SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR FEMUR PLATE SYSTEM

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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: 08903993FPS011L8 (For Stainless Steel Implants) and 0890399FPT011UC (for Titanium Implants)

SRN: IN-MF-000018837

The Femur plate System includes the following as listed below:

- 4.5/5.0mm AV-Wiselock Condylar Femur Plate
- 4.5/5.0mm AV-Wiselock Distal Femur Plate
- 5.0mm Wise-Lock Cable Prosthesis and Revision Femur Plate
- 5.0mm Wise-Lock Cable Straight Plate
- 4.5/5.0mm Wise-Lock Distal Femur Plate
- 4.5/5.0mm Wise-Lock Condylar Femur Plate
- 4.5/5.0mm Wise-Lock Proximal Femur Plate
- 4.5/5.0mm Wise-Lock Proximal Femur Hook Plate
- 4.5/5.0mm Wise-Lock Proximal Femur Lateral Plate (Type-II)
- 4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts
- 4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate with LC under cuts
- 4.5/5.0mm Wise-Lock Curved Broad Plate
- 4.5/5.0mm Wise-Lock Osteotomy Lateral Distal Femur Plate
- 4.5/5.0mm Wise-Lock Osteotomy Medial Distal Femur Plate
- 5.0mm Wise-Lock Distal Femur Plate (LISS)
- 5.0mm Wise-Lock Femoral Neck Plate
- Wise-Lock DHS Plate
- Wise-Lock DHS Plate, Short Barrel

- 95° Wise-Lock DCS Plate
- 4.5/5.0mm Wise-Lock Trochanter Stabilizing Plate for DHS – Adjustable
- Dynamic Hip Compression Plate
- 135° Dynamic Hip Compression Plate, Short Barrel
- 95° DCS Plate
- 95° Condylar Blade Plate
- 130° Angle Blade Plate
- Angle Blade Plate for Adults
- Angle Blade Plate for Intertrochanteric - Femoral Osteotomies in Adults
- 4.5mm Narrow Dynamic Compression Plate
- 4.5mm Narrow Limited Contact Dynamic Compression Plate
- 4.5mm Broad Dynamic Compression Plate
- 4.5mm Broad Limited Contact Dynamic Compression Plate
- 4.5mm Narrow Lengthening Plate
- 4.5mm Broad Lengthening Plate
- 4.5mm Condylar Buttress Plate
- 4.5mm Cobra Head Plate
- 4.5mm Proximal Femur Plate
- 4.5mm Distal Femur Plate
- 130°/135° Jewett Nail Plate

Bone Screws:

- DHS/DCS Compression Screw
- DHS/DCS Screw
- 4.5mm Cortical Screw, Self-Tapping, (Hex Head)
- 5.0mm Wise-Lock Screw, Self-Tapping, (Hex Head)

- 6.5mm Cancellous Screw, 16mm Thread
- 6.5mm Cancellous Screw, 32mm Thread
- 6.5mm Cancellous Screw, Full Thread
- 6.5mm Cannulated Screw, 16mm Thread, Self-Drilling
- 6.5mm Cannulated Screw, 32mm Thread, Self-Drilling
- 6.5mm Cannulated Screw, Full Thread, Self-Drilling
- 7.0mm Cannulated Cancellous Screw, 16mm Thread, Self-Drilling
- 7.0mm Cannulated Cancellous Screw, 32mm Thread, Self-Drilling
- 7.0mm Cannulated Cancellous Screw, Full Thread, Self-Drilling
- 7.3mm Cannulated Cancellous Screw, 16mm Thread, Self-Drilling
- 7.3mm Cannulated Cancellous Screw, 32mm Thread, Self-Drilling
- 7.3mm Cannulated Cancellous Screw, Full Thread, Self-Drilling
- Ø10.0mm Bolt for Femoral Neck Plate, Length 75mm, Titanium
- Ø6.4mm Anti-Rotation Screw for Femoral Neck Plate, Length 75mm, Titanium
- 5.0mm AV-Wiselock Screw, Self-Tapping, (Star Head), Stainless Steel/Titanium
- 4.5mm Cortical Screw, Self-Tapping, (Star Head), Stainless Steel
- 5.0mm Wise-Lock Screw, Self-Tapping & Self-Drilling, (Hex Head), Stainless Steel/Titanium
- 5.0mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head), Stainless Steel/Titanium
- 5.0mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head), Stainless Steel/Titanium
- 5.0mm Wise-Lock Cannulated Screw, Full Thread, Self-Tapping, Stainless Steel/Titanium
- 5.0mm Wise-Lock Cannulated Screw, Partial Thread, Self-Tapping, Stainless Steel/Titanium

C. Other Components

- Cable
- Cable Connector, Curve Bone

- Needle
- Bone Needle with Hole
- Washer For Large Fragment Screw

Details Regarding the device are provided in below table:

Device Trade Name:	**Femur 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, Femur plate System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev 2
Year when the first certificate (CE) was issued covering the device	2014		
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per EN ISO 5832-3:2021 and Stainless steel alloy SS 316 L as per EN ISO 5832-1:2019.		

USFDA Approved	Yes (DCS & DHS Plate) **510(k) Number:** K221787
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 areclassified as class IIa; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Femur plate intended to be placed in femur 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 Femur plate comes in contact with the femur 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 Femur 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 Femur plate system is made up of medical grade metallic elements. These metallic*

elements have high metallic bonds that do not undergo chemical change in the body.

5. Are intended to administer medicinal products, in which casethey are classified as class III;
   Applicable/ Not Applicable: *Not Applicable*
   Justification: *The Femur plate implants made up of metal alloys to provide support for the fractured femur bone. The system is not intended to administer medicinal products.*

6. 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 intendedto transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. The Femur plate system does not depend on a source of energy*

7. Are breast implants or surgical meshes, in which cases they areclassified as class III;
   Applicable/ Not Applicable: *Not Applicable*
   Justification: *The Femur plate system treats femur 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 Femur plate system treats femur 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 Femur plate system is an implantable device to treat femur 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 Femur plate System is part of the Femur Bone has the following indications: **4.5/5.0mm AV-Wiselock Condylar Femur Plate** - Buttressing of multifragmentary distal femur fractures - Supracondylar fractures - Intra-articular and extra-articular condylar fractures - Malunions and nonunions of the distal femur - Periprosthetic fractures - Osteotomies of the femur

	- Osteopenic bone **4.5/5.0mm AV-Wiselock Distal Femur Plate** - Distal shaft fractures - Supracondylar fractures - Intra-articular fractures - Periprosthetic fractures **5.0mm Wise-Lock Cable Prosthesis and Revision Femur Plate** - Trochanteric osteotomy - Extended trochanteric osteotomy - Trochanteric fracture - Periprosthetic long bone fractures - Comminuted long bone fractures - Fractures in osteopenic bone **5.0mm Wise-Lock Cable Straight Plate** - Trochanteric osteotomy - Extended trochanteric osteotomy - Trochanteric fracture - Periprosthetic long bone fractures - Comminuted long bone fractures - Fractures in osteopenic bone **4.5/5.0mm Wise-Lock Distal Femur Plate**

	Buttressing of multifragmentary distal femur fractures, Supracondylar fractures, Intra-articular and extra-articular condylar fractures, Malunions and nonunions of the distal femur Periprosthetic fractures **4.5/5.0mm Wise-Lock Condylar Femur Plate** Buttressing of multifragmentary distal femur fractures, Supracondylar fractures, Intra-articular and extra-articular condylar fractures, Malunions and nonunions of the distal femur Periprosthetic fractures, Osteopenic bone. **4.5/5.0mm Wise-Lock Proximal Femur Plate** - Fractures of the trochanteric region, trochanteric simple, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric reversed or transverse or with additional fracture of the medial cortex - Fractures of the proximal end of the femur combined with ipsilateral shaft fractures - Metastatic fracture of the proximal femur - Osteotomies of the proximal femur - Also for use in fixation of osteopenic bone and fixation of nonunions or malunions **4.5/5.0mm Wise-Lock Proximal Femur Hook Plate** - Intertrochanteric reversed or transverse or with additional fracture of the medial cortex. - Fractures of the proximal end of the femur combined with ipsilateral shaft fractures - Metastatic fracture of the proximal femur - Osteotomies of the proximal femur - Also for use in fixation of osteopenic bone and fixation of nonunions or malunions

4.5/5.0mm Wise-Lock Proximal Femur Lateral Plate (Type-II)

- Fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, reversed or transverse fractures of the trochanteric region or with additional fracture of the medial cortex.
- Fractures of the proximal end of the femur combined with ipsilateral shaft fractures.
- Metastatic fracture of the proximal femur
- Osteotomies of the proximal femur
- Also for use in fixation of osteopenic bone and fixation of nonunions or malunions Periprosthetic Fractures

4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts

Indicated for fixation of various long bones, such as the femur and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients.

4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate with LC under cuts

Indicated for fixation of various long bones, such as the femur and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients.

4.5/5.0mm Wise-Lock Curved Broad Plate

The 4.5/5.0mm Wise-Lock Curved Broad Plate is indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones such as femur.

