Get back to: *my life*

Non-fusion treatment for lumbar spinal stenosis

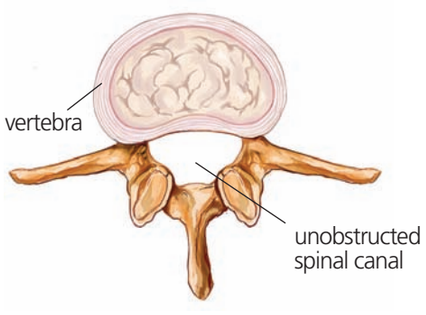
coflex®
Interlaminar Stabilization®

Understanding lumbar spinal stenosis

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.

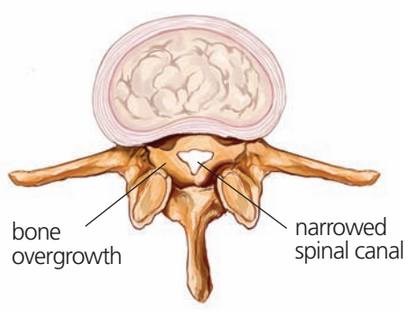
When any of these conditions occur, the spinal nerve, which runs down along the spinal canal, gets compressed. **This pressure on the nerve causes the pain you feel in your buttocks, legs and/or lower back.**

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.

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, and you know how uncomfortable it can be. Unfortunately, spinal stenosis is NOT a condition that gets better with time. In fact, it can only get worse.

Surgical treatment options

In some cases, spinal stenosis symptoms may be relieved through non-surgical options such as pain medication or injections, physical therapy or chiropractic care. If those methods are not successful, surgical options may need to be considered.

Spinal Stenosis Surgical Options	Benefits	Drawbacks
Decompression Through a small incision, the surgeon will remove the bone and soft tissue that are putting pressure on the spinal nerve, which will relieve your pain and its cause.	Minimally invasive, addresses stenosis, relieves leg pain.	Decompression may cause instability in the spine, as a result of the surgeon's need to fully address the causes of the pressure on your spinal nerve.
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.	Mimimally invasive, addresses stenosis, relieves leg and back pain, preserves motion in your spine.	***coflex***® may not be for everyone - it depends on the severity of your spinal stenosis, and how your surgeon views your condition.
Decompression with Spinal Fusion 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.	Addresses stenosis, relieves leg and back pain.	Fusion surgery is invasive, and the recovery process can be difficult. Because your bones are fused together, you have less overall mobility and flexibility.

Get back to: the outdoors

For decades, the surgical options for patients with lumbar spinal stenosis were limited to either decompression or decompression with spinal fusion. In 2012, the FDA approved the ***coflex***® Interlaminar Stabilization® device , a small U-shaped titanium implant that provides spinal stability without the invasiveness and loss of mobility associated with spinal fusion.

The *coflex*® device and procedure:
After the surgical decompression, which removes pressure on the impinged nerves, your surgeon will insert the ***coflex***® device through the same small incision. The device is positioned on the laminar bone, which is the strongest bone in the back of your spine.

The unique design of the ***coflex***® device maintains stability in the spine after direct surgical decompression while preserving more natural movement in the treated area.

FDA approved
The ***coflex***® device was studied and compared to pedicle screw fusion surgery after decompression in an FDA clinical trial. The ***coflex***® patients performed as well as, if not better than, fusion patients in many clinical measurements!*

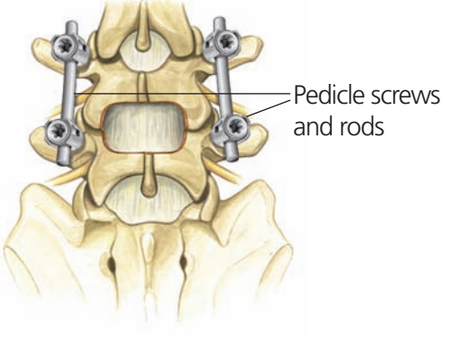
At five years, ***coflex***® patients were more satisfied with their outcomes compared to spinal fusion:
94% ***coflex***® vs 87% spinal fusion

At six weeks, ***coflex***® patients had faster relief of their symptoms compared to spinal fusion:
90% ***coflex***® vs 77% spinal fusion

At two years, ***coflex***® patients had lasting relief of their symptoms compared to spinal fusion:
94% ***coflex***® vs 87% spinal fusion

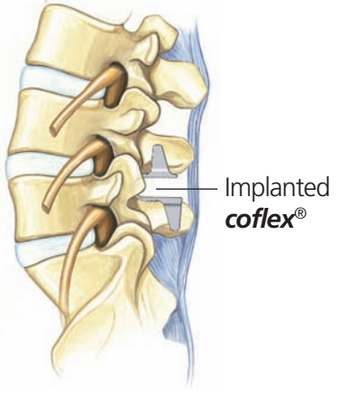
In comparative research vs. pedicle screw spinal fusion, the data demonstrates that *coflex*® patients do better, faster.

