INSTRUCTIONS FOR USE

Important Information – Please Read Prior to Use

IFU NO: **JIPL-IFU-03-TSFS**

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SRN: DE-AR-000004974

Device System Name:

Thoraco Lumbar Spinal Fixation System

Implantation to be performed by a qualified surgeon

JAYON

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1. Device Description

Thoracolumbar spinal fixation System is a multiple component system comprised of a variety of non-sterile, single use components, made of titanium, that allow the surgeon to build a spinal implant construct. The systems are attached to the vertebral body by means of screw. Thoracolumbar Fixation System consists monoaxial screws, Polyaxial screws, Polyaxial reduction screws, connecting rods straight, connecting rods contoured and locking screws. All the screws and rods are available in a variety of diameters and lengths. Thoracolumbar Spinal Fixation System implants are not compatible with components or metal from any other manufacturer's system.

Material used for thoraco lumbar fixation system is Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136 Polyaxial, Uniaxial, Monoaxial, reduction Screws, set screws, connectors and rods.

2. Intended use:

To stabilize and strengthen the spine conditions including spondylolisthesis, chronic degenerative disc disease, traumatic fracture, tumor, infections and other forms of spinal instability including scoliosis.

Spinal fixation devices function to reduce deformities and fractures, stabilize the spine, and replace vertebrae because of disease or abnormality. Spinal fixation is used in the thoracic spine to provide stability and restore anatomic alignment in the treatment of fractures, degenerative disease, and infection and to correct deformities such as scoliosis. Internal fixation provides immediate stability, but the devices are of inadequate strength to withstand prolonged periods of stress and will eventually fail in most cases if bone fusion does not occur. Internal fixation is used to maintain position and alignment and to prevent motion as the bone fuses.

In certain clinical situations, the Thoracolumbar Spinal Fixation System (TSFS) may be used in conjunction with intervertebral body fusion cages or corpectomy cages to achieve spinal stability and promote fusion. Intervertebral body fusion cages are used to restore disc height, provide stability, and allow bony fusion across the disc space, whereas corpectomy are intended to replace an entire vertebral body (or multiple) and provides load-bearing support to maintain spinal column height.

The decision to use cages in combination with the TSFS should be made by the operating surgeon based on patient pathology, anatomical considerations, and the overall surgical plan.

Target population for Thoracolumbar Spinal Fixation System (TSFS) is adults.

3. Indication for use:

Thoraco lumbar fixation system is intended for posterior, pedicle fixation of the spine. The system is intended to be used as an adjunct to fusion using auto graft. The device is indicated for all of the following indications.

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and imaging studies)
2. Spondylolisthesis
3. Trauma (i.e., fracture or dislocation)
4. Spinal stenosis
5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis

The Thoracolumbar Spinal Fixation System is intended for use in the non-cervical spine for posterior pedicle fixation. It provides additional support during fusion procedures using autograft or allograft in adults for the treatment of the above-mentioned acute and chronic instabilities or deformities.

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4. Contraindications:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, elevated white blood count, obesity, pregnancy and other medical conditions which would prohibit beneficial surgical outcome.
- Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems or manufacturers.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.
- Do not use this system in patients with known or suspected metal allergies.
- MRI: The safety and performance of the device in the MR environment have not been established, as MRI compatibility testing/evidence is not available.

5. Potential Adverse Events:

- These devices can break, loosen or back out when subjected to increased loading associated with delayed union or non-union.
- Foreign body (allergic) reaction to implants, debris formation from corrosion products, including metallosis, tissue staining, and immune responses to the materials, extrusion of graft material.
- Pressure on the skin from components in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Vertebral body fracture at, above, or below the level of surgery.
- Loss of neurological function, including paralysis (complete or incomplete).
- Non-union, delayed union.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Hemorrhage.
- Cessation of any potential growth of the operated portion of the spine.
- Hematoma
- Death

Note: Additional surgery may be necessary to correct some of these adverse events.

6. Warnings and Precautions:

- The implantation of the thoraco-lumbar spinal fixation system must be performed only by an orthopaedic surgeon experienced in spinal surgery, with specific training in the use of this thoraco-lumbar spinal fixation system, because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Re-use of devices labeled as single-use, could result in injury or re-operation due to breakage or infection.
- Do not re-sterilize single use implants that come in contact with body fluids.
- Corrosion/Metal compatibility: Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Thus, mixing implant components from different manufacturers is not recommended for metallurgical, mechanical and functional reasons.
- The screws, rods and instruments are sold non-sterile and therefore must be sterilized before use.
- The implants are provided non-sterile. Prior to use, each implant must be sterilized according to standard hospital

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procedure.

- Based on the fatigue testing results, the physician should consider the levels of implantation, patient's weight, patient's activity level, and other patient conditions which may impact the performance of the system.
- To optimize bony union, perform an anterior discectomy or corpectomy as indicated.
- To facilitate fusion, a sufficient quantity of autologous bone should be used.
- Excessive torque applied to the screws while fastening may strip the threads in the bone.
- Failure to achieve arthrodesis will result in eventual loosening and failure of the construct.
- Thoraco lumbar spinal fixation system fixation has not been evaluated for safety and compatibility in the MR environment.
- 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 medical implants, which may require additional surgery include.
  1. Device or component failure (bending, loosening or failure).
  2. Loss of fixation.
  3. Non-union.
  4. Fracture
  5. Neurological injury.
  6. Vascular and visceral injury.
  7. Neurological complications.
  8. Over distraction.
  9. Trauma to nerve root or dura.
  10. Incorrect implant positioning.
  11. Implant migration.
  12. Allergic or inflammation
  13. General adverse effects related to surgical procedures (E.g.: anesthesia, infections),
  14. Expulsion

7. Implant Selection:

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical 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 post- operative management to minimize stresses on the implant, such stresses may cause metal 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.

