

# ***Growing your ASC spine practice***

## ***A discussion on contemporary MIS technology for Spinal Stenosis***

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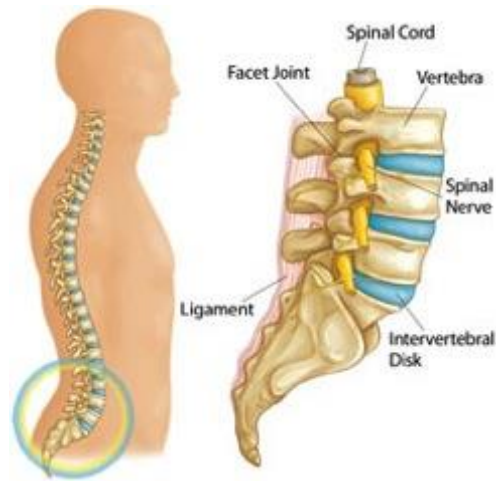
**New York, NY**

# Agenda

- Lumbar Spinal Stenosis Overview and Current Treatment Options
- The coflex<sup>®</sup> Device as a Solution
- Clinical Evidence and Patient Outcomes
- Understanding the Patient Mindset
- coflex<sup>®</sup> Patient Selection, Patient Examples, and Rehabilitation
- Reimbursement and Financing Strategies
- How to Best Work with Payer Providers

# Lumbar Spinal Stenosis Overview

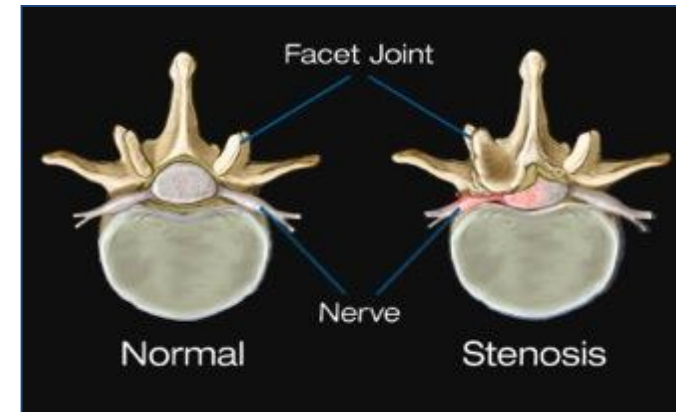
## PREVALENT CONDITION



- LSS incidence: 8% - 11% of U.S. population<sup>1</sup>
- Most common indication for lumbar spine surgery in people >65 years of age<sup>2</sup>

## CLINICAL PRESENTATION

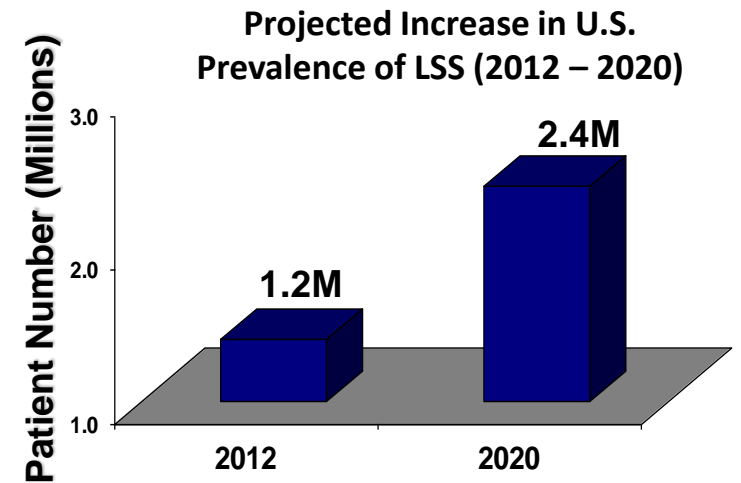
### Narrowing of Lumbar Spinal Canal



- Patients typically present with low back pain, radicular leg pain, or neurogenic claudication<sup>1,2</sup>

