

## Corporate Medical Policy

# Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

<b>File Name:</b>	interspinous_and_interlaminar_stabilization-distraction_devices
<b>Origination:</b>	7/2006
<b>Last CAP Review:</b>	5/2020
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<b>Last Review:</b>	5/2020

### Description of Procedure or Service

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Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation the device is opened or expanded to distract (open) the neural foramina and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery or as an alternative to decompression surgery.

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

Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery. Interlaminar spacers have 2 sets of wings that are placed around the inferior and superior spinous processes. These may be referred to as interlaminar implants or an interspinous U. These implants aim to restrict painful motion while otherwise 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. Other types of dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; these are not covered in this policy.

#### **Regulatory Status**

In 2015 the Superior® Interspinous Spacer (ISS VertiFlex), now Superior® Indirect Decompression System, was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The Superior® ISS, as stated in the premarket approval, is to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging, and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superior® ISS is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of nonoperative treatment. The Superior® ISS may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated and at no more than two levels, from L1 to L5.

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

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

The coflex® Interlaminar Technology implant (Paradigm Spine) was approved by the FDA in 2012 (P110008). It is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. This device was previously called the Interspinous U. The coflex® is indicated for use in 1- or 2-level lumbar stenosis from L1-L5 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 non-operative treatment. The coflex® is intended to be implanted midline between adjacent lamina of one or two contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

The 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 of greater than 25 degrees).
- 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 magnetic resonance imaging (MRI) 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, FDA requested additional postmarketing studies to provide longer-term device performance and device performance under general conditions of use. The first was the 5-year follow-up of the pivotal investigational device exemption trial. The second was a multicenter trial with 230 patients in Germany who were followed for 5 years, comparing decompression alone with

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decompression plus coflex®. The third, a multicenter trial with 345 patients in the United States who were followed for 5 years, compared decompression alone with decompression plus coflex®.

## Related Policies

Total Facet Arthroplasty  
Interspinous Fixation (Fusion) Devices

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**Interspinous or interlaminar distraction devices as a stand-alone procedure are considered investigational for all applications. Use of an interlaminar stabilization device following decompression surgery is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Interspinous and Interlaminar Stabilization/Distraktion Devices (Spacers) are covered

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Not applicable

## When Interspinous and Interlaminar Stabilization/Distraktion Devices (Spacers) are not covered

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Interspinous or interlaminar distraction devices as a stand-alone procedure are considered investigational as a treatment of spinal stenosis.

Use of an interlaminar stabilization device following decompression surgery is considered investigational for all applications.

## Policy Guidelines

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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 two randomized controlled trials (RCTs) of two spacers (Superion Indirect Decompression System, coflex interlaminar implant). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal decompression has shown high failure and complication rates. A pivotal trial regulated by the U.S. Food and Drug Administration compared the Superion ISS to the X-STOP (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superion ISS on some outcome measures. For example, the percentage of patients experiencing improvement was reported as over 80%. Interpretation of this trial is limited by questions about the number of patients used to calculate success rates, the lack of

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efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression. The coflex interlaminar implant (also called the interspinous U) was compared with decompression in the multicenter, double-blind Foraminal Enlargement Lumbar Interspinous distraXion (FELIX) trial. Functional outcomes and pain were similar in the two groups at one-year followup, but reoperation rates due to absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At two years, reoperations due to absence of recovery had been performed in 33% of the coflex group and in 8% of the bony decompression group. The evidence is insufficient to determine the effects of the technology on 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 two RCTs with a mixed population of patients. 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 two 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 patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time (104 vs. 157 minutes;  $p < 0.001$ ) and blood loss (106 vs. 336 ml,  $p < 0.001$ ). 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 patients with pseudoarthrosis. The report indicated 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 and 14% in the coflex group ( $p = 0.18$ ), including 8 (8%) coflex cases that required conversion to fusion. This secondary analysis is considered hypothesis-generating, and a prospective trial in patients 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 (ODI), between the patients treated with coflex plus decompression vs. decompression alone. "Composite clinical success" (CCS), defined as 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, was used to assess superiority. A greater proportion of patients 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 CCS was primarily driven by a greater proportion of patients 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 patient'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 patients who had grade 1 spondylolisthesis, leaving the question open about whether the implant would improve outcomes in this population. Limitations of the published evidence preclude determining the effects of the technology on net health outcome, and evidence reported through clinical input is not universally supportive of a clinically meaningful improvement in net health outcome. While some respondents considered the shorter recovery

