rod distance.

Using the Left and Right 4-in-1 Benders, place the preselected Cross Connector in the 4-in-1 arch bending slots and begin gently bending medially and downward *(Fig. 66)*.

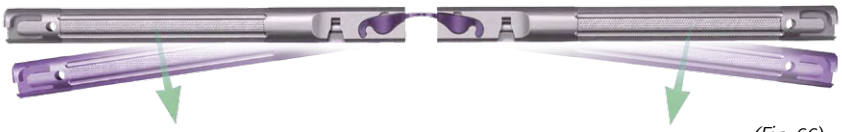
2. Non-Parallel Bend

a. A non-parallel bend is useful if Rods lie divergent (non-parallel) in the coronal plane, due to the medial/lateral shift occurring from the cervical to the thoracic junction.

b. As a result, a Fixed Cross Connector may require additional non-parallel bending to accommodate the attachment of a Cross Connector onto non-parallel Rods.

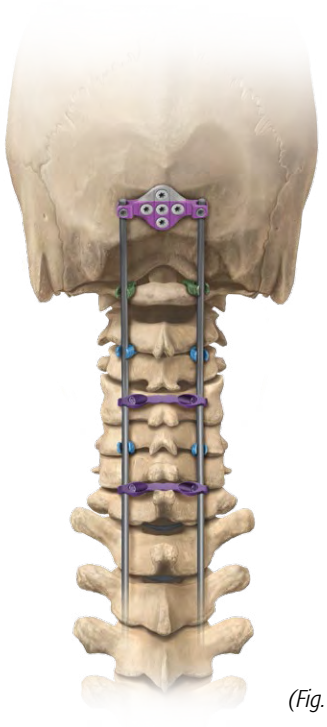
Using the Left and Right 4-in-1 Benders, place the preselected Cross Connector in the 4-in-1 non-parallel bending slots and begin gently bending either medially or laterally *(Fig. 67)*.

CAUTION
To maintain the mechanical integrity of the Cross Connector, once the Connector is bent in one direction, further bending only in that same direction should be attempted. Unbending of the Connector may cause mechanical compromise.



(Fig. 66)

(Fig. 67)



(Fig. 68)

STEP 18:

SUPPLEMENTAL INSTRUMENTATION (CONT.)

Crossing the cervical to thoracic junction can often present Rod contouring challenges due to the medial/lateral shift in the coronal plane and lordotic/kyphotic shift in the sagittal plane. Three Offset Connector options help minimize excessive Rod contouring, as Multi Axial Screws or Laminar Hook Heads are occasionally non-linear, relative to each other.

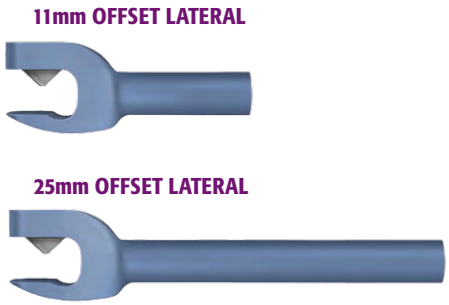
Two Offset Lateral Connectors

Two sizes are available, 11mm and 25mm, which allow for 8mm and 23mm of medial/lateral adjustment, respectively *(Fig. 69)*. Further, the connectors are open in design, which allows the intraoperative flexibility of attaching a Lateral Connector to the Rod in situ, without having to extract the entire Rod *(Fig. 70)*.

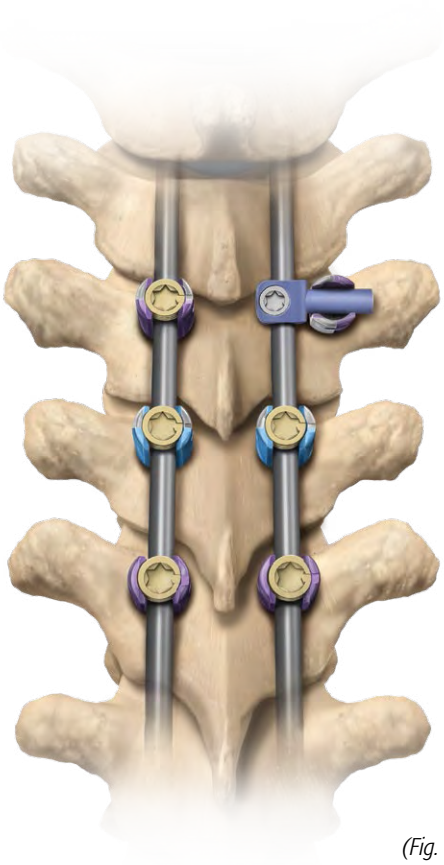
One Acute-Angle Offset Connector

The Acute-Angle Offset Connector offers a 30mm rod extension angled at 45° to address difficult pathologies or surgeon requirements *(Fig. 71)*.

