Summary of Safety and Clinical Performance for Tibia Plate system

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, A3-REG-QF-002-F1

The following information is intended for users'/healthcare professionals.

1. The identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN.
Basic UDI-DI: 08903993TPS012RY (For Stainless Steel Implants) and 0890399TPT01227 (for Titanium Implants)
SRN: IN-MF-000018837

The Tibia Plate System includes the following as listed below:

- 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
- 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 Screw

Details Regarding the device are provided in below table:

Device Trade Name:	**Tibia plate System**		
Manufacturer Details	**Name & Address of Manufacturer:** Auxein Medical Pvt. Ltd. **Manufacturing Unit:** Plot No. 168-169-170, Phase IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonipat, Haryana– 131028, India **Phone:** +91-9910643638 **Email: info@auxeinmedical.com** **Website: www.auxein.com**		
Manufacturer's SRN	IN-MF-000018837		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Tibia plate System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev 2
Year when the first certificate (CE) was issued covering the device	2014		
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per EN ISO 5832-3:2021 and Stainless steel alloy SS 316 L as per EN ISO 5832-1:2019.		
USFDA Approved	Yes (Tibia plate are approved by USFDA whose details are as follow:) **510(k) Number:** K213059, K141680		
Risk Class	**IIb {According to REGULATION (EU) 2017/745 (MDR) OF THEEUROPEAN PARLIAMENT, Annex VIII, Chapter-3, Rule 8** - Implantable devices and long-term surgically invasive devices (>30 days)} are in Class IIb unless they are intended: 1. Are intended to be placed in the teeth, in which case they areclassified as class IIa; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Tibia plate intended to be placed in Tibia boneto treat fracture not intended for teeth.*		

2. Are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III;

Applicable/ Not Applicable: *Not Applicable*

Justification: *The Tibia plate comes in contact with the Tibia bone.Thus, it does not come in contact with the heart, the central circulatory system or the central nervous system.*

3. Have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;

Applicable/ Not Applicable: *Not Applicable*

Justification: *The Tibia plate system is made up of medical grade metallic alloy. Metallic alloy does not achieve its intended use by biological effect or by absorption.*

4. Are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;

Applicable/ Not Applicable: *Not Applicable*

Justification: *The Tibia plate system is made up of medical grade metallic elements. These metallic elements have high metallic bonds that do not undergo chemical change in the body.*

5. Are intended to administer medicinal products, in which casethey are classified as class III;

Applicable/ Not Applicable: *Not Applicable*

Justification: *The Tibia plate implants made up of metal alloys to provide support for the fractured Tibia bone. The system is not intended to administer medicinal products.*

6. Are active implantable devices or their accessories, in which cases they are classified as class III;

Applicable/ Not Applicable: *Not Applicable*

	Justification: 'Active Device' *means any device, the operation ofwhich depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intendedto transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. The Tibia plate system does not depend on a source of energy.* 7.Are breast implants or surgical meshes, in which cases they areclassified as class III; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Tibia plate system treats Tibia bone fracture.Not intended as breast implants or surgical meshes.* 8. Are total or partial joint replacements, in which case they are classified as class III, except ancillary components such as screws, wedges, plates and instruments; or; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Tibia plate system treats Tibia bone fracture. Not intended for Total or Partial Joint Replacements.* 9.Are Spinal Disc Replacement Implants or are implantable devices that come into contact with the Spinal Column, in which case they are classified as class III except components such as screws, wedges, plates and instruments: ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Tibia plate system is an implantable device totreat Tibia bone fractures. The Plate system is not recommended for the Spinal Disc Replacement Implants and do not come into contact with the spinal column.*
Authorized Representative Name and Address	**Name:** CMC Medical Devices & Drug S.L **Address:** 29015 Málaga, Spain
Authorized Representative SRN	ES-AR-00000029
Notified Body Name and Single	**Name:** DNV Product Assurance AS

Identification Number	**Single Identification Number:** 2460

2. The intended purpose of the device and any indications, contraindications and target populations.

The Indications, Contraindication and Intended Patient Population related information is provided in below table:

Indications of Use	The Tibia Plate System is part of the Tibia Bone has the following 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.
Contraindications	The implant should not be used in a patient who has currently, or who has a history of: ● Infection local to the operative site ● Signs of local inflammation. ● Fever or leucocytosis. ● Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care. ● Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodelling, e.g. the presence of tumours or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells (WBC) count, or a marked left shift in the WBC differential count. ● Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant (content of the implant material is presented in IMPLANT MATERIAL). ● Any case not needing a surgical intervention. ● Any case not described in the indications. ● Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or

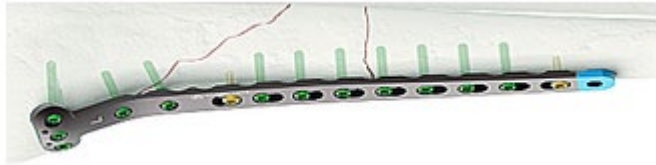
	substance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage. ● Any case where the implant components selected for use would be too large or too small to achieve a successful result. ● Any case that requires the simultaneous use of elements from different systems that are made of different metals. ● Any case in which implant utilization would disturb physiological processes. ● Blood supply limitation in the operative site. ● Morbid obesity (defined according to the WHO. standards). ● Any case in which there is inadequate tissue coverage of the operative site.
Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Tibia plate System can be used for Skeletally Mature patients with Age group of 18-70 Years. The patient conditions and/or pre-dispositions such as those addressed in the contraindications should be avoided.
Intended Users	The Tibia plate Systems are to be used by well experienced, qualified & specialized trained surgeons only.
Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
Use	For Single Use only
Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
Biocompatibility	The devices covered in the Tibia Plate System are Bio-compatible. Biocompatibility of the devices is tested as per EN ISO 10993-1:2020 series of International Standard.

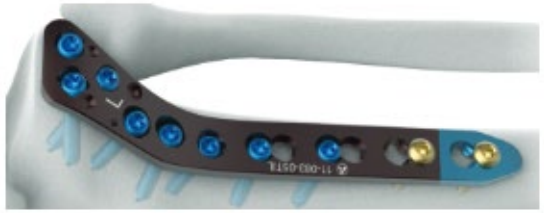
3. Description of the device

1	**Device Name**	**3.5mm AV-Wiselock Proximal Tibia Plate, Small Bend**
	Image	
	Product Code	For SS: 11-026-XYSS, For Titanium: 11-026-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft Hole	04, 06, 08, 10, 12, 14
	Plate Length	87 to 237mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

2	**Device Name**	**3.5mm AV-Wiselock Proximal Tibia Plate, Large Bend**
	Image	

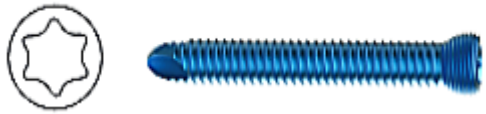
	Product Code	For SS: 11-027-XYSS, For Titanium: 11-027-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Plate Thickness	2.8mm
	Shaft Hole	4, 6, 8, 10, 12, 14
	Head Width	32.6mm
	Shaft Width	14mm
	Head Height	33.3mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

3	**Device Name**	**3.5mm AV-Wiselock Medial Proximal Tibia Plate**
	Image	
	Product Code	For SS: 11-080-XYSS, For Titanium: 11-080-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft Hole	4, 6, 8, 10, 12, 14, 16, 18 & 20
	Shaft Width	28.21mm
	Plate Thickness	3.7mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

4	**Device Name**	**4.5/5.0mm AV-Wiselock Proximal Lateral Tibia Plate**
	Image	
	Product Code	For SS: 11-083-XYSS, For Titanium: 11-083-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft Hole	5, 7, 9, 11, 13
	Shaft Width	24.30mm
	Plate Thickness	3.70, 3.80 ,4.10mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

5	**Device Name**	**3.5mm AV-Wiselock Screw, Self-Tapping (Star Head)**
	Image	

	Product Code	For SS: 11-024-XSS, For Titanium: 11-024-XTI (Where X=Length)
	Head Diameter	4.94mm
	Core Diameter	2.8mm
	Thread Diameter	3.50mm
	Star Size	3.35mm
	Star Diameter	2.4mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

6	**Device Name**	**5.0mm AV-Wiselock Screw, Self-Tapping (Star Head)**
	Image	
	Product Code	For SS: 11-089-XSS, For Titanium: 11-089-XTI (Where X=Length)
	Head Diameter	6.80mm
	Core Diameter	4mm
	Thread Diameter	5mm
	Star Diameter	3.20mm
	Head Length	5mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

7	**Device Name**	**3.5mm Wise-Lock Medial Distal Tibia Plate**

	Image	
	Product Code	For SS: 746.104-XYSS, For Titanium: 746.104-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft Hole	4 ,6, 8, 10, 12, 14
	Head Width	21.6mm
	Shaft Width	11mm
	Head Height	17.4mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

8	**Device Name**	**3.5mm Wise-Lock Proximal Tibia Plate**
	Image	

		
	Product Code	For SS: 747.104-XYSS, For Titanium: 747.104-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft Hole	4 ,6, 8, 10, 12, 14
	Total Length	237mm
	Plate Thickness	3.5mm
	Shaft Width	11mm
	Combi Hole Length	7.5mm
	Combi Hole Width	4.5mm
	Round Hole Minimum Diameter	3.8mm
	Head Width	33.1mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

