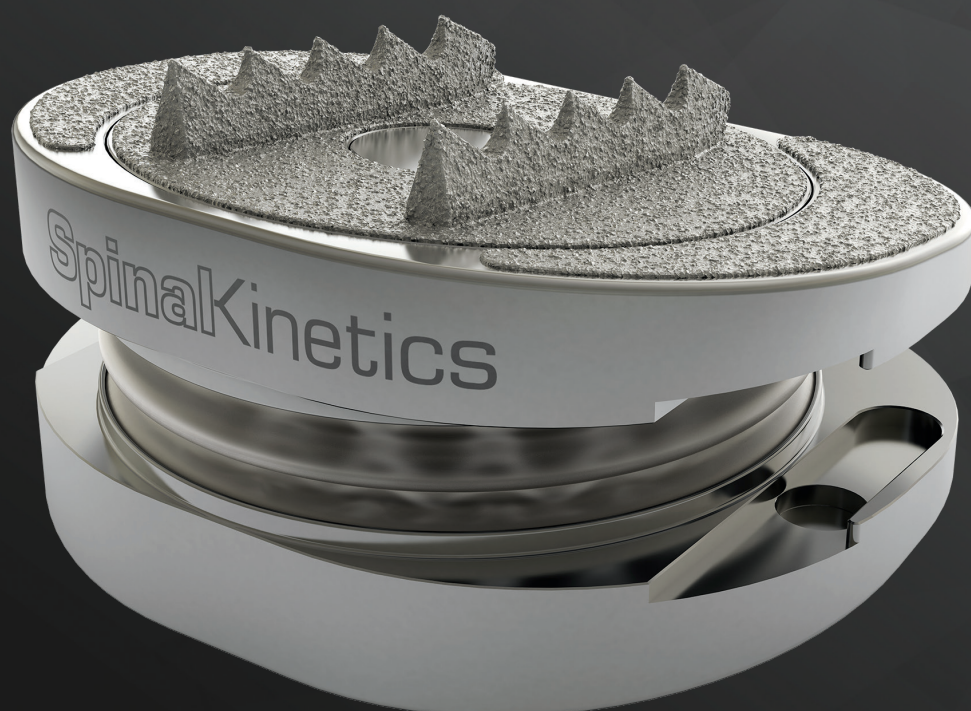


M6^L
artificial lumbar disc

Operative Technique



For use outside the United States only

 **SpinalKinetics**[™]
AN ORTHOFIX COMPANY

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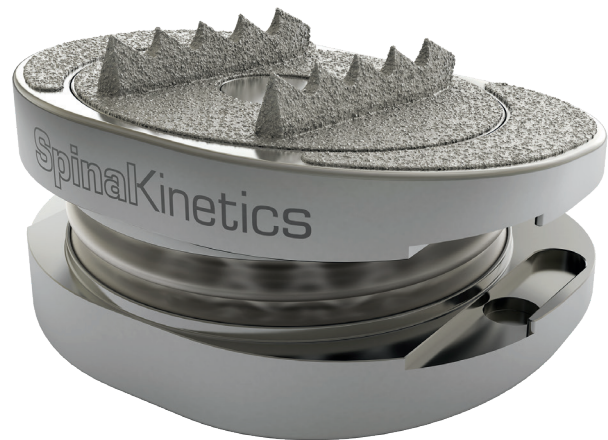
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The M6-L Artificial Lumbar Disc System

The Spinal Kinetics M6-L™ Artificial Lumbar Disc is an intervertebral disc prosthesis designed to maintain motion of a functional spinal unit in the lumbar spine when the native disc is diseased. The M6-L Artificial Disc is designed to maintain the natural behavior of a functional spinal unit by replicating the biomechanical characteristics of the native disc. The core of the disc is composed of a polycarbonate urethane polymer material. It is surrounded by a polyethylene fiber construct. The device is comprised of an assembly of ultra high molecular weight polyethylene (UHMWPE) fibers wound in multiple redundant layers around a polycarbonate urethane polymer (PCU) core and through titanium alloy endplates. Biomechanical studies demonstrate that this unique design provides a progressive resistance to motion, leading to physiologic motion in flexion, extension, lateral bending and axial rotation as well as in compression and shear. The prosthetic disc also has a PCU sheath surrounding the core and fiber construct designed to minimize any tissue ingrowth as well as the migration of wear debris. Serrated fins located on the exterior surfaces of the device provide acute fixation to the superior and inferior vertebral bodies. Both the endplates and fins are coated with porous titanium to increase bone contact surface area and promote osseointegration.

