SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR ELASTIC 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: 0890399ENS001K2 for Titanium Implants

SRN: IN-MF-000018837

Auxein's Elastic Nail is a flexible nail which is designed curved with a tapered tip to facilitate insertion. It is non- cannulated, one piece with straight shaft design that can be cut to size intraoperatively. The nail is available in 1.5 to 4.0mm diameter and 440mm length. This is a single-use device intended for temporary implantation that restores the diaphyseal and certain metaphyseal/epiphyseal fracture of the long bone to its natural state. The nail is available in titanium alloy. The nail with the component is enlisted below:

- Elastic Nail
- End Cap for Elastic Nail, Size 1, Titanium (For Ø3.0-4.0mm)
- End Cap for Elastic Nail, Size 2, Titanium (For Ø1.5-2.5mm)

Details Regarding the device are provided in below table:

Device Trade Name:	**Elastic 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, Elastic Nailing System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000363901-PA-NA-IND Rev 2
Year when the first certificate (CE)	2014		

was issued covering the device	
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium alloy Ti-6AL-4V as per ISO 5832-3:2021.
USFDA Cleared	Yes (Elastic Nailing are approved by USFDA whose details are as follow:) **510(k) Number:** K210792, K192003
EMDN Code	P09120201
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.
Risk Class	IIb {According to REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT, Annex VIII, Chapter-3, Rule 8 - Implantable devices and long-term surgically invasive devices (> 30 days)} are in Class IIb unless they are intended: 1. Are intended to be placed in the teeth, in which case they are classified as class IIa; ***Applicable/ Not Applicable:*** *Not Applicable* ***Justification:*** *The elastic nail intended to be placed in 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 elastic nail comes in contact with the 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 elastic 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 elastic nail 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 elastic nail implants made up of metal alloys to provide support for the fractured 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 elastic 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 elastic nailing system treats 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 elastic nailing system treats 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 elastic nailing system is an implantable device to treat bone fractures. The nailing system is not recommended for the Spinal Disc Replacement Implants and does 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 Elastic Nailing System include: **Titanium Elastic Nail** ● Diaphyseal and certain metaphyseal fractures of long bones, certain metaphyseal/epiphyseal fractures (Salter Harris, I and II), including but not limited to radial neck fractures complex clavicular fractures (significant dislocation, including shortening, “floating shoulder”) open fractures, threat of skin perforation at fracture ends pathologic fractures, diaphyseal fractures of long bone in upper extremity and lower extremity in pediatrics.
Contraindications	Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome: ○ Any active or suspected latent infection or marked local inflammation in or about the affected area. ○ Compromised vascularity that would inhabit adequate blood supply to the fracture or the operative site.

	○ Bone stock compromised by disease, infection or prior implantation that can not proved adequate support and/or fixation of the devices. ○ Material Sensitivity, documented or suspected ○ Insufficient blood flow ○ Obesity: The use of this device is contraindicated in patients who are obese. ○ Weight Limitation for Lower Limbs: The use of this device is contraindicated in patients weighing more than 49 kg when treating lower limbs. ○ Patients having inadequate tissue coverage over the operative site. ○ Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care
Intended Patient Population	Subject legal Guardian/ Parent willing and able to give informed consent for participation in the study, Girl and Boy between 6 to 15 years, subject diagnosed with diaphyseal fractures, metaphyseal and epiphyseal fractures of long bones.
Intended Users	The Auxein's Elastic 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 Elastic 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

ELASTIC NAILING SYSTEM		
1.	**Device Name**	**Elastic Nail**
	Image	
	Total Length	440mm
	Nail Diameter	1.5, 2.0, 2.5, 3.0, 3.5 and 4.0mm
	Tip Length	12.6 (Ø1.5), 20.5 (Ø2.0), 20.5 (Ø2.5), 21.5 (Ø3.0), 22.5 (Ø3.5), 22.5 (Ø4.0)
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021
2.	**Device Name**	**End Cap for Titanium Elastic Nail, Size 1**
	Image	
	Diameter	3.0 to 4.0mm
	Total Length	14mm
	Thread Length	6.90mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

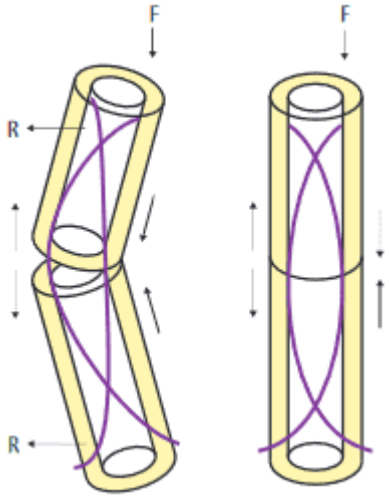
3	**Device Name**	**End Cap for Titanium Elastic Nail, Size 2**
	Image	
	Diameter	1.5 to 2.5mm
	Total Length	25mm
	Thread Length	10.80mm
	Directional Configuration (Left & Right)	Not Applicable
	Raw Material Specification	Titanium Alloy as per ISO 5832-3:2021

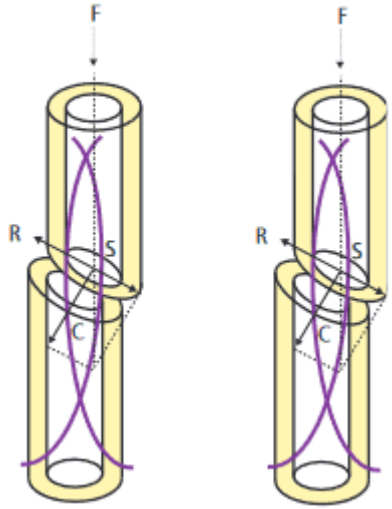
Other details of Elastic Nailing System:

Device Compliance to regulation		We are proposing the Elastic 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 Elastic Nailing System
	General Description	Auxein's Elastic Nail is a flexible nail which is designed curved with a tapered tip to facilitate insertion. It is non- cannulated, one piece with straight shaft design that can be cut to size intraoperatively. The nail is available in 1.5 to 4.0mm diameter and 440mm length. This is a single-use device intended for temporary implantation that restores the diaphyseal and certain metaphyseal/epiphyseal fracture of the long bone to its natural state. The nail is available in titanium alloy. The nail with the component is enlisted below:

