MIS Screw System

Surgical Technique

Contents

LnK MIS System for minimally invasive posterior rod and screw fixation. Ii is designed to minimize soft tissue trauma by using a transmuscular approach and subfascial rod insertion. Patient benefits from the reduced trauma by less pain, shorter hospitalization and shortened recovery time.

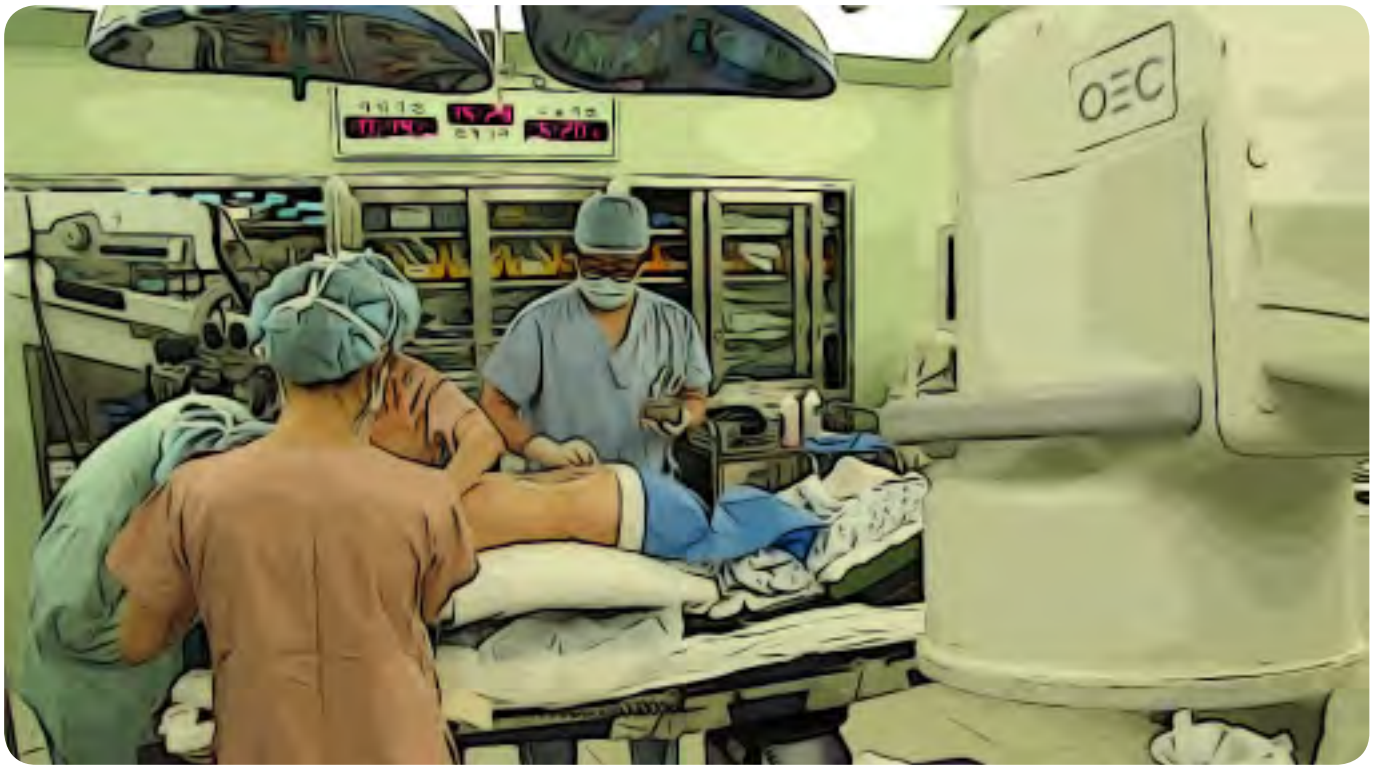
LnK MIS System is based on wire guided insertion of cannulated polyaxial long sleeve screws and sleeve guided rod insertion through the same incision.
The instruments provide the surgeon with tactile feedback and have built in safety mechanisms.
The logical flow of the surgery guarantees for efficients and excellent results.

