SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR CLAVICLE AND SCAPULA PLATE SYSTEM

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

Basic UDI-DI: 0890399CST016UG for Titanium Implants and 08903993CSP016KP for Stainless Steel Implants

SRN: IN-MF-000018837

The Clavicle and Scapula Plate System includes the following variants as listed below:

Bone Plates:

1. 3.5mm Wise-Lock Reconstruction Plate
2. 3.5mm Wise-Lock Symphyseal Plate with Coaxial Combi-Holes
3. 3.5mm Wise-Lock Clavicle Hook Plate
4. 3.5mm Wise-Lock Superior Anterior Clavicle Plate
5. 3.5mm Wise-Lock S Clavicle Plate
6. 3.5mm Clavicle Hook Plate
7. 3.5mm Wise-Lock Scapula Glenoid Plate
8. 3.5mm Wise-Lock Scapula Acromion Plate
9. 3.5mm Wise-Lock Scapula Lateral Border Plate
10. 3.5mm Wise-Lock Scapula Medial Border Plate
11. 2.7/3.5mm Wise-Lock Superior Anterior Clavicle Plate with Lateral Extension
12. 2.7/3.5mm AV-Wiselock Superior Anterior Clavicle Plate with Lateral Extension
13. 3.5mm Wise-Lock Low Profile Reconstruction Plate with Coaxial Combi-Holes
14. 3.5mm Wise-Lock "J" Reconstruction Plate with Coaxial Combi-Holes

Bone Screws:

1. 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head)
2. 3.5mm Cortical Screw, (Hex Head)

3. 3.5mm AV-Wiselock Screw, Self-Tapping
4. 3.5mm Wise-Lock Screw, Self-Tapping, (Star Head)
5. 3.5mm Cortical Screw, Self-Tapping, (Star Head)
6. 3.5mm Cortical Screw, Self-Tapping, (Hex Head)
7. 3.5mm Wise-Lock Screw, Self-Tapping (Hex Head)

Details Regarding the device are provided in below table:

Device Trade Name:	**Clavicle and Scapula Plate System**		
Manufacturer Details	**Name & Address of Manufacturer:** Auxein Medical Pvt. Ltd. **Manufacturing Unit:** Plot No. 168-169-170, Phase IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonipat, Haryana– 131028, India **Phone:** +91-9910643638 **Email: info@auxeinmedical.com** **Website: www.auxein.com**		
Manufacturer's SRN	IN-MF-000018837		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Clavicle and Scapula Plate System (Certified under MDD 93/42/EEC)	DQS	170753735
Year when the first certificate (CE) was issued covering the device	2020		
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 316L as per EN ISO 5832-1:2019.		
USFDA Cleared	Yes (Clavicle and Scapula Plate System 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)}are in Class IIb unless they are intended:

1. Are intended to be placed in the teeth, in which case they are classified as class IIa;

Applicable/ Not Applicable: Not Applicable

Justification: The Clavicle and Scapula plate intended to be placed in Clavicle and Scapula bone to treat fracture not intended for teeth.

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

Applicable/ Not Applicable: Not Applicable

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

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

Applicable/ Not Applicable: Not Applicable

Justification: The Clavicle and Scapula Plate system is made up of medical grade metallic alloy. Metallic alloy does not achieve its intended use by biological effect or by absorption.

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

Applicable/ Not Applicable: Not Applicable

Justification: The Clavicle and Scapula Plate system is made up of medical grade metallic elements. These metallic elements have high metallic bonds that do not undergo chemical change in the body.

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

Applicable/ Not Applicable: Not Applicable

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

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

Applicable/ Not Applicable: Not Applicable

Justification: 'Active Device' means any device, the operation of which 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 Clavicle and Scapula Plate system does not depend on a source of energy.

7.Are breast implants or surgical meshes, in which cases they are classified as class III;

Applicable/ Not Applicable: Not Applicable

Justification: The Clavicle and Scapula Plate system treats Clavicle and Scapula bone fracture. Not intended as breast implants or surgical meshes.

8. Are total or partial joint replacements, in which case they are classified as class III, except ancillary components such as screws, wedges,plates and instruments; or;

Applicable/ Not Applicable: Not Applicable

Justification: The Clavicle and Scapula Plate system treats Clavicle and Scapula bone fracture. Not intended for Total or Partial JointReplacements.

9.Are Spinal Disc Replacement Implants or are implantable devices that come into contact with the Spinal Column,

	in which case they are classified as class III except components such as screws, wedges, plates and instruments: Applicable/ Not Applicable: Not Applicable Justification: The Clavicle and Scapula Plate system is an implantable device to treat Clavicle and Scapula 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:

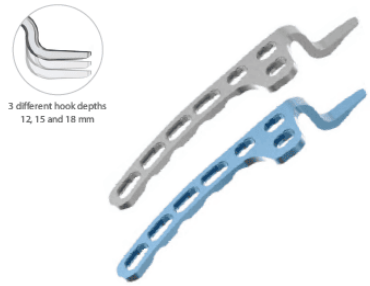
Indications of Use	The Auxein's Clavicle Plate System is intended for clavicle fractures, Malunion, Non-unions of clavicle shaft and Clavicle bone: Neer type II or Jäger and Breitner type II, Acromioclavicular joint dislocation type: Tossy III or Rockwood III to V. The Auxein's Scapula Plate System provides fixation during fractures, fusions, and osteotomies for the scapula.
Contraindications	The implant should not be used in a patient who has had an implant, or Who has a history of: ○ Any Active Local Infection to the operative site. ○ Signs of local inflammation. ○ Fever or leukocytosis. ○ Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care. ○ Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodeling, e.g. the presence of tumours or congenital abnormalities, fracture local to the

	operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells (WBC) count, or a marked left shift in the WBC differential count. ○ Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant (content of the implant material is presented in (IMPLANT MATERIAL). ○ Any case not needing a surgical intervention. ○ Any case not described in the indications. ○ Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage. ○ Any case where the implant components selected for use would be too large or too small to achieve a successful result. ○ Any case that requires the simultaneous use of elements from different systems that are made of different metals. ○ Any case in which implant utilization would disturb physiological processes. ○ Blood supply limitation in the operative site. ○ Morbid obesity (defined according to the WHO. standards). ○ Any case in which there is inadequate tissue coverage of the operative site.
Intended Patient Population	Male or Female, aged between 18 to 75 years and skeletally mature patient.
Intended Users	The Clavicle and Scapula 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 Clavicle and Scapula Plate System are Bio-compatible. Biocompatibility of the devices is tested as per EN ISO 10993-1:2020 series of International Standard.

