TOPS™ System Surgical Technique

December 2022

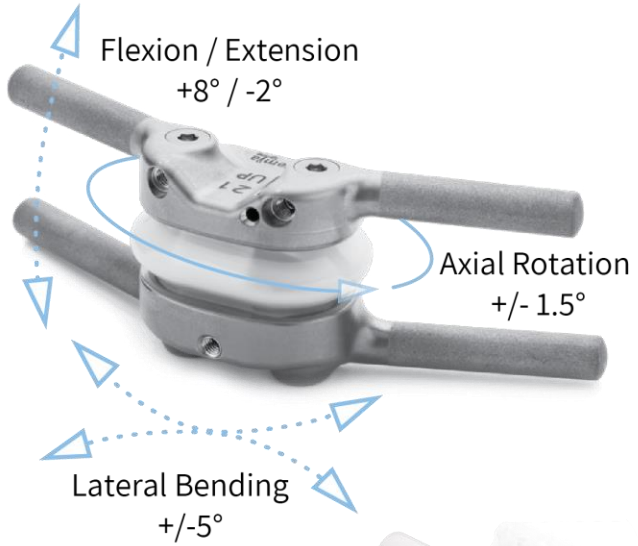
CL-3867-US Rev.03

Contact: info@premiaspine.com with questions

TOPS™ System: Motion preservation for Spinal Stenosis and Spondylolis-thesis

Indications For Use of the TOPS™ System:

The TOPS™ System is a motion-preserving spinal implant that is inserted into the lumbar vertebral joint and affixed to the 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 the ages of 35 and 80 years suffering from degenerative spondylolisthesis up to Grade I with moderate to severe lumbar spinal stenosis and either thickening of the ligamentum flavum or scarring of the facet joint capsule at one level from L2 to L5.

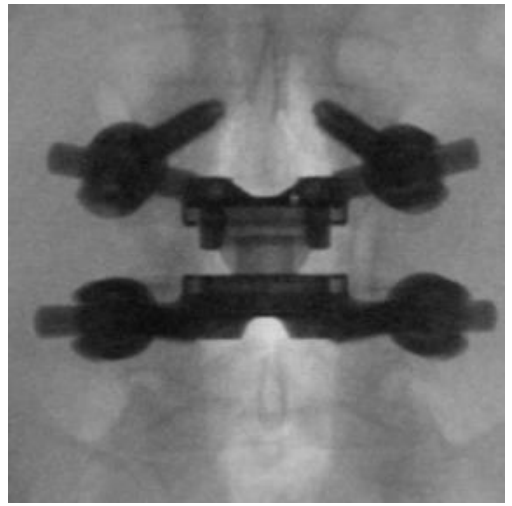


CAUTION: Federal (USA) law restricts this implant to sale by or on the order physician

CL-3867-US Rev.03

TOPS™ System: Motion preservation for Spinal Stenosis and Spondylolis-thesis

Contraindications: The TOPS™ System should not be implanted in patients with the following conditions:
•Presence of free fragment disc herniation at the index level •Spondylolisthesis greater than Grade I •Traumatic or dysplastic spondylolisthesis •Lytic spondylolisthesis •Back or non-radicular leg pain of unknown etiology •Stenosis caused by an extruded spinal disc fragment (e.g., herniation) or where the etiology is considered to be congenital, iatrogenic, post-traumatic, or metabolic •Known allergy or sensitivity to PEEK, titanium, and/or polyurethane •Scoliosis >10 °by major Cobb angle (both angular and rotational) •Morbid obesity defined as a body mass index > 40 •Osteoporosis (lumbar spine T score < -2) •Active infection - systemic or local •Cauda equina syndrome or neurogenic bowel/bladder dysfunction



TOPS™ System: Motion preservation for Spinal Stenosis and Spondylolis-thesis

Clinical Summary:

TOPS demonstrates clinical superiority in overall trial success compared to fusion at 24 months.

The difference between the TOPS success rate of 74% and fusion's rate of 26% is statistically superior.

See full clinical section for additional safety and efficacy information.

5 elements to the TOPS surgical technique

1. Patient positioning & incision
2. Screw position & orientation
3. Decompression

Sequence can be switched

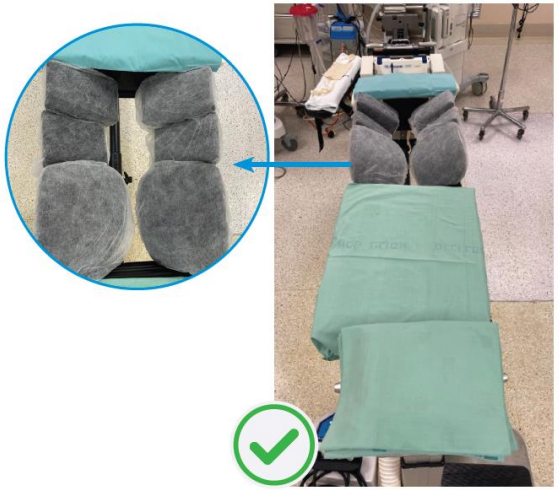
4. TOPS Implant Sizing & Screw Alignment
5. TOPS device preparation & insertion

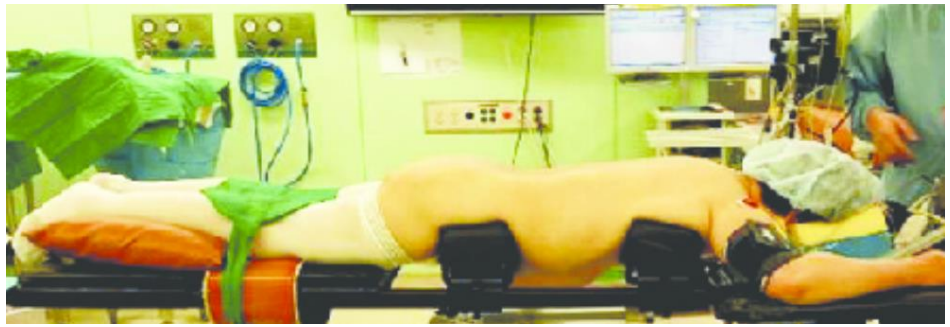
CL-3867-US Rev.03

1-Minute TOPS Surgery Video

1. Patient positioning for post-op success

- Use frame/table that supports the abdomen
- Avoid placing patient in lordosis
- Place patient in neutral position. Legs may be slightly bent at the hips



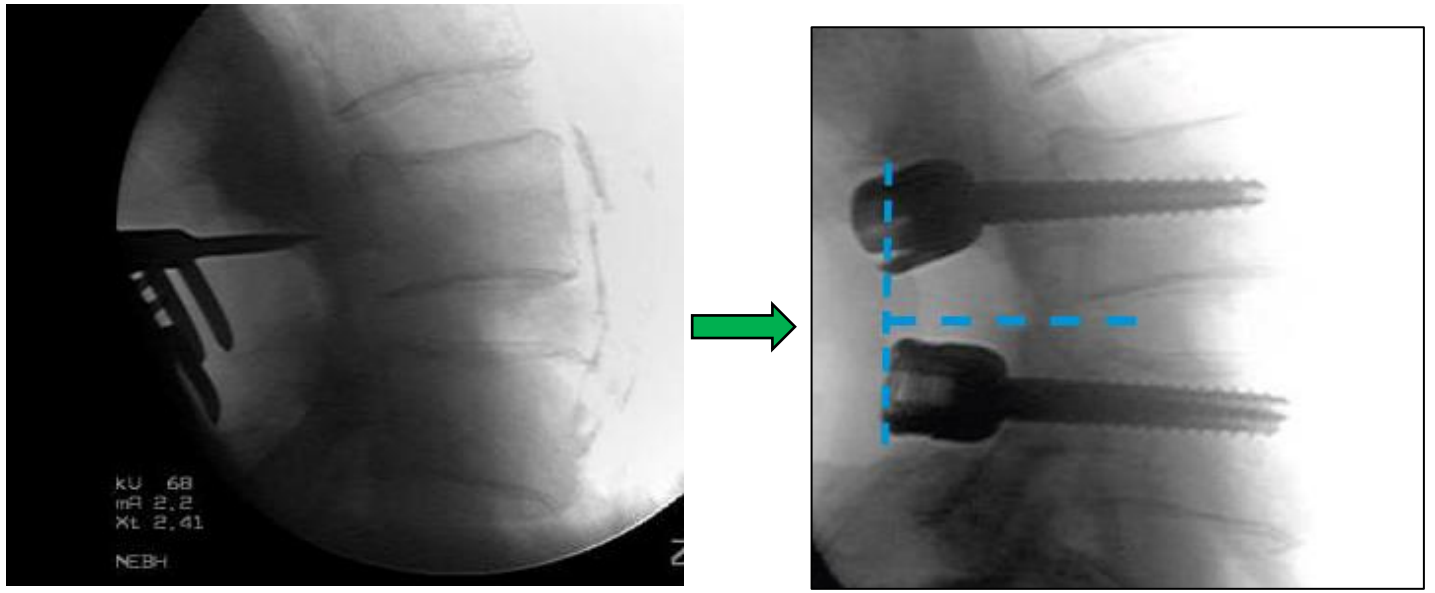


1. Incision

- Perform a **midline incision of 6 to 14 cm** and muscle dissection to the spinous process
- **Tip: Larger incision facilitates screw /device placement**
- Ensure bilateral facet visualization

