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.

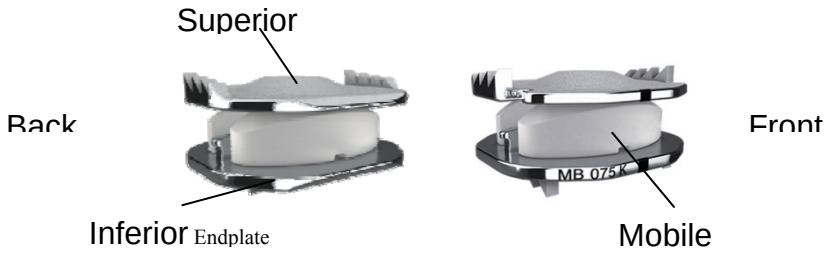
HOW SUPPLIED

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

DEVICE DESCRIPTION

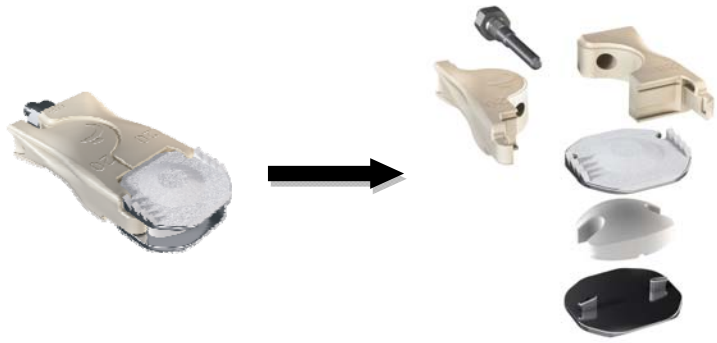
The Mobi-C® Cervical Disc Prosthesis (Mobi-C®) is a single use device for cervical intervertebral disc replacement at two contiguous levels from C3 to C7 in order to maintain/restore segmental motion and disc height. The components of the Mobi-C® include a cobalt, chromium, molybdenum (CoCrMo per ISO 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 controls and limits 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 from C3-C7 following discectomy at two contiguous levels for intractable radiculopathy (arm pain and/or neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, or 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 two diseased or immobile cervical spine levels 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 two levels 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 339 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 two contiguous levels 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	2) Reported to have an increased risk of osteoporosis/osteopenia. This was defined as a

Study Inclusion Criteria	Study Exclusion Criteria
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 3) Symptomatic at two contiguous levels from C3 to C7 4) Radiographically determined pathology at two contiguous level(s) 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 5) NDI Score of ≥ 15/50 or ≥ 30% 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 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 8) Reported to be medically cleared for surgery 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 10) Written informed consent provided by subject or subject's legally authorized representative 11) Willingness to discontinue all use of non-steroidal anti-inflammatory drugs (NSAIDs) from one week before surgery until 3 months after surgery	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) Reported to have had any prior spine surgery at the operative levels 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) Reported to have had prior cervical fusion procedure at any level 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, for both operative levels 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) Spondylolysis 9) Previous trauma to the C3 to C7 levels resulting in significant bony or disco-ligamentous cervical spine injury 10) Reported to have a history of or anticipated treatment for active systemic infection, including HIV or Hepatitis C 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 20) Reported to have rheumatoid arthritis, lupus, or other autoimmune disease that affect 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)

Study Inclusion Criteria	Study Exclusion Criteria
	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
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

Evaluation	Pre-op	Surgery/ Hospital Discharge	6 wks	3 mo	6 mo	12 mo	18 mo	24 mo & annually
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 339 subjects completed study surgery. This included 234 subjects treated with Mobi-C® (225 randomized, 9 training) and 105 ACDF control subjects. There were an additional 17 subjects who were randomized, but withdrew prior to surgery. At the time of database lock, of the 339 subjects with surgery, complete 24 month primary endpoint data was available for 208 Mobi-C® patients (98.6%), 83 ACDF control patients (93.3%) and 6 non-randomized Mobi-C® patients (75.0%). At this time point, 195 Mobi-C® patients (92.4%), 81 ACDF control patients (91.0%) and 5 non-randomized Mobi-C® patients (62.5%) 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	225	105	9	225	105	9	225	105	9
Theoretical	225	105	9	225	105	9	225	105	9
Deaths	0	0	0	1	0	0	1	0	0

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
Failures[1]	8	6	0	13	16	1	14	17	1
Not yet overdue	-	-	-	-	-	-	-	-	-
Expected[2]	217	99	9	211	89	8	210	88	8
Actual, efficacy[3] (% Follow-up)	205 (94.5%)	89 (89.9%)	8 (88.9%)	208 (98.6%)	83 (93.3%)	6 (75.0%)	185 (88.1%)	70 (79.5%)	3 (37.5%)
Actual, efficacy in window[4] (% Follow-up)	199 (91.7%)	83 (83.8%)	8 (88.9%)	195 (92.4%)	81 (91.0%)	5 (62.5%)	165 (78.6%)	65 (73.9%)	2 (25.0%)
Actual, any data[5] (% Follow-up)	208 (95.9%)	89 (89.9%)	9 (100.0%)	208 (98.6%)	83 (93.3%)	7 (87.5%)	188 (89.5%)	70 (79.5%)	5 (62.5%)

[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: $28 \leq day \leq 56$, 3 mo: $77.25 \leq day \leq 105.25$, 6 mo: $152.5 \leq day \leq 212.5$, 12 mo: $305 \leq day \leq 425$, 18 mo: $487.5 \leq day \leq 607.5$, 24 mo: $670 \leq day \leq 790$
[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=225), randomized ACDF control subjects (N=105), and Mobi-C® non-randomized training subjects (N=9) 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 (225 randomized Mobi-C® subjects, 105 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. Patient Demographics and Baseline Characteristics – Primary Analysis Population

Demographic Measure	Randomized Mobi-C® (N=225)	Non-Randomized Mobi-C® (N=9)	Randomized ACDF (N=105)	P-value (Randomized groups)
Gender				
Male	113 (50.2%)	6 (66.7%)	45 (42.9%)	0.2375**
Female	112 (49.8%)	3 (33.3%)	60 (57.1%)	
Age (years)	45.3 ±8.10 Range: 27-67	40.0 ±9.45 Range: 23-51	46.2±7.99 Range: 27-66	0.3725***
Ethnicity				
Hispanic or Latino	14 (6.2%)	1 (11.1%)	7 (6.7%)	>0.9999**
Not Hispanic or Latino	211 (93.8%)	8 (88.9%)	98 (93.3%)	
Race				
American Indian Alaska Native	3 (1.3%)	0	1 (1.0%)	
Caucasian	212 (94.2%)	7 (77.8%)	99 (94.3%)	
Asian	4 (1.8%)	0	0	>0.9999**
Black	5 (2.2%)	2 (22.2%)	4 (3.8%)	
Native Hawaiian/other Pacific Islander	0	0	0	
Other	1 (0.4%)	0	1 (1.0%)	
Height (in)	67.86±3.604 Range: 59.0-78.0	68.61±2.497 Range: 65.0-72.5	67.51±3.765 Range: 60.0-76.0	0.4093***
Weight (lbs)	181.71±36.117 Range: 92.0-300.0	172.11±44.363 Range: 105.0-235.0	182.86±34.828 Range: 115.0-280.0	0.7858***
BMI (kg/m^2)	27.625 ±4.4697 Range: 16.83 – 39.54	25.41±4.982 Range: 16.44-31.43	28.102±4.1953 Range: 19.66-39.78	0.3586***
Smoke more than one pack per day (yes)*	0	0	0	>0.9999**
History non-op care (yes):				
Pain Medication[1]	208 (92.4%)	9 (100.0%)	100 (95.2%)	0.7169**
Opioid Use[2]	-	-	-	-
Opium Alkaloid	27 (12.0%)	2 (22.2%)	7 (6.7%)	0.1741**
Semi-Synthetic Opioid Derivative	119 (52.9%)	5 (55.6%)	60 (57.1%)	0.4794**
Synthetic Opioid	18 (8.0%)	0	18 (17.1%)	0.0215**
Physical therapy	110 (48.9%)	4 (44.4%)	49 (46.7%)	0.9290**
Collar	27 (12.0%)	0	15 (14.3%)	0.6324**
Chiropractic	61 (27.1%)	2 (22.2%)	23 (21.9%)	0.5518**
Cervical Traction	45 (20.0%)	3 (33.3%)	21 (20.0%)	0.6021**
Bedrest /Immobilization	110 (48.9%)	3 (33.3%)	49 (46.7%)	0.6397**
Acupuncture	18 (8.0%)	11 (11.1%)	6 (5.7%)	0.4529**
Work Status (Being able to Work)	141 (62.7%)	5 (55.6%)	64 (61.0%)	>0.9999**
Driving Status (Being able to drive)	210 (93.3%)	8 (88.9%)	102 (97.1%)	0.4026**

*Data on amount and length of tobacco use was not captured.
**Using Fisher Exact test to compare frequencies between the treatments.
***Using unpaired t test to compare across treatment group.
[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=225)	Non-Randomized Mobi-C® (N=9)	Randomized ACDF (N=105)	P-Value (Randomized Groups)
NDI	53.86 ± 15.576	58.5±15.78	55.35±15.321	0.4150**
VAS Neck Pain	71.24 ±20.504	71.63±12.386	74.56±18.937	0.1619**
VAS Left Arm Pain	48.32 ±34.818	51.31±32.212	49.92±33.799	0.6948**
VAS Right Arm Pain	41.91 ±35.265	47.38±36.115	45.64±35.440	0.3726**
SF-12 PCS	33.390 ±6.7184	31.521±6.0942	32.524±7.6635	0.3051**
SF-12 MCS	41.944 ±11.3041	43.588±14.6502	42.019±11.9173	0.9564**
Neurological Status (normal[1])				
Motor	99 (44.0%)	4 (44.4%)	54 (51.4%)	0.2363*
Sensory				
Light Touch	110 (48.9%)	3 (33.3%)	56 (53.3%)	0.4796*
Pin Prick	108 (48.0%)	4 (44.4%)	52 (49.5%)	0.8140*
Reflexes	80 (35.6%)	3 (33.3%)	41 (39.0%)	0.5424*
Other assessments (gait[2])	215 (95.6%)	9 (100.0%)	98 (93.3%)	0.5908*
Baseline ROM Flexion-extension (°)				
Superior Level	9.13±4.849	7.39±3.728	9.33±4.875	0.7355**
Inferior Level	7.44±4.341	6.30±4.382	7.14±3.860	0.5574**
Baseline ROM Lateral bending (mm)				
Superior Level	5.76±3.374	4.38±2.522	5.48±3.041	0.4777**
Inferior Level	4.91±3.265	6.65±5.526	4.77±2.866	0.7227**

*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.

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 20.22 minutes longer for the Mobi-C® randomized group than for the control ACDF randomized group. Mean blood loss was similar for both groups. Mean return to work time was 20.9 days shorter for the Mobi-C® randomized group than the ACDF randomized 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. A total of 234 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=9)	Randomized Mobi-C® (N=225)	Randomized ACDF (N=105)	P Value **	P Value ***
Treated Level				-	-
C3-C4, C4-C5 (%)	0	1 (0.4%)	2 (1.9%)		
C4-C5, C5-C6 (%)	1(11.1%)	60 (26.7%)	23 (21.9%)		
C5-C6, C6-C7 (%)	8 (88.9%)	164 (72.9%)	80 (76.2%)		
Surgery Time (hours)	2.740±0.6846	2.135±0.7680	1.798±0.8598	0.0291	0.0002
Blood Loss (mls)	75.0±57.10	67.0±90.87	70.3±78.78	0.8306	0.7803
Hospitalization (days)	2.3±0.5	2.2±0.5	2.4±2.07	0.4160	0.2306
Return to Work Time (days)	38.0±23.25	45.9±102.31	66.8±113.70	0.5735	0.1923

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	C4-C5, C5-C6	C5-C6, C6-C7	Total
13×15 H5	0	60	123	**183**
13×15 H6	1	6	13	**20**
13×15 H7	0	0	1	**1**
13×17 H5	0	11	36	**47**
13×17 H6	0	3	14	**17**
13×17 H7	0	0	2	**2**
15×17 H5	1	23	101	**125**
15×17 H6	0	15	30	**45**
15×17 H7	0	1	2	**3**
15x20 H5	0	2	12	**14**
15x20 H6	0	1	8	**9**
15x20 H7	0	0	0	**0**
Total	**2**	**122**	**342**	**466**

Safety and Effectiveness Results

Safety Results

The analysis of safety was based on the Safety Population cohort of 339 total patients with surgery (225 randomized Mobi-C® patients, 9 non-randomized Mobi-C® patients, and 105 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 seriousness of the event. The information is presented in **Table 8**. The overall adverse event rate was similar for the randomized Mobi-C® group (89.3%), non-randomized Mobi-C® training group (100.0%), and ACDF control group (95.2%).

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

	Mobi-C® Non-Randomized (N=9)			Mobi-C® Randomized (N=225)			ACDF with Anterior Cervical Plate (N=105)				
	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	54	9 (100.0%)	(0.664, 1.000)	1467	201 (89.3%)	(0.845, 0.930)	884	100 (95.2%)	(0.892, 0.984)	0.0202	0.0952
Treatment-Emergent Adverse Events	54	9 (100.0%)	(0.664, 1.000)	1442	200 (88.9%)	(0.840, 0.927)	867	100 (95.2%)	(0.892, 0.984)	0.0209	0.0665
Related Adverse Events (a)	6	4 (44.4%)	(0.137, 0.788)	75	36 (16.0%)	(0.115, 0.215)	78	30 (28.6%)	(0.202, 0.382)	0.0158	0.0116
Definitely Related	0	0		10	9 (4.0%)	(0.018, 0.075)	10	8 (7.6%)	(0.033, 0.145)	0.1804	0.1855
Possibly Related	6	4 (44.4%)	(0.137, 0.788)	65	34 (15.1%)	(0.107, 0.205)	68	26 (24.8%)	(0.169, 0.341)	0.0283	0.0457
Related Adverse Events (b)	5	3 (33.3%)	(0.075, 0.701)	67	36 (16.0%)	(0.115, 0.215)	74	36 (34.3%)	(0.253, 0.442)	0.0060	0.0003
Definitely Related	0	0	-	10	9 (4.0%)	(0.018, 0.075)	5	5 (4.8%)	(0.016, 0.108)	0.9042	0.7730
Possibly Related	5	3 (33.3%)	(0.075, 0.701)	57	34 (15.1%)	(0.107, 0.205)	69	34 (32.4%)	(0.236, 0.422)	0.0045	0.0004
Serious Adverse Events	1	1 (11.1%)	(0.003, 0.482)	103	55 (24.4%)	(0.190, 0.306)	68	34 (32.4%)	(0.236, 0.422)	0.1730	0.1438
Related Serious Adverse Events (c)	0	0	-	10	7 (3.1%)	(0.013, 0.063)	23	13 (12.4%)	(0.068, 0.202)	0.0156	0.0021
Definitely Related	0	0	-	1	1 (0.4%)	(0.000, 0.025)	10	8 (7.6%)	(0.033, 0.145)	0.0105	0.0006
Possibly Related	0	0	-	9	6 (2.7%)	(0.010, 0.057)	13	7 (6.7%)	(0.027, 0.133)	0.1610	0.1244
Related Serious Adverse Events (d)	0	0	-	16	8 (3.6%)	(0.015, 0.069)	22	15 (14.3%)	(0.082, 0.225)	0.0331	0.0008
Definitely Related	0	0	-	3	2 (0.9%)	(0.001, 0.032)	5	5 (4.8%)	(0.016, 0.108)	0.1401	0.0355
Possibly Related	0	0	-	13	7 (3.1%)	(0.013, 0.063)	17	12 (11.4%)	(0.060, 0.191)	0.0736	0.0043
Unanticipated Adverse Device Effects	0	0	-	1	1 (0.4%)	(0.000, 0.025)	1	1 (1.0%)	(0.000, 0.052)	0.6296	0.5358

* 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. The percentage of subjects with treatment emergent adverse events was equivalent for the Mobi-C® and the ACDF groups across all levels. There was a trend across levels toward fewer device-related AEs, and device-related serious AEs for the Mobi-C® group. Across treatment groups, relatively fewer subjects were treated at C3-4, C4-5 (N=3) compared with treatment at the C4-5, C5-6 (N=84) and C5-6, C6-7 (N=252) levels.

