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

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Summary

Description

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in individuals 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 are also being evaluated for stand-alone use in individuals with spinal stenosis and/or spondylolisthesis.

Summary of Evidence

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes one systematic review of randomized controlled trials (RCTs) of X-STOP spacer devices (which is no longer marketed) or other devices not approved in the US, an RCT of interspinous spacer device (ISD) versus surgical decompression, observational retrospective claims data analyses, and 2 RCTs of 2 spacers compared to each other (Superion Indirect Decompression System, coflex interlaminar implant). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, the use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal decompression has shown high failure and complication rates. A systematic review of RCTs comparing ISDs and decompression surgery in patients with lumbar spinal stenosis found that ISD resulted in an increased rate of reoperation compared to decompression, as well as no statistically significant differences in pain, functional, and quality of life outcomes. A small RCT of ISD versus decompression surgery found no differences in clinical outcomes between groups. Additional longitudinal retrospective comparative claims analyses found that there was a significantly lower rate of reoperation in patients with lumbar spinal stenosis who received ISD compared to open surgery. However, there are many limitations inherent to claims analyses, including the possibility of coding or data entry errors and the omission of clinical details not needed to justify payment. For example, diagnosis codes identified in claims data lack clinical context, such as the severity of lumbar spinal stenosis or postoperative complications, as well as other prior therapies. Claims data also does not capture patient-reported outcomes, such as visual analog scale scores or Zurich Claudication Questionnaire scores, limiting the ability to determine true efficacy. It is unknown if authors were able to see when a patient was lost to follow-up due to death or end of Medicare coverage, as these rates were not reported. Additionally, in 1 of the studies, since the baseline characteristics of patients receiving ISD indicated that these patients may be inherently sicker than those receiving open surgery, we need clinical context to infer if the reason they did not receive additional surgical procedures post initial ISD placement is because they truly did not require intervention, or they were too sick to tolerate the procedure. While claims data gives us some information related to re-operation rates, direct or indirect comparative studies using clinical data and validated outcomes measures are required to draw conclusions on the utility of ISDs compared to open surgery. A pivotal trial compared the Superion Interspinous Spacer with the X-STOP Interspinous Process Decompression System (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superion Interspinous Spacer on some measures. For example, the trial reported more than 80% of individuals experienced improvements in certain quality of life outcome domains. Interpretation of this trial is limited by questions about the number of individuals 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 (formerly called the interspinous U) was compared with decompression in the multicenter, double-blind Foraminal Enlargement Lumbar Interspinous distraXion (FELIX) trial. Functional outcomes and pain levels were similar in the 2 groups at 1-year follow-up, but reoperation rates due to the absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For individuals 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 and 8% of the bony decompression group. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

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, the evidence includes 2 RCTs with a mixed population of individuals. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 situations as an adjunct to decompression compared with decompression alone (superiority) and as an alternative to spinal fusion after decompression (noninferiority). For decompression with coflex versus decompression with lumbar spinal fusion, 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. A secondary (unplanned) analysis of individuals with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time (104 vs. 157 minutes; p<.001) and blood loss (106 vs. 336 mL, p<.001). 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. In that analysis, 62.8% of coflex patients and 62.5% of fusion patients met the criteria for operative success. The efficacy of the comparator in this trial is uncertain because successful fusion was obtained in only 71% of the control group, leaving nearly a third of individuals with pseudoarthrosis. The report indicated no significant differences in Oswestry Disability Index or visual analog scale between the individuals with pseudoarthrosis or solid fusion, but Zurich Claudication Questionnaire scores were not reported. There were 18 (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 and 14% in the coflex group (p=.18), including 8 (8%) coflex cases that required conversion to fusion. This secondary analysis is considered hypothesis-generating, and a prospective trial in individuals with grade 1 spondylolisthesis is needed. In an RCT conducted in a patient population with moderate-to-severe lumbar spinal stenosis with significant back pain and up to grade 1 spondylolisthesis, there was no difference in the primary outcome measure, the Oswestry Disability Index, between the individuals treated with coflex plus decompression versus decompression alone. Composite clinical success, defined as 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 was used to assess superiority. A greater proportion of individuals who received coflex plus decompression instead of decompression alone achieved the composite endpoint. However, the superiority of coflex plus decompression is uncertain because the difference in the composite clinical success was primarily driven by a greater proportion of individuals in the control arm who received a secondary rescue epidural steroid injection. Because the trial was open-label, surgeons' decision to use epidural steroid injection could have been affected by their knowledge of the individual's treatment. Consequently, including this component in the composite clinical success measure might have overestimated the potential benefit of treatment. Analysis was not reported separately for the group of individuals who had grade 1 spondylolisthesis, leaving the question open about whether the implant would improve outcomes in this population. 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. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, the evidence includes RCT and a retrospective study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. 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, in addition to concerns about the efficacy of fusion in this study, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in individuals 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 as the standard of care for individuals 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 individuals represented in the pivotal trial is uncertain, especially since the publication of the Swedish Spinal Stenosis Study, and the Spinal Laminectomy versus Instrumented Pedicle Screw study, 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 individuals 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Fixation

For individuals who are undergoing spinal fusion who receive an interspinous fixation device with interbody fusion, the evidence includes a systematic review of nonrandomized comparative studies and case series and 2 small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. 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). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have spinal stenosis and/or spondylolisthesis who receive an interspinous fixation device alone, the evidence includes a small RCT and a retrospective series. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. There is a lack of evidence on the efficacy of interspinous fixation devices as a stand-alone procedure. Well-designed randomized controlled trial are needed that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

2018 Input

Clinical input was sought to help determine whether the use of interlaminar spacer with spinal decompression surgery for 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.

- 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 outcomes. 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.

Further details from clinical input are included in the Appendix.

OBJECTIVE

The objective of this evidence review is to determine whether the use of an interspinous distraction device interlaminar stabilization device, or interspinous fixation device improves the net health outcomes in individuals with lumbar spinal stenosis.

PRIOR APPROVAL

Not applicable.

POLICY

Distraction Devices

Interspinous or interlaminar distraction devices are considered **investigational** for all indications including as a stand-alone procedure as a treatment of spinal stenosis because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

Stabilization Devices

Interspinous stabilization devices are considered **investigational** for all indications including but not limited to following decompression surgery because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

Fixation Devices

Interspinous fixation (fusion) devices are considered **investigational** for any indication, including but not limited to use:

- in combination with interbody fusion, or
- alone for decompression in individuals with spinal stenosis.

Note: Please see the Regulatory Status section for a list of representative products.

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

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 individuals 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 individual. This uncertainty also complicates research on spinal stenosis, particularly the selection of appropriate eligibility criteria and comparators.

Treatment

The largest group of individuals with spinal stenosis is minimally symptomatic individuals with mild back pain and no spinal instability. These individuals are typically treated nonsurgically. At the other end of the spectrum are individuals 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 individuals 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 individuals 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 an individual fails to respond to conservative treatment but there is no agreement about what constitutes an adequate course or duration of treatment.

The term "conservative management" may refer to "usual care" or to specific programs of nonoperative treatment, which use defined protocols for the components and intensity of conservative treatments, often in the context of an organized program of coordinated, multidisciplinary care. The distinction is important in defining what constitutes a failure of conservative treatment and what comparators should be used in trials of surgical versus nonsurgical management. The rationale for surgical treatment of symptomatic spinal stenosis rests on the Spine Patient Outcomes Research Trial (SPORT), which found individuals who underwent surgery for spinal stenosis and spondylolisthesis had better outcomes than those treated nonoperatively. The SPORT investigators did not require a specified program of nonoperative care but rather let each site decide what to offer. A subgroup analysis of the SPORT trial found that only 37% of nonsurgically treated individuals received physical therapy in the first 6 weeks of the trial and that those who received physical therapy before 6 weeks had better functional outcomes and were less likely to cross over to surgery later. These findings provide some support for the view that, in clinical trials, individuals who did not have surgery may have had suboptimal treatment, which can lead to a larger difference favoring surgery. The SPORT investigators asserted that their nonoperative outcomes represented typical results at a multidisciplinary spine center at the time but recommended that future studies compare the efficacy of specific nonoperative programs to surgery.

A recent trial by Delitto et al (2015) compared surgical decompression with a specific therapy program emphasizing physical therapy and exercise. Individuals with lumbar spinal stenosis and from 0 to 5 mm of slippage (spondylolisthesis) who were willing to be randomized to decompression surgery versus an intensive, organized program of nonsurgical therapy were eligible. Oswestry Disability Index scores were comparable to those in the SPORT trial. A high proportion of individuals assigned to nonsurgical care (57%) crossed over to surgery (in SPORT the proportion was 43%), but crossover from surgery to nonsurgical care was minimal. When analyzed by treatment assignment, Oswestry Disability Index scores were similar in the surgical and nonsurgical groups after 2 years of follow-up. The main implication is that about one-third of individuals who were deemed candidates for decompression surgery but instead entered an intensive program of conservative care achieved outcomes similar to those of a successful decompression.

Diagnostic criteria for fusion surgery are challenging because individuals without spondylolisthesis and those with grade 1 spondylolisthesis are equally likely to have predominant back pain or predominant leg pain. The SPORT trial did not provide guidance on which surgery is appropriate for individuals who do not have spondylolisthesis, because nearly all individuals with spondylolisthesis underwent fusion whereas nearly all those who did not have spondylolisthesis underwent decompression alone. In general, patients with predominant back pain have more severe symptoms, worse function, and less improvement with surgery (with or without fusion). Moreover, because back pain improved to the same degree for the fused spondylolisthesis patients as for the unfused spinal stenosis individuals at 2 years, the SPORT investigators concluded that it was unlikely that fusion led to better surgical outcomes in individuals with spondylolisthesis than those with no spondylolisthesis.

Throughout the 2000s, decompression plus fusion became more widely used until, in 2011, it surpassed decompression alone as a surgical treatment for spinal stenosis. However, in 2016, findings from 2 randomized trials of decompression alone versus decompression plus fusion were published. The Swedish Spinal Stenosis Study found no benefit of fusion plus decompression compared with decompression alone in individuals who had spinal stenosis with or without degenerative spondylolisthesis. The Spinal Laminectomy Versus Instrumented Pedicle Screw (SLIP) trial found a small but clinically meaningful improvement in the Physical Component Summary score of the 36-Item Short-Form Health Survey but no change in Oswestry Disability Index scores at 2, 3, and 4 years in individuals who had spinal stenosis with grade 1 spondylolisthesis (3 – to 14 mm).18, The individuals in SLIP who had laminectomy alone had higher reoperation rates than those in Swedish Spinal Stenosis Study, and the individuals who underwent fusion had better outcomes in SLIP than in Swedish Spinal Stenosis Study. While some interpret the studies to reflect differences in patient factors-in particular, Swedish Spinal Stenosis Study but not SLIP included individuals with no spondylolisthesis, the discrepancy may also be influenced by factors such as time of follow-up or national practice patterns. As Pearson (2016) noted, it might have been helpful to have patient-reported outcome data on the individuals before and after reoperation, to see whether the threshold for reoperation differed in the 2 settings. A small trial conducted in Japan, Inose et al. (2018) found no difference in patient-reported outcomes between laminectomy alone and laminectomy plus posterolateral fusion in individuals with 1-level spinal stenosis and grade 1 spondylolisthesis; about 40% of the individuals also had dynamic instability. Certainty in the findings of this trial is limited because of its size and methodologic flaws.

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 individuals 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 – to 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.

Fixation Devices

Contemporary models of interspinous fixation devices have evolved from spinous process wiring with bone blocks and early device designs (e.g., Wilson plate, Meurig-Williams system, Daab plate). The newer devices range from paired plates with teeth to U-shaped devices with wings that are attached to the spinous process. They are intended as an alternative to pedicle screw and rod constructs to aid in the stabilization of the spine with interbody fusion. Interspinous fixation devices are placed under direct visualization, while screw and rod systems may be placed under direct visualization or percutaneously. Use of an interspinous fixation device in combination with a unilateral pedicle screw system has also been proposed. Interspinous fixation devices are not intended for stand-alone use.

For use in combination with fusion, it has been proposed that interspinous fixation devices are less invasive and present fewer risks than pedicle or facet screws. While biomechanics studies have indicated that interspinous fixation devices may be similar to pedicle screw-rod constructs in limiting the range of flexion and extension, they may be less effective than bilateral pedicle screw-rod fixation for limiting axial rotation and lateral bending. There is a potential for a negative impact on the interbody cage and bone graft due to focal kyphosis resulting from the interspinous fixation device. There is also a potential for spinous process fracture.

Unlike interspinous fixation devices, interspinous distraction devices (spacers) are used alone for decompression and are typically not fixed to the spinous process. In addition, interspinous distraction devices have been designed for dynamic stabilization, whereas interspinous fixation devices are rigid. However, interspinous fixation devices might also be used to distract the spinous processes and decrease lordosis. Thus, interspinous fixation devices could be used off-label without interbody fusion as decompression (distraction) devices in patients with spinal stenosis. If interspinous fixation devices are used alone as a spacer, there is a risk of spinous process fracture.