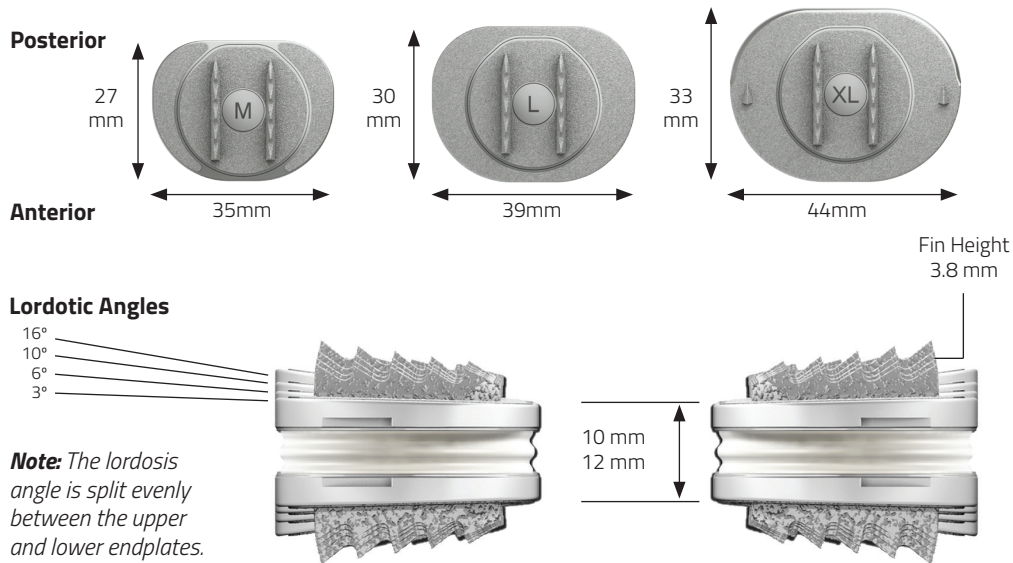
The M6-L artificial lumbar disc system is intended to be used only by surgeons with training particular to the implant system, lumbar spine surgery, and related surgical techniques and biomechanical principles of the spine and spine arthroplasty.

Caution: Read and understand the M6-L artificial lumbar disc system Instructions for Use prior to use.



The M6-L Artificial Lumbar Disc

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



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°

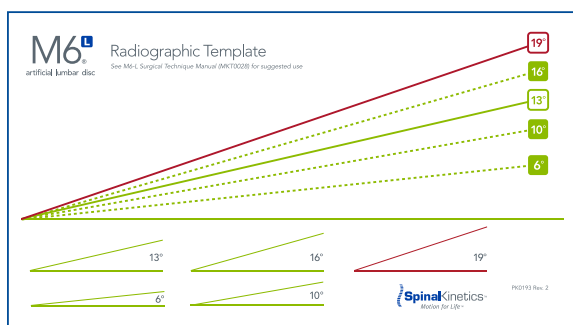
M6-L Lumbar Instruments



PATIENT SELECTION

Note: Refer to the M6-L™ Instructions for Use for a complete description of patient indications.

- Evaluation of the index level disc angle in the standing neutral position is a critical component when selecting a patient for implantation of the M6-L device. Matching the disc lordosis angle to within 3° of the disc space is highly recommended (example: place a 10° disc in a disc space ranging from 7° to 13° at neutral). Implantation outside of a 3° range may result in limiting the range of motion and high shear forces, affecting the stability of the device.
- Use of a radiographic template during the preoperative screening process may aid the surgeon in excluding patients with excessive disc angles for implantation of the M6-L device.



- If a patient with a disc height of < 5mm is selected for implant, it may be difficult to position the device in the optimal posterior position. For patients with a disc height of < 5mm, it is important to achieve adequate posterior mobilization.

