rti surgical®

coflex®
Interlaminar Stabilization®

Surgical Technique

A **HIGHER** STANDARD®

TABLE OF CONTENTS

DEVICE DESCRIPTION

The coflex Interlaminar Technology is an interlaminar functionally dynamic implant designed to impart a stabilization effect at the operative level(s). It consists of a single, U-shaped component, fabricated from medical grade titanium alloy (Ti6Al4V, per ASTM F136 and ISO 5832-3). In clinical use, the "U" is positioned horizontally, with its apex oriented anteriorly and the two long arms of the "U" paralleling the long axis of the spinal processes. The bone-facing surfaces are ridged to provide resistance to migration.

A set of two wings extends vertically from the superior long arm of the "U", with a second set of wings extending the inferior long arm. Both sets of wings have serrated bonefacing surfaces, which are designed to further stabilize the coflex device to the superior and inferior spinous processes, respectively, at the treated level.

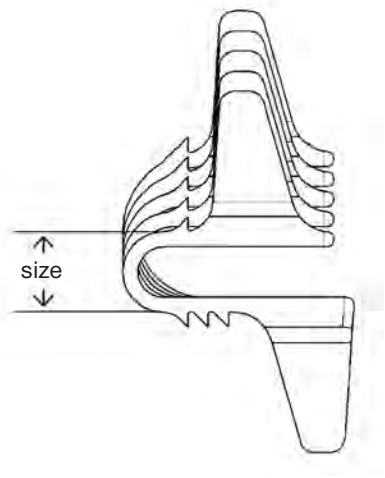
In addition, the opposing wing surfaces are spaced such that they surround the midportion of the spinous process between the base and the tip, but are more narrowly set (after intraoperative crimping, if necessary) than the flared posterior tip of the spinous process. Spacing of the superior and inferior wing sets is staggered, preventing overlapping of the wings if the coflex device is implanted at adjacent levels.

To properly fit into the space between the spinous processes in a range of patient anatomies, the coflex implant is manufactured in five sizes: 8, 10, 12, 14 and 16mm. The size corresponds to the size of the "U" as measured from opposing long arms. The number of teeth and the dimensions of the teeth are the same for all device sizes. The "gap" between the upper and lower arms of the "U" is 5mm for the size 8 device, 7mm for the size 10, 9mm for the size 12, 11mm for the size 14, and 13mm for the size 16.

COFLEX IMPLANTS

Color Code on Implant Box	Size	Article Number
	16mm	UQI00016
	14mm	UQI00014
	12mm	UQI00012
	10mm	UQI00010
	8mm	UQI00008

Table 1
coflex implant part numbers, sizes and color codes



MATERIAL:

Wrought titanium 6-aluminum
4-vanadium alloy according to ASTM F136 and ISO 5832-3
The coflex implant is delivered in sterile packaging.

COFLEX INSTRUMENTS

TRIALS

During surgery, trial implants (trials) are inserted to determine the appropriate implant size. Manufactured from medical grade acetal co-polymers, these trials are also used as impactors, i.e., one end of the instrument is a sizer while the opposite end holds the implant in place during insertion. The trials are color coded according to size, and are supplied in five colors corresponding to the five sizes of the coflex implant. The 8mm is gray; the 10mm is yellow; the 12mm is dark green; the 14mm is red; and the 16mm is dark blue.

Figure 1
coflex trial

WING TRIAL

The coflex wing trial is a reusable instrument that is intended to aid in assessing wing clearance of 7.7mm and interlaminar placement prior to implantation of the coflex device. A viewing window allows for direct visualization of the device's proximity to the dura, and includes a striking cap used for impaction, which is removable for visualization and cleaning.

Although the wing trial is provided in 8mm height; it is not intended as a height trial. For height trialing, use the standard height trials.

Figure 2
coflex wing trial

PLIERS

Two sets of specially designed pliers are used during implantation of the coflex implants: the coflex bending pliers and the coflex crimping pliers. The coflex bending pliers are used to open the wings of the implant, and the coflex crimping pliers are used to close the wings in place to conform to the spinous process. A picture of both pliers is provided in Figure 3.

