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Subject: Interspinous and Interlaminar Stabilization/Distraction (Spacers) and Fixation (Fusion) Devices

DESCRIPTION:

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in those with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. 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.

Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. Interspinous fixation devices (IFDs) are also being evaluated for stand-alone use in individuals with spinal stenosis and/or spondylolisthesis.

Summary and Analysis of Evidence: Xin et al (2023) conducted a systematic review and meta-analysis of RCTs comparing interspinous spacer devices (ISDs) to decompressive surgery for patients with lumbar spinal stenosis. Eight RCTs including patients (N=852) with lumbar spinal stenosis who received either ISD or decompressive surgery were included. Follow-up duration of trials ranged from 6 to 40 months. The pooled data indicated that patients in the ISD group experienced shorter operation time (p=.003) and otherwise similar hospital stay time and dural violation compared to decompressive surgery. After initial ISD or decompressive surgery, there was a significantly higher rate or reoperation after ISD compared to decompression (odds ratio [OR], 3.21; 95% confidence interval. In terms of clinical efficacy

endpoints, there was no significant difference in mean visual analog scale leg and back pain scores, Oswestry Disability Index (ODI) scores, or Zurich Claudication Questionnaire symptom severity subscores between groups. There was a significantly lower Zurich Claudication Questionnaire physical function subscore with ISD compared to decompression, but the clinical significance is unknown. The studies included X-STOP ISD devices or other, non-FDA approved ISD devices, which contributed to heterogeneity. Also, there was no discussion or stratification of patients based on severity of lumbar spinal stenosis.

Hagedorn et al (2022) conducted a retrospective study to determine the incidence of lumbar decompression surgery following minimally invasive lumbar decompression or treatment with the Superion interspinous spacer. Of the 199 patients included in the final analysis, 57 patients underwent minimally invasive lumbar decompression only, 124 patients underwent treatment with the Superion interspinous spacer only, and 18 patients underwent minimally invasive lumbar decompression followed by treatment with the Superion interspinous spacer. After 2 years of follow-up, subsequent spine surgery was received by 3 patients who initially underwent minimally invasive lumbar decompression and 1 patient who initially underwent treatment with the Superion interspinous spacer. All patients who underwent subsequent surgery were noted to have severe lumbar spine stenosis.

Whang et al (2023) conducted a retrospective, comparative claims analysis using Medicare claims data to compare rates of subsequent interventions between patients with lumbar spinal stenosis treated initially with ISD and open surgery (such as decompression or fusion). Patients were included in the analysis if they were at least 50 years of age with lumbar spinal stenosis and a qualifying procedure during 2017 to 2021 in the Medicare database. Once identified, patients were reviewed from the qualifying procedure until the end of data availability, up to a 3-year follow-up period. Claims data reflected inpatient hospital, outpatient hospital, skilled nursing facility, or home health encounters for Medicare beneficiaries, but not medication coverage. A total of 400,685 patients (mean age, 71.5 years; 50.7% male) received a qualifying procedure (4183 [10%] treated with ISD; 211,014 [52.7%] with decompression alone; 76,935 [19.2%] with decompression + fusion; and 108,553 [27.1%] with fusion alone) and were included in the analysis. Patients who received ISD were older at baseline compared to open surgery group and had increased prevalence of comorbidities, including hypertension, osteoarthritis, diabetes, obesity, chronic obstructive pulmonary disease, atrial fibrillation, osteoporosis, and congestive heart failure.

Rosner et al (2024) also conducted a retrospective Medicare claims analysis to determine rates of subsequent spinal procedures between individuals receiving ISD alone versus minimally invasive lumbar decompression (MILD) during 2017 to 2021. Patients receiving ISD and MILD were matched 1:1 using propensity score matching based on demographics and clinical characteristics. A total of 3614 patients from each group were included after matching (mean age, 74 years; mean follow-up, 20 months). At 20 months of follow-up, the ISD cohort showed lower rates of any subsequent surgical intervention and lumbar spinal stenosis surgical intervention compared to the MILD cohort. There were no significant differences in safety endpoints between the cohorts, including postoperative complications or life-threatening complications. Authors concluded that the safety was comparable between procedures, with a lower re-operation rate at 20 months after ISD compared to MILD. Limitations are similar to the other claims analysis, since the study did not examine changes in symptoms, functionality, or pain. Because the enrollment criteria was the same as that in Whang et al (2023), there may have been patients included in both analyses. Patients were also not randomized to treatment groups and MILD

and ISD do not always have identical clinical indications, which could increase the risk of implicit bias in patient selection.

A European, multicenter, randomized, double-blind trial (Foraminal Enlargement Lumbar Interspinous distraXion; FELIX) assessed the superiority of coflex (without bony decompression) over bony decompression in 159 patients who had intermittent neurogenic claudication due to lumbar spinal stenosis (Moojen et al, 2013). The primary outcome at 8-week and 1-year follow-ups was the Zurich Claudication Questionnaire score. The score increases with increasing disability. At 8 and 52 weeks, the primary outcome efficacy measure in the coflex arm was not superior to that for standard decompression. In addition, more coflex recipients required reoperation than the standard decompression patients at the 1- and 2-year follow-ups. Given the substantially higher frequency of reoperation in the absence of statistically significant improvements in the efficacy outcome, further summarization of study limitations was not done for this trial.

The FDA approved coflex on the basis of an open-label, randomized, multicenter, noninferiority trial

(-10% noninferiority margin) that compared coflex plus decompression to decompression plus posterolateral fusion in patients who had stenosis, significant back pain, and either no spondylolisthesis or grade 1 spondylolisthesis (Davis, Errico et al, 2013; Davis, Auerbach et al, 2013; FDA, Summary of Safety and Effectiveness Data (SSED): coflex Interlaminar Technology, 2012). The control group was treated with pedicle screw and rod fixation with autograft but without an interbody (intervertebral) cage or bone morphogenetic protein. A total of 398 patients were randomized, of whom 322 were included in the per-protocol analysis. Composite clinical success (a minimum 15-point improvement in Oswestry Disability Index score, no reoperations, no device-related complications, no epidural steroid injections in the lumbar spine, and no persistent new or worsening sensory or motor deficit) at 24 months showed that coflex was noninferior to screw and rod fixation (-10% noninferiority margin). Secondary effectiveness criteria, which included Zurich Claudication Questionnaire score, visual analog scale scores for leg and back pain, SF-12 scores, time to recovery, patient satisfaction, and several radiographic endpoints, tended to favor the coflex group. The percentages of device-related adverse events (5.6%) did not differ statistically between the 2 groups. Wound problems were more frequent in the coflex group (14% vs. 6.5%) but all of these were resolved by 3 months. There was a 14% incidence of spinous process fractures in the coflex arm, which were reported to be mostly asymptomatic. The reported follow-up rates through 5 years were at least 85% (Bae et al, 2016). At 2 years, overall success was similar for patients treated with the coflex device at 1 or 2 levels (68.9% and 69.4%, respectively). At 60 months, the composite clinical success was achieved in 48.3% of 1 level and 60.9% of 2 level patients (Abjornson et al, 2018).