9	**Device Name**	**3.5mm Wise-Lock Medial Proximal Tibia Plate**

	Image	
	Product Code	For SS: 530.00-XYSS, For Titanium: 530.00-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Total Length	301mm
	Plate Thickness	4.0mm
	Shaft Width	11mm
	Shaft Holes	4, 6, 8, 10, 12, 14, 16, 18, 20
	Combi Hole Length	7.5mm
	Combi Hole Width	4.5mm
	Round Hole Minimum Diameter	3.8mm
	Head Width	27.5mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

10	**Device Name**	**3.5mm Wise-Lock Posterior Medial Proximal Tibia Plate**

	Image	
	Product Code	For SS: 531.00-XYSS, For Titanium: 531.00-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft Width	3.4mm
	Shaft Holes	11mm
	Combi Hole Length	1, 2, 4, 6, 8, 10
	Combi Hole Width	9.5mm
	Round Hole Minimum Diameter	6.5mm
	Head Width	19mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

11	**Device Name**	**3.5mm Wise-Lock Anterolateral Distal Tibia Plate**

	Image	
	Product Code	For SS: WS1.0-XYSS, For Titanium: WS1.0-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft Holes	5, 7, 9, 11, 13, 15, 17, 19, 21
	Plate Thickness	4mm
	Shaft Width	13.5mm
	Combi Hole Length	7.5mm
	Combi Hole Width	4.5mm
	Capsule Hole Length	12mm
	Capsule Hole Width	4.5mm
	Round Hole Minimum Diameter	3.8mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

12	**Device Name**	**3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab**

	Image	
	Product Code	For SS: WS3.X (For left Directions), WS4.X (For Right Directions), For Titanium: TI-WS1.X (For left Directions), TI-WS2.X(For Right Directions) (Where X=No. of shaft holes)
	Shaft Holes	4, 6, 8, 10, 12, 14
	Plate Length	113 to 213mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

13	**Device Name**	**3.5mm Wise-Lock Low Profile Medial Distal Tibia Plate, Without Tab**
	Image	

		
	Product Code	For SS: 10-002-XYSS, For Titanium: 10-002-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft Hole	4, 6, 8, 10, 12, 14
	Total Length	109 to 239mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

14	**Device Name**	**3.5mm Wise-Lock Metaphyseal Plate for Medial Distal Tibia**

	Image	
	Product Code	For SS: 741.1XY, For Titanium: TI-741.1XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Plate Holes	4+4, 4+5, 4+6, 4+7, 4+8, 4+9, 4+10, 4+12, 4+14+, 4+16, 4+18 & 4+20
	Shaft Holes	04, 05, 06, 07, 08, 09, 10, 12, 14, 16, 18, 20
	Total Length	126.5 to 414.5mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

15	**Device Name**	**3.5mm Wise-Lock Pilon Plate**

	Image	
	Product Code	For SS: 799.20X, For Titanium: TI-799.20X (Where X=No. of shaft holes and Direction Not Applicable)
	Shaft holes	7, 9
	Total Length	147, 173mm
	Head Hole to Hole Distance	9.8mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

16	**Device Name**	**3.5mm Wise-Lock Small Dynamic Compression Plate with LC under Cut**
	Image	

		
	Product Code	For SS: 721.2X, For Titanium: TI-721.2-X (Where X=No. of shaft holes and Direction Not Applicable)
	Shaft holes	05, 06, 07, 08, 09, 10, 11, 12
	Total Length	57.6 to 161.6mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

17	**Device Name**	**3.5mm Wise-Lock Hook Plate**
	Image	
	Product Code	For SS: 729.2X, For Titanium: TI-729.2X (Where X=No. of shaft holes and Direction Not Applicable)

	Shaft Holes	3, 4, 5
	Total Length	63, 81 & 99mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

18	**Device Name**	**3.5mm Wise-Lock Cloverleaf Plate**
	Image	
	Product Code	For SS: 715.2X, For Titanium: TI-715.2-X (Where X=No. of shaft holes and Directions Not Applicable)
	Shaft Holes	03, 04, 05, 06
	Total Length	90.3, 106.3, 122.3 & 138.3mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

19	**Device Name**	**4.5/5.0mm Wise-Lock Proximal Lateral Tibia Plate**
	Image	

		
	Product Code	For SS: 733.2XY, For Titanium: TI-733.2XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	No. of Holes	05, 07, 09, 11 & 13
	Total Length	147 to 307mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

20	**Device Name**	**4.5/5.0mm Wise-Lock Medial Proximal Tibial Plate**
	Image	
	Product Code	For SS: 747.2XY, For Titanium: TI-747.2XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Total Length	107 to 323mm

	Shaft Holes	04, 06, 08, 10, 12, 14, 16
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

21	**Device Name**	**4.5/5.0mm Wise-Lock Proximal Tibia Plate**
	Image	
	Product Code	For SS: 749.1XY, For Titanium: TI-749.1XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	No. of Holes	04, 06, 08, 10, 12, 14
	Total Length	83 to 299mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

22	**Device Name**	**4.5/5.0mm Wise-Lock “L” Buttress Plate**

	Image	
	Product Code	For SS: 706.2XY, For Titanium: TI-706.2XY (Where X=No. of shaft holes and Directions Not Applicable)
	Total Length	73.5 to 217.5mm
	No. of Holes	03, 04, 05, 06, 07, 08, 09, 10 & 12
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

23	**Device Name**	**4.5/5.0mm Wise-Lock "T" Buttress Plate**
	Image	
	Product Code	For SS: 714.2X, For Titanium: TI-714.2X (Where X=No. of shaft holes and Direction Not Applicable)
	Total Length	88 to 216mm

	No. of Holes	04, 05, 06, 07, 08, 09, 10, 11 & 12
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

24	**Device Name**	**4.5/5.0mm Wise-Lock "T" Plate**
	Image	
	Product Code	For SS: 709.2XY, For Titanium: TI-709.2XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Total Length	70 to 246mm
	Head Width	03, 04, 05, 06, 07, 08, 09, 10 & 12
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

25	**Device Name**	**4.5mm/5.0mm Wise-Lock Osteotomy Medial High Tibia Plate**

	Image	
	Product Code	For SS: 507.005, For Titanium: TI-507.005
	Total Length	115mm
	No. of Holes	5
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

26	**Device Name**	**4.5/5.0mm Wise Lock Osteotomy Lateral High Tibia Plate**

	Image	
	Product Code	For SS: 576.003Y, For Titanium: TI-576.003Y (Where X=No. of shaft holes and Y=Left/Right Directions)
	Total Length	103.3mm
	Shaft Holes	3
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

27	**Device Name**	**5.0mm Wise-Lock Proximal Lateral Tibia Plate (LISS)**
	Image	
	Product Code	For Titanium: 10-017-XYTI (Where X=No. of shaft holes and Y=Left/Right Directions)

	Total Length	136.4, 156.5, 216.9, 257.2, 297.6mm
	Shaft Holes	05, 07, 09, 11 & 13
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021.

28	**Device Name**	**2.7mm Wise-Lock Screw, Self-Tapping, (Hex Head)**
	Image	
	Product Code	For SS: 118.0X, For Titanium: TI-118.0X (Where X=Length and Direction Not Applicable)
	Total Length	10 to 60mm
	Outer Diameter	2.70mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

29	**Device Name**	**3.5mm Wise-Lock Screw, Self-Tapping (Hex Head)**

	Image	
	Product Code	For SS: 117.0X, For Titanium: TI-117.0X (Where X=Length and Direction Not Applicable)
	Total Length	10 to 80mm(2mm & 5mm increments)
	Outer Diameter	3.50mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

30	**Device Name**	**3.5mm Wise-Lock Screw, Self-Drilling (Hex Head)**
	Image	
	Product Code	For SS: 117.2X, For Titanium: TI-117.2X (Where X=Length and Direction Not Applicable)
	Total Length	10 to 60mm (2mm increments)
	Thread Diameter	3.5mm
	Directional Configuration	Not Applicable

	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

31	**Device Name**	**3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head)**
	Image	
	Product Code	For SS: 188.2X, For Titanium: TI-188.2X (Where X=Length and Direction Not Applicable)
	Total Length	10 to 60mm (2mm increments & 5mm increments)
	Thread Diameter	3.5mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

32	**Device Name**	**3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping (Hex Head)**
	Image	
	Product Code	For SS: 1257.X, For Titanium: TI-1257.X (Where X=Length and Direction Not Applicable)

	Total Length	10 to 60mm (2mm to 5mm increments)
	Thread Diameter	3.50mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

33	**Device Name**	**5.0mm Wise-Lock Screw, Self-Tapping (Hex Head)**
	Image	
	Product Code	For SS: 119.0XY, For Titanium: TI-119.0XY (Where X=No. of shaft holes and Direction Not Applicable)
	Total Length	12 to 90mm (2mm & 5mm increments)
	Thread Diameter	5mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

34	**Device Name**	**5.0mm Wise-Lock Screw, Self-Tapping & Self-Drilling, (Hex Head)**

