

M6^c
artificial cervical disc

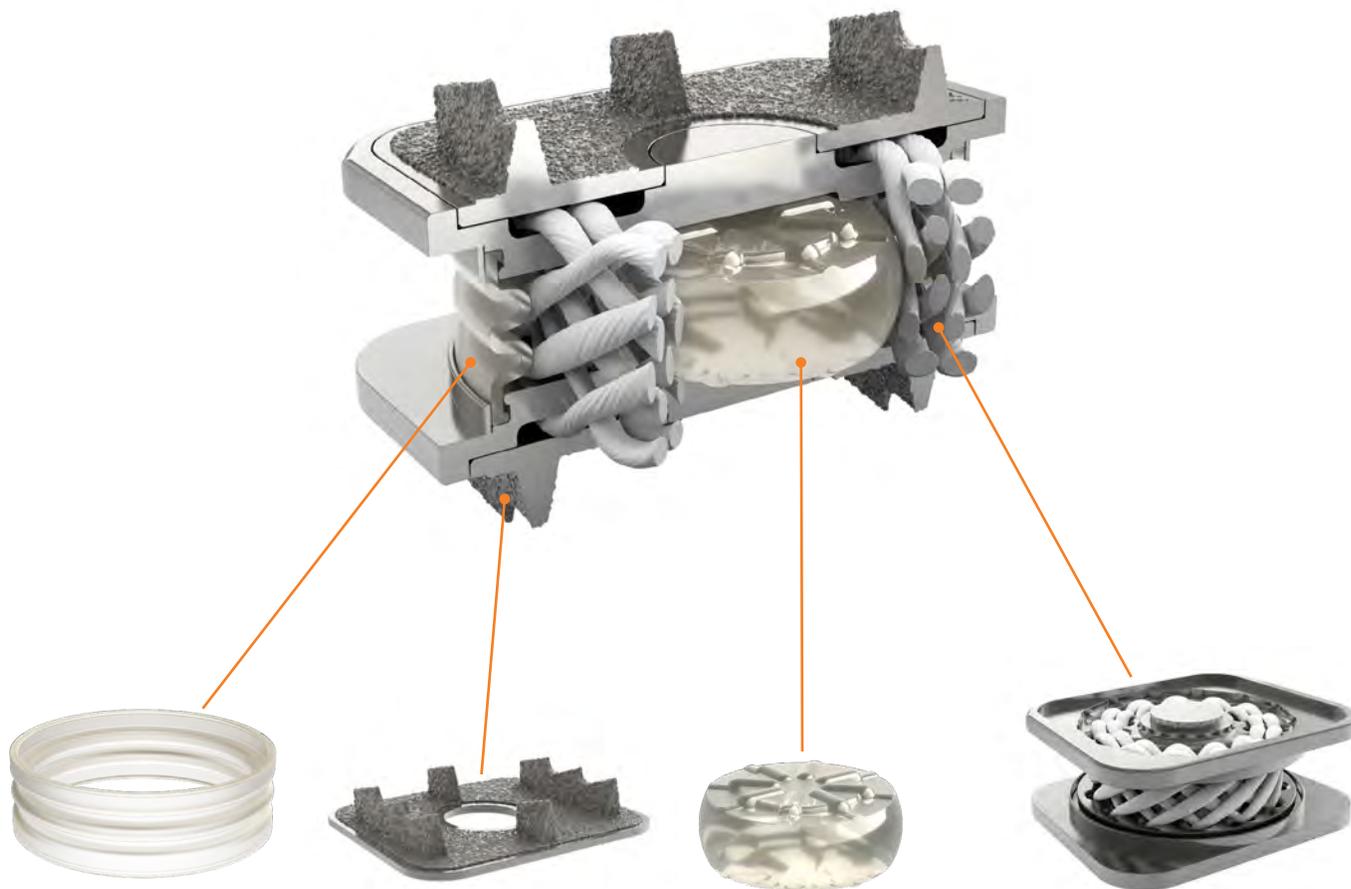
The Natural Choice

For Cervical Disc Replacement

The Natural Choice

The M6-C™ artificial cervical disc technology provides an alternative to spinal fusion and is designed to restore natural and physiologic motion. Preserving motion with the M6-C disc provides an opportunity to restore biomechanical function at the treated level after native disc removal, as well as the

possibility to reduce subsequent degeneration of adjacent segments. With its innovative single piece design for ease of implantation and ability to replicate a natural disc's motion, the M6-C artificial cervical disc is the natural choice.



