

Unified Spine

PCT POSTERIOR CERVICAL THORACIC SPINAL SYSTEM

SURGICAL TECHNIQUE GUIDE



PCT SPINAL SYSTEM SURGICAL TECHNIQUE

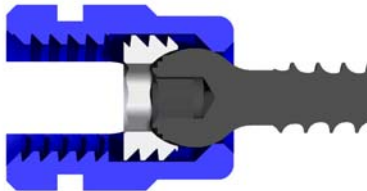
Introduction

The Unified Spine, LLC PCT (Posterior Cervical Thoracic) Spinal System designed in conjunction with Mohammad Majd, M.D. and Richard Holt, M.D. incorporates both strength and function into a competitively priced Spinal Fixation System. The multi-axial head design with a full 28° (56° Total) of angulation in any direction allows for easier rod insertion. The sturdy 3-piece construction provides great strength.

The PCT Spinal system is designed for the treatment of acute and chronic instabilities or deformities of the cervical and thoracic spine. This is achieved through the use of the multiple available sizes of multi-axial screws, rods, hooks, and Cross Connectors.

The following surgical technique is that used by Mohammad Majd, M.D. and Richard Holt, M.D. of Louisville, KY. Unified Spine, LLC as a manufacture does not practice medicine and does not recommend a specific surgical technique for use on any individual patient.

II. Implant Description



Multi-axial Screw:

- 3 Piece Design
- Material: CP Titanium and Titanium Alloy
- 28° of Angulation in Any Direction
- Locking Cap to Secure Position
- Self-tapping Bone Screw
- Uses a 2.0mm Hex Drive

CROSS-SECTION shows the screw fit inside the multi-axial head with the locking cap positioned above the screw.

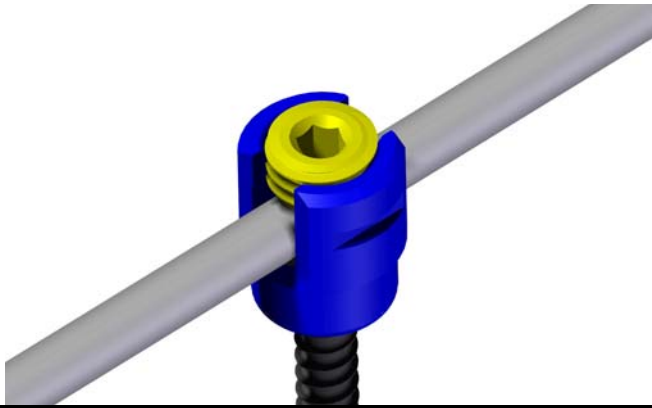
COLOR CODED HEADS allow easy visual distinctions for the 3.5mm, 4.0mm, and 4.5mm diameter Multi-Axial Screws.

PCT SPINAL SYSTEM SURGICAL TECHNIQUE



Set Screw:

- Material: Titanium Alloy
- Buttress Thread for Secure Locking
- Standard 2.5mm Hex Driver
- Torque Limiting Driver Assures Proper Tightening



Rods:

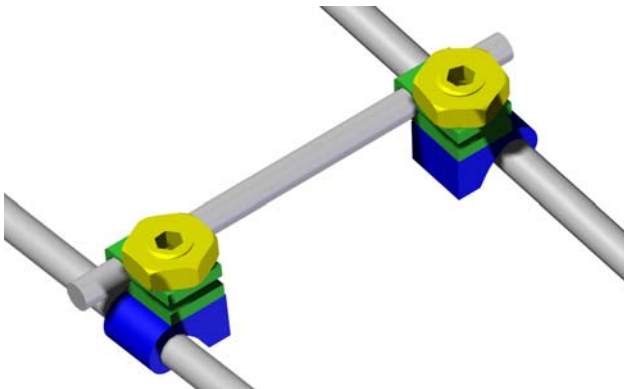
- Material: Titanium Alloy
- Available in 3.5mm diameter
- Available in lengths of:

40mm	80mm
120mm	160mm
200mm	240mm



Hooks:

