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PathLoc-LC®

SURGICAL TECHNIQUE

LATERAL LUMBAR INTERBODY FUSION CAGE SYSTEM

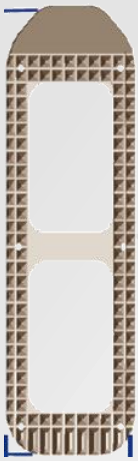
Minimally invasive fusion technique

LEARNING & KNOWLEDGE BIOMED
L&K BIOMED

PathLoc is a registered trademark

Contents

Features & Benefits

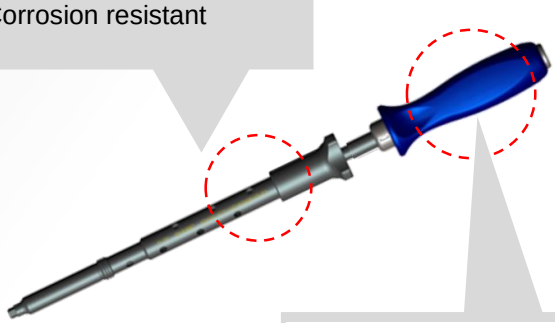


Cage design

- Variety of sizes to match the patient's anatomy.
- Pyramidal teeth to avoid cage migration once positioned between the vertebral body end plates
- Wide bone graft space
- 6 tantalum markers to guide positioning

AlTiN coated instruments

- Reduces light reflection by 70%
- Wear resistant
- Corrosion resistant

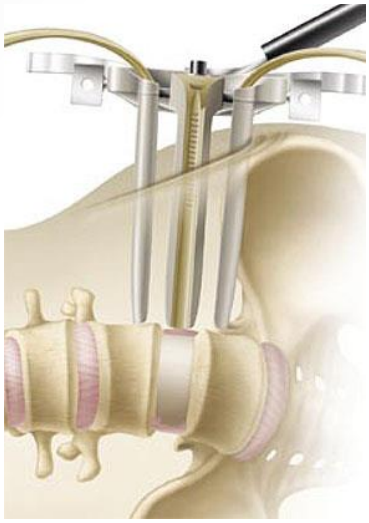


Silicon handle

- Improves grip
- Designed to offer both precision and performance
- Ergonomically superior

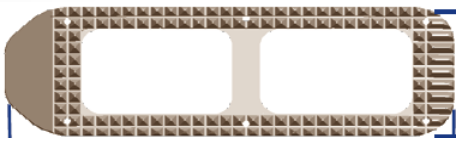
Retractor design

- 3 self-retaining blades
- Independent retraction & tilt of blades
- Top & bottom loading – switch blades on-the-spot without starting over
- Radiolucent material
- Illuminated access
- Anchoring arm attachment



MIS
Surgical Technique

Rectangular with one end bullet shaped.



Width = 18 mm

Angle 0°
Height mm: 8, 10, 12, 14, 16
Length: 40, 45, 50, 55, 60

Angle 6°
Height mm: 10, 12, 14, 16
Length: 45, 50, 55, 60

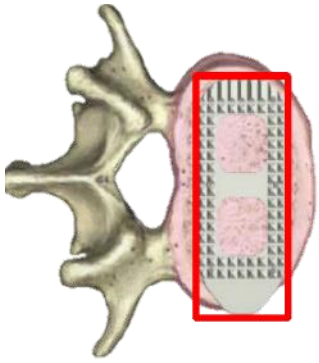
Angle 12°
Height mm: 12, 14, 16
Length: 45, 50, 55, 60

Width = 22 mm

Angle 0°
-

Angle 6°
Height mm: 10, 12, 14, 16
Length mm: 45, 50, 55, 60

Angle 12°
Height mm: 12, 14, 16
Length: 45, 50, 55, 60



Final placement

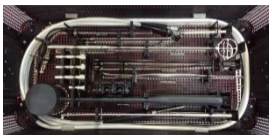
Set configuration

PathLoc-LC® set configuration

Retractor set

Set 1

Upper tray



Lower tray

Set 2

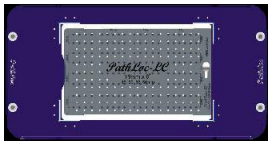
Upper tray

Lower tray

Implant set

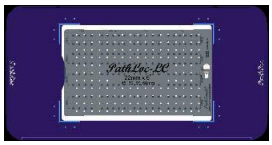
18 mm width implants

Upper tray
0° and 6° angle implants

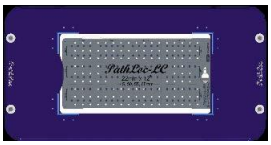


Lower tray
12° angle implants

22 mm width implants



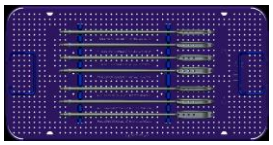
Upper tray
6° angle implants



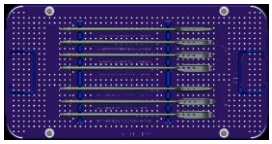
Lower tray
12° angle implants

Trials set

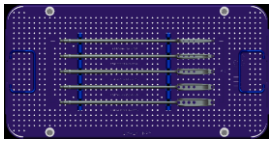
Basic trials



Upper tray

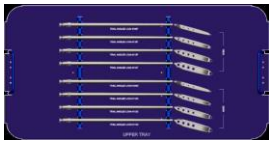


Middle tray

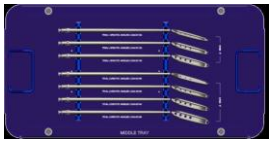


Lower tray

Angled trials



Upper tray

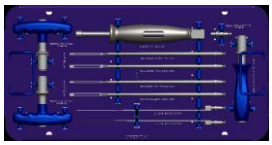


Lower tray

PathLoc-LC® set configuration

Disc preparatory set

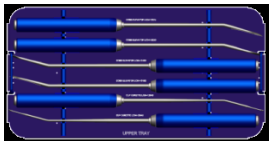
Basic set



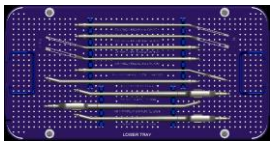
Upper tray

Lower tray

Angled set



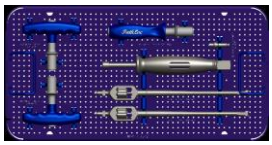
Upper tray



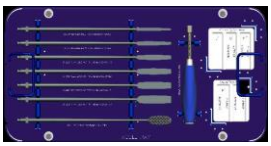
Lower tray

Cage instrument set

Basic set



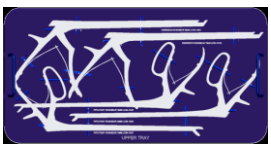
Upper tray



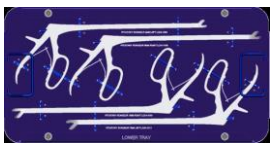
Middle tray

Lower tray

Rounger set



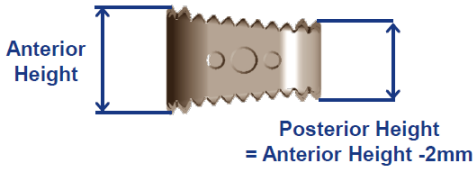
Upper tray

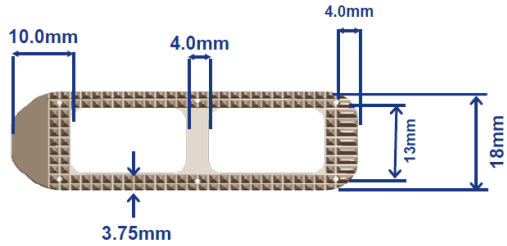


Lower tray

Ordering information

Cages





Lateral View (Lordotic)

