



The leading choice for cervical motion preservation¹



Mobi-C[®]

Cervical Disc





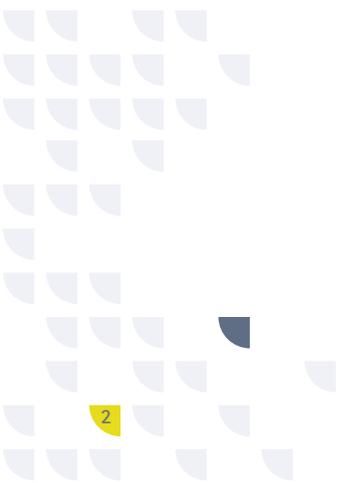
Mobi-C[®]

Cervical Disc

Over 150,000 Mobi-C Discs have been implanted in 25 countries since 2004.

Mobi-C Cervical Disc was the first cervical disc in the United States approved to treat more than one level of the cervical spine. 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. At 10 years, all patient-reported outcomes were equivalent to or improved from 7 years.^{2,3}

”
ANATOMIC DESIGN
THAT FITS THE
NATURAL VERTEBRAL
ANATOMY



Superior Dome

- Designed to match the natural, bony anatomy, enabling short and long term stability

Plasma Sprayed Titanium and Hydroxyapatite Coated Endplates

- Encourage bony ongrowth for long term stability



Lateral Inclined Teeth

- The teeth purchase in to the apophyseal ring to provide initial stability
- Designed to resist migration

Patented, Mobile Bearing Core

- Ultra-High Molecular Weight Polyethylene insert
- Domed surface designed to articulate angularly with the superior endplate
- Flat bottom designed to translate up to 1 mm and rotate on the inferior endplate

Intact Endplates

- Cobalt Chromium Molybdenum Alloy endplates
- Intact endplates, compared to endplates prepared for keels, provide a preserved surface for the implant ideal for two-level implantation and provide intraoperative flexibility to optimize implant positioning
- Tabs provide a safety stop designed to control mobility and to resist expulsion



PATENTED MOBILE CORE TECHNOLOGY

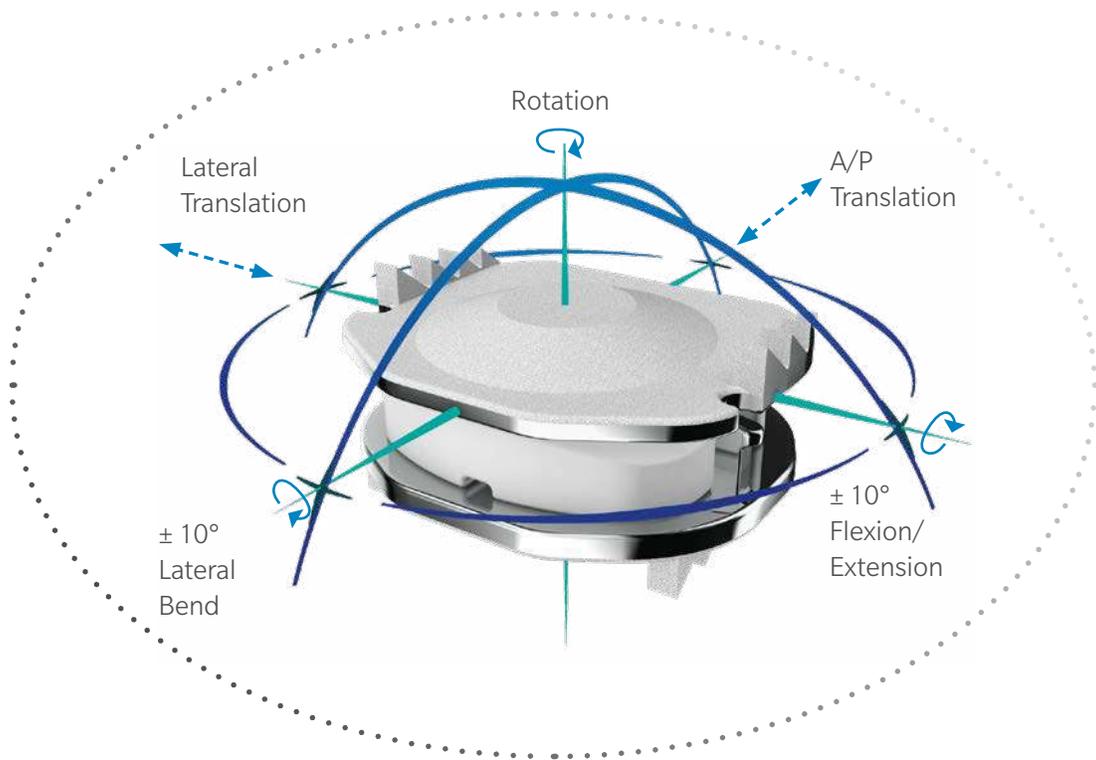


Mobile Bearing Technology

Controlled Mobility

Restoring natural motion to the cervical spine

The controlled mobility of the patented mobile core is the foundation of Mobi-C. With vertebrae and neck muscle movement, the Mobi-C implant is free to twist and slide left-to-right, and front-to-back, as well as rotate.