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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. 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 effect of the technology on 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 an RCT. 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 patients with no spondylolisthesis. Fusion after open decompression laminectomy is a more invasive procedure that requires longer operative time and has a potential for higher procedural and postsurgical complications. When the trial was conceived, decompression plus fusion was viewed 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 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 patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal Investigational Device Exemption trial have been published, but comparison with decompression alone in this population has not been reported. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 22867, 22868, 22869, 22870, 22899, C1821*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **Scientific Background and Reference Sources**

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### **Spinal Surgery Using Interspinous Distraction Technology**

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National Institute for Health and Clinical Excellence (NICE). (2005). Interventional Procedure Consultation Document - Interspinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine. Retrieved 6/15/06 from <http://www.nice.org.uk/page.aspx?o=ip191consultation>.

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**Interspinous and Interlaminar Stabilization/Distraktion Devices (Spacers) – Name change**

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North American Spine Society. Interspinous device without fusion. 2014. Available online at: <https://www.spine.org/Documents/PolicyPractice/CoverageRecommendations/InterspinousFixationWithFusion.pdf> . Last accessed October, 2014.

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Specialty Matched Consultant Advisory Panel – 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 4/16/2020

Specialty Matched Consultant Advisory Panel – 5/2020

## Policy Implementation/Update Information

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### Spinal Surgery Using Interspinous Distraction Technology

- 7/24/06 New policy. Spinal surgery using interspinous distraction technology is considered investigational. Notification given 7/24/06. Effective date 10/2/06.
- 10/30/06 Added statement indicating "Until a specific code is created for this procedure, it is anticipated that providers will use the unlisted code, 22899, when submitting claims." to the "Billing/Coding" section.
- 1/17/07 Added new 2007 CPT codes 0171T and 0172T to "Billing/Coding" section.
- 6/18/07 Specialty Matched Consultant Advisory Panel review 5/23/2007. No changes to policy statement. References added.
- 7/6/09 Specialty Matched Consultant Advisory Panel review 5/28/2009. "Description" revised. No change to policy statement. Updated rationale in "Policy Guidelines" section. References added. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 6/21/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. "Description" section revised. "Policy Guidelines" updated. No change to policy intent. References added. (btw)
- 4/17/12 Description section revised. Reworded the When Not Covered statement for consistency, no change to policy intent. Policy Guidelines updated. Reference added. Medical Director review 3/21/2012. (btw)
- 2/12/13 Reference added. (btw)
- 7/1/13 Description section and Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/15/2013. No change to policy intent. (btw)

### Interspinous and Interlaminar Stabilization/Distracton Devices (Spacers) – Name change

- 8/27/13 Policy name changed from "Spinal Surgery Using Interspinous Distraction Technology" to "Interspinous and Interlaminar Stabilization/Distracton Devices (Spacers)". Description section updated. Policy statement updated to indicate: "Interspinous distraction devices and interlaminar stabilization devices are considered investigational for all applications." Added new statement under the When Not Covered section; "Use of an interlaminar stabilization device following decompressive surgery is considered investigational for all applications." Senior Medical Director review 8/6/2013. Reference added. (btw)
- 4/15/14 CPT code 22899 added to Billing/Coding section. (btw)
- 6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/2014. No change to policy. (btw)
- 10/28/14 References added. (sk)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/26/2015. (sk)
- 9/1/15 Reference added. (sk)

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- 7/1/16 Reference added. Policy Guidelines updated. Regulatory Status updated. Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)
- 12/30/16 Codes 22867, 22868, 22869, and 22870 added to Billing/Coding section. Codes 0171T and 0172T removed from policy. (sk)
- 6/30/17 Reference added. Description section updated. Policy Statement revised for clarity. Policy Guidelines updated. Regulatory Status updated. Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)
- 8/11/17 Code C1821 added to Billing/Coding section. Notification given 8/11/2017 for effective date 10/13/2017. (sk)
- 6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)
- 9/28/18 Reference added. Policy Guidelines updated. Regulatory Status updated. (sk)
- 6/11/19 References added. Policy Guidelines updated. Regulatory Status updated. Specialty Matched Consultant Advisory Panel review 5/15/2019. (sk)
- 6/9/20 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/20/2020. (sk)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.