SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR FEMUR NAILING SYSTEM

Table of Contents

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

Basic UDI-DI: 08903993FNT002KQ for Titanium Implants and 08903993FNS002KH for Stainless Steel Implants.

SRN: IN-MF-000018837

The Femur Nailing System includes the following variants as listed below:

AJAX ADVANCE NAIL

130° AJAX Advance Nail, Short, Titanium, 130° AJAX Advance Nail, Long, Left/Right, Titanium, AJAX 4.9mm Locking Bolt, Self-Tapping, Titanium, AJAX Blade, Titanium, AJAX Nail End Cap (For Ajax Blade), Titanium, AJAX Nail End Cap (For Cephalic Screw), Titanium, Inner Screw for Ajax Cephalic Screw, Titanium, End Cap for Ajax Cephalic Screw, Titanium.

EXPERT FEMUR NAIL

Expert Femur Nail, Left/Right, Stainless Steel/Titanium, End Caps For Expert Femur Nail, Stainless Steel/Titanium, Ø4.8mm Locking Bolt, Self-Tapping, For Expert Femur Nail, Stainless Steel/Titanium, Ø6.4mm Cannulated Anti-Rotation Screw, Self-Tapping, For Expert Femur Nail, Stainless Steel/Titanium.

ATHOS NAILING SYSTEM

125° Athos Nail Type-II, Short, Stainless Steel/Titanium, 125° Athos Nail Type-II, Long, Left/Right, Stainless Steel/Titanium, 130° Athos Nail Type-II, Short, Stainless Steel/Titanium, 130° Athos Nail Type-II, Long, Left/Right, Stainless Steel/Titanium, End Cap For Athos Nail Type-II, Stainless Steel/Titanium, Inner Screw For Athos Nail Type-II, Stainless Steel/Titanium, End Cap For Ø10.5mm Cephalic Screw For Athos Nail, Stainless Steel/Titanium, Ø4.8mm Locking Bolt, Self-Tapping, For Athos Nail, Stainless Steel/Titanium, 125° Anti-Rotation Athos Nail, Short, Stainless Steel/Titanium, 125° Anti-Rotation Athos Nail, Long, Left/Right, Stainless Steel/Titanium, 130° Anti-Rotation Athos Nail, Short, Stainless Steel/Titanium, 130° Anti-Rotation Athos Nail, Long, Left/Right, Stainless Steel/Titanium, End Cap For Anti-Rotation Athos Nail, Stainless Steel/Titanium, Inner Screw For Anti-Rotation Athos Nail-Long (For Cephalic Screw), Stainless Steel/Titanium, Inner Screw For Anti-Rotation Athos Nail-Short (For Anti-Rotation Screw), Stainless Steel/Titanium, Ø6.4mm Cannulated Anti-Rotation Screw for Athos Nail, Stainless Steel/Titanium, Ø10.5mm Cephalic Screw, For Athos Nail, Stainless Steel/Titanium, End Cap For Ø10.5mm Cephalic Screw For Athos Nail, Stainless Steel/Titanium, Ø4.8mm Locking Bolt, Self-Tapping, For Athos

Nail, Stainless Steel/Titanium.

JIN TYPE FEMUR NAILING SYSTEM

JIN Type - Femur Nail, Stainless Steel/Titanium, End Cap For JIN Type - Femur Nail, Stainless Steel/Titanium, Ø4.5mm Locking Bolt, Self-Tapping, For JIN Type - Femur Nail, Stainless Steel/Titanium

KONZEPT FEMUR NAILING SYSTEM

Universal Intramedullary Cannulated Femur Nail, Left/Right, Stainless Steel/Titanium, End Cap For Universal Intramedullary Cannulated Femur Nail M10x1, Compression Screw For Universal Intramedullary Cannulated Femur Nail, 4.5mm Locking Bolt For Universal Intramedullary Cannulated Femur Nail, Stainless Steel/Titanium, 6.5mm Cannulated Reconstruction Screw For Universal Intramedullary Cannulated Femur Nail, Stainless Steel/Titanium, 6.5mm Locking Bolt for Universal Intramedullary Cannulated Femur Nail, Full Thread, Stainless Steel/Titanium, 6.5mm Blocking set for Universal Intramedullary Cannulated Femur Nail, Stainless Steel/Titanium

RETROGRADE FEMUR NAILING SYSTEM

Retrograde Femur Nail, Stainless Steel/Titanium, 5.0mm Locking Screw For Retrograde Femur Nail, Stainless Steel/Titanium, End Cap For Retrograde Femur Nail, Stainless Steel/Titanium

Details Regarding the device are provided in below table:

Device Trade Name:	**Femur Nailing 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
CE Mark (Legacy device)	CE Approved by **ITC (1023)** under MDD 93/42/EEC **Initial Certificate No.** 09 0394 QS/NB CE Approved by **DNV (2460)** under MDD 93/42/EEC **Re Certificate No.** 4825-2014-CE-IND-NA **Re certification Certificate No.**: 10000363901-PA-NA-IND Rev 2 Extension Letter By **DNV (2460)** **Notified Body Confirmation Letter Reference:** C666881
Year when the first certificate (CE) was issued covering the device	2009
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per EN ISO 5832-3:2021 and Stainless steel alloy SS 316 L as per EN ISO 5832-1:2019.
USFDA Cleared	Yes (Femur Nailing are approved by USFDA whose details are as follow:) **510(k) Number:** K192003, K210792
Risk Class	**IIb (According to the EU Regulation 2017/745 (MDR) Annex VIII Rule 8)** All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: **1.** Are intended to be placed in the teeth, in which case they are classified as class IIa; ***Applicable/Not Applicable:*** *Not Applicable* ***Justification:*** *The devices used for treatment of femoral Bone fractures. Not intended for the 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 devices directly come in contact with the femoral bone so, not intended for 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 device is made up of Medical Grade Metallic Raw Materials Titanium, Stainless Steel alloy. This does not have a biological effect or are wholly or mainly Absorbable.* **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 device is made up of Medical Grade Metallic Raw Materials Titanium, Stainless Steel alloy So, Not intended to undergo chemical change in the body.* **5.** Are intended to administer medicinal products, in which case they are classified as class III; ***Applicable/Not Applicable:*** *Not Applicable* ***Justification:*** *The device is made up of Medical Grade Metallic Raw Materials Titanium, Stainless Steel alloy So, Not intended to administer medicinal products.* **6.** Are active implantable devices or their accessories, in which cases they are classified as class III; ***Applicable/Not Applicable:*** *Not Applicable* ***Justification: 'Active Device'*** *means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.*

