

Interspinous Fixation (Fusion) Devices

Effective: April 1, 2023

Next Review: December 2023

Last Review: February 2023

IMPORTANT REMINDER

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

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

DESCRIPTION

The spinous process fixation orthosis is marketed as a minimally invasive alternative to pedicle screw instrumentation in spinal interbody fusion. The device is inserted through a small incision over the spinal level being fused. It includes an enclosure in which bone graft material is placed.

MEDICAL POLICY CRITERIA

Implantation of spinous process fixation orthoses is considered **investigational** for all indications.

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

CROSS REFERENCES

1. [Dynamic Stabilization of the Spine](#), Surgery, Policy No. 143
2. [Interspinous and Interlaminar Stabilization and Distraction Devices \(Spacers\)](#), Surgery, Policy No. 155
3. [Percutaneous Axial Anterior Lumbar Fusion](#), Surgery, Policy No. 157
4. [Total Facet Arthroplasty](#), Surgery, Policy No. 171
5. [Image-Guided Minimally Invasive Spinal Decompression \(IG-MSD\) for Spinal Stenosis](#), Surgery, Policy No. 176
6. [Lumbar Spinal Fusion](#), Surgery, Policy No. 187

BACKGROUND

This device may also be referred to as an interspinous anchor, spinous fixation system, or spinal interlaminar fixation orthosis. It differs from interspinous process spacers (e.g., X-STOP) and dynamic stabilization systems in that it is intended for fixation/fusion rather than as motion preserving devices.

REGULATORY STATUS

There are a number of spinous process fixation orthoses under investigation, some of which have received approval for marketing from the U.S. Food and Drug Administration (FDA) for single-level fixation with bone graft material for achieving supplemental fusion. **These devices are not approved for stand-alone use, and the list may not be exhaustive:**

Device name	Manufacturer	FDA Approved?
Aerial™ Interspinous Fixation	Globus Medical Inc.	Yes
Affix™ Spinous Process Plate Systems	NuVasive®	Yes
Aileron® Posterior Fusion System and Interspinous Fixation System	Life Spine®	Yes
Aspen® Spinous Process Fixation System	Lanx® (acquired by BioMet)	Yes
Axle™ Interspinous Fusion System	X-Spine	Yes
BacFus® Spinous Process Fusion Plate	RTI Surgical™ (formerly Pioneer® Surgical)	Yes
BridgePoint™ Spinous Process Fixation System	Alphatec Spine®	Yes
Coflex-F® Implant Systems*	Paradigm Spine	Yes
Inspan™ Spinous Process Plate System	SpineFrontier®	Yes
InterBRIDGE Interspinous Posterior Fixation System	LDR Spine	Yes
Minuteman® Interspinous Interlaminar Fusion Device (percutaneous spinal fusion)	Spinal Simplicity	Yes
Octave™ Posterior Fusion System	Life Spine®	Yes
PrimaLOK™ SP Interspinous Fusion System	OsteoMed Spine	Yes
SP-Fix™ Spinous Process Fixation System	Globus Medical	Yes
SP-Link™ System	Medical Designs LLC	Yes
Spire™ Stabilization System	Medtronic Sofamor Danek	Yes
ZIP™ MIS Interspinous Fusion System	Aurora Spine	Yes

*The non-fusion coflex® Interlaminar Implant is addressed separately in the medical policy for Interspinous and Interlaminar Stabilization/Distracton Devices, see Cross References.

EVIDENCE SUMMARY

Evaluating the safety and effectiveness of spinous process fixation orthoses requires randomized comparisons with spinal fusion using conventional devices (e.g., pedicle screws). These comparisons are necessary to determine whether the benefits of spinous process fixation orthoses outweigh any risks and whether they offer advantages over conventional devices (e.g., pedicle screws, rods, cages) with respect to the following:

- Pain and functioning
- Durability of treatment effects (the benefits of spinal surgery are known to diminish over time; therefore, it cannot be assumed that any early benefits will remain stable in the long term)
- Adverse events (e.g., vertebral fracture)
- Device failure/replacement
- Impact on future surgical options in the same or adjacent spinal levels.

Spinous process fixation devices are not approved by the U.S. Food and Drug Administration (FDA) for stand-alone use; therefore, this indication is considered off-label.

