

Does the pain radiating down your legs, buttocks or lower back prevent you from walking long distances?

Do you experience weakness, tingling, numbness, stiffness, or cramping in your legs, buttocks or lower back, especially during physical activity?

Do you tend to lean on the shopping cart at the grocery store to help relieve your pain?

Is pain medication or physical therapy no longer effective?

The **coflex**[®] Solution could help patients like you with spinal stenosis become independent and functional again.



If you and your doctor are discussing various treatment options, consider the new non-fusion solution:

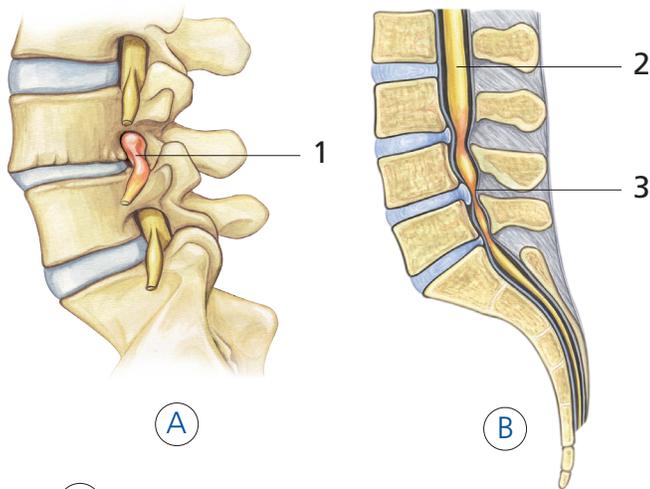


coflex[®]
Non-Fusion
Interlaminar Stabilization™

“The spinal stenosis treatment option that gets you walking again”

WHAT IS LUMBAR SPINAL STENOSIS?

Lumbar spinal stenosis is a narrowing of the spinal canal in your lower back. People who have spinal stenosis are not able to walk for long periods of time.



(A) Lateral Spinal Stenosis

1 – Pinched Nerve from Stenosis

(B) Central Spinal Stenosis

2 – Spinal Canal

3 – Stenosis

WHAT CAUSES LUMBAR SPINAL STENOSIS?

The most common cause of lumbar spinal stenosis is the “wear and tear” that occurs with the natural aging and degeneration process. As we age, the tissue in our lower spine that connects bones together (ligaments) may start to thicken and harden from arthritis, discs may start to collapse and bulge (or herniate), and bone spurs, known as osteophytes, may grow on bone in the spine. All of these things narrow the amount of space in the spinal canal, reducing the nerve’s ability to exit to your lower extremities. Therefore, the nerves in the lumbar spine become pinched, causing pain in the lower back, buttocks and legs. Pain is especially notable with physical activity or when walking, and may be relieved by sitting or leaning forward.

TREATMENT OPTIONS

Non-Surgical Treatment Options

Once your doctor has told you that you have spinal stenosis, treating the condition usually starts with non-surgical treatment options.

Non-surgical options include:

- Patient education
- Rest or restricted activity
- Weight loss
- Medication
- Chiropractic care
- Massage
- Acupuncture
- Physical therapy
- Exercise
- Injections

Surgical Treatment Options

If your pain cannot be controlled with non-surgical treatment options, a surgical procedure may help relieve you of your pain from spinal stenosis.

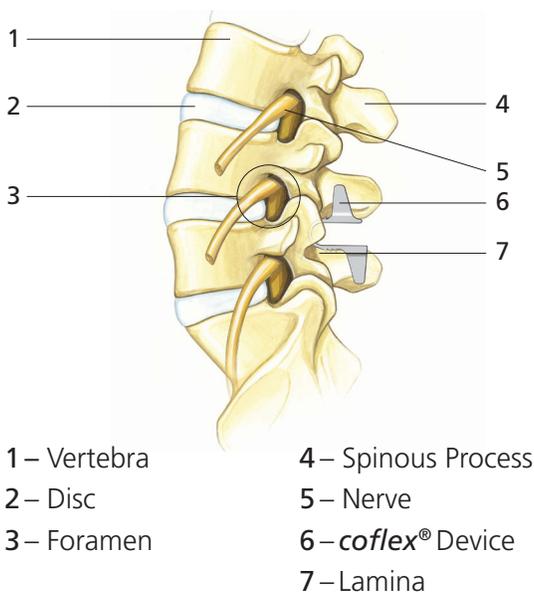
Surgical options include:

- **Decompression.** In a surgical decompression procedure, your surgeon removes the bone and soft tissue that is putting pressure on the nerves of your spinal canal.
- **Surgical Decompression with Spinal Fusion.** A surgical decompression procedure may cause the spine to become unstable. In this case, spinal fusion may be used to provide stability to your spine. The surgeon uses metal rods and screws to hold the bones in place while the vertebrae fuse together. The fusion stops the motion in that portion of your spine.
- **Surgical Decompression with *coflex*[®] Non-Fusion Interlaminar Stabilization™.** A surgical decompression procedure may cause the spine to become unstable. The *coflex*[®] Solution provides stability to your spine without the need to fuse your vertebrae bones together. The *coflex*[®] device is a metal implant that goes in the back of your spine after decompression to provide stability while maintaining the motion in your spine. The *coflex*[®] implant also helps keep normal height in the area where nerves leave the spine (foramen) so they can exit freely without being pinched.