	The devices are not Active Implantable Devices as it does not need any Internal or External Energy. **7.** Are breast implants or surgical meshes, in which cases they are classified as class III; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The Implants are used for the treatment of Femur Bone Fracture. Not intended as Breast Implant 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 Devices are used for the treatment of femur bone fracture. Not intended for Total or Partial Joint Replacements.* **9.** Are Spinal Disc Replacement Implants or are implantable devices that come into contact with the Spinal Column, in which case they are classified as class III except components such as screws, wedges, plates and instruments: ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The devices are used for the treatment of Femur bone fractures. Not intended for the Spinal Disc Replacement Implants and this devices that come into contact with the spinal column are classified as class III except components such as screws, wedges, plates and instruments.*
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 Nailing System is part of the Femur Bone has the following indications: **130°AJAX ADVANCE NAIL, SHORT** ● Pertrochanteric fractures (31-A1 and 31-A2) ● Intertrochanteric fractures (31-A3) ● High subtrochanteric fractures (32-A1) **130°AJAX ADVANCE NAIL, LONG** ● Low and extended subtrochanteric fractures ● Ipsilateral trochanteric fractures ● Combination fractures (in the proximal femur) ● Pathological fractures **EXPERT FEMUR NAIL** ● 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1) **ATHOS NAILING SYSTEM** ● Intertrochanteric fractures (31-A3) ● Pertrochanteric fractures (31-A1 and 31-A2) ● Nonunion and malunion **ANTI-ROTATION ATHOS NAIL, SHORT AND LONG** Intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures (31-A1 and 31-A2), intertrochanteric fractures (31-A3), high subtrochanteric fractures (32-A1) and combinations of these fractures,

	including non-union, malunion and tumor resections. **JIN TYPE-FEMUR NAIL** ● 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1) **Universal Intramedullary Cannulated Femur Nail** Intended to treat stable and unstable proximal neck fractures or trochanteric fractures and combinations of these fractures, Femur shaft fracture, distal end fractures **RETROGRADE FEMUR NAIL** ● 33-A1/A2/A3 ● 33-C1/C2/C3 ● 32-A/B/C
Contraindications	The implant should not be used in a patient who has currently, or who has a history of: ○ Any case not described in the indications. ○ Infection local 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. ○ Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops an allergic reaction to the material of the implant. ○ 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 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. ○ Shaft fractures with a fissure less than 5 cm from the nearest interlocking hole of the nail.
Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Femur Nailing System can be used for Skeletally Mature patients with Age group of 18 years or above. The patient conditions and/or pre-dispositions such as those addressed in the contraindications should be avoided.
Intended Users	The Femur Nailing Systems are to be used by well experienced, qualified & specialized trained surgeons only.
Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
Use	For Single Use only
Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
Biocompatibility	The devices covered in the Femur Nailing 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

FEMUR NAILING SYSTEM/AJAX ADVANCE NAIL		
1.	Device Name	130° AJAX Advance Nail, Short

	Image	
	Total Length	170, 200, 240mm
	Nail Diameter	Ø9, Ø10, Ø11, Ø12mm
	Cannulation	4.5mm
	Proximal End Diameter	16.5mm
	End Slot length	10mm
	Directional Configuration (Left & Right)	Not Applicable.
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021.
2.	Device Name	130° AJAX Advance Nail, Long
	Image	
	Total Length	300mm to 420mm (with 20mm increment)
	Diameter	Ø9, Ø10, Ø11, Ø12mm
	Cannulation	4.5mm
	Proximal End Diameter	Ø16.5mm
	End Hole Diameter	5.2mm
	Directional Configuration (Left & Right)	Available for both left and right directions.
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021.

3	Device Name	Ajax Blade
	Image	
	Total Length	75-120 (5mm Increments)
	Blade Length	35mm
	Cannulation	Ø10.50mm
	Diameter	Ø11mm
	Shaft Width	12.10mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021.
4	Device Name	Ajax Cephalic Screw
	Image	
	Length	70-120 (5mm Increment)
	Core Diameter	Ø7.5mm
	Thread Diameter	Ø10.5mm

	Thread Length	22mm
	Head Diameter	Ø10.50mm
	Punch Depth	5mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021.
5	Device Name	4.9mm Locking Bolt for AJAX Nail, Self-Tapping
	Image	
	Length	26-100mm
	Head Length	4.60mm
	Core Diameter	Ø3.90mm
	Thread Diameter	Ø4.90mm
	Head Diameter	Ø8mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021.
6	Device Name	End Cap of Ajax Cephalic Screw

	Image	
	Head Length	4.20mm
	Head Diameter	Ø7mm
	Drill Depth	4mm
	Thread Length	7.5mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021.
7	Device Name	Inner Screw for Ajax Cephalic Screw
	Image	
	Length	24mm
	Head Length	9.6mm
	Head Diameter	Ø8mm
	Shaft Length	14.4mm
	Drill Depth	4.2mm
	Directional Configuration (Left & Right)	Not Applicable

	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021.
8	Device Name	AJAX Nail End Cap (For Ajax Blade)
	Image	
	Length	0, 5, 10, 15mm
	Head Length	4mm
	Head Diameter	Ø13.50mm
	Thread Diameter	Ø12mm
	Thread Length	8mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021.
9	Device Name	Ajax Nail End Cap for Cephalic Screw
	Image	
	Length	0, 5, 10, 15mm
	Head Length	4.0mm
	Head Diameter	Ø13.50mm
	Thread Outer Diameter	12.0mm

	Thread Length	9.6mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021.

FEMUR NAILING SYSTEM/ATHOS NAIL		
10.	Device Name	125° Athos Nail Type-II, Short
	Image	
	Total Length	180, 200, 220, 240mm
	Nail Diameter	Ø9, Ø10, Ø11, Ø12, Ø13mm
	Cannulation Diameter	4.5mm
	Proximal End Diameter	16mm
	Cephalic Screw Insert Angle	125°
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
11.	Device Name	125° Athos Nail Type-II, Long

	Image	
	Total Length	320mm to 440mm (in 20mm Increment)
	Diameter	Ø9, Ø10, Ø11, Ø12, Ø13mm
	Cannulation	4.5mm
	Proximal End Diameter	Ø16mm
	Cephalic Screw Insert Angle	125°
	Directional Configuration (Left & Right)	Available for both left and right directions.
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
12.	Device Name	130° Athos Nail Type-II, Short
	Image	
	Total Length	180, 200, 220, 240mm
	Diameter	9, 10, 11, 12, 13mm
	Cannulation	4.50mm
	Proximal End Diameter	Ø16mm
	End Hole Diameter	5mm

	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
13.	Device Name	130° Athos Nail Type-II, Long
	Image	
	Total Length	320mm to 440mm (in 20mm Increment)
	Diameter	9, 10, 11, 12, 13mm
	Cannulation	4.50mm
	Proximal End Diameter	Ø16mm
	End Hole Diameter	5mm
	Directional Configuration (Left & Right)	Available for both left and right directions.
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
14.	Device Name	End Cap for Athos Nail Type-II
	Image	
	Length	0, 5, 10, 15
	Thread Diameter	10mm

	Thread Length	8mm
	Head Diameter	Ø15.50mm
	Punch Depth	4.50mm
	Punch Width	7mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
15.	Device Name	Inner Screw for Athos Nail-Type-II
	Image	
	Thread Diameter	Ø6mm
	Shaft Diameter	Ø4mm
	Hex Size	3.5mm
	Drill Depth	4.1mm
	Punch Depth	3mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
16.	Device Name	Ø10.5mm Cephalic Screw for Athos Nail

	Image	
	Length	70 to 120 (5mm Increment)
	Core Diameter	Ø7.5mm
	Thread Diameter	Ø10.5mm
	Thread Length	22mm
	Head Diameter	Ø10.50mm
	Punch Depth	5mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
17.	Device Name	End Cap for Ø10.5mm Cephalic Screw for Athos Nail
	Image	
	Head Diameter	Ø12.50mm
	Head Length	5mm
	Thread Length	8.50mm
	Thread Diameter	Ø5mm
	Total Length	18.0mm
	Directional Configuration (Left & Right)	Not Available.

