

# Farapulse™

**Category:**

Best Medical Technology

**Company Name:**

Boston Scientific

**Product/Solution Name:**

Farapulse™

**Compound/Tech Name:**

Farapulse™

**Trade Name:**

Farapulse™

**Corporate Name:**

Farapulse™

**Date of Approval:**

2024-01-30

**Indications:**

The Farapulse™ ablation system represents a major advance in interventional cardiology, introducing electroporation as a new treatment for the management of patients with paroxysmal Atrial Fibrillation (AF), while minimizing the risk of complications thanks to its non-thermal nature. Indeed, the Farapulse™ ablation system treats cardiac lesions sustainably, while preserving healthy tissue such as the esophagus or phrenic nerve.

**Therapeutic Areas:**

Atrial Fibrillation (AF).

**General Information File Document upload:**

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### **Background information and need for drug / device:**

The Galenus prize would reward the most innovative medical device that leads to a better therapeutic treatment. The FARAPULSE system meets this definition perfectly. It is built on the first to market and most clinically proven PFA system. Moreover, FARAPULSE promises to be a better therapeutic treatment than current alternative treatments, as initial studies show that the therapy creates durable PVI and improves safety. It also promises to be a more efficient and faster technique based on the results of these studies.

The technique offers benefits to the patient as well as to the physician, the hospital and the NIHDl. The shorter procedure time, the reduced risk of complications and the durable lesions are likely to result in improved patient safety, higher efficiency for the hospitals and physicians and are expected to reduce costs for the healthcare system. Given these innovative features, FARAPULSE has the potential to completely transform AF (ablation) management.

### **Background File Document upload:**

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### **History of the development of the solution/product:**

There exist several risk factors related to the development of AF. Some of these factors can be influenced by the patient e.g., hypertension, obesity, endurance exercise, obstructive sleep apnea, thyroid disease, and alcohol consumption. However, others cannot be modified such as age, sex, family history, race, tall stature, and other types of heart and valvular disease. Of all these risk factors, age is the most determined one which can possibly be explained by fibrosis development over the years. The risk to develop AF from an age of 40 is 25%. Circa 1 out of 15 adults aged above 65 and 1 out of 10 adults aged above 80 are diagnosed with AF. The risk factors are also shown to be associated with AF recurrence after ablation, AF progression, and complications related to AF (e.g., stroke).

Catheter ablation is recommended for patients suffering from paroxysmal AF with no or minimal structural heart disease and who feel that their symptoms could not be sufficiently controlled by means of prior therapy with antiarrhythmic and rate-control drugs. Ablation is a technique where one or more catheters are inserted into the left atrium. These are introduced through a vein into the heart and are punctured through the interatrial septum under radioscopic control into the left atrium. Nowadays

Pulmonary vein isolation (PVI) is the main strategy for catheter ablation in drug-resistant AF patients. The procedure can take several hours. The current standard ablation techniques (radiofrequency, cryotherapy, and laser ablation) are based on time-dependent heating or cooling. Their aim is to \"burn\" the inner surface of the left atrium around the outflow of the pulmonary veins to eliminate the transmission of the electrical impulses coming from the pulmonary veins causing the AF. Because of the \"burning\" aspect of these thermal techniques short-term complications such as edema, intramural hemorrhage, and microvascular damage may occur. In the long term, acute lesions lead to areas of reparative fibrosis. A high level of fibrosis may impair the left atrial reservoir function and result in specific complications such as PV stenosis and stiff LA syndrome. Life-threatening complications occur in 1-3% of the procedures. Less severe complications possibly resulting in hospitalizations occur in 5% of the procedures. Furthermore, The thermal ablation procedures tend to be long and require skills and expertise. In addition, often reinterventions are needed because of non-durable lesions after PVI. To overcome the thermal complications, pulsed field ablation (PFA) was developed.

## **Development File Document upload:**

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## **Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:**

The benefits and added values of FARAPULSE for the patient, the physician, the hospital and the health care system can be summarized as follow:

Less (severe) complications due to the non-thermal nature of PFA result in patient safety and potentially less rehospitalizations and therefore less costs for the health care system

Less procedure time may result in less costs for the hospital, and optimization for the Cath lab workflow and patient safety.

At the 1-year follow-up, data demonstrated fewer adverse events and more durable lesions, contributing to improved patient outcomes.

FARAPULSE demonstrates clear benefits and added value compared to legacy ablation modalities. The Farapulse system continues to push the boundaries of innovation, leading the advancement of the PFA market and transforming the way we treat atrial fibrillation.

## **Innovation File Document upload:**

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### **Please provide appropriate references (PubMed, Abstract, Website):**

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10. Boston Scientific. Data on file 2025.

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