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Medtronic Aurora EV-ICD™ system demonstrates exceptional results at six months in the Enlighten real-world post-market study while the OmniaSecure™ defibrillation lead sustains performance at three years in the LEADR Pivotal Trial

APHRS.25: Medtronic showcases breadth of defibrillation portfolio with outcomes from extravascular and transvenous defibrillation studies for the treatment of dangerous heart rhythm episodes

Researchers presented results from two late-breaking presentations at the Asia Pacific Heart Rhythm Society (APHRS) Scientific Session 2025 held in Yokohama, Japan. The six-month results from the Enlighten Study – the Aurora EV-ICD Post Approval Registry – showed high anti-tachycardia pacing (ATP) success, effective defibrillation, low rate of chronic, system-related major complications, and a reduced inappropriate shock rate for the first-of-its-kind Aurora EV-ICD™ system in a real-world setting. In addition, the final three-year results from the LEADR (Lead Evaluation for Defibrillation and Reliability) Pivotal Trial reinforced the safety, efficacy, and reliability of the smallest-diameter OmniaSecure™ defibrillation lead used with traditional transvenous implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-Ds), such as the Medtronic Cobalt™ and Crome™ family of ICDs/CRT-Ds.

"ICDs are the cornerstone for preventing sudden cardiac death for millions of people, but each patient's needs may be different. For the majority of patients, the Aurora EV-ICD offers protection as the only ICD positioned outside the vascular space that also provides ATP in a single device. For the remainder of patients who require chronic pacing therapy, the 4.7 French, lumenless, OmniaSecure lead built for reliability can offer protection when connected to a transvenous ICD or CRT-D," said Trevor Cook, vice president and general manager, Defibrillation Solutions within the Cardiac Rhythm Management business, which is part of the Cardiovascular Portfolio at Medtronic. "These technological innovations are revolutionizing the patient experience while protecting them from this deadly condition."

Six-Month Real-World Outcomes for the Aurora EV-ICD – Results from the Enlighten Study

Results from the Enlighten Study of 786 patients across 23 countries demonstrated that the Aurora EV-ICD had high ATP success and effective defibrillation in a single device positioned safely outside the vascular space in a real-world population. ATP, which delivers pacing pulses to the heart to terminate ventricular tachycardia and restore the heart's normal rhythm without a shock, successfully avoided 44 shocks in 17 patients and with a termination rate (67%)[i] in line with transvenous ICDs and with the EV-ICD Pivotal Trial.[ii] The system was safe with a low risk of complications, showing 97.8% of patients were free from a chronic major system-related complication through six months, and 100% of spontaneous lethal arrhythmic episodes were effectively treated. Furthermore, performance of the commercial device was improved as 32% fewer patients experienced an inappropriate shock compared to the pre-market EV-ICD Pivotal Trial (5.5% vs. 8.1% at six months, respectively).

The Aurora EV-ICD system is a first-of-its-kind extravascular defibrillator with ATP therapy to provide the life-saving benefits of traditional, transvenous ICDs with a lead placed under the sternum, outside of the heart and veins via a device similar in size, shape, and projected longevity to traditional, transvenous ICDs. The device is equipped with Smart Sense technology that reduces cardiac oversensing, one of the most common reasons for inappropriate shocks.

"The strong safety profile and consistent performance of the Aurora EV-ICD in real-world settings reinforces the benefit that patients are experiencing with a defibrillator outside of the vasculature that avoids unnecessary shocks," said Ian Crozier, M.D., cardiologist at Christchurch Hospital in Christchurch, New Zealand, who presented the Enlighten data at the meeting. "These real-world outcomes confirm the results observed in the Pivotal Trial showing high defibrillation and ATP success, a low system-related major complication rate, and a reduced rate of inappropriate shocks compared to the Pivotal Trial. We look forward to continued follow up of these patients out to five years."

Final Three-Year LEADR Pivotal Trial Results Show Consistent Performance of the OmniaSecure Defibrillation Lead Over Time

Building on advancements in transvenous defibrillation, final results from the LEADR Pivotal Trial confirmed the continued high defibrillation efficacy, safety, and reliability of the lumenless, small-diameter OmniaSecure defibrillation lead in traditional locations within the right ventricle.

The lead demonstrated high defibrillation success at implant (97.5%) and in the ambulatory setting through three years (95.3%). There was a low risk of complications with 96.5% of patients free from an OmniaSecure lead-related major complication. The OmniaSecure defibrillation lead also exhibited reliable performance with a high success rate of ATP (75.4%), an appropriate shock delivery in 22.3% of patients, and stable electrical performance (stable pacing thresholds, sensing amplitudes, and impedance). Additionally, the lead displays high reliability with a fracture-free rate consistent with predicted 98.2% 10-year reliability modeling.

Medtronic engineers designed the OmniaSecure defibrillation lead, which connects to an ICD or CRT-D to treat life-threatening cardiac arrhythmias, based on the highly durable Medtronic SelectSecure™ Model 3830 pacing lead, which has offered safe and effective treatment to patients for more than 20 years. The prospective, multi-center LEADR Pivotal trial enrolled 675 patients at 45 sites in 17 countries in North America, Europe, Asia, and Australia. The lead received FDA approval in April 2025 for traditional placement in the right ventricle and is being evaluated for placement in the left bundle branch area (LBBA) for physiologic pacing in the LEADR LBBAP trial. Globally, the OmniaSecure defibrillation lead is investigational for use in the LBBA and will require separate

regulatory approvals in the future.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow Medtronic on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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[i] GEE-adjusted event rate.

[ii] Friedman P, Murgatroyd F, Boersma LVA, et al. Performance and Safety of the Extravascular Implantable Cardioverter Defibrillator Through Long-Term Follow-Up: Final Results From the Pivotal Study. Circulation. 2025 Jan 28;151(4):322-332.

https://news.medtronic.com/Medtronic-Aurora-EV-ICD-TM-system-demonstrates-exceptional-results-at-six-months-in-the-Enlighten-real-world-post-market-study-while-the-OmniaSecure-TM-defibrillation-lead-sustains-performance-at-three-years-in-the-LEADR-Pivotal-Trial