4.5/5.0mm Wise-Lock Osteotomy Lateral Distal Femur Plate

- Open-wedge and closed-wedge osteotomy of the lateral distal femur for the treatment of:

- Unicompartmental medial or lateral gonarthrosis with malalignment of the distal femur.
- Idiopathic or post-traumatic varus or valgus deformity of the distal femur.

4.5/5.0mm Wise-Lock Osteotomy Medial Distal Femur Plate

- Closed-wedge osteotomies of the medial distal femur for the treatment of:
- Unicompartmental lateral gonarthrosis with valgus malalignment of the distal femur
- Idiopathic or posttraumatic valgus deformity of the distal femur
- Additional fixation for complex distal femoral fractures

5.0mm Wise-Lock Distal Femur Plate (LISS)

Indicated for the stabilization of fractures of the distal femur. These include:

- Distal shaft fractures
- Supracondylar fractures
- Intra-articular fractures
- Periprosthetic fractures

5.0mm Wise-Lock Femoral Neck Plate

Femoral neck fractures (AO type 31-B)

Wise-Lock DHS Plate

- Pertrochanteric fractures of type 31-A1 and 31-A2
- Intertrochanteric fractures of type 31-A3
- Basilar neck fractures 31-B

	Wise-Lock DHS Plate, Short Barrel - Pertrochanteric fractures of type 31-A1 and 31-A2 - Intertrochanteric fractures of type 31-A3 - Basilar neck fractures 31-B **95° Wise-Lock DCS Plate** - Proximal femur: Very proximally located, purely sub-trochanteric fractures of types 32-A and 32-B - Distal femur: Fractures of type 33-A (extra-articular, supracondylar) and fractures of type 33-C (fully articular fractures) **4.5/5.0mm Wise-Lock Trochanter Stabilizing Plate for DHS – Adjustable** Unstable pertrochanteric fractures of type 31-A2 and 31-A3, especially multifragmentary fractures with a separated or longitudinally split greater trochanter **130°/135°/140°/145°/150° Dynamic Hip Compression Plate** - Pertrochanteric fractures of type 31-A1 and 31-A2 - Intertrochanteric fractures of type 31-A3 - Basilar neck fractures 31-B **135° Dynamic Hip Compression Plate, Short Barrel** - Pertrochanteric fractures of type 31-A1 and 31-A2 - Intertrochanteric fractures of type 31-A3 - Basilar neck fractures 31-B **95° DCS Plate**

	- IntercondylarfracturesUnstable pertrochanteric fractures of type 31-A2 and 31-A3, especially multifragmentary fractures with a separated or longitudinally split greater trochanter - Supracondylar fractures - Unicondylar fractures **95° Condylar Blade Plate** Fractures and revisions of the proximal and distal third of the femur in skeletally mature patients. **130° Angle Blade Plate** Fractures and revisions of the proximal third of the femur in skeletally mature patients **Angle Blade Plate for Adults** Unstable pertrochanteric fractures of type 31-A2 and 31-A3, especially multifragmentary fractures with a separated or longitudinally split greater trochanter **Angle Blade Plate for Intertrochanteric - Femoral Osteotomies in Adults** Unstable pertrochanteric fractures of type 31-A2 and 31-A3, especially multifragmentary fractures with a separated or longitudinally split greater trochanter **4.5mm Narrow Dynamic Compression Plate** indicated for fixation of: - Various long bones, such as the femur. - Peri-prosthetic fractures and fractures in osteopenic bone - Nonunions or malunions in adult patients

4.5mm Narrow Limited Contact Dynamic Compression Plate
indicated for fixation of:

- Various long bones, such as the femur.
- Peri-prosthetic fractures and fractures in osteopenic bone
- Nonunions or malunions in adult patients

4.5mm Broad Dynamic Compression Plate
indicated for fixation of:

- Various long bones, such as the femur.
- Peri-prosthetic fractures and fractures in osteopenic bone
- Nonunions or malunions in adult patients

4.5mm Broad Limited Contact Dynamic Compression Plate
indicated for fixation of:

- Various long bones, such as the femur.
- Peri-prosthetic fractures and fractures in osteopenic bone
- Nonunions or malunions in adult patients

4.5mm Narrow Lengthening Plate
These Plates are indicated to fix fractures, non-union and malunion of femur bone.

4.5mm Broad Lengthening Plate
These Plates are indicated to fix fractures, non-union and malunion of femur bone.

	4.5mm Condylar Buttress Plate Indicated to be used for buttress comminuted supracondylar fractures of femur bone **4.5mm Cobra Head Plate** Use to treat fractures of femur head bone. **4.5mm Proximal Femur Plate** 4.5mm Proximal Femur Plate is indicated to treat fractures of the femur including: - Fractures of the trochanteric region, trochanteric simple, trochanterodiaphyseal, multifragmentary pertrochanteric, interotrochanteric reversed or transverse or with additional fracture of the medial cortex. - Metastatic fracture of the proximal femur. - Fracture of the proximal end of the femur combined with ipsilateral shaft fractures. - Osteotomies of the proximal femur. - Fixation of osteopenic bone and fixation of nonunions or malunions. **4.5mm Distal Femur Plate** 4.5mm Distal Femur Plate is indicated to fix fractures of distal femur with or without involvement of the joints. **130°/135° Jewett Nail Plate** - Pertrochanteric fractures of type 31-A1 and 31-A2 - Intertrochanteric fractures of type 31-A3 - Basilar neck fractures 31-B
Contraindications	The implant should not be used in a patient 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	Skeleteally mature Male and female subjects between 18-55 years of age with Proximal, shaft & Distal fractures of

	femur/Articular fractures/Osteotomies, Malalignment/Non-unions, Mal-union.
Intended Users	The Femur plate system is recommended to be used by only well-trained, certified and experienced surgeons.
Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
Use	For Single Use only
Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
Biocompatibility	The devices covered in the Femur plate System are Bio-compatible. Biocompatibility of the devices is tested as per EN ISO 10993-1:2020 series of International Standard.

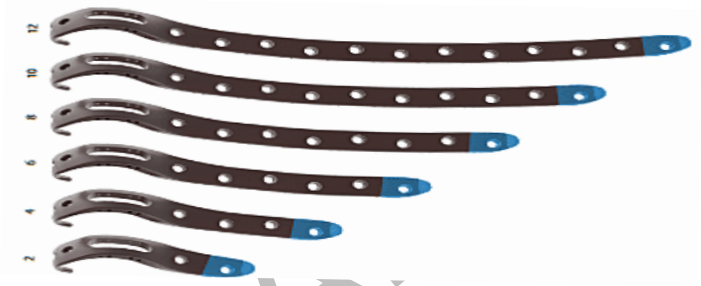
3. Description of the device

S.No.	A. Plates	
1.	**Device Name**	4.5/5.0mm AV-Wiselock Condylar Femur Plate
	Picture	
	Plate Thickness	6mm
	Shaft Width	16mm
	Head Width	49.2mm
	Pitch	0.4mm or 0.6mm

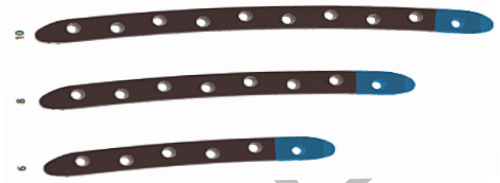
	Combi Hole Length	10mm
	Combi Hole Width	5.5mm
	Combi Hole Distance	18mm
	Directional Configuration (Left & Right)	Left & Right
	Raw Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

2.	**Device Name**	4.5/5.0mm AV-Wiselock Distal Femur Plate
	Picture	
	Holes	5, 7, 9, 11, 13, 15
	Diameter	4.5mm, 5.0mm
	Directional Configuration (Left & Right)	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO

		5832-3

3.	**Device Name**	5.0mm Wise-Lock Cable Prosthesis and Revision Femur Plate
	Picture	
	Holes	2, 4, 6, 8, 10, 12
	Length	357mm
	Plate Thickness	6mm
	Plate Width	18mm
	Thread Pitch	5mm
	Head Height	41.50mm
	Centre Hole Distance	50mm
	Directional Configuration(Left & Right)	Left & Right

	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

4.	**Device Name**	5.0mm Wise-Lock Cable Straight Plate
	Picture	
	Holes	6, 8, 10
	Length	268.50mm
	Plate Thickness	5.80mm
	Plate Width	18mm
	Thread Pitch	0.6mm
	Directional Configuration **(Left & Right)**	Not Available
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

5.	**Device Name**	4.5/5.0mm Wise-Lock Distal Femur Plate

	Picture	
	Plate Thickness	6mm
	Shaft Width	15mm
	Head Width	31.8mm
	Number of Holes	5, 7, 9, 11, 13, 15
	Length	153, 193, 223, 273, 313, 353
	Hole to Hole Distance	20mm
	Directional Configuration **(Left & Right)**	Left & Right

6.	**Device Name**	4.5/5.0mm Wise-Lock Condylar Femur Plate

	Picture	
	Holes	7, 9, 11, 13, 15
	Length	159, 195, 230, 266, 301, 336, 370
	Plate Thickness	6mm
	Shaft Width	16mm
	Head Width	49.2mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

