Spinal Kinetics M6-C Artificial Cervical Disc System Instruction Manual

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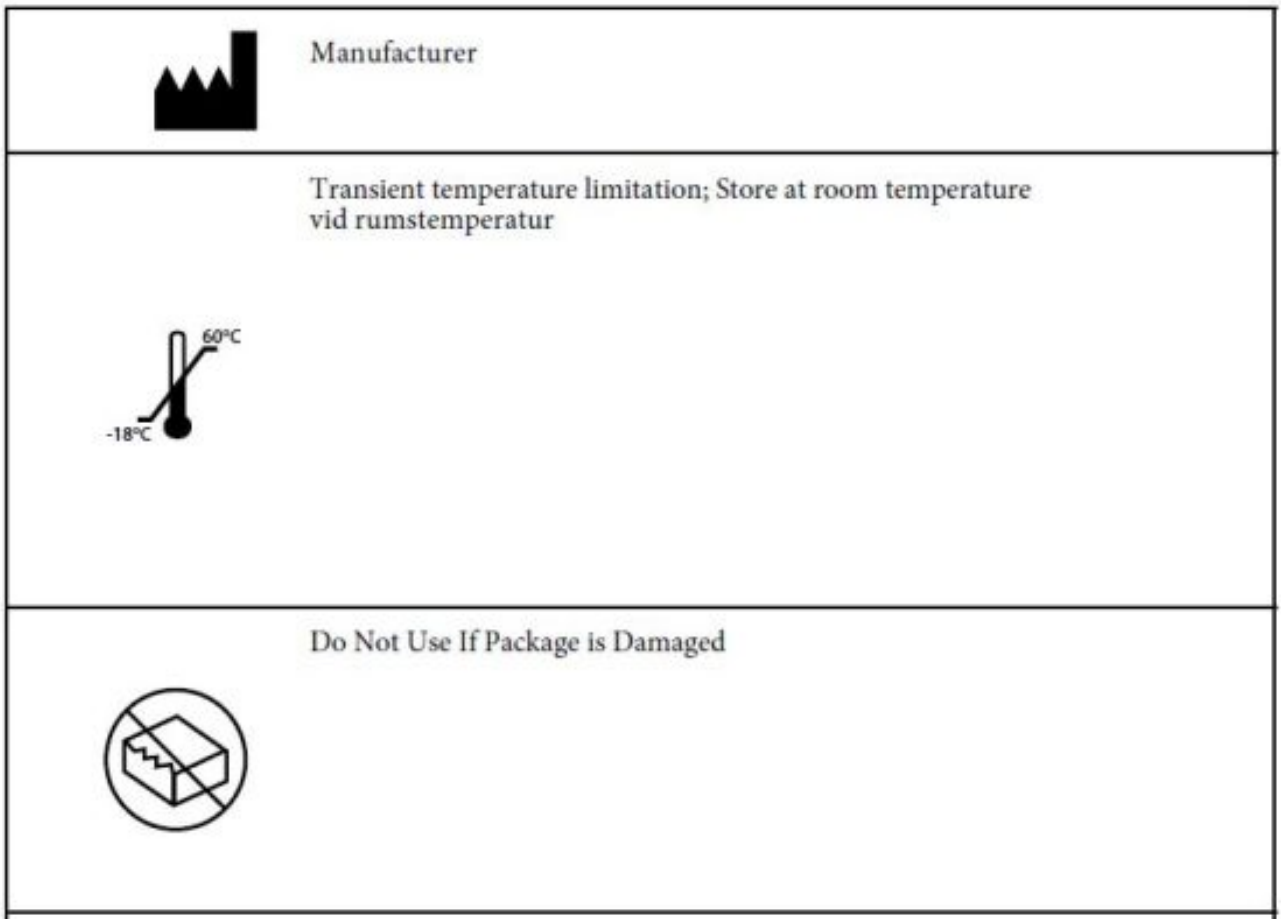
Definitions Of Symbols On Device Label

REF	Catalog number/Bestell-Nr./Référence catalogue
LOT	Lot number
SN	Serial number
	Use by date

STERILE EO	Sterilized with ethylene oxide gas/Mit Ethylenoxidgas sterilisiert
	Single use only
	Read instructions prior to use

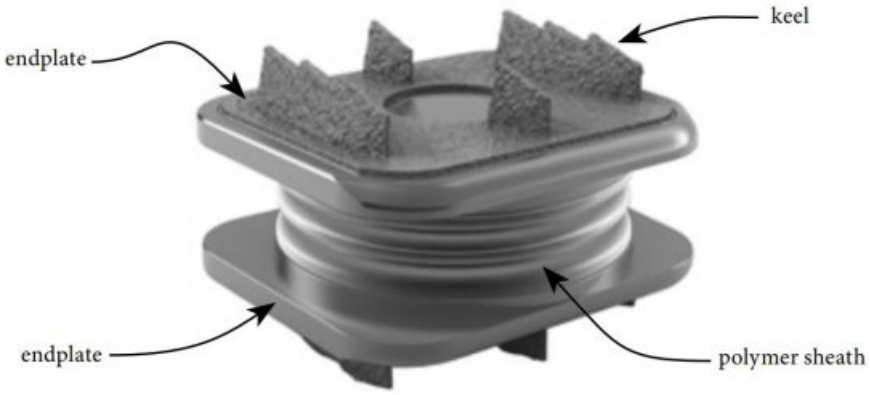


The M6® artificial cervical disc is intended to be used with the M6 artificial cervical disc instruments. Refer to the M6 artificial cervical disc Surgical Technique Manual for implantation instructions.

Description

The Spinal Kinetics M6-C Artificial Cervical Disc is an intervertebral disc prosthesis designed to maintain motion of a functional spinal unit in the cervical spine when the native disc is diseased.
The M6-C Artificial Disc is designed to maintain the natural behavior of a functional spinal unit by replicating the biomechanical characteristics of the native disc. The core of the disc is composed of a polycarbonate urethane

polymer material. It is surrounded by a polyethylene fiber construct. The device is comprised of an assembly of ultra high molecular weight polyethylene (UHMWPE) fibers wound in multiple redundant layers around a polycarbonate urethane polymer (PCU) core and through titanium alloy endplates. Biomechanical studies demonstrate that this unique design provides a progressive resistance to motion, leading to physiologic motion in flexion, extension, lateral bending and axial rotation as well as in compression and shear. The prosthetic disc also has a PCU sheath surrounding the core and fiber construct designed to minimize any tissue ingrowth as well as the migration of wear debris. Serrated keels located on the exterior surfaces of the device provide acute fixation to the superior and inferior vertebral bodies. Both the endplates and keels are coated with porous titanium to increase
bone contact surface area and promote osseointegration.



Indications for Use

The M6 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 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 l – evel as evidenced by:

-Bridging osteophytes;
– Average ROM <4º;
– 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 >20º on neutral radiographs.

Precautions

- Read and understand the M6 cervical disc System Instructions for Use prior to use.
- The M6 artificial cervical disc is intended to be used with the M6 artificial cervical disc Instruments. Refer to the M6 artificial cervical disc Surgical Technique Manual for implantation instructions.
- The M6 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 artificial cervical disc Surgical 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 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 cervical disc to ensure it exhibits no signs of damage (e.g., metal and plastic damage).
- The M6 cervical disc must be implanted using the M6 cervical disc instrumentation. 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 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 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 cervical disc, incorrect surgical techniques, including improper use of instruments, the limitations of treatment methods, or inadequate asepsis.
- Adequately 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.
- Physicians should instruct patients to contact surgeon in the event of significant increase in pain which may indicate a device performance issue.
- The M6-C Artificial Disc has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.

⚠WARNING:
Failure to read and follow the Instructions for Use and the instructions in the M6 artificial cervical disc Surgical Technique Manual may result in patient injury or death.

