innov8ortho

www.innov8ortho.com

Value Analysis Guide

artemis
Proximal Femoral Nail System

Value Analysis Guide

This publication sets forth detailed recommended procedures for using Altior Trauma Innovations' Artemis Proximal Femoral Nail System. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to first surgery.

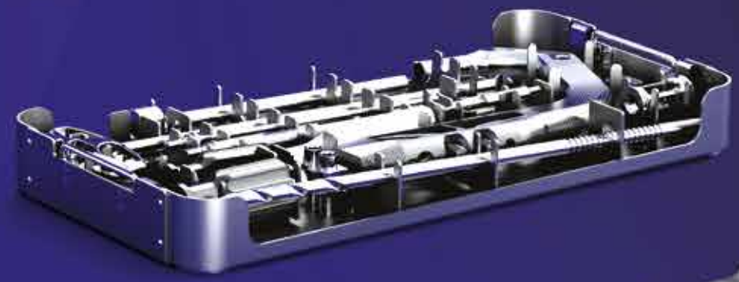
Artemis PFN Contents

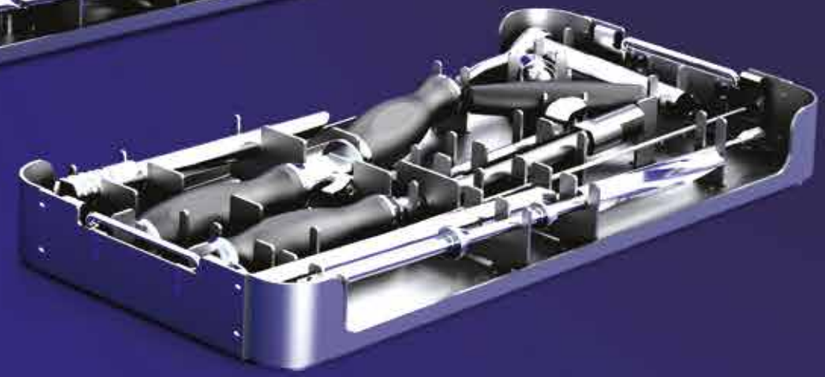
Product Brochure 4
510K Letter 18
Instructions for Use (IFU) 23
Company Info 28
Part List 30

www.innov8ortho.com

Artemis Proximal Femoral Nail System

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





Design Features

The Artemis Proximal Femoral Nail System encompasses four implant components. All components are available in sterile packaging only.

Proximal Femoral Nail Kit

The proximal femoral nail kits, consist of the **Nail** and a preassembled **Set Screw**. Its universal design is intended for left and right application.

The nail is constructed of a titanium alloy core encompassed by injection molded carbon fiber reinforced (CFR) polyether ether ketone (PEEK). The set screw is made of titanium alloy.

Lag Screw

The lag screw has a diameter of 11mm and is available in lengths ranging from 70 to 130mm in 5mm increments. The most common lengths are offered in 2.5mm increments. The lag screw is made of titanium alloy.

Anti-Rotational Locking Pin

The anti-rotational locking pin is designed to provide additional rotational stability and fixation performance.

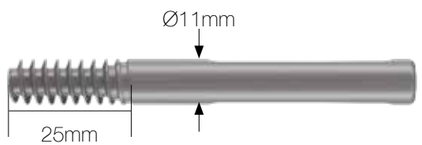
Locking Screw

The locking screw of the Artemis Proximal Femoral Nail System is blunt tipped, self tapping, dual lead thread and have a diameter of 5mm. It is fully threaded and comes in a wide range from 25mm to 110mm in 2.5mm increments up to 50mm and in 5mm increments up to 110mm. A high torque transfer is achieved through the T25 torx screw head.

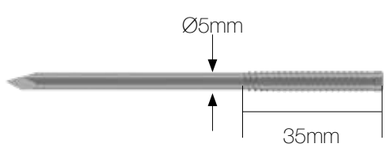
Instrumentation

The Artemis system has a state-of-the-art instrument platform. The instruments are designed for a minimally invasive surgical technique.

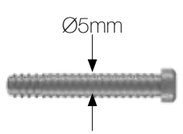
Lag screw
(70–130mm)



Anti-Rotational Locking Pin
(70, 95, 110mm)



Locking screw
(25-110mm)



REDUCED
WASTE
MANUFACTURING

Hybrid Materials and Manufacturing

Patented* manufacturing process utilizes a combination of titanium and composite materials. The nails structural benefits are provided by the strength of titanium and the flexibility of CFR PEEK which allows for increased micro movements and callus formation. The process of minimized titanium milling with the benefit of injection molded CFR PEEK results in reduced waste manufacturing.

