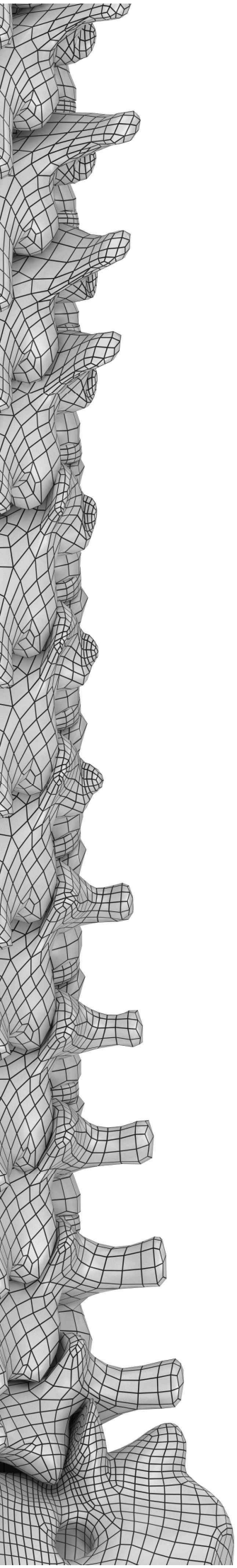
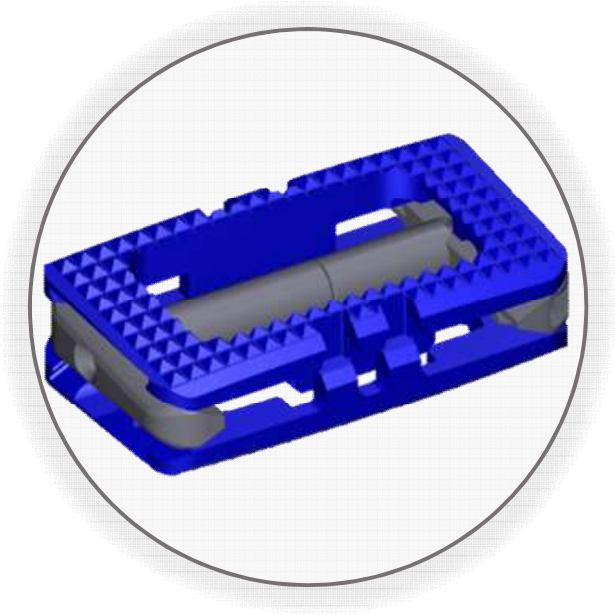


AccelFix-XL

Expandable LLIF Cage System

Lateral Lumbar Interbody Fusion Cage System



L&K BIOMED

TABLE OF CONTENTS

Introduction.....3
Features 4
Instruments.....5-11

Surgical Technique

Preoperative Planning.....12
Patient Positioning.....13
Patient Preparation.....14
Incision Planning.....15
Access.....16
Dilation.....17-19
Retraction.....20
Disc Space Preparation.....21
Distraction.....22
Cage Insertion.....23
Height Expansion.....24
Final Placement.....25
Postoperative Care.....26

