

Sierra™ OCT System

Surgical Technique



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Sierra™ Occipito-Cervico-Thoracic Fixation System

Design Rationale

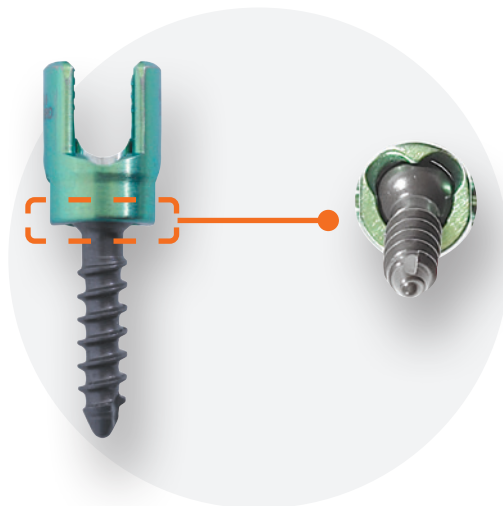
SeaSpine designed the Sierra™ instrument/implant system for posterior cervical fixation. Utilizing the same patented locking cap concept as the Malibu™ system, Sierra offers numerous size and implant options for high clinical versatility.



System Features

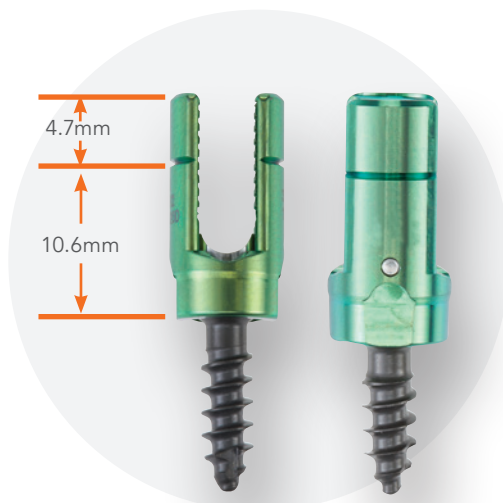
Self-Tapping Polyaxial Screws

- Low profile
- Two preferred angle notches provide maximum screw trajectory of 45° in one direction
- Lag screws standard in system
- 3.5, 4.0 and 4.5mm diameter screw options



Extended Tab Screws

Sierra Extended Tab screws provide an additional 5mm sleeve for easy, sequential rod capture and reduction in the upper thoracic spine.



3.5mm Precontoured Rods

- Laser marked to confirm orientation of lordotic curve



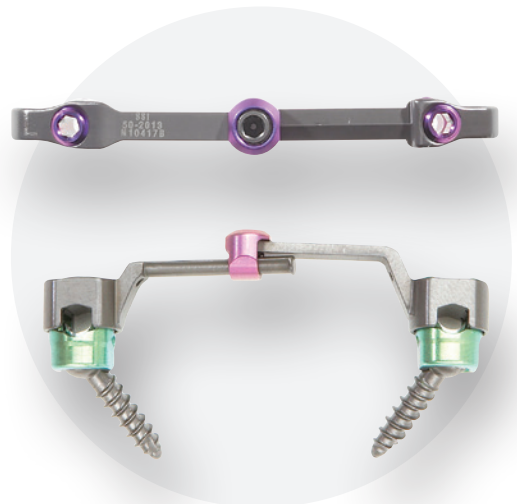
Locking Cap

- Integrated cap and set screw prevents tulip head splay
- Buttress thread concept minimizes cross threading
- Cap actively persuades rod and aligns set screw with tulip



CrossBar

- Telescopes, pivots and rotates for maximum adjustability
- Contoured design for exceptional anatomic fit
- S2S (screw-to-screw) CrossBar option for cases with limited rod space



Occipito-Cervico-Thoracic Options

- Hooks for cervical laminae
- Complete line of lateral and rod connectors
- Transitional rods



Occipital System

- Multiple occipital plate footprints
 - Occipital rods offered in 60°, 75° and 90° configurations
- **Note:** For Occipital surgical technique see document D0000438.

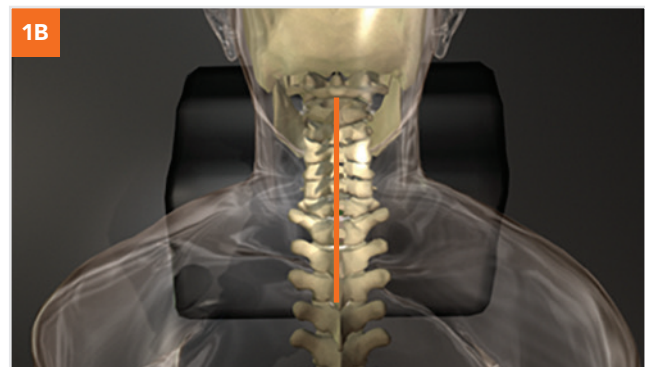
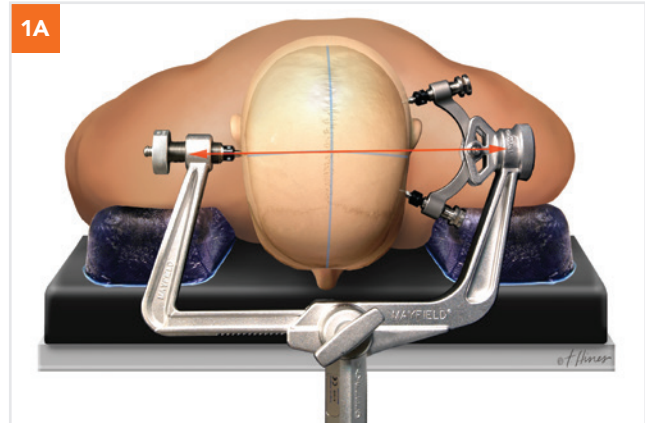


