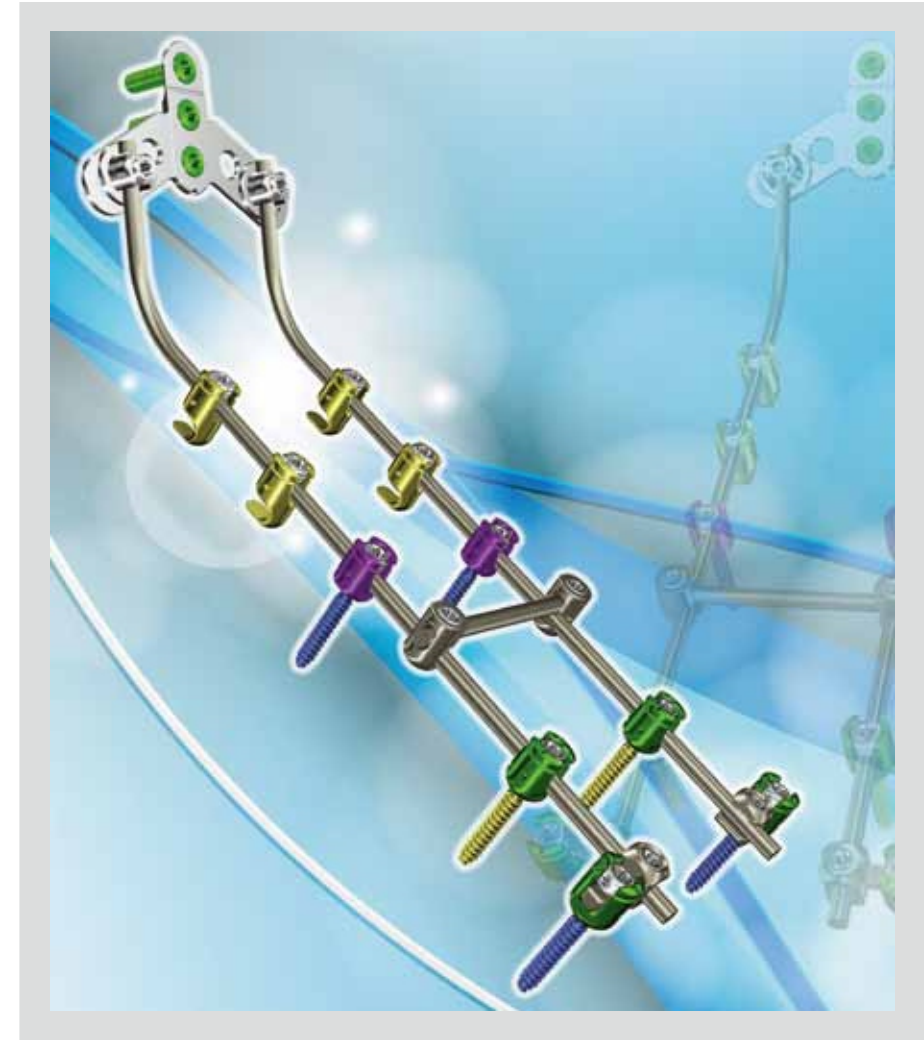


KANGHUI

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Cobra II

Posterior Cervical System

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The Cobra II Posterior Cervical System offers a comprehensive solution for rigid posterior fixation of the occipito-cervico-thoracic regions of the spine. This unique system combines simplicity and versatility allowing the surgeon to design constructs which are responsive to the unique anatomy and the requirements of the pathology being treated – not the constraints of the implant system.

Product Features

1. Extensive application scope from occiput to T3
2. Top loading, easy to use
3. Reversed angle thread locking mechanism
4. OC plate design enables midline keel fixation and is available for 180° adjustment; adjustable distance between two rods is maximum 4mm.
5. Favored angle screws have a 60° cone of angulation with an additional 15° bias in one direction

Indications

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/axial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

Contraindications

- Active infection
- Morbid Obesity
- Signs of local inflammation
- Fever or leukocytosis
- Suspected or documented metal allergy or intolerance
- Severe osteoporosis



Surgical Technique

Pre-operative Planning

It is a pre-requisite that, due to the anatomic variability of each patient, the surgeon has available the range of necessary images in order to be equipped to plan the operation appropriately.