	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
18.	Device Name	4.8mm Locking Bolt, Self-Tapping for Athos Nail
	Image	
	Length	26 to 90mm
	Head Length	4.6mm
	Head Diameter	Ø8mm
	Core Diameter	Ø3.4mm
	Thread Diameter	Ø4.8mm
	Thread Depth	0.70mm
	Thread Pitch	1.75mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.

FEMUR NAILING SYSTEM/ANTI-ROTATION ATHOS NAIL		
19.	Device Name	125° Anti-Rotation Athos Nail, Short

	Image	
	Total Length	180, 200, 220, 240mm
	Distal Diameter	Ø9, Ø10, Ø11, Ø12, Ø13mm
	Cannulation Diameter	4.5mm
	Proximal End Diameter	16mm
	Cephalic Screw Insert Angle	125°
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
20.	Device Name	125° Anti-Rotation Athos Nail, Long
	Image	
	Total Length	320mm to 420mm (in 20mm Increment)
	Distal Diameter	Ø9, Ø10, Ø11, Ø12, Ø13mm
	Cannulation Diameter	4.5mm
	Proximal End Diameter	Ø16mm
	Directional Configuration (Left & Right)	Available for both left and right directions.
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.

21.	Device Name	130° Anti-Rotation Athos Nail, Short
	Image	
	Total Length	180, 200, 220, 240mm
	Diameter	9, 10, 11, 12, 13mm
	Cannulation	4.50mm
	Proximal End Diameter	Ø16mm
	End Hole Diameter	5mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
22.	Device Name	130° Anti-Rotation Athos Nail, Long
	Image	
	Total Length	320mm to 440mm (in 20mm Increment)
	Diameter	Ø9, Ø10, Ø11, Ø12, Ø13mm
	Cannulation	4.50mm
	Proximal End Diameter	Ø16mm

	End Hole Diameter	20mm
	Directional Configuration (Left & Right)	Available for both left and right directions.
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
23.	Device Name	End Cap for Anti-Rotation Athos Nail
	Image	
	Length	0, 5, 10, 15mm
	Thread Diameter	10mm
	Thread Length	8mm
	Head Diameter	Ø15.50mm
	Punch Depth	4.50mm
	Punch Width	7mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
24.	Device Name	Inner Screw for Anti-Rotation Athos Nail-Long (For Cephalic Screw)

	Image	
	Thread Diameter	Ø6mm
	Shaft Diameter	Ø4mm
	Shaft Length	9.80mm
	Drill Depth	4.1mm
	Punch Depth	3mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
25.	Device Name	Inner Screw for Anti-Rotation Athos Nail- Short (For Anti-Rotation Screw)
	Image	
	Thread Diameter	6mm
	Shaft Diameter	4mm
	Hex Size	3.5mm
	Drill Depth	4mm
	Punch Depth	3mm

	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
26.	Device Name	Ø6.4mm Cannulated Anti-Rotation Screw
	Image	
	Length	60 to 130 (5mm Increment)
	Shaft Thread Length	25mm
	Head Diameter	8mm
	Core Diameter	4.50mm
	Cannulation	2.7mm
	Outer Thread Diameter	6.40mm
	Directional Configuration (Left & Right)	Not Available.
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
27.	Device Name	End Cap for Ø10.5mm Cephalic Screw for Athos Nail
	Image	
	Head Length	5mm
	Head Diameter	Ø12.50mm

	Thread Length	8.50mm
	Thread Diameter	Ø5mm
	Total Length	18.0mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.

FEMUR NAILING SYSTEM/EXPERT FEMUR NAIL		
28.	Device Name	Expert Femur Nail
	Image	
	Diameter	9, 10, 11, 12, 13mm
	Total length	320-440 (20mm increment)
	Cannulation	4.50mm
	End Hole Diameter	4.90mm
	Proximal End Diameter	13.5mm
	Directional Configuration (Left & Right)	Available for both left and Right directions.
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
29.	Device Name	End Cap for Expert Femur Nail

	Image	
	Length	0, 5, 10, 15, 20mm
	Head Diameter	10mm
	Head Length	3.2mm
	Thread Length	4mm
	Outer Thread Diameter	8mm
	Inner Thread Diameter	3.5mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
30.	Device Name	Ø4.8mm Locking Bolt, Self-Tapping for Expert Femur Nail
	Image	
	Length	26 to 90mm
	Head Length	4.6mm
	Head Diameter	8mm
	Core Diameter	3.4mm
	Thread Diameter	4.8mm

	Shaft Thread Pitch	1.75mm
	Shaft Thread Depth	0.70mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
31.	Device Name	Ø6.4mm Cannulated Anti-Rotation Screw, Self-Tapping, For Expert Femur Nail
	Image	
	Length	60 to 130mm
	Shaft Thread Length	25mm
	Head Diameter	8mm
	Core Diameter	4.50mm
	Cannulation	2.7mm
	Outer Thread Diameter	6.40mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
32.	Device Name	JIN- Type Femur Nail

	Image	
	Nail Diameter	9, 10, 11, 12, 13mm
	Nail Length	320 to 440mm
	Cannulation Diameter	4.5mm
	Dynamic Hole Length	12mm
	Dynamic Hole Width	5.6mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
33.	Device Name	End Cap for JIN- Type Femur Nail
	Image	
	End Cap Hex Diameter	3.5mm
	Thread Length	11.50mm
	Head Diameter	11.60mm
	Directional Configuration (Left & Right)	Not Applicable

	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
34.	Device Name	Ø4.5mm Locking Bolt, For JIN Type - Femur Nail
	Image	
	Length	20 to 80mm (5mm Increment)
	Core Diameter	Ø3.7mm
	Thread Diameter	Ø4.5mm
	Head Diameter	8mm
	Total Length	20 to 80mm
	Head Length	4.6mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
35.	Device Name	Retrograde Femur Nail
	Image	
	Total Length	180-400mm (20mm Increment)
	Diameter (Ø)	9.5, 10, 11, 12mm
	Cannulation	Ø4.50mm

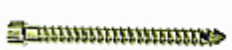
	Proximal End Diameter	Ø12.5mm
	End Hole Distance	24mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
36.	Device Name	5.0mm Locking Screw for Retrograde Femur Nail
	Image	
	Total Length	32-80mm (in 2mm increment)
	Head Outer Diameter	Ø8mm
	Head Length	5.10mm
	Thread Outer Diameter	Ø5mm
	Core Diameter	Ø4mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
37.	Device Name	End Cap for Retrograde Femur Nail
	Image	
	Total Length	13mm

	Head Outer Diameter	Ø8.15mm
	Head Length	5mm
	Thread Outer Diameter	Ø8mm
	Thread Length	5.8mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.

