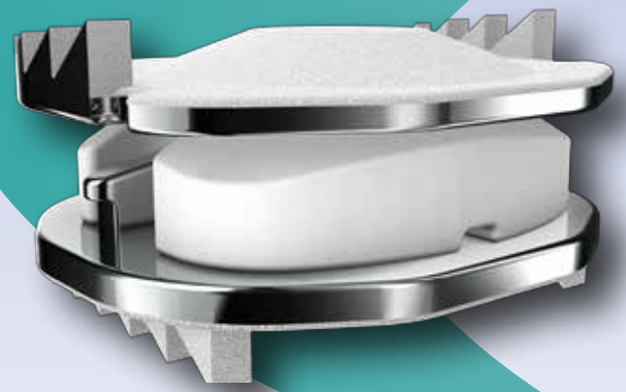
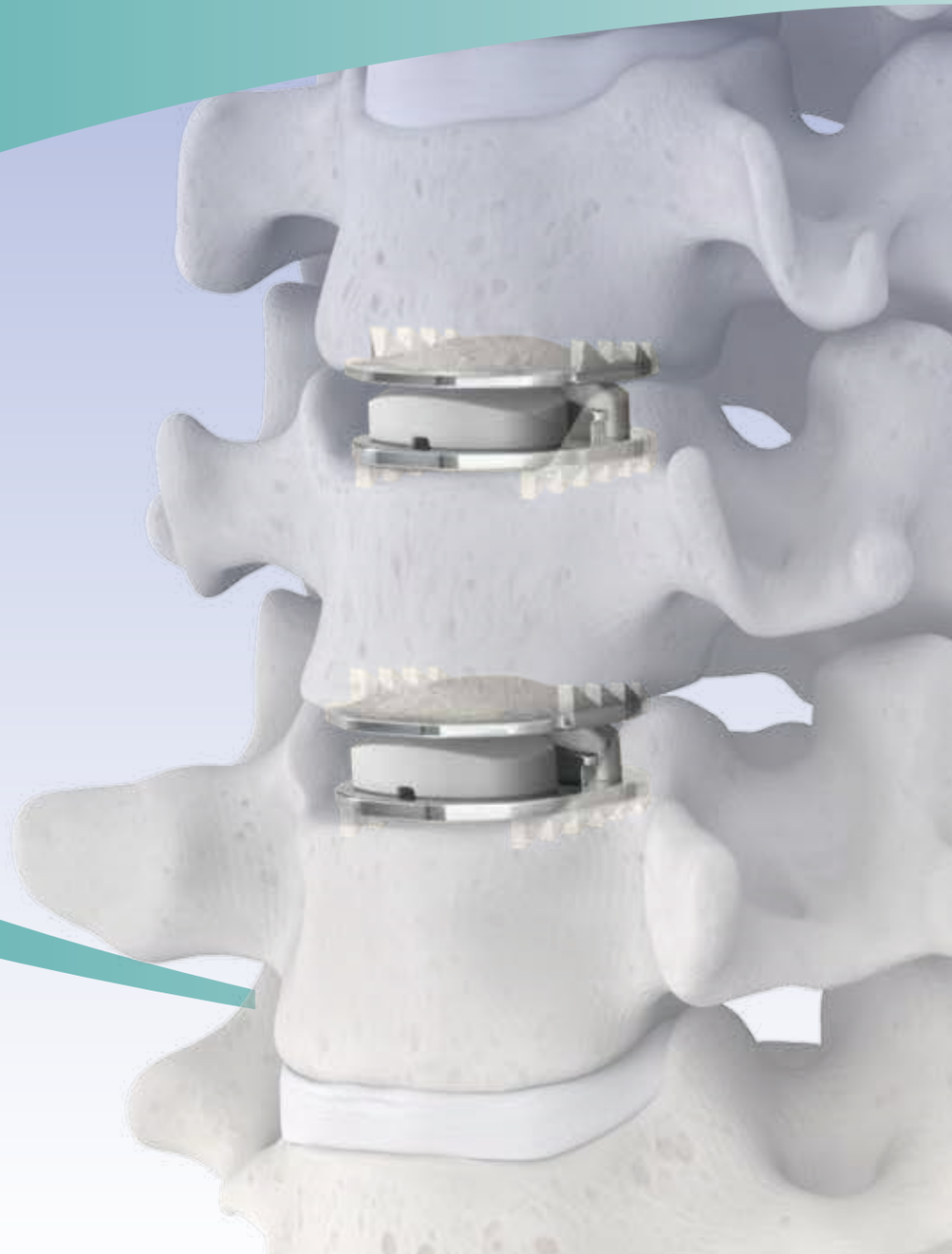
Mobi-C®
CERVICAL DISC