PATIENT POSITIONING AND APPROACH

- Place the patient in a supine position. The spine should be in a neutral and straight position with the pedicles and spinous processes aligned.
- Expose the intervertebral disc and the adjacent vertebral bodies through an anterior approach to the lumbar spine.
- Confirm the target disc space with fluoroscopy.

MIDLINE IDENTIFICATION

- Insert the Midline Marker (**Fig. A**) into the shaft of the Midline Marker Handle (**Fig. B**).
- Screw the Midline Marker into the center of the intervertebral disc or vertebral body and detach the Handle from the Marker.
- Confirm that the Marker is in a midline position using A/P fluoroscopy. The Marker may remain as a reference if placed into the vertebral body. If placed into the intervertebral disc, mark the midline of the vertebral bodies above and below the disc space before removal.

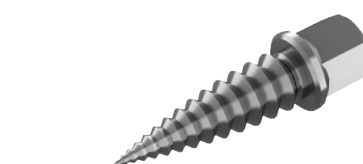


Fig. A



Fig. B

INITIAL DISTRACTION

- The Initial Distractor and Discectomy Blocks with Handle are used to facilitate the discectomy. (**Fig. C, D**)
- Use the Initial Distractor to open the disc space and the Discectomy Blocks to keep the disc space open as needed.
- The Discectomy Blocks are available in 6mm x 8mm, 8mm x 10mm, and 10mm x 12mm heights. The 10mm x 12mm height block is available in 3°, 6°, 10° and 16° to help determine the lordotic angle of the disc space.



Fig. C

DISCECTOMY AND VERTEBRAL ENDPLATE PREPARATION

- Resect the anterior annulus.
- Remove the entire nucleus and cartilaginous endplates. Take care to preserve subchondral bone.
- The lateral annulus should be preserved.
- The posterior annulus, PLL, and posterior osteophytes can be resected as needed.

Note: It is important to preserve the bony endplates.



Fig. D

FOOTPRINT SIZING

- With fluoroscopic guidance and visualization, use the Footprint Template to determine the correct size (medium, large or extra large) M6-L™ Artificial Lumbar Disc footprint (Fig. A).
- Lay the Template on the prepared vertebral endplates.
- Advance the Template until the posterior edge is positioned on the posterior vertebral rim, and determine which size provides maximum endplate coverage (Fig. B).

Note: Take care to ensure that the footprint covers cortical bone.

INTERVETEBRAL DISTRACTION AND POSTERIOR MOBILIZATION

- Distraction and mobilization of the disc space are important factors in achieving optimal outcomes.
- The Lumbar Distractor Handle and Footprint Paddles (Fig. C, D) are used to restore disc space height and mobilize the disc space.
- Choose the Footprint Paddles that correspond to the previously selected Footprint Template and the appropriate lordosis angle (3°, 6°, 10° or 16°).
- Attach the Footprint Paddles to the Distractor Handle so the grooved sides are facing outward.
- With fluoroscopic guidance, insert the Paddles into the disc space until the posterior edges are positioned on the posterior vertebral rim.
- Use the Distractor Spacers (Fig. E) to assist in controlled restoration of the desired height and disc space mobilization. The Spacers and Paddles are provided in heights that combine to match the Trial and implant sizes of 10mm and 12mm.

Note: Distraction and mobilization of the disc space are important factors in achieving optimal outcomes. A 10mm disc needs to have 10mm of posterior distraction, and a 12mm disc needs to have 12mm of posterior distraction.

- Open the Distractor Handle to the point where the Distractor Spacer can be inserted.
- Insert the Distraction Spacer between the Footprint Paddles until the stop is reached (Fig. F). Rotate the Spacer handle 90° in either direction to distract to the chosen height.
- Repeat the above step on the opposite side to achieve equal bilateral mobilization.

Note: It is important to place the Footprint Paddles all the way to the posterior disc space so that they rest on cortical bone to facilitate a complete release and mobilization.

Caution: Take care not to over-distract the disc space.



