JAYON®
IMPLANTS PRIVATE LIMITED

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REPORT (SSCP) 2024-25

THORACOLUMBAR SPINAL FIXATION SYSTEM - TSFS

Summary of Safety and Clinical Performance

JAYON IMPLANTS PRIVATE LIMITED

SECTION-A (Information intended for healthcare professionals)

1. SUMMARY

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

2. DEVICE IDENTIFICATION AND GENERAL INFORMATION

2.1. Device trade names and specifications

SL NO	Generic Name	Component Name	Size of Medical Device in use (Dia/Length/Holes)	Type
1	Monoaxial Screw	Monolock Ultra Monoaxial Screw	Diameter; 4.5 mm to 7 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 60 mm (Range: 5 mm difference in length)	Class II b
2	Polyaxial Screw	Monolock Ultra Polyaxial Screw	Diameter; 4.5 mm to 7.5 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 120 mm (Range: 5 mm difference in length)	Class II b
3	Polyaxial screws	Monolock Ultra polyaxial Reduction Screw	Diameter; 4.5 mm to 7 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 60 mm (Range: 5 mm difference in length	Class II b

4	Polyaxial screws	DTAP Monolock Polyaxial Screw (SQ)	Diameter: 4.5 mm to 8 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 120 mm long (Range: 5 mm difference in diameter)	Class II b
5	Polyaxial screws	MIS Monolock Polyaxial Screw	Diameter: 4.5 mm to 7 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 70 mm (Range: 5 mm difference in length)	Class II b
6	Monoaxial Screw	Monolock Monoaxial Screw	Diameter: 4.5 mm to 7.0 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 60 mm (Range: 5 mm difference in length)	Class II b
7	Polyaxial screws	Monolock Polyaxial Screw	Diameter: 4.5 mm to 7.0 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 120 mm (Range: 5 mm difference in length	Class II b

8	Polyaxial screws	Monolock Polyaxial Reduction Screw	Diameter: 4.5 mm to 6.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm (Range: 5 mm difference in length)	Class II b
9	Polyaxial screws	Monolock Osteo Polyaxial Screw (SQ)	Diameter: 5.5 mm to 7.5 mm (Range: 0.5 mm difference in diameter) Length: 30 mm to 120 mm long (Range: 5 mm difference in length)	Class II b
10	Monoaxial Screw	Monolock Deformity Monoaxial Screw	Diameter: 4.5 mm to 6.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm long (Range: 5 mm difference in length)	Class II b
11	Polyaxial screws	Monolock Deformity Polyaxial Screw	Diameter: 4.5 mm to 7.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm long (Range: 5 mm difference in length)	Class II b
12	Uniaxial screws	Monolock Deformity Uniaxial Screw	Diameter: 4.5 mm to 6.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm long (Range: 5 mm difference in length)	Class II b

13	Polyaxial screws	Monolock Deformity Polyaxial Reduction Screw	Diameter: 4.5 mm to 6.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm long (Range: 5 mm difference in length)	Class II b
14	Connecting Rods Straight	MIS Monolock Straight Connecting Rod	Diameter: 5.5 mm Length: 30 mm to 350 mm	Class II b
15	Connecting Rods Contoured	MIS Monolock Contoured Connecting Rod	Diameter: 5.5mm Length: 30 mm to 350mm	Class II b
16	Connecting Rods Straight	Monolock Connecting Rod	Diameter: 5.5mm Length: 30 mm to 500mm	Class II b
17	Connecting Rods Straight	DTAP Connecting Rod	Diameter: 5.5mm Length: 30 mm to 500mm	Class II b
18	Locking Screws	Set Screw Square Thread	9mmx1.25mm, 10mm	Class II b
19	Locking Screws	Set Screw Star Socket (Buttress Thread)	9mm	Class II b

2.2. Manufacturer's name and address:

JAYON IMPLANTS PVT LTD
IV Industrial Development Area, Kanjikode,
Palakkad-678623, Kerala, India

