AOSYS®

Revolutionising healthcare with innovation

Instruction for Use:
Trauma System: Bone Plates & Screws

Instruction Concerning
Trauma System: Bone Plates & Screws
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
Trauma System: Bone Plates & Screws

Clavicle:
- Locking Clavical Hook Plate, Blade 12mm, 3.5mm
- Locking Clavical Hook Plate, Blade 15mm, 3.5mm
- Locking Clavical Hook Plate, Blade 18mm, 3.5mm
- Locking Superior Anterior Clavicle Plate, 3.5mm
- Locking Superior Anterior Clavicle Plate with Lateral Extension, 2.7/3.5mm

Humeral:
- Locking Proximal Humerus Plate Multi Angle, 3.5mm
- Locking Periarticular Proximal Humerus Plate, 3.5mm
- Locking Distal Humerus Plate, 2.7/3.5mm
- Locking Distal Humerus Plate with Lateral Support, 2.7/3.5mm
- Locking Metaphyseal Plate for Distal Medial Humerus, 3.5mm
- VA Locking Metaphyseal Plate for Distal Medial Humerus, 3.5mm
- Locking Extra-Articular Distal Humerus Plate, 3.5mm
- Locking Distal Humerus Medial Plate, 2.7/3.5mm
- Locking Bone Compression Plate, Small, 3.5mm
- Locking Bone Compression Plate, Small, 2.7mm

Radius:
- Locking Distal Radius Plate, 2.4/2.7mm
- Locking Distal Radius Buttress Plate, 2.4/2.7mm
- Locking Distal Radius Plate Extra Articular, 2.4/2.7mm
- Locking Distal Radius Plate, Straight, 2.4/2.7mm
- Locking L Distal Radius Plate, 2.4/2.7mm
- Locking L-Oblique Distal Radius Plate, 2.4/2.7mm
- Locking T Distal Radius Plate, 2.4/2.7mm
- Locking Volar Distal Radius Plate, Standard, 2.7/3.5mm
- Locking Volar Distal Radius Plate, Wide, 2.7/3.5mm
- Locking Radial Head Rim Plate, 2.4mm
- Locking Radial Head Neck Plate, 2.4mm
- Locking Wrist Fusion Plate, 2.7/3.5mm
- 2.4mm VA Locking Two-Column Distal Radius Plates Volar, Narrow, 6 holes, width 19.5 mm
- 2.4mm VA Locking Two-Column Distal Radius Plates Volar, Standard, 6 holes, width 22 mm
- 2.4mm VA Locking Two-Column Distal Radius Plates Volar, Wide, 7 holes, width 25.5 mm
- 2.4mm VA Locking Volar Rim Distal Radius Plates, 6 Head Holes
- 2.4mm VA Locking Volar Rim Distal Radius Plates, 7 Head Holes
- Locking T Small Plate, 3.5mm
- Locking T Oblique Plate, 3.5mm

Ulna:
- Locking Olecranon Plate, 3.5mm

Femur:
- Locking Dynamic Hip Plate 130°, B.C. Hole
- Locking Dynamic Hip Plate 135°, B.C. Hole
- Locking Proximal Femoral Plate, 5.0mm
- Locking Proximal Femoral Plate Type, 2 5.0mm
- Locking Distal Femoral Plate, B.C. Hole, 95°
- Locking Distal Femoral Plate, 5.0mm
- Locking Medial Distal Femur Plate, 5.0mm
- Locking Bone Compression Plate, Broad, 5.0mm
- Locking Bone Compression Plate, Narrow, 5.0mm
- Locking Proximal GT Cable Plate, Dia. 1.0mm, 1.4mm, 1.6mm
- Locking Proximal GT Cable
- Locking Cable Plate, Broad
- VA Locking Curved Condylar Cable Plate, 5.0mm
- Locking Proximal Femur Lateral Support Plate

Pelvis:
- Locking Reconstruction Plate Round Hole, 3.5mm
- Locking Reconstruction Plate B.C. Hole, 3.5mm

