Interspinous Distraction Devices

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DESCRIPTION

Interspinous distraction (decompression) devices are intended to restrict painful motion while otherwise enabling normal motion. The devices, also known as spacers, distract the spinous processes and restrict extension. Theoretically, this enlarges the neural foramen in patients with spinal stenosis and neurogenic claudication.

The procedure involves implantation of an interspinous decompression spacer between the spinous processes of the vertebrae at the affected level to open the foramen and reduce compression of the exiting nerve. The spacers can be implanted at one or two lumbar levels and are designed to remain in place without being permanently affixed to the bone or ligamentous structures of the spine with screws. The supraspinous ligament is maintained and assists in holding the implant in place. There are several types of interspinous devices, which are considered a minimally invasive alternative to lumbar laminotomy or laminectomy for patients with exacerbations of lumbar spinal stenosis who do not respond to conservative, nonsurgical treatment.

Spinal Stenosis
Lumbar spinal stenosis, which affects over 200,000 people in the United States (U.S.), involves a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, resulting in pain as well as limitation of activities such as walking, traveling, and standing. In adults over 60 in the U.S., 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.

Some sources describe the course of lumbar spinal stenosis as "progressive" or "degenerative," implying that neurologic decline is the usual course. Longer-term data from the control groups of clinical trials as well as from observational studies suggest that, over time, most patients remain stable, some improve, and some deteriorate.

The lack of a valid classification for lumbar spinal stenosis contributes to wide practice variation and uncertainty about who should be treated surgically, and which surgical procedure is best for each patient. This uncertainty also complicates research on spinal stenosis, particularly the selection of appropriate eligibility criteria and comparators.

Spinal Stenosis Treatment
The largest group of patients with spinal stenosis is minimally symptomatic patients with mild back pain and no spinal instability. These patients are typically treated nonsurgically. At the other end of the spectrum are patients who have severe stenosis, concomitant back pain, and grade 2 or higher spondylolisthesis or degenerative scoliosis >25 Cobb angle who require laminectomy plus spinal fusion.

Surgical treatments for patients with spinal stenosis not responding to conservative treatments include decompression with or without spinal fusion. There are many types of decompression surgery and types of fusion operations. In general, spinal fusion is associated with more complications and a longer recovery period and, in the past, was generally reserved for patients with spinal deformity or moderate grade spondylolisthesis.

Conservative treatment for spinal stenosis may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities. The terms "nonsurgical" and "nonoperative" have also been used to describe conservative treatment. Professional societies recommend that surgery for lumbar spinal stenosis should be considered only after a patient fails to respond to conservative treatment but there is no agreement about what constitutes an adequate course or duration of treatment.

Spacer Devices
Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). These

devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication.

Interspinous Implants

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. One type of 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 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. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.

Interlaminar Spacers

Interlaminar spacers are implanted midline between the adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery. Interlaminar spacers have 2 sets of wings placed around the inferior and superior spinous processes. They may also be referred to as interspinous U. These implants aim to restrict painful motion while enabling normal motion. The devices (spacers) distract the laminar space and/or 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.

Clinical Context and Therapy Purpose

The purpose of the interspinous or interlaminar spacer in patients with spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis or stability is to provide a treatment option that is less invasive than lumbar spinal decompression surgery and more effective for back pain than lumbar spinal decompression surgery alone. Although not tested in trials, another potential purpose could be to provide an alternative to conservative therapy in patients who are medically unsuitable for undergoing general anesthesia for more invasive lumbar surgery or nonsurgical conservative therapy. Features that may affect the choice of the surgical procedure include the severity of leg pain, back pain, and instability; the presence of facet hypertrophy, diminished disc height, or deformity; the risk of general anesthesia, and the patient's preferences

The question addressed in this evidence review is: Does the use of an interspinous or interlaminar spacer in patients with spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis, when used as a stand-alone treatment, improve the net health outcome?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with one of the following:

- Spinal stenosis and no spondylolisthesis or instability
- Spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis
- Severe spinal stenosis and grade 1 spondylolisthesis or instability who have not responded to conservative treatment.

Interventions
The treatment being considered is the placement of an interspinous or interlaminar spacer as a stand-alone treatment or in combination with a spinal fusion

Comparators
The following practices are currently being used as treatment:

- Nonsurgical conservative therapy
- Lumbar spinal decompression surgery without fusion
- Lumbar spinal decompression with spinal fusion

Outcomes
The main outcomes of interest are (1) improvements in symptoms of spinal stenosis (e.g., claudication, leg pain), (2) reductions in back pain, and (3) reductions in limitations on activities related to symptoms. Symptoms can be measured by scores of validated instruments such as the Oswestry Disability Index and the Zurich Claudication Questionnaire as well as visual analog scale for back and leg pain. Other measures such as the SF-36 to assess the quality of life are relevant. Other key outcome measures are reoperations, including fusion procedures, and adverse events. The window to judge treatment success is a minimum of 2 years post-procedure.

Coflex Device
(2015) Moojen et al. completed a double-blind randomized controlled trial on the two-year results of IPD without bony decompression versus conventional surgical decompression for lumbar spinal stenosis. Allocations were stored in prepared opaque, coded and sealed envelopes, and patients and research nurses were blind throughout the follow-up. Five neurosurgical centers (including one academic and four secondary level care centers) included participants. 211 participants were referred to the Leiden-The Hague Spine Prognostic Study Group. 159 participants with INC based on lumbar spinal stenosis at one or two levels with an indication for surgery were randomized into two groups. Patients and research nurses were blinded for the allocated treatment throughout the study period. 80 participants received an IPD and 79 participants underwent spinal bony decompression. The primary outcome at long-term (2-year) follow-up was the score for the Zurich Claudication Questionnaire. Repeated measurement analyses were applied to compare outcomes over time. The results noted at two years, the success rate according to the Zurich Claudication Questionnaire for the IPD group [69 % (95 % CI 57-78 %)] did not show a significant difference compared with standard bony decompression [60 % (95 % CI 48-71 %) p value 0.2]. Reoperations, because of absence of recovery, were indicated and performed in 23 cases (33 %) of the IPD group versus 6 (8 %) patients of

the bony decompression group ($p < 0.01$). Furthermore, long-term VAS back pain was significantly higher [36 mm on a 100 mm scale (95 % CI 24-48)] in the IPD group compared to the bony decompression group [28 mm (95 % CI 23-34) p value 0.04]. The authors concluded in this double-blinded study could not confirm the advantage of IPD without bony decompression over conventional 'simple' decompression, two years after surgery. Moreover, in the IPD treatment arm, the reoperation rate was higher and back pain was even slightly more intense compared to the decompression treatment arm.

(2013) Moojen et al. completed a randomized control trial with 80 participants received an interspinous process device and 79 participants underwent spinal bony decompression. The primary outcome at short term (eight weeks) and long term (one year) follow-up was the Zurich Claudication Questionnaire score. Repeated measurements were made to compare outcomes over time. The results noted at eight weeks, the success rate according to the Zurich Claudication Questionnaire for the interspinous process device group (63%, 95% confidence interval 51% to 73%) was not superior to that for standard bony decompression (72%, 60% to 81%). No differences in disability (Zurich Claudication Questionnaire; P=0.44) or other outcomes were observed between groups during the first year. The repeat surgery rate in the interspinous implant group was substantially higher (n=21; 29%) than that in the conventional group (n=6; 8%) in the early post-surgical period (P<0.001). In conclusion, this double blinded study could not confirm the hypothesized short-term advantage of interspinous process device over conventional "simple" decompression and even showed a fairly high reoperation rate after interspinous process device implantation.

Coflex Device Plus Decompression Versus Decompression Alone

(2021) Zhong et al. 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.

