What is the TOPS clinical trial?
It is a research study offered to volunteers who suffer from spondylolisthesis, spinal stenosis and additional spinal symptoms. Physicians will be comparing the TOPS to lumbar fusion in a randomized clinical trial. This pivotal study is designed to determine the safety and efficacy of the TOPS implant after which the U.S. Food and Drug Administration (FDA) will determine if the device will become available to the general public.

How are patients randomized?
If you choose to participate and you qualify for this study, you will not be able to choose the group to which you are assigned. Your treatment assignment will be made by randomization, a method similar to tossing a coin. You will have a two in three chances of receiving the TOPS System (67%) and a one in three chance of receiving posterior lumbar spinal fusion (33%).

Has this type of surgery ever been done prior to this clinical trial?
Yes. TOPS is approved and used in Europe and Australia for many years. The TOPS completed a pilot study in the United States.

What is my commitment?
You will be evaluated at regular follow-up visits. There will be one visit 6 weeks after surgery and then other visits at 3, 6, 12, and 24 month, and annually there after until the study ends. During these visits one or more medical professionals will evaluate your physical condition. Enrollment in this study requires that you complete all follow-up visits in a timely manner. This is an agreement that you make with the physician and the sponsor of the study. No matter what your assignment group is, your follow-up data is very important to help determine the safety and efficacy of the TOPS device.

Study sponsored by Premia Spine

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Are there any risks associated with this clinical trial or the surgical procedure?
The risks are the same as those associated with fusion spine surgery. If you are interested in enrolling in the study, you will be asked to sign an Informed Consent form that contains a list of potential adverse events. The physician conducting this clinical trial will have a detailed discussion with you prior to enrollment in the study. This trial is being conducted under the auspices of FDA. Additionally the hospital's associated Institutional Review Board has approved this clinical trial.

Indications For Use of the TOPS™ System
The TOPS System is indicated for patients between 35 and 80 years of age suffering from neurogenic claudication resulting from degenerative spondylolisthesis up to Grade I with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum or scaring facet joint capsule.
Degenerative spondylolisthesis refers to an abnormal alignment with slippage of one spinal vertebra in relation to another that can cause pain in the lower back and legs. This condition can often occur concomitantly with a narrowing of the spinal canal, compression of the traversing nerves, and also increased abnormal movement of the two vertebrae in relation to each other. The TOPS™ System is intended to provide stabilization following decompression in skeletally mature patients with disease at one level from L2 to L5 who have not achieved sufficient symptom relief with prior conservative care.
If you have symptoms of spinal stenosis and spondylolisthesis, talk to your doctor about all your treatment options, and find out if the TOPS™ System trial is the right option for you.
To enroll in this study, you must be: ■ between 35 and 80 years of age ■ have tried conservative therapy for at least 6 months without significant pain relief ■ suffer from: (1) degenerative spondylolisthesis or retrolisthesis up to Grade I and (2) moderate to severe lumbar spinal stenosis and (3) thickening of the ligamentum flavum or scaring facet joint capsule.

