

SAXXONY®
Posterior Cervical Thoracic System

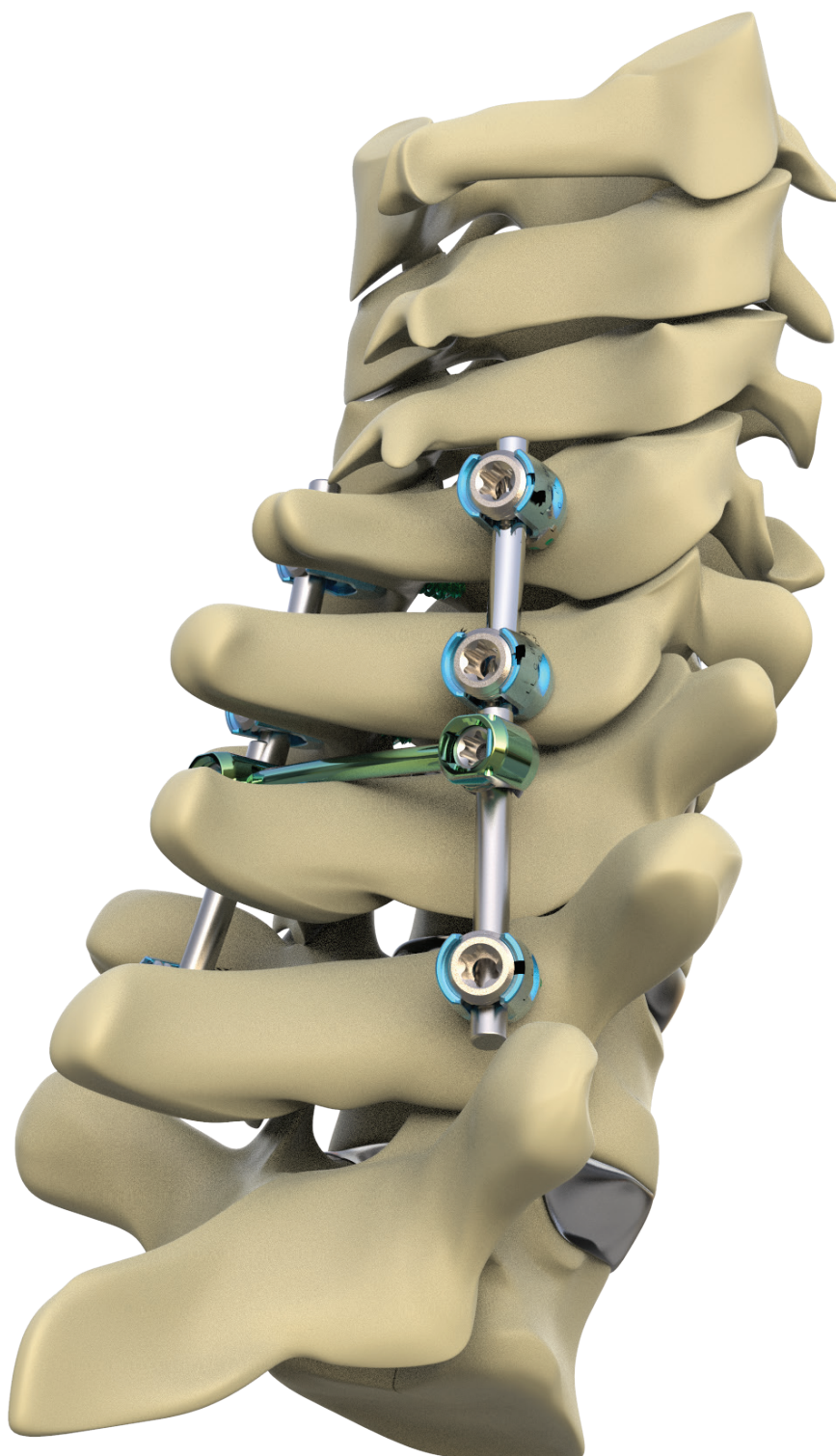


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System Overview

The Saxxony® Posterior Cervical Thoracic System consists of Rods, Pedicle Screws and Hook Anchors, Connectors and Set Screws. Rods are available in either straight, prebent (curved) or transition forms in a variety of lengths. Polyaxial Pedicle Screws are available fully threaded or having a partially smooth shaft in a variety of diameter-length combinations. Connectors include Rod-Rod, Rod-Screw, and Screw-Screw. Set Screws fasten the Rod, Anchors and Connectors. All implant components are manufactured from titanium alloy (Ti-6AL-4V ELI) per ASTM F136; Transition Rods are additionally available manufactured from cobalt chromium alloy per ASTM F1537.