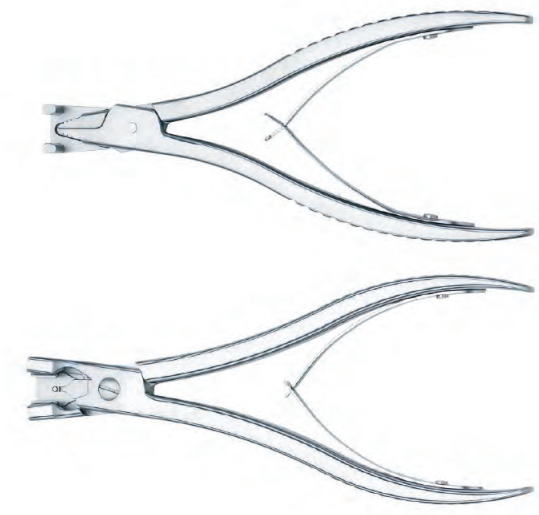


Figure 3
coflex bending pliers (top) and crimping pliers (bottom)

MALLET

A general purpose mallet may also be included to aid in insertion of the coflex device. A photograph of the mallet is included in Figure 4.

Figure 4
coflex mallet

STERILIZATION TRAY

All necessary trials and instruments fit in the coflex sterilization tray shown in Figure 5.

Figure 5
Sterilization Tray

Part Number	Description
UBT10008	coflex trial size 8mm
UBT10010	coflex trial size 10mm
UBT10012	coflex trial size 12mm
UBT10014	coflex trial size 14mm
UBT10016	coflex trial size 16mm
UET00008	coflex wing trial
UAT10100	coflex blending pliers
UAT10200	coflex crimper pliers
UAT20100	coflex mallet
UBC00000	coflex sterilization tray

Table 2
coflex instrument part numbers and descriptions

INDICATIONS FOR USE

The coflex Interlaminar Technology is an interlaminar stabilization device indicated for use in one or two level lumbar stenosis from L1–L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment.

The coflex® is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

CONTRAINDICATIONS

The coflex® is contraindicated in patients with:

- Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy 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°).
- Osteoporosis.
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Active or chronic infection – systemic or local.
- Known allergy to titanium alloys or MR contrasting agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.

WARNINGS

The coflex Interlaminar Technology should only be used by surgeons who are experienced and have undergone hands-on training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the coflex Interlaminar Technology should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events.

Data has demonstrated that spinous process fractures can occur with coflex implantation. Potential predictors for spinous process fractures include:

- Over-decompression during surgery leading to instability in the spine
- Resection of the spinous process to ≤ 14mm.
- Height of the spinous process ≤ 23mm preoperatively.
- Osteopenia or osteoporosis.
- “Kissing” spinous processes

If a spinous process fracture occurs during the surgical procedure, the surgeon should assess if sufficient bone stock exists for coflex implantation.

PRECAUTIONS

- Prior to use, thoroughly read the Instructions for Use and become familiar with the Surgical Technique. Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.
- The coflex Interlaminar Technology is provided sterile. Do not resterilize.
- Selection of appropriate implant size is essential towards obtaining proper function of the device and good clinical results.
- The use of an instrument for tasks other than those for which they are intended may result in damaged/ broken instruments or patient injury.
- Avoid the use of excessive force when using a trial. Use of such force may result in injury to the patient and/or failure of a trial.
- Do not use the trial to remove the coflex device. Such use may result in damage to the coflex, the trial, or both.
- Use only the surgical pliers provided in the coflex instrument set to adjust the wings of the device. Use of other instruments may lead to wing damage or breakage.
- Do not implant a broken or damaged coflex device.
- Keep the Instructions for Use accessible to all staff.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- Under no circumstances may modular implant components from different suppliers be combined with this device.
- Each patient's record shall document the implant used (name, article number, lot number).
- During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed about post-surgical regimen.
- Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of implant dysfunction, the implant must be checked periodically postoperatively using appropriate techniques.
- A recent study (Kim et al, 2012) has identified an association between degenerative spondylolisthesis and spinous process fractures in patients undergoing interspinous process spacer surgery. This study did not include the coflex Interlaminar Technology.
- Never reuse an implant. Although the implant may appear undamaged, previous stresses may have created non-visible damage that could result in implant failure.
- Never use implants if the packaging is damaged.
- An implant with damaged packaging might be damaged itself and thus may not be used.
- The safety and effectiveness of the coflex Interlaminar Technology has not been evaluated in patients with the following:
  - More than two vertebral levels requiring surgical decompression.
  - Prior surgical procedure that resulted in translatory instability of the lumbar spine (as defined by White & Panjabi).
  - More than one surgical procedure at any combination of lumbar levels.
  - Disc herniation at any lumbar level requiring surgical intervention.
  - Osteopenia.
  - Pregnancy.
  - Chronically taking medications or any drug known to potentially interfere with bone/soft tissue healing (e.g., steroids), not including a medrol dose pack.
  - History of significant peripheral neuropathy.
  - Significant peripheral vascular disease (e.g., with diminished dorsalis pedis or posterior tibial pulses).