Product Brochure
TWO-LEVEL INDICATIONS





LDR
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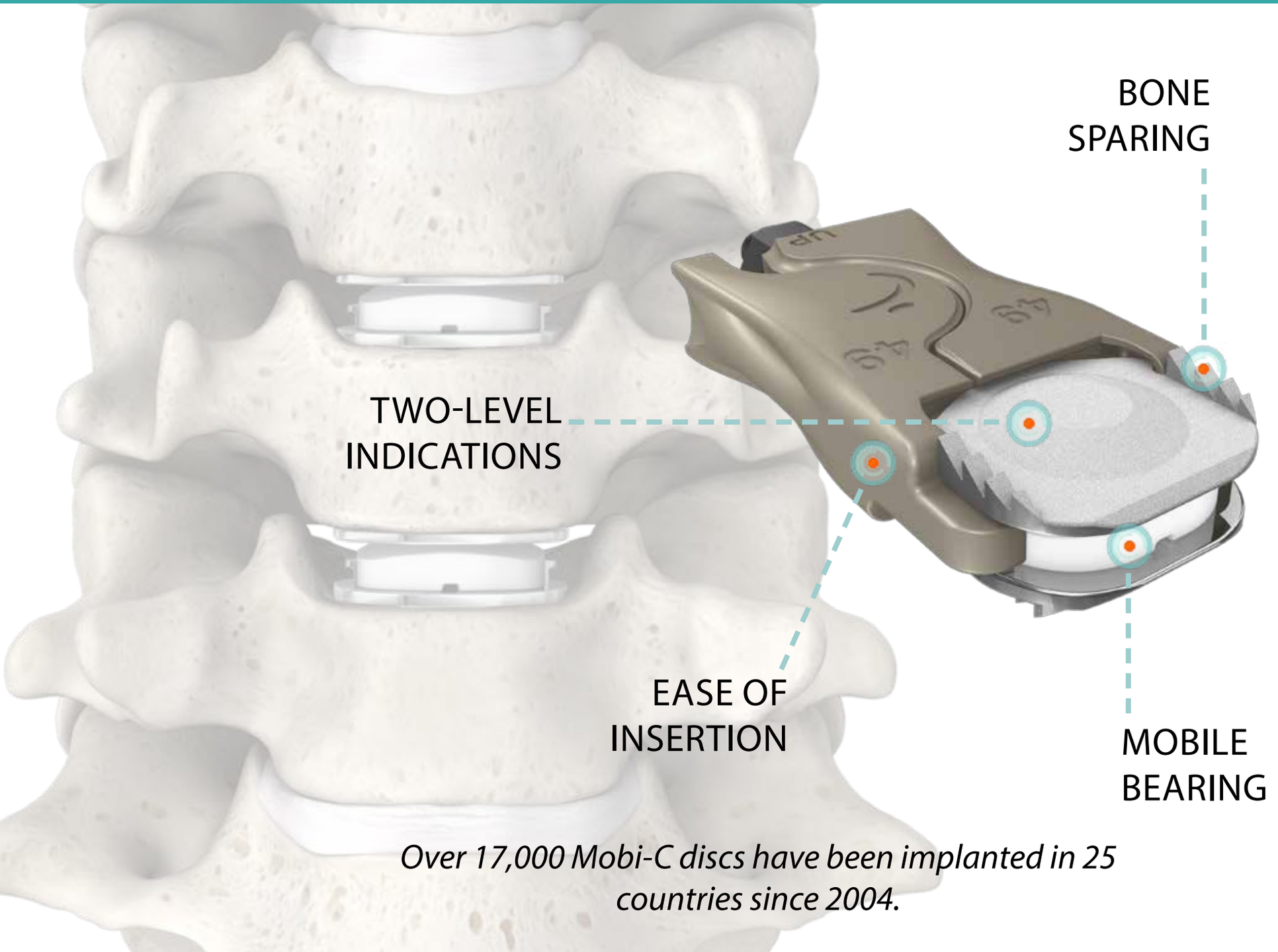
MOBI-C® CERVICAL DISC