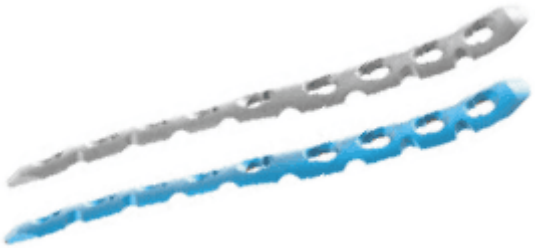
3. Description of the device

1	Device Name	3.5mm Wise-Lock Reconstruction Plate
	Image	
	Product Code	For SS: 727.2XX For Ti: TI-727.2XX (Where X=No. of Shaft Holes)
	Shaft Hole	5 to 22
	Head Holes	Not Applicable
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

2	Device Name	3.5mm Wise-Lock Symphyseal Plate with Coaxial Combi-Holes
	Image	
	Product Code	For SS: 1126.0X For Ti: TI-1126.0X (Where X=No. of Shaft Holes)
	Shaft Hole	4, 6
	Head Holes	Not Applicable
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

3	Device Name	3.5mm Wise-Lock Clavicle Hook Plate
	Image	

	Product Code	For SS: 752.Z.XXY, For Ti: TI-752.4.XXY (Where, Z= No. of Shaft Holes, XX=Hook DepthNo. of Shaft Holes, Y=L for left direction and R for Right Direction)
	Shaft Hole	4, 5, 6, 7
	Hook Depth (mm)	12, 15, 18
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

4	Device Name	3.5mm Wise-Lock Superior Anterior Clavicle Plate
	Image	
	Product Code	For SS: 526.00XY For Ti: TI-526.00XY (Where X=No. of Shaft Holes, Y=L for left direction and R for Right Direction)
	Shaft Hole	5, 6, 7, 8
	Head Holes	Not Applicable

	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

5	Device Name	3.5mm Wise-Lock S Clavicle Plate
	Image	
	Product Code	For SS: 762.10XY For Ti: TI-762.10XY (Where X=No. of Shaft Holes, Y=L for left direction and R for Right Direction)
	Shaft Hole	3, 4, 6, 8
	Available in	4 (Medium), 6 Small, 6 Large, 8 Medium
	Head Holes	Not Applicable
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

6	Device Name	3.5mm Clavicle Hook Plate
	Image	
	Product Code	For SS: 751.Z.XXY For Ti: TI-751.Z.XXY (Where, Z= No. of Shaft Holes, XX=Hook DepthNo. of Shaft Holes, Y=L for left direction and R for Right Direction)
	Shaft Hole	4, 5, 6, 7
	Hook Depth (mm)	12, 15, 18
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

7	Device Name	3.5mm Wise-Lock Scapula Glenoid Plate
	Image	

	Product Code	For Left: 10-045-04LTI For Right: 10-045-04RTI
	Shaft Hole	4
	Head Holes	Not Applicable
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021.

8	Device Name	3.5mm Wise-Lock Scapula Acromion Plate
	Image	
	Product Code	For Left: 10-045-0XLTI For Right: 10-046-0XRTI (Where X=No. of Shaft Holes)
	Shaft Hole	6, 7
	Head Holes	Not Applicable
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021

9	Device Name	3.5mm Wise-Lock Scapula Lateral Border Plate
	Image	
	Product Code	For Left: 10-047-10LTI For Right: 10-047-10RTI
	Shaft Hole	10
	Head Holes	Not Applicable
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021

10	Device Name	3.5mm Wise-Lock Scapula Medial Border Plate
	Image	

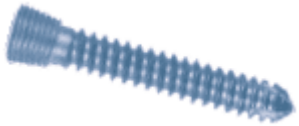
	Product Code	For Left: 10-058-XXLTI For Right: 10-058-09RTI (Where XX=No. of Shaft Holes)
	Shaft Hole	9, 13
	Head Holes	Not Applicable
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021

11	Device Name	2.7/3.5mm Wise-Lock Superior Anterior Clavicle Plate with Lateral Extension
	Image	
	Product Code	For SS: 527.00XY For Ti: TI-527.00XY (Where X=No. of Shaft Holes, Y=L for left direction and R for Right Direction)
	Shaft Hole	3 to 8
	Head Holes	Not Applicable
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

12	Device Name	2.7/3.5mm AV-Wiselock Superior Anterior Clavicle Plate with Lateral Extension
	Image	
	Product Code	For SS: 11-087-0XYSS For Ti: 11-087-0XYTI (Where X=No. of Shaft Holes, Y=L for left direction and R for Right Direction)
	Shaft Hole	3 to 8
	Head Holes	Not Applicable
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

13	Device Name	3.5mm Wise-Lock Low Profile Reconstruction Plate with Coaxial Combi-Holes
	Image	
	Product Code	For SS: 1125.XX For Ti: TI-1125.03 (Where XX=No. of Shaft Holes)
	Shaft Hole	3 to 20
	Head Holes	Not Applicable
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

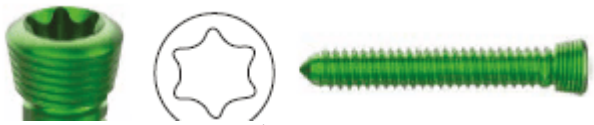
14	Device Name	3.5mm Wise-Lock "J" Reconstruction Plate with Coaxial Combi-Holes
	Image	
	Product Code	For SS: 1125.XXJY For Ti: TI-1125.XXJY (Where XX=No. of Shaft Holes, Y=L for left direction and R for Right Direction)
	Shaft Hole	10, 12, 14, 16
	Head Holes	Not Applicable
	Directional Configuration	Available for left and right directions
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

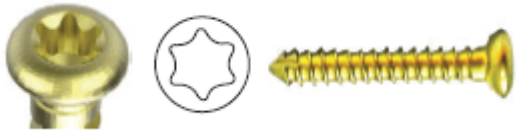
15	Device Name	2.7mm Wise-Lock Screw, Self-Tapping (Hex Head)
	Image	
	Product Code	For SS: 118.0XX For Ti: TI-118.0XX (Where XX=Length of Screw)
	Diameter (mm)	2.7mm
	Length (mm)	10 to 60 (2mm Increment)
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