2.3. Manufacturer's single registration number (SRN)

IN-MF-000033446

2.4. Basic UDI-DI

89043350TSFSVN

2.5. EMDN code & nomenclature (required for IIb)

Code: P09070302
Nomenclature: Thoracolumbosacral Fixation Systems

2.6. Risk class of device

Class IIb

2.7. Year when the first certificate (CE) was issued covering the device

Thoracolumbar spinal fixation system received first MDD CE Certification on 01 February 2021

2.8. Details of authorized representative

EUROPECERT Alsstr. 97, 41063 Mönchengladbach, Germany

SRN: DE-AR-000004974

2.9. Details of notified body and CE certificate

Project number	PRJC-579152-2018-PRC-IND
Certificate number	10000322025-PA-NA-IND
Certified date	01-02-2021
Certified body (name and address)	DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway
Certified body number	2460

2.10. Conformity Assessment Route:

The Thoracolumbar Spinal Fixation System (TSFS) has been assessed for conformity in accordance with Annex IX of Regulation (EU) 2017/745 – Conformity assessment based on a quality management system and on assessment of the technical documentation.

The SSCP has been prepared and maintained in line with MDR requirements and is part of the conformity assessment documentation submitted to the Notified Body.

2.11. Hyperlink of Instructions for Use

https://www.jayonimplants.com/wp-content/uploads/2025/02/3.JIPL-IFU-03-TSFS-REV-1002-09-24.pdf

3. INTENDED USE OF DEVICE

3.1 Intended purpose

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.

3.2 Indications

Thoracolumbar 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. Tumors
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.

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

3.3 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.

4. 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 and ilium 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 thoracolumbar fixation system is Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136 Polyaxial, Uniaxial, Monoaxial, reduction Screws, set screws and rods.

For details refer JIPL-IFU-03-TSFS

4.1 Description of Accessories Intended for Use with the Device

Certification status: The instruments are not CE-certified.

The Thoracolumbar Spinal Fixation System is used in combination with a dedicated set of surgical instruments designed for implantation, removal, and adjustment of the system components. These instruments are not implanted and are intended for use exclusively by trained surgeons. The intended usage of instruments was comminated through surgical technique. The following is the list of instruments used in this system:

1.Monolock Sounding Probe PD (Straight)
2.Monolock Sounding Probe PD (Curved)
3.Pedicle Probe Straight PD

4.Pedicle Probe Curved PD
5.Pedicle Awl PD
6.Pedicle Marker Bulged PD
7.Pedicle Marker Long Bulged PD
8.Mono Screw Introducer PD
9.Mono Lock Poly Introducer PD
10.Bone Tap 4mm PD
11.Locking Screw Inserter PD
12.Final Tightener PD
13.Rod Pusher Straight PD
14.Anti-Torque Device PD
15.Rod Fork PD
16.Depth Gauge PD
17.Gear Shift (Curved)
18.Rod Holder PD
19.Rod Bender
20.Rod Persuader
21.Parallel Spreader
22.Parallel Compressor
23.Vice Grip

5. RISKS AND WARNINGS

5.1 The following residual risks have been identified

1. Undiagnosed comorbidities.
2. Use of adult implants in pediatric patients.
3. Biological contamination due to improper sterilization of instruments.
4. Hematoma due to blood vessel injury.
5. Cardiac arrest due to underlying medical conditions
6. Loss of intended spinal correction.
7. Hemorrhage due to implant mechanical failure

5.2 Warnings and Precautions

- The implantation of thoraco lumbar spinal fixation system fixation must be performed only by experienced spinal surgeons with specific training in the use of this thoraco lumbar spinal fixation system fixation 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 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.
  - Device or component failure (bending, loosening or failure).
  - Loss of fixation.
  - Non-union.
  - Fracture
  - Neurological injury.
  - Vascular and visceral injury.
  - Neurological complications.
  - Over distraction.
  - Trauma to nerve root or dura.
  - Incorrect implant positioning.
  - Implant migration.
  - Allergic or inflammation
  - General adverse effects related to surgical procedures (E.g.: anesthesia, infections),
  - Expulsion.