Systematic Reviews

A network meta-analysis of decompression alone versus posterior lumbar interbody fusion or an interspinous device (Coflex) in the treatment of lumbar degenerative disease was published by Fan (2020).^[1] A total of 10 RCTs (N=946) were included in the review, two of the RCTs evaluated decompression alone versus Coflex, four RCTs evaluated decompression alone versus lumbar interbody fusion, and four RCTs evaluated Coflex versus lumbar interbody fusion. There was a high risk of bias in random sequence generation in one study and a high risk of bias in allocation concealment in another. All studies had unclear risk of bias in at least one domain. Outcomes of Oswestry Disability Index (ODI) and visual analogue scale (VAS) were analyzed using mean differences (MD) with 95% credible interval (CrI). Compared with the decompression alone group, there was no significant difference of post-operation ODI score in Coflex or lumbar interbody fusion groups (MD=0.65 (95% CrI=-5.3, 5.8) and MD=0.54 (95% CrI=-5.2, 5.5, respectively). Reduced VAS scores were found in the Coflex and fusion groups compared with decompression alone (MD=-0.42 [95% CrI=-1.3, 0.30] and MD=-0.37 [95% CrI=-1.3, 0.34], respectively). No comparison of post-surgical VAS between Coflex and fusion groups was provided. The incidence rate for adverse events was not calculated, however the authors noted the count of adverse events in each group: in the decompression group, 13 adverse events including eight relapse and three dural sac rupture; four events in the Coflex group including two dural sac ruptures, one “Coflex intervention loose”, and one vertebral fracture; and 14 adverse events in the fusion group including three relapse, two infection, two dural sac rupture, one venous thromboembolism, two “intervention loose,” and one vertebral fracture. No comparisons of pre-post operation outcomes by group were provided. Long-term outcomes were not evaluated.

Lopez (2017) published a systematic review (SR) evaluating the literature on lumbar spinous process fixation and fusion devices.^[2] The review included both interspinous plates and fixation devices, and excluded dynamic devices such as the X-Stop. A total of 15 articles met the inclusion and exclusion criteria, including four comparative studies (level III evidence), two case series (level IV evidence), and nine in vitro biomechanics studies (level V evidence). Two of the nonrandomized studies compared interspinous fixation devices (IFDs) to pedicle screws

in patients undergoing interbody fusion and two included IFD alone or pedicle screws plus an IFD in patients undergoing interbody fusion. Use of an IFD decreased surgical time and blood loss compared to pedicle screws. No study showed that IFDs reduced the length of stay compared to pedicle screw implantation. The authors stated no class I or II evidence was available, the studies had methodological limitations, and data was inadequate to determine safety and efficacy. Randomized clinical trials (RCTs) are needed to examine the impact of IFDs on health outcomes.

Randomized Clinical Trials

Subsequent to the systematic review by Lopez (2017), two small RCTs (total N=149) were published in individuals with single level lumbar degenerative diseases undergoing spinal fusion who received an interspinous fixation device (IFD) with interbody fusion as an alternative to pedicle screw and rod constructs. The first RCT was a single-center study by Huang (2017) that randomized 46 individuals to either an IFD or pedicle screws and followed them for 24 months.^[3] The second was a multicenter study by Panchal (2018) that randomized 103 individuals to either the Aspen MIS Fusion System or pedicle screws and followed them for 12 months.^[4] Compared to the pedicle screw control groups, similar or better fusion, disability, and quality of life outcomes were observed for the IFD groups. Comparative complications rates were mixed across studies, but comparative treatment effects were not calculated. In the study by Panchal (2018), revisions were numerically lower in the IFD group, but comparative treatment effects were not calculated. Interpretation of these findings is limited by important weaknesses, however. In the RCT by Panchal (2018), weaknesses included insufficient follow-up duration, lack of control for selection bias, and data incompleteness. In the RCT by Huang (2017), weaknesses 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.

