SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR HUMERUS NAILING SYSTEM

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

Basic UDI-DI: 0890399HNT004UK and 08903993HNS004LF for Titanium and Stainless Steel Implants respectively.

SRN: IN-MF-000018837

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

Konzept Humerus Nail

Intramedullary Cannulated Humerus Nail, Stainless Steel/Titanium, End Cap for Intramedullary Humerus Nail, Stainless Steel/Titanium, Compression Screw for Intramedullary Humerus Nail, Stainless Steel/Titanium, Ø4.5mm Locking Bolt for Humerus Nail, Stainless Steel/Titanium, Ø4.5mm Proximal Screw, Stainless Steel/Titanium

Reconstruction Nail, Cannulated, Stainless Steel/Titanium

Reconstruction Cannulated Intramedullary Humerus Nail, Stainless Steel/Titanium

End Cap for Reconstruction Cannulated Intramedullary Nail, Stainless Steel/Titanium, Ø3.5mm Locking Bolt for Humerus Nail, Stainless Steel/Titanium, Ø4.5mm Locking Bolt for Humerus Nail, Stainless Steel/Titanium

JIN Type Humerus Nail

JIN Type - Humerus Nail, Stainless Steel/Titanium, End Cap For JIN Type -Humerus Nail, Stainless Steel/Titanium, Ø3.5mm Locking Bolt, Self-Tapping, For JIN Type - Humerus Nail, Stainless Steel, Titanium

Details Regarding the device are provided in below table:

Device Trade Name:	**Humerus 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		
EMDN Code	P091205		
Conformity Assessment Route	Conformity Assessment of Class IIb devices has been conducted as per Article 52 (4), Chapter I and III of Annex IX of EU MDR 2017/745		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Humerus Nailing System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev 2
Year when the first certificate (CE) was issued covering the device	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 (Humerus 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 humerus nail intended to be placed in humerus bone to treat fracture not intended for teeth.* **2.** Are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III; ***Applicable/Not Applicable:*** *Not Applicable* ***Justification:*** *The humerus nail comes in contact with the humerus bone. Thus, it does not come in contact with the*		

heart, the central circulatory system or the central nervous system.

3. Have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;
Applicable/Not Applicable: *Not Applicable*
Justification: *The humerus nailing system is made up of medical grade metallic alloy. Metallic alloy does not achieve its intended use by biological effect or by absorption*

4. Are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;
Applicable/Not Applicable: *Not Applicable*
Justification: *The humerus system is made up of medical grade metallic elements. These metallic elements have high metallic bonds that do not undergo chemical change in the body.*

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

6. Are active implantable devices or their accessories, in which cases they are classified as class III;
Applicable/Not Applicable: *Not Applicable*
Justification: *The humerus nailing system does not depend on a source of energy. Thus it is not an active device.*

7. Are breast implants or surgical meshes, in which cases they are classified as class III;
Applicable/ Not Applicable: *Not Applicable*
Justification: *The humerus nailing system treats humerus bone fracture. Not intended as breast implants or surgical*

	meshes. **8.** Are total or partial joint replacements, in which case they are classified as class III, except ancillary components such as screws, wedges, plates and instruments; or; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The humerus nailing system treats humerus 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 humerus nailing system is an implantable device to treat humerus bone fractures. The nailing system is not recommended for the Spinal Disc Replacement Implants and do not come into contact with the spinal column.*
Authorized Representative Name and Address	**Name:** CMC Medical Devices & Drug S.L **Address:** 29015 Málaga, Spain
Authorized Representative SRN	ES-AR-00000029
Notified Body Name and Single Identification Number	**Name:** DNV Product Assurance AS **Single Identification Number:** 2460

2. The intended purpose of the device and any indications, contraindications and target populations.

The Indications, Contraindication and Intended Patient Population related information is provided in below table:

Indications of Use	The indications for use of the Humerus Nailing System include: **Konzept Humerus Nail** **Intramedullary Cannulated Humerus Nail** The intramedullary cannulated humerus nail is indicated for comminuted fractures of the humerus shaft, severe closed and open fractures of I degree, Pathological fractures, malunion or non-union of the fragments of the humeral shaft. **Reconstruction Nail, Cannulated** The Reconstruction Nail, cannulated is indicated for the fractures of the proximal humerus, including: ○ 2-part surgical neck fractures ○ 3-part fractures ○ 4-part fractures **Reconstruction Cannulated Intramedullary Humerus Nail** The Reconstruction Cannulated Intramedullary Humerus Nail is indicated for: ○ Fractures of the humeral diaphysis ○ Fractures of the proximal humerus with diaphyseal extension ○ Combined fractures of the proximal humerus and the humeral diaphysis **JIN Type Humerus Nail** ○ The JIN Type Humerus Nail is indicated for Proximal and Shaft fracture of the Humerus.
Contraindications	Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome: ○ 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. ○ Any case in which there is inadequate tissue coverage of the operative site.
Intended Patient Population	Male or Female, aged 18 years or above, skeletally mature patient.
Intended Users	The Humerus Nailing System is recommended to be used by only well-trained, certified and experienced surgeons.
Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
Use	For Single Use only
Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
Biocompatibility	The devices covered in the Humerus Nailing System are Bio-compatible. Biocompatibility of the devices is tested as per EN ISO 10993-1 series of International Standard.

