ApolloAnkle™
Fracture Plating System

GLW medical innovation

Plate fixation with premium single-use instrumentation and sterile implants

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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].

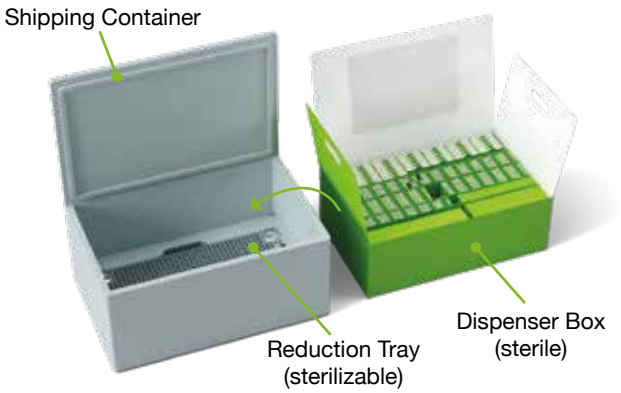

Figure 1: Apollo One Box Solution.

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.

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

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.

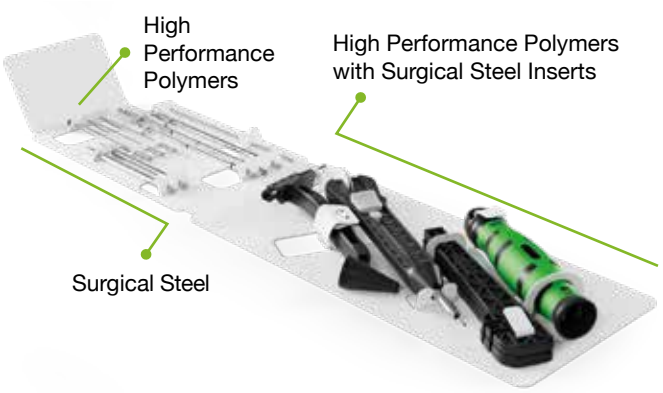

Figure 4: Sterile Convenience Kit (starter screws and sterile packaging not shown).

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.

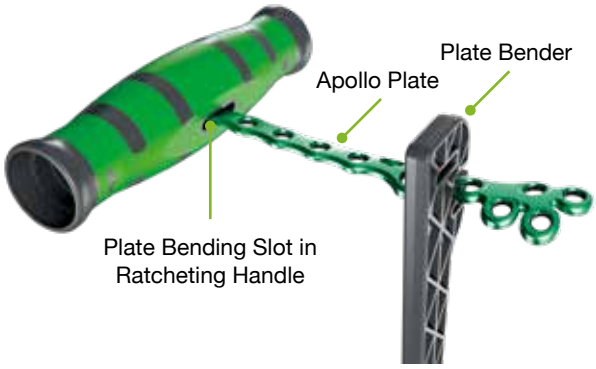

Figure 6: Ratcheting Handle with incorporated slot for bending Apollo Plates.

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.

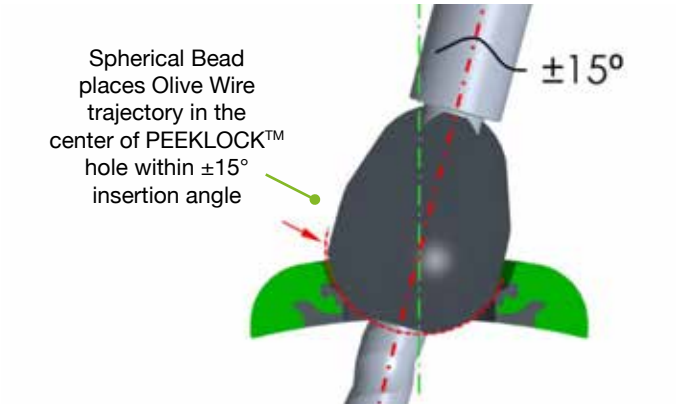

Figure 7: Self-Centering Olive Wire – illustration of its self-centering function.

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.

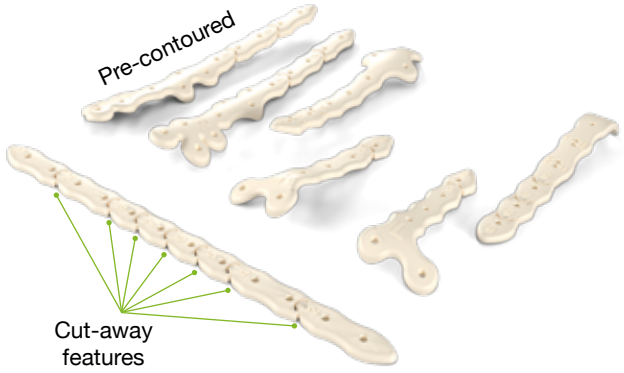

Figure 9: Sterile Trials.

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

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