DePuySpine™
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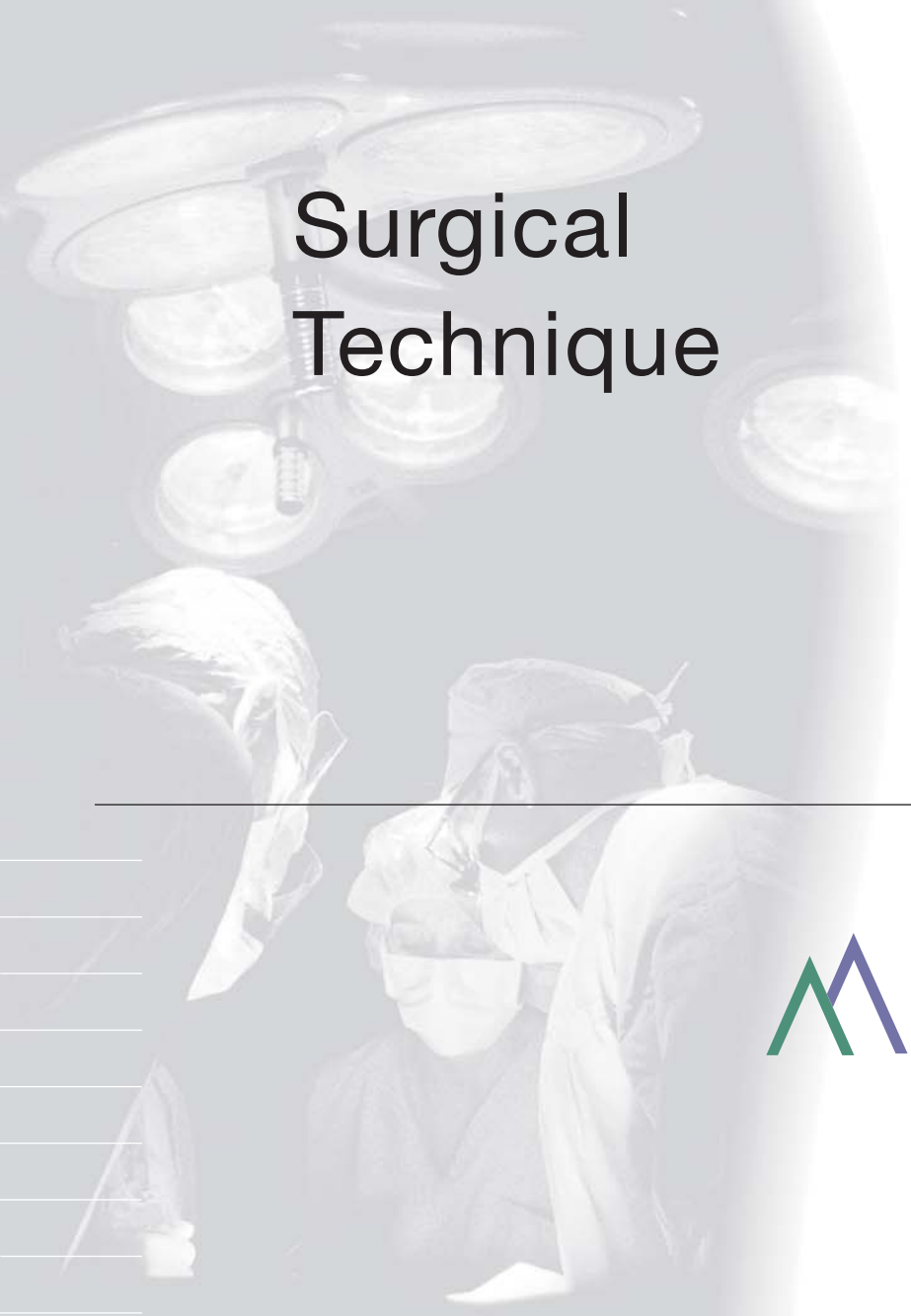
Surgical Technique



MOUNTAINEER™

OCT Spinal System

SURGEON DESIGNERS

Bradford L. Currier, M.D.
Associate Professor of
Orthopedic Surgery
Mayo Clinic Rochester
Rochester, MN

Iain Kalfas, M.D.
Chairman
Department of Neurosurgery
The Cleveland Clinic Foundation
Cleveland, OH

Carl Lauryssen, M.D.
Director
Institute for Advanced Spinal Research
Los Angeles, CA

Michael O'Brien, M.D.
Division Spine Surgery
Department of Orthopedics
Miami Children's Hospital
Miami, FL

Mr. Gerry Towns, F.R.C.S.
Consultant, Neurosurgery
Leeds General Infirmary
Leeds, England

MOUNTAINEER™

OCT Spinal System

INTRODUCTION

The MOUNTAINEER™ Occipito-Cervico-Thoracic Spinal 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.

The intra-operative benefits of the system are realized by the integration of uniquely designed system components that allow:

- *Secure, rigid, midline and lateral occipital bone plate fixation*
- *Rigid posterior rod fixation*
- *Anatomical screw placement*
- *Efficient rod placement with minimal contouring*
- *Low profile*
- *Interface with other DePuy Spine thoracolumbar systems*

CONTENTS

Surgical Technique

The following Occipito-Cervico-Thoracic Surgical Technique Guide, describes the recommended placement and use of all MOUNTAINEER OCT Spinal System components. It may also be used as a reference for other applications where the selection of system implants may vary depending on the procedure and desired outcome, e.g., occipito-cervical and cervico-thoracic fixation.

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 or halo with MAYFIELD™ attachment will securely hold the occiput and cervical spine in position. Confirm proper alignment with an image intensifier, or radiograph as well as direct visualization prior to draping. Accurate positioning is especially important when fixing the occiput to the cervical and thoracic spine.

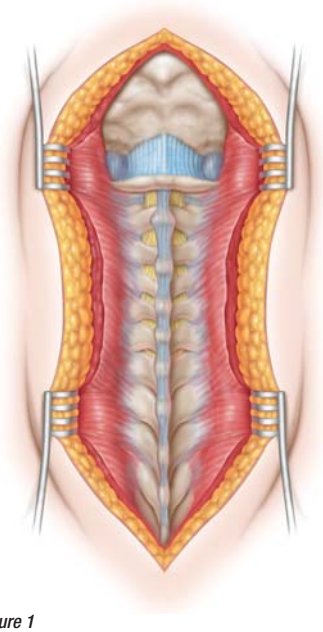


Figure 1

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 (Figure 1). **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.**

Intra-operative Planning

- Once the required exposure is achieved, evaluate the anatomy and assess its ability to accept the pre-operative construct strategy. Identify all system components required for the final construct.

- Bone anchors that are most constrained in their placement by the anatomy should be placed first. These are typically the C1 and C2 fixation points. It is recommended to insert the bone anchors with the greatest anatomical constraints first. The appropriate OC Plate size can then be selected once the distance between the longitudinal rods is determined.

Note: Hooks and Cross Connectors are available for fixation in the cervical spine. Additionally, patented Dual Diameter Rods are available for fixation of the cervico-thoracic junction. Depending on the degree of instability and patient size, the surgeon may choose to cross the cervico-thoracic junction with the patented Dual Diameter Rod System, placing the 3.5mm, 4.0mm or 4.35mm Minipolyaxial Screws into the upper thoracic vertebrae. Alternatively, the patented Dual Diameter Rod will allow standard fixation in the cervical spine and pedicle screw fixation in the thoracic spine using a 4.75mm, 5.5mm or 6.35mm rod system. Lastly, if the surgical goal is primarily fixation in the thoracic spine, the patented Dual Diameter Rod will allow pedicle screw fixation in the upper thoracic pedicles and fixation using a standard system with a larger diameter rod distally. Adjustable Rods, Wedding Bands and Axial Connectors are also available when it is desirable to link to other titanium rod systems, such as EXPEDIUM,™ ISOLA,® TiMX,™ MOSS MIAMI™ or MONARCH.™ *See System-to-System Components, page 30, for further details.*

Surgical Technique

Placement of Laminar Hooks

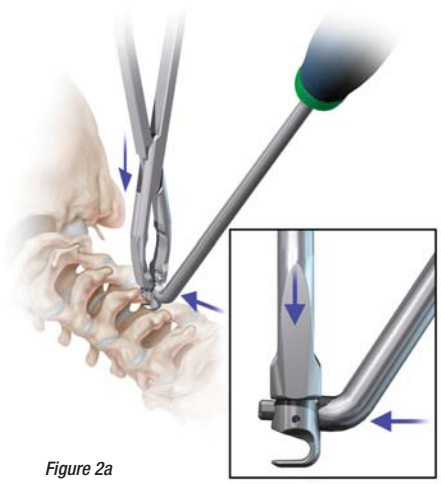


Figure 2a

Indications for Use of Laminar Hooks

Laminar Hooks are FDA cleared for use throughout the cervical spine. Steps 1 and 18 refer to implants and instruments for hook placement.

