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Novel Medtronic Affera™ Mapping and Ablation System with the Sphere-9™ Catheter Demonstrates Safety and Performance for the Treatment of Atrial Fibrillation

12-month results reinforce versatility and durability for the treatment of paroxysmal and persistent AFib with the first-of-its-kind pulsed field ablation, radiofrequency, and high density mapping Sphere-9™ Catheter

Medtronic today announced the 12-month findings that supported the Affera™ Mapping and Ablation System CE Mark, demonstrating that the Sphere-9™ Catheter can successfully treat patients with either paroxysmal or persistent atrial fibrillation (AFib) using a variety of ablation lesion sets. The data was published in the *JACC: Clinical Electrophysiology*. The Sphere-9 Catheter is an all-in-one wide-area focal catheter with pulsed field ablation (PFA), radiofrequency (RF) and high density (HD) mapping capability. The Affera Mapping and Ablation System, which includes the Sphere-9 Catheter and Affera Mapping System, received CE Mark approval in March 2023.

Treatment with the Sphere-9 Catheter provided 85% one-year freedom from atrial arrhythmias in patients receiving the PULSE3 waveform (the optimized, commercial Affera System pulsed field waveform). In paroxysmal and persistent AF patients who underwent a catheter ablation, 78% of both cohorts remained free from all atrial arrhythmias at the conclusion of the study. The study achieved its primary safety endpoint of 0.6%, including zero incidences of atrio-esophageal fistula, coronary spasm, pulmonary vein stenosis, and phrenic nerve injury.

“With an increasing number of patients presenting with AFib each year, clinicians need greater ability to customize treatment tailored to a patient’s specific needs,” said Vivek Y. Reddy, M.D., Director of Cardiac Arrhythmia Services, Icahn School of Medicine at Mount Sinai and primary investigator of the study. “With the Affera Mapping and Ablation system, we can treat patients safely and efficiently, while also providing durability of lesions to help support long-term outcomes.”

The EU study to support the CE Mark for the Affera Mapping and Ablation System was a prospective, single-arm, multicenter study performed in three European centers with 14 operators. The study enrolled 70 patients with paroxysmal AFib and 108 patients with persistent AFib. Waveform configurations were optimized as the study progressed, and efficacy and durability improved (PULSE1, PULSE2, and PULSE3). During the procedure from first

to last energy application, ablation time was efficient, and ablations were performed in less than 22 minutes among a combination of RF and PF energy modalities. Re-mapping procedures were conducted at 96±43 days to assess lesion durability. Patients were monitored with 48-hour Holter monitoring at six and 12 months, and weekly trans-telephonic monitoring transmissions were collected for 8 weeks and for monthly and symptomatic events thereafter.

“The meticulous design of the study including vigorous clinical follow up, thorough cardiac monitoring, and invasive remapping, and brings great confidence in the excellent safety, efficacy, and durability of the Sphere-9 Catheter and Affera Mapping and Ablation System.” said Khaldoun Tarakji, M.D., MPH, vice president, chief medical officer, Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. “Putting the patient at the center of our innovation is our top priority, and I’m looking forward to seeing how this first of its kind, dual-energy source, all-in-one Sphere-9 Catheter can advance the care of arrhythmia patients globally.”

The Sphere-9 Catheter, coupled with the Affera™ Prism-1 Mapping Software, quickly generates sophisticated electro-anatomical maps and allows the physician to deliver wide-area focal ablation lesions of RF or PF energy based on the patient and procedure needs, all with a single catheter. Given its size, the all-in-one catheter's nitinol 9-mm ablation tip has the potential to require fewer focal ablation lesion applications that may result in lower procedure times than standard irrigated ablation catheters[1]. The intuitive mapping software enables an optimized user experience by delivering streamlined insights and feedback to support procedure performance.

AFib is the most common atrial arrhythmia, and nearly 60 million people are affected worldwide[2] and five million patients will be added every year by 2030[3]. Atrial arrhythmias, such as AFib, are associated with serious complications including heart failure, stroke and increased risk of death[4-7].

The Affera Mapping and Ablation System is investigational in the United States. Medtronic acquired Affera in August 2022.

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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For more information, contact:

Allison Kyriagis

Director of Communications

Medtronic

+1-612-750-6061

Ryan Weispfenning

Vice President & Head of Investor Relations

Medtronic

+1-763-505-4626

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

2 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.

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

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

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

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

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

https://news.medtronic.com/Affera-TM-Mapping-and-Ablation-System-Demonstrates-Safe,-Efficient-and-Effective-Pulmonary-Vein-Isolation