INSTRUCTION FOR USE, A3-REG-QF-13-F9

Device System Name

Retrograde Femoral Nailing System

Device Description

The Retrograde Nailing system, which consists of Retrograde Femoral Nail, End Cap For Retrograde Nail, 5.0mm Locking Bolt Retrograde Nail.

These nails are manufactured in Titanium material.

Materials

The Retrograde Femoral Nailing System are made from Titanium Alloy Ti- 6AL4V as per ISO 5832-3. This material is not compatible with other metal alloys.

Plates and screws combination:

Nails	Screws used with nails
Retrograde Femoral Nail	○ 5.0mm Locking Screw for Retrograde Femoral Nail ○ End Cap for Retrograde Femoral Nail

Indications

The indications and contraindications of Retrograde Femoral Nailing System should be well understood by the surgeon.

The AUXEIN MEDICAL Retrograde nail is indicated for use in a variety of femoral fractures, such as:

- Metaphyseal fractures
- Diaphyseal fractures
- Intra-articular fractures
- Peri-prosthetic fractures
- Non-unions
- Mal-unions

SPECIFIC INDICATIONS

RETROGRADE Femoral Nails:

This nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of long bones being treated.

5.0mm Locking Screw for Retrograde Femoral Nail: It is used to fix the femoral Nail.

End Cap for Retrograde Femoral Nail: End cap prevents ingrowth of tissue and facilitates nail extraction.

Contraindications

Contraindications may be relative or absolute. The choice of particular device must be carefully weighed against the patient's overall condition. The conditions listed below may preclude or reduce the chance of a successful outcome:

- Isolated or combined medial femoral neck fractures
- Low subtro-chanteric fractures
- Femoral shaft fractures
- Isolated or combined medial femoral neck fractures
- Medial neck fractures
- Signs of local inflammation
- Infection local to the operative site.
- Fever or leukocytosis.
- Neuro muscular disorders which can create unacceptable risk of fixation failure or complications inpostoperative care.
- Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodeling, e.g. the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells *(WBC)* count, or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant *(content of the implant material is presented in IMPLANT MATERIAL)*.
- Any case not needing a surgical intervention.
- Any case not described in the indications.
- 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 theimplant usage.
- Any case where the implant components selected for use would be too large or too small to achieve asuccessful result.
- Any case that requires the simultaneous use of elements from different systems that are made of different metals.
- 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

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 implantsafter re sterilization may not result in the same responses.

- The AUXEIN MEDICAL Retrograde Femoral Nailing System is not intended to support the body weight of the patient as it is too heavy.
- While rare, intra operative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive force are more susceptible to fractures, depending on care taken during surgery, number of procedures performed and attention paid. Instruments should be examined for wear or damage prior to surgery.
- While inserting the screw, it is essential to correctly set the screwdriver in relation to the screw. Following the instructions given allows for reduction of the risk of mechanical damage to the screw, screwdriver, or bony hole:
  - screwdriver should be set in the screw axis,
  - apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible,
  - the final phase of tightening shall be performed carefully.
- 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.
- The important medical information given in this document should be conveyed to the patient.
- The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon is responsible for this choice.
- Patients who are overweight, malnourished and/or abusing alcohol or drugs, with weak muscles and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.
- The surgeon must warn the patient that the device cannot and does not restore the function and efficiencyof a healthy bone.
- For Qualified surgeon use only.
- 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).

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.

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.
- Federal Law restricts this device to sale by or on the order of a physician.

MRI Compatibility

The AUXEIN MEDICAL Retrograde Femoral Nailing System 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 Retrogrades before entering the MRI (Magnetic Resonance Imaging) environment.

Potential Adverse Events

All of the possible adverse events associated with Retrograde Femoral Nailing System implantation without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is notlimited to:

- The adverse effects may necessitate re operation or revision. The surgeon should warn the patient aboutthe possibility of adverse effects occurrence.
- The undermentioned list does not exhaust the topic of adverse events. There is a risk of occurrence of adverse events with unknown aetiology which may be caused by many unpredictable factors.
- Potential adverse events include but are 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 because of, contact with other materials.
- Body reaction to implants as foreign bodies e.g. possibility of tumour metaplasia, autoimmune disease and/or scarring.
- Compression on the surrounding tissue or organs
- Infection
- Bone fracture or "Stress Sheilding" phenomenon causing loss of bone above, below or at the operative site.
- Haemorrhage of blood vessels and /or hematomas.

- Pain
- Metal sensitivity
- Inability to perform everyday activities.
- Mental condition changes.
- Death
- Deep vein thrombosis, thrombophlebitis.
- Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary.
- Infection, disturbed lung growth, respiratory acidosis, etc.
- Scar formation that could cause neurological impairment, or nerves compression and /or pain.
- Late bone fusion or no visible fusion mass and pseudoarthrosis.
- Loss of proper curvature and/or length of bone.

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 Retrograde Femoral Nailing System 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 thesuccess of the procedure.
- It is essential to follow all of Surgeon's postoperative directions and warnings.
- 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 ofunion 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 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 medicalauthors are known and observed.
- Re-use of any implant is prohibited as it including risk of infection/disease.
- All components and instruments should be cleaned and sterilized before use.

Intra-operative:

- AUXEIN MEDICAL Retrograde Femoral Nailing System 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 relatedto the selection of a particular sizes.
- The correct use of these components should be clearly described in the relevant product literature corresponding with the Retrograde Femoral Nailing System being implanted.

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 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). It is important that immobilization of the hip surgical site be maintained until firm bony union is established and confirmed by roentgen graphic examination.
- 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 artificial joint replacement implants are always inferior to the function of the natural joint, and only a relative improvement of thepreoperative 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, offersno 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 orthopaedic implants, none of the Retrograde Femoral Nailing System 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:** 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 orthopedicsurgery.
- 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 Retrograde Femoral 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 Retrograde Femoral Nailing System 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 in 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.

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 Retrograde Femoral Nailing Systeming 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 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.

<u>Details of various Symbols used in Labeling</u>

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	5.1.3

			requirements.	
	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 can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels— General requirements.	5.1.6
	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
	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	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be	5.4.2

		on a single patient during a single procedure.	used with medical device labels— General requirements.	
	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 requirements.	5.2.8
	Do not re-sterilize	Indicates a medical device that has already subjected to a sterilization process, so do not re-sterilize.	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

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Revision Table:

S. No.	Document No	Rev. No.	Description of Revision	Effective date	Prepared by	Approved by
1.	A3-IFU-GS-006-04	00	Initially released.	08-07-2018		
2.	A3-IFU-GS-006-04	01	IFU format has been updated.	16-03-2023		