3. Description of the device

A.	**Konzept Humerus Nail**	
1	Device Name	Intramedullary Cannulated Humerus Nail
	Picture	
	Nail Diameter	Ø6, Ø7, Ø8, Ø9mm
	Total Length	180, 200, 220, 240, 260, 280, 300, 320mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel EN ISO 5832-1:2019
2	Device Name	End Cap For Intramedullary Humerus Nail
	Picture	
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel EN ISO 5832-1:2019
3	Device Name	Compression Screw For Intramedullary Humerus Nail
	Picture	
	Directional Configuration (Left & Right)	Not Applicable

	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel EN ISO 5832-1:2019
4	Device Name	Ø4.5mm Locking Bolt For Humerus Nail
	Picture	
	Length	20-70mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel EN ISO 5832-1:2019
5	Device Name	Ø4.5mm Proximal Screw
	Picture	
	Length	25-70mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel EN ISO 5832-1:2019
6	Device Name	Reconstruction Nail, Cannulated
	Picture	

	Nail Diameter	Ø6, Ø7, Ø8, Ø9mm
	Total Length	150mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel EN ISO 5832-1:2019
7	Device Name	Reconstruction Cannulated Intramedullary Humerus Nail
	Picture	
	Nail Diameter	Ø6, Ø7, Ø8, Ø9mm
	Total Length	200, 220, 240, 260, 280, 300, 320mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel EN ISO 5832-1:2019
8	Device Name	End Cap For Reconstruction Cannulated Intramedullary Nail
	Picture	
	Directional Configuration (Left & Right)	Not Applicable
	c	
9		

	Device Name	Ø3.5mm Locking Bolt For Humerus Nail
	Picture	
	Length	20-70mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel EN ISO 5832-1:2019
10	Device Name	Ø4.5mm Locking Bolt For Humerus Nail
	Picture	
	Length	20-70mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel EN ISO 5832-1:2019

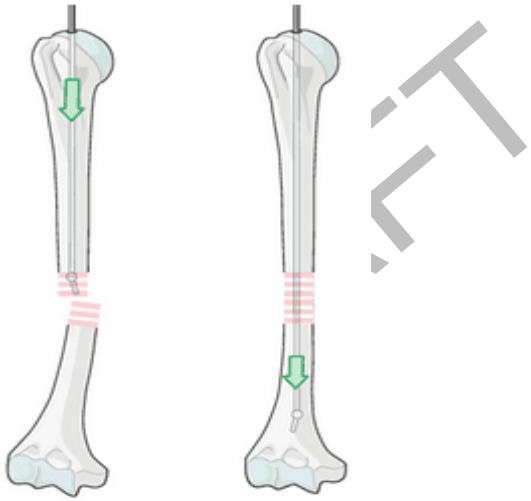
Other details of Humerus Nailing System:

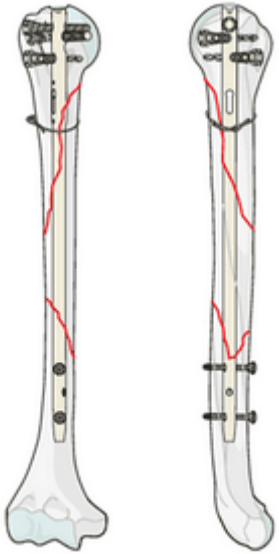
Device Compliance to regulation	We are proposing the Humerus Nailing System as per the compliance to European Union Medical Device Regulation (EU MDR 2017/745).
1.	DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES
1.1	Device Description and Specification

a.	Product/Trade Name	Auxein Humerus Nailing System
	General Description	Auxein's Humerus Nailing System is designed to fix, stabilize and restore the proximal, diaphysis and distal fracture of the humerus bone to its natural state. The AUXEIN MEDICAL'S Humerus Nailing System consists of a variety of shapes and sizes of nails, screws, end caps, bolts which can be rigidly locked into a variety configurations. The nails with components are enlisted below: **1. Konzept Humerus Nail** ○ Intramedullary Cannulated Humerus Nail ○ Reconstruction Nail, Cannulated ○ Reconstruction Cannulated Intramedullary Humerus Nail **2. JIN Type Humerus Nail** **Konzept Humerus Nail** Intramedullary Cannulated Humerus Nail, Stainless Steel/Titanium End Cap for Intramedullary Humerus Nail, Stainless Steel/Titanium, Compression Screw for Intramedullary Humerus Nail, Stainless Steel/Titanium, Ø4.5mm Locking Bolt for Humerus Nail, Stainless Steel/Titanium, Ø4.5mm Proximal Screw, Stainless Steel/Titanium **Reconstruction Nail, Cannulated, Stainless Steel/Titanium** Reconstruction Cannulated Intramedullary Humerus Nail, Stainless Steel/Titanium End Cap for Reconstruction Cannulated Intramedullary Nail, Stainless Steel/Titanium, Ø3.5mm Locking Bolt for Humerus Nail, Stainless Steel/Titanium, Ø4.5mm Locking Bolt for Humerus Nail, Stainless

		Steel/Titanium JIN Type Humerus Nail JIN Type - Humerus Nail, Stainless Steel/Titanium, End Cap For JIN Type -Humerus Nail, Stainless Steel/Titanium, Ø3.5mm Locking Bolt, Self-Tapping, For JIN Type - Humerus Nail, Stainless Steel, Titanium
	Intended Purpose	The Humerus nails are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of humerus bone fragments.
	Intended Users	The Humerus Nailing System is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Male or Female, aged 18 years or above, skeletally mature patient.
	Medical Conditions to be diagnosed, treated and/or monitored	Humerus Nail is used to treat simple and complex fractures of the humerus bone. Specifically designed humerus nail intended for treatment of fracture that provides strong fixation and restore the bone fragments.
	Patient Selection Criteria	**Inclusion criteria** 1. Male or Female, aged 18 -75 years. 2. Patients presenting to Orthopaedic emergency/ OPD with Humerus shaft fracture will be included in the study. **Exclusion criteria** 1. Infection, local or Systemic Acute or Chronic Inflammation to the operative site. 2. Subjects with a disease entity or condition that could hindered bone healing and create unacceptable risk of fixation failure complications such as known active cancer, neuromuscular disorder etc. 3. In case subject has inadequate tissue coverage of the operative site.

