Summary of Safety and Clinical Performance for Hand Plate system

The following information is intended for users/healthcare professionals.

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

Basic UDI-DI: 0890399HWT018XZ for Titanium and 08903993HWS018PV for Stainless Steel

SRN: IN-MF-000018837

The Hand Plate System includes the following as listed below:

0.8mm Bone Plates:

- 0.8mm Wise-Lock Low Profile Avulsion Fracture Plate, Titanium
- 0.8mm Wise-Lock Low Profile Straight Plate, Titanium
- 0.8mm Wise-Lock Low Profile Curved Medial/Lateral Plate, Titanium
- 0.8mm Wise-Lock Low Profile Curved Medial/Lateral Plate, Short, Titanium
- 0.8mm Wise-Lock Low Profile Compression Plate, Titanium
- 0.8mm Wise-Lock Low Profile T-Plate, Titanium
- 0.8mm Wise-Lock Low Profile L-Plate, Titanium
- 0.8mm Wise-Lock Low Profile Offset Plate, Titanium

1.3mm Bone Plates:

- 1.3mm Wise-Lock Low Profile Metacarpal Neck Plate, Titanium
- 1.3mm Wise-Lock Low Profile Compression Plate, Titanium
- 1.3mm Wise-Lock Low Profile Straight Plate, Titanium
- 1.3mm Wise-Lock Low Profile T-Plate, Titanium
- 1.3mm Wise-Lock Low Profile Rolando Fracture Hook Plate, Titanium
- 1.3mm Wise-Lock Low Profile Rotational Correction Plate, Titanium

1.5mm Bone Plates:

- 1.5mm Wise-Lock Plate, Straight, Titanium
- 1.5mm Wise-Lock Adaption Plate, Straight, Titanium
- 1.5mm Wise-Lock Adaption T-Plate, Titanium
- 1.5mm Wise-Lock Strut Plate, Titanium
- 1.5mm Wise-Lock Adaption Y-Plate, Titanium
- 1.5mm Wise-Lock Condylar Plate, Titanium

2.0mm Bone Plates:

- 2.0mm Wise-Lock Plate, Straight, Titanium

- 2.0mm Adaption Plate, Straight, Titanium
- 2.0mm Wise-Lock Adaption Plate, Straight, Titanium
- 2.0mm Wise-Lock Condylar Plate, Titanium
- 2.0mm Wise-Lock Rotation Correction Plate, Titanium
- 2.0mm Wise-Lock T-Plate, Titanium
- 2.0mm Wise-Lock T-Adaption Plate, Titanium
- 2.0mm Wise-Lock Y-Adaption Plate, Titanium
- 2.0mm Mini Condylar Plate, Titanium
- 2.0mm Wise-Lock Mini H-Plate, Titanium
- 2.0mm Wise-Lock Distal Ulna Hook Plate, Titanium
- 2.0mm Mini "L" Plate – Left/Right, Stainless Steel/Titanium
- 2.0mm Mini Straight Plate, Stainless Steel/Titanium
- 2.0mm DCP Plate, Stainless Steel/Titanium
- 2.0mm Mini "T" Plate, Stainless Steel/Titanium/Titanium

2.4mm Bone Plates:
- 2.4mm Wise-Lock Plate, Straight, Titanium
- 2.4mm Adaption Plate, Straight, Titanium
- 2.4mm Wise-Lock Adaption Plate, Straight, Titanium
- 2.4mm Wise-Lock Condylar Plate, Titanium
- 2.4mm Wise-Lock T-Adaption Plate, Titanium
- 2.4mm Wise-Lock T-Plate, Titanium
- 2.4mm Wise-Lock Y-Adaption Plate, Titanium
- 2.4mm AV-Wiselock RSL Fusion M Plate, Titanium/Stainless Steel
- 2.4mm AV-Wiselock Wrist Fusion M Plate, Titanium/Stainless Steel
- 2.4mm AV-Wiselock Dorsal Wrist Fusion M Plate, Radiocapitate, Titanium/Stainless Steel
- 2.4mm AV-Wiselock Dorsal Total Wrist Fusion M Plate, Titanium/Stainless Steel

3.5mm Bone Plates:
- 3.5mm Wise-Lock Wrist Fusion Plate, Titanium/Stainless Steel, (Standard bend, short bend & Straight Bend)

Bone Screws:
- 1.5mm Cortical Screw, Self-Tapping, (Star Head), Titanium
- 1.5mm Cortical Screw, (Hex Head), Stainless Steel/Titanium

- 1.5mm Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium
- 1.5mm Wise-Lock Screw, Self-Tapping, (Star Head), Titanium
- 1.5mm Low Profile Screw, (Star Head), Titanium
- 1.5mm Wise-Lock Low Profile Screw, (Star Head), Titanium
- 1.8mm Buttress Screw, (Star Head), Titanium
- 2.0mm Cortical Screw, Self-Tapping, (Star Head), Titanium
- 2.0mm Cortical Screw, (Hex Head), Stainless Steel/Titanium
- 2.0mm Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium
- 2.0mm Wise-Lock Screw, Self-Tapping, (Star Head), Titanium
- 2.3mm Wise-Lock Low Profile Screw, (Star Head), Titanium
- 2.3mm Low Profile Screw, (Star Head), Titanium
- 2.4mm Cortical Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel
- 2.4mm Variable Angle Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel
- 2.4mm Wise-Lock Screw, Self-Tapping, (Star Head), Titanium/Stainless Steel
- 2.7mm Cortical Screw, (Hex Head), Stainless Steel/Titanium
- 2.7mm Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium
- 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 Cortical Screw, Self-Tapping, (Hex Head), Stainless Steel/Titanium

Other Components:

- Staple U - Type, Stainless Steel/Titanium
- Straight Staple, Titanium
- Staple with Offset, Titanium
- Three-Legged Staple, Titanium
- Staple Coventry, Titanium
- Steinman Pins, Stainless Steel
- Centrally Threaded Steinman Pin, Stainless Steel
- Suture Wire, Stainless Steel
- Kirschner Wire with Trocar Tip Both End, Stainless Steel
- Kirschner Wire Fully Threaded, Stainless Steel
- Circlage Wire with Loop, Stainless Steel
- Kirschner Wire with One Side Trocar Tip, Stainless Steel

Details Regarding the device are provided in below table:

Device Trade Name:	**Hand 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@auxein.com Website**:** www.auxein.com		
Manufacturer's SRN	IN-MF-000018837		
EMDN Code	P091205		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Hand Plate System (Certified under MDD 93/42/EEC)	DQS Medizintechnik GmbH	170753735
Year when the first certificate (CE) was issued covering the device	2009		
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per EN ISO 5832-3:2021 and Stainless-steel alloy SS 316 L as per EN ISO 5832-1:2019.		
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.		
USFDA Approved	Yes (Hand plate are approved by USFDA whose details are as follow:) **510(k) Number:** K213059, K141680		
Risk Class	IIb {According to REGULATION (EU) 2017/745 (MDR) OF THEEUROPEAN PARLIAMENT, Annex VIII, Chapter-3, Rule 8 - Implantable devices and long-term surgically invasive devices (>30 days)} are in Class IIb unless they are intended: Are intended to be placed in the teeth, in which case they areclassified as class IIa; **Applicable/ Not Applicable:** Not Applicable **Justification:** The hand plate intended to be placed in phalanges, metacarpals, carpals, wrist bone and Distal Radius bone to treat fracture not intended for teeth. 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 hand plate comes in contact with the phalanges, metacarpals, carpals, wrist bone and Distal Radius bone.Thus, it does not come in contact with the heart, the central circulatory system or the central nervous system. 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 Hand plate System is made up of medical grade metallic alloy. Metallic alloy does not achieve its intended use by biological effect or by absorption. 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 Hand 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. Are intended to administer medicinal products, in which casethey are classified as class III; **Applicable/ Not Applicable:** Not Applicable ***Justification:*** The hand plate implants made up of metal alloys to provide support for the fractured phalanges, metacarpals, carpals, wrist bone and Distal Radius bone. The system is not intended to administer medicinal products. Are active implantable devices or their accessories, in whichcases they are classified as class III; **Applicable/ Not Applicable:** Not Applicable **Justification: 'Active Device'** means any device, the operation ofwhich depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. The Hand plate System does not depend on a source of energy. Are breast implants or surgical meshes, in which cases they areclassified as class III; **Applicable/ Not Applicable:** Not Applicable **Justification:** The Hand plate System treats phalanges, metacarpals, carpals, wrist bone and Distal Radius bone

	fracture.Not intended as breast implants or surgical meshes 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 Hand plate System treats phalanges, metacarpals, carpals, wrist bone and Distal Radius bone fracture.Not intended for Total or Partial Joint Replacements. 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 Hand plate System is an implantable device totreat phalanges, metacarpals, carpals, wrist bone and Distal Radius 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

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:

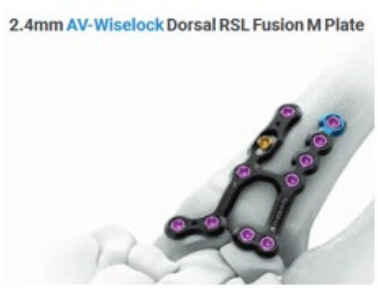
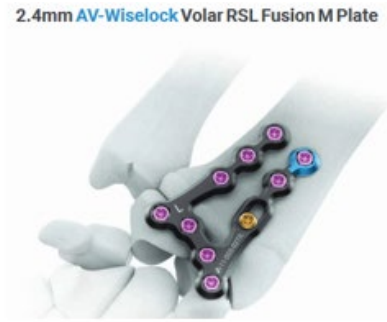
Indications of Use	**0.8mm & 1.3mm Bone Plates**: Fixation of fractures, fusions, and osteotomies of the proximal, middle and distal phalanges and metacarpals. **1.5mm Bone Plates**: o Fracture fixation of the phalanges and metacarpals o Osteotomies o Arthrodeses o Replantations and reconstructions of phalanges and metacarpals, particularly in osteopenic bone. **2.0mm Bone Plates**: o Fractures of the Phalanges (middle and distal) and wrist bones o Fractures of the metacarpals

