

Atoll™ OCT System

Surgical Technique

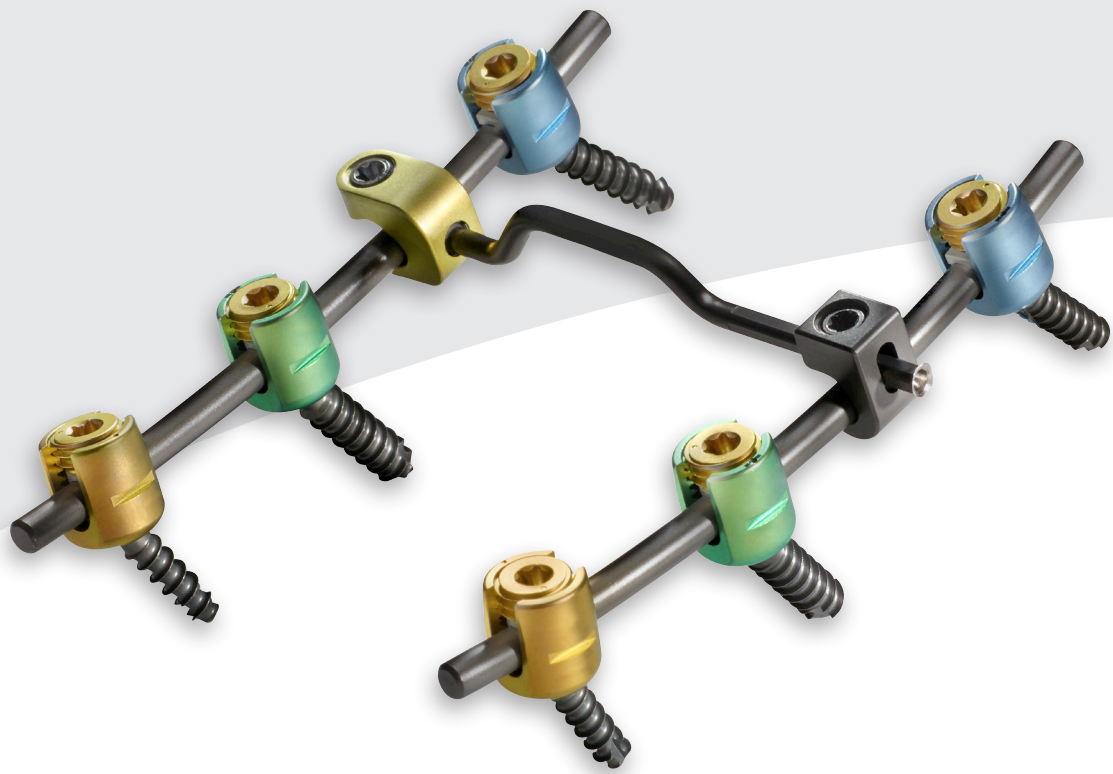


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Atoll™ Occipito-Cervico-Thoracic System

Design Rationale

The Atoll™ OCT exemplifies the company's commitment to their design philosophy; "Limit Uncertainty". The Atoll OCT contains minimal instruments, eight of which are multifunctional.

Surgeons agree; the simpler the instrumentation and fewer implants, the easier it is on the surgeon, support staff, and patient.

The Atoll OCT is comprised of polyaxial screws, hooks, rods, locking screw assemblies, and connectors. The system components may be rigidly locked together in a variety of configurations to promote fusion for a wide variety of patient anatomies.

System Features

Complete Cervical Fusion System (Occiput-T3) OC Plating:

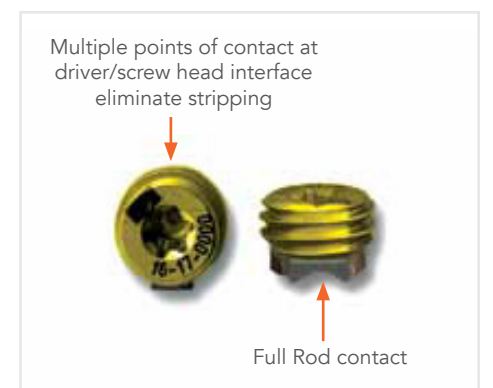
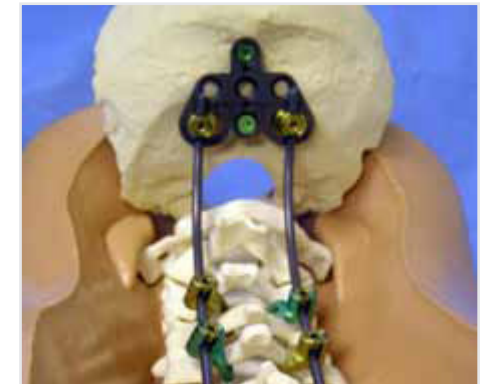
- Laminar Hooks
- Pedicle Screws
- Transverse Rod Connectors
- Low Profile Design
- Small screw/hook head diameter decreases facet joint impingement and provides more room for bone graft
- Minimal run on rod is good for C1-T3 fusions for fitting cross connectors
- Smaller overall profile enables better vision of the anatomy

Innovation Polyaxial Screw Design

- Polyaxial "friction head" screws
- Two screw diameter options: 3.5 mm and 4.0 mm
- Internal buttress thread reduces head splay
- 60° screw variability
- Self-tapping screw tip
- Smooth shaft poly-axial screws

Locking Screw Assembly

The pre-timed self-aligning locking screw assembly is designed to seat the rod consistently and securely in the optimal position within the screw/hook seat. The locking screw assembly virtually eliminates the possibility for cross threading.