Table 9. Total Adverse Events by Level Treated

	Mobi-C® (N=234)*			ACDF (N=105)		
	Events N	**Subjects n (%)**	**Subject-Level CI****	**Events N**	**Subjects n (%)**	**Subject-Level CI****
Treated Segment: C3-C4, C4-C5		(N=1)			(N=2)	
TEAEs	6	1 (100%)	-	16	2 (100.0%)	-
Treated Segment: C4-C5, C5-C6		(N=61)			(N=23)	
TEAEs	379	53 (86.9%)	(0.758, 0.942)	225	22 (95.7%)	(0.781, 0.999)
Treated Segment: C5-C6, C6-C7		(N=172)			(N=80)	
TEAEs	1111	155 (90.1%)	(0.846, 0.941)	626	76 (95.0%)	(0.877, 0.986)

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 339 total patients (225 randomized Mobi-C® patients, 105 ACDF control patients, 9 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 24 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.

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 234)**	**Total Events**	**#Patients (% of 105)**	**Total Events**
All Adverse Events[1]	133	67	211	126	181	127	215	126	257	176	309	152	245	116	209 (89.3%)	1496	100 (95.2%)	867
Anatomy/Technical Difficulty	1	0	2	0	1	0	1	1	3	2	0	1	2	1	9 (3.8%)	9	5 (4.8%)	5
Cervical –Study Surgery	1	0	2	0	1	0	1	0	0	1	0	0	1	1	6 (2.6%)	6	2 (1.9%)	2
Cervical – Non Study Surgery	0	0	0	0	0	0	0	1	3	1	0	0	1	0	3 (1.3%)	3	2 (1.9%)	2
Non-Cervical	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1 (1.0%)	1
Cancer	0	0	0	0	0	0	0	0	1	1	1	0	0	0	3 (1.3%)	3	1 (1.0%)	1
Cardiovascular	1	2	2	1	2	1	0	0	8	4	10	1	7	3	21 (9.0%)	29	10 (9.5%)	12
Death	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1 (0.4%)	1	0	0
Dysphagia/Dysphonia	12	6	10	10	6	2	2	1	4	2	2	2	3	2	39 (16.7%)	43	24 (22.9%)	27
Dysphagia	9	6	10	10	6	2	2	1	4	1	1	2	2	1	37 (15.8%)	38	24 (22.9%)	25
Dysphonia	3	0	0	0	0	0	0	0	0	1	1	0	1	1	5 (2.1%)	5	2 (1.9%)	2
Gastrointestinal	26	12	13	3	11	9	5	3	8	2	17	13	16	9	47 (20.1%)	97	32 (30.5%)	52
Heterotopic Ossification	0	0	0	1	0	0	1	0	2	0	2	0	3	0	6 (2.6%)	6	1 (1.0%)	1
Cervical - Index Level	0	0	0	0	0	0	0	0	2	0	1	0	1	0	3 (1.3%)	3	0	0
Cervical - Adjacent Level	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1 (0.4%)	1	0	0
Non Cervical	0	0	0	1	0	0	0	0	0	0	1	0	2	0	2 (0.9%)	2	1 (1.0%)	1
Infection	6	5	16	6	7	11	12	9	16	6	17	6	24	7	56 (23.9 %)	98	30 (28.6%)	50
Superficial Wound – Cervical	4	3	3	1	0	0	0	0	1	0	0	0	0	0	8 (3.4%)	8	4 (3.8%)	4
Deep Wound – Cervical	0	0	0	0	0	0	0	0	0	0	0	0	0	0	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 234)**	**Total Events**	**#Patients (% of 105)**	**Total Events**
Other Wound - Non Study Surgery	0	0	0	0	1	1	0	0	0	1	0	1	0	0	3 (1.3%)	3	3 (2.9%)	3
Systemic	1	0	1	1	1	1	2	0	1	1	3	0	5	2	10 (4.3%)	13	5 (4.8%)	5
Local	1	2	12	4	5	9	10	9	14	4	14	5	19	5	47 (20.1%)	74	23 (21.9%)	38
Malpositioned Implant	0	0	1	0	0	0	1	0	0	0	2	0	0	0	4 (1.7%)	4	0	0
Neck and/or Arm Pain	10	2	27	17	27	19	30	18	34	20	20	22	24	11	102 (43.6%)	167	63 (60.0%)	111
Neck Pain	9	2	14	14	12	12	20	9	16	13	12	10	14	5	75 (32.1%)	95	49 (46.7%)	68
Arm Pain	1	0	10	3	12	6	9	5	14	3	7	10	5	6	40 (17.1%)	55	25 (23.8%)	32
Neck And Arm Pain	0	0	3	0	3	1	1	4	4	4	1	2	5	0	8 (3.4%)	17	6 (5.7%)	11
Neurological	21	8	69	54	61	49	79	42	70	57	67	40	85	40	124 (53.0%)	426	78 (74.3%)	278
Upper Extremity – Sensory	1	0	45	27	26	21	39	14	41	23	37	20	39	24	70 (29.9%)	218	47 (44.8%)	119
Upper Extremity – Motor	3	1	4	2	4	1	2	2	3	6	3	3	2	3	17 (7.3%)	19	16 (15.2%)	17
Upper Extremity – Reflex	0	0	3	11	19	12	15	15	8	10	7	2	22	4	21 (9.0%)	65	17 (16.2%)	53
Lower Extremity – Sensory	0	0	2	4	0	0	6	0	3	1	3	3	1	1	9 (3.8%)	14	6 (5.7%)	8
Lower Extremity – Motor	1	0	1	1	0	1	1	0	1	1	2	0	2	0	5 (2.1%)	7	4 (3.8%)	4
Lower Extremity – Reflex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Upper & Lower Extremity – Sensory	0	0	2	0	0	0	0	0	0	0	0	0	0	0	1 (0.4%)	2	0	0
Upper & Lower Extremity - Motor	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.4%)	1	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	6	1	6	3	3	7	2	5	3	4	4	4	7	2	29 (12.4%)	30	17 (16.2%)	25
Back	0	1	3	0	2	1	2	1	3	2	0	1	3	1	11 (4.7%)	13	7 (6.7%)	8
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	0	0	0	0	2	1	1	0	1	1	1	0	3 (1.3%)	5	2 (1.9%)	2
Non Specific	0	1	1	0	1	2	0	1	0	2	1	2	0	1	3 (1.3%)	3	6 (5.7%)	9
Other*	9	4	2	6	6	4	10	3	7	8	9	4	8	4	40 (17.1%)	49	26 (24.8%)	33
Non-Union	0	0	0	0	0	0	0	2	0	8	3	7	0	0	1 (0.4%)	3	13 (12.4%)	18
Other**	36	25	26	11	14	10	19	13	26	13	48	21	22	12	99 (42.3%)	189	58 (55.2%)	104
Other Pain	11	0	30	17	34	21	46	19	42	32	68	25	32	19	131 (56.0%)	267	64 (61.0%)	132
Shoulder	4	0	12	7	8	8	9	5	9	7	13	5	6	3	52 (22.2%)	61	33 (31.4%)	36
Back	2	0	4	4	8	3	19	5	10	7	23	5	11	5	64 (27.4%)	80	25 (23.8%)	29
Torso	0	0	0	1	0	1	0	0	0	2	2	1	2	0	4 (1.7%)	4	4 (3.8%)	5
Lower Extremity	2	0	2	2	5	2	8	5	7	9	19	5	9	8	37 (15.8%)	51	21 (20.0%)	29
Headache	3	0	10	2	11	6	8	3	12	5	10	7	4	2	47 (20.1%)	58	20 (19.0%)	25
Other***	0	0	2	1	2	1	2	1	4	2	1	2	0	1	8 (3.4%)	13	8 (7.6%)	8
Respiratory	4	1	3	1	1	1	1	5	7	1	11	2	4	1	19 (8.1%)	29	11 (10.5)	12
Spinal Disorder	0	1	2	1	1	0	2	3	4	7	5	4	4	4	13 (5.6%)	18	13 (12.4%)	20
Cervical - Study Surgery	0	1	2	0	0	0	1	1	0	0	1	3	0	1	3 (1.3%)	4	6 (5.7%)	6
Cervical - Non Study Surgery	0	0	0	0	0	0	1	0	3	4	3	1	2	2	6 (2.6%)	8	4 (3.8%)	7
Non Cervical	0	0	0	1	1	0	0	2	1	3	1	0	2	1	5 (2.1%)	6	5 (4.8%)	7
Trauma	2	1	4	2	10	2	10	7	27	12	25	3	13	7	52 (22.2%)	89	20 (19.0%)	36
Upper Extremity Nerve Entrapment	1	0	2	0	4	0	3	2	2	3	2	2	2	0	13 (5.6%)	16	6 (5.7%)	7
Urogenital	0	2	3	0	2	2	3	1	3	6	7	3	4	0	15 (6.4%)	23	10 (9.5%)	14
Vascular Intraop	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (1.0%)	1
Wound Issue - Non-Infection	2	1	1	2	0	0	0	0	0	0	1	0	0	0	4 (1.7%)	4	3 (2.9%)	3
Hematoma	2	0	1	2	0	0	0	0	0	0	0	0	0	0	3 (1.3%)	3	2 (1.9%)	2
Hematoma Evacuation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CSF Leakage	0	1	0	0	0	0	0	0	0	0	1	0	0	0	1 (0.4%)	1	1 (1.0%)	1

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.

AE Category or Subcategory	Definition
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.
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		
Complication	**#Patients (% of 234)**	**Total Events**	**Subject-Level CI***	**#Patients (% of 105)**	**Total Events**	**Subject-Level CI***
Anatomy/Technical Difficulty	11 (4.7%)	11	(2.4, 8.3)	5 (4.8%)	5	(1.6, 10.8)
Cervical – Non Study Surgery	4 (1.7%)	4	(0.5, 4.3)	2 (1.9%)	2	(0.2, 6.7)
Cervical –Study Surgery	6 (2.6%)	6	(0.9, 5.5)	2 (1.9%)	2	(0.2, 6.7)
Non-Cervical	1 (0.4%)	1	(0.0, 2.4)	1 (1.0%)	1	(0.0, 5.2)

