SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR TIBIA 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: 0890399TNT003ZD and 08903993TNS003R9 for Titanium and Stainless Steel Implants respectively.

SRN: IN-MF-000018837

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

EXPERT TIBIA NAIL

Expert Tibia Nail, Stainless Steel/Titanium, End Cap For Expert Tibia Nail, Stainless Steel/Titanium, Ø4.8mm Locking Bolt, Self-Tapping, For Expert Tibia Nail, Stainless Steel/Titanium, Ø4.4mm Locking Bolt, Self-Tapping, For Expert Tibia Nail, Stainless Steel/Titanium

JIN-TYPE TIBIA NAIL

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

KONZEPT TIBIA NAIL

Interlocking Cannulated Tibia Nail, Stainless Steel/Titanium, End Cap For Interlocking Cannulated Tibia Nail, Stainless Steel/Titanium, Compression Screw For Interlocking Cannulated Tibia Nail, Stainless Steel/Titanium, 4.5mm Locking Bolt For Interlocking Cannulated Tibia Nail, Stainless Steel/Titanium

Details Regarding the device are provided in below table:

Device Trade Name:	**Tibia 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		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Tibia 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	2014		
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per EN ISO 5832-3:2021 and Stainless steel alloy SS 316 L as per EN ISO 5832-1:2019.		
USFDA Cleared	Yes (Tibia 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 tibial 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 tibial 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 Tibia 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 Tibia 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 Tibia 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 Tibia Nailing System is part of the Tibia Bone has the following indications: **EXPERT TIBIA NAIL** Indicated for fractures in the tibial shaft as well as for metaphyseal and certain intraarticular fractures of the tibial head and the pilon tibiale: ○ 41-A2/A3 (Tibia, proximal end segment, extraarticular, simple fracture/wedge or multifragmentary fracture) ○ 43-A1/A2/A3 (Tibia, distal end segment, extraarticular, simple fracture/wedge fracture/multifragmentary fracture) ○ All shaft fractures ○ Combinations of these fractures **JIN TYPE TIBIA NAIL** Indicated for fractures in the tibial shaft as well as for metaphyseal and certain intraarticular fractures of the tibial head and the pilon tibiale: ○ 41-A2/A3 (Tibia, proximal end segment, extraarticular, simple fracture/wedge or multifragmentary fracture) ○ 43-A1/A2/A3 (Tibia, distal end segment, extraarticular, simple fracture/wedge fracture/multifragmentary fracture) ○ All shaft fractures ○ Combinations of these fractures **KONZEPT TIBIA NAIL** Intended to stabilize fractures of the proximal and distal tibia and the tibial shaft, open and closed tibial shaft fractures, certain pre- and postisthmic fractures, and tibial malunions and Nonunions. ○ 41-A2/A3 (Tibia, proximal end segment, extraarticular, simple fracture/wedge or multifragmentary fracture) ○ 42: Tibia, diaphyseal segment ○ 43-A1/A2/A3 (Tibia, distal end segment, extraarticular, simple fracture/wedge fracture/multifragmentary fracture)
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. ○ Signs of local inflammation. ○ Infection local to the operative site ○ Fever or leukocytosis. ○ Pregnancy ○ 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 tumors or congenital abnormalities, fracture local to the operating site. ○ Suspected or documented allergy or intolerance to implant materials. The 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. ○ Any case in which implant utilization would disturb physiological processes. ○ Blood supply limitation in the operative site. ○ Morbid obesity (defined according to the WHO standards). ○ Any case in which there is inadequate tissue coverage of the operative site.
Intended Patient Population	Male or Female, aged 18 years or above, skeletally mature patient.
Intended Users	The Tibia 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 Tibia 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

EXPERT TIBIA NAILING SYSTEM		
1.	Device Name	Expert Tibia Nail
	Image	
	Total Length (mm)	255 to 375 (15mm Increment)
	Nail Diameter (mm)	8 to 12 (1mm Increment)
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.
2.	Device Name	End Cap for Expert Tibia Nail
	Image	
	Length (mm)	0 to 15 (5mm Increment)

	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.
3	Device Name	Ø4.8mm Locking Bolt, Self-Tapping, For Expert Tibia Nail
	Image	
	Length (mm)	25 to 90 (5mm Increment)
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.
4	Device Name	Ø4.4mm Locking Bolt, Self-Tapping, For Expert Tibia Nail
	Image	
	Length (mm)	24 to 88 (2mm Increment)
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