Regulatory Status

Distraction Devices

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*)

Table 1. Interspinous and Interlaminar Stabilization/Distraction Devices with Premarket Approval

Device Name	Manufacturer	Approval Date	PMA
X Stop Interspinous Process Decompression System	Medtronic Sofamor Danek	2005 (withdrawn 2015)	P040001
Coflex® Interlaminar Technology	Paradigm Spine (acquired by RTI Surgical)	2012	P110008
Superion® Indirect Decompression System (previously Superion® Interspinous Spacer)	VertiFlex (acquired by Boston Scientific)	2015	P140004

PMA: premarket approval.

The Superion Indirect Decompression System (formerly InterSpinous Spacer) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging (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:
  - Instability of the lumbar spine, eg, isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4)
  - An ankylosed segment at the affected level(s)
  - Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral);
  - Scoliosis (Cobb angle >10 degrees)
- *Cauda equina* syndrome, defined as neural compression causing neurogenic bladder or bowel dysfunction.
  - Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA [dual-energy x-ray absorptiometry] scan or equivalent method) in the spine or hip that is more than 2.5 S.D. [standard deviations] 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."

The coflex Interlaminar Technology implant (Paradigm Spine) is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes.

The coflex (previously called the Interspinous U) is indicated for use in 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).

FDA lists the following contraindications to use of the coflex:

- "Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle greater than 25°).
- Osteoporosis.
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Active or chronic infection - systemic or local.
- Known allergy to titanium alloys or MR [magnetic resonance] contrast agents.
    - Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction."

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 post marketing 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.

Fixation Devices

The following interspinous fixation devices have received clearance to market by the U.S. Food and Drug Administration (FDA). This is not intended to be an all-inclusive list.

- Aerial™ Interspinous Fixation (Globus Medical Inc.)
- Affix™ (NuVasive)
- Affix II (NuVasive)
- Aileron™ (Life Spine)
- Aspen™ (Lanx, acquired by BioMet)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- Benefix Interspinous Fixation System
- BridgePoint™ (Alphatec)
- CD HORIZON™ Spinal Fixation System (Medtronic Sofamor Danek)
- Coflex-F® (Paradigm Spine)

- Inspan™ (Spine Frontier)
- InterBRIDGE® Interspinous Posterior Fixation System (LDR Spine)
- Minuteman™ G3 Interspinous Interlaminar Fusion Device (Spinal Simplicity)
- Octave™ Posterior Fusion System (Life Spine)
- PrimaLOK™ SP Interspinous Fusion System (OsteoMed)
- SP-Link™ System (Medical Designs LLC)
- SP-Fix™ Spinous Process Fixation Plate (Globus)
- Spire™ (Medtronic)
- StabiLink® MIS Interspinous Fixation System
- Zip® MIS Interspinous Fusion System (Aurora Spine)

FDA product code: PEK.

Interspinous fixation devices are intended for use as an adjunct to interbody fusion. For example, the indication for the coflex-IF® implant is as:

- "a posterior, nonpedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies - with up to Grade 1 spondylolisthesis."

A number of interspinous plate systems have also been cleared for marketing by the FDA.

Use of an interspinous fixation device for a stand-alone procedure is considered off-label.

RATIONALE

This evidence review was created in January 2007 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

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, spinal instability, or degenerative scoliosis >25 Cobb angle who require laminectomy plus spinal fusion.

The literature is dominated by reports from non-U.S. centers evaluating devices not approved by the U.S. Food and Drug Administration (FDA), although a number of them are in trials at U.S. centers. As of April 2018, only the X-STOP® Interspinous Process Decompression System, coflex Interlaminar Stabilization, and Superion Interspinous Spacer devices had received the FDA approval for use in the U.S. Manufacturing of the X-STOP device stopped in 2015. This review focuses on devices currently available for use in the U.S.

Interspinous or Interlaminar Spacer as a Stand-Alone Treatment

Clinical Context and Therapy Purpose

The purpose of the interspinous or interlaminar spacer in individuals with spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis is to provide a treatment option that is better than lumbar spinal decompression surgery. 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.

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

Populations

The relevant population of interest is patients with spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis.

Interventions

The treatment being considered is the placement of an interspinous or interlaminar spacer as a stand-alone treatment.

Comparators

The following practices are currently being used to treat spinal stenosis with no spondylolisthesis or grade 1 spondylolisthesis: lumbar spinal decompression surgery and nonsurgical conservative therapy.

Outcomes

The general outcomes of interest are whether the placement of an interspinous or interlaminar spacer improves pain, function, and quality of life.

The visual analog scale for pain is a continuous scale that depicts pain intensity along a line that is anchored by 2 verbal descriptors. For pain intensity, the scale is most commonly anchored by "no pain" (score of 0) and "worst imaginable pain" (score of 10) on 10 cm (100 mm) scale.

Function can be measured by a 15-point improvement in the Oswestry Disability Index scores.

Other measures such as 36-Item Short-Form (SF-36) Health Survey or 12-item Short-Form (SF-12) Health Survey to assess the quality of life, and the Zurich Claudication Questionnaire also to assess the quality of life for patients with lumbar spinal stenosis. The 12-item Short-Form (SF-12) and 36-Item Short-Form (SF-36) Health Survey is a measure of perceived health that describes the degree of general physical health status and mental health distress. The 12-item Short-Form (SF-12) is a shorter alternative to the 36-Item Short-Form (SF-36) and has at least 1 question from each of the SF-36's original 8 domains. Both scales are scored such that the adult population mean is 50, with a standard deviation of 10, and higher scores represent a better function.

Freedom from secondary interventions is also of interest to determine whether the placement of an interspinous or interlaminar spacer improves the net health outcome. In addition, the adverse events of treatment need assessment. The window to judge treatment success is a minimum of 2 years postprocedure.

Zurich Claudication Questionnaire
The Zurich Claudication Questionnaire was designed specifically for use in the evaluation of physical function in patients with lumbar spinal stenosis. Subscales of the questionnaire may be used separately. For example, the 5-item Physical Function Scale is used primarily to evaluate walking capacity. These 5 items assess the distance walked and activities of daily living that involve walking. The Physical Function Scale has been used to assess walking as an outcome for surgical and nonsurgical treatment in patients with lumbar spinal stenosis.

The Zurich Claudication Questionnaire consists of 3 subscales:
1. Symptom severity scale (questions I to VII) [further subdivided into pain domain (questions I to IV) and a neuro-ischemic domain (questions V to VII)]: Possible range of the score is 1 to 5.
2. Physical function scale (questions VIII to XII): Possible range of scores is 1 to 4.
3. Patient's satisfaction with treatment scale (questions XIII to XVIII): The range of the scale is 1 to 4.

Scoring Method/Interpretation
The result is expressed as a percentage of the maximum possible score. The score increases with worsening disability.

Oswestry Disability Index
The Oswestry Disability Index is a self-administered questionnaire used by clinicians and researchers to quantify disability for low back pain. The maximum score is 50. The Minimum Detectable Change (at 90% confidence) is 10 percentage points.

Interpretation of the Oswestry Disability Index:
1. 0% to 20%: Minimal disability: This group can cope with most living activities. Usually, no treatment is indicated, apart from advice on lifting, sitting posture, physical fitness, and diet. In this group, some patients have particular difficulty with sitting, and this may be important if their occupation is sedentary (e.g., a typist or truck driver).
2. 20% to 40% Moderate disability: This group experiences more pain and problems with sitting, lifting, and standing. Travel and social life are more difficult, and they may well be off work. Personal care, sexual activity, and sleeping are not grossly affected, and the back condition can usually be managed by conservative means.
3. 40% to 60%: Severe disability: Pain remains the main problem in this group of patients, but travel, personal care, social life, sexual activity, and sleep are also affected. These patients require detailed investigation.
4. 60% to 80%: Crippled: Back pain impinges on all aspects of these patients' lives, both at home and at work, and positive intervention is required.
5. 80% to 100%: These patients would be bed-bound.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Interspinous Spacer Devices versus Decompression Surgery

Systematic Reviews

A systematic review and meta-analysis of RCTs comparing interspinous spacer devices (ISDs) to decompressive surgery for patients with lumbar spinal stenosis was conducted by Xin et al (2023). Eight RCTs including patients (N=852) with lumbar spinal stenosis who received either ISD or decompressive surgery were included (Table 2). Follow-up duration of trials ranged from 6 to 40 months. Characteristics of the included patients are summarized in Table 3. 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 [CI], 1.91 tp 5.40; p<.0001). Additionally, in terms of clinical efficacy endpoints, there was no significant difference in mean visual analog scale leg and back pain scores, Oswestry Disability Index scores, or Zurich Claudication Questionnaire symptom severity subscores between groups who received ISD or decompression. There was a significantly lower Zurich Claudication Questionnaire physical function subscore with ISD compared to decompression (mean difference, -0.27; 95% CI, -0.53 to -0.02; p=.03), but the clinical significance is unknown. Table 4 summarizes relevant clinical efficacy outcomes from the systematic review. The studies included X-STOP ISD devices or other, non-FDA approved ISD devices, which contributed to heterogeneity. Additionally, there was no discussion or stratification of patients based on severity of lumbar spinal stenosis.

In 2021, Hayes Inc. published an evolving evidence review last reviewed October 2024 that reported there is no evidence to inform if outcomes related with the Superion Interspinous Spacer are superior when comparing the Superion Interspinous Spacer with other minimally invasive interventions or other more well-known surgeries involving spinal fusion. They also noted the guidance on the use of spacers is mixed.

Table 2. Comparison of Studies Included in Systematic Reviews and Meta-Analyses

Study	Xin et al (2023)
Moojen et al (2013)	⬤
Strömqvist et al (2013)	⬤
Marsh et al (2014)	⬤
Lonne et al (2015)	⬤
Mohar et al (2016)	⬤
Meyer et al (2017)	⬤
Schmidt et al (2018)	⬤

Borg et al (2021)	●

Table 3. Systematic Reviews and Meta-Analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Xin et al (2023)	Through 2023	8	Patients with symptomatic LSS receiving either ISD or decompressive surgery	852 (12 to 230)	RCT	range, 6 to 40 months

ISD: interspinous spacer device; LSS: lumbar spinal stenosis; RCT: randomized controlled trial;.

Table 4. Systematic Reviews and Meta-Analyses Results

Study	VAS leg pain	VAS back pain	ODI	ZCQ physical function	ZCQ symptom severity
Xin et al (2023)					
Total N	3 studies (n=212)	4 studies (n=242)	3 studies (n=371)	2 studies (n=244)	2 studies (n=244)
Pooled effect (95% CI)	SMD, -0.08 (-0.27 to 0.11)	SMD, -0.20 (-0.55 to 0.15)	SMD, -0.81 (-1.70 to 0.09)	SMD, -0.27 (-0.53 to -0.02)	SMD, -0.67 (-2.62 to 1.27)
I^2 (p)	*0%* (.38)	*72%* (.01)	*93%* (<.00001)	*0%* (.34)	*98%* (<.00001)

CI: confidence interval; ODI: Oswestry Disability Index; SMD: standardized mean difference;; VAS: visual analog scale; ZCQ: Zurich Claudication Questionnaire.

Randomized Controlled Trial

Baranidharan et al (2024) conducted a randomized multicenter study in patients with lumbar spinal stenosis who received an ISD or surgical decompression. Forty eight patients were randomized and followed for 2 years. Mean reduction in ODI from baseline was 35% to 56% during follow-up for patients who received an ISD and 49% to 78% for patients who received surgical decompression; however, this difference was not statistically significant. There were no significant differences in leg pain, back pain, or the physical function component of the Zurich Claudication Questionnaire between groups. Blood loss was significantly less among patients who received ISD compared to decompression surgery (p=.024).

Retrospective Observational Studies

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 groups (p<.0001 vs all 3 surgery groups) and had increased prevalence of comorbidities, including hypertension, osteoarthritis, diabetes, obesity, chronic obstructive pulmonary disease, atrial fibrillation, osteoporosis, and congestive heart failure.

