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**Medical Policy Manual** Surgery, Policy No. 155

# *Interspinous and Interlaminar Stabilization and Distraction Devices (Spacers)*

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## IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

## DESCRIPTION

Lumbar interspinous process decompression (IPD), also known as interspinous distraction or posterior spinal distraction, and interlaminar stabilization have been proposed as minimally invasive alternatives to laminectomy and fusion.

## MEDICAL POLICY CRITERIA

**Note:** This policy only addresses IPD devices. Dynamic stabilization devices across pedicle screws and the Coflex-F device are considered in separate medical policies (see Cross References below).

Interspinous process and interlaminar distraction/stabilization devices are considered **investigational** for all indications.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## CROSS REFERENCES

1. Dynamic Stabilization of the Spine, Surgery, Policy No. 143

2. Total Facet Arthroplasty, Surgery, Policy No. 171
3. Interspinous Fixation (Fusion) Devices, Surgery, Policy No. 172
4. Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. 176
5. Lumbar Spinal Fusion, Surgery, Policy No. 187

# BACKGROUND

## SPINAL STENOSIS

Spinal stenosis, which can involve a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, is a common cause of back pain and disability, particularly as individuals age. It can result from a number of pathologic processes, but in adults over 60 in the United States, spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of lumbar spinal stenosis is neurogenic claudication with back and leg pain, sensory loss, and weakness in the legs. Symptoms are typically exacerbated by standing or walking and relieved with sitting or flexion at the waist.

## TREATMENT

Conservative treatments for spinal stenosis include physical therapy, pharmacotherapy, and epidural steroid injections. If conservative treatments fail, surgical approaches for spinal stenosis may be used. They include decompression surgery with or without spinal fusion, which is the standard surgical treatment for patients with moderate to severe spinal stenosis.

Spinal fusion is associated with complications and is generally reserved for patients with spinal instability or moderate grade spondylolisthesis when a vertebral body slips forward relative to an adjacent vertebral body. The Swedish Spinal Stenosis Study found no benefit of fusion plus decompression compared with fusion alone in patients who had spinal stenosis with our without degenerative spondylolisthesis.[1] The Spinal Laminectomy versus Instrumented Pedicle Screw trial found some improvements in patients who had spinal stenosis with grade 1 spondylolisthesis, but also more complications.[2] However, the different findings might have been influenced by factors such as time of follow-up and national practice patterns.[3-7]

Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). Lumbar interspinous process decompression (IPD), also known as interspinous distraction or posterior spinal distraction, and interlaminar stabilization have been proposed as minimally invasive alternatives to laminectomy and fusion. Interlaminar or interspinous devises stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract the neural foramina and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery.

- One type of interspinous process spacer is inserted between the spinous processes through a small (4–8 cm) incision. The supraspinous ligament is maintained and assists in holding the implant in place. No laminotomy, laminectomy or foraminotomy is performed. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.

- Interlaminar spacers are implanted midline between adjacent lamina and spinous processes following surgical decompression at the affected level(s). These implants have two sets of wings that are placed around the inferior and superior spinous processes.

These devices are intended to restrict painful motion while enabling otherwise normal motion. The devices theoretically enlarge the neural foramen, decompresses the cauda equina, and act as spacers between the spinous processes to maintain the flexion of the spinal interspace.

Proponents of these spacers list the advantages compared with standard surgical decompression techniques to be the option of local anesthesia, shorter hospital stay and rehabilitation period, preservation of local bone and soft tissue, reduced risk of epidural scarring and cerebrospinal fluid leakage, and reversibility that does not limit future treatment options. The potential complications of spacers are implant dislodgement, incorrect positioning of implant, fracture of the spinous process, foreign body reaction (e.g., allergic reaction to titanium alloy), and mechanical failure of the implant.

