rti surgical®

coflex®

Interlaminar Stabilization®

The coflex Patient

A **HIGHER** STANDARD®

coflex®
Interlaminar Stabilization®

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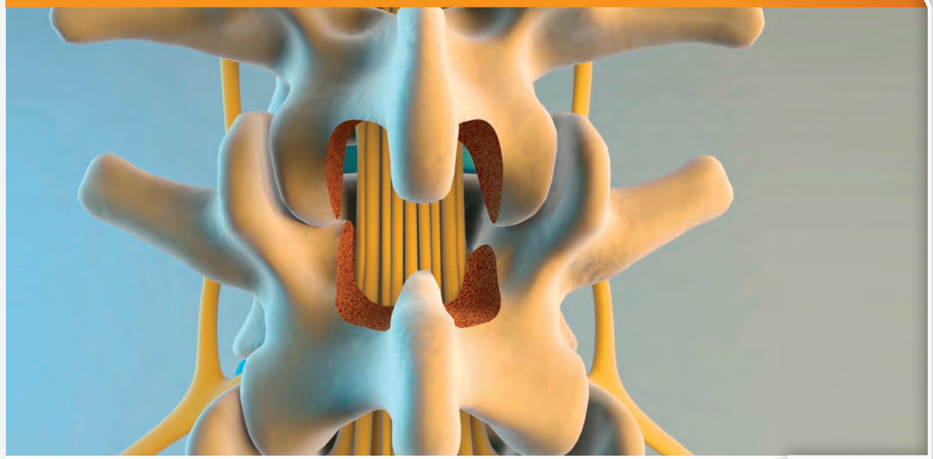
Lumbar Spinal Stenosis Surgical Treatment Options

The coflex Device is an **Alternative to Fusion** for a Subset of Lumbar Spinal Stenosis Patients

DECOMPRESSION ALONE



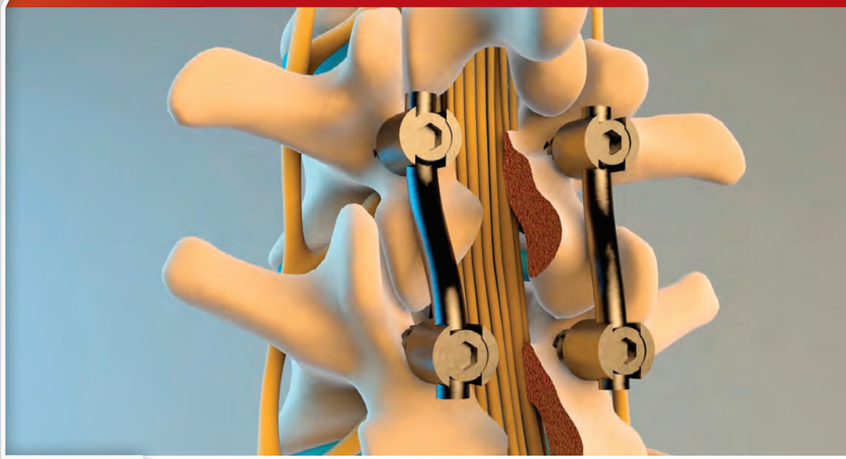
370,639* Annually

- Mild Stenosis
- ODI <40
- With **NO** Low Back Pain
- With **NO** Spondylolisthesis
- With **NO** Instability

THE DECISION ZONE

- Moderate to Severe Stenosis
- ODI >40
- Back Pain (VAS >50)
- Up to Stable Grade I Spondylolisthesis
- Anticipated Instability†

FUSION



259,844* Annually

- Mild to Severe Stenosis
- ODI >40
- Back Pain (VAS >50)
- > Grade I Spondylolisthesis
- Gross Instability / Deformity

DECOMPRESSION ALONE — coflex® — FUSION

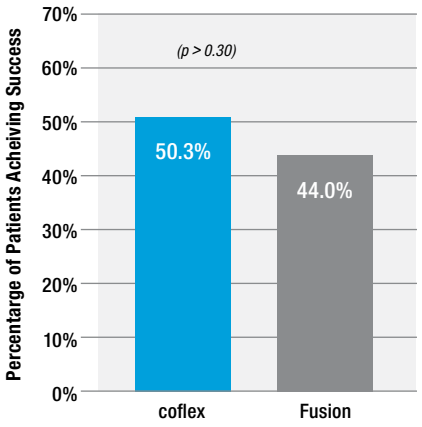
*Based on IMS Data, 2016. †Post-operative. Please see coflex Instructions For Use (IFU) for Indications, Contraindications, Warnings, Precautions.