(2018) Schmidt et al. reported on results of an RCT in patients with moderate-to-severe lumbar spinal stenosis and back pain with or without spondylolisthesis randomized to open microsurgical decompression with interlaminar stabilization using the coflex device (n=110) or open microsurgical decompression alone (n=115).46, Trial characteristics and results at 24 months. The proportion of patients who met the criteria for composite clinical success at 24 months was statistically and significantly higher in the coflex arm (58.4%) than in the decompression alone 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 an epidural steroid injection in the coflex arm (4.5%) versus the decompression alone arm (14.8%; p=0.010) at 24 months. The proportion of patients with Oswestry Disability Index 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). The difference in the proportion of patients overall who had Oswestry Disability Index success in the overall sample was also not statistically significant (55% vs. 44%, p=0.091). None of the other outcomes (data not shown) showed statistically significant differences between the treatment and control arms; outcomes included success measured on the Zurich Claudication Questionnaire (success was defined as an improvement in 2 or 3 Zurich Claudication Questionnaire criteria), success measured on a visual analog scale for pain (success defined as a >20-mm change from baseline), reduction in visual analog scale 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 1- and 2-year survival (Kaplan-Meier) estimates without secondary surgical interventions or survival curves for time to first secondary intervention. The limitations noted are:

- Based on the reporting 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. While the proportion of patients excluded was comparable in both arms, the investigators 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, to handle missing data, makes interpretation of trial results challenging.
- The observed treatment effect on the primary composite outcome was primarily driven by a reduction in the use of rescue epidural steroid injection. One concern is a 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.
- The inclusion of epidural and facet joint injections in the endpoint may be inappropriate for this trial. Epidural injections are less invasive than reoperations, revisions, removal, and supplemental fixations. Nonsurgical therapy, including epidural or facet injections, would be an expected adjunct to decompression alone in patients with predominant back pain. In this context, epidural injections may be offered to provide temporary pain relief that allows a patient to progress with a rehabilitative stretching and exercise program. Censoring patients who undergo particular components of nonsurgical back care may be inappropriate in this context. A better approach would be to measure and report Oswestry Disability Index for all patients, or Oswestry Disability Index success in all patients except for those who have revisions or reoperations, at 24 months.

- Because of concerns about potential bias, 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.

(2015) Röder et al. reported on a small cross-registry study that compared lumbar decompression plus coflex (SWISSspine Registry) with lumbar decompression alone (Spine Tango Registry) in 50 pairs matched by a multifactorial propensity score. The SWISS spine 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 for back and leg pain, as well as the Core Outcome Measures Index as the patient-based outcome instrument. The Core Outcome Measures Index consists of 7 questions to evaluate pain, function, well-being, quality of life, and disability. At 7- to 9-month follow-up, the coflex group had greater reductions in numeric rating scale back pain score (3.8 vs. 2.5, p=0.014), numeric rating scale leg pain score (4.3 vs. 2.5, p<0.001), numeric rating scale maximum pain score (4.1 vs. 2.3, p=0.002), and greater improvement in Core Outcome Measures Index score (3.7 vs. 2.5; p=0.029). Back pain improved by the minimum clinically relevant change in about 60% of patients in the decompression alone group versus 78% in the coflex plus decompression group. Because of substantial baseline differences between the compared groups, small sample size, and short follow-up time, there is a high-risk the study's estimate of the effect of decompression alone versus decompression plus coflex is biased. Decompression alone had better outcomes than those reported by Röder et al (2015) in a larger, well-conducted, 12-month European registry study of patients with spinal stenosis, significant back, and no spondylolisthesis.

(2010) Richter et al. reported on a prospective case-control study of the coflex device in 60 patients who underwent decompression surgery. Richter et al (2014) also published a 2-year follow-up. The surgeon determined whether the midline structures were preserved or resected and whether the coflex device was implanted (1 or 2 levels). The indications for the 2 groups were identical and the use of the device was considered incidental to the surgery. At 1- and 2-year follow-ups, placement of a coflex device did not significantly improve the clinical outcome compared with decompression surgery alone.

Some radiologic findings with the coflex device require additional study to determine their clinical significance.
(2016) Lee et al. reported erosion around the spinous process and reductions in disc height and range of motion in patients treated with a coflex device plus spinal decompression and had at least 24 months of follow-up. Erosion around the coflex device, which was observed in 47% of patients, has the potential to result in spinous process fracture or device malposition. Continued follow-up is needed.

(2013) Tian et al. reported a high rate (81.2%) of heterotopic ossification at follow-up (range, 24-57 months) in patients who had received a coflex device. In 16 (50%) of 32 patients, heterotopic ossification was detected in the interspinous space but had not

bridged the space, while in 2 (6.3%) patients there was interspinous fusion. In the 9 patients followed for more than 3 years, class II (interspinous space but not bridging) and class III (bridging) heterotopic ossification were detected in all 9.

Subsection Summary: Coflex Device Plus Decompression Versus Decompression Alone

One RCT, conducted in a patient population who had moderate-to-severe lumbar spinal stenosis with or without spondylolisthesis, showed that a greater proportion of patients who received coflex plus decompression achieved the primary endpoint of composite clinical success compared with decompression alone. This composite endpoint was primarily driven by a greater proportion of patients who received a secondary rescue epidural steroid injection in the control arm while there was no difference in the proportion of patients who achieved a meaningful reduction of 15 points in Oswestry Disability Index score in the treatment and the control arms. However, the decision to use rescue epidural steroid injection introduced possible bias given that the trial was open label. No attempts were made to mitigate this potential bias using protocol-mandated standard objective clinical criteria to guide decisions about the use of secondary interventions and subsequent adjudication of these events by an independent blinded committee. Given these critical shortcomings, trial results might have been biased. Greater certainty about the net health outcome of adding coflex to decompression surgery might be demonstrated when results of 5-year follow-up of this trial and an ongoing RCT, A 2- and 5-Year Comparative Evaluation of Clinical Outcomes in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex® (NCT02555280) on decompression with and without the coflex implant in the U.S. are published. Consideration of existing studies as indirect evidence regarding the outcomes of using spacers in this subgroup is limited by substantial uncertainty regarding the balance of potential benefits and harms. Limitations of the published evidence preclude determining the effects of the technology on net health outcome.

Coflex Device Plus Decompression versus Decompression Plus Fusion

(2020) Grinberg et al. completed a prostpective, multicentered, randomized controlled trail on the interlaminar stabilization for spinal stenosis in the Medicare population. Patients from 21 sites in the United States underwent surgery for moderate stenosis with up to a grade 1 degenerative spondylolisthesis and failure of conservative treatment with low back pain at 1 or 2 contiguous levels from L1-L5. Preoperatively, patient-reported assessment had to meet the criteria of significant pain and disability (Visual Analog Scale [VAS back pain] ≥50 mm on a 100 mm scale; Oswestry Disability Index [ODI] of ≥20/50). The primary outcome was overall Composite Clinical Success (CCS) as determined by ODI scores, incidence of postoperative epidural injections and/or reoperations, incidence of device-related complications, and persistent or progressive neurological deficit. Secondary outcomes included patient satisfaction as measured by VAS for back and worse leg pain and Zurich Claudication Questionnaire scores. Narcotic usage data and radiographic assessment of changes in postoperative posterior disc height and foraminal height were also evaluated. At 1- or 2-levels, 84 patients ≥age 65

underwent decompression with ILS, 57 patients ≥age 65 underwent decompression with fusion, and 131 patients <age 65 underwent decompression with ILS. Comparisons were made between ≥age 65 ILS patients and ≥age 65 fusion patients and between <age 65 and ≥age 65 ILS patients. The patients were assessed before and after surgery at 6 weeks and 3, 6, 12, 18, 24, 48, and 60 months. They resulted, at 24 and 60 months, there were no statistically significant differences in CCS or any of the individual components of CCS between the ≥ age 65 ILS and fusion groups or between the < age 65 and ≥ age 65 ILS groups. ILS Medicare patients experienced significantly shorter surgeries ($p<.001$), less blood loss ($p<.001$), and a shorter hospital stay ($p<.001$) than fusion patients. There were no significant differences radiographically or with regards to postoperative narcotic usage. In conclusion, clinically, ILS patients ≥age 65 performed as well as both those receiving fusion and those <age 65 who received ILS. Importantly, however, for this older population, ILS Medicare patients experienced less blood loss, a shorter operation and shorter hospital stay than fusion Medicare patients.

