Late-Breaking Data For Abbott's TactiFlex™ Duo Ablation Catheter Reveal Positive Outcomes For Treating Complex AFib Cases

- Abbott's TactiFlex™ Duo Ablation Catheter, Sensor Enabled™ combines pulsed field ablation (PFA) and radiofrequency (RF) energy in a single catheter to treat complex atrial fibrillation (AFib) cases
- Twelve-month clinical evidence presented at the European Society of Cardiology Congress 2026 demonstrates the device's high rates of safety and effectiveness in treating AFib patients

ABBOTT PARK, Ill., Aug. 31, 2026 – Abbott, the global healthcare leader, announced today new late-breaking 12-month data from the FlexPulse Global IDE study that show favorable safety and effectiveness outcomes for its investigational TactiFlex™ Duo Ablation Catheter, Sensor Enabled™ to treat patients with challenging cases of atrial fibrillation (AFib). The results were presented in a late-breaking session at the European Society of Cardiology (ESC) Congress in Munich, Germany, on Aug. 29, 2026, and simultaneously published in *EP Europace*.

TactiFlex Duo is a dual-energy catheter designed to give physicians more flexibility when treating AFib. The investigational technology offers both pulsed field ablation (PFA) and radiofrequency (RF) energy approaches to treatment, which can help a physician tailor therapy to a patient's individual needs. Abbott's EnSite™ X EP System also provides physicians with real-time feedback as an integrated mapping solution with the PFA Index (PI), a tool designed to assess lesion formation during ablation with TactiFlex Duo. Both PFA and RF are used to create therapeutic lesions, or small areas of scar tissue, that block the abnormal electrical signals causing an irregular heartbeat while helping minimize the impact on surrounding healthy tissue. Successfully treating these areas can help restore the heart's normal rhythm and improve outcomes for patients living with AFib.

Positive results support TactiFlex Duo Ablation Catheter, Sensor Enabled

The 12-month data presented at ESC showed positive outcomes in patients with paroxysmal atrial fibrillation (irregular heart rhythm episodes that come and go).

Key findings from the FlexPulse IDE late-breaker include:

- A majority (92.6%) of patients did not have a documented recurrence of AFib, atrial flutter, or atrial tachycardia during follow-up when assessed using standard-of-care monitoring.
- In protocol-driven monitoring, which follows more rigorous, heart rhythm assessments throughout the study, (77.4%) of patients experienced no documented recurrence of AFib, atrial flutter, or atrial tachycardia during follow-up.
- The study met its primary effectiveness endpoint, with 74.6% of patients remaining free from documented arrhythmias, medication changes, or repeat procedures.
- The study reported a consistently high patient safety profile (98.3%) with no major safety events.

"As physicians, we're looking for technologies that help us confidently deliver the best possible outcomes for our patients, not just at the time of the procedure, but for years afterward," said Ayman Hussein, M.D., Director of the Atrial Fibrillation Center and Director of Cardiac Electrophysiology Research at Cleveland Clinic, who presented the late-breaking FlexPulse IDE data at the European Society of Cardiology Congress. "The evidence behind this device helps increase confidence in ablation therapy and hopefully support lasting outcomes for patients with atrial fibrillation."

The FlexPulse IDE study was designed to secure U.S. Food and Drug Administration (FDA) approval for the TactiFlex Duo. The catheter received CE Mark in Europe earlier this year.

For U.S. important safety information go to:

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

Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™

https://electrophysiology.abbott.com/Advisor-HD-Grid-X.html

ViewFlex™X ICE Catheter, Sensor Enabled™ and EnSite™ Echo Module

https://www.cardiovascular.abbott/us/en/hcp/products/electrophysiology/imaging-diagnostic-systems/viewflex-x-and-ensite-x.html

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"At Abbott, we are committed to helping physicians with the advanced tools they need to treat complex heart rhythms with greater precision and flexibility," said Christopher Piorkowski, M.D., chief medical officer of Abbott's electrophysiology business. "As the demand for more flexible ablation technologies grows, the strong 12-month outcomes demonstrate that TactiFlex Duo is advancing the standard of care and helping improve outcomes for patients worldwide."

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