Instructions for Use: coflex® Interlaminar Technology

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

HOW SUPPLIED

Implant Components - Sterile
Surgical instruments - Non-Sterile (unless otherwise noted on the package label)

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 below the inferior long arm. Both sets of wings have serrated bone-facing 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.

Figure 1: coflex® Interlaminar Technology

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. A second option of trials is offered with guide and x-ray marker to provide greater guidance, support and visibility during implantation.

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 evenly open the wings of the implant, and the coflex® crimping pliers are used to evenly close the wings in place to conform to the spinous process. In addition, revision pliers are available if needed to assist in the removal of the coflex® implant during a revision surgery. A general purpose mallet may also be included to aid in insertion of the coflex® device.

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 (i.e., bending and crimping pliers), 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 ≤ 14 mm,
- Height of the spinous process ≤23 mm pre-operatively,
- Osteopenia or osteoporosis, and
- "Kissing" spinous processes.

It is important to only use the Paradigm Spine bending and crimping pliers to evenly crimp the wings to help avoid spinous process fractures. If a spinous process fracture occurs during the surgical procedure, the surgeon should assess if sufficient bone stock exists for coflex® implantation.

There were no associated clinical sequelae of spinous process fractures at 24 months. The long-term clinical sequelae of unhealed spinous process fractures are not well known.

The safety and effectiveness of coflex® Interlaminar Technology has been demonstrated compared to posterolateral fusion (66.2% coflex CCS Success vs. 57.7% posterolateral fusion CCS Success). The effectiveness of coflex® Interlaminar Technology compared to decompression alone has not been established.

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.
- 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 crimping and bending 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 fracture in patients

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undergoing interspinous process spacer surgery (e.g., X-Stop, Aspen). 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, which is addressed above).
  - 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.
  - History of substance abuse (e.g., recreational drugs, narcotics, or alcohol).

POTENTIAL ADVERSE EVENTS

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the coflex® Interlaminar Technology identified from the coflex® clinical study results, approved device labeling for other interlaminar devices, and published scientific literature including: (1) those associated with any surgical procedure; (2) those associated with decompressive procedures and posterolateral fusion for the treatment of spinal stenosis and instability; and (3) those associated with an interlaminar stabilization device, including the coflex® Interlaminar Technology. In addition to the risks listed below, there is also the risk that surgery may not be effective in relieving symptoms, or may cause worsening of symptoms. Additional surgery may be required to correct some of the adverse effects.

1. Risks associated with any surgical procedure include: infection; pneumonia; atelectasis; septicemia; injury to blood vessels; soft tissue damage; phlebitis, thromboembolus, or pulmonary embolus; hemorrhage; respiratory distress; pulmonary edema; reactions to the drugs or anesthetic agent used during and after surgery; reactions to transfused blood; failure of the tissue to heal properly (e.g., hematoma, seroma, dehiscence, etc.) which may require drainage, aspiration, or debridement or other intervention; incisional pain; heart attack; stroke; and death.

2. Risks associated with decompressive procedures and posterolateral fusion for treatment of spinal stenosis and instability include: damage to nerves leading to sensory or motor deficits; paralysis; parasthesia; cauda equina syndrome; damage to nerves, blood vessels, and nearby tissues; epidural bleeding, hematoma, or fibrosis; instability; blindness secondary to pressure on the eye during surgery; osteolysis; injury to the spinal cord or the nerves leaving or entering the cord; loss of bowel or bladder function; retrograde ejaculation, sexual dysfunction, or sterility; disc herniation; injury to blood vessels; dural violation, with or without CSF leakage; impaired muscle or nerve function; hemorrhage; epidural injection reaction; epidural injection failure; fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery; postoperative muscle and tissue pain; surgery may not reduce the preoperative pain experienced; 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; failure of the fusion to heal or spontaneous fusion; the spine may undergo adverse changes or deterioration including loss of proper spinal curvature, correction, height, and/or reduction, or malalignment, and another surgery may be required; and adverse bone/implant interface reaction.

3. Risks associated with an interlaminar stabilization device, including the coflex® Interlaminar Technology, include: implant malposition or incorrect orientation; allergies to implant materials; possible wear debris, implantation at the wrong spinal level; fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery; the implant may loosen, deform, break, fatigue, or move, which may necessitate another surgery to correct the problem; and instruments also may break or malfunction in use, which may cause damage to the operative site or adjacent structures.

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. Non-compliance could lead to failure of the device and/or of the surgery.

CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of coflex® Interlaminar Technology for the treatment of moderate to severe spinal stenosis with back pain in the US under IDE #G060059. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between October 2006 and March 2010. The database for this PMA reflected data collected through March 2012. A total of 384 patients were enrolled consisting of up to 40 non-randomized "roll-in" patients and 344 randomized patients. Excluding 22 protocol violators, 215 randomized coflex® patients and 107 randomized control patients were enrolled. There were 21 investigational sites.

The study was a prospective, randomized, multi-center, concurrently controlled clinical study. Surgeons were blinded prior to patient randomization, and patients were blinded until after surgery. The control group was posterolateral fusion with autograft bone and pedicle screw fixation, following surgical decompression. Based on the well-established performance of posterolateral fusion in the medical literature, a 2:1 randomization ratio was applied with block randomization and a randomly changing block size. A Bayesian statistical plan utilizing Jeffries non-informative priors and a single late-information time interim analysis (Maislin, 2011) was used to analyze the success of the device. After 70% of patients were evaluable for month 24 composite clinical success, the Bayesian posterior probability was to be computed and compared to 0.975. If larger than 0.975, the interim analysis sample was to be used to support approval. If not, the data on the remaining patients would be included in the analysis cohort after they complete 24 months of follow-up and again the posterior probability would be compared to 0.975 in a final analysis. Subsequently, FDA requested submission of the patient data for the entire cohort.

An independent Data Safety Monitoring Board (DSMB) evaluated all safety events on a quarterly basis during the course of the study to ensure patient safety was not compromised. All adverse events were independently reviewed and adjudicated by a Clinical Events Committee (CEC), with their decision binding on the study sponsor. All radiographs were analyzed by an independent core lab (Medical Metrics, Inc.).

The control group was the accepted standard of care for this indication, posterolateral fusion with pedicle screw fixation. The systems utilized were the Expedium™ (Johnson and Johnson, Inc.) and the CD Horizon Legacy™ (Medtronic, Inc.).

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the coflex® study was limited to patients who met the following inclusion criteria.

- Radiographic confirmation of at least moderate lumbar stenosis, which narrows the central spinal canal at one or two contiguous levels from L1-L5 that require surgical decompression. Moderate stenosis is defined as > 25% reduction of the antero-posterior dimension compared to the next adjacent normal level, with nerve root crowding compared to the normal level, as determined by the investigator on CT Scan or MRI. The patient may have, but is not required to have for inclusion in the study:
  - Facet hypertrophy and subarticular recess stenosis at the affected level(s);
  - Foraminal stenosis at the affected level(s);
  - Up to Grade I stable degenerative spondylolisthesis (Meyerding classification) or equivalent retrolisthesis as determined by flexion/extension X-ray:
    - For single level disease, there may be up to a Grade I stable spondylolisthesis or equivalent retrolisthesis at the affected level as determined on flexion/extension films by the investigator.
    - For two level disease, there may be up to a Grade I stable spondylolisthesis or equivalent retrolisthesis at only one of the two contiguous affected levels as determined on flexion/extension films by the investigator. Patients with up to Grade I stable spondylolisthesis at two contiguous levels are excluded, but patients with up to Grade I stable

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spondylolisthesis at one level and equivalent retrolisthesis at the adjacent level may be included.
  - Mild lumbar scoliosis (Cobb angle up to 25º)
- Radiographic confirmation of the absence of angular or translatory instability of the spine at index or adjacent levels (instability as defined by White & Panjabi: Sagittal plane translation >4.5mm or 15% or sagittal plane rotation >15° at L1-L2, L2-L3, and L3-L4; >20° at L4-L5 based on standing flexion/extension X-rays)
- VAS back pain score of at least 50 mm on a 100 mm scale.
- Neurogenic claudication as defined by leg/buttocks or groin pain that can be relieved by flexion such as sitting in a chair.
- Patient has undergone at least one epidural injection at any prior time point, AND at least 6 months of prior conservative care without adequate and sustained symptom relief.
- Age between 40 to 80 years.
- Oswestry Low Back Pain Disability Questionnaire score of at least 20/50 (40%).
- Appropriate candidate for treatment using posterior surgical approach.
- Psychosocially, mentally, and physically able to fully comply with this protocol, including adhering to scheduled visits, treatment plan, completing forms, and other study procedures.
  - Personally signed and dated informed consent document prior to any study-related procedures indicating that the patient has been informed of all pertinent aspects of the trial.

