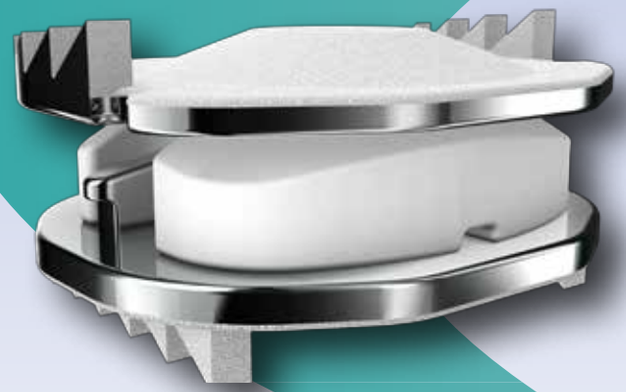
Mobi-C®
CERVICAL DISC

Product Brochure
ONE-LEVEL INDICATIONS



LDR
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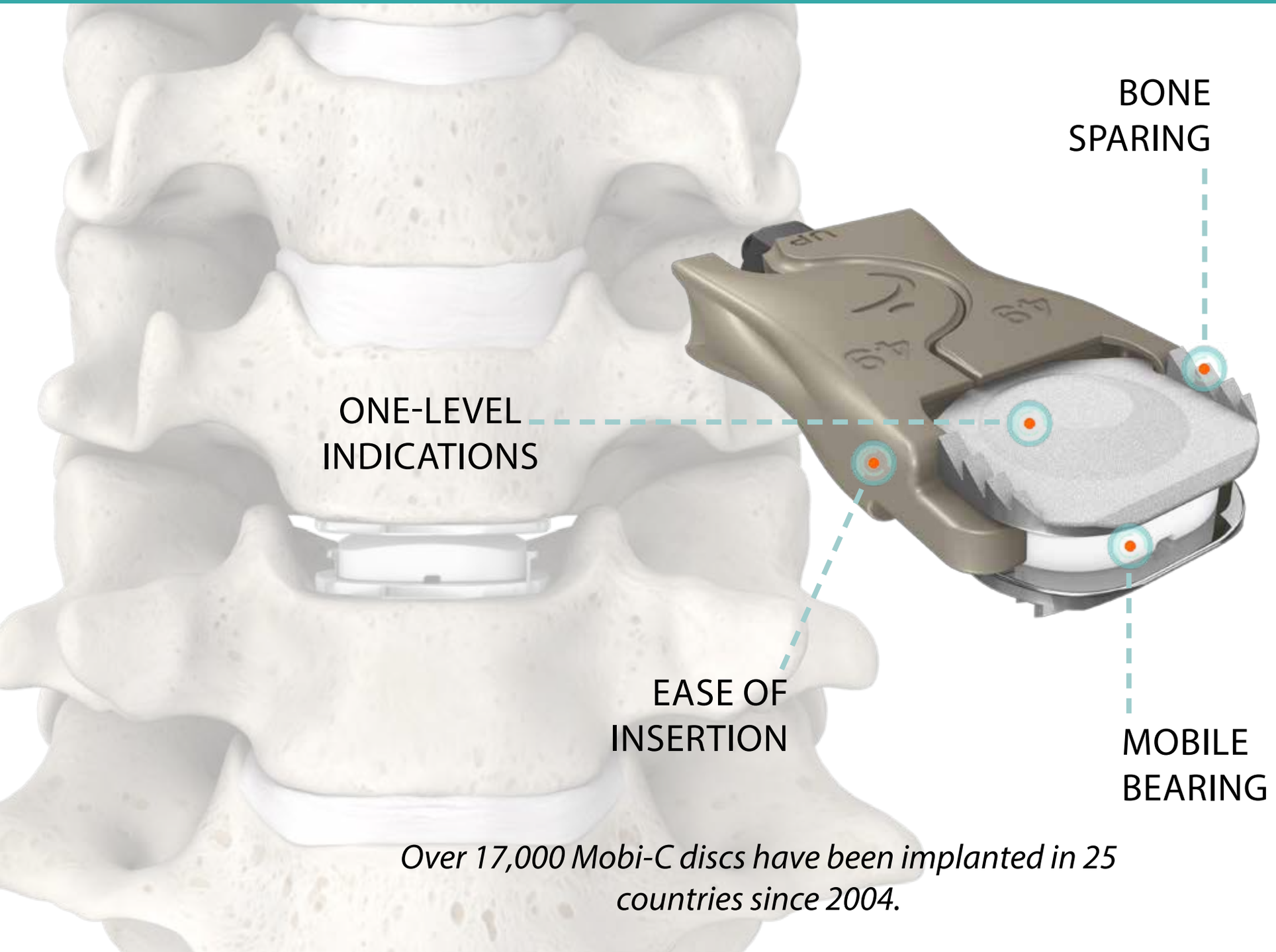
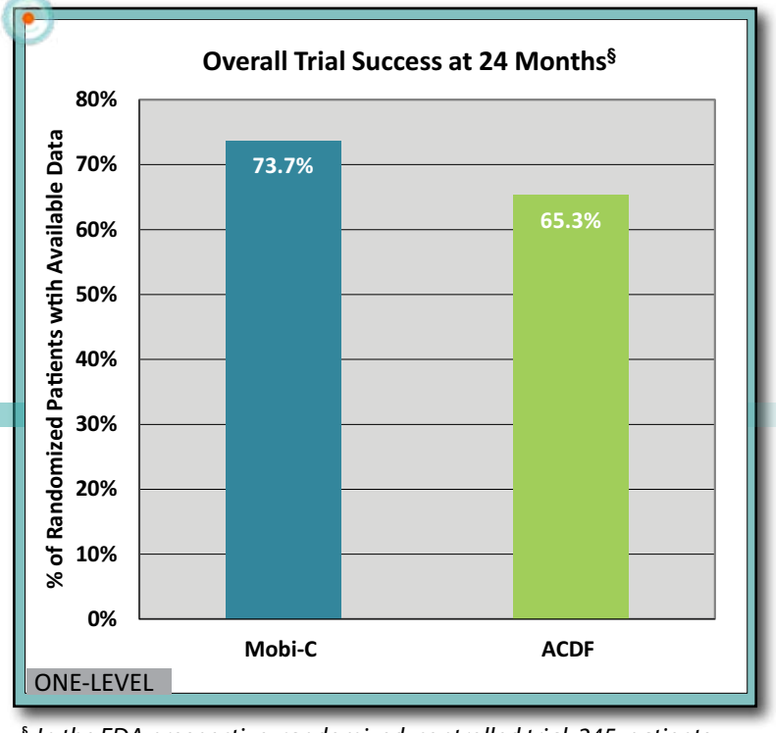
MOBI-C® CERVICAL DISC