(2018) Abjornson et al. completed a review on the spinal stenosis in the absence of spondylolisthesis can interlaminar stabilization at single and multi-levels provide sustainable relief. Decompression with ILS offers a nonterminal surgical option for the treatment of the symptomology of spinal stenosis, a progressive degenerative condition, that potentially can provide longer durability and stability than decompression alone. Under an FDA-regulated investigational device exemption (IDE) study, a total of 322 patients were enrolled in the prospective, randomized trial. This investigation focuses only on the subset of patients (116 total) from this overall cohort who were treated with decompression plus ILS at 1 or 2 levels and who did not present with spondylolisthesis preoperatively. The patients were assessed before and after surgery up to 60 months. The results noted at 60-month follow up, there was no statistically significant difference in ODI ≥ 15-point improvement between patient populations (81.6% of 1 level, 90.3% of 2 level). At 60 months, 83.1% of 1 level and 86.3% of 2 level patients did not require a secondary surgical procedure. At 60 months, 94.7% of 1 level and 100% of 2 level reported ≥20 mm improvement in Visual Analogue Scale leg pain. Patients reported improvement in their physical state according to Short Form-12 scores (89.3% of 1 level, 88.9% of 2 level). Patient satisfaction at 60 months was 97.4% for 1 level and 93.3% for 2 level. In conclusion, the therapeutic sustainability for the treatment of spinal stenosis without spondylolisthesis with ILS at 1 or 2 levels in the lumbar region has been shown to be safe and efficacious for patients who have failed conservative treatment.

(2018) Simon et al. reviewed the two-level experience of interlaminar stabilization with a five-year follow-up of a prospective, randomized clinical experience compared to fusion for the sustainable management of spinal stenosis. This is the first 5-year analysis of the 2-level ILS experience, which supplements previous studies that describe the advantages of ILS by extending such advantages to 2-level cases. They had 322 patients enrolled in the Investigational Device Exemption clinical trial, 116 required surgical treatment at 2 levels. The ILS group consisted of 77 patients, and the fusion group consisted of 39 patients. Efficacy was measured using composite clinical success (CCS). Patients achieve CCS if they achieve all 4 of the following outcomes: ≥15-point

improvement from baseline Oswestry Disability Index (ODI); no reoperation or epidural injections; no persistent, new, or increasing neurological deficits; and no major device-related complications. The results noted there was a 91% rate of follow-up within the participant population in the 5-year data. There was a difference trending toward significance between groups for the absence of reoperation or epidural injection, with 68.8% of ILS patients and only 51.3% of fusion patients meeting this criterion (P = .065); 13.0% of ILS patients and 25.7% of fusion patients required secondary surgery. The percentage of patients achieving overall CCS was much greater in the ILS group than the fusion group, with 55.1% (38/69) of ILS patients and only 36.4% (12/33) of fusion patients achieving CCS at month 60 (P = .077). With regard to the ODI, the visual analog scale back and worse leg pain, the Short Form-12, and the Zurich Claudication Questionnaire, both groups had significantly better results at every follow-up time point when compared to their respective baseline scores. In conclusion, the 2-level ILS patient group performed as well as, if not better than, the 2-level fusion group across almost all outcome measures, demonstrating both clinical outcome success and favorably low reoperation rates in patients who received ILS surgery.

(2016) Bae et al. completed a randomized controlled trail on the three-year follow-up of the prospective randomized, controlled trail of coflex interlaminar stabilization vs. instrumented fusion in patients with lumbar stenosis. The results noted composite clinical success at 36 months was achieved by 62.2% among 196 coflex Interlaminar Stabilization patients and 48.9% among 94 fusion patients (difference = 13.3%, 95% confidence interval, 1.1%-25.5%, P = .03). Bayesian posterior probabilities for noninferiority (margin = -10%) and superiority of coflex Interlaminar Stabilization vs fusion were >0.999 and 0.984, respectively. Substantial and comparable improvements were observed in both groups for patient-reported outcomes, although the percentage with a clinically significant improvement (≥15) in the Oswestry Disability Index seemed larger for the coflex Interlaminar Stabilization group relative to the fusion group (P = .008). Radiographic measurements-maintained index level and adjacent level range of motion in coflex Interlaminar Stabilization patients, although range of motion at the level superior to fusion was significantly increased (P = .005). The author's concluded Coflex Interlaminar Stabilization for stenosis is proven to be effective and durable at improving overall composite clinical success without altering normal spinal kinematic motion at the index level of decompression or adjacent levels. The limitations noted, the main limitation for this study is that the duration of follow-up is limited to 36 months at this time. In this trial, patients with lumbar stenosis with and without spondylolisthesis were studied. They acknowledge that the need for post decompression stabilization in patients without spondylolisthesis has not been thoroughly studied or proven as necessary. The results of this trial suggest that these patients without spondylolisthesis benefit from stabilization with ILS after decompression, but a further study to compare decompression with ILS stabilization to decompression alone will help to determine the appropriateness of ILS in these patients. A second phase multicenter prospective, randomized, controlled trial comparing decompression and ILS to decompression alone will commence in the very near future

(2016) Musacchio et al. prospective, randomized, controlled trial was conducted at 21 centers. Patients with moderate to severe lumbar stenosis at one or two contiguous levels and up to Grade I spondylolisthesis were randomized (2:1 ratio) to decompression and interlaminar stabilization (D+ILS; n=215) using the coflex® Interlaminar Stabilization® device (Paradigm Spine, LLC) or decompression and fusion with pedicle screws (D+PS; n=107). Clinical evaluations were made preoperatively and at 6 weeks and 3, 6, 12, 18, 24, 36, 48, and 60 months postoperatively. Overall Food and Drug Administration success criteria required that a patient meet 4 criteria: 1) > 15-point improvement in Oswestry Disability Index (ODI) score; 2) no reoperation, revision, removal, or supplemental fixation; 3) no major device-related complication; and 4) no epidural steroid injection after surgery. The results noted at 5 years, 50.3% of D+ILS vs. 44% of D+PS patients (p>0.35) met the composite success criteria. Reoperation/revision rates were similar in the two groups (16.3% vs. 17.8%; p >0.90). Both groups had statistically significant improvement through 60 months in ODI scores with 80.6% of D+ILS patients and 73.2% of D+PS patients demonstrating > 15-point improvement (p>0.30). VAS, SF-12, and ZCQ scores followed a similar pattern of maintained significant improvement throughout follow-up. On the SF-12 and ZCQ, D+ILS group scores were statistically significantly better during early follow-up compared to D+PS. In the D+ILS group, foraminal height, disc space height, and range of motion at the index level were maintained through 5 years. In conclusion, both treatment groups achieved and maintained statistically significant improvements on multiple outcome assessments throughout 5-year follow-up. On some clinical measures, there were statistically significant differences during early follow-up favoring D+ILS. At no point were there significant differences favoring D+PS. Results of this 5-year follow-up study demonstrate that decompression and interlaminar stabilization with coflex is a viable alternative to traditional decompression and fusion in the treatment of patients with moderate to severe stenosis at one or two lumbar levels. The study did have some limitations. The study was not blinded during follow-up. Clinically, this would be very difficult to achieve, but may have introduced a bias. There is always difficulty in determining how to address patients who undergo additional surgery or injections after the study surgery, as their outcome measures may then be reflecting the effect of the additional intervention rather that the index procedure. In the current protocol, these patients were classified outcome failures in the composite assessment of success and excluded from the analyses of individual outcome assessments such as VAS and ZCQ.

(2015) Bae et al. completed a review on a four-year assessment on the therapeutic sustainability and durability of coflex interlaminar stabilization after decompression for lumbar spinal stenosis. A retrospective analysis of data generated from a prospective, randomized, level-1 trial that was conducted at 21 US sites was carried out. Three hundred forty-four per-protocol subjects were enrolled and randomized to ILS or fusion after decompression for lumbar stenosis with up to grade 1 degenerative spondylolisthesis. Clinical, safety, and radiographic data were collected and analyzed in both groups. Four-year outcomes were assessed, and the TSE was calculated for both cohorts. The clinical and radiographic factors thought to be associated with therapeutic sustainability were added to the CCS endpoints which were used for premarket approval

(PMA). The results noted a success rate, comprised of no second intervention and an ODI improvement of ≥ 15 points, was 57.6% of ILS and 46.7% of fusion patients ($p = 0.095$). Adding lack of fusion in the ILS cohort and successful fusion in the fusion cohort showed a CCS of 42.7% and 33.3%, respectively. Finally, adding adjacent level success to both cohorts and maintenance of foraminal height in the coflex cohort showed a CCS of 36.6% and 25.6%, respectively. With additional follow-up to five years in the U.S. PMA study, these trends are expected to continue to show the superior therapeutic sustainability of ILS compared to posterolateral fusion after decompression for spinal stenosis. In conclusion, there are clear differences in both therapeutic sustainability and intended clinical effect of ILS compared to posterolateral fusion with pedicle screw fixation after decompression for spinal stenosis. There are CCS differences between coflex, and fusion cohorts noted at four years post-op similar to the trends revealed in the two year data used for PMA approval. When therapeutic sustainability outcomes are added to the CCS, ILS is proven to be a sustainable treatment for stabilization of the vertebral motion segment after decompression for lumbar spinal stenosis.

