

Interspinous Fixation (Fusion) Devices

Effective: March 1, 2019

Next Review: December 2019

Last Review: February 2019

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

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?
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
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

Lopez (2017) published a systematic review (SR) evaluating the literature on lumbar spinous process fixation and fusion devices.^[1] They 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

No RCTs were identified.

Nonrandomized Studies

Included in the SR 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).^[2] 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 trial evidence for stand-alone procedures is limited to two retrospective chart reviews [3,4] ($n=34$ and $n=86$), nonrandomized case series [5-7], 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 (NASS)

The NASS clinical practice guidelines for the diagnosis and treatment of lumbar disc herniation with radiculopathy^[8] and degenerative lumbar spinal stenosis^[9] do not address interspinous process fixation devices.

The NASS published a coverage position statement stating that the use of interspinous fixation with fusion is currently not indicated as an alternative to pedicle screw fixation with lumbar fusion procedures.^[10] This recommendation is based on a determination that the current evidence “is limited, low-level evidence” and a lack of prospective, randomized, controlled trials with sufficient follow-up comparing the efficacy and safety of these devices with pedicle screws, the current gold standard for spinal fusion.

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.

REFERENCES

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5. Kim, DH, Shanti, N, Tantorski, ME, et al. Association between degenerative spondylolisthesis and spinous process fracture after interspinous process spacer surgery. *Spine J*. 2012;12:466-72. PMID: 22622239
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10. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. [cited 12/6/2017]; Available from: <http://www.spine.org/Documents/PolicyPractice/CoverageRecommendations/InterspinousFixationWithFusion.pdf>
11. BlueCross BlueShield Association Medical Policy Reference Manual "Interspinous Fixation (Fusion) Devices." Policy No. 7.01.138

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