



FARAPULSE™

Pulsed Field Ablation System

**A minimally invasive
treatment for atrial fibrillation**



► What is atrial fibrillation (AF)?

AF is a disorder of the heart's electrical activity in which your heart beats irregularly (often fast).

► Symptoms of AF include:



Fatigue



Trouble breathing



Chest discomfort



Dizziness



Heart palpitations

► Treating AF?

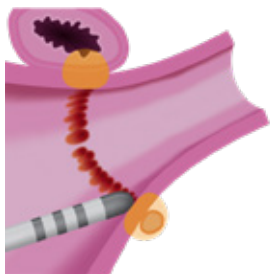
Catheter ablation is a minimally-invasive treatment, where long flexible tubes (catheters) are threaded through blood vessels to the heart. Electrodes on the tips of the catheters then transmit heat, cold or electrical energy to treat the cells responsible for the faulty irregular beats.

FARAPULSE™ Pulsed Field Ablation System is a minimally invasive option designed to return your heartbeat back to normal.



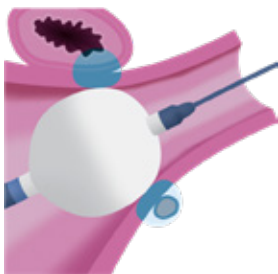
Thermal energy modalities use high frequency energy or extreme cold to neutralise the arrhythmic tissue.

Radiofrequency ablation



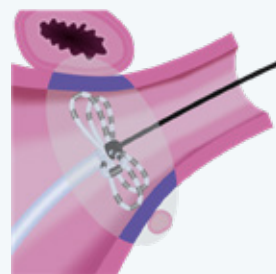
Uncontrolled heat conduction to surrounding structures may **cause thermal damage to surrounding anatomical structures (e.g. phrenic nerve, oesophagus and pulmonary veins)**.

Cryo Ablation



Pulsed field ablation uses high energy electrical pulses without heating or cooling therefore is considered as a non-thermal ablation modality.

Pulsed Field Ablation

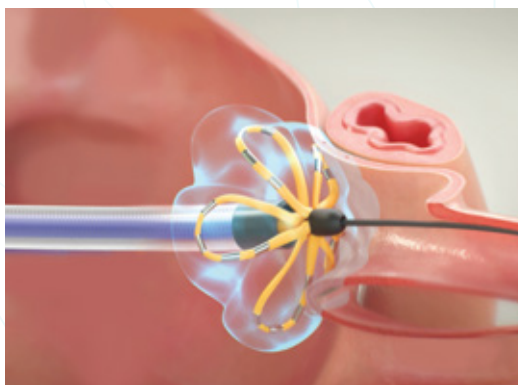


Pulsed field ablation is only dependent on the instantaneous electric field distribution. **This feature makes PFA lesion myocardial specific.**

A common form of cardiac ablation called **pulmonary vein isolation (PVI)** targets specific joining points where the veins enter the left atrium, to stop them being able to transmit abnormal signals from the veins to the left atrium.

Ablation technology has evolved over the years to increase the precision and efficiency of the procedure and to minimise the risk of damage to healthy heart tissue or nerves. **The latest innovation in cardiac ablation is pulsed-field ablation (PFA)³.**

► What is the FARAPULSE™ System?



Unlike radiofrequency and cryoablation, PFA works with pulsed, high-energy electrical fields and is therefore a non-thermal ablation method. Because cardiac cells are more sensitive to this electrical field, surrounding structures, such as the oesophagus or the phrenic nerve are usually not affected. PFA aims at selectively targeting and neutralising the tissue responsible for your AF.

During this procedure you will undergo general anaesthetic or deep sedation.

The pulsed field ablation process itself is very short (microseconds) and requires minimal applications per vein. The procedure only takes approximately one hour⁴.



Atrial fibrillation is the most common arrhythmia affecting

~33 million

people globally and is expected to more than

double

by 2030 due to widespread population aging in developing countries^{1,2}.