Cat No.	Width	Length (depth) mm	Angle °	Height mm	Remarks
3810-4008	18	40	0	8	Optional
3810-4010	18	40	0	10	
3810-4012	18	40	0	12	
3810-4508	18	45	0	8	
3810-4510	18	45	0	10	Included
3810-4512	18	45	0	12	
3810-5008	18	50	0	8	Optional
3810-5010	18	50	0	10	Included
3810-5012	18	50	0	12	
3810-5014	18	50	0	14	
3810-5016	18	50	0	16	
3810-5508	18	55	0	8	Optional
3810-5510	18	55	0	10	Included
3810-5512	18	55	0	12	
3810-5514	18	55	0	14	
3810-5516	18	55	0	16	
3810-6010	18	60	0	10	
3810-6012	18	60	0	12	
3810-6014	18	60	0	14	
3810-6016	18	60	0	16	
3810-6514	18	65	0	14	
3810-6516	18	65	0	16	
3816-5010	18	50	6	10	
3816-5012	18	50	6	12	
3816-5014	18	50	6	14	
3816-5016	18	50	6	16	
3816-5510	18	55	6	10	
3816-5512	18	55	6	12	
3816-5514	18	55	6	14	
3816-5516	18	55	6	16	
3816-6010	18	60	6	10	
3816-6012	18	60	6	12	
3816-6014	18	60	6	14	
3816-6016	18	60	6	16	
3816-6510	18	65	6	10	
3816-6512	18	65	6	12	
3816-6514	18	65	6	14	
3816-6516	18	65	6	16	
3832-5012	18	50	12	12	
3832-5014	18	50	12	14	
3832-5016	18	50	12	16	
3832-5512	18	55	12	12	

Axial View

Cat No.	Width	Length (depth) mm	Angle °	Height mm	Remarks
3832-5514	18	55	12	14	Included
3832-5516	18	55	12	16	
3832-6012	18	60	12	12	
3832-6014	18	60	12	14	
3832-6016	18	60	12	16	
3850-4508	22	45	0	8	Optional
3850-4510	22	45	0	10	Included
3850-4512	22	45	0	12	
3850-5008	22	50	0	8	Optional
3850-5010	22	50	0	10	Included
3850-5012	22	50	0	12	
3850-5014	22	50	0	14	
3850-5016	22	50	0	16	
3850-5508	22	55	0	8	Optional
3850-5510	22	55	0	10	Included
3850-5512	22	55	0	12	
3850-5514	22	55	0	14	
3850-5516	22	55	0	16	
3850-6010	22	60	0	10	
3850-6012	22	60	0	12	
3850-6014	22	60	0	14	
3850-6016	22	60	0	16	
3856-5010	22	50	6	10	
3856-5012	22	50	6	12	
3856-5014	22	50	6	14	
3856-5016	22	50	6	16	
3856-5510	22	55	6	10	
3856-5512	22	55	6	12	
3856-5514	22	55	6	14	
3856-5516	22	55	6	16	
3856-6010	22	60	6	10	
3856-6012	22	60	6	12	
3856-6014	22	60	6	14	
3856-6016	22	60	6	16	
3862-5012	22	50	12	12	
3862-5014	22	50	12	14	
3862-5016	22	50	12	16	
3862-5512	22	55	12	12	
3862-5514	22	55	12	14	
3862-5516	22	55	12	16	
3862-6012	22	60	12	12	
3862-6014	22	60	12	14	
3862-6016	22	60	12	16	

Optional products have been included

Instrument Set

Trials set

Basic trials 0°

Cat. No.	Description
LC04-0108B	Trial 0°18 (W) X8 (H) mm
LC04-0110B	Trial 0°18 (W) X10 (H) mm
LC04-0112B	Trial 0°18 (W) X12 (H) mm
LC04-0114B	Trial 0°18 (W) X14 (H) mm
LC04-0116B	Trial 0°18 (W) X16 (H) mm

Basic trials 6°

Cat. No.	Description
LC04-0210C	Trial 6°18 (W) X10 (H) mm
LC04-0212C	Trial 6°18 (W) X12 (H) mm
LC04-0214C	Trial 6°18 (W) X14 (H) mm
LC04-0216C	Trial 6°18 (W) X16 (H) mm
LC04-0210D	Trial 6°22 (W) X10 (H) mm
LC04-0212D	Trial 6°22 (W) X12 (H) mm
LC04-0214D	Trial 6°22 (W) X14 (H) mm
LC04-0216D	Trial 6°22 (W) X16 (H) mm

Basic trials 12°

Cat. No.	Description
LC04-0212E	Trial 12°18 (W) X12 (H) mm
LC04-0214E	Trial 12°18 (W) X14 (H) mm
LC04-0216E	Trial 12°18 (W) X16 (H) mm
LC04-0212F	Trial 12°22 (W) X12 (H) mm
LC04-0214F	Trial 12°22 (W) X14 (H) mm
LC04-0216F	Trial 12°22 (W) X16 (H) mm

Angled trials 6°

Cat. No.	Description
LC04-0210G	Angled Trial 6°18 (W) X10 (H) mm
LC04-0212G	Angled Trial 6°18 (W) X12 (H) mm
LC04-0214G	Angled Trial 6°18 (W) X14 (H) mm
LC04-0216G	Angled Trial 6°18 (W) X16 (H) mm
LC04-0210H	Angled Trial 6°22 (W) X10 (H) mm
LC04-0212H	Angled Trial 6°22 (W) X12 (H) mm
LC04-0214H	Angled Trial 6°22 (W) X14 (H) mm
LC04-0216H	Angled Trial 6°22 (W) X16 (H) mm

Angled trials 12°

Cat. No.	Description
LC04-0212I	Angled Trial 12°18 (W) X12 (H) mm
LC04-0214I	Angled Trial 12°18 (W) X14 (H) mm
LC04-0216I	Angled Trial 12°18 (W) X16 (H) mm
LC04-0212J	Angled Trial 12°22 (W) X12 (H) mm
LC04-0214J	Angled Trial 12°22 (W) X14 (H) mm
LC04-0216J	Angled Trial 12°22 (W) X16 (H) mm

Basic disc preparatory set

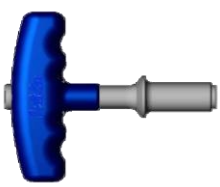
Cat. No.	Description
LC04-0318	Cobb Elevator Straight 18mm
LC04-1322	Cobb Elevator Straight 22mm

LC04-1207: Osteotome

LC04-1207S: Box Curette

Cat. No.	Description
LC04-1204S	Cup Curette 4mm
LC04-1206S	Cup Curette 6mm

Cat. No.	Description
LC04-0601	Box Chisel 4 (H) X 18 (W) mm Straight
LC04-0602	Box Chisel 6 (H) X 18 (W) mm Straight
LC04-0604	Box Chisel 4 (H) X 22 (W) mm Straight
LC04-0605	Box Chisel 6 (H) X 22 (W) mm Straight

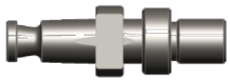


LC04-0400: Modular T-Handle(Hudson Type)

LC04-0400I: Modular I-handle (Hudson type)

