# DRAFT

# 7.01.107 – Interspinous Distraction Devices (Spacers)



## Description

These interspinous implants aim to restrict painful motion while otherwise enabling normal motion. The devices (spacers) distract the spinous processes and restrict extension. This procedure theoretically enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication. Other types of posterior dynamic stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; these are not covered in this policy.

The interspinous implant is inserted between the spinous processes through a small (4–8 cm) incision and acts as a spacer between the spinous processes, maintaining the flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage.

In November 2005, the XSTOP® Interspinous Process Decompression System (Kyphon) was approved by the U.S. Food and Drug Administration (FDA) for "treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis." It is approved for patients with moderately impaired physical function who have had a regimen of at least 6 months of non-operative treatment, and who have relief of their pain when in flexion. The device is approved for implantation at 1 or 2 lumbar levels in patients whose condition warrants surgery at no more than 2 levels.

The Wallis System (Abbott Spine) was introduced in Europe in 1986. The first generation Wallis implant was a titanium block, the second generation device is composed of a plastic-like polymer that is inserted between adjacent processes and held in place with a flat cord that is wrapped around the upper and lower spinous processes. The Wallis System is currently being tested in a FDA-regulated clinical trial. Also in a FDA-regulated clinical trial is the DIAM Spinal Stabilization System (Medtronic Sofamor Danek), which is a soft interspinous spacer with a silicone core. The DIAM system requires removal of the interspinous ligament, and is secured with laces around the upper and lower spinous processes.

# DRAFT

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The Coflex implant (Paradigm Spine) is used in Europe but is not currently FDA approved. ExtendSure and CoRoent (both from NuVasive) were launched in Europe in 2005 and 2006.

## Policy

Interspinous distraction devices are considered **investigational** as a treatment of neurogenic intermittent claudication.

## Policy Guidelines

Effective January 1, 2007, there are specific CPT category III codes for this procedure:

0171T Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion, and imaging guidance), lumbar; single level
0172T each additional level

Effective January 1, 2007, there is also a HCPCS "C" Medicare pass-through code for the device:

C1821 Interspinous process distraction device (implantable)

Prior to 2007, the procedure should have been coded using CPT code 22899 (unlisted procedure, spine).

## Rationale

One prospective randomized trial with follow-up of both groups to 2 years has been reported for this device. The control group had medical (nonoperative) therapy including epidural injection. Using the entire study population, the Zucherman report (1) noted an improvement of 45% over the mean baseline Symptom Severity Score in the treated patients at 2 years compared with 7% improvement in the control group. Anderson and colleagues (2) reported a success rate of 63% in treated patients compared with 13% in controls; their study reported on a subset of 75 randomized patients who had spondylolisthesis

(out of the total group of 191 patients with one- or two-level lumbar spinal stenosis). Four-year follow-up has been reported for 18 of the treated patients in the study (3).

While these results are promising, some questions still remain. One question is about the durability of the device. Another concern about the studies is the lack of blinding and related bias. There also are concerns about more patients with incomplete follow-up in the control (medical) treatment group. At 1 year, there was complete data on 68 of the 91 control patients compared to 88 of the 100 patients in the experimental group. Additional studies to better control for potential biases and methodological issues need to be completed. Because of these open issues, this device is considered investigational.

2007 Update
A search of the MEDLINE database for the period of September 2006 through August 2007 did not identify any evidence that would alter the conclusions reached above. Quality of life data (SF-36) were reported from the Zucherman trial. (1, 4) The patients, who had to meet a number of inclusion/exclusion criteria, were assessed at baseline and at 6 weeks, 6 months, 1 year, and 2 years following the initial treatment. The X STOP group showed improvements (by single-factor ANOVA or t-test) in both physical and mental component scores compared to both baseline and control subjects. As indicated above, there was a large loss to follow-up (42%) in the medical-treatment group; 6% of the experimental and 26% of the control subjects underwent laminectomy. Another industry-sponsored trial examined the neural foramina and spinal canal area in 26 patients with spinal stenosis and neurogenic intermittent claudication who had not responded to nonoperative treatment. (5) Positional MRI showed a 21% increase in spinal canal area when patients were in seated-neutral and a 23% increase when erect. The neural foramen was significantly increased on the left side only with extension (20%) and flexion (19%). Additional measured areas were found to increase with double-level surgeries.

The addition of a DIAM implant to simple lumbar surgery (laminectomy and/or microdiscectomy) was examined in a case-control study of 62 patients. (6) Radiographic imaging, pain scores, and clinical assessments at a mean of 12-months follow-up showed no differences in the patients (n=31) who had received both surgery and the implant in comparison with patients (n=31) who had undergone laminectomy/microdiscectomy alone.

The North American Spine Society published new guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis. (7) They concluded that with a single Level 1 study on the X STOP, "there remains insufficient evidence to make a recommendation."