Investigators found that individuals with initial ISD treatment were significantly less likely to receive surgical interventions than comparators in the 3-year follow-up period. Patients receiving open surgery initially were 1.5 to 2.5 times more likely to have subsequent fusion (ISD vs decompression alone: hazard ratio [HR], 1.49; 95% CI, 1.17 to 1.89; p=.001; ISD vs decompression + fusion: HR, 1.78; 95% CI, 1.40 to 2.27; p<.0001; ISD vs fusion alone: HR, 2.54; 95% CI, 2 to 3.23; p<.0001). Patients in the surgery cohorts were also more likely to have other lumbar spine surgeries (all comparisons p<.001), but less likely to have a drug delivery implant (all comparisons p<.001). In patients with at least 3 months of follow-up, the re-operation rates at 3 months were 1.7%, 1.6%, and 2.5% for the decompression, decompression + fusion, and fusion cohorts, respectively, compared to 0.6% re-operation rate for the ISD cohort (all p<.001). Adjusted logistic regression demonstrated that patients receiving decompression initially (with or without fusion) were 2.6 to 2.8 times more likely to have a re-operation at 3 months compared to ISD patients, and patients receiving initial fusion were 3.9 times more likely to receive re-operation compared to ISD. Short-term life-threatening events within 30 days were 2.4 to 6.4 times more likely to occur in the open surgery cohorts compared to ISD, driven primarily by blood loss associated with fusion procedures and re-admission (all p<.001). Additionally, patients in the open surgery cohorts were 1.3 to 2.4 times more likely to have a long-term complication (all p<.001) and 1.6 to 3 times more likely to have sustained a spinous process fracture compared to ISD (all p<.001). This study has many limitations. Firstly, there are many limitations inherent to claims analyses, including the possibility of coding or data entry errors and the omission of clinical details not needed to justify payment. For example, diagnosis codes identified in claims data lack clinical context, such as the severity of lumbar spinal stenosis or postoperative complications, as well as other prior therapies. Claims data also does not capture patient-reported outcomes, such as visual analog scale scores or Zurich Claudication Questionnaire scores, limiting the ability to determine true efficacy. It is unknown if authors were able to see when a patient was lost to follow-up due to death or end of Medicare coverage, as these rates were not reported. Additionally, since the baseline characteristics of patients receiving ISD indicated that these patients may be inherently sicker than those receiving open surgery, we need clinical context to infer if the reason they did not receive additional surgical procedures post initial ISD placement is because they truly did not require intervention, or they were too sick to tolerate the procedure.

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 (13.9% vs 17.2%; p<.001) and lumbar spinal stenosis surgical intervention (11% vs 14.8%; p<.001) 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.

While claims data gives us some information related to re-operation rates, direct or indirect comparative studies using clinical data and validated outcomes measures are required to draw conclusions on the utility of ISDs compared to open surgery.

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

Randomized Controlled Trials

Patel et al (2015) reported on the results of a multicenter randomized noninferiority trial (10% margin) comparing the Superion interspinous spacer with the X-STOP Trial characteristics and results are summarized in Tables 5 and 6. 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. Nunley et al (2018) 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.

The purpose of the tables below is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 5: Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Patel et al (2015); NCT00692276	U.S.	29	2008-2011	Patients with intermittent neurogenic claudication despite 6 mo of nonsurgical management (N=440)	Superion interspinous spacer (n=218)	X-STOP spacers (n=222)

NCT00692276: Randomized Study Comparing the VertiFlex® Superion® interspinous process spacer to the X-STOP® Interspinous Process Decompression (IPD®) System in Patients With Moderate Lumbar Spinal Stenosis.

Table 6: Results of Noninferiority Trials Comparing Superion With X-STOP

Study	Group	n	Success Rates	VAS Leg Pain[a]	VAS Back Pain[a]	ODI Scores[b]	Spinous Process Fractures	Reoperation Rates
2 years								
Patel et al. (2015)	Superion	136	75%[c]	76%	67%	63%	16.4%	44 (23.2%)
	X-STOP	144	75%[c]	77%	68%	67%	8.5%	38 (18.9%)
3 years								
Patel et al. (2015)	Superion	120	52.5%[c]	69/82	63/82	57/82		
	X-STOP	129	38.0%[c]	53/76	53/76	55/77		
4 years								
Nunley et al. (2017)	Superion	122	84.3%[d]	67/86	57/86	55/89		
5 years								
Nunley et al. (2017)	Superion	88	84%[d]	68/85	55/85	57/88		

ODI: Oswestry Disability Index; VAS: visual analog scale.
[a] Percentage achieving at least a 20 mm improvement on a 100-mm VAS score.
[b] Percentage achieving at least a 15% improvement in ODI scores.
[c] Composite outcome based on 4 components: improvement in 2 of 3 domains of the Zurich Claudication Questionnaire, no reoperations at the index level, no major implant/procedure-related complications, and no clinically significant confounding treatments.
[d] Clinical success on at least 2 of 3 Zurich Claudication Questionnaire domains.

Table 7: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Patel et al. (2015)					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 8: Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Patel et al (2015)	3. Allocation concealment unclear	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician		1. High loss to follow-up and/or missing data: 11% of patients not randomized; and data for 28% missing at 2 y; 36% at 3 y.	3. Unclear why a 10% noninferiority margin selected	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Coflex Device (Interlaminar) versus Decompression Surgery

Systematic Review

In October 2021 Hayes completed a Health Technology Assessment which was last reviewed in October 2024 on Coflex Interlaminar Stabilization Device (Surgalign Spine Technologies Inc.) for treatment of lumbar spinal stenosis. Hayes rated use of the coflex Interlaminar Stabilization device with decompression for the treatment of lumbar spinal stenosis (LSS) in adult patients with and without grade I spondylolisthesis or lumbar disc herniation (LDH) a C. According to Hayes a C rating indicates, “potential but unproven benefit. Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns."

Randomized Controlled Trials

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. The primary outcome at 8-week and 1-year follow-ups was the Zurich Claudication Questionnaire score. The score increases with increasing disability. Trial characteristics and results are summarized in tables below. 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.

Table 9: Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Moojen et al (2013) FELIX	Netherlands	5	2008-2011	Patients with intermittent neurogenic claudication due to lumbar stenosis with an indication for surgery (N=159)	Coflex (n=80)	Decompression (n=79)

FELIX: Foraminal Enlargement Lumbar Interspinous distraXion.

Table 10: Summary of Key Randomized Controlled Trial Outcomes

Study	Proportions of Patients Achieving ZCQ Success, [a] (95% CI), %		Reoperations, n (%)
	8 Weeks	***52 Weeks***	
Moojen et al (2013; 2014); FELIX (1-yr follow-up)	142	144	Not reported
Coflex	63 (51 to 73)	66 (54 to 74)	21 (29)
Decompression alone	72 (60 to 81)	69 (57 to 78)	6 (8)
Odds ratio (p)	0.73 (.44)	0.90 (.77)	p<.001
Moojen et al (2015); FELIX (2-yr follow-up)	145		Not reported
Coflex	69		23 (33)
Decompression alone	60		6 (8)
Odds ratio (p)	0.65 (.20)		p<.001

CI: confidence interval; FELIX: Foraminal Enlargement Lumbar Interspinous distraXion; ZCQ: Zurich Claudication Questionnaire.
[a] Reductions in ZCQ scores were categorized as successful if at least 2 domain subscales were judged as "success." The ZCQ has 3 domains: symptoms severity, physical function, and patient's satisfaction.
Success in the domains was defined as a decrease of at least 0.5 points on the symptom severity scale and on the physical function scale or a score of less than 2.5 on the patient's satisfaction subscale.

Section Summary: Interspinous or Interlaminar Spacer as Stand-Alone Treatment

A systematic review of RCTs comparing ISD and decompression surgery in patients with lumbar spinal stenosis found that ISD resulted in an increased rate of reoperation compared to decompression, as well as no statistically significant differences in pain, functional, and quality of life outcomes. A more recent RCT failed to find a difference in pain or functional outcomes between ISD and surgical decompression, possibly due to a lack of power. Additional longitudinal retrospective comparative claims analyses found that there was a significantly lower rate of reoperation in patients with lumbar spinal stenosis who received ISD compared to open surgery. However, there are many limitations inherent to claims analyses, including the possibility of coding or data entry errors and the omission of clinical details not needed to justify payment. For example, diagnosis codes identified in claims data lack clinical context, such as the severity of lumbar spinal stenosis or postoperative complications, as well as other prior therapies. Claims data also does not capture patient-reported outcomes, such as visual analog scale scores or Zurich Claudication Questionnaire scores, limiting the ability to determine true efficacy. It is unknown if authors were able to see when a patient was lost to follow-up due to death or end of Medicare coverage, as these rates were not reported. Additionally, in 1 of the studies, since the baseline characteristics of patients receiving ISD indicated that these patients may be inherently sicker than those receiving open surgery, we need clinical context to infer if the reason they did not receive additional surgical procedures post initial ISD placement is because they truly did not require intervention, or they were too sick to tolerate the procedure. While claims data gives us some information related to re-operation rates, direct or indirect comparative studies using clinical data and validated outcomes measures are required to draw conclusions on the utility of ISDs compared to open surgery.

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.

Interlaminar Stabilization Devices Used with Spinal Decompression Surgery in Individuals with Severe Spinal Stenosis and Grade 1 Spondylolisthesis or Instability

Clinical Context and Therapy Purpose

The purpose of placement of an interlaminar spacer in individuals with severe spinal stenosis and grade 1 spondylolisthesis or instability is to provide a treatment option that is less invasive than lumbar spinal decompression surgery with fusion and more effective for back pain than lumbar spinal decompression surgery alone. Lumbar spinal stenosis has a broad clinical spectrum. 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 following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with 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 interlaminar spacer as an adjunct to spinal decompression.

Comparators
The comparators are lumbar spinal decompression with spinal fusion and lumbar spinal decompression surgery without 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 the 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.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Coflex Device Plus Decompression versus Decompression Plus Fusion

Randomized Controlled Trials

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 individuals who had stenosis, significant back pain, and either no spondylolisthesis or grade 1 spondylolisthesis. 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. Of 215 coflex patients in the per-protocol analysis, 11 were lost to follow-up at the 2-year endpoint. In the fusion group, 3 of 107 were lost to follow-up. Results of long-term follow-up to 5 years were reported subsequently.

Trial characteristics and results are summarized in the tables below. 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%.

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.

A secondary (unplanned) analysis of patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time (104 vs. 157 minutes; p<.001) and blood loss (106 vs. 336 mL; p <.001). 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. In that analysis, 59 (62.8%) of 94 coflex patients and 30 (62.5%) of 48 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 (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 (8%) 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. Clinical outcomes (e.g., Oswestry Disability Index, visual analog score, Zurich Claudication Questionnaire, epidural injections) were measured out to 60 months. Patients age 65 years or older who received the interlaminar implant with decompression (n=84) had clinical outcomes that were not significantly different to patients 65 years or older who received decompression and fusion (n=57), and to patients younger than 65 who received the interlaminar implant with decompression (n=131). In contrast, perioperative outcomes such as operative time (100 vs. 153 min; p<.001), blood loss (106 vs. 358 mL, p<.001), and hospital stay (2.1 vs. 3.3 days; p<.001) were improved with the interlaminar implant compared to posterolateral fusion.

Table 11: Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator

Davis et al (2013) NCT00534235[a]	U.S.	21	2006-2008	Patients with spinal stenosis with up to grade 1 spondylolisthesis, 1 or 2 levels with VAS > 50 and ODI > 20 (N=344)	Decompression plus coflex (n=262)	Decompression plus pedicle screw and rod fixation (n=136)

NCT00534235: Post-Approval Study to Investigate The Long Term (5-Year) Survivorship of Coflex Compared to Control Fusion Study Patients; ODI: Oswestry Disability Index; VAS: visual analog score
[a] Noninferiority study.

Table 12: Summary of Key Randomized Controlled Trial Outcomes

Study	CCS[a]	15-Point Improvement in ODI Score	No Secondary Surgical Intervention or Lumbar Injection	No Secondary Surgical Intervention	No Secondary Lumbar Injection
2-year follow-up					
Davis et al (2013)					
N	308	248	322	215	215
coflex	135 (66)	139 (86)	173 (81)	192 (89)	190 (88)
Fusion	104 (58)	66 (77)	89 (83)	99 (93)	94 (88)
% D (95% CI)	8.5[b] (-2.9 to 20.0)	9 (NR)	2 (NR)	-4 (NR)	0
3-year follow-up					
Bae et al (2016)					
N	290	214	Unclear	NR	NR
Coflex	(62)	129 (90)	(76)	NR	NR
Fusion	(49)	53 (76)	(79)	NR	NR
% D (95% CI) or p	13.3(1.1 to 25.5)	.008	NR	NR	NR
4-year follow-up					
Bae et al (2015)					
N	274	181	NR	NR	NR
coflex	106 (58)	106 (86)	NR	NR	NR
Fusion	42 (47)	42 (72)	NR	NR	NR

% D (95% CI) or p	10.9(-1.6 to 23.5)	.038	NR	NR	NR
5-year follow-up					
Musacchio et al (2016)					
N	282	179	322	322	322
coflex	96 (50)	100 (81)	148 (69)	179 (83)	173 (81)
Fusion	40 (44)	41 (75)	71 (66)	89 (83)	82 (77)
% D (95% CI) or p	6.3 (NR); >.90	>.40	>.70	>.90	>.40

Values are n or n (%.)
CCS: composite clinical success; CI: confidence interval; D: decompression; ODI: Oswestry Disability Index (reported as mean score or percent with at least 15-point improvement); NR: not reported
[a] CCS was composed of a minimum 15-point improvement in ODI 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.
[b] The lower bound of Bayesian posterior credible interval for the device group difference in CCS was equal to -2.9%, which is within the prespecified noninferiority margin of -10%.

The tables 13 and 14 display notable limitations identified in each study.

