

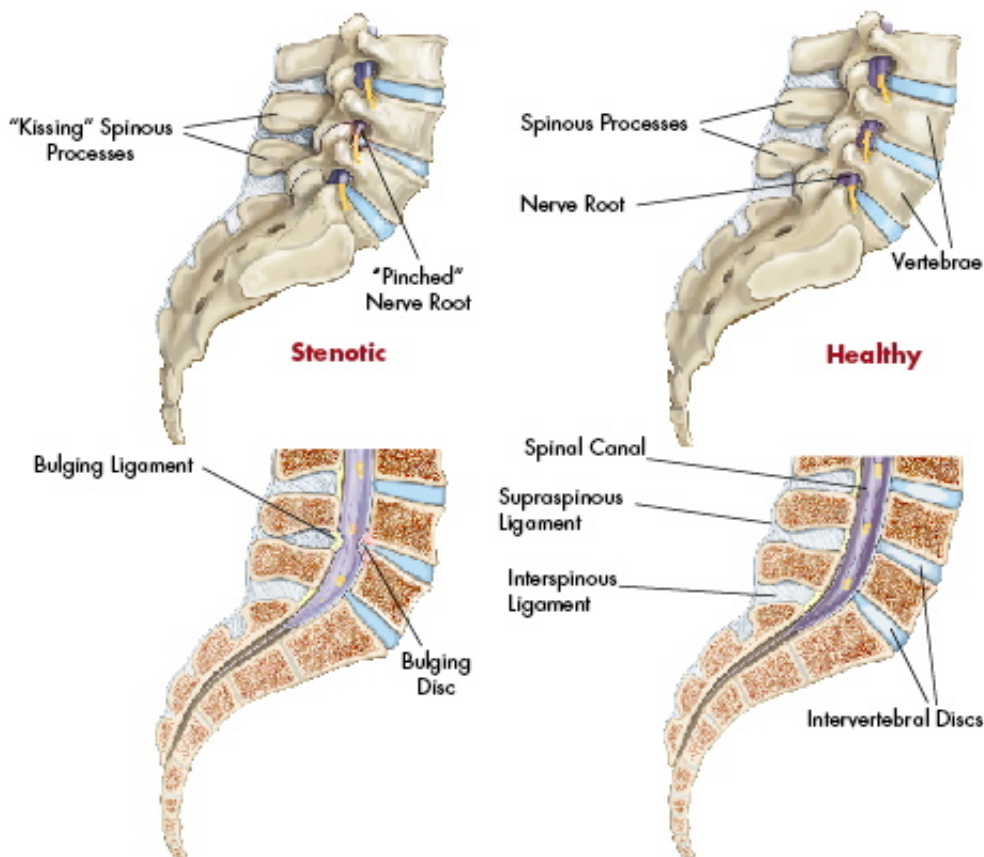
X Stop Spinal Stenosis Decompression

Am I a candidate for X Stop spinal surgery?

You may be a candidate for the X Stop spinal surgery if you have primarily leg pain rather than mostly back pain and your pain is due to spinal stenosis/ foraminol stenosis. Your leg pain is worse with prolonged standing and bending backwards. You must get significant relief of your pain when you sit down and bend forward or stand and bend forward.

What is Spinal Stenosis ?

Spinal stenosis is a narrowing of the spinal canal. Some patients are born with this narrowing, but most often spinal stenosis is the result of a degenerative condition that develops in people over the age of 50. Spinal stenosis is the gradual result of aging and “wear and tear” on the spine from everyday activities. Degenerative or age-related changes in our bodies can lead to compression of nerves (pressure on the nerves that may cause pain and/or damage).



As we age:

- the ligaments of the spine can thicken and calcify (harden from deposits of calcium)
- bones and joints may also enlarge
- bone spurs, called osteophytes, may form
- discs may collapse and bulge (or herniate)
- one vertebra may slip over another (called spondylolisthesis)

Symptoms of Spinal Stenosis



If you suffer from lumbar spinal stenosis you may feel various symptoms, including:

- dull or aching back pain spreading to your legs
- numbness and “pins and needles” in your legs, calves or buttocks
- weakness, or a loss of balance, and
- a decreased endurance for physical activities



Symptoms increase after walking a certain distance or standing for a time. Symptoms can

improve when you:

- sit
- bend or lean forward (see Figure below)
- lie down, or
- put your foot on a raised rest

Diagnosing Lumbar Spinal Stenosis

Before confirming a diagnosis of stenosis, it is important for your doctor to rule out other conditions that may produce similar symptoms. In order to do this, most doctors use a combination of techniques, including:

- History - Your doctor will begin by asking you to describe any symptoms you have and how the symptoms have changed over time. Your doctor will also need to know how you have been treating these symptoms, including medications you have tried.
- Physical Examination - Your doctor will then examine you and check for any limitations of movement in your spine, problems with balance, and signs of pain. Your doctor will also look for any loss of reflexes, muscle weakness, sensory loss, or abnormal reflexes.
- Tests - After examining you, your doctor may use a variety of tests to confirm the diagnosis. Examples of these tests include:
 - X-ray - shows the structure of the vertebrae and the outlines of joints.
 - MRI (Magnetic Resonance Imaging) - provides a three-dimensional view of our back and can show the spinal cord, nerve roots, and surrounding spaces, as well as signs of degeneration, tumors or infection.
 - CAT Scan (Computerized Axial Tomography) - depicts the three-dimensional shape and size of your spinal canal and bony structures surrounding it.
 - Myelogram - highlights the spinal cord and nerves after a dye is injected into your spinal column, which appears white on an X-ray film

Precaution: Radiological evidence of stenosis must be correlated with your symptoms before the diagnosis can be confirmed.

Treatment Options

Once a diagnosis of spinal stenosis is confirmed, the process of treating the condition usually begins with a regimen of non-invasive, “conservative” therapy.

Non-surgical Treatment of spinal stenosis

There are a number of ways a doctor can treat stenosis without surgery, including:

- Medications, such as non-steroidal anti-inflammatory drugs (NSAIDs) to reduce swelling and pain, and analgesics to relieve pain.
- Corticosteroid injections (epidural steroids) to reduce swelling and treat acute pain that radiates to the hips or down the leg. Pain relief from an epidural injection may be temporary and patients are usually advised to get no more than 3 injections per 6-month period.
- Rest or restricted activity.
- Physical therapy and/or exercises to help stabilize the spine, build endurance and increase flexibility.

While some patients obtain relief from symptoms with these treatments, others do not.

Surgical Treatment of spinal stenosis

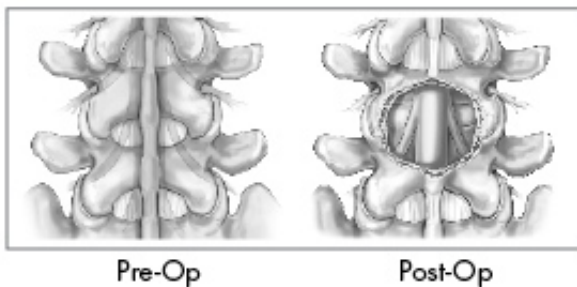
Decompression

Non-surgical treatments may temporarily relieve pain. More severe cases of stenosis may require surgery.

The most common surgical procedure for stenosis is a decompressive laminectomy sometimes accompanied by fusion. Often referred to as “unroofing” the spine, this procedure involves the removal of various parts of the vertebrae, including:

- the lamina, as well as the attached ligaments, that cause compression of the spinal cord and nerve roots, and/or
- enlarged facets, osteophytes and bulging disc material

The goal of the surgery is to relieve pressure on the spinal cord and nerves by increasing the area of the spinal canal and neural foramen.



Other types of surgery to treat stenosis include:

- Laminotomy - only a small portion of the lamina is removed to relieve local pressure on the spinal cord and nerve roots.
- Foraminotomy - the foramen (the opening through which the nerve roots exit the spinal canal) is enlarged to increase space for the nerves. This surgery can be done alone or with a laminotomy.
- Facetectomy - part of the facet joint is removed to increase space for the nerves

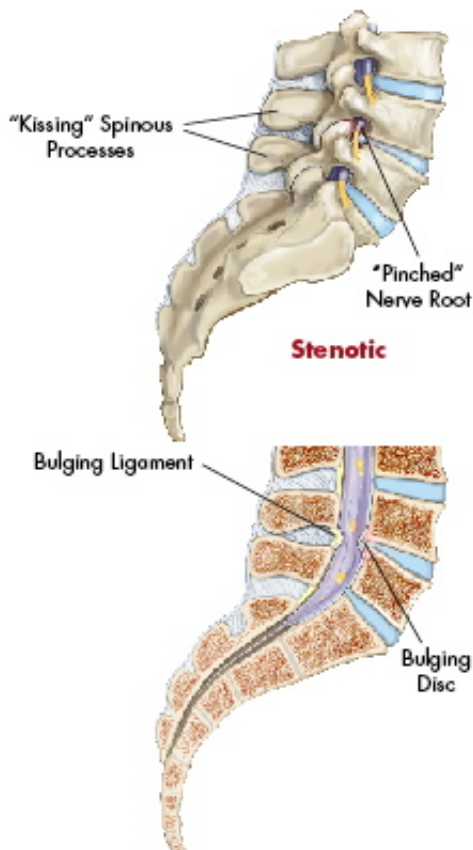
What is the X STOP®?



