Boston Scientific
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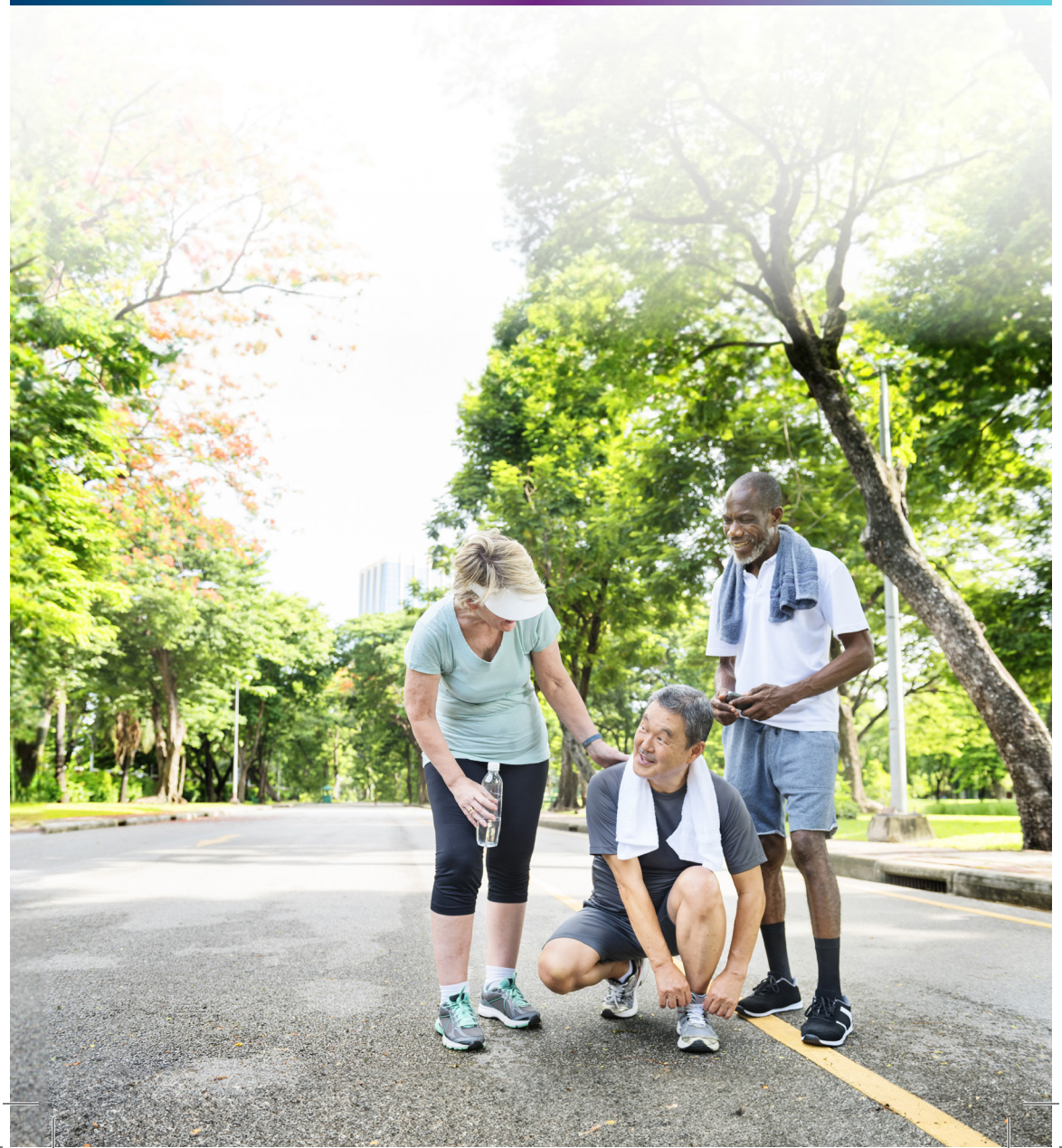
AVANT GUARD
CLINICAL TRIAL
Patient Information Brochure



PEOPLE WITH PERSISTENT ATRIAL FIBRILLATION DESERVE MORE OPTIONS.

