LnK

PLIF/TPLIF Cage System

LnK Lumbar Interbody Fusion Cage System

LnK PLIF / T-PLIF Cage

The LnK Interbody Fixation System implants are interbody fusion devices intended for use as an aid in spinal fixation. These bullet type tip implants are offered in a variety of widths, lengths, heights and lordotic angles designed for anatomically diverse patients. The shape of serration of the cage on the superior and inferior surface is designed for a firm fixation as ergonomically shaped anterior bullet edges and flat posterior edges are applied. Also, the radiopaque markers are embedded into the cage to allow visualization of the cage's position in radiographic images.

Implant Specification

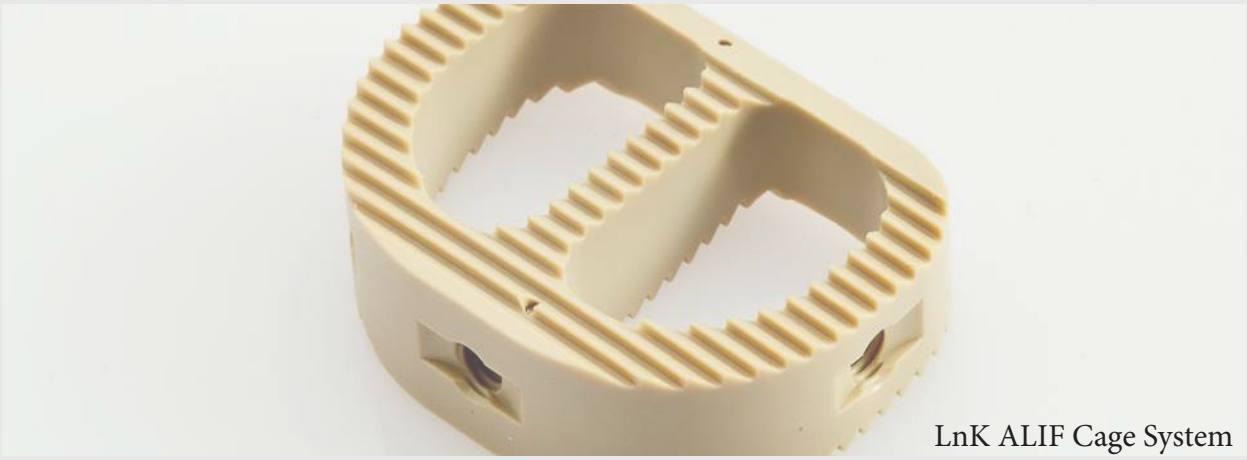
Part No.	Dimension (mm)				Part No.	Dimension (mm)			
	L(A-P)	W(M-L)	A(°)	H(mm)		L(A-P)	W(M-L)	A(°)	H(mm)
3410-2506	25	11	0	6	3414-2813	28	11	4	13
3410-2507	25	11	0	7	3414-2814	28	11	4	14
3410-2508	25	11	0	8	3414-2815	28	11	4	15
3410-2509	25	11	0	9	3414-2816	28	11	4	16
3410-2510	25	11	0	10	3418-2806	28	11	8	6
3410-2511	25	11	0	11	3418-2807	28	11	8	7
3410-2512	25	11	0	12	3418-2808	28	11	8	8
3410-2513	25	11	0	13	3418-2809	28	11	8	9
3410-2514	25	11	0	14	3418-2810	28	11	8	10
3410-2515	25	11	0	15	3418-2811	28	11	8	11
3410-2516	25	11	0	16	3418-2812	28	11	8	12
3414-2506	25	11	4	6	3418-2813	28	11	8	13
3414-2507	25	11	4	7	3418-2814	28	11	8	14
3414-2508	25	11	4	8	3418-2815	28	11	8	15
3414-2509	25	11	4	9	3418-2816	28	11	8	16
3414-2510	25	11	4	10	3510-3206	32	11	0	6
3414-2511	25	11	4	11	3510-3207	32	11	0	7
3414-2512	25	11	4	12	3510-3208	32	11	0	8
3414-2513	25	11	4	13	3510-3209	32	11	0	9
3414-2514	25	11	4	14	3510-3210	32	11	0	10
3414-2515	25	11	4	15	3510-3211	32	11	0	11
3414-2516	25	11	4	16	3510-3212	32	11	0	12
3418-2507	25	11	8	7	3510-3213	32	11	0	13
3418-2508	25	11	8	8	3510-3214	32	11	0	14
3418-2509	25	11	8	9	3510-3215	32	11	0	15
3418-2510	25	11	8	10	3510-3216	32	11	0	16
3418-2511	25	11	8	11	3514-3206	32	11	4	6
3418-2512	25	11	8	12	3514-3207	32	11	4	7
3418-2513	25	11	8	13	3514-3208	32	11	4	8
3418-2514	25	11	8	14	3514-3209	32	11	4	9
3410-2806	28	11	0	6	3514-3210	32	11	4	10
3410-2807	28	11	0	7	3514-3211	32	11	4	11
3410-2808	28	11	0	8	3514-3212	32	11	4	12
3410-2809	28	11	0	9	3514-3213	32	11	4	13
3410-2810	28	11	0	10	3514-3214	32	11	4	14
3410-2811	28	11	0	11	3514-3215	32	11	4	15
3410-2812	28	11	0	12	3514-3216	32	11	4	16
3410-2813	28	11	0	13	3518-3206	32	11	8	6
3410-2814	28	11	0	14	3518-3207	32	11	8	7
3410-2815	28	11	0	15	3518-3208	32	11	8	8
3410-2816	28	11	0	16	3518-3209	32	11	8	9
3414-2806	28	11	4	6	3518-3210	32	11	8	10
3414-2807	28	11	4	7	3518-3211	32	11	8	11
3414-2808	28	11	4	8	3518-3212	32	11	8	12
3414-2809	28	11	4	9	3518-3213	32	11	8	13
3414-2810	28	11	4	10	3518-3214	32	11	8	14
3414-2811	28	11	4	11	3518-3215	32	11	8	15
3414-2812	28	11	4	12	3518-3216	32	11	8	16

