Instructions for Use
MOBI-C® CERVICAL DISC PROSTHESIS

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CAUTION: Federal (United States) law restricts this device to sale by or on the order of a Physician.

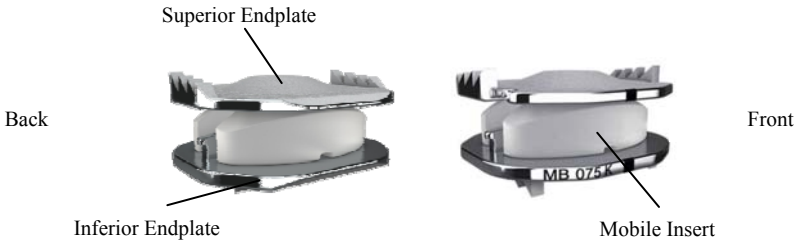
HOW SUPPLIED

Mobi-C® Cervical Disc Implants – Sterile
Surgical Instruments – Non-sterile (unless otherwise noted on the package label)

DEVICE DESCRIPTION

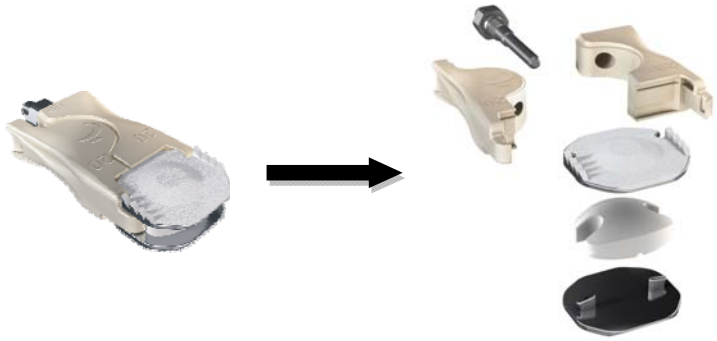
The Mobi-C® Cervical Disc Prosthesis (Mobi-C®) is a single use device for cervical intervertebral disc replacement at one level from C3 to C7 in order to maintain/restore segmental motion and disc height. The components of the Mobi-C® include a cobalt, chromium, molybdenum (CoCrMo per ISO 5832-12) alloy superior spinal plate, an inferior CoCrMo spinal plate, and an ultra high molecular weight polyethylene (UHMWPE per ISO 5834-2) mobile insert. The inner contact surfaces of the superior and inferior spinal plates are spherical and flat, respectively. This allows for fully congruent contact surfaces between the spinal plates and mobile insert. The two lateral stops of the inferior plate control and limit the mobility of the mobile insert. The spinal plates, both superior and inferior, feature two rows of teeth to allow for initial and long term fixation and stability. The teeth sink into the bone to facilitate endplate fixation and do not require any bone removal or chiseling prior to insertion. The Mobi-C has a bone sparing design and technique. A titanium (per ASTM F1580) and hydroxyapatite (per ISO 13779) plasma spray coating is applied to the bony interface surfaces of the superior and inferior spinal plates. The Mobi-C® is illustrated in **Figure 1.**

Figure 1. Mobi-C® Cervical Disc Prosthesis



The implants are provided in a pre-assembled configuration with a disposable holder. The disposable holder is made of two 'jaws' of Polyetheretherketone (PEEK) with a stainless steel pin:

Figure 2. Mobi-C® Cervical Disc Prosthesis Packaging Assembly



Mobi-C® implants are provided in a variety of configurations, included in **Table 1.**

Table 1. Mobi-C® Cervical Disc Implant Sizes

Depth x Width (mm)	**Inferior/Superior Plate & Mobile Insert Size Combinations**							**Height (mm)**
Endplates	13 x 15	14 x 15	15 x 15	13 x 17	14 x 17	15 x 17	15 x 19	H5 H6 H7
Mobile Insert	11 x 12	11 x 12	11 x 12	11 x 12	11 x 12	13 x 14	13 x 14	
Product Scope								

Part Number	Footprint (mm)	Height (mm)
MB 3355	13×15	H5
MB 3356	13×15	H6
MB 3357	13×15	H7
MB 3455	14×15	H5
MB 3456	14×15	H6
MB 3457	14×15	H7
MB 3555	15×15	H5
MB 3556	15×15	H6
MB 3557	15×15	H7
MB 3375	13×17	H5
MB 3376	13×17	H6
MB 3377	13×17	H7
MB 3475	14×17	H5
MB 3476	14×17	H6
MB 3477	14×17	H7
MB 3575	15×17	H5
MB 3576	15×17	H6
MB 3577	15×17	H7
MB 3595	15×19	H5
MB 3596	15×19	H6
MB 3597	15×19	H7

The superior and inferior spinal plates and the mobile inserts feature a lordosis angle of 0°.

All Mobi-C® components are sterilized using gamma radiation. The implantable device (pre-assembled with the disposable holder) is provided sterile in a double peel pouch dual sterile barrier configuration to allow for easy transfer to the sterile field. Each implantable device is identified with a unique lot number.

Specialized instrumentation has been designed for implantation of the Mobi-C® Cervical Disc Prosthesis. The instruments are provided non-sterile in an instrument box (i.e. tray) and must be sterilized before use. Information regarding the use of the instrumentation before, during, and after Mobi-C® surgery is provided in the ***Mobi-C® Surgical Technique Manual*** and the ***Mobi-C® Instrument System Instructions for Use***. Users are advised to read and understand the surgical technique manual and instructions for use prior to surgery.

INDICATIONS FOR USE
The Mobi-C® Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height compared to adjacent levels. The Mobi-C® Cervical Disc Prosthesis is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C® Cervical Disc Prosthesis.

CONTRAINDICATIONS
The Mobi-C® Cervical Disc Prosthesis should not be implanted in patients with the following conditions:

- Acute or chronic infection, systemic or at the operative site;
- Known allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, titanium, hydroxyapatite, or polyethylene);
- Compromised vertebral bodies at the index level due to previous trauma to the cervical spine or to significant cervical anatomical deformity or disease (e.g., ankylosing spondylitis, rheumatoid arthritis);
- Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5mm, and/or > 11° angular difference to that of either adjacent level;
- Osteoporosis or osteopenia defined as DEXA bone mineral density T-score < -1.5;
- Severe facet joint disease or degeneration.

WARNINGS
The Mobi-C® Cervical Disc should only be used by surgeons who are experienced with anterior cervical spinal procedures and have undergone hands-on training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the Mobi-C® Cervical Disc should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.

Correct selection of the appropriate implant size is extremely important to assure the placement and function of the device. Information regarding proper implant size selection, implant site preparation, and the use of the instrumentation before, during, and after Mobi-C® surgery is provided in the *Mobi-C® Surgical Technique Manual* and the *Mobi-C® Instrument System Instructions for Use*. Users are advised to read and understand the surgical technique manual and instructions for use prior to surgery.

Due to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of the device. Care must be taken to identify and protect these structures.

Heterotopic Ossification (HO) is a potential complication associated with artificial cervical discs and could lead to reduced cervical motion. However, the presence of HO has not been correlated with adverse clinical outcomes involving the Mobi-C® Cervical Disc Prosthesis in the G050212 clinical trial.

PRECAUTIONS

The safety and effectiveness of this device has not been established in patients with the following conditions:

- Skeletally immature patients, pediatric or adolescent children (<21 years old), or those over the age of 67;
- Prior cervical spine surgery, including prior surgery at the index level;
- More than one diseased or immobile cervical spine level requiring surgical intervention;
- Disc height less than 3mm measured from the center of the disc in a neutral position and disc height less than 20% of the anterior-posterior width of the inferior vertebral body;
- Significant kyphotic deformity or significant reversal of lordosis;
- Active malignancy;
- Paget's disease, osteomalacia, or other metabolic bone disease;
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g. steroids);
- Pregnancy;
- Diabetes mellitus requiring daily insulin management;
- Clinical extreme obesity (class III) as defined by the NIH Clinical Guidelines Body Mass Index (i.e. BMI >40);
- Neck or arm pain of unknown etiology;
- Systemic disease including AIDS, HIV, and Hepatitis;
- Intractable radiculopathy or myelopathy due to pathology at more than one level and/or pathology not localized to the level of the disc space;
- Prior fusion at an adjacent vertebral level;
- Neck pain alone;
- Rheumatoid arthritis or other autoimmune disease;
- Neuromuscular disorders such as muscular dystrophy, spinal muscular atrophy, or amyotrophic lateral sclerosis;
- Acute mental illness or substance abuse.

Pre-operative

Patient selection is extremely important. In selecting patients for total disc replacement, the following factors can be of importance to the success of the procedure: the patient's occupation or activity level, prior injury or other ongoing illness, alcoholism, or drug abuse; and certain degenerative diseases (e.g., degenerative scoliosis or ankylosing spondylitis) that may be so advanced at the time of implantation that the expected useful life of the device is substantially decreased.

In order to minimize the risk of periprosthetic vertebral fractures, surgeons must consider all co-morbidities, past and present medications, previous treatments, etc. A screening questionnaire for osteopenia or osteoporosis, SCORE (Simple Calculated Osteoporosis Risk Estimation), may be used to screen patients to determine if a DEXA bone mineral density measurement is necessary. If DEXA is performed, the patient should be excluded from receiving the device if the DEXA bone density measured T score is < -1.5, as the patient may be osteoporotic or osteopenic.

The patient should be informed of the potential adverse effects (risks/complications) contained in the insert (see ADVERSE EVENTS).

Preoperative planning may be used to estimate the required implant size and to assure that the appropriate range of sizes is available for surgery. The procedure should not take place if the appropriate range of sizes will not be available.

Examine all instruments prior to surgery for wear or damage. Instruments which have been used excessively may be more likely to break. Replace any worn or damaged instruments

Intra-operative

Use aseptic technique when removing the Mobi-C® from the innermost packaging. Carefully inspect each component and its packaging for any signs of damage, including damage to the sterile barrier. Do not use Mobi-C® implants if the packaging is damaged or the implant shows signs of damage.

Use care when handling the Mobi-C® to ensure that it does not come in contact with objects that could damage the implant. Damaged implants are no longer functionally reliable. Visual inspection of the prosthesis assembly is recommended prior to implanting the device. If any part of the assembly appears damaged or not fully assembled, do not use.

To prevent unnecessary damage to the bearing surfaces, ensure that tissue or other debris is not trapped within the device.

The Mobi-C® should not be used with components or instruments of spinal systems from other manufacturers. See the surgical technique for step by step instructions.

Surgical implants must never be re-used or re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

Perform a complete discectomy of the disc space between the unci and up to the posterior ligament. Take care to release the foramen bilaterally. It is important to remove all anterior and posterior osteophytes on the superior and inferior vertebral endplates. Liberally cover bleeding with bone wax. To prevent weakening of the endplates, use of a burr is discouraged during endplate preparation. Use the Caspar Retractor as needed to maintain or modify distraction. Ensure proper alignment and placement of device components as misalignment may cause excessive wear and/or early failure of the device.

Post-operative
Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device including the avoidance of heavy lifting, repetitive bending, and prolonged or strenuous activity initially and for a period of weeks to months depending on the individual patient's progress and the stability and functioning of the implant.

Note to Physician: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the Mobi-C® Cervical Disc Prosthesis is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 970 Gauss/cm (9.7 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Mobi-C® Cervical Disc Prosthesis is expected to produce a maximum temperature rise of less than 3 ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 29 mm from the Mobi-C® Cervical Disc Prosthesis when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH
Below is a list of the potential adverse effects (e.g., complications) identified from the Mobi-C® Cervical Disc Prosthesis clinical study results, approved device labeling for other cervical total disc replacement devices, and published scientific literature including: (1) those associated with any surgical procedure; (2) those associated with anterior cervical spine surgery; and (3) those associated with a cervical artificial disc device, including the Mobi-C® Cervical Disc Prosthesis. 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: abscess; cellulitis; wound dehiscence; wound, local, and/or systemic infection; wound necrosis; edema; hematoma; heart and vascular complications; hypertension; thrombosis; ischemia; embolism; thromboembolism; hemorrhage; thrombophlebitis; adverse reactions to anesthesia; pulmonary complications; organ, nerve or muscular damage; gastrointestinal or genitourinary compromise; seizure, convulsion, or changes to mental status; complications of pregnancy including miscarriage and fetal birth defects; inability to resume activities of daily living; and death.

2. Risks associated with anterior cervical spine surgery include: dysphagia; dysphonia; hoarseness; vocal cord paralysis; laryngeal palsy; sore throat; recurring aspirations; tracheal, esophageal, or pharyngeal perforation; airway obstruction; warmth or tingling in the extremities; neurologic complications including damage to nerve roots, other nerves or the spinal cord, possibly resulting in weakness, pain or even paralysis; dural tears or leak; cerebrospinal fistula; discitis, arachnoiditis, and other types of inflammation; loss of disc height; loss of anatomic sagittal plane curvature, vertebral listhesis; scarring, herniation or degeneration of adjacent discs; surrounding soft tissue damage, spinal stenosis; spondylolysis; fistula; vascular damage and/or rupture; and headache.

3. Risks associated with a cervical artificial disc device, including the Mobi-C® Cervical Disc Prosthesis, include: early or late loosening of the components; disassembly; bending or breakage of any or all of the components; implant migration; implant malpositioning; implant subsidence; loss of fixation; sizing issues with components; anatomical or technical difficulties; bone fracture; possible tissue reaction; metallosis, and/or scarring; bone resorption; bone formation (including heterotopic ossification) that may reduce spinal motion or result in a fusion, either at the treated level or at adjacent levels; development of new radiculopathy, myelopathy, or pain; tissue or nerve damage caused by improper positioning or placement of implants or instruments; bending or breakage of a surgical instrument; loss of neurological function; decreased strength of extremities; decreased reflexes; cord or nerve root injury; interference with radiographic imaging because of the presence of the implant; and the need for subsequent surgical intervention.

These conditions do not include all potential adverse events that may occur, but are important considerations in relation to the use of the Mobi-C® prosthesis. For the specific adverse events that occurred in the clinical study of the Mobi-C® Cervical Artificial Disc, please see the Safety Results in the CLINICAL STUDIES section below.

CLINICAL STUDIES

The pivotal clinical study compared the Mobi-C® to the control treatment consisting of conventional anterior cervical discectomy and fusion (ACDF) (using allograft corticocancellous bone followed by placement of a semi-constrained, rotational anterior cervical plate). The study was a prospective, randomized (2:1), multi-center, two arm, unmasked, concurrently controlled, non-inferiority clinical study in 260 subjects treated at 24 sites carried out under IDE # G050212. The primary objective of the study was to evaluate the overall success rate of the investigational device through 24 months as compared to the control in the treatment of subjects with radiculopathy or myelopathy localized to the level of the disc space at one level between C3 and C7 who were unresponsive to non-operative conservative treatment after radiculopathy or myelopathy symptom onset. To be eligible for the Mobi-C® IDE study, patients had to meet all of the inclusion criteria and none of the exclusion criteria:

Study Inclusion Criteria	Study Exclusion Criteria
1) Age 18-69 years	1) Reported to have an active systemic infection or infection at the operative site
2) Diagnosis of radiculopathy or myeloradiculopathy of the cervical spine, with pain, paresthesias or paralysis in a specific nerve root distribution C3 through C7, including at least one of the following: o Neck and/or arm pain (at least 30 mm on the 100 mm visual analogue scale [VAS] scale). o Decreased muscle strength of at least one level on the clinical evaluation 0 to 5 scale. o Abnormal sensation including hyperesthesia or hypoesthesia; and/or o Abnormal reflexes	2) Reported to have an increased risk of osteoporosis/osteopenia. This was defined as a T-score less than (worse than) -1.5 on a previous or required Hologic Sahara or dual energy X-ray absorptiometry (DEXA) scan. All subjects that met one or more of the following were to undergo a Hologic Sahara or DEXA scan as part of the study enrollment procedures: o Females 50 years and older; o Females who were post-menopausal or post-hysterectomy with oophorectomy; o Subjects taking bisphosphonate medication for the treatment of osteoporosis; and/or o Subjects with history of chronic use of high dose steroids. High dose steroid use is defined as part of Exclusion Criterion #4. All females less than 50 years of age, and all males, who had not had a Hologic Sahara or DEXA scan within six months of surgery, were screened for osteoporosis using the Simple Calculated Osteoporosis Risk Estimation (SCORE) questionnaire. Subjects whose screening suggests increased risk (SCORE greater than 6) were to undergo a Hologic Sahara or DEXA scan as part of the study enrollment procedures.
3) Symptomatic at one level from C3 to C7	3) Reported to have had any prior spine surgery at the operative level
4) Radiographically determined pathology at the level to be treated correlating to primary symptoms including at least one of the following: o Decreased disc height on radiography, computed tomography (CT), or magnetic resonance imaging (MRI) in comparison to a normal adjacent disc. o Degenerative spondylosis on CT or MRI. o Disc herniation on CT or MRI	4) Reported concomitant conditions requiring daily, high-dose oral and/or inhaled steroids. High dose steroid use is defined as: o Daily, chronic use of oral steroids of 5 mg/day or greater. o Daily, chronic use of inhaled corticosteroids (at least twice per day). o Use of short-term (less than 10 days) oral steroids at a daily dose greater than 40 mg within one month of the study procedure
5) NDI Score of ≥ 15/50 or ≥ 30%	5) Reported to have had prior cervical fusion procedure at any level
6) Unresponsive to non-operative, conservative treatment (rest, heat, electrotherapy, physical therapy, chiropractic care and/or analgesics) for: o Approximately six weeks from radiculopathy or myeloradiculopathy symptom onset; or o Have the presence of progressive symptoms or signs of nerve root/spinal cord compression despite continued non-operative conservative treatment	6) Marked cervical instability on resting lateral or flexion-extension radiographs demonstrated by: o Translation ≥ 3.5 mm, and/or o Greater than 11° angular difference to that of either adjacent level
7) Appropriate for treatment using an anterior surgical approach, including having no prior surgery at the operative level and no prior cervical fusion procedure at any level	7) More than one immobile vertebral level between C1 to C7 from any cause including but not limited to congenital abnormalities and osteoarthritic "spontaneous" fusions
8) Reported to be medically cleared for surgery	8) Spondylolysis
9) Reported to be physically and mentally able and willing to comply with the Protocol, including the ability to read and complete required forms and willing and able to adhere to the scheduled follow-up visits and requirements of the Protocol	9) Previous trauma to the C3 to C7 levels resulting in significant bony or disco-ligamentous cervical spine injury
10) Written informed consent provided by subject or subject's legally authorized representative	10) Reported to have a history of or anticipated treatment for active systemic infection, including HIV or Hepatitis C
11) Willingness to discontinue all use of non-steroidal anti-inflammatory drugs (NSAIDs) from one week before surgery until 3 months after surgery	11) Axial neck pain in the absence of other symptoms of radiculopathy or myeloradiculopathy justifying the need for surgical intervention
	12) Disc height less than 3 mm as measured from the center of the disc in a neutral position and disc height less than 20% of the anterior-posterior width of the inferior vertebral body
	13) Radiographic confirmation of severe facet joint disease or degeneration
	14) Reported to have Paget's disease, osteomalacia or any other metabolic bone disease other than osteoporosis, which is addressed above
	15) Reported active malignancy that included a history of any invasive malignancy (except non-melanoma skin cancer), unless the subject had been treated with curative intent and there had been no clinical signs or symptoms of the malignancy for at least five years
	16) Symptomatic DDD or significant cervical spondylosis at more than two levels
	17) Known allergy to cobalt, chromium, molybdenum or polyethylene
	18) Segmental angulation of greater than 11° at treatment or adjacent levels
	19) Reported pregnancy or nursing at time of enrollment, or with plans to become pregnant within the next three years

Study Inclusion Criteria	Study Exclusion Criteria
	20) Reported to have rheumatoid arthritis, lupus, or other autoimmune disease that affects the musculoskeletal system 21) Congenital bony and/or spinal cord abnormalities that affect spinal stability 22) Reported to have diseases or conditions that would preclude accurate clinical evaluation (e.g. neuromuscular disorders) 23) Reported to have current or recent history of substance abuse (alcoholism and/or narcotic addiction) requiring intervention 24) Clinically Severe Obesity, as defined by National Institutes of Health (NIH) Clinical Guidelines Body Mass Index (BMI) > 40) 25) Reported use of any other investigational drug or medical device within the last 30 days prior to surgery 26) Evidence of symptomatic moderate to severe facet joint degeneration or disease where the investigator felt this was a major contributor to the subject's pain as diagnosed by injection and imaging 27) Reported to be taking medications known to potentially interfere with bone/soft tissue healing (e.g., high-dose oral and/or inhaled steroids, immunosuppressant medication, chemotherapeutic agents) 28) Reported to have pending personal litigation relating to spinal injury (worker's compensation was not an exclusion) 29) Reported to have a current history of heavy smoking (more than one pack of cigarettes per day) 30) Anticipated or potential relocation greater than 50 miles that may interfere with completion of follow-up examinations 31) Reported to have mental illness or belonged to a vulnerable population, as determined by the investigator (e.g., prisoner or developmentally disabled), that would compromise ability to provide informed consent or compliance with follow-up requirements 32) Reported to have an uncontrolled seizure disorder 33) Reported to have taken epidural steroids within 14 days prior to surgery

Postoperative Care

The recommended postoperative care was according to the individual investigator's discretion and consisted of a physician-managed individual post-operative rehabilitation program which may have included the optional of use of a cervical collar. Subjects were advised according to the individual physician's discretion to increase daily activity (sitting, standing and walking), shower only in absence of wound drainage, and drive after collar removal. The study excluded subjects with a current history of heavy smoking defined as more than one pack of cigarettes per day. Subjects were requested to discontinue the use of NSAIDs from one week prior to surgery until 3 months following surgery in both treatment groups. Control group subjects were permitted to use bone growth stimulators.

