Orthofix US LLC
3451 Plano Parkway
Lewisville, Texas 75056-9453 U.S.A.
+1 888-298-5700
www.orthofix.com

INSTRUCTIONS FOR PATIENTS

Important Information – Please Read

Spinal Kinetics LLC
501 Mercury Drive
Sunnyvale, CA 94085 USA
+1 888-298-5700
www.orthofix.com
M6info@orthofix.com

CH REP Effectum CH-REP AG
Kirchgasse 11
CH-4600 Olten

EC REP MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels Germany
+49 6442 962073

UK Responsible Person:
Emergo Consulting (UK) Limited
Compass House, Vision Park Histon
c/o Cr360 – UL International
Cambridge CB24 9BZ
United Kingdom

CE 0123

M6-L™ Artificial Lumbar Disc

DEVICE IDENTIFICATION AND GENERAL INFORMATION

Device Trade Name	Proprietary Name (Trade Name): M6-L Artificial Lumbar 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	0812338803B000069A
Year When the First Certificate (CE) was Issued Covering the Device	2009

INTENDED PURPOSE AND INDICATIONS OF THE DEVICE

Intended Use	The M6-L Artificial Lumbar Disc is intended to allow motion of the lower back when your natural disc goes bad.
Indications for Use	The M6-L Artificial Lumbar Disc is a prosthesis for those who need surgery to replace either one or two discs in their lower back to maintain the motion of their spine. This surgery is done when the original disc is diseased. Surgery is only for those people who have not got better with other care.
Intended Patient Groups	The M6-L Artificial Lumbar Disc is for adults who need surgery to replace either one or two discs in their lower back.

Contraindications	The M6-L Artificial Lumbar Disc should not be used in patients who are: • Older than 75 years of age, or younger than 18 years of age • Have poor quality bone that makes it weaker • Have an ongoing infection or have infection at their lower back • 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 problems that makes their bones weak or abnormal (e.g., Paget's disease) • Have rheumatoid arthritis or other autoimmune disease or a systemic disorder such as HIV or active hepatitis • Previous abdominal surgery that would make the surgery dangerous • Previous surgery at the operating site • 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 • Need a treatment in the spine that destabilizes it (e.g., posterior element decompression) • Bony narrowing of the spinal cord canal in the lower back • Where a slipped disc or worn bit of spine bone pushes on a nerve coming out of the spine causing pain. • Be pregnant • Stress fracture of the spine in the lower back • Greater than normal motion in your spine • Spine problems, such as if a vertebrae above the diseased disc is slipped forward • X-ray confirmation of severe joint disease or problem at the back part of your vertebrae • Have changes of spine where the surgery is needed that are getting worse by time • The disc height is less than 3mm before surgery

DEVICE DESCRIPTION AND MATERIAL/SUBSTANCES IN CONTACT WITH PATIENT TISSUES

The M6-L artificial lumbar disc is one of a kind replacement. The M6-L moves and absorbs shock in the similar way as your natural disc. Made to mimic your own disc, the M6-L is the only artificial disc that looks like a natural disc. It has a jelly-like interior called 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 lower back to move naturally. It also tries to protect the surrounding discs and other important spinal joints from pressure.

The M6-L 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-L more strongly to the bone.