## REGULATORY STATUS

There are several interspinous implants and interlaminar spacers that have premarket approval (PMA) status by the U.S. Food and Drug Administration (FDA) with product code NQO and other interspinous implants and interlaminar spacers that are under investigation. The table below lists examples of devices that have PMA approval.

| Device name | Manufacturer | FDA Approved? |
|---|---|---|
| Aperius ™-PercLID ™ System | Medtronic | No |
| Coflex® Interlaminar Stabilization Device* (formerly Interspinous U) | Paradigm Spine | Yes |
| DIAM™ Spinal Stabilization System | Medtronic Sofamor Danek | No<br>IDE only |
| Falena ® Interspinous Decompression Device | Mikai Spine | No |
| FLEXUS ™ | Globus Medical | No<br>IDE only |
| Helifix® Interspinous Spacer System | Alphatec Spine® | No |
| In-Space | Synthes® | No<br>IDE only |
| NL-Prow ™ Interspinous Spacer | Non-Linear Technologies | No |
| Stenofix | Synthes® | No |
| Superion® Indirect Decompression System | VertiFlex, Inc. | Yes |
| Wallis® System | Zimmer Spine (formerly Abbott Spine) | No<br>IDE only |
| X-STOP® Interspinous Process Decompression (IPD®) System | Kyphon/Medtronic Spine | Withdrawn |
| X-STOP® PEEK (polyetheretherketone) | Medtronic | Withdrawn |

The Superion® Indirect Decompression System (formerly InterSpinous Spacer) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs

secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging, and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. It is intended for patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least six months of nonoperative treatment.

FDA lists the following contraindications to use of the Superion® Indirect Decompression System:

- "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:
    - Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4)
    - An ankylosed segment at the affected level(s)
    - Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral);
    - Scoliosis (Cobb angle >10 degrees)
- Cauda equina syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction.
- Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA [dual-energy x-ray absorptiometry] scan or equivalent method) in the spine or hip that is more than 2.5
- S.D. below the mean of adult normal.
- Active systemic infection, or infection localized to the site of implantation.
- Prior fusion or decompression procedure at the index level.
- Morbid obesity defined as a body mass index (BMI) greater than 40."[8]

The coflex® Interlaminar Technology implant (Paradigm Spine) is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. The coflex® (previously called the Interspinous U) is indicated for use in one- or two-level lumbar stenosis from the L1 to L5 vertebrae in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least six months of nonoperative treatment. The coflex® "is intended to be implanted midline between adjacent lamina of one or two contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s)."

FDA lists the following contraindications to use of the coflex®:

- "Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).

- Degenerative lumbar scoliosis (Cobb angle greater than 25°).
- Osteoporosis.
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Active or chronic infection − systemic or local.
- Known allergy to titanium alloys or MR [magnetic resonance] contrast agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction."[9]

The FDA labeling also contains multiple precautions and the following warning: "Data has demonstrated that spinous process fractures can occur with coflex® implantation." At the time of approval, FDA requested additional postmarketing studies to provide longer-term device performance and device performance under general conditions of use. The first was the 5-year follow-up of the pivotal investigational device exemption trial. The second, a multicenter trial with 230 patients in Germany who were followed for 5 years, compared decompression alone with decompression plus coflex®. The third, also a multicenter trial with 345 patients in the United States who were followed for 5 years, compared decompression alone with decompression plus coflex®.[10] FDA product code: NQO.

## EVIDENCE SUMMARY

The primary beneficial outcomes of interest for treatment of low back pain are relief of pain and improved function. Both outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, data from large, blinded, randomized controlled trials (RCTs) with sufficient long-term follow-up are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from interspinous process and interlaminar distraction/stabilization spacers provides a significant advantage over conventional surgical decompression or nonsurgical treatment. In addition, adverse effects related to complications, such as spinous process fracture and implant dislodgement or breakage, must be considered in evaluating the net health impact of spacers compared with conventional surgical decompression with or without fusion.

The literature on this technology is dominated by reports from non-U.S. centers on devices that have not received U.S. Food and Drug Administration (FDA) approval, though many of them are in trials at U.S. centers. The focus of this literature appraisal is on systematic reviews (SRs), RCTs, and nonrandomized comparative studies on devices that are approved for use in the United States.

### SYSTEMATIC REVIEWS

Zhao (2017) published a SR comparing interspinous process devices (IPD) to boney decompression, for patients with lumbar spinal stenosis.[11] Four RCTs with 200 patients in each group were included. Hospital stays, visual analogue scale (VAS) leg pain scores, and complication rates were not significantly different. VAS low back pain scores and reoperation rates were higher in the IPD group. Cost-effectiveness was lower in the IPD group. The authors stated that although both procedures are acceptable, but risks, indications and cost need to be evaluated prior to each procedure.