Step 1: Patient Positioning

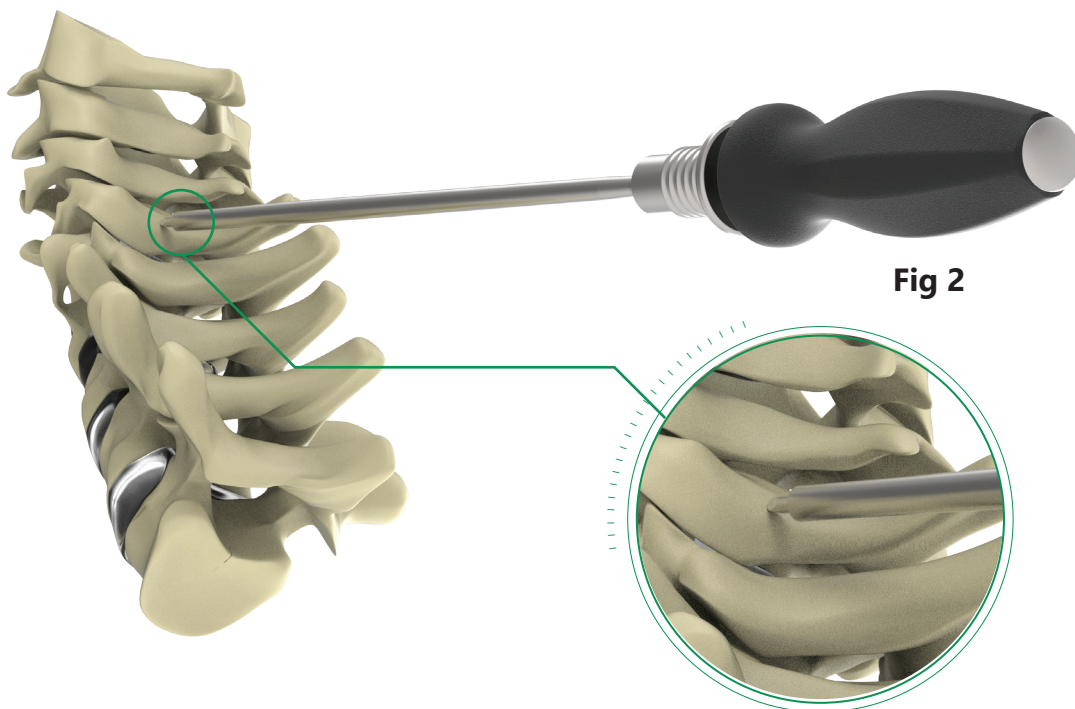
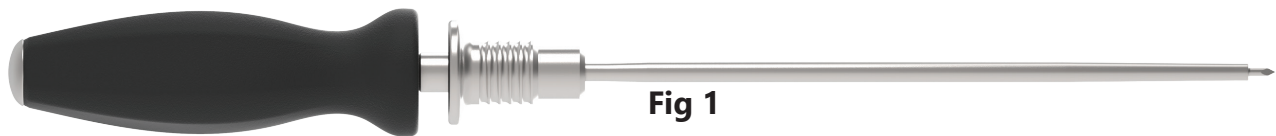
The patient should be positioned in the prone position as appropriate for a posterior approach. Operative level(s) and physiological alignment should be confirmed with radiographic imaging and direct visualization. A standard midline exposure may be used to perform the procedure.

NOTE: Care must be taken to avoid vital structures.

Step 2: Screw Hole Preparation

2A) Awl: Attach the Awl to the Quick Connect Handle. Utilize the Awl (Fig 1) to establish the desired trajectory of the screw by creating a pilot hole (Fig 2).

NOTE: The Awl has a hard stop that limits insertion to 7mm.