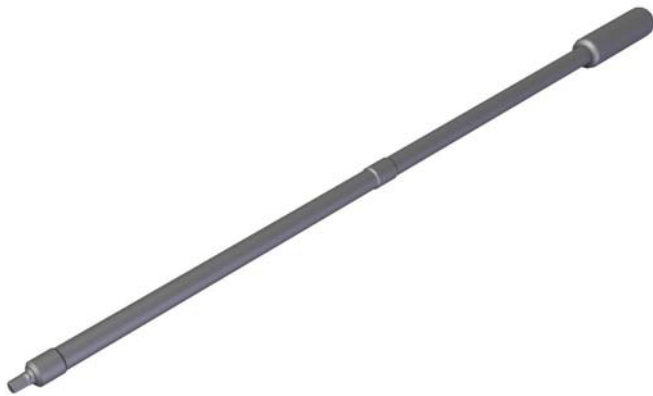
- Two sizes, 4.5mm and 6.0mm, are available to achieve a secure fit with vertebral anatomy
- Utilizes the same top load design of the screws and requires the same set screw



Cross Connectors:

- Material: Titanium
- 1 Size is fully adjustable
- Fits 3.5mm Rods
- Accommodates any deviations of rod alignment from perfectly parallel.

PCT SPINAL SYSTEM SURGICAL TECHNIQUE



Implant Specific Instrumentation:

- This System is designed to use a minimal amount of implant specific instrumentation. This instrumentation includes:

Multi-Axial Screw Inserter – Designed to grasp the Multi-Axial screw head and engage the bone screw for implant insertion.

Anti-Torque Instrument – Designed to shield the torsional force applied from tightening the set screw from undesired forces on the head and screw that may transfer to patient anatomy. This device also features a lever to disengage the instrument from the screw being tightened without the need for any side-to-side or rotational movement being applied to the construct.

Set Screw Starter – Used to preliminarily tighten the set screw into the Multi-Axial Heads.

Rod Bender
Rod Holder
Bone Awl
Probe
Taps
Ball Tip Probe

Quick Connect Handles
Rod Gripper
Soft Tissue Retractor
In-Situ Rod Benders
Rod Reducer

Common Instrumentation:

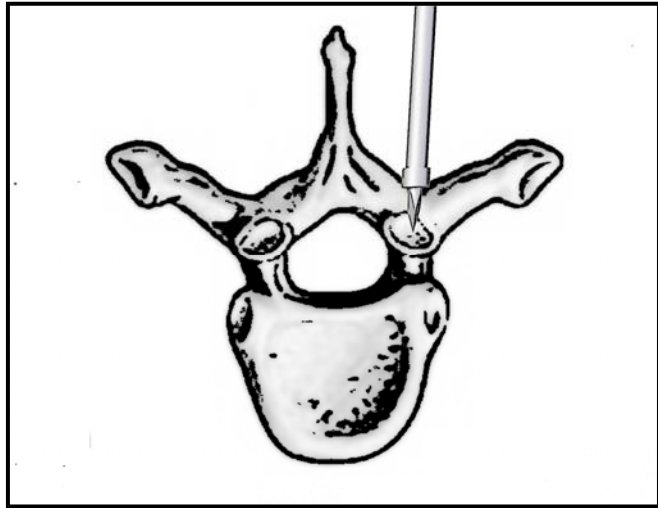
- This System is designed to be compatible with most common instruments currently available in an operation room equipped for Spine Surgery. These Items are listed to the left.

III. Surgical Technique – *Multi-Axial Screw Placement (For use in T1-T3 Only)*

A. Site Preparation

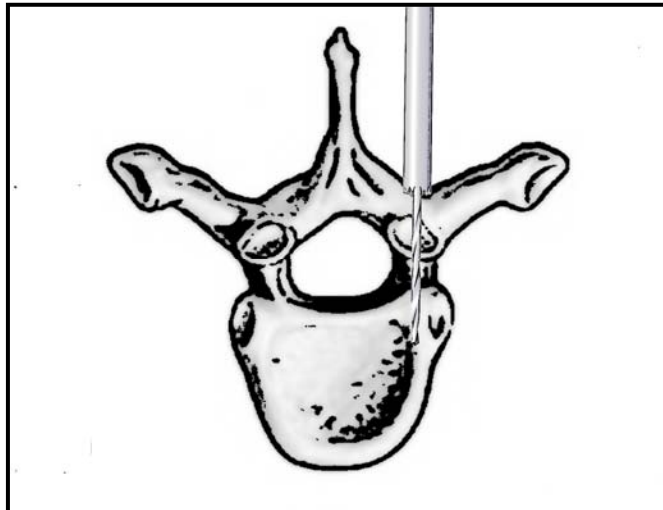
1. Awl

After the preparation of the pertinent posterior spinal elements is complete, determine the screw location and trajectory. Use a screw trajectory that will not endanger neural vascular or visceral structures. Penetrate the cortical bone using either an awl or burr. Use a feeler probe, EMG, or radiograph to verify position.