		4. Subjects with Symptomatic Arthritis. 5. Subjects with Suspected or documented metal allergy or intolerance. 6. Subjects with substance abuse/alcohol issues. 7. Subjects who are incarcerated or have pending incarceration. 8. Female participant who is pregnant or planning pregnancy during the course of the study. 9. Fracture that are not amenable to humerus nailing technique. 10. Any patient unwilling to cooperate with the post-operative instructions. 11. Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site. 12. Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices. 13. Implant utilization that would interfere with anatomical structures or physiological performance.
c.	Principles of Operation Mode of Action	Humerus 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 humerus 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. 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, humerus nail is an implant used in humans for medical purposes to treat humerus 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 humerus nail is an implant used for the treatment of humerus 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 humerus nail is an implantable device used for the treatment of humerus 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 humerus nail is intended to treat humerus 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 Humerus nail is made up of metal alloy and employed to fix humerus 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 humerus 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 humerus nailing system used to stabilize humerus 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 humerus nailing system is intended for fixation for fractures of the humerus bone. The system is not meant for cleaning, disinfection or sterilization of device.
e.	Novel Features	The Humerus 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 Humerus Nailing System comprises of the following accessories which act as functional elements : ● End caps ● Instrument set

		Instruments are used for fixation of nail at fracture site. The instruments are used during surgical procedures, each with their specific use. Only Auxein Instruments shall be used with the humerus nailing system. The instruments should be CE Marked. ***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.
g.	Sterility	All Products covered in Humerus 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 Humerus 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 AUXEIN MEDICAL Humerus Nail have not been evaluated for safety and compatibility in the MR environment. The AUXEIN MEDICAL implants have not been tested for heating or migration in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic

		Resonance Imaging) environment.
1.2	Reference to Previous and Similar Generations of the device	
a.	CE Mark (Legacy device)	CE Approved by DNV (2460) under MDD 93/42/EEC Initial Certificate No. 4825-2014-CE-IND-NA Re certification Certificate No.: 10000363901-PA-NA-IND Rev 2
	USFDA clearance	Yes (Humerus 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: ■ DePuy Synthes MultiLoc® Humeral Nail:- Depuy Synthes (CE 0123) ■ Charfix - Compression Humerus Nail (CE 0197)

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 DASH Scores
- Measure the VAS Score
- Adverse Event assessment.

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

Residual risks and undesirable effects

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

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

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 isany 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. 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.
7. Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

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

Prospective Clinical Data (PMCF Study):

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

Identity of the investigation/study: A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Humerus Nailing System intended for Fracture Fixation.

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

	(Yes/No)	study is conducted	/and the target no.	incidents	rate (%)	
CR_PMCF/P_04	Ongoing	INDIA	07/20	0	0	0
Study Title	Post Market Clinical Follow-Up Study, A Prospective, Single Arm, Post Market Clinical Follow- up (PMCF) Study to Evaluate the Safety and Performance of Humerus Nailing System intended for Fracture Fixation.					
CTRI Number	CTRI/2024/07/071664					
CTRI Registration Date	31/07/2024					
Number of study sites	One					
Name of Study Sites	Site 001	Hi-Tech Multispeciality Hospital				
No. of Patients enrolled	7					

Study design: A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Humerus Nailing System intended for Fracture Fixation. This is a post-marketing clinical follow-up study. This study was carried out following marketing (CE) approval intended to answer the clinical performance, efficacy and safety (i.e. residual risks) of a device when used in accordance with its approved labeling. These may examine issues such as medium-term performance, the appearance of clinical events, events specific to defined patient populations, or the performance of the device in a more representative population of providers and patients with Humerus fracture.

Inclusion criteria

Patient will be screened for the following Inclusion Criteria:

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

Exclusion criteria

1. Infection, local or Systemic Acute or Chronic Inflammation to the operative site.
2. Subjects with a disease entity or condition that could hindered bone healing and create unacceptable risk of fixation failure complications such as known active cancer, neuromuscular disorder etc.
3. In case subject has inadequate tissue coverage of the operative site.

4. Subjects with Symptomatic Arthritis.
5. Subjects with Suspected or documented metal allergy or intolerance.
6. Subjects with substance abuse/alcohol issues.
7. Subjects who are incarcerated or have pending incarceration.
8. Female participant who is pregnant or planning pregnancy during the course of the study.
9. Fracture that are not amenable to humerus nailing technique.
10. Any patient unwilling to cooperate with the post-operative instructions.
11. Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
12. Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices
13. Implant utilization that would interfere with anatomical structures or physiological performance.

Primary Objective

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

Secondary Objective

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

Primary Endpoints

1. Radiological evaluation by X-ray radiographs to calculate mean time to achieve bone fusion and deformity correction or stabilization.
2. Quality of movement in arm and shoulder by calculating DASH score.

Secondary Endpoints

1. Analyzing Visual analogue score (VAS) for pain assessment.
2. Any adverse event or serious adverse event during follow up, especially the one mentioned in the Product Description. Follow up will be done at - Baseline, at 6 week, 3 month, 6 month and 12 month.

