Premia Spine

TOPS™ System Surgical Technique Guide

“There are hip replacements and knee replacements. Why can’t we replace the facet joints with a physiologic motion solution instead of fusion?”

That simple question became our compass in 2003.

After nearly two decades of development and clinical research, we are proud of our achievement a motion-preservation spinal implant for spinal stenosis and spondylolisthesis.

Welcome to the TOPS™ System.

Mobility. Stability. Durability.

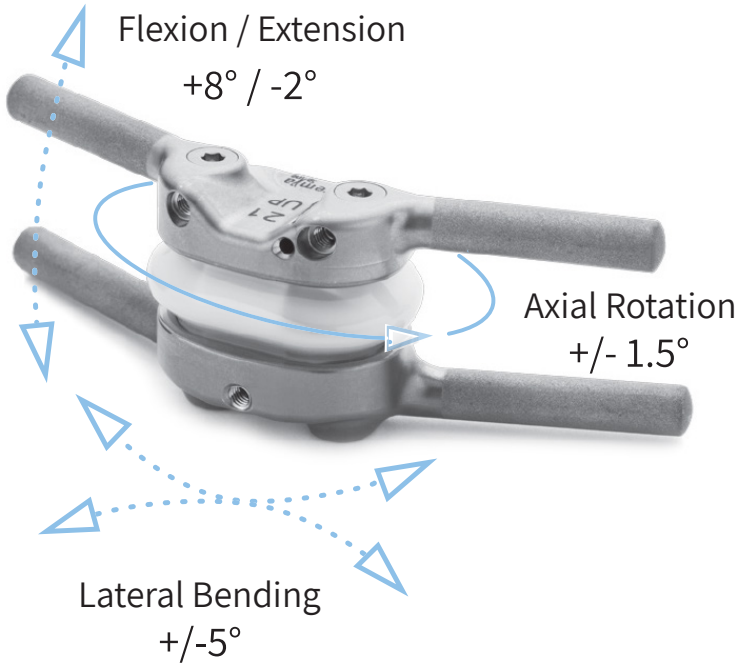
TABLE OF CONTENTS

1. DESCRIPTION OF THE TOPS™ SYSTEM

The TOPS™ System is a motion-preserving spinal implant that is inserted into the lumbar spine via pedicle screws. The device is implanted via a posterior surgical approach to replace the degenerated skeletal elements such as the lamina and the facet joints that are removed during the decompression.

The TOPS™ System is comprised of a motion device ("TOPS Motion Implant") and four pedicle screws. The TOPS Motion Implant is comprised of two Titanium Endplates connected by a polycarbonate urethane (PcU) Boot. Housed between the Titanium Endplates is an internal motion mechanism comprised of titanium and PcU articulating parts and an interlocking woven Polyether Ether Ketone (PEEK) ribbon. The Top Articulating and Bottom Articulating parts are attached to their respective upper and lower Titanium Endplates. The flexible Boot and the internal articulating parts allow relative movement between the endplates.

The device is designed to maintain motion in axial rotation, lateral bending, extension, and flexion, and to block translation when implanted into the human spine.



The TOPS Motion Implant is available in various sizes to meet a range of human anatomy. The TOPS™ System utilizes four polyaxial pedicle screws for fixation to the vertebrae. The Pedicle Screws are made of titanium alloy (Ti-6Al-4V in compliance with ASTM F136). Each polyaxial pedicle screw consists of a screw body, an insert, a screw Tulip, and a locking Set Screw. The Set Screw is threaded into the pedicle screw Tulip to secure the interconnection of the TOPS Motion Implant's arm and lock the polyaxial orientation in place. The Pedicle Screws are available in diameters of 5.5 mm, 6.5 mm and 7.5 mm. Their lengths vary in 5 mm increments from 25 to 60 mm. The heads of the pedicle screws are color anodized to allow for easy identification of screw diameter (5.5 mm - green, 6.5 mm - magenta, and 7.5 mm - blue).

See **Section 6: "TOPS™ System and Instrumentation Set"** and **Appendix 3: "TOPS™ System Catalog"** for additional information regarding the available sizes.

CAUTION: Federal (USA) law restricts this implant to sale by or on the order of a physician.

WARNING: Use of the TOPS™ System should only be undertaken after the surgeon has become thoroughly knowledgeable about the spinal anatomy and biomechanics, has had experience with posterior approach spinal surgeries and has had training in the implantation of the TOPS™ System. Only surgeons who are familiar with the TOPS™ System components, instruments, procedure, clinical applications, biomechanics, adverse events (AEs) and associated risks should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events.

WARNING: Correct selection of the appropriate pedicle screws and TOPS Motion Implant sizes and their correct placement are essential to assure proper performance and functioning of the TOPS™ System and good clinical results. Follow the step-by-step instructions in this Surgical Technique guide on the required surgical technique, the selection and positioning of the pedicle screws and TOPS Motion Implant, and the use of the appropriate TOPS™ System Instruments to assure optimal implant size selection and positioning. Use of inappropriate implant size and mispositioning may lead to suboptimal performance and functionality of the TOPS™ System and to a higher incidence of adverse events.

Key to Success

i. **Patient selection.** Choose patients who have primary leg pain and will benefit from the decompression.

ii. **Go wide with your decompression.** The TOPS Motion Implant is designed to with stand normal shear forces and compressive loads on the posterior spinal column. Performing a complete facetectomy/laminectomy and ensuring that the nerve roots are free to the lateral recesses will maximize the chances for clinical success.

iii. **Rely on the instrumentation. Seek precision.** The TOPS™ System is different from a fusion procedure as it requires proper implant positioning. This surgical technique guide and the TOPS Instrumentation will help you achieve your goals.

2. INDICATIONS AND CONTRAINDICATIONS

Indications for Use

The TOPS™ System is a motion preserving spinal implant that is inserted into the lumbar spine via pedicle screws. The TOPS™ System is intended to stabilize the spine following a lumbar decompression without rigid fixation.

The TOPS™ System is indicated for patients between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade I, with moderate to severe lumbar spinal stenosis and either thickening of the ligamentum flavum and/or scarring of the facet joint capsule at one level from L3 to L5.

Contraindications

The TOPS™ System should not be implanted in patients with the following conditions:

- Presence of extruded or free fragment disc herniation at the index level
- Spondylolisthesis greater than Grade I
- Traumatic dysplastic or lytic spondylolisthesis
- Back or non-radicular leg pain of unknown etiology
- Stenosis where the etiology is considered to be congenital, iatrogenic, post-traumatic, or metabolic
- Known allergy or sensitivity to PEEK, titanium, and/or polyurethane
- Scoliosis greater than 10 degrees by major Cobb angle (both angular and rotational)
- Morbid obesity defined as a body mass index greater than 40
- Lumbar spine T score less than -2.0
- Active infection - systemic or local
- Cauda equina syndrome or neurogenic bowel/bladder dysfunction

Clinical Summary

TOPS demonstrates clinical superiority in overall trial success compared to fusion at 24 months. The difference between the TOPS success rate of 77% and fusion's rate of 24% is statistically superior. See TOPS™ System Instructions for Use (IFU) for additional safety and efficacy information.

3. WARNINGS AND PRECAUTIONS

Warnings

- Use of the TOPS™ System should only be undertaken after the surgeon has become thoroughly knowledgeable about the spinal anatomy and biomechanics, has had experience with posterior approach spinal surgeries and has had training in the implantation of the TOPS™ System. Only surgeons who are familiar with the TOPS™ System components, instruments, procedure, clinical applications, biomechanics, adverse events (AEs) and associated risks should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.
- Correct selection of the appropriate pedicle screws and TOPS Motion Implant sizes and their correct placement are essential to assure proper performance and functioning of the TOPS™ System and good clinical results. Follow the step-by-step instructions in this Surgical Technique guide on the required surgical technique, the selection and positioning of the TOPS™ System, and the use of the appropriate TOPS™ System instruments. Use of inappropriate implant size and mispositioning may lead to suboptimal performance and functionality of the TOPS™ System and to a higher incidence of adverse events.
- Explants are considered biologically contaminated and should be treated with universal precautions. Contact Premia Spine for instructions for explant handling.
- **Do not** use instruments for any action for which they are not intended. Improper use may result in damaged/broken instruments or patient injury.
- Examine all instruments prior to surgery for wear or damage. **Do not** use worn or damaged instruments or instruments that do not function properly. Any form of distortion or excessive wear on instruments may cause a malfunction that could lead to serious patient injury.

Precautions

General:

- The safety and effectiveness of the TOPS™ System has not been evaluated in patients with the following Condition:
  - > Prior surgery at any lumbar vertebral level with instrumentation.
  - > Prior surgery at an adjacent lumbar vertebral level without instrumentation.
  - > More than one vertebral level requiring surgical decompression.
  - > More than one surgical procedure at any combination of lumbar levels.
  - > Disc herniation at any lumbar level requiring surgical intervention.
  - > Pregnancy.
  - > Chronically taking medications or any drug known to potentially interfere with bone/soft tissue healing (e.g., steroids).
  - > Uncontrolled diabetes.
  - > Known history of Paget's disease, osteomalacia, or any other metabolic bone disease.
  - > Rheumatoid arthritis or other autoimmune diseases.
- The patient should review the Patient Labeling and be informed of the potential adverse effects (risks/complications) associated with the TOPS™ System procedure and general spinal surgery included in this guide (see Section 4: Potential Adverse Effects of the Device on Health section).
- Keep the TOPS™ System Instructions for Use and this guide accessible to all staff.
- Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- Each patient's record shall document the implant used (name, serial number, lot number).

Preoperative:

- Proper patient selection is extremely important. Please refer to Sections 1, 2, 3 and 4 of this guide for detailed indications, contraindications, potential adverse events, warnings, and precautions.
- Preoperative planning should be used to estimate the required implant size and to ensure that the appropriate sizes are available for surgery. Correct selection of the appropriate implant size is important to assure the performance and function of the device. The procedure should not take place if the appropriate range of sizes is not available.
- The TOPS™ System is indicated for use only with pedicle screws supplied by Premia Spine. **Do not** implant the TOPS™ System with components from any other manufacturer.
- Use care when handling the TOPS™ System's implants to ensure that they do not come in contact with sharp objects that may damage the implants and render the TOPS™ System functionally unreliable. **Do not** use if any part of the device appears damaged or not fully assembled.
- The TOPS™ System (TOPS Motion Implant and Pedicle Screws) is provided sterile and intended for a single use only. **Do not** use if sterility is compromised. **Do not** re-sterilize.
- The TOPS™ System implants are packaged in a double-blister pack sealed with a Tyvek® lid and contained in a carton cardboard box. The integrity of the packaging should be confirmed to ensure that the sterility of the contents is not compromised. **Do not** use if package has been compromised.
- The "use by" date must be checked. **Do not** use if the date on the lable has expired.
- Always remove the TOPS™ System's implants (Pedicle Screws and TOPS Motion Implants) from the packaging using standard aseptic techniques only after the correct size has been determined.
- **Do not** re-use or re-implant the TOPS™ System. Although the implant may appear undamaged, non-visible damage could result in implant failure.
- The TOPS™ System must not be used with instruments of spinal systems from other manufacturers.
- The TOPS™ System instruments are reusable, provided non-sterile and must be thoroughly cleaned and sterilized in accordance with the validated cleaning and sterilization instructions described in the TOPS™ System Instrumentation Set Instructions for Use (IFU) prior to use.
- The K-Wires are part of the TOPS™ System Instrumentation Set and are provided non-sterile and must be sterilized in accordance with the validated instructions described in the TOPS™ System Instrumentation Set Instructions for Use (IFU) prior to use.
- The K-Wires are intended for a single use only and should be discarded after use. **Do not** re-sterilize. **Do not** re-use.

Intraoperative:

- Pay special attention to match the patient's neutral standing lordosis and the lordosis on the operating room table for optimal implant placement. To best achieve this with the TOPS Motion Implant, place the patient in a slight flexion position in surgery.
- The TOPS™ System is indicated for use only with pedicle screws supplied by Premia Spine. **Do not** implant the TOPS™ System with components from any other manufacturer.
- Use the appropriate TOPS™ System Instruments according to the instructions in this guide and in the TOPS™ System Instruments Set Instruction For Use (IFU) to assure correct positioning of the pedicle screws and the TOPS Motion Implant. Failure to correctly use the TOPS instruments can lead to misalignment of the pedicle screws and the TOPS Motion Implant and may force the TOPS Motion Implant into an asymmetrical position which might compromise implant performance and functionality.
- Correct selection of the appropriate pedicle screws size is essential to ensure proper performance and functionality of the TOPS™ System. Too long screws might breach the anterior cortex of the vertebra and cause patient injury.
- Be sure that the Pendulum Marker falls anywhere between the two notches of the Pendulum. If the Pendulum Marker extends beyond the range of the Pendulum (± 10°), then the TOPS Motion Implant arms may not sit properly into the bottom of the Pedicle Screw Heads. Choose a different screw trajectory that fits within the proper range.
- Be sure not to violate the superior facet capsule when placing the superior pedicle screws.
- Be sure that the Gauge Handle is parallel to the disc.
- The TOPS Motion Implant is supplied with a sterile 27G stainless steel needle connected to the filling port:
    - > **Do not** remove the needle until after the TOPS Motion Implant has been filled with saline.
    - > **Do not** attempt to redirect the needle during filling as this may damage the needle. If for any reason the needle becomes disengaged or damaged before the TOPS Motion Implant has been properly filled, remove the needle, and replace it with a 25G x 5/8'' hypodermic needle.
- Make sure the UP and DOWN indicators on the Loading Base match these indicators on the TOPS Motion Implant to ensure correct orientation and positioning of the TOPS Motion Implant during implantation, which are crucial for performance and functioning of the device.
- Prior to implantation of the TOPS Motion Implant, make sure that the TOPS Motion Implant device is filled with saline. Follow the instructions provided in this guide for adequate saline filling to avoid insufficient initial lubrication which might lead to mechanical failure.
- Never actively reduce the lumbar spondylolisthesis, as it could lead to device malfunction.
- TOPS Motion Implant should only be inserted into the patient via the TOPS Inserter. Manual insertion can lead to device misalignment.
- **Do not** release the TOPS Motion Implant from the TOPS Inserter before final tightening to keep the optimal positioning of the TOPS Motion Implant until torquing the set screws.
- Carefully inspect the TOPS Motion Implant to ensure that the arms are well seated in the pedicle screw heads and that there is no evidence of set screw cross-threading.

Postoperative:

- Patients should be advised to follow the postoperative care procedures instructed by the surgeon. Following completion of the procedure, each patient should receive postoperative care customized to his/her postoperative needs and demonstrated progress. Patients should receive approval from a healthcare professional before commencing to ambulate. Guidance on types and timing of physical activity after surgery, including an exercise program, should be determined by a physician or a physical therapist.
- Patients should be instructed to avoid heavy lifting (greater than 20 pounds) for 6 weeks, and impact sports for 3 months.

4. ADVERSE EFFECTS AND RISKS

Potential Adverse Effects of the Device on Health

As with any surgery, surgical treatment of lumbar spine disorders is not without risk. A variety of complications related to the surgery or the use of the TOPS™ System may occur. The following is a list of the potential adverse effects (i.e., complications, risks) associated with the use of the TOPS™ System identified from the TOPS™ System clinical trial results, use of the TOPS™ System outside of the United States, approved device labeling for other lumbar spinal devices, and published scientific literature. The Adverse Effects are sub-divided into three categories: (1) those commonly associated with any surgical procedure; (2) those associated with lumbar spinal surgery procedures using a posterior approach; and (3) those associated with posterior spinal implants, including those pertaining to the TOPS™ System. These risks may occur singly or in combination, and may be severe and/or negatively impact patient outcomes.

The causality of these adverse effects is not exclusive to these categories, nor does the list below necessarily imply a causal relationship between an individual AE and a particular category. In addition to the risks listed below, there is also the risk that the procedure may not be effective and may not relieve or may cause worsening of pre-operative symptoms. Additional surgery may be required to correct some of the potential adverse effects.

