



**Boston  
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Advancing science for life™



**WATCHMAN™**  
LEFT ATRIAL APPENDAGE CLOSURE IMPLANT



SIMPLAAFY LAAC Drug Regimen Trial

Is the  
**SIMPLAAFY**  
clinical trial  
right for you?

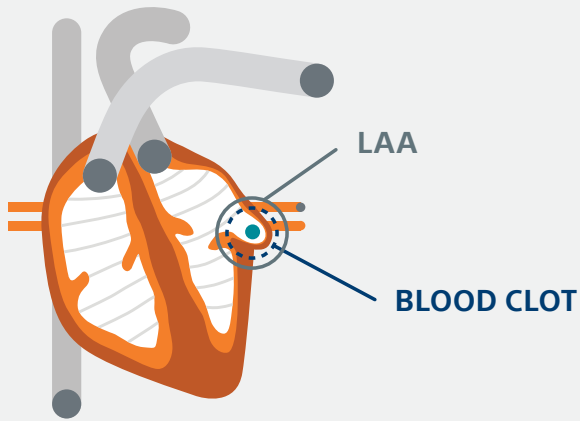
**SIMPLAAFY**  
LAAC DRUG REGIMEN TRIAL

# What is the connection between AFib and stroke?

Atrial fibrillation (AFib)\* is a heart condition where the two upper chambers of the heart quiver. This condition can cause blood clots to form in an area of the heart called the left atrial appendage (LAA). If a blood clot forms here, it can travel through an artery to the brain and cause a stroke. Some people have AFib that is not caused by a heart valve problem. These people are said to have non-valvular AFib.

People with AFib have a five times greater risk for stroke than people with normal heart rhythms.<sup>1</sup>

\*All mentions of 'AFib' or 'Atrial fibrillation' specifically indicate atrial fibrillation not caused by a heart valve problem.



## Understanding the WATCHMAN FLX™ Pro Implant

The WATCHMAN Implant requires a one-time, minimally invasive procedure. The implant may reduce your stroke risk worry for life. The FDA has approved the WATCHMAN Implant.



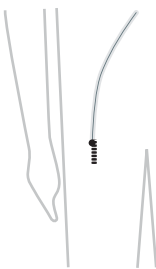
## Managing your stroke risk with the WATCHMAN Implant

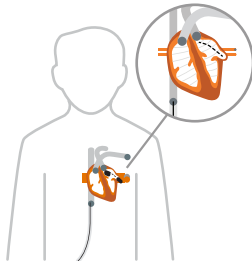


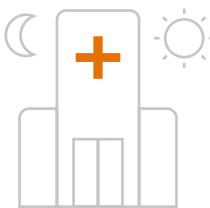
Blood thinners are an effective way to lower the risk of stroke. Many people with non-valvular AFib use blood thinners to lower their risk. But blood thinners can come with challenges and a higher risk of bleeding.

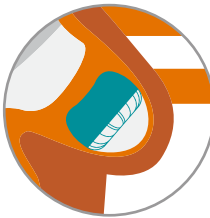
The WATCHMAN Implant is for people with non-valvular AFib who need another option to reduce their stroke risk. The WATCHMAN Implant lowers the risk of stroke by closing off the LAA. This prevents blood clots from forming in this part of the heart and causing a stroke.

## The WATCHMAN Implant procedure

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1 To begin the procedure, your doctor makes a small cut in your upper leg. The doctor then inserts a narrow tube.
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2 Your doctor guides the WATCHMAN Implant through the tube into your left atrial appendage (LAA).
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3 The procedure is typically done under general anesthesia. You'll be asleep and won't feel any pain. Many patients who get the WATCHMAN Implant stay in the hospital for a day or less.
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4 After the procedure, your own heart tissue will grow over the WATCHMAN Implant. This tissue will form a barrier against blood clots.

## Talk to your doctor



Schedule a visit with your heart doctor to find out if you're an appropriate candidate for this trial. You can also visit [bsci.com/SIMPLAAFY](https://bsci.com/SIMPLAAFY) for more information.



Scan this QR code for more information.



# The SIMPLAAFY clinical trial

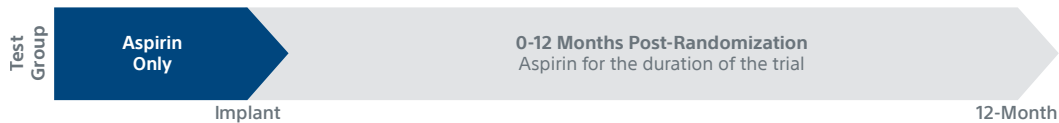
The WATCHMAN Implant is an alternative for AFib patients who cannot tolerate long-term blood thinner medication.

Typically, after the WATCHMAN procedure, your doctor will prescribe antiplatelet, aspirin or blood thinner medication. The medication will help the tissue in your heart grow over the device. In this trial, the doctor will prescribe based on the randomization to either a single drug or several drugs to support the healing process. The trial will evaluate which option can help to reduce stroke and bleeding risk.

If you decide to participate, you will be randomized into either the test or control group. Randomization means that you are put into a group by chance.

**Patients assigned to the test group will receive one of the lower dose medications:**

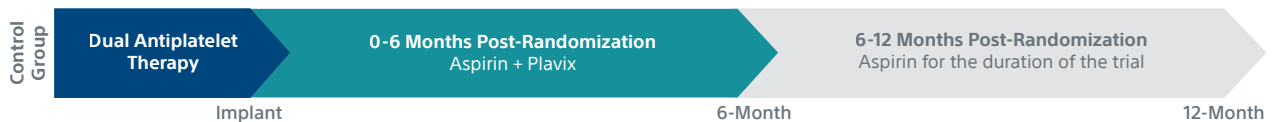
EITHER aspirin only for the entire 12 months of the study.



OR a lower dose of blood thinners for 3 months, and then aspirin for 9 months. Blood thinners are also known as NOACs.



**Patients assigned to the control group will receive a full dose of medication:** Dual antiplatelet therapy for 6 months. This therapy includes aspirin and clopidogrel, also known as Plavix™. Then patients will take aspirin only for 6 months.



## Is the SIMPLAAFY clinical trial right for me?

You may be a candidate for the trial if you answer **YES** to the following statements:

- ✓ My doctor diagnosed me with non-valvular atrial fibrillation
- ✓ My doctor approved me to take blood thinners and seek a non-pharmacologic alternative to blood thinners



Please talk to your doctor about the risks related to this clinical trial.

## **Important Safety Information**

The WATCHMAN FLX™ and WATCHMAN FLX™ Pro Devices are permanent implants designed to close the left atrial appendage in the heart in an effort to reduce the risk of stroke.

With all medical procedures there are risks associated with the implant procedure and the use of the device. The risks include but are not limited to accidental heart puncture, air embolism, allergic reaction, anemia, anesthesia risks, arrhythmias, AV (Arteriovenous) fistula, bleeding or throat pain from the TEE (Trans Esophageal Echo) probe, blood clot or air bubbles in the lungs or other organs, bruising at the catheter insertion site, clot formation on the device, cranial bleed, excessive bleeding, gastrointestinal bleeding, groin puncture bleed, hypotension, infection/pneumonia, pulmonary edema, renal failure, stroke, thrombosis, and transient ischemic attack. In rare cases death can occur.

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of the device.

\* “AFib” and “atrial fibrillation” refer to atrial fibrillation not caused by a heart valve problem.

1. Holmes D. Atrial Fibrillation and Stroke Management: Present and Future. Semin Neurol 2010, 30:528-536.

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