Premia Spine

TOPS™ System Instrumentation Set

Instructions for Use

TOPS™ System Instrumentation Set – Instructions for Use

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

1. Important Information for TOPS™ System Instrumentation Set

This Instructions for Use (IFU) guide describes the methods for caring, cleaning, sterilization and storage of the TOPS™ System Instrument Set. Recommended surgical procedure, including use of the instrument set, are described in the TOPS™ System Surgical Technique Guide and the TOPS™ System Instructions 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.

For the TOPS™ System Indications, Contraindications, Warnings and Cautions, and other important medical information, please refer to the TOPS™ System Instructions for Use and the TOPS™ System Surgical Technique Guide.

WARNING:

- **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.

CAUTION:

- The TOPS™ System instruments are provided non-sterile and must be sterilized prior to each use.
- The instruments are intended for re-use and therefore must be thoroughly cleaned and steam sterilized at the clinical site prior to each use.
- The K-Wires are provided non-sterile and must be sterilized at the clinical site 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 TOPS™ System instruments should be thoroughly cleaned and sterilized prior to first use and following each use per the instructions in **Section 4 "Reprocessing Instructions"** below. Upon first receipt and after each use, inspect all instruments for any damage as instructed below. If any instruments are damaged or malfunctioning, inform and send the instruments to Premia Spine and replace the instruments as necessary.

CAUTION: The instruments should be cleaned and sterilized according to the reprocessing instructions before returning used instruments to Premia Spine, to ensure safe handling of biologically contaminated instruments.

A. Materials

- The tissue-contacting parts of the TOPS™ System instruments are made of Stainless-Steel Alloys: 302, 304, 316, 420, 440C, and 630 (PH-17-4).
- The TOPS Inserter contains an internal Nitinol pin.
- Handles and Adaptors are made of Silicone, RADEL and Polyether Ether Ketone (PEEK).
- The K-Wires are made of SST 316 LVM or CoCr or Nitinol.
- The container is made of: HPP, AL 5052-H32 with Anodize Coating\Gray Powder Coating and Stainless Steel 304.

B. Warnings and Precautions

Warnings:

- **Do not** use the TOPS™ System 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.
- Handle device with care to prevent cutting surgical gloves with sharp-edged surgical instruments.

Precautions:

- The TOPS™ System instruments are reusable, provided non-sterile and must be thoroughly cleaned and steam sterilized in accordance with the validated instructions described in this insert, prior to each use.
- The TOPS™ System tray is intended only for use with TOPS™ System Instrumentation set. **Do not** add instruments to the set. Sterilization of contents other than TOPS™ System Instrumentation set has not been validated.
- **Do not** use immediate-use steam sterilization (IUSS).
- The K-Wires are provided non-sterile and must be steam sterilized in accordance with the validated instructions described in this insert, 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.
- In case of a damaged or malfunctioned instrument, contact Premia Spine for further instructions. The instruments should be cleaned and sterilized according to the reprocessing instructions before returning used instruments to Premia Spine, to ensure safe handling of biologically contaminated instruments.
- Care must be exercised in handling of wrapped cases to prevent damage to the sterile barrier. The user must be aware that maintenance of sterility is event related not time related. Sterilized items are considered sterile until use, unless an event causes contamination. Repeated handling increases the probability of a contaminating event.
- TOPS™ System must not be used with instruments of spinal systems from other manufacturers.

C. Possible Adverse Events

Any surgical techniques applicable for use with the TOPS™ System should be carefully followed. Following are possible adverse events that may be associated with the use of surgical instruments. Please refer to TOPS™ System Instructions for use (IFU) for a complete list of possible adverse effects.

- Breakage, damage, bending, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient or operative personnel.
- Improper maintenance, handling, or poor cleaning and sterilization procedures can render the instrument unsuitable for its intended purpose, or transmit infectious pathogens to the patient or surgical staff.
- Possibility that fragments of a broken instrument may remain in the patient after implantation.

