

FDA Clearance and First in Human Use for SoloPace™ Temporary Pacing System for TAVR

SAN FRANCISCO, Calif – April 17, 2025 – Solo Pace Incorporated, an emerging medical technology company, announced both FDA Clearance and First-In-Human use of their SoloPace Control System for temporary pacing in Transcatheter Aortic Valve Replacement (TAVR) procedures. With standardized workflows, the Control System is engineered to improve TAVR temporary pacing efficiency and reduce patient risks. Initial cases were completed this month at Scripps Clinic by Chief of Cardiology, Paul Teirstein, MD and Curtiss Stinis, MD.

“Solo Pace has modernized pacing during TAVR valve deployment. The device takes variability out of the procedure by giving the operator full control while automating ramp-up and back-up algorithms. The TAVR procedure is simplified, reducing physician and staff workload,” said Dr. Teirstein. “We pre-program pacer settings to reliably deliver the same procedure every time. This allows us to focus on the patient and free up resources, especially at centers where nurses and technologists currently control the pacemaker generator.”

SoloPace Control System’s operator-specific protocols and automated pace capture checks may improve procedural efficiency, while the intuitive interface and sterile remote-control operation are designed to reduce unnecessary communications errors. In addition, the system is compatible with patient cables for all common procedural pacing methods, making it easy to integrate into current practice.

“Precise pacing is essential for safe TAVR procedures, yet today’s devices are not purpose-built for TAVR, offer no standard pre-sets, and require inefficient verbal commands,” stated Solo Pace Founder and CEO, David Daniels, MD. “FDA clearance and the use of our technology in patients are both significant milestones for the Company and first steps on our journey to advance transcatheter heart valve pacing solutions.”

About Solo Pace, Inc.

Solo Pace, Inc., based in San Francisco, California, is a privately held company that is dedicated to bringing solutions to transcatheter heart valve pacing. For more information, visit www.solopace.health

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