Surgical Technique

STEP 1

Patient Positioning

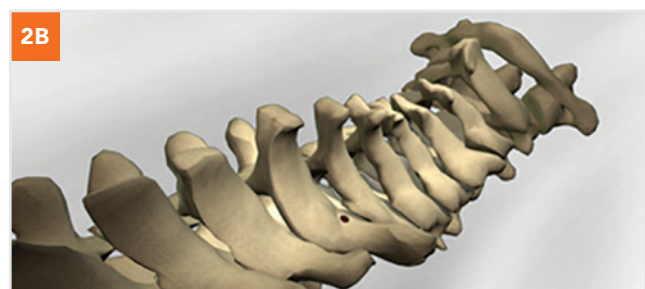
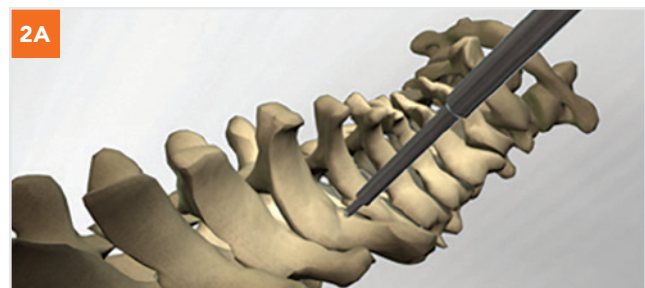
- 1A** The illustration on the right shows the patient on the operating table in the prone position. The head and neck held securely with the **MAYFIELD® Skull Clamp** holding the occiput and the cervical spine in alignment.
- 1B** It is recommended that an intra-operative scan is taken to confirm alignment. Accurate positioning is important when fixing the occiput to the cervical and thoracic spine.
- A midline incision is made and dissection is completed down to the appropriate vertebrae.



STEP 2

Awl and Probe

- 2A** Once the entry point and trajectory for the screw are determined, the **Awl** (95-0110) is used to penetrate the cortical bone and create a starting hole. A **Probe** (95-0143) is provided standard in the set to assist in creating the screw path.



STEP 3

Drill

Drills are provided in a variety of lengths:

- 10mm – 18mm (2mm increments)
- Variable Drill (20mm – 50mm)

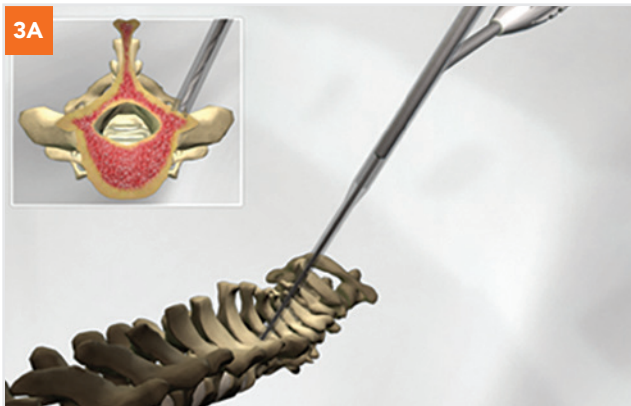
The drills have a **Quick Connect** fitting to attach to the **Modular Handle** (95-0104).

3A

Fixed Length Drills:

To drill a hole, select the appropriate **Drill** length, place the **Drill Bit** into the barrel of the **Drill Guide** (95-0112) and apply downward pressure while turning the **Drill** clockwise until the stop of the **Drill** shaft contacts the **Guide**.

3A

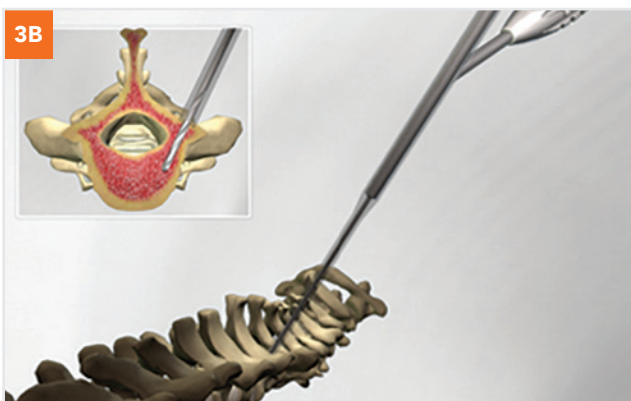


3B

Variable Drill:

Use the **Variable Drill** (95-0121) for drilling holes greater than 18mm in depth. The **Drill** features markings to indicate depth when used with the **Drill Guide**. Etching on the **Drill** indicates depth when the number corresponding to the desired length matches up with the top of the **Drill Guide**.

3B



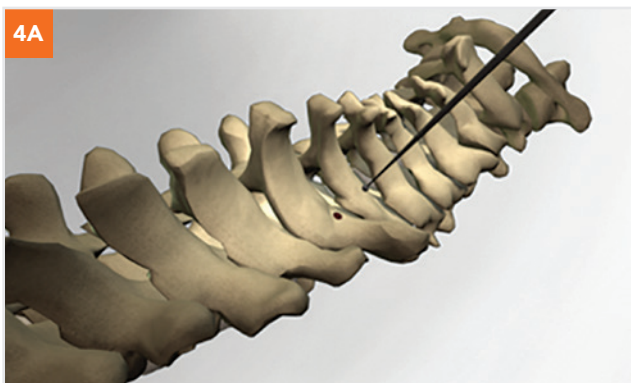
STEP 4

Verify Pedicle Integrity

4A

Insert the **Sounder** (95-0111) into the pedicle to verify the integrity of the pedicle wall.

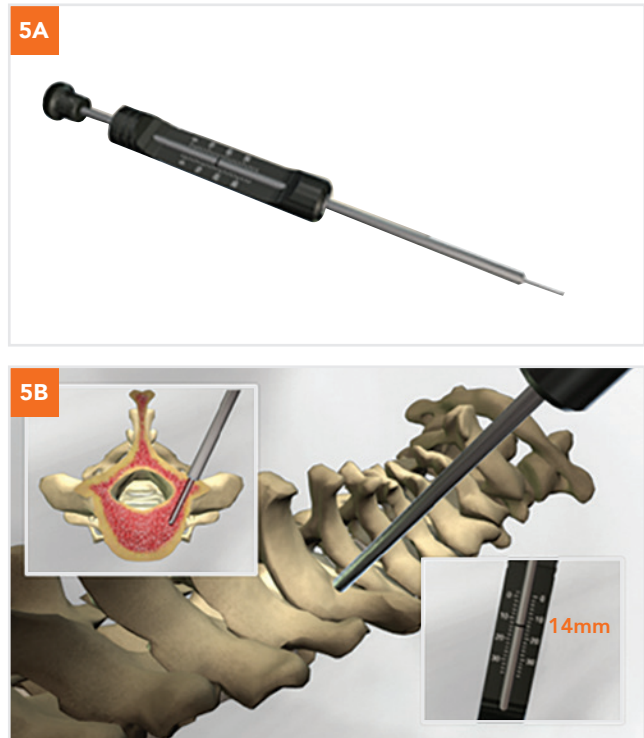
4A



STEP 5

Depth Verification

- 5A** The depth of the drill hole can be confirmed using the **Depth Gauge** (95-0113). Insert the tip of the **Depth Gauge** into the drill hole until the tip contacts the bottom of the hole.
- 5B** The depth of the hole can be measured by reading the scale located on the shaft of the **Depth Gauge**.