Patient Positioning

The patient is placed on the operating table in the prone position with head and neck held securely in proper alignment. Whenever it is safe to do so, position the spine in physiological alignment. The use of a pinion head holder will securely hold the occiput and cervical spine in position.

Exposure

A standard midline sub-periosteal exposure of the portion of the cervical and thoracic spine to be fused is carried out. A wide exposure extending to the lateral aspect of the facet joints in the cervical spine and the transverse processes in the thoracic spine is achieved. Extend the exposure to the external occipital protuberance (EOP) if the fusion will include the occiput.

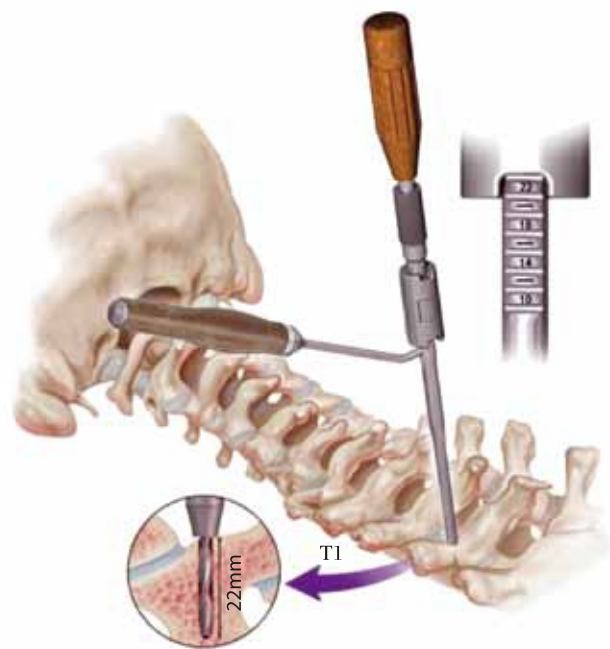
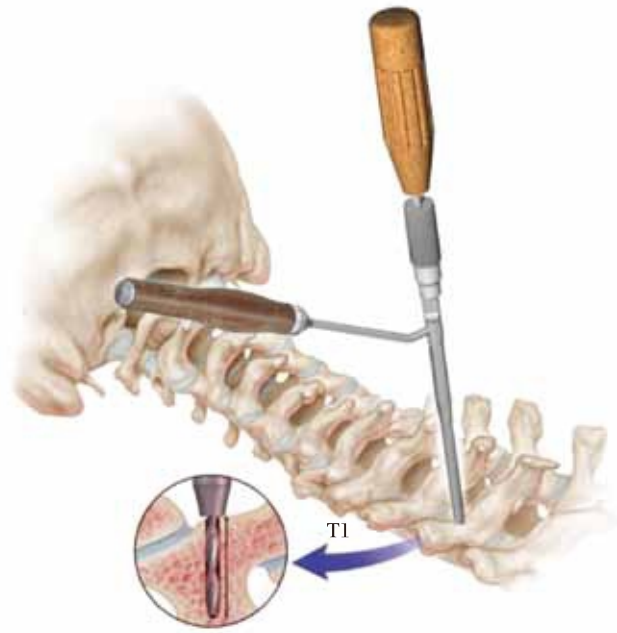
Care must be taken to avoid injury to the spinal cord, vertebral arteries, and C2 nerve roots in the upper cervical spine, and the facet capsules and interspinous ligaments at levels that will not be fused.



Placement of Multiaxial Pedicle Screws

Following preparation of the relevant posterior spinal elements, by removing all soft tissue and decorticating the facets and laminae, determine and mark the ideal entry point for all Multiaxial Pedicle Screws with an Awl. Prior to drilling the initial pilot hole, determine the desired depth of the drill penetration. There are two drill options available, fixed and adjustable.

Fixed Depth Drills are available in 2mm increments (12mm, 14mm and 16mm). Position the Fixed Drill Guide at the desired entry site. Place the appropriate 2.4mm Fixed Depth Drill into the guide and drill the pilot hole.