What to expect?

To prepare for your ablation procedure, pre-examinations below might be required:

► Discuss with your doctor if the FARAPULSE™ PFA System is right for you if

-  You suffer from paroxysmal or persistent AF (AF episodes may come and go, often resolving without treatment, or may persist over time)
-  You meet the criteria for a cardiac ablation procedure called pulmonary vein isolation (PVI)

► Preparation

-  Fasting after midnight prior to your procedure
-  Transesophageal echocardiogram to assess how well the heart is working
-  Blood test to check if your kidneys are healthy
-  Studies or scans to gather up-to-date information on how your heart is behaving. These may include an echocardiogram, and/or a 3D scan of your heart using MRI (magnetic resonance imaging) or CT (computed tomography)

► During catheter ablation

-  Medication through an intravenous (IV) line inserted in your arm
-  General anaesthesia or deep sedation
-  Small incision at your groin to insert catheter into the heart for pulsed field ablation delivery

► After catheter ablation

-  Minor soreness in the chest or bruising at the groin insertion site
-  Follow-up visits to monitor healing and heart rhythm
-  Update your physicians if you experience other discomforts or ongoing chest pain





Visit our website

<https://www.treatingatrialfibrillation.com/home.html>

1. Rahman, F., G.F. Kwan, and E.J. Benjamin, *Nature Reviews Cardiology*, 2014, 11: p. 639.
2. Patel, N.J., *et al.*, *Circulation*, 2014, 129: p. 2371-2379. 3. Lloyd-Jones, D.M., *et al.*, *Circulation*, 2004, 110(9): p. 1042-1046
3. Reddy VY, Gerstenfeld EP, Natale A, *et al.* ADVENT: Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation *New England Journal of Medicine* (August, 2023)
4. Schmidt B, Bordignon S, Neven K, *et al.* European real-world outcomes with Pulsed field ablation in patients with symptomatic atrial fibrillation: lessons from the multi-centre EU-PORIA registry. *Europace*. 2023 Jul 4;25(7):euad185. doi: 10.1093/europace/euad185.

Catheter ablation results vary across different patient groups.
Consult your physician on the most suitable catheter ablation for you.

CAUTION: This material is for informational purposes only and not meant for medical diagnosis. This information does not constitute medical or legal advice, and Boston Scientific makes no representation regarding the medical benefits included in this information. Boston Scientific strongly recommends that you consult with your physician on all matters pertaining to your health.

Not all types of atrial fibrillation are suitable for treatment with cardiac ablation or with the FARAPULSE™ Pulsed Field Ablation System. Your doctor will be able to advise you if it could be a suitable treatment for you according to diagnostic and treatment guidelines. As with any medical procedure, there are risks involved with pulsed field ablation with the FARAPULSE™ PFA System. FARAPULSE™ Pulsed Field Ablation System.

The FARAPULSE Pulsed Field Ablation (PFA) System is intended for the isolation of the pulmonary veins in the treatment of paroxysmal or persistent atrial fibrillation by rendering targeted cardiac tissue electrically non-conductive to prevent cardiac arrhythmia initiation or maintenance. With all medical procedures there are risks associated with the use of the device. The risks include but are not limited to pain or discomfort, electric shock, hypotension, infection/inflammation, allergic reaction, anesthesia risk, radiation injury/tissue burn, heart failure, renal failure, respiratory distress, arrhythmia, nerve injury (such as phrenic nerve or vagal nerve), gastrointestinal disorders, vessel trauma, cardiac trauma (such as perforation), injury related to adjacent structures (esophageal injury, atrio-esophageal fistula, pulmonary injury), pulmonary vein stenosis, surgical and access complications, muscle spasm, injury due to blood clot or air bubbles in the lungs or other organs, heart attack, TIA, stroke, and/or damage to red blood cells. In rare cases, cardiac arrest or death may occur. Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation and use of the device.

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EP-1616702-AC

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