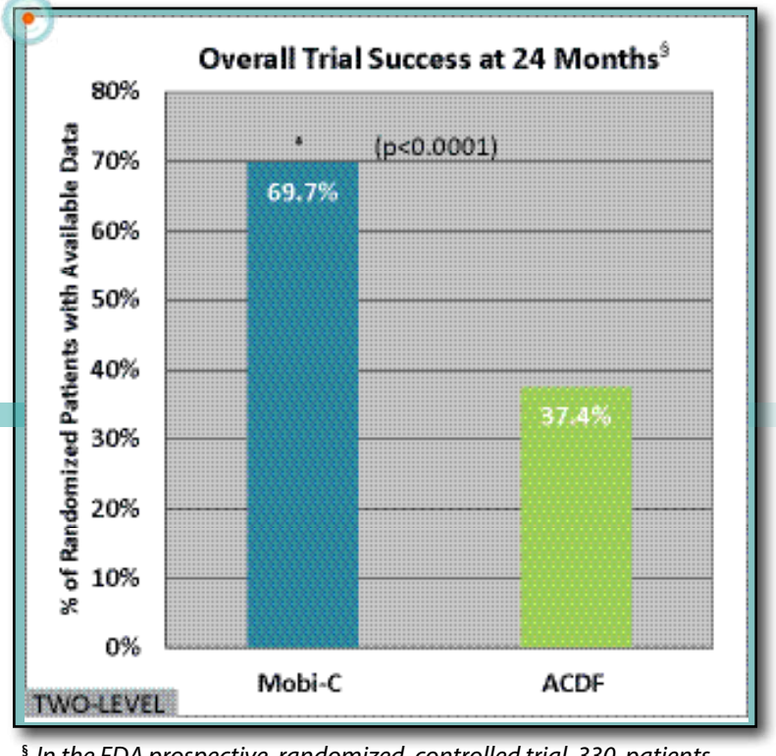


Over 17,000 Mobi-C discs have been implanted in 25 countries since 2004.

MOBI-C IS THE FIRST AND ONLY APPROVED TWO-LEVEL DISC[1]

MOBI-C IS SUPERIOR TO ACDF AT TWO LEVELS[2]

Mobi-C demonstrated <u>superiority</u> in overall trial success compared to ACDF at 24 months.



§ *In the FDA prospective, randomized, controlled trial, 330 patients were studied at 24 centers.*

* *Fisher Exact test used to compare treatments to establish superiority.*

MOBI-C HAD LOWER RATES OF ADJACENT LEVEL DEGENERATION

The deterioration of adjacent segments at 24 months compared to baseline was:

- 2.9% for Mobi-C compared to 18.1% for ACDF at the inferior level.
- 13.1% for Mobi-C compared to 33.3% for ACDF at the superior level.

