



M6[®]C

artificial cervical disc

The Natural Choice

Patient 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 hands.

This patient information 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 the M6-C™ Artificial Cervical Disc, a novel technology used to treat some of these painful degenerative cervical spine (neck) 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.

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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

***“I’ve been in the fire service
for 32 years, to be back
fighting fires with my
brothers and sisters is
incredible.”***

*Randy, firefighter
and M6-C™ Artificial Cervical Disc patient*



Glossary of Terms

Annulus Fibrosus - A fibrous, tire-like outer band of the spinal disc that surrounds the central gel-like substance called the nucleus pulposus

Anterior Cervical Discectomy and Fusion (ACDF) - A surgical procedure through the front of the neck where the damaged spinal disc is removed to reduce spinal cord and/or nerve pressure relieving symptoms of pain, weakness, numbness and tingling. After the disc is removed, the vertebrae on either side of the disc space are joined together in a process called spinal fusion

Artificial Disc - An implant that is designed to replace a damaged spinal disc by maintaining normal disc height and preserving motion at the treated level

Biomechanical - Relating to the mechanics of the human body, especially of the forces exerted by muscles and gravity on the skeletal structure

Cervical Spine - The upper part of the spine that is made up of the spinal bones of the neck

Cervical Intervertebral Disc - A shock-absorbing pillow located between each vertebra that helps maintain proper spacing, stability and motion within the cervical spine

Cervical Disc Degeneration - Changes in the spine and surrounding areas that result from the natural aging process or from injury that can limit the movement and stability of the cervical spine

Decompression - A surgical treatment that involves relieving pressure on the spinal cord and/or the nerve roots that is caused by disc degeneration or disc herniation

Discectomy - The removal of part or all of the intervertebral disc

Disc Herniation - Occurs when part of the central gel-like substance pushes through a hole in the outer layer of the spinal disc

Facet Joints - Small, paired joints located behind the vertebrae that provide stability to the spine while allowing movement

Incision - A cut or opening in the skin made during surgery to provide access to the surgical site

MRI - Magnetic Resonance Imaging is a non-invasive medical imaging procedure that uses a magnetic field and pulses of radio wave energy to produce pictures of structures inside the body

Nerve - A fiber or bundle of fibers that transmits messages to and from the brain. Nerves control movement throughout the body and sensations such as touch, pain, numbness, etc.

Nerve Root - The portion of the nerve that passes through a bony opening in a vertebra

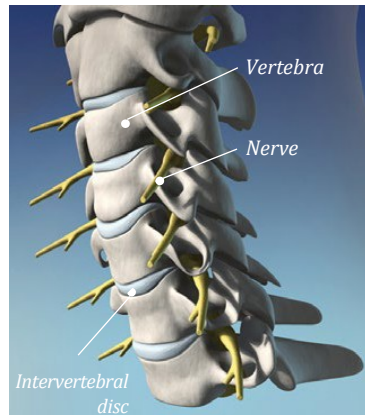
Nucleus Pulposus - The soft, gel-like center of the spinal disc

Vertebrae - The bones that form the spinal column or backbone. A single spinal bone is called a vertebra

The Cervical Spine

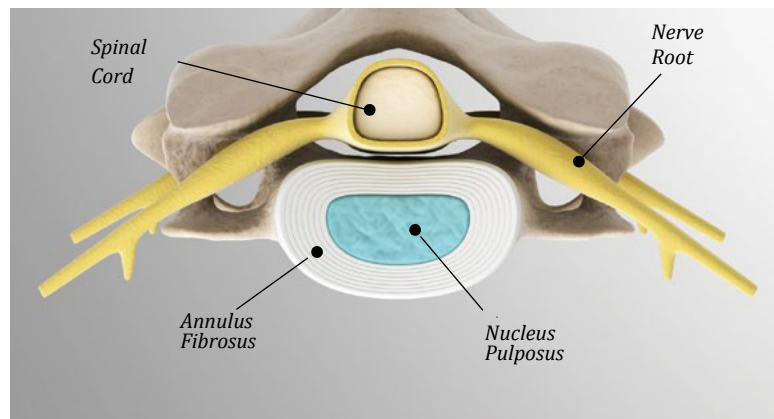
The Cervical Spine

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, chest and legs.



