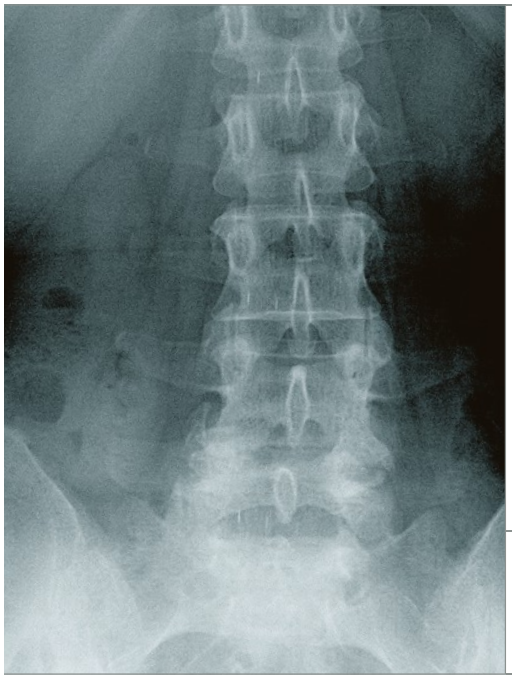
PARADIGM SPINE
the movement in spine care



Minimally Invasive
Lumbar Fusion

coflex-F+™

Interlaminar Stabilization

A UNIQUE MIS ALTERNATIVE TO PEDICLE SCREW FIXATION

The Gold Standard

The combined use of surgical decompression and different types of fusion is generally considered the "gold standard" in the treatment of patients with degenerative lumbar diseases with significant back pain and/or lumbar instabilities. According to the current clinical consensus the outcomes with the different fusion techniques, commonly performed with pedicle screws, are acceptable.[1,2]
Still this surgical treatment might be associated with a morbid approach and possible side effects related to the use of pedicle screws.

Minimally invasive pedicle screw systems may reduce the morbidity of the approach, but may increase the incidence of cranial facet violations[3] and go hand-in-hand with a high radiation dosage for surgeons, OR-staff and patients.

Lumbar Surgery and its Implications for Geriatric Patients

Particularly for elderly patients with comorbidities and a high ASA (American Society of Anesthesiologists) risk status the rates of general and surgery-related complications are significantly higher.[4,5]

Taking the increased complication rates in this age group into account, an ideal treatment option combines short operative times with a less invasive fixation procedure.

Posterior MIS Fusion System

The ***coflex-F+***™ implant is an interlaminar stabilization device that can be delivered through a small skin incision. It provides significant segmental stability and allows for posterior fixation as an adjunct to fusion post decompression.

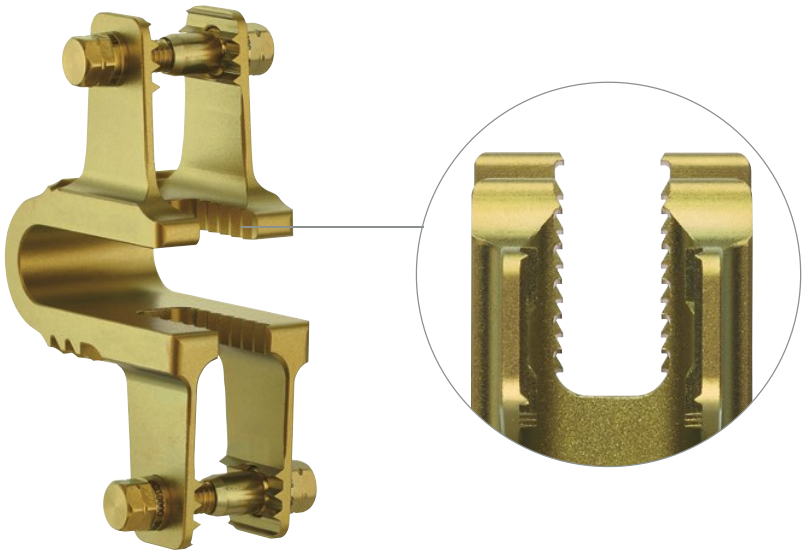
The implantation technique is safe and easy. Complications encountered with conventional pedicle screw systems can be avoided.

