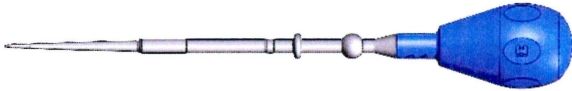

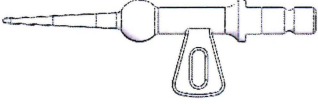
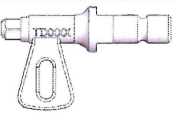
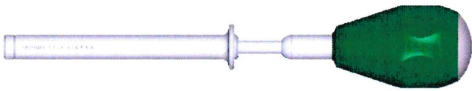
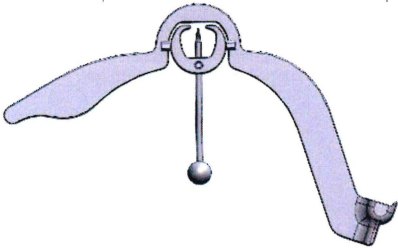
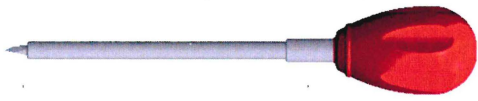



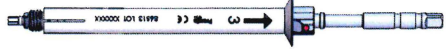
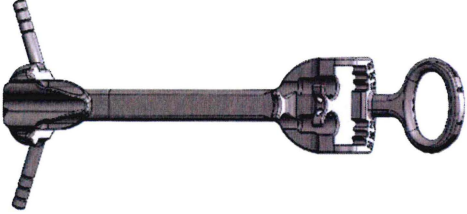







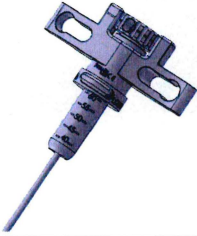

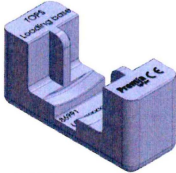
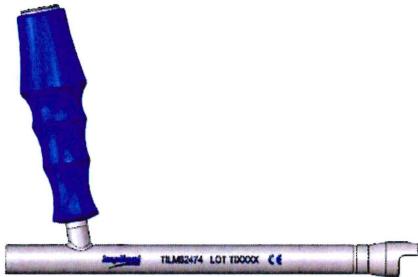
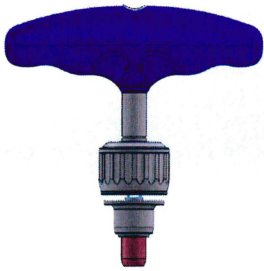






## **TOPS™ System Instrumentation Set – Instructions for use**


The document includes the cleaning and sterilization process, in addition, it serves as a checklist. The instrumentation set is to be cleaned and sterilized prior to first use and following each use. For cleaning and sterilization instructions for the first time follow the cleaning and sterilization instructions presented in the reprocessing section and follow through.



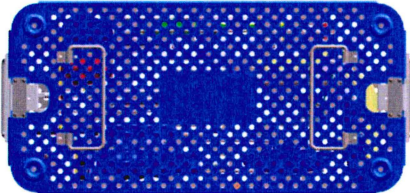
Instrument	Brief Description	P/N	Qty
	The Probe works in conjunction with a pendulum to assist in preparing the pedicle canal in a proper Medial/Lateral trajectory to optimal accept the geometry of the TOPS System.	Probe 81717	1
	The IPD Sleeve works in conjunction with a Probe to assist in determining proper Caudal cephalad trajectory and ensure sufficient distance between unilateral screws to accept the TOPS device	IPD sleeve 81714	1
	The bone flag and screw flag work in conjunction with the ball sleeve to mark and measure the IPD between adjacent unilateral screws to verify sufficient IPD to accommodate the TOPS	81711 Bone Flag	1
		81712 Screw Flag	1
	The flag inserter is designed to hold and position the bone and screw flags	00046 Flag Inserter	1
	The Pendulum is used to ensure that pedicle screw insertion is performed at the proper medial-lateral angle within the range of $\pm 10^\circ$	Pendulum 82775	1
	Pedicule Awl is used in order to open the cortex and ease screw insertion	Pedicule Awl 83159	1
	The Tap is used in cases of dense, sclerotic, or osteoporotic bone for tapping through the pedicle canal to minimize risk for splitting or fracturing of the pedicle.	Tap Ø 5.5 for Pendulum Adaptor 86639	1
		Tap Ø 6.5 for Pendulum Adaptor 86640	1
	Depth Gauge and Feeler can be used to measure the depth and evaluate the screw length	Feeler gauge 83210 (DA 2025-49)	1
	The Cannulated Screwdriver works in conjunction with the Pendulum to ensure insertion of the screw in a proper	Cannulated Screwdriver 86507	1

