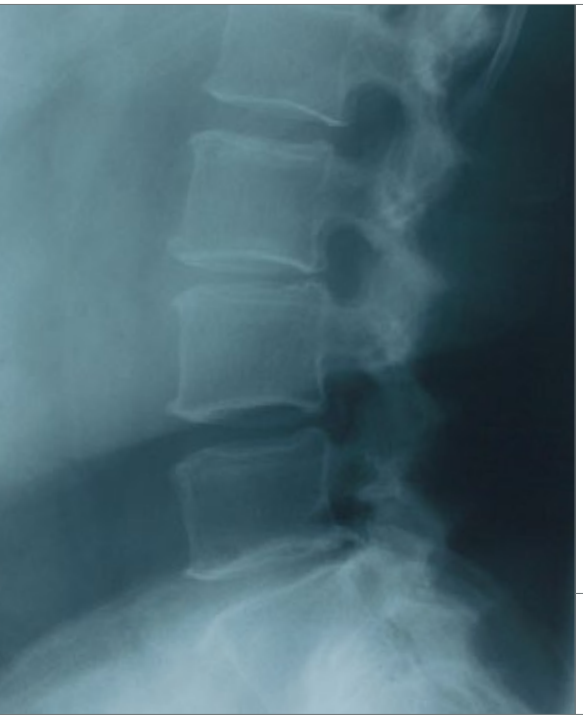
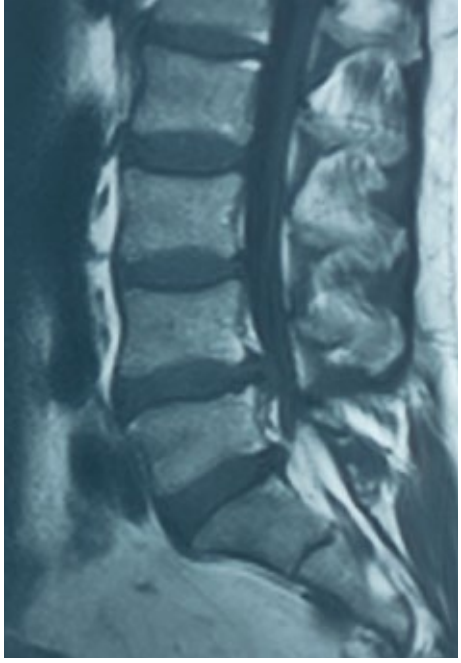
PARADIGM SPINE

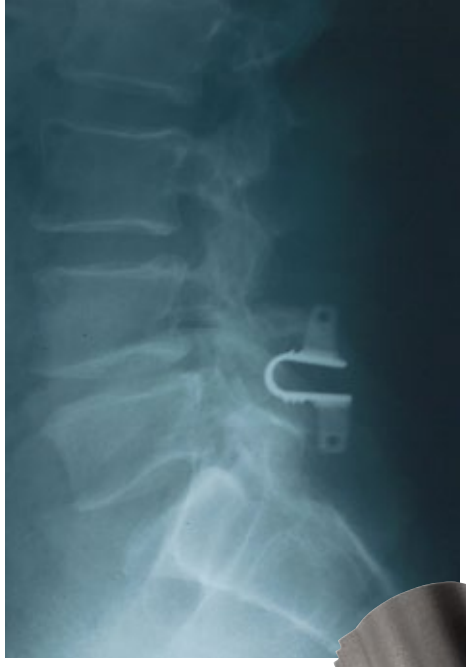
the movement in spine care

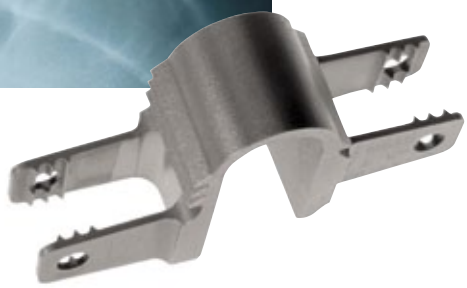


Interlaminar Implant **coflex™**

Interlaminar Technology







Stabilizati

Non Fusion

A paradigm shift from fusion to non-fusion is not a conceptual exercise. The gap in the treatment continuum from conservative care to fusion is being filled with early-stage technologies such as interlaminar stabilization. The success of these technologies will evolve through surgeon driven, indication specific solutions for the clinical problems faced in the surgeon's daily practice.

