Device System Name
Elastic Nailing System

Device Description
The Elastic Nailing is a permanent implant that is intended for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is important. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small-stature patients

The Elastic Nailing, which consists of Titanium Elastic Nail, which are especially designed for the fixation of diaphyseal fractures where the canal is narrow and it is manufactured from Titanium material.

Purpose
The Elastic Nail System is intended to help immobilization and stabilization of metaphyseal and epiphyseal fracture, such as radial neck fracture, and is intended for fixation of small long bones, such as carpal and tarsal bones.

Materials
The Elastic Nailing which consists of Titanium Elastic Nail is made from Titanium Alloy Ti-6AL-4V as per ISO 5832- 3. This material is not compatible with other metal alloys.

Indications
The indications and contraindications of Elastic Nailing (Titanium Elastic Nail) should be well understood by the surgeon.

The AUXEIN MEDICAL's Elastic Intramedullary Nail System is indicated for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is important. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small-stature patients. This system is also intended to treat metaphyseal and epiphyseal fractures, such as radial neck fractures and is intended for fixation of small long bones, such as carpal and tarsal bones.

End Cap for Elastic Nail, Size 1: This End Cap is used to prevent Nail migration and soft tissue irritation.
It also facilitates extraction of the Nail.

End Cap for Elastic Nail, Size 2: This End Cap is used to prevent Nail migration and soft tissue irritation. It also facilitates extraction of the Nail.

Contraindications
Metal bone fixation devices should not be used in patients with:
The implant should not be used in a patient who has currently, or who has a history of:

- Local or Systemic acute or chronic inflammation.
- Active infection or inflammation.
- Suspected or documented metal allergy or intolerance.
- Symptomatic Arthiritis.
- Intraarticular fractures
- known sensitivity to metals
- An inability to follow a postoperative treatment.
- Elastic nails cannot be used to treat unstable fractures, such as long oblique fractures or long

spiroids.

Warnings & Precautions

See package insert for warnings, precautions, adverse effects, information for patients and other essential product information.

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

- Lacks good general physical condition
- Has severe osteoporosis
- Demonstrates anatomical or physiological anomalies.
- The patient should be informed that the life expectancy of the device is unpredictable and once implanted, successful results cannot be guaranteed if adequate care and precautions are not taken. The reuse of implants after re-sterilization may not result in the same responses.
- The AUXEIN MEDICAL Elastic Nails is not intended to support the body weight of the patient as it is too heavy.
- The AUXEIN MEDICAL Elastic Nails is not indicated for the treatment of lower extremity fractures in adults.
- Vascular disorders, including thrombophlebitis, pulmonary embolism, wound hematoma, avascular necrosis
- Delayed consolidation or nonunion that can lead to implant rupture
- Has immunological response, sensitization or hypersensitivity for foreign materials.
- Do Not Re-Use. Do not re-process. The device is not designed for re-processing. Reuse of the medical device intended for single use devices may lead to infection, degraded performance or a loss of functionality. The cleaning and disinfection / sterilization for re-processing of these single use devices has not been validated nor is any authentic information available. So re-process of the single use device is not allowed.
- For Qualified surgeon use only.

Note: It is the responsibility of the surgeon to discuss, with the patient, the precautions, possible risks, warnings, consequences, complications and adverse reactions which may occur as a result of the surgical procedure and implantation of the device(s).

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.

If adverse effects happen, it may necessitate re-operation, revision or removal surgery, arthrodesis or the involved joint and/or amputation of the limb.

Intended Patient Group

Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those addressed in the contraindications mentioned above should be avoided. The age limit depends on the biological development of the child. Experience has shown that the lower limits is 3-4 years and the upper limit 13-15 years.

Surgeon Note

Although the surgeon is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

Caution

- To be used by Qualified and Trained Surgeons Only.
- Federal law restricts this device to sale by or on the order of a physician.

MRI Compatibility

The AUXEIN MEDICAL Elastic Nails has not been evaluated for safety and compatibility in the MR environment. The AUXEIN MEDICAL Elastic Nail has not been tested for heating or migration in the MR environment. Patients should seek opinion of medical experts before entering MRI (Magnetic Resonance Imaging) environment.

Potential Adverse Events

All of the possible adverse events associated with Elastic Nails implantation without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- Loss of reduction and/or fixation
- Nonunion, malunion, delayed Union, or incomplete union
- Soft tissue irritation or damage
- Local Dislocation
- Osteonecrosis
- Inflammatory reactions and osteolysis
- Infection or pain
- Metal sensitivity
- Corrosion of metal components (the significance and long-term implications are uncertain and await further clinical evidence and evaluation).
- Interference with CT, and/or MR imaging because of the presence of the implants.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Nail Protrusions
- Neuromuscular Injury
- Incisional numbness

Note:

Additional surgery may be necessary to correct some of these anticipated adverse events.

Other Preoperative, Intraoperative, And Postoperative Warnings Are As Follows

A successful result is not always achieved in every surgical case. This fact is especially true in Elastic Nails surgery, where many extenuating circumstances may compromise the results.

Preoperative:

- The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure.
- Only patients that meet the criteria described in the indications should be selected. Elastic Nail can be used for skeletally mature patient and pregnant women.
- Before surgery, the surgeon must plan the operation with a view to correct selection and sizing of the implant components and their positioning in the bone. The surgeon needs to ensure that: Instruments have been properly disassembled prior to cleaning and sterilization; Instruments have been properly assembled post-sterilization; Instruments have maintained design integrity; and, Proper size configurations are available.
- The implant bed is prepared using the appropriate Auxein Medical's instruments for the specific

replacement procedure being performed.

