Spinal System

Lospa IS

CRENTEC
IMPLANT SPECIALIST

Contents

I. Introduction

Lospa IS Spinal System aims for the spinal fixation system which resembles human anatomy closely while maximizing the surgeon's convenience and actively accepting the patient's demand. With this goal in mind, researchers at Corentec Co., Ltd. have created the spinal fixation system, adapting a new design concept of 'small but more commodious and strong like one's own'.

The design concept of Lospa IS is"Compromise". There is a precisely manufactured saddle inside of the pedicle screw and rod; therefore, even though the screw and the rod; the rod and rod are not perfectly fitted, an excellent fixation can be achieved with the saddle sliding. This epochal design will assist in easy and safe spinal fusion for one and all.

The design concept of Lospa IS is "Intelligent Innovation". Lospa IS is developed to solve the drawbacks of current spinal fixation systems, while considering the suitable spinal fixation system configuration for new generation. The surgeon can obtain a strong fixation without complications, avoiding the discomfort which the patient has after the usage of a high-profile fixation system.

Manufacturing Environment

The top-notch spinal fixation system at Corentec Co., Ltd. is manufactured by the specialized and long-term experienced experts from all over the world using the high-tech equipments and the highly regulated quality control system. The manufacturing facilities, newly established in 2005, include the most advanced manufacturing equipments: the environment-friendly streamlined purifying system; the cleanroom that fulfills the guidelines of the pharmaceutical affairs law; the safe operating zone with a constant level of temperature and humidity; and subsidiary facilities where staffs and visitors can make themselves at home. To lead in the future market, we're producing the new-concept spinal fixation system under the excellent working environment as described above.

II. Product Specification

[Pedicle Screw]

- Material: Ti-6Al-4V ELI (ASTM F 136-78)
- Having the low profile (Ø13mm x L 11mm) minimizes the post-surgical projection
- Available in Standard and Guided types to be selected to meet the surgeon's preference
- Anodized with various colors for distinguishing the different size
- The application of the double tapered thread has improved the screw's pull-out strength
- Self - tappered

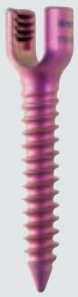
Set Screw

As the specially designed screw thread tightens the set screw, the screw head gets restrained, hence, even without a cap or a sleeve, a strong fixation can be obtained by the application of the set screw itself.

Rod

- Diameter: 6.0 mm
- Length: 40 - 500 mm

Monoaxial Pedicle Screw



Monoaxial Guided Pedicle Screw

Advanced Polyaxial Pedicle Screw

- Possible rotation of approximately 25°(50°-conical angle) from the axis of the housing of the rod
- Ability to stably place the rod even at a sudden rod bending

Rod Link

- It is simple assembling and strong stable fixation (Oblique fixation design)

Polyaxial Pedicle Screw

Polyaxial Guided Pedicle Screw

Ⅲ. Surgical Technique

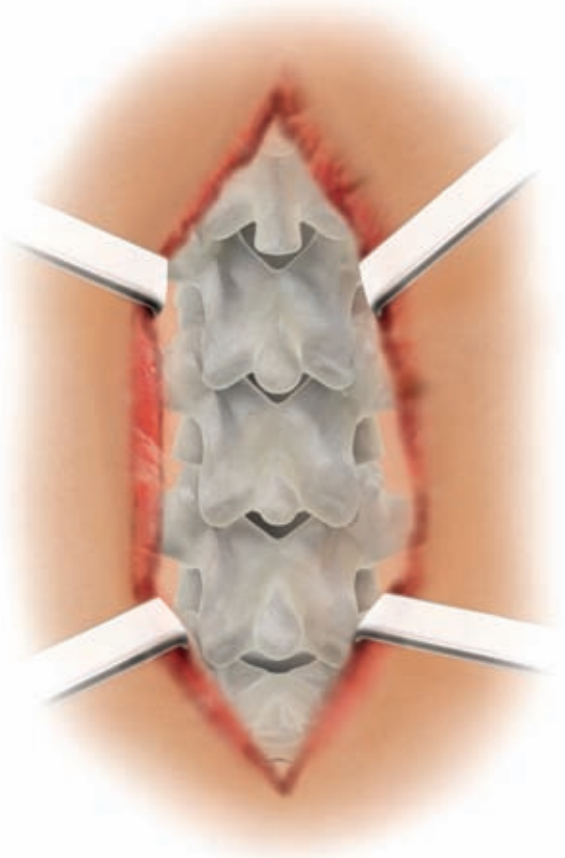
[Patient Positioning]

