INSTRUCTIONS FOR USE – AUSTRALIA ONLY

Important Information – Please Read Prior to Use

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Device System Name:

M6-C™ Artificial Cervical Disc

INTENDED USE

The M6-C™ Artificial Cervical Disc is an intervertebral disc prosthesis intended to permit motion of a functional spinal unit in the cervical spine when the native disc is diseased.

DEVICE DESCRIPTION

The M6-C™ Artificial Cervical Disc is an intervertebral disc prosthesis designed to permit motion of a functional spinal unit in the cervical spine when replacing a degenerated native disc. The device is comprised of ultra-high molecular weight polyethylene (UHMWPE) fiber wound in a specific pattern, with multiple redundant layers, creating a fiber matrix (artificial annulus). The fiber is wound around a polycarbonate urethane polymer (PCU) core (artificial nucleus) and through the slots in two Ti6Al4V titanium alloy inner endplates (see **Figure 1**). The core is situated between and in contact with the two inner endplates, but not affixed to them. A PCU sheath surrounds the fiber matrix and is retained by two Ti6Al4V weld bands that are welded to the inner endplates. Two Ti6Al4V outer endplates are also welded to the inner endplates. The exterior surfaces of the outer endplates include low profile fins and are coated with titanium plasma spray (TPS).

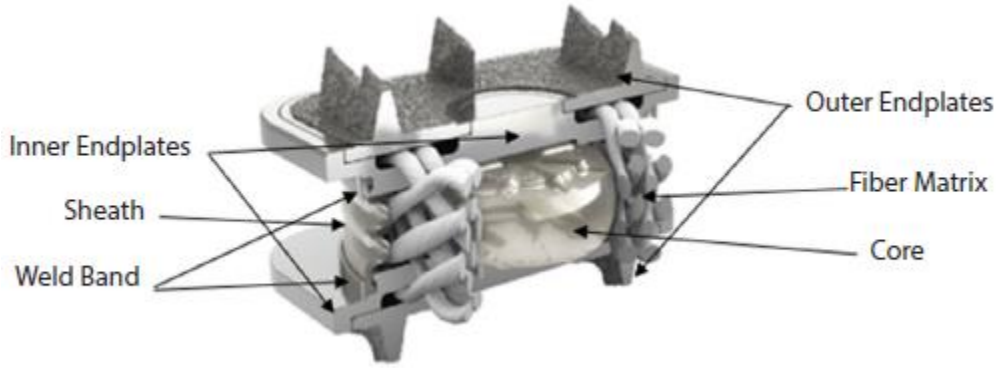

Figure 1: Cross-Section View of the M6-C™ Artificial Cervical Disc

The M6-C™ Artificial Cervical Disc is designed to maintain the natural behavior of a functional spinal unit by replicating the biomechanical characteristics of the native disc. This design enables the M6-C™ Artificial Cervical Disc to move in all six degrees of freedom, with independent angular rotations (flexion-extension, lateral bending and axial rotation) along with independent translational motions (anterior-posterior and lateral translations as well as axial compression). The device is intended to replicate the physiological phenomenon of progressive resistance to motion in all six degrees of freedom. The sheath is designed to minimize any tissue ingrowth as well as the migration of wear debris. The serrated fins provide acute fixation to the superior and inferior vertebral bodies. The TPS coating increases the bone contact surface area.

The M6-C™ Artificial Cervical Disc is currently offered in four different footprint sizes and two heights, as shown in **Figure 1** and **Table 1**.

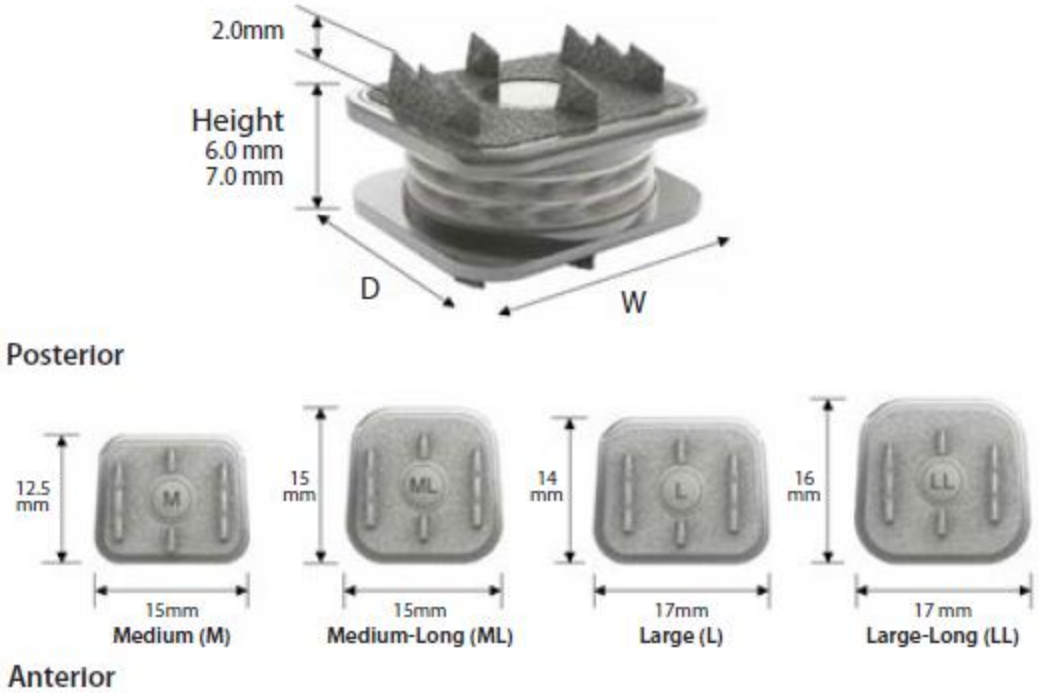

Figure 1: M6-C™ Artificial Cervical Disc Heights and Footprint Sizes

Table 1: M6-C™ Artificial Cervical Disc Catalog Number and Size

REF	Description	Provided Sterile
CDM-625	Cervical Disc – 6 Medium (15mm W x 12.5mm D x 6mm H)	Yes
CDM-725	Cervical Disc – 7 Medium (15mm W x 12.5mm D x 7mm H)	Yes
CDL-627	Cervical Disc – 6 Large (17mm W x 14mm D x 6mm H)	Yes
CDL-727	Cervical Disc – 7 Large (17mm W x 14mm D x 7mm H)	Yes
CDM-635L	Cervical Disc – 6 Medium-Long (15mm W x 15mm D x 6mm H)	Yes
CDM-735L	Cervical Disc – 7 Medium-Long (15mm W x 15mm D x 7mm H)	Yes
CDL-637L	Cervical Disc – 6 Large-Long (17mm W x 16mm D x 6mm H)	Yes
CDL-737L	Cervical Disc – 7 Large-Long (17mm W x 16mm D x 7mm H)	Yes

INDICATIONS FOR USE

The M6-C™ Artificial Cervical Disc System is intended for use in skeletally mature patients undergoing primary surgery for treatment of symptomatic disc diseases of the cervical spine at any one level or multiple levels between C3 through C7, who have not responded to non-operative conservative

management.* The disease state is demonstrated by signs and/or symptoms of disc herniation, osteophyte formation, or loss of disc height.
** The non-operative conservative management requirement may be waived in the cases of myelopathy requiring immediate treatment and/or cervical radiculopathy with worsening neurological functions (i.e. motor weakness).*

CONTRAINDICATIONS

The M6-C™ Artificial Cervical Disc should not be implanted in patients with the following conditions:

- Be ≥70 years of age.
- Have a bone mineral density with T-score ≤-1.5 as determined by spine DXA if male ≥60 years of age or female ≥50 years of age.
- Have an active systemic infection or infection at the operative site.
- Have sustained an osteoporotic fracture of the spine, hip or wrist.
- Have received medications (e.g., methotrexate, alendronate) that interfere with bone and mineral metabolism within 2 weeks of the planned date of the index surgery.
- Have any medical or surgical condition precluding the potential benefit of spinal surgery.
- Have a history of endocrine or metabolic disorders (e.g., Paget's disease) known to affect bone and mineral metabolism.
- Have rheumatoid arthritis or other autoimmune disease or a systemic disorder such as HIV or active hepatitis.
- Have spinal metastases.
- Have a known allergy to titanium, polyurethane, polyethylene or ethylene oxide residuals.
- Have type 1 or type 2 diabetes requiring daily insulin management.
- Be pregnant.
- Have axial neck pain as the solitary symptom.
- Have severe cervical myelopathy as evidenced by any sign of gait disturbance, unilateral or bilateral leg weakness, and/or uncontrollable bowel/bladder symptoms related to cervical spine disease.
- Require a treatment (e.g., posterior element decompression) that destabilizes the spine.
- Have advanced cervical anatomical deformity (e.g., ankylosing spondylitis, scoliosis) at the operative site.
- Have advanced degenerative changes (e.g., spondylosis) at the index vertebral level as evidenced by:
  - Bridging osteophytes;
  - Average ROM <4°;
  - Disc height <25% of the AP width of the inferior vertebral body; as measured in a lateral radiograph in neutral position;
  - Subluxation >3mm;
  - Kyphotic deformity at >20° on neutral radiographs.

PRECAUTIONS

- Read and understand the M6-C™ Artificial Cervical Disc System Instructions for Use prior to use.
- The M6-C™ Artificial Cervical Disc is intended to be used with the M6-C™ Manual Surgical Instruments.
- Refer to the M6-C™ Artificial Cervical Disc Operative Technique Manual for implantation instructions.
- The M6-C™ Artificial Cervical Disc System is intended to be used only by surgeons with training in cervical spine surgery and related surgical techniques, and biomechanical principles of the spine and spine arthroplasty.
- Prior to use, the surgeon must be trained in the surgical procedure as outlined in the M6-C™ Artificial Cervical Disc Operative Technique Manual and thoroughly familiar with the implant and instruments.
- Improper surgical use and technique may lead to suboptimal clinical outcomes.
- Do not use the M6-C™ Artificial Cervical Disc after the last day of the month of the "Use by date" on the label.

- Inspect the device package before opening. Do not use if package is damaged or shows any evidence of breached packaging, compromised device sterility, or storage above 60˚C (140˚F). The temperature recorder label on the box turns black if the product has reached 60˚C (140˚F).
- Use sterile technique to carefully remove the Disc from the packaging. Inspect the M6-C™ Artificial Cervical Disc to ensure it exhibits no signs of damage (e.g., metal and plastic damage).
- The M6-C™ Artificial Cervical Disc must be implanted using the M6-C™ Manual Surgical Instruments. The use of the Spinal Kinetics Instruments for purposes other than those for which they are intended may result in damaged or broken instruments. Do not use any other implant components or instrumentation. Detailed instructions on the use and limitations of the M6-C™ Artificial Cervical Disc must be given to the patient. Postoperative rehabilitation and restrictions must be reviewed with the patient prior to discharge from the hospital.
- The M6-C™ Artificial Cervical Disc serial number and the size must be documented for each patient record.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect M6-C™ Artificial Cervical Disc, incorrect surgical techniques, including improper use of instruments, the limitations of treatment methods, or inadequate asepsis.
- The surgeon should instruct the patient on postoperative rehabilitation and limitations. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful osseointegration of the implant. The patient must be made aware of the limitations of the implant and that early strenuous physical activity and high load bearing have been implicated in premature loosening of fixation prior to proper integration. An active, debilitated, or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
- Instructions for postoperative care should be according to the surgeon's discretion and may consist of a physician-managed, individual post-operative rehabilitation program. Certain activities should be limited or avoided for two weeks postoperative. It is recommended that the surgeon discuss with the patient the following limitations:
    - Excessive neck movements: Short term use of a soft neck collar to stabilize the neck and reduce excess movement is an option. Instruct patient to avoid excessive flexion/extension for two weeks postoperative.
    - Heavy lifting: Avoid lifting anything heavier than about 3.5-4.5 kilograms (8-10 pounds) for two weeks postoperative.
    - Returning to work: In general, return to light work, such as a desk job or school, approximately one week after surgery. Returning to a more physical job, such as construction, may take six weeks or longer.
    - Resuming sports and other physical activities: The timeline for returning to sports and other recreational activities can vary. The weight permitted for lifting may gradually increase starting after two weeks. Some light sport activities may be permitted at about 4 weeks, such as jogging, biking, or swimming. A return to competitive sports may take 6 weeks or longer, depending on the integration of the device and the ability to perform the sport's movements pain-free. There is currently a lack of data regarding cervical artificial discs and contact or extreme sports.
- Physicians should instruct patients to contact surgeon in the event of significant increase in pain which may indicate a device performance issue.
- Routine long term clinical and radiographic monitoring of patients implanted with the M6-C is suggested to assess any changes in implant condition or surrounding anatomy.
- Changes in disc position, loss of height and peri-prosthetic bone loss may be indicative of onset of osteolysis. Peri-prosthetic osteolysis may result in neck pain and serious neurological sequelae including cervical spinal cord compression and quadriplegia.

WARNINGS

- Correct placement of the M6-C™ Artificial Cervical Disc is essential to optimal performance.
- The M6-C™ Artificial Cervical Disc should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with this device. A lack of adequate

experience and/or training may lead to a higher incidence of adverse events, such as vascular or neurological complications.

- The M6-C™ Artificial Cervical Disc is single use only. Do not re-sterilize or reuse the M6-C™ Artificial Cervical Disc. Re-sterilizing and/or reusing the M6-C™ Artificial Cervical Disc may result in impaired performance and could cause patient injury and/or the communication of infectious diseases between patients.
- The M6-C™ Manual Surgical Instruments are reusable, supplied non-sterile and must be sterilized in accordance with the recommended cleaning and sterilization procedures contained within the individual instrument Instructions for Use booklet.
- During implantation, the surgeon should ensure that none of the surgical instruments or the M6-C™ Artificial Cervical Disc progress beyond the posterior border of the vertebral bodies. 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 this device and allowing the instruments or the M6-C™ Artificial Cervical Disc to progress beyond the posterior border of the vertebrae may result in injury to these structures.
- Fluoroscopic confirmation of positioning of certain instruments and the implant should be performed during the surgical procedure. Failure to confirm position of instruments and the implant during the surgical implantation procedure may result in patient injury.
- Ensure that the appropriate size M6-C™ Artificial Cervical Disc is chosen. Using an inappropriately sized M6-C™ Artificial Cervical Disc may result in less than optimal clinical outcomes. Proper sizing should be determined in accordance with the M6-C™ Artificial Cervical Disc Operative Technique Manual.

CAUTIONS

- Perform a complete discectomy of the disc space between the uncinates and up to the posterior ligament. Take care to release / decompress the foramen bilaterally.
- It is important to remove all anterior and posterior osteophytes on the superior and inferior vertebral endplates. To prevent weakening of the endplates, use of a burr/drill is discouraged during endplate preparation. Use the Cervical Retainer as needed to maintain distraction. Take care not to over-distract the disc space. Ensure proper alignment and placement of the device as misalignment may cause excessive wear and/or early failure of the device.
- Excessive removal of subchondral bone during the preparation of the vertebral endplates may lead to less than optimal clinical outcomes and is not recommended.
- Once removed from the package, keep the M6-C™ Artificial Cervical Disc from coming into contact with any cloth, sponges or other foreign material that may become attached to the Titanium Plasma Spray Coating of the endplates. The Packaging Clip may be used to safely store the loaded M6-C™ Artificial Cervical Disc.
- The M6-C™ Artificial Cervical Disc is designed to be implanted with the endplates parallel to each other. Excessive endplate lordosis or kyphosis can lead to less than optimal M6-C™ Artificial Cervical Disc performance.
- The M6-C™ Artificial Cervical Disc cannot be re-positioned in an anterior direction without complete removal. Take care not to place the M6-C™ Artificial Cervical Disc too posterior.
- 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.