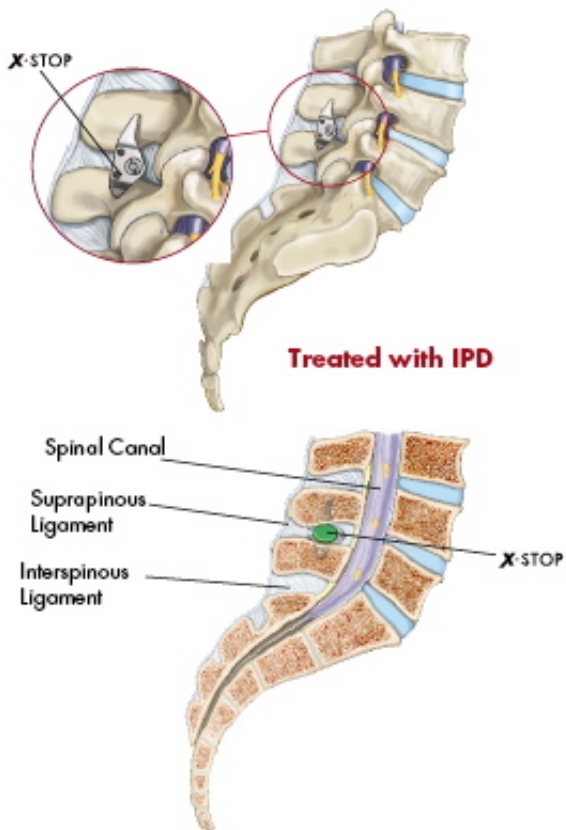
The X STOP is a titanium metal implant designed to fit between the spinous processes of the vertebrae in your lower back. It is designed to remain safely and permanently in place without attaching to the bone or ligaments in your back. The oval spacer fits between the spinous processes and the wings are designed to prevent the implant from moving. Warning: The X STOP implant is manufactured from a titanium alloy of metal. Please inform your doctor if you think you are allergic to titanium or titanium alloy. Caution: The X STOP is manufactured from a titanium alloy which is known to produce artifacts if you undergo an MRI exam. If you have an MRI exam, after you have had X STOP surgery, inform your doctor that you have the X STOP. Failure to inform your doctor may affect the quality of diagnostic information obtained from these scans. The X STOP is MRI safe.

What is IPD®?

Interspinous Process Decompression (IPD) IPD is a surgical procedure in which an implant, called the X STOP®, is placed between two bones called spinous processes in the back of your spine.



With IPD surgery or x-stop spinal stenosis surgery there is no removal of bone or soft tissue. The X STOP implant is not positioned close to nerves or the spinal cord, but rather behind the spinal cord between the bony spinous process.



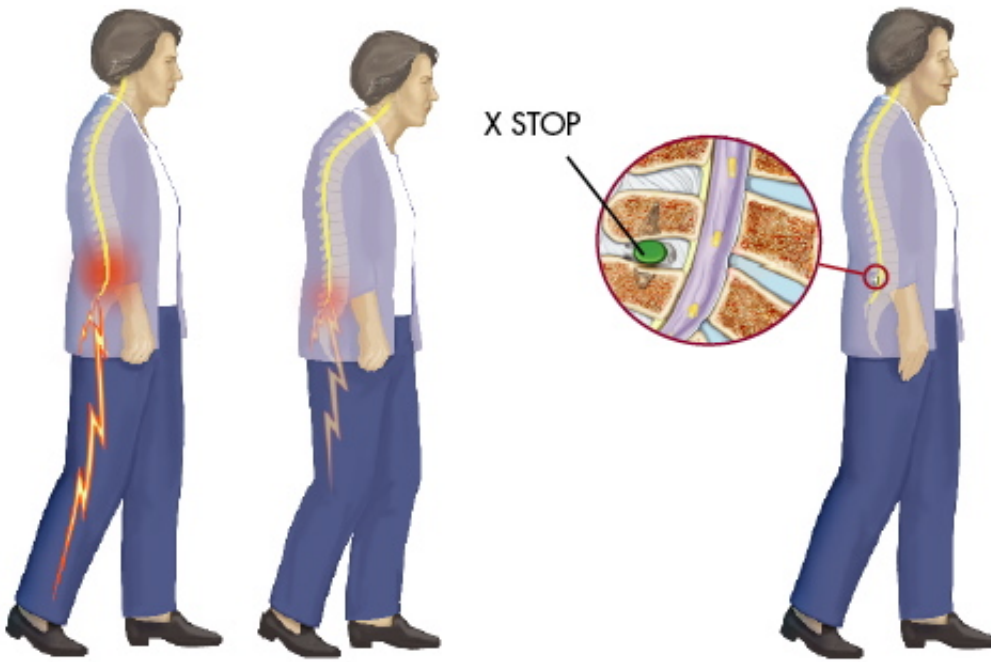
The X STOP® procedure

The x-stop spinal surgery procedure may be performed in either the operating room or special procedures room at the hospital. Using local anesthesia and with the help of X-ray guidance, the X STOP implant is inserted through a small incision in the skin of your back. Alternatively, your surgeon may elect to use general anesthesia.