Design Rationale

Cannulated Poly Axial Screw

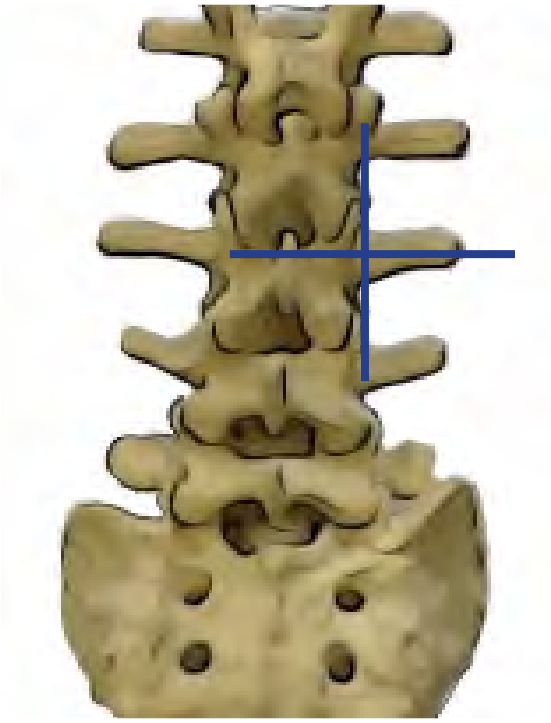
Consists of three components: the screw shank, the tulip portion of the screw, and pressure valve.
The screw shank has a combine thread type that the core is conical upper region and cylindrical lower region and cylindrical out thread.
Long sleeve cannulated screw with 30mm extra long thread can make easy reduction of rod with less invasive surgery.
Unique thread pitch offers improved pullout strength in the vertebral body.
360° total angulation.
A pressure valve within the tulip head lock the Poly Axial Screw into a Fixed Angle Screw when toque with a Set Screw.
This also maintains a friction fit allowing the tulip to remain in place during Rod and Set Screw application.

Patient Positioning



The Patient should be positioned prone, lying flat on the table. Verify that adequate fluoroscopic images of the pedicles can be obtained in both AP and Lateral view before proceeding.

Fluoroscopic Planning of Incision Points



To determine the incision point, identify the entry point of the pedicle, which is at the intersection of the superior facet and the transverse process, with the fluoroscopic imaging of the C-arm on AP view. The incision point is located at 1cm lateral or more depending on patient size - to the targeted pedicle entry point. This is to achieve an ideal guide path for
the pedicle screw by considering muscles and the depth from the skin to the pedicle entry point.

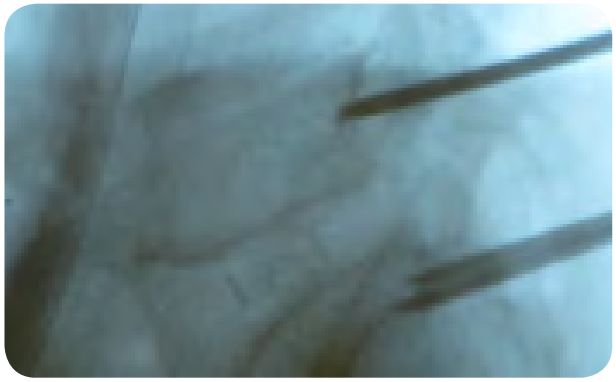
Mark the incision point using a skin marker.

*Jamshidi needle can be used to verify the appropriate location of the skin incision.

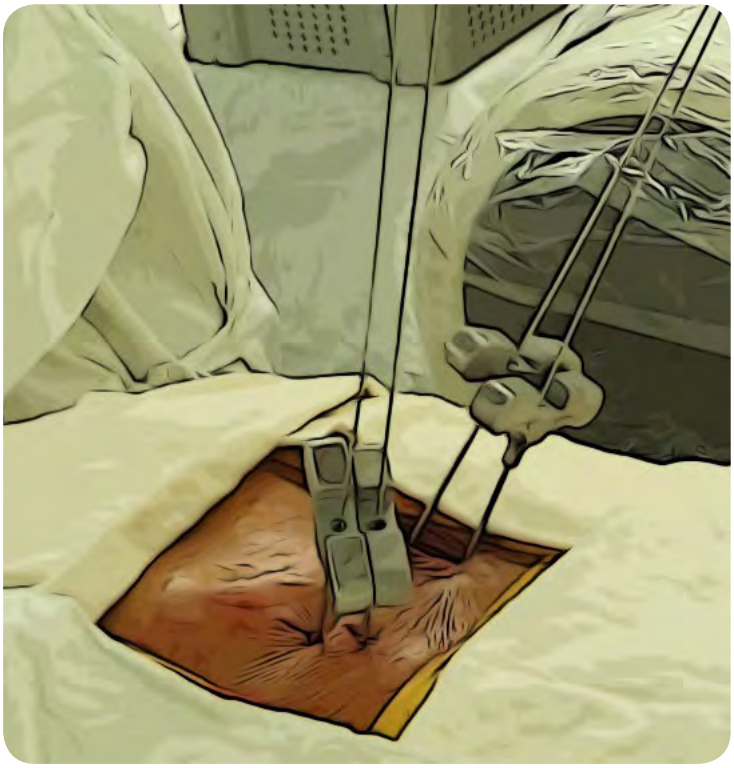
Jamshidi Needle Docking

Both AP and Lateral images are refer to confirm that the appropriate starting place has been determined, confirm the needle has been positioned at pedicle's lateral, superior margin. Advance Jamshidi needle to desired depth within vertebral body.

Confirm Jamshidi Needle PositionPoints



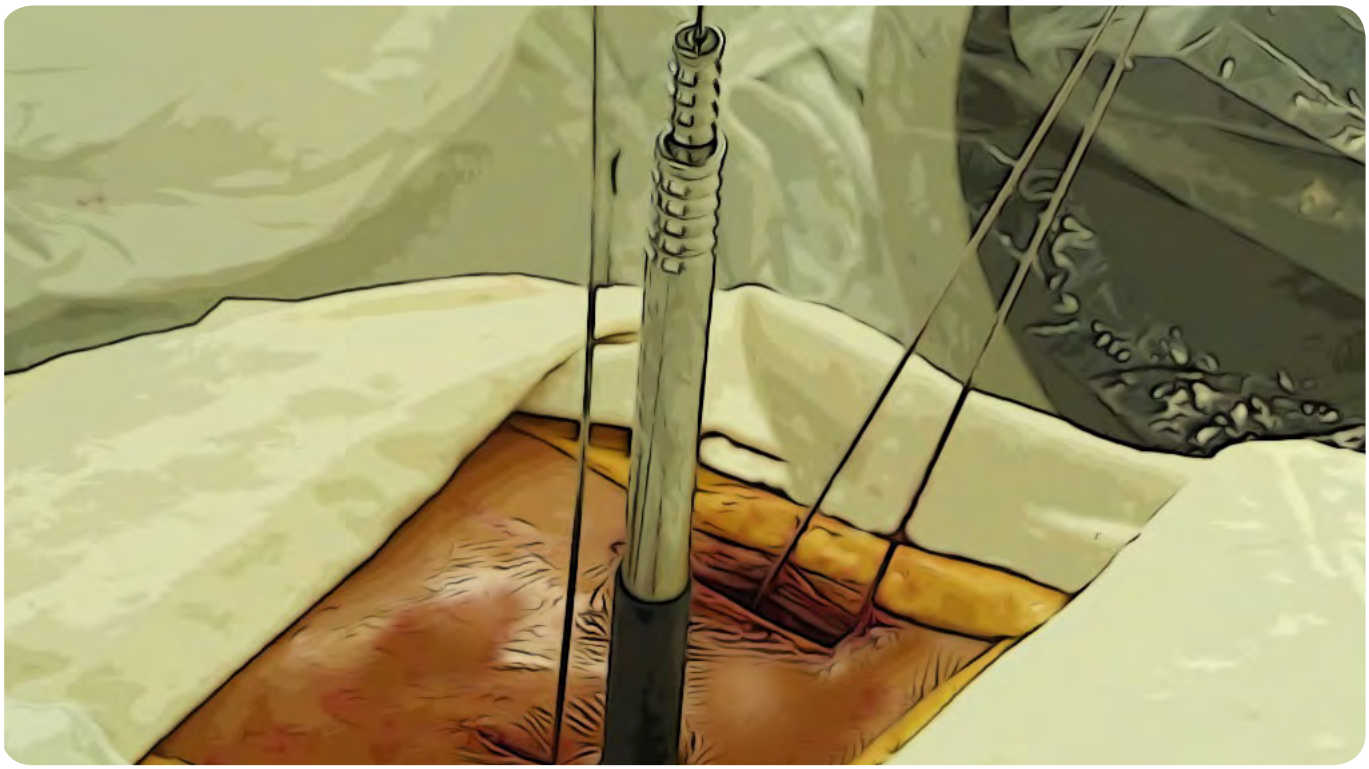
Guide wire insertion



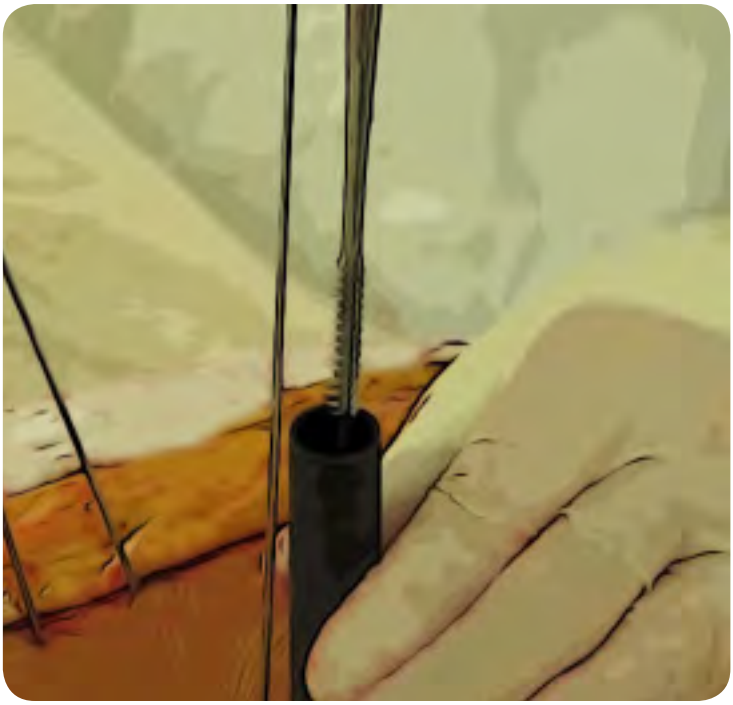
With the Jamshidi needle docked, remove sharp stylet and insert guide wire through cannulated sheath. Remove the Jamshidi sheath with remaining inserted guide wire, then impact guide wire with mallet. With guide wire firmly docked, remove targeting needle.!

Muscle Dilation

Place first of three dilators over guide wire; repeat with each dilator until all docked on pedicle. Once final dilator is placed, Remove inner two dilators..



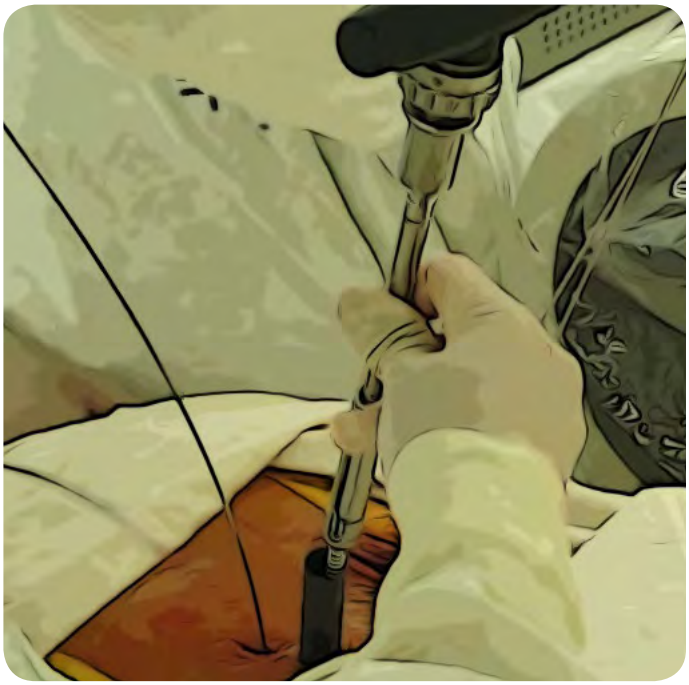
Pedicle Preparation



Pass the cannulated Drill bit over the guide wire, further perforating cortical bone and remove drill bit. Place Tap over the guide wire, fluoroscopically verifying that Tap does not advance further than wire's distal tip.

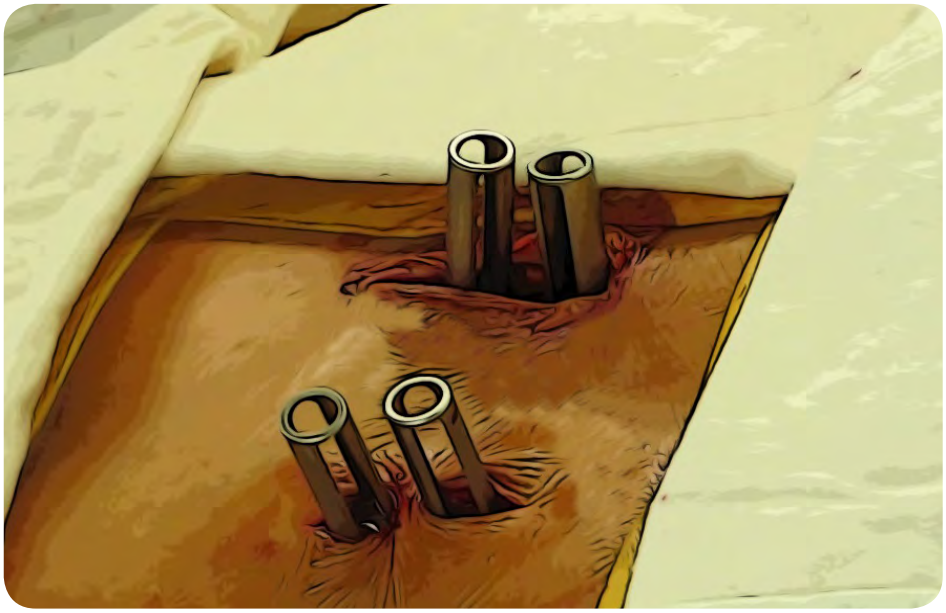
Long Sleeve Percutaneous Screw Insertion

Slide screw over guide wire, advancing it into pedicle under fluoroscopic guidance by reaching right position of vertebral body. Remove guide wire, continuing to advance screw until head snug against facet joint base. Turn one quarter rotation counterclockwise, ensuring poly-axial function. Remove screwdriver and dilator, with leaving screw only.



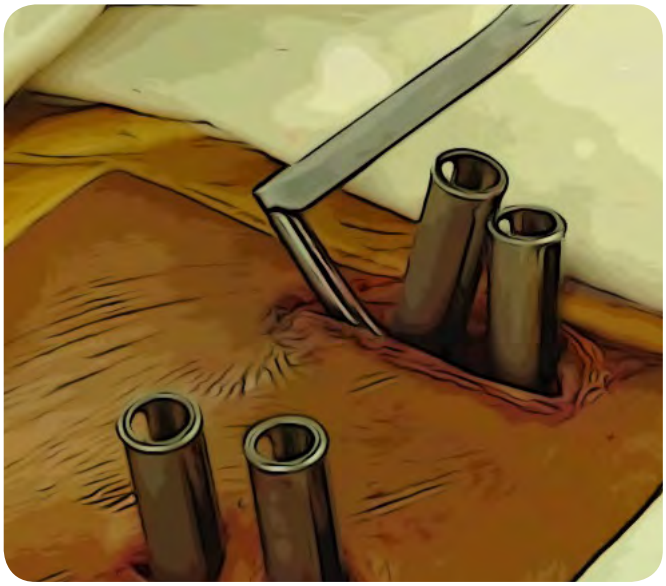
Additional Screw Placement

Insert Targeting Needle down Extender Sleeve and wand to second pedicle via newly created path. Fluoroscopically confirm accurate pedicle targeting and place additional screw in same manner as first.