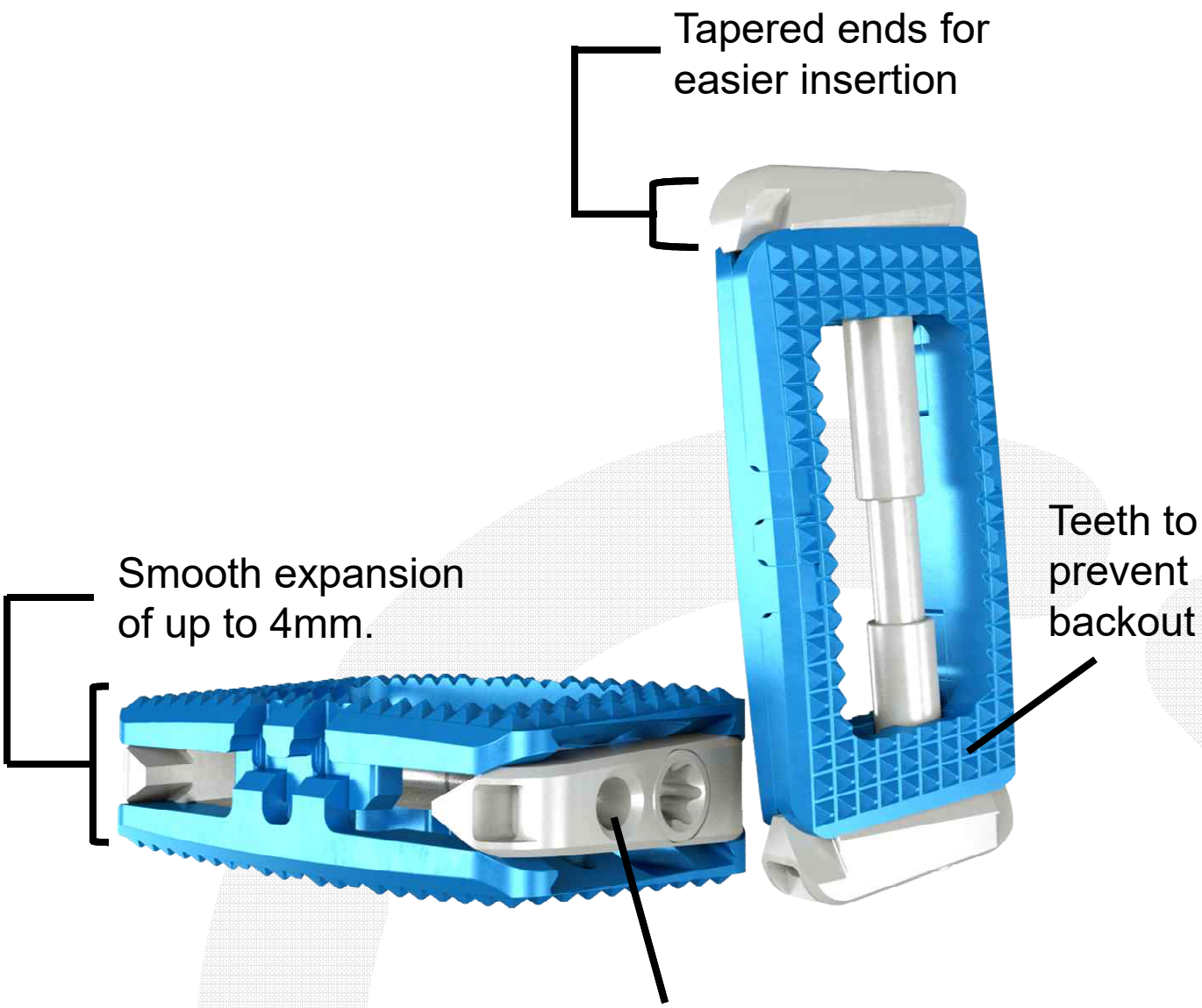
General Information

Instructions for Use/Disclaimers.....27-29
Notes.....30

The *AccelFix Lumbar Interbody Fusion Cage System* is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or Sacral Spine with a variety of implant options to treat multiple spinal pathologies.

MATERIALS
The material is Titanium alloy (Titanium-6Aluminum-4Vanadium ELI, per ASTM F136) approved for medical use.

INDICATIONS
AccelFix Lumbar Expandable 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 and/or allogenous bone graft composed of cancellous and/or corticocancellous bone. AccelFix Lumbar Expandable 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.


Tapered ends for easier insertion
Smooth expansion of up to 4mm.
Teeth to prevent backout
Hole for post-expansion bone graft insertion