# Why Spinal Stenosis Is Relevant To Your Practice Today

- Spinal stenosis is currently the largest diagnosed patient population in spine at 1.2M per year\*
- It is expected that this group will increase to 2.4M by the year 2020
- Over 600,000 of these patients choose surgical treatment each year
- On average, a spine practice treats over 100 stenosis patients per year, which is an average of 40%-50% of the total annual procedures performed<sup>+</sup>



**LSS is the largest growing patient demographic in spine care**

# Current Treatment Options for Lumbar Spinal Stenosis

- Most LSS patients initially receive at least 6 months of conservative treatment
- Of these, only ~15% are likely to improve over the long term; 70% will continue to experience neurogenic claudication<sup>1</sup>
- Better LSS treatment outcomes reported with surgical intervention vs. non-surgical treatment, particularly for severe disease<sup>2,3</sup>



## Conservative

NSAIDs/narcotics  
Physical therapy  
Epidural injections

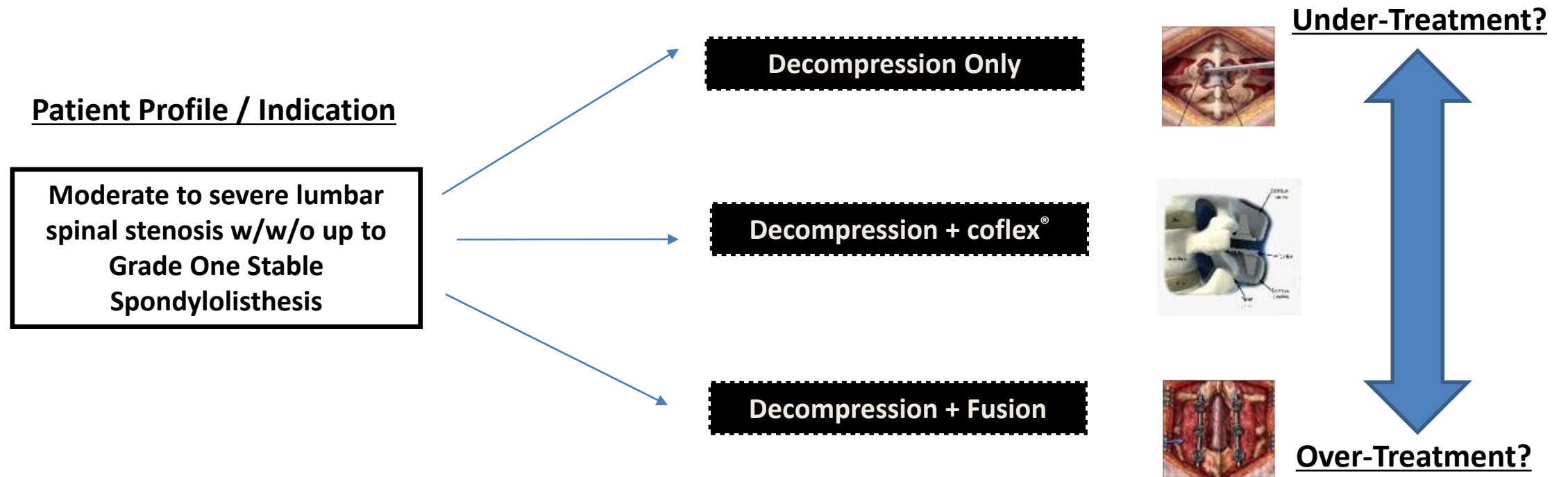


## Surgery

Decompression | Spacers | Fusion

# The coflex<sup>®</sup> Device as a Solution

coflex<sup>®</sup> provides a definitive and appropriate solution for patients with degenerative lumbar spinal stenosis



**coflex<sup>®</sup> Solves The Under-Treatment/Over-Treatment Dilemma For Treating LSS!**

# coflex<sup>®</sup> Interlaminar Stabilization<sup>®</sup>

Motion Preserving Non-Fusion Stabilization Post Decompression for Spinal Stenosis