- Unremitting back pain in any position.
- Uncontrolled diabetes.
- Known history of Paget's disease, osteomalacia, or any other metabolic bone disease (excluding osteopenia, previously addressed).
- Fixed and complete motor, sensory, or reflex deficit.
- Rheumatoid arthritis or other autoimmune diseases.
- Known or documented history of communicable disease, including AIDS, HIV, active Hepatitis.
- Active malignancy and/or patients with a primary bony tumor.
- Subject has a history of substance abuse (e.g., recreational drugs, narcotics, or alcohol).

MRI COMPATIBILITY

Non-clinical testing has demonstrated that the coflex Interlaminar Technology is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) or 3.0-Tesla (3.0T).
- Spatial gradient field of up to:
  - 11,230 G/cm (112.3 T/m) for 1.5T systems.
  - 5,610 G/cm (56.1 T/m) for 3.0T systems.
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

Additional information on MRI compatibility can be found in the Instructions for Use.

See product insert for complete labeling limitations related to this device.

PREOPERATIVE PATIENT PREPARATION

All patients must meet inclusion criteria with clinical findings on examination, failed non-operative measures, and radiographic confirmation of diagnoses.

Prior to surgery, candidates for the coflex device must be diagnosed with symptomatic lumbar stenosis. This includes symptoms not responsive to 6 months of nonoperative treatment, clinical findings of mechanical back pain and or radicular or claudicatory pain. Radiographic confirmation must include CT and or MRI showing lumbar stenosis of at least moderate degree with or without up to Grade 1 spondylolisthesis.

Proper informed consent is routine and mandatory.

A detailed and correct assessment of the indication is the key for successful treatment of the patient's spinal stenosis.

Radiographic studies are needed to understand coflex device sizing, the patient's anatomy, and possible anatomical issues. These radiographic studies include:

Basic diagnosis:

- X-ray, anterior/posterior (AP) and lateral.
- X-ray, flexion/extension and lateral inclination (patient standing).
- Magnetic resonance imaging (MRI).

Other assessment and diagnostic tools include:

- Computed tomography (CT).
- Three-dimensional CT angiography.
- Bone densitometry (T-score not less than –1).

Additional equipment includes C-arm fluoroscopy. IOM (intraoperative monitoring) is optional but not necessary. A basic laminectomy ordiscectomy surgical set is sufficient.

The Instructions for Use should be reviewed prior to surgery.

The patient should review the Patient Labeling and understand all possible risks and complications associated with the coflex device and general spinal surgery.

SURGICAL PREPARATION

- Patient is placed in prone position on surgical frame. A Jackson and/or Andrews table/frame can be used (Figure 6).
- For the surgical decompression as well as for appropriate interspinous distraction a neutral position or a slight kyphosis may be advantageous.
  - Surgeon should avoid creating either an excessively kyphotic or hyper-lordotic curve at the spinal segment to be operated on.

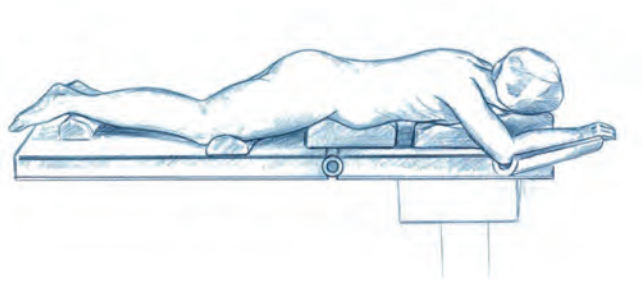


Figure 6
Preoperative patient positioning

SURGICAL APPROACH

- Paramedian or midline approach is taken, and the supraspinous ligament should be preserved if possible. (Figure 7).
  - The muscle is sharply dissected lateral to the supraspinous ligament preserving the entire thickness of the supraspinous ligament.
- The coflex device can accommodate a variety of approaches and degrees of decompression from open bilateral hemilaminectomy and partial facetectomy, to minimally invasive unilateral foraminotomy. The basic surgical approach entails a midline incision and reflection of the supraspinous ligament. For minimally invasive approach, this reflection of tissues extends to the base of the spinous process, which affords microsurgical access through the ligamentum flavum into the spinal canal. For open approach, this reflection of tissues extends to the facet capsules affording total access to the entirety of the posterior elements. Pathology specific decompression is then carried out in fashion standard for the approach.

