PARADIGM SPINE
the movement in spine care

coflex®

Brochure

***coflex*® Interlaminar Stabilization™**

SPINAL STENOSIS WITH BACK PAIN – THE RATIONALE FOR STABILIZATION

For the treatment of spinal stenosis, surgeons have various treatment options. The continuum of care includes conservative treatment, interspinous distraction, direct decompression with or without additional stabilization, and decompression with fusion.

Decompressive surgical treatment options are intended to address leg symptoms, but a patient's back pain often remains residual.

Kleinstück et al.[1] have studied the degree of impact with back pain in relation to leg pain, and have analyzed patient outcomes for spinal stenosis after decompression.

The study demonstrated a significant correlation between outcomes and the degree of associated back pain. Patients who presented themselves with significant back pain, in addition to their leg pain, had a significantly worse outcome after decompression.

Therefore, the clinical outcome in treating lumbar spinal stenosis after decompression depends significantly on the degree of associated back pain.

The authors of the study suggest in their discussion that "future studies should also assess whether the addition of fusion to decompression in patients with notable LBP (low back pain) results in a better overall outcome."

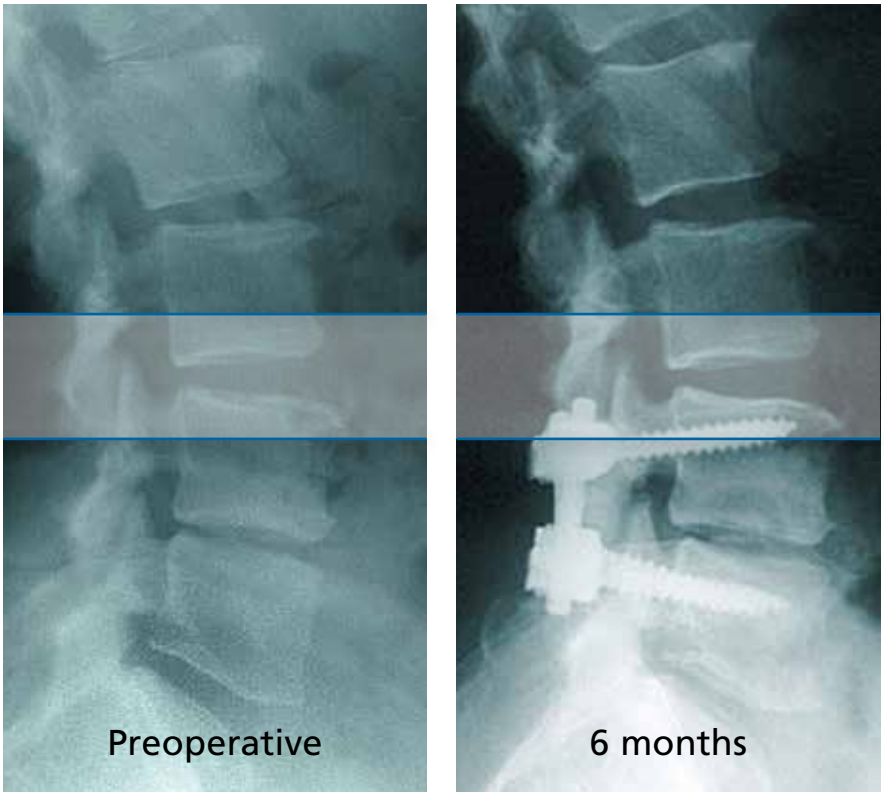
The ***coflex***® FDA[2] study addressed just that. Patients in the study had to have significant back pain in addition to their leg pain. After microsurgical decompression, the operated segment was stabilized; either through the ***coflex***® implant or through pedicle screw fusion.

Patient satisfaction of 94% in the ***coflex***® group and 87% in the fusion group for this challenging patient population clearly shows:

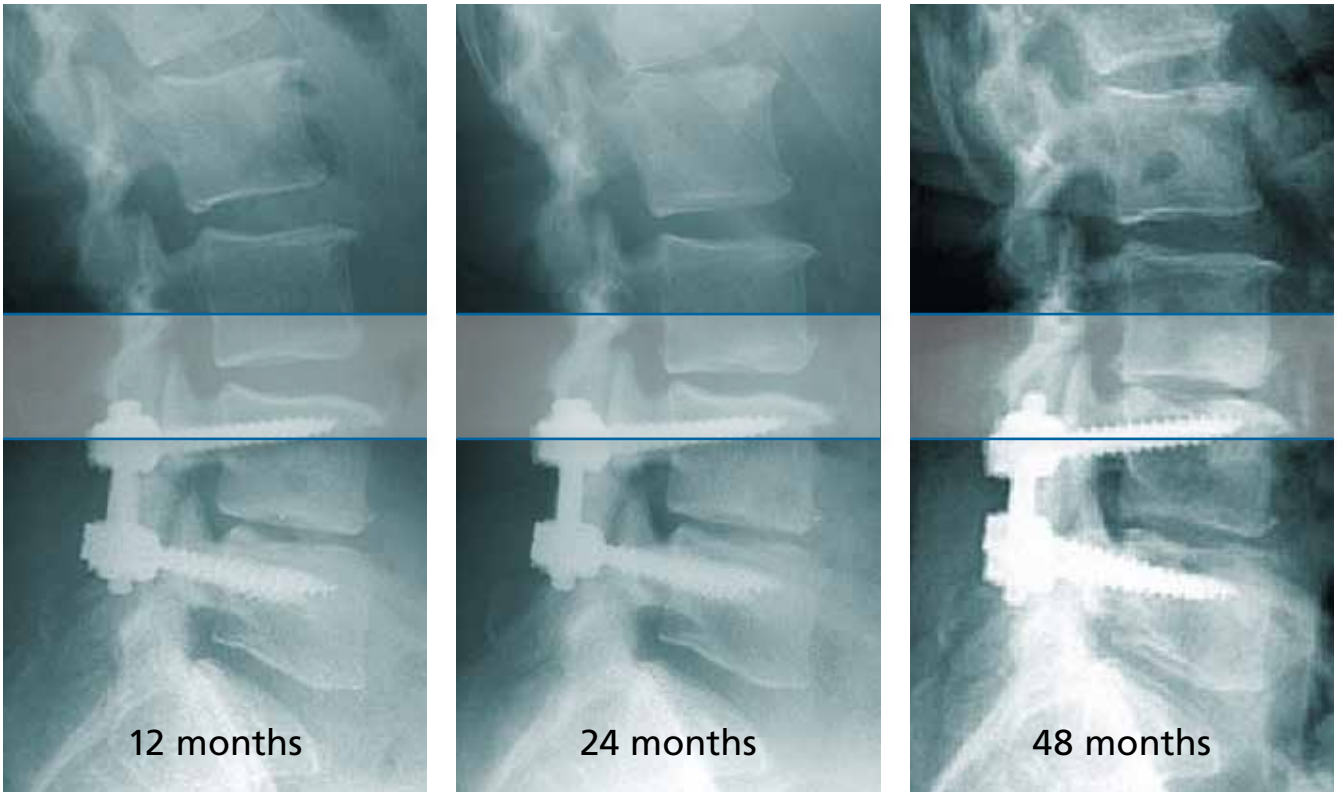
Back pain in patients with spinal stenosis can be effectively addressed through additional stabilization!

[1] Kleinstück et al. The Influence of Preoperative Back Pain on the Outcome of Lumbar Decompression Surgery. Spine 2009; Volume 34; Number 11; pp 1198-1203

[2] FDA: Food and Drug Administration



coflex®
CHALLENGING THE GOLD STANDARD …



Adjacent Segment – The Rationale for *coflex*®

A paradigm shift from fusion to motion preservation requires confidence, compelling clinical and radiographic data and strong Level 1 evidence – in short, it is not a conceptual exercise. The gap in the treatment continuum from conservative care to fusion is being filled with a new technology – the *coflex*® Interlaminar Stabilization™ Procedure.

In cases of spinal stenosis treatment requiring supplemental stabilization post decompression, fusion has been the only option to date – an over-treatment in many cases? Extended operative time, a more complex OR setup and a greater need for intraoperative imaging can be a strain for surgeons, OR staff and patients. Adjacent segment breakdown may even require additional surgeries at a later stage.

The motion preserving *coflex*® procedure allows for a direct microsurgical decompression, Interlaminar Stabilization™ and foraminal height/volume maintenance.

This technology also allows for facet off-loading and physiologic range of motion and translation at the index level, thereby maintaining physiological adjacent segment kinematics and restoring natural anatomic function.

The *coflex*® study demonstrated that on average, fusion patients exhibited more hypermobility at the adjacent segment at two years compared to *coflex*® patients.

Additionally, there was a statistically significant higher rate of adjacent segment surgery at two years in the fusion group, compared to the *coflex*® group.

The *coflex*® procedure is simple and elegant, while providing all the stability needed for pain relief. Operative time, surgical intensity and overall patient morbidity is significantly reduced.

The *coflex*® procedure – Motion Preserving Interlaminar Stabilization™.


PMA
Application
APPROVED

… WITH COMPARATIVE EFFECTIVENESS …

coflex® – The 1st & Only **Motion Preserving Interlaminar Stabilization**™ Procedure for Spinal Stenosis Surgery Post Decompression

coflex® – 1st Comparative Effectiveness Study in Stenosis!

All PMA studies are not the same – especially with 96% follow-up at 2 years. The *coflex*® study was designed as a prospective, randomized trial, which included independence of every activity (e.g. contract research organizations, data safety monitoring board, clinical events committee, biostatistician and core laboratory for radiographic analyses) in order to eliminate bias. More than 55,000 pages of patient CRFs, 12,000 radiographs and greater than 375,000 data points of Level 1 data were collected showing the *coflex*® benefits.

coflex® – A True Alternative to Fusion

The *coflex*® device outperformed fusion in nearly all clinical, radiographic, perioperative and health economic outcomes, measured through 589 data points evaluated for each individual study subject over a 2 year follow-up period. It has also demonstrated a lower overall surgical reoperation rate up to 4 years, as well as a lower rate of adjacent segment surgery at 2 years, compared to fusion.