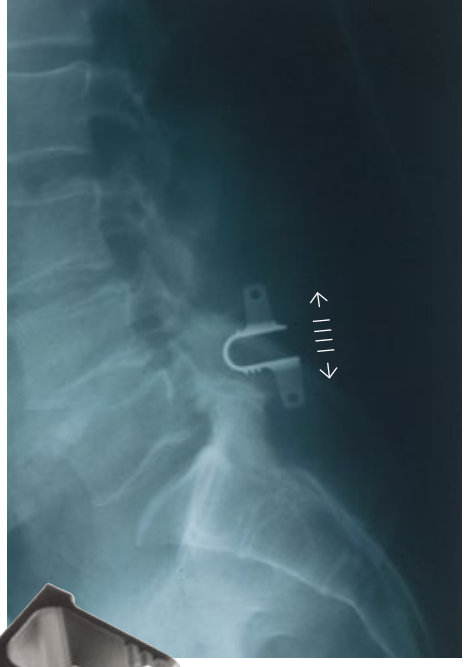
Non-fusion procedures will allow for the spine to restabilize toward its natural biomechanical state, allow for rebalancing of the spinal segment, restoring natural anatomical function, and perhaps lead to some degree of "re-healing". These procedures will fill the large gap in the treatment continuum while being reversible and delaying a permanent surgical procedure such as a spinal fusion. Intraoperative instability after decompression can be stabilized by interlaminar devices.
If late instability is projected, interlaminar stabilization may prevent this.

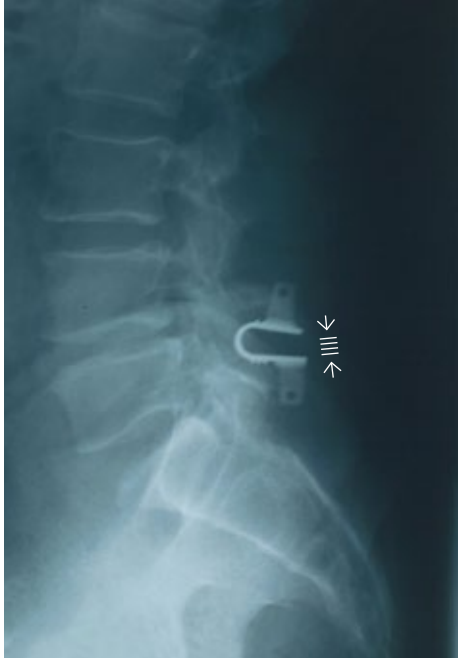
Interlaminar stabilization with the ***coflex***™ implant is ideal in cases of facet arthrosis and all related decompressive procedures. Implantation of the ***coflex*** implant allows for segmental stabilization, controlling motion.

Stabilization does not necessarily equate with fusion.

on

Stab





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Controlled Motion

Up to 18 years of clinical history and more than 80,000 implantations worldwide have proven the clinically successful concept of the implant.

The *coflex* implant is ideal for spinal stabilization after surgically addressing neural compression from soft and bony stenosis of the spinal canal.

Design Features:
- 5 anatomical sizes
- Color coded instrumentation
- Titanium alloy – biocompatible – X-Ray visible
- Crimping of wings for increased primary stability

Functionally Dynamic
- Compressible in extension, allowing flexion
- Increased rotational stability
- Center of rotation close to spinal canal

Protection of Posterior Elements
- Stress reduction on facet joints
- Maintenance of foraminal height

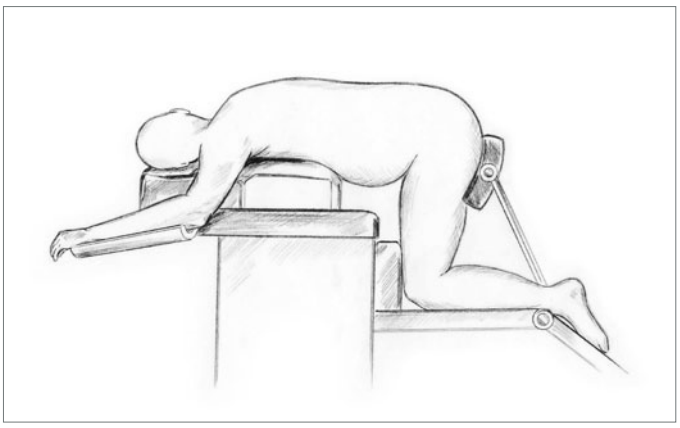
Ease of Use
- Less invasive, tissue-sparing procedure
- Easy and precise application

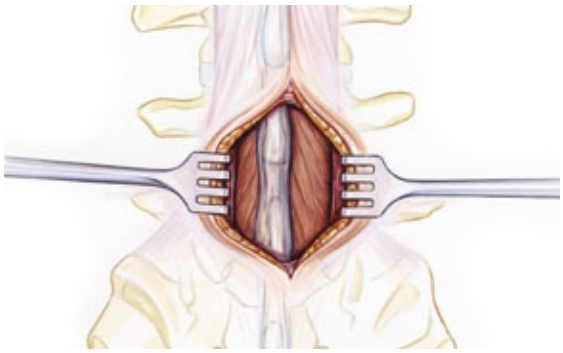
coflex more than a spacer – a functionally dynamic implant.

1. Preparation

Patient is placed in prone position on surgical frame avoiding hyperlordosis of the spinal segment(s) to be operated upon.

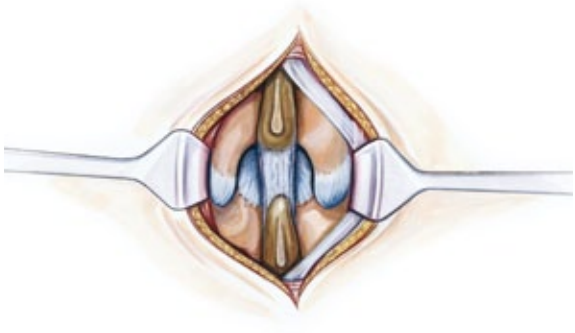
A neutral position or a slight kyphosis may be advantageous for surgical decompression as well as for appropriate interspinous distraction.





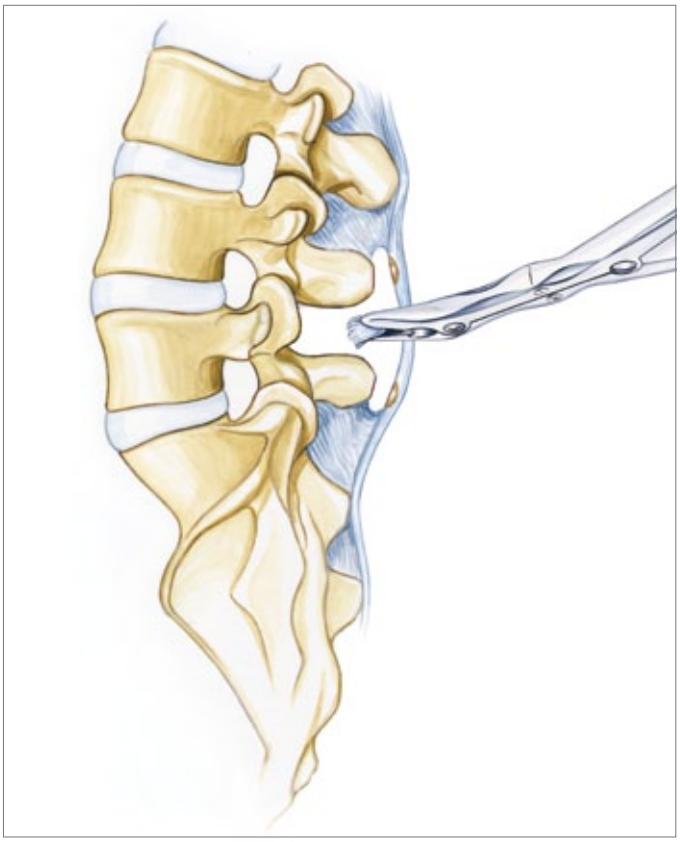
Routine (midline) skin incision is performed. The muscle is sharply dissected lateral to the supraspinous ligament preserving the entire thickness of the supraspinous ligament.

Alternatively the supraspinous ligament may be resected depending on surgeon's preference.



Paraspinal muscles are stripped off the laminae while preserving the facet capsules. The supraspinous ligament is dissected subperiostally and preserved as a thick cuff and retracted laterally. If possible a small portion of the bony tip can be resected together with the supraspinous ligament. This will aid a faster healing after reconstruction of the ligament.

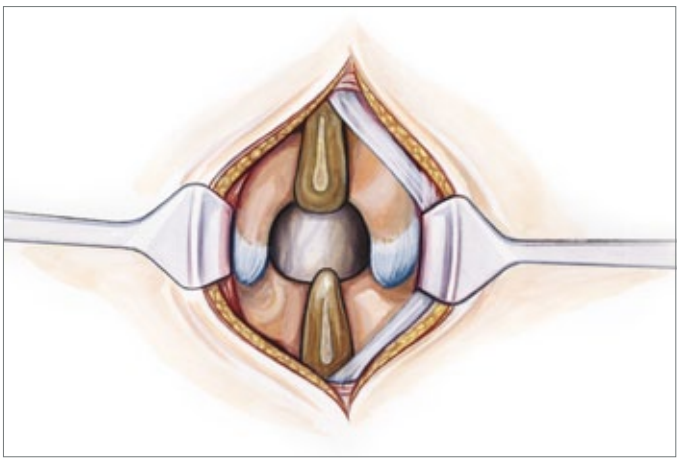
Note: Dependent on the pathology a microsurgical unilateral decompression can be performed and then the supraspinous ligament together with the fascia and muscle from the opposite side can be mobilized together. Completion of the microsurgical decompression can then be performed.

