Introducing New Spine Technology in Any Setting of Care:

Support from The Medical Science Liaison

Our Speakers for Today

Hallett Mathews, MD, MBA
Chief Medical Officer
Paradigm Spine, LLC

Devon Billeter
Medical Science Liaison
Midwest/Central US
Paradigm Spine, LLC

Sponsored By:

PARADIGM SPINE
the movement in spine care

Overview of Presentation

- Introduce the role of a MSL in the medical device industry with new technology
- Better understand the responsibility of MSL integration with interlaminar stabilization post decompression for progressive moderate to severe spinal stenosis
- Discuss and recognize 2017 CMS Payment rule changes for CPT and site of service procedures

What is a Medical Science Liaison (MSL)?

A MSL is a clinically-focused educator who helps all stakeholders in a patient's healthcare cycle understand and navigate new spine technology, disease-state management, patient selection, and advocacy

The Difference Between Sales Personnel and MSLs

SALES PERSONNEL

•Work in the field targeting sales growth and developing market penetration

•Sell product based upon integration of key brand messaging and appropriate use of the product

•Supports distribution teams by coordinating daily activities in the field

MEDICAL SCIENCE LIAISONS

•Work primarily with healthcare providers collaboratively teaching, training, and advocating for what is best for the patient

•Provide fair balanced scientific exchange, medical information, and engage in disease state discussion

•Work in scientific education and clinical research

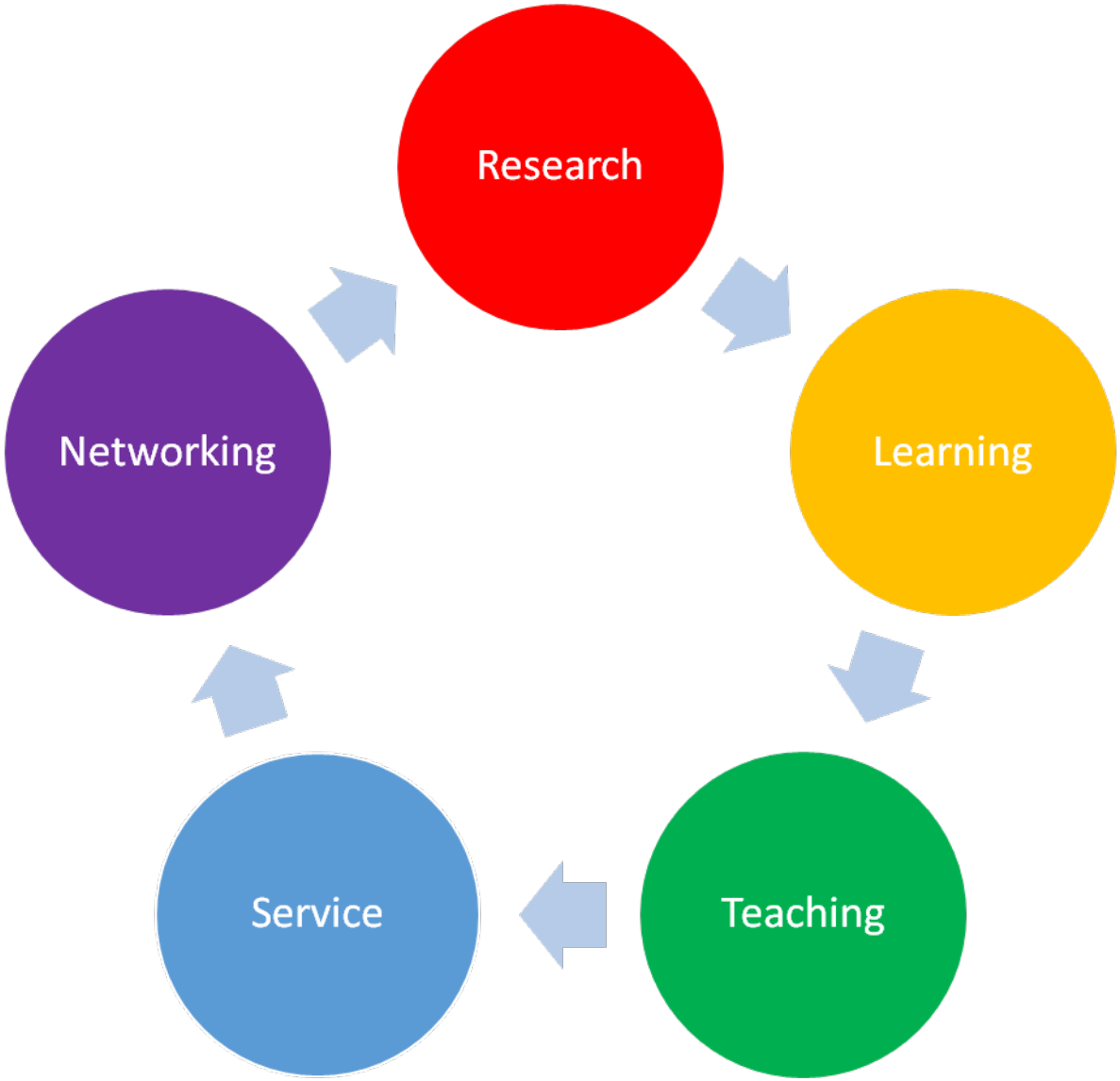
MSLs are Resources to:

- Physician Offices, ASCs, and Hospitals
- Allied Healthcare Providers (RN's, PA's, APRN's, CST's, PT's, RT's)
- Hospital Stakeholders (CEO, COO, CFO, CNO)
- KOL's
- Academic Thought Leaders
- Academic Institutions
- Patient Advocacy Groups and Associations
- Hospital Research Departments
- Patients

Why are MSLs Important?

