LnK

Anterior Cervical Cage System

LnK Anterior Cervical Cage

The design rationale for the LnK Anterior cervical Interbody Fusion Cage System revolves around offering surgeons an attractive alternative to current methods of treating degenerative disc disease in the cervical spine.

The LnK Anterior cervical Interbody Fusion Cage System uses a simple, easy-to-implant threaded cage, indicated for single-level ACDF's.

Its tapered design provides for optimal restoration of normal cervical lordosis.
The wide range of sizes accommodates a large range of cervical anatomies.
The LnK Anterior cervical cage is implanted via an open anterior approach. The versatile, straightforward design of the associated general instrument allows for precise sizing of the disc space and end plate preparation. A series of sequential, color-coded instruments guide the surgeon through the procedure in a simple, intuitive manner. The following monograph introduces the LnK anterior cervical cage system along with the general instrument designed specifically for its placement.

The LnK Anterior cervical cage must be used with supplemental fixation, to increase the primary stability of the implant, whenever necessary.
The LnK Anterior cervical cage is radiolucent allowing visualization of bone growth through the implant.
The bio-compatibility and mechanical qualities of PEEK-Optima® LTI have now been largely recognized in inter-body applications. This material has elasticity close to that of bone so that there is no graft weight-bearing problem. There is consequently, a biomechanical consistency between two spine segments, the fusion of which can be assessed and controlled overtime due to the radiolucency of the cage.
The LnK Anterior cervical Interbody Fusion Cage System is implanted according to a reproducible operating technique. As soon as they are placed, the serrated profile of the implants ensures their self-retaining properties, until fusion takes place.

LnK Anterior Cervical Interbody Fusion Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as disogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. LnK Anterior Cervical Interbody Fusion Cage System is used to facilitate Interbody fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. LnK Anterior Cervical Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

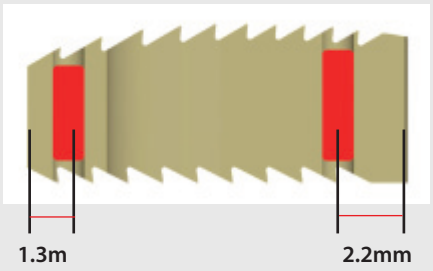
Features & Benefits

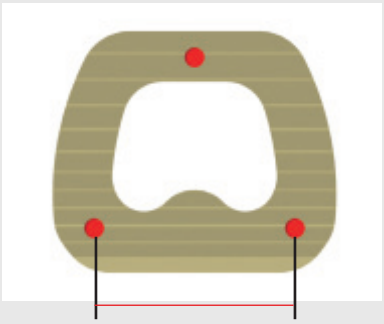
The LnK anterior cervical interbody fusion cage system is simply to use, easy to implant impacting cage, indicated for single-level ACDF's.

Features:

- Anatomical shape : Upper convex
- Wide range of sizes
- Simple Instruments for easier and faster surgery
- PEEK-Optima® LTI
- Radiopaque markers allows for visualization in radiographic image

Radiopaque Marker Location





10mm(12 X 14mm)
13mm(14 X 17mm)

