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Pulsed Field Ablation with the FARAPULSE™ PFA System

A Guide to Your Procedure

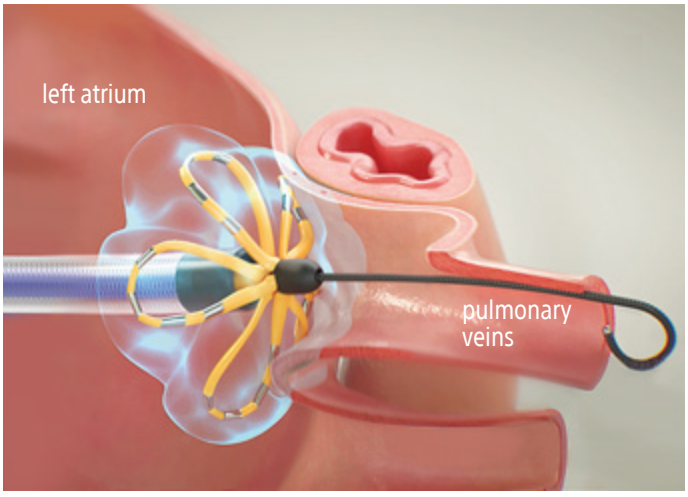
What is pulsed field ablation with the FARAPULSE™ PFA System?

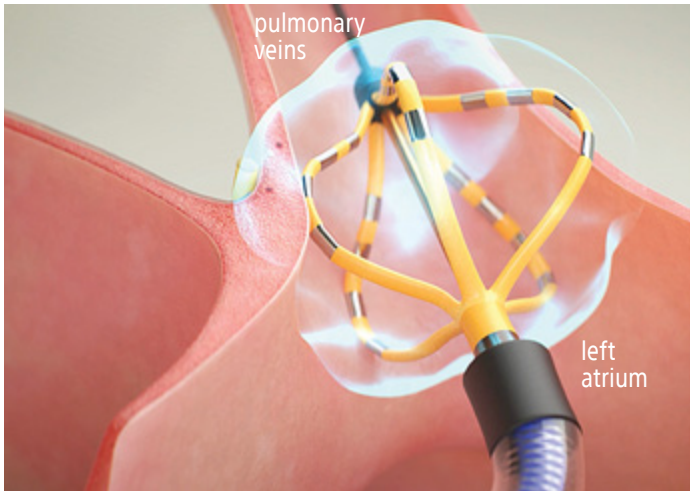
Pulsed field ablation (PFA) is one of the most recent advancements in the technology used for cardiac ablation – a minimally invasive treatment which targets specific sections of your heart to stop them transmitting the abnormal electrical signals that cause atrial fibrillation (AF).

The FARAPULSE™ PFA System is the most widely used PFA technology and the most comprehensively studied. Backed by 10 years' research, PFA with FARAPULSE™ has now been adopted as a treatment for AF in many centres around Europe and used to treat approximately 125,000 patients globally.[1]

How does it work?

The abnormal electrical signals that cause AF are often transmitted into the heart via the tissue at the joining points where the four pulmonary veins enter the left atrium. The FARAPULSE™ PFA System delivers microsecond electrical pulses to these specific areas to "neutralise" or deactivate the tissue so it can no longer transmit these abnormal electrical signals. The procedure is called pulmonary vein isolation or PVI.





What should I expect?

Preparation and treatment processes will vary by country and individual hospital. Your doctor will give you more specific information regarding your treatment, but the following gives a general overview of what to expect.

Prior to the FARAPULSE™ PFA procedure

Medication

Your doctor will advise you if any changes to your medication are needed prior to the procedure.

Testing

A routine blood test to check how healthy your kidneys are.

Studies or scans to gather up-to-date information on how your heart is behaving. These may include an echocardiogram and/or a 3D computed tomography (CT) scan of your heart.

Questions

Use the time before the procedure to ask questions on anything you are unsure or nervous about.

Fasting

You might be asked not to eat or drink anything for a certain period of time before your procedure.

During the FARAPULSE™ PFA procedure

Intravenous (IV) line

You will have a small needle inserted into a vein in your arm to create access for a thin tube that will deliver into your body the medications required for the procedure.

Anaesthesia/sedation

The anaesthetist or sedation practitioner will give you the medication required for either a general anaesthetic or deep sedation and monitor you until they are sure the procedure will be pain-free.

Catheter access

Your specialist (cardiologist/electrophysiologist) will make a small cut in your groin, through which a thin flexible tube called a catheter is inserted and gently guided up into your heart.

FARAPULSE™ PFA

The FARAPULSE™ System will be advanced through this first catheter.

Your specialist will open up the petals of the flower-shaped tip using different configurations to ensure only very specific areas (where the pulmonary veins enter the heart) are targeted.

When the catheter is in the correct location, your specialist will deliver tiny microsecond electrical pulses through electrodes on the FARAPULSE™ catheter to neutralise the precise anatomical areas and prevent abnormal electrical signals from transmitting from the pulmonary veins into your heart to cause AF. This is called pulmonary vein isolation or PVI.

The whole procedure will take approximately one hour.[2]

After the FARAPULSE™ PFA procedure

- Depending on what time of day you have your procedure and whether you have a general anaesthetic or sedation, you may be able to go home the same day or may need to spend a night in hospital.
- If any changes are required to your medication, you will be advised of this either when you are discharged, or at your follow-up appointment(s).
- Your heart rhythm should be restored to normal, and you should start to feel better.
- There may be minor soreness or bruising in your groin where the catheter was inserted.
- You should be able to return to normal activities within a few days.
- You will need to attend follow-up appointment(s) to monitor healing of the groin and your heart rhythm.
- You should advise your doctor if any of your symptoms return.

For more information on atrial fibrillation and pulsed field ablation with the FARAPULSE™ PFA System, visit our website

References:

1. Data on file. Boston Scientific.
2. 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.

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 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.

EP-1937708-AA

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