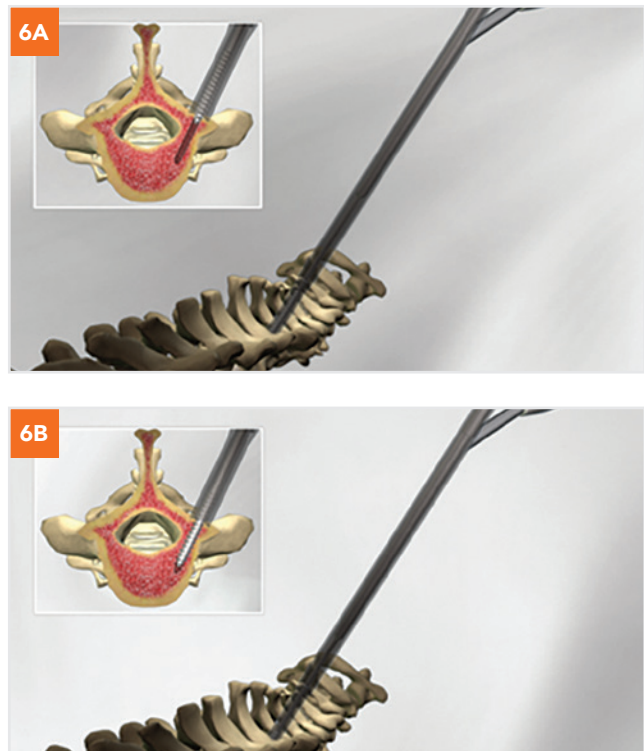
STEP 6

Tap

- 6A** **Taps** (95-01xx) are provided in three diameters (3.5mm, 4.0mm and 4.5mm) and two lengths (short and long). All taps are color coded to match the screw size (3.5mm – Green, 4.0mm – Blue, 4.5mm – Magenta).
- 6B** **Short Tap:** To tap a hole, select the appropriate **Tap** and apply downward pressure while turning the **Tap** clockwise. Advance the **Tap** until the desired depth is achieved.

Long Tap: To tap a hole, select the appropriate **Tap**, place the **Tap** into the barrel of the **Tap Guide** and apply downward pressure while turning the **Tap** clockwise. Advance the **Tap** until the number corresponding to the desired depth aligns with the top of the **Tap Guide**.

► **Note:** The short tap will not fit down the barrel of the guide and should be used freehanded with caution.



STEP 7

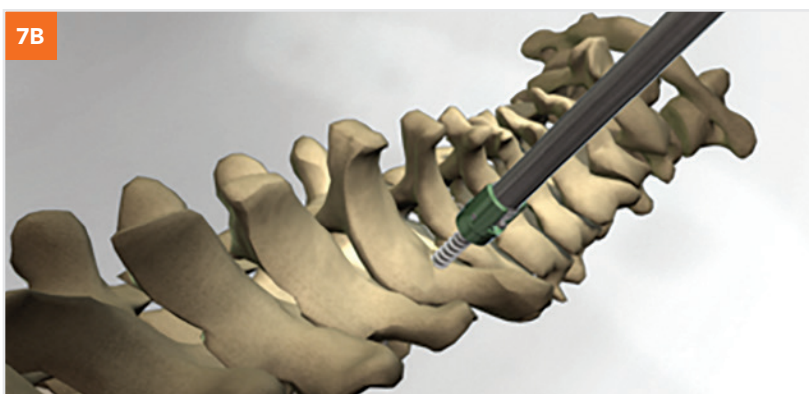
Screw Insertion

► **Note:** The use of the **Polyaxial Screws** is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

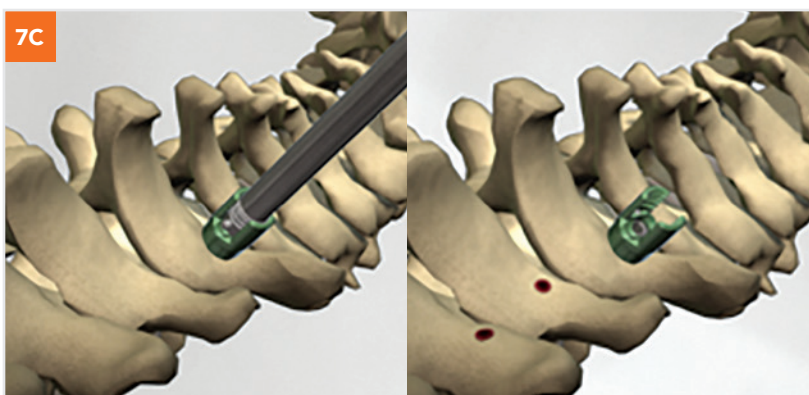
7A After determining appropriate screw length, load hex cavity of screw onto hex tip of **Screwdriver** (95-0119). Secure the screw to **Screwdriver** by turning knob on **Screwdriver** sleeve clockwise until **Screwdriver** is fully engaged with seat of the screw.