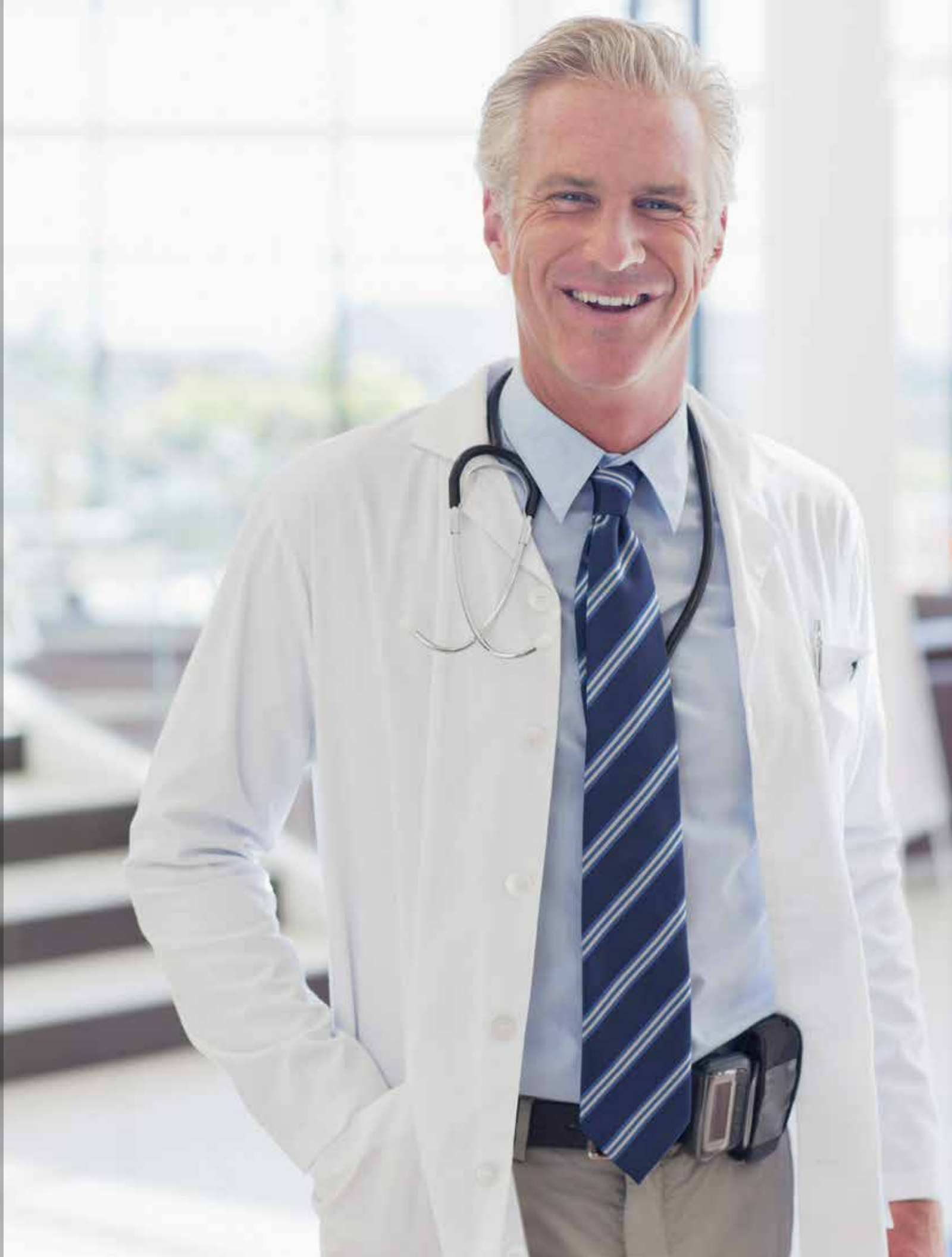
coflex® – Saves Everyone Money

The use of *coflex*® leads to a decrease in operative time, hospital length of stay and patients' blood loss. The *coflex*® procedure also provides an opportunity for outpatient surgery, a faster recovery and less narcotics to manage pain. It also controls costs, mitigates patient risk, delivers better patient outcomes and results in higher patient satisfaction compared to pedicle screw fusion.

coflex® – Intended Clinical Effect at Day 0

The intended clinical effect for *coflex*®, including direct surgical decompression, maintenance of foraminal height, and motion preservation, occurs at day zero compared to the unknown long-term effects of both failed and successful fusion after decompression.

1st ever prospective, randomized, controlled Level 1 study collecting comparative effectiveness data in spinal stenosis.



… FOR A GREATER PEACE OF MIND.

The ***coflex***® PMA study has demonstrated that the ***coflex***® procedure benefits both your patients and your practice by focusing on:

Your Time™

- On average, the surgery with ***coflex***® is an hour shorter than fusion surgery
- ***coflex***® patients were able to return home two days earlier compared to fusion patients
- ***coflex***® decreases the number of hospital rounds and follow-up visits
- ***coflex***® reduces stress on your surgical care team
- ***coflex***® offers the potential for outpatient surgery

Your Patient Success

- ***coflex***® patients were more satisfied with their outcomes compared to fusion patients
- More ***coflex***® patients would recommend the same treatment compared to fusion patients
- ***coflex***® preserves motion and maintains physiological kinematics in the adjacent segments

Your Efficiency

- Decreased cost per procedure
- Only a few surgical steps
- Very few instruments
- Neuro-monitoring unnecessary
- Significantly reduced intraoperative fluoroscopy
- No concern of non-union

The ***coflex***® procedure – for a greater peace of mind for everyone involved.

DESIGN RATIONALE

Over 15 years of clinical experience and almost 100,000 implantations worldwide have proven the clinical success of the ***coflex***® implant. This device is ideal for spinal stabilization after surgically addressing neural compression from soft and bony stenosis of the spinal canal.

Intelligent Implant Design

- Excellent fatigue strength and durability
- Single-piece design; no wear debris
- Easy 1 and 2-level implantation

Functionally Loading and Motion Preserving

- Compressible in extension, allowing flexion
- Increased rotational stability
- Center of rotation close to spinal canal
- Load-sharing design

Simplicity

- 5 anatomical sizes
- Color coded instrumentation
- Titanium alloy; biocompatible; X-Ray visible
- Crimping of wings for increased primary stability
- Less invasive, tissue-sparing procedure
- Easy and precise application

2 PART FUNCTIONAL DESIGN

Interlaminar Stabilization™

- Unique ***coflex***® design allows for deep insertion post surgical decompression
- Apex of "U" permanently maintains foraminal height and volume
- Offloads facets and posterior annulus

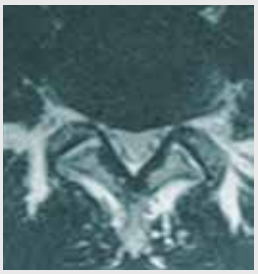
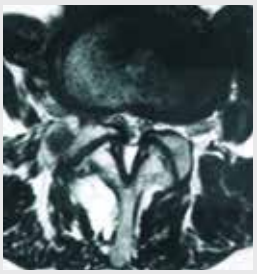
Motion Preservation

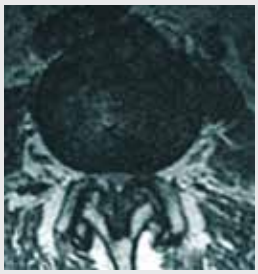
- ***coflex***® is compressible in extension
- Axial force shock absorption
- Maintains sagittal balance and lordosis
- Maintains physiological adjacent segment kinematics

INDICATION

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).

Please see Instructions For Use and Surgical Technique Manual for contraindications, warnings and precautions.

	Leg Pain	
	Back Pain	
	Instability	
		
PATIENT PROFILE	• Intermittent neurogenic claudication	• Intermittent neurogenic claudication
	• Insignificant back pain	• Insignificant back pain
	• Early or infrequent symptomatology	• Too sick for general anesthesia
TREATMENT	• Modification of daily activities	• Decompression
		• Interspinous distraction
	Stabilization	



• Mild to moderate stenosis	• At least moderate stenosis	• At least moderate stenosis	• Severe stenosis
• Insignificant back pain	• Significant back pain (> leg pain)	• Significant back pain (> leg pain)	• Dominant back pain
	• No instability	• Up to Grade I spondylolisthesis (stable)	• Unstable spondylosisthesis > Grade I
		• Degenerative lumbar scoliosis ≤ 25° Cobb Angle	• Degenerative lumbar scoliosis > 25° Cobb Angle
			• Unstable isthmic spondylolisthesis
• Decompression	• Decompression + *coflex*®		• Decompression + fusion

STUDY OVERVIEW

Introduction

In order to demonstrate the safety and effectiveness of the *coflex*® implant, **Paradigm Spine**® set out to develop the most rigorous clinical protocol that encompassed any and all questions regarding the possible data gathered throughout the study. In addition to developing a rigorous protocol, **Paradigm Spine**® wanted to establish the most comprehensive and scientific clinical study practices and conduct.

Study Design and Execution

The investigation was a prospective, randomized, multicenter, concurrently controlled comparison of the *coflex*® procedure to the current standard of care (posterolateral fusion with autograft and pedicle screw fixation), following surgical decompression in both groups. The objective of this clinical trial was to evaluate the safety and effectiveness of the *coflex*® device for the treatment of 1 or 2-level lumbar stenosis with or without degenerative spondylolisthesis up to Grade I, from L1–L5, that requires surgical decompression, and in patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain with back pain and who have undergone at least six months of conservative treatment.

215 randomized *coflex*® patients and 107 randomized control patients were enrolled in 21 investigational sites all across the United States.

