coflex-F®

THE UNIQUE, MINIMALLY INVASIVE FUSION DEVICE

The coflex-F implant is designed to deliver surgeon confidence and patient satisfaction.

coflex-F – A Unique Solution

There are a number of surgical options for spinal fusion procedures. They range from pedicle screw fixation to the use of spinous process plates. Pedicle screw fixation procedures often require an extensive dissection, and spinous process plates are affixed to the weakest bone of the posterior spine, the spinous process.

coflex-F – Creating Confidence

Only coflex-F combines the advantages of minimally invasive lumbar fusion with stabilization on the strongest part of the posterior spine, the lamina. Due to its unique “U” design, the coflex-F implant is placed between the two laminae, covering a large surface area which allows for optimal load distribution and stable fixation. This placement provides a strong stabilization and reduces pain that is normally associated with the facet joints and foramen.

coflex-F – Increasing Patient Satisfaction

A minimally invasive fusion technique may result in faster recovery time for the patient. Compared to a pedicle screw fusion surgery, the coflex-F procedure often results in a smaller skin incision, less blood loss during surgery, and reduced intraoperative time.¹

coflex-F – A unique solution for minimally invasive fusion.

¹ Internal Data Available at Paradigm Spine
UNIQUE DESIGN

A Unique Solution

With the introduction of pedicle screws in the 1980s and cages in the 1990s, lumbar fusion with instrumentation became a common procedure for treating degenerative disc disease. Scientific literature demonstrates that many fixation techniques that utilize pedicle screws or interspinous devices improve fusion rates.

The coflex-F® implant¹ is an interlaminar² stabilization device that can be delivered through a minimally invasive approach. It provides significant segmental stability and posterior fixation.

Interlaminar stabilization with the coflex-F implant is an ideal adjunct to fusion in cases of degenerative disc disease with or without mild instabilities in the lumbar spine.

The coflex-F implant allows segmental stabilization in combination with interbody fusion cages and is bridging the gap between stand-alone anterior solutions and 360° fusions using pedicle screw fixation.

Design Features

Designed to allow for a low profile, tissue friendly, anatomical fit; implant wings can be precisely adjusted to individual variability in morphology of spinous processes.

- Interlaminar positioning
- Secure anchorage through rivet fixation
- Large contact area for optimized stress distribution
- Five anatomical sizes
- Color-coded instrumentation
- Titanium alloy – biocompatible

Reduced Iatrogenic Trauma

- Less muscle trauma
- Less blood loss
- Smaller skin incision

Reduced Surgical Risks

- Excellent safety profile of implant
- Avoids proximity to neural structures

Reduced Cost

- Shorter operating time
- Faster patient rehabilitation

Ease of Use

- Simple surgical technique
- Intuitive instrumentation

¹ This product covered under U.S. Patent Nos. 5,645,599 and 7,922,750 as well as other pending patent applications in the U.S. and internationally.
² Laminar bone is 2–5 x stronger than the spinous process (Trautwein et al.: Determination of the in vivo posterior loading environment of the coflex™ interlaminar-interspinous implant, The Spine Journal 10 (2010)).
The coflex-F® implant is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1 – S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease – defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies – with up to Grade 1 spondylolisthesis.

Please see Instructions for Use for Contraindications, Warnings, and Precautions.
Biomechanical Rationale

Biomechanical studies demonstrate that the solid interlaminar anchoring of the coflex-F® implant through rigid fixation to the spinous processes and laminae provides similar posterior stabilization as pedicle screws, thereby increasing the likelihood of successful anterior fusion (Table 1).

Comparative Testing* – coflex-F

Comparative mechanical side-by-side testing using a clinically valid test protocol demonstrates that the coflex-F design results in a stronger and stiffer environment to stabilize the motion segment compared to other spinous process plates (Table 2).

Table 1: Range of motion (ROM) and neutral zone normalized to the intact state (100%). In combination with cages anteriorly both the coflex-F implant and the pedicle screw system reduced the ROM significantly.

Table 2: Static Testing: Compression, Rotation/Torsion Dynamic Testing (5 Mill. Cycles): Compression, Compression/Tension. Lanx® Aspen™ = 100%

* Internal Data available at Paradigm Spine. This product covered under U.S. Patent Nos. 5,645,599 and 7,922,750 as well as other pending patent applications in the U.S. and internationally.
Clinical Validation*

A prospective, non-randomized post-market surveillance study with 6 surgeons and 68 patients has shown the following results:

**Fact:**
- The clinical data has validated the biomechanical experience: The coflex-F® device is a safe implant that achieves fusion.
- In addition, the fusion rate, using established radiographic criteria, was achieved in 95.2% of the treated patients.