JIN-Type Tibia Nail		
5	Device Name	JIN- Type Tibia Nail
	Image	
	Nail Diameter (mm)	8 to 12 (1mm Increment)
	Nail Length (mm)	240 to 380 (20mm Increment)
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.
6	Device Name	End Cap for JIN-Type Tibia Nail
	Image	
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

7	Device Name	Ø4.5mm Locking Bolt, Self-Tapping, For JIN Type-Tibia Nail
	Image	
	Total Length (mm)	20 to 80 (5mm Increment)
	Head Length	4.5mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.
Konzept Tibia Nail		
8	Device Name	Interlocking Cannulated Tibia Nail
	Image	
	Nail Diameter (mm)	8 to 12 (1mm Increment)
	Total Length	270 to 390 (15mm Increment)
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-

		1:2019.
9	Device Name	End Cap For Interlocking Cannulated Tibia Nail
	Image	
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.
10	Device Name	Compression Screw For Interlocking Cannulated Tibia Nail
	Image	
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.
11	Device Name	4.5mm Locking Bolt For Interlocking Cannulated Tibia Nail
	Image	
	Length (mm)	30 to 90 (5mm increment)

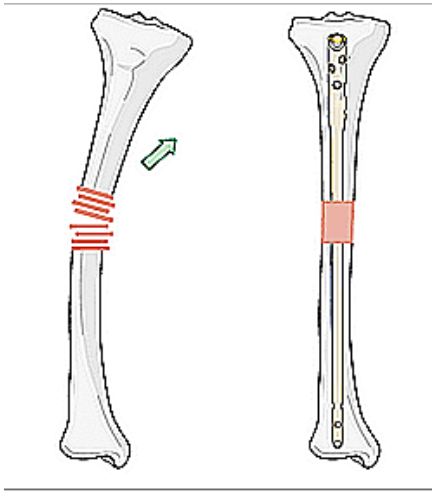
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per EN ISO 5832-3:2021 and Stainless Steel as per EN ISO 5832-1:2019.

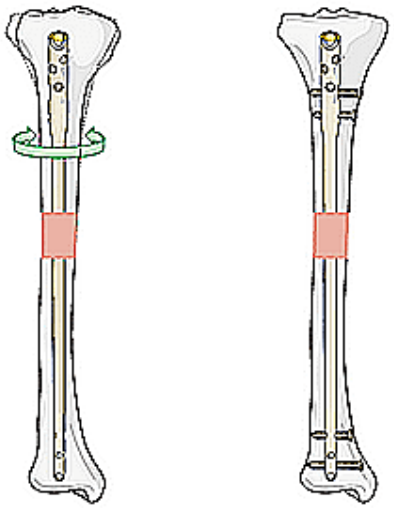
Other details of Tibia Nailing System:

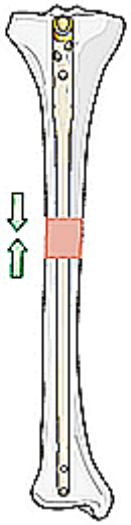
Device Compliance to regulation		We are proposing the Tibia Nailing System as per the compliance to European Union Medical Device Regulation (EU MDR 2017/745).
1.	DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES	
1.1	Device Description and Specification	
a.	Product/Trade Name	Auxein Tibia Nailing System
	General Description	The Auxein Medical Tibia Nailing comprise of Nails, Screws, End Caps, Bolts in various shapes and sizes, which is anatomically precontoured with the bone. The Tibia Nailing consist of Expert Tibia Nail, JIN Type-Tibia Nail and Konzept Tibia Nail which are used in proximal, shaft and distal end of the Tibia Bone. These nails and components are available in Stainless Steel or Titanium. The nails with components are enlisted below: Expert Tibia Nail ○ Expert Tibia Nail ○ End Cap For Expert Tibia Nail ○ Ø4.8mm Locking Bolt, Self-Tapping, For Expert Tibia Nail ○ Ø4.4mm Locking Bolt, Self-Tapping, For Expert Tibia Nail JIN Type Tibia Nail ○ JIN Type - Tibia Nail ○ End Cap For JIN Type -Tibia Nail