Instrument Specification

No1	Catalog #	Description
1	LC01-0107	Trial 7mm
2	LC01-0108	Trial 8mm
3	LC01-0109	Trial 9mm
4	LC01-0110	Trial 10mm
5	LC01-0111	Trial 11mm
6	LC01-0112	Trial 12mm
7	LC01-0113	Trial 13mm
8	LC01-0114	Trial 14mm
9	LC01-0207	Blunt Reamer(PLIF) 7mm
10	LC01-0208	Blunt Reamer(PLIF) 8mm
11	LC01-0209	Blunt Reamer(PLIF) 9mm
12	LC01-0210	Blunt Reamer(PLIF) 10mm
13	LC01-0211	Blunt Reamer(PLIF) 11mm
14	LC01-0212	Blunt Reamer(PLIF) 12mm
15	LC01-0213	Blunt Reamer(PLIF) 13mm
16	LC01-0214	Blunt Reamer(PLIF) 14mm
17	LC01-0307	Sharp Reamer(PLIF) 7mm
18	LC01-0308	Sharp Reamer(PLIF) 8mm
19	LC01-CM028	Sharp Reamer(PLIF) 8mm
20	LC01-0309	Sharp Reamer(PLIF) 9mm
21	LC01-CM029	Sharp Reamer(PLIF) 9mm
22	LC01-0310	Sharp Reamer(PLIF) 10mm
23	LC01-CM0210	Sharp Reamer(PLIF) 10mm
24	LC01-0311	Sharp Reamer(PLIF) 11mm
25	LC01-CM0211	Sharp Reamer(PLIF) 11mm
26	LC01-0312	Sharp Reamer(PLIF) 12mm
27	LC01-CM0212	Sharp Reamer(PLIF) 12mm
28	LC01-0313	Sharp Reamer(PLIF) 13mm
29	LC01-CM0213	Sharp Reamer(PLIF) 13mm
30	LC01-0314	Sharp Reamer(PLIF) 14mm
31	LC01-0501	PLIF Cage Holder
32	LC01-0502	PLIF Cage Holder(M3)
33	LC01-CM03	PLIF Cage Holder
34	LC01-0602	Rasp
35	LC01-0603	Rasp(Short)
36	LC01-0700	Root Retractor
37	LC01-0800	Final Impactor
38	LC01-CM04	Final Impactor
39	LC01-0900	Slotted Hammer
40	LC01-1300	Graft Holder
41	LC01-1400	Graft Impactor
42	LC01-1003	Curette Triangular
43	LC02-CM01	Curette Straghted
44	LC02-CM02	BAYONETT Curette Straghted
45	LC01-0200	Strart Reamer(PLIF)
46	LC01-CM01A	Strart Reamer(PLIF) 7mm
47	LC01-8001	PLIF Implant Case 25 .
48	LC01-8002	PLIF Implant Case 28 .
49	LC01-8003	PLIF Implant cover .