Li (2017) published a SR that compared decompression and corflex® interlaminar stabilization

with fusion for lumbar spinal stenosis.[12] The coflex® procedure was found to be safe and effective and not inferior to decompression with fusion in terms of Oswestry Disability Index. Patients with corflex® had less blood loss and shorter length of stays. There were no significant differences in VAS and device-related complications.

Phan (2016) published a SR comparing various interspinous process spacers to traditional decompression for lumbar spinal stenosis.[13] The SR included four RCTs, four prospective observational studies, two retrospective observational studies, and one retrospective registry evaluation. The authors stated IPDs are not better than decompression surgery for the mid to long-term and although IPD procedures have fewer complications, but the incidences of reoperation are higher and is the chance of increased cost.

Wu (2016)[14] conducted a meta-analysis of two RCTs[15, 16] and three non-randomized prospective comparative studies[17-19]. There were 204 patients in the interspinous spacer group and 217 patients in the decompressive surgery group. The interspinous spacers that were studied were the X-STOP, Aperius, Coflex, DIAM, and distraXion. Pooled analysis showed no significant difference at 12 and 24 months between the spacer and decompression groups for low back pain, leg pain, Oswestry Disability Index (ODI), Roland Disability Questionnaire (RDQ) or complications. However, the traditional decompressive surgery group had a significantly lower incidence of reoperation, with 11 of 160 cases requiring reoperation compared to 31 of 161 cases in the interspinous spacer group (relative risk [RR] 3.34; 95% CI: 1.77, 6.31). Several limitations to this meta-analysis were listed, with the primary concern being the small number of studies in the published literature comparing spacers and traditional decompression surgery. Although risk of bias was analyzed, no narrative critical appraisal of the included articles was provided. The authors noted the high reoperation rate associated with spacer use and stated that the indications, risks, and benefits of these devices required careful consideration before surgery.

Hong (2015) published a meta-analysis that included 20 studies with 3,155 patients in the interspinous spacers group and 50,983 patients treated with open decompression.[20] Devices studied were the X-STOP, DiAM, Aperius, Coflex, Wallis, and SPIRE. Results of this meta-analysis were similar to those obtained in the more selective analysis by Wu et al. There was no significant difference between the two procedures for improvement rate, ODI, or visual analog scale (VAS) for back or leg pain. Although secondary outcomes such as operative and hospitalization time, perioperative blood loss, and postoperative complication rate were superior in the spacer group, reoperation rate was higher in that group (16.5% vs 8.7%). Because of the higher reoperation rate the authors concluded that, while the use of spacers may be a viable technique, they could not conclude that it had replaced open decompression surgery as the gold standard for treatment of lumbar spinal stenosis.

Two SRs of studies that compared spacers to traditional decompression surgery for lumbar spinal stenosis were published in 2010.[21, 22] Both noted that outcomes seem promising, but that the level of evidence is low. The authors call for well-designed, large randomized studies with long-term follow-up and consistent outcome measures.

## RANDOMIZED CONTROLLED TRIALS

### Spacers Compared with Nonoperative Treatment

The U.S. Food and Drug Administration (FDA) approval of the X STOP Interspinous Process Decompression System was based on laboratory, mechanical and cadaver studies, and a

multi-center, prospective randomized controlled clinical study.[23-25] In this clinical study, patients were randomized to either the XSTOP® at one (n=64) or two (n=36) levels or to a control group (n=91) which received continued non-operative therapy which included bed rest, a lumbar corset and a varied number of epidural injections. The Symptom Severity and Physical Function scores were measured at six weeks, six months, one year and two years. The scores for the X STOP patients were significantly higher than the scores for the control group at each follow-up point. At two years, the mean Symptom Severity score for the X-STOP and the control groups was 45.4% above baseline scores and 7.4 ($p<0.001$), respectively. The mean Physical Function score changes were 44.3% and -0.4% ($p<0.001$), respectively. While these short-term results are promising, the study precludes scientific conclusions related to long-term health outcomes.

The following are additional reports on various subsets of the participants in this RCT:

A subsequent article has been published by the same authors using the two-year quality of life date (SF-36) data from this trial.[26] As with other reports, 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. However, in this report the authors considered the patients from both treatment and control groups who went on to have laminectomy within the two-year follow-up period as lost to follow-up rather than as treatment failures; thus, the beneficial outcomes reported are misleadingly inflated. The article also notes a conflict of interest for the two primary authors of these articles.

