



## **X-STOP Spacer**

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Back and leg pain from lumbar spinal stenosis (LSS) occurs when the space between the vertebrae is reduced, causing bone or tissue to come in contact with the spinal nerve. Most people with LSS get relief from pain when they bend forward or sit down. That's because this position opens the space around the pinched nerve. The X-STOP Spacer uses this principle and can provide sustained relief—even when you stand up straight and walk.

### **Lifting the pressure off of pinched nerves relieves pain**

The X-STOP Spacer (figure 1 and 2) is a small implant that fits between two bones in the back of your spine - at the level of the pinched nerve. You can feel these bones, called the spinous processes, when you run your fingers down your spine. Once in place, the X-STOP Spacer can lift the vertebra off the pinched nerve.



Figure 1. X-Stop Spacer.

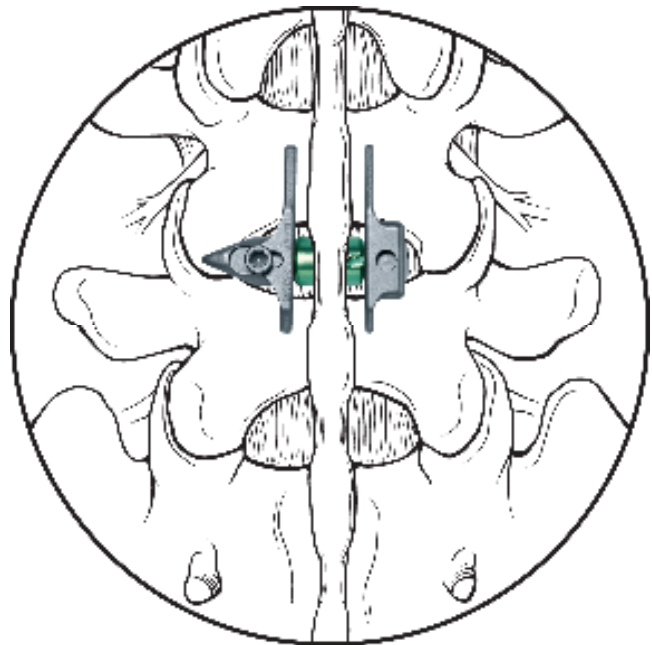


Figure 2. Posterior view of X-Stop.

### **Sustained pain relief—even when you stand and walk**

The unique X-STOP Spacer is designed to stay safely and permanently in place without being attached to bone or ligaments, by screws or other hardware, and there's no fusion involved. It works with your spinal anatomy to keep the space around the nerve open - and can relieve your pain and other symptoms - even when you stand up straight and walk. With the X-STOP Spacer you should not need to bend forward to relieve your symptoms.

The X-STOP Spacer may relieve the kinds of pain and discomfort caused by LSS:

- Dull or aching back pain that travels to your legs
- Numbness and a pins-and-needles sensation in your legs, calves, or buttocks

### **Short recovery and rapid pain relief**

The X-STOP Spacer is implanted during a short procedure - typically 45 to 90 minutes. In some patients, it can be performed on an outpatient basis and with local anesthesia, which is an especially important benefit for people who should avoid general anesthesia due to their age or other health conditions. However, this is usually performed with general anesthesia and the patient spends the night in the hospital. You and your surgeon will decide what's best for you.

The X-STOP procedure is minimally invasive. It's not like traditional surgery, such as a laminectomy, which removes structurally important bone (lamina) and tissue (ligaments that connect the vertebrae). The X-STOP Spacer preserves your anatomy and your spinal stability. That's why it may offer a short recovery time and a low complication rate. And the spacer is not positioned close to nerves or the spinal column, but rather behind the spinal cord between the spinous processes.

### **Is the X-STOP Spacer right for you?**

The X-STOP Spacer is indicated for patients aged 50 or older suffering from lumbar spinal stenosis (LSS). A diagnosis of LSS should be confirmed by a doctor with X-ray, MRI, or CT scans. The X-STOP Spacer is indicated for patients with moderately impaired ability to function, who experience relief from their pain symptoms when bending forward. Patients receiving the X-STOP Spacer should have been on a regime of nonsurgical treatment for their symptoms for at least six months. The X-STOP Spacer may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels. At times this is performed in conjunction with other minimally invasive procedures.

If you can answer yes to all of the following four statements, you may be eligible for the X-STOP Spacer.

- I am 50 years of age or older.
- I have been diagnosed with and suffer from the symptoms of LSS.
- My pain is relieved when I sit down or lean forward.
- I have been in treatment for LSS for at least 6 months.

### **The X-STOP Spacer should not be used if you have:**

- An allergy to titanium or titanium alloy
- Spinal anatomy that would prevent placement of the device or cause the device to be unstable in your body
- Cauda equina syndrome, which is a spinal nerve compression that causes groin numbness, bowel and/or bladder dysfunction
- Osteoporosis with fragility fracture
- A current infection

## **Postoperative care**

The X-STOP Spacer may offer a short recovery, and pain relief may be rapid. You may be able to walk the same day and be discharged from the hospital within 24 hours.

As with any surgery, you may feel some soreness after the procedure. Your doctor will discuss the need for appropriate medications based on your level of discomfort.

Following the procedure, physical therapy may be recommended and your doctor may ask you to return for an examination approximately 6 weeks later. You may also be advised to avoid strenuous activity, but light activities and travel should be okay. Walking is usually acceptable as long as it is comfortable and does not exceed one hour in duration.

You may be asked to limit physical activities such as:

- Bending backward
- Heavy lifting
- Climbing stairs
- Sports like swimming, golf, tennis, racquetball, running, and jogging

Most normal physical activities can be resumed with your doctor's recommendation within 2 to 6 weeks after the procedure. In order to fully recover from the procedure, it's important to follow your doctor's directions carefully.

If you're planning to have other diagnostic procedures (such as an MRI) or treatments, be sure to tell your doctor and dentist that you've had the X-STOP Spacer procedure.

## **Possible Complications**

Complications that may be associated with the X-STOP Spacer procedure include, but are not limited to, the following: Implant dislodgement (movement out of place); implant not positioned correctly; fracture of the spinous process; foreign body reaction (ex. allergic reaction); additional surgery, which could include removal of the X-STOP implant; mechanical failure of the implant.

## **Conclusion**

Patients treated with the X-STOP Spacer demonstrated superior outcomes to patients treated with nonsurgical therapies, such as epidural steroid injections, pain medications, and physical therapy.

It is also important to note that the X-STOP Spacer provided patients with rapid relief of symptoms. Most patients who receive nonsurgical treatment do not experience sustained symptom relief, which means that patients need to continue a regimen of epidural steroid injections, pain medications, and physical therapy to maintain symptom relief.

If you are looking for sustained pain relief, or if you're tired of ongoing treatment and the side effects of pain medications, the X-STOP Spacer may offer an effective alternative to relieve your painful symptoms.