

MEDICAL POLICY

INTERSPINOUS DECOMPRESSION DEVICE (X-STOP)

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POLICY

- **Not recommended due to lack of long-term follow-up, regarding efficacy and adverse effects.**
- X-Stop has been approved by the FDA and shows promising results in a number of studies. However, the studies tend to have limitations in study design that includes small sample size and shorter time frames. There is also some conflict among recent results. Nadakumar (2010) found that the effectiveness of X-Stop in decompressing the stenosed spinal segment had been maintained at two years post-op. However, Tuschel (2011) found a relatively high revision rate and recommended improved criteria for patient selection. A potentially more definitive phase IV, prospective five-year post approval study of the X-Stop called the Condition of Approval Study (COAST) has been completed but has not yet been published.
- While ACOEM does not evaluate the device, the ODG does not recommend it due to the above reasoning. A major carrier, Anthem, consequently finds such implants to be “investigational and not medically necessary.”

SUPPORTING DOCUMENTATION

ODG:

Not recommended due to the lack of sufficient literature evidence (absent long term studies, potential risks), with initially encouraging results. While short-term results are promising, there are currently no long-term clinical trials for interspinous process decompression (IPD). The X-Stop® Interspinous Process Decompression System (Kyphon, Inc., St. Francis Medical Technologies, Inc.) is the only IPD system that has received clearance from the U.S. Food and Drug Administration (FDA), but there are several others in trials. FDA approval is as indicated below. A prospective, Phase IV, five-year, post approval study of the X-Stop called the Condition of Approval Study (COAST) is currently in progress. Interspinous process decompression with the X-Stop device offers an intermediate step in the continuum of care for patients with neurogenic intermittent claudication associated with lumbar spinal stenosis. With careful patient selection for this procedure, progression to more invasive surgical interventions, such as decompressive laminectomy, may be avoided or delayed. The X-Stop procedure is performed in under

half an hour with only local anesthesia and the patient generally can go home after one day. This randomized controlled trial demonstrated that only approximately 5% of participants assigned to continuation of conservative treatment met the treatment success criteria for the study after 24 months of follow up, with approximately 28% requiring decompressive laminectomy due to unresolved symptoms. This contrasted sharply with the findings in patients treated with the X-Stop device, approximately 48% of whom satisfied the three success criteria, with 7% still requiring laminectomy. (Zucherman, 2005) This study concluded that, while the X-Stop does improve the clinical situation, a good outcome is achieved less often than previously reported, with 31% of the patients having a good outcome. A good outcome was not related to smoking, BMI, or number of implanted X-Stops; however, a good outcome was related to the absence of orthopaedic co-morbidity or male gender. (Brussee, 2007) The X-Stop interspinous distraction device has shown to be an attractive alternative to conventional surgical procedures in the treatment of symptomatic degenerative lumbar spinal stenosis; however, we do not recommend the X-Stop for the treatment of spinal stenosis complicating degenerative spondylolisthesis. (Verhoof, 2007) The X-Stop is appropriate for patients with moderately severe functional impairment whose symptoms are exacerbated in extension and relieved in flexion. Implanted between the spinous processes without disrupting the normal anatomical structures, the X-Stop limits narrowing of the spinal canal and neural foramina by reducing extension at the symptomatic level(s). (Laurysen, 2007) CMS has approved the new technology application for the X-Stop Interspinous Process Decompression System for Medicare coverage. (GAO, 2007) Although there is fair evidence that an interspinous spacer device is superior to nonsurgical therapy for 1- or 2-level spinal stenosis with symptoms relieved with forward flexion, insufficient evidence exists to judge long-term benefits or harms. (Chou, 2009) Kyphon Inc. acquired St. Francis Medical Technologies, Inc., a privately held, California-based company that manufactures the X-Stop System, the first FDA-approved interspinous process device for treating lumbar spinal stenosis. The transaction broadened Kyphon's focus in minimally invasive spine to its existing KyphX® Balloon Kyphoplasty technologies for repairing vertebral compression fractures and its recently launched Functional Anaesthetic Discography procedure for diagnosing the source of low back pain. Medtronic has recently acquired US-based Kyphon. The X-Stop consists of a titanium alloy cylindrical spacer (available in five different sizes) that fits in between the spinous processes of two adjacent vertebrae, with two wings on either end to secure the device in place. The device works by maintaining the space between the spinous processes when the patient is standing or flexing backwards. By keeping the spinous processes apart, the nerve impingement by the narrowing spinal canal is reduced, relieving the symptoms.

Indications for Surgery -- Interspinous decompression device (X-Stop®) --

The X-Stop Procedure is indicated for patients aged 50 or older who are suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis, who would otherwise be candidates for laminectomy.

- Confirmation should be based on x-ray film, MR imaging, and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal narrowing.
- It is indicated for patients with moderately impaired physical function who experience relief in flexion (bending forward) from their symptoms of leg/buttock/groin pain, with or without back pain, and who have undergone a regimen of at least 6 months of non-surgical treatment.
- The X-Stop may be implanted at one or two lumbar levels in patients in whom surgical treatment is indicated at no more than two levels.
- The following conditions are contraindications for this procedure: (1) an allergy to titanium or titanium alloy; (2) spinal anatomy or disease that would prevent implantation of the device or cause it to be unstable in situ (this includes significant instability of the lumbar spine [for example, isthmic spondylolisthesis greater than Grade I]; an ankylosed segment at the affected level(s); acute fracture of the spinous process or pars interarticularis; and significant scoliosis [Cobb angle $\geq 25^\circ$]); (3) cauda equina syndrome, defined as neural compression causing neurogenic bowel or bladder dysfunction; (4) diagnosis of severe osteoporosis, defined as bone mineral density (based on dual-energy x-ray absorptiometry scan or some comparable study) in the spine or hip that is more than 2.5 standard deviations below the mean of adult normal individuals in the presence of one or more fragility fractures; & (5) active systemic infection or infection localized to the site of implantation.

REFERENCES

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Tuschel, Alexander MD, MSc; Chavanne, Albert MD; Eder, Claudia MD; PhD; Meissl, Michael MD; Becker, Philipp MD; Ogon, Michael MD. *Implant survival analysis and failure modes of the X STOP interspinous distraction device.* Spine, 9 February 2011.