Follow-up Schedule

All patients were evaluated preoperatively (within 60 days prior to surgery), immediately postoperatively (prior to discharge) and postoperatively at 6 weeks, 3, 6, 12, 18, and 24 months, and annually thereafter as shown in Table 1. Effectiveness parameters assessed during follow-up included neck pain and function, measured by the Visual Analog Scale ("VAS") and Neck Disability Index ("NDI"), as well as quality of life as measured by the Medical Outcomes Study 12-Item Short Form Health Survey ("SF-12"), and a subject satisfaction questionnaire. Other parameters assessed during follow-up included neurological assessment and radiographic studies (neutral AP, neutral lateral). Complications and adverse events, device-related or not, were evaluated over the course of the study.

Table 2. Clinical Evaluation Schedule

Evaluation	Pre-op	Surgery/ Hospital Discharge	6 wks	3 mo	6 mo	12 mo	18 mo	24 mo & annually
Neck Disability Index	X		X	X	X	X	X	X
Neck and Arm Pain (VAS)	X		X	X	X	X	X	X
Health Status (SF-12)	X				X	X	X	X
Neurological Status/Gait	X		X	X	X	X	X	X
Dysphagia Scale (FOSS)*			X	X	X	X	X	X
Adverse Events**	X	X	X	X	X	X	X	X
Demographic/Baseline Data	X							
Operative Data		X						
Medication Use	X	X	X	X	X	X	X	X

Evaluation	Pre-op	Surgery/ Hospital Discharge	6 wks	3 mo	6 mo	12 mo	18 mo	24 mo & annually
Radiographs								
Neutral (AP & Lateral)	X	X	X	X	X	X	X	X
Dynamic(F/E/RSB/LSB) [§]	X		X	X	X	X	X	X
CT and/or MRI	X							
Radiographic Outcomes:								
Fusion status	X				X	X	X	X
Device condition	X	X	X	X	X	X	X	X
Subsidence/ migration	X	X	X	X	X	X	X	X
Range of motion	X	X	X	X	X	X	X	X
Radiolucency	X			X	X	X	X	X
Disc height	X	X	X	X	X	X	X	X
Patient Satisfaction				X	X	X	X	X

[*] Functional Outcome Swallowing Scale for Dysphagia (FOSS)
[**] Adverse events and complications were recorded at all visits (both scheduled and unscheduled)
[§] Dynamic radiographs included flexion (F) / extension (E) bending and right side bending (RSB)/ left side bending (LSB) radiographs

Clinical Endpoints
The effectiveness of the Mobi-C® was assessed using a composite definition of study success. Effectiveness was further evaluated by monitoring improvement in the Neck Disability Index (NDI), neck and arm pain based on a Visual Analog Scale (VAS), and quality of life using the short-form 12 questionnaire (SF-12) as well as patient satisfaction compared to the ACDF control group. The same criteria were used to measure success in both groups.

The safety of the Mobi-C® Cervical Disc Prosthesis was assessed by comparison to the ACDF control group with respect to the nature and frequency of adverse events (overall and in terms of seriousness and relationship to the implant), secondary surgical procedures as well as maintenance or improvement in neurological status.

In addition, several radiographic endpoints were considered in evaluating both safety and effectiveness, including range of motion, disc height, device condition, device subsidence, device migration, radiolucency, spinal fusion status, heterotopic ossification, and adjacent segment degeneration.

According to the IDE protocol, an individual patient in either treatment group was considered a success if the following criteria were met at 24 months:

- Improvement in NDI of at least 15/50 points in subjects with a baseline NDI score of ≥ 30/50 points, or a 50% improvement in subjects with a baseline NDI score of < 30/50 points;
- No study failures due to secondary surgical interventions at the index level;
- Absence of major complications defined as radiographic failure, neurological failure, or failure by adverse event as adjudicated by the CEC.

A variation of the primary endpoint analysis was prospectively planned to assess subject success when major complications due to radiographic assessment were removed from the analysis. This variation was considered in order to compare the treatment groups after removing the radiographic assessments altogether.

In addition, FDA requested an additional variation of the primary endpoint analysis in which major complications due to neurological failure were assessed as any deterioration in neurologic function instead of the IDE protocol definition of neurological deterioration which considered deterioration as a two point decrease in any motor or reflex assessment or a one point decrease in sensory assessment when compared to baseline.

Secondary endpoints, measured in both treatment groups, included neck pain (VAS), arm pain (VAS), muscle strength, sensory deficit, significant neurological deterioration, adjacent segment degeneration, displacement or migration of the device, range of motion, radiolucency, quality of life (SF-12), dysphagia (FOSS scale), and gait analysis (Nurick's classification).

Overall study success criteria were based on a comparison of individual patient success rates, such that the patient success rate for the Mobi-C® investigational group must be non-inferior to that of the ACDF fusion control group. Frequentist statistical methods were used to test for non-inferiority using an exact 95% one-sided confidence bound for the difference between the study and control success rates; if a 10% offset could be ruled out according to the 95% lower bound, then superiority was to be tested. A closed testing procedure was used to allow for superiority to be tested in the event that non-inferiority was established for the primary effectiveness endpoint.

Accountability of PMA Cohort
A total of 260 subjects completed study surgery. This included 179 subjects treated with Mobi-C® (164 randomized, 15 training) and 81 ACDF control subjects. There were an additional 11 subjects who were randomized, but withdrew prior to surgery. At the time of database lock, of the 260 subjects with surgery, complete 24 month primary endpoint data was available for 148 Mobi-C® patients (94.3%), 69 ACDF control patients (92.0%) and 15 non-randomized Mobi-C® patients (100%). At this time point, 135 Mobi-C® patients (86%), 61 ACDF control patients (81.3%) and 15 non-randomized Mobi-C® patients (100%) presented with complete data within the FDA Guidance Window. As the protocol specified follow-up windows were narrower than those specified in FDA guidance documents, accountability according to protocol-specified visits

windows has also been provided. A summary of patient accountability data for the 12 month, 24 month, and 36 month follow-up visits is provided in **Table 3**.

Table 3. Patient Accountability (based on treatment assignment)

Number of Patients	12 Months (±2 Months)			24 Months (±2 Months)			36 Months (±2 Months)		
	Mobi-C®	ACDF	Training	Mobi-C®	ACDF	Training	Mobi-C®	ACDF	Training
w/ Surgery	164	81	15	164	81	15	164	81	15
Theoretical	164	81	15	164	81	15	164	81	15
Deaths	0	0	0	0	0	0	0	0	0
Failures[1]	5	4	0	7	6	0	8	7	0
Not yet overdue	-	-	-	-	-	-	-	-	-
Expected[2]	159	77	15	157	75	15	156	74	15
Actual, efficacy[3] (% Follow-up)	147 (92.5%)	65 (84.4%)	15 (100.0%)	148 (94.3%)	69 (92.0%)	15 (100.0%)	128 (82.1%)	56 (75.7%)	15 (100.0%)
Actual, efficacy in window[4] (% Follow-up)	137 (86.2%)	60 (77.9%)	15 (100.0%)	135 (86.0%)	61 (81.3%)	15 (100.0%)	116 (74.4%)	51 (68.9%)	14 (93.3%)
Actual, any data[5] (% Follow-up)	148 (93.1%)	67 (87.0%)	15 (100.0%)	148 (94.3%)	69 (92.0%)	15 (100.0%)	136 (87.2%)	57 (77.0%)	15 (100.0%)

[1]A failure is any patient who experienced a major complication via the CEC assessment of adverse events or was a study failure due to subsequent surgical intervention. Note that this row is cumulative.
[2]Expected equals theoretical minus cumulative failures.
[3]Refers to any patient having a value for the composite endpoint, i.e., for patient success, if all composite endpoint measures were collected and successes for that particular timepoint, or for patient failure, at least one composite endpoint measure was a failure for that particular timepoint.
[4]Refers to defined follow-up windows from the FDA Guidance Document entitled "Clinical Data Presentations for Orthopedic Device Applications" (2004): 6 wks: $28 \leq$ day ≤ 56, 3 mo: $77.25 \leq$ day ≤ 105.25, 6 mo: $152.5 \leq$ day ≤ 212.5, 12 mo: $305 \leq$ day ≤ 425, 18 mo: $487.5 \leq$ day ≤ 607.5, 24 mo: $670 \leq$ day ≤ 790
[5]Any data refers to patients with any evaluation data available for that visit. That is, the patient appears at the visit.

Throughout this summary, the population of all subjects treated with surgery, including randomized Mobi-C® subjects (N=164), randomized ACDF control subjects (N=81), and Mobi-C® non-randomized training subjects (N=15) will be used for safety analyses and will be termed as the **"Safety Population."** The as treated population (also termed **"Primary Analysis Population"**) is used for effectiveness analyses (164 randomized Mobi-C® subjects, 81 randomized ACDF control subjects).

Study Population Demographics and Baseline Parameters
The demographics of the study population are consistent with demographics reported for prior cervical artificial disc studies conducted in the US. Demographic data showed that the treatment groups were well-balanced and no statistically significant differences were noted in the demographic characteristics, as shown below (**Table 4**).

Table 4. Demographics — Primary Analysis Population

Demographic Measure	Randomized Mobi-C® (N=164)	Non-Randomized Mobi-C® (N=15)	Randomized ACDF (N=81)	P-Value (Randomized Groups)
Gender				
Male	78 (47.6%)	6 (40.0%)	36 (44.4%)	0.6843**
Female	86 (52.4%)	9 (60.0%)	45 (55.6%)	
Age (years)	43.3 ±9.23 Range: 21 - 67	43.0±8.10 Range: 22 - 54	44.0 ±8.21 Range: 27-65	0.5657***
Ethnicity				
Hispanic or Latino	3 (1.8%)	1 (6.7%)	2 (2.5%)	0.6667**
Not Hispanic or Latino	161 (98.2%)	14 (93.3%)	79 (97.5%)	
Race				
American Indian Alaska Native	2 (1.2%)	1 (6.7%)	1 (1.2%)	0.0710**
Caucasian	152 (92.7%)	14 (93.3%)	69 (85.2%)	
Asian	3 (1.8%)	0	1 (1.2%)	
Black or African American	4 (2.4%)	0	10 (12.3%)	
Native Hawaiian/other Pacific Islander	1 (0.6%)	0	0	
Other	2 (1.2%)	0	0	
Height (in)	67.90 ±3.960 Range: 58.0-82.0	67.65±2.878 Range: 64.0 - 74.0	67.02 ±3.714 Range: 60.0-77.0	0.0952***
Weight (lbs)	180.06 ±38.510 Range: 107.0 -289.4	177.89±38.808 Range: 131.0 – 247.0	176.16 ±36.598 Range: 106.0 - 270.0	0.4494***
BMI (kg/m^2)	27.28 ±4.42 Range: 17.91 - 37.88	27.14±4.67 Range: 20.46 – 38.73	27.39 ±4.18 Range: 17.23 - 39.15	0.8460***
Smoke more than one pack per day (yes)*	0	0	0	>0.9999**
History non-op care (yes):				
Pain Medication[1]	152 (92.7%)	13 (86.7%)	79 (91.4)	0.0099**
Opioid Use[2]				
Opium Alkaloid	23 (14.0%)	3 (20.0%)	5 (6.2%)	0.0875**
Semi-Synthetic Opioid Derivative	87 (53.0%)	6 (40.0%)	44 (54.3%)	0.8922**
Synthetic Opioid	20 (12.2%)	3 (20.0%)	7 (8.6%)	0.5170**
Physical therapy	63 (38.4%)	7 (46.7%)	34 (42.0%)	0.7356**
Collar	19 (11.6%)	0	11 (13.6%)	0.3905**
Chiropractic	43 (26.2%)	3 (20.0%)	16 (19.8%)	0.5029**
Cervical Traction	37 (22.6%)	5 (33.3%)	17 (21.0%)	0.5596**
Bedrest / Immobilization	87 (53.0%)	9 (60.0%)	38 (46.9%)	0.5542**
Acupuncture	9 (5.5%)	1 (6.7%)	5 (6.2%)	0.8255**
Work Status (Being able to Work)	108 (65.9%)	13 (86.7%)	46 (56.8%)	0.3264**
Driving Status (Being able to drive)	155 (94.5%)	14 (93.3%)	79 (97.5%)	0.5035**

* Using unpaired t-test to compare age, height, weight, and BMI across treatment groups. Using Fisher Exact test to compare gender, ethnicity, race, work status, driving status, and smoking status across treatment groups.

** Subjects with multiple races are included with the Non-Caucasian subjects. Fisher Exact p-value calculation is based on Caucasian vs. Non-Caucasian subjects.

*** Fisher Exact p-value calculation is based on 'Being able to' vs. 'Not being able to'.

[1]Aggregate usage of medications determined to be Pain Medication presented for baseline comparison.

[2]Opioid usage (aggregate) with specific categories is presented separately as a subset of Pain Medication.

Note – 'Injections' were not categorically defined in the Study Protocol, and as such are not presented here.

The mean baseline pre-operative assessments for NDI, VAS neck pain, VAS arm pain, and both component scales of SF-12 were also similar between treatment groups. There were no statistical differences between pre-operative neurological status or range of motion between the groups, as shown in **Table 5.**

Table 5. Pre-operative Evaluation of Endpoints

Variable	Randomized Mobi-C® (N=164)	Non-Randomized Mobi-C® (N=15)	Randomized ACDF (N=81)	P-Value (Randomized Groups)
NDI	53.98±14.038	46.8±15.38	54.15±14.642	0.9290**
VAS Neck Pain	70.76 ±22.392	65.67±24.189	70.14±21.478	0.8354**
VAS Left Arm Pain	46.66±36.499	38.83±37.374	55.33±37.326	0.0839**
VAS Right Arm Pain	40.98±36.198	26.63±28.812	34.83±35.635	0.2104**
SF-12 PCS	32.451±5.9075	34.948±5.6139	33.821±6.3590	0.1055**
SF-12 MCS	42.107±13.1166	42.895±13.3983	42.151±10.4407	0.9792**
Neurological Status (normal[1])				
Motor	72 (43.9%)	8 (53.3%)	31 (38.3%)	0.4131*
Sensory				
Light Touch	79 (48.2%)	9 (60.0%)	41 (50.6%)	0.7862*
Pin Prick	79 (48.2%)	7 (46.7%)	45 (55.6%)	0.2816*
Reflexes	74 (45.1%)	5 (33.3%)	38 (46.9%)	0.8916*
Other assessments (gait[2])	160 (97.6%)	15 (100.0%)	75 (94.9%)[3]	0.2796*[3]
Baseline ROM Flexion-extension (°)	8.21±4.493	8.59±4.918	7.48±4.066	0.2313**
Baseline ROM Lateral bending (mm)	5.04±2.897	4.84±2.370	5.38±3.218	0.4277**

*Using Fisher Exact test to compare frequencies between the treatments.
**Using unpaired t-test to compare across treatment groups.
[1] Normal defined as normal status for both left and right sided assessments.
[2] Gait was the only other neurological assessment performed, per the study protocol.
[3]Two ACDF subjects did not have baseline gait data available; these values are based on 79 subjects.

Surgery and Hospitalization Data

Surgical data is provided in **Table 6**. The most common treated surgical levels were C5-C6 and C6-C7. Mean surgery time was 8.94 minutes longer for the randomized investigational Mobi-C® group than for the control ACDF group. There was no significant difference between mean operative times between all Mobi-C® subjects and control subjects. Mean blood loss was similar for both groups. Mean return to work time was 7.5 days shorter for the randomized Mobi-C® group than the ACDF group, though no statistical difference was found between the mean return to work time for all Mobi-C® subjects as compared to control subjects. Data regarding the amount/type of decompression and handling of the posterior longitudinal ligament for each procedure was not systematically collected. There were no statistically significant differences between the randomized and non-randomized Mobi-C® populations with respect to reported operative parameters which supports a relatively minimal learning curve associated with use of the Mobi-C® device. A total of 179 Mobi-C® devices were implanted during the study. The design, footprint and height of the Mobi-C® devices used are presented in **Table 7**.