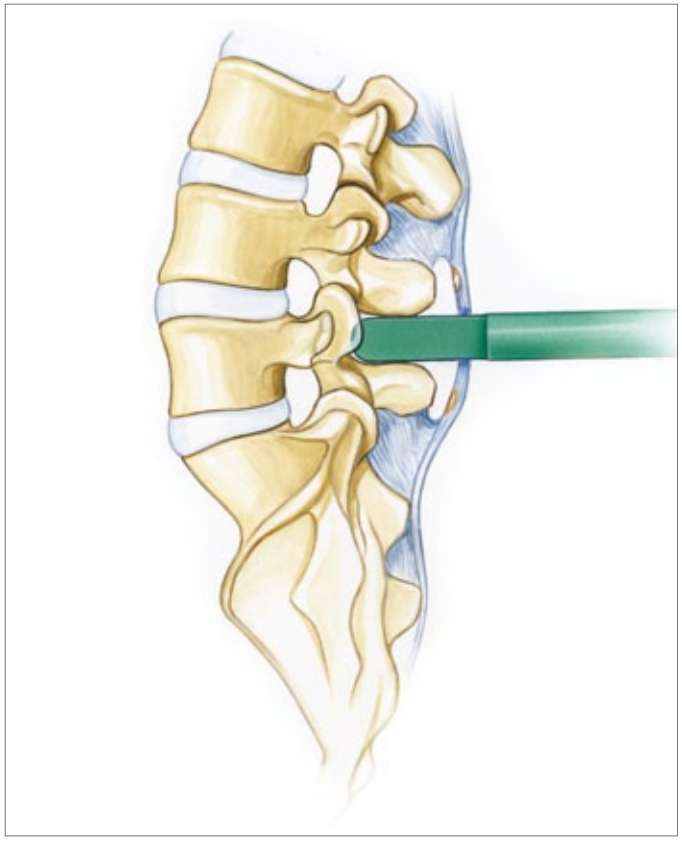


The interspinous ligament is sacrificed and any bony overgrowth of the spinous process that may interfere with insertion is resected.

2. Microsurgical Decompression

Ligamentum Flavum is resected and microsurgical decompression is performed, relieving all points of neural compression.



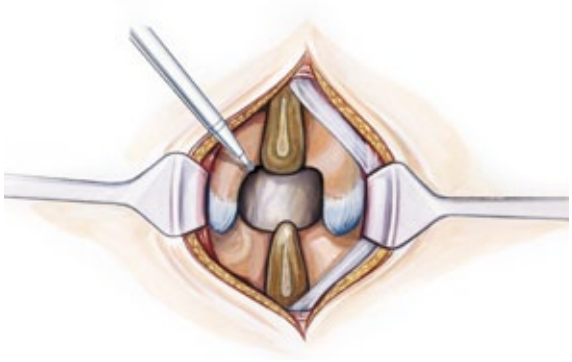


3. Implant Site Preparation

Trials are utilized to define appropriate implant size.

Trial instrument is placed to evaluate proper contact with spinous process and amount of interspinous distraction. Some bony resection of the spinous process may be needed to ensure proper contact of the implant.

Distraction is considered to be appropriate to prevent any settling of the interspinous distance after successful decompression of the spinal stenosis.



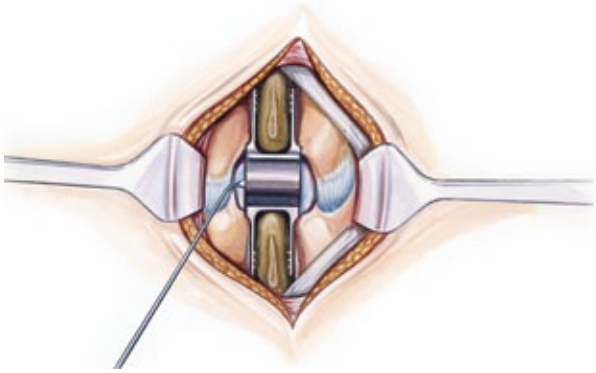
To ensure proper depth of implant insertion a small portion of the laminar surface may need partial resurfacing.

4. Implant Insertion

Prior to insertion the wings may need to be opened slightly using the bending pliers to ensure appropriate depth of insertion (Fig. 1). The implant is introduced via impaction utilizing a mallet.

Fig. 1

Proper depth is determined if a beaded tip probe can be passed freely leaving 3-4 mm separation from the dura. If the implant is not seated appropriately further resurfacing or slightly more impaction force may be utilized.



Once proper placement has been achieved, it is recommended to securely crimp the wings of the implant using the crimping pliers (Fig. 2).

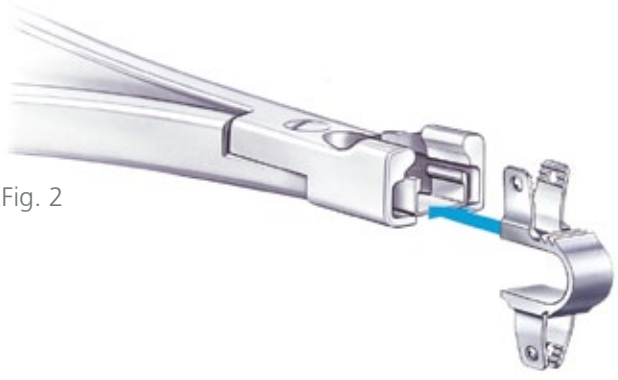
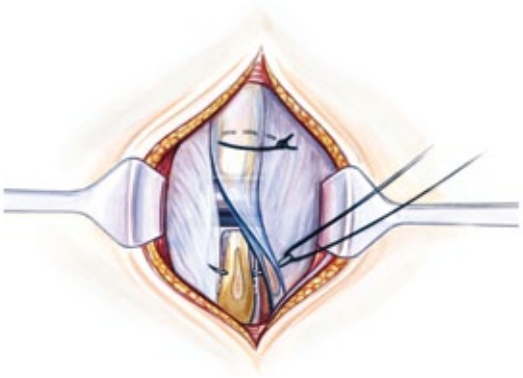


