



SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REPORT (SSCP) 2025-26

SPINAL INTERBODY FUSION DEVICE - SIFD

Summary of Safety and Clinical Performance

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	Spinal cage	Cedix P Spacer	5 mm to 12 mm thickness (Range: 1 mm difference in thickness)	Class III
2	Spinal cage	Cedix 7 Degree Spacer	5 mm to 12 mm thickness (Range: 1 mm difference in thickness)	Class III
3	Bone Screw	Disc Spacer Locking Bone Screw	- 4 mm dia. x 10 mm - 4 mm dia. x 12 mm - 4 mm dia. x 14 mm - 4 mm dia. x 16 mm - 4 mm dia. x 18 mm - 4 mm dia. x 20 mm - 4 mm dia. x 22 mm - 4 mm dia. x 24 mm	Class III
4	Spinal cage	PROLESS Cage – 0,7 Degree	5 mm to 12 mm thickness (Range: 1 mm difference in thickness)	Class III
5	Bone Screw	PROLESS Bone Screw	- 4 mm dia. x 12 mm - 4 mm dia. x 14 mm - 4 mm dia. x 16 mm - 4 mm dia. x 18 mm - 4 mm dia. x 20 mm - 4 mm dia. x 22 mm - 4 mm dia. x 24 mm	Class III
6	Spinal cage	POS FUSE PLIF Cage – 0,4,8 Degree	- 7 mm dia. x 20 mm - 8 mm dia. x 20 mm - 9 mm dia. x 20 mm	Class III

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SL NO	Generic Name	Component Name	Size of Medical Device in use (Dia/Length/Holes)	Type
			- 10 mm dia.x 20 mm - 11 mm dia. x 20 mm - 12 mm dia. x 20 mm - 13 mm dia. x 20 mm - 14 mm dia. x 20 mm - 15 mm dia. x 20 mm - 7 mm dia. x 25 mm - 8 mm dia. x 25 mm - 9 mm dia. x 25 mm - 10 mm dia. x 25 mm - 11 mm dia. x 25 mm - 12 mm dia. x 25 mm - 13 mm dia. x 25 mm - 14 mm dia. x 25 mm - 15 mm dia. x 25 mm	
7	Spinal cage	POS FUSE TLIF Cage- 0,4,8 Degree	- 7 mm dia. x 25 mm - 8 mm dia.x 25 mm - 9 mm dia. x 25 mm - 10 mm dia.x 25 mm - 11 mm dia. x 25 mm - 12 mm dia. x 25 mm - 13 mm dia. x 25 mm - 14 mm dia. x 25 mm - 15 mm dia. x 25 mm - 7 mm dia. x 29 mm - 8 mm dia. x 29 mm - 9 mm dia. x 29 mm - 10 mm dia. x 29 mm - 11 mm dia. x 29 mm - 12 mm dia. x 29 mm - 13 mm dia. x 29 mm - 14 mm dia. x 29 mm - 15 mm dia. x 29 mm	Class III

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SL NO	Generic Name	Component Name	Size of Medical Device in use (Dia/Length/Holes)	Type
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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

89043350SIFD001LS-Thoracolumbar Cages

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89043350SIFD002LU-Cervical Cages

89043350SIFD003LW-Bone Screws

2.5. EMDN code & nomenclature (required for III)

Code: P09070101

Nomenclature: Spinal Cages

2.6. Risk class of device

Class III

2.7. Year when device was introduced in EU market

Spinal Interbody Fusion Device received first MDD CE Certification on 01 February 2021

2.8. Details of authorized representative

EUROPECERT Alstr. 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 Spinal Interbody Fusion Device (SIFD) 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/products/spine/spinal-interbody-fusion-device/>

3. INTENDED USE OF DEVICE

3.1. Intended purpose

The Spinal Interbody Fusion Device is a versatile solution for both thoraco-lumbar and cervical indications. Indicated for intervertebral body fusion of the lumbar spine, specifically from C2 to S1, in adult patients who have undergone six months of non-operative treatment. This device is suitable for use at either one level or two contiguous levels to treat degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. Additionally, for patients with degenerative disc disease (DDD), the implant, packed with autogenous bone graft, is strategically designed for implantation via an anterior approach. Spinal interbody fusion devices are intended for use with supplemental fixation.

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3.2. Indications

The Spinal Interbody Fusion Device is indicated for anterior & Posterior interbody fusion procedures in Adults with degenerative disc disease at one level from C2 to S1. This device is suitable for use at either one level or two contiguous levels to treat degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. Additionally, for patients with degenerative disc disease (DDD), the implant, packed with autogenous bone graft, is strategically designed for implantation via an anterior approach.

