Retrospective Evaluation of the Clinical and Radiographic Performance of coflex® Interlaminer Technology Versus Decompression With or Without Fusion.

Study ID Number: CRDC2016

Version 5.0

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Study Phase: Post-Market

Paradigm Spine

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Change History

Version	Version Date	Summary of Changes
1.0	14June2016	Original
2.0	28June2016	Data collection to include 1 or 2 level decompression with or without fusion.
3.0	11July2016	Protocol title to reflect evaluation of coflex versus efficacy.
4.0	19August2016	Study Start Date and End Date applicable for Baptist IRB
5.0	22Novmeber2016	Data collection to include 5000 patients from 50 sites. Primary and Secondary Endpoints.

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Investigator Signature Page

My signature below attests that I have read the contents of this protocol and agree to conduct the study according to the protocol and that the study will not be initiated without the approval of the appropriate Institutional Review Board or Independent Ethics Committee.

Investigator:

Print Name:	Signature:	Date:
_____	_____	_____

Protocol Summary

Study Title	Retrospective Evaluation of the Clinical and Radiographic Performance of coflex® Interlaminar Technology Versus Decompression With or Without Fusion.
Purpose	To evaluate clinical, radiologic and patient-reported outcomes who have been treated 1 or 2 levels with the coflex® Interlaminar Technology or decompression with or without fusion.
Study Design	Retrospective, multi-center, post-market clinical study
Devices	coflex® Interlaminar Technology
Data Collection	Clinical, radiologic and patient reported outcomes data will be collected for approximately 5000 patients from 50 sites
Study Duration	Up to 6 months for data collection Start Date: June 2013 End Date: April 2017
Study Objectives	Primary Objective: • To assess the operative details and safety outcomes associated with the use of the coflex device • To assess post-operative adverse events • To assess post-operative follow-up duration Secondary Objectives: • To measure and compare patient reported outcomes (e.g., VAS, Patient Satisfaction and ODI) at baseline and final follow-up • To measure and compare clinical and radiologic outcomes at baseline and final follow-up • To measure and compare the clinical, radiologic, and patient reported outcomes at interim follow-up visits • To assess the impact of demographics and risk factors on clinical, radiologic, and patient reported outcomes •
Inclusion Criteria	Patients must meet the criteria specified in the device labeling including radiographic confirmation of at least moderate lumbar stenosis, which narrows the central spinal canal at one or two contiguous levels from L1-L5 that require surgical decompression.
Exclusion Criteria	There are no exclusion criteria's for this study.

Risk/Benefit Assessment	The study is a retrospective analysis of medical records that poses no risk to the patients and minimal risk to loss of patient privacy. All results will be de-identified in the process of data review. There are no benefits to the subject as this data is being collected to obtain additional clinical evidence to support publications and marketing.

Study Abbreviations

Abbreviation	Definition
BMI	Body Mass Index
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICH	International Committee on Harmonization
IRB	Institutional Review Board
MRI	Magnetic Resonance Imaging
CT	Computed Tomography
DEXA	Dual Energy X-ray Absorptiometry

1.0 Introduction

The coflex® Interlaminar Technology - manufactured by Paradigm Spine - is intended for use as a permanent implant between the lamina of 1 or 2 lumbar motion segments in the treatment of moderate to severe lumbar spinal stenosis. The device is specifically designed to provide stabilization without fusion in cases of stenosis with or without facet joint hypertrophy, subarticular recess stenosis or foraminal stenosis. It is restricted for use to one or two levels in the region of L1 – L5.

The height of the neuroforamen is maintained and the facet joints will be relieved. By this a further destruction is prevented. Unlike conventional stabilization methods as for example spinal fusion, the function of the segment will be maintained and adjacent structures will be effectively protected.

Possible risks, which could occur after implantation of the coflex® Interlaminar Technology are breakage of the implant, displacement of the implant, pain which is caused by the implant, infections, bleedings and hematoma. The benefit of the study lies in the fact that first-time retrospective data is raised for potential improvement regarding therapy of lumbar back pain with the treatment of the lumbar spinal stenosis, which, in the future, can lead to an improvement of the therapy.