		○ Ø4.5mm Locking Bolt, Self-Tapping, For JIN Type - Tibia Nail Konzept Tibia Nail ○ Interlocking Cannulated Tibia Nail ○ End Cap For Interlocking Cannulated Tibia Nail ○ Compression Screw For Interlocking Cannulated Tibia Nail ○ Ø4.5mm Locking Bolt For Interlocking Cannulated Tibia Nail
	Intended Purpose	The Tibia nails are intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization of tibia bone fragments.
	Intended Users	The Tibia 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	Tibia Nail is used to treat tibia bone fracture or non-union. Specifically designed tibia nail intended for treatment of fracture that provides strong fixation and restore the bone fragments.
	Patient Selection Criteria	Inclusion criteria Male or Female, aged 18 years or above, skeletally mature patient. Subject's diagnosed as per indication that include fractures in tibial shaft as well as for metaphyseal shaft and certain intra-articular fractures of the tibial head and the pilon tibiale: (Proximal End Segment, 41-A2/A3, All shaft fractures and Distal end Segment 43-A1/A2/A3) Patient Exclusion Criteria: ○ Subjects with a disease entity or condition that could hinder bone healing and create unacceptable risk of fixation failure or complications such as known active cancer, neuromuscular disorder etc. ○ In case in subject has inadequate tissue coverage of the operative site (Open fracture, Gustilo type IIIC)

		○ Subjects who are incarcerated or have pending incarceration. ○ Female participant who is pregnant or planning pregnancy during the study. ○ Fracture that are not amenable to intramedullary tibia nailing technique ○ Morbid obesity (BMI (Kg/m^2)) > 35
c.	Principles of Operation Mode of Action	Tibia 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 Tibia 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, Tibia nail is an implant used in humans for medical purposes to treat tibia 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 Tibia nail is an implant used for the treatment of tibia 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 Tibia nail is an implantable device used for the treatment of tibia 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 Tibia nail is intended to treat tibia 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 Tibia nail is made up of metal alloy and employed to fix tibia 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 Tibia 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 Tibia Nailing System used to stabilize tibia 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 Tibia Nailing System is intended for fixation for fractures of the tibia bone. The system is not meant for cleaning, disinfection or sterilization of device
e.	Novel Features	The Tibia 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 Tibia Nailing System comprises of : ● Nails in varying lengths and types ● Screws

		● Locking Bolts ● End caps Nails are used with accessories for implantation in the tibia to correct the abnormal curvature. The Tibia 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. 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.
g.		
	Sterility	All Products covered in Tibia 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 Tibia 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 Tibia 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 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 (Tibia 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: ■ Expert Tibial Nail:- Synthes (CE 0123) ■ T2 Alpha Tibia Nailing System:- Stryker (CE 0123) ■ Tibia Nail:- ChM (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 VAS Scores
- Measure the LEFS
- 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. 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.
2. Generally, the fracture heals within a year and after that the manufacturer recommends removing the implant from the body. However, it is the patient's choice and after consulting with the surgeon, the implants can be removed. Removal of the nails should be undertaken between 3 to 5 months providing x-rays are satisfactory.
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.

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 Single arm prospective case series, to evaluate the safety and effectiveness of Intramedullary Tibia Nailing System intended for Tibia bone related fracture fixation (PMCF-INITIA NAIL)

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	35/35	0	0	0
Study Title	Post Market Clinical Follow-Up Study, A Single arm prospective case series, to evaluate the safety and effectiveness of Intramedullary Tibia Nailing System intended for Tibia bone related fracture fixation (PMCF-INITIA NAIL)					
CTRI Number	CTRI/2022/10/046936					
CTRI Registration Date	31/10/2022					
Number of study sites	Two					
Name of Study Sites	Site 001	Eternal Hospital, Gujarat, India	Site 002	Akhila Hospital, Rajasthan, India		
No. of Patients enrolled	1		34			

Study design: Post Market Clinical Follow-up (PMCF) study has been carried out to evaluate the safety and performance of Tibia Nail System (PMCF-INITIA NAIL). 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 Tibia fracture.