D. Disclaimer

The TOPS™ System Instrumentation Set Container is intended to protect the instruments and facilitate the sterilization process by allowing steam penetration and drying. Laboratory testing has verified that the Instrumentation Set Container is suitable for the specific sterilization methods and cycles for which it has been tested, as described herein. Health care facilities bear the ultimate responsibility for ensuring cleanliness and sterility and for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to ensure that conditions essential to sterilization can be achieved. Premia Spine does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by Premia Spine that should have been properly cleaned and sterilized by the end user prior to use.

E. 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 Implant/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.**

F. Warranty

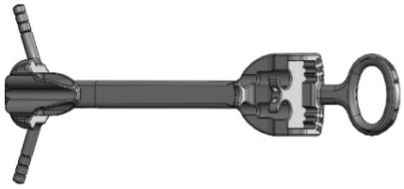
Premia Spine products are sold without expressed or implied warranties. Warranties of merchantability or fitness for a particular purpose are hereby disclaimed.

G. Instrumentation Set Related Symbols and Their Interpretation:

Graphic	Title – and Description
	Manufacturer – Indicates the medical device manufacturer
	**Do not** use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use – Indicates the need for the user to consult the instructions for use
	Caution – Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Upper limit of temperature – Indicates the upper limit of temperature to which the medical device can be safely exposed
	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process
	Catalogue number – Indicates the manufacturer's catalogue's number so that the medical device can be identified
	Importer – Indicates the entity importing the medical device into the locale
	Distributor – Indicates the entity distributing the medical device into the locale

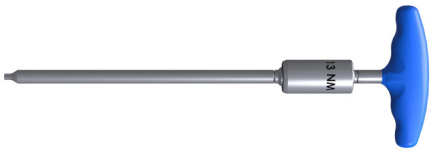
2. TOPS™ System Instrumentation

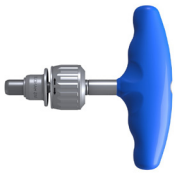
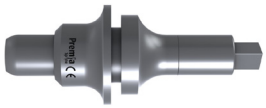
Four unique instruments along with several traditional spine surgery instruments make up the TOPS™ System Instrumentation Kit. These instruments are described below. They are designed to facilitate the TOPS™ System surgery and ensure proper sizing and placement of the TOPS Pedicle Screws and the TOPS Motion Implant.

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.
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. 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.
 Left Alignment Gauge Superior Crossbars **P/N:** 83107-Long, 86189-Medium	
 Right Alignment Gauge Superior Crossbars **P/N:** 83106-Long, 86187-Medium	
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 facilitate 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.

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.

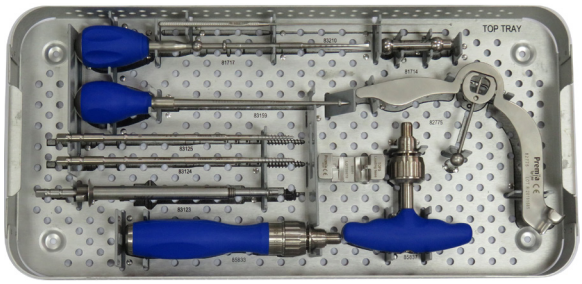
Instruments	Brief Description
 Integrated Depth Gauge Knob **P/N**: 87363	Determines the required pedicle screw's length without the need for an AP x-ray. Works in conjunction with the Awl-Shidi technique (the Integrated K-Wire Handle and Cannulated Awl).
 T-Handle with Pendulum Adaptor **P/N**: 86263	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.