FEMUR NAILING SYSTEM/KONZEPT FEMUR NAIL		
38.	Device Name	Universal Intramedullary Cannulated Femur Nail
	Image	
	Diameter	9, 10, 11, 12, 13, 14
	Length	200 to 480mm (20mm Increment)
	Outer Head Diameter	Ø13.0mm
	Slot Length	10.6mm
	Slot Width	4.60mm
	Thread Outer Diameter	10.3mm
	Hole to Slot Distance	33mm
	Hole Diameter	4.6mm

	Hole to Hole Distance	10mm
	Directional Configuration (Left & Right)	Available for both left and Right directions.
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
39.	Device Name	End Cap for Universal Intramedullary Cannulated Femur Nail
	Image	
	Length	0, 5, 10, 15mm
	Head Length	2.60mm
	Head Diameter	Ø12.90mm
	Thread Length	6.35mm
	Thread Diameter	9.90mm
	Core Diameter	8.6mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
40.	Device Name	Compression Screw for Universal Intramedullary Cannulated Femur Nail
	Image	

	Shaft Length	33.50mm
	Shaft Diameter	4.75mm
	Head Diameter	9.90mm
	Thread Length	11.80mm
	Drill Depth	9.94mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
41.	Device Name	6.5mm Cannulated Reconstruction Screw for Universal Intramedullary Cannulated Femur Nail
	Image	
	Total Length	60-120 (5mm increment)
	Cannulation	6.50mm
	Head Diameter	8mm
	Core Diameter	4.50mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
42.	Device Name	4.5mm Locking Bolt for Universal Intramedullary Cannulated Femur Nail

	Image	
	Length	30-90mm (5mm increment)
	Head Length	4.50mm
	Head Diameter	6mm
	Thread Diameter	4.50mm
	Core Diameter	3.70mm
	Punch Depth	2.5mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
43.	Device Name	6.5mm Locking Bolt for Universal Intramedullary Cannulated Femur Nail, Full Thread
	Image	
	Length	40 to 110mm (5mm Increment)
	Head Length	5.90mm

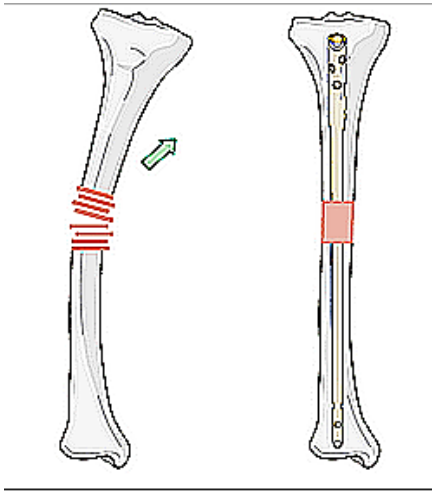
	Head Diameter	Ø8mm
	Thread Diameter	6.50mm
	Core Diameter	Ø4.50mm
	Punch Depth	3.75mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.
44.	Device Name	6.5mm Blocking set for Universal Intramedullary Cannulated Femur Nail
	Image	
	Length	50, 60, 70, 80, 90mm
	Head Length	4mm
	Head Diameter	7.9mm
	Thread Diameter	4.30mm
	Shaft Diameter	6.50mm
	Drill Depth	4mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 Stainless Steel EN ISO 5832-1:2019.

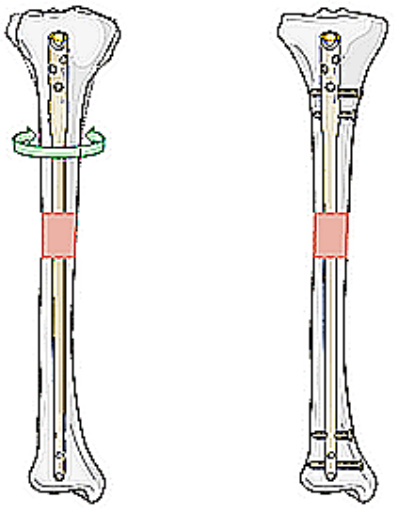
Other details of Femur Nailing System:

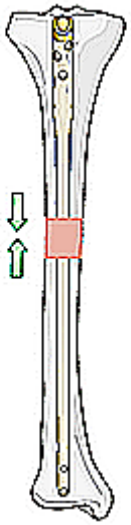
Device Compliance to regulation		We are proposing the Femur Nailing System as per the compliance to European Union Medical Device Regulation (EU MDR 2017/745).
1.	DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES	
1.1	Device Description and Specification	
a.	Product/Trade Name	Auxein Femur Nailing System
	General Description	Auxein's Femur Nailing System is designed to fix, stabilize and restore the proximal, diaphyseal and distal fracture of the femur bone to its natural state. This nailing system consist of left & right nail in addition to the antigrade and retrograde approach to preserve bone physiology. The femur nailing system offers variety of nails with different shapes and size, locking screws, locking bolts, end caps, Ajax Blade, Compression screw, inner screw, cannulated anti- rotation Screw, Cephalic screw and cannulated reconstruction screw which can be rigidly locked into a variety configurations, tailor-made for the individual case. The nails are enlisted below: 1. AJAX Advance Nail 2. Expert Femur Nail 3. Retrograde Femur Nail 4. ATHOS Femur Nail 5. JIN-Type Femur Femur Nail 6. Konzept Femur Nail
	Intended Purpose	The Femur nails are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of femur bone fragments.
	Intended Users	The Femur Nailing System is recommended to be used by only well-trained, certified and experienced surgeons.

b.	Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Femur Nailing System is used for Skeletally Mature patients with Age group of 18 years or above. The patient conditions and/or pre-dispositions such as those addressed in the contraindications should be avoided.
	Medical Conditions to be diagnosed, treated and/or monitored	Femur Nail is used to treat femur bone fracture or non-union. Specifically designed femur nail intended for treatment of fracture that provides strong fixation and restore the bone fragments.
	Patient Selection Criteria	Patient Inclusion Criteria: Male and female subjects aged 18 years or above, who had Comminuted fracture, Segmental fracture, Proximal and distal fracture, Non-unions, Sub-trochanteric fracture, Inter-trochanteric fracture of the femur, and were willing to attend all study visits, were recruited for this study. Before enrolment, written informed consent for participation was obtained from all the study subjects. Patient Exclusion Criteria: Subjects with Isolated or combined medial femoral neck fractures, Low sub-trochanteric fractures, Femoral shaft fractures, Isolated or combined medial femoral neck fractures, and Medial neck fracture were not eligible for participation in the study. Additionally, subjects displaying signs of local inflammation or infection at the operation site were excluded. Those with fever or leukocytosis, neuromuscular disorders that could pose a high risk of fixation failure or complications in postoperative care, any other condition that could hinder the potential benefits of implant insertion surgery and disrupt the normal process of bone remodelling (e.g., the presence of tumors or congenital abnormalities, fractures local to the operating site), elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell (WBC) count, or a marked left shift in the WBC differential count were also excluded. Moreover, subjects with suspected or documented allergy or intolerance to implant materials were not included in the study. Surgeons were required to identify any allergic reactions to the material of the implant (information on the implant material is provided in the IMPLANT MATERIAL section) and

		exclude such subjects from the study.
c.	Principles of Operation	Femur Nailing system works on the AO Principle of Fracture Management. The key concept of fracture management involves: 1. Restoration of anatomy 2. Stable fixation 3. Preservation of blood supply 4. Early mobilization of the limb and patient The Auxein's femur nailing system aims for restoration of bone anatomy by stabilizing the fracture and provides temporarily supporting loads while the fracture heals. The proper fixation of nails preserves the blood supply and early immobilization of bone union by following surgical technique provided by the manufacturer.
	Mode of Action	The nail inserted into medullary cavity of fracture bone exerts longitudinal, transverse and rotational forces. Static locking of nail by employing screws proximally and distally prevent rotation & sliding movements between the bones. The nail fixed with this approach maintains leg length on axial loading, physiological alignment of the system while dynamic locking allow compression of the fracture with weight bearing.