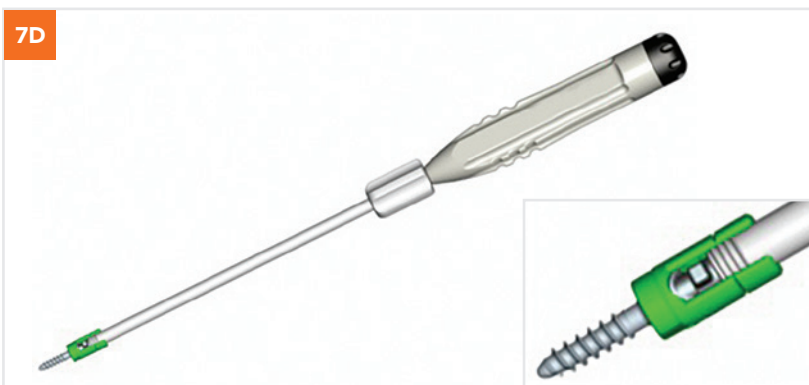
7B Screw length may be confirmed by using gauge located on corresponding screw caddy. Insert screw into bone. Repeat this process for remaining screws.



7C To disengage the screw from the **Screwdriver**, hold the handle and turn the knob on **Screwdriver** sleeve counter-clockwise until completely disengaged from tulip.



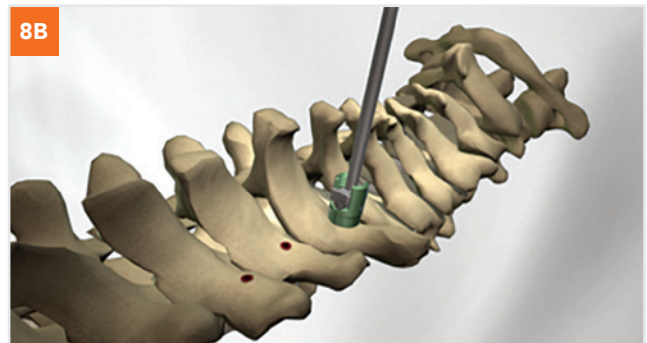
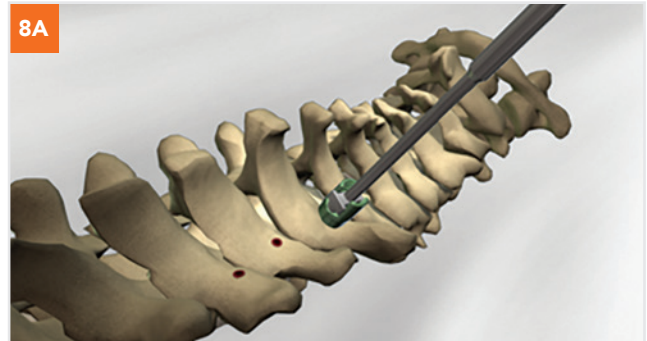
7D **Extended Tab Screws:** Follow same insertion protocol as described above for the extended tab screws.



STEP 8

Seat Adjustment

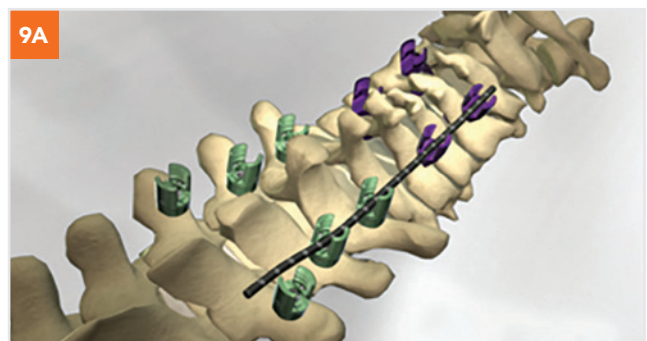
- 8A** To simplify rod placement, the tulips of the screws may be aligned using the **Seat Alignment Tool** (95-0125).
- 8B** Place **Seat Alignment Tool** into seat of screw with inner bar resting in rod channel of screw and turn **Alignment Tool** until rod channels of each screw are parallel to anticipated direction of rod.
- 8C** Repeat process for remaining screws.



STEP 9

Rod Selection

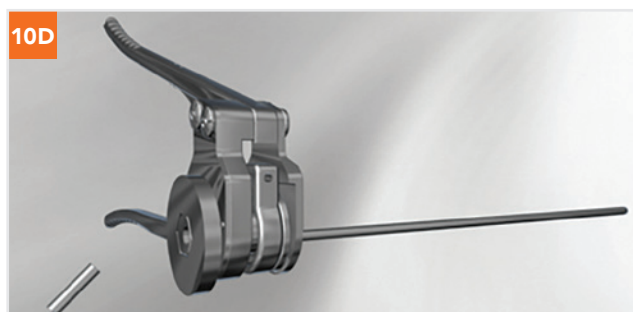
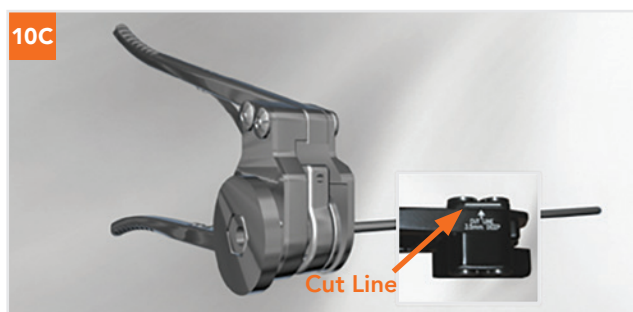
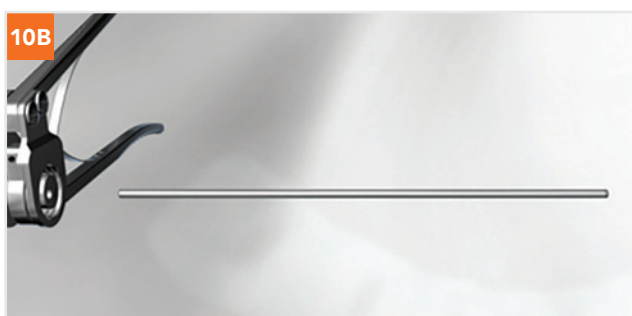
- 9A** The **Rod Templates** (95-0105 and 95-0106) may be used to determine appropriate curvature and length of rod.



