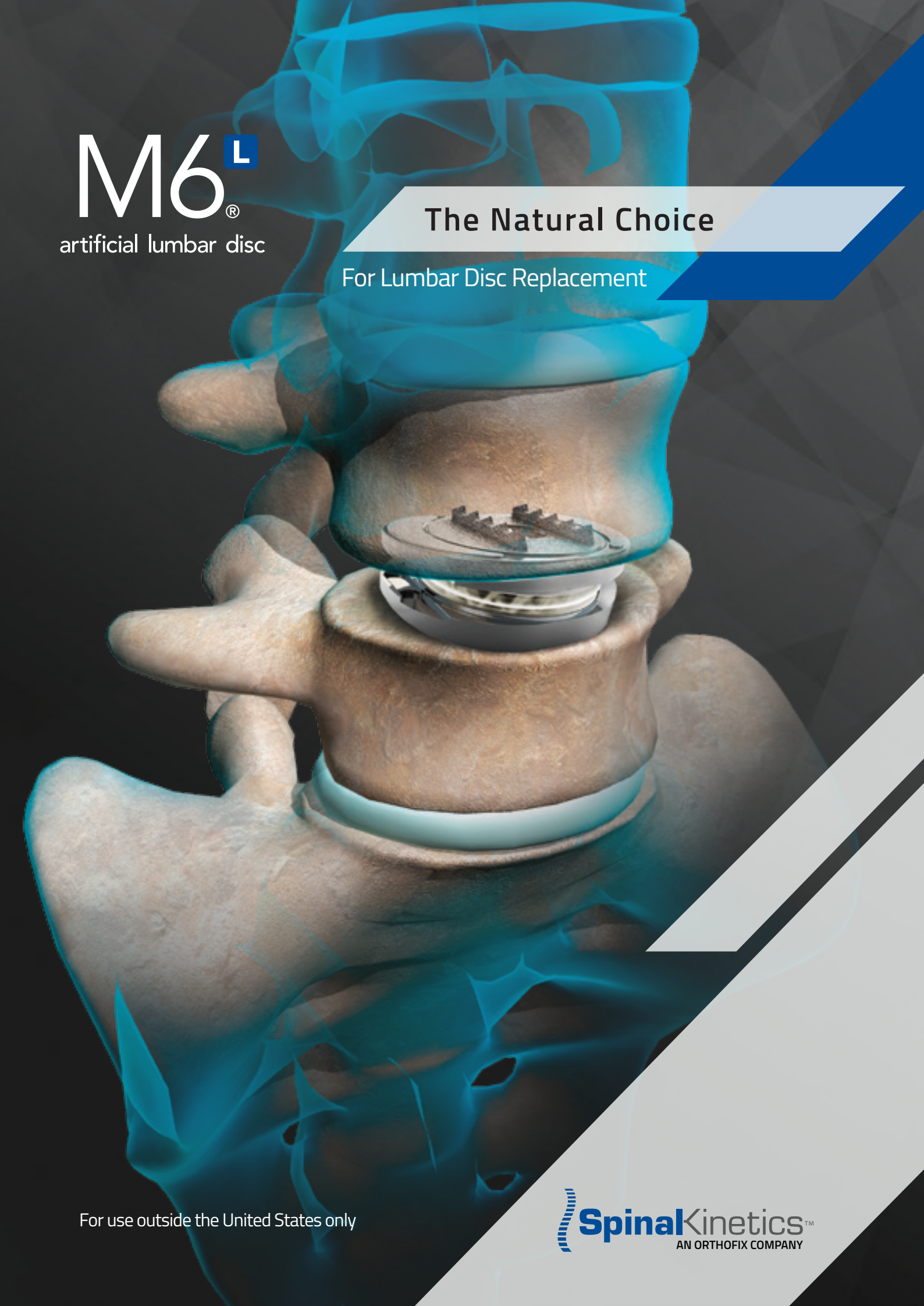
M6-L®

artificial lumbar disc

The Natural Choice

For Lumbar Disc Replacement



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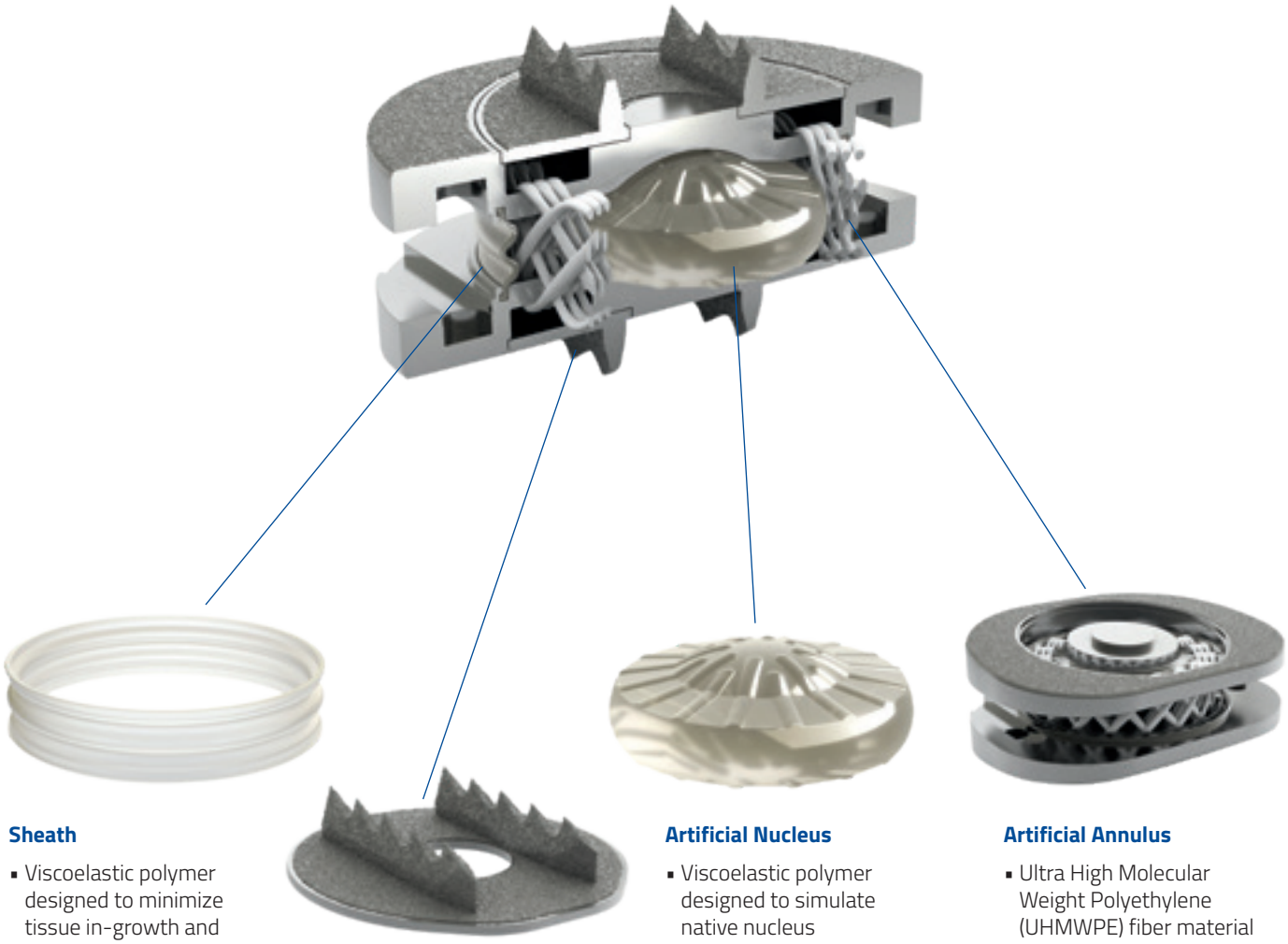
SpinalKinetics™
AN ORTHOFIX COMPANY

The Natural Choice

The M6-L™ artificial lumbar disc is designed to replicate the anatomic structure and biomechanical performance of a natural disc. Its innovative design incorporates an artificial nucleus to allow axial compression and a woven fiber annulus for controlled range of motion in all six degrees of freedom. This physiologic motion is intended to preserve segmental motion and possibly prevent or delay additional adjacent level degeneration.



Sheath

- Viscoelastic polymer designed to minimize tissue in-growth and debris migration
- Flexible design allows for full range of motion

Fixation

- Titanium endplates with low-profile fin design provides for optimal acute and long-term fixation
