Saxxony®

Posterior Cervical Thoracic System

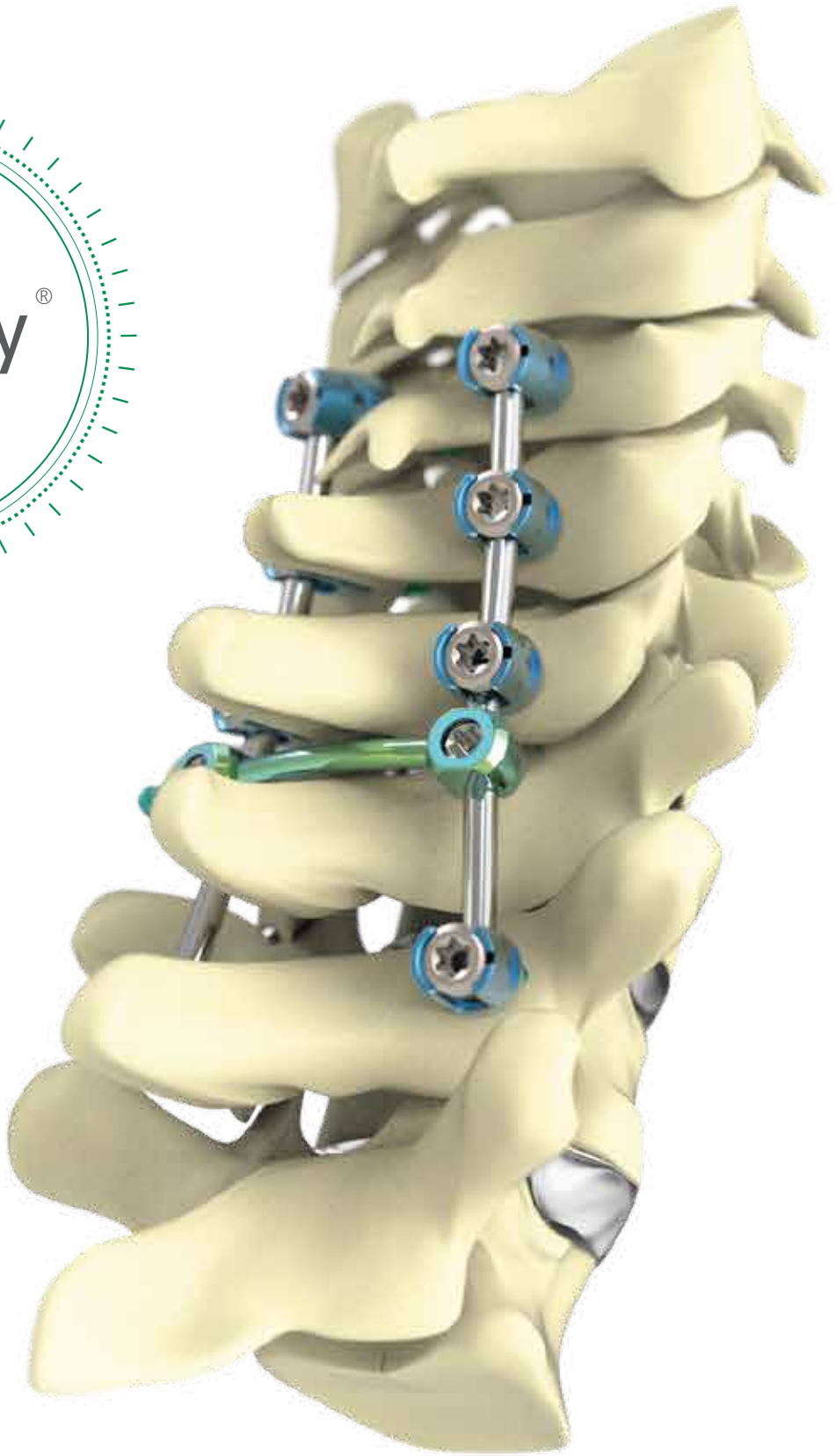


Table of Contents

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.