STEP 10

Rod Preparation

- 10A** Use the **Ratcheting Rod Cutter** (95-0148) to cut 3.5mm rod to appropriate length. Prior to inserting the rod, **align two lines** on **Rod Cutter** by rotating wheel counterclockwise.
- 10B** Place the rod through side of **Rod Cutter** with the desired rod length you want to implant exposed on the side of the cutter.
- 10C** The **Rod Cutter** will cut the rod on the “CUT LINE” plane indicated on the instrument.
- 10D** Squeeze and release the **Rod Cutter** handles. Repeat this step until the rod shears off smoothly.
- **Note:** Cut line is approximately 3.5mm deep. It generally requires three squeezes to cut the rod.
- 10E** The **French Rod Bender** (95-0142) and **In-Situ Benders** (95-0149 and 95-0150) may be used to contour the rod if necessary.
- **Note:** Multiple bends in rods should be performed in one direction only.

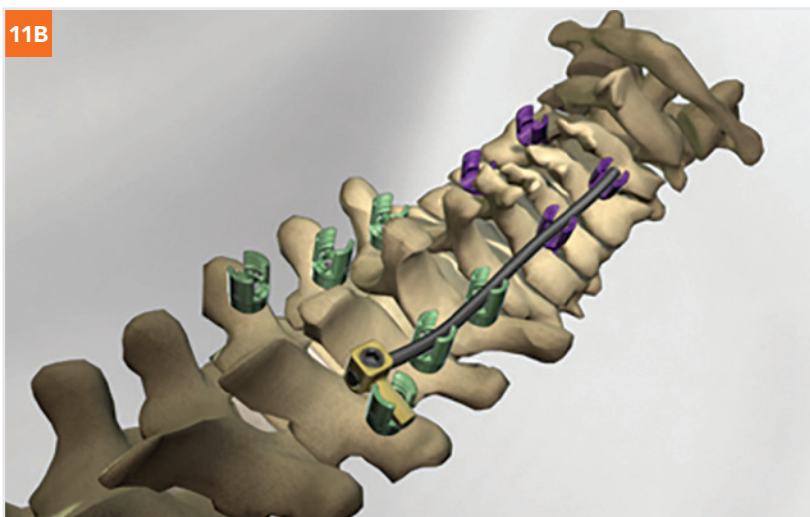
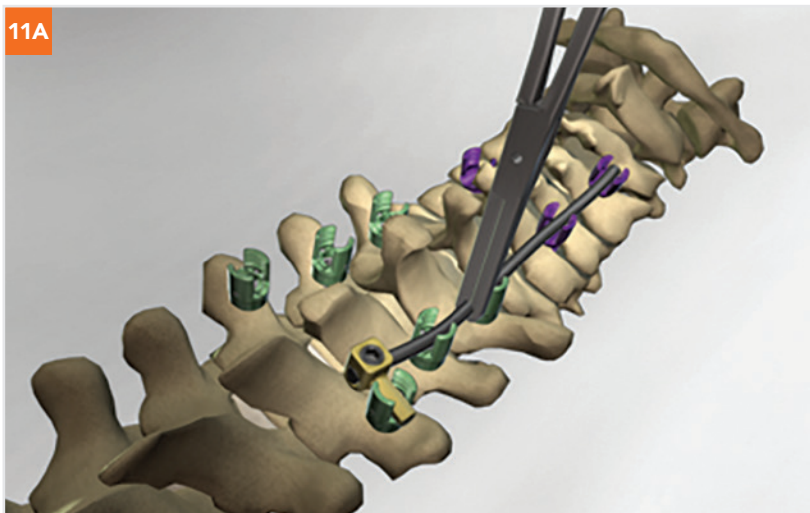


STEP 11

Final Rod Placement

11A Insert the rod into the construct using the **Rod Holder** (95-0140).

11B Ensure the black line on the rod, which indicates lordosis, is facing up prior to final tightening of locking caps



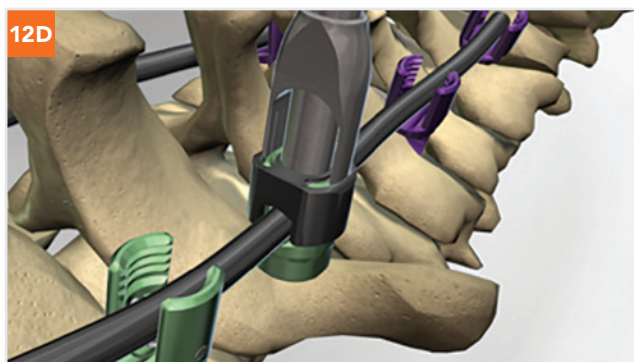
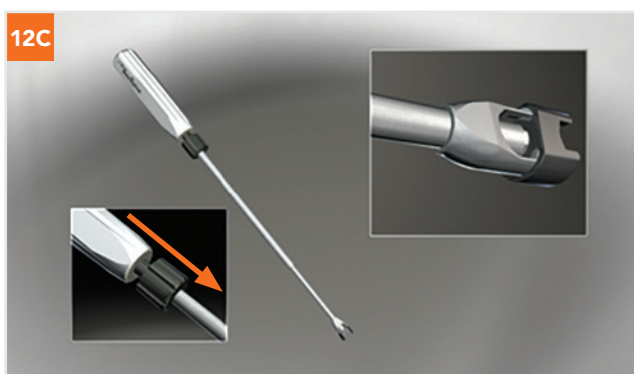
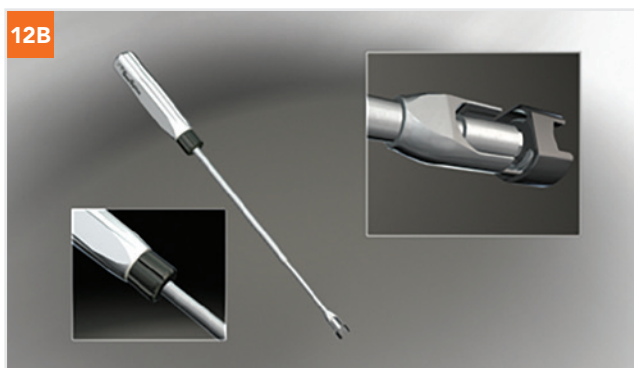
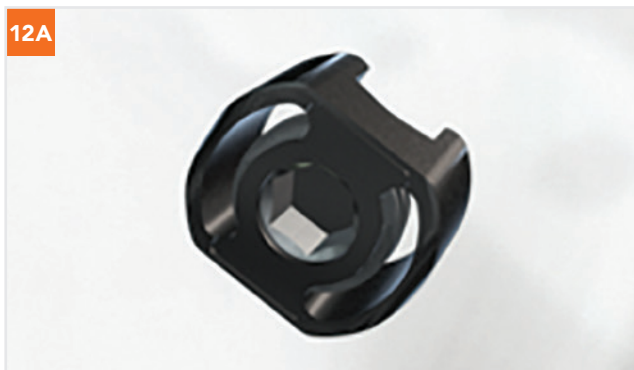
STEP 12**Locking Cap Placement**

12A The rod is locked to the screw using a **Locking Cap** (50-1000).