Sheath

- Viscoelastic polymer (PCU) designed to minimize tissue in-growth and debris migration

Fixation

- Titanium alloy endplates with low profile tri-fin design provides acute fixation to the superior and inferior vertebral bodies
- Titanium Plasma Spray (TPS) coating intended to promote bone growth, providing long-term stability

Artificial Nucleus

- Viscoelastic polymer (PCU) designed to simulate native nucleus structure
- In combination with the artificial annulus, allows physiologic axial compression
- Retained between endplates by fiber annulus matrix

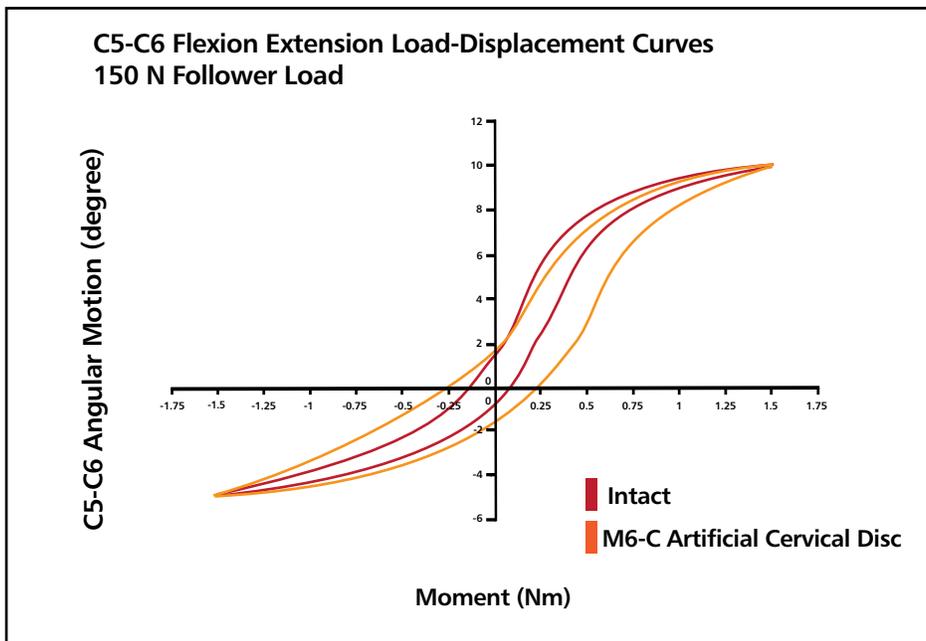
Artificial Annulus

- Ultra High Molecular Weight Polyethylene (UHMWPE) fiber matrix designed to simulate native annular structure
- In combination with the artificial nucleus, allows controlled motion in all planes and axes of rotation
- Robust fiber matrix with multiple fiber layers similar to native annulus

Quality of Motion

Quality of Motion assesses how well the motion of an implanted functional spine unit approximates the motion of a healthy one over the entire range of motion, not just its endpoints. Through biomechanical testing, a load vs. angular displacement curve (“kinematic signature”) is generated that allows assessment of the Quality of Motion parameters.

Biomechanical testing with the M6-C™ artificial cervical disc has demonstrated similar Quality of Motion compared to the native disc. The innovative artificial fiber annulus and nucleus construct of the M6-C disc is the critical component in replicating this physiologic motion, as it is designed to provide the necessary restraint and control needed throughout the spine’s natural range of motion.