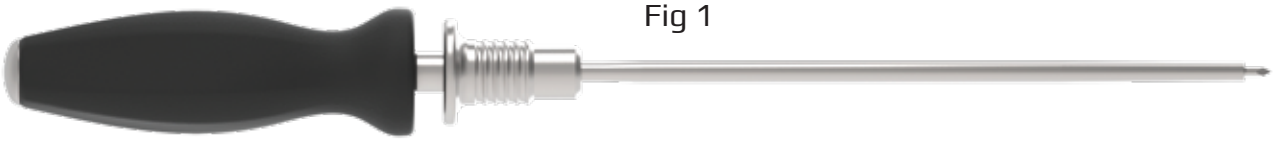
Note: Care must be taken to avoid vital structures.

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.

Fig 1



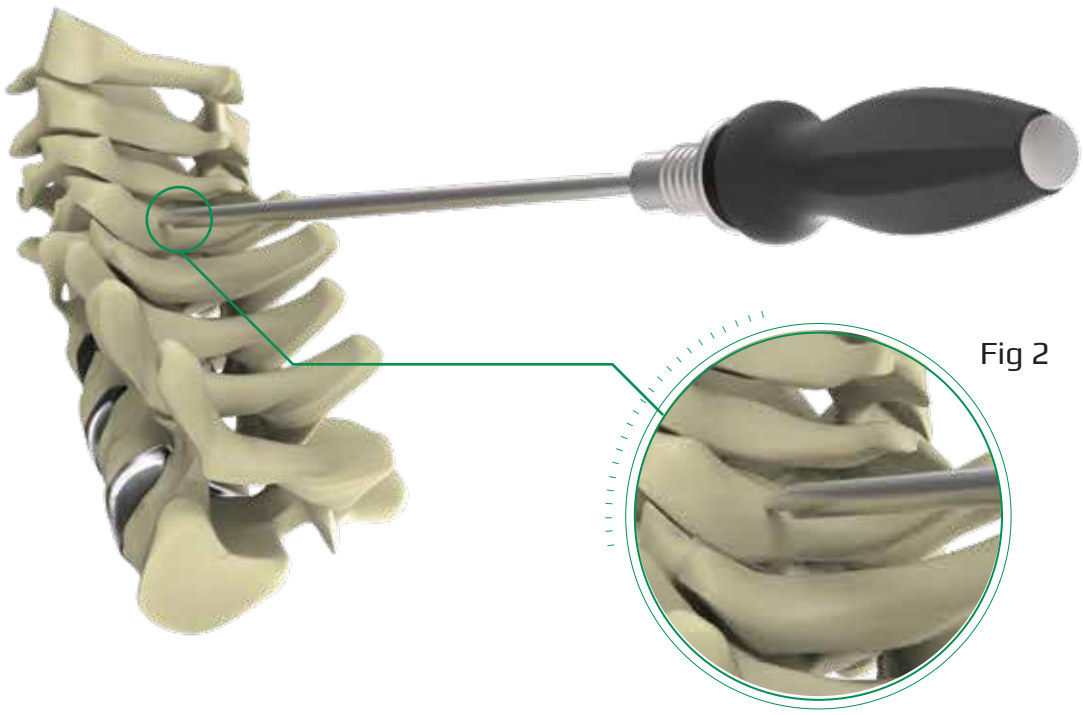


Fig 2

2B) Drill: Once the desired screw trajectory has been determined, the Adjustable Drill Guide may be used to drill to the desired depth. Turn the adjustment knob either clockwise or counterclockwise to lock the drill guide to the chosen drill depth (Fig 3). The depth is set correctly when the pin located in the visualization window indicates the depth desired.

Note: Turn counterclockwise to decrease depth or clockwise to increase depth.

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

Note: The use of a Ball Tip Sounder is recommended to confirm hole integrity.