Complication	Mobi-C®			ACDF		
	#Patients (% of 234)	Total Events	Subject-Level CI*	#Patients (% of 105)	Total Events	Subject-Level CI*
Cancer	4 (1.7%)	4	(0.7, 3.3)	1 (1.0%)	1	(0.1, 3.4)
Cardiovascular	32 (13.7%)	42	(10.7, 17.1)	20 (19.0%)	24	(14.0, 25.0)
Death	1 (0.4%)	1	(0.1, 1.5)	1 (1.0%)	1	(0.1, 3.4)
Dysphagia/Dysphonia	37 (15.8%)	41	(11.4, 21.1)	22 (21.0%)	26	(13.6, 30.0)
Dysphagia	34 (14.5%)	35	(10.3, 19.7)	22 (21.0%)	24	(13.6, 30.0)
Dysphonia	6 (2.6%)	6	(0.9, 5.5)	2 (1.9%)	2	(0.2, 6.7)
Gastrointestinal	53 (22.6%)	115	(18.9, 26.7)	33 (31.4%)	62	(25.2, 38.2)
Heterotopic Ossification	13 (5.6%)	13	(3.0, 9.3)	4 (3.8%)	4	(1.0, 9.5)
Cervical - Adjacent Level	2 (0.9%)	2	(0.1, 3.1)	3 (2.9%)	3	(0.6, 8.1)
Cervical - Index Level	7 (3.0%)	7	(1.2, 6.1)	0	0	N/A
Non Cervical	4 (1.7%)	4	(0.5, 4.3)	1 (1.0%)	1	(0.0, 5.2)
Infection	61 (26.1 %)	109	(20.6, 32.2)	33 (31.4%)	62	(22.7, 41.2)
Local	50 (21.4%)	83	(16.3, 27.2)	25 (23.8%)	48	(16.0, 33.1)
Other Wound - Non Study Surgery	1 (0.4%)	1	(0.0, 2.4)	3 (2.9%)	3	(0.6, 8.1)
Superficial Wound – Cervical	8 (3.4%)	8	(1.5, 6.6)	4 (3.8%)	4	(1.0, 9.5)
Systemic	13 (5.6%)	17	(3.0, 9.3)	7 (6.7%)	7	(2.7, 13.3)
Malpositioned Implant	4 (1.7%)	4	(0.7, 3.3)	0	0	N/A
Neck and/or Arm Pain	112 (47.9%)	201	(41.3, 54.5)	66 (62.9%)	124	(52.9, 72.1)
Arm Pain	46 (19.7%)	67	(14.8, 25.3)	29 (27.6%)	38	(19.3, 37.2)
Neck And Arm Pain	11 (4.7%)	21	(2.4, 8.3)	7 (6.7%)	12	(2.7, 13.3)
Neck Pain	81 (34.6%)	113	(28.5, 41.1)	52 (49.5%)	74	(39.6, 59.5)
Neurological	139 (59.4%)	556	(52.8, 65.8)	81 (77.1%)	374	(67.9, 84.8)
Back	13 (5.6%)	15	(3.0, 9.3)	10(9.5%)	11	(4.7, 16.8)
Gait Disturbance	4 (1.7%)	6	(0.5, 4.3)	3 (2.9%)	3	(0.6, 8.1)
Lower Extremity – Motor	7 (3.0%)	9	(1.2, 6.1)	4 (3.8%)	5	(1.0, 9.5)
Lower Extremity – Sensory	14 (6.0%)	19	(3.3, 9.8)	8 (7.6%)	10	(3.3, 14.5)
Neck	37 (15.8%)	41	(11.4, 21.1)	18 (17.1%)	28	(10.5, 25.7)
Non Specific	5 (2.1%)	5	(0.7, 4.9)	6 (5.7%)	9	(2.1, 12.0)
Other**	45 (19.2%)	57	(14.4, 24.9)	28 (26.7%)	37	(18.5, 36.2)
Upper & Lower Extremity - Motor	1 (0.4%)	1	(0.0, 2.4)	0	0	N/A
Upper & Lower Extremity - Sensory	1 (0.4%)	2	(0.0, 2.4)	0	0	N/A
Upper Extremity – Motor	20 (8.5%)	24	(5.3, 12.9)	18 (17.1%)	24	(10.5, 25.7)
Upper Extremity – Reflex	25 (10.7%)	78	(7.0, 15.4)	18 (17.1%)	65	(10.5, 25.7)
Upper Extremity – Sensory	81 (34.6%)	299	(28.5, 41.1)	53 (50.5%)	182	(40.5, 60.4)
Non-Union	1 (0.4%)	3	(0.2, 2.2)	14 (13.3%)	18	(9.0, 18.7)
Other* **	110 (47.0%)	238	(42.4, 51.6)	62 (59.0%)	128	(52.1, 65.8)
Other Pain	142 (60.7%)	320	(54.1, 67.0)	73 (69.5%)	170	(59.8, 78.1)
Back	70 (29.9%)	96	(24.1, 36.2)	28 (26.7%)	35	(18.5, 36.2)
Headache	49 (20.9%)	63	(15.9, 26.7)	23 (21.9%)	34	(14.4, 31.0)
Lower Extremity	48 (20.5%)	69	(15.5, 26.3)	25 (23.8%)	38	(16.0, 33.1)
Other****	9 (3.8%)	13	(1.8, 7.2)	9 (8.6%)	10	(4.0, 15.6)
Shoulder	58 (24.8%)	70	(19.4, 30.8)	39 (37.1%)	44	(27.9, 47.1)
Torso	7 (3.0%)	9	(1.2, 6.1)	8 (7.6%)	9	(3.3, 14.5)
Respiratory	21 (9.0%)	36	(6.5, 11.9)	11 (10.5)	14	(6.7, 15.4)
Spinal Disorder	20 (8.5%)	28	(5.3, 12.9)	20 (19.0%)	29	(12.0, 27.9)
Cervical - Non Study Surgery	9 (3.8%)	12	(1.8, 7.2)	9 (8.6%)	12	(4.0, 15.6)
Cervical - Study Surgery	3 (1.3%)	4	(0.3, 3.7)	8 (7.6%)	8	(3.3, 14.5)
Non Cervical	8 (3.4%)	12	(1.5, 6.6)	7 (6.7%)	9	(2.7, 13.3)
Trauma	60 (25.6%)	116	(21.7, 29.9)	28 (26.7%)	54	(20.8, 33.2)
Upper Extremity Nerve Entrapment	14 (6.0%)	18	(4.0, 8.5)	6 (5.7%)	8	(3.0, 9.8)
Urogenital	19 (8.1%)	26	(5.8, 11.0)	13 (12.4%)	20	(8.2, 17.6)
Vascular Intraop	0	0	N/A	1 (1.0%)	1	(0.1, 3.4)
Wound Issue – Non-Infection	4 (1.7%)	4	(0.5, 4.3)	3 (2.9%)	3	(0.6, 8.1)

Complication	Mobi-C®			ACDF		
	#Patients (% of 234)	Total Events	Subject-Level CI*	#Patients (% of 105)	Total Events	Subject-Level CI*
CSF Leakage	1 (0.4%)	1	(0.0, 2.4)	1 (1.0%)	1	(0.0, 5.2)
Hematoma	3 (1.3%)	3	(0.3, 3.7)	2 (1.9%)	2	(0.2, 6.7)

*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 7 (3.1%) randomized Mobi-C® subjects and 12 (11.4%) 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=234)	F (N=105)
Revision	0	0	1	0	0	0	0	0	0	0	0	2	0	0	0	2	1 (0.4%)	4 (3.8%)
Reoperation	0	0	0	0	0	0	0	0	1	1	0	1	1	0	1	0	3 (1.3%)	2 (1.9%)
Removal	0	0	0	0	1	0	0	0	0	2	2	1	1	2	0	1	4 (1.7%)	6 (5.7%)
Supplemental Fixation	0	0	0	0	0	0	0	0	0	1	0	0	0	2	1	0	1 (0.4%)	3 (2.9%)
Total	0	0	1	0	1	0	0	0	1	4	2	4	2	4	2	3	9 (3.8%)	15 (14.3%)

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	Hematoma	Revision - Repositioning of the device at the inferior index level during hematoma evacuation	0.25
M	Device migration	Removal of Mobi-C® at the inferior index level and conversion to ACDF; the superior index level was left intact	2
M	Ongoing bilateral arm pain	Reoperation - cervical posterior foraminotomy of the inferior index level and the adjacent level below	8
M	Sub optimal bony fixation	Removal of Mobi-C® at both index levels and conversion to ACDF	13
M	Neck and shoulder pain	Removal of Mobi-C® at both index levels and conversion to ACDF	17
M	Facet spondylosis	Reoperation – posterior bilateral facet decortication at both index levels and posterior fusion hardware	22
M	Neck and arm pain	Removal of Mobi-C® at the inferior index level and conversion to ACDF; the superior index level was left intact	23
M	Radiculopathy	Supplemental fixation in the form of posterior fusion instrumentation at the inferior index level and adjacent level below	40
M	Stenosis	Removal of Mobi-C® at inferior index level and conversion to ACDF; the superior level was left intact	52

Group	Associated AE(s)	Secondary Surgical Intervention Detail	Months Post-Op*
F	Pseudoarthrosis at both index levels	Reoperation – posterior hemilaminotomy at both index levels	8
F	Pseudoarthrosis at both index levels	Supplemental Fixation in the form of posterior fusion instrumentation at both index levels	9
F	Failure of fusion	Removal of ACDF hardware and repeat ACDF at the index levels and addition of ACDF at the adjacent level above	9
F	Pseudoarthrosis at inferior index level	Removal of ACDF hardware and repeat ACDF at the inferior index level	10
F	Cervical spondylosis and arthrosis at superior index level	Removal of ACDF hardware and repeat ACDF at the superior index level	13
F	Fusion failure	Revision – posterior cervical facet fusion at inferior index level	14
F	Pseudoarthrosis at both index levels	Revision – posterior cervical fusion at both index levels	15
F	Radiculopathy	Reoperation - hemilaminotomy and posterior decompression at both index levels	16
F	Pseudoarthrosis at inferior index level	Supplemental fixation in the form of posterior fusion instrumentation at the inferior index level	19
F	Pseudoarthrosis at both index levels	Supplemental fixation in the form of posterior fusion instrumentation at both index levels and the inferior adjacent level	20
F	Herniated Disc at superior adjacent level	Removal of ACDF hardware and extension of fusion with ACDF to superior adjacent level	20
F	Degeneration at adjacent level	Removal of ACDF hardware and adjacent level anterior discectomy and arthroplasty	22
F	Cervical facet syndrome and spondylosis	Removal of ACDF hardware and repeat fusion at inferior index level and extension of fusion at inferior adjacent segment	33
F	Spinal stenosis	Revision – removal of ACDF hardware and extension of fusion to inferior adjacent level	35
F	Motor vehicle accident	Revision – posterior decompression at both index levels	40

M=Mobi-C® Group; F= ACDF Control Group
*The number of months between the study surgery and the second surgery

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 (28.6%) compared to randomized (16.0%) Mobi-C® subjects reported device-related adverse events as determined by investigators. During this period, device-related adverse events as determined by investigators were reported in 44.4% of non-randomized Mobi-C® subjects. Similarly, as determined by the CEC, 34.3% of ACDF, 16.0% of randomized Mobi-C®, and 33.3% 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 neurological neck (Mobi-C®, 0.9% ; ACDF , 5.7%) and dysphagia (Mobi-C®, 3.4% ; ACDF, 7.6%); neck pain (Mobi-C® 6.0%, ACDF 12.4%); non-union[1] (Mobi-C® 0.4%, ACDF 8.6%).

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

[1] One Mobi-C© patient had 3 non-union events that occurred after the index level Mobi-C© implants were removed and converted to a two level ACDF. The 3 events were associated with the subsequent ACDF procedure.

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

	Mobi-C® (N=234)*		ACDF (N=105)	
Device Relationship of Adverse Event Determined by Investigator	**Events N**	**Patients N (%)**	**Events N**	**Patients N (%)**
Anatomy/Technical Difficulty	2	2 (0.9%)	2	2 (1.9%)
Cervical - Non Study Surgery	1	1 (0.4%)	1	1 (1.0%)
Cervical - Study Surgery	1	1 (0.4%)	1	1 (1.0%)
Dysphagia/Dysphonia	10	9 (3.8%)	9	8 (7.6%)
Dysphagia	9	9 (3.8%)	8	8 (7.6%)
Dysphonia	1	1 (0.4%)	1	1 (1.0%)
Gastrointestinal	1	1 (0.4%)	0	0
Heterotopic Ossification	3	3 (1.3%)	0	0
Cervical - Index Level	2	2 (0.9%)	0	0
Cervical - Adjacent Level	1	1 (0.4%)	0	0
Malpositioned Implant	4	4 (1.7%)	0	0
Neck and/or Arm Pain	23	19 (8.1%)	23	16 (15.2%)
Neck Pain	16	14 (6.0%)	13	11 (10.5%)
Arm Pain	6	5 (2.2%)	5	5 (4.8%)
Neck and Arm Pain	1	1 (0.4%)	5	2 (1.9%)
Neurological	20	12 (5.1%)	25	10 (9.5%)
Upper Extremity - Sensory	10	7 (3.0%)	14	5 (4.8%)
Neck	4	3 (1.3%)	3	2 (1.9%)
Upper Extremity - Reflex	4	1 (0.4%)	0	0
Upper Extremity - Motor	1	1 (0.4%)	3	3 (2.9%)
Other	0	0	2	2 (1.9%)
Lower Extremity – Sensory	0	0	1	1 (1.0%)
Back	1	1 (0.4%)	1	1 (1.0%)
Non Specific	0	0	1	1 (1.0%)
Non-Union	0	0	9	8 (7.6%)
Other	1	1 (0.4%)	2	2 (1.9%)
Other Pain	11	10 (4.3%)	3	2 (1.9%)
Headache	6	5 (2.1%)	2	2 (1.9%)
Shoulder	4	4 (1.7%)	1	1 (1.0%)
Back	1	1 (0.4%)	0	0
Respiratory	1	1 (0.4%)	0	0
Spinal Disorder	4	3 (1.3%)	5	5 (4.8%)
Cervical - Study Surgery	4	3 (1.3%)	5	5 (4.8%)
Trauma	1	1 (0.4%)	0	0

*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, 32.4% of ACDF control subjects reported at least one SAE compared to 23.9% (56/234) of all Mobi-C® subjects (11.1% non-randomized Mobi-C®, 24.4% 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=234)*		ACDF (N=105)	
System Organ Class/Preferred Term	**Events N**	**Subjects n (%)**	**Events N**	**Subjects n (%)**
Anatomy/Technical Difficulty	1	1 (0.4%)	1	1 (1.0%)
Cervical - Study Surgery	1	1 (0.4%)	1	1 (1.0%)
Cancer	1	1 (0.4%)	0	0
Cardiovascular	9	7 (3.0%)	1	1 (1.0%)
Death	1	1 (0.4%)	0	0
Dysphagia/Dysphonia	2	2 (0.9%)	2	2 (1.9%)
Dysphagia	2	2 (0.9%)	2	2 (1.9%)
Gastrointestinal	3	3 (1.3%)	2	2 (1.9%)
Infection	9	6 (2.6%)	4	3 (2.9%)
Systemic	4	3 (1.3%)	1	1 (1.0%)

	Mobi-C® (N=234)*		ACDF (N=105)	
System Organ Class/Preferred Term	**Events N**	**Subjects n (%)**	**Events N**	**Subjects n (%)**
Local	5	5 (2.1%)	3	2 (1.9%)
Malpositioned Implant	1	1 (0.4%)	0	0
Migration of Implant	1	1 (0.4%)	0	0
Neck And/Or Arm Pain	15	10 (4.3%)	8	6 (5.7%)
Neck And Arm Pain	5	3 (1.3%)	3	1 (1.0%)
Arm Pain	2	2 (0.9%)	1	1 (1.0%)
Neck Pain	8	7 (3.0%)	4	4 (3.8%)
Neurological	5	5 (2.1%)	5	5 (4.8%)
Upper Extremity – Sensory	0	0	1	1 (1.0%)
Neck	1	1 (0.4%)	3	3 (2.9%)
Back	1	1 (0.4%)	0	0
Other	3	3 (1.3%)	1	1 (1.0%)
Non-Union	3	1 (0.4%)	14	11 (10.5%)
Other	14	12 (5.1%)	13	9 (8.6%)
Other Pain	15	10 (4.3%)	3	3 (2.9%)
Shoulder	5	4 (1.7%)	0	0
Back	4	4 (1.7%)	0	0
Torso	1	1 (0.4%)	0	0
Lower Extremity	1	1 (0.4%)	3	3 (2.9%)
Headache	3	3 (1.3%)	0	0
Other	1	1 (0.4%)	0	0
Respiratory	3	3 (1.3%)	0	0
Spinal Disorder	4	4 (1.7%)	8	7 (6.7%)
Cervical - Study Surgery	1	1 (0.4%)	5	5 (4.8%)
Cervical - Non Study Surgery	2	2 (0.9%)	2	1 (1.0%)
Non Cervical	1	1 (0.4%)	1	1 (1.0%)
Trauma	10	7 (3.0%)	3	2 (1.9%)
Upper Extremity Nerve Entrapment	5	4 (1.7%)	0	0
Urogenital	1	1 (0.4%)	1	1 (1.0%)
Wound Issue – Non-Infection	2	2 (0.9%)	3	3 (2.9%)
Hematoma	2	2 (0.9%)	2	2 (1.9%)
CSF Leakage	0	0	1	1 (1.0%)

*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 3.0% of all Mobi-C® subjects compared to 12.4% of ACDF subjects (**Table 17**). In Mobi-C® subjects device-related serious adverse events were noted in 7 randomized Mobi-C® subjects (3.1%) and 0 non-randomized Mobi-C® subjects.