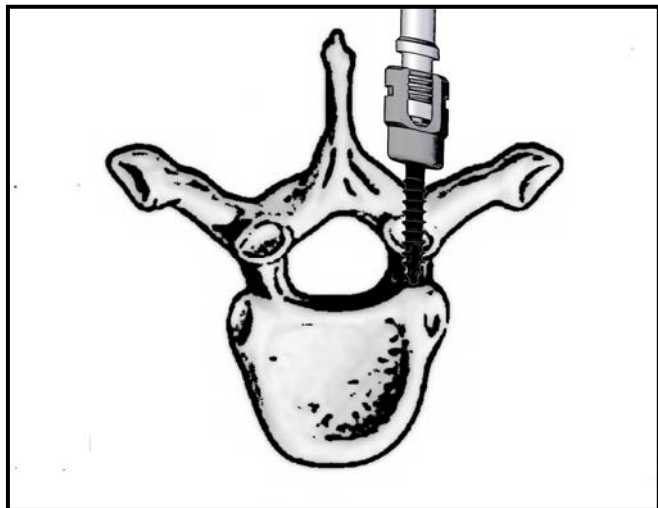
2. Drill and Tap

Utilizing the Drill Guide, drill the appropriate depth hole while maintaining the correct trajectory during drilling. Use a ball tip probe to ensure the drill hole does not break thru the bone on the side walls. A depth gage can be used to confirm the hole depth. Tapping the screw hole is advised for sclerotic bone and optional for non-sclerotic bone.



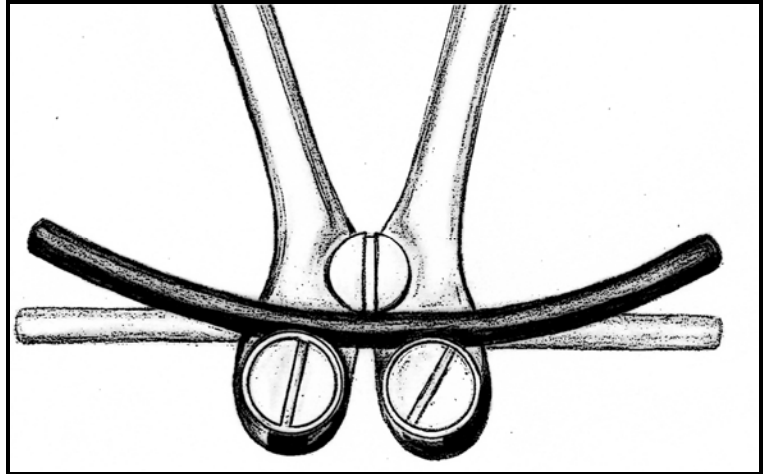
B. Screw Insertion

Load the selected Multi-Axial Screw on the inserter by engaging the hex drive and tightening the threaded sleeve into the threads in the screw head. Insert the screw into the prepared site following the pedicle canal. Utilize care and tactile feedback for proper insertion. Screw heads should not be driven tightly to bone to prevent loss of multi-axial motion. Screws heads should be positioned to form a smooth arc to facilitate rod contouring. Verify screw positioning by radiograph, electro-diagnosis, or palpation of the pedicle wall.



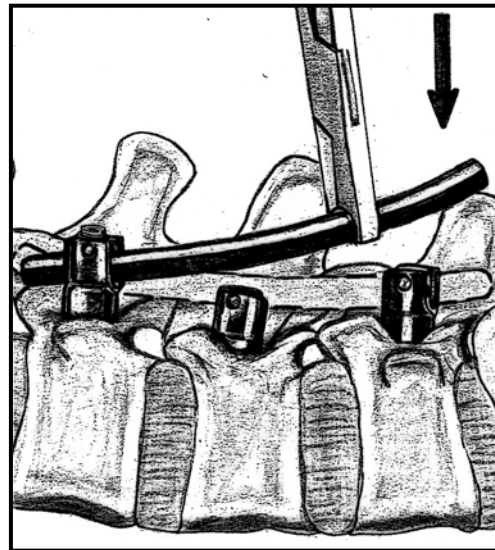
C. Rod Contouring

Contour the rod to fit the screws and stabilize the spine in the desired position. Use the appropriate contour to address any deformity correction. Contour the rods with gentle bends and smooth arcs. Avoid repeated bending and the use of sharp angles.