Single-piece implant made of titanium alloy

5 anatomical sizes

Can be used for 1- and 2-Level implantation

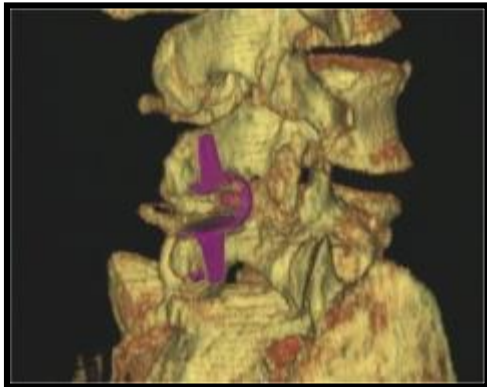
2-part functional design allows for:

## Non-fusion interlaminar stabilization

- Engages with interlaminar bone (3-5 x stronger vs spinous process)
- Maintains foraminal height and off-loads the facets

## Motion Preservation

- Implant compresses in extension and allows for flexion
- Maintains sagittal balance and lordosis
- Maintains physiologic adjacent segment kinematics



# The coflex<sup>®</sup> Investigational Device Exemption (IDE) Trial

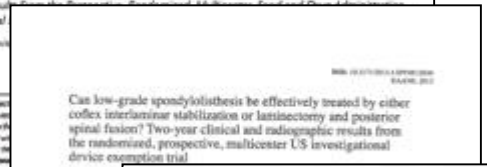
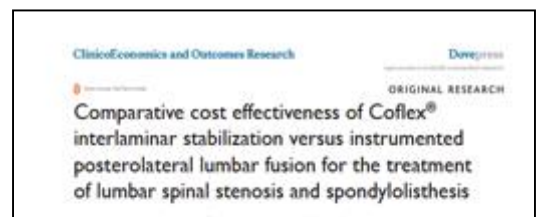
## *A Landmark Study in Lumbar Spinal Stenosis*

- Unprecedented amount of Level 1 clinical and radiographic data
- 95% follow-up at 2 years sets a new standard
- First LSS IDE study to complete enrollment with a fusion control group
- First orthopedic device PMA with an independent CEC to blindly evaluate and adjudicate all adverse events with binding decisions on sponsor
- First spine study to include **all lumbar epidurals as failures**
- Study designed to address every issue previous IDEs and panels cited as design flaws



# Clinical Evidence

- SPINE: 2-Year Study Results
- JNS: 2-Year Spondy Cohort Study Results
- JBJS: Adverse Event Reporting Bias
- The Spine Journal: In-Vivo Posterior Loading
- SPINE: Influence of Preoperative Back Pain
- Asian Spine Journal: Role of coflex® as Adjunct to Decompression
- ClinicoEconomics Research: Comparative Cost Effectiveness



# Patient Outcomes

Compared to fusion patients in the clinical study, patients receiving coflex® experienced:

- HIGHER PERCENTAGE OF PATIENT SATISFACTION
- FASTER RELIEF OF SPINAL STENOSIS SYMPTOMS
- LASTING RELIEF OF SPINAL STENOSIS SYMPTOMS
- EARLIER IMPROVEMENT IN PAIN AND FUNCTION
- LASTING IMPROVEMENT IN PAIN AND FUNCTION
- EARLIER IMPROVEMENT IN PHYSICAL FUNCTION
- LASTING IMPROVEMENT IN PHYSICAL FUNCTION
- BACK AND LEG PAIN RELIEF
- LESS BLOOD LOSS, SHORTER OPERATING TIME, SHORTER HOSPITAL STAY

