The TOPS™ System U.S. Clinical Study
The TOPS™ System has been available worldwide for over a decade. In the US, the TOPS System underwent an FDA clinical trial to establish its safety and effectiveness for the treatment of degenerative spinal stenosis and spondylolisthesis. The clinical trial involved 306 patients who were randomized and underwent surgery for either TOPS device implantation or lumbar fusion. The chart below shows outcomes for 115 TOPS subjects and 53 fusion subjects that were followed for 24 months after their operation.

Study of Treatment with the TOPS™ System versus Lumbar Fusion
Two years after surgery, 77% of TOPS patients achieved overall clinical success compared to 24% of fusion patients.

Parameter	TOPS Outcome	Fusion Outcome
Overall clinical success* Multiple imputation Observed data	77% 76% (82/108)	24% 24% (11/46)
No reoperations after surgery	96% (110/115)	89% (46/52)
Oswestry Disability Index (ODI) Reduction of ≥ 15 points	95% (90/95)	79% (26/33)
No new or worsening neurological deficit	97% (103/106)	88% (36/41)
No major device adverse event	94% (97/103)	95% (37/39)
Maintenance of non-fusion status (tops group) or achievement of fusion status (fusion group)	98% (101/103)	56% (22/39)
No lumbar injection after 2 years	90% (104/115)	89% (46/52)

* Multiple Imputation is a statistical method that includes patients with missing data by predicting success/failure and Observed includes only patients with known success/failure status.

TOPS demonstrates clinical superiority in overall trial success compared to fusion at 24 months. The difference between the TOPS success rate of 77% and fusion s rate of 24% is statistically superior.

Based on the results of the clinical trial, TOPS may help to relieve symptoms of spinal cord or nerve root compression resulting from spinal stenosis and spondylolisthesis. Additionally, TOPS may:
- Minimize your leg and back pain.
- Minimize tingling, weakness, and numbness in your legs.
- Help you return to your normal activities of work, family, and recreation.

Mobility. Stability. Durability.

TOPS is a Breakthrough
On October 26, 2020, Premia Spine received a Breakthrough Designation letter from the FDA. To quote, "We are pleased to inform you that your device and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device."

The FDA granted the TOPS™ System designation as a Breakthrough Device.

The TOPS System is a mechanical device that is designed to maintain motion in flexion, extension, side bending, and rotation. Instead of permanently locking the two vertebrae with a fusion, your surgeon allows the two vertebrae to continue moving with the assistance of the TOPS™ device.

The internal stoppers of the TOPS System replace the removed bony elements that served as stoppers during rotation, flexion, extension, and side bending. The implant facilitates twisting, bending, and straightening movements at the affected level of the spine.

Indications For Use of the TOPS™ System: The TOPS™ System is a motion-preserving spinal implant that is inserted into the lumbar vertebral joint and affixed to the spine via pedicle screws. The TOPS™ System is intended to stabilize the spine following a lumbar decompression without rigid fixation. The TOPS™ System is indicated for patients between the ages of 35 and 80 years with symptomatic degenerative spondylolisthesis up to Grade I with moderate to severe lumbar spinal stenosis and either thickening of the ligamentum flavum or scarring of the facet joint capsule at one level from L3 to L5.

Contraindications: The TOPS™ System should not be implanted in patients with the following conditions: • Presence of free fragment disc herniation at the index level • Spondylolisthesis greater than Grade I • Traumatic or dysplastic spondylolisthesis • Lytic spondylolisthesis • Back or non-radicular leg pain of unknown etiology • Stenosis caused by an extruded spinal disc fragment (e.g., herniation) or where the etiology is considered to be congenital, iatrogenic, post-traumatic, or metabolic • Known allergy or sensitivity to PEEK, titanium, and/or polyurethane • Scoliosis >10° by major Cobb angle (both angular and rotational) • Morbid obesity defined as a body mass index > 40 • Lumbar spine T-Score <-2.0 • Active infection - systemic or local • Cauda equina syndrome or neurogenic bowel/bladder dysfunction.