Tibia:
- Locking Lateral Tibial Plate, 5.0mm
- Locking Proximal Tibial Plate, 3.5mm
- Locking Proximal Medial Tibial Plate, 3.5mm
- Locking Posteromedial Proximal Tibial Plate, 3.5mm
- Locking Medial Distal Tibial Plate, 3.5mm
- Locking Distal Tibial Plate with Knob, 3.5mm
- Locking Tomo Fixation Plate, Without Capsule
- Locking Tomo Fixation Plate, With Capsule
- Block For Locking Tomo Fixation Plate With & Without Capsule
- Locking Tomo Fixation Plate, Small, Without Capsule
- Locking Tomo Fixation Plate, Small, With Capsule
- Locking Anterolateral Distal Tibial Plate, 3.5mm
- Locking L Buttress Plate, 5.0mm
- Locking T Simple Plate, 5.0mm
- Locking T Buttress Plate, 5.0mm

Fibula:
- Locking Lateral Distal Fibula Plate, 2.7mm
- Locking Lateral Distal Fibula Plate, 3.5mm
- Locking Periarticular Distal Lateral Fibular Plate, 2.7mm
- Locking Periarticular Distal Lateral Fibular Plate, 2.7/3.5mm
- Locking One Third Plate, 3.5mm

Foot
- Locking Calcaneal Plate, 3.5mm

Screw
- Cortical Bone Screw, Ø 2.4mm, Self Tapping
- Cortical Bone Screw, Ø 2.7mm, Self Tapping
- Cortical Bone Screw, Ø 3.5mm x 20 TPI, Self Tapping
- Cortical Bone Screw, Ø 4.5mm, Self Tapping, Ø 2.4mm VA Locking Screw ST Stardrive
- Locking Head Bone Screw, Ø 2.4mm, Self Tapping
- Locking Head Bone Screw, Ø 2.7mm, Self Tapping
- Locking Head Bone Screw, Ø 3.5mm, Self Tapping
- Locking Head Bone Cancellous Screw, Ø 3.5mm, Self Tapping
- Locking Head Bone Cannulated Screw, Ø 3.7mm, Self Drilling & Self Tapping,
- Cannulated Conical Screw, Ø 3.7mm, Short Thread
- Locking Head Bone Screw, Ø 5.0mm, Self Tapping
- Locking Head Cancellous Bone Screw, Ø 5.0mm x Fully Thread, Self Tapping
- Locking Head Bone Screw, Ø 5.0mm, Cannulated, Self Tapping
- Cannulated Conical Screw, Ø 5.0mm x Short Thread, Self Tapping
- Locking Head Bone Screw, Ø 6.0mm Cannulated, Self Tapping
- Cannulated Conical Screw, Ø 6.0mm x Short Thread, Self Tapping
- Cannulated Conical Screw, Ø 7.3mm x Short Thread, Self Tapping
- Locking Head Bone Cannulated Screw, Ø 7.3mm x Full Thread, Self Tapping
- Dynamic Hip Screw, Ø 12.5mm
- Compression Bone Screw DHS, Ø 4.0mm
- Cannulated Cancellous Bone Screw, Dia.6.5mm, 16.0mm Thread
- Cannulated Cancellous Bone Screw, Dia.6.5mm, 32.0mm Thread
- Cannulated Cancellous Bone Screw, Dia.6.5mm, Fully Thread
- Cancellous Bone Screw, Dia.6.5mm, 16.0mm Thread
- Cancellous Bone Screw, Dia.6.5mm, 32.0mm Thread
- Cancellous Bone Screw, Dia.6.5mm, Fully Thread
- Cannulated Cancellous Bone Screw, Dia.4.0mm, Short Thread
- Cannulated Cancellous Bone Screw, Dia.4.0mm, Fully Thread
- Cancellous Bone Screw, Dia.4.0mm, Short Thread
- Cancellous Bone Screw, Dia.4.0mm, Fully Thread
- Headless Compression Screw, Dia. 4.5mm
- Headless Compression Screw, Dia. 5.5mm
- Headless Compression Screw, Dia. 6.5mm
- Headless Compression Screw, Dia. 8.0mm
- Herbert Screw, Short Thread, Dia. 2.4mm
- Herbert Screw, Short Thread, Dia. 3.0mm
- Spacer
- Wire Mount