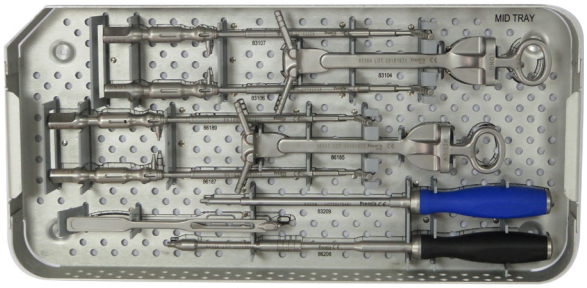
TOPS Instrumentation Container **P/N:** 83117
Container size: 520*255*135 mm

Container for instruments for steam sterilization.

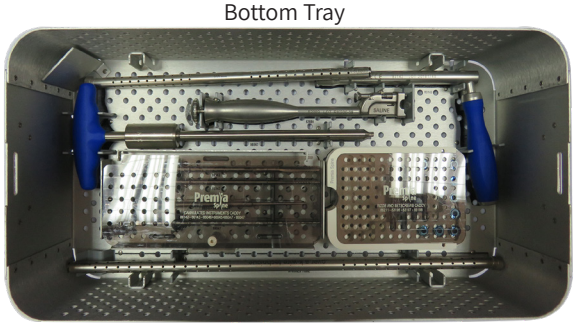
TOP Tray



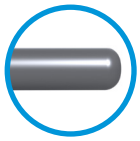
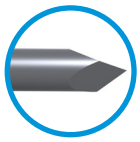
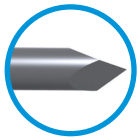
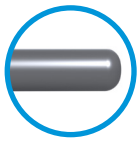
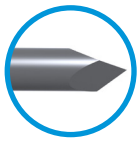
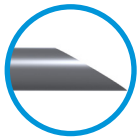
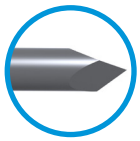
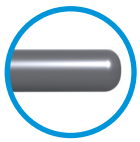
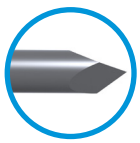
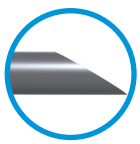
Mid Tray

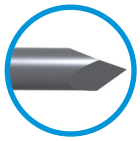
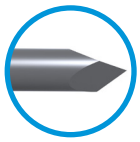
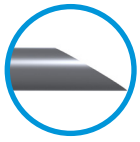
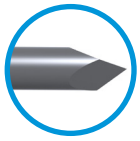
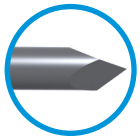
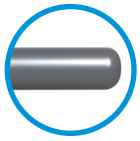


Bottom Tray



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.

3. Inspection and Functional Testing:

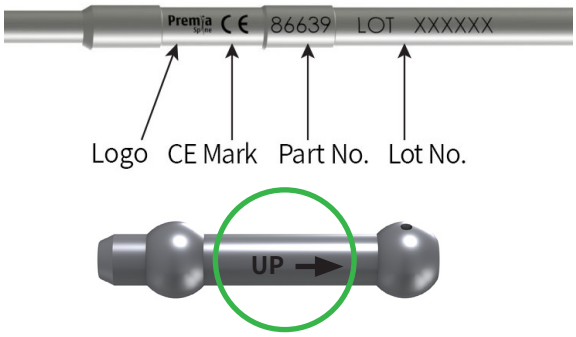
General Instructions:

NOTE: Reprocessing procedures have only a limited impact on a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. At some point in time, instruments wear out and should be replaced. It is the responsibility of the user to ensure that each instrument is visually/functionally inspected according to the instructions provided below.

- Carefully inspect all instruments before using in a surgical procedure. Inspection should include a visual inspection to confirm that instruments are free of defects (e.g., corrosion, cracks, wear, dull edges of cutting instruments, etc.).
- In addition, the functionality and smooth operation of the instruments should be confirmed prior to surgery. If instruments have defects or do not function properly, they must not be used. Please see **Section 4 "Reprocessing Instructions"** for further details on functional testing. Further instructions for instruments that require assembly/ disassembly and specific functional testing are provided in **Section 5 "Instruments that require Assembly/ Disassembly / Special Functional Testing"**.

