

What is The M6-C Artificial Cervical Disc?

What is the M6-C™ artificial cervical disc?

The M6-C artificial cervical disc is a next-generation artificial disc developed to replace a vertebral disc damaged by cervical disc degeneration. The M6-C disc is designed to help restore motion to the spine and is an option for patients needing artificial disc replacement as an alternative to cervical fusion. By allowing your spine to move naturally, the M6-C artificial disc is designed to potentially minimize the stress to adjacent discs and other vertebral structures.

What else is unique about the M6-C artificial cervical disc?

The M6-C disc is the only disc designed with a shock-absorbing nucleus and fiber annulus that work together to replicate the controlled range of movement and cushioning effect of the natural disc. This unique product is designed to mimic your spine's natural structure and movement, including backward and forward, side to side, up and down, and rotate left and right.

When did the M6-C artificial cervical disc receive approval?

Orthofix Medical Inc. announced U.S. Food and Drug Administration (FDA) approval of the M6-C artificial cervical disc for patients suffering from cervical disc degeneration in early February 2019. The M6-C disc received CE Mark approval for distribution in the European Union and other international geographies in 2006. There have been more than 45,000 implants of the M6-C disc outside of the U.S. to date.

What is cervical disc degeneration?

Cervical disc degeneration is a common condition that can cause pain in the neck, shoulders, arms and hands and lead to numbness and weakness in the arm or hands. Often this condition is the result of a vertebral disc that has deteriorated or been damaged due to the natural aging process or an injury. For many patients with cervical disc degeneration, spine surgeons have used the M6-C disc to replace the patient's damaged disc with one that closely mimics their natural disc, enabling the patient to regain motion and return to their normal activities.

Overall Patient Satisfaction Rates*

93%

The rate of the M6-C disc patients who said they would have the surgery again



92%

The rate of the M6-C disc patients satisfied with their surgery

38.2%

Decrease of Pain Medications Usage – Including Opioids*

14%



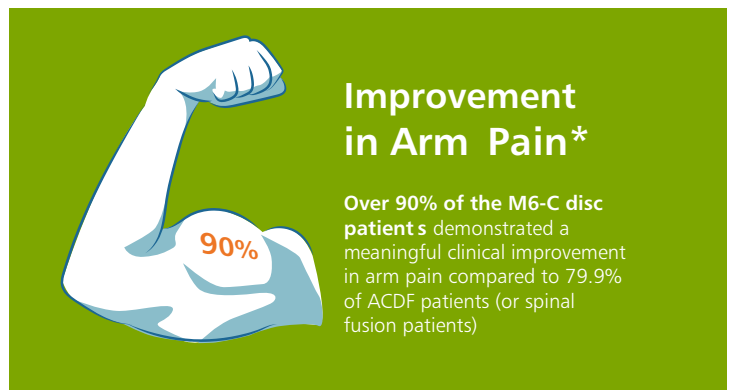
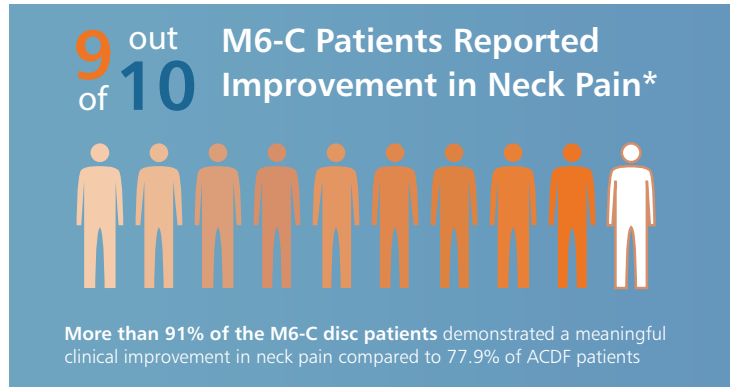
At 24 months, the rate of the M6-C disc patients still taking some type of pain medication dropped to 14.0% compared to 38.2% of ACDF patients. Of these, ACDF patients had a seven times higher rate of opioid use than the M6-C disc patients.

How common is neck pain?

More than one third of a billion people worldwide had neck pain in 2015, according to studies summarized by the Global Spine Care Initiative and published by the National Institutes of Health¹. In addition, more than 1.5 billion people worldwide suffer from chronic pain; neck pain (15%) is the third most common type of chronic pain². Throughout the world, the pain and disability associated with chronic neck pain have a large impact on individuals and their families, communities, healthcare systems and businesses.

Who developed the M6-C artificial cervical disc?

The M6-C disc was developed by Spinal Kinetics, a company acquired by Orthofix in April 2018. Orthofix Medical Inc. is a global medical device company focused on musculoskeletal products and therapies. Orthofix's mission is to improve patients' lives by providing superior reconstruction and regenerative musculoskeletal solutions to physicians worldwide. Headquartered in Lewisville, Texas, Orthofix's spine and orthopedic extremities products are distributed in more than 70 countries via the company's sales representatives and distributors. For more information, please visit www.orthofix.com.



*Clinical data from a U.S. Investigational Device Exemption study at 24 months evaluating the safety and effectiveness of the M6-C™ artificial cervical disc compared to anterior cervical discectomy and fusion

1. <https://www.ncbi.nlm.nih.gov/pubmed/29480409> 2. <https://www.thegoodbody.com/chronic-pain-statistics/>