artemis
Proximal Femoral Nail System

℞ Only
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INSTRUCTIONS FOR USE ARTEMIS IMPLANTS

Legal Manufacturer:

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Distributed by:

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Important information – please read prior to use

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Definitions:

Symbols and abbreviations may be used on the package label.
The following table provides the definition of these symbols and abbreviations.

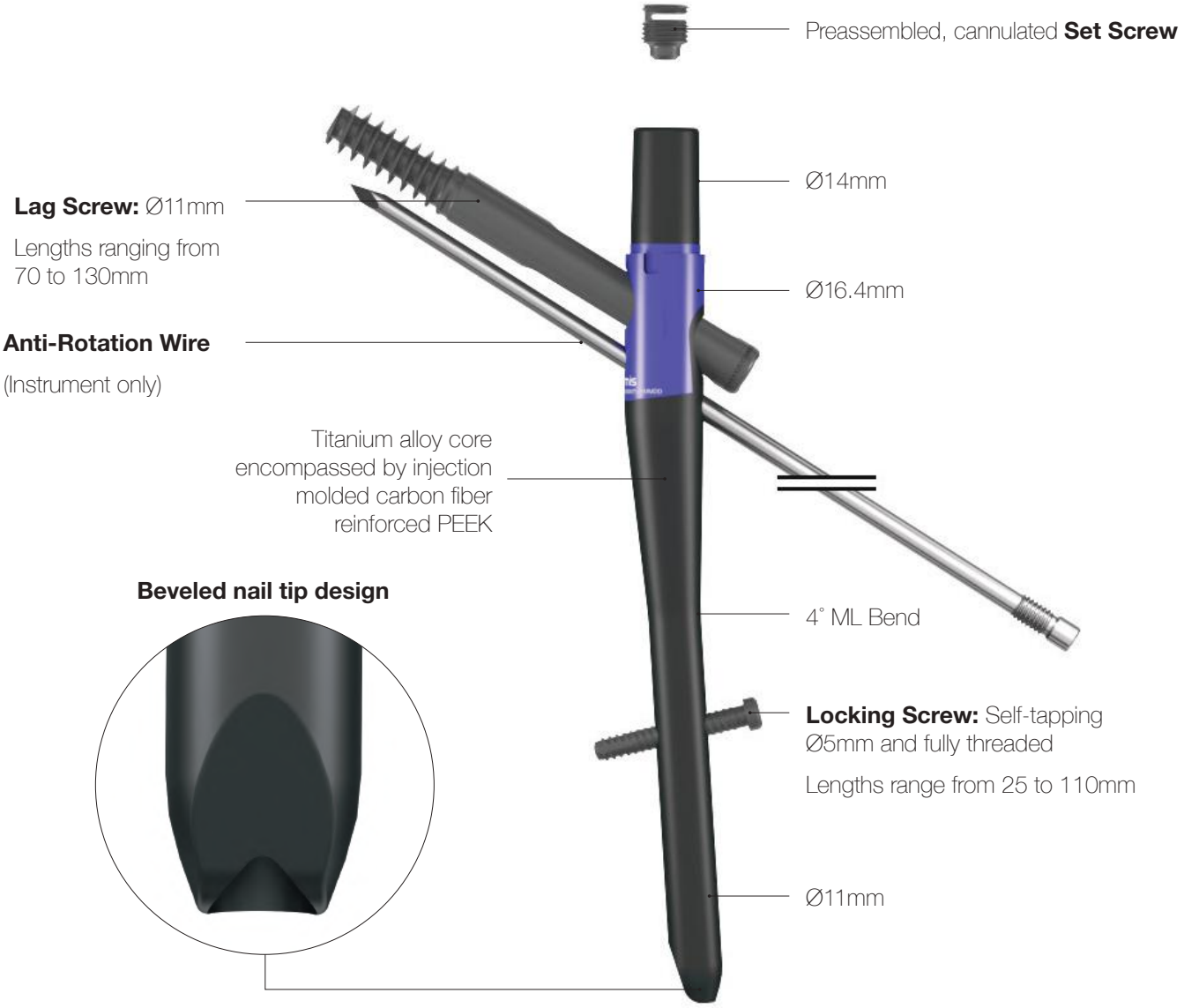
Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Catalog number.
	Batch number.
	Date of manufacture.
	Manufacturer.
	Use by.
	Sterilized using irradiation.
	Caution, consult accompanying documents.
	Do not re-use.
	Do not use if package is damaged.
	Do not resterilize.
	Non-sterile.
R_X Only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

Abbreviation	Material
Ti	Titanium alloy Ti-6AL-4V ELI
Ti6Al4V	Titanium Alloy
CF-PEEK	Carbon Fiber Reinforced Polyetheretherketone

Device Description:

Proximal Femoral Nail Kit Short



- Lag Screw, Locking Screw and Proximal Femoral Nail Kit Short are packaged separately (double-wrapped). Each pack contains a ready-to-use implant.
- STERILE SINGLE USE IMPLANT – DO NOT REUSE OR RESTERILISE.
- An instrument tray including a targeting device is provided separately to perform the implantation.

A. Indications

The Artemis Proximal Femoral Nail System is indicated for the fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections.