4. Reprocessing Instructions

Point of Use:	• Cleaning should be performed before blood and debris are dry. • Rinse the instruments with cold water (<40°C) immediately after use to remove all visible soil. **CAUTION: Do not** use a fixating detergent or hot water (>40°C), as this can cause the fixation of soil which might prevent cleaning. • Thoroughly 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.
Transportation:	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.
Preparation for Decontamination:	The following instruments must be dismantled before cleaning: • TOPS Inserter (P/N: 82889) • Cannulated Screwdriver (P/N: 86507) • K-Wire Adaptor (86494) • Integrated K-Wire Handle (86046) • Dynamic K-Wire Adaptor (87130) Refer to **Section 5 "Instruments that require Assembly/ Disassembly / Special Functional Testing"**, for instructions regarding disassembly, assembly and/or functional testing for each of these instruments.
Instruments Pre-Cleaning:	• Immerse the instruments into cold utility water for at least 5 minutes. • Ensure that all surfaces are wetted and any lumens filled with water. • Place the instruments in an ultrasonic bath with an enzymatic detergent solution prepared per the manufacturer's recommendations for at least 5 minutes. • Thoroughly clean the instruments by brushing them with a suitable cleaning brush under running utility water until all discernible soil residue is removed from the surface. • Brush any lumens or dead ends at least three times. • Flush any hidden corners and cavities on the instruments with a water jet pistol (water pressure ≥2 bar) for at least 10 seconds.

Products	Premia Spine TOPS System Instrumentation Set
Automated Cleaning:	Trays Cleaning and Inspection: • Thoroughly clean the trays by brushing them with a suitable cleaning brush under running utility water until all visible soil residue is removed. • Visually inspect the trays for cleanliness to ensure they are visibly clean. • Repeat cleaning until the trays are visibly clean. Instruments Cleaning: • Put the instruments into the washer-disinfector on a tray or trays and start the following program: > Pre-washing with cold utility water for at least 2 minutes. > Draining. > Wash with an enzymatic detergent using the manufacturer's recommendations with 40°C tap water for at least 5 minutes. > Draining. > Rinse with cold critical water for at least 3 minutes. > Draining. > Rinse with cold critical water for at least 2 minutes. > Draining.
Thermal Disinfection:	Perform automated thermal disinfection in washer-disinfector that complies with national requirements in regard to A0-Value (see EN 15883).
Drying:	• Drying of outside of instruments occurs through drying cycle of washer-disinfector. • If visible water residues or droplets are observed on the instrument, perform additional manual drying with a lint free towel. • Insufflate cavities of instruments by using sterile compressed air.
Visual Inspection for Cleanliness:	• Visually inspect all instruments for cleanliness of the instruments to ensure they are visibly clean and free of stains and tissue. • Repeat the reprocessing process until all instruments are visibly clean.
Visual Inspection for Damage and Wear:	• Instruments and their parts shall have no defects, scratches, cracks, dents or any other damage. • Surface color shall be uniform.
Inspection for Laser Marking:	Identification and functional marks (see example in the figure below) must be clear and readable. 
Assembly:	• Reassemble the dismantled instruments according to the instructions in **Section 5 "Instruments that require Assembly/Disassembly/Special Functional Testing"**. • Perform additional visual inspection to these instruments according to the instructions above following reassembly.

Functional Testing:	Perform the following tests for all instruments:
Hinged instruments	Check for smooth movement of hinge without excessive “play.”
Locking mechanisms	Check for action.
Cutting features	Check edges for distortion/large nicks. Edges should be continuous.
Trials	Articular surfaces should be smooth and free of cracks and deep nicks.
Mating parts	Check to make sure that mating parts fit together without complications.
Metal surfaces	Inspect for corrosion and major deformation.
Packaging:	Put the instruments in the Premia Spine TOPS™ System container trays and prepare the trays for sterilization.