- MSLs are a resource to practices adopting new technology committed to providing clinically-focused information for the patient, physician, and payor community
- MSLs deliver information on value-based disease management, clinical evidence, peer-reviewed publications, and financial facts about coding and reimbursement that are publically available, for any site of service
- MSLs help educate the front, clinical, and back office on identifying patients for disease-specific treatment that yields excellent patient outcomes
- MSLs ensure that products are utilized effectively and accurately, serving as clinical resources to the entire practice

The 5 Basic Components of the Medical Science Liaison



MSLs are Dedicated to Clinical Research

- Evaluates and understands current literature and treatment guidelines
- Understands the preclinical research concepts and application to the clinical setting
- Discusses unmet needs and/or remaining research questions for spine treatments
- Provides Medical Affairs assistance for clinical research, studies, and trials

MSLs are Dedicated to Learning

- Committed to understanding the current and future state of science and medicine in spinal conditions and treatment
- Dedicated to learning past and evolving technologies that focus on patient care
- Devoted to continuous studying of general medical education for a well-rounded professional background

MSLs are Dedicated to Teaching

- Provide field-based, free from bias medical information regarding various products to managed care customers and allied healthcare professionals
- Provide evidence regarding specific disease-state and therapeutic treatment options
- Provide medical education to all stakeholders within the patient's healthcare cycle

MSLs are Dedicated to Service

- Act as dedicated resource and informational conduit between the academic thought leader and other stakeholders in any setting of care
- Facilitate open communication between healthcare providers and third party groups
- Assists internal departments with educational and advocacy-related endeavors
- Provide literature reviews and educational materials to thought leaders and managed care providers

MSLs are Dedicated to Networking

- Introduces internal partners to external thought leaders for education and research collaboration
- Engages thought leaders to other external customers (patient advocacy groups, physician advocacy, practice advocacy, educational programs, or other academic institutions)
- Provides needs-based, value-added services to improve patient and physician advocacy

How MSLs Become a Resource for Your Entire Practice

- MSLs integrate with ASC or hospital staff (office/practice manager, scheduler, biller, coder, nurse practitioner, etc.) during the initial product introduction
- MSLs onboard the entire office with clinical and product education, providing awareness about available resources, expanding the depth of technology knowledge
- MSLs help identify the right patient indicated for a particular technology
- MSLs assist with practice development and coordinates the navigation process with the Coverage Access Program
- MSLs maintain ongoing engagement with practice; create regularly scheduled visits, troubleshoot issues, and update staff on new information or resources about the product

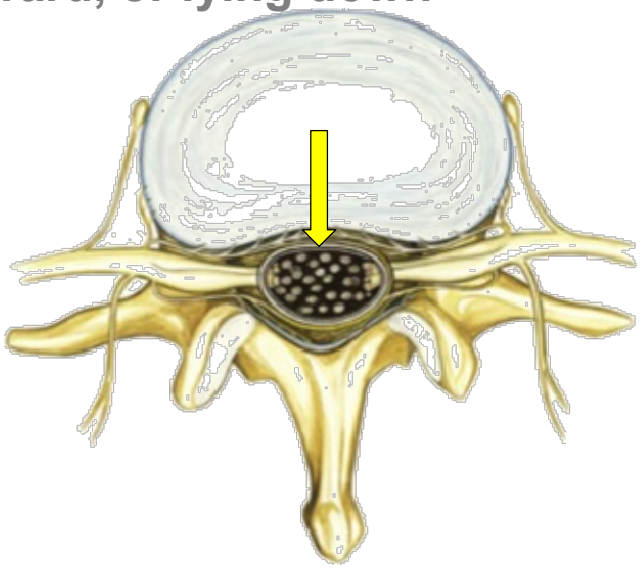
This evidence-based resource will help your entire office get up and running, and help lumbar spinal stenosis patients gain access to new technology.

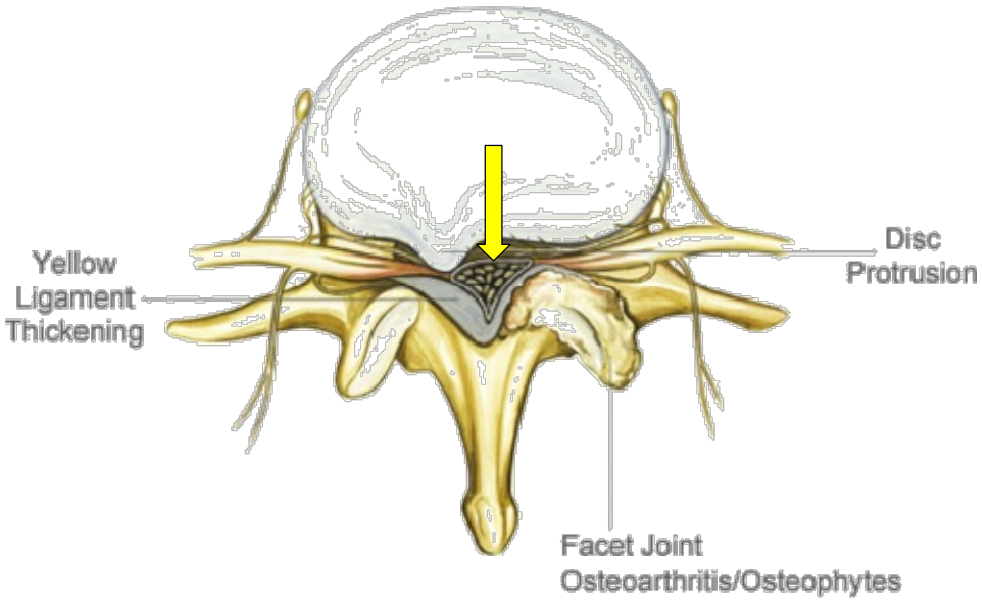
Spine Conditions that May Require Surgical Intervention

- Tumor
- Trauma
- Deformity
- Degenerated Disc Disease
- Neurogenic Claudication
- Spondylolisthesis
- Lumbar Spinal Stenosis

What is Lumbar Spinal Stenosis (LSS)?

- Lumbar spinal stenosis is the narrowing of spaces in the lower area of the spine that results in pressure on the spinal cord and/or nerve roots
- This narrowing can be the result of one or more several causes
- Lumbar spinal stenosis is a common cause of leg and back pain, and symptoms include pain and/or numbness, weakness, tingling in the legs brought on by walking and standing, and is relieved by sitting, leaning forward, or lying down





What are the Symptoms of Lumbar Spinal Stenosis?