Table 17. Device Related Serious Adverse Events

Group	Event Term(s)	Investigator Relationship to device*
M	1. Migration of Implant	1. Definitely
M	1. Neck pain	1. Possibly
M	1. Pain in Extremity	1. Possibly
M	1. Dysphagia 2. Neck Pain	1. Possibly 2. Possibly
M	1. Neck Pain 2. Pain in Extremity	1. Possibly 2. Possibly
M	1. Neck Pain 2. Shoulder Pain	1. Possibly 2. Possibly
M	1. Cervical spinal stenosis	1. Possibly
7 Total w/ Related SAE	**10 Serious Adverse Events**	**10 Total Related SAE**
F	1. Neuralgia 2. No therapeutic response	1. Possibly 2. Definitely
F	1. Radiculopathy 2. No therapeutic response	1. Possibly 2. Possibly
F	1. Intervertebral disc protrusion	1. Possibly
F	1.Spinal osteoarthritis** 2. No therapeutic response	1. Possibly** 2. Definitely
F	1. Shoulder pain 2. Hypoesthesia 3. No therapeutic response 4. Pain in extremity 5. Neck pain	1. Possibly 2. Possibly 3. Possibly 4. Possibly 5. Possibly
F	1. No therapeutic response	1. Definitely
F	1. Intervertebral disc degeneration	1. Definitely
F	1. Pain in Extremity	1. Possibly
F	1. No therapeutic response 2. Intervertebral disc protrusion 3. Neck pain	1. Definitely 2. Possibly 3. Possibly
F	1. Neck pain	1. Definitely
F	1. Dysphagia	1. Possibly
F	1. No therapeutic response 2. Radiculopathy	1. Definitely 2. Definitely
F	1. No therapeutic response 2. Spinal disorder	1. Definitely 2. Definitely
13 Total w/ Related SAE	**24 Serious Adverse Events**	**24 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

**Indicates a post-month 24 SAE which was in the clinical database at the time of the PMA

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 similar percentages of patients with stable/improved neurologic status as the control ACDF group at each time point and this finding was consistent for both the protocol-specified and FDA-specified definitions for neurologic deterioration. No deterioration in spinal cord function was observed in any study subjects. Gait disturbance was noted in 3 (1.3%) randomized Mobi-C® subjects and 2 (1.9%) control ACDF subjects.

Table 18. Neurological Status

Visit (months)	Status	Randomized Mobi-C® (N=225) Protocol Definition[1]	Non-Randomized Mobi-C® (N=9) Protocol Definition[1]	Randomized ACDF (N=105) Protocol Definition[1]	p-value*
6	No Deterioration Deterioration	207/216 (95.8%) 9/216 (4.2%)	8/8 (100.0%) 0/8	92/97 (94.8%) 5/97 (5.2%)	p=0.7690
12	No Deterioration Deterioration	204/213 (95.8%) 9/213 (4.2%)	8/9 (88.9%) 1/9 (11.1%)	83/92 (90.2%) 9/92 (9.8%)	p=0.0676
18	No Deterioration Deterioration	197/209 (94.3%) 12/209 (5.7%)	7/7 (100.0%) 0/7	82/85 (96.5%) 3/85 (3.5%)	p=0.5662
24	No Deterioration Deterioration	204/216 (94.4%) 12/216 (5.6%)	7/8 (87.5%) 1/8 (12.5%)	83/89 (93.3%) 6/89 (6.7%)	p=0.7897
Visit (months)	**Status**	**Randomized Mobi-C® (N=225) FDA Definition[2]**	**Non-Randomized Mobi-C® (N=9) FDA Definition[2]**	**Randomized ACDF (N=105) FDA Definition[2]**	**p-value***
6	No Deterioration Deterioration	197/216 (91.2%) 19/216 (8.8%)	8/8 (100.0%) 0/8	89/98 (90.8%) 9/98 (9.2%)	p=1.0000
12	No Deterioration Deterioration	194/213 (91.1%) 19/213 (8.9%)	8/9 (88.9%) 1/9 (11.1%)	76/92 (82.6%) 16/92 (17.4%)	p=0.0486
18	No Deterioration Deterioration	183/209 (87.6) 26/209 (12.4%)	7/7 (100.0%) 0/7	78/85 (91.8%) 7/85 (8.2%)	p=0.4150
24	No Deterioration Deterioration	193/216 (89.4%) 23/216 (10.6%)	7/8 (87.5%) 1/8 (12.5%)	78/89 (87.6%) 11/89 (12.4%)	p=0.6908

*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 (0.9%, 2/234) reported such events compared to ACDF control subjects (3.8%, 4/105). Following 24 month follow-up, six subjects have experienced or reported new adjacent level SAEs including 3 subjects in the ACDF group and 3 subjects in the Mobi-C® group bringing the combined total known adjacent level SAE rate to (2.1%, 5/234) in the Mobi-C® group and (6.7%, 7/105) 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 (2.1%, 5/234) reported such events compared to ACDF control subjects (6.7%, 7/105).

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

Group	Treated Levels	Study Surgery Date	Event Term(s)	Time to Adjacent Level Surgery	Description of Subsequent Adjacent Level Surgery
M	C5-6 C6-7	05 Mar 2007	C4-5 Herniated nucleus pulposus	1 year, 4 months	Index levels implants intact, adjacent level anterior discectomy and fusion at C4-5
M	C5-6 C6-7	12 Jul 2007	Severe neck pain	1 year, 8 months	Index levels implants intact, rhizomtomy at adjacent superior level and at above adjacent
M	C5-6 C6-7	09 Jul 2007	C4-5 Herniated nucleus pulposus	3 years	Index levels implants intact, adjacent level anterior discectomy and fusion at C4-5
M	C4-5 C5-6	20 Dec 2007	C6-7 Radiculopathy	3 years, 5 months	Index levels implants intact, adjacent level anterior discectomy and fusion at C6-7
M	C5-6 C6-7	08 Jan 2007	C7-8 Radiculopathy	3 years, 6 months	Index levels implants intact, adjacent level foraminotomy at C7-T1
F	C4-5 C5-6	23 Jan 2008	Neck pain	9 months	Removal of implants at index levels and repeat ACDF including the adjacent level above at C3-4
F	C5-6 C6-7	28 Sep 2006	C4-5 Herniated nucleus pulposus	1 year, 8 months	Removal of implants at index levels and adjacent level anterior discectomy and fusion at C4-5
F	C3-4 C4-5	21 Mar 2008	C5-6 Adjacent level degeneration	1 year 10 months	Removal of implants at index levels and adjacent level arthroplasty at C5-6
F	C5-6 C6-7	23 Jul 2007	C7-T1 Herniated nucleus pulposus	2 years, 3 months	Index levels implants intact, adjacent level fusion at C7-T1
F	C5-6 C6-7	03 Mar 2008	C4-5 Herniated nucleus pulposus	2 years, 9 months	Index levels implants intact, adjacent level fusion at C4-5 level
F	C5-6 C6-7	04 Feb 2008	C7-T1 cervical facet syndrome and spondylosis	2 years, 9 months	Removal of implants at index levels and adjacent level anterior discectomy and fusion at C7-T1
F	C4-5 C5-6	02 Oct 2007	C6-7 Adjacent level degeneration	1 year, 9 months	Removal of implants at index levels and repeat ACDF at inferior index level and inferior adjacent level. Additional posterior fusion with posterior hardware at both original index levels and inferior adjacent level.

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 330 total patients with surgery (225 randomized Mobi-C® patients, and 105 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 randomized Mobi-C® subjects was 69.7% at the 24-month visit, 32.3% higher than the 37.4 % 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 non-inferiority of Mobi-C® compared to control. **Table 21** shows the alternative primary endpoint analysis (Variation 1) which confirms the primary analysis results. **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=9)	Randomized Mobi-C® (N=225)	Randomized ACDF (N=105)	p-value
NDI Improvement	5/7 (71.4%)	169/216 (78.2%)	55/89 (61.8%)	p=0.0042**
No failure due to Subsequent Surgery	9/9 (100%)	218/225 (96.9%)	93/105 (88.6%)	p<0.0044**
No Major Complications	7/9 (77.8%)	197/225 (87.6%)	76/105 (72.4%)	p<0.0001**
Overall Success	4/7 (57.1%)	154/221 (69.7%)	37/99 (37.4%)	p<0.0001**

* Patients 101-041 (ACDF), 102-011 (ACDF), 102-014 (ACDF), 102-026 (Mobi-C®), 104-004 (Mobi-C®), 104-007 (ACDF), 105-043 (ACDF), 105-068 (ACDF), 106-006 (Mobi-C®), 111-002 (ACDF), 114-015 (Mobi-C®), 114-047 (Mobi-C®), 121-013 (ACDF), 130-020 (ACDF), and 121-055 (ACDF) 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=9)	Randomized Mobi-C® (N=225)	ACDF (N=105)	p-value
NDI Improvement	5/7 (71.4%)	169/216 (78.2%)	55/89 (61.8%)	p=0.0042**
No failure due to Subsequent Surgery	9/9 (100%)	218/225 (96.9%)	93/105 (88.6%)	p<0.0043**
No Major Complications	7/9 (77.8%)	205/225 (91.1%)	92/105 (87.6%)	p=0.3301**
Overall Success	4/7 (57.1%)	160/221 (72.4%)	49/99 (49.5%)	p<0.0001**

* Patients 101-041 (ACDF), 102-011 (ACDF), 102-014 (ACDF), 102-026 (Mobi-C®), 104-004 (Mobi-C®), 104-007 (ACDF), 105-043 (ACDF), 105-068 (ACDF), 106-006 (Mobi-C®), 111-002 (ACDF), 114-015 (Mobi-C®), 114-047 (Mobi-C®), 121-013 (ACDF), 130-020 (ACDF), and 121-055 (ACDF) 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=9)**	4/7 (57.1%)	2/8 (25.0%)	4/7 (57.1%)	1/4 (25.0%)
	R Mobi-C® (N=225)	156/216 (72.2%)	148/213 (69.5%)	154/221 (69.7%)	133/199 (66.8%)
	R ACDF (N=105)	24/97 (24.7%)	32/95 (33.7%)	37/99 (37.4%)	36/87 (41.4%)
Protocol – Specified Definition (Variation 1)	**NR Mobi-C® (N=9)**	4/7 (57.1%)	2/8 (25.0%)	4/7 (57.1%)	2/5 (40.0%)
	R Mobi-C® (N=225)	157/216 (72.7%)	151/213 (70.9%)	160/221 (72.4%)	143/201 (71.1%)
	R ACDF (N=105)	49/96 (51.0%)	44/95 (46.3%)	49/99 (49.5%)	40/87 (46.0%)
FDA Defined Alternative Definition *	**NR Mobi-C® (N=9)**	4/7 (57.1%)	2/8 (25.0%)	4/7 (57.1%)	1/4 (25.0%)
	R Mobi-C® (N=225)	146/216 (67.6%)	138/213 (64.8%)	143/221 (64.7%)	128/200 (64.0%)
	R ACDF (N=105)	20/98 (20.4%)	25/95 (26.3%)	32/99 (32.3%)	29/87 (33.3%)
FDA Defined Alternative Definition* (Variation 1)	**NR Mobi-C® (N=9)**	4/7 (57.1%)	2/8 (25.0%)	4/7 (57.1%)	2/5 (40.0%)
	R Mobi-C® (N=225)	147/216 (68.1%)	141/213 (66.2%)	148/221 (67.0%)	136/201 (67.7%)
	R ACDF (N=105)	40/97 (41.2%)	34/95 (35.8%)	42/99 (42.4%)	32/87 (36.8%)

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; C4-5, C5-6 and C5-6, C6-7 according to the protocol-specified definition.

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

	Success in Mobi-C® Non-Randomized Group: n/N' – (proportion: pm) (N=9)	**Success in Mobi-C® Randomized Group: n/N' – (proportion: pm) (N=225)**	**Success in ACDF Randomized Group: n/N' (proportion: pc) (N=105)**	**Difference/Lower Bound* for pm-pc (ITT)**
PROTOCOL-SPECIFIED				
Treated Segment: C3-C4, C4-C5	(N=0)	(N=1)	(N=2)	
Month 24	0	1/ 1 (1.0000)	0/2	1.000 / 1.000
Treated Segment: C4-C5, C5-C6	(N=1)	(N=60)	(N=23)	
Month 24	1/ 1 (1.0000)	36/59 (0.6102)	6/23 (0.2609)	0.3493 / 0.1660
Treated Segment: C5-C6, C6-C7	(N=8)	(N=164)	(N=80)	
Month 24	3/6 (0.5000)	117/161 (0.7267)	31/74 (0.4189)	0.3078 / 0.1972
VARIATION 1				
Treated Segment: C3-C4, C4-C5	(N=0)	(N=1)	(N=2)	
Month 24	0	1/ 1 (1.0000)	0/2	1.000 / 1.000
Treated Segment: C4-C5, C5-C6	(N=1)	(N=60)	(N=23)	
Month 24	1/ 1 (1.0000)	37/59 (0.6271)	8/23 (0.3478)	0.2793 / 0.0859
Treated Segment: C5-C6, C6-C7	(N=8)	(N=164)	(N=80)	
Month 24	3/6 (0.5000)	122/161 (0.7578)	41/74 (0.5541)	0.2037 / 0.0936

* 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 than the control group in every age, race, and gender subgroup.