POTENTIAL ADVERSE EFFECTS

Below is a list of the potential adverse effects (e.g., complications) identified for: (1) those associated with any general surgical procedure; (2) those associated with anterior cervical spine surgery; and (3) those associated with a cervical artificial disc device, including the M6-C™ Artificial Cervical Disc. 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.

General Surgery Risks

General surgical risks are, but may not be limited to:

- Infection/abscess/cyst, localized or systemic
- Blood clots, including pulmonary emboli
- Medication and anesthesia reactions
- Phlebitis
- Pneumonia
- Atelectasis
- Soft tissue damage
- Septicemia
- Hemorrhage possibly requiring a blood transfusion, with possible transfusion reaction
- Myocardial infarction
- Paralysis
- Poor tissue healing
- Cerebrovascular accident (CVA)
- Death

Anterior Cervical Surgery Risks

Anterior cervical surgical risks are, but may not be limited to:

- Infection/abscess/cyst, localized or systemic
- Injury or damage to the trachea, esophagus, nerves or blood vessels
- Dysphagia
- Hoarseness
- Vocal cord paralysis
- Paresis
- Recurrent laryngeal nerve palsy
- Soft tissue damage
- Spinal cord damage
- Dural tear with cerebrospinal fluid leakage
- Arm weakness or numbness
- Death
- Bowel, bladder or sexual dysfunction
- Nerve root injury
- Airway obstruction
- Epidural hematoma or bleeding
- Epidural fibrosis
- Vertebral body fracture
- Dysesthesia or numbness
- Paresthesia
- Unresolved pain
- Surgical intervention at incorrect level
- Need for supplemental fixation
- Spinal instability

Cervical Artificial Disc Risks

Risks specific to cervical artificial discs, including the M6-C™ Artificial Cervical Disc, are but may not be limited to:

- Infection/abscess/cyst, localized or systemic
- Allergic reaction to the implant materials
- Implant failure
- Device migration
- Device translation
- Device subsidence
- Device fatigue or fracture or breakage
- Device instability
- Separation of device components
- Placement difficulties, device malposition
- Improper device sizing
- Excessive device height loss
- Wear debris (manifested as osteolysis and/or device damage/breakage/failure)
- Disc space collapse
- Material degradation (manifested as osteolysis and/or device damage/breakage/failure)
- Excessive facet loading
- Dural tear with cerebrospinal fluid leakage
- Soft tissue damage
- Epidural fibrosis
- Nerve injury, paralysis or weakness that is temporary or permanent
- Injury or damage to the trachea, esophagus, or blood vessels
- Epidural hematoma or bleeding
- Dysesthesia or numbness
- Paresthesia
- Failure to relieve symptoms including unresolved pain
- Additional surgery due to loss of fixation, infection or injury
- Heterotopic ossification (Grades 1-4); Spontaneous fusion due to heterotopic ossification, development of bridging bone or osteophytes
- Periarticular calcification and/or fusion

- Kyphosis or hyper-extension
- Loss of flexibility
- Asymmetric range of motion
- Vertebral body fracture
- Spinal cord damage, cord compression, paralysis, or quadriplegia that is temporary or permanent
- Development of spinal conditions, including but not limited to spinal stenosis, spondylolisthesis, or retrolisthesis
- Removal, revision, reoperation or supplemental fixation of the disc
- Peri-prosthetic osteolysis, bone loss, or bone resorption
- Death

These conditions do not include all potential adverse effects that may occur, but are important considerations in relation to the use of the M6-C™ Artificial Cervical Disc.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the M6-C™ Artificial Cervical Disc is MR Conditional. A patient with the M6-C™ Artificial Cervical Disc can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-T or 3.0-T, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the M6-C™ Artificial Cervical Disc is expected to produce a maximum temperature rise of 2.2°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the M6-C™ Artificial Cervical Disc extends approximately 10-mm from this device when imaged using a gradient echo pulse sequence and a 3.0-Tesla MR system.

HOW SUPPLIED

- The M6-C™ Artificial Cervical Disc is supplied sterile and is single use only. Do not re-sterilize or reuse the M6-C™ Artificial Cervical Disc. Re-sterilizing and/or reusing the M6-C™ Artificial Cervical Disc may result in impaired performance and could cause patient injury and/or the communication of infectious diseases between patients.
- Do not use the M6-C™ Artificial Cervical Disc after the last day of the month of the “Use by date” on the label.
- Inspect the device package before opening. Do not use if package is damaged or shows any evidence of breached packaging, compromised device sterility, or storage above 60˚C (140˚F). The temperature recorder label on the box turns black if the product has reached 60˚C (140˚F).
- Use sterile technique to carefully remove the Disc from the packaging. Inspect the M6-C™ Artificial Cervical Disc to ensure it exhibits no signs of damage (e.g., metal and plastic damage).
- Once removed from the package, keep the M6-C™ Artificial Cervical Disc from coming into contact with any cloth, sponges or other foreign material that may become attached to the Titanium Plasma Spray Coating of the endplates.
- The M6-C™ Artificial Cervical Disc serial number and the size must be documented for each patient record.

DEVICE RETRIEVAL

Please contact Spinal Kinetics to receive specific instructions regarding the preferred method for explant handling and transport as well as data collection, including histopathological, mechanical, patient, and adverse event information. Please refer to M6-C™ Artificial Cervical Disc Operative Technique Manual for

step-by-step instructions on the required surgical technique for device removal. All explanted devices must be returned to Spinal Kinetics for analysis.

It is preferred that no cleaning, decontamination or sterilization be performed at the hospital. Some surgical centers may require that the device be decontaminated or sterilized prior to leaving the facility. Note that many sterilization methods will damage the device (e.g., autoclaving, immersion in alcohol), and the effects of other methods are unknown. Rinsing with water or saline is acceptable. If decontamination and sterilization are required, 10% neutral buffered formalin is best. If cleaning, decontamination or sterilization is performed, note what cleaning methods and materials were used.

It is preferred that the explanted device is packed “dry” (no fluid) or wrapped in formalin-soaked gauze. The device can be gently rinsed with water or saline to remove excess blood and fluids.

Send explant in a leak-proof container, with the date of removal, explanting surgeon, and any known information regarding initial implantation, reasons for removal, and adverse event information. Please note that the explanted M6-C™ Artificial Cervical Disc should be removed as carefully as possible in order to keep the implant and surrounding tissue intact if possible. 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. Spinal Kinetics will request additional information regarding the reason for removal, patient information and associated clinical outcomes.

NOTE: All implant removals must be reported immediately to Spinal Kinetics.

CONTACT INFORMATION **Manufactured by:**

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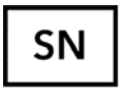
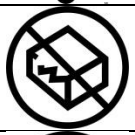
Definitions of symbols on device label

	Catalog Number
	Lot Number
	Serial Number
	Use by Date
	Sterile with Ethylene Oxide Gas
	Single Use Only / Do Not Reuse
	Read Instructions Prior to Use: www.orthofix.com/IFU
	Manufacturer
	Transient temperature limitation; Store at room temperature
	Do not use if package is damaged
	Do not resterilize
	Authorized Representative in the European Community
	MR Conditional

PK 0278 Rev 02