Table 6. Surgical Data

Measure	Non-Randomized Mobi-C® (N=15)	Randomized Mobi-C® (N=164)	Randomized ACDF (N=81)	P Value **	P Value ***
Treated Level					
C3-C4 (%)	0	1 (0.6%)	4 (4.9%)	-	-
C4-C5 (%)	0	11 (6.7%)	2 (2.5%)		
C5-C6 (%)	8 (53.3%)	92 (56.1%)	46 (56.8%)		
C6-C7 (%)	7 (46.7%)	60 (36.6%)	29 (35.8%)		
Surgery Time (hours)	1.638±0.6415	1.482±0.6389	1.333±0.6311	0.3677	0.0572
Blood Loss (mls)	78.3±104.84	45.0±37.08	48.1±55.21	0.2957	0.9628
Hospitalization (days)	2.3±0.98	2.0±0.45	2.1±0.47	0.2816	0.9829
Return to Work Time (days)	37.4±41.12	29.3±22.18	36.8±40.34	0.5145	0.3016

Mean ± standard deviation
* Duration of hospitalization is defined as [Date of Discharge - Date of Surgery + 1].
**Using unpaired t-test to make comparison across randomized and non-randomized Mobi-C subjects.
*** Using unpaired t-test to make comparison across treatments for all Mobi-C® subjects compared to ACDF subjects.

Table 7. All Mobi-C® Devices Implanted by Size and Level

	C3-C4	C4-C5	C5-C6	C6-C7	Total
13×15 H5	0	3	55	14	**72**
13×15 H6	1	3	4	2	**10**
13×15 H7	0	1	0	0	**1**
13×17 H5	0	2	10	7	**19**
13×17 H6	0	0	0	5	**5**
13×17 H7	0	0	0	0	**0**
15×17 H5	0	1	21	20	**42**
15×17 H6	0	1	7	10	**18**
15×17 H7	0	0	1	1	**2**
15x20 H5	0	0	1	3	**4**
15x20 H6	0	0	1	4	**5**
15x20 H7	0	0	0	1	**1**
Total	**1**	**11**	**100**	**67**	**179**

Safety and Effectiveness Results

Safety Results

The analysis of safety was based on the Safety Population cohort of 260 total patients with surgery (164 randomized Mobi-C® patients, 15 non-randomized Mobi-C® patients, and 81 ACDF control patients).

A summary of the total number of adverse events is shown in **Table 8**. Adverse events were classified by both the Clinical Events Committee (CEC) and the Investigator for relationship to the device and for seriousness of the event. This information is presented in **Table 8.** The overall adverse event rate was similar for the randomized Mobi-C® group (95.1%), non-randomized Mobi-C® training group (93.3%), and ACDF control group (92.6%).

Table 8. Summary of Adverse Events through Month 24 – Safety Population

	Mobi-C® Non-Randomized (N=15)			Mobi-C® Randomized (N=164)			ACDF with Anterior Cervical Plate (N=81)				
	Events N	Subjects N (%)	Subject-Level CI*	Events N	Subjects N (%)	Subject-Level CI***	Events N	Subjects N (%)	Subject-Level CI***	Event Level P-value*	Subject Level P-value**
All Adverse Events	89	14 (93.3%)	(0.681, 0.998)	1140	156 (95.1%)	(0.906, 0.979)	688	75 (92.6%)	(0.846, 0.972)	0.2081	0.5591
Treatment-Emergent Adverse Events	89	14 (93.3%)	(0.681, 0.998)	1140	156 (95.1%)	(0.906, 0.979)	685	75 (92.6%)	(0.846, 0.972)	0.2173	0.5591
Related Adverse Events (a)	9	3 (20.0%)	(0.043, 0.481)	70	31 (18.9%)	(0.132, 0.257)	63	20 (24.7%)	(0.158, 0.355)	0.1706	0.3178
Definitely Related	0	0		8	7 (4.3%)	(0.017, 0.086)	7	6 (7.4%)	(0.028, 0.154)	0.3566	0.3656
Possibly Related	9	3 (20.0%)	(0.043, 0.481)	62	27 (16.5%)	(0.111, 0.230)	56	19 (23.5%)	(0.148, 0.342)	0.1941	0.2237
Related Adverse Events (b)	6	4 (26.7%)	(0.078, 0.551)	66	39 (23.8%)	(0.175, 0.310)	58	23 (28.4%)	(0.189, 0.395)	0.1224	0.4391
Definitely Related	0	0		1	1 (0.6%)	(0.000, 0.034)	2	2 (2.5%)	(0.003, 0.086)	0.3144	0.2547
Possibly Related	6	4 (26.7%)	(0.078, 0.551)	65	38 (23.2%)	(0.169, 0.304)	56	23 (28.4%)	(0.189, 0.395)	0.1326	0.4327
Serious Adverse Events	5	2 (13.3%)	(0.017, 0.405)	60	30 (18.3%)	(0.127, 0.251)	52	21 (25.9%)	(0.168, 0.369)	0.2220	0.1828
Related Serious Adverse Events (c)	2	1 (6.7%)	(0.002, 0.319)	5	3 (1.8%)	(0.004, 0.053)	15	6 (7.4%)	(0.028, 0.154)	0.1524	0.0629
Definitely Related	0	0		1	1 (0.6%)	(0.000, 0.034)	5	5 (6.2%)	(0.020, 0.138)	0.0468	0.0160
Possibly Related	2	1 (6.7%)	(0.002, 0.319)	4	3 (1.8%)	(0.004, 0.053)	10	3 (3.7%)	(0.008, 0.104)	0.2818	0.4001
Related Serious Adverse Events (d)	1	1 (6.7%)	(0.002, 0.319)	7	5 (3.0%)	(0.010, 0.070)	13	6 (7.4%)	(0.028, 0.154)	0.1723	0.1860
Definitely Related	0	0	-	0	0	-	2	2 (2.5%)	(0.003, 0.086)	0.1586	0.1084
Possibly Related	1	1 (6.7%)	(0.002, 0.319)	7	5 (3.0%)	(0.010, 0.070)	11	4 (4.9%)	(0.014, 0.122)	0.2725	0.4832
Unanticipated Adverse Device Effects	0	0	-	0	0	-	0	0	-		>0.9999

* The event-level incidences between Mobi-C® Randomized and ACDF treatment groups will be analyzed using an unpaired t-test.

** The subject-level p-value between Mobi-C® Randomized and ACDF treatment groups will be calculated using Fisher Exact test.

*** The subject-level incidences of these outcomes will be analyzed using a 95% two-sided Binomial exact confidence interval.

(a) Adverse events classified by the investigator as possibly or definitely related to study device.

(b) Adverse events classified by CEC members as possibly or definitely related to study device.

(c) Serious adverse events classified by the investigator as possibly or definitely related to study device.
(d) Serious adverse events classified by CEC members as possibly or definitely related to study device.

Table 9 provides data on the number of adverse events in each treatment group stratified by level of treatment. There was a trend across levels toward fewer device-related AEs, serious AEs, and device-related serious AEs for the Mobi-C® group. Across treatment groups, relatively fewer subjects were treated at the C3-4 (N=5) and C4-5 (N=13) compared with treatment at the C5-6 (N=146) and C6-7 (N=96) levels.

Table 9. Total Adverse Events by Level Treated – Safety Population

	Mobi-C® (N=179)*			**ACDF (N=81)**		
	Events N	**Subjects N (%)**	**Subject-Level CI****	**Events N**	**Subjects N (%)**	**Subject-Level CI****
Treated Segment: C3-C4	(N=1)			(N=4)		
TEAEs	5	1 (100%)		24	3 (75.0%)	(0.194, 0.994)
Treated Segment: C4-C5	(N=11)			(N=2)		
TEAEs	97	11 (100%)		18	1 (50.0%)	(0.013, 0.987)
Treated Segment: C5-C6	(N=100)			(N=46)		
TEAEs	705	95 (95.0%)	(0.887, 0.984)	478	44 (95.7%)	(0.852, 0.995)
Treated Segment: C6-C7	(N=67)			(N=29)		
TEAEs	422	63 (94.0%)	(0.854, 0.983)	165	27 (93.1%)	(0.772, 0.992)

TEAE = treatment emergent adverse event
* Includes all Mobi-C® study subjects.
**The subject-level incidences of these outcomes are analyzed using a 95% two-sided Binomial exact confidence interval.

The adverse events reported in the PMA from all 260 total patients (164 randomized Mobi-C® patients, 81 ACDF control patients, 15 non-randomized Mobi-C® patients) are shown in **Table 10**. This table includes adverse events from all patients, randomized and non-randomized, to establish the safety profile of the device for the primary study endpoint (24 months). Adverse events are listed in alphabetical order according to adverse event categories. Definitions of the adverse event categories are provided in **Table 11**. **Table 12** is presented in a similar fashion as **Table 10** (using the categories as defined in **Table 11**), and includes all known adverse event data at the time of PMA submission, including all available subject AE data through 60 months of follow up. Adverse event rates are based on the number of patients having at least one occurrence of an adverse event, divided by the number of patients in that treatment group. Events per patient are based on the number of adverse events, divided by the number of patients. No deaths or unanticipated adverse device effects were reported during the study.

Table 10. All Treatment Emergent Adverse Events through 24 Months in US IDE Study – All Study Subjects

	Surgery to Discharge		Discharge to Week 6		Week 6 to Month 3		Months 3 to 6		Months 6 to 12		Months 12 to 18		Months 18 to 24		Mobi-C®		ACDF	
Complication	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**#Patients (% of 179)**	**Total Events**	**#Patients (% of 81)**	**Total Events**
All Adverse Events[1]	148	53	149	76	137	134	156	96	288	166	232	102	140	84	170 (95.0%)	1229	75 (92.6%)	688
Anatomy/Technical Difficulty	2	0	0	1	2	2	1	0	1	1	5	0	1	0	11 (6.1%)	12	2 (2.5%)	4
Cervical – Study Surgery	1	0	0	1	1	1	0	0	0	1	2	0	0	0	4 (2.2%)	4	2 (2.5%)	3
Cervical – Non Study Surgery	1	0	0	0	0	1	1	0	1	0	2	0	1	0	5 (2.8%)	6	1 (1.2%)	1
Non-Cervical	0	0	0	0	1	0	0	0	0	0	1	0	0	0	2 (1.1%)	2	0 (0.0%)	0
Cancer	0	0	0	0	0	0	0	0	0	2	2	0	3	0	4 (2.2%)	5	1 (1.2%)	2
Cardiovascular	6	1	2	2	0	0	4	2	6	2	4	3	4	0	20 (11.2%)	26	10 (12.3%)	10
Death	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Dysphagia/Dysphonia	9	5	7	5	4	2	0	1	2	3	1	4	3	0	20 (11.2%)	26	17 (21.0%)	20
Dysphagia	8	2	6	5	4	2	0	1	1	3	1	4	2	0	19 (10.6%)	22	15 (18.5%)	17
Dysphonia	1	3	1	0	0	0	0	0	1	0	0	0	1	0	3 (1.7%)	4	3 (3.7%)	3
Gastrointestinal	28	9	2	3	2	2	2	1	16	11	9	6	1	5	39 (21.8%)	60	15 (18.5%)	37
Heterotopic Ossification	0	0	0	0	0	0	1	0	5	2	2	1	2	1	9 (5.0%)	10	4 (4.9%)	4
Cervical - Index Level	0	0	0	0	0	0	0	0	3	0	1	0	1	0	5 (2.8%)	5	0 (0.0%)	0
Cervical - Adjacent Level	0	0	0	0	0	0	1	0	0	1	0	0	0	0	1 (0.6%)	1	1 (1.2%)	1
Non Cervical	0	0	0	0	0	0	0	0	2	1	1	1	1	1	4 (2.2%)	4	3 (3.7%)	3
Infection	3	1	14	4	5	8	7	0	9	8	8	5	5	2	33 (18.4%)	51	20 (24.7%)	28
Superficial Wound – Cervical	2	0	5	0	0	1	0	0	0	0	0	0	0	0	6 (3.4%)	7	1 (1.2%)	1
Deep Wound – Cervical	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other Wound - Non Study Surgery	0	1	0	0	0	0	0	0	1	1	0	0	0	1	1 (0.6%)	1	3 (3.7%)	3
Systemic	0	0	2	0	0	0	1	0	3	3	2	0	1	0	8 (4.5%)	9	2 (2.5%)	3
Local	1	0	7	4	5	7	6	0	5	4	6	5	4	1	20 (11.2%)	34	18 (22.2%)	21
Malpositioned Implant	0	1	0	0	0	0	1	0	0	0	1	0	0	0	2 (1.1%)	2	1 (1.2%)	1
Neck and/or Arm Pain	30	8	28	9	26	23	25	17	41	20	41	13	21	8	102 (57.0%)	212	47 (58.0%)	98
Neck Pain	25	8	17	7	11	7	11	10	26	12	23	6	10	6	74 (41.3%)	123	37 (45.7%)	56
Arm Pain	3	0	11	1	12	10	10	3	13	4	16	5	11	2	46 (25.7%)	76	20 (24.7 %)	25
Neck And Arm Pain	2	0	0	1	3	6	4	4	2	4	2	2	0	0	9 (5.0%)	13	7 (8.6%)	17
Neurological	33	11	47	25	48	54	65	36	91	43	70	17	47	29	121 (67.6%)	401	52 (64.2%)	215
Upper Extremity – Sensory	4	2	17	11	25	45	31	24	43	20	36	9	19	15	67 (37.4%)	175	32 (39.5%)	126
Upper Extremity – Motor	7	3	5	2	3	2	5	2	10	5	5	2	8	4	26 (14.5%)	43	15 (18.5%)	20

	Surgery to Discharge		Discharge to Week 6		Week 6 to Month 3		Months 3 to 6		Months 6 to 12		Months 12 to 18		Months 18 to 24		Mobi-C®		ACDF	
Complication	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**#Patients (% of 179)**	**Total Events**	**#Patients (% of 81)**	**Total Events**
Upper Extremity – Reflex	0	0	5	10	12	4	11	5	6	1	4	0	6	0	18 (10.1%)	44	7 (8.6%)	20
Lower Extremity – Sensory	2	0	0	0	0	0	1	0	9	0	6	2	4	1	11 (6.1%)	22	2 (2.5%)	3
Lower Extremity – Motor	1	0	1	0	0	1	0	1	4	1	1	0	2	1	6 (3.4%)	9	4 (4.9%)	4
Lower Extremity – Reflex	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0 (0.0%)	0	1 (1.2%)	1
Upper & Lower Extremity - Sensory	0	1	0	0	0	0	0	0	1	0	0	0	0	0	1 (0.6%)	1	1 (1.2%)	1
Upper & Lower Extremity – Motor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Upper & Lower Extremity - Reflex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Neck	10	5	10	1	4	0	9	3	10	7	6	0	2	5	41 (22.9%)	51	21 (25.9%)	21
Back	1	0	0	0	1	0	2	0	1	1	1	1	2	0	7 (3.9%)	8	2 (2.5%)	2
Spinal Cord Disturbance	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Gait Disturbance	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1 (0.6%)	1	1 (1.2%)	1
Non Specific	5	0	1	0	0	0	0	0	0	1	0	0	0	0	6 (3.4%)	6	1 (1.2%)	1
Other*	3	0	7	1	3	2	6	0	7	7	11	3	4	2	35 (19.6%)	41	8 (9.9%)	15
Non-Union	0	0	0	1	0	0	0	1	0	2	0	0	0	0	0 (0.0%)	0	4 (4.9%)	4
Other**	17	8	14	10	7	3	12	9	25	19	25	9	14	8	77 (43.0%)	114	33 (40.7%)	66
Other Pain	12	3	18	7	33	27	29	18	60	29	48	35	26	25	102 (57.0%)	226	47 (58.0%)	144
Shoulder	4	1	6	2	6	7	8	2	12	5	12	8	7	6	39 (21.8%)	55	21 (25.9%)	31
Back	2	0	2	2	6	8	5	3	15	7	13	4	7	6	44 (24.6%)	50	18 (22.2%)	30
Torso	0	0	2	0	0	1	1	0	4	2	0	1	0	0	5 (2.8%)	7	3 (3.7%)	4
Lower Extremity	1	0	3	0	4	0	3	5	12	3	13	15	4	6	26 (14.5%)	40	12 (14.8%)	29
Headache	5	1	3	3	15	10	9	7	14	11	7	4	5	5	45 (25.1%)	58	26 (32.1%)	41
Other***	0	1	2	0	2	1	3	1	3	1	3	3	3	2	15 (8.4%)	16	8 (9.9%)	9
Respiratory	3	2	1	1	1	3	0	0	0	2	0	0	1	0	6 (3.4%)	6	6 (7.4%)	8
Spinal Disorder	2	0	0	2	0	0	2	0	1	7	2	1	0	2	6 (3.4%)	7	10 (12.3%)	12
Cervical - Study Surgery	0	0	0	1	0	0	0	0	1	1	0	0	0	0	1 (0.6%)	1	2 (2.5%)	2
Cervical - Non Study Surgery	2	0	0	1	0	0	2	0	0	1	2	0	0	1	5 (2.8%)	6	3 (3.7%)	3
Non Cervical	0	0	0	0	0	0	0	0	0	5	0	1	0	1	0 (0.0%)	0	5 (6.2%)	7
Trauma	1	1	14	2	9	7	7	9	22	9	9	6	8	4	47 (26.3%)	70	20 (24.7%)	38
Upper Extremity Nerve Entrapment	0	0	0	1	0	2	0	1	4	0	3	1	2	0	8 (4.5%)	9	4 (4.9%)	5
Urogenital	0	3	2	1	0	1	0	1	5	6	2	0	2	0	9 (5.0%)	11	9 (11.1%)	12
Vascular Intraop	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.6%)	1	0 (0.0%)	0

	Surgery to Discharge		Discharge to Week 6		Week 6 to Month 3		Months 3 to 6		Months 6 to 12		Months 12 to 18		Months 18 to 24		Mobi-C®		ACDF	
Complication	M	F	M	F	M	F	M	F	M	F	M	F	M	F	**#Patients (% of 179)**	**Total Events**	**#Patients (% of 81)**	**Total Events**
Wound Issue - Non-Infection	1	0	0	2	0	0	0	0	0	0	0	1	0	0	1 (0.6%)	1	3 (3.7%)	3
Hematoma	1	0	0	2	0	0	0	0	0	0	0	1	0	0	1 (0.6%)	1	3 (3.7%)	3
Hematoma Evacuation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CSF Leakage	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

M= All Mobi-C® Subjects; F = All ACDF Subjects

[1] Sum of all treatment emergent adverse events experienced in the study for each treatment group.

*Neurological Other includes Neurological events not appropriately defined elsewhere in the Neurological category. This includes amnesia, convulsion, facial neurologic events (dysaesthesia, hypoaesthesia), unexplained loss of consciousness, 'other' nerve compression, Parkinson's disease, and stroke.

**Other includes events not appropriately defined elsewhere. This includes adverse drug reactions, allergies, anemia, anxiety, arthritis, attention deficit disorder, benign neoplasm, blood & lymphatic system disorders, complications from other medical procedures, congenital defects, dehydration, dermatitis, diabetes, dizziness, ear/eye disorders, endocrine disorders, fatigue, feeling hot, fever, gout, high/low cholesterol, immune system disorders, injury/poisoning, lupus, menopause, miscarriage, muscle atrophy, nutritional disorders, obesity, osteoarthritis, osteoporosis, other inflammation, other medical procedures, plantar fasciitis, polyps, pregnancy, psychiatric disorders, rotator cuff syndrome, skin disorders, sinus infection, social issues, sleep disorders, swelling, tendonitis, thyroid conditions, vascular disorders, and weight gain/loss.