8. Pre-operative:

- Carefully screen the patient, choosing only those that fit the indications described above.
- The implant is provided non-sterile and should be stored in its original packaging until sterilized. Prior to use, each implant must be sterilized according to standard hospital procedure. See "Sterilization" section for details.
- The implants should not be scratched bent repeatedly or otherwise damaged. Store away from corrosive environments.
- An adequate inventory should be available at surgery than the exact device expected to be used.
- All components and instruments should be cleaned and sterilized prior to each use. Additional sterile components should be available in case of an unexpected need.

9. Intra-operative:

- Instructions should be carefully followed.
- Extreme caution should be exercised around the spinal cord and nerve roots.
- The implant surface should not be scratched or notched since such actions may reduce the functional strength of the construct.
- Proper handling of the implant before and during the operation is crucial. Contouring of metallic implants should be avoided. Avoid sharp bends, reverse bending, notching or scratching the device, as these factors may produce internal stresses and weaken the implant.
- Bone grafts can be placed in the area to be fused such that the grafts fit snugly against the upper and lower vertebral

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bodies.

- Before closing the incision, check each screw to make sure that none have loosened.

10. Post-operative:

- The patient should be advised about the advantages and disadvantages of the implant and of any postoperative limitations.
- The patient should be advised about weight bearing and load bearing stresses on the device which could affect secure bone healing
- To achieve best results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process.
- The patient should be advised on their limitations and taught to compensate for this permanent physical restriction in body motion
- If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred
- The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the spine during the normal healing process. After the spine is fused, the devices serve no functional purpose and can be removed.

11. Cleaning and Decontamination:

All instruments and implants are provided non-sterile and must be sterilized prior to use. All components are sterilizable by steam autoclave using standard hospital practices.

Implants are supplied in steam sterilizable medical grade validated pouches. Implants and Instruments should be sterilized in closed container (provided by Jayon implants)

12. Sterilization:

Implants & Instruments:

The following procedure is applicable for both implants & instruments.

Carry out sterilization by steam autoclaving at 121°C Celsius/15 PSI pressure for 20 minutes in such a manner that protects the integrity of the implants. Do not sterilize implants in contact with instruments or implants of other materials. Metallic oxide could transfer to the implant, initiating undesirable conditioning. Re sterilization is possible upto 200 cycles.

Method	Cycle	Temperature	Minimum exposure time	Drying Time
Moist Heat	Pre-vacuum	(121 °c) at 15 Psi	20 min	20 min

Note:

- Steam sterilization should be carried out at the hospital.
- Because of the many variables involved in sterilization, each medical facility should calibrate & verify this sterilization process (E.g.: temperature, time) used for their equipment.

13. Packaging:

Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use.

The Jayon Thoraco lumbar spinal fixation system implants and instruments are provided in modular cases specifically intended to contain and organize each systems component. The instruments are organized into trays within each modular case for easy retrieval during surgery. The trays also provide protection to the system components during shipping. Additionally, individual instruments and implants are provided in sealed pack with individual product labels.

14. Storage:

Store implants prior to use in such a manner as to maintain the device's surface finish or configuration, or both. Implants

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are identified by a reference number and lot number on the package label, package insert, or surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting, and possible traceability to the manufacturer. Stock rotation, the principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant's surface, sterility, and configuration. Keep implants made of different metals separated. Store the implants in the operating room in such a manner as to isolate the instruments from the implants.

15. MRI compatibility Information:

Titanium is MRI Compatible as per researches carried out worldwide, hence Jayon Thoraco lumbar spinal fixation system need not been evaluated for safety and compatibility in the MR environment. Jayon Thoraco lumbar spinal fixation system has also not been tested for heating and migration in the MR environment.

16. Summary of Safety and Clinical Performance (SSCP):

The SSCP provides public access to an updated overview of the safety and clinical performance of the device. It does not replace the Instructions for Use as the primary document for safe device use, and it does not provide diagnostic or therapeutic guidance. This document includes information prepared in two levels of detail: one part for healthcare professionals and another simplified part for patients and laypersons.

The SSCP can be accessed online via the following web link. The SSCP is available at the bottom section of the webpage, providing users with the most up-to-date and authorized version for reference.

Click here to access the SSCP for Thoracolumbar Spinal Fixation System (TSFS).

16. Traceability:

There is always a lot/batch number on the label provided for each Jayon Thoraco lumbar spinal fixation system components. This label with batch number must be attached to the file of the patient in order to trace back production details. For the same reason distributional documents have to be maintained for 15 years.

17. Product Complaints:

Communicate suspected deficiencies in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance directly to **JAYON IMPLANTS PVT LTD** by email: feedbacks@jayon.in, +91-491-2566816.When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint, surgeon name and the date you became aware of the complaint. Sterilize and return all component(s) to your local Jayon Implants representative or distributor. Notify Jayon Implants immediately of an incident resulting in serious injury or patient death.

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- Date of manufacturing
- DO NOT REUSE
- NON-STERILE
- KEEP AWAY FROM SUNLIGHT
- KEEP DRY
- MD MEDICAL DEVICE
- DO NOT USE IF PACKAGE IS DAMAGED
- CONSULT INSTRUCTION FOR USE
- 30°C TEMPERATURE LIMITATION
- CAUTION : CARRY OUT STERLIZATION BY STEAM AUTOCLAVING BEFORE USE (REFER IFU)
  : IMPLANTATION TO BE PERFORMED BY A QUALIFIED SURGEON
- DE REP EUROPEAN REPRESENTATIVE

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JAYON