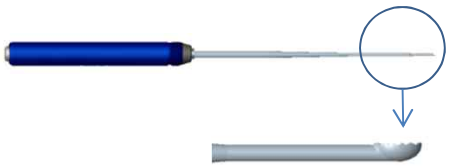
CATALOG NUMBERS

Cat. No.	Name	QTY.
LC04-1318	Cobb Elevator Straight 18mm	1
LC04-1322	Cobb Elevator Straight 22mm	1
LC04-1207	Osteotome	1
LC04-1207S	Box Curette	1
LC04-1204S	Cup Curette 4mm	1
LC04-1206S	Cup Curette 6mm	1
LC04-0601	Box Chisel 4H/18mmW/Straight	1
LC04-0602	Box Chisel 6H/18mmW/Straight	1
LC04-0604	Box Chisel 4H/22mmW/Straight	1
LC04-0605	Box Chisel 6H/22mmW/Straight	1
LC04-0400	Modular T-Handle (Hudson Type)	2
LC04-0400I	Modular I-Handle (Hudson Type)	1
LC04-0906	Sliding RAM Adaptor	1
LC04-1001	Sliding RAM	1
LC04-0300	Lateral Slide	2
XL01-0002	Expandable Cage Inserter(22mm)	2
XL01-0003	Height Adjustable Driver	2
XL01-0004	XL Height Indicator Module	1
LC04-0306A	Blunt Reamer 6mm	1
LC04-0308A	Blunt Reamer 8mm	1
LC04-0310A	Blunt Reamer 10mm	1
LC04-0312A	Blunt Reamer 12mm	1
LC04-0314A	Blunt Reamer 14mm	1
LC04-0316A	Blunt Reamer 16mm	1
LC04-0306B	Sharp Reamer Ring Type 6mm	1
LC04-0308B	Sharp Reamer Ring Type 8mm	1
LC04-0310B	Sharp Reamer Ring Type 10mm	1
LC04-0312B	Sharp Reamer Ring Type 12mm	1
LC04-0314B	Sharp Reamer Ring Type 14mm	1
LC04-0316B	Sharp Reamer Ring Type 16mm	1
LC04-0106D	Trial with Rasp W18X6mm	1
LC04-1004	Kerrison Rongeur 5mm	1
LC04-1012	Kerrison Rongeur 7mm	1
LC04-1005	Pituitary Rongeur (Ferris Smith) 3mm	1
LC04-1006	Pituitary Rongeur (Ferris Smith) 5mm	1
LC04-1008	Pituitary Rongeur 5mm Right	1
LC04-1009	Pituitary Rongeur 5mm Left	1
LC04-1010	Pituitary Rongeur 7mm Right	1
LC04-1011	Pituitary Rongeur 7mm Left	1
XL01-0114	Expandable Trial 50x22x6d	1
XL01-0115	Expandable Trial 50x22x12d	1
XL01-0117	Expandable Trial 55x22x6d	1
XL01-0118	Expandable Trial 55x22x12d	1
XL01-0401	Bone Funnel	1
XL01-0402	Bone Funnel inserter	1

LC04-1318 Cobb Elevator Straight 18mm
LC04-1322 Cobb Elevator Straight 22mm

LC04-1207 Osteotome

LC04-1207S Box Curette



LC04-1204S Cup Curette 4mm
LC04-1206S Cup Curette 6mm

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)

INSTRUMENTS - BASIC SET

	LC04-0906	Sliding RAM Adaptor
	LC04-1001	Sliding RAM
	LC04-0300	Lateral Slide
	XL01-0002	Expandable Cage Inserter (22mm)
	XL01-0003	Height Adjustable Driver
	XL01-0004	XL Height Indicator Module
	XL01-0114 XL01-0115 XL01-0117 XL01-0118	Expandable Trial 50x22x6d Expandable Trial 50x22x12d Expandable Trial 55x22x6d Expandable Trial 55x22x12d

LC04-0306A	Blunt Reamer 6mm
LC04-0308A	Blunt Reamer 8mm
LC04-0310A	Blunt Reamer 10mm
LC04-0312A	Blunt Reamer 12mm
LC04-0314A	Blunt Reamer 14mm
LC04-0316A	Blunt Reamer 16mm

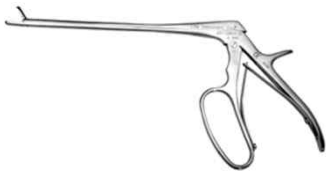
LC04-0306B	Sharp Reamer Ring Type 6mm
LC04-0308B	Sharp Reamer Ring Type 8mm
LC04-0310B	Sharp Reamer Ring Type 10mm
LC04-0312B	Sharp Reamer Ring Type 12mm
LC04-0314B	Sharp Reamer Ring Type 14mm
LC04-0316B	Sharp Reamer Ring Type 16mm