The ***coflex-F***$^{+}$™ implant – **when less is more!**

1 Jansson et al. Eur Spine J 2005; 14(7):659-663.
2 Aalto et al. Scand J Surg 2012; 101(4):255-260.
3 Park et al. Spine J 2011; 11(04): 295-302.
4 Daubs et al. Spine 2007; 32(20):2238-2244.
5 Sobottke et al. Eur Spine J 2012; 21(3):411–417.

coflex-F+™ POSTERIOR MIS FUSION SYSTEM

Interlaminar stabilization with the ***coflex-F+***™ implant* is an ideal adjunct to different fusion techniques in cases of back pain due to lumbar degenerative processes with or without mild instabilities. The unique implant design allows for segmental stabilization after decompression to promote fusion and offers an important alternative to pedicle screw fixation.



coflex-F+™ =	MIS Posterior Stabilization	+	Fusion
	• Deep, interlaminar positioning to counteract posterior forces while maintaining foraminal height • Large contact surface for optimized load distribution • Strong rivet fixation for a perfect fit to the spinous processes		Posterior fenestration for placement of bone graft and/ or bone substitutes in combination with posterolateral fusion

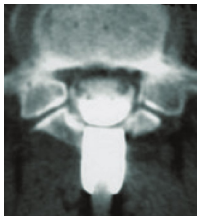
* US Patent 5, 645, 599. Also Patented in other Foreign Countries. Additional Patents Pending in the U.S. and worldwide.

DESIGN RATIONALE

The combination of the ***coflex-F***+™ design features provides segmental stabilization post-surgical decompression until fusion is achieved.

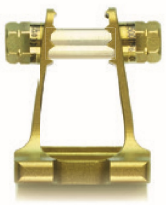
Interlaminar Positioning

Insertion at the level of the facet joints allows the implant to counteract the majority of posterior column forces to maintain foraminal height and unload the facet joints. The ***coflex-F***+™ implant is positioned on the strongest bony structure of the posterior column, the lamina.



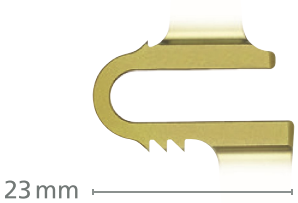
Rivet Fixation

Designed to allow for a low profile, tissue friendly, anatomical fit. The implant wings can be precisely adjusted to the morphology of the spinous processes for an always perfect fit.



Large Contact Surface

Maximum coverage of the spinous processes and the laminae allows for optimal load distribution and reduced stresses on the anatomical structures.

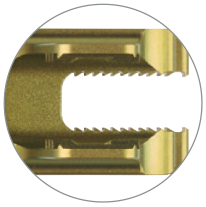


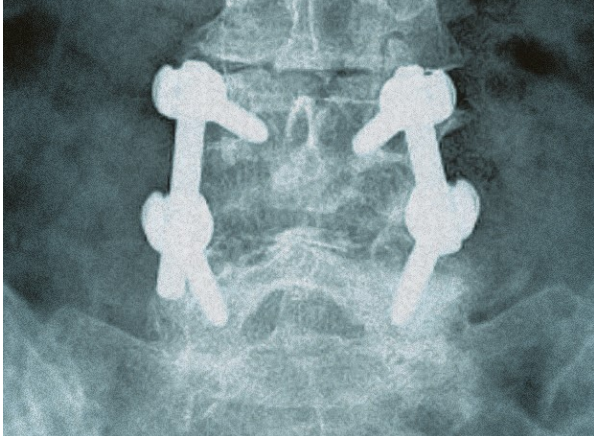
Serrated Teeth

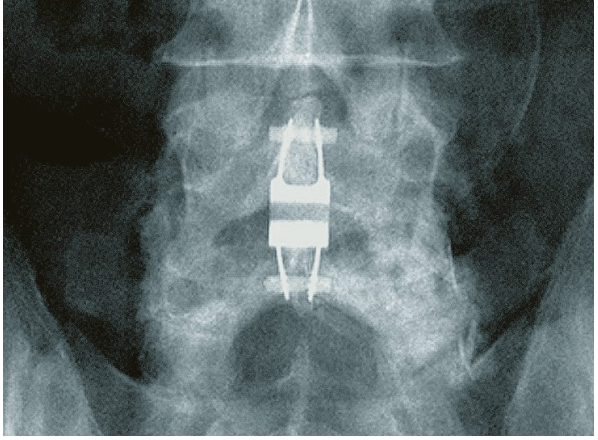
Serrated teeth both inside the wings and on superior and inferior arm of the ***coflex-F***+™ implant provide excellent primary stability.

Posterior Fenestration

Designed for placement of autograft and/ or bone substitutes to support fusion.







