Medtronic News

Medtronic announces key Affera™ clinical study milestones for Sphere-9™ and Sphere-360™ catheters as global adoption continues

- HRS late-breaking data: Interim results highlight six-month outcomes for patients treated with the Sphere-9 catheter for sustained monomorphic ventricular tachycardia (VT)
- Breakthrough device designation granted for use of the Sphere-9 catheter for treatment of VT; U.S. pivotal trial approved by FDA
- New at HRS: data show consistent durability for the Sphere-360 catheter across patient anatomies; Sphere-360 approved in CE Mark geographies
- First patients enrolled in Conquer-AF trial to evaluate the Sphere-9 catheter for repeat atrial fibrillation procedures

GALWAY, Ireland and CHICAGO, April 25, 2026 /PRNewswire/ -- Medtronic plc, (NYSE: MDT), a global leader in healthcare technology, today announced continued momentum for the Affera™ family of technologies for cardiac arrhythmia treatment, including promising data presented at the Heart Rhythm Society (HRS) Annual Meeting and the start of a new trial to evaluate a broader population of atrial fibrillation (AFib) patients. With ongoing positive physician feedback and global commercial expansion, Medtronic continues to invest in clinical research to study the Affera mapping and ablation system for potential new indications.

Results from the ongoing early feasibility study evaluating the Affera mapping and ablation system and the Sphere-9™ catheter for treatment of recurrent sustained monomorphic ventricular tachycardia (VT) after a heart attack were presented as a late-breaking clinical trial. Patients treated at centers across the U.S. were followed for six months post-ablation. Results showed 65.5% of patients remaining free from VT recurrence at six months.[1]

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

In recognition of this critical unmet need, the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation for the Sphere-9 catheter for the treatment of VT, providing an expedited regulatory pathway for the technology.

"Physicians urgently need better tools for VT that are safe, effective, and increase procedure efficiency, so it's exciting to see sustained outcomes for ischemic patients treated with the Affera mapping and ablation system and the Sphere-9 catheter after six months," said Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services for the Mount Sinai Health System in New York City. "Moving this research forward to the IDE trial and expanding the patient population to include non-ischemic patients are positive next steps for VT patients."

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

Also at HRS, a new sub-analysis from the Sphere-360™ European study demonstrated positive results related to durability of lesions in AFib procedures in patients with left common pulmonary veins. Results showed 100% lesion durability, highlighting consistency across patients with varied anatomies. Previously reported durability data showed 98% per vein and 93% per patient durability through invasive remapping at 75 days post-ablation. The Sphere-360 catheter is an all-in-one mapping and single-shot pulsed field ablation (PFA) catheter for treatment of paroxysmal AFib that is approved in Europe and investigational in the U.S., with the U.S. IDE trial underway.

Medtronic also announced the first patient enrollment in Conquer-AF, a prospective, multi-center, interventional, non-

randomized study to characterize the safety and effectiveness of the Sphere-9 catheter in patients with recurrent paroxysmal or persistent AFib who have previously had an ablation procedure. The study is enrolling patients in the U.S., Europe, and Australia.

"Our robust clinical research program reinforces our commitment to advancing safe, effective, and efficient therapies to help physicians treat a wide range of cardiac arrhythmias and improve patients' lives," 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 encouraging results shown in this VT study underscore the versatility of the Sphere-9 catheter in treating a variety of different arrhythmias and the potential to advance care and outcomes for patients whose disease is often complex. With the Sphere-360 catheter, consistent durability across a wide range of patient anatomies is good news for patients and for physicians' workflow."

The Sphere-9 catheter is approved in multiple geographies including the U.S., Europe, Australia, and Japan. Indications vary by geography. The Sphere-9 catheter is not approved for VT in any geography. The Sphere-360 catheter received CE Mark in January 2026, and the Horizon 360 IDE trial is enrolling patients in the U.S.

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 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. Reddy VY, et al. Six-month outcomes from the Sphere-9 ventricular tachycardia early feasibility study: Dual-energy lattice-tip mapping and ablation catheter for ventricular tachycardia treatment. Late-Breaking Clinical Trial, Heart Rhythm Society Annual Meeting, April 25, 2026; Chicago IL.
2. 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.
3. Cronin EM, et al. 2019 HRS/EHRA/APHRS/LAHRS expert consensus statement on catheter ablation of ventricular arrhythmias. EP Europace. 2019 Aug 1;21(8):1143-4.
4. Zeppenfeld K, et al. 2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. Eur Heart J. 2022 Oct 21;43(40):3997-4126.

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