You will be placed on your side during the procedure so that you can bend your spine when the X STOP is inserted. The surgery to implant the X STOP typically lasts 45 minutes to an hour-and-a-half. During this time you may be awake and able to communicate with your doctor.

Why may X STOP® IPD work?

The X STOP implant is designed to keep the space between your spinous processes open, so that when you stand upright the nerves in your back will not be pinched or cause pain. With the X STOP implant in place, you should not need to bend forward to relieve your symptoms.



IPD offers several benefits compared to traditional surgery for lumbar spinal stenosis, including:

- the option of local anesthesia
- the potential to be an outpatient procedure
- usually no removal of bone or soft tissue allowing for potentially quicker recovery
- fully reversible procedure that does not limit any future non-surgical and surgical treatment options
- the implant can be removed
- virtually no chance of dural tear or neurologic complication
- does not create instability
- insignificant blood loss

X STOP® IPD®: Clinical Study Results

The X STOP IPD System was tested in a carefully controlled research study that took place in nine hospitals across the United States. In this study, 100 patients with lumbar spinal stenosis had x-stop spinal surgery with the X STOP device. These patients were compared to 91 patients who did not have surgery, but were treated by their doctors in other ways (for example, with medications, corsets, physical therapy, etc.).

Approximately half of the patients who received the X STOP device in this two-year research study experienced a degree of pain relief and ability to increase their activity levels that was sufficient to be considered a successful outcome at two years after the surgery. The clinical benefit beyond two years has not been measured.

The likelihood of needing an additional operation during the study was low. During the study, 6% of patients did not have a satisfactory treatment outcome and decided to have a laminectomy operation (removal of part of the vertebra in the spine), at which time the X STOP was removed. In addition, the implant dislodged (moved out of proper position) in one patient after a fall, and the

implant was later removed. A second operation was also required in three other X STOP patients for the following conditions: drainage of a collection of blood, drainage of fluid around the wound, and removal of damaged tissue with secondary closure of the wound (allowing the wound to close on its own). Overall, 90% of patients had significant improved clinical outcome with visual analogue pain scale (VAS), Oswestry disability score/index (ODI), were achieved.

4 Year Update of IPD Clinical Results

Abstract: X-STOP is the first interspinous process decompression device that was shown to be superior to nonoperative therapy in patients with neurogenic intermittent claudication secondary to spinal stenosis in the multicenter randomized study at 1 and 2 years. We present 4-year follow-up data on the X-STOP patients. Patient records were screened to identify potentially eligible subjects who underwent X-STOP implantation as part of the FDA clinical trial. The inclusion criteria for the trial were age of at least 50 years, leg, buttock, or groin pain with or without back pain relieved during flexion, being able to walk at least 50 feet and sit for at least 50 minutes. The exclusion criteria were fixed motor deficit, cauda equina syndrome, previous lumbar surgery or spondylolisthesis greater than grade I at the affected level. Eighteen X-STOP subjects participated in the study. The average follow-up was 51 months and the average age was 67 years. Twelve patients had the X-STOP implanted at either L3-4 or L4-5 levels. Six patients had the X-STOP implanted at both L3-4 and L4-5 levels. Six patients had a grade I spondylolisthesis. The mean preoperative Oswestry score was 45. The mean postoperative Oswestry score was 15. The mean improvement score was 29. Using a 15-point improvement from baseline Oswestry Disability Index score as a success criterion, 14 out of 18 patients (78%) had successful outcomes. Our results have demonstrated that the success rate in the X-STOP interspinous process decompression group was 78% at an average of 4.2 years postoperatively and are consistent with 2-year results reported by Zucherman et al previously and those reported by Lee et al. Our results suggest that intermediate-term outcomes of X-STOP surgery are stable over time as measured by the Oswestry Disability Index.

Extract from the following article:

Interspinous Process Decompression With the X-STOP Device for Lumbar Spinal Stenosis

A 4-Year Follow-Up Study

Dimitriy G. Kondrashov, MD, Matthew Hannibal, MD, Ken Y. Hsu, MD, and James F. Zucherman, MD