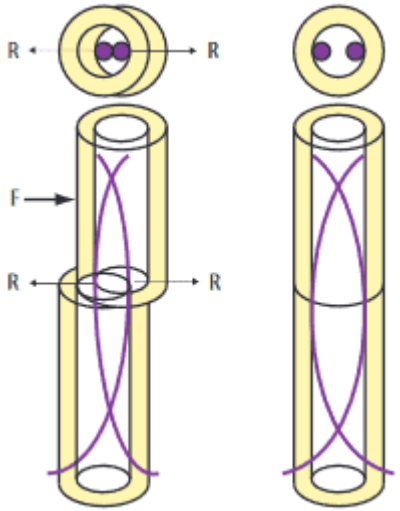
		○ Elastic Nail ○ End Cap for Elastic Nail, Size 1, Titanium (For Ø3.0-4.0mm) ○ End Cap for Elastic Nail, Size 2, Titanium (For Ø1.5-2.5mm)
	Intended Purpose	Intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization bone fragments.
	Intended Users	The Auxein's Elastic Nailing System is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Elastic Nailing System is recommended for used in Girl and Boy between 6 to 15 years. The patient conditions and/or pre-dispositions such as those addressed in the contraindications should be avoided.
	Medical Conditions to be diagnosed, treated and/or monitored	Elastic Nail is used to treat diaphyseal and metaphyseal/epiphyseal fracture of the long bone. Specifically designed elastic nail intended for treatment of fracture that provides strong fixation and restore the bone fragments.
	Patient Selection Criteria	**Patient Inclusion criteria** The device is to be used in children with the age group of 6 to 15 years and diagnosed with diaphyseal fractures, metaphyseal and epiphyseal fractures of long bones. **Patient Exclusion criteria** Subjects with Local or Systemic acute or chronic inflammation, Active infection or inflammation, Suspected or documented metal allergy or intolerance, Symptomatic Arthiritis, Patient with Mental Disorders as well as comprehensive legal support, Lack of willingness to make a commitment to return for required follow up visits and Drug and/or alcohol abuse, Morbid obesity are not included.
c.	Principles of Operation	Elastic Nailing system works to achieve a level of reduction and stabilization of Fracture. The biomechanical principle of elastic nail is based on the symmetrical bracing action of two elastic nails inserted into the metaphysis, each of which bears against the inner bone at three points. This produces the following four properties:

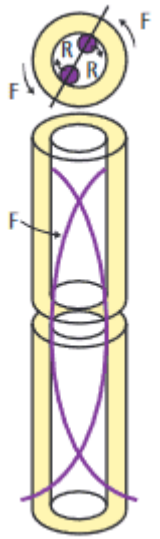
	Mode of Action	This produces the following four properties: 1. Flexural Stability 2. Axial Stability 3. Translational Stability 4. Rotational Stability The nails are performed in a C-shaped manner through the metaphysis into the medullary canal, advanced through the fracture site and impacted into the opposite metaphysis. The biomechanical principle is based on the symmetric bracing action of two nails inserted into the metaphysis, each of which bears against inner bone at three points. This produces the following four properties: flexural stability, axial stability, translational stability and rotational stability. All four are essential for achieving optimal results.

	Scientifically demonstration of Principle of Operation	**Step 1**: Flexural stability  **Step 2**: Axial stability



Step 3: Translational stability

		 **Step 4**: Rotational stability

		 F = force acting on the bone R = restoring force of the nail S = shear force C = compressive force
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, elastic nail is an implant used in humans for medical purposes to treat diaphyseal and certain metaphyseal/epiphyseal fractures of long bones in upper extremity and clavicle shaft 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 elastic nail is an implant used in humans for medical purposes to treat diaphyseal and certain metaphyseal/epiphyseal fractures of long bones in upper extremity and clavicle shaft 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 Elastic nail is an implantable device used for the treatment of 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 elastic nail is intended to treat diaphyseal, certain metaphyseal/epiphyseal and clavicle shaft 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*** Elastic nail is made up of metal alloy and employed to fix diaphyseal, metaphyseal/epiphyseal and clavicle shaft bone fracture. 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 elastic 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 elastic nailing system used to stabilize bone 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 elastic nailing system is intended for fixation of diaphyseal and metaphyseal/epiphyseal fracture of long bone and clavicle shaft fracture. The system is not meant for cleaning, disinfection or sterilization of device

e.	Novel Features	The Elastic 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 the device related to raw material, design, manufacturing process (coolants, lubricants, chemicals), intended use, post processing, etc.
f.	Description of key functional elements	The Elastic Nailing System comprises of : ● Nails in varying diameter ● End caps Nails are used with accessories for implantation in the bone to correct the abnormal curvature. The Elastic Nailing System is clinically improved by using Internal Fixation with Angular Stability (Internal Fixators) in fractures. **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. ○ Two sizes of end caps to cover the nail diameters ○ The end cap ensures that the elastic does not slide back through the insertion sit. ○ Maintain repositioning and length of the bone are retained until healing is complete, and leg shortening is prevented. ○ The end cap also provides protection against painful soft-tissue irritation. ○ The end cap can be introduced in a minimally invasive manner without additional enlargement of the incision or drilling ○ Using the end cap makes it easier to extract the nail.
g.		
	Sterility	All Products covered in Elastic 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 15 minutes (Moist Heat Sterilization/Autoclave Sterilization) as instructed in IFU for Non-sterile devices before implantation.
	Radioactivity	Products covered in Elastic 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 Elastic Nailing System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Elastic Nailing System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.
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 (Elastic Nails are approved by USFDA whose details are as follow:) **510(k) Number:** K210792, K192003

b.	Similar devices available in Union or international market.	The Similar devices available in the Union or International Market enlisted below: ■ Elastic Nail System: Depuy Synthes (CE 0123) ■ Flexible Nailing System:- Stryker (CE 0123) ■ Austofix Junior Elastic Nail:- Austofix (CE 2797)

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

Residual risks and undesirable effects

A listing of possible adverse events may take maximum of 6 Months to develop/appear which includes, but is not limited to:

- Adverse tissue reaction, allergic reaction or anaphylaxis
- Infection
- Loss of fixation, attributable to non-union, osteoporosis, unstable comminuted fracture
- Poor joint mechanic
- Damage to surrounding structures
- Pain and discomfort
- Phlebitis
- Soft tissue damage (including compartment syndrome)
- Allergies and other metal sensitivity reactions to device materials
- Loosening or migration of the implant
- Decrease of bone density due to stress shielding
- Delayed or nonunion that may lead to implant breakage
- Vascular disorders including thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis

Warning & Precautions:

1. Demonstrates anatomical or physiological abnormalities.
2. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, good reduction of bone fragments, proper patient selection and correct placement of the implants are all equally important for the successful use of these products.
3. Use extreme care in the handling and storage of implants and instruments. Cutting, bending or scratching the surface of metal components can significantly reduce the corrosion, strength, and fatigue resistance of the implant and instrument system.
4. Reuse and Re-process of a device is strictly forbidden. Each implant used once must be disposed of properly. Reuse of the medical device intended for single use devices may lead to infection, degraded performance or a loss of functionality.
5. Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. We decline all responsibility in the case of implants from difference sources being mixed.
6. Elastic Nail is not intended to support the patient's weight as excessive loads may cause the device to fail. Weight bearing will depend upon the fracture pattern and stability, patient compliance and other associated injuries. Progression of weight bearing should be at the discretion of the surgeon.