Possible Risks Associated with any Surgical Procedure include:

- Anesthesia complications including allergic reaction, anaphylaxis, or other reactions to anesthesia
- Reactions to transfused blood
- Anemia
- Blood loss/ hemorrhage
- Heart or vascular complications including:
    - > excessive bleeding or injury to blood vessels
    - > edema
    - > hematoma or seroma
    - > hypotension or hypertension
    - > ischemia
    - > cardiac event
    - > myocardial infarction,
    - > embolism including pulmonary embolism
    - > thrombosis
    - > thromboembolism
    - > thrombophlebitis
    - > phlebitis
    - > stroke
    - > hemorrhage or vascular damage resulting in catastrophic or potentially fatal bleeding
- Septicemia
- Cerebral Vascular Accident (Stroke)
- Pulmonary complications including atelectasis, pneumothorax or pneumonia, pulmonary edema and respiratory distress
- Blindness secondary to pressure on the eye during surgery
- False aneurysm
- Headache
- Infection (wound, local, and/or systemic) abscess, or cellulitis
- Soft tissue damage or fluid collections, including edema, hematoma or seroma, which may require drainage, aspiration, or debridement or other intervention
- Surgical wound dehiscence, necrosis, or scarring of tissue around the wound
- Post-surgical pain, bruising, tenderness or discomfort at the surgical site or incision and/or skin or muscle sensitivity over the incision which may result in skin breakdown, pain, and/or irritation
- Impairment of the gastrointestinal system including ileus or bowel obstruction, nausea or vomiting

- Impairment of the genitourinary system including incontinence, bladder dysfunction, urinary tract infection, or reproductive system complications
- Neurological complications including nerve damage, paralysis, seizures or convulsions, changes to mental status, or reflex sympathetic dystrophy
- Psychological illness
- Injury to muscles, or organs
- Insomnia
- Narcotic addiction
- Numbness
- Complications of pregnancy including miscarriage or congenital defects
- Inability to resume activities of daily living
- Death

Possible Risks Associated with the Posterior Lumbar Spinal Surgery Procedure include:

- Risks to neurological structures:
    - > dural tear dural leak and/or dural injury with or without CSF leakage
    - > arachnoiditis
    - > compressive neuropathy
    - > neurologic deterioration - injury to nerves or nerve roots associated with the spinal cord (resulting in pain, weakness, paralysis (partial or complete), paresthesia, altered reflexes, numbness, tingling, or other changes in sensation)
    - > coordination abnormalities
    - > dysphasia
    - > gait disturbance
    - > headache
    - > otitis media
    - > tremors
    - > cerebrospinal fluid leakage
    - > cerebrospinal fistula
    - > Reflex Sympathetic Dystrophy (RSD)
- Cauda equina syndrome
- Damage to nerves, blood vessels, and nearby tissues
- Impaired muscle or nerve function
- Epidural bleeding, hematoma, or fibrosis
- Bone necrosis
- Degenerative changes in adjacent segment
- Surgery at incorrect level
- Osteolysis
- Loss of bowel or bladder function
- Incontinence (loss of bowel or bladder control)
- Fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery
- Postoperative muscle and tissue pain
- Development of disc degeneration at adjacent levels
- Inflammatory conditions
- Loss of disc height
- Disc herniation
- Undesirable change in lordosis
- Scarring or soft tissue damage
- Spinal instability

- Spondylolisthesis acquisita (vertebral slippage)
- Retrolisthesis
- Spinal stenosis (narrowing of the spinal canal)
- Spondylosis
- Facet joint deterioration
- Infection of the bone, or surrounding soft tissue
- Musculoskeletal spasms (back or leg)
- Perineural fibrosis
- Surgery may not reduce the preoperative pain experienced
- Pain and discomfort associated with the presence of implants
- Pain and discomfort associated with the surgical procedure (e.g., cutting of muscles, ligaments, and tissue) and healing
- The spine may undergo adverse changes or deterioration including loss of proper spinal curvature, correction, height, and/or reduction, or malalignment, and another surgery may be required
- Adverse bone/implant interface reaction

Possible risks associated with posterior lumbar spinal implants including the TOPS™ System:

- Adverse reaction or allergy to the device materials [Titanium, Polycarbonate Urethane (PCU), and Polyether Ether Ketone (PEEK)], or device wear debris which may lead to an adverse reaction of the local tissues or chronic inflammation that may lead to implant loosening or failure of the device, adverse tissue reaction, osteolysis, tumor formation, autoimmune disease, metallosis, scarring, or other symptoms
- Interference with radiographic imaging because of the presence of the device
- Adverse reaction or allergy to contrast media
- Herniated nucleus pulposus
- Heterotopic ossification
- Risks directly related to the device position and condition, including
    - > implants malposition
    - > implant breakage
    - > implant degradation
    - > implant disassembly
    - > implant displacement
    - > implant migration, subsidence, loosening or dislocation
    - > implant separation
    - > improper sizing
    - > anatomical difficulties during the surgery
- Misplaced screws in pedicle
- Nerve root or spinal cord impingement or injury
- Neurologic deterioration
    - > cauda equina
    - > clumsiness
    - > foot drop
    - > limp
    - > numbness
    - > paralysis
    - > short step
    - > slow moving gait
    - > weakness
- Osteophyte resorption
- Osteolysis or vertebral inflammation

- Reoperation including revision, removal, or supplemental fixation
- Vertebral overload resulting in device failure
- Development of new pain
- Failure of the device to improve symptoms or function
- Problems during placement of the device including trouble sizing the device, anatomical or technical difficulties implanting the device
- Implantation at the wrong spinal level
- Issues with the device instruments (e.g., bending/damage or breakage) including the possibility that a fragment of a broken instrument may remain in the patient after implantation, and improperly cleaned/disinfected instruments
- Device/joint noise
- Change in the alignment of the spine or loss of proper anatomic curvature, correction, height or reduction of the spine including spondylolisthesis, change in lordosis, or instability of the spine
- Degeneration of other parts of the spine including the facet joints or adjacent discs
- Development of a new or recurrent spinal problem at the surgery level, or at the level above or below the treated spinal level
- Fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery
- Unintended bone formation (i.e., heterotopic ossification, annular ossification) that may result in bridging trabecular bone and may reduce spinal motion or result in unintended fusion at either the treated level or adjacent levels
- Device failure which may require a subsequent surgical intervention at the treated spinal level or at the level above or below the treated spinal level (including removal of the TOPS™ System, revision, re-operation or supplemental fixation
- Additional radiography and contrast media may be used during the subsequent surgical intervention

Specific Adverse Events that Occurred in the Clinical Study

- Musculoskeletal disorders
- Surgery-related complications (dural tear, wound healing)
- Neurological disorders
- Urogenital disorders
- Fever, wound infections, other infections
- Gastrointestinal disorders
- Vascular events (DVT, hypotension)
- Respiratory events
- Abnormal blood and other tests
- Pedicle screw loosening or implant migration
- Pain medication-related events
- Cardiovascular events
- Other events (not identified with other event categories)

5. MRI SAFETY INFORMATION:

A person with the TOPS™ System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	**TOPS™ System**
Static Magnetic Strength (B0)	1.5 or 3.0 T
Maximum Spatial Field Gradient	20 T/m
RF Excitation	Circularly Polarized
RF Transmit Coil Type	There are no Trasmit Coil Restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In non-clinical testing, the image artifact caused by the TOPS (Total Posterior Spine) System extends approximately 10-mm from this device when imaged with a gradient echo pulse sequence and a 3T MRI system.

Patients who have other MR Conditional devices can be scanned as long as all the MR Conditional scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met.

Device	**Size/Configuration**	**Length**
TOPS Motion Implant	21 (IPD)	L/M/S
	30 (IPD)	L/M/S
	38 (IPD)	L/M/S
Pedicle screws	Ø5.5 mm	25 to 60 mm
	Ø6.5 mm	25 to 60 mm
	Ø7.5 mm	25 to 60 mm

6. TOPS™ SYSTEM AND INSTRUMENTATION SET

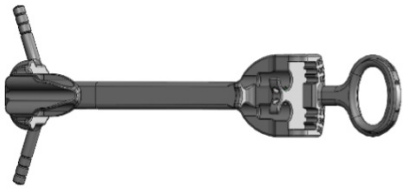
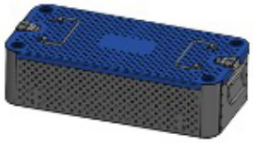
Implants	Description
	TOPS Motion Implants are available in nine sizes. The numerical descriptor signifies the interpedicular distance (IPD) measured between the distal ends of the top plate and bottom plate arms (21, 30 or 38), and the letter descriptor (S, M, or L) signifies the three arm lengths. The TOPS Motion Implant is provided sterile in a double blister pack sealed with Tyvek® lids.
	The pedicle screws are available in three diameters identified by a unique head color: 5.5mm (green), 6.5mm (magenta) and 7.5mm (blue). Their lengths range from 25mm to 60mm in 5mm increments. Each pedicle screw is provided sterile in a double blister pack sealed with Tyvek® lids which also contains a locking Set Screw.

WARNING: Correct selection of the appropriate pedicle screws and TOPS Motion Implant sizes and their correct placement are essential to assure proper performance and functioning of the TOPS™ System and good clinical results. Follow the step-by-step instructions in this guide on the required surgical technique, the selection and positioning of the pedicle screws and TOPS Motion Implant, and the use of the appropriate TOPS™ System Instruments to assure optimal implant size selection and positioning. Use of inappropriate implant size and mispositioning may lead to suboptimal performance and functionality of the TOPS™ System and to a higher incidence of adverse events.

There are 4 key TOPS™ System instruments. These instruments are designed to facilitate the TOPS™ System surgery and ensure proper sizing and placement of the TOPS Pedicle Screws and the TOPS Motion Implant. **APPENDIX 4 "INSTRUMENTATION KIT"** lists all available instruments that can be used in the TOPS™ System procedure.

CAUTION: TOPS™ System must not be used with instruments of spinal systems from other manufacturers.

Instruments	Description
PEDICLE PREPARATION INSTRUMENT	**Purpose: To ensure proper trajectory of the pedicle screws for the TOPS Motion Implant**
 Pendulum **P/N:** 82775	The Pendulum is designed to guide the surgeon on the proper medial-lateral trajectory of the pedicle screw placement to accommodate the four TOPS Motion Implant arms. The Pendulum is comprised of a hanging construct, and two moving elements: a marker that freely moves in the medial-lateral trajectory and a rounded plate that moves along the cephalad–caudal axis. Correct trajectory is achieved when the marker is between the +10° and -10° notches. The Pendulum works with Premia Spine's pedicle preparation and pedicle screw insertion instruments–the probes, taps, awls, and screwdrivers–which have a dedicated interface to hold the Pendulum.

Instruments	Description
TOPS TRIALING INSTRUMENTS	**Purpose: To confirm a sufficient decompression, identify the proper size TOPS Motion Implant and achieve proper dorsal height of the pedicle screws**
 Alignment Gauge handle **P/N:** 83104-Long, 86185-Medium	**The Alignment Gauge comes in two configurations: Medium and Long** Each Alignment Gauge is comprised of 3 parts: the Gauge Handle and two crossbars (Left Superior Crossbar and Right Superior Crossbar), and fits all levels and TOPS Motion Implant Configurations. The Gauge Handle serves as a template to confirm the physical accommodation of the TOPS Motion Implant after the decompression. The Alignment Gauge is also used to determine the proper size of the TOPS Motion Implant: • The Gauge Handle assists the surgeon to identify the proper TOPS Motion Implant length (Long, Medium or Short) based on the rod overhang. • The Alignment Gauge assists the surgeon to identify the proper TOPS Motion Implant IPD (21, 30, or 38). The tool has a handling ring on top, two sockets at its base to receive the Left and Right Superior Crossbars into their distal slots, and left/right configuration notch selectors to indicate the IPD configuration. The Left and Right Superior Crossbars have a collar mechanism that locks the Crossbar into the Gauge Handle implant size indicator.
 Left Alignment Gauge Superior Crossbars **P/N:** 83107-Long, 86189-Medium	
 Right Alignment Gauge Superior Crossbars **P/N:** 83106-Long, 86187-Medium	In addition, the Alignment Gauge is used to determine the dorsal alignment of the screw heads. The instrument indicates whether any of the four screws needs to be advanced to create a plane among the four screws to properly seat the four TOPS Motion Implant arms in the pedicle screws.
TOPS INSERTION INSTRUMENTS	**Purpose: To prepare the TOPS Motion implant for insertion.**
 TOPS Loading Base **P/N:** 86991	The TOPS Loading Base serves as a holder for the TOPS Motion Implant, to facilitates mounting the TOPS Motion Implant onto the TOPS Inserter. The instrument has laser markings to properly orient the TOPS Motion Implant into the Loading Base. The TOPS Loading Base works in conjunction with the TOPS Inserter and with all TOPS Motion Implants.
 TOPS Inserter **P/N:** 82889	The TOPS Inserter secures the TOPS Motion Implant for insertion into the four pedicle screws while performing final tightening of the set screws. The TOPS Inserter holds the TOPS Motion Implant during saline filling and assures that the filling port is closed. The TOPS inserter has two locating pins, a plug pusher, and a locking thread controlled by a circular knob located on the top of the instrument. In case of difficulty in releasing the lock, the Premia Spine Standard Screwdriver can be connected to knob's head to release the implant. There is a mechanism that maintains the thread in the locked position until the plug pusher is advanced forward.
CONTAINER TRAY	**Purpose: One TOPS Instrumentation container to house the Instruments for the entire procedure**
 TOPS Container **P/N:** 83117	The TOPS Instrumentation Container is an anodized aluminum container suitable for sterilization. The container has three levels: a base, a middle tray, and an upper tray, as well as a lid. In addition, there is caddy with cannulated instruments, and a stainless-steel tube with K-Wires.

NOTE: For further instructions and information on the TOPS™ System and its instrumentation set, including information about storage and shelf life, refer to the instructions for Use (IFU) provided with the products (see **Section 7 - I "Other Information"** for details).

7. SURGICAL TECHNIQUE:

A Pre-operative/interoperative Planning

Preoperative or interoperative planning using X-ray, CT, or MRI assists in pedicle screw selection (diameter and length) and screw placement. The selected diameter of the screws should be based on the inner mediolateral pedicle diameter at its isthmus (see Figure 1a). The lengths should be measured from the pedicle screw entry point to the anterior edge of the vertebrae (see Figure 1b). It is recommended to take into consideration when choosing the screw length that the two superior TOPS pedicle screws should be positioned 2 to 5 millimeters dorsally proud for final height adjustment to accommodate the TOPS Motion Implant as well as to have the TOPS Motion Implant parallel to the patient's disc in spondylolisthesis.

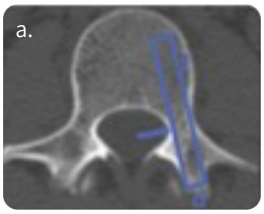


Figure 1a: Determination of screw diameter

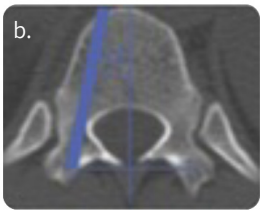


Figure 1b: Determination of screw length

CAUTION: Proper patient selection is extremely important. Please refer to Sections 2, 3 and 4 of this guide for detailed indications, contraindications, potential adverse events, warnings and precautions.

CAUTION: Preoperative planning should be used to estimate the required implant size, and to ensure that the appropriate sizes are available for surgery. Correct selection of the appropriate implant size is important to assure the performance and function of the device. The procedure should not take place if the appropriate range of sizes is not available.

CAUTION: Use care when handling the TOPS™ System's implants to ensure that they do not come in contact with sharp objects that may damage the implants and render the TOPS™ System functionally unreliable. **Do not** use if any part of the device appears damaged or not fully assembled.

CAUTION:

- The TOPS™ System (TOPS Motion Implant and Pedicle Screws) is provided sterile and intended for a single use only. **Do not** use if sterility is compromised. **Do not** resterilize.
- The TOPS™ System implants are packaged in a double-blister pack sealed with a Tyvek® lid and contained in a carton cardboard box. The integrity of the packaging should be confirmed to ensure that the sterility of the contents is not compromised. **Do not** use if package has been compromised.
- The "use by" date must be checked. **Do not** use if the date on the label has expired.
- Always remove the TOPS™ System's implants (Pedicle Screws and TOPS Motion Implants) from the packaging using standard aseptic techniques only after the correct size has been determined.
- **Do not** re-use or re-implant the TOPS™ System. Although the implant may appear undamaged, non-visible damage could result in implant failure.

CAUTION: The TOPS™ System instruments are reusable, provided non-sterile and must be cleaned and sterilized in accordance with the validated instructions described in the TOPS™ System Instrumentation Set Instructions for Use (IFU) prior to use.

CAUTION:

- The K-Wires are part of the TOPS™ System instrumentation Set. They are provided non-sterile and must be sterilized at the clinical site in accordance with the validated instructions described in the TOPS™ System Instrumentation Set Instructions for Use (IFU) prior to use.
- The K-Wires are intended for a single use only and should be discarded after use. **Do not** re-sterilize. **Do not** re-use.

WARNING: Examine all instruments prior to surgery for wear or damage. **Do not** use worn or damaged instruments or instruments that do not function properly. Any form of distortion or excessive wear on instruments may cause a malfunction that could lead to serious patient injury.

B Patient Positioning

i. Place the patient in a prone position on a radiolucent table suitable for AP and lateral fluoroscopy performed during the surgery (Figure 2).

ii. Position the patient in a neutral to flexion position with the legs bent at the hips, similar to a laminectomy or discectomy procedure.

iii. Place abdominal supports on the lateral sides of the patient (Figures 2a, 2b). Verify that the belly is free to ensure normal intra-abdominal bleeding pressure during surgery.

iv. A Wilson frame (Figure 2c) can be used to facilitate achieving proper patient positioning.

v. Confirm spinal alignment and the location of the target level incision by pre-operative fluoroscopy.

Figure 2: Jackson Table

Figure 2a: Proper patient support for TOPS cases

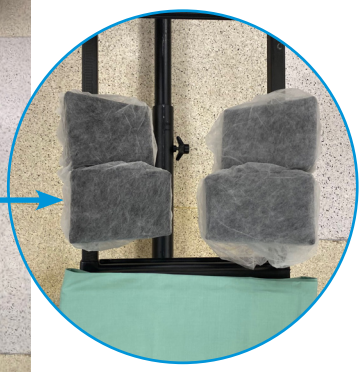


Figure 2b: Insufficient patient support for TOPS cases

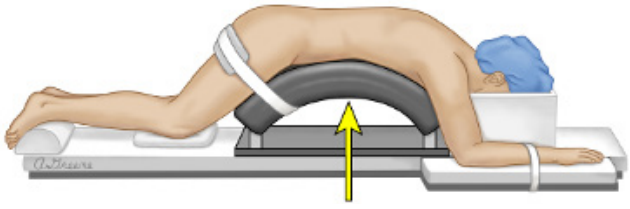


Figure 2c: Wilson Frame

C Surgical Exposure

The surgical exposure for the TOPS posterior approach is performed with a midline incision of 6 to 14 cm. The exposure should provide complete visualization of the facet joints and medial aspects of the transverse processes on both the superior and inferior operative vertebrae for the purpose of decompression, pedicle screw placement and TOPS Motion Implant placement. Each of these steps is described in detail below:

i. Use a standard posterior midline dissection to expose the facet joints and the pars interarticularis.

ii. Surgical exposure is obtained using a self-retaining retractor system.

D Pedicle Preparation and Screw Insertion

CAUTION: The TOPS™ System is indicated for use only with pedicle screws supplied by Premia Spine. **Do not** implant the TOPS™ System with components from any other manufacturer.

The standard open screw placement technique is described below. Other screw placement techniques appear in **APPENDIX 2" ADDITIONAL SCREW PLACEMENT TECHNIQUES"**.
This surgical technique describes the screw placement first and decompression second. This sequence can be reversed depending on surgeon preference.

A. Goal of Screw Placement

i. The goal of screw placement is to provide a stable base for the TOPS Motion Implant and allow fixation of the TOPS Motion Implant to the spine.

ii. To achieve this goal, there are several steps which must be followed to ensure that the pedicle screws are placed at the correct trajectory and dorsal height.

iii. When this is achieved, the pedicle screws appear symmetrical on imaging (Figure 3a). The left and right interpedicular distances must be symmetrical for TOPS Motion Implant insertion (See images of Antero-Posterior (AP) and Lateral views of TOPS Motion Implant placed symmetrically pedicle screws in Figure 3b and Figure 3c, respectively).

iv. Advance the screws until the dorsal pedicle screw tulip heights are aligned to the adjacent level screws' tulip height such that the TOPS Motion Implant sits parallel to the disc (Figure 3d). Note that the TOPS end plates are parallel to the lumbar disc end plates.