Occipital Plate

- Three sizes, 25-48 mm adjustable rod separation
- 2.5 mm plate thickness, 10.0 mm overall height
- Attaches with a minimum of two occipital bone screws
- Bend zones enable plate to be contoured in saggital and coronal planes



Hooks

- Multiple hook profiles for use around the lamina, pedicle or transverse process
- Low-profile design minimizes soft tissue irritation
- Specialized lamina hooks for cervical and thoracic applications
- Lateral Offset hooks reduce need for rod contouring



Cross Connectors

- Straight, Arched and Head to Head designs
- Self contained system requires no assembly
- 20° pivoting heads eliminate the need for bending
- Adjustable sizes to fit widths from 25 - 70 mm



Rods

- 3.5 mm diameter Ti alloy rods
- Pre-cut lengths accommodate most applications
- 80 mm, 120 mm, and 240 mm
- 3.5 mm x 5.5 mm diameter Transition Rod
- Pre-lordosed rods (optional)



Offset Connector

- Provide up to 10 mm of flexibility in medial-lateral screw placement



Rod to Rod Connector

- Available in 3.5 mm/5.5 mm rod connections and 3.5 mm/3.5 mm rod connections
- Available in multiple profiles to better fit each patients anatomy

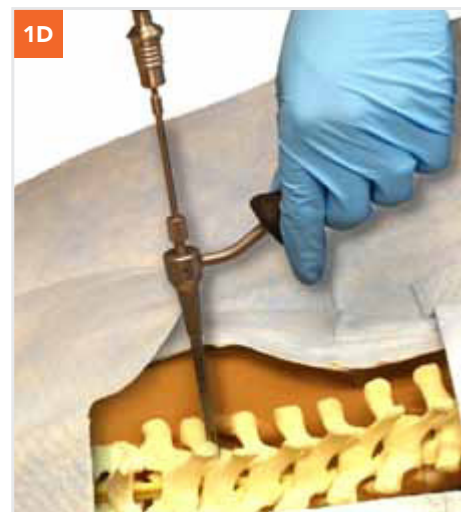


Surgical Technique

STEP 1

Pedicle Preparation

- 1A** Prepare the patient using a standard surgical approach.
Expose the spinous processes and laminae of the vertebrae to be fused.
- 1B Prepare Entry Point**
Once the entry point is determined, a pilot hole may be prepared with the **Awl** (16-40-0100). This will help to prevent displacement of the drill bit during initial insertion. The **Awl** has a 8 mm 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** (16-40-1300) allows for a single drill to be used for preparation of variable depths
- 1C** To set **Adjustable Drill Guide** depth, depress the adjustment button and slide depth stop to desired depth as indicated on the calibrated depth stop.
- 1D** To drill a hole, place the 3.5 mm or 4.0 mm **Drill** (16-40- 0235 & 16-40-0240) 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.
- ▶ **Caution:** The use of the **Drill** without the **Depth Stop** could lead to patient injury.



STEP 1

Pedicle Preparation continued

- 1E Prepare Entry Point**
If the surgeon prefers, the path may be prepared with the **Bone Probe** (16-40-0101). 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 calibrated and 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.
- 1F Verify Pathway**
Check the prepared pathway with the **Sound** (16-40-0300) 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 calibrated and 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.
- 1G Measure Pathway**
The depth of the drill hole can be confirmed using the **Depth Gauge** (16-40-0630). Insert the tip of the **Depth Gauge** into the drill hole until the tip contacts the bottom of the hole.



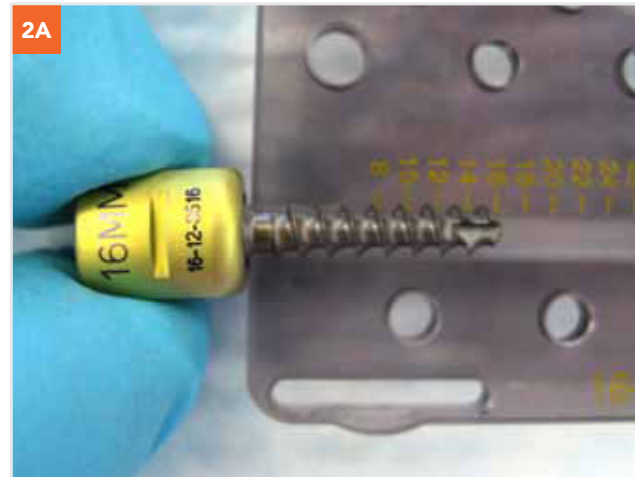
STEP 2**Pedicle Markers and Screw Selection****Verify Screw Diameter**

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

- Gold – 3.5mm
- Light Blue – 4.0mm

2A Verify Screw Length

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

**2B Tapping (Optional)****Tapping Technique**

Tapping is optional since the screws have a self-tapping starter tip. **Taps** (16-40-0435 & 16-40-0440) are undersized by 0.5mm from the screw diameter and are available for the 3.5mm and 4.0mm 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.

**STEP 3****Screw Insertion****3A Attach**

Insert the **Polyaxial Screw Inserter** (16-40-0701) into the drive mechanism in the screw.

- ▶ **Note:** For standard fixed screws use standard screw inserter (16-40-0702).

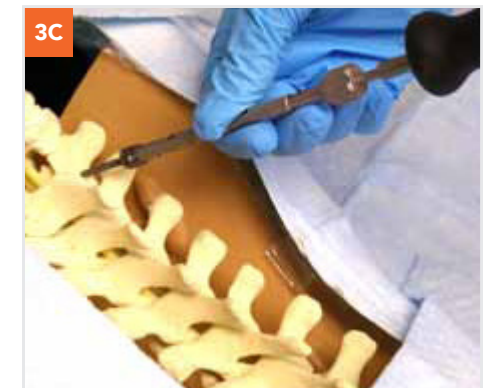
**3B Lock**

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.