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

Retrospective Clinical Data through Published Literatures:

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

The clinical data that were Retrospectively analyzed by surgeon was considered in this evaluation, which includes 38 patients' (from 1 Clinical Papers). These all patients have femur diaphyseal fracture and were treated using Auxein's Elastic Nailing System. From the analysis of the data it is found that there are no safety and performance concerns regarding the use of device. There were no complications noticed related to Elastic Nailing System in literature and hardware related complications were also not encountered.

S.No.	Clinical Paper Title	Injury Type	Implant Used	Patients	Complications, if any
1.	S. Nury Jumadurdy and I. N Mohamed	Femoral Diaphyseal	Elastic Nail Size	38	No complication was

	S.Nury, Functional outcomes of femoral diaphyseal fractures using titanium elastic nail: A retrospective study	Fracture			reported till final 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 non- randomized, prospective Post Market Clinical Follow-up study to evaluate the Safety and Performance of Elastic Nailing.

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_06	Ongoing	India	30/30	0	0	0
Study Title	A non- randomized, prospective Post Market Clinical Follow-up study to evaluate the Safety and Performance of Elastic Nailing.					
CTRI Number	CTRI/2023/05/052536					
CTRI Registration Date	11/05/2023					
Number of study sites	One					
Name of Study Sites	Site 001	Dr.Saini Orthopedic Super Speciality Centre				
No. of Patients enrolled	30					

The study design is a prospective, Interventional, post Marketing Clinical follow up of the commercially available Auxein Elastic intramedullary nail. The study will require site to obtain IRB approval prior to study enrollment. All the study subjects will participate in the informed consent procedure. All study

subjects will undergo preoperative radiographic and clinical assessment before the surgery. The post-operative clinical and radiological evaluation will be conducted at 1, 3, 6 months and then on 1 year.

Inclusion criteria

Subject legal Guardian/ Parent willing and able to give informed consent for participation in the study, Girl and Boy between 6 to 15 years, subject diagnosed with diaphyseal fractures, metaphyseal and epiphyseal fractures of long bones, were recruited for this study. Prior to enrollment, written informed consent for participation is obtained from all the study subjects.

Exclusion criteria

Subjects with Local or Systemic acute or chronic inflammation, Active infection or inflammation, Suspected or documented metal allergy or intolerance, Symptomatic Arthiritis, Patient with Mental Disorders as well as comprehensive legal support, Lack of willingness to make a commitment to return for required follow up visits and Drug and/or alcohol abuse, Morbid obesity are not included in the study.

Primary Objective

To assess the effectiveness/performance of the Elastic nail system by evaluating the quality of fusion through Radiological Evaluation. To analyze safety assessment by measuring the rate of Adverse Event, complications and pain reduction by using Elastic Intramedullary Nailing through Flynn Questainnaire.

Secondary Objective

- Pain evaluation through Visual Analogue Scale (VAS).

Primary Endpoints

Fracture fusion, [Time Frame: 12 months post operatively]

Secondary Endpoints

Rate of implant related, surgery related, postoperative and general complications.

[Time Frame : Baseline, 1month, 3 month,6 month and 12 month postoperatively]

Population Detail:

Table 1: Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)
Mean (n=30)	10.98±3.60	36.56±14.80	142.4±19.27	17.1±4.20

Table 2: Gender distribution of study subjects

Male	19/30 (63%)
Female	11/30 (37%)

Table 3: Clinical Outcomes Measures

Pain and functional scores in study participants at baseline and follow up visits

Scoring	**Baseline (n=30) [a]**	**1 Month (n=29) [b]**	**3 Month (n=26) [c]**	**6 Month (n=29) [d]**	**12 Month (n=23) [e]**	**P value**
VAS Score	8.6±0.7 (n=30)	2.9±1.7 (n=29)	1.8±1.4 (n=26)	0.72±0.88 (n=29)	0.28±1.1 (n=23)	b vs. c=0.011 b vs. d<0.001 b vs. e<0.001
LEFS Score#	1.6±2.1 (n=17)	47.4±18.8 (n=16)	52.1±21.8 (n=15)	59.8 ± 23.3 (n=17)	78.41±5.48 (n=12)	b vs. c=0.52 b vs. d=0.10 b vs. e<0.001

DASH Score##	88.1±6.3 (n=13)	23.1±21.1 (n=13)	19.7±18.9 (n=11)	2.3±5.4 (n=12)	0.7±0.24 (n=11)	b vs. c=0.68 b vs. d=0.003 b vs. e=0.002

Seventeen patients were of the lower limb in the study.

Thirteen patients were of the upper limb in the study.

Table 4: Flynn score in study participants at baseline and follow up visits

	Baseline (n=30)		**1 Month**		**3 Month**		**6 Month**		**12 Month**	
Parameter	**Satisfactory/Excellent**	**Poor**	**Satisfactory/Excellent**	**Poor**	**Satisfactory/Excellent**	**Poor**	**Satisfactory/Excellent**	**Poor**	**Satisfactory/Excellent**	**Poor**
Limb length inequality	30/30	0/30	29/29	0/29	26/26	0/26	29/29	0/29	23/23	0/23
Malalignment	30/30	0/30	29/29	0/29	26/26	0/26	29/29	0/29	23/23	0/23
Pain	29/30	1/30	29/29	0/29	26/26	0/26	29/29	0/29	23/23	0/23
Complications (Minor/Major)	29/30	1/30	29/29	0/29	26/26	0/26	29/29	0/29	23/23	0/23

The study included a total of 30 subjects with a mean age of 10.98±3.60 years, ranging from to 6 to 15 years. Notably, a significant proportion of the subjects were above 6 years of age. The majority of participants were Asian, with 19 males and 11 females recruited in the study. The mean weight of the subjects was 10.98±3.60 kg. The mean BMI of the subjects was 17.1±4.20. In terms of height, the subjects had an average of 142.4±19.27 cm. These demographic and baseline characteristics are essential for understanding the composition of the study population and provide valuable insights for the interpretation of the study results.

Study Method

The study design is a prospective, Interventional, post Marketing Clinical follow up of the commercially available Auxein Elastic intramedullary nail.

The study will require site to obtain IRB approval prior to study enrollment. All the study subjects will participate in the informed consent procedure. All study subjects will undergo preoperative radiographic and clinical assessment before the surgery. The post-operative clinical and radiological evaluation will be conducted at 1, 3, 6 months and then on 1 year.

This study is designed to identify the potential for residual risks of Auxein Medical Elastic Intra and to collect data and gain clarity regarding the long-term clinical performance of these implants. This study will confirm the clinical performance and safety of these implants in real-world use and help Auxein medical to manage acceptable risk. The safety and performance data collected from real world device usage, is expected to feed back into re-evaluation of risk determination over the life cycle of these devices. All the patients will be screened for eligibility to be included in the study. The Patients must meet all inclusion and exclusion criteria. The Post-operative follow-up duration of patient's data to be enrolled in this study will be for minimum 1 year from the date of surgery. Follow-up visits data of patients will be at 1 months, 3 months, 6 months and 12 months post operatively.