1. Degenerative Disc Disease (DDD) defined as neck & back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
2. Spondylolisthesis.
3. Spinal Stenosis.
4. Trauma (i.e., Fracture or Dislocation)

Target population for Spinal Interbody Fusion Devices (SIFD) is adults.

3.3. Contraindications:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, 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.

4. DEVICE DESCRIPTION

The Spinal Interbody Fusion Device is available in various configurations based on surgical approaches and patient anatomies. It comprises the spinal interbody fusion device, which can be implanted as a single unit via either an anterior or posterior approach. The spinal interbody implants and surgical instruments are intended for use by or on the order of a physician. These surgical instruments designed to perform precise functions. The Spinal Interbody Fusion Devices include spacers, locking bone screws, and cages, all of which are available in a variety of diameters and lengths.

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The Spinal Interbody Fusion Device implant components are made of titanium alloy (in accordance to ISO 5832-3) ASTM F136. The cages are lordotic, parallel, convex to fit well on the anatomical curvatures of the Spinal Vertebra. Available in different height and foot print sizes to assist the surgeon with proper placement of the device. The Spinal interbody fusion device bone screws are made up of titanium alloy (in accordance to ISO 5832-3) ASTM F136 Sizes available in 4mm diameter screw in 10mm to 24mm length.

For details refer JIPL-IFU-37-SIFD

4.1. Description of Accessories Intended for Use with the Device

Certification status: The instruments are not CE-certified.

The Spinal Interbody Fusion Device 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. Introducer Small
2. Locking Introducer Large
3. Drill With Handle 2.7mm
4. Entry Hole Punch
5. Trail 5mm,6mm,7mm & 8mm
6. End Plate Rasp 5mm,6mm,7mm & 8mm
7. Straight Curette 3mm & 5mm
8. Temporary Spike Cum
9. Vertibral Body Pin
10. Introducer
11. Temporary Spike Cum Vertibral Body Pin Introducer
12. Pin For Cervical Body Distractor
13. Temporary Spike
14. Self-Holding Screw Driver 3.5mm
15. Cervical Distractor Double Action
16. Quick Coupling Handle Long
17. PLIF Cage Introducer
18. TLIF Cage Introducer
19. PLIF Cage Rasp
20. PLIF Cage Trial 7 Mm, 8mm, 9mm, 10mm, 11mm, 12mm
21. Graft Filling Block
22. TLIF Graft Filler
23. Bone Grafting Punch
24. Graft Funnel
25. TLIF Cage Trial 7 Mm, 8mm, 9mm, 10mm, 11mm, 12mm
26. Bone Curette Oval Shape Left Hand
27. Bone Curette Oval Shape Right Hand
28. Bone Curette Rectangle Shape Right Hand
29. Bone Curette Rectangle Shape Left Hand
30. TLIF Cage Impactor Straight
31. TLIF Impactor Curved
32. Quick Coupling Handle Long

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33. Inter Vertebral Disc Shaver 7 Mm, 8mm, 9mm, 10mm, 11mm, 12mm

5. RISKS AND WARNINGS

5.1. The following residual risks have been identified

1. Inadequate communication of patient-related risks. (D36)
2. Medical condition (D41)
3. Medical condition (D43)
4. Surgical procedural risk/anatomical structure damage (D46)
5. Medical condition (D47)
6. Mechanical failure of implant leading to vascular injury (D49).

5.2. Warnings and Precautions

- The implantation of the Spinal Interbody Fusion Device must be performed only by an orthopaedic surgeon experienced in spinal surgery, with specific training in the use of this spinal interbody fusion device, 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 cages, screws 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.
- Always orient the cage along the midline of the spine.
- 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 when seating the cage may strip the threads in the bone
- Failure to achieve arthrodesis will result in eventual loosening and failure of the construct.
- Spinal Interbody Fusion device 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.

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10. Incorrect implant positioning.
11. Implant migration.
12. Allergic or inflammation
13. General adverse effects related to surgical procedures (E.g.: anesthesia, infections),
14. Subsidence, 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 Spinal interbody fusion device in patients undergoing thoracolumbar and cervical fusion surgery for various degenerative disc diseases, Spondylolisthesis, Spinal Stenosis and Trauma (i.e., fracture or dislocation)

A thorough analysis of clinical literature, registry study, internal case studies and complaint analysis was conducted. This report highlights that Spinal interbody fusion device for thoracolumbar and cervical fusion surgery provide consistently predictable outcomes and they have a role in optimizing quality of life, providing relief from pain, neck disabilities, Cervical sagittal alignment including cervical lordosis and segmental angle and a high improvement in neurological functions with known risks. The published clinical data clearly reveals that Spinal interbody fusion device for thoracolumbar and cervical fusion surgery 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 Spinal Interbody Fusion Devices 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.