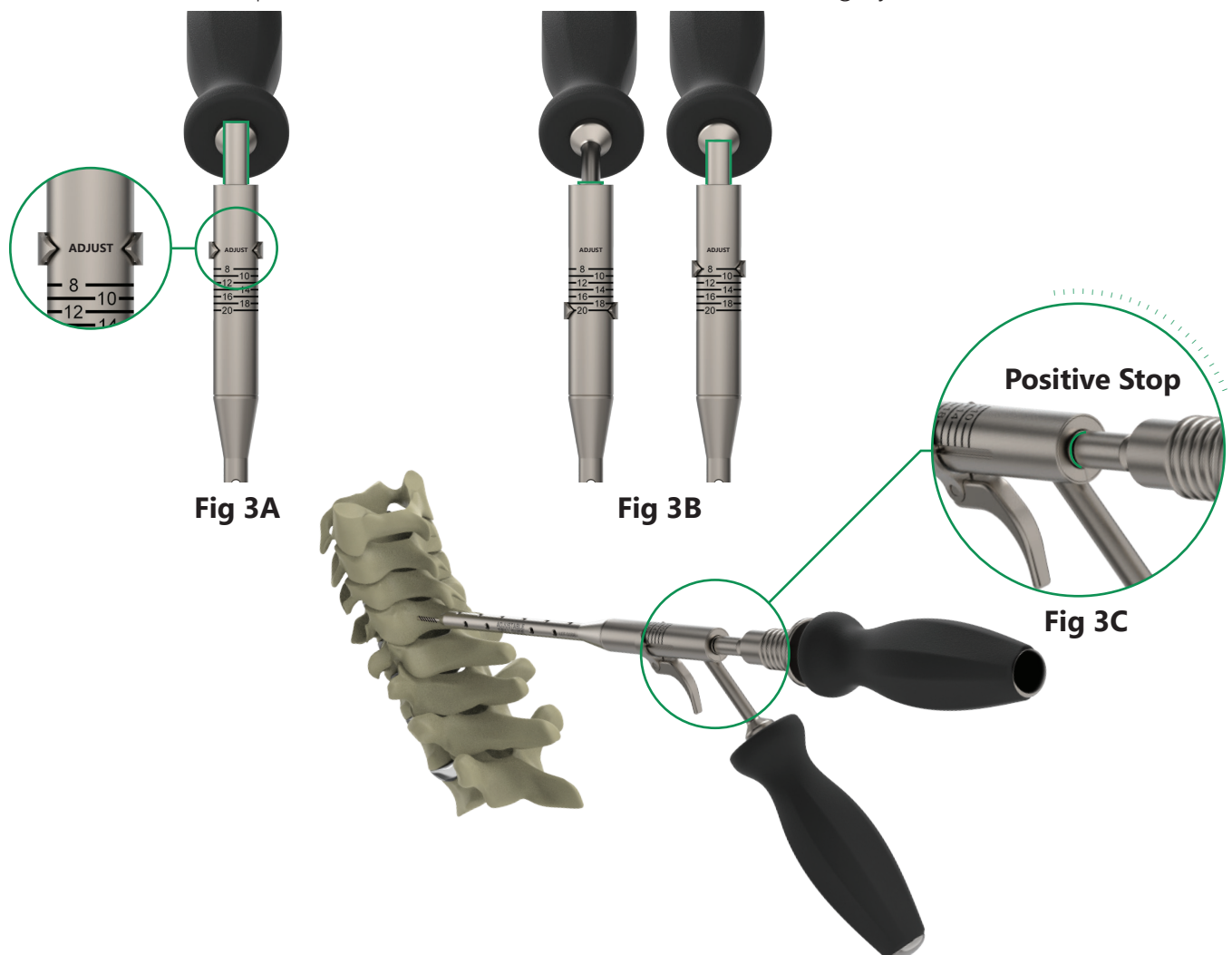


2B) Drill: Once the desired screw trajectory has been determined, the Adjustable Drill Guide may be used to drill to the desired depth. To adjust the Drill Guide, pull the trigger all the way up until the trigger lines up with the word “ADJUST” (Fig 3A). When released, the Adjustable Drill Guide will increase by increments of 2mm. After 20mm, the drill depth will reset to 8mm (Fig 3B). The depth of the markings indicates the drill depth at that setting. For example, if the Adjustable Drill Guide is set to 16, a 16mm deep hole will be drilled.

Attach the Drill to the Quick Connect Handle. Insert the Drill into the Adjustable Drill Guide (or a Fixed Drill Guide) and drill through the pilot hole until the positive depth stop is reached (Fig 3C). This hard stop prevents the drill from penetrating any deeper than intended. Upon drilling, the provided 100mm depth gage may be used to verify drill depth. Repeat for all screw placement sites.