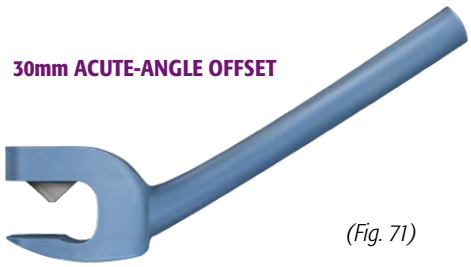
> ***Note***
>
> *The long 25mm and 30mm Offset Connectors can be cut to size with the Rod Cutter, depending on the required length.*



(Fig. 69)



(Fig. 70)



(Fig. 71)

STEP 18:
SUPPLEMENTAL INSTRUMENTATION (CONT.)

Thoracic Transition

Certain pathologies require a construct to extend farther down the thoracic spine while utilizing a larger diameter Rod. These particular constructs can be extended with Offset Rod-to-Rod Connectors *(Fig. 72)*, Inline Rod-to-Rod Connectors *(Fig. 73)*, or Transition Rods *(Fig. 74)*.

Rod-to-Rod Connectors

Four size options are available in each of the two styles of Rod-to-Rod Connectors, giving eight total Rod-to-Rod Connector options:

Size Options	Style
3.5mm to 3.5mm	Inline and Offset
3.5mm to 4.5mm	Inline and Offset
3.5mm to 5.5mm	Inline and Offset
3.5mm to 6.25mm	Inline and Offset

Insert the 3.5mm VuePoint® OCT Rod into the smaller diameter hole and provisionally tighten the Set Screw down onto the Rod, using the NV15 Rod-to-Rod Final Tightening Shaft and Universal Handle. Then select the appropriate Rod diameter for the opposite end, and again provisionally tighten the Set Screws down onto the Rod.

Once both Rods are in place, use the NV15 Rod-to-Rod Final Tightening Shaft and Universal Handle assembly to white-knuckle tighten the Set Screws down on the back table.

Note

An audible titanium squeak may occur, which also indicates the Set Screws are locked in place.

Note

The NV15 Rod-to-Rod Final Tightening Shaft is limited to only Rod-to-Rod Connectors. This larger NV15 Rod-to-Rod Final Tightening Shaft should not be mistaken for the smaller, black-colored, NV12 Final Tightening Shaft used for locking down Multi Axial Screws, Hooks, Lateral Connectors, Keel Plate, and Eyelet Connectors.

OFFSET

(Fig. 72)

INLINE

(Fig. 73)

STEP 18:
SUPPLEMENTAL INSTRUMENTATION (CONT.)

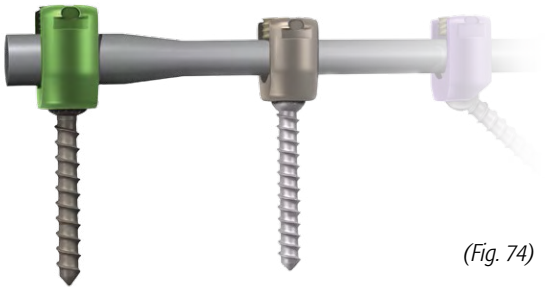
Transition Rods

Alternatively, single-component Transition Rods offer the ability to transition from a 3.5mm to a 5.5mm Rod system without the need for the Rod-to-Rod Connectors.