2. C-arm positioning

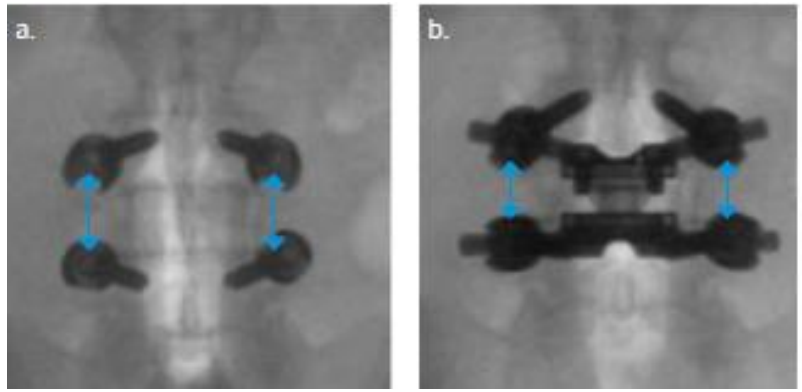
- Rotate the C-arm to a lateral position and ensure no parallax
- Maintain same C-arm position throughout the screw placement process
- **Tip: Superimpose screws on lateral image to achieve ideal alignment**



2. Screw positioning goals

Insert the screws at an optimal trajectory and align them on the same dorsal height for proper fit with the TOPS implant

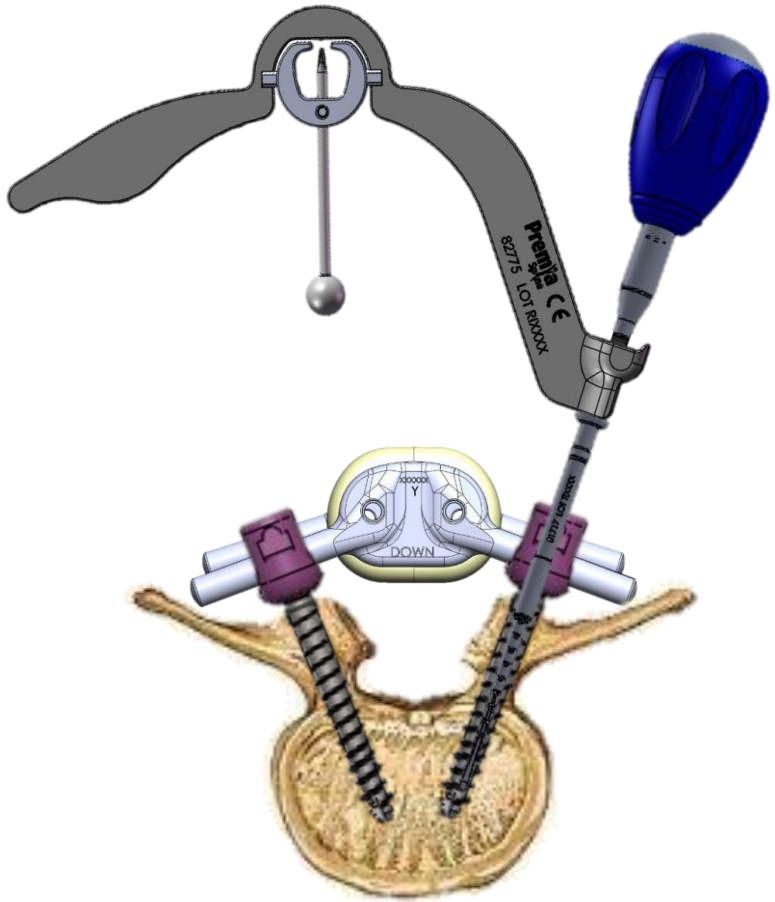
Interpedicular (left and right) symmetry is important to fit TOPS implant as well



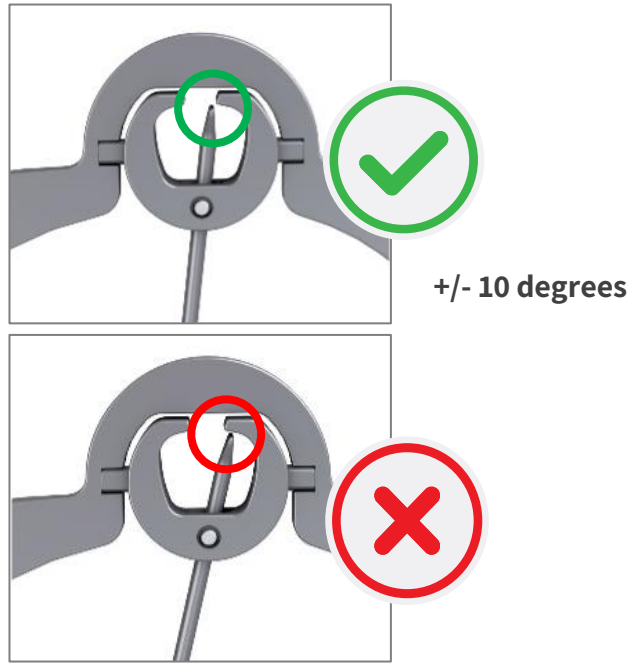
Ensure at least a 6mm interpedicular gap (e.g., L4 to L5) between the tulips with Superior Alignment Gauge Arm

2. Screw trajectory with the Pendulum

The pendulum attaches to all pedicle preparation and screw insertion instruments



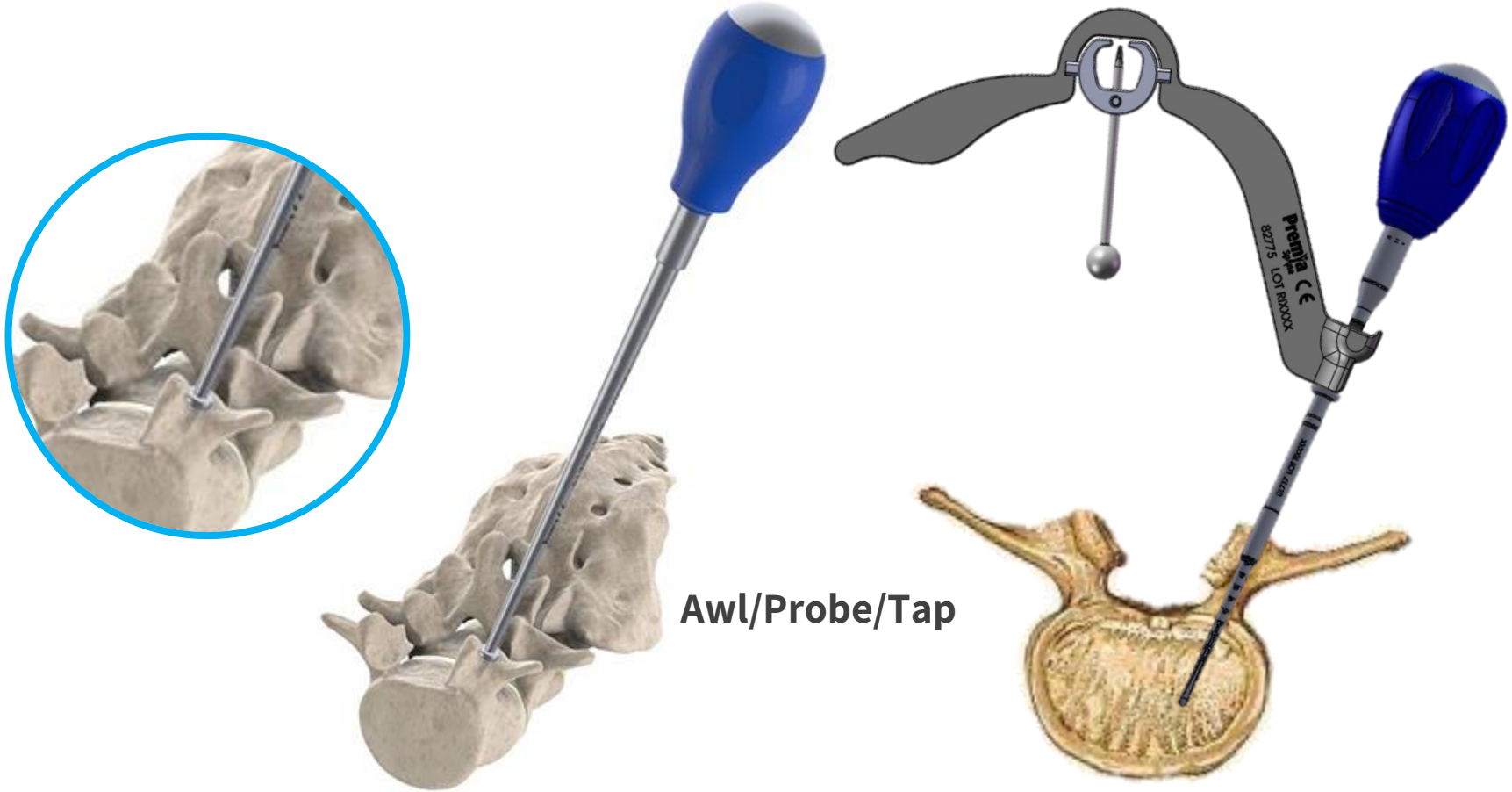
Correct trajectory is confirmed when the needle **is between the two notches** of the pendulum