Added Visibility

The composite materials provide clinical benefits with improved visualization in both long and short nail configurations. This added visibility allows for easier assessment of bone healing and Lag Screw position.

Lagshield™ Function

Lagshield is a protective layer of CFR PEEK on the lateral side of the nail.

This prevents the lag screw reamer from notching the nails load bearing titanium core during the reaming procedure.

The proximal femoral nail kits, consist of the **Nail** and a preassembled **Set Screw**. Its universal design is intended for left and right application.

Smooth nail insertion, preventing anterior impingement

Lagshield™ Function

Lagshield is a protective layer of CFR PEEK on the lateral side of the nail. This prevents the lag screw reamer from notching the nails load bearing titanium core during the reaming procedure.

Lag shield aids in guidance of the reamer and protects the load bearing titanium, preventing the lag screw reamer from notching the nails titanium core during the reaming procedure.

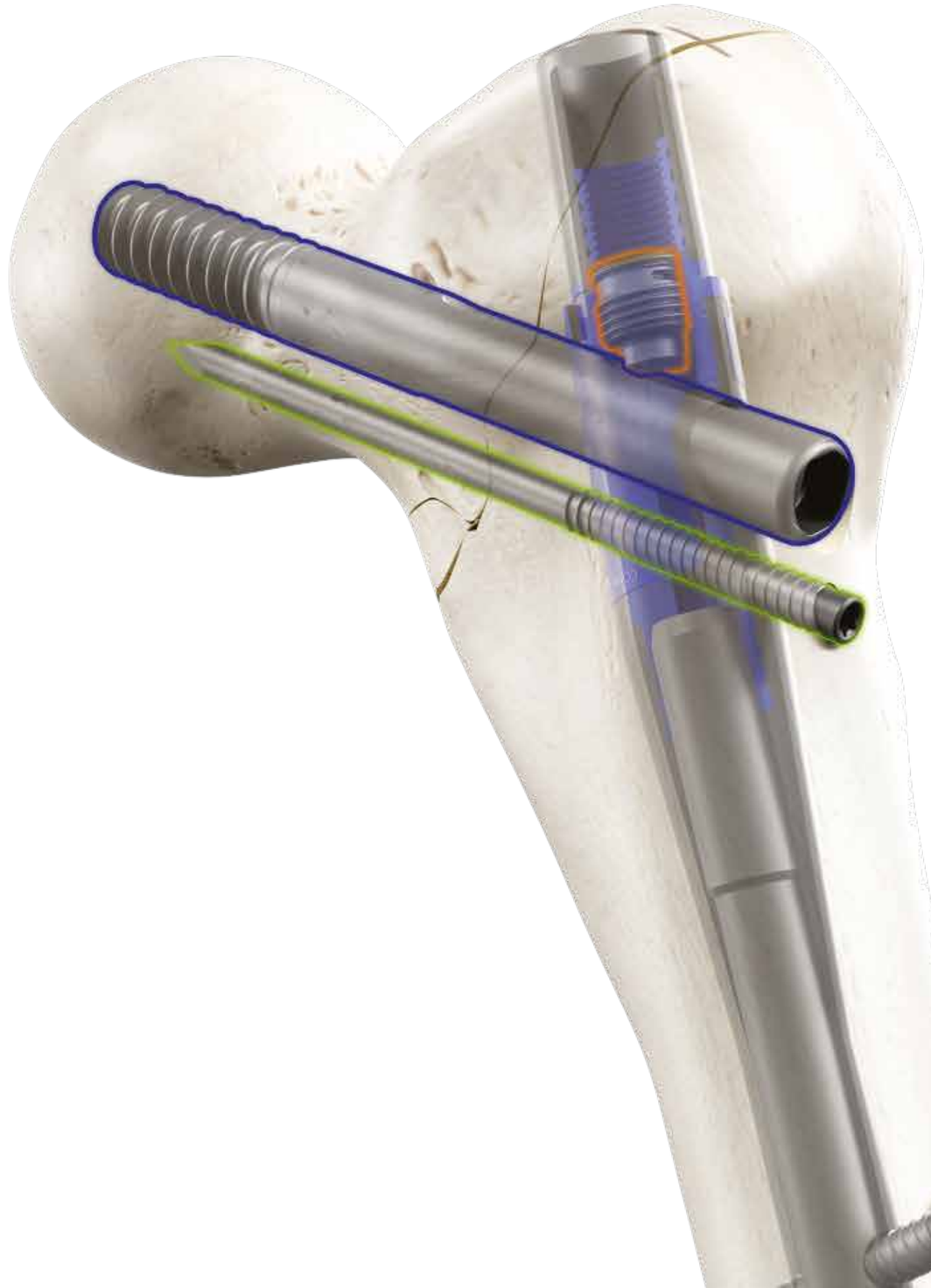
Stability and Rotational Control

Enhanced Stability and Rotational Control: Consists of a Lag Screw with optional combination of integrated anti-rotational Locking Pin which supports compression and helps to remove the Z-effect.

A simple, one piece cannulated set screw locks in to the lag screw, preventing rotation of the lag screw.

The lag screw can move backwards, with the head fragment but cannot rotate.

Locking pin locks into the lateral cortex and the nail, providing additional stability allowing the head fragment to collapse with the lag screw.



Added Visibility

The composite materials provide clinical benefits with improved visualization in both long and short nail configurations. This added visibility allows for easier assessment of bone healing.

The radiolucent proximal end of the nail provides better radiographic visibility of the femoral neck in an oblique medio-lateral image.

Instrumentation

Streamlined one instrument system tray with three dedicated layers for preparation, insertion and extraction.

Carefully redesigned instrumentation for ease of use, allowing for a minimally invasive technique.

GLW, Inc.
% Cheryl Wagoner
Principal Consultant
Wagoner Consulting LLC
5215 Crosswinds Drive
Wilmington, North Carolina 28409

October 27, 2022

Re: K221489
Trade/Device Name: Artemis Proximal Femoral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: September 29, 2022
Received: September 30, 2022

Dear Cheryl Wagoner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2022.10.27 17:55:05 -04'00'

For Victoria Lilling, M.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221489

Device Name
