Introducing a Non-Fusion Alternative for Lumbar Spinal Stenosis in the ASC

Motion Preserving
Lumbar Stabilization
After Decompression
For Spinal Stenosis

Moderated by: Hallett Mathews, MD, MBA
Presented by: Thomas Scully, MD and Devon Billeter
Spine Conditions that May Require Surgical Intervention

- Trauma
- Degenerated Disc Disease
- Neurogenic Claudication
- Spondylolisthesis
- Lumbar Spinal Stenosis
Lumbar Spinal Stenosis is a Degenerative Process

- Lumbar spinal stenosis usually occurs over time as the spine gets more degenerated.
- The more each spinal segment degenerates, the spine may become more unstable.
- If the spinal segment is not aligned and “slips” forward, it is called a spondylolisthesis.

Normal Alignment

Spondylolisthesis
LSS Non-Surgical Treatment Options

- Rest or restricted activity
- Weight loss
- Medication (non-steroidal anti-inflammatories)
- Chiropractic care
- Massage
- Acupuncture
- Physical therapy & exercise
- Injections
- Patient education
LSS Surgical Treatment Options

• Indirect Decompression (Superion, X-Stop)
• Decompression alone (Kleinstuck, Berven, Asian Spine Journal)
• Decompression + fusion stabilization (Herkowitz)
• Decompression + coflex® Interlaminar Stabilization® (Davis, Musacchio)
coflex® Interlaminar Stabilization®

- Decompression + coflex® Interlaminar Stabilization® for lumbar spinal stenosis
What is **coflex® Interlaminar Stabilization®**?

The **coflex®** device is a non-fusion interlaminar stabilization device that is inserted post direct surgical decompression for patients suffering from lumbar spinal stenosis.

**coflex® Interlaminar Stabilization®**
- Preserves motion
- Addresses leg and back pain
- Maintains foraminal height
- Preserves normal kinematics
- at operative and adjacent levels

**coflex® loads on interlaminar bone**

*NOT* the spinous process

*Claims based on US FDA PMA P110008. October 2012.*

[Link to FDA approval](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm)
The coflex® device offers a new option for treating lumbar spinal stenosis patients who may need more than a decompression alone, but not require the extensiveness of a fusion.
When to Think About Utilizing coflex® as a Treatment Option for Lumbar Spinal Stenosis Patients

1. Preserve Your Decompressions WITHOUT FUSION
   - The coflex® device maintains foraminal height, and is proven sustainable and durable out to 5 years.*
     - Decompression alone could compromise the structural integrity of the segment, and potentially cause iatrogenic instability.
     - The natural progression of the degenerative cascade could cause the segment to restenose, leading to reemergence of LSS symptoms, and further surgery down the line.

2. Address Both LEG AND BACK PAIN With Motion Preservation
   - The coflex® device allows you to achieve the same decompression value as fusion* - achieve a comprehensive decompression to address the leg pain and stabilize with non-fusion to address the back pain.
     - Evidence shows decompression alone does not address back pain¹
     - Patients with mechanical back pain benefit with stabilization¹

3. Keep Stable Spondylolisthesis Patients STABLE
   - The coflex® device is a proven, non-fusion treatment option that fills the gap between decompression alone and decompression with fusion for patients with lumbar spinal stenosis and no instability.
     - Decompression alone in stable spondylolisthesis stenosis patients may advance the slip and lead to instability faster²
     - Those patients with a stable Grade I spondylolisthesis (<3mm translation) don't necessarily require the permanence of a fusion procedure.

* Findings based on US FDA PMA P110008, October 2012. Please see SSED or IFU for indications, contraindications, warnings and precautions.
¹ Kleinmüller et al.: The Influence of Preoperative Back Pain on the Outcome of Lumbar Decompression Surgery. Spine Volume 34, Number 11, pp 1198–1203
INDICATIONS FOR USE

The *coflex®* Interlaminar Technology is an interlaminar stabilization device indicated for use in one or two 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 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

CONTRAINDICATIONS

- 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°)
- 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
Surgical Procedure for Decompression with coflex®
Decompression with coflex® Interlaminar Stabilization® was studied against pedicle screw fusion surgery in a FDA clinical trial for the treatment of lumbar spinal stenosis. The coflex® patients outperformed fusion patients in all clinical measurements!*

Paradigm Spine is committed to research and data. The coflex® device has been studied in over 70 publications. Provide value-based proven disease management of lumbar spinal stenosis.