Anderson and colleagues reported two-year outcomes of a subset of patients in the original randomized trial reported above.[27] This subset consisted of patients in the randomized trial whose symptoms were due to degenerative spondylolisthesis at one or two levels. The overall success was defined as a case in which all outcome measures (i.e., Zurich Claudication Questionnaire (ZCQ), Patient Satisfaction Survey, Short Form-36 (SF-36) scores, and additional surgery) were met. In the X-STOP® group (n=42) 63.4% of patients met success criteria while 12.9% of the control group (n=33) met success criteria. The difference was statistically significant. Five patients (12%) in the X-STOP® group and four patients (12%) in the control group underwent laminotomy during the follow-up period. Again, short-term results were encouraging but long-term outcomes are needed.

Kondrashov and Zucherman (2016) published the four year outcomes of another subset of patients in the randomized trial noted above.[28] Eighteen patients from one center were selected from the original nine-center sample based on the availability of preoperative Oswestry Disability Index (ODI) scores and willingness to complete the ODI at four years following surgery. Using a 15-point improvement from baseline ODI score as a success criterion, 14 out of 18 patients (78%) had successful outcomes at the four-year follow-up. The outcomes of the original control group were not included in this article. This intermediate-term study suffered from the same design flaws noted previously, specifically, the small size, lack of a control group for comparison, and lack of long-term health outcomes.

Puzzilli (2014) reported a multicenter controlled trial of X-STOP versus non-surgical management.[29] A total of 542 patients with lumbar spinal stenosis (LSS) and intermittent claudication relieved on flexion were enrolled. All patients had failed a six-month trial of conservative therapy (medical and/or physical). Initially patients were randomized, but randomization to conservative management was terminated after the first 120 patients due to poor outcomes. These patients were followed for a minimum of three years. By three years,

the overall failure rate was 12.3% of X-STOP patients, with 24 of 422 requiring device removal, compared to 50% of patients with continued non-surgical management with 38 of 120 patients having decompression and/or spinal fixation surgery.

**Spacers Compared with Decompression Surgery and/or Fusion**

Schmidt (2018) published two-year results of the Germany RCT that is one of the FDA post approval studies required to provide long-term device performance and to evaluate device performance under the actual condition of use. Patients with moderate-to-severe lumbar spinal stenosis (LSS) with or without spondylolisthesis were randomized to open microsurgical decompression with interlaminar stabilization using the coflex® device (n=110) or open microsurgical decompression alone (n=115).[30] The proportion of patients who met the primary outcome of composite clinical success at 24 months was statistically and significantly lower in the treatment arm (58.4%) than in the control arm (41.7%; p=0.017), with a treatment difference of 16.7% (95% confidence interval, 3.1% to 30.2%). This result was driven primarily by the lower proportion of patients who received a rescue epidural steroid injection in the treatment arm (95.5%) vs control arm (85.2%; p=0.010) at 24 months.

The proportion of patients with Oswestry Disability Index (ODI) success among those censored for subsequent secondary interventions was not statistically significant between the treatment (75.6%) and the control arms (70.4%; p=0.47). None of the other outcomes showed statistically significant differences between the treatment and control arms; outcomes included success measured on the ZCQ (success was defined as an improvement in two or three ZCQ criteria), success measured on a visual analogue scale (VAS) for pain (success defined as a >20-mm change from baseline), VAS leg pain, success on a walking distance test (either ≥8-minute walk improvement or the ability to walk to the maximum 15-minute limit), the proportion of patients receiving secondary surgical interventions, or one- and two-year survival (Kaplan-Meier) estimates without secondary surgical interventions or survival curves for time to first secondary intervention.

Weaknesses in this trial limit its interpretation. Major limitations are discussed below.

- Based on the reporting by Schmidt (2018), 254 patients were randomized but data for only 204 patients were analyzed for the primary outcome measure. Thus, data of 20% of patients were excluded.[30] While the proportion of patients excluded was comparable in both arms, the trialists did not explain the missing data of these 50 patients. Lack of a consistent approach in reporting and handling of missing data (patients who remained in the trial but for whom data for repeated longitudinal measures were missing), including describing methods to minimize missing data, reporting reasons for missing data, and using appropriate multiple imputation statistical techniques and sensitivity analysis[31] to handle missing data, makes interpretation of trial results challenging.
- The observed treatment effect on the primary composite outcome was primarily driven by reduction in the use of rescue epidural steroid injection. A concern is bias that could have been introduced by the open-label design where the treating surgeon also made the assessment that additional intervention with lumbar steroid was needed. The trial design did not include features commonly used to address this problem, such as preset criteria for subsequent intervention, or independent blinded adjudication to verify that subsequent intervention was merited.
- Because of concerns about potential bias and inconsistent reporting of analysis as intention-to treat, and a lack of critical discussion of the number, timing, pattern, and

reason for and possible implications of missing values, the magnitude of difference might have been overestimated.

