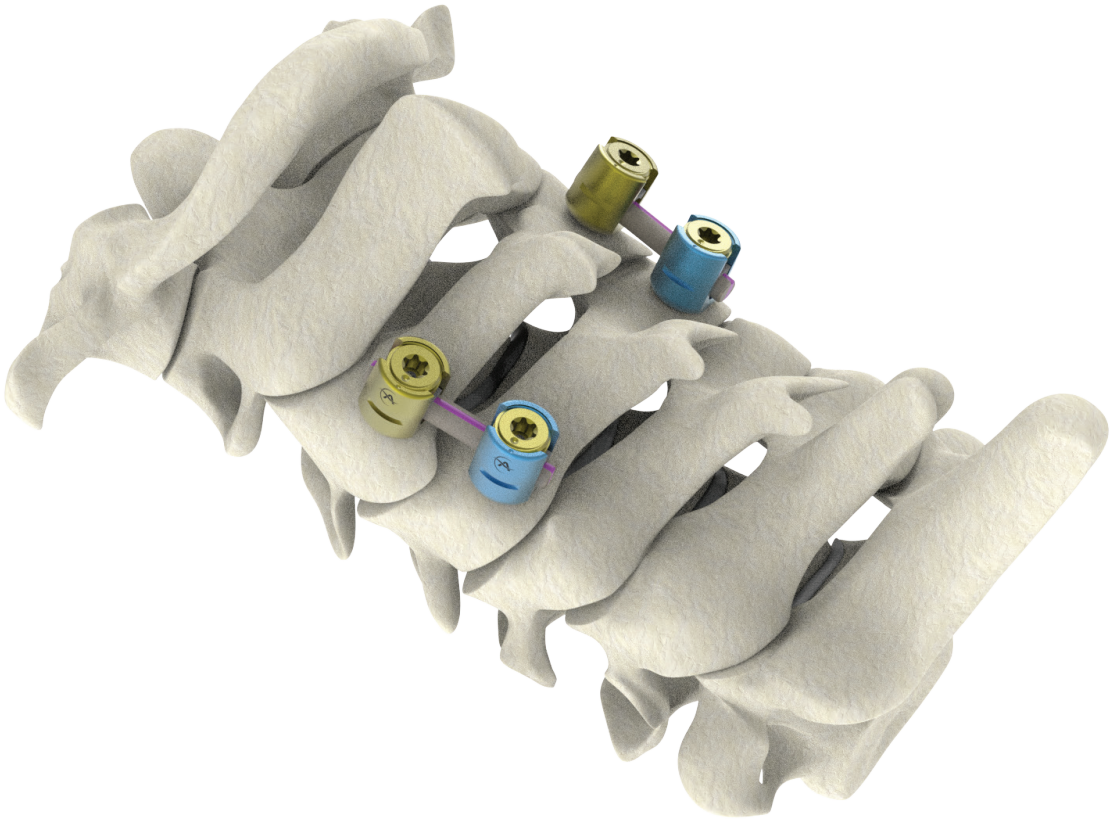
AltusSpine

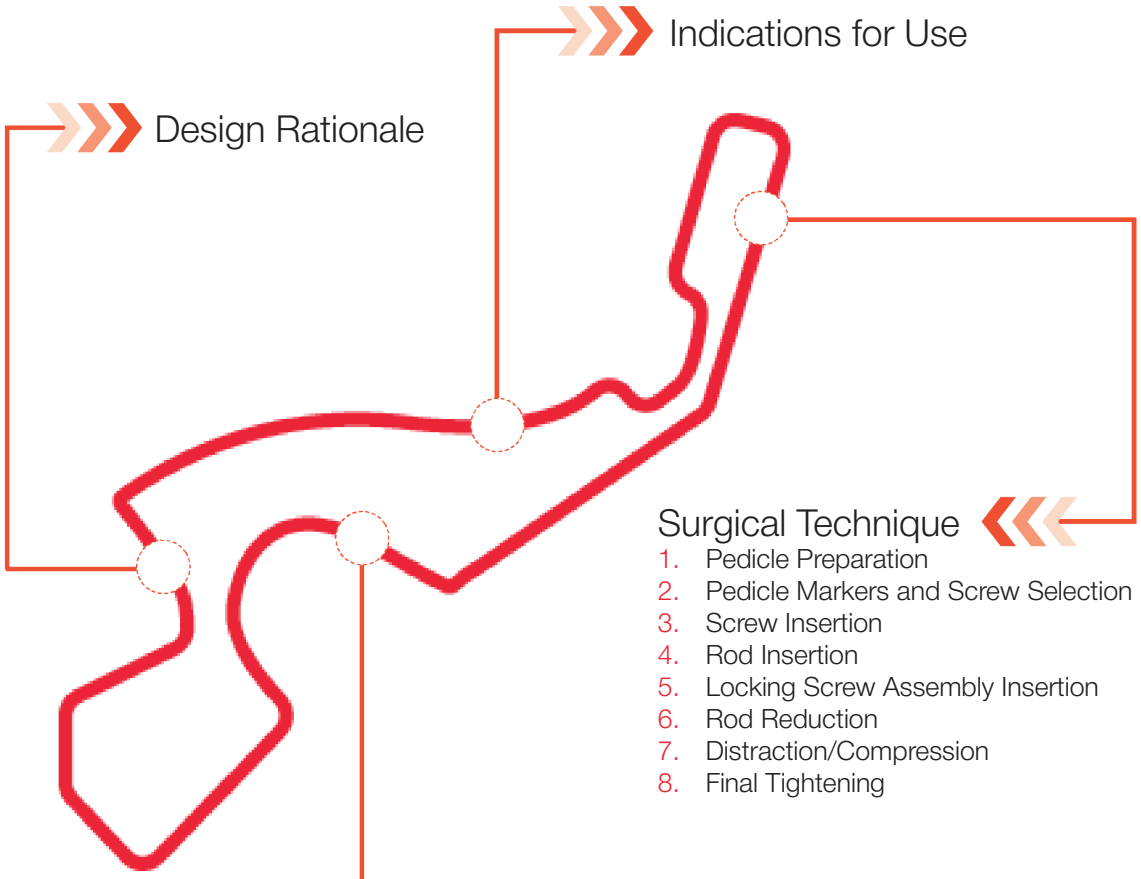


Sochi OCT System
Surgical Technique