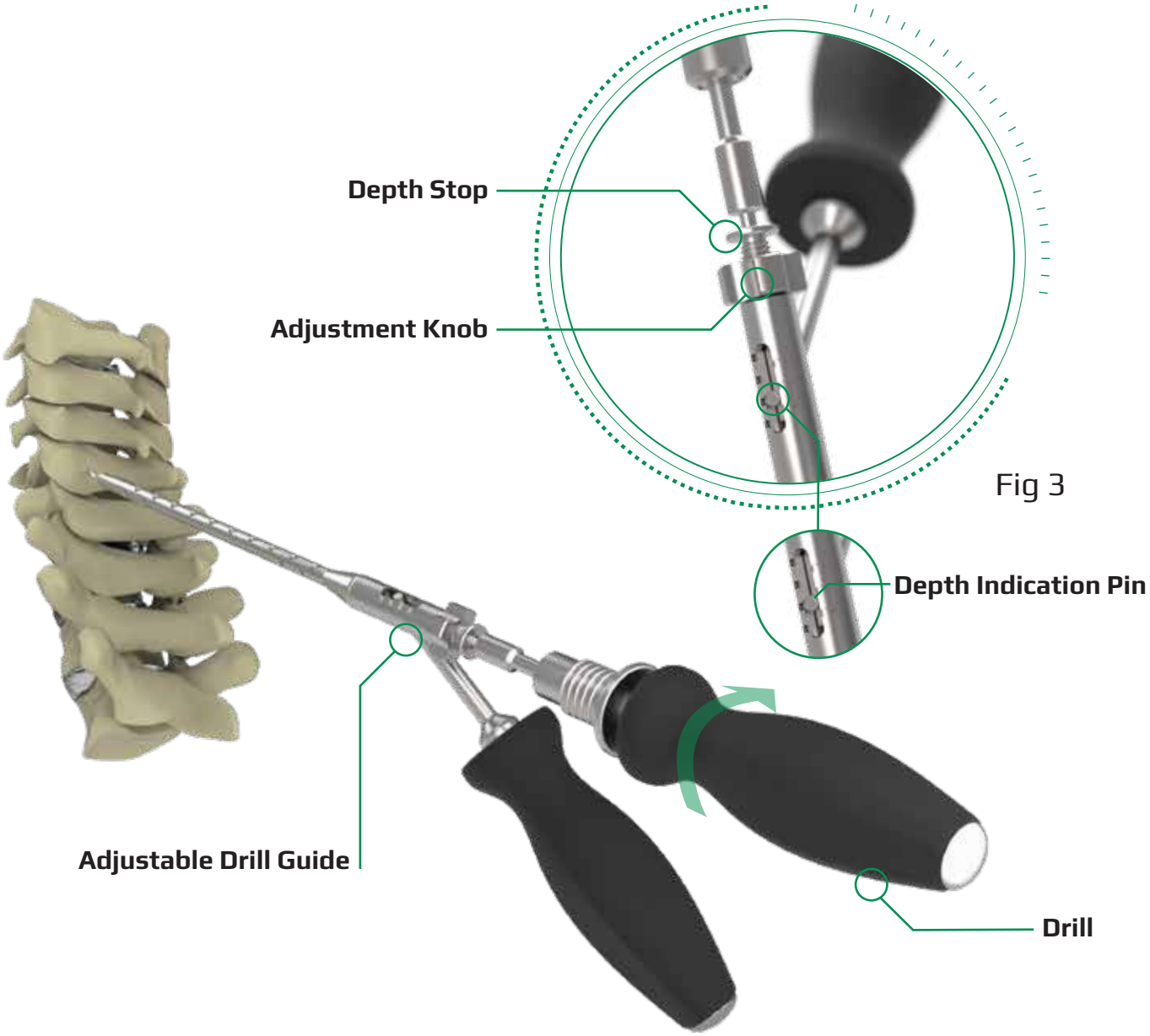


Fig 3

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.

Note: Tap diameters are line-to-line. Tap diameters match screw diameters. (Fig 4).

