Abbott Receives FDA Approval And CE Mark For Implantable Cardioverter-Defibrillator Lead Designed To Work With The Heart's Natural Electrical System

- The UltiSynq™ defibrillation lead is designed for implantation in the left bundle branch area of the heart to deliver both cardiac pacing and defibrillation therapy, as studied in the ASCEND CSP IDE clinical trial [1, 2]
- The ASCEND trial was a global implantable cardioverter-defibrillator (ICD) conduction system pacing (CSP) lead trial that demonstrated systematic electrocardiogram confirmation of left bundle branch area pacing (LBBAP), and high rates of true or likely left bundle branch pacing (LBBP) (86%)[1]
- LBBAP is a conduction system pacing (CSP) approach that works with the heart's natural electrical system to help restore a more coordinated heartbeat

ABBOTT PARK, Ill., Nov 10, 2026 – Abbott, the global healthcare leader, announced today it received U.S. Food and Drug Administration (FDA) approval and CE Mark for the UltiSynq™ defibrillation lead, which is designed to deliver both conduction system pacing and defibrillation therapy. These approvals for the U.S. and EU provide an additional lead option for patients who are candidates for both conduction system pacing and defibrillation protection.[1]

Approximately 150,000 ICDs are implanted in the United States and 140,000 in Europe each year, representing a significant patient population for whom pacing performance has meaningful long-term consequences.3,[4] Left bundle branch area pacing (LBBAP) has emerged as a conduction system pacing approach aiming to restore the heart's natural pattern of electrical activation.

Clinical Study Results Supporting FDA Approval and CE Mark

The UltiSynq defibrillation lead has been designated as an FDA breakthrough device, a program that expedites the development and prioritizes review of medical devices that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating conditions.

FDA approval and CE Mark of the UltiSynq defibrillation lead was supported by results from the ASCEND CSP IDE trial, a prospective, multicenter, global study evaluating the safety and effectiveness of the UltiSynq defibrillation lead in patients indicated for ICD or cardiac resynchronization therapy defibrillator (CRT-D) therapy.

Presented as late-breaking data at the Heart Rhythm Society annual meeting in April 2026, the three-month results demonstrated that UltiSynq defibrillation lead exceeded all pre-specified primary safety and effectiveness endpoints.[1]

Key study findings included:

- Among 205 implant attempts, lead implantation was successful in 98.5% of patients.[1]
- Leads required a mean of less than one reposition attempt per patient to identify pacing target.[1]
- Among successfully implanted patients, 86% achieved LBBP or likely LBBP, meaning the lead stimulated or likely stimulated the heart's natural conduction pathway. The remaining 14% had left ventricular septal pacing. Together with LBBP, these approaches constitute LBBAP.
- The three-month major complication-free rate was 97.5%, exceeding the pre-specified safety performance goal.[1]
- In the 120 patients who completed defibrillation testing, successful defibrillation was observed in 100%. No lead repositioning was required to achieve defibrillation.[1]

UltiSynq is built on a proven reliable ICD lead platform with distinct, true bipolar sensing, which uses two closely spaced electrodes within the lead to accurately detect the heart's signals from the ventricles. It incorporates a short shock coil designed to support positioning precision. UltiSynq's ease of implantation is designed to deliver CSP benefits, working with the heart's natural electrical wiring system for a coordinated heartbeat, while its true bipolar sensing may help reduce susceptibility to P-wave oversensing, which occurs when a device mistakes the upper heart's signal for a lower chamber beat and could trigger unnecessary therapy.[1,2,5]

"UltiSynq demonstrates what is achievable when a lead is designed to support conduction system pacing," said Pugazhendhi Vijayaraman, MD, system director of Cardiac Electrophysiology at Geisinger Heart Institute, Danville, Pa. "The observed implant success, LBBAP capture results, and defibrillation testing outcomes give physicians compelling data on this lead option for patients who require defibrillation protection and are candidates for conduction system pacing."

"UltiSynq represents an important advance as Abbott continues to build a comprehensive cardiac rhythm management portfolio," said Randel Woodgrift, senior vice president of Abbott's cardiac rhythm management business. "Physicians now have a compelling option for conduction system pacing in patients who also need ICD or CRT-D therapy. UltiSynq extends physiologic pacing to patients who require both rhythm management and defibrillation protection."

About the UltiSynq defibrillation lead

The UltiSynq defibrillation lead is designed for long-term attachment to compatible ICD or CRT-D systems in patients who are at risk of sudden cardiac death due to life-threatening tachyarrhythmias. The ASCEND CSP IDE trial was conducted across centers in the United States, Canada, Europe, and the Asia-Pacific region.[1]

Important Safety Information

https://www.cardiovascular.abbott/us/en/hcp/products/cardiac-rhythm-management/leads/ultisynq.html

About Abbott

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[1] Schaller RD, et al. Safety and performance of a novel ICD lead for left bundle branch area pacing: Results from the ASCEND CSP trial. Heart Rhythm, 2026. ClinicalTrials.gov: NCT06830746.

[2] Varma, N., Burri, H. et al 'Cardiac resynchronization therapy using a conduction system pacing defibrillation lead in patients meeting CRT-D indications: Six-month clinical outcomes results from the ASCEND CSP study', JACC: Clinical Electrophysiology. Available at: https://doi.org/10.1016/j.jacep.2026.10.003 (Accessed: 27 October 2026).

[3] Yousef, O., et al. Appropriateness of implantable cardioverter-defibrillator device implants in the United States. Heart Rhythm. 2024.

[4] Osca Asensi, J., Fernández-Lozano, I. and Calvo, D., on behalf of the Spanish implantable cardioverter-defibrillator registry collaborators (2025) 'Spanish implantable cardioverter-defibrillator registry. 21st official report of the Heart Rhythm Association of the Spanish Society of Cardiology (2024)', Revista Española de Cardiología (English Edition), 78(12), pp. 1100-1112. Available at: https://doi.org/10.1016/j.rec.2025.08.010

[5] Kato, H., Kajiura, H., Makino, Y., Murakami, H., Kada, K. and Tsuboi, N. (2026) 'Unexpected P-wave oversensing after cardiac resynchronization therapy-defibrillator implantation with an integrated bipolar defibrillation lead', JACC: Clinical Electrophysiology. Available at: https://doi.org/10.1016/j.jacep.2026.08.002

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