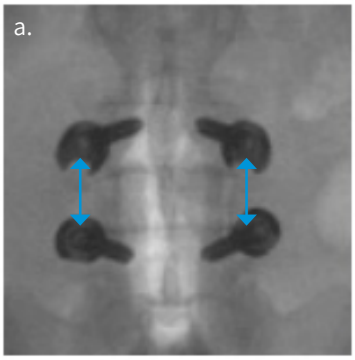


Figure 3a: AP view of symmetrically-placed pedicle screws

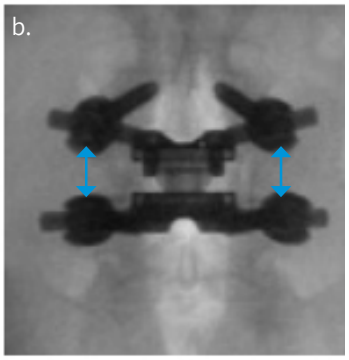


Figure 3b: AP view of TOPS Motion Implant placed in symmetrically-positioned pedicle screws

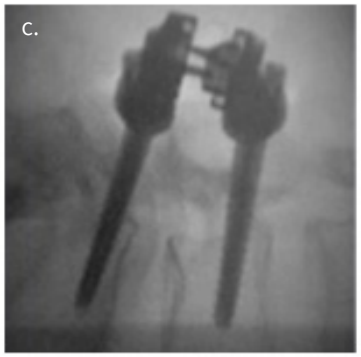


Figure 3c: Lateral view of TOPS Motion Implant placed pedicle screws

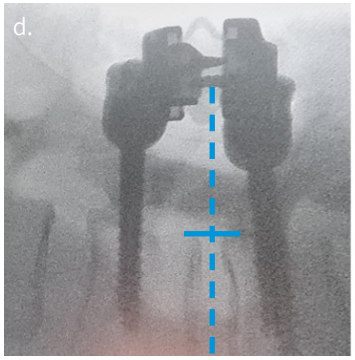


Figure 3d: Lateral view of TOPS Motion Implant placed parallel to the disc.

v. Use the TOPS™ System instruments to align the pedicle screws and the TOPS Motion Implant. Avoid misplacement which can lead to TOPS Motion Implant misalignment in AP due to forcing the TOPS Motion Implant into the pedicle screws (Figure 4a) or misalignment in lateral position having the TOPS device tilt forward due to incorrect screw dorsal height (Figure 4b).

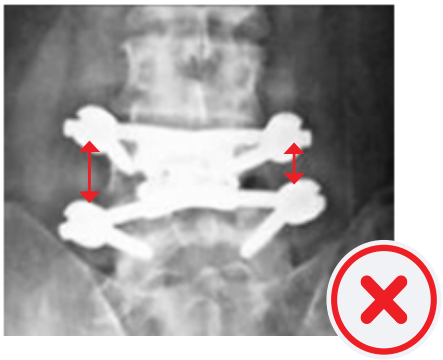


Figure 4a: Improper or lack of use of the TOPS instruments can lead to misplacement of the pedicle screws and may force the TOPS Motion Implant into an asymmetrical position.

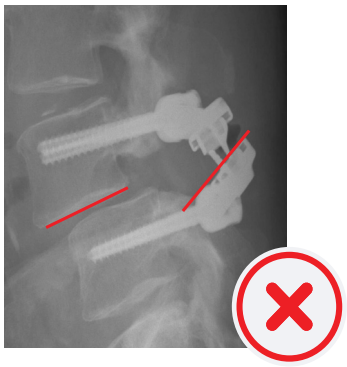


Figure 4b: Misalignment in lateral position due to poor dorsal height alignment causing the TOPS device to tilt forward.

CAUTION: Use the appropriate TOPS™ System Instruments according to the instructions in this guide to assure correct positioning of the pedicle screws and the TOPS Motion Implant.

Failure to correctly use the TOPS instruments can lead to misalignment of the pedicle screws and the TOPS Motion Implant and may force the TOPS Motion Implant into an asymmetrical position which might compromise implant performance and functionality.

B. Pedicle Channel Preparation

i. It is important to ensure proper pedicle screw trajectory during preparation of the pedicle for screw insertion. The Pendulum provides guidance on the correct medial-lateral plane.

ii. The Pendulum attaches all pedicle preparation and pedicle screw insertion instruments to confirm a correct Pedicle Screw trajectory (Figure 5a and 5b).

a.

Figure 5a: The Pendulum provides guidance on the correct medial-lateral plane of screw preparation channel. The figure is for illustration only

b.

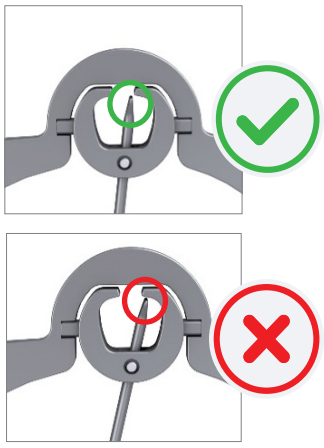


Figure 5b: The Pendulum's marker is between the +10° and -10° notches

iii. Introduce the Pedicle Awl into the bone until reaching its hard stop (Figure 6a). Remove the Pedicle Awl and advance the Pedicle Probe into the vertebral body. Place the Pendulum on the Pedicle Probe shaft to confirm that proper medial-lateral angle is achieved (Figure 6b). The Depth Gauge and Feeler may be used to ensure that the pedicle walls have not been breached (Figure 6c). Use the Depth Gauge and Feeler to measure optimal screw length. Identify the proper diameter screw, recognizing that the largest diameter should be used to maximize the screw bone purchase. Select a screw length that allows the superior pedicle screws to be 2 to 5 mm proud dorsally. **You may want to consider using a pedicle screw that is 5mm longer than you would normally choose for a fusion case--especially in a segment with a more pronounced Grade I spondylolisthesis.**

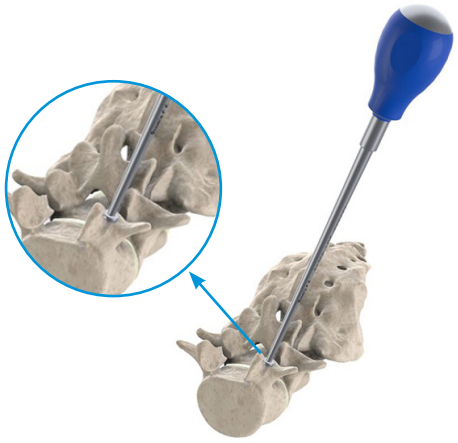


Figure 6a: Introduce the Pedicle Awl into the bone until reaching its hard stop

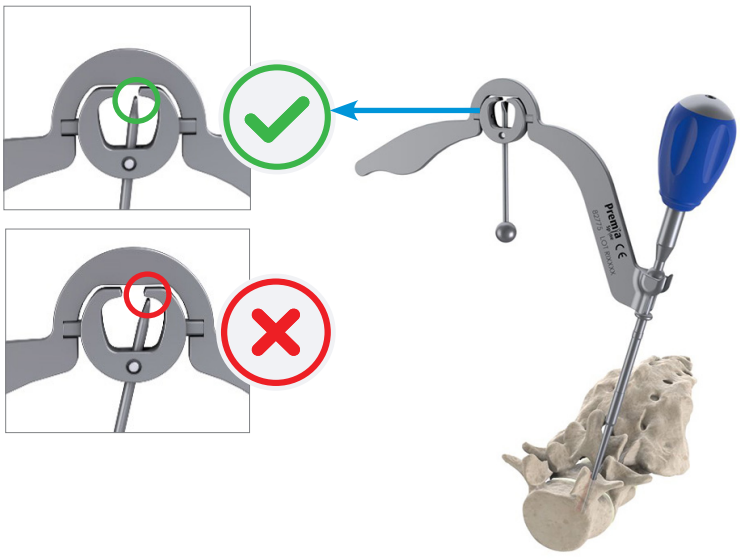


Figure 6b: Advance the Pedicle Probe into the vertebral body

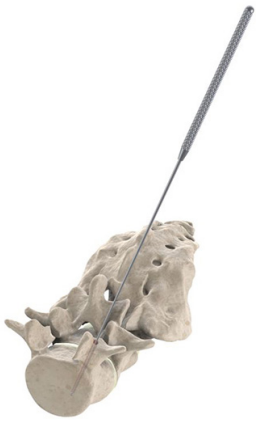


Figure 6c: Ensure that the pedicle walls have not been breached with the Depth Gauge and Feeler

CAUTION: Correct selection of the appropriate pedicle screws size according to the instructions in this guide is essential to ensure proper performance and functionality of the TOPS™ System. Be sure to avoid breaching the anterior cortex of the vertebra and causing patient injury.

iv. Premia Spine's pedicle screws are self-tapping and self-drilling. Nevertheless, tapping may be desired. Choose a Tap which is 1mm smaller in diameter than the pedicle screw to be implanted. There are 3 available sizes (Tap 4.5 mm, 5.5 mm, and 6.5mm).

v. Attach the Tap to a Ratchet Straight or T-Handle. Pull the Handle's locking ring upward and slide it onto the ¼" connector of the Tap shaft. Verify proper attachment by slightly pulling the Tap shaft in the opposite direction to confirm that the Tap is secured to the Handle. Adjust the ratchet direction by shifting the ring clockwise for standard motion or counter clockwise for rachet motion. Place the Tap in the pilot hole and advance into the pedicle bone. Be sure to confirm proper trajectory with the Pendulum (Figure 7).

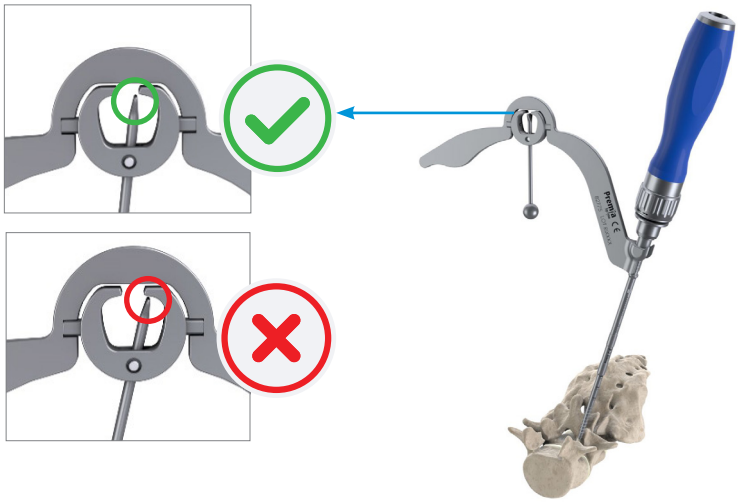


Figure 7: Place the Tap in the pilot hole and advance

v. Attaching the Handle and Pedicle Screw to the Pedicle Screwdriver

i. Mount a Rachet Straight or T-Handle onto the ¼” connector of the Pedicle Screwdriver shaft.

ii. Select the appropriate size pedicle screw (as described in **Section B-iii Pedicle Channel Preparation**).

iii. Open the inner most Pedicle Screw sterile packaging onto the sterile field using standard practices.

Note: The pedicle screw comes with a set screw in the blister pack.

CAUTION: Always remove the pedicle screw and set screw from the packaging using standard aseptic techniques only after the correct size has been determined.

iv. Hold the pedicle screw head firmly while inserting the hexagon tip of the Screwdriver into the pedicle screw socket (Figure 8a).

v. Be sure that the hexagon tip is completely seated in the pedicle screw socket (Figure 8b).

Figure 8a: Insert the hexagon tip into pedicle screw socket

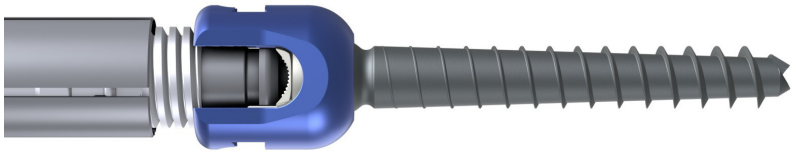


Figure 8b: Hexagon tip must be completely seated in the pedicle screw socket

vi. Secure the Screwdriver into the pedicle screw by turning the butterfly knob and advancing the Screwdriver Sleeve and the threads of the Screwdriver clockwise (in the direction of the lock symbol located on the butterfly knob). An audible sound indicates that the Screwdriver's locking mechanism is engaging (Figure 8c).

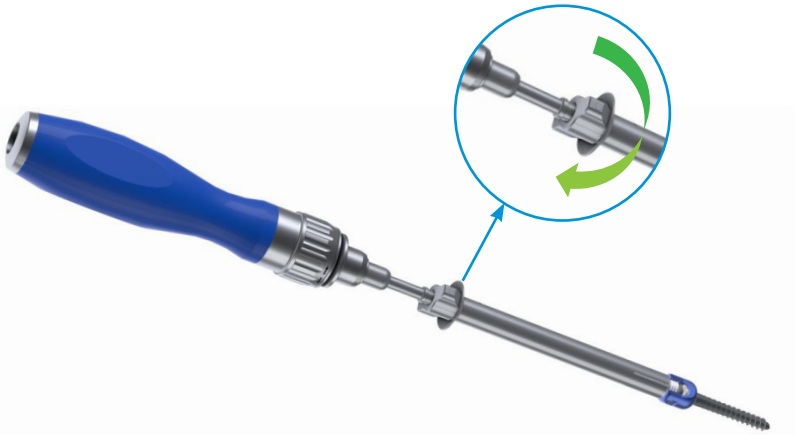


Figure 8c: Locking the screw on the screw driver by turning the butterfly

vii. Tighten the Screwdriver until it cannot be further advanced. The Sleeve should be freely rotating around the Screwdriver Shaft. Verify that the pedicle screw is secured by visually inspecting the Screwdriver and pedicle screw. The threads on the Screwdriver should be fully seated in the pedicle screw head (Figure 8d).

Figure 8d: Pedicle Screwdriver hexagon and threads inserted into pedicle screw

viii. Introduce the pedicle screw into the pilot hole (See Figure 9a). Attach the Pendulum to the Screwdriver and verify the correct trajectory (Figure 9b). If the Pendulum's marker extends beyond the allowed range, redirect the screw trajectory to be within the Pendulum range. Once the screw is properly inserted, unlock the Screwdriver from the screw by turning the butterfly knob counter clockwise (Figure 9c).

Figure 9a: Screw into the pilot hole

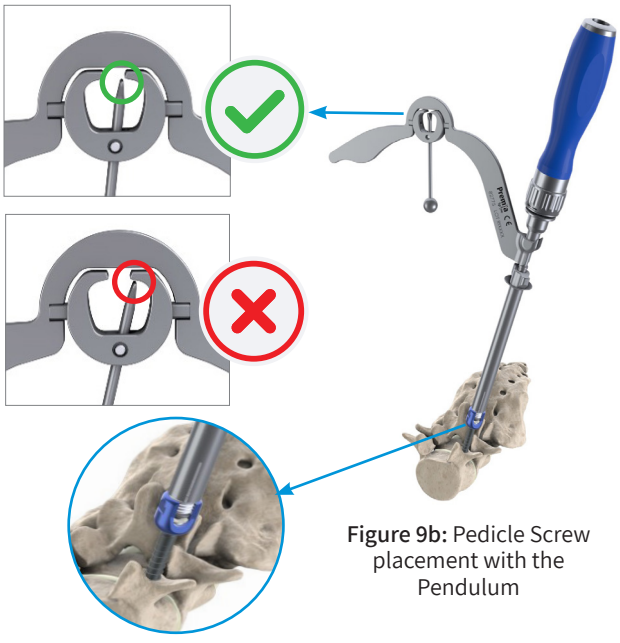


Figure 9b: Pedicle Screw placement with the Pendulum

Figure 9c: Remove the Screwdriver from screw head

CAUTION: Be sure that the Pendulum Marker falls anywhere between the two notches of the Pendulum. If the Pendulum Marker extends beyond the range of the Pendulum (± 10°), then the TOPS Motion Implant arms may not sit properly into the bottom of the Pedicle Screw Heads. Choose a different screw trajectory that fits within the proper range.

ix. After inserting the first pedicle screw, plan the placement of the second screw at the adjacent level such that there will be at least a 6mm gap between screws' tulip heads. Take one of the Alignment Gauge Superior Crossbars and use its 6mm toe for measurement by placing it between the Pedicle Screw tulip heads. Change the trajectory and/or the entry point of the second screw, if necessary, to ensure that the Crossbar toe passes in the gap (Figure 10).

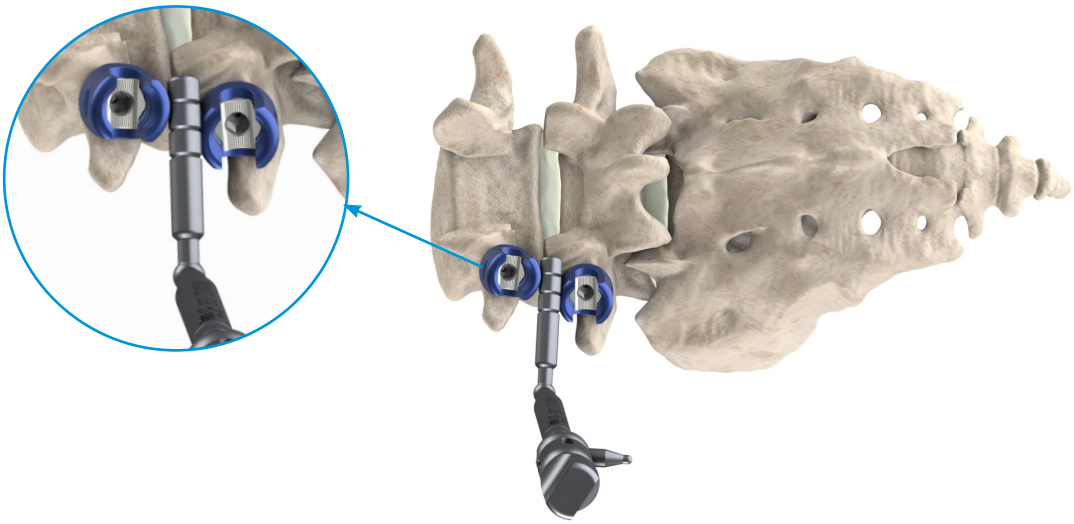


Figure 10: Required minimum clearance between the pedicle screw heads

x. When inserting the contralateral pedicle screw in the same vertebra, ensure that the screws are aligned in a mirroring caudal-cephalad trajectory. Use the implanted contralateral pedicle screw as a guide by placing the blue-handled Standard Screwdriver into its socket (Figure 11a). Use the orientation of blue-handled Standard Screwdriver to guide pedicle preparation such as tapping and screw insertion (Figures 11b and 11c).