6. SUMMARY OF CLINICAL EVALUATION AND PMCF

6.1 Conclusions on performance, safety and benefit-risk determination

The objective of this clinical evaluation was to investigate safety and performance of Thoracolumbar spinal Fixation system in patients undergoing, chronic degenerative disc disease, traumatic fracture, tumour, infections and other forms of spinal instability.

A thorough analysis of clinical literature, registry study, internal case studies and complaint analysis was conducted. This report highlights that Thoracolumbar spinal Fixation system intended to stabilise and strengthen the spine conditions including slippage of the spine, chronic degenerative disc disease, traumatic fracture, tumor, infections and other forms of spinal instability including scoliosis have consistently predictable outcomes and they have a role in optimizing quality of life, providing relief from pain, i neurological functions with known risks. The published clinical data clearly reveals that Thoracolumbar spinal Fixation system will not compromise the clinical condition or safety of patients and health professionals provided that these devices are used for the conditions and purposes intended. Information collected through Jayon implants post market surveillance activities provide sufficient data to address risks. The risks associated with the device, including potential undesirable adverse effects constitute acceptable risks when weighed against the benefits to the patient, in accordance with the GSPR set forth as per *Medical Device Regulation (EU) 2017/745 (MDR*). Jayon implants develops state of the art devices through best practices of design, manufacturing and testing methods as per standards which result in low-risk profiles and high degree of safety and performance when used as intended.

6.2 Summary of clinical investigations

Not Applicable. No clinical investigations were deemed necessary for Thoracolumbar spinal fixation System because it was determined through the risk assessment that post market surveillance activities (literature study, registry study, post market complaints) were adequate to confirm the safety and efficacy of the devices. The subject devices do not contain any novel materials or design features and are similar to existing commercially available devices which are used in the same anatomical location. The Post-market Clinical Follow up studies of Thoracolumbar spinal fixation System is in an ongoing state and the details regarding this subject will be updated soon after its completion.

6.3 Summary/Conclusion of PMCF

Abstract form of PMCF studies are as follows,

Study 1

This was a hypothesis driven, multicentric single arm prospective observational study to examine the efficacy and safety of a specific thoracolumbar spinal fixation device in patients with spinal disorders or instabilities. Clinical objective is the considerable improvement in VAS scale and ODI whereas radiological objective aims at checking whether the fusion rates are acceptable.

The overall baseline VAS score was 7.33±1.44 before surgery but had dropped to 4.11±1.19 post surgery. VAS score after 3 months post-surgery further exhibited a dip to 2.65 ±0.72 and after 6 months it had further reduced to 2.25±0.85.

The overall baseline ODI score was 35.96±7.68 before surgery but had dropped to 28.52±9.36 post surgery. ODI score after 3 months post-surgery further exhibited a dip to 24.82±10.78 and after 6 months it had further reduced to 16.52±5.90.

Some of the complications related to study are 1) Two screw loosening cases due to osteoporosis were reported 2) one rod breakage was reported and hence titanium rod was replaced with cobalt chromium rod.3) one Cage removal was reported due to backing out. 4)One Proximal junction failure was reported due to osteoporosis

Study 2

A Post Market Clinical Follow up study was conducted in SP Fort hospital, Trivandrum. A total of 80 patients were enrolled in this retrospective study. This study was aimed to compare the outcomes of minimally invasive surgeries and open surgeries.

7. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Surgical options are recommended for people who experience chronic pain, difficulty in performing daily activities and patients with advancing neurological complications that is not adequately relieved after a couple of months with non-surgical treatments, Also, if neurological complications are caused by cervical DDD there is a risk of permanent nerve damage, and surgery may be recommended to alleviate pressure on the nerve.
Some other surgical and non-surgical treatment methods are detailed below.

