

Medtronic's Cryoballoon approved in the US & Europe

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Medtronic has announced that the Arctic Front Advance ST Cryoablation Catheter has received the US Food and Drug Administration (US FDA) approval for the treatment of patients with drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation. In Europe, where the Cryoballoon has a broader indication, Arctic Front Advance ST Cryoballoon has received CE (Conformit   Europ  enne) Mark for the treatment of patients with atrial fibrillation.

An integral part of the Arctic Front Advance System, the third-generation cryoballoon has a 40 percent shorter tip than the previous generation, designed to help physicians visualize ablation success in real-time with the Achieve Mapping Catheter, as well as allow increased maneuverability for accessing some pulmonary vein anatomies.

The Arctic Front Advance ST Cryoballoon is used in a minimally invasive procedure to isolate the pulmonary veins, which are a source of erratic electrical signals that cause atrial fibrillation. The device uses coolant rather than heat (radiofrequency). Cryoballoon technology is associated with shorter procedure times than point-by-point radiofrequency ablation and better treatment outcomes than drug therapies on the market. The Arctic Front Advance System has been shown to improve quality of life for patients and significantly reduce paroxysmal (sporadic) atrial fibrillation symptoms, with patients experiencing reduction in atrial fibrillation episodes, palpitations, fatigue, rapid heartbeat, swelling, and syncope⁴, and has become a widely adopted treatment for atrial fibrillation.

"The next-generation Arctic Front Advance ST Cryoballoon builds upon the successful performance of the Arctic Front Advance System, and its shorter tip was designed in response to physicians' needs in a real-world, clinical setting," said Mr Reggie Groves, vice-president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic.

The Arctic Front Advance System is the only cryoballoon system approved in the US for the treatment of paroxysmal atrial fibrillation and in Europe for treatment of atrial fibrillation. It has been used to treat more than 120,000 patients in more than

50 countries worldwide.