(2013) Davis et al. completed a clinical article on the multicenter U.S. investigational device exemption, randomized, prospective trial on the two-year clinical and radiographic results. The results noted esults: At a minimum of 2 years, patient follow-up was 94.9% and 94.1% in the coflex and fusion control groups, respectively. There were no group differences at baseline for any demographic, clinical, or radiographic parameter. The average age was 63 years in the coflex cohort and 65 years in the fusion cohort. Coflex subjects experienced significantly shorter operative times ($p < 0.0001$), less estimated blood loss ($p < 0.0001$), and shorter length of stay ($p < 0.0001$) than fusion controls. Both groups experienced significant improvements from baseline at 2 years in ODI, VAS back, VAS leg, and ZCQ, with no significant group differences, with the exception of significantly greater ZCQ satisfaction with coflex at 2 years. FDA overall success was achieved in 62.8% of coflex subjects (59 of 94) and 62.5% of fusion controls (30 of 48) ($p = 1.000$). The reoperation rate was higher in the coflex cohort (14 [14.1%] of 99) compared with fusion (3 [5.9%] of 51, $p = 0.18$), although this difference was not statistically significant. Fusion was associated with significantly greater angulation and translation at the superior and inferior adjacent levels compared with baseline, while coflex showed no significant radiographic changes at the operative or index levels. The authors concluded low-grade spondylolisthesis was effectively stabilized by coflex and led to similar clinical outcomes, with improved perioperative outcomes, compared with PSF at 2 years. Reoperation rates, however, were higher in the coflex cohort. Patients in the fusion cohort experienced significantly increased superior and inferior level angulation and translation, while those in the coflex cohort experienced no significant adjacent or index level radiographic changes from baseline. Coflex Interlaminar Stabilization is a less invasive, safe, and equally efficacious clinical solution to PSF to treat low-grade spondylolisthesis, and it appears to reduce stresses at the adjacent levels. Clinical trial registration no.: NCT00534235 (ClinicalTrials.gov).

(2013) Davis et al. completed a review on the two-year results from the prospective, randomized, multicenter, Food and Drug Administration Investigational Device

Exemption trial to evaluate the safety and efficacy of Coflex interlaminar stabilization compared with posterior spinal fusion in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis. Three hundred twenty-two patients (215 Coflex and 107 fusions) from 21 sites in the United States were enrolled between 2006 and 2010. Subjects were randomized to receive laminectomy and Coflex interlaminar stabilization or laminectomy and posterolateral spinal fusion with spinal instrumentation in a 2:1 ratio. Overall device success required a 15-point reduction in Oswestry Disability Index, no reoperations, no major device-related complications, and no postoperative epidural injections. The results noted, patient follow-up at minimum 2 years was 95.3% and 97.2% in the Coflex and fusion control groups, respectively. Patients taking Coflex experienced significantly shorter operative times ($P < 0.0001$), blood loss ($P < 0.0001$), and length of stay ($P < 0.0001$). There was a trend toward greater improvement in mean Oswestry Disability Index scores in the Coflex cohort ($P = 0.075$). Both groups demonstrated significant improvement from baseline in all visual analogue scale back and leg parameters. Patients taking Coflex experienced greater improvement in Short-Form 12 physical health outcomes ($P = 0.050$) and equivalent mental health outcomes. Coflex subjects experienced significant improvement in all Zurich Claudication Questionnaire outcomes measures compared with fusion (symptom severity [$P = 0.023$]; physical function [$P = 0.008$]; satisfaction [$P = 0.006$]). Based on the Food and Drug Administration composite for overall success, 66.2% of Coflex and 57.7% of fusions succeeded ($P = 0.999$), thus demonstrating noninferiority. The overall adverse event rate was similar between the groups, but Coflex had a higher reoperation rate (10.7% vs. 7.5%, $P = 0.426$). At 2 years, fusions exhibited increased angulation ($P = 0.002$) and a trend toward increased translation ($P = 0.083$) at the superior adjacent level, whereas Coflex maintained normal operative and adjacent level motion. In conclusion, coflex interlaminar stabilization is a safe and efficacious alternative, with certain advantages compared with lumbar spinal fusion in the treatment of spinal stenosis and low-grade spondylolisthesis.

Subsection Summary: Coflex Device Plus Decompression Versus Decompression Plus Fusion

The FDA's approval of coflex was based on an open label, randomized, noninferiority trial that compared the noninferiority of coflex plus decompression to decompression plus posterolateral fusion in patients who had spinal stenosis, significant back pain, and up to grade 1 spondylolisthesis. Use of the noninferiority framework by the FDA assumed that decompression plus fusion was the standard of care for patients with spinal stenosis with up to grade 1 spondylolisthesis and because fusion is a more invasive procedure that requires longer operative time and has a potential for higher surgical and postsurgical complications, demonstrating noninferiority with a less invasive procedure such as coflex would be adequate to demonstrate a net benefit in health outcomes. However, subsequent to the approval of coflex, 2 RCTs, the Swedish Spinal Stenosis Study and the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial assessing the superiority of adding fusion to decompression over decompression alone reported a lack of or marginal benefit. The Swedish Spinal Stenosis Study trial, which was adequately powered to detect a 12-point difference in Oswestry Disability Index

score, showed no difference in Oswestry Disability Index scores between the 2 treatment arms. Hence, the results generated from a noninferiority trial using a comparator whose net benefit on health outcomes is uncertain confound meaningful interpretation of its results. Secondary (posthoc) comparison of the subgroup of patients with grade 1 spondylolisthesis, which may be a more relevant analysis, found similar outcomes between the coflex and fusion groups. However, almost a third of the fusion group had unsuccessful fusion with pseudoarthrosis which raises additional questions about the efficacy of the comparator. Oswestry Disability Index and visual analog scale did not significantly differ between the pseudoarthrosis and solid fusion groups, but the Zurich Claudication Questionnaire results were not reported. In addition, posthoc analysis is considered hypothesis-generating. Given the multiple concerns, a prospective trial that compares coflex to fusion in patients with severe spinal stenosis and grade 1 spondylolisthesis is needed.

Coflex Device Plus Decompression Versus Decompression Plus Posterolateral Fusion

(2018) Abjornson et al. reported outcomes from the subgoup of patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal investigational device exemption trial, but comparison with decompression alone in this population has not been reported. The major weakness in this trial was its use of lumbar spinal fusion as a comparator for patients with no spondylolisthesis. The underlying premise that patients with back pain and spinal stenosis do not respond well to decompression (alone or followed by nonsurgical treatments for back pain) has been challenged. For example, the Oswestry Disability Index success rate for decompression alone in the European Study of Coflex and Decompression Alone trial, was comparable to the Oswestry Disability Index success rate for decompression plus fusion in the pivotal trial.

Section Summary: Interlaminar Stabilization Devices Used with Spinal Decompression Surgery in Patients with No Spondylolisthesis or Instability

The pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. However, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in patients with no 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. When the trial was conceived, decompression plus fusion was viewed the standard of care for patients with spinal stenosis with up to grade 1 spondylolisthesis and back pain; thus, demonstrating noninferiority with a less invasive procedure such as coflex would be adequate to result in a net benefit in health outcomes. However, the role of fusion in the population of patients represented in the pivotal trial is uncertain, especially since the publication of the Swedish Spinal Stenosis Study and SLIP, 2 RCTs comparing decompression alone with decompression plus spinal fusion that were published in 2016. As a consequence, results generated from a noninferiority trial using a comparator whose

net benefit on health outcome is uncertain confounds meaningful interpretation of trial results. Therefore, demonstrating the noninferiority of coflex plus spinal decompression versus spinal decompression plus fusion, a comparator whose benefit on health outcomes is uncertain, makes it difficult to apply the results of the study. Outcomes from the subgroup of patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal investigational device exemption trial have been published, but comparison with decompression alone in this population has not been reported. Limitations of the published evidence preclude determining the effects of the technology on net health outcome.