Nonrandomized Studies

A retrospective review of 109 patients with adjacent segment disease (ASD) treated with an IFD (n = 48) or extended pedicle screw fixation (PSF, n = 61) was published by Bae (2020).^[5] Clinical outcomes (a visual analog scale [VAS] and the Oswestry disability index [ODI]) and radiographic outcomes (fusion rate, incidence of cage subsidence, and additional radiographic ASD) were assessed. The mean incision length, operative time, blood loss, and length of hospital stay were significantly lower in the IFD group ($p < 0.001$). Postoperative back and leg pain and mean preoperative VAS scores were improved in both groups. At 36 months postoperative, 10 of the 56 patients (17.9%) in the PSF group had developed additional radiographic ASD compared with 2 of 44 patients (4.5%) in the IFD group, however this difference was not statistically significant. Results from retrospective chart review cannot address possible confounding effects resulting from lack of blinding and randomization; additional data from RCTs are needed.

A retrospective analysis of 83 patients with lumbar stenosis and grade 1 stable spondylolisthesis who underwent either single-level laminectomy alone (n=37) or primary single-level decompression and implantation of the Coflex Interlaminar Stabilization® device (CID, n=46) was published by Zhong (2020).^[6] CID patients 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, $p=0.001$) than the group receiving laminectomy alone. Total perioperative complications (21.7% vs

5.4%, $p=0.035$) and instrumentation related complication (10.9% vs 0%, $p=0.039$) was higher in CID than in the laminectomy group. Similar overall revision and neurologic complication rates were noted compared to laminectomy at last follow up. These outcomes may be impacted by significant group differences at baseline; the CID cohort was older (CID 69.0 ± 9.4 vs laminectomy 64.2 ± 11.0 , $p=0.042$) and had higher American Society of Anesthesiologists (ASA) grade (CID 2.59 ± 0.73 vs laminectomy 2.17 ± 0.48 , $p=0.020$) than the laminectomy group.

Included in the systematic review from Lopez (2017) above was a nonrandomized retrospective study by Kim (2012) that compared the SPIRE® IFD to pedicle screw implantation in patients who underwent posterior lumbar interbody fusion (PLIF).^[7] Forty patients underwent IFD with PLIF and 36 underwent pedicle screw fixation with PLIF during the same time period. The two groups were comparable at baseline, but the treatment selection criteria were not described. At a minimum one-year follow-up, scores on the visual analog scale (VAS) for pain and on the Korean version of the Oswestry Disability Index improved to a similar extent in the two groups. For example, VAS scores in the IFD group improved from 7.16 to 1.3 while VAS scores in the pedicle screw group improved from 8.03 to 1.2. Range of motion at the adjacent segment was increased in the pedicle screw group but not in the IFD group, and adjacent segment degeneration was more prevalent in the pedicle screw group (36.1%) than in the IFD group (12.5%, $p=0.029$). Other adverse events, such as deep infection and cerebrospinal fluid leakage, were higher in the pedicle screw group. The authors concluded a RCT with long-term follow-up is needed to confirm how the SPIRE® IFD impacts health outcomes.

Other clinical evidence is limited to retrospective chart reviews,^[8-10] nonrandomized case series^[11-13], and ex vivo biomechanical studies on cadaver spines. Conclusions from cadaver studies cannot be used to determine the outcomes of device implantation in living human subjects.

Summary

Current studies are insufficient to reach conclusions about the safety and effectiveness of these devices due to significant methodological limitations such as small sample size, lack of a control group, short-term follow-up periods, and lack of randomized treatment allocation.

PRACTICE GUIDELINE SUMMARY

NORTH AMERICAN SPINE SOCIETY

In 2019, the North American Spine Society (NASS) issued a coverage position on the use of interspinous devices with lumbar fusion.^[14] The 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 extraspinous process decortication and fusion, and/or an interbody fusion of the same motion segment. The 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."

The NASS clinical practice guidelines for the diagnosis and treatment of lumbar disc herniation with radiculopathy^[15] and degenerative lumbar spinal stenosis^[16] do not address interspinous process fixation devices.

SUMMARY

There is not enough research to show that interspinous process fixation devices used alone or in combination with conventional spinal fusion devices improve health outcomes for any indication. No clinical guidelines based on research recommend interspinous process fixation devices. Therefore, interspinous process fixation devices used alone or in combination with conventional spinal fusion devices are considered investigational for all indications.

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CODES

NOTE: There are no specific codes for spinal instrumentation using the spinous process fixation orthoses. The appropriate code for reporting this procedure is 22899.

Codes	Number	Description
CPT	22899	Unlisted procedure, spine
HCPCS	None	

Date of Origin: May 2010