Artemis Proximal Femoral Nail System

Indications for Use *(Describe)*
The Artemis Proximal Femoral Nail System is indicated for fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections.

Additionally, the long nail kit is indicated for the fixation of subtrochanteric fractures and shaft fracture extending distally to a point approximately 10 cm proximal to the intercondylar notch.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Premarket Notification
Artemis Proximal Femoral Nail System
K221489

510(k) Summary

Submitter	GLW Medical Innovation
Address	300 Sylvan Ave Englewood Cliff, NJ 07632
Telephone	917-0794-2583

Contact Person	Arundhati Radhakrishnan
Address	300 Sylvan Ave Englewood Cliff, NJ 07632
Telephone	201-268-3281
email	Arundhati.radhakrishnan@glwmed.com

Date Prepared	October 24, 2022

Trade Name	Artemis Proximal Femoral Nail System
Common Name	Rod, fixation, intramedullary and accessories Screw, fixation, bone
Panel Code	Orthopaedics/87
Classification	21 CFR 888.3020 Intramedullary fixation rod 21 CFR 888.3040 Smooth or threaded metallic bone
Class	Class II
Product Code	HSB: Rod, fixation, intramedullary and accessories HWC: Screw, fixation, bone

Predicate Device (primary)	**510(k) #**	**Manufacturer**
Artemis Proximal Femoral Nail System	K201379	GLW Medical Innovation
Predicate Device (additional)	**510(k) #**	**Manufacturer**
Gamma 3 TNail System	K043431	Stryker
Apollo Ankle Plating System	K213005	GLW Medical Innovation
CREED Cannulated Screws	K200291	GLW Medical Innovation
Zimmer Biomet Affixus Hip Fracture Nail	K183162	Zimmer Biomet

Description	The Artemis Proximal Femoral Nail System is an intramedullary fracture fixation system intended for temporary stabilization of bone segments or fragments in the proximal femur. The system includes single-use, sterile implants (Proximal Femoral Nail Kit Short, Proximal Femoral Nail Kit Long, Locking Screw, Lag Screw, and optional anti-rotational locking pins) as well as non-sterile, reusable, Class I and II surgical instruments. The nail and screws are made of titanium alloy Ti-6Al-4V. The titanium alloy nail is partially over-molded with carbon fiber reinforced polymer (CFR PEEK). The Artemis Nails are available in short or long lengths from 180mm to 440mm and are cylindrical rods with preassembled Set Screws. The Nail is designed with holes, at the proximal and distal sections, for the

	insertion of a Lag Screw and Locking Screw, respectively. The Lag Screw has a diameter of 11mm and is available in various lengths ranging from 70mm to 130mm. The Locking Screw has a diameter of 5mm and is available in various lengths ranging from 25mm to 110mm. Optional Anti-rotational Locking Pins are also available to aid in rotational stability.