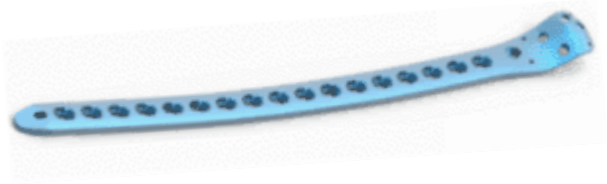
7.	**Device Name**	4.5/5.0mm Wise-Lock Proximal Femur Plate

	Picture	
	Plate Thickness	6.5mm
	Shaft Width	2.6mm
	Head Width	18mm
	Holes	2, 4, 6, 8, 10, 12, 14, 16
	Length	139,175,211,247, 283,319,355,391.
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

8.	**Device Name**	4.5/5.0mm Wise-Lock Proximal Femur Hook Plate

	Picture	
	Holes	2, 4, 6, 8, 10, 12, 14, 16, 18
	length	140-421
	Plate Thickness	6.30mm
	Head hook width	29.9mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

9.	**Device Name**	4.5/5.0mm Wise-Lock Proximal Femur Lateral Plate (Type-II)

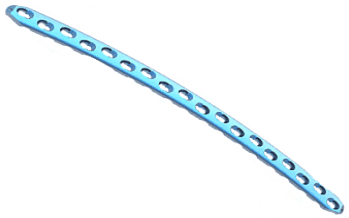
	Picture	
	Holes	4, 5, 6, 7, 8, 9, 10, 12, 14, 16
	Length	152, 170, 188, 206, 224, 242, 260, 295, 331, 367
	Shaft Width	18.5mm
	Plate Thickness	5mm
	Head Width	27.7mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

10.	**Device Name**	4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts
	Picture	
	length in mm	42-438

	Holes	4-24 holes
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

11.	**Device Name**	4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate with LC under cuts
	Picture	
	Holes	4-24 Holes
	length	80-440
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

12.	**Device Name**	4.5/5.0mm Wise-Lock Curved Broad Plate

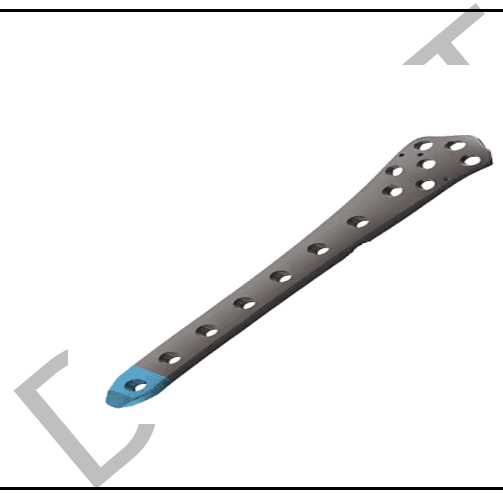
	Picture	
	Holes	12-18 Holes
	Length	230-336mm
	Plate Width	17.40mm
	Plate Thickness	6mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

13.	**Device Name**	4.5/5.0mm Wise-Lock Osteotomy Lateral Distal Femur Plate
	Picture	

	Holes	5 Holes
	Head Width	30.8mm
	length	141mm
	Shaft Width	15.9mm
	Plate Thickness	5.9mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

14.	**Device Name**	4.5/5.0mm Wise-Lock Osteotomy Medial Distal Femur Plate
	Picture	
	Holes	4 Holes
	Plate Thicnkness	4mm
	Head width	23.5
	Shaft width	14.5

	length	114mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

15.	**Device Name**	5.0mm Wise-Lock Distal Femur Plate (LISS)
	Picture	
	Holes	5,7,9,11,13
	length	156, 196, 236, 276, 316
	Shaft width	16.1mm
	Shaft thickness	5.4mm
	Head Width	33.2mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

16.	**Device Name**	5.0mm Wise-Lock Femoral Neck Plate
	Picture	
	Holes	1, 2
	Screw Angulation	130^0
	Slot length	19,6mm
	Slot width	6.7mm
	Directional Configuration	Left & Right
	Material Specification	Titanium Alloy Ti-6AL-4V as per ISO 5832-3

17.	**Device Name**	Wise-Lock DHS Plate

	Picture	
	Holes	2,3,4,5,6,7,8,9,10,12,14,16,18,20,22
	Barrel Length	42.4mm
	Angles	130,135,140,145,150
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

18.	**Device Name**	Wise-Lock DHS Plate, Short Barrel

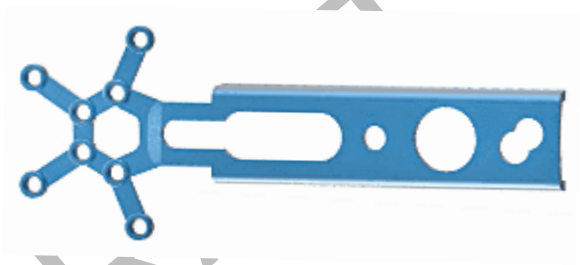
	Picture	
	Holes	2,3,4,5,6,7,8,9,10,12,14,16,18,20,22
	Barrel Length	25.4mm,
	Angles	130,135,140,145,150
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

19.	**Device Name**	95° Wise-Lock DCS Plate

	Picture	
	Holes	6,7,8,9,10,12,14,16,18
	Angle	95 Degree
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

20.	**Device Name**	95° DCS Plate
	Picture	
	Holes	6,7,8,9,10,12,14,16,18

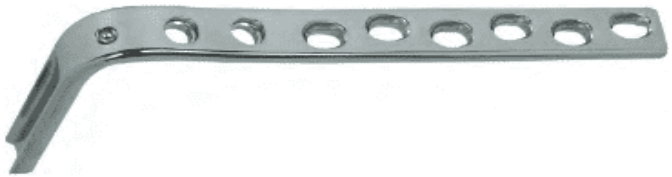
	Length	130mm
	Angle	95 Degree
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

21.	**Device Name**	4.5/5.0mm Wise-Lock Trochanter Stabilizing Plate For DHS - Adjustable
	Picture	
	Plate thickness	2.5mm
	Length	130mm
	Plate width	25
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

22.	**Device Name**	Dynamic Hip Compression Plate
	Picture	
	Holes	2,3,4,5,6,7,8,9,10,12,14,16,18
	Angles	135, 140, 145, 150 Degrees
	Plate thickness	5.8mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

23.	**Device Name**	135° Dynamic Hip Compression Plate, Short Barrel
	Picture	
	Holes	4,5,6,7,8,9,10
	Angle	135

	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

24.	**Device Name**	95° Condylar Blade Plate
	Picture	
	Holes	5,7,9,12,14,16,18
	Angle	95 Degree
	Plate thickness	6.1mm
	Plate Width	16.2mm
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

25.	**Device Name**	130° Angle Blade Plate

	Picture	
	Holes	4, 5, 6, 7, 8, 9, 10, 11, 12
	Angles	130 Degree
	Length	50mm, 60mm, 70mm, 75mm, 80mm, 85mm, 90mm, 95mm, 100mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

26.	**Device Name**	Angle Blade Plate for Adults
	Picture	
	Holes	4 Holes
	Displacement	10mm, 15mm, 20mm
	Blade Length	40, 50, 60, 70

	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

27.	**Device Name**	Angle Blade Plate for Intertrochanteric-Femoral Osteotomies in Adults
	Picture	
	Angles	110, 120, 130 Degrees
	Blade Length	60, 65, 70, 75, 80, 85, 90, 95, 100
	Plate Width	16mm
	Plate Thickness	6mm
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

28.	**Device Name**	4.5mm Narrow Dynamic Compression Plate

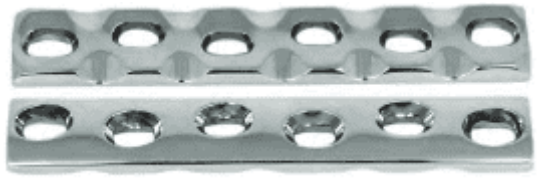
	Picture	
	length	71-295mm
	Plate Width	12.2mm
	Plate Thickness	3.8mm
	Holes	4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

29.	**Device Name**	4.5mm Narrow Limited Contact Dynamic Compression Plate
	Picture	
	Length	71-323
	Holes	4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18

	Plate Width	13.5mm
	Plate Thickness	4mm
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

30.	**Device Name**	4.5mm Broad Dynamic Compression Plate
	Picture	
	Length	31-327mm
	Holes	4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20
	Plate Width	16mm
	Plate Thickness	5mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

31.	**Device Name**	4.5mm Broad Limited Contact Dynamic Compression Plate

	Picture	
	Length	71-359mm
	Plate Width	17.5mm
	Plate Thickness	5.75mm
	Holes	4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

32.	**Device Name**	4.5mm Narrow Lengthening Plate
	Picture	
	Holes	8 Holes
	Length	135, 145, 155, 165, 175, 185 mm

	Plate Thickness	4mm
	Plate Width	12mm
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