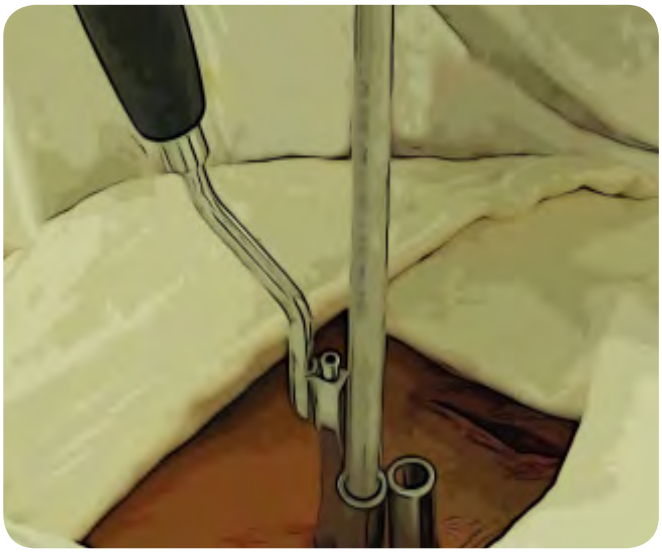
Rod Placement

Before insertion of rod, you can use pre-bent rod or with bending the rod. The important thing for rod bending is 'MUST' bend the rod without detach the rod inserter. With rod inserter, guide rod down to Sleeves of Screw into screw heads. Fluoroscopically confirm rod position. If rod is not reduced to the head of the screw, set screw can be used for reduction of the rod in the housing of the screw.



Closure Set Screw Placement

Place the set screw through the sleeve to the screw head.

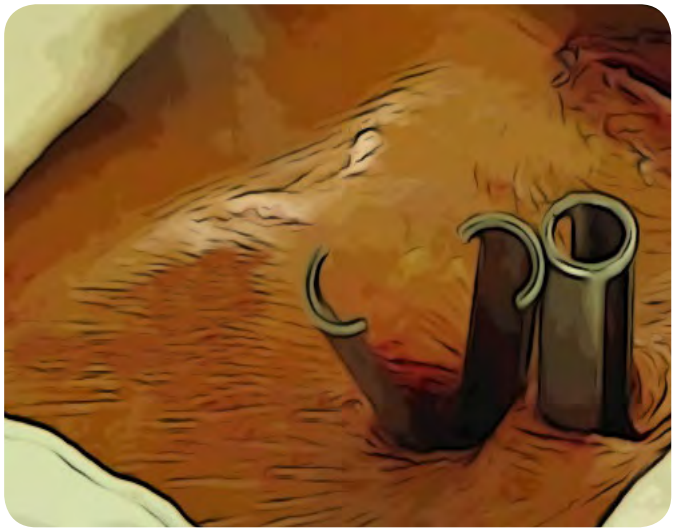


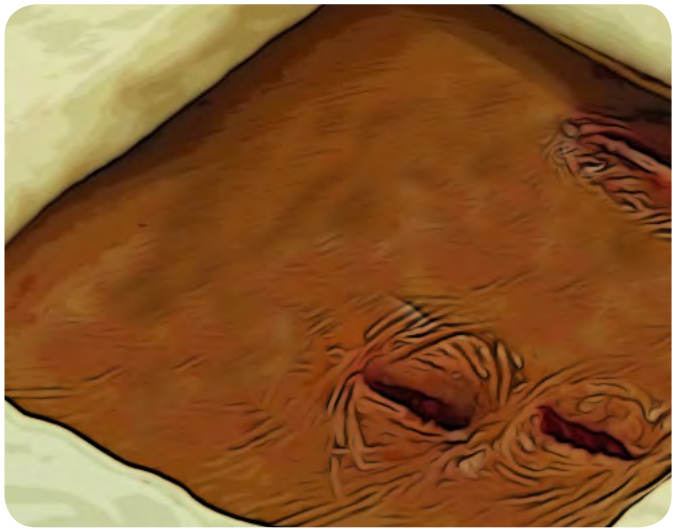
Final Tightening

Set screw is tightened with audible click torque limit handle and screw driver adaptor. Rod inserter can be used as the anti Torque device. Tighten the set screw firmly until hearing click sound.

Removal Of Sleeves

Cut the ring of screw completely and insert the sleeve breaker into the sleeve. Break the sleeve by pulling or pushing with a cutting bar and remove cut sleeves





Removal Procedures

The 4.5mm hexa driver should be used on axis for the removal of set screw first. And then remove Rod by Rod holder. And use the 4.0mm hexa Quick Removal driver can be used for Pedicle screw removal.