Fig. A

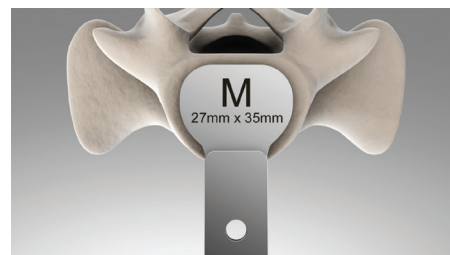


Fig. B



Fig. C

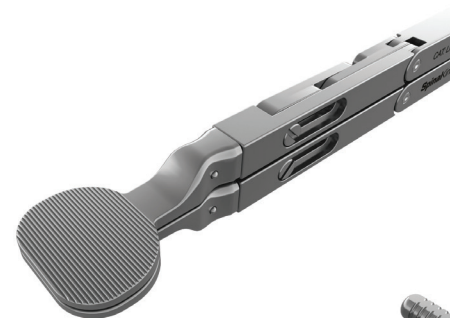


Fig. D



Fig. E

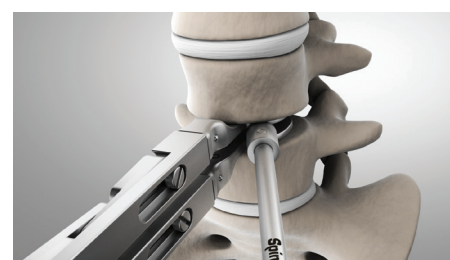


Fig. F

TRIAL ASSESSMENT: DISC SIZING

- Based on the amount of distraction achieved, select the appropriate (medium/large/extra large 3°/6°/10°/16°) 10mm or 12mm Trial.
- Attach the Trial Head to the Instrument Handle by rotating the End Cap of the handle clockwise (**Fig. A**).
- Rotate the Stop Adjuster Knob counterclockwise until the Stop is flush with the Trial Head (**Fig. A**).
- Align the midline of the Trial to the previously marked midline of the vertebral bodies. Orient the Stop either caudal or cephalad.
- Carefully insert the Trial into the disc space under close fluoroscopic guidance.
- Use the Center Alignment Port (CAP) to aid in aligning the C-arm on plane to the disc space so that the Trial is properly viewed for correct placement and positioning. Once the C-arm is on plane, the CAP will become a complete circle (**Fig. B, C**).

Note: The CAP is an aid to alignment of the C-arm to the disc space for best viewing of the Trial position. Alignment of the C-arm to the CAP will not validate correct Trial position. Verify the correct position of the Trial as described in the following steps before cutting fin tracks.

- Continue advancing the Trial using fluoroscopic guidance until the posterior edge of the Trial reaches the posterior vertebral rim. Incrementally adjust the position of the Stop as needed by rotating the Stop Adjuster Knob clockwise to allow more posterior placement of the Trial (**Fig. D, E**). Verify that the anterior edge of the Trial is on the anterior vertebral rim.

Note: Inability to reach the posterior vertebral rim may indicate that sufficient posterior height and/or mobilization has not been achieved. A smaller size posterior height Trial and/or additional distraction and mobilization may be indicated.