	Scientifically demonstration of Principle of Operation	Step 1: Angular stability  Step 2: Rotational stability

		 Step 3: Longitudinal Stability

		
d.	Rationale for considering as a Medical device	As per Article 2 (1) of EU MDR 2017/745 'Medical Device' means any instruments, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: Thus, femur nail 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 nail 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 injury or disability- Applicable Rationale for Applicability The Femur nail 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 process or state- Not Applicable Rationale for Non Applicability The femur nail is intended to treat femur bone fracture in order to maintain its anatomical state. The nail 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 nail 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.

		Moreover, the device does not achieve its principal intended action by any pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Hence, the femur nailing 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 nailing system 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 Article 1(4) and of those referred to in the first paragraph of this point- Not Applicable Rationale for Non Applicability The femur nailing 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 Nailing System comprises of already existing devices approved in EU market under the regulation MDD 93/42/EEC. Since the device was placed on the market, there are no changes or modifications in device related to raw material, design, manufacturing process (coolants, lubricants, chemicals), intended use, post processing, etc.
f.	Description of key functional elements	The Femur Nailing System comprises of : ● Nails in varying lengths and types ● Screws

		• Locking Bolts • Blade • End caps Nails are used with accessories for implantation in the femur to correct the abnormal curvature. The Femur Nailing 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 nail to fix the fracture enlisted below. End Cap: ○ For axial stabilization and simultaneous protection of soft tissue. ○ Using the end cap makes it easier to extract the nail. ○ The end cap also provides protection against painful soft-tissue irritation. ○ This is intended to prevent nail migration (push-out). ○ It is used to securely lock the most proximal oblique locking screw or help extend the length of a nail. AJAX Blade: ○ It helps in compacting the cancellous bone which provides a better hold especially in case of any osteoporotic bone. Locking Screw: ○ These Locking screws are inserted where the neck of femur has been fractured. ○ Additionally, locking screws may be used as a fixed angle device for short metaphyseal fragments and juxta-articular shaft fractures. ○ Double thread for more contact points leading to enhanced stability. ○ Larger cross-section for improved mechanical resistance. ○ Thread closer to screw head providing better bone purchase and improved stability.

		Locking Bolt: ○ Thread diameter, engages bone and nail for superior holding capacity. ○ Fully-threaded shaft for easier insertion and extraction. ○ Core diameter for greater strength. ○ Low head profile for areas with minimal soft tissue coverage. ○ Self-cutting trocar tip to eliminate tapping Compression Screw: ○ It provides the compression on the proximal section of a fractured bone to close the fracture gap with the distal section which can then be locked into final position. Inner Screw: ○ It is intended to be used for the implantation of any type of an Internal Orthopedic Fixation System. Cannulated Anti-rotation Screw: ○ It is used for internal orthopaedic fracture fixation by being screwed into bone to hold nails with bone. ○ It also provide direct inter-fragmentary stabilization of bone, or it may fasten soft tissue to bone. Cephalic Screw: ○ It helps in compacting the cancellous bone which provides a better hold especially in case of any osteoporotic bone. Cannulated Reconstruction Screw: ○ This screw provides direct inter-fragmentary stabilization of bone, or it may fasten soft tissue to bone.

		○ This is used to obtain compression across bone fragments.
g.		
	Sterility	All Products covered in Femur Nailing System are supplied in either Non-sterile or in Sterile state. The Sterile implants which are placed on the market are sterilized by using Gamma Irradiation Sterilization (SAL 10^{-6}). The Non-Sterile implants which are placed on market are to be sterilized at 121 degree centigrade for 20 minutes (Moist Heat Sterilization/Autoclave Sterilization) as instructed in IFU for Non-sterile devices before implantation.
	Radioactivity	Products covered in Femur Nailing System are metal products and does not emit any ionizing or non-ionizing radiation.
	Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
	Use	For Single Use only
	Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
	MRI Compatibility	The Femur Nails have not been evaluated for safety and compatibility in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic Resonance Imaging) environment.
1.2	Reference to Previous and Similar Generations of the device	
a.	CE Mark (Legacy device)	CE Approved by **ITC (1023)** under MDD 93/42/EEC **Initial Certificate No.** 09 0394 QS/NB CE Approved by **DNV (2460)** under MDD 93/42/EEC **Re Certificate No.** 4825-2014-CE-IND-NA **Re certification Certificate No.**: 10000363901-PA-NA-IND Rev 2

		Extension Letter By **DNV (2460)** **Notified Body Confirmation Letter Reference:** C666881
	USFDA clearance	Yes (Femur Nailing are cleared by USFDA whose details are as follow:) 510(k) Number: K192003, K210792
b.	Similar devices available in Union or international market.	The Similar devices available in the Union or International Market enlisted below: PFNA Nail:- Depuy Synthes Expert LFN:- Depuy Synthes Gamma Nail:- Stryker and Zimmer Expert R/AFN - Depuy Synthes, Stryker, Smith & Nephew Charfix Femur Nail:- Charfix

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

Comparison table:

S.No.	Properties/ Parameter	Titanium bone nail	Stainless steel bone nail	Remark
1.	Biocompatibility	Final finish device of TI bone nail is biocompatible when tested according to ISO 10993-1.	Final finish device of SS bone nail is biocompatible when according to ISO 10993-1.	Both nails are Biocompatible.
2.	Mechanical performance	Final finish device of Ti bone nail mechanically safe tested according to ASTM F1264.	Final finish device of SS bone nail mechanically safe tested according to ASTM F1264.	Both nails are mechanically safe during the mechanical testing.
3.	Clinical performance	Ti bone nail achieved the indented use without any complication and are clinically safe.	SS bone nail achieved the indented use without any complication and are clinically safe.	Both nails 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 nails give the same range of motion but the lighter nail gives more comfort during movement.
5.	Corrosion resistance ability	Corrosion resistance.	Corrosion resistance.	Both nails are corrosion resistance. But SS nails have chance of corrosion. Corrosion resistance test (Cyclic potentiodynamic polarization test) has performed on the SS it shows the positive result.
6.	Elasticity	On the high load Ti shows less bending.	On the high load SS shows bending.	Both nails can bear the standard load with factor of safety without any bending.

Measurable safety and performance parameters

- Measure the VAS Scores
- Measure the Harris Hip Score
- Record of any adverse event, serious adverse event and complication

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

Residual risks and undesirable effects

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 as a result of contact with other materials.
- Body reaction to implants as foreign bodies e.g. possibility of tumour metaplasia, autoimmune disease and/or scarring.
- Non Union.
- Delayed Union
- Hematoma
- Compression on the surrounding tissue or organs.
- Deep Vein Thrombosis
- Local Wound
- Fixation Failure
- Wound Infection
- Superficial Wound Infection
- Lateral migration
- Malreduction
- Poor Reduction
- Anterior Knee pain
- Implant removal due to pain
- Spontaneous Dynamisation

Warning & Precautions:

1. Demonstrates anatomical or physiological anomalies.
2. 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.
3. 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.

4. The important medical information given in this document should be conveyed to the patient.
5. The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
6. For Qualified surgeon use only.
7. 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.
8. Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

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

Retrospective Clinical Data through Published Literatures:

The Femur Nailing 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 2009.

There are numbers of clinical data available on the different journals that were Retrospectively analyzed by different surgeons around the world. Those several studies, which were published by different surgeons and the manufacturer of the device includes 149 patients' (from 4 Clinical Papers, Detail given below in the table). These all patients have femoral fracture and were treated using Auxein's Femur Nailing 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 Nailing 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.	Selim et al, A Rare Case of Ipsilateral Floating Hip with Femoral Neck Fracture and Contralateral Floating Knee Injury – Proposal for a Management Flowchart and Literature	Femoral Shaft fractures	Retrograde Femur Nail	1 (M)	No Complication (at final 12th Post-Operative Week)

	Review				
2.	Akbareen et al, Clinical Outcomes of Femur Bone Fixation using femur nail.	Femur Shaft Fracture	JIN-Type Femur Nail	50 (36M, 14F)	No Complication (at final 12th Post-Operative Week)
3.	Akbareen et al, Comparison of outcomes after the treatment of femur fracture using Intramedullary Femur Nails (Expert and JIN-Type)	Femur Shaft Fracture	Expert and JIN-Type Femur Nail	56 (30M, 26F)	No Complication (at final 12th Post-Operative Week)
4.	Akbareen et al, Evaluation of Clinical study outcomes after the surgical treatment of proximal femoral fracture with femur nail.	Proximal Femur Fracture	AJAX Nail	42 (30M, 12F)	No Complication (at final 12th Post-Operative Week)

Prospective Clinical Data (PMCF Study):
Prospective Study of the legacy device has been approved by the ethics committee.

Identity of the investigation/study: Post Market Clinical Follow- up study: A interventional, non-randomized, prospective to evaluate the Safety and Performance of Proximal Femur Nailing System intended for Femoral Nailing related fracture fixation. Identity of the device including any model number/version:Femur Nailing System (Auxein"s Brand name- Ajax Advance Nailing, Generic name- Proximal femoral nail anti rotation).

Name or Code of Study	Completed (Yes/No)	Name of countries in study is conducted	No. of patients enrolled /and the target no.	No. of serious incidents	Serious incident rate (%)	No. of deaths
CR_PMCF/P_18	Ongoing	INDIA	50/50	0	0	0
Study Title	A non-randomized, prospective to evaluate the safety and performance of proximal femoral nail anti rotation (PFNA) intended for femur related fracture fixation.					

CTRI Number	CTRI/2022/03/041158					
CTRI Registration Date	16-03-2022					
Number of study sites	Three					
Name of Study Sites	Site 001	GSVM, Kanpur, India	Site 002	LBC, Kolkata, India	Site 003	AIIMS, Delhi, India
No. of Patients enrolled	14		06		30	

Study design: This is a non randomized, Post Market Clinical Follow-up study. It will include up to 50 subjects, which are aimed to evaluate the safety and performance outcome in femoral fracture injuries.

Inclusion criteria

Male and female subjects aged 18 years or above, who had Comminuted fracture, Segmental fracture, Proximal and distal fracture, Non-unions, Sub-trochanteric fracture, Inter-trochanteric fracture of the femur, and were willing to attend all study visits, were recruited for this study. Prior to enrollment, written informed consent for participation was obtained from all the study subjects.

Exclusion criteria

Subjects with Isolated or combined medial femoral neck fractures, Low sub-trochanteric fractures, Isolated or combined medial femoral neck fractures, and Medial neck fracture were not eligible for participation in the study. Additionally, subjects displaying signs of local inflammation or infection at the operation site were excluded. Those with fever or leukocytosis, neuromuscular disorders that could pose a high risk of fixation failure or complications in postoperative care, any other condition that could hinder the potential benefits of implant insertion surgery and disrupt the normal process of bone remodeling (e.g., the presence of tumors or congenital abnormalities, fractures local to the operating site), elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell (WBC) count, or a marked left shift in the WBC differential count were also excluded. Moreover, subjects with suspected or documented allergy or intolerance to implant materials were not included in the study. Surgeons were required to identify any allergic reactions to the material of the implant (information on the implant material is provided in the implant material section) and exclude such subjects from the study.

Primary Objective

The primary objective of this study was to assess the performance of Proximal Femoral Nail Anti-rotation (PFNA) used in surgical treatment of patients by analyzing the fracture union status post-operatively using Hip joint function, deformity and hip range of motion through MHHS score and pain evaluation through Visual Analogue Scale (VAS).

Secondary Objective

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

Primary Endpoints

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

Secondary Endpoints

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

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristic	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)
Mean	58.2	57.7	165.0	21.2

Gender distribution of study subjects

Male	31
Female	19

The study included a total of 50 subjects with a mean age of 58.2 years. Notably, a significant proportion of the subjects were above 50 years of age. The majority of participants were Asian males, with 31 males and 19 females recruited in the study. The mean weight of the subjects was 57.7 kg. The mean BMI of the subjects was 21.2. In terms of height, the subjects had an average of 165.0 cm. These demographic and baseline characteristics are essential for understanding the composition of the study population and provide valuable insights for the interpretation of the study results.

Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Proximal Femoral Nail Anti-rotation (PFNA) device. This longitudinal study was designed as a single-arm study. The target population for this research comprised both males and females aged 18 years or older at the time of surgery. The study aimed to recruit a total of 50 subjects who met with proximal femur related fracture , and they were treated using a Proximal Femoral Nail Anti-rotation (PFNA) construct.

A Post-Market Clinical Follow-Up (PMCF) study was conducted to assess the safety and performance of the Proximal Femoral Nail Anti-rotation (PFNA) device. This study was carried out after obtaining marketing (CE) approval, with the primary objective of evaluating the clinical

Performance, efficacy, and safety (including residual risks) of the device when used in accordance with its approved labeling. The study aimed to investigate various aspects, such as medium-term performance, the occurrence of clinical events, specific events related to defined patient populations, and the device's performance in a broader population of healthcare providers and patients with femoral fractures.

The study consisted of up to seven study visits over a maximum period of 1 year. Subjects were expected to attend all study visits. All assessments were recorded and performed at Visit 1 to Visit 7 on all the study subjects. Subjects were screened for entry (Visit 1) and then were treated for the surgery (Visit 2). Subjects were assessed post-surgery for safety. Additional safety & effectiveness follow-up visits were occurred at 1, 3, 6 and 12 months. The final study visit was occurred at Visit 7 i.e. at 12 months.

Study Result

The study presented provides valuable insights into the composition of the study population and the changes observed in vital signs over time, along with the impact of the intervention on pain relief and functional improvement. The majority of participants were above 50 years of age is worth noting, as age can

often influence health outcomes and treatment responses. Additionally, the gender distribution and average weight and height of the subjects provide important context for understanding the study results.

.

