Medtronic News

Medtronic announces positive results from real-world registries for the Sphere-9™ catheter and PulseSelect™ PFA System at APHRS 2026

- *Global APEX and REAL PULSE Registry analyses report strong safety and procedural outcomes across atrial and ventricular arrhythmias*
- *Medtronic continues to strengthen its position in cardiac ablation, building on a legacy of innovation in electrophysiology*

GALWAY, Ireland, Oct. 22, 2026 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced positive real-world registry results for the Affera™ Mapping and Ablation System with the Sphere-9™ Catheter and the PulseSelect™ Pulsed Field Ablation (PFA) System. The global registry analyses, presented at the Asia Pacific Heart Rhythm Society (APHRS) 2026 scientific meeting, evaluated prospectively enrolled patients with atrial fibrillation (AFib) and ventricular tachycardia (VT).

"These favorable results reinforce our confidence in the safety and performance of our ablation technologies worldwide. It is very encouraging to see physicians' positive response and real-world evidence that supports effective, safe, and efficient care for patients with a wide range of arrhythmias," said Khaldoun Tarakji, M.D., MPH, Vice President and Chief of Science, Research and Technology, Electrophysiology Therapies at Medtronic.

APEX registry: Sphere-9 real-world outcomes in atrial fibrillation

The APEX global prospective registry analysis included 1,050 patients with AFib treated with the Sphere-9 catheter and Affera Mapping and Ablation System across 28 global sites. The major complication rate was low at 1.1%, with no acute kidney injury, severe coronary spasm or phrenic nerve injury. Major complication rates did not differ significantly between de novo and repeat ablation procedures.

REAL PULSE global registry: PulseSelect real-world safety and performance

The REAL PULSE global prospective registry analysis included 1,160 atrial fibrillation patients treated with the PulseSelect PFA system across 38 global sites. Results were positive, including a 100% acute success rate and a low acute major complication rate of 0.09%.

APEX registry: Expanding evidence in ventricular tachycardia

A separate European APEX registry analysis evaluated use of the Sphere-9 catheter in patients undergoing ablation for VT, demonstrating promising results for the potential of the Sphere-9 catheter and pulsed field ablation in a patient population that can be challenging to treat.

- The analysis included 46 patients with ischemic and non-ischemic sustained VT and demonstrated high acute success (87%) and estimated six-month freedom from VT recurrence (75%).
- There was no significant difference in long-term freedom from arrhythmia recurrence in ischemic and non-ischemic cardiomyopathy patients.
- Six major complications were reported in four patients.

Sphere-9 is CE marked for VT and is investigational only and not approved for VT in the United States. The ventricular ablation indication may not be approved or cleared in all markets.

"As momentum continues to build across our portfolio, it is encouraging to see long-term data support the safety and efficacy profiles of our ablation technologies and the positive impact they are having on procedural workflows," said Felicia Kurz, Vice President and General Manager, Cardiac Ablation Solutions, which is part of the Electrophysiology Therapies business at Medtronic. "We will continue to innovate and strengthen our leadership in cardiac ablation, with a focus on advancing safe, effective and efficient care for patients."

The Medtronic cardiac ablation portfolio offers physicians multiple technologies for patient care, including the Sphere-9 catheter, an all-in-one catheter that combines high-definition mapping with pulsed field and radiofrequency ablation using the Affera mapping and ablation system, and the PulseSelect PFA system, a single-shot solution for pulmonary vein isolation.

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, 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.

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