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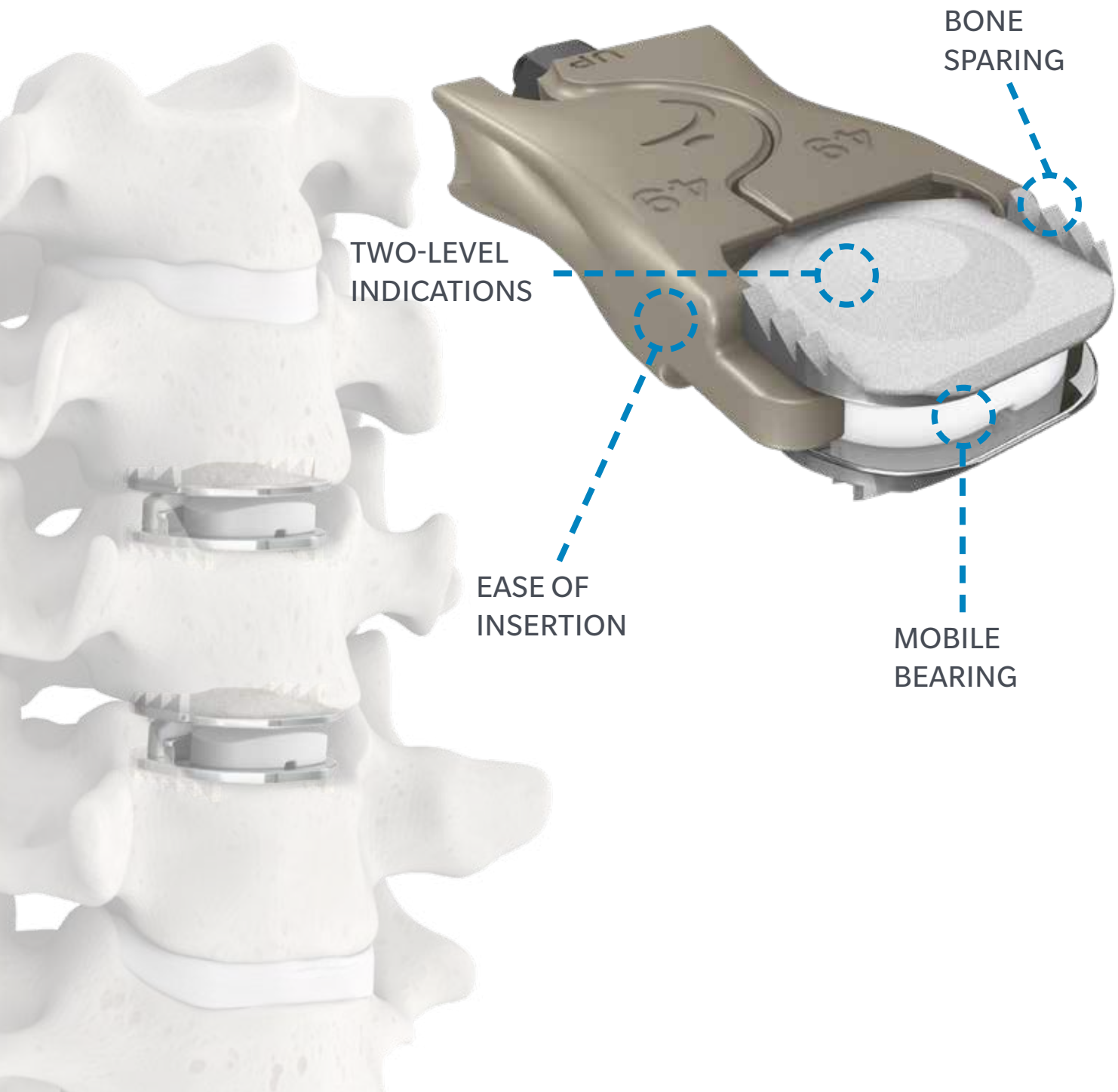
Cervical Solutions