6.3. Summary/Conclusion of PMCF

Study 1

A single-center **retrospective** PMCF study was conducted at **SP Fort Hospital** involving 50 patients who underwent **single-level Posterior Lumbar Interbody Fusion (PLIF) using the Spinal Interbody Fusion Device (SIFD – PLIF Cage)** in combination with posterior pedicle screw fixation via Open PLIF and MIS-PLIF approaches. The cohort included 23 males and 27 females with a mean age of 48.14 years. Patients were treated for degenerative lumbar spinal disorders including lumbar disc prolapse, spinal stenosis, degenerative spondylolisthesis, radiculopathy, and segmental instability.

Clinical outcomes demonstrated significant and progressive improvement in both pain and functional status over the 6-month follow-up period. Mean VAS scores improved from 8.14 preoperatively to 0.68 at 6 months, while mean ODI scores improved from 69.82 to 7.72, indicating substantial recovery in

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functional ability. MIS-PLIF patients demonstrated superior outcomes compared to Open PLIF across follow-up intervals.

Radiological evaluation confirmed 100% satisfactory fusion progression in all cases, with stable implant positioning and no evidence of cage migration, subsidence, screw loosening, or mechanical failure.

No device-related complications, infections, revision surgeries, or implant failures were reported during the study period.

The current PMCF study demonstrated:

- Approximately 91.6% VAS improvement
- Approximately 89% ODI improvement
- 100% radiological fusion progression
- Zero device-related complications

Conclusion:

The SIFD (PLIF Cage) demonstrated excellent clinical safety and performance in lumbar interbody fusion procedures, with significant pain reduction, functional improvement, reliable fusion outcomes, and a favorable safety profile, supporting its continued use within the intended clinical indication.

Refer: PMCF -1

Study 2

A single-center retrospective PMCF study was conducted at S P Fort Hospital, Thiruvananthapuram, involving 33 patients who underwent Anterior Cervical Discectomy and Fusion (ACDF) using the Jayon PROLESS Cervical Stand-Alone Interbody Cage. The cohort included 24 males and 9 females, with a mean age of 47.91 years (range 28–78 years). Patients were treated for cervical spinal conditions including degenerative disc disease, radiculopathy, disc prolapse with compressive myelopathy, spinal stenosis, spondylolisthesis, and other degenerative cervical conditions.

Clinical outcomes demonstrated progressive and sustained improvement in pain and functional status over the 6-month follow-up period. Mean VAS scores decreased from 7.73 preoperatively to 2.24 at 6 months, representing an approximately 70.98% reduction in pain. Mean NDI scores decreased from 33.73 to 13.15, representing an approximately 61.01% reduction in cervical functional disability. Both VAS and NDI demonstrated statistically significant improvement over the follow-up period ($p < 0.001$).

Radiological evaluation at 6 months demonstrated 100% documented radiological fusion, with 33 out of 33 patients showing fusion. The PROLESS Cage maintained its position in all evaluated cases, with no documented cage migration or displacement. No cage breakage, deformation, or gross structural failure was identified in the available radiographic assessments.

During the evaluated 6-month follow-up period, no cage-related complications or unexpected device-related safety signals were documented. In particular, no cage migration, displacement, pull-out, or gross implant-related mechanical complication was reported, and no revision or reoperation related to the PROLESS Cage was documented.

The current PMCF study demonstrated:

- Approximately 70.98% VAS improvement
- Approximately 61.01% NDI improvement

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- 100% radiological fusion (33/33 patients)
- 0% documented cage migration/displacement
- Zero device related complications such cage-related pull-out, breakage, or gross structural failure
- No unexpected device-related safety signal during the evaluated 6-month follow-up period.

Conclusion:

The PMCF evaluation demonstrated satisfactory clinical and radiological performance and a favourable short-term safety profile of the Jayon PROLESS Cervical Stand-Alone Interbody Cage when used in ACDF within its intended purpose. The substantial reductions in VAS and NDI, together with 100% documented radiological fusion and absence of documented cage migration or unexpected device-related complications, support the continued clinical use of the PROLESS Cage within its intended clinical indication. The findings support short-term benefit–risk acceptability, while the retrospective study design, limited cohort size, and 6-month follow-up do not establish long-term implant durability.