Implant Specification

Length 12mm– Width 14mm		Length 12mm– Width 17mm		Length 13mm– Width 15mm	
Cat.No.	Height	Cat.No.	Height	Cat.No.	Height
5105-1214	5mm	5105-1217	5mm	5105-1315	5mm
5106-1214	6mm	5106-1217	6mm	5106-1315	6mm
5107-1214	7mm	5107-1217	7mm	5107-1315	7mm
5108-1214	8mm	5108-1217	8mm	5108-1315	8mm
5109-1214	9mm	5109-1217	9mm	5109-1315	9mm
5110-1214	10mm	5110-1217	10mm	5110-1315	10mm
Length 14mm– Width 14mm		**Length 14mm– Width 17mm**		**Length 14mm– Width 19mm**	
Cat.No.	Height	Cat.No.	Height	Cat.No.	Height
5105-1414	5mm	5105-1417	5mm	5105-1419	5mm
5106-1414	6mm	5106-1417	6mm	5106-1419	6mm
5107-1414	7mm	5107-1417	7mm	5107-1419	7mm
5108-1414	8mm	5108-1417	8mm	5108-1419	8mm
5109-1414	9mm	5109-1417	9mm	5109-1419	9mm
5110-1414	10mm	5110-1417	10mm	5110-1419	10mm
Length 15mm– Width 15mm		**Length 15mm– Width 17mm**		**Length 15mm– Width 19mm**	
Cat.No.	Height	Cat.No.	Height	Cat.No.	Height
5105-1515	5mm	5105-1517	5mm	5105-1519	5mm
5106-1515	6mm	5106-1517	6mm	5106-1519	6mm
5107-1515	7mm	5107-1517	7mm	5107-1519	7mm
5108-1515	8mm	5108-1517	8mm	5108-1519	8mm
5109-1515	9mm	5109-1517	9mm	5109-1519	9mm
5110-1515	10mm	5110-1517	10mm	5110-1519	10mm

Instrument Specification

Cat. No.	Description	Cat. No.	Description
CC15-1214	Trial 12x14x5mm	CC18-1517	Trial 15x17x8mm
CC15-1217	Trial 12x17x5mm	CC18-1519	Trial 15x19x8mm
CC15-1315	Trial 13x15x5mm	CC19-1214	Trial 12x14x9mm
CC15-1414	Trial 14x14x5mm	CC18-1217	Trial 12x17x9mm
CC15-1417	Trial 14x17x5mm	CC19-1315	Trial 13x15x9mm
CC15-1419	Trial 14x19x5mm	CC19-1414	Trial 14x14x9mm
CC15-1515	Trial 15x15x5mm	CC19-1417	Trial 14x17x9mm
CC15-1517	Trial 15x17x5mm	CC19-1419	Trial 14x19x9mm
CC15-1519	Trial 15x19x5mm	CC19-1515	Trial 15x15x9mm
CC16-1214	Trial 12x14x6mm	CC19-1517	Trial 15x17x9mm
CC16-1217	Trial 12x17x6mm	CC19-1519	Trial 15x19x9mm
CC16-1315	Trial 13x15x6mm	CC10-1214	Trial 12x14x10mm
CC16-1414	Trial 14x14x6mm	CC10-1217	Trial 12x17x10mm
CC16-1417	Trial 14x17x6mm	CC10-1315	Trial 13x15x10mm
CC16-1419	Trial 14x19x6mm	CC10-1414	Trial 14x14x10mm
CC16-1515	Trial 15x15x6mm	CC10-1417	Trial 14x17x10mm
CC16-1517	Trial 15x17x6mm	CC10-1419	Trial 14x19x10mm
CC16-1519	Trial 15x19x6mm	CC10-1515	Trial 15x15x10mm
CC17-1214	Trial 12x14x7mm	CC10-1517	Trial 15x17x10mm
CC17-1217	Trial 12x17x7mm	CC10-1519	Trial 15x19x10mm
CC17-1315	Trial 13x15x7mm	CC02-0100	Pin for Caspa
CC17-1414	Trial 14x14x7mm	CC02-0200	Caspa Retractor
CC17-1417	Trial 14x17x7mm	CC02-0300	Ring Curette Small
CC17-1419	Trial 14x19x7mm	CC03-0100	Pin Holder
CC17-1515	Trial 15x15x7mm	CC03-0200	Cage Holder
CC17-1517	Trial 15x17x7mm	CC03-0300	Graft Holder for Cervical Cage
CC17-1519	Trial 15x19x7mm	CC04-0100	Bone Graft Impactor
CC18-1214	Trial 12x14x8mm	CC04-0200	Final Impactor for Cervical Cage
CC18-1217	Trial 12x17x8mm	LC01-0900	Slotted Hammer
CC18-1315	Trial 13x15x8mm	CC90-8001	ACIF Implant CONTAINER
CC18-1414	Trial 14x14x8mm	CC90-8002	ACIF Implant COVER
CC18-1417	Trial 14x17x8mm	CC90-9001	ACIF INSTRUMENT CONTAINER
CC18-1419	Trial 14x19x8mm	CC90-9002	ACIF INSTRUMENT COVER