- Titanium Plasma Spray (TPS) coated endplates provide for osseointegration

Artificial Nucleus

- Viscoelastic polymer designed to simulate native nucleus
- Allows physiologic axial compression
- Retained between endplates by fiber annulus matrix
- Designed to facilitate physiologic Center of Rotation (COR)

Artificial Annulus

- Ultra High Molecular Weight Polyethylene (UHMWPE) fiber material
- Intended to simulate native annulus and its performance characteristics
- Designed to provide controlled motion in all planes & axes of rotation
- Robust fiber matrix with multiple fiber layers similar to native annulus

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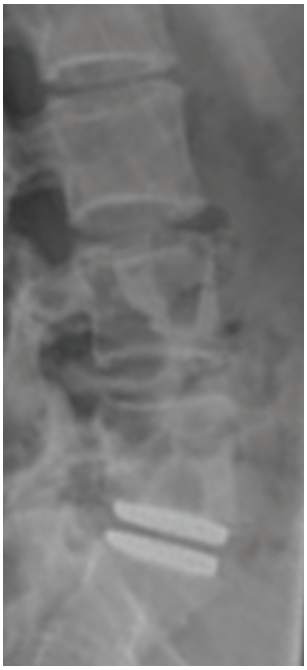
Quality of Motion

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-L™ artificial lumbar disc has demonstrated equivalent Quality of Motion compared to the healthy disc. The innovative artificial fiber annulus and nucleus construct of the M6-L 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.