Step 1

- Select the appropriate hook size and configuration for the anatomy. There are four hook options: Large Hooks, Small Hooks, Large Medial/Lateral Hooks and Small Medial/Lateral Hooks.
- Hooks are inserted with the Hook Inserter (Figure 2a).
- Medial/Lateral Hooks can be used in conjunction with a Lateral Offset Connector (Figure 2b).
- See Step 18 for final tightening instructions.

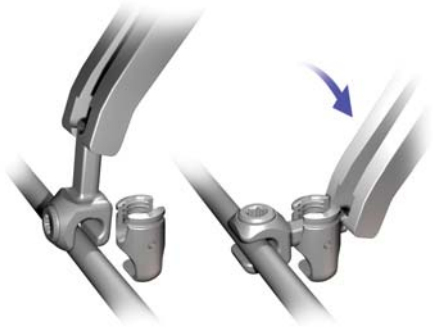


Figure 2b

Placement of Minipolyaxial Screws

Indications for Use of Minipolyaxial Screws
Minipolyaxial Screws are FDA cleared for use in the upper thoracic spine (T1-T3), Steps 1-7, 18 and 24, reference the implants and instruments of the MOUNTAINEER OCT Spinal System (with Minipolyaxial Screws).

Step 2

- 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 Minipolyaxial Screws with a burr or marking pen. An awl is also available to provide a starting point for the screw (Figure 2a).

- A pre-operative CT scan with sagittal and coronal reconstructions is advised to assess the dimensions and orientation of the posterior elements, pedicles and lateral masses. If necessary, a small laminotomy may be performed to palpate the cephalad and medial borders of the pedicle to determine the appropriate starting point for the pilot hole and screw trajectory. To ensure easy rod insertion with minimal contouring, it helps to align screw holes as co-linear as possible in the coronal (frontal) plane.

Surgical Technique

Step 3

- 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 Minipolyaxial Fixed Depth Drill into the guide and drill the pilot hole (Figure 3b).

- Adjustable Drill bit and Drill Guide Stop offer a drilling depth range from 10mm - 34mm in 2mm increments (Figure 3a). The depth is defined by the position of the Drill Guide Stop relative to the scale on the Adjustable Drill bit. The Adjustable Drill bit is easily inserted into the Drill Stop by depressing the locking button on the Drill Guide Stop and advancing the Adjustable Drill bit into the Drill Guide Stop.

Note: Alternatively, a "tap-drill" technique may be used in which the 2.4mm drill bit is incrementally advanced into the pedicle with a low-speed power drill. As the bit advances, the surgeon taps the drill bit against the bone at the anterior aspect of the hole to confirm that the drill bit remains within the confines of the bone. A Drill Guide will prevent plunging if the bit breaches the cortex of the pedicle. Some surgeons prefer to use a small Pedicle Probe, or a 2.4mm drill bit attached to a handle, to bluntly enter the pedicle rather than use a power drill.

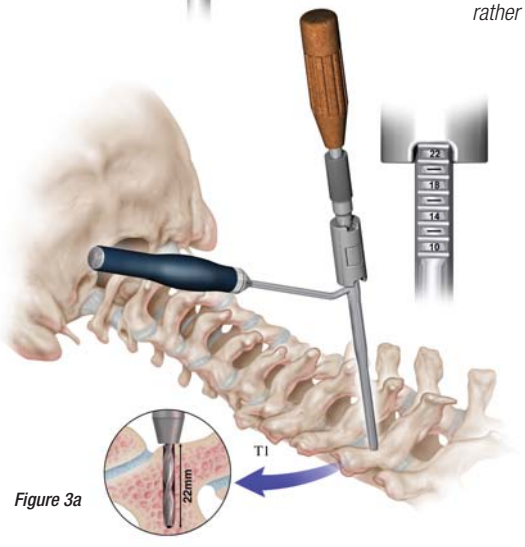


Figure 3a

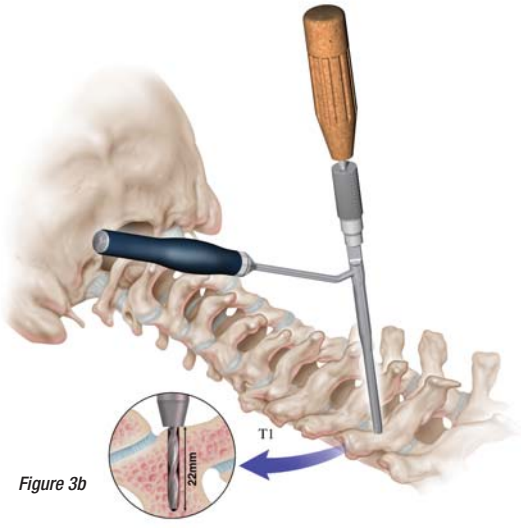


Figure 3b

Figure 4

Step 4

- Confirm depth and containment within the bone of pilot hole with the Depth Gauge (Figure 4) or Thoracic Pedicle Probe.

Note: The Depth Gauge reflects the actual screw thread length, therefore select the same screw length as indicated by gauge, e.g., 22mm Depth Gauge reading, select 22mm Minipolyaxial Screw.

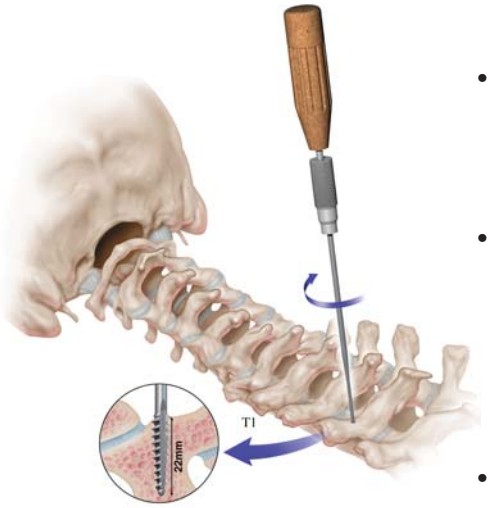


Figure 5

Step 5

- Tap the pilot hole using the 3.5mm, 4.0mm or 4.35mm Minipolyaxial Tap while maintaining the appropriate trajectory (Figure 5).

- Each size tap has a color ring that corresponds to the color of each Minipolyaxial Screw Shank Diameter:
  - 3.5mm = Silver (titanium)
  - 4.0mm = Blue
  - 4.35mm = Pink

- In the same manner, drill and tap the remaining pilot holes.

Note: A 3.0mm tap is available if under-tapping is necessary for a 3.5mm screw.

- Remove bony prominences that may cause the screws to be seated too far dorsally.

Surgical Technique

Figure 6a

Step 6

- Insert the hex tip of the Minipolyaxial Screwdriver (Figure 6a) 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) (Figure 6b).
- Insert the screw into the prepared pilot hole (Figure 6c). 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 (Figure 6d).

Note: 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 Minipolyaxial Screwdriver, turn the screw ***counter-clockwise*** *until the polyaxial motion is achieved.*

Figure 6b

Figure 6c

Figure 6d

- The Minipolyaxial Screwdriver was designed to both insert and back out the Polyaxial Screws. To back out the screw, insert the hex tip of the Minipolyaxial Screwdriver into the head of the screw and lower the Counter Rotation Sleeve onto the screw head (Figure 6e).

- Hold the Counter Rotation Sleeve with one hand and turn the Threaded Sleeve **clockwise** until the screw head is fully engaged (Figure 6f).

- 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** (Figure 6g).

