

## Medical Policy Manual

**Topic:** Dynamic Stabilization of the Spine

**Date of Origin:** October 2005

**Section:** Surgery

**Last Reviewed Date:** May 2014

**Policy No:** 143

**Effective Date:** August 1, 2014

### 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

Dynamic stabilization, also known as soft stabilization or flexible stabilization, has been proposed as an adjunct or alternative to spinal fusion for the treatment of severe refractory pain due to degenerative spondylolisthesis, or continued severe refractory back pain following prior fusion, sometimes referred to as failed back surgery syndrome. Dynamic stabilization uses flexible materials rather than rigid devices to stabilize the affected spinal segment(s). These flexible materials may be anchored to the vertebrae by synthetic cords or by pedicle screws. Unlike the rigid fixation of spinal fusion, dynamic stabilization is intended to preserve the mobility of the spinal segment.

### Regulatory Status

- No dynamic stabilization devices have received approval from the U.S. Food and Drug Administration (FDA) for use other than as an adjunct to spinal fusion. The FDA has specified that separate approval is required for “off-label” marketing of these devices, including but not limited to use as a stand-alone device for spinal stabilization in the absence of fusion.
- The following dynamic stabilization devices have received clearance from the FDA *for use in spinal fusion* of the thoracic, lumbar and/or sacral spine for degenerative spondylolisthesis with neurologic impairment, and for failed previous fusion (pseudoarthrosis):

Device Name	Manufacturer
AccuFlex™ System (K0520690)	Globus Medical
BioFlex System with Nitinol spring rod and memory loops (Bio-Spine) (K072321)	Bio-Spine
CD Horizon Agile™ Dynamic Stabilization device (K060615)	Medtronic Sofamor Danek, Inc
Cosmic™ Posterior Dynamic System (K080841)	Ulrich GmbH & Co.
DSS (Dynamic Soft Stabilization) system (K090099)	Paradigm Spine
Dynabolt™ Dynamic Stabilization System (formerly Modified VertiFlex® Spinal Screw System) (K073143)	VertiFlex, Inc
Dynesys® and DTO (Dynesys-to-Optima) (K031511)	Zimmer Spine, Inc
Isobar® (K991326)	Scient'x
NFix™ II Dynamic Stabilization System (K053623)	N Spine, Inc.
REVERE™ Stabilization System (K061202)	Globus Medical
Satellite™ Spinal System (K051320)	Medtronic Sofamor Danek, Inc.
TRANSITION® Stabilization System (K073439)	Globus Medical
Viper™ (K061520) and Expedium™ (K041801)	Depuy Spine
Zodiak® DynaMo™ System (K072081)	Alphatec

When used as a pedicle screw fixation system, these devices are indicated for use in patients who are receiving fusion with autogenous graft only, and who are having the device removed after development of a solid fusion mass.

- The following dynamic stabilization devices have **not** received FDA clearance:
  - Bronsard's Ligament
  - FASS (Fulcrum Assisted Soft Stabilization) (AO International)
  - Graf ligament (SEM Co)
  - Leeds-Keio Ligamentoplasty (Neoligament LTD)
  - LemiFlex Spinal Stabilization System (Simpirica Spine)
  - NFlex™ Controlled Motion System (indicated for non-fusion only) (N Spine, Inc.)
  - Stabilimax NZ® Dynamic Spine Stabilization System (Applied Spine Technologies Inc.)

**Note:** This policy considers only dynamic stabilization devices across pedicle screws. See Cross References section below for separate policies on other surgical spinal stabilization and fusion techniques.

## **MEDICAL POLICY CRITERIA**

Use of any spinal dynamic stabilization device is considered **investigational** for the treatment of disorders of the spine at any level.

## **SCIENTIFIC EVIDENCE**

The primary beneficial outcomes of interest for treatment of spinal pain are relief of pain and improved function. Both of these outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, evaluating the safety and effectiveness of dynamic stabilization alone or as an adjunct to spinal fusion requires data from randomized controlled trials (RCTs) comparing dynamic stabilization with spinal fusion using conventional devices (e.g., rigid rods, cages). These comparisons are necessary to determine whether any benefits of dynamic stabilization outweigh any risks and whether they offer advantages over conventional spinal fusion techniques with respect to the following:

- Pain and functioning
- Durability of treatment effects
- Adverse effects (e.g., vertebral fracture)
- Device failure/replacement and reoperation rates
- Impact on future surgical options in the same or adjacent spinal levels.