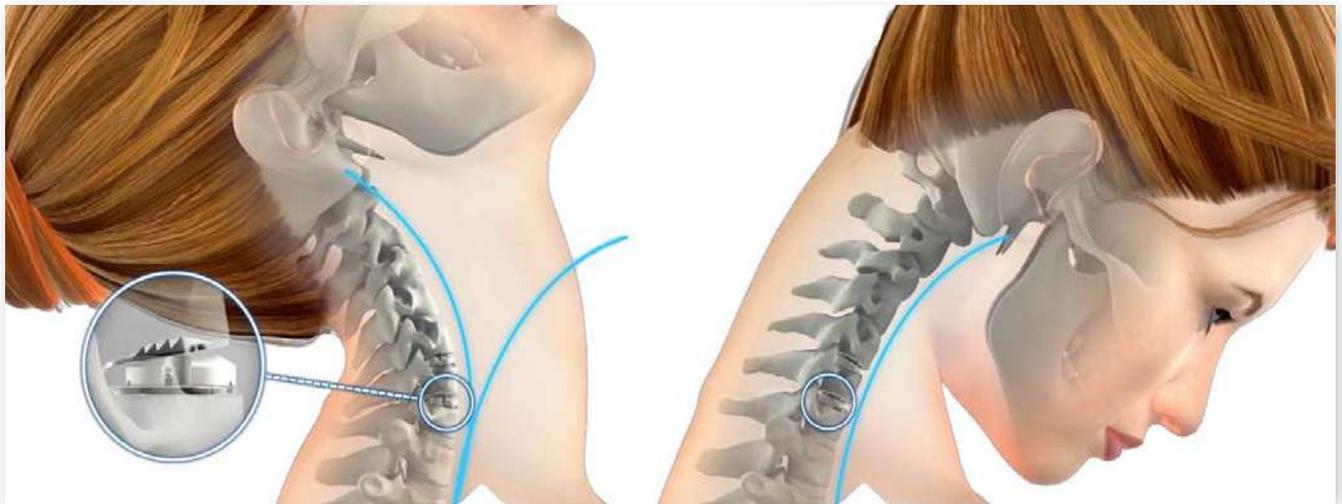


Self-Adjusting

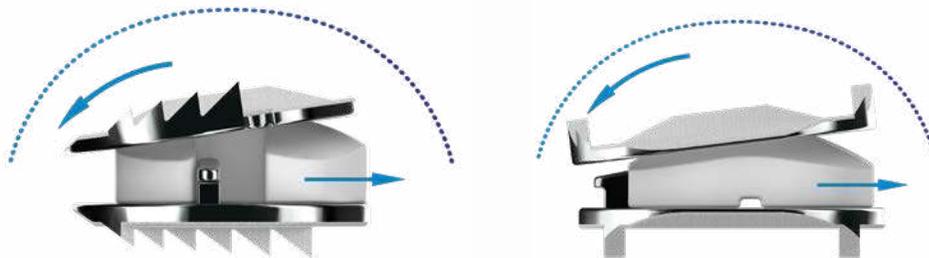
A return to physiological mobility

The center of rotation at each level of the cervical spine is variable and constantly changing.⁴ Mobi-C was designed to adapt to the Instantaneous Axis of Rotation through its self-adjusting mobile core. The mobile core allows the vertebrae above and below the disc to move, to maintain normal neck motion.

Mobi-C moves with the spine and does not dictate a predetermined, fixed axis of rotation. This facilitates independent and coupled motion similar to natural cervical spine motion.



Mobi-C is composed of three parts: two metal plates and a medical grade polyethylene insert in between. The top plate rotates over the domed insert, allowing for a continuous path of cyclic movements: Flexion-Extension (FE), Lateral Bending (LB), and Axial Rotation (AR).

