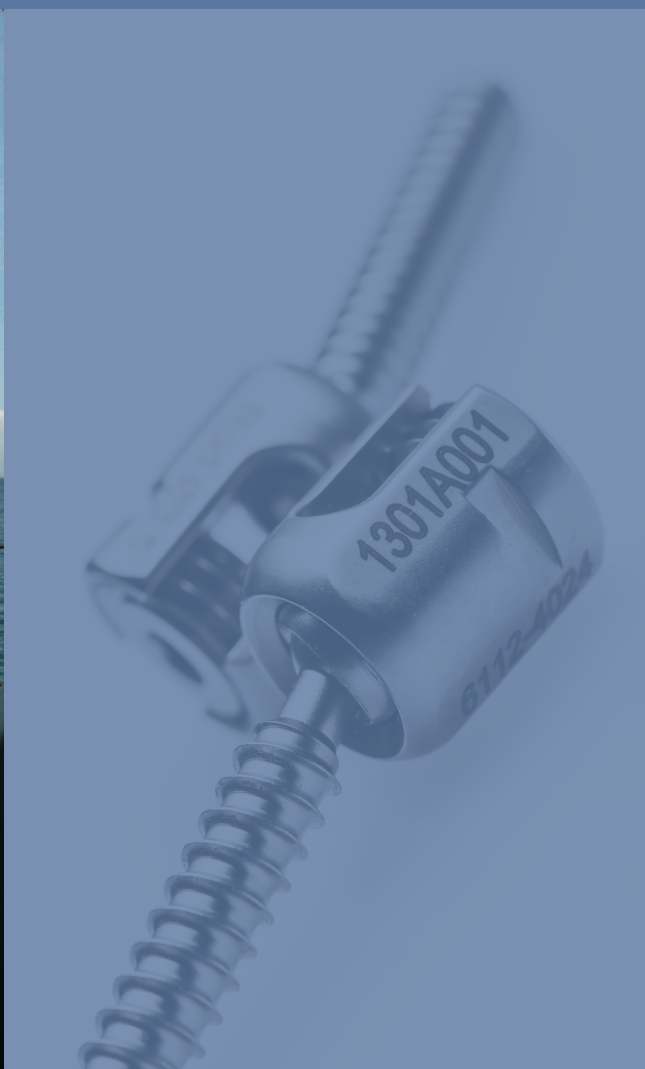
LnK
Cervical Screw System



LnK Posterior Cervical Screw

The LnK Cervical Fixation System provides a top-loading, simple and secure system for rigid fixation.
The LnK Cervical Fixation system includes instrumentation and spinal implants for posterior spinal fixation in the C1-T3 vertebral levels in the Cervical and upper levels of the thoracic spine.

Features:

- Top-loading polyaxial screws with friction heads enable quick and simple construct assembly
- Self-tapping flute centers screw for easy insertion
- Low profile screw head
- Two diameters with cancellous profile (3.5 mm & 4.0 mm Rescue Screw)
- 3.5 mm diameter rod
- 3.5 mm and 4.0 mm cancellous screws offer up to 45° angulation
- Pre-cut and pre-contoured rods eliminate the need to cut and contour rods in the operating room
- Instrumentation designed for both MIS and open procedures

Indication

The LnK Cervical Fixation System is indicated for the following:

- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors
- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)

The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 –T3) spine.

The pedicle screws are limited to placement in T1 -T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

Poly Axial Screw			
Ø3.5mm		Ø4.0mm	
Cat.No.	Length	Cat.No.	Length
6111-3508	8mm	6111-4080	8mm
6111-3510	10mm	6111-4010	10mm
6111-3512	12mm	6111-4012	12mm
6111-3514	14mm	6111-4014	14mm
6111-3516	16mm	6111-4016	16mm
6111-3518	18mm	6111-4018	18mm
6111-3520	20mm	6111-4020	20mm
6111-3522	22mm	6111-4022	22mm
6111-3524	24mm	6111-4024	24mm
6111-3526	26mm	6111-4026	26mm
6111-3528	28mm	6111-4028	28mm
6111-3530	30mm	6111-4030	30mm
6111-3532	32mm	6111-4032	32mm
6111-3534	34mm	6111-4034	34mm
6111-3536	36mm	6111-4036	36mm
6111-3538	38mm	6111-4038	38mm
6111-3540	40mm	6111-4040	40mm
6111-3542	42mm	6111-4042	42mm
6111-3544	44mm	6111-4044	44mm
6111-3546	46mm	6111-4046	46mm
6111-3548	48mm	6111-4048	48mm
6111-3550	50mm	6111-4050	50mm