***Other Pain Other includes events not appropriately defined elsewhere. This includes facial pain, fibromyalgia, muscle soreness, chronic pain, nerve pain and arthritis.

Table 11. Adverse Event Categories and Subcategories

AE Category or Subcategory	Definition
Anatomy/Technical Difficulty	Includes surgical procedure related events, such as technical issues with the device or with the anatomy during surgery or post-operative. Where events are more accurately described in another category (such as 'Malpositioned Implant') they will be placed into the more accurate category.
Cervical – Study Surgery	Stratified by cervical study surgery related to illustrate clinical relevance to the study. Study Surgery is intended to mean the index level, or other events directly attributed to the study surgery or device. Includes technical issues with the device or with anatomy during surgery or post-operative.
Cervical – Non Study Surgery	Stratified by cervical non-study surgery related to illustrate clinical relevance to the study. This AE subcategory is unrelated (lacks clinical relevance) to the index level and is unrelated to study surgery.
Non-Cervical	Non Cervical captures non-study related events, such as technical difficulty with an unrelated procedure.
Cancer	All reported AEs of cancer (malignancy or malignant tumor/neoplasm).
Cardiovascular	All reported AEs of the cardiovascular system.
Death	All reports of death.
Dysphagia/Dysphonia	
Dysphagia	All reported AEs of Dysphagia and other terms consistent with "difficulty swallowing".
Dysphonia	All reported AEs of Dysphonia and other terms consistent with "voice change and/or disruption".
Gastrointestinal	All reported AEs of the gastrointestinal system, except those more appropriately categorized elsewhere.
Heterotopic Ossification	
Cervical – Index Level	All reported AEs of Heterotopic Ossification, stratified by cervical events at the index level.
Cervical – Adjacent Level	All reported AEs of Heterotopic Ossification, stratified by cervical events at the adjacent levels.
Non-Cervical	Events that occur outside of the cervical spine, or non-specific event reports, are displayed separately in this category.
Infection	
Superficial Wound - Cervical	Superficial Wound – superficial surgical incision or surgical wound related infections (includes only study surgery events).
Deep Wound - Cervical	Deep Wound – deep surgical incision or surgical wound related infections (includes only study surgery events).
Other Wound – Non Study Surgery	Other Wound – superficial and/or deep wound related events from non-study surgery.
Systemic	Systemic infections include infections such as Hepatitis and Influenza.
Local	Local infections include infections isolated to a specific region or organ.
Malpositioned Implant	All AE reports of Malpositioned Implant, such as 'misplaced screw' and 'subsidence'. The term Malpositioned indicates an implant or component that is reported in a sub optimal or undesired position, regardless of causality. This is not mutually exclusive to surgeon error or sub-optimal placement of the original implant configuration.
Neck and/or Arm Pain	All AE reports of pain (and related pain terms) specific to neck, arm, or neck and arm.
Neck Pain	All AE reports of pain (and related pain terms) specific to neck. Neck includes the anatomy consistent with the cervical spine (spinal disorders are recorded elsewhere).
Arm Pain	All AE reports of pain (and related pain terms) specific to arm.
Neck and Arm Pain	All AE reports of pain (and related pain terms) specific to neck and arm. Neck includes the anatomy consistent with the cervical spine (spinal disorders are recorded elsewhere).
Neurological	All neurological AEs defined further as follows.
Upper Extremity – Sensory	Upper Extremity - shoulder, arm and hand neurologic AEs stratified by sensory changes.
Upper Extremity – Motor	Upper Extremity - shoulder, arm and hand neurologic AEs stratified by motor changes.
Upper Extremity - Reflex	Upper Extremity - shoulder, arm and hand neurologic AEs stratified by reflex changes.
Lower Extremity – Sensory	Lower Extremity - hip, leg, buttocks, and foot neurologic AEs stratified by sensory changes.
Lower Extremity – Motor	Lower Extremity - hip, leg, buttocks, and foot neurologic AEs stratified by motor changes.
Lower Extremity - Reflex	Lower Extremity - hip, leg, buttocks, and foot neurologic AEs stratified by reflex changes.
Upper & Lower Extremity –Sensory	Upper & Lower Extremity – both, stratified by sensory changes.
Upper & Lower Extremity – Motor	Upper & Lower Extremity – both, stratified by motor changes.
Upper & Lower Extremity - Reflex	Upper & Lower Extremity – both, stratified by reflex changes.
Neck	Neck – includes neurologic AEs reported in the neck (including the cervical spine region) that were clearly identified as neurologic in nature according to the AE term reported by the investigator. This includes events such, burning and/or tingling sensation, muscle spasms and muscle stiffness and/or weakness in the neck. These events differ from "Neck Pain" because the primary reported term is neurological in nature as opposed to pain-related in nature.

AE Category or Subcategory	Definition
Back	Back – includes neurologic AEs reported in the back (including thoracic and lumbar regions) that were clearly identified as neurologic in nature according to the AE term reported by the investigator. This includes events such, numbness and/or tingling sensation, muscle spasms, and muscle stiffness and/or weakness in the back. These events differ from "Back Pain" because the primary reported term is neurological in nature as opposed to pain-related in nature.
Spinal Cord Disturbance	Includes AEs reported as resulting in spinal cord disturbance
Gait Disturbance	Includes AEs reported as resulting in gait disturbance.
Non Specific	Non-Specific - includes general neurological AEs such as 'tingling' or 'numbness' and neurological AEs of unspecified origin.
Other	Other - neurological events not otherwise defined above, such as 'facial neuralgia' and neurological diseases like Parkinson's.
Non-Union	All reported AEs of non-union, including cervical fusion failure, pseudarthrosis, and pending non-unions as reported. This category is limited to study surgery related events of non-union.
Other	Includes AEs not otherwise more appropriately defined by the remaining categories. Other included events classified as disorders of: Blood & Lymphatic System, Congenital/Genetic, Ear & Labyrinth, Endocrine, Eye, Immune System, Metabolism/Nutrition, Musculoskeletal & Connective Tissue, Benign Neoplasm, Nervous System, Psychiatric, Reproductive System, Skin, and Vascular System as well as events including Poisoning, Pregnancy, Social Circumstances, and Surgical/Medical procedures not defined elsewhere.
Other Pain	Includes AEs reported as pain specific to an anatomic region. This group is stratified as follows:
Shoulder	Shoulder –includes pain reported in the shoulder joint, scapula, clavicle, AC joint, and other reports of 'shoulder pain'.
Back	Back - includes pain reported in the thoracic, lumbar, and sacral spine, as well as other reports of back pain, such as low back pain.
Torso	Torso – includes pain reported in the torso region, including rib & abdominal region, and chest pains.
Lower Extremity	Lower Extremity – includes pain reported in the hip, buttock, thigh, knee, lower leg, ankle, foot, and other reports of 'lower extremity or leg pain'.
Headache	Headaches – includes all AE reports of headaches and pain from headache (including migraine).
Other	Other –includes all other Pain AE reports not categorized elsewhere.
Respiratory	All reported AEs of the respiratory system, except those more appropriately categorized elsewhere.
Spinal Disorder	Spinal Disorder consists of events reported as a spinal diagnosis/disorder, such as degenerative disc disease, disc herniation, stenosis, adjacent level degeneration, etc. As reported, these AEs are categorized as cervical and non-cervical and will be categorized on relatedness to study surgery.
Cervical – Study Surgery	AEs are categorized as cervical and will be categorized on relatedness to study surgery.
Cervical – Non Study Surgery	AEs are categorized as cervical and will be categorized on relatedness to study surgery.
Non-Cervical	Non-cervical includes events not related to the study surgery.
Trauma	Includes all AEs of trauma or similar terms, as reported. This includes falls, motor vehicle accidents, assault, injury, etc. This category includes both cervical and non-cervical AEs of Trauma.
Upper Extremity Nerve Entrapment	All reported AEs of Carpal Tunnel Syndrome and Cubital Tunnel Syndrome, including AEs directly attributed to Carpal Tunnel Syndrome or Cubital Tunnel Syndrome, as well as Carpal Tunnel surgery.
Urogenital	All reported AEs of the urogenital anatomy, except those more appropriately categorized elsewhere.
Vascular Intraop	Includes all vascular AEs from surgery or during surgery – such as excessive bleeding.
Wound Issue – Non Infection	
Hematoma	Hematoma categories will be populated according to the medical definition for these events and will only capture Study Surgery events.
Hematoma Evacuation	Hematoma categories will be populated according to the medical definition for these events and will only capture Study Surgery events.
CSF Leakage	CSF categories will be populated according to the medical definition for these events and will only capture Study Surgery events.

Table 12. All Treatment Emergent Adverse Events through 60 Months in US IDE Study – Safety Population

	Mobi-C®			ACDF		
Adverse Event Category & Subcategory	**#Patients (% of 179)**	**Total Events**	**Subject -Level CI***	**#Patients (% of 81)**	**Total Events**	**Subject -Level CI***
Anatomy/Technical Difficulty	12 (6.7%)	13	(3.5, 11.4)	2 (2.5%)	4	(0.3, 8.6)
Cervical – Non Study Surgery	6 (3.4%)	7	(1.2, 7.2)	1 (1.2%)	1	(0.0, 6.7)
Cervical –Study Surgery	4 (2.2%)	4	(0.6, 5.6)	2 (2.5%)	3	(0.3, 8.6)
Non-Cervical	2 (1.1%)	2	(0.1, 4.0)	0 (0.0%)	0	N/A
Cancer	5 (2.8%)	6	(1.3, 5.1)	3 (3.7%)	6	(1.4, 7.9)
Cardiovascular	26 (14.5%)	32	(11.0, 18.6)	12 (14.8%)	13	(9.7, 21.2)
Dysphagia/Dysphonia	21 (11.7%)	30	(7.4, 17.4)	17 (21.0%)	20	(12.7, 31.5)

Adverse Event Category & Subcategory	Mobi-C®			ACDF		
	#Patients (% of 179)	Total Events	Subject -Level CI*	#Patients (% of 81)	Total Events	Subject -Level CI*
Dysphagia	20 (11.2%)	26	(7.0, 16.7)	15 (18.5%)	17	(10.8, 28.7)
Dysphonia	3 (1.7%)	4	(0.3, 4.8)	3 (3.7%)	3	(0.8, 10.4)
Gastrointestinal	43 (24.0%)	71	(19.7, 28.8)	17 (21.0%)	43	(15.0, 28.1)
Heterotopic Ossification	13 (7.3%)	16	(3.9, 12.1)	4 (4.9%)	4	(1.4, 12.2)
Cervical - Adjacent Level	4 (2.2%)	4	(0.6, 5.6)	1 (1.2%)	1	(0.0, 6.7)
Cervical - Index Level	7 (3.9%)	7	(1.6, 7.9)	0 (0.0%)	0	N/A
Non Cervical	5 (2.8%)	5	(0.9, 6.4)	3 (3.7%)	3	(0.8, 10.4)
Infection	37 (20.7%)	61	(15.0, 27.3)	22 (27.2%)	37	(17.9, 38.2)
Local	24 (13.4%)	43	(8.8, 19.3)	20 (24.7%)	30	(15.8, 35.5)
Other Wound - Non Study Surgery	1 (0.6%)	1	(0.0, 3.1)	3 (3.7%)	3	(0.8, 10.4)
Superficial Wound – Cervical	6 (3.4%)	7	(1.2, 7.2)	1 (1.2%)	1	(0.0, 6.7)
Systemic	9 (5.0%)	10	(2.3, 9.3)	2 (2.5%)	3	(0.3, 8.6)
Malpositioned Implant	3 (1.7%)	3	(0.6, 3.6)	1 (1.2%)	1	(0.1, 4.4)
Neck and/or Arm Pain	112 (62.6%)	253	(55.0, 69.7)	48 (59.3%)	112	(47.8, 70.1)
Arm Pain	58 (32.4%)	93	(25.6, 39.8)	21 (25.9%)	30	(16.8, 36.9)
Neck And Arm Pain	9 (5.0%)	13	(2.3, 9.3)	7 (8.6%)	18	(3.5, 17.0)
Neck Pain	83 (46.4%)	147	(38.9, 54.0)	39 (48.1%)	64	(36.9, 59.5)
Neurological	127 (70.9%)	499	(63.7, 77.5)	55 (67.9%)	264	(56.6, 77.8)
Back	10 (5.6%)	11	(2.7, 10.0)	3 (3.7%)	3	(0.8, 10.4)
Gait Disturbance	2 (1.1%)	2	(0.1, 4.0)	2 (2.5%)	2	(0.3, 8.6)
Lower Extremity – Motor	7 (3.9%)	10	(1.6, 7.9)	4 (4.9%)	4	(1.4, 12.2)
Lower Extremity – Reflex	0 (0.0%)	0	N/A	1 (1.2%)	1	(0.0, 6.7)
Lower Extremity – Sensory	13 (7.3%)	27	(3.9, 12.1)	3 (3.7%)	5	(0.8, 10.4)
Neck	44 (24.6%)	56	(18.5, 31.6)	22 (27.2%)	24	(17.9, 38.2)
Non Specific	7 (3.9%)	7	(1.6, 7.9)	3 (3.7%)	3	(0.8, 10.4)
Other**	41 (22.9%)	54	(17.0, 29.8)	11 (13.6%)	23	(7.0, 23.0)
Upper & Lower Extremity - Sensory	1 (0.6%)	1	(0.0, 3.1)	1 (1.2%)	1	(0.0, 6.7)
Upper Extremity – Motor	28 (15.6%)	45	(10.7, 21.8)	18 (22.2%)	25	(13.7, 32.8)
Upper Extremity – Reflex	20 (11.2%)	59	(7.0, 16.7)	11 (13.6%)	27	(7.0, 23.0)
Upper Extremity – Sensory	75 (41.9%)	227	(34.6, 49.5)	34 (42.0%)	146	(31.1, 53.5)
Non-Union	0 (0.0%)	0	N/A	5 (6.2%)	5	(3.0, 11.1)
Other* **	90 (50.3%)	151	(45.0, 55.6)	35 (43.2%)	77	(35.5, 51.2)
Other Pain	117 (65.4%)	281	(57.9, 72.3)	56 (69.1%)	166	(57.9, 78.9)
Back	53 (29.6%)	65	(23.0, 36.9)	22 (27.2%)	37	(17.9, 38.2)
Headache	50 (27.9%)	67	(21.5, 35.1)	27 (33.3%)	45	(23.2, 44.7)
Lower Extremity	36 (20.1%)	54	(14.5, 26.7)	17 (21.0%)	37	(12.7, 31.5)
Other****	19 (10.6%)	20	(6.5, 16.1)	9 (11.1%)	10	(5.2, 20.0)
Shoulder	43 (24.0%)	63	(18.0, 31.0)	22 (27.2%)	33	(17.9, 38.2)
Torso	9 (5.0%)	12	(2.3. 9.3)	3 (3.7%)	4	(0.8, 10.4)
Respiratory	9 (5.0%)	11	(3.0, 7.8)	7 (8.6%)	9	(4.8, 14.1)
Spinal Disorder	13 (7.3%)	14	(3.9, 12.1)	12 (14.8%)	16	(7.9, 24.4)
Cervical - Non Study Surgery	7 (3.9%	8	(1.6, 7.9)	5 (6.2%)	6	(2.0, 13.8)
Cervical - Study Surgery	1 (0.6%)	1	(0.0, 3.1)	3 (3.7%)	3	(0.8, 10.4)
Non Cervical	5 (2.8%)	5	(0.9, 6.4)	5 (6.2%)	7	(2.0, 13.8)
Trauma	52 (29.1%)	85	(24.4, 34.1)	24 (29.6%)	45	(22.7, 37.3)
Upper Extremity Nerve Entrapment	11 (6.1%)	14	(3.9, 9.2)	4 (4.9%)	5	(2.2, 9.5)
Urogenital	13 (7.3%)	16	(4.8, 10.5)	11 (13.6%)	14	(8.7, 19.8)
Vascular Intraop	1 (0.6%)	1	(0.1, 2.0)	0 (0.0%)	0	N/A
Would Issue-Non-Infection	1 (0.6%)	1	(0.0, 3.1)	3 (3.7%)	3	(0.8, 10.4)
Hematoma	1 (0.6%)	1	(0.0, 3.1)	3 (3.7%)	3	(0.8, 10.4)

*The subject-level incidences of these outcomes are analyzed using a 95% two-sided Binomial exact confidence interval.

**Neurological Other includes Neurological events not appropriately defined elsewhere in the Neurological category. This includes amnesia, convulsion, facial neurologic events (dysaesthesia, hypoaesthesia), unexplained loss of consciousness, 'other' nerve compression, Parkinson's disease, and stroke.

***Other includes events not appropriately defined elsewhere. This includes adverse drug reactions, allergies, anemia, anxiety, arthritis, attention deficit disorder, benign neoplasm, blood & lymphatic system disorders, complications from other medical procedures, congenital defects, dehydration, dermatitis, diabetes, dizziness, ear/eye disorders, endocrine disorders, fatigue, feeling hot, fever, gout, high/low cholesterol, immune system

disorders, injury/poisoning, lupus, menopause, miscarriage, muscle atrophy, nutritional disorders, obesity, osteoarthritis, osteoporosis, other inflammation, other medical procedures, plantar fasciitis, polyps, pregnancy, psychiatric disorders, rotator cuff syndrome, skin disorders, sinus infection, social issues, sleep disorders, swelling, tendonitis, thyroid conditions, vascular disorders, and weight gain/loss.

****Other Pain Other includes events not appropriately defined elsewhere. This includes facial pain, fibromyalgia, muscle soreness, chronic pain, nerve pain and arthritis.

Adverse Events Resulting in Secondary Surgical Interventions

Some adverse events resulted in surgical intervention at the index level, subsequent to the initial surgery. Secondary surgical interventions, classified as revisions, removals, reoperations or supplemental fixations at the index level, qualify as study failures and are reported in **Table 13**, with details provided in **Table 14**. There were fewer secondary surgeries at the index level in the Mobi-C® group compared to the ACDF control group. With respect to subsequent surgical interventions, in total only 2 (1.2%) randomized Mobi-C® subjects and 5 (6.2%) control subjects reported subsequent surgical interventions qualifying as study failures (i.e. at the index level) through 24 months, with no non-randomized Mobi-C® subjects reporting subsequent surgical interventions qualifying as study failures.

Table 13. Secondary Surgical Interventions at the Index Level by Time - Safety Population

Type of Procedure	Intra-operative		6 Weeks		3 Months		6 Months		12 Months		18 Months		24 Months		≥24 Months		Total Patients (%)	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M (N=179)	F (N=81)
Revision	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1 (1.2%)
Reoperation	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1 (0.6%)	0
Removal	0	0	0	0	0	0	1	0	0	1	0	2	0	0	3	0	4 (2.2%)	3 (3.7%)
Supplemental Fixation	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	2	0	4 (4.9%)
Total	0	0	0	0	1	0	1	1	0	1	0	3	0	0	3	3	5 (2.8%)	8 (9.9%)

M= All Mobi-C® Subjects; F = All ACDF Subjects

Note – interval captures interventions between the two study time points.