Randomized controlled trials (RCTs) for dynamic stabilization should also include the following:

- Blinding of study participants, caregivers, and investigators to the treatment assignments to help control for bias for or against the treatment
- Large study populations in order to rule out the role of chance as an explanation of study findings
- Sufficient long-term follow-up to determine the durability of any treatment effects of dynamic stabilization compared with conventional fusion

In a 2004 review article, Sengupta identified the pertinent questions in dynamic stabilization as: (a) how much control of motion is desirable, and (b) how much load should be shared by the system to unload the damaged disc.<sup>[1]</sup> The author concluded that, while dynamic stabilization procedures may prove to have a promising role in preventing the adjacent segment disease inherent with fusion, randomized controlled trials are essential to prove safety, efficacy and appropriateness of these procedures. Schwarzenbach and colleagues reached the same conclusion in their review article.<sup>[2]</sup>

## **Literature Appraisal**

The published clinical trial data currently available consists of a single RCT and small, short-term non-randomized case series and retrospective reviews. The following literature review is limited to those studies with an appropriate spinal fusion control group.

## Randomized Controlled Trials (RCTs)

Korovessis and colleagues reported on a study of 45 adults randomized into three groups.<sup>[3]</sup> All patients had decompression and fusion with instrumentation as follows: Group A had rigid instrumentation, Group B had semi-rigid instrumentation, and Group C had dynamic instrumentation. Follow-up was between 33 and 61 months. All fusions in all three groups healed without pseudoarthrosis or malunion within six months after surgery. Hardware failures were seen only in the dynamic instrumentation group and included one asymptomatic and one symptomatic pedicle screw breakage and one symptomatic rod breakage. Donor site pain for six to twelve months postoperatively was reported only in the rigid and semirigid instrumentation groups. There was no degeneration at the adjacent vertebral segments above or below the instrumentation level in any group. Due to the small number of patients and the need for longer follow-up, the authors made no recommendation in favor of any of the devices used in this study.

## Comparative Nonrandomized Trials

Three case series compared the efficacy and adverse effects of conventional spinal fusion with either dynamic stabilization as an adjunct to fusion or dynamic stabilization alone.<sup>[4-7]</sup> Two other case series also studied adjacent level disc degeneration.<sup>[8,9]</sup> However, it is not possible to reach conclusions from these studies due to methodological limitations, including non-randomization and selection bias, investigator conflict of interest, under-reporting of adverse events which could have been related to the device, lack of a control group, lack of long-term outcomes, and notable differences in outcomes between study centers.

## **Adverse Effects**

The most commonly reported symptomatic adverse effects of dynamic stabilization were device breakage and screw loosening.<sup>[6,10-14]</sup> Other reported adverse effects included the following:<sup>[6,15-19]</sup>

- Cerebrospinal fluid pseudocele
- Bleeding
- Impaired wound healing
- Instability with stenosis in adjacent segment
- Persistent pain, stenosis and/or disk protrusion in index segment
- Osteoporotic fracture of adjacent vertebra
- Pedicle perforation
- Screw malposition requiring surgical correction
- Compensatory increase in lordosis in superior adjacent segment
- Symptomatic malalignment (e.g., insufficient lumbar lordosis)

## **Clinical Practice Guidelines and Position Statements**

No clinical practice guidelines or position statements from U.S. professional associations were found that recommend dynamic stabilization of the spine.

## **Summary**

Due to the lack of data from well-designed, long-term, randomized controlled clinical trials, current evidence is insufficient to permit conclusions about whether any beneficial effect from dynamic

stabilization provides a significant advantage over conventional fusion techniques. In addition, the complication rates and reoperation rates for dynamic stabilization compared with conventional fusion are unknown. Therefore, use of these devices by any technique at any spinal level is considered investigational.

## REFERENCES

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## CROSS REFERENCES

[Interspinous and Interlaminar Stabilization/Distrraction Devices \(Spacers\)](#); Surgery Policy No. 155

[Total Facet Arthroplasty](#), Surgery, Policy No. 171

[Interspinous Fixation \(Fusion\) Devices](#), Surgery, Policy No. 172

[Lumbar Spinal Fusion](#), Surgery, Policy No. 187

CODES	NUMBER	DESCRIPTION
CPT	22899	Unlisted procedure, spine
	64999	Unlisted procedure, nervous system
HCPCS	None	