Biomechanical results showing the M6-C artificial cervical disc (orange) maintained total ROM (14.6) vs. the intact disc (14.4) with excellent Quality of Motion. The “kinematic signatures” of the intact disc (red) and the M6-C artificial cervical disc are nearly identical.

Testing on file at Orthofix-Spinal Kinetics (Sunnyvale, CA)

Single-Level M6-C Artificial Cervical Disc Case



Extension



Neutral



Flexion

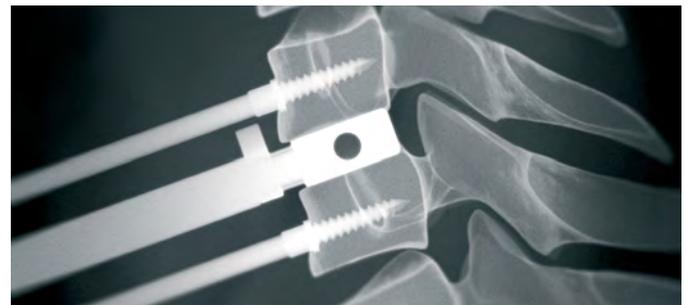
Surgical Instrumentation

The M6-C™ artificial cervical disc surgical instrumentation was designed with surgeon feedback for simple, safe, and reproducible implantation of the disc. Instrumentation includes trials to assess optimal disc size and placement, fin cutters to cut fin tracks for disc insertion, and inserters to easily implant

the single piece M6-C disc into the intervertebral space. The M6-C trials and fin cutters feature the CAP system (Center Alignment Port) that facilitates overall alignment under fluoroscopy in both lateral and AP views to better assess M6-C disc placement



1. Footprint template used to determine endplate coverage



2. Trials to determine the appropriate size and position



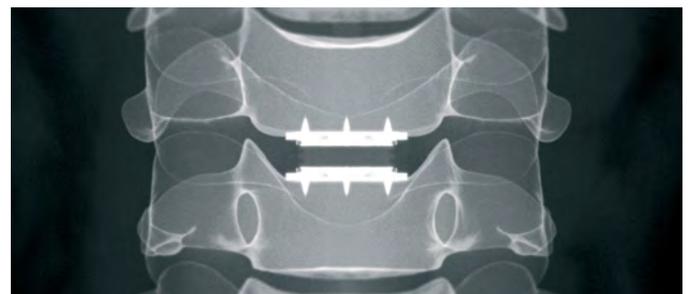
3. Fin cutters to create tracks in the superior and inferior vertebral endplates



4. Implant inserter to place the single piece M6-C disc into the desired position

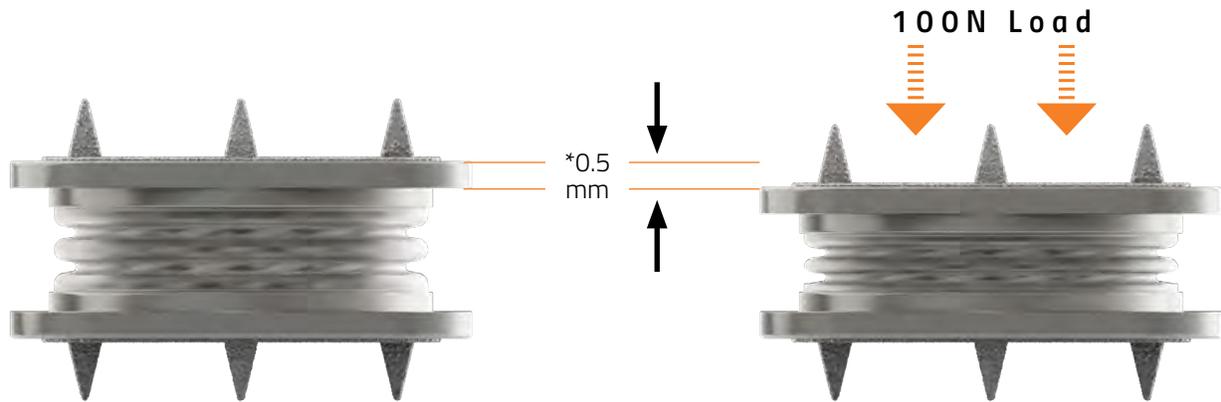


5. Implanted M6-C disc Lateral View



6. Implanted M6-C disc A/P View

The M6-C artificial cervical disc allows for axial compression at the implanted level