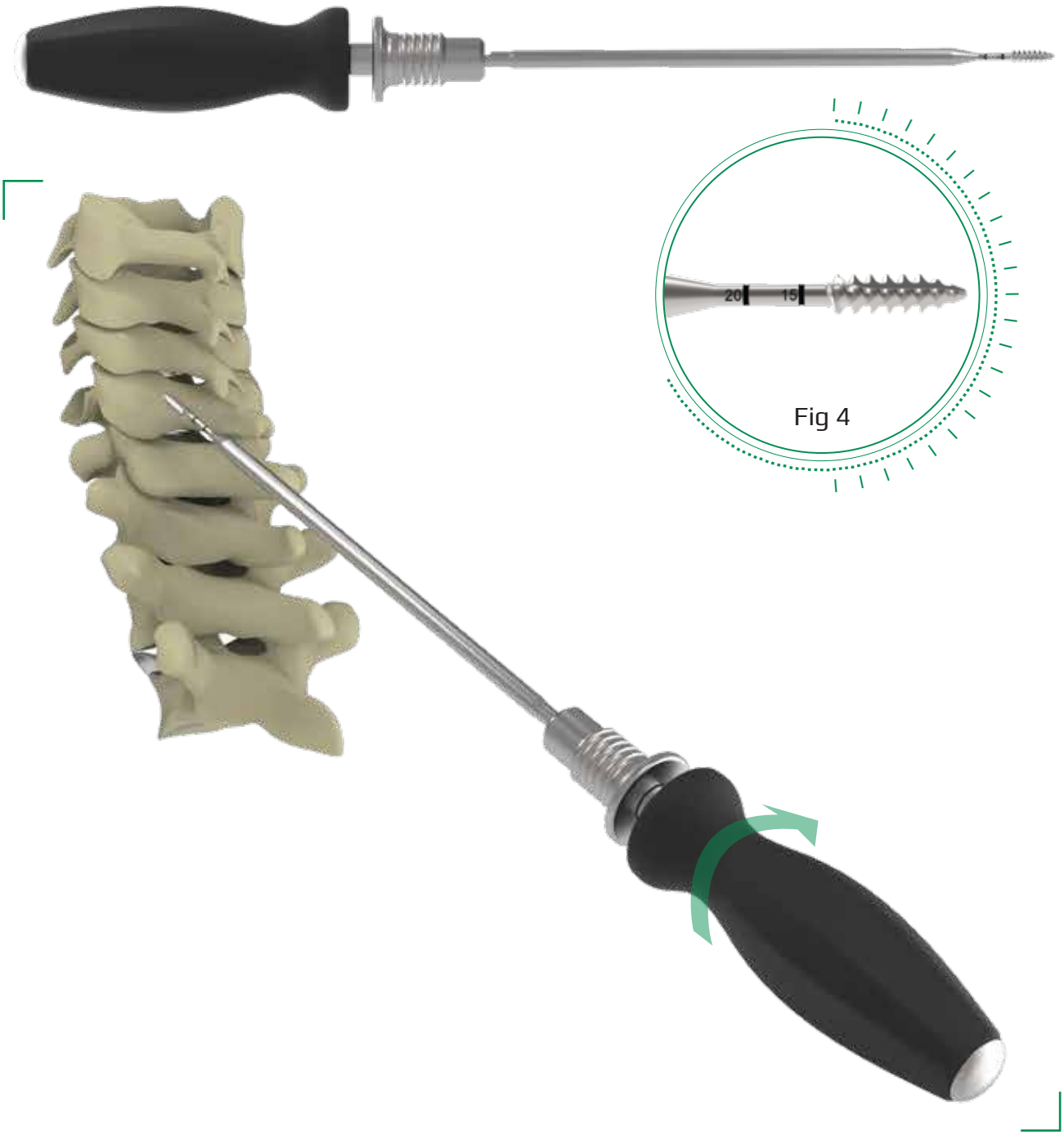


Fig 4

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 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.

