



Medtronic, Inc.
1221 Crossman Ave.
Sunnyvale, CA 94089
www.medtronic.com
tel 877.459.7466

Couple Says “I Do” to Identical Treatment for Symptoms of Painful Lumbar Spinal Stenosis

Over their 56 years of marriage, Enrique and Amparo Velazquez of Algonquin, IL have shared many experiences together, including both being treated in March of 2010 with the X-STOP® Spacer for symptoms of lumbar spinal stenosis.

Prior to the minimally invasive surgery, Enrique and Amparo were both experiencing debilitating leg pain. Lumbar spinal stenosis, or LSS, is a narrowing of the spinal canal that impinges on the nerves in the spinal canal or on the nerves exiting to the legs. This condition, suffered by an estimated 6 million Americans,ⁱ is normally caused by aging.

Enrique and Amparo are not alone. LSS is the most common reason for back surgery in people age 65 and older in the United States.ⁱⁱ The pain the couple was experiencing affected their quality of life.

Their daughter, Dr. Carmen Velazquez, an internist in Elgin, IL, was worried about her parents' condition. She began researching treatments and discovered the X-STOP Spacer, the first and only interspinous process decompression device approved in the United States by the FDA.

Those like Enrique and Amparo who suffer from 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 to potentially provide sustained relief. The X-STOP Spacer is designed to limit extension of the lumbar spine and maintain the spine in a neutral or slightly flexed position, thereby increasing the area of the spinal canal and decompressing the nerves. By "unpinching" the nerve, the X-STOP Spacer can relieve pain even when a person with LSS stands up straight and while walking.

When talking with her sister, Dr. Velazquez learned of Dr. Thomas McNally, orthopedic surgeon with Suburban Orthopaedics in Bartlett, IL. She was impressed that Dr. McNally was highly proficient with the X-STOP Spacer procedure, having completed approximately 20 surgeries with this device. He is among over 3,500 trained physicians who have implanted an estimated 60,000 X-STOP Spacers worldwide. Her parents were living in California at the time, so Dr. Velazquez decided to bring them to Illinois to meet with Dr. McNally to discuss this potential treatment.

According to Dr. McNally, Enrique and Amparo had received the maximum of non-operative care over the years, but it had failed to sufficiently reduce their pain. Since their symptoms improved in the seated position and when leaning on a shopping cart, Dr. McNally felt this made them good candidates for the X-STOP Spacer procedure.

Since their surgery, Enrique and Amparo are doing well and improving daily, according to Dr. Velazquez. They are back to traveling between Mexico, California and Illinois and to taking walks together. Dr. Velazquez said that the improvement in her father's LSS symptoms was the most dramatic. She estimates that his symptoms have decreased by 80 percent, while she said her mother has experienced a 50 percent improvement. While this couple had positive results, serious adverse events can occur with this treatment and, although rare, may be fatal.

Note: This treatment is prescribed by your doctor. It is not for everyone. Please talk with your doctor and see if it is right for you. Your doctor should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, approximately half of the patients who received the X-STOP Spacer in the two-year 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 surgery. For important safety information, including a full discussion of treatment options, please go to www.xstop.com.

For more information, contact Denise Moore at Medtronic Public Relations, (408) 548-5394, or Ann Gyro at Suburban Orthopaedics, (630) 233-7019.

Who is a candidate for the X-STOP Spacer procedure? The X-STOP System is indicated for patients ages 50 or older who have lumbar spinal stenosis. A diagnosis of lumbar spinal stenosis should be confirmed by a doctor with X-ray, MRI or CT scans. The X-STOP System 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 Implant should have already been under a doctor's care and getting non-surgical treatment for their symptoms for at least 6 months. The X-STOP Implant may be implanted at one or two levels.

Who should not receive the X-STOP Spacer procedure? The X-STOP System should not be used if you have:

An allergy to titanium or titanium alloy (the X-STOP Implant is made from this metal); spinal anatomy that would prevent implantation of the device or cause the device to be unstable in your body; cauda equina syndrome, which is a spinal nerve compression that causes bowel or bladder dysfunction; bone fractures or a diagnosis of severe osteoporosis; an infection in your blood or anywhere near your lower back where the surgery is planned.

Possible Complications

Spinal surgery is not without risk. Specific information on the rates of complications for the X-STOP IPD System and spinal surgery should be discussed with your doctor.

Complications that may be associated with X-STOP IPD surgery 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.

Complications related to any type of surgery may include, but are not limited to, the following:

Reaction to anesthesia; heart attack; infection, which could require medication or an operation; blood vessel damage/bleeding; bruising (hematoma); pneumonia; blood clots; wound closure problems; spinal cord or nerve damage; pain or discomfort; paralysis; stroke; death.

After the X-STOP Spacer procedure

It is important to follow your doctor's instructions carefully in order to fully recover from surgery. Failure to follow post-operative care recommendations may result in recurrence of symptoms and discomfort. A stress fracture of the spinous process may occur if strenuous physical activity is resumed too soon after the procedure.

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ⁱ US Census data and "Prevalence of Symptoms of Cervical and Lumbar Stenosis Among Participants in the Osteoporotic Fractures in Men Study" (Vogt, et al) *SPINE* 2006 Vol.31, Num 13, pp. 1445 - 1451

ⁱ Ciol MA, Deyo RA, Howell E, Kreif S. An assessment of surgery for spinal stenosis: time trends, geographic variations, complications, and reoperations. *J Am Geriatr Soc* 1996;44:285-90.

Indications for Use: The X-STOP® Interspinous Process Decompression (IPD®) System 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 non-operative 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 Implant must be placed in the concavity between the spinous processes. Posterior positioning of the implant may result in dislodgement. 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 dislodgement, 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 System may not be indicated; the safety and effectiveness of the X-STOP Device 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 2 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 Implant 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 System; some of these adverse events were reported in the Pivotal Clinical Trial. X-STOP System related: implant dislodgement/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.