SOCHI AUTODROM

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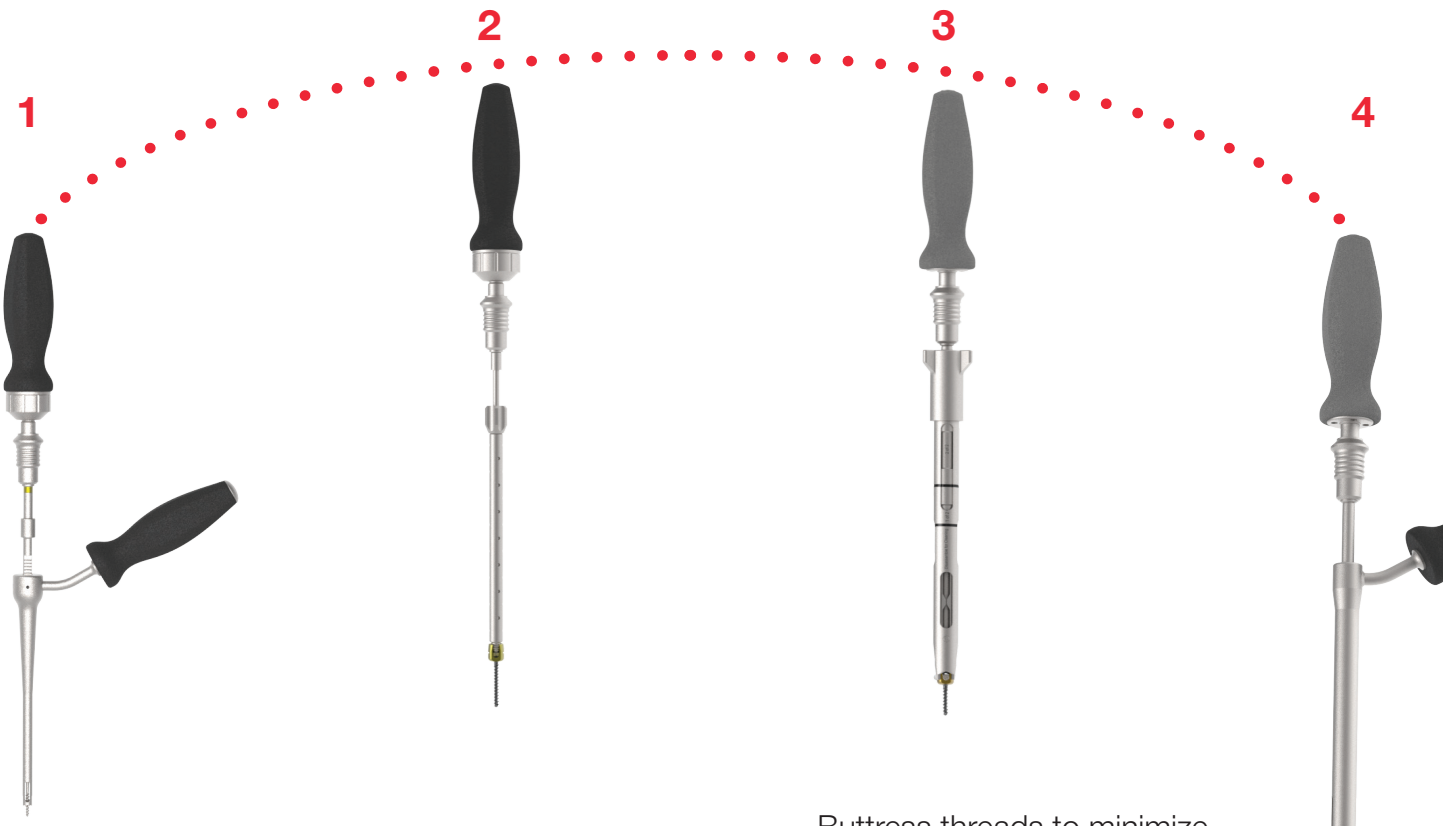
Indications for Use