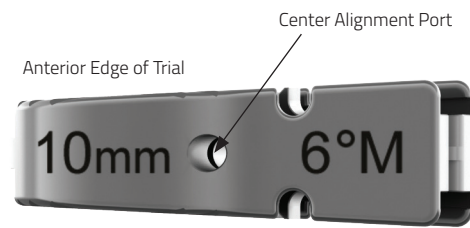


Fig. B - Misaligned C-arm

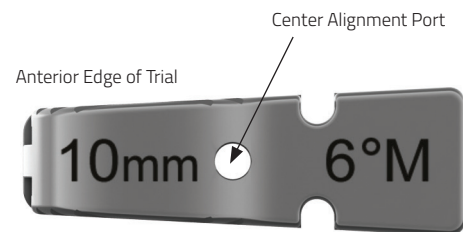


Fig. C - Properly aligned C-arm

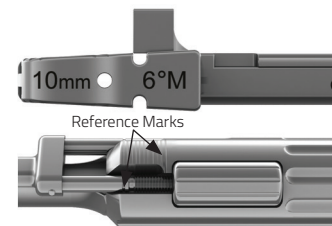


Fig. D - Stop Most Posterior

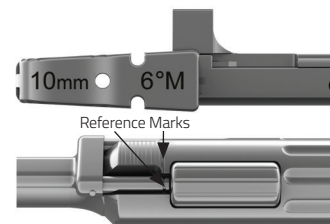


Fig. E - Stop Most Anterior

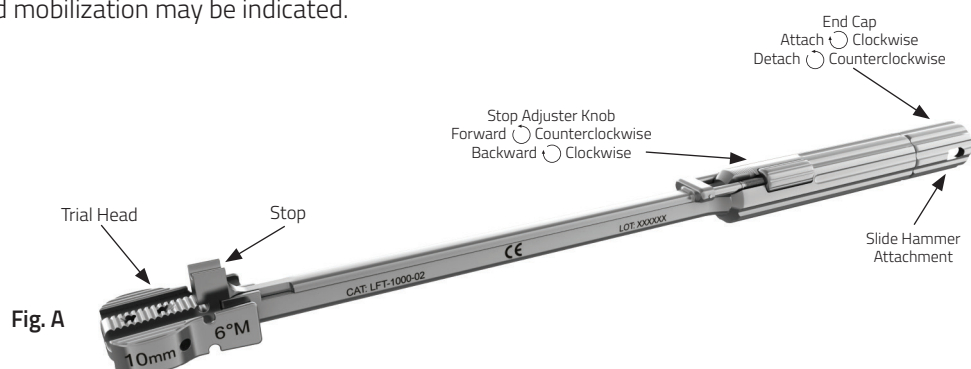


Fig. A

- Firmly seat the Stop against the anterior vertebral body.
- With the Trial in place, observe the treatment level disc height, disc angle, facet joints, and spinous process. Compare to adjacent levels, and ensure that overdistracted has not occurred.

Note: The goal of proper device angle selection is to achieve as close to parallel inner endplates as possible. The selected M6-L™ disc angle should be within 3° of the index level disc angle. If this is not achieved, limited range of motion in extension and high shear forces may occur.

- Confirm that the Trial provides maximum endplate coverage

USE OF THE TRIAL GUIDE

The Trial Guide may be used to facilitate insertion and extraction of the Trial.

- Attach the appropriate Trial Guide Tips (3°, 6°, 10°, 16°) (**Fig. A**) to the Distractor Handle.
- Align the midline mark of the Trial Guide to the midline mark on the vertebral bodies.
- Insert the Trial Guide into the disc space.
- Distract the disc space to facilitate placement of the Trial.
- Slide the Trial down the forks of the Trial Guide Tips.
- Remove the Trial Guide from the disc space (**Fig. B, C**).

Caution: Take care not to over distract the disc space.

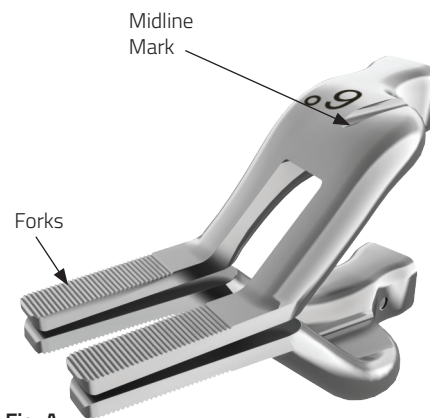


Fig. A



Fig. B



Fig. C

TRIAL ASSESSMENT: MIDLINE VERIFICATION

- Remove the Universal Handle from the Trial by rotating the End Cap at the end of the handle counterclockwise.
- Place the C-arm into A/P position. The Center Alignment Port (CAP) allows quick angular alignment of the C-arm to the plane of the disc space (**Fig. A, B**).
- Once the C-arm is aligned to the spine and disc space, use fluoroscopy to visualize the Trial and confirm that it is in the midline.
- Make any necessary adjustments to the Trial.

REALIGN C-ARM TO LATERAL VIEW

- Return the C-arm to the lateral position and re-align to the lateral CAP. Use this C-arm position for the M6-L insertion.
- Re-attach the Universal Handle to the Trial.
- Confirm that the Stop makes contact with the anterior vertebral body.

Important: To prevent unwanted posterior movement during the Fin Cutting steps, the Stop must be firmly seated against the anterior vertebral body.

