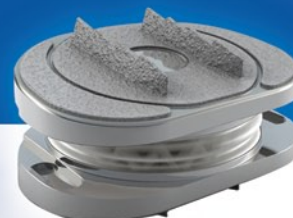


M6^L
artificial lumbar disc



Quality of Life. Quality of Motion.



M6^L
artificial lumbar disc

*This brochure is provided to you
courtesy of your doctor's office.*

*This brochure was developed by
Spinal Kinetics, Inc., makers of the
M6-L artificial lumbar disc*



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MKT-0075 Rev. 2

*A Patient's Guide to
Artificial Lumbar
Disc Replacement*

Each year, hundreds of thousands of adults are diagnosed with Lumbar Disc Degeneration, a lower spine condition that can cause chronic back pain.

This patient guide is intended to provide you with a better understanding of lumbar disc replacement as well as introduce you to the M6®-L Artificial Lumbar Disc, a novel and unique technology used to treat these painful degenerative lumbar conditions.

This guide is not intended as a substitute for an informed discussion with your physician. If you have questions regarding this booklet, please write them down so that your doctor or other health care professional can answer them for you.



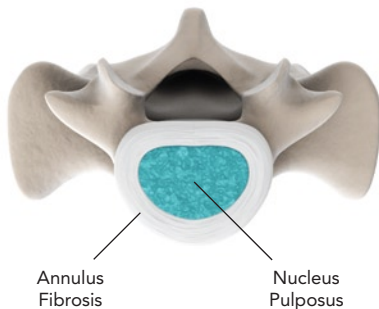
The Lumbar Spine

What is the Lumbar Spine?

The lumbar spine is a complex system of bones, muscles, cartilage, and nerves designed to support the weight of the upper body while allowing movement in multiple directions. The low back officially begins with the lumbar region of the spine directly below the cervical and thoracic regions and directly above the sacrum. The lumbar spine consists of five vertebrae called L1 through L5.

The Lumbar Intervertebral Disc

Between each vertebra is a disc; a shock-absorbing pillow that helps maintain proper spacing, stability, and motion within the lumbar spine. Each disc has a fibrous, tire-like outer band (called the annulus fibrosus) that encases a central gel-like substance (called the nucleus pulposus). The nucleus and annulus work together to absorb shock, help stabilize the spine, and provide a controlled range of motion between each vertebra.



Lumbar Disc Degeneration (DDD)

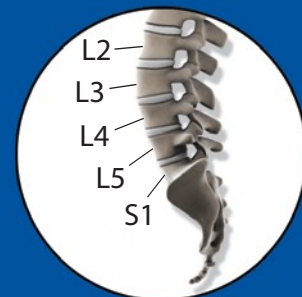
As we age, the discs in our lumbar spine begin to flatten and wear down. When a disc flattens, it forces the vertebrae closer together, which can put added stress not only on the disc itself, but also on the surrounding joints, muscles, and nerves. This process is called Lumbar Disc Degeneration, and can lead to several painful conditions.

Cervical

Thoracic

Lumbar

Sacrum & Coccyx



Treating Lumbar Disc Degeneration

Current Treatment Options

For most patients, non-surgical or conservative treatments will effectively relieve symptoms of Lumbar Disc Degeneration. These treatments may include a combination of rest, physical therapy, or the use of painkillers or anti-inflammatory medications. If pain persists despite these treatments, surgical treatment options may be considered. Your doctor will review the various treatment options available so that you can make an informed decision.

Fusion

The most common surgical procedure for treating Lumbar Disc Degeneration is Spinal Fusion, which removes the degenerated, painful disc and replaces it with a bone graft. Over time, the bone graft will unite with the vertebrae above and below the disc space, thus “fusing” the two vertebrae together to form a single column of bone. The goal of spinal fusion is to eliminate pain by eliminating motion between the two vertebrae and restore proper spacing between them. Thus, fusion may reduce or eliminate chronic low back pain. However, because it also eliminates the motion and shock absorption at that segment, the adjacent segments are subject to increased stress, which may lead to more rapid degeneration, a condition known as Adjacent Level Degeneration.

