Medtronic News

Medtronic receives CE Mark approval for Affera™ Mapping and Ablation System to treat atrial arrhythmias

First of its kind, all-in-one Sphere-9™ Catheter with pulsed field ablation, radiofrequency, and high density mapping integrated with intuitive mapping and navigation platform

DUBLIN, March 15, 2023 /PRNewswire/ -- Medtronic (NYSE:MDT) announced today that it has received CE (*Conformité Européenne*) Mark for the Affera™ Mapping and Ablation System, which includes the Sphere-9™ Catheter and the Affera™ Prism-1 Mapping Software. Together, the full system creates a new paradigm in electrophysiology through the unique integration of the Sphere-9 pulsed field ablation (PFA), radiofrequency (RF), and high density (HD) mapping catheter, which maps and ablates atrial arrhythmias (fast, abnormal heart rhythms) and provides real-time feedback through its intuitive mapping and navigation software. Atrial fibrillation (AFib) is the most common atrial arrhythmia, and nearly 60 million people are affected worldwide[1] and five million patients will be added every year by 2030[2]. Atrial arrhythmias, such as AFib, are associated with serious complications including heart failure, stroke and increased risk of death[3-6].

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 lower procedure times than standard irrigated ablation catheters[7]. The intuitive mapping software enables an optimized user experience by delivering streamlined insights and feedback to support procedure performance.

"The revolutionary Affera Mapping and Ablation System combined with the novel Sphere-9 Catheter represent a great advancement in the field of HD mapping and focal ablation," said Khaldoun Tarakji, M.D., MPH, vice president, chief medical officer, Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. "Current technologies require the use of separate HD mapping and ablation catheters. The ability to map, ablate, and validate with the Sphere-9 Catheter enables the physician to eliminate the need to exchange catheters and empowers them to choose the energy source, whether RF or PF, based on the patient's needs. All this leads to improving efficiency and most importantly, enhancing the safety of ablation procedures for our patients."

Supported by results from clinical studies assessing the safety and performance of the Sphere-9 Catheter and Mapping System, CE Mark approval comes on the heels of a December 2022 announcement that enrollment was completed in the Affera SPHERE Per-AF Clinical Trial, a randomized, controlled U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) pivotal trial. Designed to evaluate the safety and effectiveness of the Affera Mapping and Ablation System for the treatment of persistent atrial fibrillation, the SPHERE PER-AF IDE trial is currently in its 12 month follow up phase.

"Electrophysiology is evolving at a rapid pace, and we believe we are uniquely positioned to be category creators once again with the all-in-one Sphere-9 Catheter, just as we did when Medtronic pioneered cryoablation technology," said Rebecca Seidel, president, Cardiac Ablation Solutions. "Along with the PulseSelect™ PFA System, we are proud to be among the first to bring novel single shot and focal PF technologies to patients around the world."

The Affera Mapping and Ablation System will be commercially available beginning in the first half of 2023 in Europe and is investigational in the United States. Medtronic acquired Affera in August 2022. Worldwide, the PulseSelect System is investigational and not approved for sale or distribution.

The Affera Mapping and Ablation system is limited to investigational use in the United States, Japan, and Canada. Formal product names in instructions for

use (IFU) and user manuals may differ from those seen in this communication.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, 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 90,000+ 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 all. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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