DEVICE SYSTEM NAME

Tibia Plate System

DEVICE DESCRIPTION

Plates and Screws included in the Tibia Plate System helps in the fixation of all type fractures like Proximal epiphysis fracture, diaphysis fracture and distal epiphysis fracture of tibia bone. The Tibia bone is one of the larger and stronger bones that carries most of the weight of the human body. Therefore, the plate and screws available for it are also made strong enough to bear the weight. The plates and screws are gone through different types of testing like mechanical testing, clinical testing, biocompatibility testing, etc. The Tibia Plate System strictly complies and full fill the regulatory and statutory requirements. As per the EU MDR classification, the Tibia Plate System is classified as class IIb long term medical devices.

The plates of Tibia Plate System is facilitated with both locking and conventional hole system. For which the standard combi and/or capsule hole are provided. Some of the plates are also provided with the variable angle locking system of about 15 degree in all direction. The Tibia Plates System also has fixed angle holes. Properties of fixed angle plates enable their successful using even in less quality and osteoporotic bones. It is mainly useful during intra-articulatory fractures treatment. Some plates can be anatomically shaped for a better fit to the natural anatomy in the proximal and distal tibia bone.

Fixation is achieved by inserting bone screws through the openings in the plate into the fractured Tibia bone. The plates of the Tibia Plate System can be intended through ORIF (Open Reduction and Internal Fixation).

The plates and screws included in the system are as follows:

- 3.5mm AV-Wiselock Proximal Tibia Plate, Small Bend
- 3.5mm AV-Wiselock Proximal Tibia Plate, Large Bend
- 3.5mm AV-Wiselock Medial Proximal Tibia Plate
- 4.5/5.0mm AV-Wiselock Proximal Lateral Tibia Plate
- 3.5mm Wise-Lock Medial Distal Tibia Plate
- 3.5mm Wise-Lock Proximal Tibia Plate
- 3.5mm Wise-Lock Medial Proximal Tibia Plate
- 3.5mm Wise-Lock Posterior Medial Proximal Tibia Plate
- 3.5mm Wise-Lock Anterolateral Distal Tibia Plate
- 3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab
- 3.5mm Wise-Lock Low Profile Medial Distal Tibia Plate, Without Tab
- 3.5mm Wise-Lock Metaphyseal Plate for Medial Distal Tibia, Left/Right
- 3.5mm Wise-Lock Pilon Plate
- 3.5mm Wise-Lock Pilon Plate, Cruciform
- 3.5mm Wise-Lock Small Dynamic Compression Plate with LC Under Cuts
- 3.5mm Wise-Lock Hook Plate
- 3.5mm Wise-Lock Cloverleaf Plate
- 4.5/5.0mm Wise-Lock Proximal Lateral Tibia Plate

- 4.5/5.0mm Wise-Lock Medial Proximal Tibia Plate
- 4.5/5.0mm Wise-Lock Proximal Tibia Plate
- 4.5/5.0mm Wise-Lock "L" Buttress Plate
- 4.5/5.0mm Wise-Lock "T" Buttress Plate
- 4.5/5.0mm Wise-Lock "T" Plate, Left/Right
- 4.5/5.0mm Wise-Lock Osteotomy Medial High Tibia Plate
- 4.5/5.0mm Wise-Lock Osteotomy Lateral High Tibia Plate
- 5.0mm Wise-Lock Proximal Lateral Tibia Plate (LISS)
- 3.5mm Small Dynamic Compression Plate
- 3.5mm Small Limited Contact Dynamic Compression Plate
- 3.5mm Cloverleaf
- 3.5mm Hook Plate
- 4.5mm Lateral Tibial Head Buttress Plate
- 4.5mm Proximal Tibia Medial Plate
- 4.5mm Proximal Tibia Plate with Round Holes
- 4.5mm Proximal Lateral Tibia Plate
- 4.5mm Distal Tibia Plate
- 4.5mm Distal Lateral Tibia Plate with Round Holes
- 4.5mm Distal Tibia Lateral Plate
- 4.5mm Fibular Distal Tibia Plate
- 4.5mm "T" Plate
- 4.5mm "T" Buttress Plate
- 4.5mm "L" Buttress Plate, Left/Right
- 4.5mm Hook Plate

Bone Screws:

- 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head)
- 3.5mm AV-Wiselock Screw, Self-Tapping
- 3.5mm Cortical Screw, Self-Tapping (Star Head)
- 3.5mm Wise-Lock Screw, Self-Tapping (Hex Head)
- 3.5mm Wise-Lock Screw, Self-Drilling, (Hex Head)
- 3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head)
- 3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head)
- 3.5mm Cortical Screw, Self-Tapping, (Hex Head)
- 3.5mm Cortical Screw, (Hex Head)
- 3.5mm Cancellous Screw, Short Thread
- 3.5mm Cancellous Screw, Full Thread
- 4.0mm Cancellous Screw, Short Thread
- 4.0mm Cancellous Screw, Full Thread
- 4.5mm Cortical Screw, Self-Tapping, (Star Head)
- 4.5mm Cortical Screw, (Hex Head)
- 5.0mm AV-Wiselock Screw, Self-Tapping, (Star Head)
- 5.0mm Wise-Lock Screw, Self-Tapping, (Hex Head)

- 5.0mm Wise-Lock Screw, Self-Tapping & Self-Drilling, (Hex Head)
- 5.0mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head)
- 5.0mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head)
- 5.0mm Wise-Lock Cannulated Screw, Full Thread, Self-Tapping
- 5.0mm Wise-Lock Cannulated Screw, Partial Thread, Self-Tapping
- 6.5mm Cancellous Screw, 16mm Thread
- 6.5mm Cancellous Screw, 32mm Thread
- 6.5mm Cancellous Screw, Full Thread
- Washer for Small Fragment Screws
- Washers for 4.5mm to 7.0mm Screws

MATERIALS

Tibia Plates System implants are manufactured using;

Titanium alloy Ti-6Al-4V conforming to the standard EN ISO 5832-3:2021 and stainless steel conforming to the standard EN ISO 5832-1:2019. These materials are bio-compatible and the biocompatibility is tested as per the series of EN ISO 10993-1. These material is not compatible with other metal alloys. Do not use any of the Tibia Plates System implants with implants from any other system or manufacturer.

INTENDED USE/PURPOSE

The Tibia Plate System is intended to treat Nonunion, Malunions and fracture of tibia bone.

INDICATIONS

3.5mm AV-Wiselock Proximal Tibia Plate, Small Bend and 3.5mm AV-Wiselock Proximal Tibia Plate, Large Bend

Fractures of the proximal tibia having; Simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depressions, Peri-prosthetic and fractures with associated shaft fractures. Plates can also be used for treatment of non-unions, malunions, tibial osteotomies and osteopenic bone.

3.5mm AV-Wiselock Medial Proximal Tibia Plate

To treat buttress metaphyseal fractures of the medial tibial plateau, split-type fractures of the medial tibial plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibial plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia, as well as segmental fractures of the proximal tibia.

4.5/5.0mm AV-Wiselock Proximal Lateral Tibia Plate

The Plate is intended for treatment of osteopenic bone, tibial osteotomies, nonunions, malunions, and fractures of the proximal tibia including:

- Simple, comminuted fractures
- Lateral wedge fractures
- Depression medial wedge fractures

- Bicondylar combination of lateral wedge and depression fractures
- Periprosthetic fractures
- Proximal fractures with associated shaft fractures

3.5mm Wise-Lock Medial Distal Tibia Plate

Indicated for the fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intra articular and distal tibia fractures with a shaft extension, malleolar and distal fibular fractures.

3.5mm Wise-Lock Proximal Tibia Plate

Intended for treatment of nonunions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

3.5mm Wise-Lock Medial Proximal Tibia Plate

Intended to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia as well as segmental fractures of the proximal tibia.

3.5mm Wise-Lock Posterior Medial Proximal Tibia Plate

Indicated for internal fixation of posteromedial proximal tibia fractures including buttressing of fractures of the proximal, distal, and metaphyseal areas of the tibia.

3.5mm Wise-Lock Anterolateral Distal Tibia Plate

Intended for fractures, osteotomies and non-unions of the distal tibia, particularly in osteopenic bone.

3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab, 3.5mm Wise-Lock Low Profile Medial Distal Tibia Plate, Without Tab

Intended for fixation of complex intra and extra articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Metaphyseal Plate for Medial Distal Tibia

The plate allows optimal treatment of juxta-articular fractures of the distal tibia extending into the shaft area. This plate takes the following characteristics of the distal tibia into account: Thin, soft tissue coverage, Complex anatomic shape of the bone.

3.5mm Wise-Lock Pilon Plate

Intended for fixation of intra and extra articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Pilon Plate, Cruciform

Intended for fixation of intra and extra articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Small Dynamic Compression Plate with LC Under Cuts

Fixation of fractures, osteotomies and non-unions of the distal tibia and fibula, particularly in osteopenic bone.

3.5mm Wise-Lock Hook Plate

Indicated for fractures, osteotomies and nonunions of small bones, including the tibia and fibula, particularly in osteopenic bone.

3.5mm Wise-Lock Cloverleaf Plate

Intended for Distal tibia for comminuted fractures to buttress its medial side.

4.5/5.0mm Wise-Lock Proximal Lateral Tibia Plate

The Plate is intended for treatment of osteopenic bone, tibial osteotomies, nonunions, malunions, and fractures of the proximal tibia including:

- Simple, comminuted fractures
- Lateral wedge fractures
- Depression medial wedge fractures
- Bicondylar combination of lateral wedge and depression fractures
- Periprosthetic fractures
- Proximal fractures with associated shaft fractures

4.5/5.0mm Wise-Lock Medial Proximal Tibia Plate

The plate is intended to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia, as well as segmental fractures of the proximal tibia.

The 4.5/5.0mm version may also be used for fixation of nonunions and malunions of the medial proximal tibia and tibia shaft, as well as opening and closing wedge tibial osteotomies.

4.5/5.0mm Wise-Lock Proximal Tibia Plate

The plates are indicated for treatment of nonunions, malunions and fractures of the proximal tibia including:

- Simple fractures
- Comminuted fractures
- Lateral wedge fractures
- Depression fractures
- Medial wedge fractures
- Bicondylar, combination of lateral wedge and depression fractures
- Fractures with associated shaft fractures

4.5/5.0mm Wise-Lock "L" Buttress Plate

4.5/5.0mm Wise-Lock ‘L’ Buttress Plate is indicated for fixation of fractures, osteotomies and non-

unions of the distal tibia particularly in osteopenic bones.

4.5/5.0mm Wise-Lock "T" Buttress Plate

4.5/5.0mm Wise-Lock ‘T’ Buttress Plate is indicated for fixation of fractures, osteotomies and non-unions of the distal tibia particularly in osteopenic bones.

4.5/5.0mm Wise-Lock "T" Plate

4.5/5.0mm Wise-Lock "T" Plate is intended to buttress metaphyseal fractures of the medial tibial plateau and distal tibia. Also for use in fixation of osteopenic bone and fixation of non-unions and malunions.

4.5/5.0mm Wise-Lock Osteotomy Medial High Tibia Plate

Open-wedge and closed-wedge osteotomies of the medial proximal tibia for the treatment of:

- Uni compartmental medial or lateral gonarthrosis with malalignment of the proximal tibia.
- Idiopathic or post traumatic varus or valgus deformity of the proximal tibia.

4.5/5.0mm Wise-Lock Osteotomy Lateral High Tibia Plate

The 4.5/5.0mm Wise-Lock Osteotomy Lateral High Tibia Plate are indicated for open- and closed-wedge osteotomies, fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the lateral proximal high tibia.