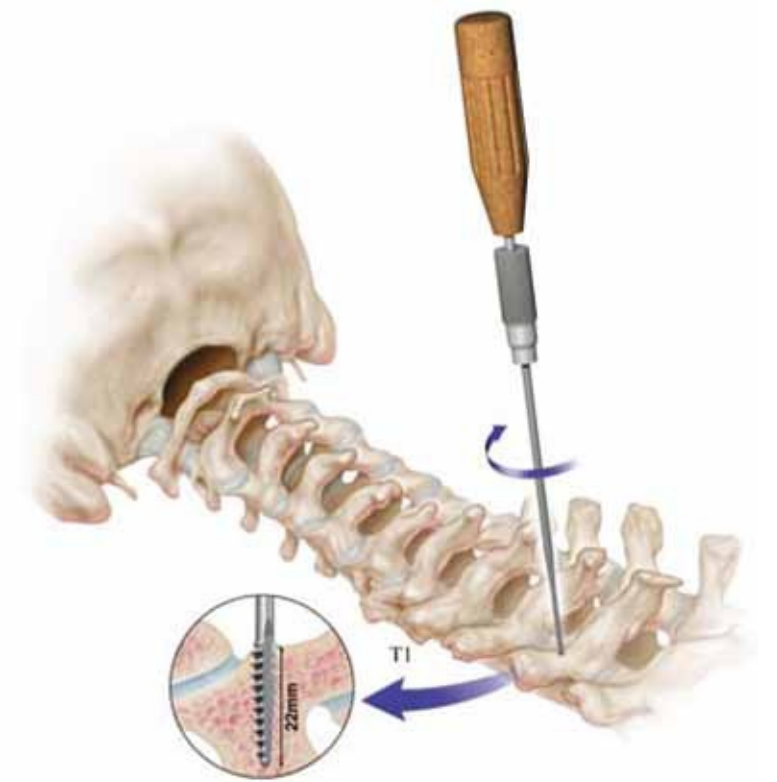
Adjustable Drill Bit and Drill Guide Protector offer a drilling depth range from 10mm - 34mm in 2mm increments. The depth is defined by the position of the Drill Guide Protector relative to the scale on the Adjustable Drill Bit. The Adjustable Drill Bit is easily inserted into the Drill Protector by depressing the locking button on the Drill Guide Protector and advancing the Adjustable Drill Bit into the Drill Guide Protector.



Confirm depth and containment within the bone of pilot hole with the Depth Gauge or Probe. The Depth Gauge reflects the approximate screw thread length, therefore select the same screw length as indicated by gauge.



