

Minimal Invasive Lumbar Fusion

coflex-F™



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the movement in spine care

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4. Biomechanical Evaluation
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6. Surgical Technique
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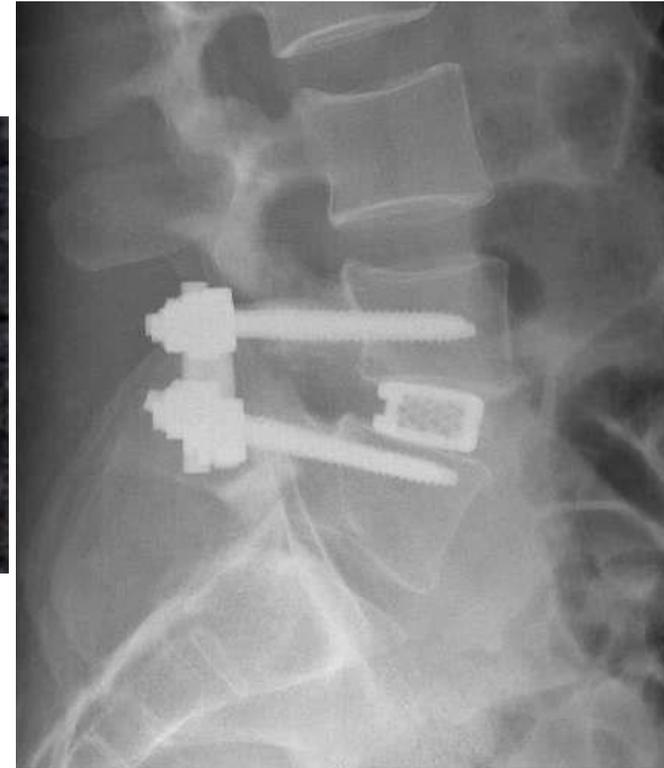
coflex-F™

Philosophy



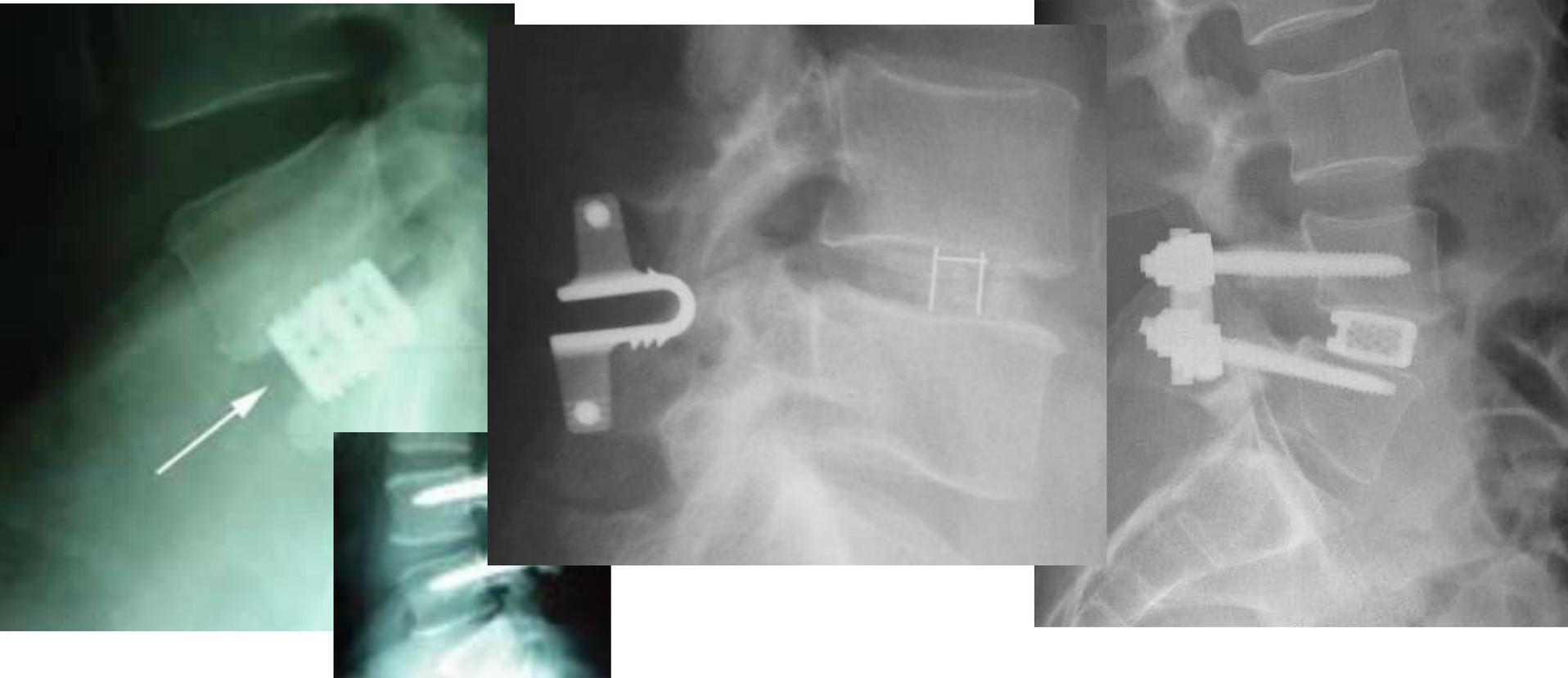
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Philosophy



... bridging the gap

Philosophy



The *coflex-F™* implant offers an alternative to pedicle screw fixation.

... bridging the gap

Philosophy

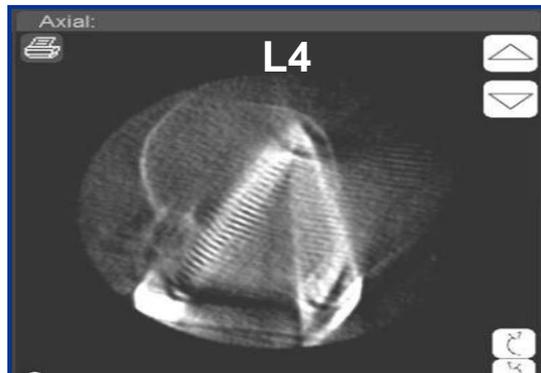
- Interspinous stabilization with ***coflex-F™*** is an ideal adjunct to fusion in cases of degenerative disc disease with or without mild instabilities in the lumbar spine.
- ***coflex-F™*** allows for segmental stabilization in combination with interbody fusion cages and is bridging the gap between stand-alone anterior solutions and 360-Fusions using pedicle screw fixation.
- ***coflex-F™*** can be applied in a less-invasive tissue-sparing procedure significantly reducing iatrogenic damage and promoting shorter rehabilitation for patients.

Philosophy

Limitations of Pedicle Screw Instrumentation

Time

- └ Potentially morbid approach (open)
- └ Radiation to surgeon/patient
- └ Risk to neurologic structures
- └ Cranial facet joint violations with MIS screw insertion
- 50% violation - ASD
- └ Learning curve



Philosophy

Limitations of Pedicle Screw Instrumentation

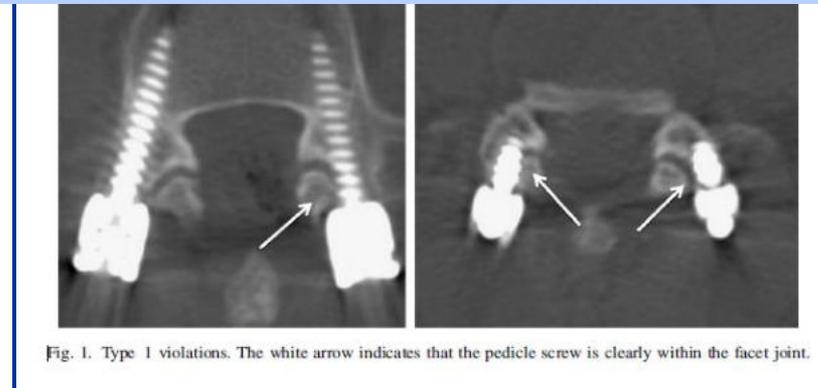
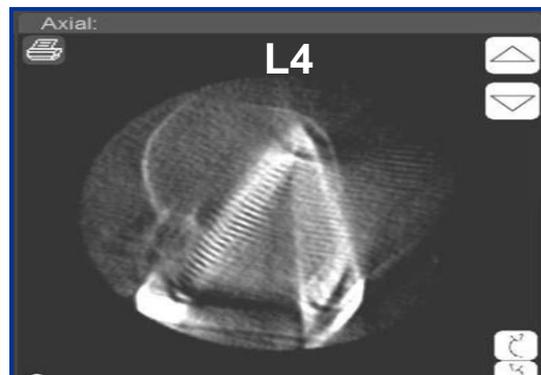
Time



2006 Survey of SRS membership:

Among male SRS surgeon members, there is a 25-fold higher incidence of thyroid cancer than expected, and a higher overall cancer rate.

L Learning curve



Philosophy

coflex-F™ vs. Pedicle Screws

Reduced Iatrogenic Trauma

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

Reduced Surgical Risks

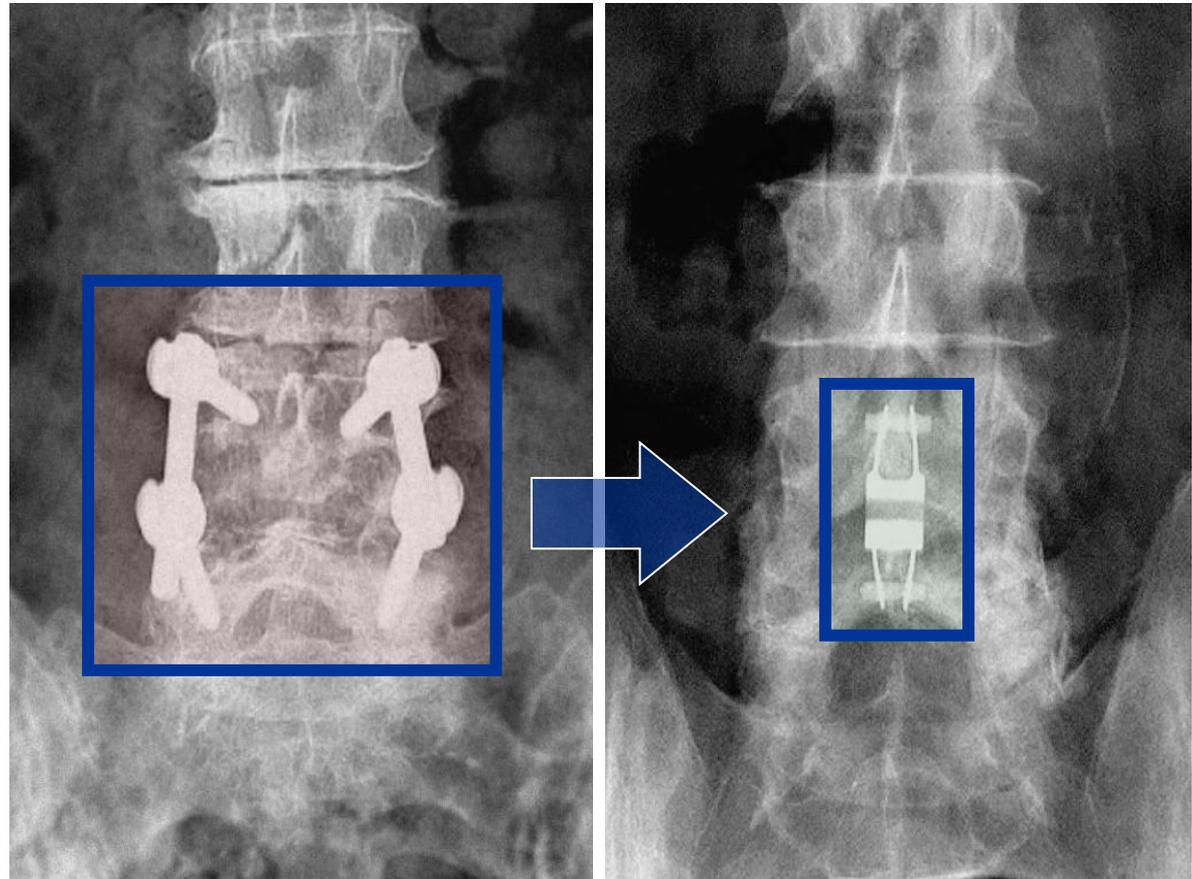
- └ Excellent safety profile of implant
- └ Protection of neurological structures
- └ Easy and precise application

Reduced Cost

- └ Shorter operating time
- └ Faster patient rehabilitation

Ease of Use

- └ Simple surgical technique
- └ Easy instrumentation



Philosophy

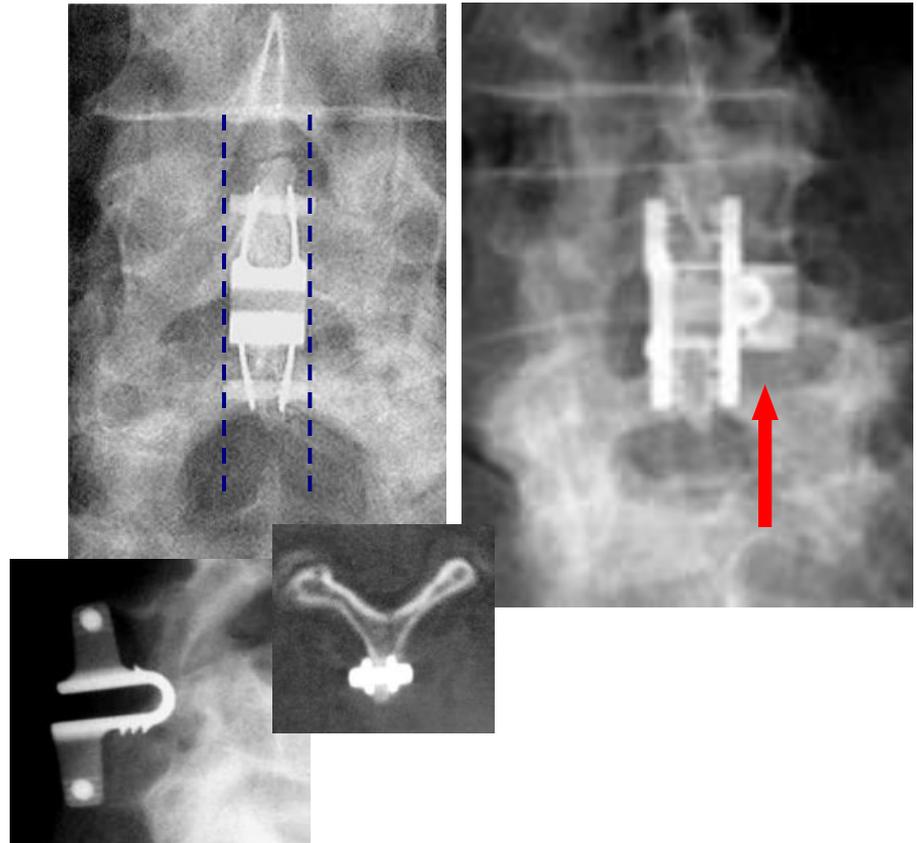
coflex-F™ vs. Spinous Process Plates

Interlaminar vs. Interspinous

- └ Supports facet joints
- └ Maintains foraminal height
- └ Utilizes stronger laminar bone
- └ Provides large contact surface for reduced stress on spinous proc.

Anatomical Fit

- └ Accommodates anatomy
- └ Tissue friendly
- └ Minimum space requirement
- └ Reduced risk of tissue irritations
- └ Rigid, stable rivet fixation



coflex-F™

Design Rationale



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Design Rationale

Secure anchorage through screw and sleeve fixation



Ball and socket screw/wing interface for optimized load distribution in various wing angulations



coflex-F™

Pin allows press fit wing attachment on spinous process

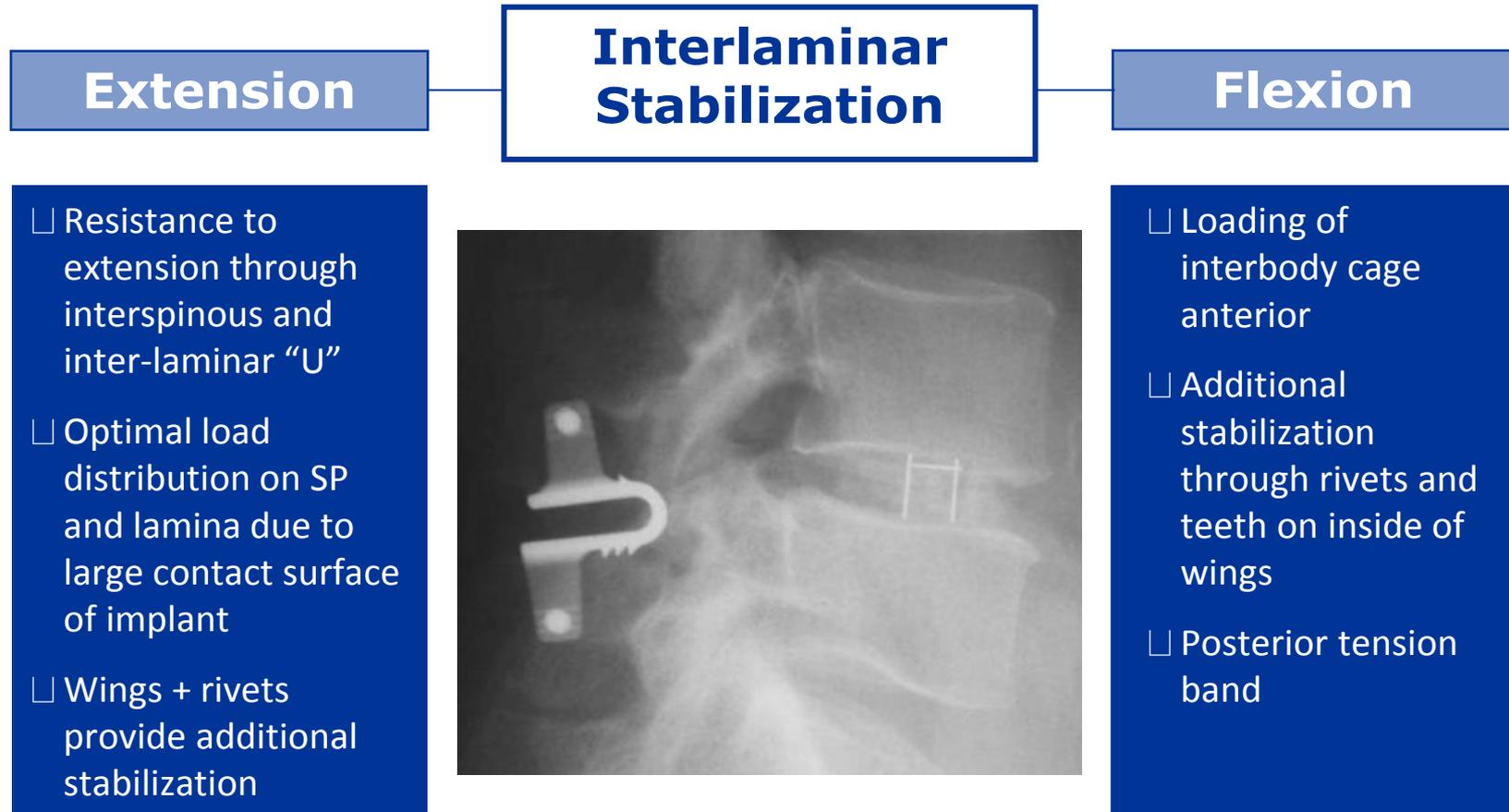


U-shape provides large surface area, different sizes allow adjustment of sagittal balance

Good bone anchorage through teeth on inside of wings

Design Rationale

Interlaminar Stabilization with coflex-F™

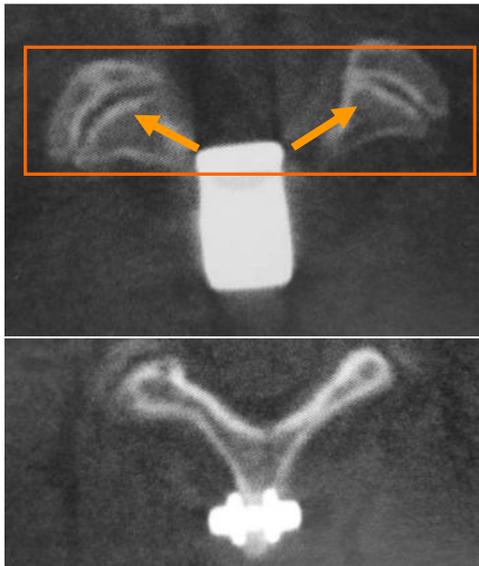


Design Rationale

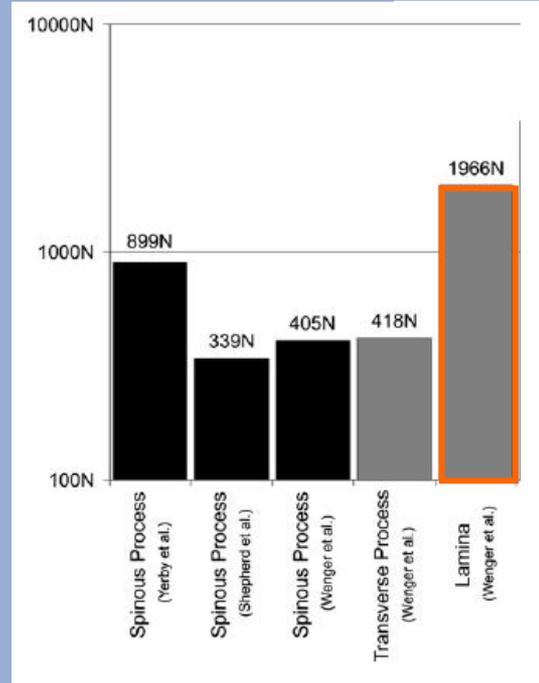
Interlaminar Positioning of *coflex-F™*

Intended to:

- └ Unload facet joints
- └ Maintain foraminal height
- └ Lamina factor 2 to 5 times



Implant position close to spinal canal with optimal load sharing



Design Rationale

Form Follows Function

Stabilization is achieved through a combination of different mechanisms...