If outside of the notches, the screw must be repositioned

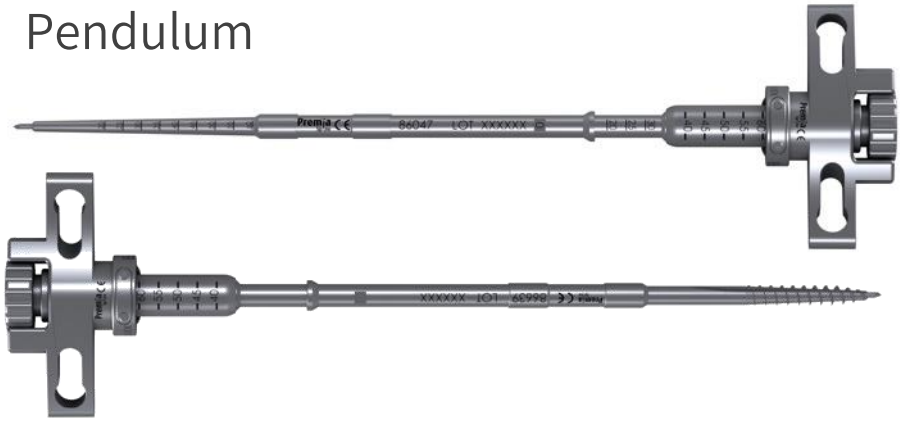
2. Screw hole preparation instruments

Traditional open approach with an Awl + Probe +/- Tap is performed with the Pendulum



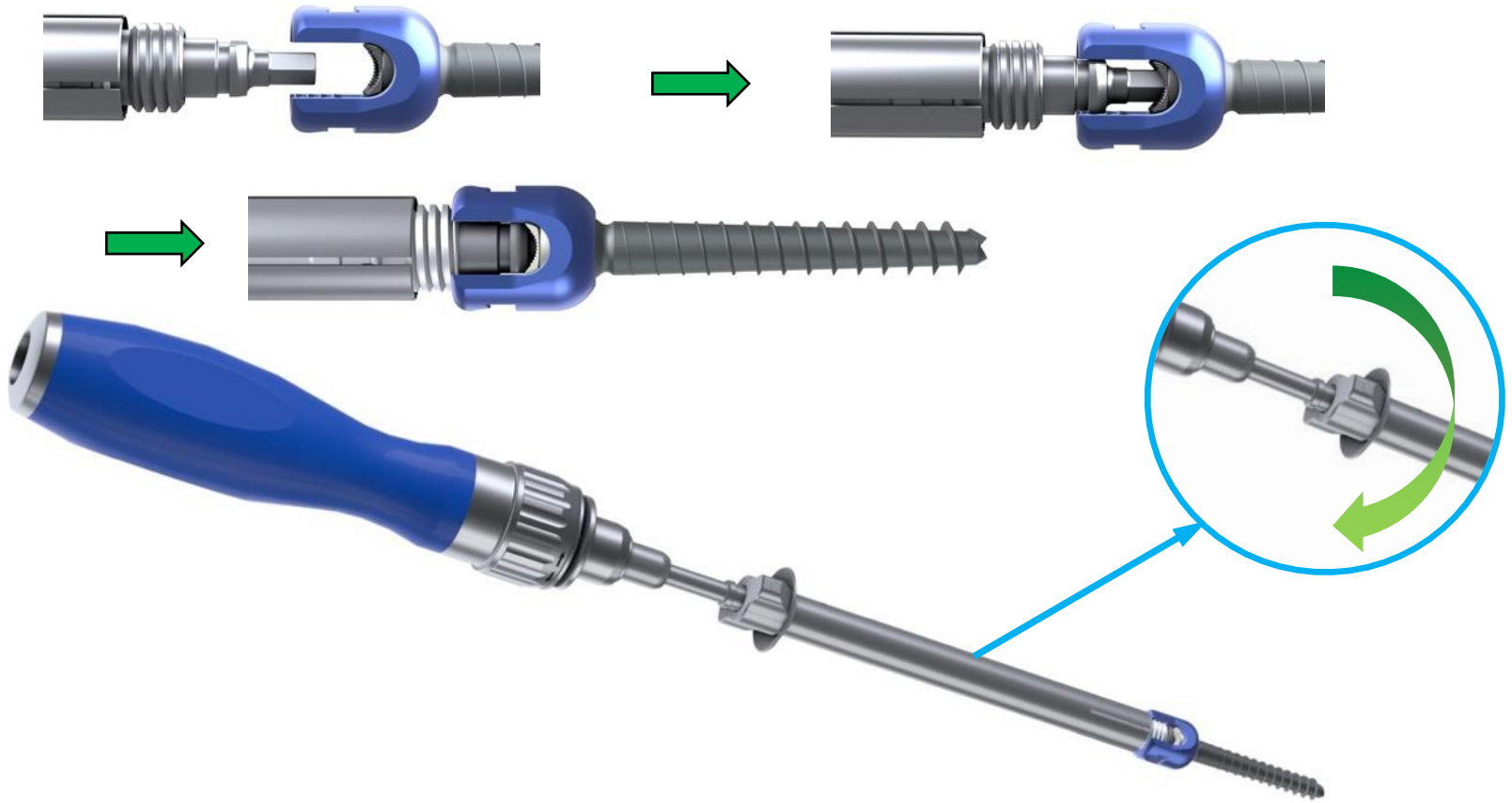
2. Screw hole preparation instruments

Alternative approach with a k-wire and **Jamshidi or Tapshidi** with the Pendulum



2. Screw connection to driver

Hexagonal driver bit fits into the base of the screw tulip. Slide the sleeve down and lock the screwdriver flywheel



2. Key tips for screw placement

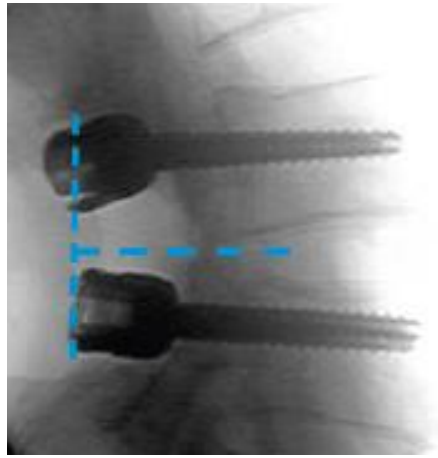
Lock the C-arm in a fixed position for the entire screw placement process:

Begin with the superior vertebra, inserting the first screw (e.g., L4 left) parallel to the endplate without violating the superior facet capsule

When inserting the second screw in the same vertebra (e.g., L4 right), make sure that the screw tulips are superimposed on a lateral view

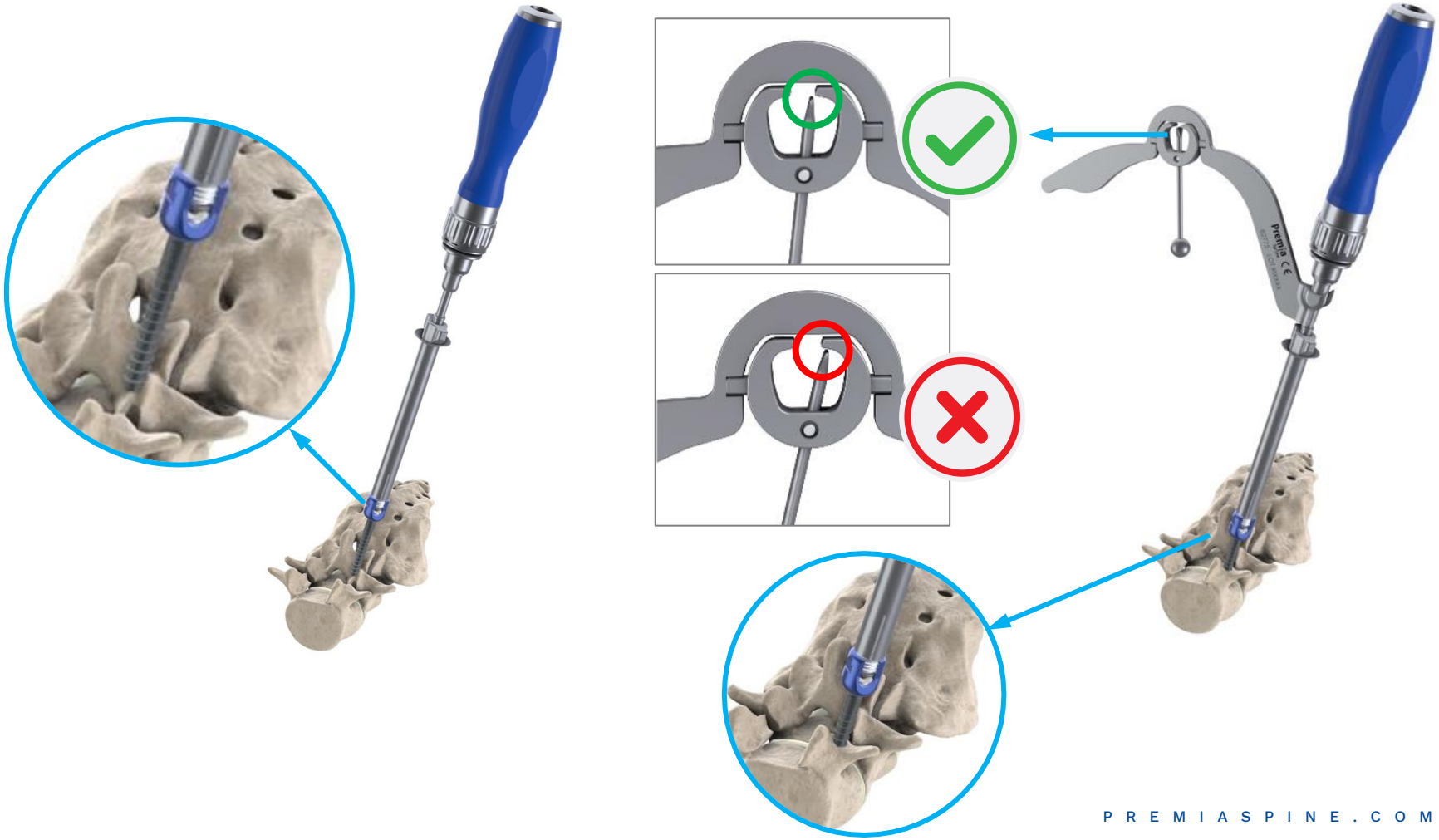
Then perform the same technique for the inferior screws (e.g., L5 left and L5 right)

Confirm that the heads of all four screws have the same dorsal height



2. Screw placement

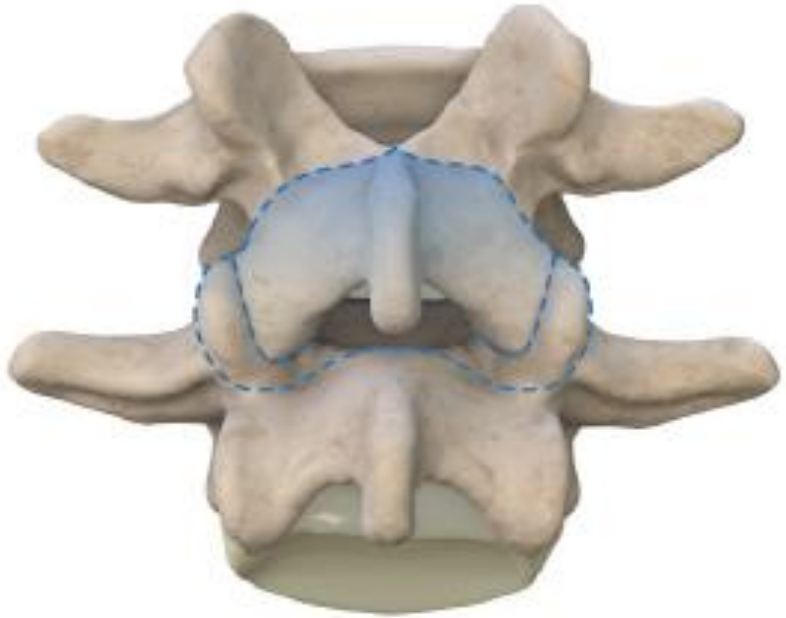
Pendulum confirms correct screw trajectory when placing the pedicle screws



3. Decompression

Spondy + Stenosis patients benefit from a wide decompression

Resect the spinous process, the lamina including the Pars, and the medial+lateral facet joints for a “pedicle-to-pedicle” decompression



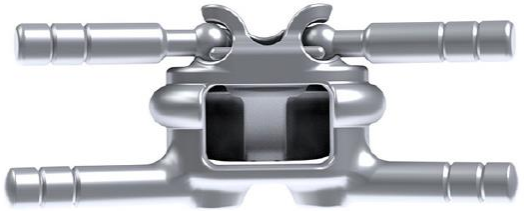
Confirm that the nerve roots are free

Smooth any sharp bony edges

The goal is to remove all possible present and future pain generators

3. Decompression Confirmation

The Inferior Alignment Gauge serves as a decompression template. It has the same size and ventral form of the actual TOPS Motion Implant



Place the Inferior Alignment Gauge in the inferior pedicle screws

If the Inferior Alignment Gauge does not drop easily into the tulips, expand the decompression