FDA approval of coflex® in 2012 was based on a noninferiority trial. Use of a noninferiority framework by FDA was based on the assumption that decompression plus fusion is the standard of care for patients with spinal stenosis with up to grade 1 spondylolisthesis. Fusion after open decompression laminectomy is a more invasive procedure that requires longer operative time and has a potential for higher procedural and postsurgical complications, thus, demonstrating noninferiority with a less invasive procedure such as coflex® would be adequate to result in a net benefit in health outcomes.

However, after the approval of coflex®, two RCTs published in 2016 assessing the superiority of adding fusion to decompression over decompression alone reported conflicting results. The Swedish Spinal Stenosis Study (SSSS) included patients with lumbar spinal stenosis with or without spondylolisthesis (degree of spondylolisthesis (degree of spondylolisthesis <3 mm)[1] while the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial included patients with spinal stenosis and grade 1 spondylolisthesis (degree of spondylolisthesis, 3-14 mm).[2] The SSSS trial conducted in Sweden, which was adequately powered to detect a mean difference in the ODI score of at least 12 points between treatment arms, showed no statistical significant difference in the mean ODI scores at 2 years. In contrast, the SLIP trial reported a small but clinically meaningful improvement in the Physical Component Summary score of the SF-36 but no change in ODI scores at two, three, and four years after surgery (not powered to detect differences in the ODI scores). Therefore, results generated from a noninferiority trial using a comparator whose net benefit on health outcome is uncertain confounds meaningful interpretation of trial results.

In 2015 and 2016, the four- and five-year outcomes of the investigational device exemption (IDE) trial for the coflex® Interlaminar Technology.[32, 33] The reported rate of follow-up at five years ranged from 40% to 100%, depending on the outcome measured. For example, the ODI at six months was reported for 56% of patients, while major device-related complications and composite clinical success were reported for 100% of patients. Interpretation of the five-year results is limited by the variable loss to follow-up in outcomes.

Another post-hoc analysis of the pivotal RCT evaluated the use of the device in patients 65 years or older.[34] Clinical outcomes (eg, Oswestry Disability Index, visual analog score, Zurich Claudication Questionnaire, epidural injections) were measured out to 60 months. Patients age 65 years or older who received the interlaminar implant with decompression (n=84) had clinical outcomes that were not significantly different to patients 65 years or older who received decompression and fusion (n=57), and to patients younger than 65 who received the interlaminar implant with decompression (n=131). In contrast, perioperative outcomes such as operative time (100 vs 153 min, p<.001), blood loss (106 vs 358 cc, p<.001), and hospital stay (2.1 vs 3.3 days, p<.001) were improved with the interlaminar implant compared to posterolateral fusion.

Lonne (2015) reported a trial of X-STOP versus minimally invasive decompression in 96 patients with symptoms of neurogenic intermittent claudication relieved on flexion.[35] Intention-to-treat analysis showed no significant differences between the groups in primary and secondary outcome measures at up to two-year follow-up. However, the number of patients having secondary surgery due to persistent or recurrent symptoms was significantly higher in the X-STOP group (25% vs 5%, odds ratio = 6.5). In addition, two patients had fracture of the

spinous process and one had dislocation of the implant.[36] Three patients in the decompression group had secondary surgery during the first hospital stay due to hematoma. Mean days of rehabilitation were 66 for X-STOP and 48 for surgical decompression. The study was terminated after planned mid-term analysis due to the higher reoperation rate with X-STOP.