Also available.

LnK TLIF Cage System



LnK ALIF Cage System

LnK MIS System

LnK Screw Fixation System

LnK Lumbar Intervertebral body Fusion Cage System

The LnK Lumbar Intervertebral body 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 Cages are to be implanted via posterior approach.
• TLIF(Transforaminal Lumbar Intervertebral body Fusion) PEEK Cages are to be implanted via transforaminal approach.
• ALIF(Anterior Lumbar Intervertebral body Fusion) PEEK Cages are to be implanted via anterior approach.

INDICATIONS
LnK Lumbar Intervertebral body 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 spondylolistesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. LnK Lumbar Intervertebral body 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.

GENERAL CONDITIONS OF USE
The implantation of intervertebral body fusion devices must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

CAUTION
Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the intervertebral body fusion device.
The implantation of the intervertebral body fusion device must 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.
Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery,
include: device component fracture, loss of fixation, pseudoarthrosis (i.e. non-union), fracture of the vertebrae, neurological injury, and vascular or visceral injury.

Specialized instruments are provided by L&K Biomed and must be used to assure accurate implantation of the intervertebral body fusion device. While rare, intraoperative fracture or breakage of instruments can occur, instruments, which have experienced extensive use or extensive force, are more susceptible to fracture depending on the operative precaution, number of procedures, and disposal attention. Instruments must be examined for wear or damage prior to surgery. Instruments for implantation of the LnK Lumbar Intervertebral body Fusion Cage System is provided non-sterile and must be sterilized prior to use.

The LnK Lumbar Intervertebral body Fusion Cage System has not been evaluated for safety and compatibility in the MR environment. The LnK Lumbar Intervertebral body Fusion Cage System has not been tested for heating or migration in the MR environment.

INFECTION
Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical
procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be
advisable to use antibiotic prophylaxis before and after such procedures.
INSTRUMENTS
Specialized instruments are provided by L&K Biomed and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments must be examined for wear or damage prior to surgery.

REUSE
An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.

Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

HANDLING
Correct handling of the implant is extremely important. The operating surgeon must avoid notching or scratching the device.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES
When hypersensitivity is suspected or proven, it is highly recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.

CONTRAINDICATIONS
Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:
• Prior fusion at the levels to be treated.
• An active infection at the operative site.
• Use except as indicated.
• Marked local inflammation.
• Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
• Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
• Open wounds.
• Pregnancy.
• Patients having inadequate tissue coverage of the operative site.
• Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
• Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
• A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
• Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
• Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count. These contra-indications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

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, orthopaedic 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.

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.

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.

ADVERSE EFFECTS
Include but are not limited to:
• Late bone fusion or no visible fusion mass and pseudarthrosis;
• Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis;
• While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
• Superficial or deep-set infection and inflammatory phenomena;
• Allergic reactions to the implanted materials although uncommon can occur;
• Decrease in bone density due to stress shielding;
• Dural leak requiring surgical repair.
• Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
• Cessation of growth of the fused portion of the spine.
• Loss of proper spinal curvature, correction, height and/or reduction.
• Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/ nonunion results, the implant will be subject to excessive and repeatedstresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) must be revised or removed immediately before serious injury occurs.
• Neurological and spinal dura mater lesions from surgical trauma;
• Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, vertebral endplate injury or pain.
• Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
• Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
• Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock. Adverse effects may necessitate reoperation.
Adverse effects may necessitate reoperation or revision.
The surgeon must warn the patient of these adverse effects as deemed necessary.

IMPLANT REMOVAL
If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the LnK Lumbar Intervertebral body 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.

CLEANING AND STERILIZATION
All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Sterilization: recommended method to achieve a degree of sterility equal to at least 10-6.The gravity displacement sterilization parameters we suggested comply with AAMI ST79.L&K BIOMED recommends the following parameters:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Gravity	270°F(132°C)	15Minutes (Dry time, 15~30 Minute)

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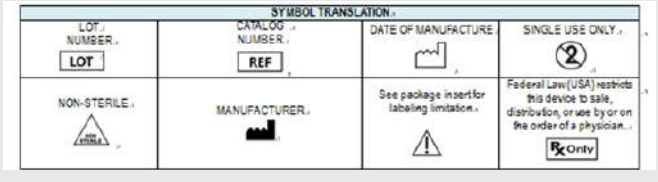

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