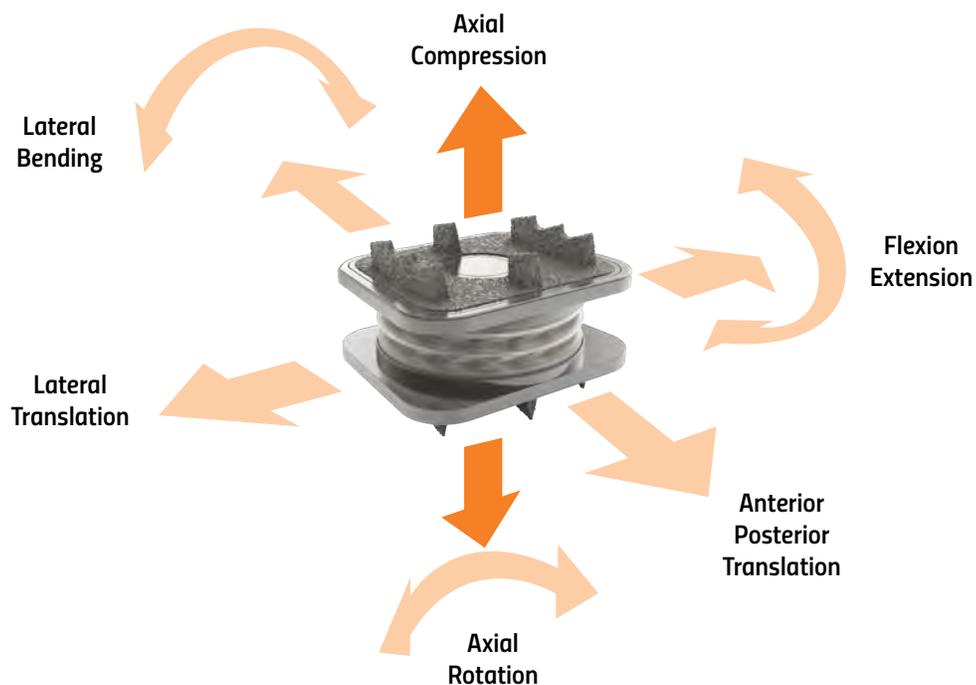


**The M6-C artificial cervical disc compresses approximately 0.5mm under physiologic conditions (i.e. 100N Load, 37 deg C, Hydrated).
Testing on file at Orthofix-Spinal Kinetics (Sunnyvale, CA)*

The M6-C™ artificial cervical disc is the only artificial disc that mimics the anatomic structure of a natural disc by incorporating an artificial viscoelastic nucleus and fiber annulus in its design. Like a natural disc, this unique

construct allows for shock absorption at the implanted level, along with a controlled range of motion in all six degrees of freedom.

The M6-C artificial cervical disc enables motion in all six degrees of freedom



To accommodate the various anatomical ranges, the M6-C artificial cervical disc is available in a variety of heights and endplate footprints



6mm Disc Height

Catalogue #	Descriptor	Footprint [mm]
CDM-625	6M - Medium	15 width x 12.5 depth
CDM-635L	6ML - Medium Long	15 width x 15 depth
CDL-627	6L - Large	17 width x 14 depth
CDL-637L	6LL - Large Long	17 width x 16 depth

7mm Disc Height

Catalogue #	Descriptor	Footprint [mm]
CDM-725	7M - Medium	15 width x 12.5 depth
CDM-735L	7ML - Medium Long	15 width x 15 depth
CDL-727	7L - Large	17 width x 14 depth
CDL-737L	7LL - Large Long	17 width x 16 depth

Please visit Orthofix.com/IFU for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

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