Reduction Poly Axial Screw			
Ø3.5mm		Ø4.0mm	
Cat.No.	Length	Cat.No.	Length
6112-3508	8mm	6112-4080	8mm
6112-3510	10mm	6112-4010	10mm
6112-3512	12mm	6112-4012	12mm
6112-3514	14mm	6112-4014	14mm
6112-3516	16mm	6112-4016	16mm
6112-3518	18mm	6112-4018	18mm
6112-3520	20mm	6112-4020	20mm
6112-3522	22mm	6112-4022	22mm
6112-3524	24mm	6112-4024	24mm
6112-3526	26mm	6112-4026	26mm
6112-3528	28mm	6112-4028	28mm
6112-3530	30mm	6112-4030	30mm
6112-3532	32mm	6112-4032	32mm
6112-3534	34mm	6112-4034	34mm
6112-3536	36mm	6112-4036	36mm
6112-3538	38mm	6112-4038	38mm
6112-3540	40mm	6112-4040	40mm
6112-3542	42mm	6112-4042	42mm
6112-3544	44mm	6112-4044	44mm
6112-3546	46mm	6112-4046	46mm
6112-3548	48mm	6112-4048	48mm
6112-3550	50mm	6112-4050	50mm

Reduction Poly Axial Screw			
Ø3.5mm		Ø4.0mm	
Cat.No.	Length	Cat.No.	Length
6113-3508	8mm	6113-4080	8mm
6113-3510	10mm	6113-4010	10mm
6113-3512	12mm	6113-4012	12mm
6113-3514	14mm	6113-4014	14mm
6113-3516	16mm	6113-4016	16mm
6113-3518	18mm	6113-4018	18mm
6113-3520	20mm	6113-4020	20mm
6113-3522	22mm	6113-4022	22mm
6113-3524	24mm	6113-4024	24mm
6113-3526	26mm	6113-4026	26mm
6113-3528	28mm	6113-4028	28mm
6113-3530	30mm	6113-4030	30mm
6113-3532	32mm	6113-4032	32mm
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6113-3538	38mm	6113-4038	38mm
6113-3540	40mm	6113-4040	40mm
6113-3542	42mm	6113-4042	42mm
6113-3544	44mm	6113-4044	44mm
6113-3546	46mm	6113-4046	46mm
6113-3548	48mm	6113-4048	48mm
6113-3550	50mm	6113-4050	50mm

Straight Rod(Ø3.5mm)			
Cat.No.	Length	Cat.No.	Length
6121-3580	80mm	6121-35160	160mm
6121-3590	90mm	6121-35170	170mm
6121-35100	100mm	6121-35180	180mm
6121-35110	110mm	6121-35190	190mm
6121-35120	120mm	6121-35200	200mm
6121-35130	130mm	6121-35220	220mm
6121-35140	140mm	6121-35240	240mm
6121-35150	150mm		

Curved Rod(Ø3.5mm)			
Cat.No.	Length	Cat.No.	Length
6122-3580	80mm	6122-35160	160mm
6122-3590	90mm	6122-35170	170mm
6122-35100	100mm	6122-35180	180mm
6122-35110	110mm	6122-35190	190mm
6122-35120	120mm	6122-35200	200mm
6122-35130	130mm	6122-35220	220mm
6122-35140	140mm	6122-35240	240mm
6122-35150	150mm		