2008 Update

The policy was updated with a MEDLINE search through November 2008. Three studies published since the last update reporting on the X-STOP device were identified. Verhoof et al. report that, in a cohort of 12 consecutive patients with symptomatic lumbar spinal stenosis caused by degenerative spondylolisthesis who were treated with X-STOP and followed for a mean of 30.3 months, 8 patients had complete relief of symptoms post-operatively while 4 had no relief. (8) Recurrence of pain, neurogenic claudication, worsening of neurological symptoms was observed in 3 patients within 24 months. Post-operative radiographs and MRI did not show changes in percentage of slip or spinal dimensions. Seven patients had posterior fusion within 24 months. The authors do not recommend the device for treatment of spinal stenosis complicating degenerative spondylolisthesis. Siddiqui and colleagues conducted a prospective observational study of 40 consecutive patients implanted with the X-STOP device. (9) Patients were evaluated at 3, 6, and 12 months using the Zurich Claudication Questionnaire, Oswestry Disability Index, and SF-36. Only twenty-four (60%) completed all questionnaires and were analyzed. By 12 months, clinically significant improvement in symptoms and physical function was noted by 54% and 33% of the 24 patients respectively. Twenty-nine percent of patients required caudal epidural after 12 months after surgery for recurrence of symptoms of neurogenic claudication. The authors conclude that while the device offers significant short-term improvement over a 1-year period, results are less favorable than those reported in a multicenter randomized trial. Brussee et al. reviewed pre- and post-operative Zurich and SF-36 questionnaires completed by 65 patients who received the X-STOP device between 2003 and 2006. (10) A good outcome was achieved by 31% of patients. Good outcome was not related to BMI (body-mass index) or number of implanted devices, but was related to the absence of orthopedic co-morbidity or male gender. The authors conclude that X-STOP does improve the clinical situation; however a good outcome is achieved less often than previously reported. These recent publications do not lead to a change in the current policy statement. Data from rigorous randomized controlled trials are needed to adequately evaluate this device.

No interspinous distraction devices other than the X-STOP have received FDA Premarket Approval. Results of case series of the Wallis, Diam and CoFlex devices have been reported. Floman and

colleagues report that implantation of the Wallis interspinous implant failed to reduce the incidence of recurrent disc herniations. (11) In their series of 37 consecutive patients, 5 were diagnosed with recurrent herniation between 1 and 9 months after surgery; 2 of them underwent additional discectomy and fusion.

References:


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2. Anderson PA, Tribus CB, Kitchel SH et al. Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis. J Neurosurg Spine 2006; 4(6):463-71.

3. Kondrashov DG, Hannibal M, Hsu KY et al. Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: a 4-year follow-up study. J Spinal Disord Tech 2006; 19(5):323-7.

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6. Kim KA, McDonald M, Pik JH et al. Dynamic intraspinous spacer technology for posterior stabilization: case-control study on the safety, sagittal angulation, and pain outcome at 1-year follow-up evaluation. Neurosurg Focus 2007; 22(1):E7.

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# DRAFT

# 7.01.107 – Interspinous Distraction Devices (Spacers)



8. Verhoof OJ, Bron JL, Wapstra FH et al. High failure rate of the interspinous distraction device (X-Stop) for the treatment lumbar spinal stenosis caused by degenerative spondylolisthesis. Eur Spine J 2008; 17(2):188-92.

9. Siddiqui M, Smith FW, Wardlaw D. One-year results of X Stop interspinous implant for the treatment of lumbar spinal stenosis. Spine 2007; 32(12):1345-8.

10. Brusee P, Hauth J, Donk RD et al. Self-rated evaluation of outcome of the implantation of interspinous process distraction (X-Stop) for neurogenic claudication. Eur Spine J 2008; 17(2):200-3.

11. Floman Y, Millgram MA, Smorgick Y et al. Failure of the Wallis interspinous implant to lower the incidence of recurrent lumbar disc herniations in patients undergoing primary disc excision. J Spinal Disord Tech. 2007; 20(5):337-41.

| Codes | Number | Description |
|---|---|---|
| CPT | 0171T | Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion, and imaging guidance), lumbar; single level |
| | 0172T | each additional level |
| | 22899 | Unlisted procedure, spine |
| ICD-9 Procedure | 84.58 | Implantation of interspinous process decompression device (code discontinued effective 10/1/07) |
| | 84.80 | Insertion or replacement of interspinous process device(s)(new code effective 10/1/07) |
| ICD-9 Diagnosis | | Investigational for all codes |

# DRAFT

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|---|---|---|
| HCPCS | C1821 | Interspinous process distraction device (implantable) (effective 1/1/07) |

## Policy History

| Date | Action | Reason |
|---|---|---|
| 10/10/06 | Add to surgery section | New policy |
| 09/18/07 | Replace policy | Policy updated with literature review; reference numbers 4-7 added; policy statement unchanged. ICD-9-CM procedure codes updated in code table. |
| 12/11/08 | Replace policy | Policy updated with literature review, reference numbers 8–11 added. Policy statement unchanged. |