

FARAPULSE<sup>™</sup> Pulsed Field Ablation System

### The way your heart was born to beat.



Introducing FARAPULSE<sup>™</sup> Pulsed Field Ablation (PFA) for people with AFib. Next-generation ablation that safely treats the source of AFib symptoms.<sup>1\*</sup>

#### FARAPULSE<sup>™</sup> is the #1 doctor-recommended Pulsed Field Ablation (PFA) in the world.<sup>2</sup>

Atrial fibrillation (AFib) doesn't just disrupt the rhythm of your heart. It disrupts the rhythm of your life. It's time to get back to the beat you were born with. The FARAPULSE procedure is here to help you do just that.



# The FARAPULSE<sup>™</sup> PFA procedure treats the source of AFib symptoms. Safely and effectively.<sup>3\*\*</sup>

### Medications are designed to manage symptoms.

The first line of defense against AFib symptoms is usually medications like antiarrhythmics, but even when taking them, patients may continue to struggle with heart palpitations, shortness of breath or lightheadedness. Without proper treatment, AFib can progress, leading to serious complications like blood clots, stroke and heart failure. Studies have shown that early cardiac ablation in patients with paroxysmal (occasional) AFib can reduce the risk of recurrence and lower the chances of heart failure or stroke compared to later intervention.<sup>4</sup>

### Designed to target the source of irregular heartbeats.

FARAPULSE Pulsed Field Ablation, or PFA, is an advanced, minimally invasive procedure to treat AFib. FARAPULSE PFA technology uses short, precise pulses of electrical energy to target the areas in your heart that cause irregular beats, while minimizing damage to surrounding tissue.



Treating AFib with ablation has been shown to slow its progression.<sup>5</sup>

### Proven to turn disrupted into uninterrupted for many patients



FARAPULSE<sup>™</sup> PFA can significantly reduce or even eliminate episodes of AFib for many people.<sup>3\*\*</sup>

### **73**%

For patients who had the FARAPULSE PFA procedure, over 73% remained atrial arrhythmia free, and off of heart rhythm medications at one year.<sup>6</sup>

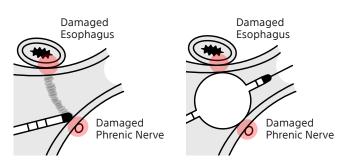
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In a clinical trial, 8 out of 10 experienced no return of AFib symptoms within a year of the procedure.<sup>3\*\*</sup>

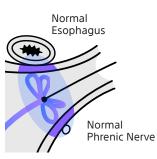


# FARAPULSE<sup>™</sup> PFA is the next generation of cardiac ablation.

Catheter ablation has been done for over 20 years. Traditional methods use thermal, or intensely hot or cold temperature energy to put the heart back in rhythm. The FARAPULSE PFA procedure offers a new generation of ablation technology approved by the FDA that works differently by using pulses of electrical energy. **Here is a closer look at how each one works.** 



Traditional thermal cardiac ablation uses extreme heat or cold to create scar tissue that blocks signals causing abnormal rhythms, but has the potential to damage surrounding tissue in important areas.



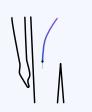
**FARAPULSE Pulsed Field Ablation** uses short rapid pulses of energy to selectively target the area in the heart that causes an irregular heart rhythm, while preserving surrounding tissue.

# Get to know the FARAPULSE PFA procedure.

This safe, effective, minimally invasive procedure is the world's most studied FDA-approved PFA procedure, with a less than 2.1% rate of complications.<sup>7</sup>

2.

3.



A small cut is made in the upper leg and a narrow tube is inserted.



A catheter is guided through the tube, into the left atrium of the heart where it sends energy pulses to precisely target the cells causing AFib.



Most people experience little or no pain during or after the procedure and can return home in a day or less.<sup>3</sup>

As with all medical procedures there are risks associated with this procedure. Be sure to talk to your doctor so that you thoroughly understand all of the risks and benefits associated with the procedure and use of the device.