Patients were <u>not</u> permitted to enroll in the coflex® study if they met any of the following exclusion criteria:

- 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.
- Prior fusion, implantation of a total disc replacement, complete laminectomy, or implantation of an interspinous process device at any 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.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle of greater than 25°).
- Disc herniation at any lumbar level requiring surgical intervention.
- Osteopenia: A screening questionnaire for osteopenia, SCORE (Simple Calculated Osteoporosis Risk Estimation), will be used to screen patients who require a DEXA bone mineral density measurement. If DEXA is required, exclusion will be defined as a DEXA bone density measured T score of ≤ -1.0 (The World Health Organization definition of osteopenia).
- 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.
- Pregnant or interested in becoming pregnant in the next three years.
- Known allergy to titanium, titanium alloys, or MR contrast agents.
- Active or chronic infection – systemic or local.
- 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, which is addressed above).
- Cauda equina syndrome, defined as neural compression causing neurogenic bowel (rectal incontinence) or bladder (bladder retention or incontinence) dysfunction.
- 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: a patient with a history of any invasive malignancy (except nonmelanoma skin cancer), unless he/she has been treated with curative intent and there has been no clinical signs or symptoms of the malignancy for at least five years. Patients with a primary bony tumor are excluded as well.
- Prisoner or ward of the state.
- Subject has a history of substance abuse (e.g., recreational drugs, narcotics, or alcohol).
- Subject is currently involved in a study of another investigational product for similar purpose.
- Currently seeking or receiving workman's compensation.
- In active spinal litigation.

2. <u>Follow-up Schedule</u>

All patients were scheduled to return for follow-up examinations at 6 weeks, 3 months, 6 months, 12 months, 18 months, and 24 months postoperatively.

Patients were evaluated for Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), SF-12, back and leg pain (via visual analog scale (VAS)), and neurological assessment at preoperative visit and at all postoperative visits. Radiographic evaluation was performed at all timepoints. Adverse events and complications were recorded at all visits.

The key time points are shown below in the tables summarizing safety and effectiveness.

3. <u>Clinical Endpoints</u>

The safety of the coflex® Interlaminar Technology was assessed by comparing adverse event incidence, epidural steroid injections, reoperations, revisions, and neurological function in comparison to the posterolateral fusion control group.

The effectiveness of the coflex® Interlaminar Technology was assessed by evaluating clinical pain and function (evaluated by ODI) compared to the posterolateral fusion control group.

Per the protocol, an individual patient was considered a Composite Clinical Success (CCS) if all of the following criteria were met at 24 months:

- Improvement of at least 15 points in the Oswestry Low Back Pain Disability Index (ODI) at 24 months compared to baseline;
- No reoperations, revisions, removals, or supplemental fixation; and
- No major device-related complications, including but not limited to permanent new or increasing sensory or motor deficit at 24 months; and
- No epidural steroid injections in the lumbar spine.

Overall study success criteria were based on a comparison of individual patient success rates, such that the patient success rate for the coflex® investigational group must be non-inferior to that of the posterolateral fusion control group. Bayesian statistical methods were used to obtain the posterior probabilities of non-inferiority and superiority. According to the statistical analysis plan, if non-inferiority was demonstrated, then superiority would be evaluated as defined more specifically in the analysis plan. The posterior probability threshold of 0.975 was used to determine non-inferiority.

Secondary effectiveness evaluations specified in the protocol included comparisons of the following: ZCQ Symptom Severity, ZCQ Physical Function, ZCQ Patient Satisfaction, Leg and Back Pain (via VAS), SF-12, time to recovery, and patient satisfaction.

In addition, several radiographic endpoints were considered in evaluating both safety and effectiveness, including index level and adjacent level range of motion, translation, instability, and device-related effects (e.g., device fracture or migration, fusion/non-fusion, spinous process fracture).

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B. Accountability of PMA Cohort

At the time of database lock (March 11, 2012), of 322 per protocol patients (215 coflex® and 107 fusion) enrolled in PMA study 95.7% (204 coflex® and 104 fusion) had data available for analysis at the completion of the study. Patient accountability is shown in Table 1, a patient accounting tree is shown in Figure 2, and a summary of data available at 24 months for each specific evaluation is provided in Table 2.

Table 1: Patient Accounting and Follow-Up Compliance Table – Efficacy Evaluable (PP) coflex® (I) and Fusion Control Patients (C)

Date of data transfer 03/11/2012	Pre-Op		Week 6		Month 3		Month 6		Month 12		Month 18		Month 24	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
(1) Theoretical follow-up	215	107	215	107	215	107	215	107	215	107	215	107	215	107
(2) Cumulative deaths	0	0	0	0	0	0	0	0	0	0	0	0	0	0
(3) Cumulative 'Study Failures'	0	0	8	3	11	6	20	10	26	12	35	17	42	18
(4) Not Yet Overdue	0	0	0	0	0	0	0	0	0	0	0	0	1	0
(5) Deaths+failures among theoretical due	0	0	8	3	11	6	20	10	26	12	35	17	42	18
(6) Expected due for clinic visit[B]	215	107	207	104	204	101	195	97	189	95	180	90	172	89
(7) Failures among theoretical due	0	0	8	3	11	6	20	10	26	12	35	17	42	18
(8) Expected due+failures among theoretical due	215	107	215	107	215	107	215	107	215	107	215	107	214	107
All Evaluated Accounting (Actual[B]) Among Expected Due Procedures														
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
(9) # of procedures with any clinical data in interval	215	107	205	104	200	99	189	95	176	94	163	83	162	86
(10) All Evaluated Visit Compliance (%)	100.0%	100.0%	99.0%	100.0%	98.0%	98.0%	96.9%	97.9%	93.1%	98.9%	90.6%	92.2%	94.2%	96.6%
(11) Change in Oswestry Disability Score	215	107	202	102	196	96	187	95	176	92	163	83	162	86
(12) Radiographic evaluation	215	107	202	102	196	98	186	95	171	93	149	79	139	68
(13) CCS at Month 24													204	104
(14) Actual[B] % Follow-up for CCS at Month 24 or for change in ODI at other times.	100.0%	100.0%	97.6%	98.1%	96.1%	95.0%	95.9%	97.9%	93.1%	96.8%	90.6%	92.2%	95.3%	97.2%
Within Window Accounting (Actual[A]) Among Expected Due														
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
(15) Change in Oswestry Disability Score	215	107	184	93	187	92	165	82	168	88	151	72	149	78
(16) Radiographic evaluation	215	107	183	94	188	94	162	82	164	88	137	69	131	63
(17) CCS at Mos. 24													191	95
(18) ActualA% Follow-up for CCS at Month 24 or and change in ODI at other times.	100.0%	100.0%	88.9%	89.4%	91.7%	91.1%	84.6%	84.5%	88.9%	92.6%	83.9%	80.0%	89.3%	88.8%

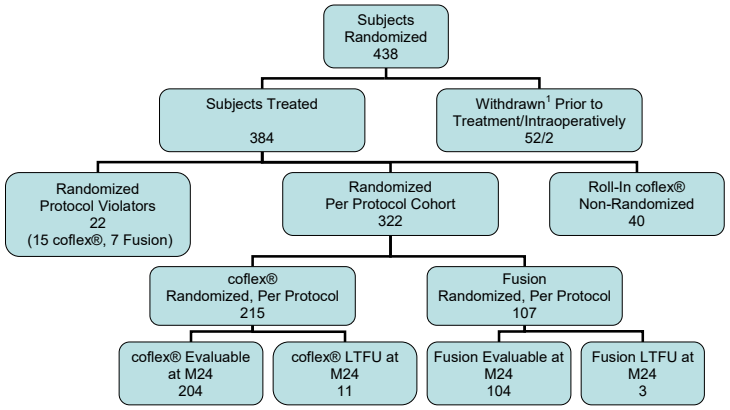

Figure 2: Patient Accounting Tree for coflex® IDE Study

[1] Reasons for withdrawal prior to treatment: 17 patients failed to meet inclusion and exclusion criteria, 22 patients withdrew consent, and 13 patients elected not to have surgery.