33.	**Device Name**	4.5mm Broad Lengthening Plate
	Picture	
	Holes	8 Holes
	Length	135, 145, 155, 165mm
	Plate Width	15.5mm
	Plate Thickness	5mm
	Directional Configuration	Not Applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

34.	**Device Name**	4.5mm Condylar Buttress Plate

	Picture	
	Length	164, 196, 228, 244, 260, 292 mm
	Holes	7, 9, 11, 12, 13, 15 Holes
	Shaft Width	16mm
	Head width	48.2mm
	Plate Thickness	6mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

35.	**Device Name**	4.5mm Cobra Head Plate
	Picture	
	Holes	8, 9, 10, 11, 12, 13, 14

	Shaft width	16mm
	Plate Thickness	6mm
	Head Width	38.80mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

36.	**Device Name**	4.5mm Proximal Femur Plate
	Picture	
	Total Length	(121-211) with 18mm Increment
	Shaft Width	16mm
	Head Width	24mm
	Plate Thickness	2.50mm
	Holes	3, 5, 7, 9, 11, 13
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

37.	**Device Name**	4.5mm Distal Femur Plate

	Picture	
	Holes	3, 5,7,9,11,13
	length	101, 119, 137, 155, 173, 191
	Shaft width	16mm
	Head width	23.8mm
	Plate thickness	2.5mm
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

38.	**Device Name**	Jewett Nail Plate
	Picture	
	Holes	4 to 15

	Length	50 to 100mm
	Angle	130, 135, 140, 145 degrees
	Directional Configuration	Left & Right
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

B. Screws		
1.	**Device Name**	DHS/DCS Compression Screw
	Picture	
	Head Diameter	9.50mm
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

2.	**Device Name**	DHS/DCS Screw

	Picture	
	Length	50mm to 145mm (Increment of 5mm)
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

3.	**Device Name**	4.5mm Cortical Screw, Self-Tapping, (Hex Head)
	Picture	
	Head Diameter	8mm
	Core Diameter	3mm
	Thread Diameter	4.50mm
	Drill Depth	3.90mm
	Punch Width	3.50mm
	Punch Depth	2.9mm

	Shaft Thread Pitch	1.75mm
	Shaft Thread Depth	0.75mm
	Head Length	4.5mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

4.	**Device Name**	5.0mm Wise-Lock Screw, Self-Tapping, (Hex Head)
	Picture	
	Head Diameter	6.25mm
	Core Diameter	4.4mm
	Thread Diameter	5mm
	Drill Depth	3.8mm
	Punch Width	3.50mm
	Punch Depth	2.8mm
	Shaft Thread Pitch	1.0mm
	Shaft Thread Depth	0.30mm
	Head Length	4.3mm
	Directional Configuration	Not applicable

	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

5.	**Device Name**	6.5mm Cancellous Screw, 16mm Thread
	Picture	
	Head Diameter	8mm
	Core Diameter	3mm
	Thread Diameter	6.5mm
	Drill Depth	3.90mm
	Punch Width	3.50mm
	Punch Depth	2.90mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1.75mm
	Head Length	4.76mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

6.	**Device Name**	6.5mm Cancellous Screw, 32mm Thread

	Picture	
	Head Diameter	8mm
	Core Diameter	3mm
	Thread Diameter	6.5mm
	Drill Depth	3.90mm
	Punch Width	3.50mm
	Punch Depth	2.90mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1.75mm
	Head Length	4.76mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

7.	**Device Name**	6.5mm Cancellous Screw, Full Thread

	Picture	
	Head Diameter	5mm
	Core Diameter	3mm
	Thread Diameter	6.5mm
	Drill Depth	3.90mm
	Punch Width	3.50mm
	Punch Depth	2.90mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1.75mm
	Head Length	4.76mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

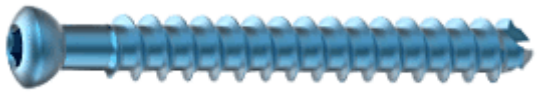
8.	**Device Name**	6.5mm Cannulated Screw, 16mm Thread, Self-Drilling

	Picture	
	Head Diameter	8mm
	Core Diameter	4.50mm
	Thread Diameter	6.5mm
	Drill Depth	3.3mm
	Punch Depth	2.90mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1mm
	Head Length	4.6mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

9.	**Device Name**	6.5mm Cannulated Screw, 32mm Thread, Self-Drilling

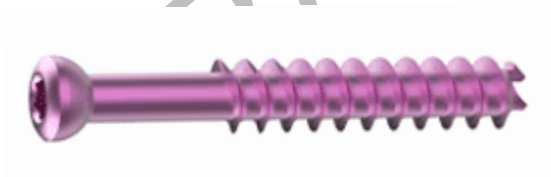
	Picture	
	Head Diameter	8mm
	Core Diameter	4.50mm
	Thread Diameter	6.5mm
	Drill Depth	3.3mm
	Punch Depth	2.90mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1mm
	Head Length	4.6mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

10.	**Device Name**	6.5mm Cannulated Screw, Full Thread, Self-Drilling

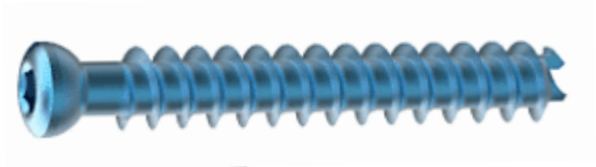
	Picture	
	Head Diameter	8mm
	Core Diameter	4.50mm
	Thread Diameter	6.5mm
	Drill Depth	3.3mm
	Punch Depth	2.90mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1mm
	Head Length	4.6mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

11.	**Device Name**	7.0mm Cannulated Cancellous Screw, 16mm Thread, Self-Drilling
	Picture	
	Head Diameter	5mm

	Core Diameter	4.50mm
	Thread Diameter	7mm
	Punch Depth	3.5mm
	Punch Depth	2.90mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1.25mm
	Head Length	4.6mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

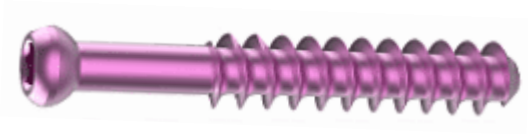
12.	**Device Name**	7.0mm Cannulated Cancellous Screw, 32mm Thread, Self-Drilling
	Picture	
	Head Diameter	5mm
	Core Diameter	4.50mm
	Thread Diameter	7mm
	Punch Depth	3.5mm
	Punch Depth	2.90mm
	Shaft Thread Pitch	2.75mm

	Shaft Thread Depth	1.25mm
	Head Length	4.6mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

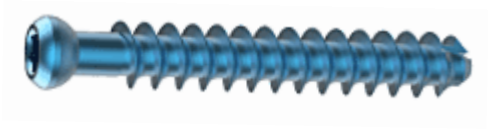
13.	**Device Name**	7.0mm Cannulated Cancellous Screw, Full Thread, Self-Drilling
	Picture	
	Head Diameter	5mm
	Core Diameter	4.50mm
	Thread Diameter	7mm
	Punch Depth	3.5mm
	Punch Depth	2.90mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1.25mm
	Head Length	4.6mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

14.	**Device Name**	7.3mm Cannulated Cancellous Screw, 16mm Thread, Self-Drilling
	Picture	
	Head Diameter	4.5mm
	Core Diameter	4.50mm
	Thread Diameter	7.3mm
	Drill Depth	3.42mm
	Punch Depth	3mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1.40mm
	Head Length	4.5mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

15.	**Device Name**	7.3mm Cannulated Cancellous Screw, 32mm Thread, Self-Drilling

	Picture	
	Head Diameter	4.5mm
	Core Diameter	4.50mm
	Thread Diameter	7.3mm
	Drill Depth	3.42mm
	Punch Depth	3.0mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1.40mm
	Head Length	4.5mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

16.	**Device Name**	7.3mm Cannulated Cancellous Screw, Full Thread, Self-Drilling

	Picture	
	Head Diameter	4.5mm
	Core Diameter	4.50mm
	Thread Diameter	7.3mm
	Drill Depth	3.42mm
	Punch Depth	3.0mm
	Shaft Thread Pitch	2.75mm
	Shaft Thread Depth	1.40mm
	Head Length	4.5mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

17.	**Device Name**	Ø10.0mm Bolt for Femoral Neck Plate, Titanium

	Picture	
	Length	75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130mm
	Cannulated Diameter	3.50mm
	Bolt Outer Diameter	10mm
	Pitch	1.25mm
	Depth	0.63mm
	Directional Configuration	Not applicable
	Material Specification	Titanium Alloy Ti-6AL-4V as per ISO 5832-3

18.	**Device Name**	Ø6.4mm Anti-Rotation Screw for Femoral Neck Plate, Titanium
	Picture	

	Length	75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130mm
	Head Diameter	7mm
	Core Diameter	3.13mm
	Thread Diameter	4.34mm
	Shaft Thread Length	21.5mm
	Directional Configuration	Not applicable
	Material Specification	Titanium Alloy Ti-6AL-4V as per ISO 5832-3