Refer: PMCF -2

Study 3

A single-center retrospective, observational PMCF study was conducted at KIMSHEALTH, Trivandrum, involving 31 patients who underwent Transforaminal Lumbar Interbody Fusion (TLIF) using the Jayon POSFUSE Titanium TLIF Interbody Cage. The cohort included 16 males and 15 females, with a mean age of 53.94 years. Patients were treated for degenerative lumbar spinal disorders including degenerative disc disease, spinal stenosis, and spondylolisthesis.

Clinical outcomes demonstrated significant and progressive improvement in both pain and functional status over the 6-month follow-up period. Mean VAS scores improved from 7.77 preoperatively to 1.39 at 6 months, while mean ODI scores improved from 42.26 to 21.29, indicating substantial reduction in pain and improvement in functional ability. Statistical analysis confirmed significant improvement over time

Radiological evaluation confirmed 100% radiological fusion in all 31 patients, with maintained cage position and no evidence of cage migration, displacement, breakage, or gross structural failure during the 6-month follow-up.

A single complication (3.2%) of screw pull-out was reported in one elderly osteoporotic patient. The event did not require revision surgery, and successful radiological fusion was achieved. No other complications were documented.

The current PMCF study demonstrated:

- Approximately 82.1% VAS improvement
- Approximately 49.6% ODI improvement
- 100% radiological fusion
- No cage migration or implant structural failure
- One non-revision screw pull-out event (3.2%)

Conclusion:

The Jayon POSFUSE Titanium TLIF Interbody Cage demonstrated favorable clinical safety and performance in lumbar interbody fusion procedures, with significant pain reduction, functional improvement, reliable fusion outcomes, and a favorable short-term safety profile, supporting its continued use within the intended clinical indication.

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7. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Surgical intervention using spinal interbody fusion devices is indicated for patients with degenerative disc disease, spondylolisthesis, spinal stenosis, Trauma (i.e; Fracture or Dislocation) .who experience persistent pain, neurological deficits, or functional limitation that do not respond adequately to conservative management. In cases of instability, progressive deformity, or neurological compromise, non-surgical management may increase the risk of permanent damage, making fusion and stabilization necessary. Some other surgical and non-surgical treatment methods are detailed below.

a) Conservative (Non-surgical) Management:

- **Pharmacological treatment:** Analgesics, NSAIDs, muscle relaxants, neuropathic pain medications.
- **Physical therapy & rehabilitation:** Cervical or lumbar strengthening, range-of-motion exercises, posture correction.
- **External orthoses:** Cervical collars or thoracolumbar braces for temporary immobilization

Advantages:

- Non-invasive, avoids surgical and implant-related risks.
- Useful for early-stage or mild symptoms.
- Can reduce pain, muscle spasm, and inflammation.
- Cost-effective and widely accessible.
- May delay or avoid surgery when symptoms are stable and neurological function is intact.

Disadvantages:

- Does not correct structural pathology (disc degeneration, instability, spinal deformity).
- Limited effectiveness in advanced DDD, spondylolisthesis, stenosis, or trauma.
- Symptom relief is often temporary.
- Long-term medication use may cause adverse effects.
- Prolonged use of orthoses can lead to muscle deconditioning.
- Delayed surgery may risk progressive neurological deterioration

Limitations:

- Ineffective for mechanical instability, fractures, tumors, infection, or advanced degeneration.
- Cannot restore structural integrity or prevent progression of deformity.

b) Decompression Alone (Without Instrumentation)

Cervical -Anterior cervical discectomy without fusion, laminoplasty, foraminotomy

Thoracolumbar- Laminectomy, laminotomy, foraminotomy

Advantages:

- Relieves neural compression.
- Avoids implants and implant related complications.
- Shorter operative time, reduced surgical complexity.
- Motion preservation in selected motion-sparing procedures
- Suitable for single-level disease without instability

Disadvantages:

- Does not stabilize the spine after disc or bone removal.
- Risk of postoperative instability or kyphotic deformity
 - Cervical kyphosis after multilevel laminectomy
 - Lumbar instability after wide decompression

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- Lower long-term success in degenerative or unstable spines.
- Recurrent symptoms possible, may require secondary fusion surgery

Limitations:

Decompression alone is generally **not recommended** for:

- Degenerative disc disease with instability
- Spondylolisthesis requiring stabilization
- Multilevel cervical stenosis
- Fractures/dislocations or tumor resection requiring structural support
- Revision surgery for pseudarthrosis
- Spinal infections compromising stability
- Progressive deformity (kyphosis or loss of lordosis)

c) Novel / Emerging Technologies

- 3D-printed patient-specific interbody cages or implants.
- Bioactive or nanocoated surfaces to enhance osseointegration.
- Dynamic or semi-constrained stabilization systems allowing controlled motion.
- Robotic or AI-assisted navigation for implant placement.

