

# Get back to:

Non-fusion treatment for lumbar spinal stenosis



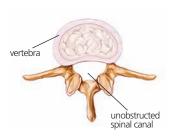
# Do you have any of these symptoms?

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.

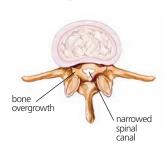
# Understanding the causes of spinal stenosis

## 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

To put it simply, 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 nerve, which runs down along the spinal canal, gets compressed. This pressure on the nerve causes the pain you feel in your buttocks, legs and/or lower back.



# **Treatment Options**

#### **Conservative treatment:**

 Pain medications, physical therapy, chiropractic treatment and epidural steroid injections

### **Surgical treatment:**

• Decompression surgery for mild cases

# New treatment option:

- coflex® device for moderate to severe spinal stenosis without instability.
  See next page for more details.
- Spinal fusion surgery for severe cases

# Consult a surgeon

If you think or know you have spinal stenosis, contact a surgeon to establish the causes and the current degree of the condition.

Or use our surgeon locator online: www.coflexsolution.com/surgeon-locator

Names listed on the surgeon locator consist of surgeons who have been trained and have recent experience using the *coflex*® Interlaminar Stabilization® device.



# A procedure you can live with.

**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, and with real relief from pain!

In an FDA 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 about *coflex*® by name!

As soon as the anesthesia wore off, !!

- Ed D., Birmingham, AL coflex® patient

# This is the shape of real relief.



The **coflex**® device is a small titanium implant that can help relieve the pain caused by spinal stenosis.

It's FDA approved and has 5 years of clinical evidence to support that it's a proven alternative to spinal fusion.

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



# What to do now:

#### If you're in pain but have not seen a surgeon:

Schedule an appointment with a spine surgeon, such as an orthopedist or a neurosurgeon, and explain your symptoms. You'll likely get x-rays and/or an MRI to accurately assess your condition.

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

# If you're in pain, have seen a surgeon, 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're in pain, and have tried conservative therapy treatments for at least six months with little or no improvement, it may be time for surgery.

# **Spinal stenosis surgery options:**

Spinal stenosis is a degenerative process, which means it won't get better over time. So, trying conservative care may help with the pain in the short term, but it will never treat the cause.

There are several surgical options to treat spinal stenosis. Consider the benefits and drawbacks of each:

# **Decompression surgery:**

In a decompression, the surgeon 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.

Drawbacks: sometimes, a decompression surgery may cause instability in the spine, as a result of the surgeon's need to fully address your stenosis.

# "A Randomized Trial of Epidural Glucocorticoid Injections for Spinal Stenosis." JL Friedly, MD. The New England Journal of Medicine. July 2014.

#### **Decompression with fusion surgery:**

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

Drawbacks: 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 surgeon can now provide decompression with the *coflex*® Interlaminar Stabilization® device. This non-fusion procedure is minimally invasive, and has 5 years of clinical evidence to prove that it works.

Drawbacks: **coflex**® may not be for everyone - it depends on the severity of your spinal stenosis, and how your surgeon views your condition.

# Get back to...whatever!

Discuss the 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 the FDA study, 94% of patients were satisfied with their outcomes after two years\*. Ask your doctor if you're a candidate for *coflex*<sup>®</sup>.

I feel like *coflex*® has given me **)**hope again.

 Laura, 38 years old coflex® patient



#### Risks

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, the *coflex*® device 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 the *coflex*® device. The Patient Labeling or your doctor can provide a description of the risks and benefits of the *coflex*® device and procedure, as well as clinical data showing that the *coflex*® device is in fact safe and effective.

Discuss your alternatives with your physician 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.

\*This data is based on validated pain and function measurements from a randomized FDA clinical study comparing *coffex*\* 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 at Paradigm Spine, LLC.

The only FDA approved device offering non-fusion, motion preserving interlaminar stabilization



www.coflexsolution.com