LC04-0106D Trial with Rasp W18X6mm

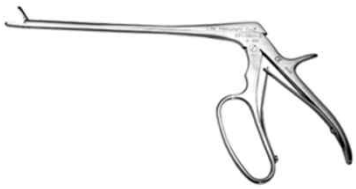
XL01-0401 Bone Funnel

XL01-0402 Bone Funnel Inserter

LC04-1004 Kerrison Rongeur 5mm
LC04-1012 Kerrison Rongeur 7mm



LC04-1005 Pituitary Rongeur (Ferris Smith) 3mm
LC04-1006 Pituitary Rongeur (Ferris Smith) 5mm



LC04-1008 Pituitary Rongeur 5mm Right
LC04-1009 Pituitary Rongeur 5mm Left
LC04-1010 Pituitary Rongeur 7mm Right
LC04-1011 Pituitary Rongeur 7mm Left

LC04-1318D Cobb Elevator Angled Down 18mm
LC04-1322D Cobb Elevator Angled Down 22mm

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

LC04-0601 Box Chisel 4 (H) X 18 (W) mm Angled
LC04-0602 Box Chisel 6 (H) X 18 (W) mm Angled
LC04-0604 Box Chisel 4 (H) X 22 (W) mm Angled
LC04-0605 Box Chisel 6 (H) X 22 (W) mm Angled

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

XL01-0001 Expandable Cage Inserter (18mm)

XL01-0101 Expandable Trial 18Wx45Lx0D
XL01-0102 Expandable Trial 18Wx45Lx6D
XL01-0103 Expandable Trial 18Wx45Lx12D
XL01-0104 Expandable Trial 18Wx50Lx0D
XL01-0105 Expandable Trial 18Wx50Lx6D
XL01-0106 Expandable Trial 18Wx50Lx12D
XL01-0107 Expandable Trial 18Wx55Lx0D
XL01-0108 Expandable Trial 18Wx55Lx6D
XL01-0109 Expandable Trial 18Wx55Lx12D
XL01-0110 Expandable Trial 22Wx45Lx0D
XL01-0111 Expandable Trial 22Wx45Lx6D
XL01-0112 Expandable Trial 22Wx45Lx12D
XL01-0113 Expandable Trial 22Wx50Lx0D
XL01-0116 Expandable Trial 22Wx55Lx0D

INSTRUMENTS - OPTIONAL SET

LC04-0108B	Trial 0° 18 (W) X8 (H) mm
LC04-0108B	Trial 0° 18 (W) X10 (H) mm
LC04-0108B	Trial 0° 18 (W) X12 (H) mm
LC04-0108B	Trial 0° 18 (W) X14 (H) mm
LC04-0108B	Trial 0° 18 (W) X16 (H) mm

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

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
LC04-0212E	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

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) X12 (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

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

Preoperative Planning

Preoperative planning can be useful in determining:
Location of the iliac crest and lower ribs in relation to disc space of interest.
Position of the anterior vasculature and posterior nerve structures via axial MRI
Curvature of the spine.

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.

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.

The patient is secured to the surgical table with tape at four locations:
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.

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

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.

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.

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

Incision planning

An AP image should be obtained to ensure the patient is positioned laterally. Clear, distinct pedicles that are equidistant from the spinous process should be visible. Next a lateral x-ray should be obtained and distinct end plates should be seen.

Lateral and A/P images may require readjustment of the bed position separately for each level.

Incision point

Identify the level to be fused and confirm the position using fluoroscopy.

The incision point for a single level should be over the disc of the level to be fused. For two levels, the incision point should be over the vertebral body that is separating the two discs to be removed.

The incision point can be marked by the angle of the disc space, the anterior margin, posterior margin and midpoint to the posterior third of the disc space.

It may be possible to access multiple levels through one skin incision, depending on patient anatomy. Though a single incision may be used to reach multiple levels, the surgeon must perform separate dilations through the psoas for each disc.

