

M6-C™

Artificial Cervical Disc

Adjustable Stop Instrumentation
Sales Brochure

**Patient Focused.
Proven Results.**

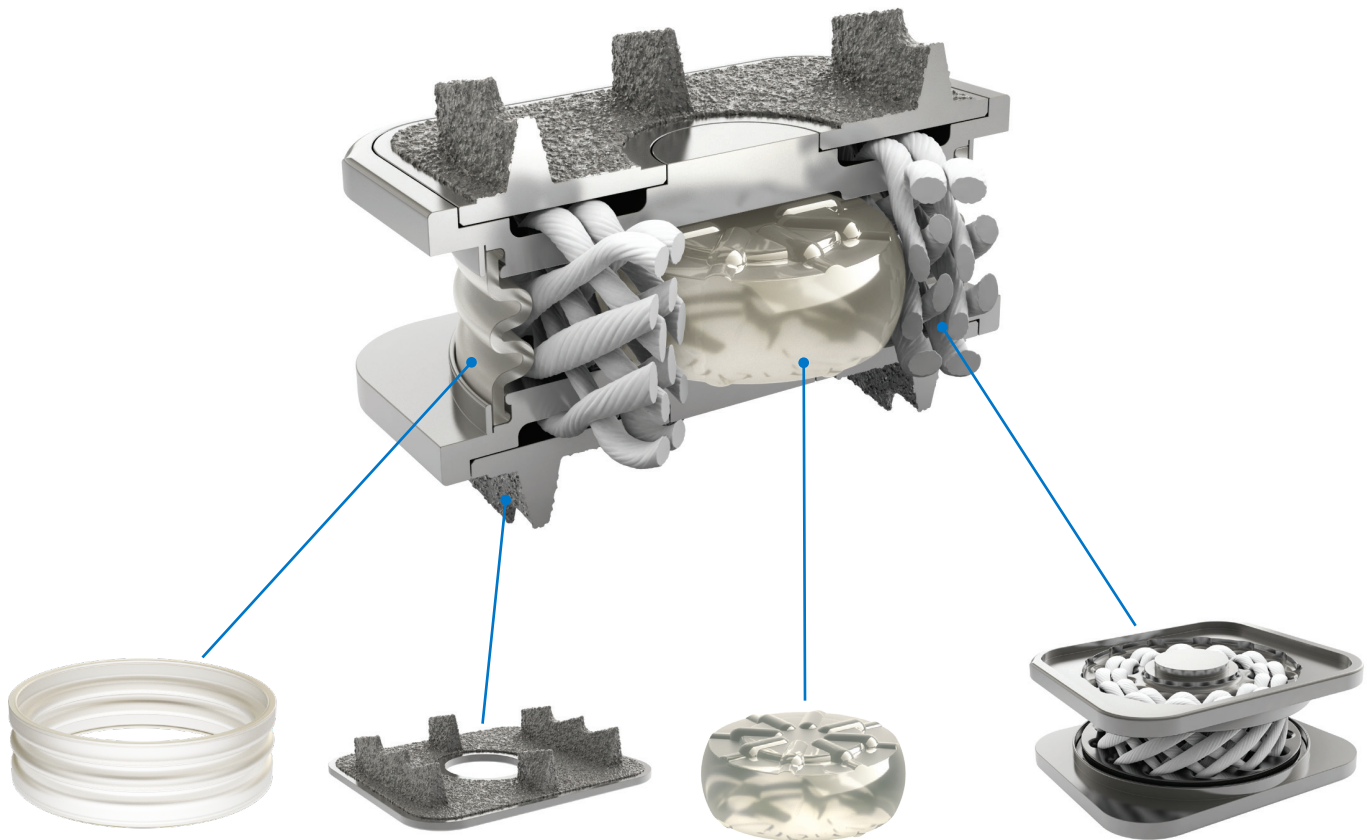
 **ORTHOFIX®**
SPINE

M6-C™

Artificial Cervical Disc

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

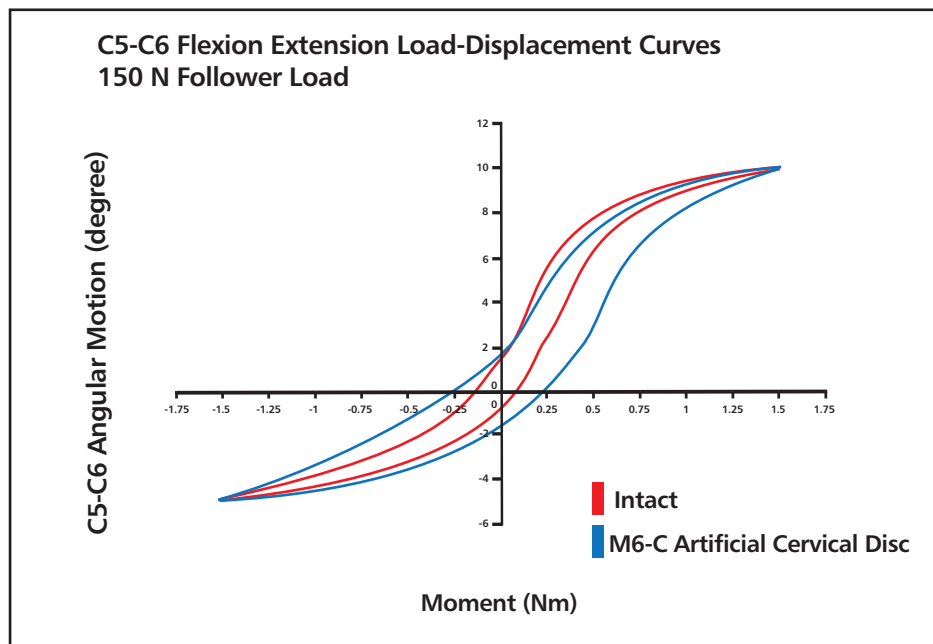
Artificial Annulus

- 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

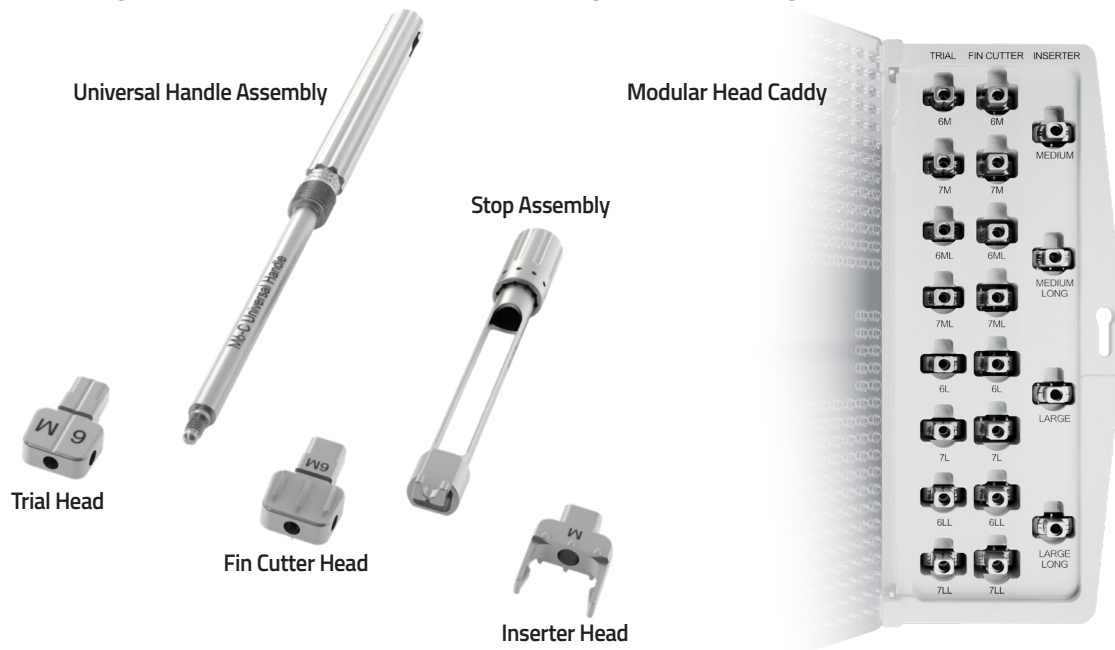


Flexion

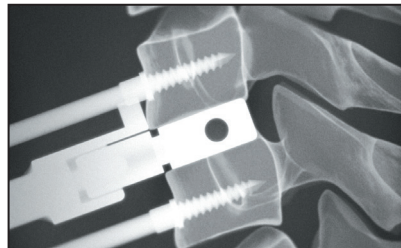
Adjustable Stop Instrumentation

