



A Patient's Guide to
Artificial Cervical Disc Replacement

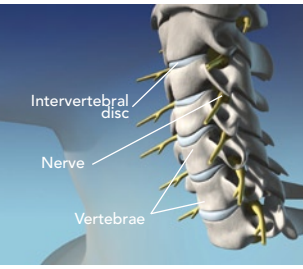
Each year, hundreds of thousands of adults are diagnosed with Cervical Disc Degeneration,

an upper spine condition that can cause pain and numbness in the neck, shoulders, arms, and even hands. This patient guide is intended to provide you with a better understanding of cervical disc degeneration as well as an overview of certain treatment options. Additionally, this guide will introduce you to the M6™ Artificial Cervical Disc, a novel and unique technology used to treat some of these painful degenerative cervical 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.

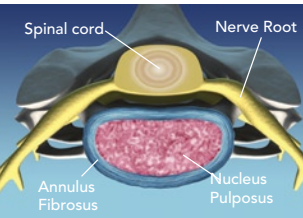


The Cervical Spine



What is the Cervical Spine?

The cervical spine is a complex system of bones, muscles, cartilage, and nerves designed to support the weight of the head while allowing movement in multiple directions. The cervical spine begins at the base of the skull and has seven small bones called vertebrae. It forms a protective pathway for your spinal cord and the nerve roots that carry signals to and from the brain, shoulders, arms and chest.



Top view of cervical vertebra and its structures

The Cervical Intervertebral Disc

Between each vertebra is a disc; a shock-absorbing pillow that helps maintain proper spacing, stability and motion within the cervical 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.

Cervical Disc Degeneration

As we age, the discs in our cervical 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 Cervical Disc Degeneration, and can lead to several painful conditions.

Conditions Caused By Cervical Disc Degeneration

Herniated Disc

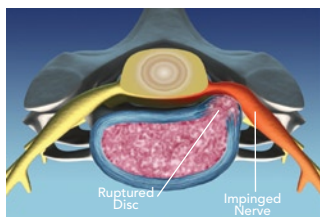
A Herniated Disc, known as a Herniated Nucleus Pulposus (HNP), occurs when the outer layer of the disc (the annulus fibrosus) tears or ruptures due to stress from the surrounding vertebrae. These tears can cause the disc's soft central core (the nucleus pulposus) to bulge out or even detach completely, putting pressure on the nearby nerves or spinal cord. This nerve pressure can cause symptoms of pain or weakness in specific parts of the body, depending on which nerves are being compressed.



Herniated discs shown impinging on adjacent nerves and spinal cord

Bone Spurs (Osteophytes)

Bone spurs, also called osteophytes, are small bony ridges that form on vertebrae as a result of increased stress on these bones. Usually, these spurs cause nothing more than an occasional stiff or sore neck. However, as with a HNP, bone spurs may press against nearby nerves or the spinal cord, causing symptoms of pain or weakness in specific parts of the body.



Symptoms of Cervical Disc Degeneration

Although many people experience Cervical Disc Degeneration as a result of aging, few people experience severe symptoms.

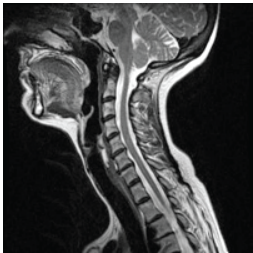
Typically, Cervical Disc Degeneration symptoms are mild such as aches or stiffness in the neck and shoulder, as well as occasional headaches. However, Cervical Disc Degeneration symptoms can become severe when nerves are pinched due to a herniated disc or bone spurs. This can lead to painful conditions known as Cervical Radiculopathy and Cervical Myelopathy.



- **Cervical Radiculopathy** - When spinal nerves are pinched, it can lead to pain, weakness, or numbness in the neck, shoulder, arms, and hands. Oftentimes, this feels like a shooting pain traveling down the arm.
- **Cervical Myelopathy** - Occasionally, the spinal cord itself is pinched, which can lead to severe pain or weakness in the arms and legs. This pain can cause difficulty walking as well as trouble using the hands.

Diagnosis

Your physician will conduct a history and physical examination to understand your symptoms and to determine if you have any nerve or spinal cord impairment caused by conditions related to Cervical Disc Degeneration.



MRI & X-ray helps your physician detect any degeneration that could be causing pain

Your posture, neck motion, reflexes, muscle strength and areas of pain are all evaluated during the examination. If Cervical Disc Degenerations suspected, your doctor may order an X-ray or MRI to evaluate your discs, nerves and spinal cord to help outline a course of treatment.