	Image	
	Product Code	For SS: 119.2-XY, For Titanium: TI-119.2-XY (Where X=No. of shaft holes and Direction Not Applicable)
	Total Length	12 to 90mm (2mm & 5mm increments)
	Thread Diameter	5mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

35	**Device Name**	**5.0mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head)**
	Image	
	Product Code	For SS: 1360-X, For Titanium: TI-1360-X (Where X=Length and Direction Not Applicable)
	Length	20mm to 110mm (2mm & 5mm increments)
	Head Diameter	6.25mm
	Thread Diameter	5mm
	Core Diameter	2.6mm

	Head Thread Length	4.40mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

36	**Device Name**	**5.0mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping (Hex Head)**
	Image	
	Product Code	For SS: 1256-X, For Titanium: TI-1256-X (Where X=No. of shaft holes and Y=Not Applicable)
	Length	20mm to 110mm (2mm & 5mm increments)
	Head Diameter	6.25mm
	Core Diameter	2.6mm
	Thread Diameter	5mm
	Head Thread Length	4.40mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

37	**Device Name**	**3.5mm Small Dynamic Compression Plate**
	Image	

	Product Code	For SS: 720.1X, For Titanium: TI-720.1-X (Where X=No. of shaft holes)
	Plate Width	10.20mm
	Shaft hole	02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12
	Hole Width	4.50mm
	End Hole Distance	2.60mm
	Plate Thickness	3.2mm
	Hole Length	6.50mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

38	**Device Name**	**3.5mm Small Limited Contact Dynamic Compression Plate**
	Image	
	Product Code	For SS: 721.1X, For Titanium: TI-721.1X (Where X=No. of shaft holes)
	Shaft hole	03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14
	Plate Width	11mm
	Hole Width	4.50mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

39	**Device Name**	**3.5mm Cloverleaf Plate**

	Image	
	Product Code	For SS: 715.1X, For Titanium: TI-715.1-X (Where X=No. of shaft holes)
	Shaft hole	03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14
	Head Width	38mm
	Shaft Width	15mm
	Plate Thickness	2mm
	Slot Length	10mm
	Slot Width	4.50mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

40	**Device Name**	**3.5mm Hook Plate**
	Image	
	Product Code	For SS: 729.1X, For Titanium: TI-729.1X (Where X=No. of shaft holes)
	Hook Height	12, 15 & 18mm
	Shaft Hole	04, 05, 06, 07, 08, 10
	Directional Configuration	Not Applicable

	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

41	**Device Name**	**4.5mm Lateral Tibial Head Buttress Plate**
	Image	
	Product Code	For SS: 733.1XY, For Titanium: TI-733.10-XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	No. of Holes	5, 7, 9, 11 & 13
	Total Length	118, 150, 182, 214 & 246mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

42	**Device Name**	**4.5mm Proximal Tibia Medial Plate**
	Image	
	Product Code	For SS: 763.1XY, For Titanium: TI-763.1XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft hole	03, 05, 07, 09, 11, 13
	Head Width	25.30mm
	Shaft Width	17.50mm
	Plate Thickness	2.90mm

	Slot Length	17mm
	Slot Width	5mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

43	**Device Name**	**4.5mm Proximal Tibia Plate with Round Holes**
	Image	
	Product Code	For SS: MP03.XY, For Titanium: TI-MP03.XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Total Length	81 to 178mm
	Shaft Holes	04, 05, 06, 07, 08, 09, 10
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

44	**Device Name**	**4.5mm Proximal Lateral Tibia Plate**
	Image	
	Product Code	For SS: 736.10XY , For Titanium: TI-736.10-XY (Where X=No. of shaft holes and Y=Left/Right Directions)

	Shaft hole	03, 05, 07, 09, 11, 13
	Head Width	24mm
	Shaft Width	16mm
	Plate Thickness	2.50mm
	Hole Distance	18mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

45	**Device Name**	**4.5mm Distal Tibia Plate**
	Image	
	Product Code	For SS: 737.10XY, For Titanium: TI-737.10XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Total Length	83 to 263mm
	Shaft Holes	03, 05, 07, 09, 11,13
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

46	**Device Name**	**4.5mm Distal Lateral Tibia Plate with Round Holes**
	Image	

	Product Code	For SS: CP01.XY, For Titanium: TI-CP01.XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft Hole	5, 7, 9, 11, 13
	Directional Configuration	6.6mm
	Material	Available in both left and right directions

47	**Device Name**	**4.5mm Distal Tibia Lateral Plate**
	Image	
	Product Code	For SS: 737.2XY, For Titanium: TI-737.20-XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Head Width	24mm
	Shaft Width	16mm
	Slot Length	17mm
	Plate Thickness	2.50mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

48	**Device Name**	**4.5mm Fibular Distal Tibia Plate**
	Image	

	Product Code	For SS: CP12.XY, For Titanium: TI-CP12.XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Shaft hole	07, 09, 13
	Slot Width	5.20mm
	Plate Thickness	2.9mm
	Shaft Width	17.4mm
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

49	**Device Name**	**4.5mm "T" Plate**
	Image	
	Product Code	For SS: 713.1X, For Titanium: TI-713.1X (Where X=No. of shaft holes)
	Total Length	66.3mm to 242.3mm
	Shaft Holes	03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13 & 14
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

50	**Device Name**	**4.5mm "T" Buttress Plate**
	Image	

	Product Code	For SS: 714.1X, For Titanium: TI-714.1X (Where X=No. of shaft holes)
	Total Length	80 to 240mm
	Shaft Holes	04, 05, 06, 07, 08, 09, 10, 11, 12, 13 & 14
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

51	**Device Name**	**4.5mm "L" Buttress Plate**
	Image	
	Product Code	For SS: 706.1XY, For Titanium: TI- 706.1XY (Where X=No. of shaft holes and Y=Left/Right Directions)
	Total Length	70.5mm to 246.5mm
	Shaft Hole	03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13 & 14
	Directional Configuration	Available in both left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

52	**Device Name**	**4.5mm Hook Plate**

	Image	
	Product Code	For SS: 730.106, For Titanium: TI-730.106
	Shaft hole	06
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

53	**Device Name**	**3.5mm Cortical Screw, Self-Tapping, (Star Head)**
	Image	
	Product Code	For SS: 11-002-XSS, For Titanium: 11-002-XTI (Where X=Length)
	Total Length	10 to 95mm
	Thread Diameter	3.45mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

54	**Device Name**	**3.5mm Cortical Screw, Self-Tapping, (Hex Head)**
	Image	
	Product Code	For SS: 104.2XY, For Titanium: TI-104.2XY (Where X=Length and Y=Direction Not Applicable)
	Total Length	10 to 90mm(2mm & 5mm increments)
	Thread Diameter	3.45mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

55	**Device Name**	**3.5mm Cortical Screw, (Hex Head)**
	Image	
	Product Code	For SS: 104.0XY, For Titanium: TI-104.0XY (Where X=Length and Y=Direction Not Applicable)
	Total Length	10 to 90mm (2mm & 5mm increments)
	Thread Diameter	3.50mm
	Directional Configuration	Not Applicable

	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

56	**Device Name**	**3.5mm Cancellous Screw, Short Thread**
	Image	
	Product Code	For SS:108.0XS, For Titanium: TI-108.0XS (Where X=Length and Direction Not Applicable)
	Total Length	10 to 60mm (2mm increments)
	Thread Diameter	3.5mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

57	**Device Name**	**3.5mm Cancellous Screw, Full Thread**
	Image	
	Product Code	For SS: 108.0X, For Titanium: TI-108.0X (Where X=Length)
	Total Length	10 to 60mm (2mm increments)
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

58	**Device Name**	**4.0mm Cancellous Screw, Short Thread**
	Image	

	Product Code	For SS: 109.0XY, For Titanium: TI-109.0XY(Where X=Length and Y=Direction Not Applicable)
	Total Length	12 to 60mm (2mm increments)
	Thread Diameter	4mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

59	**Device Name**	**4.0mm Cancellous Screw, Full Thread**
	Image	
	Product Code	For SS: 110.0XY, For Titanium: TI-110.0XY (Where X=Length and Y=Direction Not Applicable)
	Total Length	12 to 60mm (2mm increments)
	Thread Diameter	4mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

60	**Device Name**	**4.5mm Cortical Screw, Self-Tapping, (Star Head)**
	Image	

	Product Code	For SS: 11-090-0XSS, For Titanium:11-090-0XTI, (Where X=Length and Y=Direction Not Applicable)
	Total Length	12 to 90mm (2mm increments)
	Thread Diameter	4.50mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

61	**Device Name**	**4.5mm Cortical Screw, (Hex Head)**
	Image	
	Product Code	For SS: 105.0X, For Titanium: TI-105.0X (Where X=Length)
	Total Length	12 to 90mm (2mm & 5mm increments)
	Thread Diameter	4.50mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

62	**Device Name**	**6.5mm Cancellous Screw, 16mm Thread**

	Image	
	Product Code	For SS: 111.0XY, For Titanium: TI-111.0XY (Where X=Length and Y=Direction Not Applicable)
	Total Length	25 to 120mm
	Thread Diameter	6.50mm
	Punch Width	3.50mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

63	**Device Name**	**6.5mm Cancellous Screw, 32mm Thread**
	Image	
	Product Code	For SS: 112.0XY, For Titanium: TI-112.0XY (Where X=Length and Y=Direction Not Applicable)
	Total Length	35 to 120mm
	Thread Diameter	6.50mm
	Punch Width	3.50mm

	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

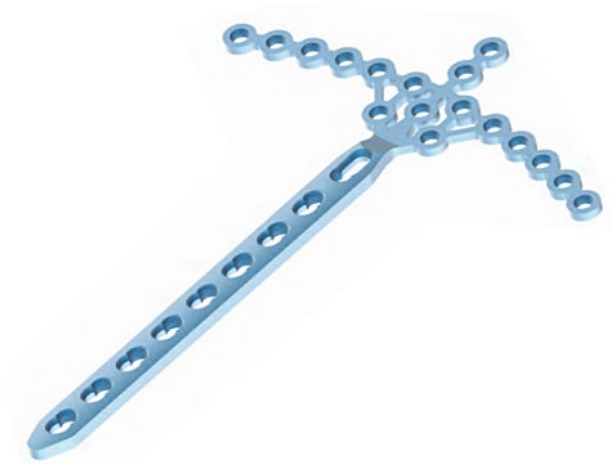
64	**Device Name**	**6.5mm Cancellous Screw, Full Thread**
	Image	
	Product Code	For SS: 113.0XY, For Titanium: TI-113.0XY (Where X=Length and Y=Direction Not Applicable)
	Total Length	25 to 120mm
	Punch Width	3.50mm
	Thread Diameter	6.50mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

65	**Device Name**	**Washer for Small Fragment Screws**

	Image	
	Product Code	For SS: 100.110, For Titanium: TI-100.110
	Washer Hole Dia	4.3mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

66	**Device Name**	**Washers for 4.5mm to 7.0mm Screws**
	Image	
	Product Code	For SS: 100.120, For Titanium: TI-100.120
	Washer Hole Dia	10mm
	Directional Configuration	Not Applicable

	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

67	**Device Name**	**3.5mm Wise-Lock Pilon Plate, Cruciform**
	Image	
	Product Code	For SS: 799.00X, For Titanium: TI-799.00X (Where X=Length)
	Shaft hole	7, 9
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

68	**Device Name**	**5.0mm Wise-Lock Cannulated Screw, Full Thread, Self-Tapping**

	Image	
	Product Code	For SS: 156.0X, For Titanium: TI-156.0X (Where X=Length)
	Length	20mm to 120mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

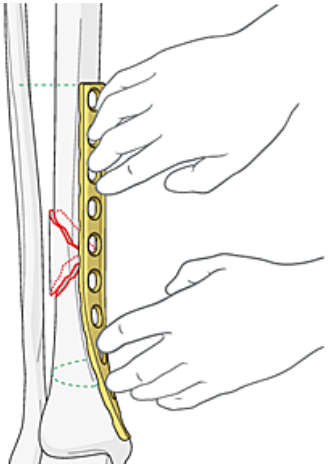
69	**Device Name**	**5.0mm Wise-Lock Cannulated Screw, Partial Thread, Self-Tapping**
	Image	
	Product Code	For SS: TI-1269.X, For Titanium: TI-1269.X (Where X=Length)
	Length	30mm to 100mm
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

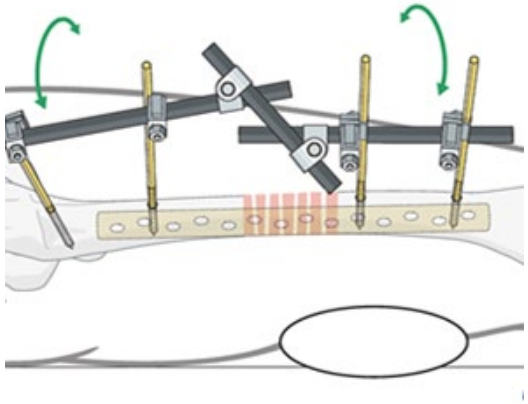
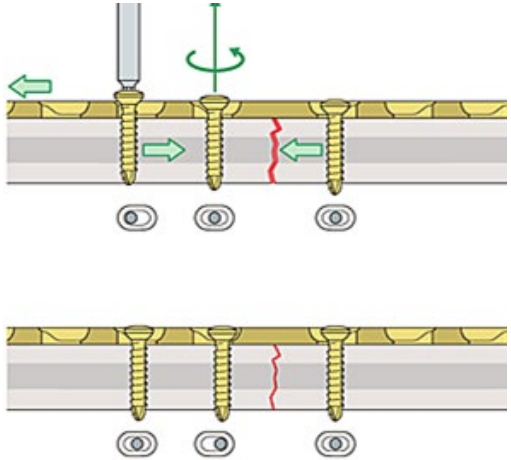
A Detailed device description is given in below table.

Other details of the Tibia Plate System:

Device Compliance to regulation		We are proposing the Tibia plate System as per the compliance to European Union Medical Device Regulation (EU MDR 2017/745).
1.	DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES	
1.1	Device Description and Specification	
a.	Product/Trade Name	Auxein Tibia plate System
	General Description	Auxein's Tibia Plate System is designed to fix, stabilize and restore the proximal, diaphyseal and distal fracture of the Tibia bone to its natural state. This plate system consists of left & right plate. The Tibia Plate System offers a variety of bone screws and plate with different shapes and sizes i.e. locking screws, Non-locking screw, AV-Wiselock, Wise-lock & non-locking plates, which can be rigidly locked into a variety configurations, tailor-made for the individual case.
	Intended Purpose	The Tibia plate system is intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of Tibia bone fragments.
	Intended Users	The Tibia plate system is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Tibia plate System can be used for Skeletally Mature patients with Age group of 18-70 Years. The patient conditions and/or pre-dispositions such as those addressed in the contraindications should be avoided.
	Medical Conditions to be diagnosed, treated and/or monitored	The Tibia Plate System is used to treat Tibia bone fractures or non-union. Specifically designed tibia plate intended for treatment of fractures that provides strong fixation and restores the bone fragments.
	Patient Selection Criteria	Patient Inclusion Criteria: Male and female subjects between 18 - 70 years of age with Proximal, shaft & Distal fractures of tibia/Articular fractures/Osteotomies, Nonalignment/Non-unions, Mal-unions were recruited in the study. A written informed consent for participation in the study was taken from all the study subjects before

		enrolment. Exclusion Criteria: Subjects with a disease entity or condition that could hinder bone healing and create an unacceptable risk of fixation failure or complications such as known active cancer, neuromuscular disorder etc. were excluded from the study. Also subject with inadequate tissue coverage of the operative site. (Open fracture, Gustilo type IIIC), with substance abuse/alcohol issues. - Subjects who are incarcerated or have pending incarceration were excluded. Female participants who is pregnant or planning pregnancy during the course of the study were not included in the study. Fracture that are not amenable to Tibia Plate Osteosynthesis technique - Morbid obesity (BMI (Kg/m^2)) > 35 were also excluded from the study.
c.	Principles of Operation	Tibia plate System works on the AO Principle of Fracture Management. The key concept of fracture management involves: 1. Restoration of anatomy 2. Stable fixation 3. Preservation of blood supply 4. Early mobilization of the limb and patient The Auxein's Tibia Plate System aims for restoration of bone anatomy by stabilizing the fracture and provides temporarily supporting loads while the fracture heals. The proper fixation of plate s preserves the blood supply and early immobilization of bone union by following surgical technique provided by the manufacturer.
	Mode of Action	The plate fixed to the bone exerts compression, bending forces. Locking of the plate by employing screws along its shaft prevents fixation failure between the bones. The plate fixed with this approach maintains anatomical stabilization and anatomical reduction of the fractured bone and promotes the bone's healing.
	Scientifically demonstration of	Step 1: Angular stability

	Principle of Operation	 Step 2: Rotational stability

		 Step 3: Longitudinal Stability 
d.	Rationale for considering as a	**As per Article 2 (1) of EU MDR 2017/745**

	Medical device	'Medical Device' means any instruments, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: *Thus, Tibia plate system is an implant used in humans for medical purposes to treat tibia fracture.* **Applicable/Non-Applicable defines applicancy of the statement:** a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease- **Not Applicable** ***Rationale for Non Applicability*** *The Tibia plate system is an implant used for the treatment of tibia bone fracture.* Thus, it is not used for diagnosis, prevention, monitoring, prediction, prognosis or alleviation of disease. b) diagnosis, monitoring, treatment, alleviation of, or compensationfor an injury or disability- **Applicable** ***Rationale for Applicability*** The Tibia plate is an implantable device used for the treatment of Tibia bone fractures c) investigation, replacement or modification of the anatomy or ofa physiological or pathological processor state- **Not Applicable** ***Rationale for Non Applicability*** The Tibia plate is intended to treat Tibia bone fracture in order to maintain its anatomical state. The Plate is not meant for investigation, replacement or modification of the anatomy or of a physiological or pathological state purpose of use.