A secondary (unplanned) analysis of patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time and blood loss. There were no statistically significant differences between the coflex and fusion groups in Oswestry Disability Index, visual analog scale, and Zurich Claudication Questionnaire scores after 2 years (Davis, Auerbach, et al, 2013). In that analysis, 62.8% coflex patients and 62.5 fusion patients met the criteria for operative success. Fusion was obtained in 71% of the control group, leaving nearly a third of patients with pseudoarthrosis. The authors reported no significant differences in Oswestry Disability Index or visual analog scale between the patients with pseudoarthrosis or solid fusion, but Zurich Claudication Questionnaire scores were not reported. There were 18% spinous process fractures in the coflex group, of which 7 had healed by the 2-

year follow-up. Reoperation rates were 6% in the fusion group (p=.18) and 14% in the coflex group, including 8% of coflex cases that required conversion to fusion. Another post-hoc analysis of the pivotal RCT evaluated the use of the device in patients 65 years or older (Grinberg et al, 2020). Clinical outcomes (eg, Oswestry Disability Index, visual analog score, Zurich Claudication Questionnaire, epidural injections) were measured out to 60 months. Patients age 65 years or older who received the interlaminar implant with decompression (n=84) had clinical outcomes that were not significantly different to patients 65 years or older who received decompression and fusion (n=57), and to patients younger than 65 who received the interlaminar implant with decompression (n=131). In contrast, perioperative outcomes such as operative time, blood loss, and hospital stay were improved with the interlaminar implant compared to posterolateral fusion. A limitation in the study is that other published evidence about the use of coflex as an alternative to fusion is sparse. The results of a single randomized trial do not always correspond with the rates of treatment response, complications, and reoperations in actual practice. Although thousands of coflex operations have been performed in the U.S. and elsewhere, there are few data on the performance of coflex plus decompression surgery other than in randomized trials.

Zheng et al (2021) retrospectively compared the long-term outcomes of coflex plus decompression to decompression plus fusion for lumbar degenerative disease. The coflex group was comprised of 39 patients and the decompression plus posterior lumbar interbody fusion group (PLIF) was comprised of 43 patients. Both groups had a mean follow-up period of 104 months. Both the Oswestry disability index and visual analog scale leg and back pain scores of both groups significantly improved compared to the baseline, with no difference detected between groups. Compared to the PLIF group, the coflex group displayed preserved mobility, shorter duration of surgery, decreased amount of blood loss, and shorter hospital stay.

Schmidt et al (2018) 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). The proportion of patients who met the criteria for composite clinical success at 24 months was statistically significantly higher in the coflex arm (58.4%) than in the decompression alone arm (41.7%), with a treatment difference of 16.7%. 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%) at 24 months.

Zhong et al (2021) evaluated perioperative outcomes in a comparative study of 83 patients. Patients who had the coflex interlaminar implant in combination with laminectomy (n=46) had higher estimated blood loss, longer operative time, and longer length of stay compared to laminectomy alone (n=37). Total perioperative complications (21.7% vs. 5.4%) and instrumentation-related complications (10.9% vs. 0%) were also higher in the interlaminar implant cohort.

Gilbert et al (2022) retrospectively evaluated interlaminar stabilization with coflex following decompressive laminectomy in 20 patients with lumbar stenosis without instability or spondylolisthesis. The average visual analog scale score for low back pain preoperatively was 8.8, which improved postoperatively to 4.0, 3.7, and 3.9 at 2 months, 6 months, and 1 year, respectively. The average visual analog scale score for lower extremity pain preoperatively was 9.0, which improved postoperatively to 2.7, 2.5, and 2.5 at 2 months, 6 months, and 1 year, respectively. Furthermore, the average Oswestry

Disability Index scores significantly improved from 66.6 preoperatively to 23.8, 23.3, and 24.5 at 2 months, 6 months, and 1 year postoperatively, respectively. The difference in visual analog scale or Oswestry Disability Index scores between 2 months, 6 months, and 1 year did not reach statistical significance. The retrospective nature of the study and short follow-up period after surgery limit conclusions on the role of coflex interlaminar stabilization.

The evidence for use of an interspinous fixation device with interbody fusion for those undergoing spinal fusion consists of a systematic review of nonrandomized comparative studies (Lopez et al, 2017) and 2 small RCTs (Panchal et al, 2018; Huang et al, 2017). The randomized trials found comparable benefits for interspinous fixation devices with interbody fusion for those undergoing spinal fusion compared with interbody fusion with pedicle screws, but the comparative safety was less clear. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Additionally, the RCTs had important methodological and relevancy weaknesses that limited their interpretation. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of interspinous fixation devices compared with the established standard (pedicle screw with rod fixation).

There is a lack of evidence (only a retrospective series) on the efficacy of interspinous fixation devices as a stand-alone procedure for those who have spinal stenosis and/or spondylolisthesis. RCTs that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression are needed. Sclafani et al (2014) reported on an industry-sponsored, retrospective series of the polyaxial PrimaLOK interspinous fusion device. Thirty-four patients were implanted with interspinous fixation devices alone, 16 patients received the PrimaLOK plus an interbody cage, and 3 patients received the PrimaLOK plus pedicle screw instrumentation and an interbody cage. Evaluation at 6 weeks found no cases of fracture or device migration, although there were 4 cases of hardware removal and 2 cases of reoperation for adjacent-level disease during follow-up. At a mean 22 months after the index surgery, the average pain score had improved from 7.2 to 4.5 on a 10-point scale (method(s) of pain score collection were not specified). There was a statistically significant improvement in pain score for patients with degenerative disc disease with lumbar stenosis (2.8; n=25) and spondylolisthesis (4.6; n = 6), but not for patients with lumbar disc herniation (2.2; n=10).

Falowski et al (2023) investigated the efficacy of minimally invasive treatments for low back pain during the early period after treatment and their utility in setting the course for longer term success. This study utilized patient evaluations at 3- and 6-months following treatment and is part of an actively enrolling, institutional review board (IRB) approved, single-arm, multicenter, prospective, open-label 12-month study. Clinical efficacy was assessed primarily using the change from baseline in Oswestry Disability Index (ODI), Visual Analog Scale (VAS) of the back and leg pain during walking and standing, and Zurich Claudication Questionnaire (ZCQ), and secondarily using the Patient Global Impression of Change (PGIC) and Patient-Reported Outcomes Measurement Information System (PROMIS) 29 v2.1. The safety endpoints were the adverse events and reoperations or revisions at the index level(s). At 6-month post-op, 76%, 62%-64%, and 64% of patients demonstrated clinical meaningful, and statistically significant improvement in their pain as defined by ZCQ, VAS (back and leg), and ODI, respectively. In addition, 78% of patients noted improvement in PGIC. Two procedure-related adverse events were noted which fully resolved without surgical intervention. Six-month interim analysis at 42% enrollment of patients was conducted to determine prolonged safety and efficacy of the interspinous fusion device. The authors concluded “(o)ur analysis showed a sustained improvement in clinical efficacy, and safety endpoints, when compared to the 3-months evaluations, across both interventional pain and neurosurgery

specialties." Author acknowledged study limitations included relatively short term of follow up; anesthesia use controlled by the protocol and was decided per patient, based on provider preference; no imaging conducted during follow-up to evaluate structural changes, stability, or fusion; no study randomization; and inclusion of only patients who were approved for the procedure, being a single-arm, prospective study.