Level I Clinical Data

coflex vs. Fusion

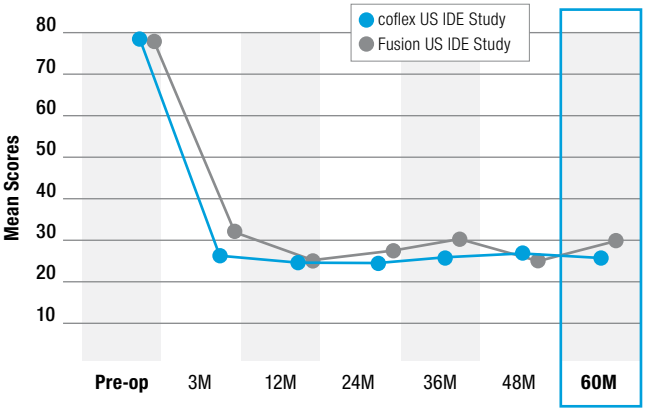
- **US IDE/PMA Prospective, Randomized, Controlled Trial**
- **Moderate to Severe Lumbar Spinal Stenosis**
- **Inclusion Criteria**
  - ODI >40 (average = 61)
  - Back pain (VAS >50) (average = 82)
  - Up to Grade 1 spondylolisthesis
- **322 Patients; 21 Sites**
- **5 Year Follow-up (91%)**
- **Study Primary Endpoint:**
  Composite Clinical Success[1]
  - ODI improvement >15pts
  - No reoperations, revisions, removals, or supplemental fixation
  - No major device-related complications
  - No epidural steroid injections in the lumbar spine

Composite Clinical Success at 5 Years[2]

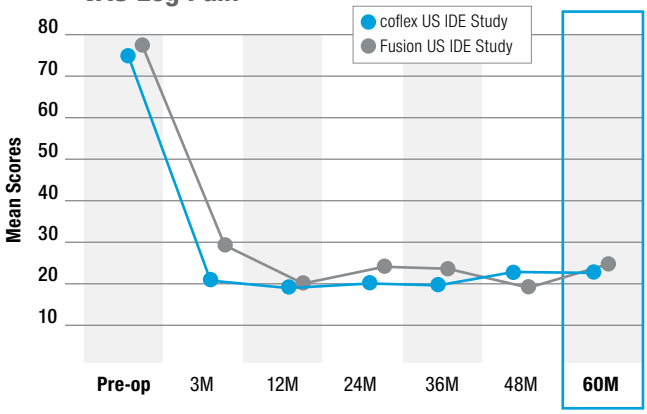


- coflex was non-inferior to fusion at 5 years
- coflex superior considering: less OR time, rehab, complications, cost

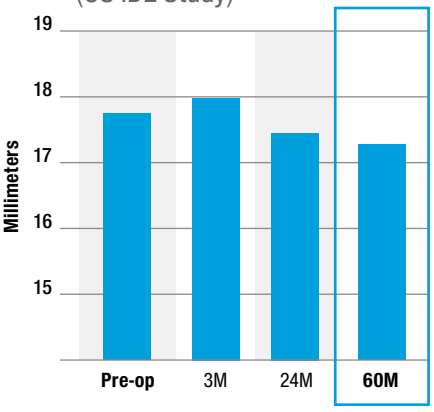
VAS Back Pain[2]



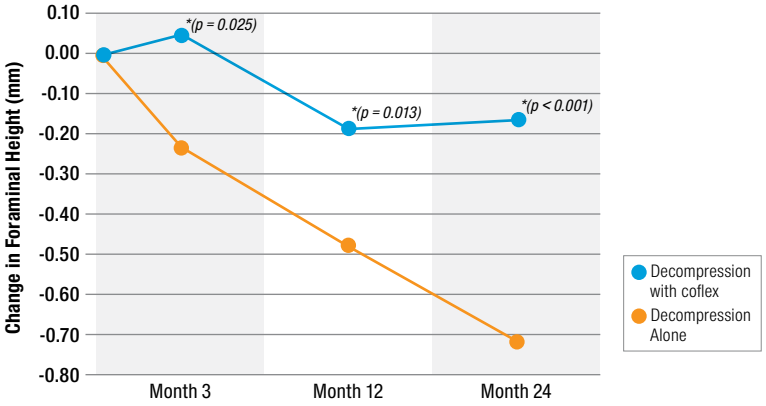
VAS Leg Pain[2]



Foraminal Height Maintenance[2]
(US IDE Study)



Foraminal Height Maintenance[3]
(ESCADA: European Study of coflex and Decompression Alone)



1. All must be met for a patient to be considered a success.
2. Claims based on US FDA PMA P110008. October 2012.
3. Claims based on ESCADA, published in Journal of Neurosurgery: Spine. Volume 28 Issue 4, April 2018.

Clinical cases are unique and individual results may vary.

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