Indications and Intended Use	The Artemis Proximal Femoral Nail System is indicated for fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections. Additionally, the long nail kit is indicated for the fixation of subtrochanteric fractures and shaft fracture extending distally to a point approximately 10 cm proximal to the intercondylar notch.

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device, Artemis Proximal Femoral Nail System is substantially equivalent to the primary predicate Artemis Proximal Femoral Nail System (K201379). The subject and predicate (K201379) are identical in intended use, material, and manufacturing processes. The difference in the indications for use use statements includes the addition of the subject long nail kit. Additionally, the proposed changes to technological characteristics do not raise different questions of safety and effectiveness as compared to the predicate device.

	Comparison
Materials	**Identical**
Sterilization method	**Identical**
Diameter	**Identical**
Length	**Short-unchanged** **Subject Long-additional sizes**
Angle	**Identical**
Locking options	**Short-unchanged** **Subject Long-identical + additional anti rotational locking screws**
Lag screw/locking screw	**Identical**
Method of fixation	**Identical**
Mechanics of action	**Identical**

Performance Data	The Artemis Proximal Femoral Nail System successfully underwent mechanical testing in accordance with ASTM F1264 and ASTM F543. Performance testing of the Artemis Proximal Femoral Nail System components also included static and dynamic bending of the construct based on ISO 7206-4. No clinical data was necessary.

Conclusion	Based on the indications for use, technological characteristics, materials, and comparison to the predicate devices, the subject Artemis Proximal Femoral Nail System has been shown to be substantially equivalent to a legally marketed predicate device.

℞ Only

Last revision 01/2023

artemis
Proximal Femoral Nail System

INSTRUCTIONS FOR USE ARTEMIS IMPLANTS

Legal Manufacturer:
GLW, Inc.
300 Sylvan Ave, 2nd Floor
Englewood Cliffs, NJ 07632

Distributed by:
Innov8ortho, LLC.
300 Sylvan Ave, 2nd Floor
Englewood Cliffs, NJ 07632

Important information – please read prior to use

Outline:

Definitions / Description

A. Indications
B. Contraindications
C. Precautions
D. Potential Adverse Effects
E. MRI Safety Information
F. Warnings
G. Implant Materials
H. Sterilization
I. Surgical Procedures
J. Post-Operative Protocol
K. Pateint Counseling Information
L. Caution
M. Liability

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
REF	Catalog number.
LOT	Batch number.
	Date of manufacture.
	Manufacturer.
	Use by.
STERILE R	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

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.

Additionally, the Long Nail Kit is indicated for the fixation of subtrochanteric fractures and shaft fracture extending distally to a point approximately 10 cm proximal to the intercondylar notch.

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 Ti6Al4V / 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.

Orders – Customer Service

Phone: 917.765.7847

Email: custsvc@innov8ortho.com

Shipping FOB Origin, Freight Prepay & Add
*Expedited shipments will be invoiced for the change associated with the expedited delivery

510 K Clearance #'s

Creed Screws K200291

Apollo AFX Plating K213005

FusionFrame K200343

Artemis PFN Nail K221489

Remit to Address

Innov8ortho, LLC

P.O. Box 154

Edgewater, NJ 07020

CORPORATE OFFICE

Innov8ortho, LLC

300 Sylvan Ave, 2nd Floor

Englewood Cliffs, NJ 07632

Email: enquiries@innov8ortho.com

Website

www.innov8ortho.com

Terms and Conditions of Sale

The following terms and conditions of sale constitute an integral part of this Innov8ortho, LLC. ("Innov8ortho") product list and are applicable to all purchase orders. All prices and terms are subject to change.

I. Acceptance of Purchase Orders
All purchase orders are subject to acceptance at Innov8ortho's customer service department located in Englewood Cliffs, NJ and will be deemed accepted only when confirmed in writing or upon Innov8ortho's commencement of performance. For convenience, customers may place purchase orders or make inquiries (between the hours of 8:30 a.m. – 5:30 p.m. EST, Monday – Friday, exclusive of all federal and state holidays) by calling 917.765.7847 or emailcustsvc@innov8ortho.com.

