

INSTRUCTIONS LEAFLET

LDR Spine – USA

Easyspine® Posterior Spinal System: Sterile

CE 0459



WARNINGS

- 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 severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, 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.
- Risks associated with general surgery, orthopedic surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is also recommended that the advantages and disadvantages of surgery, the implants, as well as alternative treatment methods be explained to the patient.
- 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, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudoarthrosis, disc height loss, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, expulsion
- Discard all damaged or mishandled implants.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the implant.
- Implants removed from a patient that contact bodily tissues or fluids should never be reused at risk of contamination of the patient.
- Internal fixation devices cannot withstand activity and loads 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 an implant other than rods, may reduce its fatigue strength and cause its failure. If spinal implants (except rods) are bent or otherwise damaged during insertion or adjustment, they may 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 (e.g. stainless steels and titanium), 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 may also increase. Internal fixation devices such as rods, connectors, screws, hooks, etc, which come into contact with other metal objects must be made from like or compatible metals.
- Because different manufacturers employ different materials, varying tolerances, manufacturing specifications, and differing design parameters, components of the Easyspine® Posterior Spinal System should not be used in conjunction with components from any other manufacturer's spinal systems. Any such use will negate the responsibility of LDR Spine USA 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 surgeon 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 Easyspine® Posterior Spinal System has not been evaluated for safety and compatibility in the MR environment.
- The Easyspine® Posterior Spinal System has not been tested for heating or migration in the MR environment.

PRECAUTIONS

- Being a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of pedicle screw systems should be performed only by experienced spine surgeons with specific training in the use of this system and who have knowledge of the present instruction for use.
- The surgeon should consider the level of implantation, the weight of the patient, the patient's activity level or general conditions and any other factor which may have an impact on the performance of the system based on published fatigue test results of the system.
- Patients who smoke have been shown to have an increased risk 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 of significant loads, or muscle strain), resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life to the device. 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 system. 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 should be taught to govern their activities accordingly. Internal fixation appliances are load sharing devices which hold a segment in alignment until healing occurs. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. 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. 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 implants.)
- Care must be taken to protect the components from being marred, nicked or notched as a result of a 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.
- Inspection and trial assembly are recommended prior to surgery to determine if the instruments have been damaged during storage or prior procedures.

IMPORTANT NOTE

The users of the Easyspine® Posterior Spinal System must read and acknowledge the conditions in this insert, prior to use.

BASIC STRUCTURE

The Easyspine® Posterior Spinal System is a single use device for mono- and multi-segmental stabilization of the lumbar and thoracic vertebrae to promote fusion. The Easyspine® Posterior Spinal System consists of sacral and pedicle screws cross connections, hooks, and rods of different rigidities. Associated instrumentation is designed for implantation of these devices and for the distraction, compression or reduction of the lumbar and thoracic spine.

MATERIAL

All implants of the Easyspine® Posterior Spinal System are made of surgical titanium alloy (Ti6Al4V), which complies with ASTM F136. Instruments used to implant the System are made of medical grade stainless steel.

INDICATIONS FOR USE

The Easyspine® Posterior Spinal System is a posterior, non cervical pedicle and non pedicle system 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 of the thoracic, lumbar and sacral spine:

- 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
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Note: The Easyspine® Posterior Spinal System Surgical Technique should be followed carefully. Important information on the proper usage of implants and instruments is included.

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 surgical and medical indications, the potential risks and limitations related to this type of surgery, the contraindications, side effects and precautions. The surgeon should also possess knowledge of the metallurgical and biological characteristics of the implants.
- It is recommended that the Easyspine® Posterior Spinal System not be used in conjunction with implants from a different source, a different manufacturer or made from a different material. If this should occur, LDR Spine USA declines all responsibility.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the implant.

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 post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and or fixation to the implant.
- Obesity 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 hyper-leukocytosis
- Bony abnormalities preventing safe screw fixation
- Open wounds
- Metal sensitivity, documented or suspected
- Bone absorption, osteopenia and/or osteoporosis
- Patients having inadequate tissue coverage over the operative site
- Pregnancy
- Excessive local inflammation
- Other medical (for example : anesthetics risks) 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.

SIDE EFFECTS

- Late bone grafting or no visible fusion mass and pseudoarthrosis
- Neurological complication, paralysis, soft tissue lesions, pain due to the surgical procedure, breakage deformation and or migration of the implant
- Pedicle fracture while preparing and inserting the pedicle screw
- Superficial or deep-set infection and inflammatory phenomena
- Allergic reaction to the Ti6Al4V ELI alloy
- Reduction in bone density due to different distribution of mechanical stresses
- Pain and abnormal sensations due to hardware bulkiness
- Neurological and spinal dura matter lesions from surgical trauma
- Bursitis
- Presence of micro-particles 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 effects is not exhaustive. These side effects can sometimes necessitate further surgical treatment.

LDR SPINE USA cannot be held responsible for any complications arising from:

- incorrect diagnosis,
- choice of incorrect implants or operating techniques,
- limitations of treatment methods,
- inadequate asepsis,
- any change in the product after delivery in your establishment,
- incorrect handling before, during and after the intervention.

PACKAGING, LABELING & STORAGE

- Implants removed from a patient that contact bodily tissues or fluids should never be reused.
- The implants are delivered in packages. These must be intact at the time of receipt. The labeling with each package includes the Instructions Leaflet, individual patient labels, and external package labeling.
- The Easyspine® Posterior Spinal System implants come in sterile double packaging.
- The packaging is impermeable and prevents product contamination in normal conditions of handling and transport.

- It is necessary to check the integrity of the packaging before use.
- Store in a clean, dry environment at ambient (room) temperature.

CLEANING AND STERILIZATION PROCEDURES

All the Easyspine® Posterior Spinal System implants range, being cleaned and irradiated by gamma radiation with a minimum dose of 25 kGy, are delivered sterile and non-pyrogenic. The packaged implant is sterile for 5 years provided that the packaging remains intact. The implants are for single use and should not be re-sterilized.

Manual Cleaning Procedure – Instruments Only

1. Use the neutral pH enzyme soaking solution that has been prepared.
 2. 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.*
3. 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.
 4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
 5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
 6. 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.
 7. Repeat Steps 5 and 6 with freshly prepared cleaning solution.
 8. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.

Automated Cleaning Procedure – Instruments Only

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 sodium hydroxide (NaOH) is prohibited. 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 Procedure – Instruments Only

- All instruments of the Easyspine® Posterior Spinal System are provided non-sterile.
- Recommended method to achieve a degree of sterility equal to at least 10⁻⁶. Sterilize by the autoclaving procedure with parameters being at least the ones described below.

Steam condition	Temperature	Sterilization time
Steam, Pre-vacuum Cycle	134° C (273° F)	18 min

CALIBRATION SPECIFICATIONS

It is recommended that the torque wrenches receive periodic calibration and maintenance at a qualified facility.

COMPLAINTS

Any healthcare professional (e.g. a surgeon using a product) who has a complaint or is dissatisfied with the quality, identification, reliability, safety, efficacy, and/or performance of the system should notify LDR Spine USA. In the event of an incident or risk of a serious incident liable to result in, or to have resulted in, the death or serious deterioration in the health condition of a patient or user, telephone, fax or letter should notify LDR SPINE USA as soon as possible. All complaints should be accompanied by the name(s), reference(s), and batch number(s) of the component(s). The person formulating the complaint should give as many details as possible and state the response required. For further information, kindly contact LDR Spine USA.

= See package insert for labeling limitations = Do not re-use = Do Not Use if the Packaging is Damaged	= Batch number = Catalog number = Do not re-sterilize	= Sterile (by radiation) = Expiration date <p style="text-align: right;">Rx Only</p>
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For further information, including the surgical technique manual, kindly contact LDR Spine:

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