Revision Procedures

After the removal of pedicle screw, you can revise with larger diameter of long sleeve poly axial screws by the same procedure as above procedures or standard pedicle screw insertion procedure.

Long Sleeve Percutaneous Screw

Description	Catalog #
(POLY)5.5 x 30mm	2712-5530
(POLY)5.5 x 35mm	2712-5535
(POLY)5.5 x 40mm	2712-5540
(POLY)5.5 x 45mm	2712-5545
(POLY)5.5 x 50mm	2712-5550
(POLY)5.5 x 55mm	2712-5555
(POLY)5.5 x 60mm	2712-5560
(POLY)6.5 x 30mm	2712-6530
(POLY)6.5 x 35mm	2712-6535
(POLY)6.5 x 40mm	2712-6540
(POLY)6.5 x 45mm	2712-6545
(POLY)6.5 x 50mm	2712-6550
(POLY)6.5 x 55mm	2712-6555
(POLY)6.5 x 60mm	2712-6560
(POLY)7.5 x 30mm	2712-7530
(POLY)7.5 x 35mm	2712-7535
(POLY)7.5 x 40mm	2712-7540
(POLY)7.5 x 45mm	2712-7545
(POLY)7.5 x 50mm	2712-7550
(POLY)7.5 x 55mm	2712-7555
(POLY)7.5 x 60mm	2712-7560

Instrument

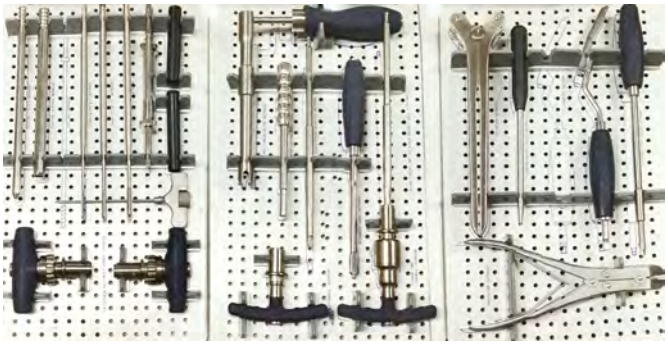
Description	Catalog #
1/4"Square Ratchet T-Handle	LS01-0502
Modular T-Handle	LS02-0301
Torque Limit T-Handle	LS01-0504
In-Line Torque Limiting Set Set Screw Driver	LS02-0407
Dilator 1.8-10.0	LS02-0101
Dilator 10.0-14.0	LS02-0102
Dilator 14.0-16.0	LS02-0103
Cannula Tap 4.5	LS02-0245
Cannula Tap 5.5	LS02-0255
Cannula Tap 6.5	LS02-0265
Rod Inserter	LS02-0401
Set Screw Driver Adaptor	LS02-0402
4.0Hex Screw Cannula Driver	LS02-0403
Inserter Driver 3.0Hex	LS02-0404
Set Screw First Driver I-Handle(Ball)	LS02-0405
Anti Torque Device	LS02-0406
Sleeve Cutting Bar Type-1	LS02-0501
Rod Bender	LS02-0503
Pin Cutter	LS02-0504
Alignment Guide	LS02-0505
Drill Bit	LS02-0506
Stainless Steel K-Wire	LS02-1648
K-Wire(Nitinol) 1.5*480mm	LS02-1748
Spinal Needle	LS02-0601
MIS SYSTEM IMPLANT TRAY	LS02-8006
MIS SYSTEM IMPLANT COVER	LS02-8007