Instrument Set

Basic disc preparatory set



LC04-0906: Sliding RAM Adaptor

LC04-1001: Sliding RAM

LC04-0300: Lateral Slide

Angled disc preparatory set

Cat. No.	Description
LC04-1318D	Cobb Elevator Angled Down 18mm
LC04-1322D	Cobb Elevator Angled Down 22mm

Cat. No.	Description
LC04-1318U	Cobb Elevator Angled Up 18mm
LC04-1322U	Cobb Elevator Angled Up 22mm

LC04-1204D: Cup Curette Angled Down 4mm

LC04-1204U: Cup Curette Angled Up 4mm

Cat. No.	Description
LC04-0601	Box Chisel 4 (H) X 18 (W) mm Angled
LC04-0602	Box Chisel 6 (H) X 18 (W) mm Angled
LC04-0604	BoxChisel 4 (H) X 22 (W) mm Angled
LC04-0605	BoxChisel 6 (H) X 22 (W) mm Angled

Cat. No.	Description
LC04-0505	Cage Holder(Wire Type) 18mm
LC04-0505A	Cage Holder(Wire Type) 22mm

LC04-0503B: Implant Extractor(Wire Type)

LC04-0106H: Trial with Rasp Angled 18 (W) X6 (H) mm

LC04-0800A: Impactor Angled

Instrument Set

Basic cage instrument set

Cat. No.	Description
LC04-0502B	Cage Holder 18mm
LC04-0502C	Cage Holder 22mm

Cat. No.	Description
LC04-0306A	Blunt Reamer 6mm
LC04-0308A	BluntReamer 8mm
LC04-0310A	BluntReamer 10mm
LC04-0312A	Blunt Reamer 12mm
LC04-0314A	Blunt Reamer 14mm
LC04-0316A	Blunt Reamer16mm

Cat. No.	Description
LC04-0306B	SharpReamer Ring Type 6mm
LC04-0308B	SharpReamer Ring Type 8mm
LC04-0310B	SharpReamer Ring Type 10mm
LC04-0312B	SharpReamer Ring Type 12mm
LC04-0314B	SharpReamer Ring Type 14mm
LC04-0316B	SharpReamer Ring Type 16mm

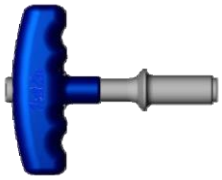
LC04-0906: Sliding RAM Adaptor

LC04-1001: Sliding RAM

LC04-0106D: Trial with Rasp W18X6mm

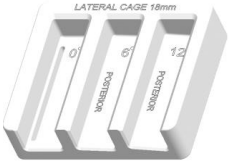
LC04-0800: Impactor

LC04-0503A: Implant Extractor

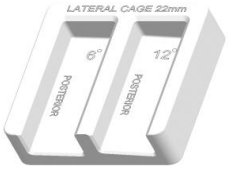


LC04-0400: Modular T-Handle(Hudson Type)

LC04-0400I: Modular I-handle (Hudson type)



LC04-0903: Bone Graft Holder 18mm



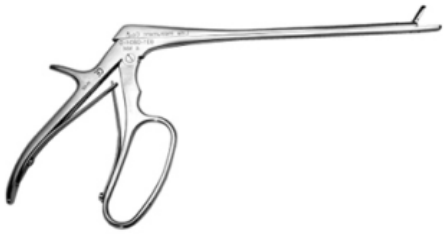
LC04-0904: Bone Graft Holder 22mm

LC04-0803: Graft Impactor

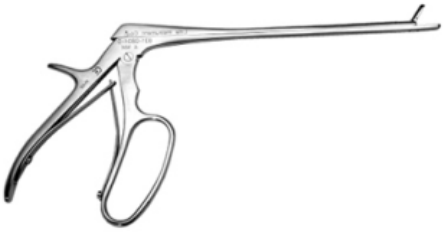
Instrument Set

Rounger set

Cat. No.	Description
LC04-1004	Kerrison Rongeur 5mm
LC04-1012	Kerrison Rongeur 7mm



Cat. No.	Description
LC04-1005	Pituitary Rongeur(Ferris Smith) 3mm
LC04-1006	Pituitary Rongeur(Ferris Smith) 5mm



Cat. No.	Description
LC04-1008	Pituitary Rongeur5mm Right
LC04-1009	Pituitary Rongeur5mm Left
LC04-1010	Pituitary Rongeur7mmRight
LC04-1011	Pituitary Rongeur7mm Left

Surgical Technique

Instrument guide

PREOPERATIVE PLANNING

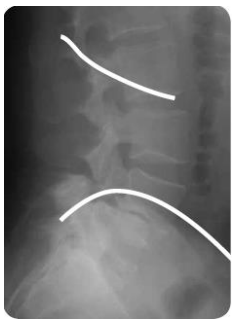


Figure 1: Lateral radiograph

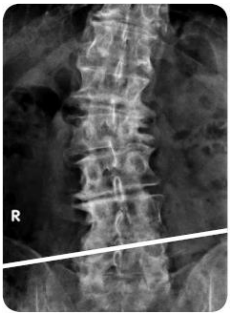


Figure 2: AP radiograph

Preoperative planning

Preoperative planning can be useful in determining:

- Location of the iliac crest and lower ribs in relation to disc space of interest (Figure 1)
- Position of the anterior vasculature and posterior nerve structures via axial MRI
- Curvature of the spine (Figure 2)

Although infrequent, a few patients may have a deep-seated L4 – L5 disc space that could be difficult to reach via a direct lateral approach, even if table breaking options are employed. Obtaining standing anterior-posterior x-ray images with the patient bending laterally can help determine whether or not a level can be accessed above the iliac crest.

Standard lateral surgical positioning is right lateral decubitus, or left side up, however the surgeon should consider ease of access and surgeon preference in determining which side to approach. Correction can be achieved equally from either the convex or concave side of the curve. However, approaching from the concave side allows the skin incision to be minimized in some cases.

PATIENT POSITIONING

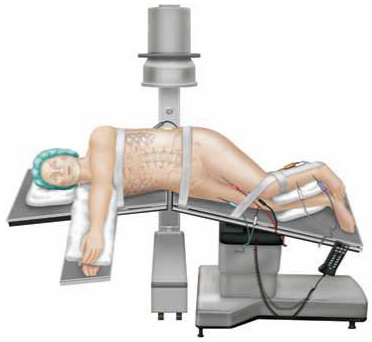


Figure 3:

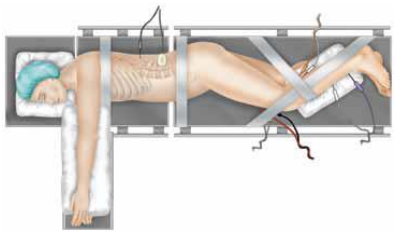


Figure 4

Patient positioning

The patient is placed in the lateral decubitus position and should be positioned so that the top of the iliac crest is in line with the break of the radiolucent surgical table. An axillary roll is placed to protect the neurovascular structures in the axilla. Padding is placed between the arms to ensure they remain suspended in the neutral position. The top leg of the patient should be flexed in order to relax the psoas muscle and prevent spreading of the nerves across the psoas. Padding is also placed beneath and in between the legs from the knees distally (Figure 3).

The patient is secured to the surgical table with tape at four locations (Figure 4):
1. Just beneath the iliac crest
2. Over the thoracic region, just beneath the shoulder
3. From the back of the table, over the ankle, and past the knee to the front of the table
4. From the shin to the back of the table

Starting in a reverse trendelenburg position, the head of the table is dropped and a slight flexion is applied to the surgical table. This technique allows for better access to the lumbar spine by increasing the distance between the iliac crest and lower rib as well as by opening up the disc to be entered.