Another limitation in the study, not listed in the limitation's tables, 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. A retrospective cohort study Evaluation of the Clinical and Radiographic Performance of Coflex® Interlaminer Technology Versus Decompression With or Without Fusion (NCT03041896) trial, undertaken by the manufacturer was completed, but only limited descriptive results are published on Clinicaltrials.gov and a full publication of the trial is not available. Per the website, the proportion of participants undergoing secondary surgical interventions at 6 months was 8.8% (126/1428) with decompression, 6.1% (125/2058) with coflex, and 9.8% (99/1009) with fusion. Additionally, a large registry study, the Coflex® COMMUNITY Study: An Observational Study of Coflex® Interlaminar Technology (NCT02457468) trial, has been completed but results are not published.

Table 13: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Davis et al (2013); NCT00534235	4. Study population combines no and grade 1 spondylolisthesis		2. Noninferiority to a comparator whose benefit is uncertain does not permit meaningful interpretation of the net benefit.	1. Outcomes did not include success of the fusion procedure	
Davis et al (2013); NCT00534235			2. The benefit of the comparator is uncertain. Fusion was not obtained in 29% of cases.		

			Intervertebral cages and BMP were not allowed in the FDA IDE study.		

BMP: bone morphogenetic protein; IDE: investigational device exemption; FDA: U.S. Food and Drug Administration; NCT00534235: Post-Approval Study to Investigate The Long Term (5-Year) Survivorship of Coflex Compared to Control Fusion Study Patients.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 14: Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Davis et al (2013) NCT00534235		4. No independent adjudication or preset criteria for subsequent intervention	3. Evidence of selective reporting			
Davis et al (2013) NCT00534235			3. Evidence of selective reporting. ZCQ scores were not reported for the comparison of pseudoarthrosis and solid fusion.			1. Secondary (unplanned) superiority testing in patients with grade 1 spondylolisthesis patients from the pivotal non-inferiority trial. 3. A non-inferiority margin for the subgroup analysis was not defined or discussed and confidence intervals were not reported.

NCT00534235: Post-Approval Study to Investigate The Long Term (5-Year) Survivorship of Coflex Compared to Control Fusion Study Patients; ZCQ: Zurich Claudication Questionnaire.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician. 4 No independent adjudication or preset criteria for subsequent intervention.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4.

Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intention-to-treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Studies

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 (about 8.7 years). Both the Oswestry disability index and visual analog scale leg and back pain scores of both groups significantly improved compared to the baseline (p<.05 for all), with no difference detected between groups. Compared to the PLIF group, the coflex group displayed preserved mobility (p<.001), shorter duration of surgery (p=.001), decreased amount of blood loss (p<.001), and shorter hospital stay (p=.040).

Subsection Summary: Coflex Device Plus Decompression Versus Decompression Plus Posterolateral 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. A 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 Alone

Randomized Controlled Trials

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).[47,] Trial characteristics and results at 24 months are summarized in Tables 15 and 16. 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=.017), with a treatment difference of 16.7% (95% CI, 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=.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=.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=.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.

Tables 15: Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Schmidt et al (2018); NCT01316211	Germany	7	2008-2014	Patients with moderate-to-severe LSS with or without spondylolisthesis and significant back pain (N=255)	Decompression with interlaminar stabilization (n=129)	Open microsurgical decompression alone (n=131)

NCT01316211: Comparative Evaluation of Clinical Outcome in the Treatment of Degenerative Spinal Stenosis with Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex™ Interlaminar Technology.
LSS: lumbar spinal stenosis;

Tables 16: Summary of Key Randomized Controlled Trial Outcomes

Study	CCS[a]	15-Point Improvement in ODI Score (all patients)	15-Point Improvement in ODI Score (those not receiving a secondary intervention)	No Secondary Surgical Intervention or Lumbar Injection	No Secondary Surgical Intervention	No Secondary Lumbar Injection
Schmidt et al (2018)						
N	204	255	132	225	225	225
D plus ILS	59 (58)	69 (55)	62 (76)	91 (83)	96 (87)	105 (96)
D alone	43 (42)	57 (44)	50 (70)	84 (73)	98 (85)	98 (85)

%D (95% CI)	16.7 (3.1 to 30.2)	10.6 (-1.6 to 22.8)	5.2 (-8.9 to 19.3)	9.7 (-1.1 to 20.4)	2.1 (-6.9 to 11.0)	10.2 (2.7 to 17.8)
p	.017	.091	.470	.081	.655	.010

Values are n, n (%), or %.
CCS: composite clinical success; CI: confidence interval; D: decompression; ILS: interlaminar stabilization; ODI: Oswestry Disability Index;
[a] CCS defined as meeting all 4 criteria: (1) ODI success with improvement >15 points; (2) survivorship with no secondary surgical intervention or lumbar injection; (3) neurologic maintenance or improvement without worsening; and (4) no device- or procedure-related severe adverse events.

The purpose of the limitations in the tables below is to display notable limitations identified in each study. Major limitations are discussed below.

- Based on the reporting by Schmidt et al (2018), 254 patients were randomized but data for only 204 patients were analyzed for the primary outcome measure. Thus, data of 20% of patients were excluded. 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.

Table 17: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Schmidt et al (2018)			1. In the control arm, nonsurgical treatment for back pain after decompression	3. No CONSORT reporting of harms	1, 2. Present study reports 2-y follow-up

			should be described		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 18: Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Schmidt et al (2018)		1. Not blinded to treatment assignment 4. No independent adjudication or preset criteria for subsequent intervention		1. High loss to follow-up or missing data 2. Inadequate handling of missing data. LOCF may not be the most appropriate approach 6. Not intention-to-treat analysis		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
LOCF: last observation carried forward.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician. 4. No independent adjudication or preset criteria for subsequent intervention.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intention-to-treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Studies

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 (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.

Röder et al (2015) reported on a small cross-registry study that compared lumbar decompression plus coflex (SWISS spine 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=.014), numeric rating scale leg pain score (4.3 vs. 2.5; p<.001), numeric rating scale maximum pain score (4.1 vs. 2.3; p=.002), and greater improvement in Core Outcome Measures Index score (3.7 vs. 2.5; p=.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 that the Röder et al (2015) 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.

Richter et al (2010) reported on a prospective case-control study of the coflex device in 60 patients who underwent decompression surgery.56, 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. Tian et al. (2013) 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 patients. Lee et al (2016) 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.

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 outcomes.

Interlaminar Stabilization Devices Used with Spinal Decompression Surgery in Individuals with No Spondylolisthesis or Instability

Clinical Context and Therapy Purpose

The purpose of placement of an interlaminar spacer in patients with spinal stenosis and no spondylolisthesis or spinal instability is to provide a treatment option that is less invasive than lumbar spinal decompression surgery with fusion and more effective for back pain than lumbar spinal decompression surgery alone. Lumbar spinal stenosis has a broad clinical spectrum. 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 clinical feature that best distinguishes the target population for coflex is the severity of back pain, specifically, back pain that is worse than leg pain. The hypothesis underlying this use of coflex is that decompression alone, while effective for claudication and other symptoms of spinal stenosis, may be less effective for severe back pain than decompression plus a stabilizing procedure.

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

Populations

Individuals with spinal stenosis and no spondylolisthesis or instability who have not responded to conservative treatment.

Interventions

The treatment being considered is the placement of an interlaminar spacer as an adjunct to spinal decompression.

Comparators

The comparators are lumbar spinal decompression alone.

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 a 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Coflex Device Plus Decompression Versus Decompression Plus Posterolateral Fusion

Abjornson et al (2018) reported outcomes from the subgroup 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.

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 ($p<.001$). 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 ($p<.001$). 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 ($p<.001$). 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.

Section Summary: Interlaminar Stabilization Devices Used With Spinal Decompression Surgery in Individuals 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 a longer operative time and has a potential for higher procedural and postsurgical complications. When the trial was conceived, decompression plus fusion was viewed as 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 the net health outcomes.

Interspinous Fixation Device With Fusion

Clinical Context and Therapy Purpose

The purpose of interspinous fixation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals who are undergoing spinal fusion.

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

Populations

The relevant population of interest are the following individuals who are undergoing spinal fusion.

Interventions

The therapy being considered are interspinous fixation devices with interbody fusion

Comparators

The following practice is currently being used for individuals who are undergoing spinal fusion: interspinous fixation devices with pedicle screw construct.

Outcomes

The general outcomes of interest include symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity.

Study Selection Criteria

- Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

A systematic review by Lopez et al (2017) evaluated the literature on lumbar spinous process fixation and fusion devices. Reviewers included both interspinous plates and fixation devices and excluded dynamic devices such as the X-Stop. Fifteen articles met inclusion and exclusion criteria, including 4 comparative studies (level III evidence), 2 case series (level IV evidence), and 9 in vitro biomechanics studies (level V evidence). Two of the nonrandomized studies compared interspinous fixation devices with pedicle screws in patients undergoing interbody fusion and 2 included interspinous fixation devices alone or pedicle screws plus an interspinous fixation device in patients undergoing interbody fusion. Use of an interspinous fixation device decreased surgical time and blood loss compared with pedicle screws. No study showed that interspinous fixation devices reduced the hospital length of stay compared with pedicle screw implantation.

Randomized Controlled Trials

Subsequent to the systematic review by Lopez et al (2017), 2 small RCTs (N = 149) have been published in individuals with single-level lumbar degenerative diseases undergoing spinal fusion who received an interspinous fixation device with interbody fusion as alternatives to pedicle screw and rod constructs (Table 19). The first was a single-center study by Huang et al (2017) that randomized 46 individuals to either an unknown type of interspinous fixation device or pedicle screws and followed them for 24 months. The second was a multicenter study by Panchal et al (2018) that randomized 103 individuals to either the Aspen MIS Fusion System or pedicle screws and followed them for 12 months. Compared to the pedicle screw control groups (Table 20), similar or better fusion, disability, and quality of life outcomes were observed for the interspinous fixation device groups. Comparative complication rates were mixed across studies, but comparative treatment effects were not calculated. In the study by Panchal et al (2018), revisions were numerically lower in the interspinous fixation device group, but comparative treatment effects were not calculated. Interpretation of these findings is limited by important weaknesses, however. In the RCT by Panchal et al (2018), weaknesses included insufficient follow-up duration, lack of control for selection bias, and data incompleteness (Tables 21 and 22). In the RCT by Huang et al (2017), limitations include unclear blinding of outcome assessors and potential use of a device that is not commercially available in the United States. Larger, longer-term, and more rigorous multicenter RCTs are needed to confirm these findings.

Table 19. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Huang et al (2017)	China	1	2013-2014	Single-level lumbar degenerative diseases, including lumbar disc herniation, lumbar spinal stenosis, or lumbar degenerative spondylolisthesis	PLIF+ISF, N=23	PLIF+pedicle screws, N=23
Panchal et al (2018)	United States	9	NR	Single-level lumbar degenerative disc disease and/or spondylolisthesis (grade ⩽ 2)	ALIF or LLIF +ISPF, N=66	ALIF or LLIF + pedicle screws, N=37

ALIF: anterior lateral lumbar interbody fusion; ISF: interspinous fastener (Wego, Weihai, China); ISPF: interspinous process fixation; LLIF: lateral lumbar interbody fusion; NR: not reported; PLIF: posterior lumbar interbody fusion; RCT: randomized controlled trial.
[1] Aspen MIS Fusion System, Zimmer Biomet Spine.

Table 20. Summary of Key RCT Results

Study	Fusion	Disability	Quality of life	Revisions	Overall Complications
Huang et al (2017)	43	43	N/A	N/A	43

Outcome definition	24-mo: radiograph/CT-scan	% of patients achieved MCID on ODI[1]	N/A	N/A	
PLIF+ISF	17 (77%)/15 (68%)	33 (77%) overall[2]	NR	NR	2 (9%)
PLIF+pedicle screws	17 (81%)/16 (76%)		NR	NR	1 (5%)
p-value	1.000/0.736	NR	N/A	N/A	NR
Panchal et al (2018)	88	88	88	88	88
Outcome definition	12-mo radiographic fusion based on BSF-3/BSF-2/BSF-1 (95% CI)	ODI mean improvement ± SD at 12 mo	SF-36 physical component mean improvement ± SD at 12 mo	Required secondary surgical intervention	Rated as device-related/NOT device-related
ALIF or LLIF +ISPF	45.5% (32.7%–59.6%)/45.5% (32.7%–59.6%) /9.1% (0.0%–23.2%)	25.97±4.23	10.87±2.79	1 (1.5%)	5 (7.5%) / 14 (21.2%)
ALIF or LLIF + pedicle screws	50% (33.3%–67.8%)/50% (3.3%–67.8%)/0% (0.0%–17.8%)	22.38±5.84	9.10±3.89	4 (10.8%)	6 (16.2%) / 7 (18.9%)
p-value	0.33	<0.01	⩾0.22	NR	NR

ALIF: anterior lateral lumbar interbody fusion; BSF criteria: Brantigan, Stelfee, Fraser criteria: BSF-1, radiographic pseudoarthrosis with loss of intervertebral height with lucency around the implant; BSF-2, radiographic locked pseudoarthrosis with lucency within the cage but solid bone growth into the cage from each vertebral endplate;
and BSF-3, radiographic fusion with bony bridges in at least half of the fusion area; CI: confidence interval; ISF: interspinous fastener (Wego, Weihai, China); ISPF: interspinous process fixation; LLIF: lateral lumbar interbody fusion; MCID: minimally important clinical difference; N/A: not available; NR: not reported; ODI: Oswetry Disability Index; PLIF: posterior lumbar interbody fusion; RCT: randomized controlled trial; SD: standard deviation; SF-36: 36-Item Short Form Health Survey.

