Medtronic News

Medtronic receives FDA approval for smallest-diameter, lumenless defibrillation lead, the OmniaSecure™ lead and announces investigational clinical study results

Adding to the Medtronic portfolio of catheter-based lead solutions, the novel OmniaSecure defibrillation lead allows for precise delivery and placement in the right ventricle

Heart Rhythm 2025: Late-breaking clinical study results evaluating the OmniaSecure lead for investigational use in the LBBAP location show high defibrillation success

GALWAY, Ireland and SAN DIEGO, April 25, 2025 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, received U.S. Food and Drug Administration (FDA) approval for the OmniaSecure™ defibrillation lead for placement within the right ventricle. The lead, built on the highly reliable SelectSecure™ Model 3830 pacing lead and delivered via catheter, builds on the Medtronic portfolio of lead solutions designed for precise delivery and placement. The lead connects to an implantable defibrillator, and treats potentially life threatening ventricular tachyarrhythmias, ventricular fibrillation (VT/VF) and bradyarrhythmias. As the world's smallest defibrillation lead (4.7 French, or 1.6mm), the OmniaSecure lead represents a meaningful innovation in electrophysiology, and is indicated for stimulation in the right ventricle for adults and adolescent pediatric patients ages 12 and up, including those with smaller anatomies.

Separately, the company is also studying placing the novel, small-diameter OmniaSecure defibrillation lead in the left bundle branch (LBB) area, which has the potential to enable physiologic pacing to more closely mimic the heart's natural conduction system. Investigational outcomes of this study were presented at Heart Rhythm 2025 in San Diego. The results from the study demonstrate high defibrillation success of 100% at implant when the lead is implanted in the LBB area. Globally, the OmniaSecure defibrillation lead is investigational for use in LBB area and requires FDA approval in the future.

Implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) are the standard for preventing sudden cardiac death. The ICD/CRT-D connects to a defibrillation lead (insulated electrical wire) that forms the electrical conduit between the device and the heart. The lead senses the heartbeat, and transmits signals to the implanted device, which then delivers therapy to correct or interrupt abnormally fast rhythms. The lead must flex with millions of heart contractions over a lifetime.

Existing defibrillation leads are larger in diameter than the OmniaSecure lead. A larger-diameter lead may increase the potential for downstream complications, such as venous occlusion or tricuspid valve regurgitation.

"FDA approval for the OmniaSecure defibrillation lead furthers our ability to offer physicians and patients a transvenous solution designed to be smaller to help minimize complications–including vascular complications and valve interaction–with strong, reliable lead durability. We engineered the OmniaSecure lead based on the trusted SelectSecure Model 3830 pacing lead, which has been the lead of choice for many physicians for more than 20 years," said Alan Cheng, M.D., chief medical officer of the Cardiac Rhythm Management business, which is part of the Cardiovascular Portfolio at Medtronic. "This milestone underscores our commitment to driving clinical innovations that help patients today while paving the way for future innovations that will usher in the next era of electrophysiology."

Previously, researchers presented late breaking data from the global Lead Evaluation for Defibrillation and Reliability (LEADR) Pivotal Trial showing the OmniaSecure defibrillation lead met its primary safety and effectiveness endpoints and exceeded prespecified performance goals when placed within the right ventricle. The results were presented during Heart Rhythm 2024, simultaneously published in *Heart Rhythm*, and are the basis of FDA approval for the traditional right ventricular lead placement indication.

Late-Breaking LEADR LBBAP Results Presented at Heart Rhythm 2025

Researchers presented late-breaking results at Heart Rhythm 2025 for the LEADR LBBAP (Lead Evaluation for Defibrillation and Reliability in Left Bundle Branch Area Pacing) study that showed the OmniaSecure defibrillation lead demonstrated high defibrillation success when placed in the LBB area for patients indicated for an ICD or CRT-D. Placing the defibrillation lead in the LBB area is being evaluated as an alternative to right ventricular stimulation for sensing, pacing, cardioversion and defibrillation.

Defibrillation testing conducted in 162 patients at device implantation was successful in 100% of cases, with the study meeting the prespecified efficacy goal of 88%. Of the first 193 patients implanted in the study, the OmniaSecure lead was successfully implanted per protocol in 95.8% of the procedures as reported by physician investigators. There were no procedure-related major complications such as early helix or lead fracture, system revision, or death.

"The left bundle branch area is emerging as an option for more physiologic pacing for patients who receive an ICD or CRT-D to treat dangerous heart rhythms," said Pugazhendhi Vijayaraman, M.D., cardiac electrophysiologist at Geisinger Wyoming Valley Medical Center in Wilkes-Barre, Pa., who presented the data at the meeting. "The option to place a lead in the left bundle branch area may provide for physiologic pacing by engaging the heart's natural conduction system. These positive preliminary results for the LEADR LBBAP study are encouraging and highlight the potential versatility of the OmniaSecure defibrillation lead."

The LEADR LBBAP trial is a global, prospective, non-randomized, multi-center study. The study has enrolled approximately 300 patients at 24 sites in 11 countries in North America, Europe, Asia and Australia. Patients enrolled in the study indicated for an ICD are being followed out to 3 months while patients indicated for CRT-D are being followed out to 6 months post-implant.

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 (NYSE: MDT), 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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