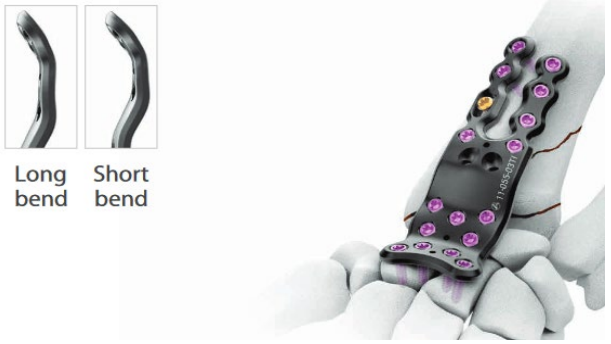
	○ Osteotomies and arthrodeses on the hand ○ Osteotomies and arthrodeses of the interphalangeal joints ○ Fractures of distal radius (double-plate technique) ○ Sub capital radial head fractures **2.4mm Bone Plates**: Fractures, osteotomies and arthrodesis of the bones of the wrist ○ Fusion plates ○ Arthrodesis of wrist bones ○ Fractures of the metacarpal and wrist bones ○ Fractures of distal radius (double-plate technique) ○ Osteotomies and arthrodeses on the hand ○ Subcapital radial head fractures **3.5mm Bone Plates**: The Wise Lock Wrist Fusion System is indicated for wrist arthrodesis and fractures of other small bones of the carpus. Specific indications include: ○ Post-traumatic arthrosis of the joints of the wrist ○ Rheumatoid wrist deformities requiring restoration ○ Complex carpal instability ○ Postseptic arthritis of the wrist ○ Brachial plexus nerve palsies ○ Tumor resection ○ Spastic deformities
Contraindications	Contraindications for hand 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 deep tissue infections. ○ Severe vascular compromise: Poor blood supply to the hand 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. It is essential for the surgeon to carefully evaluate the patient's individual case and balance the risks and benefits before proceeding with hand plate surgery.
Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Hand Plate System can be used for Skeletally Mature patients with Age group of 18-65 Years.
Intended Users	The Hand Plate Systems are to be used by well experienced, qualified & specialized trained surgeons only.
Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
Use	For Single Use only
Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
Biocompatibility	The devices covered in the Hand Plate System are Bio-compatible. Biocompatibility of the devices is tested as per EN ISO 10993-1:2020 series of International Standard.

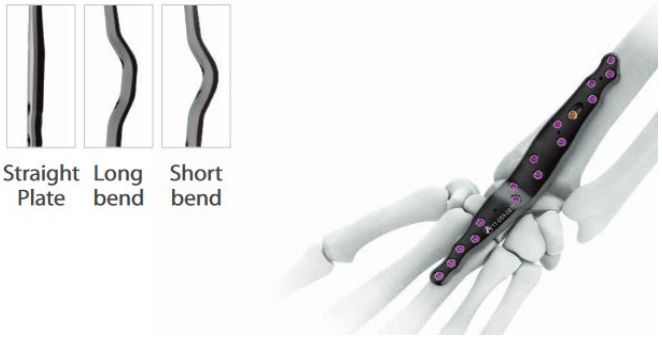
3. Description of the device

S.No.	A. Plates	
1.	**Device Name**	**2.4mm AV-Wiselock RSL Fusion M Plate**

	Picture	 
	Total Length	For Dorsal RSL Fusion-50mm For Volar RSL Fusion -42mm
	Total Width	For Dorsal RSL Fusion-28mm For Volar RSL Fusion- 26mm
	Types of Fusion Plate	Dorsal RSL Fusion and Volar RSL Fusion
	Thickness	1.6mm
	No. of Shaft Holes	For Dorsal RSL Fusion - 11 Holes For Volar RSL Fusion - 10 Holes
	Directional Configuration (Left & Right)	Left & Right
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

2.	**Device Name**	**2.4mm AV-Wiselock Wrist Fusion M Plate**
	Picture	
	Total Length	For Long Bend Plate-66mm For Short Bend Plate-59mm
	Total Width	For Long Bend Plate-23mm For Short Bend Plate-22mm
	Thickness	2.4mm
	Type of Bend	Long and Short Bend
	No. of Shaft Holes	For Long Bend Plate-18 &19 Holes For Short Bend Plate-18 & 19 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

3.	**Device Name**	**2.4mm AV-Wiselock Dorsal Wrist Fusion M Plate, Radiocapitate**
	Picture	 
	Total Length	For Long Bend-67mm For Short Bend-61mm
	Plate Width	14mm
	Thickness	2.6mm
	No. of Shaft Holes	Long and Short Bend
	Types of Bend	For Long Bend Plate-12 Holes For Short Bend Plate-12 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

4.	**Device Name**	**2.4mm AV-Wiselock Dorsal Total Wrist Fusion M Plate**
	Picture	
	Total Length	For Straight Plate - 116mm For Long Bend Plate- 116mm For Short Bend Plate-110mm
	Plate Width	22.6 & 16mm
	Thickness	2.6mm
	Types of Bend	Straight Plate, Long bend and short Bend
	No. of Shaft Holes	For Straight Plate - 15 & 16 Holes For Long Bend Plate-16 Holes For Short Bend Plate-16 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

5.	**Device Name**	**1.5mm Wise-Lock Plate, straight**
	Picture	
	No. of Shaft Holes	4 and 6 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

6.	**Device Name**	**1.5mm Wise-Lock Adaption Plate, straight**
	Picture	
	No. of Shaft Holes	6 and 12 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

7.	**Device Name**	**1.5mm Wise-Lock Adaption T-Plate**
	Picture	
	Head Holes	3 & 4 Holes
	No. of Shaft Holes	8 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

8.	**Device Name**	**1.5mm Wise-Lock Strut Plate**
	Picture	
	No. of Shaft Holes	8 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

9.	**Device Name**	**1.5mm Wise-Lock Adaption Y-Plate**
	Picture	
	Head Holes	3 Holes
	No. of Shaft Holes	8 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

10.	**Device Name**	**1.5mm Wise-Lock Condylar Plate**
	Picture	
	Head Holes	2 Holes
	No. of Shaft Holes	6 & 8 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

11.	**Device Name**	**2.0mm Wise-Lock Plate, straight**
	Picture	
	No. of Shaft Holes	4, 5, 6, 7, 8 & 10 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

12.	**Device Name**	**2.0mm Adaption Plate, straight**
	Picture	
	No. of Shaft Holes	12 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

13.	**Device Name**	**2.0mm Wise-Lock Adaption Plate, straight**
	Picture	
	No. of Shaft Holes	12 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

14.	**Device Name**	**2.0mm Wise-Lock Condylar Plate**
	Picture	
	Types of Holes	2 Holes
	No. of Shaft Holes	4, 5, 6, 7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

15.	**Device Name**	**2.0mm Wise-Lock Rotation Correction Plate**
	Picture	
	Head Holes	2 Holes
	No. of Shaft Holes	4 & 5 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

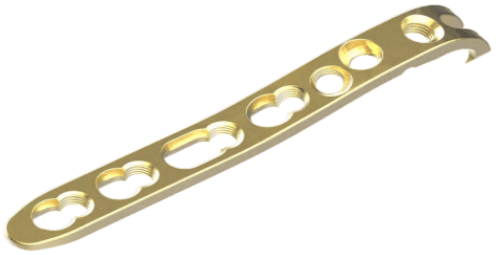
16.	**Device Name**	**2.0mm Wise-Lock T-Plate**
	Picture	
	Head Holes	3 Holes
	No. of Shaft Holes	4, 5, 6, 7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

17.	**Device Name**	**2.0mm Wise-Lock T-Adaption Plate**
	Picture	
	Head Holes	2 Holes
	No. of Shaft Holes	7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

18.	**Device Name**	**2.0mm Wise-Lock Y-Adaption Plate**
	Picture	
	Head Holes	3 Holes
	No. of Shaft Holes	7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

19.	**Device Name**	**2.0mm Mini Condylar Plate**
	Picture	
	No. of Shaft Holes	7 Holes
	Directional Configuration (Left & Right)	Left and right
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

20	**Device Name**	**2.0mm Wise-Lock Mini H-Plate**
	Picture	
	No. of Holes	4 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

21.	**Device Name**	**2.0mm Wise-Lock Distal Ulna Hook Plate**
	Picture	
	No. of Shaft Holes	7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

22.	**Device Name**	**2.4mm Wise-Lock Plate, straight**
	Picture	
	No. of Shaft Holes	4, 5, 6, 7, 8, 10
	Directional Configuration (Left & Right)	Not Application
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

23.	**Device Name**	**2.4mm Adaption Plate, straight**
	Picture	
	No. of Shaft Holes	12 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

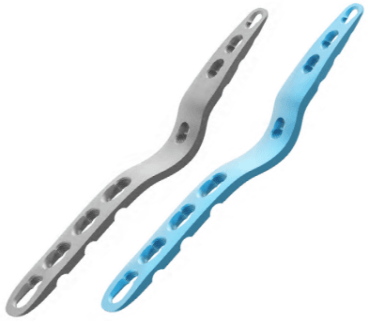
24.	**Device Name**	**2.4mm Wise-Lock Adaption Plate, straight**
	Picture	
	No. of Shaft Holes	12 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

25.	**Device Name**	**2.4mm Wise-Lock Condylar Plate**
	Picture	
	Head Holes	2 Holes
	No. of Shaft Holes	4, 5, 6 & 7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