16	Device Name	3.5mm Cortical Screw, (Hex Head)
	Image	

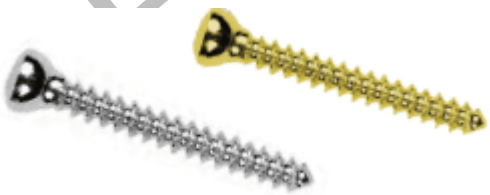
	Product Code	For SS: 104.0XX For Ti: TI-104.0XX (Where XX=Length of Screw)
	Diameter (mm)	3.5mm
	Length (mm)	10 to 50 (2mm Increment)
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

17	Device Name	3.5mm AV-Wiselock Screw, Self-Tapping
	Image	
	Product Code	For SS: 11-024-0XXSS For Ti: 11-024-0XXTI (Where XX=Length of Screw)
	Diameter (mm)	3.5mm
	Length (mm)	10 to 95 (10 to 60 have 2mm Increment and 60 to 95 have 5mm Increment)
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

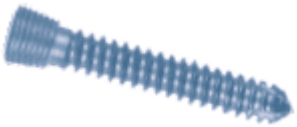
18	Device Name	3.5mm Wise-Lock Screw, Self-Tapping, (Star Head)
	Image	
	Product Code	For SS: 1473-0XX For Ti: TI-1473-0XX (Where XX=Length of Screw)
	Diameter (mm)	3.5mm
	Length (mm)	10 to 95 (10 to 60 have 2mm Increment and 60 to 95 have 5mm Increment)
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

19	Device Name	3.5mm Cortical Screw, Self-Tapping, (Star Head)
	Image	
	Product Code	For SS: 11-002-0XXSS

		For Ti: 11-002-0XXTI (Where XX=Length of Screw)
	Diameter (mm)	3.5mm
	Length (mm)	10 to 95 (10 to 60 have 2mm Increment and 60 to 95 have 5mm Increment)
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

20	Device Name	3.5mm Cortical Screw, Self-Tapping, (Hex Head)
	Image	
	Product Code	For SS: 104.2XX For Ti: TI-104.2XX (Where XX=Length of Screw)
	Diameter (mm)	3.5mm
	Length (mm)	10 to 90 (10 to 50 have 2mm Increment and 50 to 90 have 5mm Increment)
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

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

	Image	
	Product Code	For SS: 118.0XX For Ti: TI-118.0XX (Where XX=Length of Screw)
	Diameter (mm)	3.5mm
	Length (mm)	10 to 60 (2mm Increment)
	Directional Configuration	Not Applicable
	Material	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

Other details of Clavicle and Scapula Plate System:

Device Compliance to regulation		We are proposing the Clavicle and Scapula Plate System as per the compliance to European Union Medical Device Regulation (EU MDR 2017/745).
1.	DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES	
1.1	Device Description and Specification	
a.	Product/Trade Name	Auxein Clavicle and Scapula Plate System
	General Description	The comprehensive Auxein Clavicle and Scapula System portfolio includes various plate options to treat a variety of fractures and fracture-dislocations of the clavicle and scapula bone. The Clavicle and scapula Plating System offers low and narrow-profile plate solutions that are pre-contoured to match the natural shape of the clavicle and scapula. The Auxein Clavicle and Scapula Plate System is designed to treat

		simple and complex fractures, malunions, and nonunions. The system can be used with either hex or hexalobe screws. The Auxein Clavicle Hook Plating System includes a plate with a hook at the lateral end designed to maintain reduction of the AC joint or distal clavicle fragments. Following are the variants included in the Clavicle and scapula plate system: Bone Plates: 1. 3.5mm Wise-Lock Reconstruction Plate 2. 3.5mm Wise-Lock Symphyseal Plate with Coaxial Combi-Holes 3. 3.5mm Wise-Lock Clavicle Hook Plate 4. 3.5mm Wise-Lock Superior Anterior Clavicle Plate 5. 3.5mm Wise-Lock S Clavicle Plate 6. 3.5mm Clavicle Hook Plate 7. 3.5mm Wise-Lock Scapula Glenoid Plate 8. 3.5mm Wise-Lock Scapula Acromion Plate 9. 3.5mm Wise-Lock Scapula Lateral Border Plate 10. 3.5mm Wise-Lock Scapula Medial Border Plate 11. 2.7/3.5mm Wise-Lock Superior Anterior Clavicle Plate with Lateral Extension 12. 2.7/3.5mm AV-Wiselock Superior Anterior Clavicle Plate with Lateral Extension 13. 3.5mm Wise-Lock Low Profile Reconstruction Plate with Coaxial Combi-Holes 14. 3.5mm Wise-Lock "J" Reconstruction Plate with Coaxial Combi-Holes Bone Screws: 1. 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head) 2. 3.5mm Cortical Screw, (Hex Head) 3. 3.5mm AV-Wiselock Screw, Self-Tapping 4. 3.5mm Wise-Lock Screw, Self-Tapping, (Star Head) 5. 3.5mm Cortical Screw, Self-Tapping, (Star Head)

		6. 3.5mm Cortical Screw, Self-Tapping, (Hex Head) 7. 3.5mm Wise-Lock Screw, Self-Tapping (Hex Head)
	Intended Purpose	The Clavicle and Scapula plate system is intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of clavicle and Scapula bone fragments.
	Intended Users	The Clavicle and Scapula Plate system is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Male or Female, aged between 18 to 75 years and skeletally mature patient.
	Medical Conditions to be diagnosed, treated and/or monitored	The Clavicle and Scapula Plate System is used to treat the clavicle and scapula bone fractures or non-union. Specifically designed for the Clavicle and Scapula plate intended for treatment of fractures that provides strong fixation and restores the bone fragments.
	Patient Selection Criteria	**Inclusion criteria** Male or Female, aged between 18 to 75 years and skeletally mature patient. **Exclusion criteria** Infection, local or Systemic Acute or Chronic Inflammation to the operative site. Female subject who is pregnant or planning pregnancy during the study. Subject having Soft tissue or material sensitivity. Subjects having diagnosed Sepsis and Subjects who are incarcerated or have pending incarceration.
c.	Principles of Operation Mode of Action	Clavicle and Scapula Plate system works on the AO Principle of Fracture Management. The key concept of fracture management involves: 1. Restoration of anatomy 2. Stable fixation 3. Preservation of blood supply 4. Early mobilization of the limb and patient The Auxein's Clavicle and Scapula 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.
d.	Rationale for considering as a Medical device	As per Article 2 (1) of EU MDR 2017/745 'Medical Device' means any instruments, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: Thus, the Clavicle and Scapula Plate system is an implant used in humans for medical purposes to treat Clavicle and Scapula bone 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 Clavicle and Scapula Plate system is an implant used for the treatment of clavicle and scapula 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 Clavicle and Scapula plate is an implantable device used for the treatment of Clavicle and Scapula 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 Clavicle and Scapula plate is intended to treat Clavicle and Scapula 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 Clavicle and Scapula plate is made up of metal alloy and employed to fix Clavicle and Scapula 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 Clavicle and Scapula 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 Clavicle and Scapula Plate system is used to stabilize Clavicle and Scapula 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 Clavicle and Scapula Plate system is intended for fixation for fractures of the Clavicle and Scapula bone. The system is not meant for cleaning, disinfection or sterilization of device.
e.	Novel Features	The Clavicle and Scapula 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, etc.
f.	Description of key functional elements	The Clavicle and Scapula Plate system comprises of : ● Screws The Clavicle and Scapula Plate system is clinically improved by using Internal Fixation with Angular Stability (Internal Fixators) in complicated fractures. The description of the components used with Plate to fix the fracture enlisted below. Screw ○ It is intended to be used for the implantation of any type of internal Orthopedic Fixation System.