Dissection to the psoas

After making the skin incision, the fat layers are dissected until the abdominal musculature is reached. A 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 is the first plane encountered and is the only layer that will need to be dissected sharply. A Kelly Clamp is then used to bluntly dissect through the fibers of the external oblique, internal oblique, and transversalis muscles. Dissection is done in line with the muscle fibers, as these muscles layers run in opposite directions. After penetrating the transversalis fascia, the retroperitoneal fat is exposed.

Once inside the retroperitoneal space, the index finger is used to follow the internal abdominal wall posteriorly down to the psoas muscle. Use of the finger to sweep the peritoneal contents will allow a clear path down to the psoas muscle.

Initial dilator insertion

Insert the neuromonitoring probe into the first dilator.

Guide the initial dilator down into the retroperitoneal space until the tip of the dilator is at the lateral margin of the psoas muscle.

Verify the position of the dilator using fluoroscopy.

Note: The dilator can be held in place with the initial dilator holder while using fluoroscopy.

Advance the dilator

Insert the dilator through the psoas muscle by rotating it to ensure the dilator is all the way down.

After insertion confirm the dilator is still in an acceptable position using lateral fluoroscopy.

Retractor blade length

With the initial dilator fully advanced, the retractor blade length can be determined by noting the depth marked on the initial dilator.

It is advisable to use the blade length that is one size longer than is indicated by the mark on the initial dilator.

Second dilator

Advance the second dilator over the initial dilator.

Rotate slowly to ensure the dilator has advanced all the way through the psoas and is against the disc.

Inserting the retractor

Attach the blades to the retractor base and put the assembly over the dilator. The retractor should be inserted using a back and forth twisting motion.

Line up the retractor with the C-arm and check that the blades of the retractor are in line with the disc space using fluoroscopy. Confirm correct retractor position using fluoroscopy.

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

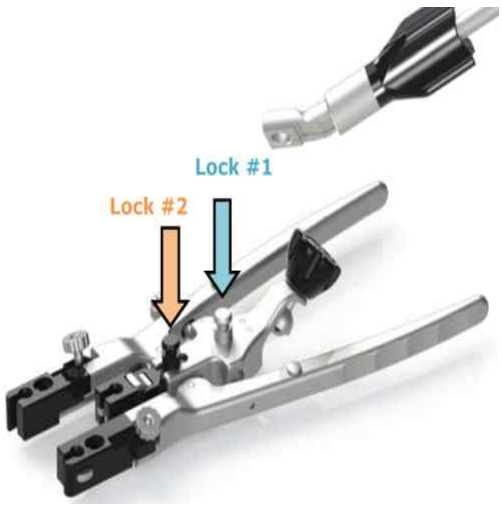
Verify the top surface of the retractor is parallel to the floor. Attach the articulating arm in a triangular configuration, with the bend toward the ceiling, so that the assembly applies a downward force on the retractor. The black knob of the articulating arm should be above the level of the retractor.

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.

INSTRUMENTS IN USE

LC04-1318D Cobb Elevator 18mm
LC04-1322D Cobb Elevator 22mm

LC04-0601 Box Chisel 4Hx18Wmm
LC04-0602 Box Chisel 6Hx18Wmm
LC04-0604 Box Chisel 4Hx22Wmm
LC04-0605 Box Chisel 6Hx22Wmm

LC04-1204S Cup Curette 4mm
LC04-1206S Cup Curette 6mm

LC04-1207S Box Curette

LC04-1207 Osteotome

LC04-0400 Modular T-Handle

LC04-0400I Modular I-Handle

Annulotomy

After defining the anterior border of the disc space, use the bayoneted annulotomy knife to cut into the annulus.

The annulotomy should be at minimum the width of the implant to be used (18mm or 22mm).

Discectomy

Use a cobb elevator to remove the disc from both vertebral endplates and release the contralateral annulus.

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

Distraction

Blunt & sharp reamers are placed into the disc space and rotated several times to clean the end plates. Fluoroscopy should be used to center the shaver in the disc before turning. The appropriate sized shavers should be sequentially inserted to ensure the end plates are not compromised.

Trials

Use trials to determine the correct implant size.

Expandable trials are provided in the set. Confirm correct placement of the trial using fluoroscopy.

