AOSYS®

Revolutionising healthcare with innovation

Instruction for Use:
Spine System

Instruction Concerning
Spine System
Manufactured By

Aosys Private Limited,

Located At: Survey No. 1381,
Near Swadheen Industrial Park,
Indore Highway, Village Kuha,
Taluka Daskroi, District Ahmedabad-382433

Manuals are subject to change;
the current version of manual is
available on our website.

Instructions for Use
Spine System

5.5mm Pedicle Screws
- Mono Axial Screw Dual Thread, Dia.4.5mm, 5.5mm, 6.5mm & 7.5mm
- Poly Axial Screw Dual Thread, Dia.4.5mm, 5.5mm, 6.5mm & 7.5mm
- UNI Planar Screw Dual Thread, Dia.4.5mm, 5.5mm & 6.5mm
- Mono Reduction Screw Dual Thread, Dia.4.5mm, 5.5mm, 6.5mm & 7.5mm
- Poly Reduction Screw Dual Thread, Dia.4.5mm, 5.5mm, 6.5mm & 7.5mm
- Poly Axial Screw Cannulated - Fenestrated, Dia.5.5mm, 6.5mm & 7.5mm
- Poly Reduction Screw Cannulated - Fenestrated, Dia.5.5mm, 6.5mm & 7.5mm
- Mono Axial Screw Single Thread, Dia.4.5mm, 5.5mm & 6.5mm
- Poly Axial Screw Single Thread, Dia.4.5mm, 5.5mm & 6.5mm
- Poly Reduction Screw Single Thread, Dia.4.5mm, 5.5mm & 6.5mm
- Inner Screw for Pedicle Screw
- Break off Inner Screw for Pedicle Screw
- Cross link Connector
- Spinal Rod, Dia. 5.5 mm
- Spinal Rod CoCr, Dia. 5.5 mm
- Inline Connector 5.5 x 5.5mm
- Inline Connector Long 5.5 x 5.5mm
- Spine Staple
- Domino Connector Square 5.5 x 5.5mm
- Domino Connector Rectangle 5.5 x 5.5mm
- Open Domino Connector Square 5.5 x 5.5mm
- Open Domino Connector Rectangle 5.5 x 5.5mm
- Lateral Connector 5.5mm (20mm, 30mm & 40mm)

MIS Pedicle Screw System
- MIS Poly Axial Reduction Dual ThreadScrew - Fenestrated, Dia.5.5mm, 6.5mm & 7.5mm
- MIS Prebend Rod Dia. 5.5mm
- MIS Straight Rod Dia. 5.5mm

Anterior Cervical System
- Anterior Cervical Plate
- Cervical Screw Dia. 4.0mm, 4.3mm & 4.5mm

Cages
- Pinnacle Plif-Bullet Cage
- Zenith Plif-Bullet Cage
- Tlif-Banana Cage
- Mesh Cage
- Expandable Corpectomy Cage
- Expandable Corpectomy Cage with Plate
- Duo- Anterior Cervical Cage
- Stand Alone Anterior Cervical Cage
- Stand Alone Locking Screw
- Stand Alone Expandable Ant. Cervical Bladed Cage

Posterior Cervical System
- Posterior Cervical Screw Full Thread Dia. 3.5mm
- Posterior Cervical Screw Short Thread Smooth Shank 10mm Dia. 3.5mm
- Posterior Cervical Screw Full Thread Dia. 4.0mm
- Posterior Cervical Screw Short Thread Smooth Shank 10mm Dia. 4.0mm
- Inner Screw for PCS
- Adjustable Occipital Plate (Small, Medium & Large)
- Adjustable Occipital Plate II
- Occipital Screw
- Posterior Cervical Connecting Rod Ø 3.5 mm
- Tappered Spine Rod Ø 3.5 mm to 5.5 mm.
- Pre Bend Connecting Rod Ø 3.5mm
- Transverse Connector for PCS
- Lamina Hook for PCS
- Offset Domino Connector 3.5mm to 5.5mm Rod
- Axial domino connector for 3.5mm Rod
- Triangle Connector 3.5mm to 5.5mm
- Cannulated Odontoid Screw System

Before use, read these instructions, the AOSYS "Important Information," and the Surgical Technique Guide carefully. Be familiar with the correct surgical method.
Spine System Implants include various metallic components like Mono Axial Screw, Polt Axial Screw, Spianl Rod, Connecter, etc. All are single-packed and may be sterile or non-sterile.
Note: These instructions do not cover all details for device selection or use - refer to full labeling and guides for complete information.

Material(s):

Material(s)	**Standards**
PEEK	: ASTM F2026
CoCr	: ASTM F75
Titanium Alloy	: ISO 5832-3, ASTM F 136

Intended Use:
Spinal Implant is intended to promote fusion of the cervical and thoracic spine (CI-T3) for the following conditions: degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies); spondylolisthesis; spinal stenosis; trauma (fracture/dislocation); failed previous fusion; and/or tumors. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (CI -T3) spine. The uses of multi axil screws (ploy axial)/ connectors are limited to placement in TI -T3 vertebrae for treating thoracic conditions only. Screws are not intended to be placed in the cervical spine. (Please refer our catalogue for more information.)

Contraindications:
- Inadequate bone quantity and/or bone quality
- Hypersensitivity to metal or allergic reaction
- Early or Late Infection, both deep and / or superficial
- Patients with limited blood supply
- Patient within whom co-operation or mental competence is lacking, thereby reducing patient compliance
- Patient with Osteopenia and Osteoporosis

Adverse Reactions:
Adverse reactions may include but are not limited to:
- Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration.
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant.
- Primary and/or secondary infections.
- Allergic reactions to implant material.
- Necrosis of bone or decrease of bone density, Osteopenia/or Osteoporosis.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area.