Instrument guide

PATIENT PREPARATION

Figure 5

Neuromonitoring
After the patient is asleep, needle recording electrodes are placed in the innervated muscles in the legs to monitor the affected nerve roots during the procedure.

RETRACTOR ARM ASSEMBLY

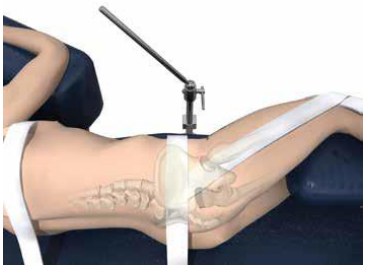


Figure 6

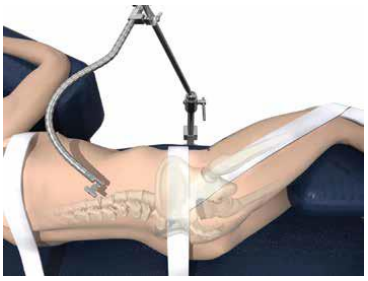


Figure 7

Arm assembly
The Arm Post mounts to the hospital bed rail. Check the compatibility of the Arm Post to the hospital bed prior to surgery.

Mount the Arm Post to the bed rail on the opposite side of the surgeon near the patient's hip. Make sure to place the Arm Post out of the way of the anticipated direction of fluoroscopy. (Figure 7)

Turn the Arm Post locking mechanism clockwise to secure it to the bed.

Once the Arm Post is secure, attach the articulating Arm, to the Arm Post and lock into place. The arm should be positioned to lie across the patient and wrapped in front of the surgeon. (Figure 8)

Next, set up the light source device and keep it ready for use.

Instrument guide

INCISION PLANNING

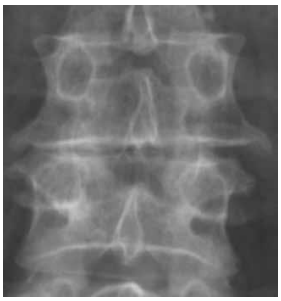


Figure 8

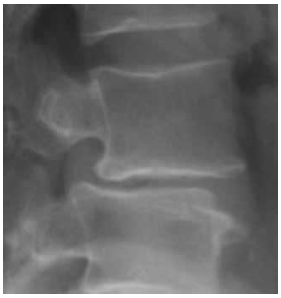


Figure 9

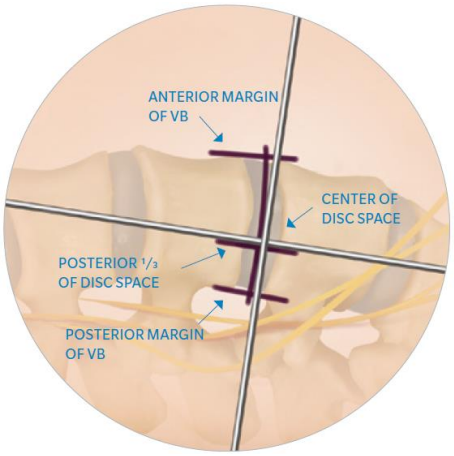


Figure 10

Incision planning
A true AP image should be obtained to ensure the patient is positioned in a true lateral position. On the AP x-ray, clear, distinct pedicles that are equidistant from the spinous process should be visible. (Figure 8). Then a lateral x-ray is obtained and clean, distinct end plates should be seen (Figure 9).

True A/P orientation of the surgical level has been achieved when the spinous process is centered directly between the pedicles, the pedicles appear round and the endplates are distinguished as a solid line on the A/P radiograph/fluoro.

True lateral and A/P images may require adjusting the bed position separately for each level. True lateral orientation is noted by observing a sharp view of the endplates at the operative level and when the neural foramina align perfectly on the lateral radiograph/fluoro.

Incision point
Identify the level to be fused by laying two crossed K-wires on the skin above the proposed surgical site.

Confirm the position using fluoroscopy.

The incision point for a single level should be centered over the disc of the level to be fused.

For two levels, the incision point should be centered over the vertebral body, separating the two discs to be resected.

Mark the incision point by marking the angle of the disc space, the anterior margin, posterior margin and midpoint to the posterior third of the disc space (Figure 10).

It may be possible to access multiple levels through one vertical skin incision, depending on the anatomy and curvature of the spine. Although a single incision may be used to reach multiple levels, the surgeon must perform separate dilations through the psoas for each operative disc space.

Instrument guide

ACCESS

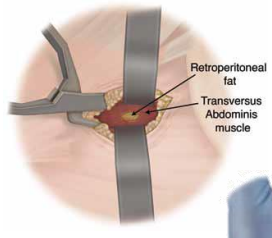


Figure 11

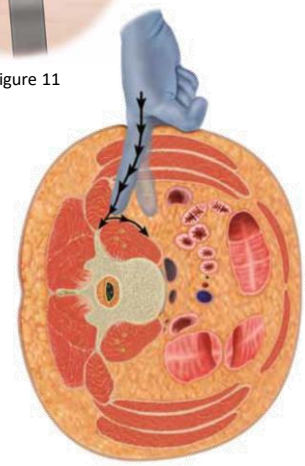


Figure 12

Dissection to the psoas

After making a single skin incision, the subcutaneous fat layers are dissected until the abdominal musculature is reached. A monopolar cautery may be used for hemostasis and a small self-retaining retractor can be used for initial dissection of the skin and subcutaneous layer.

The external oblique fascia will be the first plane encountered and is the only layer that will need to be sharply incised. A Kelly Clamp is then used to bluntly spread through the fibers of the external oblique, internal oblique and transversalis muscles. All dissection is done in line with the muscle fibers as these muscles layers run in opposite directions. After bluntly penetrating the transversalis fascia, the yellow retroperitoneal fat is exposed (Figure 11).

Once inside the retroperitoneal space, the index finger is used to follow the internal abdominal wall posteriorly down to the psoas muscle, which can be visualized. Use of the finger to sweep the peritoneal contents as well as the retroperitoneal fat anteriorly will allow a clear path down to the psoas muscle (Figure 12).

Palpating the quadratus muscle, followed by the tip of the transverse process and finally the psoas muscle will verify that the correct retroperitoneal plane is being entered and ensures that the peritoneum is not compromised.

DILATION

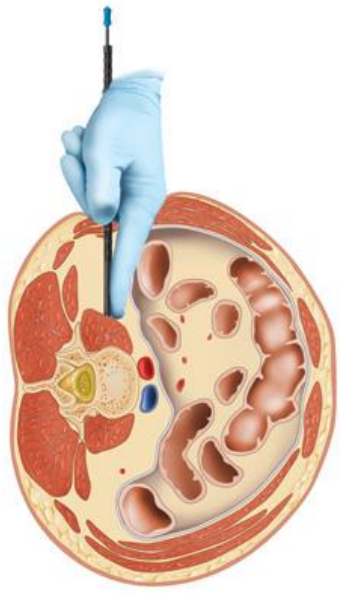


Figure 13

Initial dilator insertion

Insert the neuromonitoring probe into the dilator.

While holding the index finger on the surface of the psoas muscle with the palm of the hand facing posteriorly, carefully guide the initial dilator down the palm of the hand and into the retroperitoneal space until the tip of the dilator is at the lateral margin of the psoas muscle (Figure 13).