94%

of coflex® patients  
were satisfied  
compared to 87% of fusion  
patients

90%

of coflex® patients  
had early relief  
compared to 77% of  
fusion patients

88%

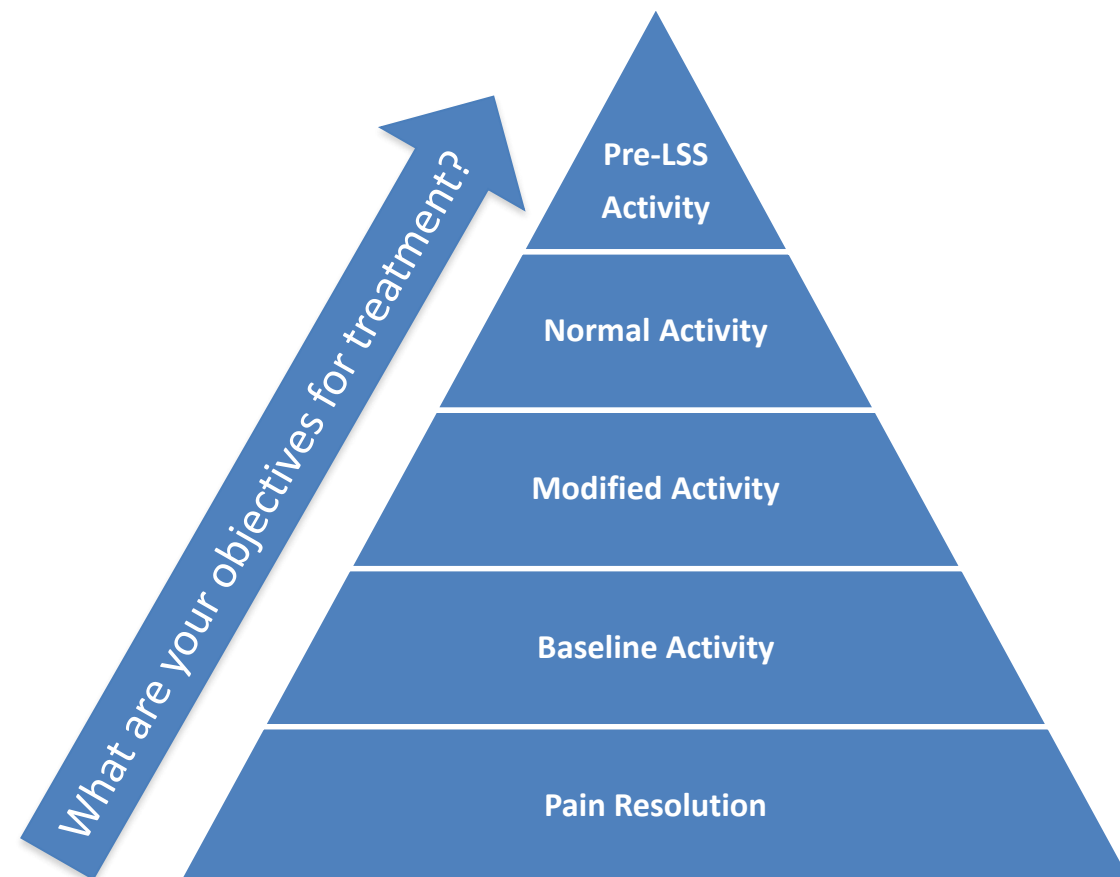
of coflex® patients  
had lasting relief  
compared to 78%  
of fusion patients

# Understanding the Patient Mindset

What do lumbar spinal stenosis patients want?

- Return to normal lives and activity
- Most advanced and reputable technology
- Proven and consistent outcomes
- Fast recovery
- Minimally invasive procedure

## Hierarchy of LSS Patient Needs

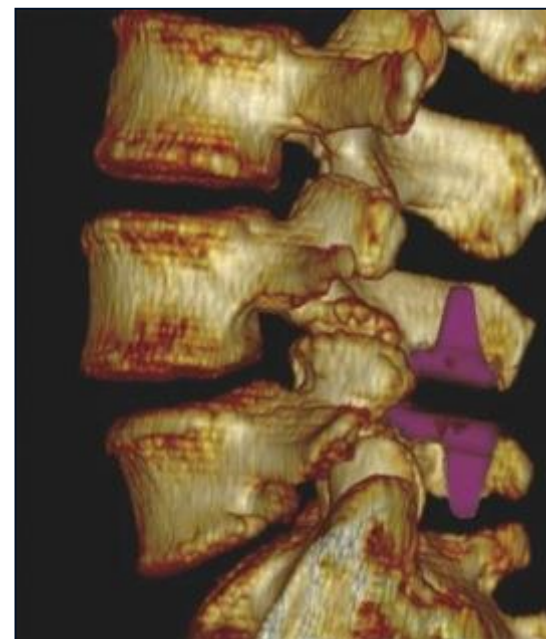


# Patient Selection

- Appropriate candidate for surgery
- At least moderate lumbar stenosis
- No more than 2 levels should require surgery
- No prior lumbar fusion at index level
- Must have had at least 6 months of failed conservative care

## coflex<sup>®</sup> Patient Indication

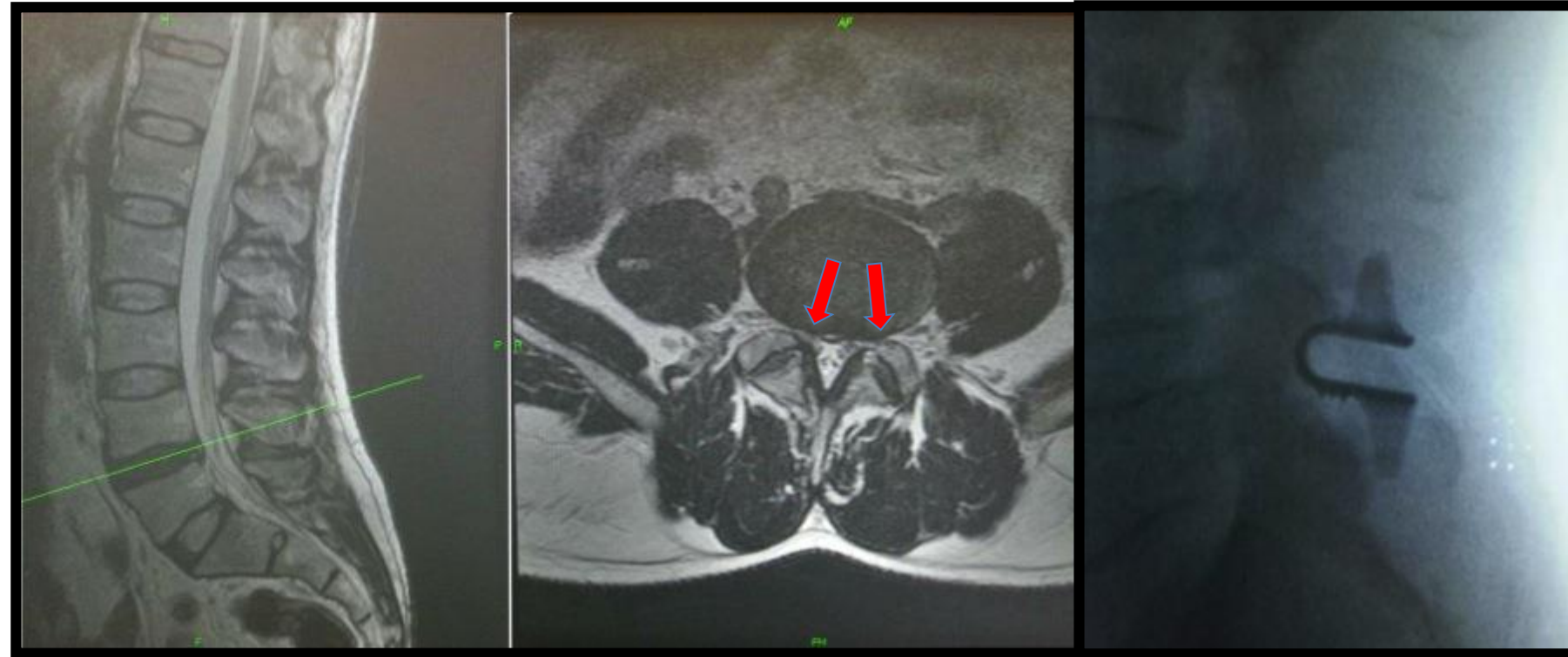
**Moderate to Severe Lumbar Spinal Stenosis with  
or without up to Grade I Spondylolisthesis**



# coflex<sup>®</sup> Patient Examples

## Case Study 1

- 42 year old male
- Back and bilateral pain
- Failed conservative treatment: physical therapy, epidural blocks, facet injections and work restriction