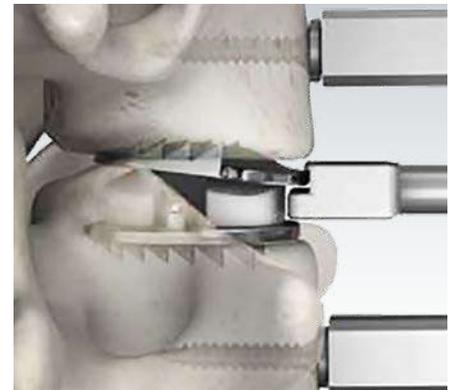
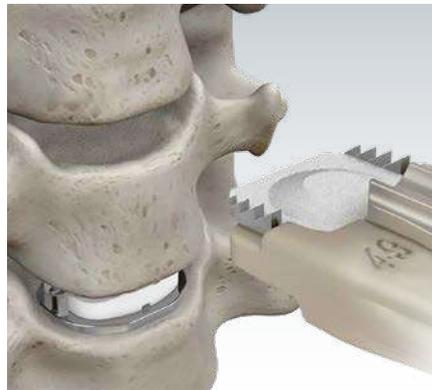


WATCH IT WORK!

Ease of Insertion

One-Step Insertion

To insert the Mobi-C Cervical Disc, no additional exposure or operative steps are required for screw or keel placement, eliminating the need for drilling or chiseling.



**Mobi-C is inserted
in one easy step.**



WATCH IT WORK!

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.





Bone Sparing

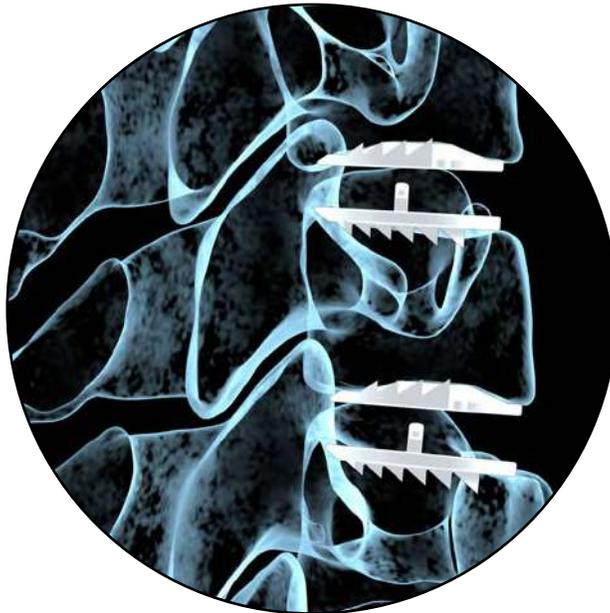
No Bone Chiseling

Preserves Bone Surface

Mobi-C's mobile core is designed to create low stress at the implant to bone interface. Implantation of the Mobi-C requires no invasive keels or screws, no bone removal for keel preparation, and no additional operative steps for keel cutting.

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

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



10-Year Outcomes of 1- and 2-Level Mobi-C Patients

Extended Follow-Up from the Mobi-C 7-year IDE Study

The following summarizes key results of the Mobi-C 10-year study, published in Neurosurgery.² Upon completion of the 7-year FDA Investigational Device Exemption (IDE) study of the Mobi-C Cervical Disc, follow-up continued on a subset of patients from nine high-enrolling centers.

All patients in the study had undergone cervical disc arthroplasty (CDA) with Mobi-C for the treatment of degenerative disc disease (DDD) with radiculopathy or myeloradiculopathy at one or two contiguous levels from C3-C7.

Clinical and radiographic outcomes of 187 Mobi-C patients were collected through 10 years postoperatively to assess the long-term safety and effectiveness of Mobi-C. The 10-year outcomes of the Mobi-C patients were assessed without comparisons to ACDF, as follow-up of the ACDF control group from the IDE study was completed after 7 years of follow-up.³ The aim of this analysis was to determine whether the statistically significant improvement observed in both 1- and 2-level Mobi-C patients from baseline to 7 years postoperatively was maintained out to 10 years.