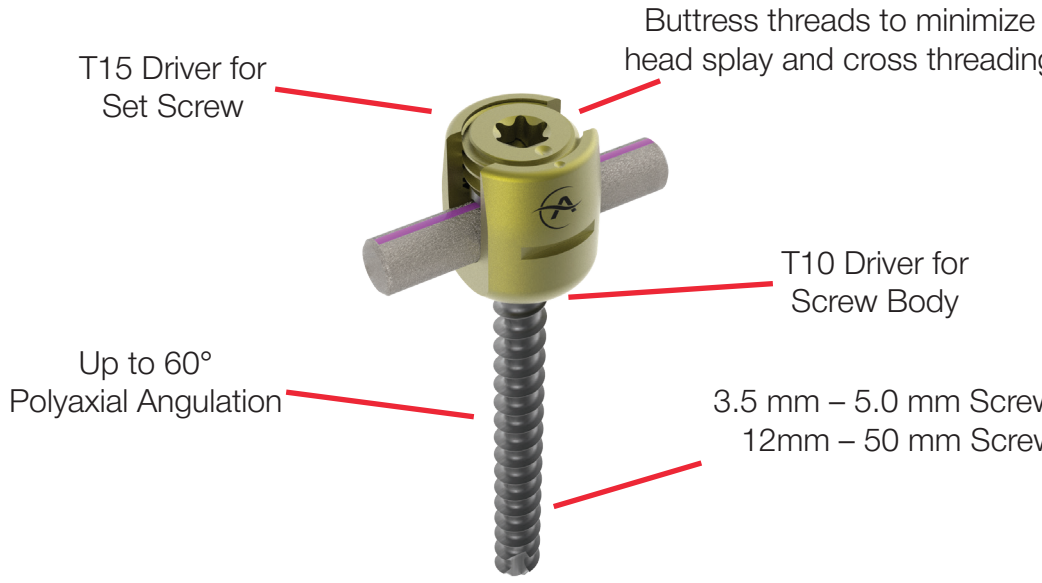
Design Rationale

Surgical Technique
1. Pedicle Preparation
2. Pedicle Markers and Screw Selection
3. Screw Insertion
4. Rod Insertion
5. Locking Screw Assembly Insertion
6. Rod Reduction
7. Distraction/Compression
8. Final Tightening

Additional Surgical Options
- Occipital Plates
- Lamina/Pedicle Hooks

DESIGN RATIONALE





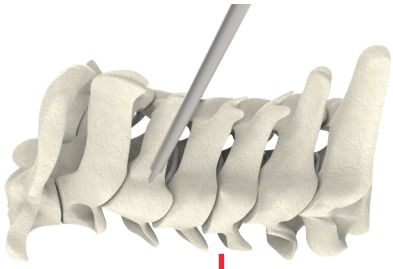
INDICATIONS FOR USE

The Sochi OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3; Traumatic spine fractures and/or traumatic dislocations; Instability or deformity; Failed previous fusions (e.g. pseudarthrosis); Tumors involving the cervical spine; Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Sochi OCT System is also intended to restore the integrity of the spinal column even in the absent of fusion for a limited time in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the Sochi OCT System may be used with the Theken Coral Spinal System with the use of transition rods and rod connectors.

Reference product insert (PI-013) for complete system indications for use, description, warnings and precautions.

1. PEDICLE PREPARATION

Prepare the patient using a standard surgical approach. Expose the spinous processes and laminae of the vertebrae to be fused.

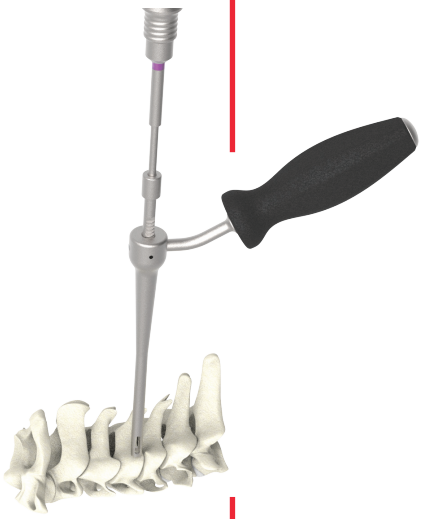


Prepare Entry Point
Once the entry point is determined, a pilot hole may be prepared with the **Awl**. This will help to prevent displacement of the drill bit during initial insertion. The **Awl** has an 8mm depth stop distance to prevent over-plunging. If desired, the **Awl** may be used with the **Adjustable Drill Guide**.



Prepare Pathway
The **Adjustable Drill Guide** allows for a single drill to be used for preparation of variable depths.
To set **Adjustable Drill Guide** depth, depress the adjustment button and slide depth stop to desired depth as indicated on the depth stop.

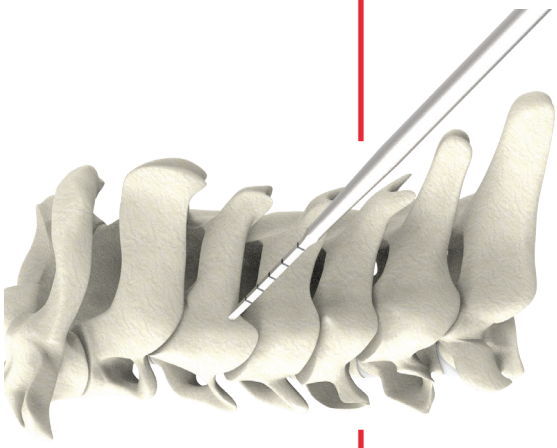
To drill a hole, place the 2.3mm or 2.8mm **Universal Drill** into the barrel of the **Adjustable Drill Guide** and apply downward pressure while turning the **Drill** clockwise until the step of the drill shaft contacts the guide.
Alternatively, fixed length drills are available for use with the **Fixed Drill Guide**, in 2mm increments from 10-16mm lengths, and 2.0mm, 2.3mm, and 2.8mm diameters. Load the chosen drill length into **Fixed Drill Guide** and apply downward pressure while turning the **Drill** clockwise until the step of the drill shaft contacts the guide.



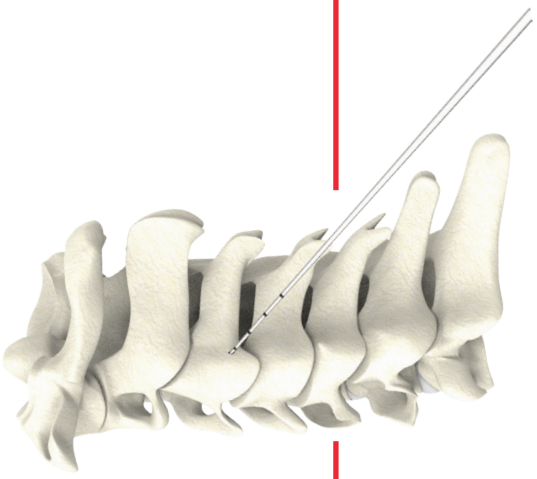
Caution: The use of the **Drill** without the **Depth Stop** could lead to patient injury.

