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Value Analysis Guide

ApolloAnkle™

Fracture Plating System

Value Analysis Guide

This publication sets forth detailed recommended procedures for using Apollo Ankle. 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.

Seeing is Believing

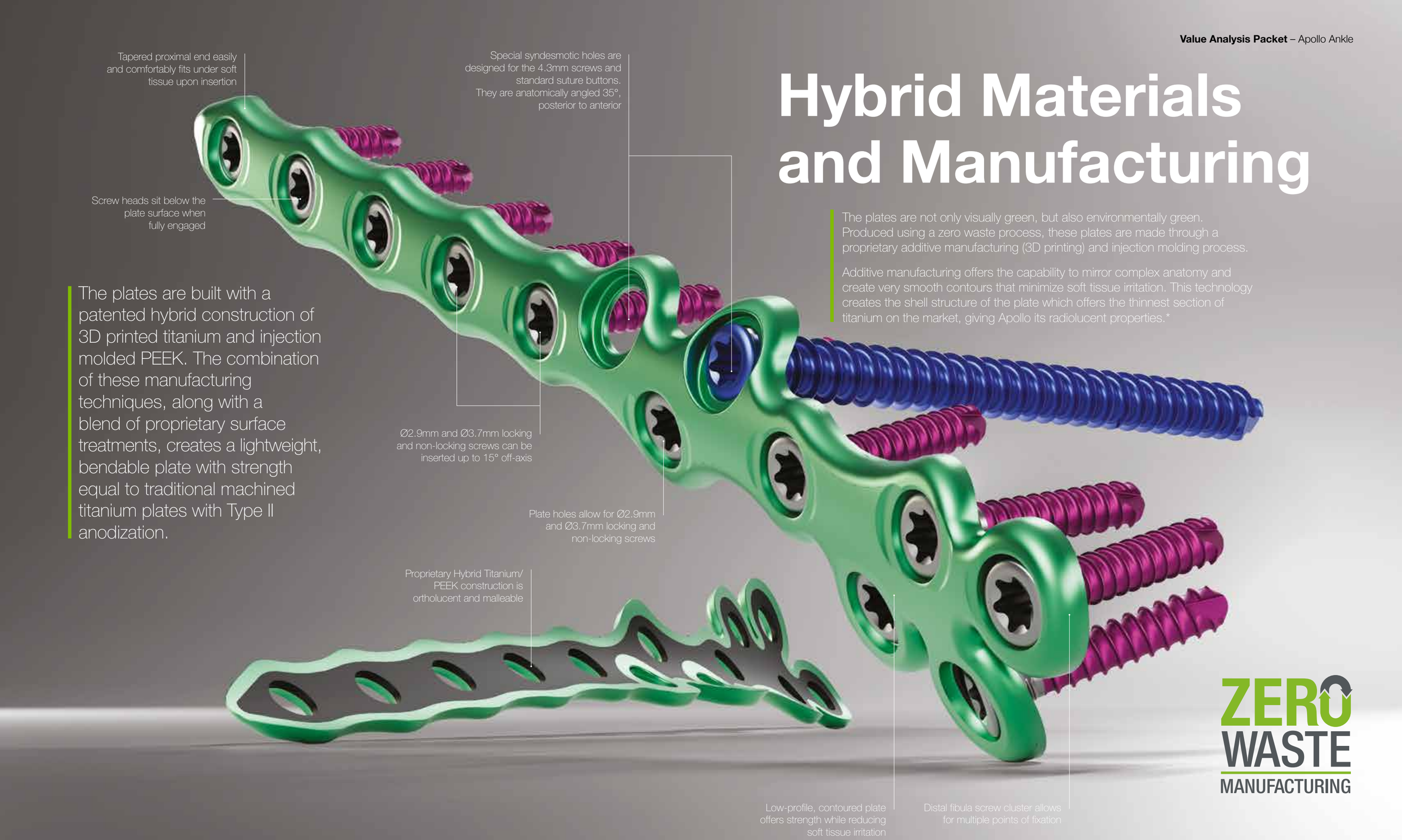
Apollo AFX Contents

Hybrid Materials and Manufacturing

The plates are not only visually green, but also environmentally green. Produced using a zero waste process, these plates are made through a proprietary additive manufacturing (3D printing) and injection molding process.

Additive manufacturing offers the capability to mirror complex anatomy and create very smooth contours that minimize soft tissue irritation. This technology creates the shell structure of the plate which offers the thinnest section of titanium on the market, giving Apollo its radiolucent properties.*

The plates are built with a patented hybrid construction of 3D printed titanium and injection molded PEEK. The combination of these manufacturing techniques, along with a blend of proprietary surface treatments, creates a lightweight, bendable plate with strength equal to traditional machined titanium plates with Type II anodization.



ZERO WASTE MANUFACTURING

*PEEK pellets are melted and injected into a custom mold. Any left over sprues or scrap can be reground into the raw material and used again. Components produced using additive manufacturing require minimal to no additional machining and create no titanium waste.

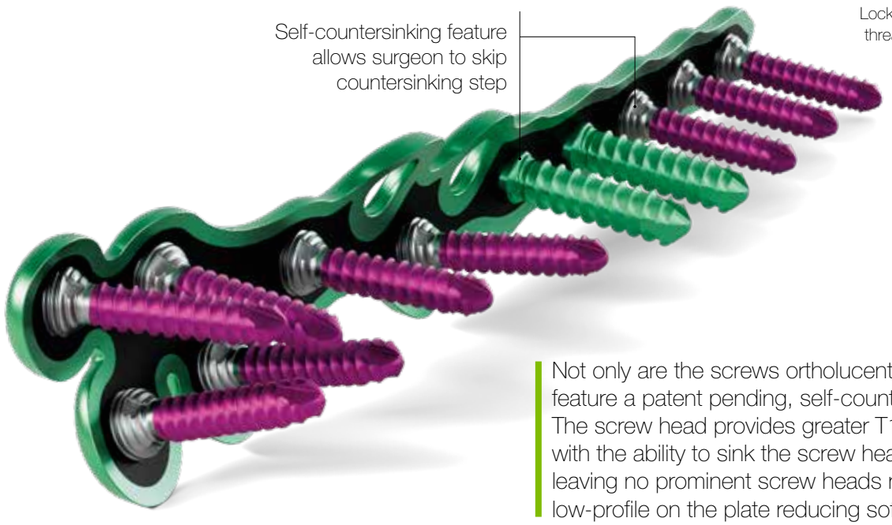
Screw Technology

The unique combination of additive manufactured titanium and injection molded PEEK leads to the patented screw locking technology of **PEEKLOC™**.

The PEEK construct allows for a quick thread engagement, and smooth tactile feel, while the proprietary hidden titanium structure enforces the solid locking strength. PEEKLOC™ technology creates the elastic locking friction and greatly reduces the risk of cold-welding during screw insertion.

Hybrid Cortical / Cancellous Screw System
The optimized thread design and slightly larger OD provide greater pull out strength in both bone types. So, only one screw type needed, simplifying the surgery.

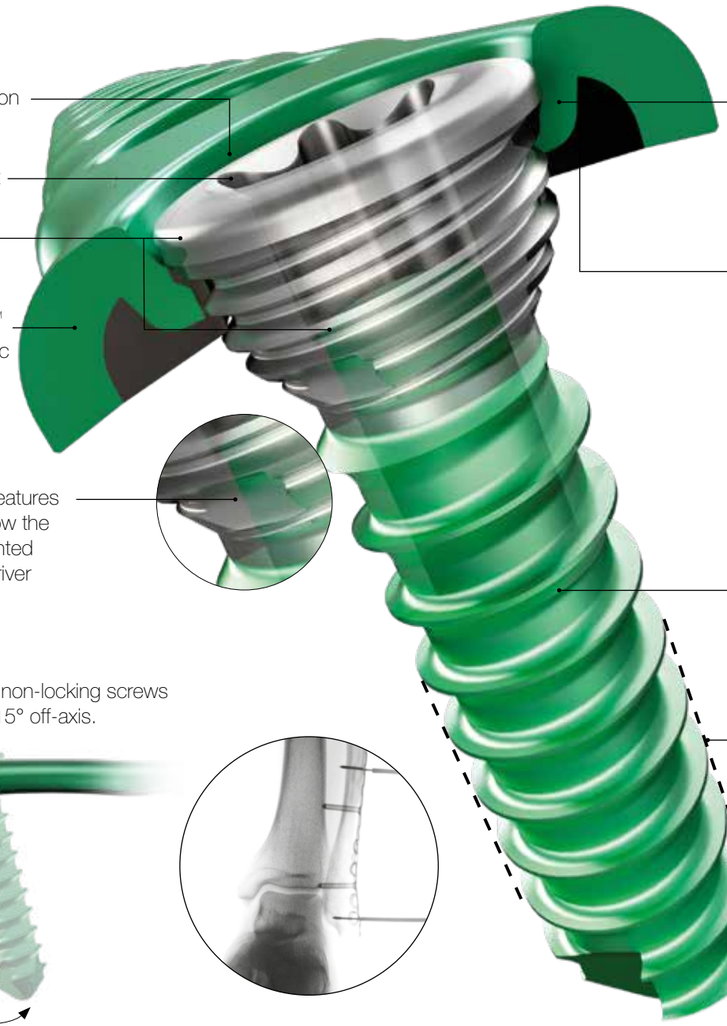
Locking threads are designed to form threads into the Apollo plates, giving superior cantilever strength.



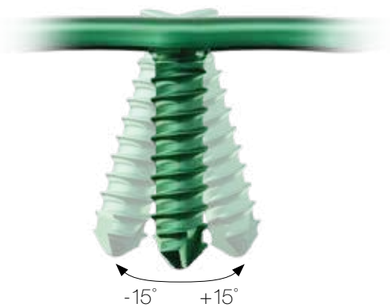
All heads have self-countersinking cutting flutes.

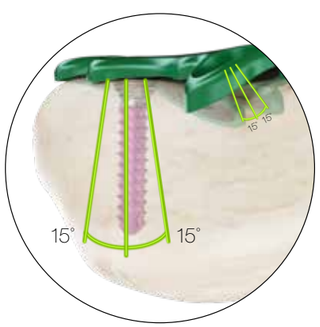
Not only are the screws ortholucent, but they feature a patent pending, self-countersinking screw head. The screw head provides greater T15 driver engagement, with the ability to sink the screw head deeper into the bone, leaving no prominent screw heads resulting in a very low-profile on the plate reducing soft tissue irritation.

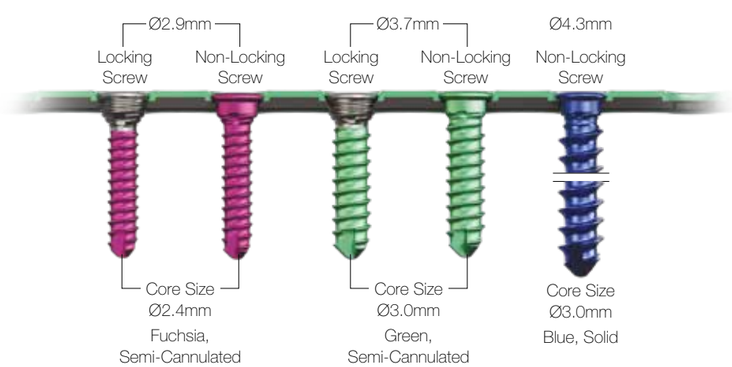
PEEKLOC™ and Self-countersinking Screws

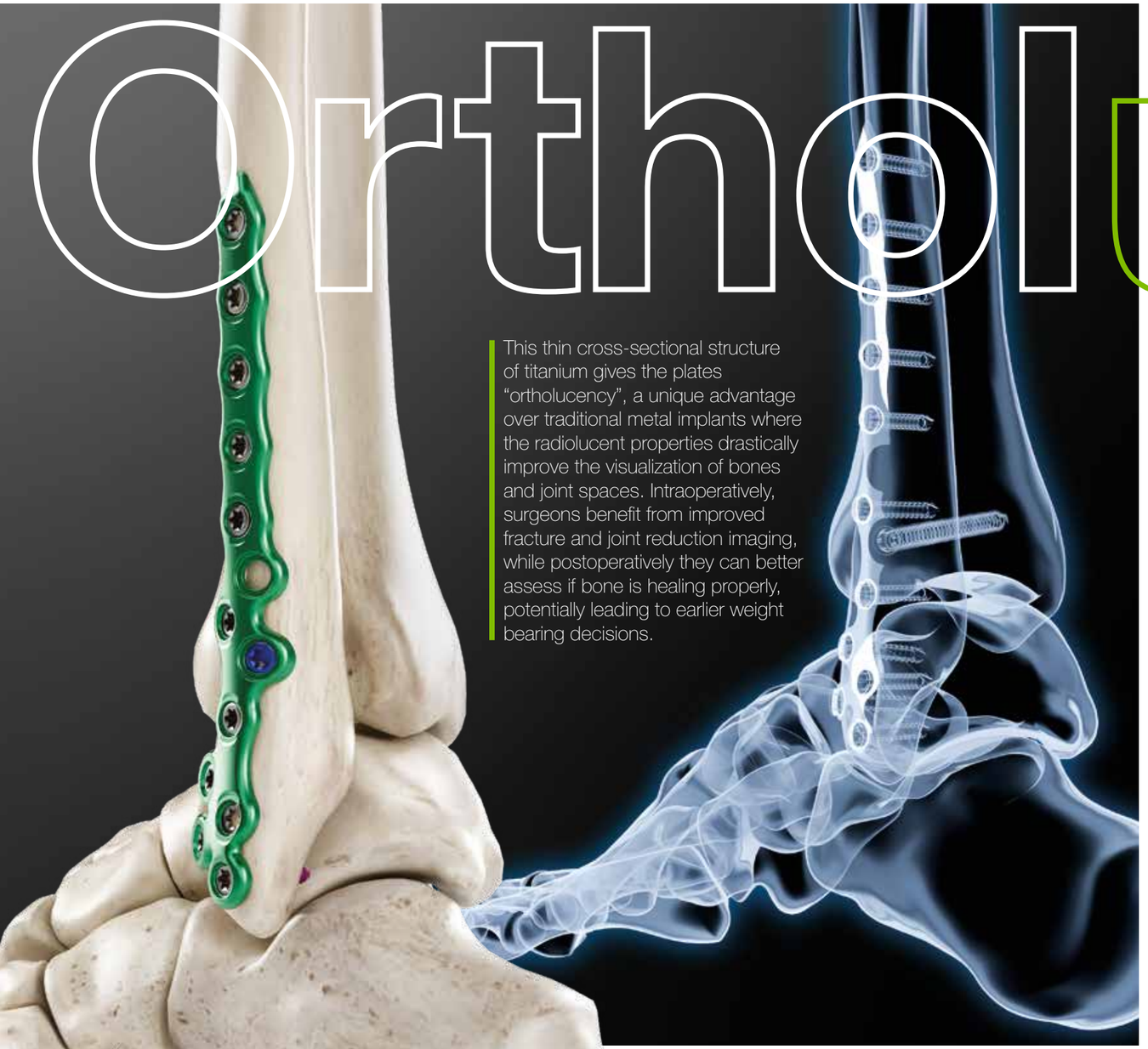


All Apollo locking and non-locking screws can be placed up to 15° off-axis.





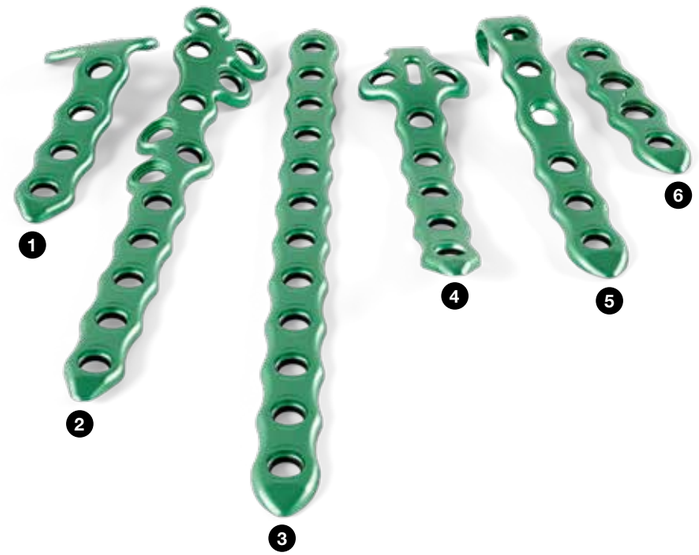


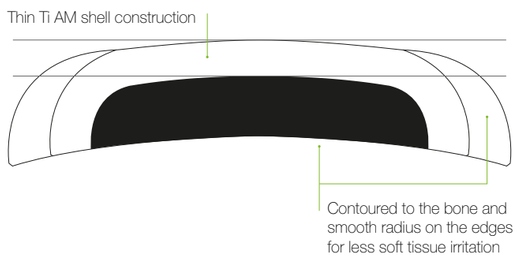


Orthol ucent Technology

This thin cross-sectional structure of titanium gives the plates "ortholucency", a unique advantage over traditional metal implants where the radiolucent properties drastically improve the visualization of bones and joint spaces. Intraoperatively, surgeons benefit from improved fracture and joint reduction imaging, while postoperatively they can better assess if bone is healing properly, potentially leading to earlier weight bearing decisions.

Apollo Ankle Fracture Plating System





1. Posterior Tibial Plate
- Left/Right anatomical designs.
- Distal holes angled away from tibiotalar joint.

2. Fibular Plate
- Syndesmotic holes positioned to aim 35°, posterior to anterior.
- Syndesmotic holes designed to accept typical suture buttons.
- Multiple points of fixation in the distal cluster.

3. One-third Tubular Plate
- Versatile plate with hole choices from 4 to 12 holes.

4. Medial Malleolar Plate
- Extra thin distal portion to minimize soft tissue irritation.

5. Hook Plate
- Versatile design for both lateral and medial malleoli.
- Compression slot with 2mm compressive action.

6. Syndesmotic Plate
- 2 and 4 hole designs.
- Syndesmotic hole designed for typical suture button.

Sterile, Disposable Instrument Kits

Optimize your work flow within the surgical procedure.

Single-use Convenience Kit, including two starter screws

T15 Driver	2
Drill Ø3.7mm / Ø4.3mm – Core	1
Drill Ø2.9mm – Core	1
Drill 3.7 – Lag	1
Olive Wire Assembly	3
Ratcheting Handle, Single Use	1
Drill Guide, Polyaxial/Straight	1
Countersink/Depth Gauge,	1
K-Wires, Ø1.6mm x 150mm	2
Plate Benders	2
Ø2.9mm x 12mm Non-Locking Screw	1
Ø3.7mm x 14mm Non-Locking Screw	1

Lag Drill Guide Kits, 2.9, 3.7 and 4.3

Single-use Hook Plate Kit

Single-use Radiopaque Trials

Optional Reduction Instruments*

*Reusable instruments and sterilization tray.

Medial Malleolar Plate

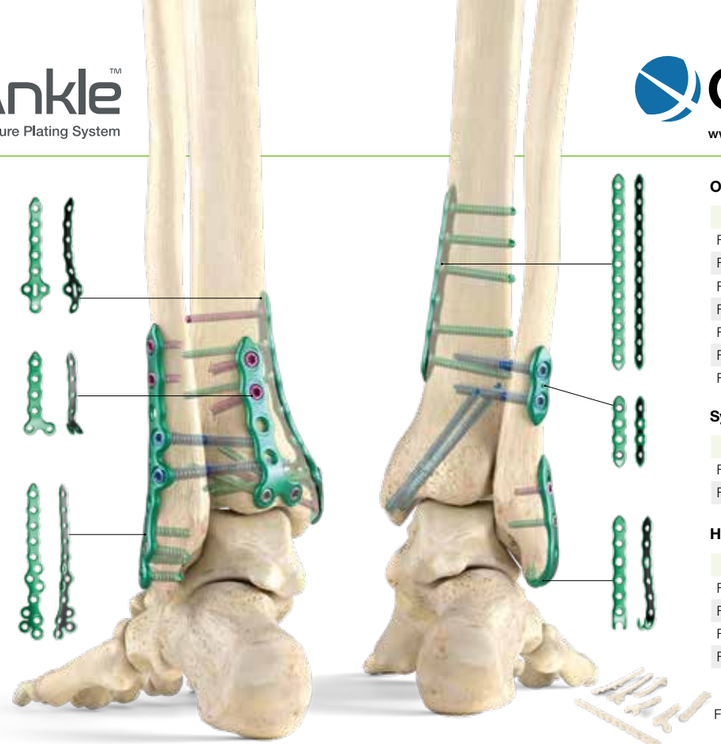
REF	Hole	Orientation
F3-0003-003S	6	Universal
F3-0003-004S	7	Universal
F3-0003-005S	8	Universal

Posterior Tibial Plates

REF	Hole	Orientation
F3-1002-003S	5	Left
F3-2002-003S	5	Right
F3-1002-004S	6	Left
F3-2002-004S	6	Right

Distal Lateral Fibula Plates

REF	Hole	Orientation
F3-1001-004S	9	Left
F3-2001-004S	9	Right
F3-1001-006S	11	Left
F3-2001-006S	11	Right
F3-1001-008S	13	Left
F3-2001-008S	13	Right



One Third Tubular Plates

REF	Hole	Orientation
F3-0004-004S	4	Universal
F3-0004-005S	5	Universal
F3-0004-006S	6	Universal
F3-0004-007S	7	Universal
F3-0004-008S	8	Universal
F3-0004-010S	10	Universal
F3-0004-012S	12	Universal