- The Counter Rotation Sleeve of the Minipolyaxial Screwdriver has laser etchings that match up with the additional biased angle of both the Favored Angle Polyaxial Screw and the Medial/Lateral Favored Angle Screw (Figure 6h). This provides easier alignment of the biased angle screw.

Note: The screw can also be advanced or removed using the screwdriver alone without the two sleeves.

Figure 6e

Figure 6f

Figure 6g

Figure 6h

Surgical Technique

Figure 7a

Figure 7b

Step 7

- In the same manner, insert all remaining Minipolyaxial Screws. Adjust the A-P height of the screws to allow a smoothly contoured rod to seat fully in each of the bone anchors (Figure 7a).

- All Minipolyaxial Screws in the MOUNTAINEER OCT Spinal System have the follow attributes:

  - **Favored Angle:** All Favored Angle Screws have a 60° cone of angulation with an additional 15° bias in one direction. This additional biased angulation allows optimal contact with the posterior elements in situations where the patient presents with challenging anatomy.
    - Polyaxial Drag: The screw shank has a more rigid coupling with the screw head. This provides more control of the screw shank and head.
    - Self-Forming Tip: The tip allows for easier insertion into bone (Figure 7b).

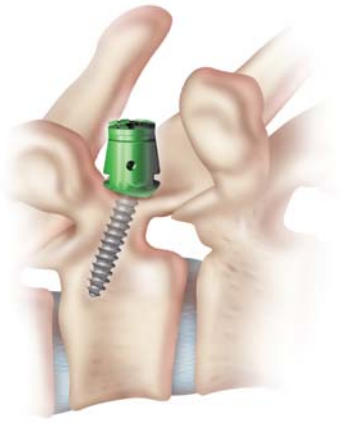


Figure 7c

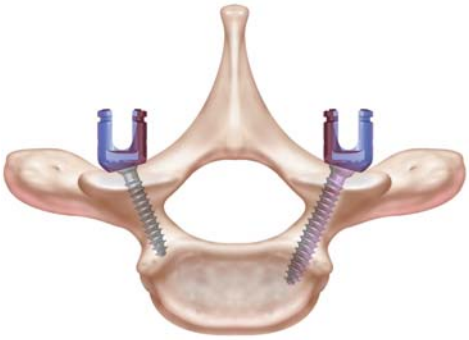


Figure 7d

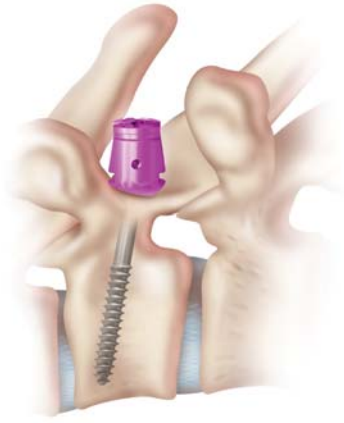


Figure 7e

- There are three Favored Angle Minipolyaxial Screw options and each is color-coded (as shown) to distinguish them from other types of Minipolyaxial Screws.

  - **Favored Angle Screw Heads are Green** – the additional 15° biased angulation in the rostral/caudal direction (in line with the rod) (Figure 7c).
    - *Screw Shank Diameter Options:* 3.5mm and 4.0mm
    - *Screw Length Options:* 10mm - 50mm (increments of 2mm)

  - **Medial/Lateral Favored Angle Screw Heads are Violet** – the additional 15° biased angulation in a lateral direction (Figure 7d).
    - *Screw Shank Diameter Options:* 3.5mm, 4.0mm and 4.35mm
    - *Screw Length Options:*
      - *3.5mm and 4.0mm:* 10mm - 50mm (increments of 2mm)
      - *4.35mm:* 20mm - 50mm (increments of 5mm)

  - **Long Shank Favored Angle Screw Heads are Pink** – the additional 15° biased angulation is in the rostral/caudal direction (in line with the rod) (Figure 7e).
    - *Screw Shank Diameter Options:* 3.5mm and 4.0mm
    - *Screw Length Options:* 26mm - 50mm (increments of 2mm)

  - **Minipolyaxial Screw Shank Diameter Colors:**
    - 3.5mm = Silver (titanium)
    - 4.0mm = Blue
    - 4.35mm = Pink

Note: Additional sizes are available through customer service.

Surgical Technique

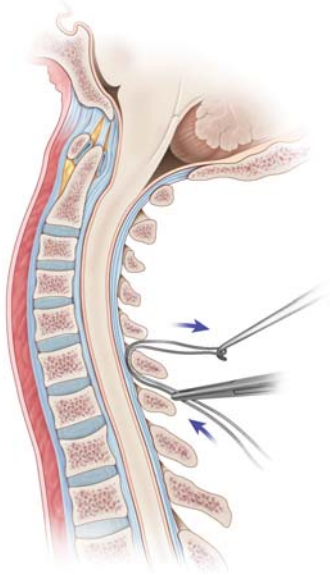


Figure 8a

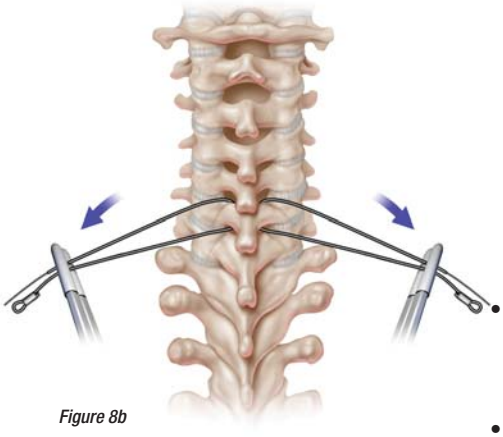


Figure 8b

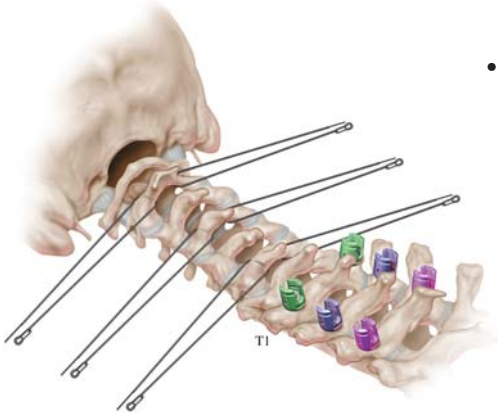


Figure 8c

Placement of Sublaminar Cables

Cable placement in the cervical spine, Step 8 and 19 - 21, reference the implants and instruments of the SONGER® Cable System. It is recommended to use SONGER Titanium Double Cables with Leader, allowing two cables to be applied simultaneously at each vertebral level using one sublaminar passage (except at the end of the construct where it is necessary to preserve the interspinous ligament).

Step 8

- Contour the cable leader in the shape of a “C”. Starting at the most caudal cervical level, introduce the leader inferiorly beneath and around the laminae. The cable is passed in the epidural space, which is exposed by removing the ligamentum flavum. If the correct plane is utilized, the cable should pass freely. If resistance is encountered, the dissection should be carefully inspected to ensure that the epidural space is properly exposed. As the leader emerges on the superior side, it is caught with rubber-shod forceps (a hemostat) or blunt hook, and pulled upwards to maintain tension on the cable (Figure 8a).
- The tip of the leader is cut and the cables are separated laterally and clamped at each side of the wound (Figure 8b).
- In the same manner, pass cables at all remaining cervical levels (Figure 8c).
- Refer to steps 20 - 21 for final tightening of the cables.

MOUNTAINEER is indicated for use with the SONGER Cable System. The SOF'WIRE™ Cable System is also available for use in the cervico-thoracic spine.

Below is a table outlining the attributes of both SONGER AND SOF'WIRE Titanium Cables.

Cable Options

	SONGER	SOF'WIRE
Material	**Titanium**	**Titanium**
Gauge (Diameter)	18 gauge (1mm)	20 gauge (0.9mm)
Single Cable Option	22″ (Rigid Leader – Top Hat Crimp)	24″ (Beaded & Central Leader)
Single Isola Cable Option	18.25″ (Malleable Leader with Looped Tip & Eyelet)	N/A
Double Cable Option	18.5″ (Malleable Leader with Eyelet)	24″ (Beaded & Central Leader)
Multi-Filament Wire System	Yes	Yes
Sterility	Sterile & Non Sterile	Sterile
Torque Wrench Range – Cervical Spine	8 - 10 lbs.	8 - 10 lbs.
Torque Wrench Range – Cervical Spine, Rheumatoid Arthritis	6 - 8 lbs.	6 - 8 lbs.