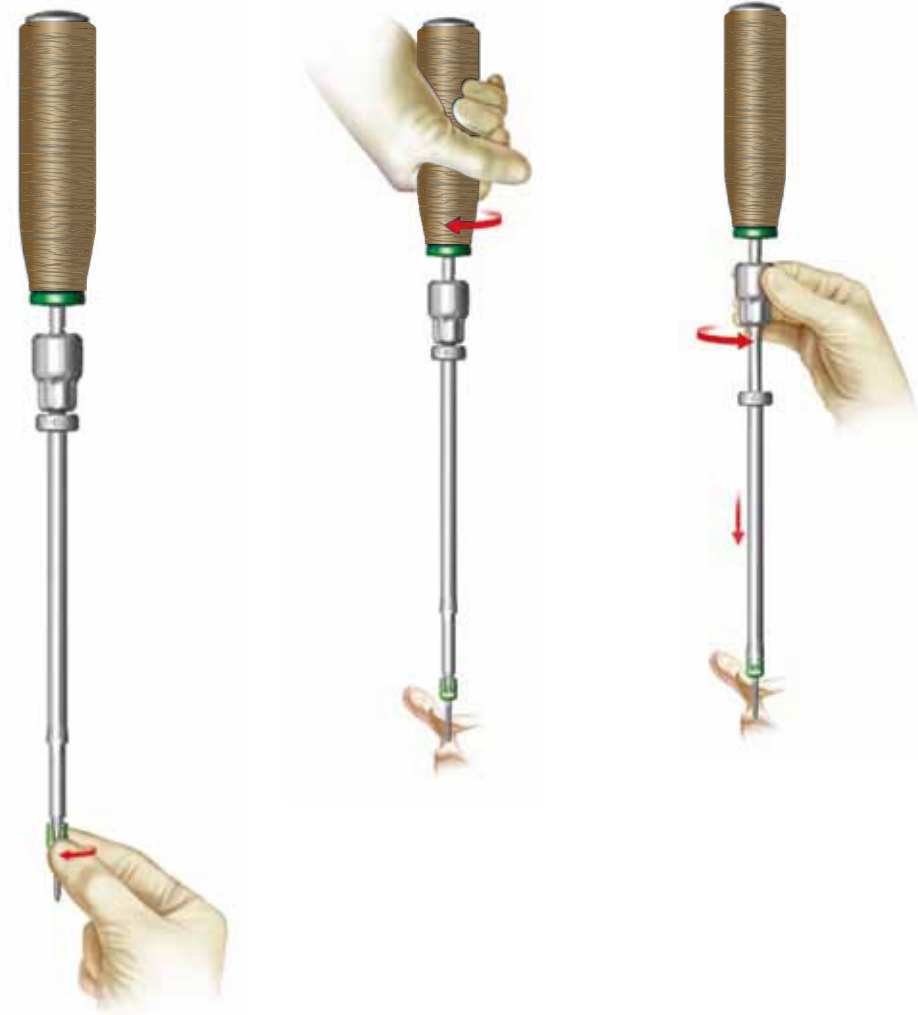
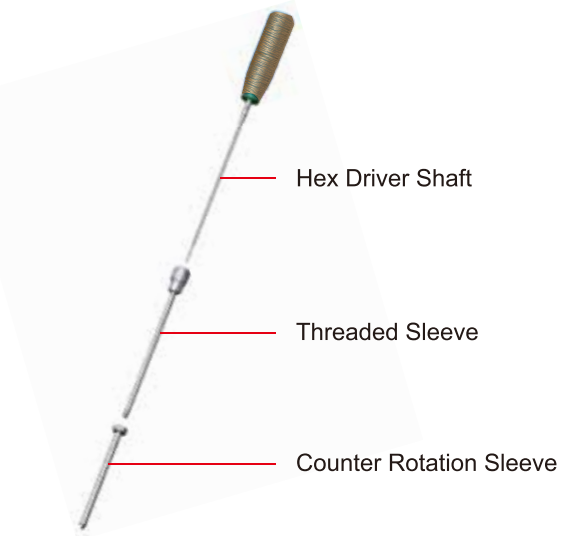
Tap the pilot hole using the 3.0mm, 3.5mm or 4.0mm Tap while maintaining the appropriate trajectory.



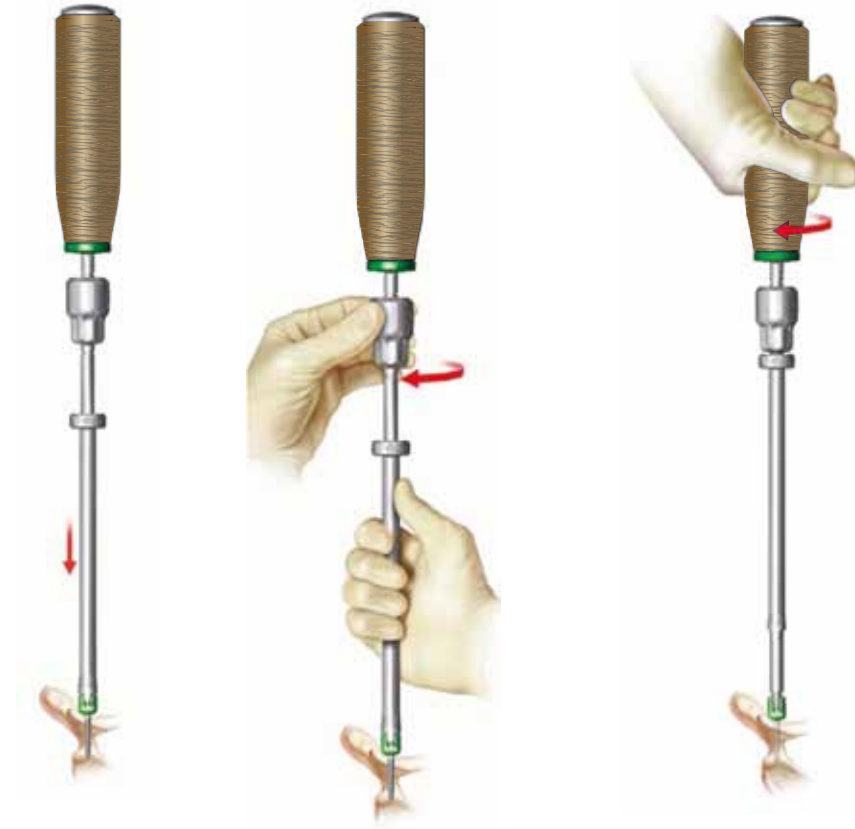
Insert the hex tip of the Polyaxial Screwdriver into the head of the appropriate length screw and load the screw onto the driver (be sure the screw is straight and rigidly connected and co-axial on the longitudinal axis of the screwdriver).

