TOPS™ System Surgical Technique

Introduction

The TOPS™ System is a unitary device comprised of a titanium construct with an interlocking polycarbonate urethane (PcU) articulating core. The design allows relative movement between the titanium plates so as to create axial rotation, lateral bending, extension, and flexion. The implant is designed to allow near normal range of motion while also blocking excessive posterior and anterior sagittal translation.

The TOPS™ System uses polyaxial head pedicle screws (fig. 1) for fixation to the vertebrae (fig. 2).

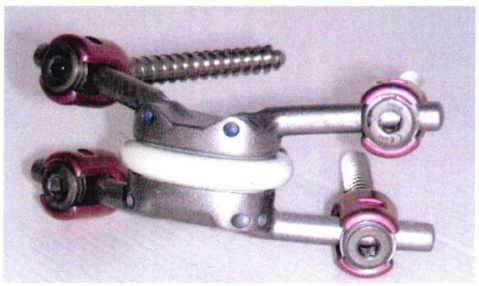


Figure 1

Figure 2

The TOPS™ system for mobile stabilization is implanted via a posterior surgical approach to replace the skeletal elements, such as the lamina and facet joints, which may be removed to achieve the desired decompression. As an alternative to fusion, the TOPS™ enables near normal motion preservation and addresses the inherent disadvantages of rigid instrumentation and fusion. By using the TOPS™ mobile posterior device, the surgeon can replace pathological bony elements with posterior elements replacement technology which preserves spinal biomechanics, while enabling motion at the treated segment.

Indications:

The TOPSTM System Family is indicated for adult patients with lower back and leg pain with, or without spinal claudication, that results from moderate or severe lumbar spinal stenosis at one vertebral level between L3 and L5. Patients may also have, in addition to lumbar spinal stenosis, degenerative spondylolisthesis (up to grade I) and/or facet arthrosis. The TOPS™ System is indicated for patients between 40 and 75 years of age.
Refer to the TOPS™ System and Instrumentation Set Instructions for Use (Doc. No. 2464-CL-RS or 2480-CL-SP-OUS and 2446-CL-RI) for a complete listing of precautions, warnings and patient selection criteria.

TOPS System Instrumentation Set Container Trays:
The Instrumentation Set is provided non-sterile and should be cleaned and sterilized prior to first use and following each use per the TOPS System Instrumentation Instructions for Use (Doc No. 2446-CL) which includes a list and description of each instrument along with proper reprocessing instruction.

Surgical Technique:

1. General:

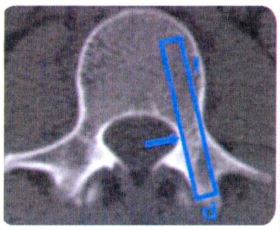
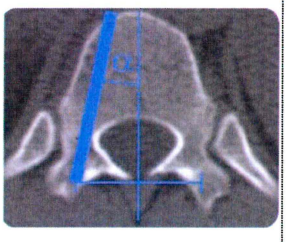
The TOPS™ System is to be ***used only*** with pedicle screws supplied by Premia Spine. Do not use any TOPS™ **System with components of any other manufacturer's system.**

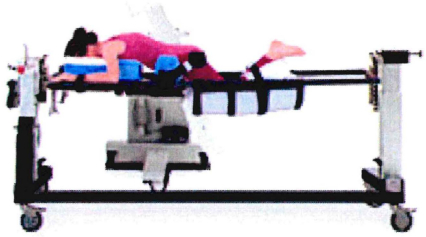
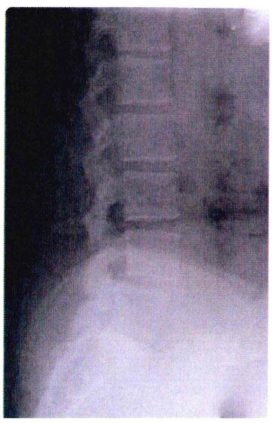
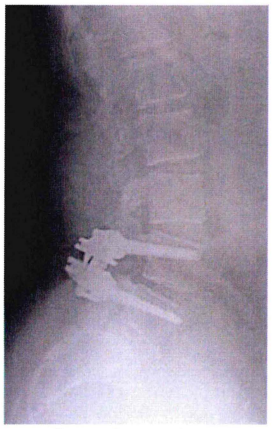
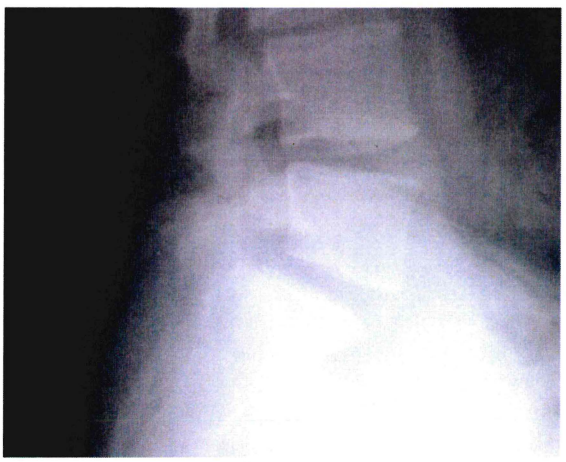
Correct selection of the appropriate size of the TOPS™ and Pedicle Screws is extremely important to assure the correct function of the device and correct sizing and placement of the device is essential to optimal performance.

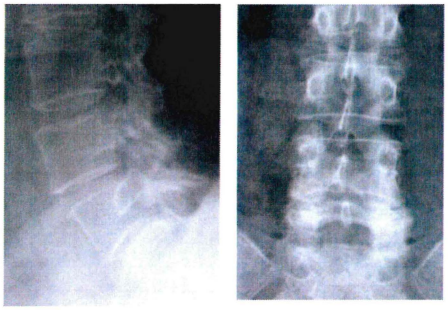
Notes:

- All alternatives to non-operative and operative treatment must be considered prior to pursuing surgery.
- The surgeon must verify the level of the diseased vertebrae that will be operated on.
- The patient must be mentally capable of not only realizing the significance of the precautions but also following them.
- The patient must consent to the operation after being fully informed of the associated risks.

2. Preoperative Planning

2-1	Preoperative planning using x-ray guidance (plain films or CT Scan) may assist in the determination of pedicle screw length. The diameter of the screw should be based on the inner mediolateral pedicle diameter at its isthmus. The length should be measured from the pedicle screw entry point (see section 6.1) to the anterior edge of the vertebrae. ***NOTE:*** magnification markers must be used during x-ray evaluation to accurately calculate the necessary screw sizes.		