For additional information on implanting the SONGER Cable System or the SOF'WIRE Cable System please reference their respective Surgical Technique Guides.

Note: Titanium cables must be used to avoid electrolysis from dissimilar metals.

Note: The SONGER Cable System and the SOF'WIRE Cable System are also available in stainless steel. Either the SOF'WIRE or the SONGER Cable Systems may be used as a stand-alone fixation option.

Surgical Technique

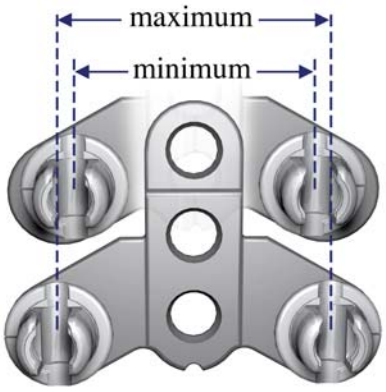


Figure 9 – 31mm OC Plate

Selection and Placement of OC Plate

Steps 9-19 and 22-24 reference the implants and instruments in the Occipito-cervical (OC) System and Cervico-thoracic (CT) System.

Step 9

- The MOUNTAINEER Spinal Fixation System offers an OC Plate for occipital fixation. The OC Plate is available in three sizes (Small – 31mm, Medium – 37mm and Large – 45mm) maximizing versatility in the medial-lateral position of the rods (Table 1). Each OC Plate size has three midline holes for occipital fixation and two lateral arms with sliding and rotating connection points for the rods (Figure 9).

- The Large OC Plate (45mm) offers two lateral holes for additional fixation (Figure 11c, page 17).

Table 1

Distance Between Rods (mm)

	Small	Medium	Large
OC Plate	31mm (+/- 4mm)	37mm (+/- 4mm)	45mm (+/- 4mm)

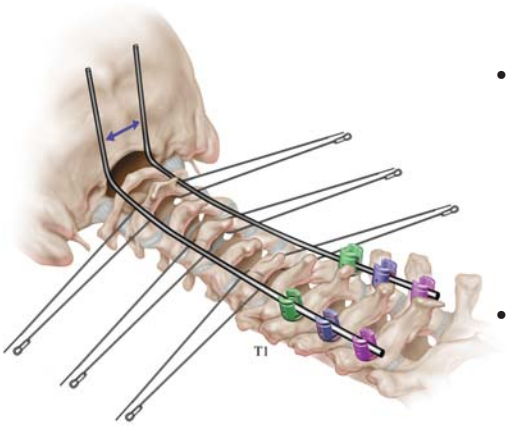


Figure 10a

Step 10

- There are two OC transition rod options:
  - Prebent 3.5mm Rod (Figure 10a)
  - Adjustable Rod – Includes a joint that allows a full range of angulation in one plane to reduce the amount of rod contouring necessary (Figure 10b).
- Optimal OC Plate size is determined by measuring the distance between the two longitudinal rods at the occiput.
- When using the Adjustable Rod, simply adjust the angle of the joint to match patient anatomy and tighten the screw. For final tightening use the Inner Screw Torque Driver to lock the joint (Figure 10c).

Note: Angulation of the Adjustable Rod can be revisited intra-operatively by loosening the screw, readjusting the angle, and retightening.

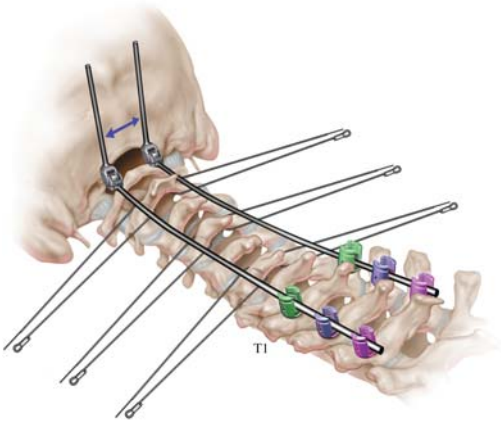


Figure 10b

Figure 10c

Surgical Technique

Figure 10d

Step 10 cont.

- Cut and contour the rods so that they lie smoothly against the posterior surface of the occiput and insert easily into all Minipolyaxial Screw Heads. The final length of the rod should extend from the occipital fixation points (approximately 1cm 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 Hand Held Rod Bender and gently contour until desired radius is achieved (Figure 10d). OC Tube Benders are also available and can be slid over each end of the rod to provide additional leverage in contouring the rod.

Note: To avoid potential fatigue of the implant, do not make sharp bends or "unbend" the rod. Hand malleable rod templates are available and can be used to determine optimal configuration and placement of the rod.

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

- Place contoured rods in the Minipolyaxial 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 (Figures 10a and 10b).

Step 11

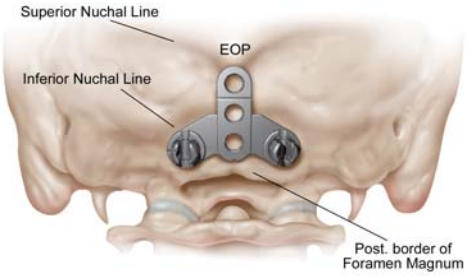


Figure 11a

- Identify the external occipital protuberance (EOP) and the posterior border of the foramen magnum. Utilizing the OC Plate Holder, grasp the OC Plate and position it in the midline between the EOP and the foramen magnum.
- The OC Plate can be oriented with the single limb of the implant cephalad in the midline and below the EOP (Figure 11a) or with the V portion of the implant cephalad in the midline and below the EOP (Figure 11b). The two limbs of the OC Plate should be placed above the foramen magnum allowing for a generous bone graft caudal to the implant.

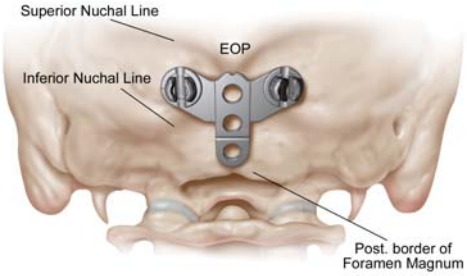


Figure 11b

Note: The OC Plate can be fixed to the occiput first or to the rods and then fixed to the occiput (as show in Figure 11c).

Figure 11c

Surgical Technique

Figure 12a

Step 12

- 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 bender and gently bend to desired radius (Figure 12a). The contouring should be performed only in the bend zones to avoid damage to the sliding connectors. The OC Plate can be bent to a maximum of 15° in either direction (Figure 12b).

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

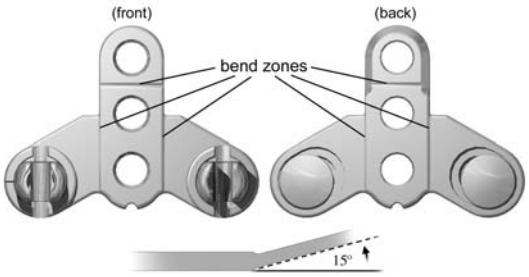


Figure 12b

Step 13

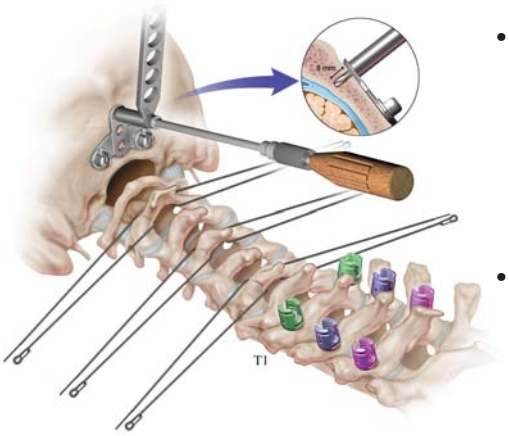


Figure 13a

- Select the appropriate Occipital Fixed Depth Drill Guide. With the OC Plate in position, insert the Fixed Depth Drill Guide into the superior midline hole of the OC Plate. Utilizing the 3.5mm Drill bit, drill the initial occipital pilot hole (Figure 13a). For difficult anatomy a Flexible Shaft Drill is available.

