Anthem

Medical Policy

Subject: Intervertebral Stabilization Devices
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Description/Scope

This document addresses the use of flexible intervertebral stabilization devices as an adjunct to spinal fusion procedures to provide immobilization and stabilization of spinal segments. Such devices are designed to allow some degree of spinal flexibility following spinal fusion surgery.

Note: This document does NOT address the use of rigid spinal fixation devices or instrumentation.

Note: Please see the following for additional information regarding devices used for spinal surgery:

- SURG.00092 Implanted Devices for Spinal Stenosis
- SURG.00134 Interspinous Process Fixation Devices

Position Statement

Investigational and Not Medically Necessary:

Use of intervertebral stabilization devices is considered **investigational and not medically necessary** for all indications.

Rationale

Isobar™ Spinal System
Fu and colleagues (2014) conducted a study to evaluate the functional and radiological outcomes of dynamic stabilization in conjunction with spinal fusion. Prospective follow-up was conducted for 24 months on 36 participants who underwent posterior Isobar dynamic stabilization for single-level degenerative lumbar disc disease with instability (DLDI) and mild adjacent level degeneration. The authors assessed participant status with the collection of functional [visual analog scale (VAS) and Oswestry Disability Index (ODI)] and radiological data (resting, functional X-rays and MRI). At 24 months, functional outcomes demonstrated significant improvement in mean visual analog scale (VAS) score by 38.9 points ($p<0.01$) and ODI by 22.4 points ($p<0.01$). The disc height at the index and adjacent levels and intervertebral angle (IVA) at the index level showed a slight decreasing trend at each follow-up ($p>0.05$), while IVA at the adjacent level showed a slight increasing trend ($p>0.05$). Range of motion at the index level averaged 2.84° and remained unchanged at the adjacent level ($p>0.05$). With regard to adverse events, there were no reoperations, loosening of screws or infection reported. Two participants experienced a dural tear during the surgery and were given immediate repair. The authors concluded that individuals with single-level DLDI and mild adjacent level degeneration treated with Isobar semi-rigid stabilization demonstrated a significant improvement in functional scores 2 years postoperatively. However, disc degeneration at the adjacent and index levels appears to continue despite using semi-rigid dynamic stabilization. The authors stated that additional long-term follow-up is ongoing to provide more extensive information.

Guan and colleagues (2022) reported the results of a meta-analysis that combined data from randomized controlled trials and cohort studies of isobar nonfusion and PLIF for treatment of lumbar degenerative diseases. The analysis included 7 RCTs with 394 participants. The results demonstrated that isobar nonfusion surgery reduced the surgical duration ($P=0.03$), decreased intraoperative bleeding ($P=0.001$), retained the range of motion (ROM) of surgical segment ($P<0.00001$) and the ROM of the lumbar spine ($P<0.00001$), and decreased the incidence of adjacent segment disease (ASD) ($P=0.0001$). However, the study did not demonstrate any significant difference in the postoperative ODI index ($P=0.81$), VAS score of low back pain ($P=0.59$), VAS score of lower limb pain ($P=0.05$), or Japanese Orthopaedic Association (JOA) score ($P=0.27$). The study had several limitations, including its small size, short follow-up time (maximum of two years), and lack of subgroup analysis. Randomized controlled trials that span more than 2 years are still lacking.

