Tenon Medical® Announces FDA 510(k) Clearance for SImmetry®+ SI Joint Fusion System

~Clearance expands Company's competitive advantage of clinically proven, minimally invasive technologies to treat debilitating SI joint conditions from multiple surgical approaches~

~SImmetry+'s New 3D printed titanium implants, robust joint decorticator, and simple bone graft delivery system provides physicians treatment options rooted in established fusion principles~

~Company initiating alpha launch of SImmetry® + with select group of physician users to provide initial feedback to support broader launch~

LOS GATOS, CA / ACCESS Newswire / October 21, 2025 / Tenon Medical, Inc. (NASDAQ:TNON) ("Tenon" or the "Company"), a company transforming care for patients suffering with certain sacro-pelvic disorders, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the SImmetry+ SI Joint Fusion System. The SImmetry+ System is indicated for sacroiliac (SI) joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis, providing physicians with treatment options rooted in established fusion principles.

Utilizing the systems new 3D printed titanium implants and proprietary instrumentation, the SImmetry+ is a novel minimally invasive lateral access SI joint fusion system that uses proven orthopedic principles, including joint decortication, bone graft delivery, and fixation to achieve a true fusion. The Company is finalizing preparation for the initial alpha launch of the SImmetry+ targeting a launch by the end of the year. The alpha will provide important initial user feedback from a select group of physician users to support a broader market introduction in the coming months.

With this clearance, SImmetry+ now joins Tenon's Catamaran® SI Joint Fusion System in the Company's growing portfolio of advanced technologies. Together, these platforms uniquely position Tenon with multiple surgical approaches-lateral and inferior-posterior-both designed to be minimally invasive, enable authentic arthrodesis and supported by robust clinical evidence, including the published prospective Mainsail™ and EVoluSIon™ SI joint fusion studies. These differentiated technologies will enable physicians to customize treatment plans for their patients with an innovative portfolio that spans SI joint, spinal fusion, and deformity adjuncts - each solution engineered to deliver fusion outcomes more reliably. This multi-platform, multi-approach strategy strengthens Tenon's competitive advantage in the expanding SI joint fusion market and underscores the Company's commitment to delivering proven, durable outcomes for physicians and patients.

"Achieving true fusion of the SI joint is a major element of long-term stability for patients suffering from sacroiliac joint dysfunction. The new SImmetry+ System reflects an adherence to core AO principles-joint preparation, bone grafting, and rigid fixation-which are fundamental to successful bone healing" said Ali Araghi,DO, Orthopedic Spine Surgeon at the Core Institute in Phoenix, Arizona. "The introduction of the SImmetry+ SI joint system and its new 3D-printed titanium implant represents a meaningful advancement in SI joint fusion. The porous structure promotes bone ingrowth and biological fixation, while the precision-engineered threads and surface texture enhance initial stability across the joint. Combining these features with the SImmetry system's simple and proven minimally invasive approach to true arthrodesis has the potential to deliver more consistent fusion outcomes for my patients."

"The FDA clearance of SImmetry+ marks a significant inflection point in Tenon's growth trajectory," said Steven M. Foster, President and CEO of Tenon Medical. "By expanding our portfolio to include both the Catamaran and SImmetry+ systems, we have created a differentiated market position with multiple approaches to SI joint fusion backed by proven clinical outcomes including pain reduction, patient satisfaction, and independent confirmation of bridging bone fusion across the joint. This unique competitive advantage strengthens our ability to drive adoption, increase procedure volumes, and capture a larger share of this rapidly expanding market, all of which supports long-term value creation for our shareholders. We look forward to initiating our alpha launch of SImmetry and collaborating with our initial physician users to gain their feedback on performance and outcomes."

About Tenon Medical, Inc.

Tenon Medical, Inc., a medical device company formed in 2012, has developed The Catamaran SI Joint Fusion System that offers a novel, less invasive approach to the SI joint using a single, robust titanium implant. The system features the Catamaran™ Fixation Device which passes through both the axial and sagittal planes of the ilium and sacrum, stabilizing and transfixing the SI Joint along its longitudinal axis. The angle and trajectory of the Catamaran surgical approach is also designed to provide a pathway away from critical neural and vascular structures and into the strongest cortical bone. Since the national launch of the Catamaran SI Joint Fusion System in October 2022, Tenon is focused on three commercial opportunities with its System in the SI Joint market which include: 1) Primary SI Joint procedures, 2) Revision procedures of failed SI Joint implants and 3) Augmenting spinal fusion. For more information, please visit www.tenonmed.com.

The Tenon Medical logo shown above, and Catamaran®, PiSIF®, CAT PiSIF®, ETAD®, Posterior Inferior Sacroiliac Fusion®, CAT SIJ Fusion System®, Catamaran SIJ Fusion System®, Catamaran Inferior Posterior Fusion System®, Catamaran Transfixation Fusion System®, Catamaran Transfixation Fusion Device®, SImmetry® are registered trademarks of Tenon Medical, Inc. MAINSAIL™, and SImmetry+™ are also trademarks of Tenon Medical, Inc.

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