The objectives was to analyze and compare the data recorded at different time points i.e at 1 Month, 3 Month, 6 Month and 12 Month follow-up to evaluate the objectives. The bone union rate will be analyzed by calculating the mean of days required for union of bones as verified by the Principal Investigator based on radiological evaluations. DASH and LEFS score will be recorded in continuous data format and the same will be compared between different time points to assess the functionality of that particular bone and Flynn outcome score will be recorded to check effectiveness of the device. Similarly VAS score will be recorded in continuous data form for the assessment for the pain. Safety related assessment has been analyzed based on the number of adverse event occurred during the study.

Study Result

The study presented 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 6 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 vital signs were clinical stable and the slight changes observed in blood pressure as well as in respiratory rate and heart rate cannot be commented upon due to small number during follow up. It would be interesting to explore these factors further as we would have more number of patients in follow up. However, it may be mentioned that stable respiratory rate throughout the study period suggests that the intervention may not have directly impacted the subjects' respiratory function.

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 lower extremity functional scale (LEFS) highlights improved functional performance. The progressive increase in LEFS scores over the follow-up visits indicates a consistent and sustained improvement in functional ability. This demonstrates that the intervention not only provided short-term relief but also led to lasting improvements in the patients' functional status, which is crucial for their overall recovery and well-being.

As per our interim data analysis, we have observed very significant positive results with respect to our Elastic Nail device efficacy and safety. Overall, the interim findings of study 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 their quality of life and recovery from their condition after intervention with intramedullary elastic nail.

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.

Conclusion

The analysis of data from the thirty patients enrolled in the study provides valuable insights into the safety and performance of the implants. The key findings are as follows:

1. Significant improvement in pain and function scores: Patients experienced marked improvements, demonstrating the intervention's effectiveness.
2. No serious adverse events reported: The absence of major complications highlights the favorable safety profile of the implants.
3. Notable reduction in VAS scores: The considerable decrease in Visual Analog Scale (VAS) scores confirms the intervention's ability to effectively relieve pain in the study population.

These results suggest that the intervention is both safe and effective in reducing pain and enhancing functionality among the participants.

6. Possible diagnostic or therapeutic alternatives.

To diagnose upper and lower extremity fractures, doctor will review your symptoms and medical history and conduct a thorough physical examination to look for signs of swelling, bruises, rupture of the skin, or any other bone deformities. In order to confirm the diagnosis and obtain further information on the severity of the fracture, doctor may recommend:

- **X-rays**: This study uses high electromagnetic energy beams to produce images of the bones and helps to detect whether the fracture is intact or broken and the type of fracture and its location.
- **CT scan**: This scan uses special x-rays that produce images of the cross-section of your limb with clear images of any damage present that is not visible in an x-ray.
- **MRI Scan**: This study produces images that help in detecting damage to soft tissues or ligaments using large magnetic fields and radio waves.

Non-surgical Treatment

Nonsurgical treatment of a fractured bone may be recommended for the following patients includes:

- **Casting and splinting**: In this method, a cast or a splint is used to hold the fractured bone fragments in proper position until the bone heals. Casts and splints are typically made of plastic, fiber, or Velcro that encases the affected limb to support, stabilize, and protect the injured or fractured bones and joints while they heal.

- **Traction**: This method is employed if significant leg-length discrepancy is noted and involves placing the limb in a weight and counterweight system (traction) to ensure the bones are realigned properly to stabilize the bone.

- **Closed reduction**: For severe angled fractures in which the bones have not broken through the skin, your doctor will gently manipulate and align the bones properly without the need for surgery. This procedure is called a closed reduction and is performed under local anesthesia to numb the area while the doctor manipulates the bones. Once the procedure is complete, a cast is applied to hold the bones in place while they heal.

Surgical Treatment

There is no tendency that a bone fracture will heal by itself. The fractures that do not heal with non-surgical methods are treated with surgical procedure. The nails are the preferred method for treating fractures of the upper extremity fractures in all patients and lower extremity fractures in paediatric or small-stature patients. Surgical treatment is recommended for complex or open fractures and may involve the use of:

a) External fixation: In this procedure, metal pins or screws are placed into the bone below and above the site of the fracture. The screws and pins are secured to a rod outside the skin which holds the bones in the correct position while they heal.

b) Open reduction and internal fixation:

- **Intramedullary nailing**: During this procedure, surgeon makes an incision to access the fracture site and a metal rod is placed into the central canal of the bone passing across the fracture site. Both ends of the intramedullary nail are screwed to the bone to keep the bones and nail in proper position while the fracture heals.
- **Plates and screws**: In this procedure, your surgeon makes an incision to access the fracture site and the bone fragments are reduced or repositioned into their normal alignment and held together by metal plates and screws fixed to the outer surface of the bone. The plates and screws method is employed when intramedullary nailing is not a viable option.

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 Elastic 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 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
7.	EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
8.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
9.	EN ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
10.	EN ISO 11737-2:2020	Sterilization of health care products -Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
11.	EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020).
12.	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 (ISO 11137-1:2006, including Amd

		1:2013)
13.	EN ISO 11137-2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)

Non Harmonized Standards	
Standard	**Description**
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
IEC 62366-1:2015/Amd 1:2020	Medical devices - Application of usability engineering to medical devices
ISO 17665-2024	Sterilization of health care products — Moist heat — 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 14602:2010	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
ISO 14630:2024	Non-active surgical implants - General Requirements
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 14644-5:2025	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 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
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 F136-13 (2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
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	07-02-2024	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	27-05-2024	Updated as per as per queries received from 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	16-04-2025	Addition of Conformity Assessment Route and EMDN code	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
03	01-08-2025	Addition of Obesity Related Contraindication in the SSCP at Page Number 7, 37 of 55.	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

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

Document revision: 03
Date issued: 01-08-2025

Device identification and general information

Device Trade Name: Auxein Elastic 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: 0890399ENS001K2 (For Titanium Implants)
Year when the device was first CE-marked: 2014

Intended use of the device

Intended Purpose	Intended to maintain anatomical integrity of the fracture site by temporary fixation and stabilization bone fragments.
Indications of Use	The indications for use of the Elastic Nailing System include: **Titanium Elastic Nail** Diaphyseal and certain metaphyseal fractures of long bones, certain metaphyseal/epiphyseal fractures (Salter Harris, I and II), including but not limited to radial neck fractures complex clavicular fractures (significant dislocation, including shortening, “floating shoulder”) open fractures, threat of skin perforation at fracture ends pathologic fractures, diaphyseal fractures of long bone in upper extremity and clavicle shaft fractures.
Contraindications	Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome:

	○ Any active or suspected latent infection or marked local inflammation in or about the affected area. ○ Compromised vascularity that would inhabit adequate blood supply to the fracture or the operative site. ○ Bone stock compromised by disease, infection or prior implantation that can not proved adequate support and/or fixation of the devices. ○ Material Sensitivity, documented or suspected ○ Insufficient blood flow ○ Obesity: The use of this device is contraindicated in patients who are obese. ○ Weight Limitation for Lower Limbs: The use of this device is contraindicated in patients weighing more than 49 kg when treating lower limbs. ○ Patients having inadequate tissue coverage over the operative site. ○ Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care
Intended Patient Population	Only patients that meet the criteria described in the indications should be selected. The Elastic Nailing System is recommended for used in Girl and Boy between 6 to 15 years. The patient conditions and/or pre-dispositions such as those addressed in the contraindications should be avoided.

