Instructions for Use: CoFix® Posterior MIS Fusion System

Caution: Federal law restricts this device to sale by or on the order of a physician

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The CoFix® implant system consists of one CoFix® interlaminar implant and two CoFix® screw/sleeves. The individual package contains either one CoFix®® implant system, one CoFix® interlaminar implant, or two CoFix® screws/sleeves. See package label for identification.

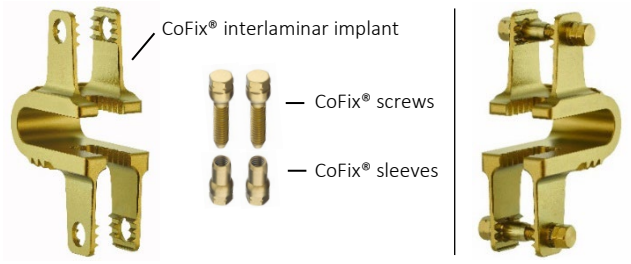

Figure 1: CoFix® Posterior MIS Fusion System

DEVICE DESCRIPTION

The CoFix® is a spinous process fixation device that stabilizes the spinous processes and spine to act as an adjunct to fusion. It consists of an interlaminar implant and two sets of screw and sleeves, fabricated from medical grade titanium alloy (Ti6Al4V). The interlaminar implant is a U-shaped component. A set of two wings extends vertically from the superior long arm of the device, with a second set of wings extending below the inferior long arm. A screw and sleeve are inserted through a prepared hole and fixes the crimped wings to the superior and inferior spinous processes.

MATERIAL

The CoFix® implant is made from wrought titanium 6-aluminum 4-vanadium alloy (ISO 5832-3). It is supplied sterile.

INDICATIONS

The CoFix® is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1 - S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies - with up to Grade 1 spondylolisthesis.

CONTRAINDICATIONS

- Prior decompressive laminectomy at the index lumbar level
- Radiographically compromised vertebral bodies at the index 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
- Degenerative lumbar scoliosis (Cobb angle of greater than 25°)
- Previous history of systemic infection or infection at the site of surgery
- Previous history of osteopenia, osteoporosis, or osteomalacia
- Previous history of disease of bone metabolism
- Previous history of allergy to any component of the CoFix® device
- Mixing of implant components in the same construct from other manufacturers
- Previous history of severe allergy or anaphylaxis
- Previous history of malignancy
- Unwilling or unable to follow postoperative care instructions

ADVERSE REACTIONS

The risks associated with any surgery include, but are not limited to:

- The implant may loosen, deform, break, fatigue, or move, which may necessitate another surgery to correct the problem.
- Implant component migration
- Implant malposition, instability
- Due to device placement between the spinous processes, there is a risk for spinous process fracture or other adverse event at the device interface with the spinous process
- Infection, early or late
- Nonunion, delayed union,
- Disc herniation
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations directly due to the implant
- Nerve damage due to surgical intervention or presence of the implant.
- Neurological difficulty including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
- Bursitis
- Paralysis
- Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Death
- Vascular damage due to surgical intervention or presence of the device. Vascular damage could result in catastrophic or fatal bleeding.
- Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period
- Damage to lymphatic vessels and/or lymphatic fluid exudation
- Spinal cord impingement or damage
- Fracture of bony structures, spinous processes
- Degenerative changes or instability in segments adjacent to fused vertebral levels
- Pain and discomfort associated with the presence of implants used to aid in the fusion surgery or reaction to the metal used in the implant, as well as the cutting and healing of tissues
- Allergies to implant materials
- Possible wear debris
- Implantation at the wrong spinal level
- Instruments also may break or malfunction in use, which may cause damage to the operative site or adjacent structures.

WARNINGS

The safety and effectiveness of this device has not been established for the intended use of spinal stabilization without fusion. This device is only for single level procedures and must be used for fusion with an interbody fusion cage and autogenous bone graft.

The CoFix® device is designed for single patient use only and must never be reused. As with all other orthopedic implants, the CoFix® device should never be reimplanted under any circumstances. The CoFix® is intended to act as an adjunct to fusion. Therefore, it is intended to be a supplemental device.