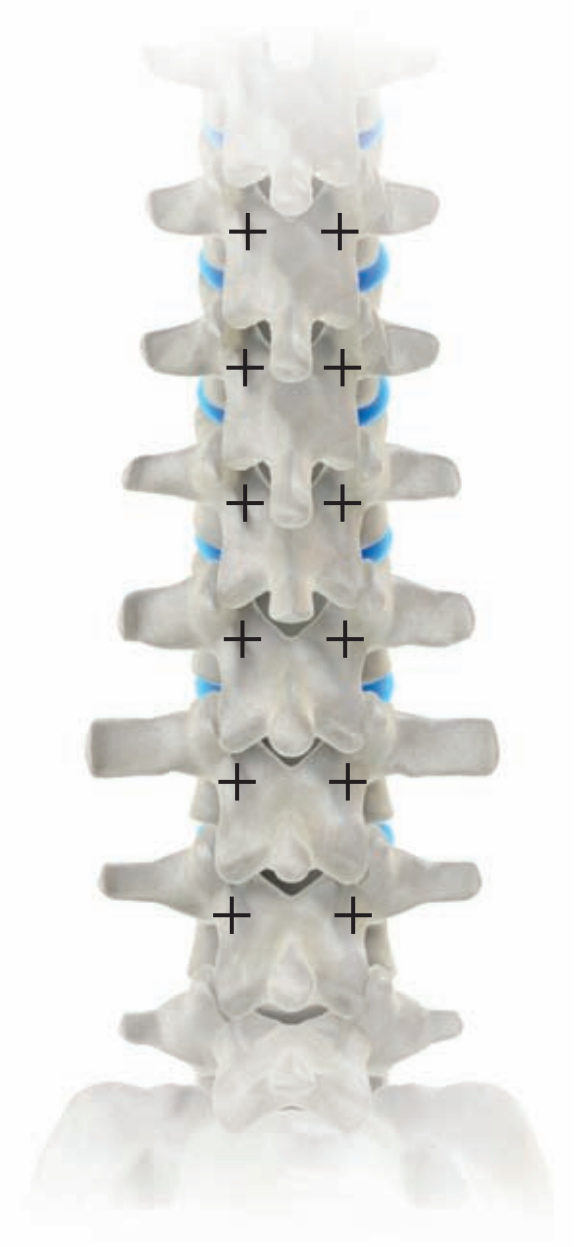
The patient is positioned on the operating table the prone position. There are numerous framed that can be used including, but not limited to The Wilson Frame, Chest Rolls, Relton Hall Frame, Heffington Frame, and the Andrews Frame. The patient should be positioned to minimize intra-abdominal pressure to avoid venous congestion and excess intra-operative bleeding and allow adequate ventilation under anesthesia. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbasacral junction.

[Exposure]

The surgical approach is carried out through a standard midline incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinous process should extend one additional level. The spinal column is then exposed in routine fashion by the surgeon and decompression in carried out needed.

Note :
Decortications and placement of bone grafts are usually done after pedicle screw preparation just prior to insertion of the pedicle screw. Meticulous fusion techniques are critical for success of the procedure.





[Pedicle Entry Point Location and Creation]

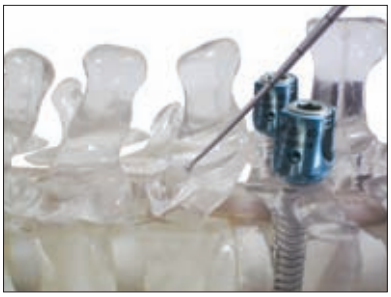
The pedicle entry point is intersected by the vertical line that connects the lateral edges of bony crest extension of the pars inter-articularis, and the horizontal line that bisects the middle of the transverse process. Anatomical variation in individual patients may cause slight differences in the entry site.

