

FEB 1, 2024

Medtronic announces successful first cases using PulseSelect™ pulsed field ablation system

Physician feedback confirms clinical evidence: safe, efficient, and effective treatment offers most versatile new option for atrial fibrillation

FEBRUARY 1, 2024 - Medtronic today announced the successful completion of the first worldwide commercial cases using the PulseSelect™ pulsed field ablation (PFA) system together with its bi-directional 10F FlexCath Contour™ sheath.

“PulseSelect has the potential to redefine how atrial fibrillation is treated today. In our initial experience, we are already seeing the benefits of this technology over currently available single-shot therapies,” said Lucas V.A. Boersma, MD, PhD, a cardiologist at St. Antonius Hospital in Nieuwegein, The Netherlands, and a professor of cardiology at Amsterdam University Medical Centers, University of Amsterdam. “The 10F sheath makes it easy to maneuver the catheter and is well visualized on any mapping system or fluoroscopy. The signal quality is excellent for post-ablation pulmonary vein validation, and full procedure times have been very short, just over 30 minutes, with no noticeable muscle contraction, which is beneficial for patient experience.”

Medtronic is the only company with both single shot (PulseSelect) and focal (Affera™ Mapping and Ablation System) commercially available PFA options to meet different patients’ and clinicians’ needs. PulseSelect was the first PFA system approved by the U.S. Food and Drug Administration (FDA) and is the only system available to treat paroxysmal (intermittent) and persistent atrial fibrillation (AFib).

“Not all catheters are created equally, especially in PFA. PulseSelect is clinically proven and offers the unique versatility of treating both paroxysmal and persistent Afib. The design lends itself well to providing therapy tailored to the patient’s anatomy. It’s a plug-and-play system that integrates easily with any workflow and handles exceptionally well. And our decade of research provides the peace of mind that comes with our commitment to safety,” said Rebecca Seidel, president of the Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio. “PulseSelect is an amazing new choice for physicians in our rapidly growing portfolio of products that are disrupting the market and establishing us as a trusted leader in arrhythmia management.”

In addition to the recent PulseSelect milestone approvals in the U.S. and Europe, the Affera Mapping and Ablation System received European approval in March 2023 and includes the unique integration of the all-in-one Sphere-9™ PFA and radiofrequency (RF) ablation and high density (HD) mapping catheter, which maps, ablates and

validates atrial arrhythmias and provides real-time feedback through its intuitive mapping and navigation software.

“Physicians in Europe are raving about Affera’s capabilities, and we are excited to share our IDE trial results anticipated later this year,” continued Seidel. “We can’t wait to showcase PulseSelect, Affera and our broader innovations with the community at the AF Symposium and beyond.”

AF Symposium 2024 Highlights

Medtronic innovations will be highlighted at the AF Symposium in Boston, MA, in several live and pre-recorded cases focused on the Affera technology, including:

- **Thursday, February 1, 10:00 a.m.-12:30 p.m. (pre-recorded)**

Pulmonary Vein Isolation Using SPHERE-360 Large Lattice Tip PFA Catheter

Petr Neuzil, MD, PhD and Vivek Reddy, MD (New York, NY)

- **Friday, February 2, 8:30-9:30 a.m. (live)**

Ablation of Atrial Fibrillation Using SPHERE-9 Lattice Tip PFA Catheter

Andreas Metzner, MD (Hamburg, Germany)

- **Friday, February 2, 10:00 a.m.-12:30 p.m. (pre-recorded)**

Ablation of Atrial Fibrillation Using SPHERE-9 Lattice Tip PFA Catheter

Andrea Sarkozy, MD (Brussels, Belgium)

Booth Experience

In addition to the Arctic Front Advance™ Cryoballoon and DiamondTemp™ catheters, Medtronic’s Booth #301 will offer visitors the opportunity to interact with the new PulseSelect PFA catheter, FlexCath Contour™ sheath and FlexCath Cross™ transseptal catheter. The Tech Suite #MR4 will be an opportunity for clinicians to engage and provide feedback to Medtronic’s future innovation across our portfolio, including next generation PFA technologies.

About Atrial Fibrillation

Atrial fibrillation (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 current 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. Affera is investigational in the United States. Medtronic acquired Affera in August 2022.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, 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 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](https://twitter.com/Medtronic) on Twitter and [LinkedIn](#) 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.

For more information, contact:

Leslie Williamson	Ryan Weispfenning
Director of Communications	Vice President & Head of Investor Relations
+1-612-227-5099	+1-763-505-4626

¹ 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.

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

³ 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.

⁴ 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.

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

⁶ 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

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

<https://news.medtronic.com/2024-02-01-Medtronic-announces-successful-first-cases-using-PulseSelect-TM-pulsed-field-ablation-system>