1. PEDICLE PREPARATION (CONT.)

Prepare Entry Point
If the surgeon prefers, the path may be prepared with the **Bone Probe**. The **Bone Probe** should be in contact with the bone at all times. By gently following the path of least resistance, the **Bone Probe** is inserted without violating the walls of the pedicle.
Re-evaluate the entry point and trajectory if significant resistance is encountered.
The **Bone Probe** is laser etched in 5mm intervals to help indicate the depth to which the **Probe** is inserted as well as to help determine proper screw length.



Verify Pathway
Check the prepared pathway with the **Sound** to verify that all walls of the pedicle are intact and cancellous bone is felt at the distal end of the path.
The **Sound** is laser etched in 5mm intervals to help further indicate the depth to which the **Probe** was inserted as well as to help determine proper screw length.

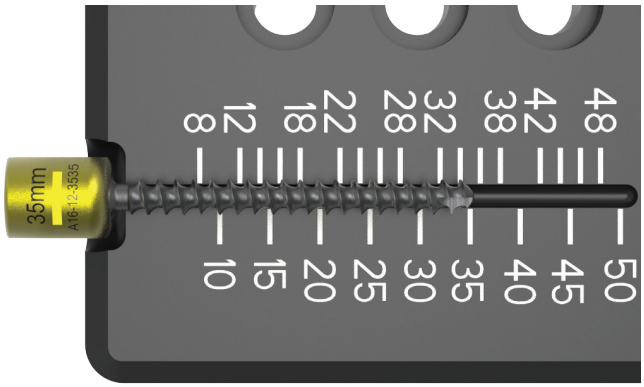


Measure Pathway
The depth of the drill hole can be confirmed using the **Depth Gauge**. Insert the tip of the **Depth Gauge** into the drill hole until the tip contacts the bottom of the hole.

2. PEDICLE MARKERS AND SCREW SELECTION

Verify Screw Diameter
Screws are color-coded based on the screw diameter. Determine the screw diameter and select the screw.

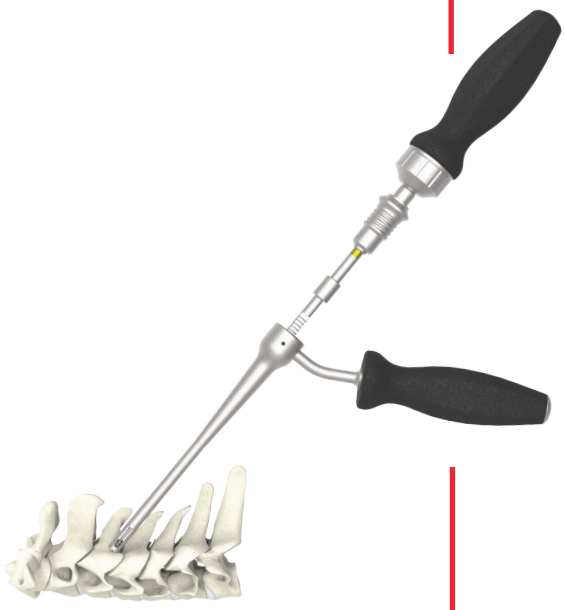
- Gold – 3.5mm
- Light Blue – 4.0mm
- Green – 4.5mm
- Magenta – 5.0mm



Verify Screw Length
The screw length may be verified by placing the screw in the screw-sizing slot located on the screw caddy. Place the screw in the slot making sure the screw seat is flush with the top of the screw sizing slot.

Tapping (Optional)

Tapping Technique
Tapping is optional since the screws have a self-tapping starter tip. **Taps** are undersized by 0.5mm from the screw diameter and are available for the 3.5mm, 4.0mm, 4.5mm, and 5.0mm screws. The appropriate **Tap** may be used to prepare the pedicle canal when the surgeon is having difficulty starting the self-tapping screw.



Taps may be utilized with the **Adjustable Drill Guide** in order to control the depth to which they are inserted. To tap a hole, place the **Tap** into the barrel of the **Adjustable Drill Guide** and apply downward pressure while turning the **Tap** clockwise until the tap shaft step contacts the guide.

With the pedicle pathways prepared and the proper screw length and diameter determined, the screw is prepared for insertion.

3. SCREW INSERTION



Attach
Insert the **Polyaxial Screw Inserter** into the drive mechanism in the screw.

Lock
Thread the sleeve of the **Polyaxial Screw Inserter** clockwise to seat the screw firmly into the **Inserter**.

Note: The **Polyaxial Screw Inserter** must be fully seated in the screw seat before proceeding to the next step.

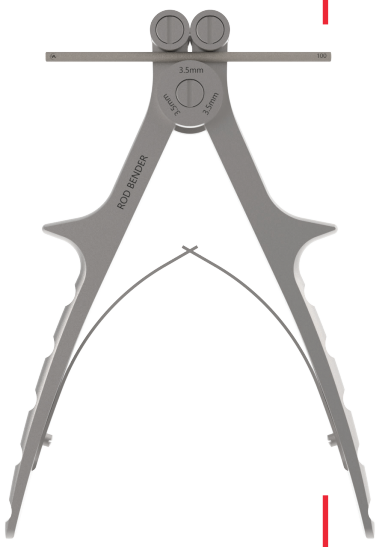


Insert
To insert the screw into the pedicle, apply a gentle downward force to the **Polyaxial Screw Inserter** and rotate the **Inserter** clockwise.
Rotate the **Polyaxial Screw Inserter** sleeve counter-clockwise to remove the screw **Inserter** from the screw seat.