These differences should be considered carefully and noted on the pre-operative MRI, CT images and on the intra-operative x-ray. A small rongeur or a burr may be used to decorticate the pedicle entry point. The awl is used to make an entry hole though the cortex at the pedicle entry point.

[Pedicle Preparation]

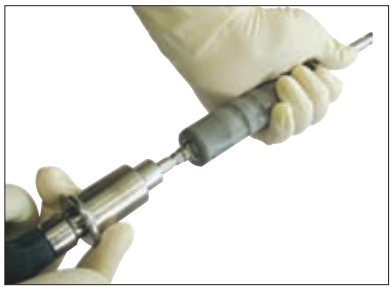
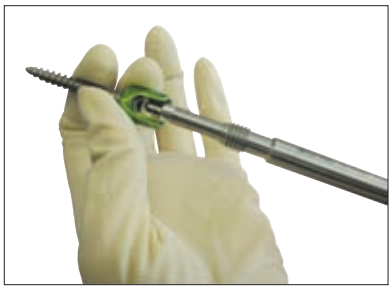
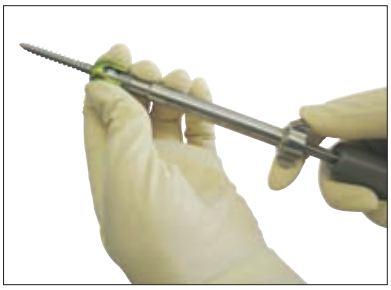
After the determination of the pedicle entry point location, pedicle hole is performed by using an Awl. The pedicles are opened up with the Probe. The probe is passed through the pedicle canal until the anterior cortex of the vertebral body is reached. The pedicle probe is calibrated in 5mm intervals and it helps indicate the pedicle depth.





[Assemble the Mono/Polyaxial Screw and Screwdriver]

1) Assemble the Mono/Poly axial screw Driver shaft and T or T – Ratchet handle.
2) Place tip of the Mono/Polyaxial Screwdriver in head of screw.
3) Thread Screwdriver into head of the screw making sure screw shank is straight.
4) Slide Screwdriver sleeve down over the head of Screw.

[Screw Insertion]

The pedicle screws are inserted using the Polyaxial/Monoaxial Screw Driver to the desired depth. Both of screw driver head are inserted into the of screw head. The pedicle screw should parallel the endplates and extend 50–80% into the vertebral body when fully seated.

[Rod Placement]

After the appropriate length of rod has been selected, place rod into Mono/Poly axial Screw Heads by using Rod Pusher or Persuader. The rod must be seated in the head of Lospa & Lospa IS Screw for locking.

Lordosis may be bent in to the rod via French bender. The polyaxial adjustability of the system eliminates the need for precision bending of the rod. A simple lordotic bending is sufficient and the amount of lordosis is based on the patient's anatomy and the amount of reduction to be achieved.
There are 3 alternatives for Rod insertion technique.

1) Rod Pusher : Rod Pusher allows rod to be seated firmly into the head of Lospa IS Screw.

2) Persuader : Center the persuader over the head squeeze handle to seat the rod into the poly axial screw head.

Note :
This persuader should be used with only for poly axial pedicle screw

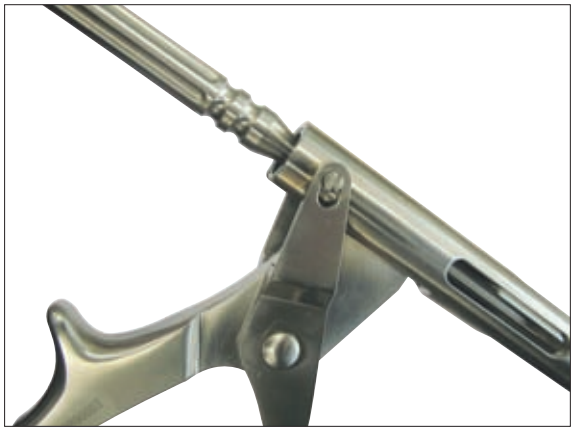
3) Mono Forcep : The holes in the tip of Mono Forcep placed on the hole of mono screw head, then push rod down rod to seat into the Mono axial screw head.