Coflex Miscellaneous

(2020) Du et al. completed a clinical study on the long-term follow-up to evaluate coflex interspinous process dynamic stabilization in the treatment of lumbar spinal stenosis. he clinical and imaging data of 73 patients undergoing Coflex dynamic stabilization surgery from July 2008 to June 2012 were retrospectively analyzed. All patients had a minimum of 8 years of follow-up. Clinical data were used to assess the clinical efficacy, and radiographic parameters were measured for evaluation of ASD. The results noted 56 Patients were followed up for 107.6 ± 13.3 months. The visual analogue scale of pain (VAS), Owestry disability index (ODI) and Japanese Orthopedic Association Scores (JOA) improved significantly after surgery. At 6 months after surgery and the last follow-up, lumbar range of motion (ROM) was significantly lower than that before surgery ($P < 0.001$). ROM was slightly increased at the last follow-up compared with that 6 month after operation ($P > 0.05$). ROM of adjacent segments increased at 6 months and at the last follow-up compared with that before surgery ($P > 0.05$). At 6 months after surgery, intervertebral space height (ISH) and intervertebral foramen height (IFH) of implanted segment was significantly higher than that before surgery ($P < 0.05$). At the last follow-up, there was a decrease in ISH and IFH ($P > 0.05$). During the follow-up period, a total of 11 patients (19.6%) experienced complications and 6 patients (10.7%) underwent secondary surgery. The authors noted found that lamina decompression combined with Coflex interspinous process dynamic stabilization relieved patients' symptoms, the long-term efficacy was satisfactory. The incidence of ASD was 10.7%, the incidence of complications was 19.6%, and the reoperation rate is 10.7%, which has a good safety and effectiveness. Coflex can maintain the disc height of the surgical segment for a short period of time, retain a small range of motion, and reduce the risk of degeneration in adjacent segments. However, the number of cases in this study is small, and further multicenter randomized controlled trials with large samples are needed for further verification.

Superion Interspinous Spacer Device versus X-STOP Device (Interspinous)

(2019) Tekmyster et al. reported a registry of patients who had been treated with the Superion interspinous spacer for spinal stenosis and back and leg pain. Out of 2090 patients included at baseline, less than 25% provided data at 12 months. The low response rate raises the possibility of bias and is insufficient to derive any conclusions regarding the study.

(2018) Nunley et al. completed a study which estimated the type, dosage, and duration of opioid medications through 5 years of follow-up after IPD with the Superion Indirect Decompression System (Vertiflex Inc., Carlsbad, CA USA). Data was obtained from the Superion-treatment arm of a randomized controlled noninferiority trial. The prevalence of subjects using opiates was determined at baseline through 60 months. Primary analysis included all 190 patients randomized to receive the Superion device. In a subgroup of 98 subjects, we determined opioid-medication prevalence among subjects with a history of opioid use. At baseline, almost 50% (94 of 190) of subjects were using opioid medication. Thereafter, there was a sharp decrease in opioid-medication prevalence from 25.2% (41 of 163) at 12 months to 13.3% (20 of 150) at 24 months to 7.5% (8 of 107) at 60 months. Between baseline and 5 years, there was an 85% decrease in the proportion of subjects using opioids. A similar pattern was also observed among subjects with a history of opiates prior to entering the trial. The author's concluded, stand-alone IPD is associated with a marked decrease in the need for opioid medications to manage symptoms related to LSS. In light of the current opiate epidemic, such alternatives as IPD may provide effective pain relief in patients with LSS without the need for opioid therapy. reported a decrease in opioid use (n=107) and improvement in the quality of life (n=68) at 5 years, however, results were reported only for patients who had not undergone reoperation or revision, limiting interpretation of these results.

(2015) Patel et al. reported on the results of a multicenter randomized noninferiority trial (10% margin) comparing the Superion interspinous spacer with the X-STOP. The participants had intermittent neurogenic claudication despite 6 months of nonsurgical management with the superion interspinous space. The primary outcome was a composite of a clinically significant improvement in at least 1 of 3 Zurich Claudication Questionnaire domain scores compared with baseline; freedom from reoperation, epidural steroid injection, nerve block, rhizotomy, or spinal cord stimulator; and freedom from a major implant or procedure-related complications.

The results at 2 years of follow-up indicated that the primary noninferiority endpoint was met, with a Bayesian posterior probability of 0.993. However, 111 (28%) patients (54 Superion interspinous spacer, 57 X-STOP) withdrew from the trial during follow-up because they received a protocol-defined secondary intervention. Modified intention-to-treat analysis showed similar levels of clinical success for leg pain, back pain, and Oswestry Disability Index scores. Rates of complications and reoperations were similar between groups. Spinous process fractures, reported as asymptomatic, occurred in 16.4% of Superion interspinous space patients and 8.5% of X-STOP patients. Subsequently, long-term follow-up results were reported. At 3 years, 120 patients in the Superion interspinous process spacer group and 129 in the X-STOP group remained (64% [249/391]). Of them, composite clinical success was achieved in 52.5% of patients in the Superion interspinous spacer group and 38.0% of the X-STOP group (p=0.023). The 36-month clinical outcomes were reported for 82 patients in the Superion interspinous spacer group and 76 patients in the X-STOP group (40% [158/391]). It is unclear from the reporting whether the remaining patients were lost to follow-up or were considered treatment failures and censored from the results. Also, trial interpretation is limited by

questions about the efficacy of the comparator and lack of a control group treated with surgical decompression. At the 4-year and 5-year follow-ups, only data for the Superion arm were reported, which included data for 90% and 65% of originally randomized patients, respectively. Of these, success on at least 2 of 3 Zurich Claudication Questionnaire domains was observed in 84% of patients at years 4 and 5. The limitations noted it was not blinded to treatment assignment or outcome assessment. Outcomes were assessed by the treating physician. There was a high loss to follow-up and/or missing data.: 11% of patient were not randomized, and data from 28% missing at 2 years; 35% at 3 years. Additionally, it is unclear why there was a 10% noninferiority margin selected.

Section Summary: Interspinous or Interlaminar Spacer as Stand-Alone Treatment
The evidence for the Superion interspinous spacer for lumbar spinal stenosis includes a pivotal trial. This trial compared the Superion interspinous spacer with the X-STOP Interspinous Process Decompression System but did not include comparison groups for conservative treatment or standard surgery. The trial reported significantly better outcomes on some measures. For example, the percentage of patients experiencing improvements in certain quality of life outcome domains was reported at over 80%. However, this percentage was based on 40% of the original dataset. Interpretation of this trial is limited by uncertainty about the number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression.

The coflex interlaminar implant was compared with decompression in the multicenter, double-blind FELIX trial. Functional outcomes and pain levels between the 2 groups at 1-year follow-up did not differ statistically but reoperation rates due to lack of recovery were statistically higher with the coflex implant (29%) compared with bony decompression (8%). It is not clear whether patients with reoperations were included in pain and function assessments; if they were, this would have decreased assessment scores at 1 year. For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to the absence of recovery had been performed in 33% of the coflex group compared with 8% of the bony decompression group. This is an off-label use of the device. Use consistent with the FDA label is reviewed in the next section.

Devices: Miscellaneous
(2021) Aggarwal and Chow completed a review on the real-world adverse events of interspinous spacer using manufacturer and user facility device experience data. They noted the following methodically; disproportionality analysis was conducted to determine whether a statistically significant signal exists in the three interspinous spacers and the reported adverse events using the Manufacturer and User Facility Device Experience (MAUDE) database maintained by the US Food and Drug Administration. The results noted a statistically significant signals were found with each of the three interspinous spacer devices (Coflex, Vertiflex, and X-Stop) and each of the following adverse events: fracture, migration, and pain/worsening symptoms. In conclusion further studies such as randomized controlled trials are needed to validate the findings.