The Cervical Disc

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



Top view of cervical vertebra and its structures

What is Cervical Disc Degeneration?

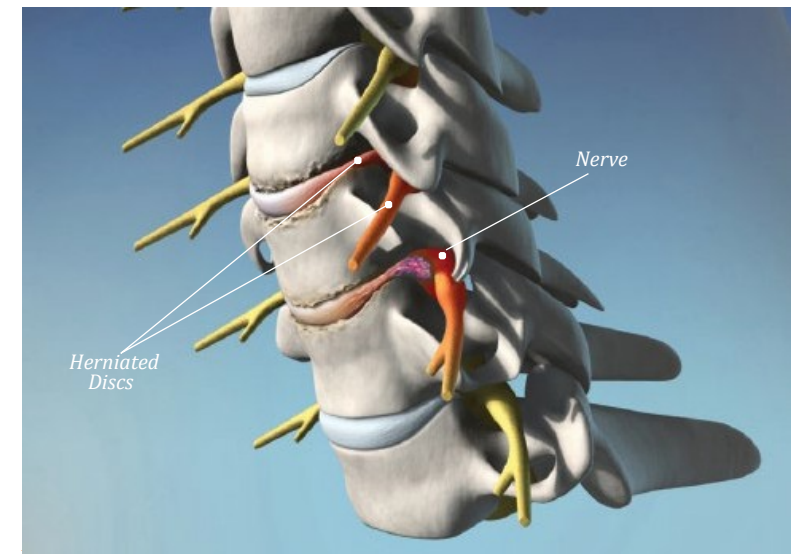
As we age, the discs in our cervical spine begin to flatten and wear down, bringing the vertebrae closer together, which can put added stress not only on the disc but also on the surrounding joints, muscles and nerves. In addition, the loss of disc height may result in the formation of bony growths that can push against your spinal cord and/or nerves. This process is known as cervical disc degeneration and can lead to several painful conditions.

Disc Herniation

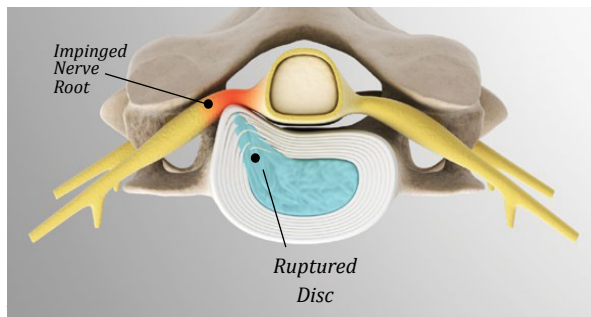
Occurs when the outer layer of the disc tears or ruptures due to stress from the surrounding vertebrae. These tears can cause the soft central core of the disc to bulge out or detach completely putting pressure on the nearby nerves or spinal cord.

Bone Spurs

Bone spurs are small bony ridges that can form on vertebrae as a result of increased stress on these bones. Usually, bone spurs cause nothing more than an occasional stiff or sore neck.



However, as with a herniated disc, bone spurs may press against nearby nerves or the spinal cord, resulting in pain or weakness in certain parts of the body.



Symptoms of Cervical Disc Degeneration

Although many people experience cervical disc degeneration due to aging, a 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 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, shoulders, arms and hands. Oftentimes, this feels like a shooting pain traveling down the arm.

Diagnosis and Treatment Options

Your physician will conduct a health history and physical examination to understand your symptoms and to determine if you have any nerve or spinal cord injury caused by cervical disc degeneration. Your posture, neck motion, reflexes, muscle strength and locations of pain are all evaluated during the examination. If cervical disc degeneration is a possible cause of the pain, your doctor may order an X-ray or an MRI (magnetic resonance imaging) to evaluate your discs, nerves and spinal cord to help outline a course of treatment.