Device description

Auxein's Elastic Nail is a flexible nail which is designed curved with a tapered tip to facilitate insertion. It is non- cannulated, one piece with straight shaft design that can be cut to size intraoperatively. The nail is available in 1.5 to 4.0mm diameter and 440mm length. This is a single-use device intended for temporary implantation that restores the diaphyseal and certain metaphyseal/epiphyseal fracture of the long bone to its natural state. The nail is available in titanium alloy. The nail with the component is enlisted below:

- Elastic Nail
- End Cap for Elastic Nail, Size 1, Titanium (For Ø3.0-4.0mm)
- End Cap for Elastic Nail, Size 2, Titanium (For Ø1.5-2.5mm)

The details regarding Elastic bone nails can be found at **www.auxein.com**.

The more details regarding components are mentioned below:

Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, Elastic 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 ISO 5832-3:2021.		
USFDA Cleared	Yes (Elastic Nails are approved by USFDA whose details are as follow:) **510(k) Number:** K210792, K192003		
EMDN Code	P09120201		
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.		
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

Elastic Nailing system works to achieve a level of reduction and stabilization of Fracture. The biomechanical principle of elastic nail is based on the symmetrical bracing action of two elastic nails inserted into the metaphysis, each of which bears against the inner bone at three points. This produces the following four properties:

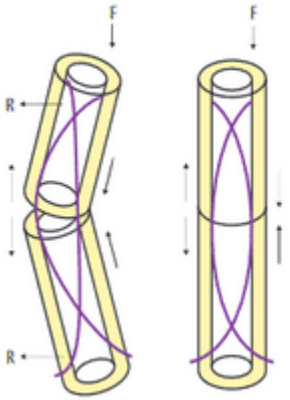
This produces the following four properties:

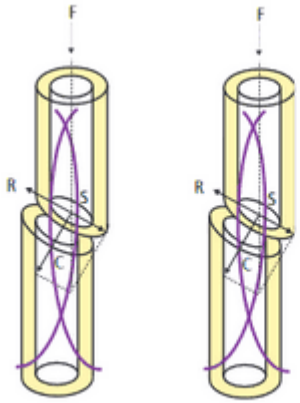
1. Flexural Stability
2. Axial Stability
3. Translational Stability
4. Rotational Stability

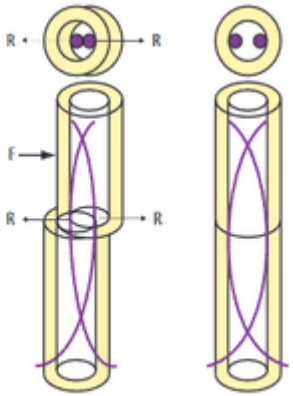
Mode of Action

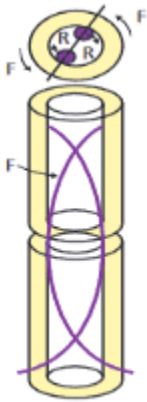
The nails are performed in a C-shaped manner through the metaphysis into the medullary canal, advanced through the fracture site and impacted into the opposite metaphysis. The biomechanical principle is based on the symmetric bracing action of two nails inserted into the metaphysis, each of which bears against inner bone at three points. This produces the following four properties: flexural stability, axial stability, translational stability and rotational stability. All four are essential for achieving optimal results.

Step 1: Flexural stability **Step 2**: Axial stability **Step 3**: Translational stability **Step 4**: Rotational stability









Description of Key functional elements:

The Elastic Nailing System comprises of :

- Nails in varying diameter
- End caps

Nails are used with accessories for implantation in the bone to correct the abnormal curvature. The Elastic Nailing System is clinically improved by using Internal Fixation with Angular Stability (Internal Fixators) in fractures.

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.
- Two sizes of end caps to cover the nail diameters
- The end cap ensures that the elastic does not slide back through the insertion sit.
- Maintain repositioning and length of the bone are retained until healing is complete, and leg shortening is prevented.
- The end cap also provides protection against painful soft-tissue irritation.
- The end cap can be introduced in a minimally invasive manner without additional enlargement of the incision or drilling
- Using the end cap makes it easier to extract the nail.

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.

- Demonstrates anatomical or physiological abnormalities.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, good reduction of bone fragments, proper patient selection and correct placement of

the implants are all equally important for the successful use of these products.

- Use extreme care in the handling and storage of implants and instruments. Cutting, bending or scratching the surface of metal components can significantly reduce the corrosion, strength, and fatigue resistance of the implant and instrument system.
- Reuse and Re-process of a device is strictly forbidden. Each implant used once must be disposed of properly. Reuse of the medical device intended for single use devices may lead to infection, degraded performance or a loss of functionality.
- Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. We decline all responsibility in the case of implants from difference sources being mixed.
- Elastic Nail is not intended to support the patient's weight as excessive loads may cause the device to fail. Weight bearing will depend upon the fracture pattern and stability, patient compliance and other associated injuries. Progression of weight bearing should be at the discretion of the surgeon.

