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Medtronic announces CE mark and first commercial implants in Europe for the small-diameter, lumenless OmniaSecure™ defibrillation lead

Medtronic, a global leader in healthcare technology, today announced CE mark and first commercial implants in Europe for the OmniaSecure™ defibrillation lead for traditional 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[1] (4.7 French, or 1.6mm), the OmniaSecure lead represents a meaningful innovation in electrophysiology, and is indicated for stimulation in the right ventricle.

Implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) are the standard for preventing sudden cardiac death[2]. 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 transvenous defibrillation lead remains a vulnerable point in ICD/CRT-D systems today[3] due to potential lead degradation and fracture, which may result in various adverse patient outcomes. 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.[4-6]

The OmniaSecure™ defibrillation lead was evaluated in the LEADR trial, a prospective, multicenter clinical study, enrolling 675 patients across 45 global sites. The study met and exceeded its primary safety and performance goals, showing high defibrillation efficacy, a low rate of lead-related complications, and reliable performance through three years of follow-up.[7]

Implant success was high at 97.9%, with nearly all leads placed in the intended right ventricular position. The lead demonstrated excellent durability and electrical performance. [7] Long-term modeling predicts 98.2% fracture-free

performance at 10 years. [8] Freedom from major lead-related complications was 96.5% atthree years.[7]

Results from the study were published in Circulation: Arrhythmia and Electrophysiology.

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 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.

Contacts:
Maria Trenzado
Communications for Western Europe
maria.trenzado@medtronic.com

1. Size Comparison of Medtronic OmniaSecure Defibrillation Lead versus Other Commercially Available Defibrillation Leads. 2024. Medtronic data on file
2. 2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (p.51)
3. Swerdlow CD, et al. J Am Coll Cardiol. 2016;67:1358–1368.
4. Bharmanee A, et al. Pacing Clin Electrophysiol. 2015 Nov;38(11):1343-50.
5. Çeliker C, et al. Int J Angiol. 1998 May;7(3):265-7.
6. Tatum R, et al. Pacing Clin Electrophysiol. 2021;44(8):1297-1302.
7. Crossley, George H., et al. "Safety and Efficacy of the Novel OmniaSecure Defibrillation Lead through Long-Term Follow-Up: Final Results from the LEADR Trial." Circulation: Arrhythmia and Electrophysiology, vol. 19, no. 1, Jan. 2026,
8. Crossley, George H, et al. "High Predicted Durability for the Novel Small-Diameter OmniaSecure Defibrillation Lead." Heart Rhythm, vol. 22, no. 2, Feb. 2025, pp. 302–310, pubmed.ncbi.nlm.nih.gov/39341436/, https://doi.org/10.1016/j.hrthm.2024.09.005.

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