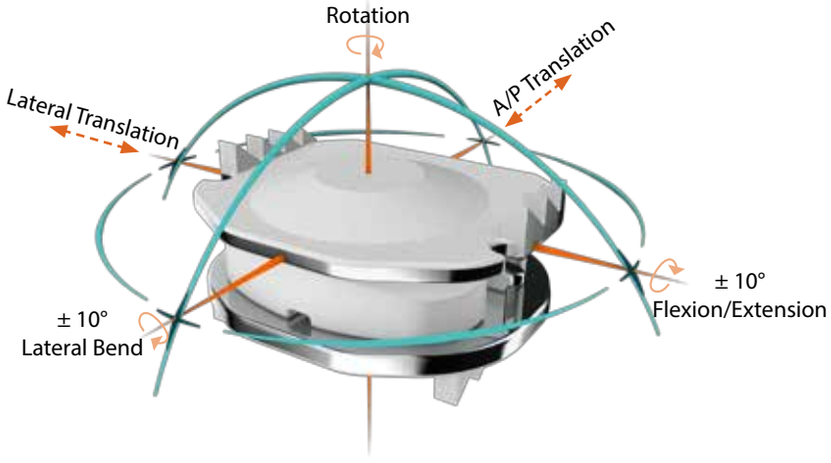
MOBI-C HAD FEWER SECONDARY SURGERIES

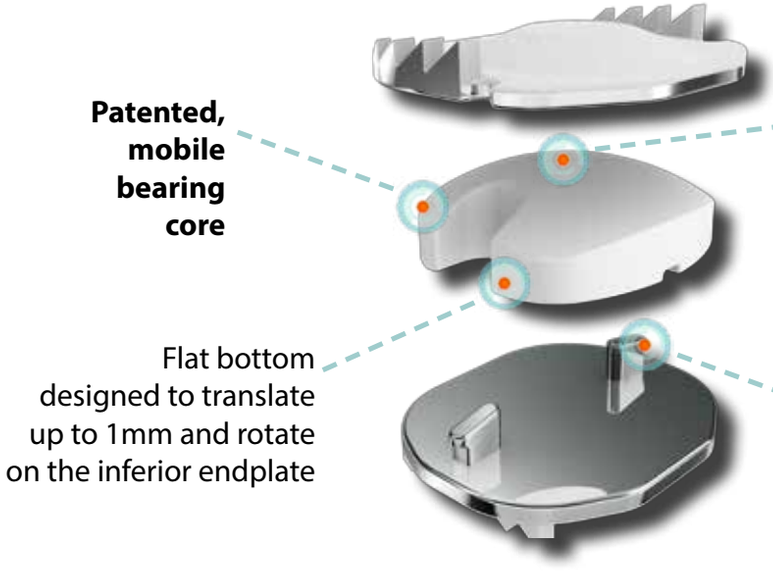
Only 3.1% of Mobi-C patients compared to 11.4% of ACDF patients reported secondary surgeries at the index levels through 24 months.

Note: Success criteria for these Mobi-C Independent Device Exemption (IDE) trial results can be found on page 7.

MOBI-C: MOBILE BEARING

CONTROLLED MOBILITY



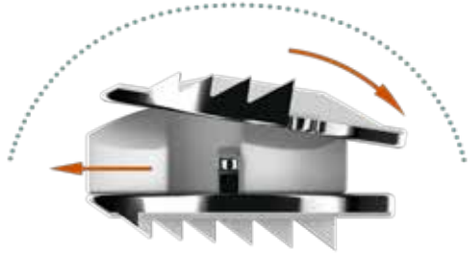


SELF-ADJUSTING

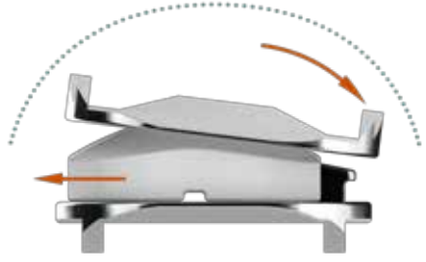
The center of rotation at each level of the cervical spine is variable and constantly changing[3]. Mobi-C was designed to adapt to the Instantaneous Axis of Rotation through its self-adjusting mobile core.

The Mobi-C mobile core:

- Is designed to facilitate independent and coupled motion similar to natural cervical spine motion.
- Moves with the spine and does not dictate a predetermined, fixed axis of rotation.



Flexion/Extension with A/P translation



Lateral Bending with lateral translation

MOBI-C: BONE SPARING

NO BONE CHISELING

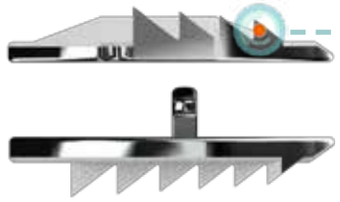
Mobi-C's mobile core is designed to create low stress at the implant to bone interface. The Mobi-C requires:

- No invasive keels or screws.
- **No bone removal for keel preparation.**
- No additional operative steps for keel cutting.

Intact endplates, compared to endplates prepared for keels, provide:

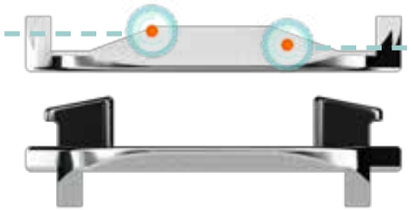
- **A preserved surface for the implant, ideal for two-level implantation.**
- Intraoperative flexibility to optimize implant positioning.

SHORT AND LONG TERM STABILITY



Lateral, inclined teeth:

- Purchase in the apophyseal ring to provide initial stability
- Designed to resist migration



Superior dome:

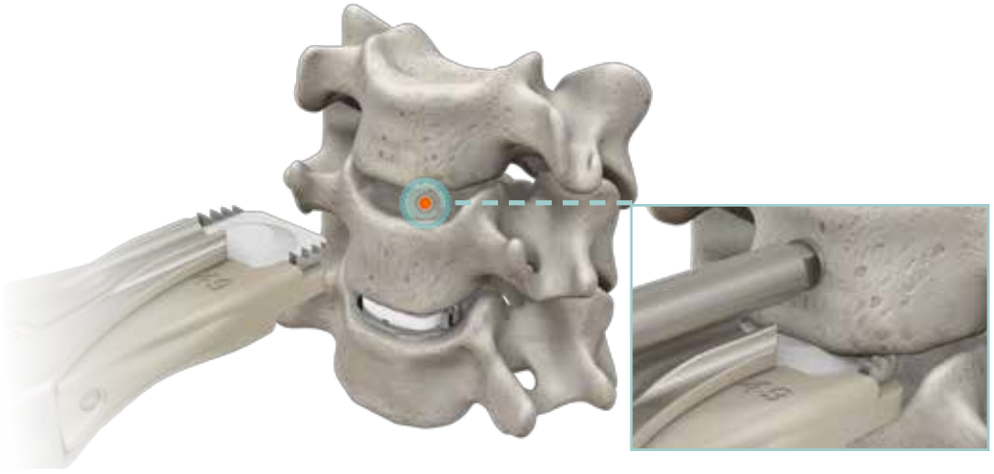
- Designed to match the natural, bony anatomy enabling short and long term stability