5.0mm Wise-Lock Proximal Lateral Tibia Plate (LISS)

5.0mm Wise-Lock Proximal Lateral Tibia Plate (LISS) are indicated for the stabilization of fractures of the proximal tibia. These include:

- Proximal shaft fractures
- Metaphyseal fractures
- Intra-articular fractures
- Periprosthetic fractures

3.5mm Small Dynamic Compression Plate

Fracture fixation and fixation after for example osteotomies, malunions, nonunions including but not limited to proximal and distal and shaft of tibia.

3.5mm Small Limited Contact Dynamic Compression Plate

Fracture fixation and fixation after for example osteotomies, malunions, nonunions including but not limited to proximal and distal and shaft of tibia.

3.5mm Cloverleaf Plate

Intended for Distal tibia for comminuted fractures to buttress its medial side.

3.5mm Hook Plate

Indicated for fractures, osteotomies and nonunions of small bones, including the tibia and fibula,

particularly in osteopenic bone.

4.5mm Lateral Tibial Head Buttress Plate

These plates are indicated for treating shaft fractures, metaphyseal fracture, intra-articular and periprosthetic fractures of proximal tibia.

4.5mm Proximal Tibia Medial Plate

4.5mm Proximal Tibia Medial Plate is indicated for treatment of-

- Osteopenic bone, tibial osteotomies, nonunions, malunions and fractures of proximal tibia.
- Simple, comminuted fractures
- Lateral wedge fractures
- Depression medial wedge fractures
- Bicondylar combination of lateral wedge and depression fracture
- Periprosthetic fractures
- Proximal fractures with associated shaft fractures

4.5mm Proximal Tibia Plate with Round Holes

4.5mm Proximal Tibia Plate with Round Holes is indicated for treatment of-

- Osteopenic bone, tibial osteotomies, nonunions, malunions and fractures of proximal tibia.
- Simple, comminuted fractures
- Lateral wedge fractures
- Depression medial wedge fractures
- Bicondylar combination of lateral wedge and depression fracture
- Periprosthetic fractures
- Proximal fractures with associated shaft fractures

4.5mm Proximal Lateral Tibia Plate

4.5mm Proximal Lateral Tibia Plate is indicated for treatment of-

- Osteopenic bone, tibial osteotomies, nonunions, malunions and fractures of proximal tibia.
- Simple, comminuted fractures
- Lateral wedge fractures
- Depression medial wedge fractures
- Bicondylar combination of lateral wedge and depression fracture
- Periprosthetic fractures
- Proximal fractures with associated shaft fractures

4.5mm Distal Tibia Plate

4.5mm Distal Tibial Plate is indicated for-

- Temporary internal fixation and stabilization of osteotomies and fractures, including Comminuted fractures, Supracondylar fractures, Intra-articular and extra-articular condylar fractures of tibia.
- Fractures in osteopenic bone, Nonunions and Malunions of tibia.

4.5mm Distal Lateral Tibia Plate with Round Holes

4.5mm Distal Lateral Tibia Plate with Round Holes is indicated for-

- Temporary internal fixation and stabilization of osteotomies and fractures, including Comminuted fractures, Supracondylar fractures, Intra-articular and extra-articular condylar fractures of tibia.
- Fractures in osteopenic bone, Nonunions and Malunions of tibia.

4.5mm Distal Tibia Lateral Plate

4.5mm Distal Lateral Tibia Plate with Round Holes is indicated for-

- Temporary internal fixation and stabilization of osteotomies and fractures, including Comminuted fractures, Supracondylar fractures, Intra-articular and extra-articular condylar fractures of tibia.
- Fractures in osteopenic bone, Nonunions and Malunions of tibia.

4.5mm Fibular Distal Tibia Plate

4.5mm Fibular Distal Tibia Plate are indicated in the regions where there is ventrolateral instability, and/or when the soft tissue cover of the medial distal tibia is poor. These can be applied to the ventrolateral surface of the tibia after minimal removal of periosteum.