Insert the screw into the prepared pilot hole. Stop advancing the screw when the polyaxial head contacts the bone. To disengage the screw, lower the Counter Rotation Sleeve and turn the Threaded Sleeve counter-clockwise until the screw head is completely disengaged.

Once the screw is fully seated, confirm polyaxial motion of the screw head. If the screw is over-tightened the head will not rotate. In this situation, utilizing the Polyaxial Screwdriver, turn the screw counter-clockwise until the polyaxial motion is achieved.

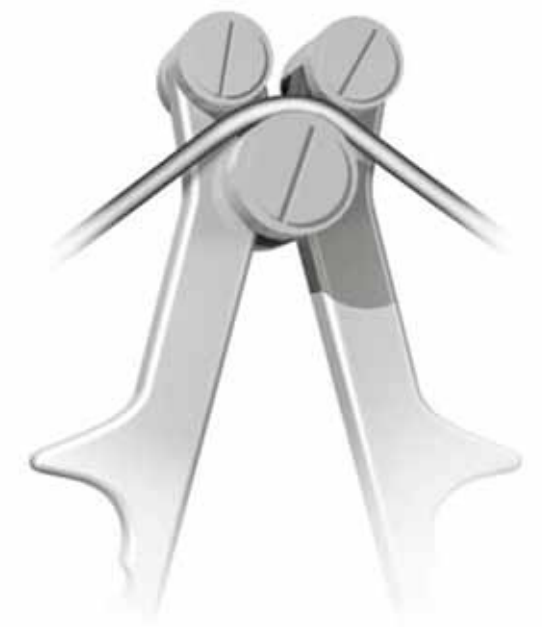


The Polyaxial Screwdriver was designed to both insert and back out the Multiaxial Screws. To remove the screw, insert the hex tip of the Polyaxial Screwdriver into the head of the screw and lower the Counter Rotation Sleeve onto the screw head. Hold the Counter Rotation Sleeve with one hand and turn the Threaded Sleeve clockwise until the screw head is fully engaged. Once the screw head is engaged, simply back the screw out by turning the handle counter-clockwise. To advance the screw, turn the handle clockwise.



Rod Preparation

The Rod Template is available and can be used to determine the optimal configuration and placement of the rod. Cut and contour the rods so that they lie smoothly against the posterior surface of the occiput and insert easily into all Multiaxial Screw heads. The final length of the rod should extend from the occipital fixation points (approximately 3-4mm caudal to the EOP) and 1-2mm distal to the first caudal fixation point. Care should be taken to protect adjacent uninstrumented levels. To contour the rods, secure the rod within the Rod Bender and gently contour until desired radius is achieved. Note: To avoid potential fatigue of the implant, do not make sharp bends or "unbend" the rod.



Adjust height and alignment of Multiaxial Screw heads such that the slot within each screw head is directed in line with the intended rod position. Utilize the Polyaxial Screwdriver to adjust the A-P height of screws and the Screwhead Adjuster to change the orientation of the screw head.

Place contoured rods in the Multiaxial Screw heads and position along cervical spine and up to the occiput. Once properly positioned, measure the distance between rods at the occiput and select the appropriate occipital implant.