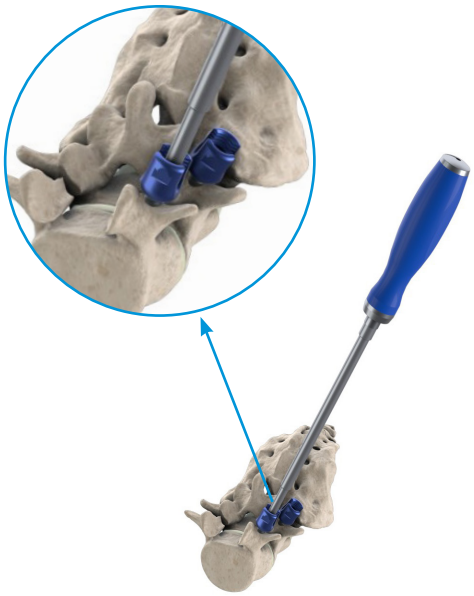


Figure 11a: Placing the Standard Screwdriver in the first screw

Figure 11b: Inserting the second screw in the same vertebral level

Figure 11c: Aligning the second screw by mirroring the caudal-cephalad trajectory of the first screw

xi. Alternatively, use fluoroscopic guidance. When placing the contralateral screw, acquire a lateral fluoroscopic image to verify screw position. Superimpose the second contralateral screw with the previously placed screw in the same vertebral body, as shown in the image below (Figure 12).

xii. The screws should be advanced until the dorsal pedicle screw tulip heights are aligned to the adjacent level screws' tulip heights to ensure that the TOPS Motion Implant will be parallel to the patient's disc.

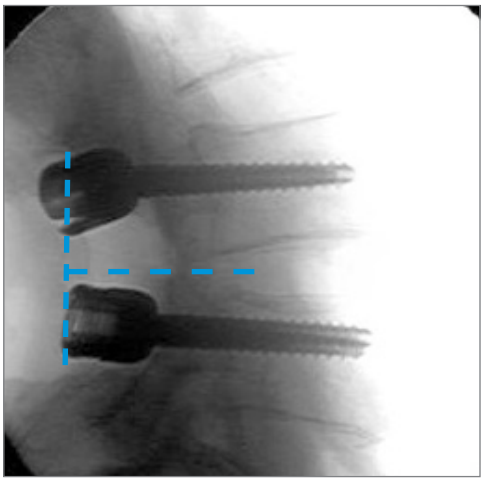


Figure 12: Lateral fluoroscopic image demonstrating screw alignment

CAUTION: Be sure not to violate the superior facet capsule when placing the superior pedicle screws.

E Decompression

A. Goal of Decompression

i. Decompression is carried out by resection of the lamina, spinous process, and the facet joints.

ii. The breadth of decompression is determined by the current nerve root impingement, and any bony elements or soft tissue which could create future nerve root impingement, especially in extension. Bony resection should extend through the lateral margin of the pars interarticularis. Complete excision of the Inferior Articular Process and the Superior Articular Process should be performed as required. (Figure 13).

iii. Standard spine surgery tools, including kerrisons, ronguers, osteotomes, chisels, and curettes, should be utilized according to surgeon preference.

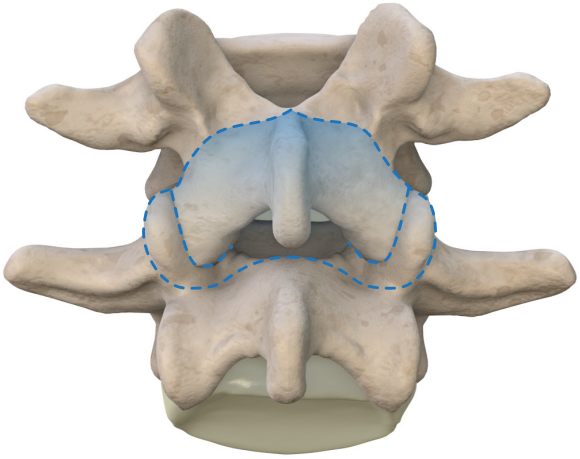


Figure 13: Breadth of Decompression

B. Confirmation of Nerve Root Release

i. Following bony resection, adequate bilateral neural decompression should be confirmed using standard surgical techniques with a Woodson elevator over the thecal sac and the traversing/exiting nerve roots. (Figure 14).

ii. Be sure there are no sharp bone edges. Use a rounded curette to smooth the bone surface.

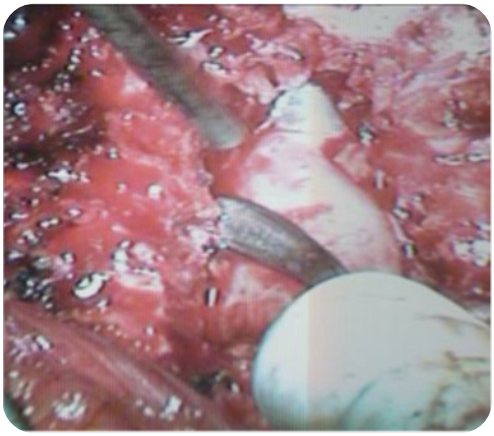


Figure 14: Confirmation of Adequate Neural Decompression

F TOPS Templating with the Alignment Gauge

A. Introduction

i. The Alignment Gauge is used as (1) a decompression template, (2) a tool to determine the proper size of the TOPS Motion Implant, and (3) as a guide to achieving proper dorsal alignment of the screw heads.

ii. The Alignment Gauge indicates whether any of the four screws needs to be advanced to create a proper geometric plane in order to accept the 4 arms of the TOPS Motion Implant.

B. Decompression Template

i. The Gauge Handle of the Alignment Gauge serves as a decompression template and an implant size trialer (Figure 15).

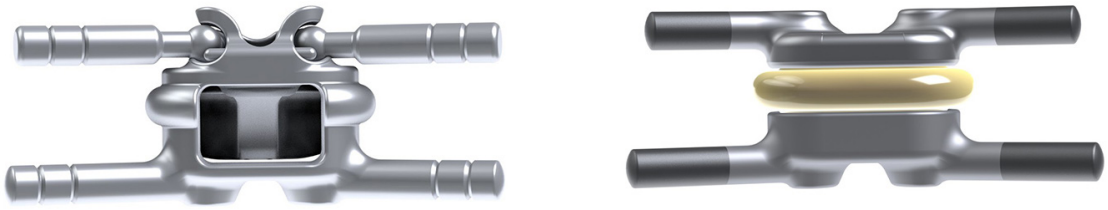


Figure 15: The base of the Gauge Handle (Left) is identical to the TOPS Motion Implant (Right).

Choose either the Medium or Long Gauge Handle. Verify proper “UP” and “DOWN” orientation.
The “UP” and “DOWN” corresponds to the superior (UP) and inferior (DOWN) pedicle screws (Figure 16).

Start by orienting the pedicle screw heads in the medial- lateral direction (rather than a caudal-cranial direction as in fusion surgery).

Figure 16: Correct/incorrect orientation of Gauge Handle

Use the Head Releaser if necessary. (Figure 17).

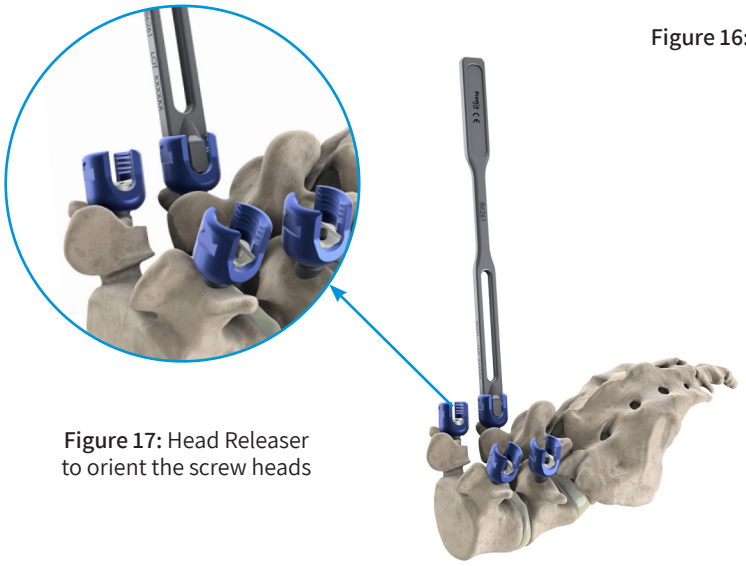


Figure 17: Head Releaser to orient the screw heads

Place the Gauge Handle in the inferior pedicle screws with "UP" facing cranially (Figure 18).

If the Gauge Handle does not easily fit into both inferior screws, remove and decompress the bony elements and/or soft tissue that block the Gauge Handle from seating in the pedicle screw heads.

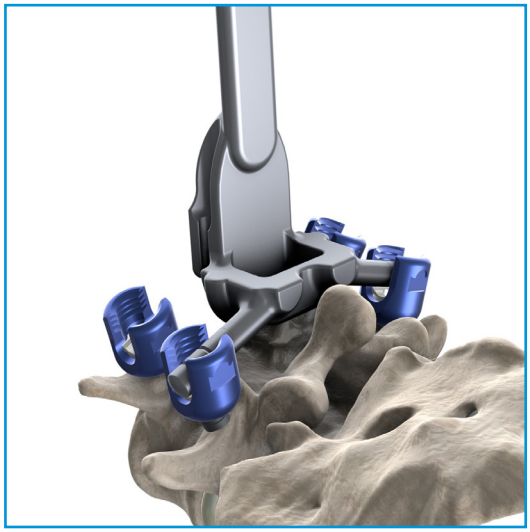


Figure 18: Gauge Handle in the inferior pedicle screw

ii. Center the Gauge Handle in relation to the superior spinous process. Then place and tighten the set screws (Figure 19). Confirm that there is overhang of the rods lateral to both pedicle screw heads (Figure 20a).

iii. If there is insufficient overhang of less than 2 millimeters (Figure 20b), switch to the Long Gauge Handle. If there is excess rod overhang (i.e., more than 5 millimeters on both sides), switch to the Medium Gauge Handle. The Long "L" or Medium "M" TOPS Motion Implant needs to be selected in accordance with the size of the Gauge Handle.

iv. If there remains more than 5 millimeters of overhand on both sides with the Medium Gauge Handle, continue to work with the Medium Gauge Handle but implant the Short "S" TOPS Motion Implant.

Figure 19: Locking the Gauge Handle and set screw with the Set Screw Inserter

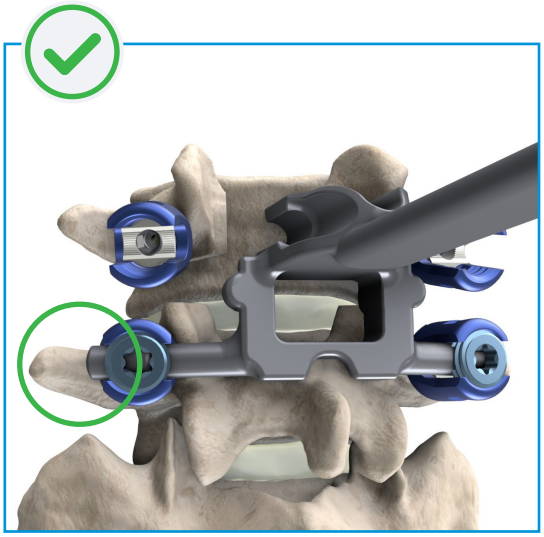


Figure 20a: Verify overhang of rods lateral to both pedicle screw heads

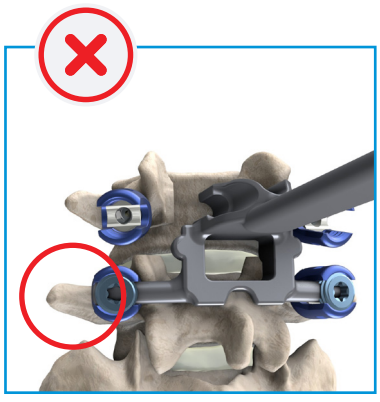


Figure 20b: overhang less than 2 millimeters

v. After placing the Gauge Handle and securing the set screws, confirm that the Gauge Handle stands vertically and does not tilt to one side (Figure 21).

vi. If the Gauge is not parallel to the disc or if it leans to one side, remove the Gauge Handle and adjust the screw height by driving in the more proud screw. so as to achieve proper positioning. Note that it is better to drive in a pedicle screw rather than back out a pedicle screw. Also be aware not to drive the pedicle screw so deep into the pedicle as to lose its polyaxiality. After adjustment, reintroduce the Gauge Handle and lock down the set screws, leaving the Gauge Handle standing vertically and parallel to the disc.

Figure 21: Gauge Handle is behind the index level disc and is parallel to the disc (see blue line)

CAUTION: Be sure that the Gauge Handle is parallel to the disc.

C. TOPS Motion Implant Sizing

i. Select either the Left **(L)** or Right **(R)** Superior Crossbar (Figure 22).

An **"L"** or an **"R"** is marked on the proximal end of each Superior Crossbar. Note the "Ball joint Heel" and "Front Toe" of the Superior Crossbar (Figure 22).

ii. Place the Crossbar Front Toe in the pedicle screw tulip head while dropping the Ball Joint Heel into the distal slot of the Gauge Handle (See Figure 23a for Right side and Figure 23b for Left side).

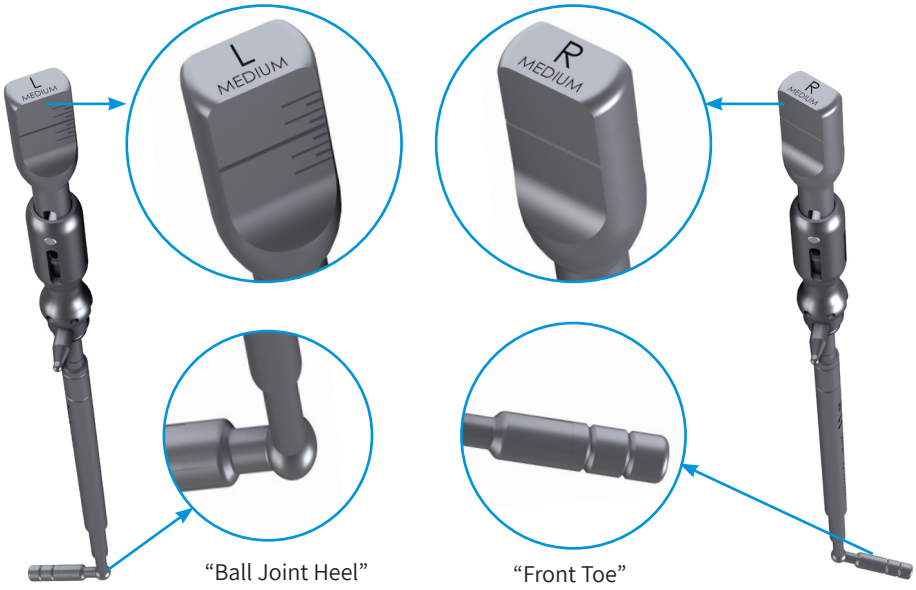


Figure 22: Left **(L)** or Right **(R)** Superior Crossbar

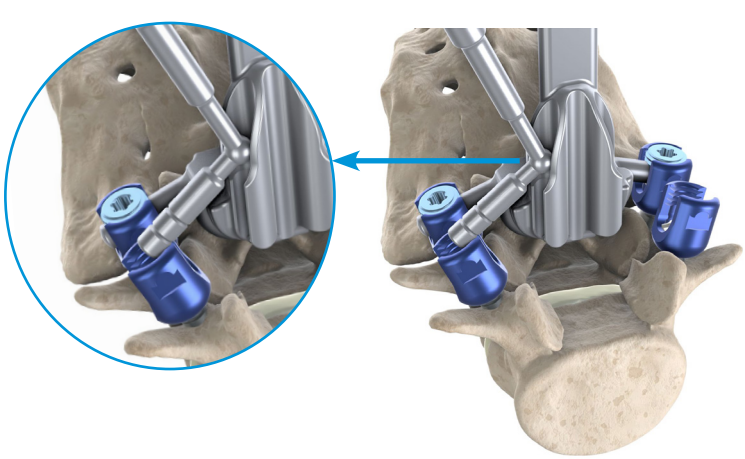


Figure 23a: Slide right Superior Crossbar into the Gauge Handle slot

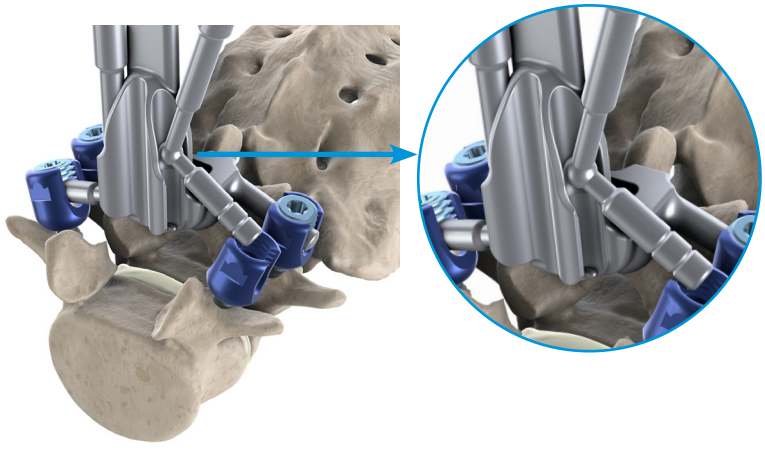


Figure 23b: Slide left Superior Crossbar into the Gauge Handle slot

iii. Slide down on the collar of the Superior Crossbar until it locks into an IPD slot on the Gauge Handle with a clicking sound. The IPD numbers correspond to the size (21, 30, 38) of the TOPS Motion Implant (Figure 24). Place and tighten the set screw. Repeat this step for the contralateral Superior Crossbar.