(2021) Welton et al. completed a retrospective review on the comparison of adverse outcomes follow placement of Superion interspinous spacer device vs. laminectomy and laminotomy. The purpose of this study is to compare the short-term complications of the SISS with laminectomy or laminotomy and highlight device-specific long-term outcomes with SISS. Having no differences in adverse events between laminectomies or laminotomies and SISS plus evidence of substantial device-specific long-term adverse outcomes and reoperation should be given consideration when deciding on surgical intervention of 1-2 level lumbar spinal stenosis. 89 patients who received lumbar level SISSs were compared with 378 matched controls who underwent primary lumbar spine laminectomy or laminotomy; data were collected from the American College of Surgeons National Surgical Quality Improvement Program database. Complications analyzed included rates of wound infection, pulmonary embolism, deep venous thrombosis, urinary tract infection, sepsis, septic shock, cardiac arrest, death, and reoperation within 30 days of index surgery. Differences between groups were analyzed using the $\chi 2$test. Device-specific complication (DSC) rates included device malfunction or misplacement (DM), device explantation (DE), spinous process fracture (SPF), and subsequent spinal surgery (SSS). The noted results included no differences in demographics or comorbidities existed between groups. There was no significant difference in rates of complications between groups. A total of 44.4% of patients in the SISS group experienced DSCs with 11.1% of patients experiencing DM, 21.1% experiencing an SPF, 20.1% requiring DE, and 24.3% requiring SSS. Having at least 1 DSC significantly increased odds of SSS, odds ratio >120, $P < .0001$. In conclusion, the rates of 30-day complications in the SISS group were not significantly different from patients undergoing laminectomy or laminotomy. Rates of 2-year DSC within SISS and cumulative risk associated with these complications should be considered further as they likely represent need for additional procedures for patients and substantial cost to the healthcare system.

(2020) Tram et al. completed a retrospective review examined the literature on the efficacy and complications associated with decompression and interspinous devices (ISDs) used in surgeries for LSS. LSS is a debilitating condition that affects the lumbar spinal cord and spinal nerve roots; however, a comprehensive report on the relative efficacy and complication rate of ISDs as they are compared to traditional decompression procedures is currently lacking. The PubMed database was queried to identify clinical studies that exclusively investigated decompression, those that exclusively investigated ISDs, and those that compared decompression with ISDs. Only prospective cohort studies, case series, and RCTs that evaluated outcomes using the VAS, ODI, or JOA scores were included. A random-effects model was established to assess the difference between pre-operative and the 1- to 2-year post-operative VAS scores between ISD surgery and lumbar decompression. This study included 40 papers that matched the selection criteria. A total of 25 decompression-exclusive clinical trials with 3,386 patients and a mean age of 68.7 years (range of 31 to 88 years) reported a 2.2 % incidence rate of dural tears and a 2.6 % incidence rate of post-operative infections. A total of 8 ISD-exclusive clinical trials with 1,496 patients and a mean age of 65.1 (range of 19 to 89 years) reported a 5.3 % incidence rate of post-operative leg pain and a 3.7 %

incidence rate of spinous process fractures; 7 studies that compared ISDs and decompression in 624 patients found a re-operation rate of 8.3 % in ISD patients versus 3.9 % in decompression patients; they also reported dural tears in 0.32 % of ISD patients versus 5.2 % in decompression patients. A meta-analysis of the RCTs found that the differences in pre-operative and post-operative VAS scores between the 2 groups were not significant. Both decompression and ISD interventions were unique surgical interventions with different therapeutic efficacies and complications. The authors concluded that the collected studies did not consistently demonstrate superiority of either procedure over the other but understanding the differences between the 2 techniques could help tailor treatment regimens for patients with LSS. These researchers stated careful patient selection remains crucial for either surgical procedure to ensure optimal surgical outcomes tailored to each patient. They stated that more diverse studies are needed to determine the superiority of one technique over the other for different patient populations. The authors stated that limitations of this study included inconsistent reporting of measurements among studies. Inconsistencies were also found in the extent of complications reported, with more exhaustive studies reporting unique complications, while some studies simply stated that no major complications were encountered. Another limitation of this paper was the variation in post-operative care, which was important for long-term complications such as re-operation rates.

(UpToDate 2020; Last updated January 2022) Levin et al completed a review on "Lumbar spinal stenosis: Treatment and prognosis" states that "Intraspinous spacer implantation -- A potentially less invasive treatment option involves implanting a device between the spinous processes at one or two vertebral levels, relieving compression. This procedure is said to be appropriate for those patients with spinal stenosis without spondylolisthesis who have intermittent claudication symptoms that are exacerbated in extension and relieved in flexion. A randomized, multicenter study in 191 patients compared the implantation of the X STOP implant, a titanium alloy device, with nonoperative treatment. At 6 months, symptoms were relieved in 52 % of treated patients, compared with 9 % of controls. Benefit was maintained at 2 and 4 years of follow-up and was associated with reduced disability and improved quality of life. Subsequent uncontrolled observations have found that implantation of the X STOP device has been efficacious in many patients, if not in as large a proportion as was found in the clinical trial. While radiologic improvement in spinal canal and neuroforaminal narrowing can be measured after surgery, these changes are not correlated with clinical benefit and are not maintained over time in most patients. These procedures appear to be associated with higher rates of subsequent surgery than patients initially treated with laminectomy. Adverse effects also appear to be more commonly reported in general clinical experience; these include discitis/osteomyelitis, device dislocations, spinous process fractures, recurrent disc herniation, hematoma, cerebrospinal fluid fistula, and foot drop. It is unclear how this newer procedure compares with the standard surgical procedure, decompressive laminectomy, in terms of effectiveness, side effects, recovery time, and long-term outcomes. This treatment does not appear to be helpful in patients who have spondylolisthesis". Furthermore, intraspinous spacer implantation is not listed

in the “Summary and Recommendations” section of this review. (*Accessed February 2022*)

(2015) Doulgeris et al. compared an interspinous fusion device with posterior pedicle screw system in a lateral lumbar interbody lumbar fusion. These researchers biomechanically tested 6 cadaveric lumbar segments (L1 to L2) under an axial preload of 50N and torque of 5Nm in flexion-extension, lateral bending and axial rotation directions. They quantified range of motion, neutral zone/elastic zone stiffness in the following conditions: intact, lateral discectomy, lateral cage, cage with interspinous fusion, and cage with pedicle screws. A complete lateral discectomy and annulectomy increased motion in all directions compared to all other conditions. The lateral cage reduced motion in lateral bending and flexion/extension with respect to the intact and discectomy conditions but had minimal effect on extension stiffness. Posterior instrumentation reduced motion, excluding interspinous augmentation in axial rotation with respect to the cage condition. Interspinous fusion significantly increased flexion and extension stiffness, while pedicle screws increased flexion/extension and lateral bending stiffness, with respect to the cage condition. Both posterior augmentations performed equivalently throughout the tests except in lateral bending stiffness where pedicle screws were stiffer in the neutral zone. The authors concluded that a lateral discectomy and annulectomy generated immediate instability. Stand-alone lateral cages restored a limited amount of immediate stability, but posterior supplemental fixation increased stability. Both augmentations were similar in a single level lateral fusion in-vitro model, but pedicle screws are more equipped for coronal stability. They stated that an interspinous fusion is a less invasive alternative than pedicle screws and is potentially a conservative option for various interbody cage scenarios.

