



## Largest Real-World Study of Wearable Defibrillators Confirms Strong Effectiveness and Safety Performance of Kestra's ASSURE Device

November 10, 2025

KIRKLAND, Wash., Nov. 10, 2025 (GLOBE NEWSWIRE) -- Kestra Medical Technologies, Ltd. (Nasdaq: KMTS), a wearable medical device and digital healthcare company, today announced primary results from the ASSURE® WCD Clinical Evaluation Post-Approval Study (ACE-PAS), presented as a late-breaking science session at the American Heart Association (AHA) Scientific Sessions 2025 in New Orleans. ACE-PAS, the largest prospective real-world study of wearable defibrillators to date, confirmed the strong safety and effectiveness of the ASSURE WCD in clinical practice.

"ACE-PAS delivers robust, real-world evidence on how the ASSURE WCD performs in routine care and provides contemporary data describing the risk of life-threatening ventricular tachycardia and fibrillation in diverse populations with reduced cardiac function," said Jeanne E. Poole, MD, Professor of Medicine at the University of Washington and Principal Investigator. "Life-threatening arrhythmias can occur early in patients with low ejection fraction who have recently experienced a myocardial infarction, undergone coronary revascularization, or have been newly diagnosed with heart failure. These patients may have significant recovery of heart function during a waiting period of one to six months, such that a permanently implanted defibrillator is not indicated. The ASSURE WCD should be considered to protect patients at elevated risk of sudden cardiac death during this vulnerable time."

The study enrolled 21,612 patients across the United States. Key findings demonstrate consistent safety, effectiveness, and compliance in real-world use:

- **Proven effectiveness**
  - The primary effectiveness endpoint was achieved, with **100% successful conversion** for ventricular tachycardia and fibrillation (VT/VF) events, surpassing the prespecified performance goal.
- **Validated safety**
  - The study met its primary safety endpoint, with an **inappropriate-shock rate of 0.0065 per patient-month**, below the prespecified performance goal and confirming a strong safety profile.
- **Minimal false alarms**
  - **94% of patients experienced no false positive shock alarms**, ensuring confidence and comfort during wear.
- **Critical protection**
  - **2.6% of patients experienced at least one life-threatening VT/VF event** within only a few months, highlighting the importance of protection in this vulnerable population.
- **Additional clinically relevant arrhythmias revealed**
  - The ASSURE system facilitated detection of high-rate atrial fibrillation in 4.2% of patients (35% previously undiagnosed) and severe bradycardia/asystole in 0.3%, enabling the potential of timely intervention.
- **High compliance**
  - Patients wore the device for a **median of more than 23 hours per day**, and **one-third continued use beyond 90 days**—highlighting its practicality in real-world, long-term care.

"These results reinforce the critical role wearable device monitoring and therapy can play in protecting patients during periods of elevated risk," said Brian Webster, President and Chief Executive Officer of Kestra Medical Technologies. "As the largest and most contemporary study of its kind, ACE-PAS provides compelling evidence that may help inform future updates to clinical practice—particularly around how physicians identify and protect patients at early risk of sudden cardiac death. By pairing proven performance with connected, data-driven insight, Kestra is redefining what's possible in wearable protection and advancing evidence-based innovation."

The ACE-PAS results represent a significant step forward in understanding and managing sudden cardiac arrest risk. Additional analyses from the study will be shared in forthcoming scientific forums.

A recorded panel discussion featuring ACE-PAS investigators and other leading clinical experts, hosted by MedAxiom, offers further perspective on the study's design, outcomes, and implications for patient care. The full discussion can be viewed here: <https://na2.hubs.ly/H01ZZM90>

## **About ACE-PAS**

The ASSURE WCD Clinical Evaluation Post-Approval Study (ACE-PAS) is a prospective, multicenter registry evaluating the use, safety, and effectiveness of the ASSURE Wearable Cardioverter Defibrillator in the prevention of sudden cardiac death. The study enrolled 21,612 patients from November 2021 through July 2025 across the U.S. Primary endpoints were overall VT/VF shock conversion and inappropriate-shock rate.

## **About Kestra**

Kestra Medical Technologies, Ltd. is a commercial-stage wearable medical device and digital healthcare company focused on transforming patient outcomes in cardiovascular disease using monitoring and therapeutic intervention technologies that are intuitive, intelligent, and connected. For more information, please visit [www.kestramedical.com](http://www.kestramedical.com).

## **Forward-Looking Statements**

Except where otherwise noted, the information contained in this press release is as of November 10, 2025. Statements in this press release that express a belief, expectation or intention, as well as those that are not historical fact, are forward-looking statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about, among other topics, the Company's goals and prospects, the ACE-PAS study, the potential uses and benefits of the evidence collected therefrom and additional analyses that may be shared from the ACE-PAS study in the future. Given their forward-looking nature, these statements involve substantial risks, uncertainties and potentially inaccurate assumptions, and we cannot ensure that any outcome expressed in these forward-looking statements will be realized in whole or in part. You can identify these statements by the fact that they use future dates or use words such as "will," "may," "could," "likely," "ongoing," "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "assume," "target," "forecast," "guidance," "goal," "objective," "aim," "seek," "potential," "hope" and other words and terms of similar meaning. Among the factors that could cause actual results to differ materially from past results and future plans and projected future results are the following: risks related to our limited operating history and history of net losses; our ability to successfully achieve substantial market adoption of our products; competitive pressures; our ability to adapt our manufacturing and production capacities to evolving patterns of demand, governmental actions and customer trends; product defects or complaints and related liability; our ability to obtain and maintain adequate coverage and reimbursement levels for our products; our ability to comply with changing laws and regulatory requirements and resulting costs; our dependence on a limited number of suppliers; and other risks and uncertainties, including those described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended April 30, 2025 filed with the U.S. Securities and Exchange Commission ("SEC") on July 17, 2025, and in other periodic reports filed by the Company with the SEC. These filings, when made, are available on the Investor Relations section of our website at <https://investors.kestramedical.com/> and on the SEC's website at <https://sec.gov/>.

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