Pedicle Screw Spinal Fusion



Spinal fusion requires significant hardware to hold the two fused bones together.

coflex®



coflex® requires no hardware aside from the device itself.

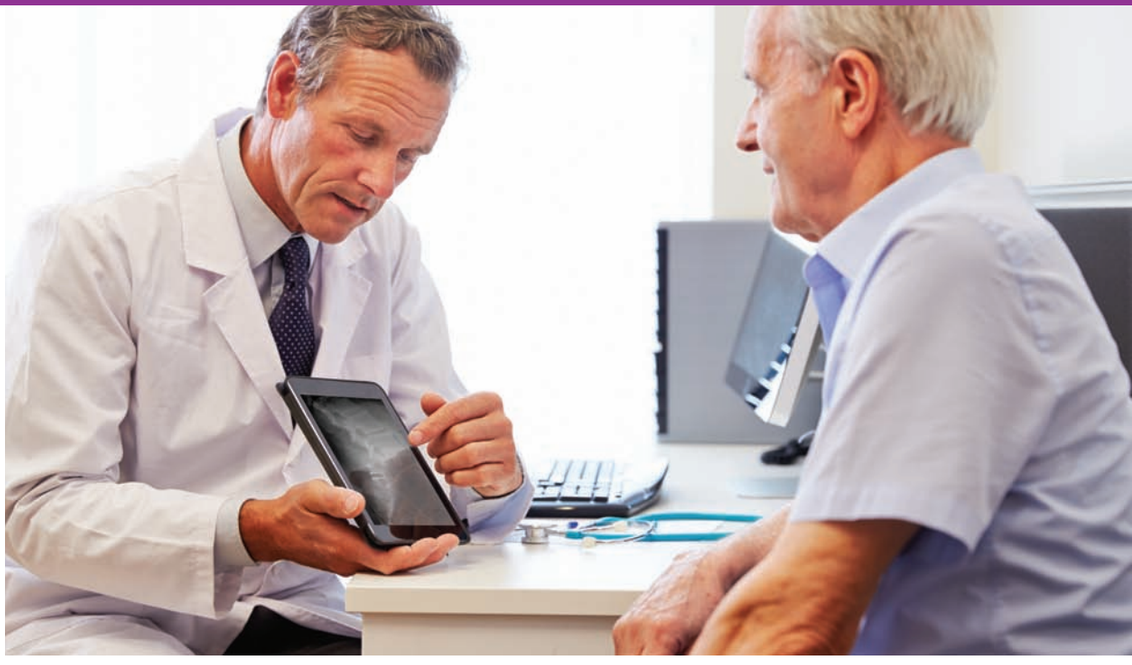
Decompression with the ***coflex***® device is faster than decompression with spinal fusion, causes less blood loss and requires a shorter hospital stay*. (See next page for comparison chart.)

coflex® advantages*

Spinal Fusion	VS.	*coflex*®
YES	FDA APPROVED	YES
4 PEDICLE SCREWS, 2 STABILIZATION RODS	TYPICAL HARDWARE	1 *coflex*® IMPLANT
180 MINUTES	AVERAGE SURGICAL TIME	98 MINUTES
350 CC	AVERAGE BLOOD LOSS	110 CC
3.2 DAYS	AVERAGE HOSPITAL STAY	1.9 DAYS
MUST WAIT FOR BONES TO FUSE (TYPICALLY 6 TO 12 MONTHS)	TYPICAL RECOVERY PROCESS	EFFECTIVE AS SOON AS SURGERY IS COMPLETE; MOST PATIENTS ARE UP AND WALKING THE SAME DAY

Is *coflex*® the right choice for me?
To be a candidate for decompression with the ***coflex***® device, you must be skeletally mature and must have moderate to severe spinal stenosis in your lower back. In order to receive the ***coflex***® device, you must have been treated by a doctor for at least six months with non-surgical treatments.

What to expect



On the day of surgery
Following a decompression, insertion of the ***coflex***® device is a relatively short procedure, so the length of your surgery will largely depend on the extent of the decompression. Most patients are under general anesthesia, so a short recovery period is necessary following the procedure. On average, the entire procedure, including decompression and implantation of the ***coflex***® device usually takes approximately 100 minutes°.

Immediately following surgery
When you wake from recovery, you may be encouraged to get up and walk nearly immediately, taking into consideration your overall health at the time of surgery. Since there is no fusion, and therefore no healing bone to wait for, you'll most likely be able to do this right after your procedure. You'll notice that your pain has been significantly relieved, and your spine should feel stable and strong. Most patients do need to wait several days following the surgery for the incision wound to heal°.

