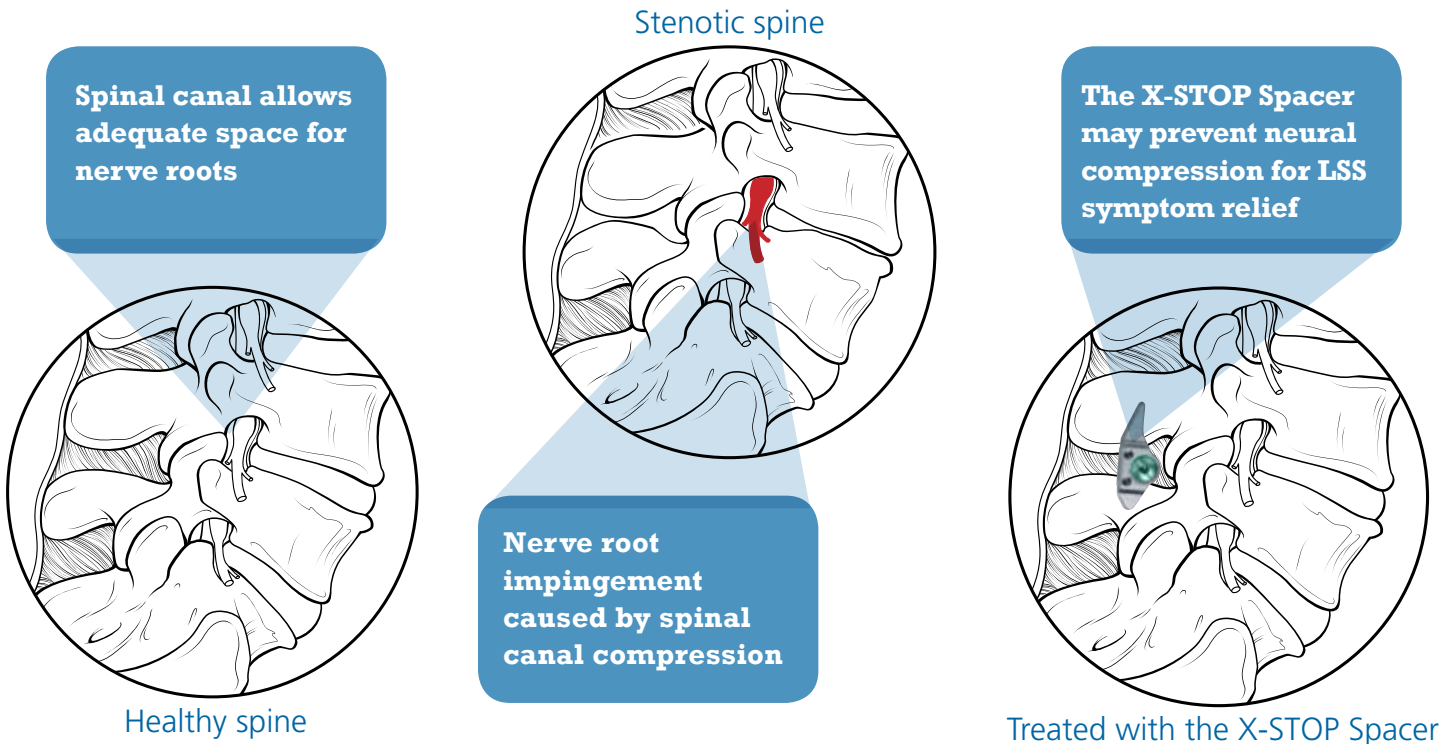


INFORMATION FOR YOUR DOCTOR ABOUT THE X-STOP® SPACER

For symptoms of lumbar spinal stenosis (LSS)

The FDA-approved X-STOP Spacer can provide safe, effective, and sustained relief from the painful symptoms of LSS. For the right LSS patient, the X-STOP Spacer presents an appealing alternative to major surgery.



A simple solution

The X-STOP Spacer limits extension of the stenotic segment, which may prevent nerve root impingement, without altering spinal anatomy. The small implant fits between two spinous processes at the compressed disc level and stays in place without being attached to bone or ligaments. Decompression may be achieved without cutting or removing structurally important bone or tissue, such as lamina and ligaments.

