

JAN 17, 2025

Medtronic drives continued momentum with new data and case presentations for Affera™ Mapping and Ablation System and PulseSelect™ at AF Symposium

Data include durability of PulseSelect integrated with the Affera system, same day discharge and zero fluoroscopy with Affera and Sphere-9™ Catheter

Highlights underscore positive momentum of commercial launch of Affera in the U.S. and continued strong adoption of PulseSelect globally

Real-world use continues to demonstrate safety, efficacy and efficiency of both PFA technologies amid global expansion

JANUARY 17, 2025 - Medtronic, a global leader in healthcare technology, today announced new data and case presentations for the company's pulsed field ablation (PFA) technologies, Affera™ Mapping and Ablation System with Sphere-9™ Catheter and PulseSelect™, to be presented at the AF Symposium in Boston, MA.

"We are encouraged by the continued successful adoption of both our PFA technologies, including commercial case roll out of Affera and Sphere-9 in the U.S. and the ongoing global expansion of PulseSelect, and the real-world feedback we are receiving that supports existing clinical evidence for safety, efficacy and efficiency," said Rebecca Seidel, president of the Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. "These new data and cases at AF Symposium will provide physicians with additional valuable insight as awareness and use of our PFA offerings continue to increase around the world."

AF Symposium 2025 Highlights

Medtronic PFA technologies to be featured in data presentations and live and pre-recorded cases at the AF Symposium include:

Data presentations

- **Chronic durability** of pulmonary vein isolation using the PulseSelect PFA Catheter integrated with Affera
- **Same-day discharge** can be performed safely after AF catheter ablation using a wide-footprint lattice-tip dual energy system

- Impact of using Affera with Sphere-9 wide-footprint dual energy mapping and ablation system on **fluoroscopy usage**

Case presentations

Friday January 17

- **Redo Ablation of Atrial Fibrillation Using Sphere-9 PFA Catheter**
Srinivas Dukkipati, MD & Daniel Musikantow, MD
- **Ablation of Paroxysmal Atrial Fibrillation Using the PulseSelect PFA Catheter**
Stavros Mountantonakis, MD, MBA
- **Ablation of Persistent Atrial Fibrillation Using Sphere-9 PFA Catheter**
Amin Al-Ahmad, MD & Weeranun Bode, MD

Saturday, January 18

- **Pulmonary Vein Isolation Using the Sphere 360 Large Lattice Tip PFA Catheter**
Josef Kautzner, MD, PhD
- **Ablation of Persistent Atrial Fibrillation Using the PulseSelect PFA Catheter**
Devi Nair, MD

Medtronic is the only company with both single shot (PulseSelect) and focal (Affera Mapping and Ablation System with Sphere-9 Catheter) commercially available PFA options to meet patients' and clinicians' varied needs. Affera is a first-of-its-kind, all-in-one HD-mapping and dual-energy (radiofrequency and pulsed field) ablation catheter approved by the United States Food and Drug Administration (FDA) in October 2024 for the treatment of persistent atrial fibrillation (AFib) and cavotricuspid isthmus (CTI) dependent atrial flutter. Affera received CE Mark in March 2023.

PulseSelect was the first PFA system approved by the FDA and is the only system available to treat paroxysmal (intermittent) and persistent AFib.

AFib is the most common atrial arrhythmia with nearly 60 million people affected worldwide¹ and an additional five million more patients anticipated every year by 2030². Atrial arrhythmias, such as AFib, are associated with serious complications including heart failure, stroke and increased risk of death³⁻⁶.

About PulseSelect

PulseSelect uses pulsed field ablation, a non-thermal approach to preferentially target the pulmonary veins for ablation, avoiding unwanted injury to surrounding structures, which is a risk of traditional ablation technologies (thermal energy sources). The catheter utilizes a proprietary biphasic waveform, a unique built-in over-the-wire design and 20-degree forward tilt to support procedural maneuverability, reliability, and safety, as demonstrated by one of the safest global ablation clinical trials to-date, PULSED AF. Based on data from this trial, the catheter has demonstrated efficient pulmonary vein isolation with an average of 30 seconds of total energy delivery time to isolate all veins.

About Affera

The Affera Mapping and Ablation System includes the Sphere-9 Catheter and the Affera Prism-1 Mapping Software. The Sphere-9 Catheter, coupled with the integrated mapping and navigation system, quickly generates sophisticated electro-anatomical maps allowing the physician to deliver wide-area focal ablation lesions of choice between RF or PFA, based on the patient and procedure needs. Given its size, the all-in-one catheter's nitinol 9mm ablation tip has the potential to require fewer focal ablation lesion applications that may result in shorter procedure times than standard irrigated ablation catheters⁷. The intuitive mapping software enables an optimized user experience by delivering streamlined insights and feedback to support procedure performance.

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.

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Roth GA, Mensah GA, Johnson CO et al. Global Burden of Cardiovascular Diseases and Risk Factors, 1990-2019: Update From the GBD 2019 Study. *J Am Coll Cardiol* 2020;76:2982-3021.

²Di Carlo A, et al. *Europace*. 2019;21:1468-1475.

Miyasaka Y, Barnes ME, Bailey KR, et al. Mortality trends in patients diagnosed with
3first atrial fibrillation: a 21-year community-based study. J Am Coll Cardiol
2007;49:986-92.

Hindricks G, Potpara T, Dagres N, et al. 2020 ESC Guidelines for the diagnosis and
4management of atrial fibrillation developed in collaboration with the European
Association of Cardio-Thoracic Surgery (EACTS). Eur Heart J 2020.

5Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for
stroke: the Framingham Study. Stroke 1991;22:983-8.

Lubitz SA, Moser C, Sullivan L, et al. Atrial fibrillation patterns and risks of
6subsequent stroke, heart failure, or death in the community. J Am Heart Assoc
2013;2:e000126

7Reddy VY, et al. Circ Arrhythm Electrophysiol. 2020;13:e008718.

<https://news.medtronic.com/Medtronic-drives-continued-momentum-with-new-data-and-case-presentations-for-Affera-TM-Mapping-and-Ablation-System-and-PulseSelect-TM-at-AF-Symposium>