		○ It is used for internal orthopaedic fracture fixation by being screwed into bone to hold Plate with Clavicle and Scapula bone. ○ In the Clavicle and Scapula Plate system various types of screws are included like Cortical, Wise-Lock and AV-Wiselock screw.
g.		
	Sterility	All Products covered in Clavicle and Scapula Plate system are supplied in either Non-sterile or in Sterile state. Sterile implants which are placed on the market are sterilized by using Gamma Irradiation Sterilization (SAL 10-6). The Non-Sterile implants which are placed on market are to be sterilized at 121 degree centigrade for 20 minutes (Moist Heat Sterilization/Autoclave Sterilization) as instructed in IFU for Non-sterile devices before implantation.
	Radioactivity	Products covered in Clavicle and Scapula Plate System are metal products and does not emit any ionizing or non-ionizing radiation.
	Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
	Use	For Single Use only
	Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
	MRI Compatibility	The AUXEIN MEDICAL Clavicle and Scapula Plate System have not been evaluated for safety and compatibility in the MR environment. The AUXEIN MEDICAL implants have not been tested for heating or migration in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic Resonance Imaging) environment.
1.2	Reference to Previous and Similar Generations of the device	
a.	CE Mark (Legacy device)	CE Approved by DNV (2460) under MDD 93/42/EEC Certificate No. 10000363901-PA-NA-IND Rev 2
	USFDA clearance	Yes (Clavicle and Scapula 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 enlisted below: DePuy Synthes 3.5 mm LCP Clavicle Plate System DePuy Synthes VA LCP™ Clavicle Plate 2.7 System Scapula Plating System: Acumed

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

Comparison table:

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

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

Measurable safety and performance parameters

- Quality of fusion through Radiological Evaluation
- Change in Disability of the Arm, Shoulder and Hand Score (DASH Score)
- Pain evaluation through Visual Analogue Scale (VAS)
- Record of any adverse event, serious adverse event and complication

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

Residual risks and undesirable effects

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

Potential adverse events include but are not limited to:

- Corrosion of metal components (the significance and long-term implications are uncertain and await further clinical evidence and evaluation).
- Interference with roentgen graphic, CT, and/or MR imaging because of the presence of the implants.
- Bone fracture or “stress shielding” phenomenon causing loss of bone above, below or at the operative site.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Limitations of normal, everyday activities.
- ○ Scar formation that could cause neurological impairment, or nerve compression and/or pain.
- Seroma
- Hematoma
- Infection
- Hardware irritation
- Loss of reduction
- Loss of alignment
- Nonunion
- Delayed union
- Wound Complications
- Secondary procedures
- Malunion
- Pain around osteotomy
- Implant Failure
- Revision
- Skin Necrosis
- Sepsis
- Wound dehiscence
- Superficial infection

Warning & Precautions:

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

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

Prospective Clinical Data (PMCF Study):

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

Identity of the investigation/study: A Prospective, Single arm, Post Market Clinical Follow- up (PMCF) study to evaluate the Safety and Performance of Clavicle 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_02	Ongoing	INDIA	09/20	0	0	0
Study Title	A Prospective, Single arm, Post Market Clinical Follow- up (PMCF) study to evaluate the Safety and Performance of Clavicle Plate System.					
CTRI Number	CTRI/2023/11/060230					
CTRI Registration Date	24/11/2023					

Number of study sites	One
Name of Study Sites	Panimalar Medical College Hospital & Research Institute, Chennai, India
No. of Patients enrolled	09

Study design: This PMCF study is designed as a Single-arm, Prospective study. The target population for this study is comprised of both males and females aged between 18 years to 75 years at the time of surgery. The study aimed to recruit a total of 20 subjects, who met with Inclusion and Exclusion criteria as per the protocol. This study is carried out following marketing approval intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of a device when used in accordance with its approved labeling. These may examine issues such as medium-term performance, the appearance of clinical events, events specific to defined Subject populations, or the performance of the device in a more representative population of providers and subjects with fracture fixation of the clavicle bone related problem.

Inclusion criteria

Male and female subjects between 18 - 75 years of age.

Exclusion criteria

Infection, local or Systemic Acute or Chronic Inflammation to the operative site. Female subject who is pregnant or planning pregnancy during the study. Subject having Soft tissue or material sensitivity. Subjects having diagnosed Sepsis and Subjects who are incarcerated or have pending incarceration

Primary Objective

1. To assess the safety and performance of the Clavicle Plate system by evaluating the quality of fusion through Radiological Evaluation.
2. The Change in Disability of the Arm, Shoulder and Hand Score (DASH Score) from preoperative to follow-up visits at 6 weeks, 3 month, 6 month and 12 month.

Secondary Objective

1. Pain evaluation through Visual Analogue Scale (VAS).

2. Adverse Event assessment.

Primary Endpoints

Completion of clinical investigation i.e. 12 month of study period.