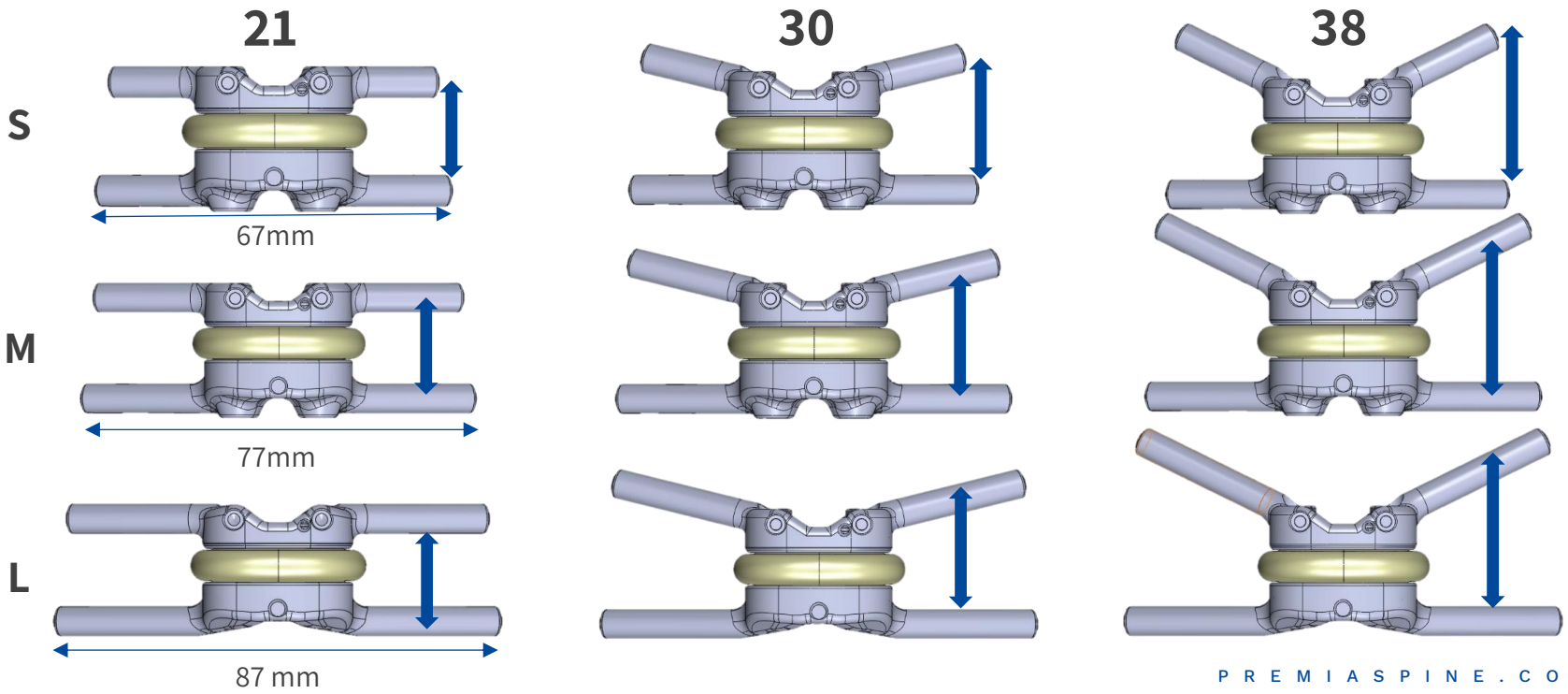
4. Alignment instrument

The Alignment Gauge also determines the correct TOPS Motion Implant size and ensures that the 4 pedicle screws are on the same plane with the same dorsal height

4. TOPS™ System Sizes

The Alignment Gauge covers all patient anatomies and TOPS sizes. Choose the Medium or Long Inferior Alignment Gauge based on the distance between the pedicle screws on inferior vertebral body (e.g., L5)

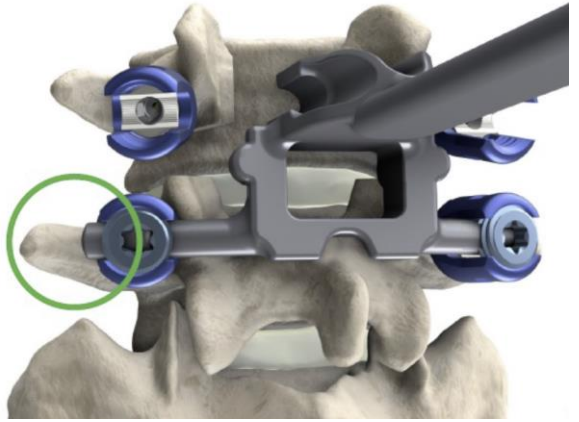
Device	Size / Configuration	Length
TOPS Motion Implant	21 (IPD)	L/M/S
	30 (IPD)	L/M/S
	38 (IPD)	L/M/S



4 Alignment: Step 1

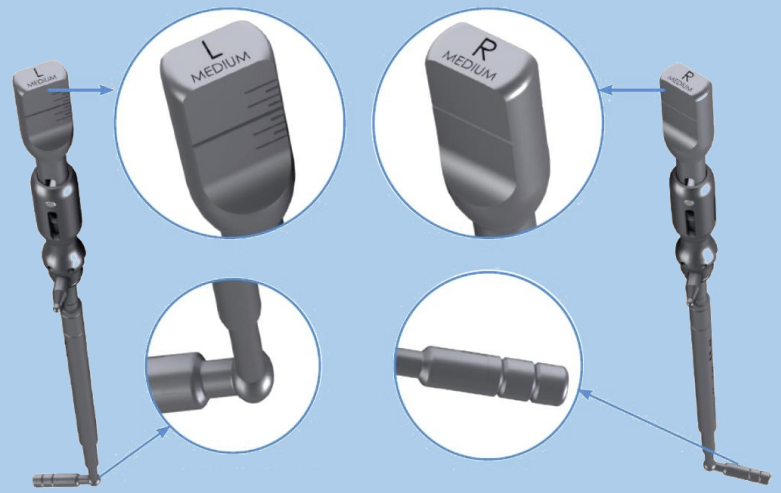
Insert the Inferior Alignment Gauge in the inferior screws (e.g., L5) and tighten set screws loosely. Adjust the Gauge so that it sits directly in the midline relative to the spinous process above, and is parallel to the disc. **Tighten the set screws**

Confirm that there is overhang of the arms beyond the tulips. If not, exchange for a Long Gauge. If the Gauge leans to one side, advance the prouder screw to ensure that the Gauge is vertical. **Then re-tighten the set screws**



4. Alignment: Step 2

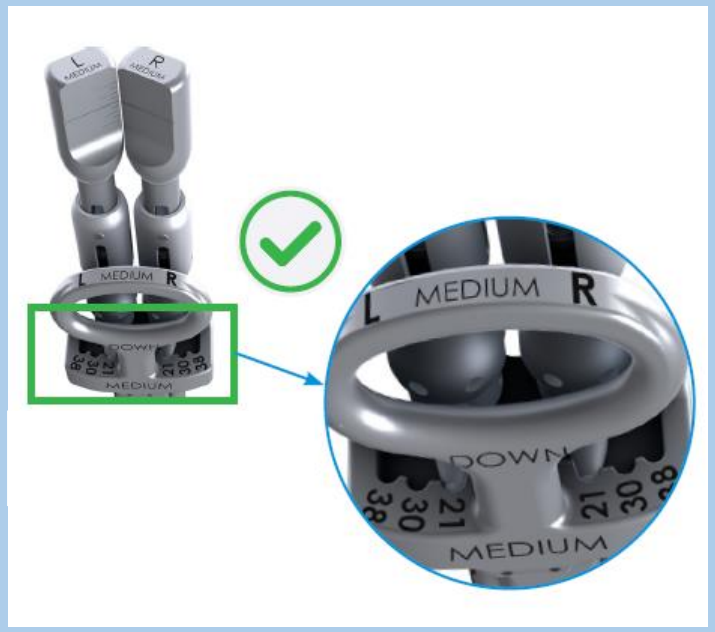
Introduce the Left and Right Superior Alignment Gauge Arms (marked “R” and “L”) into the Inferior Alignment Gauge



Place the ball heel into the base of the slot while aiming its front toe into the tulip. **Lock down the set screw.** Confirm that the Arms are snugly adjoined to the Inferior Alignment Gauge post

4. Alignment: Step 3

Slide the Arm collar down into the most natural of the 3 groove slots



The grooves should indicate the same size on both sides: 21, 30 or 38

If the sizes are different, lift one of the Arm sleeves and leave the other in place. Rotate the Alignment Gauge caudal and cranial to see if the indicator drops into the same size slot as the contralateral side. If not, try the same technique with the opposite Arm. If the sizes cannot match, reposition one of the superior pedicle screws.