Dynesys® Spinal System
Zhou and colleagues reported the results of a meta-analysis that examined the medium and long-term clinical and radiographic outcomes of the Dynesys stabilization system vs instrumented fusion in participants with degenerative lumbar spinal disease with or without grade I spondylolisthesis. A total of 17 studies (one RCT, 16 comparative cohort studies) and 1296 participants were included in the meta-analysis. Participants were followed for a minimum of 2 years. Clinical outcomes were measured in terms of VAS and Owestry Disability Index (ODI) scores, screw loosening and breakage, and surgical revision. Radiographic outcomes were evaluated in terms of postoperative range of movement (ROM) and disc height. Additionally, adjacent segment degeneration (ASDeg) and adjacent segment disease (ASDis) were evaluated. A total of four prospective studies provided data on post-operative back pain and leg pain scores between the Dynesys and fusion groups. The combined results revealed that the postoperative VAS scores for low back pain in the Dynesys group were better than those in the fusion group. The pooled data of seven studies indicated that the Dynesys group was associated with a significantly lower rate of surgical revision than the fusion group. The pooled data of eight studies indicated that the Dynesys group showed less ASDeg than the fusion group. The pooled data of five studies revealed that the ROM at the stabilized segment in the fusion group decreased significantly more than that in the Dynesys group. Data also demonstrated that post-operative ROM in the fusion group at proximal adjacent segment increased significantly more that in the Dynesys group. Pooled data indicated that there was not a significant difference from the fusion and Dynesys group in terms of ASDis, postoperative ODI scores, screw breakage and loosening and disc height at the surgical segment. The strength of this meta-analysis is limited by it's inclusion of only one RCT, heterogeneity of measured outcomes, and relatively short follow-up times. The authors noted that screw loosening after fusion procedures is likely to occur earlier than failure of dynamic stabilization and recommend further study with follow-up longer than 10 years.

A meta-analysis of studies on the efficacy of the Dynesys system was published by Lee and colleagues in 2016. To be eligible for inclusion in the review, studies needed to compare clinical and radiological outcomes between individuals who underwent surgery with Dynesys versus posterior lumbar interbody fusion (PLIF) for degenerative spinal disease. A total of seven studies with 506 participants met the eligibility criteria. Of these, one was a randomized controlled trial (RCT), two were prospective cohort studies and four were retrospective cohort studies. None of the studies was conducted in the U.S. and four were conducted in China. Clinical and

radiological outcomes, including the ODI and pain measured by a visual analogue scale (VAS), were assessed at baseline and at approximately 2 years. Pooled analyses did not find significant differences between the two surgical methods in change in the Owestry Disability Index (ODI) or in back or leg pain VAS scores. Rates of complications and length of hospital stay were similar in the two groups.

Several additional retrospective comparative observational studies have been published. In 2017, Wu and colleagues reported on outcomes after Dynesys stabilization (n=26) and PLIF (n=31) in individuals with lumbar degenerative disease. After a mean follow-up of 50 months (range, 46 to 65 months), there were no statistically significant differences between groups in ODI or VAS scores. Hu and colleagues (2019) published a retrospective study in individuals with multi-segmental lumbar spinal stenosis, 22 of whom were treated with Dynesys stabilization and 44 of whom had PLIF. After a minimum of 5 years of follow-up, there were no statistically significant differences in clinical outcomes (i.e.; pain and function) in the two groups.

In addition to the controlled studies, a number of case series have been published (Grob, 2005; Putzier, 2005; Schaeren 2008; Schnake 2006; Würgler-Hauri, 2008; Zhang, 2018). A study by Welch and colleagues (2007) was conducted in the U.S. as part of a multicenter prospective U.S. Food and Drug Administration (FDA) investigational device exemption (IDE) clinical trial. The study included 101 participants from six IDE sites who underwent dynamic stabilization with the Dynesys system. To be eligible, participants were required to have degenerative spondylolisthesis or retrolisthesis (Grade I), central or lateral spinal stenosis, and their physician's determination that the participant required decompression and instrumented fusion for one or two contiguous spinal levels between L-1 and S-1. The authors reported significant improvement in mean pain and function scores from the baseline to 12-month follow-up evaluation. In addition to lack of a control group, this study had only 12 months of follow-up which is inadequate to judge safety and long-term durable outcome of the Dynesys system.

Pham and colleagues (2016) conducted a systematic review of the literature that focused on complications associated with the Dynesys stabilization system. The researchers evaluated 21 studies which included a total of 1166 participants with a mean age of 55.5 years and a mean follow-up period of 33.7 months. The data demonstrated a surgical-site infection rate of 4.3%, a pedicle screw loosening rate of 11.7%, a pedicle screw fracture rate of 1.6%, and an adjacent-segment disease (ASD) rate of 7.0%. Of studies reporting surgical revision rates, 11.3% of participants required reoperation. Of participants who developed ASD, 40.6% required a reoperation for treatment. The authors concluded that the Dynesys stabilization system has a similar complication rate compared with lumbar fusion studies and has a slightly lower incidence of ASD.