A two-year outcomes of double-blind RCT (the FELIX trial) comparing the use of the coflex® spacer without bony decompression to surgical decompression were reported in 2015.[37] Functional outcomes were measured by ZCQ and Modified Roland-Morris Disability Questionnaire (RMDS), and pain was measured with visual analogue scale (VAS) and McGill Pain Questionnaire. All 159 participants had intermittent neurogenic claudication due to lumbar spinal stenosis. Surgery time was shorter, but reoperation rates due to absence of recovery were higher in the coflex group compared with the bony decompression group (29% vs 8%, $p<0.001$). For patients with two-level surgery, the reoperation rate was 38% for coflex versus 6% for bony decompression ($p<0.05$). At two years, reoperations due to absence of recovery had been performed in 33% of the coflex group compared with 8% of the bony decompression group. VAS back pain at final follow-up was also higher in the coflex group (36 mm vs 28 mm/100). A number of methodological limitations were reported that limit interpretation and generalizability of the study findings. Differences may not have been found due to the lack of power, though the authors were not certain that a larger sample size would lead to a different study result. “To the contrary, the higher reoperation rate and the higher intensity of [low back pain] in the [spacer] group do suggest inferiority compared to classical decompression.”

Marsh (2015) reported a RCT that compared decompression alone (n=30) versus decompression with a Wallis implant (n=30).[38] Follow-up at an average of 40 months showed no significant differences between the groups in visual analogue scale (VAS) for back or leg pain or in the ODI. Improvement in back pain was 3.5 out of 10 with the Wallis implant compared with 2.7 without ($p=0.1926$). Improvement in ODI was 19.3 with the Wallis implant compared with 10.6 without ($p=0.0787$). Additional study in a larger population is needed.

The two-year outcomes of the pivotal investigational device exemption (IDE) trial for the coflex® Interlaminar Technology were published in 2013. This was a non-blinded randomized multi-center non-inferiority trial that compared implantation of the coflex spacer with decompression and posterolateral fusion with pedicle screw fixation.[39, 40] The condition treated was back pain due to spinal stenosis or low-grade degeneration spondylolisthesis. A total of 322 patients were randomized to undergo either laminectomy and coflex insertion (n=215) or laminectomy and fusion (n=107).

At a minimum of two years follow-up, non-inferiority was reported, with 66.2% success with coflex and 57.7% success with fusion ($p=0.999$). There were no statistically significant between-group differences in pain and function scores. The percentage of device-related adverse events was the same (5.6%) for both groups, and the rate of spinous process fractures was not significantly different between the groups (14% for coflex and 12% for fusion). The vast majority of spinous process fractures were asymptomatic. A separate article reported similar outcomes for the spondylolisthesis subgroup in the study.[41] The overall reoperation rate was 10.7% in the coflex group and 7.5% in the fusion control ($p=0.426$). One limitation of this study was the lack of participant blinding to the treatment allocation; however, since the postoperative protocols are different for these procedures, blinding can be difficult to maintain. In addition, the two-year follow-up does not permit conclusion about long-term outcomes.

Stromqvist (2013) reported the two-year outcomes of a noninferiority randomized trial of 100 patients with symptomatic one- or two-level lumbar spinal stenosis with neurogenic claudication relieved on flexion.[15] Patients were randomized in a 1:1 ratio to undergo either X-STOP implantation or conventional surgical decompression. At 6, 12, and 24 months follow-up, there was no significant difference in scores for symptoms and function, or for complication rates. Reoperation rates were significantly higher ($p<0.04$) in the X-STOP group (n=13; 26%) than in the decompression group (n=3; 6%). (The X-STOP patients who later underwent decompression were not considered to be treatment failures.) For the reasons noted above, longer-term data is needed to determine the durability of treatment effects and to compare the long-term reoperation rates.

**Comparisons of Different Devices**

Nunley (2017) evaluated five-year health outcomes of patients with spinal stenosis who participated in the FDA noninferiority RCT, by undergoing interspinous process decompression (IPD) with the Superion® spacer.[42] Five-year evaluations included the Zurich Claudication Questionnaire (ZCQ) symptom severity (ss), physical function (pf), and patient satisfaction (ps) subdomains, leg and back pain visual analog scale (VAS), and Oswestry Disability Index (OSI). There was 42%, 39%, 75%, 66%, and 58% improvement for ZCQss, ZCQpf, leg and back pain VAS, and ODI respectively. Seventy-five percent of the patients did not require reoperation, revision of supplemental fixation. Although the authors stated Superion® provides clinical benefit, the initial RCT only compared Superion® with another IPD and not to other forms of treatment.

