ApolloAnkle™
Fracture Plating System

℞ Only

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INSTRUCTIONS FOR USE APOLLO SINGLE USE AND REUSABLE INSTRUMENTS

Legal Manufacturer:
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Distributed by:
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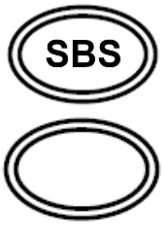
Important information – please read prior to use

Outline:

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
PARA GF50	Polyarylamide with 50% glass fiber
SST	Stainless Steel
PEEK	Zeniva ZA-600 Polyetheretherketone
PP	Polypropylene
TPE	Thermoplastic Elastomer

Device Description:

- Apollo Ankle Fracture plating system offers set of single use sterile instrument kit. Each instrument kit contains a ready-to-use components.
- STERILE SINGLE USE INSTRUMENT – DO NOT REUSE OR RESTERILIZE.
- An instrument tray with set of reusable instruments is provided separately for reduction procedure and supplied non-sterile.

SINGLE USE INSTRUMENTS		REUSABLE INSTRUMENTS	
REF Numbers	Description	REF Numbers	Description
F5-0116-100	Olive Wire	F5-9002-000	Instrument Tray
F5-5001-000	Ratcheting Handle	F5-9003-000	Reduction Forceps
F5-4015-100	T15 Driver	F5-9004-000	Lobster Clamp
F5-2001-070	Countersink/Depth Gauge	F5-9005-000	Syndesmotic Clamp
F5-3000-000	Straight/Poly-axial Drill Guide	F5-9006-000	Verbrugge Clamp
F5-7001-000	Plate Bender/Tamp	F5-9007-000	Hohmann Retractor
F5-0016-150	K-wires, Ø1.6mm	F5-9008-000	Periosteal Elevator
F5-1024-140	Ø2.4mm Drill, Pin Driver	F5-9009-000	Dental Pick
F5-1031-160	Ø3.1mm Drill, Pin Driver	F5-9010-000	Curette, Size 00
F5-1033-145	Ø3.35mm Drill, Pin Driver	F5-9011-000	Metal Trails Set
F5-1040-145	Ø4.0mm Drill, Pin Driver	F5-9012-000	Drill Guide, Straight/ Poly-axial
F5-1045-145	Ø4.5mm Drill, Pin Driver	F5-9013-000	Plate Bender
F5-3010-029	2.9 Lag Drill Guide	F5-9014-000	Countersink
F5-3010-037	3.7 Lag Drill Guide	F5-9015-000	Depth Gauge
F5-3010-043	4.3 Lag Drill Guide	F5-9016-000	Ratcheting handle
F5-9001-000	Trials	F5-9017-000	Lag Drill Guide, 2.9
F5-0020-090	K-wires, Ø2.0mm	F5-9018-000	Lag Drill Guide, 3.7
F5-3001-000	Hook Drill Guide	F5-9019-000	Lag Drill Guide, 4.3
		F5-4015-100	T15 Driver

A. Indications

These instruments are intended for use in surgery and should be used only for the introduction of associated GLW products. None of the instruments shall be implanted.

Apollo™ Ankle Fracture 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 Systems.

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. Precautions

- If either instruments or its packaging appears faulty or damaged, those instruments should not be used and sent to Novastep Inc. for disposition.
- The single-use instruments are supplied sterile. It should never be re-sterilized after contact with body tissues or fluids.
- The reusable instruments are supplied non-sterile in a tray. It should be cleaned thoroughly and sterilized before its use.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.
- Failure to use dedicated, unique Apollo system instruments for each step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury.

C. Potential Adverse Effects

GLW Inc. manufactures single use and reusable surgical instruments intended to prepare the site and aid in implantation of Apollo implants. The potential adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the implants can be found in the Implant - Instructions for use of Apollo Ankle Fracture Plating System.

D. MRI Safety Information

The Apollo Ankle Fracture 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 Ankle Fracture 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.

E. Instrument Materials

The instruments of Apollo Ankle Fracture Plating System are manufactured from Stainless Steel, PA66 GF50 , PP, TPE and PEEK.

F. Cleaning and 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 the distributor.

- 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.
- Reusable instruments must be thoroughly cleaned before initial sterilization. Trained personnel must perform cleaning (manual and/or automated cleaning) along with maintenance and mechanical inspection prior to initial sterilization.
- DO NOT REUSE single use disposable instruments.
- GLW, Inc. instruments should be inspected for damage such as corrosion, scratches, notches, debris, visible wear, discoloration or residue. Damaged instruments should be replaced or sent to the distributor for disposition.

MANUAL CLEANING

1. Disassemble instruments to their most basic level.
2. Rinse instruments under lukewarm running water to remove all gross soil for at least one (1) minute. Use a soft bristled brush to aid in the brushing. Agitate the instruments under the running water. Agitation includes actuating all movable parts such as opening and closing hinges and moving the instruments around under the running water. Use a clean soft bristled brush and/or pipe cleaner to brush and aid in the rinse for the exterior and interior of instruments. Use a syringe to flush any lumens with lukewarm water.
3. Prepare a fresh solution of pH enzymatic detergent with lukewarm tap water. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
4. Allow the immersed devices to soak for a minimum of two (2) minutes.
5. Rinse devices in lukewarm water for a minimum of one and a half (1.5) minutes to remove any detergent residuals. In accordance with Step 2, agitate the instruments under the running water, being sure to actuate all movable parts, and using a soft bristled brush for internal and exterior device surfaces.
6. Prepare an ultrasonic bath using pH enzymatic detergent and lukewarm tap water in a sonicator. Fully immerse the devices in the detergent and sonicate for ten (10) minutes.
7. After sonication, rinse the devices with running deionized water for at least three (3) minutes. Agitate the instruments under the running water, being sure to actuate all movable parts, and using a clean soft bristled brush for internal and exterior device surfaces and flush all lumens with deionized water using a syringe.
8. Dry the devices using a clean lint free cloth and/or filtered compressed air.
9. Visually inspect each device for any remaining contamination. If a device is not visually clean, repeat the cleaning steps from 1 to 5.

AUTOMATED CLEANING

1. Prepare a solution of pH enzymatic detergent with lukewarm tap water.
2. Fully immerse the devices and allow to soak for a minimum of two (2) minutes.
3. Following the soak time, flush any lumens of the device with detergent solution using a syringe.

4. Rinse the devices under running deionized water for a minimum of at least one (1) minute, while agitating the devices. Agitation includes actuating all movable parts, such as opening and closing hinges and moving the devices around under the running water.
5. Use a clean soft bristled brush and/or pipe cleaner to brush and aid in the rinse for the exterior and interior of device components. Use a syringe to flush any lumens with lukewarm water.
6. Place the instruments into the tray and load the tray set into an automated washer (Steris 444 or equivalent).
7. The washer cycle parameters are as follows:

Phase	Recirculation Time (minutes)	Water Temperature	Detergent
Pre-wash	02:00	Cold water	N/A
Enzyme wash	01:00	Hot water	Neutral, Enzymatic Cleaner
Wash	02:00	60°C	Neutral, pH detergent
Rinse	10:00	Hot water	N/A

8. Use the highest available grade of water for the final rinse cycle.
9. After washing, dry the devices using a clean lint free cloth and/or filtered compressed air.

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.

G. Surgical Procedures

- GLW does not practice medicine and does not recommend any specific operating technique. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon.
- It is the surgeon's responsibility to select the appropriate surgical technique and instruments for each individual patient, in accordance with the surgeon's practice, experience, training, standard of care and knowledge of the relevant medical literature. GLW is not responsible for selection of appropriate surgical technique to be utilized for an individual patient.
- Criteria for patient selection are the responsibility of the surgeon. The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and device being implanted in the surgical procedure. The surgeon should refer to the instructions for use accompanying the device. Information contained within this document should be taken into consideration during the selection process.

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

H. Storage Conditions

Store in a dry place, clean environment, at ambient temperature and protected from direct sunlight.

I. Caution

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

J. 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.