A follow-up rate of nearly 96% underlines the credibility of the study findings. The primary success criteria was centered around measuring safety of the *coflex*® device (i.e. evaluating reoperations, revisions and major complications) and its effectiveness (i.e. pain and function before and after receiving the *coflex*® device). The patient had to demonstrate no safety failures and show improvement in pain and function to be a clinical success.

The *coflex*® clinical trial was conducted entirely per the United States FDA's Good Clinical Practices guidance. In order to prevent bias, at no time did **Paradigm Spine**® have any direct contact with the study data, data analysis process, or outcomes. All data management for this study was outsourced to completely independent, highly reputable third parties. The role of **Paradigm Spine**® was limited to ensuring each of these parties performed their duties in an efficient and timely manner, as well as coordinating Data Safety Monitoring Board (DSMB), Clinical Events Committee (CEC) meetings, and subject randomization.

215 *coflex*® vs. 107 Fusions 96% Follow-up

Inclusion Criteria

- Back pain with neurogenic claudication with at least moderate stenosis (L1 to L5) at 1 or 2 levels
- ODI > 40
- VAS LBP > 50
- Age 40 to 80
- Six months conservative care + ≥ 1 epidural injection

Exclusion Criteria

- Greater than 2 stenotic levels
- Previous fusion or multiple surgeries
- BMI > 40
- Bone density < –1.0 (Osteopenia/Osteoporosis)
- Scoliosis > 25° Cobb Angle
- Spondylolisthesis > Grade I
- Isthmic spondyloslisthesis

Data Collected Within the Study

- **Clinical**

  ODI, SF–12, ZCQ, VAS, operative details, demographics, etc.

- **Radiographic**

  ROM, disc heights, foraminal heights, bone resection analysis, fusion and lack of fusion, fractures, etc.

- **Safety**

  Collection and reporting of any adverse event that occurred during the course of the study

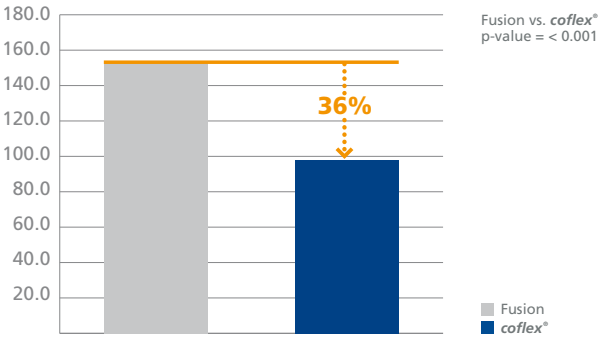
STUDY OUTCOMES

The study has shown that the ***coflex***® procedure outperformed fusion in nearly all outcome measures at 2 year follow-up. The following pages summarize the most relevant information of this study. For a further detailed summary, please reference the FDA Summary of Safety and Effectiveness Data (SSED).

Perioperative Outcomes

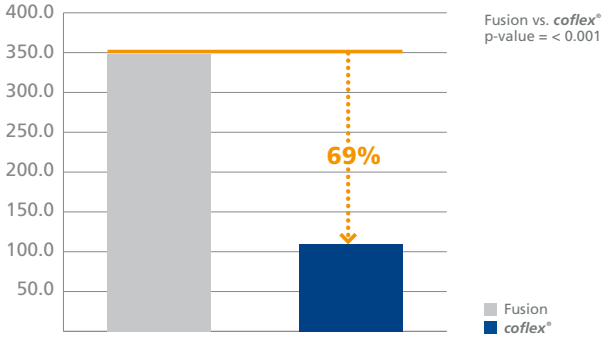
The ***coflex***® procedure has proven to decrease the length of surgery, hospital length of stay and, due to its less invasive application, the amount of blood loss during surgery.

Operative Time (minutes)*



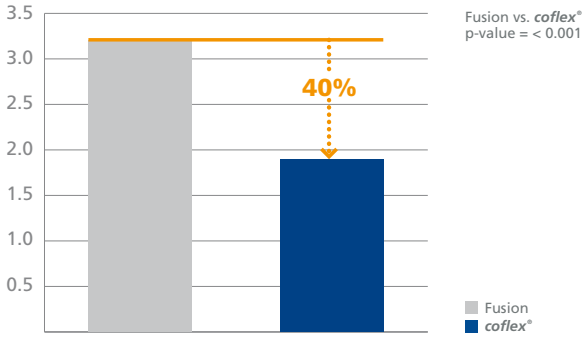
The use of the ***coflex***® device reduced the operative time by **36%** compared to fusion

Estimated Patients' Blood Loss During Surgery (cc)*



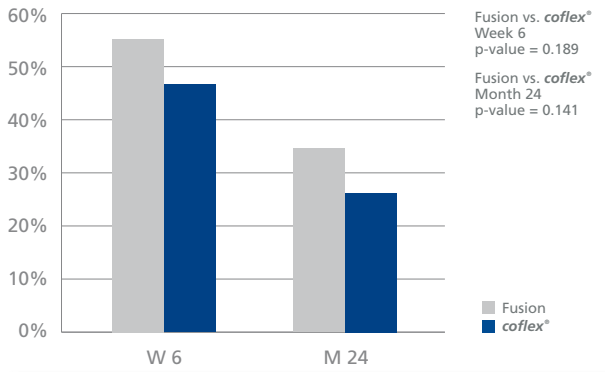
The use of the ***coflex***® device reduced the patients' blood loss by **69%** compared to fusion

Hospital Length of Stay (days)*



The use of the ***coflex***® device reduced the length of hospital stay by **40%** compared to fusion

Number of Patients Getting Post-Op Narcotics



Fewer ***coflex***® patients needed narcotics 6 weeks after surgery, which was sustained through 2 years, compared to fusion

FACT

The study has shown that the ***coflex***® procedure outperformed fusion in all perioperative outcome measures at 2 year follow-up!

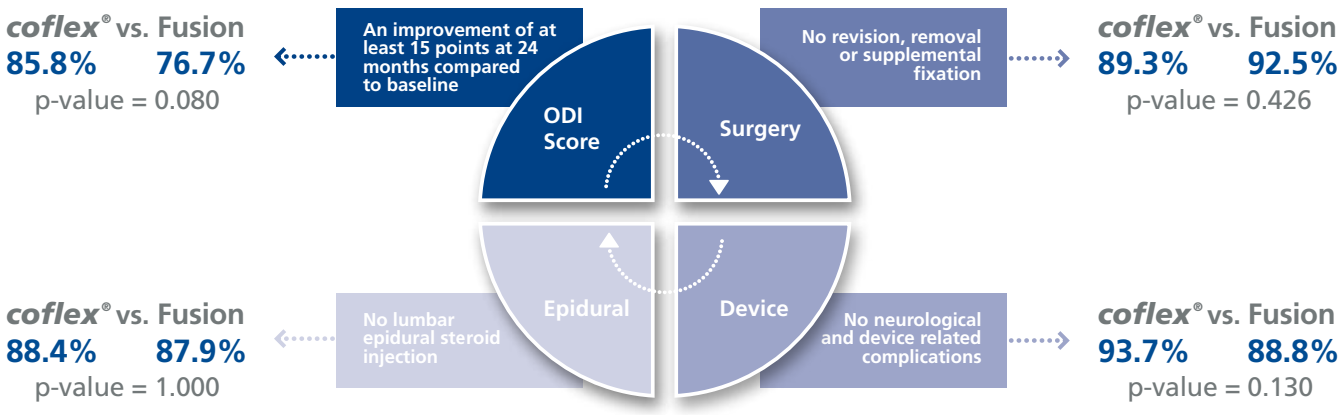
*Results were consistent between 1 and 2-level procedures.

Clinical Outcomes

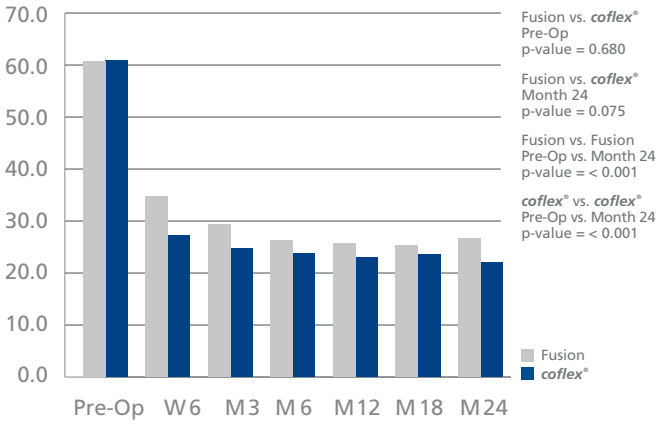
Primary Endpoint CCS Composite Clinical Success

Patients were deemed a clinical success if they had clinically significant improvement in pain and function (at least a 15-point improvement in Oswestry Low Back Pain Disability Index (ODI)); no revisions, reoperations, removals, or major device related complications (including permanent new or increasing sensory or motor deficit); and no epidural injections. A patient had to fulfill every single one of these criteria to be deemed a clinical success.