Inclusion criteria

- Subject is willing and able to give informed consent for participation in the study.
- Male or Female, aged 18 years or above, skeletally mature patient.
- Subject is willing and able to complete required study visits or assessments.
- Subject's diagnosed as per indication that include fractures in tibial shaft as well as for metaphyseal shaft and certain intra-articular fractures of the tibial head and the pilon tibiale:
  - 41-A2/A3
  - All shaft fractures
  - 43-A1/A2/A3

Exclusion criteria

- Subjects with a disease entity or condition that could hindered bone healing and create unacceptable risk of fixation failure or complications such as known active cancer, neuromuscular disorder etc.
- In case in subject has inadequate tissue coverage of the operative site. (Open fracture, Gustilo type IIIC)
- Subjects unwilling to sign the Informed Consent document.
- Subjects who are incarcerated or have pending incarceration.
- Female participant who is pregnant or planning pregnancy during the course of the study.
- Fracture that are not amenable to intramedullary tibia nailing technique
- Morbid obesity (BMI (Kg/m^2)) > 35

Primary Objective

- To assess the effectiveness of the device by evaluating the prospective results of surgical treatment of patients treated with Intramedullary tibia Nailing System

- To analyse the safety associated with Intramedullary tibia nailing system

Secondary Objective

- Quality of fusion through radiological evaluation.
- Pain evaluation through Visual Analogue Scale (VAS).
- Residual Risk assessment.

Primary Endpoints

Primary endpoint that is patient reported Lower extremity functional score (LEFS) score will be presented with mean, SD, median min and max with 95% two-sided confidence interval. Change in patient reported Lower extremity functional score (LEFS) score from baseline to 12 months will be analyzed using paired t-test at 5% level of significance.Rate of any adverse event and complications during follow-up will be presented with count and percentages.

Secondary Endpoints

Visual Analog Scale (VAS) – pain will be presented with mean, median, SD, min and max. Significant change in VAS score from baseline to each visit will be analysed using paired t-test at 0.05 level of significance. Radiologic Evaluation - X-rays will be used to calculate mean time to callus formation & bone union. Duration of Hospital stay will be presented with mean, median, sd, min and max. Revision rate (Removal of any Component), Re-operation Rate will be presented with counts and percentages.

Population Detail:

Summary of Demographics and Baseline Characteristics

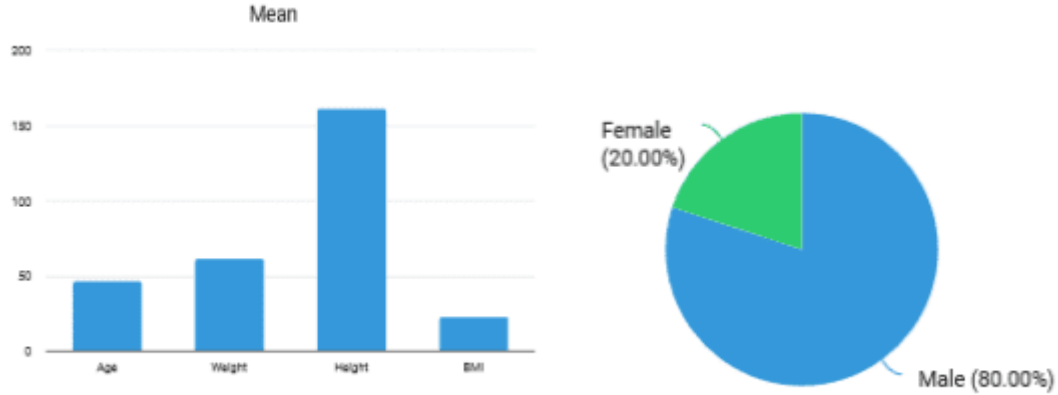
Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (kg/m^2)
Mean	47	62	162	23.4
Range	18-83	40-73	151-178	19.6-30.3

Gender distribution of study subjects

Male	28
Female	7

The study included a total of 35 subjects with a mean age of 47 years, ranging from 18 to 83 years. Notably, a significant proportion of the subjects were above 40 years of age. The mean weight of the subjects was 62 kg, with weights ranging from 40 to 73 kg. The mean BMI of the subjects was 23.4 kg/m2. In terms of height, the subjects had an average of 162 cm, with heights ranging from 151 to 178 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.

The figures provides the information of demographic and baseline characteristics.



Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the KN-2T Tibia 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 35 subjects who experienced tibia related fracture, and they were treated using a tibia Nail construct.

Post Market Clinical Follow-up (PMCF) study has been carried out to evaluate the safety and performance of Tibia Nail System (PMCF-INITIA NAIL). 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 Tibia fracture.