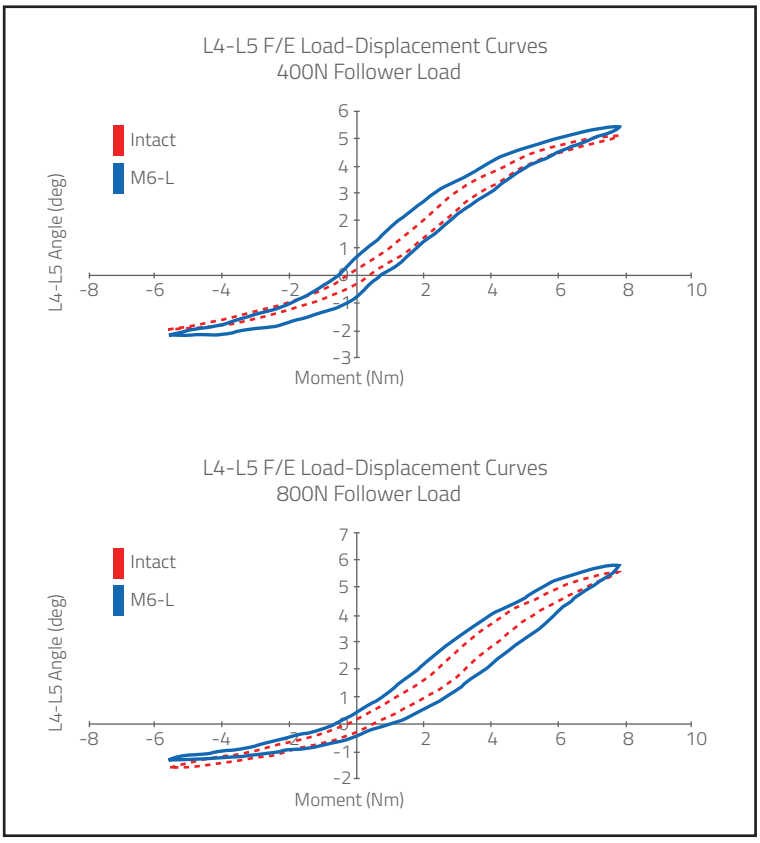
Extension

Neutral



Flexion

AP X-Ray



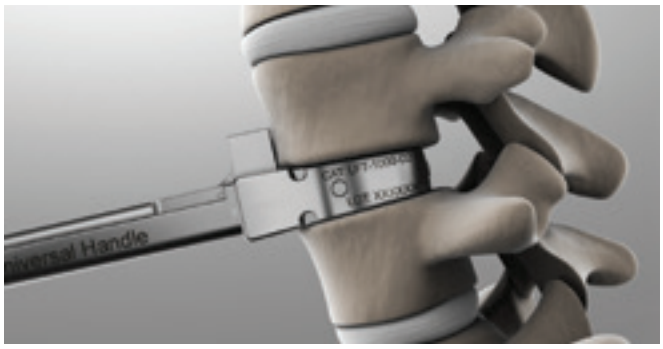
The "kinematic signatures" of the intact disc (red) and M6-L lumbar disc (blue) are nearly identical. The M6-L lumbar disc maintained total ROM, vs. Intact , at 400N [9.4°±2.2° vs. 8.8°±1.1°, p=0.56], and at 800N [9.5°±2.1° vs. 8.4°±1.2°, p=0.32], with excellent Quality of Motion.

Patwardhan et al. Musculoskeletal Biomechanics Laboratory, Edward Hines Jr. VA Hospital, Hines, Illinois, USA

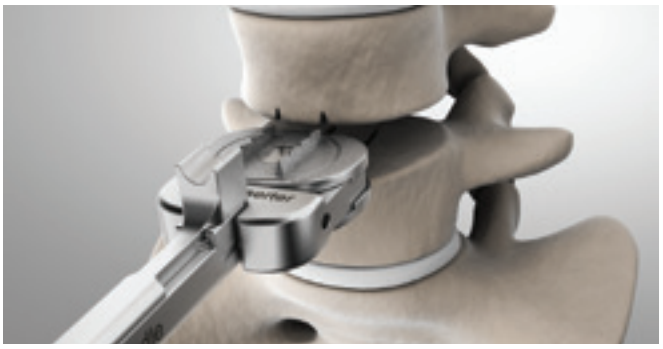
Surgical Instrumentation

The M6-L™ surgical instrumentation system 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 Cutter to cut fin tracks for disc insertion, and an Inserter to easily implant the M6-L into the intervertebral space.