Artificial Lumbar Disc Replacement

Artificial Disc Replacement has been developed as an alternative to fusion. Once the damaged disc is removed, it is replaced by an artificial disc. The artificial disc is designed to restore proper spacing between the vertebrae while preserving motion associated with a healthy disc. This motion may eliminate the occurrence of Adjacent Level Degeneration.



The M6-L Artificial Lumbar Disc

The M6-L artificial lumbar disc offers an innovative option compared to other artificial lumbar disc replacement because of its unique design, which is based on the qualities of the natural disc.

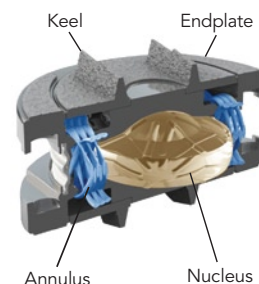
The M6-L is the only artificial disc that incorporates an artificial nucleus (made from polycarbonate urethane) and a woven fiber annulus (made from polyethylene). The M6-L artificial nucleus and annulus are designed to provide the same physiologic motion characteristics of a natural disc. Extensive biomechanical testing with the M6-L artificial lumbar disc has demonstrated equivalent Quality of Motion compared to the healthy disc.

Together, the M6-L's artificial nucleus and annulus provide compressive capabilities and a controlled range of natural motion. This “natural” motion is designed to provide the freedom to move your back naturally while minimizing the stress to adjacent discs and other important spinal joints, and possibly preventing or delaying additional adjacent level degeneration.

The M6-L has two titanium outer plates with keels for anchoring the disc into the bone of the vertebral body. These outer plates are coated with a titanium plasma spray that promotes bone growth into the metal plates, providing long-term fixation and stability of the disc in the bone.



M6-L Artificial Lumbar Disc



M6-L Artificial Lumbar Disc

Is the M6-L Artificial Lumbar Disc For Me?

Please speak with your doctor to understand the benefits and risks associated with the M6-L artificial lumbar disc replacement and to find out if you're a candidate for lumbar disc replacement using the M6-L artificial disc.



M6-L Case Example



Lumbar spine
extending backwards



Lumbar spine in
neutral position



Lumbar spine
flexing forward

The Procedure

What Happens During Surgery?

During the disc replacement surgery, you will be lying on your back and the surgeon will operate on your spine through an incision near the belly button. The damaged disc is removed (discectomy), and the M6-L lumbar disc is then inserted into the disc space using specialized and precise instruments. After the M6-L is successfully placed, the incision is closed.

What Can I Expect After Surgery?

After surgery, your doctor will give you guidelines for activities and follow up requirements before you leave the hospital. You may undergo therapy to help heal and strengthen your lumbar spine. Follow-up examinations are performed after surgery with your physician to assess your recovery.



Disc Removed



Determination of
M6-L Disc Size



M6-L Artificial Lumbar
Disc Insertion



Final M6-L Lumbar
Disc Placement

Glossary of Terms

Adjacent Level Degeneration

Condition resulting from treatment at one level leading to increased stress, which may lead to more rapid degeneration at adjacent segments.

Annulus Fibrosus

The fibrous tire-like outer band of a natural disc that encases the central gel-like substance (called the nucleus pulposus).

Artificial Disc

A lumbar prosthesis that is inserted between vertebral bodies after a degenerated disc is removed. The artificial disc is designed to maintain disc height as well as facilitate motion at the treated vertebral level.

Discectomy

The removal of part or the entire intervertebral disc.

Fusion

Removal of the degenerated, painful disc and replacement with a bone graft. Over time, the bone graft will unite with the vertebra above and below the disc space, thus "fusing" the two vertebrae together to form a single column of bone.

Lumbar Disc

Located between each vertebrae. Helps maintain proper spacing, stability, and motion within the lumbar spine. Each disc is comprised of a nucleus pulposus and annulus fibrosus.

Lumbar Disc Degeneration

Changes of the spine and its associated surrounding areas (intervertebral disc, spinal joints, etc.) that result from the natural aging process or injury that can limit the spine's mobility and stability.

Nucleus Pulposus

A gel-like substance in the center of the disc encased by a fibrous tire-like outer band (called the annulus fibrosus).

Vertebrae (Vertebral Body)

Bony segments that form the spinal column of humans. The lumbar spine consists of five vertebrae called L1 through L5.

Notes: