

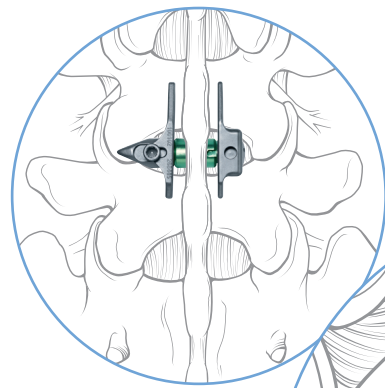
X·STOP® IPD® System

The first minimally invasive
solution to lumbar spinal stenosis.

KYPHON®
AHEAD OF THE CURVE™



INTERSPINOUS PROCESS DECOMPRESSION (IPD®) WITH THE X-STOP® DEVICE



The X-STOP device is implanted between the spinous processes of the symptomatic disc levels

Limits pathologic extension and prevents compression of the nerves

Preserves anatomical structures and mobility

- 6 mm 
- 8 mm 
- 10 mm 
- 12 mm 
- 14 mm 

The X-STOP IPD System features spacers in five color-coded sizes to match the patient's anatomy



A FIRST-LINE SURGICAL OPTION FOR LSS PATIENTS

The X-STOP® Interspinous Process Decompression (IPD®) System is the first alternative to conventional spinal stenosis surgery proven to significantly improve symptom severity and physical function.¹ The X-STOP device is implanted during a short procedure that usually requires only local anesthesia. And because it's minimally invasive, the X-STOP IPD procedure is associated with a low rate of complications and rapid recovery.

- > Limits extension at the symptomatic levels and preserves structure, mobility, and alignment²
- > Procedure typically completed in 45 minutes to 1½ hours using local anesthesia
- > Usually no tissue or bone removal: completely reversible
- > Superior treatment success vs. non-operative care¹
- > Low rate of complications¹
- > Significantly greater patient satisfaction vs. non-operative care¹

References

1. X-STOP Interspinous Process Decompression (IPD) System Package Insert, St. Francis Medical Technologies, November 2005.
2. Lindsey DP, Swanson KE, Fuchs P, Hsu KY, Zucherman JF, Yerby SA. The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine. *Spine*. 2003; 28(19):2192-2197.
3. Zucherman JF, Hsu KY, Hartjen CA, et al. A multicenter, prospective, randomized trial evaluating the X-STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine*. 2005; 30(12):1351-1358.

Study supported by, and one or more authors are consultants of, St. Francis Medical Technologies, Inc. and/or Kyphon Inc.

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 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 may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

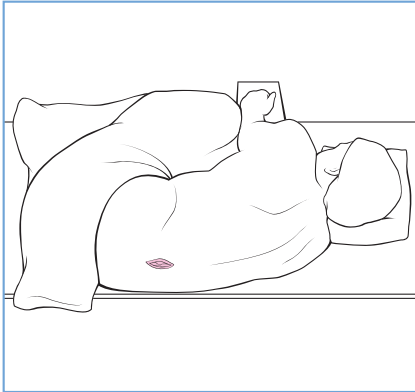
Contraindications: The device is contraindicated in patients with: an allergy to titanium or titanium alloy; spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as: significant instability of the lumbar spine, e.g. isthmic spondylolisthesis 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.



The X-STOP IPD Surgical Procedure

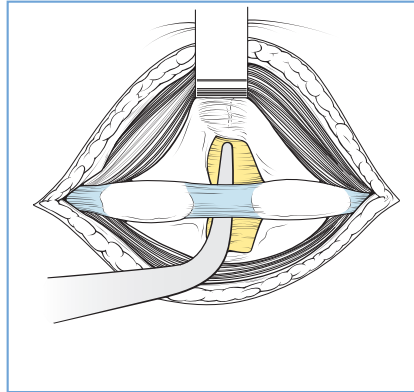


1. POSITION PATIENT. INCISE.

The procedure is performed with the patient in the lateral decubitus position (right side down).

Make a 4- to 8-cm midline incision, exposing the fascia.

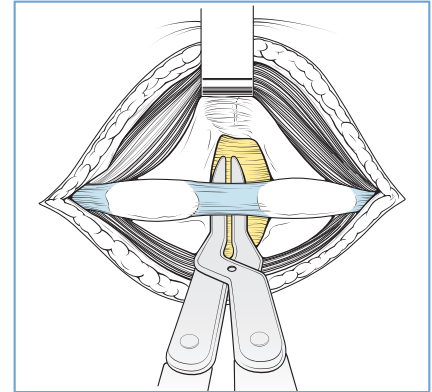
Incise the fascia on either side of the spinous processes and the supraspinous ligament.



2. DILATE.

Advance the small dilator parallel to the spinous processes until you encounter the facets.

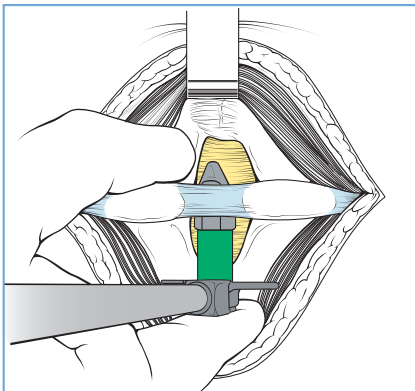
Rotate the instrument 90° and dilate the interspinous ligament with the tip of the dilator.



3. SIZE.

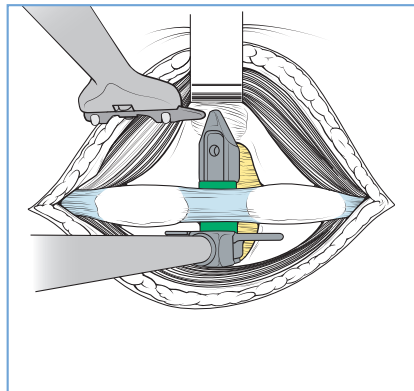
Place the leading edge of the sizer through the hole made by the dilator in the interspinous ligament.

Squeeze handles slowly until resistance is encountered. Palpate the supraspinous ligament during sizing to gauge resistance.



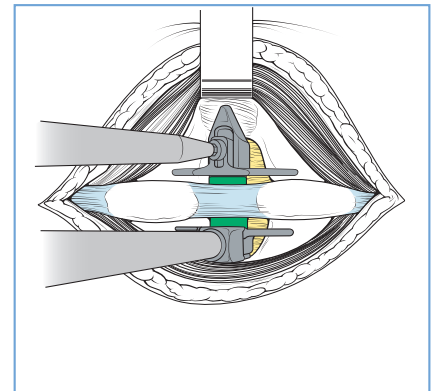
4. IMPLANT.

The spacer assembly of the device is inserted from below, or the right side of the spinous processes from lateral to medial.



5. ATTACH WING.

Align the universal wing to the fixed wing on the spacer assembly.



6. SECURE.

Lifting or rotating the handle of the spacer insertion instrument upward will angle the tissue expander anteriorly, exposing the screw hole.

Use the spacer insertion instrument as a counter-force while tightening with the hex head driver to pre-set torque value.

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