26.	**Device Name**	**2.4mm Wise-Lock T-Adaption Plate**
	Picture	
	Head Holes	2 Holes
	No. of Shaft Holes	7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

27.	**Device Name**	**2.4mm Wise-Lock T-Plate**
	Picture	
	Head Holes	3 Holes
	No. of Shaft Holes	4, 5, 6 & 7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

28.	**Device Name**	**2.4mm Wise-Lock Y-Adaption Plate**
	Picture	
	Head Holes	3 Holes
	No. of Shaft Holes	4, 5, 6 & 7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

29.	**Device Name**	**3.5mm Wise-Lock Wrist Fusion Plate**
	Picture	
	Total Length	For Standard Bend -117.50mm For Short Bend -117mm For Straight Bend - 112mm
	Types of Bend	Standard Bend, Short Bend, Straight Bend
	No. of Shaft Holes	For Standard Bend -8 Holes For Short Bend -8 Holes For Straight Bend - 9 Holes
	Directional Configuration (Left & Right)	Not applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

30.	**Device Name**	**0.8mm Wise-Lock Low Profile Avulsion Fracture Plate**
	Picture	
	No. of Shaft Holes	2 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

31.	**Device Name**	**0.8mm Wise-Lock Low Profile Straight Plate**
	Picture	
	Total Length	52mm
	No. of Shaft Holes	3, 4, 5, 6, 7, 10 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

32.	**Device Name**	**0.8mm Wise-Lock Low Profile Curved Medial/Lateral Plate**
	Picture	
	No. of Shaft Holes	9 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

33.	**Device Name**	**0.8mm Wise-Lock Low Profile Curved Medial/Lateral Plate, Short**
	Picture	
	No. of Shaft Holes	4, 5, 6 Holes
	Directional Configuration (Left & Right)	Left and right
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

34.	**Device Name**	**0.8mm Wise-Lock Low Profile Compression Plate**
	Picture	
	No. of Shaft Holes	4, 5, 6 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

35.	**Device Name**	**0.8mm Wise-Lock Low Profile T-Plate**
	Picture	
	No. of Shaft Holes	5, 6, 8 & 12 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

36.	**Device Name**	**0.8mm Wise-Lock Low Profile L-Plate**
	Picture	
	No. of Shaft Holes	4, 6, 8 Holes
	Directional Configuration (Left & Right)	Left and right
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

37.	**Device Name**	**0.8mm Wise-Lock Low Profile Offset Plate**
	Picture	
	No. of Shaft Holes	4, 6, 10 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

38.	**Device Name**	**1.3mm Wise-Lock Low Profile Metacarpal Neck Plate**
	Picture	
	No. of Shaft Holes	6 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

39.	**Device Name**	**1.3mm Wise-Lock Low Profile Compression Plate**
	Picture	
	No. of Shaft Holes	4, 5, 6 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

40.	**Device Name**	**1.3mm Wise-Lock Low Profile Straight Plate**
	Picture	
	No. of Shaft Holes	3, 4, 5, 6, 7 & 10 holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

41.	**Device Name**	**1.3mm Wise-Lock Low Profile T-Plate**
	Picture	
	No. of Shaft Holes	4, 5, 6, 7, 8 & 11
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

42.	**Device Name**	**1.3mm Wise-Lock Low Profile Rolando Fracture Hook Plate**
	Picture	
	No. of Shaft Holes	7 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

43.	**Device Name**	**1.3mm Wise-Lock Low Profile Rotational Correction Plate**
	Picture	
	No. of Shaft Holes	6 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

44.	**Device Name**	**2.0mm Mini "L" Plate**
	Picture	
	Total Length	18.60mm-53.40mm
	Head Holes	2 Holes
	No. of Shaft Holes	2, 4, 6, 8 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

45.	**Device Name**	**2.0mm Mini Straight Plate**
	Picture	
	Total Width	5.2mm
	Thickness	1.2mm
	No. of Shaft Holes	2, 3, 4, 5, 6, 7 & 8 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

46.	**Device Name**	**2.0mm DCP Plate**
	Picture	
	Total Length	22-42mm
	No. of Shaft Holes	4, 5, 6, 7 & 8
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

47.	**Device Name**	**2.0mm Mini "T" Plate**
	Picture	
	Head Holes	2 Holes
	No. of Holes	2+2 Holes
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

B. Screw		
1.	**Device Name**	**1.5mm Cortical Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	6-24mm
	Shaft Thickness	1.5mm
	Recess	Star Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

2.	**Device Name**	**1.5mm Wise-Lock Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	6-24mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

3.	**Device Name**	**1.8mm Buttress Screw, (Star Head)**
	Picture	
	Total Length	12-18mm
	Shaft Thickness	1.8mm
	Recess	Star Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

4.	**Device Name**	**2.0mm Cortical Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	6-40mm
	Shaft Thickness	2.0mm
	Recess	Star Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

5.	**Device Name**	**2.0mm Wise-Lock Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	6-40mm
	Shaft Thickness	2.0mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

6.	**Device Name**	**2.4mm Cortical Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	6-40mm
	Shaft Thickness	2.4mm
	Recess	Star Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

7.	**Device Name**	**2.4mm Variable Angle Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	8-34mm
	Shaft Thickness	2.4mm
	Recess	Star Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

8.	**Device Name**	**2.4mm Wise-Lock Screw, Self-Tapping, (Star Head)**
	Picture	
	Total Length	6-50mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

9.	**Device Name**	**1.5mm Wise-Lock Low Profile Screw, (Star Head)**
	Picture	
	Total Length	5-20mm
	Shaft Thickness	1.5mm
	Recess	Star Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

10.	**Device Name**	**1.5mm Low Profile Screw, (Star Head)**
	Picture	
	Total Length	5-20mm
	Shaft Thickness	1.5mm
	Recess	Star Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

11.	**Device Name**	**2.3mm Wise-Lock Low Profile Screw, (Star Head)**
	Picture	
	Total Length	5-20mm
	Shaft Thickness	2.3mm
	Recess	Star Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

12.	**Device Name**	**2.3mm Low Profile Screw, (Star Head)**
	Picture	
	Total Length	5-20mm
	Shaft Thickness	2.3mm
	Recess	Star Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

13.	**Device Name**	**1.5mm Cortical Screw, (Hex Head)**
	Picture	
	Total Length	6-20mm
	Shaft Thickness	1.5mm
	Recess	Hex Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

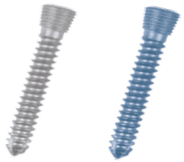
14.	**Device Name**	**1.5mm Cortical Screw, Self-Tapping, (Hex Head)**
	Picture	
	Total Length	6-20mm
	Shaft Thickness	1.5mm
	Recess	Hex Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

15.	**Device Name**	**2.0mm Cortical Screw, (Hex Head)**
	Picture	
	Total Length	6-20mm
	Shaft Thickness	2.0mm
	Recess	Hex Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

16.	**Device Name**	**2.0mm Cortical Screw, Self-Tapping, (Hex Head)**
	Picture	
	Total Length	6-20mm
	Shaft Thickness	2.0mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

17.	**Device Name**	**2.7mm Cortical Screw, (Hex Head)**
	Picture	
	Total Length	6-30mm
	Shaft Thickness	2.7mm
	Recess	Hex Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

18.	**Device Name**	**2.7mm Cortical Screw, Self-Tapping, (Hex Head)**
	Picture	
	Total Length	6-30mm
	Shaft Thickness	2.7mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

19.	**Device Name**	**2.7mm Wise-Lock Screw, Self-Tapping (Hex Head)**
	Picture	
	Total Length	10-60mm
	Shaft Thickness	2.7mm
	Recess	Hex Head
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

20.	**Device Name**	**3.5mm Wise-Lock Screw, Self-Tapping (Hex Head)**
	Picture	
	Total Length	10-80mm
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

21.	**Device Name**	**2.7mm Cortical Screw, Self-Tapping, (Hex Head)**
	Picture	
	Total Length	10-80mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

22.	**Device Name**	**3.5mm Cortical Screw, Self-Tapping, (Hex Head)**
	Picture	
	Total Length	6-30mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

C. Other Components		
1.	**Device Name**	**Staple U-Type**
	Picture	
	Staple Length	15mm, 20mm, 25mm
	Staple Dia.	1.5, 2.0, 2.5, 3.0mm
	Geometrical Shape	U shape
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

2.	**Device Name**	**Straight Staple**
	Picture	
	Staple Length	25mm
	Staple Width	10, 16, 20, 22, 26, 28, 30mm
	Staple Thickness	3mm
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

3.	**Device Name**	**Staple with offset**
	Picture	
	Staple Length	36, 40, 44mm
	Staple offset	5, 10, 14mm
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024 and Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

4.	**Device Name**	**Three-Legged Staple**
	Picture	
	Staple length	34mm
	Staple Width	14mm
	Staple Thickness	3mm
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

5.	**Device Name**	**Staple Coventry**
	Picture	
	Staple Length	5mm, 10mm, 15mm
	Raw Material Specification	Titanium Alloy Ti-6AL-4V as per EN ISO 5832-3:2021

6.	**Device Name**	**Steinmann Pins**
	Picture	
	Total Length	150, 175, 200, 225, 230, 300mm
	Pin Dia.	Ø2.0, 2.3, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0mm
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024

7.	**Device Name**	**Centrally Threaded Steinmann Pin**
	Picture	
	Total Length	100, 200, 225, 226, 250, 300mm
	Shaft Diameter	Ø2.0, 3.5, 4.0, 4.5, 5.0, 6.0mm
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024

8.	**Device Name**	**Suture wire**
	Picture	
	Wire Length	5meter - 10 meter
	Wire Dia	Ø1.60, 1.50, 1.25, 1.00, 0.90, 0.80, 0.70, 0.60, 0.55, 0.45, 0.35, 0.28, 0.30mm
	Geometrical Shape	Cylindrical
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024