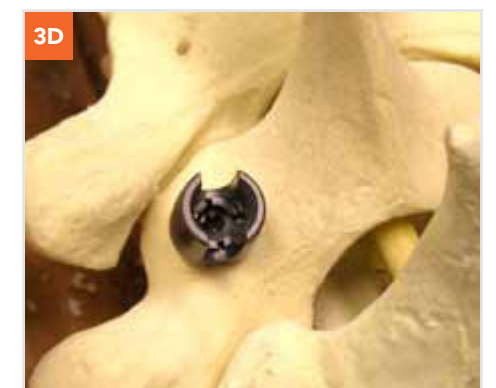
**3C Insert**

To insert the screw into the pedicle, apply a gentle downward force to the **Polyaxial Screw Inserter** and rotate the Inserter clockwise.

**3D**

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.



STEP 4 Hook Placement

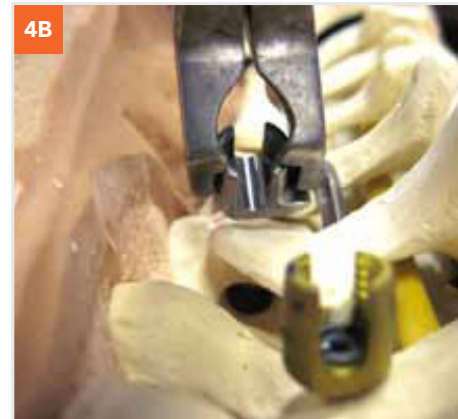
4A Prepare pedicle or lamina for an inline or lateral offset lamina hook using a standard preparation technique.

4B Place Hook

Place the hook in the desired location utilizing the **Hook Holder** (16-40-0802). The **Hook Impactor** (16-40-0801) may be used to facilitate placement of the hook.

Place Remaining Hooks

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



STEP 5 Rod Insertion

5A Determine Spinal Curve Configuration

Prior to inserting the rods, verify the cervical and/or thoracic configuration of the spine. Place the **Rod Template** (16-40-0903) into the screw/hook seat and mold the template by bending it to fit.

5B Rod Bending

Remove the **Rod Template** and choose the appropriate length pre-cut rod. Bend the rod (if necessary) using the **Rod Bender** (16-40-0901) to match the **Rod Template**.

► **Note:** Multiple bends in rods can be performed in one direction only.

Rod Cutting

The rod length may be altered using the **In-Situ Cutter** (16-40-0909). 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 rod is cut.

5C Insert

Once the rod is bent to the desired contour, the **Rod Cross Connector Holder** (16-40-0904) or the **Rod Pusher** (16-40-0905) may be used to place the rod into the screw/hook seat. If the rod is not firmly placed in the screw/hook seat, follow the **Rod Reduction** technique on step 7, page 12 .



STEP 6**Locking Screw Assembly Insertion****6A Attach**

Attach the **Locking Screw Assembly** to the tip of the self-retaining **Locking Screw Inserter** (16-40-1201) and insert the **Locking Screw Assembly** into the screw/hook seat.

► **Note:** The Locking Screw Inserter has a gold band to match the Locking Screw Assembly.

6B Position

If the laser etch marks are not lined up, turn the **Locking Screw Assembly** counterclockwise until the timing marks on the **Locking Screw Assembly** and screw/hook seat line up. In this position, the threads are pre-timed to align automatically and thereby minimize the chance of cross threading.

6C 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/hook seat. This will help resist the reaction forces generated by the final tightening maneuvers.

► **Caution:** Extra caution advised when:

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

**STEP 6****Locking Screw Assembly Insertion continued****Locking Screw Assembly Insertion (Optional Technique)****6D Attach**

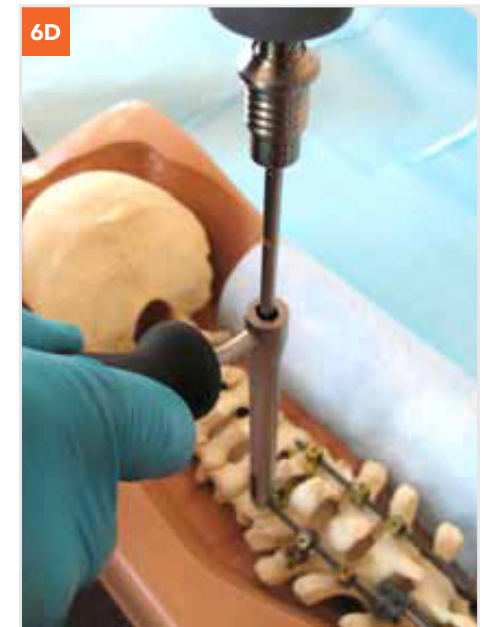
Place **Alignment/Counter Torque Tube** (16-40-1100) over the screw/hook head. Attach the **Locking Screw Assembly** on the tip of the self-retaining **Locking Screw Inserter** and insert the **Locking Screw Assembly** into the **Alignment/Counter Torque Tube**, using it as your guide for accurate screw placement.

Position

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

6E Tighten

Loosely tighten the **Locking Screw Assembly** down into the screw/hook 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/hook seat. This will help resist the reactive forces generated by the final tightening maneuvers.



STEP 7 Rod Reduction

7A Persuasion

Use the **Rod Persuader** (16-40-0906) when additional physical assistance is required to ease the rod to the screw/ hook seat. The Rod Persuader pushes the rod into the screw/hook seat and then is used to guide the **Locking Screw Assembly**.

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

7B Attach the Locking Screw Assembly to the self-retaining Locking Screw Inserter. Insert the Locking Screw Assembly through the Rod Persuader, into the screw/hook seat.

Loosely tighten the **Locking Screw Assembly**.

Disengage the **Rod Persuader** from the screw/hook seat and repeat as necessary.