The M6-C Adjustable Stop represents an alternative instrument offering that allows for simple and safe implantation of the M6-C disc. The instrumentation includes detachable threaded trial, fin-cutter, and inserter heads, which allow up to 5mm of depth adjustment. Additional benefits of the instrumentation include:

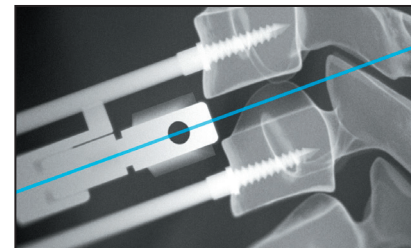
- An improved safety profile as the adjustable stop is intended to reduce the likelihood of risk of excessive posterior placement.
- A potential reduction in fluoroscopy as depth is determined during trialing and maintained throughout the fin-cutting and insertion steps.
- A zero-touch assembly as the heads can be loaded directly from the modular head caddy.
- An intuitive surgical technique that incorporates the same surgical flow as the original M6-C disc instrumentation.



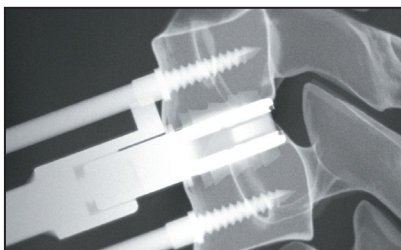
1. Footprint template used to determine endplate coverage



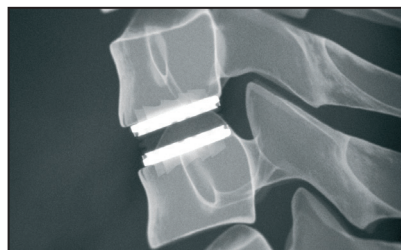
2. Trials to determine the appropriate size and position



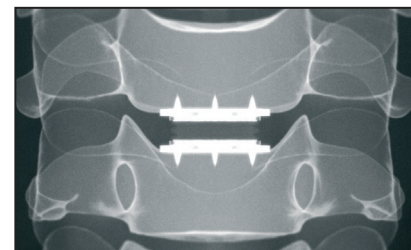
3. Fin cutters to create tracks in the superior and inferior vertebral endplates