Conservative (Non-surgical) Management:

- Pharmacological treatment: analgesics, anti-inflammatories, muscle relaxants, and neuropathic pain agents.
- Physical therapy & rehabilitation: strengthening, mobility exercises, posture training.
- External orthoses / bracing: thoracolumbosacral orthosis (TLSO) used especially in fractures, mild deformity, or when surgery is contraindicated.
- Limitations: does not restore stability in severe trauma, progressive deformity, or advanced degeneration; pain and disability often persist.

Decompression Alone (Without Instrumentation):

- Procedures: laminectomy, laminoplasty, foraminotomy for neural decompression.
- Use cases: spinal stenosis, neural compression without gross instability.
- Limitations: decompression alone may destabilize the spine → often requires supplemental fixation, especially in multilevel or deformity cases.

Novel / Emerging Technologies

- 3D-printed patient-specific implants for complex deformity or tumor cases.
- Dynamic stabilization rods that allow controlled motion instead of rigid fixation.
- Nanocoated or bioactive surface implants to accelerate fusion.
- Robotic or AI-assisted minimally invasive fixation as surgical technique enhancement, not strictly a different treatment but an evolving alternative approach.

8. SUGGESTED PROFILE AND TRAINING FOR USERS

JAYON offers training courses on how to place JAYON implants successfully which includes cadaver sessions and has an array of restorative options for learning. First-time users should attend thetraining to realize the benefit of implants. More experienced users can also benefit from hands-on training courses

9. LIST OF HARMONIZED STANDARDS

For more details regarding harmonized standards kindly refer JIPL/QA/F-005

SECTION-B (Information intended for patients/laymen)

1. SUMMARY

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

2. DEVICE IDENTIFICATION AND GENERAL INFORMATION

2.1 Device trade names and specifications

SL NO	Generic Name	Component Name	Size of Medical Device in use (Dia/Length/Holes)	Type
1	Monoaxial Screw	Monolock Ultra Monoaxial Screw	Diameter; 4.5 mm to 7 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 60 mm (Range: 5 mm difference in length)	Class II b
2	Polyaxial Screw	Monolock Ultra Polyaxial Screw	Diameter; 4.5 mm to 7.5 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 120 mm (Range: 5 mm difference in length)	Class II b
3	Polyaxial screws	Monolock Ultra polyaxial Reduction Screw	Diameter; 4.5 mm to 7 mm (Range: 0.5 mm difference in diameter)	Class II b

			Length: 25 mm to 60 mm (Range: 5 mm difference in length	
4	Polyaxial screws	DTAP Monolock Polyaxial Screw (SQ)	Diameter: 4.5 mm to 8 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 120 mm long (Range: 5 mm difference in diameter)	Class II b
5	Polyaxial screws	MIS Monolock Polyaxial Screw	Diameter: 4.5 mm to 7 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 70 mm (Range: 5 mm difference in length)	Class II b
6	Monoaxial Screw	Monolock Monoaxial Screw	Diameter: 4.5 mm to 7.0 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 60 mm (Range: 5 mm difference in length)	Class II b
7	Polyaxial screws	Monolock Polyaxial Screw	Diameter: 4.5 mm to 7.5 mm (Range: 0.5 mm difference in diameter) Length: 25 mm to 120 mm (Range: 5 mm difference in length	Class II b

8	Polyaxial screws	Monolock Polyaxial Reduction Screw	Diameter: 4.5 mm to 6.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm (Range: 5 mm difference in length)	Class II b
9	Polyaxial screws	Monolock Osteo Polyaxial Screw (SQ)	Diameter: 5.5 mm to 7.5 mm (Range: 0.5 mm difference in diameter) Length: 30 mm to 120 mm long (Range: 5 mm difference in length)	Class II b
10	Monoaxial Screw	Monolock Deformity Monoaxial Screw	Diameter: 4.5 mm to 6.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm long (Range: 5 mm difference in length)	Class II b
11	Polyaxial screws	Monolock Deformity Polyaxial Screw	Diameter: 4.5 mm to 7.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm long (Range: 5 mm difference in length)	Class II b
12	Uniaxial screws	Monolock Deformity Uniaxial Screw	Diameter: 4.5 mm to 6.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm long (Range: 5 mm difference in length)	Class II b