STEP 8 Distraction/Compression

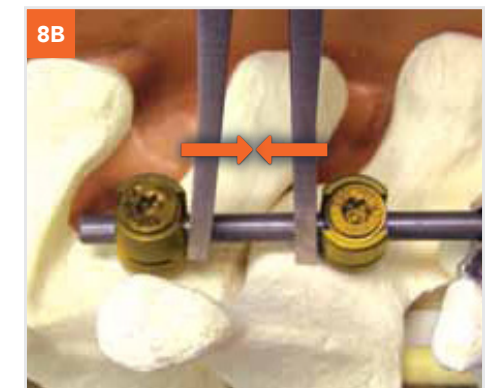
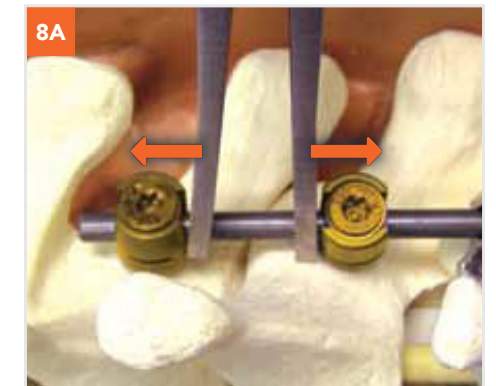
Loosen the **Locking Screw Assembly** of the level to be adjusted.

8A Use the Distractor (16-40-1002) around the rod to achieve distraction.

8B Use the Compressor (16-40-1001) to achieve compression.

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

Repeat for each segment as required.



STEP 9 Final Tightening

Attach the **Locking Screw Inserter** to the **Torque Limiting Handle** (16-40-1202).

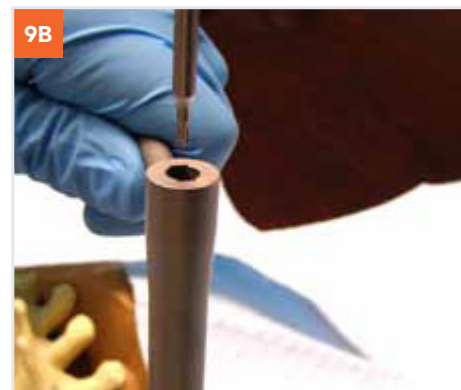
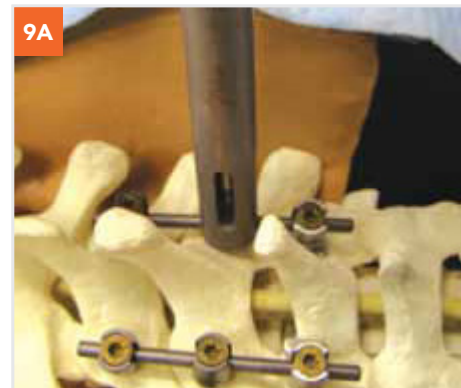
► **Note:** The **Torque Limiting Handle** is grey.

9A Place the **Alignment/Counter Torque Tube** over the screw/hook seat.

9B Insert the **Locking Screw Inserter** and **Torque Limiting Handle** assembly into the **Alignment/Counter Torque Tube**.

9C Firmly hold the **Torque Limiting Handle** and perform final tightening of the **Locking Screw Assembly** until the **Torque Limiting Handle** "clicks".

► **Note:** **Torque Limiting Handles** require periodic recalibrations. A SeaSpine representative will contact you when required.



STEP 10 Cross Connector Options

It is recommended to use cross connectors to increase the rotational stability of the construct. Trimming of the spinous process may be required if a **Cross Connector** is used.

Choose the appropriate **Cross Connector** (straight, arched, or head to head).

Choose the appropriate **Cross Connector** length.

If desired, the **Cross Connector** may be bent to accommodate divergent rods or screw/hook heads.

10A Head to Head Connectors

The head to head **Cross Connector** are intended to be used in situations where the screw heads are too close to allow for placement of the straight or arched rod to rod cross connector.

10B ► **Note:** The **Locking Screw Inserter** has a gold band to match the **Locking Screw Assembly**.

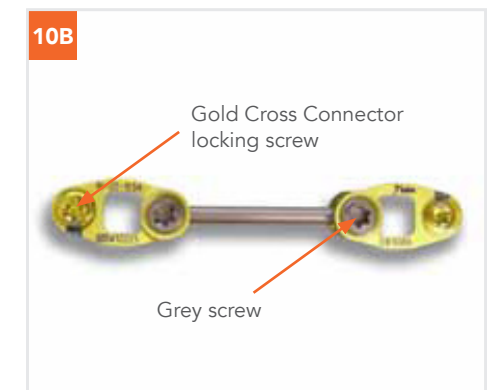
Ensure that the laser etch line on the gold cross connector locking screw lines up with the laser etch band on the gold pivoting head. Push each end of the cross connector over the desired screw head until an audible "snap" is heard.

Attach the **Torque Limiting Handle** to the **Cross Connector Inserter**.

Turn the golden screws on the **Cross Connector** such that the laser marks are 180° (opposite) each other.

Tighten the grey screws using slight force.

To remove, complete steps in reverse order.



STEP 11**Cross Connector Insertion****10A Straight and Arched Connectors**

Attach the **Cross Connector** locking screws to the two self retaining **Cross Connector Inserters** (16-40-1500), using the driver shafts only (do not attach driver handles).