Note: If minor screw depth or seat angle adjustment is needed, the **Polyaxial Screw Inserter** may be used.

4. ROD INSERTION

Determine Spinal Curve Configuration
Prior to inserting the rods, verify the cervical and/or thoracic configuration of the spine. Place the **Rod Template** into the screw seat and mold the template by bending it to fit.



Rod Bending
Remove the **Rod Template** and choose the appropriate length pre-cut rod. Bend the rod (if necessary) using the **Rod Bender** to match the **Rod Template**.

Note: Multiple bends in rods can be performed in one direction only. Reverse bending may produce internal stresses which may become the focal point for eventual breakage of the implant.

Rod Cutting
The rod length may be altered using the **In-Situ Cutter**. Align marks on adjustment knob with the etched line on side of **Rod Cutter**. Place the rod in the **Rod Cutter** and squeeze handle 2-3 times until the rod is cut.



Insert
Once the rod is bent to the desired contour, the **Rod/Cross Connector Holder**, **Flex Guide**, or **Adjustable Rod Pusher** may be used to place the rod into the screw seat. If the rod is not firmly placed in the screw seat, follow the **Rod Reduction** technique shown in Step 6.

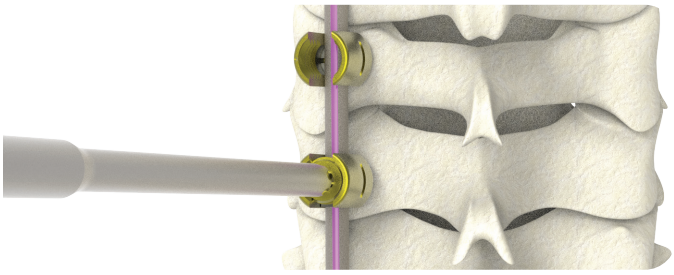
5. LOCKING SCREW ASSEMBLY INSERTION

Attach
Attach the **Locking Screw Assembly** to the tip of the self-retaining **T15 Tapered Inserter** and insert the **Locking Screw Assembly** into the screw seat.

Tighten
Loosely tighten the **Locking Screw Assembly** down into the seat.
Do not over tighten.
In the event that physical assistance is required to hold the rod down while tightening the **Locking Screw Assembly**, be sure the **Locking Screw Assembly** is fully engaged in the screw seat. This will help resist the reaction forces generated by the final tightening maneuvers.

Extra Caution Advised when:
1. The rod is not horizontally placed into the screw/ hook seat.
2. The rod is high in the screw seat.
3. An acute convex or concave bend is contoured into the rod near the screw-rod interface.





5. LOCKING SCREW ASSEMBLY INSERTION (CONT.)

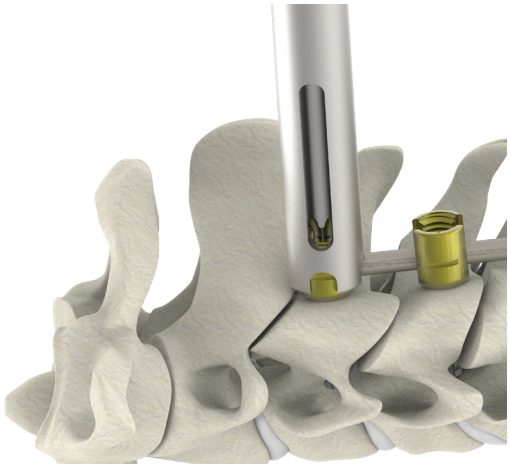
Locking Screw Assembly Insertion (Optional Technique)

Attach
Place **Alignment/Counter Torque Tube** over the screw head. Attach the **Locking Screw Assembly** on the tip of the self-retaining **Locking Screw Inserter** and insert the **Locking Screw Assembly** into the **Alignment/ Counter Torque Tube**, using it as your guide for accurate screw placement.

Position
When using the **Alignment/Counter Torque Tube**, the threads are automatically aligned to minimize the chance of cross threading.

Tighten
Provisionally tighten the **Locking Screw Assembly** down into the screw seat. Do not over tighten. In the event that physical assistance is required to hold the rod down while tightening the **Locking Screw Assembly**, be sure the **Locking Screw Assembly** is fully engaged in the screw seat. This will help resist the reactive forces generated by the final tightening maneuvers.





6. ROD REDUCTION

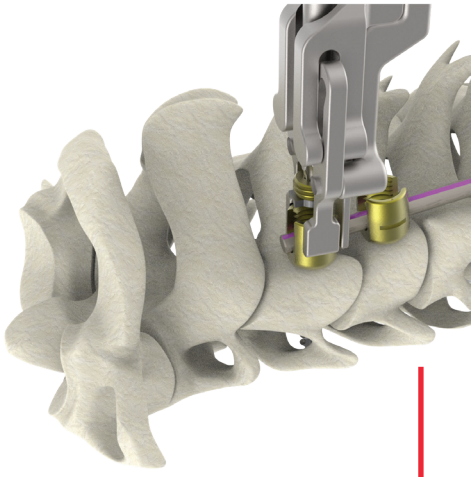
Persuasion
Use the **Threaded Reduction Tower** or **Rod Persuader** when additional physical assistance is required to ease the rod to the screw seat. The **Rod Persuader** pushes the rod into the screw seat and then is used to guide the **Locking Screw Assembly**.

Engage the **Rod Persuader** with the slots on the screw seat. Squeeze the handle to introduce the rod into the screw seat.

Attach the **Locking Screw Assembly** to the self-retaining **Locking Screw Inserter.** Insert the **Locking Screw Assembly** through the **Rod Persuader**, into the screw seat.

Provisionally tighten the **Locking Screw Assembly**.
Disengage the **Rod Persuader** from the screw seat and repeat as necessary.