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (kg/m2)
Mean ± SD	33.5 ± 11.5	65 ± 12.6	162.8 ± 4.5	24.4 ± 3.79
Median	31	58	162	22.9
Range	20-55	56 - 86	159 - 170	21.2 - 29.8

Gender distribution of study subjects

Male	6/7 (85.71%)
Female	1/7 (14.2%)

The mean age of recruited subjects is 33.5 years, mean weight is 65 kg and mean height is 162.8cm. The mean BMI of the study participants is 24.4 kg/m2.

Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Humerus Nailing device. This longitudinal study was designed as a single-arm study. The target population for this research comprised both males and females aged 18 years or above, skeletally mature patient at the time of surgery. The study aimed to recruit a total of 20 subjects who experienced humerus related fracture, and they were treated using a Humerus Nail construct.

A total of seven study visits are there. Subject is screened, and followed at Baseline 1 (pre surgery) and Baseline 2 (post surgery). After which 4 follow-up visits are conducted. All the respective assessments are performed and recorded from Visit 1 to Visit 7 for all the study subjects as per the study protocol. From the date of surgery, subject are followed at 6 week, 3 month, 6 month and 12 month. Assessments included standardized clinical evaluation and completion of the VAS score and the DASH.

Study Result

The study provides valuable insights into the composition of the study population and the changes observed in cardiovascular and respiratory status over time, along with the impact of the intervention on pain relief and functional improvement. Additionally, the gender distribution and average weight and height of

the subjects provide important context for understanding the study results. The study's focus on monitoring cardiovascular and respiratory status at different time points is significant. The observed difference were non significant which implicate that there was no significant effect on blood pressure post intervention. It was interesting to explore these factors further to understand the implications for patient health and treatment outcomes. 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 DASH highlights the intervention's effectiveness in improving functional performance. The progressive increase in DASH score 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. With regards to the Auxein's Humerus 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.

6. Possible diagnostic or therapeutic alternatives.

On plain radio graphs, anterior-posterior (AP) and lateral views demonstrate most fractures.. If standard radio graph findings are negative 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

Non-surgical treatment is often effective for stable fractures or fractures that are minimally displaced.

a. Immobilization

- Splints, Slings, or Braces:
  - Proximal humerus fractures: Treated with a sling or shoulder immobilizer.
  - Humeral shaft fractures: Functional braces or coaptation splints may be used.
  - Distal humerus fractures: Splints or casts may be applied to stabilize the elbow.
- Duration:
  - Typically 4–8 weeks, depending on the type and severity of the fracture.

b. Pain Management

- Medications:
  - Over-the-counter pain relievers (e.g., acetaminophen or ibuprofen).
  - Prescription medications for severe pain.
- Ice packs to reduce swelling and pain.

c. Physical Therapy

- Gradual rehabilitation to restore range of motion and strength after immobilization.
- Early passive range-of-motion exercises may be started under supervision, depending on the fracture.

Surgical Treatment

Surgery is required for unstable fractures, open fractures, fractures involving nerve or blood vessel damage, or when non-surgical treatment fails.

a. Indications for Surgery

- Displaced fractures.
- Open fractures (bone pierces the skin).
- Comminuted fractures (multiple bone fragments).
- Associated nerve or vascular injury.
- Pathological fractures caused by conditions like osteoporosis or cancer.

b. Surgical Techniques

1. Open Reduction and Internal Fixation (ORIF):
   - The fractured bone is realigned (open reduction) and stabilized using plates, screws, or intramedullary nails.
   - Commonly used for:
     - Proximal humerus fractures.
     - Humeral shaft fractures.
     - Distal humerus fractures involving the elbow joint.

2. Intramedullary Nailing:

- A rod is inserted into the marrow cavity of the bone to stabilize the fracture.
- Used for humeral shaft fractures.

3. External Fixation:
   - Metal pins and rods are placed outside the body to stabilize the bone.
   - Often used for severe open fractures or when internal fixation is not feasible.

The treatment of a humerus fracture should be individualized based on the type of fracture and patient-specific factors. Early intervention, appropriate therapy, and consistent follow-up are key to achieving successful outcomes.

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 Humerus Nailing System:

Harmonized Standards		
S. No.	**Standard Designation**	**Title of Standard**
1.	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
2.	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
3.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
4.	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
5.	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
6.	EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

7.	EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
8.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.

Non Harmonized Standards	
Standard	**Description**
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
ISO 17665-1:2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good Clinical Practice.
ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
ISO 14630:2012	Non-active surgical implants - General Requirements
ISO 11137-2:20/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.
ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)
ISO 11607-1:2020/A11:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
ISO 11607-2:2020/A11:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
ISO 14644-1:2015	Clean-rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
ISO 14644-2:2015	Clean-rooms and associated controlled environments - Part 2: Monitoring to provide evidence of clean-room performance related to air cleanliness by particle concentration.
ISO 14644-3:2019	Clean-rooms and associated controlled environments - Part 3: Test Methods.

ISO 14644-4:2022	Clean-rooms and associated controlled environments - Part 4: Design, construction and start-up.
ISO 14644-5:2004	Clean-rooms and associated controlled environments - Part 5: Operations
ISO 14644-7:2004	Clean-rooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, Isolators and mini).
ISO 14644-8 :2022	Clean-rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC).
ISO 14644-9 :2022	Clean-rooms and associated controlled environments – Part 9: Classification of surface cleanliness by particle concentration.
ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020).
ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 5832-1:2019	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel (ISO 5832-1:2016)
ISO 5832-3:2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)
ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-2: 2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
ASTM F138-19	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
ASTM F136-13 (2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM F1264-16e1	Standard Specification and Test Methods for Intramedullary Fixation Devices
ASTM F384-17	Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices.
ASTM D4169-22	Standard Practice for Performance Testing of Shipping containers and System.

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

MDCG Guidelines	
Guidance Documents	**Description**
MDCG 2023-7	Practical Application of Article 61(4)
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2020-13	Clinical Evaluation Assessment Report Template
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2020-7	Guidance on PMCF plan template
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
MDCG 2019-9, Rev.01	Summary of safety and clinical performance
MDCG 2019-5	Registration of legacy devices in EUDAMED
MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
MDCG 2018-2	Future EU medical device nomenclature - Description of requirements
MDCG 2021-11	Guidance on Implant Card –'Device types'
MDCG 2022-16	Guidance on Authorized Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746
MDCG 2022-9	Summary of safety and performance template
MDCG 2019-14	Explanatory note on MDR codes
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
MDCG 2023-7	Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR
MDCG 2018-1, Rev.04	Guidance on BASIC UDI-DI and changes to UDI-DI
MDCG 2021-25	Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26

	May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022
MEDDEV 2.7/1 revision 4, 2016	Clinical Evaluation: A guide for manufacturers and notified bodies.

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
00	13-12-2024	Initial Release	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
01	31-01-2025	Updated as per PRJN-629776 (List of finding, Phase-I)	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

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

Document revision: 01
Date issued: 31-01-2025

Device identification and general information

Device Trade Name: Auxein Humerus 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: 08903993HNS004LF (For Stainless Steel Implants) and 0890399HNT004UK (For Titanium Implants).
Year when the device was first CE-marked: 2009

Intended use of the device

Intended Purpose	The Humerus nails are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of humerus bone fragments.
Indications of Use	The indications for use of the Humerus Nailing System include: **Konzept Humerus Nail** **Intramedullary Cannulated Humerus Nail** The intramedullary cannulated humerus nail is indicated for comminuted fractures of the humerus shaft, severe closed and open fractures of I degree, Pathological fractures, malunion or non-union of the fragments of the humeral shaft. **Reconstruction Nail, Cannulated** The Reconstruction Nail, cannulated is indicated for the fractures of the proximal humerus, including: ○ 2-part surgical neck fractures ○ 3-part fractures

	○ 4-part fractures **Reconstruction Cannulated Intramedullary Humerus Nail** The Reconstruction Cannulated Intramedullary Humerus Nail is indicated for: ○ Fractures of the humeral diaphysis ○ Fractures of the proximal humerus with diaphyseal extension ○ Combined fractures of the proximal humerus and the humeral diaphysis **JIN Type Humerus Nail** ○ The JIN Type Humerus Nail is indicated for Proximal and Shaft fracture of the Humerus.
Contraindications	Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome: ○ 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. ○ Any case in which there is inadequate tissue coverage of the operative site.
Intended Patient Population	Male or Female, aged 18 years or above, skeletally mature patient.

Device description

The humerus bone nail is used for treating the fractures of proximal, diaphysis and distal fracture of the humerus bone. These nails help to align the fractured bone fragments together with the help of bone screws/locking screws. The humerus nails consist of various types of bone nails including Konzept, JIN-Type 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 humerus bone nails and screws can be found at **www.auxein.com**.

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

Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Humerus Nailing System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev 2
EMDN Code	P091205		
Conformity Assessment Route	Conformity Assessment of Class IIb devices has been conducted as per Article 52 (4), Chapter I and III of Annex IX of EU MDR 2017/745		
Material/substances in contact with patient tissues	The Material/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 (Humerus 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

Humerus 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 humerus 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 Humerus Nailing System comprises of the following accessories which act as functional elements :

- End caps
- Instrument set

Instruments are used for fixation of nail at fracture site. The instruments are used during surgical procedures, each with their specific use. Only Auxein Instruments shall be used with the humerus nailing system. The instruments should be CE Marked.

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.

Risks and Warnings

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

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

Warning & Precautions:

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 isany 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. 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.
7. Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

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

Till now, regarding Auxein's Humerus 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 humerus is the long bone of the upper arm, connecting the shoulder to the elbow. It is an essential component of the skeletal system, playing a key role in arm movement and supporting muscles involved in lifting, pulling, and rotating.

Anatomical Features of the Humerus:

1. **Proximal End**:
   - Head: A smooth, rounded structure that fits into the glenoid cavity of the scapula, forming the shoulder joint.
   - Anatomical Neck: A groove just below the head, marking the border between the head and the rest of the bone.
   - Greater and Lesser Tubercles: Bony prominences where shoulder muscles attach.
   - Surgical Neck: A narrow region below the tubercles, prone to fractures.

2. **Shaft**:
   - Cylindrical in shape at the proximal end but flattens and becomes triangular toward the distal end.
   - Deltoid Tuberosity: A rough area on the lateral side where the deltoid muscle attaches.
   - Radial Groove: A shallow groove on the posterior surface that houses the radial nerve and deep brachial artery.

3. **Distal End**:
   - Condyle: Includes the trochlea (medial) and capitulum (lateral), which articulate with the ulna and radius, respectively, to form the elbow joint.
   - Epicondyles:
     - Medial epicondyle: A prominent structure for muscle attachment.
     - Lateral epicondyle: A smaller projection for muscle attachment.
   - Coronoid Fossa: Anterior depression that accommodates the coronoid process of the ulna during elbow flexion.
   - Olecranon Fossa: A posterior depression that accommodates the olecranon of the ulna during elbow extension.

