Medtronic Canada receives licence for Affera system, Sphere-9 catheter

BRAMPTON, ONT. – Medtronic Canada announced Health Canada license of the Affera™ Integrated Mapping System and Affera Ablation System with Sphere-9™ Catheter, 1

At a presentation in Toronto, Dr. Jason Andrade, director of electrophysiology at the Vancouver General Hospital, observed that cardiac ablation has been shown to be a far better solution to treating atrial fibrillation than medication.

While ablation effectively targets the cause of cardiac fibrillation and restores the heart to regular rhythms, medication only addresses the symptoms. "Medications don't change the trajectory of the disease, and the condition of the heart gets worse," said Dr. Andrade.

Meanwhile, the wait lists for cardiac ablation continue to grow and the costs are rising. "In Canada, over $1 billion [annually] is spent on managing atrial fibrillation," he noted. "Over 50 percent of that cost is hospitalization."

That's why, he said, it's best to conduct cardiac ablation as early in the course of the disease as possible. By waiting, the disease progresses and the patient only gets worse – often leading to hospitalization.

As Dr. Andrade noted, those wait lists are not good for patients. "The disease is festering while patients should be getting treatment," he asserted.

The benefit of Medtronic's Affera system is that it enables physicians to treat different types of arrythmias using the same catheter. That allows them to perform their work faster – they don't have to stop and start over using a different catheter.

It's also less expensive, as they're using one catheter for the procedure instead of two.

Vancouver General is the first site to use the Affera system in Canada. Dr. Andrade noted that it has recently been used in the US and Europe, and now Canadian hospitals – and patients – will obtain the benefits.

"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, in a Medtronic news release.

"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."



Dr. Jason Andrade

The license 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 license 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 percent of the general population – or more than 1 million Canadians, according to the Canadian Cardiovascular Society.

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

Sectra Digital Pathology has manifold benefits for Michigan Medicine

In 2024, Michigan Medicine, an academic medical centre in Ann Arbor, Michigan, went live with the Sectra module for digital pathology, joining the institution's previously deployed Sectra enterprise imaging solution, dramatically reimagining the pathology workflow. Also under way is a planned transition to Sectra One Cloud early next year.

"About 20 percent of the large academic centres in the U.S. are moving to digital adoption for pathology," estimated Dr. Mustafa Yousif, Michigan Medicine's medical director of digital pathology, associate director of pathology informatics and associate chief medical information officer (ACMIO) for pathology. "It's still not at the same pace as radiology, but we're getting there," he said.

Dr. Yousif said the field is now moving from early adopters to the early majority. The COVID-19 pandemic, which made remote sign-out a necessity, was the first major catalyst; today, artificial intelligence is the main driver. "Without digital pathology, you simply cannot deploy predictive or diagnostic AI tools," he said.

Genomic and other ancillary results can take days, if not weeks, to come back, while an algorithm run on a digital slide can return a result within hours or even minutes, allowing oncologists to begin planning treatment sooner. Many private practices, he added, are already fully digital, with no physical slide distribution at all.

But the biggest shift, according to Dr. Yousif, is in how pathology thinks about its workflow. Most laboratory information systems (LIS) were never designed for digital pathology, which was typically bolted on as an add-on, and many still struggle to orchestrate a digital workflow.

Michigan Medicine took a hybrid approach instead, adopting the enterprise imaging model and building on two decades of experience in radiology.

Ordering, billing and reporting remain in the LIS, while the case itself follows the pixels: a PACS-driven, image-centred workflow. "LIS vendors are often uncomfortable with the term 'PACS-driven,' worried that pathologists will leave their environment. I don't see it that way," he said. "The LIS remains the system of record, but the workflow should follow the image."

The result, he said, has transformed how pathologists approach each case, giving them the flexibility, efficiency and orchestration that drove high adoption among faculty. It has also made it far easier to add new AI and digital image analysis tools into the workflow.

Since 2021, Dr. Yousif has led the digital transformation of Michigan Medicine's Department of Pathology – one of the largest implementations of its kind at a U.S. academic medical centre. Today, nearly one million slides per year are digitized and routed through the pathology imaging environment he designed.

By integrating pathology into Michigan Medicine's Sectra enterprise imaging platform alongside radiology, cardiology, obstetrics and gynecology, and other specialties, he was instrumental in helping to establish a unified, health system-wide diagnostic imaging ecosystem.

Hospitals planning to adopt a digital imaging solution for pathology can choose a standalone, siloed system, but that didn't make sense for Michigan Medicine, given that it already had a Sectra PACS for all other specialties.

Using AI has allowed savings of between 11.5 and 24 hours of scan tech working time every day.

Michigan Medicine knew the limits of the siloed approach first-hand. The department had used whole slide imaging since about 2012, but only in a standalone system for research, education, archiving and consultations. "It lived only inside pathology," said Dr. Yousif. "We could not exchange those images with radiology, oncology or clinicians, and it was never meant for primary diagnosis. It was a decade of fragmented, siloed growth."

"All we needed to do was upscale our environment and make it ready for digital pathology," said Dr. Yousif. The enterprise solution allowed pathology to share storage, security, disaster recovery, and support while also cutting 18 months of implementation time. The enterprise decision was also less costly.

Digital pathology eliminates the onerous logistics of distributing, transporting, and retrieving glass slides. Instead, they're scanned using one of the 15 scanning devices used by Michigan Medicine, uploaded to the Sectra PACS, and instantly accessible for consultations and tumor boards through the integration of Sectra with the hospital's EHR.

Having easily accessible images when a case is ready for review saves anywhere from 30 minutes to an hour that it used to take to look for a slide, said Dr. Yousif.

The department handles roughly 3,500 slides a day, including 500 to 1,000 received for outside consultation. Before digitization, close to 10,000 staff hours a year went into collating, transporting and retrieving glass slides, and administrative staff spent about four hours a day on slide logistics alone.

Using AI has allowed Michigan Medicine to report savings of between 11.5 and 24 hours of scan tech working time every day.