INSTRUMENTS IN USE

LC04-0306A Blunt Reamer 6mm
LC04-0308A Blunt Reamer 8mm
LC04-0310A Blunt Reamer 10mm
LC04-0312A Blunt Reamer 12mm
LC04-0314A Blunt Reamer 14mm
LC04-0316A Blunt Reamer 16mm

LC04-0306B Sharp Reamer 6mm
LC04-0308B Sharp Reamer 8mm
LC04-0310B Sharp Reamer 10mm
LC04-0312B Sharp Reamer 12mm
LC04-0314B Sharp Reamer 14mm
LC04-0316B Sharp Reamer 16mm

LC04-0106D Trial with Rasp 18x6

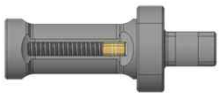
XL01-0114 Expandable Trial 50x22x6d
XL01-0115 Expandable Trial 50x22x12d
XL01-0117 Expandable Trial 55x22x6d
XL01-0118 Expandable Trial 55x22x12d

INSTRUMENTS IN USE

XT01-0003 Torque Limiting T-Handle 3Nm

XL01-0002 Expandable Cage Inserter (22mm)

LC04-0300 Lateral Slide



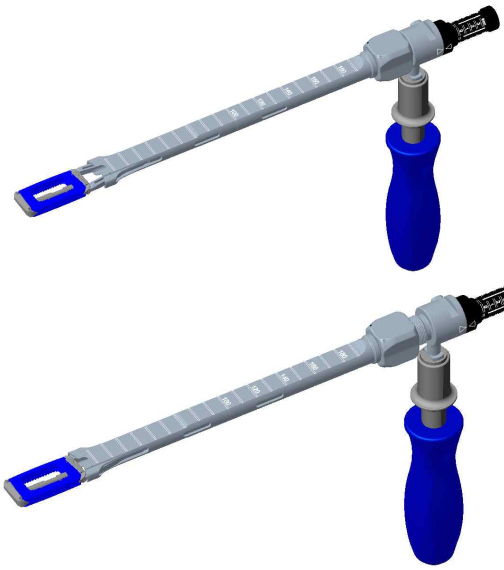
XL01-0004 XL Height Indicator Module

LC04-0400I Modular I-Handle

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 the 3Nm Torque-limiting handle.

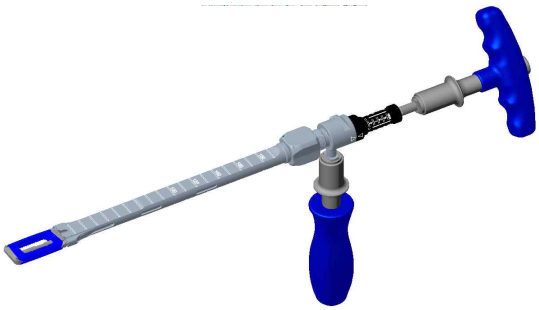


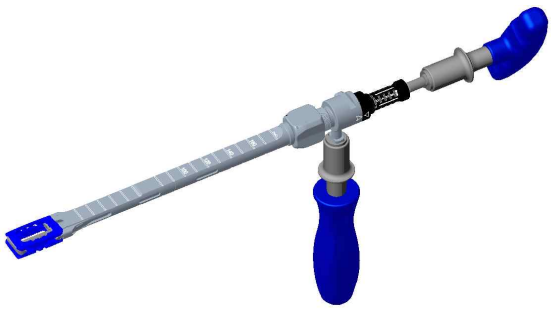
Pack the implant with bone graft, being careful not to over-pack the implant. Use the bone graft holder & graft impactor.

Cage insertion

Carefully insert 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 cover the apophyseal ring and be centered in the disc space.





Height Expansion

Attach the Height Adjustment Driver to the Torque Limiting T-Handle.

With the cage and Expandable Cage Inserter still fully engaged, insert the Height Adjustment Driver/Torque Limiting T-Handle assembly through the proximal opening of Expandable Cage Inserter, until it is fully seated.

