

Foundation Surgical Receives FDA 510(k) Clearance for Navigated Lateral Disc Preparation Instruments

April 17, 2026 / SCOTTSDALE, AZ — Foundation Surgical, a spine implant company focused on advancing motion-preserving and lateral surgical techniques, today announced it has received FDA 510(k) clearance for its Navigated Lateral Disc Preparation instrument system.

The navigated platform is designed for compatibility with established intraoperative imaging and navigation technologies, including Medtronic's O-Arm™ imaging system and StealthStation™ navigation platform. This clearance expands Foundation Surgical's capabilities in navigation-enabled lateral spine procedures and reflects the company's continued focus on precision-driven surgical solutions.

The Interwedge® system includes a comprehensive suite of navigated instruments intended to support disc space preparation and instrumentation during lateral procedures, including:

- Navigated Lateral Disc Preparation Instruments: Trials, paddle shavers, osteotomes, and Cobb elevators
- Navigated Screw Instrumentation: Taps and awls
- Navigation-Enabled Access Instruments: Probes and dilator compatible with StealthStation™ workflows

By integrating with widely adopted navigation platforms, the system enables real-time intraoperative visualization during key procedural steps, supporting accuracy and consistency without requiring changes to existing operating room workflows.

“At Foundation Surgical, we are focused on developing technologies that enhance surgical precision while remaining practical for real-world use,” said Randal Betz, MD, Founder of Foundation Surgical. “This clearance represents an important step in expanding our platform and providing surgeons with tools that integrate seamlessly into navigation-enabled environments.”

The addition of navigated instrumentation addresses growing surgeon demand for increased visualization and control during lateral spine procedures, particularly during disc preparation and implant placement.

“This clearance allows for a fully integrated navigated workflow during lateral procedures,” said Baron Lonner, MD, a spine surgeon working with Foundation Surgical. “Having navigated lateral instruments can improve intraoperative confidence and surgical efficiency.”

About Foundation Surgical

Foundation Surgical is a spine implant company committed to advancing motion preservation and lateral surgical techniques. The company is developing a portfolio of solutions, including the Interwedge® Standalone Lateral System and the Vertiwedge® motion-sparing intraosseous device designed for the Vertebral Body Osteotomy (VBO®) procedure. Founded by deformity surgeon Randal Betz, MD, Foundation Surgical is focused on developing technologies that support improved patient outcomes through precision, efficiency, and preservation of motion.

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