Abbott's Next-Generation Amulet 360™ Device Receives CE Mark To Treat People With Atrial Fibrillation At Risk Of Stroke

- Amulet 360 helps seal the left atrial appendage (LAA) of a person's heart, reducing the need for blood-thinning medication
- Amulet 360 builds upon Abbott's first-generation LAA device with design updates to enhance how the implant conforms to and seals the LAA to help reduce the risk of a stroke
- Recent clinical trial data show Amulet 360 met benchmarks for safety and effectiveness

ABBOTT PARK, Ill., Aug. 27, 2026 /PRNewswire/ -- Abbott (NYSE: ABT), the global healthcare leader, announced today it has received CE Mark for the Amulet 360™ Left Atrial Appendage (LAA) Occluder, a next-generation device designed to reduce risk of stroke in patients with atrial fibrillation (AFib) not caused by a heart valve issue (non-valvular).

Following approval, the first European cases using Amulet 360 were completed by Prof. Boris Schmidt at the Cardiovascular Clinic Bethanien in Frankfurt, Germany; Prof. Ingo Eitel at the University Heart Center in Lubeck, Germany; and Prof. Jens Erik Nielsen-Kudsk at Aarhus University Hospital in Aarhus, Denmark. The company will further expand the use of Amulet 360 across European countries in the coming weeks.

The LAA is a small, structurally complex pouch attached to the upper left chamber (atrium) of the heart. It is the most common place for blood clots to form and can potentially lead to stroke for people with AFib, an irregular heartbeat in the heart's upper chambers. For patients with AFib who are unable to take blood-thinning medication long-term, physicians may opt for closure of the LAA through a minimally invasive procedure using devices like Abbott's Amulet 360 to seal off the LAA entirely and reduce the risk of stroke.

Design updates improve closure and ease of use
Amulet 360 is made of two primary components. The device's redesigned body, called a lobe, is softer and more conformable than Abbott's previous-generation LAA occluder to help doctors treat more people with different types of LAA shapes. Amulet 360's lobe has smaller anchors than the previous version to secure it in the LAA. The implant's outer disk is a second sealing layer to help close off the LAA. Together, the lobe and disk are designed to help prevent blood clots and reduce the risk of stroke.

"With Amulet 360, doctors can help protect more people with AFib from stroke by confidently closing the left atrial appendage," said Xavier Freixa, M.D., Ph.D., at Hospital Clínic de Barcelona, Spain, and a globally recognized interventional cardiologist. "By helping doctors treat a wider range of anatomies, this next-generation device has the potential to improve outcomes and help more people benefit from stroke prevention across Europe."

Strong clinical data supports Amulet 360
CE Mark for Amulet 360 was supported by insights from the VERITAS Study, which included 400 patients at more than 30 hospitals across the U.S., Canada and Europe. The study's 45-day results – originally presented in a late-breaking session at the AF Symposium in Boston and simultaneously published in JACC: Clinical Electrophysiology earlier this year – showed clinically meaningful closure rates and device safety, including[1]:

- **Favorable outcomes.** The device was successfully implanted in 99.8% of patients.
- **Positive safety profile.** Amulet 360 met early safety benchmarks, including no reported patient complications such as additional surgery, strokes, or blood clots within the first seven days after implantation.
- **Clinically relevant closure.** A majority (93.9%) of patients implanted with the Amulet 360 achieved complete closure of the LAA by 45 days with zero leaks greater than 3 mm.

"Amulet 360 builds on the proven legacy of our unique dual-seal design seen in the first-generation LAA occluder, which helped many people with AFib reduce their risk of stroke without the need for long-term blood thinners," said Christopher Piorkowski, M.D., chief medical officer of Abbott's electrophysiology business. "As the latest addition to Abbott's growing portfolio of stroke prevention technologies, Amulet 360 reflects our commitment to advancing treatment options and improving outcomes for patients around the world."

Advancing Abbott's growing portfolio of stroke prevention technologies
The CE Mark approval of Amulet 360 further expands Abbott's portfolio of technologies designed to help physicians treat patients with cardiac arrhythmias. It is the company's fourth major electrophysiology approval in just over a year, following US and European approvals for the Volt™ PFA System in 2025 and the European approval of TactiFlex™ Duo earlier this year.

Frequently Asked Questions:
What is Amulet 360?
The Amulet 360 device is a minimally invasive treatment option with dual-seal technology that can adapt to the unique shape of a patient's LAA to immediately close it, potentially eliminating the need for blood-thinning medication when clinically appropriate. The next-generation Amulet 360 is built upon Abbott's Amplatzer™ Amulet™ LAA Occluder, which has been in use in Europe since 2013 and the U.S. since 2021.

What is atrial fibrillation?
Atrial fibrillation (AFib) is the most common sustained cardiac arrhythmia (irregular heartbeat). It occurs when the upper

chambers of the heart (atria) beat out of coordination with the lower chambers (ventricles) and contract rapidly and irregularly.

What is the left atrial appendage?
The left atrial appendage (LAA) is a small pocket (or recess) connected to the upper left chamber of the heart that, in people with AFib, can allow blood to pool and increase the likelihood of a clot forming and traveling to the brain to cause a stroke.

How does Amulet 360 reduce stroke risk?
Delivered through a vein in the leg, Amulet 360 closes the LAA to reduce the risk of stroke.

How does Amulet 360 fit into Abbott's treatments for AFib?
Amulet 360 is part of Abbott's holistic portfolio of technologies designed to diagnosis and treat AFib, and ultimately, reduce the risk of stroke.

Where commercially available, doctors use cardiac ablation therapies such as Abbott's TactiFlex™ Duo Ablation Catheter, Sensor Enabled™, or Volt™ PFA System, which use different types of specialized energy to safely stop the heart's erratic signals that can trigger AFib. Abbott's EnSite™ X EP System creates highly detailed three-dimensional maps of the heart to help doctors find and treat the source of an irregular heartbeat. Procedures designed to combine Abbott's LAA closure device and treat AFib simultaneously are currently being investigated in Europe.

The Amulet 360™ Left Atrial Appendage Occluder is approved for investigational use only in the U.S.

For U.S. important safety information go to:

Volt™ PFA System,
https://www.cardiovascular.abbott/us/en/ep-clinical-evidence/volt-clinical-evidence.html

EnSite™ X EP System, https://www.cardiovascular.abbott/us/en/hcp/products/electrophysiology/mapping-systems/ensite-x.html

About Abbott:
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[1] Nair D. Early outcomes with a next-generation dual-seal device for left atrial appendage closure: Results from the VERITAS Amulet 360 Pivotal Study [Late Breaking Presentation]. Presented at: AF Symposium; February 6, 2026; Boston, MA, USA.

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