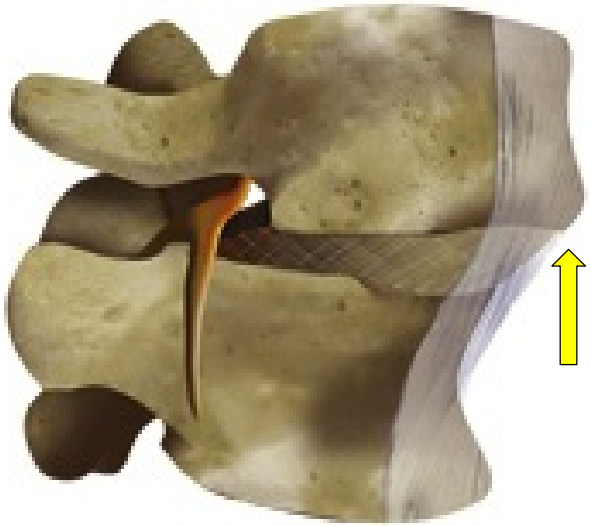
- Pain and/or numbness in the legs brought on by walking and standing, and relieved by leaning forward, sitting or lying down
- The leg pain is frequently associated with lower back pain
- The cardinal symptom of lumbar stenosis is intermittent neurogenic claudication

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



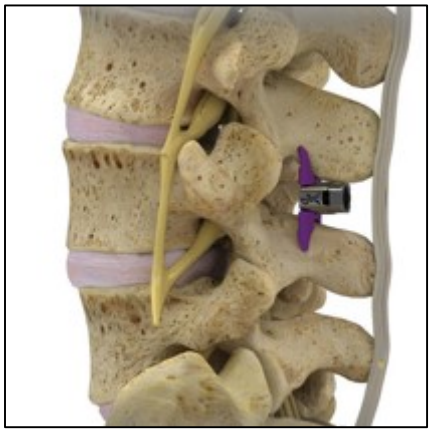
LSS Non-Surgical Treatment Options

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

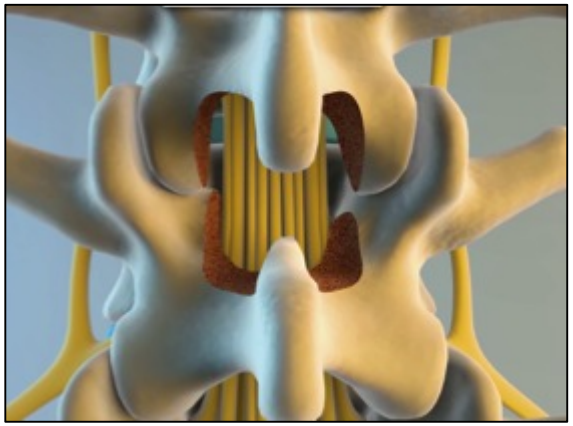
LSS Surgical Treatment Options

- **Indirect Decompression (Superion, X-Stop)**
- **Decompression alone**
- **Decompression + fusion stabilization**
- **Decompression + *coflex*® Interlaminar Stabilization®**

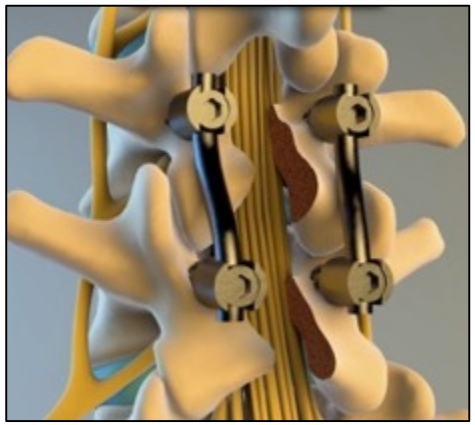
Indirect Decompression with Superion



Decompression Alone



Decompression + fusion stabilization

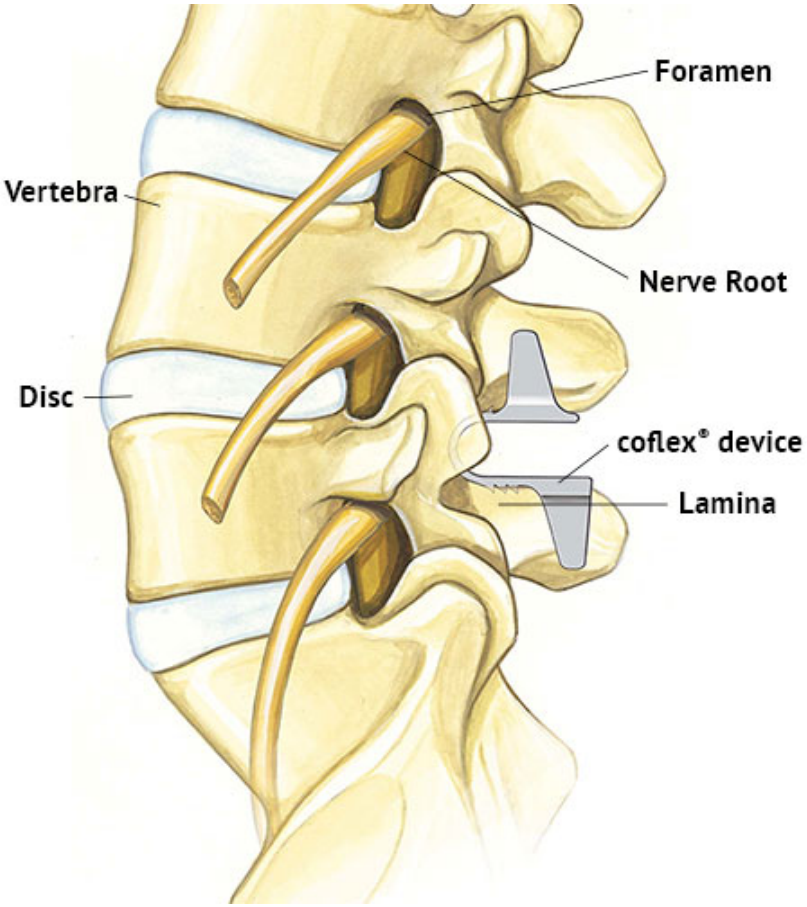


Where does *coflex*® Fit Compared to Other Surgical Treatments for Stenosis?

