Medtronic News

A new paradigm in electrophysiology: Medtronic receives FDA approval of Affera™ Mapping and Ablation System and Sphere-9™ Catheter

- First-of-its-kind, all-in-one HD-mapping and dual energy (pulsed field and radiofrequency) ablation catheter
- Highly anticipated by electrophysiologists for its innovation and demonstrated safety and efficacy as well as improved workflow and short learning curve
- Now with two pulsed field ablation (PFA) offerings and a portfolio of electrophysiology solutions, Medtronic is shaping the future of arrhythmia treatment today

GALWAY, Ireland, Oct. 24, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced United States Food and Drug Administration (FDA) approval of the Affera™ Mapping and Ablation System with Sphere-9™ Catheter, an all-in-one, high-density (HD) mapping and pulsed field (PF) and radiofrequency (RF) ablation catheter for treatment of persistent atrial fibrillation (AFib) and for RF ablation of cavotricuspid isthmus (CTI) dependent atrial flutter.

With this approval, Medtronic is now the first and only company with two PFA technologies available for patients with Afib. The PulseSelect™ Pulsed Field Ablation System, which was FDA approved in December 2023, offers physicians a safe, single-shot solution for pulmonary vein isolation (PVI) while the Affera Sphere-9 catheter enables physician treatment flexibility with its wide area focal design and 9mm lattice tip that can used with an 8.5Fr sheath.

"The significance of this innovative technology should be underscored; Affera is a game changer for treatment of Afib and atrial flutter," said Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services for the Mount Sinai Health System in New York City. "The Affera system provides physicians with one safe, effective and efficient solution to this common and increasing problem in heart disease that needs optimized solutions for patients. With a short learning curve for experienced physicians, the possibilities are boundless for the treatment of Afib."

With a trailblazing design, the Sphere-9 catheter offers physicians the option of both PF and RF energy delivery, fully integrated with the Affera Mapping and Ablation System. The Sphere-9 catheter enhances workflow efficiency for physicians while providing excellent safety and efficacy outcomes.

"The Affera system was designed to address procedural challenges faced by the electrophysiology community while maintaining a high standard of safety and efficacy for patients. By enabling a single transeptal, zero-fluoroscopy, and zero-exchange workflow, the Sphere-9 catheter uniquely integrates both mapping and ablation technologies, offering the flexibility to use either pulsed field or radiofrequency energy," said Doron Harlev, vice president of engineering for Cardiac Ablation Solutions at Medtronic and founder of Affera. "This marks an exciting milestone for the field, with Medtronic's robust innovation pipeline poised to drive continued progress."

The approval was based on excellent results demonstrated in the pivotalSPHERE Per-AF study, an FDA Investigational Device Exemption (IDE) trial, which compared the Sphere-9 catheter with the Affera Mapping and Ablation System to the conventional Thermocool SmartTouch® SF radiofrequency ablation catheter with the Carto™*3 System. The Affera Mapping and Ablation System and Sphere-9 catheter also received CE Mark in March 2023 and was approved in Australia in September 2024. In October 2024, Medtronic announced the start of anearly feasibility study to evaluate the Sphere-9 catheter for treatment of ventricular tachycardia (VT), a cardiac arrhythmia in which the lower chamber of the heart beats abnormally fast.

"At Medtronic, we have a 75-year tradition of bringing disruptive innovation to market, guided by our mission and commitment to address the unmet needs of patients. With the approval of Affera, we are excited to bring a novel mapping and ablation solution to clinicians that is intended to make atrial fibrillation treatment safer, more effective, and more efficient," said Rebecca Seidel, president of the Cardiac Ablation Solutions business, which is part of the Medtronic Cardiovascular Portfolio. "The potential of

Affera is limitless. We will continue to fulfill our commitment to innovation, including new indications, to advance cardiovascular care and improve patient outcomes."

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 paroxsymal 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].

For more information on Affera and the Sphere-9 catheter, visitMedtronic.com.

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 (NYSE:MDT), 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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Dr. Reddy is a paid consultant for Medtronic.

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