Single-level Anterior Cervical Discectomy with Fusion (ACDF)



Single-level M6-C™ Artificial Cervical Disc

For many patients, non-surgical treatments will effectively relieve symptoms of cervical disc degeneration. These treatments may

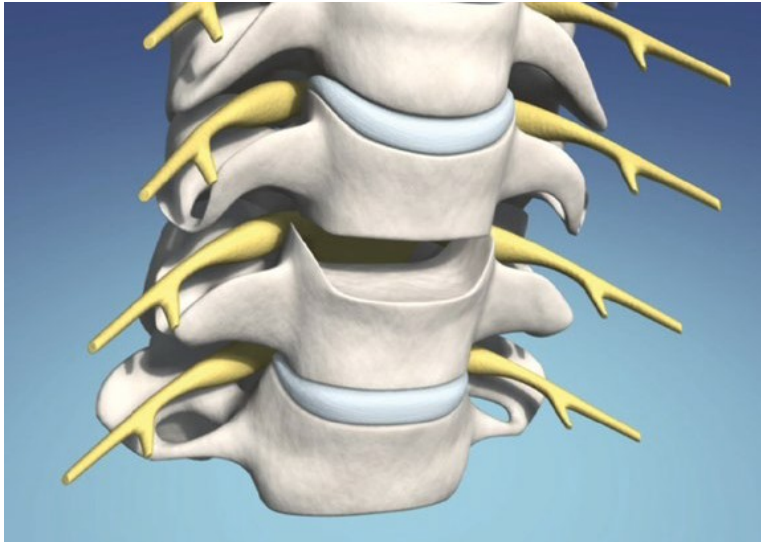
include a combination of rest, physical therapy, or the use of pain relief and/or anti-inflammatory medications. If pain or numbness persists despite non-surgical treatment, surgical treatment options are considered. Surgical treatment involves removing the herniated disc material and/or bone spurs causing your symptoms, a procedure known as decompression.

During both the M6-C™ Artificial Cervical Disc and the Anterior Cervical Discectomy and Fusion (ACDF) surgeries, the unhealthy disc is removed. After the disc is removed during the ACDF procedure, the disc space may be stabilized with a spacer to restore disc height and a device called a plate that restricts motion while fusion of the vertebrae occurs. The M6-C™ Artificial Cervical Disc surgery also involves the removal of the unhealthy disc, but after this occurs, the M6-C™ Artificial Cervical Disc is placed to provide natural motion and shock absorption to the degenerated cervical spine level.

Both non-surgical and surgical treatments are designed to relieve your painful symptoms. Your doctor will determine the best course of treatment based on the severity of your cervical disc degeneration.

Artificial Disc Replacement Surgery

During an artificial disc replacement, your doctor will remove the damaged disc and any disc or bony materials compressing the spinal cord and/or nerves. The disc space is then filled with an implant called an artificial disc. This implant is designed to restore proper spacing between the vertebrae while preserving the motion associated with a healthy disc.



*Herniated Disc
Removed*



M6-C™ Artificial Cervical Disc Insertion



Final M6-C™ Artificial Cervical Disc Placement

The M6-C™ Artificial Cervical Disc

The M6-C™ Artificial Cervical Disc offers an innovative option for cervical disc replacement for symptomatic, single-level cervical disc degeneration. The M6-C™ Artificial Cervical Disc was designed to provide motion and shock absorption characteristics similar to that of a natural disc. The M6-C™ Artificial Cervical Disc is the only artificial disc that incorporates an artificial polymer nucleus and an artificial fiber annulus. Biomechanical studies show that the artificial nucleus and annulus together provide controlled motion in all directions much like the natural disc. The M6-C™ Artificial Cervical Disc has a polymer sheath surrounding the artificial nucleus and artificial annulus designed to minimize any tissue ingrowth as well as the migration of wear debris. The titanium plates have serrated fins for anchoring the disc to the bones of neighboring vertebrae. These titanium plates are coated with a titanium plasma spray that is intended to promote bone growth onto the plates, providing long-term stability of the M6-C™ Artificial Cervical Disc in the disc space.



“I enjoy climbing inverted rock walls. Before surgery, I thought I might not ever climb again. It’s awesome to be back in the gym.”

*Alisha, climbing enthusiast
and M6-C™ Artificial Cervical Disc patient*

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Am I a Candidate for Artificial Disc Replacement Surgery with the M6-C™ Artificial Cervical Disc?

Conservative or non-surgical treatments such as physical therapy, injections and rest will be tried first by your doctor to relieve your pain or dysfunction. If these types of treatments fail and do not provide relief then your doctor may determine that you are a candidate for artificial cervical disc replacement.