Table 14. Secondary Surgical Interventions at the Index Level - Procedure Details

Group	Associated AE(s)	Secondary Surgical Intervention Detail	Months Post-Op*
M	Right C4-C5 radiculopathies	Reoperation - laparoscopic right C4-C5 cervical laminectomy	3
M	Radiculopathy & spondylosis	Removal of Mobi-C® and conversion to ACDF at the index level	5
M	Recurrent neck pain	Removal of Mobi-C® and conversion to ACDF at the index level	24
M	Device malpositioning	Removal of Mobi-C® and conversion to ACDF at the index level	31
M	Cervical discogenic pain	Removal of Mobi-C® and conversion to ACDF at the index level and at the adjacent level below	38
F	Foraminal stenosis and pseudarthrosis at the index level	Supplemental fixation in the form of posterior fusion instrumentation at the index level	6
F	Failure of fusion	Removal of ACDF hardware and repeat ACDF at the index level	12
F	Misplaced screw	Removal of ACDF hardware and addition of ACDF at the adjacent level below	13
F	Pseudarthrosis at the index level and herniated disc at adjacent level above	Removal of ACDF hardware and repeat ACDF at the index level and addition of ACDF at the adjacent level above and addition of ACDF two levels above (three level ACDF)	15
F	Pseudarthrosis at the index level and radiculopathy	Supplemental fixation in the form of posterior fusion instrumentation at the index level	16
F	Cervical stenosis	Supplemental fixation in the form of posterior fusion instrumentation at the index level and at the adjacent level above and two levels above (three level posterior fusion)	26
F	Pseudarthrosis at the index level	Supplemental fixation in the form of posterior fusion instrumentation at the index level	27
F	Stenosis - cervical spine	Removal of ACDF hardware and addition of ACDF at the adjacent level above	42

M = Mobi-C® Group; F= ACDF Control Group

*The number of months between the study surgery and the second surgery.

Note: There were zero (0) non-randomized Mobi-C® subjects experiencing study failure due to subsequent surgical intervention.

Device - Related Adverse Events

The relationship between adverse events and the implant (using a 4-tier classification of definitely device-related, possibly device-related, probably not device-related, or unrelated) was assessed separately by both Investigators and the Clinical Events Committee (CEC) from data coded according to Preferred Terms (PT) of the MedRA (Medical Dictionary for Regulatory Activities) Classification. The independent CEC reviewed all adverse events reported in the study and was included in the database for analysis.

Throughout the study, AEs were collected during the course of subject follow-up visits by the Investigators, and relationship was recorded. The AE data were then sent periodically to CEC members using CEC adjudication forms. These adjudication forms provided the adverse event term (verbatim), the date of study surgery, the date of event onset, the date of resolution, the event status, and the investigator's determination of relatedness. In addition, CEC members received narratives for all serious adverse events (SAEs) captured in the safety database. These materials were sent separately and concurrently to all three CEC members for adjudication. Each CEC member performed the adjudication independent from the other members. CEC members were also permitted to request additional information, including complete case report forms (CRFs) and radiographs, for individual subjects. The prevailing assessment among the three CEC members was entered in the database. The CEC used their expert medical judgment (including knowledge and experience as cervical spine surgeons) in conjunction with guidance from the study protocol to determine device relatedness to events.

According to both investigator and CEC assessment, the device-related adverse event profile is lower for the Mobi-C® group compared to the ACDF control group. Events classified as definitely device-related or possibly device-related were grouped together and analyzed as "device-related events". Through the primary endpoint (24 months), a larger percentage of ACDF subjects (24.7%) compared to both randomized (18.9%) and non-randomized (20.0%) Mobi-C® subjects reported device-related adverse events as determined by investigators. Similarly, as determined by the CEC, 28.4% of ACDF, 23.8% of randomized Mobi-C®, and 26.7% of nonrandomized Mobi-C® subjects experienced device-related adverse events. Device-related adverse events which occurred in greater than 5% of subjects in either treatment group (using the CEC determination) were neck pain (Mobi-C®, 7.8%, ACDF, 8.6%) , dysphagia (Mobi-C®, 4.5% , ACDF, 7.4%), and Upper Extremity Sensory (Mobi-C® 3.9%, ACDF 9.9%).

Table 15 provides additional and complete detail on device related adverse events and the determination of relationship by the investigator.

Table 15. Device-Related Adverse Events According to Investigator – Safety Population

	Mobi-C® (N=179)*		ACDF (N=81)	
Device Relationship of Adverse Event Determined by Investigator	**Events N**	**Patients N (%)**	**Events N**	**Patients N (%)**
Anatomy/Technical Difficulty	4	4 (2.2%)	4	2 (2.5%)
Cervical - Non Study Surgery	1	1 (0.6%)	1	1 (1.2%)
Cervical - Study Surgery	3	3 (1.7%)	3	2 (2.5%)
Cancer	0	0	0	0
Dysphagia/Dysphonia	9	8 (4.5%)	7	7 (8.6%)
Dysphagia	7	7 (3.9%)	7	7 (8.6%)
Dysphonia	2	2 (1.1%)	0	0
Heterotopic Ossification	3	3 (1.7%)	1	1 (1.2%)
Non Cervical	1	1 (0.6%)	0	0
Cervical - Index Level	2	2 (1.1%)	0	0
Cervical - Adjacent Level	0	0	1	1 (1.2%)
Malpositioned Implant	2	2 (1.1%)	1	1 (1.2%)
Neck and/or Arm Pain	29	15 (8.4%)	12	7 (8.6%)
Neck Pain	15	11 (6.1%)	6	6 (7.4%)
Arm Pain	10	4 (2.2%)	4	3 (3.7%)
Neck and Arm Pain	4	2 (1.1%)	2	1 (1.2%)
Neurological	22	15 (8.4%)	26	10 (12.3%)
Upper Extremity - Sensory	15	10 (5.6%)	18	7 (8.6%)
Neck	3	3 (1.7%)	3	3 (3.7%)
Upper Extremity - Motor	2	2 (1.1%)	3	2 (2.5%)
Other	0	0	2	2 (2.5%)
Lower Extremity - Motor	1	1 (0.6%)	0	0
Non Specific	1	1 (0.6%)	0	0
Non-Union	0	0	4	4 (4.9%)
Other Pain	8	7 (3.9%)	4	4 (4.9%)
Headache	5	5 (2.8%)	2	2 (2.5%)
Shoulder	2	2 (1.1%)	1	1 (1.2%)
Other	1	1 (0.6%)	1	1 (1.2%)
Spinal Disorder	1	1 (0.6%)	2	2 (2.5%)
Cervical - Study Surgery	1	1 (0.6%)	2	2 (2.5%)
Trauma	1	1 (0.6%)	1	1 (1.2%)
Wound Issue – Non-Infection	0	0	1	1 (1.2%)
Hematoma	0	0	1	1 (1.2%)

*Includes all Mobi-C® subjects, including randomized and training subjects.

Serious Adverse Events

In this study, a serious adverse event (SAE) was defined as an event meeting one or more of the following criteria: 1) resulted in death; 2) was life-threatening (immediate risk of death); 3) required inpatient hospitalization or prolonged hospitalization; 4) resulted in persistent or significant disability or incapacity; 5) necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure; or 6) was a congenital anomaly or birth defect.

The percentage of subjects experiencing an SAE was lower for Mobi-C® subjects compared to the ACDF control group subjects. Through 24 months, 25.9% of ACDF control subjects reported at least one SAE compared to 17.9% (32/179) of all Mobi-C® subjects (13.3% non-randomized Mobi-C®, 18.3% randomized Mobi-C®).

Table 16. Summary of Serious Adverse Events (SAE) by System Organ Class and Preferred Term through Month 24 - Safety Population

	Mobi-C® (N=179)*		ACDF (N=81)	
System Organ Class/Preferred Term	**Events N**	**Subjects N (%)**	**Events N**	**Subjects N (%)**
Anatomy/Technical Difficulty	1	1 (0.6%)	0	0
Cervical - Study Surgery	1	1 (0.6%)	0	0
Cancer	2	1 (0.6%)	1	1 (1.2%)
Colon Cancer	2	1 (0.6%)	0	0
Basal Cell Carcinoma	0	0	1	1 (1.2%)
Cardiovascular	4	4 (2.2%)	1	1 (1.2%)
Deep Vein Thrombosis	1	1 (0.6%)	0	0
Hypertension	1	1 (0.6%)	0	0
Hypotension	0	0	1	1 (1.2%)
Thrombosis	1	1 (0.6%)	0	0
Vertebral Artery Stenosis	1	1 (0.6%)	0	0

	Mobi-C® (N=179)*		ACDF (N=81)	
System Organ Class/Preferred Term	**Events N**	**Subjects N (%)**	**Events N**	**Subjects N (%)**
Dysphagia/Dysphonia	0	0	2	1 (1.2%)
Dysphagia	0	0	2	1 (1.2%)
Gastrointestinal	8	5 (2.8%)	2	1 (1.2%)
Abdominal Pain Lower	1	1 (0.6%)	0	0
Gastric Perforation	1	1 (0.6%)	0	0
Gastrointestinal Hemorrhage	1	1 (0.6%)	0	0
Gastrointestinal Motility Disorder	1	1 (0.6%)	0	0
Haematemesis	0	0	1	1 (1.2%)
Haematochezia	1	1 (0.6%)	0	0
Hepatitis Acute	1	1 (0.6%)	0	0
Ileal Ulcer	1	1 (0.6%)	0	0
Ileitis	1	1 (0.6%)	0	0
Nausea	0	0	1	1 (1.2%)
Heterotopic Ossification	1	1 (0.6%)	0	0
Non Cervical	1	1 (0.6%)	0	0
Infection	5	3 (1.7%)	6	4 (4.9%)
Systemic	1	1 (0.6%)	2	2 (2.5%)
Local	4	2 (1.1%)	4	4 (4.9%)
Malpositioned Implant	1	1 (0.6%)	1	1 (1.2%)
Medical Device Complication	1	1 (0.6%)	1	1 (1.2%)
Neck And/Or Arm Pain	4	3 (1.7%)	4	2 (2.5%)
Neck And Arm Pain	2	1 (0.6%)	2	1 (1.2%)
Arm Pain	1	1 (0.6%)	1	1 (1.2%)
Neck Pain	1	1 (0.6%)	1	1 (1.2%)
Neurological	8	5 (2.8%)	4	3 (3.7%)
Upper Extremity – Motor	1	1 (0.6%)	0	0
Lower Extremity – Motor	2	1 (0.6%)	0	0
Neck	2	2 (1.1%)	1	1 (1.2%)
Back	0	0	1	1 (1.2%)
Non Specific	0	0	1	1 (1.2%)
Other	3	2 (1.1%)	1	1 (1.2%)
Non-Union	0	0	5	5 (6.2%)
No Therapeutic Response	0	0	5	5 (6.2%)
Other	8	6 (3.4%)	1	1 (1.2%)
Breast Mass	1	1 (0.6%)	0	0
Device Failure	0	0	1	1 (1.2%)
Fatigue	1	1 (0.6%)	0	0
Foot Operation	1	1 (0.6%)	0	0
No Therapeutic Response	1	1 (0.6%)	0	0
Pregnancy	1	1 (0.6%)	0	0
Tendonitis	1	1 (0.6%)	0	0
Vision Blurred	1	1 (0.6%)	0	0
Visual Disturbance	1	1 (0.6%)	0	0
Other Pain	7	6 (3.4%)	4	4 (4.9%)
Shoulder	0	0	2	2 (2.5%)
Back	2	2 (1.1%)	2	2 (2.5%)
Lower Extremity	3	2 (1.1%)	0	0
Headache	2	2 (1.1%)	0	0
Respiratory	2	2 (1.1%)	1	1 (1.2%)
Acute Respiratory Failure	0	0	1	1 (1.2%)
Apnea	1	1 (0.6%)	0	0
Pneumothorax	1	1 (0.6%)	0	0
Spinal Disorder	3	3 (1.7%)	8	7 (8.6%)
Cervical - Study Surgery	1	1 (0.6%)	2	2 (2.5%)
Cervical - Non Study Surgery	2	2 (1.1%)	2	2 (2.5%)
Non Cervical	0	0	4	3 (3.7%)
Trauma	5	4 (2.2%)	8	5 (6.2%)
Rotator Cuff Syndrome	2	2 (1.1%)	2	2 (2.5%)
Fall	1	1 (0.6%)	1	1 (1.2%)
Tendon Rupture	2	1 (0.6%)	0	0
Cervical Vertebra Injury	0	0	1	1 (1.2%)
Limb Injury	0	0	1	1 (1.2%)
Physical Assault	0	0	1	1 (1.2%)

	Mobi-C® (N=179)*		ACDF (N=81)	
System Organ Class/Preferred Term	**Events N**	**Subjects N (%)**	**Events N**	**Subjects N (%)**
Road Traffic Accident	0	0	1	1 (1.2%)
Skin Laceration	0	0	1	1 (1.2%)
Urogenital	3	2 (1.1%)	0	0
Upper Extremity Nerve Entrapment	3	3 (1.7%)	2	1 (1.2%)
Wound Issue – Non-Infection	0	0	2	2 (2.5%)
Hematoma	0	0	2	2 (2.5%)

*Includes all Mobi-C® subjects, including randomized and training subjects.

Device-Related Serious Adverse Events

Serious adverse events classified as "device-related" were defined as serious events which were rated as "definitely device-related" or "possibly device-related". The percentage of subjects experiencing device-related serious adverse events was lower for Mobi-C® subjects compared to ACDF control group subjects. Based on classification by investigators, device-related serious adverse events were noted in 2.2% of all Mobi-C® subjects compared to 7.4% of ACDF subjects (**Table 17**). In Mobi-C® subjects device-related serious adverse events were noted in 3 randomized Mobi-C® subjects (1.8%) and 1 non-randomized Mobi-C® subject (6.7%).

Table 17. Device Related Serious Adverse Events

Group	Event Term(s)	Investigator Relationship to device*
M	1. Radiculopathy 2. Muscle twitching	1. Possibly 2. Possibly
M	1. Spinal ligament ossification 2. Neck pain	1. Definitely 2. Possibly
M	1. Intervertebral disc protrusion 2. Muscle weakness	1. Possibly 2. Possibly
M	1. Medical device complication (1-2 mm subsidence of superior endplate)	1. Possibly
4 Total w/ Related SAE	**7 Serious Adverse Events**	**7 Total Related SAE**
F	1. Pseudarthrosis 2. Radiculopathy	1. Possibly 2. Possibly
F	1. Pseudarthrosis	1. Definitely
F	1. Pseudarthrosis	1. Definitely
F	1 .Radiculitis cervical 2. Neck pain	1. Possibly 2. Definitely
F	1. Pseudarthrosis 2. Cervical vertebra injury 3. Intervertebral disc protrusion 4. Post procedural hematoma 5. Post procedural complication 6. Neck pain 7. Neck pain 8. Pain in extremity	1. Definitely 2. Possibly 3. Possibly 4. Possibly 5. Possibly 6. Possibly 7. Possibly 8. Possibly
F	1. Medical device complication (Misplaced screw)	1. Definitely
6 Total w/ Related SAE	**15 Serious Adverse Events**	**15 Total Related SAE**

M = Mobi-C® Group; F= ACDF Control Group

Note - Device Related SAEs were classified by the investigator as possibly or definitely related to study device.

*Relationship between an AE and the implant: this was assessed on the basis of the following definitions:

- Definitely device-related - there was a definitive causal and/or temporal connection between the AE and the device.
- Possibly device-related - there was a reasonable possibility that the AE may have been primarily caused by the device.
- Probably not device-related - there was no reasonable possibility that the AE may have been caused by the device.
- Unrelated - there was no causal connection between the AE and the device.

Neurological Status:

Neurologic status data is summarized in **Table 18**. Diminished neurological status resulted in study failure, and was assessed using a neurological status scale, based on five types of measurement parameters (motor, sensory-light touch, sensory-pin prick, reflexes, and gait assessment) at 24 months relative to pre-operative baseline.

The protocol-specified analysis defined neurologic deterioration as a decrease of two points in any of the treated level motor or reflex assessments or a decrease of one point for any of the treated level sensory tests. A secondary analysis using an FDA definition of change in neurologic status defined as any neurologic deterioration compared to baseline status was also performed. The randomized Mobi-C® subjects demonstrated numerically greater percentages of patients with stable/improved neurologic status than the control ACDF group at each time point for the protocol-specified definition for neurologic deterioration. The randomized Mobi-C® subjects demonstrated similar percentages of patients with stable/improved neurologic status compared to the control ACDF group for the FDA-specified definition for neurologic deterioration. No deterioration in spinal cord function or gait was observed in any study subjects.

Table 18. Neurological Status

Visit (months)	Status	Randomized Mobi-C® (N=164) Protocol Definition[1]	Non-Randomized Mobi-C® (N=15) Protocol Definition[1]	Randomized ACDF (N=81) Protocol Definition[1]	p-value*
6	No Deterioration Deterioration	150/154 (97.4%) 4/154 (2.6%)	13/14 (92.9%) 1/14 (7.1%)	66/69 (95.7%) 3/69 (4.4%)	p=0.6795
12	No Deterioration Deterioration	149/152 (98.0%) 3/152 (2.0%)	15/15 (100.0%) 0/15	63/69 (91.3%) 6/69 (8.7%)	p=0.0281
18	No Deterioration Deterioration	141/145 (97.2%) 4/145 (2.8%)	13/13 (100.0%) 0/13	58/61 (95.1%) 3/61 (4.9%)	p=0.4248
24	No Deterioration Deterioration	151/154 (98.1%) 3/154 (1.9%)	15/15 (100.0%) 0/15	68/70 (97.1%) 2/70 (2.9%)	p=0.6489
Visit (months)	**Status**	**Randomized Mobi-C® (N=164) FDA Definition[2]**	**Non-Randomized Mobi-C® (N=15) FDA Definition[2]**	**Randomized ACDF (N=81) FDA Definition[2]**	**p-value***
6	No Deterioration Deterioration	141/154 (91.6%) 13/154 (8.4%)	11/14 (78.6%) 3/14 (21.4%)	64/69 (92.8%) 5/69 (7.2%)	p=1.0000
12	No Deterioration Deterioration	139/152 (91.4%) 13/152 (8.6%)	14/15 (93.3%) 1/15 (6.7%)	59/69 (85.5%) 10/69 (14.5%)	p=0.2337
18	No Deterioration Deterioration	134/145 (92.4%) 11/145 (7.6%)	12/13 (92.3%) 1/13 (7.7%)	54/61 (88.5%) 7/61 (11.5%)	p=0.4195
24	No Deterioration Deterioration	146154 (94.8%) 8/154 (5.2%)	15/15 (100.0%) 0/15	67/70 (95.7%) 3/70 (4.3%)	p=1.0000

*Using Fisher Exact test to compare frequencies between the treatments.

[1] Study protocol definition of neurologic failure defined as a decrease of two points in any of the treated level motor or reflex assessments or a decrease of one point for any of the treated level sensory tests.