Potential risks identified with this device system, which may require additional surgery include: device component failure (bending, loosening, or fracture of the implant), loss of fixation, nonunion or delayed union, infection, fracture of the vertebrae, neurological injury and vascular or visceral injury.

Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Do not use implants or instruments from other systems or manufacturers, and do not mix stainless steel and titanium implant components together in the same spinal construct.

The CoFix® device can break if subjected to increased loading associated with delayed union or nonunion. Internal fixation implants are load-sharing devices that hold the spine in alignment until correction occurs. If healing is delayed or does not occur, the implant could break due to metal fatigue. Factors such as the patient's weight, activity level and adherence to weight-bearing or load-bearing instructions can also affect implant stresses and longevity.

The CoFix® device is intended to be used by experienced surgeons specializing in spinal surgery who have had specific training in the use of this particular spinous process plate system; this is a technically demanding procedure presenting a risk of serious injury to the patient.

Pre-operative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of x-rays, CT scans and other radiological studies. Only patients that meet the criteria described in the labeling should be selected.

Internal fixation implants are load-sharing devices intended to stabilize and hold an alignment in place until normal healing occurs. If the device is not removed after completion of its intended use, then possible corrosion, migration, bending, loosening, breakage, pain, risk of infection, bone loss and post-operative trauma may result.

Correct selection of the implant is extremely important: The bone defect to be treated as well as the patient's weight, height, occupation and/or degree of physical activity should be considered. Proper implant handling before and during the operation is crucial: Excessive contouring of metallic implants should be avoided. Sharp bends, reverse bending, notching and scratching should be avoided as these factors may produce internal stresses and weaken the implant.

Adequately instruct the patient: The physician should inform the patient about spinal implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses that could affect bone healing, implant limitations, and the fact that physical activity and full weight/load bearing stresses have been implicated in premature loosening, bending and/or fracture of internal fixation devices.

PRECAUTIONS

- Prior to use, thoroughly read these 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.

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- 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.
- Use only the surgical pliers provided in the coflex-F® 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 CoFix® 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.
- 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 resterilized/used.

SAFETY PRECAUTIONS

- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.
- Patient compliance with post-operative instructions from his/her surgeon is very important for success of the treatment. Noncompliance could lead to failure of the device and/or of the surgery.

MRI COMPATIBILITY

Non-clinical evaluation has demonstrated that the CoFix® implant system 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:
  - 7,480 G/cm (74.80 T/m) for 1.5T systems
  - 3,740 G/cm (37.40 T/m) for 3.0T systems.
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 1.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
  - - 1.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

3.0T RF HEATING

The CoFix® implant is expected to produce a temperature rise of less than 1.0 ºC at a maximum whole body averaged specific absorption rate (SAR) of 1.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 3.0T Siemens Trio (MRC20587) MR scanner with SYNGO MR A30 4VA30A software as determined by non-clinical evaluation.

1.5T RF HEATING

The CoFix® implant is expected to produce a temperature rise of less than 3.0 ºC at a maximum whole body averaged specific absorption rate (SAR) of 1.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 1.5T Siemens Espree (MRC30732) MR scanner with SYNGO MR B17 software as determined by non-clinical evaluation.

MR ARTIFACT

The shape of the image artifact follows the approximate contour of the device and extends radially up to 21 mm from the implant in a 3.0T system with spinecho sequencing as determined by non-clinical evaluation.

STORAGE, INSPECTION AND STERILIZATION

The CoFix® is provided sterile. The device is sterilized with gamma sterilization (25 kGy minimum) validated by ISO 11134 to SAL 10^{-6}. The implant is individually packed in protective packaging that is labeled according to its contents.

- Always store the implant in the original protective packaging.
- Do not remove the implant from the packaging until immediately before use.
- The implant should be stored in ambient temperature in a secure location.

Both inner and outer packaging, including seals, should be thoroughly inspected prior to implantation.

DISINFECTION / CLEANING

The implant is not designed to be disinfected or cleaned by the user.

RESTERILIZATION

The implant is not designed to be sterilized by the user.

PROCEDURE

The CoFix® implant system must be implanted only with the applicable instruments. The instruments are available from the manufacturer at any time.