- 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 and permanence of a fusion

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.

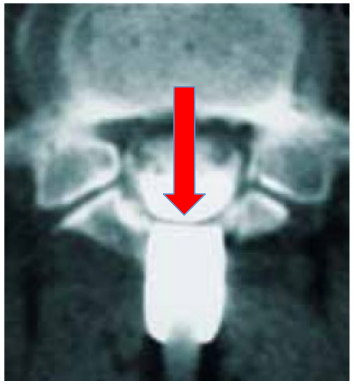
***coflex*® Interlaminar Stabilization®**

- Preserves motion
- Addresses leg and back pain
- Maintains foraminal height
- Preserves normal kinematics at operative and adjacent levels

Allows for flexion

Allows for extension through device compression

***coflex*® loads on interlaminar bone NOT the spinous process**



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

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm

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 pain[1]
- Patients with mechanical back pain benefit with stabilization[1]

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 faster[2]
- Those patients with a stable Grade I spondylolsithesis (<3mm translation) don't necessarily require the permanence of a fusion procedure

coflex®
Interlaminar Stabilization®

* Findings based on US FDA PMA P110008, October 2012. Please see SSED or IFU for indications, contraindications, warnings and precautions.

1 Kleinstück et al.: The Influence of Preoperative Back Pain on the Outcome of Lumbar Decompression Surgery. Spine Volume 34, Number 11, pp 1198–1203
2 Herkowitz et al.: Degenerative Lumbar Spondylolisthesis with Spinal Stenosis. A Prospective Study Comparing Decompression With Decompression and Intertransverse Process Arthrodesis. The Journal of Bone and Joint Surgery. J Bone Joint Surg Am, 1991 Jul; 73(6): 802-808 . http://dx.doi.org/

coflex® Indications For Use and Contraindications

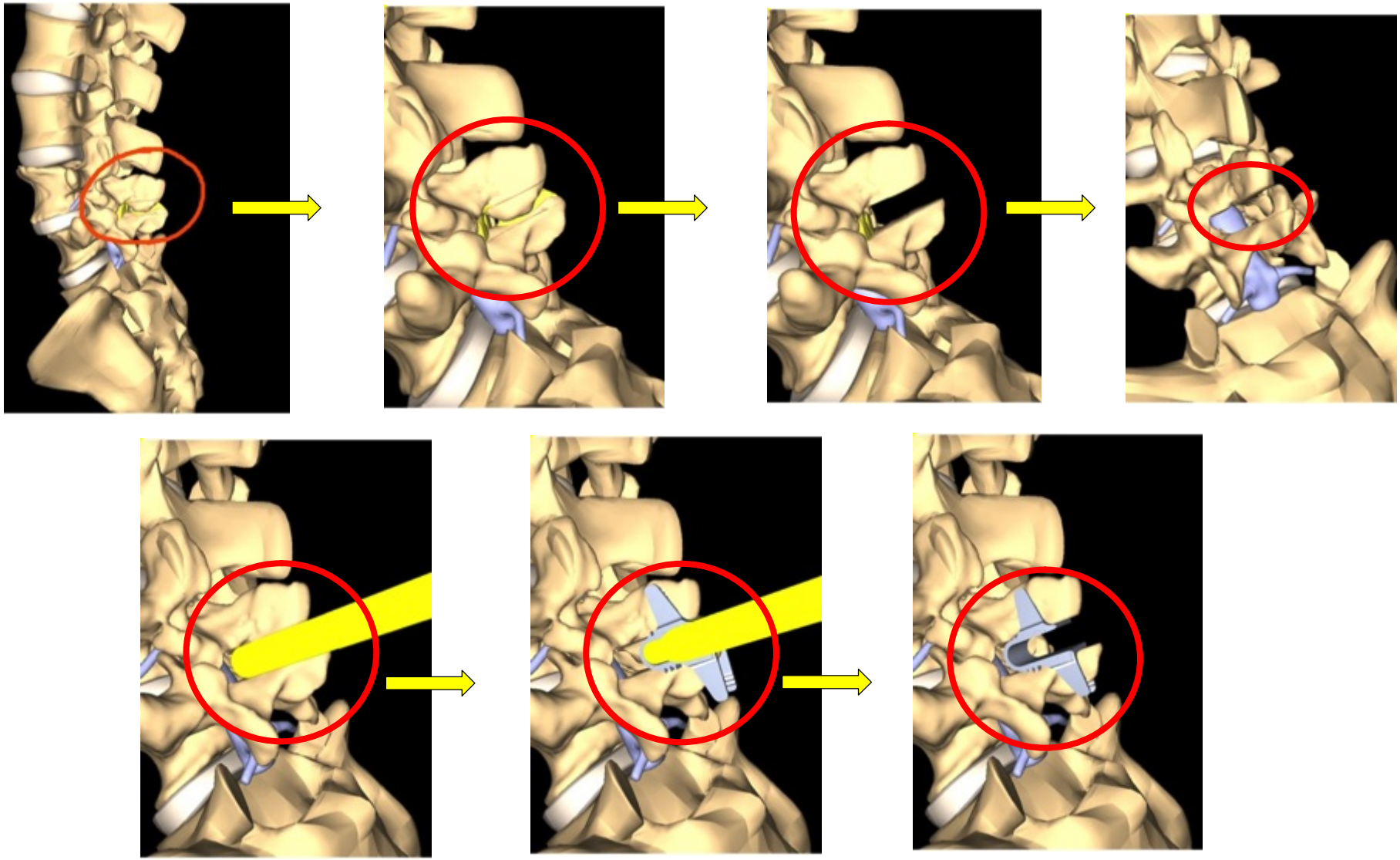
INDICATIONS FOR USE

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*®



coflex® Data – 5 Year Patient Reported Outcomes

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. *coflex*® allows healthcare professionals to provide value-based proven disease management of lumbar spinal stenosis.