Anatomical Region / Fracture Type	Implants	Detailed Indication for Use
Distal Humerus Fractures	• Locking Distal Humerus Plate 2.7/3.5 mm • Locking Distal Humerus Plate with Lateral Support 2.7/3.5 mm • Locking Metaphyseal Plate for Distal Medial Humerus 3.5 mm • Locking Extra-Articular Distal Humerus Plate 3.5 mm • Locking Distal Humerus Medial Plate 2.7/3.5 mm • VA Locking Metaphyseal Plate for Distal Medial Humerus	Intra-articular, Extra-articular, Bicondylar, Supracondylar, Metaphyseal, and Comminuted Distal Humerus fractures require angular stability.
Olecranon Fractures	• Locking Olecranon Plate 3.5 mm	Simple, Comminuted, Oblique, or Transverse Olecranon Fractures; Olecranon Osteotomies requiring stable fixation.
Radial Head / Neck Fractures	• Locking Radial Head Rim Plate 2.4 mm • Locking Radial Head Neck Plate 2.4 mm	Partial Articular, Rim, and Neck fractures of the Radial Head requiring stable low-profile fixation.
Distal Radius Fractures	• Locking Volar Distal Radius Plate Standard/Wide 2.7/3.5 mm • Locking L Distal Radius Plate 2.4/2.7 mm • Locking L-Oblique Distal Radius Plate 2.4/2.7 mm • Locking Distal Radius Plate 2.4/2.7 mm • Locking Distal Radius Buttress Plate 2.4/2.7 mm • Locking Distal Radius Plate Extra-Articular 2.4/2.7 mm • Locking Distal Radius Plate Straight 2.4/2.7 mm • Locking T Distal Radius Plate 2.4/2.7 mm • 2.4 mm VA Locking Two-Column Distal Radius Plate Volar (Standard / Wide / Narrow) • 2.4 mm VA Locking Volar Rim Distal Radius Plate	Unstable, comminuted, Intra-articular, Extra-articular, Volar Rim, Marginal Fragment, and Two-column Distal Radius fractures requiring Variable-Angle fixation.
Wrist Fusion / Arthrodesis	• Locking Wrist Fusion Plate 2.7/3.5mm (Straight, Short Bend, Standard Bend)	Arthrodesis of the wrist in degenerative disease, post-traumatic arthritis, or salvage procedures.
General Reconstruction / Small Fragment Fixation	• Locking One Third Plate 3.5 mm • Locking T Small Plate 3.5 mm • Locking T Oblique Plate 3.5 mm • Locking Reconstruction Plate Round Hole 3.5 mm • Locking Reconstruction Plate B.C. Hole 3.5 mm	Fixation of small bone fragments, periarticular regions, or complex anatomical reconstructions where plate contouring is required.
Proximal Femur Fractures	• Locking Proximal Femoral Plate 5.0 mm • Locking Proximal Femoral Plate Type 2 5.0 mm • Locking Proximal GT Cable Plate • Locking Cable Plate Broad • Locking Proximal Femur Lateral Support Plate • VA Locking Curved Condylar Cable Plate 5.0mm	Unstable Intertrochanteric, Subtrochanteric, and Proximal Femoral Fractures; fixation of greater trochanter fragments with cable augmentation.
Distal Femur Fractures	• Locking Distal Femoral Plate 5.0 mm • Locking Medial Distal Femoral Plate 5.0 mm • Locking Distal Femoral Plate B.C. Hole 90°, 95° & 135°	Intra-articular, extra-articular, supracondylar, comminuted, and metaphyseal distal femur fractures.
Intertrochanteric / Subtrochanteric Fractures	• Locking Dynamic Hip Plate 130° B.C. Hole	Intertrochanteric and subtrochanteric proximal femoral fractures requiring fixed-angle dynamic support.
Proximal Tibia / Tibial Plateau Fractures	• Locking Lateral Tibial Plate 5.0 mm • Locking Proximal Tibial Plate 3.5 mm • Locking Proximal Medial Tibial Plate 3.5 mm • Locking Posteromedial Proximal Tibial Plate 3.5 mm	Unicondylar, bicondylar, periarticular, comminuted, and metaphyseal proximal tibia or tibial plateau fractures.