- **The Lateral Fixation Washer with the OC Plate:** The Lateral Fixation Washer provides two additional lateral fixation points. The Lateral Fixation Washer connects to the OC Plate with a sliding dovetail connection (Figure 13b). When using the Lateral Fixation Washer assemble the washer to the OC Plate first, then select the appropriate Occipital Fixed Depth Drill Guide. With the OC Plate in position, insert the Fixed Depth 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 (Figure 4, page 7).

Figure 13b

- 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 (example; when drilling 10mm deep, select a 12mm screw).

Note: 5.25mm bone screws, with a self-tapping feature, are also available. Use 4.5mm bone screws first and reserve the 5.25mm bone screws for revision purposes.

Note: The midline ridge of bone is shaped like a keel, and it is possible to penetrate the inner cortex on one side of the ridge and still be unicortical in the midline. The occipital sinus is located in the midline and drains into the transverse sinus. The consequences, if any, of penetrating this small sinus are unknown.

Surgical Technique

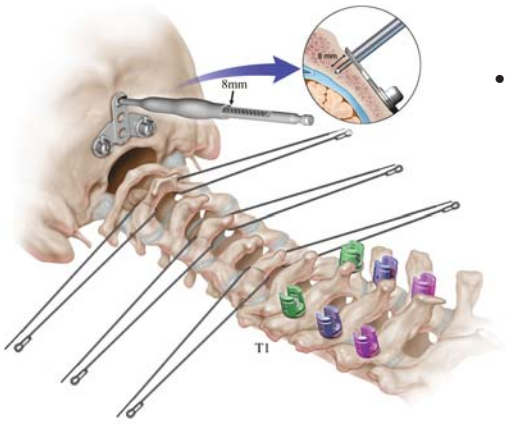


Figure 14

Step 14

- Confirm depth of the pilot hole with the Depth Gauge (Figure 14).

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

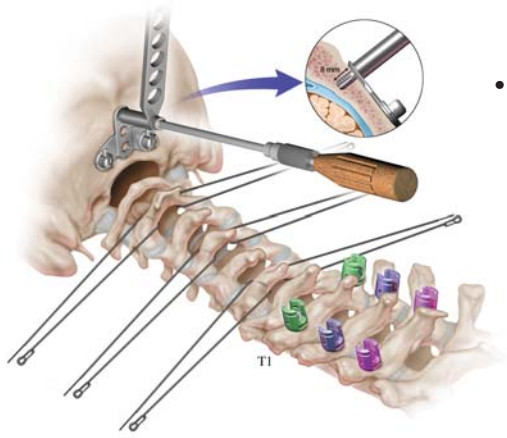


Figure 15

Step 15

- The pilot hole is then tapped with a 4.5mm Tap (Figure 15). For difficult anatomy, a Minimal Access Tap with a universal joint is available.

Note: Use the same Fixed Depth 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.

Figure 16

Step 16

- Utilizing the 2.5mm Self-Retaining Screwdriver, insert the selected 4.5mm Outer Diameter Occipital Bone Screw and tighten provisionally. For difficult anatomy, a Minimal Access Self-Retaining Screwdriver is available (Figure 16).

Note: 5.25mm bone screws are also available.

- Do not fully tighten the bone 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 Occipital Bone Screws in same manner. Final tightening is performed once the construct is fully assembled.

Surgical Technique

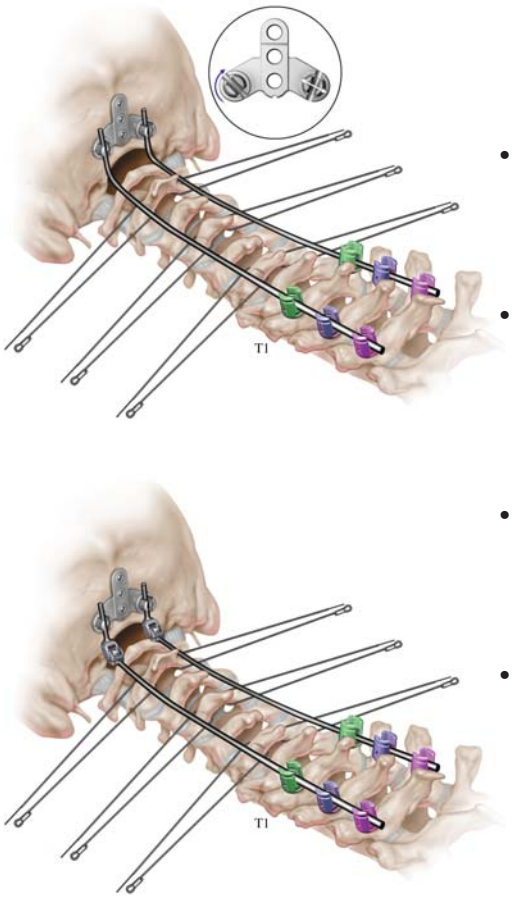


Figure 17

Construct Assembly

Step 17

- Confirm height and alignment of Minipolyaxial Screw Heads, such that the slot within each screw head is directed in line with the intended rod position.
- Place the rod in the Minipolyaxial Screw Heads and then into the slots of the OC Plate. The sliding connectors in the OC Plate should allow nearly parallel alignment of the rods with minimal, if any, additional contouring required in coronal plane (Figure 17).
- The final length of the rod should extend from just rostral to the OC Plate connection to the lowest level to be instrumented taking care to preserve adjacent anatomy.
- If additional contouring is required, secure the rod within the Hand Held Rod Bender or the OC Tube Benders and gently contour until desired radius is achieved.

Note: Utilize the Minipolyaxial Screwdriver to adjust the A-P height of screws. The orientation of the screw head can be changed with the Minipolyaxial Head Adjuster.

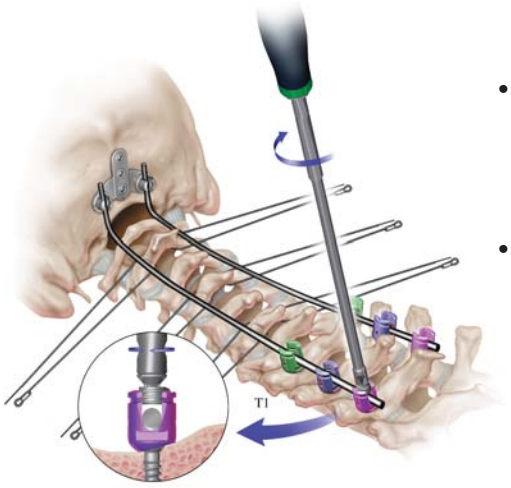


Figure 18a

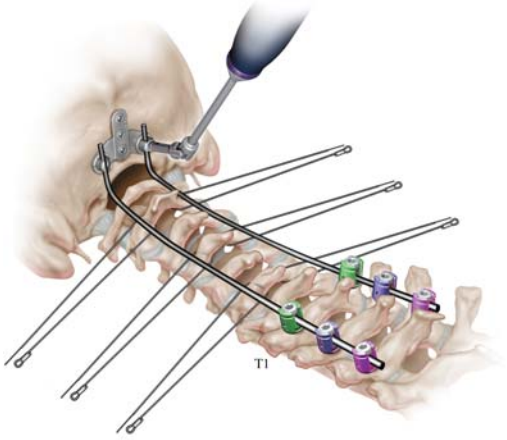


Figure 18b

Step 18

- Utilizing the Inner Set Screw Inserter, apply the Inner Set Screw to Hooks, Minipolyaxial Screws (Figure 18a) and the sliding connectors on the OC Plate (Figure 18b).
- Tighten provisionally by rotating the Inner Set Screw Inserters in a **clockwise** motion.

Note: Straight and Minimal Access Drivers are available for OC Inner Set Screws.