2-2 Patient positioning	Positioning of the patient must be prone on a radiolucent table suitable for AP and lateral C-arm fluoroscopy, which will be performed during the course of surgery. ***Note:*** It is important to position the patient on the table in such a way that approximates the patient's pre-operative neutral standing position as closely as possible using standard positioning techniques.	
2-3	***Caution:*** A significant mismatch between the patient's neutral standing lordosis and the lordosis on the O.R. table may result in device misalignment.	 Pre-op  6-weeks post-op
2-4	***Caution:*** It is important to note that the TOPS™ device is not intended to be a spondylolisthesis reduction device and reduction resulting from positioning should be minimized.	 Grade 1 Spondylolisthesis

2-5	Preoperative biplanar fluoroscopic confirmation of the spinal alignment and the location of the target level incision are obtained.	

3. *Surgical Exposure*

The surgical exposure for implantation of the TOPS™ System is a posterior approach with a vertical midline incision of approximately 10-14 cm. In general, the TOPS™ surgical procedure will require an exposure identical to what is required for a standard posterior lateral decompression and fusion. This type of decompression will provide the surgeon complete visualization of the facet joints and medial aspects of the transverse processes on both the superior and inferior operative vertebrae. The TOPS™ System includes a template which indicates the required amount of bony resection needed to accommodate the device. Once achieved, the surgeon can proceed with pedicle screw insertion and attachment of the TOPS™ device to the pedicle screws. Each of these steps is described in detail below.

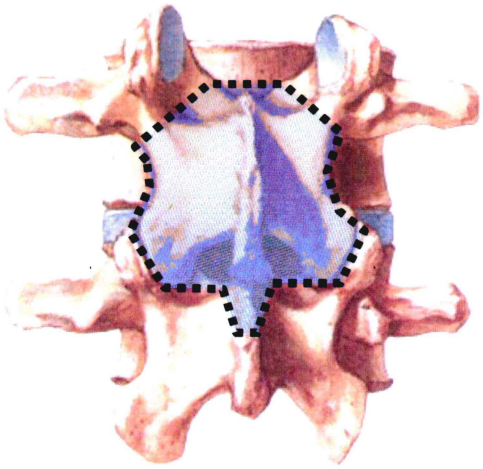
4. Muscle Dissection and Retraction

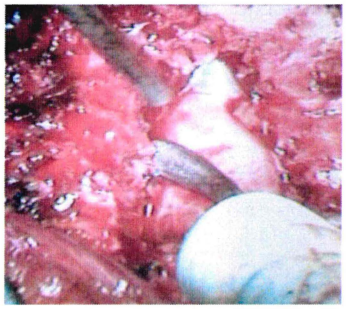
As in all surgical procedures, damage to surrounding soft tissues should be minimized. Standard monopolar and bipolar cautery should be used to control bleeding during muscle and soft tissue dissection.

5. Bone Dissection

To implant the TOPS™ System the surgeon should use a standard posterior midline dissection exposing facets, pars interarticularis and transverse processes. Surgical exposure is obtained using a self-retaining retractor system. Decompression is then carried out by resection of the laminae, spinous process, and medial facets (inferior facets from the level above).

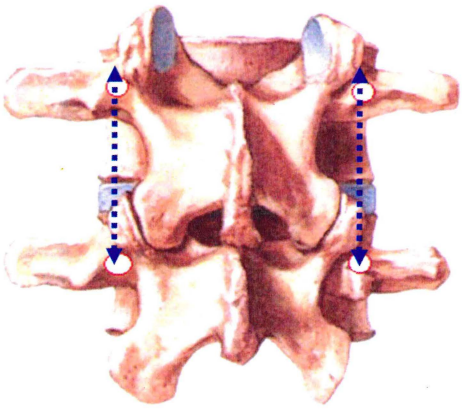
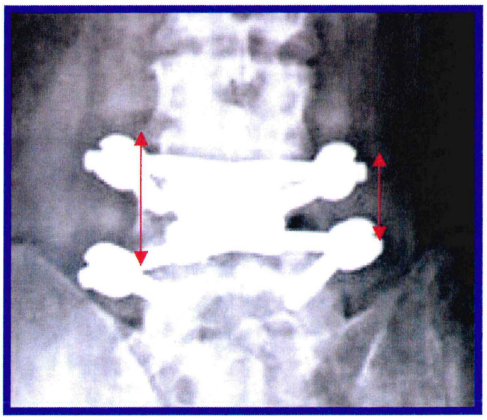
Note: If preferred, the surgeon may elect to place the pedicle screws prior to performing the decompression. If this is the case, please proceed to section 6.1 first.

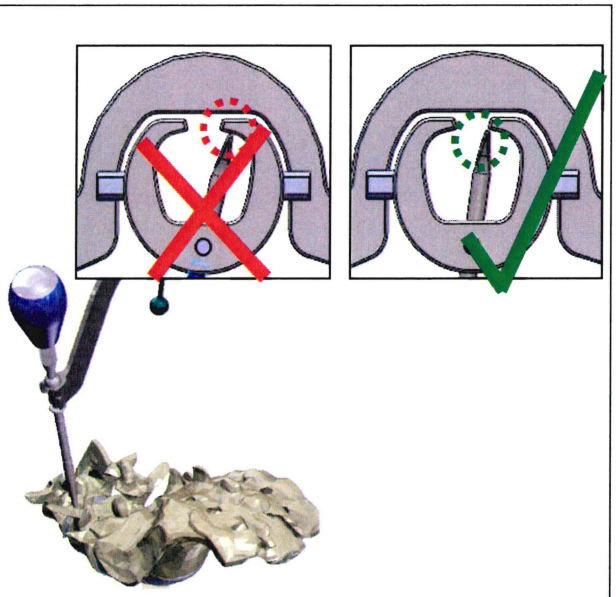
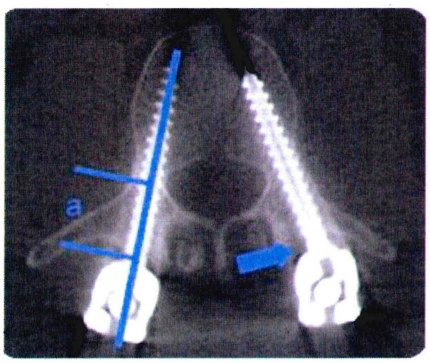
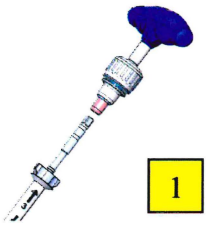
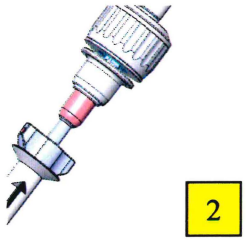
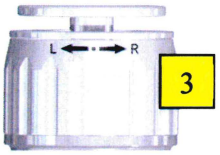
5-1	The Alignment Gauge handle / Decompression template is placed between the decompressed vertebrae to guide the degree of decompression required for subsequent TOPS™ device implantation. Confirmation of appropriate Cephalad / caudal bony resection can be visualized by aligning the decompression template crossbar with the pedicles on the inferior level.	 **Decompression Template**
5-2 Decompression	The breadth of decompression is to optimally resolve the moderate to severe stenosis. Ideal bony resection should extend through the lateral margin of the pars interarticularis and complete excision of the Inferior Articular Process of the superior vertebrae should be performed. Standard spine surgery tools including kerrison leksell ronguers, osteotomes, chisels, high speed burrs and curettes can be utilized based on the discretion and preference of the surgeon.	

