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INSTRUCTIONS FOR PATIENTS
Important Information – Please Read

M6-C™ Artificial Cervical Disc

DEVICE IDENTIFICATION AND GENERAL INFORMATION

Device Trade Name	Proprietary Name (Trade Name): M6-C Artificial Cervical Disc Common Name: Intervertebral Discs Replacement Systems
Manufacturer Name and Address	Spinal Kinetics LLC 501 Mercury Drive Sunnyvale, CA 94085, USA Telephone: +1 888-298-5700 Fax: +1 408-636-2599
Parent Company, Corporate Headquarters	Orthofix US LLC 3451 Plano Parkway Lewisville, Texas 75056
Basic UDI-DI	0812338803B0000598
Year When the First Certificate (was Issued Covering the Device	2006

INTENDED PURPOSE AND INDICATIONS OF THE DEVICE

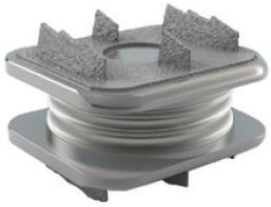
Intended Use	The M6-C Artificial Cervical Disc is intended to allow motion of the neck when your natural disc goes bad.
Indications for Use	The M6-C is for adults who need surgery to replace either one or multiple discs in their neck. These problems may be in more than one part of the neck. Surgery is only for those people who have not gotten better with other care.
Intended Patient Groups	The M6-C is for adults who need surgery to replace either one or two adjacent discs in their neck. This may be because they have severe pain, weakness, numbness that has not got better despite other care.
Contraindications	The M6-C Artificial Cervical Disc should not be used in patients who are: • 70 years old or older. • Have poor quality bone that makes it weaker. • Have an ongoing infection. • Have an infection in their teeth • Have broken bones before because their bones are weaker than they should be. • Are still taking the medications methotrexate or alendronate 2 weeks before surgery. • Have any medical or surgical problems that would not help surgery. • Have any medical problems that makes their bones weak or abnormal. • Have rheumatoid arthritis or other autoimmune disease or a systemic disorder such as HIV or active hepatitis. • Have any cancer in the spine.

	• Have an allergy to titanium, polyurethane, polyethylene, or ethylene oxide residuals. • Have type 1 or type 2 diabetes requiring daily insulin management. • Be pregnant. • Only have pain when pushing on the head downwards and no other problems. • Are not able to walk normally, have leg weakness in one or both legs, are having toilet accidents that leads to the patient wetting or soiling themselves. • Require other types of spine surgery. • Have an abnormal shape to the spine or a medical problem that causes this (e.g., ankylosing spondylitis, scoliosis) at the part of the spine that is being looked at for surgery.If the surgeon has found profoundly serious wear and tear changes (e.g., spondylosis) that have caused: - Bridging osteophytes – small bony stumps. - Average ROM <4° - poor movement. - Disc height <25% of the AP width of the inferior vertebral body; as measured in a lateral radiograph in neutral position. - Subluxation >3mm – lost a lot of disc height. - Kyphotic deformity at >20° on neutral radiographs – a large bend in your spine. The M6-C Artificial Cervical Disc is contraindicated for use in constructs with anterior cervical disc fusion (ACDF) (hybrid constructs). The M6-C Artificial Cervical Disc is contraindicated for non-contiguous multilevel use or at more than 2 levels.

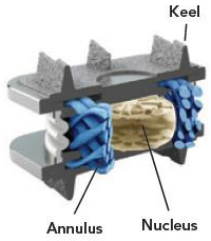
DEVICE DESCRIPTION AND MATERIAL/SUBSTANCES IN CONTACT WITH PATIENT TISSUES

The M6-C Artificial Cervical Disc is one of a kind replacement. The M6-C Artificial Cervical Disc moves and absorbs shock in the similar way as your natural disc. Made to mimic your own disc, the M6-C is the only artificial disc that looks like a natural disc. It has the jelly-like interior called a nucleus (made from a springy plastic called polycarbonate urethane) and a woven tire-like tougher outer annulus (made from a plastic called polyethylene). Laboratory testing shows that the artificial nucleus and annulus together provide controlled motion in all directions much like the natural disc. This “natural” motion allows your neck to move naturally. It also tries to protect the surrounding discs and other important spinal joints from pressure.

The M6-C artificial annulus and nucleus is sandwiched between two titanium plates. These metal plates have small fins that help anchoring the artificial disc to the bony blocks (vertebrae) above and below. The parts of the metal in contact with bone are coated with a special titanium plasma spray that helps bone growth into the metal plates. This helps to fix the M6-C more strongly to the bone.



M6 Artificial Cervical Disc



The unique artificial annulus and nucleus of the M6 cervical disc are designed to work together to provide motion that is similar to a natural disc

Information about Medicinal Substances in the Device if Any

The M6-C Artificial Cervical Disc does not contain materials from human or animal sources. It does not contain any medicines.

Description of How the Device is Achieving its Intended Mode of Action

The M6-C Artificial Cervical Disc is made to act like the normal disc to support the movement of the vertebrae. The design of the M6-C gives it a lot of movement including bending forward), bending backward, bending right, and left and twisting. It has a sheath that surrounds its middle that is made to protect the device and stop any wear or lose parts moving elsewhere. The fins help keep the device fixed between the top and bottom vertebrae. The titanium plasma spray helps bone growth into the metal plates.

Description of Accessories if Any

No accessories are to be used with the M6-C Artificial Cervical Disc.

RISKS AND WARNINGS

Side-effects are problems after surgery that may be caused by the surgery. A risk is the chance of a problem or complication happening. If you believe that you are having side-effects or are worried about risks, please contact your doctor or healthcare professional.

How Potential Risks Have Been Controlled or Managed

No operation is completely safe. Any surgery may cause problems for patients. These problems or risks may be found after any surgery. Problems or complications may happen in surgery using an M6-C Artificial Cervical Disc. These problems may lead to injury, or other serious problems that cause death. The company has tried to make sure the chance of any problem happening is as low as possible.

As with any surgical procedure, complications may occur when you are treated with the M6-C Artificial Cervical Disc. Potential complications can include, but may not be limited to, the following:

Risks Associated with Any Surgery

- Surgical wound healing complications including infection near the surgical cut or in the blood
- Lung problems including pneumonia, collapsed lung and blood clots
- A negative reaction to the drugs used to put you to sleep before surgery (anesthesia)
- Swelling of the vein at the site (usually on the lower arm) where fluids are administered during and after surgery
- Continued bleeding after surgery that may require another surgery or transmission of additional blood (transfusion)
- Problems associated with the heart or blood movement and in rare instances heart attack, strike, or death

Risks Associated with Anterior Spine Surgery

- Injury or damage to the surgery site area including the nerves, blood vessels, spinal cord, swallowing tubes and skin
- Hoarseness or problems with swallowing or talking
- Partial paralysis or arm numbness, tingling or weakness
- Spinal cord damage or damage to the nerves at the back of the vertebrae
- Tear in the covering of the spinal cord with possible spinal fluid leakage, bowel, bladder, or sexual dysfunction
- Bleeding and possible collection of blood or scarring on the covering of the spinal cord
- Surgical intervention at incorrect level

Risks Associated with Artificial Cervical Disc Surgery including the M6-C Artificial Cervical Disc

- Removal, revision, reoperation, or additional fixation of the M6-C Artificial Cervical Disc
- Movement of the M6-C Artificial Cervical Disc out of the disc space or into the vertebrae
- Instability of the M6-C Artificial Cervical Disc
- Device placement difficulties including in the incorrect position or level
- Development of unstable conditions at the surgery level or other cervical spine levels
- Additional surgery due to the M6-C Artificial Cervical Disc loosening, breaking, or wearing excessively
- Fractures to the cervical vertebrae or bones on the back of the vertebrae
- Loss of motion, asymmetric range of motion or spinal fusion at the treated level due to bone overgrowth
- Development of recurrent pain at the surgery level
- Allergic reaction to implanted materials

This is not a full list of complications. There may be other risks associated with treatment using the M6-C Artificial Cervical Disc, as well as the possibility that this surgery may not be effective in relieving your symptoms or even cause worsening of your symptoms. If this happens, you may require additional surgery. You should discuss these risks and any other concerns with your doctor prior to making a final decision regarding artificial disc replacement surgery.

The following possible side effects may happen when you receive the M6-C Artificial Cervical Disc. There are other potential side effects that might occur during surgery and because these side effects do not directly relate to the use of the device, they are only included in the product manual.

Remaining Risks and Undesirable Effects

The following is a summary of the complications and risks reported in published papers and clinical studies, and national registries.

- Heterotopic ossification (Abnormal bone growth) (Grades 3-4)
- Failure to relieve symptoms including unresolved pain (Pain with no relief)
- Complaints leading to additional surgery
- Infection/abscess/cyst, localized or systemic (Infection/Swollen pocket/cyst, at site of surgery or whole body)
- Dysphagia/Dystonia (Difficulty swallowing, uncontrollable muscle twitches causing repetitive, twisting movements)
- Adjacent disc degeneration (Degeneration of other discs in the spine that are close to the surgical site)
- Granuloma (A small area of inflammation)
- Hoarseness (Scratchy voice)
- Implant failure
- Inflammation
- Wear debris (manifested as osteolysis and/or device damage/breakage/failure) (Small pieces of the device due to wear and tear could cause bone destruction)
- Device subsidence (Device sinking into the bone that it is attached to)
- Material degradation (manifested as osteolysis and/or device damage/breakage/failure) (Break down of the material of the implant can cause bone destruction)
- Epidural hematoma or bleeding (Bleeding in your spine)
- Allergic reaction to the implant materials
  Asymmetric range of motion (Unevenness in ability to move neck in all directions)
- Device fatigue, fracture, or breakage (Device breaking down or failing)

The following are complications and risks reported from the Registry analysis that led to additional surgery.

- Loosening
- Device fatigue or fracture or breakage (Device breaking down or failing)
- Other
- Placement difficulty, device malposition (device does not sit in properly)
- Failure to relieve symptoms including unresolved pain
- Neurological (changes to normal functioning of brain, spinal cord, nerve)
- Peri-prosthetic osteolysis, bone loss, or bone resorption (bone wearing off around implant)

WARNINGS AND PRECAUTIONS

Warnings

The following warnings have been identified for the device.

- Correct placement of the M6-C Artificial Cervical Disc is essential to have a desired outcome.
- The M6-C Artificial Cervical Disc should only be used by surgeons who have experience in this surgical procedure. They should have participated in training with this device. A lack of experience and/or training may lead to more risks, such as vascular or neurological complications.
- The M6-C Artificial Cervical Disc is single use only.
- During implantation, the surgeon should make sure that the surgical instruments he is using to implant the M6-C Artificial Cervical Disc do not push too deep into the back bones. This warning is because there are a lot of nerves and vessels in the area that can be damaged.
- X-rays must be taken during the surgery. Failure to take X-rays during the procedure may result in patient injury.
- Surgeons need to choose the proper size of the M6-C Artificial Cervical Disc. A wrong sized M6-C Artificial Cervical Disc may result in less than optimal outcomes.

- Use of the M6-C Artificial Cervical Disc at the desired level where the treatment involves a long hybrid (combination of fusion and artificial disc), or multi-level hybrid construct may lead to extra loading on the spine, increased device wear, and early failure.

Precautions

The safety and effectiveness of the M6-C Artificial Cervical Disc has not been established in patients with the following conditions:

- 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 infection control practices.
- Care after the surgery is a critical part of the treatment. Your ability and willingness to follow instructions are two of the most important aspects of successful outcomes. There are certain things such as heavy exercising, carrying heavy weight that are limited after the surgery as they can cause problems with the implant.
- Instructions for the recovery period after surgery are given to you by your doctor. Certain activities should be avoided for two weeks after the procedure. You can expect the following limitations:
    - Too much neck movements: You will have to wear a soft neck collar to stabilize the neck and reduce movements for a short period of time. You cannot bend your neck forward and backward too much for the first two weeks.
    - Heavy lifting: Avoid lifting anything heavier than about 3.5-4.5 kilograms (8-10 pounds) for two weeks after the surgery.
    - 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 allowed at about 4 weeks, such as jogging, biking, or swimming. A return to competitive sports may take 6 weeks or longer, depending on healing 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.
- Please contact your doctor in the event of significant increase in pain which may indicate a device problem.
- Routine long term clinical follow-ups are suggested to see any changes.

Summary of Any Field Safety Action (FSN or FSCA), if Applicable

There have been no field corrective actions initiated. A field corrective action is an action taken by Orthofix to report any technical or medical reason leading to a recall of the M6-C devices.

LIFETIME OF THE DEVICE

The M6-C Artificial Cervical Disc implants are designed and intended to remain in the patient for the rest of the patient's life. Removal may be justified or necessary if there are complications; however, the risks and benefits of implant removal must be carefully assessed by your surgeon.

MRI STATEMENT

The M6-C Artificial Cervical Disc has undergone testing to determine how it will react with MRI testing. There are specific conditions that should be met for safe MRI testing. Please inform your doctor or other medical professional that you have an M6-C Artificial Cervical Disc and ask that they follow the conditions contained in the instructions for use.

SUGGESTED PROFILE AND TRAINING FOR USERS

The M6-C Artificial Cervical Disc should only be used by surgeons who are experienced in this kind of surgery and have undergone adequate training with this device.

SERIOUS ISSUE REPORTING

If you experience any significant issue with your implant, you should report it to Orthofix using the contact information at the beginning of this document, as well as the Competent Authority (e.g., Therapeutic Goods Administration, www.tga.gov.au) in your Country.

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