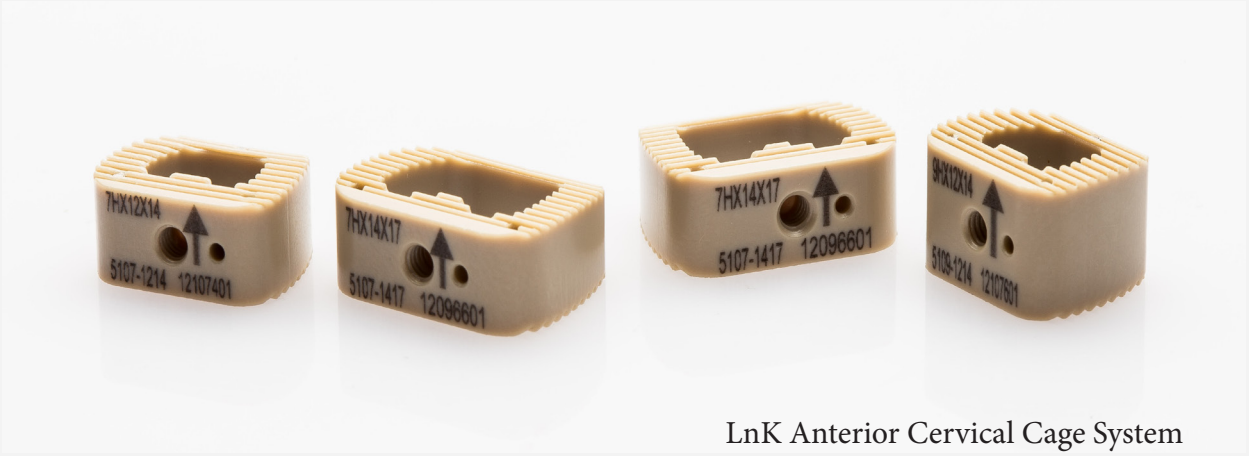
Set Screw	
Cat.No.	Type
6101-6036	Hexa
6102-6036	Star
6103-7037	Hexa
6104-7037	Star

Hook					
Lamina Hook		Angled Hook(Right)		Angled Hook(Left)	
Cat.No.	Length	Cat.No.	Length	Cat.No.	Length
6131-1604	16mm	6132-1704	17mm	6133-1704	17mm
6131-1705	17mm	6132-1805	18mm	6133-1805	18mm
6131-1806	18mm	6132-1906	19mm	6133-1906	19mm

Description	Catalog #
Awl	CS01-0101
Probe-Straight	CS01-0102
Probe-Curved	CS01-0103
Depth Gauge	CS01-0104
Tester-Straight	CS01-0105
Tester-Curved	CS01-0106
Drill Guide	CS01-0201
Drill Bit 2.6 mm length 12mm	CS01-0326A
Drill Bit 2.6 mm length 14mm	CS01-0326B
Tap 3.0mm length 12mm	CS01-0430A
Tap 3.0mm length 14mm	CS02-0430B
Tap 3.5mm length 12mm	CS01-0435A
Tap 3.5mm length 14mm	CS02-0435B
Torque Limiting Driver	CS01-0601
Alignment Guide	CS01-0603
Quick Screw Driver	CS01-0604
Anti-Torque Device	CS01-0605
Set Screw Driver	CS01-0606
Poly Screw Driver	CS01-0607
Set Screw First Driver	CS01-0608
Semi Reduction Poly Screw Driver	CS01-0609
Reduction Poly Screw Driver	CS01-0610
Set Screw Driver(Star)	CS01-0611
Set Screw First Driver(Star)	CS01-0612
Rod Holder	CS01-0702
Rod Template	CS01-0703
Rod Cutter	CS01-0704
Bender	CS01-0706
In-Situ Bender Left	CS01-0707
In-Situ Bender Right	CS01-0708
Compressor	CS01-0710
Distractor	CS01-0711
Reduction Cutter	CS01-0712
Quick Coupling Handle	CP01-0501

Also available.

LnK Anterior Cervical Plate System



LnK Anterior Cervical Cage System

LnK MIS System

LnK Screw Fixation System

IMPORTANT NOTE

Before using a product placed on the market by L&K Biomed, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical technique). L&K Biomed is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection, and similar matters outside the control of L&K Biomed.

Compatibility between all L&K Biomed Spine product lines, including acquisitions of pre-existing product lines, has not been established. Only authorized combinations of products should be used. Only use as indicated in the Instructions for Use (Package Insert) and/or the Surgical Technique.

DEVICE DESCRIPTION

The LnK Cervical Fixation System is a top-loading, multiple component, posterior (cervical-thoracic) spinal fixation system which consists of polyaxial screws, reduction poly screw ,straight rods, curved rods, set screws, hooks and hook set screws.

Materials: All products are made of titanium alloy (Ti-6Al-4V ELI/ in conformance with ASTM F136) approved for medical use.

INDICATIONS

The LnK Cervical Fixation System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)

Spondylolisthesis

Spinal stenosis

Fracture/dislocation

Failed previous fusion

Tumors

The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/upper thoracic (C1 –T3) spine.