[2] FDA definition of neurologic failure defined as any neurologic deterioration compared to baseline status.

Adjacent Level Symptoms and Treatments

Data regarding radiographic changes resulting from adjacent segment radiographic degeneration was reported as a secondary radiographic endpoint. Serious adverse events (SAEs) were closely tracked and data which is known regarding adjacent level SAEs is discussed here. Regarding SAEs occurring at an adjacent level during the primary analysis study period (through 24 months), fewer Mobi-C® subjects (1.7%, 3/179) reported such events compared to ACDF control subjects (7.4%, 6/81). Following 24 month follow-up, three subjects have experienced or reported new adjacent level SAEs including 1 subject in the ACDF group (adjacent level herniated nucleus pulposus) and two subjects in the Mobi-C® group (both subjects developed an adjacent level herniated nucleus pulposus) bringing the combined total known adjacent level SAE rate to (2.8%, 5/179) in the Mobi-C® group and (8.6%, 7/81) in the ACDF group. Secondary surgeries reported at adjacent levels were also documented, and reported in **Table 19.** This table reports all known adjacent level surgeries, including those reported beyond the primary analysis endpoint. Fewer Mobi-C® subjects (1.7%, 3/179) reported such events compared to ACDF control subjects (7.4%, 6/81).

Table 19. Secondary Surgical Interventions at Level Adjacent to Index Level

Group	Index Level	Study Surgery Date	Event Term(s)	Time to Adjacent Level Surgery	Description of Subsequent Adjacent Level Surgery
M	C5-6	16 Feb 2007	C4-5 Herniated nucleus pulposus	18 months	Index level implant intact, adjacent level anterior discectomy and fusion at C4-5.
M	C5-6	20 Feb 2007	C6-7 Cervical discogenic pain	3 years, 2 months	Removal of the implant at index level and adjacent level anterior discectomy; two level fusion C5-6 & C6-7
M	C6-7	30 Jan 2007	C5-6 Cervical spondylosis	4 years, 4 months	Index level implant intact, adjacent level anterior discectomy and fusion at C5-6
F	C4-5	22 May 2007	C5-6 Misplaced screw	1 year	Removal of implant at index level and adjacent level anterior discectomy; two level fusion C4-5 & C5-6
F	C5-6	23 Aug 2007	C4-5 Herniated nucleus pulposus	1 year, 2 months	Removal of implant at index level and adjacent level anterior discectomy with additional discectomy above adjacent level; three level fusion C3-4, C4-5, & C5-6
F	C5-6	27 Jul 2007	C6-7 Foraminal disc herniation	1 year, 8 months	Index level implant intact, adjacent level anterior discectomy and fusion at C6-7
F	C5-6	30 Oct 2007	C3-6 Cervical stenosis	2 years, 2 months	Posterior decompression at index level, adjacent level, and level above adjacent level; three level posterior supplemental fixation fusion C3-4, C4-5, & C5-6
F	C6-7	13 Dec 2006	C5-6 Cervical stenosis	3 years, 8 months	Removal of implant at index level and adjacent level anterior discectomy; one level fusion C5-6
F	C5-6	09 Mar 2007	C6-7 Herniated nucleus pulposus	4 years, 4 months	Removal of implant at index level and adjacent level anterior discectomy; one level fusion C6-7

M = Mobi-C® Group; F= ACDF Control Group

Effectiveness Results

Primary Effectiveness Analysis

The analysis of effectiveness was based on the Primary Analysis Population of 245 total patients with surgery (164 randomized Mobi-C® patients, and 81 ACDF patients). The hypothesis for the study was that the Mobi-C® study device would be non-inferior to conventional ACDF, using allograft corticocancellous bone followed by placement of a semi-constrained, rotational anterior cervical plate, with respect to the rate of individual subject success. The analysis goal was to establish non-inferiority using a composite success measure. The primary endpoint of the study was individual patient success defined as: 1) improvement in NDI at 24 months as compared to baseline (date of surgery), 2) absence of protocol defined Subsequent Surgical Intervention (i.e. index level Removal, Revision, Reoperation, or Supplemental Fixation), and 3) absence of major complications. There were three specific types of major complications defined as failures: 1) neurologic deterioration, 2) radiologic failure (bridging bone and lack of motion at the index level for Mobi-C® subjects; failure of fusion for ACDF subjects), and 3) adverse events determined to be major complications and related to the study device (as determined by the independent CEC oversight committee). Fusion in ACDF control subjects was defined as evidence of bridging trabecular bone and < 2° total angular motion (from flexion to extension) and < 50% radiolucency along the graft/endplate interface. For Mobi-C® subjects, radiologic failure was defined as evidence of continuous bridging bone and < 2° total angular motion (from flexion to extension). An alternative primary endpoint analysis was prospectively planned to assess subject success when major complications due to radiographic assessment were removed from the analysis. Non-inferiority was tested using an exact 95% one-sided confidence bound for the difference between the study and control success rates; if a 10% offset could be ruled out according to the 95% lower bound, then superiority was to be tested. A closed testing procedure was used to allow for superiority to be tested in the event that non-inferiority was established for the primary effectiveness endpoint. A similar approach was used for the secondary effectiveness endpoints.

The individual patient success rate was defined in the original IDE protocol as the number of patients classified as success divided by the number of patients evaluated at 24 months. The overall success rates at 24 months postoperative and the success rates for each of the individual success components is provided in **Table 20**. The composite success rate seen for Mobi-C® subjects was 73.7% at the 24-month visit, 8.4% higher than the 65.3% success rate observed in the ACDF subjects. The protocol specified that the trial would successfully demonstrate non-inferiority if the exact 95% one-sided confidence bound for the difference between the Mobi-C® and control success rate ruled out a 10% offset. The results of the primary composite endpoint analysis demonstrated a lower bound for the 95% one-sided confidence bound of the success rate of -2.35%, higher than the required -10% non-inferiority margin. Therefore, the results of the primary composite endpoint analysis demonstrated non-inferiority of Mobi-C® compared to control. **Table 21** shows the alternative primary endpoint analysis (Variation 1) which confirms the primary analysis results. Although higher success rates under Variation 1 in the ACDF group led to smaller differences between groups, non-inferiority was confirmed on a statistical basis**. Table 22** includes data for the protocol specified primary endpoint, the protocol specified variation 1 of the primary endpoint, the FDA requested primary endpoint, and the FDA requested variation 1 of the primary endpoint.

Table 20. Overall Success (Protocol -Specified) at 24 Months

Component	Non-Randomized Mobi-C® (N=15)	Randomized Mobi-C® (N=164)	Randomized ACDF (N=81)	p-value
NDI Improvement	14/15 (93.3%)	123/155 (79.4%)	54/70 (77.1%)	p=0.7271**
No failure due to Subsequent Surgery	15/15 (100%)	162/164 (98.8%)	76/81 (93.8%)	p=0.0414**
No Major Complications	15/15 (100%)	151/164 (92.1%)	69/81 (85.2%)	p=0.1163**
Overall Success	14/15 (93.3%)	115/156 (73.7%)	49/75 (65.3%)	p=0.2162**

*Patients 101-060 (ACDF), 103-031 (ACDF), 106-053 (ACDF), 107-019 (ACDF), 114-021 (ACDF), and 114-065 (Mobi-C®), have had their data censored after a revision, removal, or supplemental fixation surgery.
**Using Fisher Exact test to compare frequencies between the treatments.

Table 21. Overall Success (Alternative Primary Endpoint Variation 1) at 24 Months

Component	Non-Randomized Mobi-C® (N=15)	Randomized Mobi-C® (N=164)	Randomized ACDF (N=81)	p-value
NDI Improvement	14/15 (93.3%)	123/155 (79.4%)	54/70 (77.1%)	p=0.7271**
No failure due to Subsequent Surgery	15/15 (100%)	162/164 (98.8%)	76/81 (93.8%)	p=0.0414**
No Major Complications	15/15 (100%)	156/164 (95.1%)	77/81 (95.1%)	p=1.000**
Overall Success	14/15 (93.3%)	119/156 (76.3%)	54/75 (72.0%)	p=0.5185**

*Patients 101-060 (ACDF), 103-031 (ACDF), 106-053 (ACDF), 107-019 (ACDF), 114-021 (ACDF), and 114-065 (Mobi-C®), have had their data censored after a revision, removal, or supplemental fixation surgery.
**Using Fisher Exact test to compare frequencies between the treatments.
Variation 1 definition utilizes the composite endpoint with the radiographic component of major complication being removed from consideration.

Table 22. Detail - Timecourse of Overall Success

		6 mo	12 mo	24 mo	36 mo
Protocol – Specified Definition	**NR Mobi-C®(N=15)**	12/14 (85.7%)	12/15 (80.0%)	14/15 (93.3%)	11/15 (73.3%)
	R Mobi-C® (N=164)	117/156 (75.0%)	115/152 (75.7%)	115/156 (73.6%)	95/136 (69.9%)
	R ACDF (N=81)	29/70 (41.4%)	36/69 (52.2%)	49/75 (65.3%)	37/63 (58.7%)
Protocol – Specified Definition (Variation 1)	**NR Mobi-C® (N=15)**	12/14 (85.7%)	12/15 (80.0%)	14/15 (93.3%)	11/15 (73.3%)
	R Mobi-C® (N=164)	117/156 (75.0%)	116/152 (76.3%)	119/156 (76.3%)	105/141 (74.5%)
	R ACDF (N=81)	45/70 (64.3%)	44/69 (63.8%)	54/75 (72.0%)	40/64 (62.5%)
FDA Defined Alternative Definition	**NR Mobi-C® (N=15)**	10/14 (71.4%)	11/15 (73.3%)	13/15 (86.7%)	11/15 (73.3%)
	R Mobi-C® (N=164)	108/156 (69.2%)	105/152 (69.1%)	111/156 (71.2%)	92/137 (67.2%)
	R ACDF (N=81)	27/70 (38.6%)	32/69 (46.4%)	45/75 (60.0%)	36/63 (57.1%)
***FDA Defined Alternative Definition (Variation 1)**	**NR Mobi-C® (N=15)**	10/14 (71.4%)	11/15 (73.3%)	13/15 (86.7%)	11/15 (73.3%)
	R Mobi-C® (N=164)	108/156 (69.2%)	106/152 (69.7%)	115/156 (73.7%)	101/141 (71.6%)
	R ACDF (N=81)	41/70 (58.6%)	38/69 (55.1%)	50/75 (66.7%)	39/64 (60.9%)

NR Mobi-C®=Non-randomized Mobi-C®; R Mobi-C®=Randomized Mobi-C®; R ACDF=Control
Protocol specified definition utilizes a two point reduction in any motor or reflex assessment or one point reduction in sensory assessment at the treated level as the definition of neurologic deterioration.
Variation 1 definition utilizes the composite endpoint with the radiographic component of major complication being removed from consideration.
FDA Alternative definition counts any subject with any neurological deterioration compared to baseline status at the treated level as a failure due to a neurological major complication at that timepoint.

**FDA Defined Alternative Definition (Variation 1)* includes both the FDA Alternative definitions of neurological major complication (counts any subject with any neurological deterioration compared to baseline status at the treated level as a failure due to neurological major complication at that timepoint) and Variation 1 (the composite endpoint with the radiographic component of major complication being removed from consideration).
Note: Percentages are based on the number of available observations.

Table 23 provides data on overall success in each treatment group stratified by level treated. There were no statistical differences in overall success between the randomized groups at C3-4, C4-5, C5-6 and C6-7 according to the protocol-specified definition.

Table 23. Primary Effectiveness Analyses by Level Treated at 24 Months

	Success in Non-Randomized Mobi-C Group (N=15)	Success in Mobi-C® Randomized Group: n/N' – (proportion: pm) (N=164)	Success in ACDF Randomized Group: n/N' (proportion: pc) (N=81)	Difference/Lower Bound* for pm-pc (ITT)
PROTOCOL-SPECIFIED				
Treated Segment: C3-C4	(N=0)	(N=1)	(N=4)	
Month 24	0	1/ 1 (1.0000)	3/ 4 (0.7500)	0.2500/-0.1061
Treated Segment: C4-C5	(N=0)	(N=11)	(N=2)	
Month 24	0	6/11 (0.5455)	1/ 2 (0.5000)	0.0455/-0.5863
Treated Segment: C5-C6	(N=8)	(N=92)	(N=46)	
Month 24	7/8 (0.8750)	67/88 (0.7614)	26/42 (0.6190)	0.1423/-0.0018
Treated Segment: C6-C7	(N=7)	(N=60)	(N=29)	
Month 24	7/7 (1.0000)	41/56 (0.7321)	19/27 (0.7037)	0.0284/-0.1458
VARIATION 1				
Treated Segment: C3-C4	(N=0)	(N=1)	(N=4)	
Month 24	0	1/ 1 (1.0000)	3/ 4 (0.7500)	0.2500/-0.1061
Treated Segment: C4-C5	(N=0)	(N=11)	(N=2)	
Month 24	0	6/11 (0.5455)	1/ 2 (0.5000)	0.0455/-0.5863
Treated Segment: C5-C6	(N=8)	(N=92)	(N=46)	
Month 24	7/8 (0.8750)	69/88 (0.7841)	28/42 (0.6667)	0.1174/-0.0223
Treated Segment: C6-C7	(N=7)	(N=60)	(N=29)	
Month 24	7/7 (1.0000)	43/56 (0.7679)	22/27 (0.8148)	-0.0470/-0.2010

* The 95% one-sided confidence bound is presented for testing non-inferiority of Mobi-C® using two proportion test with a 10% non-inferiority margin.
Note: Proportions are based on the number of available observations.
Note: Primary effectiveness analysis variation 1 is the composite endpoint with the radiographic component of major complication being removed from consideration.

Subgroup Analyses
Subgroup analyses examining the primary endpoint success rate and its NDI success component by subgroup were conducted, and the results for the 24 Month Visit are summarized in **Table 24**. The Mobi-C® primary endpoint success rates were higher in every age, race, and gender subgroup with the exception of those subjects < 40 years of age, in which both treatment groups demonstrated an identical 64.7% success rate.

Table 24. Primary Effectiveness Subgroup Analyses at Month 24 - Primary Analysis Population

Subgroup	Success in Randomized Mobi-C® (N=164)	Success in Randomized ACDF (N=81)	P-Value*	P-Value**
Age				
<40 years	33/51 (0.6471)	11/17 (0.6471)	0.2364	>0.9999
40 - <50 years	52/68 (0.7647)	27/40 (0.6750)	0.0163	0.3705
>50 years	30/37 (0.8108)	11/18 (0.6111)	0.0106	0.1855
Race				
Caucasian	109/144 (0.7569)	43/64 (0.6719)	0.0026	0.2364
Black or African American	3/4 (0.7500)	6/9 (0.6667)	0.6561	>0.9999
Other***	3/8 (0.3750)	0/2	0.1765	>0.9999
Gender				
Male	56/74 (0.7568)	24/33 (0.7273)	0.0759	0.8111
Female	59/82 (0.7195)	25/42 (0.5952)	0.0060	0.2230

*Using Farrington-Manning test to compare between the treatments.
**Fisher Exact test to compare the frequencies between the treatments.
***Other consists of the following classifications: American Indian or Alaska Native, Asian, Native Hawaiian/other Pacific Islander, or Other.
Note: Percentages are based on the number of available observations.

Secondary Effectiveness Analysis

In addition to the components of the primary endpoint presented above, secondary effectiveness variables were also assessed for the Primary Analysis population. Thirteen secondary endpoints were measured at the 24 Month Visit compared to baseline:

- Neck pain
- Arm pain
- Muscle strength
- Sensory deficit
- Significant neurological deterioration
- Adjacent segment degeneration
- Displacement or migration of the device, graft, or plate
- Range of motion
- Absence of radiolucency
- Patient satisfaction.
- Qualify of life (SF-12)
- Dysphagia - Functional outcome swallowing scale (FOSS)• Observational gait analysis using Nurick's classification of cervical spondylotic myelopathy (CSM).

Pre-defined sequential testing was outlined for five secondary endpoints using the following pre-defined sequential testing order: Neck Disability Index, dysphagia (FOSS), SF-12(PCS), subject satisfaction, and VAS neck pain. Non-inferiority was tested first before superiority was tested with the exception of dysphagia where only superiority was tested. Endpoints were tested in the stated order until significance was no longer achieved and the testing was stopped at that point. The following secondary endpoint success definitions were specified:

- Neck disability index: 10%, 24 Months
- Dysphagia (graded Stage 0 – Stage V): Overall/6 weeks/3 months/6 months
- SF-12 PCS: 5 units, 24 Months
- Patient Satisfaction (1 question answered on a 4 point scale): 0.4 units, 24 Months
- VAS neck pain: 10 mm, 24 Months

Table 25. Secondary Effectiveness Patient Outcomes at 24 Months

Component	R Mobi-C® (N=164)	R ACDF (N=81)
Neck Disability Index Improvement[1]	134/156 (85.9%)	58/75 (77.3%)
VAS Neck Pain Improvement[2]	122/156 (78.2%)	56/75 (74.7%)
VAS Left Arm Pain Improvement[2]	78/156 (50.0%)	42/75 (56.0%)
VAS Right Arm Pain Improvement[2]	75/156 (47.4%)	27/75 (36.0%)
SF-12 PCS[3]	121/148 (81.8%)	49/67 (73.1%)
SF-12 MCS[3]	78/148 (52.7%)	36/67 (53.7%)
Satisfaction[4]	138/164 (89.0%)	59/81 (84.3%)
Recommendation[5]	134/164 (87.0%)	59/81 (84.3%)

[1] Defined as ≥ 15 point improvement from baseline.
[2] Defined as > 20 mm improvement from baseline.
[3] Defined as ≥ 15% improvement from baseline.
[4] Patient response of "Very Satisfied" to Question: How satisfied are you with the surgical treatment you received?
[5] Patient response of "Definitely Yes" to Question: Would you recommend the same treatment to a friend with the same condition?