Please speak to your physician to understand the benefits and risks associated with the M6-C™ Artificial Cervical Disc and to find out if you are a candidate for a cervical disc replacement using the M6-C™ Artificial Cervical Disc.



Who Should Not Receive the M6-C™ Artificial Cervical Disc (Contraindications)?

If you been diagnosed with or are experiencing any of the following conditions, it is recommended that you do not receive the M6-C™ Artificial Disc:

- An unnatural shape (deformity) of the spine at the proposed surgery level or the level above or below
- Advanced abnormal changes at the proposed surgery level
- Advanced degeneration to the joints on the back of the vertebrae
- An active systemic (whole body) infection or infection at the surgery site
- History of osteoporosis
- A known allergy to the materials the device is made from, including titanium, stainless steel, polyurethane, polyethylene or ethylene oxide residuals

What are the Warnings Associated with the M6-C™ Artificial Cervical Disc?

As with all surgeries there are potential risks, including but not limited to those listed below. Speak with your doctor to learn more about risks specific to the M6-C™ Artificial Disc surgery.

- Correct placement of the M6-C™ Artificial Cervical Disc is essential to achieving a desired outcome.
- The M6-C™ Artificial Cervical Disc should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with this device.
- A lack of adequate surgeon experience and/or training may lead to a higher incidence of adverse events, such as vascular or neurological complications
- Advancement of the surgical instruments or the M6-C™ Artificial Cervical Disc beyond the back border of the vertebral bodies may result in surgical complications
- X-rays must be taken during the surgical procedure. Failure to take appropriate x-rays during the M6-C™ Artificial Cervical Disc surgery may result in patient injury

What are the Precautions Associated with the M6-C™ Artificial Cervical Disc?

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

- Patients over the age of 68
- More than one cervical spine level requiring surgery
- Previous surgery at the spine level currently requiring surgery
- Soreness of the neck muscles as the only symptom
- Prior surgery causing an unstable cervical spine
- Very limited forward/backward motion at the surgery level
- Unstable spine at the surgery level or at the level above or below
- Diseases of the bone that affect bone development or mineral levels
- Taking medications that may interfere with bony/soft tissue healing including chronic steroid use
- Insulin-dependent diabetes
- Extremely overweight patients (Body Mass Index > 40)

What are the Risks of this Type of Surgery?

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, stroke or death

Risks Associated with Anterior Cervical 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
- 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 vertebrae
- Loss 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 M6-C™ Artificial Cervical Disc U.S. Clinical Study

The M6-C™ Artificial Cervical Disc was evaluated in a United States clinical trial for the safe and effective treatment of single-level degeneration of the cervical spine that causes problems with nerve function due to pressure on the spinal cord and/or nerve roots. The clinical trial involved a total of 160 patients who received the M6-C™ Artificial Cervical Disc compared to 189 who received an anterior cervical discectomy and fusion (ACDF) procedure. The ACDF procedure is done from the front of the neck and involves the removal of the spinal disc to address symptoms, followed by the stabilization of the disc space with a device such as a small metal plate, which serves as a brace on the front of the vertebrae to allow for bony fusion.

Patients participating in the M6-C™ Artificial Cervical Disc study had to be between 18 and 75 years old and not responsive to non-surgical treatments, such as physical therapy, for at least six weeks. A brief summary of some of the 24-month benefits and adverse effects from the M6-C™ Artificial Cervical Disc clinical trial appear below. The clinical benefit of the M6-C™ Artificial Cervical Disc beyond two years has not been measured.

What are the Expected Outcomes and Benefits of the M6-C™ Artificial Cervical Disc?

For those patients that are candidates, the M6-C™ Artificial Cervical Disc replacement surgery offers another option of treatment that may help stop the pain and other problems associated with a damaged cervical disc.

Artificial cervical disc replacement with the M6-C™ Artificial Cervical Disc is expected to relieve symptoms of spinal cord and/or nerve root compression resulting from cervical disc degeneration. Additionally, it may:

- Help movement of your neck in all directions (forward, backwards, side to side, rotating)
- Minimize your neck and/or arm pain
- Minimize tingling in your arm
- Help you return to your normal activities of work, family and recreation

Below are various outcomes and results from the M6-C™ Artificial Cervical Disc U.S. clinical study two years after surgery. Please ask your doctor for more details regarding this clinical trial and its associated clinical outcomes and results.

