Abbott Receives CE Mark For The TactiFlex™ Duo Ablation Catheter To Treat Patients With Abnormal Heart Rhythms

- Abbott's TactiFlex™ Duo Ablation Catheter, Sensor Enabled™, is designed with dual-energy to treat atrial fibrillation patients with the most challenging cases
- It can deliver both radiofrequency energy and pulsed field ablation (PFA) energy during procedures to target and treat an irregular heart rhythm
- The availability of TactiFlex Duo in Europe adds a dual-energy, focal ablation catheter to Abbott's growing PFA portfolio, following the company's Volt PFA System approvals in the U.S. and Europe last year

ABBOTT PARK, Ill., Jan. 20, 2026 /PRNewswire/ -- Abbott (NYSE: ABT) today announced it has received CE Mark in Europe for the TactiFlex™ Duo Ablation Catheter, Sensor Enabled™ to treat patients with atrial fibrillation (AFib). Following the new approval, the first successful commercial cases using TactiFlex Duo in the European Union were completed this week.

Abbott's TactiFlex Duo Catheter is the latest advancement in the company's pulsed field ablation (PFA) technology portfolio. An effective cardiac ablation – a minimally invasive procedure to stop an irregular heart rhythm – relies on the quality of the scars (lesions) created by a catheter to stop the source of an arrhythmia. TactiFlex Duo is designed to deliver tailored therapy lesions in two ways: radiofrequency energy (uses heat to destroy tissue responsible for erratic heart signals), and pulsed field ablation energy (uses high energy electrical pulses to destroy the cells causing abnormal heart rhythms, which can reduce the risk of damaging adjacent tissue in patients with complex disease or anatomy).

"TactiFlex Duo's most unique feature is its dual options that allow physicians to seamlessly switch treatment during a procedure based on the patient's personalized needs and anatomy," said Prof. Isabel Deisenhofer, M.D., head of the department of Electrophysiology at the German Heart Center Munich in Germany, and one of the first physicians to use TactiFlex Duo following CE Mark approval. "For patients who do not respond to medication and other traditional treatments, a successful cardiac ablation is critical as it can reduce the risk of recurrence of AFib and provide long-lasting relief."

TactiFlex Duo Supported by Strong Data
CE Mark approval for the TactiFlex Duo Ablation Catheter was supported by data from Abbott's FOCALFLEX CE Mark study, a global clinical trial conducted at centers in the European Union, United Kingdom and Australia. The trial showed that TactiFlex Duo demonstrated clinically meaningful performance in the safety and effectiveness of treating patients with AFib[1].

Approximately eight million Europeans over the age of 65 are living with AFib, a number expected to double over the next 30 years[2,3]. People living with AFib face an increased risk of stroke, heart failure and death, and many rely on cardiac ablation to treat the condition effectively.

"AFib is a progressive disease that becomes harder to treat over time, and there is not a one-size-fits all approach, which makes long-term management complex," said John Silberbauer, M.D., electrophysiologist at the Sussex Cardiac Centre in Brighton, United Kingdom, who treated patients as part of the FOCALFLEX study. "TactiFlex Duo allows me to safely tailor each ablation treatment to the patient's anatomy, and results show that it consistently improves symptoms and quality of life for many."

TactiFlex Duo integrates with Abbott's EnSite™ X EP System, which creates highly detailed three-dimensional maps of the heart to help doctors find and treat the source of the arrhythmia. The technology builds on the catheter's previous generation flexible electrode tip and contact force sensing to now include PFA energy delivery, resulting in more effective and safer procedures[4].

Significant Regulatory Progress Across Abbott's PFA Portfolio
TactiFlex Duo marks the third significant approval in Abbott's electrophysiology portfolio in less than a year. The company's Volt PFA System received FDA and CE Mark approvals in 2025.

"The TactiFlex Duo Catheter provides another advanced tool to Abbott's growing PFA portfolio for treating patients with more complex cases such as those with co-existing heart disease and heart failure, long-lasting AFib, ventricular arrhythmias and patients with a history of failed ablations," said Christopher Piorkowski, M.D., chief medical officer of Abbott's electrophysiology business. "By focusing on a holistic view of patient care, physicians now have multiple clinically proven tools to enhance workflow and to effectively treat a wide range of arrhythmias."

Enrollment for Abbott's FLEXPULSE IDE trial to evaluate TactiFlex Duo for the treatment of AFib in the United States was completed last year. In October 2025, the FDA granted it Breakthrough Device Designation for the treatment of ventricular tachycardia (VT) using PFA. To qualify for this breakthrough designation, products must address an unmet need and show it has the potential to provide more effective treatment of life-threatening diseases. VT is a fast heart rate that can be life-threatening and requires immediate attention.

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

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[1] Abbott FOCALFLEX Trial Data on File, November 2025

[2] *Fact Sheets for Press*. European Society of Cardiology. (n.d.-a). https://www.escardio.org/The-ESC/Press-Office/Factsheets

[3] *Atrial fibrillation set to affect more than 14 million over-65s in the EU by 2060* European Society of Cardiology. (n.d.). https://www.escardio.org/The-ESC/Press-Office/Press-releases/Atrial-fibrillation-set-to-affect-more-than-14-million-over-65s-in-the-EU-by-2060

[4] Abbott FOCALFLEX Trial Data on File, November 2025

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