Doctors and scientists are always working to find new and better treatments.

A clinical study called AVANT GUARD is taking place at your hospital or clinic. Your doctor thinks you might be a candidate. By participating in this study, you could help other people with persistent atrial fibrillation have more treatment options in the future.

This booklet outlines the visits and tests you can expect if you choose to participate in the AVANT GUARD Study. This booklet may contain words you do not recognize or understand. Please ask your doctor or healthcare provider to answer your questions or explain anything that is not clear to you. Before you enroll in the study, your doctor will determine if you are eligible and willing to participate. Your doctor or healthcare provider will discuss study participation and guide you through the informed consent process. Please discuss all questions with your doctor.

What is a clinical study?

Clinical studies are research trials to gather information about different medical treatments. The goal of the study may be to gain regulatory approval of a medical device or therapy, helping doctors to have additional knowledge about an illness or explore whether already-approved treatments may work for additional conditions or groups of people.

Clinical studies follow strict guidelines to ensure participants' safety and well-being as well as to ensure accurate collection of data.

What is AVANT GUARD?

AVANT GUARD is the short name for the clinical study titled "A Prospective Randomized Multicenter Global Study Comparing Pulsed Field Ablation (PFA) versus Anti-Arrhythmic Drug (AAD) Therapy as a First-Line Treatment for Persistent Atrial Fibrillation".

This study is going to look at whether people with your medical condition could benefit from having an ablation treatment with the FARAPULSE™ Pulsed Field Ablation System as a first treatment type, instead of receiving Anti-Arrhythmic Drug therapy.

What is the medical condition that qualifies me for this study?

To participate in this study, you must have persistent atrial fibrillation and meet the study eligibility criteria.

What will happen if I decide to participate in the study?

Those who choose to participate in the AVANT GUARD study will be randomly assigned to receive either Pulsed Field Ablation (PFA) or Anti-Arrhythmic Drug (AAD) treatment. Randomization will be done in a 2:1 manner, meaning that two out of every three participants will be randomly assigned to receive the PFA treatment and one will receive AAD treatment. Site personnel will not know which treatment you will be assigned to until you are randomized.

What are Anti-Arrhythmic Drugs (AADs)?

Anti-Arrhythmic Drug (AAD) Treatment

Currently people with your medical condition are prescribed Anti-Arrhythmic Drugs as the first line of treatment. Anti-Arrhythmic Drugs are already approved for use in people with your condition. There are many kinds of AADs available. If you are assigned to the AAD treatment, your doctor will determine the best one for you to take. If the AAD treatment does not resolve your arrhythmia, after 3 months, you may qualify to receive the PFA treatment procedure. Your doctor will discuss this treatment option with you.

What is Pulsed Field Ablation (PFA)?

Pulsed Field Ablation Treatment

If you are randomized to the pulsed field ablation, you will receive this treatment first instead of an AAD. Pulsed field ablation is a type of ablation procedure to destroy abnormal tissues in your heart that cause atrial fibrillation. Ablation procedures can be done using heat (radiofrequency energy), cold (cryo energy), or electrical energy emitted by pulses (pulsed

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FARAWAVE™ PULSED FIELD ABLATION CATHETER, PART OF THE FARAPULSE PFA SYSTEM

field ablation). The latter (PFA) is the one that is being used as part of the AVANT GUARD Study.