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

Subgroup	Success in Randomized Mobi-C® (N=225)	Success in Randomized ACDF (N=105)	Difference for pm-pc
Age			
<40 years	35/54 (0.6481)	6/20 (0.3000)	0.3481
40 - <50 years	72/101 (0.7129)	17/46 (0.3696)	0.3433
>=50 years	47/66 (0.7121)	14/33 (0.4242)	0.2879
Race			
Caucasian	147/208 (0.7067)	35/93 (0.3763)	0.3304
Black or African American	2/5 (0.4000)	1/4 (0.2500)	0.1500
Other***	5/8 (0.6250)	1/2 (0.5000)	0.1250
Gender			
Male	69/100 (0.6273)	20/41 (0.4878)	0.1395
Female	85/111 (0.7658)	17/58 (0.2931)	0.4727

*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®	R ACDF
Neck Disability Index Improvement[1]	191/221 (86.4%)	67/99 (67.7%)
VAS Neck Pain Improvement[2]	179/221 (81.0%)	73/99 (73.7%)
VAS Left Arm Pain Improvement[2]	130/221 (58.8%)	55/99 (55.6%)
VAS Right Arm Pain Improvement[2]	116/221 (52.5%)	44/99 (44.4%)
SF-12 PCS[3]	**157/203 (77.3%)**	**52/83 (62.7%)**
SF-12 MCS[3]	**113/203 (55.7%)**	**43/83 (51.8%)**
Satisfaction[4]	185/225 (85.6%)	68/81 (78.2%)
Recommendation[5]	185/225 (85.6%)	63/81 (72.4%)

[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 levels 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 3a and 3b**. 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 range of motion values of superior and inferior levels respectively were 10.10 ° (±5.938°), 8.30 ° (±5.277°) for flexion/extension bending and 5.45° (±3.260°), 5.35° (±3.296°) for left/right lateral bending. ACDF superior and inferior mean range of motion values respectively were 0.50° (±0.717°), 1.17° (±1.699°) for flexion/extension bending and 0.74° (±1.024°) ,0.82° (±0.938°) for left/right lateral bending.

Table 26. Radiographic Range of Motion

Component		**Preoperative**			**12 months**			**24 months**		
		T (N=8)	**M (N=222)**	**F (N=100)**	**T (N=8)**	**M (N=213)**	**F (N=91)**	**T (N=8)**	**M (N=216)**	**F (N=89)**
Range of Motion (°) Flexion-Extension	Superior Level	7.39± 3.728	9.13± 4.849	9.33± 4.875	11.46± 5.248	10.07± 5.635	0.83± 1.116	10.84± 6.404	10.10± 5.938	0.50± 0.717
	Inferior Level	**T (N=8)**	**M (N=209)**	**F (N=98)**	**T (N=8)**	**M (N=209)**	**F (N=89)**	**T (N=8)**	**M (N=214)**	**F (N=88)**
		6.30± 4.382	7.44± 4.341	7.14± 3.860	9.16± 4.453	8.30± 4.860	1.44± 1.485	7.80± 4.938	8.30± 5.277	1.17± 1.699
Component		**Preoperative**			**12 months**			**24 months**		
		T (N=6)	**M (N=206)**	**F (N=96)**	**T (N=8)**	**M (N=212)**	**F (N=90)**	**T (N=7)**	**M (N=216)**	**F (N=89)**
Range of Motion (°) Lateral Bending	Superior Level	4.38± 2.522	5.76± 3.374	5.48± 3.041	5.83± 1.180	5.64± 3.191	0.92± 0.945	5.19± 2.236	5.45± 3.260	0.74± 1.024
	Inferior Level	**T (N=6)**	**M (N=206)**	**F (N=96)**	**T (N=8)**	**M (N=212)**	**F (N=90)**	**T (N=7)**	**M (N=216)**	**F (N=89)**
		6.65± 5.526	4.91± 3.265	4.77± 2.866	4.35± 1.978	5.36± 3.097	1.08± 1.058	3.97± 2.591	5.35± 3.296	0.82± 0.938

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

Figure 3a. Mobi-C® Time Course of Mean Flexion/Extension Range of Motion at Superior Index Level

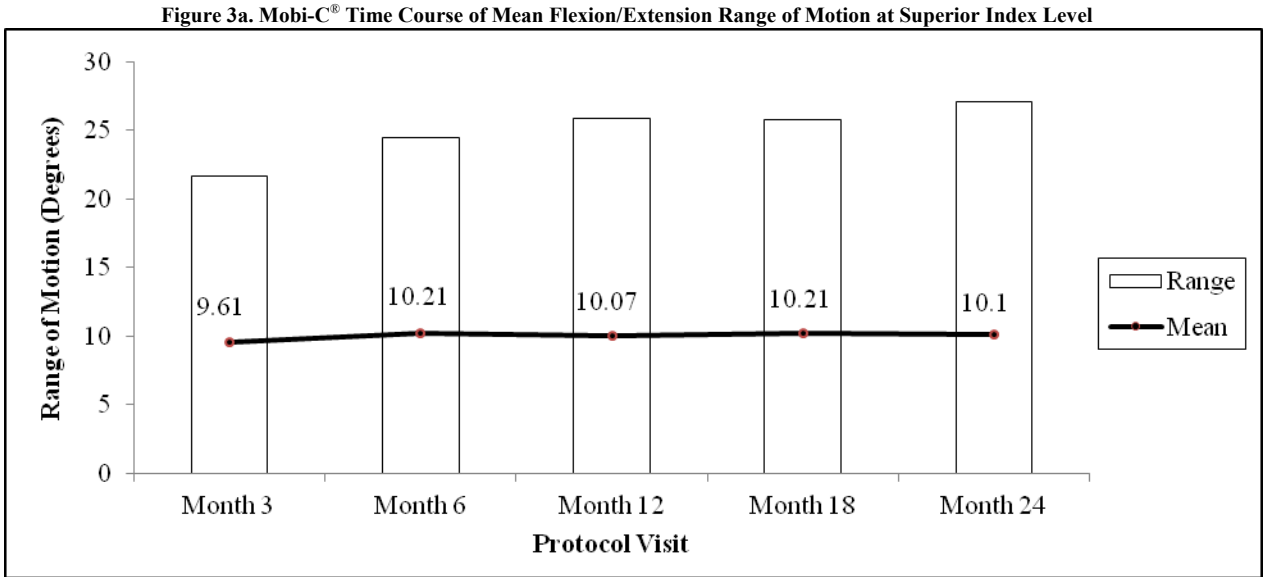
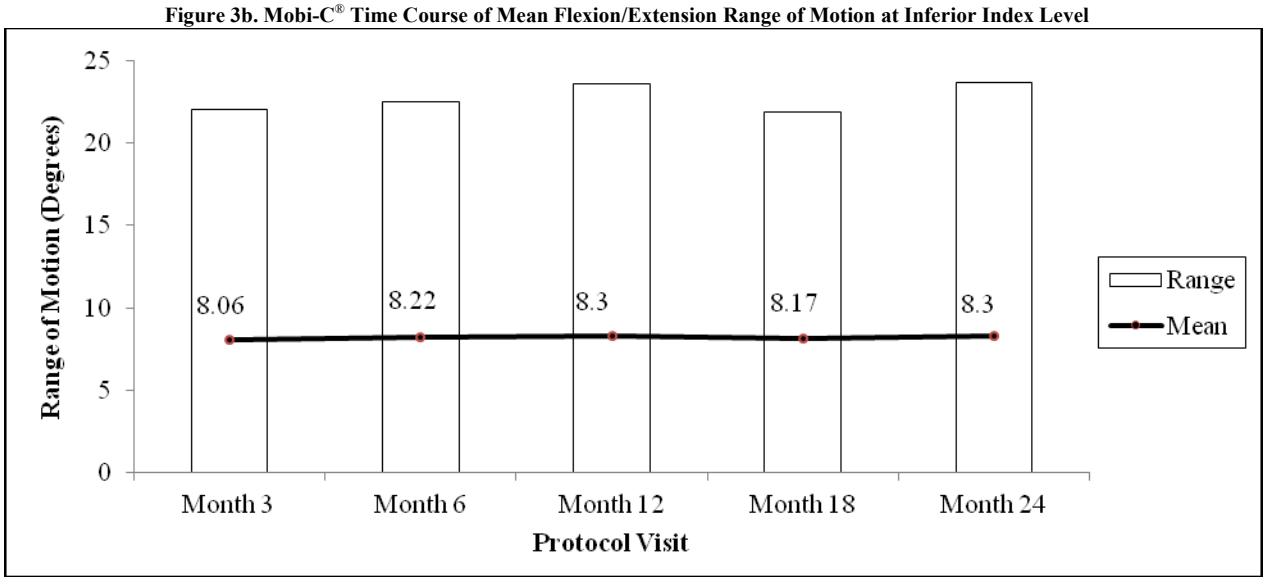


Figure 3b. Mobi-C® Time Course of Mean Flexion/Extension Range of Motion at Inferior Index Level



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, 98.6% (211/214) randomized Mobi-C® subjects achieved ROM success according to the protocol specified criteria (≥ 2° ROM with no bridging bone) while 1.4% (3/214) 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 combined superior and inferior index level motion which demonstrated that 95.8% (205/214) Mobi-C® subjects achieved ROM success while 4.2% (9/214) 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, 67/229 (29.3%) 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.

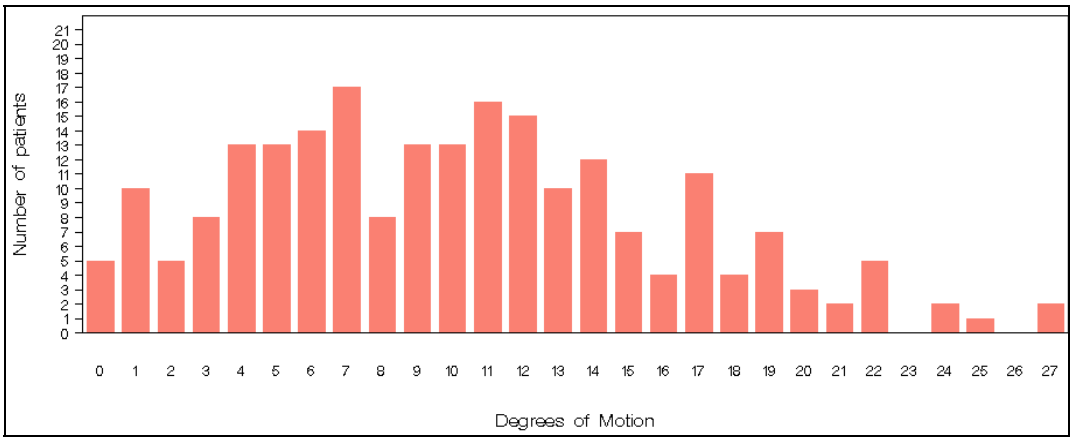
Table 27. Radiographic Change in Range of Motion for Mobi-C®

			24 Month
NR Mobi-C® N=8	Superior Level	Increased (≥2°)	4(50.0%)
		No change (≥-2 to <2)	1 (12.5%)
		Decreased (<-2)	2 (25.0%)
	Inferior Level	Increased (≥2°)	3(37.5%)
		No change (≥-2 to <2)	1 (12.5%)
		Decreased (<-2)	3 (37.5%)
	Combined	Increased (≥2°)	4 (50.0%)
		No change (≥-2 to <2)	0
		Decreased (<-2)	3 (37.5%)
R Mobi-C® N=221	Superior Level	Increased (≥2°)	93 (42.1%)
		No change (≥-2 to <2)	63 (28.5%)
		Decreased (<-2)	57 (25.8%)
	Inferior Level	Increased (≥2°)	89 (40.3%)
		No change (≥-2 to <2)	57 (25.8%)
		Decreased (<-2)	55 (24.9%)
	Combined	Increased (≥2°)	106 (48.0%)
		No change (≥-2 to <2)	31 (14.0%)
		Decreased (<-2)	64 (29.0%)
All Mobi-C® N=229	Superior Level	Increased (≥2°)	97 (42.4%)
		No change (≥-2 to <2)	64 (27.9%)
		Decreased (<-2)	59 (25.8%)
	Inferior Level	Increased (≥2°)	92 (40.2%)
		No change (≥-2 to <2)	58 (25.3%)
		Decreased (<-2)	58 (25.3%)
	Combined	Increased (≥2°)	110 (48.0%)
		No change (≥-2 to <2)	31 (13.5%)
		Decreased (<-2)	67 (29.3%)

Note: Patients 101007, 101041, 102011, 102014, 102026, 104004, 104007, 105016, 105043, 105068, 106006, 110017, 111002, 114015, 114047,121013, 121055, 130020, 130030, and 123004 have had their data censored after a revision, removal, or supplemental fixation surgery.

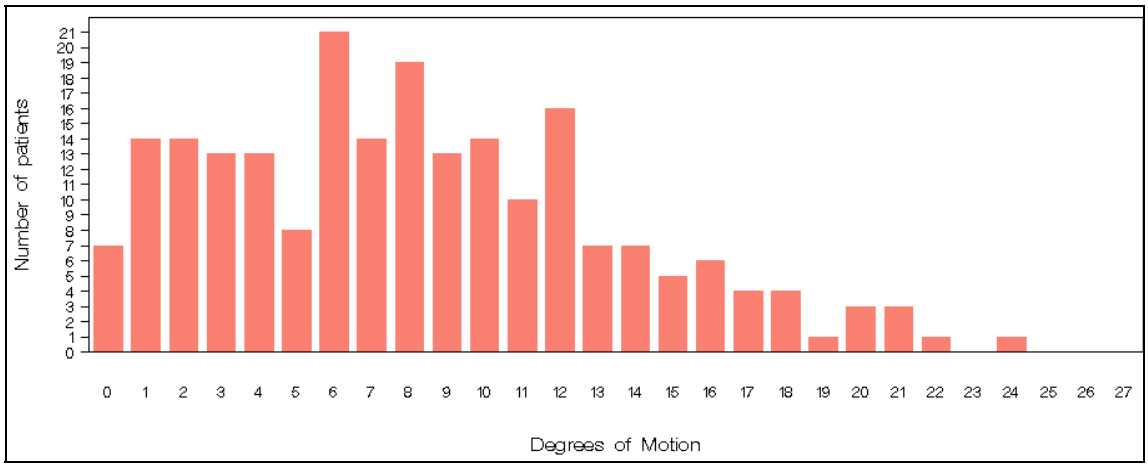
A histogram of angular range of motion on flexion/extension radiographs at 24 months for all patients treated with Mobi-C® is provided in **Figure 4a** and **Figure 4b** below. This histogram uses values obtained by rounding recorded range of motion for each subject to the nearest integer.

Figure 4a. Histogram of Mobi-C® Angular Range of Motion at Month 24, Superior Treated Level – Primary Analysis Population



Note: Degrees of motion have been rounded to the nearest integer. The range of motion values are measured from flexion/extension radiographs at 24 months.

Figure 4b. Histogram of Mobi-C® Angular Range of Motion at Month 24, Inferior Treated Level - Primary Analysis Population



Note: Degrees of motion have been rounded to the nearest integer. The range of motion values are measured from flexion/extension radiographs at 24 months

Fusion

For control subjects, failure of fusion at either of the treated levels 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 MMI protocol. The ACDF subjects were required to demonstrate fusion status at both treated segments. 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	42/94 (44.7%)	61/94(64.9%)	79/99 (79.8%)

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 one case of migration and no cases of 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 baseline in FSU height at the superior level ranged from -0.26 mm (6 weeks post-op) to -0.43 mm (24 months post op) in the randomized Mobi-C® subjects, compared with -0.50 mm (6 weeks post-op) to -0.70 mm (24 months post op) in the ACDF group. Mean change from baseline in FSU height at the inferior level ranged from -0.24 mm (6 weeks post-op) to -0.35 mm (24 months post op) in the randomized Mobi-C® subjects, compared with -0.73 mm (6 weeks post-op) to -0.81 mm (24 months post op) in the ACDF group.