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

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm

coflex® Data – 5 Year Follow-Up

Published January 2016 in International Journal of Spine Surgery

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

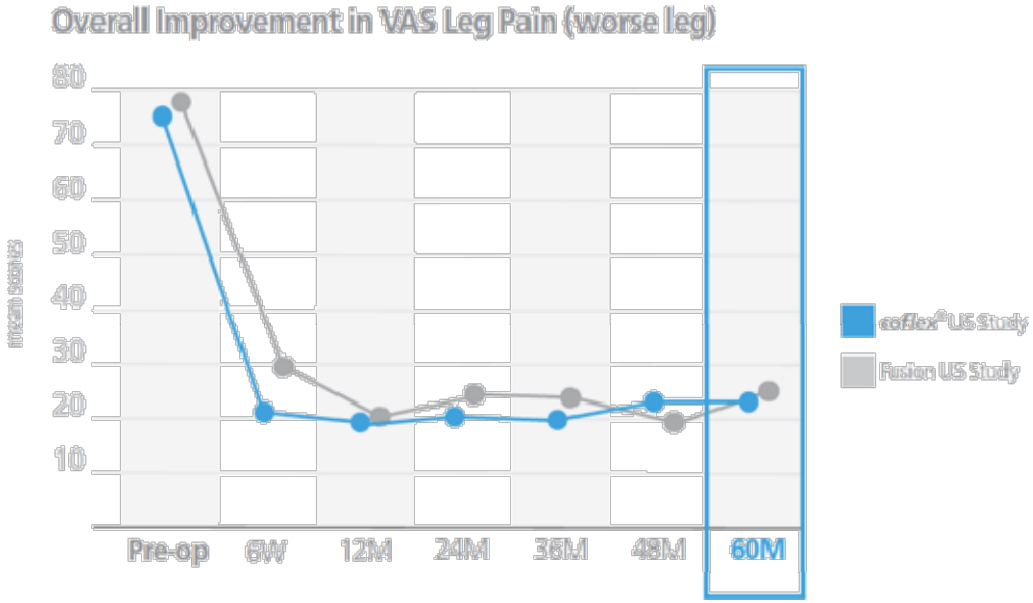
Michael J. Musacchio, MD,[1] Carl Lauryssen, MD,[2] Reginald J. Davis, MD,[3] Hyun W. Bae, MD,[4] John H. Peloza, MD,[5] Richard D. Guyer, MD,[6] Jack E. Zigler, MD,[6] Donna D. Ohnmeiss, DrMed,[7] Scott Leary, MD[8]

[1]Department of Neurosurgery, NorthShore University HealthSystem, Evanston, IL, [2] NeuroTexas, Austin, TX, [3]Laser Spine Institute, Philadelphia, PA, [4]The Spine Institute, Santa Monica, CA, [5]Texas Back Institute, Frisco, TX, [6]Texas Back Institute, Plano, TX, [7]Texas Back Institute Research Foundation, Plano, TX, [8]Senta 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

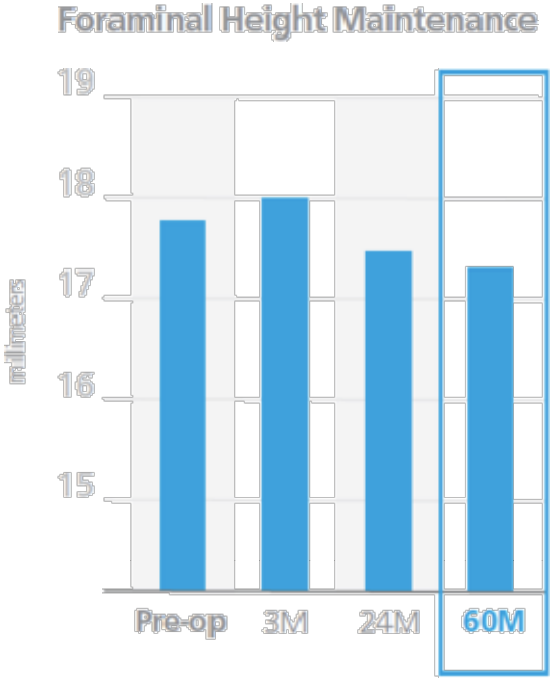
**Claims based on US FDA PMA P110008. October 2012.*

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



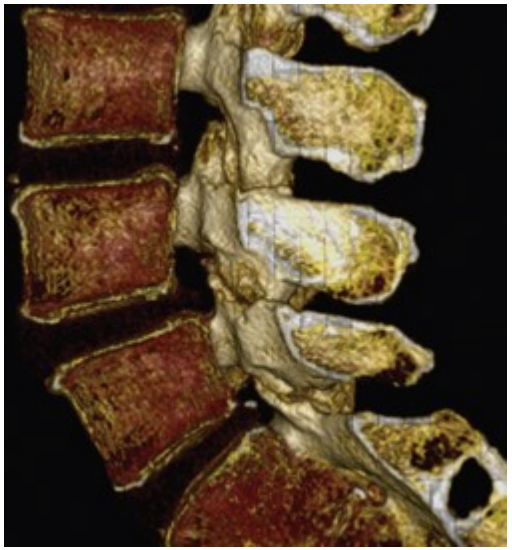
coflex® preserves the durability of your decompression

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

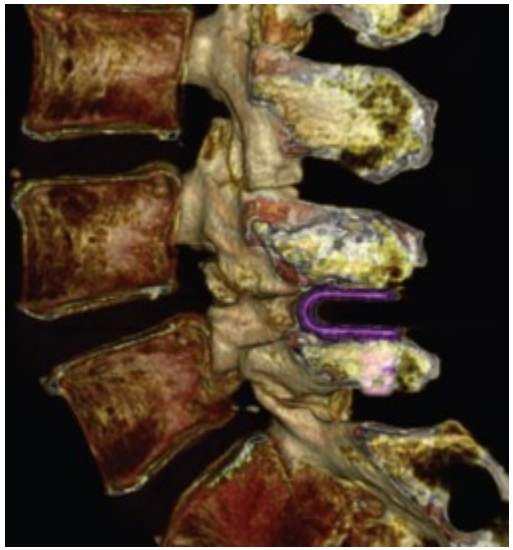
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm

Provide Neutral Stabilization Post Decompression

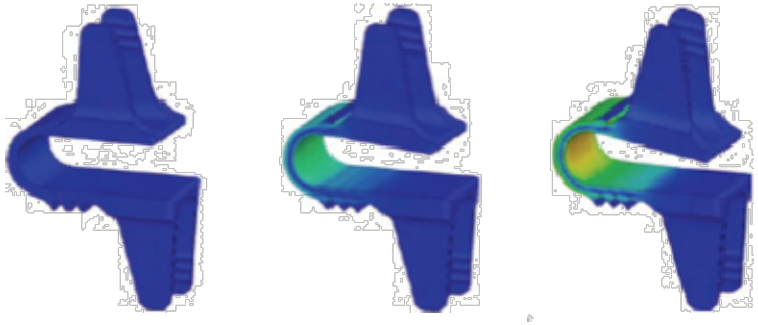
After a microsurgical decompression, *coflex*® is inserted and bears load on interlaminar ridge



Preoperative stenotic spine



Postoperative spine with *coflex*®



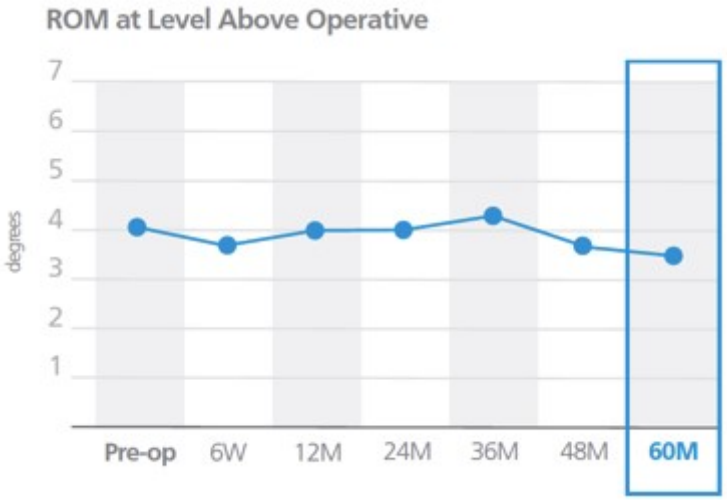
***coflex*® controls patient's movement in extension**

Maintain Structural Integrity and Preserve Kinematics

coflex® maintains motion at operative and adjacent levels

Allows for Flexion

Allows for Extension Through Device Compression

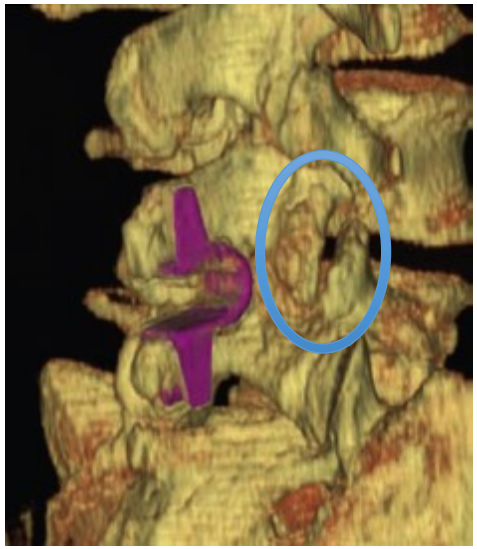


*Claims based on US FDA PMA P110008. October 2012.

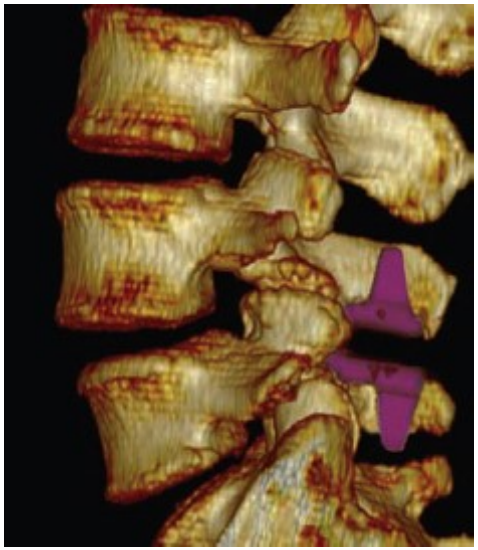
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm

Off-load Facets and Address Back Pain

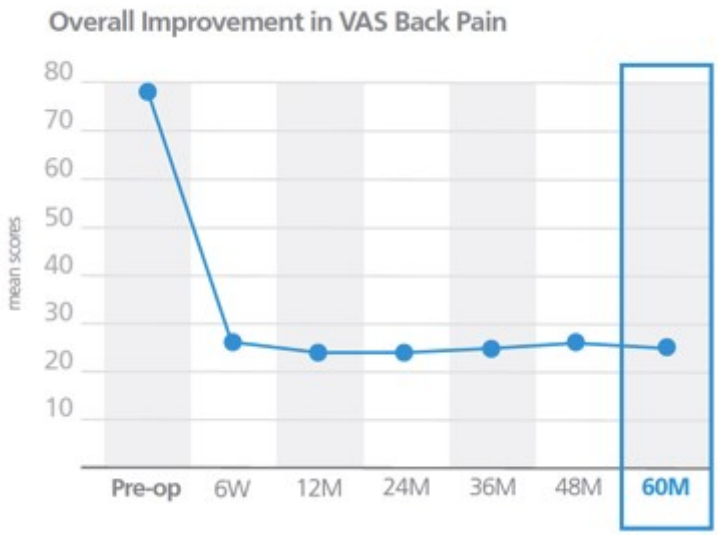
***coflex*® Addresses Facetogenic Issues and Immediately Decreases Back Pain Through 5 Years**