9.	**Device Name**	**Kirschner Wire with Trocar Tip both End**
	Picture	
	Total Length	70, 100, 150, 225, 230, 300, 310 mm
	Wire Dia.	Ø0.8, 0.9, 1.0, 1.1, 1.2, 1.4, 1.5, 1.6, 1.8, 2.0, 2.2, 2.3, 2.8, 2.5, 3.0mm
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024

10.	**Device Name**	**Kirschner Wire Fully Threaded**
	Picture	
	Total Length	150, 225mm
	Wire Dia.	Ø1.5, Ø2.0, Ø2.5mm
	Geometrical Shape	Cylindrical
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024

11.	**Device Name**	**Circlage Wire with Loop**
	Picture	
	Wire Length	280 & 600mm
	Wire Dia	0.50 to 1.50mm
	Geometrical Shape	Cylindrical
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024

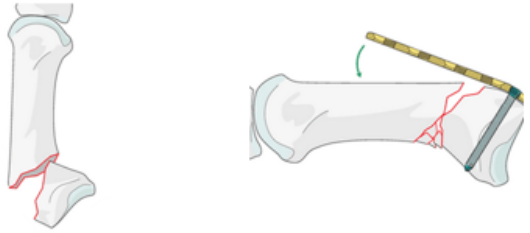
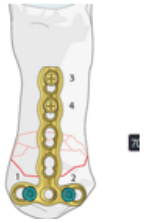
12.	**Device Name**	**Kirschner Wire with One Side Trocar Tip**
	Picture	
	Wire Length	150, 225, 250, 300, 310mm
	Wire Dia.	Ø0.8, 0.9, 1.0, 1.2, 1.4, 1.6, 1.8, 2.0, 2.2, 2.5, 3.0mm
	Tip length	5.5mm
	Geometrical Shape	Cylindrical
	Raw Material Specification	Stainless Steel Alloy as per EN ISO 5832-1:2024

A Detailed device description is given in below table.

Other details of the Hand Plate System:

Device Compliance to regulation		We are proposing the Hand 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	Hand Plate System
	General Description	Auxein's Hand plate System is designed to repair, stabilize, and restore the arthrodesis of the phalanges, metacarpals, carpals, wrist bone and Distal Radius that have been fractured. The Hand 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 configuration.
	Intended Purpose	Intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of phalanges, metacarpals, carpals, wrist bone and Distal Radius bone fragments.
	Intended Users	The Hand Plate System is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Hand Plate System can be used for Skeletally Mature patients with Age group of 18-65 Years.
	Medical Conditions to be diagnosed, treated and/or monitored	The Hand plate System is used to treat phalanges, metacarpals, carpals, wrist bone and Distal Radius bone fractures or non-union. Specifically designed Hand plate intended for treatment of fractures that provides strong fixation and restores the bone fragments.
	Patient Selection Criteria	**Patient Inclusion Criteria**: 1. Both male and female above 18 to 65 years patients. 2. Patients presenting to Orthopaedic emergency/ OPD with hand fracture and need internal fixation will be included in the study. **Exclusion Criteria:** 1. Any past or present evidence of infection of the treated joint.

		2. Physical conditions that would eliminate or tend to eliminate adequate implant support or delayed healing, viz.: blood supply limitations, poor skin quality, previous or active infections, sepsis, metabolic diseases, etc. 3. Signs of any local inflammation. 4. Patient susceptibility to allergic reaction to the components of the alloy, the implant is manufactured from. 1. Mental or neurological conditions which tend to pre-empt the patient's ability or willingness to restrict activities during the healing period, viz.: Parkinson's disease, chronic alcoholism, Charcot's joints, drug abuse, mental illness, patient noncompliance, etc. 2. Patients having inadequate tissue coverage over the operative site. 3. Patient having foreign body sensitivity. 4. Patient with compromised skin. 5. Severe osteopenia and/or osteoporosis, or in the presence of marked or rapid bone absorption, metabolic bone disease, cancer, or any other tumor-like condition of the bone which may compromise fixation. 6. Patient who is pregnant or intends to become pregnant during the study.
c.	Principles of Operation Mode of Action	Hand 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 hand 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. 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: Fracture Reduction:  Fracture Fixation: 
d.	Rationale for considering as a Medical device	'Medical Device' means any instruments, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: Considering the definition of medical device, it can be concluded that the Hand plate System is a medical device because it is an implant used in humans for medical purposes to treat phalanges, metacarpals, carpals, wrist bone and Distal Radius fracture. **Applicable/non-applicable defines applicancy of the statement**: a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease- **Not Applicable** **Rationale for non-applicability** The Hand plate System is an implant used for the treatment of phalanges, metacarpals, carpals, wrist bone and Distal Radius 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 hand plate is an implantable device used for the treatment of phalanges, metacarpals, carpals, wrist bone and Distal Radius bone fractures. c) investigation, replacement or modification of the anatomy or of a physiological or pathological processor state- **Not Applicable** **Rationale for non-applicability** The hand plate is intended to treat phalanges, metacarpals, carpals, wrist bone and Distal Radius 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** Hand plate is made up of metal alloy and employed to phalanges, metacarpals, carpals, wrist bone and Distal Radius bone fractures. This system does not contain the In-vitro examination of specimens derived from the human body, including organ, blood and tissue donations. The device does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Hence, the Hand 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 Hand plate System is used to stabilize phalanges, metacarpals, carpals, wrist bone and Distal Radius 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 Article1(4) and of those referred to in the first paragraph of this point-**Not Applicable** **Rationale for non-applicability** The Hand plate System is intended for fixation for fractures of the phalanges, metacarpals, carpals, wrist bone and Distal Radius bone. The system is not meant for cleaning, disinfection or sterilization of device.
e.	Novel Features	The Hand Plate System comprises of already existing devices approved in EU market under the regulation

		MDD 93/42/EEC. Since the device was placed on the market, there are no changes or modifications in device related to raw material, design, manufacturing process (coolants, lubricants, chemicals), intended use, post processing materials, etc.
f.	Description of key functional elements	The Hand plate System comprises of functional element such as: • Screws The Hand 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 element used with Plate to fix the fracture enlisted below.** ***Screw*** o It is intended to be used for the implantation of any type of internal Orthopedic Fixation System. o It is used for internal orthopaedic fracture fixation by being screwed into bone to hold plate with phalanges, metacarpals, carpals, wrist bone and Distal Radius bone. o In the Hand plate System various types of screws are included like cortical, Cancellous, Wise-Lock and Av-wiselock screw. The accessories used with hand 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. The description of some of the instruments is as follows: Only Auxein Instruments shall be used with the hand plate system. The instruments should be CE Marked.
g.		
	Sterility	All Products covered in Hand Plate System are supplied in either Non-sterile or in Sterile state. Sterile implants which are placed on the market are sterilized by using Gamma Irradiation Sterilization (SAL 10^{-6}). The non-sterile implants which are placed on market are to be sterilized at 121 degrees centigrade for 20 minutes (Moist Heat Sterilization/Autoclave Sterilization) as instructed in IFU for Non-sterile devices before implantation.
	Radioactivity	Products covered in Hand Plate System are metal products and does not emit any ionizing or non-ionizing

		radiation.
	Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
	Use	For Single Use only
	Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
	Biocompatibility	The devices covered in the Hand Plate System are Bio-compatible. Biocompatibility of the devices is tested as per ISO 10993 series of International Standard.
	MRI Compatibility	The hand plates have not been evaluated for safety and compatibility in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic Resonance Imaging) environment.
1.2	Reference to Previous and Similar Generations of the device	
a.	CE Mark (Legacy device)	CE Approved by DQS (0297) under MDD 93/42/EEC Certificate No**.** 170753735
	USFDA Approved	Yes (Hand Plate System are cleared by USFDA whose details are as follow:) 510(k) Number: K141680
b.	Similar devices available in Union or international market.	The Similar devices available in the Union or International Market are listed below: DePuy synthes compact hand system (CE 0123) Medartis Arthrodesis System 2.0 / 2.3, 2.5 (CE 0197) Acumed Hand Fracture System, (CE 0473)

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

Comparison table:

S.No.	Properties/ Parameter	Titanium bone plate	Stainless steel bone plate	Remark
1.	Biocompatibility	Final finish device of TI bone plate is biocompatible when tested according to ISO 10993-1.	Final finish device of SS bone plate is biocompatible when according to ISO 10993-1.	Both plates are Biocompatible.
2.	Mechanical performance	Final finish device of Ti bone plate mechanically safe tested according to ASTM 382.	Final finish device of SS bone plate mechanically safe tested according to ASTM 382.	Both plates mechanically safe during the mechanical testing.

3.	Clinical performance	Ti bone plates achieved the indented use without any complication and are clinically safe.	SS bone plate achieved the indented use without any complication and are clinically safe.	Both plates are implanted in the patient. The results of clinical and radiological are satisfactory.
4.	Density	4.43 g/cc (Light weight).	8.00 g/cc (Heavy weight).	Both plates give the same range of motion but the lighter plate gives more comfort during movement.
5.	Corrosion resistance ability	Corrosion resistance	Corrosion resistance.	Both plates are corrosion resistance. But SS plate have chance of corrosion. Corrosion resistance test (Cyclic potentiodynamic polarization test) has performed on the SS it shows the positive result.
6.	Elasticity	On the high load Ti shows less bending.	On the high load SS shows bending.	Both plates can bear the standard load with factor of safety without any bending.