Although the Dynesys system has been in clinical use for several years, there has been only one RCT published and only a few prospective comparative studies. The available comparative studies, including the RCT, did not find that pain and function improved significantly more after undergoing Dynesys compared with PLIF. A meta-analysis of seven comparative studies also did not find a significant difference between groups in length of hospital stay or the complication rate. Thus there is insufficient published evidence that the use of this device results in improved health outcomes compared to standard treatments.

DSS™ Stabilization System
In 2018, Bieri and colleagues published an analysis of data on the Spine Tango Registry, an international registry that captures data on surgical treatment of spinal disorders. The investigators identified 202 individuals who used the DSS stabilization system and 269 individuals who underwent PLIF. Propensity-score matching was undertaken to balance groups in analysis for various patient characteristics. Matching was possible for 77 DSS-PLIF pairs. At a mean follow-up of 3 years, there was not a statistically significant difference in the mean Core Outcomes Measure Index (COMI) score improvement (3.4 points in the DSS group and 3.2 points in the PLIF group), p=0.69. Matched pairs were also similar in terms of back and leg pain relief, blood loss during surgery and complication rates. However, there were significantly fewer repeat surgeries after DSS (0.8 per 100 observed person-years) than with PLIF (2.9 per 100 observed person-years). The authors noted that there are no published prospective comparative studies evaluating the DSS stabilization system.

Regulatory Information
Several dynamic stabilization devices that have received United States (U.S.) Food and Drug Administration (FDA) 510(k) clearance, including the Isobar Spinal System (Alphatec Spine, Inc. Carlsbad, CA), the Dynesys® System (Zimmer Inc., Minneapolis MN), the BioFlex® (BioSpine Co., Ltd, Sungdong-gu, Seoul Korea) and the DSS™ Stabilization System (Paradigm Spine, LLC, New York, NY). The 510(k) review process does not involve or require extensive review of clinical trial data demonstrating the safety and efficacy of the device under review. In order to qualify for a 510(k) clearance, a manufacturer need only prove that their device is similar in function to a predicate device previously cleared or approved by the FDA. Thus, many devices cleared under this process have not yet been proven to be safe and effective based on the merits of data prospectively collected from clinical trials of the devices in question.

Background/Overview

Spondylolisthesis is a condition in which a back bone (vertebra) slips forward on the vertebra below it. In adults, the most common cause is degenerative arthritis involving the fourth and fifth lumbar vertebrae. Other causes of spondylolisthesis include, but are not limited to, spinal fracture, and bone disease. Symptoms may include lower back pain and pain in the thighs and buttocks, stiffness, muscle tightness, and spinal tenderness. Neurologic damage (leg weakness or sensory changes) may result from pressure on nerve roots and may cause pain radiating down the legs.

Treatment varies depending on the severity of the spondylolisthesis. Most individuals require only strengthening and stretching exercises combined with activity modification (avoiding hyperextension of the back and contact sports). Some practitioners may also use a rigid brace.

For cases with severe pain not responding to therapy, if the slip is severe, or there are neurologic changes (loss of feeling in the legs, etc.), the slipping vertebra might be surgically fused to adjacent vertebrae to prevent further slippage and provide relief of symptoms.

Fusion procedures involve placement of a bone graft or equivalent substance into the joint space after removal of the intervertebral disc as well as attachment of a rigid metal frame to adjacent vertebral bodies. The frame is used to hold the joint in place while the joint space fuses over time. As a result of fusion surgery, there is a subsequent loss of mobility where the intervertebral joint once was. This loss of mobility has been associated with increased loading on adjacent joints and potential complications related to failure of those joints.