Treating Cervical Disc Degeneration

Current Treatment Options

For many patients, non-surgical or conservative treatments will effectively relieve symptoms of Cervical Disc Degeneration. These treatments may include a combination of rest, physical therapy, or the use of painkillers or anti-inflammatory medications. If pain or numbness persists despite these treatments, surgical treatment options are considered. Surgical treatment involves removing the herniated disc, osteophytes, and bone spurs causing your symptoms; a process called decompression.

Both conservative and surgical treatments are designed to relieve your pain symptoms. Your doctor will determine the best treatment based on the severity of your degenerative disorders.

Artificial Cervical Disc Replacement

If surgical intervention is required, your doctor will remove the damaged disc. The disc space is then filled with a specialized implant called an artificial disc. The artificial disc is designed to restore proper spacing between the vertebrae while preserving motion associated with a healthy disc.



MRI showing a herniated disc of the cervical spine

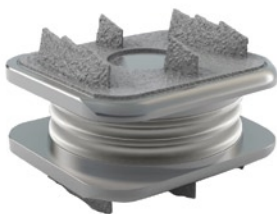
The M6 Artificial Cervical Disc

The M6 artificial cervical disc offers an innovative option for artificial cervical disc replacement because of its unique design which is based on a natural disc's qualities.

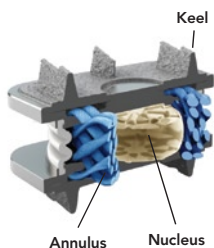
Engineered to replicate your own disc, the M6 is the only artificial disc that incorporates an artificial nucleus (made from polycarbonate urethane) and a woven fiber annulus (made from polyethylene). The M6 artificial nucleus and annulus are designed to provide the same motion characteristics of a natural disc.

Together, the M6's artificial nucleus and annulus provide compressive capabilities along with a controlled range of natural motion along each vertebra. This "natural" motion is designed to provide the freedom to move your neck naturally while minimizing the stress to adjacent discs and other important spinal joints.

The M6 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 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

Is the M6 Artificial Cervical Disc For Me?

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



M6 Case Example



Cervical spine extending backwards



Cervical spine in neutral position



Cervical spine flexing forward

The Procedure

What Happens During Surgery?

During the disc replacement surgery, a small 3-to-4 centimeter incision is made in the front of your neck to access your cervical spine. The damaged disc is removed (discectomy), and the impinged nerve is then relieved (decompression). The M6 cervical disc is then inserted into the disc space using specialized and precise instruments. After the M6 is successfully placed, the incision is closed.

What Can I Expect After Surgery?

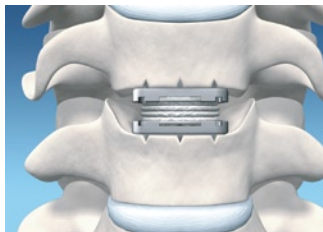
After surgery, your doctor will give you guidelines for activities and follow up requirements before you leave the hospital. You may undergo therapy to help heal and strengthen your cervical spine. Follow-up examinations are performed after surgery with your physician to assess your recovery.



Herniated Disc Removed



M6 Artificial Disc Insertion



Final M6 Cervical Disc Placement

Glossary of Terms

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 cervical 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.

Cervical Disc

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

Cervical 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.

Decompression

A surgical treatment that involves relieving pressure on the spinal cord or nerve roots caused by a herniated disc, osteophytes, and bone spurs.

Discectomy

The removal of part or the entire intervertebral disc.

Herniated Nucleus Pulposus (HNP)

A disc herniates or ruptures when part of the central gel-like substance (nucleus) pushes through a tear in the tire-like outer band of the disc (annulus), putting pressure on the adjacent nerves or spinal cord. This migration of disc material beyond the edges of the vertebral body is referred to as Herniated Nucleus Pulposus (HNP). There are varying degrees of HNP that when identified are treated accordingly.

Myelopathy

Results from spinal cord compression caused by bony and/or disc protrusions.

Nucleus Pulposus

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

Radiculopathy

Compression of one or more cervical nerve roots. Nerve root compression resulting from a herniated disc or bony spurs (osteophytes).

Vertebrae (Vertebral Body)

Bony segments that form the spinal column of humans. The cervical (neck) vertebrae are the upper 7 vertebrae in the spinal column (the vertebral column). They are designated C1 through C7 from the top down.

Notes:

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

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

MKT-0016 Rev. 3

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