



## SINTX Technologies Receives FDA Clearance for SINAPTIC® Foot & Ankle Implant System

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*FDA cleared and U.S. manufactured implant system positions SINTX to enter billion-dollar U.S. market*

**SALT LAKE CITY, Utah, Oct. 20, 2025 (GLOBE NEWSWIRE) -- SINTX Technologies, Inc.** (NASDAQ: SINT) ("SINTX" or the "Company"), a leader in advanced ceramics specializing in biomedical applications of silicon nitride ( $\text{Si}_3\text{N}_4$ ), today announced U.S. Food and Drug Administration (FDA) 510(k) clearance for the **SINAPTIC® Foot & Ankle Osteotomy Wedge System**, enabling SINTX's commercial entry into reconstructive foot and ankle surgery in the United States. SINTX plans a U.S. commercial launch in Q1 2026, leveraging its U.S.-based manufacturing to drive revenue acceleration and operating efficiency.

The SINAPTIC implant system combines SINTX's proprietary silicon nitride biomaterial with surgeon-informed implant designs and a planned sterile, single-use instrument kit engineered to enhance surgical efficiency, precision and reproducibility. By combining differentiated material science with practical surgical innovation, the SINAPTIC implant system exemplifies SINTX's strategy to leverage its unique biomaterials platform into scalable, high-value medical solutions that address unmet clinical needs and drive long-term growth.

"Orthopedics is evolving beyond traditional materials," said Lisa Marie Del Re, Chief Commercial Officer. "With growing demand for non-metal solutions, the SINAPTIC system delivers the proven performance of silicon nitride to foot and ankle reconstruction—elevating expectations for surgical outcomes."

As cleared under the FDA submission, some of the material claims of SINTX's silicon nitride relevant to the device include:

- **Pro-osteogenic:** Unique surface chemistry mechanisms have demonstrated superior protein absorption and osteointegration when compared to traditional biomaterials.
- **Bacteriostatic:** Surface properties have been shown to actively repel and/or inhibit the growth of various types of bacteria in a laboratory and animal studies.
- **Hydrophilic:** Attracts fluids, further deterring bacteria colonization and enhancing bone-building mechanisms.
- **Enhanced visibility on imaging:** Unlike metal implants, silicon nitride allows for clear visualization of the surrounding tissues in X-rays and CT scans.

"FDA clearance of our SINAPTIC portfolio is a defining commercial milestone for the Company," said Eric Olson, Chairman, President & CEO. "By entering the high-value, procedure-driven market with a differentiated biomaterial and surgeon-validated designs, we expect to generate meaningful clinical impact and build shareholder value as we execute our commercial strategy."

Industry estimates place the global foot & ankle device market at approximately \$4.75–\$5.4 billion in 2024. While osteotomy wedges represent a subset of this category, SINTX believes procedure growth, ASC migration, and workflow-enhancing single-use instrumentation together create a compelling revenue opportunity.

For more information on SINTX Technologies or its materials platform, visit [www.sintx.com](http://www.sintx.com).

### About SINTX Technologies, Inc.

Located in Salt Lake City, Utah, SINTX Technologies is an advanced ceramics company that develops and commercializes materials, components, and technologies for medical and other high-value applications. SINTX is a global leader in the research, development, and manufacturing of silicon nitride, and its products have been implanted in humans since 2008. Through innovation and strategic partnerships, SINTX continues to expand its portfolio across multiple markets.

### Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding the Company's plans and expected timing for commercialization of the SINAPTIC™ Foot & Ankle Osteotomy Wedge System; anticipated surgeon adoption, procedural and operating-room efficiencies, and revenue impact; planned product configurations such as sterile, single-use instrumentation; expected U.S. based manufacturing scale-up, supply-chain efficiency, and quality systems; the Company's commercialization strategy, ability to generate clinical impact and build shareholder value; and market size and growth expectations, trends, and the associated commercial opportunity. Forward-looking statements are based on current expectations and are often identified by words such as "may," "will," "could," "should," "would," "expect," "plan," "anticipate," "intend," "believe," "estimate," "project," "target," "continue," and similar expressions. These statements involve risks and uncertainties that could cause actual results to differ materially, including risks

related to commercialization execution, surgeon training and utilization, inventory and channel build-out, manufacturing scale-up and quality, supply chain and third-party components, pricing and reimbursement, hospital and ASC purchasing dynamics, competitive products, intellectual property, integration of acquisitions, macroeconomic conditions, and the accuracy of third-party market estimates. FDA 510(k) clearance does not assure commercial success, and any discussion of potential infection-prevention attributes of silicon nitride reflects platform-level materials research and is not part of the cleared indications for this system. Additional risks and uncertainties are described in SINTX's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, available at [www.sec.gov](http://www.sec.gov). Forward-looking statements speak only as of the date of this release, and SINTX undertakes no obligation to update them, except as required by law.

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