Secondary Endpoints

1. Analyzing Visual analogue score (VAS) for pain assessment.[Baseline, Follow-up at 6 weeks, 3 Month, 6 Month and 12 Months]
2. Any adverse event or serious adverse event during follow up, especially the one mentioned in the Product Description(PD). [Baseline, Follow-up at 6 weeks, 3 Month, 6 Months and 12 Month]

Population Detail:

Summary of Demographics and Baseline Characteristics

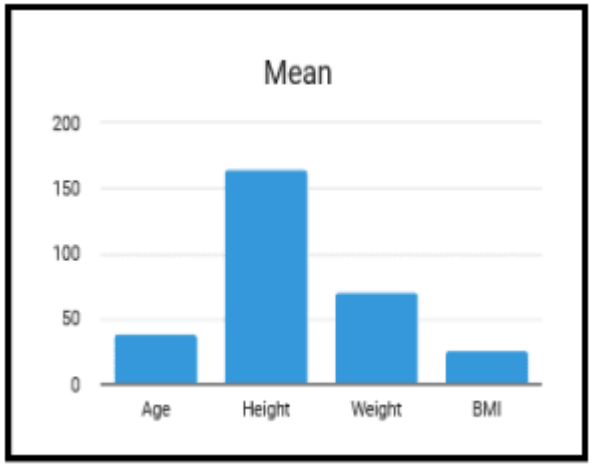
Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (BMI)
Mean ± SD	38 ± 12.09	69.5 ± 9.34	164.3 ± 8.86	25.7 ± 2.97
Range	23-57	52-80	155-176	21.4-29.6
Median	39	73	165	24.6

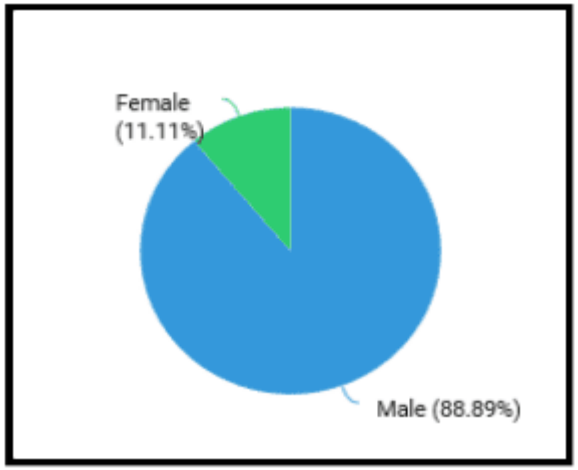
Gender distribution of study subjects

Male	8
Female	1

A total of 9 subjects with a mean age of 38 years have been recruited in the study so far. The mean weight of the subjects is 69.5 kg and mean height is 164.3 cm. The mean BMI of the study participants is 25.7 kg/m2. The demographic characteristics of study participants reflect the composition of the study population and provide valuable insights for the interpretation of the study results.

The figures provide information of demographic and baseline characteristics.





Study Method

This PMCF study is designed as a Single-arm, Prospective study. The target population for this study is comprised of both males and females aged between 18 years to 75 years at the time of surgery. The study aimed to recruit a total of 20 subjects, who met with Inclusion and Exclusion criteria as per the protocol. This study is carried out following marketing approval intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of a device when used in accordance with its approved labeling. These may examine issues such as medium-term performance, the appearance of clinical events, events specific to defined Subject populations, or the performance of the device in a more representative population of providers and subjects with fracture fixation of the clavicle bone related problem.

The study consisted total 7 study visits. Subject is screened and followed at Baseline 1 (pre surgery) and Baseline 2 (post surgery). After which 4 follow-up visits are conducted. All assessments are performed and recorded from Visit 1 to Visit 7 for all the study subjects. After Baseline 2 visit, subjects are followed at 6 weeks, 3 month, 6 month and 12 month. Assessment included standardized clinical evaluation and completion of the VAS score and the Disability of the Arm, Shoulder and Hand (DASH) score.

Study Result

The interim analysis of data of nine patients recruited in the study so far provides significant information with respect to implants safety and performance.

Principal findings of the study are (i) significant improvement in pain and functional scores, and (ii) No occurrence of AEs and SAEs. The substantial reduction in VAS scores indicates that the intervention effectively alleviated pain in study population. This is particularly important as pain levels at baseline were reported to be high, indicating that the intervention has a positive impact on the subjects' quality of life. Furthermore, the decrease in functional score; DASH highlights the effectiveness of the intervention. The progressive decrease in DASH over the follow-up done so far indicates a consistent and sustained improvement in functional ability. This demonstrates that the intervention not only provided shor tterm relief but also led to lasting improvements in the patients' functional ability that is crucial for their overall recovery. Findings of the interim report on nine patients shows that clavicle plate system manufactured by Auxein Medical Private Limited is safe and perform the intended function.

6. Possible diagnostic or therapeutic alternatives.

Diagnosing a clavicle or scapula injury or problem includes a medical examination and usually the use of a diagnostic procedure(s) such as an x-ray, MRI, CT scan. Both non-operative and surgical treatment options are available to treat pain and problems depending on the type and severity of the condition.

Non-surgical Treatment

The most common way to treat the fractures in the middle is with immobilization with either a sling or a special bandage called a figure-of-8 splint. Studies have shown that these fractures heal just as quickly and as well with a sling as with the figure-of-8 splint, so a sling in a majority of cases. The figure-of-8 splint is generally uncomfortable, difficult to wear nonstop for six or eight weeks and can result in skin problems and a smelly patient because it should not be removed to wash the armpit. Figure-of-8 splints are not indicated or useful in fractures of the clavicle near the AC joint. However, some orthopaedic doctors have strong opinions about the use of this figure-of-8 device, and it can produce an acceptable result.

The second thing that helps in the treatment of clavicle fractures is pain relief with cold therapy and pain medication. It is recommended that ice the fractured area for 15 to 20 minutes every two hours for as long as necessary to decrease the pain and swelling. Heat is not recommended. Pain medication in the form of narcotics is the best for relief of pain from a fractured clavicle, and you may need it for several weeks, especially to help you sleep. Many patients with this injury have to sleep sitting up to be comfortable. Other pain-relieving medications such as acetaminophen or nonsteroidal medications may be used, but they generally will not be adequate by themselves until the pain and swelling start to subside.

Surgical Treatment

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

Non-Surgical Treatment	Surgical Treatments
○ figure-of-8 splint ○ Cold therapy and pain medication ○ Pain Medications	○ Bone Plate and Screws

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 Clavicle and Scapula Plate System:

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

		sealing and assembly processes (ISO 11607-2:2019)
8.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
Non Harmonized Standards		
9.	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
10.	EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
11.	ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good Clinical Practice.
12.	ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
13.	ISO 14630:2012	Non-active surgical implants - General Requirements
14.	ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
15.	ISO 14644-1:2015	Clean-rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
16.	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.
17.	ISO 14644-3:2019	Clean-rooms and associated controlled environments - Part 3: Test Methods.
18.	ISO 14644-4:2022	Clean-rooms and associated controlled environments - Part 4: Design, construction and start-up.
19.	ISO 14644-5:2004	Clean-rooms and associated controlled environments - Part 5: Operations
20.	ISO 14644-7:2004	Clean-rooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, Isolators and mini).
21.	ISO 14644-8 :2022	Clean-rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC).
22.	ISO 14644-9 :2022	Clean-rooms and associated controlled environments – Part 9: Classification of surface cleanliness by particle concentration.