13	Polyaxial screws	Monolock Deformity Polyaxial Reduction Screw	Diameter: 4.5 mm to 6.5 mm (Range: 1 mm difference in diameter) Length: 25 mm to 60 mm long (Range: 5 mm difference in length)	Class II b
14	Connecting Rods Straight	MIS Monolock Straight Connecting Rod	Diameter: 5.5 mm Length: 30 mm to 350 mm	Class II b
15	Connecting Rods Contoured	MIS Monolock Contoured Connecting Rod	Diameter: 5.5mm Length: 30 mm to 350mm	Class II b
16	Connecting Rods Straight	Monolock Connecting Rod	Diameter: 5.5mm Length: 30 mm to 500mm	Class II b
17	Connecting Rods Straight	DTAP Connecting Rod	Diameter: 5.5mm Length: 30 mm to 500mm	Class II b
18	Locking Screws	Set Screw Square Thread	9mmx1.25mm, 10mm	Class II b
19	Locking Screws	Set Screw Star Socket (Buttress Thread)	9mm	Class II b

2.2 Manufacturer's name and address:

JAYON IMPLANTS PVT LTD
IV Industrial Development Area, Kanjikode,
Palakkad-678623, Kerala, India

2.3 Basic UDI-DI

89043350TSFSVN

2.4 Year when the first certificate (CE) was issued covering the device

Thoracolumbar spinal fixation system received first MDD CE Certification on 01 February 2021

2.5 Hyperlink of Instructions for Use

https://www.jayonimplants.com/wp-content/uploads/2025/02/3.JIPL-IFU-03-TSFS-REV-1002-09-24.pdf

3. INTENDED USE OF DEVICE

3.1 Intended purpose

To stabilize and strengthen the spine conditions including spondylolisthesis[1], chronic degenerative disc disease[2], traumatic fracture[3], tumor[4], infections and other forms of spinal instability including scoliosis[5].

3.2 Indications

Thoracolumbar 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[2] (defined as discogenic back pain with degeneration of the disc confirmed by history and imaging studies)
2. Spondylolisthesis[1]
3. Trauma[3] (i.e., fracture or dislocation)
4. Spinal stenosis[7]
5. Deformities or curvatures (i.e., scoliosis[5], kyphosis[6], and/or lordosis[8])
6. Tumors[4]
7. Pseudoarthrosis[9]

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.

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

3.3 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[18], 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[10], bone absorption, osteopenia[11]. Osteoporosis[12] 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.
  - Reuse or multiple uses.
  - Do not use this system in patients with known or suspected metal allergies.

4. 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 and ilium 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 thoracolumbar fixation system is Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136 Polyaxial, Uniaxial, Monoaxial, reduction Screws, set screws and rods.

For details refer JIPL-IFU-03-TSFS

5. RISKS AND WARNINGS

5.1 The following residual risks have been identified

1. Undiagnosed comorbidities[13].
2. Use of adult implants in pediatric patients.
3. Biological contamination due to improper sterilization of instruments.
4. Hematoma[14] due to blood vessel injury.
5. Cardiac arrest due to underlying medical conditions
6. Loss of intended spinal correction.
7. Hemorrhage[15] due to implant mechanical failure.

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional.

5.2 Warnings and Precautions

- The implantation of thoraco lumbar spinal fixation system fixation must be performed only by experienced spinal surgeons with specific training in the use of this thoraco lumbar spinal fixation system fixation 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 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[19] or corpectomy[20] 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[16] 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.
  - Device or component failure (bending, loosening or failure).
  - Loss of fixation.
  - Non-union.
  - Fracture
  - Neurological injury.
  - Vascular and visceral injury.
  - Neurological complications.
  - Over distraction.
  - Trauma to nerve root or dura.
  - Incorrect implant positioning.
  - Implant migration.
  - Allergic or inflammation
  - General adverse effects related to surgical procedures (E.g.: Anesthesia[17], infections),
  - Expulsion.