		d) providing information by means of in vitro examination of specimens derived from the human body, including organs, blood and tissue donations- **Not Applicable** ***Rationale for Non Applicability*** Tibia plate is made up of metal alloy and employed to fix tibia fractures. This system does not contain the In-vitro examination of specimens derived from the human body, including organ, blood and tissue donations. The **device does not** achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Hence, the Tibia plate system is considered to be a medical device. ***The following products shall also be deemed to be medical devices*** e) Devices for the control or support of conception- **Not Applicable** ***Rationale for Non Applicability*** The Tibia plate system is used to stabilize Tibia fracture. This device is not for the control or support of conception. f) Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article1(4) and of thosereferred to in the first paragraph of this point-**Not Applicable** ***Rationale for Non Applicability*** The Tibia plate system is intended for fixation for fractures of the tibia bone. The system is not meant for cleaning, disinfection or sterilization of device.

e.	Novel Features	The Tibia Plate System comprises of already existing devices approved in EU market under the regulation MDD 93/42/EEC. Since the device was placed on the market, there are no changes or modifications in device related to raw material, design, manufacturing process (coolants, lubricants, chemicals), intended use, post processing materials, etc.
f.	Description of key functional elements	The Tibia Plate System comprises of: ● Plate in varying lengths and types ● Screws ● Washer Plate used with accessories for implantation in the Tibia to correct the abnormal curvature. The Tibia Plate System is clinically improved by using Internal Fixation with Angular Stability (Internal Fixators) in complicated fractures and in Osteopenic Bone. **The description of the components used with Plate to fix the fracture enlisted below.** ***Screw*** ○ It is intended to be used for the implantation of any type of internal Orthopedic Fixation System. ○ It is used for internal orthopaedic fracture fixation by being screwed into bone to hold Plate with tibia bone. ○ In the Tibia plate system various types of screws are included like cortical, Cancellous, Wise-Lock and AV-Wiselock screw. ***Washer*** ○ It is intended to distribute the load of screw during the tightening and prevent slipping of screw.
g.		
	Sterility	All Products covered in Tibia Plate System are supplied in either Non-sterile or in Sterile state. Sterile

		implants which are placed on the market are sterilized by using Gamma Irradiation Sterilization (SAL 10^{-6}). The Non-Sterile implants which are placed on market are to be sterilized at 121 degree centigrade for 20 minutes (Moist Heat Sterilization/Autoclave Sterilization) as instructed in IFU for Non-sterile devices before implantation.
	Radioactivity	Products covered in Tibia plate System are metal products and does not emit any ionizing or non-ionizing radiation.
	Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
	Use	For Single Use only
	Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
	Biocompatibility	The devices covered in the Tibia Plate System are Bio-compatible. Biocompatibility of the devices is tested as per ISO 10993 series of International Standard.
	MRI Compatibility	The Tibia plate s have not been evaluated for safety and compatibility in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic Resonance Imaging) environment.
1.2	Reference to Previous and Similar Generations of the device	
a.	CE Mark (Legacy device)	CE Approved by **DNV (2460)** under MDD 93/42/EEC **Initial Certificate No.** 4825-2014-CE-IND-NA **Re certification Certificate No.**: 10000363901-PA-NA-IND Rev 2
	USFDA Approved	Yes (Tibia plate system are approved by USFDA whose details are as follow:) 510(k) Number:K213059, K141680

b.	Similar devices available in Union or international market.	The Similar devices available in the Union or International Market enlisted below: Synthes, USA-3.5mm LCP Medial Distal Tibia Plate Synthes, USA-3.5/4.5mm LCP Medial Proximal Tibia Plates Synthes, USA-3.5mm Titanium LCP Proximal Tibia Plat Synthes, USA-3.5mm LCP Posteromedial Proximal Tibia Plates Synthes, USA- Synthes (USA) 3.5/4.5mm LCP Medial Proximal Tibia Plates

The Following table shows the comparison between stainless steel and titanium bone plate.

Comparison table:

S.No.	Properties/ Parameter	Titanium bone plate	Stainless steel bone plate	Remark
1.	Biocompatibility	Final finish device of TI bone plate is biocompatible when tested according to ISO 10993-1.	Final finish device of SS bone plate is biocompatible when according to ISO 10993-1.	Both plates are Biocompatible.
2.	Mechanical performance	Final finish device of Ti bone plate mechanically safe tested according to ASTM 382.	Final finish device of SS bone plate mechanically safe tested according to ASTM 382.	Both plates mechanically safe during the mechanical testing.
3.	Clinical performance	Ti bone plates achieved the indented use without any complication and are clinically safe.	SS bone plate achieved the indented use without any complication and are clinically safe.	Both plates are implanted in the patient. The results of clinical and radiological are satisfactory.
4.	Density	4.43 g/cc (Light weight).	8.00 g/cc (Heavy weight).	Both plates give the same range of motion but the lighter plate gives more comfort during movement.

5.	Corrosion resistance ability	Corrosion resistance.	Corrosion resistance.	Both plates are corrosion resistance. But SS plate have chance of corrosion. Corrosion resistance test (Cyclic potentiodynamic polarization test) has performed on the SS it shows the positive result. Report is attached in Annexure A.
6.	Elasticity	On the high load Ti shows less bending.	On the high load SS shows bending.	Both plates can bear the standard load with factor of safety without any bending.

4. Information on any residual risks and any undesirable effects, warnings and precautions.

Residual risks and undesirable effects

A listing of potential adverse events includes, but is not limited to:

- Implant damage (fracture, deformation or detachment).
- Early or late loosening or displacement of the implant from the initial place of insertion.
- Possibility of corrosion due to, contact with other materials.
- Body reaction to implants as foreign bodies e.g. possibility of tumor metaplasia, autoimmune disease and/or scarring.
- Compression on the surrounding tissue or organs.
- Infection.
- Bone fractures or “stress shielding” phenomenon causing loss of bone above, below or at the operative site.
- Haemorrhage of blood vessels and /or hematomas.

- Pain.
- Metal sensitivity
- Inability to perform everyday activities.
- Deep vein thrombosis, thrombophlebitis.
- Scar formation that could cause neurological impairment, or nerves compression and /or pain.
- Late bone fusion or no visible fusion mass and pseudarthrosis.
- Loss of proper curvature and/or length of bone.

Warning & Precautions:

1. Avoid notching, scratching, or striking the device.
2. Every implant must be discarded after use and should never be reused. Reuse may lead to infection & cross infection. It should be bent & then disposed of properly so that it becomes unfit for reuse.
3. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.
4. After healing occurs, these devices serve no functional purpose and therefore should be removed.
5. Patients should be informed about the possible complications from not removing the device (corrosion with localized tissue reaction or pain, migration on resulting in injury to so issue, visceral organs, or joints, risk of additional injury from postoperative trauma, breakage which could make removal impractical or difficult, pain, discomfort, or abnormal sensations which may occur due to the presence of the device, possible increased risk of infection, and bone loss due to stress shielding).
6. If a cortical screw will be used, the arrows on the sleeve should correspond to the arrow under the etched Cortical on the aiming arm.
7. If a locking screw is used, ensure the arrows on the sleeve correspond to the arrow under the etched Locking on the aiming arm.
8. Any decision to remove the device should consider the potential risk to the patient of a second surgical procedure and should be followed by adequate post-operative management to avoid re-fracture.
9. Do not mix dissimilar metals and alloys that can accelerate corrosion and enhance fracture of implants. It is important that mechanical fit and metallurgical compatibility be considered in selecting mating implants.
10. Placing the plate too high increases the risk of sub-acromial impingement. Placing the plate too low can prevent the optimal distribution of screws in the humeral head.

11. 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.

12. If adverse effects happen, it may necessitate re-operation, revision or removal surgery, arthrodesis or the involved joint and / or amputation of the limb.

Safety and Performance Parameters:

- Measure the LEFS Score
- Measure the VAS Score
- Record of any adverse event, serious adverse event and complication

5. The summary of clinical evaluation and relevant information on post-market clinical follow-up.

Retrospective Clinical Evaluation:

The Tibia Plate System was approved under MDD 93/42/EEC. The conformity of the device was accessed using the data from legacy device that is already on the market since 2014.

There is clinical data available on the journals that were Retrospectively analysed by surgeons around the world. The study which was published by surgeons includes 60 patients. These all patients have tibial fracture and were treated using Auxein's Tibia Plate System. From the analysis of the data it is found that there are no safety and performance concerns regarding the use of device. There were no complications noticed related to Tibia Plate System in literature and hardware related complications were also not encountered.

S.No.	Clinical Paper Title	Injury Type	Implant Used	Patients	Complications, if any
1.	Akbareen et al, Comparison of clinical and radiological outcomes of Titanium and stainless steel bone plates used for treating tibia bone fractures.	Tibia bone fracture	3.5mm Wise-Lock Proximal tibia plate (Titanium and Stainless Steel)	60 (30 Titanium Plates Implanted, 30 Stainless Steel Plates Implanted)	No Complication till final follow up.

Prospective Clinical Evaluation:

Prospective Study of the legacy device has been approved by the ethics committee.

Identity of the investigation/study: Post Market Clinical Follow-up (PMCF) study to evaluate the safety and performance of Tibia Plate System (PMCF - TIPS).