Surgical Technique

STEP1.Patient Positioning & Incision

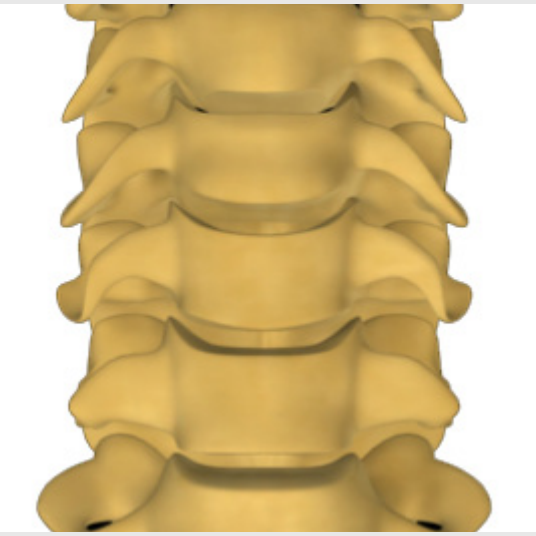
The patient is placed in the supine position with the head in slight extension. The posterior cervical spine is supported to establish and maintain normal lordosis. The surgeon must then choose a right- or left-sided approach to the cervical vertebral column. After the approach is considered, the head may be rotated to allow for adequate exposure of the upper cervical spine. The anterior aspect of the vertebral bodies cephalad and caudal to the segment involved are exposed.
After the anterior vertebral column has been exposed, the longuscolli muscles are elevated and the medial/lateral self-retaining retractor blades are securely positioned beneath them. The slotted blade may be used if an anterior osteophyte prevents proper positioning
Then the longitudinal self-retaining retractor may be placed to provide optimal visualization.

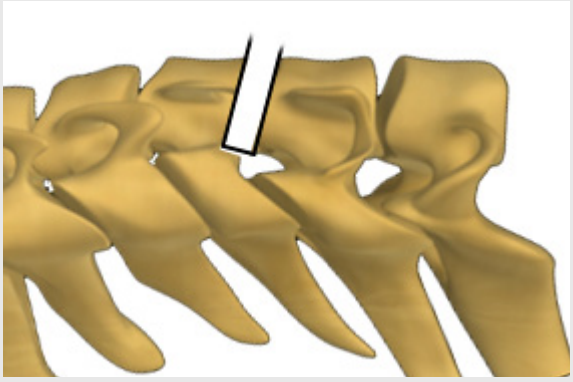
STEP 2.Exposure

A vertebral body distractor may be used. The distraction pins are positioned midline in the vertebral bodies adjacent to the discectomy. The distractor is placed over the pins and the appropriate amount of distraction is applied.

STEP 3.Discectomy

Discectomy is completed at the disc. Ring curette small may be mainly used for removal of disc (CC02-0300). Pituitaries and kerrisons may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament

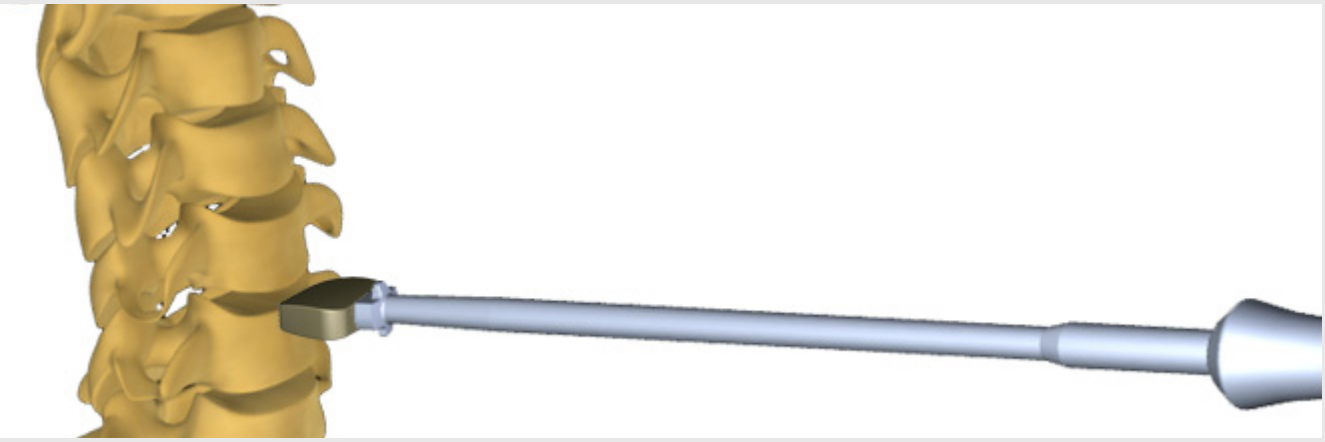


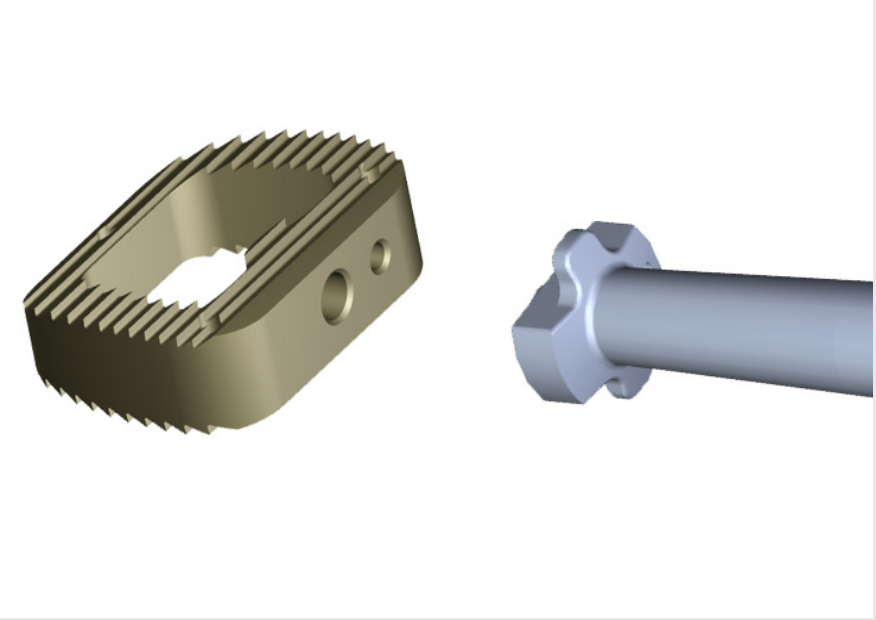


Once the decompression is completed, endplate preparation is carried out. This consists of creating a precisely matched mortise with the cage.