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

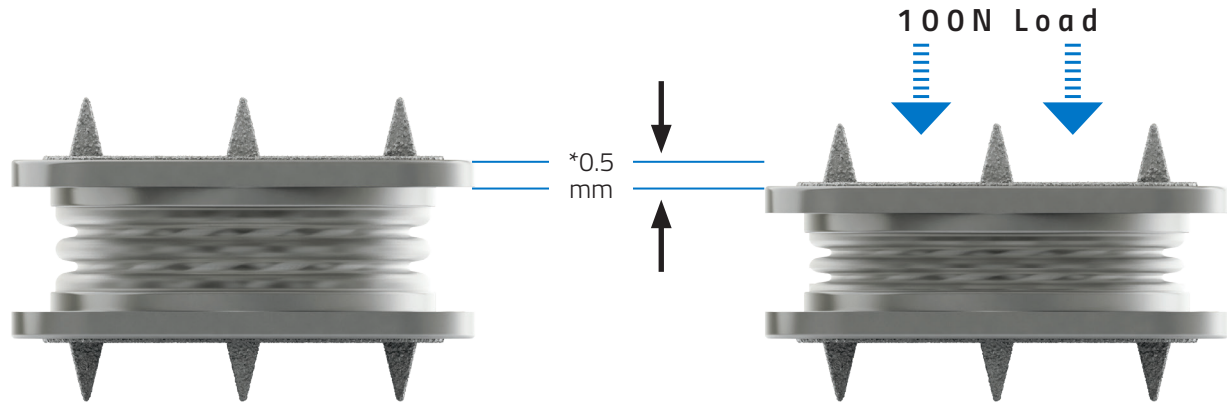


5. Implanted M6-C disc Lateral View



6. Implanted M6-C disc A/P View

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

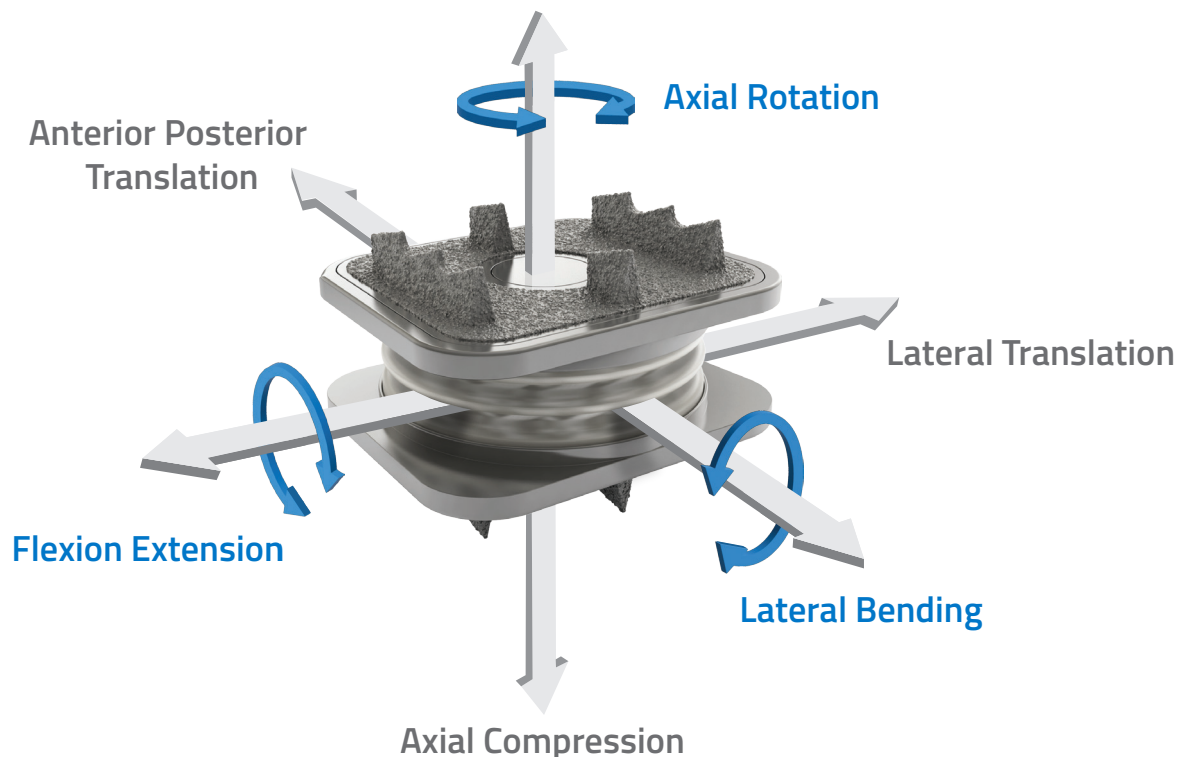


*The M6-C artificial cervical disc compresses approximately 0.5mm under physiologic conditions (i.e. 100N Load, 37 deg C, Hydrated). Testing on file at Orthofix-Spinal Kinetics (Sunnyvale, CA)