Placement of the OC Plate

The Cobra II Posterior Cervical System offers an OC Plate for occipital fixation. The OC Plate is available in three sizes, 31mm, 37mm and 45mm. Optimal OC Plate size is determined by measuring the distance between the two longitudinal rods at the occiput.

Identify the external occipital protuberance (EOP) and the posterior border of the foramen magnum. Utilizing the Plate Holder, grasp the OC Plate and position it in the midline between the EOP and the foramen magnum.

The OC Plate should lie smoothly against the occiput. It may be necessary to smooth irregular bony protuberances slightly to optimize the bone to OC Plate interface, but avoid removing significant portions of cortical bone especially in the vicinity of planned screw holes.

To contour the OC Plate, place it securely in the Plate Bender and gently bend to desired radius. The contouring should be performed only in the bend zones to avoid damage to the sliding connectors.

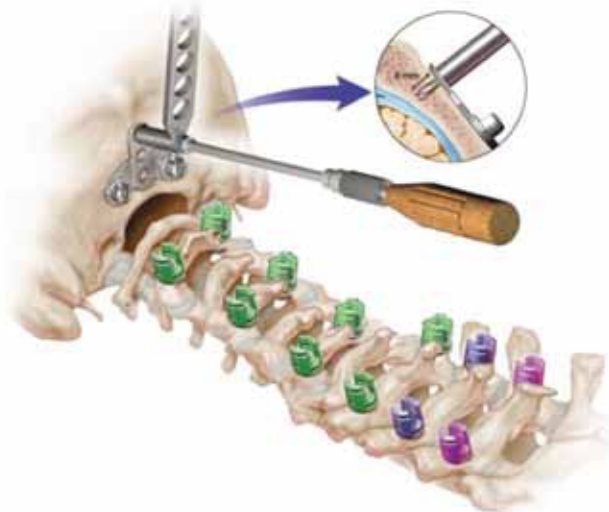
Note: To maintain the integrity of the occipital implant, the OC Plate must be bent in one direction only.



OC Screw Insertion

Determine the OC Screw length according to the pre-operative or intra-operative fluoroscopy.

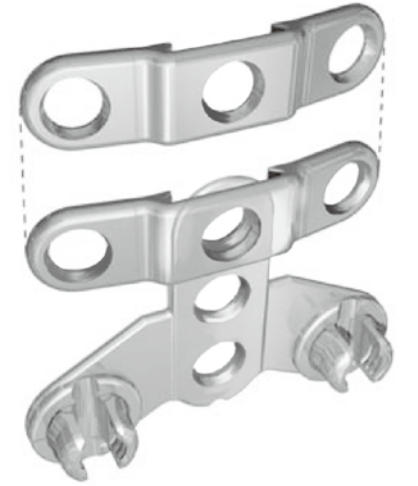
Select the appropriate OC Drill Guide. With the OC Plate in position, insert the OC Drill Guide into the superior midline hole of the OC Plate. Utilizing the 3.5mm Drill Bit, drill the initial occipital pilot hole. For difficult anatomy a 3.5mm Flexible Drill is available.



The Lateral Washer with the OC Plate: The OC Lateral Washer provides two additional lateral fixation points. The Lateral Fixation Washer connects to the OC Plate with a sliding dovetail connection. When using the OC Lateral Washer, assemble the washer to the OC Plate first, then select the appropriate OC Drill Guide. With the OC Plate in position, insert the OC Drill Guide into the superior midline hole of the OC Plate (and washer). Utilizing the 3.5mm Drill Bit, drill initial occipital pilot hole through both the plate and washer. Always confirm drilling depth with the Depth Gauge.

If drilling the initial occipital pilot hole directly to bone instead of through the OC Plate, increase the screw length by 2mm to allow for the OC Plate and washer width.

Note: 5.2mm OC Screws are also available. Use 4.5mm OC Screws first and reserve the 5.2mm OC Screws for revision purposes.



Depth Confirmation

Confirm depth of the pilot hole with the Depth Gauge.

Note: The Depth Gauge reflects approximate screw thread length. Therefore, select the same screw length as indicated by the gauge (e.g., 8mm Depth Gauge reading, select 8mm OC Screw).



Tapping

The pilot hole is then tapped with a 4.5mm Tap.