Function:

- The humerus supports arm mobility and strength.
- It forms joints at both ends:
  - Proximally: The shoulder joint with the scapula.
  - Distally: The elbow joint with the radius and ulna.

- It serves as an attachment site for muscles of the shoulder, arm, and forearm.

Clinical Significance:

- Fractures: Common at the surgical neck, shaft, or distal end. These injuries can impact nearby nerves (e.g., radial nerve) or blood vessels.
- Osteoporosis: May weaken the humerus, making it more prone to fractures.
- Shoulder or Elbow Dislocations: Can involve the humerus, leading to restricted movement and pain.

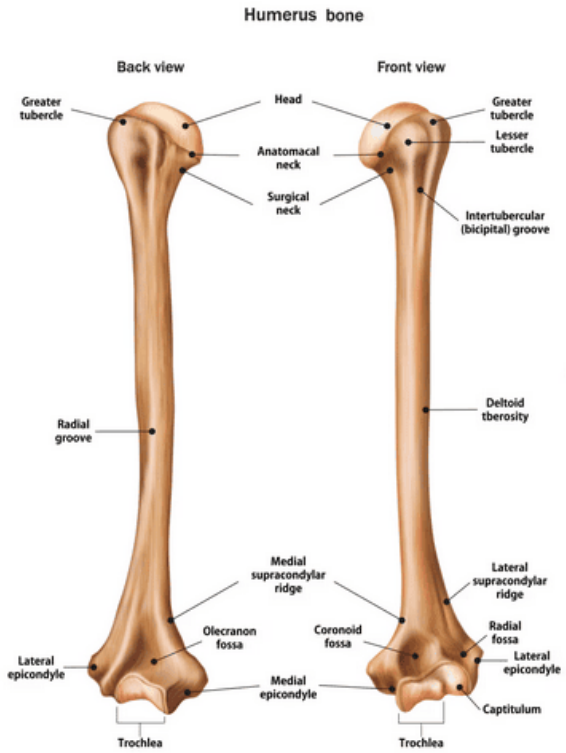


Figure: Humerus bone anatomy.

Types of Humerus Fracture

Humerus fractures are categorized based on their location on the bone and the nature of the break. These fractures can vary in severity and may involve surrounding soft tissues, nerves, or blood vessels. Below are the main types of humerus fractures:

1. **Proximal Humerus Fractures (Near the Shoulder)**

These occur near the upper end of the humerus, involving the head, anatomical neck, surgical neck, or tubercles.

- **Subtypes**:
  - Nondisplaced: The bone fragments remain aligned.
  - Displaced: The bone fragments are misaligned.
  - Comminuted: The bone is shattered into multiple pieces.
  - Fracture-Dislocation: Associated with shoulder dislocation.
- Common Causes: Falls on an outstretched arm, direct trauma to the shoulder.
- Common Complications: Damage to the axillary nerve or blood supply (avascular necrosis).

2. **Humeral Shaft Fractures (Middle Section)**

These fractures involve the cylindrical shaft of the humerus.

- **Subtypes**:
  - Transverse Fracture: A horizontal break across the shaft.
  - Oblique Fracture: A diagonal break across the shaft.
  - Spiral Fracture: Caused by twisting forces, resulting in a spiral-shaped fracture.
  - Comminuted Fracture: Multiple bone fragments.
  - Pathological Fracture: Caused by diseases like osteoporosis or bone cancer.
- Common Causes: High-energy trauma (e.g., motor vehicle accidents) or falls in older adults.
- Common Complications: Radial nerve injury, leading to wrist drop.

3. **Distal Humerus Fractures (Near the Elbow)**

These fractures occur at the lower end of the humerus, involving the condyles, epicondyles, or olecranon fossa.

- **Subtypes**:
  - Intercondylar Fracture: A "T" or "Y"-shaped fracture between the medial and lateral condyles.
  - Supracondylar Fracture: Occurs above the condyles and is common in children.

- Transcondylar Fracture: A horizontal fracture through the condyles.
- Medial or Lateral Epicondyle Fracture: Fractures limited to the epicondyles.

- Common Causes: Falls on an outstretched hand, direct trauma to the elbow.
- Common Complications: Ulnar nerve injury or stiffness in the elbow joint.

Special Fracture Types:

1. Greenstick Fracture: Incomplete fractures common in children, where the bone bends and cracks on one side.
2. Pathological Fractures: Result from weakened bone due to conditions like osteoporosis, infection, or tumors.
3. Open (Compound) Fractures: The bone pierces the skin, increasing the risk of infection.
4. Stress Fractures: Rare in the humerus but can occur due to repetitive overuse, often seen in athletes like baseball pitchers.

Causes

High-energy collisions, such as an automobile or motorcycle crash, are common causes of humerus 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:

A humerus bone fracture can cause a variety of symptoms depending on the location, severity, and whether surrounding tissues, nerves, or blood vessels are affected. Below are the common symptoms associated with humerus fractures:

General Symptoms:

1. Pain:
   - Severe and immediate pain at the site of the fracture.
   - Worsens with movement of the arm or shoulder.
2. Swelling: Localized swelling around the fracture site.
3. Bruising:
   - Discoloration of the skin due to bleeding beneath the surface.
   - May appear soon after the injury or develop over a few hours.
4. Deformity:
   - Visible misalignment of the arm, especially in displaced or severe fractures.
   - Shortening of the arm may occur in comminuted fractures.