Final Tightening

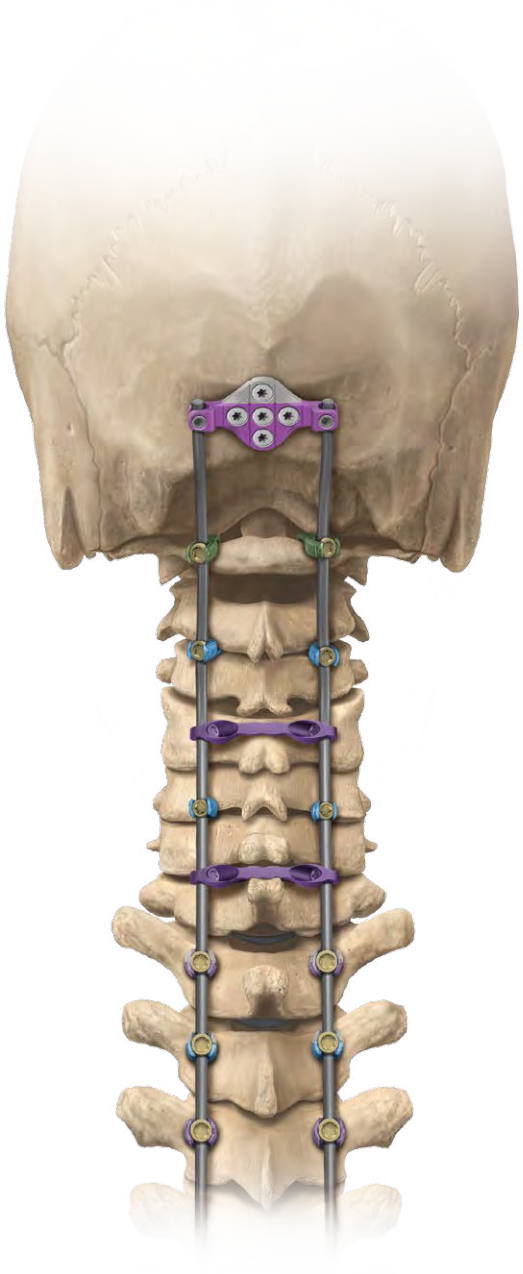
Once all VuePoint® OCT screws are placed in the upper thoracic spine and the thoracolumbar system screws (e.g., Armada®) are placed in the lower thoracic spine, place the Rod-to-Rod assembly or Transition Rod in position and lock down the Rods using the suitable Set Screws and Final Tightening Shaft, employing Rod reduction tools when necessary.

TRANSITION ROD



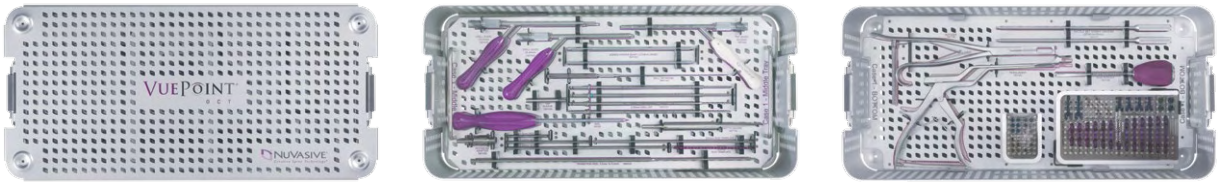
(Fig. 74)

FINAL CONSTRUCT



VUEPOINT® OCT INSTRUMENTS (CASE ONE)

VUEPOINT OCT INSTRUMENTS (CASE ONE)



TAP SHAFT, 3.5mm

TAP SHAFT, 4.0mm

DRILL BIT

SCREWDRIVER SHAFT (STAB-N-GRAB)

TACTILE SET SCREW DRIVER (STAB-N-GRAB)

BALL TIP PROBE

ROD TEMPLATE

TAP SLEEVE

DEPTH GAUGE

VUEPOINT® OCT INSTRUMENTS (CASE ONE)

AWL

JACOBS AO ADAPTER

ROD PUSHER

DRILL GUIDE 10-24MM

DRILL GUIDE 26-40MM

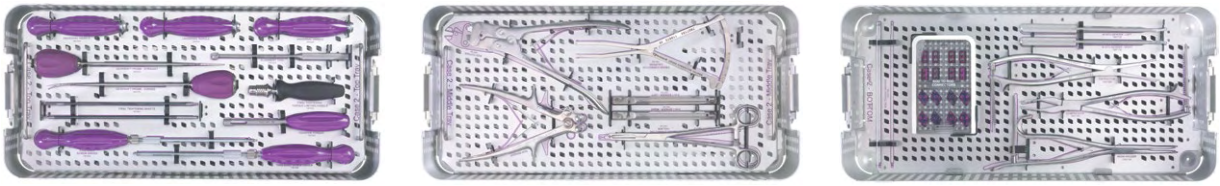
TAP GUIDE

PERSUADER

ROCKER

VUEPOINT® OCT INSTRUMENTS (CASE TWO)

VUEPOINT OCT INSTRUMENTS (CASE TWO)

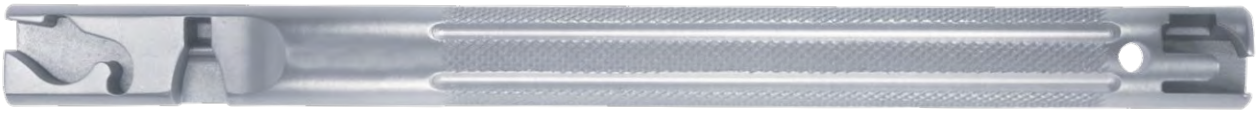


FINAL TIGHTENING SHAFT

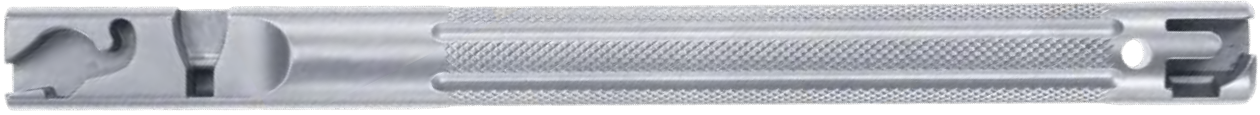
ROD-TO-ROD DRIVER SHAFT

ALIGNMENT TOOL

4-IN-1 BENDER (RIGHT)