12B The **Loader** (95-0120) is used to place the **Locking Cap** onto the seat.

12C To load the **Locking Cap**, pull back on the small black knob and place the hex of the Loader into the hex on the **Locking Cap**. Release the black knob and press the forks on the Loader into the cavities on the **Locking Cap**.

12D With gentle downward pressure applied to the Loader, turn the handle clockwise to thread the **Locking Cap** onto the screw. Provisionally tighten the **Locking Cap**.



STEP 12

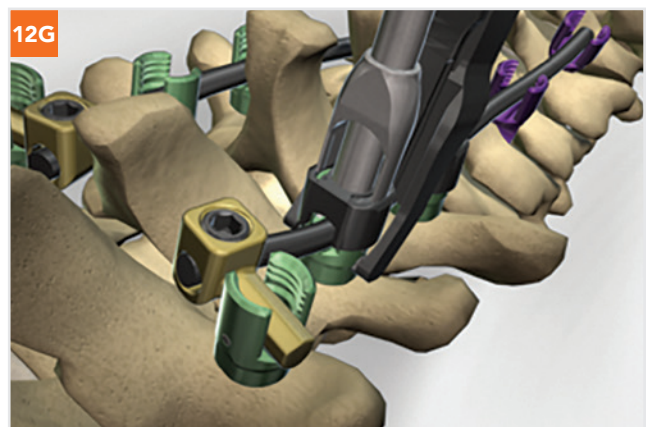
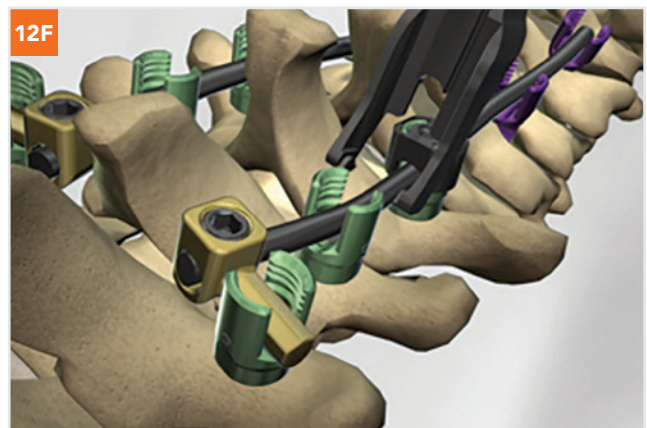
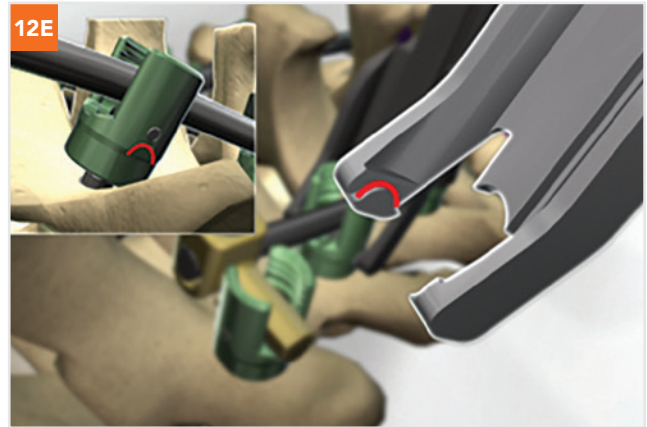
Locking Cap Placement continued

12E Rod Persuader

A **Rod Persuader** (95-0145) is provided standard in set. The Persuader is used when additional force is needed to seat rod into seat of screw.

12F Connect the **Rod Persuader** to the screw by hooking the tips of the **Rod Persuader** into the recesses of the screw seat. Squeeze the handle of the **Persuader** until the rod is fully seated into the seat of the implant.

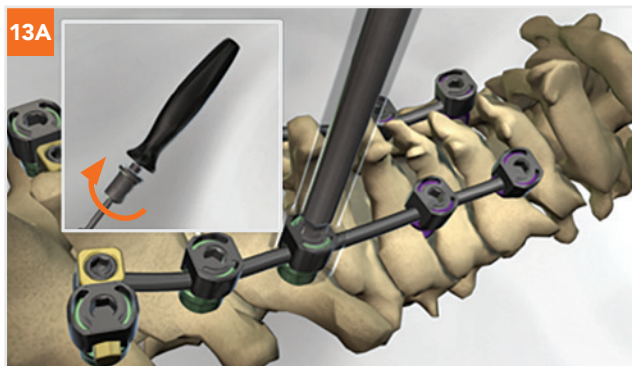
12G The **Loader** is used to place the **Locking Cap** onto the seat of the screw. Provisionally tighten the **Locking Cap**.



