

## Exactech Announces FDA 510(k) Clearance of the World's First Surgical Navigation for Total Ankle Replacement

**GAINESVILLE, FL (Dec. 5, 2023)** -- Exactech, a developer and producer of innovative implants, instrumentation and smart technologies for joint replacement surgery, announced its subsidiary, BlueOrtho, has received 510(k) clearance from the Food and Drug Administration for ExactechGPS® Ankle, the world's first surgical navigation system for total ankle arthroplasty (TAA).

GPS Ankle is a first-of-its-kind technology, which connects the preoperative plan with real-time intraoperative instrument guidance and confirms that resections meet the surgical plan. The system uses proprietary active tracker technology and a compact touchscreen tablet in the sterile field to provide surgeons with dynamic intraoperative feedback throughout their cases.

"I am already a fan of Exactech's patient-specific instrumentation solution and am thrilled how GPS Ankle provides intraoperative flexibility at my fingertips. The ability to quantify soft tissue laxity will be a game changer for me and my patients," said design team surgeon Edward Haupt, MD, of the Mayo Clinic in Florida.

GPS Ankle is compatible with Exactech's flagship [Vantage® Total Ankle System](#), and will be available to hospitals and ASC centers without capital cost. Pre-clinical studies, based on bench testing, reported an accuracy of 2mm and 2 degrees relative to the CT-based surgical plan.<sup>1</sup> This was further confirmed by two studies performed on sawbones, which were recently accepted by the Orthopaedic Research Society.<sup>2-3</sup>

"Exactech has introduced new concepts in the ankle market, but this clearance represents the first intraoperative guidance for ankle surgery and solidifies us as a company focused on innovation," said Laurent Angibaud, Exactech's vice president of development for advanced surgical technologies.

GPS Ankle is the latest product introduction of Exactech's Active Intelligence® dynamic ecosystem of enabling technologies and smart solutions that empowers surgeons with data-rich, comparatively low-cost solutions to help improve patient outcomes. The company's GPS technology has been in use across the globe for more than a decade for shoulder and knee surgery.

GPS Ankle is only available in the U.S. and will enter pilot launch with limited availability starting in 2024. Contact your local Exactech rep for more information.

### References:

1. Data on file.
2. Rueff M. et al. Accuracy and Precision Evaluation of Image-based Computer Assisted Surgical System for Total Ankle Arthroplasty. 2023. Accepted to ORS.
3. Rueff M. et al. Evaluation of error sources for an Image-based Computer Assisted Surgical System for Total Ankle Arthroplasty. 2023. Accepted to ORS.

GPS, Equinoxe Planning App and Predict+ are developed by Blue Ortho, an Exactech subsidiary, and distributed by Exactech, Inc.



 **EXACTECH, INC**  
2320 NW 66th Court  
Gainesville, FL 32653  
USA

 352.377.1140

 352.378.2617

#### About Exactech, Inc.

Exactech is a global medical device company that develops and markets orthopaedic implant devices, related surgical instruments and the Active Intelligence® platform of smart technologies to hospitals and physicians. Headquartered in Gainesville, Fla., Exactech markets its products in the United States, in addition to more than 30 markets in Europe, Latin America, Asia and the Pacific. Visit [www.exac.com](http://www.exac.com) for more information and connect with us on [LinkedIn](#), [VuMedi](#), [YouTube](#), [Twitter](#) and [Instagram](#). *With Exactech by your side, you've got EXACTLY what you need.*

#### Media Contact:

Samantha DiVirgilio

Marketing Communications Senior Manager

[samantha.divirgilio@exac.com](mailto:samantha.divirgilio@exac.com)