Table 2: 24 Month Data Accounting for coflex® IDE

Parameter	coflex®	Fusion Control
Randomized	262	136
Withdrawn Prior to Treatment	32	22
Subjects Treated (mITT)	230	114
Protocol Violators	15	7
Per Protocol Cohort	215	107
Radiologic Assessments:		
• Foraminal Height*	• 180 (83.7%)	• n/a
• ROM	• 187 (87.0%)	• 102 (95.3%)
• Translation	• 185 (86.0%)	• 95 (88.8%)
• Fusion†	• n/a	• 102 (95.3%)
Clinical Failures Among Implanted[1]	42	18
Expected (Per Protocol)	172	89
ODI	162 (94.2%)	86 (96.6%)
ZCQ	161 (93.6%)	86 (96.6%)
VAS Leg and Back Pain	162 (94.2%)	85 (95.5%)
SF-12:		
• Physical Component Score	• 132 (76.7%)	• 70 (78.7%)
• Mental Component Score	• 139 (80.8%)	• 75 (84.3%)

*This measurement taken only on coflex® patients
†This measurement taken only on fusion patients and defined as bridging bone
[1]Patients with Reoperations, Revisions, and Epidural Steroid Injection

In the tables that follow throughout this summary, the randomized per protocol cohort is used for safety and efficacy analyses, unless otherwise indicated.

C. Study Population Demographics and Baseline Parameters

The clinical study sites represent a mix between academic and community hospital settings, urban and regional settings of care, and were selected from varied geographic regions of the country.

Table 3: Summary of Baseline and Demographic Variables - coflex® and Fusion Control Efficacy Evaluable (PP) Cohorts

	coflex®			Fusion Control		
Demographics - All	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
Age at surgery (yrs)	215	62.1	9.2	107	64.1	9.0
Height (inches)	215	67.0	4.1	107	66.6	4.1
Weight (lbs)	215	190.3	35.4	107	187.7	38.1
BMI (k/m^2)	215	29.7	4.5	107	29.6	4.9
Demographics - Male	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
Age at surgery (yrs)	109	61.7	9.3	49	64.2	10.4
Height (inches)	109	69.9	2.7	49	69.9	2.9
Weight (lbs)	109	207.1	27.3	49	207.6	32.3
BMI (k/m^2)	109	29.8	3.7	49	29.7	4.4
Demographic - Female	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
Age at surgery (yrs)	106	62.6	9.1	58	64.1	7.7
Height (inches)	106	64.0	2.9	58	63.8	2.5
Weight (lbs)	106	173.1	34.6	58	170.8	34.5
BMI (k/m^2)	106	29.6	5.2	58	29.5	5.4
Baseline Functional Status	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
Oswestry (ODI)	215	60.8	11.8	107	60.7	11.5
Zurich Claudication Qx Severity	214	3.6	0.6	107	3.6	0.6
Zurich Claudication Qx Physical	214	2.7	0.4	107	2.8	0.4
SF-12 PCS (Physical)	195	28.1	6.6	95	28.2	6.0
SF-12 MCS (Mental Health)	195	45.5	13.0	95	44.9	12.2
VAS Back pain	215	79.5	15.0	106	79.2	13.5
VAS Leg pain (worse leg)	215	76.0	20.4	106	78.3	18.4

Table 4: Summary of Baseline and Demographic Categorical Variables - coflex® and Fusion Control Efficacy Evaluable (PP) Cohorts

	coflex®		Control	
	n	**%**	**n**	**%**
Number of subjects	215		107	
Males	109	50.7	49	45.8
Females	106	49.3	58	54.2
Number of levels	**n**	**%**	**n**	**%**
1-level decompression	138	64.2	68	63.6
2-level decompression	77	35.8	39	36.4
Current smoker	**n**	**%**	**n**	**%**
Yes	22	10.2	15	14.0
No	193	89.8	92	86.0
Comorbidities	**n**	**%**	**n**	**%**
Cardiovascular	137	63.7	74	69.2
Musculoskeletal	112	52.1	61	57.0
Endocrine	55	25.6	35	32.7
Duration of Back Pain	**n**	**%**	**n**	**%**
None	0	0.0	0	0.0
Fewer than 6 months	3	1.4	1	0.9
6 months to a year	24	11.2	14	13.1
More than one year	188	87.4	92	86.0
Duration of Leg Pain (maximum)	**n**	**%**	**n**	**%**
None	1	0.5	1	0.9
Fewer than 6 months	6	2.8	8	7.5
6 months to a year	38	17.7	22	20.6
More than one year	170	79.1	76	71.0
Duration of Buttock Pain	**n**	**%**	**n**	**%**
None	32	14.9	21	19.6
Fewer than 6 months	11	5.1	7	6.5
6 months to a year	41	19.1	22	20.6
More than one year	131	60.9	57	53.3
Duration of Groin Pain	**n**	**%**	**n**	**%**
None	157	73.0	74	69.2
Fewer than 6 months	6	2.8	5	4.7
6 months to a year	13	6.0	12	11.2
More than one year	39	18.1	16	15.0

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Table 5: Summary of Baseline and Demographic Categorical Variables - coflex® and Fusion Control Efficacy Evaluable (PP) Cohorts (Continued)

	coflex®		Control	
Previous Conservative Treatment of the Spine	**n**	**%**	**n**	**%**
None	28	13.0	9	8.4
Physical therapy	132	61.4	70	65.4
NSAIDs/ASA/Acetinomphen only	121	56.3	65	60.7
Chiropractic	82	38.1	41	38.3
Corset/Brace	37	17.2	22	20.6
Any narcotic use	107	49.8	55	51.4
Other	34	15.8	15	14.0
Previous Surgical Treatment of the Spine	**n**	**%**	**n**	**%**
None	0	0.0	0	0.0
Discectomy	4	1.9	0	0.0
Fusion	3	1.4	0	0.0
IDET	1	0.5	1	0.9
Epidural injections	210	97.7	105	98.1
Other injections	35	16.3	18	16.8
Laminotomy	10	4.7	2	1.9
Race	**n**	**%**	**n**	**%**
American Indian / Alaskan Native	1	0.5	3	2.8
Asian	4	1.9	3	2.8
Black or African American	11	5.1	6	5.6
White	191	88.8	93	86.9
Other	8	3.7	2	1.9

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the per protocol cohort of 322 patients (215 coflex® patients and 107 fusion patients). Adverse events reported by the investigating surgeons and adjudicated by the CEC are reported in Table 6 to Table 8. The key safety outcomes for this study are presented below in Table 9 through Table 13.