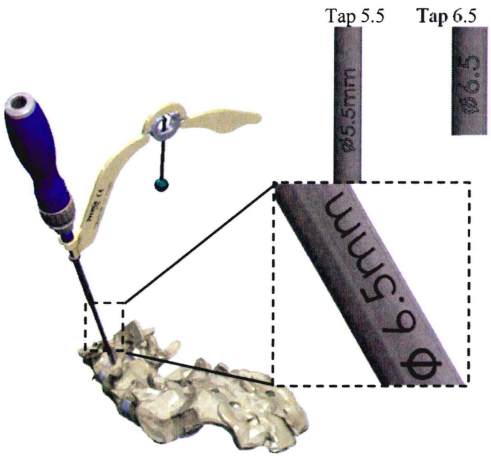
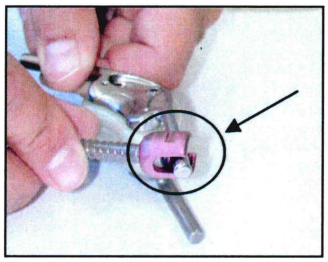
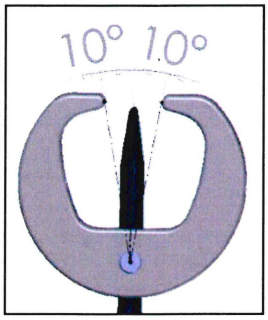
5-3	Following bony resection, adequate neural decompression is confirmed using standard surgical techniques with a Woodson elevator bilaterally over the thecal sac and exiting and traversing nerve roots.	

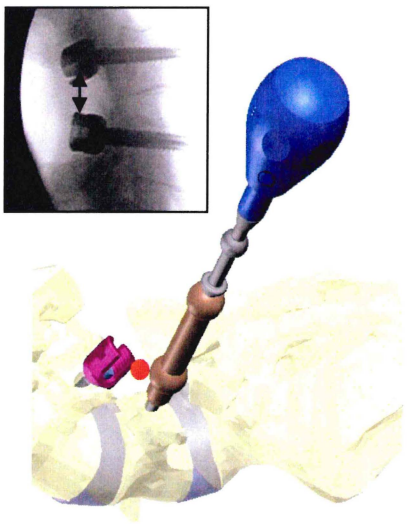
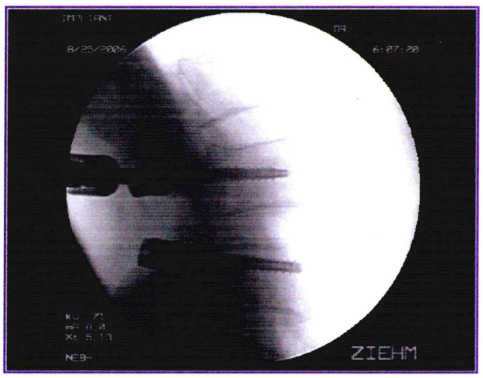
6. Pedicle Screw Insertion

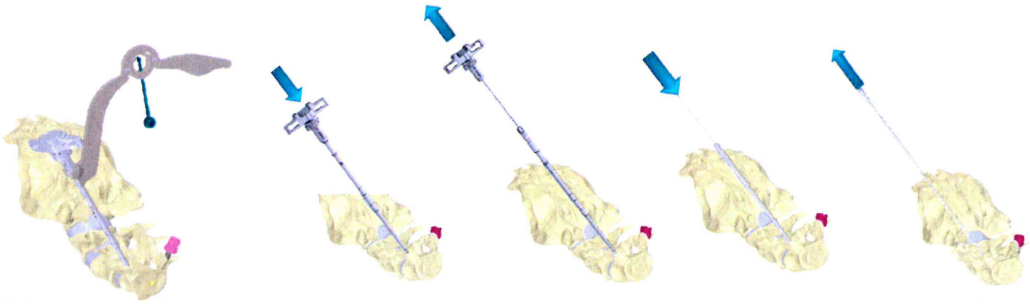
The TOPS™ System is to be used only with pedicle screws supplied by Premia Spine. Do not use any TOPS™ System with components of any other manufacturer's system.
Correct sizing and placement of the device is essential for optimal performance.

6-1	To properly meet the crossbar geometry of the TOPS™ System, it is important that the distance between the pedicle screws is approximately equal on the left and right sides.	
6-2	***Note:*** If a significant mismatch in the distance between the pedicle screws exists, the device will be asymmetrically loaded as illustrated in this image.	