4.5mm "T" Plate

4.5/5.0mm "T" Plate is intended to buttress metaphyseal fractures of the medial tibial plateau and distal tibia. Also for use in fixation of osteopenic bone and fixation of non-unions and malunions.

4.5mm "T" Buttress Plate

4.5/5.0mm Wise-Lock ‘T’ Buttress Plate is indicated for fixation of fractures, osteotomies and non-unions of the distal tibia particularly in osteopenic bones.

4.5mm "L" Buttress Plate

4.5/5.0mm ‘L’ Buttress Plate is indicated for fixation of fractures, osteotomies and non-unions of the distal tibia particularly in osteopenic bones.

4.5mm Hook Plate

Indicated for fractures, osteotomies and nonunions of small bones, including the tibia and fibula, particularly in osteopenic bones.

CONTRA INDICATIONS

The implant should not be used in a patient who has currently, or who has a history of:

- Local or Systemic acute or chronic inflammation.
- Active infection or inflammation.
- Suspected or documented metal allergy or intolerance.
- Symptomatic Arthritis.

- Severely comminuted fractures in which bone fragments are too small or numerous to adequately fix or maintain a reduced position.
- Mental illness or schizophrenia, which may cause patients to ignore the limitations and precautions of the implanted material, leading to implants fracture and complication.
- Alcohol or drug addict
- Severe osteopenia and/or osteoporosis, or in the presence of marked or rapid bone absorption, metabolic bone disease, cancer, or any other tumor-like condition of the bone which may compromise fixation. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation.
- Any patient unwilling to cooperate with the post-operative instructions.
- Autoimmune disease, or vascular disease
- Pre-existing tibial bone deformity
- Fractures associated with neurovascular injury
- Overlapping of implant during the re-surgery are not allowed.
- Patients who had local disorders (e.g., tumors, Paget disease)
- Patients who are unable to consent for themselves to treatment
- Motor function disorder

The above-mentioned list does not exhaust the topic of contraindications.

WARNINGS & PRECAUTIONS

Serious Post-operative complications may occur from the use of implant in a patient who:

- Demonstrates anatomical or physiological anomalies.
- The patient should be informed that the life expectancy of the device is unpredictable and once implanted, successful results cannot be guaranteed if adequate care and precautions are not taken.
- While inserting the screw, it is essential to set the screwdriver in relation to the screw correctly. Following the instructions given allows for reduction of the risk of mechanical damage to the screw, screwdriver, or bony hole:
  - screwdriver should be set on the screw axis,
  - apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible.
  - the final phase of tightening shall be performed carefully.
- Has immunological response, sensitization or hypersensitivity for foreign materials.
- Do Not Re-Use. Do not re-process. The device is not designed for re-processing. Reuse of the medical device intended for single use devices may lead to infection, degraded performance or a loss of functionality. The cleaning and disinfection / sterilization for re-processing of these single use devices has not been validated nor is any authentic information available. So re-process of the single use device is not allowed.
- The important medical information given in this document should be conveyed to the patient.
- The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon is responsible for this choice.
- Patients who are overweight, malnourished and/or abusing alcohol or drugs, with weak muscles

and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.

- The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
- For Qualified surgeon use only.
- In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.
- Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

Note: It is the responsibility of the surgeon to discuss, with the patient, the precautions, possible risks, warnings, consequences, complications and adverse reactions which may occur as a result of the surgical procedure and implantation of the device(s).
If adverse effects happen, it may necessitate re-operation, revision or removal surgery, arthrodesis or the involved joint and/or amputation of the limb.

TARGET PATIENT GROUP

Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those addressed in the contraindications mentioned above should be avoided. The device can be used in skeletally mature patient only (aged 18 to 70 years).

INTENDED USER GROUP

All qualified and well-trained/experienced Surgeons can use this device.

SURGEON NOTE

Although the surgeon is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION

For use on or by the order of a surgeon only.

MRI COMPATIBILITY

The AUXEIN MEDICAL Tibia Plate System have not been evaluated for safety and compatibility in the MR environment. The AUXEIN MEDICAL implants have not been tested for heating or migration in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic Resonance Imaging) environment.