Name or Code of Study	Completed (Yes/No)	Name of countries in study is conducted	No. of patients enrolled /and the target no.	No. of serious incidents	Serious incident rate (%)	No. of deaths
CR_PMCF/P_01	Ongoing	INDIA	40/44	0	0	0
Study Title	Post Market Clinical Follow-up (PMCF) study to evaluate the safety and performance of Tibia Plate System (PMCF - TIPS).					
CTRI Number	CTRI/2022/12/048209					
CTRI Registration Date	16-12-2022					
Number of study sites	One					
Name of Study Sites	Hi-tech Hospital (Gujarat, India)					
No. of Patients enrolled	40					

Study design: The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Tibia Plate device. This longitudinal study was designed as a single-arm study. The target population for this research comprised both males and females aged 18 years or older at the time of surgery. The study aimed to recruit a total of 44 subjects who experienced tibia related fracture, and they were treated using a tibia plate construct.

Inclusion criteria

Male and female subjects between 18 - 70 years of age with Proximal, shaft & Distal fractures of tibia/Articular fractures/Osteotomies, Malalignment/Non-unions, Mal-unions were recruited in the study. A written informed consent for participation in the study was taken from all the study subjects before enrolment.

Exclusion criteria

Subjects with a disease entity or condition that could hindered bone healing and create unacceptable risk of fixation failure or complications such as known

active cancer, neuromuscular disorder etc. were excluded from the study. Also subject with inadequate tissue coverage of the operative site. (Open fracture, Gustilo type IIIC), with substance abuse/alcohol issues. - Subjects who are incarcerated or have pending incarceration were excluded. Female participant who is pregnant or planning pregnancy during the course of the study were not included in the study. Fracture that are not amenable to Tibia Plate Osteosynthesis technique - Morbid obesity (BMI (Kg/m^2)) > 35 were also excluded from the study.

Primary Objective

The primary objective of this study was to assess the performance of Tibia Plate System used in surgical treatment of patients by analysing the fracture union status post-operatively using Lower Extremity Functional Score (LEFS) score and pain evaluation through Visual Analogue Scale (VAS).

Secondary Objective

The secondary objective of this study was to evaluate the Safety of Device by record of any adverse event, serious adverse event and complication during follow up.

Primary Endpoints

The primary endpoints of this study include the use of X-ray radiographs to determine the average time taken for bone union. Additionally, the Lower Extremity Functional Score (LEFS) score has been recorded to assess functional performance from baseline to the last follow-up. Pain levels has been measured using the Visual Analog Scale (VAS) with mean and standard deviation presented. The change in VAS score from baseline to each visit has been analysed using paired t-tests at a significance level of 0.05.

Secondary Endpoints

The secondary endpoints focus on monitoring complications and adverse events, including fracture non-union, incision issues, infection, etc. These endpoints have been assessed at multiple time points, specifically at baseline, and at 1, 3, 6, and 12 months post operatively.

Population Detail:

Summary of Demographics and Baseline Characteristics (with Titanium Implants)

Characteristics	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)
Mean	43.18±12.6	69.78±10.76	165.6±2.44	25.36±2.44

Range	18-70	54-89	151-186	19.3-30.2
Median	42.5	68	168	25.38

Gender distribution of study subjects for Titanium

Male	21
Female	11

Summary of Demographics and Baseline Characteristics (with Stainless Steel Implants)

Characteristics	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)
Mean	46.87±15.54	67.12±1.86	159.87±10.43	25.12±2.0
Range	20-69	48-81	138-174	21.6-26.8
Median	48	70	161.5	24.9

Gender distribution of study subjects for Stainless Steel

Male	7
Female	1

A total of 40 subjects have been recruited in the study till date. This includes 32 patients with Titanium implants and 8 patients with stainless steel implants. Thirty-three (33/33) subjects have completed one month follow up visit (100% compliance), 30/32 have completed three months follow up visit (93.75% compliance), 24/26 have completed 6 months follow up visit (92.3% compliance), and 8/8 have completed one year follow up (100% compliance). Follow up of the remaining subjects will be done once it is due.

Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Tibia Plate device. This longitudinal study was designed as a single-arm study. The target population for this research comprised both males and females aged 18 years or older at the time of surgery. The study aimed to recruit a total of 44 subjects who experienced tibia related fracture, and they were treated using a tibia plate construct.

Post Market Clinical Follow-up (PMCF) study has been carried out to evaluate the safety and performance of Tibia Plate System (PMCF - TIPS. This is a post-

marketing clinical follow-up study. This study was carried out following marketing (CE) approval intended to answer the clinical performance, efficacy and safety (i.e. residual risks) of a device when used in accordance with its approved labelling. These may examine issues such as medium-term performance, the appearance of clinical events, events specific to defined patient populations, or the performance of the device in a more representative population of providers and patients with Tibia fracture.

The study consisted of up to seven study visits over a maximum period of 1 year. Subjects were expected to attend all study visits. All assessments were recorded and performed at Visit 1 to Visit 7 on all the study subjects. Subjects were screened for entry (Visit 1) and then were treated for the surgery (Visit 2). Subjects were assessed post-surgery for safety. Additional safety & effectiveness follow-up visits were occurred monthly for 1 years. The final study visit occurred at Visit 7.

Study Result

As per our interim data analysis, we have observed very significant positive results with respect to our Tibia plate device efficacy and safety. Overall, the study's findings suggest that the intervention led to significant pain reduction and enhanced functional performance in the patients. These improvements indicate the positive impact of the treatment on their quality of life and recovery from their condition after intervention of plate.

There is no any adverse event related to device in any medical device registry. The benefit-risk analysis has outweighed the benefit against the risk regarding the device.

6. Possible diagnostic or therapeutic alternatives.

On plain radio graphs, anterior-posterior (AP) and lateral views demonstrate most hip fractures. For patients in whom tibia bone fracture is strongly suspected but standard x-ray findings are negative, an AP view with internal rotation provides a better view of the tibia. If standard radio graph findings are negative and fracture is still strongly suspected, MRI and bone scan have high sensitivity in identifying occult injuries; MRI is 100% sensitive in patients with equivocal radiographic findings. Treatment of broken bones follows one basic rule: the broken pieces must be put back into position and prevented from moving out of place until they are healed.

Non-surgical Treatment

Most tibial shaft fractures require surgery to heal. It is unusual for tibial shaft fractures to be treated without surgery. Very young children are sometimes treated with a cast.

Surgical Treatment

Timing of surgery. Most tibia plate fractures are fixed within 24 to 48 hours. On occasion, fixation will be delayed until other life-threatening injuries or unstable medical conditions are stabilized. To reduce the risk of infection, open fractures are treated with antibiotics as soon as you arrive at the hospital. The open wound, tissues, and bone will be cleaned during surgery. For the time between initial emergency care and your surgery, your doctor may place your leg either in a long-leg splint or in traction. This is to keep your broken bones as aligned as possible and to maintain the length of your leg. Skeletal traction is a pulley system of weights and counterweights that holds the broken pieces of bone together. It keeps your leg straight and often helps to relieve pain.

External fixation. In this type of operation, metal pins or screws are placed into the bone above and below the fracture site. The pins and screws are attached to a bar outside the skin. This device is a stabilizing frame that holds the bones in the proper position. Surgery is sometimes required to treat a fracture. The type of treatment required depends on the severity of the break, whether it is "open" or "closed," and the specific bone involved. Surgery is required as soon as possible (within 8 hours after injury) in all open fractures. The exposed soft tissue and bone must be thoroughly cleaned (debrided) and antibiotics maybe given to prevent infection. Either external or internal fixation methods will be used to hold the bones in place. If the soft tissues around the fracture are badly damaged, the doctor may apply a temporary external fixation. Internal fixation with plates or screws maybe utilized at a second procedure several days later.

Note:

Most tibial fractures require surgery to heal. It is unusual for tibial fractures to be treated without surgery. Very young children are sometimes treated with a cast.

Available treatments based on the severity and type of fracture diagnosed by the doctor:

Non-Surgical Treatment	Surgical Treatments
Cast	• Intramedullary Nail • Plate and screws (Device in Scope) • An external fixation (a stabilizing frame outside the body that holds the bones in the proper position so they can heal). • Any combination of these techniques.

7. Suggested profile and training for users.

The intended user (surgeon) should be well-qualified and must have gained sufficient training regarding the use of the device and should have experience in trauma surgery. The training materials i.e. Surgical Technique, Instructions for Use, catalogue are already available on the manufacturer website (https://www.auxein.com/).

8. Reference to any harmonized standards and CS applied.

The following harmonized standards and guidance documents are applicable on Tibia Plate System:

S.No.	Standard Designation	Title of Standard
1.	EN ISO 5832-1:2019	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel (ISO 5832-1:2016)
2.	EN ISO 5832-3:2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)
3.	ASTM F138-19	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
4.	ASTM F136-13 (2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
5.	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
6.	EN ISO 10993-2: 2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements
7.	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
8.	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
9.	EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
10.	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
11.	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
12.	EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
13.	EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020).

14.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021).
15.	ISO/TR 10993-33:2015	Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3.
16.	EN ISO 14644-1:2015	Clean-rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
17.	EN ISO 14644-2:2015	Clean-rooms and associated controlled environments - Part 2: Monitoring to provide evidence of clean-room performance related to air cleanliness by particle concentration.
18.	EN ISO 14644-3:2019	Clean-rooms and associated controlled environments - Part 3: Test Methods.
19.	EN ISO 14644-4:2022	Clean-rooms and associated controlled environments - Part 4: Design, construction and start-up.
20.	EN ISO 14644-5:2004	Clean-rooms and associated controlled environments - Part 5: Operations
21.	EN ISO 14644-7:2004	Clean-rooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, Isolators and mini).
22.	EN ISO 14644-8 :2022	Clean-rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC).
23.	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
24.	EN ISO 14644-9 :2022	Clean-rooms and associated controlled environments – Part 9: Classification of surface cleanliness by particle concentration.
25.	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
26.	EN ISO 11607-1:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
27.	EN ISO 11607-2:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.