Pre-op

Post-op

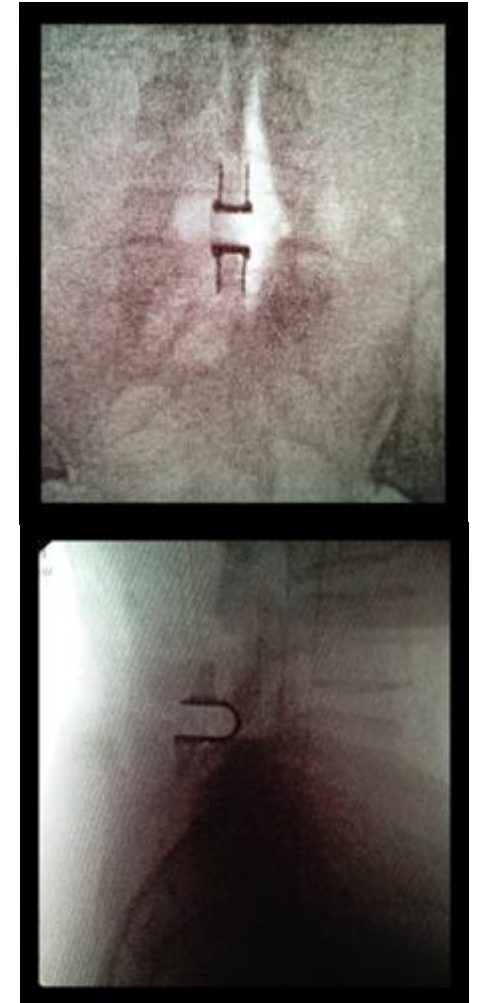
# coflex<sup>®</sup> Patient Examples

## Case Study 2

- 50 year old female
- Complaining of lower back pain and bilateral radiculopathy
- Pain radiates into the left hip and is aggravated by standing and walking, alleviated by rest
- Failed conservative therapy
- No previous spinal surgery