When complete, tighten two superior set screws to the Arms

4. Alignment: Step 4

Screw dorsal height:

If the Arms do not show one continuous line, the dorsal height of the screws is wrong. A screw height adjustment must be made

Tip: it is best to advance the prouder superior screw due to the conical design of screws

Note the required adjustment (e.g., a full turn or a half turn). Then remove the set screw and the Arm of the prouder screw

Use the blue-handle screw driver with a line on its cap to guide screw insertion:

Long line = 1 full turn

Short line = ½ turn

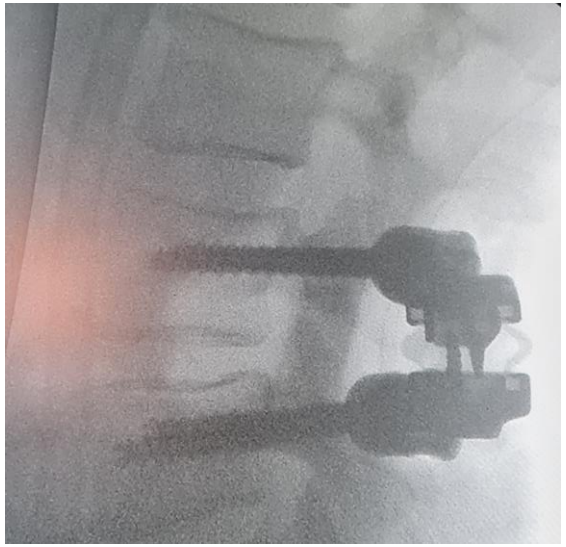
Reposition the Arm. Lock the set screw and confirm one continuous line

4. Alignment: Step 5

Final checks before removing Alignment Gauge

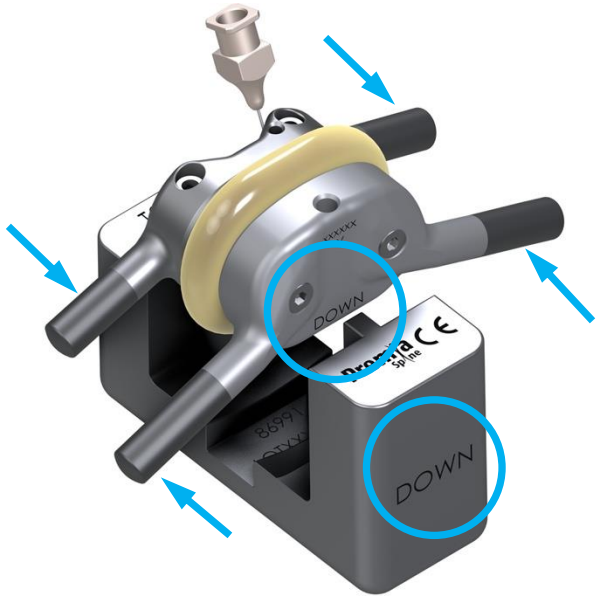
Check for 3mm clearance between the TOPS superior plate and spinous process above. Remove some of the superior spinous process if necessary for sufficient clearance on extension.

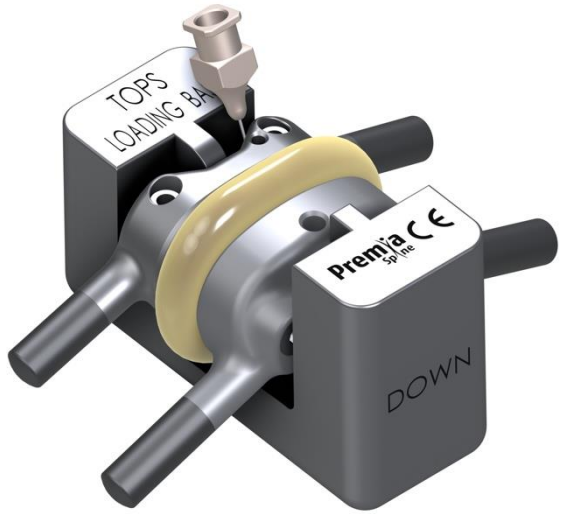
Confirm that the Gauge is not leaning caudal/cranial. If the Gauge leans too caudal/cranial, adjust the height of either the inferior or superior pair of screws to correct. If the Gauge is not parallel to the disc, or is leaning to one side, return to Step 1. Proper Gauge alignment facilitates TOPS Motion implant insertion and function



5. Implant preparation

Remove TOPS from its sterile packaging. Slightly compress the TOPS arms and push into the Loading Base





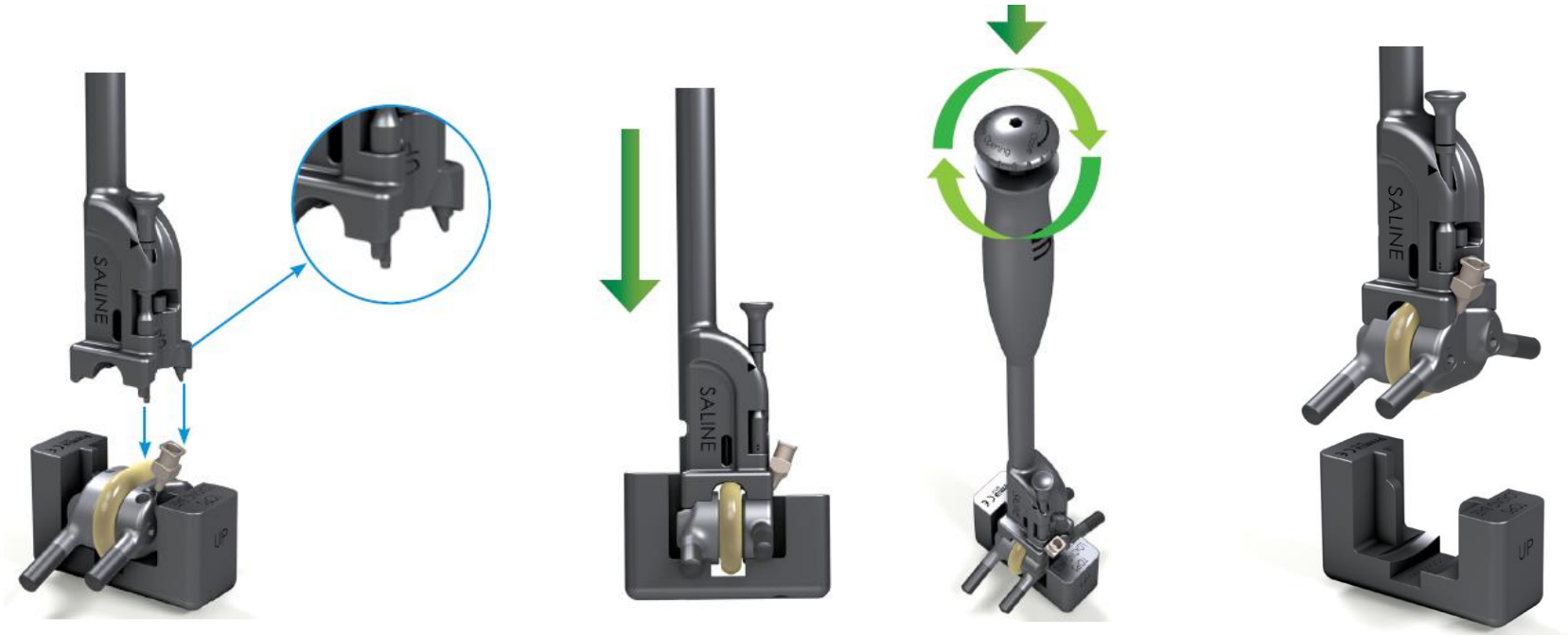
Keep pressing down until the TOPS™ Motion implant is seat at the Base's bottom

The TOPS™ is delivered sterile with a preassembled needle.
The needle should only be removed after filling of the device

5. Implant preparation

Attach the TOPS Inserter's two superior pins into the two holes in the TOPS implant superior endplate. Turn clockwise several times to lock the upper knob on the Inserter. **Tip:** Make it tight.