Tip: Make sure that the expansion indicator on Expandable Cage Inserter is at the initial position of 0 mm. If it is not in the 0mm position, disengage the cage from the Expandable Cage Inserter, and then insert the Height Adjust Driver into the Expandable Cage Inserter and rotate it counterclockwise to move it to 0mm.

Turn the Height Adjust Driver/Torque Limiting T-Handle clockwise to expand the cage to desired height. As the cage expands, you will be able to see the height expanded on the indicator.

INSTRUMENTS IN USE

XT01-0003 Torque Limiting T-Handle 3Nm

XL01-0001 Expandable Cage Inserter (18mm)
XL01-0002 Expandable Cage Inserter (22mm)

LC04-0300 Lateral Slide

XL01-0004 XL Height Indicator Module

LC04-0400I Modular I-Handle

XL01-0003 Height Adjustable Driver

INSTRUMENTS IN USE

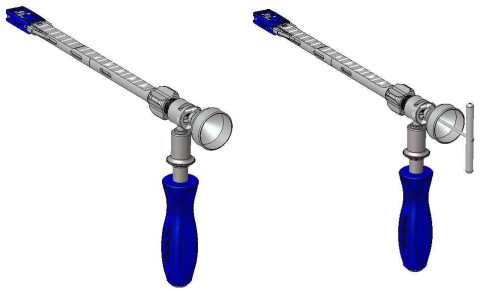
XL01-0401 Bone Funnel

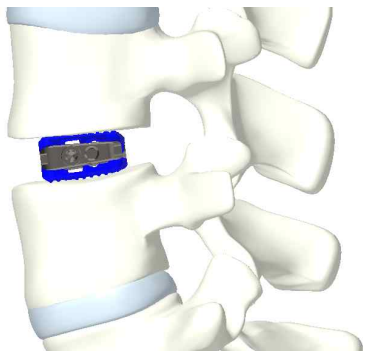
XL01-0402 Bone Funnel Inserter

Confirming cage position
Before removing the cage holder, insert extra bone graft material using the bone graft funnel.

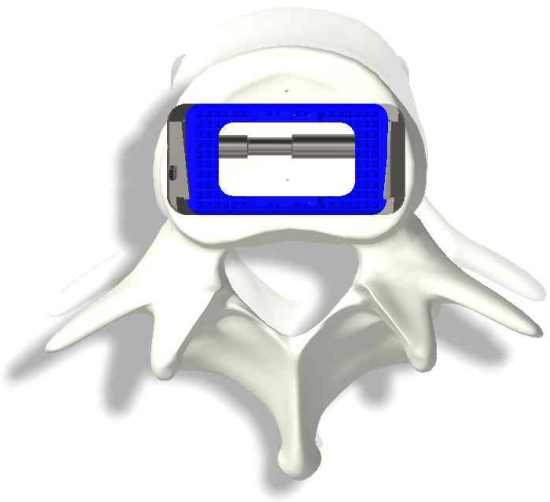
Remove the cage holder from the implant and verify the final position of implant with fluoroscopy.

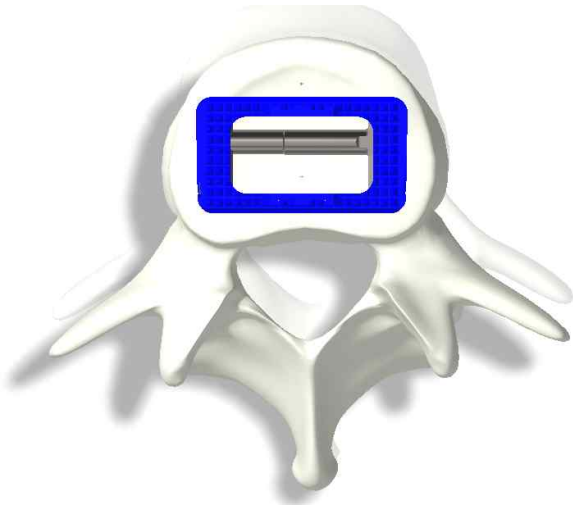
Ensure that no graft material has extruded out of the implant's graft chamber





Final placement
Both A/P and lateral images are needed to ensure proper placement and height expansion.