All Auxein's Tibia Plate System is manufactured in metallic material and does not emit any ionizing radio-active radiation.

CLINICAL BENEFITS

If the device is implanted as per the labelling and recommended technique, then it helps to achieve anatomical stabilization, fracture reduction and fracture fixation by radiological evaluation of the Tibia bone by reducing pain (VAS Score), regains its range of motion as prior to fracture, increases Lower Extremity Functional Score (LEFS) score and change in patient quality of life (WHO-BREF).

PERFORMANCE CHARACTERSTICS

The Tibia Plate System system has good load-bearing capacity (static and fatigue strength), stiffness, rigidity, flexibility, it is also biocompatible for use and are capable of bending deformation and have sufficient strength to allow the insertion of fixing components.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The link to Summary of Safety and Clinical Performance (SSCP) will be updated in this Instructions for Use when the SSCP will be made available to the EUDAMED Database.

POTENTIAL ADVERSE EFFECTS

The adverse effect may necessitate re operation or revision. The surgeon should warn the patients about the possibility of adverse effects occurrence.

Potential adverse events include but are not limited to:

1. Corrosion of metal components (the significance and long-term implications are uncertain and await further clinical evidence and evaluation).
2. Interference with roentgen graphic, CT, and/or MR imaging because of the presence of the implants.
3. Bone fracture or “stress shielding” phenomenon causing loss of bone above, below or at the operative site.
4. Bone loss or decrease in bone density, possibly caused by stress shielding.
5. Deep vein thrombosis, thrombophlebitis embolism.
6. Limitations of normal, everyday activities.
7. Scar formation that could cause neurological impairment, or nerve compression and/or pain.
8. Seroma
9. Hematoma
10. Infection
11. Deep venous thrombosis
12. Hardware irritation
13. Loss of reduction
14. Loss of alignment
15. Nonunion
16. Delayed union
17. Wound Complications
18. Secondary procedures
19. Malunion
20. Pain around osteotomy

21. Implant Failure
22. Revision
23. Skin Necrosis
24. Sepsis
25. Sec. displacement
26. Algodystrophy
27. Peroneal nerve complications
28. Paralysis of the dorsiflexion muscles
29. Anterior knee pain
30. Wound dehiscence
31. marginal necrosis of the surgical wound
32. superficial infection
33. muscle hernia

OTHER PREOPERATIVE, INTRA OPERATIVE, AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected. The Tibia Plate System can be used for skeletally mature patients.
- Patient conditions and/or predispositions such as those addressed in the contraindications mentioned above should be avoided.
- The type of construct to be assembled for the case should be determined before beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
- The Tibia Plate System devices are not to be combined with the devices from another manufacturer.
- Different metal types should not be used together.

INTRA OPERATIVE

- The Instruction for Use, Surgical Techniques and Product Brochure should be carefully followed.

- Always, extreme caution should be used to protect the branches of Tibial nerve.
- The plates should not be repeatedly or excessively bent any more than necessary. The plates should not be reverse bent at the same location.
- Before closing the soft tissues, all of the screws should be seated on the plate.
- Recheck the tightness of all screws after finishing making sure that none has loosened during the tightening of the other screws.

Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are crucial.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required before firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur because of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active. The patient should be warned to avoid falls or sudden jolts.
- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone healing process.
- If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the Tibial surgical site be maintained until a firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- The Tibial Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the fractured bone is fused, these devices serve no functional purpose and may be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur:

  (1) Corrosion, with localized tissue reaction or pain,(2) Migration of implant position possibly resulting in injury, (3) Risk of additional injury from postoperative trauma, Bending, loosening and/or breakage, which could make removal impractical or difficult, (5) Pain, discomfort, or abnormal sensations due to the presence of the device, (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding.While the surgeon must make the final decision on implant

removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should consider the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.

- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the Tibial Plate System components should ever be reused under any circumstances. Reuse may lead to infection & cross infection. The reuse of implants after re sterilization may not result in the same responses.
- Orthopedic surgeries do not generally involve major risks and complications. Orthopedic Surgeons are properly trained to avoid potential difficulties which might occur during an intervention, as well as to efficiently correct such problems if they appear. However, some of the risks and complications which may accompany an orthopedic surgical procedure are:
  - **Postoperative infections:** In order to avoid this complication, patients will be administered antibiotics before, during and after the surgery. If patient have an ongoing infection (throat, urinary, dental etc.), it is highly recommended to treat it prior to the intervention, as it can reach your joint and a late infection could develop months or even years following orthopedic surgery.
  - Bleeding
  - **Blood clots:** They may occasionally appear after orthopedic surgery. Blood clots can be avoided with appropriate medication and physical exercise.
  - **Blood vessel damage:** This complication may appear if blood vessels located in close proximity of the implant are affected during the procedure.
  - **Allergic reactions:** The patient might experience an allergic reaction to the metal components or cement used to fix the implant (titanium, stainless steel etc.)

PACKAGING

Packages for each component should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage before use. Damaged packages or products should not be used, and should be returned to AUXEIN MEDICAL PVT LTD.

DECONTAMINATION BY STEAM STERILIZATION METHOD

All implants that have been taken into a surgical field must first be sterilized/decontaminated by using steam autoclaving process and introduction into a sterile surgical field.

The following method has been validated and recommended by the company:

Method:	Steam Sterilization (Autoclaving)
Temperature	Minimum 121 Degree Centigrade
Exposure Time:	15 Minutes
Pressure	15 Psi

Cycle Type	Vacuum Type

Note: FDA Approved wrap or clothes shall be used for sterilization.

STORAGE

Store the implants at a dry place. Care should be taken in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the implants.

DISPOSAL

The Orthopaedic implant is to be disposed off as per the Hospital and Regulatory norms.

PRODUCT COMPLAINTS

Customers or users of products, who have any complaints or who have experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the Manufacturer, AUXEIN MEDICAL or EU Representative. Further, if any of the implanted component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the Manufacturer or EU Representative should be notified immediately.

If any AUXEIN MEDICAL's product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the Manufacturer or EU Representative should be notified Immediately By Telephone, Fax Or Written Correspondence. When Filing A Complaint, Please Provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact your representative or distributor or contact the manufacturers direct at https://www.auxein.com/ where IFU, Surgical Technique and Catalog are also available

Details of various Symbols used in Labelling

Symbol	Symbol Title	Description	Standard Title	Reference Number
	Date of Manufacture	Indicates the date when the medical device was manufactured.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.3

	Manufacturer	Indicates the medical device manufacturer	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.1
	Authorized representative in the European community	Indicates the authorized representative in the European Community/European Union	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.2
	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.6
	Conformité Européene (European Conformity)	Signifies European technical conformity.	EU MDR 2017/745.	MDD 93/42/EEC, MDR 2017/745 (Annex XII, Article 20)
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.5
	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.4.2
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.4
	Keep away from the sunlight	Indicates a medical device that needs protection from light	EN ISO 15223-1 Medical devices—Symbols to be used with medical device	5.3.2

		sources	labels— General requirements.	
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.3
	Do not use if package is damaged.	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.8
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.7
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.7
	Use by date	Indicates the date after which the medical device is not to be used.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.4
	Prescription only	The symbol for Prescription Device Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	N/A	21 CFR 801.15 ad 21 CFR 801.109 ((c) (1) (i) (F) (b) (1)).

MD	Medical device	Indicates the item is a medical device	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.7.7
UDI	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.7.10

CE 2460

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EC REP

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REVISION HISTORY TABLE:

S. No.	Document No	Rev. No.	Description of Revision	Effective date	Prepared by	Approved by

1.	AMPL-IFU-TFS/NS-012	00	Initially released.	13-06-2023		
2.	AMPL-IFU-TFS/NS-012	01	Updated the IFU as per query received from PRJN-629776 (EU MDR Project)	02-11-2023