In this study, Paradigm Spine will retrospectively collect clinical and radiographic data for patients treated with the coflex® Interlaminar Technology during normal conditions of use. This data will provide evidence to support publications and marketing.

2.0 Study Purpose

2.1 Primary Objective

- To assess the operative details and safety outcomes associated with the use of the coflex device
- To assess post-operative adverse events
- To assess post-operative follow-up duration

2.2 Secondary Objectives

The secondary objectives of this study are:

- To measure and compare patient reported outcomes (e.g., VAS, Patient Satisfaction and ODI) at baseline and final follow-up
- To measure and compare clinical and radiologic outcomes at baseline and final follow-up
- To measure and compare the clinical, radiologic, and patient reported outcomes at interim follow-up visits
- To assess the impact of demographics and risk factors on clinical, radiologic, and patient reported outcomes

3.0 Eligibility Criteria

3.1 Inclusion criteria

Patient considered for enrollment in this study must meet all of the following inclusion criteria:

- Patients must meet the criteria specified in the device labeling including radiographic confirmation of at least moderate lumbar stenosis, which narrows the central spinal canal at one or two contiguous levels from L1-L5 that require surgical decompression.

3.2 Exclusion criteria

There are no exclusion criteria for this study.

4.0 Study Design

This is a retrospective, multi-center, post-market study collecting clinical, radiographic, and patient reported outcomes for subjects who have been treated 1 or 2 levels with the coflex® Interlaminar Technology or decompression with or without fusion.

4.1 Endpoints

Patient reported outcomes will be assessed as part of the primary objective.

Clinical and radiologic outcomes, demographics and risk factors will be assessed as part of the secondary objectives. These include, but are not limited to:

- Age
- Gender
- Ethnicity
- Height and Weight
- BMI
- Narcotics use
- Comorbidities
- Bone Density
- Presenting Symptoms
- Radiologic Data (Anterior/Posterior and Flexion/Extension films, as well as, MRI and/or CT Scan used to confirm diagnosis of spinal stenosis)
- Operative Data
- Intra-Operative Complications
- Return to Work
- Changes in Activities of Daily Living (ADL)
- Patient Satisfaction
- Repeat Surgery Details

4.2 Data Collection Summary

Subjects will have undergone a decompression surgery with the coflex® Interlaminar Technology, 1 or 2 level decompression with or without fusion according to the physician's standard procedures. Table 1 describes the anticipated time points which will be collected as part of the retrospective data review. Please see Section 4.4, Data Collection Procedures for additional details regarding the data points intended to be captured at the designated time points.

	Baseline	**Surgical Treatment**	**Post-Operative Hospital Stay**	**Follow-Up Visit(s)**
Demographics & Risk Factors	X			
Prior Surgery Detail *(If available)*	X			
Diagnosis	X			
Operative Summary		X		
Procedure Payer Information		X		
Secondary Treatments			X	X
Complications		X	X	X
Work Status / ADL *(If available)*	X		X	X
Patient Questionnaires *(If available)*	X	X	X	X
Diagnostic Imaging History	X	X	X	X

4.3 Informed Consent

A waiver of informed consent will be requested from the IRB for all subjects as this study is collecting retrospective data. As indicated above, the study is a review of medical records that poses no risk to the patients and minimal risk to loss of patient privacy. All individual information used in the study will be de-identified and, if published or presented publicly, the information will be disclosed in aggregate with no links or identifiers to individual subjects.

4.4 Data Collection Procedures

Site staff or a Paradigm Spine representative will review and evaluate medical charts for enrollment into the study based on the inclusion/exclusion criteria. All people involved with the collection or analysis of the data will be familiar with HIPAA requirements for handling Protected Health Information (PHI). For purposes of de-identification, eligible patients (subjects) will be given a unique subject identification number that will help to protect their privacy in the study records. The research team will not capture any patient-specific identifiers such as date of birth or initials in the study records. Data will be entered into CRF's and then sent to the biostatisticians for analysis.

The following data points will be captured at the designated time points.