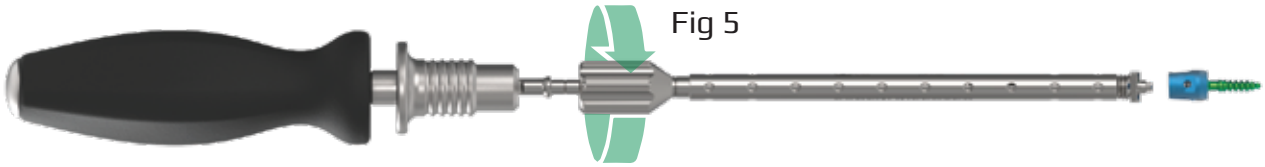


Fig 5

Fig 6

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 30-50; in 5mm increments
Ø4.5mm x 20-50mm; in 5mm increments
Ø5.0mm x 20-50mm; in 5mm increments

Smooth Posterior Screw

Smooth Posterior Screw:
Ø3.5mm x 18-44mm; in 2mm increments
Ø4.0mm x 18-44mm; in 2mm increments

Step 4: Rod Insertion

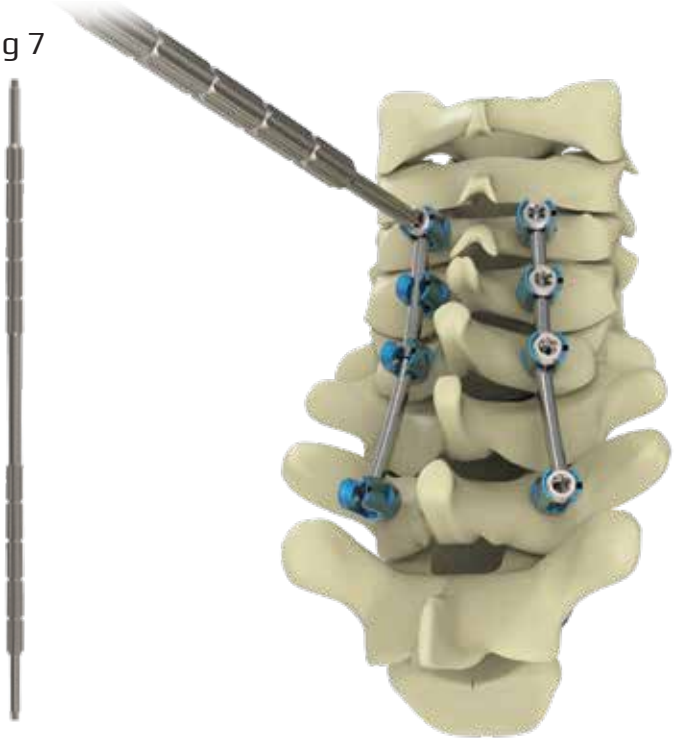
Utilize the Rod Template to determine the required length and contour of the Rods. After the desired length and contour has been identified, the Rod may be cut to the appropriate length using the Rod Cutter and formed to the desired contour using the Rod Bender. Insert the Rod into the head of each screw.

Step 5: Set Screw Insertion

Press the Double-Ended Set Screw Inserter (Fig 7) onto the Set Screw to retain it. Then, insert the retained Set Screw into the head 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.

Fig 7



Note: In the event the Rods need to be reduced, the Rod Reducer and Rod Rocker Fork are available.

Step 6: Compression / Distraction

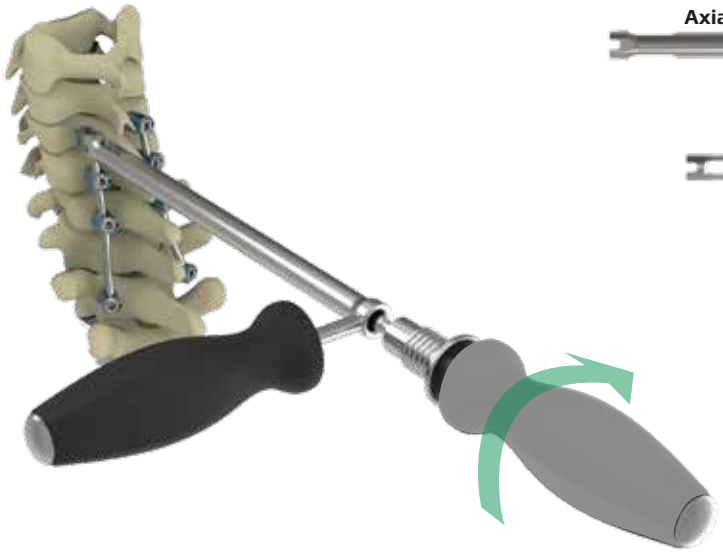
Prior to compression or distraction, one Set Screw should be tightened. To compress, place the inner edges of the Compressor around the screws and squeeze the handles together gently until the appropriate distance apart is achieved. To distract, place the outer edges of the Distractor inside the screws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