Deep interlaminar positioning allows for facet offloading



Facet unloading, adjacent levels unchanged

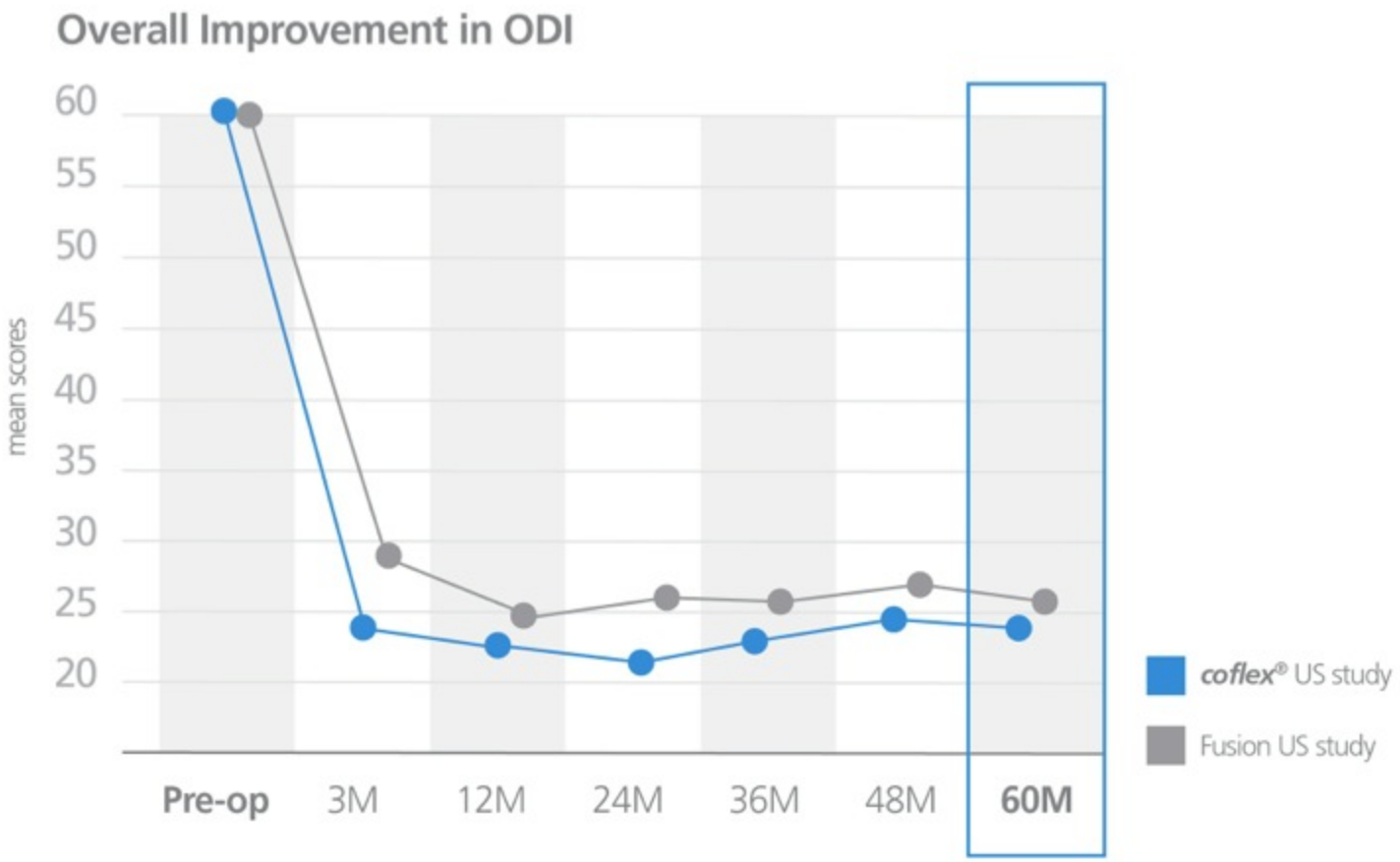


**Claims based on US FDA PMA P110008. October 2012.*

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



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

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327502.htm

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 new 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**

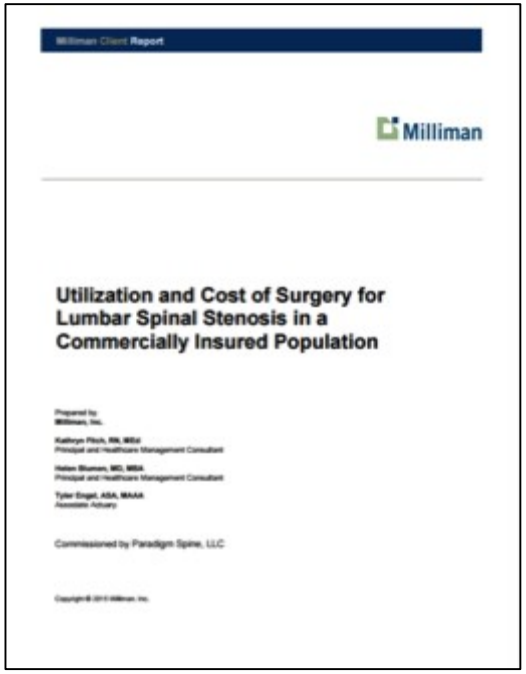
- **CPT Level 1 Physician Payment Coding Implementation in January 2017**

- **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**

AMA
AMERICAN MEDICAL ASSOCIATION


Milliman Client Report

Milliman

Utilization and Cost of Surgery for Lumbar Spinal Stenosis in a Commercially Insured Population

Prepared by
Milliman, Inc.

Kathryn Fitch, RN, MSc
Principal and Healthcare Management Consultant

Helen Stassen, MD, MBA
Principal and Healthcare Management Consultant

Tyler Engel, ASA, MAAA
Associate Actuary

Commissioned by Paradigm Spine, LLC

Copyright © 2015 Milliman, Inc.