Radiographic Assessments

Range of Motion

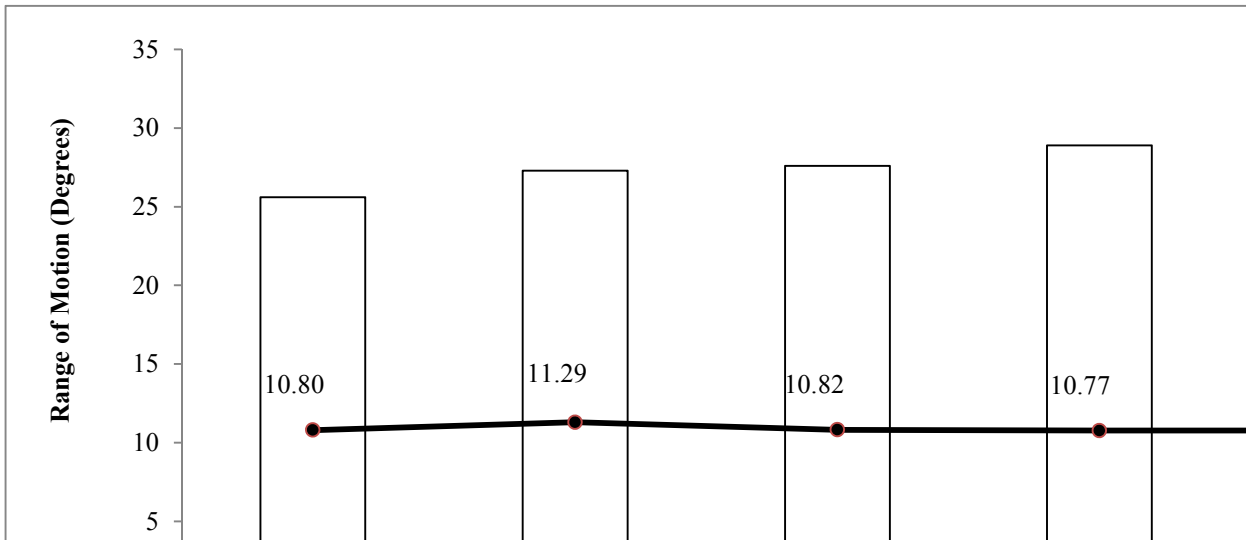
Radiographic evaluation of mean ranges of motion for flexion/extension bending and left/right lateral bending for the treated level at the preoperative, 12 month, and 24 month time point are shown in **Table 26** for all subjects. The range of motion for flexion/extension at months 3 through 24 for Mobi-C® is shown in **Figure 3**. Anticipated differences between ACDF and Mobi-C® were noted in view of differing modes of action (fusion vs. motion preservation). At the 24 Month Visit, Mobi-C® mean values were 10.78° (±6.4°) for flexion/extension bending and 5.4° (±3.1°) for left/right lateral bending. ACDF values were 0.88° (±0.9°) for flexion/extension bending and 0.8° (±0.6°) for left/right lateral bending.

Table 26. Radiographic Range of Motion

Component	Preoperative			12 months			24 months		
	T (N=15)	M (N=155)	F (N=78)	T (N=14)	M (N=149)	F (N=67)	T (N=14)	M (N=154)	F (N=68)
Range of Motion (°) Flexion-Extension	8.59 ±4.918	8.21 ±4.493	7.48 ±4.066	6.94 ±5.288	10.82 ±5.853	1.14 ±1.077	9.32 ±6.707	10.78 ±6.469	0.88 ±0.952
Component	**Preoperative**			**12 months**			**24 months**		
	T (N=14)	**M (N=155)**	**F (N=76)**	**T (N=15)**	**M (N=149)**	**F (N=65)**	**T (N=15)**	**M (N=155)**	**F (N=69)**
Range of Motion (°) Lateral Bending	4.84 ±2.370	5.04 ±2.897	5.38 ±3.218	5.37 ±3.367	5.70 ±3.218	1.33 ±1.591	5.67 ±4.207	5.44 ±3.095	0.84 ±0.637

T = Non-randomized Mobi-C®; M = Randomized Mobi-C®; F = ACDF Control Randomized

Figure 3. Mobi-C® Time Course of Mean Flexion/Extension Range of Motion



The protocol-specified range of motion (ROM) success criteria for Mobi-C® subjects required ROM greater than or equal to 2° in flexion-extension and lack of bridging bone at the index level. The criteria for fusion in the ACDF group required development of bridging bone and < 2° of angular motion. In the Primary Analysis population, 89.0% (138/155) randomized Mobi-C® subjects achieved ROM success according to the protocol specified criteria (≥ 2° ROM with no bridging bone) while 8.4% (13/155) of Mobi-C® subjects were ROM failures (< 2° ROM with bridging bone). FDA requested a secondary analysis using the ROM success criteria of ≥4 ° flexion-extension motion which demonstrated that 83.9% (130/155) Mobi-C® subjects achieved ROM success while 13.5% (21/155) of randomized Mobi-C® subjects were ROM failures (≤ 4° ROM).

Table 27 presents data on change in range of motion from preoperative baseline to Month 24 for the primary analysis endpoint. In total, 42/170 (24.7%) experienced a decrease in ROM of greater than 2 degrees, though many of these subjects did not experience bridging bone and were therefore not ROM failures by protocol definition.

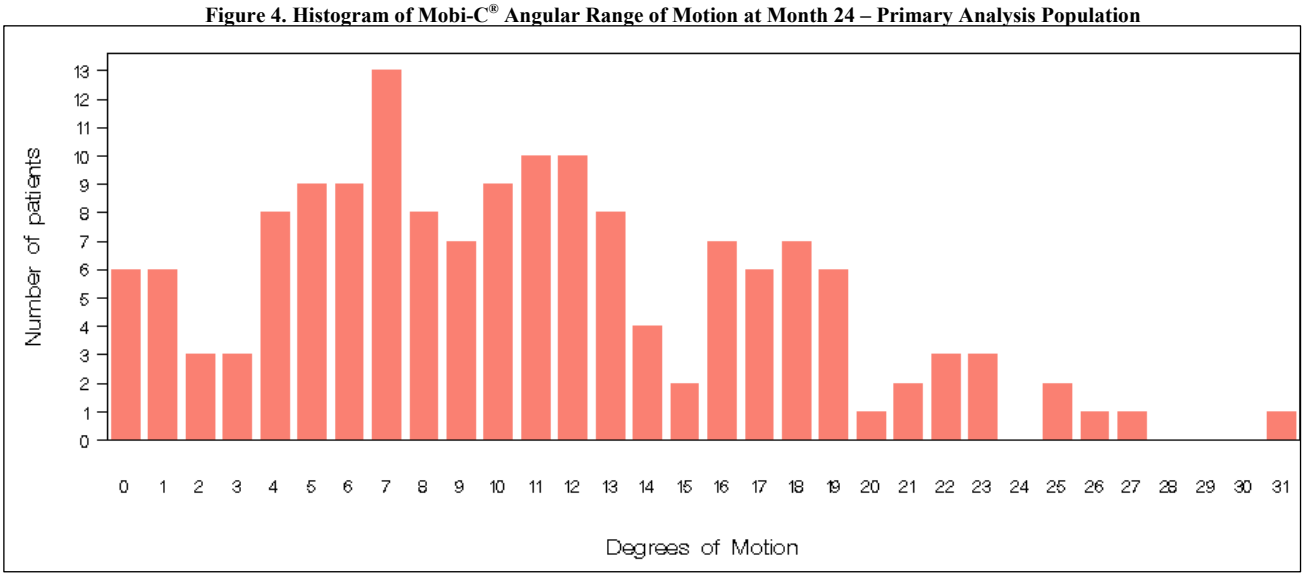
Table 27. Radiographic Change in Range of Motion for Mobi-C®

		24 Month
NR Mobi-C® n=15	Increased (≥2°)	6(40.0%)
	No change (≥-2° to <2°)	2 (13.3%)
	Decreased (<-2°)	6 (40.0%)
R Mobi-C® n=155	Increased (≥2°)	74 (47.7%)
	No change (≥-2° to <2°)	32 (20.6%)
	Decreased (<-2°)	36 (23.2%)
All Mobi-C® n=170	Increased (≥2°)	80 (47.1%)
	No change (≥-2° to <2°)	34 (20.0%)
	Decreased (<-2°)	42 (24.7%)

Note: Patients 101-060 (ACDF), 103-031 (ACDF), 106-053 (ACDF), 107-019 (ACDF), 114-021 (ACDF), and 114-065 (Mobi-C®), have had their data censored after a revision, removal, or supplemental fixation surgery.

A histogram of angular range of motion on flexion/extension radiographs at 24 months for all patients treated with Mobi-C® is provided in **Figure 4** below. This histogram uses values obtained by rounding recorded range of motion for each subject to the nearest integer.

Figure 4. Histogram of Mobi-C® Angular Range of Motion at Month 24 – Primary Analysis Population



Fusion
For control subjects, failure of fusion of the treated level was defined as ≥ 2° of segmental movement on lateral flexion-extension X-rays, radiolucent lines at greater than 50% of the graft-vertebral interfaces or lack of evidence of bridging trabecular bone . This assessment was determined by independent qualitative radiographic analysis of the 24 month radiographs, in accordance with the study protocol. Fusion status of the control ACDF group at the 6 month, 12 month and 24 month time points is provided in **Table 28**.

Table 28. Radiographic Fusion Status for Control ACDF

	6 mo	12 mo	24 mo
Fusion status	42/69 (60.9%)	57/69 (82.7%)	67/75 (89.3%)

Radiolucency
Radiolucency was evaluated using a qualitative scale as defined in the study protocol as: none, mild (< 25%), moderate (25-50%), or severe (>50%). Radiolucency was assessed in 2 Mobi-C® subjects at the 24 Month Visit (1.3%), and in 2 ACDF subjects at the 24 Month Visit (2.9%), and in all cases was reported as mild in severity (≤ 25% coverage of radiolucent lines along the device/endplate interface) in both treatment groups.

Subsidence or Migration of the Device, Graft or Cage
Subsidence was defined in the study protocol as ≥ 3 mm cranial or caudal motion of the device (or device component) perpendicular to the vertebral endplates. Migration was defined in the study protocol as ≥ 3 mm anterior or posterior motion of the device (or device component) parallel to the vertebral endplates. The radiographic assessments revealed no cases of migration or subsidence according to this definition in either treatment group.

Functional Spinal Unit (FSU) Height Change
Radiographic disc height was assessed by an independent radiographic core laboratory according to the study protocol. Functional Spinal Unit height measurements were collected preoperatively, postoperatively (at discharge) and again at study follow-up visits. Change in FSU was calculated by subtracting the FSU height at the follow up visit from the FSU height postoperatively (at discharge) in order to compare the ability of the two treatments to maintain disc height. Mean change from postoperative FSU height ranged from -0.27 mm (6 weeks post-op) to -0.41 mm (24 months post op) in the randomized Mobi-C® subjects, compared with -0.71 mm (6 weeks post-op) to -0.88 mm (24 months post op) in the ACDF group. The difference between groups was statistically significant ($p<0.0001$) at every follow-up time point indicating that Mobi-C® subjects experienced less loss of FSU height after surgery.

Table 29. Radiographic Disc FSU Height – Safety Population

	Pre-Operative			24 Months		
	T (N=15)	M (N=160)	F (N=81)	T (N=15)	M (N=154)	F (N=69)
FSU Height & (SD) mm	29.31 (2.413)	29.29 (2.785)	28.97 (2.684)	30.81 (2.144)	30.79 (2.642)	29.55 (2.674)
FSU Change* & (SD) mm	-	-	-	-0.45 (0.336)	-0.41 (0.427)	-0.88 (0.832)

T = Non-randomized Mobi-C®; M = Randomized Mobi-C®; F = ACDF Control Randomized
* Change calculated as difference between Post-Operative FSU Height and FSU Height at timepoint. All available radiographs used in the analysis.
Note – SD stands for Standard Deviation.

Table 30. Summary of FSU Height Change at 24 Months for ITT Population – Radiographic Measurements

Component	Randomized Mobi-C®	Randomized ACDF	P-Value
Disc Height Change	-0.41 ± 0.427	-0.88 ± 0.832	<0.0001

* Using unpaired t-test to compare the change from baseline value between the treatments.
Note: Patients 101060, 103031, 104022, 105009, 106053, 107008, 107019, 111008, 111014, 114065, and 114021 have had their data censored after a revision, removal, or supplemental fixation surgery.

Heterotopic Ossification
Available radiographs for all treated Mobi-C® patients at the 6, 12, 24 month and later time points were assessed for heterotopic ossification (HO) by two independent radiologists and a third radiologist to adjudicate in instances of disagreement using a classification system adapted from McAfee (4) and Mehren (5).

Radiographs were assessed to determine the HO grade (**Table 31**) as well as to determine the number of patients with stable or progressing HO (progressing by at least one grade) from visit to visit. Grade 0, I, or II HO was defined as not being clinically-relevant while grade III or IV HO was defined as clinically relevant. The majority of Mobi-C® subjects (randomized and non-randomized) were assessed as having HO defined as not being clinically relevant (Grade 0, I, or II). The HO grade was unchanged or changed by 1 grade only through 36 months across both Mobi-C® groups in the majority of subjects. Note that 9 of 125 subjects (randomized) and 1 of 15 subjects (non-randomized) with determinate radiographs at both 12 and 36 months experienced an increase in HO of two grades and no subjects experienced an increase in more than two grades. At 36 months 11 Mobi-C® randomized subjects and 1 Mobi-C® non-randomized subject were assessed as having Grade IV HO.

Table 31. Heterotopic Ossification for All Mobi-C® Subjects by Visit

Time Period/ Grade	Non-Randomized Mobi-C®	Randomized Mobi-C®	All Mobi-C®
24 months	N=14	N=150	N=164
Grade 0	1 (7.1%)	13 (8.7%)	14 (8.5%)
Grade I	1 (7.1%)	12 (8.0%)	13 (7.9%)
Grade II	10 (71.4%)	99 (66.0%)	109 (66.5%)
Grade III	1 (7.1%)	15 (10.0%)	16 (9.8%)
Grade IV	1 (7.1%)	9 (6.1%)	10 (6.1%)
Indeterminate	0	2 (1.3%)	2 (1.2%)
Stable*	11 (78.6%)	97 (68.8%)	108 (69.7%)
Worsening**	3 (21.4%)	44 (31.2%)	47 (30.3%)

*Stable = No change in grade from previous visit.
**Worsening = Increase in grade from previous visit.
[4] McAfee PC, et al. Classification of heterotopic ossification (HO) in artificial disc replacement. *J Spinal Disorders & Techniques* 2003; 16(4):384-389.
[5] Mehren C, Suchomel P, Grochulla F, Barsa P, Sourkova P, Hradil J, Korge A, Mayer H. Heterotopic Ossification in Total Cervical Artificial Disc Replacement. Spine 31(24):2802-2806, 2006.

Demographic and baseline characteristics and clinical outcomes were evaluated for potential correlation with the presence of HO. The only statistically significant correlations observed between demographic and baseline characteristics and the presence of HO were Body Mass Index (BMI) and male gender. There was no correlation found between presence of HO and clinical outcomes, including NDI, VAS neck and arm pain. Although use of NSAIDs was not part of the post-operative regimen, 21.3% of Mobi-C® subjects reported use of NSAIDS between discharge to week 6 and 25.6% between week 6 and month 3. Based on independent assessment of HO, there was not a correlation between post-operative NSAID use and HO at month 24.

HO will be studied further as part of a 7-year Postapproval Study (PAS) and ten year Enhanced Surveillance Postmarket Study (ESS) that will be conducted by the applicant.

Adjacent Segment Degeneration
Adjacent segment degeneration following Mobi-C® and ACDF was assessed at the spinal segment immediately above and below the treated level based on analysis of radiographs by an independent core lab following the study protocol. Adjacent segment degeneration was determined by assessment of disc space degeneration using a five point scale (Kellgren-Lawrence classification). Facet degeneration was not considered in the assessment of adjacent segment degeneration post-surgery as subjects with evidence of severe facet joint disease or degeneration were excluded from the study. Data is reported as stable (improvement or no change) and progressing (negative change from prior visit).

At the **above treated level**, the number of subjects reporting no negative changes from baseline in adjacent segment deterioration at the 24 Month visit was higher for the Mobi-C® randomized group (85. 4%) than for the ACDF group (75.0%) but this number was not statistically significant (**Table 32**).

At the **below treated level**, the number of subjects reporting no negative changes from baseline in adjacent segment deterioration at the 24 Month visit was higher for the Mobi-C® randomized group (92.3%) than the ACDF group (79.0%) (**Table 33**).

Table 32. Adjacent Segment Degeneration - Above Level- All Subjects by Visit

Time Period/ Grade	Non-Randomized Mobi-C®	Randomized Mobi-C®	All Mobi-C®	ACDF
12 months	N = 15	N = 148	N = 163	N = 69
Grade 0	7 (46.7%)	80 (54.1%)	87 (53.4%)	30 (43.5%)
Grade I	4(26.7%)	41 (27.7%)	45 (27.6%)	19 (27.5%)
Grade II	2 (13.3%)	14 (9.5%)	16 (9.8%)	13 (18.8%)
Grade III	1 (6.7%)	10 (6.8%)	11 (6.7%)	6 (8.7%)
Grade IV	1 (6.7%)	3 (2.0%)	4 (2.5%)	1 (1.4%)
Indeterminate	0	0	0	0
24 months	N = 15	N = 154	N = 169	N = 68
Grade 0	6 (40.0%)	75 (48.7%)	81 (47.9%)	26 (38.2%)
Grade I	5 (33.3%)	45 (29.2%)	50 (29.6%)	18 (26.5%)
Grade II	2 (13.3%)	19 (12.3%)	21 (12.4%)	14 (20.6%)
Grade III	1 (6.7%)	11 (7.1%)	12 (7.1%)	9 (13.2%)
Grade IV	1 (6.7%)	3 (1.9%)	4 (2.4%)	1 (1.5%)
Indeterminate	0	1 (0.6%)	1 (0.6%)	0
Stable	13 (86.7%)	129 (85.4%)	142 (85.5%)	51 (75.0%)
Progressing	2 (13.3%)	22 (14.6%)	24 (14.5%)	17 (25.0%)
36 months	N = 15	N = 135	N = 150	N = 58
Grade 0	6 (40.0%)	57 (42.2%)	63 (42.0%)	21 (36.2%)
Grade I	3 (20.0%)	36 (26.7%)	39 (26.0%)	12 (20.7%)
Grade II	4 (26.7%)	24 (17.8%)	28 (18.7%)	13 (22.4%)
Grade III	2 (13.3%)	14 (10.4%)	16 (10.7%)	12 (20.7%)
Grade IV	0	3 (2.2%)	3 (2.0%)	0
Indeterminate	0	1 (0.7%)	1 (0.7%)	0
Stable	12 (80.0%)	91 (68.4%)	95 (67.9%)	35 (60.3%)
Progressing	3 (20.0%)	42 (31.6%)	45 (32.1%)	23 (39.7%)

Kellgren-Lawrence Scale - Absence of degeneration in the disc [0]; Minimal anterior osteophytosis [1]; Definite anterior osteophytosis with possible narrowing of the disc space and some sclerosis of the vertebral endplates [2]; Moderate narrowing of the disc space with definite sclerosis of the vertebral endplates and osteophytosis [3]; Severe narrowing of the disc space with sclerosis of the vertebral endplates and multiple large osteophytes [4] Kellgren J, Lawrence J. Osteo-arthrosis and disk degeneration in an urban population. British Medical Journal 1958;17: 388.

