Coflex Interlaminar Stabilization Device (Paradigm Spine LLC) for treatment of lumbar spinal stenosis

HAYES, Inc.

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' conclusions
Description of Technology: The coflex Interlaminar Stabilization device is a functionally dynamic, implantable, titanium interspinous process device (IPD) that is intended to limit lumbar spinal extension in order to maintain direct neurological decompression, unload the facet joints, and stabilize the motion segment at the treated vertebral level(s). The coflex is a U-shaped implant with 2 pairs of serrated wings extending from the upper and lower long arms of the U. The U portion is inserted horizontally between 2 adjacent spinous processes. The wings are crimped over bone to hold the implant in place. The device is implanted after decompression of stenosis at the affected level(s). Patient Population: The coflex device is indicated for use in skeletally mature patients with 1- or 2-level lumbar spinal stenosis (LSS) from L1 to L5; at least moderate impairment in function; relief from leg, buttocks, or groin pain and symptoms when in flexion; and ≥6 months of nonoperative treatment. Back pain does not have to be present. Clinical Alternatives: Conservative treatments for LSS include nonsteroidal anti-inflammatory drugs, analgesics, epidural steroid injections, physical therapy, exercise, bedrest, chiropractic manipulation, and acupuncture. Surgical options include laminectomy, laminotomy, foraminectomy, facetectomy, and discectomy, alone or followed by spinal fusion. A variety of IPDs are available on the market, including X-Stop Interspinous Process Decompression Device (Kyphon Inc.), the Wallis interspinous device (Abbott Spine), and the Diam Spinal Stabilization System (Medtronic Sofamor Danek).

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