

Options for Cervical Disc Degeneration A GUIDE TO THE M6-C ARTIFICIAL DISC ARM OF THE M6-C 2-LEVEL CLINICAL STUDY



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^M 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^M 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, nonsurgical 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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