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

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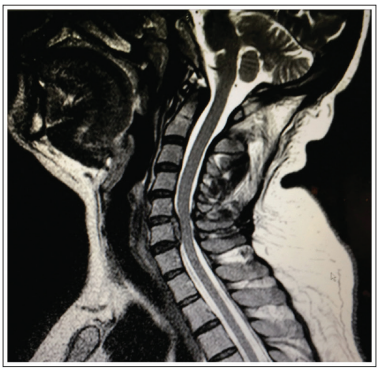
SPINE

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.

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

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?

This study is seeking patients with degenerative cervical radiculopathy (confirmed clinically and radiographically) requiring surgical intervention at two contiguous vertebral levels from C3 to C7.

- 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.

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