Premia Spine Ltd. TOPS™ System Family Instructions for Use

STERILE R

Device Description:

The TOPS™ System Family 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 normal human range of motion in these axes varies with age, strength, flexibility, and general physical state. Most studies indicate that individuals can achieve ranges of motion of ±1.5° of axial rotation, ±5° of lateral bending, 2° of extension, and 8° of flexion. The device is designed to allow near normal range of motion while also blocking excessive posterior and anterior sagittal translation.

The TOPS™ System Family uses polyaxial head pedicle screws for fixation to the vertebrae. These screws undergo surface blasting to enhance bony ingrowth. The TOPS™ System Family is to be used only with pedicle screws supplied by Premia Spine as part of the TOPS™ System Family.

The TOPS™ System Family is marked for appropriate placement:

- The Premia Spine logo and the word "UP" mark are the cranial aspect of the implant
- The word "DOWN" and Lot number mark are the caudal aspect of the implant

Intended use:

The TOPS™ System Family is a lumbar spine solution comprised of a central implant affixed to the spine via pedicle screws. The TOPS System is intended to stabilize the spine following a lumbar decompression without rigid fixation in skeletally mature patients with lower back pain and sciatica with or without spinal claudication at one level from L3 to L5 who have not achieved sufficient symptom relief with prior conservative care.

Indications:

The TOPS™ 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.

Warnings:

The TOPS™ System Family should **NOT** be implanted in patients meeting **ANY** of the following conditions:

a) Primary diagnosis of discogenic back pain
b) Back or leg pain of unknown etiology
c) More than one (1) motion segment involved in the degenerative pathology to the extent that justifies its inclusion in the surgical procedure, unless a decompression alone can be done at that level without compromising stability.
d) Known allergy to PEEK, titanium and/or polyurethane
e) Supplemental interbody support required (e.g., bone graft, spacers, VBRs, or fusion cages)
f) Clinically compromised vertebral bodies at the affected level(s) due to any traumatic, neoplastic, metabolic or infectious pathology.
g) Deformity of the spine that would compromise the implant, e.g. scoliosis of greater than ten (10) degrees
h) Morbid obesity defined as a body mass index > 40
i) Osteoporosis or osteopenia as defined by a DEXA bone density measured T score equal to or lower than – 2
j) Active infection - systemic or local
k) Medical conditions requiring treatment with any drugs known to potentially interfere with bone/soft tissue healing
l) Cauda equina syndrome or neurogenic bowel/bladder dysfunction

m) Sustained pathologic fractures of the vertebra or multiple fractures of the vertebra or hip

Directions of Use:

Refer as appropriate to the TOPS™ System Surgical Technique Manual CL-RS-EN-2372.

Precautions:

Use of the TOPS™ System Family should only be undertaken after the surgeon has become thoroughly knowledgeable about the spinal anatomy and biomechanics, has had experience with posterior approach spinal surgeries and has had training in the implantation of the device.

The TOPS™ System Family products should be implanted only in patients who meet all of the indications of use and none of the warnings as noted above.

The TOPS™ System Family (central units and pedicle screws) are provided sterile (gamma irradiated) in a double-blister pack sealed with a Tyvek lid and contained in a carton cardboard box. The integrity of the packaging should be confirmed to ensure the sterility of the contents is not compromised. **Do not use if package has been compromised**.

Always remove the TOPS™ System Family products (central units and pedicle screws) from the packaging using standard aseptic techniques only after the correct size has been determined. **Do not reuse or re-sterilize** even if the device appears undamaged (for single use only). The "use by" date must be checked. Do not use if the package has an expired label. The Set Screw is supplied together with the pedicle screw.

Use care when handling the TOPS™ System Family product to ensure it does not come into contact with objects that could damage the device. **Do not** handle the TOPS™ System Family products with any instrument other than the mating end of the device Inserter. If the TOPS™ System Family products are dropped or mishandled in any way **do not use**.

Correct selection of the appropriate size of the TOPS™ System Family products is extremely important to assure the correct function of the device.

Prior to implantation of the TOPS™ System Family products, **fill the appropriate device with sterile saline** as described in the appropriate Surgical Technique Manual.

Verify the device is orientated correctly with the "UP" side of the device placed cephalad (superiorly). Device implanted upside down would not function properly.

Do not use any of the TOPS™ System Family product with components of any other manufacturer's system.

Patients should be instructed in the postoperative care procedures and should be advised of the importance of adhering to those procedures for successful treatment with the TOPS™ System Family products.

All implants are to be kept at room temperature.

Damaged or operatively removed implants should not be reused under any circumstances.

Potential Adverse Events

Potential Risks Associated with the TOPS™ System Family:

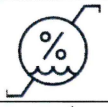
- Foreign body or allergic reaction, including adverse response to wear debris
- Implant migration, subsidence, loosening or dislocation
- Fracture or breakage of the implant
- Overload on vertebra that may cause failure
- Misplaced screws in pedicle
- Herniated nucleus pulposus
- Nerve root or spinal cord impingement
- Neurological deterioration
- Subsequent surgical interventions
- Adjacent segment degeneration
- Increased spondylolisthesis
- Foot Drop
- Back pain
- Heterotopic ossification
- Spontaneous fusion of the implant

Potential risks associated with posterior spinal surgery are also possible since the TOPS™ System Family products use a standard posterior surgical approach.

Instruments:

Refer as appropriate to TOPS™ System Instrumentation Instructions for Use (1473-CL-SP) or to (2446-CL-RI).

Symbols and labels:

1		Manufacturer	9		Consult instructions for use
2		Authorized representative in the European Community	10		Do not use if package is damaged
3		Use-by date	11		Temperature limit
4		Batch code	12		Humidity limitation
5		Catalogue number	13		Keep dry
6		Serial number	14		Sterilized using irradiation
7		Do not re-use	15		Do not resterilize
8		Caution	16		Date of Manufacture

Technical Specifications

Environmental Conditions for Storage and Operation	
Temperature	15°C to 22°C
Relative humidity	Up to 70%
Environmental Conditions for Shipping (up to 72 hours)	
Temperature	-29°C to +60°C
Relative humidity	Up to 85%

Further Information:

For further information, please contact:

	EC REP
Premia Spine Ltd. 7 Giborey Israel St., Ramat Poleg 4250407, Netanya, Israel email: info@PremiaSpine.com	MedNet EC-REP III GmbH 10 Borkstrasse, 48163 Munster, Germany

CE 1023