xDot Medical Receives FDA Approval to Initiate Pivotal IDE Trial of Its Large-Bore Vascular Closure System

MAPLE GROVE, MN, UNITED STATES, July 6, 2026 /EINPresswire.com/ -- xDot Medical today announced that the U.S. Food and Drug Administration (FDA) has approved the company's Investigational Device Exemption (IDE) application to initiate its pivotal clinical trial evaluating the xDot Access Management System (AMS) for closure of femoral arterial and femoral venous access sites.

The prospective, multicenter, dual-cohort, single-arm, open-label study will enroll patients undergoing catheter-based interventional procedures requiring large-bore femoral arterial or femoral venous access. The study will enroll 266 subjects (including roll-in subjects), with follow-up through 30 days after the procedure.

Dr. Rahul P. Sharma, Director of Structural Interventions at Stanford Healthcare, and Dr. Devi G. Nair, Chief of Cardiac Electrophysiology & Research at St. Bernards Medical Center, will serve as the National Principal Investigators for the study.

"Despite the continued growth of large-bore catheter-based therapies, vascular closure failure and access-site complications remain important clinical challenges," said Dr. Sharma. "The xDot AMS represents a promising new approach, and I am excited to co-lead this pivotal study evaluating its safety and effectiveness."

“As electrophysiology procedures increasingly rely on larger-bore venous access, there is a growing need for closure technologies that deliver reliable, reproducible hemostasis,” said Dr. Nair. “I’m pleased to co-lead this pivotal trial with Dr. Sharma and to help generate the rigorous evidence needed to define the role of the xDot AMS in large-bore venous closure.”

Dr. Susheel Kodali, Structural Heart Interventional Cardiologist, who has advised xDot Medical since its early development and served as lead investigator for the company's first-in-human study, "The xDot AMS was specifically engineered to overcome the challenges of large-bore vascular closure, incorporating novel features such as maintained guidewire access and automated coaxial suture cinching. I look forward to seeing the clinical evidence generated through this pivotal trial."

"The FDA approval of our pivotal IDE is a significant milestone for xDot Medical," said Aashiish

Agnihotri, Founder and CEO of xDot Medical. "We appreciate the contributions of our team and collaborators and look forward to evaluating the xDot AMS with leading clinical investigators in this pivotal study.”

Caution: The xDot Access Management System™ is an investigational device and not available for sale.

About xDot Medical
xDot Medical is a medical technology company developing xDot AMS to simplify vascular closure following catheter-based procedures while addressing the evolving needs of structural heart, electrophysiology, and other large-bore interventions. xDot is currently enrolling patients in its Early Feasibility Study (EFS) and plans to start enrollment in the pivotal study after enrollment in the EFS is complete. To learn more about xDot Medical, please visit: www.xdotmedical.com

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