Plasma sprayed titanium and hydroxyapatite coated endplates:

- Encourage bony ongrowth for long term stability

MOBI-C: EASE OF INSERTION

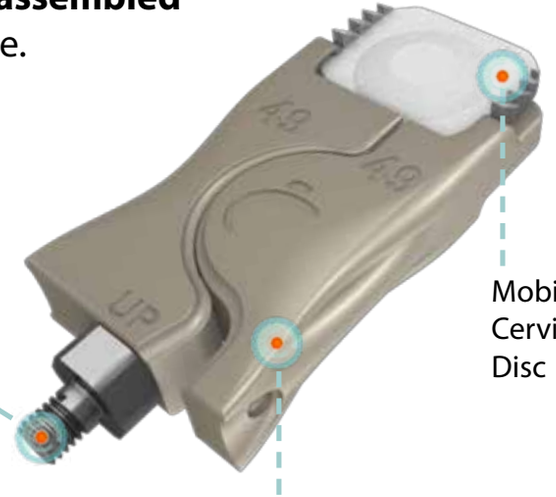
ONE-STEP INSERTION



- **No drilling or chiseling required**
- No additional exposure or operative steps required for screw or keel placement

PRE-ASSEMBLED IMPLANTS

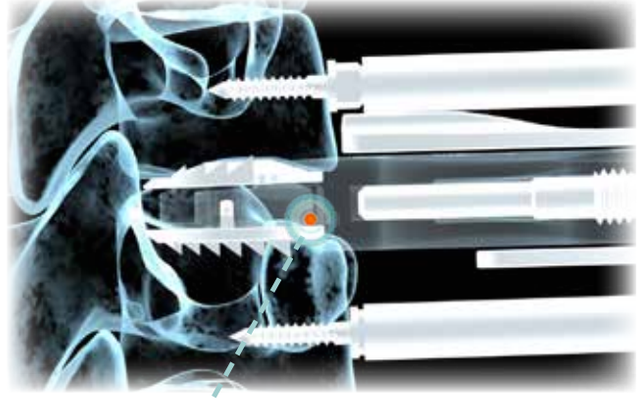
The Mobi-C is **delivered pre-assembled** on a disposable PEEK cartridge.



PEEK cartridge assembles easily to the implant inserter saving operative steps

Mobi-C Cervical Disc

PEEK Cartridge



PEEK cartridge allows a radiolucent view of the implant for optimal positioning

INDICATIONS

The Mobi-C® Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at 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 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C® Cervical Disc Prosthesis.

SIZING OPTIONS

Depth x Width (mm)	Height (mm)
13x15	5, 6, and 7
13X17	
15X15	
15X17	
15X19	

IDE Success Criteria		
Overall Trial Success Trial success was based on a composite endpoint. A patient was considered a success at 24 months if all of the following criteria were met: • Sufficient NDI improvement • No secondary surgery at the treated level • No radiographic failure • No neurologic deterioration • No adverse event determined to be a major complication	**Adjacent Segment Degeneration** Adjacent segment degeneration was assessed at the spinal segment immediately above and below the treated levels. An independent core lab assessed degeneration using the Kellgren-Lawrence five point grading scale. An adjacent segment was counted as having degenerated if the segment worsened by 1 grade or more.	**Secondary Surgeries At the Treated Levels** The patient was considered a success in terms of secondary surgery if none of the following were necessary at either of the treated levels: removal, revision, reoperation, or supplemental fixation.
References		
[1]As of 7/30/13 in the USA [2]The control group in the Mobi-C IDE clinical trial was ACDF using allograft bone and an anterior cervical plate. [3]Amevo *et al* 1991		

Indications for Use:
The Mobi-C® Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at 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 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C® Cervical Disc Prosthesis.

Note: Please refer to the Mobi-C Summary of Safety and Effectiveness Data (PMA P110009) at www.fda.gov for complete study results.

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