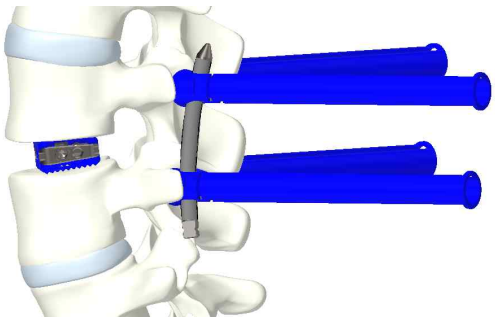


Removing the retractor

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 seen closing back into place.

The wound is closed using standard techniques.



Fixation

Supplemental instrumentation is placed according to the appropriate surgical technique

AccelFix Lumbar Interbody Fusion Cage System(Sterile)
(LKIFU-A006EX_Rev.2019.03)

PURPOSE

This device is a Lumbar Interbody Fusion Cage 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 AccelFix 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. The implants can be expanded in height after insertion in the unexpanded state using the system instrumentation. The implants have serrations on the superior and inferior surfaces designed for fixation, ergonomically shaped anterior edges, and flat posterior edges.

Surgical approach

- AccelFix-XT TLIF Expandable Cage is to be implanted via transforaminal and posterior approach.
- AccelFIx-XA ATP Expandable Cage is to be implanted via anterior to psoas approach.
- AccelFix-XL LLIF Expandable Cage is to be implanted via Direct Lateral approach.

Raw Material: Cage Body – Titanium 6AL-4V Alloy (ASTM F136)

INDICATIONS

AccelFix 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 and/or allogenous bone graft composed of cancellous and/or corticocancellous bone. AccelFix 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 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 AccelFix 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 AccelFix 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.

If package is opened, damaged or expiration date has passed, do not use in surgery.

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:

• "The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient."

• 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 AccelFix 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 sterile and are for single use only. Re-sterilization of the implants is strictly forbidden, regardless of the method that might be employed. 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 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.

1. 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.

2. 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
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.

1. 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

For implants delivered Gamma irradiation sterile:

The implants are sterilized by Gamma radiation at doses of 25k Gray. Sterilization is valid 5 years from the date of manufacturing. The expiry date of sterile parts is indicated on the packaging.

For instruments delivered non-sterile:

All 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 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.

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

1. All instruments should be placed in the instrumentation which will be either wrapped in an FDA cleared sterilization wrap or placed in a rigid sterilization container.
2. 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 Min utes)
Steam	Pre-Vacuum	270°F(132°C)	4Minutes (Dry time, 20 Min utes)
		275°F(135°C)	3Minutes (Dry time, 16 Min utes)

PRODUCT COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and/or its performance should notify L&K BIOMED. Moreover, if a device malfunctioned, L&K BIOMED or its distributor must be advised immediately.
If a L&K BIOMED product has ever worked improperly and could have caused or contributed to the serious injury or death of a patient, the distributor must be informed as soon as possible by telephone, fax or in writing, For all complaints, please include the device name and reference along with the lot number of the component(s), your name and address and an exhaustive description of the event to L&K BIOMED understand the cause of the complaint.
For further information or complaints, please contact as below address:

STORAGE

At room temperature(1-35℃)

SHELF-LIFE

5 years under recommended conditions

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:
L&K BIOMED Co.,Ltd.
: #201, 202, 16-25, Dongbaekjungang-ro 16 beon-gil, Giheung-gu, Yongin-si,
Gyeonggi-do, 17015, Korea
Tel. 82 - 1600 – 0841 Fax. 82 -1600-0843

SYMBOL TRANSLATION

LOT	LOT NUMBER	REF	CATALOG NUMBER	QTY	QUANTITY
	SINGLE USE ONLY	NON STERILE	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

LEARNING & KNOWLEDGE BIOMED
L&K BIOMED

Head Office: #201, 202 16-25, Dongbaekjungang-ro, Giheung-gu, Yongin-si, Gyeonggi–do, 17015, Korea
Seoul Office: 159-1, Mokdongseo-ro. 17th Floor. Yangcheon-gu. Seoul,. South Korea
Tel. +82-1600-0841 Fax: +82-1600-0843 www.lnkbiomed.com