UPMC Pinnacle

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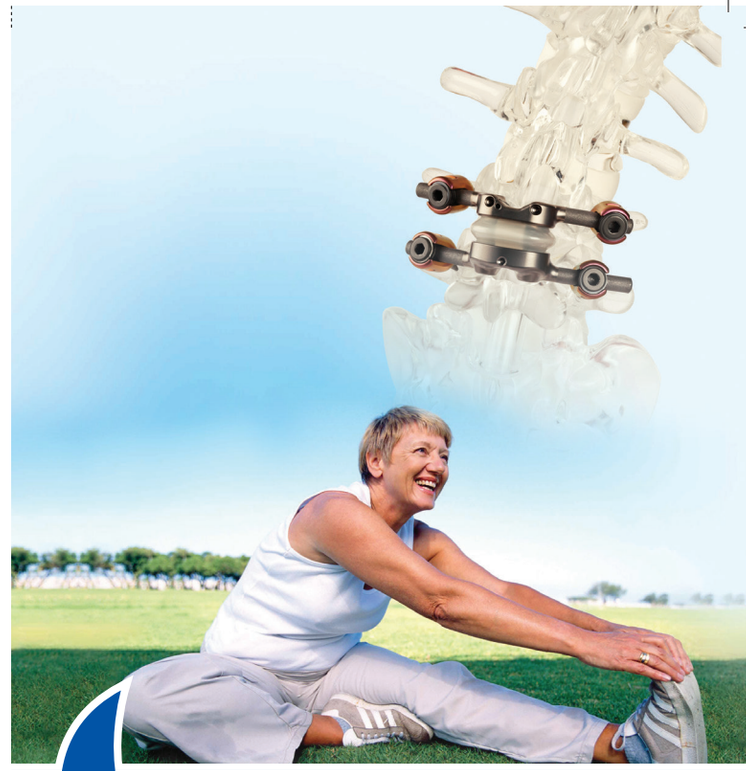
CAUTION
Investigational device. Limited by Federal (or United States) law to investigational use



Am I eligible for the TOPS study?

Possibly, if you suffer from one or more of the following conditions:

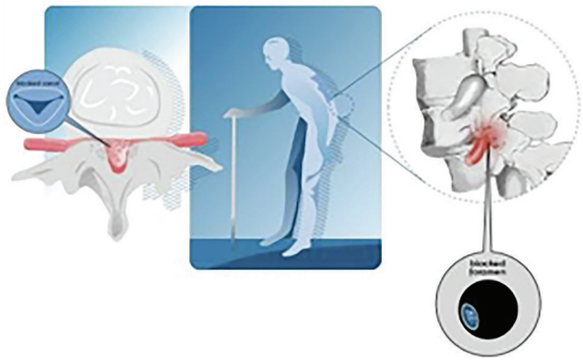
- **Radiating leg pain**
- **Greater leg / buttock pain than back pain**
- **Severe pain sets in when walking as little as 100 yards or 2 minutes**
- **Pain reduces when sitting, bending forward, or leaning over a shopping cart**

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

Consult your physician to determine if participating in the TOPS™ System study could be relevant 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 (stenosis) and a slipped disc (spondylolisthesis), and 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—the placement of pedicle screws and rods—to stabilize your lower back after the operation.

The TOPS implant is an alternative to pedicle screws and rods in a fusion. This mobile device is undergoing a comparative clinical study to fusion.

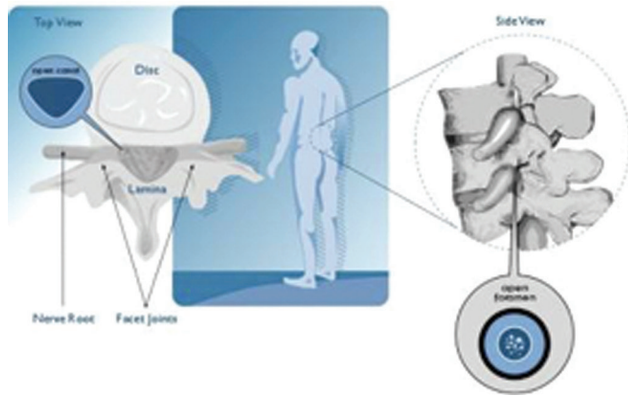
After the decompression, the surgeon will either implant pedicle screws and rods, or the TOPS to replace the diseased skeletal structures and stabilize the spine.

The TOPS System is a mechanical device that restores motion in all directions – flexion, extension, lateral bending, and axial 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 implant facilitates bending, straightening and twisting movements at the affected level of the spine while blocking excessive sagittal translation motions.

The internal stoppers of the TOPS System replace the removed bony elements that served as stoppers during axial rotation, flexion, extension, and side bending.

Healthy Spine



Full recuperation will vary from patient to patient in the study.

Ask your surgeon if you can participate.