Verify the position of the dilator using lateral fluoroscopy.

Note:
The dilator can be held in place with the initial dilator holder while using lateral fluoroscopy. The cranial/caudal position of the dilator should be the center of the disc space. The A/P position of the dilator should be between the posterior third and center of the disc space.

Instrument guide

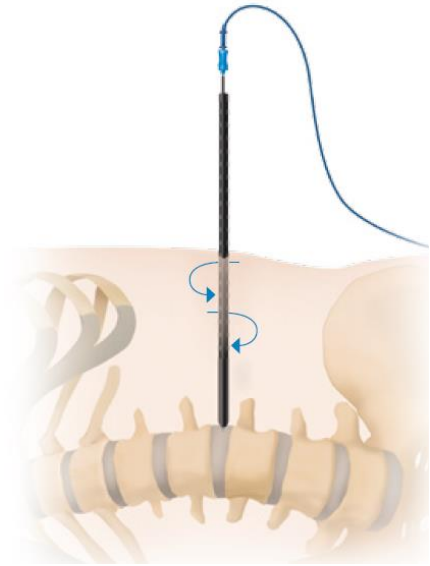


Figure 14

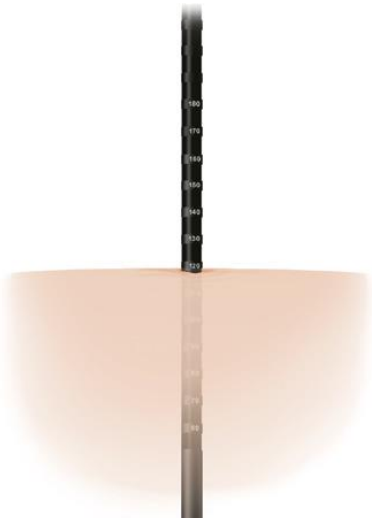


Figure 15

Advance the dilator

Carefully advance the dilator through the psoas muscle using a rotating motion to ensure the dilator is all the way down to the disc, and to ensure there are no muscle fibers underneath the dilator.

Use the initial dilator holder to maintain the position of the dilator; confirm the dilator is still in an acceptable position using lateral fluoroscopy.

Initiate the EMG stimulation, this will help determine if the initial dilator is in a safe position relative to the nerves.

Retractor blade length

With the initial dilator fully advanced to the ipsilateral annulus of the disc, the retractor blade length can be chosen by noting the depth marked on the initial dilator at the skin edge.

The blade length is measured from the bottom side of the retractor. Use the blade length one size longer than that indicated by the skin edge mark.

Instrument guide

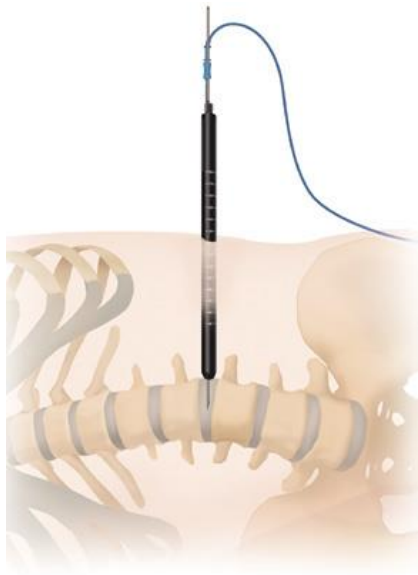


Figure 16

Second dilator

Carefully advance the second dilator over the initial dilator.

Use a slow rotating motion to ensure the dilator has advanced all the way through the psoas and is down against the disc.

Re-stimulate after the second dilator has been completely inserted to check for nearby nerves and help ensure the femoral nerve remains posterior to the dilators.

RETRACTOR INSERTION

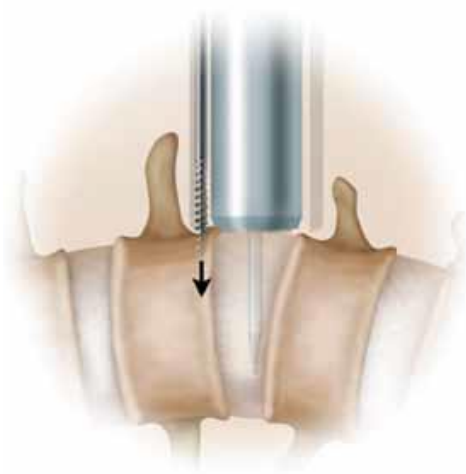


Figure 17

Inserting the retractor

Attach the blades to the direct lateral retractor base and place the assembly over the dilator. the retractor should be advanced employing a back and forth twisting motion with only gentle downward pressure through the fascia and muscle.

This technique helps to ensure the facial and muscle fibers are not pulled down into the surgical corridor.

Align the retractor with the C-arm and verify the blades of the retractor are in line with the disc space using fluoroscopy. The retractor handle should be parallel to the disc space, and unless ribs or the iliac crest prevent it, the retractor working channel should be aligned with the disc space. Confirm correct positioning of the retractor using A/P and lateral fluoroscopy.

Instrument guide

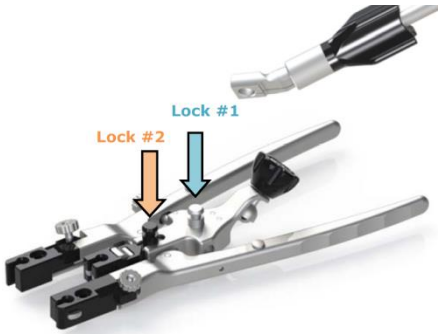


Figure 18

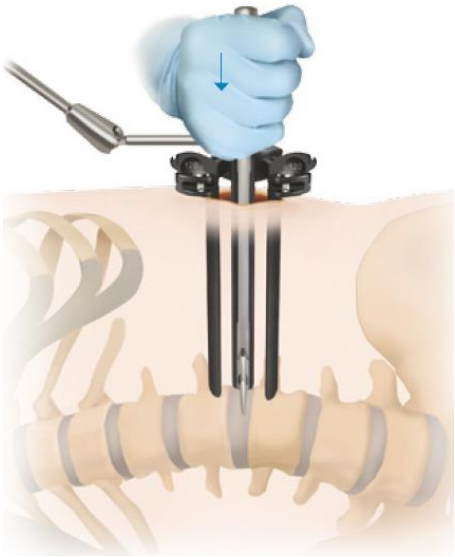


Figure 19

Attaching the retractor

Once the retractor is properly positioned, while maintaining downward pressure on the retractor, attach the articulating arm to the retractor body or posterior arm.

There are 2 options available for the attachment:

1. Central blade is mobile & lateral blades are fixed: Use the lock #1
2. Central blade is fixed and lateral blades are mobile: Use the lock #2

Verify the top surface of the retractor is parallel to the floor. Attach the articulating arm in a triangular configuration, with the bend toward the ceiling, so that the assembly applies a downward force on the retractor. The black knob of the articulating arm should be above the level of the retractor.

While applying downward pressure to the retractor, lock the articulating arm in the desired position.

The articulating arm knob instrument may be used to tighten the articulating arm to the retractor.

Support the weight of the articulating arm when attaching it to the retractor.

Insert the lights.

If necessary, a 4th blade, shims & broaches may be used.

Retraction

Open the cranial/caudal blades by rotating the cranial/caudal handle. Retract anteriorly or posteriorly by rotating the posterior handle counterclockwise.