Baranidharan et al (2024) conducted an early-stage, multi-centre, prospective, randomized control trial with five-year follow-up to compare the efficacy of a minimally invasive, laterally implanted interspinous fixation device (IFD) to open direct surgical decompression in treating lumbar spinal stenosis (LSS). Forty-eight participants were randomly assigned to IFD or decompression. Primary study endpoints included changes from baseline at 8-weeks, 6, 12 and 24-months follow-ups for leg pain (visual analogue scale, VAS), back pain (VAS), disability (Oswestry Disability Index, ODI), LSS physical function (Zurich Claudication Questionnaire), distance walked in five minutes and number of repetitions of sitting-to-standing in one minute. Secondary study endpoints included patient and clinician global impression of change, adverse events, reoperations, operating parameters, and fusion rate. Both treatment groups demonstrated statistically significant improvements in mean leg pain, back pain, ODI disability, LSS physical function, walking distance and sitting-to-standing repetitions compared to baseline over 24 months. Mean reduction of ODI from baseline levels was between 35% and 56% for IFD ($p<0.002$), and 49% to 55% for decompression ($p<0.001$) for all follow-up time points. Mean reduction of IFD group leg pain was between 57% and 78% for all time points ($p<0.001$), with 72% to 94% of participants having at least 30% reduction of leg pain from 8-weeks through 24-months. Walking distance for the IFD group increased from 66% to 94% and sitting-to-standing repetitions increased from 44% to 64% for all follow-up time points. Blood loss was 88% less in the IFD group ($p=0.024$) and operating time parameters strongly favoured IFD compared to decompression ($p<0.001$). An 89% fusion rate was assessed in a subset of IFD participants. There were no intraoperative device issues or re-operations in the IFD group, and only one healed and non-symptomatic spinous process fracture observed within 24 months. The authors concluded "(d)espite a low number of participants in the IFD group, the study demonstrated successful two-year safety and clinical outcomes for the IFD with significant operation-related advantages compared to surgical decompression." Study strengths included the randomized controlled design of the trial; comparing a new IFD to a conventional treatment option; and the inclusion of physical mobility tests. Study limitations included low enrollment numbers, at least two cases of nonadherence to treatment assignments, and the lack of early data points.

POSITION STATEMENT:

Interspinous and interlaminar distraction devices are considered **experimental or investigational** for all indications, including as treatment of spinal stenosis.

Interlaminar stabilization devices used alone, or following decompressive surgery is considered **experimental or investigational**.

Interspinous fixation (fusion) devices are considered **experimental or investigational** for any indication, including but not limited to use in combination with interbody fusion, or used alone for decompression to treat spinal stenosis.

There is insufficient clinical evidence in the peer reviewed literature demonstrating the safety and efficacy of these procedures, or demonstrating the effects of these procedures on long-term health outcomes.

BILLING/CODING INFORMATION:

The following codes may be used to describe distraction devices:

CPT Coding

22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level **(Investigational)**
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) **(Investigational)**
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level **(Investigational)**
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) **(Investigational)**

HCPCS Coding

C1821	Interspinous process distraction device (implantable) **(Investigational)**

There are no specific CPT codes for insertion of interspinous fixation (fusion) devices.

REIMBURSEMENT INFORMATION:

Refer to sections entitled **POSITION STATEMENT** and **PROGRAM EXCEPTIONS**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

Neural foramen: the passage formed by the inferior and superior notches on the pedicles of adjacent vertebrae; it transmits a spinal nerve and vessels.

Neurogenic claudication: a type of claudication that is accompanied by pain and paresthesias in the back, buttocks, and lower limbs and is relieved by stooping or sitting. The usual cause is a mechanical disturbance due to posture, and a rare cause is ischemia of the cauda equina.

Spinal stenosis: narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space; symptoms are caused by compression of the cauda equina and include pain, paresthesias, and neurogenic claudication. The condition may be either congenital or due to spinal degeneration.

RELATED GUIDELINES:

Total Facet Arthroplasty, 02-20000-37

OTHER:

Index terms:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

- Affix™ Next Gen Spinous Process Plate System
- Affix II and Affix II Mini Spinous Process Plating System
- Aileron™ Interspinous Fixation System
- Aperius® PercLID System
- Aspen™ MIS Fusion System
- Aspen Spinous Process Fixation System
- Aurora Spine ZIP™ MIS Interspinous Fusion System
- Axle™ Interspinous Fusion System
- BacFuse® Spinous Process Fusion Plate
- Benefix Interspinous Fixation System
- BioFlex intervertebral stabilization device
- Biomet Aspen fusion system
- BridgePoint™ Spinous Process Fixation System
- CD HORIZON SPIRE Z Spinal System or plate
- CD Horizon Agile Dynamic Stabilization Device
- coflex® Interlaminar Technology implant
- coflex-F® Implant System
- CoRoent Extensure
- DIAM™ Spinal Stabilization System
- DSS Dynamic Soft Stabilization System
- Dynabolt Dynamic Stabilization System
- Dynesys Spinal System
- ExtenSure
- Falena® Interspinous Decompression Device

- FLEXUS™
- Helifix Interspinous Spacer System
- In-Space
- Inspan™
- Interbridge Interspinous Posterior Fixation System
- Isobar Spinal System
- Minuteman™ Fusion Devices
- NFix®
- NL-Prow™ Interspinous Spacer
- PrimaLOK™ SP, SP-Fix Interspinous Fusion System
- Octave™
- Satellite Spinal System
- Spire™ MIS Spinal Fixation System
- Stabilimax NZ Dynamic Spine Stabilization System
- Stabilink MIS Interspinous Fixation Device
- Stenofix
- Superion™ ISS Interspinous Spacer
- SP-Fix™ Spinous Process Fixation Plate
- VertiFlex®
- X-STOP® Interspinous Process Decompression System (IPD®)
- X-STOP® PEEK Interspinous Process Decompression (IPD®)
- Wallis® System
- Zip Mis Interspinous Fusion System
- Zodiak DynaMo System

REFERENCES:

1. Abjornson C, Yoon BV, Callanan T, Shein D, Grinberg S, Cammisa FP. Spinal Stenosis in the Absence of Spondylolisthesis: Can Interlaminar Stabilization at Single and Multi-levels Provide Sustainable Relief? Int J Spine Surg. 2018 Mar 30;12(1):64-69. doi: 10.14444/5011.
2. AHRQ National Guideline Clearinghouse. Guideline Summary 10647: Low back pain medical treatment guidelines. Colorado Division of Workers' Compensation. Denver (CO): Colorado Division of Workers' Compensation; 2014 Feb 3.
3. American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) Joint Section on the Disorders of the Spine and Peripheral Nerves (DSPS): Comments on NASS Coverage Policy Recommendations on Lumbar Interspinous Device without Fusion and Decompression.
4. American Society of Pain and Neuroscience (ASPN). ASPN Position Statement: Appropriate Performance of Minimally Invasive Surgical Procedures 10/21). Accessed at https://aspnpain.com/aspn-position-statement-appropriate-performance-of-minimally-invasive-surgical-procedures/.