Quantitative based risk is evident

Safety Parameters	Article No.	Patients Included in the study	No. of Patients having Adverse Events	Percentage of Patients (%)
Entry site skin irritations, valgus angulations, refracture, migration of the nail, and delayed healing	1	103	Entry site skin irritations: 3 Patients Valgus angulations: 3 Patients Refracture: 1 Patient Migration of the nail: 1 Patient Delayed healing: 1 Patient	Entry site skin irritations: 2.91% Valgus angulations: 2.91% Refracture: 0.97% Migration of the nail: 0.97% Delayed healing: 0.97%
Entry-site skin irritations, skin infection, refractures, nail migration, injury of ulnar nerve, and pseudoarthrosis	2	173	Entry-site skin irritations: 8 Patients Skin infection: 2 Patients Refractures: 2 Patients Nail migration: 1 Patient Injury of ulnar nerve: 1 Patient Pseudoarthrosis: 1 Patient	Entry-site skin irritations: 4.62% Skin infection: 1.15% Refractures: 1.15% Nail migration: 0.57% Injury of ulnar nerve: 0.57% Pseudoarthrosis: 0.57%

Reactive bursitis,Retrotorsion, Diminished anteversion, Cortical perforation by ESIN	3	22	Anteversion: 3 Patients Retrotorsion: 2 Patients Diminished anteversion: 2 Patients	Anteversion: 13.6% Retrotorsion: 9.09% Diminished anteversion: 9.09%
Irritation, Refracture, Superficial infection, Keloid, Metalwork failure, Non-union, Anterior interosseous nerve palsy, Extensor pollicis longus (EPL) entrapment	4	109	Irritation: 12 Patients Refracture: 4 Patients Superficial infection: 2 patients Keloid: 2 Patients Metalwork failure: 2 Patients Non-union: 1 Patient Anterior interosseous nerve palsy: 1 Patient Extensor pollicis longus (EPL) entrapmen: 1 Patient	Irritation: 11.0% Refracture: 3.66% Superficial infection: 1.83% Keloid: 1.83% Metalwork failure: 1.83% Non-union: 0.91% Anterior interosseous nerve palsy: 0.91% Extensor pollicis longus (EPL) entrapmen: 0.91%
Superficial wound infection, Refractures following nail removal, Neuropraxia of the sensory radial nerve	5	102	Superficial wound infection: 5 Patients Refractures following nail removal: 6 Patients Neuropraxia of the sensory radial nerve: 7 patients	Superficial wound infection: 4.90% Refractures following nail removal: 5.88% Neuropraxia of the sensory radial nerve: 7 patients: 6.86%
Entry site irritation/bursitis, Superficial infection, Limb length discrepancy 1-2 cm, Varus/Valgus angulation	6	45	Entry site irritation/bursitis: 9 Patients Superficial infection: 3 Patients Limb length discrepancy 1-2 cm: 2 patients Varus/Valgus angulation: 3 Patients	Entry site irritation/bursitis: 20% Superficial infection: 6.66% Limb length discrepancy 1-2 cm: 4.44% Varus/Valgus angulation: 6.66%
limb lengthening, varus angulation, peculiar entry site	7	18	limb lengthening: 3 Patients varus angulation: 2 patients peculiar entry site medial localized	limb lengthening: 16.6% varus angulation: 2 patients peculiar entry site medial localized cortical

medial localized cortical fracture			cortical fracture: 1 Patient	fracture: 1 Patient
Pain at the site of nail insertion, Knee stiffness	9	38	Pain at the site of nail insertion: 16 Patients Knee stiffness: 2 Patients	Pain at the site of nail insertion: 42.10% Knee stiffness: 5.26%

Warning & Precautions:

1. Demonstrates anatomical or physiological abnormalities.
2. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, good reduction of bone fragments, proper patient selection and correct placement of the implants are all equally important for the successful use of these products.
3. Use extreme care in the handling and storage of implants and instruments. Cutting, bending or scratching the surface of metal components can significantly reduce the corrosion, strength, and fatigue resistance of the implant and instrument system.
4. Reuse and Re-process of a device is strictly forbidden. Each implant used once must be disposed of properly. Reuse of the medical device intended for single use devices may lead to infection, degraded performance or a loss of functionality.
5. Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. We decline all responsibility in the case of implants from difference sources being mixed.
6. Elastic Nail is not intended to support the patient’s weight as excessive loads may cause the device to fail. Weight bearing will depend upon the fracture pattern and stability, patient compliance and other associated injuries. Progression of weight bearing should be at the discretion of the surgeon.

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

Till now, regarding Auxein's Elastic 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 Titanium Elastic Nail, also known as flexible intramedullary nail was invented primarily for fixation of fractures where the medullary canal is narrow or where the flexibility of implant is needed. Titanium Elastic Nail system (TENS) is the latest minimally invasive surgical technique employed for the treatment of the upper extremity fractures in all patients and lower extremity fractures in paediatric or small-stature patients. Due to the minimally invasive nature of the procedure, ESIN offers several benefits such as a small incision, minimal muscle trauma, quick recovery, and safe and excellent stability without the need for plaster cast immobilization. They are particularly suitable for fractures that are unstable but do not require rigid fixation, as they provide stabilization while allowing for physiological movement and growth of the bone.

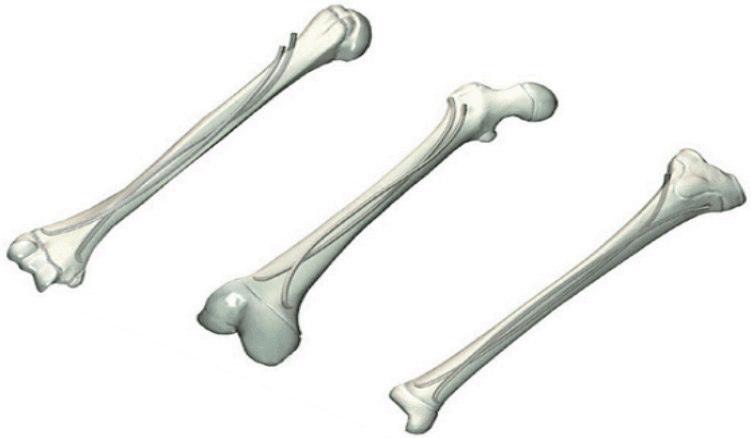


Figure: Elastic nail in long bones..

Types of long bone fracture

The common types of long bone fractures include.

- Transverse fracture: In this type of fracture, the break occurs as a straight, horizontal line going across the bone shaft.

- Oblique fracture: In this type, the break occurs as an angled line across the bone shaft.
- Comminuted fracture: A severe type of fracture where the bone breaks into 3 or more pieces.
- Spiral fracture: A type of fracture caused by a twisting force with a fracture line that encircles the bone.
- Open fracture: This is also known as a compound fracture and causes serious damage to the surrounding soft tissue structures as the bone fragments to protrude out through the skin to the external air exposing the fracture site.
- Stress fracture: Also called a hairline fracture, this fracture appears as small thin cracks in the bone and occurs due to overuse or wear and tear.

Symptoms:

- Immediate Pain
- Tenderness
- Bruising
- Swelling, bruising, or bleeding
- Numbness and tingling
- Broken skin with bone protruding
- Limited mobility or inability to move a limb or put weight on the leg

Diagnosis

To diagnose upper and lower extremity fractures, doctor will review your symptoms and medical history and conduct a thorough physical examination to look for signs of swelling, bruises, rupture of the skin, or any other bone deformities. In order to confirm the diagnosis and obtain further information on the severity of the fracture, doctor may recommend:

- **X-rays**: This study uses high electromagnetic energy beams to produce images of the bones and helps to detect whether the fracture is intact or broken and the type of fracture and its location.
- **CT scan**: This scan uses special x-rays that produce images of the cross-section of your limb with clear images of any damage present that is not visible in an x-ray.
- **MRI Scan**: This study produces images that help in detecting damage to soft tissues or ligaments using large magnetic fields and radio waves.