Advantages:

- Improved anatomical fit and load distribution
- Enhanced fusion rates via bioactive surfaces
- Reduced adjacent segment stress with dynamic systems
- Improved accuracy and reproducibility with navigation systems
- Beneficial in complex, multilevel, or revision surgeries

Disadvantages:

- Limited long-term clinical outcome data
- Higher cost and infrastructure requirements
- Increased procedural planning and complexity
- Dynamic systems may provide less immediate rigidity
- Primarily adjunctive; not replacements for conventional fusion techniques

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 the training 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**

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SECTION-B (Information intended for patients/laymen)

1 SUMMARY

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SL NO	Generic Name	Component Name	Size of Medical Device in use (Dia/Length/Holes)	Type
			- 10 mm dia.x 20 mm - 11 mm dia. x 20 mm - 12 mm dia. x 20 mm - 13 mm dia. x 20 mm - 14 mm dia. x 20 mm - 15 mm dia. x 20 mm - 7 mm dia. x 25 mm - 8 mm dia. x 25 mm - 9 mm dia. x 25 mm - 10 mm dia. x 25 mm - 11 mm dia. x 25 mm - 12 mm dia. x 25 mm - 13 mm dia. x 25 mm - 14 mm dia. x 25 mm - 15 mm dia. x 25 mm	
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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

89043350SIFD001LS-Thoracolumbar Cages
89043350SIFD002LU-Cervical Cages
89043350SIFD003LW-Bone Screws

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

Spinal Interbody Fusion Device received first MDD CE Certification on 01 February 2021

2.5 Hyperlink of Instructions for Use

<https://www.jayonimplants.com/products/spine/spinal-interbody-fusion-device/>

3 INTENDED USE OF DEVICE

3.1 Intended purpose

The Spinal Interbody Fusion Device is a versatile solution for both thoraco-lumbar and cervical indications. Indicated for intervertebral body fusion of the lumbar spine, specifically from C2 to S1, in adult patients who have undergone six months of non-operative treatment. This device is suitable for use at either one level or two contiguous levels to treat degenerative disc disease (DDD)¹ with up to Grade I spondylolisthesis² or retrolisthesis³. Additionally, for patients with degenerative disc disease (DDD), the implant, packed with autogenous bone graft, is strategically designed for implantation via an anterior approach. Spinal interbody fusion devices are intended for use with supplemental fixation.

3.2 Indications

The Spinal Interbody Fusion Device is indicated for anterior & posterior interbody fusion procedures in adults with degenerative disc disease at one level from C2 to S1. This device is suitable for use at either one level or two contiguous levels to treat degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. Additionally, for patients with degenerative disc disease (DDD), the implant, packed with autogenous bone graft, is strategically designed for implantation via an anterior approach.

1. Degenerative Disc Disease (DDD)¹ defined as neck & back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

2. Spondylolisthesis².

3. Spinal Stenosis³

4. Trauma⁴. (i.e., Fracture or Dislocation)

Target population for Spinal Interbody Fusion Devices (SIFD) is adults.

3.3 Contraindications:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity⁵, 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 disease⁶, bone absorption, osteopenia⁷. Osteoporosis⁸ 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

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- 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.

4 DEVICE DESCRIPTION

The Spinal Interbody Fusion Device is available in various configurations based on surgical approaches and patient anatomies. It comprises the spinal interbody fusion device, which can be implanted as a single unit via either an anterior or posterior approach. The spinal interbody implants and surgical instruments are intended for use by or on the order of a physician. These surgical instruments designed to perform precise functions. The Spinal Interbody Fusion Devices include spacers, locking bone screws, and cages, all of which are available in a variety of diameters and lengths.

The Spinal Interbody Fusion Device implant components are made of titanium alloy (in accordance to ISO 5832-3) ASTM F136. The cages are lordotic, parallel, convex to fit well on the anatomical curvatures of the Spinal Vertebra. Available in different height and foot print sizes to assist the surgeon with proper placement of the device. The Spinal interbody fusion device bone screws are made up of titanium alloy (in accordance to ISO 5832-3) ASTM F136 Sizes available in 4mm diameter screw in 10mm to 24mm length.