23.	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).
24.	ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
25.	ISO 5832-3:2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)
26.	EN ISO 5832-1:2019	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel (ISO 5832-1:2016)
27.	ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
28.	ISO 10993-2: 2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements
29.	ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
30.	ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
31.	ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
32.	ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
33.	ASTM F138-19	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
34.	ASTM F136-13 (2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
35.	ASTM D4169-22	Standard Practice for Performance Testing of Shipping containers and System.
36.	ASTM 1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.
37.	ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials
38.	ISO 19227:2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements
39.	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		
40.	MDCG 2023-7	Practical Application of Article 61(4)
41.	MDCG 2021-24	Guidance on classification of medical devices
42.	MDCG 2020-13	Clinical Evaluation Assessment Report Template
43.	MDCG 2020-8	Guidance on PMCF evaluation report template
44.	MDCG 2020-7	Guidance on PMCF plan template
45.	MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
46.	MDCG 2020-5	Guidance on clinical evaluation – Equivalence
47.	MDCG 2019-9, Rev.01	Summary of safety and clinical performance
48.	MDCG 2019-5	Registration of legacy devices in EUDAMED
49.	MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
50.	MDCG 2018-2	Future EU medical device nomenclature - Description of requirements
51.	MDCG 2021-11	Guidance on Implant Card –‘Device types’
52.	MDCG 2022-16	Guidance on Authorized Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746
53.	MDCG 2022-9	Summary of safety and performance template
54.	MDCG 2019-14	Explanatory note on MDR codes
55.	MDCG 2021-19	Guidance note integration of the UDI within an organisation’s quality management system
56.	MDCG 2023-7	Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR
57.	MDCG 2018-1, Rev. 04	Guidance on BASIC UDI-DI and changes to UDI-DI
58.	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
59.	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 -

		December 2022
60.	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	19-07-2024	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	11-12-2024	Updated standard and comparison for stainless steel and titanium material is included on page no. 31, 40 of 55 as per query received during PRJN-629776.	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

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

Document revision: 01
Date issued: 11-12-2024

Device identification and general information

Device Trade Name: Clavicle and Scapula 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: 0890399CST016UG for Titanium Implants and 08903993CSP016KP for Stainless Steel Implants
Year when the device was first CE-marked: 2020

Intended use of the device

Intended Purpose	The Clavicle and Scapula plate system is intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of clavicle and Scapula bone fragments.
Indications of Use	The Clavicle and Scapula Plate System is used to treat the clavicle and scapula bone fractures or non-union. Specifically designed for the Clavicle and Scapula plate intended for treatment of fractures that provides strong fixation and restores the bone fragments.
Contraindications	The implant should not be used in a patient who has had an implant, or Who has a history of: ○ Any Active Local Infection to the operative site. ○ Signs of local inflammation. ○ Fever or leukocytosis. ○ Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care. ○ Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodeling, e.g. the presence of tumours or congenital abnormalities, fracture local to the

	operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells (WBC) count, or a marked left shift in the WBC differential count. ○ Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant (content of the implant material is presented in (IMPLANT MATERIAL). ○ Any case not needing a surgical intervention. ○ Any case not described in the indications. ○ Any case that requires the simultaneous use of elements from different systems that are made of different metals. ○ Any case in which implant utilization would disturb physiological processes. ○ Blood supply limitation in the operative site. ○ Morbid obesity (defined according to the WHO. standards). ○ Any case in which there is inadequate tissue coverage of the operative site.
Intended Patient Population	Male or Female, aged between 18 to 75 years and skeletally mature patient.

Device description

The comprehensive Auxein Clavicle and Scapula System portfolio includes various plate options to treat a variety of fractures and fracture-dislocations of the clavicle and scapula bone. The Clavicle and scapula Plating System offers low and narrow-profile plate solutions that are pre-contoured to match the natural shape of the clavicle and scapula. The Auxein Clavicle and Scapula Plate System is designed to treat simple and complex fractures, malunions, and nonunions. The system can be used with either hex or hexalobe screws. The Auxein Clavicle Hook Plating System includes a plate with a hook at the lateral end designed to maintain reduction of the AC joint or distal clavicle fragments. The details regarding Clavicle and Scapula Plate System and screws can be found at **www.auxein.com**.

The more details regarding these Clavicle and Scapula Plate System are mentioned below:

Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Clavicle and Scapula Plate System (Certified under MDD 93/42/EEC)	DQS	170753735
Material/substances in contact with	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per EN ISO 5832-		

patient tissues	3:2021 and Stainless steel alloy SS 316L as per EN ISO 5832-1:2019.
USFDA Cleared	Yes (Clavicle and Scapula Plate System are approved by USFDA whose details are as follow:) 510(k) Number: K141680
Risk Class	IIb (According to the EU Regulation 2017/745 (MDR) Annex VIII Rule 8)
Authorized Representative Name and Address	Name: CMC Medical Devices & Drug S.L Address: 29015 Málaga, Spain
Notified Body Name and Single Identification Number	Name: DQS Medizinprodukte GmbH Single Identification Number: 0297

Principle of operation

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.

Description of Key functional elements:

The Clavicle and Scapula Plate system comprises of :

- Screws

The Clavicle and Scapula Plate system is clinically improved by using Internal Fixation with Angular Stability (Internal Fixators) in complicated fractures. The description of the components used with Plate to fix the fracture enlisted below.

Screw

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

Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

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

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

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

Warning & Precautions:

1. This product should only be used by or on the order of a surgeon.
2. The fixation provided by this device should be protected until healing is complete. Failure to follow the postoperative regimen prescribed by the surgeon could result in the failure of the device and compromised results.
3. Any decision to remove the device should consider the potential risk of a second surgical procedure. Adequate postoperative management should be followed after implant removal.
4. The patient should be advised of the use and limitations of this device.
5. This device must never be reused. Reuse or re-sterilization may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use devices can also cause cross- contamination leading to patient infection.
6. This device must never be re-sterilized.
7. Appropriate instrumentation should be used to implant this device.