5. Limited Mobility: Difficulty or inability to move the shoulder, elbow, or arm due to pain and mechanical obstruction.
6. Tenderness: Sensitivity to touch at the fracture site.

Symptoms Based on Fracture Location:

1. Proximal Humerus Fracture (Near the Shoulder):
   - Pain and swelling near the shoulder.
   - Difficulty lifting the arm.
   - Bruising around the shoulder and possibly extending to the chest or upper arm.
   - Possible signs of nerve injury, such as numbness or weakness in the shoulder or arm (axillary nerve damage).

2. Humeral Shaft Fracture (Middle Section):
   - Pain, swelling, and bruising along the middle of the arm.
   - Difficulty or inability to raise the arm.
   - Potential radial nerve injury causing:
     - Wrist drop: Inability to extend the wrist or fingers.
     - Numbness on the back of the hand.

3. Distal Humerus Fracture (Near the Elbow):
   - Swelling, pain, and bruising around the elbow joint.
   - Stiffness or difficulty bending or extending the elbow.
   - Possible deformity at the elbow.
   - Ulnar nerve symptoms, such as tingling, numbness, or weakness in the ring and little fingers.

Severe or Complicated Fractures:

1. Open Fracture:
   - Bone protruding through the skin.
   - High risk of infection.

2. Nerve or Blood Vessel Injury:
   - Nerve injury symptoms:

- Numbness, tingling, or weakness in the hand, forearm, or upper arm.

- Blood vessel injury symptoms:
  - Pale or cold arm below the fracture.
  - Weak or absent pulse in the wrist.

3. Shock:
   - Rare in isolated humerus fractures but possible in severe trauma.
   - Symptoms may include fainting, rapid breathing, or confusion.

Diagnosis

The diagnosis of a humerus bone fracture involves a combination of a patient's medical history, physical examination, and imaging studies. Proper diagnosis is essential to determine the location, type, and severity of the fracture and to guide appropriate treatment. Below is an overview of the diagnostic process:

1. **Physical Examination**

- Inspection:
  - Check for visible deformity, swelling, or bruising.
  - Look for open wounds (indicating a compound fracture).

- Palpation:
  - Assess for tenderness, crepitus (grating sensation), or abnormal mobility at the site of injury.

- Range of Motion:
  - Assess the patient's ability to move the shoulder, elbow, and arm.
  - Movement may be limited or impossible due to pain or structural damage.

- Neurovascular Assessment:
  - Check for nerve injury:
    - ◊ Radial nerve: Test wrist and finger extension, and assess sensation on the back of the hand.
    - ◊ Ulnar nerve: Check sensation in the ring and little fingers and test hand grip.
    - ◊ Axillary nerve: Assess sensation over the lateral shoulder and deltoid function.
  - Assess blood flow by checking the radial pulse and capillary refill in the hand.

2. Imaging Studies

Imaging is the cornerstone of fracture diagnosis and helps confirm the extent, location, and type of fracture.

a. X-rays

- Standard Views:
  - AP (Anteroposterior) and lateral views of the humerus.
  - Special views may be taken to visualize difficult-to-see fractures.

- Findings:
  - Fracture lines, displacement, comminution (multiple fragments), or angulation.
  - Joint involvement (in proximal or distal fractures).

b. CT Scan (Computed Tomography)

  - Complex fractures (e.g., comminuted or intra-articular fractures).
  - Pre-surgical planning to assess fragment positions.
- Provides detailed 3D imaging of bone structure.

c. MRI (Magnetic Resonance Imaging)

- Rarely used for primary fracture diagnosis.
- Helpful to evaluate:
  - Soft tissue injuries (e.g., rotator cuff tears, ligaments).
  - Nerve damage.
  - Suspected pathological fractures.

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. A doctor may recommend pain killer medicines to relieve pain and inflammation. If the pain is severe, the doctor may suggest a prescription-strength medication for a few days. Patients should talk to their doctor if the pain has not begun to improve within a few days of surgery.

Rehabilitation and Return to Activity

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. 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 data regarding the device.

Prospective Clinical Evaluation

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

Identity of the investigation/study: A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Humerus Nailing System intended for Fracture Fixation.

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_04	Ongoing	INDIA	07/20	0	0	0
Study Title	Post Market Clinical Follow-Up Study, A Prospective, Single Arm, Post Market Clinical Follow- up (PMCF) Study to Evaluate the Safety and Performance of Humerus Nailing System intended for Fracture Fixation.					
CTRI Number	CTRI/2024/07/071664					
CTRI Registration Date	31/07/2024					
Number of study sites	One					
Name of Study Sites	Site 001	Hi-Tech Multispeciality Hospital				
No. of Patients enrolled	7					

Study design: A Prospective, Single Arm, Post Market Clinical Follow-up (PMCF) Study to Evaluate the Safety and Performance of Humerus Nailing System intended for Fracture Fixation. This is a post-marketing clinical follow-up study. This study was carried out following marketing (CE) approval intended to answer the clinical performance, efficacy and safety (i.e. residual risks) of a device when used in accordance with its approved labeling. These may examine issues such as medium-term performance, the appearance of clinical events, events specific to defined patient populations, or the performance of the device in a more representative population of providers and patients with Humerus fracture.