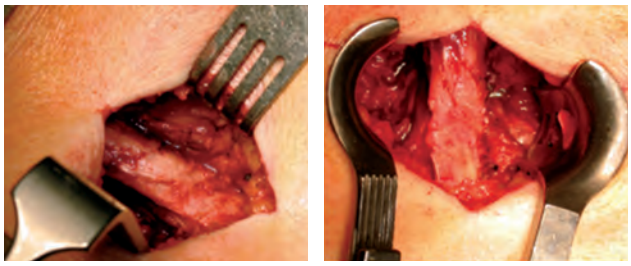


Figure 7
Midline surgical approach

MICROSURGICAL DECOMPRESSION

- Initiate the decompression from the base of the superior spinous process, 'outwards' toward the medial facets. Proceed bilaterally.
- Resect enfolded or hypertrophied ligamentum flavum as needed.
  - Prepare hemi-quadrilateral box decompression midline inferior to the superior spinous process, taking the decompression laterally as necessary.
- As MRI or direct visualization dictates, turn attention to lateral recesses or hypertrophied medial facets. Preserve at least 50% of the facets and facet capsule.
- The interspinous ligament is sacrificed (Figure 8).

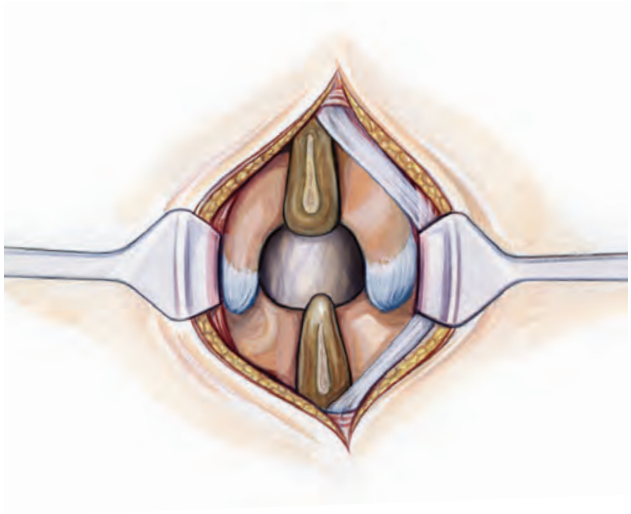


Figure 8
Sacrifice of interspinous ligament

IMPLANT SITE PREPARATION

- Some bony resection of the spinous process may be needed to ensure proper contact of the implant.
  - 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 spinous process so that wings seat at the appropriate depth.

WARNING: *Data has demonstrated that spinous process fractures can occur with coflex device implantation. Potential predictors for spinous process fractures include:*

- *Over-decompression during surgery leading to instability in the spine.*
- *Resection of the spinous process to ≤ 14mm.*
- *Height of the spinous process ≤ 23mm preoperatively.*
- *Osteopenia or osteoporosis.*
- *"Kissing" spinous processes.*

If a spinous process fracture occurs during the surgical procedure, the surgeon should assess if sufficient bone stock exists for coflex device implantation.

- Trials are utilized to define appropriate implant size. A full set of trials covering the range of coflex devices are provided in the sterilization tray, corresponding to 8–16mm high.
- The trial instrument is placed to evaluate proper contact with spinous process and amount of interspinous distraction. Surgeons should begin with the smaller size trials and sequentially advance in size until the proper size is determined.
- The ideal implant size should achieve 1–2mm of facet distraction.

PRECAUTION: *Selection of appropriate implant size is essential towards obtaining proper function of the device and good clinical results.*

- The trial must be able to be advanced linearly to the midlevel of the facet joint (Figure 9). Any rotation, angulation or rocking of the trial necessary to reach mid-facet level during the trialing process forecasts failure of the device implantation procedure for anatomic obstruction. The trial must be advanced using a mallet in direct linear fashion to its final position before any attempt to implant the device.
- After initial spinous process shaping and height trialing with standard height trials, insert the coflex wing trial into the interspinous space to assess wing clearance around the spinous process and implant depth. The striking cap can be used for impaction and is removable for visualization of trial placement. Ensure the wing trial clears both the superior and inferior spinous process such that the apex of the "U" sits 1-2mm from the dura as seen through the viewing window. Address any bony areas that may be preventing insertion of proper depth, and reinsert for final checks.

PRECAUTION: *Avoid the use of excessive force when using a trial. Use of such force may result in injury to the patient and/or failure of a trial.*

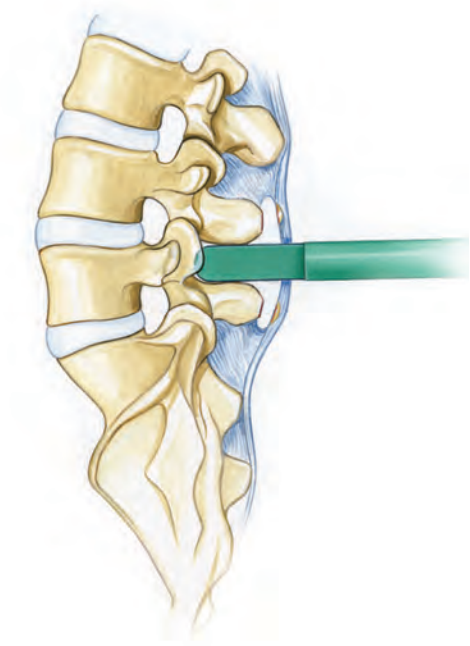


Figure 9
Sizing of appropriate coflex device

BENDING PLIERS

- The wings may need to be opened slightly using bending pliers to ensure appropriate depth of insertion.
- Remove the coflex device from the sterile packaging using the implant end of the corresponding size trial.
- Insert the bending plier jaws into the wings of the coflex device (Figure 10).
- Apply gentle force to the handles of the bending pliers to bend the wings of the device open (Figure 11).
- Repeat wing opening process for other set of wings.

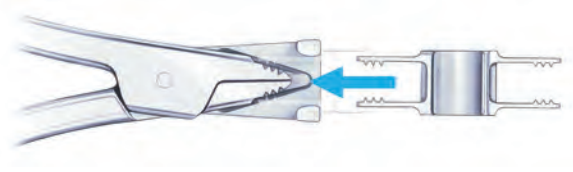


Figure 10
Insertion of the coflex device into the bending pliers

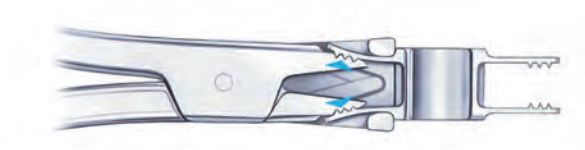


Figure 11
Bending of wings for spinous process placement

PRECAUTIONS:

Use only the surgical pliers provided in the coflex instrument set to adjust the wings of the device. Use of other instruments may lead to wing damage or breakage.

Take care to avoid damage to the device during implantation.

Damaged devices or devices with compromised sterility should not be implanted.

Never reuse an implant. Although the implant may appear undamaged, previous stresses may have created non-visible damage that could result in implant failure.

Do not use the trial to remove the coflex device. Such use may result in damage to the device, the trial or both.

Never use implants if the packaging is damaged.

An implant with damaged packaging might be damaged itself and thus may not be used.

Do not implant a broken or damaged coflex device.

Each patient's record shall document the implant used (name, article number, lot number).

IMPLANT INSERTION

- Guide the coflex device into the interlaminar space by using the “implant” side of the trial (Figure 12).
- Seat the coflex device into the interlaminar space via impaction utilizing a mallet.
- Proper depth is determined if the beaded tip probe can be passed freely leaving 1–2mm separation from the dura and the apex of the “U” is at the midline of the facet joint (Figure 13).