For details refer JIPL-IFU-37-SIFD

5 RISKS AND WARNINGS

5.1 The following residual risks have been identified

1. Inadequate communication of patient-related risks. (D36)
2. Medical condition(D41)
3. Medical condition (D43)
4. Surgical procedural risk/anatomical structure damage (D46)
5. Medical condition (D47)
6. Mechanical failure of implant leading to vascular injury (D49).

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 the Spinal Interbody Fusion Device must be performed only by an orthopaedic surgeon experienced in spinal surgery, with specific training in the use of this spinal interbody fusion device, 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

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process due to galvanic corrosion effects. Thus, mixing implant components from different manufacturers is not recommended for metallurgical, mechanical and functional reasons.

- The cages, screws 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.
- Always orient the cage along the midline of the spine.
- To optimize bony union, perform an anterior discectomy¹² or corpectomy¹³ as indicated
- To facilitate fusion, a sufficient quantity of autologous bone should be used
- Excessive torque applied to the screws when seating the cage may strip the threads in the bone
- Failure to achieve arthrodesis¹⁴ will result in eventual loosening and failure of the construct.
- Spinal Interbody Fusion device 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.: anesthesia¹⁵, infections),
 14. Subsidence, 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 Spinal interbody fusion device in patients undergoing thoracolumbar and cervical fusion surgery for various degenerative disc diseases, Spondylolisthesis, Spinal Stenosis and Trauma (i.e., fracture or dislocation)

A thorough analysis of clinical literature, registry study, internal case studies and complaint analysis was conducted. This report highlights that Spinal interbody fusion device for thoracolumbar and cervical fusion surgery provide consistently predictable outcomes and they have a role in optimizing quality of life, providing relief from pain, neck disabilities, Cervical sagittal alignment including cervical lordosis and

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segmental angle and a high improvement in neurological functions with known risks. The published clinical data clearly reveals that Spinal interbody fusion device for thoracolumbar and cervical fusion surgery 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 Spinal Interbody Fusion Device 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.

6.3 Summary/Conclusions of PMCF

Study 1

A single-center **retrospective** PMCF study was conducted at **SP Fort Hospital** involving 50 patients who underwent **single-level Posterior Lumbar Interbody Fusion (PLIF) using the Spinal Interbody Fusion Device (SIFD – PLIF Cage)** in combination with posterior pedicle screw fixation via Open PLIF and MIS-PLIF approaches. The cohort included 23 males and 27 females with a mean age of 48.14 years. Patients were treated for degenerative lumbar spinal disorders including lumbar disc prolapse, spinal stenosis, degenerative spondylolisthesis, radiculopathy, and segmental instability.

Clinical outcomes demonstrated significant and progressive improvement in both pain and functional status over the 6-month follow-up period. Mean VAS scores improved from 8.14 preoperatively to 0.68 at 6 months, while mean ODI scores improved from 69.82 to 7.72, indicating substantial recovery in functional ability. MIS-PLIF patients demonstrated superior outcomes compared to Open PLIF across follow-up intervals.

Radiological evaluation confirmed 100% satisfactory fusion progression in all cases, with stable implant positioning and no evidence of cage migration, subsidence, screw loosening, or mechanical failure.

No device-related complications, infections, revision surgeries, or implant failures were reported during the study period.

The current PMCF study demonstrated:

- Approximately 91.6% VAS improvement
- Approximately 89% ODI improvement
- 100% radiological fusion progression
- Zero device-related complications

Conclusion:

The SIFD (PLIF Cage) demonstrated excellent clinical safety and performance in lumbar interbody fusion procedures, with significant pain reduction, functional improvement, reliable fusion outcomes, and a favorable safety profile, supporting its continued use within the intended clinical indication.

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Refer: PMCF -1

Study 2

A single-center retrospective PMCF study was conducted at S P Fort Hospital, Thiruvananthapuram, involving 33 patients who underwent Anterior Cervical Discectomy and Fusion (ACDF) using the Jayon PROLESS Cervical Stand-Alone Interbody Cage. The cohort included 24 males and 9 females, with a mean age of 47.91 years (range 28–78 years). Patients were treated for cervical spinal conditions including degenerative disc disease, radiculopathy, disc prolapse with compressive myelopathy, spinal stenosis, spondylolisthesis, and other degenerative cervical conditions.