Two years after surgery, 132 out of 152 M6-C™ Artificial Cervical Disc patients (86.8%) achieved overall study success, compared to 130 out of 164 ACDF patients (79.3%).

Other key results from the study at two years after surgery include:

- The number of M6-C™ Artificial Cervical Disc patients who experienced a Serious Adverse Event through two years was 15 out of 160 (9.4%) patients compared to 28 out of 189 (14.8%) patients in the ACDF group. Of those, 6 out of 160 (3.8%) in the M6-C™ patients compared to 12 out of 189 (6.3%) in the ACDF patients were considered either device or procedure related.
- At two years 133 out of 147 M6-C™ patients (90.5%) demonstrated meaningful improvement in the Neck Disability Index (NDI), an outcome measure designed to evaluate patient function, compared to 131 out of 154 ACDF patients (85.1%).
- In addition, a meaningful decrease in neck pain was seen in 134 out of 147 M6-C™ patients (91.2%) compared to 120 out of 154 ACDF patients (77.9%) and for arm pain, a meaningful improvement was seen in 133 out of 147 (90.5%) M6-C™ patients and 123 out of 154 ACDF (79.9%) patients.
- At two years, 144 M6-C™ patients and 152 ACDF patients were evaluated for range of motion (ROM) in flexion and extension (forward/backward) at the operative level compared to their pre-operative motion. Motion was maintained for the M6-C™ patients (pre-op mean ROM 8.33 degrees/two years 8.78 degrees), while it was reduced in the fusion patients (pre-op mean ROM 8.02 degrees/two years 1.16 degrees).
- Prior to the study surgery, 129 out of 160 (80.6%) of the M6-C™ patients compared to 162 of 189 (85.7%) of the ACDF patients were taking some type of pain medication for the treatment of their cervical spine condition.
- At two years, 21 of 150 (14.0%) M6-C™ patients were still taking some type of pain medication compared to 68 of 178 (38.2%) of the ACDF patients.
- Of the patients still taking pain medication for their cervical spine problem, only 3 out of 150 (2.0%) M6-C™ patients were **taking some type of opioid drug** compared to 27 of 178 (15.2%) patients in the ACDF group (**over 7 times higher than the M6-C™ patients**)
- Another surgery at the treated level was needed for 9 out of 189 ACDF patients (4.8%), compared to 3 out of 160 M6-C™ patients (1.9%)
- At two years, 150 M6-C™ patients and 162 ACDF patients were asked if they would have surgery again. The majority of patients in both arms responded "Yes".

What are the Potential Adverse Effects of the M6-C™ Artificial Cervical Disc?

During the M6-C™ Artificial Cervical Disc FDA clinical trial, patients in the study experienced various health-related problems that could be attributed to either the surgical procedure, the patient's physical health or the M6-C™ Artificial Cervical Disc itself. Some of these problems were identified earlier in the Risk of Surgery section of this pamphlet (pages 15-16). Listed below are various adverse event rates from the US trial that occurred in both the M6-C™ Artificial Cervical Disc and ACDF patient groups. As stated earlier, there were 160 patients in the M6-C™ Artificial Cervical Disc patient group and 189 in the ACDF patient group.

ADVERSE EVENT CATEGORY	M6-C™ Artificial Cervical Disc Patient Group N=160	ACDF Patient Group N=189
Pain other than in the cervical spine (back, legs, headache, etc.)	35.0%	40.2%
Neurological (events related to the nervous system)	28.8%	38.6%
Neck and/or Arm Pain	28.1%	32.3%
Other events not associated with any previously identified categories	13.8%	24.3%
Non-infected wound Issue	11.9%	4.8%
Dysphagia (difficulty swallowing) or dysphonia (difficulty speaking)	9.4%	6.3%
Trauma (events related to a fall, car accident, etc)	8.8%	19.0%
Gastrointestinal (events related to the stomach or intestines)	5.6%	9.0%
Spinal Disorder	3.8%	11.6%
Infection	3.8%	10.1%
Upper extremity (arm) nerve entrapment	3.1%	5.8%
Urogenital (events associated with excretion)	2.5%	4.2%
Respiratory (events related to breathing)	2.5%	3.2%
Cardiovascular (events related to heart function)	1.9%	4.8%
Non-Union	0%	5.3%

A comprehensive list of risks is provided in the package insert for the device, which your doctor has received. **Please ask your doctor for more information about any additional risks that could be related to your planned surgery.**

How Do I Prepare for Surgery?