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

Till now, regarding Auxein's Clavicle and Scapula 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 clavicle is the bone that connects the breastplate (sternum) to the shoulder. It is a very solid bone that has a slight S-shape and can be easily seen in many people. It connects to the sternum at a joint with cartilage called the sternoclavicular joint. At the other end, the bone meets the shoulder area at a part of the shoulder blade (scapula) called the acromion. The joint at that end of the bone containing cartilage is called the acromioclavicular joint.

The collarbone acts as a strut to connect the sternum to the shoulder blade. Because of the critical location of the clavicle, any severe force on the shoulder, such as falling directly onto the shoulder or falling on an outstretched arm, transfers force to the clavicle. As a result, the collarbone is one of the most commonly broken bones in the body.

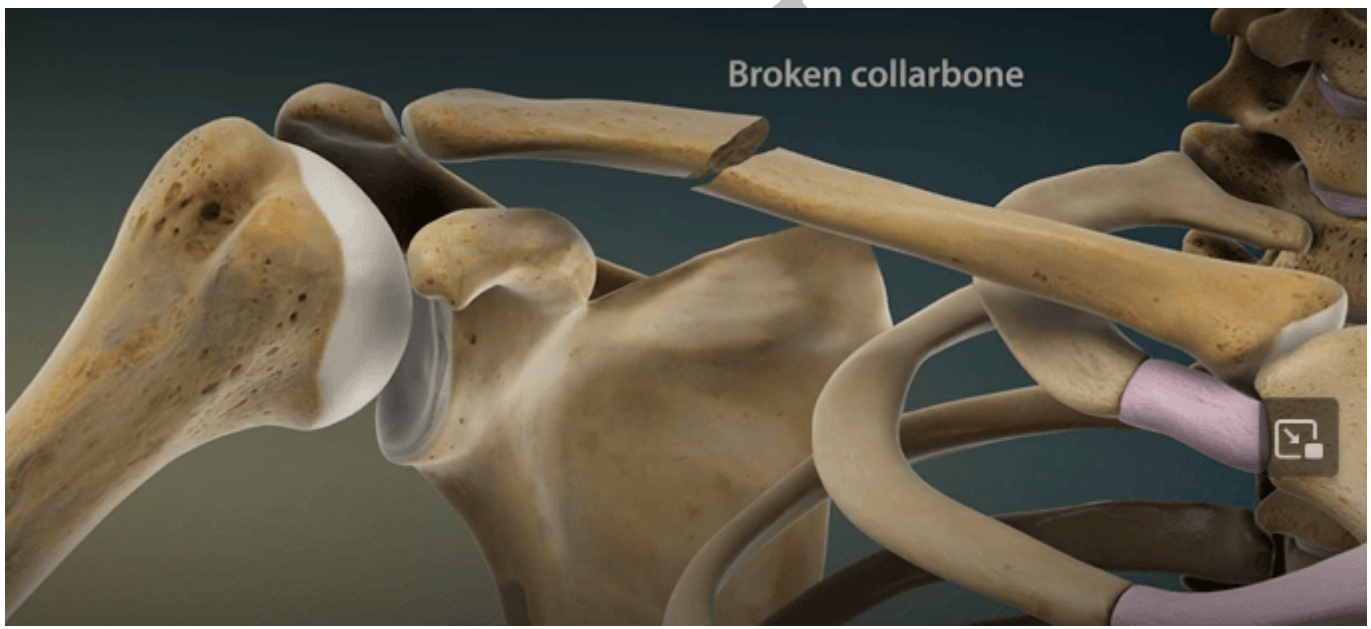


Figure: Clavicle Bone/Collar Bone

Collar Bone Injuries

A broken collarbone is a common injury. The collarbone, also known as the clavicle, connects the shoulder blade to the breastbone. Common causes of a broken collarbone include falls, sports and traffic accidents. Infants sometimes break their collarbones while being born.

Seek medical help quickly for a broken collarbone. Most heal well with ice, pain relievers, a sling, physical therapy and time. Some breaks might require surgery to put plates, screws or rods into the bone to hold the pieces in place during healing.

Causes

Common causes of a broken collarbone include:

- Falls, such as falling onto the shoulder or onto an outstretched arm.
- Sports injuries, such as a direct blow to the shoulder on the field, rink or court.
- Traffic accidents, from a car, motorcycle or bike crash.

Symptoms:

Symptoms of a broken collarbone include:

- Pain that increases when moving the shoulder.
- Swelling, tenderness or bruising.
- Skin over the break might look like a tent when gently pinched.
- A bump on or near the shoulder.
- A grinding or crackling sound when moving the shoulder.
- Stiffness or not being able to move the shoulder.

Diagnosis

The doctor will perform a series of tests that will check the muscle strength. Depending on the extent of your shoulder joint, emergency surgery may be required. The following tests will be performed to get a visual image of the fracture as follows:

- X-rays- To have an image of the fracture
- MRI scan-For a detailed image of the muscles, ligaments around the fracture.

Pain Management

The thing that helps in the treatment of clavicle fractures is pain relief with cold therapy and pain medication. It is recommended that ice the fractured area for

15 to 20 minutes every two hours for as long as necessary to decrease the pain and swelling. Heat is not recommended. Pain medication in the form of narcotics is the best for relief of pain from a fractured clavicle, and you may need it for several weeks, especially to help you sleep. Many patients with this injury have to sleep sitting up to be comfortable. Other pain-relieving medications such as acetaminophen or nonsteroidal medications may be used, but they generally will not be adequate by themselves until the pain and swelling start to subside.

Rehabilitation and Return to Activity

The healing depends upon many factors, such as age, the location of the fracture and how many pieces it is broken into. Fractures in adults or teenagers who have stopped growing take 10 to 12 weeks to heal and may take longer. Most clavicle fractures will heal completely by four months in an adult. There are some indications that clavicle fractures broken into more pieces take longer than ones with a fewer fragments.

Clinical Evidence/Safety of the device

Prospective Clinical Evaluation

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

Prospective Clinical Data (PMCF Study):

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

Identity of the investigation/study: A Prospective, Single arm, Post Market Clinical Follow- up (PMCF) study to evaluate the Safety and Performance of Clavicle 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_02	Ongoing	INDIA	09/20	0	0	0
Study Title	A Prospective, Single arm, Post Market Clinical Follow- up (PMCF) study to evaluate the Safety and Performance of Clavicle Plate System.					
CTRI Number	CTRI/2023/11/060230					
CTRI Registration Date	24/11/2023					
Number of study sites	One					
Name of Study Sites	Panimalar Medical College Hospital & Research Institute, Chennai, India					
No. of Patients enrolled	09					

Study design: This PMCF study is designed as a Single-arm, Prospective study. The target population for this study is comprised of both males and females

aged between 18 years to 75 years at the time of surgery. The study aimed to recruit a total of 20 subjects, who met with Inclusion and Exclusion criteria as per the protocol. This study is carried out following marketing approval intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of a device when used in accordance with its approved labeling. These may examine issues such as medium-term performance, the appearance of clinical events, events specific to defined Subject populations, or the performance of the device in a more representative population of providers and subjects with fracture fixation of the clavicle bone related problem.

Inclusion criteria
Male and female subjects between 18 - 75 years of age.

Exclusion criteria
Infection, local or Systemic Acute or Chronic Inflammation to the operative site. Female subject who is pregnant or planning pregnancy during the study. Subject having Soft tissue or material sensitivity. Subjects having diagnosed Sepsis and Subjects who are incarcerated or have pending incarceration

Population Detail:
Summary of Demographics and Baseline Characteristics

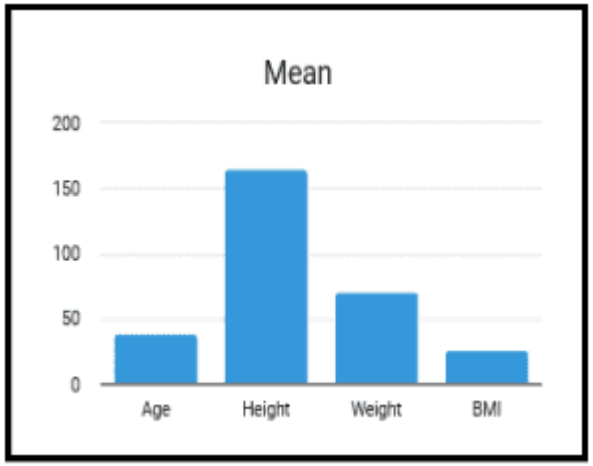
Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (BMI)
Mean ± SD	38 ± 12.09	69.5 ± 9.34	164.3 ± 8.86	25.7 ± 2.97
Range	23-57	52-80	155-176	21.4-29.6
Median	39	73	165	24.6

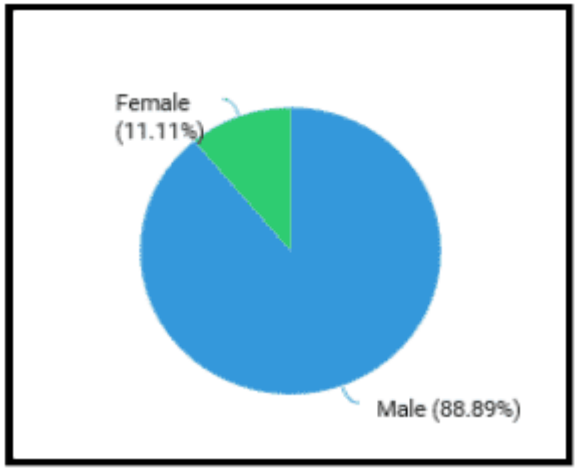
Gender distribution of study subjects

Male	8
Female	1

A total of 9 subjects with a mean age of 38 years have been recruited in the study so far. The mean weight of the subjects is 69.5 kg and mean height is 164.3 cm. The mean BMI of the study participants is 25.7 kg/m2. The demographic characteristics of study participants reflect the composition of the study population and provide valuable insights for the interpretation of the study results.

The figures provide information of demographic and baseline characteristics.





Study Method

This PMCF study is designed as a Single-arm, Prospective study. The target population for this study is comprised of both males and females aged between 18 years to 75 years at the time of surgery. The study aimed to recruit a total of 20 subjects, who met with Inclusion and Exclusion criteria as per the protocol.

Study Result

The interim analysis of data of nine patients recruited in the study so far provides significant information with respect to implants safety and performance. Principal findings of the study are (i) significant improvement in pain and functional scores, and (ii) No occurrence of AEs and SAEs. The substantial reduction in VAS scores indicates that the intervention effectively alleviated pain in study population. This is particularly important as pain levels at baseline were reported to be high, indicating that the intervention has a positive impact on the subjects' quality of life. Furthermore, the decrease in functional score; DASH highlights the effectiveness of the intervention. The progressive decrease in DASH over the follow-up done so far indicates a consistent and sustained improvement in functional ability. This demonstrates that the intervention not only provided short term relief but also led to lasting improvements in the patients' functional ability that is crucial for their overall recovery. Findings of the interim report on nine patients shows that clavicle plate system manufactured by Auxein Medical Private Limited is safe and perform the intended function.

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

Diagnosing a clavicle or scapula injury or problem includes a medical examination and usually the use of a diagnostic procedure(s) such as an x-ray, MRI, CT scan. Both non-operative and surgical treatment options are available to treat pain and problems depending on the type and severity of the condition.

Non-surgical Treatment

The most common way to treat the fractures in the middle is with immobilization with either a sling or a special bandage called a figure-of-8 splint. Studies have shown that these fractures heal just as quickly and as well with a sling as with the figure-of-8 splint, so a sling in a majority of cases. The figure-of-8 splint is generally uncomfortable, difficult to wear nonstop for six or eight weeks and can result in skin problems and a smelly patient because it should not be removed to wash the armpit. Figure-of-8 splints are not indicated or useful in fractures of the clavicle near the AC joint. However, some orthopaedic doctors have strong opinions about the use of this figure-of-8 device, and it can produce an acceptable result.

The second thing that helps in the treatment of clavicle fractures is pain relief with cold therapy and pain medication. It is recommended that ice the fractured area for 15 to 20 minutes every two hours for as long as necessary to decrease the pain and swelling. Heat is not recommended. Pain medication in the form of narcotics is the best for relief of pain from a fractured clavicle, and you may need it for several weeks, especially to help you sleep. Many patients with this injury have to sleep sitting up to be comfortable. Other pain-relieving medications such as acetaminophen or nonsteroidal medications may be used, but they generally will not be adequate by themselves until the pain and swelling start to subside.

Surgical Treatment

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

Non-Surgical Treatment	Surgical Treatments
○ Figure-of-8 splint ○ Cold therapy and pain medication ○ Pain Medications	○ Bone Plate and Screws

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/).