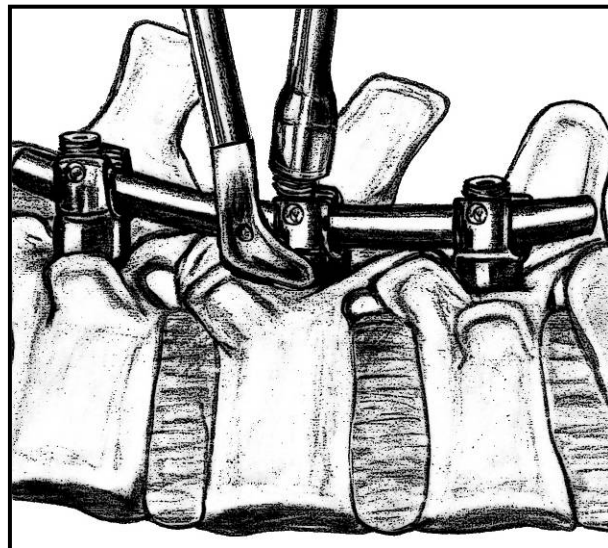
D. Rod Insertion

Insert Rod into position using rod holders. Place set screw in the first Multi-axial Screw Head using the Set Screw Starter. The Set Screw Starter is designed to allow the set screw to be easily started and tightened only finger tight. Once the first Set Screw is in place, move to all subsequent Multi-axial Screw Heads placing Set Screw in each.



E. Rod Reduction

Use any of the variety of available rod reducers, if needed, to seat the rod inside the Multi-axial Screw Head. Once in the desired position, place the Set Screw with the same finger tight technique.

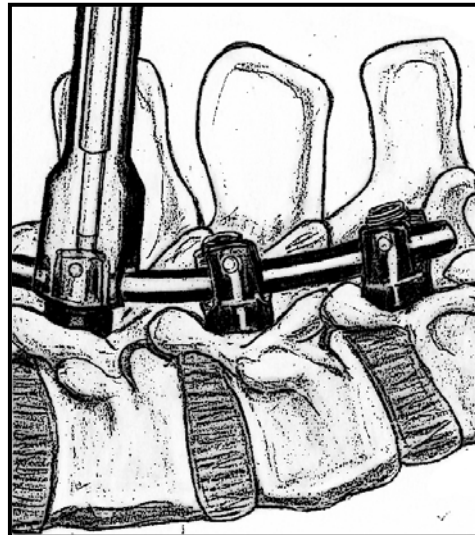


NOTE: SET SCREW SHOULD BE STARTED WITH THE SET SCREW STARTER WITH FINGER TIGHTENING TO ENSURE PROPER THREAD ALIGNMENT. SET SCREWS SHOULD BE INSERTED WITH THE SILVER FACE UPWARDS. THREADS WILL NOT MATE IF SET SCREW IS INSERTER UPSIDE DOWN. FINAL TIGHTENING SHOULD BE PERFORMED WITH THE ANTI-TORQUE INSTRUMENT IN PLACE AND SET SCREWS SHOULD BE TIGHTENED TO 40 IN-LBS.

Once the set screws are preliminarily placed, use Compressors and Distractors as shown to position the spine in the desired position before tightening the set screws.

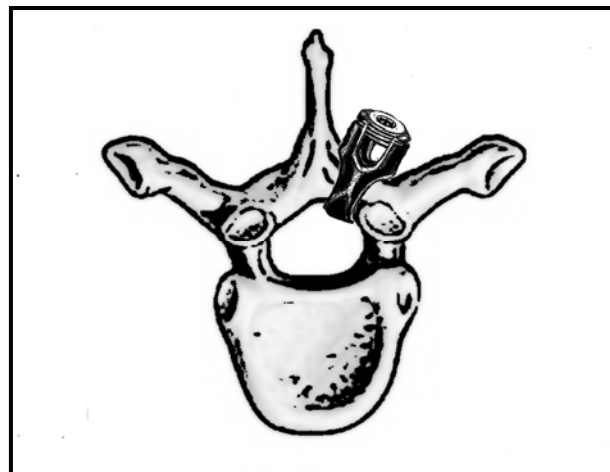
F. Final Tightening

Once the rod is placed in the desired position with the Set Screws finger tight, final tightening can be performed. The anti-torque device must be placed over the head of the Multi-axial Screw. The Set Screw is then tightened to 40 in-lbs. using a torque measuring or torque limiting driver to ensure proper tightening. Ensure the driver is fit properly into the Set Screws and that the Set Screw is threaded properly in the Multi-axial Head. Avoid cross threading. All Set Screws will be tightened with this method taking care not to miss any Set Screws.