Figure 24: Slide down on the collar of each Superior Crossbar

iv. Confirm that the indicated size of the TOPS Motion Implant is the same for both Superior Crossbars. If not, you must adjust one of the Superior Crossbars to match the size of the other Superior Crossbar (Figure 25a). To adjust the IPD measurement, slightly release the four set screws while keeping them in the pedicle screw heads. Release the collar of one of the Superior Crossbars and lever the Alignment Gauge in the caudal and cephalad directions while trying to lock down the collar to the same IPD slot number as the contralateral Superior Crossbar (Figure 25b).

v. If unsuccessful, return this Superior Crossbar to its previous IPD slot number by sliding down its collar. Release the collar of the other Superior Crossbar and lever the Alignment Gauge in the caudal and cephalad directions while trying to lock down the collar to the same IPD slot number as the contralateral Superior Crossbar.

vi. Once successful, hand tighten all the set screws. If unsuccessful, reposition one of the superior pedicle screws and begin the alignment process from the beginning.

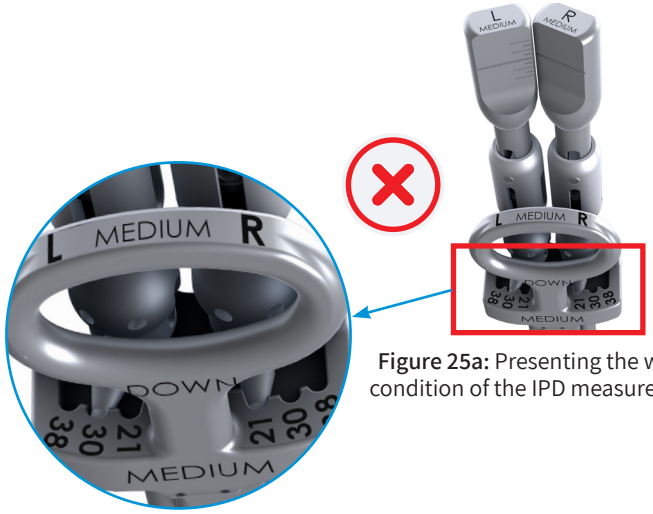


Figure 25a: Presenting the wrong condition of the IPD measurement.

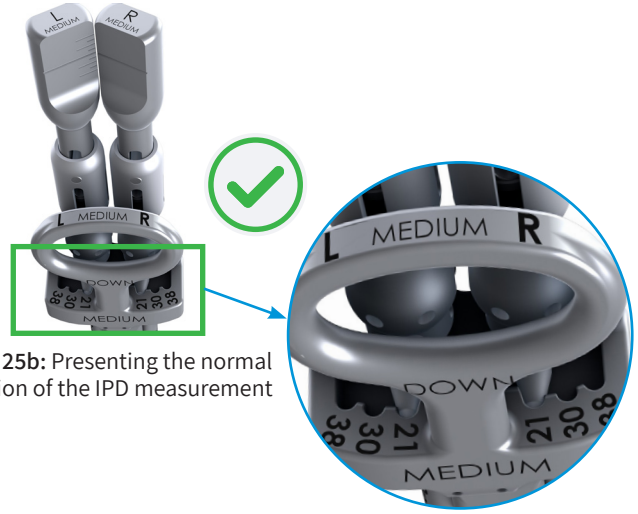


Figure 25b: Presenting the normal condition of the IPD measurement

NOTE: The IPD measurement on the Alignment Gauge should be the same on the Left and Right Superior Crossbars (Figure 25a). In the event that the IPD slot numbers differ, adjust one of the Superior Crossbars until its IPD slot number match the other one (Figure 25b).

D. Dorsal Alignment of Screw Heads:

i. The Alignment Gauge is also used to determine the dorsal alignment of the screw heads. The Alignment Gauge indicates whether any of the four screws needs to be advanced to achieve a geometric plane that corresponds to the 4 arms of the TOPS Motion Implant.

ii. Dorsal height adjustment should only take place after size of the TOPS Motion Implant (i.e., 21, 30, 38) has been established.

iii. Examine the marks on the upper portion of the Alignment Gauge's Superior Crossbars. If the long lines on both Superior Crossbars form a continuous straight line, then there is no need for adjustment (Figure 26a).

Figure 26a: Confirmation of dorsal leveling. The long lines on both Superior Crossbars form a continuous straight line

iv. However, if the long lines do not correspond to each other, an adjustment must be made.

1. Short line = ½ turn (Figure 26b).
2. Long line = 1 full turn (Figure 26c).

Figure 26b: Short line adjustment. A half turn is required

Figure 26c: Long line adjustment. A full turn is required

NOTE: It is easiest to adjust one of the superior screws. It is also best that the adjustment is made by advancing a screw rather than partially backing out a pedicle screw because of Premia Spine's conical screws.

v. For example, if the markings are offset by 1 long line gradation, this indicates that the more dorsal superior screw is too proud and needs to be driven in by 360° or one full turn. If the markings are offset by 1 small line gradation, this indicates that the more dorsal superior screw is too proud and needs to be driven in by 180° or half of one full turn. There is a laser marked arrow on the proximal end of the blue-handle Standard Screwdriver Handle. This line marking assists the surgeon to count full turns and half turns when adjusting pedicle screw height with the Screwdriver (Figure 27).

Figure 27: Adjustment of pedicle screw height with blue-handle Standard Screwdriver

vi. To make the dorsal adjustment, remove the Superior Crossbar of the Alignment Gauge of the proud screw. Advance the screw to the measured depth using the Standard Screwdriver. Once this is performed, reposition the Superior Crossbar in the Alignment Gauge, lock the set screw, and verify that all screws are in alignment based on the two long lines (Figure 28).

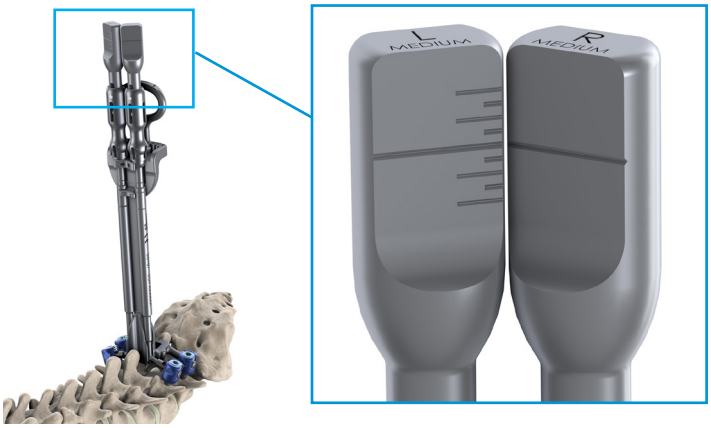


Figure 28: Confirmation of dorsal leveling. Long lines on both Superior Crossbars form a continuous straight line

vii. With all screws aligned properly, the Alignment Gauge should be parallel to the disc (Figure 29a).

If the shaft leans caudal, the two superior screws should be equally driven in to achieve proper alignment with the spine. If the shaft leans cranial, the inferior screws should be equally driven in to achieve proper alignment with the spine. If the Alignment Gauge is tilted laterally to one side, advance (or slightly back out) the two screws on one side by the same number of turns or partial turns to gain a parallel to the disc (Figure 29b).

Figure 29a: The Alignment Gauge is parallel to the disc

viii. Remove the set screws and the Alignment Gauge.

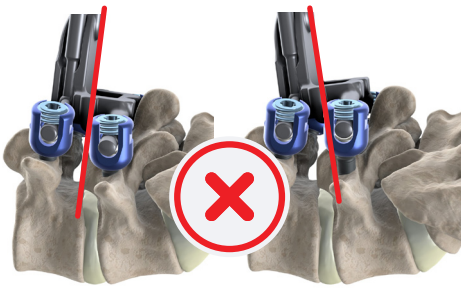


Figure 29b: The Alignment Gauge is not parallel to the disc

G TOPS Motion Implant Implantation

A. Connect TOPS Motion Implant to the TOPS Inserter

CAUTION: The TOPS Motion Implant is supplied with a sterile 27G stainless steel needle connected to the filling port.

- **Do not** remove the needle until after the TOPS Motion Implant has been filled with saline.
- **Do not** attempt to redirect the needle during filling as this may damage the needle. If for any reason the needle becomes disengaged or damaged before the TOPS Motion Implant has been properly filled, remove the needle, and replace it with a 25G x 5/8'' hypodermic needle.

CAUTION: Always remove the TOPS Motion Implant from the packaging using standard aseptic techniques only after the correct size has been determined.

i. Open the most inner TOPS implant sterile packaging onto the sterile field using standard practices.

ii. Place the TOPS Loading Base on a flat surface making note of the "UP" and "DOWN" orientation. Note that the TOPS Motion Implant also has "UP" and "DOWN" markings. Place the TOPS Motion Implant in the Loading Base. Ensure that the UP and DOWN indicators on the TOPS Motion Implant match those on the Loading Base. Make sure that the 3 mounting holes on the TOPS Motion Implant are facing upwards. Slightly compress the TOPS Motion Implant arms and push the TOPS Motion Implant into the bottom of the Loading Base (Figure 30a). Confirm correct fitting of the TOPS in the Loading Base by ensuring no gaps between the implant and the dorsal wall of the Load Base (Figure 30b).

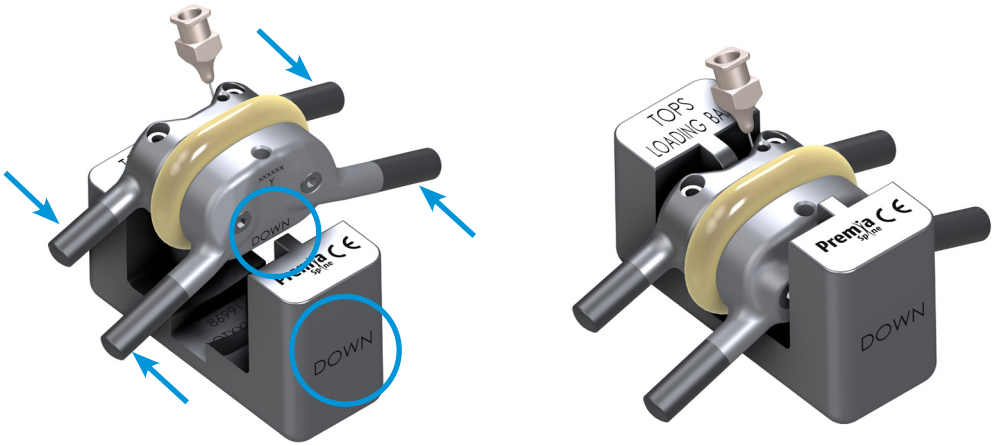


Figure 30a: Compress the TOPS Motion Device arms to facilitate inserting into the Loading Base

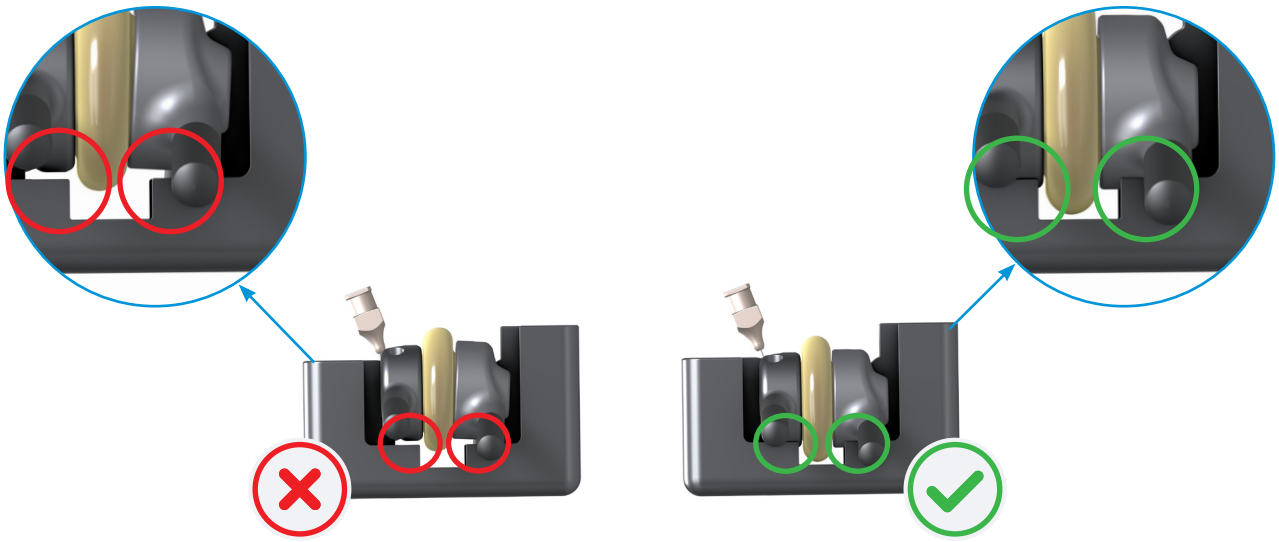


Figure 30b: Placement of TOPS Mobile Device in Loading Base (side view)

CAUTION: Make sure the UP and DOWN indicators on the Loading Base match these indicators on the TOPS Motion Implant to ensure correct orientation and positioning of the TOPS Motion Implant during implantation which are crucial for performance and functioning of the device.

iii. With the implant lying flat in the Loading Base, align the pins of the TOPS Inserter into the mounting holes of the TOPS Motion Implant (Figure 31a). Lock the threaded pin by pushing the upper knob of the TOPS Inserter and turning it clockwise until it locks (Figure 31b).

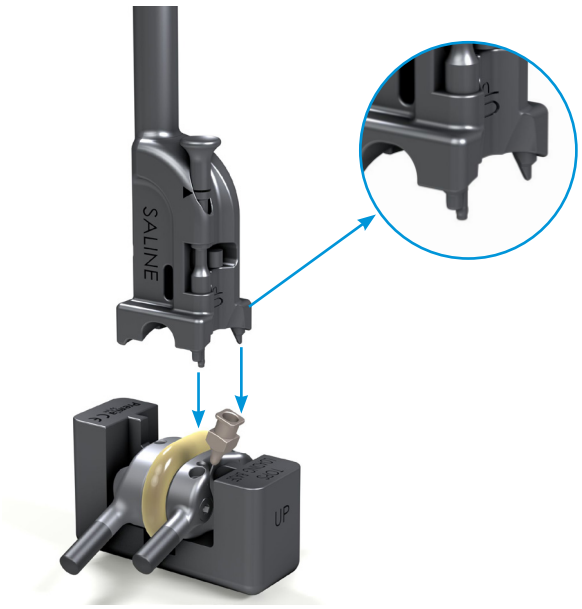


Figure 31a: Inserting The TOPS Inserter into the mounting holes of the TOPS Motion Implant

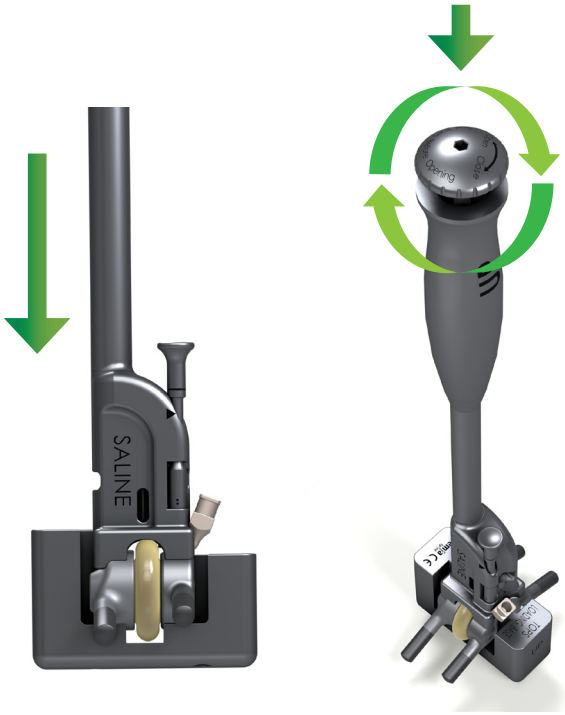


Figure 31b: Securing of the TOPS Motion Implant into the TOPS Inserter

iv. Remove the TOPS Inserter with the attached TOPS Motion Implant from the Loading Base and examine that there are no gaps between the TOPS Motion Implant and the TOPS Inserter (Figure 32).

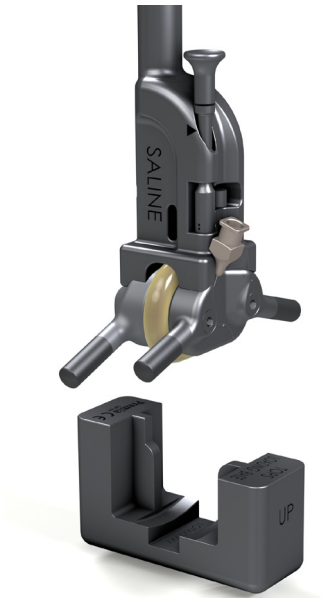


Figure 32: Remove the TOPS Inserter with the TOPS Motion Implant

B. Filling the TOPS Motion Implant with Sterile Saline

CAUTION: Prior to implantation of the TOPS Motion Implant, make sure that the TOPS Motion Implant device is filled with saline. Follow the instructions provided below for adequate saline filling to avoid insufficient initial lubrication which might lead to mechanical failure.

i. Fill a syringe with sterile injectable 0.9% NaCl (saline) to at least 1.7cc. Attach the syringe to the luer of the needle in the TOPS Motion Implant. Hold the TOPS Inserter with the TOPS Motion Implant and the word "SALINE" facing upward towards the ceiling (Figure 33).