Table 6: Incidence of Adverse Events coflex® and Fusion Control Efficacy Evaluable (PP) Cohort

	coflex® (N=215)		Control (N=107)	
	n	**%**	**n**	**%**
Operative Site				
Pain; new, + frequency, worsening	71	33.0%	37	34.6%
Wound problems[1]	30	14.0%	9	8.4%
Fracture[2]	11	5.1%	2	1.9%
Other[3]	9	4.2%	3	2.8%
Component loosening	3	1.4%	4	3.7%
Component migration	3	1.4%	1	0.9%
Component breakage	2	0.9%	2	1.9%
Infection (deep)	2	0.9%	0	0.0%
Component deformation	0	0.0%	0	0.0%
Incidental durotomy (<= 5 mm)	0	0.0%	0	0.0%
Tear >5mm	0	0.0%	0	0.0%
Heterotopic ossification	0	0.0%	0	0.0%
Hematoma requiring drainage	0	0.0%	1	0.9%
Non-Operative Site				
Musculoskeletal[4]	121	56.3%	65	60.7%
Neurological[5]	51	23.7%	23	21.5%
Other[6]	29	13.5%	16	15.0%
Cardiovascular	21	9.8%	11	10.3%
Gastrointestinal	15	7.0%	12	11.2%
Skin and Subcutaneous Tissue	14	6.5%	9	8.4%
Genitourinary	13	6.0%	9	8.4%
Respiratory	9	4.2%	6	5.6%
Endocrine/Metabolic	8	3.7%	4	3.7%
Cancer/Neoplasm	6	2.8%	9	8.4%
EENT	6	2.8%	4	3.7%
Hematological	5	2.3%	4	3.7%
Immune	1	0.5%	0	0.0%
Psychiatric/Substance abuse	1	0.5%	7	6.5%

[1] Wound problems: Include wound drainage, superficial infections, dehiscence, seroma, and delayed healing of incision
[2] Fracture: Includes spinous process fracture, pars fracture, and other fractures of the vertebral bodies reported by investigators.
[3] Other Operative Site: Includes events not placed into a specific category by investigators, including clicking sound, spondylolisthesis, drain complications, incisional pain, spinal swelling, and cellulitis.
[4] Musculoskeletal: Includes weakness, cramping, joint pain, joint surgery or replacement, and other non-lumbar spinal musculoskeletal tissues.
[5] Neurological: Includes balance problems, headaches, numbness and/or tingling, and changes in sensation.
[6] Other Non-Operative Site: Includes psychological disorders, infectious diseases, insomnia, and fever.

Table 6 shows the comparison of percentages of complications between the coflex® and fusion Per Protocol cohorts at specific operative and non-operative sites. With the exception of wound problems, adverse events rates were comparable between coflex® and fusion control. The numerical difference of wound complications between coflex® 14.0% (30/215) and control 8.4% (9/107) was 5.6%. This difference was not statistically significant. Table 7 demonstrates the time course of all adverse events.

Table 7: Time Course of Adverse Events coflex® (I) and Fusion Control (C) Efficacy Evaluable (PP) Cohort

	Day of Surgery Relative Day 0		Immed. Post-Op to Month 3 (RelDay 1-90)		>Mo. 3 to Mo 6 (RelDay 91-180)		>Mo. 6 to Mo.12 (RelDay 181-365)		>Mo. 12 to Mo. 24 (RelDay 365-730)	
	I	C	I	C	I	C	I	C	I	C
Expected Due	215	107	204	101	195	97	189	95	172	89
Operative Site										
Pain; new , + frequency, w orsening	0	0	21	10	13	11	25	7	24	17
Wound problems	2	0	29	10	0	0	0	0	0	0
Fracture	1	0	4	0	3	2	1	1	1	0
Other	0	0	2	2	1	0	2	1	4	0
Device component loosening	0	0	0	0	0	0	1	1	2	2
Device component migration	0	0	2	0	0	1	0	0	1	0
Device component breakage	1	0	0	0	0	1	1	4	0	0
Infection (deep)	0	0	2	0	0	0	0	0	0	0
Hematoma requiring drainage	0	1	0	0	0	0	0	0	0	0
Non-Operative Site										
Musculoskeletal	1	1	61	27	26	27	59	24	72	34
Neurological	0	0	25	7	11	9	16	3	25	11
Other	0	0	12	3	3	2	1	2	14	6
Cardiovascular	1	1	2	4	5	0	8	4	9	3
Gastrointestinal	0	0	3	2	3	2	10	1	4	5
Skin and Subcutaneous Tissue	0	1	4	5	1	1	6	2	4	2
Genitourinary	0	2	4	4	1	1	0	0	5	2
Respiratory	0	0	3	3	2	0	2	1	3	3
Endocrine/Metabolic	0	0	1	0	0	1	0	0	5	1
Cancer/Neoplasm	0	0	1	0	1	0	0	1	2	5
EENT	0	0	0	0	2	0	0	0	2	1
Hematological	0	1	2	1	1	0	0	1	2	2
Immune	0	0	0	0	0	0	0	0	1	0
Psychiatric/Substance abuse	0	0	0	3	1	1	0	0	0	2
Total	6	7	178	81	74	59	132	53	180	96

[1] Selected adverse events are described in more detail in Table 8.

Table 8: Numbers of Specific Device and Surgery Related Complications by Time of Occurrence coflex® (I) and Fusion Control (C) Efficacy Evaluable (PP) Cohort

Type of Adverse Event/Complication	Day of Surgery Relative Day 0		Immed. Post-Op to Mth 3 (Day 1-90)		>Mth 3 to Mth 6 (Day 91-180)		>Mth 6 to Mth 12 (Day 181-365)		>Mth 12 to Mth 24 (Day 365-730)		Overall	
Treatment Group (I = coflex®, C = control)	I	C	I	C	I	C	I	C	I	C	I (%)	C (%)
# Patients at each Follow-Up Interval	215	107	204	101	195	97	189	95	172	89	(N=215)	(N=107)
DEVICE-RELATED ADVERSE EVENTS[1]												
Device migration	0	0	2	0	0	1	0	0	0	0	2 (0.9%)	1 (0.9%)
Device breakage	1	0	0	0	0	1	1	2	0	0	2 (0.9%)	3 (2.8%)
Device loosening	0	0	0	0	0	0	1	1	2	1	3 (1.4%)	2 (1.9%)
Fracture	0	0	3	0	1	0	1	0	0	0	5 (2.3%)	-
SUBTOTAL	1	0	5	0	1	2	3	3	2	1	12 (5.6%)	6 (5.6%)
SURGERY-RELATED ADVERSE EVENTS[1]												
Wound problems	2	0	28	7	0	0	0	0	0	0	30 (14.0%)	7 (6.5%)
Decompression-Related Fracture	0	0	1	0	1	0	0	0	0	0	2 (0.9%)	-
Hematoma requiring drainage	0	1	0	0	0	0	0	0	0	0	-	1 (0.9%)
Infection (deep)	0	0	2	0	0	0	0	0	0	0	2 (0.9%)	-
Pain, Back	0	0	9	7	6	6	14	7	18	11	47 (21.9%)	31 (29.0%)
Pain, Leg/Buttock and Back	0	0	2	0	0	0	1	0	0	0	3 (1.4%)	-
Pain, Leg /Buttock	0	0	2	0	0	0	0	0	0	0	2 (0.9%)	-
Pain, Back & Leg	0	0	5	0	2	4	1	0	4	4	12 (5.6%)	8 (7.5%)
Pain, Back & Buttock	0	0	0	0	0	0	1	0	0	0	1 (0.5%)	-
Pain, Buttock	0	0	1	0	1	0	0	0	0	0	2 (0.9%)	-
Pain, Leg	0	0	3	3	4	1	4	0	2	0	13 (6.0%)	4 (3.7%)
Pain, Hip	0	0	0	1	0	0	0	0	0	0	-	1 (0.9%)
SUBTOTAL	2	1	53	18	14	11	21	7	24	15	114 (53.0%)	52 (48.6%)
TOTAL # of Events	3	1	58	18	15	13	24	10	26	16	126 (58.6%)	58 (54.2%)

Spinous Process Fractures:

Spinous process fractures were observed by the core radiographic laboratory in 30 coflex® patients (14.0%) and 8 fusion patients (11.9% of patients with spinous processes retained by partial laminectomy). Spinous process fractures were also observed by the investigator surgeons. The incidence of fractures observed by the surgeons differed from that observed by the core radiographic laboratory, as 8 coflex® patients (3.7%) and no fusion patients (0.0%) had spinous process fractures noted by the investigational sites. 83% of patients in the coflex® group and 75% of patients in fusion group who had spinous process fractures observed by the radiographic laboratory did not have any associated symptoms at the time the fracture was observed. Table 9 and Table 10 detail the incidence of spinous process fractures in coflex® and fusion patients.