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm
Evaluation of Decompression and Interlaminar Stabilization Compared with Decompression and Fusion for the Treatment of Lumbar Spinal Stenosis: 5-year Follow-up of a Prospective, Randomized, Controlled Trial

Michael J. Musacchio, MD,1 Carl Laurysen, MD,2 Reginald J. Davis, MD,3 Hyun W. Bae, MD,4 John H. Peloza, MD,5 Richard D. Guyer, MD,6 Jack E. Zigler, MD,6 Donna D. Ohnmeiss, DrMed,7 Scott Leary, MD8

1Department of Neurosurgery, NorthShore University HealthSystem, Evanston, IL, 2 NeuroTexas, Austin, TX, 3Laser Spine Institute, Philadelphia, PA, 4The Spine Institute, Santa Monica, CA, 5Texas Back Institute, Frisco, TX, 6Texas Back Institute, Plano, TX, 7Texas Back Institute Research Foundation, Plano, TX, 8Senta Clinic, San Diego, CA
Achieve a Comprehensive Decompression
Without the Need for Fusion

Decompression with up to 50% bilateral partial medial facetectomies can be performed before insertion of coflex®

coflex® provides similar decompression value compared to fusion through five years

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm
Stabilize Decompressions without Fusion
Preserve the durability of your decompression with the coflex® device

coflex® provides stabilization without fusion

coflex® preserves the durability of your decompression

Foraminal Height Maintenance

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm
Provide Neutral Stabilization Post Decompression

After a microsurgical decompression, coflex® is inserted and bears load on interlaminar ridge.

Preoperative stenotic spine

Postoperative spine with coflex®

coflex® controls patient’s movement in extension
Maintain Structural Integrity and Preserve Kinematics

coflex® maintains motion at operative and adjacent levels

Allows for Flexion

Allows for Extension Through Device Compression

ROM at Operative Level

<table>
<thead>
<tr>
<th>Time</th>
<th>Degree</th>
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<tbody>
<tr>
<td>Pre-op</td>
<td>4</td>
</tr>
<tr>
<td>6W</td>
<td>3</td>
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<tr>
<td>12M</td>
<td>4</td>
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<td>24M</td>
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<td>48M</td>
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<tr>
<td>60M</td>
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ROM at Level Above Operative

<table>
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<th>Time</th>
<th>Degree</th>
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<tbody>
<tr>
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http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm
Off-load Facets and Address Back Pain

coflex® Addresses Facetogenic Issues and Immediately Decreases Back Pain Through 5 Years

Deep interlaminar positioning allows for facet offloading

Facet unloading, adjacent levels unchanged


http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm
Effective, Durable, and Sustainable Treatment

coflex® Maintains Improvement in Pain and Function Measurements Through 5 Years

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm
Thomas Scully, MD FAANS
Northwest NeuroSpecialists
Tucson, Arizona

coflex® in the ASC/Outpatient Setting
**coflex® Surgical Pearls**

- It is first and foremost a decompression, so, **do an adequate decompression!**
- Given the above, **must not be too aggressive** with facet joint removal
- **coflex®** is an interLAMINAR device, not spinous process device: **position it deep, 1-2 mm from the dura**
- Tendency in first few cases is to undersize the device, after gaining confidence, one tends to oversize…..like Goldilocks, **the porridge should be just the right temperature!!**
coflex® Surgical Pearls

- Distract the facet joints 1-2 mm
- Use intra-op x-ray as an adjunct
- Directly visualize the distraction
- Do not position the patient in kyphosis
- Get the spinous processes in parallel fashion
- More “carpentry” work with spinous processes than with other surgeries
- If the coflex® is not fitting well, look for laminar “moguls”
- Soft tissue may hold up the implant as well
coflex® Patient Selection

• Never grade 2 spondy
• Check flexion/extension films pre-op
• Up to 2 contiguous levels
• Failure of conservative treatment
coflex® Patient Expectations

• Encourage patient pre-op that they will be going home day of or next day after surgery

• Remind them it is SURGERY…pain will be there

• Early mobilization is key

• Ice to incision area early and frequently reduces pain

• Despite the muscle and bony work, many coflex® patients have less pain post-op

• Not sure why that is, but, it is advantageous to early discharge
**coflex® Patient Expectations**

- **Toradol intra-op** reduces post-op pain
- **Pre-emptive analgesia** with local **anesthetic and epi** to incision site
- **Post-op urinary retention** may delay discharge
- **+/- use of foley** intra-op to keep bladder decompressed
- Especially true in **elderly males**
Patient

- 64 year-old male (L.M.)
- Was walking 3 miles per day
- Previous L5/S1 Discectomy 20 years ago
- Now has LBP and leg pain
- Failed PT/ESI

Exam

- Lumbar scar
- Good ROM
- Exercises regularly
- Motor 5/5 bilaterally
- Absent right AJ
coflex® Case Examples
Patient

- 71 year-old male (R.C.)
- Plumber
- Has 3 year old son and twins on the way!!!! (should leave the country??)
- Low back and bilateral leg pain

Exam

- Failed PT and ESI
- Ability to do many activities becoming curtailed
- Exam with decreased ROM throughout
- Motor normal
- Reflexes normal
Patient

- 46 year-old female (L.D.)
- Previous synovial cysts with radicular pain
- Secretary to neurosurgeon in town
- Did well from previous surgeries
- Now with back and leg pain
- Very active, exercises, runs
- No longer able to do that

Exam

- Normal motor power
- Decreased range of motion
- Failed PT/ESI
Options for Treatment?