Instrument	Brief Description	P/N	Qty
	medial/lateral angle		
	<p>The Alignment Gauge (83105 Long &amp; 86202 Medium) is used to determine the dorsal alignment of the screw heads and indicates whether any of the four screws need to be advanced to properly accept the geometry of the 4 arms of the TOPS System. The Alignment Gauge is used to verify that the proper implant type (either 21, 30 or 38) has been selected.</p> <p>The Alignment Gauge fits all levels and TOPS™ configurations</p>	Gauge Handle Long 83104 Gauge Handle Medium 86185	1
		Gauge Superior crossbar right Long 83107 Gauge Superior crossbar right Medium 86189	1
		Gauge Superior crossbar Left Long 83106 Gauge Superior crossbar Left Medium 86187	1
	<p>Setscrew Insert is used for placement of the set screw</p> <p><b>Warning:</b> Do not use this instrument for final tightening of the setscrews</p>	Torx Setscrew Insert 86208	1
	Standard Screwdriver is used to advance the screw to the desired depth.	Standard Screwdriver 83209 (01.20202.110)	1
	<p>The Tap is used in cases of dense, sclerotic, or osteoporotic bone for tapping through the pedicle over the K- Wire canal to minimize risk for splitting or fracturing of the pedicle.</p>	Cannulated Tap Ø6.5 86143	1
		Cannulated Tap Ø5.5 86142	1
	<p>The Cannulated Probe works over the K- Wire on connected to integrated K- Wire handle (86046) in conjunction with a pendulum to assists in preparing the pedicle canal in a proper Medial/Lateral trajectory to optimal accept the geometry of the TOPS System.</p>	Cannulated Pedicle Probe 86047	

Instrument	Brief Description	P/N	Qty
	The integrated K- Wire handle Assy work with Cannulated Taps (86143, 86142) and a Cannulated Pedicle Probe (86047) in conjunction with a pendulum, the K- Wire should protrude the tip of tools	integrated K- Wire handle 86046	
	The TOPS™ Inserter is designed to conveniently hold the TOPS™ implant in zero position during implantation	TOPS™ Inserter 82889	1
	The TOPS Loading Base is designed to help the surgical staff attaching the TOPS Implant to the TOPS Inserter in zero position.	TOPS Loading Base 86991	1
	Counter Torque is used to firmly hold the pedicle screws during final tightening and prevent the torquing moments from being transferred to the spine.	Counter torque 82474	1
	1/4" fitting Straight and T handle works in conjunction with 1/4" fitting instruments (Taps, Screwdriver and torque limiter) to facilitate insertion and tightening of pedicle screws.	Ratchet T handle with pendulum adaptor 86263/ 87866(optional)	1
		STR Ratchet handle with pendulum adaptor 86273/ 87867(optional)	1
		Optional: Straight Handle with Pendulum Adaptor w/o Ratchet 86802	1
	The Screwdriver with Torque Limiter (Torx) limits the moment applied for tightening the setscrews to 13NM.	Torque Limiter 86567	1
	K- Wire 230 mm	86828	10
	K- Wire 470 mm	86264	10



	<b>Title:</b> <b>TOPS™ System Instrumentation Set</b> <b>Instructions for Use – English</b>	<b>Doc. No.:</b> <b>CL-2446</b>	<b>Page: 4 of: 7</b>
		<b>Revision: 18</b>	

Instrument	Brief Description	P/N		Qty
	Setscrews used in cases were additional setscrew are needed to fasten the pedicle screws.	86211		9
	Fusion Rod	50 mm	83196/86242	2
		70 mm	83197/86244	2
	TOPS™ Instrumentation Container	83117		1

#### General Instructions:

All instruments are required to be carefully examined before using in a surgical procedure. Inspection should include a visual examination to confirm that instruments are free of defects (e.g., corrosion, cracks, etc.). In addition, the functionality of the instruments should be confirmed prior to surgery. If instruments have defects or do not function properly they should not be used. Please contact Premia Spine for further direction.