Criteria Defining the Composite Clinical Success (CCS)

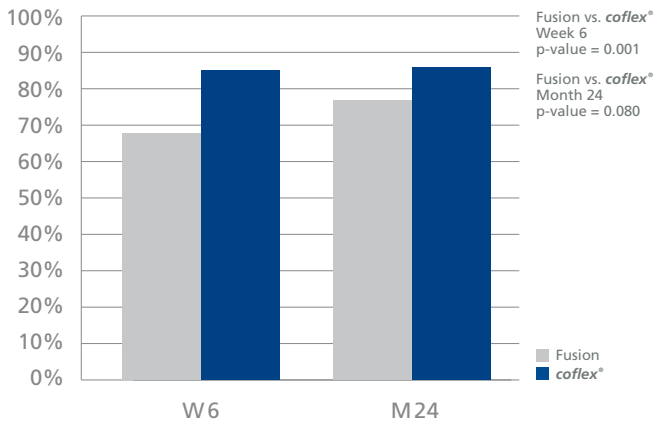


Overall Improvement After Two Years in ODI



coflex® patients outperformed fusion patients in ODI over the course of 2 years

Improvement of at least 15 points in ODI

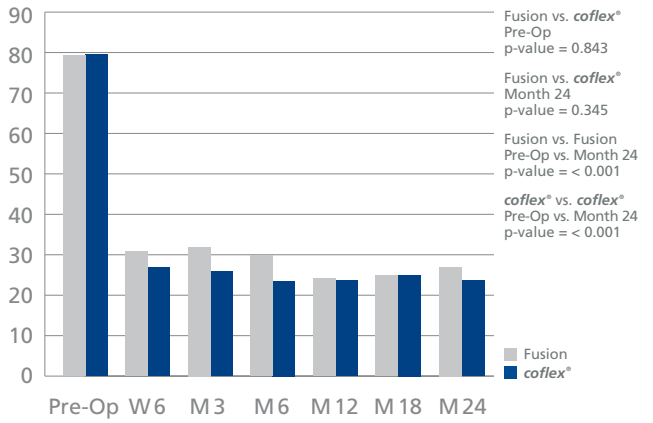


coflex® patients felt significantly better 6 weeks after surgery, which was sustained through 2 years, compared to fusion

FACT

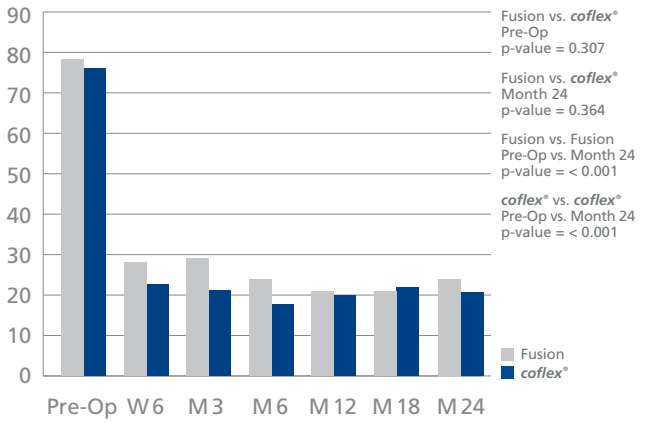
The study has shown that the **coflex®** procedure outperformed fusion in nearly all clinical outcome measures at 2 year follow-up!

Improvement VAS Back Pain



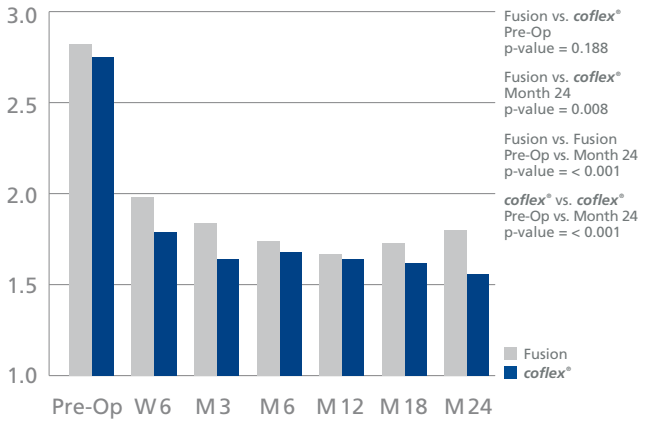
coflex® significantly decreased the degree of back pain

Improvement VAS Leg Pain (worse leg)



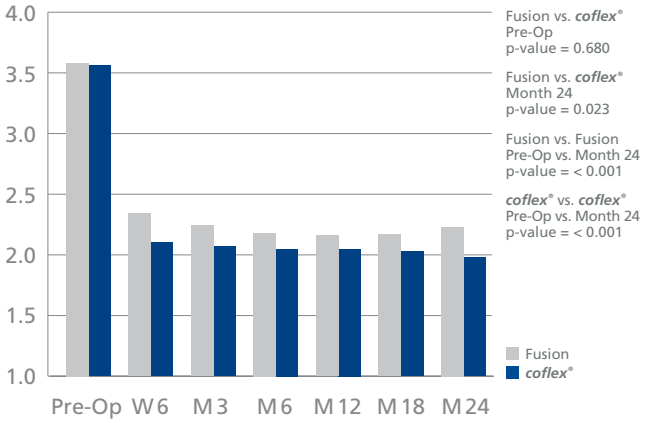
coflex® significantly decreased the degree of leg pain

Improvement ZCQ Physical Function



coflex® significantly improved the physical function

Improvement ZCQ Symptom Severity



coflex® significantly decreased the symptom severity

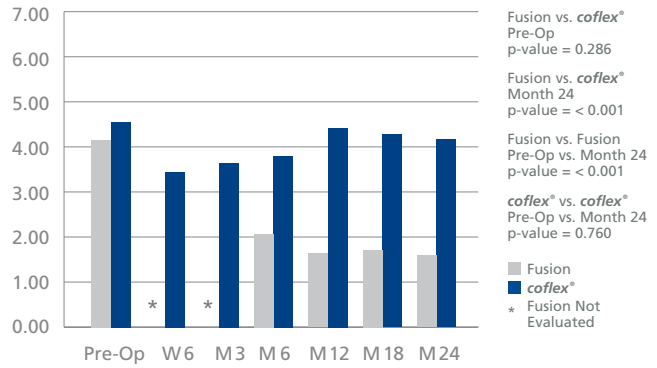
FACT

The study has shown that the associated back pain can be addressed effectively by ***coflex***®!

Radiographic Outcomes

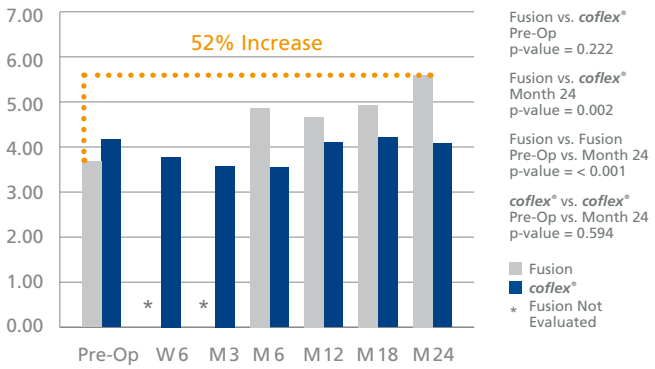
The *coflex*® device has been shown to maintain stability while still allowing for motion in the index level and maintaining physiological adjacent segment kinematics.

ROM at **Index** Level of Implant (degrees)



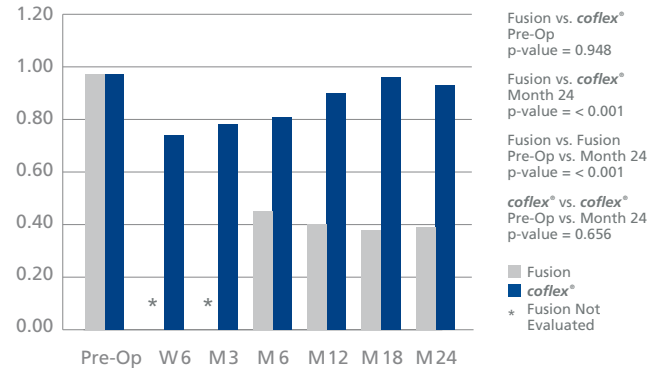
coflex® maintained motion at the index level at 24 months

ROM **Above** Level of Implant (degrees)



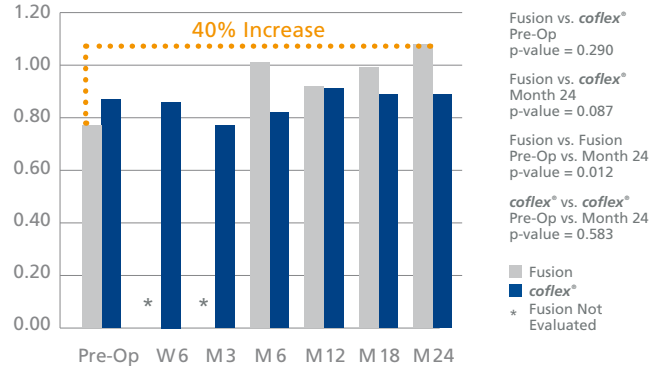
coflex® maintained physiological adjacent segment kinematics at 24 months

Translation at **Index** Level of Implant (mm)



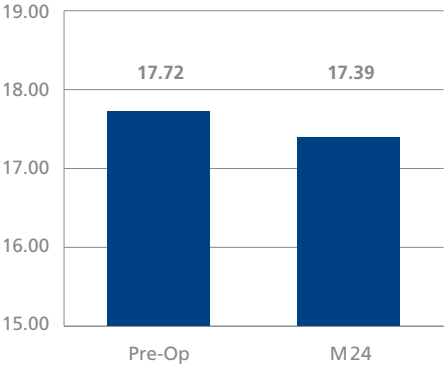
coflex® maintained translational motion at the index level at 24 months

