

ElectroWire Medical Receives 510(k) Clearance for LightningWire™ Transseptal Puncture System

LEXINGTON, S.C., July 15, 2026 /PRNewswire/ -- ElectroWire Medical announced today that the U.S. Food and Drug Administration has granted 510(k) clearance for its LightningWire™ Transseptal Puncture System, which is indicated to create an atrial septal defect in the heart, whereby various cardiovascular catheters are introduced.

The LightningWire system combines a novel electrosurgical guidewire with a dedicated activation cable to simplify procedures using preferred transseptal introducers and existing electrosurgical generators. The LightningWire's proprietary insulation design optimizes electrosurgical performance and mechanical properties along the length of the wire. Robust distal insulation allows transseptal puncture at low power settings. Despite its 0.032-inch labeled diameter, which facilitates broad compatibility with various transseptal devices, the LightningWire is stiffer than the market-leading 0.035-inch guidewire to support efficient transseptal delivery of therapy devices. The LightningWire's activation cable connects to separately cleared electrosurgical generators and puts control of radiofrequency energy in the operator's hands on the sterile field. Designed for compatibility, the LightningWire technology is positioned to bring value to all procedures in the rapidly growing transseptal access systems market, including catheter ablation of atrial fibrillation, left atrial appendage occlusion, and transcatheter mitral valve repair and replacement.

ElectroWire Medical looks forward to immediate commercialization of the LightningWire system in a limited market release. Dr. James Stewart, structural interventional cardiologist at Piedmont Atlanta's Marcus Heart Valve Center, commented that he is "extremely excited to use the new LightningWire. The ability to cross the septum in a precise location using the transseptal catheter of my choice and then deliver bulky equipment into the left side of the heart should streamline our left-sided procedures tremendously." Dr. William Brabham, Director of Cardiac Electrophysiology at Lexington Medical Center, added, "Safe, effective, and efficient transseptal access is critical in the electrophysiology space. LightningWire meets all of these needs in a versatile device that can be used across industry platforms. It also has the potential to add cost savings for health systems as the economics of these important procedures evolve."

ElectroWire Medical is a Lexington, South Carolina-based medical device technology startup founded by Dr. Robert Leonardi, a structural interventional cardiologist. According to Dr. Leonardi, "ElectroWire was founded to set a new standard for transseptal access and device delivery. We think we've done that with our LightningWire technology, which we expect to benefit patients, their physicians, and the hospitals and ambulatory surgery centers where transseptal procedures are done." ElectroWire Medical is currently raising capital. For more information, visit electrowiremedical.com. For updates, follow ElectroWire Medical on LinkedIn and X.

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