<b>Products:</b>	Premia Spine TOPS System Instrumentation set
<b>CAUTIONS:</b>	<ul style="list-style-type: none"> <li>Reprocessing procedures have only a limited impact on a surgical instrument.</li> <li>The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device.</li> <li>In case of damage the device should be reprocessed before sending back to the manufacturer for repair.</li> <li>Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.</li> </ul>
<b>Reprocessing Instructions</b>	
<b>Preparation at the Point of Use:</b>	Rinse the instruments with cold water (<40°C) immediately after use to remove gross soiling. Clean any lumens using a syringe filled with sterile water. Use a K-wire to clean any cannulation from soft tissue and bone residuals. Pass the K-wire through the cannulation several times to make sure no tissue is left. Do not use a fixating detergent or hot water (>40°C), as this can cause the fixation of soil which might prevent cleaning. Cleaning should be performed before blood and debris are dry.
<b>Transportation:</b>	House the instruments in a safe container during transportation to the reprocessing area to avoid any instrument damage and contamination to the environment or personnel.
<b>Preparation for Decontamination:</b>	The following instruments must be dismantled before cleaning: <ul style="list-style-type: none"> <li>TOPS System Inserter (82889)</li> </ul>


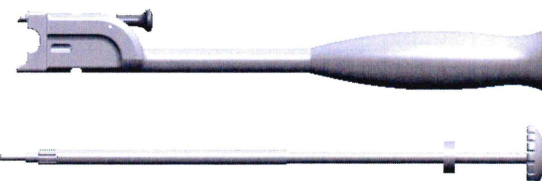



	<ul style="list-style-type: none"> <li>• Cannulated Screwdriver (86507)</li> <li>• K-Wire Adaptor (86494)</li> <li>• Integrated K-Wire Handle Assy (86046)</li> </ul>												
<b>Pre-Cleaning:</b>	<ul style="list-style-type: none"> <li>• Immerse the instruments into cold utility water for at least 5 minutes.</li> <li>• Take care to ensure that all surfaces are wetted and any lumens filled with water.</li> <li>• Place the instruments in an ultrasonic bath with an enzymatic detergent or alkaline detergent solution prepared per the manufacturer's recommendations for at least 5 minutes.</li> <li>• Brush the instruments with a suitable cleaning brush under running utility water until all discernible soil residue is removed from the surface.</li> <li>• Brush any lumens or dead ends at least three times.</li> <li>• Flush any hidden corners and cavities on the instruments with a water jet pistol (water pressure <math>\geq 2</math> bar) for at least 10 seconds.</li> </ul>												
<b>Automated Cleaning:</b>	<p>Put the instruments into the washer-disinfector on a tray or trays and start the following program:</p> <ul style="list-style-type: none"> <li>• Pre-washing with cold utility water for at least 2 minutes</li> <li>• Draining</li> <li>• Wash with an enzymatic detergent or alkaline detergent using the manufacturer's recommendations with 40 °C tap water for at least 5 minutes</li> <li>• Draining</li> <li>• Rinse with cold demineralized water for at least 3 minutes</li> <li>• Draining</li> <li>• Rinse with cold demineralized water for at least 2 minutes</li> <li>• Draining</li> <li>• </li> </ul>												
<b>Thermal Disinfection:</b>	<p>Perform automated thermal disinfection in washer-disinfector that complies with national requirements in regards to A<sub>0</sub>-Value (see EN 15883)</p>												
<b>Drying:</b>	<ul style="list-style-type: none"> <li>• Drying of outside of instruments occurs through drying cycle of washer-disinfector.</li> <li>• If needed, additional manual drying can be performed with a lint free towel.</li> <li>• Insufflate cavities of instruments by using sterile compressed air.</li> </ul>												
<b>Functional Testing, Maintenance:</b>	<ul style="list-style-type: none"> <li>• Visually inspect all instruments for cleanliness of the instruments followed by reassembling.</li> <li>• Perform functional testing according to instructions of use.</li> <li>• If necessary, perform reprocessing process again until all instruments are visibly clean.</li> </ul>												
<b>Packaging:</b>	<p>Put the instruments in the Premia Spine TOPS System container trays and prepare the trays for sterilization.</p>												
<b>Sterilization:</b>	<ul style="list-style-type: none"> <li>• Sterilize the instruments within the tray in accordance with the following steam sterilization parameters (according to ISO EN 17665-01) in conformance with the respective country requirements: <table> <tr> <td>Cycle Type:</td><td>Pre-vacuum</td></tr> <tr> <td>Temperature Set-point:</td><td>132°C</td></tr> <tr> <td>Exposure Time:</td><td>4 minutes</td></tr> <tr> <td>Drying Time:</td><td>10 minutes</td></tr> </table> </li> <li>• The following alternate cycles are also qualified <p><b>Alternate Cycle 1</b></p> <table> <tr> <td>Cycle Type:</td><td>Pre-vacuum</td></tr> <tr> <td>Temperature Set-point:</td><td>134°C</td></tr> </table> </li> </ul>	Cycle Type:	Pre-vacuum	Temperature Set-point:	132°C	Exposure Time:	4 minutes	Drying Time:	10 minutes	Cycle Type:	Pre-vacuum	Temperature Set-point:	134°C
Cycle Type:	Pre-vacuum												
Temperature Set-point:	132°C												
Exposure Time:	4 minutes												
Drying Time:	10 minutes												
Cycle Type:	Pre-vacuum												
Temperature Set-point:	134°C												