The M6 cervical disc is single use only. Do not re-sterilize or reuse the M6 cervical disc. Re-sterilizing and/or reusing the M6 cervical disc may result in impaired performance and could cause patient injury and/or the communication of infectious diseases between patients.

The M6 artificial cervical disc 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.

The trial, chiseling, and insertion steps for the device must be performed under fluoroscopic visualization. Extreme care must be taken to avoid placing the device or any instrument beyond the posterior edge of either vertebral body. The user must maintain control and visual reference via fluoroscopy. Failure to visualize the trial, chiseling, and insertion steps could result in patient injury.

Ensure that the appropriate size M6 artificial cervical disc is chosen. Using an inappropriately sized M6 cervical disc may result in less than optimal clinical outcomes. Proper sizing should be determined in accordance with the M6 artificial cervical disc Surgical Technique Manual.

CAUTION:
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 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 Package Clip may be used to safely store the loaded M6 cervical disc.

The M6 cervical disc cannot be re-positioned in an anterior direction without complete removal. Take care not to place the M6 cervical disc too posterior.

Take care not to over-distract the disc space.

Potential Risks and Adverse Events

- Adverse/allergic reaction to implant materials
- M6 cervical disc migration in the anterior-posterior direction
- M6 cervical disc subsidence requiring subsequent surgical intervention
- Placement difficulties requiring acute implant removal
- Excessive facet loading
- Kyphosis or hyper-extension
- Loss of flexibility
- Asymmetric range of motion
- Spondylotic bridging
- Vertebral body fracture
- Infection
- Spinal cord damage
- Neurologic damage or failure to relieve symptoms
- Im plant failure M6 cervical disc wear, fatigue or fracture – M6 cervical disc instability leading to unstable movement of the spine – Separation of M6 cervical disc components – Excessive M6 cervical disc height loss requiring subsequent surgical intervention – Wear debris – Material degradation
- Risks associated with general and spine surgery include: – Excessive bleeding – Anesthesia reaction – Respiratory disorders – Heart attack – Nerve or spinal cord damage leading to sensory loss – Pneumonia – Blood mass/clot – Side effects from medicine used during and after surgery – Scarring of the spinal canal sheath – Bruising – Damage to blood vessels near spine – Opening of the wound – Loss of fluid surrounding the spinal cord – Stroke – Superficial or deep wound infection – Accumulation of fluid within the incision – Additional surgery – Incorrect treatment level – Ongoing pain – Spinal fractures

How Supplied

- The M6-C cervical disc is supplied sterile and is single use only. Do not re-sterilize or reuse the M6-C. Re-sterilizing and/or reusing the M6-C 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 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 to ensure it exhibits no signs of damage (e.g., metal and plastic damage).
- Once removed from the package, keep the M6-C 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 serial number and the size must be documented for each patient record.

Device Retrieval

Should it be necessary to remove a M6-C Artificial Disc, please contact Spinal Kinetics to receive instructions regarding the data collection, including histopathological, mechanical, and adverse event information. Please refer to the M6-C Surgical Technique Manual for step by step instructions on the required surgical technique for device retrieval. All explanted devices must be returned to Spinal Kinetics for analysis.

Please note that the artificial disc should be retrieved 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, e.g. intact or in pieces.

Limited Warranty

Spinal Kinetics, Inc. warrants that reasonable care has been used in the manufacture of this device. There are no express or implied warranties, including fitness for a particular purpose, for this M6 artificial cervical disc system. Any description or specifications provided are solely to describe the product at the time of manufacture and do not constitute any express or implied warranties. Spinal Kinetics, Inc. is not responsible for any direct, incidental, special, or consequential loss, damage, or expense based on any defect, failure, or malfunction of this product, other than as expressly provided by mandatory provisions of applicable law. No person has the authority to bind Spinal Kinetics, Inc. to any representation or warranty except as provided in this Limited Warranty.

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Documents / Resources

	Spinal Kinetics M6-C Artificial Cervical Disc System [pdf] Instruction Manual M6-C, Artificial Cervical Disc System, M6-C Artificial Cervical Disc System