Translation **Above** Level of Implant (mm)



coflex® maintained physiological adjacent segment kinematics at 24 months

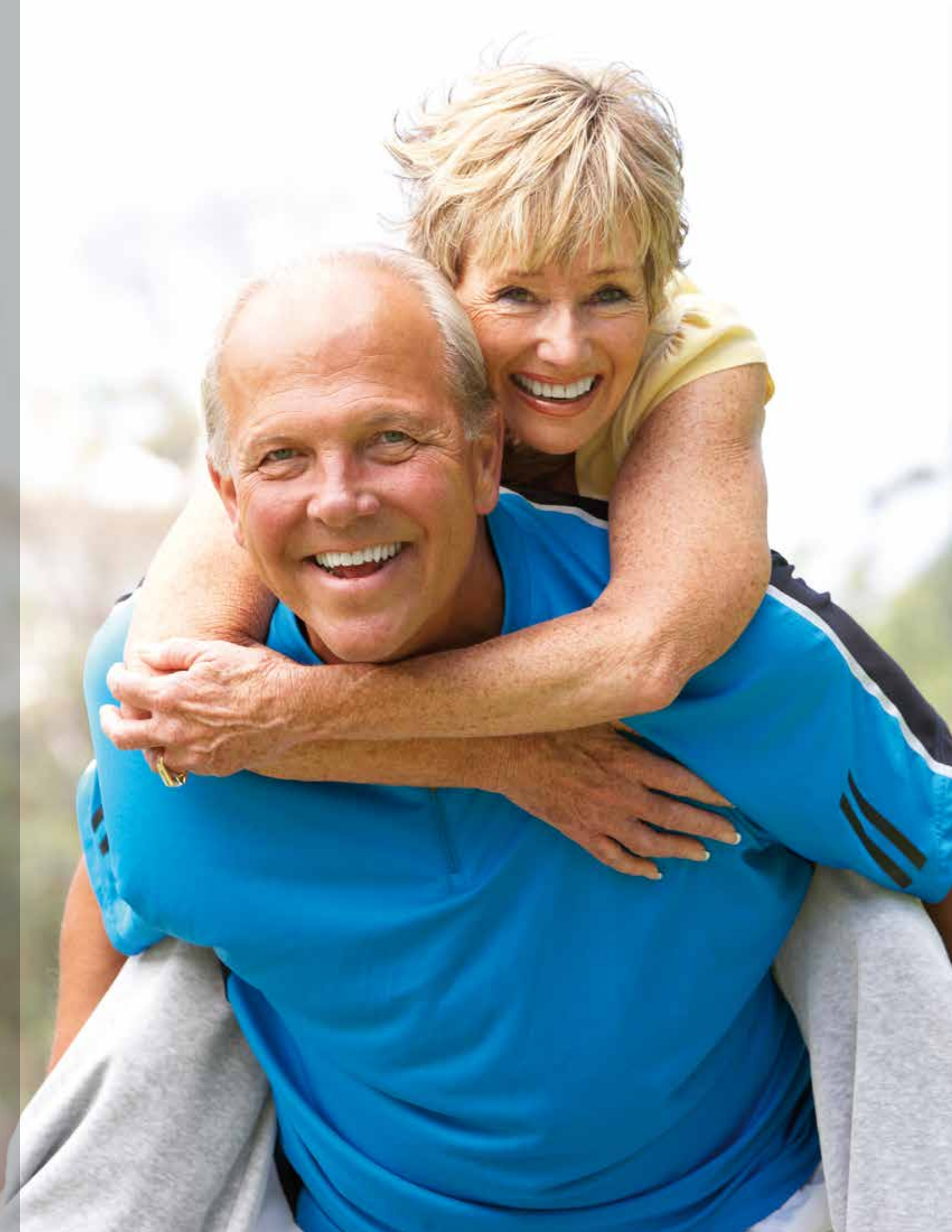
Foraminal Height – X-Ray Analysis (mm)



coflex® maintained foraminal height at 24 months

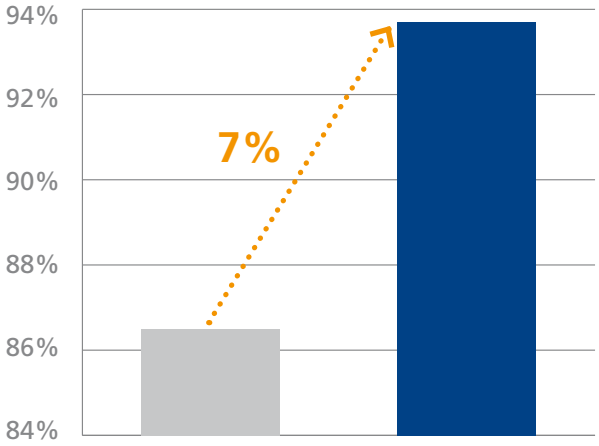
FACT

During the study, range of motion and translation were analyzed by a core radiographic laboratory, which found that ***coflex***® preserves index and adjacent level motion compared to pedicle screw fusion!



Patient Satisfaction

Patients That Were Satisfied With Outcome at 2 Years

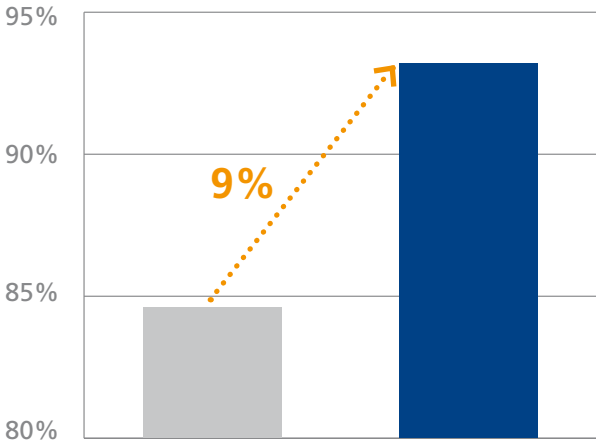


More patients were satisfied with the ***coflex***® procedure compared to fusion

Fusion vs. ***coflex***®
p-value = 0.052

Fusion
coflex®

Patients Who Would Recommend Same Treatment



More patients would recommend the ***coflex***® procedure compared to fusion

Fusion vs. ***coflex***®
p-value = 0.024

Fusion
coflex®

FACT

At 2 years after surgery, more ***coflex***® patients were satisfied with their outcome and would recommend the same treatment compared to fusion patients!

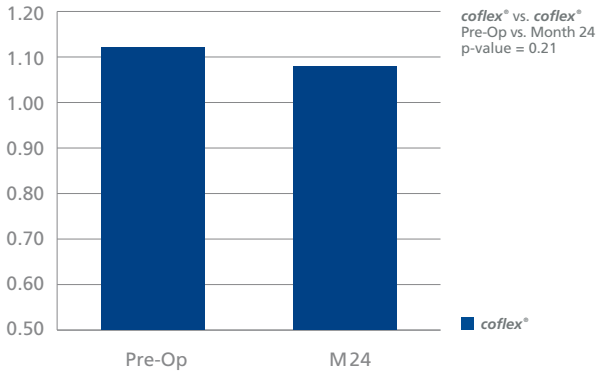
Spondylolisthesis Cohort Results

Among the 322 patients enrolled in the study, 150 (99 in the ***coflex***® group, 51 in control group) had a stable (no increase in slip from extension to flexion) up to Grade I spondylolisthesis. The average preoperative slip was approximately 9.2% in both study groups (p=0.999).

This section presents the overall result of the spondylolisthesis cohort of patients.

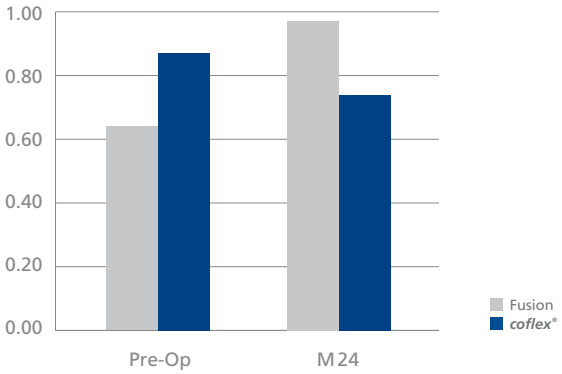
In summary, ***coflex***® stabilized the index level spondylolisthesis, with no significant increase in adjacent segment translation. In addition, ***coflex***® provided superior perioperative benefits and similar clinical outcome results compared to pedicle screw fusion. Interestingly, fusion stabilized the index level translation, but created a statistically significant increase in adjacent segment translation.

Translation at **Index** Level of Implant (mm)



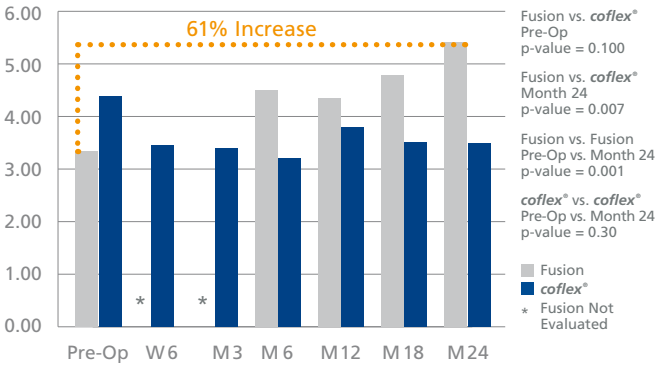
coflex® maintained translational motion at the index level

Translation **Above** Level of Implant (mm)



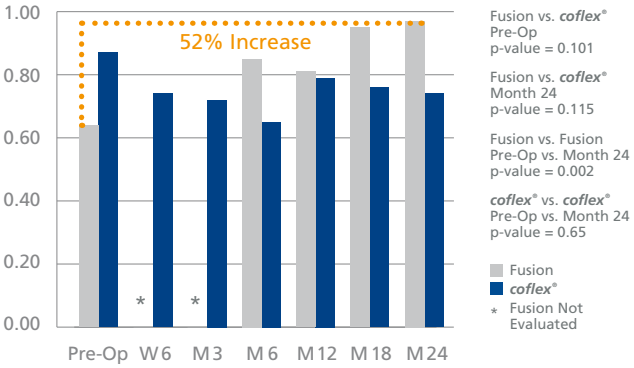
coflex® maintained physiological adjacent segment kinematics at 24 months

ROM **Above** Level of Implant (degrees)



coflex® maintained physiological adjacent segment kinematics at 24 months

Translation **Above** Level of Implant (mm)