4-IN-1 BENDER (LEFT)



IN SITU ROD BENDER (RIGHT)

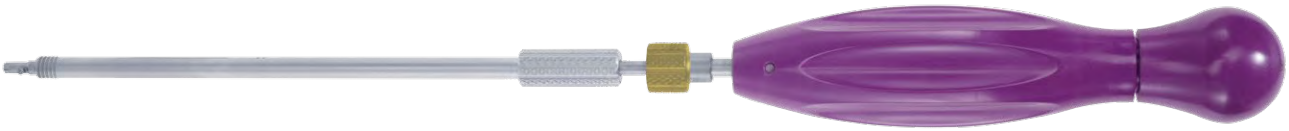
IN SITU ROD BENDER (LEFT)

VUEPOINT® OCT INSTRUMENTS (CASE TWO)

GEARSHIFT PROBE – STRAIGHT

GEARSHIFT PROBE – CURVED

THREADED SCREWDRIVER



COUNTER TORQUE

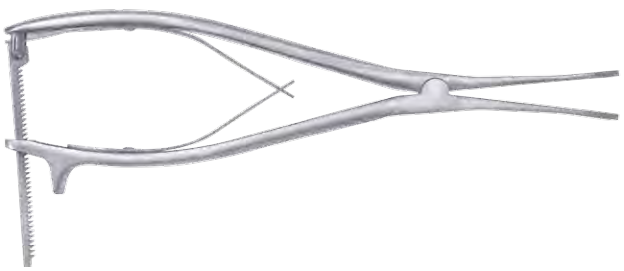
UNIVERSAL HANDLE

FINAL TIGHTENING TORQUE LIMITING HANDLE

VUEPOINT® OCT INSTRUMENTS (CASE TWO)