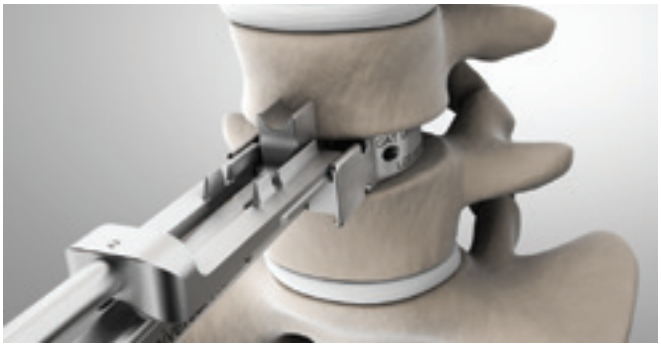
The M6-L instrumentation incorporates the CAP (Center Alignment Port) system that provides optimal alignment under fluoroscopy to the Trial in both A/P and lateral views to better access midline placement



1. Trial Placement



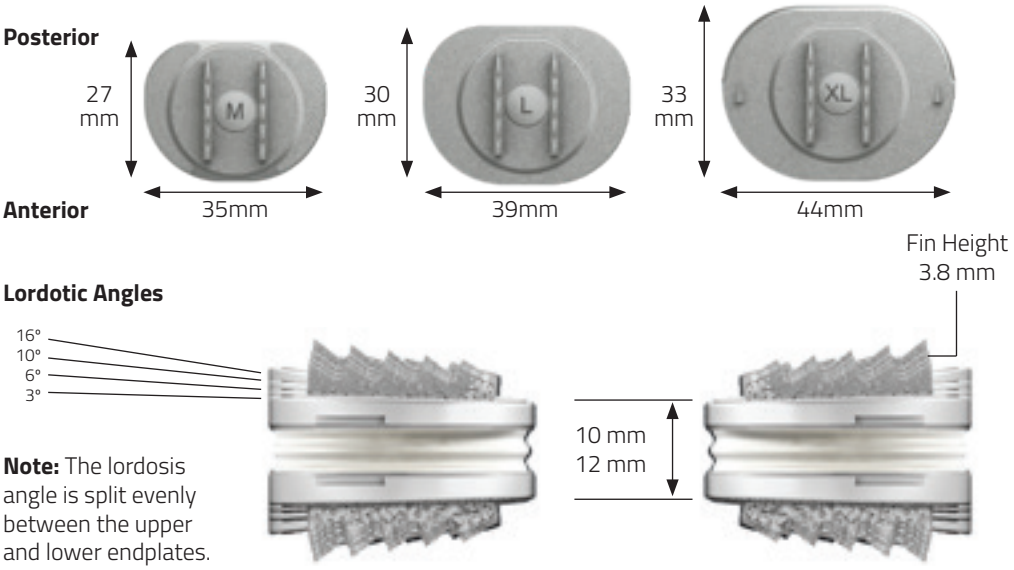
3. Disc Insertion



2. Fin Cutter Insertion

4. Implanted M6-L Lumbar Disc

To accommodate the various anatomical ranges, the M6-L artificial lumbar disc is available in a variety of angles and endplate footprints.



Note: The lordosis angle is split evenly between the upper and lower endplates.

CATALOG NUMBER	FOOTPRINT	ENDPLATE FOOTPRINT (mm)	POSTERIOR HEIGHT (mm)	ANTERIOR HEIGHT (mm)	LORDOSIS
MEDIUM					
LDM-1003	M	35mm W x 27mm D	10.0	11.5	3°
LDM-1006	M	35mm W x 27mm D	10.0	13.0	6°
LDM-1010	M	35mm W x 27mm D	10.0	14.5	10°
LDM-1016	M	35mm W x 27mm D	10.0	17.0	16°
LARGE					
LDL-1003	L	39mm W x 30mm D	10.0	12.0	3°
LDL-1006	L	39mm W x 30mm D	10.0	13.5	6°
LDL-1010	L	39mm W x 30mm D	10.0	15.5	10°
LDL-1016	L	39mm W x 30mm D	10.0	18.0	16°
LDL-1206	L	39mm W x 30mm D	12.0	15.5	6°
LDL-1210	L	39mm W x 30mm D	12.0	17.0	10°
EXTRA LARGE					
LDXL-1006	XL	44mm W x 33mm D	10.0	14.0	6°
LDXL-1010	XL	44mm W x 33mm D	10.0	16.0	10°
LDXL-1016	XL	44mm W x 33mm D	10.0	19.5	16°

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

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