Distal Tibia Fractures	• Locking Medial Distal Tibial Plate 3.5 mm • Locking Distal Tibial Plate with Knob 3.5 mm • Locking Anterolateral Distal Tibial Plate 3.5 mm	Intra-articular, extra-articular, metaphyseal, and comminuted distal tibial fractures require angular stability.
Fibula Fractures	• Locking Lateral Distal Fibula Plate 2.7 mm • Locking Lateral Distal Fibula Plate 3.5 mm • Locking Periarticular Distal Lateral Fibular Plate 2.7 mm • Locking Periarticular Distal Lateral Fibular Plate 2.7/3.5 mm	Distal fibula fractures, malleolar, periarticular, or comminuted fractures requiring low-profile fixation.
Calcaneal Fractures	• Locking Calcaneal Plate 3.5 mm	Intra-articular, extra-articular, and comminuted calcaneal fractures requiring contourable fixation.
Corrective Osteotomy / Deformity Fixation	• Locking Tomo Fixation Plate Small (With / Without Capsule)	Opening or closing wedge corrective osteotomies of long bones requiring rigid fixation.
Bone Compression Applications	• Locking Bone Compression Plate Small 2.7 mm • Locking Bone Compression Plate Small 3.5 mm • Locking Bone Compression Plate Broad 5.0 mm • Locking Bone Compression Plate Narrow 5.0 mm	Simple diaphyseal or metaphyseal fractures requiring compression for primary bone healing.
Periarticular / Buttress Applications (Large Fragment)	• Locking L Buttress Plate 5.0 mm • Locking T Simple Plate 5.0 mm • Locking T Buttress Plate 5.0 mm	Periarticular fractures requiring buttress support in load-bearing anatomical locations.
Distal Femur	• VA Locking Curved Condylar Plate	For fixation of fractures of the distal femur or metaphyseal / diaphyseal regions requiring angular stability.
Proximal Humerus	• VA Locking Proximal Humerus Plate	For fixation of fractures of the proximal humerus requiring variable-angle locking.
Proximal Humerus	• Locking Periarticular Proximal Humerus Plate	For fixation of periarticular fractures of the proximal humerus, providing angular stability near the joint surface.
Clavicle (Lateral)	• Locking Clavicle Hook Plate	For fixation of lateral clavicle fractures, acromioclavicular joint dislocations, or fractures requiring hook stabilization under the acromion.
Clavicle (Midshaft)	• Locking Superior Anterior Clavicle Plate	For fixation of midshaft or segmental clavicle fractures using a superior-anterior plate position with angular stability.
Clavicle (Lateral)	• Locking Superior Anterior Clavicle Plate with Lateral Extension	For fixation of lateral or multi-fragmentary clavicle fractures requiring additional lateral extension support and stability.

Before use, read these instructions, the AOSYS "Important Information," and the Surgical Technique Guide carefully. Be familiar with the correct surgical method.
Trauma System: Bone Plates & Screws Implants include various metallic components like Plates & Screws. 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:
The Bone Plates & Screws are intended to be used for Internal Fixation of fractures and reconstruction of bones including the Scapula, Olecranon, Humerus, Radius, Ulna, Pelvis, Tibia, Fibula, Femoral. Examples of these Internal Fixations and reconstructions include compression fractures, Intra-articular and Extra Articular Fractures, Displaced Fractures, Osteotomies, non-unions and malunions. This system can be used for Ventral, Dorsal or Orthogonal applications. (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 Trauma System Bone Plates & Screws:

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
	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
Website : www.aosys.in