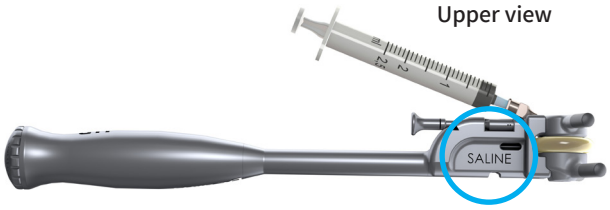


Figure 33: Face Holder so "SALINE" is facing the ceiling

ii. Fill the TOPS Motion Implant. The goal is to fill the TOPS Motion Implant to its filling line (Figure 34).

iii. Begin slowly injecting the saline. The saline filling port is also the air escape port, so slowly injecting the saline into the TOPS Motion Implant will minimize water leakage. Water leakage is not a problem. Observe as the water line rises, while continuing to inject saline until the water level crosses the laser mark line on the TOPS Motion Implant. Be sure that you are holding the Inserter parallel to the floor. Once the saline level is above the laser marked minimum level line, you can stop filling the TOPS Motion Implant (Figure 34).

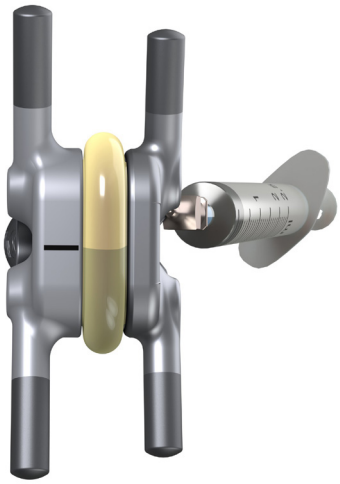


Figure 34: Fill saline above the laser marking line

iv. If more saline is required, continue to add saline until the required level is reached.

v. Remove the syringe and the Needle from the TOPS implant (Figure 35a), and push forward the plug pusher until it reaches a hard stop at the laser mark triangle (Figure 35b).

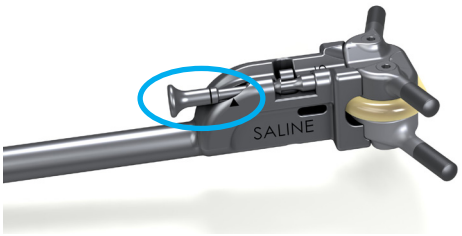


Figure 35a: Pre-push the plug pusher after removing the Needle

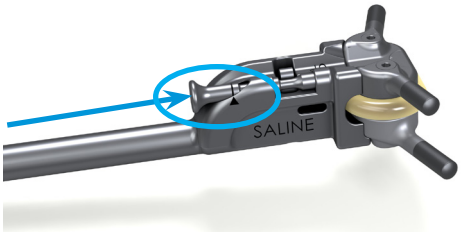


Figure 35b: Advance the Plug Pusher

C. TOPS Motion Implant Implantation

i. It is recommended to irrigate the wound and to apply topical antibiotics (e.g., vancomycin powder) prior to TOPS Motion Implant insertion.

ii. Examine the dura carefully to ensure that there is no evidence of leaks.

iii. Prior to inserting the TOPS Motion Implant, use the Head Releaser to unlock the polyaxiality of the pedicle screw joints if they are locked (Figure 36).

iv. Verify that the Implant is oriented correctly with the "UP" side of the TOPS Inserter and the TOPS Motion Implant facing cranially. Place the TOPS Motion Implant's four arms into the pedicle screw heads (Figure 37).

v. After the four arms are seated in the pedicle screw heads, insert four set screws and partially tighten them using the Set Screw Inserter to secure the TOPS Motion Implant to the pedicle screws (Figure 38a).

vi. Medialize the TOPS Motion Implant relative to the superior spinous process. Be sure that there is a sufficient gap (i.e., 3mm) between the top plate of the TOPS Motion Implant and the superior spinous process to avoid bone contact when the patient goes into extension (Figure 38b). If necessary, remove some of the superior spinous process to create additional clearance.

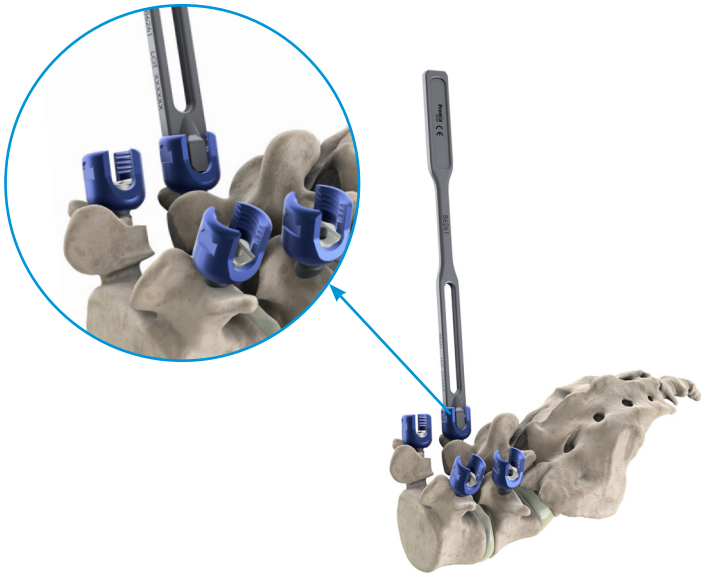


Figure 36: Head Releaser to unlock the polyaxiality of the pedicle screw joints

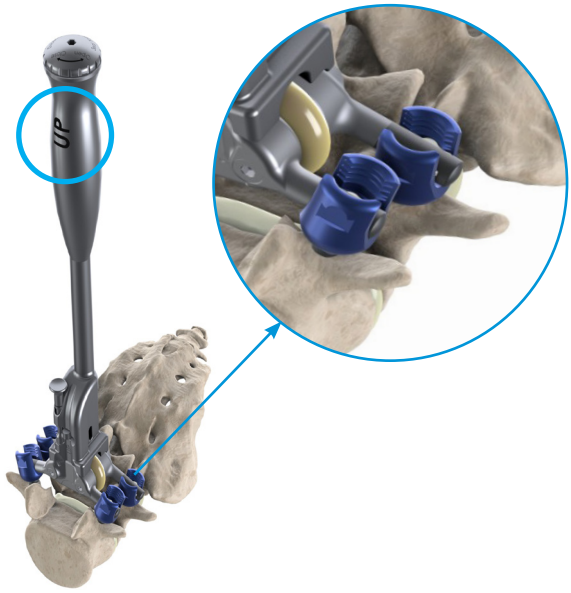


Figure 37: Place TOPS Motion Device with "UP" oriented cranially into pedicle screws

CAUTION: Never actively reduce the lumbar spondylolisthesis, as it could lead to device malfunction.

CAUTION: TOPS Motion Implant should only be inserted into the patient via the TOPS Inserter. Manual insertion can lead to device misalignment.

CAUTION: Do not release the TOPS Motion Implant from the TOPS Inserter before final tightening to keep the optimal positioning of the TOPS Motion Implant until torquing the set screws.

CAUTION: Carefully inspect the TOPS Motion Implant to ensure that the arms are well seated in the pedicle screw heads, and that there is no evidence of set screw cross-threading.

Figure 38a: Insert four set screws and partially tighten

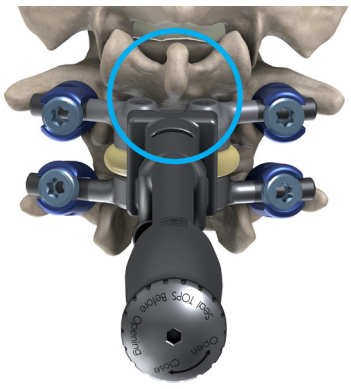


Figure 38b: Be sure that there is sufficient space

NOTE: Verify that the TOPS Motion Implant's arms extend laterally at least 2 mm beyond all four pedicle screws (Figure 39). In case there is not a 2mm minimum, remove the TOPS implant and replace it with the next size up of the TOPS Motion Implant length. Be sure to repeat all of the TOPS preparation steps in **Section G "TOPS Motion Implant Implantation"**.

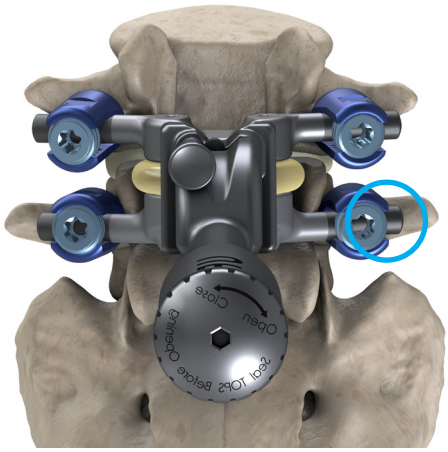


Figure 39: Verify that the crossbar extends laterally at least 2 mm beyond all four pedicle screws

D. Final Torque of Set Screws

i. Place the Counter Torque on the pedicle screw's head and the Screwdriver with Torque Limiter (Torx) through the Counter Torque. Insert the tip of the Screwdriver with Torque Limiter (Torx) into the set screw.

ii. Secure the Counter Torque onto the pedicle screw head making sure that the arch of the counter torque tip fits properly onto the TOPS Motion Implant (Figure 40).

iii. Tighten each set screw until an audible click is heard, confirming a force of 13 Nm.

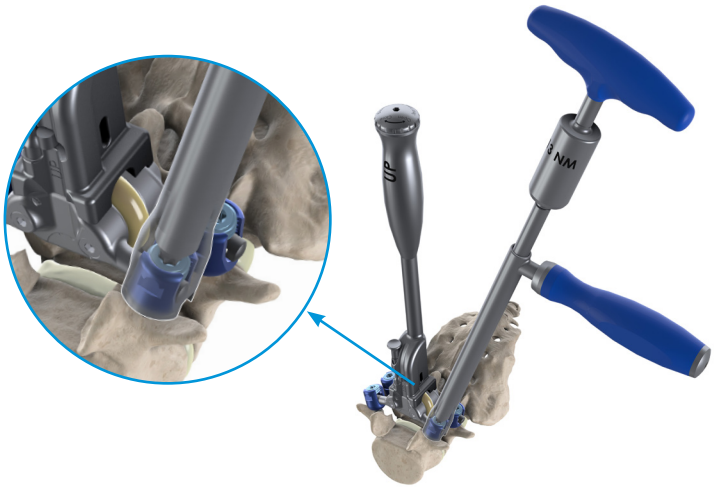


Figure 40: Tighten each set screw until an audible click is heard, confirming a force of 13 Nm

E. Detach TOPS Inserter

i. After the four set screws have undergone final tightening, unlock the knob on the TOPS Inserter by turning the knob counterclockwise until it releases. Remove the Inserter from the TOPS Motion Implant.

ii. If it is difficult to manually unlock the TOPS Inserter's knob, ensure that the plug pusher is advanced all the way forward, and try again (Figure 41). In case it is still difficult to unlock the TOPS inserter manually, attach the Standard Screwdriver to the hexagon socket on the top of the TOPS Inserter, and turn counterclockwise to detach (Figure 42).

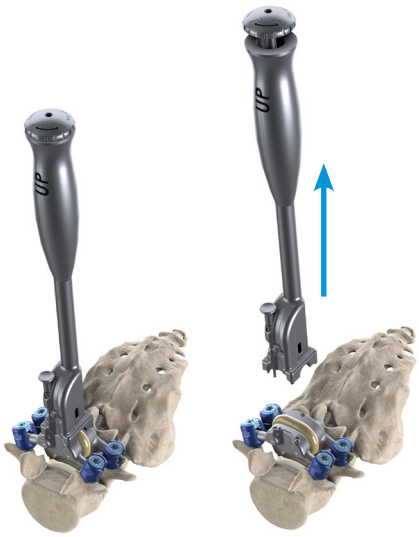


Figure 41: Remove the Inserter from the TOPS Motion Implant

Figure 42: Attach the Standard Screwdriver to the hexagon socket

iii. Verify TOPS positioning under direct visualization. Take a lateral and AP image to confirm proper alignment (Figure 43).

iv. If misalignment is noted, remove the Implant by reversing the torque sequence, take out the set screws, and remove the TOPS Motion Implant.

v. Place the TOPS Motion Implant in the Loading Base and reload onto the TOPS Inserter.

vi. Repeat the steps of TOPS insertion.

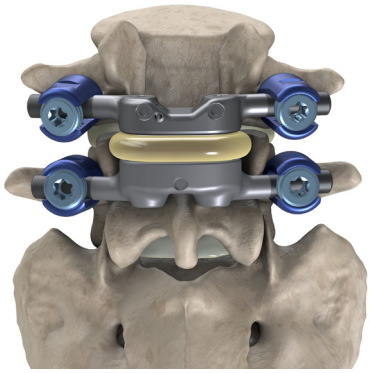


Figure 43: Intraoperative AP and lateral images before suturing the patient closed

F. Confirmation of Implant Orientation

i. Confirm that the endplates of the TOPS Motion Implant are parallel, and that the articulating surfaces are parallel as well (**Figure 44a** and **Figure 44b** indicate correct orientation, and **Figure 44c** indicates incorrect orientation).

ii. Confirm that the TOPS Motion Implant is parallel to the disc. If the implant is leaning forward or backward relative to the disc, you need to adjust the pair of superior or inferior screws to achieve correct positioning (Figure 44d).

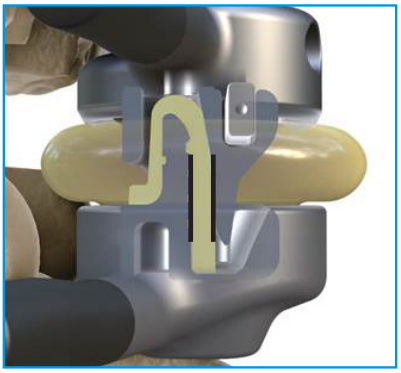


Figure 44a: Parallel articulating surfaces of TOPS Motion Implant

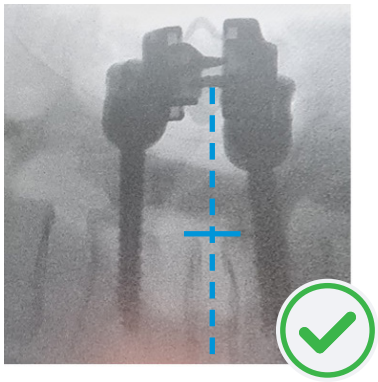


Figure 44d: Lateral view of TOPS Motion Implant placed parallel to the disc

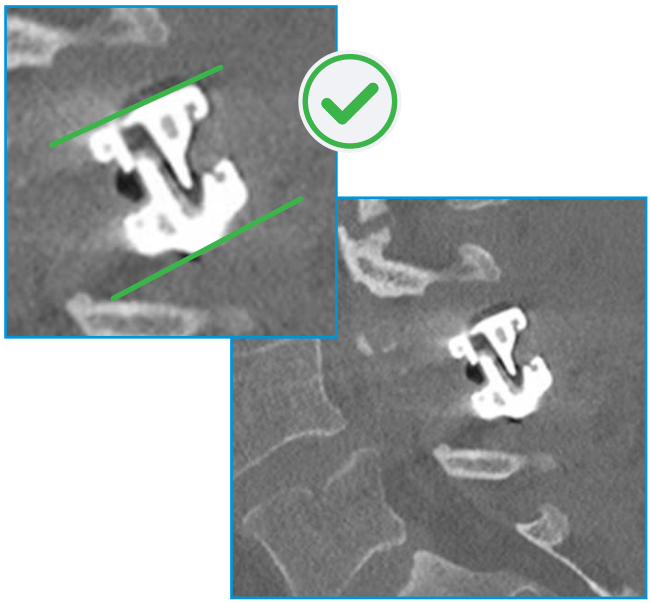


Figure 44b: Correct orientation

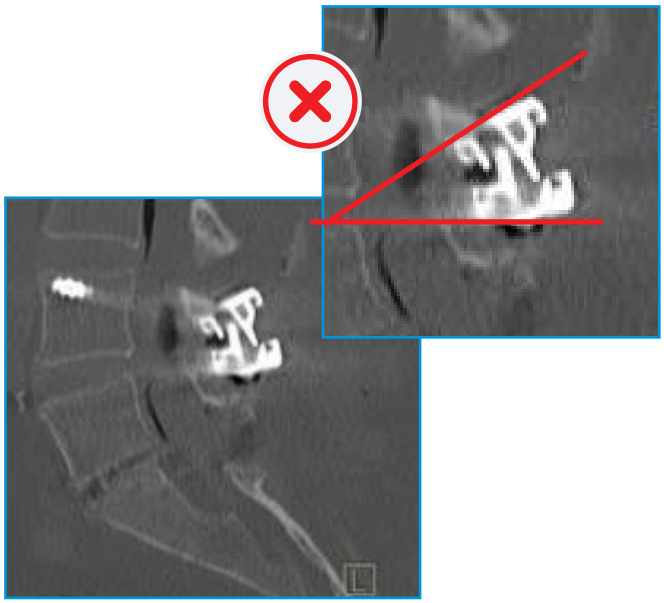


Figure 44c: Incorrect orientation

iii. Take a lateral image of the articulating surfaces to confirm that they are parallel (**Figure 45a** indicates correct orientation, and **Figure 45b** indicates incorrect orientation).

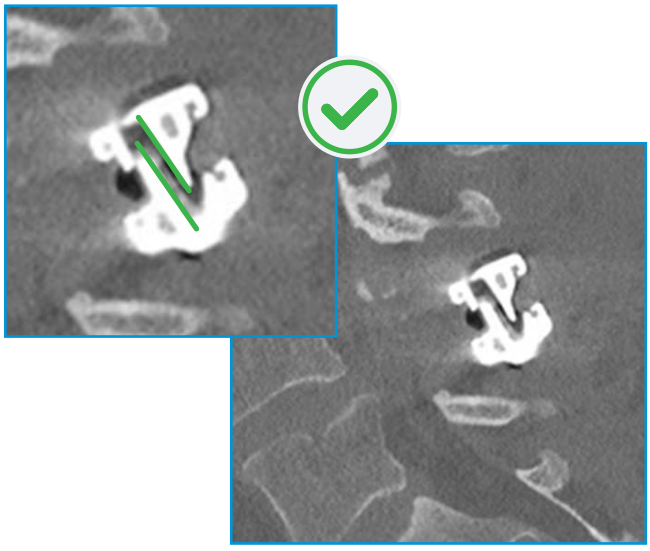


Figure 45a: Correct orientation

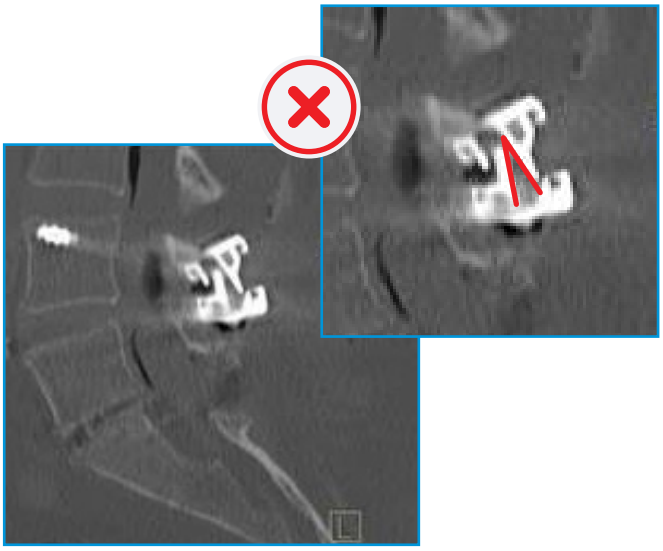


Figure 45b: Incorrect orientation

iv. Medialize the TOPS Motion Implant relative to the superior spinous process (**Figure 46**)

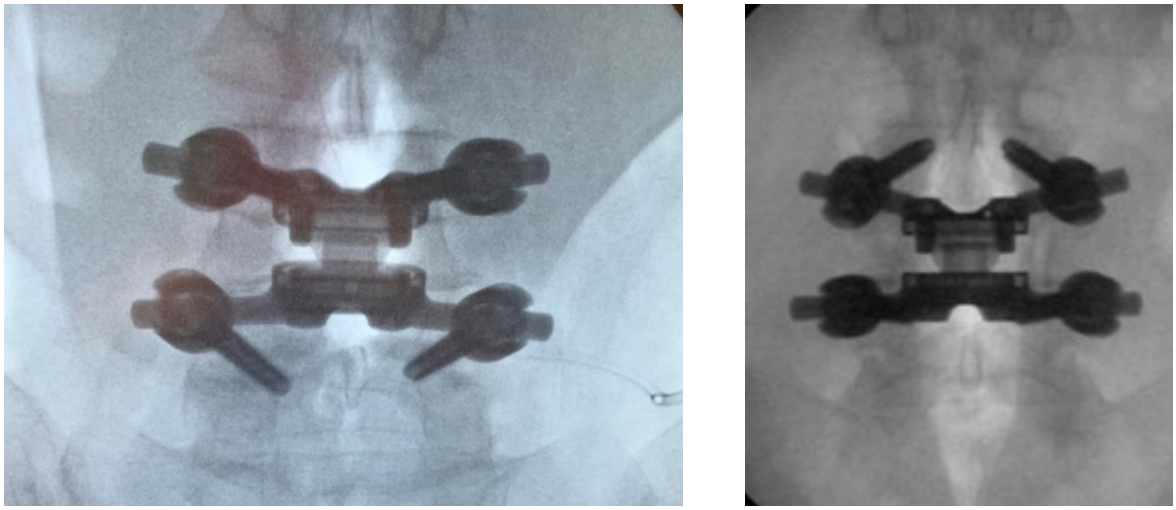


Figure 46: Anteroposterior view of two TOPS Motion Implants relative to the superior spinous process

G. Revision or correction of the implant orientation

i. Unlock the four set screws.

ii. Remove the implant from the screw heads.

iii. For correction of TOPS Motion Implant orientation, repeat templating the TOPS Motion Implant with the alignment gauge **(See Section F "TOPS Templating with the Alignment Gauge")**.

iv. For revision to fusion, select appropriate size fusion rods from Caddy and proceed with fusion procedure according to standard practice.

H. Procedure Completion

i. Verify that all instrumentation has been removed from the surgical field.

ii. Place a Penrose or Jackson Pratt style drain per standard protocols for 24 to 72 hours post-op until there is less than 50ml of fluid accumulation over a 12-hour period. If an active drain suction is used, place the drain above the TOPS Motion Implant and not between the implant and the dura.

iii. Prior to closure, irrigate the wound and check for any capillary bleeding. As per standard surgical techniques, standard hemostatic agents should be used if any persistent bleeding exists.

iv. Close the incision using standard surgical techniques.

CAUTION:

- Patients should be advised to follow the postoperative care procedures instructed by the surgeon. Following completion of the procedure, each patient should receive postoperative care customized to his/her postoperative needs and demonstrated progress. Patients should receive approval from a healthcare professional before commencing to ambulate. Guidance on types and timing of physical activity after surgery, including an exercise program, should be determined by a physician or a physical therapist.
- Patients should be instructed to avoid heavy lifting (greater than 20lbs) for 6 weeks, and impact sports for 3 months.

H Summary

Top 10 technical keys to success

i. Put patient in neutral to flexion position--as in a laminectomy or discectomy procedure--with side lumbar supports as necessary

ii. Hold the C-arm in a fixed lateral position and work with the pendulum during drilling, tapping, and screw insertion.

iii. Verify the screw is properly attached to the screwdriver without wobbling.

iv. Verify at least 6 millimeters gap between the tulip heads of the two adjacent levels.

v. Verify by lateral imaging that the screw tulips are superimposed and that all screws are properly positioned within the pedicles.

vi. Verify adequate decompression.

Verify correct steps with the Alignment Gauge:
- Decompression templating
- Gauge does not tilt to one side
- Gauge is parallel to the disc and does not lean caudal or cranial to confirm proper dorsal alignment of screw heads
- Proper sizing of the TOPS Motion Implant with sufficient rod overhang

vii. Verify correct loading of the TOPS Inserter to the TOPS Motion Implant via the Loading Base and fill saline to the filling line.

viii. Verify before 13Nm torque is applied for final tightening of the Set Screws:
- The TOPS Motion Implant is medialized in the mid-line
- No dural leaks left behind
- No sharp bony elements
- Decompression is adequate to ensure no nerve root impingement on segmental motioning
- At least 3mm gap between top plate and the superior spinous process

ix. Verify that TOPS Motion Implant endplates and articulating surfaces have parallel orientation, that the TOPS Motion Implant is placed parallel to the disc, that the screws share the same dorsal height in relation to the non-spondylolisthesis segments, and that there is adequate rod overhang.

x. Do not force the TOPS Motion Implant arms into the pedicle screws. If necessary, go back to the Alignment Gauge stage **(Section F "TOPS Templating with the Alignment Gauge")**. If performed properly no force is needed to place the TOPS

I Other Information

A. TOPS™ System™ Retrieval

i. Should it become necessary to explant a TOPS™ System, please contact Premia Spine prior to performing the procedure.

ii. Whenever possible, return the explanted TOPS Motion Implant and pedicle screws to Premia Spine for analysis. The Company will provide further instruction, including the required labels and packaging materials for the transportation of explanted devices.

iii. In case of any re-intervention procedure, including removal or revision of any of the TOPS™ System components, please refer to **APPENDIX 1 "TOPS™ SYSTEM REVISION PROCEDURE"**.

WARNING: Explants are considered biologically contaminated and should be treated with universal precautions. Contact Premia Spine for instructions for explant handling.

B. Product Complaints

Any health care professional who has complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance should notify Premia Spine. Further, if an Instrument ever malfunctions, (i.e., does not meet any of the performance specifications or otherwise does not perform as intended) or may have caused or contributed to the death or serious injury of a patient, Premia Spine should be notified immediately by telephone or written correspondence. When filing a complaint, please provide the device name, lot number, your name and address, and the nature of the complaint. Complaints may also be reported directly to Medwatch at **http://www.fda.gov/medwatch**.

C. Product Instructions for Use

For further instructions and information, including information about storage and shelf life, refer to Premia Spine's instructions for Use (IFU) documents provided with the products:

- TOPS™ System Instructions for Use.
- Pedicle Screws Instructions for Use.
- TOPS™ System Instrumentation Set Instructions for Use.

D. Warranty and disclaimer:

Premia Spine products are sold without expressed or implied warranties. Warranties of merchantability or fitness for a particular purpose are hereby disclaimed.

APPENDIX 1 – TOPS™ SYSTEM REVISION PROCEDURE

i. Place the patient in a prone position on a radiolucent table suitable for AP and lateral fluoroscopy.

ii. Perform a midline incision of 6 to 14 centimeters that provides direct access and full visualization of the TOPS Motion Implant and the pedicle screws.

iii. Expose each pedicle screw head.

iv. Place the Counter Torque on the pedicle screw's head and the Screwdriver with Torque Limiter (Torx) through the Counter Torque. Insert the tip of the Screwdriver with Torque Limiter (Torx) into the set screw.

v. Secure the Counter Torque onto the pedicle screw head making sure that the arch of the counter torque tip fits properly onto the TOPS Motion Implant arm.

vi. Loosen and remove each set screw.

vii. Remove the TOPS Motion Implant and or pedicle screws.

viii. Place screws, rods, interbody cage and/or bone grafting according to standard fusion surgical protocol.

ix. Perform final tightening.

APPENDIX 2 – ADDITIONAL SCREW PLACEMENT TECHNIQUES

CAUTION: The TOPS™ System is to be used with pedicle screws supplied by Premia Spine. **Do not** implant the TOPS™ System with components of any other manufacturer.

CAUTION:

- The K-Wires are part of the TOPS™ System instrumentation Set and are provided non-sterile and must be sterilized in accordance with the validated instructions described in the TOPS™ System Instrumentation Set Instructions for Use (IFU) prior to use.
- The K-Wires are intended for a single use only and should be discarded after use. **Do not** re-sterilize. **Do not** re-use.

The standard open screw placement technique is described earlier. Other screw placement techniques appear below.

In addition to the standard open screw placement technique (METHOD 1), any one of the following 3 methods may also be used for insertion of pedicle screws:
METHOD 2 - Using cannulated instruments
METHOD 3 - Using a K-Wire Adaptor/Dynamic K-Wire Adaptor
METHOD 4 - Using Medtronic Stealth Station (for navigation)

METHOD 2 - Pedicle channel preparation by using cannulated instruments:

The following cannulated instruments are available:
Cannulated Pedicle Probe
Cannulated Taps (4.5 mm, 5.5 mm, 6.5mm diameter)
Cannulated Pedicle Awl.

All shafts are connected to an integrated K-Wire handle which locks in a dedicated K-Wire (locking is performed with the aid of a screwdriver).

To prepare the instrument:
Unscrew and remove the knob from the Integrated K-Wire Handle.
Introduce the blunt tip of the K-Wire into the dedicated hole found on the underside of the knob. Use the Standard Screwdriver to lock the K-Wire in place.
Insert the K-Wire connected to the knob into the Integrated K-Wire Handle and screw the knob in.
Insert the K-Wire into the shaft and lock it in by pressing down on the button located on the Integrated K-Wire Handle.
The K-Wire should protrude 2 to 3 millimeters from the tip of the pedicle probe.

Three technique options can be used with cannulated instruments: Jam-shidi, Tap-shidi, or Awl-shidi:

Option 1: Jamshidi Technique for Pedicle Channel Preparation:
Introduce the Pedicle Probe of the Jamshidi needle (**Figure 47**) into the bone by manual manipulation or mallet. AP and lateral fluoroscopy should be used to confirm correct trajectory. Use the pendulum to verify proper medial-lateral trajectory.

If the pedicle is ready for screw insertion, disconnect the Integrated K–Wire Handle with the K-Wire from the Cannulated Pedicle Probe, and insert a 470 mm K-Wire via the Cannulated Pedicle Probe. Remove the Pedicle Probe but leave the 470 mm K-Wire in place.

Figure 47: Jamshidi needle for pedicle channel preparation

Option 2: Tap-shidi Technique for Pedicle Channel Preparation:
Introduce the Tap of the Tap-shidi needle (**Figure 48**) into the bone by manual swiveling. Use AP and lateral fluoroscopy to confirm correct positioning. Use the Pendulum to verify proper medial-lateral trajectory. If the pedicle is ready for screw insertion, disconnect the Integrated K–Wire Handle from the Cannulated Pedicle Tap and replace it with a 470 mm K-Wire. Remove the Tap with a swiveling motion while leaving the K-Wire in place.

Figure 48: Tap-shidi needle for pedicle channel preparation

Option 3: Awl-shidi Technique for Pedicle Channel Preparation:
Assemble the Pedicle Awl shaft onto the Integrated K-Wire Handle (**Figure 49**). Introduce the Pedicle Awl into the bone by manual manipulation or mallet until reaching the Instrument's hard stop.

Remove the knob from the Integrated K-Wire Handle and replace it with the Integrated Depth Gauge Knob. Insert the marked K-Wire 470mm through the Gauge and the Cannulated Pedicle Awl.

Advance the Marked K-Wire into the pedicle and use lateral imaging to determine the desired depth of the screw. Once the desired depth is reached, the screw length is defined by the black marking on the K-Wire that meets the scale on the Integrated Depth Gauge Knob. Remove the Pedicle Awl while leaving the K-Wire in place.

Figure 49: Awl-shidi needle for pedicle channel preparation

Method 3: Screw Insertion Using K-Wire Adaptor / Dynamic K-Wire Adaptor

This method allows for direct screw placement.
Connect the pedicle screw to the Screwdriver as described in **Section D "Pedicle Preparation and Screw Insertion"**. Load the K-Wire / Dynamic K-Wire Adaptor with a dedicated K-Wire:
Remove the threaded inner shaft by rotating the knob counter-clockwise until the screw releases.
Insert the dedicated K-Wire (335mm, 1.7 mm diameter for K-Wire Adaptor; 340mm, 1.65 mm diameter CoCr for Dynamic K-Wire Adaptor) into the threaded inner shaft until it is flush with the upper surface of the screw.

Using the K-Wire Adaptor:

- Lock the K-Wire by fastening the screw at the proximal end of the threaded inner shaft using a set screw inserter.
- Verify that the K-Wire end is flush with the upper surface of the threaded inner shaft.
- Place the loaded threaded inner shaft back into the K-Wire Adaptor (**Figure 50**).
- Introduce the K-Wire connected to the K-Wire Adaptor through the Cannulated Screwdriver with a screw attached.
- Connect the K-Wire Adaptor to the Screwdriver by pushing the button on the K-Wire Adaptor.
- Rotate the knob of the Adaptor clockwise to advance the tip distally (towards the screw tip). Adjust the length of the K-Wire by turning the knob on the handle of the Adaptor clockwise until the tip of the wire protrudes 2 to 3 millimeters from the pedicle screw tip.
- Ensure that the threaded inner shaft of the K-Wire Adaptor is below the upper surface of the Adaptor.
- Insert the screw:
- Introduce the pedicle screw (with the Screwdriver connected to the K-Wire Adaptor) into the pedicle entry point.
- Hammer on the K-Wire Adaptor impact ring until the K-Wire passes through the cortical bone.

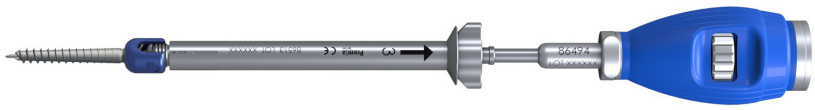


Figure 50: Screw Insertion Using K-Wire Adaptor

Using the Dynamic K-Wire Adaptor:

- When using the Dynamic K-Wire Adaptor (**Figure 51**), it is possible to advance and retract the K-Wire independently from the screw within bone.
- The scale on the Dynamic K-Wire Adaptor indicates the depth of the K-Wire from the tip of the screw (adjusted according to the screw length).
- Attach the Pendulum to the screwdriver and verify the trajectory of the screw. If the pendulum needle exceeds the range of the instrument (± 10°), the screw should be redirected to be within the Pendulum range (± 10°).
- Use lateral imaging to confirm correct pedicle penetration prior to advancing the screw to the desired insertion depth.
- Advance the pedicle screw beyond the posterior wall of the vertebral body, retract the K-Wire into the body of the pedicle screw, and then proceed to fully insert the pedicle screw.
- Once the screw is properly inserted, unlock the screwdriver from the screw by turning the locking sleeve counterclockwise.

Figure 51: Screw Insertion Using the Dynamic K-Wire Adaptor

NOTE: Be sure to hammer on the Impact Ring at the upper aspect of the handle only. **Do not** hammer on the threaded portion.

Working with a Power Drill:

Premia Spine supplies a Power Drill Adaptor (**Figure 52**) which enables working with a power drill connected to the Cannulated Screw-driver. The procedure is as follows:

- Attach the Power Drill Adaptor to the Cannulated Screwdriver by pulling the locking ring upward and sliding the shaft into the hole in the distal aspect of the Adaptor. Verify that the shaft is firmly connected.
- Attach the Power Drill to the Power Drill Adaptor by inserting the triangle shaped bit to the dedicated hole on the Power Drill.
- Lock the Adaptor by fastening the chuck of the Power Drill.
- Verify proper attachment by slightly pulling the shaft in the opposite direction.

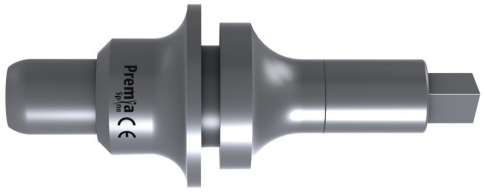
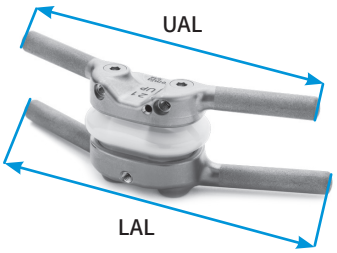


Figure 52: Power Drill Adaptor

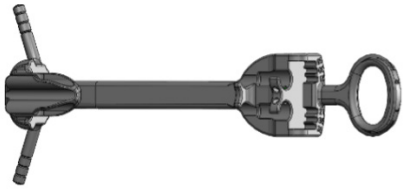
Method 4 - Using Medtronic Stealth Station (for navigation)

Refer to a separate Surgical Technique: **”XL Instruments for TOPS™ System - Surgical Technique”** and **“XL Instruments for TOPS™ System - Instructions for Use”**.