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 as per protocol. The final study visit will be Visit 7.

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. The majority of participants were above 40 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 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 would be interesting to explore these factors further to better 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 had a positive impact on the patients' quality of life.

Furthermore, the enhancement in functional scores as measured by the Lower Extremity Functional Scale highlights the intervention's effectiveness in improving functional performance. The progressive increase in Lower Extremity Functional Scale 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 Tibia 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 Tibia 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 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

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

Surgical Treatment

Timing of surgery. Most Tibial 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 tibial shaft fractures require surgery to heal. It is unusual for tibial 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 Tibia 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	02-02-2024	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	20-05-2024	SSCP Revised as per queries received from List of Findings - Assessment PRJN-629776	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
02	15-07-2024	SSCP Revised as per queries received from List of Findings - Assessment PRJN-629776	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

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

Document revision: 00
Date issued: 30-10-2023

Device identification and general information

Device Trade Name: Auxein Tibia 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: 08903993TNS003R9 (For Stainless Steel Implants) and 0890399TNT003ZD (For Titanium Implants).
Year when the device was first CE-marked: 2014

Intended use of the device

Intended Purpose	The Tibia Nailing System is intended for fracture fixation of tibia bone including proximal, shaft and distal Tibia.
Indications of Use	EXPERT TIBIA NAIL Indicated for fractures in the tibial shaft as well as for metaphyseal and certain intraarticular fractures of the tibial head and the pilon tibiale: ○ 41-A2/A3 (Tibia, proximal end segment, extraarticular, simple fracture/wedge or multifragmentary fracture) ○ 43-A1/A2/A3 (Tibia, distal end segment, extraarticular, simple fracture/wedge fracture/multifragmentary fracture) ○ All shaft fractures ○ Combinations of these fractures JIN TYPE TIBIA NAIL Indicated for fractures in the tibial shaft as well as for metaphyseal and certain intraarticular fractures of the tibial head and the pilon tibiale:

	○ 41-A2/A3 (Tibia, proximal end segment, extraarticular, simple fracture/wedge or multifragmentary fracture) ○ 43-A1/A2/A3 (Tibia, distal end segment, extraarticular, simple fracture/wedge fracture/multifragmentary fracture) ○ All shaft fractures ○ Combinations of these fractures KONZEPT TIBIA NAIL Intended to stabilize fractures of the proximal and distal tibia and the tibial shaft, open and closed tibial shaft fractures, certain pre- and postisthmic fractures, and tibial malunions and Nonunions. ○ 41-A2/A3 (Tibia, proximal end segment, extraarticular, simple fracture/wedge or multifragmentary fracture) ○ 42: Tibia, diaphyseal segment ○ 43-A1/A2/A3 (Tibia, distal end segment, extraarticular, simple fracture/wedge fracture/multifragmentary fracture)
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. ○ Signs of local inflammation. ○ Infection local to the operative site ○ Fever or leukocytosis. ○ Pregnancy ○ 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 tumors or congenital abnormalities, fracture local to the operating site. ○ Suspected or documented allergy or intolerance to implant materials. The 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. ○ Any case in which implant utilization would disturb physiological processes. ○ Blood supply limitation in the operative site. ○ Morbid obesity (defined according to the WHO standards).

	○ Any case in which there is inadequate tissue coverage of the operative site.
Intended Patient Population	Male or Female, aged 18 years or above, skeletally mature patient.

Device description

The Tibia bone nail is used for treating the fractures of proximal, distal and shaft tibial fractures. These nails help to align the fractured bone fragments together with the help of bone screws/locking screws. The tibial nails consist of various types of bone nails including Expert, 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 tibia bone nails and screws can be found at **www.auxein.com**.

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

Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Tibia Nailing System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev 2
Material/substances in contact with patient tissues	The Material/substances that comes in contact with patient tissues used are Titanium alloy Ti-6AL-4V as per EN ISO 5832-3:2021 and Stainless steel alloy SS 316 L as per EN ISO 5832-1:2019.		
USFDA Cleared	Yes (Tibia 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

Tibia 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 Tibia 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 Tibia Nailing System comprises of :

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

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

The Tibia 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.

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.

