

DEC 3, 2025

Medtronic announces first procedure in Denmark using the Affera™ Mapping and Ablation System at Aarhus University Hospital

Medtronic, a global leader in healthcare technology, today announced that Aarhus University Hospital has completed its first cardiac ablation procedure using the Affera™ Mapping and Ablation System, including the Sphere-9™ Catheter and the Affera™ Prism-1 Mapping Software. This marks the first commercial usage of the system in Denmark. The Affera system is designed to map, ablate and validate atrial arrhythmias (fast, abnormal heart rhythms) and provides real-time feedback through intuitive mapping and navigation software. This introduction at Aarhus University Hospital represents an important advancement for cardiac ablation in Denmark.

Supported by results from clinical studies assessing the safety and performance of the Sphere-9™ Catheter, the Affera™ Mapping and Ablation System received CE Mark in March 2023. In April 2023, 12-month findings from the EU clinical study supporting the CE Mark were published in *JACC: Clinical Electrophysiology*, demonstrating that the Sphere-9™ Catheter can successfully treat patients with either paroxysmal or persistent atrial fibrillation (AF) in an efficient, safe, and clinically effective manner.

The first patient treated with the Affera™ system in Denmark was cared for by the electrophysiology team at Aarhus University Hospital, led by **Steen Buus Kristiansen, Head of Arrhythmia, Department of Cardiology**.

“For patients, this means we can offer a more individualized and tailored catheter-based treatment for atrial fibrillation, with an expected good and lasting outcome. In addition, we expect to optimize workflows during procedures with this new technology, allowing us to offer even more patients an effective catheter treatment for their atrial fibrillation.

We are constantly working to maintain and strengthen our national and international position within treatment, clinical development, and research in cardiac arrhythmias. That is why we are pleased that we are the first in Denmark to offer our patients treatment with this new technology” - Steen Buus Kristiansen, Chief Physician at Heart Diseases, Aarhus University Hospital.

Atrial fibrillation affects more than 60 million people worldwide.¹ Persistent AF occurs when symptoms last for more than seven days and do not resolve without intervention, while paroxysmal AF episodes last from seconds to

days but stop spontaneously. Without early or timely intervention, AF can progress² and is associated with higher rates of cardiovascular admissions³, heart failure hospitalization⁴, mortality⁵, and reduced quality of life⁶.

Treatment options include medication, cardioversion, or catheter ablation.

In clinical studies, treatment with the Sphere-9™ Catheter using the optimized PULSE³ waveform (the commercial Affera System pulsed field waveform) achieved **85% one-year freedom from recurrence of atrial arrhythmias in persistent AF patients**. Across all paroxysmal and persistent AF patients who underwent an ablation and all PFA waveforms tested, **78% remained free from all atrial arrhythmias** at the conclusion of the study. The system achieved a **primary safety endpoint of 0.6%**, with zero cases of atrio-esophageal fistula, coronary spasm, pulmonary vein stenosis, or phrenic nerve injury.⁷

For more information about the Medtronic Affera Mapping and Ablation System and available treatment options, visit **Medtronic.eu**.

References:

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