Table 29a. Radiographic FSU Height Superior Level – Safety Population

	Pre-Operative			24 Months		
	T (N=6)	M (N=221)	F (N=101)	T (N=8)	M (N=215)	F (N=89)

FSU Height & (SD) mm	27.68 (3.149)	28.96 (2.614)	28.47 (2.668)	29.03 (2.618)	30.70 (2.508)	29.21 (2.601)
FSU Change* & (SD) mm	-	-	-	-0.54 (0.336)	-0.43 (0.398)	-0.70 (0.675)

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 timepoints. All available radiographs used in the analysis.
SD = Standard Deviation

Table 29b. Radiographic FSU Height Inferior Level – Safety Population

	Pre-Operative			24 Months		
	T (N=6)	M (N=215)	F (N=99)	T (N=8)	M (N=209)	F (N=87)
FSU Height & (SD) mm	28.72 (2.117)	29.71 (2.604)	29.22 (2.537)	30.21 (1.758)	31.50 (2.393)	29.61 (2.577)
FSU Change* & (SD) mm	-	-	-	-0.46 (0.294)	-0.35 (0.385)	-0.81 (0.866)

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.

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

Component	Randomized Mobi-C®	Randomized ACDF	P-Value
Superior Disc Height Change	-0.43 ± 0.398	-0.70 ± 0.675	0.0006
Inferior Disc Height Change	-0.35 ± 0.385	-0.81 ± 0.866	<0.0001

* Using unpaired t-test to compare the change from baseline value between the treatments.
Note: Patients 101007, 101041, 102011, 102014, 102026, 104004, 104007, 105016, 105043, 105068, 106006, 110017, 111002, 114015, 114047,121013, 121055, 130020, 130030, and 123004 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 at the superior and inferior disc space (**Tables 31a and 31b**) 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 1 of 179 subjects (randomized) and 0 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 12 Mobi-C® randomized subjects and 0 Mobi-C® non-randomized subject were assessed as having Grade IV HO.

Table 31a. Heterotopic Ossification for All Mobi-C® Subjects by Visit – Superior Level

Time Period/ Grade	Non-Randomized Mobi-C®	Randomized Mobi-C®	ALL Mobi-C®
24 months	N=7	N=218	N=225
Grade 0	2 (28.6%)	21 (9.6%)	23 (10.2%)
Grade I	0	15 (6.9%)	15 (6.7%)
Grade II	5 (71.4%)	156 (71.6%)	161(71.6%)
Grade III	0	17 (7.8%)	17 (7.6%)
Grade IV	0	8 (3.7%)	8 (3.6%)
Indeterminate	0	1 (0.5%)	1 (0.4%)
Stable*	6 (100.0%)	165 (79.0%)	171 (79.5%)
Worsening**	0	44 (21.1%)	44 (20.5%)

*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.

Table 31b. Heterotopic Ossification for All Mobi-C® Subjects by Visit – Inferior Level

Time Period/ Grade	Non-Randomized Mobi-C®	Randomized Mobi-C®	ALL Mobi-C®
24 months	N=7	N=218	N=225
Grade 0	1 (14.3%)	19 (8.7%)	20 (8.9%)
Grade I	0	7 (3.2%)	7 (3.1%)
Grade II	5 (71.4%)	157 (72.0%)	162 (72.0%)
Grade III	1 (14.3%)	16 (7.3%)	17 (7.6%)
Grade IV	0	6 (2.8%)	6 (2.7%)
Indeterminate	0	13 (6.0%)	13 (5.8%)
Stable*	5 (83.3%)	139 (70.6%)	144 (70.9%)
Worsening**	1 (16.7%)	58 (29.4%)	59 (29.1%)

*Stable = No change in grade from previous visit.
**Worsening = Increase in grade from previous visit.

Demographic and baseline characteristics and clinical outcomes were evaluated for potential correlation with the presence of HO. The only statistically significant correlation observed between demographic and baseline characteristics and the presence of HO was male gender. There was no correlation found between presence of HO and clinical outcomes, including NDI, VAS neck and VAS arm pain. Although use of NSAIDs was not part of the post-operative regimen, 25.8% of randomized Mobi-C® subjects reported use of NSAIDS between discharge to week 6 and 23.1% between week 6 and month 3. Based on independent assessment of HO, there was a small negative correlation between post-operative NSAID use and HO at month 24 that approaches but does not reach significance.

HO will be studied further as part of a 7-year Postapproval Study(PAS) and ten year Enhanced Surveillance Postmarket Study 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 levels 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 (86.9%) than for the ACDF group (66.7%) (**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 (97.1%) than the ACDF group (81.9%) (**Table 33**).

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

Time Period/ Grade	Non-Randomized Mobi-C®	Randomized Mobi-C®	All Mobi-C®	ACDF
12 months	N=8	N=214	N=222	N=91
Grade 0	6 (75.0%)	146 (68.2%)	152 (68.5%)	53 (58.2%)
Grade I	2 (25.0%)	39 (18.2%)	41 (18.5%)	19 (20.9%)
Grade II	0	17 (7.9%)	17 (7.7%)	14 (15.4%)
Grade III	0	8 (3.7%)	8 (3.6%)	4 (4.4%)
Grade IV	0	4 (1.9%)	4 (1.8%)	1 (1.1%)
Indeterminate	0	0	0	0
24 months	N=8	N=216	N=224	N=87
Grade 0	6 (75.0%)	135 (62.5%)	141 (62.9%)	40 (46.0%)
Grade I	2 (25.0%)	43 (19.9%)	45 (20.1%)	21 (24.1%)
Grade II	0	23 (10.6%)	23 (10.3%)	15 (17.2%)
Grade III	0	8 (3.7%)	8 (3.6%)	7 (8.0%)
Grade IV	0	6 (2.8%)	6 (2.7%)	4 (4.6%)
Indeterminate	0	1 (0.5%)	1 (0.4%)	0
Stable	7 (100.0%)	185 (86.9%)	192 (87.3%)	56 (66.7%)
Progressing	0	28 (13.2%)	28 (12.7%)	28 (33.3%)
36 months	N=6	N=194	N=200	N=75
Grade 0	3 (50.0%)	110 (56.7%)	113 (56.5%)	22 (29.3%)
Grade I	3 (50.0%)	35 (18.0%)	38 (19.0%)	13 (17.3%)
Grade II	0	31 (16.0%)	31 (15.5%)	27 (36.0%)
Grade III	0	13 (6.7%)	13 (6.5%)	9 (12.0%)
Grade IV	0	4 (2.1%)	4 (2.0%)	3 (4.0%)
Indeterminate	0	1 (0.5%)	1 (0.5%)	1 (1.3%)
Stable	4 (80.0%)	140 (73.3%)	144 (73.5%)	29 (40.8%)
Progressing	1 (20.0%)	51 (26.7%)	52 (26.5%)	42 (59.2%)

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=8	N=214	N=222	N=91
Grade 0	5 (62.5%)	192 (89.7%)	197 (88.7%)	72 (79.1%)
Grade I	1 (12.5%)	11 (5.1%)	12 (5.4%)	11 (12.1%)
Grade II	2 (25.0%)	4 (1.9%)	6 (2.7%)	5 (5.5%)
Grade III	0	2 (0.9%)	2 (0.9%)	2 (2.2%)
Grade IV	0	1 (0.5%)	1 (0.5%)	1 (1.1%)
Indeterminate	0	4 (1.9%)	4 (1.8%)	0
24 months	N=8	N=216	N=224	N=87
Grade 0	5 (62.5%)	190 (88.0%)	195 (87.1%)	65 (74.7%)
Grade I	1 (12.5%)	12 (5.6%)	13 (5.8%)	8 (9.2%)
Grade II	1 (12.5%)	3 (1.4%)	4 (1.8%)	7 (8.0%)
Grade III	1 (12.5%)	3 (1.4%)	4 (1.8%)	5 (5.7%)
Grade IV	0	0	0	1 (1.1%)
Indeterminate	0	8 (3.7%)	8 (3.6%)	1 (1.1%)
Stable	6 (85.7%)	198 (97.1%)	204 (96.7%)	68 (81.9%)
Progressing	1 (14.3%)	6 (2.9%)	7 (3.3%)	15 (18.1%)
36 months	N=6	N=194	N=200	N=75
Grade 0	2 (33.3%)	131 (67.5%)	133 (66.5%)	34 (45.3%)
Grade I	0	18 (9.3%)	18 (9.0%)	7 (9.3%)
Grade II	1 (16.7%)	10 (5.2%)	11 (5.5%)	13 (17.3%)
Grade III	2 (33.3%)	1 (0.5%)	3 (1.5%)	6 (8.0%)
Grade IV	0	1 (0.5%)	1 (0.5%)	5 (6.7%)
Indeterminate	1 (16.7%)	33 (17.0%)	34 (17.0%)	10 (13.3%)
Stable	1 (25.0%)	134 (84.8%)	135 (83.3%)	33 (53.2%)
Progressing	3 (75.0%)	24 (15.2%)	27 (16.7%)	29 (46.8%)

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=9)	Randomized Mobi-C® (N=225)	Randomized ACDF (N=105)
Baseline Preoperative			
ACETIC ACID DERIVATIVES	0	10 (4.4%)	3 (2.9%)
ANILINE ANALGESICS	0	10 (4.4%)	5 (4.8%)
ANILINE ANALGESICS, SALICYLATE	0	3 (1.3%)	2 (1.9%)
ANTIEPILEPTIC	0	14 (6.2%)	12 (11.4%)
ANTISPASMODICS	5 (55.6%)	87 (38.7%)	37 (35.2%)
BARBITURATE	0	2 (0.9%)	1 (1.0%)
BENZODIAZEPINE	2 (22.2%)	33 (14.7%)	15 (14.3%)
COX, LOX INHIBITOR	0	0	0
COX-2 INHIBITOR	2 (22.2%)	9 (4.0%)	3 (2.9%)
ENOLIC ACID	0	4 (8.1%)	5 (4.8%)
OPIUM ALKALOID	2 (22.2%)	27 (12.0%)	7 (6.7%)
PROPIONIC ACID	2 (22.2%)	67 (29.8%)	39 (37.1%)
SALICYLATE	0	25 (11.1%)	11 (10.5%)
SEMI-SYNTHETIC OPIOID DERIVATIVE	5 (55.6%)	119 (52.9%)	60 (57.1%)
SYNTHETIC OPIOID	0	18 (8.0%)	18 (17.1%)
24 months Postoperative			
ACETIC ACID DERIVATIVES	0	10 (4.5%)	3 (3.0%)
ANILINE ANALGESICS	1 (12.5%)	12 (5.4%)	9 (9.1%)
ANILINE ANALGESICS, SALICYLATE	0	4 (1.8%)	2 (2.0%)
ANTIEPILEPTIC	1 (12.5%)	21 (9.5%)	15 (15.2%)
ANTISPASMODICS	3 (37.5%)	68 (30.8%)	31 (31.3%)
BARBITURATE	0	3 (1.4%)	1 (1.0%)
BENZODIAZEPINE	1 (12.5%)	30 (13.6%)	16 (16.2%)
COX, LOX INHIBITOR	0	0	0
COX-2 INHIBITOR	1 (12.5%)	15 (6.8%)	8 (8.1%)
ENOLIC ACID	0	7 (3.2%)	4 (4.0%)
OPIUM ALKALOID	0	40 (18.1%)	12 (12.1%)
PROPIONIC ACID	4 (50.0%)	69 (31.2%)	26 (26.3%)
SALICYLATE	0	32 (14.5%)	9 (9.1%)
SEMI-SYNTHETIC OPIOID DERIVATIVE	3 (37.5%)	68 (30.8%)	39 (39.4%)
SYNTHETIC OPIOID	0	14 (6.3%)	8 (8.1%)

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 ***Mobi-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 e

- 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

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
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 P110009.

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:
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
Email: Surgeoninfo@LDRSpine.com

 = Caution: Consult Accompanying Documentation

 = Sterile (by Radiation)

 = Single Use / Do Not Reuse

REF = Catalog Number

LOT = Batch Number

 = Sterility – Use by Date

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

Mobi-C® Cervical Artificial Disc
Two Contiguous Levels
Patient Education

a passion for innovation

This patient education book explains:

- How the neck works.
- What happens when cervical discs wear out.
- What are the risks and benefits of cervical artificial disc surgery.
- How the Mobi-C® Cervical Disc (Mobi-C) may help your arm pain and related problems.

Your doctor may have said that surgery using the Mobi-C could help reduce your arm pain and/or neurologic symptoms (such as weakness or numbness). This book will help answer questions on what to expect before, during, and after surgery.

Reading this book should not take the place of talking with a doctor. Please go to your doctor with questions about how you are feeling. Talk to a doctor about the best way to help your neck or arm problems.

The Mobi-C has been used outside the United States since 2003 in thousands of cases. In 2013, the Mobi-C was approved for use in the United States by the Food and Drug Administration (FDA).

Table of Contents

Glossary

annulus fibrosus - The outer protective ring of a spinal *disc*, which covers the soft center (*nucleus pulposus*). Made from strong rings of fibers.

ACDF - Anterior cervical discectomy and fusion (ACDF) is a fusion surgery where an unhealthy cervical disc is removed and replaced with bone or an implant. For more information see page 25.

artificial disc - A medical *implant* used to replace a worn out *disc*.

blood vessels - Flexible tubes that carry blood throughout the body.

cervical spine - Includes the first seven *vertebrae* of the spinal column (neck).

CT - Computerized tomography (CT) is *an x-ray* procedure that combines many images to create cross-sectional images (like slices) of the body.

contiguous disc levels - Disc levels located next to each other (adjacent). When Mobi-C is implanted at two-levels, the second disc should be implanted at the level next to the first disc.

degeneration - Deterioration of tissue, which may include loss of function.

disc - Soft pad of cartilage between each *vertebrae* of the *spine*. The discs hold the *vertebrae* apart, act as cushions, and allow the *vertebrae* to move.

facet joint - *Joint* in the back (posterior) of the *spine* that connect the *vertebrae* together.

fluoroscopy - An *x-ray* procedure used to take moving pictures of a body part.