Once the retractor has been opened to the desired position, remove the initial dilator, second dilator, and the K-wire.

An implant trial or box cutter may be placed into the working channel to verify there is adequate room for the procedure. Lateral fluoroscopy can be used to confirm proper alignment of the templating instrument with the disc space.

Instrument guide

Cat. No.


LC04-1318D
LC04-1322D


LC04-1318U
LC04-1322U


LC04-1204D

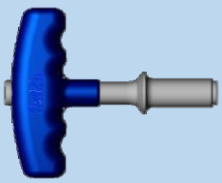

LC04-1204U


LC04-0318
LC04-1322


LC04-1207


LC04-1207S


LC04-1204S
LC04-1206S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LC04-0400I

DISC SPACE PREPARATION

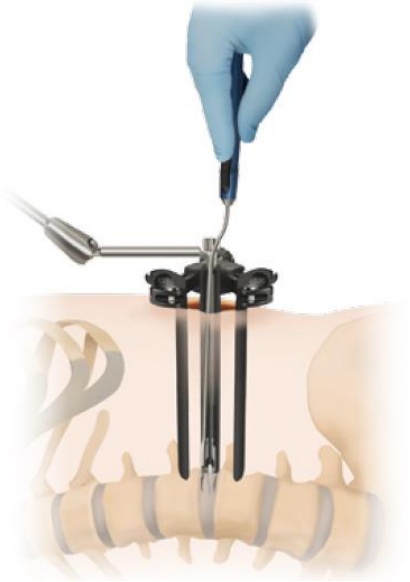
Figure 20

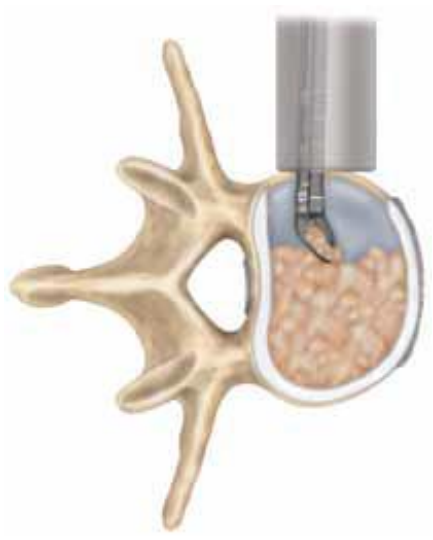
Figure 21

Annulotomy

Having first defined the anterior border of the disc space, use the bayoneted annulotomy knife to cut the annulus.

Care is taken to avoid traversing the anterior longitudinal ligament and the anteriorly situated vessels.

The annulotomy should be at least as long as the width of the implant to be used (i.e., 18mm, 22mm).

Discectomy

Use a cobb elevator to disrupt the disc from both vertebral endplates and release the contralateral annulus. This will allow for an implant to sit on the contralateral apophyseal ring.

Confirm under radiographic evaluation.

Box chisel, pituitary rongeurs, curettes, & ring curettes can be used to resect the disc material and prepare the bony endplates for fusion.

It is important that the working trajectory of the instruments stay perpendicular to the floor in order to avoid injury to vessels or nerve structures.

Instrument guide

LC04-0601
LC04-0602
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LC04-0605

LC04-0106H

LC04-0601
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LC04-0605

LC04-0306A
LC04-0308A
LC04-0310A
LC04-0312A
LC04-0314A
LC04-0316A

LC04-0306B
LC04-0308B
LC04-0310B
LC04-0312B
LC04-0314B
LC04-0316B

LC04-0106D

Basic trials 0°

Basic trials 6°

Basic trials 12°

Angled trials 6°

Angled trials 12°

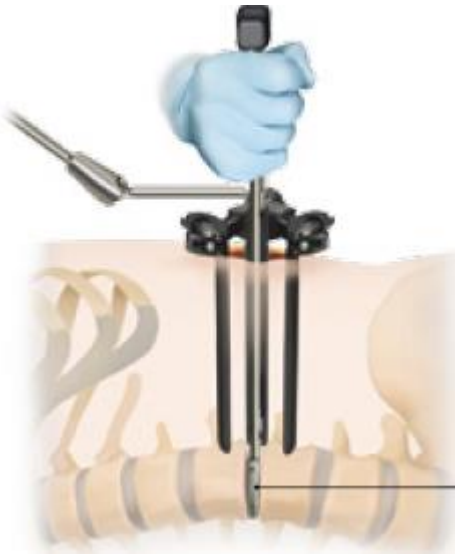


Figure 22

Distraction

Blunt & sharp reamers are placed into the disc space and rotated several times to clean the end plates. A/P fluoro should be used to center the shaver in the disc before turning. The appropriate sized shavers should be carefully selected to ensure the end plates are not compromised.

It is extremely important that the end plates be meticulously prepared for fusion by removing the cartilaginous disc without destroying the cortical end plates

TRIALING

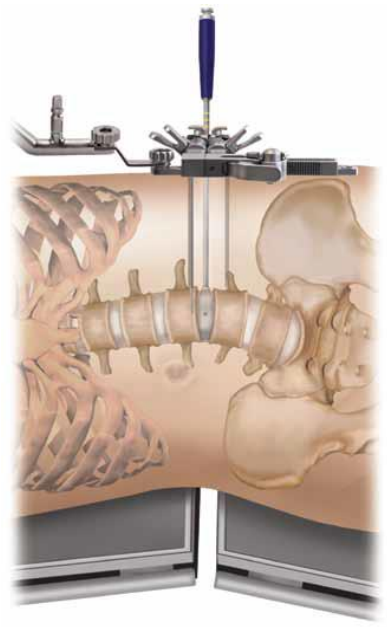


Figure 23

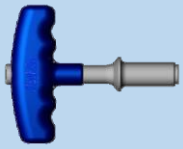
Trials

Use trials to determine the correct implant size as well as achieve additional distraction.

Trials for each implant width, lordotic angle and height are provided in the kit. Start with the smallest size trial and move up in size as needed. Confirm correct placement of the trial using lateral and A/P fluoroscopy.

A properly sized Trial should be centered with the spinous process and span the ring apophysis in order to reach fully across the vertebral body end plate.

Instrument guide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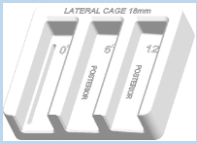

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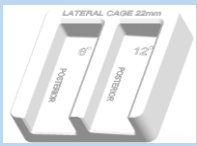

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LC04-0502C


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LC04-0803

LC04-0800

CAGE INSERTION

Figure 24

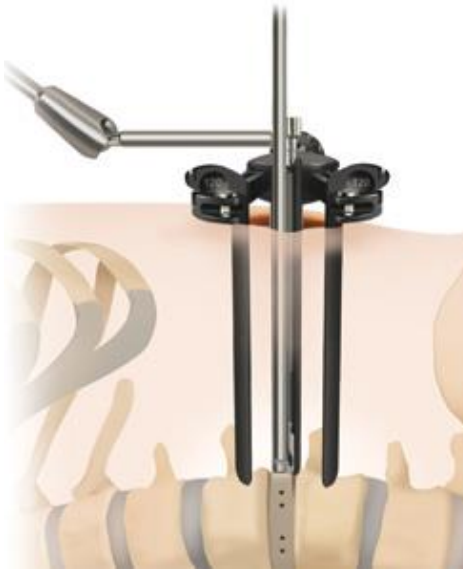

Figure 25

Cage preparation

Select the corresponding size implant.