NOTES:

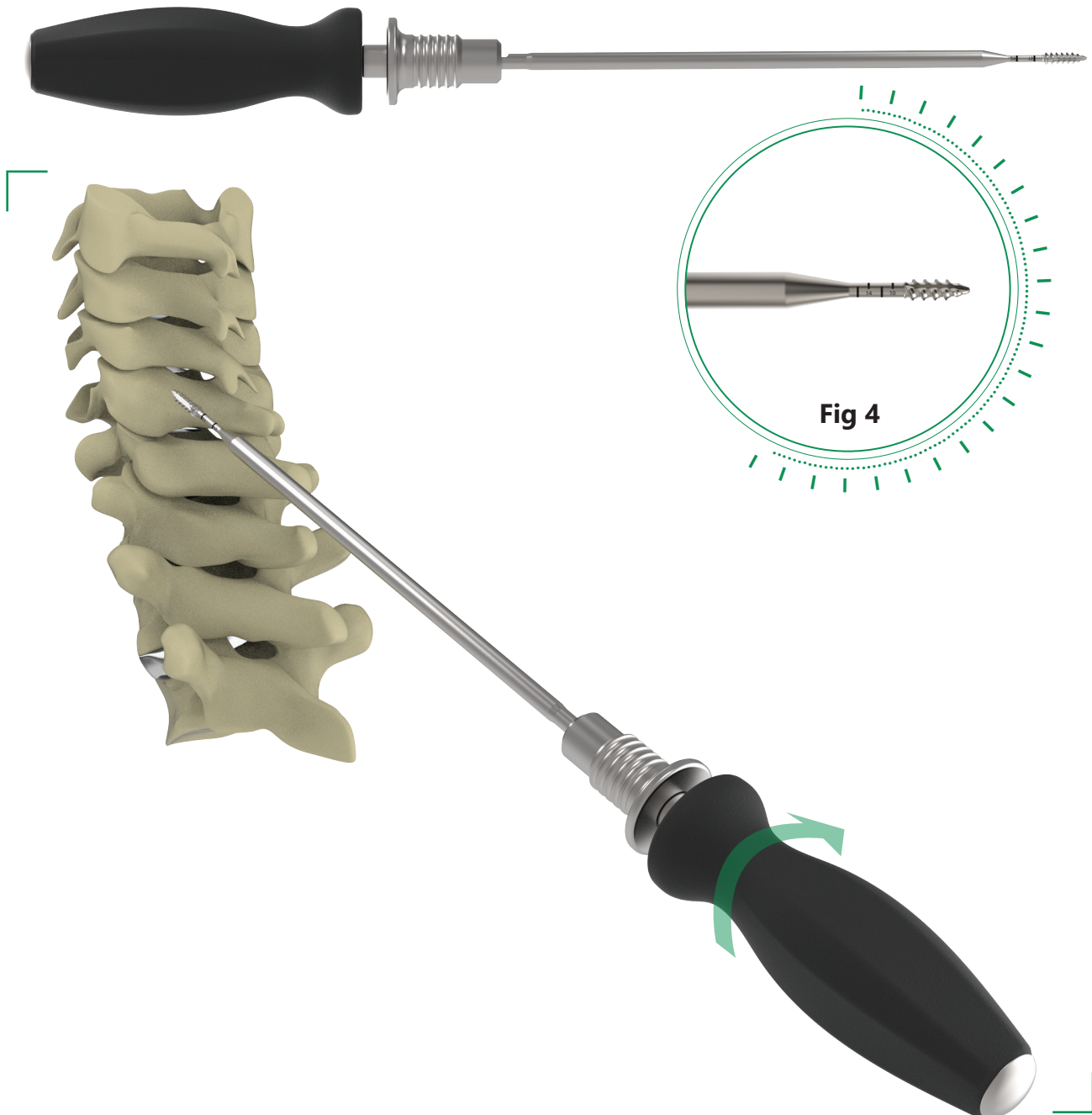
- Fixed Drill Guides are available providing fixed drill depths of 10, 12, 14, and 16mm increments.
- The use of a Ball Tip Sounder is recommended to confirm hole integrity.