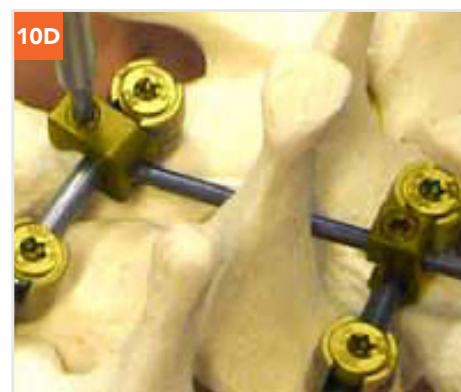
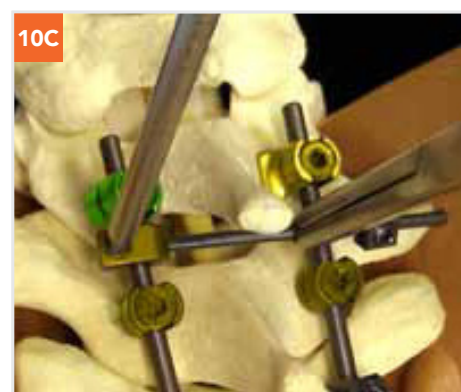
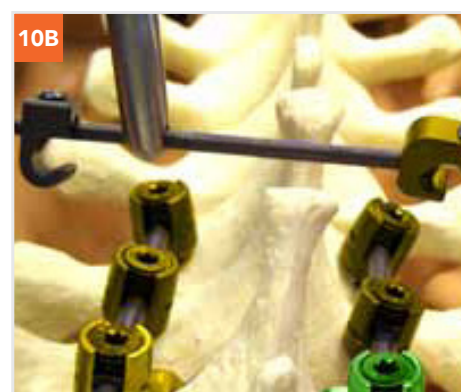
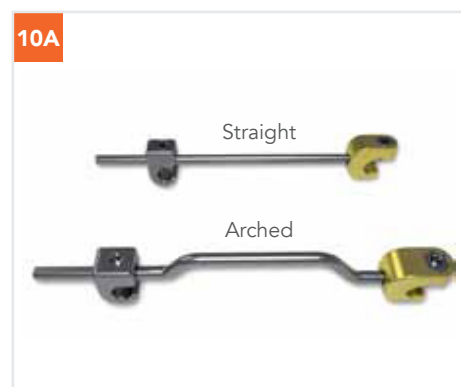
10B Place the grey head onto the rod first, then slide the gold head into position on the opposite rod. If either **Cross Connector** head will not slide onto the rod, turn the locking screw counterclockwise until the connector head slides onto the rod.

10C Loosely tighten the locking screws on the **Cross Connector** with the **Cross Connector Inserter**.

The **Torque Limiting Handle** (16-40-1202) may now be attached to the **Cross Connector Inserter**.

10D Rotate the **Torque Limiting Driver** clockwise until an audible "click" is heard.

Repeat for all remaining **Cross Connector** screws.

**STEP 12****Occipital Plate Insertion****12A Occipital Plate Choice**

The occipital plate available in the Atoll™ OCT System is used for occipital stabilization in conjunction with posterior cervicothoracic fixation. The Atoll occipital plate is available in three sizes. It is contained in a separate set called "OCT".

Select the appropriate occipital plate based on patient anatomy (plate sizes are measured from center of rod to center of rod; small 25-35 mm, medium 31-41 mm, large 38-48 mm).

► **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.

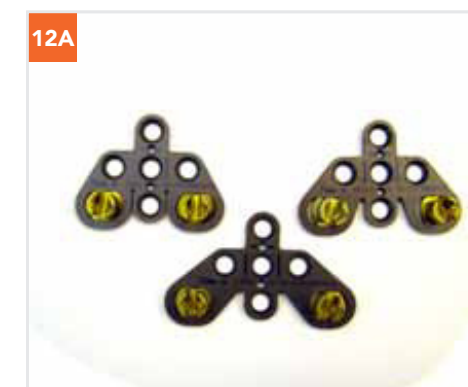
12B Occipital Plate Positioning

Place the occipital plate with the **Plate Holder** (16-40-3300) 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** (16-40-3500) or the **Occipital Plate Bending Pliers** (16-40-3525).

► **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**.



STEP 12**Occipital Plate Insertion** continued**12C Drill Guide Positioning**

Select the drill **Depth Stop** and insert the stop into the **Occipital Adjustable Drill Guide** (16-40-3200). Depress the button on the distal end of the **Occipital Adjustable Drill Guide** and slide the **Drill Depth Stop** to the desired depth.

12D 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).

Attached the 4.0mm diameter **Occipital Drill** (16-40-3000) to the **Ratcheting Handle** (16-40-1400). 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.

12E Flexible Instruments

In the event access is limited due to patient anatomy, use the 4.0mm diameter **Flexible Occipital Drill** (16-40-3001). The flexible shaft is able to bend up to 90°. 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** (16-40-0101). Once the hole is of desired depth continue with the procedure.

Attach the 4.0mm diameter **Occipital Tap** (16-40-3100) 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** (16-40-3350) to the **Flexible Occipital Drill** or **Tap** to use as a guide for the instruments.

12F Tapping

In the event access is limited due to patient anatomy, use the 4.0mm diameter **Flexible Occipital Tap** using flexible instruments 16-40-3101. The flexible shaft is able to bend up to 90°. Insert the **Flexible Occipital Tap** through the **Occipital Adjustable Drill Guide** and tap hole until the **Tap** contacts the **Depth Stop**.

**STEP 12****Occipital Plate Insertion** continued

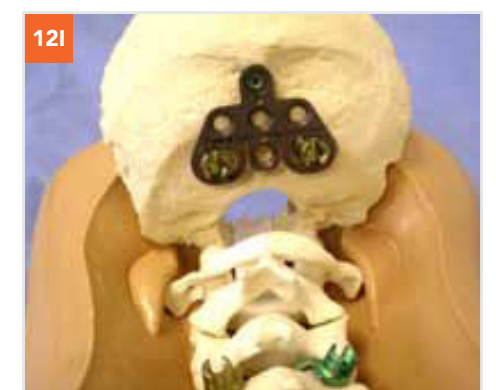
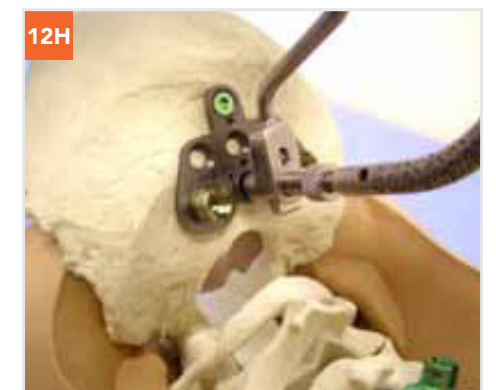
12G Select and confirm screw size and length with screw measuring gage provided. 4.0 mm diameter primary screws and 4.5mm diameter rescue screws are available.