Clinical outcomes of 1- and 2-level Mobi-C patients

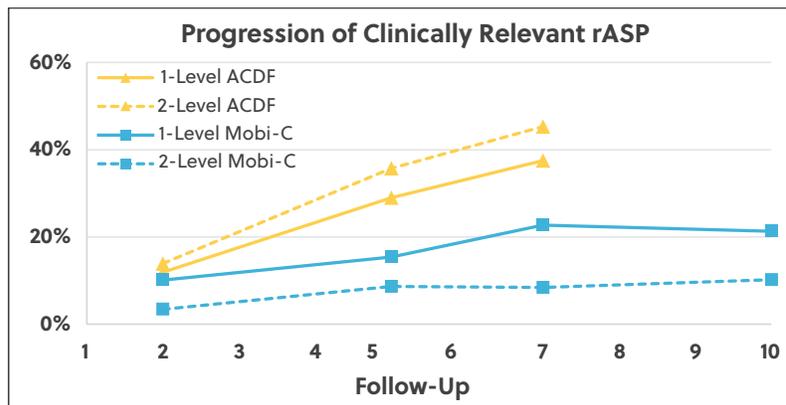
Outcome	Baseline	7 Years	10 Years	Baseline vs. 10-Year p-value	7-Year vs. 10-Year p-value
NDI	54.4	19.3	15.1	<0.0001*	0.003*
Neck Pain	72.1	20.3	13.3	<0.0001*	0.002*
Arm Pain	69.9	15.5	11.3	<0.0001*	0.037*
SF-12 Physical	32.9	45.7	47.5	<0.0001*	0.13
SF-12 Mental	41.6	51.0	51.5	<0.0001*	0.91

*Denotes a statistically significant difference

Segmental and Global ROM (degrees) in Mobi-C patients through 10 years

	Flexion/Extension			Lateral Bending			Global ROM (C2-C6 flexion/extension)	
	2-Level Superior	2-Level Inferior	1-Level	2-Level Superior	2-Level Inferior	1-Level	2-Level	1-Level
Preop	8.9	6.8	7.8	5.6	4.9	5.0	37.0	38.8
7 Years	9.4	6.8	9.7	5.1	4.7	5.2	37.9	42.7
10 Years	9.5	6.9	9.3	4.9	4.5	5.1	38.2	41.6
P-value*	0.91	0.97	0.59	0.99	0.99	0.90	0.99	0.19

*10 years vs. 7 years



Progression of clinically relevant rASP throughout follow-up. ACDF reporting ends at 7 years due to completion of the FDA IDE study.

Key Findings of 10-year Outcomes

Mobi-C continues to be a safe and effective treatment for 1- and 2-level cervical degeneration

- 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 both 1-level and 2-level constructs.
 - Clinically relevant radiographic adjacent segment pathology (rASP) did not differ significantly in either 1-level or 2-level patients.
 - No subsequent surgery at an adjacent level after 7 years.

Mobi-C® Cervical Disc

Indications

Mobi-C Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit with or without neck pain) or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height compared to adjacent levels. The Mobi-C Cervical Disc Prosthesis is implanted using an anterior approach. Patients should have failed at least six weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C Cervical Disc Prosthesis.

Contraindications

The Mobi-C Cervical Disc Prosthesis should not be implanted in patients with the following conditions:

- Acute or chronic infection, systemic or at the operative site;
- Known allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, titanium, hydroxyapatite, or polyethylene);
- Compromised vertebral bodies at the index level due to previous trauma to the cervical spine or to significant cervical anatomical deformity or disease (e.g., ankylosing spondylitis, rheumatoid arthritis);
- Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5mm, and/or > 11° angular difference to that of either adjacent level;
- Osteoporosis or osteopenia defined as DEXA bone mineral density T-score < -1.5;
- Severe facet joint disease or degeneration

Full risk and contraindication information can be found at Cervicaldisc.com

Mobi-C® Footprints (mm) available in U.S. and Japan	All footprints available in 5, 6, and 7mm heights								
	DEPTH	13	15	13	15	17	15	17	
	WIDTH	15	15	17	17	17	19	19	
Footprints (mm) available in EMEA, APAC, LATAM, and Canada	All footprints available in 4.5, 5, 6, and 7mm heights								
	DEPTH	13	15	13	15	17	15	17	19
	WIDTH	15	15	17	17	17	19	19	19

References

1. Data on file. Based on available market data at the time of this publication.
2. Kim K, Hoffman G, Bae H, et al. Ten-Year Outcomes of 1- and 2-Level Cervical Disc Arthroplasty From 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.
4. Amevo B, et al Instantaneous axes of rotation of the typical cervical motion segments: a study in normal volunteers. *Clin Biomech (Bristol, Avon)*. 1991 May;6(2):111-7

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Common post-operative risks from surgery with the Mobi-C include pain in the neck, arm, back, shoulder, or head, and dysphagia.

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The clinical data presented is from use of the Mobi-C US implant design which has minor design differences compared to the Mobi-C in other countries.

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