

coflex[®]
Interlaminar Stabilization

Get back to: **my life**



Motion preserving treatment
for lumbar spinal stenosis

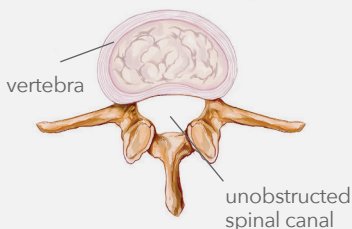
Do you have any of these symptoms?

- Numbness, weakness or pain in the lower legs
- Difficulty walking long distances
- Lower back pain that is relieved by bending over or sitting down
- Pain or numbness in the buttocks

If any of these symptoms describe you, you may have spinal stenosis. Unfortunately, spinal stenosis is NOT a condition that gets better with time. In fact, it can only get worse.

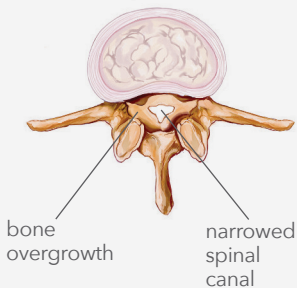
Understanding the causes of spinal stenosis

View of healthy spine (top view)



Notice that the opening in the spinal canal has sufficient room for the spinal nerve.

View of spine with stenosis (top view)



Overgrowth of bone and tissue has narrowed the spinal canal, and is now pressing on the nerve, causing pain that radiates down the legs and in the buttocks.

Simply stated, spinal stenosis is a **narrowing of the spinal canal**. This narrowing may be caused by any number of conditions, including bone spurs, thickening of ligaments, or collapsing disc heights in the lower spine.



When any of these conditions occur, the spinal nerves, which run down along the spinal canal, become compressed. **This pressure on the nerves causes the pain you feel in your buttocks, legs and/or lower back.**

Spinal stenosis treatment options:

Conservative treatment: Pain medications, physical therapy, chiropractic treatment and epidural steroid injections.

Decompression surgery: For minor cases and mild stenosis, a decompression surgery may be sufficient to relieve symptoms.

New treatment option: coflex® for moderate to severe spinal stenosis without instability. See back page for more details.

Spinal fusion surgery: For the most severe cases.

A person is riding a bicycle through a sunlit forest. The person's hand is on the handlebar, and they are wearing a light-colored t-shirt. The background is a soft-focus green forest with sunlight filtering through the trees.

Get back to:

**bike rides
together**

This is the shape of real relief.

coflex® is implanted during a **minimally invasive surgery** that does NOT involve spinal fusion. In many cases, patients are up and walking the same day of surgery, with real relief from pain!

In a clinical study comparing coflex® to fusion surgery, patients who received coflex® experienced:*

- Shorter surgery
- Less blood loss
- Shorter hospital stay
- Significant and lasting pain relief

Ask your doctor for coflex® by name!

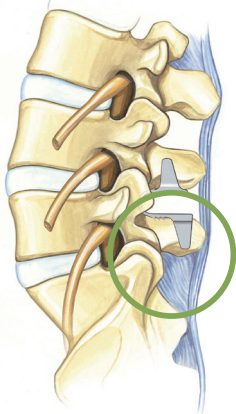


more than 200,000 patients
around the world have been
treated with coflex®

coflex® is a small u-shaped titanium alloy implant that can help relieve the pain caused by spinal stenosis.

This non-fusion procedure is minimally invasive and has been proven to be safe and effective based on significant clinical data.

If you have lumbar spinal stenosis, you can finally stand up to it with a **safe and effective treatment solution that is proven to work***.



What to do now:

If you are in pain but have not seen a doctor: Schedule an appointment with a spine doctor, such as an orthopedist or a neurosurgeon, and explain your symptoms. You will likely get x-rays and/or an MRI to accurately assess your condition.

You will also likely start conservative treatment, like anti-inflammatory medication (such as Ibuprofen), physical therapy, and/or chiropractic treatment.

If you are in pain, have seen a doctor, but are not ready for surgery: Many patients who are not ready for surgery may receive epidural steroid injections to help relieve their pain. However, evidence states that these injections may offer minimal or no short-term benefit in the treatment of lumbar spinal stenosis.

If you are in pain, and have tried conservative therapy treatments for at least six months with little or no improvement, it may be time for surgery.



"As soon as the anesthesia wore off, I was able to walk."

—Ed D., Birmingham, AL
coflex® device patient

Consult a doctor:

If you think or know you have spinal stenosis, contact a doctor to establish the causes and the current degree of the condition. **Or use our doctor locator online:**

Spinal Stenosis Surgery Options

Decompression surgery:

In a decompression, the doctor simply removes the impinging bone or soft tissue that is narrowing the spinal canal and causing you pain. If your stenosis is mild enough, decompression may be sufficient on its own.

However, in some cases, a decompression surgery may cause instability in the spine, as a result of the doctor's need to fully address your stenosis.

Decompression with fusion surgery:

For more severe cases of spinal stenosis, a doctor may opt for decompression with spinal fusion. This is when two or more of your lumbar bones are permanently "fused" together to provide stability.

Fusion surgery is invasive, and the recovery process can be lengthy and difficult. Also, because your bones are fused together, you have less overall mobility and flexibility.

Decompression with coflex®:

For moderate to severe cases of spinal stenosis, a doctor can now perform an open decompression followed by placement of coflex® through the same small incision. This non-fusion procedure is minimally invasive and has been available in the US since 2012.

Get back to: **whatever!**

Discuss your surgical options with your doctor, and be sure to ask for coflex® by name. It can help you get back to a life without pain, faster than fusion*. (Please note - every patient is different, and postoperative care and activity levels may vary.)

In a clinical study, 94% of patients were satisfied with their outcomes after two years.* Ask your doctor if you are a candidate for coflex®.



coflex®

Interlaminar Stabilization

Minimally invasive non-fusion
motion-preserving implant
for lumbar spinal stenosis

paradigmspine.com

As a patient, there is always potential risk in having surgery or when receiving a medical device. Usually these risks are rare and the coflex® Patient Labeling should be referred to for a list of all potential risks and hazards observed during the clinical study. For patients receiving coflex®, the risks included continued pain, wound healing problems (such as infection or drainage), brief numbness or tingling in the legs, and bone fractures. In some patients, coflex® may not help your pain, and you may need another surgery to remove the device. It is hard to predict who will not benefit from this surgery.

Please refer to the coflex® Patient Labeling or ask your doctor about all warnings, precautions, and who should be implanted with coflex®. The Patient Labeling or your doctor can provide a description of the risks and benefits of coflex® and the procedure, as well as clinical data showing that coflex® is in fact safe and effective.

Discuss your alternatives with your doctor and select the treatment method that best seems to meet your current pain level and lifestyle. This content is for educational purposes only and does not replace having a conversation with your doctor. Clinical cases are unique and individual results may vary.

This data is based on validated pain and function measurements from a randomized clinical study comparing coflex® Interlaminar Stabilization to pedicle screw fusion surgery for moderate to severe spinal stenosis. Every patient is different; therefore, results may vary.

*Claims based on FDA PMA P110008, October 2012. All data is on file.



PARADIGM SPINE



COMPANION
SPINE

Changing spine care for good.

WARNING: In the USA, this product has labeling limitations.
See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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