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

Residual risks and undesirable effects

Hand plate surgery, often used to treat fractures or other conditions requiring stabilization in the hand, involves the implantation of plates and screws to stabilize bones. While it can be highly effective, there are potential adverse events and risks associated with this procedure. Below are some possible complications:

1. Infection
2. Implant-Related Issues (Plate or screw loosening or breakage, Implant irritation)
3. Nerve or Vascular Damage
4. Delayed Bone Healing or Nonunion
5. Stiffness and Loss of Motion

6. Chronic Pain or Complex Regional Pain Syndrome (CRPS)
7. Discomfort
8. Hardware Allergies or Sensitivities
9. Long-Term Weakness (Grip strength or hand functionality may never return to full pre-injury levels, even with physical therapy)
10. Sensory Changes (Persistent numbness, tingling, or altered sensation may remain due to nerve irritation or damage during surgery)
11. Allergic Reaction
12. Tendon Irritation or Rupture
13. Reoperation (Secondary procedures)
14. Scar Formation
15. Limitations of normal, everyday activities

Warning & Precautions:

When performing hand plate surgery, there are several warnings and precautions to consider to minimize complications and ensure a successful outcome. These include factors related to the patient, surgical technique, and postoperative care.

WARNINGS:

Preoperative

- Patient selection: Ensure the patient is an appropriate candidate. Avoid surgery in cases of active infections, severe vascular compromise, or other contraindications.
- Allergies: Confirm the patient has no known allergies to implant materials (e.g., titanium, stainless steel) or surgical supplies (e.g., latex, adhesives).
- Smoking and substance use: Smoking or substance abuse can impair healing and increase the risk of complications such as delayed union or infection.
- Preexisting conditions: Conditions like diabetes, peripheral neuropathy, or autoimmune diseases increase the risk of complications. Proper management of these conditions is essential before surgery.
- 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.

Intraoperative

- Implant positioning and fixation: Improper placement of the plate or screws can lead to damage to surrounding structures such as tendons, nerves, and blood vessels. It can also result in loss of fracture stability.
- Avoid over-tightening screws: Excessive force during screw placement can strip the bone or damage surrounding tissues.
- Soft tissue handling: Minimize trauma to surrounding soft tissues to reduce the risk of adhesions, scarring, or vascular compromise.
- Sterility: Maintain strict aseptic techniques to prevent postoperative infections.
- The selection of the proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon is responsible for this choice.
- Different metal types should not be used together.

- The Hand Plate System devices are not to be combined with the devices from another manufacturer.
- The Instruction for Use, Surgical Techniques and Product Brochure should be carefully followed.
- The plates should not repeatedly be or excessively bent any more than necessary. The plates should not be reverse bent at the same location.
- Before closing the soft tissues, all of the screws should be seated on the plate.
- Recheck the tightness of all screws after finishing making sure that none has loosened during the tightening of the other screws.

Postoperative

- Infection risk: Monitor for signs of infection (e.g., redness, swelling, drainage, fever). Early intervention is critical if infection develops.
- Implant failure or loosening: Plate or screw failure can occur due to improper fixation, overuse, or patient non-compliance with activity restrictions.
- Hardware prominence or irritation: Plates or screws may irritate tendons, skin, or soft tissues, especially in thinner patients, necessitating implant removal later.
- Do Not Re-Use. Do not re-process. The device is not designed for re-processing. Reuse of the medical device intended for single-use devices may lead to infection, degraded performance or a loss of functionality. The cleaning and disinfection / sterilization for re-processing of these single use devices has not been validated nor is any authentic information available. So, re-process of the single use device is not allowed.
- The 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.
- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone healing process.
- If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the surgical site be maintained until a firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- The Hand Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the fractured bone is fused, these devices serve no functional purpose and may be removed. In most patients' removal is indicated because the implants are not intended to transfer or support forces developed during normal activities.

PRECAUTIONS:

Preoperative

- Detailed imaging and planning: Use X-rays, CT, or MRI to thoroughly evaluate fracture type, displacement, and surrounding anatomy.
- Patient education: Inform the patient about the risks, benefits, and limitations of surgery, including the need for compliance with postoperative restrictions and rehabilitation.
- Prophylactic antibiotics: Administer appropriate antibiotics to reduce the risk of surgical site infection.

Intraoperative

- Preservation of blood supply: Avoid excessive periosteal stripping to ensure bone healing and prevent nonunion or necrosis.
- Tendon and nerve protection: Carefully identify and protect tendons and nerves during dissection to avoid postoperative complications like tendon adhesions or nerve injury.
- Avoid unnecessary implant use: Only use plates and screws that are essential for stable fixation to minimize foreign body reaction and future implant irritation.

Postoperative

- Immobilization: Ensure proper splinting or casting as needed to stabilize the hand and allow for initial healing.
- Early but controlled movement: Initiate physical therapy early to prevent stiffness and loss of range of motion but avoid excessive force that may jeopardize fixation.
- Pain management: Use analgesics appropriately while avoiding over-reliance on opioids.
- Regular follow-ups: Schedule periodic evaluations to monitor fracture healing, implant stability, and functional recovery through imaging and clinical examination.

Safety and Performance Parameters:

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

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

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 Hand 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_017	Ongoing	India	09/15	0	0	0

Study Title	A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Hand Plate System.
CTRI Number	CTRI/2024/04/065090
CTRI Registration Date	02-04-2024
Number of study sites	One
Name of Study Sites	Sancheti Institute for Orthopedics and Rehabilitation, Pune, Maharashtra, India
No. of Patients enrolled	09

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 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.

The study is intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of the device. This is a single arm, prospective one year follow-up study. The target population for this research comprises both males and females aged 18 years to 65 years at the time of surgery. Study is designed to evaluate aspects related to issues with medium-term performance, the appearance of clinical events.

Inclusion criteria

1. Both male and female above 18 to 65 years patients.
2. Patients presenting to Orthopaedic emergency/ OPD with hand fracture and need internal fixation will be included in the study.

Exclusion criteria

1. Any past or present evidence of infection of the treated joint.
2. Physical conditions that would eliminate or tend to eliminate adequate implant support or delayed healing, viz.: blood supply limitations, poor skin quality, previous or active infections, sepsis, metabolic diseases, etc.
2. Signs of any local inflammation.
3. Patient susceptibility to allergic reaction to the components of the alloy, the implant is manufactured from.
4. Mental or neurological conditions which tend to pre-empt the patient's ability or willingness to restrict activities during the healing period, viz.: Parkinson's disease, chronic alcoholism, Charcot's joints, drug abuse, mental illness, patient noncompliance, etc.
5. Patients having inadequate tissue coverage over the operative site.
6. Patient having Foreign body sensitivity.
7. Patient with compromised skin.
8. Severe osteopenia and/or osteoporosis, or in the presence of marked or rapid bone absorption, metabolic bone disease, cancer, or any other tumor-like

condition of the bone which may compromise fixation.

9. Patient who is pregnant or intends to become pregnant during the study.

Primary Objective

1. To assess the safety and performance of the Hand Plate system by evaluating the quality of fusion and deformity correction through Radiological Evaluation.
2. The change in Total Active Flexion (TAF 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 Hand movement by calculating TAF score [Time Frame: baseline, 1 week, 3-month, 6-month, 12 months after surgery].

Secondary Endpoints

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

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (BMI)
Mean	36.44 ± 17.4	64.71 ± 6.93	171.7 ± 6.67	22.0 ± 1.92
Median	28	67	170.6	23
Range	21 - 61	48 - 73.4	162.4 -184.4	18.2 – 23.8

Gender distribution of study subjects

Male	8/9 (88.8%)
Female	1/9 (11.1%)

The study included a total of 09 subjects with a mean age of 36.44 ± 17.4 years. The majority of participants were Asian males, with 08 males and 01 female recruited in the study. The mean weight of the subjects was 64.71 ± 6.93kg. The mean BMI of the subjects was 22.0 ± 1.92. In terms of height, the subjects had an average of 171.7 ± 6.67 cm. These demographic and baseline characteristics are essential for understanding the composition of the study population and provide valuable insights for the interpretation of the study results.

Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Hand Plate device. This longitudinal study was designed as a single-arm study. The target population for this research comprised both males and females aged 18 years or older at the time of surgery. The study aimed to recruit a total of 15 subjects who experienced hand & wrist related fracture, and they were treated using a hand plate construct.

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

A total of seven study visits are there. Subject is screened, and followed at Baseline 1 (pre surgery) and Baseline 2 (post-surgery). After which 4 follow-up visits are conducted. All the planned assessments are being done and recorded from visit 1 to visit 7 in all the recruited study participants as per the study protocol. Study participants are followed at 6-week, 3-month, 6 month and 12 months. Assessment includes standardized clinical evaluation, and completion of the VAS score and the Total Active Flexion (TAF).

Study Result

As per the analysis, we have observed very significant positive results with respect to our hand plate device efficacy and safety. Overall, the study's findings suggest that the intervention led to significant pain reduction and enhanced functional performance in the patients. These improvements indicate the positive impact of the treatment on their quality of life and recovery from their condition after intervention of plate. There is no any adverse event related to device in any medical device registry. The benefit-risk analysis has outweighed the benefit against the risk regarding the device.

6. Possible diagnostic or therapeutic alternatives.

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

The treatment of hand and wrist bone fractures depends on the location, severity, and type of fracture, as well as the patient's overall health and activity level. Treatment aims to restore function, alignment, and strength while minimizing complications.

1. Non-Surgical Treatment

Non-surgical treatment is preferred for non-displaced or minimally displaced fractures.

- Immobilization
- Closed Reduction
- Pain Management
- Physical Therapy

2. Surgical Treatment

Surgery is recommended for severely displaced, unstable, or open fractures. Surgical intervention ensures proper alignment and promotes optimal healing.

- Open Reduction and Internal Fixation (ORIF) (Plates, Screws)
- External Fixation
- Percutaneous Pinning (Wire)

7. Suggested profile and training for users.

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

8. Reference to any harmonized standards and CS applied.

The following harmonized standards and guidance documents are applicable on Hand 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 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
7.	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.
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.