Table 9: Spinous Process Fracture Incidence in coflex® IDE Study

	coflex®		Fusion Control	
	n/N	%	n/N	%
Spinous Process Fracture	30/215	14.0%	8/67[1]	11.9%

[1] Fusion patients with spinous processes retained by partial laminectomy.

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Table 10: Time Course of Spinous Process Fracture Incidence in coflex® IDE Study

Group	Time of Initial Fracture Observation							Total
	Post-op	6 W	3 M	6 M	12 M	18 M	24 M	
coflex®	5	13	6	1	-	-	5[1]	30
Fusion Control	4	2	2	-	-	-	-	8

[1] 3 out of the 5 observations at 24 months had unreadable or missing 6 week, 3 month, 6 month, 12 month, and 18 month X-rays

By month 24, 48% of the coflex® spinous process fractures were resolved. Of the unresolved spinous process fractures, 75% were asymptomatic and resulted in no clinical sequelae or loss of foraminal height during the study. None (0%) of the fusion spinous process fractures were resolved by month 24, and 75% of these patients were asymptomatic.

The adverse event rate associated with spinous process fractures was not significantly higher than the patients without spinous process fractures. The long term effects of these spinous process fractures past 24 months are unknown.

Surgery and Hospitalization Data:

Table 11: Summary of Operative Details Continuous Variables coflex® and Fusion Control Efficacy Evaluable (PP) Cohorts

	coflex®				Fusion Control			
1- and 2-level procedures	**N**	**Mean**	**SD**	**95% CI (LB, UB)**	**N**	**Mean**	**SD**	**95% CI (LB, UB)**
Hospital LOS (days)	215	1.90	1.08	(1.75, 2.04)	107	3.19	1.61	(2.88, 3.50)
Estimated blood loss (cc)	215	109.7	120.0	(93.5, 125.8)	105	348.6	281.8	(294.0, 403.1)
Operative time (minutes)	214	98.0	41.1	(92.5, 103.6)	107	153.2	55.5	(142.5, 163.8)
1-level procedures	**N**	**Mean**	**SD**	**95% CI (LB, UB)**	**N**	**Mean**	**SD**	**95% CI (LB, UB)**
Hospital LOS (days)	138	1.86	1.14	(1.66, 2.05)	68	2.87	1.45	(2.52, 3.22)
Estimated blood loss (cc)	138	98.0	96.3	(81.8, 114.3)	66	290.9	207.0	(240.0, 341.8)
Operative time (minutes)	137	90.8	44.0	(83.4, 98.2)	68	142.0	56.0	(128.4, 155.5)
2-level procedures	**N**	**Mean**	**SD**	**95% CI (LB, UB)**	**N**	**Mean**	**SD**	**95% CI (LB, UB)**
Hospital LOS (days)	77	1.97	0.95	(1.76, 2.19)	39	3.74	1.74	(3.18, 4.31)
Estimated blood loss (cc)	77	130.5	152.1	(95.9, 165.0)	39	446.2	358.4	(330.0, 562.3)
Operative time (minutes)	77	110.9	31.8	(103.7, 118.1)	39	172.7	49.3	(156.7, 188.7)

The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage. Non-overlapping confidence intervals imply statistically reliable device group differences.

Table 11 demonstrates that the average operating time in the fusion patients was 55.2 minutes greater than the coflex® patients. Average blood loss in fusion patients was 238.9 cc greater in the fusion patients than in coflex® patients. The average hospital length of stay was 1.29 days longer in the fusion patients.

Reoperations and Revisions:

Through 24 months of follow up, the overall reoperation rate was 10.7% in the coflex® group and 7.5% in the fusion control. Reoperations where the device was maintained are summarized in Table 12 and revision surgeries are summarized in Table 13.

Table 12: Reoperation Events in the coflex® Clinical Trial

Reoperation Type	Treatment Group	Event Time Course (months)							Total (events)	Reasons
		<1.5	1.5-3	3-6	6-12	12-24	24-36	36-48		
Irrigation and Debridement	coflex®	4	-	-	-	-	-	-	4	2 wound dehiscence, 2 deep infections
Supplemental Decompression	coflex®	-	-	-	1	1	1	1	4	3 leg and/or low back pain, 1 herniation
CSF Repair	coflex®	1	-	-	-	-	-	-	1	1 CSF leak
Non-Index Lumbar Fusion	coflex®	-	-	-	-	-	1	1	2	2 leg and/or low back pain
Hematoma Drainage	Fusion	1	-	-	-	-	-	-	1	1 wound hematoma
Irrigation and Debridement	Fusion	-	-	-	-	-	2	-	2	2 deep infections[1]
Supplemental Decompression	Fusion	-	-	-	-	-	1	1	2	1 synovial cyst, 1 herniation

[1] A single fusion patient had 2 operations for deep infection

Table 13: Revision Events in the coflex® Clinical Trial

Revision Type	Treatment Group	Event Time Course (months)							Total (events)	Reasons
		<1.5	1.5-3	3-6	6-12	12-24	24-36	36-48		
Device replacement (with coflex®)	coflex®	-	2	-	-	-	-	-	2	1 bone-related fracture, 1 seroma
Decompression and Device Removal	coflex®	-	-	-	1	1	-	-	2	2 leg and/or low back pain
Transition to fusion	coflex®	-	-	2	4	7	6	3	22	14 leg and/or low back pain[2], 4 bone-related fracture, 2 component loosening, 1 herniation, 1 synovial cyst
Debridement and Device Removal	coflex®	1	-	-	-	-	-	-	1	1 deep infection[2]
Device Removal	Fusion	-	-	-	-	-	-	2	2	1 component loosening, 1 back and/or leg pain
Device replacement	Fusion	-	-	-	1	3	-	1	5	2 broken pedicle screws[1], 3 component loosening
Adjacent level extension	Fusion		1	1	1	2	3	2	10	7 back and/or leg pain, 2 pseudoarthrosis, 1 bone-related fracture

[1] A single fusion patient had 2 revisions for broken pedicle screws
[2] Three coflex® patients had a transition to fusion after a previous reoperation or replacement of coflex®.

Through 24 months, the reoperations and revisions in the coflex® group included 5 irrigation and debridement procedures (including 1 cerebrospinal fluid leak), 2 supplemental decompression surgeries retaining the device, 2 revisions for coflex® removal & replacement, 2 decompressions and device removal, 1 debridement and device removal, and 13 (6.0%, 13/215) conversions to primary fusion. Two patients had a reoperation prior to a revision. There were no revisions related to device breakage.

Through 24 months, the reoperations and revisions in the fusion control group included 1 reoperation due to post-operative hematoma, 4 revisions of the fusion system due to device breakage or component loosening, and 5 extensions of the fusion to an adjacent level.

Between 24 months and 48 months of follow up, there were 13 additional reoperations or revisions in 12 coflex® patients (6.3% (12/192)) and 12 additional reoperations or revisions in 10 fusion patients (10.1% (10/99)). One of each of the coflex® and fusion revisions was in a patient who had a reoperation prior to 2 years. Based on available patient data through 48 months, the coflex® revision rate is 15.8% and the fusion control revision rate is 15.9%.

2. Effectiveness Results

Primary Effectiveness Analysis:

The analysis of effectiveness was based on the per protocol cohort of 322 patients (215 coflex® patients and 107 fusion patients) evaluable at the 24-month time point. Key effectiveness outcomes are presented in Table 14 through Table 29.

Table 14: Posterior Probabilities of Success at 24 Months in coflex® Clinical Trial

	Number and Percentage Achieving Month 24 CCS*						Posterior Probability of Non-Inferiority
	coflex®			Fusion Control			
	N	n	%	N	n	%	
Month 24	204	135	66.2%	104	60	57.7%	0.999

*Composite Clinical Success

Non-inferiority of the coflex® group compared to the control group was demonstrated for the Composite Clinical Success (CCS) at 24 months.