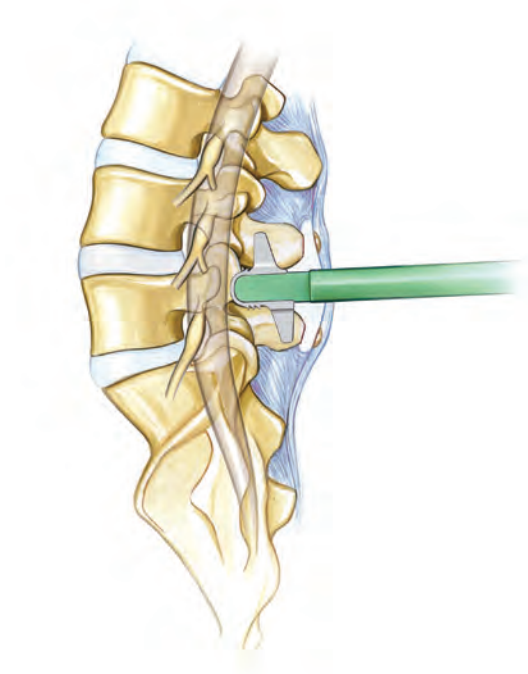
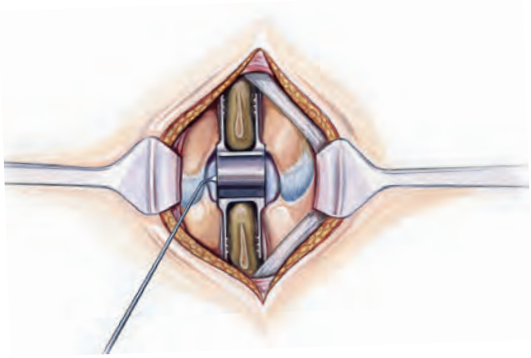


Figure 12
Insertion of the coflex device



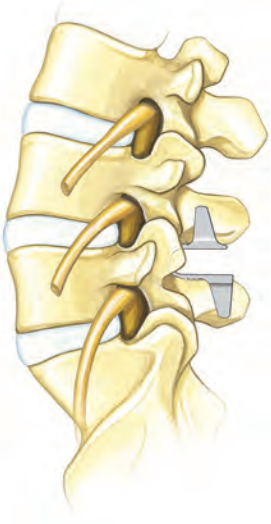


Figure 13
Interlaminar placement of the coflex device

IMPLANT POSITION

PRECAUTIONS:

The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.

The implant wings must have proper contact with the spinous processes after insertion.

CRIMPING PLIERS

- Additional stability is achieved by slightly crimping the wings.
- The crimping plier should be inserted into coflex device's wings (Figure 15).
- Gentle pressure should be applied to the handles of the coflex crimping pliers such that the coflex device's wings crimp around the spinous process (Figure 16).
- Repeat crimping process for other set of wings.

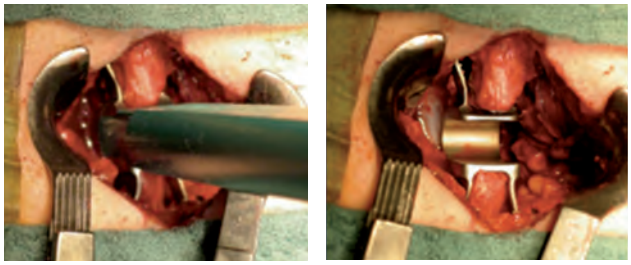


Figure 14
Placement of the coflex device

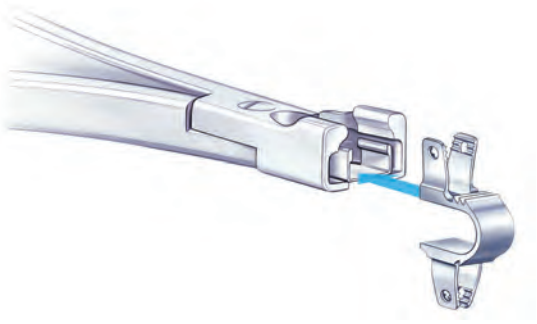


Figure 15
Insertion of coflex device into the crimping pliers

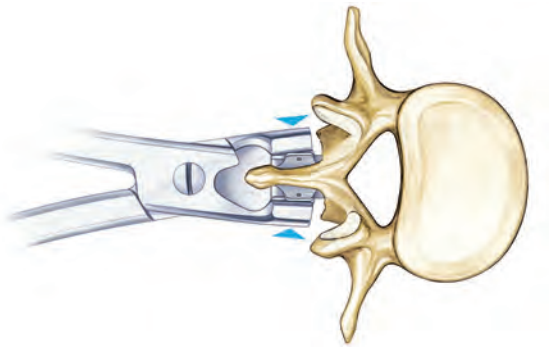


Figure 16
Crimping of the wings

ONE 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).