Treatment

There are the following factors which help in determining the treatment of a bone fracture:

- Location of the fracture
- Displacement of the fracture
- Alignment of the fracture
- Associated injuries
- Soft tissue condition around the fracture
- Patient general health
- Extent of the injury, taking into account the amount of damage to soft tissues
- the reasons for the injury
- overall health and medical history
- personal preferences

Clinical Evidence/Safety of the device

There are prospective and retrospective data regarding the device.

Retrospective Clinical Evaluation:

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

The clinical data that were Retrospectively analyzed by surgeon was considered in this evaluation, which includes 38 patients' (from 1 Clinical Papers). These all patients have femur diaphyseal fracture and were treated using Auxein's Elastic Nailing System. From the analysis of the data it is found that there are no safety and performance concerns regarding the use of device. There were no complications noticed related to Elastic Nailing System in literature and hardware related complications were also not encountered.

S.No.	Clinical Paper Title	Injury Type	Implant Used	Patients	Complications, if any
1.	S. Nury Jumadurdy and I. N Mohamed S.Nury, Functional outcomes of femoral diaphyseal fractures using titanium	Femoral Diaphyseal Fracture	Elastic Nail Size	38	No complication was reported till final follow up.

	elastic nail: A retrospective study				

Prospective Clinical Evaluation

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

Identity of the investigation/study: A non- randomized, prospective Post Market Clinical Follow-up study to evaluate the Safety and Performance of Elastic Nailing.

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_06	Ongoing	INDIA	30/30	0	0	0
Study Title	A non- randomized, prospective Post Market Clinical Follow-up study to evaluate the Safety and Performance of Elastic Nailing.					
CTRI Number	CTRI/2023/05/052536					
CTRI Registration Date	11/05/2023					
Number of study sites	One					
Name of Study Sites	Site 001	Dr.Saini Orthopedic Super Speciality Centre				
No. of Patients enrolled	30					

The study design is a prospective, Interventional, post Marketing Clinical follow up of the commercially available Auxein Elastic intramedullary nail. The study will require site to obtain IRB approval prior to study enrollment. All the study subjects will participate in the informed consent procedure. All study subjects will undergo preoperative radiographic and clinical assessment before the surgery. The post-operative clinical and radiological evaluation will be conducted at 1, 3, 6 months and then on 1 year.

Inclusion criteria

Subject legal Guardian/ Parent willing and able to give informed consent for participation in the study, Girl and Boy between 6 to 15 years, subject diagnosed with diaphyseal fractures, metaphyseal and epiphyseal fractures of long bones, were recruited for this study. Prior to enrollment, written informed consent for participation is obtained from all the study subjects.

Exclusion criteria

Subjects with Local or Systemic acute or chronic inflammation, Active infection or inflammation, Suspected or documented metal allergy or intolerance, Symptomatic Arthiritis, Patient with Mental Disorders as well as comprehensive legal support, Lack of willingness to make a commitment to return for required follow up visits and Drug and/or alcohol abuse, Morbid obesity are not included in the study.

Primary Objective

To assess the effectiveness/performance of the Elastic nail system by evaluating the quality of fusion through Radiological Evaluation. To analyze safety assessment by measuring the rate of Adverse Event, complications and pain reduction by using Elastic Intramedullary Nailing through Flynn Questainnaire.

Secondary Objective

- Pain evaluation through Visual Analogue Scale (VAS).

Primary Endpoints

Fracture fusion, [Time Frame: 12 months post operatively]

Secondary Endpoints

Rate of implant related, surgery related, postoperative and general complications.
[Time Frame : Baseline, 1month, 3 month,6 month and 12 month postoperatively]

Population Detail:

Table 1: Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)	Weight (kg)	Height(cm)	Body Mass Index (BMI)
Mean (n=30)	10.98±3.60	36.56±14.80	142.4±19.27	17.1±4.20

Table 2: Gender distribution of study subjects

Male	19/30 (63%)
Female	11/30 (37%)

Table 3: Clinical Outcomes Measures

Pain and functional scores in study participants at baseline and follow up visits

Scoring	**Baseline (n=30) [a]**	**1 Month (n=29) [b]**	**3 Month (n=26) [c]**	**6 Month (n=29) [d]**	**12 Month (n=23) [e]**	**P value**
VAS Score	8.6±0.7 (n=30)	2.9±1.7 (n=29)	1.8±1.4 (n=26)	0.72±0.88 (n=29)	0.28±1.1 (n=23)	b vs. c=0.011 b vs. d<0.001 b vs. e<0.001
LEFS Score#	1.6±2.1 (n=17)	47.4±18.8 (n=16)	52.1±21.8 (n=15)	59.8 ± 23.3 (n=17)	78.41±5.48 (n=12)	b vs. c=0.52 b vs. d=0.10 b vs. e<0.001
DASH Score##	88.1±6.3	23.1±21.1	19.7±18.9	2.3±5.4	0.7±0.24	b vs. c=0.68

	(n=13)	(n=13)	(n=11)	(n=12)	(n=11)	b vs. d=0.003 b vs. e=0.002

Seventeen patients were of the lower limb in the study.

Thirteen patients were of the upper limb in the study.

Table 4: Flynn score in study participants at baseline and follow up visits

	Baseline (n=30)		**1 Month**		**3 Month**		**6 Month**		**12 Month**	
Parameter	**Satisfactory/Excellent**	**Poor**	**Satisfactory/Excellent**	**Poor**	**Satisfactory/Excellent**	**Poor**	**Satisfactory/Excellent**	**Poor**	**Satisfactory/Excellent**	**Poor**
Limb length inequality	30/30	0/30	29/29	0/29	26/26	0/26	29/29	0/29	23/23	0/23
Malalignment	30/30	0/30	29/29	0/29	26/26	0/26	29/29	0/29	23/23	0/23
Pain	29/30	1/30	29/29	0/29	26/26	0/26	29/29	0/29	23/23	0/23
Complications (Minor/Major)	29/30	1/30	29/29	0/29	26/26	0/26	29/29	0/29	23/23	0/23

The study included a total of 30 subjects with a mean age of 10.98±3.60 years, ranging from to 6 to 15 years. Notably, a significant proportion of the subjects were above 6 years of age. The majority of participants were Asian, with 19 males and 11 females recruited in the study. The mean weight of the subjects was 10.98±3.60 kg. The mean BMI of the subjects was 17.1±4.20. In terms of height, the subjects had an average of 142.4±19.27 cm. These demographic and baseline characteristics are essential for understanding the composition of the study population and provide valuable insights for the interpretation of the study

results.