Sterilization:

- 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:

Cycle Type:	Pre-vacuum
Temperature Set-point:	132°C
Exposure Time:	4 minutes
Drying Time:	>30 minutes

- The following alternate cycle is also qualified:

Alternate Cycle 1-OUS cycle

Cycle Type:	Pre-vacuum
Temperature Set-point:	134°C
Exposure Time:	3 minutes
Drying Time:	>30 minutes

Maximal Sterilization temperature: 138°C

- Following sterilization and after the instrumentation are fully dry, wrap the trays according to hospital guidance using FDA cleared sterilization wrap or other FDA cleared accessory intended to allow sterilant penetration as well as sterility maintenance.
  The trays may be stacked on each other in the following order: bottom tray, mid tray, and top tray on top.
- **Do not** stack any other trays on or below dedicated instrument trays.

Storage and Shelf Life: Store sterilized instruments in a dry, clean, and dust free environment at temperatures between 5°C to 40°C.

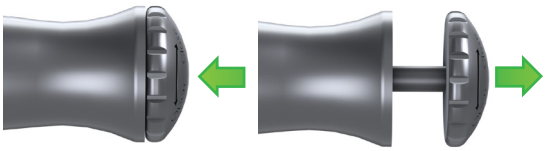
Reprocessing validation study information: The following test devices, materials and machines have been used in the validation study:

Detergent:	neodisher MediZym (Chemische Fabrik Dr. Weigert, Hamburg)
Brush	Any brush
Washer-Disinfector:	Miele G7836 CD
Instrument rack:	Miele rack with two layers.

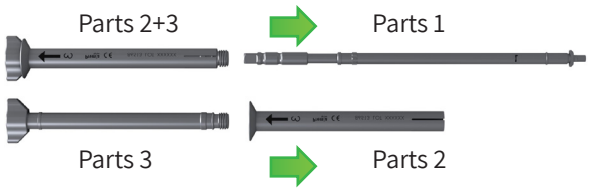
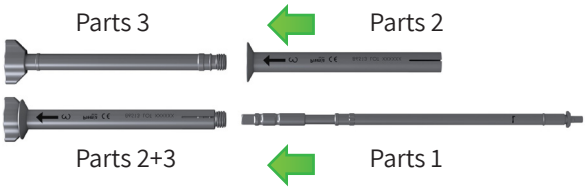
NOTE: The instructions provided above have been validated by Premia Spine Ltd. as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

5. Instruments that require Assembly/Disassembly/Special Functional Testing

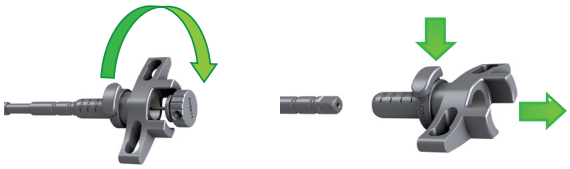
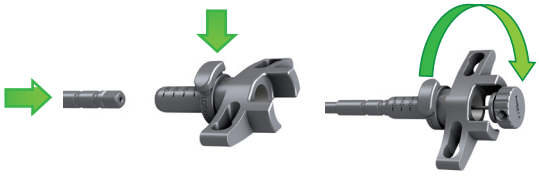
TOPS Inserter

Illustration	Functional instructions and testing
Disassembly before Cleaning	
Step 1 	Pull apart the inner shaft. Turn the knob counterclockwise 3-5 full turns.
Cleaning and Drying	
Step 2 	Thoroughly clean and dry all components prior to reassembly according to the procedure described in **Section 4 "Reprocessing Instructions"** above.
Reassemble	
Step 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.
Step 4  Position 1 Position 2	• Push the internal shaft until it reaches the handle (Position 1). • Release the knob and let the spring push the knob to its original position (Position 2). • The TOPS Inserter is ready to undergo sterilization as described in the instruction.