Side Effects:
- Pain or loss of function in the implant area
- Weakness or fatigue
- Diarrhea
- Headaches

Safety Precautions:
- The Product should only be used by the medical personnel who hold relevant qualification.
- Never use the product that has been damaged by Improper handling in the hospital or in any other way.
- Never reuse an implant. Although the implant appears to be undamaged, previous stresses may have created non-visible damage that could result in implant failure.

Safety Precaution for Special Cases Pregnant Women:
- Ensure that there should be less blood loss during the surgery.

- Anaesthesia should not be used in such case.
- Operational environment must be free from radiation.

Infant / Children:
- Ensure that there should be less blood loss during the surgery.
- Operational environment must be free from radiation.
- Epiphysis should not be damaged

Polymorbid & Breast Feeding Women:
- On Polymorbid patients and breast feeding women, the implant shall be used at the discretion of surgeon.

WARNING:
- The use of implants for surgery other than those for which they are intended may result in damage/ breakage of implants or patient injury.
- The operating surgeon and operating room team must be thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects must be readily available at the workplace.
- The operating surgeon must be especially trained in orthopedic surgery, biomechanical principles of the skeleton, and the relevant operating techniques.
- The patient is aware of the risks associated with general surgery, orthopedic surgery, and with general anesthesia.
- The patient has been informed about the advantages and disadvantages of the implant & implantation procedure and about possible alternative treatments.
- The implant can be failed due to excessive load, wear and tear or infection.
- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload too early through extreme strain, work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- The patient must have his/her physician to carry out follow-up examinations of the implants at regular intervals.
- If device used in joints, kindly inform to patient do not move excessively, it may cause pain or damage surrounding tissue where implant was placed.

Packaging / Storage:
- The implants are individually packed in protective packaging that is labelled to its contents properly.
- All Single use Non-Sterile & Sterile implants are supplied.
- Implants should be stored in the original protective packaging.
- Store the implants in a dry and dust-free place (standard hospital environment).

Inspection:

Before use, inspect the box carefully. Do not use when
- Implants has scratches & damage
- Improper threads with damages
- Prior to surgery check suitability of fixation of this implant with its corresponding implant, and also ensure strength of whole assembly.
- Any modification in the implants size, shape and surface condition is not permissible or possible.

Operating Instructions/ Instruction For Use:

Selection of Implant
- The selection of the proper size, shape & design of the implant for each patient is extremely important to the success of the procedure.
- Responsibility of the proper selection of patients, adequate training, experience in the choice, placement of the implant & the decision to leave or remove implant postoperatively, rests with the surgeon.
- The product should be used in the correct anatomical location, consistent with the accepted standard for the internal fixation. Failure to use the appropriate product for the application may result in a premature clinical failure. Failure to use the proper component to ensure adequate blood supply & provide rigid fixation may result in loosening, bending or cracking of the product and / or bone fracture.
- The product should be used in combination made up with similar material only.
- For selection of suitable implants, accessories & related devices, kindly consult a specialist or refer a product combination chart available on our website.

Implant Fixation:

The Aosys Private Limited implants should be implanted only with the related corresponding instruments made by Aosys Private Limited
- Also ensure the availability of same implant as standby.
- Surgeon should document the implant details (Name, Item, Number, Lot Number) in surgery record. Combination Chart are useful to minimize specific risks associated with implantation.

MRI Safety Information:
- Many implants have not been evaluated for safety in the magnetic resonance (MR) environment, and scanning patients with these devices may pose risks.
- Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic or magnetic fields, including a magnetic field, including a magnetic resonance environment.
- Doctor shall analyze the Risk before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.
- The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.
- The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

MR Image Artefacts:

Magnetic Resonance (MR) imaging and multi-detector computed tomography (CT), artifacts arising from metallic orthopedic hardware are an obstacle to obtaining optimal images.

Clinical Evaluation of Spinal System:

The Aosys Private Limited Spinal System is clinically safe, and effective in use as discussed and proved up to the mark in the clinical evaluation of the device.

SYMBOLS & DEFINITIONS	
LOT	**Batch Code** **Note:** This symbol should be accompanied by the batch code relevant to the device bearing the symbol.
	**Date Of Manufacture** **Note:** This symbol is accompanied by the date that the device was manufactured. The date could be year, year and month, or year, month and day, as appropriate
	**Consult Instructions For Use** **Note:** This symbol advises the reader to consult the Instruction for use for information needed for the proper use of the device.
	**Manufacturer** AOSYS PRIVATE LIMITED Survey No. 1381, Near Swadheen Industrial Park, Indore Highway, Village Kuha, Taluka Daskroi, District Ahmedabad-382433. Email: info@aosys.in Contact: +(91) 9227253532, +(91) 9825528258 Website: www.aosyspvtltd.com
REF	**Catalogue Number** **Note:** This symbol be accompanied by the catalogue number relevant to the device bearing the symbol
	**Do Not Use If Package Is Damaged** Do not use, if the packaging is compromised.
	Non-Sterile
STERILE R	Sterile Irradiated
STERILE EO	Sterile EtO
	Keep Dry
	Keep Away From Sunlight
	**Do not reuse Implant** Used implants which appear undamaged may have internal and external defects. It is possible that individual stress analysis of every part may fail to reveal the accumulated stress on the metals as a result of use within the body. This may ultimately lead to implant failure.
	**Caution** This symbol is to denote that there some warning or precautions associated with device, which are not otherwise found on labels
	Barcode
AOSYS	Manufacturers Company Logo
QTY	In Single Pack Number of Quantity Packed

For Further Information:

Please Contact Aosys Private Limited in case of any Query,
Complain or Adverse Effect
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