Interspinous/Interlaminar “U”:

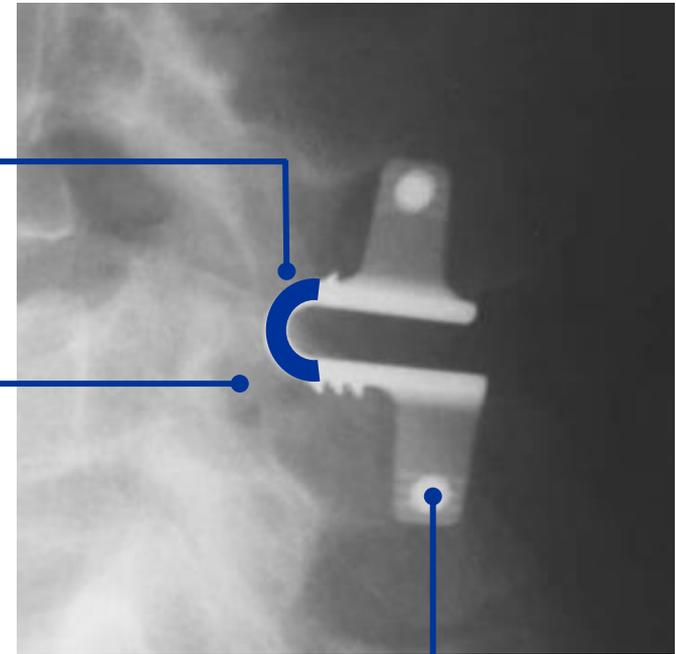
Maximum coverage of spinous process (SP) and laminar surface for optimal load distribution and reduced stress on SP

Deep, interlaminar insertion

(at the level of the facet joints) allows the implant to counteract the majority of posterior column forces

Rivet fixation

for additional stability



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Design Rationale

Implant Wings and Rivet Fixation

Precise. Stable. Validated.

Anatomical Fit – Low Profile

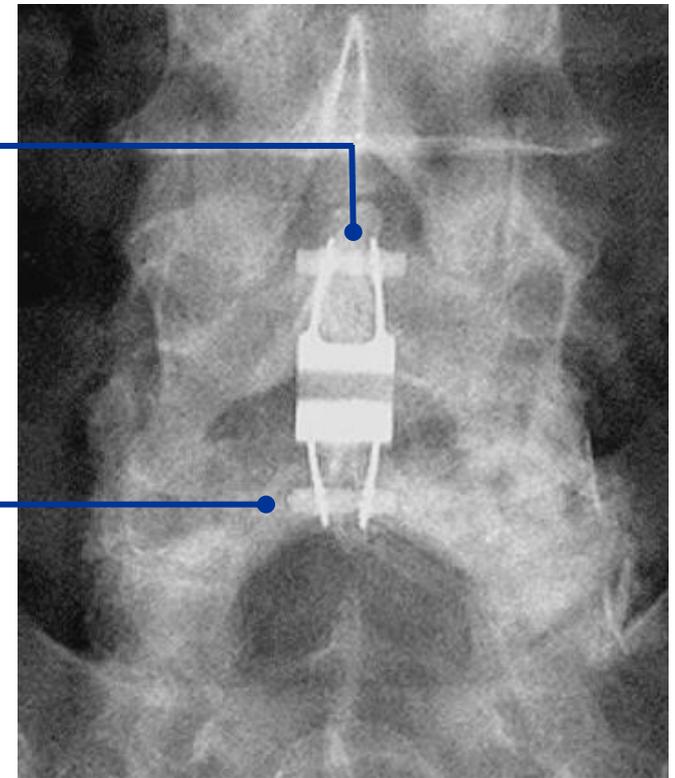
Allows precise adjustment to morphology leading to optimized spinous process contact

Additional Fixation

Non-aggressive, stable rivet and clamp fixation. Optimized bone anchorage through teeth on inside of wings

Validated

Mechanical, biomechanical and clinical data validates stable rivet fixation mechanism



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coflex-F™

Indication -
Contraindication



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Indication

- The **coflex-F™** system is intended for permanent implantation as an adjunct to fusion in the region from L1-5 in one level.
- The purpose is to achieve stabilization and to promote fusion in patients with degenerative disc disease - DDD defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.



Contraindications

- Degenerative Spondylolisthesis greater than °1 according to Meyerding classification.
- Any forms of isthmic spondylolisthesis.
- Prior decompressive laminectomy, hemilaminectomy or significant lamina fenestration which weakens the spinous process.
- Multilevel applications
- Cases of L5/S1

coflex-F™

Biomechanical Evaluation



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Biomechanical Evaluation



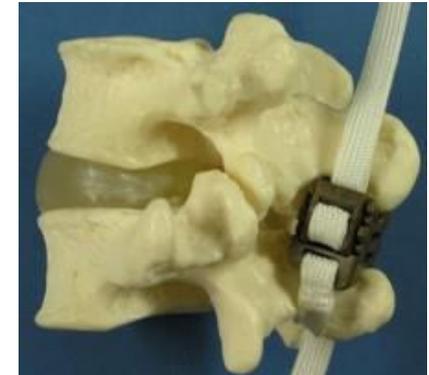
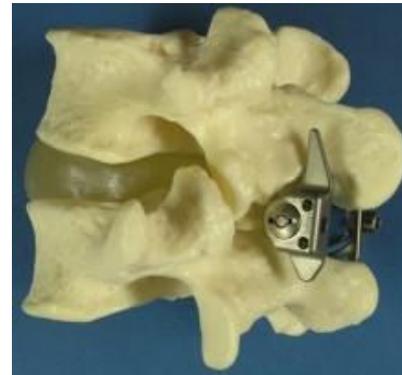
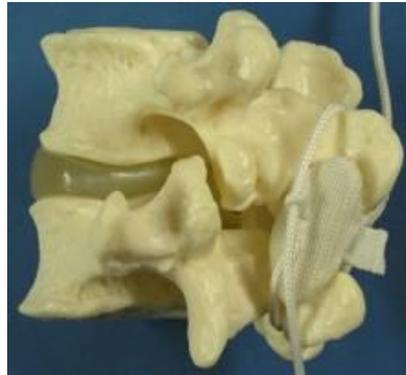
Institute of Orthopaedic Research and Biomechanics
Heinholdtstrasse 14, 89081 Ulm, Germany

Biomechanical evaluation of the Coflex interspinous implant
Project No.: 493

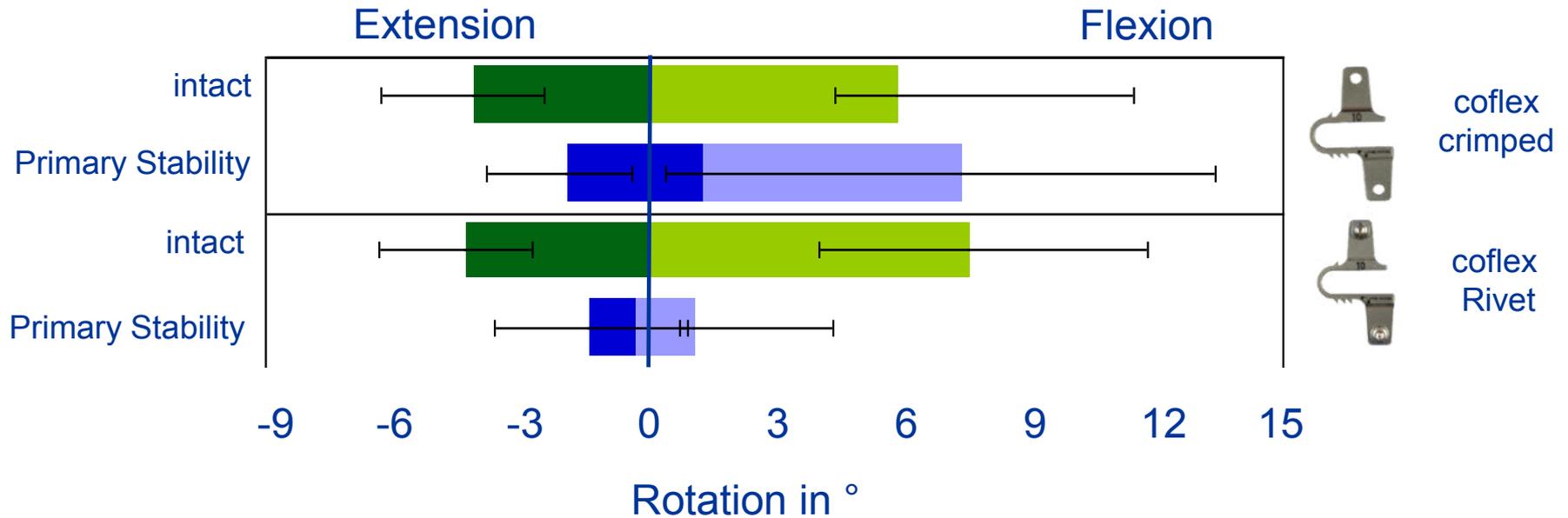
Test report

| | |
|------------------------|--|
| Client: | Paradigm Spine, 78573 Wurmlingen, Germany |
| Project director: | Prof. Dr. Hans-Joachim Wilke |
| Testers/ Participants: | Dr. J. Drumm, K. Häussler, Dr. A. Kettler, C. Mack |
| Test period: | June 2005 – September 2005 |
| Implants: | Coflex and competitive implants |
| Author: | C. Mack, Dr. A. Kettler |
| Copy to: | Wilke, Werner, Häussler, Drumm |

Rivet

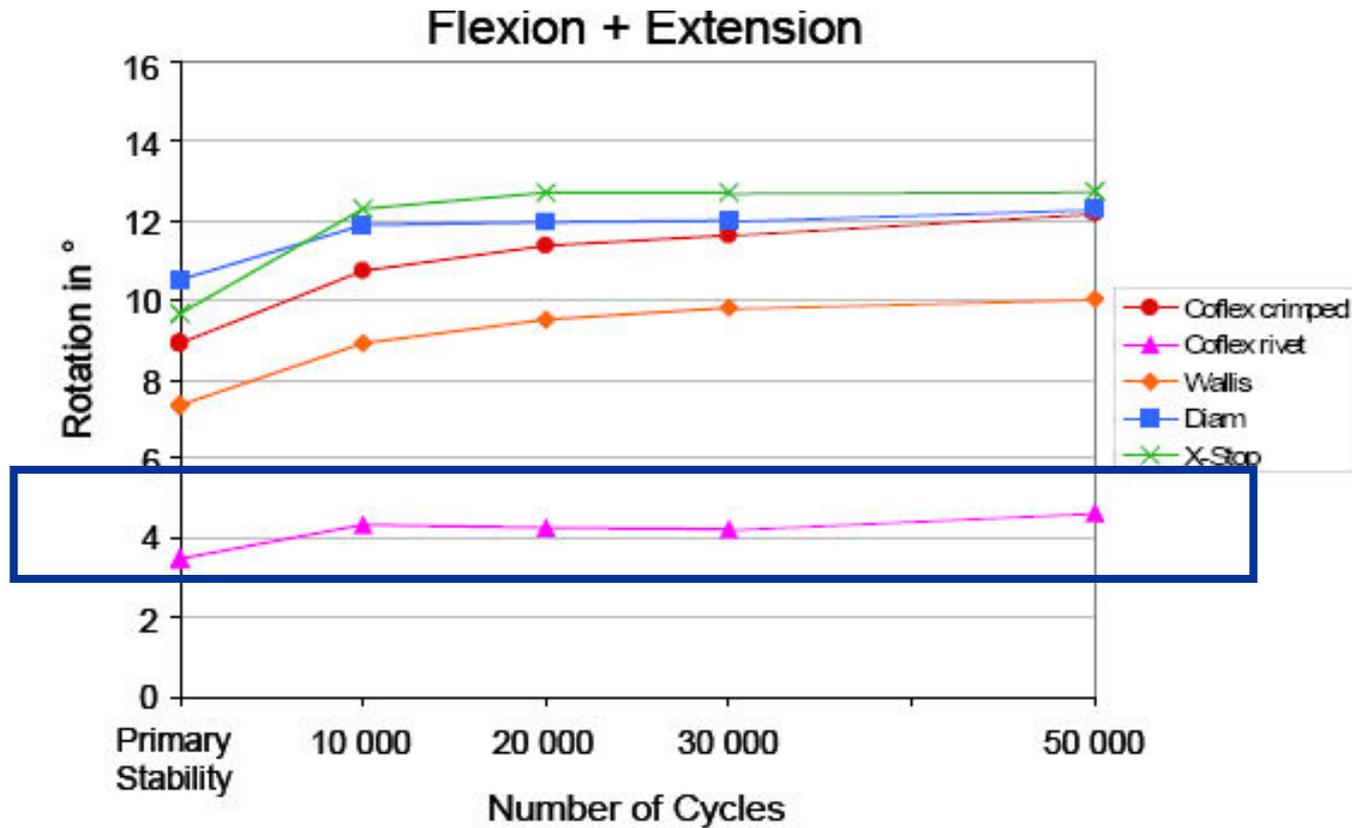


Biomechanical Evaluation



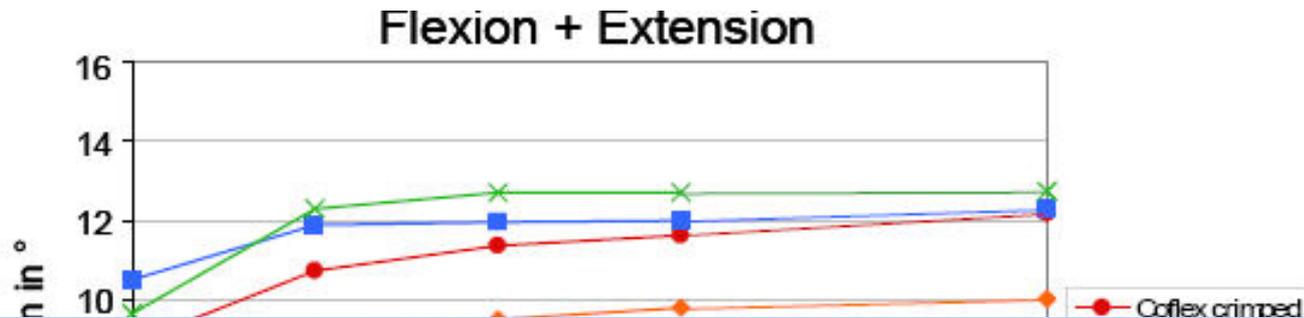
Test without intervertebral support!

Biomechanical Evaluation



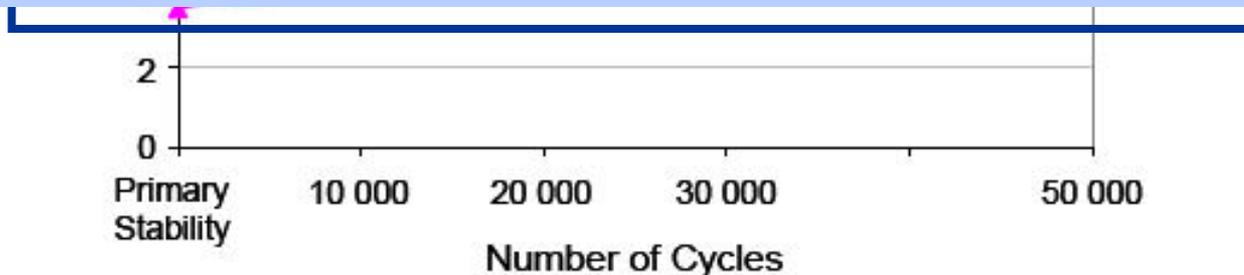
Test without intervertebral support!

Biomechanical Evaluation



Fact

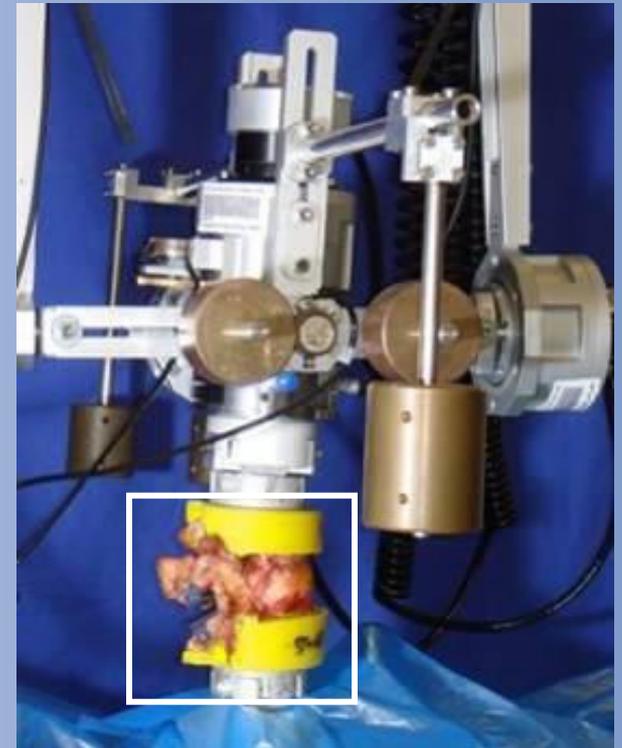
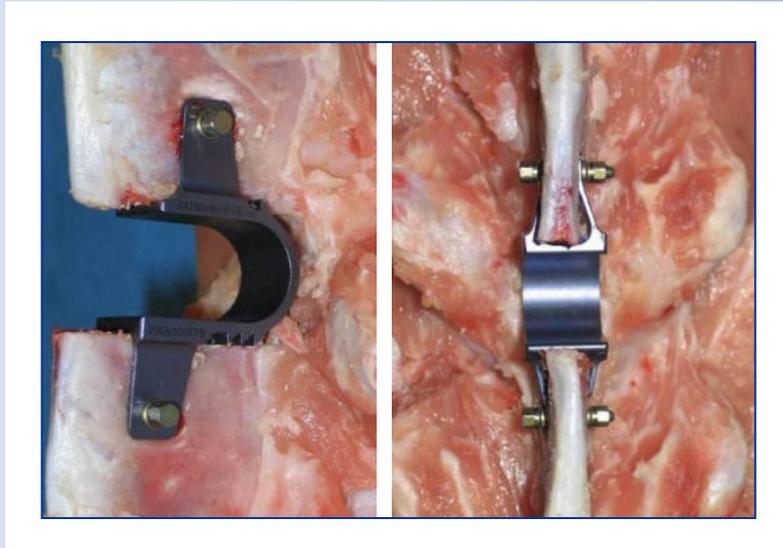
The biomechanical evaluation over 50 000 cycles proves the stabilizing effect of *coflex-F™* on the spine! It limits flexion and extension to allow for spinal fusion.



Test without intervertebral support!