28.	EN ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
29.	EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
30.	EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
31.	EN ISO 11137-2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.
32.	EN ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)
33.	EN ISO 17665-1:2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
34.	EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good Clinical Practice.
35.	EN ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
36.	EN ISO 14630:2009	Non-active surgical implants - General Requirements
37.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
38.	EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
39.	EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
40.	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
41.	ASTM F543-17	Standard Specification and Test Methods for Metallic Medical Bone Screws
42.	ASTM F382-17	Standard Specification and Test Methods for Metallic Bone Plates.
43.	ASTM D4169-22	Standard Practice for Performance Testing of Shipping containers and System.
44.	ASTM F88	Standard Test Method for Seal Strength of Flexible Barrier Materials
45.	ISO 19227:2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements

46.	MDCG 2021-24	Guidance on classification of medical devices
47.	MDCG 2020-8	Guidance on PMCF evaluation report template
48.	MDCG 2020-7	Guidance on PMCF plan template
49.	MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
50.	MDCG 2020-5	Guidance on clinical evaluation – Equivalence
51.	MDCG 2019-9, Rev.01	Summary of safety and clinical performance
52.	MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
53.	MDCG 2021-11	Guidance on Implant Card –'Device types'
54.	MDCG 2019-8 v2	Guidance document implant card on the application of Article 18 Regulation (EU) 2017/745 on medical devices
55.	MDCG 2022-9	Summary of safety and performance template
56.	MDCG 2019-14	Explanatory note on MDR codes
57.	MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
58.	MDCG 2018-1, Rev.04	Guidance on BASIC UDI-DI and changes to UDI-DI
59.	MDCG 2021-25	Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
60.	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022
61.	MEDDEV 2.7/1 revision 4, 2016	Clinical Evaluation: A guide for manufacturers and notified bodies.
62.	EU MDR 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017.

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body

00	05-02-2023	Initial Release	☐Yes Validation language: ☐No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
01	30-10-2023	Added comparison table (of Titanium and Stainless Steel bone plates), at page number 85, 86 of 189 as per query received during PRJN-629776.	☐Yes Validation language: ☐No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
02	07-08-2024	Stainless Steel related data added in SSCP.	☐Yes Validation language: ☐No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

A summary of the safety and clinical performance of the device, intended for patients, is given below:

Document revision: 02
Date issued: 07-08-2024

Device identification and general information

Device Trade Name: Auxein Tibia Plate System

Manufacturer Name: Auxein Medical Private Limited

Manufacturer Address: Plot No. 168-169-170, Phase-IV, Sector-57, Kundli, HSIIDC, Industrial Area, Sonipat, Haryana 131028, India

Basic UDI-DI: 08903993TPS012RY (For Stainless Steel Implants) and 0890399TPT01227 (for Titanium Implants)

Year when the device was first CE-marked: 2014

Intended use of the device

Intended Purpose	The Tibia Plate system is intended for fracture fixation of Tibia bone including proximal, shaft and distal tibia.
Indications of Use	The Tibia Plate System is part of the Tibia Bone has the following 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.
Contraindications	The implant should not be used in a patient who has currently, or who has a history of:

	• Infection local to the operative site • Signs of local inflammation. • Fever or leucocytosis. • Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care. • Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodelling, e.g. the presence of tumours or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells (WBC) count, or a marked left shift in the WBC differential count. • Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant (content of the implant material is presented in IMPLANT MATERIAL). • Any case not needing a surgical intervention. • Any case not described in the indications. • Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage. • Any case where the implant components selected for use would be too large or too small to achieve a successful result. • Any case that requires the simultaneous use of elements from different systems that are made of different metals. • Any case in which implant utilization would disturb physiological processes. • Blood supply limitation in the operative site. • Morbid obesity (defined according to the WHO. standards). • Any case in which there is inadequate tissue coverage of the operative site.
Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Tibia Plate System can be used for Skeletally Mature patients with Age group of 18-70 Years. The patient conditions and/or pre-dispositions such as those addressed in the contraindications should be avoided.

Device description

The tibia bone plate is used for treating the fractures of proximal, distal and shaft tibial fractures. These plate helps to align the fractured tibia bone fragments together with the help of bone screws. The tibia plates consist of various types of bone plates including Locking, Non-Locking and AV-Wiselock and for fixing these plates with the bone Auxein provides various types of bone screws which are compatible with different type of bone plates. The details regarding tibia bone plates and screws can be found at www.auxein.com.

The more details regarding these bone plates and screws are mentioned below:

Parameter	**Details**	**Certified By**	**Certificate Number**
Material/substances in contact with patient tissues	The Material/substances that comes in contact with patient tissues used are Titanium alloy Ti-6AL-4V as per EN ISO 5832-3:2021 and Stainless steel alloy SS 316 L as per EN ISO 5832-1:2019.		
USFDA Approved	Yes (Tibia plate are approved by USFDA whose details are as follow:) 510(k) Number: K213059, K141680		
Risk Class	IIb {According to REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT, Annex VIII, Chapter-3, Rule 8 - Implantable devices and long-term surgically invasive devices (>30 days).		
Authorized Representative Name and Address	Name: CMC Medical Devices & Drug S.L Address: 29015 Málaga, Spain		
Notified Body Name and Single Identification Number	Name: DNV Product Assurance AS Single Identification Number: 2460		

Principle of operation

Bone plates are the most common internal fixation implants used for fixating fractures. They are attached to bone fragments with screws and function to reduce the fracture and prevent any movement, while also shielding the fracture site from stress to allow healing. Bone plates provide a frame to which the fractured bone may be attached facilitating anatomic reduction of the boney column in some cases and, if the implant is selected and applied correctly, neutralization of the forces acting on the fractured bone during the healing process.

Description of Key functional elements:

The Tibia Plate System comprises of:

- Screws
- Washer

The Tibia Plate System is clinically improved by using Internal Fixation with Angular Stability (Internal Fixators) in complicated fractures and in Osteopenic Bone.

The description of the components used with Plate to fix the fracture enlisted below.

Screw

- It is intended to be used for the implantation of any type of internal Orthopedic Fixation System.
- It is used for internal orthopaedic fracture fixation by being screwed into bone to hold Plate with tibia bone.
- In the Tibia plate system various types of screws are included like cortical, Cancellous, Wise-Lock and AV-Wiselock screw.

Washer

It is intended to distribute the load of screw during the tightening and prevent slipping of screw.

Risks and Warnings

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 if needed.

The potential risks that arise regarding the device are controlled using risk mitigation method and conveying those risk to the patients from surgeon.

A listing of Remaining Risk and undesirable effects includes, but is not limited to:

- Implant damage (fracture, deformation or detachment).
- Early or late loosening or displacement of the implant from the initial place of insertion.

- Body reaction to implants as foreign bodies e.g. possibility of tumor metaplasia, autoimmune disease and/or scarring.
- Compression on the surrounding tissue or organs.
- Infection.
- Bone fractures or “stress shielding” phenomenon causing loss of bone above, below or at the operative site.
- Haemorrhage of blood vessels and /or hematomas.
- Pain.
- Metal sensitivity
- Inability to perform everyday activities.
- Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary
- Late bone fusion or no visible fusion mass and pseudarthrosis.
- Loss of proper curvature and/or length of bone.

Warning & Precautions:

1. Avoid notching, scratching, or striking the device.
2. After healing occurs, these devices serve no functional purpose and therefore should be removed.
3. Patients should be informed about the possible complications from not removing the device (corrosion with localized tissue reaction or pain, migration on resulting in injury to so issue, visceral organs, or joints, risk of additional injury from postoperative trauma, breakage which could make removal impractical or difficult, pain, discomfort, or abnormal sensations which may occur due to the presence of the device, possible increased risk of infection, and bone loss due to stress shielding).
4. Any decision to remove the device should consider the potential risk to the patient of a second surgical procedure and should be followed by adequate post-

operative management to avoid re-fracture.

5. 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.
6. If adverse effects happen, it may necessitate re-operation, revision or removal surgery, arthrodesis or the involved joint and / or amputation of the limb.

Summary of any field safety corrective action, (FSCA including FSN) if applicable

Till now, regarding Auxein's Tibia plate system there is no FSCA.

Summary of clinical evaluation and post-market clinical follow-up

Clinical background of the device:

Description and consequences

The tibia (shin bone) is the second longest bone in human body, and it’s an important part of ability to stand and move. Tibia also supports lots of important muscles, tendons, nerves and ligaments. Because it’s so strong, it usually takes a severe trauma like a fall or car accident to break tibia. If there is a fracture, you’ll likely need surgery to repair tibia bone and physical therapy to help regain strength and ability to move. Tibia, like all bones, can be affected by osteoporosis. The tibia runs from just under knee to your ankle. It’s closer to the inside of body (medial) than the fibula.

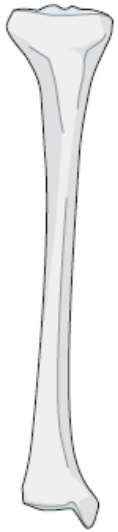


Figure: Tibia bone anatomy

Tibia Fracture

A tibia fracture is a break in the tibia that usually occur from serious traumas like car accidents, fall from height or if bone get weakened by osteoporosis. The may affect the proximal, shaft or distal tibia.

Causes of tibia bone fracture

High-energy collisions, such as an automobile or motorcycle crash, are common causes of tibial shaft fractures. In cases like these, the bone can be broken into several pieces (comminuted fracture). Sports injuries, such as a fall while skiing or running into another player during soccer, are lower-energy injuries that can cause tibial shaft fractures. These fractures are typically caused by a twisting force and result in an oblique or spiral type of fracture.

Symptoms

1. Pain
2. Inability to walk or bear weight on the leg
3. Deformity or instability of the leg
4. Bone "tenting" the skin or protruding through a break in the skin
5. Occasional loss of feeling in the foot

Diagnosis

The doctor will then perform a series of tests that will check the muscle strength. Whether you can feel sensation in the lower leg, foot, and ankle. Depending on the extent of your injury, you may need emergency surgery. Conditions requiring surgery include the bone penetrating the skin, multiple broken bones, or injury to a major artery or nerve.

The following tests will be performed to get a visual image of the fracture as follows:

People who have injured their leg and are experiencing any of the symptoms should consult a doctor for a diagnosis. The following steps occur during the diagnosis process:

1. Physical the fracture and see if a bone has been displaced.
2. Magnetic resonance imaging (MRI): This type of test provides a more detailed scan and can generate detailed pictures of the interior bones and soft tissues.
3. Bone scans, computerized tomography (CT), and examination: A thorough examination will be conducted and the doctor will look for any noticeable deformities. X-ray: These are used to see other tests may be ordered to make a more precise diagnosis and judge the severity of the fracture.

Pain Management

Most fractures hurt moderately for a few days to a couple of weeks. Many patients find that elevation (holding their arm up above their heart) helps to relieve pain. Doctor may recommend pain killer medicines to relieve pain and inflammation. If the pain is severe, the doctor may suggest a prescription-strength medication for a few days. Patients should talk to their doctor if the pain has not begun to improve within a few days of surgery.

Rehabilitation and Return to Activity

Most people return to all their former activities after a fracture. The nature of the injury, the treatment received, and the body's response to the treatment all have an impact, so the answer is different for individual. Most patients will have some stiffness in the wrist. This will generally lessen in the month or two after the cast is taken off or after surgery, and continue to improve for at least 2 years. If the doctor thinks it is needed, the patient will start physical therapy within a few days to weeks after surgery, or right after the last cast is taken off.

Most patients will be able to resume light activities, such as swimming or exercising the lower body in the gym, within 1 to 2 months after the cast is removed or within 1 to 2 months after surgery. Vigorous activities, such as skiing or football, may be resumed between 3 and 6 months after the injury.

Clinical Evidence/Safety of the device:

There are prospective and retrospective data regarding the device.

Retrospective Clinical Evaluation:

The Tibia Plate System was approved under MDD 93/42/EEC. The conformity of the device was accessed using the data from legacy device that is already on the market since 2014.

There is clinical data available on the journals that was Retrospectively analysed by surgeons around the world. The study, which were published by surgeons includes 60 patients'. These all patients have tibial fracture and were treated using Auxein's Tibia Plate System. From the analysis of the data it is found that there are no safety and performance concerns regarding the use of device. There were no complications noticed related to Tibia Plate System in literature and hardware related complications were also not encountered.

S.No.	Clinical Paper Title	Injury Type	Implant Used	Patients	Complications, if any
1.	Akbareen et al, Comparison of clinical and radiological outcomes of Titanium and stainless steel bone plates used for treating tibia bone fractures.	Tibia bone fracture	3.5mm Wise-Lock Proximal tibia plate (Titanium and Stainless Steel)	60 (30 Titanium Plates Implanted, 30 Stainless Steel Plates Implanted)	No Complication till final follow up.

Prospective Clinical Evaluation:

Prospective Study of the legacy device has been approved by the ethics committee.

Identity of the investigation/study: Post Market Clinical Follow-up (PMCF) study to evaluate the safety and performance of Tibia Plate System (PMCF - TIPS).

Name or Code of Study	Completed (Yes/No)	Name of countries in study is conducted	No. of patients enrolled/and the target no.	No. of serious incidents	Serious incident rate (%)	No. of deaths
CR_PMCF/P_01	Ongoing	INDIA	40/44	0	0	0
Study Title	Post Market Clinical Follow-up (PMCF) study to evaluate the safety and performance of Tibia Plate System (PMCF - TIPS).					
CTRI Number	CTRI/2022/12/048209					
CTRI Registration Date	16-12-2022					
Number of study sites	One					
Name of Study Sites	Hi-tech Hospital (Gujarat, India)					
No. of Patients enrolled	40					

Population Detail:

Summary of Demographics and Baseline Characteristics (with Titanium Implants)

Characteristics	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)
Mean	43.18±12.6	69.78±10.76	165.6±2.44	25.36±2.44
Range	18-70	54-89	151-186	19.3-30.2
Median	42.5	68	168	25.38

Gender distribution of study subjects for Titanium

Male	21
Female	11

Summary of Demographics and Baseline Characteristics (with Stainless Steel Implants)

Characteristics	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)
Mean	46.87±15.54	67.12±1.86	159.87±10.43	25.12±2.0
Range	20-69	48-81	138-174	21.6-26.8
Median	48	70	161.5	24.9

Gender distribution of study subjects for Stainless Steel

Male	7
Female	1

A total of 40 subjects have been recruited in the study till date. This includes 32 patients with Titanium implants and 8 patients with stainless steel implants. Thirty-three (33/33) subjects have completed one month follow up visit (100% compliance), 30/32 have completed three months follow up visit (93.75% compliance), 24/26 have completed 6 months follow up visit (92.3% compliance), and 8/8 have completed one year follow up (100% compliance). Follow up of the remaining subjects will be done once it is due.

Study Result

As per our interim data analysis, we have observed very significant positive results with respect to our Tibia plate device efficacy and safety. Overall, the study's findings suggest that the intervention led to significant pain reduction and enhanced functional performance in the patients. These improvements indicate the positive impact of the treatment on their quality of life and recovery from their condition after intervention of plate.

There is no any adverse event related to device in any medical device registry. The benefit-risk analysis has outweighed the benefit against the risk regarding the device.

Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

On plain radio graphs, anterior-posterior (AP) and lateral views demonstrate most hip fractures. For patients in whom tibia bone fracture is strongly suspected but standard x-ray findings are negative, an AP view with internal rotation provides a better view of the tibia. If standard radio graph findings are negative and fracture is still strongly suspected, MRI and bone scan have high sensitivity in identifying occult injuries; MRI is 100% sensitive in patients with equivocal radiographic findings. Treatment of broken bones follows one basic rule: the broken pieces must be put back into position and prevented from moving out of place until they are healed.

Non-surgical Treatment

Most tibial shaft fractures require surgery to heal. It is unusual for tibial shaft fractures to be treated without surgery. Very young children are sometimes treated with a cast.

Surgical Treatment

Timing of surgery. Most tibia plate fractures are fixed within 24 to 48 hours. On occasion, fixation will be delayed until other life-threatening injuries or unstable medical conditions are stabilized. To reduce the risk of infection, open fractures are treated with antibiotics as soon as you arrive at the hospital. The open wound, tissues, and bone will be cleaned during surgery. For the time between initial emergency care and your surgery, your doctor may place your leg either in a long-leg splint or in traction. This is to keep your broken bones as aligned as possible and to maintain the length of your leg. Skeletal traction is a pulley system of weights and counterweights that holds the broken pieces of bone together. It keeps your leg straight and often helps to relieve pain.

External fixation. In this type of operation, metal pins or screws are placed into the bone above and below the fracture site. The pins and screws are attached to a bar outside the skin. This device is a stabilizing frame that holds the bones in the proper position. Surgery is sometimes required to treat a fracture. The type of treatment required depends on the severity of the break, whether it is "open" or "closed," and the specific bone involved. Surgery is required as soon as possible (within 8 hours after injury) in all open fractures. The exposed soft tissue and bone must be thoroughly cleaned (debrided) and antibiotics maybe given to prevent infection. Either external or internal fixation methods will be used to hold the bones in place. If the soft tissues around the fracture are badly damaged, the doctor may apply a temporary external fixation. Internal fixation with plates or screws maybe utilized at a second procedure several days later.

Available treatments based on the severity and type of fracture diagnosed by the doctor:

Non-Surgical Treatment	**Surgical Treatments**

Cast	• Intramedullary Nail • Plate and screws (Device in scope) • An external fixation (a stabilizing frame outside the body that holds the bones in the proper position so they can heal). • Any combination of these techniques.

Suggested training for users

The intended user (surgeon) should be well-qualified and must have gained sufficient training regarding the use of the device and should have experience in trauma surgery. The training materials i.e Surgical Technique, Instructions for Use, catalogue are already available on the manufacturer website (https://www.auxein.com/).