STEP 13**Final Tightening**

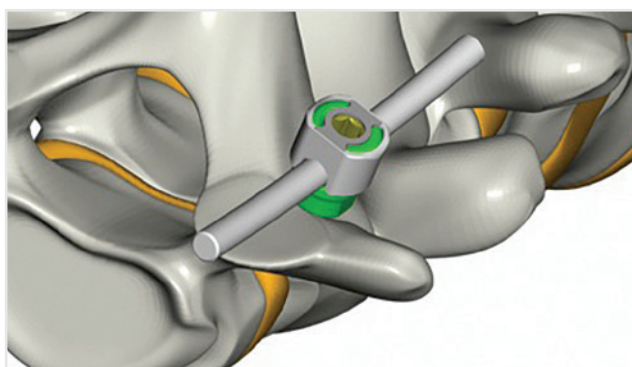
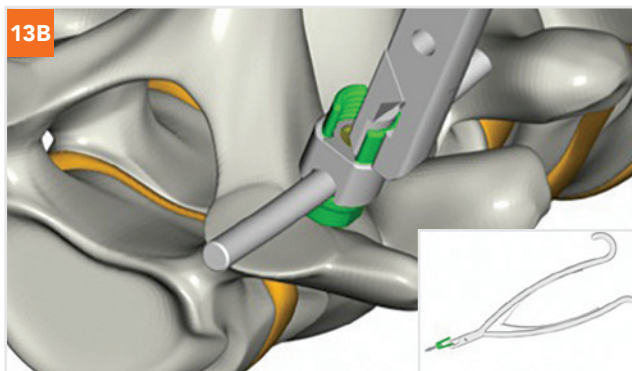
After final adjustment to the construct is complete, final tightening of all **Locking Caps** is performed.

- 13A** Securely tighten each **Locking Cap** using the **Black Torque Limiting Handle** (95-0127) and 3mm **Driver Shaft** (95-0155) in conjunction with the **Counter Torque** (95-0122). The proper torque of 35 in-lbs is identified by an audible click.



- **Note:** For the **Extended Tap Screws**, the caps are tightened using the same **Torque Limiting Handle** and 3mm **Driver Shaft**, however the **Extended Tab Counter Toque** (95-0323) should be used for final tightening.

- 13B** After the caps are locked down, use the **Tab Breaker** (95-0157) to remove each tab as shown.

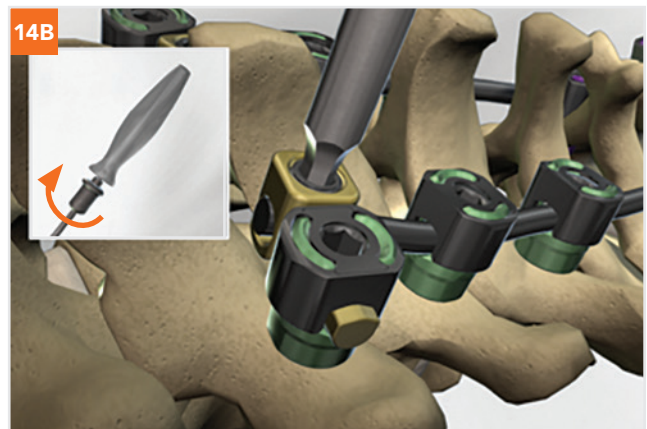
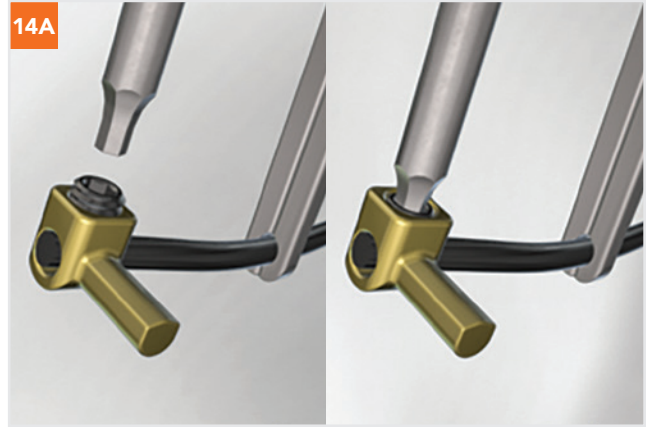


STEP 14

Lateral Connector

14A **Lateral Connectors** (50-0035) may be used to facilitate coupling of the screws to the rod if necessary. To introduce the **Lateral Connector** ensure the set screw is loose and slide the opening of the connector over the rod.

14B Securely tighten the **Set Screw** on each **Lateral Connector** using the **Grey Torque Limiting Handle** (95-0126) and 2.5mm **Driver Shaft** (95-0128). The proper torque of 25 in-lbs is identified by an audible click.



STEP 15

Laminar Hook Placement

15A **Laminar Hooks** are available if needed for additional support and are available in a variety of offsets and throat sizes.

► **Note:** The 4.5mm throat hooks are color coded teal and the 6.0mm throat hooks are purple.

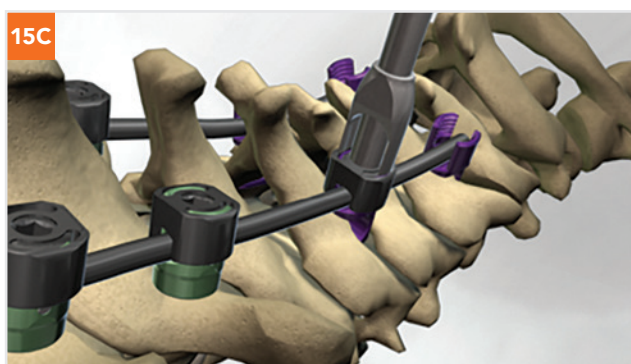
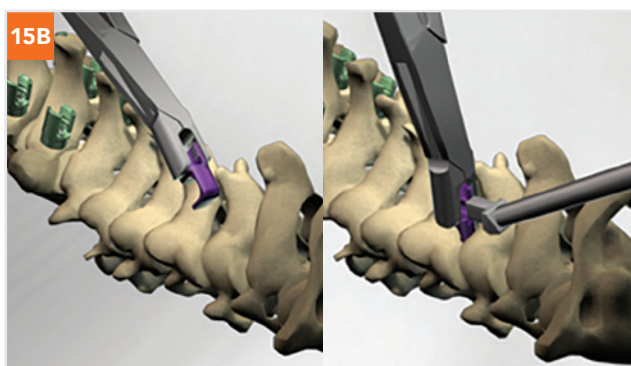
15B Select the appropriate hook. Place the hook using the **Hook Holder** (95-0160) and/or **Hook Pusher** (95-0161).

Repeat the process for the remaining hooks.

15C Use the **Loader** to place the **Locking Cap** onto the hook. Load the **Locking Cap** onto the **Loader** and slide the **Locking Cap** over the arms of the hook. Provisionally tighten the **Locking Cap**.