Nunley (2017) published four-year results from the FDA noninferiority Superion® RCT.[43] Eight-nine enrollees had intermittent neurogenic claudication relieved with back flexion and failed six months or greater medical management, prior to the procedure. The authors concluded the Superion device procedure had an 84.3% clinical success, with continued relief of intermittent neurogenic claudication at four years.

At three-year follow-up of the IDE non-inferiority trial comparing the Superion interspinous spacer to the X-STOP, there were 120 patients in the Superion ISS group and 129 in the X-STOP group remaining (64% of 391).[44] Of these, composite clinical success was obtained in 52.5% of patients in the Superion ISS group and 38.0% of the X-STOP group ($p=0.023$). The 36-month clinical outcomes were reported for 82 patients in the Superior ISS group and 76 patients in the X-STOP group (40% of 391). It is not clear from the report whether the remaining patients were lost to follow-up or were considered treatment failures and censured from the results. In addition, interpretation of this study is limited by questions about the efficacy of the comparator and lack of a control group treated by surgical decompression.

Preliminary and[45]two-year follow-up[46] results have been published from an FDA-regulated multicenter randomized IDE non-inferiority trial comparing the Superion interspinous spacer to the X-STOP.[45] At baseline, all patients (N=391) had intermittent neurogenic claudication despite six months nonsurgical management. The FDA-mandated primary endpoint of this trial was non-inferiority to X-STOP at 2 years, with additional postmarket surveillance for 10 years. The reported outcome was a composite of clinically significant improvement in at least two of three ZCQ domain scores compared with baseline, freedom from reoperation, revision, removal, or supplemental fixation at the index level, freedom from epidural steroid injection or nerve block within 12 weeks of the two-year visit, freedom from rhizotomy or spinal cord stimulator at any level, and freedom from major implant or procedure-related complications.

The primary non-inferiority endpoint was met, with a Bayesian posterior probability of 0.993. However, 111 patients (28%, 54 Superion and 57 XSTOP) were withdrawn from the study during follow-up due to a protocol-defined secondary intervention. Modified intent-to-treat analysis showed clinical success (improvement ≥ 20 mm/100) for leg pain in 76% to 77% of patients and for back pain in 67% to 68% of patients, with no significant differences between groups. At two-years, ODI success was achieved in 63% of Superion patients and 67% of XSTOP patients (p=0.061). Rates of complications and reoperations (44 [23.2%] Superion and 38 [18.9%] XSTOP) were similar between groups. Spinous process fractures, reportedly asymptomatic, occurred in 16.4% of Superion patients and 8.5% of XSTOP patients. Interpretation of this study is limited by the lack of blinding and lack of control groups treated by surgical decompression or medical management.

### NONRANDOMIZED CONTROLLED TRIALS

Zhong (2021) evaluated perioperative outcomes in a comparative study of 83 patients. Patients who had the coflex interlaminar implant in combination with laminectomy (n=46) had higher estimated blood loss (97.50 ± 77.76 vs 52.84 ± 50.63 mL, p = 0.004), longer operative time (141.91 ± 47.88 vs 106.81 ± 41.30 min, p = 0.001), and longer length of stay (2.0 ± 1.5 vs 1.1 ± 1.0 days, p = 0.001) compared to laminectomy alone (n=37). Total perioperative complications (21.7% vs 5.4%, p = 0.035) and instrumentation related complications (10.9% vs 0% p = 0.039) were also higher in the interlaminar implant cohort.

Roder (2015) reported a cross registry study that compared lumbar decompression plus coflex (SWISSspine registry) to lumbar decompression alone (Spine Tango registry) in 50 pairs matched by a multifactorial propensity score.[47] SWISSspine is a governmentally mandated registry from Switzerland for coverage with evidence development. Spine Tango is a voluntary registry from the Spine Society of Europe. Both registries use the numeric rating scale (NRS) for back and leg pain and the Core Outcome Measures Index (COMI) as the patient-based outcome instrument. The COMI consists of seven questions to evaluate pain, function, wellbeing, quality of life, and disability. At 7 to 9 month follow-up, the coflex group had greater reduction in NRS back pain (3.8 vs 2.5, p=0.014), NRS leg pain (4.3 vs 2.5, p<0.001), NRS maximum pain (4.1 vs 2.3, p=0.002) and greater improvement in the COMI score (3.7 vs 2.5, p = 0.029).