1. Decompression: open vs MIS
2. Decompression with fusion; which levels?
3. Open vs MIS
4. Fusion L3-4, L4-5
5. MIS TLIF, instrumented fusion L3-5, coflex at L2/3
coflex® Case Examples
Devon Billeter

Medical Science Liaison
National Team Leader
Paradigm Spine, LLC
How does the MSL assist with new spine technology and adoption at your facility?

- Evidence-based clinical education
- Patient identification and selection
- Navigating coverage with a dedicated resource

MSLs Help Bridge the Gap for New Treatment Adoption
2017 CMS Rule Change – Patient Needs and Site of Service

- Patients now have more options for a convenient, quality-driven and positive outcome spine procedure, in any site of service

- Disease specific treatment and medical necessity is the key to documentation

- Historically, codes for lumbar spinal stenosis patients consisted of 63047 and 63048 for decompression; 22612 and 22840 for fusion and non-segmental stabilization

- There is a new code for a third treatment option for these patients, which is called interlaminar stabilization

- The coflex device is an interlaminar stabilization device that is applicable to any setting of care
New AMA Coding Clarity for Interlaminar Stabilization

- Favorable Site of Service Payment According to Patient’s Medical Necessity

- CPT Level 1 Physician Payment Coding Implementation in January 2017

- Milliman – 3rd Party Actuarial Analysis
  - coflex® saves 14-27%+ in Per-Member Per-Month (PMPM) costs, when 3% is considered significant
  - Clear ROI analysis for payors & large self-funded employers

- Building Success with Payors
  - Working collaboratively to educate payors
  - Anticipate positive coverage policies with 5 year data

- Long-Term Opportunity to Partner with Payors
New AMA Coding Clarity for Interlaminar Stabilization

Reimbursement Support Center | 1-888-796-8411 | reimbursementps@mcra.com

Current as of January 1, 2017

### Physician Coding

**Insertion of interlaminar / interspinous process stabilization / distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level.**

<table>
<thead>
<tr>
<th>CPT 22867&lt;sup&gt;1&lt;/sup&gt;</th>
<th>$1,025</th>
<th>CPT 22868&lt;sup&gt;1&lt;/sup&gt;</th>
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<tr>
<td><strong>Primary Procedure</strong></td>
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<td><strong>2nd level</strong></td>
<td>2017 Medicare National Average Payment&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
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</table>

Note: Medicare Average Payment Amounts are calculated here as Total Reimbursement Adjusted to the 2017 Final Conversion Factor

<sup>1</sup>CPT 2017 Professional Edition, 2016 American Medical Association (AMA); CPT is a trademark of the AMA


### Hospital Inpatient

**ICD-10-PCS<sup>3</sup> Inpatient Procedure Code Options**

- **OSB00Z**: Excision / Lumbar Vertebral Joint, Open Approach
- **00NY0ZZ**: Release Lumbar Spinal Cord, Open Approach
- **0SH00BZ**: Insertion of Interspinous Process Spinal Stabilization Device into Lumbar Vertebral Joint, Open Approach

**MS-DRG 518<sup>4</sup>**

- **Back and Neck Procedures Except Spinal Fusion with MCC or Disc Device / Neurostimulator**
- **Total Facility Use, Office**, $17,253

2017 Medicare National Average Payment<sup>5</sup>


<sup>5</sup>2017 MS-DRG relative weight multiplied by 2017 rate per IPPS Final Rule; payment rates will vary by facility. Calculation includes labor related, non-labor related and capital payment rates

### Hospital Outpatient

**5116-Level 6 Musculoskeletal Procedures<sup>6</sup>**

- **C-APC 5116<sup>6</sup>**
  - **$14,698**
  - 2017 Medicare National Average Payment<sup>7</sup>

**Ambulatory Surgery Center<sup>8</sup>**

- **C-APC 5116<sup>9</sup>**
  - **$10,542**
  - 2017 Medicare National Average Payment<sup>10</sup>

<sup>6</sup>CMS 1555 RC - Hospital Outpatient Prospective Payment – Final Rule with Comment and Final CY2017 Payment Rates – Addendum C, www.cms.gov


<sup>8</sup>2017 payment rate for Medicare Certified Ambulatory Surgery Centers

<sup>9</sup>CMS 1555 RC – Hospital Outpatient Prospective Payment – Final Rule with Comment and Final CY2017 Payment Rates – Addendum C, www.cms.gov


