Abbott's Volt™ Pulsed Field Ablation System Receives FDA Approval To Treat Patients With Atrial Fibrillation

- Abbott's Volt™ PFA System, the latest generation of cardiac ablation technology, is designed for people battling heart rhythm disorders such as atrial fibrillation (AFib)
- Pulsed field ablation – or PFA – is a minimally invasive procedure that uses high-energy electrical pulses in targeted areas of the heart to treat irregular heart rhythms
- Abbott's Volt PFA System is an all-in-one product that is clinically proven to simplify the treatment of AFib that is gentler on the heart, has shorter procedure times and supports better recovery and long-term results

ABBOTT PARK, Ill., Dec. 22, 2025 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the U.S. Food and Drug Administration (FDA) has approved the company's Volt™ PFA System to treat patients battling atrial fibrillation (AFib). Abbott will soon begin commercial PFA cases in the United States and will continue its expansion of sites in the European Union following Volt CE Mark approval earlier this year.

Approximately 12 million people in the United States over the age of 65 have AFib, a number expected to double over the next 20 years[1]. People living with AFib face a fivefold increased risk of stroke, and the condition has been a contributing cause of death for more than two decades in the United States[2]. When medication and other treatment options fail to work, many patients rely on a minimally invasive cardiac ablation procedure to effectively treat the condition by stopping irregular heart rhythms.

Volt Demonstrates Strong Patient Outcomes for Abnormal Heart Rhythms
FDA approval for the Volt PFA System was secured based on strong results from Abbott's VOLT-AF IDE study, a clinical trial of 392 patients conducted at 40 centers in the United States, Europe, Canada and Australia. The data showed that the Volt PFA System demonstrated clinically meaningful performance in both safety and effectiveness in two different patient groups: people battling paroxysmal atrial fibrillation (PAF) - *episodes that come and go* - as well as persistent AFib (PersAF) - *episodes that last longer than seven days*.

"AFib is a progressive condition where timely intervention is critical to disease management and, ultimately, the patient's quality of life. When I perform a cardiac ablation, I look for a tool with an excellent patient safety profile that can simplify the treatment of AFib," said DJ Lakkireddy, M.D., executive medical director of the Kansas City Heart Rhythm Institute and one of the first physicians to use Volt in the United States. "Volt is a promising option for patients. Its real-time contact visualization and unique balloon-in-basket design provide superior tissue contact and focused energy delivery, while addressing some of the limitations of the early generation PFA systems."

Volt PFA System: Designed with Physician Feedback in Mind
Abbott's Volt PFA System builds upon the company's leading electrophysiology portfolio by providing an all-in-one product that allows physicians to safely map, pace and ablate with the same catheter. Volt's proprietary balloon-in-basket design features multiple handling options for ease of use and allows for efficient energy transfer directly to the targeted tissue to stop the heart's erratic signals.

With improved physician workflow in mind, Volt's PFA System was designed to integrate with Abbott's EnSite™ X EP System by providing physicians accurate 3D cardiac mapping and fewer catheter exchanges during an ablation. While current on-market competitive PFA systems often require several therapy applications with a catheter positioned in various locations, the Volt PFA System integration with EnSite X was designed to address such limitations and has been clinically proven to provide:

- **Minimal number of therapy applications and enhanced patient outcomes.** The Volt PFA System is designed to deliver precise, targeted energy during ablation, which helps achieve durable lesions with fewer pulses. This level of accuracy supports effective first-time procedures, reducing the likelihood of repeat ablations and minimizing the risk of complications.
- **More procedural options for patients.** Patients who undergo a minimally invasive ablation procedure with the Volt PFA Catheter can be placed under conscious sedation instead of general anesthesia, which is a significant benefit for patients where anesthesia is a barrier to performing ablations. The Volt PFA System also reduces exposure to radiation (fluoroscopy) and limits the breakdown of red blood cells (hemolysis).

"We heard the physician feedback that patients need an alternative to general anesthesia during a PFA ablation procedure that doesn't sacrifice strong outcomes," said Christopher Piorkowski, M.D., chief medical officer of Abbott's electrophysiology business. "The Volt PFA System is an option for patients who prefer conscious sedation, which can also lead to faster recovery times and shorter procedures for the millions of Americans who suffer from an abnormal heart rhythm."

For U.S. important safety information go to:
Volt™ PFA System
https://www.cardiovascular.abbott/us/en/ep-clinical-evidence/volt-clinical-evidence.html#isi

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

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[1] CDC. Atrial Fibrillation Fact Sheet. https://www.cdc.gov/heartdisease/atrial_fibrillation.htm, 8 Sept. 2020. Accessed 19 Sept. 2020.

[2] CDC. About Atrial Fibrillation. About Atrial Fibrillation | Heart Disease | CDC, 8 Oct. 2025. Accessed 15 Oct. 2025.

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