6-3	Prepare the pedicle channel for the superior screw by carefully advancing the Probe until the tip is approximately 75% into the vertebral body. Use the Probe under pendulum guidance to ensure that subsequent pedicle screw insertion is performed at the proper medial-lateral angle so that the TOPS™ arms will sit properly in the pedicle screw head saddle. **IMPORTANT**: The goal is to have the Pendulum Marker within the ± 10° zone in the instrument during screw advancement to ensure proper medial/lateral pedicle screw alignment.	
6-4	Once the pedicle channel is prepared to the desired depth, the surgeon should use the supplied Streamer if necessary to ream the pedicle isthmus in preparation for the pedicle screw.	
6-5	Prior to pedicle screw insertion, the surgeon should verify the integrity of the pedicle and confirm the exact depth using the combined Depth Gauge & Feeler.	
6-6	The largest diameter screw that can be accepted by the anatomy of the pedicle should be used to maximize the pull-out strength of the screw. Select screw lengths that will extend 2-3 mm above the vertebral process to allow for proper attachment of the TOPS™ device. **CAUTION:** If the screw length selected is too short, this may lead to inadequate screw purchase and subsequent screw loosening.	
	Instruction for attaching Premia Spine 1/4" fitting handles. Premia Spine supplies a Ratchet handle and T shape ratchet handle, Both of which can be attached to either of the instruments below: • Tap Φ 5.5 for Pendulum Adaptor • Tap Φ 6.5 for Pendulum Adaptor • Cannulated Screwdriver • Torque Limiter To mount the handle simply pull d the locking ring upward and slide the shaft into the hole in the distal side of the handle [1]. Verify proper attachment by slightly pulling the shaft to the opposite direction [2] Adjust the ratchet direction by twisting the ring clockwise or counterclockwise [3].	  

6-7	***Note:*** **Premia Spine pedicle screws are self-tapping and self-drilling. The decision whether to use a Tap to facilitate subsequent pedicle screw placement in cases of dense, sclerotic, or brittle bone is left to surgeon discretion.** Choose a Tap at least 1mm smaller in diameter than the pedicle screw chosen to be implanted and attach it to the ratchet or Straight handle. Tap Φ 5.5 for Pendulum Adaptor Tap Φ 6.5 for Pendulum Adaptor The diameter of the Tap is clearly marked on the shaft.	
6-8	Place the selected pedicle screw on the Screwdriver. First insert the hexagonal bit of the screwdriver all the way into the pedicle screw socket. Then hold the pedicle screw head firmly while rotating the sleeve clockwise to lock the pedicle screw in place. Visually verify that the hexagonal bit is properly placed in the socket. To ensure accurate measurement of the angle and to secure the pendulum from detachment, hold the probe pendulum at its rear end with two fingers and slightly push it downwards. Insert the superior pedicle screw under lateral fluoroscopic guidance to ensure proper placement. This step should be repeated for the remaining three pedicle screws. **Recommendation:** pedicle screw dorsal alignment will be performed later in the procedure. The Alignment gauge is designed to enable convenient adjustment of the superior screws, therefore it is recommended to leave those screws a bit proud (~ 5 mm) to allow future adjustments.	
6-9	If for any reason the pendulum marker exceeds the range of the instrument (± 10°), try to redirect the screw or abort TOPS™ implantation and convert to fusion. **CAUTION:** If the pedicle screw insertion angle exceeds the range of the polyaxial head (± 10°), the TOPS™ arm will not sit properly in the bottom of the pedicle screw head saddle. See figure on the right.	 

6-10	Place the inferior screw using the same technique. To ensure minimum distance of 6 mm between superior and inferior screw heads, mount the ball sleeve over the Ball Probe and advance the Ball Probe into the pedicle (as fully described in section 6.3). The 6mm gap is verified by inserting a 6mm alignment gauge crossbar between the superior screw head and the ball sleeve. If the rod fits between the screw and the ball sleeve continue with screw placement, if not, choose a lower entry point or redirect the Ball Probe to a more caudal trajectory. ***Note:*** Bi-planar fluoroscopy should be used throughout the screw insertion process to verify proper screw trajectory and positioning.	
6-11	To place the two contralateral screws, first ensure a true lateral fluoroscopic image is created to avoid errors due to parallax. Then care should be taken to superimpose the two screws with the previously placed screws as shown in the image on the right. The screws should be advanced until the screw heights are synchronized with the ipsilateral screws to avoid the need for gross adjustments later in the procedure.	
6-12 K-Wire guided screw placement	**Alternate screw insertion technique for surgeons who are familiar with the Jamshidi needle technique:** After the skin incision is performed at the appropriate entry point, the Integral K-wire Handle is connected to a reusable cannulated pedicle probe. The K-wire should protrude 2-3mm from the tip of the pedicle probe.	
6-13 K-Wire guided screw placement	Introduce the pedicle probe into the bone by manual manipulation or by using a mallet. A/P and lateral fluoroscopy control should be used to confirm correct positioning. Use the pendulum to verify proper medial lateral trajectory Disconnect the Integral K–wire handle from the cannulated pedicle probe and replace it with a 470mm K-wire. Remove the pedicle probe leaving the K-wire in place.	

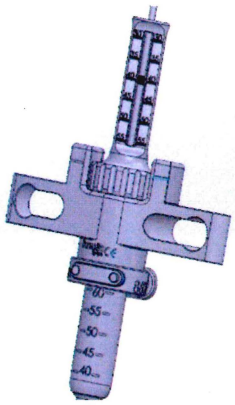


Additional way to determine the proper screw length (using the Awl-Shidi technique - optional)

- Assemble the pedicle awl shaft to the integrated k- wire handle (Awl-shidi)
- Introduce the Pedicle Awl into the bone by manual manipulation or by using a mallet until reaching a hard stop (the awl's hard stop shaft is reaching the pedicle - the entire tip is inserted)

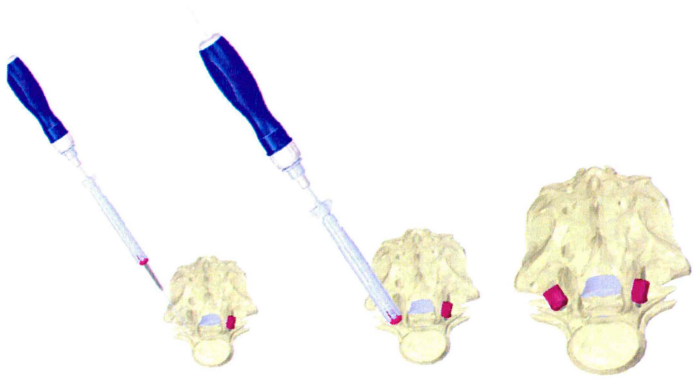
- Remove the knob from the silver handle.
- Connect the Integrated Depth Gauge Knob to the silver Handle (thread connection).