STEP 5.Trial Implant

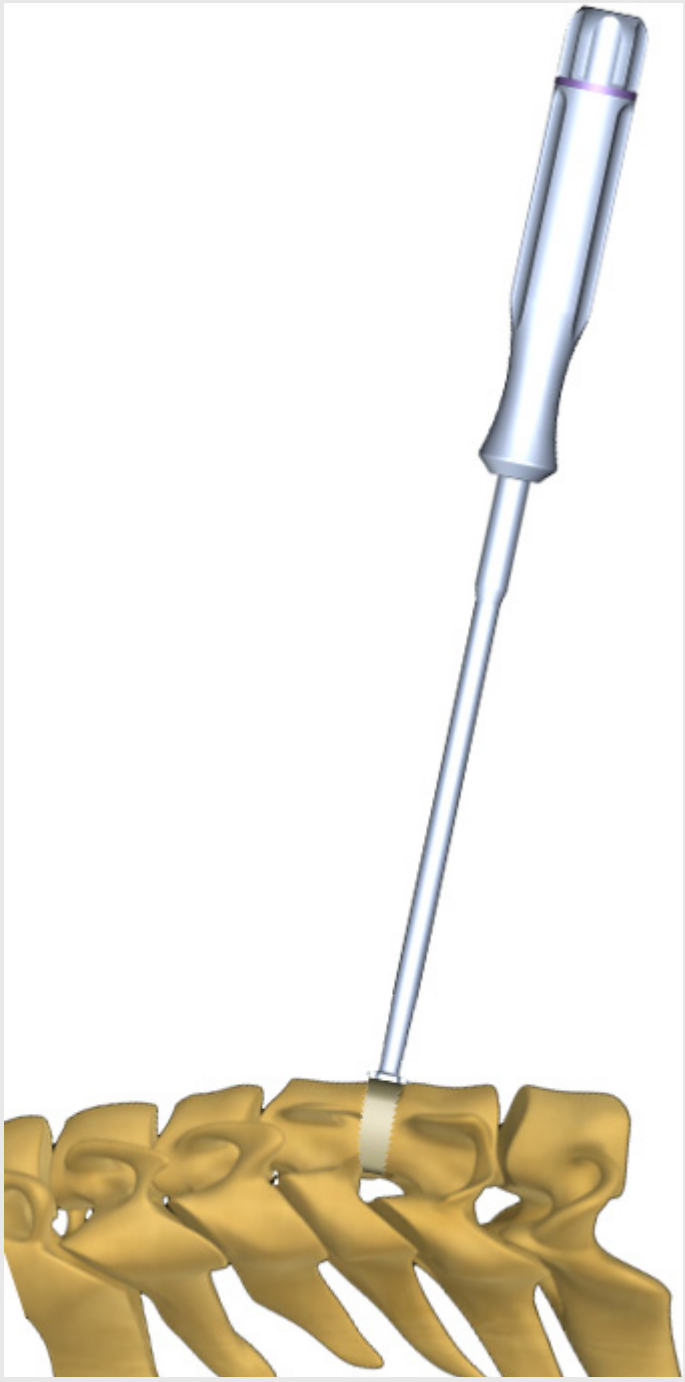
Cage sizing is determined by selecting the trial that provides the most satisfactory fit in the prepared disc space. Cage/Trial holder is used for holding trial. Trial and Cage's superior surface is designed with convex shape.





STEP 6.Cage Insertion

Select the LnK cage size that corresponds to the final trial. The cage is held in place with the cage holder. The center of the implant is then packed with an autograft bone graft.



The cage is introduced into the prepared disc. Then impact cage into prepared disc using a mallet or slotted hammer

STEP 7. Removal of Implant*(Optional)*

If the instrumentation must be removed, before fusion, the cervical approach is used, down to the instrumented area. Bone bridges between the implant and the vertebral bodies must be sectioned. The cage holder is placed on the cage to facilitate implant removal. If Slotted Hammer is used, implant can be easily removed.

Also available.

LnK Anterior Cervical Plate System

LnK Posterior Cervical Fixation System

LnK MIS System

LnK Screw Fixation System

LnK Cervical Interbody Fusion Cage System

PURPOSE
The LnK Cervical Interbody Fusion Cage System Cervical Interbody Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C3 disc to the C7 disc.

DESCRIPTION
LnK Cervical Interbody Fusion Cage System intended for use as an interbody fusion cage device and is to be used with supplemental fixation. The devices are available in a variety of different sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The devices are made of PEEK-OPTIMA® LTI with marker pins made of titanium alloy (Ti-6Al-4V ELI). LnK Cervical Interbody Fusion Cage System devices are designed for an anterior approach.