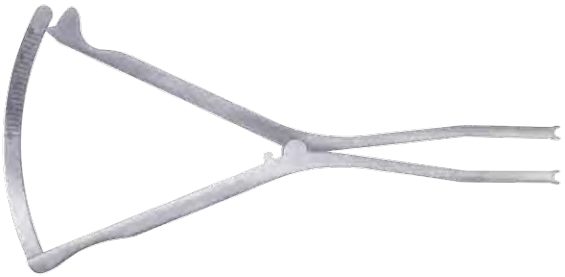
COMPRESSOR

DISTRACTOR



HOOK HOLDER

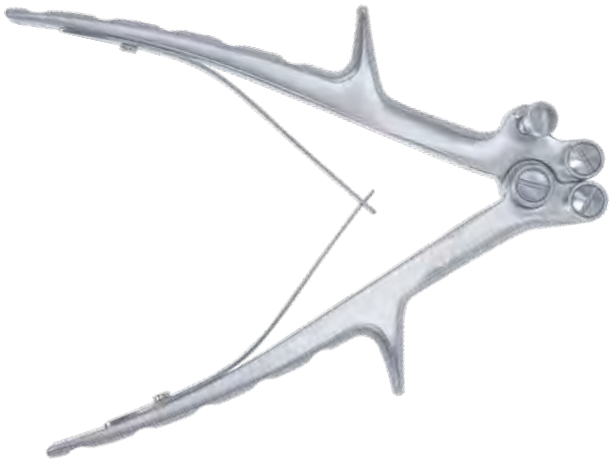
CROSS CONNECTOR CALIPERS



ROD HOLDER

CROSS CONNECTOR HOLDER

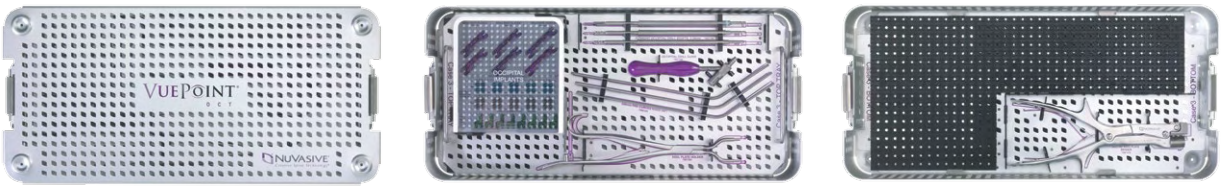
ROD BENDER



ROD CUTTER

VUEPOINT® OCT OCCIPITAL INSTRUMENTS CASE

VUEPOINT® OCT OCCIPITAL INSTRUMENTS CASE



STRAIGHT OCCIPITAL DRILL BIT SHAFT

STRAIGHT OCCIPITAL TAP

OCCIPITAL DRILL/TAP GUIDE

KEEL PLATE HOLDER

MIDLINE KEEL PLATE BENDER

MULTI AXIAL SCREWS

DESCRIPTION	CATALOG #
3.5mm MULTI AXIAL SCREWS	
3.5mm x 10mm Multi Axial Screw	7905310
3.5mm x 12mm Multi Axial Screw	7905312
3.5mm x 14mm Multi Axial Screw	7905314
3.5mm x 16mm Multi Axial Screw	7905316
3.5mm x 18mm Multi Axial Screw	7905318
3.5mm x 20mm Multi Axial Screw	7905320
3.5mm x 22mm Multi Axial Screw	7905322
3.5mm x 24mm Multi Axial Screw	7905324
3.5mm x 26mm Multi Axial Screw	7905326
3.5mm x 28mm Multi Axial Screw	7905328
3.5mm x 30mm Multi Axial Screw	7905330
3.5mm x 32mm Multi Axial Screw	7905332
3.5mm x 34mm Multi Axial Screw	7905334
4.0mm MULTI AXIAL SCREWS	
4.0mm x 10mm Multi Axial Screw	7905410
4.0mm x 12mm Multi Axial Screw	7905412
4.0mm x 14mm Multi Axial Screw	7905414
4.0mm x 16mm Multi Axial Screw	7905416
4.0mm x 18mm Multi Axial Screw	7905418
4.0mm x 20mm Multi Axial Screw	7905420
4.0mm x 22mm Multi Axial Screw	7905422
4.0mm x 24mm Multi Axial Screw	7905424
4.0mm x 26mm Multi Axial Screw	7905426
4.0mm x 28mm Multi Axial Screw	7905428
4.0mm x 30mm Multi Axial Screw	7905430
4.0mm x 32mm Multi Axial Screw	7905432
4.0mm x 34mm Multi Axial Screw	7905434
4.0mm x 36mm Multi Axial Screw	7905436
4.0mm x 38mm Multi Axial Screw	7905438
4.0mm x 40mm Multi Axial Screw	7905440
3.5mm FAVOURED ANGLE MULTI AXIAL SCREWS	
3.5mm x 10mm Favoured Angle Multi Axial Screw	7905510
3.5mm x 12mm Favoured Angle Multi Axial Screw	7905512
3.5mm x 14mm Favoured Angle Multi Axial Screw	7905514
3.5mm x 16mm Favoured Angle Multi Axial Screw	7905516
3.5mm x 18mm Favoured Angle Multi Axial Screw	7905518
3.5mm x 20mm Favoured Angle Multi Axial Screw	7905520
3.5mm x 22mm Favoured Angle Multi Axial Screw	7905522
3.5mm x 24mm Favoured Angle Multi Axial Screw	7905524
3.5mm x 26mm Favoured Angle Multi Axial Screw	7905526
3.5mm x 28mm Favoured Angle Multi Axial Screw	7905528
3.5mm x 30mm Favoured Angle Multi Axial Screw	7905530
3.5mm x 32mm Favoured Angle Multi Axial Screw	7905532
3.5mm x 34mm Favoured Angle Multi Axial Screw	7905534