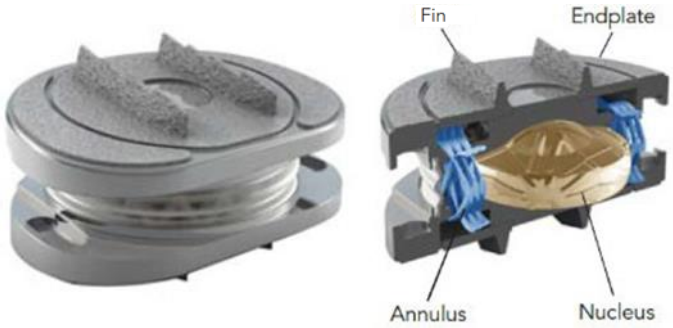

Figure 1. M6-L Artificial Lumbar Disc

Information about Medicinal Substances in the Device if Any

The M6-L Artificial Lumbar 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-L Artificial Lumbar Disc device is made to act like the normal disc to support the movement of the vertebrae. The design of the M6-L 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-L Artificial Lumbar 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-L Artificial Lumbar 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-L Artificial Lumbar Disc. Potential complications can include, nut 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
- Problems related to your nerves and brain. They can cause things like nerve damage, paralysis, seizures, or changes in how your mind works.
- Inability to resume activities of daily living
- Issues with your stomach and intestines, such as things like a blockage or an ileus (when your bowels stop moving altogether).
- Issues with which involves your bladder, kidneys, and reproductive organs. Problems here can lead to things like incontinence (when you can't control your pee), bladder dysfunction (when your bladder doesn't work properly), or complications with your reproductive system (like trouble having babies).
- Complications of pregnancy
- Parts of your body stop working, like if you are unable to move your legs.

Risks Associated with Anterior Spine Surgery

- Injury or damage to the surgery site area including the nerves, blood vessels, spinal cord, peritoneum, and skin
- 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
- Back or leg pain
- Scoliosis

Risks Associated with Artificial Lumbar Disc Surgery including the M6-L Artificial Lumbar Disc

- Removal, revision, reoperation, or additional fixation of the M6-L Artificial Lumbar Disc
- Movement of the M6-L Artificial Lumbar Disc out of the disc space or into the vertebrae
- Instability of the M6-L Artificial Lumbar Disc
- Device placement difficulties including in the incorrect position or level
- Development of unstable conditions at the surgery level or other lumbar spine levels
- Additional surgery due to the M6-L Artificial Lumbar Disc loosening, breaking, or wearing excessively
- Fractures to the lumbar 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 new or recurrent pain at the surgery level
- Allergic reaction to implanted materials
- Change in alignment of the spine

This is not a full list of complications. There may be other risks associated with treatment using the M6-L Artificial Lumbar 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-L Artificial Lumbar 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 followings are 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)
- Complaints leading to additional surgery
- Infection/abscess/cyst, localized or systemic (Infection/Swollen pocket/cyst, at site of surgery or whole body)

- Adjacent disc degeneration (Degeneration of other discs in the spine that are close to the surgical site)
- Hematoma or bleeding (Bleeding in your spine)
- Neurological (Changes to normal functioning of brain, spinal cord, nerve)
- Blood Vessel Damage
- Retrograde Ejaculation
- Migration (Device shifting location)
- Complaints leading to removal of device

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

- Prosthesis Dislocation
- Other

WARNINGS AND PRECAUTIONS

Warnings

The following warnings have been identified for the device.

- Correct placement of the M6-L Artificial Lumbar Disc device is essential to have a desired outcome.
- The M6-L Artificial Lumbar 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-L Artificial Lumbar Disc is sterile and single use only.
- During implantation, the surgeon should make sure that the surgical instruments he is using to implant the M6-L Artificial Lumbar Disc do not push too deep into the back bones. This warning is due to the fact that 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-L Artificial Lumbar Disc. A wrong sized M6-L Artificial Lumbar Disc may result in less-than-optimal outcomes.

Precautions

The safety and effectiveness of the M6-L Artificial Lumbar 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-L Artificial Lumbar Disc, incorrect surgical techniques, including improper use of instruments, the limitations of treatment methods, or inadequate infection control practices.
- Care after 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 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 low back movements: you will likely have to wear a low back support (sacral orthosis (LSO)) to stabilize the low back and reduce movement for a short period of time.
    - Heavy lifting: Avoid lifting anything heavier than about 3.5-4.5 kilograms (8-10 pounds) for two weeks after 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 the healing and the ability to perform the sport's movements pain-free. There is currently a lack of data regarding lumbar 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.
- Store the device in a room temperature environment, and away from heat source.

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-L devices.

LIFETIME OF THE DEVICE

The M6-L Artificial Lumbar 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-L Artificial Lumbar 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-L Artificial Lumbar Disc and ask that they follow the conditions contained in the instructions for use.

SUGGESTED PROFILE AND TRAINING FOR USERS

The M6-L Artificial Lumbar 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 serious 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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CE Mark 0123 Applicable to Implant Only