19.	**Device Name**	5.0mm AV-Wiselock Screw, Self-Tapping, (Star Head)
	Picture	
	Length	20mm to 50mm (Increment of 2mm), 50mm to 90mm (Increment of 5mm)
	Head Diameter	6.80mm
	Core Diameter	4.0mm
	Thread Diameter	5.0mm
	Star Diameter	3.20mm
	Head Length	5.0mm

	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

20.	**Device Name**	4.5mm Cortical Screw, Self-Tapping, (Star Head)
	Picture	
	Length	12mm to 74mm (Increment of 2mm), 75mm, 76mm, 78mm, 80mm, 85mm, 90mm
	Head Diameter	8mm
	Core Diameter	3mm
	Thread Diameter	4.5mm
	Star Diameter	3.45mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

21.	**Device Name**	5.0mm Wise-Lock Screw, Self-Tapping & Self-Drilling

	Picture	
	Length	12mm to 74mm (Increment of 2mm), 75mm, 76mm, 78mm, 80mm, 85mm, 90mm
	Diameter	5.0mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

22.	**Device Name**	5.0mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head)
	Picture	
	Length	20mm to 50mm (Increment of 2mm), 50mm to 110mm (Increment of 5mm)
	Head Diameter	6.25mm
	Core Diameter	2.6mm
	Thread Diameter	5.0mm

	Head Thread Length	4.40mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

23.	**Device Name**	5.0mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head)
	Picture	
	Length	20mm to 50mm (Increment of 2mm), 50mm to 90mm (Increment of 5mm)
	Head Diameter	6.25mm
	Core Diameter	2.6mm
	Thread Diameter	5.0mm
	Head Thread Length	4.40mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

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

	Picture	
	Length	20mm to 120mm (Increment of 5mm)
	Head Diameter	6.25mm
	Core Diameter	4.4mm
	Thread Diameter	5.0mm
	Hex Size	3.50mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

25.	**Device Name**	5.0mm Wise-Lock Cannulated Screw, Partial Thread, Self-Tapping
	Picture	
	Head Diameter	6.25mm

	Core Diameter	4.25mm
	Thread Diameter	5.0mm
	Length	30mm to 100mm (Increment of 5mm)
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

C. Other Components		
1.	**Device Name**	Cable Connector, Curved
	Picture	
	Length	500mm
	Cable Width	8mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1

2.	**Device Name**	Bone Needle
	Picture	
	Length	150mm, 250mm, 400mm
	Diameter	1.5mm, 1.8mm, 2mm
	Tip Length	4mm
	Tip Angle	14 degree
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1

3.	**Device Name**	Bone Needle with Hole

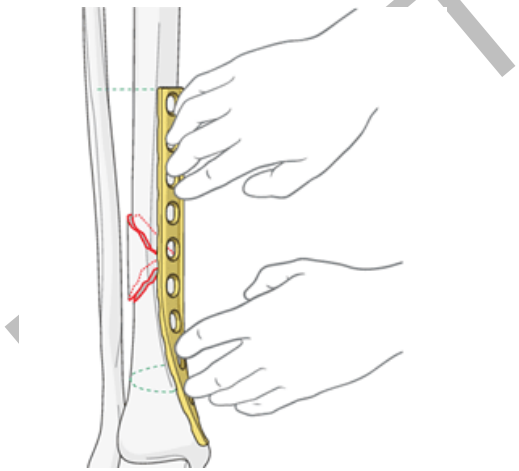
	Picture	
	Length	100mm, 120mm, 140mm
	Diameter	1.6mm, 2mm, 2.5mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1

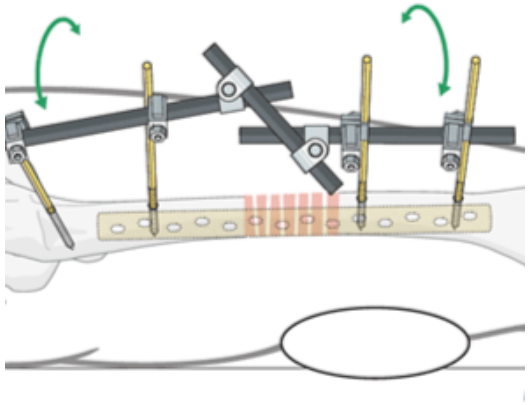
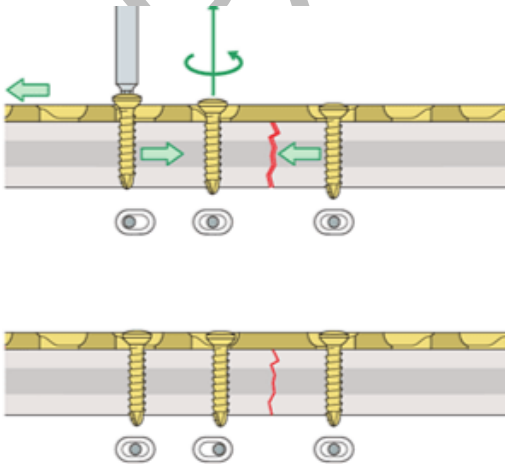
4.	**Device Name**	Washer For Large Fragment Screw
	Picture	
	Diameter	4.5mm to 7mm
	Directional Configuration	Not applicable
	Material Specification	Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3

Other details of the Femur plate System:

Device Compliance to regulation		We are proposing the Femur 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 Femur plate System
	General Description	Auxein's Femur Plate System is designed to fix, stabilize and restore the epiphyseal, metaphyseal and diaphyseal fracture of the femur bone. The Femur Plate System offers a variety of bone screws and plate with different shapes and sizes i.e. locking screws, Non-locking screw, AV-Wiselock, Wise-lock & non-locking plates, which can be rigidly locked into a variety configurations, tailor-made for the individual case.
	Intended Purpose	The Femur plate system is intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of Femur bone fragments.
	Intended Users	The Femur plate system is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Skeleteally mature Male and female subjects between 18-55 years of age with Proximal, shaft & Distal fractures of femur/Articular fractures/Osteotomies, Malalignment/Non-unions, Mal-union.
	Medical Conditions to be diagnosed, treated and/or monitored	The Femur Plate System is used to treat Femur bone fractures or non-union. Specifically designed Femur plate intended for treatment of fractures that provides strong fixation and restores the bone fragments.
	Patient Selection Criteria	Inclusion Criteria: Patient data files will be screened for following Inclusion criteria: 1. Subject is willing and able to give informed consent for participation in the study.

		2. Male and female above 18 years to 55year skeletally mature patients. 3. Subject with Femoral Neck Fracture of III and IV class (Garden Classification) schedule for FNF surgery. Exclusion Criteria: Patient data files will be screened for following; 1. Pathological fractures,open fractures or other fractures including poly- trauma, stress fractures of the femoral neck 2. Local infection in the hip joint before the fixation surgery. 3. Patient with previously diagnosed osteoporosis. 4. Fracture-dislocation of the femoral neck and hip joint. 5. Likely problems, in the judgement of the attending surgeon, with maintaining follow up. 6. Patients with severe mental disorders and psychotropic drug addictions. 7. Pregnancy.
c.	Principles of Operation	Femur 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 femur plate system aims for restoration of bone anatomy by stabilizing the fracture and provides temporarily supporting loads while the fracture heals. The proper fixation of the plate preserves the blood supply and early immobilization of bone union by following surgical technique provided by the manufacturer.

	Mode of Action	The plate fixed to the bone, exerts compression, bending forces. Locking of the plate by employing screws along its shaft prevents fixation failure between the bones. The plate fixed with this approach maintains anatomical stabilization and anatomical reduction of the fractured bone and promotes the bone's healing.
	Scientifically demonstration of Principle of Operation	Step 1: Angular stability  Step 2: Rotational stability

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

	Medical device	'Medical Device' means any instruments, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: *Thus, Femur plate system is an implant used in humans for medical purposes to treat Femur 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 Femur plate system is an implant used for the treatment of Femur 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 injuryor disability- **Applicable** ***Rationale for Applicability*** The Femur plate is an implantable device used for the treatment of Femur 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 Femur plate is intended to treat Femur 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*** Femur plate is made up of metal alloy and employed to fix Femur 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 Femur 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 Femur plate system is used to stabilize Femur fracture. This device is not for the control or support of conception. f) Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article1(4) and of thosereferred to in the first paragraph of this point-**Not Applicable**

		Rationale for Non Applicability The Femur plate system is intended for fixation for fractures of the Femur bone. The system is not meant for cleaning, disinfection or sterilization of device.
e.	Novel Features	The Femur 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 Femur plate System comprises of : ● Screws ● Washer The Femur plate System is clinically improved by using Internal Fixation with Angular Stability (Internal Fixators) in complicated fractures and in Osteopenic Bone. **The description of the components used with Plate to fix the fracture enlisted below.** ***Screw*** ○ It is intended to be used for the implantation of any type of internal Orthopedic Fixation System. ○ It is used for internal orthopaedic fracture fixation by being screwed into bone to hold Plate with femur bone. ○ In the Femur plate system various types of screws are included like cortical, Cancellous, Wise-Lock and Av-wiselock screw.

		Washer ○ It is intended to distribute the load of screw during the tightening and prevent slipping of screw.
g.		
	Sterility	All Products covered in Femur 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 Femur 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 Femur plate System are Bio-compatible. Biocompatibility of the devices is tested as per ISO 10993 series of International Standard.
	MRI Compatibility	The Femur plate system has not been evaluated for safety and compatibility in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic Resonance Imaging) environment.
1.2	Reference to Previous and Similar Generations of the device	
a.	CE Mark (Legacy device)	CE Approved by **DNV (2460)** under MDD 93/42/EEC **Initial Certificate No.** 4825-2014-CE-IND-NA **Re certification Certificate No.**: 10000363901-PA-NA-IND Rev 2

	USFDA Approved	Yes (DCS & DHS Plate) **510(k) Number:** K221787
b.	Similar devices available in Union or international market.	The Similar devices available in the Union or International Market are listed below: a. Synthes USA Condylar Buttress Plate 4.5mm Left/Right. b. LCP Distal Femur Plate Synthes. c. Synthes USA 4.5mm cortex screw d. (Double Medical) Cable Grip Locking Plate, Left/Right e. Synthes USA LCP Plate 4.5mm/5mm, Broad Curved.

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

Comparison Table:

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

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

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

Residual risks and undesirable effects

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

- Implant damage (fracture, deformation or detachment).
- Early or late loosening or displacement of the implant from the initial place of insertion.
- Possibility of corrosion due to, contact with other materials.
- Body reaction to implants as foreign bodies e.g. possibility of tumor metaplasia, autoimmune disease and/or scarring.
- Compression on the surrounding tissue or organs.

- Infection.
- Bone fractures or “stress shielding” phenomenon causing loss of bone above, below or at the operative site.
- Hemorrhage of blood vessels and /or hematomas.
- Pain.
- Metal sensitivity
- Inability to perform everyday activities.
- Deep vein thrombosis, thrombophlebitis.
- Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary.
- Scar formation that could cause neurological impairment, or nerves compression and /or pain.
- Late bone fusion or no visible fusion mass and pseudoarthrosis.
- Loss of proper curvature and/or length of bone.

Warning & Precautions:

- Demonstrates anatomical or physiological anomalies.
- The patient should be informed that the life expectancy of the device is unpredictable and once implanted, successful results cannot be guaranteed if adequate care and precautions are not taken.
- While inserting the screw, it is essential to set the screwdriver in relation to the screw correctly. Following the instructions given allows for reduction of the risk of mechanical damage to the screw, screwdriver, or bony hole:
  - screwdriver should be set on the screw axis.
  - apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible.
  - the final phase of tightening shall be performed carefully.
- Has immunological response, sensitization or hypersensitivity for foreign materials.
- Do Not Re-Use. Do not re-process. The device is not designed for re-processing. Reuse of the medical device intended for single use devices may lead to infection, degraded performance or a loss of functionality. The cleaning and disinfection / sterilization for re-processing of these single use

devices has not been validated nor is any authentic information available. So re-process of the single use device is not allowed.

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

Safety and Performance Parameters:

- Fracture healing/union time
- Measure the VAS
- Hip Harris Score (HHS) Outcome
- Record of any adverse event, serious adverse event and complication

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

Retrospective data of the subject and similar device for safety and performance is assessed.

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

The clinical data available was Retrospectively analyzed. The research paper, which was published by surgeon includes 46 patients' (from 1 Clinical

Papers, Detail given below in the table). These all patients have femoral fracture and were treated using Auxein's Femur Plate System. From the analysis of the data it is found that there is no safety and performance concerns regarding the use of device. There were no complications noticed related to Femur Plate System in literature and hardware related complications were also not encountered.

S.No.	Clinical Paper Title	Injury Type	Implant Used	Patients	Complications, if any
1.	Hans. De Monsef, A comparison of clinical outcomes between narrow and broad dynamic compression plate for femur fractures	Femur bone fracture	4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts with LC under cuts and 4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate	46 Patients (24 wise-lock narrow dynamic compression plates and 22 broad dynamic compression plates)	No Complication was reported
2.	Canadian Orthopaedic Trauma Society, Are Locking Constructs in Distal Femoral Fractures Always Best? A Prospective Multicenter Randomized Controlled Trial Comparing the Less Invasive Stabilization System With the Minimally Invasive Dynamic Condylar Screw System.	Distal femoral fracture	Distal Femur Plate(LISS) Plate, Synthes, Paoli, PA)	52 patients (28 LISS Plate and 24 DCS Plate)	7 reoperations in the LISS group and one in the DCS group
3.	Hanschen, Marc et al., Mono-versus polyaxial locking plates in distal femur fractures: a prospective	Distal Femur Fracture	Distal Femur Plate(LISS) Plate, Synthes, Paoli, PA)	27 patients (8 male, 19 female; 15 NCB®-DF, 12 LISS®).	No Complications

	randomized 84pprox.84c84c clini trial.				
4.	Shin Young-Soo et al., Periprosthetic fracture around a stable femoral stem treated with locking plate osteosynthesis: distal femoral locking plate alone versus with cerclage cable.	Distal Femur Fracture	Reverse distal femoral locking plate (LCP DFÒ)	21 patients	No Complications
5.	Ebraheim Nabil A et al. Treatment of Distal Femur Nonunion Following Initial Fixation with a Lateral Locking Plate	Distal Femur Fracture	Synthes LCPs for the distal femur	14 patients	iliac crest bone grafting, superfi-cial wound infections
6.	Hodel Sandro et al., Complications following proximal femoral locking compression plating in unstable proximal femur fractures: medium-term follow-up.	Proximal Femur frcture	Proximal femoral locking compression plate (PF-LCP 4.5/5.0, Synthes)	16 patients	Inadequate reduction, non-union, Malrotation, Late implant-associated infection, Distal screw fractures
7.	Imerci Ahmet et al., Nailing or plating for subtrochanteric femoral fractures: a non-randomized comparative study.	Subtrochanteric femoral fracture	Reverse LISS-DF plating (Synthes_, Oberdof, Switzerland)	31 Patients (PFNA group consisted of 16 patients, and the reverse LISS-DF plate group consisted of 15 patients)	No Complications
8.	Weng Chun-Jui et al., Comparison of supraintercondylar and	supraintercondyar and supracondylar	Condylar Buttress Plates (Synthes, Bettlach,	87 Patients	Infection, Stiffness, Varus deformity

	supracondylar femur fractures treated with condylar buttress plates.	femur fractures	Switzerland)		

6. Possible diagnostic or therapeutic alternatives.

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

Non-surgical Treatment

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

Surgical Treatment

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

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

Note:

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

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

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

7. Suggested profile and training for users.

The intended user (surgeon) should be well-qualified and must have gained sufficient training regarding the use of the device and should have experience in trauma surgery. The training materials i.e Surgical Technique, Instructions for Use, 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 Femur plating System:

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

10.	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
11.	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
12.	EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
13.	EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020).
14.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021).
15.	ISO/TR 10993-33:2015	Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3.
16.	EN ISO 14644-1:2015	Clean-rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
17.	EN ISO 14644-2:2015	Clean-rooms and associated controlled environments - Part 2: Monitoring to provide evidence of clean-room performance related to air cleanliness by particle concentration.
18.	EN ISO 14644-3:2019	Clean-rooms and associated controlled environments - Part 3: Test Methods.
19.	EN ISO 14644-4:2022	Clean-rooms and associated controlled environments - Part 4: Design, construction and start-up.
20.	EN ISO 14644-5:2004	Clean-rooms and associated controlled environments - Part 5: Operations
21.	EN ISO 14644-7:2004	Clean-rooms and associated controlled environments - Part 7: Separative

		devices (clean air hoods, glove boxes, Isolators and mini).
22.	EN ISO 14644-8 :2022	Clean-rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC).
23.	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
24.	EN ISO 14644-9 :2022	Clean-rooms and associated controlled environments – Part 9: Classification of surface cleanliness by particle concentration.
25.	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
26.	EN ISO 11607-1:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
27.	EN ISO 11607-2:2020/A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
28.	EN ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
29.	EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
30.	EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

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

44.	ASTM F88	Standard Test Method for Seal Strength of Flexible Barrier Materials
45.	ISO 19227:2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements
46.	MDCG 2021-24	Guidance on classification of medical devices
47.	MDCG 2020-8	Guidance on PMCF evaluation report template
48.	MDCG 2020-7	Guidance on PMCF plan template
49.	MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
50.	MDCG 2020-5	Guidance on clinical evaluation – Equivalence
51.	MDCG 2019-9, Rev.01	Summary of safety and clinical performance
52.	MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
53.	MDCG 2021-11	Guidance on Implant Card –'Device types'
54.	MDCG 2019-8 v2	Guidance document implant card on the application of Article 18 Regulation (EU) 2017/745 on medical devices
55.	MDCG 2022-9	Summary of safety and performance template
56.	MDCG 2019-14	Explanatory note on MDR codes
57.	MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
58.	MDCG 2018-1, Rev.04	Guidance on BASIC UDI-DI and changes to UDI-DI
59.	MDCG 2021-25	Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
60.	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation

		(EU) 2017/745 - December 2022
61.	MEDDEV 2.7/1 revision 4, 2016	Clinical Evaluation: A guide for manufacturers and notified bodies.
62.	EU MDR 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017.