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. Generally, the fracture heals within a year and after that the manufacturer recommends removing the implant from the body. However, it is the patient's choice and after consulting with the surgeon, the implants can be removed. Removal of the nails should be undertaken between 3 to 5 months providing x-rays are satisfactory.
4. After healing occurs, these devices serve no functional purpose and therefore should be removed.
5. 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).
6. 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.
7. 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.
8. 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 Tibia 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 tibia, also known as the shank or shin-bone, is one of the two long leg bones of the lower leg. It is a weight-bearing bone. As mentioned, the tibia is located in the lower leg, extending from the knee to the ankle. More precisely, it is situated on the distal side of the femur and the proximal side of the talus of the foot. The tibia is also located medially to the other bone of the lower leg, called the fibula. You can feel the presence of this bone by touching the front

portion of your lower leg, just below the knee. It is a long bone with two ends, proximal and distal, and an intervening shaft. The part lying on the side of the knee is known as the proximal tibia, whereas the part lying on the side of the foot is known as the distal tibia.

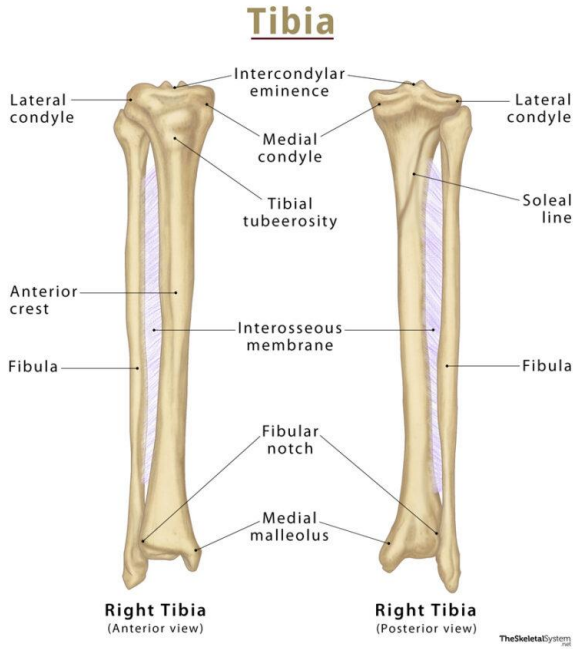


Figure: Tibia bone anatomy.

Types of tibia Fracture

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

Causes

High-energy collisions, such as an automobile or motorcycle crash, are common causes of tibial 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 tibia 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 tibia
- 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 tibia.

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: Post Market Clinical Follow-Up Study, A Single arm prospective case series, to evaluate the safety and effectiveness of Intramedullary Tibia Nailing System intended for Tibia bone related fracture fixation (PMCF-INITIA NAIL)

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	35/35	0	0	0
Study Title	Post Market Clinical Follow-Up Study, A Single arm prospective case series, to evaluate the safety and effectiveness of Intramedullary Tibia Nailing System intended for Tibia bone related fracture fixation (PMCF-INITIA NAIL)					
CTRI Number	CTRI/2022/10/046936					
CTRI Registration Date	31/10/2022					
Number of study sites	Two					

Name of Study Sites	Site 001	Eternal Hospital, Gujarat, India	Site 002	Akhila Hospital, Rajasthan, India
No. of Patients enrolled	1		34	

Study design: Post Market Clinical Follow-up (PMCF) study has been carried out to evaluate the safety and performance of Tibia Nail System (PMCF-INITIA NAIL). 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 Tibia fracture.

Inclusion criteria

- Subject is willing and able to give informed consent for participation in the study.
- Male or Female, aged 18 years or above, skeletally mature patient.
- Subject is willing and able to complete required study visits or assessments.
- Subject's diagnosed as per indication that include fractures in tibial shaft as well as for metaphyseal shaft and certain intra-articular fractures of the tibial head and the pilon tibiale:
  - 41-A2/A3
  - All shaft fractures
  - 43-A1/A2/A3

Exclusion criteria

- Subjects with a disease entity or condition that could hindered bone healing and create unacceptable risk of fixation failure or complications such as known active cancer, neuromuscular disorder etc.
- In case in subject has inadequate tissue coverage of the operative site. (Open fracture, Gustilo type IIIC)
- Subjects unwilling to sign the Informed Consent document.
- Subjects who are incarcerated or have pending incarceration.
- Female participant who is pregnant or planning pregnancy during the course of the study.
- Fracture that are not amenable to intramedullary tibia nailing technique
- Morbid obesity (BMI (Kg/m2)) > 35

Primary Objective

- To assess the effectiveness of the device by evaluating the prospective results of surgical treatment of patients treated with Intramedullary tibia Nailing System
- To analyse the safety associated with Intramedullary tibia nailing system

Secondary Objective

- Quality of fusion through radiological evaluation.
- Pain evaluation through Visual Analogue Scale (VAS).
- Residual Risk assessment.