12H Screw Insertion

Attach the **Occipital Screw Driver** (16-40-3400) to the black **Ratcheting Handle**. Insert the screw until it is flush with and tight to the plate.

12I In the event access is limited due to patient anatomy, use the **Flexible Occipital Screw Driver** (16-40-3450). 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.

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



STEP 12**Occipital Plate Insertion** continued

- 12J** 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 30° angle.

Rod Bending

Once the occipital plate is secured, the rod may be placed into the plate. A 110° pre-bent rod is available. If desired the rod may be cut by following the rod cutting technique section 8 page 12.

- If a different bend angle is desired, the **Rod Bender** (16-40-0901) 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** 10 mm down the rod and bending 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** (16-40-3550) may be used. After bending the rod to the full extension of **Rod Bender**, slide **Occipital Rod Bending Tube** over the rod and bending it around the **Rod Bender's** anvil on until the desired angle is achieved

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

**STEP 12****Occipital Plate Insertion** continued**12K Locking Screw Assembly Insertion**

Attach the **Occipital Screw Driver** (16-40-3400) to the **Ratcheting Handle**. Insert and provisionally tighten the **Locking Screw Assemblies** to secure the rods.

- 12L** In the event access is limited due to patient anatomy, use the **Flexible Occipital Screw Driver** (16-40-3450). The flexible shaft is able to bend up to 90°.

- 12M** The **Flexible Instrument Holder** (16-40-3350) 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** (16-40-3400) or the **Flexible Occipital Screw Driver** (16-40-3450) to the grey **Torque Limiting Handle**. Place the **Occipital Counter Torque Tube** (16-40-3600) over the rod and rod-seat to engage the rod in the **Counter Torque Tube**. Rotate the **Locking Screw Assemblies** clockwise until the **Torque Limiting Handle** clicks.



STEP 13**Screw Preparation and Insertion (Optional Technique)****13A Triple Barrel Drill Guide – optional**

The **Triple Barrel Drill Guide** (16-40-3250) allows for drilling, tapping, and screw insertion without removal of the **Drill Guide**. The **Triple Barrel Drill Guide** acts as a plate holder, eliminating the need for an additional instrument.

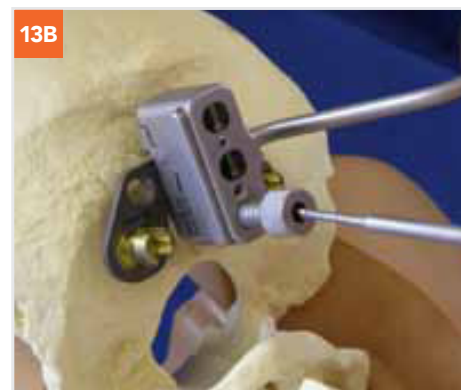
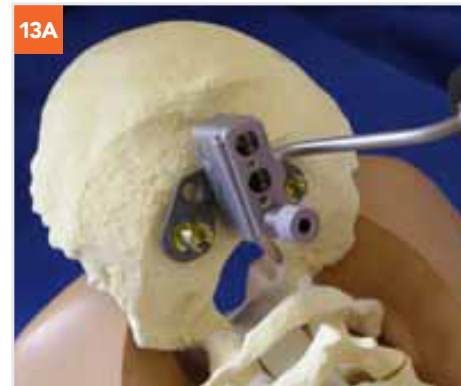
13B Screw Preparation

Attach **Triple Barrel Drill Guide** to the **Occipital Plate** in lieu of the plate holder and **Drill** and **Tap** as stated above in the technique.

Screw Insertion

In order to insert the **Occipital Screws** through the **Triple Barrel Drill Guide**, simply depress the large button on the side of the **Triple Barrel Drill Guide** and remove the **Depth Stop**. The **Occipital Screw** can be inserted into the **Occipital Plate** as described above.

13C Once all **Occipital Screws** are placed, remove the **Triple Barrel Drill Guide** by depressing the small button on the side of the **Triple Barrel Drill Guide** and removing the **Triple Barrel Drill Guide**.

**Additional Surgical Options****Transition Rods**

Transition Rods are available to link the Atoll™ OCT with the Coral Spinal System. Transition Rods (385mm length) are offered in the 3.5mm/5.5mm diameter (215mm long for the 5.5 mm diameter and 170mm long for the 3.5mm diameter) to accommodate both systems. Additionally, the transition rods contain an octagon feature which occur repeatedly down the rod to aid in rod positioning.

Rod to Rod Connectors

Rod to Rod connectors are available in 3.5 mm/5.5 mm sizes to link the Atoll OCT to the Coral System. Slightly loosen the set screws in the rod to rod connectors by inserting the self-retaining Set Screw Driver and rotating it counterclockwise. The set screws are loose when the spinal rods slide easily into the connector. Slide the spinal rods into the rod to rod connector and provisionally tighten the set screws with the self retaining screw inserter.