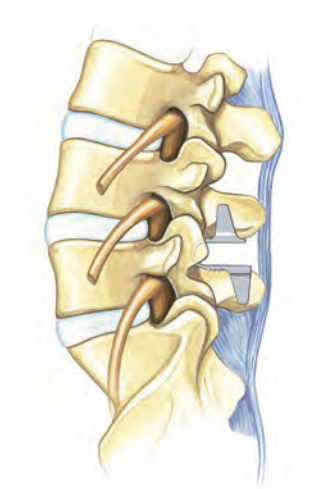


Figure 17
Final placement of the coflex device

TWO LEVEL IMPLANTATION

If a two level decompression is mandated, the implants must be sequentially placed to the appropriate depth avoiding an overlap (contact) of one pair of wings upon the other. The coflex device is indicated for contiguous level implantation only.

PRECAUTION:

Do not use for more than two contiguous levels. The performance of this device with pathology at more than two levels has not been evaluated.

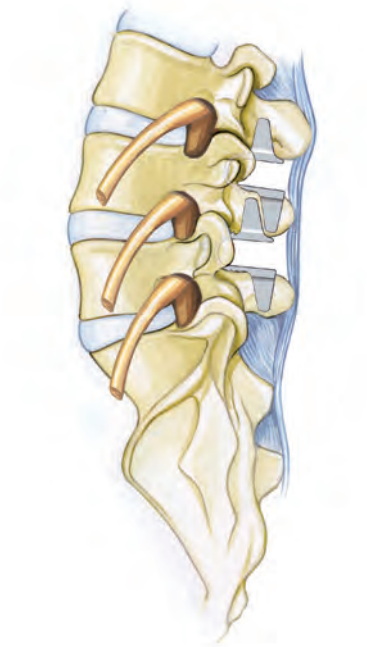


Figure 18
Two level implantation of coflex devices

LIGAMENT RECONSTRUCTION & WOUND CLOSURE

- In cases where supraspinous ligament reconstruction was needed, the fascia and the ligament can be closed in one layer over the spinous processes.
- A surgical drain may be placed as per surgeon's preference.
- Paraspinal muscles are reattached to the supraspinous ligament (Figure 19).
- Skin is closed in the usual manner.

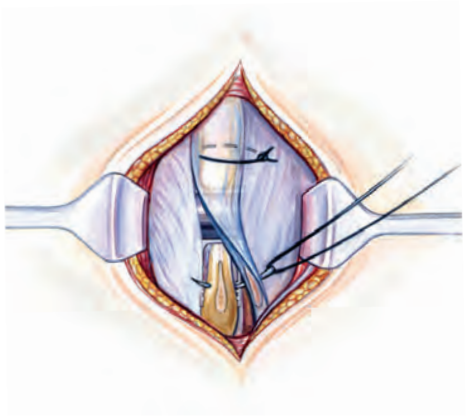


Figure 19
Reconstruction of supraspinous ligament

POSTOPERATIVE CARE

POSTOPERATIVE CARE INSTRUCTIONS

- As with other spinal implants, postoperative antibiotics are recommended. Lumbar drains are recommended at the discretion of the treating surgeon.
- Patients should keep wounds dry during the healing process to prevent infection.
- For best results, patients should engage in limited activity immediately following surgery.
- Patients can engage in light activities within 6 weeks depending on their strength, pain levels, age, and healing.

POSTOPERATIVE CARE PRECAUTIONS

- During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed about post-surgical regimen.
- Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of implant dysfunction, the implant must be checked periodically

IMPLANT REMOVAL

The coflex implant is intended for permanent implantation and is not intended for removal. When device explant is necessary, please follow these instructions:

- Follow “Surgical Preparation” and “Surgical Approach” directions as previously described to visualize the coflex implant.
- The coflex implant can be removed using standard instruments like chisels, forceps and pliers.
- Care has to be taken to remove bone overgrowing the wings of the device.
- Then the wings can be carefully bent open using a small bone chisel before the device can be taken out using pliers or forceps.

On special request, RTI Surgical offers a removal tool that is not part of the standard set.

- Additional procedures may be necessary to stabilize the spine following coflex device removal, including implantation of a new coflex device or spinal fusion.

Distributed by
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