Clinical outcomes demonstrated progressive and sustained improvement in pain and functional status over the 6-month follow-up period. Mean VAS scores decreased from 7.73 preoperatively to 2.24 at 6 months, representing an approximately 70.98% reduction in pain. Mean NDI scores decreased from 33.73 to 13.15, representing an approximately 61.01% reduction in cervical functional disability. Both VAS and NDI demonstrated statistically significant improvement over the follow-up period ($p < 0.001$).

Radiological evaluation at 6 months demonstrated 100% documented radiological fusion, with 33 out of 33 patients showing fusion. The PROLESS Cage maintained its position in all evaluated cases, with no documented cage migration or displacement. No cage breakage, deformation, or gross structural failure was identified in the available radiographic assessments.

During the evaluated 6-month follow-up period, no cage-related complications or unexpected device-related safety signals were documented. In particular, no cage migration, displacement, pull-out, or gross implant-related mechanical complication was reported, and no revision or reoperation related to the PROLESS Cage was documented.

The current PMCF study demonstrated:

- Approximately 70.98% VAS improvement
- Approximately 61.01% NDI improvement
- 100% radiological fusion (33/33 patients)
- 0% documented cage migration/displacement
- Zero device related complications such cage-related pull-out, breakage, or gross structural failure
- No unexpected device-related safety signal during the evaluated 6-month follow-up period.

Conclusion:

The PMCF evaluation demonstrated satisfactory clinical and radiological performance and a favourable short-term safety profile of the Jayon PROLESS Cervical Stand-Alone Interbody Cage when used in ACDF within its intended purpose. The substantial reductions in VAS and NDI, together with 100% documented radiological fusion and absence of documented cage migration or unexpected device-related complications, support the continued clinical use of the PROLESS Cage within its intended clinical indication. The findings support short-term benefit–risk acceptability, while the retrospective study design, limited cohort size, and 6-month follow-up do not establish long-term implant durability.

Refer: PMCF -2

Study 3

A single-center retrospective, observational PMCF study was conducted at KIMSHEALTH, Trivandrum, involving 31 patients who underwent Transforaminal Lumbar Interbody Fusion (TLIF) using the Jayon POSFUSE Titanium TLIF Interbody Cage. The cohort included 16 males and 15 females, with a mean age of 53.94 years. Patients were treated for degenerative lumbar spinal disorders including degenerative disc

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disease, spinal stenosis, and spondylolisthesis.

Clinical outcomes demonstrated significant and progressive improvement in both pain and functional status over the 6-month follow-up period. Mean VAS scores improved from 7.77 preoperatively to 1.39 at 6 months, while mean ODI scores improved from 42.26 to 21.29, indicating substantial reduction in pain and improvement in functional ability. Statistical analysis confirmed significant improvement over time

Radiological evaluation confirmed 100% radiological fusion in all 31 patients, with maintained cage position and no evidence of cage migration, displacement, breakage, or gross structural failure during the 6-month follow-up.

A single complication (3.2%) of screw pull-out was reported in one elderly osteoporotic patient. The event did not require revision surgery, and successful radiological fusion was achieved. No other complications were documented.

The current PMCF study demonstrated:

- Approximately 82.1% VAS improvement
- Approximately 49.6% ODI improvement
- 100% radiological fusion
- No cage migration or implant structural failure
- One non-revision screw pull-out event (3.2%)

Conclusion:

The Jayon POSFUSE Titanium TLIF Interbody Cage demonstrated favorable clinical safety and performance in lumbar interbody fusion procedures, with significant pain reduction, functional improvement, reliable fusion outcomes, and a favorable short-term safety profile, supporting its continued use within the intended clinical indication.

7. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Surgical intervention using spinal interbody fusion devices is indicated for patients with degenerative disc disease, spondylolisthesis, spinal stenosis, Trauma (i.e; Fracture or Dislocation) .who experience persistent pain, neurological deficits, or functional limitation that do not respond adequately to conservative management. In cases of instability, progressive deformity, or neurological compromise, non-surgical management may increase the risk of permanent damage, making fusion and stabilization necessary. Some other surgical and non-surgical treatment methods are detailed below.

a) Conservative (Non-surgical) Management:

- **Pharmacological treatment:** Analgesics, NSAIDs, muscle relaxants, neuropathic pain medications.
- **Physical therapy & rehabilitation:** Cervical or lumbar strengthening, range-of-motion exercises, posture correction.
- **External orthoses:** Cervical collars or thoracolumbar braces for temporary immobilization

Advantages:

- Non-invasive, avoids surgical and implant-related risks.
- Useful for early-stage or mild symptoms.

