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DEVICE SYSTEM NAME

Femur Nailing System

DEVICE DESCRIPTION

Auxein's femur nailing system is group of specifically designed metallic bone nail used in the intramedullary section of the bone for the fixation of femoral bone fracture. It is used for the fixation of all the type of femur fracture like comminuted fracture, non-comminuted, segmental fracture, etc. These nails consist of wide range of size for patients of different geographical reason. It is also available in two different types of bio-compatible materials i.e. Stainless Steel (as per EN ISO 5832-1:2019) and Titanium (EN ISO 5832-3:2021). All the nails are passed through the stringent test to verify their quality, safety and effectiveness like mechanical test, biocompatibility test, chemical test and clinical trial.

The following are the categories of the femur nailing system:

AJAX ADVANCE NAIL

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

EXPERT FEMUR NAIL

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

ATHOS NAILING SYSTEM

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

JIN TYPE FEMUR NAILING SYSTEM

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

KONZEPT FEMUR NAILING SYSTEM

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

RETROGRADE FEMUR NAILING SYSTEM

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

MATERIALS

The Femur Nailing System are made from Stainless Steel Alloy as per EN ISO 5832-1:2019 and Titanium Alloy Ti-6AL4V as per EN ISO 5832-3:2021. This material is not compatible with other metal alloys.

INTENDED USE/PURPOSE

The femur nail is intended to Stabilize Femoral shaft fractures, Trochanteric Fractures, Ipsilateral Neck and Femoral Head, Impending Pathologic Fractures, Nonunions and Malunions of femur bone.

INDICATIONS

AJAX ADVANCE NAIL, SHORT

- Pertrochanteric fractures (31-A1 and 31-A2)
- Intertrochanteric fractures (31-A3)
- High subtrochanteric fractures (32-A1)

AJAX ADVANCE NAIL, LONG

- Low and extended subtrochanteric fractures
- Ipsilateral trochanteric fractures
- Combination fractures (in the proximal femur)
- Pathological fractures

EXPERT FEMUR NAIL

- 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1)

ATHOS NAILING SYSTEM

- Intertrochanteric fractures (31-A3)

- Pertrochanteric fractures (31-A1 and 31-A2)
- Nonunion and malunion

ANTI-ROTATION ATHOS NAIL, SHORT AND LONG

Intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures (31-A1 and 31-A2), intertrochanteric fractures (31-A3), high subtrochanteric fractures (32-A1) and combinations of these fractures, including non-union, malunion and tumor resections.

JIN TYPE-FEMUR NAIL

- 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1)

KONZEPT FEMUR NAILING SYSTEM

Intended to treat stable and unstable proximal neck fractures or trochanteric fractures and combinations of these fractures, Femur shaft fracture, distal end fractures.

Retrograde Femur Nail

- 33-A1/A2/A3 (Femur, distal end segment, extraarticular, avulsion fracture/simple fracture/wedge or multifragmentary fracture)
- 33-C1/C2/C3 (Femur, distal end segment, complete, simple articular, simple metaphyseal fracture/wedge or multifragmentary metaphyseal fracture/multifragmentary articular fracture, simple, wedge or multifragmentary metaphyseal fracture)
- 32-A/B/C (Femur, diaphyseal segment simple fracture/wedge fracture/multifragmentary fracture)

CONTRAINDICATIONS

Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome:

- Any case not described in the indications.
- Infection local to the operative site
- Signs of local inflammation.
- Fever or leukocytosis.
- Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care.
- Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodeling, e.g. the presence of tumours or congenital abnormalities, fracture local to the operating site.
- Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops an allergic reaction to the material of the implant.
- Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage.
- Any case in which implant utilization would disturb physiological processes.
- Blood supply limitation in the operative site.
- Morbid obesity (defined according to the WHO standards).

- Any case in which there is inadequate tissue coverage of the operative site.
- Shaft fractures with a fissure less than 5 cm from the nearest interlocking hole of the nail.

The above-mentioned list does not exhaust the topic of contraindications.

WARNINGS & PRECAUTIONS

- 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.
- 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.
- The important medical information given in this document should be conveyed to the patient.
- The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
- In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.
- Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

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

TARGET 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 device can be used in skeletally mature patient only (aged 18 years or above).

INTENDED USER GROUP

All qualified and well-trained/ experienced Surgeons can use this device.

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

For use on or by the order of a surgeon only.

MRI COMPATIBILITY

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

All Auxein's Femur Nail is manufactured in metallic material and does not emit any ionizing radio-active radiation.

CLINICAL BENEFITS

If the device is implanted as per the labeling and recommended technique, then it helps to achieve anatomical stabilization, fracture reduction and fracture fixation by radiological evaluation of the femur bone by reducing pain (VAS Score), regains range of motion of femur and Hip Joint (range of motion or Harris Hip Score) and change in patient quality of life (WHO-BREF).

PERFORMANCE CHARACTERSTICS

The femur nailing system has good load-bearing capacity (static and fatigue strength), Stiffness, rigidity, flexibility, it is also biocompatible for use and are capable of bending deformation and have sufficient strength to allow the insertion of fixing components.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The link to Summary of Safety and Clinical Performance (SSCP) will be updated in this Instructions for Use when the SSCP will be made available to the EUDAMED Database.

