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Medtronic Aurora EV-ICD™ system delivers exceptional one-year performance in the Enlighten real-world study

Heart Rhythm 2026: Real-world outcomes reinforce Aurora EV-ICD system as a reliable option for indicated patients requiring protection from dangerously fast heart rhythms

Researchers presented late-breaking results from the Enlighten study – the EV-ICD Post Approval Registry, which demonstrated excellent outcomes at one year. The first-of-its-kind Aurora EV-ICD™ system showed high anti-tachycardia pacing (ATP) success, effective defibrillation, low rate of chronic, system-related major complications, and an improved inappropriate shock rate in a real-world setting. The study results were presented at Heart Rhythm 2026 in Chicago.

The Aurora EV-ICD is the only defibrillator system with a lead positioned outside the vasculature that delivers ATP therapy and other benefits of a transvenous ICD including a similar size, shape, and longevity of traditional systems.

Building on the six-month results presented at the Asia Pacific Heart Rhythm Society (APHRS) Scientific Session 2025, the latest one-year outcomes from the Enlighten Study of 787 patients demonstrated that the Aurora EV-ICD system 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 low-voltage pacing pulses to the heart to terminate ventricular tachycardia and restore the heart's normal rhythm without a shock, successfully avoided 65 shocks in 22 patients, with a high termination rate (GEE-estimated success: 74.2%)[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 95.8% of patients were free from a chronic major system-related complication through one year, and 100% of spontaneous potentially lethal VT/VF episodes were effectively treated. The rate of inappropriate shock was reduced by 30% compared to the pre-market EV-ICD Pivotal Trial (7.1% vs. 9.8% at one year, respectively) – a rate comparable to real-world results shown with other extravascular systems. The commercial Aurora EV-ICD system includes the novel Smart Sense technology that reduces cardiac oversensing, one of the most common reasons for inappropriate shocks.

Results on outcomes by age were presented at European Heart Rhythm Association Scientific Sessions 2026 and showed benefit from the Aurora EV-ICD system was consistent across age groups. A total of 17% of patients enrolled were 65 or older, and 83% of patients were younger than 65. Yet there was no difference in safety nor

effectiveness between age groups.

"We are seeing Aurora EV-ICD continue to perform as well in real-world settings as it did in the clinical trial, if not better in some areas," said Prof. Lucas V.A. Boersma, M.D., Ph.D., cardiologist at St. Antonius Hospital, Department of Cardiology, Nieuwegein, the Netherlands and professor of cardiology, Academic Medical Center (AMC), University of Amsterdam, the Netherlands, who presented the Enlighten data at the meeting. "These longer-term outcomes demonstrate consistently strong performance across age groups. Based on the growing body of evidence, the Aurora EV-ICD should be a first-line consideration for patients who haven't had a prior sternotomy and don't require pacing but can benefit from a defibrillator."

New recommendations published by Heart Rhythm Society endorse the Aurora EV-ICD system as a Class IIa device reinforcing EV-ICD for patients without prior sternotomy and chronic pacing indications.[iii]

New Data Reinforce Safety and Efficacy of OmniaSecure™ Defibrillation Lead for Conduction System Pacing

In addition to its extravascular EV-ICD platform, Medtronic announced new data in a High Impact Science Presentation at Heart Rhythm 2026 supporting its newest transvenous defibrillation lead, the OmniaSecure™ lead. Following approval by the U.S. Food and Drug Administration (FDA) for placement in traditional locations in the right ventricle in April 2025, the lead was recently approved by the FDA for placement in the left bundle branch area (LBBA) as an alternative to right ventricular stimulation, which allows for conduction system pacing (CSP) that closely mimics the heart's natural physiology.

Final results from the global LEADR LBBAP trial (Lead Evaluation for Defibrillation and Reliability in Left Bundle Branch Area Pacing), reinforced the lead's strong safety and efficacy profile in the LBBA, with high defibrillation success at implant (100%) regardless of coil position in the RV, a low rate of OmniaSecure-related major complications (3.2%) at 12 months, and stable electrical performance in all patients. Additionally, results show improved heart function and measurable improvements in patients' quality-of-life at six months in patients receiving LBBA-optimized cardiac resynchronization (LOT-CRT) – a novel therapy that combines CSP with left-ventricular pacing. At 4.7Fr (1.6 mm), the OmniaSecure lead is the smallest-diameter defibrillation lead on the market and approved by FDA for adults and adolescent pediatric patients ages 12 and up. It is approved for use in traditional right ventricle placement and in the LBBA when used with a transvenous implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-Ds), such as the Medtronic Cobalt™ and Crome™ family of ICDs/CRT-Ds. The OmniaSecure lead is approved for traditional right ventricle placement for patients in Europe, Japan, and Canada.

"Having both extravascular and transvenous defibrillation solutions allows physicians to meet patients where they are, providing different options that address patients' individual needs, which can vary widely," 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. "The Aurora EV-ICD system has revolutionized the patient experience as the only ICD that keeps the lead out of the vasculature while providing ATP in a single device, which carries many benefits for patients. With the recent launch of the OmniaSecure defibrillation lead, patients who require chronic pacing therapy and defibrillation now have access to a lead built for reliability that can safely and effectively restore the heart's natural physiology through conduction system pacing."

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.

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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.

[iii] 2026 HRS Expert Consensus Statement Update on CIED Lead Management & Extraction

https://news.medtronic.com/Medtronic-Aurora-EV-ICD-TM-system-delivers-exceptional-one-year-performance-in-the-Enlighten-real-world-study