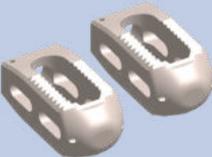
Biomechanical Rationale

All testing performed at Biomechanical Lab of Prof. Wilke, Ulm, Germany



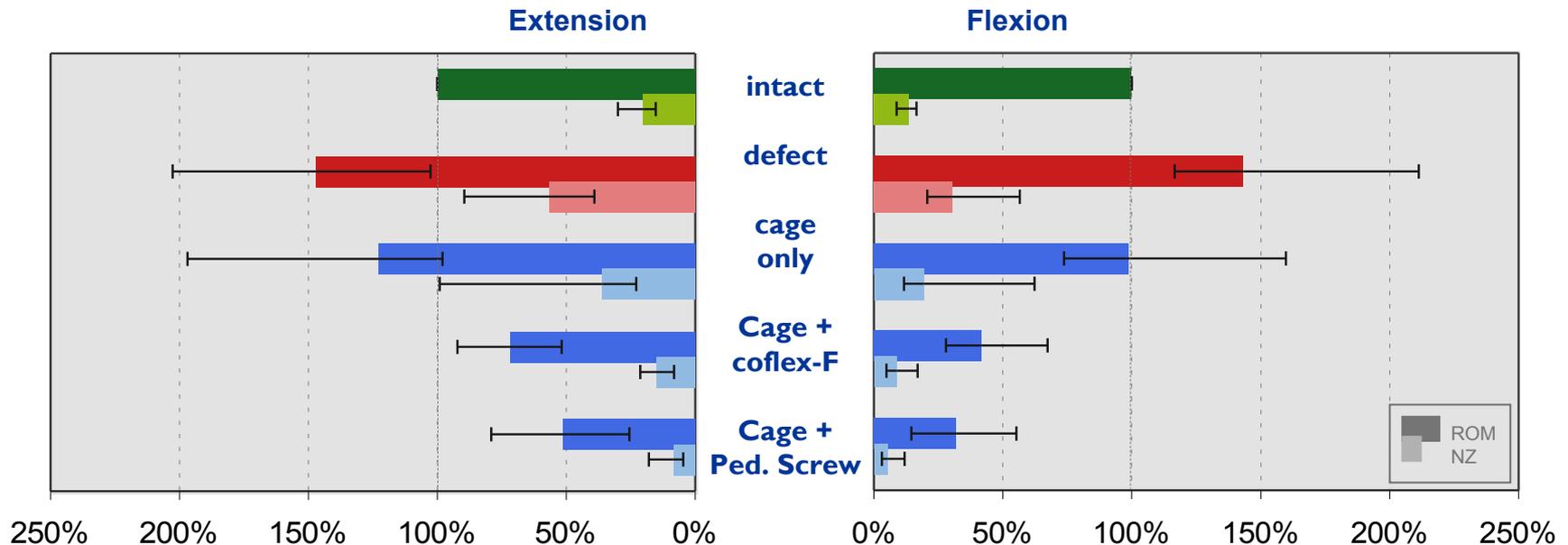
Biomechanical Rationale

Material and Methods: n=6 human lumbar specimens (3x L2-3, 3x L4-5)

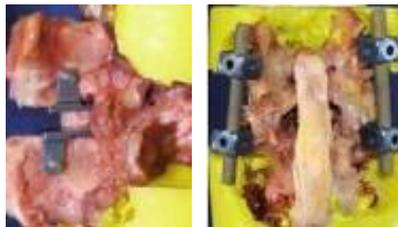
| | |
|---|---|
| Intact | Flexibility Test (Primary Stability) |
|  | Flexibility Test (Primary Stability) |
|  | Flexibility Test (Primary Stability) |
|  | Flexibility Test (Primary Stability) |

Biomechanical Rationale

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



Range of motion and neutral zone normalized with the intact state (100%).



coflex-F™

Clinical evaluation

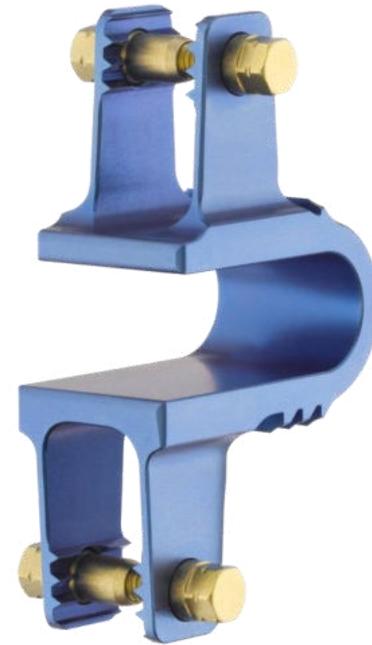


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Multicenter Case Series

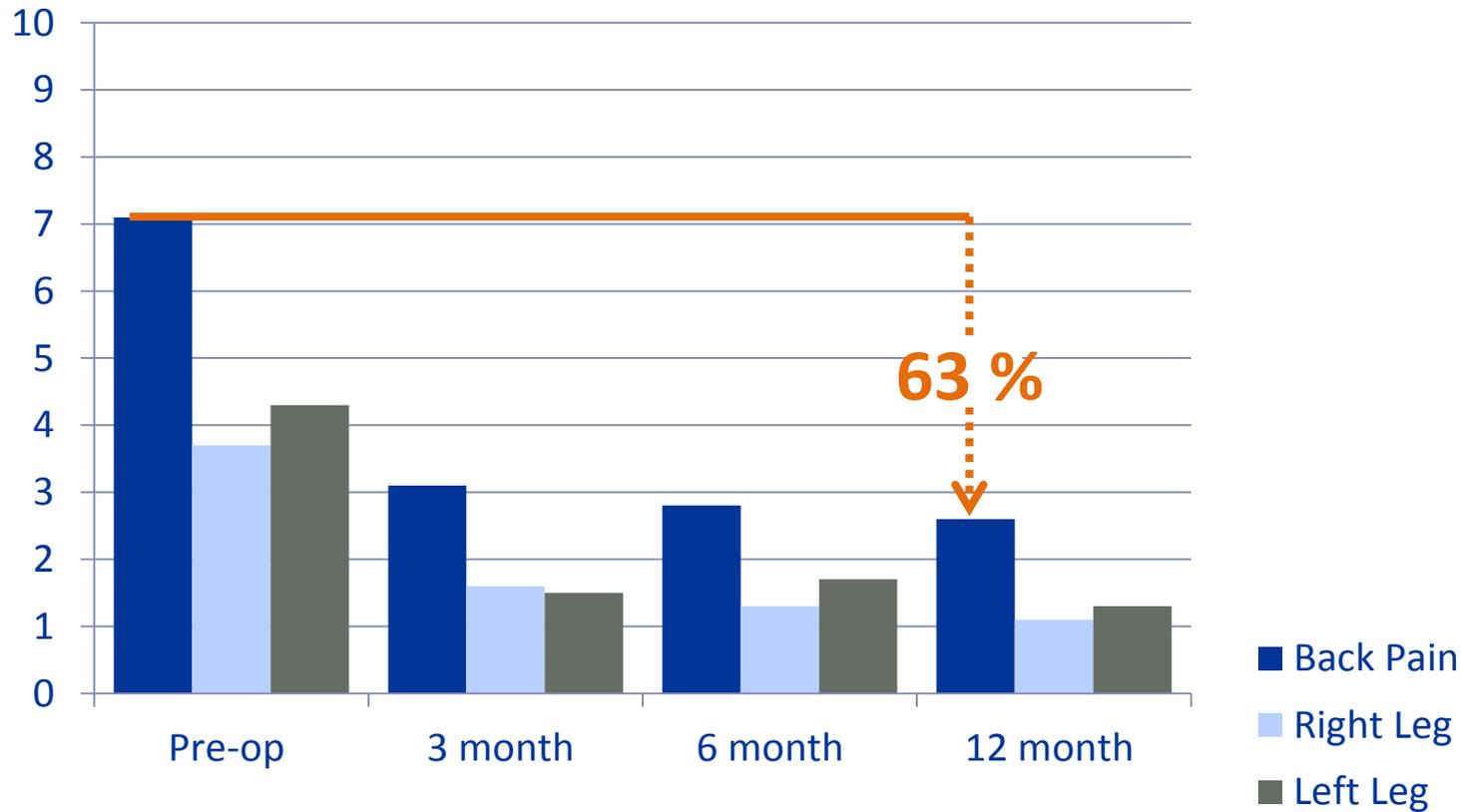
In a multicenter European trial , the *coflex-F™* interlaminar fusion device was used to stabilize lumbar interbody fusion for a variety of degenerative lumbar conditions.

- Prospective, non-randomized
- Post-Market surveillance study
- 6 surgeons
- ALIF, PLIF and TLIF cages
- End point 6-24 months
- No use of BMP included
- n=68, implants=76
- Average height: 169 cm
- Average weight: 82 kg
- Average age: 60 years



Clinical Data

VAS Pre-op vs. 3 month, 6 month, 12 month



Clinical Data

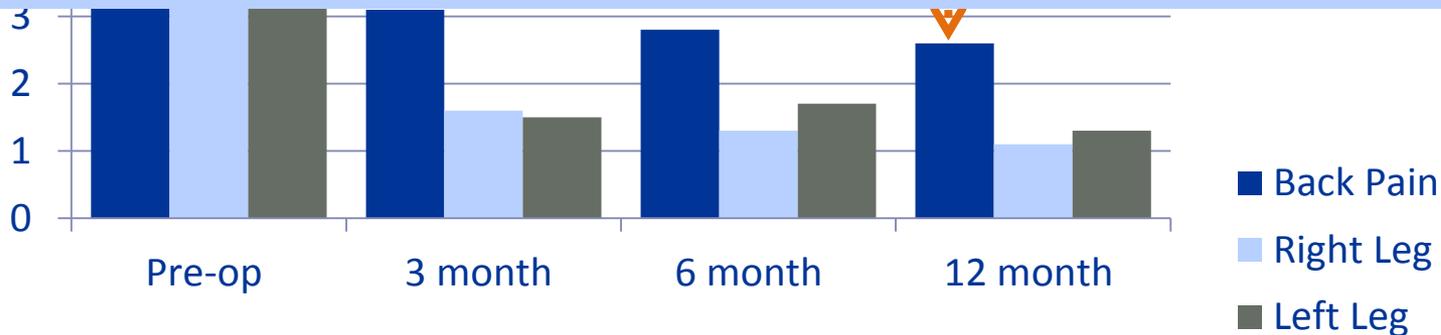
VAS Pre-op vs. 3 month, 6 month, 12 month



Fact

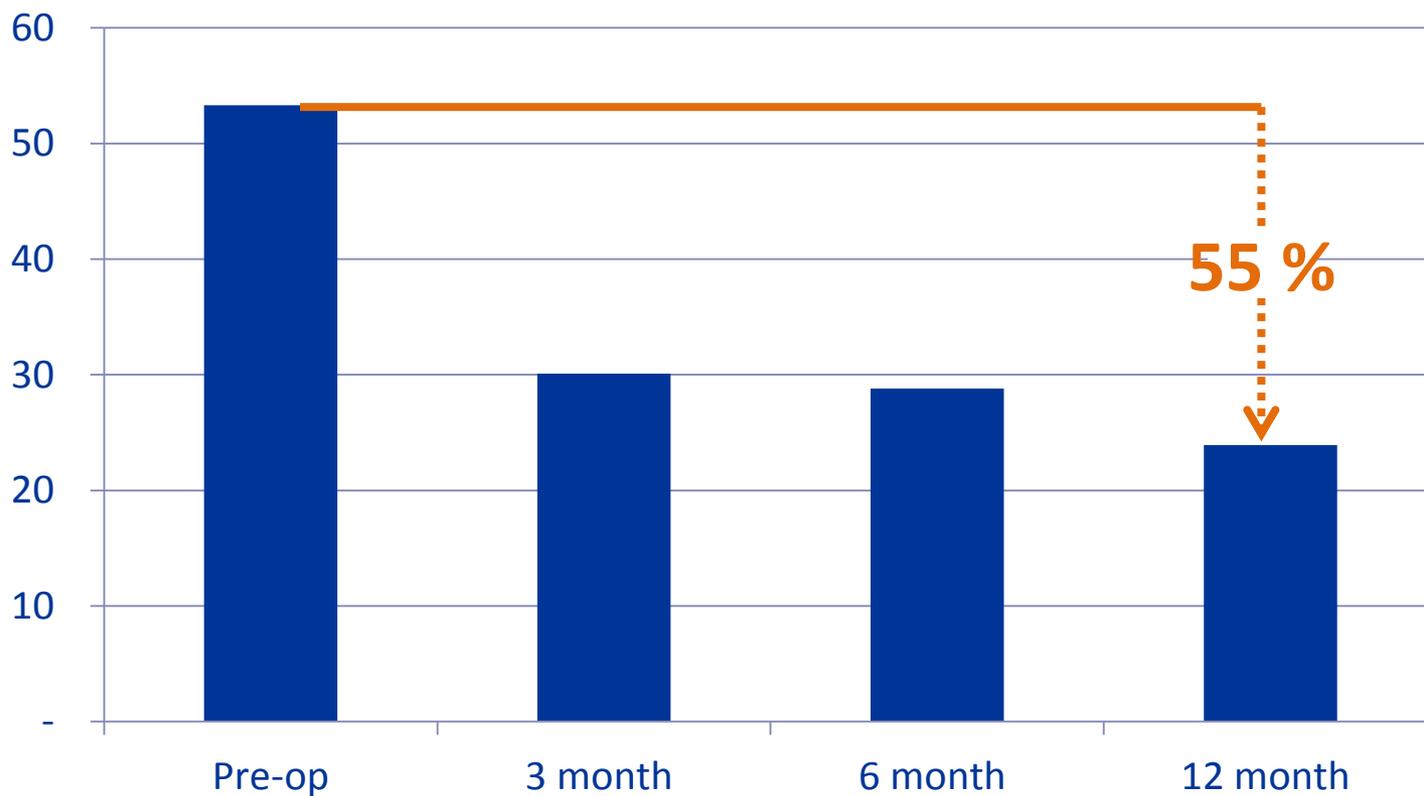
Results are comparable to those reported by Glassman et al., who reported on the clinical outcomes of 497 patients treated with lumbar spine fusions for the same indications as *coflex-F™*

Glassman S, et al. MOS Short Form 36 and Oswestry Disability Index outcomes in lumbar fusion: a multicenter experience. The Spine Journal 6 (2006) 21 – 26.



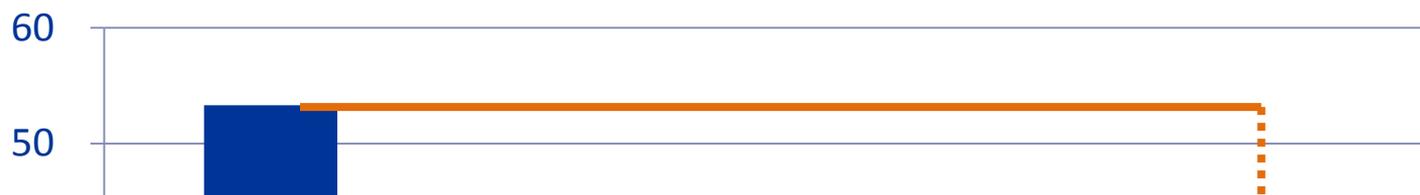
Clinical Data

ODI Pre-op vs. 3 month, 6 month, 12 month



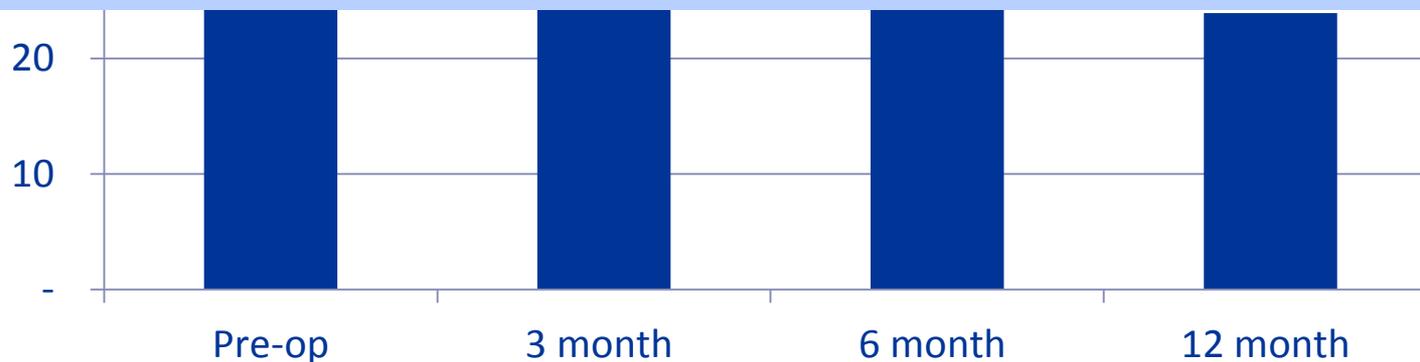
Clinical Data

ODI Pre-op vs. 3 month, 6 month, 12 month



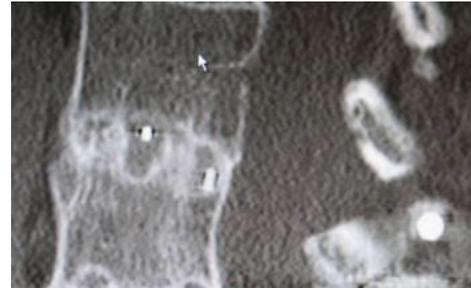
Fact

The study has shown that the associated back and leg pain can be addressed effectively by *coflex-F™*!



Radiographic Data

- 90 *coflex-F™* patients have been followed up radiographically ranging from 6-24 months post-operatively
- A board-certified, independent radiologist performed radiographic assessments
 - evidence of bridging bone
 - <3mm translational motion
 - <5 degrees of angular motion, and
 - fusion success (i.e. lack of detectable motion)



Radiographic Data

Radiographic Example I – Fusion Status with TLIF Cage

- Functional x-rays 9 months after surgery
- Solid Fusion



Radiographic Data

Radiographic Example II – Fusion Status with TLIF Cage

- CAT scan 9 months after surgery
- Solid Fusion



Radiographic Data

Radiographic Example III – Fusion Status with ALIF Cage

- CAT scan after 12 months
- Solid Fusion



6 weeks post-op



6 months post-op*



12 months post-op*

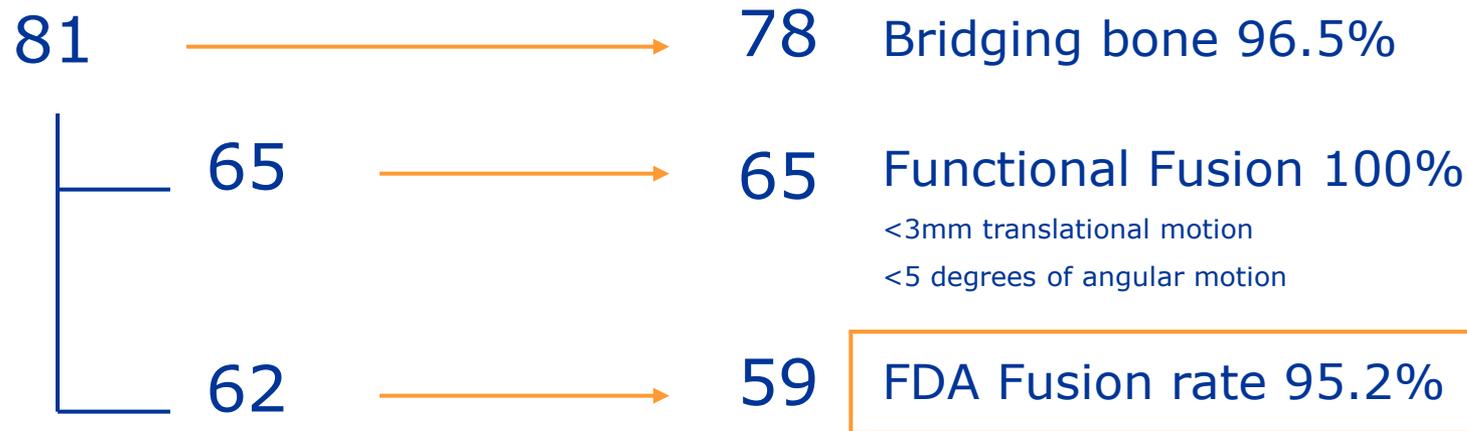
**Evidence of bridging trabecular bone between the involved vertebrae. Courtesy of Dr. Grochulla, Munich (now Fürth)*



Radiographic Data

Of the 90 patients:

81 patients (90%) had radiographic data that permitted assessment of fusion status. 65 patients had flexion-extension films, and 62 patients had all radiographic measures available for review:



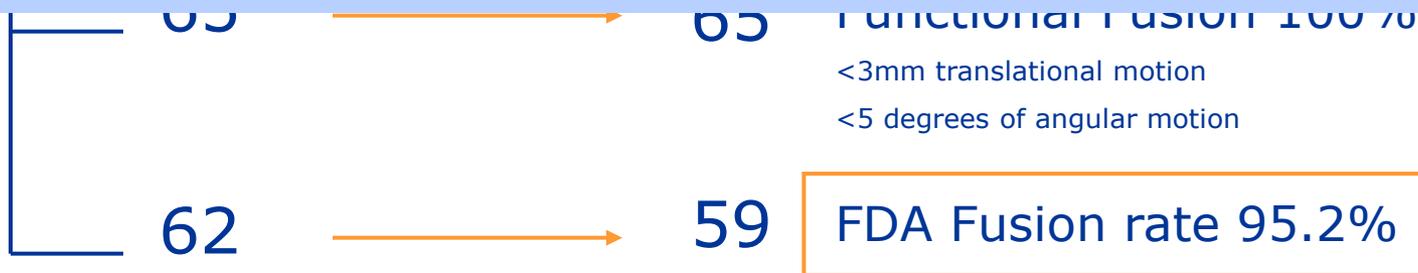
Radiographic Data

Of the 90 patients:

81 patients (90%) had radiographic data that permitted assessment of fusion status. 65 patients had flexion-extension films, and 62 patients had all radiographic measures available for review:

Fact

The fusion rate, using established radiographic criteria, was achieved in 95.2% of the with *coflex-F™* treated patients.



coflex-F™

Surgical Technique

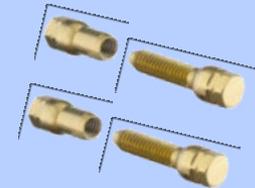
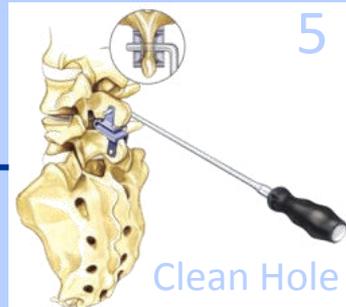
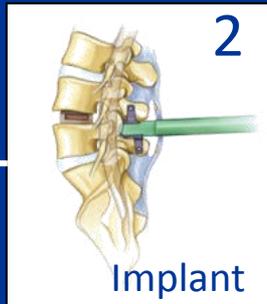
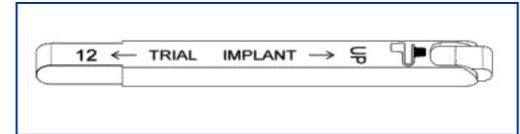


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Surgical Technique

Simple and Elegant

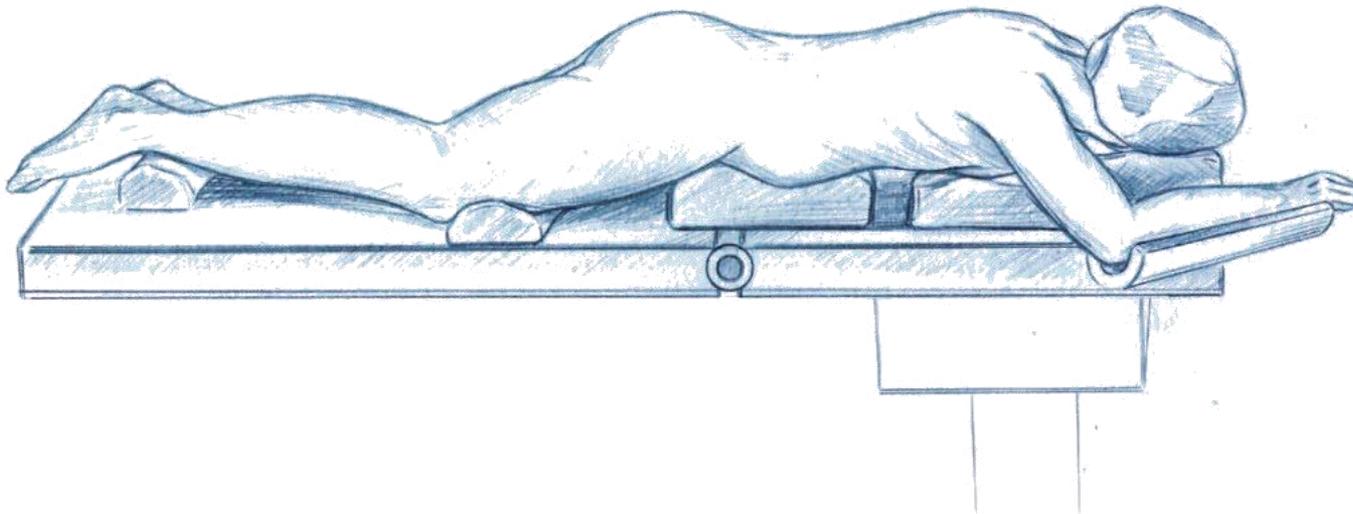
- Straight forward surgical technique, intuitive instrumentation
- Single piece implant (■) plus two rivets (■)



Surgical Technique

Patient Positioning

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

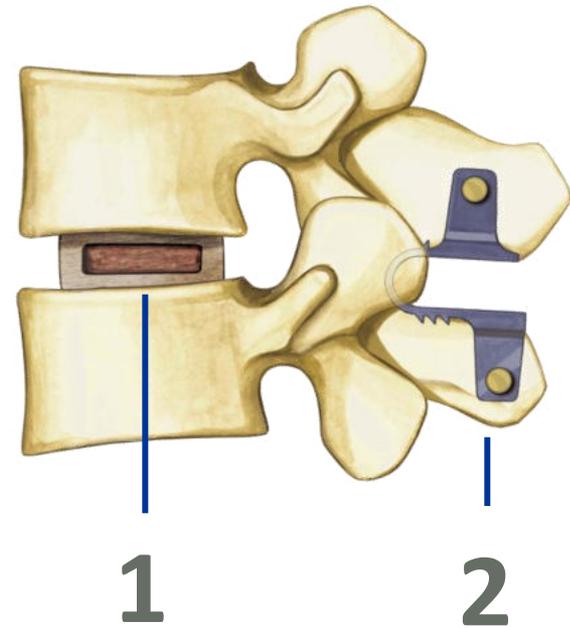


Surgical Technique

Lumbar Interbody Fusion L1 to L5

- Lumbar interbody fusion first!
- Restoration of lordosis through cages!
- Respect facet joints!

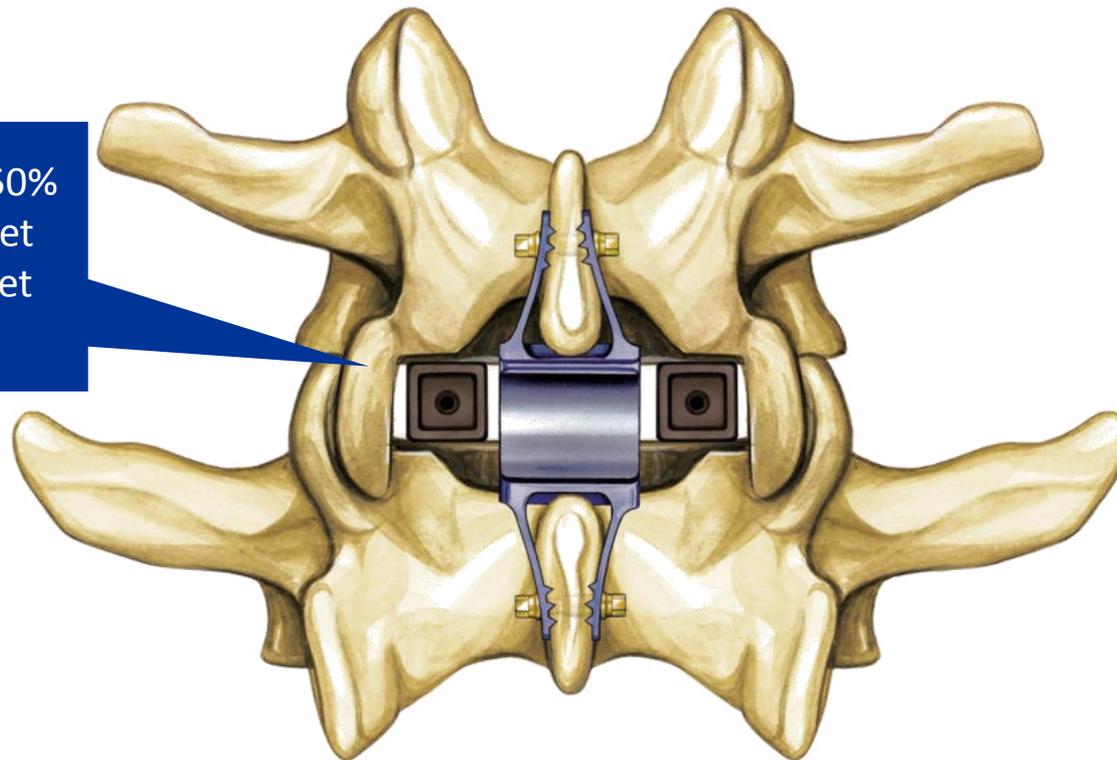
In combination with ALIF, PLIF or TLIF



Surgical Technique

Posterior Approaches

Maintain at least 50%
of the medial facet
and all of the facet
capsules

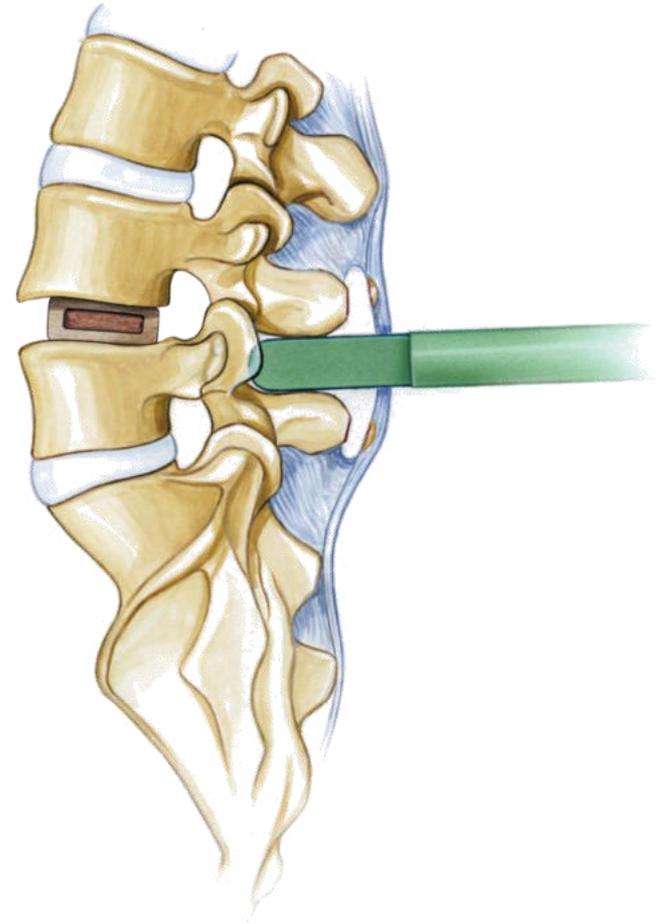


Surgical Technique

Implant Site Preparation

- After the intervertebral device (cage or machined allograft) has been inserted, trials are utilized to define the appropriate implant size.
- Trial instrument is placed to evaluate the proper contact with the spinous processes **avoiding any facet distraction.***

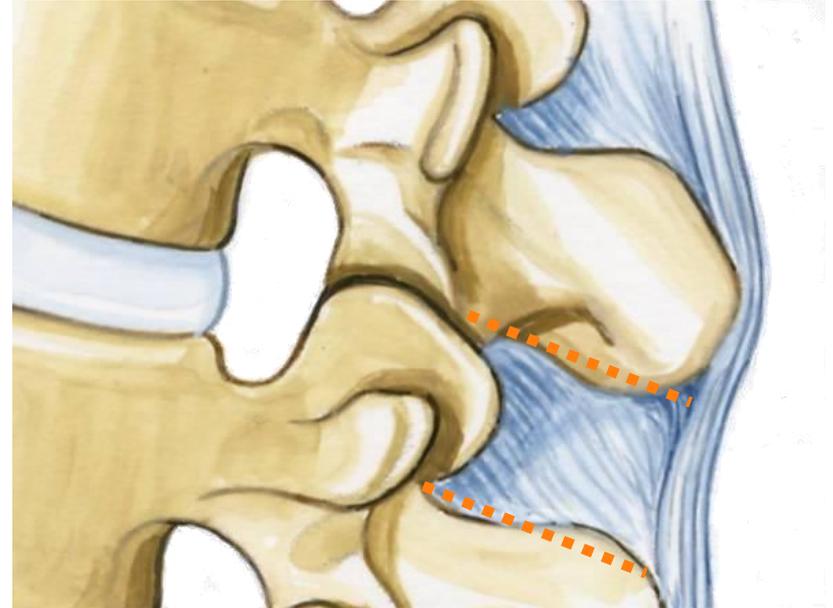
** It is most appropriate to use a **coflex-F™** implant one size smaller than to have distraction of the facets.*



Surgical Technique

Implant Site Preparation

- Make sure that the opposing facing surfaces of the superior and inferior spinous processes are parallel for enhanced contact onto the legs of the *coflex-F™* implant
- Flat surfaces can be obtained using either osteotomes, rongeurs or drills.
- Maintain adequate spinous process anatomy for optimal fixation strength.



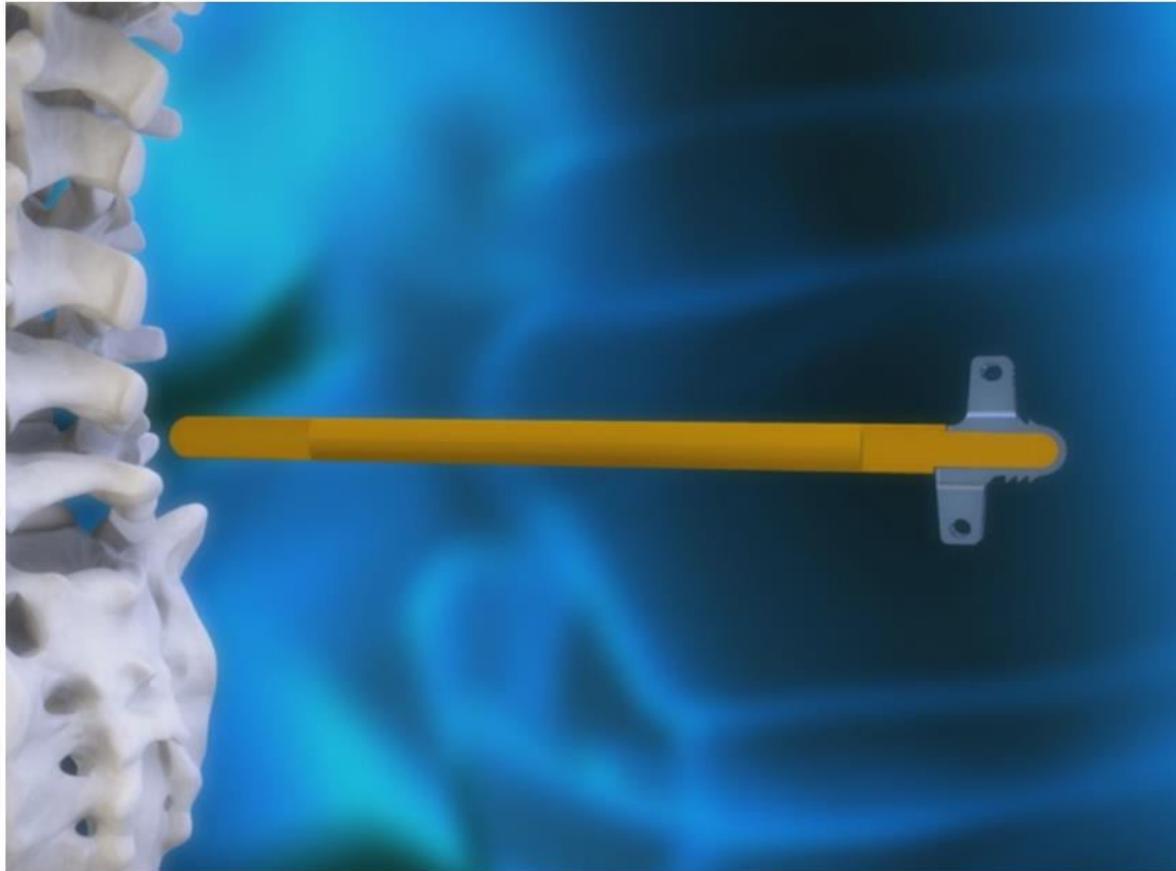
Surgical Technique

Implant Site Preparation



Surgical Technique

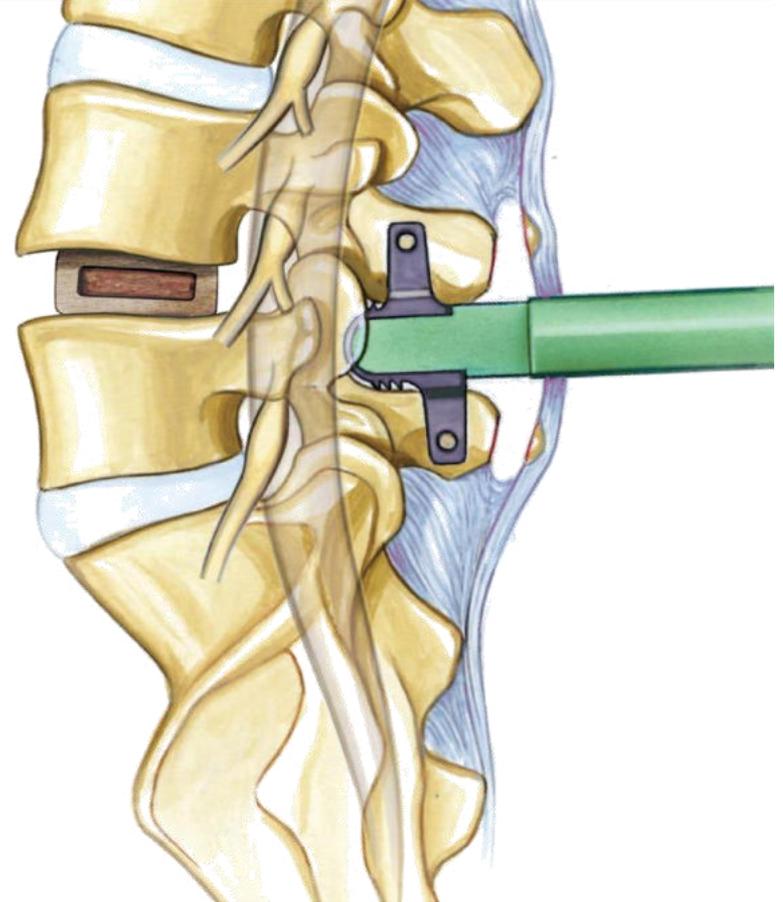
Implant Site Preparation



Surgical Technique

Implant Site Preparation

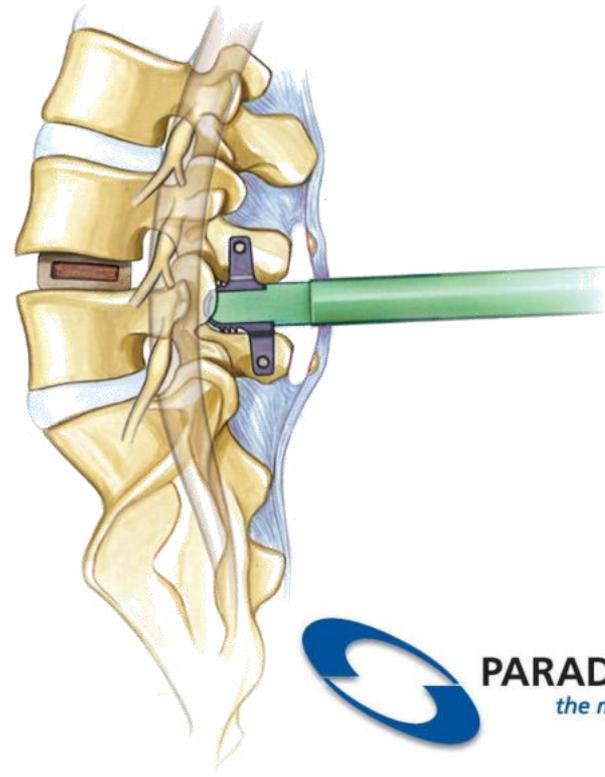
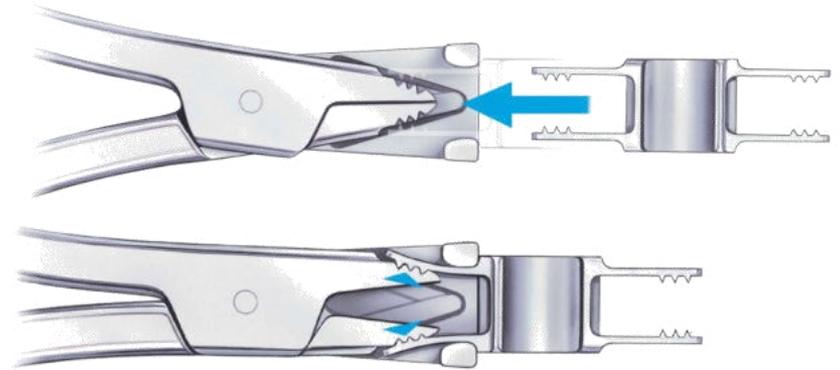
- If the laminae are steeply pitched (which can block proper seating of device wings), use a burr or rongeur to bilaterally fashion the juncture of laminae and base of interspinous process so that the wings seat at the appropriate depth.