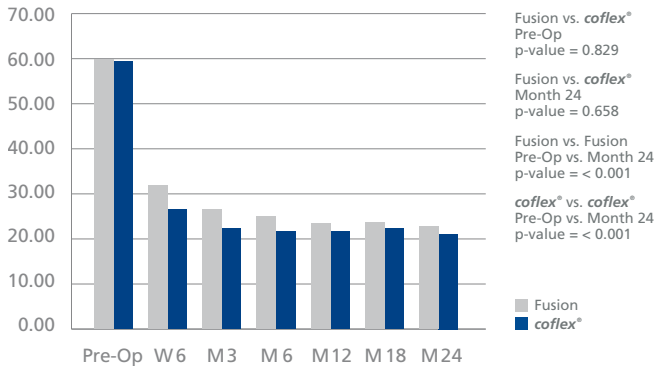


coflex® maintained physiological adjacent segment kinematics at 24 months

FACT

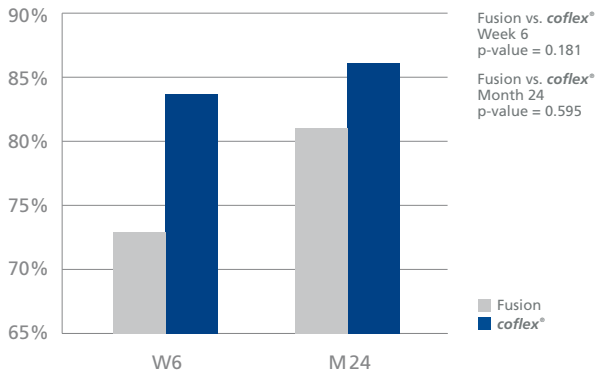
The study has shown that the ***coflex***® procedure outperformed fusion in nearly all clinical and radiographic outcome measures at 2 year follow-up in the spondylolisthesis cohort! The ***coflex***® device maintained physiological adjacent segment kinematics at 24 months!

Overall Improvement in ODI After Two Years



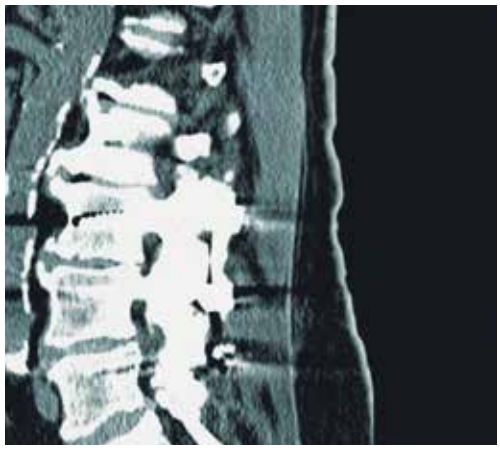
coflex® patients outperformed fusion patients in ODI over the course of 2 years

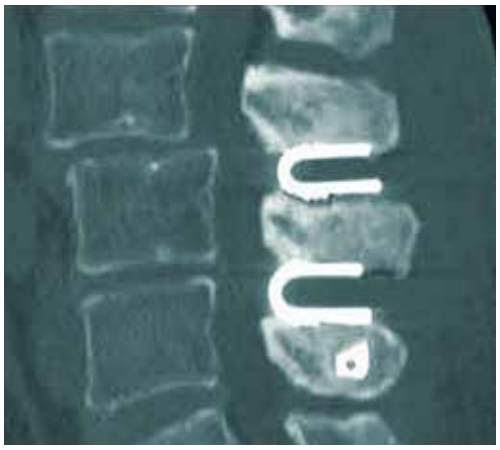
Improvement of at least 15 points in ODI



coflex® patients felt better 6 weeks after surgery, which was sustained through 2 years, compared to fusion

FIXATION vs. STABILIZATION





Fixation Shortcomings*

- Increased hypermobility in the adjacent segment
- Increased rate of adjacent segment surgery at 2 years
- More invasive and time consuming procedure
- Increased revision and reoperation rates after 2 years

Stabilization Advantages*

- Stabilizes while preserving motion at the index level
- Preserves physiological kinematics at the adjacent level
- Provides additional stabilization over time
- Allows for faster pain relief (at 6 weeks)

Interlaminar Stabilization™ provides stability without the shortcomings of fixation.

*Based on the outcomes of the *coflex*® Interlaminar Technology PMA (P110008).

Safety

An independent Data Safety Monitoring Board (DSMB) evaluated the safety profile of the ***coflex***® study on a quarterly basis to ensure that patient safety was not compromised.

All adverse events were independently reviewed and blindly adjudicated by a Clinical Events Committee (CEC), with their decision binding. All radiographs were analyzed by an independent core lab (Medical Metrics, Inc.).

Table 1: Incidence of Adverse Events *coflex*® and Fusion Control Efficacy Evaluable (PP) Cohort

	coflex® (N=215)	Control (N=107)	p-values
Operative Site			
Pain; new, + frequency, worsening	33.0%	34.6%	0.803
Wound problems[1]	14.0%	8.4%	0.204
Fracture[2]	5.1%	1.9%	0.233
Other[3]	4.2%	2.8%	0.757
Component loosening	1.4%	3.7%	0.227
Component migration	1.4%	0.9%	1.000
Component breakage	0.9%	1.9%	0.602
Infection (deep)	0.9%	0.0%	1.000
Component deformation	0.0%	0.0%	-
Incidental durotomy (≤ 5mm)	0.0%	0.0%	-
Nerve injury	0.0%	0.0%	-
Pseudarthrosis	0.0%	0.0%	-
Vascular injury	0.0%	0.0%	-
Tear > 5mm	0.0%	0.0%	-
Heterotopic ossification	0.0%	0.0%	-
Hematoma requiring drainage	0.0%	0.9%	0.332
Non-Operative Site			
Musculoskeletal[4]	56.3%	60.7%	0.474
Neurological[5]	23.7%	21.5%	0.676
Other[6]	13.5%	15.0%	0.735
Cardiovascular	9.8%	10.3%	1.000
Gastrointestal	7.0%	11.2%	0.206
Skin and Subcutaneous Tissue	6.5%	8.4%	0.646
Genitourinary	6.0%	8.4%	0.484
Respiratory	4.2%	5.6%	0.582
Endocrine/Metabolic	3.7%	3.7%	1.000
Cancer/Neoplasm	2.8%	8.4%	0.045
EENT	2.8%	3.7%	0.736
Hematological	2.3%	3.7%	0.487
Immune	0.5%	0.0%	1.000
Psychiatric/Substance abuse	0.5%	6.5%	0.002

Table 1 shows the comparison of complications between ***coflex***® and fusion Per Protocol cohorts at specific operative and non-operative sites. With the exception of wound problems, adverse event rates were comparable between ***coflex***® and fusion.

The numerical difference of wound complications between ***coflex***® 14.0% (30/215) and control 8.4% (9/107) was 5.6%. This difference was not statistically significant.

[1] Wound problems: Includes wound drainage, superficial infections, dehiscence, seroma and delayed healing of incision.

[2] Fracture: Includes spinous process fracture, pars fracture and other fractures of the vertebral bodies reported by investigators.

[3] Other Operative Site: Includes events not placed into a specific category by investigators, including clicking sound, spondylolisthesis, drain complications, incisional pain, spinal swelling and cellulitis.

[4] Musculoskeletal: Includes weakness, cramping, joint pain, joint surgery or replacement and other non-lumbar spinal musculoskeletal tissues.

[5] Neurological: Includes balance problems, headaches, numbness and/or tingling and changes in sensation.

[6] Other Non-Operative Site: Includes psychological disorders, infectious diseases, insomnia and fever.

Spinous Process Fractures

Spinous process fractures were observed by the core radiographic laboratory in 30 ***coflex***® patients (14.0%) and 8 fusion patients (11.9% of patients with spinous processes retained by partial laminectomy). Spinous process fractures were also observed by the investigator surgeons. The incidence of fractures observed by the surgeons differed from that observed by the core radiographic laboratory, as 8 ***coflex***® patients (3.7%) and no fusion patients (0.0%) had spinous process fractures noted by the investigational sites.

83% of patients in the ***coflex***® group and 75% of patients in the fusion group, who had spinous process fractures observed by the radiographic laboratory, did not have any associated symptoms at the time the fracture was observed. Table 2 and Table 3 detail the incidence of spinous process fractures in ***coflex***® and fusion patients.

Table 2: Spinous Process Fracture Incidence in the ***coflex***® IDE Study

	coflex®		Fusion Control	
	n/N	%	n/N	%
Spinous Process Fracture	30/215	14.0%	8/67[1]	11.9%

[1]Fusion patients with spinous processes retained by partial laminectomy.

Table 3: Time Course of Spinous Process Fracture Incidence in the ***coflex***® IDE Study

Group	Time of Initial Fracture Observation							Total
	Post-op	6 W	3 M	6 M	12 M	18 M	24 M	
coflex®	5	13	6	1	-	-	5[1]	30
Fusion Control	4	2	2	-	-	-	-	8

[1]3 out of the 5 observations at 24 months had unreadable or missing 6 week, 3 month, 6 month, 12 month and 18 month X-rays.

By month 24, 48% of the ***coflex***® spinous process fractures were resolved. Of the unresolved spinous process fractures, 75% were asymptomatic and resulted in no clinical sequelae or loss of foraminal height during the study. None (0%) of the fusion spinous process fractures were resolved by month 24 and 75% of these patients were asymptomatic.

The adverse event rate associated with spinous process fractures was not significantly higher than that of patients without spinous process fractures. The long-term effects of these spinous process fractures past 24 months are unknown.

The ***coflex***® IDE study has demonstrated that an over-decompression can destabilize the spine or possibly lead to subsequent spinous process fractures. Especially the resection of the spinous process to ≤ 14mm can increase the incidence of postoperative spinous process fracture. Other possible predictors for spinous process fractures are the height of the spinous process ≤ 23mm preoperatively, "kissing" spinous processes, or poor bone quality.

Safety (continued)

Reoperations and Revisions

Through 24 months of follow-up, the overall reoperation rate was 10.7% in the ***coflex***® group and 7.5% in the fusion control. A reoperation is any surgical procedure at the involved level(s) that does not remove, modify, or add any components to the system, whereas a revision is a procedure that adjusts or in any way modifies or removes part of the original implant configuration, with or without replacement of a component. Reoperations where the device was maintained are summarized in Table 4 and revision surgeries are summarized in Table 5.