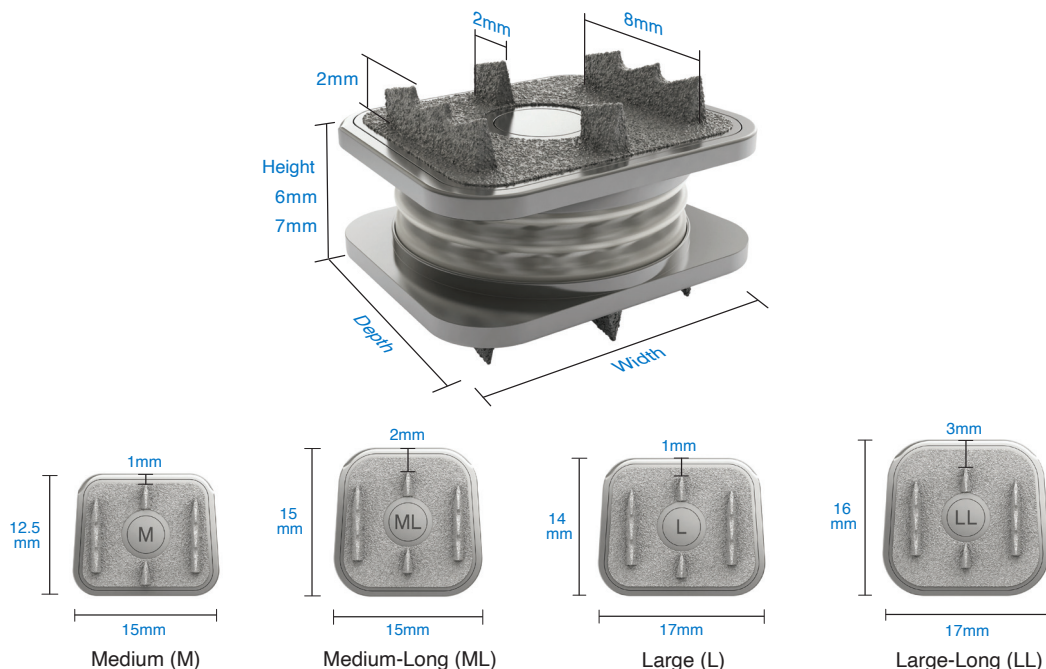
The M6-C artificial cervical disc is the only artificial disc that mimics the anatomic structure of a natural disc by incorporating an artificial viscoelastic nucleus and fiber annulus in its design. Like a natural disc, this unique

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



M6-C* Artificial Cervical Disc Footprints	Width	A/P Length	Distance of Central Fin to Edge of Implant	Heights	Compressed Height*	Endplate Height	Sheath Height	
Medium (M)	15mm	12.5mm	1mm	6 & 7mm	5.5mm & 6.5mm	1mm	3mm	
Medium Long (ML)		15mm	2mm					
Large (L)	17mm	14mm	2mm			2mm		
Large Long (LL)		16mm	3mm					

*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)

Please visit [Orthofix.com/IFU](https://www.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.

Orthofix US LLC
 3451 Plano Parkway
 Lewisville, Texas 75056-9453 U.S.A.
 ☎+1 214-937-3199/+1 888-298-5700
www.orthofix.com

 Spinal Kinetics LLC
 501 Mercury Drive
 Sunnyvale, CA 94085 USA
 ☎+1 408-636-2500
www.orthofix.com
M6info@orthofix.com

Rx Only

Orthofix products or services referenced herein are trademarks or registered trademarks of Orthofix Medical Inc. and its group of companies. All rights reserved.