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Medtronic announces positive results from early feasibility study of the Sphere-9™ Catheter with Affera™ Mapping and Ablation System for treatment of ventricular tachycardia

Findings highlight the potential of new investigational waveforms for the all-in-one mapping and dual-energy ablation system in advancing treatment for ventricular arrhythmia patients

Medtronic plc, a global leader in healthcare technology, today announced promising results, including a 100% acute procedural success rate, from an early feasibility study of the Sphere-9™ Catheter with Affera™ Mapping and Ablation System for treatment of sustained ventricular tachycardia (VT). Results were presented as a late breaking clinical trial at the 20th Annual VT Symposium in Philadelphia.

VT is a potentially life-threatening arrhythmia that causes the heart to beat abnormally fast.[1] Unlike atrial fibrillation (AFib), VT affects the lower chamber of the heart and often presents after a heart attack or together with other advanced heart disease.[1,2,3]

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-density mapping catheter for use in cardiac electrophysiology ablation procedures.

“These results, including the excellent overall procedural success rate for eliminating VT, are an encouraging step toward an IDE pivotal trial for this underserved patient population,” said Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services for the Mount Sinai Health System in New York City. “I look forward to the continued evaluation of Sphere-9 for VT patients.”

The study evaluated catheter ablation treatment with Sphere-9 and the Affera system using new investigational RF and PF waveforms for patients who suffer from VT due to scarring from a prior heart attack. A total of 20 patients treated at centers across the United States are being followed for six months post-ablation. Key acute findings include:

- 100% acute procedural success, defined as non-inducibility of clinically relevant VT at the end of the

procedure.

- A combination of RF and PF energy was used for 95% of patients, with one patient receiving RF only.
- The mean procedural time was 198.4±57.9 minutes, with a Sphere-9 catheter dwell time of 153.7±57.4 minutes.
- One primary safety event was reported, with symptoms resolving to baseline.

VT patients are treated with medications and often receive life-saving therapies from implanted defibrillators in the form of pacing or shocks.[1] Catheter ablation for VT is an established treatment option; however, outcomes have remained suboptimal[2,3] with little ablation tool innovation in recent years. As a result, a significant unmet need exists to improve patient care.[4]

"The Sphere-9 catheter, with its large footprint focal design, enhanced stability, integrated mapping and ablation capability in a single catheter, and dual-energy flexibility, introduces multiple innovations aimed at addressing key unmet needs in VT ablation," said Khaldoun Tarakji, M.D., MPH, vice president, chief medical officer, Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. "We are committed to advancing catheter ablation innovation across all cardiac arrhythmias, including complex ventricular arrhythmias for which new treatment options have long been awaited."

The Affera Mapping and Ablation System and Sphere-9 catheter received U.S. Food and Drug Administration (FDA) approval in 2024 for treatment of persistent Afib.

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 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.

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. Zeppenfeld K, et al. European Heart Journal. 2022 Oct 21;43(40):3997-4126.
4. 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.

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