STUDY TO INVESTIGATE THE LONG TERM SURVIVORSHIP OF COFLEX

CT Study: Sub-Analysis of 24 Month Spinous Process Fractures via Post-60 Month CT Scan

1. Objective

The primary objective of this study is to examine the long-term survivorship via CT Scan of the coflex® in patients who presented with spinous process fractures at 24 months in the Paradigm Spine coflex® IDE Study.

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).

2. Study Design

This is a prospective, multi-center, single-arm, radiographic evaluation of all coflex® IDE patients who presented with a spinous process fracture at 24 months as identified by the site and/or independent radiographic review (using X-ray or CT). All patients were enrolled and followed through 60 months under the IDE and extended follow-up protocol.

The specific objective of this CT Study is to perform a sub-analysis of the patients with 24 month spinous process fracture(s) via a CT scan at post-60 months. A CT Scan will be performed and analyzed by an independent radiographic review lab for evidence of fracture or healing at the long term time point.

3. Study Population

The study population consists of all living subjects who participated in the coflex® IDE Study and had a spinous process fractures at 24 months. The spinous process fractures include those identified by the site and/or those identified by the independent radiographic review lab (via X-ray or CT). The following 17 subjects presented with a spinous process fracture at 24 months, and will be reviewed based on the exclusion criteria. Those patients available for enrollment will be asked to return for a CT Scan:

Site 05	05-114	05-202	05-206	05-229	
Site 06	06-104	06-219			
Site 07	07-204				
Site 15	15-217				
Site 17	17-120	17-207			
Site 19	19-110	19-119	19-209	19-210	19-211
Site 23	23-204				
Site 32	32-112				

Since the subjects have already been screened as part of the IDE Study, and only patients that participated in that study make up the patient cohort for this CT Study population, the only inclusion criteria necessary for this study are:

1. Participant in coflex® IDE Study
2. Willing and able to give informed consent
3. Spinous process fracture identified by site and/or radiographic lab at 24 months

Exclusion criteria for the study are as follows:

1. Subjects who died, were withdrawn or withdrew consent to participate in the study
2. Subjects who are pregnant, or planning to become pregnant, during the course of this study
3. Subjects who have cancer, whether active or in remission.

4. Subject Recruitment

Each site will be responsible for contacting those patients that participated in the IDE Study and consent them for the current CT Study. Each patient will be asked to return for a CT Scan. To encourage enrollment in the study, each patient will receive a $500 gift card upon completion of the CT Scan to cover the cost of time, travel and expenses.

5. Study Procedures

Patients will have undergone placement of the coflex® Interlaminar Stabilization Device as part of the IDE study.

The only procedure performed as part of the CT Study is a CT Scan of the lumbar spine at least 5 years post-implantation of the coflex® device.

The scans will be sent to the independent radiographic review lab for analysis.

6. Risks

There are risks associated with CT Scan. The subject will be exposed to a small amount of radiation called "ionizing radiation". Studies have shown that getting a lot of radiation at one time or getting many small doses over time may cause cancer. The risk of getting cancer from the one small radiation dose in this study is very small.

The standard effective dose for a lumbar spine CT Scan is 1.5 mSv, which is equivalent to 75 chest x-rays. All patients will have 1 CT Scan.

7. Informed Consent

All patients will be consented prior to enrollment in the CT Study. The informed consent will clearly identify the procedures to be performed (i.e., CT Scan), the costs subject to payment by the participant, and compensation for participation.

8. Study Data

The data will be submitted to the Food and Drug Administration (FDA) to support the long-term safety and effectiveness of the coflex® Interlaminar Stabilization device.