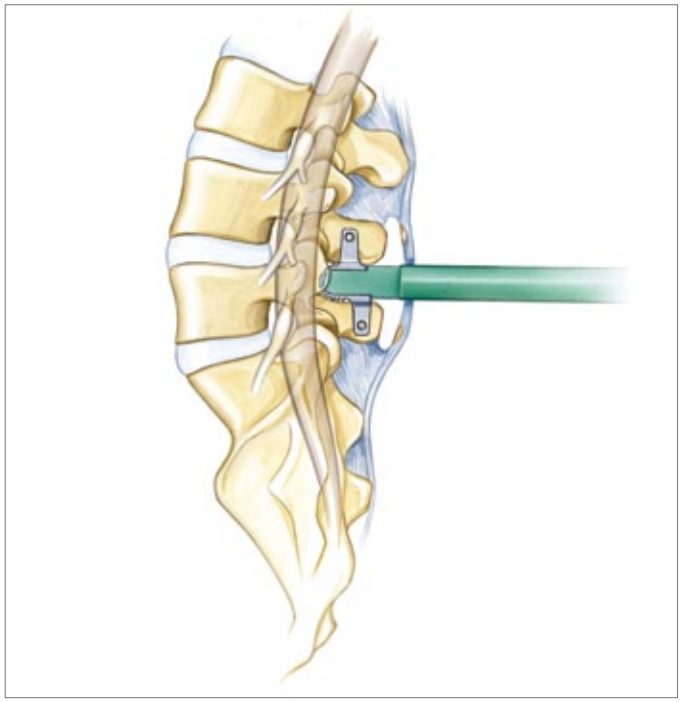
Fig. 2

In case of ligament reconstruction the fascia and the supraspinous ligament can be closed in one layer over the spinous processes. A surgical drain may be placed as per surgeon preference. Paraspinal muscles are reattached to the supraspinous ligament. Skin is closed in the usual manner.



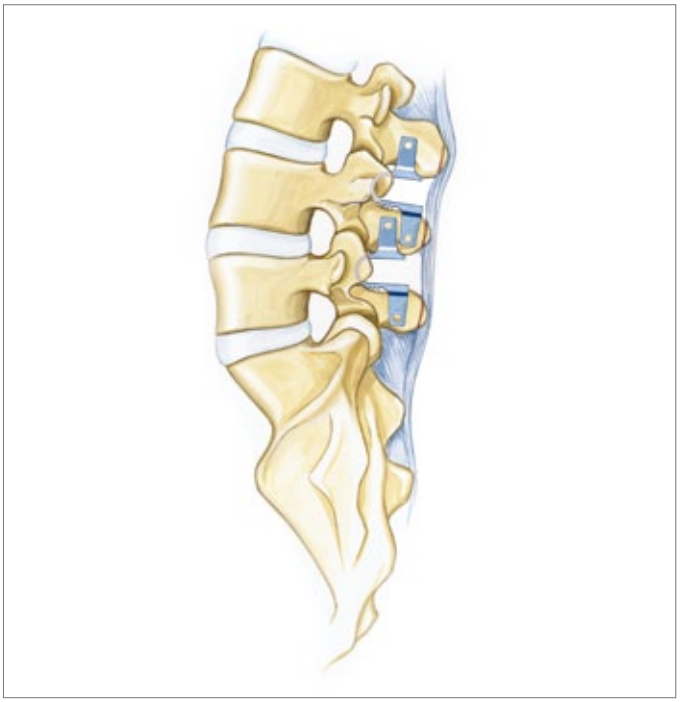
Single-Level Implantation

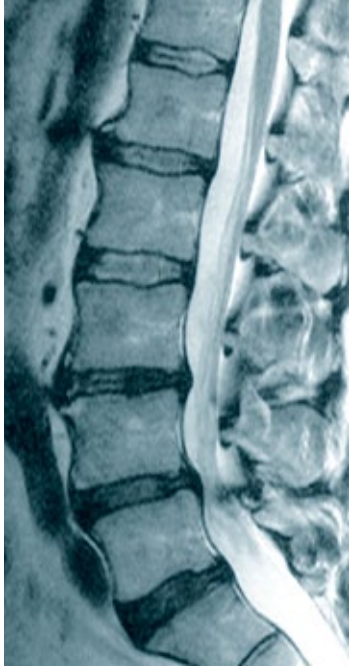
By deeply inserting the ***coflex*** implant at the level of the facet joints the implant counteracts the majority of posterior column forces (interlaminar positioning).