- Insert the Marked K-Wire 470mm through the Gauge and along the Cannulated Pedicle Awl.
- Start advancing the Marked K-Wire and use lateral imaging to decide the desired depth of the K-Wire
- Use the scaling on the Gauge to determine the length of the Pedicle Screw.



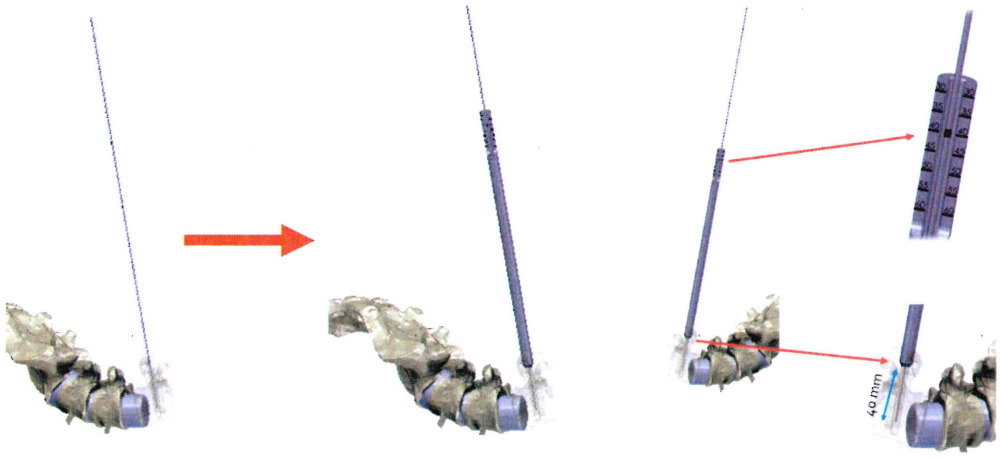
- Remove the Pedicle Awl from the bone and insert the chosen Pedicle Screw over the marked K- Wire

Connect the screw to the screwdriver (Refer to section 6-8 for detailed instructions) Verify a secure connection with the locking sleeve. Introduce the pedicle screw over the k-wire and advance it into the bone. The screw is advanced by turning the Straight or T-handle shaped retched handle. To unlock the screwdriver from the screw, turn the locking sleeve counterclockwise.
Note: 1 full turn of the screw (360°) is equivalent to a 3 mm axial adjustment.

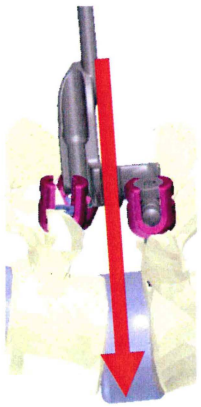
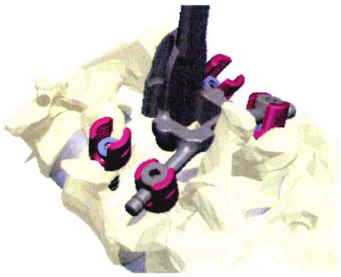
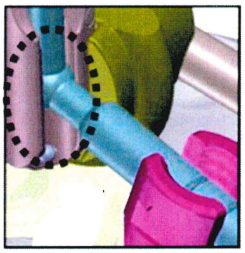
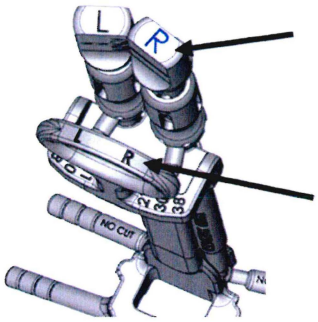


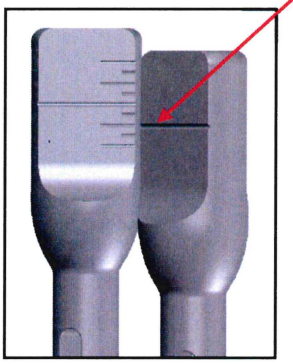
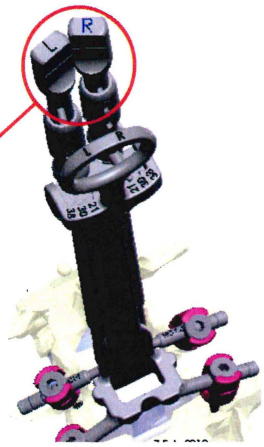
Depth Gauge Tube for screw length (optional)

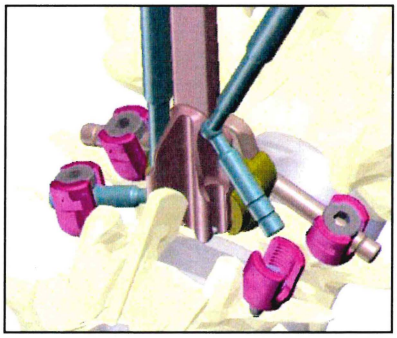
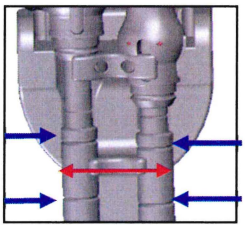
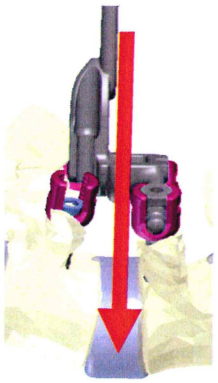
- For determining the proper size of the Pedicle Screw, use the Depth Gauge Tube (87725)
- Insert the marked K- Wire (87364) to the pedicle (with Jamshidy, Awlshidy or Tapshidy technic).
- Slip the Measurement Tube over the marked K-Wire (87364) till it reaches the pedicle bone and read the screw length by the scale at the top of the tube.
  - In case of getting a measurement in between the numbers, choose the smaller size.