2C) Tap: The screw hole may be tapped by attaching the appropriate diameter tap to the Quick Connect Handle and advancing the Tap to the desired depth, using the depth markings as a guide. Taps are available in diameters of 3.0-5.0mm in 0.5mm increments.

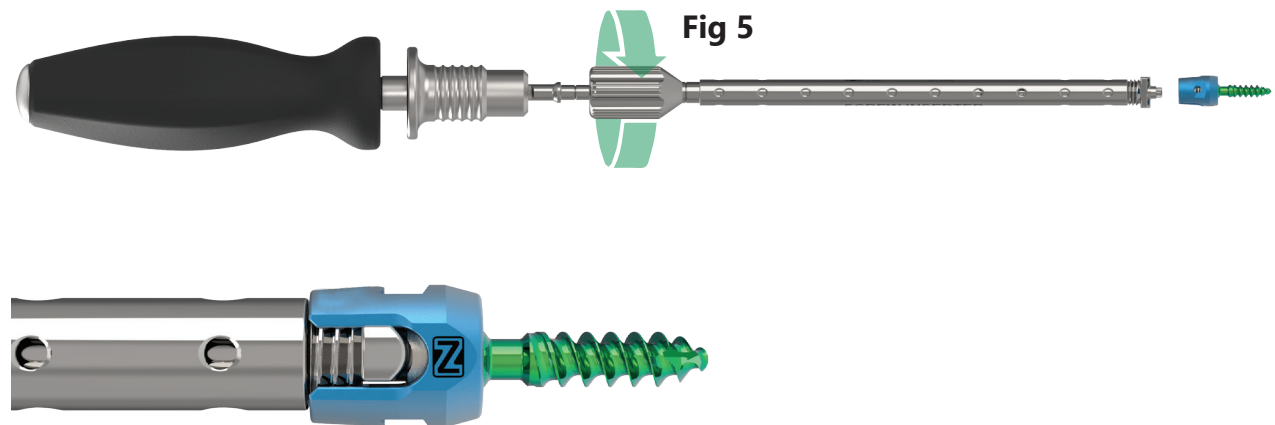
NOTES:

- Tap diameters are line-to-line. Tap diameters match Screw diameters. (Fig 4).
- Tap diameters between 3.0 + 4.0 (Cervical) have laser etch markings in 2mm increments and 4.5 + 5.0 (Thoracic) have laser etch markings in 5mm increments.



Step 3: Screw Insertion

Upon adequate hole preparation, choose the appropriate Screw style and size (Fig 6). Attach the Screw Inserter to the Quick Connect Handle and proceed to load the Screw to the tip (Fig 5). Ensure the driver is fully seated on the Screw Head and then rotate the knob clockwise to engage the threads on the Screw Inserter with the threads on the Screw. Proceed to advance the Screw into the pedicle and stop once desired depth is reached. Disengage by rotating the knob counterclockwise.



Standard Posterior Screw



Standard Posterior Screw:

Ø3.5mm x 8-28mm; in 2mm increments
Ø4.0mm x 8-28mm; in 2mm increments
Ø4.0mm x 30-50mm; in 5mm increments
Ø4.5mm x 20-50mm; in 5mm increments
Ø5.0mm x 20-50mm; in 5mm increments

Smooth Posterior Screw



Smooth region is 10mm
on all shank lengths

Smooth Posterior Screw:

Ø3.5mm x 18-44mm; in 2mm increments
Ø4.0mm x 18-44mm; in 2mm increments

Fig 6

Step 4: Rod Insertion

Utilize the Rod Template to determine the required length and contour of the Rods. After the desired length and contour has been identified, the Rod may be cut to the appropriate length using the Rod Cutter and formed to the desired contour using the Rod Bender. Insert the Rod into the head of each screw.

If additional Rod curvature is desired after inserting, use the In-Situ Rod Benders to reshape.

Step 5: Rod Reduction (Optional)

Rod Rocker

If the Rod is slightly proud above the Screw Housing, then use the Rod Rocker (Fig. 7) or Rod Rocker Fork (Fig. 8) to achieve the fully seated position of the Rod into the Screw Housing. Slide the open face of the Rod Rocker onto either the cephalad or caudal side of the Screw Housing (tulip). Rock the Rod Rocker until desired result is achieved. Insert Set Screw into Screw Housing using the Double Ended Set Screw Inserter or Single Ended Set Screw Inserter and provisionally tighten to secure to the Rod. Remove the Rod Rocker by sliding off in the opposite direction it was attached.

NOTE: If no reduction is needed, move to Step 6.

Rod Rocker

Can interface between closely spaced Screws.

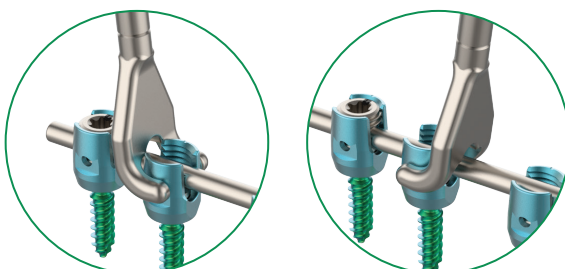


Fig 7



Rod Rocker Fork

Fits in the saddle of the adjacent Screw and captures the end of the Rod

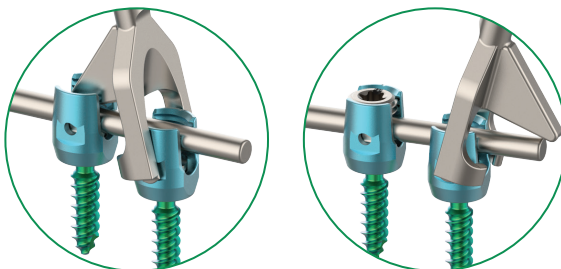


Fig 8



SAXXONY®

Posterior Cervical Thoracic System



Pistol Rod Reducer

Ensure the ratcheting handle is in the open position to connect to the Screw Housing (tulip). Press straight down over the Screw Housing (tulip) then grasp the ratcheting handle to securely attach the Pistol Rod Reducer to the Screw Housing (tulip).

Squeeze the handle of the Pistol Rod Reducer to draw the Rod down into the Screw Housing (tulip).

Insert Set Screw with the Double Ended Set Screw Inserter through the Pistol Rod Reducer into the Screw Housing (tulip) and provisionally tighten to secure the Rod.

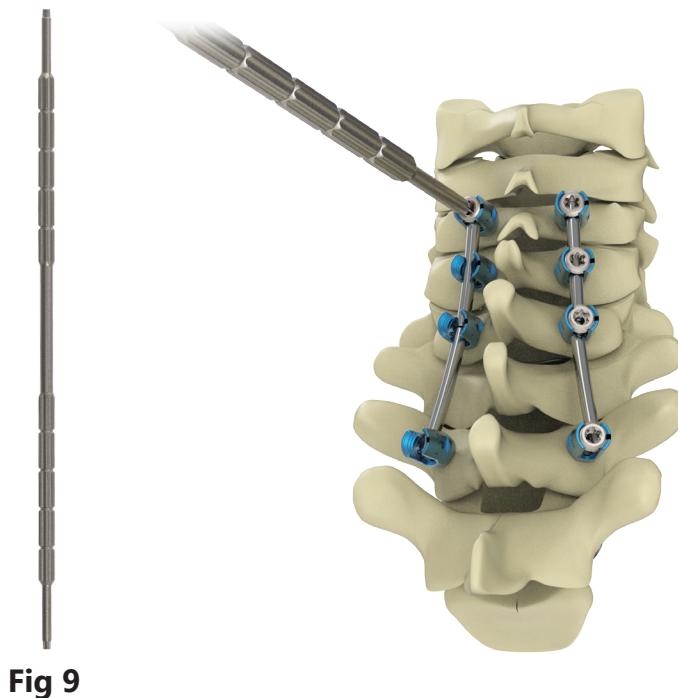
After provisionally tightening the Set Screw, the Pistol Rod Reducer can be removed. Disengage by lifting up the ratchet lever and separating handles, then the Pistol Rod Reducer is free to lift up.

NOTE: If no reduction is needed, move to Step 6.

Step 6: Set Screw Insertion

Press the Double-Ended Set Screw Inserter (Fig 9) onto the Set Screw to retain it. Then, insert the retained Set Screw into the Screw Housing (tulip) of the Screw and provisionally tighten. Repeat for all Set Screws.

NOTE: The Double-Ended Set Screw Inserter is to be used for provisional tightening only.