Inclusion criteria

Patient will be screened for the following Inclusion Criteria:

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

Exclusion criteria

1. Infection, local or Systemic Acute or Chronic Inflammation to the operative site.
2. Subjects with a disease entity or condition that could hindered bone healing and create unacceptable risk of fixation failure complications such as known active cancer, neuromuscular disorder etc.
3. In case subject has inadequate tissue coverage of the operative site.
4. Subjects with Symptomatic Arthritis.
5. Subjects with Suspected or documented metal allergy or intolerance.
6. Subjects with substance abuse/alcohol issues.
7. Subjects who are incarcerated or have pending incarceration.
8. Female participant who is pregnant or planning pregnancy during the course of the study.
9. Fracture that are not amenable to humerus nailing technique.
10. Any patient unwilling to cooperate with the post-operative instructions.
11. Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
12. Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices
13. Implant utilization that would interfere with anatomical structures or physiological performance.

Primary Objective

1. To assess the safety and performance of the Humerus Nailing system by evaluating the quality of fusion through Radiological Evaluation.

2. The Change in Disability of the Arm, Shoulder and Hand Score (DASH Score) from preoperative to follow-up visits at 6 week, 3 month, 6 month and 12 month.

Secondary Objective

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

Primary Endpoints

1. Radiological evaluation by X-ray radiographs to calculate mean time to achieve bone fusion and deformity correction or stabilization.
2. Quality of movement in arm and shoulder by calculating DASH score.

Secondary Endpoints

1. Analyzing Visual analogue score (VAS) for pain assessment.
2. Any adverse event or serious adverse event during follow up, especially the one mentioned in the Product Description. Follow up will be done at - Baseline, at 6 week, 3 month, 6 month and 12 month.

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (kg/m2)
Mean ± SD	33.5 ± 11.5	65 ± 12.6	162.8 ± 4.5	24.4 ± 3.79
Median	31	58	162	22.9
Range	20-55	56 - 86	159 - 170	21.2 - 29.8

Gender distribution of study subjects

Male	6/7 (85.71%)
Female	1/7 (14.2%)

The mean age of recruited subjects is 33.5 years, mean weight is 65 kg and mean height is 162.8cm. The mean BMI of the study participants is 24.4 kg/m2.

Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the Humerus Nailing device. This longitudinal study was designed as a single-arm study. The target population for this research comprised both males and females aged 18 years or above, skeletally mature patient at the time of surgery. The study aimed to recruit a total of 20 subjects who experienced humerus related fracture, and they were treated using a Humerus Nail construct.

A total of seven study visits are there. Subject is screened, and followed at Baseline 1 (pre surgery) and Baseline 2 (post surgery). After which 4 follow-up visits are conducted. All the respective assessments are performed and recorded from Visit 1 to Visit 7 for all the study subjects as per the study protocol. From the date of surgery, subject are followed at 6 week, 3 month, 6 month and 12 month. Assessments included standardized clinical evaluation and completion of the VAS score and the DASH.

Study Result

The study provides valuable insights into the composition of the study population and the changes observed in cardiovascular and respiratory status over time, along with the impact of the intervention on pain relief and functional improvement. Additionally, the gender distribution and average weight and height of the subjects provide important context for understanding the study results. The study's focus on monitoring cardiovascular and respiratory status at different time points is significant. The observed difference were non significant which implicate that there was no significant effect on blood pressure post intervention. It was interesting to explore these factors further to understand the implications for patient health and treatment outcomes. 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 DASH highlights the intervention's effectiveness in improving functional performance. The progressive increase in DASH score 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. With regards to the Auxein's Humerus 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.

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

On plain radio graphs, anterior-posterior (AP) and lateral views demonstrate most fractures.. If standard radio graph findings are negative 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

Non-surgical treatment is often effective for stable fractures or fractures that are minimally displaced.

a. Immobilization

- Splints, Slings, or Braces:
  - Proximal humerus fractures: Treated with a sling or shoulder immobilizer.
  - Humeral shaft fractures: Functional braces or coaptation splints may be used.
  - Distal humerus fractures: Splints or casts may be applied to stabilize the elbow.
- Duration:
  - Typically 4–8 weeks, depending on the type and severity of the fracture.

b. Pain Management

- Medications:
  - Over-the-counter pain relievers (e.g., acetaminophen or ibuprofen).
  - Prescription medications for severe pain.
- Ice packs to reduce swelling and pain.

c. Physical Therapy

- Gradual rehabilitation to restore range of motion and strength after immobilization.
- Early passive range-of-motion exercises may be started under supervision, depending on the fracture.

Surgical Treatment

Surgery is required for unstable fractures, open fractures, fractures involving nerve or blood vessel damage, or when non-surgical treatment fails.

a. Indications for Surgery

- Displaced fractures.
- Open fractures (bone pierces the skin).
- Comminuted fractures (multiple bone fragments).

- Associated nerve or vascular injury.
- Pathological fractures caused by conditions like osteoporosis or cancer.

b. Surgical Techniques

1. Open Reduction and Internal Fixation (ORIF):
   - The fractured bone is realigned (open reduction) and stabilized using plates, screws, or intramedullary nails.
   - Commonly used for:
     - Proximal humerus fractures.
     - Humeral shaft fractures.
     - Distal humerus fractures involving the elbow joint.

2. Intramedullary Nailing:
   - A rod is inserted into the marrow cavity of the bone to stabilize the fracture.
   - Used for humeral shaft fractures.

3. External Fixation:
   - Metal pins and rods are placed outside the body to stabilize the bone.
   - Often used for severe open fractures or when internal fixation is not feasible.

The treatment of a humerus fracture should be individualized based on the type of fracture and patient-specific factors. Early intervention, appropriate therapy, and consistent follow-up are key to achieving successful outcomes.

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/).