Weeks and months following surgery
In the weeks and months following surgery, your recovery depends on a number of factors, including the degree of your stenosis and the extent of the decompression that was performed. Most patients are able to return to normal activity, and even expanded activity such as golf, cycling, gardening and other activities, within weeks of the surgery. Some patients may require physical therapy to help with mobility and flexibility°.

coflex® frequently asked questions*

Get back to:
your favorite hobby

Even with a great deal of information, you may still have questions. Here are some of the more frequently asked questions about the ***coflex***® device and procedure and their answers:

How long will I have to stay in the hospital or surgery center?

Three out of four ***coflex***® patients in a clinical study left the hospital within 24-48 hours after surgery. In some cases, the surgeon may elect to perform the procedure in a surgery center, which means that some patients will not require a hospital stay.

Will I need pain medication following the surgery?

In some cases, patients have reported using pain medication to deal with post-surgery symptoms. Based on our clinical study, 85 out of 100 ***coflex***® patients had significant pain relief at six weeks post surgery compared to 68 out of 100 patients who had spinal fusion.*

Will I need physical therapy following surgery?

In some cases, your doctor may prescribe physical therapy to help you get back to an activity and mobility level that you can be comfortable with.

What will the pain in my legs and back be like following the surgery?

In almost all cases, your pain will be significantly relieved, because the cause of the stenosis will have been surgically remedied. Some patients do experience some pain at the site of the incision, but this usually subsides considerably in the days and weeks following surgery°.

How soon can I resume normal activity following surgery?

Depending on the extent of your decompression, your level of post-surgical physical activity may vary. The surgeon will likely ask you to come in for a follow-up visit approximately six weeks after your procedure. During those six weeks, the surgeon may ask you to limit your physical activity, based on various factors.

During the clinical study, walking during the first six weeks following surgery was usually acceptable and patients were allowed to travel and engage in light activity such as walking as soon as they felt they could.

It's important to remember that you have had a surgical operation. Always follow your surgeon's instructions on how much activity you can undertake and for how long°.

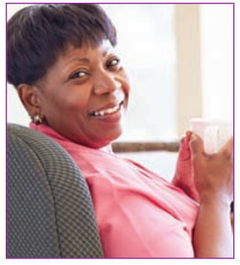
Will my *coflex*® implant set off metal detectors?

The metal that makes up the ***coflex***® device may affect MR Imaging and metal detectors. You should alert any technicians that you have a titanium device implanted in your spine. You should also consider making this declaration if you're traveling and have to pass through an electronic detection system°.

> "As soon as the anesthesia wore off, I was able to walk!"
>
> - Ed D., Birmingham, AL
> ***coflex***® patient

° Every patient is different; therefore results may vary. Your surgeon will advise you on a particular level of post-surgical activity that is right for you. This content does NOT replace having a conversation with your doctor.

Testimonials from *coflex*® patients†



"With ***coflex***®, I have my life back on track."

-Andrea, 48 years old

Andrea's story:
I had pain in my lower back and legs for eight years. There was so much pain that there was no freedom - I was very restricted. I thought that this was going to be my life, at 48 years old, a life of pain. And I decided 'no,' that's not what I wanted. ***coflex***® offered me the flexibility that I really equate to freedom. My doctor recommended the ***coflex***® surgery because he said I was too young to have fusion, and that ***coflex***® would give me my mobility, my freedom to do the things I normally did.

Once the surgery was complete I only stayed at the surgery center for an additional three hours. I was told that my recovery time would be three months, and believe it or not, in the first six weeks, I was up walking miles.

My family members, mostly my kids, see me and they see the glow now and they say "Mom, this is really working for you!" ***coflex***® has changed my life. I am happy, I am functional, I have flexibility, and I give all that thanks to ***coflex***®†.

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

-Laura, 38 years old

Laura's story:
I have had chronic back pain for years. Since I've had the ***coflex***® I'm able to bend over or lean down and I don't have intense pain in my back anymore. I'm able to move around, and I don't feel limited at all.

I was told that it will take about 8-10 weeks to be 100% recovered. I am currently at four weeks, and I feel almost completely normal again†.

† Quotes from actual ***coflex***® patients. Model portrayal of patient photo.
Every patient is different; therefore results may vary. This content does NOT replace having a conversation with your doctor.

Get back to: togetherness

"Since the ***coflex***® surgery, my life is completely different."

-Michael, 36 years old

Michael's story:
My recovery time was told to me that it would be anywhere from 3-6 months for a full recovery. The day of the surgery I was able to walk around my neighborhood that evening.

The biggest thing that I thought I'd never be able to do would be running after the surgery; I was very worried about it. I actually ran about four weeks after my surgery. I was released to be able to do any function I wanted six weeks after my surgery†.

† Quotes from actual ***coflex***® patients. Model portrayal of patient photo.
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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.

Get back to your life
with the only FDA approved device
offering non-fusion, motion preserving
interlaminar stabilization

coflex®
Interlaminar Stabilization®

www.coflexsolution.com

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 ***coflex***® 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.

*The data referenced in this brochure is based on validated pain and function measurements from a randomized FDA 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 at Paradigm Spine, LLC.