II. Payment Terms
Payment is due no later than 30 days from the date of the invoice.

Mail purchase order to:
Innov8ortho, LLC.
300 SYLVAN AVE, 2ND Flr
Englewood Cliff, NJ 07632

Mail payments to:
Innov8orth, LLC.
P.O. Box 154
Edgewater, NJ 07020

III. Additional Charges
All applicable excise, sales, or other taxes will be invoiced to customer and are not included in product prices.

IV. Shipping and Related Charges
Terms of sale on all purchase orders are F.O.B. shipping point. Each purchase order will incur a shipping and handling charge of $75.00. All shipments of product will be placed with the carrier for requested 2-day delivery.

Expedited Shipments: Customers requiring expedited delivery will be invoiced for the change associated with the expedited delivery.

Shipping Damage: Although Innov8ortho takes special care in the packaging of its products, damage may occur in transit. All products must, therefore, be inspected and any damage noted on the freight bill and reported to the carrier, upon receipt of product. Although Novastep's responsibility for damage ceases upon deposit with carrier, Innov8ortho may extend assistance in helping customer settle damage claims.

V. Return Goods and Related Charges
Return Authorization/Repairs: Customer must obtain a return authorization number from Innov8ortho or Innov8ortho account representative before any Innov8ortho product can be returned for repair, replacement, refund, or credit. To obtain a returnauthorization number, customer must provide Innov8ortho with (1) the Innov8orthocatalog number and quantity of Innov8ortho product to be returned; (2) the reason forthe return/repair; (3) a description of the Innov8ortho product being returned for repair;(4) the name and telephone number of a customer contact who may be called ifInnov8ortho requires further information; and (5) at least one of the following: (i) theapplicable customer purchase number, (ii) the applicable Innov8ortho invoice number,and (iii) the applicable Innov8ortho product lot or serial number. A purchase order isrequired for all repairs even in situations where there is no charge. If the Innov8orthoproduct to be repaired is covered by a written limited product warranty, a copy of theoriginal invoice must be sent with the Innov8ortho product. The cost of repair notcovered by a written limited product warranty must be paid by the customer.

Non-Returnable Products: Customer is not entitled to return nor eligible to receive repair, replacement, refund, or credit for any Innov8ortho product described below (collectively, "Non-Refundable Products"):

- Product damaged in transit;
- Product shipped in error and returned more than 30 days after the date of the applicable Innov8ortho invoice (unless such product is subject to a recall arising out of the negligent acts or omissions of Innov8ortho (a "Quality Recall);
- Non-defective product return in quantity less than Innov8ortho's original unit of sale;
- Non-defective product returned more than 90 days after date of applicable
- Innov8ortho invoice (unless part of a Qualified Recall);
- Defective product returned after expiration of applicable warranty period (unlesspart of a Qualified Recall);
- Product sold non-sterile that has been subjected to sterilization processing;
- Product sold for single use that has been re-used or re-processed;
- Product that has been altered, further manufactured, packaged, processed, abused, or misused;
- Product that has been adjusted or repaired by anyone other than by Innov8ortho or a person or entity authorized in writing by Innov8ortho; and
- Product that is a "custom" device unless such product is defective for a reason other than manufacture to customer's specifications.

Authorized Return Products and Freight Charges: With regard to those Innov8orthoproducts (other than Non-Returnable Products) for which customer has obtained areturn authorization number. Innov8ortho will accept returns for such products if theyare: (1) determined by Innov8ortho to be defective and returned within applicable warranty period; (2) no defective, in saleable condition and returned within 90 days of the corresponding Innov8ortho invoice date and represent product shipped in error by Innov8ortho (such products, collectively, "Authorized Return Products"). All Authorized Return Products must be returned freight prepaid by customer. All Authorized Return Product returned freight collect will be refused by Innov8ortho and returned to customer at its expense. Innov8ortho will, at its option, refund or credit customer for all freight charges incurred in connection with returning to Innov8ortho any Authorized Return Product.