Table 33. Adjacent Segment Degeneration - Below Level- for All Mobi-C® Subjects by Visit

Time Period/ Grade	Non-Randomized Mobi-C®	Randomized Mobi-C®	All Mobi-C®	ACDF
12 months	N = 15	N = 148	N= 163	N = 69
Grade 0	13 (86.7%)	101 (68.2%)	114 (69.9%)	35 (50.7%)
Grade I	2 (13.3%)	24 (16.2%)	26 (16.0%)	16 (23.2%)
Grade II	0	10 (6.8%)	10 (6.1%)	7 (10.1%)
Grade III	0	4 (2.7%)	4 (2.5%)	4 (5.8%)
Grade IV	0	0	0	2 (2.9%)
Indeterminate	0	9 (6.1%)	9 (5.5%)	5 (7.2%)
24 months	N = 15	N = 154	N = 169	N = 68
Grade 0	11 (73.3%)	100 (64.9%)	111 (65.7%)	33 (48.5%)
Grade I	2 (13.3%)	28 (18.2%)	30 (17.8%)	15 (22.1%)
Grade II	1 (6.7%)	15 (9.7%)	16 (9.5%)	8 (11.8%)
Grade III	0	3 (1.9%	3 (1.8%)	5 (7.4%)
Grade IV	0	1(0.6%)	1 (0.6%)	2 (2.9%)
Indeterminate	1 (6.7%)	7 (4.5%)	8 (4.7%)	5 (7.4%)
Stable	13 (92.9%)	131 (92.3%)	144 (92.3%)	49 (79.0%)
Progressing	1 (7.1%)	11 (7.7%)	12 (7.7%)	13 (21.0%)
36 months	N = 15	N =135	N = 150	N = 58
Grade 0	11 (73.3%)	74 (54.8%)	85 (56.7%)	20 (34.5%)
Grade I	2 (13.3%)	18 (13.3%)	20 (13.3%)	11 (19.0%)
Grade II	1 (6.7%)	24 (17.8%)	25 (16.7%)	11 (19.0%)
Grade III	0	6 (4.4%)	6 (4.0%)	9 (15.5%)
Grade IV	0	1 (0.7%)	1 (0.6%)	0
Indeterminate	1 (6.7%)	12 (8.9%)	13 (8.7%)	7 (12.1%)
Stable	13 (92.9%)	96 (78.7%)	109 (80.1%)	29 (58.0%)
Progressing	1 (7.1%)	26 (21.3%)	27 (19.9%)	21 (42.0%)

Kellgren-Lawrence Scale - Absence of degeneration in the disc [0]; Minimal anterior osteophytosis [1]; Definite anterior osteophytosis with possible narrowing of the disc space and some sclerosis of the vertebral endplates [2]; Moderate narrowing of the disc space with definite sclerosis of the vertebral endplates and osteophytosis [3]; Severe narrowing of the disc space with sclerosis of the vertebral endplates and multiple large osteophytes [4] Kellgren J, Lawrence J. Osteo-arthrosis and disk degeneration in an urban population. British Medical Journal 1958;17:388.

Pain Medication Use
Pain medication use at baseline preoperative and 24 months postoperative is reported for each group in **Table 34**. The rate of pain medication use was similar for all groups at each time point.

Table 34. Pain Medication Use at Baseline Preoperative and 24 month Postoperative

Procedure	Non-Randomized Mobi-C® (N=15)	Randomized Mobi-C® (N=164)	Randomized ACDF (N=81)
Baseline Preoperative			
ACETIC ACID DERIVATIVES	0	2 (1.2%)	2 (2.5%)
ANILINE ANALGESICS	0	5 (3.0%)	2 (2.5%)
ANILINE ANALGESICS, SALICYLATE	0	3 (1.8%)	0
ANTIEPILEPTIC	1 (6.7%)	9 (5.5%)	10 (12.3%)
ANTISPASMODICS	3 (20.0%)	62 (37.8%)	28 (34.6%)
BARBITURATE	0	3 (1.8%)	0
BENZODIAZEPINE	2 (13.3%)	23 (14.0%)	11 (13.6%)
COX, LOX INHIBITOR	0	0	1 (1.2%)
COX-2 INHIBITOR	2 (13.3%)	5 (3.0%)	2 (2.5%)
ENOLIC ACID	2 (13.3%)	2 (1.2%)	5 (6.2%)
OPIUM ALKALOID	3 (20.0%)	23 (14.0%)	5 (6.2%)
PROPIONIC ACID	3 (20.0%)	64 (39.0%)	23 (28.4%)
SALICYLATE	1 (6.7%)	7 (4.3%)	6 (7.4%)
SEMI-SYNTHETIC OPIOID DERIVATIVE	6 (40.0%)	87 (53.0%)	44 (54.3%)
SYNTHETIC OPIOID	3 (20.0%)	20 (12.2%)	7 (8.6%)
24 months Postoperative			
ACETIC ACID DERIVATIVES	0	6 (3.8%)	4 (5.3%)
ANILINE ANALGESICS	0	9 (5.8%)	4 (5.3%)
ANILINE ANALGESICS, SALICYLATE	0	4 (2.6%)	2 (2.7%)
ANTIEPILEPTIC	1 (6.7%)	14 (9.0%)	7 (9.3%)
ANTISPASMODICS	3 (20.0%)	48 (30.8%)	24 (32.0%)
BARBITURATE	0	3 (1.9%)	1 (1.3%)
BENZODIAZEPINE	3 (20.0%)	23 (14.7%)	16 (21.3%)
COX, LOX INHIBITOR	0	0	0
COX-2 INHIBITOR	1 (6.7%)	3 (1.9%)	2 (2.7%)
ENOLIC ACID	0	6 (3.8%)	3 (4.0%)
OPIUM ALKALOID	2 (13.3%)	22 (14.1%)	11 (14.7%)
PROPIONIC ACID	6 (40.0%)	64 (41.0%)	27 (36.0%)
SALICYLATE	3 (20.0%)	14 (9.0%)	9 (12.0%)
SEMI-SYNTHETIC OPIOID DERIVATIVE	4 (26.7%)	58 (37.2%)	23 (30.7%)
SYNTHETIC OPIOID	2 (13.3%)	16 (10.3%)	4 (5.3%)

Conclusions Drawn from the Study Data
The clinical data support the reasonable assurance of safety and effectiveness of the Mobi-C® Cervical Disc Prosthesis when used in accordance with the indications for use. Based on the clinical study results, it is reasonable to conclude that the clinical benefits of the use of the Mobi-C® Cervical Disc Prosthesis in terms of improvement in pain and disability, and the potential for motion preservation, appear to outweigh the risks associated with the device and surgical procedure when used in the indicated population in accordance with the directions for use.

PATIENT SELECTION AND TREATMENT
Individualization of Treatment
The risks and benefits should be carefully considered for each patient before use of the Mobi-C®. Factors such as the patient's weight, activity level, and compliance to weight bearing or load bearing instructions have an effect on the stresses to which to the prosthesis is subjected and may affect the implant longevity.
Prior to implantation, it is important that the surgeon provide the patient with information regarding the operative procedure to include:

- Potential failure of the cervical disc prosthesis due to excessive load, wear and tear, or infection
- Life of the prosthesis is determined by several factors, including body weight and daily activities
- Cervical disc prosthesis must not be subjected to overloading through extreme strain, or through work-related or athletic activities
- Revision surgery may be necessary if the prosthesis fails
- In the event of revision surgery, it may not be possible to restore segmental motion
- At regular intervals, the patient must undergo follow-up examinations of the cervical disc prosthesis

During the post-operative period, in addition to mobility and muscle therapy, it is of particular importance for the physician to keep the patient well informed regarding potential adverse events associated with an artificial disc prosthesis. Any damage to the weight-bearing structures may give rise to loosening, dislocation, or migration of the prosthesis components, as well as other serious complications. To ensure the earliest possible detection of such catalysts of dysfunction, the cervical disc prosthesis must be checked periodically post-operatively using appropriate techniques.

See CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS for more information regarding patient selection and treatment.

PACKAGING
The Mobi-C® is provided pre-packaged and sterile. It is intended for single use only. Do not use the Mobi-C® if the package is opened or damaged. The Mobi-C® components are sterilized using gamma radiation at a minimum dose of 25 kGy. The shelf life of the Mobi-C® components is five years. The use-before-date of the sterile components is provided on the external package label. Resterilization of the prosthesis supplied as sterile is prohibited. Any unused prosthesis in which the packaging has been opened or damaged must be returned to LDR Spine USA. Contact LDR Spine USA for specific instructions on device return (Refer to Contact Information section below). The superior and inferior spinal plates and mobile insert are provided pre-assembled in a sterile package. Aseptic technique must be used while opening the packaging for the correctly sized prosthesis components and transferring the device to the sterile field.

The Mobi-C® sterilization tray and associated surgical instruments are supplied non-sterile and must be cleaned and sterilized prior to use according to the instructions in this document.

The instruments are shipped and stored in the sterilization tray, which has identifying markings and specific locations for each instrument. Instruments may also be shipped individually, in packaging that is labeled according to its contents. Store the sterilization tray in normal hospital environmental conditions.

Store the devices in the original packaging or in the LDR Spine sterilization tray. Do not remove a device from the packaging until it is ready to be placed in the sterilization tray.

HANDLING
All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery. All instruments should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be use and should be returned to LDR Spine USA.

Carefully inspect the sterile package before opening. Do not use after the use-before-date. If the integrity of the sterile packaging has been compromised or damaged, contact your local LDR Spine USA Representative for return and replacement information. **DO NOT USE IF ANY DEFECTS ARE NOTED.**

It is necessary for the prosthesis to be kept in the original packaging, in a clean, dry, temperate location under normal atmospheric pressure. Storage conditions must maintain the integrity of the prosthesis, associated ancillary instrumentation, and the respective packaging.

CLEANING
REFER TO THE *MOBI-C® INSTRUMENT SYSTEM INSTRUCTIONS FOR USE MANUAL* PRIOR TO USE. THE INSTRUCTIONS HERE PROVIDE AN OVERVIEW OF THE REQUIRED PROCESS, AND USERS MUST REFER TO THE INSTRUMENT MANUAL FOR COMPLETE INSTRUCTIONS.

Cleaning precautions
- The pretreatment step is to be performed for all instruments and instrument trays.
- Do not soak instruments in any solution for more than two hours.
- Do not use steel wool, wire brushes, metallic pipe cleaners or abrasive detergents.
- Carefully protect the tips of delicate microsurgical instruments throughout the entire cleaning and sterilization process.
- Color anodized instruments may lose their color through the use of conventional, mechanical treatment processes.

Material resistance
The following substances must not be ingredients of the cleaning detergent:
- Acids/alkalis
- Highly concentrated saline solutions
- Chlorinated solutions

Preparation for cleaning (pretreatment)
It is suggested to keep the instruments moist after use and perform a thorough wipe-down prior to the cleaning process. Rinse each device with a steady stream of lukewarm tap water (below 43ºC / 110ºF) until all visible contamination is removed.

The pretreatment step helps the safety of personnel and cannot replace the cleaning / sterilization steps performed later. Flush each instrument thoroughly until no visible contamination remains.

For manual removal of impurities, only a soft brush or a clean soft tissue may be used. Do not use steel wool, wire brushes, metallic pipe cleaners or abrasive detergents.

Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations.

Devices that can be disassembled shall be disassembled to expose all surfaces to the cleaning process. Actively flush instruments containing a lumen and/or through hole. Retain all parts for reassembly.

Separate sharps and delicate surgical instruments.

Manual cleaning
Consider the following points during selection of the cleaning detergents:

- Ensure the detergent is pH neutral and aldehyde-free (such as ENZOL®)
- LDR Spine recommends using ENZOL®.

Follow the instructions of the detergent manufacturer regarding concentration. Only use freshly prepared solutions and filtered air for drying, respectively.

Procedure: Cleaning
1. Disassemble devices that can be disassembled to expose all surfaces to the cleaning process. Disassembly instructions are included in the M*obi-C® Instrument System Instructions for Use*. Retain all parts for reassembly. All instruments and instrument trays must be cleaned in accordance with these instructions.

2. Open hinged instruments.

3. Soak the instruments for a minimum of one minute in the cleaning solution with the instruments fully immersed. Carefully clean with a soft brush or a non-metallic pipe cleaner. Ensure that there is no contact between the instruments.

- For instruments with cannulas, lumina, and/or through-holes: Rinse all of these features of the instruments five times at the beginning of the soaking time by application of a single-use syringe (minimum volume 10 ml). Pay special attention to hinges and through-holes.

4. Remove the instruments from the cleaning solution. Rinse them with deionized or reverse osmosis water for a minimum of 30 seconds to allow the rinsate to run clear and foam-free.

- For instruments with cannulas, lumina, and/or through-holes: Rinse all of these features of the instruments five times at the end of the soaking time by application of a single-use syringe (minimum volume 10 ml). Pay special attention to hinges and through-holes.

5. Check the instruments (see "Inspection, function & maintenance").

Inspection, function & maintenance
Visually inspect instruments for cleanliness to ensure that instruments are visually clean (no visual contamination). If the instruments are not visually clean, repeat the entire cleaning process and repeat inspection after reprocessing.

Visually inspect instruments and sterilization tray for damage and corrosion. Cutting edges should be free of nicks and present a continuous edge. Discard blunt, damaged or corroded instruments. For hinged instruments, check for smooth movement of hinge without excessive "play." Locking (ratchet) mechanisms should be checked for action.

Reassemble devices that have been disassembled before placing into sterilization tray, if required by the layout of the tray.

STERILIZATION
The Mobi-C® is provided sterile. Re-sterilization of the implants is not recommended. The polyethylene components may not be re-sterilized for any reason. No implant should be re-used once it comes into contact with human tissue.

Background
Instruments must be sterilized by the user prior to use in surgery. Implants are provided sterile and are not to be sterilized by the user.

Packaging
Instruments shall be packaged in the LDR Spine sterilization tray or other sterilization container which fulfills the following requirements:

- Incorporates an FDA cleared wrap or pouch cleared for the cycle listed below
- Sufficient protection of the instruments and the sterilization packaging to mechanical damage
- Regular maintenance according to the instructions of the sterilization container manufacturer

The packaging (sterile wrap) should ensure sterility of instruments until opened for use at the sterile field, and should permit removal of contents without contamination.

Load the instruments as instructed – use the visual markings and internal tray labels for guidance. Wrap the trays using an appropriate method as detailed below (reference ANSI/AAMI ST79).

Additional information
When sterilizing multiple instruments in an autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

Do not stack one containment device on top of another during the sterilization process, transport or storage unless validated by the hospital.

Do not expose any instruments or sterilization trays to temperatures higher than 137 °C (279 °F).

Do not clean any instruments or sterilization trays with metal brushes or steel wool.

Sterilization
LDR Spine has shown that the instruments can be sterilized as a set using the following steam sterilization cycle:

Sterilizer Type:	Pre-vacuum
Temperature:	132°C (270F)
Full Cycle Time:	4 minutes
Dry Time:	35 minutes (30 minute cycle time with 5 minutes dwell time in sterilizer after cycle completion with sterilizer door opened for cooling)
Configuration:	Wrapped in two layers of 1-ply FDA-cleared sterilization wrap (510(k) K770933) using sequential wrapping techniques

Only sterile prostheses and instruments may be used for surgery. Information regarding the use of the Mobi-C® and instrumentation is provided in the Mobi-C® *Surgical Technique Manual and the Mobi-C® Instrument System Instructions for Use*.

After surgery
The instruments will be subjected to the same Cleaning and Sterilization cycles performed prior to the use of the instruments in surgery. After completing these cycles, the instruments will be packaged and returned to LDR Spine USA.

The package should be sent to

LDR Spine USA, Inc.
13785 Research Boulevard – Suite 200
Austin Texas USA
Phone: 512.344.3333
Fax: 512.344.3350
Toll Free Complaint Hotline: 877.449.5372

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.

For further information
Please contact LDR Spine if further information on this product is needed. Please use the information contained in this document in conjunction with the ***Mobi-C® Surgical Technique Manual*** and the ***Mobi-C® Instrument System Instructions for Use.***

CONFORMANCE TO STANDARDS
The components of the Mobi-C® include a cobalt, chromium, molybdenum (CoCrMo per ISO 5832-12) alloy superior spinal plate , an inferior CoCrMo spinal plate, and an ultra high molecular weight polyethylene (UHMWPE per ISO 5834-2) mobile insert. The inner contact surfaces of the superior and inferior spinal plates are spherical and flat, respectively. This allows for fully congruent contact surfaces between the spinal plates and mobile insert. The two lateral stops of the inferior plate control and limit the mobility of the mobile insert. The spinal plates, both superior and inferior, feature two rows of teeth to allow for initial and long term fixation and stability. A titanium (per ASTM F1580) and hydroxyapatite (per ISO 13779) plasma spray coating is applied to the bony interface surfaces of the superior and inferior spinal plates.

CONTACT INFORMATION
LDR Spine USA may be contacted at

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13785 Research Boulevard – Suite 200
Austin Texas USA
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Fax: 512.344.3350
Toll Free Complaint Hotline: 877.449.5372
www.ldrmedical.com

A complete Summary of Safety and Effectiveness (SSED), surgical technique, and labeling information for the Mobi-C® may be obtained at www.fda.gov by searching PMA number P110002.

PRODUCT COMPLAINTS
Any health care professional (e.g., customer or user of this system), who has complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify LDR Spine USA. Further, if any of the implanted system component(s) ever "malfunctions,"(i.e. does not meet any of its performance specifications or otherwise does not perform as intended), or may have caused or contributed to the death or serious injury of a patient, LDR Spine USA should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, and the nature of the complaint. Complaints may also be reported directly to Medwatch at http://www.fda.gov/medwatch. You will be contacted by

LDR Spine USA to provide specific information for an Enhanced Surveillance Study, for specific information regarding your clinical experience, regarding the complaint and overall experience with the device. In the event that the Mobi-C® requires removal for any reason, follow the instructions provided below in the **DEVICE RETRIEVAL** section**.**

DEVICE RETRIEVAL
Should it be necessary to explant a Mobi-C® Cervical Artificial Disc, please contact LDR Spine USA to receive instructions regarding data collection, including histopathological, mechanical, patient and adverse event information. Please refer to Mobi-C® Cervical Artificial Disc Surgical Technique for step-by-step instructions on the required surgical technique for device retrieval. All explanted devices must be returned to LDR Spine USA for analysis, in a leakproof container, with the date of explanation, explanting surgeon, and any known information regarding initial implantation, reasons for removal, and adverse event information. Please note that the explanted Mobi-C® device should be removed as carefully as possible in order to keep the implant and surrounding tissue intact. Also, please provide descriptive information about the gross appearance of the device *in situ*, as well as descriptions of the removal methods, i.e., intact or in pieces. LDR Spine USA will request additional information regarding the reason for removal, patient information and associated clinical outcomes.

NOTE: All impant removals must be reported immediately to LDR Spine USA.

Limited warranty and disclaimer: LDR Spine USA products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

CAUTION:
Federal (U.S.A.) Law Restricts this Device to Sale by or on the order of a Physician.

MANUFACTURED BY:
LDR Medical
Hotel de Bereaux 1
4 rue Gustave Eiffel
10430 Rosieres Pres
Troyes France

DISTRIBUTED BY:
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Fax: 512.344.3350
Toll Free Complaint Hotline: 877.449.5372
Email: Surgeoninfo@LDRSpine.com

= Caution: Consult Accompanying Documentation STERILE R = Sterile (by Radiation) MR MR Conditional

= Single Use / Do Not Reuse REF = Catalog Number LOT = Batch Number = Sterility – Use by Date

[placeholder – LDR Spine document control number – May 7, 2013]