Please be sure to follow your doctor's guidance as you prepare for surgery. Here is a list of topics that may be covered prior to the surgery:

- Assessment of your current condition and review of all possible options for treating your symptoms

- Evaluation of your overall health to ensure that it is safe for you to have surgery
- Questions about the medicines that you're currently taking to determine if you should stop taking any of them prior to surgery
- Instructions on not drinking or eating anything the night before surgery
- Confirmation that you have someone to assist you at home after surgery and that you can easily access important items you will need on a regular basis
- The benefits of reading and understanding this entire information guide
- Any additional questions you have about the risks and benefits of this surgery

What Happens During an M6-C™ Artificial Cervical Disc Surgery?

During the artificial cervical disc replacement surgery you will be under general anesthesia and a small opening (usually about 1 inch) will be made in the front of your neck to access your cervical spine. The degenerated spinal disc is removed (discectomy) and the affected nerve root is then relieved of pressure (decompression). Then, the M6-C™ Artificial Cervical Disc is inserted into the disc space using specialized instruments. After the M6-C™ Artificial Cervical Disc is successfully placed, the opening is closed.

What Happens after M6-C™ Artificial Cervical Disc Surgery?

Ask your doctor to describe how you will feel after surgery and what will help you to recover. Removing your disc and replacing it with the M6-C™ Artificial Cervical Disc is a major surgery so it is important to closely follow your doctor's instructions to recover from surgery as quickly as possible and to increase your chances of a successful result.

Similar to any major surgery you should expect some discomfort and to go through a period of post-surgery rehabilitation. Usually patients are released from the hospital within one day. Listed below are some topics your doctor or other healthcare professional may discuss with you after the surgery:

- Instructions on surgical site wound care to be followed after leaving the hospital
- Avoidance of activities that involve repeated bending, twisting and lifting
- Use of oral medications to address pain or nausea

- Possibly recommend that you wear a neck brace for limited period of time
- Schedule follow-up office visits to monitor your progress
- Guidance for gradually increasing limited activity at home
- An exercise program under the direction of a physical therapist

When Should I Call the Doctor After Surgery?

Some pain and discomfort after surgery is normal. The symptoms you had before surgery may not decrease immediately. Talk to your doctor about when to call regarding problems after surgery.

If you have any of these problems at any time after surgery contact your doctor:

- You have a fever
- The skin around the incision becomes red, swollen or more painful
- Excessive drainage or leaking from the incision
- Trouble breathing, swallowing or talking
- Difficulty urinating
- New or increased neck and/or arm pain, weakness or numbness

Frequently Asked Questions

Will I Have a Large Scar?

The average surgical incision is about 1 inch long and usually heals so that it is not very noticeable.

What Happens if the Surgery is Not Effective?

If you experience new or increased neck and/or arm pain after the surgery, it could be that the surgery was not effective or that the device is not performing properly. You may need additional surgery if your condition does not improve. Contact your doctor immediately if you experience neck and/or arm pain.

When Can I Shower After Surgery?

You will have to keep your neck incision dry after surgery. Consult with your doctor to get specific information on when and how long you can shower after surgery as your incision heals.

Can I Receive an MRI After Surgery?

Yes. However, since MRI machines can vary you should consult with your physician regarding appropriate testing conditions.

When Can I Drive?

For a period of time after surgery, your doctor may recommend that you avoid certain activities such as driving. Talk to your doctor about driving and other activities that you may need to discontinue temporarily while you recover.

For More Information, Talk to Your Doctor

This guide is intended to provide you with useful information that will help you make an informed decision regarding your treatment options. However, it is not intended to replace medical advice or instruction from your doctor.

Your doctor is the only person qualified to appropriately diagnose and treat your spinal condition. If you have specific questions regarding the M6-C™ Artificial Cervical Disc or its usefulness in your course of treatment, please contact your doctor.



Notes

Notes

Please visit [Orthofix.com/IFU](https://www.orthofix.com/IFU) for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

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