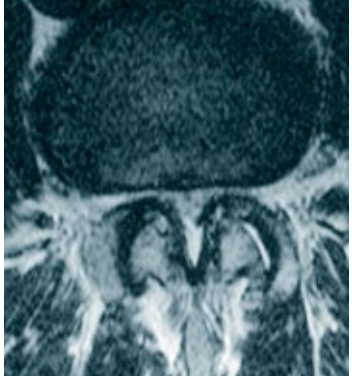


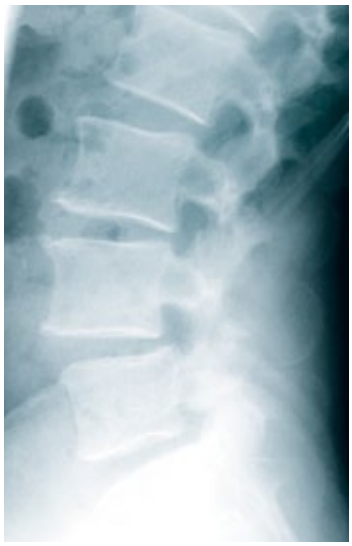
Double-Level Implantation

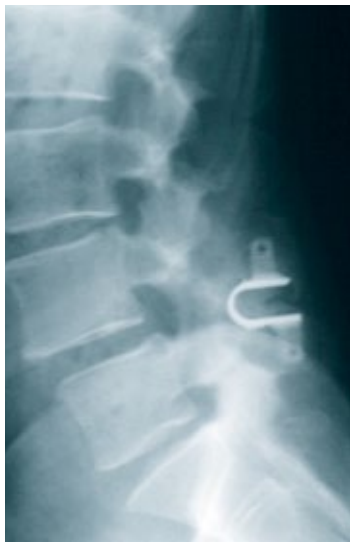
If a two level decompression is mandated the implants must be sequentially placed to the appropriate depth avoiding any overlap (contact) of one pair of wings upon the other.

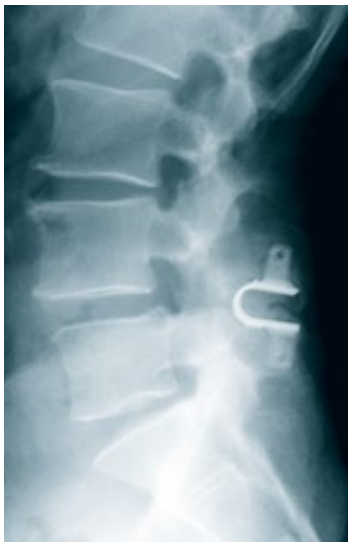












Solution

Case 1:
Male, 54 years, Teacher

- Low back pain for years and unilateral radicular pain right side for 12 months.
- No sensory deficit. Motor deficit right side (M. triceps surae).
- Reduced walking distance (less than 1000 metres).
- Diagnosis: Lumbar stenosis at L4/5.
- Previous Therapy: Failed conservative treatment.
- Surgery: Resection of synovial cyst and bilateral decompression of stenosis at level L4/5. Implantation of ***coflex*** interlaminar implant, 14 mm at level L4/5.
- Follow-up after 26 months: Complete recovery of radicular pain and low back pain. Patient very satisfied with treatment.

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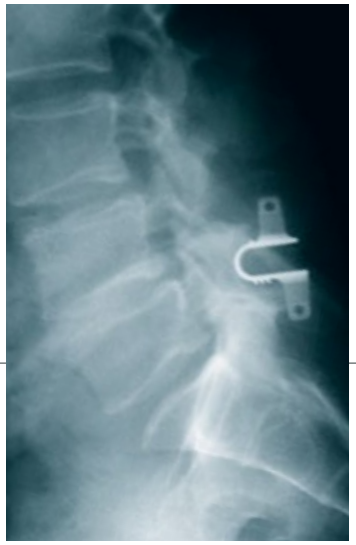
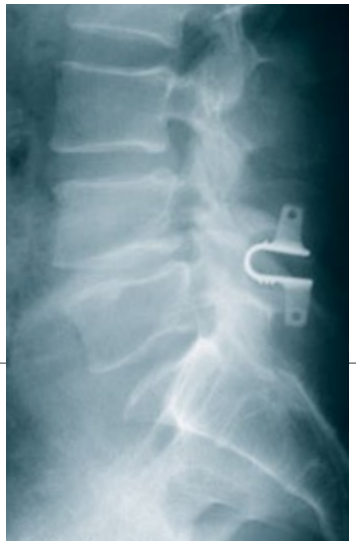
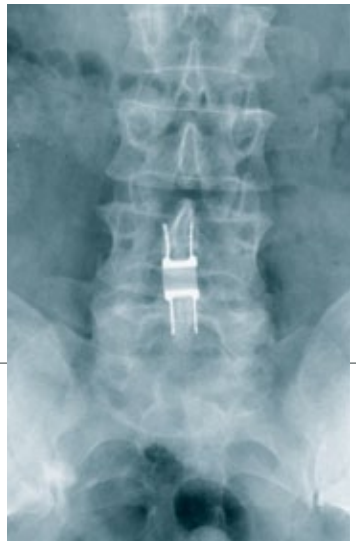
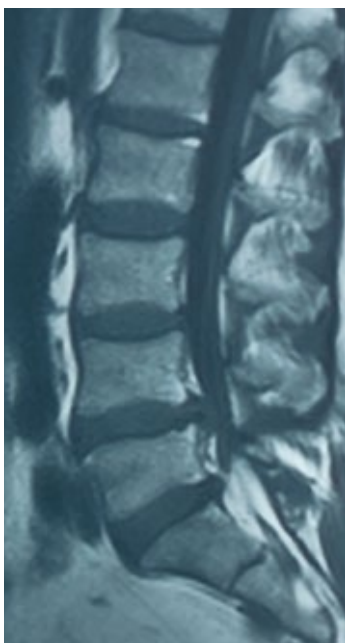
Case 2:
Male, 57 years, Locksmith