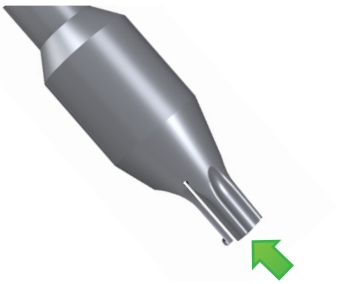
Cannulated Screwdriver

Illustration	Functional instructions and testing
Disassembly before Cleaning	
Step 1 	• Disassemble the screwdriver for cleaning. • First, release the inner shaft (Part #1) by pushing the screwdriver handle. • Second, pull the sleeve (Part #2) in the direction of the arrow to separate it from the outer shaft (Part #3).
Cleaning and Drying	
Step 2 	Thoroughly clean and dry all components prior to reassembly according to the procedure described in **Section 4 "Reprocessing Instructions"** above.
Reassemble	
Step 3 	• First, connect the handle to the outer shaft by pushing the outer shaft (Part #2) over the screwdriver handle (Part #3). • Second, connect the inner shaft to the outer shaft + screwdriver handle by pushing the inner shaft (Part #1) into the outer shaft + screwdriver handle (Parts 2+3). • Arrows directions describe the direction for connection. • The Cannulated Screwdriver is ready to undergo sterilization as described in the instruction.

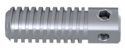
Integrated K-Wire Handle

Illustration	Functional instructions and testing
Disassembly before Cleaning	
Step 1 	• Disassemble the knob and the Probe from the integrated K-Wire Handle Assembly. • Disassemble the K-Wire from the knob.
Cleaning and Drying	
Step 2 	Thoroughly clean and dry all components prior to reassembly according to the procedure described in **Section 4 "Reprocessing Instructions"** above.
Reassemble	
Step 3 	• Assembly the 230mm of K-Wire to the knob. • Assembly the Probe. • Assembly the Knob to the Handle+ Probe. • The Integrated K-Wire Handle is ready to undergo sterilization as described in the instruction.

Torx Setscrew Inserter

Illustration	Functional instructions and testing
Cleaning and Drying	
	• Visually verify that the tip is clean from tissue residues. • Thoroughly clean and dry the Set screw Inserter according to the procedure described in **Section 4 "Reprocessing Instructions"** above. • The Torx Setscrew Inserter is ready to undergo sterilization as described in the instruction.

K-Wire Adaptor

Illustration	Functional instructions
Disassembly before Cleaning	
Step 1 	If a K-Wire is attached, remove by un-screwing the Torx nut using the setscrew inserter (Black handle).
Step 2 	Rotate the knob in the K-Wire adaptor counterclockwise until the inner threaded shaft is completely disassembled.
Cleaning and Drying	
Step 3  	Thoroughly clean and dry all components prior to reassembly according to the procedure described in **Section 4 "Reprocessing Instructions"** above.
Reassemble	
Step 4 	• Insert the threaded inner shaft into the handle and rotate the knob clockwise. • Verify smooth movement of the threaded inner shaft when rotating the knob. • Rotate counterclockwise until the locking screw is located above upper surface of the handle. • The K-Wire Adaptor is ready to undergo sterilization as described in the instruction.

Dynamic K-Wire Adaptor

Illustration	Functional instructions
Disassembly before Cleaning	
Step 1 	If a K-Wire is attached, remove it by un-screwing the Torx nut using the setscrew inserter (Black handle).
Step 2 	Rotate the black knob counterclockwise (1) until the Holder sub-assembly comes out (2).
Cleaning and Drying	
Step 3  	Thoroughly clean and dry all components prior to reassembly according to the procedure described in **Section 4 "Reprocessing Instructions"** above.
Reassemble	
Step 4 	• Rotate the black knob clockwise until the Holder sub-assembly is fully inserted into the handle. • The Dynamic K-Wire Adaptor is ready to undergo sterilization as described in the instruction.

Premia Spine

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