Remove the Inserter with the TOPS Motion implant from the Loading Base



5. Implant preparation

Attach a syringe with 1.7ml sterile 0.9% saline to the TOPS luer

Rotate the Inserter to its side so that the word “SALINE” faces upward and the needle is at the highest position on the TOPS Motion implant

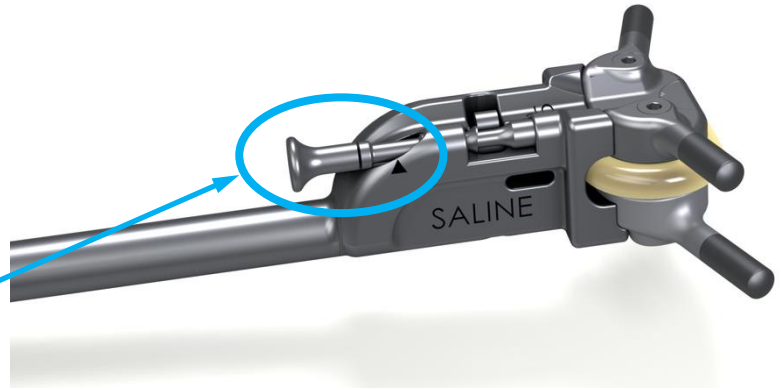
Slowly fill the TOPS Motion implant with saline such that the water line reaches the black line

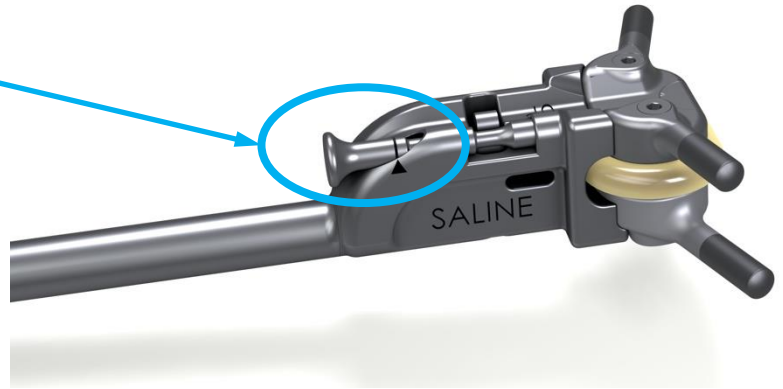
Do not bend the needle as it may break. As a substitute, a 25G x 5/8'' needle can be used

5. Implant preparation

After filling, remove the needle

Seal the TOPS™ by pushing the plunger forward.

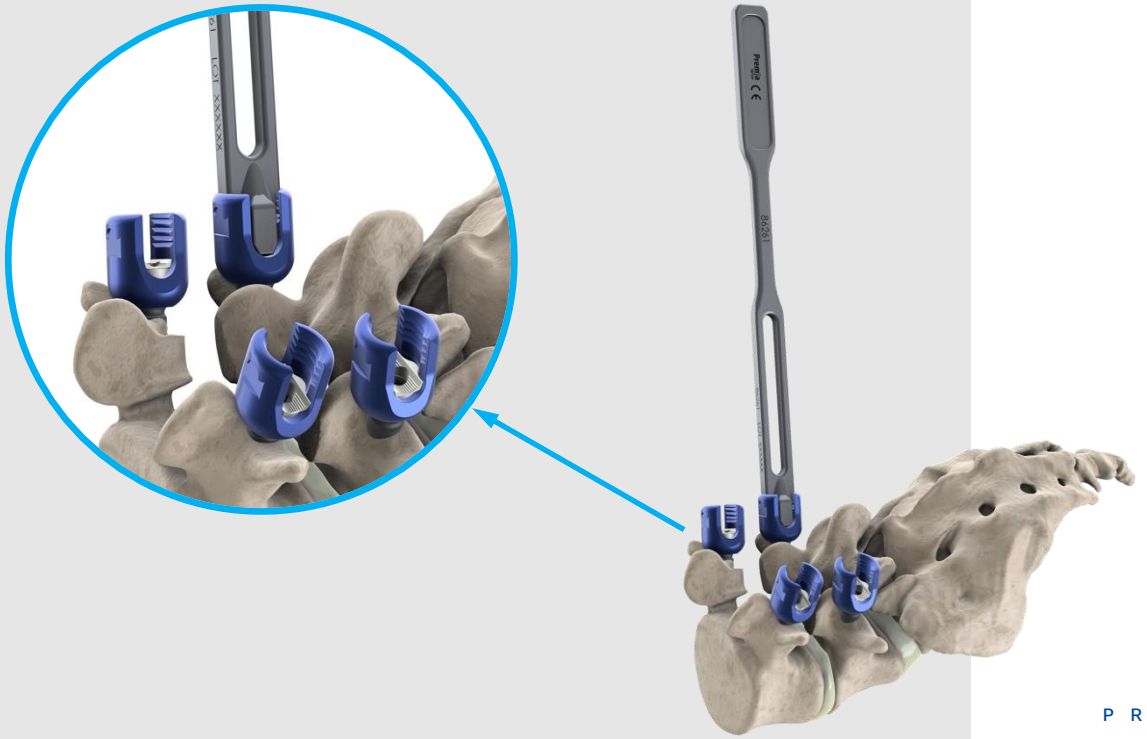




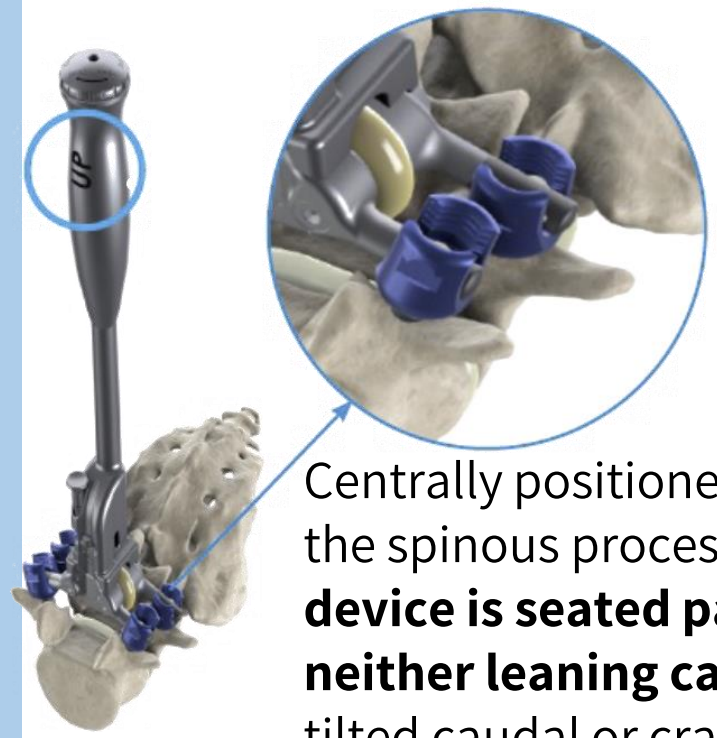
5. TOPS implantation

Use the Head Releaser to unlock the polyaxiality of the pedicle screw

Make final preparations for device insertion per hospital practice (e.g., examine the dura carefully to ensure that there is no evidence of leaks, perform a vancomycin wash, etc.)



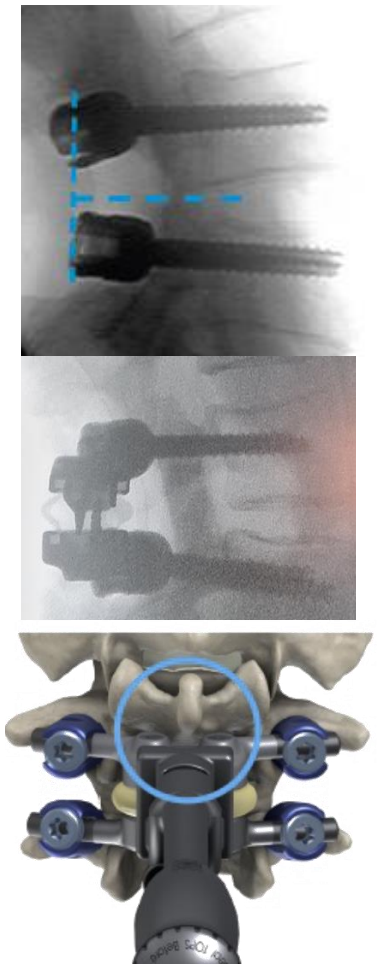
5. TOPS Implantation



Seat the TOPS Motion implant arms into the 4 pedicle screws and lock the 4 set screws loosely. **Tip:** The counter torque can be used as a guide for the set screws.

Centrally positioned the TOPS Motion implant to the spinous process above. **Confirm that the device is seated parallel to the disc and is neither leaning caudal or cranial.** If Inserter is tilted caudal or cranial, adjust the height of the superior or inferior pair of screws to have the TOPS device parallel to disc.

