

## **Enovis Receives FDA Approval of Patient Specific Instrumentation for STAR® Ankle**

December 1, 2022

The approval of the STAR PSI System marks an impactful milestone by allowing surgeons to provide a personalized pre-operative plan for their total ankle replacement patients

Wilmington, DE, Dec. 01, 2022 (GLOBE NEWSWIRE) -- Enovis Corporation (NYSE: ENOV), an innovation-driven medical technology company, announced that the U.S. Food and Drug Administration (FDA) has approved the STAR Patient Specific Instrumentation (STAR PSI System) for use with the Company's STAR® total ankle replacement system.

"Today is an exciting day for our customers and patients," said Gary Justak, President of Enovis Foot & Ankle. "We acquired the STAR Ankle just two years ago, and the FDA approval of STAR PSI is just one example of our team's commitment and investment to taking this best-in-class product to the level it deserves. Surgeons now have leading pre-operative planning and cutting guides, that when paired with years of proven, clinical data, set STAR® Ankle up for a brilliant future."

The STAR PSI System provides a personalized pre-operative plan for each patient. Surgeons receive and review a 3D visualization of the patient's ankle joint, including information about any existing implants and/or bone defects, to plan for the total ankle replacement case. The STAR PSI System is utilized with an updated and simplified surgical technique, which has the potential to reduce operative time during total ankle replacement cases.

"I'm excited about the Enovis addition of PSI technology which will have great benefit to STAR patients by providing personalized cutting guides and accurate implant sizing to match their unique anatomy," said Dr. Gregory Lundeen<sup>i</sup>, a foot and ankle orthopedic surgeon based in Reno, Nevada. "Surgeons will be able to take advantage of the improved precision and efficiency of STAR's patient specific cut guides."

The product is entering Early Product Surveillance in December with plans to fully launch by the end of March 2023.

The STAR PSI System is one of several new products introduced by Enovis Foot & Ankle this year. Enovis' growing foot and ankle portfolio features other new solutions such as the DynaNail Helix™, Arsenal Ankle® Plating System and now the STAR PSI System— all designed to improve patient outcomes.

## **About Enovis**

Enovis Corporation (NYSE: ENOV) is an innovation-driven, medical technology growth company dedicated to developing clinically differentiated solutions that generate measurably better patient outcomes and transform workflows. Powered by a culture of continuous improvement, global talent and innovation, the Company's extensive range of products, services, and integrated technologies fuels active lifestyles in orthopedics and beyond. For more information about Enovis, please visit <a href="https://www.enovis.com">www.enovis.com</a>.

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<sup>i</sup>Dr. Lundeen is a paid consultant of Enovis.

## Attachment

• STAR w PSI Guides

Katie Sweet
Vice President, Corporate Communications
+1-310-779-3518
Katie.Sweet@enovis.com



Source: Enovis Corporation



The STAR Patient Specific Instrumentation (STAR PSI System)