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# Compelling data at ESC Congress 2025 reinforce safety and performance of the Medtronic OmniaSecure™ defibrillation lead, including in the left bundle branch area

The upcoming U.S. launch of the small-diameter OmniaSecure defibrillation lead will introduce the first FDA-approved lead for both adults and adolescent pediatric patients

At the 2025 European Society of Cardiology (ESC) Congress in Madrid, researchers presented three new datasets reinforcing the safety and performance of the OmniaSecure™ defibrillation lead.

The global LEADR LBBAP trial (Lead Evaluation for Defibrillation and Reliability in Left Bundle Branch Area Pacing), evaluating the small-diameter OmniaSecure defibrillation lead, met safety and efficacy objectives at three months. Data from the full cohort of study patients showed that the lead delivered high defibrillation success (100%) and low OmniaSecure lead-related major complications (2.3%) when placed in the left bundle branch (LBB) area for physiologic pacing. Physiologic pacing, achieved by stimulating the LBB, more closely mimics the heart's natural conduction. Globally, the OmniaSecure defibrillation lead is investigational for use in the LBB and will require separate regulatory approvals in the future.

Built for reliability and engineered based on the SelectSecure™ Model 3830 pacing lead, the OmniaSecure lead is the world’s smallest defibrillation lead (4.7 French, or 1.6mm) and received FDA approval in April 2025 for traditional placement in the right ventricle. Existing defibrillation leads are larger in diameter than the OmniaSecure lead, which may increase the likelihood of downstream complications such as venous occlusion or tricuspid valve regurgitation.

“Left bundle branch area pacing continues to gain traction as a promising approach to restore normal physiologic activation in patients, including in those requiring ICD or CRT-D therapy,” said Pugazhendhi Vijayaraman, M.D., cardiac electrophysiologist at Geisinger Wyoming Valley Medical Center in Wilkes-Barre, Pa., and principal investigator of the LEADR LBBAP study. “These results build on our earlier findings and reinforce the clinical safety and defibrillation efficacy of the OmniaSecure defibrillation lead when used for conduction system pacing, including in advanced applications like LOT-CRT-D.”

**OmniaSecure Lead Demonstrates Reliable Performance in Right Ventricle Regardless of Race and Age in LEADR Pivotal Trial**

Separately, a data sub-analysis from the LEADR (Lead Evaluation for Defibrillation and Reliability) Pivotal Trial, evaluating the OmniaSecure defibrillation lead in traditional locations within the right ventricle, showed the lead exhibited high defibrillation success and a low occurrence of lead-related major complications in patients regardless of their race or age:

- Black patients experienced a slightly lower defibrillation testing success rate (91.7%) compared to white and Asian patients (98.1% and 100%, respectively).
- Patients 30 years or younger had a 100% defibrillation testing success rate, with those older than 30 years of age at 98.1%.
- Separately, the Asian, Black, and other population groups experienced a major complication-free rate of 100% at six months, and the white patient population group had a 97.8% rate. Patients older than 30 had a 97% major complication-free rate at six months, whereas those 30 years or younger had a rate of 100%.

Studies show that sudden cardiac arrest (SCA) is on the rise among adults aged 25-44, with the relative age-adjusted mortality rate nearly doubling from 1999 to 2020.[i] Despite Black patients being disproportionately more likely to experience SCA and qualify for device therapy, they are 31% less likely than white patients to receive implantable defibrillators.[ii]

“Sudden cardiac arrest remains a leading cause of death, and we know certain patient populations face higher risks and less favorable outcomes,” said Pamela K. Mason, M.D., cardiac electrophysiologist at University of Virginia Health System in Charlottesville, Va., who presented the data at the meeting. “As physicians, having a reliable defibrillation lead that performs well across populations gives us greater confidence in our ability to protect more patients from life-threatening arrhythmias and sudden cardiac death.”

In a third analysis, seven pediatric patients (median age 14) were successfully implanted with the OmniaSecure lead under Compassionate Use from the U.S. Food and Drug Administration (FDA), with no major lead-related complications at implant or during follow up. The OmniaSecure lead is the first-ever defibrillation lead approved by the FDA for traditional locations within the right ventricle for both adult and adolescent pediatric use for patients 12 years of age and older in the U.S.

Each year around 2 million cases of sudden cardiac arrest (SCA) are reported worldwide.[iii] Implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds), such as the Medtronic Cobalt™ and Crome™ family of ICDs and CRT-Ds, are the standard for preventing sudden cardiac death. As the world's smallest defibrillation lead, the OmniaSecure lead connects to an ICD or CRT-D, and treats potentially life threatening ventricular tachyarrhythmias (VT), ventricular fibrillation (VF) and bradyarrhythmias – all contributors to SCA.

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[i] Trends in Sudden Cardiac Death Among Adults Aged 25 to 44 Years in the United States: An Analysis of 2 Large US Databases | Journal of the American Heart Association.

[ii] Tertulien, T., Bush, K., Jackson, L. et al. (2023). Racial and Ethnic Disparities in Implantable Cardioverter-Defibrillator Utilization: A Contemporary Review. Current Treatment Options in Cardiovascular Medicine, 25(12), 771–791 (2023). https://doi.org/10.1007/s11936-023-01025-z.

https://news.medtronic.com/Compelling-data-at-ESC-Congress-2025-reinforce-safety-and-performance-of-the-Medtronic-OmniaSecure-TM-defibrillation-lead,-including-in-the-left-bundle-branch-area