MIS Rod

Description	Catalog #
Pre-bent 6.0x 35mm	2526-6035
Pre-bent 6.0x 40mm	2526-6040
Pre-bent 6.0x 45mm	2526-6045
Pre-bent 6.0x 50mm	2526-6050
Pre-bent 6.0x 55mm	2526-6055
Pre-bent 6.0x 60mm	2526-6060
Pre-bent 6.0x 65mm	2526-6065
Pre-bent 6.0x 70mm	2526-6070
Pre-bent 6.0x 75mm	2526-6075
Pre-bent 6.0x 80mm	2526-6080
Pre-bent 6.0x 85mm	2526-6085
Pre-bent 6.0x 90mm	2526-6090
Pre-bent 6.0x 95mm	2526-6095
Pre-bent 6.0x 100mm	2526-60100
Straight 6.0x 35mm	2516-6035
Straight 6.0x 40mm	2516-6040
Straight 6.0x 45mm	2516-6045
Straight 6.0x 50mm	2516-6050
Straight 6.0x 60mm	2516-6060
Straight 6.0 x 70mm	2516-6070
Straight 6.0 x 80mm	2516-6080
Straight 6.0 x 90mm	2516-6090
Straight 6.0 x 100mm	2516-60100
Straight 6.0 x 110mm	2516-60110
Straight 6.0 x 120mm	2516-60120
Straight 6.0 x 130mm	2516-60130
Straight 6.0 x 140mm	2516-60140
Straight 6.0 x 150mm	2516-60150
Straight 6.0 x 160mm	2516-60160
Straight 6.0 x 170mm	2516-60170
Straight 6.0 x 180mm	2516-60180
Straight 6.0 x 190mm	2516-60190
Straight 6.0 x 200mm	2516-60200

Set screw

Description	Catalog #
Set screw	1302-0000



LnK MIS Spinal System

Purpose
The LnK Spinal System is intend to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic,
lumbar, and/or sacral spine with open surgery or minimal invasive surgical approach.

Description
The LnK MIS Spinal System consists of a variety of shapes and sizes of rods, screws, crosslink, set screw. You can use and compatible cross-link
with both LnK BASIC Spinal Fixation System and LnK MIS Spinal System implant components are made out of medical grade titanium alloy described by such standards as ASTM 136 L&K BIOMED expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made implied warranties of merchantability and fitness for a particular purpose or uses are specifically excluded. See the LnK MIS Spinal System catalog for further information about warranties and limitations of liability. Never use stainless steel and titanium implant components in the same construct. To achieve best result, do not use any of the LnK MIS Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or L&K BIOMED document. As with all orthopaedic and neurosurgical implants, none of the LnK MIS Spinal System components should ever be refused under any circumstances.

INDICATIONS
The LnK MIS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. And the LnK MIS Spinal System can be used in an open approach and a percutaneous approach with MIS instrumentation. The LnK MIS Spinal System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and for lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.
When used in a percutaneous approach with MIS Instrumentation, the LnK MIS Spinal System are intended for noncervical pedicle fixation and
nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and for lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

WARNING(S)
The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture,dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion(pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. The LnK MIS Spinal System has not been evaluated for safety and compatibility in the MR environment. The LnK MIS Spinal System has not been tested for heating or migration in the MR environment.

PRE-OPERATIVE PRECAUSIONS
Anyone using L&K Biomed products can obtain a Surgical Technique brochure by requesting one from a distributor or from L&K Biomed directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version. L&K Biomed devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by L&K Biomed. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient. To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable L&K Biomed Surgical Technique. Extreme care must be taken when the instruments are used near vital organs, nerves or vessels. Particular precautions must be taken when using the instruments in pediatrics. Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

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

PRECAUTION(S)
The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

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:
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
Insufficient quality or quantity of bone which would inhibit rigid device fixation.
Previous history of infection.
Excessive local inflammation
Open wounds.
Any neuromuscular deficit which places an unusually heavy load 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.
Patients having inadequate tissue coverage of the operative site.
Pregnancy.
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 should be made prior to material selection or implantation.
Other medical or surgical conditions 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 theWBC differential count.
These contraindications 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 should warn patients of the above listed potential adverse effects, including the finite service life of the device and the need for postoperative protection of the implant.

PACKAGING
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked
for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged
packages or products should not be used, and should be returned to L&K BIOMED.

CLEANING AND DECONTAMINATION:
Unless just removed from an unopened L&K BIOMED package, all instruments and implants must be disassembled and cleaned using neutral
cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to L&K BIOMED. Cleaning and
disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures, Cleaning and decontamination must include the
use of neutral cleaners followed by a deionized water rinse.

NOTE: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some
devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.
All products should be treated with care. Improper use or handing may lead to damage and/or possible improper functioning of the device.

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, L&K BIOMED recommends the following parameters:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Gravity	270'F(132'C)	15 Minutes (Dry Time, 15~30Minutes)

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 thecomplaint.

For furtherinformation or complaints, please contact as below address:

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