7. DISTRACTION/COMPRESSION

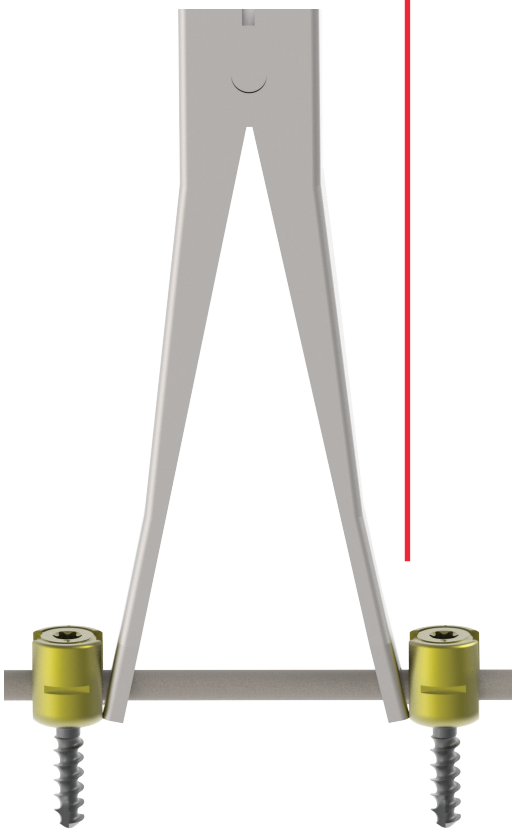
Loosen the **Locking Screw Assembly** of the level to be adjusted.

Use the **Distractor** around the rod to achieve distraction.

Use the **Compressor** to achieve compression.

Tighten **Locking Screw Assembly** after distraction/compression is achieved.

Repeat for each segment as required.



8. FINAL TIGHTENING

Attach the **Locking Screw Inserter** to the **2.0 Nm Torque Limiting Handle**.

Note: The 2.0 Nm Torque Limiting Handle is dark gray.

Place the **Alignment/Counter Torque Tube** over the screw seat.

Insert the **Locking Screw Inserter** and **2.0 Nm Torque Limiting Handle** assembly into the **Alignment/Counter Torque Tube**.

Firmly hold the **2.0 Nm Torque Limiting Handle** and perform final tightening of the **Locking Screw Assembly** until the **2.0 Nm Torque Limiting Handle** “clicks”.

Note: Torque Limiting Handles require periodic recalibrations. An Altus Spine representative will contact you when required.

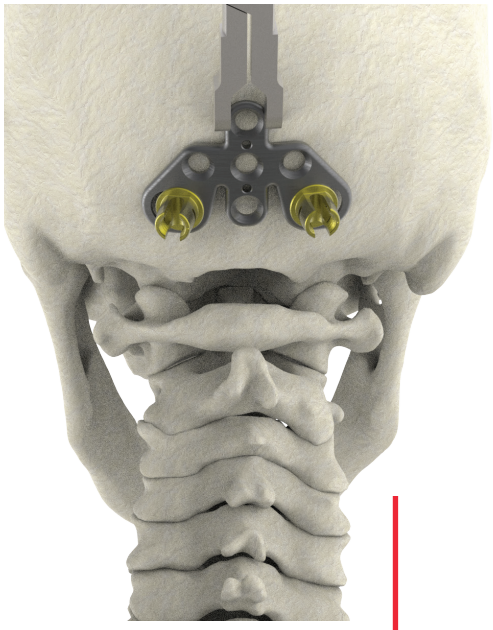


ADDITIONAL SURGICAL OPTION: OCCIPITAL PLATE

Occipital Plate Choice
The occipital plate available in the Sochi OCT System is used for occipital stabilization in conjunction with posterior cervico-thoracic fixation. The Sochi occipital plate is available in three sizes.
Select the appropriate occipital plate based on patient anatomy (plate sizes are measured from center of rod to center of rod: small 25-35mm, medium 31-41mm, large 38-48mm).



Note: Instruments marked with a green or purple band are for use with the **Occipital System**. The **Occipital Screw Driver** is marked with three colored bands (gold, purple and green) and is compatible with implants like colors (gold, purple and green). All screw drivers in the system are self-retaining.



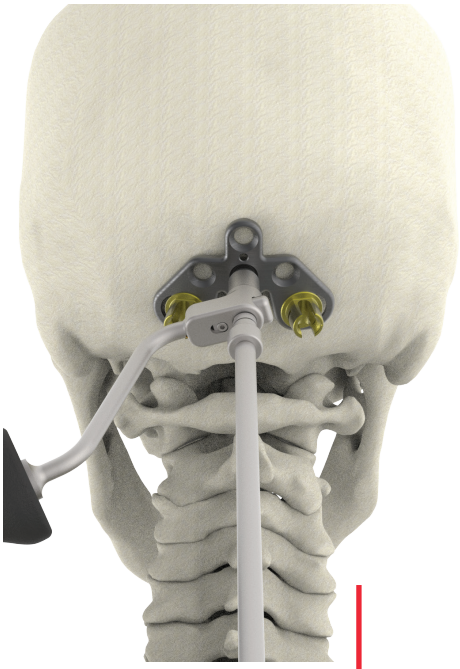
Occipital Plate Positioning
Place the occipital plate with the **Plate Holder** cranial of the foramen magnum and caudal of the external occipital protuberance. The occipital plate should lay flat on the occiput.
If desired, the occipital plate may be contoured to the occiput. Contour the occipital plate based on the anatomical geometry of the occiput using either the **Occipital Plate Bender** or the **Occipital Plate Bending Pliers**.

Note: The occipital plate should be oriented midline with the rod attachment points situated caudally.