B. Contraindications

The Artemis Proximal Femoral Nail System is not intended for femoral Neck fractures. Short nails are not intended for subtrochanteric fractures. The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment.

Conditions representing an increased risk of implant failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and / or fixation of the devices.
- Material sensitivity, documented or suspected.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neurological disorder which would present an unacceptable risk of fixation failure or complications in postoperative care.
- Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for these devices.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

C. Precautions

- If either the implant or the package appears damaged the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.
- This implantable product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

D. Potential Adverse Effects

General Surgery Related Risks:

- Early or late infections, both deep and superficial
- infection
- Pain or discomfort
- Foreign body reactions
- Loosening, bending, cracking or fracture of the implant components.
- Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
- Irritational injury of soft tissues, including impingement syndrome.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants.
- Although rare, material sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.
- Restricted range of motion of the joint adjacent to the insertion point of the Nail, usually transitory due to protruding nails.
- Delayed correction in alignment; and
- Bone resorption or over-production
- Deep venous thrombosis
- Avascular necrosis
- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.

E. MRI Safety Information

- The Artemis Proximal Femoral Nail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Artemis Proximal Femoral Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

F. Warnings (See also the Patient Counseling Information Section)

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.

- If excessive loading cannot be prevented, an implant should not be used.
- Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.
- This device has not been evaluated for safety and compatibility in the MR environment.
- This device has not been tested for heating or migration in the MR environment.

G. Implant Materials

The Artemis Proximal Femoral Nail System implants are manufactured from Ti6AI4V / CF-PEEK.

H. Sterilization

- For components provided sterile, Gamma radiation is the sterilization method used.
- Sterile packaged components are supplied in protective sterile barrier packaging.
- Inspect packages for punctures or other damage prior to surgery.
- If the sterile barrier has been broken, return the component to GLW, Inc.
- If not specifically labeled sterile, components are supplied non-sterile and must be cleaned and sterilized prior to surgery. It is important that adequate cleaning be carried out prior to sterilization.
- New instruments must be thoroughly cleaned before initial sterilization. Trained personnel must perform cleaning (manual and/or machine cleaning, ultrasound treatment, etc.) along with maintenance and mechanical inspection prior to initial sterilization. Exact compliance with the equipment manufacturers' user instructions and recommendations for chemical detergents is required.
- DO NOT STACK trays during sterilization
- DO NOT REUSE implant components or single use disposable instruments

LIMITS ON REPROCESSING

- Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on GLW, Inc. instruments.
- GLW, Inc. instruments should be inspected for damage such as corrosion, scratches, notches, debris, visible wear, discoloration or residue.
- Damaged instruments should be discarded.

POINT OF USE PROCESSING

- Disassemble instruments to their most basic level
- Directly after application, remove gross contamination using absorbent lint-free single use paper wipes and rinse soiled device under running cold (<45°C) tap water for a minute to remove gross soil.

MANUAL CLEANING

1. Disassemble instruments to their most basic level
2. Rinse soiled device under running cold (<45°C) tap water for a minute to remove gross soil. Use a soft bristled brush to assist in the removal of gross soil and debris.
3. Rinse cannulations, blind holes, hinges, joints and similar features at least three times using a syringe.
4. Soak device thoroughly in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
5. Rinse device thoroughly with cold tap water for a minimum of one minute. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
6. Rinse cannulations, blind holes, hinges, joints and similar features at least three times using a syringe.
7. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft bristled brush to thoroughly remove soil and debris. Actuate joints, handles and other moveable device features to expose all areas to the detergent solution.
8. Rinse device thoroughly with cold deionized or high purity water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable devices.
9. Visually inspect each device for any remaining contamination. If a device is not visually clean, repeat the cleaning steps 1-5 or safely dispose the device.

STERILIZATION PARAMETERS

Temperature: 132 °C (270 °F). **Exposure Time:** 4 minutes. **Dry Time:** 30 minutes.

Note: It is recommended to use an FDA-cleared wrap or pouch during sterilization.

I. Surgical Procedures

An operating technique manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedures before use.

J. Post-Operative Protocol

Patients should be cautioned against unassisted activity that requires walking or lifting. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the nail's screw hole, as this places greater stress on the nail at the location of the transverse screw hole.

K. Patient Counseling Information (See also Warnings)

In addition to the patient related information contained in the Warnings, Adverse Events and Post- Operative Protocol sections, the following information should be conveyed to the patient:

While the expected life of an implant is difficult to estimate it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved bone or joint.

L. Caution

Federal Law (United States) restricts this device to sale, distribution, and use by or on the order of a physician.

M. Liability

GLW has taken reasonable precautions in the selection of materials and in the manufacture of these products. However, GLW excludes any legal guarantee, whether express or implicit, including but not limited to, any implicit guarantee of the marketable quality or suitability for a specific use. GLW cannot under any circumstances be held responsible for any loss, damage or related costs or incidents, directly or indirectly linked to the use of this product.

GLW does not assume and does not authorize any third party to assume on its behalf, any other responsibilities relating to these products. The intention of GLW is that this device should be used only by doctors having received appropriate training in techniques of orthopedic surgery for its use.