The ***coflex-F***+™ implant – the minimally invasive alternative to traditional pedicle screw fixation

Reduced Iatrogenic Trauma

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

Reduced Surgical Risks

- Excellent safety profile of implant
- Protection of neural structures
- Reduced radiation exposure for surgeon, OR-staff and patient

Reduced Cost

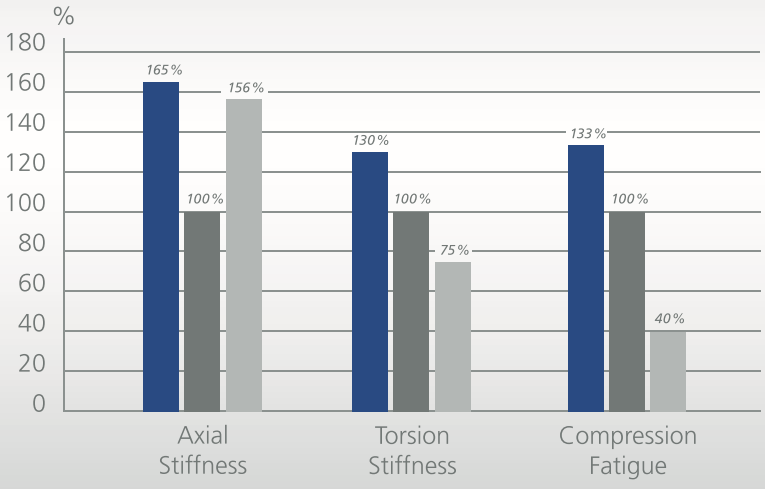
- Shorter operating time
- Faster patient rehabilitation

Ease of Use

- Simple surgical technique
- Five anatomical sizes
- Color coded instrumentation

Comparative Mechanical Testing

The ***coflex-F***+™ implant was mechanically tested based on a FDA-regulated side by FDA-regulated side-by-side testing protocol and compared to commercially available spinous process plates.*



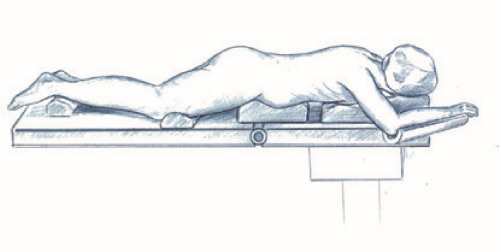
Summary:
The mechanical testing demonstrated superior mechanical properties for the ***coflex-F***+™ implant compared to the tested spinous process plates: The ***coflex-F***+™ implant allows for a stronger stabilization and has superior fatigue characteristics.

* Values for Aspen® = 100%.

SURGICAL TECHNIQUE

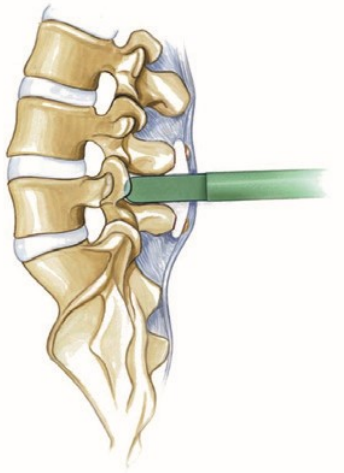
1. Preparation

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 any bony overgrowth of the spinous process that may interfere with insertion is resected. Ligamentum flavum is resected and microsurgical decompression is performed, relieving all points of neural compression.



2. Implant Site Preparation

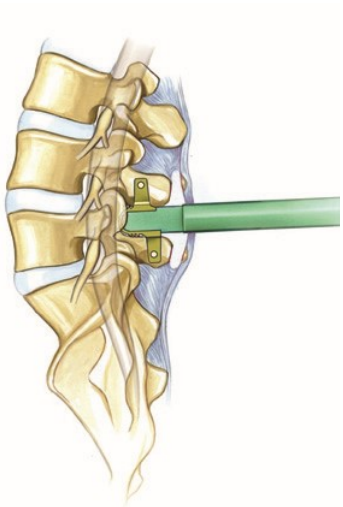
Trials are utilized to define the appropriate implant size. The trial instrument is placed to evaluate proper contact with the spinous processes avoiding any facet distraction. Some bony resection of the spinous process may be needed to ensure optimal contact of the implant.



3. Implant Insertion

The implant is introduced via impaction utilizing a mallet. Prior to insertion the wings may need to be opened slightly using the bending pliers to ensure appropriate depth of insertion (Fig. 1). Proper depth is determined by passing a beaded tip probe between the implant and the dura to ensure a 2–3 mm separation.

By deeply inserting the ***coflex-F***$^{+\text{™}}$ implant at the level of the facet joints the implant counteracts the majority of posterior column forces.