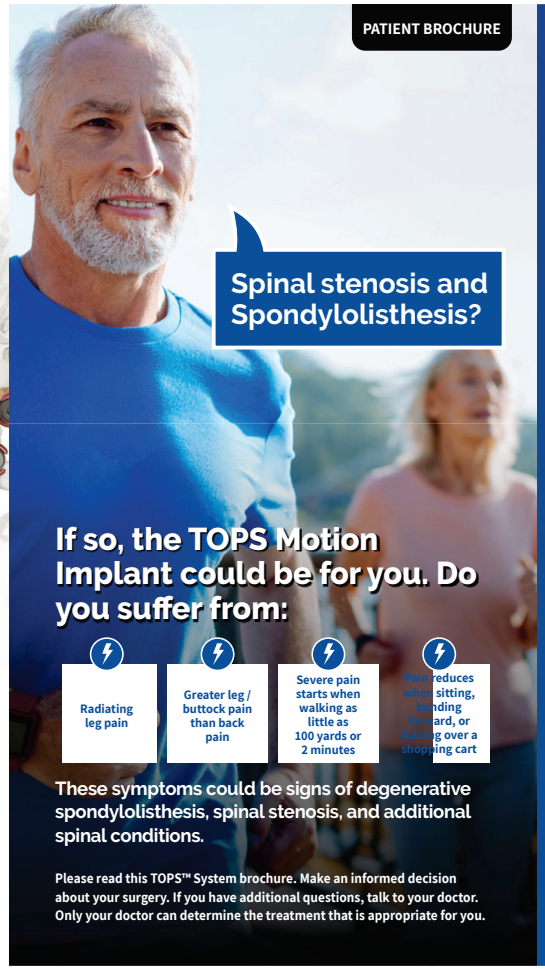
Clinical Summary: TOPS demonstrates clinical superiority in overall trial success compared to fusion at 24 months. The difference between the TOPS success rate of 77% and fusion's rate of 24% is statistically superior. See full clinical section for additional safety and efficacy information.

info@premiaspine.com
www.premiaspine.us

Premia Spine

Distributed by:
Premia Spine, Inc.
98 East Avenue,
Norwalk, CT 06851

PATIENT BROCHURE



Spinal stenosis and Spondylolisthesis?

If so, the TOPS Motion Implant could be for you. Do you suffer from:

- Radiating leg pain
- Greater leg / buttock pain than back pain
- Severe pain starts when walking as little as 100 yards or 2 minutes
- Pain reduces when sitting, bending forward, or leaning over a shopping cart

These symptoms could be signs of degenerative spondylolisthesis, spinal stenosis, and additional spinal conditions.

Please read this TOPS™ System brochure. Make an informed decision about your surgery. If you have additional questions, talk to your doctor. Only your doctor can determine the treatment that is appropriate for you.

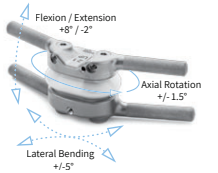
Daily activities such as carrying and lifting, along with the natural aging of the spine, cause wear and stress on the joints in your back. This can lead to nerve pressure in your spine and pain.

Degenerated Spine

Upon reviewing your MRI, CT scan and/or X rays, your surgeon may diagnose you with spinal canal narrowing and a slipped vertebra/disc. You will likely be tre ted non-surgically at first. This often includes rest, physical therapy, and injections. If these treatments do not provide relief, your doctor may recommend surgery to open your nerve pathways. Pain relief is achieved when the surgeon removes the bone elements that press on your nerves.

This procedure (also known as a "decompression") is often combined with a fusion procedure which may include the placement of pedicle screws, spinal rods, and cages to stabilize your lower back after the operation.

The TOPS implant is an alternative to rigid fixation with rods, screws, and cages. TOPS is a mobile implant that is designed to maintain motion and stabilize your back without fusion.



Speak with your doctor to understand the benefits and risks of the TOPS™ System. Your doctor will tell you if you are a candidate for this procedure.

How Do I Prepare for Surgery?

Please be sure to follow your doctor's guidance as you prepare for surgery. This guide is not intended to replace medical advice from your doctor. Your doctor is the only person qualified to diagnose and treat your spinal condition. Here is a list of topics that may be covered by healthcare professionals prior to surgery:

- Evaluation of your overall health to ensure that it's safe for you to have surgery.
- Examine your current condition and review of all possible treatment options.
- Review the medicines that you are currently taking. Your doctor will decide if you should stop taking any of them prior to surgery.
- Receive instructions for the night before surgery and the day of surgery.

Please ask your doctor for a complete list to prepare for surgery.

What Happens During Surgery?

During the TOPS surgery, you will be asleep under general anesthesia and an opening will be made in your lower back to access your lumbar spine. The degenerated facet joints, pars, lamina, and spinous process will be removed and the affected nerves will be relieved of pressure. The TOPS System will be inserted into lumbar vertebral joint space using specialized instruments. After the TOPS is placed, the opening will be closed.

What Happens After Surgery? When Should I Call My Doctor?

You may require one or more night's stay at the hospital following surgery. Ask your doctor to describe how you will feel after surgery and what will help you to recover. It is important to closely follow your doctor's instructions to recover quickly and to increase your chances of a successful result. Listed below are topics which healthcare professionals may discuss with you after the surgery:

- Instructions on surgical wound care to be followed after leaving the hospital.
- Schedule follow-up office visits to monitor your progress.
- Guidance for physical activity after surgery, including an exercise program under direction of a physical therapist.
- Ask for a card that containing information about conditions for safe MRI scanning. Present it to healthcare providers should you require medical care.

Some pain and discomfort are normal as with any major surgery. The symptoms you had before surgery may not go away immediately. Talk to your doctor about when to call regarding problems after surgery, such a fever, the skin around the incision becomes red, swollen, or more painful, excessive drainage or leaking from the incision, new or increased leg/back pain, weakness, or numbness.

What Are the Warnings Associated with TOPS™ System?

The TOPS™ System should only be used by doctors experienced with lumbar spinal surgery. The doctors must have hands-on training in the use of this device, the surgical instruments, the surgical technique, and the indications for use.

A complete list of Warnings is provided in the package insert for the device, which your doctor has received. Please ask your doctor for more information about any additional Warnings that could be related to your planned surgery.

What are Potential Adverse Effects of TOPS and Fusion?

From the time of surgery and out to 2 years afterwards, study participants experienced problems that could be related to the patient's health, the surgical procedure, and the TOPS System. For the 115 TOPS subjects and 53 fusion subjects that reached their two-year anniversary after surgery, below are adverse event rates reported during the FDA study.

Adverse Event Category	TOPS™ (N=115)			Fusion (N=53)		
	Events	Subjs	%	Events	Subjs	%
ALL	**316**	**82**	**71.3%**	**150**	**39**	**73.6%**
Blood and Lymphatic System Disorders	1	1	0.9%	3	2	3.8%
Cardiac Disorders	5	5	4.3%	4	2	3.8%
Ear and Labyrinth Disorders	2	2	1.7%	0	0	0.0%
Eye Disorders	7	7	6.1%	1	1	1.9%
Gastrointestinal Disorders	17	13	11.3%	5	5	9.4%
General Disorders & Administration Site Conditions	10	9	7.8%	5	5	9.4%
Hepatobiliary Disorders	0	0	0.0%	1	1	1.9%
Immune System Disorders	3	2	1.7%	0	0	0.0%
Infections and Infestations	28	18	15.7%	10	9	17.0%
Injury, Poisoning & Procedural Complications	41	31	27.0%	22	17	32.1%
Investigations	5	4	3.5%	4	3	5.7%
Metabolism and Nutrition Disorders	4	4	3.5%	3	2	3.8%
Musculoskeletal and Connective Tissue Disorders	112	51	44.3%	50	28	52.8%
Neoplasms Benign, Malignant & Unspecified (Incl Cysts & Polyps)	8	7	6.1%	1	1	1.9%
Nervous System Disorders	30	19	16.5%	15	12	22.6%
Product Issues	1	1	0.9%	3	2	3.8%
Psychiatric Disorders	3	3	2.6%	5	4	7.5%
Renal and Urinary Disorders	8	7	6.1%	1	1	1.9%
Reproductive System & Breast Disorders	2	2	1.7%	2	1	1.9%
Respiratory, Thoracic & Mediastinal Disorders	9	9	7.8%	5	3	5.7%

Glossary

Decompression: Surgery to relieve spinal cord and nerve root pressure by removal of bone elements and soft tissue pressing on nerves.
Facet Joint: Small joints on the back of the vertebrae for stability and motion.
Fusion: Surgery to rigidly fix adjacent vertebrae.
Lamina: Flat and arched part of the vertebrae that cover the spinal cord.
Nerve Root: Nerves that pass from the spinal cord through openings between vertebrae.
Pars: Stabilizer of the spine by preventing one vertebra from slipping forward on another.
Spinal stenosis: Narrowing of the spaces where your nerves pass within your spine.
Spinous process: A bony projection off the posterior (back) of each vertebra.
Spondylolisthesis: The slippage of one vertebra and disc forward on another vertebra.
Vertebrae: Bones that form the spinal column or backbone. A single spinal bone is called a vertebra.

What Precautions are Associated with TOPS™ System Surgery?

Below is a list of precautions to be aware of as the safety and effectiveness of the TOPS™ System has not been established in patients with the following conditions:

- More than two vertebral levels requiring surgical decompression.
- More than one surgical procedure at any combination of lumbar levels.
- Prior surgery at any lumbar vertebral level with instrumentation.
- Prior surgery at an adjacent lumbar vertebral level without instrumentation.
- Disc herniation at any lumbar level requiring surgical intervention.
- Pregnancy.
- Chronically taking medications or any drug known to potentially interfere with bone/soft tissue healing (e.g., steroids).
- Uncontrolled diabetes.
- History of Paget's disease, osteomalacia, or other metabolic bone disease.
- Rheumatoid arthritis or other autoimmune diseases.