Study Method

The study design is a prospective, Interventional, post Marketing Clinical follow up of the commercially available Auxein Elastic intramedullary nail. The study will require site to obtain IRB approval prior to study enrollment. All the study subjects will participate in the informed consent procedure. All study subjects will undergo preoperative radiographic and clinical assessment before the surgery. The post-operative clinical and radiological evaluation will be conducted at 1, 3, 6 months and then on 1 year.

This study is designed to identify the potential for residual risks of Auxein Medical Elastic Intra and to collect data and gain clarity regarding the long-term clinical performance of these implants. This study will confirm the clinical performance and safety of these implants in real-world use and help Auxein medical to manage acceptable risk. The safety and performance data collected from real world device usage, is expected to feed back into re-evaluation of risk determination over the life cycle of these devices. All the patients will be screened for eligibility to be included in the study. The Patients must meet all inclusion and exclusion criteria. The Post-operative follow-up duration of patient's data to be enrolled in this study will be for minimum 1 year from the date of surgery. Follow-up visits data of patients will be at 1 months, 3 months, 6 months and 12 months post operatively.

The objectives was to analyze and compare the data recorded at different time points i.e at 1 Month, 3 Month, 6 Month and 12 Month follow-up to evaluate the objectives. The bone union rate will be analyzed by calculating the mean of days required for union of bones as verified by the Principal Investigator based on radiological evaluations. DASH and LEFS score will be recorded in continuous data format and the same will be compared between different time points to assess the functionality of that particular bone and Flynn outcome score will be recorded to check effectiveness of the device. Similarly VAS score will be recorded in continuous data form for the assessment for the pain. Safety related assessment has been analyzed based on the number of adverse event occurred during the study.

Study Result

The study presented 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 6 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 vital signs were clinical stable and the slight

changes observed in blood pressure as well as in respiratory rate and heart rate cannot be commented upon due to small number during follow up. It would be interesting to explore these factors further as we would have more number of patients in follow up. However, it may be mentioned that stable respiratory rate throughout the study period suggests that the intervention may not have directly impacted the subjects' respiratory function.

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 lower extremity functional scale (LEFS) highlights improved functional performance. The progressive increase in LEFS scores over the follow-up visits indicates a consistent and sustained improvement in functional ability. This demonstrates that the intervention not only provided short-term relief but also led to lasting improvements in the patients' functional status, which is crucial for their overall recovery and well-being.

As per our interim data analysis, we have observed very significant positive results with respect to our Elastic Nail device efficacy and safety. Overall, the interim findings of study 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 their quality of life and recovery from their condition after intervention with intramedullary elastic nail.

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.

Conclusion

The analysis of data from the thirty patients enrolled in the study provides valuable insights into the safety and performance of the implants. The key findings are as follows:

1. Significant improvement in pain and function scores: Patients experienced marked improvements, demonstrating the intervention's effectiveness.
2. No serious adverse events reported: The absence of major complications highlights the favorable safety profile of the implants.
3. Notable reduction in VAS scores: The considerable decrease in Visual Analog Scale (VAS) scores confirms the intervention's ability to effectively relieve pain in the study population.

These results suggest that the intervention is both safe and effective in reducing pain and enhancing functionality among the participants.

Possible diagnostic or therapeutic alternatives.

To diagnose upper and lower extremity fractures, doctor will review your symptoms and medical history and conduct a thorough physical examination to look for signs of swelling, bruises, rupture of the skin, or any other bone deformities. In order to confirm the diagnosis and obtain further information on the severity of the fracture, doctor may recommend:

- **X-rays**: This study uses high electromagnetic energy beams to produce images of the bones and helps to detect whether the fracture is intact or broken and the type of fracture and its location.
- **CT scan**: This scan uses special x-rays that produce images of the cross-section of your limb with clear images of any damage present that is not visible in an x-ray.
- **MRI Scan**: This study produces images that help in detecting damage to soft tissues or ligaments using large magnetic fields and radio waves.

Non-surgical Treatment

Nonsurgical treatment of a fractured bone may be recommended for the following patients includes:

- **Casting and splinting**: In this method, a cast or a splint is used to hold the fractured bone fragments in proper position until the bone heals. Casts and splints are typically made of plastic, fiber, or Velcro that encases the affected limb to support, stabilize, and protect the injured or fractured bones and joints while they heal.

- **Traction**: This method is employed if significant leg-length discrepancy is noted and involves placing the limb in a weight and counterweight system (traction) to ensure the bones are realigned properly to stabilize the bone.
- **Closed reduction**: For severe angled fractures in which the bones have not broken through the skin, your doctor will gently manipulate and align the bones properly without the need for surgery. This procedure is called a closed reduction and is performed under local anesthesia to numb the area while the doctor manipulates the bones. Once the procedure is complete, a cast is applied to hold the bones in place while they heal.

Surgical Treatment

There is no tendency that a bone fracture will heal by itself. The fractures that do not heal with non-surgical methods are treated with surgical procedure. The nails are the preferred method for treating fractures of the upper extremity fractures in all patients and lower extremity fractures in paediatric or small-stature patients. Surgical treatment is recommended for complex or open fractures and may involve the use of:

a) External fixation: In this procedure, metal pins or screws are placed into the bone below and above the site of the fracture. The screws and pins are secured to a rod outside the skin which holds the bones in the correct position while they heal.

b) Open reduction and internal fixation:

- **Intramedullary nailing**: During this procedure, surgeon makes an incision to access the fracture site and a metal rod is placed into the central canal of the bone passing across the fracture site. Both ends of the intramedullary nail are screwed to the bone to keep the bones and nail in proper position while the fracture heals.
- **Plates and screws**: In this procedure, your surgeon makes an incision to access the fracture site and the bone fragments are reduced or repositioned into their normal alignment and held together by metal plates and screws fixed to the outer surface of the bone. The plates and screws method is employed when intramedullary nailing is not a viable option.

Advantages/disadvantages of the surgical vs non-surgical Treatment

The surgical or non-surgical treatment for pediatric fractures is based on factors like the fracture type and severity, the child's age, general health, and long-term implications. The comparative advantages/disadvantages of the surgical options vs non-surgical are as:

Factors	Surgical Treatment	Non Surgical Treatment
Bone Alignment	Surgery provides accurate alignment for displaced or unstable fracture	May result in malunion if bones aren't aligned well
Recovery Time	Promotes faster recovery for simple and complex fracture.	Promotes faster recovery for simple fracture only.
Risk of complications	Higher risk as it involves surgery.	Lower risk as no surgery is performed.
Functional outcomes	Better for fractures near joints or complex fractures	May not restore full function in complex fractures.
Fracture Type	Preferred for complex, displaced, or open fractures	Preferred to non-displaced fractures or greenstick fractures.

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

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, A3-REG-QF-002-F1

(https://www.auxein.com/).