SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR FOOT PLATE SYSTEM

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1. The identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN.

Basic UDI-DI: 0890399FOT014U7 and 08903993FOS014L3 for Titanium and Stainless Steel Implants respectively.

SRN: IN-MF-000018837

The Foot Plate System includes the following variants as listed below:

A. Plates

- Ø2.7mm-6.0mm Metatarsal Shortening Implant
- 2.4mm AV-Wiselock Endosteal Plate, Standard, Left/Right, Titanium
- 2.4mm AV-Wiselock Endosteal Plate, Curved, Left/Right, Titanium
- 2.7mm AV-Wiselock MTP Fusion M Plate, 0°/5°/10° Dorsiflexion, Left/Right, Stainless Steel/Titanium
- 2.7mm AV-Wiselock MTP Revision M Plate, 5°/10° Dorsiflexion, Left/Right, Stainless Steel/Titanium
- 2.7mm AV-Wiselock TMT-I Medial Fusion M Plate, Left/Right, Stainless Steel/Titanium
- 2.7mm AV-Wiselock TMT-I Plantar Fusion M Plate, Left/Right, Stainless Steel/Titanium
- 3.5mm AV-Wiselock Calcaneus M Plate, Small/Medium/Large, Left/Right, Stainless Steel/Titanium
- 3.5mm AV-Wiselock Medial Column Fusion Plate, Left/Right, Stainless Steel/Titanium
- 3.5mm AV-Wiselock Medial Column Fusion Plate, Talus Extension, Left/Right, Stainless Steel/Titanium
- 3.5mm AV-Wiselock Medial Column Fusion Plantar Plate, Left/Right, Stainless Steel/Titanium
- 3.5mm AV-Wiselock MIS Calcaneal Plate Type-III, Left/Right, Stainless Steel/Titanium
- 3.5mm AV-Wiselock Plantar Lapidus Plate, Left/Right, Stainless Steel/Titanium
- 3.5mm AV-Wiselock Plantar Lapidus Plate, Short, Left/Right, Stainless Steel/Titanium
- 2.7mm Wise-Lock Plate, Straight, titanium
- 2.7mm Wise-Lock Condylar Plate, titanium
- 2.7mm Wise-Lock T-Plate titanium
- 2.7mm Wise-Lock L-Plate, Left/Right, Titanium
- 2.7mm Wise-Lock L-Plate, Oblique, Left/Right, Titanium

- 2.7mm Mini Condylar Plate, Left/Right, Titanium
- 2.7mm Wise-Lock Straight Plate, titanium
- 2.4/2.7mm Wise-Lock X-Plate, titanium
- 2.7mm Wise-Lock X-Plate, (Small/Medium/Large), Stainless Steel/Titanium
- 2.7mm Wise-Lock Straight Plate with Single Start Thread, Stainless Steel/Titanium
- 3.5mm Wise-Lock Calcaneal Plate, Left/Right, Stainless Steel/Titanium
- 3.5mm Wise-Lock Calcaneal Plate Type-I, Left/Right, Stainless Steel/Titanium
- 3.5mm Wise-Lock Calcaneal Plate Type-II, Left/Right, Stainless Steel/Titanium
- 3.5mm Wise-Lock Calcaneal Plate Type-III, Left/Right, Stainless Steel/Titanium
- 3.5mm Wise-Lock Calcaneal Plate Type-IV, Left/Right, Stainless Steel/Titanium
- 3.5mm Wise-Lock Calcaneal Plate Type-V, Left/Right, Stainless Steel/Titanium
- 2.7mm Mini "L" Plate, Left/Right, Stainless Steel/Titanium
- 2.7mm "T" Plate, Stainless Steel/Titanium
- 2.7mm Quarter Tubular Plate, Stainless Steel/Titanium
- 2.7mm Dynamic Compression Plate, Stainless Steel/Titanium
- 2.7mm Reconstruction Plate, Straight, Stainless Steel/Titanium
- 3.5mm Calcaneal Plate, Stainless Steel/Titanium

B. Bone Screws

- 2.0mm Cortical Screw, Self-Tapping, (Star Head), Titanium
- 2.4mm Cortical Screw, Self-Tapping, (Star Head), Titanium
- 2.4mm Variable Angle Screws, Self-Tapping, (Star Head), Titanium
- 2.7mm Cortical Screw, Self-Tapping, (Star Head), Stainless Steel/Titanium
- 2.7mm AV-Wiselock Screw, Self-Tapping, (Star Head), Stainless Steel/Titanium
- 2.7mm Wise-Lock Screw, Self-Tapping, (Star Head), Stainless Steel/Titanium
- 4.0mm Cancellous Screw, Short Thread, Stainless Steel/Titanium,

- 3.5mm AV-Wiselock Screw, Self-Tapping, Titanium/Stainless Steel
- 3.5mm Wise-Lock Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel
- 3.5mm Cortical Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel
- 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head), Stainless Steel/Titanium
- 3.5mm Wise-Lock Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium
- 3.5mm Wise-Lock Screw, Self-Drilling, (Hex Head), Stainless Steel/Titanium
- 3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head), Stainless Steel/Titanium
- 3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head), Stainless Steel/Titanium
- 3.5mm Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium,
- 2.7mm Cortical Screw, (Hex Head), Stainless Steel/Titanium
- 2.7mm Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium
- Tarsus screw, Titanium
- 2.5mm Cannulated Herbert Screw, Short Thread, (Star Head), Titanium
- 2.5mm Cannulated Herbert Screw, Long Thread, (Star Head), Titanium
- 3.0mm Cannulated Herbert Screw, Short Thread, (Star Head), Titanium
- 3.0mm Cannulated Herbert Screw, Long Thread, (Star Head), Titanium
- Herbert Screw (Hex Head), 3.0/3.9mm Cannulated Compression Screw
- 2.5mm Headless Cannulated Screw, Micro, Titanium
- 3.5mm Headless Cannulated Screw, Mini, Titanium
- 4.0mm Headless Cannulated Screw, Standard, Titanium
- 4.7mm Headless Cannulated Screw, Titanium
- 5.5mm Headless Cannulated Screw, Titanium
- 7.5mm Headless Cannulated Screw,Titanium
- 3.0mm Cannulated Cancellous Screw,Short Thread
- 3.0mm Cannulated Cancellous Screw, Long Thread

- Washer
- 3.5mm Cannulated Cortical Screw, Short Thread
- 3.5mm Cannulated Cortical Screw, Full Thread
- 3.5mm Cannulated Cortical Screw, Short Thread, self Tapping
- 3.5mm Cannulated Cortical Screw, Full Thread, Self tapping
- 4.0mm Cannulated Cancellous Screw, Short Thread, self Tapping
- 4.0mm Cannulated Cancellous Screw, Full Thread, Self tapping
- 4.5mm Cannulated Cortical Screw, Short Thread
- 4.5mm Cannulated Cortical Screw, Full Thread
- 4.5mm Cannulated Cortical Screw, Short Thread, Self tapping
- 4.5mm Cannulated Cortical Screw, Full Thread, Self tapping

Details Regarding the device are provided in below table:

Device Trade Name:	**Foot 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		
EMDN Code	P091205		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Foot 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		
Conformity Assessment Route	Conformity Assessment of Class IIb devices has been conducted as per Article 52 (4), Chapter I and III of Annex IX of EU MDR 2017/745		
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per ISO 5832-3:2021 and Stainless steel alloy SS 316 L as per ISO 5832-1:2024.		
Risk Class	**IIb (According to the EU Regulation 2017/745 (MDR) Annex VIII Rule 8)** All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: **1.** Are intended to be placed in the teeth, in which case they are classified as class IIa; ***Applicable/Not Applicable:*** *Not Applicable* ***Justification:*** *The Foot plate intended to be placed in foot bones to 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 Foot plate comes in contact with the foot bones. 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 Foot 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 Foot 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 case they are classified as class III; ***Applicable/Not Applicable:*** *Not Applicable* ***Justification:*** The Foot plate implants made up of metal alloys to provide support for the foot 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:*** *The foot plate system does not depend on a source of energy. Thus it is not an active device.*

	7. Are breast implants or surgical meshes, in which cases they are classified as class III; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Foot plate System treats foot bone fractures.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 Foot plate System treats foot bone fractures.Not intended for Total or Partial JointReplacements.* **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 Foot plate System is an implantable device to treat foot 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 Identification Number	**Name:** DNV Product Assurance AS **Single Identification Number:** 2460 **Certificate no.:** C642947

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 indications for use of the Foot Plate System include: **Ø2.7mm-6.0mm Metatarsal Shortening Implant** Metatarsal shortening implant is intended to thread into the distal metatarsal head after performing the desired osteotomy. **2.4mm AV-Wiselock Endosteal Plate, Standard** **2.4mm AV-Wiselock Endosteal Plate, Curved** The plates are used to treat: Metatarsus primus varus (hallux valgus) **2.7mm AV-Wiselock MTP Fusion M Plate, 0°/5°/10° Dorsiflexion** **2.7mm AV-Wiselock MTP Revision M Plate, 5°/10° Dorsiflexion** **2.7mm AV-Wiselock TMT-I Medial Fusion M Plate** **2.7mm AV-Wiselock TMT-I Plantar Fusion M Plate** It is indicated for fixation of osteotomies, fusions, fractures, nonunions, malunions of the foot, and particularly in osteopenic bone. **3.5mm AV-Wiselock Calcaneus M Plate, Small/Medium/Large** It is intended for the fractures and osteotomies of the calcaneus **3.5mm AV-Wiselock Medial Column Fusion Plate** **3.5mm AV-Wiselock Medial Column Fusion Plate, Talus Extension** **3.5mm AV-Wiselock Medial Column Fusion Plantar Plate** All the plates are indicated for deformities, severe arthritis, and Arthrosis of the medial column consisting of the first metatarsal, medial cuneiform, navicular and talus. **3.5mm AV-Wiselock MIS Calcaneal Plate Type-III** It is intended to be used for treating the fracture and non-union of calcaneus bone. **3.5mm AV-Wiselock Plantar Lapidus Plate** **3.5mm AV-Wiselock Plantar Lapidus Plate, Short** It is intended to be used for TMT I joint arthrodesis.

	2.7mm Wise-Lock Plate, Straight **2.7mm Wise-Lock Condylar Plate** **2.7mm Wise-Lock T-Plate** **2.7mm Wise-Lock L-Plate** **2.7mm Wise-Lock L-Plate, Oblique** **2.7mm Mini Condylar Plate** **2.4/2.7mm Wise-Lock X-Plate** These plates are intended for the treatment of; o Fractures of metatarsal I, o Fractures of the tarsals, o MTP 1 fusions, o Osteotomies and arthrodesi of the tarsals (e.g. calcaneo-cuboidal fusion) **2.7mm Wise-Lock X-Plate, (Small/Medium/Large)** **2.7mm Wise-Lock Straight Plate with Single Start Thread** These plates are intended for the treatment of; o Fractures of the middle and distal phalanges and tarsals, o Fractures of the metatarsals, o Osteotomies and arthrodeses on the foot **3.5mm Wise-Lock Calcaneal Plate** **3.5mm Wise-Lock Calcaneal Plate Type-I** **3.5mm Wise-Lock Calcaneal Plate Type-II** **3.5mm Wise-Lock Calcaneal Plate Type-III** **3.5mm Wise-Lock Calcaneal Plate Type-IV** **3.5mm Wise-Lock Calcaneal Plate Type-V** The locking calcaneal plates address complex fractures of the calcaneus. The locking calcaneal plate is indicated for

	fractures and osteotomies of the calcaneus including, but not limited to, extra-articular, intraarticular, joint depression, tongue type, and severely comminuted fractures. **2.7mm Mini "L" Plate** **2.7mm "T" Plate** **2.7mm Quarter Tubular Plate** **2.7mm Dynamic Compression Plate** **2.7mm Reconstruction Plate, Straight** These plates are intended for the treatment of; o Fractures of the middle and distal phalanges and tarsals, o Fractures of the metatarsals, o Osteotomies and arthrodeses on the foot **3.5mm Calcaneal Plate** Used for non-articular body fractures (Non-comminuted and comminuted) **Tarsus Screw** Tarsus Screw is an implant stabilization device used in the treatment of hyper pronating instability of the Hindfoot. The implant is designed to stabilize the talus to prevent excessive anterior, and/or medial, and/or plantarflexion of the talus, while allowing normal talotarsal joint motion. **Herbert Screw System** The Herbert Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. **Headless Screw System** Headless Screws are Intended for fusions, fractures, or osteotomies of small bones and small bone fragments including talus, malleolus, and calcaneus.
Contraindications	Contraindications for Foot plate surgery generally depend on the patient's overall condition, the specific nature of the injury, and the risks associated with the procedure. Below are the common

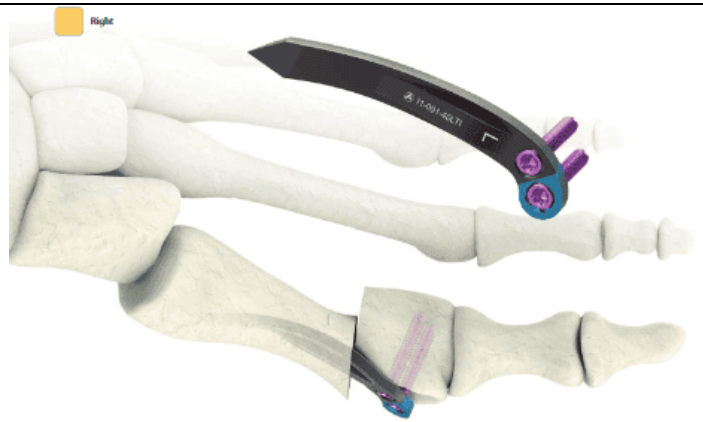
	contraindications: ○ Active infection at the surgical site: Increases the risk of complications like osteomyelitis or deeptissue infections. ○ Severe vascular compromise: Poor blood supply to the foot makes healing unlikely and may lead to necrosis. ○ Severe soft tissue damage: If the surrounding soft tissue cannot support the implanted hardware or surgical closure. ○ Allergy to implant materials: A known hypersensitivity to metals (e.g., titanium or stainless steel) used in plates. ○ Uncontrolled medical conditions: Severe comorbidities such as poorly managed diabetes, cardiovascular instability, or coagulopathy may pose excessive surgical or anesthetic risk. ○ Osteoporotic or poor bone quality: Inadequate bone stock may not provide stable fixation. ○ Patient non-compliance: A patient unwilling or unable to follow post-surgical care protocols (e.g., ○ immobilization or physical therapy). ○ Pediatric patients with growing bones: Plates may interfere with growth plates in children, ○ requiring alternative fixation methods. ○ Peripheral neuropathy or nerve damage: May impair post-surgical functional outcomes. ○ Pregnancy: Avoiding non-urgent surgeries due to anesthetic risks. ○ Non-surgical treatment (e.g., casting or splinting) may be preferred for stable fractures or when risks outweigh the benefits of surgery. ○ Plate fixation may be contraindicated in fractures that are best treated with other methods, such as external fixation or intramedullary devices, depending on fracture location and type.
Intended Patient Population	Skeleteally mature male and female subjects between 18-75 years.
Intended Users	The Foot Plate System is recommended to be used by only well-trained, certified and experienced surgeons.
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 Foot Plate System are Bio-compatible. Biocompatibility of the devices is tested as per EN

	ISO 10993-1 series of International Standard.

3. Description of the device

1.	**Device name**	**Ø2.7mm- Ø 5.0mm Metatarsal Shortening Implant, Titanium**
	Picture	
	Total Length	2.7mm-5.0mm
	Total shaft holes	Not Applicable
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

2.	**Device name**	**2.4mm AV-Wiselock Endosteal Plate, Standard**

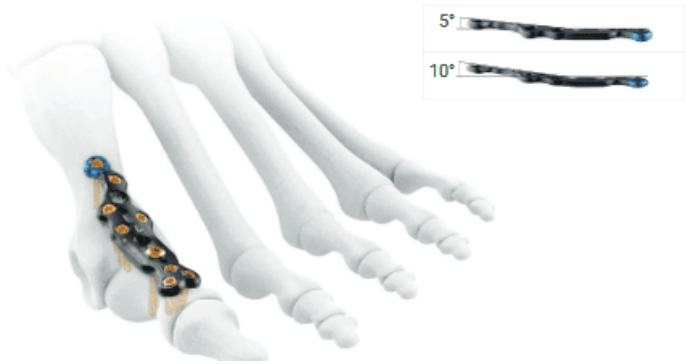
	Picture	
	Total Length	40mm-50mm
	Total shaft holes	Not Applicable
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

3.	**Device name**	**2.4mm AV-Wiselock Endosteal Plate, Curved**
	Picture	

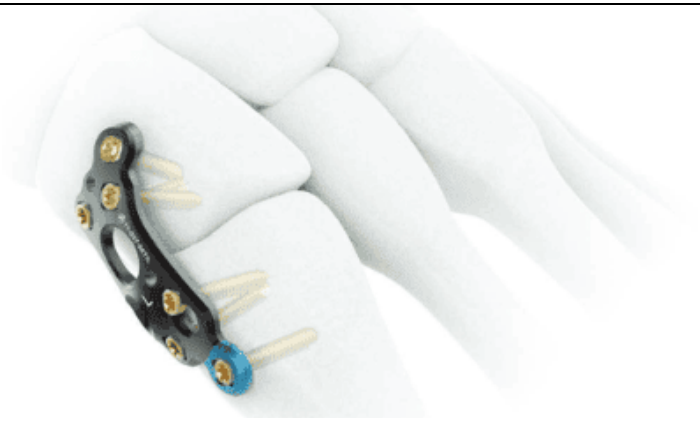
		
	Total Length	40mm-50mm
	Total shaft holes	Not Applicable
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

4.	**Device Name**	**2.7mm AV-Wiselock MTP Fusion M Plate**
	Picture	
	Total Bend	0°,5°,10°
	No. of Shaft Holes	7 Holes

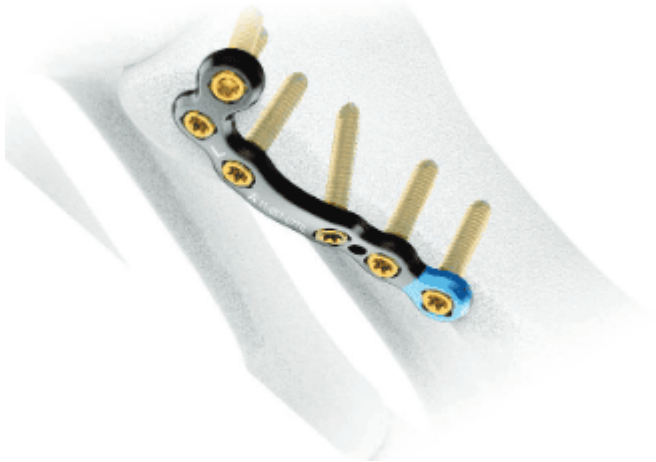
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

5.	**Device Name**	**2.7mm Av-Wiselock MTP Revision M Plate**
	Picture	
	Total Bend	5°,10°
	No. of Shaft Holes	9 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

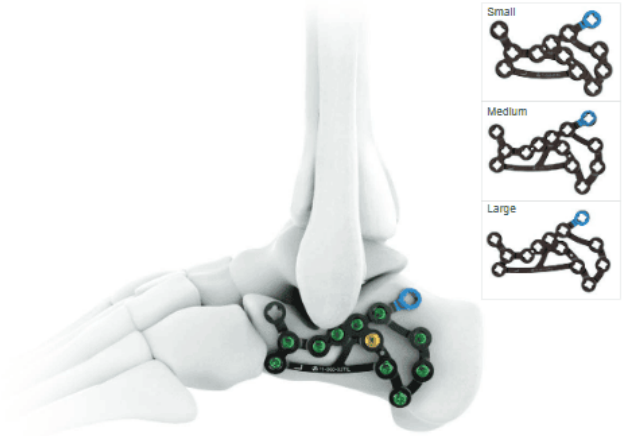
6.	**Device Name**	**2.7mm AV-Wiselock TMT-I Medical Fusion M Plate**

	Picture	
	No. of Shaft Holes	7 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

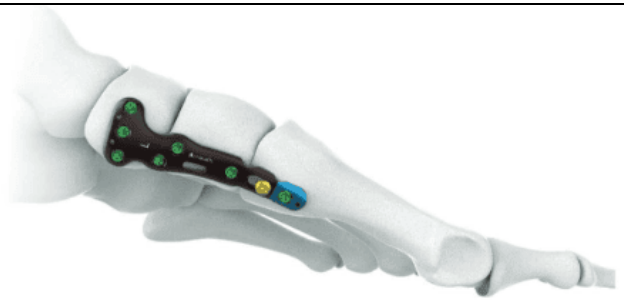
7.	**Device Name**	**2.7mm AV-Wiselock TMT-I Plantar Fusion M Plate**

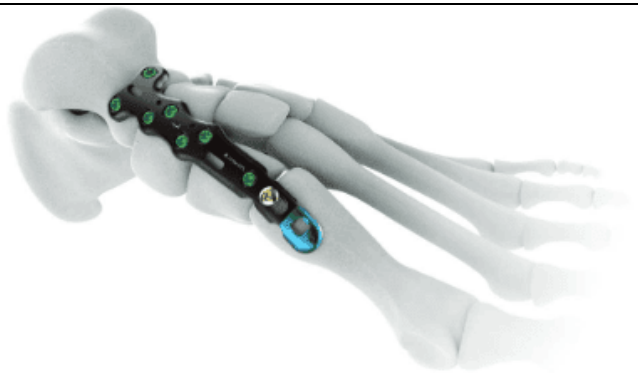
	Picture	
	No. of Shaft Holes	6 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

8.	**Device name**	**3.5mm AV-Wiselock Calcaneus M Plate**

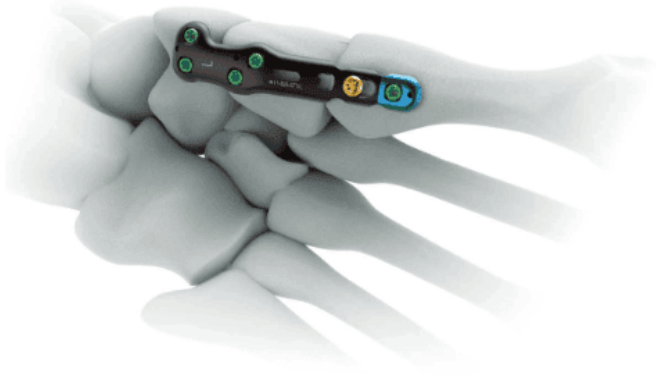
	Picture	
	Total shaft holes	Small-12 Holes Medium- 13 Holes Large- 13 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

9.	**Device name**	**3.5mm AV-Wiselock Medial Column Fusion Plate**

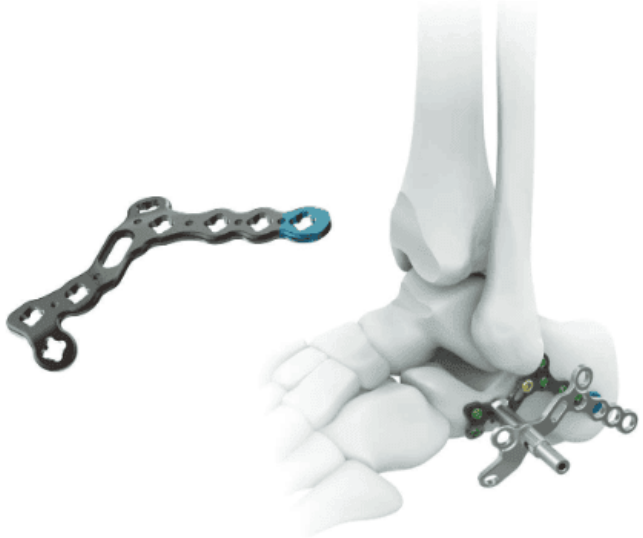
	Picture	
	Total shaft holes	8 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

10.	**Device name**	**3.5mm AV-Wiselock Medial Column Fusion Plate, Talus Extension**
	Picture	
	Total shaft holes	9 Holes

	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

11.	**Device name**	**3.5mm AV-Wiselock Medial Column Fusion Plantar Plate**
	Picture	
	Total shaft holes	7 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

12.	**Device name**	**3.5mm AV-Wiselock MIS Calcaneal Plate Type-III**

	Picture	
	Total shaft holes	6-7 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

13.	**Device name**	**3.5mm AV-Wiselock Plantar Lapidus Plate**
	Picture	

		
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

14.	**Device name**	3.5mm AV-Wiselock Plantar Lapidus Plate, Short
	Picture	
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

15.	**Device name**	**2.7mm Wise-Lock Plate, Straight**
	Picture	

	Total shaft holes	4-10 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

16.	**Device name**	**2.7mm Wise-Lock Condylar Plate**
	Picture	
	Total shaft holes	Shaft- 4-7 Holes Head - 2 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

17.	**Device name**	**2.7mm Wise-Lock T-Plate**
	Picture	
	Total shaft holes	Shaft- 3-4 Holes Head-2 Holes
	Directional Configuration (Left & Right)	Not Applicable

	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

18.	**Device name**	**2.7mm Wise-Lock L-Plate**
	Picture	
	Total shaft holes	Shaft- 3-4 Holes Head- 2 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

19.	**Device name**	**2.7mm Wise-Lock L-Plate, Oblique**
	Picture	
	Total shaft holes	Shaft- 3-4 Holes Head- 2 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

20.	**Device name**	**2.7mm Wise-Lock Mini Condylar Plate**
	Picture	
	Total shaft holes	7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

21.	**Device name**	**2.7mm Wise-Lock Straight Plate**
	Picture	
	Total Length	
	Total shaft holes	2 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

22.	**Device name**	**2.4/2.7mm Wise-Lock X-Plate**

	Picture	
	Total Length	22x14mm 24x18mm 30x20mm 36x20mm
	Total shaft holes	4 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

23.	**Device name**	**2.7mm Wise-Lock X-Plate**
	Picture	
	Size	Small, Medium, Large
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

24.	**Device name**	**2.7mm Wise-Lock Straight Plate with Single Start Thread**
	Picture	
	Total shaft holes	2 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

25.	**Device name**	**3.5mm Wise-Lock Calcaneal Plate**
	Picture	
	Total Length	69mm and 76 mm
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

26.	**Device name**	**3.5mm Wise-Lock Calcaneal Plate Type-I**
	Picture	
	Total shaft holes	3 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

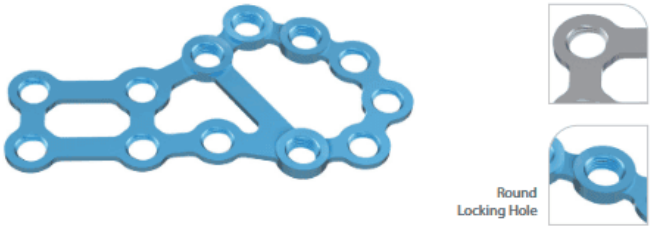
27.	**Device name**	**3.5mm Wise-Lock Calcaneal Plate Type-II**
	Picture	
	Total shaft holes	3 Holes

	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

28.	**Device name**	**3.5mm Wise-Lock Calcaneal Plate Type-III**
	Picture	
	Total shaft holes	6-7 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

29.	**Device name**	**3.5mm Wise-Lock Calcaneal Plate Type-IV**
	Picture	

	Total shaft holes	8 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

30.	**Device name**	**3.5mm Wise-Lock Calcaneal Plate Type-V**
	Picture	
	Total shaft holes	12 Holes
	Directional Configuration (Left & Right)	Left and Right
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024
31.	**Device name**	**2.7mm Mini “L” Plate**
	Picture	
	Total Length	32.80mm
	Total shaft holes	3 Holes
	Directional Configuration	Left and Right

	(Left & Right)	
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

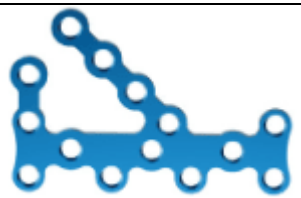
32.	**Device name**	**2.7mm "T" Plate**
	Picture	
	Total Length	34.50mm
	Total shaft holes	3 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

33.	**Device name**	**2.7mm Quarter Tubular Plate**
	Picture	
	Total Length	18mm-82mm
	Total shaft holes	2-10 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

34.	**Device name**	**2.7mm Dynamic Compression Plate**
	Picture	
	Total Length	20mm-100mm
	Total shaft holes	2-12 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

35.	**Device name**	**2.7mm Reconstruction Plate, Straight**
	Picture	
	Total Length	16.20mm-192.2mm
	Total shaft holes	2-24 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

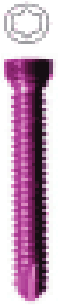
36.	**Device name**	**3.5mm Calcaneal Plate**

	Picture	
	Total Length	60-70mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

B. Bone Screws		
1.	**Device name**	**2.0mm Cortical Screw, Self-Tapping, Star Head**
	Picture	
	Total Length	6mm-40mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

2.	**Device name**	**2.4mm Cortical Screw, Self-Tapping, Star Head**

	Picture	
	Total Length	8mm-34mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

3.	**Device name**	**2.4mm Variable Angle Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	8mm-34mm

	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

4.	**Device Name**	**2.7mm Cortical Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	6mm-50mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

5.	**Device name**	**2.7mm AV-Wiselock Screw, Self Tapping, (Star Head)**
	Picture	

		
	Total Length	8mm-46mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024
6.	**Device name**	**2.7mm Wise-Lock Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	6mm – 60mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

7.	**Device name**	**4.0mm Cancellous Screw, Short Thread**
	Picture	
	Total Length	10mm – 45mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

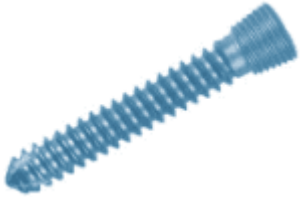
8.	**Device name**	**3.5mm AV-Wiselock Screw, Self-Tapping**
	Picture	
	Total Length	10mm-95mm

	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

9.	**Device name**	**3.5mm Wise-Lock Screw, Self Tapping, (Star Head)**
	Picture	
	Total Length	10mm-95mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

10.	**Device name**	**3.5mm Cortical Screw, Self Tapping, (Star Head)**
	Picture	
	Total Length	10mm-95mm

	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

11.	**Device name**	**2.7mm Wise-Lock Screw, Self-Tapping (Hex Head)**
	Picture	
	Total Length	10mm-60mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

12.	**Device name**	**3.5mm Wise-Lock Screw, Self-Tapping (Hex Head)**

	Picture	
	Total Length	10mm-80mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

13.	**Device name**	**3.5mm Wise-Lock Screw, Self-Drilling (Hex Head)**

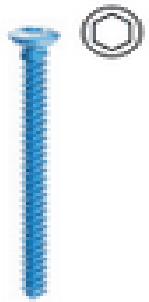
	Picture	
	Total Length	10mm-60mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

14.	**Device name**	**3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head)**
	Picture	

	Total Length	10mm-60mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

15.	**Device name**	**3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head)**
	Picture	
	Total Length	10mm-60mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

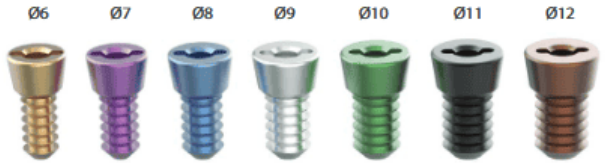
16.	**Device name**	**2.7mm Cortical Screw (Hex Head)**

	Picture	
	Total Length	6mm-30mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

17.	**Device name**	**2.7mm Cortical Screw, Self Tapping (Hex Head)**
	Picture	

	Total Length	6mm-30mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

18.	**Device name**	**3.5mm Cortical Screw, Self-Tapping, (Hex Head)**
	Picture	
	Total Length	10mm-90mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021 Stainless Steel ISO 5832-1:2024

19.	**Device name**	**Tarsus Screw**
	Picture	
	Total Length	6mm-12mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

Other details of Foot Plate System:

Device Compliance to regulation		We are proposing the Foot 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 Foot plate System
	General Description	Auxein' Foot plate system, Foot plate System offers a variety of bone screws and plate with different

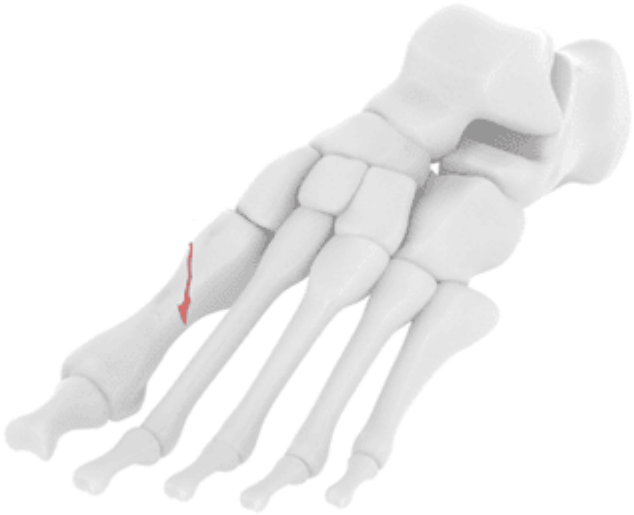
		shapes and sizes i.e. locking screws, Non-locking screw, AV-Wiselock, Wise-lock & Non-Locking plates, which can be rigidly locked into a variety configurations. **A. Plates** 1. Ø2.7mm-6.0mm Metatarsal Shortening Implant 2. 2.4mm AV-Wiselock Endosteal Plate, Standard, Left/Right, Titanium 3. 2.4mm AV-Wiselock Endosteal Plate, Curved, Left/Right, Titanium 4. 2.7mm AV-Wiselock MTP Fusion M Plate, 0°/5°/10° Dorsiflexion, Left/Right, Stainless Steel/Titanium 5. 2.7mm AV-Wiselock MTP Revision M Plate, 5°/10° Dorsiflexion, Left/Right, Stainless Steel/Titanium 6. 2.7mm AV-Wiselock TMT-I Medial Fusion M Plate, Left/Right, Stainless Steel/Titanium 7. 2.7mm AV-Wiselock TMT-I Plantar Fusion M Plate, Left/Right, Stainless Steel/Titanium 8. 3.5mm AV-Wiselock Calcaneus M Plate, Small/Medium/Large, Left/Right, Stainless Steel/Titanium 9. 3.5mm AV-Wiselock Medial Column Fusion Plate, Left/Right, Stainless Steel/Titanium 10. 3.5mm AV-Wiselock Medial Column Fusion Plate, Talus Extension, Left/Right, Stainless Steel/Titanium 11. 3.5mm AV-Wiselock Medial Column Fusion Plantar Plate, Left/Right, Stainless Steel/Titanium 12. 3.5mm AV-Wiselock MIS Calcaneal Plate Type-III, Left/Right, Stainless Steel/Titanium 13. 3.5mm AV-Wiselock Plantar Lapidus Plate, Left/Right, Stainless Steel/Titanium 14. 3.5mm AV-Wiselock Plantar Lapidus Plate, Short, Left/Right, Stainless Steel/Titanium 15. 2.7mm Wise-Lock Plate, Straight, titanium 16. 2.7mm Wise-Lock Condylar Plate, titanium 17. 2.7mm Wise-Lock T-Plate titanium 18. 2.7mm Wise-Lock L-Plate, Left/Right, Titanium

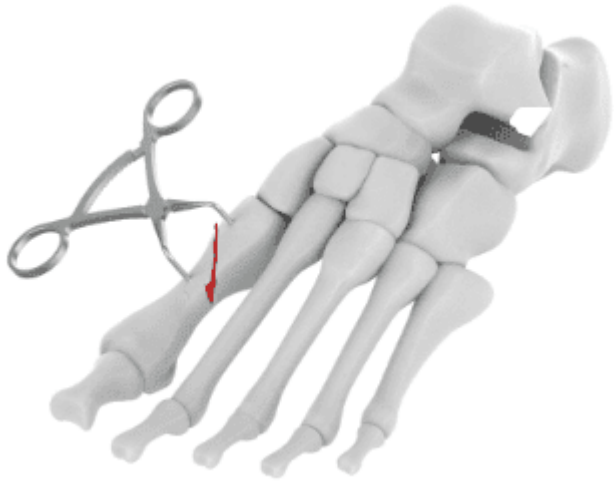
		19. 2.7mm Wise-Lock L-Plate, Oblique, Left/Right, Titanium 20. 2.7mm Mini Condylar Plate, Left/Right, Titanium 21. 2.7mm Wise-Lock Straight Plate, titanium 22. 2.4/2.7mm Wise-Lock X-Plate, titanium 23. 2.7mm Wise-Lock X-Plate, (Small/Medium/Large), Stainless Steel/Titanium 24. 2.7mm Wise-Lock Straight Plate with Single Start Thread, Stainless Steel/Titanium 25. 3.5mm Wise-Lock Calcaneal Plate, Left/Right, Stainless Steel/Titanium 26. 3.5mm Wise-Lock Calcaneal Plate Type-I, Left/Right, Stainless Steel/Titanium 27. 3.5mm Wise-Lock Calcaneal Plate Type-II, Left/Right, Stainless Steel/Titanium 28. 3.5mm Wise-Lock Calcaneal Plate Type-III, Left/Right, Stainless Steel/Titanium 29. 3.5mm Wise-Lock Calcaneal Plate Type-IV, Left/Right, Stainless Steel/Titanium 30. 3.5mm Wise-Lock Calcaneal Plate Type-V, Left/Right, Stainless Steel/Titanium 31. 2.7mm Mini "L" Plate, Left/Right, Stainless Steel/Titanium 32. 2.7mm "T" Plate, Stainless Steel/Titanium 33. 2.7mm Quarter Tubular Plate, Stainless Steel/Titanium 34. 2.7mm Dynamic Compression Plate, Stainless Steel/Titanium 35. 2.7mm Reconstruction Plate, Straight, Stainless Steel/Titanium 36. 3.5mm Calcaneal Plate, Stainless Steel/Titanium **B. Bone Screws** 1. 2.0mm Cortical Screw, Self-Tapping, (Star Head), Titanium 2. 2.4mm Cortical Screw, Self-Tapping, (Star Head), Titanium 3. 2.4mm Variable Angle Screws, Self-Tapping, (Star Head), Titanium 4. 2.7mm Cortical Screw, Self-Tapping, (Star Head), Stainless Steel/Titanium 5. 2.7mm AV-Wiselock Screw, Self-Tapping, (Star Head), Stainless Steel/Titanium 6. 2.7mm Wise-Lock Screw, Self-Tapping, (Star Head), Stainless Steel/Titanium

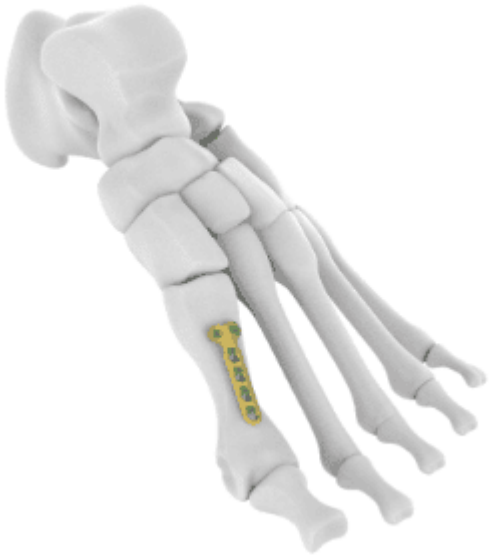
		7. 4.0mm Cancellous Screw, Short Thread, Stainless Steel/Titanium, 8. 3.5mm AV-Wiselock Screw, Self-Tapping, Titanium/Stainless Steel 9. 3.5mm Wise-Lock Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel 10. 3.5mm Cortical Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel 11. 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head), Stainless Steel/Titanium 12. 3.5mm Wise-Lock Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium 13. 3.5mm Wise-Lock Screw, Self-Drilling, (Hex Head), Stainless Steel/Titanium 14. 3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head), Stainless Steel/Titanium 15. 3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head), Stainless Steel/Titanium 16. 3.5mm Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium, 17. 2.7mm Cortical Screw, (Hex Head), Stainless Steel/Titanium 18. 2.7mm Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium 19. Tarsus screw, Titanium 20. 2.5mm Cannulated Herbert Screw, Short Thread, (Star Head), Titanium 21. 2.5mm Cannulated Herbert Screw, Long Thread, (Star Head), Titanium 22. 3.0mm Cannulated Herbert Screw, Short Thread, (Star Head), Titanium 23. 3.0mm Cannulated Herbert Screw, Long Thread, (Star Head), Titanium 24. Herbert Screw (Hex Head), 3.0/3.9mm Cannulated Compression Screw 25. 2.5mm Headless Cannulated Screw, Micro, Titanium 26. 3.5mm Headless Cannulated Screw, Mini, Titanium 27. 4.0mm Headless Cannulated Screw, Standard, Titanium 28. 4.7mm Headless Cannulated Screw, Titanium 29. 5.5mm Headless Cannulated Screw, Titanium

		30. 7.5mm Headless Cannulated Screw,Titanium 31. 3.0mm Cannulated Cancellous Screw,Short Thread 32. 3.0mm Cannulated Cancellous Screw, Long Thread 33. Washer 34. 3.5mm Cannulated Cortical Screw, Short Thread 35. 3.5mm Cannulated Cortical Screw, Full Thread 36. 3.5mm Cannulated Cortical Screw, Short Thread, self Tapping 37. 3.5mm Cannulated Cortical Screw, Full Thread, Self tapping 38. 4.0mm Cannulated Cancellous Screw, Short Thread, self Tapping 39. 4.0mm Cannulated Cancellous Screw, Full Thread, Self tapping 40. 4.5mm Cannulated Cortical Screw, Short Thread 41. 4.5mm Cannulated Cortical Screw, Full Thread 42. 4.5mm Cannulated Cortical Screw, Full Thread, Self tapping 43. 4.5mm Cannulated Cortical Screw, Full Thread, Self tapping
	Intended Purpose	Intended to maintain anatomical integrity of the fracture site by temporary fixation, correction and stabilization of bones in the foot.
	Intended Users	The Foot plate System is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Skeleteally mature male and female subjects between 18-75 years.
	Medical Conditions to be diagnosed, treated and/or monitored	The foot plate system provides temporary fixation, correction and stabilization of bones in the foot. Specifically designed Foot plate intended for treatment of fractures and correction that provides strong fixation and restores the bone fragments.
	Patient Selection Criteria	**Inclusion criteria** 1. Both male and female above 18 to 75 years patients. 2. Patients presenting to Orthopaedic emergency/ OPD with foot ailments which need internal fixation

		will be included in the study. **Exclusion criteria** 1. Infection, local or Systemic Acute or Chronic at the operative site. 2. Patient with known history of metal allergy. 3. Mental illness or schizophrenic, which may cause patients to ignore the limitations and precautions of the implanted material, leading to implants fracture and complication. 4. Patients having inadequate tissue coverage over the operative site. 5. Presence of marked or rapid bone absorption, metabolic bone disease, cancer, or any other tumor-like condition of the bone which may compromise fixation. 6. Female participant who is pregnant or planning pregnancy during the study. 7. Chronic Alchololic /Smoker 8. Any condition or anatomy that makes treatment with the Foot plate system infeasible. 9. Patients who are incarcerated or have pending incarceration.
c.	Principles of Operation	Foot plate system works on the AO Principle of Fracture Management. The key concept of fracture management involves: 1. Restoration of the anatomy 2. Stable fixation 3. Preservation of blood supply 4. Early mobilization of the limb and the patient The Auxein's foot 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 the plate 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 Principle of Operation	**Fracture Bone**  **Reduction**

		 **Plate Fixation**

		
d.	Rationale for considering as a Medical device	As per Article 2 (1) of EU MDR 2017/745 '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, foot plate is an implant used in humans for medical purposes to treat phalanges, metatarsals, tarsal, and calcaneus bone.* 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 Foot plate System is an implant used for the treatment of phalanges, metatarsals, tarsal, and calcaneus bone fracture.* Thus, it is not used for diagnosis, prevention, monitoring, prediction, prognosis or alleviation of disease. b) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or disability- Applicable Rationale for Applicability The Foot plate is an implantable device used for the treatment of phalanges, metatarsals, tarsal, and calcaneus bone. c) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state- Not Applicable Rationale for Non Applicability The Foot plate is intended to treat *p*halanges, metatarsals, tarsal, and calcaneus 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

		The Foot plate is made up of metal alloy and employed to *phalanges, metatarsals, tarsal, and calcaneus bone.* This system does not contain the In-vitro examination of specimens derived from the human body, including organ, blood and tissue donations. Moreover, the **device does not** achieve its principal intended action by any pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Hence, the foot 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 Foot plate System is used to stabilize phalanges, metatarsals, tarsal, and calcaneus bone 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 Article 1(4) and of those referred to in the first paragraph of this point- Not Applicable Rationale for Non Applicability The Foot plate System is intended for fixation for fractures of the phalanges, metatarsals, tarsal, and calcaneus bone. The system is not meant for cleaning, disinfection or sterilization of device.
e.	Novel Features	The Foot plate System consist 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 the device related to raw material, design, manufacturing process (coolants, lubricants, chemicals), intended use, post

		processing materials, etc.
f.	Description of key functional elements	The Foot plate System comprises of functional element as : ● Screws The Foot 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 phalanges, metatarsals, tarsal, and calcaneus bone. ○ In the foot plate System various types of screws are included like cortical, Cancellous, Wise-Lock and Av-wiselock screw. The accessories used with foot plate system: ● Surgical Instrument ***Surgical Instrument*** Various surgical instruments are used to assist with the insertion of the Plate and screws, including screwdrivers, drills, and specialized instruments for measuring the correct screw length. These instruments ensure the Plate is correctly placed, and the locking screws or bolts are properly inserted to secure the device in place. ○ Only Auxein Instruments shall be used with the foot plate system. The instruments should be CE Marked.
g.		

	Sterility	All Products covered in Foot Plate System are supplied in either Non-sterile or in Sterile state. The 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 15 minutes (Moist Heat Sterilization/Autoclave Sterilization) as instructed in IFU for Non-sterile devices before implantation.
	Radioactivity	Products covered in Foot 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).
	MRI Compatibility	The AUXEIN MEDICAL Foot Plate System have not been evaluated for safety and compatibility in the MR environment. The AUXEIN MEDICAL implants have not been tested for heating or migration in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic Resonance Imaging) environment.
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 3 **EU MDR 2017/745** By DNV Product Assurance AS (2460) **Certificate no.:** C642947

b.	Similar devices available in Union or international market.	The Similar devices available in the Union or International Market enlisted below: DePuy Synthes LCP compact Foot and Hand system (CE 0123) Depuy Synthes 2.7mm Variable Angle Locking Calcaneal Plating System (CE 0123) Depuy Synthes Variable Angle LCP Forefoot/Midfoot System 2.4/2.7 (CE 0123) Charfix ENDOSTEAL PLATE (CE 0197)

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 F1264.	Final finish device of SS bone plate mechanically safe tested according to ASTM F1264.	Both plates are 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 plates have chance of corrosion. Corrosion resistance test (Cyclic potentiodynamic polarization test) has performed on the SS it shows the positive result.
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.

Measurable safety and performance parameters

- Radiological evaluation by X-ray radiographs
- Measure the AOFAS Score
- Measure the VAS Score
- Adverse Event assessment.

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:

- Infection, both deep and superficial.
- Allergies and other reactions to device materials.
- Risks due to anesthesia.

Quantitative Risk:

Safety Parameters	Article Number	No. of Patients	Percentage of patients (%)	Benefit-Risk Analysis
Non-union	1, 5	6	1.08%	In the analysis of the literature study, a total of 552 patients were studied out of which 90 patients had complications. The benefit was 83.7% and risk was 16.01%. Thus, considering this, we can conclude that the overall benefit out weights the risk.
Necrosis	2, 4	6	1.08%	
Superficial wound infection	3, 5, 9	8	1.44%	
Loss of reduction	3	1	0.18%	
Delayed discharge	3	1	0.18%	
Compromised wound healing	3	1	0.18%	
Transient numbness	3	1	0.18%	
metalwork failures	5	3	0.54%	
Sinus Tarsi pain	6	53	9.6%	
Achilles Tendon	6	2	0.36%	
Decrease in Muscle strength	6	1	0.18%	
Poor wound healing	6	1	0.18%	
foreign body sensation.	6	1	0.18%	
posttraumatic arthritis	8	1	0.18%	
malunion	8	1	0.18%	
revision to subtalar fusion	8	1	0.18%	
early asymptomatic arthritis.	8	1	0.18%	
Suffered surgical wound	8	1	0.18%	

Warning & Precautions:

- Demonstrates anatomical or physiological abnormalities.

- 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.
- The plate of the system is not intended to support the body weight of the patient as it is too heavy.
- Apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible.
- The final phase of tightening shall be performed carefully.
- Has immunological response, sensitization or hypersensitivity for foreign materials.
- In the Implants Cleaning, Re-Use and Re-sterilization is not allowed. The device is not designed for re-processing.
- The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieve success of the surgery. The surgeon makes this choice.
- Patients who are overweight, malnourished and/or abusing alcohol or drugs, with weak muscles and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.
- The surgeon must warn the patient that the device does not restore the function and efficiency of a healthy bone.
- In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.
- Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

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

Prospective Clinical Data (PMCF Study):

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

Identity of the investigation/study: A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Foot Plate System.

Name or Code of Study	Completed	Name of countries	No. of patients	No. of serious	Serious incident	No. of

	(Yes/No)	**in study is conducted**	**enrolled /and the target No.**	**incidents**	**rate (%)**	**deaths**
CR_PMCF/P_11	Ongoing	India	07/20	0	0	0
Study Title	A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Foot Plate System.					
CTRI Number	CTRI/2024/04/065262					
CTRI Registration Date	03/09/2024					
Number of study sites	One					
Name of Study Sites	Triton Hospital, Nehru Enclave CC - 30 & 31, Outer Ring Road, Block C, Kalkaji, New Delhi, Delhi-110019, India					
No. of Patients enrolled	07					

Study design: The PMCF study has been designed according to the applicable rules and regulation to collect evidence based scientific data. The Sponsor in association with PI designed the study and obtained the approval from the Institutional Ethics Committee and the same has also been registered on CTRI. The study aims to recruit a total of 20 subjects, who meet inclusion and exclusion criteria as per the protocol. Subjects are being followed at stipulated time points i.e., 6 weeks, 3 months, 6 months and 12 months after surgery. evidence based scientific data. The Sponsor in association with PI designed the study and obtained the approval from the Institutional Ethics Committee and the same has also been registered on CTRI. The study aims to recruit a total of 15 subjects, who meet inclusion and exclusion criteria as per the protocol. Subjects are being followed at stipulated time points i.e., 6 weeks, 3 months, 6 months and 12 months after surgery.

Inclusion criteria

Patient will be screened for the following Inclusion Criteria:

1. Male or Female, aged 18 -75 years.
2. Patients presenting to Orthopaedic emergency/ OPD with Foot ailments will be included in the study.

Exclusion criteria

1. Infection, local or Systemic Acute or Chronic at the operative site.
2. Patient susceptibility to allergic reaction to the components of the alloy, the implant is manufactured from.

3. Mental illness or schizophrenic, which may cause patients to ignore the limitations and precautions of the implanted material, leading to implants fracture and complication.
4. Patients having inadequate tissue coverage over the operative site.
5. Presence of marked or rapid bone absorption, metabolic bone disease, cancer, or any other tumor-like condition of the bone which may compromise fixation.
6. Female participant who is pregnant or planning pregnancy during the study.
7. Chronic Alchololic /Smoker.
8. Any condition or anatomy that makes treatment with the Foot plate system infeasible
9. Patients who are incarcerated or have pending incarceration.

Primary Objective

1. To assess the safety and performance of the Foot Plate System by evaluating the quality of fusion and deformity correction through Radiological Evaluation.
2. The Change in American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Mid foot score from preoperative to follow-up visits at 6 week, 3 month, 6 month and 12 month.

Secondary Objective

1. Pain evaluation through Visual Analogue Scale (VAS).
2. Adverse Event assessment.

Primary Endpoints

1. Radiological Evaluation by X-ray radiographs to calculate meantime to achieve bone fusion and deformity correction or stabilization. [Baseline, Follow up at 6 weeks, 3 months, 6 months and 12 months].
2. Quality of Foot movement by calculating AOFAS Mid foot score. [Time Frame: baseline, 1 week, 3 months, 6 months, 12 months after surgery].

Secondary Endpoints

1. Follow-up of the patient’s recovery by analyzing Visual analogue score (VAS) for pain assessment. [Baseline, Follow-up at 6 weeks, 3 months, 6 months and 12 months].

2. Evaluation of Safety of Device by record of any adverse event, serious adverse event during follow up, especially the one mentioned in the Product Description. [Baseline, Follow-up at 6 weeks, 3 months, 6 months and 12 months].
3. Follow up will be done at - 6 weeks, 3 months, 6 months and 12 months.

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristics	**Age (years)**
Mean ± SD	43.71±16.45
Median	25 - 68
Range	46

Gender distribution of study subjects

Male	02/07
Female	05/07

Scoring	**Baselinen=07 (a)**	**6 Weekn=05 (b)**	**3 Monthn=03 (c)**	**6 Monthn=01 (d)**	**P value**
VAS Score Mean± SD	5.85±1.06	2.6±0.89	1.25±0.95	1.0±0.0	Due to small numberof patients recruited in the study analysis
VAS Score Median	6	2	1.5	1	
VAS ScoreRange	4-7	2-4	0-2	1-1	
AOFAS Mid-Foot	73.7±8.63	65.0±4.35	79.0±11.2	85±0.0	

Mean± SD					cannot be done.
AOFAS Mid-Foot Median	74	67	76	85	
AOFAS Mid-Foot Range	57-85	60-68	69-95	85-85	

Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Foot 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 above, skeletally mature patient at the time of surgery. The study aimed to recruit a total of 20 subjects who experienced foot fracture, and they were treated using a foot plate construct.

The PMCF study has been designed according to the applicable rules and regulation to collect evidence based scientific data. The Sponsor in association with PI designed the study and obtained the approval from the Independent Ethics Committee and the same has also been registered on CTRI. The study aims to recruit a total of 20 subjects, who meet inclusion and exclusion criteria as per the protocol. Subjects follow up is scheduled at 6 weeks, 3 months, 6 months and 12 months after surgery.

Study Result

As per the analysis, we have observed very significant positive results with respect to our foot 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.

Conclusion

The study of clinical data of patients enrolled in the study so far provides valuable insights into the safety and performance of the implants. Key findings include a significant improvement in pain and functional score, with no serious adverse events reported. Notably, the enhancement in functional scores as measured by the AOFAS the interventions & effectiveness in improving functional performance. The progressive decrease in VAS score over follow up visit

indicates a consistent and sustained improvement in functional ability. These results demonstrate excellent success rate, highlighting its strong efficacy and consistent reliability in clinical outcomes.

6. Possible diagnostic or therapeutic alternatives.

Foot fractures can be diagnosed through physical examination, X-rays, and other imaging techniques like bone scans, CT scans, or MRI. Treatment options include casting, removable braces or boots, taping for minor fractures, and surgery with internal fixation.

Non-surgical Treatment

For minor or stable fractures, the following options are typically recommended:

- **Rest and Elevation**: Resting the foot and elevating it above heart level to reduce swelling.
- **Ice**: Applying ice to the injured foot to reduce swelling and pain.
- **Compression**: Wrapping the foot with a soft bandage (if recommended by a doctor) to minimize swelling.
- **Footwear**: Using a special shoe (often called a "post-surgical shoe" or "boot") to protect the foot and allow proper healing. This might also include walking boots, casts, or splints to immobilize the foot.
- **Crutches or a Walker**: To keep weight off the foot and assist in mobility.
- **Pain management**: Over-the-counter pain relievers like ibuprofen or acetaminophen can help reduce pain and inflammation.

Healing time: Typically, 6-8 weeks for minor fractures, but it can vary.

Surgical Treatment

If the fracture is severe, misaligned, or involves multiple broken bones, surgery might be necessary:

- **Internal Fixation**: Surgeons may insert plates, screws, or rods to hold the bones in place and stabilize the fracture.
- **External Fixation**: In some cases, external devices may be used to stabilize the bones from the outside of the foot, usually for more complex fractures.

Recovery: Post-surgery, you may need to wear a cast or boot for several weeks. Physical therapy can also be recommended after healing to restore strength and mobility.

7. Suggested profile and training for users.

Specific training, including onsite demonstrations led by a product specialist are offered to ensure understanding of the product's functionality. Additionally, the DIAS platform for surgeons is available, focusing specifically on the surgical treatment of trauma spine, and musculoskeletal disorders offered by the Auxein. If further information on this product is needed, can visit https://www.auxein.com to review the product specific surgical technique for the system, Instruction for use, catalog available online.

8. Reference to any harmonized standards and CS applied.

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

Harmonized Standards		
S. No.	**Standard Designation**	**Title of Standard**
1.	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
2.	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
3.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021).
4.	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
5.	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
6.	EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
7.	EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
8.	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.
9.	EN ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.

10.	EN ISO 11737-2:2020	Sterilization of health care products -Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
11.	EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020).
12.	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 (ISO 11137-1:2006, including Amd 1:2013)
13.	EN ISO 11137-2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)

Non Harmonized Standards	
Standard	**Description**
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
IEC 62366-1:2015/Amd 1:2020	Medical devices - Application of usability engineering to medical devices
ISO 17665-2024	Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good Clinical Practice.
ISO 14602:2010	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
ISO 14630:2024	Non-active surgical implants - General Requirements
ISO 14644-1:2015	Clean-rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
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.
ISO 14644-3:2019	Clean-rooms and associated controlled environments - Part 3: Test Methods.

ISO 14644-4:2022	Clean-rooms and associated controlled environments - Part 4: Design, construction and start-up.
ISO 14644-5:2025	Clean-rooms and associated controlled environments - Part 5: Operations
ISO 14644-7:2004	Clean-rooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, Isolators and mini).
ISO 14644-8 :2022	Clean-rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC).
ISO 14644-9 :2022	Clean-rooms and associated controlled environments – Part 9: Classification of surface cleanliness by particle concentration.
ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 5832-3:2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)
ISO 5832-1:2024	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel (ISO 5832-1:2016)
ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-2: 2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
ASTM F138-19	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
ASTM F136-13 (2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM D4169-22	Standard Practice for Performance Testing of Shipping containers and System.

ASTM 1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.
ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials
ISO 19227:2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements
ISO/TR 10993-33:2015	Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3.

MDCG Guidelines	
Guidance Documents	**Description**
MDCG 2023-7	Practical Application of Article 61(4)
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2020-13	Clinical Evaluation Assessment Report Template
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2020-7	Guidance on PMCF plan template
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
MDCG 2019-9, Rev.01	Summary of safety and clinical performance
MDCG 2019-5	Registration of legacy devices in EUDAMED
MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
MDCG 2018-2	Future EU medical device nomenclature - Description of requirements
MDCG 2021-11	Guidance on Implant Card –‘Device types’
MDCG 2022-16	Guidance on Authorized Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746
MDCG 2022-9	Summary of safety and performance template
MDCG 2019-14	Explanatory note on MDR codes
MDCG 2021-19	Guidance note integration of the UDI within an organisation’s quality management system

MDCG 2023-7	Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR
MDCG 2018-1, Rev. 04	Guidance on BASIC UDI-DI and changes to UDI-DI
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
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022
MEDDEV 2.7/1 revision 4, 2016	Clinical Evaluation: A guide for manufacturers and notified bodies.

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
00	18-12-2024	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	29-06-2025	Updated the PMCF data	☐ 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: 29-06-2025

Device identification and general information

Device Trade Name: Auxein Foot 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: 08903993FOS014L3 (For Stainless Steel Implants) and 0890399FOT014U7 (For Titanium Implants).
Year when the device was first CE-marked: 2014

Intended use of the device

Intended Purpose	Intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of phalanges, metatarsals, tarsal, and calcaneus bone fragments.
Indications of Use	**Ø2.7mm-6.0mm Metatarsal Shortening Implant** Metatarsal shortening implant is intended to thread into the distal metatarsal head after performing the desired osteotomy. **2.4mm AV-Wiselock Endosteal Plate, Standard** **2.4mm AV-Wiselock Endosteal Plate, Curved** The plates are used to treat: Metatarsus primus varus (hallux valgus) **2.7mm AV-Wiselock MTP Fusion M Plate, 0°/5°/10° Dorsiflexion** **2.7mm AV-Wiselock MTP Revision M Plate, 5°/10° Dorsiflexion** **2.7mm AV-Wiselock TMT-I Medial Fusion M Plate** **2.7mm AV-Wiselock TMT-I Plantar Fusion M Plate**

	It is indicated for fixation of osteotomies, fusions, fractures, nonunions, malunions of the foot, and particularly in osteopenic bone. **3.5mm AV-Wiselock Calcaneus M Plate, Small/Medium/Large** It is intended for the fractures and osteotomies of the calcaneus **3.5mm AV-Wiselock Medial Column Fusion Plate** **3.5mm AV-Wiselock Medial Column Fusion Plate, Talus Extension** **3.5mm AV-Wiselock Medial Column Fusion Plantar Plate** All the plates are indicated for deformities, severe arthritis, and Arthrosis of the medial column consisting of the first metatarsal, medial cuneiform, navicular and talus. **3.5mm AV-Wiselock MIS Calcaneal Plate Type-III** It is intended to be used for treating the fracture and non-union of calcaneus bone. **3.5mm AV-Wiselock Plantar Lapidus Plate** **3.5mm AV-Wiselock Plantar Lapidus Plate, Short** It is intended to be used for TMT I joint arthrodesis. **2.7mm Wise-Lock Plate, Straight** **2.7mm Wise-Lock Condylar Plate** **2.7mm Wise-Lock T-Plate** **2.7mm Wise-Lock L-Plate** **2.7mm Wise-Lock L-Plate, Oblique** **2.7mm Mini Condylar Plate** **2.4/2.7mm Wise-Lock X-Plate** These plates are intended for the treatment of; o Fractures of metatarsal I, o Fractures of the tarsals, o MTP 1 fusions,

	o Osteotomies and arthrodesis of the tarsals (e.g. calcaneo-cuboidal fusion) **2.7mm Wise-Lock X-Plate, (Small/Medium/Large)** **2.7mm Wise-Lock Straight Plate with Single Start Thread** These plates are intended for the treatment of; o Fractures of the middle and distal phalanges and tarsals, o Fractures of the metatarsals, o Osteotomies and arthrodeses on the foot **3.5mm Wise-Lock Calcaneal Plate** **3.5mm Wise-Lock Calcaneal Plate Type-I** **3.5mm Wise-Lock Calcaneal Plate Type-II** **3.5mm Wise-Lock Calcaneal Plate Type-III** **3.5mm Wise-Lock Calcaneal Plate Type-IV** **3.5mm Wise-Lock Calcaneal Plate Type-V** The locking calcaneal plates address complex fractures of the calcaneus. The locking calcaneal plate is indicated for fractures and osteotomies of the calcaneus including, but not limited to, extra-articular, intraarticular, joint depression, tongue type, and severely comminuted fractures. **2.7mm Mini "L" Plate** **2.7mm "T" Plate** **2.7mm Quarter Tubular Plate** **2.7mm Dynamic Compression Plate** **2.7mm Reconstruction Plate, Straight** These plates are intended for the treatment of; o Fractures of the middle and distal phalanges and tarsals, o Fractures of the metatarsals, o Osteotomies and arthrodeses on the foot

	3.5mm Calcaneal Plate Used for non-articular body fractures (Non-comminuted and comminuted) **Tarsus Screw** Tarsus Screw is an implant stabilization device used in the treatment of hyper pronating instability of the Hindfoot. The implant is designed to stabilize the talus to prevent excessive anterior, and/or medial, and/or plantarflexion of the talus, while allowing normal talotarsal joint motion. **Herbert Screw System** The Herbert Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. **Headless Screw System** Headless Screws are Intended for fusions, fractures, or osteotomies of small bones and small bone fragments including talus, malleolus, and calcaneus.
Contraindications	Contraindications for Foot plate surgery generally depend on the patient's overall condition, the specific nature of the injury, and the risks associated with the procedure. Below are the common contraindications: ○ Active infection at the surgical site: Increases the risk of complications like osteomyelitis or deeptissue infections. ○ Severe vascular compromise: Poor blood supply to the foot makes healing unlikely and may lead to necrosis. ○ Severe soft tissue damage: If the surrounding soft tissue cannot support the implanted hardware or surgical closure. ○ Allergy to implant materials: A known hypersensitivity to metals (e.g., titanium or stainless steel) used in plates. ○ Uncontrolled medical conditions: Severe comorbidities such as poorly managed diabetes, cardiovascular instability, or coagulopathy may pose excessive surgical or anesthetic risk. ○ Osteoporotic or poor bone quality: Inadequate bone stock may not provide stable fixation. ○ Patient non-compliance: A patient unwilling or unable to follow post-surgical care protocols (e.g., ○ immobilization or physical therapy).

	○ Pediatric patients with growing bones: Plates may interfere with growth plates in children, ○ requiring alternative fixation methods. ○ Peripheral neuropathy or nerve damage: May impair post-surgical functional outcomes. ○ Pregnancy: Avoiding non-urgent surgeries due to anesthetic risks. ○ Non-surgical treatment (e.g., casting or splinting) may be preferred for stable fractures or when risks outweigh the benefits of surgery. ○ Plate fixation may be contraindicated in fractures that are best treated with other methods, such as external fixation or intramedullary devices, depending on fracture location and type.
Intended Patient Population	Skeletally mature male and female subjects between 18-75 years.

Device description

Auxein' Foot plate system, Foot 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. The details regarding foot plate 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**
Legacy Device	Yes, Foot 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		
EMDN Code	P091205		
Conformity Assessment Route	Conformity Assessment of Class IIb devices has been conducted as per Article 52 (4), Chapter I and III of Annex IX of EU MDR 2017/745		
Material/substances in contact with	The Material/substances that comes in contact with patient tissues used are Titanium alloy Ti-6AL-4V as per ISO		

patient tissues	5832-3:2021 and Stainless steel alloy SS 316 L as per ISO 5832-1:2024.
Risk Class	IIb (According to the EU Regulation 2017/745 (MDR) Annex VIII Rule 8)
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 Certificate no.: C642947

Principle of operation

Foot 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 foot 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 plates preserves the blood supply and early immobilization of bone union by following surgical technique provided by the manufacturer.

Description of Key functional elements:

The Foot plate System comprises of functional elements as :

- Screws

The Foot 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 phalanges, metatarsals, tarsal, and calcaneus bone.
- In the foot plate System various types of screws are included like cortical, Cancellous, Wise-Lock and Av-wiselock screw.

The accessories used with foot plate system:

- Surgical Instrument

Surgical Instrument

Various surgical instruments are used to assist with the insertion of the Plate and screws, including screwdrivers, drills, and specialized instruments for measuring the correct screw length. These instruments ensure the Plate is correctly placed, and the locking screws or bolts are properly inserted to secure the device in place.

Only Auxein Instruments shall be used with the foot plate system. The instruments should be CE Marked.

Risks and Warnings

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

- Infection, both deep and superficial.
- Allergies and other reactions to device materials.
- Risks due to anesthesia.

Warning & Precautions:

- Demonstrates anatomical or physiological abnormalities.
- 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.
- The plate of the system is not intended to support the body weight of the patient as it is too heavy.
- Apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible.
- The final phase of tightening shall be performed carefully.
- Has immunological response, sensitization or hypersensitivity for foreign materials.

- In the Implants Cleaning, Re-Use and Re-sterilization is not allowed. The device is not designed for re-processing.
- The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieve success of the surgery. The surgeon makes this choice.
- Patients who are overweight, malnourished and/or abusing alcohol or drugs, with weak muscles and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.
- The surgeon must warn the patient that the device does not restore the function and efficiency of a healthy bone.
- In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.
- Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

Summary of any field safety corrective action, (FSCA including FSN) if applicable
Till now, regarding Auxein's Foot 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 foot is a highly intricate structure made up of 26 bones that collaborate to support the body’s weight, maintain balance, and facilitate movement. These bones are grouped into three primary regions: the hindfoot, midfoot, and forefoot.

1. **Hindfoot** (Back of the foot)
   This region consists of two bones, which form the foundation of the foot and help with shock absorption and weight distribution.

   Calcaneus (Heel Bone):

   - The largest bone in the foot, located at the back.
   - It provides the heel's structure and absorbs much of the impact when walking, running, or jumping.

- The Achilles tendon attaches to the calcaneus, which is crucial for movement.

Talus (Ankle Bone):

- Sits above the calcaneus and forms the connection between the foot and the lower leg.
- It forms part of the **ankle joint**, where it articulates with the tibia and fibula (the two bones of the lower leg).
- The talus plays a key role in foot mobility and helps with movement in all directions.

2. **Midfoot** (Arch of the foot)
   The midfoot is made up of several smaller bones, which form the arch of the foot. These bones work together to provide flexibility and stability to the foot, allowing it to absorb shock and adjust to different surfaces.

Navicular:

- A small, boat-shaped bone located in front of the talus.
- It is a crucial part of the foot's arch and acts as a connector between the talus and the cuneiform bones.

Cuboid:

- A cube-shaped bone on the outer side of the foot, next to the calcaneus.
- It helps form part of the arch and provides support to the lateral (outer) side of the foot.

Cuneiforms (Medial, Intermediate, Lateral):

- Three wedge-shaped bones located in front of the navicular bone.
- They form part of the arch and help with the mobility of the foot while providing stability during walking and running.

3. **Forefoot** (Front of the foot)
   This section of the foot contains the toes and the bones that support them. It is involved in propulsion, helping the foot push off the ground when walking or running.

Metatarsals:

- Five long bones in the middle part of the foot, numbered 1 to 5 from the big toe to the pinky toe.
- They connect to the toes and provide structural support to the foot.

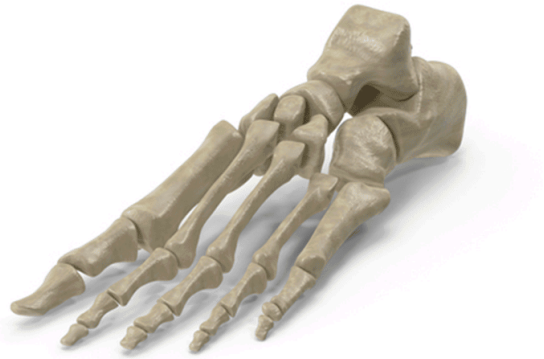
- The first metatarsal (under the big toe) is particularly important for walking, as it helps bear much of the body's weight.

Phalanges (Toes):

- The toes are made up of 14 small bones, with each toe having three phalanges (except for the big toe, which has two).
- These bones help with balance and provide leverage during walking and running.
- The big toe, or hallux, is especially critical for push-off during the walking cycle.

Function:

The bones of the foot provide support, stability, and shock absorption, helping to distribute body weight during standing and movement. They enable mobility, balance, and coordination while protecting internal structures. The bones also facilitate toe movement for grip and propulsion.



Types of Foot Fracture

Foot fractures can vary in type depending on which bones are involved, the severity of the break, and the mechanism of injury. Here's a breakdown of the main types of foot fractures:

1. Stress Fractures

Small, hairline fractures that occur due to repetitive stress or overuse, often without a specific trauma.

- Common Causes: Overuse in athletes, particularly runners or dancers, or sudden increases in activity level.
- Common Sites: Metatarsals (especially the 2nd and 3rd), calcaneus (heel), or navicular bone.
- Symptoms: Gradual onset of pain that worsens with activity and improves with rest.

2. Fractures of the Metatarsals

Breaks in the long bones of the foot that connect to the toes. These are among the most common types of foot fractures.

Types:

- **Closed Fracture**: The bone breaks but does not pierce the skin.
- **Open Fracture**: The bone breaks and protrudes through the skin, often leading to higher risk of infection.

Common Causes: Trauma such as dropping something heavy on the foot, sports injuries, or direct impact.
Symptoms: Pain, swelling, bruising, and difficulty walking.

Notable Subtypes:

- Jones Fracture: A fracture at the base of the 5th metatarsal, typically caused by twisting injuries or overuse.
- March Fracture: A stress fracture in the 2nd or 3rd metatarsal, commonly seen in soldiers or athletes.

3. Fractures of the Phalanges (Toes)

Breaks in the bones of the toes**.**

Types:

- **Simple Fractures**: Where the bone breaks into two pieces.
- **Comminuted Fractures**: The bone shatters into several pieces.
- **Displaced vs Non-displaced**: Whether the bone pieces have shifted out of place.

Common Causes: Stubbing the toe, dropping heavy objects, or sports injuries.
Symptoms: Pain, swelling, bruising, and difficulty moving the toe.

Notable Subtypes:

- **Turf Toe**: A sprain or partial fracture of the big toe joint, commonly seen in athletes.

4. Fractures of the Calcaneus (Heel Bone)

Breaks in the calcaneus, the large bone at the back of the foot, often due to high-impact trauma.

- **Common Causes**: Falling from height, car accidents, or landing awkwardly after jumping or running.
- **Symptoms**: Severe pain, swelling, bruising, and difficulty walking.
- **Risk of Complications**: These fractures can be complicated by arthritis or the need for surgical intervention due to the complex nature of the bone.

5. Fractures of the Tarsal Bones

Breaks in the bones of the midfoot (tarsal bones). These include the navicular, cuboid, and cuneiform bones.

Types:

- **Navicular Fracture**: Often caused by a sudden forceful impact or repetitive stress. These fractures can be difficult to detect on X-rays, and may require CT scans or MRIs.
- **Cuboid Fracture**: Less common, but can occur from twisting injuries.
- **Cuneiform Fractures**: These can occur as isolated injuries or with other tarsal fractures, often from direct trauma or high-impact injuries.

Symptoms: Pain, swelling, and difficulty bearing weight on the foot.

6. Fractures of the Talus (Ankle Bone)

Although the talus is technically part of the ankle joint, its fracture can affect the foot's mobility and function. These are often associated with ankle fractures.

Common Causes: High-energy trauma, such as car accidents, falls from height, or severe twisting injuries.

Symptoms: Pain, swelling, bruising, and difficulty moving the foot. Fractures of the talus can lead to long-term complications, such as arthritis or avascular necrosis (death of bone tissue due to lack of blood supply).

7. Fractures Involving Multiple Bones (Combinations)

Some injuries result in fractures involving multiple bones in the foot. For example, fractures may involve a combination of metatarsals, tarsals, and phalanges, often due to crushing injuries.

- **Common Causes**: High-impact accidents, falls, or crush injuries (e.g., industrial accidents).
- **Symptoms**: Pain, swelling, bruising, and a visible deformity in severe cases.
- **Treatment**: These fractures may require surgical intervention to realign the bones and stabilize them.

Causes

The most common causes of a broken foot include:

- **Car accidents.** The crushing injuries that can happen in car accidents may cause breaks that need surgery to be fixed.
- **Falls.** Tripping and falling can break bones in the feet. So can landing on the feet after jumping down from a height.
- **Impact from a heavy weight.** Dropping something heavy on the foot is a common cause of fractures.
- **Missteps.** Sometimes a stumble can result in a twisting injury that can cause a broken bone. A toe can break from stubbing it on furniture.
- **Overuse.** Stress fractures are common in the weight-bearing bones of the feet. Repeated force or overuse over time, such as running long distances, most often is the cause of these tiny cracks. But they also can happen with regular use of a bone that's been weakened by a condition such as osteoporosis

Symptoms:

- **Pain**: Usually sudden and localized to the area of the fracture, worsens with movement or pressure.
- **Swelling and Bruising**: Common around the site of the fracture, particularly in more severe fractures.
- **Deformity**: In some fractures, such as displaced fractures, there may be visible misalignment of the bone.
- **Inability to Bear Weight**: Difficulty or inability to walk, stand, or bear weight on the injured foot.
- **Tenderness**: The area around the fracture site will be tender to the touch

Diagnosis

- **X-rays**: The primary diagnostic tool for identifying bone fractures.
- **CT Scan or MRI**: Used in complex fractures, stress fractures, or to assess soft tissue involvement, such as ligament damage.
- **Bone Scintigraphy**: Used in cases where stress fractures are suspected but not visible on X-rays.

Pain Management

Most fractures hurt moderately for a few days to a couple of weeks. Many patients find that elevation helps to relieve pain. A 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

Rehabilitation after a foot fracture involves a multi-phased approach focused on pain management, regaining range of motion, strengthening, proprioception, and eventually, a return to functional activities. Early stages prioritize rest, ice, compression, and elevation (RICE) to reduce swelling and pain. As healing progresses, physical therapy plays a crucial role in restoring mobility, strength, and balance, with a gradual return to weight-bearing activities.

Clinical Evidence/Safety of the device

To support the clinical outcomes of foot plate system, we have the prospective study ongoing to evaluate its clinical efficacy, safety, and long-term outcomes. This study will further substantiate the performance of our device in real-world clinical settings.

Prospective Clinical Evaluation

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

Identity of the investigation/study: A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Foot Plate System.

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_11	Ongoing	India	07/20	0	0	0
Study Title	A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Foot Plate System.					
CTRI Number	CTRI/2024/04/065262					
CTRI Registration Date	03/09/2024					
Number of study sites	One					
Name of Study Sites	Triton Hospital, Nehru Enclave CC - 30 & 31, Outer Ring Road, Block C, Kalkaji, New Delhi, Delhi-110019, India					
No. of Patients enrolled	07					

Study design: The PMCF study has been designed according to the applicable rules and regulation to collect evidence based scientific data. The Sponsor in association with PI designed the study and obtained the approval from the Institutional Ethics Committee and the same has also been registered on CTRI. The study aims to recruit a total of 20 subjects, who meet inclusion and exclusion criteria as per the protocol. Subjects are being followed at stipulated time points i.e., 6 weeks, 3 months, 6 months and 12 months after surgery. evidence based scientific data. The Sponsor in association with PI designed the study and obtained the approval from the Institutional Ethics Committee and the same has also been registered on CTRI. The study aims to recruit a total of 15 subjects, who meet inclusion and exclusion criteria as per the protocol. Subjects are being followed at stipulated time points i.e., 6 weeks, 3 months, 6 months and 12 months after surgery.

Inclusion criteria

Patient will be screened for the following Inclusion Criteria:

1. Male or Female, aged 18 -75 years.
2. Patients presenting to Orthopaedic emergency/ OPD with Foot ailments will be included in the study.

Exclusion criteria

1. Infection, local or Systemic Acute or Chronic at the operative site.
2. Patient susceptibility to allergic reaction to the components of the alloy, the implant is manufactured from.
3. Mental illness or schizophrenic, which may cause patients to ignore the limitations and precautions of the implanted material, leading to implants fracture and complication.
4. Patients having inadequate tissue coverage over the operative site.
5. Presence of marked or rapid bone absorption, metabolic bone disease, cancer, or any other tumor-like condition of the bone which may compromise fixation.
6. Female participant who is pregnant or planning pregnancy during the study.
7. Chronic Alchololic /Smoker.
8. Any condition or anatomy that makes treatment with the Foot plate system infeasible
9. Patients who are incarcerated or have pending incarceration.

Primary Objective

1. To assess the safety and performance of the Foot Plate System by evaluating the quality of fusion and deformity correction through Radiological Evaluation.

2. The Change in American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Mid foot score from preoperative to follow-up visits at 6 week, 3 month, 6 month and 12 month.

Secondary Objective

1. Pain evaluation through Visual Analogue Scale (VAS).
2. Adverse Event assessment.

Primary Endpoints

1. Radiological Evaluation by X-ray radiographs to calculate meantime to achieve bone fusion and deformity correction or stabilization. [Baseline, Follow up at 6 weeks, 3 months, 6 months and 12 months].
2. Quality of Foot movement by calculating AOFAS Mid foot score. [Time Frame: baseline, 1 week, 3 months, 6 months, 12 months after surgery].

Secondary Endpoints

1. Follow-up of the patient's recovery by analyzing Visual analogue score (VAS) for pain assessment. [Baseline, Follow-up at 6 weeks, 3 months, 6 months and 12 months].
2. Evaluation of Safety of Device by record of any adverse event, serious adverse event during follow up, especially the one mentioned in the Product Description. [Baseline, Follow-up at 6 weeks, 3 months, 6 months and 12 months].
3. Follow up will be done at - 6 weeks, 3 months, 6 months and 12 months.

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)
Mean ± SD	43.71±16.45
Median	25 - 68
Range	46

Gender distribution of study subjects

Male	02/07
Female	05/07

Scoring	Baselinen=07 (a)	6 Weekn=05 (b)	3 Monthn=03 (c)	6 Monthn=01 (d)	P value
VAS Score Mean± SD	5.85±1.06	2.6±0.89	1.25±0.95	1.0±0.0	Due to small number of patients recruited in the study analysis cannot be done.
VAS Score Median	6	2	1.5	1	
VAS ScoreRange	4-7	2-4	0-2	1-1	
AOFAS Mid-Foot Mean± SD	73.7±8.63	65.0±4.35	79.0±11.2	85±0.0	
AOFAS Mid-Foot Median	74	67	76	85	
AOFAS Mid-Foot Range	57-85	60-68	69-95	85-85	

Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Foot 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 above, skeletally mature patient at the time of surgery. The study aimed to recruit a total of 20 subjects who experienced foot fracture, and they were treated using a foot plate construct.

The PMCF study has been designed according to the applicable rules and regulation to collect evidence based scientific data. The Sponsor in association with PI designed the study and obtained the approval from the Independent Ethics Committee and the same has also been registered on CTRI. The study aims to recruit a total of 20 subjects, who meet inclusion and exclusion criteria as per the protocol. Subjects follow up is scheduled at 6 weeks, 3 months, 6 months and 12 months after surgery.

Study Result

As per the analysis, we have observed very significant positive results with respect to our foot 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.

Conclusion

The study of clinical data of patients enrolled in the study so far provides valuable insights into the safety and performance of the implants. Key findings include a significant improvement in pain and functional score, with no serious adverse events reported. Notably, the enhancement in functional scores as measured by the AOFAS the interventions & effectiveness in improving functional performance. The progressive decrease in VAS score over follow up visit indicates a consistent and sustained improvement in functional ability. These results demonstrate excellent success rate, highlighting its strong efficacy and consistent reliability in clinical outcomes.

6. **Possible diagnostic or therapeutic alternatives.**

Foot fractures can be diagnosed through physical examination, X-rays, and other imaging techniques like bone scans, CT scans, or MRI. Treatment options include casting, removable braces or boots, taping for minor fractures, and surgery with internal fixation.

Non-surgical Treatment

For minor or stable fractures, the following options are typically recommended:

- **Rest and Elevation**: Resting the foot and elevating it above heart level to reduce swelling.
- **Ice**: Applying ice to the injured foot to reduce swelling and pain.
- **Compression**: Wrapping the foot with a soft bandage (if recommended by a doctor) to minimize swelling.
- **Footwear**: Using a special shoe (often called a "post-surgical shoe" or "boot") to protect the foot and allow proper healing. This might also include walking boots, casts, or splints to immobilize the foot.

- **Crutches or a Walker**: To keep weight off the foot and assist in mobility.
- **Pain management**: Over-the-counter pain relievers like ibuprofen or acetaminophen can help reduce pain and inflammation.

Healing time: Typically, 6-8 weeks for minor fractures, but it can vary.

Surgical Treatment

If the fracture is severe, misaligned, or involves multiple broken bones, surgery might be necessary:

- **Internal Fixation**: Surgeons may insert plates, screws, or rods to hold the bones in place and stabilize the fracture.
- **External Fixation**: In some cases, external devices may be used to stabilize the bones from the outside of the foot, usually for more complex fractures.

Recovery: Post-surgery, you may need to wear a cast or boot for several weeks. Physical therapy can also be recommended after healing to restore strength and mobility.

7. **Suggested profile and training for users.**

Specific training, including onsite demonstrations led by a product specialist are offered to ensure understanding of the product's functionality. Additionally, the DIAS platform for surgeons is available, focusing specifically on the surgical treatment of trauma spine, and musculoskeletal disorders offered by the Auxein. If further information on this product is needed, can visit https://www.auxein.com to review the product specific surgical technique for the system, Instruction for use, catalog available online.