5. Antony A, Stevenson J, Trimble T, Block J. Perspective: A Proposed Diagnostic and Treatment Algorithm for Management of Lumbar Spinal Stenosis: An Integrated Team Approach. Pain Physician. 2022 Dec;25(9):E1467-E1474.

6. Badve SA, Kurra S, Geisler FH, Metkar U, Tallarico R, Lavelle W. Nerve Root Sedimentation Sign: Can It Predict the Success for Surgical Intervention in Patients With Symptomatic Lumbar Spinal Stenosis? Cureus. 2020 Aug 17;12(8):e9803. doi: 10.7759/cureus.9803.

7. Bae HW, Davis RJ, Lauryssen C, Leary S, Maislin G, Musacchio MJ Jr. Three-Year Follow-up of the Prospective, Randomized, Controlled Trial of Coflex Interlaminar Stabilization vs Instrumented Fusion in Patients With Lumbar Stenosis. Neurosurgery. 2016 Aug;79(2):169-81. doi: 10.1227/NEU.0000000000001237. PMID: 27050538.

8. Bae HW, Lauryssen C, Maislin G, Leary S, Musacchio MJ Jr. Therapeutic sustainability and durability of coflex interlaminar stabilization after decompression for lumbar spinal stenosis: a four year assessment. Int J Spine Surg. 2015 May 11;9:15.

9. Baranidharan G, Bretherton B, Feltbower RG, Timothy J, Khan AL, Subramanian A, Ahmed M, Crowther TA, Radford H, Gupta H, Chandramohan M, Beall DP, Deer TR, Hedman T. 24-Month Outcomes of Indirect Decompression Using a Minimally Invasive Interspinous Fixation Device versus Standard Open Direct Decompression for Lumbar Spinal Stenosis: A Prospective Comparison. J Pain Res. 2024 Jun 13;17:2079-2097. doi: 10.2147/JPR.S453343

10. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.107 -- Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers), 05/25.

11. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.138 -- Interspinous Fixation (Fusion) Devices, 05/25.

12. Boston Scientific Corporation. Vertiflex™Procedure: Superion™ Indirect Decompression System. Value Dossier For The Implantation Of An InterSpinous Spacer (ISS) (October 27, 2021).

13. Brussee P, Hauth J, Donk RD, et al. Self-rated evaluation of outcome of the implantation of interspinous process distraction (X-Stop) for neurogenic claudication. Eur Spine J 2007 Oct 31.

14. Byun DH, et al. Finite element analysis of the biomechanical effect of coflex™ on the lumbar spine. Korean J Spine. 2012 Sep;9(3):131-6.

15. Cairns K, Deer T, Sayed D, van Noort K, Liang K. Cost-effectiveness and Safety of Interspinous Process Decompression (Superion). Pain Med. 2019 Dec 1;20(Suppl 2):S2-S8. doi: 10.1093/pm/pnz245.

16. California Technology Assessment Forum (CTAF). An Interspinous Distractor (X STOP) For The Treatment of Spinal Stenosis of The Lumbar Spine. (06/21/06).

17. Celik H, Derincek A, Kosal I. Surgical Treatment of the Spinal Stenosis with an Interspinous Distraction Device: Do We Really Restore the Foraminal Height? Turkish Neurosurgery 2012, Vol: 22, No: 1, 50-54.

18. Centers for Medicare & Medicaid (CMS). Local Coverage Determination (LCD) for Interspinous Process Decompression (L34006) (10/01/15) (Retired 04/01/20).

19. Che W, et al. Single-Level Rigid Fixation Combined with Coflex: A Biomechanical Study. Med Sci Monit. 2016 Mar 29;22:1022-7.

20. Chen M, Tang H, Shan J, Chen H, Jia P, Bao L, Feng F, Shi G, Wang R. A new interspinous process distraction device BacFuse in the treatment of lumbar spinal stenosis with 5 years follow-up study. Medicine (Baltimore). 2020 Jun 26;99(26):e20925. doi: 10.1097/MD.0000000000020925.

21. Chin KR, Pencle FJR, Benny A, Seale JA. Greater than 5-year follow-up of outpatient L4-L5 lumbar interspinous fixation for degenerative spinal stenosis using the INSPAN device. J Spine Surg. 2020 Sep;6(3):549-554. doi: 10.21037/jss-20-547.

22. Chin KR, Seale JA, Spayde E, Costigan WM, Gohel N, Aloise D, Lore V. Prospective 5-year follow-up of L5-S1 versus L4-5 midline decompression and interspinous-interlaminar fixation as a stand-alone treatment for spinal stenosis compared with laminectomies. J Spine Surg. 2023 Dec 25;9(4):398-408. doi: 10.21037/jss-23-49. Epub 2023 Nov 2.

23. Chou R, Loeser JB et al. Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain: An Evidence-Based Clinical Practice Guideline from the American Pain Society. SPINE Volume 34, Number 10, pp 1066–1077 ©2009.

24. Chou R, Huffman LH. Guideline for the Evaluation and Management of Low Back Pain: Evidence Review. American Pain Society, Publisher, Glenview, IL. © American Pain Society, 2009.

25. ClinicalTrials.gov. A 5-year Superion™ IDS Clinical Outcomes Post-Approval Evaluation (SCOPE). Identifier: NCT04192591. Verified by Boston Scientific Corporation, February 2024.

26. Clinical Trials.gov. Effects of XSTOP® Versus Laminectomy Study (EXELS). Identifier: NCT00558129 Verified by Kyphon, November 2007.

27. Clinical Trials.gov. Long-Term Outcomes for Lumbar Spinal Stenosis Patients Treated with X STOP®. Identifier: NCT00534092. Verified by Kyphon, July 2011. Last updated 02/16/12 with study results.

28. Clinical Trials.gov. Treatment of Lumbar Spinal Stenosis; Comparison of Two Different Surgical Methods; X-Stop (LSSS). Identifier: NCT00546949. Verified by Norwegian University of Science and Technology, October 2007.

29. Clinical Trials.gov. Post-Approval Clinical Trial Comparing the Long Term Safety and Effectiveness Coflex vs. Fusion to Treat Lumbar Spinal Stenosis. Identifier: NCT00534235. Verified by Paradigm Spine, November 2012.

30. Clinical Trials.gov. A Randomized Controlled Trial Comparing Surgical Decompression With an Interlaminar Implant in Patients With Intermittent Neurogenic Claudication Caused by Lumbar Stenosis (FELIX). Identifier: NCT01727752. Verified by Paradigm Spine, November 2012.

31. ClinicalTrials.gov. Efficacy of the Aspen Spinous Process System in Anterior Lumbar Interbody Fusion (ALIF). Identifier: NCT01016314. Verified by Biomet, Inc.: December 2013.

32. ClinicalTrials.gov. An Evaluation of Interlaminar Lumbar Instrumented (ILIF™). Identifier: NCT01019057. Verified by NuVasive: July 2014.

33. ClinicalTrials.gov. Clinical Trial Comparing Decompression With and Without Coflex™ Interlaminar Technology Treating Lumbar Spinal Stenosis. Identifier: NCT01316211. Verified by Paradigm Spine (October 2016).