6. SUMMARY OF CLINICAL EVALUATION AND PMCF

6.1 Conclusions on performance, safety and benefit-risk determination

The objective of this clinical evaluation was to investigate safety and performance of Thoracolumbar spinal Fixation system in patients undergoing, chronic degenerative disc disease, traumatic fracture, tumour, infections and other forms of spinal instability.

A thorough analysis of clinical literature, registry study, internal case studies and complaint analysis was conducted. This report highlights that Thoracolumbar spinal Fixation system intended to stabilise and strengthen the spine conditions including slippage of the spine, chronic degenerative disc disease[2], traumatic fracture[3], tumor[4], infections and other forms of spinal instability including scoliosis[5] have consistently predictable outcomes and they have a role in optimizing quality of life, providing relief from pain, i neurological functions with known risks. The published clinical data clearly reveals that Thoracolumbar spinal Fixation system will not compromise the clinical condition or safety of patients and health professionals provided that these devices are used for the conditions and purposes intended. Information collected through Jayon implants post market surveillance activities provide sufficient data to address risks. The risks associated with the device, including potential undesirable adverse effects constitute acceptable risks when weighed against the benefits to the patient, in accordance with the GSPR set forth as per *Medical Device Regulation (EU) 2017/745 (MDR*). Jayon implants develops state of the art devices through best practices of design, manufacturing and testing methods as per standards which result in low-risk profiles and high degree of safety and performance when used as intended.

6.2 Summary of clinical investigations

Not Applicable. No clinical investigations were deemed necessary for this thoracolumbar spinal fixation System because it was determined through the risk assessment that post market surveillance activities (literature study, registry study, post market complainants) were adequate to confirm the safety and efficacy of the devices. The subject devices do not contain any novel materials or design features and are similar to existing commercially available devices which are used in the same anatomical location. The Post-market

Clinical Follow up studies of thoracolumbar spinal fixation System is in an ongoing state and the details regarding this subject will be updated soon after its completion.

6.3 Summary/Conclusions of PMCF

Abstract form of PMCF studies are as follows,

Study 1

This was a hypothesis driven, multicentric single arm prospective observational study to examine the efficacy and safety of a specific thoracolumbar spinal fixation device in patients with spinal disorders or instabilities. Clinical objective is the considerable improvement in VAS scale and ODI whereas radiological objective aims at checking whether the fusion rates are acceptable.

The overall baseline VAS score was 7.33±1.44 before surgery but had dropped to 4.11±1.19 post surgery. VAS score after 3 months post-surgery further exhibited a dip to 2.65 ±0.72 and after 6 months it had further reduced to 2.25±0.85.

The overall baseline ODI score was 35.96±7.68 before surgery but had dropped to 28.52±9.36 post surgery. ODI score after 3 months post-surgery further exhibited a dip to 24.82±10.78 and after 6 months it had further reduced to 16.52±5.90.

Some of the complications related to study are 1) Two screw loosening cases due to osteoporosis were reported 2) one rod breakage was reported and hence titanium rod was replaced with cobalt chromium rod.3) one Cage removal was reported due to backing out. 4)One Proximal junction failure was reported due to osteoporosis

Study 2

A Post Market Clinical Follow up study was conducted in SP Fort hospital, Trivandrum. A total of 80 patients were enrolled in this retrospective study. This study was aimed to compare the outcomes of minimally invasive surgeries and open surgeries

7. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Surgical options are recommended for people who experience chronic pain, difficulty in performing daily activities and patients with advancing neurological complications that is not adequately relieved after a couple of months with non-surgical treatments, Also, if neurological complications are caused by cervical DDD there is a risk of permanent nerve damage, and surgery may be recommended to alleviate pressure on the nerve.
Some other surgical and non-surgical treatment methods are detailed below.