The most significant findings in the study revolve around pain relief and functional improvement. The substantial reduction in Visual Analog Scale (VAS) scores indicates that the intervention effectively alleviated pain in the patients, leading to improved comfort and well-being. This is particularly important as pain levels at baseline were reported to be high, indicating that the intervention positively impacted the patients' quality of life.

Furthermore, the enhancement in functional scores as measured by the Modified Hip and Harris Score (MHHS) highlights the intervention's effectiveness in improving functional performance. The progressive increase in MHHS scores over the follow-up visits indicates a consistent and sustained improvement in functional ability. This demonstrates that the intervention not only provided short-term relief but also led to lasting improvements in the patients' functional status, which is crucial for their overall recovery and well-being.

However, the study also has certain limitations that need to be acknowledged. Firstly, this is an interim report on a relatively small sample size of 37 subjects which may change after completion of study. A larger and more diverse sample could provide more robust evidence of the intervention's effectiveness. Additionally, the study lacks a longer duration of follow up, which makes it challenging to determine whether the observed improvements are consistent for a longer period of time.

With regards to the Auxein's femur Nailing System there are no any adverse event related to device in any medical device registry. The benefit-risk analysis has outweighed the benefit against the risk regarding the device.

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

6. Possible diagnostic or therapeutic alternatives.

On plain radio graphs, anterior-posterior (AP) and lateral views demonstrate most hip fractures. For patients in whom femoral neck fracture is strongly suspected but standard x-ray findings are negative, an AP view with internal rotation provides a better view of the femoral neck. If standard radio graph

findings are negative and hip 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 Nailing 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.

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 Nailing 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 F1264-16e1	Standard Specification and Test Methods for Intramedullary Fixation Devices
43.	ASTM D4169-22	Standard Practice for Performance Testing of Shipping containers and System.
44.	ASTM F88	Standard Test Method for Seal Strength of Flexible Barrier Materials
45.	ISO 19227:2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements
46.	MDCG 2021-24	Guidance on classification of medical devices
47.	MDCG 2020-8	Guidance on PMCF evaluation report template
48.	MDCG 2020-7	Guidance on PMCF plan template
49.	MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
50.	MDCG 2020-5	Guidance on clinical evaluation – Equivalence
51.	MDCG 2019-9, Rev.01	Summary of safety and clinical performance
52.	MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
53.	MDCG 2021-11	Guidance on Implant Card –‘Device types’
54.	MDCG 2019-8 v2	Guidance document implant card on the application of Article 18 Regulation (EU) 2017/745 on medical devices.

55.	MDCG 2022-9	Summary of safety and performance template
56.	MDCG 2019-14	Explanatory note on MDR codes
57.	MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
58.	MDCG 2018-1, Rev.04	Guidance on BASIC UDI-DI and changes to UDI-DI
59.	MDCG 2021-25	Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
60.	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022
61.	MEDDEV 2.7/1 revision 4, 2016	Clinical Evaluation: A guide for manufacturers and notified bodies.
62.	EU MDR 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017.

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
00	05-02-2023	Initial Release	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
01	29-12-2023	Updated Residual risks and undesirable effects	☐ Yes Validation language: ☐ No

			(only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
02	22-08-2024	Updated the Clinical Study Data	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
03	28-09-2024	Updated the CE Certificate section and year of the device since in the market.	☐ 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: 03
Date issued: 28-08-2024

Device identification and general information

Device Trade Name: Auxein Femur Nailing System

Manufacturer Name: Auxein Medical Private Limited

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

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

Year when the device was first CE-marked: 2009

Intended use of the device

Intended Purpose	The Femur Nailing system is intended for fracture fixation of Femur bone including proximal, shaft and distal Femur.
Indications of Use	The Femur Nailing System is part of the Femur Bone has the following indications: **130°AJAX ADVANCE NAIL, SHORT** ● Pertrochanteric fractures (31-A1 and 31-A2) ● Intertrochanteric fractures (31-A3) ● High subtrochanteric fractures (32-A1) **130°AJAX ADVANCE NAIL, LONG** ● Low and extended subtrochanteric fractures ● Ipsilateral trochanteric fractures ● Combination fractures (in the proximal femur) ● Pathological fractures **EXPERT FEMUR NAIL** ● 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1) **ATHOS NAILING SYSTEM** ● Intertrochanteric fractures (31-A3)

	● Pertrochanteric fractures (31-A1 and 31-A2) ● Nonunion and malunion **ANTI-ROTATION ATHOS NAIL, SHORT AND LONG** Intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures (31-A1 and 31-A2), intertrochanteric fractures (31-A3), high subtrochanteric fractures (32-A1) and combinations of these fractures, including non-union, malunion and tumor resections. **JIN TYPE-FEMUR NAIL** ● 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1) **Universal Intramedullary Cannulated Femur Nail** Intended to treat stable and unstable proximal neck fractures or trochanteric fractures and combinations of these fractures, Femur shaft fracture, distal end fractures **RETROGRADE FEMUR NAIL** ● 33-A1/A2/A3 ● 33-C1/C2/C3 32-A/B/C
Contraindications	The implant should not be used in a patient who has currently, or who has a history of: ● Infection local to the operative site ● Signs of local inflammation. ● Fever or 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. ● Shaft fractures with a fissure less than 5 cm from the nearest interlocking hole of the nail.
Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Femur Nailing System can be used for Skeletally Mature patients with Age group of 18 years or above. The patient conditions and/or pre-dispositions such as those addressed in the contraindications should be avoided.

Device description

The femur bone nail is used for treating the fractures of proximal, distal and shaft femoral fractures. These nails help to align the fractured bone fragments together with the help of bone screws/locking screws. The femur nails consist of various types of bone nails including AJAX, Expert, Konzept, JIN-Type, Retrograde and ATHOS Nail and for fixing these nails with the bone Auxein provides various types of bone screws which are compatible with different type of bone nails. The details regarding femur bone nails and screws can be found at **www.auxein.com**.

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

CE Mark (Legacy device)	CE Approved by **ITC (1023)** under MDD 93/42/EEC **Initial Certificate No.** 09 0394 QS/NB CE Approved by **DNV (2460)** under MDD 93/42/EEC **Re Certificate No.** 4825-2014-CE-IND-NA **Re certification Certificate No.**: 10000363901-PA-NA-IND Rev 2 Extension Letter By **DNV (2460)** **Notified Body Confirmation Letter Reference:** C666881
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 (Femur Nailing are approved by USFDA whose details are as follow:) 510(k) Number: K192003, K210792
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 Nailing system works on the AO Principle of Fracture Management. The key concept of fracture management involves:

1. Restoration of anatomy
2. Stable fixation

3. Preservation of blood supply
4. Early mobilization of the limb and patient

The Auxein's femur nailing system aims for restoration of bone anatomy by stabilizing the fracture and provides temporarily supporting loads while the fracture heals. The proper fixation of nails 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 Nailing System comprises of :

- Nails in varying lengths and types
- Screws
- Locking Bolts
- Blade
- End caps

Nails are used with accessories for implantation in the femur to correct the abnormal curvature.

The Femur Nailing 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 nail to fix the fracture enlisted below.