Repeat this process for all remaining **Locking Caps**.

15A	Available Hook Options	
4.5mm	Left and Right Offset Hook	
6.0mm	Left and Right Offset Hook	
6.0mm	Straight	



STEP 16

CrossBar Options

16A The **CrossBar** is designed to translate and rotate about its longitudinal axis and pivot about its midpoint allowing it to fit most screw/rod constructs without the need for bending.

16B Select the appropriate **CrossBar**. Check that the center screw is loose to allow the **CrossBar** to pivot about its midpoint. Ensure that the clamping screws at each end are in the open (down) position. Place the clamps over each rod, tighten the clamping screws and finish by securely tightening the **Set Screws** on the **CrossBar** using the **Magenta CrossBar Driver** (95-0109).

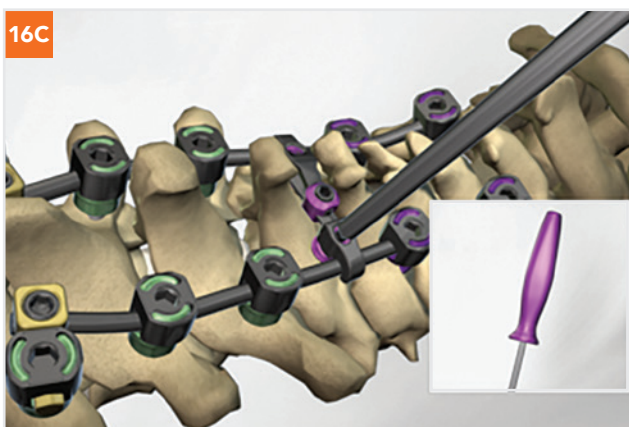
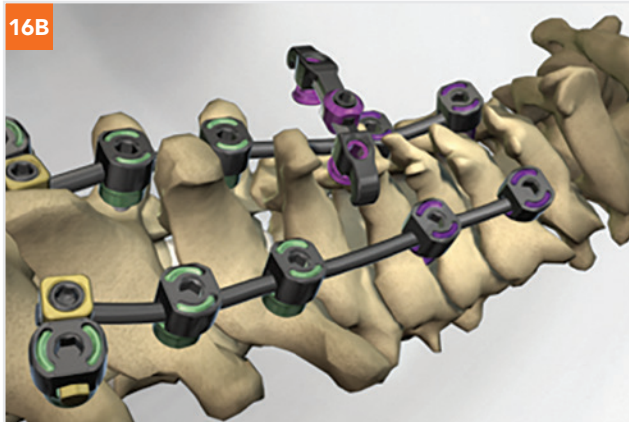
16C The proper torque of 10 in-lbs is identified by an audible click.

16D Screw to **Screw (S2S) CrossBars** are another option for cases with limited rod space.

16E Select the appropriate **CrossBar**. Check that center screw is loose to allow it to pivot about its mid point. If tight, loosen with **Magenta Torque Limiting Handle** by turning handle counter-clockwise. The ends on the crossbars replicate the locking caps, however have a separate locking screw found in the **CrossBar** caddy. Use the **Loaders** to deliver the crossbar to the screws. Place on tulips, one side at a time. When positioned, utilize **Counter-Torque** (92-0122), **Black Torque Limiting Handle** (95-0127) and 3mm **Driver Shaft** (95-0122) to final tighten each set screw on the pedicle screws. Lastly, use the **Magenta CrossBar Driver** to tighten the magenta colored middle set screw.

16A The **CrossBar** comes in a variety of sizes

Small	21mm – 26mm
Medium	24mm – 32mm
Large	30mm – 44mm
X-Large	42mm – 58mm



16D The **S2S CrossBar** comes in a variety of sizes

Small	24mm – 29mm
Medium	27mm – 35mm
Large	33mm – 47mm

STEP 17**Removal Options****17A System Removal**

Insert the 3mm **Driver Shaft** (95-0155) and **Black Torque Limiting Handle** (95-0127) into the **Counter Torque** (95-0122). Place the **Counter Torque** into position over the **Rod** and implant head then remove the locking screw with the **Final Driver**. Repeat with all implants.

Remove the **Rod** with the **Rod Holder** (95-0140).

Remove any screws using the **Sierra Screw Driver** (95-0119) or the 2.5mm **Hex Driver** (95-0118).

Remove any hooks using the **Hook Holder** (95-0160).

17B Removal of the CrossBar:

To remove the **CrossBar**, use the **Magenta Torque Limiting Handle**. Turn the center set screw counterclockwise to release any tension on the construct. After the center set screw is loose turn the outer two (2) set screws counterclockwise until the **CrossBar** is released from the rods/construct.

17C Removal of the S2S CrossBar:

To remove the S2S **CrossBar**, use the **Magenta Torque Limiting Handle** to turn the center set screw counterclockwise to release any tension on the construct. After the center set screw is loose, use the **Counter Torque**, 3mm **Driver** and **Handle** and turn the outer two (2) set screws counterclockwise until the **CrossBar** is released from the rods/construct.

Indications for Use

The intended use of the Sierra™ spinal system is to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3). The indications for use are as follows:

- Degenerative disc disease (DDD) as defined by neck pain of discogenic origin with
- Degeneration of the disc confirmed by patient history and radiographic studies,
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Spinal stenosis,
- Atlantoaxial fracture with instability,
- Occipitocervical dislocation,
- Revision of previous cervical spine surgery, and/or
- Spinal tumor.

The occipital bone screws are limited to occipital fixation only.

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

Contraindications

The contraindications of this system are similar to the other systems of similar design. Contraindications include, but are not limited to, the following conditions:

Absolute Contraindications:

- Active posterior infection.
- Allergy to titanium.
- Allergy to cobalt chromium alloy.

Relative Contraindications

- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy, unless internal fixation of the spine is indicated for unstable fracture.
- Signs of infection or inflammation in the area to be implanted.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Grossly distorted anatomy due to congenital abnormalities.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any case requiring the mixing of metals from different components.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.
- A patient unwilling or unable to follow instructions.
- Any case not described in the indications.

SeaSpine Orthopedics Corporation 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.

This is not a comprehensive list. Please refer to the Instructions for Use included in the product packaging









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