Foundation Surgical Secures 510(k) Clearance for Innovative Lateral Interbody System and Lateral Procedure Scottsdale, AZ – October 4, 2024



Foundation Surgical, an early-stage spinal implant company, is excited to announce the US Food & Drug Administration (FDA) 510(k) clearance of its Interwedge® Standalone Lateral Interbody System. This latest product clearance, used in conjunction with Foundation's new LLIF180™ procedure, represents a significant innovation in lateral spinal surgery.

LLIF180™ is the first bilateral-fixated standalone-lateral procedure performed through a single-position lateral or oblique-lateral lumbar spine approach. The LLIF180™ procedure's bilateral fixation is made possible by the Interwedge® system's novel deployable staple. The Interwedge® system also features a distinctive hinge mechanism between the spacer and lateral plate which, combined with the deployable staple, provides both ipsilateral and contralateral fixation. These innovations grant the Interwedge® system unparalleled versatility and stability to facilitate a lumbar spine fusion, while eliminating the need for supplemental posterior fixation.

Dr. Randal Betz, the founder of Foundation Surgical, shared his thoughts on this achievement: "The FDA clearance of the Interwedge® system represents a significant step forward for lateral lumbar spine surgery and implant technology. We believe the novelty of the LLIF180™ procedure and unique features of the Interwedge® system, like the bilateral fixation via the deployable staple, offer surgeons enhanced options for standalone lateral interbody spinal stabilization."

For more information about the Interwedge® Standalone Lateral Interbody System and Foundation Surgical's commitment to innovation in spinal surgery, please visit www.foundationsurgical.com or contact info@foundationsurgical.com.

About Foundation Surgical: Foundation Surgical is an innovative spine implant company, leading the way in developing novel spine procedures. Founded by renowned deformity spine surgeon Dr. Randal Betz and experienced spinal device engineer Dale Whipple, the company is committed to developing state-of-the-art surgical solutions to transform the lives of patients with spinal conditions.

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Disclaimer: This press release contains forward-looking statements about Foundation Surgical's future initiatives and performance, which involve risks and uncertainties. Actual results may differ materially from those projected.