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Mobi-C® Cervical Disc Press Education Kit

Dear ZimVie Customer,

In this press education kit you will find information and supplemental materials detailing the Mobi-C® Cervical Disc (Mobi-C), the first cervical disc approved for both one and two-level indications. We hopeyou find this press education kit useful. The materials in this kit are intended to:

- Educate patients about Mobi-C and it's availability at your practice.
- Inform your community about your Mobi-C training and/or experience.
- Provide information on the benefits of CDA and Mobi-C versus fusion to other healthcare professionals who may refer patients to your practice.
- Share some of Mobi-C's extensive clinical trial results and 10-year data: In the two-level studyMobi-C demonstrated *SUPERIORITY* to ACDF based on the primary composite endpoint. Between the 7 and 10-year follow up, no subsequent surgery at an adjacent level occurred.

Please note that this education kit has been reviewed by ZimVie's Legal, Compliance and Regulatory departments in an effort to ensure that all communications regarding Mobi-C are on-label, truthful, accurate, balanced, and not misleading. ZimVie makes no representations or warranties regarding the information provided in this press education kit as this kit is being provided as-is. In the event that you elect to utilize all or part of the materials or information contained in this kit, ZimVie strongly recommends only making changes to the highlighted fields, and not the substantive information (ZimVie will have no responsibility for any substantive changes), as changes to the latter can have negative legal, compliance and/or regulatory implications. All of the materials provided in this kit must be filled out by a member of your team and not a ZimVie team member. Further, any costs associated with media placement and/or advertising associated with this press education kit must be solely borne by your organization.

Best regards,

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Mobi-C Fact Sheet

The Mobi-C Cervical Disc is one of the most widely used cervical discs in the world. First implanted in France in November 2004, now over 200,000 Mobi-C Discs have been implantedin 25 countries[1]. Additionally, 2023 marks the 10th anniversary of Mobi-C's FDA approval.

Mobi-C entered a FDA clinical trial in 2006, in which 647 levels of Mobi-C were implanted. A total of 599 patients were involved in the clinical trial at 24 study centers across the U.S. This represents the largest clinical trial ever conducted in the U.S. for cervical disc replacement. Mobi-C received FDA approval in August of 2013, making it the first cervical disc with both oneand two-level indications.

At 7 years, Mobi-C was determined by the FDA to be statistically superior to fusion at 7 years for two-level cervical disc replacement, based on the primary study endpoint of a prospective, concurrently controlled and randomized, multi-center clinical trial. Upon completion of the 7-yearFDA IDE study, follow-up continued on a subset of CDA patients with the goal of obtaining 10- year follow-up on all eligible patients.

At 10 years, all patient-reported outcomes of Mobi-C recipients were equivalent to or improvedfrom 7 years. Recipients of Mobi-C reported improved Neck Disability Index (NDI) Scores, improved neck pain, and improved arm pain. In addition, no subsequent surgery at an adjacentlevel occurred between the 7-year and 10-year follow up.[2,3]

Mobi-C is made with two Cobalt Chromium alloy endplates that are plasma sprayed with titanium and coated with hydroxyapatite and has an Ultra High Molecular Weight Polyethyleneplastic insert (UHMWPE). These are proven materials that have been used in orthopedic applications for over 60 years.

Mobi-C is intended for adult patients (skeletally mature) with arm pain and/or neurological symptoms (such as weakness or numbness) with or without neck pain at one or two adjacent levels from C3-C7 in the cervical spine. Patients should have failed non-surgical care (such as physical therapy or medications) for at least 6 weeks or shown signs of progressively worseningsymptoms. Disc damage needs to be confirmed by a doctor's review of CT, MRI, or x-ray images. A doctor should always be consulted for proper indications and use of Mobi-C.

References:

1. Data on file at time of publication.
2. Kim K, Hoffman G, Bae H, et al. Ten-Year Outcomes of 1- and 2-Level Cervical Disc ArthroplastyFrom the Mobi-C Investigational Device Exemption Clinical Trial. Neurosurgery. 2021;88(3):497- 505.
3. Radcliff K, Davis RJ, Hisey MS, et al. Long-term evaluation of cervical disc arthroplasty with the Mobi-C Cervical Disc: a randomized, prospective, multicenter clinical trial with seven-year follow-up. Int J Spine Surg 2017;11(4):244-262.

