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Japan approves Boston Scientific's FARAPULSE Pulsed Field Ablation System

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Plans to launch the FARAPULSE PFA System in Japan in the coming weeks



US-based Boston Scientific Corporation has received Pharmaceuticals and Medical Device Agency (PMDA) approval in Japan for the FARAPULSE Pulsed Field Ablation (PFA) System.

The FARAPULSE PFA System, which is indicated for the isolation of pulmonary veins in the treatment of paroxysmal atrial fibrillation (AF), is a novel alternative to standard-of-care thermal ablation treatment.

"The FARAPULSE PFA System is the most clinically studied PFA system and its use in treating more than 125,000 patients globally to date continues to reinforce its strong safety, efficacy and efficiency profile," said Nick Spadea-Anello, president, Electrophysiology, Boston Scientific. "The rapid adoption of the FARAPULSE PFA System, which is now approved in more than 65 countries, indicates a paradigm shift for the treatment of paroxysmal AF – one that has clinical benefits to both physicians and patients – and we look forward to bringing this differentiated technology to Japan."

AF can lead to increased risk of death, stroke and heart failure and affects more than one million people in Japan, while worldwide AF prevalence is conservatively estimated to impact 38 million individuals.

Unlike traditional thermal ablation, which uses extreme heat or cold to ablate cardiac tissue associated with AF, the FARAPULSE PFA System uses non-thermal electrical fields that avoid damage to surrounding structures.

Adding to its robust body of clinical evidence for the FARAPULSE PFA System, Boston Scientific expects to initiate the OPTION-A clinical trial in Japan, China, Taiwan and Hong Kong in early 2025 to study the safety and efficacy of concomitant

procedures using the FARAPULSE PFA System for cardiac ablation and the WATCHMAN FLX Pro Left Atrial Appendage Closure Device.

Boston Scientific plans to launch the FARAPULSE PFA System in Japan in the coming weeks, following reimbursement approval.