APPENDIX 3 – TOPS™ SYSTEM CATALOG

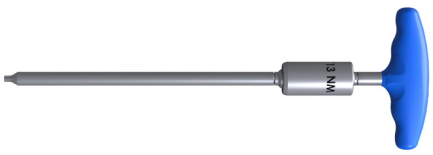
Name of the Component		Part No.	Photograph	Sterile (Gamma Irradiation)
TOPS - 21 L	TOPS L, Arm length Upper Arm Length (UAL) = 87 mm Lower Arm Length (LAL) = 93 mm	82643		Yes
TOPS - 30 L		82644		Yes
TOPS - 38 L		82645		Yes
TOPS - 21 M	TOPS M, Arm length Upper Arm Length (UAL) = 77 mm Lower Arm Length (LAL) = 83 mm	85858		Yes
TOPS - 30 M		85859		Yes
TOPS - 38 M		85860		Yes
TOPS - 21 S	TOPS S, Arm length Upper Arm Length (UAL) = 67 mm Lower Arm Length (LAL) = 73 mm	86000		Yes
TOPS - 30 S		86001		Yes
TOPS - 38 S		86002		Yes
Polyaxial Pedicle Screw Cannulated 5.5x25 mm		86120		Yes
Polyaxial Pedicle Screw Cannulated 5.5x30 mm		86121		Yes
Polyaxial Pedicle Screw Cannulated 5.5x35 mm		86122		Yes
Polyaxial Pedicle Screw Cannulated 5.5x40 mm		86123		Yes
Polyaxial Pedicle Screw Cannulated 5.5x45 mm		86124		Yes
Polyaxial Pedicle Screw Cannulated 5.5x50 mm		86125		Yes
Polyaxial Pedicle Screw Cannulated 5.5x55 mm		86126		Yes
Polyaxial Pedicle Screw Cannulated 5.5x60 mm		86390		Yes
Polyaxial Pedicle Screw Cannulated 6.5x25 mm		86127		Yes
Polyaxial Pedicle Screw Cannulated 6.5x30 mm		86128		Yes
Polyaxial Pedicle Screw Cannulated 6.5x35 mm		86129		Yes
Polyaxial Pedicle Screw Cannulated 6.5x40 mm		86130		Yes
Polyaxial Pedicle Screw Cannulated 6.5x45 mm		86131		Yes
Polyaxial Pedicle Screw Cannulated 6.5x50 mm		86132		Yes
Polyaxial Pedicle Screw Cannulated 6.5x55 mm		86133		Yes
Polyaxial Pedicle Screw Cannulated 6.5x60 mm		86391		Yes
Polyaxial Pedicle Screw Cannulated 7.5x25 mm		86134		Yes
Polyaxial Pedicle Screw Cannulated 7.5x30 mm		86135		Yes
Polyaxial Pedicle Screw Cannulated 7.5x35 mm		86136		Yes
Polyaxial Pedicle Screw Cannulated 7.5x40 mm		86137		Yes
Polyaxial Pedicle Screw Cannulated 7.5x45 mm		86138		Yes
Polyaxial Pedicle Screw Cannulated 7.5x50 mm		86139		Yes
Polyaxial Pedicle Screw Cannulated 7.5x55 mm		86140		Yes
Polyaxial Pedicle Screw Cannulated 7.5x60 mm		86392		Yes

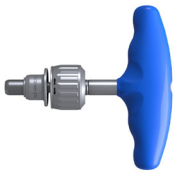
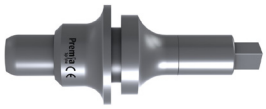
APPENDIX 4 – INSTRUMENTATION KIT

Instruments	Brief Description
 Pendulum **P/N:** 82775	See Section 6 for instrument description
 Alignment Gauge handle **P/N:** 83104-Long, 86185-Medium	See Section 6 for instrument description
 Left Alignment Gauge Superior Crossbars **P/N:** 83107-Long, 86189-Medium	See Section 6 for instrument description
 Right Alignment Gauge Superior Crossbars **P/N:** 83106-Long, 86187-Medium	See Section 6 for instrument description
 TOPS Loading Base **P/N:** 86991	See Section 6 for instrument description
 TOPS Inserter **P/N:** 82889	See Section 6 for instrument description

Instruments	Brief Description
 Head Releaser **P/N:** 80646	Unlocks the poly-axial joint of the pedicle screw and orient the tulip of the pedicle screw.
 MIS Tower Guide **P/N:** 86261	Unlocks the polyaxial joint of the pedicle screw and orients the tulip of the pedicle screw. Releases the MIS Tower from the tulip of the pedicle screw. Also reattaches to the MIS Tower to the tulip of the pedicle screw.
 Pedicle Awl-Conical **P/N:** 81708	Reams the pedicle in preparation for the pedicle screw insertion. Includes a hard stop and tear drop handle.
 Pedicle Awl **P/N** 83159	Reams the pedicle in preparation for the pedicle screw insertion. Includes a hard stop and straight handle.
 Cannulated Pedicle Awl **P/N:** 86262	Reams the pedicle in preparation for the pedicle screws insertion Includes a hard stop. Works with the Integrated K-Wire Handle and K-Wire.
 Ball Sleeve Assy **P/N:** 81714	Ensures sufficient distance between unilateral screws to simulate the position of the second Pedicle Screw. Works with Ball Probe.
 MIS Cannulated Pedicle Probe **P/N:** 86047	Prepares the pedicle channel for the pedicle screws. Connects to the Integrated K-Wire Handle and a K-Wire.
 Ball Probe **P/N:** 81717	Prepares the pedicle channel for the pedicle screws with conical straight tip.
 Pedicle Probe Sharp\Blunt Straight **P/N:** 86880/86876	Prepares the pedicle channel for the pedicle screws with blunt straight tip.

Instruments	Brief Description
 Pedicle Probe Bent with Drop handle **P/N:** 86676 Pedicle Probe Blunt-Bent **P/N:** 86878	Prepares the pedicle channel for the pedicle screws blunt bent tip.
 Pedicle Probe Sharp-Bent **P/N:** 86882	Prepares the pedicle channel for the pedicle screws with sharp bent tip.
 Non-Tapered Pedicle Probe for Screws Ø5.5 and Ø6.5 **P/N:** 86995 Non-Tapered Pedicle Probe Ø7.5 **P/N:** 86996	Prepares the pedicle channel for the pedicle screws with non-tapered tip.
 Cannulated Tap Ø 4.5 mm **P/N:** 87075 Cannulated Tap Ø 5.5 mm **P/N:** 86142 Cannulated Tap Ø 6.5 mm **P/N:** 86143	Use in the presence of dense, sclerotic, or brittle bone for tapping through the pedicle channel before advancing a Ø5.5 mm pedicle screw for the over-the-K-Wire technique and Tapshidi technique. Use in the presence of dense, sclerotic, or brittle bone for tapping through the pedicle channel before advancing a Ø6.5 mm pedicle screw for over-the-K-Wire technique and Tapshidi technique. Use in the presence of f dense, sclerotic, or brittle bone for tapping through the pedicle channel before advancing a Ø7.5 mm pedicle screw for over-the-K-Wire technique and Tapshidi technique.
 Tap Ø 4.5 for Pendulum Adaptor **P/N**: 87074 Tap Ø 5.5 for Pendulum Adaptor **P/N:** 86639 Tap Ø 6.5 for Pendulum Adaptor **P/N:** 86640	Use in the presence of dense, sclerotic, or brittle bone for tapping through the pedicle channel before advancing a Ø5.5 pedicle screw. Works with Premia Spine's handles. Use in the presence of dense, sclerotic, or brittle bone for tapping through the pedicle channel before advancing a Ø6.5 pedicle screw. Works with Premia Spine's handles. Use in the presence of dense, sclerotic, or brittle bone for tapping through the pedicle channel before advancing a Ø7.5 pedicle screw. Works with Premia Spine's handles.
 Depth Gauge and Feeler **P/N:** 83210	Verifies the integrity of the pedicle wall. Confirms the depth of the pedicle screw preparation hole for proper placement of the pedicle screw.

Instruments	Brief Description
 Standard Screwdriver **P/N:** 83209	Advances the screw to the desired depth. Works in conjunction with the TOPS Inserter Inner Shaft and the Integrated K-Wire Handle Locking Screw with a black mark on the proximal top of handle to indicate screw swivel.
 Cannulated Screwdriver **P/N:** 86507	Advances the screw to the desired depth. Works in conjunction with Premia Spine's Handles
 Counter Torque **P/N**: 83142	Counters the torque created during the final tightening of the Set Screws to 13Nm with a small and large slots.
 Counter Torque with Tight Slots **P/N:** 88048	Counters the torque created during the final tightening of the Set Screws to 13Nm with 2 small slots.
 Torx Setscrew Inserter **P/N**: 86208	Inserts and fastens Premia Spine's Set Screws.
 Screwdriver with Torque Limiter (Torx) **P/N:** 86567	Performs the final torquing of the pedicle screws' Set Screws. Designed to tighten the Set Screws by 13Nm.
 MIS Tower **P/N:** 86052	Serves as a channel for Set Screw insertion, as well as for rod passage.

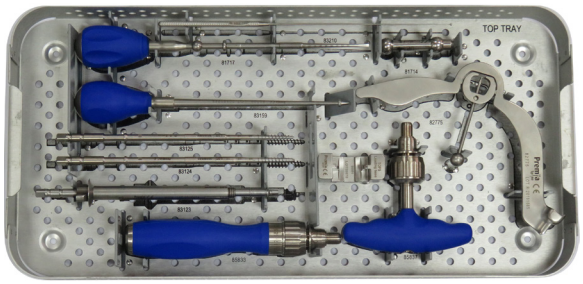
Instruments	Brief Description
 Integrated Depth Gauge Knob **P/N**: 87363	Determines the required pedicle screw's length without the need for an AP x-ray. Works in conjunction with the Awl-Shidi technique (the Integrated K-Wire Handle and Cannulated Awl).
 T-Handle with Pendulum Adaptor **P/N**: 86263	Connects to the taps and cannulated screwdriver. Facilitates insertion of the pedicle screws with or without a K-Wire while simultaneously using the Pendulum.
 Straight Handle with Pendulum Adaptor **P/N:** 86273	Connects to the taps and cannulated screwdriver. Facilitates insertion of the pedicle screws with or without a K-Wire while simultaneously using the Pendulum.
 Fix connector power drill adaptor **P/N:** 87129	Connects a power drill to Premia Spine's screwdriver and Pendulum adaptor.
 Integrated K-Wire Handle **P/N:** 86046	Allows preparing the pedicle entry point with a K-Wire attached. Works in conjunction with Cannulated Pedicle Awl, Cannulated Taps, Cannulated Pedicle Probe, Pendulum, and 230 mm K-Wire.
 K-Wire Adaptor **P/N:** 86494	Handle that works in conjunction with the cannulated screwdriver and a K-Wire. Enables manual control of the K-Wire advancement with the pedicle screw.
 Dynamic K-Wire Adapter **P/N:** 87130	Handle that works in conjunction with the cannulated screwdriver and a K-Wire. Enables manual control of the K-Wire advancement with / without the pedicle screw.

Instruments	Brief Description
 DKWA Tear Drop Handle, Coupling Connection **P/N:** 88169	Ratchet Handle for Dynamic K-Wire Adaptor.
 DKWA T- Handle, Coupling Connection **P/N:** 88168	Ratchet Handle for Dynamic K-Wire Adaptor.
Tube for K-Wire over a K-Wire technique 470mm **P/N:** 86818	Tube for K-Wires: Container for steam sterilization.
Tube for K-Wire Direct approach technique 335 mm **P/N:** 86819	Tube for K-Wires: Container for steam sterilization.
Tube for K-Wire Tapshidi/ Jamshidi technique 230mm **P/N:** 86820	Tube for K-Wires: Container for steam sterilization.

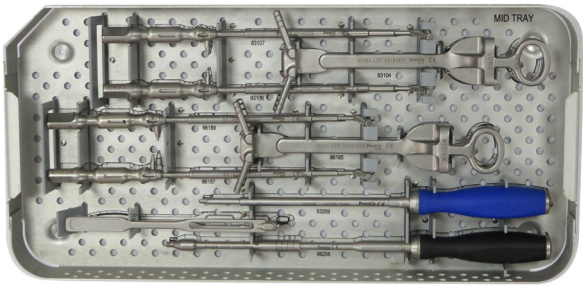
TOPS Instrumentation Container **P/N:** 83117
Container size: 520*255*135 mm

Container for instruments for steam sterilization.

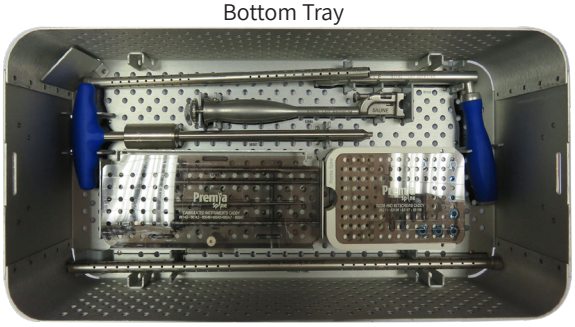
TOP Tray



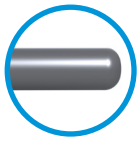
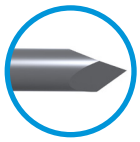
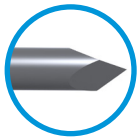
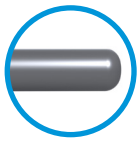
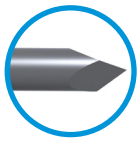
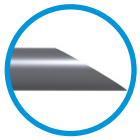
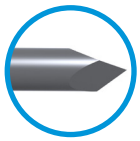
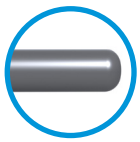
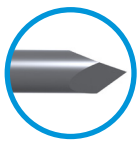
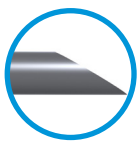
Mid Tray

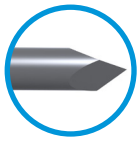
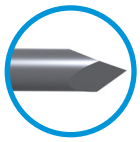
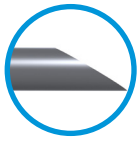
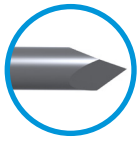
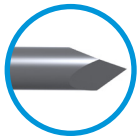
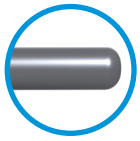


Bottom Tray



Cannulated Instruments Caddy

Technique for single use K-Wires		Brief Description
Over the K-Wire Technique Nitinol wire Blunt-Blunt Tip 470 Ø1.7 over K-Wire **P/N:** 87010		Use with Tapshidi / Jamshidi techniques for integrated K-Wire handle.
Over the K-Wire Technique Nitinol wire Blunt-Sharp Tip 470 Ø1.7 over the K-Wire **P/N:** 87009		Use for Over the K-Wire technique for surgeons who prefer nitinol.
Over the K-Wire Technique SST 316 LVM, Blunt-Beveled Tip, L=470, Ø1.7 over the K-Wire **P/N:** 87208		Use for Over the K-Wire technique for surgeons who prefer nitinol.
Over the K-Wire Technique SST 316 LVM, Blunt-Blunt Tip, L=470, Ø1.7 over the K-Wire **P/N:** 86830		Use for Over the K-Wire technique screw placement.
Over the K-Wire Technique SST 316 LVM, Blunt-Threaded Tip, L=470, Ø1.7 over the K-Wire **P/N:** 86289		Use for Over the K-Wire technique screw placement.
Over the K-Wire Technique SST 316 LVM, Blunt-Sharp Tip, Blunt- Sharp Tip, L=470, Ø1.5 over the K-Wire **P/N:** 86264		Use for Over the K-Wire technique screw placement.
Over the K-Wire Technique Nitinol wire, Blunt- Beveled Tip, L=470, Ø1.7 over the K-Wire **P/N:** 87359		Use for Over the K-Wire technique for surgeons who prefer nitinol.
Over the K-Wire Technique SST 316 LVM, L=470, Ø1.5 over the K-Wire **P/N:** 87851		Use for Over the K-Wire technique screw placement.
Over the K-Wire Technique Nitinol wire, Blunt- Sharp Tip, L=470, Ø1.5 over the K-Wire **P/N:** 87865		Use for Over the K-Wire technique screw placement.
Shidi-Technique SST 316 LVM, Blunt Sharp Tip, L=230, Ø1.7 Shidi-Technique **P/N:** 86828		Use with Tapshidi / Jamshidi techniques for integrated K-Wire Handle.
Shidi-Technique SST 316 LVM, Blunt Beveled Tip, L=230, Ø1.7 Shidi-Technique **P/N:** 87209		Use with Tapshidi / Jamshidi techniques for integrated K-Wire Handle.

Technique for single use K-Wires		Brief Description
Shidi-Technique SST 316 LVM, Blunt-Sharp Tip, L=470, Ø1.7 Awl-Shidi (Marked) **P/N:** 87364		Use for Awl-Shidi technique with the cannulated and the integrated K-Wire Handle and the depth gauge.
K- Wire Adaptor Technique SST 316 LVM, Blunt Sharp Tip, L=335, Ø1.7 KWA **P/N:** 86864		Use with the K-Wire Adaptor.
K- Wire Adaptor Technique SST 316 LVM, Blunt-Beveled Tip, L=335, Ø1.7 KWA **P/N:** 88020		Use with the K-Wire Adaptor.
Dynamic K-Wire Adaptor Technique CoCr wire, Blunt- Sharp Tip, L=340, Ø1.65mm DKWA **P/N:** 87271		Use with the Dynamic K-Wire Adaptor.
Power Drill Technique SST 316 LVM, Blunt-Sharp Tip, L=600, Ø1.7 Power Drill **P/N:** 87447		Use when using a Power Drill for Over the K-Wire technique.
Power Drill Technique SST 316 LVM, Blunt-Blunt Tip, L=600, Ø1.7 Power Drill **P/N:** 87696		Use with a Power Drill in an Over the K-Wire technique.

Premia Spine

For more information contact:
info@premiaspine.com
or visit www.premiaspine.us

Premia Spine Ltd.
7 Giborey St.
Ramat Poleg, Netanya 4250407
Israel

Premia Spine Inc.
98 East Avenue
Norwalk, CT 06851
USA