(2015) Hirsch et al. stated that lumbar spinal stenosis is a major public health issue. Interspinous devices implanted using minimally invasive techniques may constitute an alternative to the reference standard of bony decompression with or without intervertebral fusion. However, their indications remain unclear, due to a paucity of clinical and biomechanical data. These investigators evaluated the effects of four interspinous process devices implanted at L4 to L5 on the intervertebral foramen surface areas at the treated and adjacent levels, in flexion and in extension. Six fresh frozen human cadaver lumbar spines (L2 to sacrum) were tested on a dedicated spinal loading frame, in flexion and extension, from 0 to 10 N·m, after preparation and marking of the L3 to L4, L4 to L5, and L5 to S1 foramina. Stereoscopic 3D images were acquired at baseline then after implantation at L4 to L5 of each of the 4 devices (Inspace®, Synthes; X-Stop®, Medtronic; Wallis®, Zimmer; and Diam®, Medtronic). The surface areas of the 3 foramina of interest were computed. All 4 devices significantly opened the L4 to L5 foramen in extension. The effects in flexion separated the devices into 2 categories. With the 2 devices characterized by fixation in the spinous processes (Wallis® and Diam®), the L4 to L5 foramen opened only in extension, whereas with the other 2 devices (X-Stop® and Inspace®), the L4 to L5 foramen opened not only in extension, but also in flexion and in the neutral position. None of the devices implanted at L4 to L5 modified the size of the L3 to L4 foramen. X-Stop® and Diam® closed the L5 to S1 foramen in

extension, whereas the other 2 devices had no effect at this level. The authors concluded that these findings demonstrated that interspinous process devices modified the surface area of the interspinous foramina in-vitro. They stated that clinical studies are needed to clarify patient selection criteria for interspinous process device implantation. They also noted several limitations. They performed in vitro measurements of cadaver specimens of lumbar spine segments after excision of all the muscles, which act as spinal stabilizers in vivo. Therefore, the data provides only indications about in vivo biomechanical behavior, as is the case for all biomechanical studies. Furthermore, the advanced mean age of the donors does not reflect the mean age of the patients who might benefit from IPD implantation. Also, they did not measure the degree of kyphosis induced by the IPDs, which might vary across devices and would be a parameter of interest to further categories the two IPD categories. They saw two main methodological limitations to the study: the small sample size limits the statistical power of the analysis, and the differences in IPD size precluded randomization of the order of IPD implantation. Although the biomechanical effects documented in vitro seem indisputable, no information is available on whether the foraminal size increase correlates linearly with the clinical benefits. Thus, they do not know the foraminal opening cut-off above which an improvement in the clinical symptoms can be expected. Thus, the biomechanical study must be completed by a clinical study to confirm the efficacy of IPD implantation and to determine the best criteria for selecting patients likely to benefit from this procedure.

(2015) Lauryssen et al. compared the 2-year clinical outcomes of a prospective, RCT of an FDA-approved interspinous spacer with the compilation of published findings from 19 studies of decompressive laminectomy for the treatment of LSS. Back and leg pain, ODI, and ZCQ values were compared between spacer- and laminectomy-treated patients pre-operatively and at 12 and 24 months. Percentage improvements between baseline and 24 months uniformly favored patients treated with the spacer for back pain (65 % versus 52 %), leg pain (70 % versus 62 %), ODI (51 % versus 47 %) and ZCQ symptom severity (37 % versus 29 %) and physical function (36 % versus 32 %). The authors concluded that both treatments provided effective and durable symptom relief of claudicant symptoms. This stand-alone interspinous spacer offered the patient a minimally invasive option with less surgical risk. This study provided short-term follow-up data (24 months).

(2015) Lee et al. conducted a systematic literature review of interspinous dynamic stabilization, including Diam®, Wallis®, Coflex, and X-STOP®, to assess its safety and efficacy. A literature search was done in Korean and English, by using eight domestic databases which included KoreaMed and international databases, such as Ovid Medline, Embase, and the Cochrane Library. A total of 306 articles were identified, but the animal studies, preclinical studies, and studies that reported the same results were excluded. As a result, a total of 286 articles were excluded and the remaining 20 were included in the final assessment. Two assessors independently extracted data from these articles using predetermined selection criteria. Qualities of the articles included were assessed using Scottish Intercollegiate Guidelines Network (SIGN). The complication rate of interspinous dynamic stabilization has been reported to be 0% to 32.3% in 3- to 41-month

follow-up studies. The complication rate of combined interspinous dynamic stabilization and decompression treatment (32.3%) was greater than that of decompression alone (6.5%), but no complication that significantly affected treatment results was found. Interspinous dynamic stabilization produced slightly better clinical outcomes than conservative treatments for spinal stenosis. Good outcomes were also obtained in single-group studies. No significant difference in treatment outcomes was found, and the studies compared interspinous dynamic stabilization with decompression or fusion alone. The authors of the systematic review concluded that no particular problem was found regarding the safety of the technique. Its clinical outcomes were similar to those of conventional techniques, and no additional clinical advantage could be attributed to interspinous dynamic stabilization. However, few studies have been conducted on the long-term efficacy of interspinous dynamic stabilization. Thus, the authors suggest further clinical studies be conducted to validate the theoretical advantages and clinical efficacy of this technique.

(2014) Puzzilli et al. evaluated patients who were treated for symptomatic lumbar spinal stenosis with interspinous process decompression (IPD) implants compared with a population of patients managed with conservative treatment. A total of 542 patients affected by symptomatic lumbar spine degenerative disease were enrolled in a controlled trial; 422 patients underwent surgical treatment consisting of X-STOP device implantation, whereas 120 control cases were managed conservatively. Both patient groups underwent follow-up evaluations at 6, 12, 24, and 36 months using the Zurich Claudication Questionnaire, the visual analog scale (VAS) score and spinal lumbar X-rays, CT scans and MR imaging. One-year follow-up evaluation revealed positive good results in the 83.5% of patients treated with IPD with respect to 50% of the non-operative group cases. During the first 3 years, in 38 out of the 120 control cases, a posterior decompression and/or spinal fixation was performed because of unsatisfactory results of the conservative therapy. In 24 (5.7%) of 422 patients, the IPD device had to be removed, and a decompression and/or pedicle screw fixation was performed because of the worsening of neurological symptoms. The authors concluded that these findings supported the effectiveness of surgery in patients with stenosis; IPD may offer an effective and less invasive alternative to classical microsurgical posterior decompression in selected patients with spinal stenosis and lumbar degenerative disk diseases.

Summary of Evidence

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in order to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. Although the randomized device trials report short-term improvements in symptoms and functional status, when compared to nonoperative therapy, a number of questions remain. Overall, high-quality comparative data are limited. There is a need for longer-term (more than two years) outcome data on symptom relief, the need for repeat procedures, and implant survival. Future studies need to better control for potential biases and avoid other methodologic issues, including follow-up of patients in the control group and consistent use of outcome measurements. There are also questions about patient selection criteria, for instance, whether patients

with any degree of spondylolisthesis should be excluded from the treatment. In addition, comparisons with decompressive surgery without an interlaminar implant are lacking, and recent case series indicate that outcomes may be less favorable than those reported in the multi-center randomized trial. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
Clinical input was sought to help determine whether the use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain and no or grade 1 spondylolisthesis who failed conservative treatment would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 6 respondents, including 2 specialty society-level responses and 4 physician-level responses, including 2 identified through a specialty society and 2 through an academic medical center, while this policy was under review in 2018.

For individuals who have severe spinal stenosis and grade 1 spondylolisthesis or instability who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, clinical input is not universally supportive of a clinically meaningful improvement in net health outcome. While some respondents considered the shorter recovery time and lower complication rate to be an advantage compared to fusion, others noted an increase in complications and the need for additional surgery with the device.

For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, clinical input is not generally supportive of a clinically meaningful improvement in net health outcomes, with clinical experts noting an increase in complications and need for additional surgery compared to laminectomy alone.

Practice Guidelines and Position Statements

The Australian Medical Services Advisory Committee (MSAC)
(2017) The Australian Medical Services Advisory Committee provided a public summary document for minimally invasive, lumbar decompression and dynamic stabilization using an interlaminar device, with no rigid fixation to the vertebral pedicles, of one or two lumbar motions which noted the following information:

- MSAC considered a submission to include a service using the Coflex Interlaminar Stabilization device (hereafter the device) in the MBS. The proposed service involves use of 2 the device to stabilize the spine following decompression, without the need for fusion, in patients with lumbar spinal stenosis and mild degenerative instability of one or two lumbar motion segments.
- MSAC noted that the submission only compared use of the device to decompression with fusion for people with lumbar spinal stenosis. MSAC noted that the PICO Sub-Committee (PASC) had asked that use of the device also be

compared with decompression alone because of uncertainty about whether outcomes in people undergoing decompression and fusion were any better than outcomes in people undergoing decompression alone. Studies published around the time the protocol was written had compared decompression and fusion with decompression alone in people with lumbar spine stenosis (with or without spondylolisthesis). Two years post-surgery, these studies reported similar levels of disability due to back pain.