[1] MCID was prespecified as an 8-point difference.
[2] Did not stratify by group.

Table 21. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Huang et al (2017)		2. Version used unclear			

Panchal et al (2018)					1. Not sufficient duration for benefit; 2. Not sufficient duration for harms

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 22. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Huang et al (2017)	3. Allocation concealment unclear; “using closed envelopes”	3. Blinding unclear	1. Not registered			
Panchal et al (2018)	4. Inadequate control for selection bias: More males (53% vs. 30%), on sick leave (23% vs. 5%) and with degenerative disk disease (55% vs. 43%)			1. High loss to follow-up or missing data (excluded 13% vs. 21% from 12-mo analysis); 6. Not intent to treat analysis (per protocol for noninferiority trials)		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician. 3. Blinding unclear
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated

Section Summary: Interspinous Fixation Device with Fusion

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 and case series and 2 small RCTs. 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).

Interspinous Fixation Device as a Stand-Alone

Clinical Context and Therapy Purpose

The purpose of interspinous fixation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with spinal stenosis and/or spondylolisthesis.

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

Population

The relevant population of interest is individuals who have spinal stenosis and/or spondylolisthesis.

Intervention

The therapy being considered is an interspinous fixation device alone.

Comparator

The following practice is currently being used to treat spinal stenosis and/or spondylolisthesis: decompression.

Outcomes

The general outcomes of interest include symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity.

Study Selection Criteria

- Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

Baranidharan et al (2024) randomized patients to decompression surgery or an interspinous fixation device (Minuteman). Study characteristics are summarized in the table below. There were baseline differences between groups with a statistically significantly greater visual analogue scale (VAS) back pain score in the interspinous fixation device group. Study results at 24 months are summarized in the table below. Composite clinical success was defined at least 30% improvement in leg pain (VAS), at least 30% improvement in back pain (VAS), at least 30% improvement in pain-related disability (Oswestry Disability Index; ODI), and at least 0.5-point improvement in lumbar spinal stenosis physical function (Zurich Claudication Questionnaire).There was no comparative analysis between groups, but VAS scores had numerically greater improvement in the decompression group compared with the interspinous fixation device. However, blood loss was less (p=.024) and operating time was lower (p<.001) with the interspinous fixation device. This study is heavily limited (see tables below); thus, conclusions regarding the efficacy of interspinous fixation devices cannot be drawn.

Table 23. Summary of Key RCT Characteristics.

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Baranidharan et al (2024)[Baranidharan G, Bretherton B, Feltbower RG, et al..... ; 17: 2079-2097. PMID 38894862]	UK	4	NR	N=43 adults with lumbar spinal stenosis who had failed 6 months of conservative treatment and had degenerative changes at 1 or 2 levels	IFD (n=18)	Surgical decompression (n=25)

IFD, interspinous fixation device; NR, not reported; RCT: randomized controlled trial.

Table 24. Summary of Key RCT Results.

Study	Leg Pain VAS (% change)	Back Pain VAS (% change)	ODI (% change)	LSS Physical Function (% change)	Composite Clinical Success (%)
Baranidharan et al (2024)	N=43	N=43	N=43	N=43	N=43
IFD	-57	-38	-35	-22	50
Decompression	-69	-69	-54	-36	72

FD: interspinous fixation device; LSS: lumbar spinal stenosis; ODI: Oswestry Disability Index; VAS: visual analogue scale.

Table 25. Study Relevance Limitations.

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Baranidharan et al (2024)	1. Although no inclusion/exclusion criteria for stenosis severity were listed, 1 patient was moved from IFD to decompression due to severe stenosis.				3. Analysis limited to the first 24 months of the 5-year study

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 26. Study Design and Conduct Limitations.

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Baranidharan et al (2024)	5. Although randomized, crossover to other treatment group occurred	4. No mention of blinding		3,4,6		3,4

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Case Series

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 of collection, e.g., visual analog scale, 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; p<0.001) and spondylolisthesis (4.6; n = 6; p = 0.01), but not for patients with lumbar disc herniation (2.2; n=10; p>0.05).

Section Summary: Interspinous Fixation Device as a Stand-Alone

One small RCT (N=43) reported 24-month outcomes in patients with lumbar spinal stenosis randomized to an interspinous fixation device or surgical decompression. Both groups improved from baseline, but statistical comparisons of clinical outcomes were lacking. In addition, VAS and other clinical outcomes were numerically improved in patients with surgical decompression compared with interspinous fixation devices. Well-designed RCTs are needed that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2018 Input

Clinical input was sought to help determine whether the use of interlaminar spacer with spinal decompression surgery for 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.

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.

Further details from clinical input are included in the Appendix.

2011 Input

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2011. Two of those providing input agreed this technology is investigational due to the limited high-quality data on long-term outcomes (including durability). Two reviewers did not consider this technology investigational, stating that it has a role in the treatment of selected patients with neurogenic intermittent claudication.

2009 Input

In response to requests, input was received from one physician specialty society and 3 academic medical centers while this policy was under review in 2009. Differing input was received; several reviewers indicated data were sufficient to demonstrate improved outcomes.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Pain and Neuroscience (ASPN)

In 2022, the American Society of Pain and Neuroscience (ASPN) published a consensus guideline outlining best practices for minimally invasive lumbar spinal stenosis treatment. The following recommendation was provided with regard to the use of interspinous spacers:

- "Interspinous spacers should be considered for treatment of symptomatic spinal stenosis at the index level with mild-to-moderate spinal stenosis, with less than or equal to grade 1 spondylolistheses, in the absence of dynamic instability or micro-instability represented as fluid in the facets on advanced imaging. Grade A; Level of certainty high; Quality of Evidence 1-A"

In 2022, ASPN also published evidence-based clinical guidelines informed by a systematic review of randomized controlled trials on interventional treatments for low back pain. The following recommendation was provided with regard to the use of interspinous spacers:

- "Stand-alone interspinous spacers for indirect decompression are safe and effective for the treatment of mild to moderate lumbar spinal stenosis if no contraindications exist. Grade A; Level of certainty high; Quality of Evidence: I-A."

Department of Health & Human Services

In 2019, a Department of Health & Human Services inter-agency task force released a report on pain management best practices. The report provides best practices for development of effective pain management plans using a patient-centered approach in the diagnosis and treatment of acute and chronic pain. All of their statements are on generalized pain and their recommendations relate to gaps in comprehensive pain plan development. In their report, regarding interspinous process spacer devices, they state: "research has shown that interspinous process spacer devices can provide relief for patients with lumbar spinal stenosis with neuroclaudication." The guidelines do not compare therapies to each other and is not informed by a systematic review, it only offers various options to consider when building a pain management plan for a patient.

International Society for the Advancement of Spine Surgery (ISASS)

In 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:

1. Radiographic confirmation of at least moderate lumbar stenosis.
2. Radiographic confirmation of the absence of gross angular or translatory instability of the spine at index or adjacent levels.
3. 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.

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

The National Institute for Health and Care Excellence (NICE)

In 2010, 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.

The North American Spine Society (NASS)

In 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:

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

In 2019, the North American Spine Society issued a coverage position on the use of interspinous devices with lumbar fusion. The North American Spine Society noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumbar fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint and when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter- and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. The North American Spine Society also noted that "No literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
	22868	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 or fixation device]*
HCPCS		
	C1821	Interspinous process distraction device (implantable)
Type of Service	Surgery	
Place of Service	Inpatient	

POLICY HISTORY

Date	Reason	Action
June 2024	Annual Review	Policy Renewed
June 2024	Annual Review	Policy Revised
June 2023	Annual Review	Policy Renewed

Date	Reason	Action
February 2023	Annual Review	Policy Revised
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

*CPT® is a registered trademark of the American Medical Association.

Appendix

2018 Clinical Input

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 on the use of interlaminar spacer with spine decompression in individuals with spinal stenosis, predominant back pain and no or grade 1 spondylolisthesis who failed conservative treatment 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.

Respondents

Clinical input was provided by the following specialty societies and physician members identified by a specialty society or clinical health system:

- American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS)
- International Society for Advancement of Spine Surgery (ISASS)
- Patrick W. Hitchon, MD, Professor of Neurosurgery and Bioengineering, Department of Neurosurgery, identified by University of Iowa Hospitals & Clinics
- Anonymous, MD, Professor of Neurosurgery and Chairman, identified by an academic medical center
- Thiru Annaswamy, MD, Physical Medicine and Rehabilitation, Veterans Administration North Texas Health Care System, identified by the American Academy of Physical Medicine and Rehabilitation
- Anonymous, MD, Physical Medicine and Rehabilitation, identified by the American Academy of Physical Medicine and Rehabilitation

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by a specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide a review, input, and feedback on topics being evaluated by Evidence Street. However, participation in the clinical input process by a specialty society and/or physician member designated by a specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by BCBSA nor any Blue Plan.

Clinical Input Ratings

				Confidence Level That Clinical Use Expected to Provide Clinically Meaningful Improvement in Net Health Outcome											Confidence Level that Clinical Use is Consistent with Generally Accepted Medical Practice										
					NO (High – Intermediate – Low)					YES (Low – Intermediate – High)						NO (High – Intermediate – Low)					YES (Low – Intermediate – High)			
Indication	Respondent	Specialty	Identified by	Yes or No	5	4	3	2	1	1	2	3	4	5	Yes or No	5	4	3	2	1	1	2	3	4	5
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.	AANS/CNS	Neurosurgery		Yes								■			Yes									■	
	ISASS	Spine Surgery		NR											No	■									
	Dr. Hitchon	Neurosurgery	U Iowa	Yes						■					Yes						■				
	Anonymous	Neurosurgery	AMC	No					■						No					■					
	Dr. Annaswamy	Phys Med & Rehab	AAPM&R	No			■								No		■								
	Anonymous	Phys Med & Rehab	AAPM&R	No				■							No		■								

NR=not reported; grey shaded=not reported

Respondent Profile

	Specialty Society	
#	Name of Organization	Clinical Specialty

#	Name	Degree	Institutional Affiliation	Clinical Specialty	Board Certification and Fellowship Training
1	American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS)		Neurosurgery		
2	International Society for Advancement of Spine Surgery (ISASS)		Spine surgery		
	Physician				
#	**Name**	**Degree**	**Institutional Affiliation**	**Clinical Specialty**	**Board Certification and Fellowship Training**
Identified by University of Iowa Hospitals & Clinics					
3	Patrick W. Hitchon	MD	Professor of Neurosurgery and Bioengineering, Department of Neurosurgery University of Iowa Hospitals & Clinics	Neurosurgery	American Board of Neurological Surgery; Fellowship - Cardiovascular Physiology, University of Iowa Hospitals & Clinics, Iowa City, Iowa
Identified by an Academic Medical Center					
4	Anonymous	MD		Neurosurgery	American Board of Neurological Surgery
Identified by American Academy of Physical Medicine and Rehabilitation					
5	Thiru Annaswamy	MD	Veterans Administration North Texas Health Care System	Physical Medicine and Rehabilitation	Physical Medicine and Rehabilitation
6	Anonymous	MD		Physical Medicine and Rehabilitation	FAAPMR, Pain Medicine, Sports Medicine

Respondent Conflict of Interest Disclosure

#	1) Research support related to the topic where clinical input is being sought	2) Positions, paid or unpaid, related to the topic where clinical input is being sought	3) Reportable, more than $1,000 healthcare-related assets or sources of income for myself, my spouse, or my dependent children	4) Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic

					related to the topic where clinical input is being sought		where clinical input is being sought	
	YES/NO	***Explanation***	***YES/NO***	***Explanation***	***YES/NO***	***Explanation***	***YES/NO***	***Explanation***
1	No		No		No		No	
2	No		No		No		No	
3	No		No		No		No	
4	No		No		No		No	
5	No		No		No		No	
6	No		No		No		No	

Individual physician respondents answered at an individual level.Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response.
NR = not reported.

Responses

- We are seeking your opinion on whether using the interventions for the below indications provide a clinically meaningful improvement in net health outcome. Please respond based on the evidence and your clinical experience. Please address these points in your response
    - Relevant clinical scenarios (e.g., a chain of evidence) where the technology is expected to provide a clinically meaningful improvement in net health outcome;
    - Any relevant patient inclusion/exclusion criteria or clinical context important to consider in identifying individuals for this indication;
    - Supporting evidence from the authoritative scientific literature (please include PMID).