Note: Use the same OC Drill Guide as used to drill the pilot hole. Stop tapping the hole before the tap "bottoms out" on the drill guide to avoid stripping the bone threads.





Insertion

Utilizing the OC Polyaxial Screwdriver, insert the selected 4.5mm OC Screw and tighten provisionally. Do not fully tighten the OC Screws until the construct has been fully assembled. A small gap ventral to the OC Plate is helpful to allow the rod connectors to slide within the OC Plate, which facilitates placement of the rods. Insert the remaining OC Screws in same manner. Final tightening is performed once the construct is fully assembled.

Placement of the Rods

Confirm height and alignment of Multiaxial Screw heads, such that the slot within each screw head is directed in line with the intended rod position. Utilize the Polyaxial Screwdriver to adjust the A-P height of screws. The orientation of the screw head can be changed with the Screwhead Adjuster. Place the rod in the Multiaxial Screw heads and then into the slots of the OC Plate.

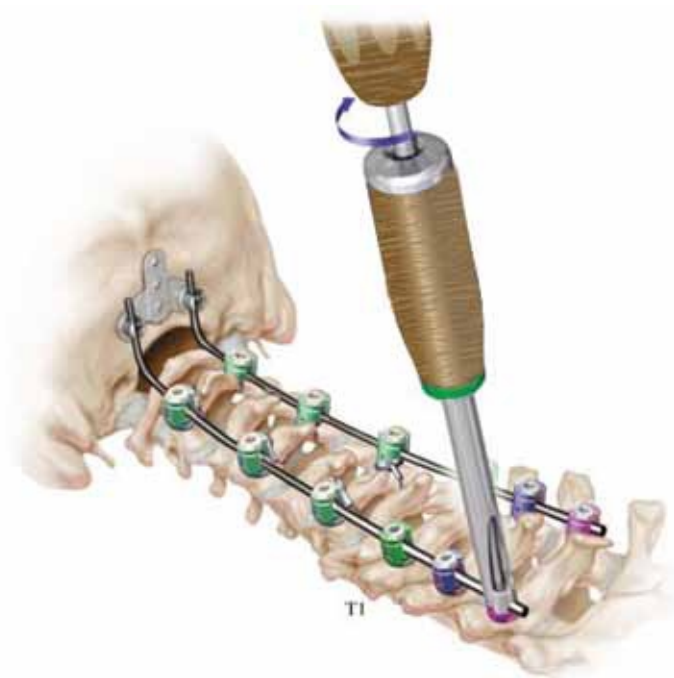
If necessary, utilize the Reduction Forceps to help seat the rod to the screw slot and the Nuts Screwdriver with Inner Screw is then applied to Multiaxial Screws and the sliding connectors on the OC Plate.

Compression/Distraction

If either compression or distraction is needed, the Inner Screw on one side of the motion segment should be provisionally tightened, with the Inner Screw loose in the implant to be compressed or distracted by utilizing the Compressor or Distractor. Once satisfactory compression or distraction has been achieved, tighten the loose Inner Screw.

Final Tightening

Once all the implants have been placed in to right position, final tightening should be performed by rotating the Torque-limiting Screwdriver clockwise while providing counter torque on the rod with the Counter Torque.



Placement of the Cross Connectors

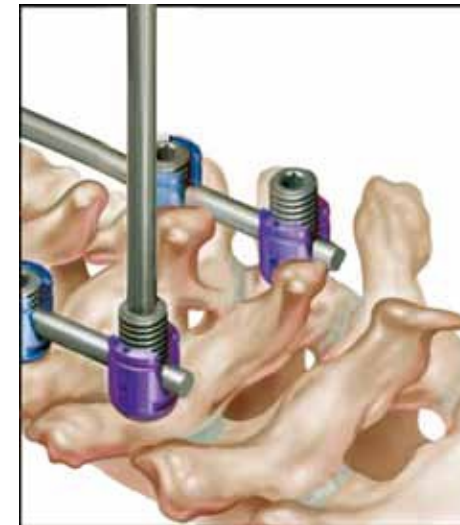
If the anatomy allows and extra stability is required, one or more pairs of Cross Connectors can be secured to the rods. There are two Cross Connector Options:

1. Crosslink Hook

Measure the distance between the medial aspects of the two 3.5mm longitudinal rods. Cut a 3.5mm rod to a length between 9mm - 11mm longer than the measured distance between the rods. Assemble a Crosslink Hook on each end of the transverse rod and position the Crosslink Hooks onto the longitudinal rods. Once the rod and Crosslink Hooks are positioned, the Inner Set Screws on both Crosslink Hooks can be tightened, clamping the Crosslink Hooks to the transverse and longitudinal rods. Final tightening with the Torque-limiting Screwdriver should occur once all components are in a satisfactory position.