34. ClinicalTrials.gov. The Coflex®COMMUNITY Study: An Observational Study of Coflex® Interlaminar Technology. Identifier: NCT02457468. Verified by Predicted, Reported and Observed Outcomes Foundation (December 2016),

35. ClinicalTrials.gov. Post-Approval 'Real Conditions of Use' Study (PAS003). Identifier: NCT02555280. Verified by Paradigm Spine (October 2016).

36. ClincalTrials.gov. A 5-year Superion™ IDS Clinical Outcomes Post-Approval Evaluation (SCOPE). Identifier: NCT04192591. Sponsor: Boston Scientific Corporation (May 2023).

37. Coe JD et al. NFlex Dynamic Stabilization System: Two-Year Clinical Outcomes of Multi-Center Study. J Korean Neurosurg Soc 51 : 343-349, 2012.

38. Davis R, Auerbach JD, Bae H, Errico TJ. Can low-grade spondylolisthesis be effectively treated by either coflex intermalimar stabilization or laminectomy and posterior spinal fusion? Two-year clinical and radiographic results from the randomized, prospective, multicenter US investigational device exemption trial. J Neurosurg: Spine | May 31, 2013.

39. Davis RJ, Errico TJ, Bae H, Auerbach JD. Decompression and Coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade

degenerative spondylolisthesis: two-year results from the prospective, randomized, multicenter, Food and Drug Administration Investigational Device Exemption trial. Spine (Phila Pa 1976). 2013 Aug 15;38(18):1529-39. doi: 10.1097/BRS.0b013e31829a6d0a. PMID: 23680830.

40. Decompression and Coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: two-year results from the prospective, randomized, multicenter, Food and Drug Administration Investigational Device Exemption trial. Spine (Phila Pa 1976). Aug 15 2013;38(18):1529-1539.
41. Deer TR, Grider JS, Pope JE, et al. The MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment. Pain Pract. 2019;19(3):250–274. doi:10.1111/papr.12744. PMID: 30369003.
42. Deer T, Sayed D, Michels J, Josephson Y, Li S, Calodney AK. A Review of Lumbar Spinal Stenosis with Intermittent Neurogenic Claudication: Disease and Diagnosis. Pain Med. 2019;20(Suppl 2):S32-S44. doi:10.1093/pm/pnz161.
43. Deyo RA, et al. Interspinous spacers compared with decompression or fusion for lumbar stenosis: complications and repeat operations in the Medicare population. Spine (Phila Pa 1976). 2013 May 1;38(10):865-72.
44. ECRI. Target Database Report. Interspinous process decompression to treat spinal stenosis. Plymouth Meeting, PA: ECRI. 09/07.
45. ECRI Institute Product Brief. Coflex and Coflex-F Implants (Paradigm Spine, LLC) for Lumbar Spinal Disorders. October 2013.
46. Epstein NE. A review of interspinous fusion devices: High complication, reoperation rates, and costs with poor outcomes. Surg Neurol Int 2012, 3:7.
47. Fabrizi AP, Maina R, Schiabello L. Interspinous spacers in the treatment of degenerative lumbar spinal disease: our experience with DIAM and Aperius devices. Eur Spine J. 2011 May;20 Suppl 1:S20-6.
48. Falowski SM, Raso LJ, Mangal V, Nairizi A, Patterson DG, Danko MD, Justiz R, Vogel RS, Koga S, Josephson Y, Pope JE, Raji OR. Early Functional Outcomes in Low Back Pain Subjects with a Novel Interspinous Fusion Device: REFINE Study 6-Month Results. J Pain Res. 2023 Dec 1;16:4113-4126. doi: 10.2147/JPR.S427407.
49. Falowski SM, Sayed D, Deer TR, Brescacin D, Liang K. Biomechanics and Mechanism of Action of Indirect Lumbar Decompression and the Evolution of a Stand-alone Spinous Process Spacer. Pain Med. 2019 Dec 1;20(Suppl 2):S14-S22. doi: 10.1093/pm/pnz129.
50. Florida Society of Interventional Pain Physicians. Position Statement: Interspinous Indirect Decompression Systems Without Fusion (December 2021).
51. Gala RJ, et al. Interspinous implants to treat spinal stenosis. Curr Rev Musculoskelet Med. 2017 Jun;10(2):182-188.
52. Gaxxeri R, et al. Controversies about interspinous process devices in the treatment of degenerative lumbar spine diseases: past, present, and future. Biomed Res Int. 2014;2014:975052.
53. Gilbert OE, Lawhon SE, Gaston TL, Robichaux JM, Tender GC. Decompression and Interlaminar Stabilization for Lumbar Spinal Stenosis: A Cohort Study and Two-Dimensional Operative Video. Medicina (Kaunas). 2022 Apr 5;58(4):516. doi: 10.3390/medicina58040516.
54. Grinberg SZ, Simon RB, Dowe C, Brecevich AT, Cammisa FP, Abjornson C. Interlaminar stabilization for spinal stenosis in the Medicare population. Spine J. 2020 Dec;20(12):1948-1959. doi: 10.1016/j.spinee.2020.06.015. Epub 2020 Jul 11. PMID: 32659365.
55. Grob D, Benini A, Junge A, Mannion AF. Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine: Surgical and Patient-Oriented Outcome in 50 Cases After an Average of 2 Years. SPINE Volume 30, Number 3, pp 324–331 ©2005.

56. Hagedorn JM, Yadav A, D'Souza RS, et al. The incidence of lumbar spine surgery following Minimally Invasive Lumbar Decompression and Superion Indirect Decompression System for treatment of lumbar spinal stenosis: a retrospective review. Pain Pract. 2022 Jun;22(5):516-521. doi: 10.1111/papr.13111. Epub 2022 Apr 12.

57. Hartman J, Granville M, Jacobson RE. The Use of Vertiflex® Interspinous Spacer Device in Patients With Lumbar Spinal Stenosis and Concurrent Medical Comorbidities. Cureus. 2019;11(8):e5374. Published 2019 Aug 12. doi:10.7759/cureus.5374.

58. Hayes, Inc. Health Technology Brief. X Stop® Interspinous Process Decompression System (Kyphon Inc.) for Lumbar Spinal Stenosis. Lansdale, PA: Hayes, Inc.; 11/13/07.

59. Hayes, Inc. Hayes alert. FDA Clears New Implant to Treat Lumbar Stenosis. Lansdale, PA: Hayes, Inc.; 01/17/06.

60. Hedman TP, Ohnmeiss DD, Leasure J, Raji OR, Hochschuler SH. Interspinous-Interbody Fusion via a Strictly Lateral Surgical Approach: A Biomechanical Stabilization Comparison to Constructs Requiring Both Lateral and Posterior Approaches. Cureus. 2023 Jul 15;15(7):e41918. doi: 10.7759/cureus.41918.

61. Heyrani N, Picinic Norheim E, Elaine Ku Y, Nick Shamie A. Interspinous process implantation for the treatment of neurogenic intermittent claudication. Anesth Pain Med. 2012 Summer;2(1):36-41.

62. Hobart J, Gilkes C, Adams W, Germon T. Interspinous spacers for lumbar foraminal stenosis: formal trials are justified. Eur Spine J. 2013 Mar;22 Suppl 1:S47-53.

63. Holinka J, Krepler P, Matzner M, Grohs JG. Stabilising effect of dynamic interspinous spacers in degenerative low-grade lumbar instability. International Orthopaedics (SICOT) (2011) 35:395–400.

64. Huang WM, Yu XM, Xu XD, Song RX, Yu LL, Yu XC. Posterior Lumbar Interbody Fusion with Interspinous Fastener Provides Comparable Clinical Outcome and Fusion Rate to Pedicle Screws. Orthop Surg. 2017 May;9(2):198-205. doi: 10.1111/os.12328. Epub 2017 May 24.

65. International Society for the Advancement of Spine Surgery. Policy Statement: Decompression with Interlaminar Stabilization (November 2016). Accessed at https://www.isass.org/public-policy/isass-policy-statement-decompression-with-interlaminar-stabilization/.

66. Kaye AD, Edinoff AN, Temple SN, Kaye AJ, Chami AA, Shah RJ, Dixon BM, Alvarado MA, Cornett EM, Viswanath O, Urits I, Calodney AK. A Comprehensive Review of Novel Interventional Techniques for Chronic Pain: Spinal Stenosis and Degenerative Disc Disease-MILD Percutaneous Image Guided Lumbar Decompression, Vertiflex Interspinous Spacer, MinuteMan G3 Interspinous-Interlaminar Fusion. Adv Ther. 2021 Sep;38(9):4628-4645. doi: 10.1007/s12325-021-01875-8. Epub 2021 Aug 14.

67. Khoo LT, Emmanuel PR, Sora Cho S, PA-C, Khoo MM. White paper: Single Position, Single Incision approach for lateral interbody fusion with supplemental posterior fixation- Technique and comparative outcomes to two incision and two position approaches.

68. Kim HJ, Bak KH, Chun HJ, Oh SJ, Kang TH, Yang MS. Posterior Interspinous Fusion Device for One-Level Fusion in Degenerative Lumbar Spine Disease: Comparison with Pedicle Screw Fixation - Preliminary Report of at Least One Year Follow Up. J Korean Neurosurg Soc 52: 359-364, 2012.

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

70. Kumar N, Shah SM, Ng YH, Pannierselvam VK, Dasde S, Shen L. Role of coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis. Asian Spine J. 2014 Apr;8(2):161-9.

71. Landi A. Elastic resistance of the spine: Why does motion preservation surgery almost fail? World J Clin Cases. 2013 Jul 16;1(4):134-9.

72. Landi A. Interspinous posterior devices: What is the real surgical indication? World J Clin Cases. 2014 Sep 16;2(9):402-8.

73. Lee SH, et al. A Systematic Review of Interspinous Dynamic Stabilization. Clin Orthop Surg. 2015 Sep;7(3):323-9.

74. Lewandrowski KU, Basil GW, Kwon B, Liu X, Alonso Cuéllar GO, de Carvalho PST, Lorio MP. Key Takeaways From the ISASS Webinar Series on Current and Emerging Techniques in Endoscopic Spine Surgery | Part 2: Polytomous Rasch Analysis of Learning Curve and Surgeon Endorsement of Biportal, Interlaminar, and Transforaminal Endoscopic Stenosis Decompression, Discectomy, and Laminectomy in Combination With Interspinous Process Spacers. Int J Spine Surg. 2024 Nov 20;18(S2):S23-S37. doi: 10.14444/8673.

75. Liu X, et al. Magnetic resonance imaging on disc degeneration changes after implantation of an interspinous spacer and fusion of the adjacent segment. Int J Clin Exp Med. 2015 Apr 15;8(4):6097-102.

76. Lopez AJ, Scheer JK, Dahdaleh NS, Patel AA, Smith ZA. Lumbar Spinous Process Fixation and Fusion: A Systematic Review and Critical Analysis of an Emerging Spinal Technology. Clin Spine Surg. 2017 Nov;30(9):E1279-E1288. doi: 10.1097/BSD.0000000000000411. PMID: 27438402.

77. Machado GC, Ferreira PH, Harris IA, Pinheiro MB, Koes BW, van Tulder M, Rzewuska M, Maher CG, Ferreira ML. Effectiveness of surgery for lumbar spinal stenosis: a systematic review and meta-analysis. PLoS One. 2015 Mar 30;10(3):e0122800.

78. Maida G, Marcati E, Sarubbo S. Heterotopic Ossification in Vertebral Interlaminar/Interspinous Instrumentation: Report of a Case. Case Reports in Surgery Volume 2012, Article ID 970642.

79. Manufacturer Instructions for Use: coflex® Interlaminar Technology, 2012. (Paradigm Spine; New York, NY)

80. Miller LE, Block JE. Interspinous Spacer Implant in Patients with Lumbar Spinal Stenosis: Preliminary Results of a Multicenter, Randomized, Controlled Trial. Pain Research and Treatment Volume 2012, Article ID 823509.

81. Modhia U, et al. Readmission rates after decompression surgery in patients with lumbar spinal stenosis among Medicare beneficiaries. Spine (Phila Pa 1976). 2013 Apr 1;38(7):591-6.

82. Moojen WA, Arts MP, Jacobs WC, van Zwet EW, van den Akker-van Marle ME, Koes BW, Vleggeert-Lankamp CL, Peul WC; Leiden-The Hague Spine Intervention Prognostic Study Group (SIPS). Interspinous process device versus standard conventional surgical decompression for lumbar spinal stenosis: randomised controlled trial. Br J Sports Med. 2015 Jan;49(2):135. doi: 10.1136/bjsports-2014-f6415rep.

83. Moojen WA et al. Effectiveness of interspinous implant surgery in patients with intermittent neurogenic claudication: a systematic review and meta-analysis. Eur Spine J (2011) 20:1596–1606.

84. Musacchio MJ, et al. Evaluation of Decompression and Interlaminar Stabilization Compared with Decompression and Fusion for the Treatment of Lumbar Spinal Stenosis: 5-year Follow-up of a Prospective, Randomized, Controlled Trial. Int J Spine Surg. 2016; 10: 6.

85. National Institute for Clinical Excellence (NICE): Non-rigid stabilisation procedures for the treatment of low back pain. Issue date: June 2006.

86. National Institute for Clinical Excellence (NICE). Interventional procedure guidance 365: Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. Issue Date: November 2010.

87. National Institute for Clinical Excellence (NICE). Interventional procedure guidance 366: Non-rigid stabilisation techniques for the treatment of low back pain. Issue date: November 2010.

88. National Institute for Clinical Excellence (NICE): Treating neurogenic claudication caused by lumbar spinal stenosis using a spacer device between the vertebrae (patient guide). November 2010.

89. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis (2008).

90. North American Spine Society. Coverage Policy Recommendation: Lumbar Interspinous Device without Fusion and with Decompression (May 2018).

91. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis, 2nd Edition (2014).

92. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and treatment of degenerative lumbar spinal stenosis. January 2007; Revised 2011.

93. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. Accessed at https://www.spine.org.

94. North American Spine Society. NASS coverage policy recommendations: Interspinous device without fusion. 2014. Accessed at https://www.spine.org.

95. North American Spine Society (NASS). NASS and MPW Advocate for Medicare Advantage Coverage of Interspinous Spacer Devices. NASS Insider. April 19, 2022.