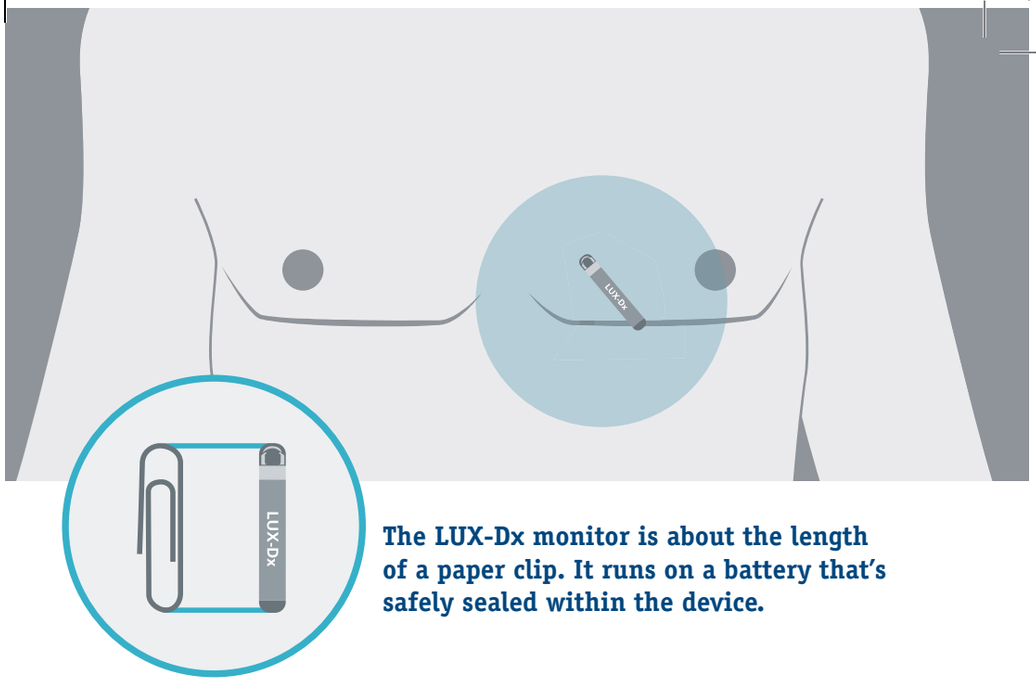
The PFA treatment is considered investigational because the system used to perform the treatment procedure is not approved as a first-line treatment of persistent atrial fibrillation. The ablation procedure that your doctor will perform as a part of this study will be like the ablation procedure that he/she would perform if you were not participating in this study, except they would use a different type of system that is already approved for use with your condition.

How will my heart condition be monitored during the study?

An insertable cardiac monitor (ICM) will be used during the study to automatically monitor and record information about your heart rhythms for your doctor. An ICM is a small device (about the size of a paper clip) that will be inserted under your skin in the left chest. The specific ICM that will be used for the study is called the LUX-Dx™. Depending on where you live, the ICM may not be commercially available (not approved for use) and will only be provided as a part of the study. The ICM does not treat cardiac arrhythmias and is not intended to assist with medical emergencies. Discuss any questions about the ICM with your doctor.

You are not able to participate in the study unless you have a LUX-Dx™ ICM. You will need to have the ICM inserted no later than the day you receive your assigned treatment, unless you already have a LUX-Dx™ ICM that was put in within the past 6 months.

Study site personnel will want to know if you feel certain symptoms or sensations (like fainting, a racing heartbeat, shortness of breath, fluttering of your heart, or lightheaded), and what you were doing when you felt the symptoms. Your



The LUX-Dx monitor is about the length of a paper clip. It runs on a battery that's safely sealed within the device.

LUX-Dx™ ICM will send a "symptomatic manual transmission" to the study site with information about what you're feeling.