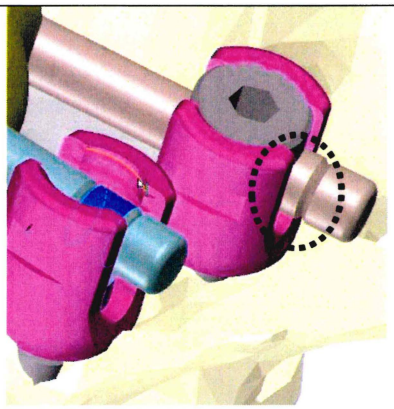
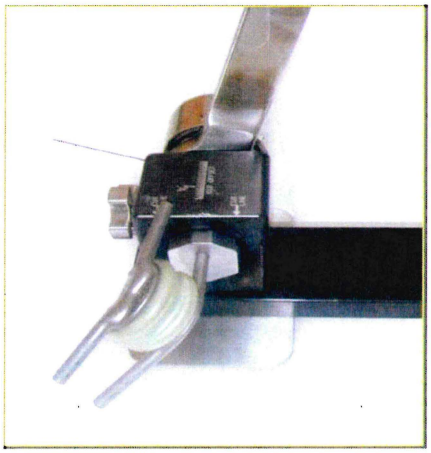


Dorsal Alignment of Screw Heads:

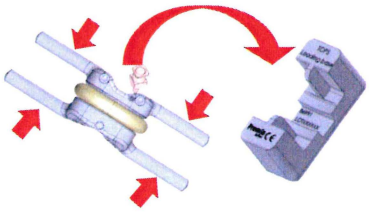
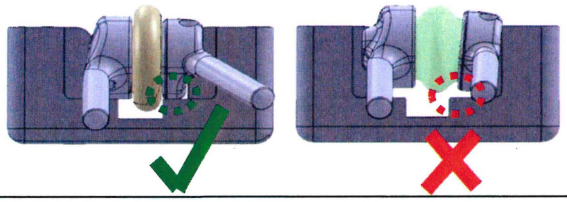
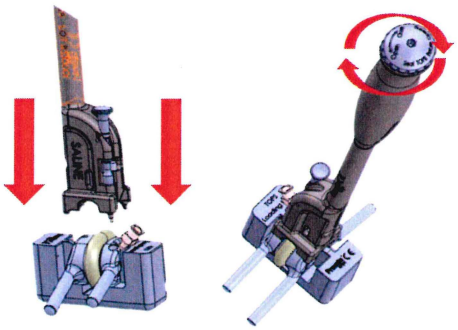
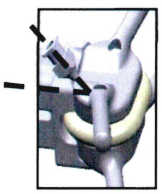
6-12 Alignment Gauge	The Alignment Gauge is used to determine the dorsal alignment of the screw heads. The Alignment gauge indicates whether any of the four screws need to be advanced to properly accept the geometry of the 4 arms of the TOPS™ System. **IMPORTANT:** Verify proper UP and DOWN orientation.	 **TOPS™ Alignment Gauge**
6-15	Place the Gauge handle in the saddles of the Inferior pedicle screws, align it with the medial plane and finger tighten the setscrews using the Setscrew Inserter. If the handle is tilting laterally to one side, advance the inferior screw on the contralateral side.	 
6-16	Chose a superior crossbar (left or right) that best fits the patient morphology and attach it to the handle. Verify that the ball joins the socket at the bottom of the instrument. ***Note:*** For surgeon convenience, the left and right crossbars are marked on the handle and the superior crossbars.	 

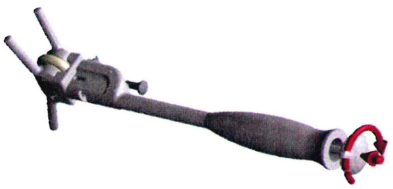
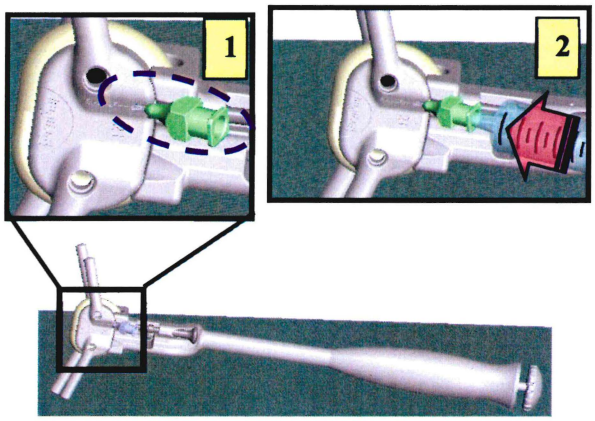
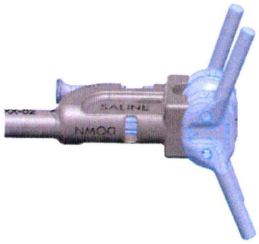
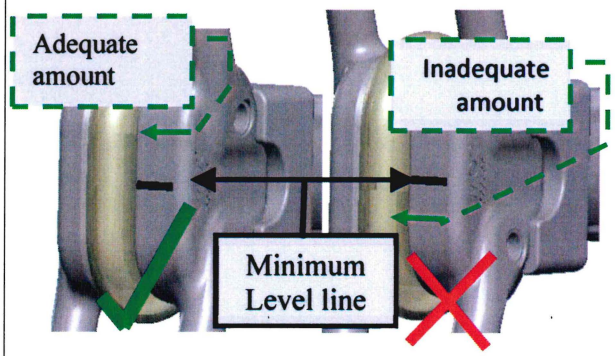
6-17	Secure the crossbar by sliding the locking sleeve downwards. Choose the configuration notch that requires the least amount of polyaxial accommodation of the pedicle screw head. The Configuration notches are marked and match the identification stickers on the TOPS™ inner and outer package. If a "30" notch provides the best fit, a "30" configuration TOPS™ pack should be opened later in the procedure. Finger tightened the setscrew using the Set Screwdriver.	
6-18	Repeat steps 6-16 to 6-17 with the second half of the superior crossbar (Left or Right). **Important:** Choose the same configuration notch as was chosen for the contralateral side. If there is a need, modify the selection of configuration notch of the first crossbar so that both crossbars fit the same notch Finger tighten the setscrew using the Set Screwdriver.	
6-19	If a height mismatch exists between the two halves of the Alignment Gauge, as seen in the image to the right, then one of the 4 screws needs to be adjusted. Alignment considerations: 1. Adjust only by advancing the screw (See cautionary note below) 2. It is easier to adjust one of the superior screws 3. Long Line = 1 full turn, Short line = ½ a turn **Note:** 1 full turn of the screw (360°) is equivalent to a 3 mm axial adjustment. Markings on the handles of the Alignment Gauge superior crossbars indicate how much the screw needs to be advanced. For example: if the markings are offset by 1 full line gradation (as shown on the picture on the right), this indicates that the superior left pedicle screws needs to be adjusted 1 full turn (360º).	 