4.4.1 Baseline Visit

- Diagnosis
    - Presenting symptoms
    - Documented failed conservative treatment
    - Patient reported outcome questionnaires, if available
    - Prior treatment details

- Pre-Operative Demographics
    - Date of visit
    - Age
    - Gender
    - Race
    - Ethnicity
    - Work Status / ADL
    - Height (in)
    - Weight (lbs)
    - BMI

- Risk Factors
    - Tobacco Use
    - Alcohol Use
    - Comorbidities
    - Diabetes
    - Bone Density
    - Medications

- Diagnostic Imaging
    - MRI and CT of affected lumbar levels
    - Radiographs

4.4.2 Surgical Treatment Visit

- Operative Summary
    - Date of surgery
    - Surgical procedure
    - Operative time
    - Estimated blood loss
    - Anesthesia details
    - Treated level(s)
    - Device size
    - Intra-operative/early post-operative complications, such as:
        - Dural tears
        - Hematomas
        - Fractures
        - Nerve injury
    - Diagnostic imaging History
    - Dictated operative notes

- Repeat Surgery Summary
    - Date of surgery
    - Reason for surgery (reoperation, revision, removal, etc.)
    - Surgical procedure
    - Operative time
    - Estimated blood loss
    - Anesthesia details
    - Treated level(s)
    - Surgical intervention performed
    - Device size
    - Intra-operative/early post-operative complications

- Dural tears
- Hematomas
- Fractures
- Nerve injury

- Diagnostic imaging

History

4.4.3 Post-Operative Hospital Stay

- Duration of hospital stay
- Post-operative complications and other observations from hospital stay
- Patient reported outcome questionnaires, if available
- Diagnostic Imaging
- Narcotics use

4.4.4 Follow-Up Visits

The following longitudinal data will be collected for all follow-up clinic visits through final follow-up:

- Work status / ADL
- Compliance with postoperative protocol/restrictions (if applicable)
- VAS (as available)
- ODI (as available)
- Patient satisfaction (as available)
- Complications
- Secondary treatments
- Narcotics use
- Diagnostic Imaging
- Incidence of Epidural Steroid Injections (ESI)

5.0 Statistical Analysis

5.1 General Information

All continuous outcome measurements at follow-up time points will be compared to baseline values using a t-test for superiority. Categorical outcome measurements will be compared using a Fisher's exact test for superiority. Statistical significance for these analyses will be demonstrated with a p-value less than 0.05.

5.2 Primary Endpoint

Overall duration of follow-up care and incidence of secondary surgical interventions will be analyzed to evaluate overall effectiveness of the use of the coflex® Interlaminer Technology

5.3 Secondary Endpoints

The clinical outcomes will be summarized; however, since the collection of these measures is not standard of care, this data will only be collected as available. In addition, data will be used to analyze the association between coflex® Interlaminar Technology use and outcomes with age, ethnicity, race, workers' compensation, smoking status, and gender. New and/or worsening complications will be summarized.

6.0 Study Management

6.1 Ethics

This study will conform to ethical principles found in the International Committee on Harmonization (ICH). The protocol and an Informed Consent waiver will be submitted to the IRB for approval. Sites may use their institutional IRB or if they do not have one, a central IRB will be provided by the sponsor. This Protocol, Informed Consent waiver, and any amendments to these documents will be reviewed and approved by the local or central IRB and Paradigm Spine prior to beginning data collection. The Investigator and staff agree to conduct the study in compliance with the HIPPA Privacy Rule, applicable 21 CFR regulations and the ethical principles found in ICH.

6.2 Data Entry

Data for this study will be collected and analyzed by Paradigm Spine representatives who are familiar with HIPAA requirements for handling of Protected Health Information (PHI). The following measures will be taken to eliminate risk to the privacy of patients whose data is being studied for this research:

- All subject identifying information will be replaced with a unique research identifier to help shield the identity of these records within the study database and during data analysis.
- Data will be entered into CRF's by Paradigm Spine representatives. Access to the data will be restricted to persons involved with data collection and data review/processing.

- The key that links the unique research identifier and subject's identifiable information will be securely maintained in a password-protected database with access restricted to key personnel responsible for the conduct of this study. It will only be shared if there is a health or research justification, or if required by law.
- All identifiers will be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
- Protected Health Information will not be reused or disclosed by the Sponsor to any other person or entity, except as required by law, or for authorized oversight of the research study.