MULTI AXIAL SCREWS

DESCRIPTION	CATALOG #
4.0mm FAVOURED ANGLE MULTI AXIAL SCREWS	
4.0mm x 10mm Favoured Angle Tulip Screw	7905610
4.0mm x 12mm Favoured Angle Tulip Screw	7905612
4.0mm x 14mm Favoured Angle Tulip Screw	7905614
4.0mm x 16mm Favoured Angle Tulip Screw	7905616
4.0mm x 18mm Favoured Angle Tulip Screw	7905618
4.0mm x 20mm Favoured Angle Tulip Screw	7905620
4.0mm x 22mm Favoured Angle Tulip Screw	7905622
4.0mm x 24mm Favoured Angle Tulip Screw	7905624
4.0mm x 26mm Favoured Angle Tulip Screw	7905626
4.0mm x 28mm Favoured Angle Tulip Screw	7905628
4.0mm x 30mm Favoured Angle Tulip Screw	7905630
4.0mm x 32mm Favoured Angle Tulip Screw	7905632
4.0mm x 34mm Favoured Angle Tulip Screw	7905634
4.0mm x 36mm Favoured Angle Tulip Screw	7905636
4.0mm x 38mm Favoured Angle Tulip Screw	7905638
4.0mm x 40mm Favoured Angle Tulip Screw	7905640
4.5mm MULTI AXIAL SCREWS	
4.5mm x 10mm Multi Axial Screw	7905710
4.5mm x 12mm Multi Axial Screw	7905712
4.5mm x 14mm Multi Axial Screw	7905714
4.5mm x 16mm Multi Axial Screw	7905716
4.5mm x 18mm Multi Axial Screw	7905718
4.5mm x 20mm Multi Axial Screw	7905720
4.5mm x 22mm Multi Axial Screw	7905722
4.5mm x 24mm Multi Axial Screw	7905724
4.5mm x 26mm Multi Axial Screw	7905726
4.5mm x 28mm Multi Axial Screw	7905728
4.5mm x 30mm Multi Axial Screw	7905730
4.5mm x 32mm Multi Axial Screw	7905732
4.5mm x 34mm Multi Axial Screw	7905734
4.5mm x 36mm Multi Axial Screw	7905736
4.5mm x 38mm Multi Axial Screw	7905738
4.5mm x 40mm Multi Axial Screw	7905740
3.5mm FAVOURED ANGLE PARTIALLY THREADED SCREWS	
3.5mm x 24mm Favoured Angle Partially Threaded Screw	7905824
3.5mm x 26mm Favoured Angle Partially Threaded Screw	7905826
3.5mm x 28mm Favoured Angle Partially Threaded Screw	7905828
3.5mm x 30mm Favoured Angle Partially Threaded Screw	7905830
3.5mm x 32mm Favoured Angle Partially Threaded Screw	7905832
3.5mm x 34mm Favoured Angle Partially Threaded Screw	7905834
3.5mm x 36mm Favoured Angle Partially Threaded Screw	7905836

CATALOG

SET SCREWS AND RODS

DESCRIPTION	CATALOG #
SET SCREWS	
Set Screw - Tulip Screw and Laminar Hook	7906000
RODS	
60mm x 3.5mm Rod	7906160
120mm x 3.5mm Rod	7906120
240mm x 3.5mm Rod	7906240
3.5mm to 5.5mm Transition Rod	7906355

LAMINAR HOOKS

DESCRIPTION	CATALOG #
5.0mm Laminar Hook	7906005
7.0mm Laminar Hook	7906007

FIXED CROSS CONNECTORS

DESCRIPTION	CATALOG #
26mm Fixed Cross Connector	7906126
28mm Fixed Cross Connector	7906128
30mm Fixed Cross Connector	7906130
32mm Fixed Cross Connector	7906132
34mm Fixed Cross Connector	7906134
36mm Fixed Cross Connector	7906136
38mm Fixed Cross Connector	7906138
40mm Fixed Cross Connector	7906140
42mm Fixed Cross Connector	7906142
44mm Fixed Cross Connector	7906144
46mm Fixed Cross Connector	7906146
48mm Fixed Cross Connector	7906148
50mm Fixed Cross Connector	7906150

CONNECTORS

DESCRIPTION	CATALOG #
OFFSET LATERAL CONNECTORS	
11mm Offset Connector (open)	7906008
25mm Offset Connector (open), Long	7906022
30mm Acute-Angle Offset Connector	7906025
INLINE ROD-TO-ROD CONNECTORS	
3.5mm to 3.5mm Inline Rod Connector	7906035
3.5mm to 4.5mm Inline Rod Connector	7906045
3.5mm to 5.5mm Inline Rod Connector	7906055
3.5mm to 6.25mm Inline Rod Connector	7906065

CONNECTORS

DESCRIPTION	CATALOG #
OFFSET ROD-TO-ROD CONNECTORS	
3.5mm to 3.5mm Offset Rod Connector	7906435
3.5mm to 4.5mm Offset Rod Connector	7906445
3.5mm to 5.5mm Offset Rod Connector	7906455
3.5mm to 6.25mm Offset Rod Connector	7906465