Richter (2010) published two-year follow-up for 60 patients who underwent decompressive surgery with or without implantation of the Coflex device.[17, 48] Though comparative, this study was not a randomized trial; treatment was allocated at the discretion of the surgeon. The authors reported no significant between-group differences in any outcome measures, and concluded that “additional placement of a Coflex™ interspinous device does not improve the already good clinical outcomes after decompression surgery for LSS in this 24-month follow up interval.”

## PRACTICE GUIDELINE SUMMARY

### INTERNATIONAL SOCIETY FOR THE ADVANCEMENT OF SPINE SURGERY

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) published recommendations for decompression with interlaminar stabilization.[49] ISASS concluded, based in part on a conference presentation of a study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Recommended indications and limitations were described in

the article. The document did not address interspinous and interlaminar distraction devices without decompression.

## NATIONAL INSTITUTE OF HEALTH AND CARE EXCELLECE (NICE)

NICE (2010) published a guidance stating that interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication can be safe and effective in the short and medium-term for selected patients.[50] Failure may occur and further treatment may be needed. A specialist should select the patients and offer a range of surgical options.

## NORTH AMERICAN SPINE SOCIETY (NASS)

North American Spine Society (NASS) published specific coverage policy recommendations on the lumbar interspinous device without fusion and with decompression in 2018.[51] NASS recommended that:

“Stabilization with an interspinous device without fusion in conjunction with laminectomy may be indicated as an alternative to lumbar fusion for degenerative lumbar stenosis with or without low-grade spondylolisthesis (less than or equal to 3 mm of anterolisthesis on a lateral radiograph) with qualifying criteria when appropriate:

1. Significant mechanical back pain is present (in addition to those symptoms associated with neural compression) that is felt unlikely to improve with decompression alone. Documentation should indicate that this type of back pain is present at rest and/or with movement while standing and does not have characteristics consistent with neurogenic claudication.
2. A lumbar fusion is indicated post-decompression for a diagnosis of lumbar stenosis with a Grade 1 degenerative spondylolisthesis as recommended in the NASS Coverage Recommendations for Lumbar Fusion.
3. A lumbar laminectomy is indicated as recommended in the NASS Coverage Recommendations for Lumbar Laminectomy.
4. Previous lumbar fusion has not been performed at an adjacent segment.
5. Previous decompression has been performed at the intended operative segment.

Interspinous devices are NOT indicated in cases that do not fall within the above parameters. In particular, they are not indicated in the following scenarios and conditions:

1. Degenerative spondylolisthesis of Grade 2 or higher.
2. Degenerative scoliosis or other signs of coronal instability.
3. Dynamic instability as detected on flexion-extension views demonstrating at least 3 mm of change in translation.
4. Iatrogenic instability or destabilization of the motion segment.
5. A fusion is otherwise not indicated for a Grade 1 degenerative spondylolisthesis and stenosis as per the NASS Coverage Recommendations for Lumbar Fusion.
6. A laminectomy for spinal stenosis is otherwise not indicated as per the NASS Coverage Recommendations for Lumbar Laminectomy.”

The 2014 revised NASS clinical guidelines on degenerative lumbar spondylolisthesis concluded that “there is insufficient and conflicting evidence to make a recommendation for or against the efficacy of interspinous spacers versus medical/interventional treatment in the management of degenerative lumbar spondylolisthesis patients.” (Grade of Recommendation

I - Insufficient Evidence)[52]

The 2011 revised clinical guidelines from the North American Spine Society (NASS) on lumbar spinal stenosis concluded that “there is insufficient evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis” (Grade of Recommendation I - Insufficient Evidence)[53]

## SUMMARY

There is not enough research to show that interspinous process or interlaminar distraction/stabilization devices improve health outcomes for any indication. Therefore, use of interspinous process or interlaminar stabilization/distraction spacers is considered investigational.

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## CODES

| Codes | Number | Description |
|---|---|---|
| CPT | 22867 | Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level |
| | 22868 | ;second level (List separately in addition to code for primary procedure) |
| | 22869 | Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level |
| | 22870 | ;second level (List separately in addition to code for primary procedure) |
| | 22899 | Unlisted procedure, spine |
| HCPCS | C1821 | Interspinous process distraction device (implantable) |

***Date of Origin:*** *October 2006*