Food and Drug Administration (FDA) - Part of the United States government. The FDA makes rules for companies that protect the patients who need medicine or medical *implants*. The FDA also helps decide which and how *implants* can be used.

fusion - When two bones grow together stopping movement.

heterotopic ossification - Unintended bone formation around or across the *disc* space, between the *vertebrae*.

implant - A device that is put in the body to fix or take the place of a damaged body part.

incision - A cut in the skin made during *surgery*.

joint - Where two or more bones meet, normally to allow movement.

ligament - A short strip of strong, flexible *soft tissue* that connects two bones.

MRI - Magnetic Resonance Imaging (MRI) is a radiographic procedure that uses magnets to create cross-sectional images (like slices) of the body.

nerves - Fibers that move messages to and from the brain. Nerves control feeling and movement. Nerves connect the skin, organs, and *muscles* through the *spinal cord* to the brain.

nucleus pulposus - The soft center of a spinal *disc*.

osteopenia - A condition in which the bones are somewhat thin or weak, which may develop into *osteoporosis*.

osteoporosis - A condition in which the bones are thin or weak and become brittle and fragile.

physical therapy (PT) - Using exercise and massage to help regain movement.

skeletal muscle - A strong tissue that makes movement for the body.

soft tissue - Connects, supports, or surrounds the organs and other structures of the body.

spinal cord - Bundle of spinal *nerves*. The spinal cord starts at the bottom of the brain and runs to the lower back. The spinal cord moves messages between the brain and the body.

spine - The 33 *vertebrae* starting under the skull and ending in the small of the back. Grouped into three sections: *cervical* (upper), thoracic (middle), and lumbar (lower). Protects the *spinal cord* and provides body support.

surgery - An operation on the body to fix, remove, or replace diseased or injured tissue.

vertebrae - The bones that form the spinal column with a hole for the *spinal cord* to pass through.

x-ray - A tool used by doctors to take a picture of a patient's bones.

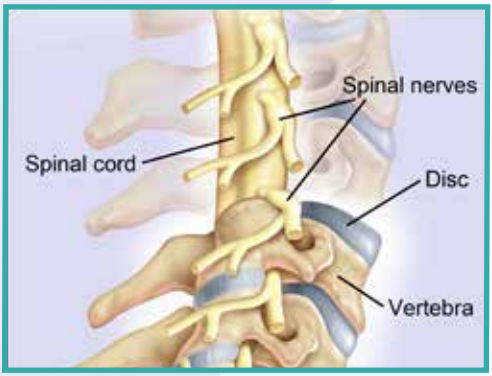
The healthy neck

The neck (cervical spine) is made up of the bones (vertebrae), spinal cord, nerves, muscles, ligaments, and the system that carries blood (blood vessels).

Side-view of a cervical spine

The top seven vertebrae make up the cervical spine and begin at the base of the skull. The vertebrae of the cervical spine protect the spinal cord and support the skull. A disc between each vertebra helps to cushion the vertebrae from moving together with the load of the body.

Each disc has a strong outer ring (annulus fibrosus). The outer ring helps keep the disc's soft center (nucleus pulposus) in place. Disc problems can start from over-use, an accident, or just the wear and tear of every day life.



Healthy cervical spine

The vertebrae and the discs allow a healthy cervical spine to:

- Bend side-to-side (lateral bend) (Figure A).
- Bend forward-to-back (flexion and extension) (Figure B).
- Turn left-to-right (rotation) (Figure C).

Figure A

Figure B

Figure C

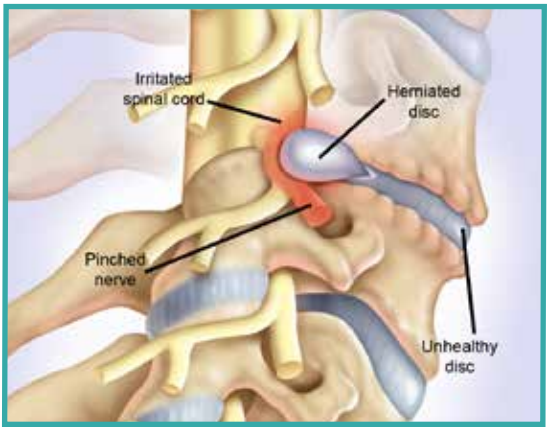
Degenerative cervical spinal pathology

Side-view of a cervical spine showing progressive examples of disc degeneration

Degenerative cervical spinal pathology may result in a damaged disc that can cause pain.

When a disc degenerates, the disc:

- Loses water. With less water, the disc becomes thinner and has less padding to absorb movement. The disc may become less flexible.
- May have tiny tears or cracks in the outer layer (annulus fibrosus) of the disc.



Side-view of cervical vertebrae showing the effect of disc degeneration

Disc degeneration can cause the:

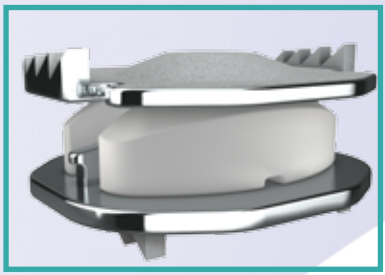
- Inner disc (nucleus pulposus) to squeeze through the outer disc (disc bulge or disc herniation).
- Spinal canal to narrow and pinch the cord and nerves (spinal canal stenosis).
- Spinal cord to be irritated causing a loss of feeling or movement (myelopathy).
- Nerve roots to be irritated or pinched causing pain, weakness, or tingling down the arm and possibly into the hands (radiculopathy).

The Mobi-C Cervical Disc

The Mobi-C is an artificial disc for the neck. The Mobi-C has three parts: two metal plates and a plastic insert in the middle.

The plates are made of a mix of metals commonly used in spine surgery (cobalt, chromium, and molybdenum). The plates have teeth on the top and bottom that help hold the plates to the vertebrae. The teeth are pressed into the bone with no bone cut out, which makes the Mobi-C design and technique bone sparing.

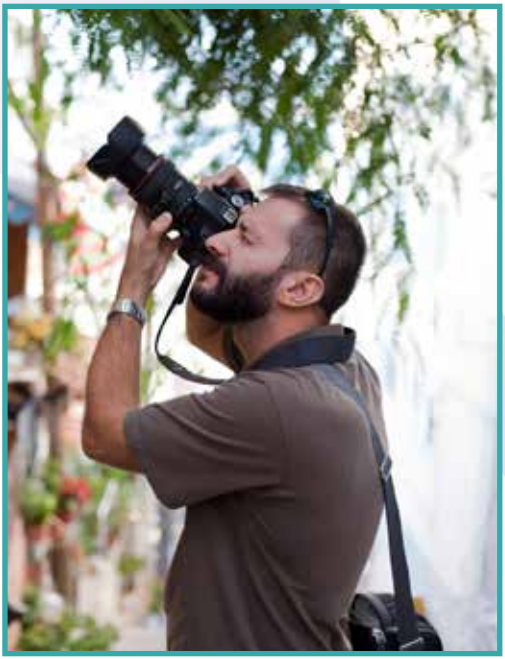
The outside of the plates are sprayed with a coating (hydroxyapatite). This coating helps the vertebrae to grow and attach to the metal plates for long term stability.



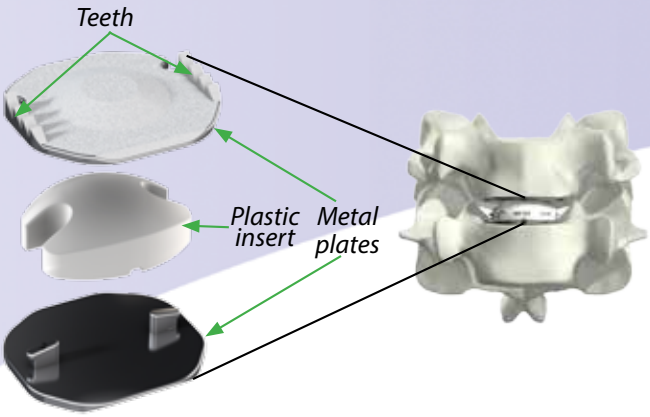
Mobi-C

The plastic insert is made from polyethylene. The insert is flat on the bottom and round on the top. The insert is made to move as you move your neck.

The Mobi-C comes in many different sizes. Your doctor will choose the size that best fits your disc.

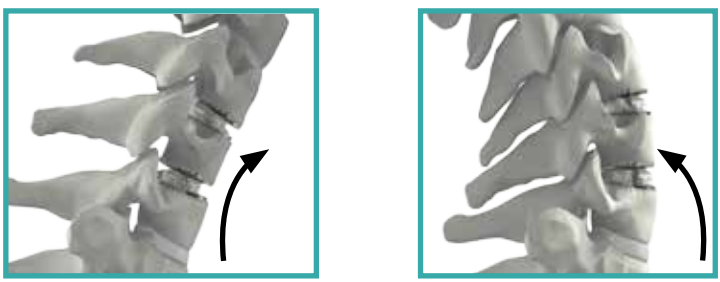


How does the Mobi-C move?

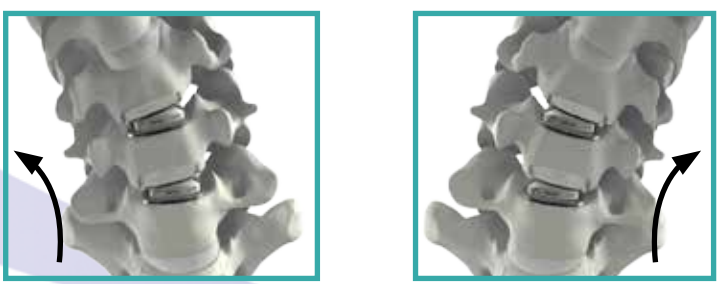


The top plate moves over the insert. The insert slides across and twists over the bottom plate.

The muscles and soft tissue in your neck move the vertebrae and the attached Mobi-C plates. With vertebrae and muscle movement, the Mobi-C is free to twist and slide left-to-right and front-to-back. This allows the vertebra above and below the Mobi-C to move.



Side view of a cervical spine showing the Mobi-C in flexion and extension



Front view of a cervical spine showing the Mobi-C lateral bending

Who should receive a Mobi-C?

The Mobi-C Cervical Disc:

- **Is for adults**; the vertebrae must be mature (age range, 21-67 years).

- **Takes the place of two damaged cervical discs** next to each other (contiguous or adjacent) from levels C3-C7.

- **Is for patients with arm pain and/or neurological symptoms** such as weakness or numbness with or without neck pain. The damaged disc may be irritating the:
  - Spinal cord (myelopathy) or nerve roots (radiculopathy). This can cause a loss of feeling, loss of movement, pain, weakness, or tingling down the arm and possibly into the hands.

- **Disc damage needs to be proven** by your doctor's review of your CT, MRI, or X-ray images. Images of the neck should show at least one of the following:
  - Inner disc squeezing through the outer disc (herniated nucleus pulposus).
  - Degeneration of the spine from wear and tear (spondylosis). There may be boney growth (osteophytes) on a vertebra.
  - Loss of disc height compared to the levels above and below.

- **Is for people who have not responded to non-surgical care**. Patient should either have:
  - Tried at least six weeks of other medical treatments such as physical therapy and medicine before having surgery; or
  - Have signs or symptoms that their condition is getting worse even with other medical treatments.

Will my doctor recommend Mobi-C surgery for me?

Non-surgical treatment, such as physical therapy, injections, and possibly a neck brace, will be prescribed first by your doctor. If these treatments do not relieve your pain or dysfunction, you and your doctor may determine that you are a candidate for artificial disc replacement.

Talk to your doctor about the risks and benefits of surgery using the Mobi-C to treat your condition. Surgery with the Mobi-C may help stop your pain and other problems from a damaged cervical disc.

Who should not receive a Mobi-C (contraindications)?

If you have any of the following, you should **NOT** have surgery with the Mobi-C:

- An active **whole body (systemic) infection**, such as pneumonia.
- An **infection at the surgery site,** such as a skin rash or infected cut.
- A known **allergy to what Mobi-C is made of:** cobalt, chromium, molybdenum, titanium, hydroxyapatite, polyethylene, and other trace elements. Talk to your doctor if you have a metal allergy.
- **Damaged cervical vertebrae** from an accident (trauma) at one of the surgery levels.
- An **unhealthy shape (deformity) of the cervical vertebrae** at one of the surgery levels. Deformity could be caused by an inflammatory disease where the vertebrae swell or grow together and limit movement, such as ankylosing spondylitis and rheumatoid arthritis.
- **A cervical spine that shows an unhealthy amount of extra movement** (instability). This can be measured by X-rays taken from your side when the spine is still and bending.
- **Low bone mineral density**, such as osteoporosis or osteopenia (defined as a DEXA bone mineral density T-score < -1.5). This condition could increase the risk of bone breaking or cause an implant to loosen.
- Severe **disease or degeneration in the joints in the back of the cervical vertebrae** (facet joints).

What are the warnings for using the Mobi-C?

Take time to understand the possible dangers from artificial disc surgery. Talk to your doctor about the **possible dangers and complications of Mobi-C surgery.**

Possible danger
Implanting artificial discs in the neck is serious surgery. There are blood vessels and nerves very close to where the implants enter the body. Your doctor will take care to find and protect the blood vessels and nerves.

Consequence
- A small cut to a blood vessel could **cause a dangerous loss of blood** (hemorrhage) or even death.
- Damage to a nerve can cause **long-term loss of movement (paralysis) or feeling.**

Possible complication
As with any artificial disc surgery, there are steps your doctor should take to make the surgery safe. **The Mobi-C should only be used by doctors,** who:
- Are skilled in neck surgery.
- Are trained in the proper use of Mobi-C , how it works, and how to choose the correct size Mobi-C.
- Understand the risks and complications of disc surgery.

Consequence
If your doctor does not have quality experience or training, there could be a higher chance of problems from surgery,

Possible complication
Bone tissue could form outside the vertebrae (heterotopic ossification (HO)). HO can happen after artificial cervical disc surgery and causes less cervical motion.

Consequence
If HO forms, it has not been shown to cause harmful results in Mobi-C patients.

What are the precautions for using the Mobi-C?

The safety and effectiveness of the Mobi-C has not been tested in patients with the following conditions:

- The young (younger than 21) and the elderly (older than 67).
- Previous cervical spine surgery, including a repeat surgery at the same levels.
- More than two cervical spine levels that are damaged or stopped moving that need surgery.
- Short disc height, defined as a disc height less than:
  - 3mm measured from the center of the disc.
  - One-fifth of the front-to-back measurement of the lower vertebra.
- An unhealthy curving of the cervical spine (kyphosis or reversal of lordosis).
- Active cancer (malignancy).
- Diseases of the bone caused by low mineral levels or genetic problems (Paget's disease, osteomalacia, or other metabolic bone diseases).
- Taking medicine that is known to get in the way of bone or soft tissue healing, such as steroids.
- Pregnancy.
- Diabetes that needs medicine (insulin) given every day.
- Very overweight (obese) (based on the NIH Clinical Guidelines Body Mass Index (BMI greater than 40).
- Neck or arm pain from an unknown source.

