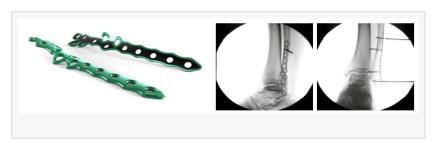


## Carbon22, a GLW, Inc. Company, Receives FDA 510(k) Clearance for Apollo™ Ankle Fracture Plating System

ENGLEWOOD CLIFFS, NJ, UNITED STATES, March 13, 2022 /EINPresswire.com/ -- Carbon22™, a GLW, Inc. medical technology company with a focus on the foot and ankle orthopedic market, today announced it has received 510(k) clearance from the



U.S. Food and Drug Administration (FDA) to market its upcoming Apollo Ankle Fracture Plating System, a novel portfolio of see-through, "ortholucent" bone plates and screws used for orthopedic ankle fracture surgery. Expected to commercially launch in late spring 2022, it will complement Carbon22's Creed Ortholucent Implant portfolio of headless and headed compression screws and it further expands Carbon22's product offering in the foot and ankle space.

The system is a streamlined, multi-component platform featuring a distinctive, proprietary plate composite consisting of an additive manufactured titanium shell injection molded with a novel Solvay Zeniva® PEEK polymer. The intelligently designed implants come with a selection of 26 unique plate options from 6 plate families.

Thomas H. Lee, MD, Chief Medical Officer of Carbon22, said "This next-generation engineering of Apollo ankle fracture plates is an important milestone for our company. Our team has spent a tremendous amount of effort with our Carbon22 consortium, a select group of orthopedic and podiatric surgeons, to develop a system that includes several groundbreaking components; all working together to make ankle plating simpler and more reproducible. The Apollo Ankle Fracture Plating System will be an important platform as we continue to develop our product portfolio. Carbon22 has created a bridge between materials science and device design, positively transforming the manufacturing process and cost-effectiveness, while maintaining, or improving patient outcomes."

Carbon22's patent pending ortholucent manufacturing technology offers several key benefits, including radio-transparency. Alan Ng, DPM, FACFAS of Advanced Orthopedic & Sports Medicine Specialists in Denver, CO noted, "While using medical imaging (both during and after surgery), the radio-translucent properties of these ankle fracture plates greatly improve visualization of

bony structures. By being able to see through the implants down to the fracture site, these plates can vastly improve visibility during post-operative healing."

The hybrid titanium/PEEK plate interface minimizes the risk of plate and screw "cold-welding" that has been seen with other plating systems currently on the market. Additionally, the hybrid titanium/PEEK construction of the plates allow for superior contouring to accommodate complex anatomy.

"The Apollo system represents a paradigm shift in orthopedic device implants and provides a distinguishing clinical advantage over traditional metal-only-implants by drastically improving intraoperative and postoperative visualization of bones and joint spaces," commented Kevin Lutta, MD, of OrthoVirginia in Arlington, VA. Adding "The system's well-designed details give surgeons the most advanced implant technology on the market to date."

## About Carbon22, a GLW Inc. Company

Carbon22 is a commercial-stage musculoskeletal foot & ankle company focused on the design and development of implant systems utilizing unique manufacturing technology that greatly enhances visualization of bony structures.

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