Table 15: Posterior Means and 95% Credible Intervals for Month 24 CCS

	Mean[1]	SD	95% Bayesian Credible Interval
coflex®	66.2%	3.3%	59.5% to 72.4%
fusion	57.7%	4.8%	48.1% to 66.9%
difference	8.5%	5.8%	-2.9% to 20.0%

[1] Mean, SD, and 95% Bayesian Credible Interval computed as the mean, standard deviation, 2.5th percentile, and 97.5th percentile of 10,000 draws from the posterior distributions

The Bayesian posterior means, standard deviations, and 95% credible intervals were determined from 10,000 draws from the posterior distributions based on the final per protocol population. The credible intervals are defined so that there is a 0.95 probability that the true success likelihoods are contained within the interval. The estimated difference is 8.5%. The lower bound of Bayesian posterior credible interval for the device group difference in success rates is equal to -2.9%, which is larger than the pre-specified non-inferiority margin of -10%.

The Statistical Analysis Plan specified that primary non-inferiority evaluation would be performed in a per protocol population. All protocol violations (PV) were confirmed by an Independent Clinical Events Committee. Among the 230 randomized patients receiving coflex®, 15 (6.5%) had a protocol violation leading to exclusion. Similarly, among the 114 randomized patients undergoing fusion, 7 (6.1%) had a protocol violation leading to exclusion. The primary efficacy variable was evaluable for all 22 PVs in this study. Among 15 coflex® PVs, 6 (40.0%) met the study success criterion. Similarly, among 7 fusion PVs, 3 (42.9%) met the study success criterion. The clinical results for the PVs were pooled with the per protocol population to construct a modified Intent-to-Treat (mITT) population defined as all randomized patients receiving a study procedure. The Bayesian posterior probability that coflex® is clinically non-inferior to fusion is 0.999, essentially the same as in the primary per protocol population.

Table 16: Posterior Probabilities of Success at 24 Months in coflex® Clinical Trial (mITT Cohort)

	Number and Percentage Achieving Month 24 CCS						Posterior Probability of Non-Inferiority
	coflex®			Fusion Control			
	N	n	%	N	n	%	
Month 24	219	141	64.4%	111	63	56.8%	0.999

Non-inferiority of the coflex® group compared to the control group was demonstrated for the CCS at 24 months in the mITT cohort.

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Table 17: Posterior Means and 95% Credible Intervals for Month 24 CCS (mITT Cohort)

	Mean[1]	SD	95% Bayesian Credible Interval
coflex®	64.4%	3.2%	57.9% to 70.5%
fusion	56.8%	4.7%	47.4% to 65.7%
difference	7.6%	5.6%	-3.4% to 18.9%

[1] Mean, SD, and 95% Bayesian Credible Interval computed as the mean, standard deviation, 2.5th percentile, and 97.5th percentile of 10,000 draws from the posterior distributions

For the per protocol population, Table 18 demonstrates the time course of success in the coflex® clinical trial.

Table 18: Time Course of Composite Clinical Success[1] in coflex® Clinical Trial

	Number and Percentage Meeting Criteria with 95% CI[2]							
	coflex®				Fusion Control			
	N	n	%	95% CI (LB, UB)	N	n	%	95% CI (LB, UB)
Week 6	210	172	81.9%	(76.7%, 87.1%)	105	69	65.7%	(56.6%, 74.8%)
Month 3	207	171	82.6%	(77.4%, 87.8%)	102	72	70.6%	(61.7%, 79.4%)
Month 6	207	162	78.3%	(72.6%, 83.9%)	105	81	77.1%	(69.1%, 85.2%)
Month 12	202	151	74.8%	(68.8%, 80.7%)	104	74	71.2%	(62.4%, 79.9%)
Month 18	198	135	68.2%	(61.7%, 74.7%)	100	68	68.0%	(58.9%, 77.1%)
Month 24	204	135	66.2%	(59.7%, 72.7%)	104	60	57.7%	(48.2%, 67.2%)

Notes:
[1] The composite clinical success criteria at times points prior to Month 24 did not include the 'no persistent new or worsening sensory or motor deficit' since 'persistence' was established by identifying new or worsening deficits at Month 18 that did not resolve by Month 24; otherwise the CCS criteria at earlier time points were consistent with the primary Month 24 CCS.
[2]The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage. Non-overlapping confidence intervals imply statistically reliable device group differences.

Table 18 demonstrates the CCS at each timepoint. The CCS at 24 months is determined by the ODI improvement compared to baseline, absence of secondary surgeries or epidural pain management and neurologic success. It should be noted that neurologic success endpoint is based on comparing changes from baseline to both Month 18 and Month 24, and thus is not definable prior to the 24 month timepoint. ODI measurements and success may fluctuate over time, while discrete events endpoints such as secondary surgeries and epidural injections were assessed as time to event variables.

Patients in the coflex® group demonstrated a 81.9% CCS at 6 weeks which increased to 82.6% at 3 months and gradually fell to 66.2% at 24 months. Patients in the control group demonstrated 65.7% CCS at 6 weeks which rose gradually from 6 Weeks to 6 Months to 77.1%. CCS fell to 57.7% at 24 months. At every assessment time period, the percentage of coflex® patients achieving CCS was greater than fusion, with the largest differences occurring at week 6 and month 3, demonstrating statistical significance at those time points. The final CCS at 24 months demonstrates numerical success that is 8.5% higher in the coflex® group when compared to the fusion control.

Table 19: Treatment Success at 24 Month Follow-Up in coflex® Clinical Trial

	Number and Percentage Meeting Criteria					
	coflex®			Fusion Control		
	N	n	%	N	n	%
Improvement of at least 15 points in ODI at Month 24 compared to baseline	**162**	**139**	**85.8**	**86**	**66**	**76.7**
No reop or epidural (Up to Day 730)	**215**	**173**	**80.5**	**107**	**89**	**83.2**
No reoperations, revisions, removals, or supplemental fixation	215	192	89.3	107	99	92.5
No epidural injection at any lumbar level	215	190	88.4	107	94	87.9
No persistent new or increasing sensory or motor deficit at 24 months	**179**	**169**	**94.4**	**97**	**89**	**91.8**
No persistent new or increasing sensory deficit at 24 mo.	199	191	96.0	99	96	97.0
No persistent new or increasing motor deficit at 24 mo.	180	177	98.3	97	91	93.8
No major device-related complications	215	212	98.6	107	103	96.3
Composite Clinical Success	**204**	**135**	**66.2**	**104**	**60**	**57.7**

With regard to the functional parameter of the CCS, the coflex® device group demonstrated a greater proportion of patients with a clinically significant improvement in ODI score compared to the fusion control. In the neurological and device related complications components of the primary endpoint, the coflex® group demonstrated similar or higher patient success percentages compared to the fusion control. Success in the reoperations and revisions component of the primary endpoint is higher in the fusion control group than in the coflex® group. This difference was not statistically significant.

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Sensitivity Analysis:

Table 20: Posterior Probabilities of Success at 24 Months in coflex® Clinical Trial

	Number and Percentage Achieving Month 24 CCS						Posterior Probability of Non-Inferiority
	coflex®			Fusion Control			
	N	n	%	N	n	%	
Per Protocol Analysis	204	135	**66.2%**	104	60	**57.7%**	**0.999**
Unresolved Spinous Process Fractures as Failures[1]	204	119	58.3%	104	56	53.8%	0.993

[1] Unresolved Spinous Process fractures counted as failures regardless of clinical significance. 83% of patients in the coflex® group and 75% of patients in fusion group who had spinous process fractures observed by the radiographic laboratory did not have any associated symptoms at the time the fracture was observed.

In sensitivity analyses, the 24 Month Composite Clinical Success endpoint was modified to include as failures patients with an unresolved spinous process fracture at 24 months. Review of the spinous process fractures and the resolution of these fractures were performed by an independent radiographic core laboratory for the purpose of this analysis. With this modification in the success definition, the Composite Clinical Success rate decreased from 66% (135 of 204) to 58% (119 of 204) in the coflex® group and from 58% (60 of 104) to 54% (56 of 104) in the fusion group, and the Bayesian posterior probability changed from 0.999 to 0.993, still meeting the a priori defined criterion for success. Therefore, including unresolved spinous process fractures in the failure definition had no appreciable impact on the comparison between the devices.