Step 7: Compression / Distraction (Optional)

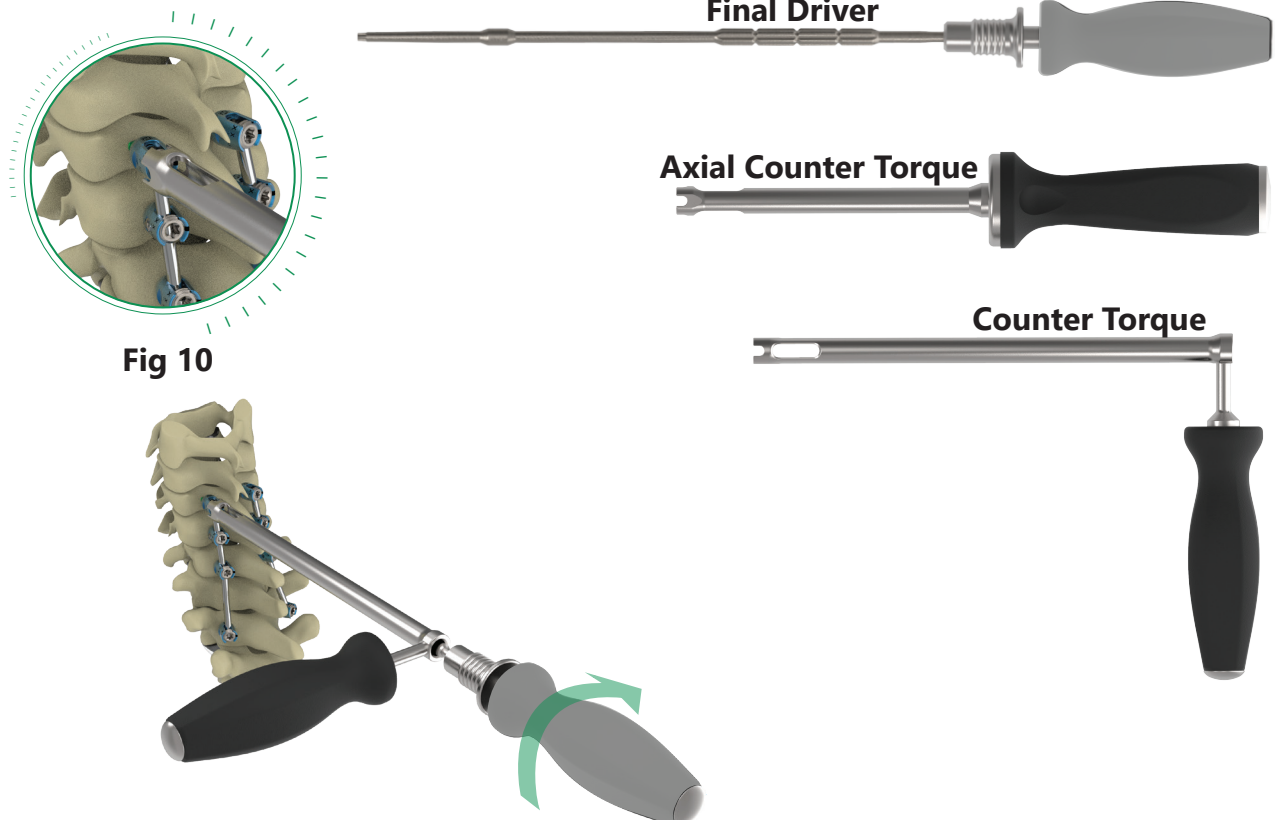
Prior to compression or distraction, one Set Screw should be tightened. To compress, place the inner edges of the Compressor around the Screws and squeeze the handles together gently until the appropriate distance apart is achieved. To distract, place the outer edges of the Distractor inside the Screws and squeeze the handles together until the appropriate distance apart is achieved.

Step 8: Final Tightening / Counter Torque

Guide the tip of the Counter Torque over the Polyaxial Screw (Fig 10). Pass the Final Driver through the Counter Torque and mate with the Set Screw. Tighten the Set Screw using the gray 35in-lb Torque Limiting Handle.

NOTES:

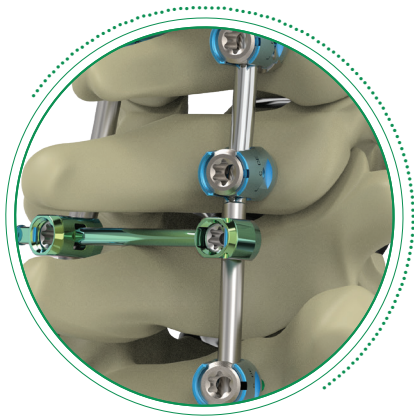
- An audible click is heard and tension is released within the Torque Limiting Handle when the required 35in-lb locking torque is achieved.
- A 35in-lb T-Handle Torque Limiting Handle is available by request.



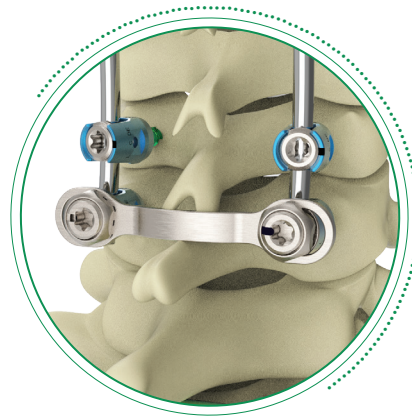
Additional Surgical Options

Cross Connectors

Using the provided Crosslink Measuring Calipers, determine the appropriate length for the Cross Connector. Place the Cross Connector in the desired location. Provisionally tighten the Set Screws with the Set Screw Inserter followed by final tightening with the Set Screw Final Driver. Utilize the Crosslink Bender to make adjustments if necessary (Fig 11).



Rod to Rod Connector



Head to Head Connector



Rod to Rod Connector

Crosslink Bender

Fig 11

Head to Head Connector



Connector Counter Torque

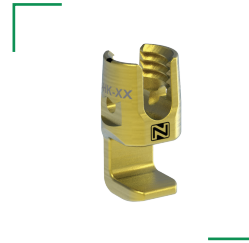
Can be used to aid in final tightening of R2R Connectors, Head to Head Connectors, and Crosslink Connectors

NOTE: This instrument cannot be used with R2R Domino or R2R Side Open Connectors

Additional Surgical Options Continued

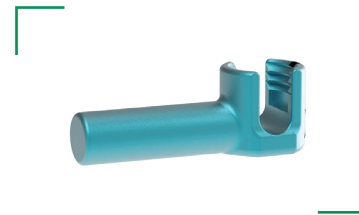
Hooks

Select appropriate size Hook given the anatomy of the region. Place the Hook in an optimal location.



Lateral Offset Connectors

If a lateral connector is desired as the result of an offset, select the appropriate size and proceed to implant with the use of the set Screw and Set Screw Inserter.



Transition Connectors

The Saxxony® Posterior Cervical Thoracic System is designed to connect seamlessly to the Inertia® Deformity Correxion System, with Ø3.5 to Ø5.5mm connectivity. When choosing which connector to use, ensure the diameter of the rod matches the diameter of the connector. The Set Screws are tightened with the Set Screw Driver.

NOTES:

- Integrated blue set screws require a locking torque of 90in-lb and integrated grey set screws require a locking torque of 35in-lb.
- Side open connector possesses connectivity for Ø3.5 to Ø5.5/6.5mm systems.



Removal

Removal of the Saxxony® components is done so by reversing the implant procedure.

INDICATIONS FOR USE

The Saxxony® Posterior Cervical Thoracic System is intended to immobilize and stabilize cervical (C1 to C7) and thoracic (T1 to T3) spinal segments as an adjunct to fusion for the treatment of the following acute and chronic instabilities: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical/thoracic spine; and 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 Saxxony® Posterior Cervical Thoracic System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period 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 Saxxony® Posterior Cervical Thoracic System rods may be connected to cervicothoracic or thoracolumbar stabilization systems ranging in diameter from 3.5mm to 6.5mm, using corresponding rod to rod connectors and/or transition rods.

CONTRAINDICATIONS

The Saxxony® Posterior Cervical Thoracic System contraindications include, but are not limited to:

1. The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. Prior fusion at the level(s) to be treated.
4. Any condition not described in the Indications for Use.

CAUTION:

Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

WARNINGS AND PRECAUTIONS

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. The Saxxony® Posterior Cervical Thoracic System devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
3. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
4. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
5. The Saxxony® Posterior Cervical Thoracic System is used to augment the development of a spinal fusion by providing temporary stabilization. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
6. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Components of this system should not be used with components of any other manufacturer.
9. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

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