Allowance Schedule for Authorized Return Products: For those Authorized Return Products that Innov8ortho has elected to provide a refund or credit, Innov8ortho will pay a refund or issue a credit to customer within 30 business days of Innov8ortho'sreceipt of the Authorized Return Product, based on the original purchase price, in accordance with following:

CONDITION	CREDIT
Defective product returned within applicable product warranty period	Full Credit*
Non-defective product returned in a saleable condition within 45 days of corresponding Innov8ortho invoice date	Full Credit*
Non- defective product returned is saleable condition within 46-90 days of corresponding Innov8ortho invoice date	Full Credit* minus 20% reprocessing charge min. $10.00 charge
Product shipped in error by Innov8ortho and returned is saleable condition within 45 days of corresponding Innov8ortho invoice date	Full Credit*
Product subject to a Qualified Recall	Full Credit*

**Less any credits issued by Innov8ortho to customer with respect to such product.*

VI. Confidentiality
Customer will not disclose to any third party these terms and conditions, including the Product List, or any other information provided by Innov8ortho to customer, without Innov8ortho's written approval, except as may be required by law or lawful order of anyapplicable government agency.

VII. Limited Product Warranty; Disclaimer and Limitation of Liability
Innov8ortho warrants to the original purchaser that each Innov8ortho product set forth in the Product List will be free from defects in material and workmanship for the period set forth in the labeling of the particular Innov8ortho product or, if no such period is set forth in the labeling, for a period of one (1) year from date of purchase. If Innov8ortho product proves to be so defective, such Innov8ortho product may be returned to Innov8ortho for repair, replacement, refund or credit at Innov8ortho's option, in accordance with Innov8ortho's return goods and allowance policy. Any alteration, abuse, misuse, further manufacture, packaging, processing, adjustment or repair by any person or entity other than Innov8ortho or a person entity authorized in writing by Innov8ortho shall void this limited product warranty ab initio. THIS LIMITED PRODUCTWARRANTY IS IN LEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE LIABILITY AND REMIDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE SOLE LIABILITY OF Innov8ortho AND REMIDY AVAILBLE TO CUSTOMER FOR Innov8ortho PRODUCTS WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND Innov8ortho WILL NOT BE LIABLE TO CUSTOMER FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE POSSIBILITY OR LIKELYHOOD OF SUCH DAMAGES. IN NO EVENT WILL Innov8ortho BE LIABLE FOR ANY CLAIM, LOSS OR DAMAGE ARISING OUT OF OR RELATING TO, IN WHOLE OR IN PART, ANY PURCHASE ORDER, THERE TERMS AND CONDITIONS OR OTHERWISE, IN EXCESS OF THE AMOUNT PAID BY CUSTOMER TO Innov8ortho PURSUANT TO THE PURCHASE ORDER TO WHICH CLAIM, LOSS OR DAMAGE RELATES.

VIII. Product Changes
All products and product specifications identified in the Product List are based upon the information available to Innov8ortho at the time of publication. Innov8ortho reserves the right to discontinue any product or to change any product specifications without notice.

IX. Termination
Any customer purchase order may be terminated by Innov8ortho as follows: (1) upon 30 days prior written notice to customer; (2) effective immediately, if customer commits a material breach of any provision of the purchase order or these terms and conditions and such breach continues for a period of 30 days following notice; or (3) effective immediately, if the customer files, or has filled against it, a petition for voluntary or involuntary bankruptcy or pursuant to any other insolvency law or makes or seeks to make a general assignment for the benefit of its creditors or applies for or consents to the appointment of a trustee, receiver, or custodian for its or substantial part of its property.

X. Force Majeure
Innov8ortho will not be liable for its failure to perform or a delay in performance of any order due to strikes, fire, explosion, flood, riot, lock out, injunction, interruption of transportation, unavoidable accidents, acts of government or a public enemy, terrorism, inability to obtain supplies at reasonable prices, or other causes beyond its control.

XI. Choice of Law
All transactions under these terms and conditions shall be governed by and construed in accordance with the laws of the State of New York as applicable to contracts made and to be performed in that state, without regard to conflicts of laws principles.

XII. General
NONE OF THE FOREGOING TERMS AND CONDITIONS MAY BE MODIFIED EXCEPT UPON NOVASTEP'S EXPRESS WRITTEN CONSENT STATING THAT IT IS AN AMENDMENT OT MODIFICATION THERETO. In the event of any inconsistency between these terms and conditions of sale and those contained in any purchase order, purchase order release, confirmation, acceptance, or any similar document, the terms and conditions set forth above shall prevail. These terms and conditions of sale constitute the entire understanding between Innov8ortho and customer and supersede all prior terms and conditions of sale published by Innov8ortho, in each case, related to the subject matter hereof.

Artemis PFN Part List

ITEM NUMBER	DEVICE DESCRIPTION
ARTEMIS DISPOSABLE INSTRUMENTS	
T4-0200-010S	Procedure Kit Short Nail (2x K-Wire, Threaded Trocar Tip and 1x Locking Screw Drill, long)
T4-0200-020S	Procedure Kit Long Nail (2x K-Wire, Threaded Trocar Tip and 1x Locking Screw Drill, short)
T5-0140-000S	Guide Wire, Ø4.0mm Ball Tip
T5-0270-000S	Anti-Rotation Wire, Short (Lag Screws of 70mm+)
T5-0550-000S	Anti-Rotation Wire, Short (Lag Screws of 95mm+)
T5-0570-000S	Anti-Rotation Wire, Short (Lag Screws of 110mm+)
ARTEMIS IMPLANTS, SHORT	
T6-0180-110S	Ø11x180mm Short Nail Kit (Set Screw Included)
ARTEMIS IMPLANTS, LEFT	
T6-1300-110	Proximal Femoral Nail Kit Long, Left 11 x 300mm
T6-1320-110	Proximal Femoral Nail Kit Long, Left 11 x 320mm
T6-1340-110	Proximal Femoral Nail Kit Long, Left 11 x 340mm
T6-1360-110	Proximal Femoral Nail Kit Long, Left 11 x 360mm
T6-1380-110	Proximal Femoral Nail Kit Long, Left 11 x 380mm
T6-1400-110	Proximal Femoral Nail Kit Long, Left 11 x 400mm
T6-1420-110	Proximal Femoral Nail Kit Long, Left 11 x 420mm
T6-1440-110	Proximal Femoral Nail Kit Long, Left 11 x 440mm
ARTEMIS IMPLANTS, RIGHT	
T6-2300-110	Proximal Femoral Nail Kit Long, Right 11 x 300mm
T6-2320-110	Proximal Femoral Nail Kit Long, Right 11 x 320mm
T6-2340-110	Proximal Femoral Nail Kit Long, Right 11 x 340mm
T6-2360-110	Proximal Femoral Nail Kit Long, Right 11 x 360mm
T6-2380-110	Proximal Femoral Nail Kit Long, Right 11 x 380mm
T6-2400-110	Proximal Femoral Nail Kit Long, Right 11 x 400mm
T6-2420-110	Proximal Femoral Nail Kit Long, Right 11 x 420mm
T6-2440-110	Proximal Femoral Nail Kit Long, Right 11 x 440mm

ITEM NUMBER	DEVICE DESCRIPTION
ANTI-ROTATION PIN	
T6-0255-070	Anti Rotation Pin Pin Short 4.2 x 70mm
T6-0255-095	Anti Rotation Pin Pin Long 4.2 x 95mm
T6-0255-110	Anti Rotation Pin Pin Extra Long 4.2 x 110mm
LAG SCREW	
T6-0200-070S	Ø11 Lag Screw, 70mm
T6-0200-075S	Ø11 Lag Screw, 75mm
T6-0200-080S	Ø11 Lag Screw, 80mm
T6-0200-085S	Ø11 Lag Screw, 85mm
T6-0200-090S	Ø11 Lag Screw, 90mm
T6-0200-092S	Ø11 Lag Screw, 92.5mm
T6-0200-095S	Ø11 Lag Screw, 95mm
T6-0200-097S	Ø11 Lag Screw, 97.5mm
T6-0200-100S	Ø11 Lag Screw, 100mm
T6-0200-102S	Ø11 Lag Screw, 102.5mm
T6-0200-105S	Ø11 Lag Screw, 105mm
T6-0200-110S	Ø11 Lag Screw, 110mm
T6-0200-115S	Ø11 Lag Screw, 115mm
T6-0200-120S	Ø11 Lag Screw, 120mm
T6-0200-125S	Ø11 Lag Screw, 125mm
T6-0200-130S	Ø11 Lag Screw, 130mm

ITEM NUMBER	DEVICE DESCRIPTION
LOCKING SCREW – 5MM	
T6-0300-025S	Ø5 Locking Screw 25mm, Fully Threaded
T6-0300-027S	Ø5 Locking Screw 27.5mm, Fully Threaded
T6-0300-030S	Ø5 Locking Screw 30mm, Fully Threaded
T6-0300-032S	Ø5 Locking Screw 32.5mm, Fully Threaded
T6-0300-035S	Ø5 Locking Screw 35mm, Fully Threaded
T6-0300-037S	Ø5 Locking Screw 37.5mm, Fully Threaded
T6-0300-040S	Ø5 Locking Screw 40mm, Fully Threaded
T6-0300-042S	Ø5 Locking Screw 42.5mm, Fully Threaded
T6-0300-045S	Ø5 Locking Screw 45mm, Fully Threaded
T6-0300-047S	Ø5 Locking Screw 47.5mm, Fully Threaded
T6-0300-050S	Ø5 Locking Screw 50mm, Fully Threaded
T6-0300-055S	Ø5 Locking Screw 55mm, Fully Threaded
T6-0300-060S	Ø5 Locking Screw 60mm, Fully Threaded
T6-0300-065S	Ø5 Locking Screw 65mm, Fully Threaded
T6-0300-070S	Ø5 Locking Screw 70mm, Fully Threaded
T6-0300-075S	Ø5 Locking Screw 75mm, Fully Threaded
T6-0300-080S	Ø5 Locking Screw 80mm, Fully Threaded
T6-0300-085S	Ø5 Locking Screw 85mm, Fully Threaded
T6-0300-090S	Ø5 Locking Screw 90mm, Fully Threaded
T6-0300-090S	Ø5 Locking Screw 90mm, Fully Threaded
T6-0300-095S	Ø5 Locking Screw 95mm, Fully Threaded
T6-0300-100S	Ø5 Locking Screw 100mm, Fully Threaded
T6-0300-105S	Ø5 locking screw 105mm, fully threaded
T6-0300-110S	Ø5 locking screw 110mm, fully threaded

ITEM NUMBER	DEVICE DESCRIPTION
ARTEMIS PREPARATION INSTRUMENTS	
T5-0460-000	Channel Tube
T5-0180-000	Guide Wire Driver
T5-0100-000	Handle, AO small
T5-0410-000	Guide Wire Pusher
T5-0170-000	Opening Reamer, Zimmer/Hall
T5-0160-000	Opening Reamer Sleeve
T5-0110-000	T-Handle, Zimmer/Hall Coupling
T5-0400-000	Strike Plate
T5-0150-000	Repositioning Guide

ARTEMIS INSERTION INSTRUMENTS	
T5-0230-000	Lag Screw Guide Sleeve
T5-0270-000	Anti-Rotation Wire
T5-0290-000	Lag Screw Driver
T5-0220-000	Ball Tip Screwdriver, 8.0mm, Zimmer/Hall
T5-0240-000	K-wire Sleeve
T5-0280-000	Lag Screw Measuring Gauge
T5-0450-000	Compression Device - Lever
T5-0200-000	Nail Holding Bolts
T5-0210-000	Targeting Device
T5-0250-000	Lag Screw Drill, Ø11mm, Zimmer/Hall
T5-0260-000	Lag Screw Drill Stop

LOCKING SCREW INSTRUMENTS	
T5-0430-000	Extraction Rod, Zimmer/Hall
T5-0420-000	Reduction Spoon, Zimmer/Hall
T5-0440-000	Slotted Hammer
T5-0120-000	Awl, Curved
T5-0350-000	Locking Screw Drill, Long
T5-0340-000	Locking Screw Trocar
T5-0330-000	Locking Screw Drill Sleeve
T5-0320-000	Locking Screw Guide Sleeve
T5-0380-000	Depth Gauge
T5-0370-000	Direct Measuring Gauge
T5-0310-000	Flexible Screwdriver, 4.0mm, AO Small
T5-0390-000	Screwdriver Bit T25, AO Small
T5-0530-000	Lag Screw Tap

innov8ortho®

ApolloAnkle™ Fracture Plating System

Scan for more
Apollo Ankle product
information

creed™ Ortholucent Implants

Scan for more
Creed product
information

artemis Proximal Femoral Nail System

Scan for more
Artemis product
information

SUPRAFUSION

Scan for more
Suprafusion product
information

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

GLW, Inc, GLW Medical Innovation, and Artemis PFN are trademarks of GLW, Inc. innov8ortho is the exclusive distributor of the Artemis Proximal Femoral Nail System.

www.innov8ortho.com

Ref: ART-VAP-BRO-10-24-EN

Distributed by:

Innov8ortho, LLC
300 Sylvan Ave, 2nd Floor
Englewood Cliffs, NJ 07632
custsvc@innov8ortho.com

innov8ortho®