INDICATIONS
LnK Cervical Interbody Fusion Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as disogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. LnK Cervical Interbody Fusion Cage System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using auto-graft bone. LnK Cervical Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of nonoperative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS
The LnK Cervical Interbody Fusion Cage System is not intended for posterior surgical implantation.
Contraindications include, but are not limited to:
• Any case needing to mix metals from different components.
• Any case not described in the indications.
• Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
• Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
• Any patient unwilling to co-operate with postoperative instructions.
• Fever or leukocytosis.
• Infection, local to the operative site.
• Mental illness.
• Morbid obesity.
• Pregnancy.
• Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
• Signs of local inflammation.
• Suspected or documented metal allergy or intolerance.
These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
Contraindications of this device are consistent with those of other spinal systems.

POTENTIAL ADVERSE EVENTS
All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:
• Bone loss or decrease in bone density, possibly caused by stress shielding.
• Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
• Cessation of any potential growth of the operated portion of the spine.Loss of spinal mobility or function. Inability to perform the activities of daily living.
• Change in mental status.
• Death.
• Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
• Disassembly, bending, and/or breakage of any or all of the components.
• Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
• Early or late loosening of the components. Implant migration.
• Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
• Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the auto-graft, or at the bone graft harvest site-at, above, and/or below the level of surgery.
• Gastrointestinal complications.
• Graft donor site complications including pain, fracture, infection, or wound healing problems.
• Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
• Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
• Infection.
• Loss of neurologial function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
• Non-union (or pseudarthrosis). Delayed union. Mal-union.
• Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
• Scar formation possibly causing neurological compromise around nerves and/or pain.
• Subsidence of the device into vertebral body(ies).
• Tissue or nerve damage, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.
NOTE : Additional surgery may be necessary to correct some of these anticipated adverse events.

WARNING(S)
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. The LnK Cervical Interbody Fusion Cage System must be used with the LnK Anterior Cervical Plate Screws to augment stability. Use of this product without auto-graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.
Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good reduction are important considerations in the success of surgery.
Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation.
Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.
The LnK Cervical Interbody Fusion Cage System has not been evaluated for safety and compatibility in the MR environment.
The LnK Cervical Interbody Fusion Cage System has not been tested for heating or migration in the MR environment.

PRECAUTION(S)
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.

FOR US AUDIENCES ONLY
CAUTON : FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

CHOICE OF IMPLANTS
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure.
Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE
• Only patients that meet the criteria described in the indications should be selected.
• Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
• Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
• Further information on the use of this system will be made available on request.
• Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
• The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
• Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE
• The instructions in any available applicable surgical technique manual should be carefully followed.
• At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
• Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
• To assure proper fusion below and around the location of the instrumentation, auto-graft should be used. Auto-graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.When using the LnK Cervical Interbody Fusion Cage System, auto-graft should be used.
• Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

POSTOPERATIVE
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
• Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
• To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume excess alcohol during the bone healing process.
• The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
• Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device. It is important that immobilization of the union is established and confirmed by roentgenographic examination. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs.
• Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING
Compnents 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 use in surgery. Examination should be thorough, and in particular, should take into account 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, bruising or distortion, and that all components of the instrument are complete.
Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

STORAGE AND HANDLING
L&K BIOMED VENUS Cervical Interbody Device should be stored in a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

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.
Manual Cleaning procedure
• Use the neutral pH enzyme soaking solution that has been prepared.
• Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Use 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 : The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
• 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.
• Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
• Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
• 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 or until there is no sign of blood or soil in the rinse stream. Repeat Steps 5 and 6 with freshly prepared cleaning solution.
• Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.

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.
• Verify that the instruments are in operation condition.

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)	15 Minutes (Dry time, 15–30 Minutes)

It is important to note that a sterilization wrap, package or sterilization container system should be used to enclose the case or tray in order to maintain sterility.
Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be resterilized.

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' 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.

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.
Manufactured by:
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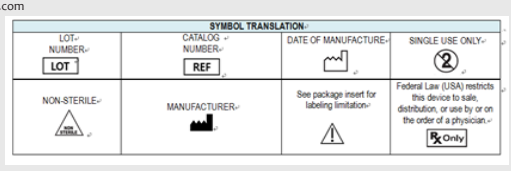

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