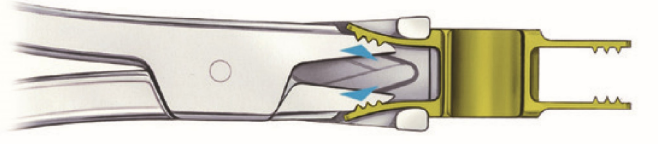


Fig. 1

Once proper placement has been achieved, it is recommended to securely crimp the wings of the implant using the crimping pliers (Fig. 2).
Then punching pliers are utilized to create a hole in each spinous process for later introduction of the ***coflex-F***+™ rivets.

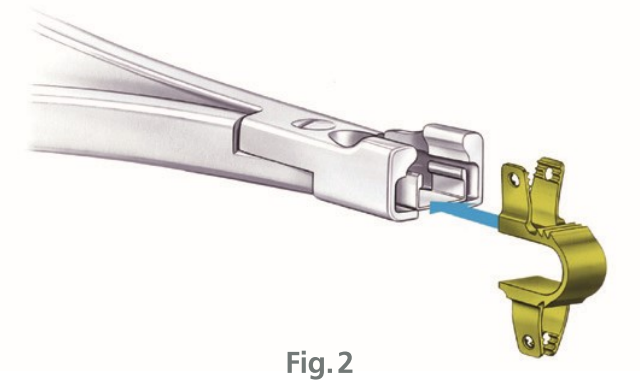
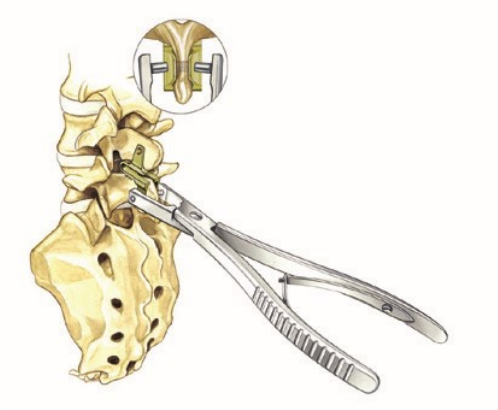
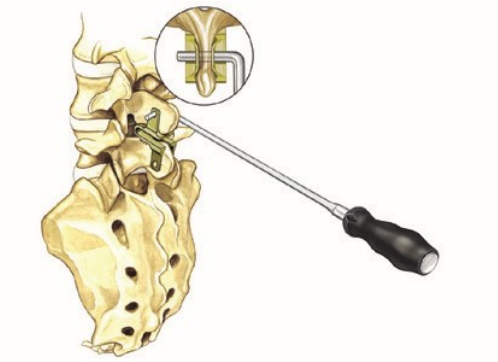


Fig. 2

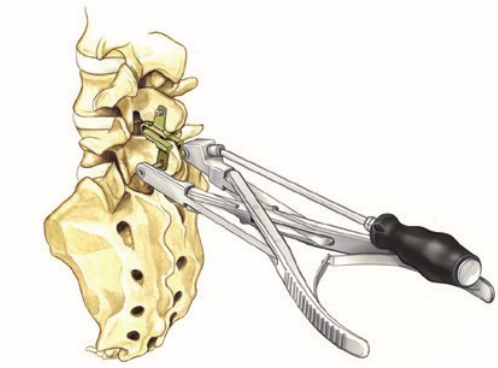


Prior to insertion of the ***coflex-F***+™ rivets it is recommended to clean the holes using the probe.
The ***coflex-F***+™ rivets are attached to the screw inserter and applied into the spinous processes using the screw driver. A tight fit is required for controlled fixation. The teeth of both wings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



4. Fusion Technique

After insertion of the ***coflex-F***+™ implant and the application of the rivets, the posterior fenestration can be filled with bone graft or bone substitutes. Arthrodesis is performed utilizing standard fusion techniques such as posterolateral or interbody fusion.



5. Wound Closure

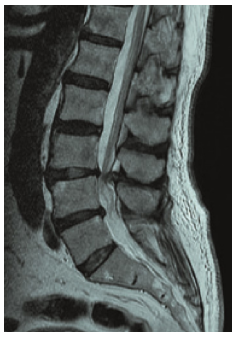
A surgical drain may be placed as per surgeons´ preference. Paraspinal muscles are reattached to the supraspinous ligament. Skin is closed in the usual manner.