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- Can reduce pain, muscle spasm, and inflammation.
- Cost-effective and widely accessible.
- May delay or avoid surgery when symptoms are stable and neurological function is intact.

Disadvantages:

- Does not correct structural pathology (disc degeneration, instability, spinal deformity).
- Limited effectiveness in advanced DDD, spondylolisthesis, stenosis, or trauma.
- Symptom relief is often temporary.
- Long-term medication use may cause adverse effects.
- Prolonged use of orthoses can lead to muscle deconditioning.
- Delayed surgery may risk progressive neurological deterioration

Limitations:

- Ineffective for mechanical instability, fractures, tumors, infection, or advanced degeneration.
- Cannot restore structural integrity or prevent progression of deformity.

b) Decompression Alone (Without Instrumentation)

Cervical -Anterior cervical discectomy without fusion, laminoplasty, foraminotomy

Thoracolumbar- Laminectomy, laminotomy, foraminotomy

Advantages:

- Relieves neural compression.
- Avoids implants and implant related complications.
- Shorter operative time, reduced surgical complexity.
- Motion preservation in selected motion-sparing procedures
- Suitable for single-level disease without instability

Disadvantages:

- Does not stabilize the spine after disc or bone removal.
- Risk of postoperative instability or kyphotic deformity
 - Cervical kyphosis after multilevel laminectomy
 - Lumbar instability after wide decompression
- Lower long-term success in degenerative or unstable spines.
- Recurrent symptoms possible, may require secondary fusion surgery

Limitations:

Decompression alone is generally **not recommended** for:

- Degenerative disc disease with instability
- Spondylolisthesis requiring stabilization
- Multilevel cervical stenosis
- Fractures/dislocations or tumor resection requiring structural support
- Revision surgery for pseudarthrosis
- Spinal infections compromising stability
- Progressive deformity (kyphosis or loss of lordosis)

c) Novel / Emerging Technologies

- 3D-printed patient-specific interbody cages or implants.
- Bioactive or nanocoated surfaces to enhance osseointegration.
- Dynamic or semi-constrained stabilization systems allowing controlled motion.

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- Robotic or AI-assisted navigation for implant placement.

Advantages:

- Improved anatomical fit and load distribution
- Enhanced fusion rates via bioactive surfaces
- Reduced adjacent segment stress with dynamic systems
- Improved accuracy and reproducibility with navigation systems
- Beneficial in complex, multilevel, or revision surgeries

Disadvantages:

- Limited long-term clinical outcome data
- Higher cost and infrastructure requirements
- Increased procedural planning and complexity
- Dynamic systems may provide less immediate rigidity
- Primarily adjunctive; not replacements for conventional fusion techniques

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 the training to realize the benefit of implants. More experienced users can also benefit from hands-on training courses.

GLOSSARY

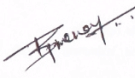
Terms	Definition
Degenerative disc disease ¹	Long-term damage or aging of the discs between the bones of the spine
Spondylolisthesis ²	A condition where one spinal bone slips forward over the bone below it

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Terms	Definition
Spinal stenosis ³	Narrowing of the spinal canal
Trauma ⁴	Damage to the spine
Obesity ⁵	A condition where a person has too much body fat
Rapid joint disease ⁶	A condition where the joints break down or get damaged quickly
Osteopenia ⁷	A condition where bones become weaker than normal
Osteoporosis ⁸	Bones become weak and are likely to fracture
Undiagnosed comorbidities ⁹	Health problems that a person has but are not yet identified
Hematoma ¹⁰	A localized collection of blood that forms outside of blood vessels within a tissue, organ, or body space
Hemorrhage ¹¹	Excessive or uncontrolled bleeding inside or outside the body.
Discectomy ¹²	A surgical procedure to remove part or all of a damaged spinal disc that's pressing on nerves and causing pain.
Corpectomy ¹³	A surgical procedure where a portion of a vertebra and the nearby discs are removed to relieve pressure on the spinal cord or nerves
Arthrodesis ¹⁴	A surgical procedure that joins two bones together
Anesthesia ¹⁵	Anesthesia is the use of medicine to prevent pain and sensation during medical procedures

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	16/07/2025	Periodic revision

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04	18/08/2026		Periodic revision and added CE certification status of Instruments (accessories).	
APPROVALS				
Stage	Name	Designation	Sign	Date
Originator	Anish Mohanan	QA Engineer		12/08/2026
Reviewer	Rajesh Menon	Asst. QA Manager		17/08/2026
Approval	Akhil Valsaraj	QA Manager		18/08/2026