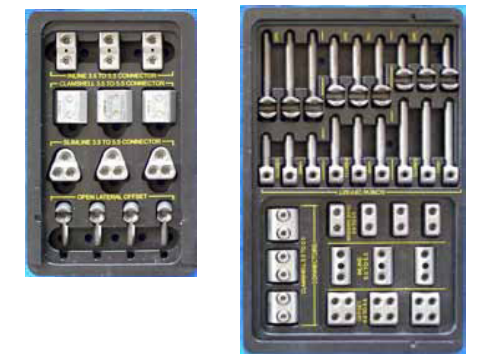
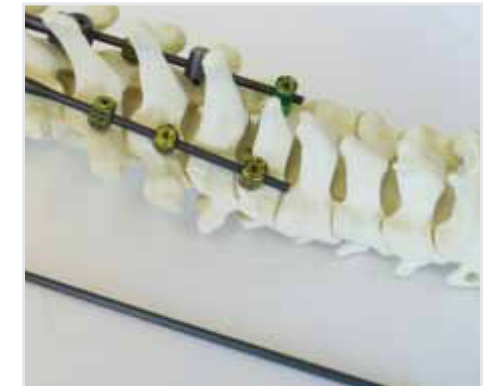
Clamshell Connectors (Open Connector Technique)

Remove both screws in the clamshell connector by inserting the self-retaining set screw inserter and rotating it counterclockwise. Remove the top half of the clamshell.

Thread the Clamshell Inserter (16-40-1700) into one of the screw holes in the bottom half of the clamshell. Using the

Clamshell Inserter, place the clamshell in the desired location underneath the spinal rod. Slide the top half of the clamshell over the clamshell inserter and slide it down until the top half of the clamshell contacts the spinal rod and aligns with bottom half of the clamshell.

Using the self-retaining Set Screw Inserter, thread one of the clamshell screws into the open hole in the clamshell and provisionally tighten the screw. Once the first screw is in place, remove the Clamshell Inserter, and insert the second screw. Provisionally tighten the screw and confirm positioning of the implants.



Additional Surgical Options continued

Connector Final Tightening

Perform final tightening by attaching the Connector Final Driver (16-40-1601) (orange bands) to the grey Torque Limiting Handle (orange bands) and rotating clockwise until an audible click is heard and tension is released within the handle.

Offset Connectors

In cases where the patient's anatomy requires significantly different medial or lateral screw positions, offset connectors may be utilized to facilitate rod attachment. The offset will allow for approximately 10 mm offset from the axial alignment. If desired the offset can be shortened in the same manner as the spinal rod by using the rod/cross connector cutter as described previously.

Using the Locking Screw Assembly Inserter, loosely attach the offset head to the spinal rod. Insert the offset rod into head of the standard or polyaxial screw. Insert the locking screw assembly into the head of the standard/polyaxial screw as described previously in the surgical technique to attach the lateral offset to the standard/polyaxial screw.

Perform final tightening of both the lateral offset and the locking screw assembly by attaching the locking screw assembly inserter to Torque Limiting Handle and rotating clockwise until an audible "click" is heard and tension is released within the handle.



Ordering Information

3.5 Polyaxial Screws

Catalog Number	Description
16-12-3508	3.5 x 8 mm poly screw assembly
16-12-3510	3.5 x 10 mm poly screw assembly
16-12-3512	3.5 x 12 mm poly screw assembly
16-12-3514	3.5 x 14 mm poly screw assembly
16-12-3516	3.5 x 16 mm poly screw assembly
16-12-3518	3.5 x 18 mm poly screw assembly
16-12-3520	3.5 x 20 mm poly screw assembly
16-12-3522	3.5 x 22 mm poly screw assembly
16-12-3524	3.5 x 24 mm poly screw assembly
16-12-3526	3.5 x 26 mm poly screw assembly
16-12-3528	3.5 x 28 mm poly screw assembly

4.0 Polyaxial Screws

Catalog Number	Description
16-12-4008	4.0 x 8 mm poly screw assembly
16-12-4010	4.0 x 10 mm poly screw assembly
16-12-4012	4.0 x 12 mm poly screw assembly
16-12-4014	4.0 x 14 mm poly screw assembly
16-12-4016	4.0 x 16 mm poly screw assembly
16-12-4018	4.0 x 18 mm poly screw assembly
16-12-4020	4.0 x 20 mm poly screw assembly
16-12-4022	4.0 x 22 mm poly screw assembly
16-12-4024	4.0 x 24 mm poly screw assembly
16-12-4026	4.0 x 26 mm poly screw assembly
16-12-4028	4.0 x 28 mm poly screw assembly

Locking Screw Assembly

Catalog Number	Description
16-17-0000	Locking screw assembly

Rod

Catalog Number	Description
16-18-0080	3.5 mm x 80 mm Rod
16-18-0120	3.5 mm x 120 mm Rod
16-18-0240	3.5 mm x 240 mm Rod

Hooks

Catalog Number	Description
16-21-0205	Inline Hook (Medium)
16-21-0206	Inline Hook (Large)
16-21-1805	Offset Hook Left (Medium)
16-21-1905	Offset Hook Right (Medium)

Cross Connectors

Catalog Number	Description
16-22-0000	Rod To Rod Cross Connector
16-22-4535	Arched Rod To Rod Cross Connector 45-35 mm assembly
16-22-5545	Arched Rod To Rod Cross Connector 55-45 mm assembly
16-22-6555	Arched Rod To Rod Cross Connector 65-55 mm assembly
16-22-1034	Head to head connectors 25-34 mm assembly
16-22-1041	Head to head connectors 32-41 mm assembly
16-22-1048	Head to head connectors 39-48 mm assembly
16-22-1055	Head to head connectors 46-55 mm assembly