96. Nunley PD, Deer TR, Benyamin RM, Staats PS, Block JE. Interspinous process decompression is associated with a reduction in opioid analgesia in patients with lumbar spinal stenosis. J Pain Res. 2018 Nov 20;11:2943-2948. doi: 10.2147/JPR.S182322.

97. Nunley PD, Patel VV, Orndorff DG, Lavelle WF, Block JE, Geisler FH. Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis. Clin Interv Aging. 2017 Sep 6;12:1409-1417. doi: 10.2147/CIA.S143503.

98. Nunley PD, Patel VV, Orndorff DG, Lavelle WF, Block JE, Geisler FH. Interspinous Process Decompression Improves Quality of Life in Patients with Lumbar Spinal Stenosis. Minim Invasive Surg. 2018 Jul 2;2018:1035954. doi: 10.1155/2018/1035954.

99. Onggo JR, Nambiar M, Maingard JT, Phan K, Marcia S, Manfrè L, Hirsch JA, Chandra RV, Buckland AJ. The use of minimally invasive interspinous process devices for the treatment of lumbar canal stenosis: a narrative literature review. J Spine Surg. 2021 Sep;7(3):394-412. doi: 10.21037/jss-21-57.

100. Oster BA, Kikanloo SR, Levine NL, Lian J, Cho W. Systematic Review of Outcomes Following 10-Year Mark of Spine Patient Outcomes Research Trial (SPORT) for Degenerative Spondylolisthesis. Spine (Phila Pa 1976). 2020 Jun 15;45(12):820-824. doi: 10.1097/BRS.0000000000003485.

101. Panchal R, Denhaese R, Hill C, Strenge KB, DE Moura A, Passias P, Arnold P, Cappuccino A, Dennis MD, Kranenburg A, Ventimiglia B, Martin K, Ferry C, Martineck S, Moore C, Kim K. Anterior and Lateral Lumbar Interbody Fusion With Supplemental Interspinous Process Fixation: Outcomes from a Multicenter, Prospective, Randomized, Controlled Study. Int J Spine Surg. 2018 Aug 3;12(2):172-184. doi: 10.14444/5025.

102. Paradigm Spine Press Release: U.S. FDA PMA Approval Of Its Landmark Coflex® Interlaminar Technology: The 1st Comparative Effectiveness Study For the Treatment Of Spinal Stenosis. October 17, 2012; New York, NY.

103. Parker SL, Anderson LH, Nelson T, Patel VV. Cost-effectiveness of three treatment strategies for lumbar spinal stenosis: Conservative care, laminectomy, and the Superion interspinous spacer. Int J Spine Surg. 2015 Jul 9;9:28.

104. Patel VV, Whang PG, Haley TR, Bradley WD, Nunley PD, Miller LE, Block JE, Geisler FH. Two-year clinical outcomes of a multicenter randomized controlled trial comparing two interspinous spacers for treatment of moderate lumbar spinal stenosis. BMC Musculoskelet Disord. 2014 Jul 5;15:221.

105. Pintauro M, et al. Interspinous implants: are the new implants better than the last generation? A review. Curr Rev Musculoskelet Med. 2017 Jun;10(2):189-198.

106. Ploumis A, et al. Surgical treatment of lumbar spinal stenosis with microdecompression and interspinous distraction device insertion. A case series. J Orthop Surg Res. 2012 Oct 29;7:35.

107. Putzier M. The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone. Spine (Phila Pa 1976). 2005 Mar 1;30 (5): E109-14.

108. Putzier M et al. Dynamic stabilization adjacent to single-level fusion: Part II. No clinical benefit for asymptomatic, initially degenerated adjacent segments after 6 years follow-up. Eur Spine J (2010) 19:2181–2189.

109. Richter A, Schutz C, Hauck M, Halm H. Does an interspinous device (CoflexTM) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. Eur Spine J (2010) 19:283–289.

110. Rosner HL, Tran O, Vajdi T, Vijjeswarapu MA. Comparison analysis of safety outcomes and the rate of subsequent spinal procedures between interspinous spacer without decompression versus minimally invasive lumbar decompression. Reg Anesth Pain Med. 2024 Jan 11;49(1):30-35. doi: 10.1136/rapm-2022-104236.

111. Sayed D, Grider J, Strand N, Hagedorn JM, Falowski S, Lam CM, Tieppo Francio V, Beall DP, Tomycz ND, Davanzo JR, Aiyer R, Lee DW, Kalia H, Sheen S, Malinowski MN, Verdolin M, Vodapally S, Carayannopoulos A, Jain S, Azeem N, Tolba R, Chang Chien GC, Ghosh P, Mazzola AJ, Amirdelfan K, Chakravarthy K, Petersen E, Schatman ME, Deer T. The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain. J Pain Res. 2022 Dec 6;15:3729-3832. doi: 10.2147/JPR.S386879. Erratum in: J Pain Res. 2022 Dec 24;15:4075-4076.

112. Schmidt S, Franke J, Rauschmann M, Adelt D, Bonsanto MM, Sola S. Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. J Neurosurg Spine. 2018 Apr;28(4):406-415. doi: 10.3171/2017.11.SPINE17643. Epub 2018 Jan 26.

113. Schnake KJ. Dynamic Stabilization in Addition to Decompression for Lumbar Spinal Stenosis with Degenerative Spondylolisthesis. Spine (Phila Pa 1976). 2006 Feb 15;31(4): 442-9.

114. Sclafani JA, Liang K, Ohnmeiss DD, Gordon C. Clinical outcomes of a polyaxial interspinous fusion system. Int J Spine Surg. 2014 Dec 1;8.

115. Sears WR, et al. Incidence and prevalence of surgery at segments adjacent to a previous posterior lumbar arthrodesis. Spine J. 2011 Jan;11(1):11-20.

116. Shabat S, Miller LE, Block JE, Gepstein R. Minimally invasive treatment of lumbar spinal stenosis with a novel interspinous spacer. Clinical Interventions in Aging 2011:6 227–233.

117. Shah A, Hagedorn JM, Latif U, Bailey-Classen A, Azeem N, Beall DP, Mehta P, Stephens C, Khoo L, Deer TR. Posterior Lateral Arthrodesis as a Treatment Option for Lumbar Spinal Stenosis: Safety and Early Clinical Outcomes. J Pain Res. 2024 Jan 5;17:107-116. doi: 10.2147/JPR.S422736.

118. Skoblar M, Hedman T, Rogers AJ, Jasper GP, Beall DP. Instrumented Posterior Arthrodesis of the Lumbar Spine: Prospective Study Evaluating Fusion Outcomes in Patients Receiving an Interspinous Fixation Device for the Treatment of Degenerative Spine Diseases. J Pain Res. 2023 Aug 24;16:2909-2918. doi: 10.2147/JPR.S417319.

119. Strube P et al. Dynamic stabilization adjacent to single-level fusion: Part I. Biomechanical effects on lumbar spinal motion. Eur Spine J (2010) 19:2171–2180.

120. Stoll TM. The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system. Eur Spine J. 2002 Oct;11 Suppl 2: S170-8. Epub 2002 Sep 10.