Caution: No single bend should be greater than 20°! Do not unbend plates. Once the occipital plate has been contoured, set the plate on the occiput using the **Occipital Plate Holder**.

ADDITIONAL SURGICAL OPTION: OCCIPITAL PLATE (CONT.)

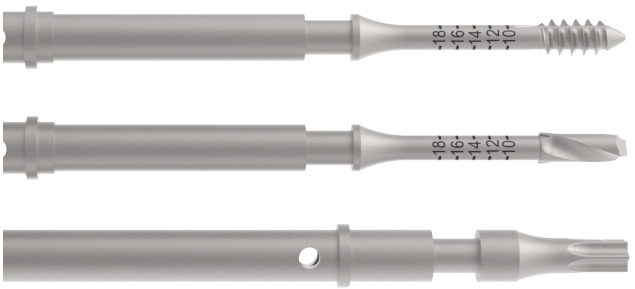
Drill Guide Positioning
Select the drill **Depth Stop** and insert the stop into the **Occipital Adjustable Drill Guide**. Depress the button on the distal end of the **Occipital Adjustable Drill Guide** and slide the Drill **Depth Stop** to the desired depth.



Screw Preparation
Insert the **Occipital Adjustable Drill Guide** into desired hole in the plate and remove the **Plate Holder** (the drill guide will hold the plate in place during the drilling process).
Attach the 4.0mm diameter **Occipital Drill** to the **Ratcheting Handle**. Insert the **Occipital Drill** through the **Occipital Adjustable Drill Guide** and drill hole until **Drill** contacts the **Depth Stop**.

Caution: The use of the **Drill** without the **Depth Stop** could lead to patient injury.

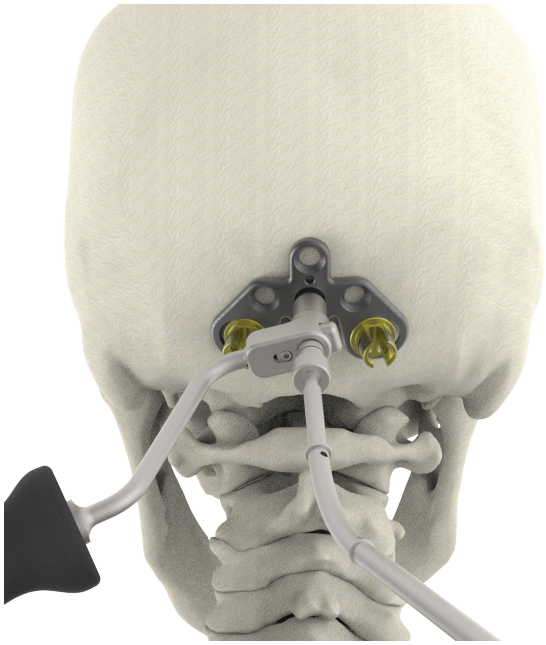
Flexible Instruments
In the event access is limited due to patient anatomy, use the 4.0mm diameter **Flexible Occipital Drill**. The flexible shaft is able to bend up to 90º. Insert the **Flexible Occipital Drill** through the **Occipital Adjustable Drill Guide** and drill hole until **Drill** contacts the **Depth Stop**.
Confirm depth of the hole using the **Bone Probe**. Once the hole is of desired depth continue with the procedure.
Attach the 4.0mm diameter **Occipital Tap** to the **Ratcheting Handle**. Insert the **Occipital Tap** through the **Occipital Adjustable Drill Guide** and tap the drilled hole until the **Tap** contacts the **Depth Stop**.



Note: In the case when it is unrealistic to use the **Adjustable Occipital Drill Guide** with the flexible instruments, attach the **Flexible Instrument Holder** to the **Flexible Occipital Drill** or **Tap** to use as a guide.

ADDITIONAL SURGICAL OPTION: OCCIPITAL PLATE (CONT.)

Tapping Using Flexible Instruments
In the event access is limited due to patient anatomy, use the 4.0mm diameter **Flexible Occipital Tap**. The flexible shaft is able to bend up to 90º. Insert the **Flexible Occipital Tap** through the **Occipital Adjustable Drill Guide** and tap hole until the **Tap** contacts the **Depth Stop**.
Select and confirm screw size and length with screw measuring gage provided. 4.0mm diameter primary screws and 4.5mm diameter rescue screws are available.



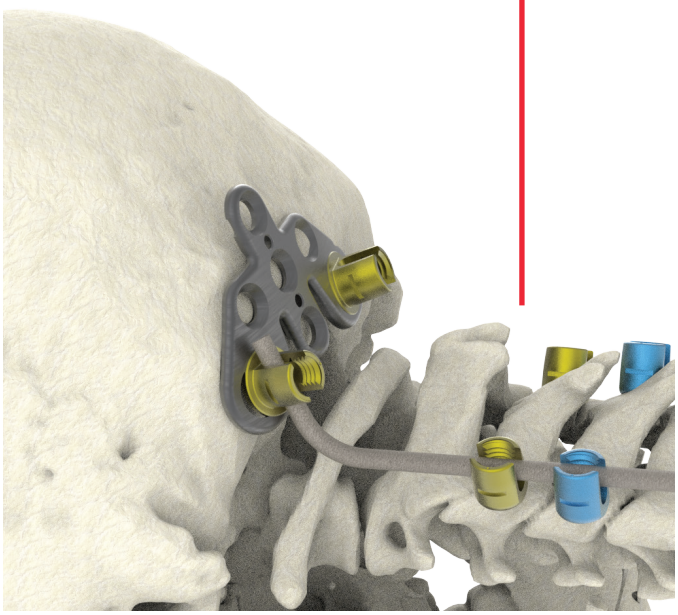
Screw Insertion
Attach the **Occipital Screw Driver** to the black **Ratcheting Handle**. Insert the screw until it is flush with and tight to the plate.
In the event access is limited due to patient anatomy, use the **Flexible Occipital Screw Driver**. The flexible shaft is able to bend up to 90º. The **Flexible Instrument Holder** may be attached to the **Flexible Occipital Screw Driver** to use as a guide for the instrument.