Mobi-C®
Cervical Disc

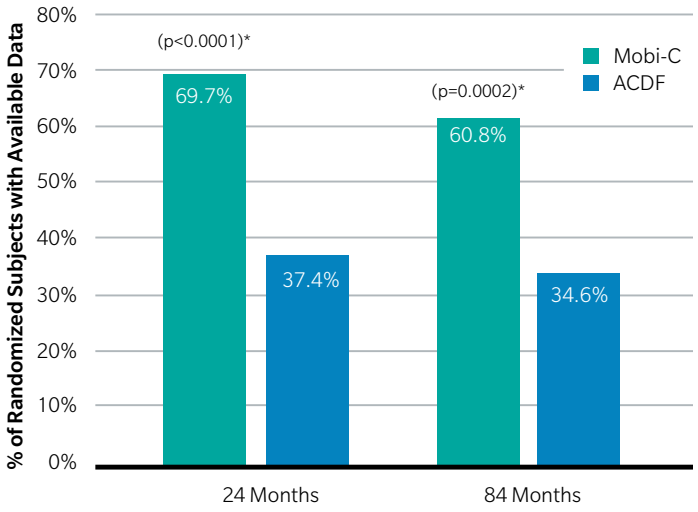
Mobi-C Cervical Disc is the first FDA approved two-level disc.[1]

OVER 70,000 MOBI-C DISCS HAVE BEEN IMPLANTED IN 25 COUNTRIES SINCE 2004.

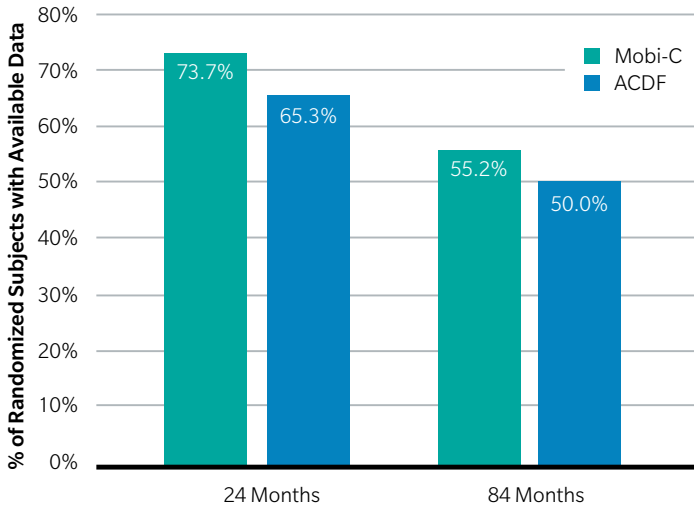
The Mobi-C Cervical Disc is the first cervical disc in the United States approved to treat more than one level of the cervical spine, and was determined by the FDA to be statistically superior to fusion at 7 years for two-level cervical disc replacement, based on the primary study endpoint of a prospective, concurrently controlled and randomized, multi-center clinical trial.[1]



Mobi-C is non-inferior to ACDF at one level and superior at two levels[2]



TWO-LEVEL OVERALL TRIAL SUCCESS



ONE-LEVEL OVERALL TRIAL SUCCESS

**Fisher's Exact test used to compare treatments*

Mobi-C had lower rates of adjacent segment degeneration at 84 months

One-level deterioration of adjacent segments at 84 months compared to baseline:

- 43.8% for Mobi-C compared to 63.0% for ACDF at the inferior level.
- 40.4% for Mobi-C compared to 65.1% for ACDF at the superior level.

Two-level deterioration of adjacent segments at 84 months compared to baseline:

- 30.3% for Mobi-C compared to 66.7% for ACDF at the inferior level.
- 37.5% for Mobi-C compared to 73.7% for ACDF at the superior level.