#	Rationale
1	Interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade I spondylolisthesis who failed conservative treatment provides a clinically meaningful improvement in net health outcomes. The rationale is that the addition of interlaminar spacer may provide the additional stability for patients with micro-instability, or decrease the chance of iatrogenic micro-instability when extensive facet joint resection is needed for decompression. The addition of interlaminar spacer might also help with pain from facet arthropathy at the treated level from unloading the facet joint. Patients with back pain predominant lumbar spinal stenosis with and without grade I spondylolisthesis represent a challenging clinical scenario. A valid comparator in this predominant back pain population would be spinal decompression surgery with fusion. As mentioned in the evidence summary, the shorter recovery time and lower complication rate associated with decompression and interlaminar spacer when compared with decompression and fusion would be expected to and does demonstrate a clinically meaningful improvement in net health outcomes. The assertion that Swedish Spinal Stenosis Study and SLIP results would remove the decompression and fusion comparator is not valid. The study groups in those two studies were not identical and SLIP did show clinical benefit of decompression and fusion. We believe that this question is beyond the scope of this query, and should be addressed in a wider evidence-based review. There is now increasing evidence of the durable noninferiority of spinal decompression with interlaminar spacer versus spinal decompression and fusion in appropriately selected patients.

	• Musacchio MJ, Lauryssen C, Davis RJ, 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. PMID 26913226
2	The "Population" is now described as a Stenosis patient with "predominant back pain."The ILS (coflex) population has never been defined as having "predominant back pain." and the population described by the PICO does not comply with the PMA approval by the FDA or with the ISASS Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization - Coverage, Indications, Limitations, and/or Medical Necessity on Decompression with Interlaminar Stabilization (D+ILS). We believe the inclusion of "predominant back pain" for the population undermines a functional and fair clinical review as this is not an indication for ILS. Lumbar Spinal Stenosis patients do not typically have "predominant back pain". We believe it is clinically inappropriate to include this in the patient population description and recommend removal. The ILS PRCT's did not study this patient, lumbar spinal stenosis with "predominant back pain," but rather, the PRCT's conducted were on lumbar spinal stenosis patients with neurogenic claudication, leg pain and with back pain. Never is it contemplated that the primary symptom is "predominant back pain" nor is this the patient ("Population") defined in any of the studies referenced in the Evidence Review. It appears these changes were made without clinical input from spine surgeons or without consideration of the Davis publication or the ILS FDA approved Indications for Use. Limiting the population for ILS devices with decompression to those patients with "predominant back pain" is inconsistent with the clinical use of ILS and the FDA approved label. The US FDA label for ILS indications states: "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" This label paints a clear picture of a patient with symptoms of moderate to severe lumbar spinal stenosis. ***ILS (coflex) is actually contraindicated in patients with "axial pain only, with no leg, buttock, or groin pain." *** The IDE trial included patients with an average Oswestry Disability Index of 61 and an MRI with severe or moderate radiographic stenosis. Patients enrolled in the trial had similar visual analog scale back and visual analog scale leg scores at baseline. Surgery for "predominant back pain" is a complex topic distinct from the evidence for lumbar spinal stenosis. Surgical treatment of lumbar spinal stenosis is uncontroversial, and we do not believe it is appropriate for ES to conflate/confuse this with "predominant back pain" surgery. We also are having difficulty understanding why ES is having such difficulty determining the net health benefits of the ILS procedure. ISASS believes the current evidence is overwhelming as reflected in the ISASS statement and position, as well as the North American Spine Society (NASS) from May 2018.

3	Interspinous non-fusion devices (IPD) such as X-Stop, Coflex, Diam, have been shown to be equally effective in the short term, as non-fusion laminectomy in the treatment of lumbar stenosis and neurogenic claudication without instability. A meta-analysis (Deyo et al, Interspinous Spacers Compared to Decompression or Fusion for Lumbar Stenosis: Complications and Repeat Operations in the Medicare Population, Spine2013 May 1; 38(10)) using Medicare inpatient claims between 2006 and 2009 data, compared comorbidity for patients with spinal stenosis having surgery (n=99,084) with (1) an interspinous process spacer alone; (2) laminectomy and a spacer; (3) decompression alone; or (4) lumbar fusion (1-2 level).Patients receiving a spacer alone had fewer major medical complications than those undergoing decompression or fusion surgery (1.2% versus 1.8% and 3.3% respectively) but had higher rates of further inpatient lumbar surgery (16.7% versus 8.5% for decompression and 9.8% for fusion at 2 years). Hospital payments for spacer surgery were greater than for decompression alone but less than for fusion procedures. Their conclusion was that "Compared to decompression or fusion, IPD pose a trade-off in outcomes: fewer complications for the index operation, but higher rates of revision". A second meta-analysis from Australia (Phan et al, Interspinous process spacers versus traditional decompression for lumbar spinal stenosis: systematic review and meta-analysis, J Spine Surg 2016;2(1):31-40) reviewed 11 published studies comparing interspinous devices with decompression alone. The conclusion of the analysis showed "no superiority for mid- to long-term patient-reported outcomes for IPD compared with traditional bony decompression, with lesser surgical complications (4% vs. 8.7%, P=0.03) but at the risk of significantly higher reoperation rates (23.7% vs. 8.5%, P<0.00001). A third review of the literature in 2017 showed that though the initial hospital stay may be shorter with the devices than laminectomy alone, a higher percentage of instrumented patients will require additional surgery with time (6-85%, Ravindra, Ghogawala, Neurosurg Clin N Am 28 (2017) 321-330). This will add to the cost, superseding laminectomy, and undermining any benefits of these implants.
4	We do not use these devices in our neurosurgery practice. Based on findings from the literature, and experiences gained from caring for patients who had these devices implanted by outside surgeons, we are not convinced they are in the patient's best interest.
5	No response
6	No response

NR = not reported

- Based on the evidence and your clinical experience for each of the clinical indications described in Question 1:
  - Respond YES or NO for each clinical indication whether the intervention would be expected to provide a clinically meaningful improvement in net health outcome; AND
  - Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

#	Indications	YES / NO	Low Confidence		Intermediate Confidence		High Confidence
			1	2	3	4	5
1	Use of interlaminar spacer with spinal decompression	Yes			X		

	surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.						
2	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.	NR					
3	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.	Yes	X				
4	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.	No	X				
5	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.	No			X		
6	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.	No		X			

NR = not reported

- Based on the evidence and your clinical experience for each of the clinical indications described in Question 1:
    - Respond YES or NO for each clinical indication whether this intervention is consistent with generally accepted medical practice; AND
    - Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

#	Indications	YES / NO	Low Confidence		Intermediate Confidence		High Confidence
			1	2	3	4	5
1	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.	Yes				X	
2	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.	No					X
3	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.	Yes	X				
4	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.	No	X				
5	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.	No				X	
6	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.	No				X	

NR = not reported

- Additional narrative rationale or comments regarding clinical pathway and/or any relevant scientific citations (including the PMID) supporting your clinical input on this topic.

#	Additional Comments
1	Interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade I spondylolisthesis who failed conservative treatment provides a clinically meaningful improvement in net health outcomes also when compared directly to those patients who underwent spinal decompression alone. The pivotal 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. The difference in success was in part attributed to a larger number of patients receiving "rescue" epidural and facet injections. Although there is potential bias from the unblinded decision of committing certain patients (more in the decompression arm) to injections without a clear algorithm there is also very clearly the potential for a confounding or masking effect of these interventions with respect to back pain. The increased use of these measures in the postoperative period could be interpreted as a failure to address the underlying pain generator and their increased use may represent a failure of the study treatment to address low back pain. More long-term results are expected. • Schmidt S, Franke J, Rauschmann M, et al. Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. *J Neurosurg Spine*. Apr 2018;28(4):406-415. PMID 29372860
2	ISASS has previously reviewed the ILS evidence and has determined that there is a net health benefit with the use of an ILS (coflex being the only one currently marketed) and have issued a coverage recommendation. We have reviewed the BCBS Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) Evidence Summary. In general, this is a comprehensive review, but we have the following comments for consideration. • Interspinous Spacers (ISP) versus Interlaminar Stabilization (ILS) devices: We feel that it is confusing to include these two classes of devices in the same context. The US FDA labels and IDE trials for current and previous interspinous process (ISP) devices are for implantation without direct surgical decompression (ie, stand-alone). The US FDA label and IDE trial for the Interlaminar Stabilization (ILS) device are for implantation with direct surgical decompression. ISP and ILS devices are biomechanically different, have different mechanisms of action and are intended for distinctly different patient populations with significant differences in disease severity. ISP devices are placed between the spinous processes without direct decompression, with their only point of contact being the spinous process. ILS devices, although also placed between the spinous processes are combined with a direct decompression and their main point of contact and fixation is on the vertebral lamina. It is unfortunate that these two types of devices are being confounded, particularly considering the poor historic clinical outcomes associated with the ISP devices. The ILS devices have a much stronger long-term (5 years published) clinical evidence. • Please note that our Coverage Recommendation, issued November 2016, is applicable to ILS devices and is silent on the ISP devices. By combining these two types of devices Evidence Street (ES) is blurring the distinction between them. This is further confounding in that ES is citing an off-label use ILS study which has no relevance to ILS evidence and coverage recommendations. Moojen et al. reported on a study of coflex, used off-label, functionally as an ISP without a direct decompression and not as an ILS is intended to be used with direct decompression. As expected when using a device inappropriately the results

of the Moojen trial are unfavorable, and unjustly is a poor reflection on the proper clinical use of the ILS device. The use of the ILS in the Moojen study is not consistent with the FDA Approved Indications for Use for coflex, which is the only ILS available in the U.S. In order to avoid this confusion and misrepresentation we recommend removing Moojen from this evidence review.

PICO Table

- With regards to the PICO Table ES provided for clinical input, we feel the new addition of the Population which now includes "predominant back pain" confuses and confounds the interpretation of the evidence. ES has newly and wrongly changed the population of patients by adding with "predominant back pain" to the Population category of the PICO table. In April 2018, ISASS submitted our response to your request for Clinical Input. We agreed with the Population in the PICO Table that was submitted at that time. We are perplexed by the change of the Population definition in the current PICO table. The ILS intended population was changed to include an inappropriate qualifier as having "predominant back pain." The addition of "predominant back pain" is an improper clinical indication for ILS.ILS is not intended for this patient population nor does any of the evidence cited utilize this indication. It appears these changes were arbitrary and made without clinical input from spine surgeons or without consideration of the Davis publication or the ILS FDA approved Indications for Use. It is clear that the PRCT's conducted using the ILS were on lumbar spinal stenosis patients with neurogenic claudication, leg pain and with concomitant back pain but never is it contemplated that the primary symptom is "predominant back pain".
- It is inappropriate and not productive to evaluate the published evidence in the context of an arbitrarily defined PICO, in which the studies conducted did not include the patient population that is now suddenly being defined in the PICO.
- The surgical treatment of patients with "predominant back pain" is a complex and controversial topic, the discussion of which cannot be subordinated to a policy on stenosis. Surgical treatment of stenosis is evidence-based, and ES cannot confuse or confound this with the controversies surrounding "predominant back pain" surgery. Lumbar spinal stenosis causes claudication and radicular pain, and its surgical treatment targets those symptoms. Secondarily, patients with stenosis may have concomitant back pain which may respond to surgery in some circumstances.
- The addition of "predominant back pain" is inconsistent with the clinical use of ILS and the FDA approved label. The US FDA label for ILS states it is indicated for:
- "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"
- ILS is actually contraindicated in patients with "axial pain only, with no leg, buttock, or groin pain." This label paints a clear picture of a patient with symptoms of moderate to severe lumbar spinal stenosis.
- The IDE trial included patients with an average Oswestry Disability Index of 61 and an MRI with severe or moderate radiographic stenosis. Patients enrolled in the trial had similar visual analog scale back and visual analog scale leg scores at baseline.
- Regarding the Overview by Evidence-Review Indications section, again it is not surprising that ES has concluded that the evidence is "Uncertain" considering that Indication 2 has inserted the "predominant back pain" language, which makes uninterpretable all the evidence supporting the use of the ILS device.