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
00	13-03-2024	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)
			☐ 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: 27-05-2024

Device identification and general information

Device Trade Name: Auxein Femur 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: 08903993FPS011L8 (For Stainless Steel Implants) and 0890399FPT011UC (for Titanium Implants)

Year when the device was first CE-marked: 2014

Intended use of the device

Intended Purpose	The Femur Plate is intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of Femur bone fragments.
Indications of Use	The Femur plate System is part of the Femur Bone has the following indications: **4.5/5.0mm AV-Wiselock Condylar Femur Plate** - Buttressing of multifragmentary distal femur fractures - Supracondylar fractures - Intra-articular and extra-articular condylar fractures - Malunions and nonunions of the distal femur - Periprosthetic fractures - Osteotomies of the femur - Osteopenic bone

	4.5/5.0mm AV-Wiselock Distal Femur Plate - Distal shaft fractures - Supracondylar fractures - Intra-articular fractures - Periprosthetic fractures **5.0mm Wise-Lock Cable Prosthesis and Revision Femur Plate** - Trochanteric osteotomy - Extended trochanteric osteotomy - Trochanteric fracture - Periprosthetic long bone fractures - Comminuted long bone fractures - Fractures in osteopenic bone **5.0mm Wise-Lock Cable Straight Plate** - Trochanteric osteotomy - Extended trochanteric osteotomy - Trochanteric fracture - Periprosthetic long bone fractures - Comminuted long bone fractures - Fractures in osteopenic bone **4.5/5.0mm Wise-Lock Distal Femur Plate**

	Buttressing of multifragmentary distal femur fractures, Supracondylar fractures, Intra-articular and extra-articular condylar fractures, Malunions and nonunions of the distal femur Periprosthetic fractures **4.5/5.0mm Wise-Lock Condylar Femur Plate** Buttressing of multifragmentary distal femur fractures, Supracondylar fractures, Intra-articular and extra-articular condylar fractures, Malunions and nonunions of the distal femur Periprosthetic fractures, Osteopenic bone. **4.5/5.0mm Wise-Lock Proximal Femur Plate** - Fractures of the trochanteric region, trochanteric simple, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric reversed or transverse or with additional fracture of the medial cortex - Fractures of the proximal end of the femur combined with ipsilateral shaft fractures - Metastatic fracture of the proximal femur - Osteotomies of the proximal femur - Also for use in fixation of osteopenic bone and fixation of nonunions or malunions **4.5/5.0mm Wise-Lock Proximal Femur Hook Plate** - Intertrochanteric reversed or transverse or with additional fracture of the medial cortex. - Fractures of the proximal end of the femur combined with ipsilateral shaft fractures - Metastatic fracture of the proximal femur - Osteotomies of the proximal femur

	- Also for use in fixation of osteopenic bone and fixation of nonunions or malunions **4.5/5.0mm Wise-Lock Proximal Femur Lateral Plate (Type-II)** - Fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, reversed or transverse fractures of the trochanteric region or with additional fracture of the medial cortex. - Fractures of the proximal end of the femur combined with ipsilateral shaft fractures. - Metastatic fracture of the proximal femur - Osteotomies of the proximal femur - Also for use in fixation of osteopenic bone and fixation of nonunions or malunions Periprosthetic Fractures **4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts** Indicated for fixation of various long bones, such as the femur and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients. **4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate with LC under cuts** Indicated for fixation of various long bones, such as the femur and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients. **4.5/5.0mm Wise-Lock Curved Broad Plate** The 4.5/5.0mm Wise-Lock Curved Broad Plate is indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones such as femur. **4.5/5.0mm Wise-Lock Osteotomy Lateral Distal Femur Plate**

	- Open-wedge and closed-wedge osteotomy of the lateral distal femur for the treatment of: - Unicompartmental medial or lateral gonarthrosis with malalignment of the distal femur. - Idiopathic or post-traumatic varus or valgus deformity of the distal femur. **4.5/5.0mm Wise-Lock Osteotomy Medial Distal Femur Plate** - Closed-wedge osteotomies of the medial distal femur for the treatment of: - Unicompartmental lateral gonarthrosis with valgus malalignment of the distal femur - Idiopathic or posttraumatic valgus deformity of the distal femur - Additional fixation for complex distal femoral fractures **5.0mm Wise-Lock Distal Femur Plate (LISS)** Indicated for the stabilization of fractures of the distal femur. These include: - Distal shaft fractures - Supracondylar fractures - Intra-articular fractures - Periprosthetic fractures **5.0mm Wise-Lock Femoral Neck Plate** Femoral neck fractures (AO type 31-B) **Wise-Lock DHS Plate** - Pertrochanteric fractures of type 31-A1 and 31-A2 - Intertrochanteric fractures of type 31-A3 - Basilar neck fractures 31-B

Wise-Lock DHS Plate, Short Barrel

- Pertrochanteric fractures of type 31-A1 and 31-A2
- Intertrochanteric fractures of type 31-A3
- Basilar neck fractures 31-B

95° Wise-Lock DCS Plate

- Proximal femur: Very proximally located, purely sub-trochanteric fractures of types 32-A and 32-B
- Distal femur: Fractures of type 33-A (extra-articular, supracondylar) and fractures of type 33-C (fully articular fractures)

4.5/5.0mm Wise-Lock Trochanter Stabilizing Plate for DHS – Adjustable

Unstable pertrochanteric fractures of type 31-A2 and 31-A3, especially multifragmentary fractures with a separated or longitudinally split greater trochanter

130°/135°/140°/145°/150° Dynamic Hip Compression Plate

- Pertrochanteric fractures of type 31-A1 and 31-A2
- Intertrochanteric fractures of type 31-A3
- Basilar neck fractures 31-B

135° Dynamic Hip Compression Plate, Short Barrel

- Pertrochanteric fractures of type 31-A1 and 31-A2
- Intertrochanteric fractures of type 31-A3
- Basilar neck fractures 31-B

	95° DCS Plate - Intercondylar fracturesUnstable pertrochanteric fractures of type 31-A2 and 31-A3, especially multifragmentary fractures with a separated or longitudinally split greater trochanter - Supracondylar fractures - Unicondylar fractures **95° Condylar Blade Plate** Fractures and revisions of the proximal and distal third of the femur in skeletally mature patients. **130° Angle Blade Plate** Fractures and revisions of the proximal third of the femur in skeletally mature patients **Angle Blade Plate for Adults** Unstable pertrochanteric fractures of type 31-A2 and 31-A3, especially multifragmentary fractures with a separated or longitudinally split greater trochanter **Angle Blade Plate for Intertrochanteric - Femoral Osteotomies in Adults** Unstable pertrochanteric fractures of type 31-A2 and 31-A3, especially multifragmentary fractures with a separated or longitudinally split greater trochanter **4.5mm Narrow Dynamic Compression Plate** indicated for fixation of: - Various long bones, such as the femur. - Peri-prosthetic fractures and fractures in osteopenic bone

	- Nonunions or malunions in adult patients **4.5mm Narrow Limited Contact Dynamic Compression Plate** **indicated for fixation of:** - Various long bones, such as the femur. - Peri-prosthetic fractures and fractures in osteopenic bone - Nonunions or malunions in adult patients **4.5mm Broad Dynamic Compression Plate** indicated for fixation of: - Various long bones, such as the femur. - Peri-prosthetic fractures and fractures in osteopenic bone - Nonunions or malunions in adult patients **4.5mm Broad Limited Contact Dynamic Compression Plate** indicated for fixation of: - Various long bones, such as the femur. - Peri-prosthetic fractures and fractures in osteopenic bone - Nonunions or malunions in adult patients **4.5mm Narrow Lengthening Plate** These Plates are indicated to fix fractures, non-union and malunion of femur bone. **4.5mm Broad Lengthening Plate** These Plates are indicated to fix fractures, non-union and malunion of femur bone.

	4.5mm Condylar Buttress Plate Indicated to be used for buttress comminuted supracondylar fractures of femur bone **4.5mm Cobra Head Plate** Use to treat fractures of femur head bone. **4.5mm Proximal Femur Plate** 4.5mm Proximal Femur Plate is indicated to treat fractures of the femur including: - Fractures of the trochanteric region, trochanteric simple, trochanterodiaphyseal, multifragmentary pertrochanteric, interotrochanteric reversed or transverse or with additional fracture of the medial cortex. - Metastatic fracture of the proximal femur. - Fracture of the proximal end of the femur combined with ipsilateral shaft fractures. - Osteotomies of the proximal femur. - Fixation of osteopenic bone and fixation of nonunions or malunions. **4.5mm Distal Femur Plate** 4.5mm Distal Femur Plate is indicated to fix fractures of distal femur with or without involvement of the joints. **130°/135° Jewett Nail Plate** - Pertrochanteric fractures of type 31-A1 and 31-A2 - Intertrochanteric fractures of type 31-A3 - Basilar neck fractures 31-B
Contraindications	The implant should not be used in a patient 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	Skeleteally mature Male and female subjects between 18-55 years of age with Proximal, shaft & Distal fractures of

	femur/Articular fractures/Osteotomies, Malalignment/Non-unions, Mal-union.