Surgical Technique

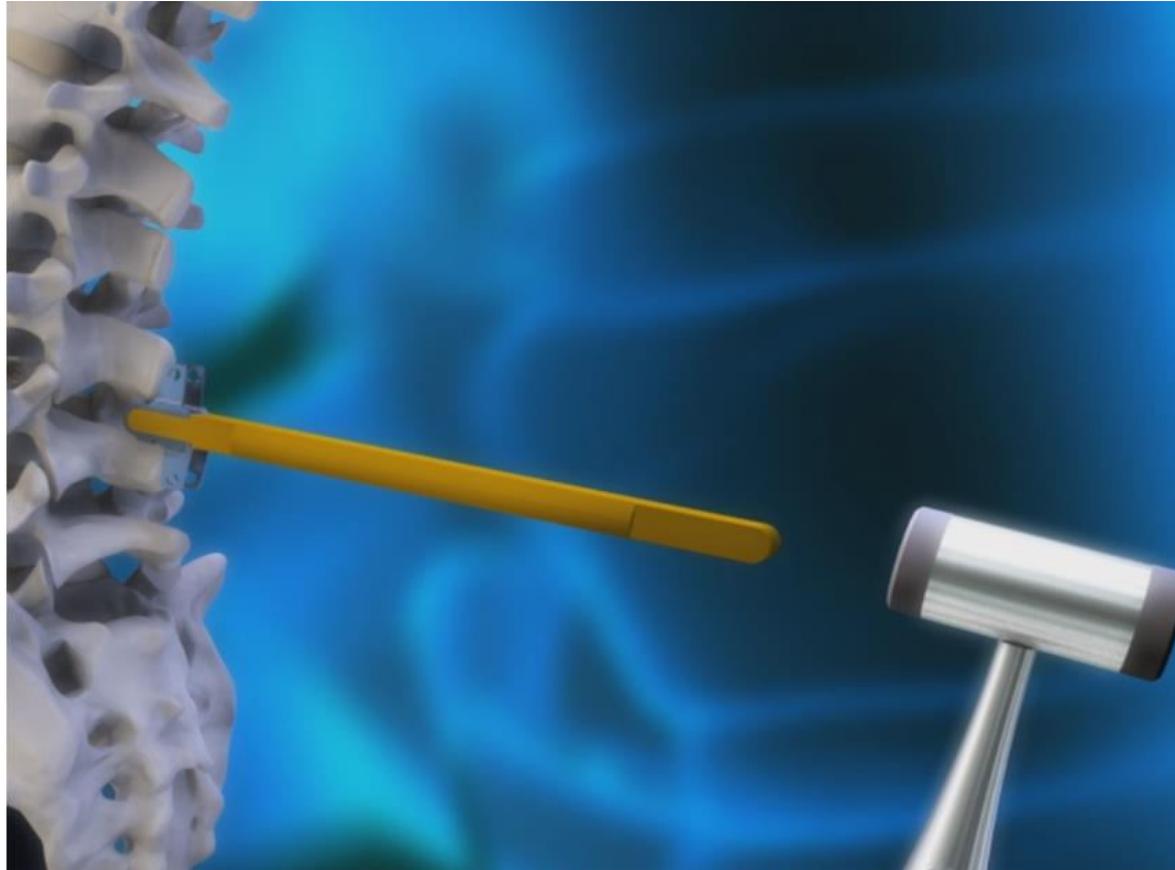
Implant Insertion

- Prior to insertion bending pliers may be necessary to separate the wings.
- The *coflex-F™* implant is introduced via impaction utilizing a mallet.
- Proper depth is determined if a beaded tip probe can be passed freely leaving 2-3 mm separation from the dura.
- The device should seat so that the apex of the „U“ rests at midlevel of the corresponding facet joints of the treated level.
- By deep insertion at the level of the facet joints the *coflex-F™* continues to counteract the majority of posterior column forces.



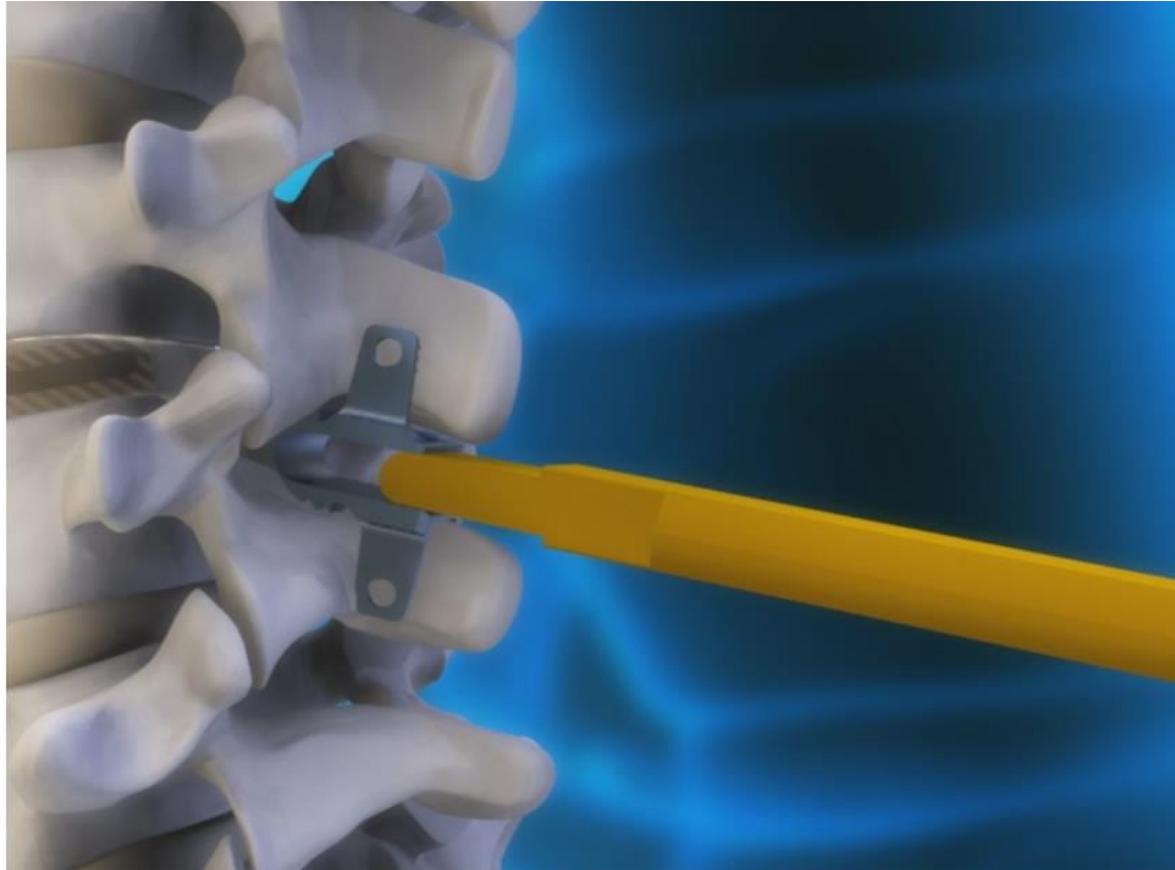
Surgical Technique

Implant Site Preparation



Surgical Technique

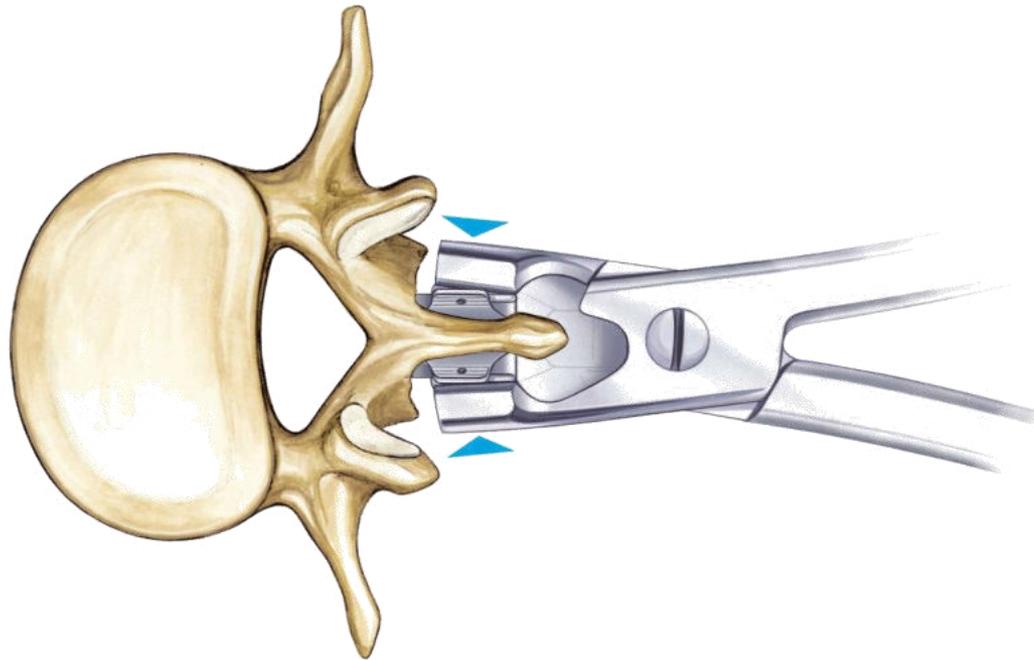
Implant Site Preparation



Surgical Technique

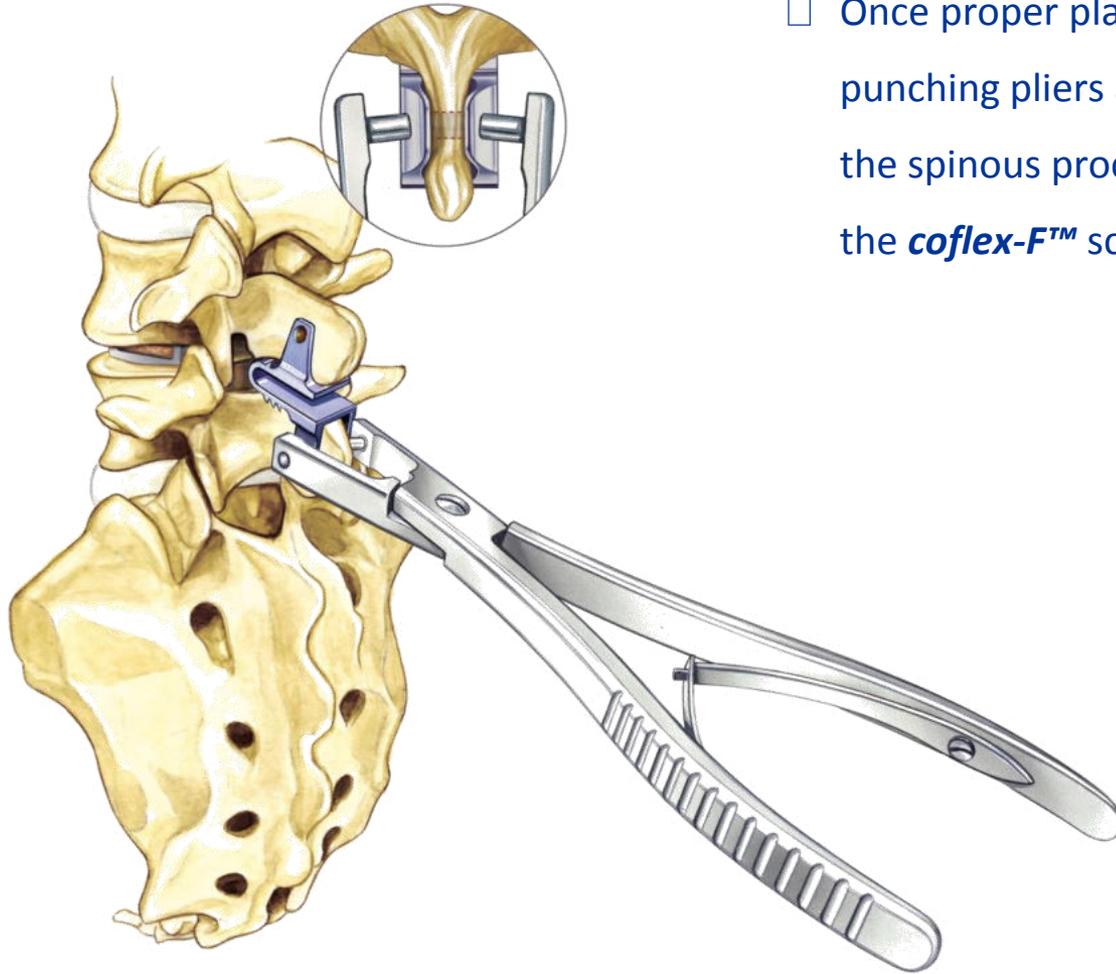
Implant Insertion

- It is recommended to crimp the implant wings prior to screw insertion. This ensures proper contact to the spinous processes and delivery of the fixation screw later.



Surgical Technique

Implant Insertion



- Once proper placement has been achieved punching pliers are utilized to create holes in the spinous processes for later introduction of the **coflex-F™** screws.