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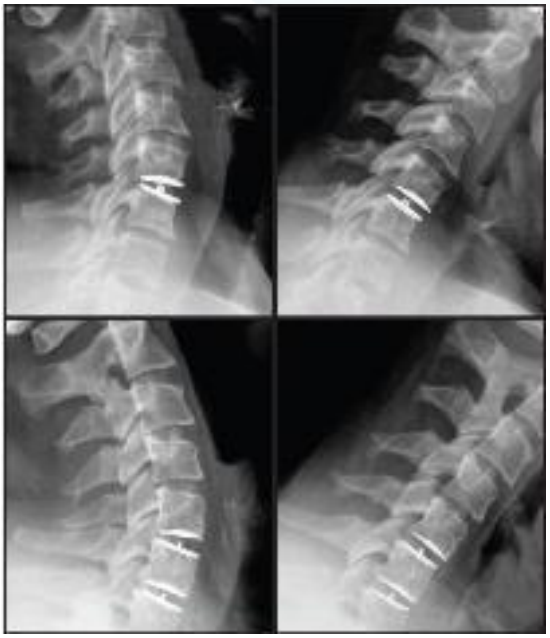
Mobi-C – How it Works

Mobile Core

Mobi-C is designed to replicate the natural motion ofthe cervical spine.

Mobi-C's mobile core slides and rotates inside thedisc, self-adjusting to the patient's cervical spine's movements. This means that Mobi-C can react tothe normal motion in the cervical spine.

In addition, the mobile core is designed to allow for some movement, reducing the forces between the implant and vertebral bodies. The Mobi-C does notneed invasive fixation features found in some cervical disc replacement devices.



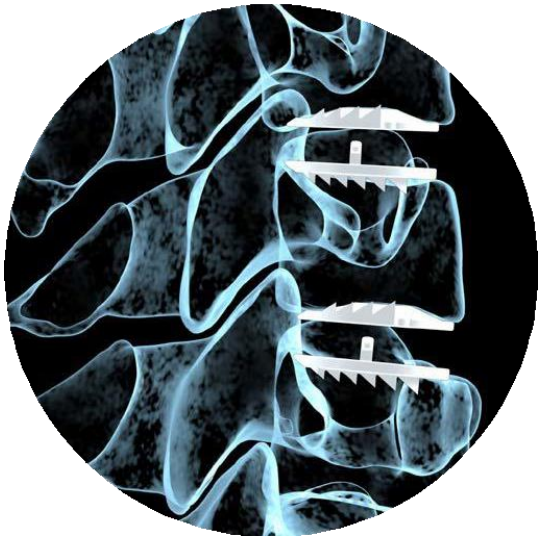
Bone Sparing

Mobi-C provides bone sparing fixation without chiselcuts into the small vertebral bodies of the cervical spine. Some competitive discs achieve their fixationvia keel cuts or screw holes into the bone.

Mobi-C was designed without a keel to minimize bone removal, applicable for both one and two-level indications. Minimizing bone removal can become important in two-level applications where integrity ofthe bone between the discs is important.

Intact endplates, compared to endplates prepared forkeels, provide a couple of benefits:

1. Preserved surface for the implant, ideal for two-level implantation.
2. Intraoperative flexibility to optimize implant positioning.



Mobi-C® 10 Years of Clinical Excellence

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Pre-assembled Implants

Mobi-C is delivered pre-assembled on a disposable PEEK cartridge. The cartridge assembles easily to the implant inserter, saving operative steps. The PEEK Cartridge allows a radiolucent view of the implant for optimal positioning.

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Mobi-C Clinical Trial Results at 7 Years and 10 Year Follow Up

7 Year Mobi-C Results[1]

The Mobi-C IDE trial was a multi-center, prospective, and randomized controlled trial. Mobi-C,the investigational treatment, was compared to the control, anterior cervical discectomy and fusion (ACDF). Trial success was based on a composite endpoint consisting of 5 different criteria. A subject was considered a success at 7 years if all five pre-defined criteria were met.