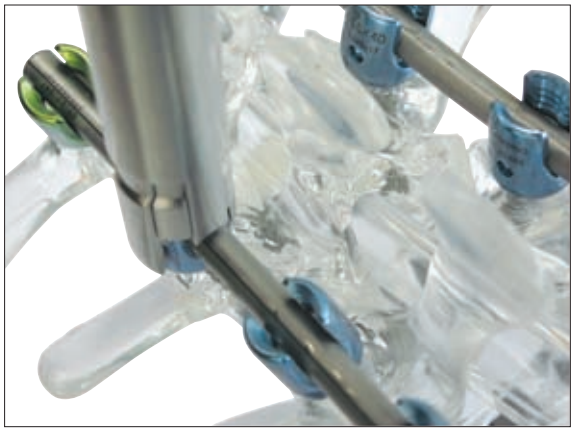
Note :
This Mono Forcep should be used with only for Mono axial pedicle screw

[Set Screw Application]

Insert the Set Screw Driver tip into a Set Screw and insert Screw Driver tip into canal of Persuader. Rotate the Screw Driver turn to the right to tighten Set Screw in the Lospa IS Screw. The screws and the Rod Pusher may be used to stabilize the head and manipulate the rod while inserting the set screw.

NOTE :
Do not over-tighten set screw without use of Anti-torgue wrench



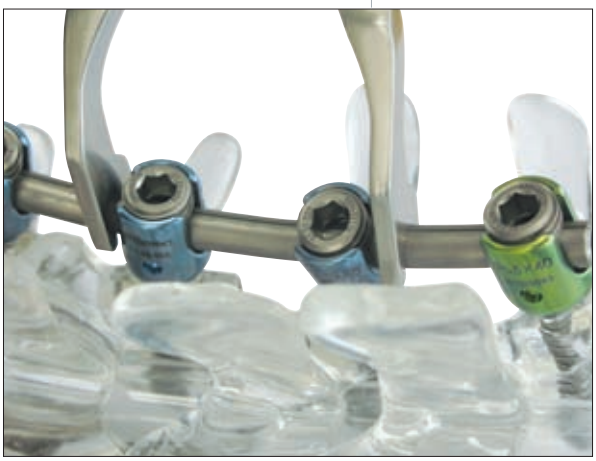


[Compression and Distraction]

After the construct has been properly assembled, segmental compression and distraction is accomplished as needed to adjust frontal or sagittal plane deformities.

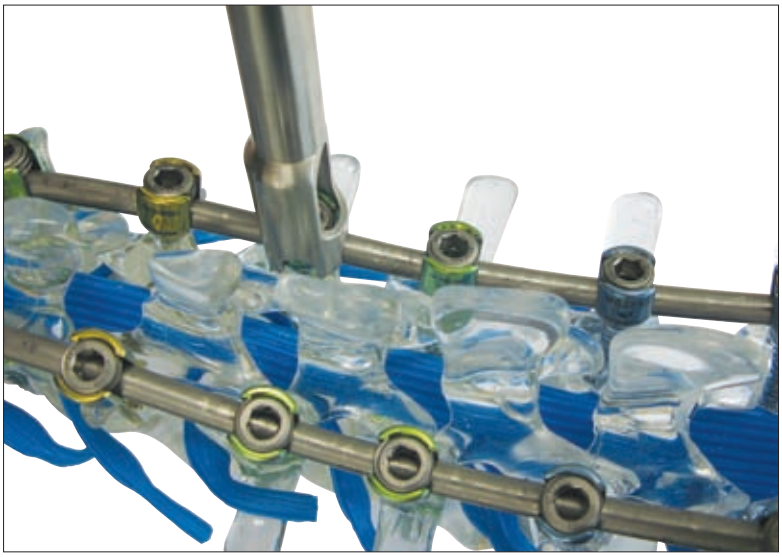
Compression is accomplished using Compressor. The Compressor fits onto the rod on the outside of the provisionally – tightened Lospa IS Screw to be compressed.
As the Compressor handle is closed, the loose Lospa IS Screw is drawn toward the other provisionally–tightened Lospa IS Screw.

Distraction is accomplished using Distractor. The Distractor fits onto the rod on the inside of the provisionally – tightened Lospa IS Screw to be distracted. As the Distractor handle is closed, the loose Lospa IS Screw is pushed toward the other provisionally–tightened Lospa IS Screw.



[Final Tightening]

After compression and distraction has been accomplished, the Anti Torque Wrench and Torque Limiting Set screw Driver are used for final tightening. The Torque Limiting Set screw Driver is designed to deliver the required torque to tighten the set screw. If set screw driver is used, it is inserted through canal of body of Anti Torque Wrench.



The Anti Torque Wrench is then inserted onto the outside of the screw, and turn the screw driver right with optimal torque within the limit of (12 N-m/ approximately 106 lbf-in), and alternatively, if Torque limiting set screw driver is used, turn the screw driver slowly clockwise until the optimal torque is achieved and an audible 'click' is heard from the driver. Each additional Set Screw then is secured.

[Rod Link Connection]

It is recommended the rod link is used to increase the rotational stability of the construct. Removal of the spinous process is recommended if rod link are used. Choose a rod link of appropriate length and apply the rod link to the rod. And use the rod link Driver, and then secure the rod link to rods by tightening the set screws by using Rod link driver. Finally, Rod Link Connection is completed by tightening the hexagonal screw in the middle of rod link by using Rod Link Driver.

NOTE :
Rod Link Driver(01.71.051) should be assembled with Torque Limiting Handle(01.71.059), that is designed with optimal Torque within the limiting 5N-m.

IV. Ordering Information

[Implant Specification]

Monoaxial Pedicle Screw

Picture	Part No.	Diameter x Length
	01.26.451	ø4.5 X 20mm
	01.26.452	ø4.5 X 25mm
	01.26.453	ø4.5 X 30mm
	01.26.454	ø4.5 X 35mm
	01.26.455	ø4.5 X 40mm
	01.26.456	ø4.5 X 45mm
	01.26.457	ø4.5 X 50mm
	01.26.458	ø4.5 X 55mm

Picture	Part No.	Diameter x Length
	01.26.551	ø5.5 X 20mm
	01.26.552	ø5.5 X 25mm
	01.26.553	ø5.5 X 30mm
	01.26.554	ø5.5 X 35mm
	01.26.555	ø5.5 X 40mm
	01.26.556	ø5.5 X 45mm
	01.26.557	ø5.5 X 50mm
	01.26.558	ø5.5 X 55mm

Picture	Part No.	Diameter x Length
	01.26.652	ø6.5 X 25mm
	01.26.653	ø6.5 X 30mm
	01.26.654	ø6.5 X 35mm
	01.26.655	ø6.5 X 40mm
	01.26.656	ø6.5 X 45mm
	01.26.657	ø6.5 X 50mm
	01.26.658	ø6.5 X 55mm

Picture	Part No.	Diameter x Length
	01.26.752	ø7.5 X 25mm
	01.26.753	ø7.5 X 30mm
	01.26.754	ø7.5 X 35mm
	01.26.755	ø7.5 X 40mm
	01.26.756	ø7.5 X 45mm
	01.26.757	ø7.5 X 50mm
	01.26.758	ø7.5 X 55mm

Picture	Part No.	Diameter x Length
	01.26.853	ø8.5 X 30mm
	01.26.854	ø8.5 X 35mm
	01.26.855	ø8.5 X 40mm
	01.26.856	ø8.5 X 45mm

Polyaxial Pedicle Screw

Picture	Part No.	Diameter x Length
	01.28.452	ø4.5 X 25mm
	01.28.453	ø4.5 X 30mm
	01.28.454	ø4.5 X 35mm
	01.28.455	ø4.5 X 40mm
	01.28.456	ø4.5 X 45mm
	01.28.457	ø4.5 X 50mm
	01.28.458	ø4.5 X 55mm

Picture	Part No.	Diameter x Length
	01.28.552	ø5.5 X 25mm
	01.28.553	ø5.5 X 30mm
	01.28.554	ø5.5 X 35mm
	01.28.555	ø5.5 X 40mm
	01.28.556	ø5.5 X 45mm
	01.28.557	ø5.5 X 50mm
	01.28.558	ø5.5 X 55mm

Picture	Part No.	Diameter x Length
	01.28.652	ø6.5 X 25mm
	01.28.653	ø6.5 X 30mm
	01.28.654	ø6.5 X 35mm
	01.28.655	ø6.5 X 40mm
	01.28.656	ø6.5 X 45mm
	01.28.657	ø6.5 X 50mm
	01.28.658	ø6.5 X 55mm

Picture	Part No.	Diameter x Length
	01.28.752	ø7.5 X 25mm
	01.28.753	ø7.5 X 30mm
	01.28.754	ø7.5 X 35mm
	01.28.755	ø7.5 X 40mm
	01.28.756	ø7.5 X 45mm
	01.28.757	ø7.5 X 50mm
	01.28.758	ø7.5 X 55mm

Monoaxial Guided Pedicle Screw

Picture	Part No.	Diameter x Length
	01.26.461	ø4.5 X 20mm
	01.26.462	ø4.5 X 25mm
	01.26.463	ø4.5 X 30mm
	01.26.464	ø4.5 X 35mm
	01.26.465	ø4.5 X 40mm
	01.26.466	ø4.5 X 45mm
	01.26.467	ø4.5 X 50mm
	01.26.468	ø4.5 X 55mm

Picture	Part No.	Diameter x Length
	01.26.561	ø5.5 X 20mm
	01.26.562	ø5.5 X 25mm
	01.26.563	ø5.5 X 30mm
	01.26.564	ø5.5 X 35mm
	01.26.565	ø5.5 X 40mm
	01.26.566	ø5.5 X 45mm
	01.26.567	ø5.5 X 50mm
	01.26.568	ø5.5 X 55mm

Picture	Part No.	Diameter x Length
	01.26.662	ø6.5 X 25mm
	01.26.663	ø6.5 X 30mm
	01.26.664	ø6.5 X 35mm
	01.26.665	ø6.5 X 40mm
	01.26.666	ø6.5 X 45mm
	01.26.667	ø6.5 X 50mm
	01.26.668	ø6.5 X 55mm

Picture	Part No.	Diameter x Length
	01.26.762	ø7.5 X 25mm
	01.26.763	ø7.5 X 30mm
	01.26.764	ø7.5 X 35mm
	01.26.765	ø7.5 X 40mm
	01.26.766	ø7.5 X 45mm
	01.26.767	ø7.5 X 50mm
	01.26.768	ø7.5 X 55mm

Picture	Part No.	Diameter x Length
	01.26.863	ø8.5 X 30mm
	01.26.864	ø8.5 X 35mm
	01.26.865	ø8.5 X 40mm
	01.26.866	ø8.5 X 45mm

Polyaxial Guided Pedicle Screw

Picture	Part No.	Diameter x Length
	01.28.462	ø4.5 X 25mm
	01.28.463	ø4.5 X 30mm
	01.28.464	ø4.5 X 35mm
	01.28.465	ø4.5 X 40mm
	01.28.466	ø4.5 X 45mm
	01.28.467	ø4.5 X 50mm
	01.28.468	ø4.5 X 55mm

Picture	Part No.	Diameter x Length
	01.28.562	ø5.5 X 25mm
	01.28.563	ø5.5 X 30mm
	01.28.564	ø5.5 X 35mm
	01.28.565	ø5.5 X 40mm
	01.28.566	ø5.5 X 45mm
	01.28.567	ø5.5 X 50mm
	01.28.568	ø5.5 X 55mm

Picture	Part No.	Diameter x Length
	01.28.662	ø6.5 X 25mm
	01.28.663	ø6.5 X 30mm
	01.28.664	ø6.5 X 35mm
	01.28.665	ø6.5 X 40mm
	01.28.666	ø6.5 X 45mm
	01.28.667	ø6.5 X 50mm
	01.28.668	ø6.5 X 55mm

Picture	Part No.	Diameter x Length
	01.28.762	ø7.5 X 25mm
	01.28.763	ø7.5 X 30mm
	01.28.764	ø7.5 X 35mm
	01.28.765	ø7.5 X 40mm
	01.28.766	ø7.5 X 45mm
	01.28.767	ø7.5 X 50mm
	01.28.768	ø7.5 X 55mm

[Implant Specification]

Rod

Picture	Part No.	Diameter x Length
	01.21.061	Rod ø6.0 X 40mm
	01.21.062	Rod ø6.0 X 50mm
	01.21.063	Rod ø6.0 X 60mm
	01.21.064	Rod ø6.0 X 70mm
	01.21.065	Rod ø6.0 X 80mm
	01.21.066	Rod ø6.0 X 90mm
	01.21.067	Rod ø6.0 X 100mm
	01.21.068	Rod ø6.0 X 110mm
	01.21.069	Rod ø6.0 X 120mm
	01.21.070	Rod ø6.0 X 130mm
	01.21.071	Rod ø6.0 X 140mm
	01.21.072	Rod ø6.0 X 150mm
	01.21.073	Rod ø6.0 X 160mm
	01.21.074	Rod ø6.0 X 170mm
	01.21.075	Rod ø6.0 X 180mm
	01.21.076	Rod ø6.0 X 190mm
	01.21.077	Rod ø6.0 X 200mm
	01.21.078	Rod ø6.0 X 250mm
	01.21.079	Rod ø6.0 X 300mm
	01.21.080	Rod ø6.0 X 350mm
	01.21.081	Rod ø6.0 X 400mm
	01.21.082	Rod ø6.0 X 450mm
	01.21.083	Rod ø6.0 X 500mm

Rod Link

Picture	Part No.	Length
	01.22.920	35~40mm
	01.22.921	40~50mm
	01.22.922	48~63mm
	01.22.923	60~78mm

Set Screw

Picture	Part No.	Diameter x Length
	01.22.020	ø10 X 5.0mm

[Instrument Specification]

01. 71. 001

AWL

01. 71. 002

Curved probe

01. 71. 003

Straight Probe

01. 71. 004

Tester

01. 71. 005

Alignment gauge (End Boss)

01. 71. 006

Alignment gauge (Middle Boss)

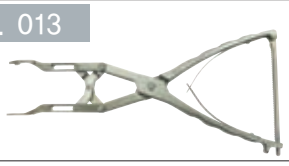
01. 71. 009

Power Gripper

01. 71. 012

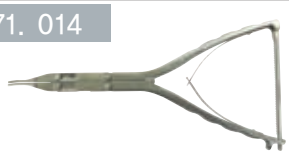
Rod Pusher

01. 71. 013



Compressor

01. 71. 014

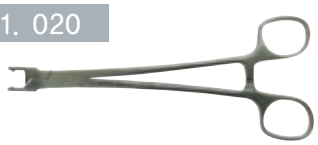


Distractor

01. 71. 016

French Bender

01. 71. 020



Mono Forcep

01. 71. 021

Persuader

[Instrument Specification]

01. 71. 023

Modular Set Screw Driver(Long)

01. 71. 024

I-Ratchet handle

01. 71. 025

T-Ratchet handle

01. 74. 027

Modular T-handle

01. 71. 033

Anti torque Wrench

01. 71. 039

5mm hexa Screw Driver-taperlook

01. 71. 048

Guide breaker

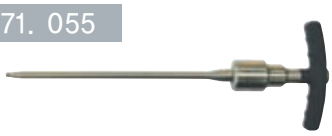
01. 71. 051

Modular Rod Link Driver

01. 71. 052

Modular Set Screw Driver(Short)

01. 71. 055



Torque Limiting Set Screw Driver

01. 71. 056

Modular Polyaxial Screw Driver

01. 71. 057

Modular Mono axial Screw Driver

01. 71. 059

Torque Limiting Handle

V. IFU for Lospa IS SPINAL SYSTEM

1. Description

The LOSPA IS spinal system consists of pedicle monoaxial and polyaxial screws, rod, rod link. The LOSPA IS spinal system components are available in titanium alloy (ASTM F136) or cobalt–chrome alloy (ASTM F1537) specifications.

2. Indications

The LOSPA IS Spinal Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

When used as an anterior screw fixation system, the LOSPA IS Spinal Systems are indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies, Spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudarthrosis, or revision of failed fusion attempts.

3. General Conditions of Use

The implants must be implanted only by physicians having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with the surgical and medical indications, the potential risks and limitations related to 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 that the LOSPA IS spinal 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, the LOSPA IS spinal system decline all responsibility.

Under no circumstances may the implants be re–used; although the device may appear intact 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.

