Medtronic News

Affera™ momentum continues as Medtronic announces CE Mark in Europe and U.S. IDE first cases for Sphere-360™ PFA catheter to treat paroxysmal atrial fibrillation

First-of-its-kind, rotation-free single-shot PFA catheter supported by strong safety and efficacy data adds to the groundbreaking Affera family of technologies in Europe

Successful completion of first cases at multiple sites kicks off Horizon 360 IDE pivotal trial in the United States

GALWAY, Ireland, Jan. 23, 2026 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced two major milestones for the Affera™ Sphere-360™ catheter, a first-of-its-kind, all-in-one mapping and single-shot pulsed field ablation (PFA) catheter for treatment of paroxysmal atrial fibrillation (AFib): CE Mark in Europe and the completion of first cases in the Horizon 360 IDE pivotal trial in the United States.

The Sphere-360 catheter was designed in response to physician feedback expressing the need for a simple, differentiated workflow and predictable outcomes using a single catheter that accommodates anatomical variations in pulmonary veins. Seamlessly integrated with the Affera mapping and ablation system, the catheter offers an adjustable configuration lattice design that conforms to the shape of the veins and allows energy delivery without the need to rotate the catheter in each position.

The Affera mapping and ablation system and the Sphere-9™ all-in-one mapping and ablation catheter have been rapidly adopted by physicians in multiple geographies for their excellent safety and durability profile.

"The Sphere-360 catheter offers an excellent balance between ease of use and consistency in outcomes. Its design conforms to the pulmonary vein in a unique way that delivers consistent, effective and durable lesions for AFib patients, without any rotation of the catheter," said Tobias Reichlin, M.D., Director of Electrophysiology at Inselspital University Hospital in Bern, Switzerland. "With the full integration into the Affera mapping system, it's an exciting step forward for patient care in Europe."

Additional benefits of Sphere-360 include:

- **Delivers circumferential, consistent lesions** from the entire 34 mm lattice without catheter rotation, enhancing workflow efficiency
- **Adapts to the vein** by adjusting the shape of the conformable lattice to the patient's anatomy
- **All-in-one catheter** for navigation, mapping, and ablation with a single transseptal puncture and zero catheter exchange
- **Real-time local impedance** information to assess catheter proximity to tissue
- **Easy access to pulmonary veins with enhanced stability** through its over-the-wire design
- **Compatible with FlexCath Contour™ 10 French** deflectable sheath designed for easy catheter positioning

"Advances in electrophysiology over the past several years are having a significant impact on care for arrhythmia patients, and Affera has been a key part of that impact," said Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services for the Mount Sinai Health System in New York City. "Now with Sphere-360, we have a new and differentiated single-shot PFA catheter with the potential to deliver the next phase of innovation. It's an exciting time for physicians and patients and we're not slowing down."

Results from the Sphere-360 European study at one year were presented at the Heart Rhythm Society Annual Meeting and published in the *Heart Rhythm Journal* in April 2025. The prospective, single-arm, multi-center trial in European centers demonstrated excellent efficacy, safety, and durability that led to CE Mark.

"The achievement of CE Mark for Sphere-360, as well as the first cases in the U.S. IDE trial, mark two major achievements in our effort to deliver new and better treatments to AFib patients," said Rebecca Seidel, president of the Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio. "We're committed to leading in PFA and bringing meaningful

innovation at a regular cadence."

The Horizon 360 IDE study is a prospective, single-arm clinical study at centers across the U.S. The study will evaluate the safety and effectiveness of the Sphere-360 catheter with the Affera mapping and ablation system for treating paroxysmal AFib.

About Medtronic PFA

Medtronic was the first company with two PFA offerings for physicians and patients. The PulseSelect™ Pulsed Field Ablation System offers physicians a safe, single-shot solution for pulmonary vein isolation (PVI) and is now available in more than 35 countries.

Sphere-9™ is the only all-in-one, dual energy mapping and ablation catheter for treatment of persistent AFib and concomitant CTI-dependent atrial flutter. The Affera system, together with the Sphere-9 catheter, enables physician treatment flexibility with its wide area focal design and 9mm lattice tip that can be used with an 8.5Fr sheath. Affera is approved in the U.S., Europe, Australia and New Zealand and Japan, with global expansion ongoing. The Affera Mapping and Ablation System with Sphere-9 Catheter received CE Mark in March 2023 and U.S. Food and Drug Administration (FDA) approval in October 2024.

The Sphere-360 catheter is approved in Europe and investigational in the United States. For more information on the Affera system, the Sphere-9 catheter and the Sphere-360 catheter, visit Medtronic.com.

About Atrial Fibrillation

AFib is one of the most common and undertreated heart rhythm disorders, affecting more than 60 million people worldwide[1]. AFib is a progressive disease, often beginning as paroxysmal AFib (presents intermittently) and progressing to persistent (lasts for more than 7+ days without stopping). As the disease progresses, the risk of serious complications including heart failure, stroke and risk of death increases[2-5].

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.

References

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