What are the precautions for using the Mobi-C? (continued...)

The safety and effectiveness of the Mobi-C has not been tested in patient with the following conditions (continued):

- Whole body (systemic) diseases, including AIDS, HIV, and hepatitis.
- Findings which suggest an irritated nerve root (radiculopathy) or spinal cord (myelopathy) where there is a poor match between the image findings (CT, MRI, or X-ray) and the physical examination.
- A previous fusion at a level above or below the surgery levels.
- Only neck pain with no arm pain.
- Diseases that cause the vertebrae to swell or grow together and limit movement, such as rheumatoid arthritis or other autoimmune diseases.
- Diseases that affect muscle movement because of problems with the nerves or muscles (neuromuscular disorders). Disease examples include: muscular dystrophy, spinal muscular atrophy, and amyotrophic lateral sclerosis.
- Serious mental illness or drug abuse.

Before surgery
Your medical history is very important in your doctor's decision to choose the Mobi-C for you. Before recommending the Mobi-C, your doctor will take into account your past and present health, such as:

- Your job and activity level.
- Past injury or ongoing illness.
- Alcoholism or drug abuse.
- Medicine use.
- Previous treatments.

You may be asked questions to help decide if you have a risk of low bone mineral density. Based on your answers, your doctor may order a bone test (DEXA measurement). The Mobi-C has not been tested in patients with a DEXA T score less than -1.5. This level of DEXA score shows the patient may be osteoporotic or osteopenic.

Your doctor will choose the best Mobi-C size for your body. A correctly sized Mobi-C helps the implants stay in place and work right. Your doctor should not start surgery without the right implant size or instruments in good working order.

Ask your doctor to see the full list of risks and complications in the insert.

During surgery
Your doctor will keep the Mobi-C clean (sterile) and undamaged.

After surgery
Take care to follow your doctor's directions. Right after surgery, you should not:

- Do any heavy lifting.
- Bend your neck multiple times.
- Do any long or difficult activity. You may need to limit activity for weeks to months depending on your level of healing.

What are the potential risks and adverse effects for using the Mobi-C?

Complications may occur when you are treated with the Mobi-C, as with any surgery. Possible complications may include, but are not limited to the following.

Risks from any surgery:

- Problems with the wound healing including pain.
- An allergic attack or infection.
- Problems with the heart (cardiovascular) or blood movement (circulation). This could include: loss of blood, a reaction to a blood transfusion, problems with circulation, or problems with blood forming into clumps (clotting).
- A sickness to the drugs used to put you asleep during surgery (anesthesia).
- Problems with the stomach and intestines (gastrointestinal).
- Problems with the urinary or genital systems (urogenital).
- Problems breathing (respiratory). Respiratory problems could include: lung infection (pneumonia), lung tissue collapsing (atelectasis), or swelling in the neck (edema).
- In rare situations, heart attack, stroke, or death.

Risks from anterior cervical spine surgery:

- Damage, infection, swelling, and problems healing at or anywhere near the surgery site. This could affect, for example, the blood vessels, nerves, spinal cord, trachea, esophagus, disc, vertebrae, and skin.
- Neck and/or arm pain.
- Headaches: weak to strong.
- Pain or damage to the organ that allows you to talk (dysphonia).
- Pain or damage to the muscles that allow swallowing (dysphagia).
- Problems with feeling, movement, or response time (neurological issues) in the upper arm, neck, back, leg, or other area.
- In rare situations, loss of movement (paralysis).

Risks specific to cervical artificial discs including the Mobi-C:

- Less neck movement than before surgery due to:
  - Stiff ligaments (spinal ligament ossification).
  - An overgrowth of bone (heterotopic calcification) at the surgery level.
  - Vertebrae fusing together.
- The implant breaking, moving, or wearing.
- Needing additional neck surgery after disc replacement.
- The development of a recurrent spinal problem at the surgery level, as well as the development of a new spinal problem above or below the treated spinal levels.

There is also the risk that the surgery may not be effective in relieving your symptoms or may cause worsening of your symptoms. If this occurs, you may need another surgery in order to help you feel better.

What are the potential risks and adverse effects for using the Mobi-C? (continued)...

Adverse effects
Throughout the Food and Drug Administration (FDA) clinical study, patients reported health related problems to their doctors. Some of the events listed on the previous page occurred in the FDA study. Some of the more common study events for the Mobi-C and the Anterior Cervical Discectomy and Fusion (ACDF) patients include:

- Neck pain in 32.1% of Mobi-C (75 out of 234 patients) and 46.7% of ACDF (49 out of 105 patients).
- Arm (extremity) pain in 17.1% of Mobi-C (40 out of 234 patients) and 23.8% of ACDF (25 out of 105 patients).
- Back pain in 27.4% of Mobi-C (64 out of 234 patients) and 23.8% of ACDF (25 out of 105 patients).
- Shoulder pain in 22.2% of Mobi-C (52 out of 234 patients) and 31.4% of ACDF (33 out of 105 patients).
- The feeling of pins and needles in the arms (sensory disturbance) in 29.9% of Mobi-C (70 out of 234 patients) and 44.8% of ACDF (47 out of 105 patients).
- Difficulty swallowing (dysphagia) in 15.8% of Mobi-C (37 out of 234 patients) and 22.9% of ACDF (24 out of 105 patients).
- Headache in 20.1% of Mobi-C (47 out of 234 patients) and 19.0% of ACDF (20 out of 105 patients).

Seven (3.1%) treated with Mobi-C and 12 patients (11.4%) treated with ACDF had additional surgery at the same level within 2 years after their surgery. Two patients (0.9%) treated with Mobi-C and four patients (3.8%) treated with ACDF, had surgery at an adjacent level within 2 years after surgery. **No mechanical failures of the Mobi-C device were observed in any study patients**.

A comprehensive list of risks is provided in the package insert for the device, which your doctor has received. **Please ask your doctor for more information about any additional risks that could be related to your planned surgery**.

What are the benefits of surgery with the Mobi-C?

This patient brochure describes many possible problems. These facts are given to help you make the right choice about artificial disc surgery.

There are good reasons, however, to choose an artificial disc. The Mobi-C may help end or lessen your pain and discomfort.

The surgery with Mobi-C:

- Will replace your worn out discs.
- May help keep neck movement:
  - Bending forward-to-back.
  - Bending side-to-side.
  - Turning left-to-right.
- Matches disc height to the levels above and below. This can help un-trap nerves.
- May lessen your neck and/or arm pain.
- May lessen any arm tingling.
- May help you return to your normal life of work, family, and fun.

What are the expected outcomes and benefits of Mobi-C?

In order to be used in the United States at two adjacent levels, the Mobi-C went through major testing and review with the Food and Drug Administration (FDA). In the US study, 234 patients were treated with Mobi-C and 105 patients were treated with ACDF (anterior cervical discectomy and fusion). Some of the study results at two years after surgery are described below. The clinical benefit beyond two years has not been measured. Ask your doctor for more details about the clinical study and its results.

Two years after surgery, 154 out of 221 Mobi-C patients (69.7%) achieved overall study success, compared to 37 out of 99 ACDF patients (37.4%). This shows that Mobi-C achieved superior outcomes to ACDF.

Other key results from the study at two years after surgery include:

- Of Mobi-C patients, 205 out of 214 (95.8%) had four or more degrees of motion while bending the head forward to backward (flexion-extension), based on the combined motion of both operated levels. Additionally, 137 of 221 Mobi-C patients (62.0%) had either the same or more motion in flexion-extension at two years as before they were treated based on the combined motion at both operated levels.
- The rate of major complications was lower for Mobi-C patients (28 out of 225 (12.4%)) compared to ACDF patients (29 out of 105 (27.6%)). Major complications included: diminished neurologic status, spontaneous fusion in the Mobi-C group or failure to fuse in the ACDF group, and adverse events determined to be major complications and related to the study device.
- Another surgery at the treated level was needed for 12 out of 105 ACDF patients (11.4%), compared to 7 out of 225 Mobi-C patients (3.1%); **a rate more than three times higher for ACDF patients**.
- Of the Mobi-C patients, 204 out of 216 (94.4%) had the same or improved neurologic status, compared to 83 out of 89 (93.3%) ACDF patients.

At two years 169 out of 216 Mobi-C patients (78.2%) demonstrated meaningful improvement in an outcome measure designed to evaluate patient function known as the NDI (Neck Disability Index), compared to 55 out of 89 ACDF patients (61.8%). Importantly, NDI scores are higher at early time points for Mobi-C patients compared to ACDF.

The patients in this study will continue to be followed for 7 years after surgery.

Preparing for your Mobi-C surgery

Follow your doctor's directions when getting ready for your surgery. Here is a list with examples of things to-do before surgery. Your doctor's directions may be different:

- Check that the medicine(s) you are taking will still be OK to take after having surgery on your neck.
- Take time before going to the hospital to arrange your life for after surgery:
  - Move anything you use a lot to an easy to reach spot.
  - Arrange to have family or friends around to help you.
- You will likely to be told not to eat or drink the night before the surgery.
- Ask your doctor to tell you what to expect from this surgery.

What happens during Mobi-C surgery?

In the operating room:

- You will lie on your back on a table and be put into deep sleep (anesthesia). Once asleep, your neck area is washed. A clean (sterile) sheet is taped around your neck.
- A cut (incision) is made on your neck. Your doctor will move the muscles, the airway (trachea), the esophagus, and blood vessels to the side. This makes a tunnel to the spine.
- Using a special X-ray (fluoroscopy), your doctor will pass a thin needle into the damaged discs to check the levels for surgery.
- Your doctor will remove the damaged discs and put in Mobi-C. Fluoroscopy may be taken during surgery to check Mobi-C placement.
- The muscle and skin incisions will be sewn together with surgical thread (sutures). A small bandage or biologic glue will be placed across the incision.
- While asleep, you will be moved to a new area (Recovery Room). Nurses will check your blood pressure, heart rate, and breathing. If you are in pain, you may be given medicine. Once awake, you will be moved to a different room.

What happens after Mobi-C surgery?

Ask your doctor to describe how you will feel and what you will need to do after surgery. Replacing your discs with the Mobi-C is a major surgery. Getting better will take time. How fast you get better depends on your age, your general health, and the reason for the surgery. **Your doctor may recommend exercise with the help of a physical therapist. As with any surgery, it is extremely important to follow your doctor's direction after surgery.**

Here are some examples of directions to follow after surgery. Your doctor's directions may be different.

- Stay one night in the hospital.
- Sit, stand, and walk the night after surgery.
- Wear a neck collar to lessen neck movement for around a week after the surgery.
- Take medicine (by mouth) for pain or sickness of the stomach (nausea) as needed.
- Put a new, clean bandage on the cut five days after surgery. The doctor or nurse may show you how to change the bandage.
- Set up a time to visit your doctor to check your healing. Your doctor may take X-rays to look at the Mobi-C placement in your neck.
- Get direction from your doctor on when it is OK to return to your normal neck bending and turning. Talk to your doctor about a physical therapy plan.

What will my surgery cut (incision) look like?
The cut will likely be a short incision in the front (anterior) part of the neck. The doctor normally makes the cut in a line you already have in the skin on your neck. The cut generally heals so that it is difficult to see.

What happens after Mobi-C surgery? (continued...)

When can I shower after Mobi-C surgery?
You will need to keep your incision dry immediately after surgery. Some doctors allow early showering. Patients normally take baths for 1-2 weeks after surgery. Get direction from your doctor on when it is OK to start showering.

When can I drive after Mobi-C surgery?
Ask your doctor when you can start driving after surgery. The timing varies from patient to patient.

Will my Mobi-C affect travel through airport security?
It is very unlikely that the metal in the Mobi-C will set off airport security detectors. However, the Transportation Security Administration (TSA) rules state, "TSA Security Officers will need to resolve all alarms associated with metal implants."

How does surgery using the Mobi-C compare to fusion?

Before artificial discs, most often a patient would get an anterior cervical discectomy and fusion (ACDF). In this fusion surgery, the doctor removes the unhealthy disc. The empty disc space is filled with a bone spacer or plastic implant. The implant helps match the disc height to the levels above and below. Restoring the disc height can help remove pressure on the nerves and/or spinal cord.

Then, a metal plate with screws is placed on the front of the neck. The plate helps:

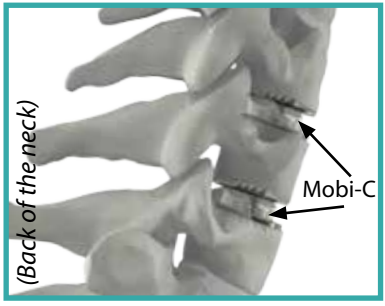
- Keep the spacer in place.
- Stop movement at that level. This helps new bone grow between the vertebrae (fusion).

Both a fusion and Mobi-C artificial disc surgery:

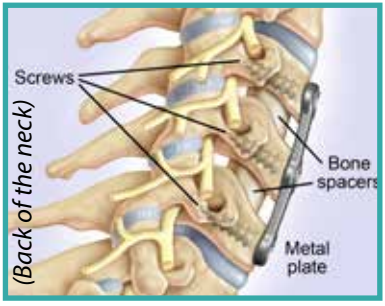
- Replace the damaged disc.
- Try to match a healthy disc height to help un-trap any nerves.

Only the Mobi-C implant:

- Tries to maintain neck movement.
- Fits entirely within the disc space.



Mobi-C



Fusion

When should I call the doctor after surgery?

Ask your doctor to describe how you will feel after surgery. Some pain and discomfort is normal. The problems you had before surgery may not lessen right away. Talk to your doctor about **when to call with problems after surgery**.

If you have any of these problems at any point after surgery, call your doctor.

- Signs that your cut (incision) may not be healing (infection):
  - The incision is draining. Although, you can expect some wetness.
  - The skin around the incision becomes red, warm, swollen, or increasingly painful.
  - You have a fever.
- Pain or problems with swallowing (dysphagia), talking (dysphonia), or breathing. It is common to experience some mild, temporary discomfort with swallowing.
- More tingling, numbness, pain, or weakness in the arms or neck than you had before surgery.

For more information on the Mobi-C

www.ldrmedical.com
www.cervicaldisc.com

LDR USA
13785 Research Blvd, Ste. 200
Austin, TX 78750

800-699-3360

Indications:
The Mobi-C® Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at two contiguous levels for intractable radiculopathy (arm pain and/or neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, or 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.

Reading this book should not take the place of talking with a doctor. Please go to your doctor with questions about how you are feeling. Talk to a doctor about the best way to help your neck or arm problems.

Ref #: MB PF 2 REV A 06.2013