Medtronic News

Medtronic announces expanded CE Mark indication for Affera™ Mapping and Ablation System and Sphere-9™ Catheter for treatment of ventricular arrhythmias

Sphere-9 all-in-one mapping and ablation, large-tip focal, dual energy catheter first to be CE Marked for ventricular ablation

New indication marks important milestone for ventricular arrhythmia patients as positive physician sentiment and global expansion for Sphere-9 continue

Sphere VT U.S. pivotal trial enrollment underway

GALWAY, Ireland, Aug. 6, 2026 /PRNewswire/ -- Medtronic (NYSE: MDT), a global leader in healthcare technology, today announced an expanded CE Mark indication for the Affera™ Mapping and Ablation System with Sphere-9™ Catheter to treat ventricular arrhythmias, including ventricular tachycardia (VT) and premature ventricular complexes (PVCs). The Sphere-9 catheter is the first all-in-one mapping and ablation, large-tip focal, dual-energy catheter CE marked for ventricular ablation.

"This milestone is a major step forward as we continue to expand the footprint of the Affera technology to more physicians and patients," said Rebecca Seidel, president of the Electrophysiology Therapies business at Medtronic. "Indication expansion to include ventricular arrhythmias unlocks another fast-growing market opportunity to keep building on our momentum, powered by the versatility, safety and efficiency of the Sphere-9 catheter."

Additionally, in recognition of the critical unmet need for ventricular arrhythmia treatments, the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation for the Sphere-9 catheter for the treatment of ventricular arrhythmias, which provides an expedited regulatory pathway for the technology in this patient population. The Sphere VT pivotal trial to evaluate Sphere-9 for the treatment of VT and support future approval in the US is now enrolling patients.

The Affera Mapping and Ablation System with Sphere-9 Catheter is an all-in-one, dual-energy pulsed field (PF) and radiofrequency (RF) ablation and high-definition mapping catheter for use in cardiac ablation procedures.

"Physicians have long needed better tools for ventricular arrhythmias, and we're proud to deliver a technology that addresses this unmet need and moves the needle on patient care," said Khaldoun Tarakji, M.D., MPH, vice president, chief medical officer, Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. "The unique features of Sphere-9, including a single catheter to map and ablate using radiofrequency or pulsed field energy and a large footprint, make it an excellent tool for a variety of arrhythmias, including those that may be challenging to treat."

About Ventricular Arrhythmias

VT is a potentially life-threatening arrhythmia that causes the heart to beat abnormally fast.[1] Unlike atrial fibrillation, VT affects the lower chamber of the heart and often presents after a heart attack or together with other advanced heart diseases.[1,2] VT patients are often treated with medications and may receive life-saving therapies from implanted defibrillators in the form of pacing or shocks.[1] Catheter ablation for VT is an established treatment option, but outcomes have remained suboptimal[2] with little ablation tool innovation in recent years. As a result, a significant unmet need exists to improve patient care.[3]

PVCs are extra or early heartbeats that start in the heart's lower chambers (ventricles), briefly disrupting normal rhythm and potentially causing a flutter-like feeling in the chest.[4]

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 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 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.

1. Sciria,C. et al. Trends and Outcomes of Catheter Ablation of Ventricular Tachycardia in Patients With Ischemic and Nonischemic Cardiomyopathy. Circ: Arr. and Elec. 2022; vol.15, no. 4.
2. 2019 HRS/EHRA/APHRS/LAHRS expert consensus statement on catheter ablation of ventricular arrhythmias.
3. Cheung, J, et al. Outcomes, Costs, and 30-Day Readmissions After Catheter Ablation of Myocardial Infarct–Associated Ventricular Tachycardia in the Real World: Nationwide Readmissions Database 2010 to 2015. Circ: Arr. and Elec. 2018; vol. 11, issue 11.
4. American Heart Association, "Premature Contractions: PACs and PVCs."https://www.heart.org/en/health-topics/arrhythmia/about-arrhythmia/premature-contractions-pacs-and-pvcs

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