Pre-op

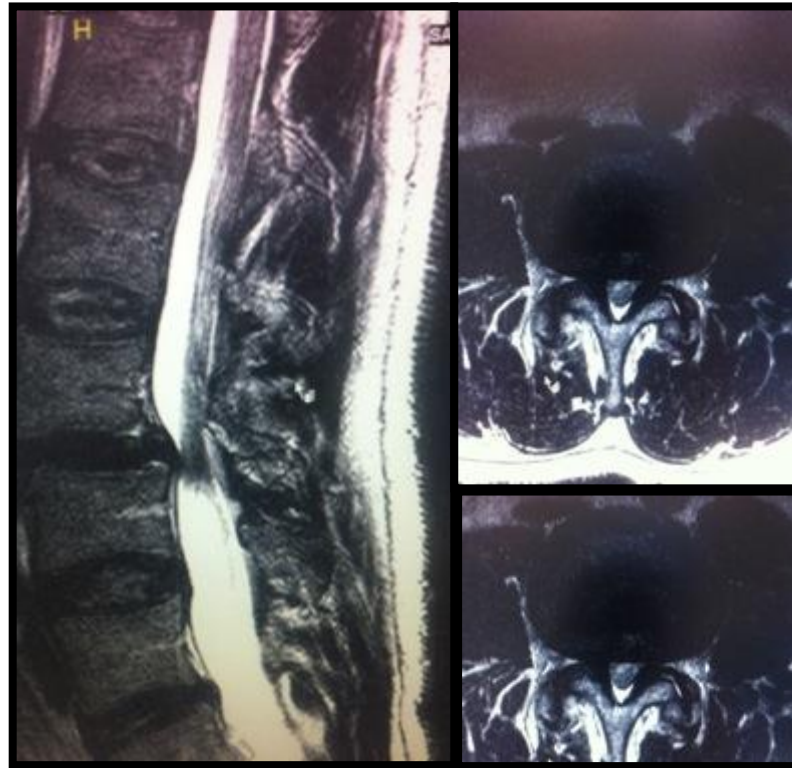


Post-op

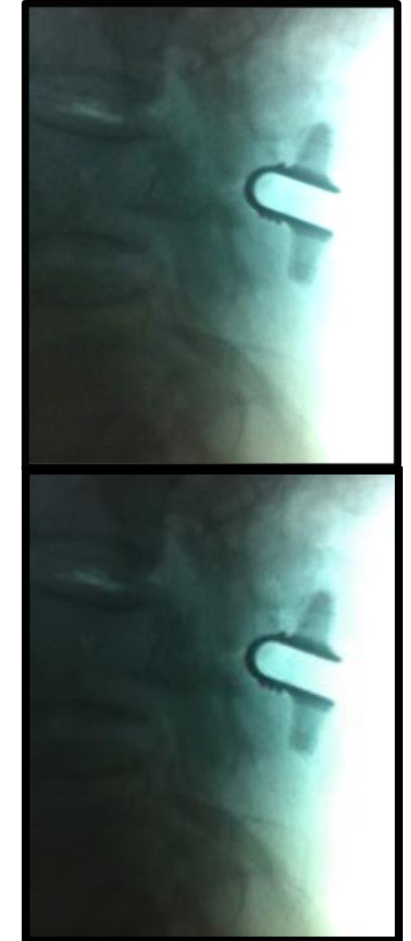
# coflex<sup>®</sup> Patient Examples

## Case Study 3

- 74 year old male
- 2 year history of bilateral buttock pain that increases with walking and severely limits his activities
- Mild mechanical LBP
- Failed PT and ESIs



Pre-op



Post-op

# Rehabilitation and Recovery of coflex® Patients

- Average expected recovery duration
- Physical therapy for coflex® patients
- Many PTs recommend exercises that emphasize range of motion, pain control, core stabilization, and back strengthening



Tim Marlow, Physical Therapist

*“My coflex® patients are happier, healthier, and are recovering at a dramatically improved pace.”*



# Optimize Practices Around Reimbursement and Financing

## Practice Initiated Activities

- Assure **healthy balance** of workers' compensation and private insurance & self pay patients with appropriate practice outreach:
  - ✓ Balance workers' comp patients, private insurance and Medicare
  - ✓ Optimize “word of mouth” referrals using brochures, newsletters, mailing, blogging, and social media marketing
  - ✓ Consider educational events for patients and referring clinicians utilizing Paradigm Spine educational resources
- Consider offering **American Healthcare** Financing Option for patients interested in the program (consider organizing webinars with AHF for eligible patients)
- Utilize **MCRA** to obtain prior authorization/pre-determination approvals
- Continue to explore all possible avenues for past coflex® cases for payment with private payers



LOOKING FOR ADDITIONAL PAYMENT OPTIONS?

AMERICAN HEALTHCARE LENDING

Don't limit your treatment alternatives!

Finance the cost of your stenosis surgery -- including any of the associated out of pocket expenses.

SUBMIT APPLICATION ONLINE → REVIEW HEALTHCARE LOAN OPTIONS → RECEIVE FUNDS VIA DIRECT DEPOSIT

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- Terms up to 84 Months
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Musculoskeletal Clinical  
Regulatory Advisers, LLC

# Reimbursement Support



- MCRA's coding, reimbursement, and compliance experts have over 50 years of combined healthcare policy and finance services experience, and have a proven track record servicing over 250 clients nationwide
- MCRA assists practice with day-to-day challenges to ensure appropriate coverage and reimbursement for coflex®
- MCRA's reimbursement services are unique and effective in assisting ASC for success:
  - ✓ Current coding, coverage and payment options
  - ✓ Strategies to affect product and procedure acceptance by insurance companies
  - ✓ Help with understanding how to get paid for using coflex® technology

**MCRA Reimbursement Support Center:**

888-796-8411

[reimbursementps@mcra.com](mailto:reimbursementps@mcra.com)

# How to Best Work with Payer Providers

MCRA assists to resolve issues regarding reimbursement for coflex<sup>®</sup> cases

- Organize standing conference call with MCRA to discuss ongoing obstacles and challenges with reimbursement
- **Call MCRA to *discuss newly scheduled*** patients that may pose a challenge based on prior experience with case/insurer

Engage insurers to demonstrate clinical utility and economic utility of coflex<sup>®</sup>

- Present coflex<sup>®</sup> utility presentation to local insurers
- Show clinical presentation to educate on outcomes with coflex<sup>®</sup> versus fusion
- Consider involving patient advocates



Present coflex<sup>®</sup> outcomes to self-funded large employers to demonstrate clinical utility and economic outcomes

**Thank you!**  
**Questions?**