The pedicle screws are limited to placement in T1 -T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

GENERAL CONDITIONS OF USE

The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with the surgical and medical indication, the potential risks and limitations related to the this type of surgery, the contra-indications, side effects, and precautions defined, and in the knowledge of the nature and metallic, metallurgic and biological characteristics of the implants to be used.

It is recommended the LnK Cervical Fixation System should not be used together with implants from a different source, a different manufacturer, or made from a different material. If this should occur, L&K BIOMED Co., Ltd. declines all responsibility.

Under no circumstances may the implants be re-used; although the device may appear infect on removal, internal modifications due to the stresses and strains placed on it, or small defects may exist, which may lead to the fracture of the implant.

CONTRA-INDICATIONS

Contraindications include, but are not limited to:

1. Infection, systemic, spinal or localized
2. Morbid obesity
3. Signs of local inflammation
4. Fever or leukocytosis
5. Metal sensitivity/allergies to the implant materials
6. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
7. Grossly distorted anatomy due to congenital abnormalities
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)
9. Any case not needing a bone graft and fusion or where fracture healing is not required
10. Any case requiring the mixing of metals from different components
11. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
12. Any case not described in the indications
13. Any patient unwilling to cooperate with the postoperative instructions
14. Any time implant utilization would interfere with anatomical structures or expected physiological performance.

POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS

Possible adverse effects include, but are not limited to:

1. Bending, loosening or fracture of the implants or instruments
2. Loss of fixation
3. Sensitivity to a metallic foreign body, including possible tumor formation
4. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications
5. Nonunion or delayed union
6. Infection
7. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage
8. Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium
9. Pain or discomfort
10. Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra)
11. Hemorrhage of blood vessels and/or hematomas
12. Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/ or height
13. Bursitis
14. Bone graft donor site pain
15. Inability to resume activities of normal daily living
16. Reoperation
17. Death

PRECAUTIONS

1. SURGCAL IMPLANTS MUST NEVER BE REUSED.

An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.

Contouring of metal implants should be done only with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage of the implant.

3. BENDING THE CONSTRUCT.

Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured it is recommended that a new construct is contoured correctly rather than reverse bending the over-contoured construct.

4. REMOVAL OF THE IMPLANT AFTER HEALING.

If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from post-operative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved in a second surgery.

1. ADEQUATELY INSTRUCT THE PATIENT.

Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and participating in any type of sports. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

WARNING

In using metallic surgical implants, the surgeon should be aware of the following:

The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.

The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including corrosive environments. They should be carefully unpacked and inspected for damage prior to use.

Correct handling of the implant is extremely important. Contouring of the metal devices is to be avoided.

All implants and instruments must be cleaned and sterilized prior to surgery.

Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together. The LnK Cervical Fixation System should not be used with components from any other system or manufacturer.

As with all orthopaedic implants, the LnK Cervical Fixation System should never be reused under any circumstances.

Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

Postoperative care is important. The patient should be instructed in the limitations of his/her metallic implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

Correct handling of the implant is extremely important. Contouring of the metal devices is to be avoided.

The LnK Cervical Fixation system has not been evaluated for safety and compatibility in the MR environment. The LnK Cervical Fixation system has not been tested for heating or migration in the MR environment.

PACKAGING, LABELING AND STORAGE

1.The implants are supplied non-sterile.

2. The implants are delivered in packages; these must be intact at the time of receipt. All the legal information required for this type of implants is given on the label of each package.

3. The implants may be delivered as a complete set: implants and instrumentation are set out on specially designed trays in boxes which can be sterilized directly.

4. Use care in handling and storage of implant components. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instrument components or implants have been damaged during storage or prior procedures.

5. LnK Cervical Fixation System non-sterile medical devices (implants & instrumentation) must be cleaned and sterilized before use according to the procedures detailed below.

STERILIZATION PROCEDURES

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}, L&K BIOMED recommends the following parameters:

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

GUARANTEE

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

CAUTION

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

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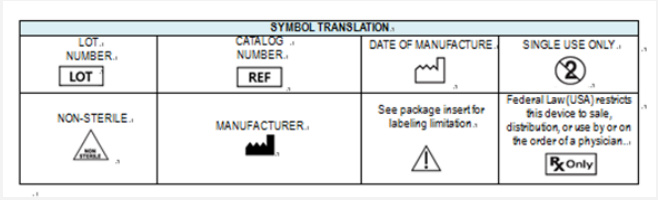

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