WHAT IS **coflex**®?

The **coflex**® device is a small, titanium implant that goes in the back of your spine to treat moderate to severe spinal stenosis. After you receive anesthesia and are prepared for surgery, the surgeon makes a small incision in your back and performs a surgical decompression, which includes the removal of bone and soft tissue in and around your spine. This surgery takes the pressure off your nerves that are causing you pain.

The surgeon then inserts the **coflex**® device through the same incision until it is secured on the lamina bone, which is the strongest bone in the back of your spine.



HOW DOES **coflex**® WORK?

The **coflex**® device is specifically designed to help keep your spine stable after a decompression surgery. The **coflex**® device also maintains the normal height between your vertebral bones so your nerves can exit the foramen and extend to your lower extremities.

Also, the **coflex**® device doesn't fuse your vertebral bones together, so motion and natural movement are kept in your spine at the operated area, as well as in the neighboring parts of your spine. It is strong yet simple, and flexible enough to support your spine without having to fuse your bones together.

The **coflex® device allows your vertebral bones to move in a controlled way so the decompressed area is not unnaturally stiffened or fused!**

FDA TESTED AND APPROVED

The **coflex**® procedure was studied and compared to pedicle screw fusion surgery after decompression in a FDA clinical trial. The **coflex**® patients outperformed fusion patients in all clinical measurements!*

coflex® patients were more satisfied with their outcome

- 94% of **coflex**® patients were satisfied with their outcome, compared to 87% of fusion patients at two years

coflex® patients had faster relief of their symptoms

- 90% of **coflex**® patients had early relief of their spinal stenosis symptoms, compared to 77% of fusion patients at six weeks

coflex® patients had lasting relief of their symptoms

- 88% of **coflex**® patients had lasting relief of their spinal stenosis symptoms, compared to 78% of fusion patients at two years

coflex® surgeries were 36% faster compared to fusion surgeries (98 minutes vs. 153 minutes)

coflex® patients stayed one less day in the hospital compared to fusion patients (1.9 days vs. 3.2 days)

coflex® patients had less blood loss during surgery compared to fusion patients (110cc vs. 349cc)

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 arms or legs, and bone fractures. In some patients, the **coflex**® surgery 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.

This data is based on validated pain and function measurements from a randomized FDA clinical study comparing the **coflex® Interlaminar Technology to pedicle screw fusion surgery for moderate to severe spinal stenosis. Every patient is different; therefore, results may vary. All data is on file at Paradigm Spine, LLC.*

GLOSSARY

Anesthesia: A drug that blocks pain impulses from nerves. With general anesthesia you are unconscious, or asleep. With local anesthesia you are conscious, or awake.

coflex® Interlaminar Stabilization™

Device: A titanium implant that rests on the lamina and fits between the spinous processes; helps stabilize the spine.



Degenerative: Growing less healthy over time.

Degenerative Disc Disease: The natural wearing down of discs in the spine.

Foramen: A natural opening or passage in bone for nerves to exit the spinal canal.

Fusion: An operation to permanently join the vertebrae together.

Intervertebral Disc: Tissue found between the bones of the spinal column, called vertebrae. The discs help cushion the spine from stress during everyday activities.

Lateral: Situated on, directed toward, or coming from the side.

Ligament: A band of tissue linking two bones in a joint.

Lumbar: The lower part of the spine between the ribs and hipbones.

Nerves: Fibers that send messages between the brain and the rest of the body.

Nerve Compression: Pressure on a nerve; may cause nerve damage and muscle weakness.

Nerve Root: The start of the nerve as it leaves the spinal cord and passes through the foramen.

Osteophyte: A bony outgrowth on the edge of a vertebra, also known as a bone spur.

Spinal Canal: The bony channel that contains the spinal cord.

Spinal Cord: A bundle of nerves that carries messages between the brain and the rest of the body.

Spinal Stenosis: A degenerative spinal disease that causes narrowing of the spinal canal.

Spinous Process: A part of the vertebra. A spinous process protrudes from each vertebra. The spinous processes create the “bumps” you feel in the middle of your back.

Vertebra: A bone of the spinal column. There are five lumbar vertebrae.



coflex[®]



The only FDA approved device offering
non-fusion Motion Preserving Interlaminar Stabilization™
after a surgical decompression for moderate to severe spinal stenosis

Please refer to the FDA 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[®]** 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.

For more information please visit our patient website at www.coflexsolution.com

GET STARTED WITH THE **coflex**[®] SOLUTION

FIND A **coflex**[®] SURGEON NEAR YOU

There are over 500 qualified surgeons who have been trained on The **coflex**[®] Solution procedure. Visit the Surgeon Locator on our website today at www.coflexsolution.com/surgeon-locator.

CALL THE **coflex**[®] SOLUTION CENTER

The **coflex**[®] Solution Center is open Monday through Friday, 9am to 5pm EST. Call and speak to a **coflex**[®] expert today. 1-855-5-COFLEX

LEARN MORE ABOUT THE **coflex**[®] DATA

The **coflex**[®] device was studied and compared to pedicle screw fusion surgery after decompression in a FDA clinical trial. See where **coflex**[®] patients outperformed fusion patients by visiting www.coflexsolution.com/coflex-data.



PARADIGM SPINE

the movement in spine care

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