- MSAC questioned the applicant's claim that decompression and fusion, rather than decompression alone, was the appropriate comparator for use of the device. In addition to the two studies identified above, MSAC noted that a Cochrane review of spinal surgery for lumbar spinal stenosis was unable to identify any clear benefit of surgery compared to nonsurgical treatment.
- MSAC noted that the submission did not provide a valid reason for failing to compare use of the device with decompression alone and as a result, the committee was unable to determine the relative safety and effectiveness of using the device compared with decompression alone. With respect to the comparator of decompression and fusion, MSAC noted that the evidence to support listing of the device relied upon a single, low-quality trial in people with moderate spinal stenosis with low back pain (>5/10) and with or without up to Meyerding grade I spondylolisthesis (the Investigational Device Exemption (IDE) trial).
- MSAC had several concerns about the quality of the IDE trial including that the study was unblinded and that study outcomes may have been selectively reported. MSAC also noted that in the analysis of disability due to back pain five years post-surgery, 30% of patients were excluded from the analysis because they had had a secondary surgical procedure or epidural injection.
- Given the uncertainty around clinical effectiveness, MSAC was unable to support the listing of the use of this device. MSAC requested this advice be provided to PLAC. MSAC noted that any resubmission required new high quality trial evidence comparing use of the device with decompression alone and comparing use of the device with decompression and fusion and for each of the indications requested (lumbar spinal stenosis with or without mild instability and mild instability alone).
- Given MSAC's concerns as to whether decompression and fusion was any better than decompression alone, MSAC queried whether decompression and fusion should be funded on the MBS. MSAC suggested that a review of the current evidence for decompression and fusion in people with lumbar spine stenosis be undertaken. MSAC noted that the MBS Review of Spinal Surgery is currently reviewing available MBS items for spinal surgery. However, MSAC considered that an in-depth review of the evidence for decompression and fusion in this population was still warranted. MSAC noted that it would be helpful if the review considered utilization and provider level data from the Department. MSAC foreshadowed that if there was insufficient evidence for decompression and fusion in lumbar spinal stenosis then a wider review including decompression and/or fusion for other conditions may be recommended.

(*Accessed February 2022*)

International Society for the Advancement of Spine Surgery (ISASS)
(2016) The International Society for the Advancement of Spine Surgery published recommendations and coverage criteria for decompression with interlaminar stabilization. The Society concluded that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Criteria included coverage rationale only pertains to patients with moderate lumbar spinal stenosis at 1 or 2 contiguous levels who do not present with gross instability because interlaminar stabilization has only been used and tested in this patient group:

- At least moderate lumbar stenosis (>25% reduction of the anteroposterior dimension) at 1 or 2 contiguous levels between L1 and L5.
- Absence of gross angular or translatory instability of the spine at index or adjacent levels.
- Patients who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 12 weeks of non-operative treatment.
- Only experienced surgeons who have undergone training on use of the device should perform the procedure.
- This ISASS policy does not formally address coverage rationale for interspinous distraction devices without decompression pending further data and review of this type of procedural approach in treating LSS.

(*Accessed February 2022*)

The National Institute for Health and Care Excellence (NICE)
(2010) The National Institute for Health and Care Excellence (NICE) published guidance that indicated "Current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication shows that these procedures are efficacious for carefully selected patients in the short and medium-term, although failure may occur, and further surgery may be needed." (*The evidence reviewed consisted mainly of reports on X-STOP® Interspinous Process Decompression System*.)
(*Accessed February 2022*)

The North American Spine Society (NASS)
(2018) The North American Spine Society (NASS) published specific coverage policy recommendations on the lumbar interspinous device *without* fusion and with decompression, 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."

(*Accessed February 2022*)

Regulatory Status

A. The following interspinous and interlaminar stabilization and distraction devices have been approved by the U.S. Food Drug Administration (FDA) through the premarket approval (FDA product code: NQO) (*This is not intended to be an all-inclusive list*)

Device	coflex® Interlaminar Technology implant
Manufacturer	Paradigm Spine (acquired by RTI Surgical)
Approval Date	2012
Premarket Approval	P110008
Information	It 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 1- or 2-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 6 months of nonoperative treatment. The coflex "is intended to

	be implanted midline between the adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s). The Coflex® device is not to be used accompanying a fusion at the treatment level. 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. o Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction." 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, the 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 was a multicenter trial with 230 patients in Germany who were followed for 5 years, comparing decompression alone with decompression plus coflex®. The third, a multicenter trial with 345 patients in the U.S. who were followed for 5 years, compared decompression alone with decompression plus coflex, FDA product code: NQO.

Device	The Superion® Indirect Decompression System (formerly InterSpinous Spacer)
Manufacturer	VertiFlex (acquired by Boston Scientific)
Approval Date	2015
Premarket Approval	P140004
Information	It is an H-shaped implant composed of titanium alloy and delivered percutaneously as a single-piece through a cannula after dilators have opened the interspinous

	space. The implant has superior and inferior cam lobes that rotate during deployment, so as to capture the superior and inferior spinous processes It 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 (MRI), 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 an 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 6 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: o Instability of the lumbar spine, eg, isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4) o An ankylosed segment at the affected level(s) o Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral). o Scoliosis (Cobb angle >10 degrees) • *Cauda equina* syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction. o 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."

Device	X Stop Interspinous Process Decompression System
Manufacturer	Medtronic Sofamor Danek
Approval Date	2005 (withdrawn 2015)
Premarket Approval	P040001
Information	It was approved for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis for those who have had a regimen of at least six months of non-operative treatment and who have relief of their pain when in flexion. The device is approved for implantation at one or two lumbar levels in patients whose

	condition warrants surgery at no more than two levels. The X-STOP® PEEK IPD® System, a modified version of the original X-STOP system, received FDA approval in 2006. Medtronic has discontinued the distribution of the X-Stop system.

B. The FDA recommended against approval for the following:
   - DIAM® Spinal Stabilization System: DIAM system (Medtronics) in an Orthopaedic & Rehabilitation Devices panel meeting in February 2016

C. Other devices still undergoing study may include but are not limited to the following:
   - Aperius PercLID System (Kyphon/ Medtronic Spine)
   - CoRoent Extensure (Nuvasive)
   - ExtenSure (Nuvasive)
   - FLEXUS (Globus Medical)
   - Falena Interspinous Decompression Device (Mikai Spine)
   - Helifix Interspinous Spacer System (Alphatec Spine)
   - In-Space (Synthes)
   - NL-Prow Interspinous Spacer (Non-Linear Technologies)
   - Stenofix (Synthes)
   - Wallis System (Abbott Spine/ Zimmer Spine)

PRIOR APPROVAL

Not applicable.

POLICY

Related Medical Policies:
- 07.01.84 Interspinous Fixation Devices

Interspinous distraction devices are considered investigational for all indications to include but not limited to the following devices:
- Coflex® Interlaminar Technology Implant
- Coflex® Intralaminar Stabilization Devices
- X-STOP® Interspinous Process Decompression (IPD®) System
- Vertiflex® Interspinous Decompression Spacer/Superion® InterSpinous Spacer

There is insufficient evidence in the peer-reviewed medical literature to demonstrate the long-term safety and efficacy of interspinous distraction devices and the durability of the devices. The impact of this technology on net health outcome is not known. Longer-term outcome data on symptom relief, the need for repeat procedures, and implant survival is needed.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- C1821 Interspinous process distraction device (implantable)
- 22867 Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
- 22868 Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; 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 Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)
- 22899 Unlisted procedure, spine [*when specified as insertion of an interspinous process distraction device*]

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POLICY HISTORY

Date	Reason	Action
February 2022	Annual Review	Policy Revised
February 2021	Annual Review	Policy Revised
October 2020	Interim Review	Policy Revised
February 2020	Annual Review	Policy Renewed
February 2019	Annual Review	Policy Revised
February 2018	Annual Review	Policy Renewed
February 2017	Annual Review	Policy Revised
February 2016	Annual Review	Policy Revised
March 2015	Annual Review	Policy Renewed
April 2014	Annual Review	Policy Renewed
May 2013	Annual Review	Policy Revised
May 2012	Annual Review	Policy Renewed
June 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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