Superior to nonsurgical care

A 2-year clinical study compared the treatment success of the X-STOP Spacer with nonsurgical therapy (epidural steroid injections, pain medications, physical therapy, etc.). The study showed that the X-STOP Spacer was clinically proven to treat the

major symptoms of lumbar spinal stenosis, by reducing pain and improving physical function, resulting in increased patient satisfaction and leading to overall treatment success.¹

An alternative to major back surgeries

The X-STOP Spacer procedure provides:

- The option to use local anesthesia
- Potential to be performed as an outpatient procedure
- Preservation of the normal bone anatomy
- Potential for a short recovery time

Over 30,000 X-STOP Spacer procedures have been performed worldwide

Who is the X-STOP Spacer indicated for?

- Aged 50 years or older
- Confirmed diagnosis of neurogenic intermittent claudication secondary to LSS
- Experiences symptom relief in flexion
- Has completed 6 months of nonsurgical treatment
- Operative treatment indicated at one or two lumbar levels

For a list of surgeons who perform the X-STOP Spacer procedure, visit XSTOPSPACER.com, or call **1-888-978-6711**.

REFERENCE

1. X-STOP® IPD® System Summary of Safety and Effectiveness, 2005.



Indications for Use: The X-STOP Spacer is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with X-ray, MRI, and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal narrowing). The X-STOP Spacer is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of nonoperative treatment. 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.

Contraindications: The device is contraindicated in patients with: an allergy to titanium or titanium alloy; spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as: significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4), an ankylosed segment at the affected level(s), acute fracture of the spinous process or pars interarticularis, and significant scoliosis (Cobb angle greater than 25 degrees); cauda equina syndrome, defined as neural compression causing neurogenic bowel or bladder dysfunction; diagnosis of severe osteoporosis,

defined as bone mineral density (from DEXA scan or some comparable study) in the spine or hip that is more than 2.5 SD below the mean of adult normals in the presence of one or more fragility fractures; and active systemic infection or infection localized to the site of implantation.

Warnings: The X-STOP Spacer must be placed in the concavity between the spinous processes. Posterior positioning of the implant may result in dislodgment. If correct placement of the implant cannot be achieved due to variant anatomy, the surgeon should consider aborting the procedure because incorrect placement may result in device dislodgment, particularly if the patient experiences a traumatic event.

Precautions: Radiological evidence of stenosis must be correlated with the patient's symptoms before the diagnosis can be confirmed; if the spinous processes at the affected level are not distracted in flexion, the X-STOP Spacer may not be indicated; the safety and effectiveness of the X-STOP Spacer has not been studied in patients with the following conditions: axial back pain without leg, buttock, or groin pain, symptomatic lumbar spinal stenosis at more than two levels, prior lumbar spine surgery, significant peripheral neuropathy, acute denervation secondary to radiculopathy, Paget's disease, vertebral metastases, morbid obesity, pregnancy, a fixed motor deficit, angina, active rheumatoid arthritis, peripheral vascular disease,

and advanced diabetes or any other systemic disease that may affect the patient's ability to walk; surgeons should not implant the X-STOP Spacer until receiving adequate training regarding surgical technique because inadequate training may result in poor patient outcomes and/or increased rates of adverse events; and a stress fracture of the spinous process may occur if strenuous physical activity is resumed too soon postoperatively.

Potential Adverse Events: The following potential adverse events may occur as a result of interspinous process decompression with the X-STOP Spacer; some of these adverse events were reported in the Pivotal Clinical Trial. X-STOP system related: implant dislodgment/migration; implant not positioned correctly; fracture of the spinous process; additional surgery, which could include removal of the X-STOP implant; foreign body reaction; mechanical failure of the device; failure of the device/procedure to improve symptoms and/or function. Surgery related: reactions to anesthesia; myocardial infarction; infection; blood vessel damage/bleeding; deep vein thrombosis; hematoma; pneumonia; neurological system compromise; stroke; nerve injury or spinal cord damage; paralysis; thrombus formation; wound dehiscence or delayed healing; pain/discomfort at the operative site; and death. Note: Medication or additional surgery may be necessary to correct some of these potential adverse events.