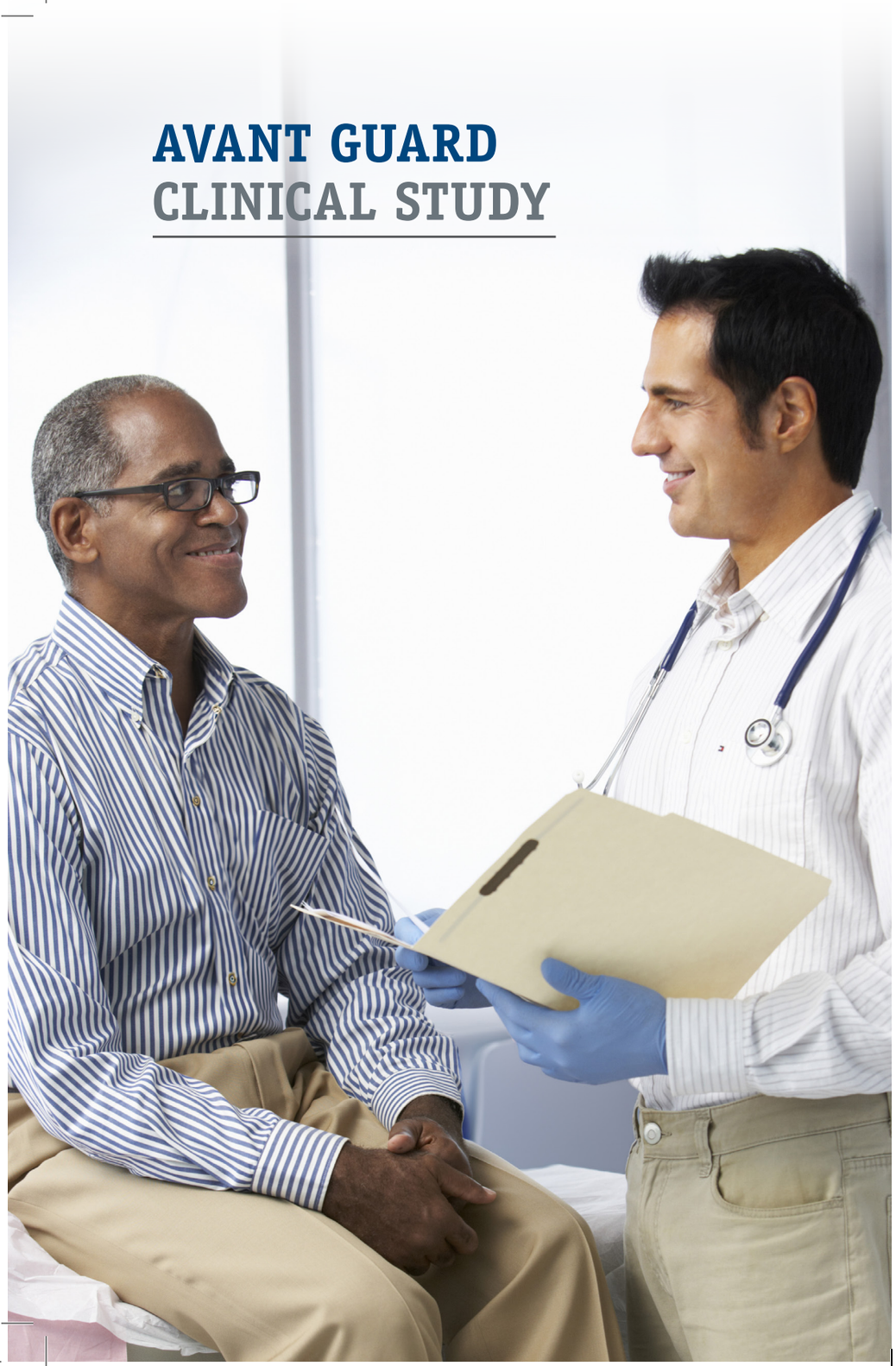
Are there any possible risks to participating in AVANT GUARD?

Risks are associated with the PFA and AAD treatments as well the ICM. Your doctor will discuss these risks with you in detail. A complete list of possible risks can be found in the informed consent form that you will be asked to sign prior to participating.

