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Medtronic announces first patient enrollment in early feasibility trial for treatment of ventricular tachycardia with Affera™ Mapping and Ablation System and Sphere-9™ Catheter

New investigational energy waveforms created specifically to target ventricular arrhythmias

Ventricular arrhythmia research will provide important clinical evidence using a new technology for patient population in need of new treatment options

Medtronic plc, a global leader in healthcare technology, today announced the first patient has been enrolled in the United States Food and Drug Administration (FDA) early feasibility study evaluating the Affera™ Mapping and Ablation System with Sphere-9™ Catheter using new investigational radiofrequency (RF) and pulsed field (PF) waveforms for treatment of sustained ventricular tachycardia (VT).

“Despite significant advances in cardiac ablation over the last several years, a significant unmet need remains for new and effective treatment options for VT,” said Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services for the Mount Sinai Health System in New York City. “With the first patient treated in this study, we’ve taken an important step forward for patients in this underserved patient population.”

The study will evaluate new investigational RF and PF waveforms for ablation treatment using Sphere-9 and the Affera system for patients who suffer from VT due to scarring from a prior myocardial infarction (heart attack). The Affera Mapping and Ablation System with Sphere-9 Catheter is an all-in-one, dual-energy RF and PF ablation and high-density mapping catheter for use in cardiac ablation procedures. While cardiac ablation is an established treatment for VT, outcomes have remained suboptimal with little innovation in recent years.

“Aligned to our mission, we are continually seeking new ways to improve care for arrhythmia patients. Sphere-9 is an excellent tool for atrial arrhythmias given its unique features, including a single catheter to map and ablate using radiofrequency or pulsed field energy,” said Khaldoun Tarakji, M.D., MPH, vice president, chief medical officer, Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. “Physicians need better tools to treat VT, and this early feasibility study demonstrates our commitment to advancing the clinical evidence in the field. It’s a major step toward evaluating the impact of Sphere-9 on VT outcomes.”

VT is a potentially life-threatening arrhythmia that causes the heart to beat abnormally fast.[1] Unlike 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] 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]

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.

Dr. Reddy is a paid consultant for Medtronic.

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.

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