Surgical Technique

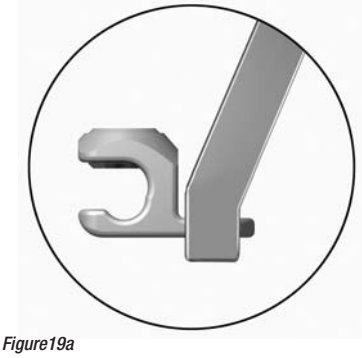


Figure19a

Figure19b

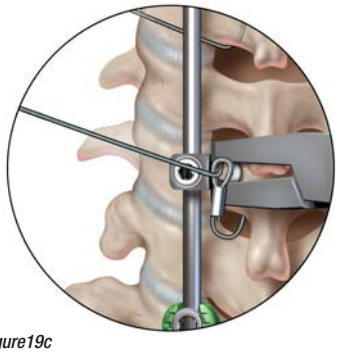


Figure19c

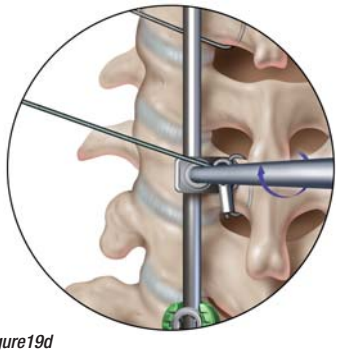


Figure19d

Step 19

- With rods loosely secured, Cable Connectors are positioned and final tightening (crimping) of cables is performed.
- Attach the Cable Connector to the Universal Connector Holder (Figure 19a).
- Beginning with the most distal end of the cable, pass the leader through the Cable Connector and then through the islet of the proximal end of the cable (Figure 19b). Continue to pull leadered end through the islet while simultaneously guiding Cable Connector onto rod (Figure 19c). Loosely secure connector by tightening the Cable Connector Set Screw with the X15 Hex Lobe Screwdriver (Figure 19d).
- In the same manner, introduce all Cable Connectors and secure, provisionally, to the rods (Figure 19e).

Note: Final tightening of Cable Connectors is done once all cables are crimped.

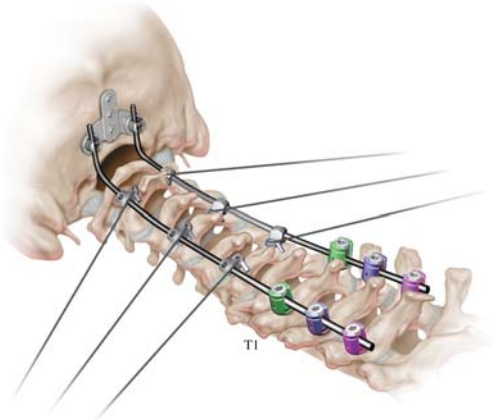


Figure19e

Step 20

Figure 20

- Utilizing the Crimp Inserter, position the Top Hat Crimp into the jaws of the Crimper-Tensioner Device, such that the brim of the crimp is on the outside of the Crimper-Tensioner jaws.
- Ratchet the Crimper-Tensioner Device one click, securing the Top Hat within the instrument (Figure 20).

Step 21

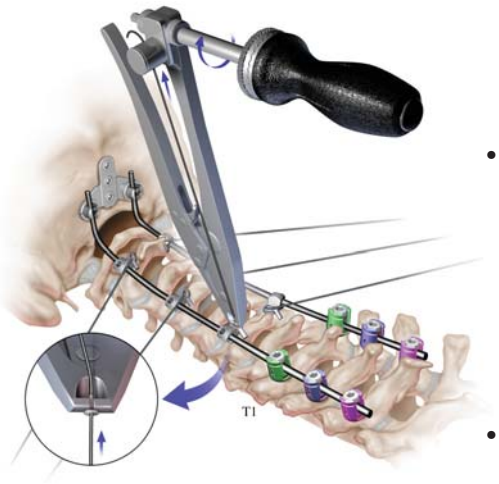


Figure 21a

- Beginning with the most distal cable, the leader is threaded through the Top Hat Crimp, up the instrument shaft and through the spindle of the Crimper-Tensioner Device.
- Adjust the Torque Wrench to the desired tension level and key into the hex of the Crimper-Tensioner Device. Turn the Torque Wrench **clockwise** until the wrench slips, indicating desired tension has been achieved (Figure 21a). Gently squeeze handles of Crimper-Tensioner Device until the ratchet releases indicating the crimp is fully swaged.
- Cut excess cable flush with crimp.
- In same manner, secure all cables by crimping remaining Top Hat Crimps (Figure 21b).

Note: In the cervical spine, the usual Torque Wrench range recommended is between 8 to 10 lbs. In rheumatoid arthritis cases, the torque range should be decreased to 6 to 8 lbs.

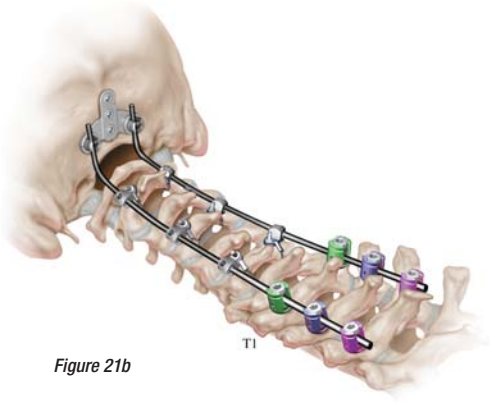
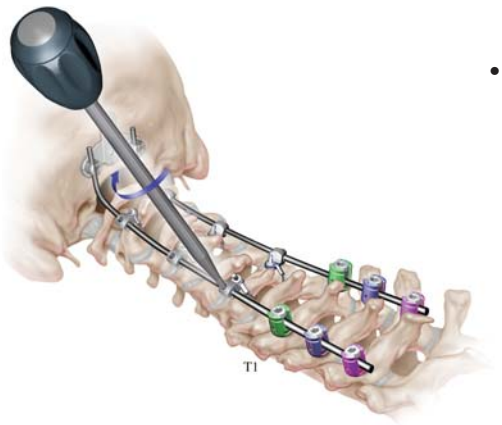
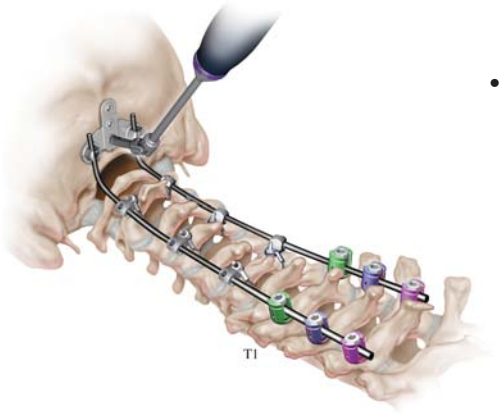


Figure 21b



Step 22

- Perform final tightening of all Cable Connector Set Screws, using the X15 Hex Lobe Torque Driver. The Set Screw is completely tightened when the X15 Hex Lobe Torque Driver automatically releases (Figure 22).



Step 23

- Perform final tightening of Occiptial Bone Screws utilizing the Universal Joint Screw Driver (Figure 23). Care must be taken to not over-tighten the Occipital Bone Screw.

Step 24

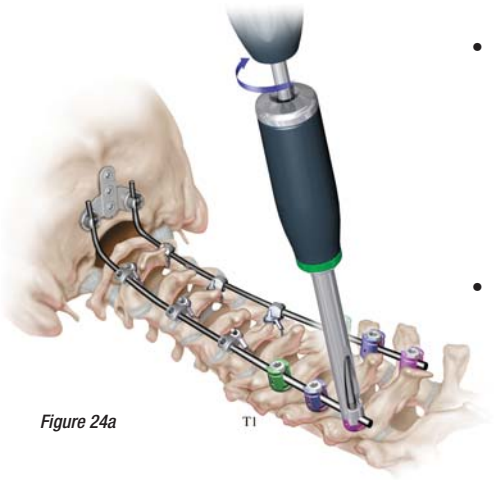


Figure 24a

- Perform final tightening of the Hooks and Minipolyaxial Inner Set Screw, by rotating the Torque Driver **clockwise** while providing counter torque on the rod with the Counter Torque Device. The Inner Set Screw is completely tightened when the Torque Driver audibly clicks (Figure 24a).

- Perform final tightening of the Inner Set Screws on the OC Plate, by rotating the Torque Driver **clockwise** while providing counter torque on the rod with the Counter Torque Device. The Inner Set Screw is completely tightened when the Torque Driver audibly clicks (Figure 24b).