Syndesmosis Plates

REF	Hole	Orientation
F3-0005-002S	2	Universal
F3-0005-004S	4	Universal

Hook Plates

REF	Hole	Orientation
F3-0006-003S	3	Universal
F3-0006-004S	4	Universal
F3-0006-005S	5	Universal
F3-0006-006S	6	Universal

F4-3006-000S Single Use Trials Kit

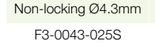
Ø3.7mm Locking and Non-locking Screws

Locking Ø3.7mm	Non-locking Ø3.7mm	Length
F3-1037-010S	F3-0037-010S	10mm
F3-1037-012S	F3-0037-012S	12mm
F3-1037-014S	F3-0037-014S	14mm
F3-1037-016S	F3-0037-016S	16mm
F3-1037-018S	F3-0037-018S	18mm
F3-1037-020S	F3-0037-020S	20mm
F3-1037-022S	F3-0037-022S	22mm
F3-1037-024S	F3-0037-024S	24mm
F3-1037-026S	F3-0037-026S	26mm
F3-1037-028S	F3-0037-028S	28mm
F3-1037-030S	F3-0037-030S	30mm
F3-1037-032S	F3-0037-032S	32mm
F3-1037-034S	F3-0037-034S	34mm
F3-1037-036S	F3-0037-036S	36mm
F3-1037-038S	F3-0037-038S	38mm
F3-1037-040S	F3-0037-040S	40mm
F3-1037-042S	F3-0037-042S	42.5mm
F3-1037-045S	F3-0037-045S	45mm
F3-1037-047S	F3-0037-047S	47.5mm
F3-1037-050S	F3-0037-050S	50mm
F3-1037-052S	F3-0037-052S	52.5mm
F3-1037-055S	F3-0037-055S	55mm
F3-1037-057S	F3-0037-057S	57.5mm
F3-1037-060S	F3-0037-060S	60mm

Ø2.9mm Locking and Non-locking Screws

Locking Ø2.9mm	Non-locking Ø2.9mm	Length
F3-1029-008S	F3-0029-008S	8mm
F3-1029-010S	F3-0029-010S	10mm
F3-1029-012S	F3-0029-012S	12mm
F3-1029-014S	F3-0029-014S	14mm
F3-1029-016S	F3-0029-016S	16mm
F3-1029-018S	F3-0029-018S	18mm
F3-1029-020S	F3-0029-020S	20mm
F3-1029-022S	F3-0029-022S	22mm
F3-1029-024S	F3-0029-024S	24mm
F3-1029-026S	F3-0029-026S	26mm
F3-1029-028S	F3-0029-028S	28mm
F3-1029-030S	F3-0029-030S	30mm
F3-1029-032S	F3-0029-032S	32.5mm
F3-1029-035S	F3-0029-035S	35mm
F3-1029-037S	F3-0029-037S	37.5mm
F3-1029-040S	F3-0029-040S	40mm

Ø4.3mm Non-locking Screws



Non-locking Ø4.3mm	Length
F3-0043-025S	25mm
F3-0043-027S	27.5mm
F3-0043-030S	30mm
F3-0043-032S	32.5mm
F3-0043-035S	35mm
F3-0043-037S	37.5mm
F3-0043-040S	40mm
F3-0043-042S	42.5mm
F3-0043-045S	45mm
F3-0043-047S	47.5mm
F3-0043-050S	50mm
F3-0043-052S	52.5mm
F3-0043-055S	55mm
F3-0043-057S	57.5mm
F3-0043-060S	60mm
F3-0043-062S	62.5mm
F3-0043-065S	65mm
F3-0043-067S	67.5mm
F3-0043-070S	70mm

Washer

F3-0075-000S	7.5mm Fits all screws

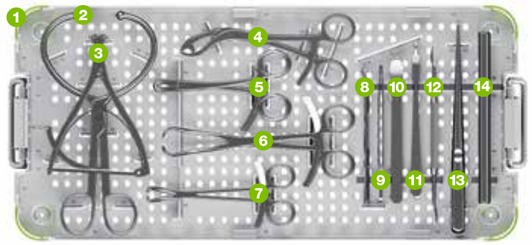
F4-3002-000S
Single Use Lag Kit, 2.9mm screw

F4-3003-000S
Single Use Lag Kit, 3.7mm screw

F4-3004-000S
Single Use Lag Kit, 4.3mm screw

F4-3005-000S
Single Use Hook Plate
Instrument Kit

Tray Layout – Optional Reduction Instruments



	REF	Description
1	F5-9002-000	Tray
2	F5-9005-000	Syndesmotic Clamp
3	F5-9022-000	Parallel Pin Distractor
4	F5-9006-000	Verbrugge Clamp
5	F5-9004-000	Lobster Clamp
6	F5-9020-000	Reduction Forceps – 8"
7	F5-9003-000	Reduction Forceps – 5"

	REF	Description
8	F5-9009-000	Dental Pick
9	F5-9024-000	Tissue forcep
10	F5-9021-000	Hohmann Retractor–15mm
11	F5-9007-000	Hohmann Retractor–8mm
12	F5-9008-000	Periosteal Elevator
13	F5-9010-000	Curette, size 00
14	F5-9023-000	Distraction Pins, Tube

Case Ready
Sterile Single Use

REF	Description
F4-3000-000S	Apollo Convenience Kit, with 2 starter screws

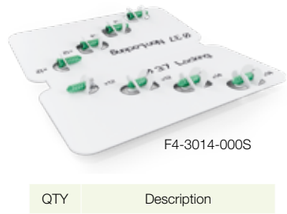
Apollo Convenience Kit Contents	Qty.
T15 Self-retaining Driver	2
Drill Ø3.7mm/Ø4.3mm Screw – Core	1
Drill Ø2.9mm Screw – Core	1
Drill Ø3.7mm Screw – Lag	1
Olive Wire Assembly	3
Ratcheting Handle, Single use	1
Drill Guide, Polyaxial/Straight	1
Countersink/Depth Gauge	1
K-Wires, Ø1.6mm x 150mm	2
Plate Bender	2
Starter Screws	
Ø2.9mm x 10mm Locking screw	1
Ø2.9mm x 12mm Locking screw	1

Push & Lift

Quick Caddy

Ø3.7mm Sterile Quick Caddy

Ø2.9mm Sterile Quick Caddy



F4-3014-000S

F4-3013-000S

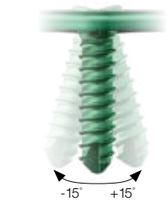
QTY	Description
2	Ø3.7mm x 12mm Non-Locking
2	Ø3.7mm x 14mm Non-Locking
2	Ø3.7mm x 12mm Locking
2	Ø3.7mm x 14mm Locking

QTY	Description
1	Ø2.9mm x 10mm Non-Locking
2	Ø2.9mm x 12mm Non-Locking
1	Ø2.9mm x 14mm Non-Locking
1	Ø2.9mm x 10mm Locking
2	Ø2.9mm x 12mm Locking
1	Ø2.9mm x 14mm Locking

PEEKLOC™

Variable angle locking

The PEEK reinforced underside of the plate creates elastic friction for locking the screw and mount below the plate surface where even angled screws can remain flush to the plate.



- No cold welding between plate and screws.
- Screws can pivot freely by ± 15° in all directions for optimal positioning.
- Self-countersinking adds more depth below the plate.

Portfolio Information

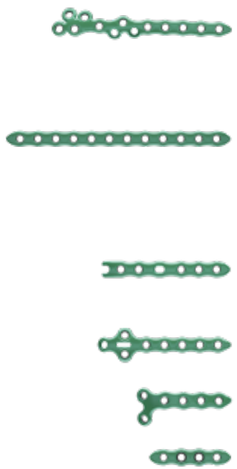
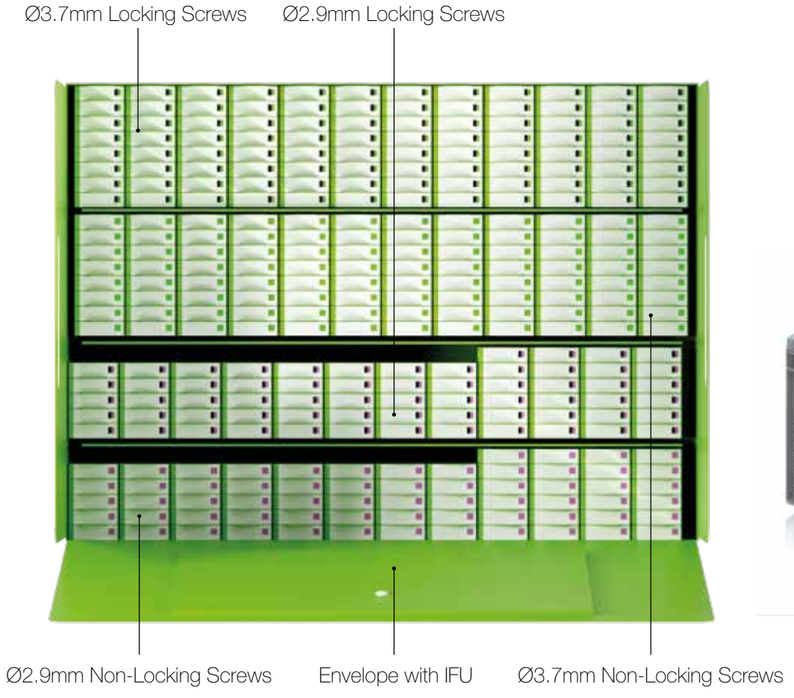


Plate	Length	Shaft Width	Head Width	Hole Count	Orientation
Lateral Fibula	67 89 111	9.6	18	9 11 13	Left / Right
One-Third Tubular	51 62 73 84 95 117 139	9.6	N/A	4 5 6 7 8 10 12	Universal
Hook	48 59 70 81	10	N/A	3 4 5 6	Universal
Medial Malleolar	60 71 83	9.6	21	6 7 8	Universal
Posterior Tibia	48 59	10.6	23	5 6	Left/Right
Syndesmosis	29 51	10.8	N/A	2 4	Universal
Material	Ti6Al4V / PEEK				

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

Screw and Instrument Caddies



March 11, 2022

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

Re: K213005
Trade/Device Name: Apollo Ankle Fracture Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 8, 2022
Received: February 9, 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

U.S. Food & Drug Administration
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Silver Spring, MD 20993
www.fda.gov

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 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,

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair, and Trauma 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)*

K213005

Device Name
Apollo Ankle Fracture Plating System

Indications for Use *(Describe)*

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.

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.

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"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."

Traditional 510(k) Premarket Notification
Apollo™ Ankle Fracture Plating System

510(k) Summary
(as required by 21 CFR 807.92)

Date Prepared	September 17, 2021
Manufacturer	GLW, Inc.
Address	300 Sylvan Ave Englewood Cliff, NJ 07632
Telephone	917-794-2583
Contact Person	Arundhati Radhakrishnan
Address	300 Sylvan Ave Englewood Cliff, NJ 07632
Telephone	201-268-3281
Email	Arundhati.radhakrishnan@glwmed.com

Trade Name	Apollo™ Ankle Fracture Plating System
Common Name	Plate, Fixation, Bone Screw, Fixation, Bone
Panel Code	Orthopaedics/87
Classification Name	Single/multiple component metallic bone fixation appliances and accessories. Smooth Or Threaded Metallic Bone Fixation Fastener
Class	Class II
Regulation Number	21 CFR 888.3030 21CFR 888.3040
Product Code	HRS HWC

Name of Primary Predicate Device	**510(k) #**	**Manufacturer**
Ortholoc 3Di Ankle Fracture System	K163044	Wright Medical
Name of Reference Device(s)	**510(k) #**	**Manufacturer**
In2Bones Colink View	K193543	In2Bones
CREED™ Cannulated Screws	K200291	GLW, Inc

Description	Apollo™ Ankle Fracture Plating System consists of implantable components that will be include an array of Titanium alloy Ti-6AL-4V ELI (ASTM F3001) / PEEK plates and locking and non-locking screws. The screws are offered in configurations that include a range of Titanium alloy Ti-6AL-4V ELI (ASTM F136) screws. A variety of instrumentation is offered as part of the kit to facilitate delivery of the implants. The implantable devices are provided sterile via Gamma irradiation.

Traditional 510(k) Premarket Notification
Apollo™ Ankle Fracture Plating System

Indications and Intended Use	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.
Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device is substantially equivalent to the primary predicate Wright Medical Ortholoc 3Di Ankle Fracture System (K1603044). The Subject device is substantially equivalent to the predicate devices in intended use, indications for use, materials, technological characteristics, and labeling.

	The Subject device is similar in size and form as the predicate(s). The Subject and predicate both contain Ti-alloy screws.

Performance Data	The plate components were tested via ASTM F382 and were shown to be at least equivalent to the predicate devices. Torsional strength, driving torque and axial pullout testing (per ASTM F543 and FDA Guidance for Bone Screws and Washers, December 2020) confirmed that the Subject device screws performed as intended and are at least equivalent to the predicate devices. Static 3-point bending, and dynamic 3-point bending per ASTM F1264 further confirmed the performance and substantial equivalence of the Subject device screws.

Conclusion	Based on the intended use, indications for use, technological characteristics, materials, and comparison to predicate/ reference devices, the Subject device has been shown to be substantially equivalent to legally marketed predicate devices.

ApolloAnkle™
Fracture Plating System

℞ Only
Last revision 04/2022

INSTRUCTIONS FOR USE APOLLO 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

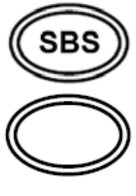
Important information – please read prior to use

Outline:

Definitions:

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 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 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 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 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.

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 Ankle Fracture Plating System implants are manufactured from Ti6Al4V / PEEK.

H. Sterilization

- The implants of Apollo Ankle Fracture 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.

ApolloAnkle™
Fracture Plating System

℞ Only

Last revision 04/2022

INSTRUCTIONS FOR USE APOLLO SINGLE USE AND REUSABLE INSTRUMENTS

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

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

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	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
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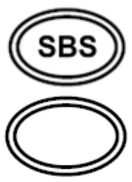
	Unique Device Identifier	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.7.10
	Double sterile barrier system	AAMI/ANSI/ISO 15223-1: 2016 Section 5 reference no. 5.2.12 No SBS letters in ISO 15223-1:2021. SBS letter added in proposal by Sterile Barrier Association “MDR requirements for labelling 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.

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 email custsvc@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 Cliffs, NJ 07632

Mail payments to:
Innov8ortho, 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 return authorization number, customer must provide Innov8ortho with (1) the Innov8ortho catalog number and quantity of Innov8ortho product to be returned; (2) the reason for the 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 if Innov8ortho requires further information; and (5) at least one of the following: (i) the applicable customer purchase number, (ii) the applicable Innov8ortho invoice number, and (iii) the applicable Innov8ortho product lot or serial number. A purchase order is required for all repairs even in situations where there is no charge. If the Innov8ortho product to be repaired is covered by a written limited product warranty, a copy of the original invoice must be sent with the Innov8ortho product. The cost of repair not covered 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 (unless part 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 Innov8ortho products (other than Non-Returnable Products) for which customer has obtained a return authorization number. Innov8ortho will accept returns for such products if they are: (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's receipt 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 any applicable 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 PRODUCT WARRANTY 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.

Apollo AFX Part List

ITEM NUMBER	DEVICE DESCRIPTION
APOLLO ANKLE FRACTURE SYSTEM (AFX)	
APOLLO ANKLE FRACTURE SYSTEM (AFX) PLATES – STERILE	
F3-1001-004S	APOLLO AFX / Fibular Plate / Left, 4 Hole 67mm Length
F3-2001-004S	APOLLO AFX / Fibular Plate / Right, 4 Hole 67mm Length
F3-1001-006S	APOLLO AFX / Fibular Plate / Left, 6 Hole 89mm Length
F3-2001-006S	APOLLO AFX / Fibular Plate / Right, 6 Hole 89mm Length
F3-1001-008S	APOLLO AFX / Fibular Plate / Left, 8 Hole 111mm Length
F3-2001-008S	APOLLO AFX / Fibular Plate / Right, 8 Hole 111mm Length
F3-1002-003S	APOLLO AFX / Posterior Plate / Left, 3 Hole 48mm Length
F3-2002-003S	APOLLO AFX / Posterior Plate / Right, 3 Hole 48mm Length
F3-1002-004S	APOLLO AFX / Posterior Plate / Left, 4 Hole 59mm Length
F3-2002-004S	APOLLO AFX / Posterior Plate / Right, 4 Hole 59mm Length
F3-0003-003S	APOLLO AFX / Medial Mal. Plate / 3 Hole 60mm Length
F3-0003-004S	APOLLO AFX / Medial Mal. Plate / 4 Hole 71mm Length
F3-0003-005S	APOLLO AFX / Medial Mal. Plate / 5 Hole 83mm Length
F3-0004-004S	APOLLO AFX / 1/3 Tubular Plate / 4 Hole 51mm Length
F3-0004-005S	APOLLO AFX / 1/3 Tubular Plate / 5 Hole 62mm Length
F3-0004-006S	APOLLO AFX / 1/3 Tubular Plate / 6 Hole 73mm Length
F3-0004-007S	APOLLO AFX / 1/3 Tubular Plate / 7 Hole 84mm Length
F3-0004-008S	APOLLO AFX / 1/3 Tubular Plate / 8 Hole 95mm Length
F3-0004-010S	APOLLO AFX / 1/3 Tubular Plate / 10 Hole 117mm Length
F3-0004-012S	APOLLO AFX / 1/3 Tubular Plate / 12 Hole 139mm Length
F3-0005-002S	APOLLO AFX / Syndesmotic Plate / 2 Hole 29mm Length
F3-0005-004S	APOLLO AFX / Syndesmotic Plate / 4 Hole 51mm Length
F3-0006-003S	APOLLO AFX / Hook Plate / 3 Hole 48mm Length
F3-0006-004S	APOLLO AFX / Hook Plate / 4 Hole 59mm Length
F3-0006-005S	APOLLO AFX / Hook Plate / 5 Hole 70mm Length
F3-0006-006S	APOLLO AFX / Hook Plate / 6 Hole 81mm Length
APOLLO ANKLE FRACTURE SYSTEM (AFX) SCREWS - VARIABLE ANGLE NON-LOCKING / STERILE 2.9MM	
F3-0029-008S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 8
F3-0029-010S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 10
F3-0029-012S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 12
F3-0029-014S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 14
F3-0029-016S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 16
F3-0029-018S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 18
F3-0029-020S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 20
F3-0029-022S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 22
F3-0029-024S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 24
F3-0029-026S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 26
F3-0029-028S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 28
F3-0029-030S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 30
F3-0029-032S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 32.5
F3-0029-035S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 35
F3-0029-037S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 37.5
F3-0029-040S	APOLLO AFX / 2.9mm / Non-Locking Screw / 2.9 mm X 40

ITEM NUMBER	DEVICE DESCRIPTION
APOLLO ANKLE FRACTURE SYSTEM (AFX) SCREWS – VARIABLE ANGLE LOCKING / STERILE 2.9MM	
F3-1029-008S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 8
F3-1029-010S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 10
F3-1029-012S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 12
F3-1029-014S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 14
F3-1029-016S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 16
F3-1029-018S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 18
F3-1029-020S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 20
F3-1029-022S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 22
F3-1029-024S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 24
F3-1029-026S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 26
F3-1029-028S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 28
F3-1029-030S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 30
F3-1029-032S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 32.5
F3-1029-035S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 35
F3-1029-037S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 37.5
F3-1029-040S	APOLLO AFX / 2.9mm / Locking Screw / 2.9 mm X 40
APOLLO ANKLE FRACTURE SYSTEM (AFX) SCREWS – VARIABLE ANGLE NON-LOCKING / STERILE 3.7MM	
F3-0037-010S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 10
F3-0037-012S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 12
F3-0037-014S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 14
F3-0037-016S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 16
F3-0037-018S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 18
F3-0037-020S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 20
F3-0037-022S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 22
F3-0037-024S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 24
F3-0037-026S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 26
F3-0037-028S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 28
F3-0037-030S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 30
F3-0037-032S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 32
F3-0037-034S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 34
F3-0037-036S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 36
F3-0037-038S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 38
F3-0037-040S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 40
F3-0037-042S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 42.5
F3-0037-045S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 45
F3-0037-047S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 47.5
F3-0037-050S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 50
F3-0037-052S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 52.5
F3-0037-055S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 55
F3-0037-057S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 57.5
F3-0037-060S	APOLLO AFX / 3.7mm / Non-Locking Screw / 3.7 mm X 60

ITEM NUMBER	DEVICE DESCRIPTION
APOLLO ANKLE FRACTURE SYSTEM (AFX) SCREWS – VARIABLE ANGLE LOCKING / STERILE 3.7MM	
F3-1037-010S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 10
F3-1037-012S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 12
F3-1037-014S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 14
F3-1037-016S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 16
F3-1037-018S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 18
F3-1037-020S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 20
F3-1037-022S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 22
F3-1037-024S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 24
F3-1037-026S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 26
F3-1037-028S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 28
F3-1037-030S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 30
F3-1037-032S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 32
F3-1037-034S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 34
F3-1037-036S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 36
F3-1037-038S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 38
F3-1037-040S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 40
F3-1037-042S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 42.5
F3-1037-045S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 45
F3-1037-047S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 47.5
F3-1037-050S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 50
F3-1037-052S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 52.5
F3-1037-055S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 55
F3-1037-057S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 57.5
F3-1037-060S	APOLLO AFX / 3.7mm / Locking Screw / 3.7 mm X 60

APOLLO ANKLE FRACTURE SYSTEM (AFX) SCREWS – VARIABLE ANGLE NON-LOCKING / STERILE 4.3MM	
F3-0043-025S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 25 mm
F3-0043-027S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 27.5 mm
F3-0043-030S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 30 mm
F3-0043-032S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 32.5 mm
F3-0043-035S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 35 mm
F3-0043-037S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 37.5 mm
F3-0043-040S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 40 mm
F3-0043-042S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 42.5 mm
F3-0043-045S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 45 mm
F3-0043-047S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 47.5 mm
F3-0043-050S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 50 mm
F3-0043-052S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 52.5 mm
F3-0043-055S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 55 mm
F3-0043-057S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 57.5 mm
F3-0043-060S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 60 mm
F3-0043-062S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 62.5mm
F3-0043-065S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 65 mm
F3-0043-067S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 67.5 mm
F3-0043-070S	APOLLO AFX / 4.3mm / Non-Locking Screw / 4.3mm X 70 mm

ITEM NUMBER	DEVICE DESCRIPTION
APOLLO ANKLE FRACTURE SYSTEM (AFX) – VARIABLE ANGLE SCREWS / QUICK CADDY – STERILE	
F4-3013-000S	APOLLO AFX / Ø2.9 Quick Caddy Kit
F4-3014-000S	APOLLO AFX / Ø3.7 Quick Caddy Kit

APOLLO ANKLE FRACTURE SYSTEM (AFX) – WASHER – STERILE	
F3-0075-000S	APOLLO AFX / Washer / 7.5 mm OD

APOLLO ANKLE FRACTURE SYSTEM (AFX) SINGLE-USE INSTRUMENT KITS – STERILE	
F4-3000-000S	APOLLO AFX / Convenience Kit, with 2 Starter Screws
F4-3002-000S	APOLLO AFX / Single-Use Lag Drill Kit for 2.9 Screw
F4-3003-000S	APOLLO AFX / Single-Use Lag Drill Kit for 3.7 Screw
F4-3004-000S	APOLLO AFX / Single-Use Lag Drill Kit for 4.3 Screw
F4-3005-000S	APOLLO AFX / Single-Use Hook Kit
F4-3006-000S	APOLLO AFX / Single-Use Trials
F4-3009-000S	APOLLO AFX / K-wire Ø1.6 x 150mm Trocar Tip (qty 2 per Kit)

APOLLO ANKLE FRACTURE SYSTEM (AFX) SINGLE-USE INSTRUMENT KITS – STERILE OTHER	
F4-3008-000S	APOLLO AFX / Single-Use Kit – Drills (2) and Olive Wires (3)
F4-3010-000S	APOLLO AFX / Single-Use Kit – Lag Drill Pin for 2.9mm Screw
F4-3011-000S	APOLLO AFX / Single-Use Kit – Lag Drill Pin for 3.7mm Screw
F4-3012-000S	APOLLO AFX / Single-Use Kit – Lag Drill Pin for 4.3mm Screw

APOLLO ANKLE FRACTURE SYSTEM (AFX) SINGLE-USE INSTRUMENT KITS - NON-STERILE OTHER	
F5-0116-100	APOLLO AFX / Olive Wire
F5-0016-150	APOLLO AFX / K-wires
F5-1024-140	APOLLO AFX / Single-Use Core Drill for 2.9 Screw (Purple, 2.4 diam.)
F5-1031-160	APOLLO AFX / Single-Use Core Drill for 3.7/4.3 screw (Green/Bule, 3.1 diam.)
F5-1033-145	APOLLO AFX / Single-Use 3mm Lag Drill for 2.9mm Screw
F5-1040-145	APOLLO AFX / Single-Use 4mm Lag Drill for 4.0mm Screw
F5-1045-145	APOLLO AFX / Single-Use 4.5mm Lag Drill for 4.3mm Screw

APOLLO ANKLE FRACTURE SYSTEM (AFX) REDUCTION INSTRUMENTS	
F5-9002-000	APOLLO AFX / Reduction Tray
F5-9005-000	APOLLO AFX / Syndesmotic Clamp
F5-9022-000	APOLLO AFX / Parallel Pin Distractor
F5-9006-000	APOLLO AFX / Verbrugge Clamp
F5-9004-000	APOLLO AFX / Lobster Clamp
F5-9020-000	APOLLO AFX / Reduction Foreceps – 8”
F5-9003-000	APOLLO AFX / Reduction Foreceps – 5”
F5-9009-000	APOLLO AFX / Dental Pick
F5-9024-000	APOLLO AFX / Pickups
F5-9021-000	APOLLO AFX / Hohmann Retractor – 15 mm
F5-9007-000	APOLLO AFX / Hohmann Retractor – 8 mm
F5-9008-000	APOLLO AFX / Periosteal Elevator
F5-9010-000	APOLLO AFX / Curette, 0
F5-9023-000	APOLLO AFX / Distraction Pins, Tube

Ankle fracture fixation with additive manufactured titanium shell polyetheretherketone filled (TI-PEEK) plates[1]

Authors: Anna Zastrozna, Garret Mauldin, Amiethab Aiyer, MD, Thomas S. Roukis, DPM, PhD

Overview

GLW Foot & Ankle (Carbon22), a GLW Medical Innovation company (GLW) has developed TI-PEEK plates which have major advantages over conventional plates, including radio-transparency, superior contouring to accommodate complex anatomy and stress shielding protection.

Keywords: Fracture fixation · Ortholucent plates · Titanium / Polyetheretherketone · Stress shielding · Thin profile plates.

Introduction

Orthopedic bone plates are a standard of care for multiple types of fractures. Current market offerings consist of stainless steel or titanium alloy plates and less common and more recent carbon fiber polymer plates.

GLW developed Apollo Ankle Fracture (AFX) Plating System, a novel portfolio of see-through, "ortholucent" bone plates and screws used for orthopedic ankle fracture surgery with a new patented[1] TI-PEEK hybrid technology, which combines both materials using titanium additive manufacturing[1,2] and PEEK injection molding. The technology delivers plate performance expected of metal and carbon fiber polymer plates, along with a series of additional unique features discussed in this paper.

TI-PEEK hybrid technology has the capacity to provide the following clinical advantages currently not available in thin and malleable plates:

Ortholucency – the radio-translucent properties of these ankle fracture plates greatly improve visualization of bony structures and allow for easier assessment of implant placement and progress of healing process as well as potential for shorter time to weight bearing.

Stress Shielding Protection – allowing more weight bearing by the bones[3], potentially leading to reduced short and long-term bone loss, faster healing, non-union prevention and less refractures upon plate removal.

More Anatomical Profile – with additive manufacturing, the plate mimics anatomy and helps reduce contouring in the Operating Room (OR) during surgery.

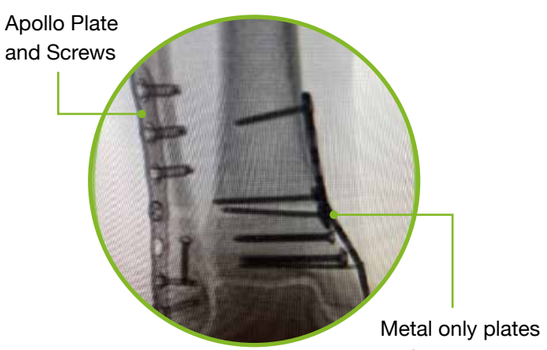


Figure 1: X-Ray image with Apollo AFX TI-PEEK vs. metal non-radiolucent implants.

[1] U.S. Pat. No. 11,628,000. Other patents pending.
[2] Additive manufacturing, often referred to as 3D printing
[3] Claim supported by existing literature and FEA analysis

Ortholucent, Malleable and Strong

Figure 2: Apollo Plates Hybrid Construction – Fibular Plate section shown.

Apollo AFX plates consist of Titanium shell and PEEK fill, as shown in Figure 2. Complex shell geometry is made possible by additive manufacturing (titanium 3D printing)[1,2] and has been created to minimize wall thickness to allow for ortholucency while maximizing plate strength as shown in Figure 3[10].

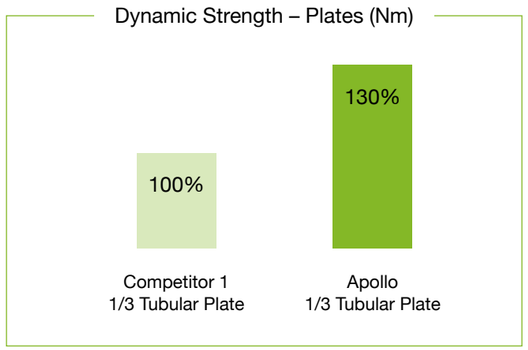


Figure 3. Dynamic Fatigue Strength of Apollo AFX plates vs. competitive plates after 1 million cycles.

Ortholucency enables clear visualization of fracture fixation and bone alignment and leads to easier assessment of bone healing process. In addition, screw trajectories and lengths are easily identifiable. This is especially advantageous in ankle fracture where often multiple plates are used as seen in clinical examples in Figure 4.

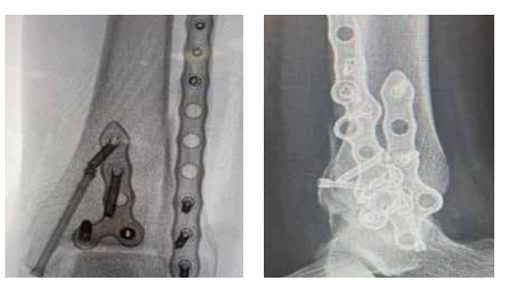


Figure 4: Examples of ortholucency of Apollo implants.

Malleability allows the plates to be contoured to patient's anatomy during the surgery, as illustrated in Figure 5, allowing the surgeon to minimize the prominence of the plate under patient's skin.

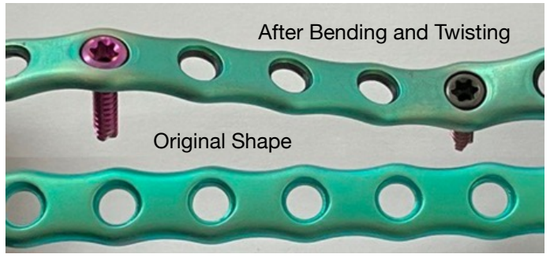


Figure 5: Apollo One-Third Tubular Plate before and after bending and twisting.

Apollo AFX plates mate with Apollo AFX hollow core screws, which are available in locking and non-locking options. Due to the hollowed nature of the screws, they offer ortholucency to complement the plates while maximizing strength as shown in Figure 6[10].

Figure 6: Torsional Strength of Apollo AFX screws vs. competitive screws.

Stress Shielding and Orthopedic Plates – Background

Traditional orthopedic bone plates have disparity in modulus of elasticity between its metals and natural bone that leads to challenges, especially stress shielding, which can hinder optimal healing and cause issues such as bone resorption.

Metal bone plates used to treat fractures have a much higher stiffness than bone and as a result carry considerably more load and shield the bone from stresses necessary for healing (Wolff's Law).This statement has been repeated in scientific research literature, along with the following potential long-term effects: delayed union, cortical bone loss underneath the plate and refracture upon removal [3,4]. These claims have been supported by scientific evidence, including results of clinical studies and X-rays[4].

Considerable amount of the research has been focused on bending stiffness as a main cause of stress shielding [5,6]. However, based on finite element analysis (FEA) and bench experiments, axial stiffness has been identified as the dominant factor in altering bone stresses[7].

Subsequently, experimental plate designs with different materials[7], elastomeric inserts [8,9] or bioresorbable inserts [4] – all aimed at reducing axial stiffness – have been developed, tested and/or analyzed, with results confirming decrease in stress shielding.

On the other hand, carbon fiber polymer plates have a much lower modulus of elasticity than metal plates. It is similar to that of cortical bone, resulting in less stress shielding – as reiterated in numerous research papers. Fatigue testing, infrared thermography and FEA confirm that bone stress under carbon fiber polymer plate is substantially higher than under metal plate, while axial stiffness is similar[3].

However, in order to maintain adequate bending stiffness for bone fracture alignment, carbon fiber polymer plates need to be substantially thicker than metal plates [11].

Stress Shielding Protection

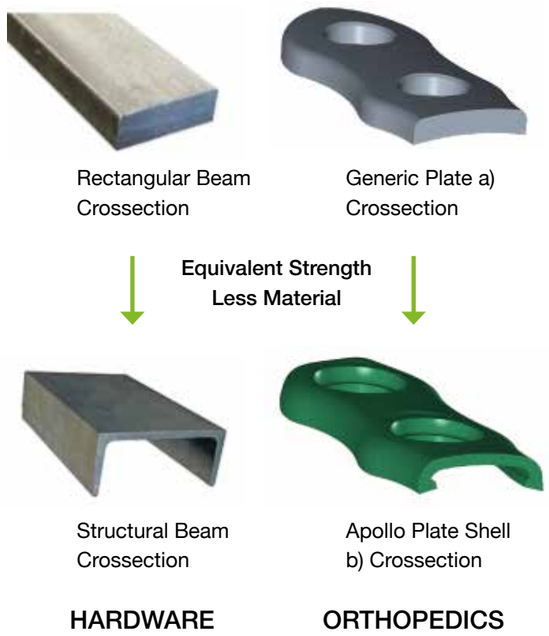


Figure 7: Illustration of the principle used in structural beams and applied to Apollo plates (not to scale). a) machined titanium plate b) additively manufactured titanium plate shell.

Two factors of the Apollo AFX plate design contribute to decreased axial stiffness which benefits the patient from stress shielding. One factor is the thin profile which can only be produced by additive manufacturing. The second factor is the PEEKLOC™ holes that act similarly to the elastomeric inserts.

Thin Profile: Apollo AFX plate strength and stiffness properties are parallel to those in structural beams used in buildings and bridges – see Figure 7. Structural beam shapes are created by removing internal material to reduce weight and cost while maintaining bending strength. Similarly, Apollo AFX plates are created by printing the shells with a hollow middle to enable ortholucency while maintaining bending strength.

PEEKLOC™ Holes: Elastomeric inserts [8,9] or bioresorbable inserts [4] can be used to decrease axial stiffness. Apollo AFX PEEKLOC™ technology – as shown in Figure 8 – acts similarly to both of those types of inserts.

Figure 8: A cross section of the PEEKLOC™ Technology screw interface that serves as an elastomeric insert.

A combination of material removal and PEEK inserts (PEEKLOC™) in the holes, decreases axial stiffness of the Apollo AFX plates and leads to lower stress shielding and higher cortical bone stress – by 16% in comparison to a generic titanium plate of equivalent strength, as shown in Figure 9 [11].

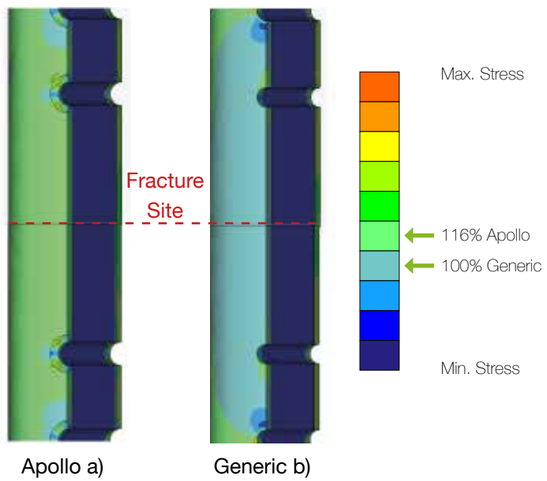


Figure 9: Stress in cortical bone under two plates of equivalent strength a) Apollo AFX TI-PEEK Plate b) Generic solid titanium Plate. Results of FEA; axial stiffness effect only.

The results of the Apollo AFX plate FEA analysis have not been confirmed by further studies, however there is ample evidence of this cause and effect in existing white papers [4,7,8].

More Accurate Anatomical Profile

Traditional or generic forms of orthopedic bone plates manufacturing methods, such as machining, forging, or milling, have limitations in producing complex and customized shapes and can only approximately fit the patient's anatomy.

The Apollo AFX additive manufacturing process enables the plate shape to closely match bone anatomy. The difference between generic and Apollo AFX plate profiles is shown in Figure 10. The matching anatomical plate means less time in the OR contouring to the bone. Also, placement and location of the screws better match the anatomy.

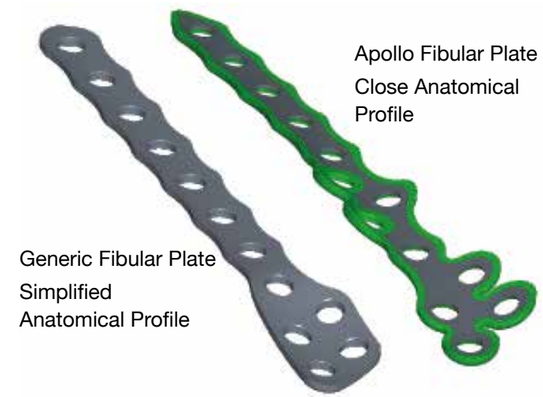


Figure 10: Comparison of anatomical fit between Apollo AFX and commercially available fibular plate.

Conclusion

GLW developed a new patented TI-PEEK hybrid technology and applied it in the creation of Apollo AFX Plates.
The benefits of this technology and clinical significance of Apollo AFX Plates lie in the fact that they combine confirmed and potential clinical advantages, only partially available in current state-of-the-art plates as seen in Table 1 and the following list:

- Ortholuency, which enables clear visualization of fracture fixation and bone alignment, leading to easier assessment of implant placement and progress of bone healing process as well as potential for shorter time to weight bearing.
- Stress shielding protection, which potentially leads to reduced short and long-term bone loss, faster healing, non-union prevention and less refractures upon plate removal.
- More accurate, thin and malleable anatomical profile, which minimizes soft tissue disruption and prominence under the skin.

Table 1: Apollo AFX vs. Competitive Plates.

Features	Metal Plate	CF Polymer Plate	Apollo AFX Plate
Ortholuency		✓	✓
Lower Stress Shielding [a]		✓	✓ [b]
Thin plate (≤1.8mm)	✓		✓
Malleable in OR	✓		✓
Anatomical Profile	✓	✓	✓✓

a) In comparison to metal plates.
b) Supported by existing literature and FEA analysis.

References

1. Meng, Meng et al. “3D printing metal implants in orthopedic surgery: Methods, applications and future prospects.” Journal of Orthopaedic Translation vol. 42 94-112. 1 Sep. 2023, doi:10.1016/j.jot.2023.08.004.
2. Xu, Weiting & Nassehi, Aydin & Liu, Fengyuan. (2023). Metal additive manufacturing of orthopedic bone plates: An overview. Materials Science in Additive Manufacturing. 2. 2113. 10.36922/msam.2113.
3. Bagheri, Zahra S et al. “Biomechanical analysis of a new carbon fiber/flax/epoxy bone fracture plate shows less stress shielding compared to a standard clinical metal plate.” Journal of Biomechanical Engineering vol. 136,9 (2014): 091002. doi:10.1115/1.4027669.
4. Uhthoff, Hans K et al. “Internal plate fixation of fractures: short history and recent developments.” Journal of orthopaedic science: official journal of the Japanese Orthopaedic Association vol. 11,2 (2006): 118-26. doi:10.1007/s00776-005-0984-7.
5. Terjesen, T, and K Apalset. “The influence of different degrees of stiffness of fixation plates on experimental bone healing.” Journal of orthopaedic research : official publication of the Orthopaedic Research Society vol. 6,2 (1988): 293-9. doi:10.1002/jor.1100060218.
6. Akeson, W H et al. “Principles of less rigid internal fixation with plates.” Canadian journal of surgery. Journal canadien de chirurgie vol. 23,3 (1980): 235-9.
7. Woo, S L et al. “Less rigid internal fixation plates: historical perspectives and new concepts.” Journal of orthopaedic research: official publication of the Orthopaedic Research Society vol. 1,4 (1984): 431-49. doi:10.1002/jor.1100010412.
8. Foux, A et al. “Improved fracture healing with less rigid plates. A biomechanical study in dogs.” Clinical orthopaedics and related research ,339 (1997): 232-45. doi:10.1097/00003086-199706000-00032.
9. Ferguson, S J et al. “Finite element stress analysis of a hybrid fracture fixation plate.” Medical engineering & physics vol. 18,3 (1996): 241-50. doi:10.1016/1350-4533(95)00041-0.
10. Lisa Ferrara, PhD, “A Biomechanical and Comparative Analyses of the GLW Medical Innovation Apollo Ankle Fracture Plate System”, performed by Element Materials Technology contracted by GLW Medical Innovation, (Apollo Test Report TR P003 006-10-02, Ver 01, conducted for 510(k) submission).
11. GLW Medical Innovation, Apollo White Paper Test Reports and Analyses TR P003 006-10-16 Ver 00 cage in sheep vertebral fusion. Artif Organs. 2013;37:E191–201. doi: 10.1111/aor.12153.

Osteosynthesis plating with multi-directional PEEKLOC™ locking screw technology[1]

Authors: Anna Zastrozna, Garret Mauldin, Kevin C. Lutta, MD, Alan Ng, DPM

Overview

GLW Foot & Ankle (Carbon22), a GLW Medical Innovation company (GLW) has developed PEEKLOC™ variable-angle locking screw technology which has major advantages over conventional locking, including flush screw head, cold welding protection and minimized screw backing out.

Keywords: Fracture fixation · Osteosynthesis plating · Variable-angle locking · Polyaxial screw placement.

Introduction

Locking plates are often used in a variety of bone fractures to achieve stable osteosynthesis at the fracture site. These plates have screws that are locked into the holes of the osteosynthesis plate. Current market offering consists of fixed and variable insertion angle options, the majority of which achieve locking by inserting a threaded screw head into a threaded hole in the plate – either metal screw to metal locking plate or metal screw to carbon fiber polymer (CFP) locking plate.

GLW developed a new patented PEEKLOC™ locking screw technology, which delivers stable fixation at $\pm 15^0$ variable insertion angle expected in current state of the art locking plates, along with a series of additional unique features described in this paper.

Figure 1: PEEKLOC™ Components.

[1] U.S. Pat. No. 11,628,000. Other patents pending.

Compact and Secure Design

Screw head prominence and shallow driver engagement are two of the challenges facing current thin metal plate design. These challenges are addressed by either using thicker plates or improving on only one of these two challenges at the cost of the other.

PEEKLOC™ incorporates a patent-pending self-countersinking screw head which provides room for deeper driver recess in a thin plate while keeping the top of the screw head essentially flush to mostly below the top of the plate – orientation dependent, as shown in Figure 2. Additionally, the locking interface utilizes patented TI-PEEK hybrid technology, which allows the internal locking features and PEEK fill to be incorporated into the design. This leads to a number of performance characteristics superior to metal-to-metal and metal-to-CFP interfaces as described in this paper.

PEEKLOC™ locking Interface has been designed with the user needs in mind, as shown in Figure 2.

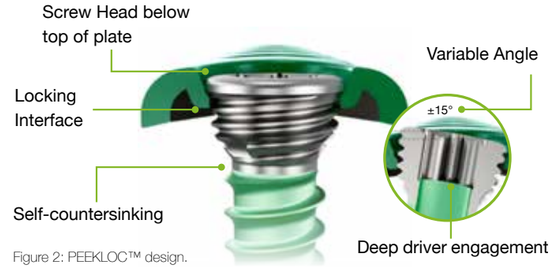


Figure 2: PEEKLOC™ design.

Minimized Risk of Stripping Screw Head

PEEKLOC™ effectively locks the screw within the full range of user insertion forces typically encountered in the OR – in the same clinical applications and screw sizes as Apollo Ankle Fracture Plating System – as shown in Figure 3[4,6,8].

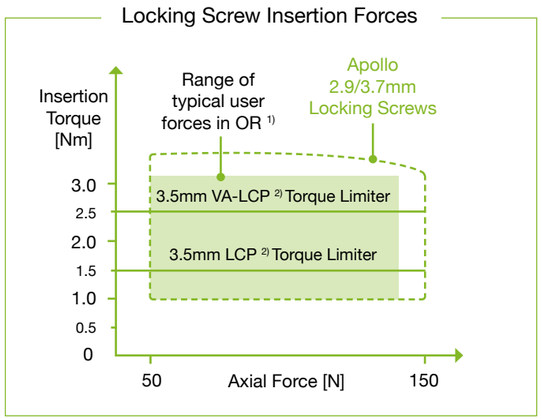


Figure 3: Range of performance parameters of 3.5mm Locking Screws
1) Range of user forces in OR assessed internally with an Apollo size handle[8]. 2) LCP and VA-LCP are plating technologies by DePuy Synthes.

Successful insertion in metal-to-metal locking interfaces relies on using torque limiters to prevent head thread stripping during insertion or on tactile feedback of the surgeon to not overtighten the screws[1].

The PEEKLOC™ ability to perform within a larger range of typical user forces in the OR minimizes the risk of head thread stripping during insertion.

Cold Welding and Screw Loosening Prevention

The locking interface between metal screws and plates is known to be susceptible to cold welding and subsequent difficulties in screw removal[2,3], as assessed during testing of Synthes 3.5mm LCP Screw[5].

GLW conducted an independent test[8] of 3.7mm Apollo Locking Screw under the same test conditions as[5] – visual graph of results shown in Figure 4.

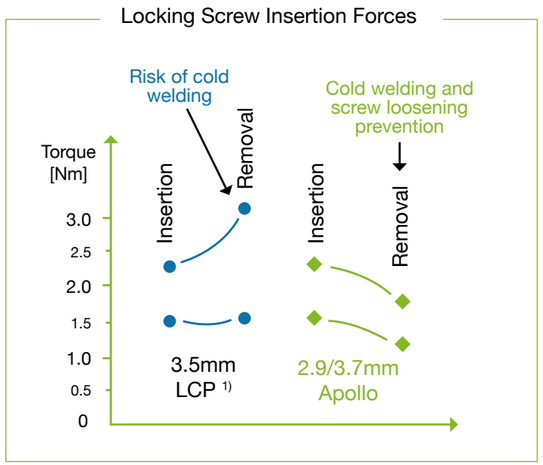


Figure 4: Locking Screw Insertion and Removal – results of independent testing [5,8].1) LCP is a plating technology by DePuy Synthes.

Comparison of test results indicate that the removal torque of the locking screw from the metal plate rises with increased insertion torque, placing the screw at risk of cold welding, while the removal torque of the locking screw from PEEKLOC™ TI-PEEK interface remains within 60-75% of the insertion torque over the entire range of the insertion torque. This offers cold welding protection.

Another known failure mode of screws is their tendency to loosen and back out of the plate in the patient. This failure mode is well known in the fastener hardware industry and overcome by using locking patches (commonly made from Nylon) on fastener threads – see Figure 5[7]. PEEK in PEEKLOC™ interface plays a similar role, acting as a wedge between the locking thread on the screw and the metal features in the plate and creating a positive resistance to micromotion and loosening.

This unique characteristic of PEEKLOC™ has the potential to lower the risk of the screw backing out of the plate, even in the case of non-union.

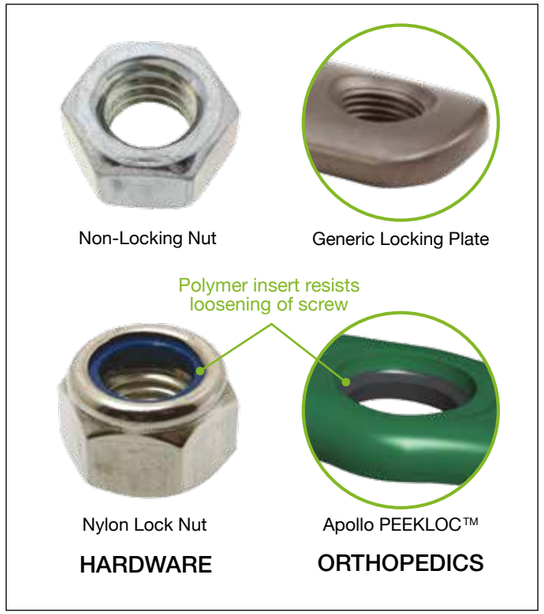


Figure 5: Illustration of the elastic locking principle used in common fastener hardware and applied to PEEKLOC™ interface.

Reliable and Resilient Locking

PEEKLOC™ design allows for multiple insertions and removal of the locking screw with little impact on the locking strength, as verified during internal testing[8] and illustrated in Figure 6.

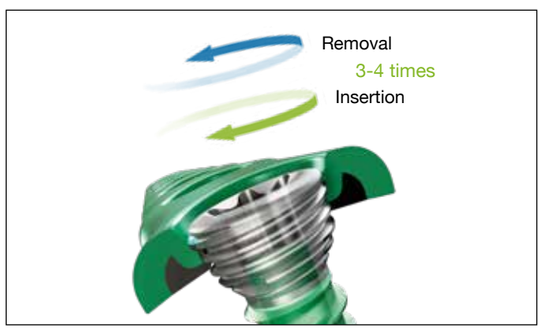


Figure 6: PEEKLOC™ Locking Interface. The screw can be inserted and removed 3-4 times with little degradation.

Effective Locking Ability

The forgiving nature of the locking interface enables the locking screws insertion after plate bending, as illustrated in Figure 7. This unique ability provides surgeons with more options to secure the plate to bone, in particular in challenging situations with small bone fragments or site inaccessibility.

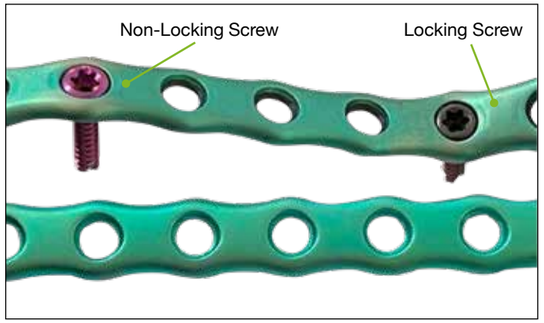


Figure 7: Apollo Tubular Plate before and after bending and twisting, with Locking and Non-Locking Screws inserted afterwards

Conclusion

GLW developed a patented PEEKLOC™ technology with a set of unique design features offering the following clinical advantages:

- Screw head essentially flush or mostly below the top of the slim profile plate, which minimizes soft tissue irritation and prominence under the patient skin.
- Deep driver engagement, which leads to a more secure driver connection with less risk of disengagement and screw head socket stripping during screw insertion and removal.
- Increased range of screw insertion torque, which covers a full range of typical user forces in the OR and minimizes the risk of head thread stripping during screw insertion.
- Elastic locking interface, which offers cold welding protection, minimizes the risk of cold welding and screw backing out in the patient as well as allows multiple screw insertions and locking engagement even after moderate plate contouring during surgery.

Ultimately, PEEKLOC™ performance is less technique sensitive while assuring a more reliable outcome than the majority of the metal and carbon fiber polymer locking plates currently on the market.

References

1. Tan, S L Ezekiel, and Zsolt J Balogh. “Indications and limitations of locked plating.” Injury vol. 40,7 (2009): 683-91. doi:10.1016/j.injury.2009.01.003.
2. Ehlinger, M et al. “Technical difficulties in hardware removal in titanium compression plates with locking screws.” Orthopaedics & traumatology, surgery & research : OTSR vol. 95,5 (2009): 373-6. doi:10.1016/j.otsr.2009.03.020.
3. Agrawal, Alok & Chandewar, MangeshMahadeo & Chandan, Rahul. (2018). “Technique for the removal of a locking screw from a broken locking plate following cold welding.” Journal of Orthopedics, Traumatology and Rehabilitation. 10. 142. 10.4103/jotr.jotr_26_18.
4. Agrawal, Alok & Chandewar, MangeshMahadeo & Chandan, Rahul. (2018). “Technique for the removal of a locking screw from a broken locking plate following cold welding.” Journal of Orthopedics, Traumatology and Rehabilitation. 10. 142. 10.4103/jotr.jotr_26_18.
5. Sandriesser, Sabrina et al. “Locking design affects the jamming of screws in locking plates.” Injury vol. 49 Suppl 1 (2018): S61-S65. doi:10.1016/S0020-1383(18)30306-1.
6. DePuy Synthes “Universal Small Fragment System - Surgical Technique”, 103532785 Rev E 05/21 DV.
7. Nylok Blue Patch and Torq-Patch® Prevailing Torque Locking Element-2019.
8. GLW Medical Innovation, Apollo White Paper Test Reports and Analyses TR P003 006-10-16 Ver. 00.

Plate fixation with premium single-use instrumentation and sterile implants

Authors: Anna Zastrozna, Garret Mauldin, Yash Dalal, Troy Ardoin, MD, Mark A. Prissel, DPM

Overview

GLW Foot & Ankle (d/b/a Carbon22), a GLW Medical Innovation company (GLW) has developed premium single use instruments (SUI) that are designed to assist surgeons with the precise fixation of orthopedic implants. They deliver performance similar to that of reusable instruments while minimizing carbon footprint and lowering costs by eliminating resource-intensive, expensive reprocessing steps.

Keywords: Single-use instruments · Osteosynthesis plating · Sterile implants · Quick Caddy sterile screws.

Introduction

For orthopedic surgical procedures, the reprocessing of surgical instruments or implants by the sterilization processing department is a key process in standard clinical practice and is thought to be essential in the prevention of surgical site infection. As part of this process, surgical instruments and implants are decontaminated, washed, reassembled, labelled, sterilized and redistributed. Since only a small portion of processed implants is used during surgery, these implants are reprocessed multiple times before surgically being implanted in a patient.

GLW developed premium single-use instruments for Apollo Ankle Fracture (AFX) Plating System that help surgeons fix orthopedic implants accurately. These instruments have the same quality as reusable ones, but they reduce environmental impact and costs by avoiding the need for reprocessing[1,2].

The Apollo AFX[1] plating platform comes with a complete surgery-ready system – see Figure 1, incorporating compact, reliable, multifunctional design solutions[1].

[1] U.S. Pat. No. 11,628,000. Other patents pending.

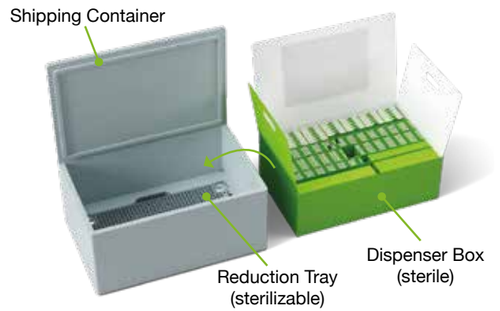


Figure 1: Apollo One Box Solution.

Highlights:

One-Box Solution – for all primary ankle fracture plating surgery needs.

Quick Caddy[1] – for multiple screws with a patent-pending “Push and Lift” function1, simplifying procedural steps and reducing time in OR.

Surgical Steel – for all cutting and compact high force transmitting instruments and components.

Superior Performance Polymers – for non-metallic components.

Innovative Instruments – combining ergonomics with usability and cost effectiveness.

Sterile Implants and Instruments

All Apollo AFX implants and instruments are provided sterile with a streamlined packaging, aimed at ease of handling and efficiency – see Figure 1 and Figure 2.

Figure 2: Apollo Dispenser Box – sterile packaged Apollo implants and instruments.

Sterile Quick Caddy – Time Saver

The Apollo AFX Quick Caddy sterile package contains many of the most commonly used locking and non-locking screws, which are removed from the caddy by pushing a self-retaining driver into the socket of the screw and lifting it. This patent pending "Push and Lift" function enables the screw to be ready for insertion in the implant without the need to pick it up and attach it to the driver manually. The solution saves time by reducing the number of single sterile-packaged screws used in surgery and minimizing the risk of screw falling on the floor – see Figure 3.

Figure 3: Sterile Quick Caddy with multiple screws – "Push and Lift" function.

SUI Instrument Kits – Strong and Reliable Materials

GLW SUI's are packaged in various sterile kits, aimed at different segments of the ankle fracture plating procedure:

- Convenience Kit with instruments and starter screws – for basic plate insertion procedure.
- Lag Kits – for inserting lag screws.
- Hook Plate Instrument Kit – for inserting Hook Plate.
- K-Wire Kit – to provide additional K-wires.
- Radiopaque Trials – to aid in selecting the best fit plate for patient before opening its sterile package.

Instruments are made from either surgical steel or high-performance polymers with surgical steel inserts. The Convenience Kit is shown in Figure 4.

All GLW Apollo AFX single use metal instruments and inserts (drills, drivers, K-wires, drill-guide tips) are made with medical grade stainless steel and their performance is equivalent to their re-usable counterparts. All parts are tested to insure high quality and predictable performance.

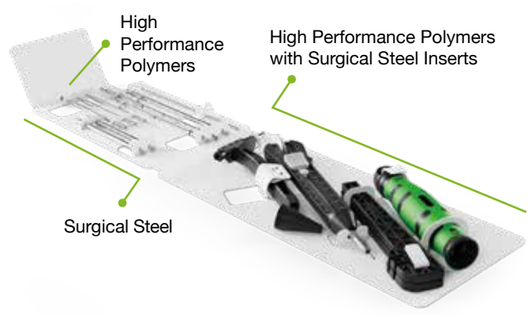


Figure 4: Sterile Convenience Kit (starter screws and sterile packaging not shown).

Advances in engineered polymers permit design and production of high quality and robust non-metallic instruments. GLW uses Ixef PARA (polyacrylamide) specialty thermoplastic, known for its extraordinary strength and stiffness[3]. Multiple manufacturers use Ixef PARA to redesign and replace their single use metal instruments. Examples include: Zilion Black curettes, forceps, needle holders, and skin staple removers[4], TruTORQ and TruPWR family of single-procedure, and precision torque limiting instruments[5].

In addition, GLW designed some SUI instruments and components with other high performance polymers, specifically selected for their function:

- Handle Overmold – TPU (Thermo-Plastic Urethane) for comfortable tactile feel (material commonly used in reusable handles).
- Olive Wire Beads – CF-PEEK (Carbon Filled Polyetheretherketone) for strength and smoothness.
- Trials – PP (polypropylene) for cost effectiveness with Barium Sulfate for visibility under X-ray.

Multifunctional, Ergonomic and Innovative Instruments

Apollo AFX single use instruments have been designed for reliable performance, ease of use and cost effectiveness – achieved by combining innovative design with multifunctionality and material selection[6].

Ratcheting Handle

Ratcheting Handle design combines in a unique way a patent pending static driver function with a forward ratcheting function – see Figure 5.

Figure 5: Ratcheting Handle – Illustration of its multifunctionality.

Plate bending slot included as an additional feature to provide surgeons with choices and convenience – see Figure 6.

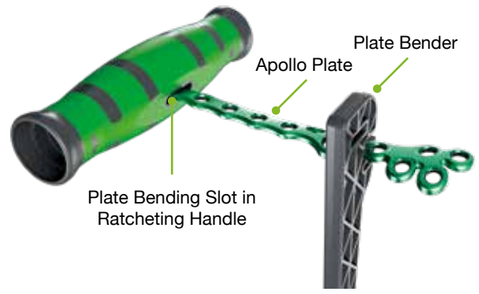


Figure 6: Ratcheting Handle with incorporated slot for bending Apollo Plates.

Self-Centering Olive Wire

A Self-Centering Olive Wire is provided with a sliding bead at the tip to ensure the wire trajectory is centered with respect to the plate hole regardless of the insertion angle before the tip enters the bone. See Figure 7.

In current state-of-the art all-metal olive wires, the bead is stationary which does not define the starting point of insertion and can lead to plate displacement if inserted off-center.

The advantages of GLW's modular design (i.e. the beadseparate from the wire):

- cost saving.
- minimized risk of plate displacement.
- grooves improve wire retention in bone.

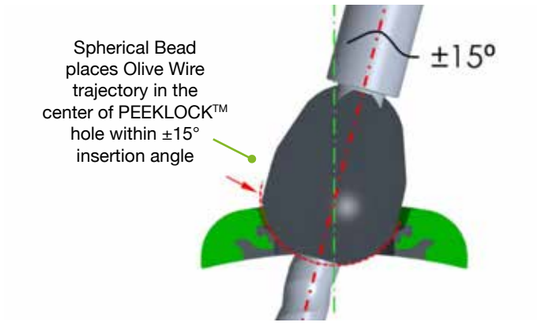


Figure 7: Self-Centering Olive Wire – illustration of its self-centering function.

Countersink/Depth Gauge

Depth Gauge is provided with a countersinking tip to combine two instruments in one.

Hole Depth Markers

Hole Depth Markers are placed on both sides of the Depth Gauge/Countersink and the straight end of the Drill Guide, Polyaxial/Straight to give surgeons flexibility to read it from either side. See Figure 8.

Figure 8: Straight Drill Guide.

Sterile Trials

Sterile Trials are pre-contoured to accurately represent Apollo Plates and aid the surgeon in the best-fit plate selection before sterile package is opened.

Cut-away feature allows all sizes of a plate family to be represented in one trial. See Figure 9.

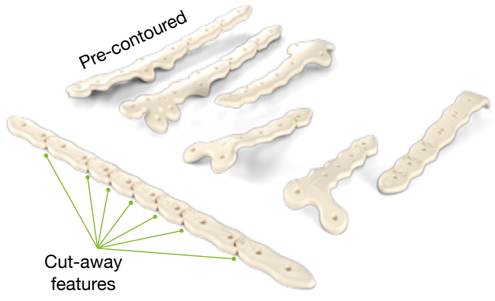


Figure 9: Sterile Trials.

Conclusion

GLW's premium single-use instrumentation can drive down per unit and life cycle costs, eliminate recalibration and resterilization, reduce the risk of infection and provide mandated sustainability gains across surgical facilities. In addition, Apollo AFX plating system surgery-ready solution offers a host of unique features with associated clinical advantages:

- One-Box Solution for all primary surgery needs.
- Quick Caddy for multiple screws with "Push and Lift" function.
- Surgical Steel for all cutting and compact high force transmitting instruments and components.
- Superior performance polymers for remaining components.
- Multifunctional and ergonomic instruments combining innovation with usability.

References

1. Maggie F. Shuler, MD, PhD • Alan Franklin, MD, PhD • John Myers, MD • Sunil Gupta, MD. Disposable vs Reusable Surgical Instruments: How to Decide? Which instruments should you choose based on cost and procedure? Retinal Physician, 1 September 2010.
2. David Doleski, Acting Branch Chief, New Drug Manufacturing Assessment Branch Office of Compliance, CDER, FDA, BPSA International Single-Use Summit Regulatory Perspective on the Adoption of Single-Use Technologies July 28, 2011 Washington, DC.
3. Surgical Devices | Syensqo; https://www.syensqo.com/en/chemical-categories/specialty-polymers/healthcare/surgical-devices.
4. Ixef PARA enables Zillion Black single-use instruments | Solvay; https://www.solvay.com/en/press-release/solvays-ixef-para-enables-zillion-black-single-use-instruments.
5. ECA Medical chooses Ixef PARA for family of torque limiting instruments - Today's Medical Developments; https://www.todaysmedicaldevelopments.com/news/solvay-ixef-para-torque-limiters-medical-instruments.
6. Deliberate Disposal: Single-Use & Disposables Technologies | Medical Device Outsourcing; https://www.mpo-mag.com/issues/2018-04-01/view_features/deliberate-disposal-single-use-disposables-technologies.

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