In the one-level study, Mobi-C demonstrated non-inferiority (or equivalency) to ACDF based onthe composite endpoint. In the two-level study Mobi-C demonstrated ***superiority*** to ACDF based on the composite endpoint.

Key results from the two-level study include:

- Overall trial success was **60.8% for Mobi-C and 34.6% for fusion**, which represents statistical superiority (p=0.0002).
- The rate of subsequent surgeries at the treated levels for Mobi-C was 5.6% compared to17.1% for fusion.
- The percentage of subjects who demonstrated clinically relevant adjacent segment degeneration (determined by x-ray) was:
    - 5.3% of Mobi-C patients compared to 40.0% of ACDF patients at the inferior adjacent level.
    - 11.0% of Mobi-C patients compared to 26.7% of ACDF patients at the superior adjacent level.
- Mean return to work time was 20.9 days sooner for Mobi-C patients compared to fusionpatients.
- The rate of major complications for Mobi-C was 4.4% compared to 15.2% for fusion.

10 Year Mobi-C Results[2]

Upon completion of the 7-year FDA IDE study, follow-up continued on a subset of CDA patientswith the goal of obtaining 10-year follow-up on all eligible patients. At 10 years, both 1- and 2- level CDA patients continued to have significant improvement of pain scores, NDI, neurologic deficit, ROM, and sagittal alignment compared to baseline.

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Key results from the ten-year follow up include:

- At 10 years, all patient-reported outcomes were equivalent to or improved from 7 years.

- Between 7-year and 10-year follow-up:
  - C2-C7 range of motion (ROM) and sagittal alignment were maintained.
  - Segmental ROM in flexion/extension and lateral bending was maintained in both1-level and 2-level constructs.
  - Clinically relevant radiographic adjacent segment pathology (rASP) did not differ significantly in either 1- or 2-level patients.
  - Incidence of motion-restricting heterotopic ossification (HO) did not differ significantly in either 1-level or 2-level patients.
  - No subsequent surgery at an adjacent level after 7 years.

For detailed clinical results, visit https://www.cervicaldisc.com/i-am-a-surgeon/clinical-results.

References:

1. Radcliff K, Davis RJ, Hisey MS, et al. Long-term evaluation of cervical disc arthroplasty with the Mobi-C Cervical Disc: a randomized, prospective, multicenter clinical trial with seven-year follow-up. Int J Spine Surg 2017;11(4):244-262.
2. Kim K, Hoffman G, Bae H, et al. Ten-Year Outcomes of 1- and 2-Level Cervical Disc ArthroplastyFrom the Mobi-C Investigational Device Exemption Clinical Trial. Neurosurgery. 2021;88(3):497- 505.

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Mobi-C Messaging Points

- Mobi-C is the first cervical disc in the U.S. approved to treat more than one level of thecervical spine. It received FDA approval for one and two-level indications in August 2013.
- 2023 marks the 10th anniversary of Mobi-C's FDA approval.
- Mobi-C demonstrated statistical superiority compared to cervical spine fusion in overallstudy success when used in two-level patients at 7 years.
- At 10 years, all patient-reported outcomes of Mobi-C recipients were equivalent to or improved from 7 years.
- Mobi-C has been implanted more than 200,000 times in 25 countries around the worldsince 2004.
- Mobi-C is differentiated from other cervical discs because of its bone sparing technique,which eliminates the need for bone chiseling and drilling, lending to two-level implantations due to its minimal bone removal.
- The patented mobile core allows the Mobi-C to angulate and slide in multiple directions,similar to natural cervical motion.
- The greatest clinical benefit of cervical disc replacement with Mobi-C compared to cervical fusion was seen in two-level indications, particularly in lower reoperation rates,lower rates of major complications, lower rates of adjacent level degeneration, and higher NDI success rates.
- In the Mobi-C clinical study, patients returned to work on average approximately one week faster (one-level patients) and three weeks faster (two-level patients) compared tofusion patients.