Note: Screws should be inserted flush with and tight to the plate to avoid screw backout.

ADDITIONAL SURGICAL OPTION: OCCIPITAL PLATE (CONT.)

Repeat steps for additional screws. A minimum of two screws is necessary to secure the plate to the occiput. Screws may be placed in any of the remaining holes, both midline and lateral. Screw holes in the plate allow screws to be inserted up to a 30º angle.

Rod Bending
Once the occipital plate is secured, the rod may be placed into the plate. A 110º pre-bent rod is available. If desired, the rod may be cut by following the rod cutting technique as shown in Step 4.



If a different bend angle is desired, the **Rod Bender** may be used by following the rod bending technique. The technique remains the same but the rod will extend up into the occipital plate.

If a sharper angle bend is desired, the **Rod Bender** can be used. Using the **Rod Bender**, bend the rod to the full extension of the **Rod Bender.** Then slide the **Rod Bender** 10mm down the rod and bend again to desired angle. This will create up to 100 degree bend in the rod.

If a sharper angle is still desired, the **Occipital Rod Bending Tubes** may be used. After bending the rod to the full extension of **Rod Bender**, slide **Occipital Rod Bending Tube** over the rod and bend it around the **Rod Bender's** anvil until the desired angle is achieved

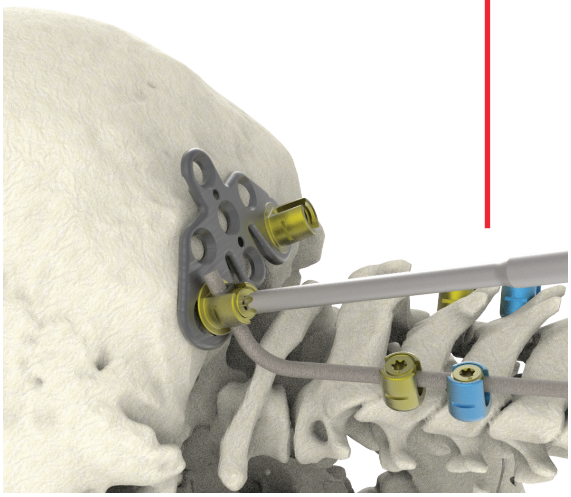
Note: When bending and cutting the rods, allow them to extend a minimum of 3mm past the seat on the occipital plate.

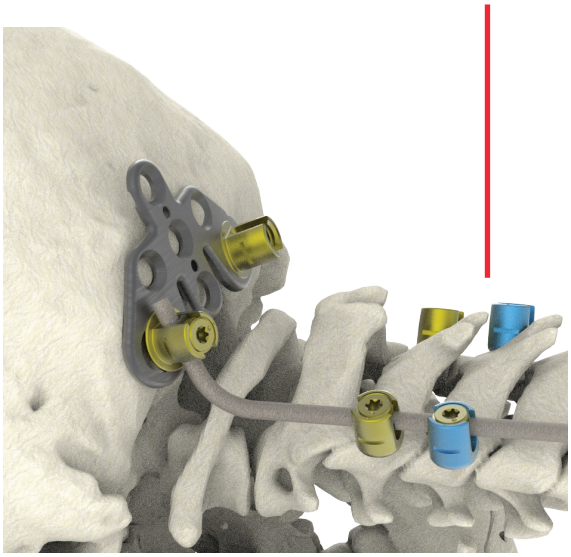
ADDITIONAL SURGICAL OPTION: OCCIPITAL PLATE (CONT.)

Locking Screw Assembly Insertion
Attach the **Occipital Screw Driver** to the **Ratcheting Handle**. Insert and provisionally tighten the **Locking Screw Assemblies** to secure the rods.

In the event access is limited due to patient anatomy, use the **Flexible Occipital Screw Driver**. The flexible shaft is able to bend up to 90°.
The **Flexible Instrument Holder** may be attached to the **Flexible Occipital Screw Driver** to use as a guide for the instrument.
Make any final adjustments to rod construct before final tightening.

Attach the **Occipital Screw Driver** or the **Flexible Occipital Screw Driver** to the gray **2.0 Nm Torque Limiting Handle**. Place the **Occipital Counter Torque Tube** over the rod and rod-seat to engage the rod in the **Counter Torque Tube**. Rotate the **Locking Screw Assemblies** clockwise until the **2.0 Nm Torque Limiting Handle** clicks.





ADDITIONAL SURGICAL OPTION: HOOKS

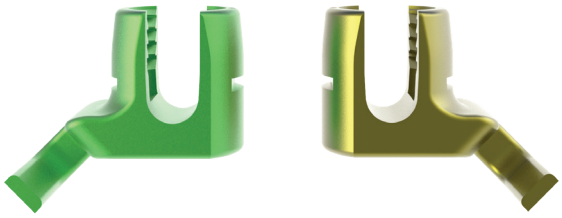


Inline (S, M, L)

Prepare pedicle or lamina for an inline or lateral offset lamina hook using a standard preparation technique.

Place Hook
Place the hook in the desired location utilizing the **Hook Holder**. The **Hook Impactor** may be used to facilitate placement of the hook.

Place Remaining Hooks
Repeat previous steps to place hooks as determined in the preoperative plan.



Offset Left

Offset Right

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info@altus-spine.com

www.altus-spine.com

CORPORATE HEADQUARTERS
1340 Enterprise Drive
West Chester, PA 19380
Office: (610) 355-4156 // Fax: (610) 300-3049

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