Be sure that the TOPS Motion implant is not leaning to one side. If there is an issue, correct by returning to the Alignment Gauge steps. Proper alignment facilitates TOPS Motion implant function. Check for sufficient clearance between the TOPS superior plate and the spinous process above. **Then hand tighten the set screws.**



5. Final tightening

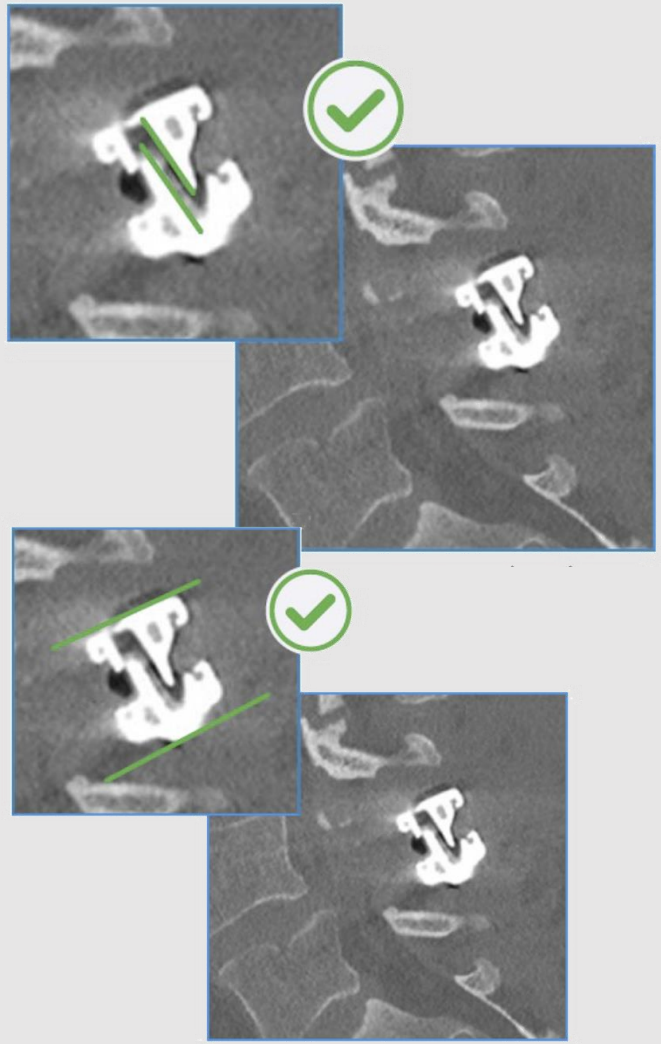
Use the torque limiter with the counter torque for final tightening to 13 Nm

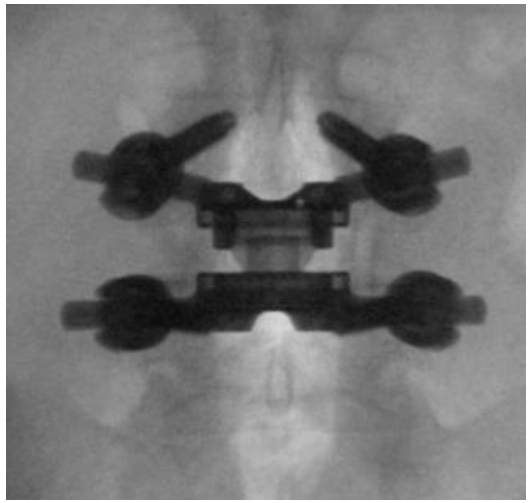
The screw orientation should not be changed while tightening the screws

Remove the inserter **only after performing the final torque**

5. Final check

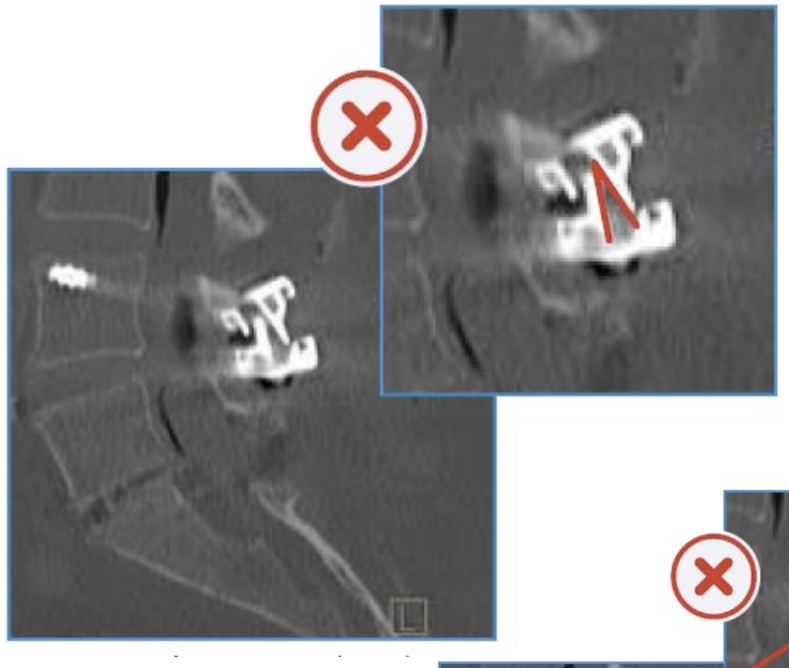
Take AP and lateral images for final verification of proper implant positioning

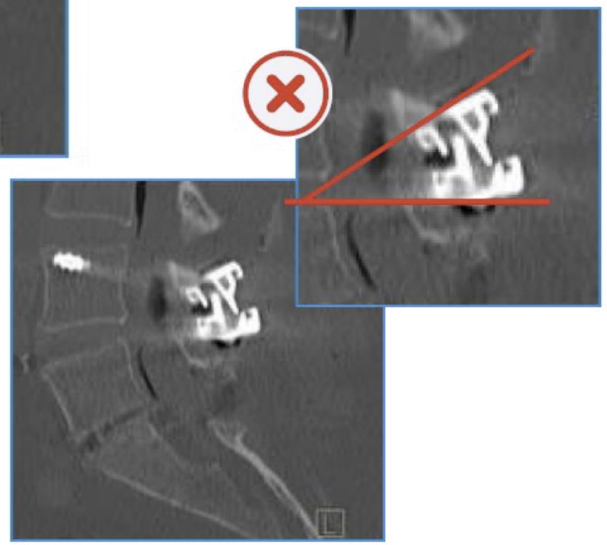


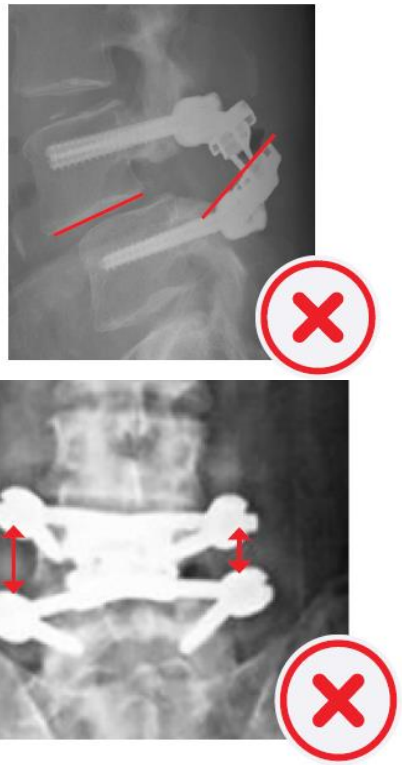


5. Final check

Failure to follow the surgical technique can lead to device malalignment and mispositioning







5. Wound closure

- Place a drain and remove it on postop day 2 or 3

Key Tips for Success

- Place the patient on table in neutral position—not in lordosis
- Hold the C-arm in a fixed lateral position throughout the insertion process
- When inserting the screws, ensure sufficient interpedicular space
- Start with superior screws and place them parallel to the end plate without violating the facet capsule
- Use a 5mm longer screw at the superior level to ensure correct final screw dorsal height
- Make sure the Inferior Alignment Gauge is not leaning to the side
- Make sure that the Alignment Gauge is parallel to the disc and not titling forward/backward
- Ensure that the implant is seated all the way down in the loading base
- Make sure that there is sufficient clearance between the TOPS and the spinous process above
- Make sure there is overhang of the TOPS arms beyond the pedicle screw tulips
- Release the TOPS Inserter only AFTER final tightening to 13Nm

CL-3867-US Rev.03

Labeling References

For complete Operative Technique see
- TOPS System Surgical Technique
- XL Instruments Surgical Technique

For complete Indications, Contraindications, Warnings and Precautions see
- TOPS System Instructions for Use
- Pedicle Screw Instructions for Use

For further instructions and information on the TOPS™System instrumentation set (including information about storage and shelf life) see
- TOPS System Instrumentation Set Instructions for Use
- XL Instrumentation Set Instructions for Use

CL-3867-US Rev.03

Thanks for your attention

Contact: info@premiaspine.com with questions