In an attempt to overcome the disadvantages of rigid instrumentation and improve the outcome of spinal fusion surgery, dynamic stabilization devices have been proposed as an alternative to the use of standard rigid frames. Like standard frame devices, these devices are fixed in place using pedicle screws which are attached to the vertebral bodies adjacent to the intervertebral space being fused. Unlike standard frames, these devices are designed using flexible materials which purport to stabilize the joint while still providing some measure of flexibility.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

22899	Unlisted procedure, spine [when specified as insertion of a dynamic intervertebral pedicle-based stabilization device]

ICD-10 Procedure

0RH00CZ-0RH04CZ	Insertion of pedicle-based spinal stabilization device into occipital-cervical joint [by approach; includes codes 0RH00CZ, 0RH03CZ, 0RH04CZ]
0RH10CZ-0RH14CZ	Insertion of pedicle-based spinal stabilization device into cervical vertebral joint [by approach; includes codes 0RH10CZ, 0RH13CZ, 0RH14CZ]
0RH40CZ-0RH44CZ	Insertion of pedicle-based spinal stabilization device into cervicothoracic vertebral joint [by approach; includes codes 0RH40CZ, 0RH43CZ, 0RH44CZ]
0RH60CZ-0RH64CZ	Insertion of pedicle-based spinal stabilization device into thoracic vertebral joint [by approach; includes codes 0RH60CZ, 0RH63CZ, 0RH64CZ]
0RHA0CZ-0RHA4CZ	Insertion of pedicle-based spinal stabilization device into thoracolumbar vertebral joint [by approach; includes codes 0RHA0CZ, 0RHA3CZ, 0RHA4CZ]
0SH00CZ-0SH04CZ	Insertion of pedicle-based spinal stabilization device into lumbar vertebral joint [by approach; includes codes 0SH00CZ, 0SH03CZ, 0SH04CZ]
0SH30CZ-0SH34CZ	Insertion of pedicle-based spinal stabilization device into lumbosacral joint [by approach; includes codes 0SH30CZ, 0SH33CZ, 0SH34CZ]

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. Bieri KS, Goodwin K, Aghayev E et al Dynamic posterior stabilization versus posterior lumbar intervertebral fusion: A matched cohort study based on the Spine Tango Registry. 2018; J Neurol Surg; 79:224-230.
2. Fu L, France A, Xie Y, et al. Functional and radiological outcomes of semi-rigid dynamic lumbar stabilization adjacent to single-level fusion after 2 years. Arch Orthop Trauma Surg. 2014; 134(5):605-610.
3. Grob D, Benini A, Junge A, Mannion AF. Clinical experience with the Dynesys semirigid fixation system for the lumbar spine: surgical and patient-oriented outcome in 50 cases after an average of 2 years. Spine. 2005; 30(3):324-331.
4. Guan J, Liu T, Li W, et al. Effects of posterior lumbar nonfusion surgery with isobar devices versus posterior lumbar interbody fusion surgery on clinical and radiological features in patients with lumbar degenerative diseases: a meta-analysis. J Orthop Surg Res. 2022; 17(1):116.
5. Hu A, Sun C, Liang Y et al. Multi-segmental lumbar spinal stenosis treated with Dynesys stabilization versus lumbar fusion in elderly patients: a retrospective study with a minimum of 5 years' follow-up. Arch Orthop Trauma Surg. 2019; 139(10):1361-1368.
6. Lee C-H, Jahng T-A, Hyan S-J et al. Dynamic stabilization using the Dynesys system versus posterior lumbar interbody fusion for the treatment of degenerative lumbar spinal disease; a clinical and radiological outcomes-based meta-analysis. Neurosurg Focus 2016; 50: 1-9.
7. Maida G, Altruda C, Gatti M, et al. Two-year follow-up after microsurgical discectomy and dynamic percutaneous stabilization in degenerate and herniated lumbar disc: clinical and neuroradiological outcome. J Neurosurg Sci. 2014; 58(2):95-102.
8. Pham M, Mehta V, Patel N, et.al. Complications associated with the Dynesys dynamic stabilization system: a comprehensive review of the literature. Neurosurg Focus. 2016: 40(1):E2.
9. Putzier M, Schneider SV, Funk JF, et al. The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone. Spine. 2005; 30(5):E109-114.
10. Schaeren S, Broger I, Jeanneret B. Minimum four-year follow-up of spinal stenosis with degenerative spondylolisthesis treated with decompression and dynamic stabilization. Spine. 2008; 33(18):E636-642.
11. Schnake KJ, Schaeren S, Jeanneret B. Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis. Spine. 2006; 31(4):442-449.
12. Welch WC, Cheng BC, Awad TE, et al. Clinical outcomes of the Dynesys dynamic neutralization system: 1-year preliminary results. Neurosurg Focus. 2007 15; 22(1):E8.
13. Wu H, Pang Q, Jiang G. Medium-term effects of Dynesys dynamic stabilization versus posterior lumbar interbody fusion for treatment of multisegmental lumbar degenerative disease. J Int Med Res 2017; 45: 1562-1573.
14. Würgler-Hauri CC, Kalbarczyk A, Wiesli M, et al. Dynamic neutralization of the lumbar spine after microsurgical decompression in acquired lumbar spinal stenosis and segmental instability. Spine. 2008; 33(3):E66-72.
15. Zhang Y, Zhang ZC, Li F et al. Long-term outcome of Dynesys dynamic stabilization for lumbar spinal stenosis. Chin Med J (Engl). 2018; 131(21):2537-2543.
16. Zhou LP, Zhang RJ, Wang JQ, et al. Medium and long-term radiographic and clinical outcomes of Dynesys dynamic stabilization versus instrumented fusion for degenerative lumbar spine diseases. BMC Surg. 2023; 23(1):46.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Food and Drug Administration 510(k) Premarket Notification Database. BioFlex System (2008). Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/K072321.pdf. Accessed on January 6, 2024.
2. U.S. Food and Drug Administration 510(k) Premarket Notification Database. DSS Stabilization System (2009). Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf9/K091944.pdf. Accessed on: January 6, 2024.
3. U.S. Food and Drug Administration 510(k) Premarket Notification Database. Dynesys Spinal System (2004). Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/k031511.pdf. Accessed January 6, 2024.
4. U.S. Food and Drug Administration 510(k) Premarket Notification Database. Isobar Spinal System (2008). Available at:

http://www.accessdata.fda.gov/cdrh_docs/pdf7/K071261.pdf. Accessed on January 6, 2024.

Websites for Additional Information

1. National Library of Medicine. Medical Encyclopedia: Spondylolisthesis. Updated 09/20/2022. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/001260.htm. Accessed on January 6, 2024.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, References and Websites for Additional Information sections.
Reviewed	02/16/2023	MPTAC review. Updated Rationale, References and Websites for Additional Information sections.
Reviewed	02/17/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	02/11/2021	MPTAC review. Index, Rationale, and References sections updated.
Reviewed	02/20/2020	MPTAC review. Rationale and References sections updated.
Reviewed	03/21/2019	MPTAC review. Rationale and References sections updated.
Reviewed	05/03/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date”. Rationale and References sections updated.
Reviewed	05/04/2017	MPTAC review. Updated Index, Rationale, References, and Websites sections.
Reviewed	05/05/2016	MPTAC review. Updated Description, Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated Description, Rationale and References sections.
Reviewed	05/15/2014	MPTAC review. No change to the position statement. Updated Description, Rationale, Background/Overview and References sections.
Reviewed	05/09/2013	MPTAC review. Updated references.
Reviewed	05/10/2012	MPTAC review. Rationale and References updated.
Reviewed	05/19/2011	MPTAC review. Stabilmax NZ® Dynamic Spine Stabilization System removed from Rationale due to termination of the IDE trial. References updated.
Reviewed	05/13/2010	MPTAC review. Description, Rationale and References updated.
Revised	05/21/2009	MPTAC review. SATELLITE™ Spinal System information removed. Title and position statement revised. Rationale and references updated.
Reviewed	05/15/2008	MPTAC review. Updated review date, references and history sections.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
	10/01/2007	Updated Coding section with 10/01/2007 ICD-9 changes.
Revised	05/17/2007	MPTAC review. Changed title to “Intervertebral Stabilization Devices (Dynesys® Spinal System, SATELLITE™ Spinal System.)” SATELLITE™ Spinal System added as investigational/not medically necessary.
Reviewed	09/14/2006	MPTAC review. No change to position.
New	09/22/2005	MPTAC initial document development.