Conservative (Non-surgical) Management:

- Pharmacological treatment: analgesics, anti-inflammatories, muscle relaxants, and neuropathic pain agents.
- Physical therapy & rehabilitation: strengthening, mobility exercises, posture training.
- External orthoses / bracing: thoracolumbosacral orthosis (TLSO) used especially in fractures, mild deformity, or when surgery is contraindicated.
- Limitations: does not restore stability in severe trauma, progressive deformity, or advanced degeneration; pain and disability often persist.

Decompression Alone (Without Instrumentation):

- Procedures: laminectomy, laminoplasty, foraminotomy for neural decompression.
- Use cases: spinal stenosis, neural compression without gross instability.
- Limitations: decompression alone may destabilize the spine → often requires supplemental fixation, especially in multilevel or deformity cases.

Novel / Emerging Technologies

- 3D-printed patient-specific implants for complex deformity or tumor cases.
- Dynamic stabilization rods that allow controlled motion instead of rigid fixation.
- Nanocoated or bioactive surface implants to accelerate fusion.
- Robotic or AI-assisted minimally invasive fixation as surgical technique enhancement, not strictly a different treatment but an evolving alternative approach.

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

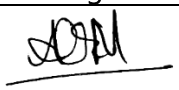
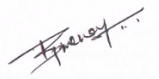
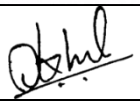
8. SUGGESTED PROFILE AND TRAINING FOR USERS

JAYON offers training courses on how to place JAYON implants successfully which includes cadaver sessions and has an array of restorative options for learning. First-time users should attend thetraining to realize the benefit of implants. More experienced users can also benefit from hands-on training course

GLOSSARY

Terms	Definition
Spondylolisthesis[1]	A condition where one spinal bone slips forward over the bone below it.
Chronic degenerative disc disease[2]/ Degenerative disc disease[2]	Long-term damage or aging of the discs between the bones of the spine
Traumatic fracture[3]/ Trauma[3]	Damage to the spine
Tumor[4]	An abnormal mass that may or may not be cancerous
Scoliosis[5]	An abnormal curve in the spine.
Kyphosis[6]	A hunching of the upper back.
Spinal stenosis[7]	Narrowing of the spinal canal
lordosis[8]	An excessive inward curve of the lower spine
Pseudoarthrosis[9]	A condition where a broken bone or fusion doesn't heal properly, leading to a false joint.
Rapid joint disease[10]	A condition where the joints break down or get damaged quickly
Osteopenia[11]	A condition where bones become weaker than normal
Osteoporosis[12]	Bones become weak and are likely to fracture
Undiagnosed comorbidities[13]	Health problems that a person has but are not yet identified
Hematoma[14]	A localized collection of blood that forms outside of blood vessels within a tissue, organ, or body space
Hemorrhage[15]	Excessive or uncontrolled bleeding inside or outside the body.
Arthrodesis[16]	A surgical procedure that joins two bones together
Anesthesia[17]	Anesthesia is the use of medicine to prevent pain and sensation during medical procedures
Obesity[18]	A condition where a person has too much body fat
Discectomy[19]	A surgical procedure to remove part or all of a damaged spinal disc that's pressing on nerves and causing pain.
Corpectomy[20]	A surgical procedure where a portion of a vertebra and the nearby discs are removed to relieve pressure on the spinal cord or nerves

REVISION HISTORY		
Revision no.	Date	Description
00	01/08/2022	Original issue
01	12/06/2023	Periodic revision
02	19/07/2024	Periodic revision
03	06/06/2025	Periodic revision
04	23/09/2025	Revised with additional details
05	26/12/2025	Failed previous fusion has been removed from the indications and added CE certification status of Instruments (accessories).

APPROVALS				
Stage	Name	Designation	Sign	Date
Originator	Anish Mohanan	QA Engineer		22/12/2025
Reviewer	Rajesh Menon	Asst. Manager		24/12/2025
Approval	Akhil Valsaraj	QA Manager		26/12/2025