Non-Harmonized Standards	
Standard	**Description**
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
ISO 17665-1:2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good Clinical Practice.
ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
ISO 14630:2012	Non-active surgical implants - General Requirements
ISO 11137-2:20/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.
ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)
ISO 11607-1:2020/A11:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
ISO 11607-2:2020/A11:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
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 14644-5:2004	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 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020).
ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 5832-1:2019	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel (ISO 5832-1:2016)
ISO 5832-3:2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)
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 F382-17	Standard Specification and Test Method for Metallic Bone Plates
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	10-12-2024	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	28-02-2025	Updated as per PRJN-629776 (List of finding, Phase-I)	☐ 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: 01
Date issued: 28-02-2025

Device identification and general information

Device Trade Name: Hand 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: 0 890399HWT018XZ for Titanium and 08903993HWS018PV for Stainless Steel

Year when the device was first CE-marked: 2009

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Intended use of the device

Intended Purpose	Intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of Hand & Wrist bone fragments.
Indications of Use	**0.8mm & 1.3mm Bone Plates**: Fixation of fractures, fusions, and osteotomies of the proximal, middle and distal phalanges and metacarpals.

	1.5mm Bone Plates: o Fracture fixation of the phalanges and metacarpals o Osteotomies o Arthrodeses o Replantations and reconstructions of phalanges and metacarpals, particularly in osteopenic bone. **2.0mm Bone Plates**: o Fractures of the Phalanges (middle and distal) and wrist bones o Fractures of the metacarpals o Osteotomies and arthrodeses on the hand o Osteotomies and arthrodeses of the interphalangeal joints o Fractures of distal radius (double-plate technique) o Sub capital radial head fractures **2.4mm Bone Plates**: Fractures, osteotomies and arthrodesis of the bones of the wrist o Fusion plates o Arthrodesis of wrist bones o Fractures of the metacarpal and wrist bones o Fractures of distal radius (double-plate technique) o Osteotomies and arthrodeses on the hand o Subcapital radial head fractures **3.5mm Bone Plates**: The Wise Lock Wrist Fusion System is indicated for wrist arthrodesis and fractures of other small bones of the carpus. Specific indications include: o Post-traumatic arthrosis of the joints of the wrist o Rheumatoid wrist deformities requiring restoration o Complex carpal instability o Postseptic arthritis of the wrist o Brachial plexus nerve palsies o Tumor resection o Spastic deformities

Contraindications	Contraindications for hand 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: o Active infection at the surgical site: Increases the risk of complications like osteomyelitis or deep tissue infections. o Severe vascular compromise: Poor blood supply to the hand makes healing unlikely and may lead to necrosis. o Severe soft tissue damage: If the surrounding soft tissue cannot support the implanted hardware or surgical closure. o Allergy to implant materials: A known hypersensitivity to metals (e.g., titanium or stainless steel) used in plates. o Uncontrolled medical conditions: Severe comorbidities such as poorly managed diabetes, cardiovascular instability, or coagulopathy may pose excessive surgical or anesthetic risk. o Osteoporotic or poor bone quality: Inadequate bone stock may not provide stable fixation. o Patient non-compliance: A patient unwilling or unable to follow post-surgical care protocols (e.g., immobilization or physical therapy). o Pediatric patients with growing bones: Plates may interfere with growth plates in children, requiring alternative fixation methods. o Peripheral neuropathy or nerve damage: May impair post-surgical functional outcomes. o Pregnancy: Avoiding non-urgent surgeries due to anesthetic risks. o Non-surgical treatment (e.g., casting or splinting) may be preferred for stable fractures or when risks outweigh the benefits of surgery. o 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. It is essential for the surgeon to carefully evaluate the patient's individual case and balance the risks and benefits before proceeding with hand plate surgery.
Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Hand Plate System can be used for Skeletally Mature patients with Age group of 18-65 Years.

Device description

The hand bone plate is used for treating the fractures of hand & wrist bone. These plate helps to align the fractured bone fragments together with the help of bone screws. The system consists of various types of bone plates including Locking, Non-Locking and AV-Wiselock and for fixing these plates with the bone Auxein provides various types of bone screws which are compatible with different type of bone plates. The details regarding bone plates, screws and other components 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, Hand Plate System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	170753735
Year when the first certificate (CE) was issued covering the device	2009		
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 patient tissues	The Material that will comes in contact with patient tissues consists of Titanium alloy Ti-6AL-4V as per EN ISO 5832-3:2021 and Stainless-steel alloy SS 316 L as per EN ISO 5832-1:2019.		
USFDA Approved	Yes (Hand plate are approved by USFDA whose details are as follow:) 510(k) Number: K141680		
Risk Class	IIb {According to REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT, Annex VIII, Chapter-3, Rule 8 - Implantable devices and long-term surgically invasive devices (>30 days).		
Authorized Representative Name and Address	Name: CMC Medical Devices & Drug S.L Address: 29015 Málaga, Spain		
Authorized Representative SRN	ES-AR-00000029		
Notified Body Name and Single Identification Number	Name: DNV Product Assurance AS Single Identification Number: 2460		

Principle of operation

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

Description of Key functional elements:

The Hand plate System comprises of functional element such as:

- Screws

The Hand 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 element 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, metacarpals, carpals, wrist bone and Distal Radius bone.
- In the Hand plate System various types of screws are included like cortical, Cancellous, Wise-Lock and Av-wiselock screw.

The accessories used with hand 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. The description of some of the instruments is as follows:

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

Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed. The potential risks that arise regarding the device are controlled using risk mitigation method and conveying those risk to the patients from surgeon.

Hand plate surgery, often used to treat fractures or other conditions requiring stabilization in the hand, involves the implantation of plates and screws to stabilize bones. While it can be highly effective, there are potential adverse events and risks associated with this procedure. Below are some possible complications:

1. Infection
2. Implant-Related Issues (Plate or screw loosening or breakage, Implant irritation)
3. Nerve or Vascular Damage
4. Delayed Bone Healing or Nonunion
5. Stiffness and Loss of Motion
6. Chronic Pain or Complex Regional Pain Syndrome (CRPS)
7. Discomfort
8. Hardware Allergies or Sensitivities
9. Long-Term Weakness (Grip strength or hand functionality may never return to full pre-injury levels, even with physical therapy)
10. Sensory Changes (Persistent numbness, tingling, or altered sensation may remain due to nerve irritation or damage during surgery)
11. Allergic Reaction

12. Tendon Irritation or Rupture
13. Reoperation (Secondary procedures)
14. Scar Formation
15. Limitations of normal, everyday activities

Prevention and Mitigation

- Following the surgeon's post-operative instructions, including wound care and activity restrictions, is crucial.
- Attending follow-up appointments ensures that complications are detected and managed early.
- Engaging in prescribed physical therapy can reduce the risk of stiffness and improve recovery outcomes.

Warning & Precautions:

When performing hand plate surgery, there are several warnings and precautions to consider to minimize complications and ensure a successful outcome. These include factors related to the patient, surgical technique, and postoperative care.

WARNINGS:

Preoperative

- Patient selection: Ensure the patient is an appropriate candidate. Avoid surgery in cases of active infections, severe vascular compromise, or other contraindications.
- Allergies: Confirm the patient has no known allergies to implant materials (e.g., titanium, stainless steel) or surgical supplies (e.g., latex, adhesives).
- Smoking and substance use: Smoking or substance abuse can impair healing and increase the risk of complications such as delayed union or infection.
- Preexisting conditions: Conditions like diabetes, peripheral neuropathy, or autoimmune diseases increase the risk of complications. Proper management of these conditions is essential before surgery.
- 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.

Intraoperative

- Implant positioning and fixation: Improper placement of the plate or screws can lead to damage to surrounding structures such as tendons, nerves, and blood vessels. It can also result in loss of fracture stability.
- Avoid over-tightening screws: Excessive force during screw placement can strip the bone or damage surrounding tissues.
- Soft tissue handling: Minimize trauma to surrounding soft tissues to reduce the risk of adhesions, scarring, or vascular compromise.
- Sterility: Maintain strict aseptic techniques to prevent postoperative infections.
- The selection of the proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon is responsible for this choice.
- Different metal types should not be used together.
- The Hand Plate System devices are not to be combined with the devices from another manufacturer.

- The Instruction for Use, Surgical Techniques and Product Brochure should be carefully followed.
- The plates should not repeatedly be or excessively bent any more than necessary. The plates should not be reverse bent at the same location.
- Before closing the soft tissues, all of the screws should be seated on the plate.
- Recheck the tightness of all screws after finishing making sure that none has loosened during the tightening of the other screws.

Postoperative

- Infection risk: Monitor for signs of infection (e.g., redness, swelling, drainage, fever). Early intervention is critical if infection develops.
- Implant failure or loosening: Plate or screw failure can occur due to improper fixation, overuse, or patient non-compliance with activity restrictions.
- Hardware prominence or irritation: Plates or screws may irritate tendons, skin, or soft tissues, especially in thinner patients, necessitating implant removal later.
- Do Not Re-Use. Do not re-process. The device is not designed for re-processing. Reuse of the medical device intended for single-use devices may lead to infection, degraded performance or a loss of functionality. The cleaning and disinfection / sterilization for re-processing of these single use devices has not been validated nor is any authentic information available. So re-process of the single use device is not allowed.
- The 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.
- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone healing process.
- If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the surgical site be maintained until a firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- The Hand Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the fractured bone is fused, these devices serve no functional purpose and may be removed. In most patients' removal is indicated because the implants are not intended to transfer or support forces developed during normal activities.