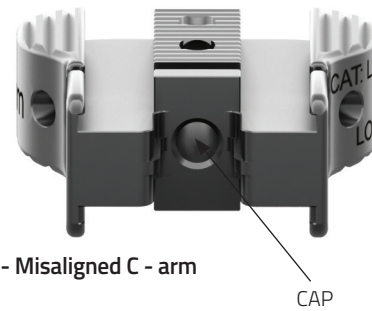


Fig. A - Misaligned C - arm

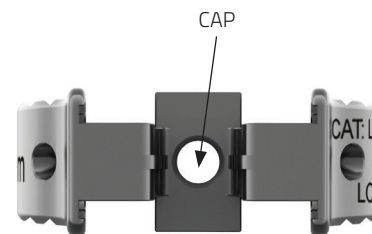


Fig. B - Properly aligned C - arm

FIN TRACK CUTTING

- Ensure that the Trial is at the desired position in all planes.

Note: The 16° Trial Heads require use of the 16° Fin Cutter exclusively. The 16° Fin Cutters are designed to minimize the size of surgical incision needed, and are not compatible with 3°, 6° and 10° Trial Heads. Mechanical keying prevents improper mating of Fin Cutters and Trial Heads.

- Align the first Fin Cutter with the guiding slots in the Trial (**Fig. A**).

Note: The angle of the Fin Cutter handles relative to the Universal Handle will be the same as half of the chosen lordosis angle. This angle should be maintained as the Fin Cutters are guided into the Trial.

Note: Prior to advancing the Fin Cutter, confirm that the Fin Cutters are engaged correctly into the Trial guiding slots.

- Using fluoroscopic guidance, carefully advance the Fin Cutter into the Trial until it reaches the limit of travel. Verify with lateral fluoroscopy.
- Align the second Fin Cutter to the other side of the Trial.
- Using fluoroscopic guidance, carefully advance the second Fin Cutter into the Trial until it reaches the limit of travel. Verify with lateral fluoroscopy (**Fig. B**).
- Connect the Slide Hammer to the Slide Hammer Attachment to remove the Fin Cutters one at a time.
- Remove the Trial from the disc space. The Trial Guide may be used to assist in removal.
- Irrigate and suction to remove debris.

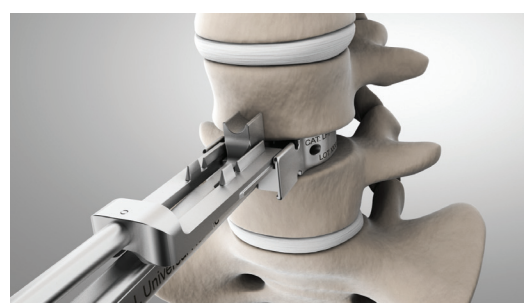
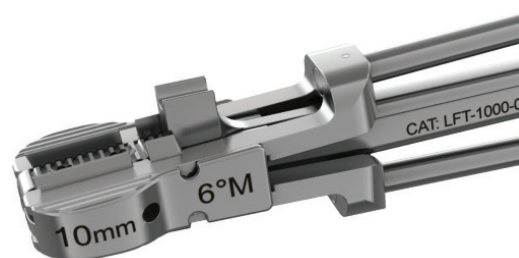