Attach the implant to the inserter. Rotate the thumb wheel clockwise until the implant is securely attached to the inserter. Attach the cage holder to a modular T-handle.

Pack the implant with bone graft, being careful not to over-pack the implant. Use the appropriate bone graft holder & graft impactor.

Cage insertion

Carefully impact the implant into the disc space. You may use the lateral slide to ensure no bone graft material falls out of the implant during insertion. Fluoroscopy should be used to confirm correct implant placement.

The implant should traverse the apophyseal ring and be centered within the disc space.

Instrument guide

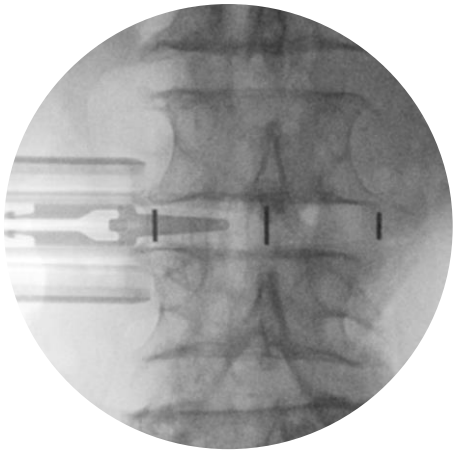

Figure 26

Confirming cage position

Remove the cage holder from the implant and verify the final position of implant with fluoroscopy.

Ensure that no graft material has extruded out of the implant's graft chamber.

Adjust with the implant impactor as necessary.

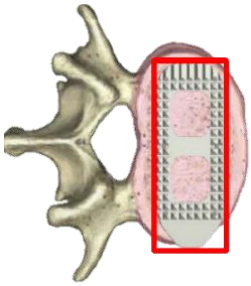

Figure 27

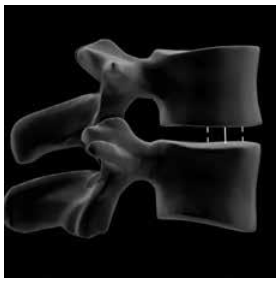

Figure 28

Final placement

There are six tantalum markers embedded within the PEEK material of the implant, which are designed to help visually confirm proper positioning and orientation of the implant in radiographic images.

POSTOPERATIVE CARE

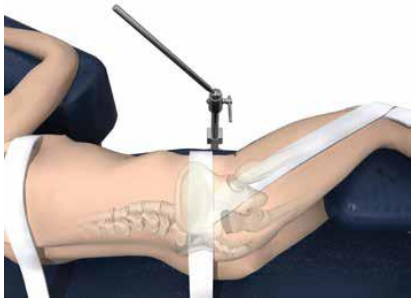

Figure 29

Removing the retractor

Collapse all the blades. Loosen the black articulating arm knob and disconnect the arm from the retractor by loosening the thumb screw.

Carefully remove the retractor. As the Retractor is removed, the muscle and fat layers can be visualized closing back into place. Ensure there is no excess bleeding.

The wound is closed using standard techniques.

FIXATION

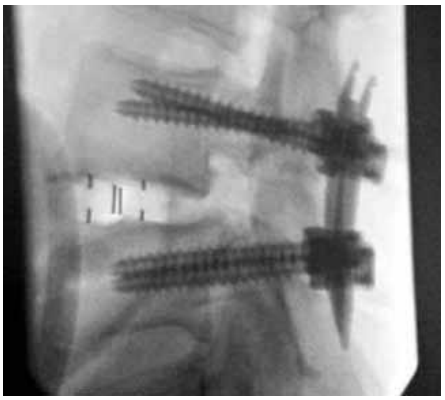

Figure 30

Fixation

Supplemental instrumentation is then placed according to the appropriate surgical technique.

Instrument guide


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LC04-0503B


LC04-0503A

CAGE REMOVAL

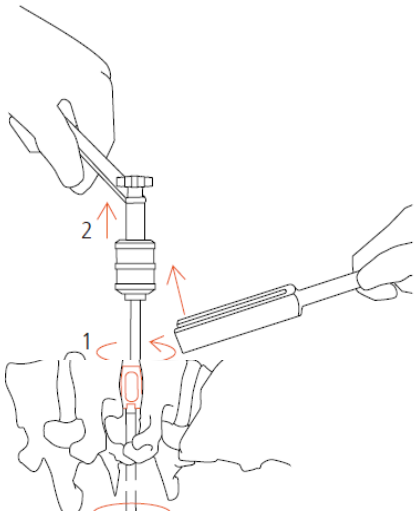

Figure 31

Removing the cage

The cage(s) may be removed by using the cage holder. Attach the cage holder to the implant and pull it out from the disc space.

If greater force is needed, use the slotted hammer on the cage holder.

Distraction and bone removal may also be required before the interbody spacer can be removed.

Instructions for Use

LnK Lumbar Interbody Fusion Cage System
(LKIFU-A006_Rev.2016.09)

PURPOSE
This device is a PEEK (POLYETHERETHERKETONE) fusion device intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

DESCRIPTION
The LnK Lumbar Interbody Fusion Cage System's implants are interbody fusion devices intended for use as an aid in spinal fixation. These hollow, rectangular implants are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies. They have serrations on the superior and inferior surfaces designed for fixation, ergonomically shaped anterior edges, and flat posterior edges. Radiopaque markers have been embedded within the implants, which are designed to allow for visualization in radiographic images
Surgical approach
•PLIF (Posterior Lumbar Intervertebral body Fusion) PEEK Cage System is to be implanted via posterior approach.
•TLIF (Transforaminal Lumbar Intervertebral body Fusion) PEEK Cage System is to be implanted via transforaminal approach.
•ALIF(Anterior Lumbar Intervertebral body Fusion) PEEK Cage System is to be implanted via anterior approach.
•DLIF (Direct Lateral Intervertebral body Fusion) PEEK Cage System is to be implanted via direct lateral approach. It can be used in an open approach and a percutaneous approach with MIS instrumentation.

Raw Material: Cage Body - PEEK-OPTIMA® LTl (ASTM F2026), Tantalum Marker – Tantalum (ASTM F560)

INDICATIONS
LnK Lumbar Interbody Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. LnK Lumbar Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS
This device is not intended for cervical spine use.
Contraindications include, but are not limited to:
1. Infection, local to the operative site
2. Signs of local inflammation,
3. Fever or leukocytosis,
4. Morbid obesity,
5. Pregnancy,
6. Mental illness,
7. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Suspected or documented allergy or intolerance to composite materials,
9. Any case not needing a fusion,
10. Any case not described in the indications,
11. Any patient unwilling to cooperate with postoperative instructions.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. Spondylolisthesis unable to be reduced to Grade 1.
14. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
15. Any case that requires the mixing of metals from two different components or systems.
16. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
17. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
18. Prior fusion at the level to be treated.
Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:
1. Severe bone resorption
2. Osteomalacia
3. Severe osteoporosis

POTENTIAL ADVERSE EFFECTS
Adverse effects may occur when the device is used either with or without associated instrumentation.
The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed.
Potential adverse events include but are not limited to:
1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/
or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or pseudoarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury.
Cerebral spinal fluid leakage.
10. Haemorrhage of blood vessels and/or hematomas.
11. Discitis, arachnoiditis, and/or other types of inflammation.
12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
13. Bone graft donor site complication.
14. Inability to resume activities of normal daily living.
15. Early or late loosening or movement of the device(s).
16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
18. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
20. Loss of or increase in spinal mobility or function.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Cessation of any potential growth of the operated portion of the spine.
25. Death.