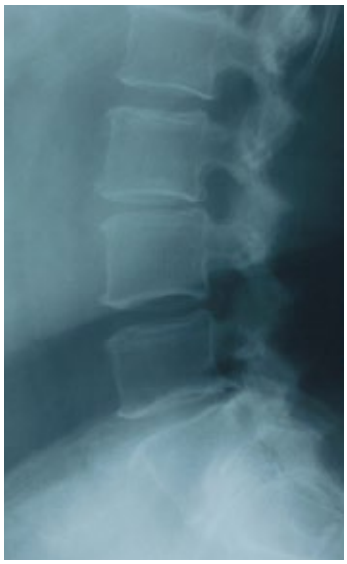
- Symptoms: Low back pain for more than 2.5 years. Worsened in last 6 months. Positive Lasègue test at 20°. Neurological deficit in the right leg.
- MRI: Sequestration caudally at level of L4/5. Modic signs L4/5 and L5/S1 and hypertrophic facet joints.
- Diagnosis: Severely herniated disc, right side at the level of L4/5.
- Previous Therapy: Failed conservative treatment including nerve root blocks.
- Surgery: Nucleotomy right side at L4/5. Implantation of ***coflex*** interlaminar implant, 12mm.
- Follow-up after 24 months: Patient extremely satisfied with treatment. No low back pain or sciatic pain with significant improvement of neurological deficit.

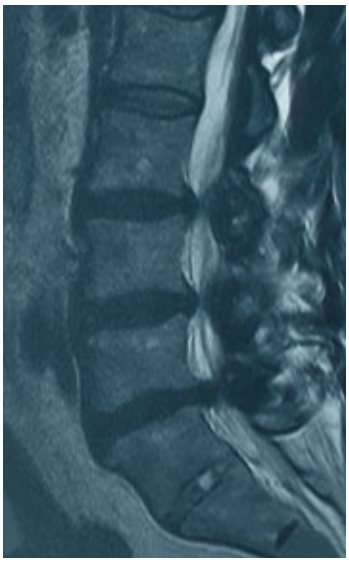




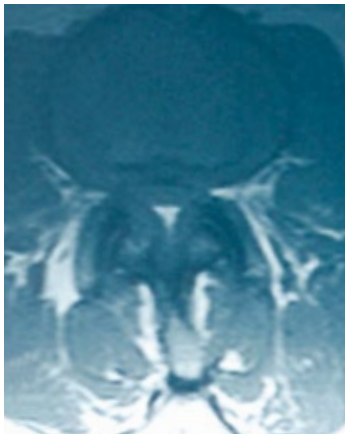


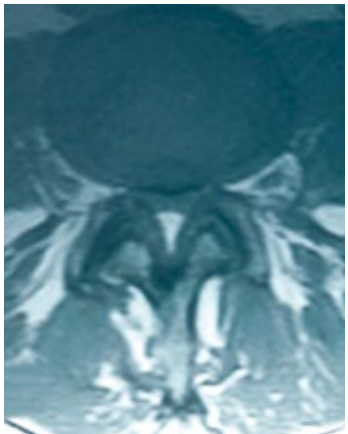
Case 3:
Female, 61 years, Retired

- Low back pain for many years, increasing significantly in the last 12 months with additional sciatica in left leg.
- Diagnosis: Lumbar stenosis most severe at levels of L3/4 and L4/L5 with intermittent claudication.
- Previous Therapy: Failed conservative treatment including facet blocks.
- Surgery: Decompression bilaterally at levels of L3/4 and L4/L5. Implantation of ***coflex*** interlaminar implant, 10mm at both levels.
- Follow-up after 7 months: Full relief of sciatic pain. Patient extremely satisfied with treatment.