Fig. A

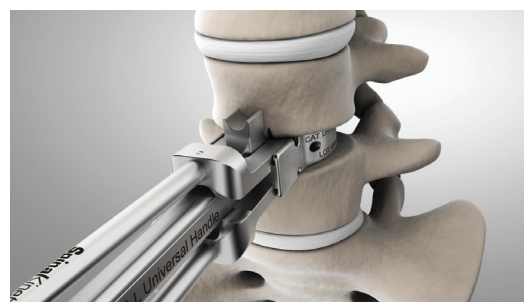
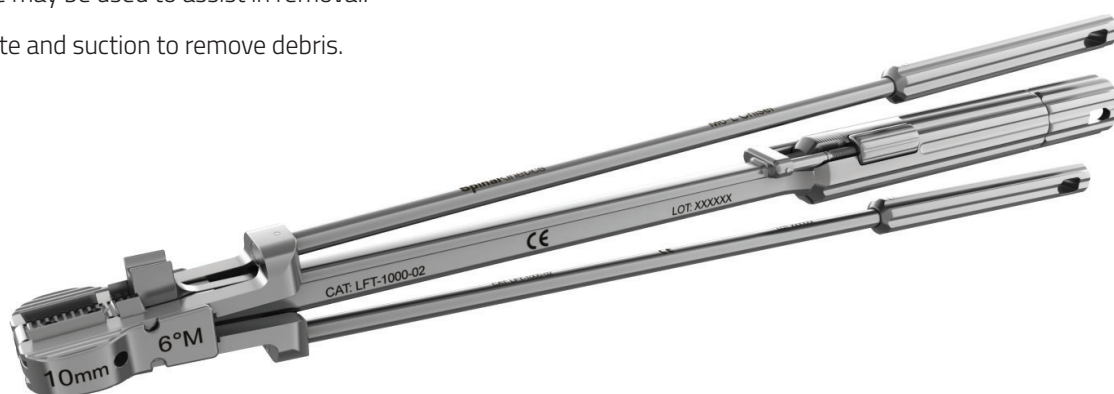
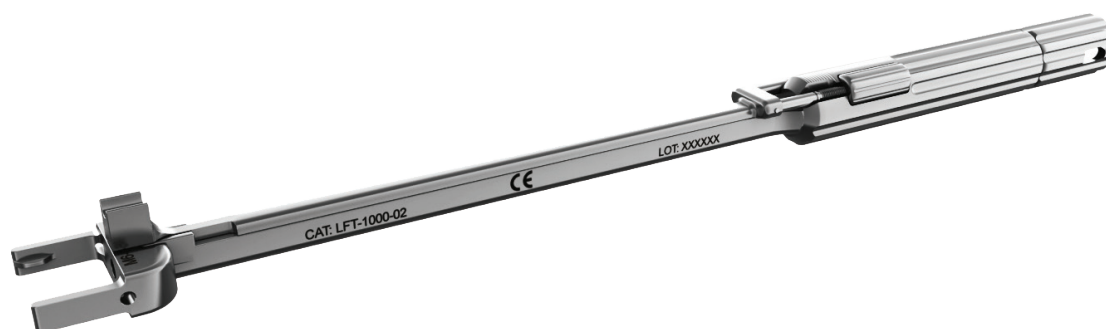
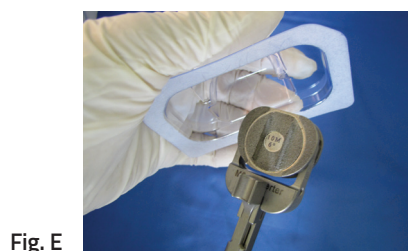
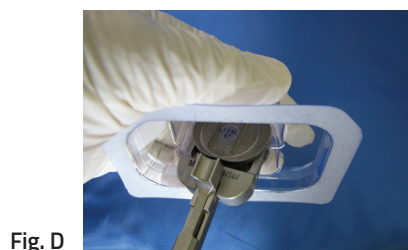
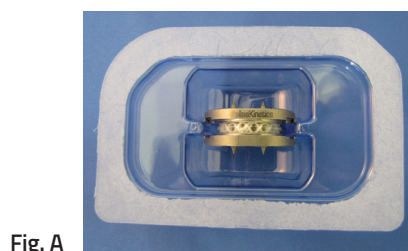


Fig. B



LOADING THE INSERTER

- Use the same Universal Handle for the Inserter steps as was used for the Trial.
- Take care not to move or adjust the Stop on the Universal Handle as the Trial is removed and the Inserter attached. Refer to the reference marks on the Universal Handle for the final Stop position. Verify the position of the Stop before insertion of the disc.
- Select the appropriate M6-L™ Disc to load onto the Inserter.
- Open the M6-L packaging tray to expose the disc (**Fig. A**).
- While holding the packaging tray, slide the Inserter forks onto the slots of the disc (**Fig. B, C**).
- Hold the packaging tray, and move the Inserter to a vertical position.
- Rotate the Inserter either to the right or left until the disc is removed from the packaging tray (**Fig. D, E**).