INSTRUMENTS

DESCRIPTION	CATALOG #
Awl	7907005
Drill Guide 10-24mm	7907015
Drill Guide 26-40mm	7907020
Tap Guide 10-24mm	7907025
Universal Handle	7907035
Tap Shaft, 3.5mm	7907040
Tap Shaft, 4.0mm	7907045
Tap Sleeve	7907050
Screwdriver Shaft (Stab-n-Grab)	7907055
Threaded Screwdriver	7907061
Tactile Set Screw Driver (Stab-n-Grab)	7907070
Alignment Tool	7907075
Persuader	7907080
Counter Torque	7907085
Final Tightening Torque Limiting Handle	7907090
Final Tightening Shaft	7907095
Depth Gauge	7907100
Rod Cutter	7907105
Rod Bender	7907110
Rod Holder	7907115
4-in-1 Bender (Right)	7907120
4-in-1 Bender (Left)	7907125
In Situ Rod Bender (Right)	7907130
In Situ Rod Bender (Left)	7907135
Ball Tip Probe	7907140
Cross Connector Holder	7907145
Cross Connector Calipers	7907150
Compressor	7907155
Distractor	7907160
Gearshift Probe - Straight	7907165
Gearshift Probe - Curved	7907170
Rod-to-Rod Final Tightening Shaft	7907180
Hook Holder	7907185
Rocker	7907190
Rod Pusher	7907195
Jacobs AO Adapter	7907200

CATALOG

OCCIPITAL INSTRUMENTS

DESCRIPTION	CATALOG #
Straight Occipital Drill Bit Shaft, 3.35mm	7907300
Straight Occipital Tap, 4.5mm	7907310
Occipital Drill/Tap Guide	7907360
Keel Plate Holder	7907365
Midline Keel Plate Bender	7907370

OCCIPITAL IMPLANTS

DESCRIPTION	CATALOG #
PRE-BENT ROD	
240mm Pre-Bent Rod (45°)	7906300
KEEL PLATES	
35mm Keel Plate	7906335
40mm Keel Plate	7906340
45mm Keel Plate	7906345
EYELET CONNECTORS	
Eyelet Connector, Occipital	7906302
4.5mm CORTICAL OCCIPITAL SCREW	
4.5mm x 6mm Cortical Occipital Screw	7906306
4.5mm x 8mm Cortical Occipital Screw	7906308
4.5mm x 10mm Cortical Occipital Screw	7906310
4.5mm x 12mm Cortical Occipital Screw	7906312
4.5mm x 14mm Cortical Occipital Screw	7906314
5.0mm CORTICAL OCCIPITAL SCREW	
5.0mm x 6mm Cortical Occipital Screw	7906356
5.0mm x 8mm Cortical Occipital Screw	7906358
5.0mm x 10mm Cortical Occipital Screw	7906360
5.0mm x 12mm Cortical Occipital Screw	7906362
5.0mm x 14mm Cortical Occipital Screw	7906364

DISPOSABLE INSTRUMENTS

DESCRIPTION	CATALOG #
2.05mm Drill Bit	7907012
120mm Rod Template	7907220
240mm Rod Template	7907240

MISCELLANEOUS SET SCREW REPLACEMENTS

DESCRIPTION	CATALOG #
Set Screw - Offset & Occipital Connectors	7907760
Set Screw - Parallel Rod Connectors	7907765
Set Screw - Inline Rod Connectors	7907770
Set Screw - Cross Connectors	7907775

CASES

DESCRIPTION	CATALOG #
VuePoint® OCT Sterilization Case (Lid)	7900001
VuePoint OCT Implant Sterilization Tray (Base)	7900010
VuePoint OCT Implant Sterilization Tray (Top)	7900011
VuePoint OCT Implant Sterilization Tray (Middle)	7900012
Multi Axial Screw Caddy	7900013
Favoured Angle Screw Caddy	7900015
4.5mm Multi Axial Screw Caddy	7900017
Partially Threaded Screw Caddy	7900019
Set Screw Caddy	7900021
Cross Connector, Lateral Connector, and Hook Caddy	7900023
VuePoint OCT Instrument Sterilization Tray (Base)	7900030
VuePoint OCT Instrument Sterilization Tray (Top)	7900031
VuePoint OCT Instrument Sterilization Tray (Middle)	7900032
Rod-to-Rod Connector Caddy	7900033
Miscellaneous Set Screw Caddy	7900035
VuePoint OCT Occipital Sterilization Tray (Base)	7900040
VuePoint OCT Occipital Sterilization Tray (Top)	7900041
Occipital Implant Caddy	7900043

VUECOCR-COBALT CHROMIUM (SEPARATE SET)

DESCRIPTION	CATALOG #
COBALT CHROMIUM RODS	
240mm Cobalt Chromium Rod	7908240
240mm Pre-bent Cobalt Chromium Rod (45°)	7908300
3.5mm to 5.5mm Cobalt Chromium Transition Rod	7908355
GRIT BLAST CROSS CONNECTORS	
26mm Grit Blasted Cross connector	7908026
28mm Grit Blasted Cross connector	7908028
30mm Grit Blasted Cross connector	7908030
32mm Grit Blasted Cross connector	7908032
34mm Grit Blasted Cross connector	7908034
36mm Grit Blasted Cross connector	7908036
38mm Grit Blasted Cross connector	7908038
40mm Grit Blasted Cross connector	7908040
42mm Grit Blasted Cross connector	7908042
44mm Grit Blasted Cross connector	7908044
46mm Grit Blasted Cross connector	7908046
48mm Grit Blasted Cross connector	7908048
50mm Grit Blasted Cross connector	7908050
Set Screw	7908052

