AOSYS®

Revolutionising healthcare with innovation

Instruction for Use:
Intramedullary Nailing System

Instruction Concerning
Intramedullary Nails,
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
Intramedullary Nailing Implant

Humerus:
- Humerus Interlocking Nail System
- Multi Lock Humerus Interlocking Nail System

Femur:
- Proximal Femoral Interlocking Nail Antirotation System
- Proximal Femoral Interlocking Nail System
- Antegrade Femur Interlocking Nail System
- Distal Femoral Nail Type 2 System
- Femur Interlocking Nail System
- Advance Femur Nail GT System
- TFA Interlocking Nail System

Tibia & Ankle:
- Distal Tibial Nail System
- Tibia Interlocking Nail System
- Tibia Nail Suprapatellar System
- Ankle Fusion Nail System

Miscellaneous:
- Flexi Nail System

Compatible Screws And End Caps
- Interlocking Bone Screw (Dia. 3.4mm, 3.9mm, 4.9mm, 6.0mm, 6.3mm, 8.0mm, 6.5mm)
- Interlocking Bone Screw Type 1 (3.4mm, 3.9mm, 4.9mm)
- Screw for Multi Lock Humerus Nail (4.5mm)
- Locking Head Bone Screw (Dia. 3.5mm)
- Blade for Proximal Femoral Interlocking Nail Antirotation
- Screw for Proximal Femoral Interlocking Nail Antirotation
- Blade for Distal Femoral Nail
- Helical Blade, Perforated for TFA Nail
- Lag Screw, Perforated for TFA Nail
- End Cap for Proximal Femoral Interlocking Nail Antirotation
- End Cap for Proximal Femoral Interlocking Nail Antirotation with Pin
- Interlocking Connecting Screw
- End Cap for Proximal Femoral & Antegrade Femur Interlocking Nail
- End Cap for Distal Femoral Nail Type 1
- End Cap for Distal Femoral Nail (With Pin) Type 1
- End Cap for Humerus Interlocking Nail
- End Cap for Multi Lock Humerus Nail
- End Cap for Tibia & Femur Interlocking Nail
- End Cap for Advanced Femur Nail GT
- End Cap for Ankle Fusion Nial & Tibia Nail Suprapatellar
- End Cap for TFA Nail

Before use, read these instructions, the AOSYS "Important Information," and the Surgical Technique Guide carefully. Be familiar with the correct surgical method.
Intramedullary Nailing Implants include various metallic components like Interlocking Nails, Blades, Screws, and Pins. 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**
Stainless Steel	:	ISO 5832-1
Stainless Steel LVM	:	ASTM F138
Titanium Alloy	:	ISO 5832-3, ASTM F 136

Intended Use:
An Intramedullary Nail is a collection of specialized surgical tools designed for the insertion and stabilization of Intramedullary Nails within the medullary cavity of long bones.
The Intramedullary Nail is intended for internal fixation of fractures and reconstruction of the Humerus, Tibia, Fibula and Femoral Bones. The I.M. Nail is having better strength with good bone healing capacity. Different sizes are available with different designs for better alignment of the fracture. (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 Intramedullary Nails:
The Aosys Private Limited Intramedullary Nails 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	Non-Sterile
STERILE R	Sterile Irradiated
STERILE EO	Sterile EtO
	Keep Dry
	Keep Away From Sunlight
2	**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
12345678	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
Email : info@aosys.in
Phone : +(91) 92272 53532, +(91) 98255 28258
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