121. Superion™ Indirect Decompression System. Instructions For Use. Boston Scientific. Accessed at https://www.bostonscientific.com/content/dam/elabeling/nm/92479815-02_Rev_A_Indirect_Decompression_System_s.pdf.

122. The International Society for the Advancement of Spine Surgery (ISASS). Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization – Coverage Indications, Limitations, and/or Medical Necessity. Volume 10, Article 41. November 2016.

123. U.S. Food and Drug Administration (FDA). 510(k) Summary K234051. Minuteman®. Accessed at http://www.fda.gov.

124. U.S. Department of Health and Human Services (2019, May). Pain Management B Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html.

125. U.S. Food and Drug Administration (FDA), Rockville (MD): U.S. Department of Health and Human Services. Available from: http://www.fda.gov.

126. U.S. Food and Drug Administration (FDA). Approval Order P110008: coflex Interlaminar Technology (October 17, 2012). Accessed at http://www.fda.gov.

127. U.S. Food and Drug Administration (FDA), Approval Order P140004: Superion® InterSpinous Spacer (ISS). June 3, 2015. Accessed at https://fda.report/PMA/P140004/14/P140004A.pdf.

128. U.S. Food and Drug Administration (FDA). Summary of safety and effectiveness data: coflex Interlaminar Technology. 2012. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110008b.pdf.

129. U.S. Food and Drug Administration (FDA). Summary of safety and effectiveness data: Superion® InterSpinous Spacer (ISS). 2015. Accessed at https://fda.report/PMA/P140004/14/P140004B.pdf.

130. Usman Latif MD, Daniel Kloster MD, Nomen Azeem MD, Krishan Chakravarthy MD, MD MR. Interspinous Fixation as a Treatment for Degenerative Lumbar Disease: A Multi-Center Retrospective Registry Analysis.

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

132. Welch WC. Clinical outcomes of the Dynesys dynamic neutralization system: 1-year preliminary results. Neurosurg Focus. 2007 Dec 15;22 (1): E8.

133. Welton L, Krieg B, Trivedi D, Netsanet R, Wessell N, Noshchenko A, Patel V. Comparison of Adverse Outcomes Following Placement of Superion Interspinous Spacer Device Versus Laminectomy and Laminotomy. Int J Spine Surg. 2021 Feb;15(1):153-160. doi: 10.14444/8020. Epub 2021 Feb 12.

134. Whang PG, Tran O, Rosner HL. Longitudinal Comparative Analysis of Complications and Subsequent Interventions Following Stand-Alone Interspinous Spacers, Open Decompression, or Fusion for Lumbar Stenosis. Adv Ther. 2023 Aug;40(8):3512-3524. doi: 10.1007/s12325-023-02562-6. Epub 2023 Jun 8.

135. Wu AM, Zhou Y, Li QL, Wu XL, Jin YL, Luo P, Chi YL, Wang XY. Interspinous spacer versus traditional decompressive surgery for lumbar spinal stenosis: a systematic review and meta-analysis. PLoS One. 2014 May 8;9(5):e97142.

136. Xin JH, Che JJ, Wang Z, Chen YM, Leng B, Wang DL. Effectiveness and safety of interspinous spacer versus decompressive surgery for lumbar spinal stenosis: A meta-analysis of randomized controlled trials. Medicine (Baltimore). 2023 Nov 17;102(46):e36048. doi: 10.1097/MD.0000000000036048.

137. Xu C, et al. Complications in degenerative lumbar disease treated with a dynamic interspinous spacer (Coflex). Int Orthop. 2013 Nov;37(11):2199-204.

138. Zang L, DU P, Hai Y, Su QJ, Lu SB, Liu T. Device related complications of the Coflex interspinous process implant for the lumbar spine. Chin Med J (Engl). 2013 Jul;126(13):2517-22.

139. Zhang JX, et al. Effectiveness of dynamic fixation Coflex treatment for degenerative lumbar spinal stenosis. Exp Ther Med. 2018 Jan;15(1):667-672.

140. Zheng X, Chen Z, Yu H, Zhuang J, Yu H, Chang Y. A minimum 8-year follow-up comparative study of decompression and coflex stabilization with decompression and fusion. Exp Ther Med. 2021 Jun;21(6):595. doi: 10.3892/etm.2021.10027. Epub 2021 Apr 9.

141. Zhong J, O'Connell B, Balouch E, Stickley C, Leon C, O'Malley N, Protopsaltis TS, Kim YH, Maglaras C, Buckland AJ. Patient Outcomes After Single-level Coflex Interspinous Implants Versus Single-level Laminectomy. Spine (Phila Pa 1976). 2021 Jul 1;46(13):893-900. doi: 10.1097/BRS.0000000000003924. PMID: 33395022.

142. Zhou D, Nong LM, DU R, Gao GM, Jiang YQ, Xu NW. Effects of interspinous spacers on lumbar degenerative disease. Exp Ther Med. 2013 Mar;5(3):952-956.

143. Zini C, Bellini M, Masala S, Marcia S. Percutaneous Interspinous Spacer in Spinal-Canal-Stenosis Treatment: Pros and Cons. Medicina (Kaunas). 2019;55(7):381. Published 2019 Jul 16. doi:10.3390/medicina55070381.

144. Zucherman JF, Hsu KY, Hartjen CA et al. A multicenter, prospective randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. Spine 2005;0(12): 1351-8.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/25/25.

GUIDELINE UPDATE INFORMATION:

07/15/08	New Medical Coverage Guideline.
04/15/09	HCPCS code C1821 deleted from policy.
06/15/09	Scheduled review; no change in position statement. Update references.
04/15/10	Annual review; added investigational statement for dynamic spinal stabilization to position statement; description of dynamic spinal stabilization devices added to description section; references updated; and guideline title revised.
12/15/11	Scheduled review; no change in position statement. Updated description section and references.
11/15/12	Scheduled review; position statement maintained. Revised description and Medicare Advantage program exception (added utilization guidelines). Updated references.
07/15/13	Revision; updated description section (coflex® Interlaminar Technology implant language). Revised Program Exceptions section and index terms. Updated references.
11/15/13	Scheduled review. Revised MCG title and description section. Maintained position statement. Revised index terms. Updated references.
01/01/15	Scheduled review. Position statement maintained. Revised description section and index terms. Updated references.
10/15/15	Scheduled review. Revised description section and index terms. Updated references.
01/01/17	Annual CPT/HCPCS update. Added 22867, 22868, 22869, 22870. Deleted 0171T, 0172T.
02/15/17	Scheduled review. Maintained Position Statement section. Updated references.
06/15/18	Unscheduled review. Maintained Position Statement section. Revised index terms. Updated references.

06/15/20	Scheduled review. Revised description. Maintained position statement and updated references.
07/01/20	Added code C1821.
03/15/22	Scheduled review. Maintained position statement and updated references.
08/15/22	Unscheduled review. Updated references and maintained position statement.
06/15/23	Unscheduled review. Updated references and maintained position statement.
01/01/24	Position statements maintained.
03/15/24	Revision. Updated references and maintained position statement.
10/15/24	Scheduled review. Revised description. Maintained position statement and updated references.
10/15/25	Scheduled review. Revised description. Updated references and maintained position statement.