POTENTIAL ADVERSE EVENTS

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

- Implant damage (fracture, deformation or detachment).
- Early or late loosening, or displacement of the implant from the initial place of insertion.
- Possibility of corrosion as a result of contact with other materials.
- Body reaction to implants as foreign bodies e.g. possibility of tumour metaplasia, autoimmune diseaseand/or scarring.
- Non Union.
- Delayed Union
- Hematoma
- Compression on the surrounding tissue or organs.
- Deep Vein Thrombosis
- Local Wound
- Fixation Failure
- Wound Infection
- Superficial Wound Infection
- Lateral migration
- Malreduction
- Poor Reduction

- Anterior Knee pain
- Implant removal due to pain
- Spontaneous Dynamisation

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 Femur Nail 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.
- It is essential to confirm proper position of the implant by roentgenographic examination.
- In postoperative period, in treatment, the correctness of implant positioning and immobilization of union should be confirmed by roentgenographic examination.
- Only patients that meet the criteria described in the indications should be selected.
- Before surgery, the surgeon must plan the operation with a view to correct selection and sizing of theimplant components and their positioning in the bone.
- All informational material concerning the range of implants, and surgical technique should be reviewed and should be available to the surgeon and the surgical team are familiar with this information.
- Re-use of any implant is prohibited as it including risk of infection/disease.
- All implants should be sterilized before use.

INTRA-OPERATIVE:

- AUXEIN MEDICAL Femur Nailing System 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 a particular size.
- The entry point of the nail should be carefully located.
- The surgery position of the patient should be as per described in the surgical technique
- Only the Auxein's instrument should be used with Auxein's Nail to make the surgery convenient as only Auxein's instruments is compatible with Auxein's Nail.
- During the surgery, there may be the possibility of using pain relief and it should be used with caution.
- Elderly patients should be positioned to avoid pressure sores if possible.

Post-operative

The Surgeon's postoperative directions and warnings to the patient and the corresponding patient compliance are crucial. 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 as a result 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 surgeon must instruct the patient regarding appropriate and restricted activities during consolidation and maturation of the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and further clinical problems. The implant may break or become damaged because of strenuous activity or trauma, and may need to be replaced in the future.
- Failure to perform appropriate immobilization of bone when delayed or non-union occurs may lead to excessive fatigue stresses in the implant. Fatigue stresses may be a potential cause of implant becoming bent, loosened or fractured. If non-union of fracture or implant bending, loosening or fracture occurs, the patient should be immediately revised, and the implants should be removed before any serious injuries occur. The patient must be appropriately warned about these risks and closely monitored to ensure compliance during the treatment until the bone union is confirmed.
- 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 ensure cooperation until bony union is confirmed. The patient must be made to understand that the bone that is fixed after the fracture are always inferior to the function of the natural bone and only a relative improvement of the preoperative condition can be achieved.
- The patient must be explained that an implant can loosen due to overloading, wear and tear, or infection. Implant loosening can necessitate a revision operation that, under some circumstances, offersno opportunity to restore the fracture.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the Femur Nail 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.
    - Bleeding
    - **Blood clots:** They may occasionally appear after orthopedic surgery. Blood clots can be avoidedwith appropriate medication and physical exercise.

- **Blood vessel damage:** This complication may appear if blood vessels located in close proximityof 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

All implants that have been taken into a surgical field must first be sterilized/decontaminated by using steam autoclaving process and introduction into a sterile surgical field.

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

Method:	Steam Sterilization (Autoclaving)
Temperature	Minimum 121 Degree Centigrade
Exposure Time:	15 Minutes
Pressure	15 Psi
Cycle Type	Vacuum Type

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

STORAGE

Store the implants at a dry place. Care should be taken in the handling and storage of the implant components. Implants 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.

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 Femur Nail 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

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a written reportfrom 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 at https://www.auxein.com/ where IFU, Surgical Technique and Catalog are also available.

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.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.3
	Manufacturer	Indicates the medical device manufacturer	EN 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/European Union	EN 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 can be identified.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.6
	Conformité Européene (European Conformity)	Signifies European technical conformity.	EU MDR 2017/745.	MDD 93/42/EEC, MDR 2017/745 (Annex XII, Article 20)

	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN 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.	EN 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.	EN 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	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	EN 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 that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.8
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.2.7

	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.3.7
	Use by date	Indicates the date after which the medical device is not to be used.	EN 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	21 CFR 801.15 ad 21 CFR 801.109 ((c) (1) (i) (F) (b) (1)).
	Medical device	Indicates the item is a medical device	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.7.7
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.	EN ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.7.10

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Revision History Table:

S. No.	Document No	Rev. No.	Description of Revision	Effective date	Prepared by	Approved by
1.	AMPL-IFU-FNS/NS-002	00	Initially released.	12-06-2023		Mohit Kumar
2.	AMPL-IFU-FNS/NS-002	01	IFU has been updated as per queries received from PA-MDR-09-A2_LOF-R1.	29-12-2023		Mohit Kumar
3.	AMPL-IFU-FNS/NS-002	02	Age limit 18 years to 65 has been changed to 18 years and above as per the study plan.	13-02-2024		Mohit Kumar