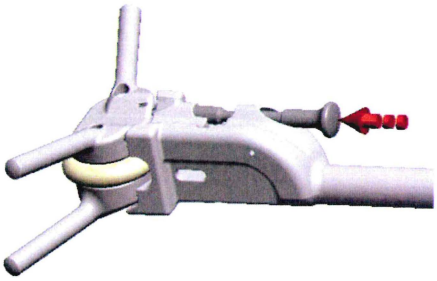
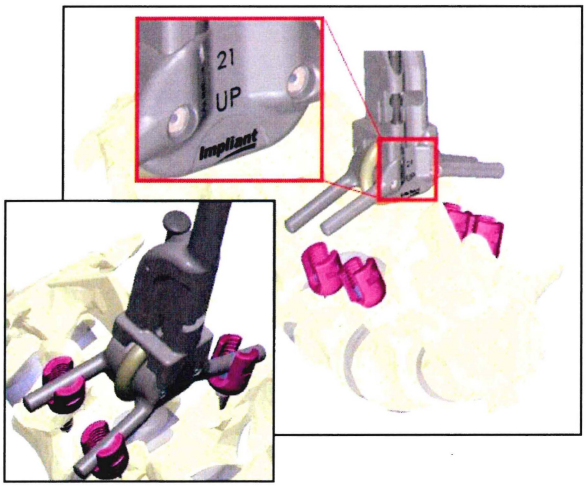
	IMPORTANT: Because of the pedicle screws' core conical shape, it is recommended to adjust the screw height by advancing the pedicle screws as opposed to backing them out to maximize screw purchase (assuming adequate anterior space exists in the vertebral body).	
6-20	To make an adjustment, remove the appropriate half of the Alignment Gauge superior crossbar, then advance the appropriate screw to the desired depth using a standard screwdriver. Once this is accomplished, re-attach the removed crossbar to verify that all screws are in perfect alignment as seen in the image to the right. Deviation of ±1/4 of a turn from perfect alignment is acceptable. Once all screws are aligned properly, the shaft of the Gauge should generally be pointing toward the disc space. If the shaft points above the disc space, the two superior screws should be lowered by the same amount until the shaft is aligned with the disc space. If the shaft points in the opposite direction, the inferior screws should be lowered by the same amount.	
6-21	***NOTE:* To Ensure proper alignment, the alignment should be performed in the true orientation of the TOPS™ device. The slots on the superior crossbars indicate the "Optimal orientation zone". When the "optimal orientation pointer" (Red Arrow) is between the slots (Between blue arrows) the gauge simulates the true orientation of the TOPS™ device.** **Make sure that the shaft of the handle points towards the disc space.**	 
6-22	**IMPORTANT:** If TOPS™ implantation needs to be aborted for any reason following pedicle screw placement, it is recommended that Premia Spine 6.0mm diameter rods be attached to the screws using standard fusion procedure techniques. Removal of the pedicle screws and subsequent screw replacement should be avoided due to loss of screw purchase strength.	
6-23	**arm cutting**:	

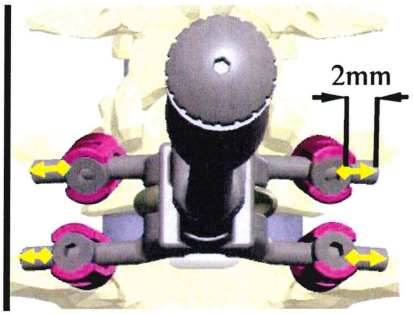
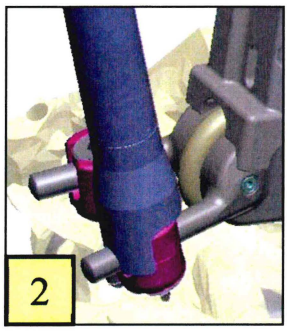
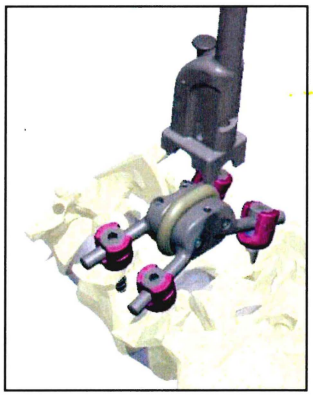
Rod Cutting	When shortening of the TOPS arms is desired, hash marks of the crossbars rods indicate the amount of arm cutting allowed. The number of hash marks that extend beyond the lateral border of the screw head indicates how much rod cutting is possible, each mark representing 5 mm. For example, if one hash mark extends laterally from the pedicle screw, the rod can be shortened by 5 mm if two hash mark extend laterally, the rod can be shortened by 10 mm. ***Note:* The final verification that the correct TOPS™ configuration was chosen and that the arms were shortened to the right length is by inspecting the TOPS™ position prior to final tightening.**	 Markings on the lateral aspect of the gauge arms indicate the amount of rod (mm) extending out lateral to the screw The arms of the Alignment Gauge identically correlate to the implant itself. Thus, the readings on the 4 arms of the Alignment Gauge should be recorded and the corresponding amounts should be carefully measured and marked on the TOPS™ Implant arms prior to cutting.
6-24	If a Rod Cutter is not provided by Premia Spine, a Table-Top rod cutter is the only type of rod cutter that should be used. This will minimize the sharpness of the cut shard at the end of the rod. **IMPORTANT**: Most table-top rod cutters have a cut line that is recessed 1cm into the machine. Care must be taken to ensure this cutting position is appropriately measured and accounted for.	
6-25	Remove the set screws and the Alignment Gauge. Select the appropriate TOPS™ device as determined in steps 6-18 (e.g., 21, 30, 38). Open the TOPS™ sterile packaging and remove the implant. Hold the TOPS™ device in your hand for the filling process.	
6-26	**<u>Optional</u>** Prior to inserting the TOPS device, use the pedicle screw unlocking handle to unlock the polyaxial joint of the screw. Insert the rounded tip at the distal end of the handle to the tulip head and rock it a little bit to regain full polyaxial movement.	