End Cap:

- For axial stabilization and simultaneous protection of soft tissue.
- Using the end cap makes it easier to extract the nail.
- The end cap also provides protection against painful soft-tissue irritation.
- This is intended to prevent nail migration (push-out).
- It is used to securely lock the most proximal oblique locking screw or help extend the length of a nail.

AJAX Blade:

- It helps in compacting the cancellous bone which provides a better hold especially in case of any osteoporotic bone.

Locking Screw:

- These Locking screws are inserted where the neck of femur has been fractured.
- Additionally, locking screws may be used as a fixed angle device for short metaphyseal fragments and juxta-articular shaft fractures.
- Double thread for more contact points leading to enhanced stability.
- Larger cross-section for improved mechanical resistance.
- Thread closer to screw head providing better bone purchase and improved stability.

Locking Bolt:

- Thread diameter, engages bone and nail for superior holding capacity.
- Fully-threaded shaft for easier insertion and extraction.
- Core diameter for greater strength.
- Low head profile for areas with minimal soft tissue coverage.
- Self-cutting trocar tip to eliminate tapping

Compression Screw:

- It provides the compression on the proximal section of a fractured bone to close the fracture gap with the distal section which can then be locked into final position.

Inner Screw:

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

Cannulated Anti-rotation Screw:

- It is used for internal orthopaedic fracture fixation by being screwed into bone to hold nails with bone.
- It also provide direct inter-fragmentary stabilization of bone, or it may fasten soft tissue to bone.

Cephalic Screw:

- It helps in compacting the cancellous bone which provides a better hold especially in case of any osteoporotic bone.

Cannulated Reconstruction Screw:

- This screw provides direct inter-fragmentary stabilization of bone, or it may fasten soft tissue to bone.

- This is used to obtain compression across bone fragments.

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.
- 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.
- Mental condition changes.
- 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:

1. Avoid notching, scratching, or striking the device.
2. Every implant must be discarded after use and should never be reused. Reuse may lead to infection & cross infection. It should be bent & then disposed of properly so that it becomes unfit for reuse.
3. After healing occurs, these devices serve no functional purpose and therefore should be removed.

4. Patients should be informed about the possible complications from not removing the device (corrosion with localized tissue reaction or pain, migration on resulting in injury to so issue, visceral organs, or joints, risk of additional injury from postoperative trauma, breakage which could make removal impractical or difficult, pain, discomfort, or abnormal sensations which may occur due to the presence of the device, possible increased risk of infection, and bone loss due to stress shielding).
5. Any decision to remove the device should consider the potential risk to the patient of a second surgical procedure and should be followed by adequate post-operative management to avoid re-fracture.
6. 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.
7. If adverse effects happen, it may necessitate re-operation, revision or removal surgery, arthrodesis or the involved joint and / or amputation of the limb.

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

Till now, regarding Auxein's Femur Nailing 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.

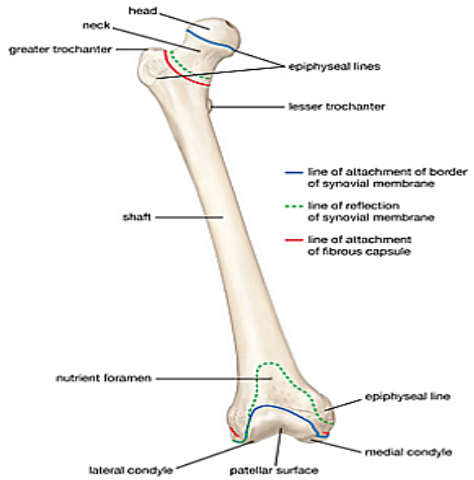


Figure: Femur bone anatomy.

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.

Clinical Evidence/Safety of the device

There are prospective and retrospective data regarding the device.

Retrospective Clinical Evaluation:

The Femur Nailing 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 2009.

There are numbers of clinical data available on the different journals that were Retrospectively analyzed by different surgeons around the world. Those several studies, which were published by different surgeons and the manufacturer of the device includes 149 patients' (from 4 Clinical Papers, Detail given below in the table). These all patients have femoral fracture and were treated using Auxein's Femur Nailing 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 Nailing 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.	Selim et al, A Rare Case of Ipsilateral Floating Hip with Femoral Neck Fracture and Contralateral Floating Knee Injury – Proposal for a Management Flowchart and Literature Review	Femoral Shaft fractures	Retrograde Femur Nail	1 (M)	No Complication (at final 12th Post-Operative Week)
2.	Akbareen et al, Clinical Outcomes of Femur Bone Fixation using femur nail.	Femur Shaft Fracture	JIN-Type Femur Nail	50 (36M, 14F)	No Complication (at final 12th Post-Operative Week)
3.	Akbareen et al, Comparison of outcomes after the treatment of femur fracture using Intramedullary Femur Nails (Expert and JIN-Type)	Femur Shaft Fracture	Expert and JIN-Type Femur Nail	56 (30M, 26F)	No Complication (at final 12th Post-Operative Week)

4.	Akbareen et al, Evaluation of Clinical study outcomes after the surgical treatment of proximal femoral fracture with femur nail.	Proximal Femur Fracture	AJAX Nail	42 (30M, 12F)	No Complication (at final 12th Post-Operative Week)

Prospective Clinical Evaluation

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

Identity of the investigation/study: Post Market Clinical Follow- up study: A interventional, non-randomized, prospective to evaluate the Safety and Performance of Proximal Femur Nailing System intended for Femoral Nailing related fracture fixation. Identity of the device including any model number/version:Femur Nailing System (Auxein"s Brand name- Ajax Advance Nailing, Generic name- Proximal femoral nail anti rotation).

Name or Code of Study	Completed (Yes/No)	Name of countries in study is conducted	No. of patients enrolled /and the target no.	No. of serious incidents	Serious incident rate (%)	No. of deaths
CR_PMCF/P_18	Ongoing	INDIA	50/50	0	0	0
Study Title	A non-randomized, prospective to evaluate the safety and performance of proximal femoral nail anti rotation (PFNA) intended for femur related fracture fixation.					
CTRI Number	CTRI/2022/03/041158					
CTRI Registration Date	16-03-2022					
Number of study sites	Three					
Name of Study Sites	Site 001	GSVM, Kanpur, India	Site 002	LBC, Kolkata, India	Site 003	AIIMS, Delhi, India
No. of Patients enrolled	14		06		30	

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristic	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)
Mean	58.2	57.7	165.0	21.2

Gender distribution of study subjects

Male	31
Female	19

The study included a total of 50 subjects with a mean age of 58.2 years. Notably, a significant proportion of the subjects were above 50 years of age. The majority of participants were Asian males, with 31 males and 19 females recruited in the study. The mean weight of the subjects was 57.7 kg. The mean BMI of the subjects was 21.2. In terms of height, the subjects had an average of 165.0 cm. These demographic and baseline characteristics are essential for understanding the composition of the study population and provide valuable insights for the interpretation of the study results.

Study Result

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

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

Possible diagnostic or therapeutic alternatives

On plain radio graphs, anterior-posterior (AP) and lateral views demonstrate most hip fractures. For patients in whom femoral neck fracture is strongly

suspected but standard x-ray findings are negative, an AP view with internal rotation provides a better view of the femoral neck. If standard radio graph findings are negative and hip 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 Nailing 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 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/).