CATALOG

VUES10-10MM SMOOTH SCREWS (SEPARATE SET)

DESCRIPTION	CATALOG #
10mm SMOOTH PARTIALLY THREADED SCREWS	
3.5mm x 24/10mm Special Partially Threaded Screw	7905924
3.5mm x 26/10mm Special Partially Threaded Screw	7905926
3.5mm x 28/10mm Special Partially Threaded Screw	7905928
3.5mm x 30/10mm Special Partially Threaded Screw	7905930
3.5mm x 32/10mm Special Partially Threaded Screw	7905932
3.5mm x 34/10mm Special Partially Threaded Screw	7905934
3.5mm x 36/10mm Special Partially Threaded Screw	7905936

NVM5® MONITORING SYSTEM

DESCRIPTION	CATALOG #
EMG Electrode Module - Surface	8020015
EMG Electrode Module - Needle	8050015
EMG/MEP Electrode Module - Surface	8020215
EMG/MEP Electrode Module - Needle	8050215
SSEP Electrode Module	8050315
NVM5 Clip	2012022
NVM5 Probe	2012021

INSTRUCTIONS FOR USE

DESCRIPTION

The NuVasive® VuePoint OCT System consists of a series of polyaxial screws, collets, rods, offset connectors, set screws, and cross connectors manufactured from Ti-6Al-4V per ASTM F-136 and ISO 5832-3, and CoCr per ASTM F90 or ASTM F1537.

INDICATIONS FOR USE

The VuePoint OCT System is intended to promote fusion of the cervical spine and occipito-thoracic junction (Occiput-T3), and is indicated for:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture/Dislocation
4. Spinal Stenosis
5. Atlantoaxial fracture with instability
6. Occipitocervical dislocation
7. Spinal tumor and/or
8. Revision of previous cervical spine surgery

The occipital bone screws are limited to occipital fixation only.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The VuePoint OCT system can also be linked to the NuVasive SpheRx® Spinal System via the rod to rod connectors or transition rods.

CONTRAINDICATIONS

Contraindications include but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Use with components of other systems.
8. Reuse or multiple use.
9. Any case not described in the indications.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur include: early or late infection which may result in the need for additional surgeries; damage to blood vessels; spinal cord or peripheral nerves, pulmonary emboli; loss of sensory and/or motor function; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal.

WARNINGS, CAUTIONS AND PRECAUTIONS

The subject device is intended for use only as indicated.

The implantation of the VuePoint OCT system should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone. Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

These devices can break when subjected to the increased load associated with delayed union or non-union. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

Care should be taken to insure that all components are ideally fixated prior to closure.

All implants should be used only with the appropriately designated instrument (Reference Surgical Technique).

Instruments and implants are not interchangeable between systems.

Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.

PATIENT EDUCATION: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

SINGLE USE: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Resterilization may result in damage or decreased performance.

MAGNETIC RESONANCE (MR) SAFETY: The VuePoint OCT System has not been evaluated for safety and compatibility in the MR environment. The VuePoint OCT System has not been tested for heating or migration in the MR environment.

COMPATIBILITY: Do not use VuePoint OCT with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

Based on the fatigue testing results, when using the NuVasive VuePoint OCT System, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

To maintain the mechanical integrity of the Cross Connector, once the Connector is bent in one direction, further bending only in that same direction should be attempted. Unbending of the Connector may cause mechanical compromise.

To maintain the mechanical integrity of the plate, once the plate is bent in one direction with either tool, further ending only in that same direction should be attempted. Unbending of the plate may cause mechanical compromise.

PREOPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. All non-sterile parts should be cleaned and sterilized before use.
5. Devices should be inspected for damage prior to implantation.
6. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POST-OPERATIVE WARNINGS

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

NOTES

NOTES

To order, please contact your NuVasive® Sales Consultant or Customer Service Representative today at:
EC REP **NuVasive, Inc.** 7475 Lusk Blvd., San Diego, CA 92121 USA • phone: 800-475-9131 fax: 800-475-9134
NuVasive UK Ltd. Suite B, Ground Floor, Caspian House, The Waterfront, Elstree, Herts WD6 3BS UK
phone: +44 (0) 208-238-7850 fax: +44 (0) 207-998-7818

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