- All informational material concerning the range of implants, instrumentation and surgical technique has been reviewed and is available and the surgeon and the surgical team are familiar with this information.
- The rules of medical skill, the state of the art, and the contents of scholarly publications by medical authors are known and observed.
- Re-use of any implant is prohibited as it including risk of infection/disease.

Intra-operative:

- AUXEIN MEDICAL Elastic Nails is available in various sizes to suit the patient's femoral anatomy. Details of the implant size are explicitly marked on the packaging and/or on the implants themselves. In addition, the related product literature carries detailed information related to the selection of particular sizes.
- The correct use of these components should be clearly described in the relevant product literature corresponding with the Elastic Nails being implanted.

Post-operative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur because of, excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices.
- The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
- If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s).
- The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed. The patient must be made to understand that artificial joint replacement implants are always inferior to the function of the natural joint, and only a relative improvement of the preoperative condition can be achieved.
- The patient must be explained that an artificial joint can loosen due to overloading, wear and tear, or infection. Implant loosening can necessitate a revision operation that, under some circumstances, offers no opportunity to restore joint function again.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Elastic Nails should ever be reused under any circumstances. Reuse may lead to infection & cross infection.
- Orthopedic surgeries do not generally involve major risks and complications. Orthopedic

Surgeons are properly trained to avoid potential difficulties which might occur during an intervention, as well as to efficiently correct such problems if they appear. However, some of the risks and complications which may accompany an orthopedic surgical procedure are:

- **Postoperative infections:** In order to avoid this complication, patients will be administered antibiotics before, during and after the surgery. If patient have an ongoing infection (throat, urinary, dental etc.), it is highly recommended to treat it prior to the intervention, as it can reach your joint and a late infection could develop months or even years following orthopedic surgery.
- Bleeding
- **Blood clots:** They may occasionally appear after orthopedic surgery. Blood clots can be avoided with appropriate medication and physical exercise.
- **Blood vessel damage:** This complication may appear if blood vessels located in close proximity of the implant are affected during the procedure.
- **Allergic reactions:** The patient might experience an allergic reaction to the metal components or cement used to fix the implant (titanium, stainless steel etc.)

Packaging

Packages for each component should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage before use. Damaged packages or products should not be used, and should be returned to AUXEIN MEDICAL PVT LTD.

DECONTAMINATION BY STEAM STERILIZATION METHOD

AUXEIN MEDICAL'S An Elastic Nailing system is supplied Sterile. Check the integrity of the packaging and labeling before opening the pack.

Instruments are mandatory to be sterilized, using steam autoclaving process regularly used in the hospitals and clinics.

The following method has been validated and recommended by the company:

Method:	Steam Sterilization (Autoclaving)
Temperature	132 Degree Centigrade
Exposure Time:	4 Minutes
Pressure	15 Psi
Cycle Type	Vacuum Type

Note: FDA Approved wrap or clothes shall be used for sterilization.

Sterilization

AUXEIN MEDICAL'S Elastic Nailing is supplied Sterile. A sterility assurance level SAL 10^{-6} was achieved using gamma irradiation sterilization with minimum dose of 25kGy. Check the integrity of the packaging and labeling before opening the pack.

Storage

Store the implants at a dry place. Care should be taken in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments. The implant surfaces

should not be scratched or notched, since such actions may reduce the functional strength of the construct and the temperature range shall be 10°C to 30°C.

Disposal

The Orthopedic implant is to be disposed off as per the Hospital and Regulatory norms.

Product Complaints

Customers or users of products, who have any complaints or who have experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the Manufacturer, AUXEIN MEDICAL or EU Representative. Further, if any of the implanted Elastic nails ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the Manufacturer or EU Representative should be notified immediately.

If any AUXEIN MEDICAL's product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Further Information

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact your representative or distributor or contact the manufacturers direct.

Details of various Symbols used in Labeling

Symbol	Symbol Title	Description	Standard Title	Reference Number
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.3
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 93/42/EEC.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.1
	Authorized representative in the European community	Indicates the Authorized Representative in the European Community.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.2
	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device	5.1.6

		can be identified.	labels— General requirements.	
CE	Conformité Européene (European Conformity)	CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.	Directive 93/42/EEC.	N/A
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.5
	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.4.2
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.4
	Keep away from the sunlight	Indicates a medical device that needs protection from light sources	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.2
	Consult instructions for use	Consult instructions for use	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.3
	Do not use if package is damaged.	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General	5.2.8

			requirements.	
	Do not re-sterilize	Indicates a medical device that has not been subjected to a sterilization process.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.7
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.4
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.7
	Quantity	Indicates quantity of medical devices contained within the packaging.	N/A	N/A
	Material	Indicates the Material from which medical device is manufactured.	N/A	N/A
	Use by date	Indicates the date after which the medical device is not to be used.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.4
	Prescription only	The symbol for Prescription Device Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	N/A	N/A

CE 2460

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EC REP

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Revision Table:

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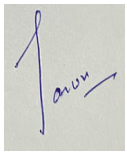
1.	A3-IFU-GS-007-04	00	IFU is Initially Released.	23.11.2019		
2.	A3-IFU-GS-007-04	01	Format of IFU is Updated.	17.03.2023