

Medtronic receives Health Canada licence for 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 now available in Canada¹⁻⁴
- Highly anticipated by electrophysiologists for its innovation, demonstrated safety and efficacy, and improved procedural workflow
- With two pulsed field ablation (PFA) technologies and a comprehensive electrophysiology portfolio, Medtronic continues to shape the future of arrhythmia treatment

BRAMPTON, Ontario, [August 5, 2026] -- Medtronic Canada today announced Health Canada licence of the Affera™ Integrated Mapping System and Affera Ablation System with Sphere-9™ Catheter, an all-in-one, high-density (HD) mapping and pulsed field (PF) and radiofrequency (RF) ablation catheter for the treatment of persistent atrial fibrillation (AFib) and for RF ablation of cavotricuspid isthmus (CTI)-dependent atrial flutter.

With this approval, Medtronic now offers two pulsed field ablation technologies for the treatment of AFib. The PulseSelect™ Pulsed Field Ablation System provides physicians with a single-shot solution for pulmonary vein isolation (PVI), while the Affera Sphere-9™ catheter enables treatment flexibility through its wide-area focal design and 9 mm lattice tip, which can be used with an 8.5 Fr sheath.

“The Affera system represents an important advancement for the treatment of atrial fibrillation and atrial flutter,” said Dr. Allan Skanes, Director of Western University Heart Rhythm Program, London Health Sciences Centre. “By combining high-density mapping and dual-energy ablation in a single catheter, this technology provides physicians with a versatile tool that can streamline procedures while maintaining strong safety and efficacy outcomes for patients.”

The Sphere-9 catheter features a novel lattice-tip design that enables both pulsed field and radiofrequency energy delivery and is fully integrated with the Affera Mapping and Ablation System. This integration supports procedural efficiency by enabling a single transseptal, zero-fluoroscopy, and zero-exchange workflow, allowing physicians to map and ablate with one catheter.

“The Affera system was designed to address key procedural challenges faced by the electrophysiology community while maintaining a high standard of safety and efficacy for patients,” said Doron Harlev, vice president of engineering for Cardiac Ablation Solutions at Medtronic and founder of Affera. “Its ability to integrate mapping and ablation technologies and offer both pulsed field and radiofrequency energy provides physicians with meaningful flexibility in treating complex arrhythmias.”

The licence is supported by results from the SPHERE Per-AF study, which evaluated the Sphere-9 catheter with the Affera Mapping and Ablation System compared with a conventional radiofrequency ablation catheter and mapping system. The Affera system received CE Mark in March 2023, FDA in October 2024, and has also been approved in other international markets.

“At Medtronic Canada, we are committed to bringing meaningful innovation to physicians and patients,” said Rob Clifton, President Medtronic Canada. “With the licence of the Affera system in our country, we are excited to expand access to a novel mapping and ablation solution that can help physicians treat atrial fibrillation more safely, effectively, and efficiently.”

Atrial fibrillation (AFib) is one of the most common heart rhythm disorders worldwide, affecting more than 60 million people globally. In Canada, it is the most common sustained heart rhythm disorder, affecting about **3% of the general population** — or more than **1 million Canadians**, according to the Canadian Cardiovascular Society⁵⁻⁶.

AFib prevalence heavily scales with age. While it affects around 1% of people under 50, that number rises to approximately 4% at 65 and jumps to 10-15% for those 80 and older. Similarly, as the disease advances, the risk of serious complications such as heart failure, stroke, and death increases⁵⁻⁶.

For more information on the Affera Mapping and Ablation System and Sphere-9 catheter, visit [Medtronic.ca](https://www.medtronic.ca).

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.

References:

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4. 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
5. Canadian Cardiovascular Society: <https://ccs.ca/>
6. Canadian Heart and Stroke Association: <https://www.heartandstroke.ca/heart-disease/conditions/atrial-fibrillation>

Additional assets available online:  [Photos \(2\)](#)

<https://canadanews.medtronic.com/2026-08-05-Medtronic-receives-Health-Canada-licence-for-Affera-TM-Mapping-and-Ablation-System-and-Sphere-9-TM-Catheter>