A tipping point analysis was also performed to determine the effect on the primary endpoint of missing Month 24 data. Results of the tipping point analysis demonstrated that the finding of non-inferiority was insensitive to missing data at Month 24.

Poolability Analysis:

Analyses were conducted to assess poolability of data across sites and between patients with 1 versus 2 level implants. There was no statistical evidence of site-to-site differences in the comparisons between coflex® and fusion. Similarly, patients receiving 2 level implants had clinical outcomes that were generally comparable to those receiving a 1 level implant.

Secondary Effectiveness Analysis:

In addition to the components of the primary endpoint presented above, secondary effectiveness variables were also assessed and the results are provided below. The following secondary endpoints were specified:

- ZCQ Symptom Severity
- ZCQ Physical Function
- ZCQ Composite Success
- VAS Leg Pain
- VAS Back Pain
- SF-12

ZCQ Symptom Severity

Table 21: ZCQ Symptom Severity at 24 Month Follow-Up in coflex® Clinical Trial

	Number and Percentage Meeting Criteria with 95% CI[1]							
	coflex®				Fusion Control			
	N	n	%	95% CI (LB, UB)	N	n	%	95% CI (LB, UB)
ZCQ Symptom Severity Improvement >0.5 points	161	142	88.2%	(83.2%, 93.2%)	86	67	77.9%	(69.1%, 86.7%)

[1]The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage. Non-overlapping confidence intervals imply statistically reliable device group differences.

Table 21 shows the subjects achieving success, defined as a decrease in ZCQ Symptom Severity of at least 0.5 points, in the Per Protocol cohort. Month 24 data demonstrates a higher percentage of coflex® patients meeting the success threshold compared to the fusion control (88.2% vs. 77.9%).

ZCQ Physical Function

Table 22: ZCQ Physical Function at 24 Month Follow-Up in coflex® Clinical Trial

	Number and Percentage Meeting Criteria with 95% CI[1]							
	coflex®				Fusion Control			
	N	n	%	95% CI (LB, UB)	N	n	%	95% CI (LB, UB)
Month 24	161	138	85.7%	(80.3%, 91.1%)	86	63	73.3%	(63.9%, 82.6%)

[1]The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage. Non-overlapping confidence intervals imply statistically reliable device group differences.

Table 22 shows the subjects achieving success, defined as a decrease in ZCQ Physical Function of at least 0.5 points, in the Per Protocol cohort. Month 24 data demonstrates a higher percentage of coflex® patients meeting the success threshold compared to fusion (85.7 vs. 73.3%).

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ZCQ Composite Success

Table 23: ZCQ Composite Success at 24 Month Follow-Up in coflex® Clinical Trial

	Number and Percentage Meeting Criteria with 95% CI[1]							
	coflex®				Fusion Control			
	N	n	%	95% CI (LB, UB)	N	n	%	95% CI (LB, UB)
ZCQ Physical Function Improvement >0.5 points	161	138	85.7%	(80.3%, 91.1%)	86	63	73.3%	(63.9%, 82.6%)

[1]The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage. Non-overlapping confidence intervals imply statistically reliable device group differences.

Table 23 shows the subjects achieving a Composite ZCQ Success in the Per Protocol cohort, defined as a decrease in ZCQ Physical Function of at least 0.5 points, a decrease in ZCQ Symptom Severity of at least 0.5 points, and ZCQ Satisfaction score >2.5. Month 24 data demonstrates a higher percentage of coflex® patients meeting the success threshold compared to the fusion control (78.3% vs. 67.4%).

VAS Leg Pain

Table 24: VAS Leg Pain Success at 24 Month Follow-Up in coflex® Clinical Trial

	Number and Percentage Meeting Criteria with 95% CI[1]							
	coflex®				Fusion Control			
	N	n	%	95% CI (LB, UB)	N	n	%	95% CI (LB, UB)
Decrease of at least 20 mm VAS leg Pain (Max)	162	134	82.7%	(76.9%, 88.5%)	85	67	78.8%	(70.1%, 87.5%)

[1]The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage. Non-overlapping confidence intervals imply statistically reliable device group differences.

Table 24 shows the subjects achieving success, defined as a decrease in VAS Leg Pain of at least 20mm in the Per Protocol cohort. Month 24 data demonstrates a higher percentage of coflex® patients meeting the success threshold compared to the fusion control (82.7% vs. 78.8%).

VAS Back Pain

Table 25: VAS Back Pain at 24 Month Follow-Up in coflex® Clinical Trial

	Number and Percentage Meeting Criteria with 95% CI[1]							
	coflex®				Fusion Control			
	N	n	%	95% CI (LB, UB)	N	n	%	95% CI (LB, UB)
Decrease of at least 20 mm VAS Back Pain	162	143	88.3%	(83.3%, 93.2%)	85	68	80.0%	(71.5%, 88.5%)

[1]The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage. Non-overlapping confidence intervals imply statistically reliable device group differences.

Table 25 shows the subjects achieving success, defined as a decrease in VAS Back Pain of at least 20mm, in the Per Protocol cohort. Month 24 data demonstrates a higher percentage of coflex® patients meeting the success threshold compared to the fusion control (88.3% vs. 80.0%).

SF-12

Table 26: SF-12 Success at 24 Month Follow-Up in coflex® Clinical Trial

	Number and Percentage Meeting Criteria with 95% CI[1]							
	coflex®				Fusion Control			
	N	n	%	95% CI (LB, UB)	N	n	%	95% CI (LB, UB)
Maintenance or improvement in SF-12 MCS	132	92	69.7%	(61.9%, 77.5%)	70	48	68.6%	(57.7%, 79.4%)
Maintenance or improvement in SF-12 PCS	132	121	91.7%	(87.0%, 96.4%)	70	58	82.9%	(74.0%, 91.7%)

[1]The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage

Table 26 shows the percentages of subjects meeting success, defined as maintaining or improving in the SF-12 Physical Function and Mental Health components of the per protocol cohort. The percentage of patients meeting SF-12 Physical Function success criterion is higher for coflex® at month 24 compared to the fusion control (91.7% vs. 82.9%).

Radiographic Assessments

Maintenance or improvement of foraminal height was a radiographic endpoint in the study. This is a measure of the mechanism of action of the coflex® device which is to maintain foraminal height. coflex® was able to improve or maintain foraminal height in 100% of patients measured at 24 months. This measurement was taken only on the coflex® patients.

Range of motion at the index level was measured at 24 months. The average range of motion was 4.5° in the coflex® group and less than 2° in the control. The analysis of the mean range of motion at the index and adjacent levels demonstrates that motion was maintained in the coflex® patients.

Translational motion as a measure of instability was assessed at 24 months in both coflex® and fusion patients. At the index level, the sagittal plane translation is reduced with fusion. The coflex® group maintained a similar sagittal plane translation from pre-op to 24 months. (see Table 27 and Table 28 for radiographic results).

The control group received the current standard of care, posterolateral fusion with pedicle screws. The radiographic endpoint in this group, the presence of fusion, was compared to the absence of bridging trabecular bone in the coflex® group. No coflex® patients had bridging bone at 24 months. 67.3% of control patients had radiographic fusion at 24 months. There were 32.7% of control patients who were not fused at 24 months and 20.2% of control patients had screw loosening; however, many of these patients were asymptomatic.

The device condition through 24 months demonstrated 1 device wing fracture of coflex®; and 3 device breakages and 21 patients with loose screws in the control patients.

As discussed above, during the study a number of spinous process fractures were observed in the coflex® patients by the independent radiologists which were asymptomatic at the timepoint and not observed by the investigator surgeons.