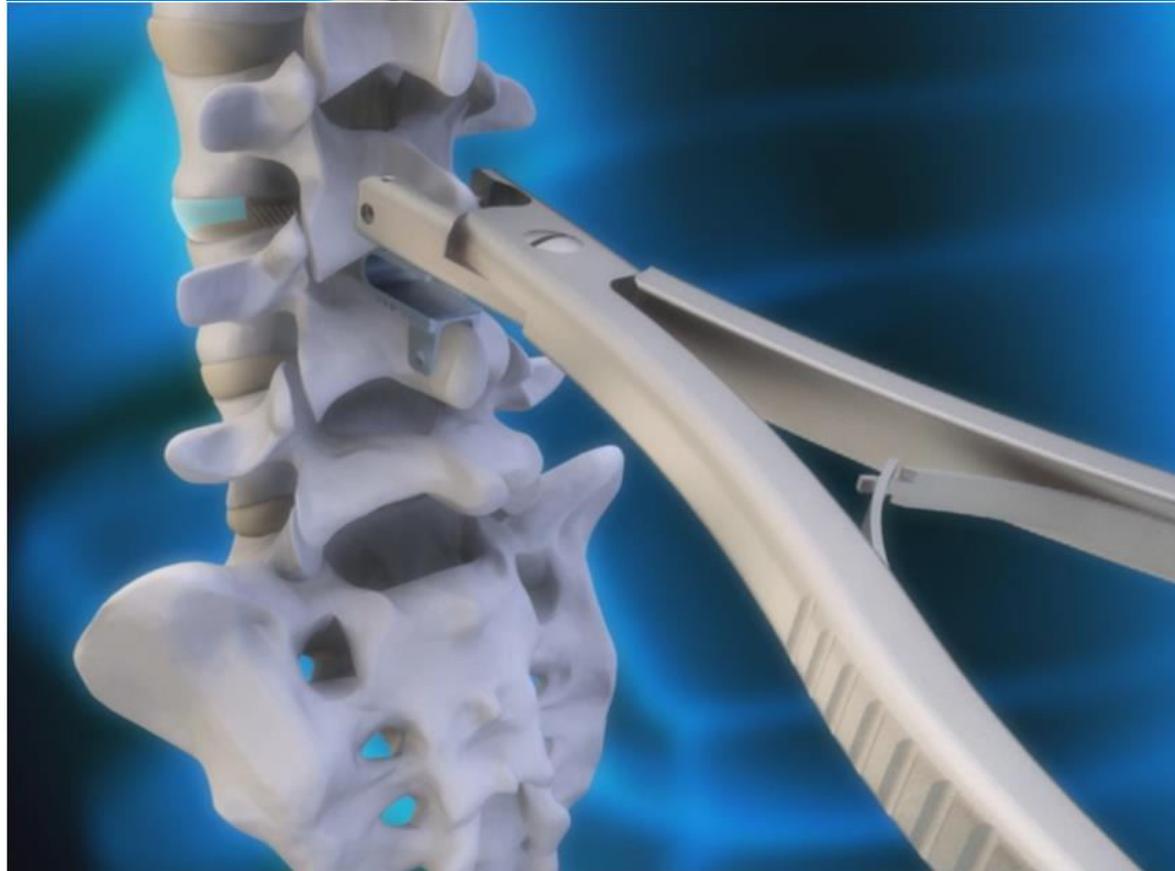
Surgical Technique

Implant Insertion



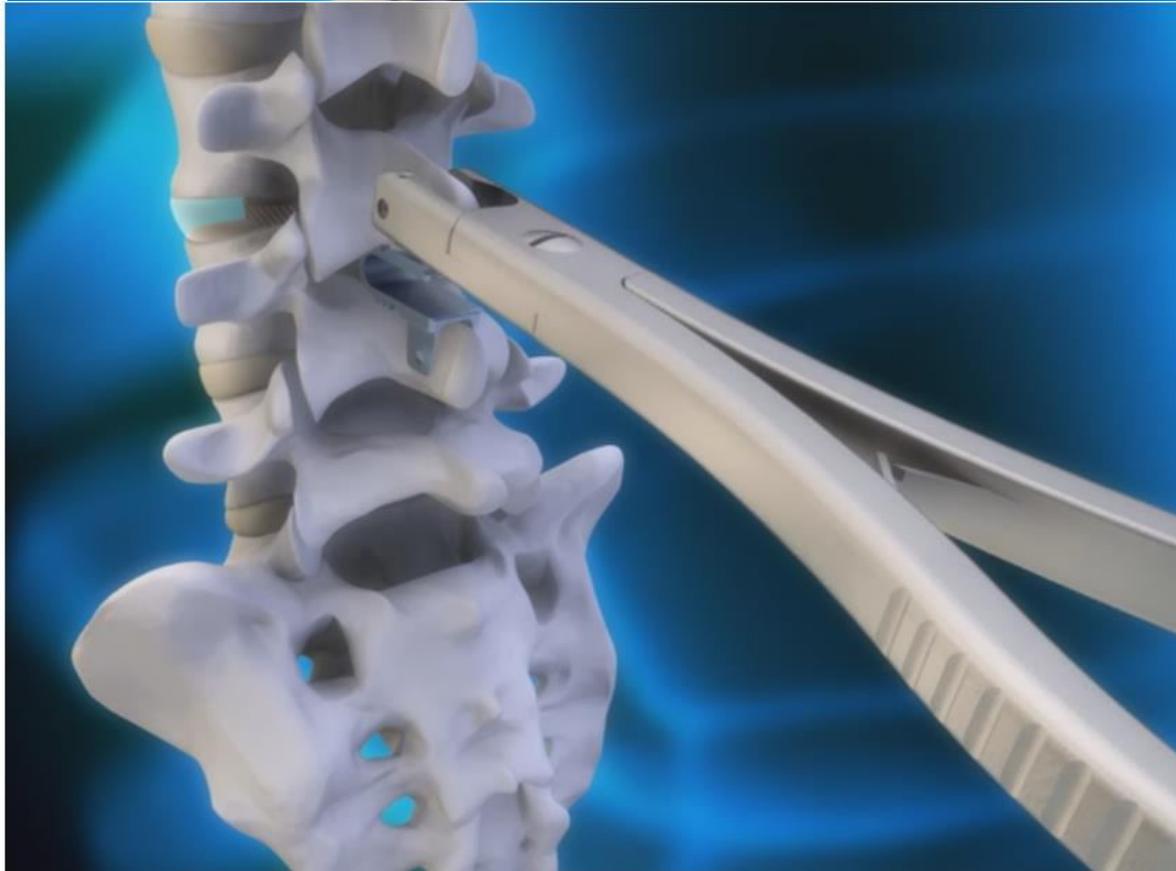
Surgical Technique

Implant Insertion



Surgical Technique

Implant Insertion



Surgical Technique

Implant Insertion



Surgical Technique

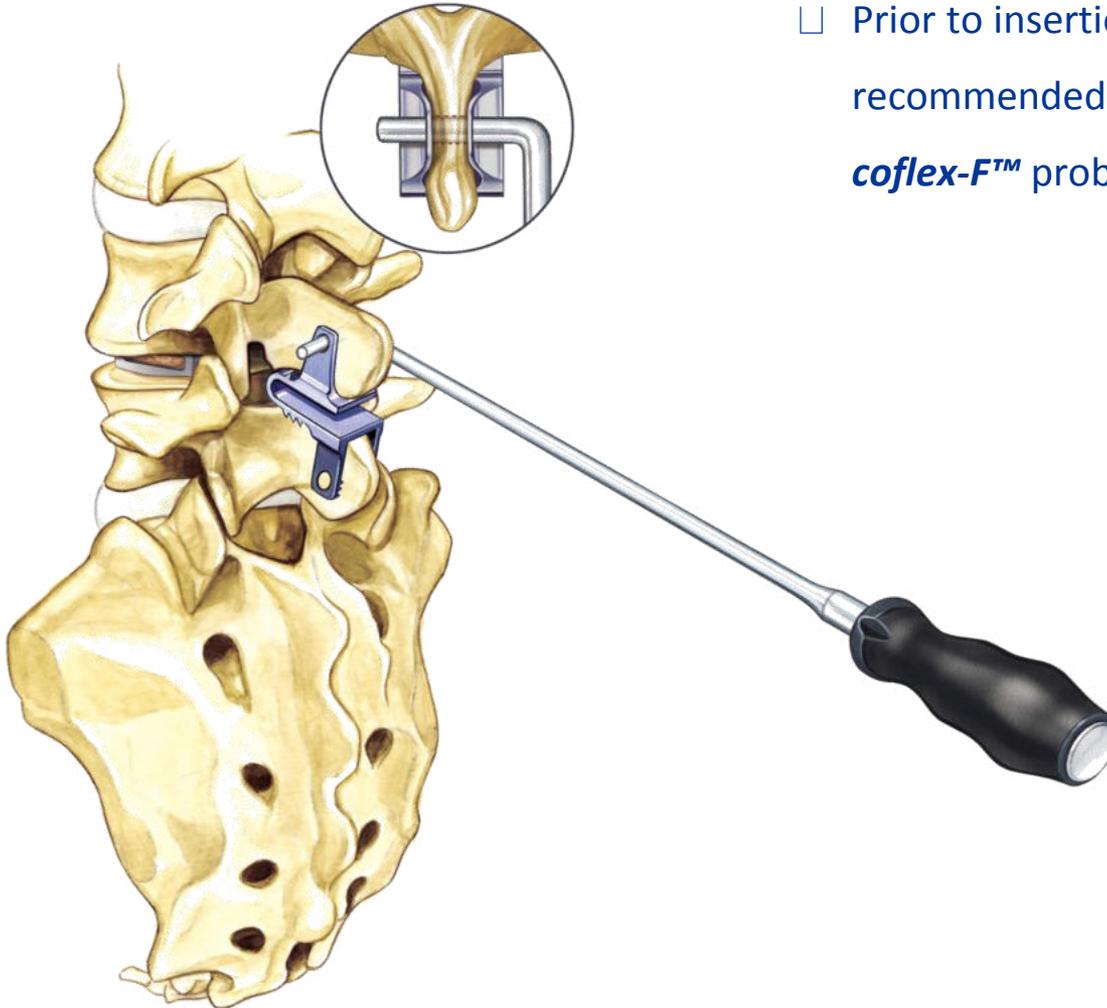
Implant Insertion



Surgical Technique

Implant Insertion

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



Surgical Technique

Implant Insertion



Surgical Technique

Implant Insertion



Surgical Technique

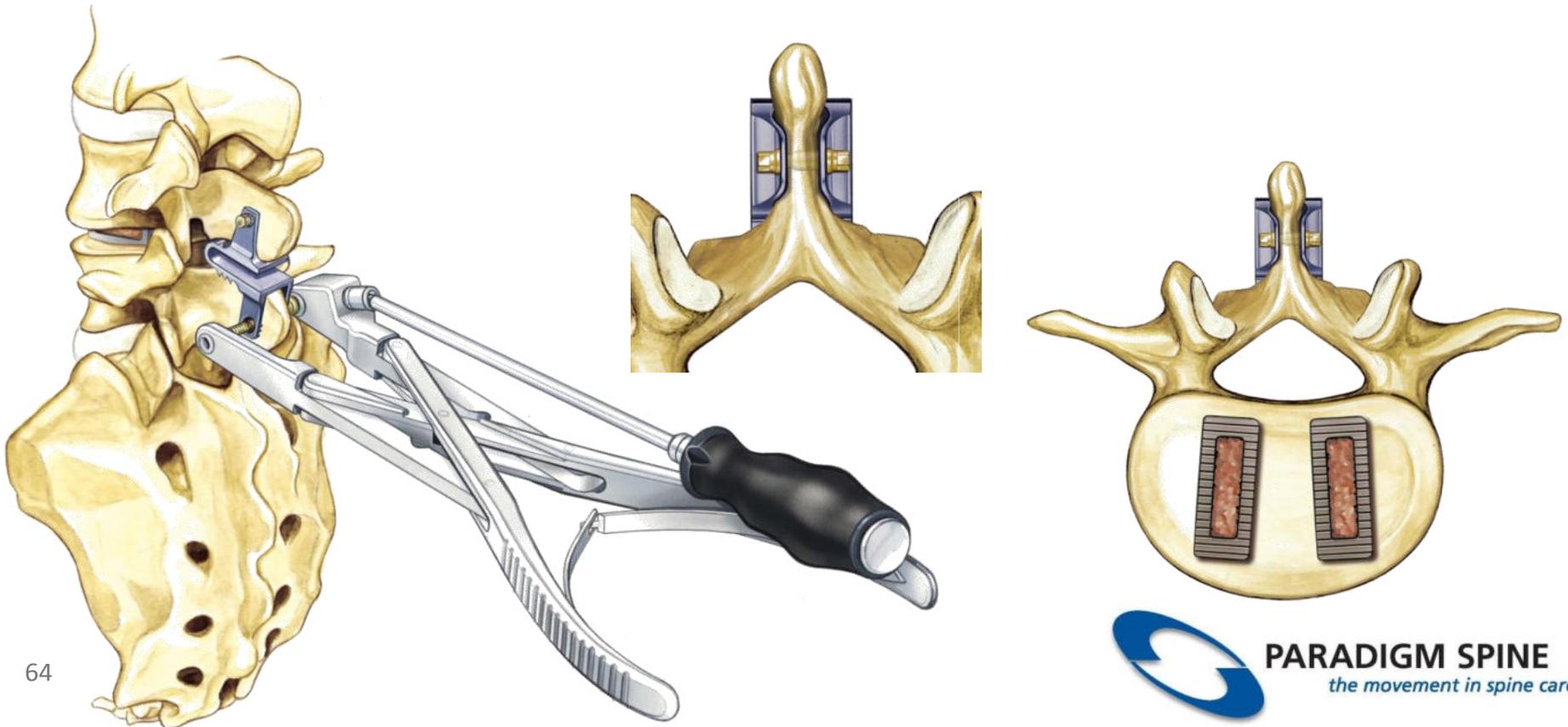
Implant Insertion



Surgical Technique

Implant Insertion

- The *coflex-F™* screws are applied using the screw inserter. A tight fit is required for controlled fixation. Teeth of both wings should be firmly engaged into the cortices of the spinous processes. Slight additional compression can be obtained manually with wrenches.



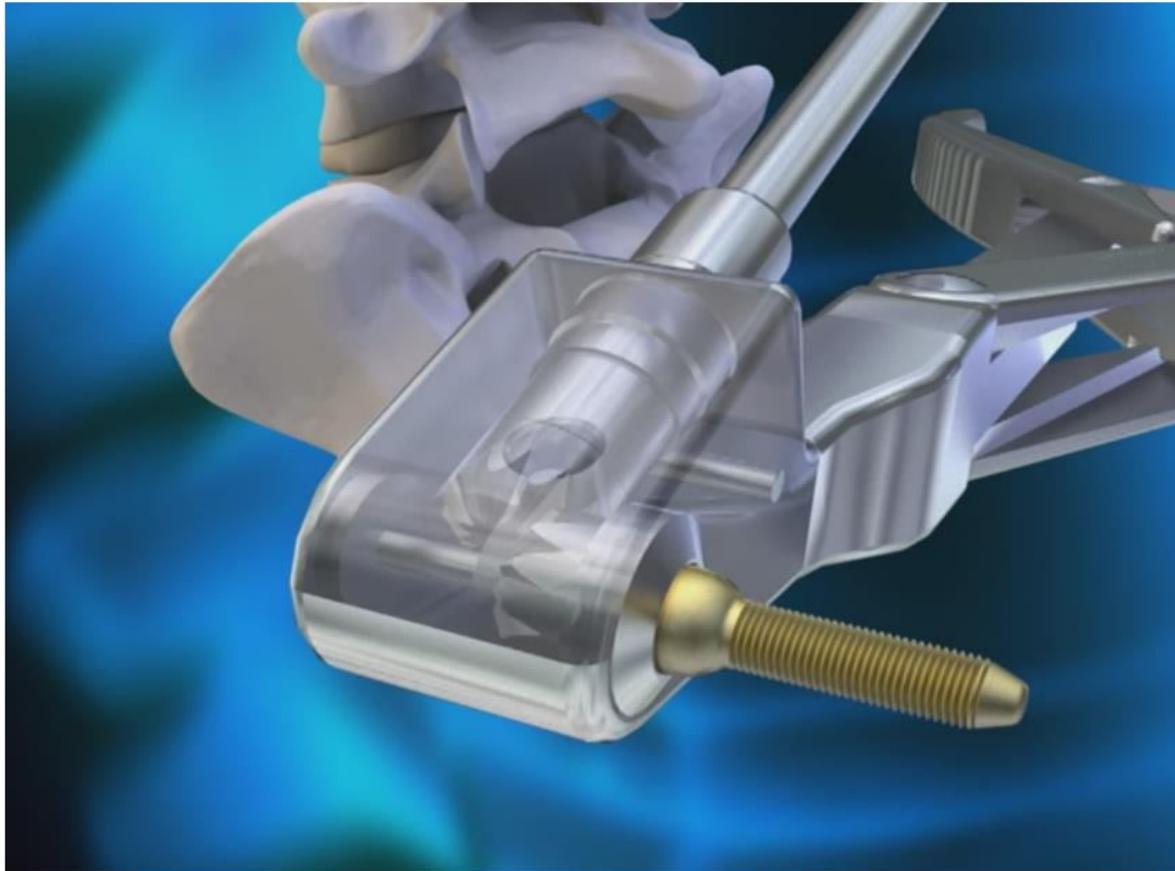
Surgical Technique

Implant Insertion



Surgical Technique

Implant Insertion



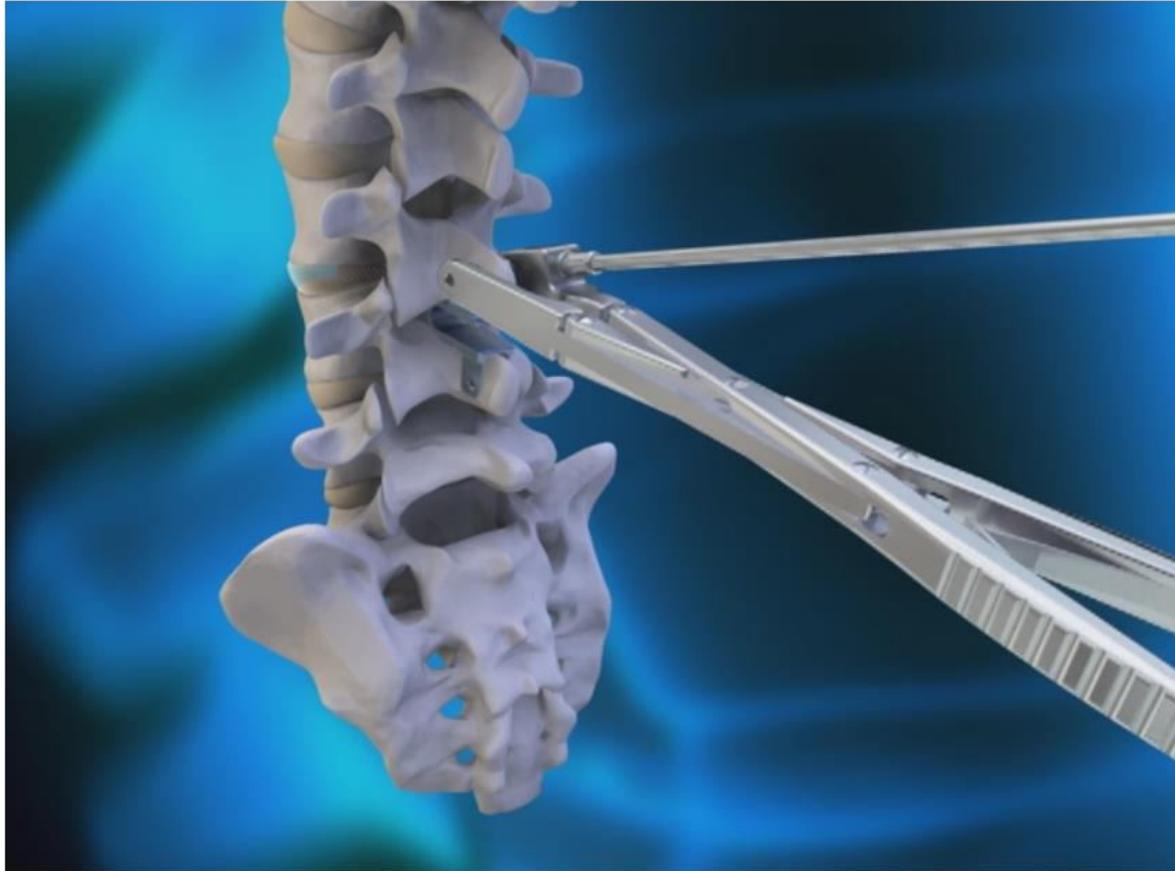
Surgical Technique

Implant Insertion



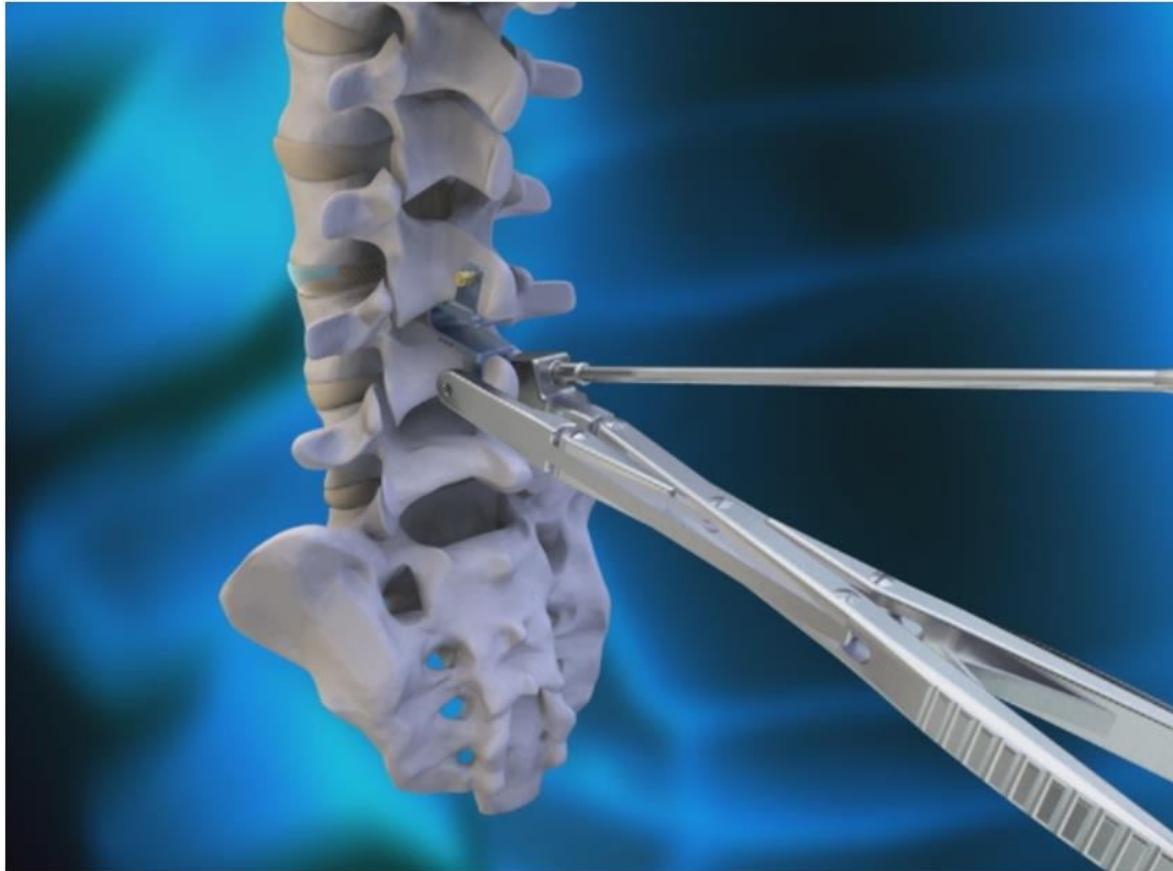
Surgical Technique

Implant Insertion



Surgical Technique

Implant Insertion



Surgical Technique

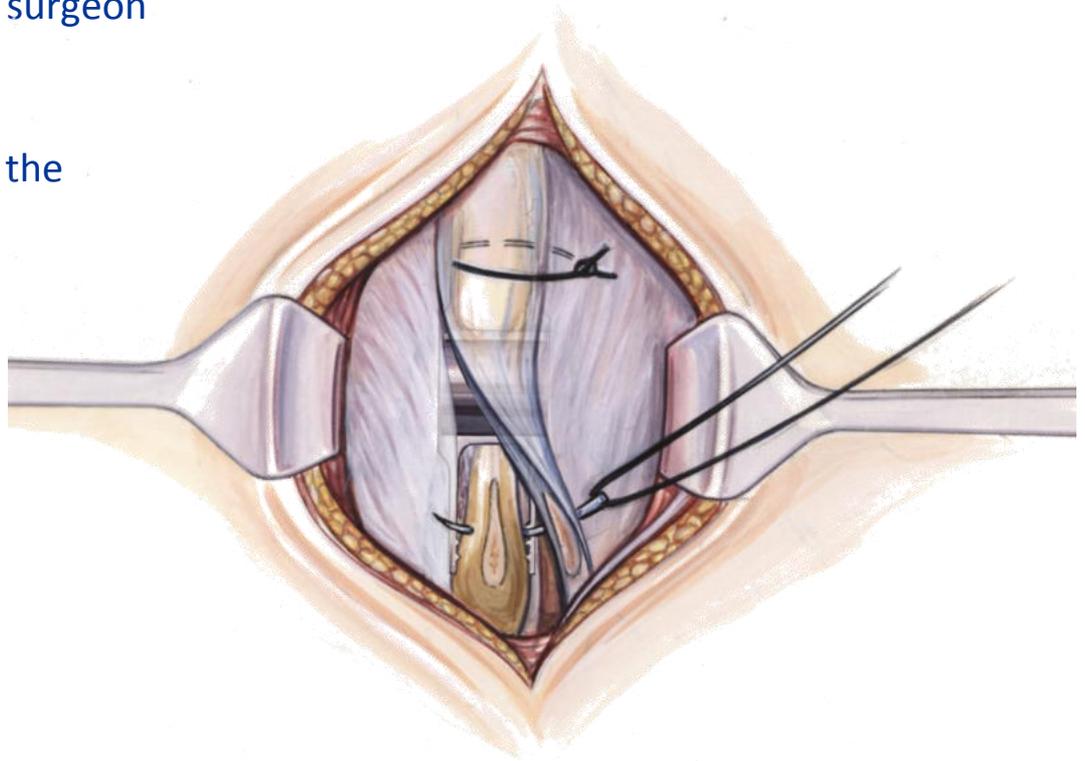
Implant Insertion



Surgical Technique

Wound Closure

- 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.



coflex-F™

Product Information

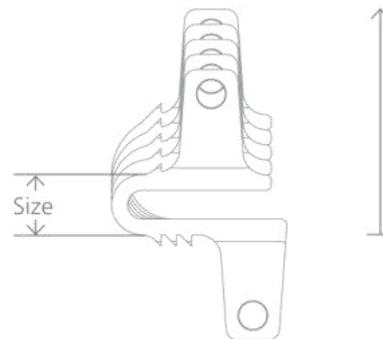


PARADIGM SPINE
the movement in spine care

Product Information

Sizes

- Five anatomical sizes
- Color coded instrumentation



| 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 |

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

Product Information

coflex-F™ Implant

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

Instrument Set



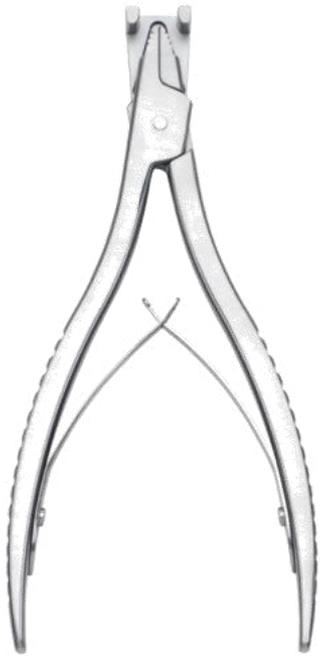
Set contains:

- | Trials (05)
- | Bending Pliers (01)
- | Crimping Pliers (01)
- | Punching Pliers (01)
- | Cleaning Tool (01)
- | Probe (01)
- | Screw Inserter (01)
- | Screwdriver (01)
- | Wrench (02)

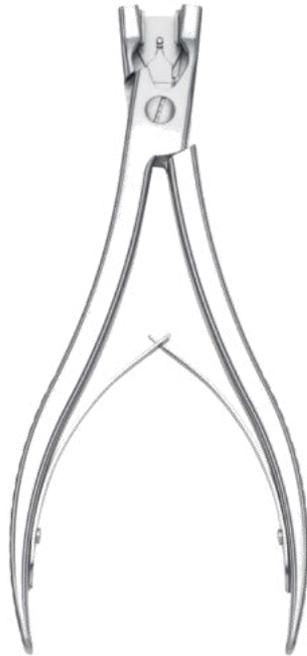


Product Information

Bending and Crimping Pliers



Bending Plier
UAT 10100



Crimping Plier
UAT 10200

Punching Pliers



Cleaning Tool
RAT 20130

Punching Plier
RAT 20100

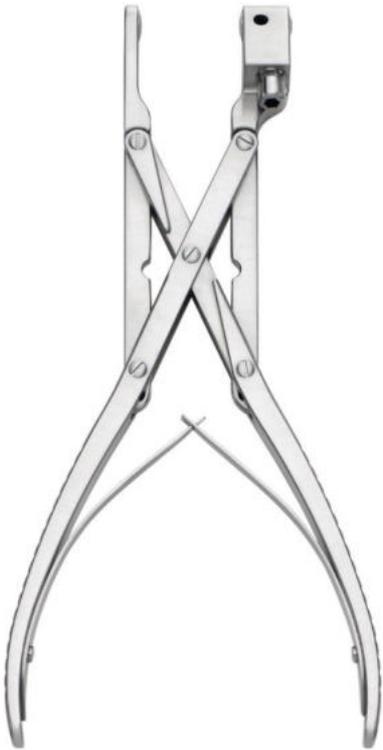


Probe
RAT 20120



Product Information

Screw Inserter - Screwdriver



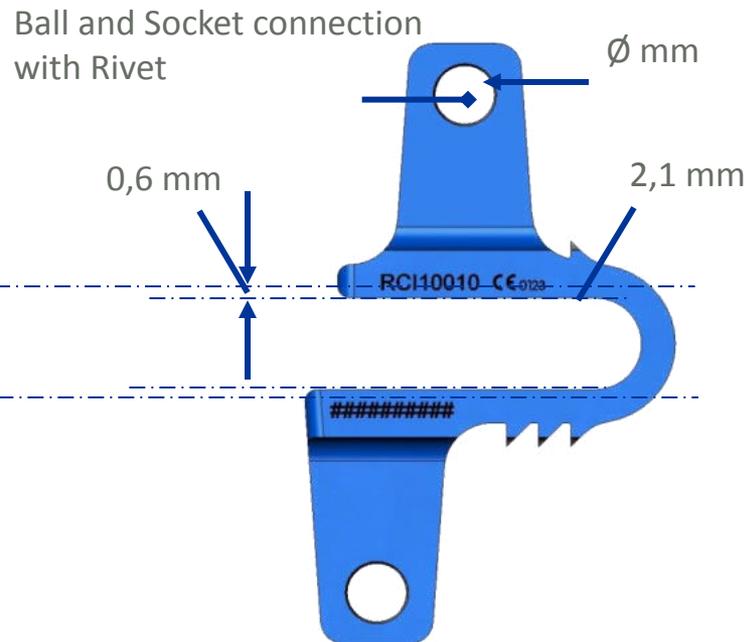
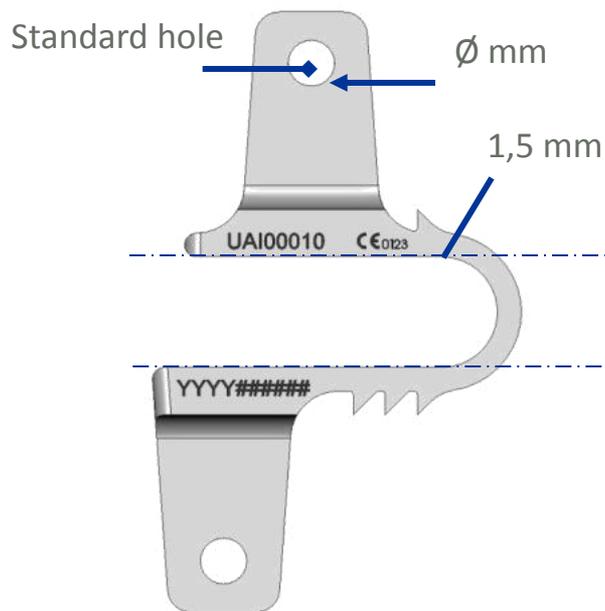
Screw Inserter
RAT 20211



Screwdriver
RAT 20204



coflex[®] vs. coflex-F[™]



coflex[™]

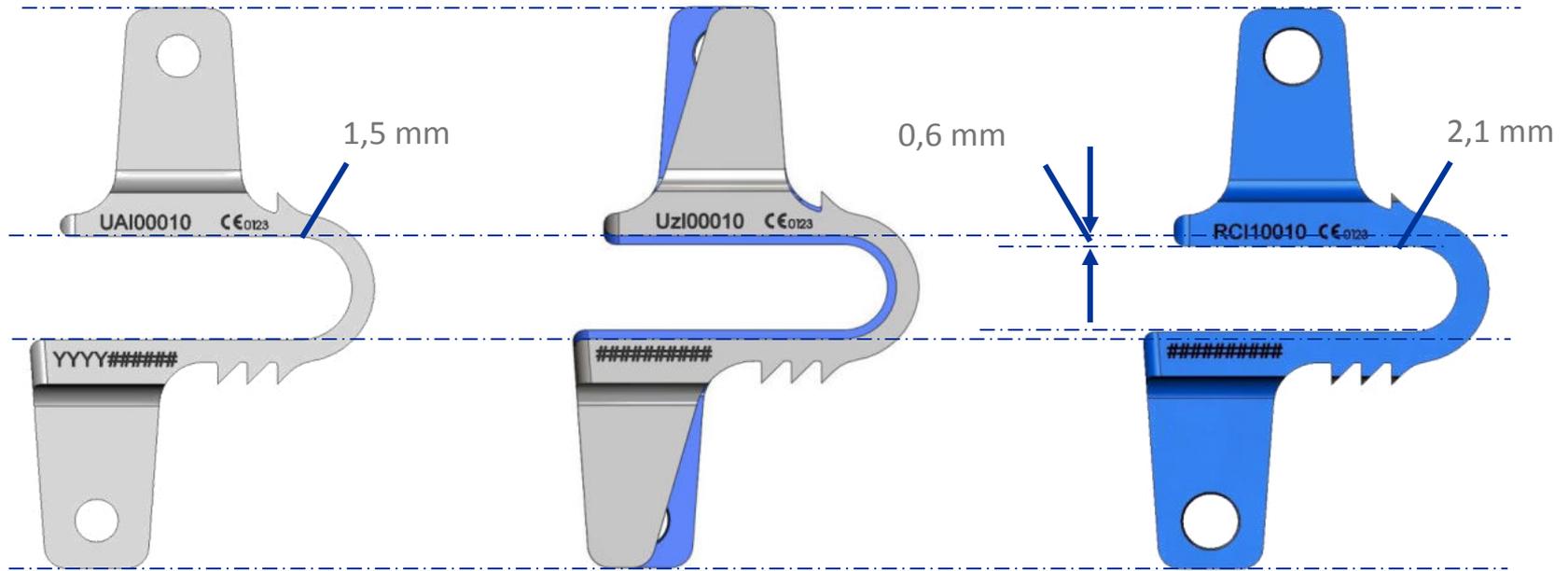


Patent Pending !

coflex-F[™]



coflex[®] vs. coflex-F[™]



Patent Pending !



coflex-F™

Case Example

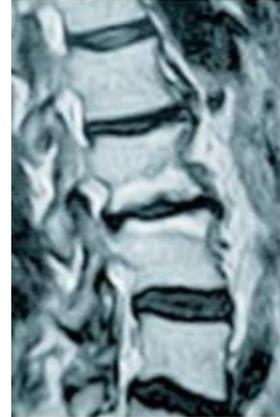


PARADIGM SPINE
the movement in spine care

Case

Female, 53 years, Scientific Consultant:

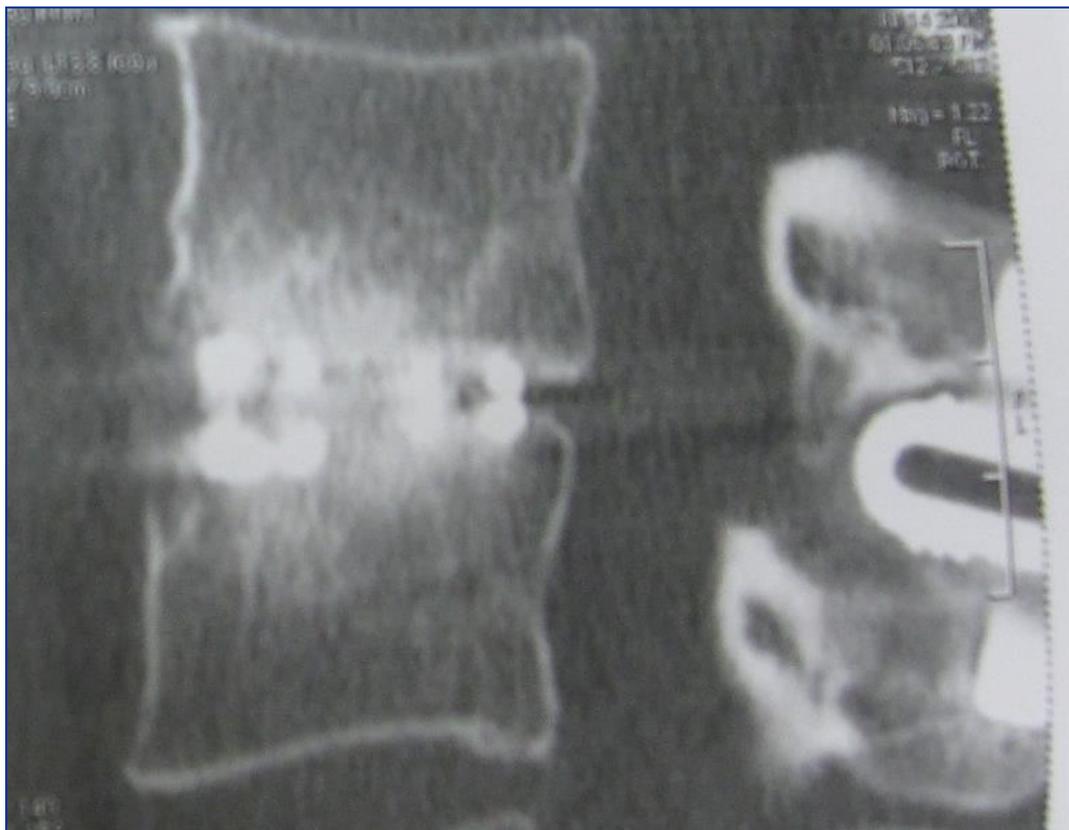
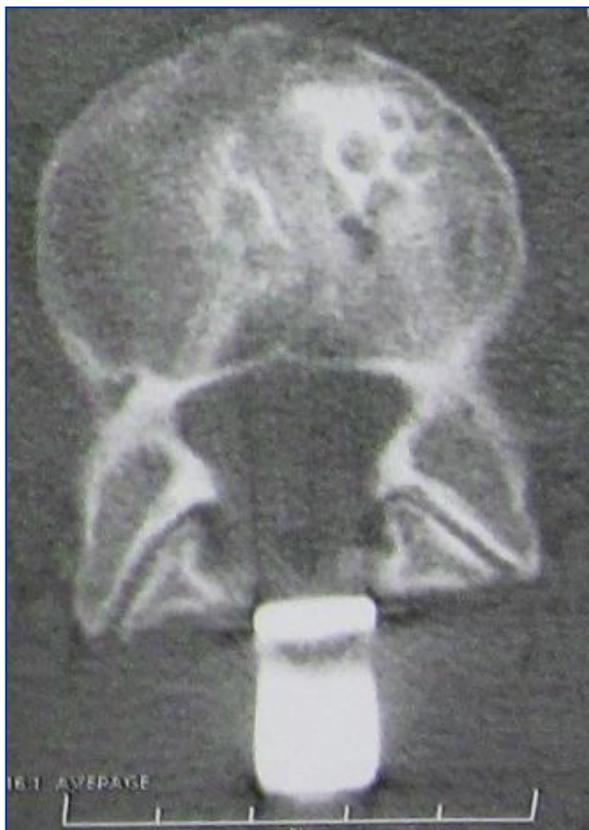
- ❑ **Symptoms:** 10+ years of progressive low back pain. 3+ years of sciatic pain and Trendelenburg signs. Reduced walking distance of 50-100 meters.
- ❑ **MRI:** Erosive osteochondrosis at level L2/3, osteochondrosis at levels L4/5 and L5/S1, disc protrusions at levels L3/4, L4/5 and L5/S1
- ❑ **Diagnosis:** Erosive osteochondrosis 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 VAS 1 at six months, VAS leg pain (left leg) improved from VAS 6 to VAS 0,5.



Case

Female, 53 years, Scientific Consultant:

CT Analysis after 12 month, confirmation of fusion



Publications



PARADIGM SPINE
the movement in spine care

Publications

Computer Methods in Biomechanics

Lo et al. Biomechanical differences of Coflex-F and pedicle screw fixation combined with TLIF or ALIF – a finite element study

Computer Methods in Biomechanics and Biomedical Engineering
First article, 2011, 1–10



Biomechanical differences of Coflex-F and pedicle screw fixation combined with TLIF or ALIF – a finite element study

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^aDepartment of Mechanical Engineering, National Chiao Tung University, Hsinchu, Taiwan; ^bDepartment of Orthopaedic Surgery, Cuihay General Hospital, Taipei, Taiwan; ^cDepartment of Physical Therapy and Assistive Technology, National Yang Ming University, Taipei, Taiwan; ^dDepartment of Orthopaedics, Tzu Chi General Hospital, Taichung, Taiwan

(Received 24 May 2010; final version received 14 June 2010)

Lumbar interbody fusion is a common procedure for treating lower back pain related to degenerative disc diseases. The Coflex-F is a recently developed interspinous spacer, the makers of which claim that it can provide stabilisation similar to pedicle screw fixation. Therefore, this study compares the biomechanical behaviour of the Coflex-F device and pedicle screw fixation with transforaminal lumbar interbody fusion (TLIF) or anterior lumbar interbody fusion (ALIF) surgeries by using finite element analysis. The results show that the Coflex-F device combined with ALIF surgery can provide stability similar to the pedicle screw fixation combined with TLIF or ALIF surgery. Also, the posterior instrumentations (Coflex-F and pedicle screw fixation) combined with TLIF surgery had lower stability than when combined with ALIF surgery.

Keywords: interspinous spacer; pedicle screw fixation; transforaminal lumbar interbody fusion; anterior lumbar interbody fusion; finite element analysis; posterior instrumentations

1. Introduction

Lumbar spinal fusion is a common surgical procedure for treating lower back pain caused by degenerative disc disease. The purpose of fusion is to prevent motion in the destabilised segments of spine, which can decrease low back pain caused by motion. Recent treatments of degenerative disc diseases and instabilities have used various approaches, such as anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF).

All types of interbody fusion approaches work ideally in combination with posterior pedicle screw fixation to increase stabilisation and fusion rates. It has some disadvantages, including paraspinous muscle dissection and retraction during instrumentation, screw malpositioning, neurologic risk and lengthy operative time with blood loss and increased risk of infection (Phillips et al. 2004). The disadvantages of pedicle screw fixation had led to the development of two new posterior fixations – the translaminar facet screw fixation and transfacet pedicle screw fixation (Ferrara et al. 2003; Aeppli et al. 2009; Fan et al. 2010). While these two fixations have similar stability and can improve the disadvantages of pedicle screw fixation, they are technically demanding and dangerous surgical processes. Translaminar facet screw fixation requires long passage through the lamina for the crossing screws before they can traverse the facet joint, necessitating a large surgical field. Transfacet pedicle screw fixation requires considerable risks of neural injury.

Thus, the development of other posterior instrumentations is still conducted by researchers.

According to recent claims, the Coflex-F device (Paradigm Spine, Würmlingen, Germany) can provide stabilisation of the posterior spinal elements similar to pedicle screw fixation when used for interbody fusion. The Coflex-F spacer is an interspinous process device with rivets modified from the original Coflex device. The rivets joining the wings of the Coflex device and the spinous processes allow for rigid attachment to the posterior element. It retains the advantages of interspinous process implants and minimally invasive surgery, such as sparing tissue, preserving pedicle anatomy and minimising muscle trauma, blood loss, skin incisions and operating time, thus speeding patient recovery.

Because the PLIF surgical process needs to remove parts of the lamina bone and spinous process to get approach, the Coflex-F cannot be implanted in the interspinous process. Therefore, the purpose of this study is to compare the biomechanical behaviour of the Coflex-F device and the traditional bilateral pedicle screw fixation, in combination with ALIF or TLIF.

2. Materials and methods

2.1 Finite element model of the intact lumbar spine (intact model)

A validated 3D finite element (FE) model of the intact lumbar spine was used (Figure 1(a)). To create this model,

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Publications

□ Computer Methods in Biomechanics

Lo et al. Biomechanical differences of Coflex-F and pedicle screw fixation combined with TLIF or ALIF – a finite element study

□ Computer Methods in Biomechanics

Lo et al. Biomechanical effect after Coflex and Coflex rivet implantation for segmental instability at surgical and adjacent segments: a finite element analysis

Computer Methods in Biomechanics and Biomedical Engineering
First article, 2011, 1–10



Biomechanical effect after Coflex and Coflex rivet implantation for segmental instability at surgical and adjacent segments: a finite element analysis

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^bDepartment of Orthopaedic Surgery, Cathay General Hospital, Taipei, Taiwan; ^cDepartment of Orthopaedics, Tzu Chi General Hospital, Taichung, Taiwan; ^dDepartment of Physical Therapy and Assistive Technology, National Yang Ming University, 155, Section 2, Li-Nang Street, Taipei, Taiwan

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The Coflex device may provide stability to the surgical segment in extension but does not restore stability in other motion. Recently, a modified version called the Coflex rivet has been developed. The effects of Coflex and Coflex rivet implantation on the adjacent segments are still not clear; therefore, the purpose of this study was to investigate the biomechanical differences between Coflex and Coflex rivet implantation by using finite element analyses. The results show that the Coflex implantation can provide stability in extension, lateral bending, and axial rotation at the surgical segment, and it had no influence at adjacent segments except for extension. The Coflex rivet implantation can provide stability in all motions and reduce disc annulus stress at the surgical segment. Therefore, the higher range of motion and stress induced by the Coflex rivet at both adjacent discs may result in adjacent segment degeneration in flexion and extension.

Keywords: lumbar spinal stenosis; interspinous process device; Coflex rivet follower load; disc annulus stress; finite element analysis

1. Introduction

Lumbar spinal stenosis (LSS) is a common disabling disease in the elderly. The reduced disc height narrows the spinal canal and the neural foramina, eventually resulting in nerve compression (Arbù and Pannullo 2001). The symptoms of LSS include bilateral radicular pain and intermittent neurogenic claudication, sensation disturbance and loss of muscle strength in the legs. Many surgeons perform decompression for spinal stenosis and reconstruct the segment with rigid fusion devices. However, rigid fusion may cause increased stress at the adjacent discs, resulting in degeneration of adjacent segments (Kuslich et al. 2000; Lai et al. 2004; Zucherman et al. 2004). Therefore, flexible nonfusion devices such as the interspinous process device were developed with the intention of reducing adjacent segment degeneration.

An interspinous process device is defined as a flexible system that can preserve spinal movement and improve load transmission of spinal motion segments through the non-fusion technique (Sengupta 2004; Christie et al. 2005). There have been a number of interspinous process devices such as Coflex, Wallis, Diam and X-Stop, tested for treating LSS with different biomechanical designs. The Coflex (Paradigm Spine, Wumlingen, Germany) was originally developed as an interspinous U-shaped device and is placed between two adjacent spinous processes (Kaech et al. 2002; Cho 2005; Eif and Schenke 2005).

After implantation, the lateral wings are crimped towards the spinous processes to improve fixation. The U-shaped structure is designed to allow the lumbar spine to have controlled movement in forward and backward bending. To improve stability in all motions, a modified version called the Coflex rivet has also been developed (Kettler et al. 2008), which adds two rivets to the Coflex.

Recently, many studies have evaluated the biomechanical behaviours of the Coflex and Coflex rivet devices. Tsai et al. (2006) used cadaveric lumbar L4 and L5 segments with implanted Coflex device to examine their biomechanical behaviour, and the results showed that the implanted Coflex device can provide stability for the lumbar spine in flexion–extension and axial rotation, except in lateral bending. Kong et al. (2007) reported 1-year follow-up outcomes after Coflex device implantation and traditional fusion for degenerative spinal stenosis. The results indicated that both the Coflex device and traditional fusion reduced the range of motion (ROM) at the surgical segment, but fewer effects were found at the adjacent segments with the Coflex device when compared with the increasing ROM with traditional fusion. Kettler et al. (2008) compared the Coflex and Coflex rivet devices using biomechanical experiments and found that both implants had strong stability in extension. However, the Coflex implant could not compensate the instability in flexion, lateral bending and axial rotation as well as the

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Publications

□ Computer Methods in Biomechanics

Lo et al. Biomechanical differences of Coflex-F and pedicle screw fixation combined with TLIF or ALIF – a finite element study

□ Computer Methods in Biomechanics

Lo et al. Biomechanical effect after Coflex and Coflex rivet implantation for segmental instability at surgical and adjacent segments: a finite element analysis

□ Science Direct 2008

Kettler et al. Can a modified interspinous spacer prevent instability in axial rotation and lateral bending? A biomechanical in vitro study resulting in a new idea



Publications

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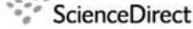
Meeting Abstract SAS 2011

Eif et al. The coflex-F™ - A new minimally invasive device for the PLIF procedure



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ScienceDirect

Clinical Biomechanics 23 (2008) 242–247

CLINICAL BIOMECHANICS

www.elsevier.com/locate/clinbiomech

Brief report

Can a modified interspinous spacer prevent instability in axial rotation and lateral bending? A biomechanical in vitro study resulting in a new idea



Städtisches Klinikum Göttingen
Klinik für Orthopädie und Unfallchirurgie



Görlitz Municipal Clinic
Clinic for Neurosurgery

The coflex-F™ - A new minimally invasive device for the PLIF procedure

Dr. Marcus Eif; Görlitz Municipal Clinic; Clinic for Neurosurgery

1. Problem
In many patient cases, the PLIF technique with pedicle screws is a state of the art surgery for the treatment of lumbar instability in combination with an additional narrowing of the spinal canal and widely performed after a decompression procedure. For the implantation of the pedicle screw based posterior part of this fusion technique a rather big or an additional approach is needed. Most of these procedures could be treated in a less invasive way. With the coflex-F™ the approach is limited to the small incision that is needed for the decompression, discectomy and implantation of the interspinous cages.

4. Indication
The treated pathologies were: instability up to Meyerding 1° in combination with lumbar spinal stenosis caused by hypertrophic changes of the ligaments and/or the facet joints.

- used in patients with degenerative disc disease
- indicated for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1 – S1)
- intended for attachment to the spinous processes
- promoting stabilization and promoting fusion

6. Conclusion
The combination of interspinous Cages and the coflex-F™ is an easy and less invasive modification of the well established PLIF-procedure in the treatment of degenerative changes of the lumbar spine. Beside the very limited blood loss due to the small approach it is a safe and fast technique. Even if there are very promising results according clinical outcome and fusion rate further investigations in a bigger amount of patients are necessary.

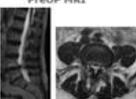
2. Fusion with coflex™-F
The Implant allows the minimal invasive stabilization of the spine in combination with Fusion Cages as an alternative to a posterior fixation with a pedicle screw system. Biomechanical studies have shown that the rigid assembly of the implant wings on top of the spinous process with the screw proves to give a high stability to the Construct which is almost close to a pedicle screw system.

5. Patient Population
Period of examination: 24 months (2008 – 2010)
Patients: n=31 patients; male=22; female=9
Age: a 69 years (50-86 years)
Weight: a 82 kg (59-124 kg)
Operations: discectomy, decompression, interspinous cages (PEEK or Titanium) and the coflex-F™
Follow up: Registration of ODI, VAS and patient satisfaction after 3, 6, 12 and 24 months. A neurological examination and X-Ray control were performed.

7. Patient Case
male, born 11.03.1933
Symptoms: Since years lumbago and since 1 year stabbing, burning pain in right leg, tickling paresthesia and hypesthesia L5 dermatome right
MRI: small intratranslaminar herniated disc L4/5 right
X-Ray: Lumbosis L4/5 Meyerding 1°



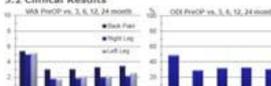
PreOP X-Ray



PreOP MRI



SAS PreOP n= 3, 6, 12, 24 month



ODI PreOP n= 3, 6, 12, 24 month



3 days PostOP



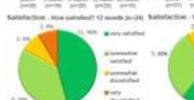
2 years PostOP

3. Implant

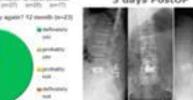


5.2 Clinical Results

Satisfaction: How satisfied? 12 month (n=28)



Satisfaction: surgery aspect? 12 month (n=28)



these implants were shown to reduce facet loading and to widen the neuroforamina and the spinal canal (Richards et al., 2005; Wiseman et al., 2005), which supports their

to compensate instability in axial rotation, lateral bending and in some cases in flexion (Fuchs et al., 2005; Lindsey et al., 2003; Wilke et al., 2007). This lack of stability might impair the clinical long-term success, which has so far only been reported to be good in the short-term (Anderson et al., 2006; Kondrashov et al., 2006; Zucherman et al.,

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coflex-F™

Marketing tools



PARADIGM SPINE
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Marketing Tools - digital

□ *coflex-F™*

Surgical Technique Video - Dr. Afshar



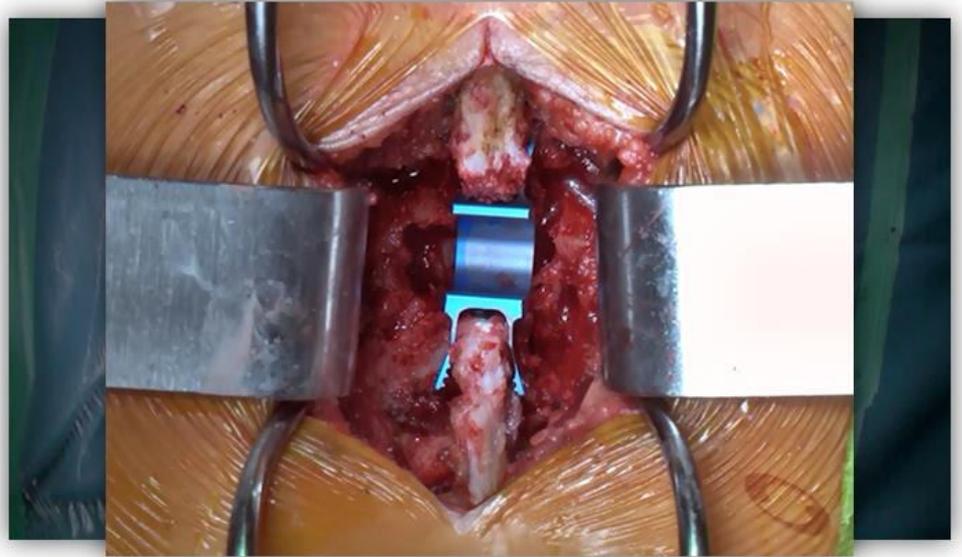
Marketing Tools - digital

☐ *coflex-F™*

Surgical Technique Video - Dr. Afshar

☐ *coflex-F™*

Surgical Technique Video - Dr. Dryer



Competition

coflex-FTM vs. SP Plates

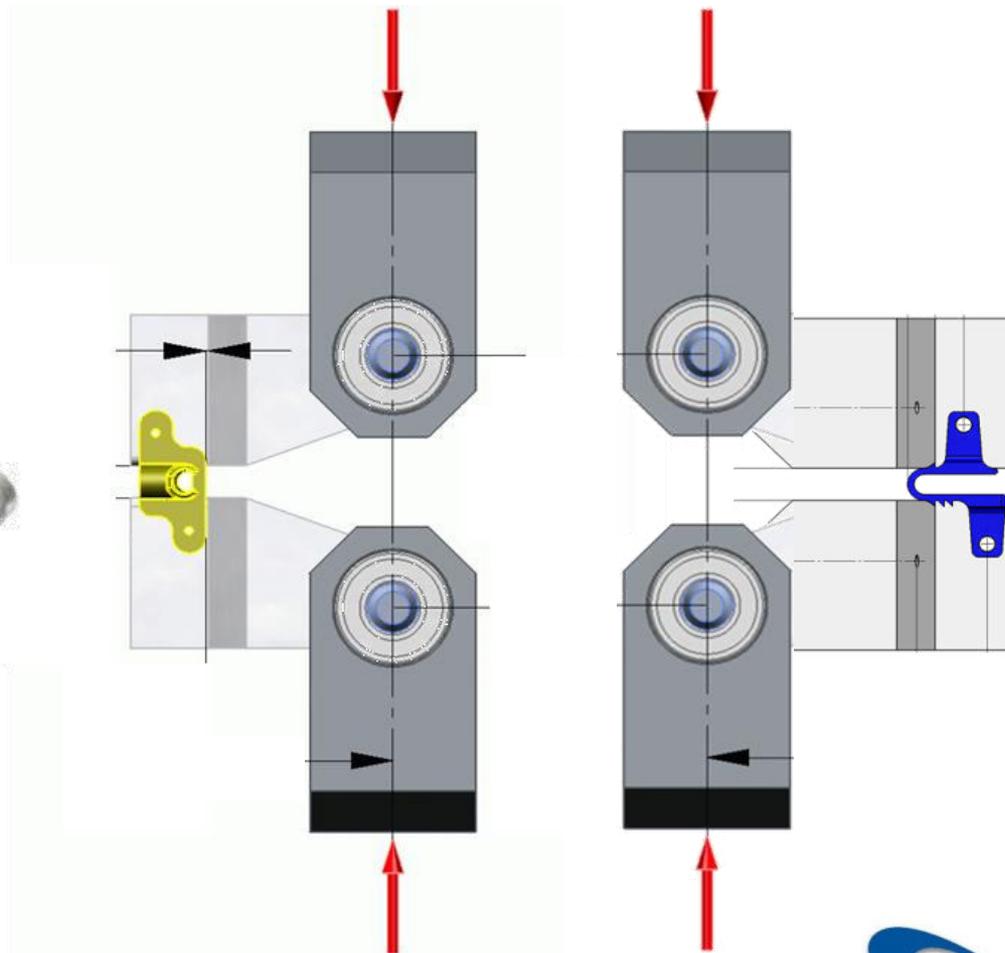


PARADIGM SPINE
the movement in spine care

Biomechanical Rationale

Additional Validation – Comparative Mechanical Testing

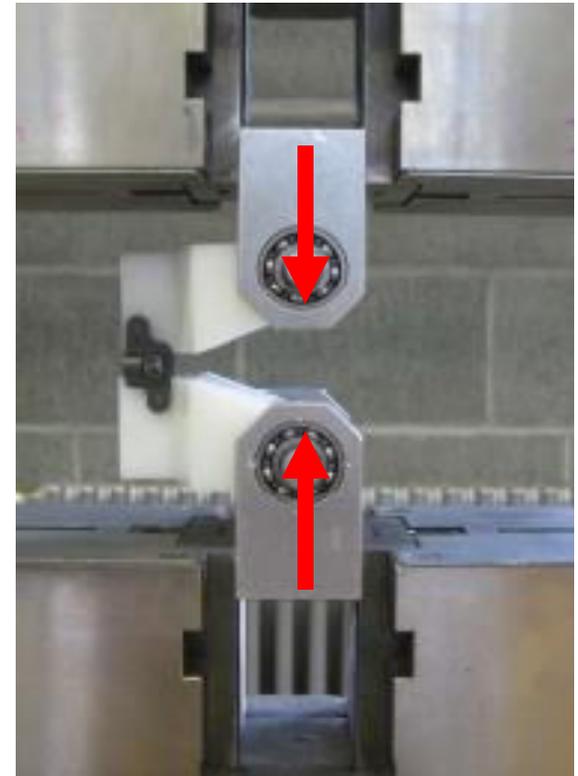
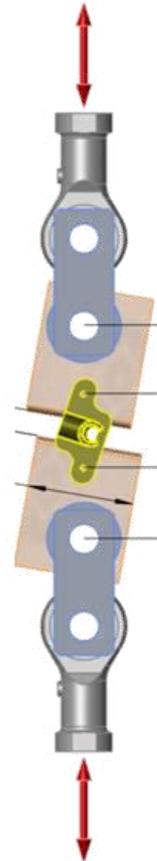
- *coflex-F™*
- Lanx Aspen
- Nuvasive AFFIX



Biomechanical Rationale

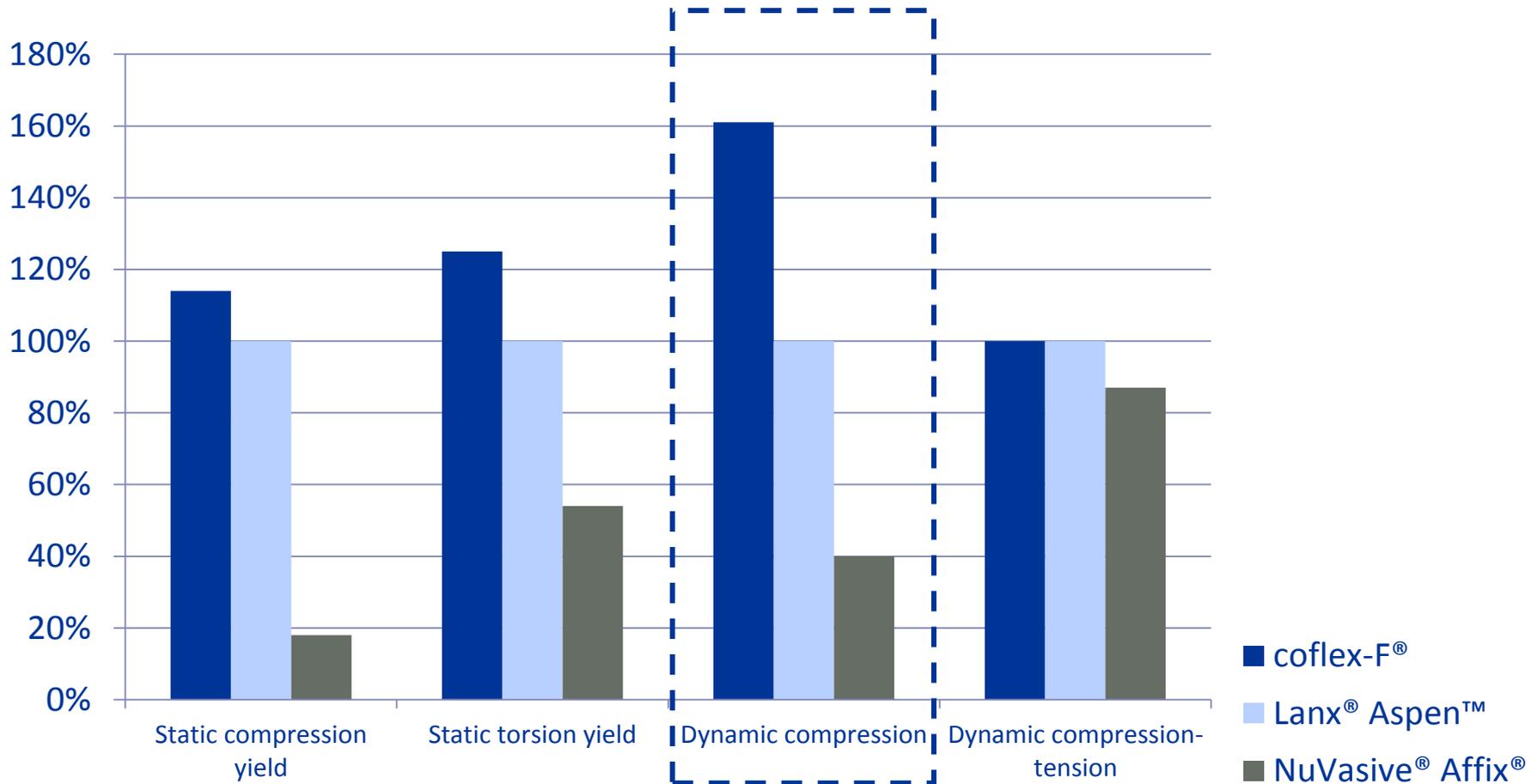
Regulated FDA Test Protocol:

- Static Testing
 - Compression
 - Rotation/Torsion
- Dynamic Testing (5 Mill. Cycles)
 - Compression
 - Compression/Tension



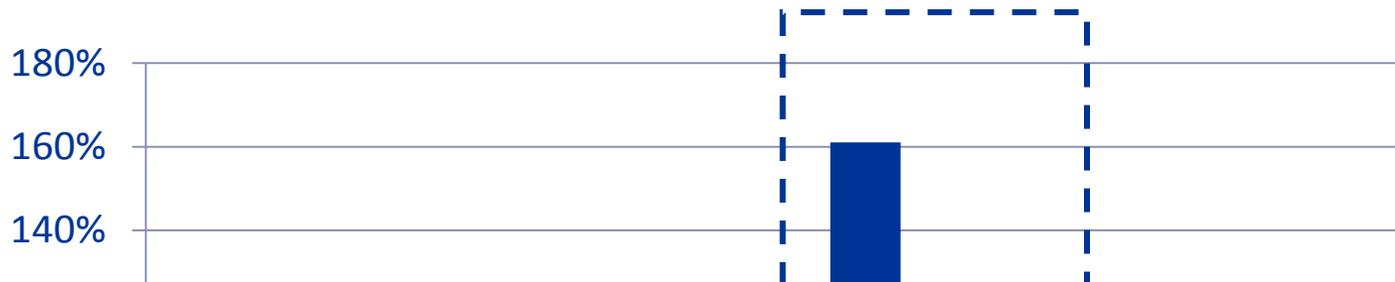
Biomechanical Rationale

Relative Fixation Strength



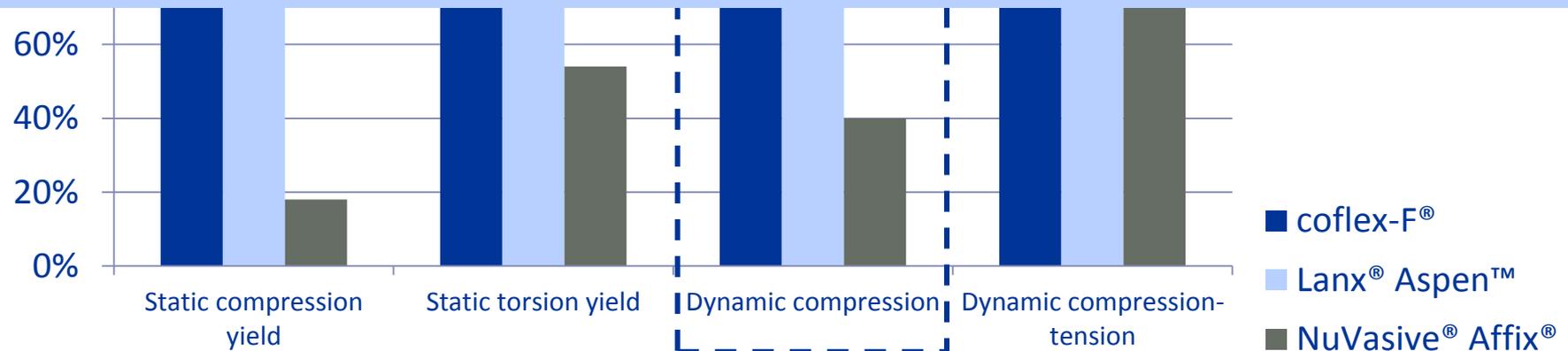
Biomechanical Rationale

Relative Fixation Strength



Fact

Significant differences in cyclic loading - *coflex-F™* provides higher fatigue strength!



Biomechanical Rationale

- Comparative Testing – *coflex-F™* vs. Aspen and Affix
- Side-by-side testing demonstrates that the *coflex-F™* design attributes result in a stronger, stiffer, and safer method to stabilize the motion segment.