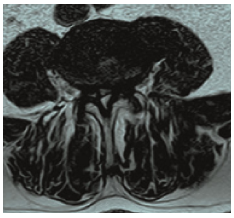
PATIENT CASE

Male, 71 Years

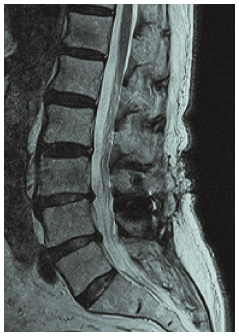
- **Symptoms:** Spinal stenosis with reduced walking distance of less than 250 meters for for the last 1.5 years. Load-dependent radicular pain L4/5 bilateral. Preoperative: VAS back pain 7.5.
- **Diagnosis:** Degenerative spinal stenosis L3/L4; Facet joint degeneration L3/4 bilateral; Protrusion L4/5; no spondylolisthesis in functional X-rays.
- **Conservative Treatment:** CT-guided facet blocks L3/4 bilateral with pain reduction to VAS 1.5 for 3-4 weeks, no effect on walking distance, persistent radicular pain.
- **Surgery:** Microsurgical decompression and implantation of ***coflex-F***$^{+\text{™}}$ 10 mm at the level of L3/4. Decortication of facet joints and application of bone substitute both, posterolaterally and inside the posterior fenestration of the implant.
- **Postoperative Care:** Mobilization the next day and start with physical therapy after removal of drain.
- **Follow-up at 3 months:** Patient is very satisfied with treatment. Mild dysaesthesia L4/L5 bilateral. VAS back pain 1.5. Walking distance increased to more than 1000 meters.

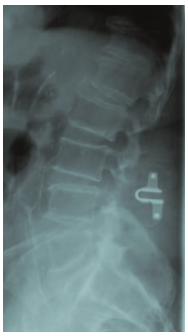
Preoperative

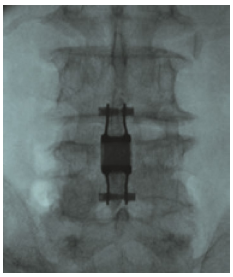




Postoperative







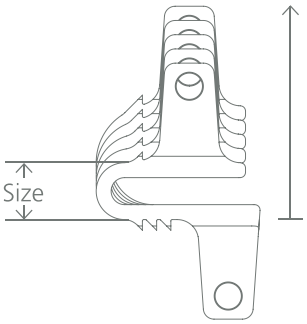
INDICATION

The ***coflex-F***$^{+\text{™}}$ system is a posterior, non-pedicle supplemental fixation device intended for permanent implantation as an adjunct to different fusion techniques in the lumbar spine (L1–S1) in one level in cases of back pain due to lumbar degenerative processes of instability as pseudospondylolisthesis (up to Meyerding grade I), osteochondrosis, instability of facet joints and lumbar stenosis or lumbar disc prolapses. The ***coflex-F***$^{+\text{™}}$ system provides additional segmental stabilization to increase the segmental stiffness and promote the fusion process. The ***coflex-F***$^{+\text{™}}$ system is intended for use with bone graft material, not intended for stand-alone use.

PRODUCT INFORMATION

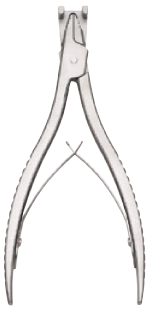
Implants

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

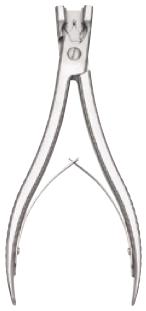


Material:
All ***coflex-F***$^{+}$™ implants consist of titanium 6-alumnium 4-vanadium (ISO 5832-3).
The ***coflex-F***$^{+}$™ implant is delivered sterile packed and includes a disposable application tool.

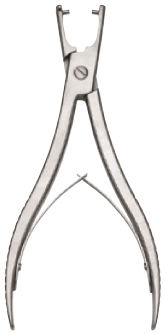
Instruments



Bending Plier
UAT 10100



Crimping Plier
UAT 10200



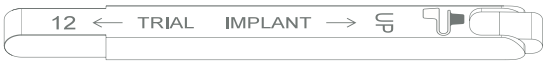
Punching Plier
RAT 20100

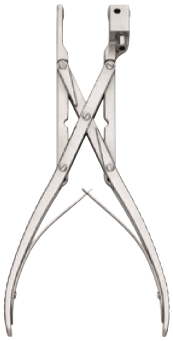
Cleaning Tool
RAT 20130

Probe
RAT 20120

Trials

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





Screw Inserter
RAT 20211

Screwdriver
RAT 20204

Wrench
RAT 20300

RDM00001 Rev. B

PARADIGM SPINE
the movement in spine care

Paradigm Spine GmbH
Eisenbahnstrasse 84
D-78573 Wurmlingen, Germany

Tel +49 (0) 7461 - 96 35 99 - 0
Fax +49 (0) 7461 - 96 35 99 - 20

info@paradigmspine.de
www.paradigmspine.com

Product not available in the USA