Mobi-C had fewer subsequent surgeries at 84 months

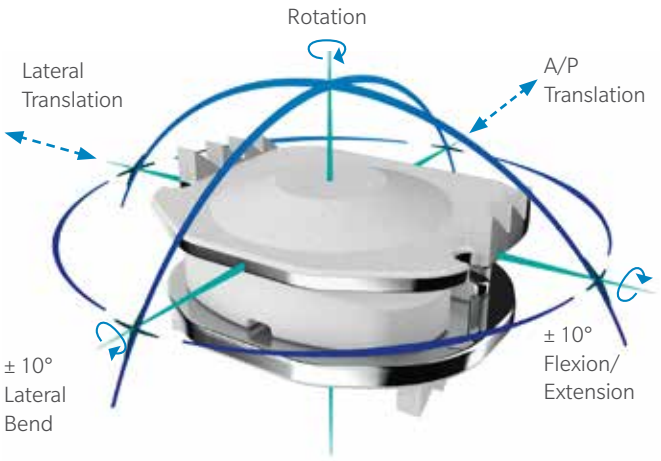
One-level: Only 3.4% of Mobi-C patients compared to 11.1% of ACDF patients reported secondary surgeries at the index levels through 84 months.

Two-level: Only 5.6% of two-level Mobi-C patients compared to 17.1% of ACDF patients reported secondary surgeries at the index levels through 84 months.

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

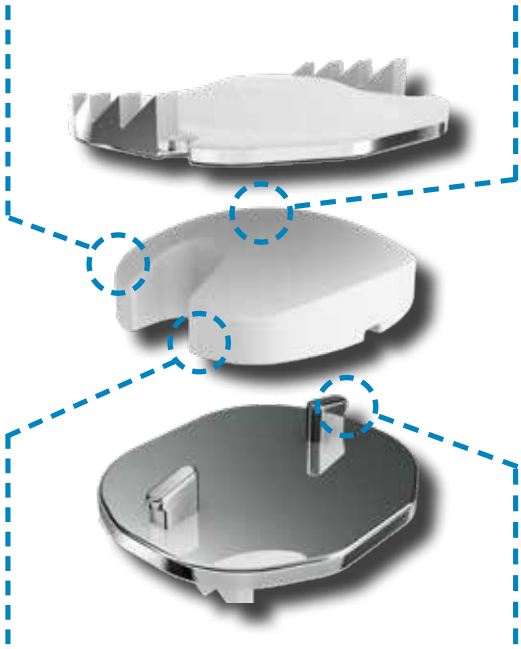
MOBI-C: MOBILE BEARING

Controlled mobility



Patented, mobile bearing core

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

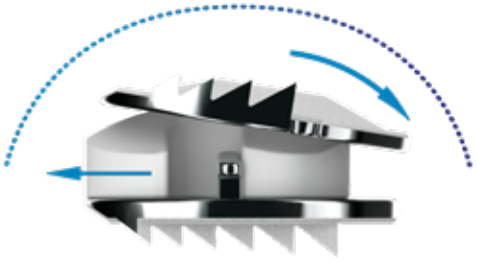
Tabs provide a safety stop designed to control mobility and to resist expulsion

Self-adjusting

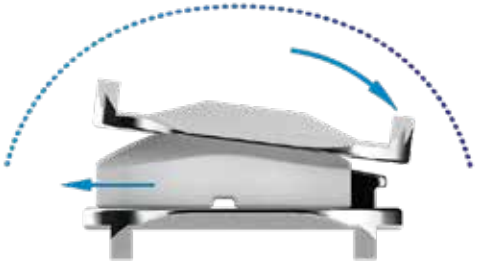
The center of rotation at each level of the cervical spine is variable and constantly changing[3]. Mobi-C was designed to adapt to the Instantaneous Axis of Rotation through its self-adjusting mobile core.

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



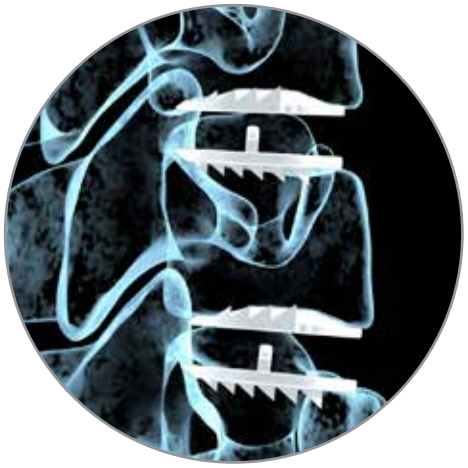
Lateral Bending with lateral translation

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:

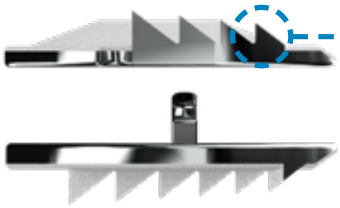
- No invasive keels or screws.
- No bone removal for keel preparation.
- No additional operative steps for keel cutting.