Primary Endpoints

Primary endpoint that is patient reported Lower extremity functional score (LEFS) score will be presented with mean, SD, median min and max with 95% two-sided confidence interval. Change in patient reported Lower extremity functional score (LEFS) score from baseline to 12 months will be analyzed using paired t-test at 5% level of significance.Rate of any adverse event and complications during follow-up will be presented with count and percentages.

Secondary Endpoints

Visual Analog Scale (VAS) – pain will be presented with mean, median, SD, min and max. Significant change in VAS score from baseline to each visit will be analysed using paired t-test at 0.05 level of significance. Radiologic Evaluation - X-rays will be used to calculate mean time to callus formation & bone union. Duration of Hospital stay will be presented with mean, median, sd, min and max. Revision rate (Removal of any Component), Re-operation Rate will be presented with counts and percentages.

Population Detail:

Summary of Demographics and Baseline Characteristics

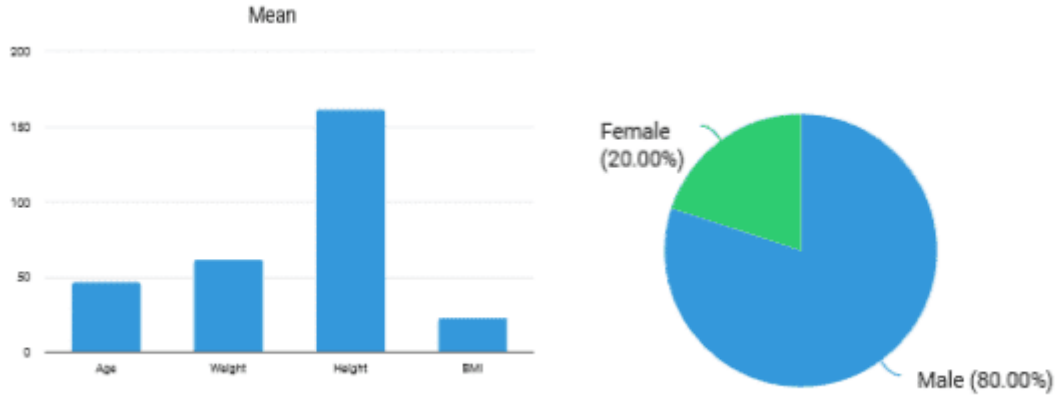
Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (kg/m2)
Mean	47	62	162	23.4
Range	18-83	40-73	151-178	19.6-30.3

Gender distribution of study subjects

Male	28
Female	7

The study included a total of 35 subjects with a mean age of 47 years, ranging from 18 to 83 years. Notably, a significant proportion of the subjects were above 40 years of age. The mean weight of the subjects was 62 kg, with weights ranging from 40 to 73 kg. The mean BMI of the subjects was 23.4 kg/m2. In terms of height, the subjects had an average of 162 cm, with heights ranging from 151 to 178 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.

The figures provides the information of demographic and baseline characteristics.



Study Method

The investigational plan involved conducting a Post Marketing Clinical Follow-Up (PMCF) study to evaluate the safety and performance of the KN-2T Tibia 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 35 subjects who experienced tibia related fracture, and they were treated using a tibia Nail construct.

Post Market Clinical Follow-up (PMCF) study has been carried out to evaluate the safety and performance of Tibia Nail System (PMCF-INITIA NAIL). 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 Tibia fracture.

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 as per protocol. The final study visit will be

Visit 7.

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. The majority of participants were above 40 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 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 would be interesting to explore these factors further to better 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 had a positive impact on the patients' quality of life.

Furthermore, the enhancement in functional scores as measured by the Lower Extremity Functional Scale highlights the intervention's effectiveness in improving functional performance. The progressive increase in Lower Extremity Functional Scale 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 Tibia 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 Tibia 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 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

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

Surgical Treatment

Timing of surgery. Most Tibial 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 tibial shaft fractures require surgery to heal. It is unusual for tibial 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/).