ApolloAnkle™
Fracture Plating System

℞ Only
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INSTRUCTIONS FOR USE APOLLO AFX IMPLANTS

Legal Manufacturer:
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Important information – please read prior to use

Outline:

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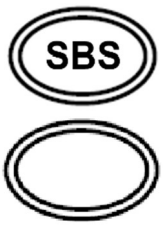
Definitions:

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations per ISO 15223-1:2016.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Description	Source
	Catalog number	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.1.6
	Batch Number	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.1.5
	Date of Manufacture	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.1.3
	Manufactured by	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.1.1
	Use by	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.1.4
	Sterilized using irradiation	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.2.4
	Caution, consult accompanying documents	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.4.3
	Do not re-use	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.4.2
	Do not use if package is damaged	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.2.6
	Do not resterilize	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.2.6
	Non-sterile	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.2.7
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician	21 U.S Code § 353, paragraph (b)(4)(A)
	Unique Device Identifier	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.7.10
	Double sterile barrier system	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.2.12 No SBS letters in ISO 15223-1:2021. SBS letter added in proposal by Sterile Barrier Association “MDR requirements for labelling of Sterile Medical Products: ‘Sterile Barrier System Indication’ and ‘Check the IFU’ Results from the survey on proposals for new symbols Survey closed 31.03.2018”

Abbreviation	Material / Description
Ti6Al4V	Titanium alloy Ti-6AL-4V ELI
PEEK	Zeniva ZA-600 Polyetheretherketone
QTY	Quantity

Device Description

- Apollo Ankle Fracture (Apollo AFX) plates, Locking and Non-locking Screws and Washer are packaged separately (double-wrapped). Each pack contains a ready-to-use implant.
- STERILE SINGLE USE IMPLANT – DO NOT REUSE OR RESTERILIZE.

Plate Options

Plate Type	Lateral Fibula	One-third Tubular	Hook	Medial Malleolar	Posterior Tibia	Syndesmosis
Hole Count	9, 11, 13	4, 5, 6, 7, 8, 10, 12	3, 4, 5, 6	6, 7, 8	5, 6	2, 4
Length	67–111mm	51–139mm	48–81mm	60–83mm	48–59mm	29–51mm
Orientation	Left/Right	Universal	Universal	Universal	Left/Right	Universal
Material	Ti6Al4V / PEEK					

Screw Options

Ø Size range	2.9mm	3.7mm	4.3mm
Type	Locking and Non-Locking		Non-Locking
Length	8 –40mm	10–60mm	25 -70mm
Material	Ti6Al4V		
Color	Fuchsia	Green	Blue

Washer Option

Washer Size	7.5mm OD
Use	Fits All Screws

A. Indications

Apollo AFX Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures

Apollo Locking Screws are intended for use with Apollo's Plating System.

Apollo Non-locking Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Apollo washer is intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments.

Apollo 1/3 tubular plates are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

B. Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of 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 cannot 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
- Pain or discomfort
- Foreign body reactions
- Loosening, bending, cracking or fracture of the implant components.
- 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
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
- Avascular necrosis
- Subclinical nerve damage may possibly occur as a result of the surgical trauma.

E. MRI Safety Information

The Apollo AFX Plating System has not been evaluated for safety in (MR) environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Apollo AFX Plating System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

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.

G. Implant Materials

The Apollo AFX Plating System implants are manufactured from Ti6Al4V / PEEK.

H. Sterilization

- The implants of Apollo AFX Plating System have been sterilized by gamma radiation.
- Do not re-sterilize if the implant comes in direct contact with human tissue. Dispose of implants that come in contact with human tissue and are not used in surgery.
- Inspect packages for punctures or other damage prior to surgery. If the sterile barrier has been broken, return the component to the distributor.

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.

Removal of devices: Should it become necessary to remove the implants, please contact the distributor for instructions and instrumentation.

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.
Protected weight bearing with below the knee walking cast or walking boot is recommended. A gradual return to limited activity in 4 to 6 weeks is allowed as tolerated. Patient specific post-operative care is the responsibility of the surgeon.

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.

K. 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.