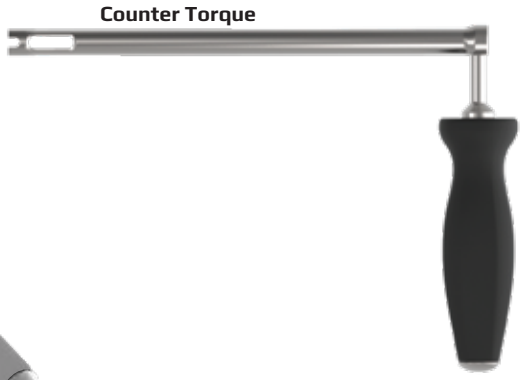
Step 7: Final Tightening / Counter Torque

Guide the tip of the Counter Torque over the polyaxial screw (Fig 8). 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.

Note: An audible click is heard and tension is released within the Torque Limiting Handle when the required 35in-lb locking torque is achieved.

Fig 8

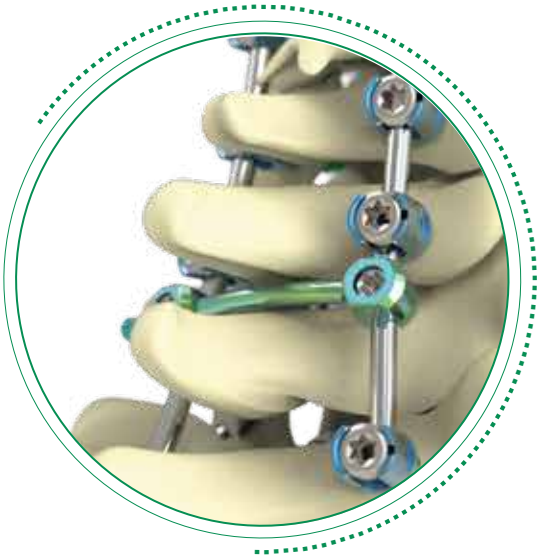




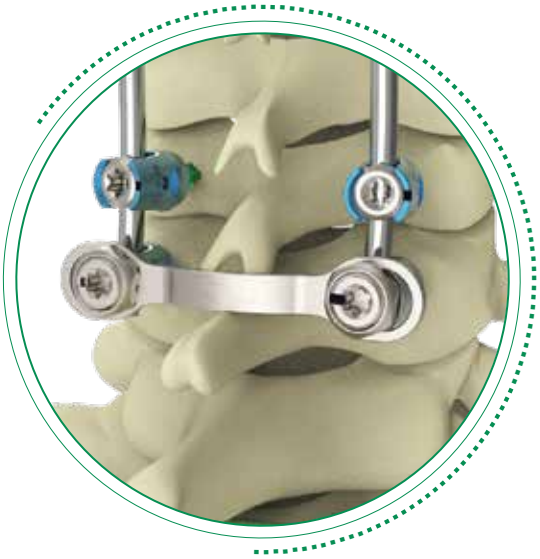
Additional Surgical Options

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 9).



Rod to Rod Connector



Head to Head Connector

Fig. 9

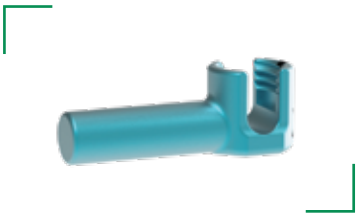
Additional Surgical Options Continued

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 Corexxion 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.

Note: Integrated blue set screws require a locking torque of 90in-lb and integrated grey set screws require a locking torque of 35in-lb.

Note: 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.

Nexxt Spine, LLC
14425 Bergen Blvd, Suite B
Noblesville, IN 46060
P: 317-436-7801 | F: 317 245-2518

70-055, Rev A