With regards to the discussion of the SPORT study on page 3 of the ES Evidence Summary we offer the following:

- Evidence Street is correct in citing that one rationale for "surgical treatment of symptomatic spinal stenosis rests on the Spine Patient Outcomes Trial (SPORT), which found that patients who underwent surgery for spinal stenosis and spondylolisthesis had better outcomes than those treated non-operatively." However, Evidence Street has selectively interpreted the many follow-up and subset analyses of this landmark trial. This appears to be due to a mistaken attempt to make isolated "predominant back pain" as the primary diagnostic criterion for fusion surgery. Evidence Street stated that "nearly all patients with spondylolisthesis underwent fusion whereas nearly all those who did not have spondylolisthesis underwent decompression alone". This was the structure of separate studies of patients with stenosis but with and without spondylolisthesis in the trial.
- However, Evidence Street fails to note that the results for patients undergoing fusion are much more nuanced than Evidence Street's mistaken attempt to isolate predominant back pain as a diagnostic criterion. Evidence Street cites Pearson et al.1 to support the statement that "patients without spondylolisthesis and with grade 1 spondylolisthesis are equally likely to have predominant back pain and predominant leg pain." However, Evidence Street fails to note that the authors' conclusion that "patients with predominant leg pain had baseline scores indicative of less severe symptoms", which is a serious confounder in the interpretation of these results. Also, only about a quarter of patients were classified as predominant back pain, and a mixed pain profile was most common. These findings limit the use of this classification as an isolated criterion.
- Evidence Street cites Pearson et al. 2 to support the assertion that "back pain improved to the same degree for the fused spondylolisthesis patients than for the unfused spinal stenosis patients at 2 years," but fails to note that patients who were fused improved more with surgery on multiple outcome measures including Oswestry Disability Index, physical function, bodily pain despite similar baseline characteristics, confounding the back pain outcomes as an isolated finding. In both the fusion and non-fusion groups, multiple univariate predictors of treatment effect have been identified that do not include back pain.3,4 Taken as a whole, the results from multiple publications of the SPORT data show that Evidence Street's attempt to isolate predominant back pain as a primary diagnostic criterion for fusion is misguided. The actual clinical reality is more nuanced.

With regards to the Inose study described on page 3 of the ES evidence summary.

- As ES noted the sample size is very small and further distributed between three treatments yielding group sizes of approximately 20 patients. The study was limited to only for one level lumbar spinal stenosis and excluded patients with foraminal stenosis. Additionally, no baseline clinical data is provided to be able to assess the severity of the lumbar spinal stenosis in these patients. For these reasons, we would suggest caution in over-interpreting this clinical report.

General comment of the ES evidence review

- In general, we would like to comment that when reviewing the evidence for the treatment of lumbar spinal stenosis is important to understand the extent of baseline pain and disability of the patient populations, rather than if they have spondylolisthesis or not. The type of treatment and the response to treatment is very dependent on the extent of stenosis and the severity of the symptoms. An lumbar spinal stenosis patient who has mild stenosis and solitary leg pain and a modest Oswestry Disability Index (<40) can be treated with a simple decompression whereas a moderate to severe stenotic patient with a high Oswestry Disability Index (>60) would require a more extensive decompression which usually requires some concomitant stabilization (fusion or ILS). For example, your Evidence Review cites two pieces of literature that question the use of fusion as an effective treatment for lumbar spinal

		stenosis and therefore question if it is an appropriate comparator for the ILS studies; the Forsth and Ghogawala studies. This is an apples and oranges comparison. Both of these studies enrolled patients with far less severe disease and disability than the patients in the Davis study. The Forsth and Ghogawala studies did not have a minimum Oswestry Disability Index as part of the patient inclusion criteria. This resulted in a patient population in both studies with significantly less severe disease than those in the Davis publication. The average patient in the Forsth and Ghogawala studies (Oswestry Disability Index=42/100, 37/100 respectively) would not have been enrollable in either the Davis or the Schmidt clinical trials which had Oswestry Disability Index inclusion criteria of a minimum of 40/100 and an actual baseline average of Davis=61/100 and Schmidt= 53/100. The patients in the Forsth and Ghogawala studies are not the typical lumbar spinal stenosis patient that would be candidates for decompression with fusion and it is not surprising that decompression alone in those patients did as well as the fusion patients. • On page 9 of the ES evidence summary under the coflex device (Interlaminar) heading there is a review of the Moojen study. • We feel it is inappropriate to cite or highlight this study as it severely biases against ILS devices. The US FDA labels and IDE trials for current and previous interspinous process (ISP) devices are for implantation without direct surgical decompression (ie, stand-alone). The US FDA label and IDE trial for the Interlaminar Stabilization (ILS) device is for implantation with direct surgical decompression. These devices are biomechanically different, have different mechanisms of action and are intended for distinctly different patient populations with significant differences in disease profile. ISP devices are placed between the spinous processes with their only point of contact being the spinous process. ILS devices although also placed between the spinous processes their main point of contact and fixation is on the lamina. • ISASS has a Coverage Recommendation, issued November 2016, that is applicable to ILS devices and is silent on the ISP devices. Please note that NASS also has two separate payer coverage policies, one covering ISP devices, issued in May 2014 and the other covering ILS devices, issued in May 2018. • Evidence Street is blurring the distinction between these devices by citing of an off-label use study which has no relevance to ILS clinical evidence and coverage recommendations. Moojen et al. reported on a study of coflex, used off-label, specifically being used as an ISP without a direct decompression and not as an ILS is intended to be used with direct decompression. As would be expected the Moojen study yielded unfavorable results. It is not surprising that any device used outside of its intended use would not perform as expected. The use of ILS in the Moojen study is not consistent with the FDA Approved Indications for Use for coflex, the only ILS available in the United States. ISASS gave ES this specific feedback on this point in a previous review in March 2018 which apparently has been ignored. In order to avoid confusion in the Indications for Use of ILS devices, due to the inappropriate use in the Moojen study, we would recommend it be removed from the ES evidence review or at a minimum be disclaimed as to the off-label use. • In the introductory paragraph headed INTERLAMINAR STABILIZATION DEVICES USED WITH SPINAL DECOMPRESSION SURGERY, page 11, the symptom of "predominant back pain" appears again. • The ILS patient described in the Population category of the PICO would not normally have predominant back pain. Significant back pain many times is a component of the patient's presentation but if the primary disease was lumbar spinal stenosis we would not expect back pain to be the predominant symptom. The predominant symptoms would be the classic lumbar spinal stenosis symptoms of leg and buttock pain, neurogenic claudication with or

without back pain. A patient with predominant back pain would have a differential diagnosis which included Degenerative Disc Disease (DDD).

- Also on page 11, under the heading CLINICAL CONTEXT AND THERAPY PURPOSE, the first sentence states: "Coflex is not intended for patients who are not candidates for lumbar decompression or decompression with fusion".
- We feel this is a very misleading statement. It would be more clinically accurate and less misleading to state that: coflex is not intended for ALL patients who are not candidates for lumbar decompression or decompression with fusion. It is shortsighted to think of all lumbar spinal stenosis patients only fitting into the decompression alone or the decompression with fusion categories. There are patients whom coflex is ideally suited who are too severe (pain, function, instability) for decompression alone but not severe enough to require a decompression with fusion. This is the ideal coflex patient, allowing a decompression while providing stabilization without having to go to the extreme highly invasive fusion surgery. Coflex provides the opportunity to avoid the extreme binary treatment for lumbar spinal stenosis that you are describing and allow an intermediate treatment for a subset of patients.
- Further on this page, in the PICO, under the category PATIENTS, again the introduction of the "predominant back pain" is a new insertion which as described above makes no clinical sense and defies the designs of the studies used as evidence in this review.
- The statement is made "The clinical feature that best distinguishes the target population for coflex is the severity of back pain, specifically, back pain that is worse than leg pain". We do not feel this is an accurate statement. The ideal coflex patient may have significant back pain that is concomitant with the other classic lumbar spinal stenosis symptoms such as leg/buttock pain, neurogenic claudication, relief on postural flexion and MRI evidence of central, lateral and foraminal stenosis. There is no requirement for the back pain to exceed the leg pain. Reviewing the baseline data from the Davis publication of the U.S. IDE PRCT clinical trial it can be seen from the Inclusion criteria there was no requirement for back pain to be greater than leg pain for inclusion in the study. visual analog scale back pain was required to be minimum 50/100 but no requirement for back pain to be greater than leg pain. Again if back pain were required to be greater than leg pain it would be defining a patient population more typical of DDD than lumbar spinal stenosis. The actual data from the study shows that the visual analog scale back and visual analog scale leg pain scores for patients were on average, nominally the same.
- On page 12 under the OUTCOMES section, we would also suggest including Composite Clinical Success under outcomes. We believe the composite clinical success outcomes which consider several aspects of a patient's outcome, (Oswestry Disability Index, the need for subsequent intervention, neurologic status, and adverse events) give a more meaningful assessment of the net health benefit of an intervention. Looking at these outcomes individually can give a myopic and skewed perspective on a patient's clinical outcome. For example, how do you assess net health benefits if a patient has had a good Oswestry Disability Index outcome at 2 years but has had a subsequent surgery or 3 epidural injections in the interim period? Or if a patient has had a major improvement in leg pain but suffers from a neurologic drop foot. Or if at 2 years the Oswestry Disability Index has improved but immediately post-surgery they had several months of treatment for an adverse event? Using a composite clinical success that combine these possibilities in a robust endpoint and gives the clearest evidence of a net health benefit when comparing two treatments.
- Under the SETTING heading also on page 12, the setting is described as "inpatient". One of the big advantages of ILS surgery particularly considering the age of the lumbar spinal stenosis population is the ability to perform the surgery in the outpatient or ASC setting. The outpatient setting can be much less stressful for these patients and usually implies a shorter anesthesia time, again which is critical for this aged population. Outpatient setting also

provides less exposure to nosocomial infections which in many cases is life-threatening for the older patient.

- Under the heading COFLEX DEVICE PLUS DECOMPRESSION VS DECOMPRESSION PLUS POSTEROLATERAL FUSION on page 12, first paragraph the coflex indication is stated as "patients who have stenosis, significant back pain, and up to grade 1 spondylolisthesis".
- This is generally correct but it potentially wrongly implies that the patients must have a spondylolisthesis up to grade 1. The authors reported that 46% of the patients had a spondylolisthesis while 54% did not.
- Also in this section, you note a 14% incidence of spinous process fractures but fail to report the comparison to the fusion group which had an 11.9% spinous fracture rate which puts the 14% in clinical perspective.
- In Table 8 on page 12 the Participants column indicates N=344, Active N=262, and Comparator N=136. These are different "N's" then you report in the paragraph above. It appears by review of the SSED that the text in the paragraph is correct.
- On page 13 you note "The major weakness in this trial was its use of lumbar spinal fusion as a comparator".
- We disagree that fusion is not an appropriate comparator for this study and population.
- The Davis publication, which was conducted using fusion as the control group is considered by ISASS, our surgeon membership and other spine specialty societies as a landmark study. It was a multi-center, long-term (5 years) PRCT with a large number of patients that we consider the most compelling evidence for the clinical benefit of the ILS treatment. Conversely, your Evidence Review concludes that this study cannot be considered or at best discounted, on what is a critical piece of ILS clinical evidence.
- Rather than conclude based on the 5-year clinical outcomes data that coflex in combination with direct decompression yields a net health benefit, your Evidence Review has questioned whether decompression with fusion is an established treatment and thus whether it was an appropriate comparator to coflex. As practicing spine surgeons we do not understand, based on all available clinical and coverage information on lumbar spinal stenosis, how Evidence Street came to this conclusion. Decompression with fusion is a widely recognized and well-established treatment for a subset of lumbar spinal stenosis patients.
- Interestingly, and to our knowledge, decompression with spinal fusion for lumbar spinal stenosis is widely covered by all major commercial insurance providers including BCBS. Additionally, decompression with fusion for certain lumbar spinal stenosis patients is supported by the Coverage Policy Recommendations from the major spine specialty societies, the North American Spine Society (NASS), the American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS) and the International Society for the Advancement of Spine Surgery (ISASS).
- There is little clinical or practical rationale for not accepting decompression with fusion as an accepted treatment for lumbar spinal stenosis patients. The draft Evidence Review cites two pieces of literature that question the use of fusion as a comparator; the Forsth and Ghogawala studies. This is an apples and oranges comparison. Both studies enrolled patients with far less severe disease and disability than the patients in the Davis study. These studies did not have a minimum Oswestry Disability Index as part of the patient inclusion criteria. This resulted in a patient population in both studies with significantly less severe disease than those in the Davis publication. The average patient in the Forsth and Ghogawala studies (Oswestry Disability Index=42/100, 37/100 respectively) would not have been enrollable in either the Davis or the Schmidt clinical trials which had Oswestry Disability Index inclusion criteria of a minimum of 40/100 and an actual baseline average of (Davis=61/100, Schmidt= 53/100). The patients in the Forsth and Ghogawala studies are not

the typical lumbar spinal stenosis patient that would be a candidate for decompression with fusion and it is not surprising that the decompression alone patients in those studies did as well as the fusion patients.