Device description

The femur bone plates are used for treating the fractures of proximal, distal and shaft femoral fractures. These plates help to align the fractured bone fragments together with the help of screws and other components. The femur plate system consist of variety of bone screws and plates with different shapes and sizes i.e. locking screws, Non-locking screw, AV-Wiselock, Wise-lock & non-locking plates types of bone plates which can be rigidly locked into a variety configurations, tailor-made for the individual case. The details regarding femur plate system and screws can be found at **www.auxein.com**.

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

Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Femur Plate System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev 2
Material/substances in contact with patient tissues	The Material/substances that comes in contact with patient tissues used are Titanium alloy Ti-6AL-4V as per EN ISO 5832-3:2021 and Stainless steel alloy SS 316 L as per EN ISO 5832-1:2019.		
USFDA Cleared	Yes (DCS & DHS Plate) **510(k) Number:** K221787		
Risk Class	IIb (According to the EU Regulation 2017/745 (MDR) Annex VIII Rule 8)		
Authorized Representative Name and Address	Name: CMC Medical Devices & Drug S.L Address: 29015 Málaga, Spain		
Notified Body Name and Single Identification Number	Name: DNV Product Assurance AS		

	Single Identification Number: 2460

Principle of operation

Femur 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 femur 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.

Description of Key functional elements

The Femur plate System comprises of :

- Screws
- Washer

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

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

Screw

- It is intended to be used for the implantation of any type of internal Orthopedic Fixation System.

- It is used for internal orthopaedic fracture fixation by being screwed into bone to hold Plate with femur bone.
- In the Femur plate system various types of screws are included like cortical, Cancellous, Wise-Lock and Av-wiselock screw.

Washer

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

Risks and Warnings

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

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

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

- Implant damage (fracture, deformation or detachment).
- Early or late loosening or displacement of the implant from the initial place of insertion.
- Body reaction to implants as foreign bodies e.g. possibility of tumor metaplasia, autoimmune disease and/or scarring.
- Compression on the surrounding tissue or organs.
- Infection.
- Bone fractures or “stress shielding” phenomenon causing loss of bone above, below or at the operative site.
- Hemorrhage of blood vessels and /or hematomas.
- Pain.
- Metal sensitivity
- Inability to perform everyday activities.
- Deep vein thrombosis, thrombophlebitis.

- Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary
- Scar formation that could cause neurological impairment, or nerves compression and /or pain.
- Late bone fusion or no visible fusion mass and pseudoarthrosis.
- Loss of proper curvature and/or length of bone.

Warning & Precautions:

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

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

and limitations.

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

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

Till now, regarding Auxein's Femur 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 femur bone is the longest, strongest bone of the body that is present in the thigh. It occupies the space of the lower limb, between the hip and the knee joints. The anatomy of the femur is unique with two round ends and a long shaft in the middle that supports the numerous muscular and ligamentous attachment within this region. Proximally, the femur articulates with the pelvic bone. Distally, it interacts with the patella and the proximal aspect of the femur. It's main function is to provide body support that helps in the movement, stability in standing and maintains the body balance.

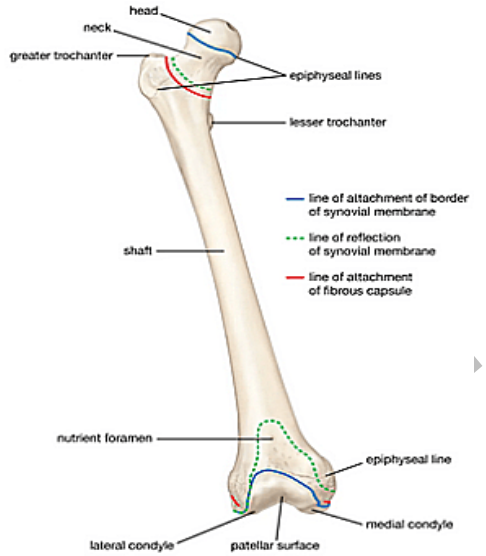


Figure: Femur bone anatomy

Types of Femur Fracture

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

Causes

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

Symptoms:

- Dull, gnawing pain in the groin or thigh

- Pain when putting weight on the leg
- Severe Pain
- Pain when lifting the leg or with movement

Diagnosis

The risk factors for a Femur fracture or any prior injury then there will be a physical examination as includes:

- bruises, especially with lots of blueness and swelling
- instability when walking
- tenderness
- any obvious deformities, such as an abnormal bend or shortening of your leg
- any associated injury to your fibula

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

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

- X-rays- To have an image of the Femur
- CT scan- CT scan is also called a CAT scan, which is more powerful than an X-ray and gives a 3-D image of the bone.
- MRI scan-For a detailed image of the muscles, ligaments, and bones around the Femur.

Pain Management

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

Rehabilitation and Return to Activity

Most people return to all their former activities after a fracture. The nature of the injury, the treatment received, and the body's response to the treatment all have an impact, so the answer is different for individual. Most patients will have some stiffness in the wrist. This will generally lessen in the month or

two after the cast is taken off or after surgery, and continue to improve for at least 2 years. If the doctor thinks it is needed, the patient will start physical therapy within a few days to weeks after surgery, or right after the last cast is taken off.

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

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

Retrospective data of the subjective and similar device for safety and performance is assessed.

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

The clinical data available was Retrospectively analyzed. The research paper, which was published by surgeon includes 46 patients' (from 1 Clinical Papers, Detail given below in the table). These all patients have femoral fracture and were treated using Auxein's Femur Plate System. From the analysis of the data it is found that there is no safety and performance concerns regarding the use of device. There were no complications noticed related to Femur Plate System in literature and hardware related complications were also not encountered.

S.No.	Clinical Paper Title	Injury Type	Implant Used	Patients	Complications, if any
1.	Hans. De Monsef, A comparison of clinical outcomes between narrow and broad dynamic compression plate for femur fractures	Femur bone fracture	4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts with LC under cuts and 4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate	46 Patients (24 wise-lock narrow dynamic compression plates and 22 broad dynamic compression plates)	No Complication was reported
2.	Canadian Orthopaedic Trauma	Distal femoral	Distal Femur Plate(LISS)	52 patients (28 LISS	7 reoperations in the LISS

	Society, Are Locking Constructs in Distal Femoral Fractures Always Best? A Prospective Multicenter Randomized Controlled Trial Comparing the Less Invasive Stabilization System With the Minimally Invasive Dynamic Condylar Screw System.	fracture	Plate, Synthes, Paoli, PA)	Plate and 24 DCS Plate)	group and one in the DCS group
3.	Hanschen, Marc et al., Mono-versus polyaxial locking plates in distal femur fractures: a prospective randomized 111pprox.111c111c cl trial.	Distal Femur Fracture	Distal Femur Plate(LISS) Plate, Synthes, Paoli, PA)	27 patients (8 male, 19 female; 15 NCB®-DF, 12 LISS®).	No Complications
4.	Shin Young-Soo et al., Periprosthetic fracture around a stable femoral stem treated with locking plate osteosynthesis: distal femoral locking plate alone versus with cerclage cable.	Distal Femur Fracture	Reverse distal femoral locking plate (LCP DFÒ)	21 patients	No Complications
5.	Ebraheim Nabil A et al. Treatment of Distal Femur Nonunion Following Initial Fixation with a Lateral Locking Plate	Distal Femur Fracture	Synthes LCPs for the distal femur	14 patients	iliac crest bone grafting, superfi-cial wound infections
6.	Hodel Sandro et al., Complications following proximal femoral locking	Proximal Femur frcture	Proximal femoral locking compression plate (PF-	16 patients	Inadequate reduction, non-union, Malrotation, Late

	compression plating in unstable proximal femur fractures: medium-term follow-up.		LCP 4.5/5.0, Synthes)		implant-associated infection, Distal screw fractures
7.	Imerci Ahmet et al., Nailing or plating for subtrochanteric femoral fractures: a non-randomized comparative study.	Subtrochanteric femoral fracture	Reverse LISS-DF plating (Synthes_, Oberdof, Switzerland)	31 Patients (PFNA group consisted of 16 patients, and the reverse LISS-DF plate group consisted of 15 patients)	No Complications
8.	Weng Chun-Jui et al., Comparison of supraintercondylar and supracondylar femur fractures treated with condylar buttress plates.	supraintercondyar and supracondylar femur fractures	Condylar Buttress Plates (Synthes, Bettlach, Switzerland)	87 Patients	Infection, Stiffness, Varus deformity

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

Non-surgical Treatment

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

Surgical Treatment

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

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

Note:

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

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

Non-Surgical Treatment	Surgical Treatments
Cast	• Intramedullary Nail • Plate and screws.

	• An external fixation (a stabilizing frame outside the body that holds the bones in the proper position so they can heal). • Any combination of these techniques.

Suggested training for users

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