PREOPERATIVE

The operating surgeon draws up an operation plan specifying and documenting the following:

- Implant component(s) and their dimensions.
- Proper position of the implant component(s) between the spinous processes.
- Determination of intraoperative orientation points.

The following conditions must be fulfilled prior to application:

- All required implant component(s) are readily available.
- Highly aseptic operating conditions are present.
- All requisite implantation instruments must be available and in working order, including the coflex-F® trial and coflex-F® instruments.

WARNING:
Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.
WARNING:
The use of an instrument for tasks other than those for which it is intended may result in damaged / broken instruments or patient injury.

- The operating surgeon and operating room team must be thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied.
  Complete information on these subjects must be readily available at the workplace.
- The operating surgeon must be especially trained in spinal surgery, biomechanical principles of the spine and the relevant operating techniques.
  The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:
- The patient is aware of the risks associated with neurosurgery, general surgery, orthopedic surgery and with general anesthesia.
- The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
- The patient has been informed that alternate fusion technologies (e.g., pedicle screw based systems) may be utilized, particularly if the patient's facet joints are inadequate post interbody fusion device implantation.
- The implant can fail due to excessive load, wear and tear, or infection.
- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload through extreme strain, or through work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails or if there is a failure of fusion.
- The patient must have their physician carry out follow-up examinations of the implant at regular intervals.

INTRAOPERATIVE

Prior to use, verify the integrity of the sterile packaging and check the product expiration date.
WARNING:
Never use implants if the packaging is damaged.
Never use implants that are past their expiration date.
The interbody fusion device must be placed prior to inserting the CoFix® implant!
The intervertebral space shall be prepared taking care to remove all nucleus material (which inhibits osteogenesis) prior to insertion of the interbody fusion device (cage). The cage shall be selected to maximize the contact between the cage and endplate - care must be taken to avoid undersizing the cage. The interbody fusion implant is then introduced using standard surgical techniques, and bone graft shall be placed anterior, lateral and medial to the cages to optimize fusion success. The sagittal balance of the spine shall be adjusted by the cage configuration / position.
The CoFix® implant system is then used to provide additional segmental stabilization to increase the segmental stiffness and promote the fusion process. Perform microsurgical decompression or prepare central interlaminar space for CoFix® Interlaminar implant insertion, and measure interspinous space utilizing the trial portion of the trial taking care to avoid facet distraction to prevent cage loosening. Load the CoFix® interlaminar implant on the insertion portion of the trial and introduce into the prepared site. The wings of the CoFix® interlaminar implant

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are opened with the bending pliers and closed with the crimping pliers. The spinous process is then prepared using the punching pliers, and the screw/sleeve is inserted upon the crimped wings and fully tightened using the applicable instruments.

POSTOPERATIVE

- Reiterate preoperative instructions to the patient.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

REVISION SURGERY / IMPLANT REMOVAL

The CoFix® implant is intended for permanent implantation and is not intended for removal. If the device is explanted, please notify Xtant at the contact information below.

WARRANTY

All warranty rights are lost if repairs or modifications are carried out by an unauthorized service center. The manufacturer does not take responsibility for any effects on safety, reliability or performance of the product if the product is not used in conformity with the instructions for use. Technical alterations reserved.

FOR FURTHER INFORMATION

Please contact Xtant Medical if further information on this product is needed.

US Contact	Manufacturer
Xtant Medical Holdings, Inc. 664 Cruiser Lane Belgrade, MT 59714 Phone: 888-886-9354 www.xtantmedical.com	Paradigm Spine GmbH Eisenbahnstraße 84 78573 Wurmlingen Germany Phone: +49 (7461) 963599-0 Fax: +49 (7461) 963599-20

Symbols

	Manufacturer
	Country and date of manufacture Note: CC is the letter country code as defined in ISO 3166-1
	Use-by date
	Batch code
	Catalog number
	Content of usable units(s)
	Sterilized using irradiation
	Double sterile barrier system
	Do not resterilize
	Do not use if package is damaged
	Keep dry
	Do not reuse
	Consult instructions for use at this website.
	Caution
	MR conditional
	Medical device
	Unique device identifier
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician