

Orthopedics

This Week

FDA Greenlights a New Material for Foot and Ankle Reconstruction

KIM DELMONICO

Foot and ankle surgeons, there's a new tool on the horizon — and it's made of something a little different than what's sitting in your implant trays.

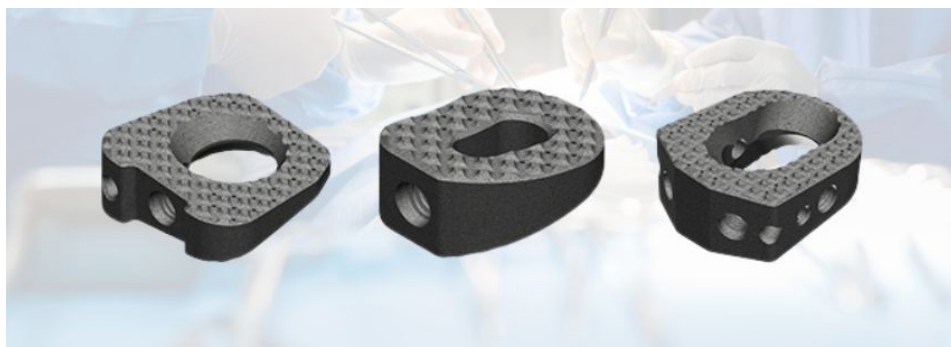
The U.S. Food and Drug Administration (FDA) has officially granted 510(k) clearance to the SiNAPTIC® Foot & Ankle Osteotomy Wedge System, a new entrant designed for internal bone fixation in fractures and osteotomies of the foot and ankle.

The system covers a familiar range of applications:

- Opening wedge osteotomies for hallux valgus correction
- Cotton osteotomies of the medial cuneiform
- Evans lengthening and calcaneal Z-osteotomies for lateral column work
- TMT/Lapidus and midfoot arthrodesis procedures
- Hindfoot work including ankle and subtalar fusions

In short: if you cut, lengthen, or realign bones below the tibia, this system wants in on the action.

A Familiar Shape – With a New Material Twist



SINAPTIC® Foot & Ankle Osteotomy Wedge System / Source: SINTX Technologies, Inc.

To qualify for its expedited 510(k) clearance, SiNAPTIC's wedge system demonstrated "substantial equivalence" to existing predicate devices — specifically Nvision Biomedical's Trigon HA Stand-Alone Wedge Fixation System. Functionally, the designs share similar geometry, fixation principles, and indications for use.

But the differentiator here isn't shape — it's substance.

The SiNAPTIC system represents the first foray into foot and ankle surgery by SINTX Technologies, Inc., a company long recognized for its expertise in silicon nitride biomaterials. Known for their advanced surface chemistry, these ceramics have made a name in spine and dental applications for combining biocompatibility with anti-bacterial behavior.

Now, SINTX is bringing that same technology to the world of bunions, calcaneal osteotomies, and midfoot reconstructions.

What Makes Silicon Nitride Interesting?

Silicon nitride has a few calling cards that could make it appealing in reconstructive foot and ankle surgery:

- Osseointegrative surface chemistry – promotes protein absorption and bone ingrowth.
- Bacteriostatic properties – its surface actively resists bacterial colonization.
- Imaging visibility – stands out clearly on X-rays and CT scans.
- Hydrophilic surface – attracts fluid and may enhance bone healing biology.

That's a lot of biological buzz packed into a wedge.

A Step Beyond Metal

"Orthopedics is evolving beyond traditional materials," said Lisa Marie Del Re, Chief Commercial Officer at SINTX.

“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.”

What's Next

SINTX acquired SiNAPTIC Surgical, LLC earlier this year to anchor its

expansion into the orthopedic implant market. With FDA clearance now in hand, the company plans a commercial launch in early 2026, leveraging its U.S.-based manufacturing to scale production.

If all goes according to plan, foot and ankle surgeons could soon have a new ceramic wedge on the back table — offering a sleek alternative to metal

implants, with the promise of better bone biology and fewer postoperative infections.

Silicon nitride may just be the material that helps the next generation of osteotomy patients stand a little taller. ♦