2. Head-to-Head Cross Connector

Close approximation of adjacent screw heads often will not allow use of traditional crosslinks. The Head-to-Head Cross Connector utilizes the heads of the Multiaxial Screws as fixation points.



Utilize the Nuts Screwdriver to select a Prolonged Inner Screw for use with the Head-to-Head Cross Connector. Insert the Prolonged Screws to the Multiaxial Screws that will be connected.



Choose the appropriate size H/H Cross Connector Plate and contour as needed, using the Bending Irons provided. Place H/H Cross Connector Plate onto screw heads so the Prolonged Inner Screws extend through the Cross Connector Plate.



Utilizing the Nut Wrench, engage the H/H Cross Connector Outer Nut and tighten onto the Prolonged Inner Screw while stabilizing the Prolonged Inner Screw.



Final tighten the Prolonged Inner Screw with Torque-limiting Screwdriver by inserting it through the H/H Cross Connector Outer Nut.

H/H Cross Connector Final Tightening Sequence

- Provisionally snug down the H/H Cross Connector Outer Nut with the Nuts Screwdriver to align the Multiaxial Screwdriver and the connector.
- Final tighten the Prolonged Inner Screw with the Torque-limiting Screwdriver to secure the Multiaxial Screw to the rod.
- Final tighten the H/H Cross Connector Outer Nut with the Nut Wrench.

Note: if the Outer Nut is final tightened first will prevent the Prolonged Inner Screw from locking onto the rod.

It is possible to add the H/H Cross Connector after the standard Inner Screws have been inserted into the Multiaxial Screw head. Simply remove the standard Inner Screws and replace with the Prolonged Inner Screws then follow the instruction above.

Lateral Offset Connectors

The Cobra II Posterior Cervical System offers the Lateral Offset Connector to accommodate medial-lateral flexibility in challenging rod/screw alignment situations.

Place a Lateral Offset Connector on the rod loosely at the level of the target screw, and finger tighten the inner screw on the Lateral Offset Connector. The Lateral Offset Connector must be secure enough to remain in contact with the rod but also be able to rotate around the rod. Rotate the head of the Multiaxial Screw to align it to the bar of the Lateral Offset Connector. Then rotate the bar into the Multiaxial Screw slot. Apply the closure mechanism to the Multiaxial Screw in the usual manner. Revisit all inner screws for the final tightening when appropriate.



Instruments



137100 Drill Bit, Φ3.5mm



137110 Tap, Φ4.5mm



137120 Drill Guide 6/8



137130 Drill Guide 10/12



137150 OC Polyaxial Screwdriver



137160 Plate Bender



137170 Plate Holder



137180 Awl



137190 Drill Guide



137200 Protector



137210 Drill Bit, adjustable



137220 Φ2.4 Drill Bit, 12mm Depth



137230 Φ2.4 Drill bit, 14mm Depth



137240 Φ2.4 Drill bit, 16mm Depth



137250 Pedicle Probe



137260 Tap, Φ3.0mm



137270 Tap, Φ3.5mm



137280 Tap, Φ4.0mm



137290 Depth Gauge



137300 Polyaxial Screwdriver



137310 Screwhead Adjuster



137320 Rod Template, 200mm



137330 Rod Holder Forceps



137340 Rod Bender



137350 Rod Bending Iron



137410 Hook Holder



137430 Rod Cutter



137460 Torque-limiting Screwdriver 3.0NM



137370 Nuts Screwdriver



137400 Compressor



137440 Handle with Quick Coupling



137490 Counter Torque



137390 Distractor



137420 Hook Pusher



137450 Probe



137500 Reduction Forceps



137510 Nut Wrench