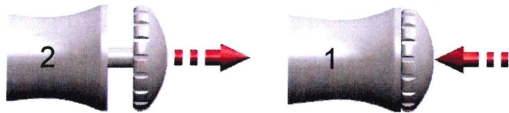
	<p>Exposure Time: 3 minutes Drying Time: 10 minutes</p> <p><b>Alternate Cycle 2</b></p> <p>Cycle Type: Pre-vacuum Temperature Set-point: 135°C Exposure Time: 3 minutes Drying Time: 10 minutes</p> <p>Maximal Sterilization temperature: 138°C <b>IMMEDIATE-USE STERILIZATION IS NOT ALLOWED ON INSTRUMENTS THAT CONTAIN LUMENS!</b></p>
<b>Storage:</b>	Store sterilized instruments in a dry, clean, and dust free environment at temperatures of 5°C to 40°C.
<b>Reprocessing validation study information</b>	<p>The following test devices, materials and machines have been used in this validation study:</p> <p>Detergent: neodisher MediZym (Chemische Fabrik Dr. Weigert, Hamburg) Brush: Any brush Washer-Disinfector: Miele G7836 CD Instrument rack: Miele rack with two layers. Details: See report SMP 10206011912 (according to ISO 17664) and SMP 10206022312 05610023303-1 and 05610023303</p>
<b>Additional Instructions:</b> None	
<p><b>Note:</b> The instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.</p>	

#### Instrument Specific Instructions:


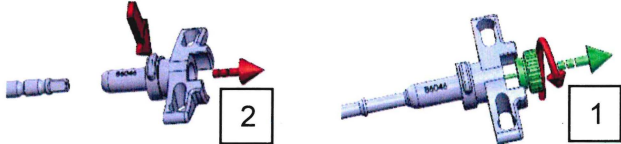
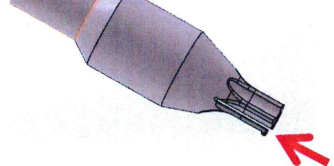
The TOPS™ Inserter is required to be disassembled prior to cleaning as follows:

#	Illustration	Description
<b>TOPS™ Inserter Disassembly</b>		
1.		To pull apart the inner shaft, Turn the knob counterclockwise 3-5 full turns
<b>Cleaning and Drying</b>		
2.		Clean all components prior to reassembly according to the procedure described above.
<b>TOPS™ Inserter Reassemble</b>		
3.		Advance the inner shaft into the handle until it reaches a hard stop then turn the knob clockwise 3-5 turns. Push the knob all the way in and turn clockwise.




4.		<b>Test:</b> - Push the internal shaft until it reaches the handle (1) - Release the knob and let the spring push the knob to its original position (2)
5.	The TOPS™ Inserter is ready to undergo sterilization as described in the instruction.	The TOPS™ Inserter is ready to undergo sterilization as described in the instruction.

#### TOPS™ screwdriver Disassembly before cleaning

6.		To disassemble the screwdriver for cleaning, first push the inner shaft (part #1) by the handle, second pull the sleeve (part #2) in the direction of the arrows.
7.	The integrated K- Wire handle Assy. Disassemble the knob and the Probe from the integrated K- Wire handle Assy for cleaning. Disassemble the K-wire from the knob.	
8.	Setscrew Inserter 86208: Verify that the tip is clean from tissue residues.	



#### Warnings

- Flash sterilization is not allowed on instruments that contain lumens!
- If instruments have defects or do not function properly they should not be used. Please contact Premia Spine for further directions.
- In case of damage, the instrument should be reprocessed before sending back to Premia Spine for repair.
- This system is provided unsterile  . Instrumentation is to be cleaned and sterilized prior to first use and following each use



Premia Spine Ltd.  
7 Giborey Israel St.,  
Ramat Poleg 4250407, Netanya,  
Israel  
email: [info@PremiaSpine.com](mailto:info@PremiaSpine.com)

EC REP

MedNet EC-REP III GmbH  
10 Borkstrasse, 48163  
Munster, Germany