Table 4: Reoperation Events in the ***coflex***® study

Treatment Group	Event Time Course (months)							Total
	< 1.5	1.5–3	3–6	6–12	12–24	24–36	36–48	
coflex®	5	-	-	1	1	2	2	11
Fusion	1	-	-	-	-	3	1	5[1]

[1] A single fusion patient had 2 operations for deep infection

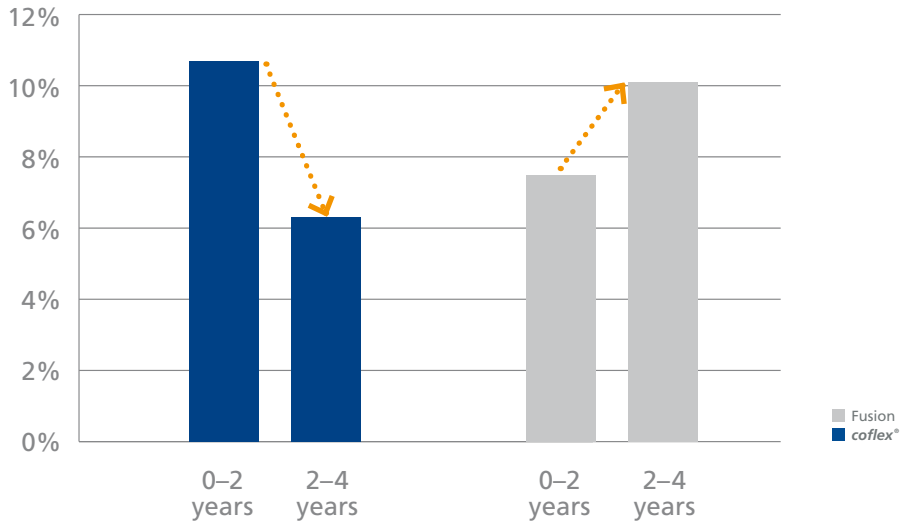
Table 5: Revision Events in the ***coflex***® study

Treatment Group	Event Time Course (months)							Total
	< 1.5	1.5–3	3–6	6–12	12–24	24–36	36–48	
coflex®	1	2	2	5	8	6	3	27[1]
Fusion	-	1	1	2	5	3	5	17[2]

[1] Three ***coflex***® patients had a transition to fusion after a previous reoperation or replacement of ***coflex***®

[2] A single fusion patient had 2 revisions for broken pedicle screws

Reoperations and Revision Trends



Through 24 months, the reoperations and revisions in the ***coflex***® group included 5 irrigation and debridement procedures (including 1 cerebrospinal fluid leak), 2 supplemental decompression surgeries retaining the device, 2 revisions for ***coflex***® removal & replacement, 2 decompressions and device removal, 1 debridement and device removal and 13 (6.0%, 13/215) conversions to primary fusion. Two patients had a reoperation prior to a revision. There were no revisions related to device breakage.

Through 24 months, the reoperations and revisions in the fusion control group included 1 reoperation due to post-operative hematoma, 4 revisions of the fusion system due to device breakage or component loosening and 5 extensions of the fusion to an adjacent segment.

Between 24 months and 48 months of follow-up, there were 13 additional reoperations or revisions in 12 ***coflex***® patients (6.3%, 12/192) and 12 additional reoperations or revisions in 10 fusion patients (10.1%, 10/99). One of each of the ***coflex***® and fusion revisions was in a patient who had a reoperation prior to 2 years. Based on available patient data through 48 months, the ***coflex***® revision rate is 15.8% and the fusion control revision rate is 15.9%. The analysis of the data from follow-up beyond 24 months was not considered in the approval decision for the ***coflex***® device.

There were no statistical differences between the ***coflex***® and fusion groups with regards to the rate of any severe complications, device related complications, or surgery related complications.

However, the revision rate in the adjacent, non-operated segment was significantly higher with the fusion patients.

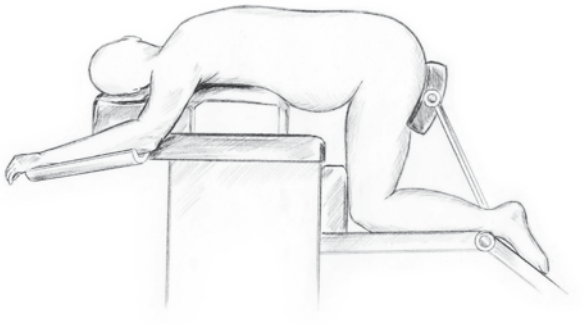
SURGICAL STEPS

IMPORTANT: See Surgical Technique Manual for detailed instructions, including all warnings and precautions, that are involved with implanting the ***coflex***® **Interlaminar Stabilization**™ technology.

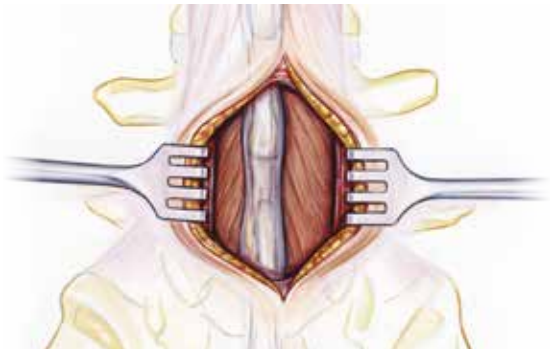
Patient Preparation and Decompression

The patient is placed in prone position on a surgical frame avoiding hyperlordosis of the spinal segment(s) to be operated on.

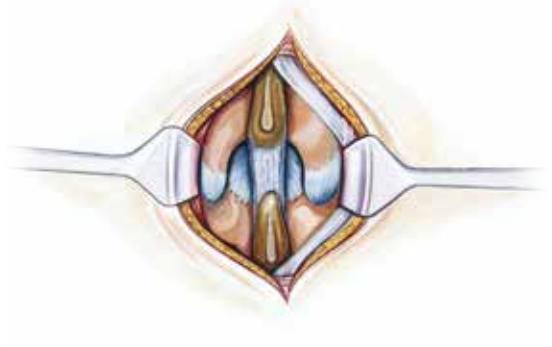
For the surgical decompression as well as for appropriate interspinous distraction, a neutral position or a slight kyphosis may be advantageous.



Paramedian or midline approach is taken with preservation of the surpaspinous ligament.



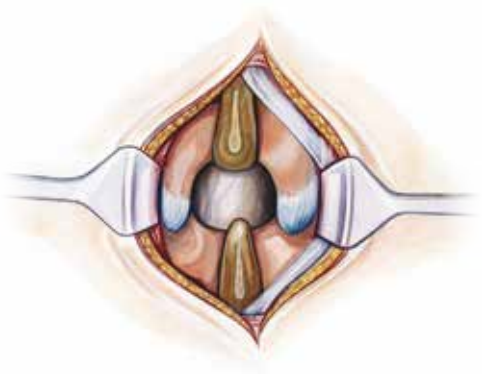
The muscle is sharply dissected lateral to the supraspinous ligament preserving the entire thickness of the supraspinous ligament.



The basic surgical approach entails a midline incision and reflection of the suprapsinous ligament. For a minimally invasive approach, this reflection of tissues extends to the base of the spinous process, which affords microsurgical access through the ligamentum flavum into the spinal canal. For an open approach, this reflection of tissues extends to the facet capsules affording total access to the entirety of the posterior elements.

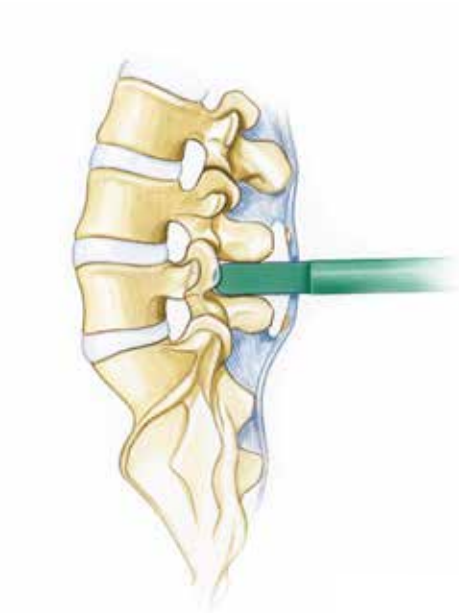
The interspinous ligament is sacrificed and any bony overgrowth of the spinous process that may interfere with insertion is resected.

Ligamentum flavum is resected and microsurgical decompression is performed, relieving all points of neural compression.



Insertion of the *coflex*® Implant

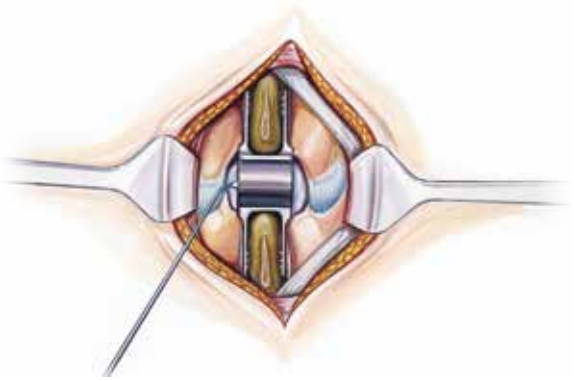
Trials are utilized to define the appropriate implant size. The trial instrument is placed to evaluate proper contact with the spinous process and the amount of facet distraction. Some bony resection of the spinous process may be needed to ensure proper contact of the implant.



Prior to insertion, the wings may need to be opened slightly using the bending plier to ensure appropriate depth of insertion.

The implant is introduced via impaction utilizing a mallet.

Proper depth is determined if a ball tip probe can be passed freely leaving 1–2mm separation from the dura.

