Consumer Information on: coflex Interlaminar Technology - P110008

U.S. Food & Drug Administration

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: coflex® Interlaminar Technology

PMA Applicant: Paradigm Spine, LLC

Address: 505 Park Avenue, 14th Floor, New York, NY 10022

Approval Date: October 17, 2012

Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110008a.pdf [1]

What is it? The coflex Interlaminar Technology is a U-shaped, titanium alloy implant that fits between two bones called the spinous processes located in the lower back (lumbar region) of the spine. The device is placed between two adjacent lower back bones after surgical relief of pressure on the spinal cord and nerves (decompression) to ease the pain associated with lumbar spinal stenosis [2], a narrowing of the passages for the spinal cord and nerves.

How does it work? The coflex device is designed to maintain a fixed distance

between the spinous processes of two lumbar segments following surgical decompression. By limiting the ability to bend backward (extension) in the affected area, the device may relieve the symptoms of lumbar spinal stenosis.

When is it used? The coflex device is intended to be implanted in the center (midline) between 1 or 2 adjacent segments of the lumbar region of the back (from L1-L5) to provide stability following surgical decompression of spinal stenosis at the affected level(s).

The coflex device is indicated for skeletally mature patients (people who have stopped growing) who experience relief from their symptoms of leg/buttocks/groin pain, with or without back pain when bending forward, and who have undergone at least 6 months of non-operative treatment.

What will it accomplish? This device should help relieve some or all of the symptoms of lumbar spinal stenosis. Unlike a fusion procedure, the coflex device is designed to allow some motion at the affected level(s).

When should it not be used? You should avoid having surgery with the coflex device if you experience any of the following conditions:

- Prior fusion or decompressive laminectomy at any index lumbar level
- Compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (such as, compression fracture)
- Severe facet hypertrophy (overgrowth of bone in the facet joint between each vertebral body) that requires extensive bone removal, which would cause instability
- Grade II or greater spondylolisthesis
- Isthmic spondylolisthesis or spondylolysis (pars fracture)
- Degenerative lumbar scoliosis (Cobb angle of greater than 25 degrees)
- Osteoporosis (thin or weak bones resulting from a loss of calcium)
- Back or leg pain of unknown origin
- Axial back pain only, with no leg, buttock, or groin pain
- Morbid obesity defined as a body mass index greater than 40
- Active or chronic infection – systemic or local
- Known allergy to titanium or titanium alloy
- Cauda Equina Syndrome (severe spinal nerve compression causing loss of bowel or bladder function, loss of sensation in the buttocks and groin, and weakness in the legs)

Additional information:

The Summary of Safety and Effectiveness Data and labeling [3] are available.

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Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110008a.pdf
[2] http://www.nlm.nih.gov/medlineplus/spinalstenosis.html
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