Table 27: Range of Motion Results in coflex® IDE Study (°, Flexion to Extension)

	Number and Percentage Meeting Criteria with 95% CI[1]							
	coflex®				Fusion Control			
	At Level(s) of Implant (per level)							
	N	Mean	SD	95% CI (LB, UB)	N	Mean	SD	95% CI (LB, UB)
Pre-Op	281	4.55	3.86	(4.10, 5.01)	145	4.15	3.33	(3.61, 4.70)
Month 24	254	4.17	3.90	(3.69, 4.65)	140	1.59	1.97	(1.26, 1.92)

	Above Level of Implant (per patient)							
	N	Mean	SD	95% CI (LB, UB)	N	Mean	SD	95% CI (LB, UB)
Pre-Op	207	4.17	3.49	(3.69, 4.65)	104	3.68	2.99	(3.10, 4.26)
Month 24	186	4.08	3.57	(3.56, 4.59)	102	5.60	4.62	(4.70, 6.51)

	Below Level of Implant (per patient)							
	N	Mean	SD	95% CI (LB, UB)	N	Mean	SD	95% CI (LB, UB)
Pre-Op	195	5.81	4.14	(5.22, 6.39)	101	5.65	3.84	(4.89, 6.41)
Month 24	176	6.53	4.66	(5.84, 7.22)	96	6.95	4.42	(6.05, 7.84)

[1]The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage. Non-overlapping confidence intervals imply statistically reliable device group differences.

Table 28: Translation Results in coflex® IDE Study (mm, Flexion to Extension)

	Number and Percentage Meeting Criteria with 95% CI[1]							
	coflex®				Fusion Control			
	At Level(s) of Implant (per level)							
	N	Mean	SD	95% CI (LB, UB)	N	Mean	SD	95% CI (LB, UB)
Pre-Op	274	0.97	0.88	(0.86, 1.07)	134	0.97	0.85	(0.83, 1.12)
Month 24	251	0.93	0.89	(0.82, 1.04)	130	0.39	0.50	(0.30, 0.48)

	Above Level of Implant (per patient)							
	N	Mean	SD	95% CI (LB, UB)	N	Mean	SD	95% CI (LB, UB)
Pre-Op	202	0.87	0.74	(0.77, 0.97)	96	0.77	0.76	(0.62, 0.92)
Month 24	184	0.89	0.82	(0.77, 1.01)	95	1.08	0.94	(0.89, 1.27)

	Below Level of Implant (per patient)							
	N	Mean	SD	95% CI (LB, UB)	N	Mean	SD	95% CI (LB, UB)
Pre-Op	190	0.56	0.53	(0.48, 0.63)	93	0.55	0.46	(0.45, 0.64)
Month 24	174	0.65	0.57	(0.56, 0.73)	89	0.80	0.85	(0.62, 0.98)

[1]The 95% confidence interval is provided as a measure of the statistical precision of the estimated treatment group mean or percentage. Non-overlapping confidence intervals imply statistically reliable device group differences.

Table 27 and Table 28 reflect the radiographic Range of Motion and Translation analyses by the core radiographic laboratory, and they demonstrate coflex® preserves index and adjacent level motion compared to pedicle screw fusion.

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3. Subgroup Analyses

Preoperative characteristics were evaluated for potential association with overall success outcomes, as demonstrated in Table 29.

Table 29: Composite Clinical Success at 24 Month Follow-Up in coflex® Clinical Trial by Preoperative Characteristics

	Number and Percentage Achieving Month 24 CCS					
	coflex®			Fusion Control		
	N	n	%	N	n	%
Central stenosis (CS) alone	18	13	72.2%	4	2	50.0%
CS + foraminal stenosis	57	38	66.7%	21	14	66.7%
CS + subarticular stenosis	32	21	65.6%	22	11	50.0%
CS + formaminal + subarticular	97	63	64.9%	57	33	57.9%
Levels Treated: One	130	83	63.8%	65	38	58.5%
Levels Treated: Two	74	52	70.3%	39	22	56.4%
Males	104	69	66.3%	48	31	64.6%
Females	100	66	66.0%	56	29	51.8%
Age 40 to 60	90	54	60.0%	39	22	56.4%
Age > 60	114	81	71.1%	65	38	58.5%
Height < 67 inches	90	61	67.8%	57	29	50.9%
Height >= 67 inches	114	74	64.9%	47	31	66.0%
Weight < 191	109	75	68.8%	61	34	55.7%
Weight >= 191	95	60	63.2%	43	26	60.5%
BMI < 29	95	62	65.3%	42	22	52.4%
BMI >= 29	109	73	67.0%	62	38	61.3%
Prior Surgery	202	134	66.3%	102	58	56.9%
No prior surgery	2	1	50.0%	2	2	100.0%
Smoker	22	13	59.1%	14	6	42.9%
Non Smoker	182	122	67.0%	90	54	60.0%
Spondylolisthesis-Grade I	94	59	62.8%	48	30	62.5%
None	110	76	69.1%	56	30	53.6%
Any severe complication	70	33	47.1%	46	19	41.3%
No severe complication	134	102	76.1%	58	41	70.7%

There were 40 non-randomized roll-in patients enrolled in the coflex® study, consisting of first one or two patients treated at each site. Of these 40 patients, 6 patients were designated as protocol violators by the independent Clinical Events Committee. Thirty-two (32, 94.1%) per protocol patients had Composite Clinical Success data at 24 Months. The per protocol roll-in patient cohort achieved a 56.3% Composite Clinical Success at Month 24.

Overall Conclusions:

Among 204 coflex® patients, 135 (66.2%) achieved Month 24 CCS, while among 104 fusion patients, 60 (57.7%) achieved Month 24 CCS. Statistical analysis demonstrated that coflex® was non-inferior to fusion with a posterior probability of 0.999, which is greater than the success criterion of 0.975.

The preclinical and clinical data in this application support the reasonable assurance of safety and effectiveness of the coflex® device when used in accordance with the Indications for Use. Based on the clinical study results, it is reasonable to conclude that a significant portion of the indicated patient population will achieve clinically significant results. The clinical benefits of the use of the coflex® device in terms of functional improvement, reduction in pain and maintenance or improvement in neurological status outweigh the risks associated with the device and surgical procedure through 2 years follow-up when used in the indicated population and in accordance with the directions for use. In conclusion, the coflex® device represents a reasonable alternative to posterolateral fusion for the treatment of spinal stenosis.

STERILIZATION, STORAGE, AND INSPECTION

The implant is sterilized with gamma sterilization (25 kGy minimum).
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 out packaging, including seals, should be thoroughly inspected prior to implantation.

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.

3.0T RF heating

In non-clinical testing with body coil excitation, the coflex® Interlaminar Technology produced a temperature rise of less than 3.5ºC at a maximum whole body averaged specific absorption rate (SAR) of 2.0 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.

1.5T RF heating

In non-clinical testing with body coil excitation, the coflex® Interlaminar Technology produced a temperature rise of less than 3.5ºC at a maximum whole body averaged specific absorption rate (SAR) of 2.0 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.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

In testing using a 3.0T system with spin-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 19 mm from the implant.

DISINFECTION/CLEANING

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

For instrument cleaning instructions, please refer to the coflex® Sterilization Tray Instructions for Use.

RESTERILIZATION

The implant is not intended for reuse. Resterilization of the implant is not permitted.

For instrument sterilization instructions, please refer to the coflex® Sterilization Tray Instructions for Use.

PROCEDURE

The coflex® implant must be implanted only with the applicable coflex® instrumentation. The coflex® instrumentation is available from the manufacturer at any time. A surgical technique is available to instruct the user on proper implantation techniques. The user must be familiar with the recommended surgical technique prior to implanting a coflex® device. Please consult the surgical technique for further information on the coflex® implantation procedure.

POSTOPERATIVE CONSIDERATIONS

As with other spinal implants, Paradigm Spine recommends using post-operative antibiotics with the coflex® device. Lumbar drains are recommended at the discretion of the treating surgeon.

IMPLANT REMOVAL

The coflex® implant is intended for permanent implantation and is not intended for removal. Please refer to the explant protocol for instructions when device explant is necessary.

FOR FURTHER INFORMATION

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

US Contact	Manufacturer
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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

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