PRECAUTIONS:

Preoperative

- Detailed imaging and planning: Use X-rays, CT, or MRI to thoroughly evaluate fracture type, displacement, and surrounding anatomy.
- Patient education: Inform the patient about the risks, benefits, and limitations of surgery, including the need for compliance with postoperative restrictions and rehabilitation.
- Prophylactic antibiotics: Administer appropriate antibiotics to reduce the risk of surgical site infection.

Intraoperative

- Preservation of blood supply: Avoid excessive periosteal stripping to ensure bone healing and prevent nonunion or necrosis.
- Tendon and nerve protection: Carefully identify and protect tendons and nerves during dissection to avoid postoperative complications like tendon adhesions or nerve injury.
- Avoid unnecessary implant use: Only use plates and screws that are essential for stable fixation to minimize foreign body reaction and future implant irritation.

Postoperative

- Immobilization: Ensure proper splinting or casting as needed to stabilize the hand and allow for initial healing.
- Early but controlled movement: Initiate physical therapy early to prevent stiffness and loss of range of motion but avoid excessive force that may jeopardize fixation.
- Pain management: Use analgesics appropriately while avoiding over-reliance on opioids.
- Regular follow-ups: Schedule periodic evaluations to monitor fracture healing, implant stability, and functional recovery through imaging and clinical examination.

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

Till now, regarding Auxein's Hand 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 bones of the hand provide structure, support, and enable the dexterous movements necessary for grasping, holding, and manipulating objects. **Key Functions of Hand Bones**

1. **Support**: Form the structural framework of the hand.
2. **Movement**: Allow gripping, holding, and fine motor tasks.
3. **Flexibility**: Joints between carpal, metacarpal, and phalangeal bones allow complex movements.
4. **Protection**: Protect delicate soft tissues, such as nerves and blood vessels, running through the hand.

The bones of the hand work in coordination with muscles, tendons, and ligaments to achieve precision and strength. The hand is composed of various types of bones, categorized into three groups:

1. Carpals (Wrist Bones)

The wrist consists of **8 small carpal bones** arranged in two rows. These bones form the base of the hand and articulate with the forearm bones (radius and ulna).

- Proximal row (closer to the forearm):

- **Scaphoid**: Boat-shaped, most commonly fractured.
- **Lunate**: Moon-shaped, central to wrist motion.

- **Distal row** (closer to the hand):
  - **Trapezium**: Articulates with the thumb's metacarpal, allowing thumb movement.
  - **Trapezoid**: Small, wedge-shaped, connects to the index finger.
  - **Capitate**: Largest carpal bone, central in the wrist.

These bones provide stability and flexibility to the wrist.

2. Metacarpals (Palm Bones)
The palm contains **5 metacarpal bones**, each corresponding to a finger. These bones are numbered from **1 to 5**, starting with the thumb (lateral to medial):
Each metacarpal has three parts:

- **Base**: Proximal end that articulates with the carpal bones.
- **Shaft**: The long body of the bone.
- **Head**: Distal end that forms the knuckles when the hand is clenched.

The metacarpals act as the framework for the palm and provide attachment points for muscles and ligaments.

3. Phalanges (Finger Bones)
The fingers consist of **14 phalanges** (singular: phalanx), which are long bones:

- **Thumb (Pollex)**: Has **2 phalanges**:
  - **Proximal phalanx**
  - **Distal phalanx**

- **Fingers (Index, Middle, Ring, Little)**: Each has **3 phalanges**:
  - **Proximal phalanx** (closest to the palm)
  - **Middle phalanx**
  - **Distal phalanx** (tip of the finger)

The phalanges are responsible for the fine, detailed movements of the hand and fingers.

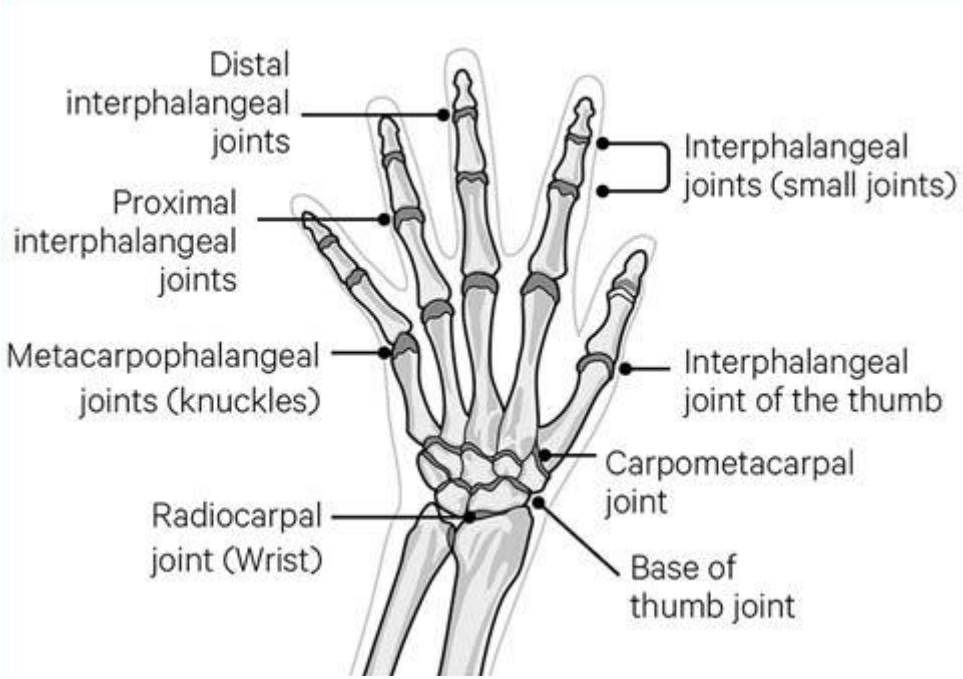

Figure: Hand bone anatomy

Types of Fracture

Hand and wrist fractures are common injuries caused by falls, accidents, or trauma. They can affect any of the bones in the hand and wrist. These fractures are categorized based on the affected bone and the nature of the break.

1. Wrist Fractures (Carpal Bones and Distal Radius/Ulna)

a. Distal Radius Fracture: A break in the radius bone near the wrist joint.
b. Scaphoid Fracture (most common carpal fracture): A break in the scaphoid bone (located on the thumb side of the wrist).
c. Lunate Fracture: Fracture of the lunate bone, often associated with wrist dislocations.

2. Metacarpal Fractures (Palm Bones)

Metacarpal fractures are classified by location and pattern.
Metacarpal Shaft Fractures: Breaks along the shaft (middle part) of the metacarpals.

3. Phalangeal Fractures (Finger Bones)

Phalangeal fractures are common and can occur in any part of the finger bones:

a. Proximal Phalanx Fracture: Fracture of the bone closest to the palm.
b. Middle Phalanx Fracture: Break in the middle bone of the finger.
c. Distal Phalanx Fracture: Fracture at the tip of the finger.

Fracture Patterns

Fractures can be further classified based on their pattern:

1. **Closed Fracture**: Bone breaks but does not penetrate the skin.
2. **Open (Compound) Fracture**: Bone pierces through the skin.
3. **Comminuted Fracture**: Bone breaks into multiple fragments.
4. **Transverse Fracture**: Break occurs straight across the bone.
5. **Oblique Fracture**: Angled fracture line.
6. **Spiral Fracture**: Twisting force causes a spiral-shaped break.

Causes of bone fracture

Hand and wrist fractures occur when significant force is applied to the bones, overwhelming their structural strength. The causes of these fractures vary based on the type of injury and the affected bone. Below are common causes:

a) Falls (fall on an outstretched hand)
b) Sports Injuries (football, boxing, skiing)
c) Crush Injuries (industrial or car accidents)
d) Direct Trauma (punching, hitting an object)
e) Twisting or Torsional Forces

Symptoms

The symptoms of hand and wrist bone fractures vary depending on the location, severity, and type of fracture. However, common signs and symptoms are as follows:

General Symptoms of Hand and Wrist Bone Fractures:

1. Pain
2. Swelling
3. Bruising or Discoloration
4. Deformity or Misalignment

5. Limited Range of Motion
6. Tenderness
7. Numbness or Tingling
8. Weakness or Loss of Function
9. Grinding or Crepitus
10. Skin Penetration (Open Fracture)

Specific Symptoms Based on Fracture Location:

1. **Wrist Fractures (e.g., Distal Radius, Scaphoid Fracture)**
   - Pain near the base of the thumb or wrist joint.
   - Swelling and bruising on the back or palm side of the wrist.
   - Difficulty rotating or bending the wrist.
   - Tenderness in the "snuffbox" area (scaphoid fracture).

2. **Metacarpal Fractures (Palm Bones)**
   - Swelling and pain in the palm of the hand.
   - A sunken or flattened knuckle (common in Boxer's fracture).
   - Difficulty gripping or making a fist.

3. **Finger (Phalangeal) Fractures**
   - Swelling and pain in the finger.
   - Finger deformity (e.g., mallet finger: fingertip droops downward).
   - Difficulty bending or straightening the affected finger.
   - Bruising around the injured phalanx.

4. **Thumb Fractures**
   - Severe pain and swelling at the base of the thumb.
   - Difficulty pinching or holding objects.
   - Misalignment at the base of the thumb.

Complications

Complications following hand and wrist fracture surgery can occur despite proper treatment and care. While most surgeries are successful, certain risks and complications may arise due to the fracture severity, patient health, or surgical procedures. Below are the potential complications:

1. Infection

2. Delayed Union or Nonunion
3. Malunion
4. Stiffness and Reduced Range of Motion
5. Nerve Damage
6. Tendon Damage or Rupture
7. Hardware Complications
8. Avascular Necrosis (AVN)
9. Complex Regional Pain Syndrome (CRPS)
10. Joint Arthritis
11. Blood Vessel Injury

Diagnosis

The diagnosis of hand and wrist bone fractures involves a thorough evaluation by a medical professional, which includes a detailed history, physical examination, and imaging studies to confirm the fracture and determine its severity.