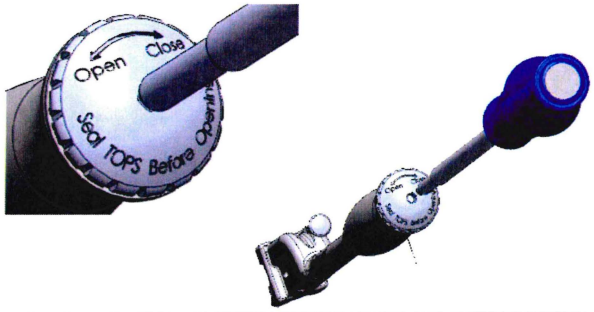
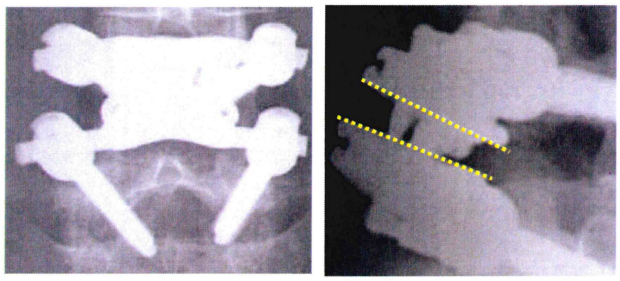
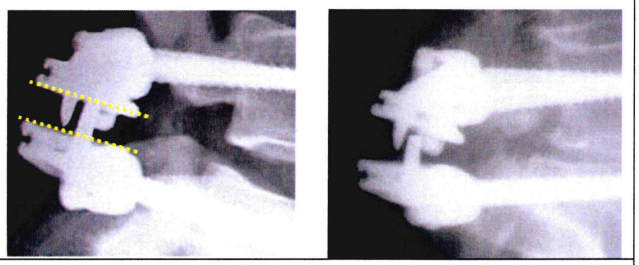
7	**TOPS™ Insertion**

7-1 Saline Injection	Use the TOPS™ inserter with the loading base to mount the TOPS™ for implantation. **IMPORTANT: The TOPS™ is supplied with a sterile 27 gauge stainless steel needle stuck inside the filling port. DO NOT remove that needle until after the TOPS™ has been filled with saline. The needle is placed in an angulated position. DO NOT attempt to redirect it during filling as this may damage the needle. If for any reason the needle is disengaged or damaged before the TOPS™ has been properly filled, remove the needle and use a 25G x 5/8" hypodermic needle.** Attach the TOPS™ onto the Loading Base. Slightly press the arms and push them to the bottom of the base. Confirm correct seating of the TOPS™ in the base.	 
	Assemble the TOPS inserter to the loaded device and fix by turning tight. Align the mounting holes in the TOPS™ device with the pins on the inserter as demonstrated in the picture to the right. Make sure that the TOPS™ is seated properly on the Inserter (no gap between the endplates and the Inserter).	 

7-2 TOPS™ Implant Insertion	Secure the TOPS™ by pushing and turning the knob clockwise on the proximal part of the inserter. Advance the knob until it locks. ***Note:*** Finger tightening is enough in order to hold the TOPS™ device in its place.	
7-3	1. Lay the TOPS™ on the table in a vertical orientation with the needle side upwards as seen in picture 1 to the right. 2. Using a 2cc syringe, fill the TOPS™ System with 1.7cc of sterile 0.9% NaCl via the filling port 3. To ensure proper needle depth throughout filling, gently push the needle and syringe while filling the TOPS™ with saline. (picture 2)	 
	Note: Before sealing the TOPS™ device, if for any reason extra verification of the saline level is required: 1. Remove the needle and syringe. 2. Hold the inserter with the TOPS™ attached horizontally and verify that the saline level is above the minimum level line marked on the anterior surface of the bottom endplate. 3. To add saline use a 25G x 5/8" hypodermic needle.	

7-4	Remove the syringe **with the needle** and seal the TOPS™ device by pushing the small knob on the head of the inserter. The knob should reach hard stop in order to ensure proper positioning of the plug.	
7-5	Verify the device is orientated correctly with the "UP" side of the TOPS™ device placed superiorly. Insert the TOPS™ System into the saddles of the pedicle screw heads.	
7-6	After all four arms are placed in the saddles of the pedicle screw heads, insert four set screws and finger tighten them using the Set Screw Inserter to secure the TOPS™ arms to the pedicle screws	

7-7	**IMPORTANT:** Align the Inserter with the medial plane and verify that a minimum of 2mm of crossbar extends beyond all four pedicle screws.	
7-8	Mount the Screwdriver with Torque Limiter (Torx), placing the Screwdriver with Torque Limiter (Torx) through the Counter Torque first then insert the tip of the Screwdriver with Torque Limiter (Torx) into the set screw. Then advance the Counter Torque onto the Pedicle Screw head making sure to maintain the pre-established orientation of the Pedicle Screw head. The set screws should be tightened clicking sounds are heard, indicating a force of 13Nm. Count at least 5 "clicks" to ensure proper tightening. **IMPORTANT:** Do not manipulate the Inserter during the torque sequence.	  
7-9 Final Tightening	Unlock the inserter by turning the knob on the handle counterclockwise then remove the Inserter from the TOPS™ System. ***Note:*** If a problem is encountered to unlock the inserter's knob make sure the plug pushing knob is pushed all the way in and try again.	

	After verifying that the plug pushing knob is pushed to its final position, the standard screwdriver can be used to assist in opening the inserter's knob if the knob cannot be opened by hand. Attach the standard screwdriver to the hexagonal socket and turn counterclockwise to open.	
7-10	**IMPORTANT:** Carefully inspect the implant to ensure that all crossbars are well seated in the pedicle screw head saddles and that there is no evidence of set screw cross-threading.	
7-11	**IMPORTANT:** Verify final positioning with biplanar fluoroscopy. If misalignment is noted, as seen on the images on the right, remove the device by reversing the torque sequence and reattach the TOPS™ following the surgical technique beginning with step 7-2. ***Note:*** If TOPS™ removal is necessary, final removal of the set screws should be performed with the Set Screwdriver to avoid dropping the set screws. **IMPORTANT:** New set screws must be used when reattaching the TOPS™ device.	Good Alignment  Negative misalignment Positive misalignment 
7-12	Verify that all instrumentation has been removed from the surgical field prior to closing the incision using standard surgical techniques. **IMPORTANT:** Prior to closure, irrigate the wound and check for any capillary bleeding. Standard hemostatic agents should be used if any persistent bleeding exists. A Penrose or Jackson Pratt style drain should be used per standard protocols for 24-72hrs post-op.	

Instructions for Use

See package insert 2464-CL-RS or 2480-CL-SP-OUS for the TOPS™ System IFU and 2446-CL-RI for the TOPS™ instrumentation set IFU.

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