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

MOBI-C IS NON-INFERIOR TO ACDF AT ONE LEVEL[1]

Mobi-C demonstrated non-inferiority in overall trial success compared to ACDF at 24 months.



§ *In the FDA prospective, randomized, controlled trial, 245 patients were studied at 24 centers.*

MOBI-C HAD LOWER RATES OF ADJACENT LEVEL DEGENERATION

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

- 7.7% for Mobi-C compared to 21.0% for ACDF at the inferior level.
- 14.6% for Mobi-C compared to 25.0% for ACDF at the superior level.

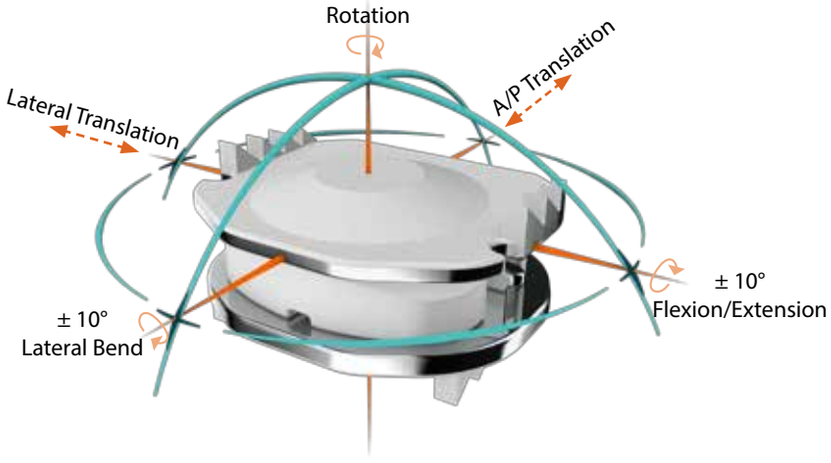
MOBI-C HAD FEWER SECONDARY SURGERIES

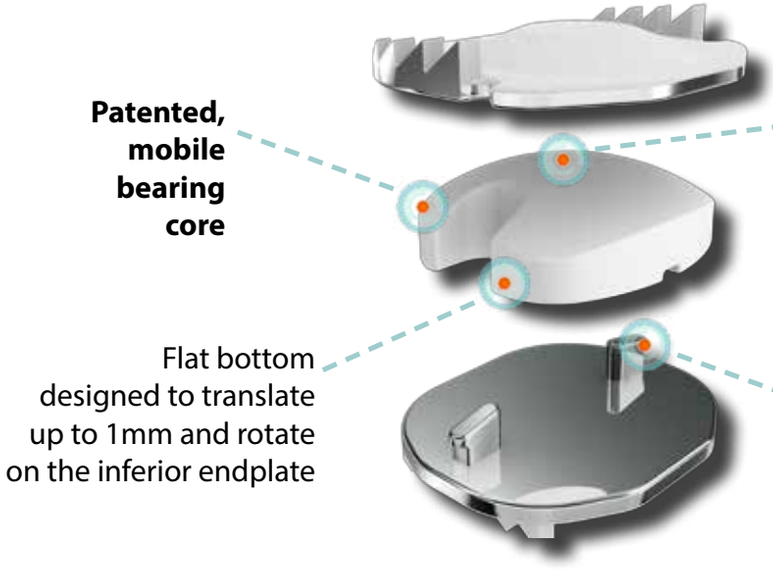
Only 1.2% of Mobi-C patients compared to 6.2% of ACDF patients reported secondary surgeries at the index level through 24 months.

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



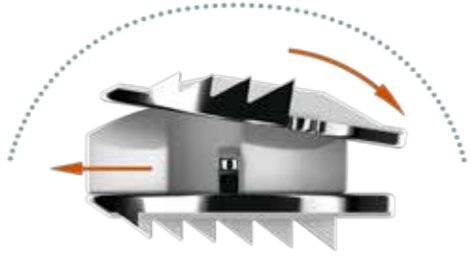


SELF-ADJUSTING

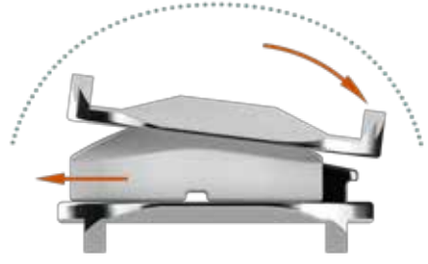
The center of rotation at each level of the cervical spine is variable and constantly changing[2]. Mobi-C was designed to adapt to the Instantaneous Axis of Rotation through its self-adjusting mobile core.

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

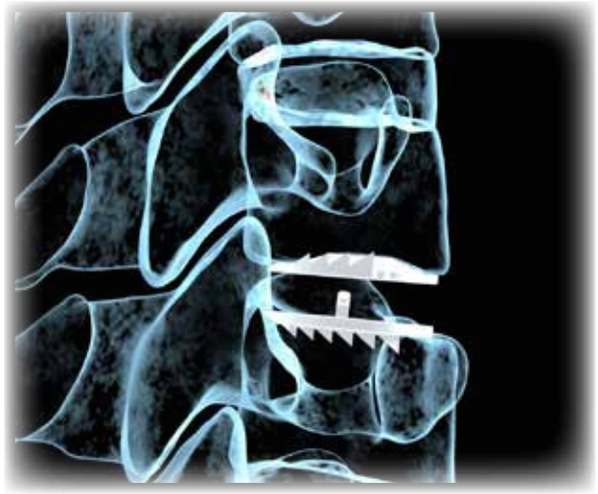
NO BONE CHISELING

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

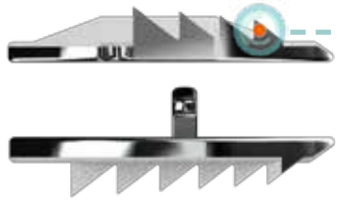
- No invasive keels or screws.
- **No bone removal for keel preparation.**
- No additional operative steps for keel cutting.

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

- **A preserved surface for the implant.**
- Intraoperative flexibility to optimize implant positioning.

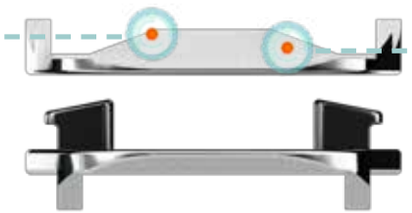


SHORT AND LONG TERM STABILITY



Lateral, inclined teeth:

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



Superior dome:

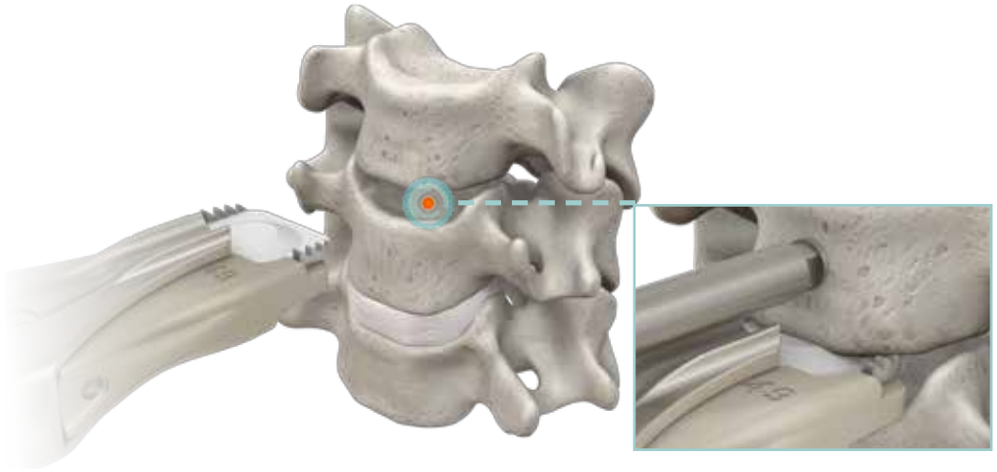
- Designed to match the natural, bony anatomy enabling short and long term stability

Plasma sprayed titanium and hydroxyapatite coated endplates:

- Encourage bony ongrowth for long term stability

MOBI-C: EASE OF INSERTION

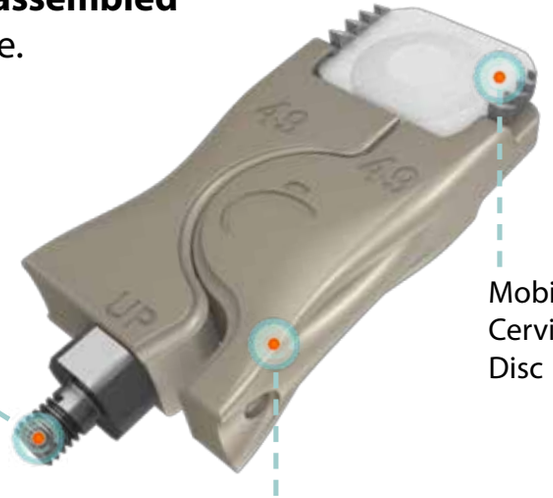
ONE-STEP INSERTION



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

PRE-ASSEMBLED IMPLANTS

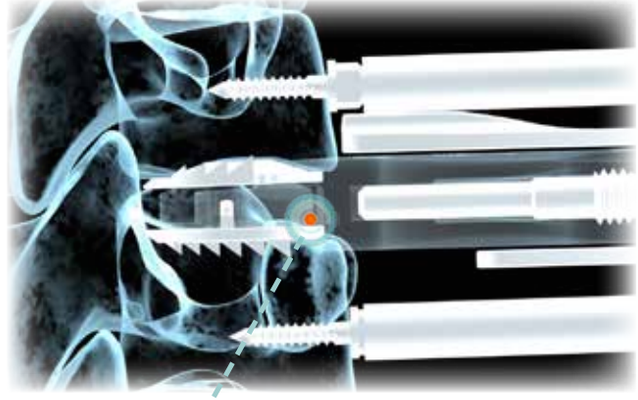
The Mobi-C is **delivered pre-assembled** on a disposable PEEK cartridge.



PEEK cartridge assembles easily to the implant inserter saving operative steps

Mobi-C Cervical Disc

PEEK Cartridge



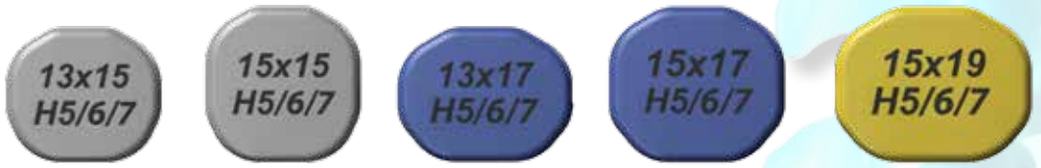
PEEK cartridge allows a radiolucent view of the implant for optimal positioning

INDICATIONS

The Mobi-C® Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level 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 level. 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 Level** The patient was considered a success in terms of secondary surgery if none of the following were necessary at the treated level: removal, revision, reoperation, or supplemental fixation.
References		
[1]The control group in the Mobi-C IDE clinical trial was ACDF using allograft bone and an anterior cervical plate. [2]Amevo *et al* 1991		

Indications for Use:
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Note: Please refer to the Mobi-C Summary of Safety and Effectiveness Data (PMA P110002) at www.fda.gov for complete study results.

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REF: MB B 5 REV A 08.2013