Note: It is recommended to use the Counter Torque Device in final tightening.

Note: The OC Tightener is only used for OC Inner Screws - 2.5mm

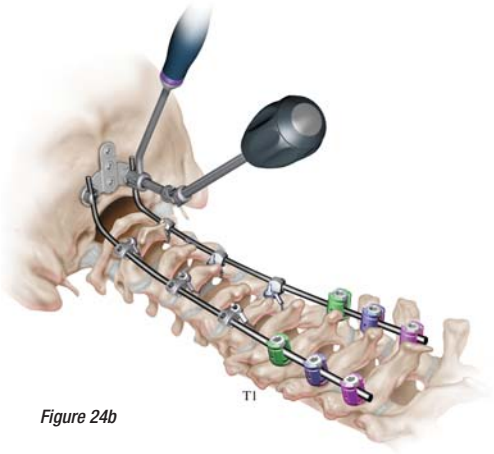


Figure 24b

Surgical Technique

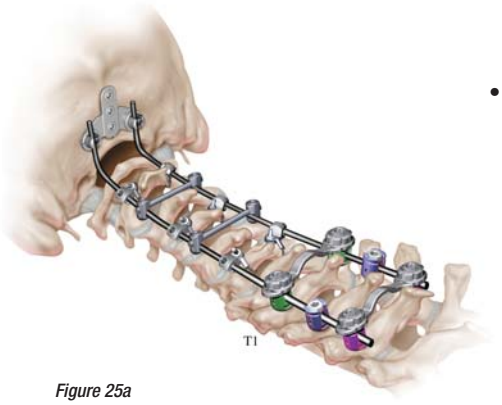


Figure 25a

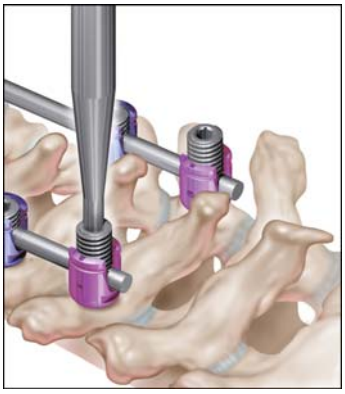


Figure 25b

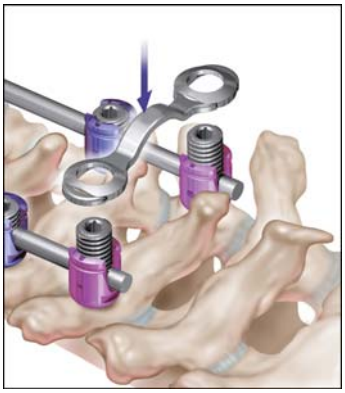


Figure 25c

Step 25

- If the anatomy allows and extra stability is required, one or more pairs of Cross Connectors can be secured to the rods. The MOUNTAINEER OCT Fixation System offers two Cross Connector Options:

  - **J-Hook Cross Connector:** 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 J-Hook Connector on each end of the transverse rod and position the J-Hooks onto the longitudinal rods. Once the rod and connectors are positioned, the Inner Set Screws on both J-Hook Connectors can be tightened, clamping the connectors to the transverse and longitudinal rods. Final tightening with the Torque Limiting Driver should occur once all components are in a satisfactory position (Figure 25a & b).

  - **Head-to-Head Cross Connector:** Close approximation of adjacent screw heads often will not allow use of traditional cross connectors. The Head-to-Head Cross Connector utilizes the heads of the Polyaxial Screws as fixation points.
    - **Head-to-Head Cross Connector OC Plate Sizes:**
      - 21mm
      - 28mm
      - 35mm
      - 42mm
      - 49mm
      - 56mm
    - Utilizing the Inner Set Screw Inserter select a Double Inner Set Screw for use with the Head-to-Head Cross Connector. Insert the Double Inner Set Screw to the Minipolyaxial Screws that will be connected (Figure 25b).
    - Choose the appropriate size Cross Connector and contour as needed, using the Bending Irons provided. Place Cross Connector onto screw heads so the Double Inner Set Screws extend through the Cross Connector (Figure 25c).
    - Utilizing the Outer Nut Driver, engage the Outer Nut (Figure 25d) and tighten onto the Double Inner Set Screw while stabilizing the Double Inner Set Screw (Figure 25e).
    - Final tighten the Double Inner Set Screw with the Head-to-Head Cross Connector Torque Driver by inserting it through the Outer Nut Driver (Figure 25f).

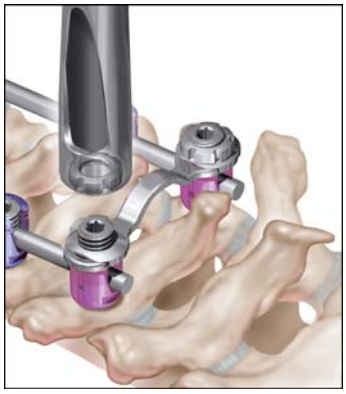


Figure 25d

- **Head-to-Head Cross Connector Final Tightening Sequence:**
  - Provisionally snug down the Outer Nuts with the Outer Nut Driver to align the Polyaxial Screws and the connector.
  - Final tighten the Double Inner Set Screw with the Torque Driver to secure the Polyaxial Screw to the rod.
  - Final tighten the Outer Nut with the Outer Nut Driver.

Note: If the Outer Nut is final tightened first this will prevent the Double Inner Set Screw from locking onto the rod.

Note: It is possible to add the Head-to-Head Cross Connector after the standard Inner Set Screws have been inserted into the Polyaxial Screw Head. Simply, remove the standard Inner Set Screws and replace with Double Inner Set Screws then follow the instructions above.

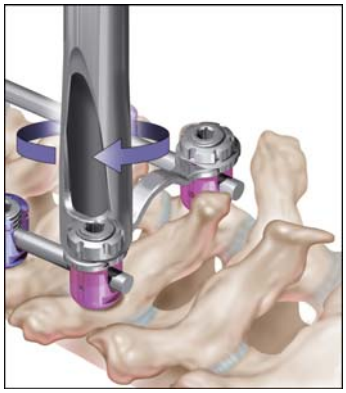


Figure 25e

Note: The Head-to-Head Cross Connector can be added to screws on the same level that do not sit directly across from each other on the rod by contouring the OC Plate to fit (Figure 25g).

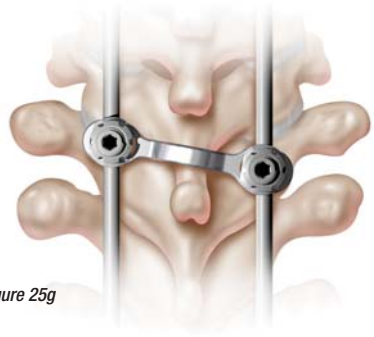


Figure 25g

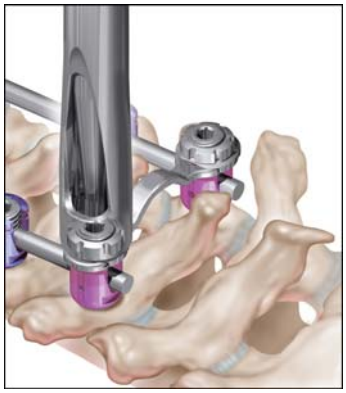


Figure 25f

Bone Grafting

- Check for cerebrospinal fluid leaks and copiously irrigate the wound.

- Lightly decorticate the exposed bony surfaces of the occiput and spine with care not to nick or scratch the implant. Apply bone graft, such as HEALOS® or SYMPHONY,™ to decorticated surfaces.

Post-Operative Care

- External bracing, with a collar or a Bremer HALO in unusually unstable circumstances may be required, at the discretion of the surgeon.