INSERTING THE M6-L DISC

- Orient the Stop in the same caudal or cephalad direction as the Trial (**Fig. A**).
- Align the fins of the M6-L™ to the fin tracks cut by the fins. Orient the Inserter Head with Handle to the trajectory of the disc space as viewed on lateral plane fluoroscopy.
- Using fluoroscopic guidance, carefully tap the M6-L into the disc space, keeping the fins aligned to the cut fin tracks (**Fig. B**).
- Continue carefully advancing the M6-L while observing the progress via serial lateral plane fluoroscopy until the final desired posterior position has been reached.
- Verify that the M6-L is at the desired posterior position before removing the Inserter. Use a gentle left-to-right motion to remove the Inserter.
- Once the Inserter is removed, make a final assessment of positioning via lateral and A/P fluoroscopy.
- The Tamp may be used to make minor adjustments to the endplate position.
- Closing: Use standard practices to close the wound.

Note: The M6-L cannot be placed more posteriorly than the final posterior position obtained by the Fin Cutter.

Caution: The M6-L cannot be repositioned anteriorly. Take care not to place the M6-L Disc beyond the desired posterior position.

M6-L MULTIPLE LEVEL TECHNIQUE

- Perform multisegmental operations one segment at a time.
- Always start with the segment that is most severely collapsed when performing multiple level surgery.

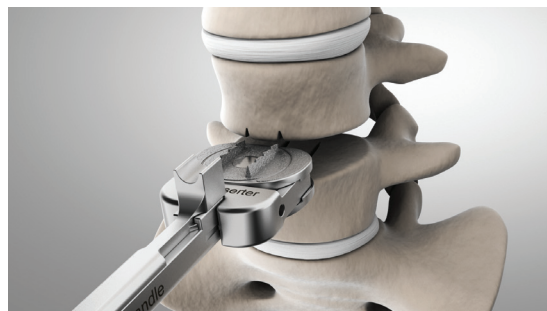


Fig. A

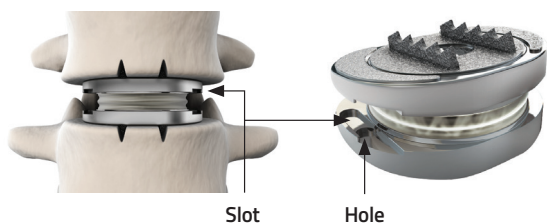


Fig. B

M6-L LUMBAR DISC EXPLANTATION

If the M6-L™ Artificial Lumbar Disc needs to be removed, use the following steps. After removal of the Implant, clinical judgment will dictate the proper method for stabilizing the disc space.

The M6-L Disc Removal Tool can aid the surgeon in situations where the implant has been placed in a sub-optimal position and needs to be removed from the intervertebral space. This instrument is designed and intended to fully remove the implant, and not to reposition the implant. The Removal Tool is designed to couple with the endplates in a “normal” alignment. An implant with translated endplates will not couple with the Removal Tool. In this case the Tamp may be used to align the endplates.



- Slide the center section of the Removal Tool backwards (towards the operator) (Fig. A).

Fig. A



- Pinch the two arms together (Fig. B).

Fig. B



- Insert the arms into the slots of the disc, then release the arms. When the pins are engaged into the holes of the disc, the arms will be flush with the slots (Fig. C).

Fig. C



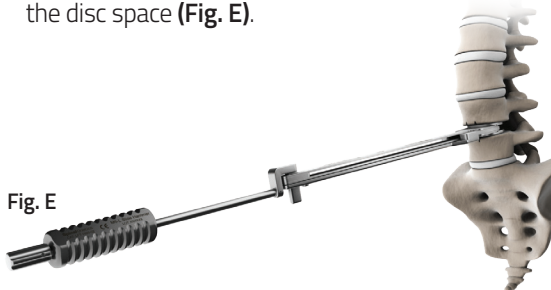
- Slide the center section forwards until the holes at the proximal end of the Removal Tool are aligned (Fig. D).

Fig. D



- Use the Slide Hammer to remove the disc from the disc space (Fig. E).

Fig. E



If the M6-L Disc Removal Tool cannot be used, use the following steps.

- Cut through the outer sheath and artificial annulus of the M6-L Disc to expose the polymer nucleus.
- Apply intervertebral distraction to relieve compressive forces on the M6-L.
- Use rongeurs or forceps to remove the polymer nucleus.
- Carefully detach the titanium endplates from the vertebral endplates using elevators or other suitable instruments.
- Irrigate and suction to remove debris.

Please visit [Orthofix.com/IFU](https://www.orthofix.com/IFU) for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

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