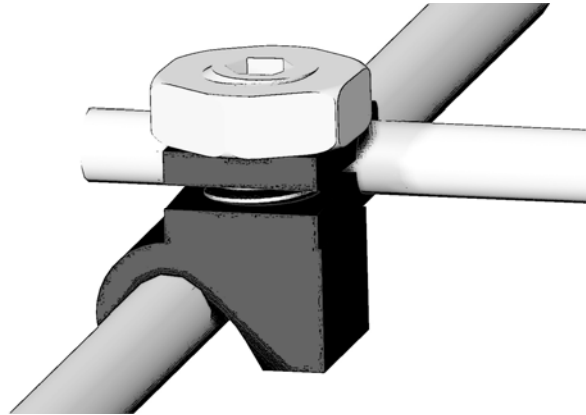
G. Hook Application

Hooks can be used as anchor points to the spine. When using hooks, consider the direction of the corrective force so that the contact of the hook on the spine will not loosen when the compressive or distractive force is applied. The appropriate hook sites can be supra of infra laminar, inter-facet, on the cephalad edge of a transverse process in the upper and mid thoracic spine, or intraosseous in previously fused spines. Care must be used to prevent neural compression when the hook foot is placed in an intra-canal position. Once hooks are placed, they are attached to the rods in the same manner as the Multi-axial screws using the same set screw and torque of 40 in-lbs. while using the anti-torque device.



H. Cross Connectors

Cross Connectors are used to increase the strength and stability of the construct. Choose the location desired for the cross connector and apply the “J” brackets to the rods and preliminarily tighten the set screw. Choose the shortest cross connector plate to span the distance from one “J” bracket to the next. After placing the crossconnector plate, apply and preliminarily tighten the nut to each set screw. Apply final tightening to the set screws followed by final tightening of the nuts.



I. Closure

After implantation is complete, wound closure should be performed to according to the surgeon’s standard protocol.

IV. INDICATIONS FOR USE:

See package insert for complete information.

The PCT Spinal System is intended to promote fusion of the cervical spine and cervico-thoracic junction (C1-T3), and is indicated for the following:

1. Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Spondylolisthesis
3. Spinal stenosis
4. Fracture or dislocation
5. Revision of previous cervical or cervico-thoracic spine surgery
6. Tumors

The use of multi-axial 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.

V. CONTRAINDICATIONS

See package insert for complete information.

Contraindications include, but are not limited to:

- a. Active infectious process or significant risk of infection (immunocompromise).
- b. Fever or leukocytoses.
- c. Any patient with bone absorption, osteopenia, osteomalacia and/or osteoporosis.
- d. Any case not requiring bone graft and fusion.
- e. Pregnancy.
- f. Any case where the components would be too large or too small to achieve a successful result.
- g. Signs of local inflammation.
- h. Any pathological condition that would preclude the potential benefit of spinal implant surgery such as presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count or a marked left shift in the WBC differential count.; elevation of sedimentation rate unexplained by other disease or elevation of white blood cell count or a marked left shift in the WBC differential count.
- i. Any patient with inadequate soft tissue coverage of operative site or inadequate bone from any cause for implants.
- j. Morbid obesity.
- k. Any patient with allergy or intolerance of the implant materials.
- l. Any patient in whom utilization would interfere with anatomical structure or physiological function.
- m. Any patient unwilling to follow post operative instructions.
- n. Any case not directed in indications.

PCT SPINAL SYSTEM SURGICAL TECHNIQUE

Rods for 3.5mm System

<u>Part Number</u>	<u>Description</u>
506100	3.5mm x 40mm
506102	3.5mm x 80mm
506104	3.5mm x 120mm
506106	3.5mm x 160mm
506108	3.5mm x 200mm
506110	3.5mm x 240mm
506111	Transitional Rod – 3.5mm to 5.5mm
506112	Transitional Rod – 3.5mm to ¼ Inch

Multi-Axial Screws for 3.5mm System

<u>Part Number</u>	<u>Description</u>
506310	3.5mm x 10mm Mult-Axial Screw
506312	3.5mm x 12mm Mult-Axial Screw
506314	3.5mm x 14mm Mult-Axial Screw
506316	3.5mm x 16mm Mult-Axial Screw
506318	3.5mm x 18mm Mult-Axial Screw
506320	3.5mm x 20mm Mult-Axial Screw
506322	3.5mm x 22mm Mult-Axial Screw
506410	4.0mm x 10mm Mult-Axial Screw
506412	4.0mm x 12mm Mult-Axial Screw
506414	4.0mm x 14mm Mult-Axial Screw
506416	4.0mm x 16mm Mult-Axial Screw
506418	4.0mm x 18mm Mult-Axial Screw
506420	4.0mm x 20mm Mult-Axial Screw
506422	4.0mm x 22mm Mult-Axial Screw
506424	4.0mm x 24mm Mult-Axial Screw
506426	4.0mm x 26mm Mult-Axial Screw
506428	4.0mm x 28mm Mult-Axial Screw
506520	4.5mm x 20mm Mult-Axial Screw
506524	4.5mm x 24mm Mult-Axial Screw
506526	4.5mm x 26mm Mult-Axial Screw
506528	4.5mm x 28mm Mult-Axial Screw
506532	4.5mm x 32mm Mult-Axial Screw

Hooks for 3.5mm System

<u>Part Number</u>	<u>Description</u>
506270	4.5mm Hook
506280	6.0mm Hook

Set Screw for 3.5mm System

<u>Part Number</u>	<u>Description</u>
506120	Set Screw

Cross Connectors for 3.5mm System

<u>Part Number</u>	<u>Description</u>
506219	Adjustable Cross Connector

Smooth Shank Multi-Axial Screws

<u>Part Number</u>	<u>Description</u>
506620	3.5mm x 20 smooth shank Multi-Axial Screws
506622	3.5mm x 22 smooth shank Multi-Axial Screws
506624	3.5mm x 24 smooth shank Multi-Axial Screws
506626	3.5mm x 26 smooth shank Multi-Axial Screws
506628	3.5mm x 28 smooth shank Multi-Axial Screws
506630	3.5mm x 30 smooth shank Multi-Axial Screws
506632	3.5mm x 32 smooth shank Multi-Axial Screws
506634	3.5mm x 34 smooth shank Multi-Axial Screws
506636	3.5mm x 36 smooth shank Multi-Axial Screws
506638	3.5mm x 38 smooth shank Multi-Axial Screws
506640	3.5mm x 40 smooth shank Multi-Axial Screws
506642	3.5mm x 42 smooth shank Multi-Axial Screws
506644	3.5mm x 44 smooth shank Multi-Axial Screws
506646	3.5mm x 46 smooth shank Multi-Axial Screws
506648	3.5mm x 48 smooth shank Multi-Axial Screws
506650	3.5mm x 50 smooth shank Multi-Axial Screws

VI. Additional Information

A. **Implant Removal**

Removal of the Unified Spine PCT Spinal System is by following the reverse order of the surgical procedure.

B. **Sterilization Recommendations**

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be cleaned and sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field.

Note: Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared, intact steam sterilization compatible wrap to maintain sterility. Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for the equipment.

¹Validated steam sterilization time required to achieve a 10^{-6} sterility assurance level (SAL). **Implants**
Unless specified otherwise, these implant products are recommended to be steam sterilized by the hospital using the following parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	¹ Pre-Vacuum	270F (132C)	4 Minutes	30 Minutes

See package insert 502010 for complete information.

Instruments

Unless specified otherwise, these instrument products are recommended to be steam sterilized by the hospital using the following parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	¹ Pre-Vacuum	270F (132C)	6 Minutes	30 Minutes

See package insert 502015 for complete information.

C. **Surgical Technique Note**

The surgical technique depicted in this brochure is that used by Mohammad Majd, M.D. and Richard Holt, M.D. of Louisville, KY. Unified Spine, LLC as a manufacture does not practice medicine and does not recommend a specific surgical technique for use on any individual patient. The surgeon performing any implant procedure is responsible for determining the appropriate product or products for each patient and choosing the appropriate surgical technique for their implantation.

Caution: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.