4. Contraindications

- Any active or suspected latent infection in or about the spine.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- 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.
- Recent infection, fever, or leukocytosis.
- Bony abnormalities preventing safe screw fixation.
- Open wounds
- Metal sensitivity, documented or suspected

- Bone absorption, osteopenia and/or osteoporosis. (Osteoporosis is a relative contraindication, as the condition may limit the degree of correction obtainable and the amount of mechanical fixation.)
- Patient having inadequate tissue coverage over the operative site.
- Pregnancy
- Excessive local inflammation
- 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 the WBC differential count.

5. Adverse effects

- Late bone grafting or no visible fusion mass and pseudarthrosis
- Neurological complications, paralysis, soft tissue lesions, pain due to the surgical procedure, the breakage, the deformation and/or migration of the implant
- Pedicle failure while preparing and inserting pedicle screw
- Superficial or deep-set infection and inflammatory phenomena
- Allergic reaction to the material used (titanium alloy or cobalt-chrome alloy)
- Reduction in bone density due to a different distribution of mechanical stresses
- Pain and abnormal sensations due to hardware bulkness
- Neurological and spinal dura mater lesions from surgical trauma
- Bursitis
- Presence of microparticles around the implants
- Growth of the fused vertebrae is altered
- Partial loss of the degree of correction achieved during surgery
- Modification of spinal curvature and stiffness of the vertebral column

The above list of side effect is not exhaustive. These side effects can sometimes necessitate further surgical treatment.

6. Precaution

- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- 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) resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may be so advanced at the time of implantation that they may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal fixation systems requires detailed knowledge of spinal surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome.
- Patients should be instructed 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 patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants.
- Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

CAUTION : Federal Law restricts this device to sale by or on the order of a licensed physician only.

7. Warning

- The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines
- Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.
- Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.
- Contouring or bending of a screw or hook may reduce its fatigue strength and cause failure under load. If spinal screws or hooks are bent or otherwise damaged during insertion or adjustment, they must not be implanted and must be replaced. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted.
- Mixing Metal : Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals.
- Because different manufactures employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the LOSPA IS spinal system should not be used in conjunction with components from any other manufacture's spinal system. Any such use will negate the responsibility of Corentec Co, Ltd. for the performance of the resulting mixed component implant.
- Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically.
- Any decision by a physician to remove the internal fixation 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.
- Implant removal should be followed by adequate postoperative management to avoid fracture.
- The LOSPA IS Spinal System have not been evaluated for safety and compatibility in the MR environment. The LOSPA IS Spinal System have not been tested for heating or migration in the MR environment.

8. Packaging, Labeling and Storage

- The implants are supplied non-sterile.
- 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.
- The implants may be delivered as a complete set : implants and instrumentation are set out on specially designed trays or in boxes which can be sterilized directly.
- Use care in handing 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.

9. Sterilization

LOSPA & LOSPA IS spinal system and its instrumentation are delivered NON-STERILE. Hence all implants and instruments used in the surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products must be place in the operative field.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table. The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying.

We recommend autoclaving according to standard hospital sterilization procedures and within the guidelines of autoclave manufacturer. The recommended sterilization parameters for LOSPA & LOSPA IS and its instrumentation are as follows.

Cycle type	Parameter	Minimum Setting value
Gravity-displacement	Exposure Temperature	132℃ (270℉)
	Exposure Time	15 Min.
	Dry Time	20 Min.
Vacuum	Exposure Temperature	132℃ (270℉)
	Exposure Time	4 Min.
	Dry Time	20 Min.

Validated by ANSI/ AAMI/ ISO 11737-1 & 11737-2 / USP 〈71〉

IMPORTANT : Any explicit instructions/ operations by the Sterilizer Manufacturer must ultimately be followed. Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contact with all surfaces.

CAUTION : Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Verify that the instruments are in operation condition.

10. Storage and disposal

– Store at cool temperature without sunlight.
– Used or fractured products should be returned to local representative to dispose safely.

11. Guarantee

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

REF	Catalogue Number		Do not use if package is damaged
LOT	Batch Code		Do not reuse
	Data of manufacture		Keep away sunlight
Rx only	Caution : Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.		Manufacturer
	Caution (follow the instructions for use)	EC REP	Authorized Representative in the European Community

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