It is the responsibility of the healthcare provider to determine the best treatment for each patient based on each patient’s condition and diagnosis. The codes denoted within are suggestions only. This information should not be construed as authoritative. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services and items in the medical record. Therefore healthcare providers must use great care and validate billing and coding requirements ascribed by payors with whom they work. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. All values have been rounded to the nearest whole number solely for ease of presentation. All data referenced herein are based on publicly available information.
ISASS Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization - Coverage Indications, Limitations, and/or Medical Necessity

Richard Goyer, MD; Michael Maniscalco, MD; Frank P. Connolly, Jr., MD; Morgan P. Levine, MD, FASCO

Starship Institute, Nixa, TX; Center for Spine Care, Dallas, TX; Hospital for Special Surgery, New York, New York; Lumbar Spine Solutions, Boston, MA

Keywords: decompression, interlaminar stabilization

Volume 34 Article 31, Issue 10, October 2012

Introduction

Broadly defined, lumbar spinal stenosis (LSS) is the progressive narrowing of the spinal canal and neural foramen resulting in pressure upon the nerve(s) leading to pain and/or numbness in the extremities, muscle weakness, bowel and bladder issues, and/or other pain-related issues. However, the difficulty arises in that spinal stenosis is a heterogeneous condition with multiple etiologies which may present with different symptoms. Therefore, there is no single surgical intervention that addresses all pathological variations of spinal stenosis; rather, there are several methods used to treat LSS. Diagnostic evaluation is needed to determine the correct surgical treatment solution to address anatomical and pathological variations as some patients can be treated by simple decompression while others may require a form of stabilization. This policy statement focuses on one treatment option: decompression with interlaminar stabilization. ISASS does not recommend any particular treatment method; the choice of treatment depends on the patient’s pathology and the expertise of the treating surgeon. ISASS recommends shared decision-making between the patient and the surgeon.

Due to a growing elderly population, there is a rising incidence of LSS and varying options of therapeutic pathways. The majority of patients diagnosed with LSS are initially managed conservatively with epidural steroid injections, physical therapy, and modification of activities of daily life. However, several studies have demonstrated that if there is no significant improvement in symptoms after 12 weeks of conservative treatment, generally, symptoms do not improve with time. Patients with a diagnosis of LSS who do not experience leg and/or back pain symptom relief from conservative care management and who experience continued worsening of symptoms may be appropriate candidates for surgical treatment. Surgical treatment options include indirect decompression with interspinous distraction devices, direct surgical decompression, direct surgical decompression with interlaminar stabilization, and direct surgical decompression with fusion.

For mild spinal stenosis (or early-stage disease), an interspinous distraction device without an associated concomitant bony decompression may be considered as an alternative option to a decompression-alone procedure. The X-STOP (Medtronic, Memphis, TN) was approved by the FDA in 2009; however, Medtronic removed the technology from the market in 2015. At present, the only non-fusion interspinous distraction device available in the United States is the Superior (VertFlex, San Clemente, CA). Superior has been CE marked since 2007 and following a clinical study of 470 patients, the FDA approved the device for use on May 20, 2015. The data was sufficient for approval of a Category IICT code effective January 1, 2017. This ISASS policy does not formally address coverage rationale for interspinous distraction devices without decompression pending further data and review of this type of procedural approach in treating LSS.

For patients with mild to moderate stenosis and no instability (absence of spondylolisthesis or presence of a stable spondylolisthesis) direct open or microsurgical decompression of the offending bony and soft tissue pathology is a widely-accepted and com-
Navigating Coverage – There are Services Available!

- Access to coverage team through a reimbursement hotline
- Team specialized in provider and patient access to treatment solutions
- Established processes with national and local payors for ease of submission
- Cognizant of up-to-the-minute payor changes in guidelines
- Pre-authorization services from initial pre-authorization to external appeal
- All levels of pre-authorization denial appeals supported
- Peer-to-peer, 1st appeal, 2nd appeal, IRO or external appeal
Resources Available to You and Your Practice

• Prior-Authorization laminated 1-pager
• Appeals Consideration laminated 1-pager
• Patient Advocacy Guide
• Physician Advocacy Guide
• Physician Advocacy Letter Template Modules
Further Resources

- Surgeon and Allied Health Training Programs
  - Online Portal (Log in anytime)
  - Live Webinar (Individually scheduled)
  - Local Sawbones (Hands-on training)
  - Local Lab (Hands-on training)

- National Education Team

- Product Manager Support Team

- Patient Education Materials

- Events available at [www.paradigmspineeevents.com](http://www.paradigmspineeevents.com)

- Resources available at [www.paradigmspineresources.com](http://www.paradigmspineresources.com)