#### Many people who had a FARAPULSE PFA procedure stayed in the hospital for a day or less.<sup>3</sup>

# © 949/0 of patients said they were satisfied with FARAPULSE<sup>™</sup> PFA<sup>2</sup>

If you're still having symptoms on medication, talk with your doctor about the FARAPULSE PFA procedure.

There are risks associated with all medical procedures. Talk to your doctor about the risks and benefits associated with the FARAPULSE<sup>™</sup> Pulsed Field Ablation procedure.

#### AFib and health risks.

AFib is a common type of cardiac arrhythmia, where the heart's upper chambers (atria) beat irregularly due to disorganized electrical signals. This can be paroxysmal (occasional) or persistent (lasting over 7 days). It is also possible to have AFib and not feel any symptoms at all (asymptomatic). You may be a candidate for the FARAPULSE<sup>™</sup> PFA procedure if you answer YES to each of the following questions:

Has your doctor ever told you that you have atrial fibrillation (AFib) and prescribed you medication for it?

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Have you ever taken medications to manage the symptoms of AFib? (These medications may have been prescribed to manage your heart rate or rhythm, but do not include blood thinners.)

Even when you are taking your AFib medication, do you have AFib symptoms that come and go, but last less than 7 days? (Your doctor might have told you that you have paroxysmal AFib.)

If your answers are yes, talk with your doctor about FARAPULSE PFA.



#### Important Safety Information

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 nonconductive 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 procedure and use of the device.

1. Ekanem E, Neuzil P, Reichlin T, et al. Safety of pulsed field ablation in more than 17,000 patients with atrial fibrillation in the MANIFEST-17K study. Nat Med. 2024;30:2020-2029. 2. Boston Scientific. Data on file. 2024. 3. Turagam MK, Neuzil P, Schmidt B, et al. Safety and effectiveness of pulsed field ablation to treat atrial fibrillation: one-year outcomes from the MANIFEST-PF registry. Circulation. 2023;148(1):35-46. 4. Tennesen J, Ruwald MH, Pallisgaard J, Rasmussen PV, Johannessen A, Hansen J, et al. Lower recurrence rates of atrial fibrillation and MACE events after early compared to late ablation: a Danish nationwide register study. https://www.ahajournals.org/doi/10.1161/JAHA.123.032722 5. Kuck KH, Lebedev DS, Mikhaylov EN, Romanov A, Gellér L, Kalējs O, Neumann T Davtyan K, On YK, Popov S, Bongiorni MG, Schlüter M, Willems S, Ouyang F. Catheter ablation or medical therapy to delay progression of atrial fibrillation: the randomized controlled atrial fibrillation progression trial (ATTEST). Europace. 2021;23(3):362–369. doi: 10.1093/europace/euaa298. PMID: 33330909; PMCID: PMC7947582. 6. Reddy VY, Gerstenfeld EP, Natale A, et al. Pulsed field or conventional thermal ablation for paroxysmal atrial fibrillation. New England Journal of Medicine. 2023;389(18):1660-1671. doi:10.1056/NEJMoa2307291 7. Reddy V, Lehmann JW, Gerstenfeld EP, et al. A randomized controlled trial of pulsed field ablation versus standard-of-care ablation for paroxysmal atrial fibrillation: The ADVENT trial rationale and design. Heart Rhythm 2023;4(5):317-328. doi: 10.1016/i.hroo.2023.03.001

\*In a clinical trial the major adverse event rate was 0.98% (n=17,642). Due to the retrospective nature of the registry, the adverse event rate was not reported at a prespecified time point. Major complication is defined as death, oesophageal fistula/ dysmotility, PV stenosis, pericardial tamponade, stroke, phrenic nerve injury (persistent), vascular complications requiring intervention and coronary artery spasm. \*\*In a clinical trial 81.6% of people with paroxysmal AFib had no atrial fibrillation, atrial flutter or atrial tachycardia after a single ablation procedure at 12 months.

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Learn more about FARAPULSE<sup>™</sup> Pulsed Field Ablation. Visit FARAPULSE.com