NORTHWEST SPECIALTY HOSPITAL

QUALITY CARE SINCE 2003 | PROUDLY OWNED AND OPERATED BY PHYSICIANS

M6-C™ Artificial Cervical Disc Two-Level IDE Clinical Study

This study is currently enrolling patients with degenerative cervical radiculopathy requiring surgical intervention, confirmed clinically and radiographically, at 2 adjacent vertebral levels between C3 and C7.

The study's primary objective is to evaluate the safety and effectiveness of the M6-C™ artificial cervical disc compared to anterior cervical discectomy and fusion (ACDF) for treating two-level symptomatic cervical radiculopathy at vertebral levels from C3 to C7 with or without spinal cord compression.

You may be eligible for this study if you:

- Have been told you need neck surgery at two adjacent levels between C3 to C7
- Are experiencing neck and/or arm pain after at least 6 weeks of conservative, non-surgical treatment
- Are willing and able to attend follow-up progress visits with your doctor over 24 months and possibly 5 years
- Do not have any autoimmune disorders, cancer, and not insulin-dependent diabetic
- Have a BMI of less than 45
- Are between 18 years and 75 years of age

Contact for more information:

Katelyn.Chemodurow@nwsh.com

208-664-0291

Scan for more information and to contact us today!

On the Move ORTHOFIX

Approved by Sterling IRB, IRB ID: 9053

M6-C™

Artificial Cervical Disc

Options for Cervical Disc Degeneration

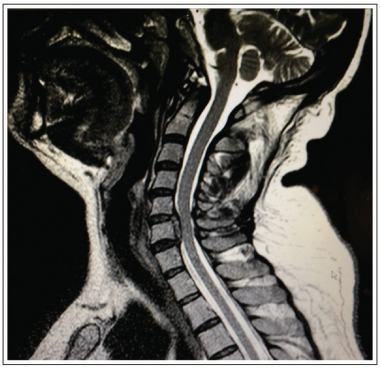
A GUIDE TO THE M6-C ARTIFICIAL DISC ARM OF THE M6-C 2-LEVEL CLINICAL STUDY

ORTHOFIX® SPINE

Millions of people around the world suffer from cervical disc degeneration, resulting in chronic pain of the neck, shoulders, arm, and even the hands. Other symptoms may include weakness, numbness, or tingling. Cervical disc degeneration occurs as we age. The spinal disc material between the bones (vertebrae) in our necks 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 but also on the surrounding joints and nerves.

Your doctor will conduct a history and physical examination to understand your symptoms to diagnosis your spine condition. To assess your study eligibility, your doctor will evaluate your posture, neck motion, reflexes, muscle strength, and areas of pain will be assessed during the exam. Your doctor may order X-rays and/or MRI to evaluate your discs and spinal cord to outline a course of treatment. Treating cervical disc degeneration involves discussing nonsurgical and/or surgical options with your doctor. Should your doctor determine you are a candidate for artificial cervical disc replacement surgery and the study, your doctor will discuss the surgical procedure and study details with you further.

The Orthofix M6-C™ artificial cervical disc is currently approved by the FDA for use in single level surgical procedures. The primary objective of the study is to evaluate the safety and effectiveness of the Orthofix M6-C™ artificial cervical disc in patients with contiguous two-level symptomatic cervical radiculopathy with or without cord compression.



Artificial disc replacement surgery is very similar to Anterior Cervical Discectomy and Fusion (ACDF) surgery. Both procedures remove the flattened disc. However, when the flattened disc is removed for disc replacement, the space in between the vertebrae is filled with a specialized implant called an artificial disc, instead of a bone graft. The artificial disc is designed to restore the spacing between the vertebrae while allowing some motion.

The M6-C™ Artificial Cervical Disc

- The M6-C artificial cervical disc offers a surgical option for symptomatic, cervical radiculopathy.
- The M6-C artificial cervical disc was designed to provide motion and shock absorption characteristics similar to that of a natural disc.
- The titanium plates have serrated fins for anchoring the disc to the bones of neighboring vertebrae.
- The 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.

Surgical Treatments

As with all surgical procedures, it is important to fully understand the potential benefits and risks of fusion surgery within the M6-C clinical study. Please discuss any questions you may have with your doctor so you can make the personal decision about whether or not to participate.