New AMA Coding Clarity for Interlaminar S

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.[1]

CPT 22867[1]
Primary Procedure
$1,025
2017 Medicare National Average Payment[2]

CPT 22868[1]
2nd level
$256
2017 Medicare National Average Payment[2]

Note: Medicare Average Payment Amounts are calculated here as Total Facility RVUs multiplied by the CY 2017 Final Conversion Factor
[1] CPT 2017 Professional Edition, 2016 American Medical Association (AMA); CPT is a trademark of the AMA
[2] 2017 Medicare Physician Fee Schedule, Final Rule, www .cms.gov

Hospital Inpatient

ICD-10-PCS[3] Inpatient Procedure Code Options

0SB00ZZ 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[4]
Back and Neck Procedures Except Spinal Fusion with MCC or Disc Device / Neurostimulator

$17,253
2017 Medicare National Average Payment[5]

[3] ICD-10-PCS Procedure Coding System, 2017 Tables and Index, Medicare/Coding/ICD-10/2017-ICD-10-PCS, www .cms.gov
[4] Medicare Severity Diagnosis Related Group (MS-DRG) Grouper and Medicare Code Editor (MCE) Version 34 ICD-10 Software, FY 2017 IPPS Final Rule, CMS-1655-F , Medicare/AcuteInpatientPPS/FY2017-IPPS, www .cms.gov
[5] 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[6]

C-APC 5116[6]
$14,698
2017 Medicare National Average Payment[7]

[6] CMS-1656-FC – Hospital Outpatient Prospective Payment – Final Rule with Comment and Final CY2017 Payment Rates – Addendum C, www .cms.gov
[7] 2017 Medicare Outpatient Prospective Payment System, Final Rule – Addendum B, www .cms.gov

Ambulatory Surgery Center[8]

5116-Level 6 Musculoskeletal Procedures[9]

C-APC 5116[9]
$10,542
2017 Medicare National Average Payment[10]

[8] 2017 payment rate for Medicare Certified Ambulatory Surgery Centers
[9] CMS-1656-FC – Hospital Outpatient Prospective Payment – Final Rule with Comment and Final CY2017 Payment Rates – Addendum C, www .cms.gov
[10] 2017 Medicare Ambulatory Surgery Center , Final Rule – Addendum AA, 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.

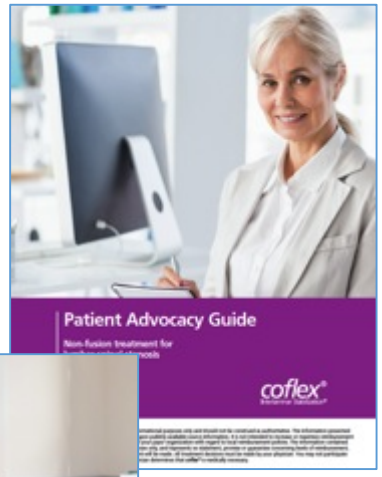
Navigating Coverage – There are Services Available!

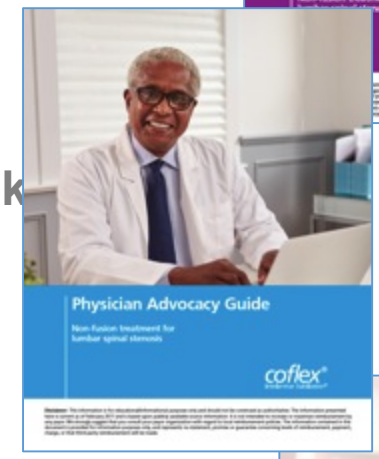
- Access to 3rd party coverage access team through a reimbursement hotline
- Team specialized in provider and patient access to treatment solutions
- Established processes with national and local payor for ease of submission
- Cognizant of up-to-the-minute payor changes in guidelines
- Pre-authorization 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

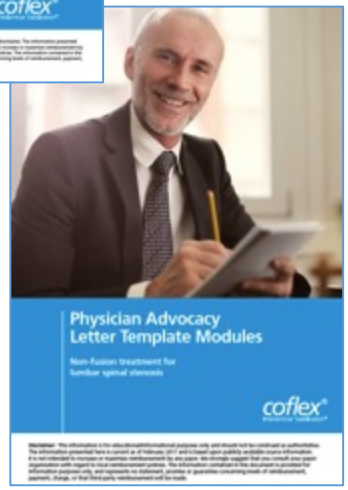
For Coverage Access Support, Contact:
Reimbursement Management Center
1-888-796-8411
reimbursementps@mcra.com

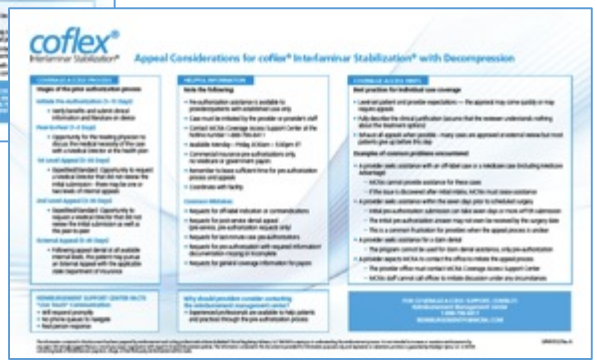
Resources Available to You and Your Practice

- Prior-Authorization laminated guide
- Appeals Consideration laminated guide
- Patient Advocacy Guide
- Physician Advocacy Guide
- Physician Advocacy Letter Template Modules Book









Further Resources

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

- Events available at www.paradigmspineevents.com
- Resources available at www.paradigmspineresources.com
- National Education Team
- Product Manager Support Team
- Patient Education Materials

Further Contacts

- Contact a MSL near you today!

WESTERN U.S.	CENTRAL U.S.	EASTERN U.S.
Erin Crawford	Devon Billeter	Gaye Zingler
erin.crawford@ paradigmspine.com	devon.billeter@ paradigmspine.com	gaye.zingler@ paradigmspine.com

THANK YOU!