WARNINGS AND PRECAUTIONS
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion.
These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and / or alcohol / drug abuse patients and those with poor muscle and bone quality and / or nerve paralysis are also poor candidates for spinal fusion.

The LnK Lumbar Interbody Fusion Cage System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The LnK Lumbar Interbody Fusion Cage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

This system should not be used with components of any other systems or manufacturers.

Based on fatigue testing results, when using this system, the physicians /surgeons should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient,
the important medical information given in this document should be conveyed to the patient.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

THE CHOICE OF IMPLANTS

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient. Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up implant fatigue and/or lead to deformation or failure of the implants. The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up. The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

PREOPERATIVE PRECAUTIONS

The surgical indication and the choice of implants must take into account certain important criteria such as:

• Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.

• Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.

• A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.

• Foreign body sensitivity. Where material sensitivity is suspected appropriate tests must be made prior to material implantation.

• Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.

•Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

INTRAOPERATIVE PRECAUTIONS

• The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by L&K Biomed.

• Discard all damaged or mishandled implants.

• Never reuse an implant, even though it may appear undamaged.

POSTOPERATIVE PRECAUTIONS

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

IMPLANT REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the LnK Lumbar Interbody Fusion Cage System is not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:

• The risk to the patient of the additional surgical procedure as well as the difficulty of removal.

• Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions.

• Pain or abnormal sensations due to the presence of the implants.

• Infection or inflammatory reactions.

• Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.

PACKAGING

Components should only be accepted if received with the factory packaging and labeling intact. All sets should be carefully inspected before use. In particular, check for completeness of the set and integrity of the components and/or instruments. Any damaged packaging and/or product must be returned to L&K BIOMED.

EXAMINATION

Instruments must always be examined by the user prior to surgery.
Examination should be thorough and must include a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, deformation,
or distortion, and that all components are complete.
Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise un-functional.

Visual Inspection

Make certain of the following:
Laser markings are legible.
No cracks are present in instrument handles or any part of the instrument.
Discoloration, corrosion, stains, or rust do not exist. If present, attempt to wipe clean in accordance with the instructions in the Manual Cleaning section of this document.
There is no handle/shaft separation in instrument should not be separate, and that the handle-to-shaft connection is secure.
No cuts or gouges in silicone are present.
There is no damage (cuts, tears, etc.) to the insulation.
There is no damage to the working ends or tips. The working end should be free of cracks, sharp edged gouges, and other damage. (When applicable, the working end should be sharp.)
There is no damage to threads.
All parts are present and free of damage and deterioration. Examples of parts that may be missing, loose, or damaged include screws, springs and pins.
Mating ends are free of damage (nicks, gouges, bends, etc.) that would interfere with the mating function.
Cannulated instruments with a guide wire or other insertion tool are visually checked.

Functional Inspection

Make certain of the following:
The parts intended to move will do so freely, without sticking, binding, or grinding.
Springs return the handle of the instrument to its original position.
Retention tabs hold appropriate mating parts and are not damaged.
The instrument will function as intended with the appropriate mating parts.
Ball detents will hold mating parts and are free from damage.
Sharp edges are sharp to the touch and are not dull, have no nicks, or any other damage.
Tips meet when appropriate.
Ratcheting mechanisms are functional. This includes handles, latches, and other mechanisms. All teeth should be present and functional.
Driver tips are not worn beyond functional use. If necessary, mate the instrument with the appropriate part.

CLEANING AND STERILIZATION

Implants are supplied non-sterile and are for single use only. So all implants used in surgery must be sterilized by the hospital prior to use. Otherwise, Instruments are supplied non-sterile and may be re-used. Instruments must be thoroughly cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
Unless just removed from an unopened L&K BIOMED package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to L&K BIOMED.

Cleaning Instruction – Point of use
Remove all visible soil from instruments using non-shedding wipes.
Place instruments in a tray of water or cover with damp towels.
Instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.

Manual Cleaning procedure
(1) Use the neutral pH enzyme soaking solution that has been prepared.
(2) Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes (water temperature: follow the manufacturer's instruction). Scrub instrument using a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
Note: Any assembled instruments, please disassemble the parts before submerge.
Note: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
(3) Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO,DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
(4) Prepare the neutral pH cleaning (detergent) solution according to the manufacturer's instructions, dilution recommendations, and temperatures and place in a sonication unit.
(5) Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
(6) Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes.
(7) Repeat Steps (5) and (6) with freshly prepared cleaning solution.
(8) Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.
(9) Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean.
(10) Verify that the devices are visually clean.

Automated cleaning procedure
Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.
CAUTION:
Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean.
Verify that the instruments are in visually clean.

STERILIZATION PROCEDURES
All implants and instruments are supplied NON-STERILE. Implants must be sterilized prior to use. Instruments must be sterilized prior to initial use, and as part of these reprocessing instructions, before re-use.
The following sterilization instructions have been validated to a sterility assurance level of 10^{-6}.

Initial Instruction for sterilization
All implants and instruments should be placed in the instrumentation / implant case which will be either wrapped in an FDA cleared sterilization wrap or placed in a rigid sterilization container.
Inspect the packaging to ensure no rips, punctures, or seal failures are present in or on the packaging prior to loading into the sterilizer.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Gravity	270°F(132°C)	15Minutes (Dry time, 30 Minutes)
Steam	Pre-Vacuum	270°F(132°C)	4Minutes (Dry time, 20 Minutes)
		275°F(135°C)	3Minutes (Dry time, 16 Minutes)

Implants previously implanted should not be re-used. Inspect visually for damage or contamination by biological residue. If damage or biological residue is observed on the Implant, it must be discarded.

GUARANTEE
The guarantee is only applicable if the device is used in accordance with normal conditions, as defined in this instruction and in conformity with the recommended surgical technique.

CAUTION
Federal (USA) Law restricts this device to sale by or on the order of a physician.

PRODUCT COMPLAINTS
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or L&K BIOMED. Further, if any of the implanted spinal system component(s) ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any L&K BIOMED Co., Ltd.'s product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

SHELF-LIFE
This product is not sterilized product. The shelf-life is not applicable to our product.

FURTHER INFORMATION
Recommended directions for use of this system are available at no charge upon request. If further information is needed or required, please contact L&K BIOMED Co., Ltd..

Manufactured by:
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SYMBOL TRANSLATION

LOT	LOT NUMBER	REF	CATALOG NUMBER	QTY	QUANTITY
	SINGLE USE ONLY		NON-STERILE		MANUFACTURER
	See package insert for labeling limitation	Rx Only	Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.		DATE OF MANUFACTURE
	Consult instruction for use		KEEP DRY		DO NOT USE IF PACKAGE IS DAMAGED
	USE BY		STORE AT ROOM TEMPERATURE		KEEP AWAY FROM SUNLIGHT

Notes

Product range

CastleLoc-C
Cervical Interbody
Fusion Cage System

CastleLoc-P
Anterior Cervical
Plate System

CastleLoc-S
Cervical Spinal
Fixation System

AcceLoc
Anterolateral Lumbar
Interbody Fusion System

Interbody fusion cages
ALIF, PLIF, T-PLIF & TLIF

PathLoc-LC
DLIF / Lateral cage

PathLoc-L
MIS spinal fixation
system

PathLoc-SI
Sacrum-iliac fixation
system

ARCHITECT

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Distributor / Local contact

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