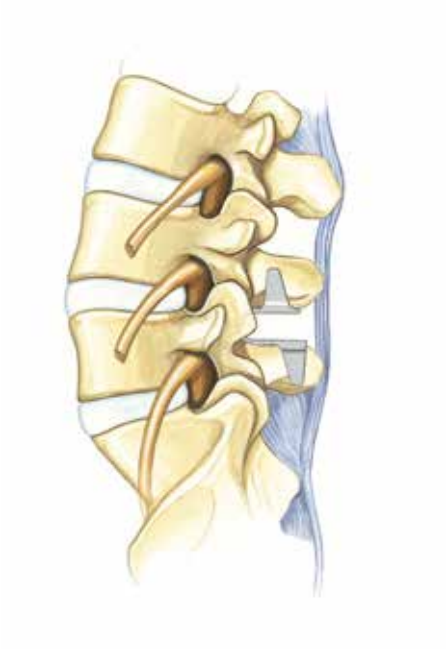


Once proper placement has been achieved, it is recommended to securely crimp the wings of the implant using the crimping plier.

In case of ligament reconstruction, the fascia and the supraspinous ligament can be closed in one layer over the spinous processes. A surgical drain may be placed as per surgeons' preference. Paraspinal muscles are reattached to the supraspinous ligament. Skin is closed in the usual manner.

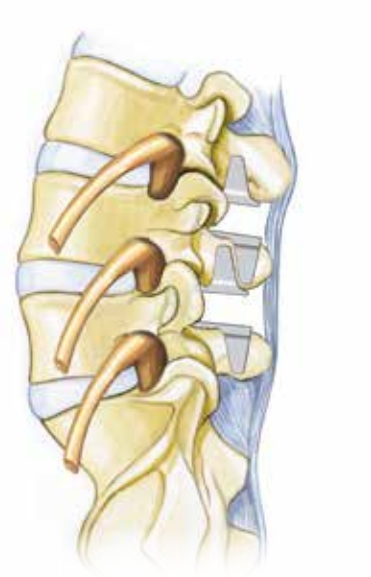
One Level Implantation

By deeply inserting the ***coflex***® implant at the level of the facet joints, the implant counteracts the majority of posterior column forces (interlaminar positioning).



Two Level Implantation

If a two level decompression is mandated, the ***coflex***® implants must be sequentially placed to the appropriate depth avoiding an overlap (contact) of one pair of wings upon the other. The ***coflex***® device is indicated for implantation at 2 contiguous levels.



PATIENT CASES

Case 1

Pre-Op neutral

48-month neutral

Spinal Stenosis With Early Spondylolisthesis

QOL Evaluation	Pre-Op	W 6	M 3	M 6	M 12	M 18	M 24	M 36	M 48
ODI	58	12	0	4	0	0	12	6	0
VAS LBACK	65	0	0	4	2	1	19	*	1
VAS LLEG	31	0	0	0	2	0	1	*	1
VAS RLEG	74	1	0	0	2	1	1	*	2
ZCQ SV	3.00	1.43	1.00	1.43	1.00	1.00	1.57	1.00	1.00
ZCQ PF	3.00	1.20	1.00	1.00	1.00	1.00	1.00	1.00	1.00
ZCQ SF	*	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
SF-12 PCS	33	39	56	56	55	56	55	56	56
SF-12 MCS	59	61	56	58	55	56	55	58	58

Male, 52 years:

- Symptoms: 18 months of lower extremity pain and back pain. Symptoms have been worsening. Conservative treatment failed.
- Examination: Diminished range of motion of lumbar spine. No tenderness to palpation along the lumbar spine, paraspinal muscles or into his S1 region.
- Diagnosis: Lumbar stenosis at L4/5 with Grade I spondylolisthesis confirmed on CT and MRI.
- Surgery: Decompression of lateral recess; removal of hypertrophied ligamentum flavum; posterior stabilization with *coflex*®.

ODI	Oswestry Disability Index
VAS LBACK	Visual Analog Score Low Back
VAS LLEG	Visual Analog Score Left Leg
VAS RLEG	Visual Analog Score Right Leg
ZCQ SV	Zurich Claudication Questionnaire Symptom Severity
ZCQ PF	Zurich Claudication Questionnaire Physical Function
ZCQ SF	Zurich Claudication Questionnaire Patient Satisfaction
SF-12 PCS	Short Form 12 Health Survey Physical Component Summary
SF-12 MCS	Short Form 12 Health Survey Mental Component Summary

*Data not evaluated.

PATIENT CASES

Case 2

Pre-Op neutral

36-month neutral

Case 3

Pre-Op neutral

48-month neutral

Spinal Stenosis With Spondylolisthesis

QOL Evaluation	Pre-Op	W 6	M 3	M 6	M 12	M 18	M 24	M 36
ODI	70	20	34	58	0	0	0	0
VAS LBACK	92	4	14	75	3	2	1	2
VAS LLEG	18	1	1	2	2	7	1	1
VAS RLEG	91	12	19	80	2	9	1	2
ZCQ SV	4.29	1.43	1.57	3.57	1.00	1.00	1.00	1.14
ZCQ PF	3.40	2.00	2.40	2.60	1.20	1.20	1.20	1.20
ZCQ SF	*	1.17	1.83	1.83	1.00	1.00	1.00	1.00
SF-12 PCS	26	32	34	31	*	66	54	59
SF-12 MCS	35	66	40	35	*	31	57	52

Female, 66 years:

- Symptoms: Greater than 2 years history of back pain with increasing inability to walk in her neighborhood and any distance. Leg pain increases with exercise and standing.
- Examination: Pain with twisting and increasing pain with extension. Prefers forward flexion. No radiculopathy at rest.
- Diagnosis: Lumbar spinal stenosis at L4/5 with Grade I spondylolisthesis confirmed on CT and MRI.
- Surgery: Direct lumbar decompression, bilateral laminotomies at L4/5; posterior stabilization with ***coflex***®.

Two Level Stenosis, One Level With Stable Spondylolisthesis

QOL Evaluation	Pre-Op	W 6	M 3	M 6	M 12	M 18	M 24	M 36	M 48
ODI	64	24	16	0	0	0	0	0	0
VAS LBACK	100	25	7	0	0	0	0	0	0
VAS LLEG	95	0	0	0	*	0	0	0	0
VAS RLEG	95	0	1	0	*	0	0	0	0
ZCQ SV	3.86	2.00	1.71	1.14	1.43	1.14	1.14	1.14	1.14
ZCQ PF	2.80	1.80	1.40	1.20	1.00	1.00	1.00	1.00	1.00
ZCQ SF	*	1.17	1.33	1.00	1.00	1.00	1.00	1.00	1.00
SF-12 PCS	23	39	*	56	56	57	57	56	57
SF-12 MCS	60	60	*	53	53	58	58	56	55

Male, 62 years:

- Symptoms: Long history of back and leg pain, with increasing numbness and buzzing sensations in both legs with walking. Cannot walk to corner. Has to sit to get relief of symptoms.
- Examination: Limited flexion and extension, poor rotation. No radiculopathy. Pulses are good at rest.
- Diagnosis: Lumbar spinal stenosis at 2 levels L3/4 and L4/5 confirmed on CT and MRI, L4/5 with Grade I spondylolisthesis
- Surgery: Two level laminotomies L3/4 and L4/5 right and left and direct decompression; L3/4 and L4/5 posterior stabilization with ***coflex***®.

*Data not evaluated.

PRODUCT INFORMATION

Sterilization Tray

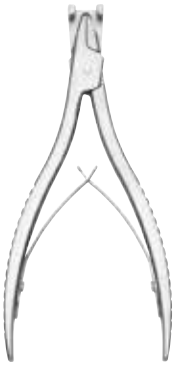
UBC00000

Trials

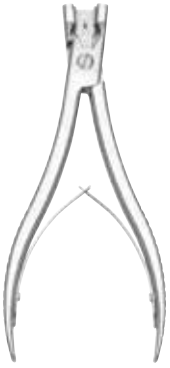
Color Code	Size	Article Number
	16mm	UBT10016
	14mm	UBT10014
	12mm	UBT10012
	10mm	UBT10010
	8mm	UBT10008

Material: Medical grade acetal copolymer

Instruments



Bending Plier
UAT10100

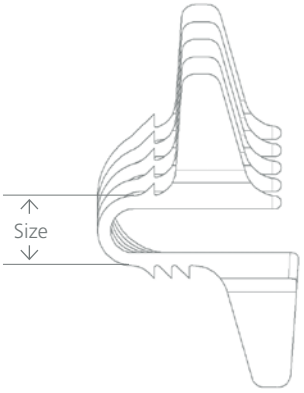


Crimping Plier
UAT10200

Mallet
UAT20100

coflex® Implant

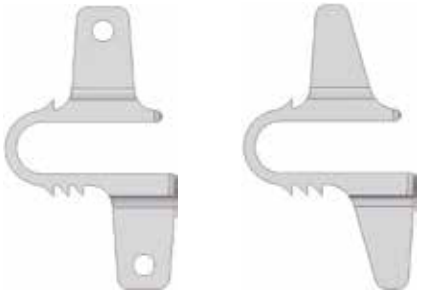
Color Code on Implant Box	Size	Article Number
	16mm	UQI00016
	14mm	UQI00014
	12mm	UQI00012
	10mm	UQI00010
	8mm	UQI00008



Material:
Wrought titanium 6-aluminium 4-vanadium alloy according to ISO 5832-3

The *coflex*® implant is delivered in sterile packaging.

During the course of the clinical trial, the wings were modified slightly for ease of stacking two devices at adjacent levels. The holes in the wings were also removed. The modification was not the result of any clinical problems, safety issues or adverse events, product complaints, or surgeon requests from within or outside the United States. As this modification was minor, it did not affect the mechanical behavior of the device or the anticipated clinical outcome.



Old Design

New Design

INTELLECTUAL PROPERTY

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UPM10002 Rev. C

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