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

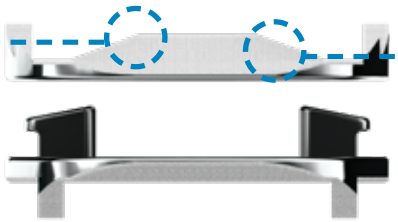


Lateral, inclined teeth:

- 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



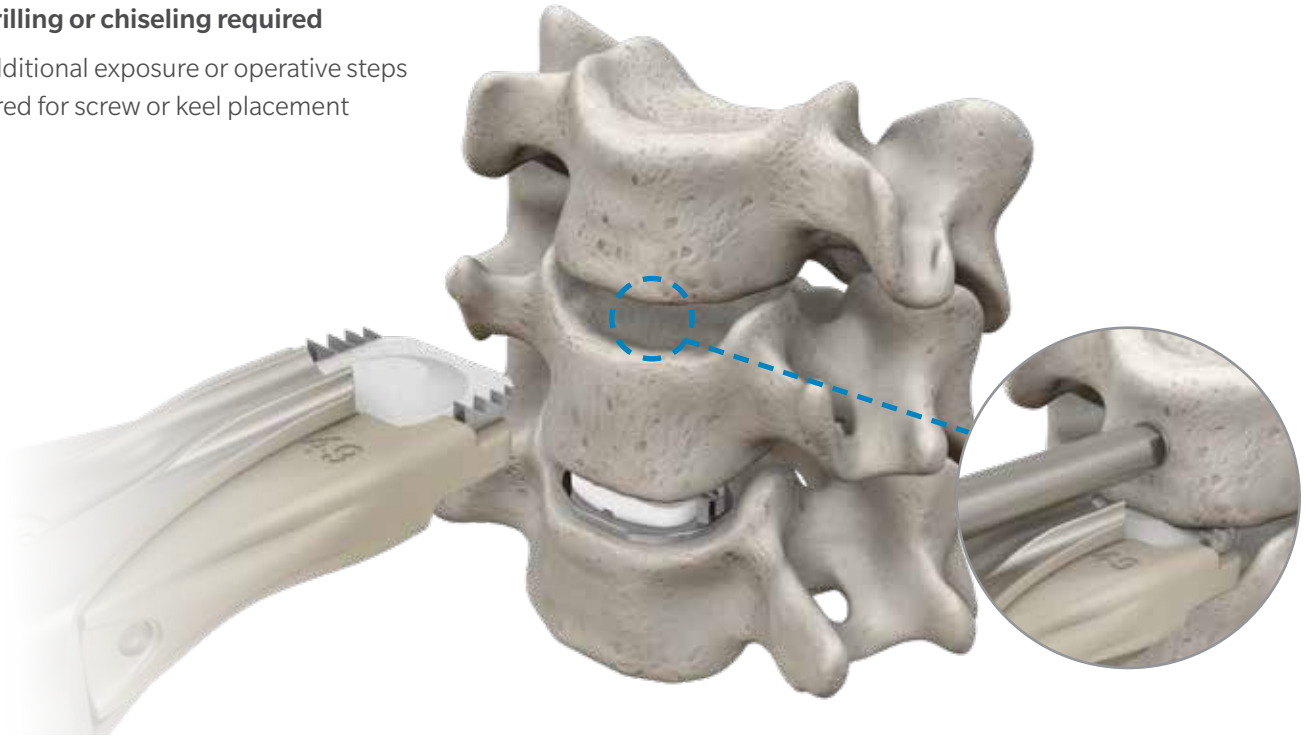
Plasma sprayed titanium and hydroxyapatite coated endplates:

- Encourage bony ongrowth for long term stability

MOBI-C: EASE OF INSERTION

One-step insertion

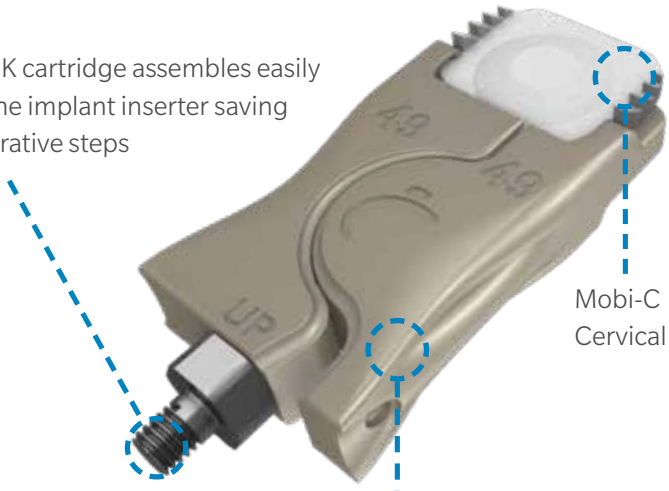
- **No drilling or chiseling required**
- No additional exposure or operative steps required for screw or keel placement



Pre-assembled implants

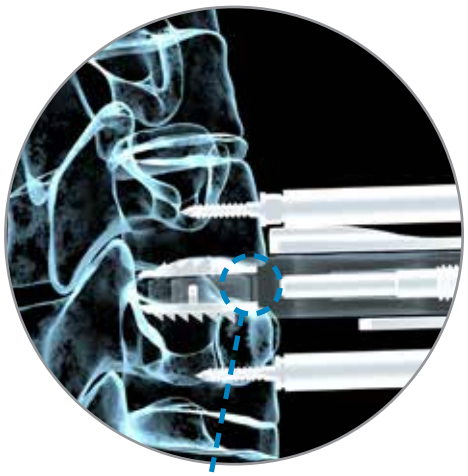
The Mobi-C is **delivered pre-assembled** on a disposable PEEK cartridge.

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

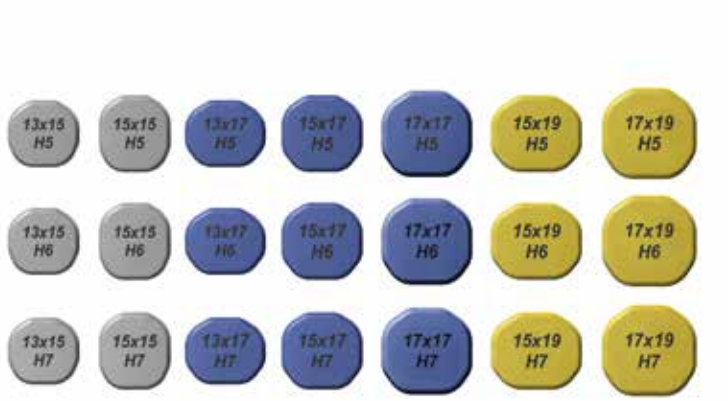
MOBI-C: PRODUCT DETAILS

Indications

The 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 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)
13 x 15	5, 6, and 7
13 x 17	
15 x 15	
15 x 17	
15 x 19	
17 x 17	
17 x 19	



IDE success criteria

Overall Trial Success

Trial success was based on a composite endpoint. A patient was considered a success at 84 months if all of the following criteria were met:

- Sufficient NDI improvement
  - If baseline NDI is ≥ 30 points out of 50 points, improvement must be ≥ 15 points out of 50 points
  - If baseline NDI is < 30 points out of 50 points, improvement must be ≥ 50% improvement

Note: NDI success criteria is measured using a subject answered questionnaire, which assesses the effect of pain on daily life. Each of the 10 assessed criteria§ receives a score from 0 to 5; the highest score (50 points) represents the most disabled. The final score can be converted to a percentage.

- 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 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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