- Another study design issue in these two studies is that the decompression and the decompression plus fusion surgical technique were not pre-specified or standardized. The Forsth study allowed surgeons to solely determine the decompression and decompression plus fusion procedures that would be performed without including any description of the procedures nor any stratification in the results of the various surgical techniques utilized. This likely had a large effect on the outcomes as various fusion techniques can have an impact on the degree of decompression that can be performed resulting in differences in outcome.
- The Davis study had a primary endpoint of composite clinical success which included four individual safety and efficacy endpoints, Oswestry Disability Index improvement (15pt), no significant adverse events, no subsequent interventions, and neurological maintenance or improvement. In order for a patient to be a success, the patient had to be successful in all four endpoints. Composite clinical success has become the standard for large PRCT's. It is preferred over a single success endpoint as it measures a patient's outcome for multiple criteria. For example, if the sole criteria for success were Oswestry Disability Index improvement and a patient had a 15 point Oswestry Disability Index improvement but also exhibited neurologic deterioration, this patient would erroneously be considered a success. In a composite clinical success endpoint study, this patient would be correctly considered a failure due to not maintaining neurologic status. An additional advantage of utilizing a composite clinical success as the success endpoint in a clinical trial is that it is a practical way of handling the survivorship bias that usually exists in these studies. In these studies, there are times when patients receive intervention subsequent to the initially assigned surgical treatment (subsequent intervention) ie, epidural steroid injections or additional surgery. Without utilizing a composite clinical success it is difficult to account for the outcomes at the final endpoint for these patients. If they have a subsequent intervention it is not appropriate to take for example their 24-month Oswestry Disability Index score knowing that it does not represent the result of the primary treatment but rather is confounded by the subsequent intervention. By using a composite clinical success that included subsequent intervention as a study failure would prevent all data collected after the subsequent intervention from confounding the patient's data who have survived to the terminal time-point without subsequent intervention.
- The use of composite clinical success as study success criteria is a comprehensive and robust methodology. By contrast, the Forsth and Ghogawala studies each had only a single success endpoint (for Forsth, Oswestry Disability Index and Ghogawala, SF-36 PCS). Additionally, in these studies, there is no description in the publications as to how the primary endpoint (Oswestry Disability Index or SF-36 PCS) was calculated at the terminal 24 months for the patients that received subsequent interventions.
- Using these two studies as evidence that decompression plus fusion is not an appropriate treatment for a subset of lumbar spinal stenosis patients is overreaching from the clinician's perspective and could withhold the clinically-appropriate treatment to many lumbar spinal stenosis patients. For these reasons, we believe decompression plus fusion is an accepted treatment for lumbar spinal stenosis patients and therefore an appropriate comparator to assess the net health benefit of an ILS treatment.
- Additionally, we find it troubling that you fail to apply the same rigorous criticisms to the two studies mentioned above and other studies used as counter-evidence throughout your review that you apply to the studies conducted with the ILS device.
- In sum, Evidence Street's negative opinion concerning the evidentiary support for coflex's net health benefit depends first upon disqualifying the rigorous Level I PRCT PMA approved by

the FDA that utilized decompression with fusion as the established alternative for the relevant population. It further depends upon disregarding that decompression with fusion is widely recognized by government agencies, Spine Specialty Societies, expert physicians, commercial insurers, and other health care stakeholders as a medically necessary and effective treatment for a subset of lumbar spinal stenosis patients. It requires doing so based on two studies that do not represent the intended population, that are methodologically flawed, and that fail to meet FDA's or Evidence Street standards for the evaluation of evidence.

- In the last sentence on page 13, which states "In addition, the underlying premise that patients with back pain and spinal stenosis do not respond well to decompression (alone or followed by non-surgical treatments for back pain) has been challenged" is inconsistent with spine clinical knowledge and practice and not substantiated with a reference. We would also reiterate that to discuss in these general terms lumbar spinal stenosis patients without clinically defining where they are on the disease continuum (mild to severe) makes it difficult and adds confusion to the broad conclusions you are drawing.
- On page 14 you indicate that the non-spondylolisthesis group analysis from the U.S. IDE PRCT IDE Study has not been published. In fact has been published: Spinal Stenosis in the Absence of Spondylolisthesis: Can Interlaminar Stabilization at Single and Multiple-levels Provide Sustainable Relief? International Journal of Spine Surgery, Vol. 12, No. 1, 2018, pp. 64-69.
- On page 14 the review states: "Another gap in evidence, not listed in the gaps table, 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." We find this statement perplexing, particularly in the area of spine. These are very difficult and challenging trials to conduct. We should encourage this level of clinical evidence commitment with a large and long-term clinical trial. It would be welcome if all devices being used in spine had such rigorous clinical evidence. We would also point out that many of the products that have received coverage recommendations from ES have an equal evidentiary basis as coflex, (ie, Minimally Invasive SI Joint Fusion.
- With regards to Table 10 on page 14 Relevance limitations: We have the same comments made relative to fusion as an appropriate comparator as above.
- With regards to Table 11 on page 14 Study Design and Conduct limitations, under Allocation 3. Allocation Concealment Unclear. In a review of the SSED study arm allocation was specified stating "The study was a prospective, randomized, multicenter, concurrently controlled clinical study. Surgeons were blinded prior to patient randomization, and patients were blinded until after surgery".
- With regards to Table 11 on page 14 Study Design and Conduct limitations, under Blinding 4. "No independent adjudication or preset criteria for subsequent intervention". We do not feel the use of independent blinded adjudication presents a potential surgeon bias in this study and a priori objective criteria would not have been possible in this study or any study of this type. In this study, the protocol with regards to subsequent intervention study reflects the usual and customary practice of clinical medicine, including the treatment of recurrent intractable pain or neurologic deterioration. It is not clinically realistic or real-world that a list of preset criteria could account for all the possible clinical circumstances that could be encountered when contemplating a subsequent treatment for a patient who has recurrent pain or a deteriorating neurologic condition.
- It is reasonable to believe that a treating surgeon would not consider performing a subsequent intervention in consultation with a patient unless it was absolutely necessary. Any

other inference would suggest that spine surgeons are willing to perform an unnecessary procedure in order to bias the outcome of a study, frankly an absurd proposition.

- Additionally, when looking at the reoperation rates of this study, specifically, the Adverse Events and Secondary Surgical Procedures section on page 1535 of the publication it can be seen that the authors state that 10.7% (23/215) and 7.5% (8/115)1) were the reoperation rates for coflex and fusion respectively. This indicates a higher reoperation rate for coflex compared to fusion, which if you suspected a surgeon bias would only be biased against coflex.
- In our opinion the use of independent blinded adjudication and a priori objective criteria is ethically and practically not possible in these types of studies and based on the data does not suggest any surgeon bias related to subsequent interventions was introduced in favor of ILS.
- On page 15 under Subsection summary, ES again discounts fusion and subsequently discounts the entire IDE/PMA clinical as an appropriate comparator on the basis that 2 RCT's (Forsth and Ghogawala) showed no difference in Oswestry Disability Index scores between decompression alone and decompression with fusion. We reiterate as above our position that these studies, due to the study design and statistical flaws do not serve as a credible basis to discount decompression with fusion as an appropriate lumbar spinal stenosis treatment for this population. Among the other issues discussed, the Swedish Spinal Stenosis Study trial used a 12-point Oswestry Disability Index difference as the study's primary endpoint. Besides being a solitary endpoint, which has the disadvantages relative to composite clinical success, already discussed the use of 12 point Oswestry Disability Index difference in lieu of a 15 point Oswestry Disability Index difference is highly unusual and possibly unprecedented in spine clinical trials. On page 1416 of the publication, the authors even state that "We chose a difference of 12 conservatively since a decrease in the Oswestry Disability Index score of 15 had been suggested by the Food and Drug Administration to indicate minimally important improvement after spinal fusion surgery".ES emphasizes that the study was powered to detect a 12 point Oswestry Disability Index difference but it is interesting to note that if the more usual and accepted 15 point Oswestry Disability Index difference was used the study would be underpowered. It is unclear whether the 12 point Oswestry Disability Index difference was prescribed a priori or was it a posthoc analysis to insure adequate power in the study. Regardless, using a 12 point Oswestry Disability Index difference in lieu of the accepted 15 point lowers the success bar and biases the study outcome in favor of the more conservative procedure. Combined with the fact that based on the low baseline Oswestry Disability Index scores, the patients in these 2 studies had only mild lumbar spinal stenosis and would not have even met the enrollment inclusion criteria of the more severe lumbar spinal stenosis disease in the coflex PMA study.

Regarding the ES review of the coflex device plus decompression versus decompression alone:

- On page 17 of the ES coflex evidence summary Table 14. Relevance limitations under the category Comparator it is stated: "In the control arm, nonsurgical treatment for back pain after decompression should be described."
- The patients in this trial have already been shown to have failed conservative care for a minimum of 3 months. It does not make clinical sense that after the initial surgery to then put the patient thru another course of non-surgical treatment. Recurrence of pain after the initial procedure is an indication that the primary surgery has failed. It is unlikely that a patient that has recurrent pain after their initial treatment is going to respond to additional conservative care, and even if they did it would still indicate a failure of the initial surgical treatment and their 24-month outcome could not be attributed solely to the initial treatment.

- On page 17 of the ES coflex evidence summary Table 14. Relevance limitations under the category Outcomes it is stated: "No CONSORT reporting of harms".
- Although not in CONSORT format the authors do describe Adverse Events in the publication that show no significant differences between groups.

Regarding Table 15. Study Design and Conduct limitations under the Blinding category it is stated that: "Not blinded to treatment assignment".

- The Schmidt article clearly states that the study was randomized and the surgeon and patient did not know the treatment assignment until the time of surgery. Therefore it is unclear why "not blinded to treatment assignment "would be considered a limitation in this study.
- Additionally, in Table 15, under the Blinding category, it is stated that "No independent adjudication or preset criteria for subsequent intervention". We offer the same comment for this proposed limitation as that described in our comments on ES Table 11 regarding the coflex versus fusion PMA study.
- Table 15 indicates a limitation under Data Completeness indicating a high loss to follow-up, use of LOCF, no intent to treat analysis and power not calculated for primary outcome.
- We disagree with the statement that this study has a high loss to follow-up. We believe this is a misrepresentation or misunderstanding by ES of the study design and data presentation. The authors state that "the analysis set (mitt) consisted of 225 patients" which "at 24 months 204 patients were evaluable for analysis representing an overall 91% follow-up rate".
- Also, ES states that: "LOCF" may not be the most appropriate approach for missing data".
- We do not see any reference or discussion of an LOCF analysis in the Schmidt publication, therefore, we are unsure of the source of this comment.
- Evidence Street states that power was not calculated for primary outcome
- The Schmidt authors include a discussion on statistical analysis which includes the power calculation and rationale.
- On page 17 of the ES review, it is stated that: "The inclusion of epidural and facet joint injections in the endpoint may be inappropriate in this trial."
- Admittedly, in clinical practice, there are scenarios although not ideal, where a surgeon may need to perform an epidural steroid injection to assist a patient through an ongoing or recurrent pain episode. But in the case of performing a clinical trial, in order to objectively compare two surgical treatments and to develop the most clinically meaningful scientific evidence, we believe epidural injections should be used as a study endpoint. A surgical treatment that required fewer post-operative epidural(s) to be successful in the long-term would be considered clinically superior to one that required post-operative epidurals to maintain pain relief. This outcome data is important clinical information for a surgeon in which to choose between two surgical treatments. Therefore, a clinical trial study design for stenosis that classified an epidural as a patient failure is a preferred protocol. It gives the surgeon a true picture of what outcome to expect when utilizing either of the two surgical treatments. It would be misleading to report two-year outcomes in a study, without being clear that to achieve those outcomes it required subsequent interventions (including) epidural injections. Additionally, the fact that the same criteria (epidural constitutes a failure) are used for both study arms, does not inherently bias the study towards one or the other treatment. For these reasons, in clinical trials, we consider the use of a post-operative epidural as a patient failure appropriate.
- With regards to the Schmidt study, there are some findings not in the primary endpoint that are clinically important. First, is the finding that the ILS group showed a 5x improvement in walking distance compared to decompression alone patients which had a 2x improvement.

	For many patients, the ability to walk is their primary presenting complaint and restoring their ability to walk leads to significant patient satisfaction. This is particularly important in the aged lumbar spinal stenosis patient population in that immobility can lead to and exacerbate other comorbidities. Secondly, the ILS group had a decreased need for compensatory pain management (opioids) at every time point. Currently, the elderly are the fastest-growing demographic identified in the "opioid epidemic" and anything a surgeon can do to decrease opioid use is significant.
3	Interspinous devices may have short term benefits, with shorter hospital stays. These benefits, however, are outweighed with the need for additional surgery, exceeding that in patients undergoing decompression without such devices. These conclusions are consistent across several peer-reviewed publications.
4	Per the section above, the limitations of these devices appear so significant, compared to more standard surgical treatment approaches that we do not use them.
5	No response
6	Clinically, these devices have utility in patients that do not want to consider decompression and fusion, or those that cannot move forward with general anesthesia.

NR = not reported

- **Is there any evidence missing from the attached draft review of evidence that demonstrates clinically meaningful improvement in net health outcome?**

#	YES / NO	Citations of Missing Evidence
1	No	
2	Yes	Richard Guyer, MD; Michael Musacchio, MD; Frank P. Cammisa, Jr., MD; and Morgan P. Lorio, MD, FACS. ISASS Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization - Coverage Indications, Limitations, and/or Medical Necessity. November 10, 2016. http://www.isass.org/public-policy/isass-policy-statement-decompression-with-interlaminar-stabilization/
3	No	
4	No	
5	No	
6	No	