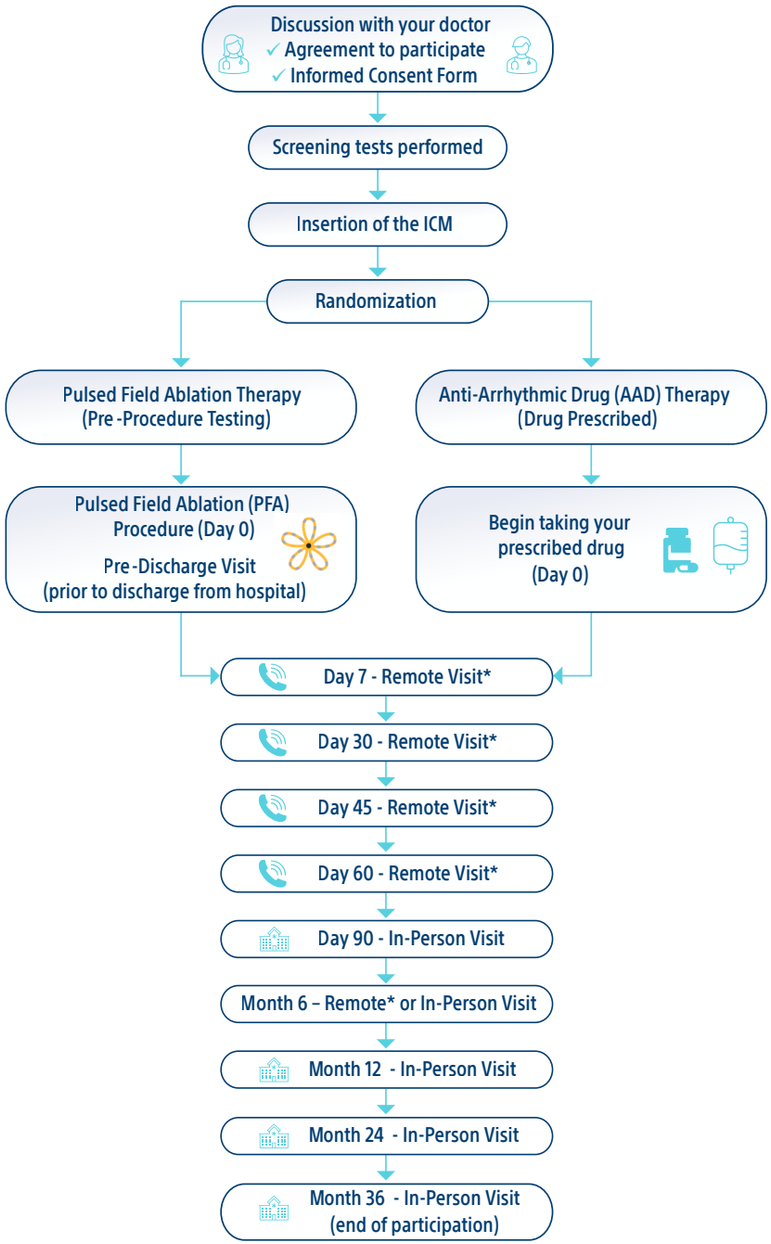
What will be expected of me if I choose to participate in AVANT GUARD?

It is important that you return to your study doctor's office for the required visits and that you participate in the phone calls from the study doctor or nurses. You can find more details on the next page and the full description of visits required in the informed consent document.

AVANT GUARD
CLINICAL STUDY



AVANT GUARD Participant Schedule



*Remote visits are done via phone or telehealth options available at your location

LEARN MORE ABOUT AVANT GUARD CLINICAL STUDY **BY TALKING WITH YOUR DOCTOR.**

Thank you for considering participation in the AVANT GUARD Study.

Study Physician Contact Name and Phone Number:

Study Research Coordinator Name and Phone Number:

Center Name:

Notes / questions

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The FARAPULSE system is an investigational device as a first-line treatment of patients with Persistent Atrial Fibrillation. The FARAPULSE system is FDA approved for treatment of patients with paroxysmal atrial fibrillation.

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