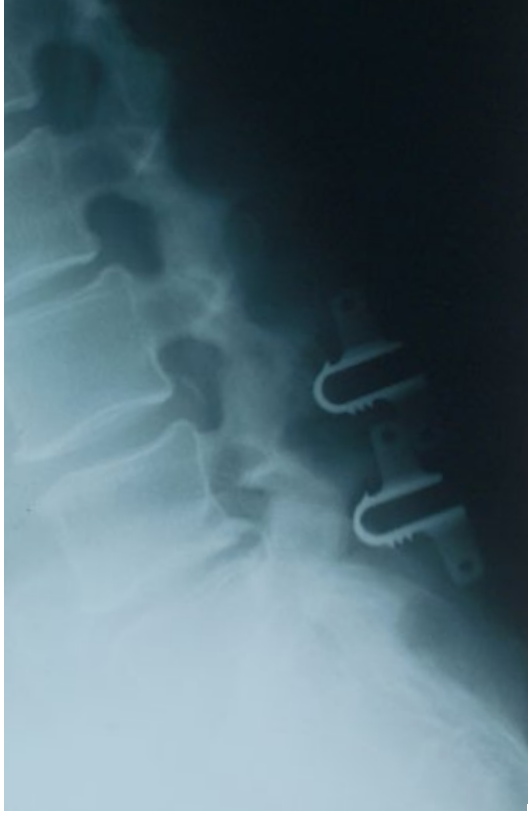


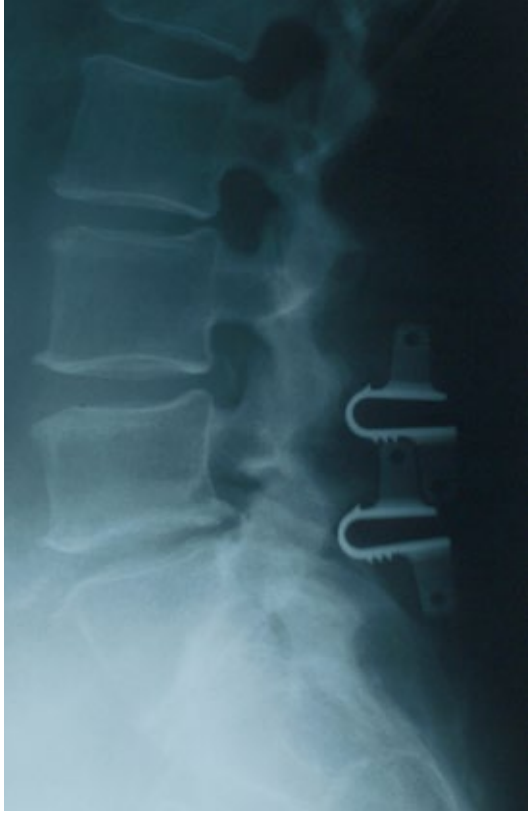






Preoperative





Postoperative

Indication

Specific

Specific Indication

For patients who fail conservative treatment, but who are not candidates for a complete laminectomy or an irreversible procedure such as fusion, functional interlaminar implants are the answer.

Main indication: Radiographically confirmed moderate to severe stenosis with neural element compromise resulting in claudication and/or radicular symptoms isolated to 1 or 2 levels, in the region of L1 to L5 with or without concomitant low back pain, including conditions such as stable grade 1 spondylolisthesis.

Extended indication: Stabilization above or below a fusion ("topping-off") in the same procedure to minimize adjacent level degeneration.

Research Activities

Research activities include:

- Instability (rotational or vertical) associated with recurrent herniations
- Large voluminous primary disc herniations

Conjunctive therapies to be envisioned:

- Combination with nucleus replacements
- Combination with total disc replacements with mild to moderate facet degeneration.

Product Information

Sterilization Tray

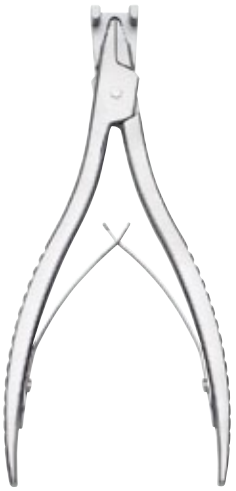
UAC 00000

Trials

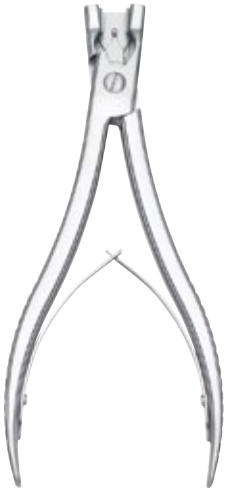
Color Code	Size	Article Number
	16 mm	UAT 00016
	14 mm	UAT 00014
	12 mm	UAT 00012
	10 mm	UAT 00010
	8 mm	UAT 00008

Material: Medical grade acetal copolymer

Instruments

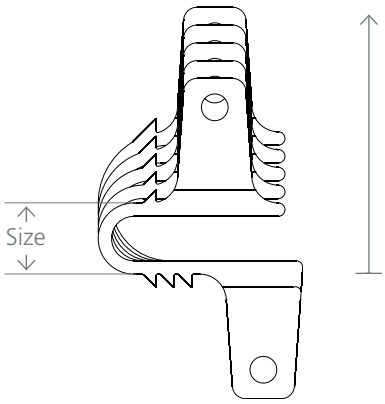


Bending Plier
UAT 10100



Crimping Plier
UAT 10200

coflex Interlaminar Implant



Color Code	Size	Article Number
	16 mm	UAI 00016
	14 mm	UAI 00014
	12 mm	UAI 00012
	10 mm	UAI 00010
	8 mm	UAI 00008

Material:
All ***coflex*** implants consist of titanium 6-aluminium 4-vanadium (ISO 5832-3)

MRT:
Titanium is a non ferromagnetic material, therefore magnetic resonance imaging can be done.

The ***coflex*** implant is delivered sterile packed.

UAM00002 12/02

Product not available in the USA

PARADIGM SPINE

the movement in spine care

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