System-to-System Components

System-to-System Components and Sizing

Dual Diameter Rods*	Axial Connectors	Wedding Band Connectors	Adjustable Wedding Band Connectors
	3.5mm / 3.5mm	3.5mm / 3.5mm	
3.5mm / 4.75mm	3.5mm / 4.75mm	3.5mm / 4.75mm	3.5mm / 4.75mm
3.5mm / 5.5mm	3.5mm / 5.5mm	3.5mm / 5.5mm	3.5mm / 5.5mm
3.5mm / 6.35mm	3.5mm / 6.35mm	3.5mm / 6.35mm	3.5mm / 6.35mm

**Available in 420mm and 600mm Lengths*

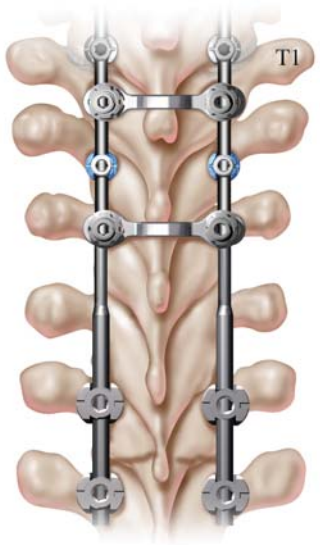


Figure 26

Dual Diameter Rods

- The MOUNTAINEER OCT Spinal System offers three Dual Diameter Rod configurations, which can be linked to thoracic components, including 3.5mm/4.75mm, 3.5mm/5.5mm and 3.5mm/6.35mm rods.

- Select the appropriate rod. Cut and contour rod to meet individual anatomical requirements. Hand-malleable templates are available to assist in determining optimal rod configuration. Contour the Dual Diameter Rod to precisely match the curve of the template (Figure 26).

Note: To avoid potential fatigue failure of the implant, do not make sharp bends or "unbend" the rod. Avoid significant bends at the transition of the Dual Diameter Rod.

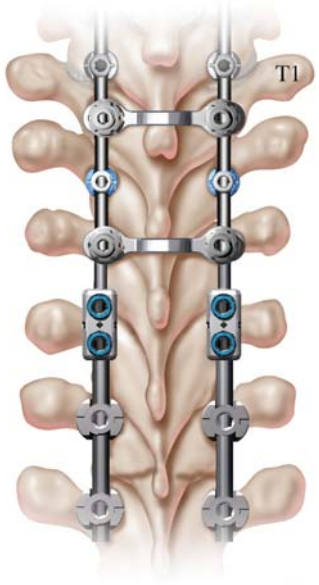


Figure 27

Axial Connectors

- The MOUNTAINEER OCT Spinal System offers three different size rod-to-rod connectors to accommodate the EXPEDIUM, ISOLA, TiMX, MOSS MIAMI AND MONARCH Systems.

- Rods are measured, cut and contoured. Axial Connectors are loaded onto the rods, which are back entered into the upper and lower foundations such that the joint between the two rods lies at the point where the center of the connector will be placed. The lower and upper Set Screws of the connector are tightened provisionally with the X25 Hex Lobe Driver. Final tightening of the Set Screws occurs once all components are in their final position (Figure 27).

- Cut and contour rods such that the ends of the rods will be closely approximated. Grasp an Axial Connector with a Hook Holder and slide it onto the 3.5mm rod. Provisionally secure the rods to the spine as described previously. Slide the connector inferiorly to capture the larger diameter rod and provisionally tighten the Set Screws of the connector once the connector is centered on the rods. Perform final tightening with the X25 Hex Lobe Driver.

System-to-System Components

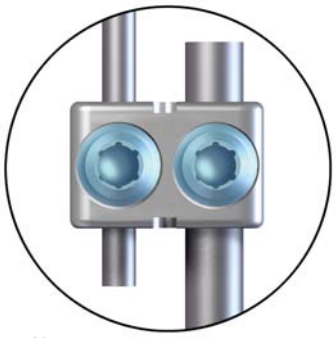


Figure 28a

Figure 28b

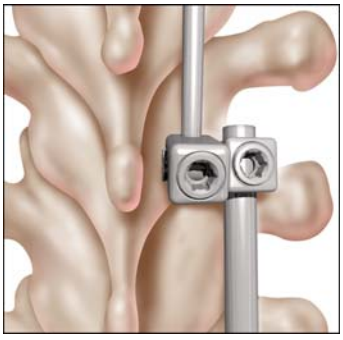


Figure 28c

Wedding Band Connectors

- The MOUNTAINEER OCT Spinal System offers four different size Wedding Band Connectors (3.5mm/3.5mm, 3.5mm/4.75mm, 3.5mm/5.5mm, 3.5mm/6.35mm) to accommodate the MOUNTAINEER, EXPEDIUM, ISOLA, TiMX, MOSS MIAMI, and MONARCH Systems.

Dual Wedding Bands

- Cut and contour the rods so that they will overlap (Figure 28a). Place the connector on a rod holder and slide it on the 3.5mm rod and back enter it onto the lower rod. Provisionally tighten the Set Screws of the connector with the X25 Hex Lobe Driver. Final tightening of the Set Screws occurs once all components are in their final position (Figure 28a).

Adjustable Wedding Band Connectors

- Adjustable Wedding Band Connectors allow for less sagittal rod contouring when connecting cervical and thoracic rods at the cervico-thoracic junction (Figure 28b & c).

Note: Adjustable Wedding Band Connectors are only available in 3.5mm/4.75mm, 3.5mm/5.5mm and 3.5mm/6.35mm.

- Slide the appropriate (smaller) side of Adjustable Wedding Band up the upper rod until it has passed the end of the lower rod. Adjust (twist) the opposite side of the Adjustable Wedding Band to the appropriate angulation to meet the lower rod and slide onto the lower rod.

- Provisionally tighten the Set Screws of the connector with the X25 Hex Lobe Driver. This secures the connector to the rods. By tightening the inner screw that locks the 3.5mm rod this will also lock the twisting function (disallowing the twisting motion). Final tightening of the Set Screws occurs once all components are in their final position.

Note: The Adjustable Wedding Band position and rotation can be readjusted by loosening the Set Screws.

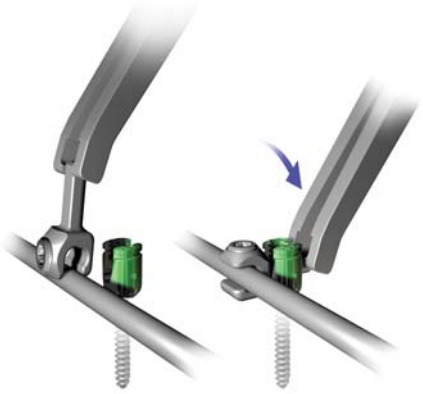


Figure 29

Lateral Offset Connectors

- The MOUNTAINEER OCT Spinal System offers a Lateral Offset Connector to accommodate medial-lateral flexibility in challenging rod/screw alignment situations.

- Screws are placed in the usual manner. Should the surgeon determine that the offset between a given screw and rod precludes connection, the surgeon may elect to use a Lateral Offset Connector. Using the Lateral Offset Connector Holder place a Lateral Offset Connector on the rod loosely at the level of the target screw. Finger tighten the Set 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 Polyaxial Screw to align it to the bar of the Lateral Offset Connector. Then rotate the bar into the Polyaxial Screw. Apply the closure mechanism to the Polyaxial Screw in the usual manner. Revisit all Set Screws for the final tightening when appropriate (Figure 29).

MOUNTAINEER™

OCT Spinal System

INDICATIONS

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput - T3), the SUMMIT™ Occipito-Cervical-Thoracic (OCT) Spinal System and the MOUNTAINEER OCT Spinal System is intended for:

- ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- spondylolisthesis
- spinal stenosis
- fracture/dislocation
- atlanto/axial fracture with instability
- occipitocervical dislocation
- revision of previous cervical spine surgery
- tumors

The Occipital Bone Screws are limited to occipital fixation only.

The use of the Minipolyaxial 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 SONGER® Cable System, to be used with the SUMMIT OCT Spinal System and MOUNTAINEER OCT Spinal System, allows for wire/cable attachment to the posterior cervical spine.

The SUMMIT OCT Spinal System and the MOUNTAINEER OCT Spinal System can also be linked to the ISOLA,® TiMX,™ MONARCH,™ MOSS MIAMI,™ and EXPEDIUM™ Systems using the Dual Wedding Band and Axial Connectors, and via Dual Diameter Rods.

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WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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All products are not currently available in all markets.

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DePuy Spine, Inc.
325 Paramount Drive
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Tel: +1 (800) 227-6633

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