

## X-STOP DECOMPRESSION

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 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.

### 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

The X-STOP Spacer works with your anatomy to stay in place. Unlike other spine surgeries, nothing is attached to bone or ligament and the procedure does not result in spinal fusion.

### 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. This is an especially important benefit for people who should avoid general anesthesia due to their age or other health conditions. You and Dr. Chang 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.

Major surgery, like a laminectomy, removes parts of your vertebrae and ligaments that protect and stabilize your spine. The X-STOP procedure preserves your spinal anatomy. [Learn more about major surgeries.](#)

## Clinical results: safety and effectiveness

The X-STOP Spacer is the first interspinous spacer shown to be superior to nonsurgical treatment in patients with [neurogenic intermittent claudication](#) (NIC) due to lumbar spinal stenosis (LSS).

The FDA approved the X-STOP Spacer using data from a 2-year, multicenter, randomized, controlled study. Research took place in 9 hospitals across the United States. In this study, 100 patients with LSS were implanted with the X-STOP Spacer. This group was compared with 91 patients who received nonsurgical treatment (epidural injections, pain medications, physical therapy, etc.) by their doctors.

The X-STOP Spacer was shown to be superior to nonsurgical care based on: device performance measures, need for additional surgery for LSS, and the Zurich Claudication Questionnaire (ZCQ). The following information details these criteria and summarizes results from additional analyses of the clinical study data.

### X-STOP Spacer device performance

Assessment of the X-STOP Spacer 2 years after implantation demonstrated:

- 84% maintenance of distraction (maintenance of the space between spinal segments as viewed by X-ray)
- 96% no dislodgement of the implant
- 94% absence of implant-related complications

### Need for additional surgery for LSS

After 2 years, 93% of patients who received the X-STOP Spacer did not require any additional surgery for LSS.

### ZCQ success

Patients involved in the clinical study were required to complete a questionnaire with specific questions about their treatment experience. The questionnaire, called the Zurich Claudication Questionnaire, is an international standard that has been scientifically validated to measure specific aspects of NIC due to LSS. Because the questionnaire is patient-completed, it is able to measure the patients' perspectives in regard to their outcomes.

Patients treated with the X-STOP Spacer reported superior improvement in all three categories: pain, function, and satisfaction.

ZCQ domains	X-STOP Spacer	Nonsurgical treatment
Reduction in pain	64%	17%

Improvement in function	66%	17%
Patient satisfaction	73%	24%
ZCQ success	56%	6%

## Overall success

For each patient in the indicated population (X-STOP Spacer = 73 patients, Nonsurgical = 66 patients), a combined score was evaluated using device performance, need for additional surgery for LSS, and ZCQ. To be considered an overall clinical success, an X-STOP patient must achieve success in all 7 criteria. The results show 8 times as many patients experienced clinical success when treated with the X-STOP Spacer as compared with patients who were treated only with nonsurgical care.

## Additional outcomes

Additional assessments of the clinical trial data show that the X-STOP Spacer:

- Decreases leg pain.
- Improves quality of life.
- Improves pain and disability.
- **Decreased leg pain**

A scientifically recognized statistical analysis called the *Fisher exact test* was used to compare back and leg pain frequency and severity scores between the X-STOP Spacer patient group and the nonsurgical patient group.

At 24 months, mean back and leg pain scores in the X-STOP Spacer group were significantly less frequent and less severe while sitting, standing, or walking as compared with the nonsurgical group.

Comparison of the *mean improvement* showed:

- The X-STOP Spacer group had significantly greater improvement in frequency and severity of back pain while standing and walking than the nonsurgical group.
- There was no significant difference in improvement scores for back pain while sitting between the two groups.
- The X-STOP Spacer group had a significantly greater improvement in the frequency and severity of leg pain while sitting, standing, or walking at 24 months than the nonsurgical group.

## Improved quality of life

SF-36 is a patient health survey questionnaire for measuring quality of life. SF stands for short form, and 36 refers to the fact that it has 36 questions. The SF-36 is a widely used scientific tool in clinical studies because it provides comparisons across a broad range of medical conditions and therapies. Well-designed, prospective clinical studies typically include both a condition-specific survey (such as the ZCQ) to assess the direct benefit of the treatment, as well as a general health survey like the SF-36, to assess the overall benefits provided by the treatment.

The results of the 2-year study demonstrated that the X-STOP Spacer is significantly more effective at improving the quality of life in patients with LSS than nonsurgical treatment.[7](#)

### Improved pain and disability

The study described above demonstrated greater ZCQ success in patients receiving the X-STOP Spacer.

Another commonly used and recommended tool for assessing the disabling effects of LSS is the Oswestry Disability Index (ODI). This assessment allows patients to measure pain intensity, personal care (washing, dressing), standing, sleeping, lifting, sex life, sitting, social life, and walking.

A 10-point improvement in ODI is considered clinically significant. One center of the X-STOP Spacer study measured ODI in 18 patients for 4 years. The ODI score for X-STOP Spacer patients showed a mean improvement of 29 points.[10](#)

The authors used more strict criteria (15-point improvement) and long follow-up (4 years) to determine success. This study showed that 78% of the X-STOP Spacer patients had a successful outcome.

### 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.[16](#)

It is also important to note that the X-STOP Spacer provided patients with rapid relief of symptoms.[16](#) 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.

The X-STOP Spacer provides another option for patients who are unsatisfied with nonsurgical care.