* Internal Data available at Paradigm Spine. This product covered under U.S. Patent Nos. 5,645,599 and 7,922,750 as well as other pending patent applications in the U.S. and internationally.
1. Lumbar Interbody Fusion

According to the pathology, interbody fusion is performed at the surgeon’s discretion. It is important to note that the coflex-F® implant is always inserted after implantation of an intervertebral device.

2. Preparation

Once intervertebral fusion has been performed the patient is prepared for posterior stabilization with the coflex-F implant. Care should be taken to preserve the facet capsules and joints wherever possible.

The patient is placed in prone position on a surgical frame avoiding hyperlordosis of the spinal segment(s) to be operated on. Routine (midline) skin incision is performed. The muscle is sharply dissected lateral to the supraspinous ligament. Paraspinal muscles are stripped off the laminae. The interspinous ligament is sacrificed and a microsurgical decompression is performed. Any bony overgrowth of the spinous process is resected that may interfere with the insertion of the coflex-F implant.

3. Implant Site Preparation

Trials are utilized to define the appropriate implant size. The trial instrument is placed to evaluate proper contact with the spinous processes avoiding any facet distraction. Some bony resection of the spinous process may be needed to ensure optimal contact of the implant.
4. Implant Insertion

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

The implant is introduced via impaction utilizing a mallet. By deeply inserting the coflex-F® implant at the level of the facet joints the implant counteracts the majority of posterior column forces. Proper depth is determined by passing a beaded tip probe between the implant and the dura to ensure a 2 – 3 mm separation.

Once proper placement has been achieved, it is recommended to securely crimp the wings of the implant using the crimping pliers.
Then punching pliers are utilized to create a hole in each spinous process for later introduction of the *coflex-F*® rivets.

Prior to insertion of the *coflex-F* rivets it is recommended to clean the holes using the *coflex-F* probe.

The *coflex-F* rivets are attached to the screw inserter and applied into the spinous processes using the screw driver. A tight fit is required for controlled fixation. The teeth of both wings should be firmly engaged into the cortices of the spinous processes.

5. Wound Closure

A surgical drain may be placed according to surgeon preference. Paraspinal muscles are reattached to the supraspinous ligament. Skin is closed in the usual manner.
PATIENT CASES

Case 1:

Male, 43 years:

- Symptoms: Long history of progressive low back pain. More than 6 months of increasing left leg pain.
- Diagnosis: Degenerative disc disease with mild instability and disc protrusion at level L4/5.
- Previous Therapy: Failed conservative treatment. One microdiscectomy ten years ago and another microdiscectomy three years ago at level L4/5 to the left. Administration of various nerve root blocks.
- Surgery: Microsurgical decompression at level L4/5 and additional implantation of PEEK TLIF cage (Scient’X) and 8 mm coflex-F® implant at level L4/5.
- Follow-up at 12 months: Patient is very satisfied with treatment and stated that he would definitely have the surgery again. ODI and VAS scores showed marked improvement over 12 months timeframe. Bone formation visible at 3 month time point (x-ray AP and lateral), functional x-rays at 8 months show no motion at the L4/5 segment.
Case 2:

Female, 53 years:

- Symptoms: 10+ years of progressive low back pain. 3+ years of sciatic pain and Trendelenburg signs. Reduced walking distance of 150 – 300 feet.

- MRI: Degenerative disc disease at level L2/3, osteochondrosis at levels L4/5 and L5/S1, disc protrusions at levels L3/4, L4/5 and L5/S1.

- Diagnosis: Degenerative disc disease at level L2/3.

- Previous Therapy: Failed conservative treatment. Infiltrations including discography with improvement for 4 weeks.

- Surgery: Spondylodesis at level L2/3 with ALIF cage (Syncage) and coflex-F® implant size 10 mm. Bone graft from left iliac crest.

- Follow-up at 12 months: Patient extremely satisfied with treatment. Back pain has improved from VAS 9 preoperatively to 0.7 at 12 months, leg pain improved from VAS 6 to 0. ODI values also show marked improvement from 50 preoperatively to 4 postoperatively at 12 month time point.
PRODUCT INFORMATION

Sterilization Tray

RAC 00000

Instruments

Bending Plier
UAT 10100

Crimping Plier
UAT 10200

Cleaning Tool
RAT 20130

Punching Plier
RAT 20100

Probe
RAT 20120

Screw Inserter
RAT 20211

Screwdriver
RAT 20204

Wrench
RAT 20300

Trials

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

The coflex-F® implant is delivered sterile packed and includes a disposable application tool.