1. Physical Examination

The surgeon will inspect and examine the hand and wrist for:

- **Visible Deformities**: Misalignment, shortening, or angulation of bones.
- **Swelling and Bruising**: Around the injured area.
- **Tenderness**: Specific points of tenderness can help identify the fracture site.
- **Range of Motion**: Assessing movement of the wrist, hand, and fingers.
- **Strength and Grip**: Testing the ability to grip or pinch objects.
- **Neurological Examination**: Checking for nerve injury by assessing sensation (numbness/tingling) and motor function.
- **Circulation**: Assessing blood flow by checking skin colour, temperature, and capillary refill in fingers.

3. Imaging Studies

- X-rays
- CT scan (Computed Tomography)
- MRI (Magnetic Resonance Imaging)
- Bone Scan

Treatment

The treatment of hand and wrist bone fractures depends on the location, severity, and type of fracture, as well as the patient's overall health and activity level. Treatment aims to restore function, alignment, and strength while minimizing complications.

1. Non-Surgical Treatment

Non-surgical treatment is preferred for non-displaced or minimally displaced fractures.

a. Immobilization
b. Closed Reduction
c. Pain Management
d. Physical Therapy

2. Surgical Treatment

Surgery is recommended for severely displaced, unstable, or open fractures. Surgical intervention ensures proper alignment and promotes optimal healing.

a) Open Reduction and Internal Fixation (ORIF) (Plates, Screws)
b) External Fixation
c) Percutaneous Pinning (Wire)

Pain Management

Pain management after hand and wrist fracture treatment is essential for ensuring comfort, promoting healing, and improving overall recovery outcomes. Effective pain control involves a combination of medications, physical therapies, and self-care strategies. Below is a detailed approach to managing pain following hand and wrist fracture treatment.

1. Medications

Pain medication is often the first step to control discomfort following treatment.

Over-the-Counter (OTC) Pain Relievers

- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (Examples: Ibuprofen, Naproxen)
- Acetaminophen (Tylenol)

B. Prescription Pain Medications

- Opioids (Oxycodone, Hydrocodone)
- Combination Medications (mix of acetaminophen and opioids (e.g., Percocet)
- Nerve Pain Medications (In cases of nerve involvement, medications like gabapentin may help relieve nerve-related pain or tingling)
- Topical Medications (Pain-relief creams or gels: Contain NSAIDs, menthol, or lidocaine, Examples: Voltaren Gel, lidocaine patches)

2. Physical Therapy and Rehabilitation

Physical therapy plays a key role in reducing pain while restoring function.

- **Gentle Range-of-Motion Exercises**: Helps prevent stiffness and improve flexibility in the hand and wrist.
- **Strengthening Exercises**: Gradual strengthening of the muscles to restore grip and mobility.
- **Manual Therapy**: Gentle techniques performed by a physical therapist to relieve pain.
- **Pain-Reducing Modalities**:

- Heat therapy: To soothe muscles and reduce stiffness.
- Cold therapy (ice packs): To reduce inflammation and numb pain.

3. Cold and Heat Therapy

Cold Therapy (Cryotherapy)

- Reduces swelling and numbs the pain in the early stages (first 48-72 hours).
- Use an ice pack wrapped in a cloth for 15-20 minutes every few hours.

Heat Therapy

- Relieves stiffness and promotes blood flow during the recovery phase.
- Use warm compresses or heating pads for 15-20 minutes as needed.

4. Elevation and Rest

- **Elevation**: Keep the injured hand or wrist elevated above heart level to reduce swelling and pain.
- **Rest**: Avoid excessive use of the injured hand or wrist until cleared for activity.

5. Splinting and Bracing

- Proper immobilization with a splint, cast, or brace can help reduce pain by stabilizing the fracture site.
- Avoid over-tightening the splint or cast, as this can worsen pain and swelling.

Rehabilitation and Recovery

Rehabilitation is a critical part of treatment to ensure full recovery.

A. Early Motion

Gentle movements of the fingers, hand, or wrist are encouraged during recovery to prevent stiffness.

B. Physical Therapy

- Focuses on:
  - Range of motion: Regaining wrist, hand, and finger mobility.
  - Strengthening: Gradual exercises to improve muscle strength.
  - Functional training: Activities to restore grip and fine motor control.

C. Duration of Recovery

- Simple fractures: 6-8 weeks for bone healing.
- Complex fractures: 3-6 months for full function restoration.

Clinical Evidence/Safety of the device:
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 Hand 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_017	Ongoing	India	09/15	0	0	0
Study Title	A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Hand Plate System.					
CTRI Number	CTRI/2024/04/065090					
CTRI Registration Date	02-04-2024					
Number of study sites	One					
Name of Study Sites	Sancheti Institute for Orthopedics and Rehabilitation, Pune, Maharashtra, India					
No. of Patients enrolled	09					

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 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.

The study is intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of the device. This is a single arm, prospective one year follow-up study. The target population for this research comprises both males and females aged 18 years to 65 years at the time of surgery. Study is designed to evaluate aspects related to issues with medium-term performance, the appearance of clinical events.

Inclusion criteria

3. Both male and female above 18 to 65 years patients.
4. Patients presenting to Orthopaedic emergency/ OPD with hand fracture and need internal fixation will be included in the study.

Exclusion criteria

3. Any past or present evidence of infection of the treated joint.
4. Physical conditions that would eliminate or tend to eliminate adequate implant support or delayed healing, viz.: blood supply limitations, poor skin quality, previous or active infections, sepsis, metabolic diseases, etc.
10. Signs of any local inflammation.
11. Patient susceptibility to allergic reaction to the components of the alloy, the implant is manufactured from.
12. Mental or neurological conditions which tend to pre-empt the patient's ability or willingness to restrict activities during the healing period, viz.: Parkinson's disease, chronic alcoholism, Charcot's joints, drug abuse, mental illness, patient noncompliance, etc.
13. Patients having inadequate tissue coverage over the operative site.
14. Patient having Foreign body sensitivity.
15. Patient with compromised skin.
16. Severe osteopenia and/or osteoporosis, or in the presence of marked or rapid bone absorption, metabolic bone disease, cancer, or any other tumor-like condition of the bone which may compromise fixation.
17. Patient who is pregnant or intends to become pregnant during the study.

Primary Objective

1. To assess the safety and performance of the Hand Plate system by evaluating the quality of fusion and deformity correction through Radiological Evaluation.
2. The change in Total Active Flexion (TAF Score) from preoperative to follow-up visits at 6-week, 3 month, 6 month and 12 month.

Secondary Objective

3. Pain evaluation through Visual Analogue Scale (VAS).
4. Adverse Event assessment

Primary Endpoints

2. 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].
3. Quality of Hand movement by calculating TAF score [Time Frame: baseline, 1 week, 3-month, 6-month, 12 months after surgery].

Secondary Endpoints

1. Follow-up of the patient’s recovery by analysing 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 follows up, especially the one mentioned in the Product Description. [Baseline, Follow-up at 6 weeks, 3 months, 6 months and 12 months].

Population Detail:
Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (BMI)
Mean	36.44 ± 17.4	64.71 ± 6.93	171.7 ± 6.67	22.0 ± 1.92
Median	28	67	170.6	23
Range	21 - 61	48 - 73.4	162.4 -184.4	18.2 – 23.8

Gender distribution of study subjects

Male	8/9 (88.8%)
Female	1/9 (11.1%)

The study included a total of 09 subjects with a mean age of 36.44 ± 17.4 years. The majority of participants were Asian males, with 08 males and 01 female recruited in the study. The mean weight of the subjects was 64.71 ± 6.93kg. The mean BMI of the subjects was 22.0 ± 1.92. In terms of height, the subjects had an average of 171.7 ± 6.67 cm. These demographic and baseline characteristics are essential for understanding the composition of the study population and provide valuable insights for the interpretation of the study results.

Study Method
The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Hand Plate device. This longitudinal study was designed as a single-arm study. The target population for this research comprised both males and females aged 18 years or older at the time of surgery. The study aimed to recruit a total of 15 subjects who experienced hand & wrist related fracture, and they were treated using a hand plate construct.

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

A total of seven study visits are there. Subject is screened, and followed at Baseline 1 (pre surgery) and Baseline 2 (post-surgery). After which 4 follow-up visits are conducted. All the planned assessments are being done and recorded from visit 1 to visit 7 in all the recruited study participants as per the study protocol. Study participants are followed at 6-week, 3-month, 6 month and 12 months. Assessment includes standardized clinical evaluation, and completion of the VAS score and the Total Active Flexion (TAF).

Study Result

As per the analysis, we have observed very significant positive results with respect to our hand plate device efficacy and safety. Overall, the study's findings suggest that the intervention led to significant pain reduction and enhanced functional performance in the patients. These improvements indicate the positive impact of the treatment on their quality of life and recovery from their condition after intervention of plate. There is no any adverse event related to device in any medical device registry. The benefit-risk analysis has outweighed the benefit against the risk regarding the device.

Possible diagnostic or therapeutic alternatives

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

The treatment of hand and wrist bone fractures depends on the location, severity, and type of fracture, as well as the patient’s overall health and activity level. Treatment aims to restore function, alignment, and strength while minimizing complications.

1. Non-Surgical Treatment

Non-surgical treatment is preferred for non-displaced or minimally displaced fractures.

- Immobilization
- Closed Reduction
- Pain Management
- Physical Therapy

2. Surgical Treatment

Surgery is recommended for severely displaced, unstable, or open fractures. Surgical intervention ensures proper alignment and promotes optimal healing.

- Open Reduction and Internal Fixation (ORIF) (Plates, Screws)
- External Fixation
- Percutaneous Pinning (Wire)

Suggested training for users

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