Other Instruments

Catalog Number	Description
16-40-0100	Awl
16-40-0101	Bone Probe
16-40-0235	3.5 mm Drill
16-40-0240	4.0 mm Drill
16-40-0300	Sound
16-40-0435	3.5 mm Tap
16-40-0440	4.0 mm Tap
16-40-0630	Depth Gauge
16-40-0702	Head Positioner/Standard Screw Inserter
16-40-0701	Polyaxial Screw Inserter
16-40-0901	3.5 mm/2.5 mm Rod Benders
16-40-0903	Rod Template
16-40-0904	Rod/Cross Connector Holder
16-40-0906	Rod Persuader
16-40-0905	Rod Pusher
16-40-1001	Compressor – Around the Rod
16-40-1002	Distractor – Around the Rod
16-40-1100	Counter Torque Tube
16-40-1201	Set Screw Inserter/Final Torque Driver
16-40-1202	Torque Limiting Driver
15-40-1300	Adjustable Drill Guide
16-40-1400	Axial Ratcheting Handle W/AO Quick Coupling
16-40-1500	Cross Connector Inserter

Ordering Information continued

Occipital Plates

Catalog Number	Description
16-30-2535	Small Occipital Plate - 25-35 mm
16-30-3141	Medium Occipital Plate - 31-41 mm
16-30-3848	Large Occipital Plate - 38-48 mm

4.0mm Occipital Screws

Catalog Number	Description
16-32-4006	4.0 x 6 mm Self-Tapping Occipital Screw
16-32-4007	4.0 x 7 mm Self-Tapping Occipital Screw
16-32-4008	4.0 x 8 mm Self-Tapping Occipital Screw
16-32-4009	4.0 x 9 mm Self-Tapping Occipital Screw
16-32-4010	4.0 x 10 mm Self-Tapping Occipital Screw
16-32-4011	4.0 x 11 mm Self-Tapping Occipital Screw
16-32-4012	4.0 x 12 mm Self-Tapping Occipital Screw
16-32-4013	4.0 x 13 mm Self-Tapping Occipital Screw
16-32-4014	4.0 x 14 mm Self-Tapping Occipital Screw
16-32-4015	4.0 x 15 mm Self-Tapping Occipital Screw
16-32-4016	4.0 x 16 mm Self-Tapping Occipital Screw

4.5 Occipital Screws

Catalog Number	Description
32-4508	4.5 x 8 mm Self-Tapping Occipital Screw
32-4510	4.5 x 10 mm Self-Tapping Occipital Screw
32-4512	4.5 x 12 mm Self-Tapping Occipital Screw
32-4514	4.5 x 14 mm Self-Tapping Occipital Screw
32-4516	4.5 x 16 mm Self-Tapping Occipital Screw
32-4518	4.5 x 18 mm Self-Tapping Occipital Screw
32-4520	4.5 x 20 mm Self-Tapping Occipital Screw
32-4522	4.5 x 22 mm Self-Tapping Occipital Screw
32-4524	4.5 x 24 mm Self-Tapping Occipital Screw
32-4526	4.5 x 26 mm Self-Tapping Occipital Screw
32-4528	4.5 x 28 mm Self-Tapping Occipital Screw
16-30-0170	3.5 mm x 170 mm Pre-bent Occipital Rod 110 degrees

Occipital Instruments

Catalog Number	Description
16-40-3000	4.0 mm Occipital Drill
16-40-3001	4.0 mm Flexible Occipital drill
16-40-3100	4.0 mm Occipital Tap
16-40-3101	4.0 mm Flexible Occipital Tap
16-40-3103	Occipital Plate Holding Pin
16-40-1400	Atoll Ratcheting Handle
16-40-3200	Adjustable Drill Guide
16-40-3300	Plate Holder
16-40-3350	Flexible Instrument Holder
16-40-3400	Occipital Screw Driver
16-40-3450	Flexible Occipital Screw Driver
16-40-3500	Occipital Plate Bender
16-40-3525	Occipital Plate Bending Pliers
16-40-3550	Occipital rod bending tube
16-40-3600	Occipital Counter Torque Tube

Transition Implants

Catalog Number	Description
16-18-0000	3.5 mm / 5.5 mm Transition Rod
16-23-5520	Inline 3.5 mm / 5.5 mm Connector Assembly
16-23-5530	Clamshell 3.5 mm to 5.5 mm Connector Assembly
10-23-0130	INLINE 5.5 mm / 5.5 mm Connector Assembly
10-23-0110	Wedding band connector 5.5 mm to 5.5 mm
10-23-0120	Clamshell connector 5.5 mm to 5.5 mm
16-23-5540	Slimline 3.5 mm to 5.5 mm Connector Assembly
16-24-0020	Open Lateral Offset
10-24-1120	Screw Offset Closed 20 mm
10-24-1130	Screw Offset Closed 30 mm
10-24-1140	Screw Offset Closed 40 mm
10-24-1420	Screw Offset Open 20 mm
10-24-1430	Screw Offset Open 30 mm
10-24-1440	Screw Offset Open 40 mm
16-40-1601	Connector Final Driver
16-40-1602	Connector Torque Handle
16-40-1700	Clamshell Insertter
16-40-1800	Screw Set Insertter

Indications for Use

The Atoll™ OCT Spinal System is indicated to promote fusion of the occipito-cervico-thoracic regions of the spine (Occiput– T3). The intended indications are as follows:

- Degenerative Disc Disease (as identified by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Tumors
- Pseudoarthrosis
- Atlanto/axial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical and upper thoracic spine surgery

The occipital bone screws are limited to occipital fixation only. The use of the screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. Screws are not intended for use in the cervical spine. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine. The Atoll OCT Spinal System can also be linked to the Theken Spine Coral Spinal System with the use of transitional rods and rod connectors.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, active infection at the site or certain metabolic disorders affecting osteogenesis.

- Insufficient quality of bone, which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit, which places an unusually heavy load on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system, which can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. If material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

As the manufacturer of this device, SeaSpine Orthopedics does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.



Caution: federal law restricts this device to sale by or on the order of a physician or practitioner.



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