Here are some benefits and risks to participating in the study:

Benefits:

- Extensive and enhanced follow-up evaluation
- Gift cards to help offset the expense of participating in follow-up visits
- Contribution to medical research

Risks:

- The risks generally associated with having surgery
- The treatment may be ineffective or have side effects
- Follow-up visit participation may be time consuming

Study Follow-up

Clinical study follow-up will ask you to return to see your doctor to evaluate your progress at the following times after surgery: six weeks, three months, six months, one year, and two years. Then you may be asked to return yearly (possibly up to five years) after surgery.

During these return follow up visits, your doctor will do the following:

- Conduct physical exam
- Test your reflexes
- Test your muscle strength of your arm muscles
- Test your ability to feel touch on different areas of your neck and arms
- Take X-rays of neck
- Answer questions about your pain, your ability to do daily activities, how you feel and how well you think you are recovering

Each visit should typically last 1-2 hours; completing the questionnaires should take you about 10-20 minutes

Are You a Candidate for Two-Level Disc Replacement?

Please answer the following questions to help determine if you may be a candidate for artificial cervical disc replacement using the M6-C™ artificial cervical disc procedure.

- Are you 18 to 75 years of age?
- Have been told that you need cervical spine (neck) surgery at two consecutive levels?
- Are you experiencing continued neck and/or arm pain after six or more weeks of conservative, non-surgical treatment?
- Have no autoimmune disorders, not insulin dependent diabetes, or cancer?
- Are you able and willing to attend follow-up progress visits with your doctor over 24 months and possibly longer?

If you answer "yes" to all five questions, cervical disc replacement may be a viable treatment option. Please consult your doctor to learn more.

FOR MORE INFORMATION

For additional information, please visit Clinicaltrials.gov NCT#04982835

Please visit Orthofix.com/IFU for full prescribing information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

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The use of the M6-C Artificial Cervical Disc in two-level replacement is an Investigational device limited to investigational use by approved investigators only.

ORTHOFIX® SPINE

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M6-C™

Artificial Cervical Disc

Options for Cervical Disc Degeneration

A GUIDE TO THE FUSION (ACDF) ARM OF THE M6-C 2-LEVEL CLINICAL STUDY

Corticocancellous structural allograft cervical interbody spacer

ORTHOFIX®
SPINE

Millions of people around the world suffer from cervical disc degeneration, resulting in chronic pain of the neck, shoulders, arm, and even the hands. Other symptoms may include weakness, numbness, or tingling. Cervical disc degeneration occurs as we age. The spinal disc material between the bones (vertebrae) in our necks 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 but also on the surrounding joints and nerves.

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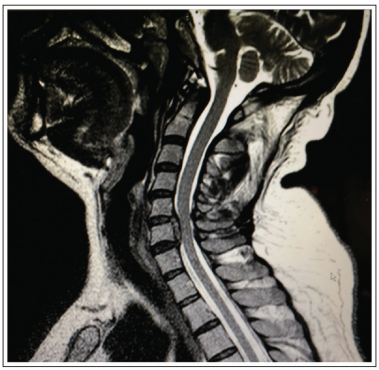
Cervical spinal fusion, also known as ACDF (Anterior Cervical Discectomy and Fusion), is commonly recognized as the standard of care for surgical treatment of cervical disc degeneration. During this procedure, the flattened disc is removed (called a discectomy) along with any bone spurs that are pressing against the nerves. This process of relieving pressure on the spinal nerves is called decompression. Once the disc is removed, the space between the vertebrae is filled with bone graft material (allograft bone with or without your own bone). Typically, a small titanium plate is also used to stabilize the two vertebrae. Over time the bone graft will grow together to form a fused column of bone.



The primary objective of the study is to evaluate the safety and effectiveness of the Orthofix M6-C™ artificial cervical disc compared to anterior cervical fusion in patients with contiguous two-level symptomatic cervical radiculopathy with or without cord compression.

The M6-C™ Artificial Cervical Disc

The M6-C™ artificial cervical disc offers a surgical option for cervical disc degeneration for some patients with symptomatic cervical radiculopathy.

The M6-C™ artificial cervical disc was designed to provide motion and shock absorption characteristics similar to that of a natural disc.

Surgical Treatments

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