A complete list of general, preoperative, interoperative, and postoperative Precautions is provided in the package insert for the device, which your doctor has received. Please ask your doctor for more information about any additional Precautions that could be related to your planned surgery.

What Are the Risks Associated with TOPS™ System Surgery?

As with any surgery, surgical treatment of lumbar spine disorders is not without risk. A variety of complications related to the surgery or the use of the TOPS™ System may occur. Potential adverse effects (i.e., complications, risks) associated with the use of the TOPS™ System identified from the TOPS™ System clinical trial results, use of the TOPS™ System outside of the United States, approved device labeling for other lumbar spinal devices, and published scientific literature appear in the package insert of the device. The Adverse Effects are sub-divided into three categories: (1) those commonly associated with any surgical procedure; (2) those associated with lumbar spinal surgery procedures using a posterior approach; and (3) those associated with posterior spinal implants, including those pertaining to the TOPS™ System. These risks may occur singly or in combination, and may be severe and/or negatively impact patient outcomes. The list below is not a full list of risks. There may be other risks with treatment using the TOPS™ System. There is the possibility that this surgery may not be effective in relieving your symptoms. It is possible your symptoms could worsen. If this happens, you may require additional surgery. You should discuss these risks and any concerns with your doctor before deciding to have TOP™ System surgery. A complete list of Risks is provided in the package insert for the device, which your doctor has received. **Please ask your doctor for more information about any additional Risks that could be related to your planned surgery.**

Risks Associated with Any Surgery:

General surgical risks are, but not limited to:

- Anesthesia complications including allergic reaction to the drugs used to put you to sleep for surgery.
- Wound healing complications at the surgical cut. Infection in the blood or at the surgical cut.
- Soft tissue damage or fluid collections which may require draining or other surgical or pharmacological intervention.
- Lung problems including pneumonia, collapsed lung, and blood clots.
- Post-surgical pain, bruising, tenderness, sensitivity or discomfort at the surgical incision or the skin over the incision which may result in skin healing complications, irritation, or pain.
- Neurological complications including nerve damage, paralysis, seizures or convulsions, changes to mental status.
- Narcotic addiction.
- Continued bleeding after surgery and possible collection of blood or scarring on the covering of the spinal cord. This may require another surgery or transmission of more blood (transfusion).
- Problems associated with the heart or blood movement. In rare instances, heart attack, stroke, or death can occur.

Risks Associated with Lumbar Spine Surgery:

- Injury or damage at the surgery site area, including to the spinal cord, nerves, cover (dura), blood vessels, and skin.
- Spinal cord damage with potential spinal fluid leakage, leading to temporary or permanent headaches, paralysis or numbness, tingling, or weakness.
- Surgery at the wrong level.
- Adverse reaction and allergy to the device materials or device wear debris from Titanium, Polycarbonate Urethane (PCU), and Polyether Ether Ketone (PEEK)], which may lead to an adverse reaction of the local tissues or chronic inflammation that may lead to implant loosening or failure of the device, adverse tissue reaction, progressive breakdown of bony tissue, tumor formation, autoimmune disease, scarring, or other symptoms.
- Degenerative changes at adjacent segment to the level of your spine surgery.
- Loss of bowel or bladder function, or incontinence (loss of bowel or bladder control).
- Fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery.
- Postoperative muscle and tissue pain.
- Pain and discomfort associated with the presence of implants.
- Pain and discomfort associated with the surgical procedure (e.g., cutting of muscles, ligaments, and tissue) and healing.
- The spine may undergo adverse changes or deterioration including loss of proper spinal curvature, correction, height, and/or reduction, or malalignment, and another surgery may be required.

Risks Associated with posterior spinal implants, including the TOPS™ System:

Risks specific to posterior spinal implants, including the TOPS™ System, are, but not limited to:

- Removal, revision, reoperation or additional fixation after procedure.
- Additional surgery due to loosening, breaking, or wearing.
- Bone formation or fusion.
- Difficulty placing the pedicle screws or TOPS device properly in the spine.
- Development of new pain or failure of the device to improve existing symptoms or function.
- Issues with the device surgical instruments.
- Device/joint noise.
- Degeneration, fracture, or other changes in alignment of the spine or loss of proper spine curvature, height, motion or stability.