WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

Boston Scientific
Advancing science for life™

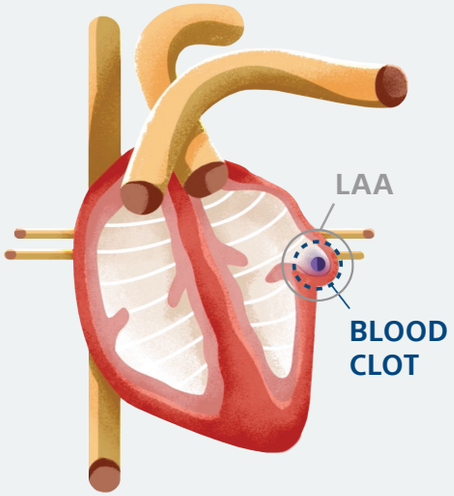
Is CHAMPION-AF Right for Me?

CHAMPION-AF
CLINICAL TRIAL

What is AFib?

Atrial Fibrillation (AFib)* is a heart condition in which the upper chambers of your heart quiver. This condition can cause blood clots to form in an area of your 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. People with AFib have a five times greater risk of stroke than people with normal heart rhythm.[1]

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



Managing AFib and Stroke Risk

Today, a number of treatments including blood thinner medication or left atrial appendage closure (LAAC) implants like WATCHMAN FLX™ are available to protect you from strokes related to your AFib.

The CHAMPION-AF clinical trial will compare WATCHMAN FLX to a category of blood thinners called non-vitamin K antagonist oral anticoagulation, or NOACs.

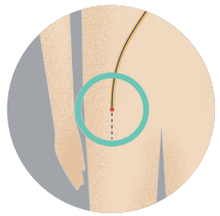
The study will research the safety and effectiveness of the WATCHMAN FLX device compared to treatment with NOAC therapy to determine its effectiveness in stroke risk reduction for patients with AFib not caused by a heart valve problem.

Understanding WATCHMAN FLX™ Technology

The WATCHMAN FLX Implant requires a one-time, minimally invasive procedure that may reduce your stroke risk worry for life.

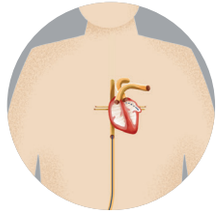
The Implant Procedure

Here's what happens during the procedure.



Step 1

To implant the device, your doctor inserts a narrow tube into a vein in your upper leg.



Step 2

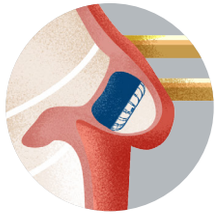
Your doctor guides the device through the tube, into your left atrial appendage (LAA).

Step 3

The procedure is typically done under general anesthesia and takes under an hour. People usually stay in the hospital overnight and go home the next day.

Step 4

After the procedure, you will be on blood thinning medication, as prescribed by your study doctor.



Step 5

Imaging of your heart will be performed 4 months after your procedure to see how well the heart tissue has grown over the implant.

The CHAMPION-AF Clinical Trial

Currently, WATCHMAN FLX™ is an FDA approved device alternative for AFib patients who are unable to tolerate long-term blood thinner medication.

The CHAMPION-AF clinical trial is studying WATCHMAN FLX as a first choice option versus blood thinners (NOAC) for AFib patients who may be medically able to tolerate long-term blood thinner use, but would consider a one-time option for stroke risk reduction.

If you decide to participate in this study, you will be "randomized" into either the "device" or "control" group. Randomization means that you are put into a group by chance, like the flip of a coin. Candidates randomized to the device group will be scheduled for a WATCHMAN FLX Implant. Control group patients will not have the device implanted and will be prescribed a blood thinner (NOAC) for the duration of the trial at the discretion of the study doctor.

Is CHAMPION-AF Right For Me?

You may be a candidate for the CHAMPION-AF clinical trial if you can answer **YES** to the following questions:

- ✔ I have been diagnosed with non-valvular atrial fibrillation
- ✔ I have been deemed suitable for long-term blood thinner therapy

Talk to Your Doctor

For more information, or to find out if you're an appropriate candidate for the CHAMPION-AF clinical trial, visit **watchman.com/champion-af-patient** and schedule an appointment with your heart doctor.

CHAMPION-AF May Be Right For You

Learn more at:
watchman.com/champion-af-patient

WATCHMAN FLX™ is an FDA approved device being studied for an expanded indication as a first line therapy vs NOAC for NVAF patients. The use of WATCHMAN or WATCHMAN FLX as a first-line therapy for stroke risk reduction in NVAF patients is considered investigational.

Caution: Investigational Device. Limited by US law to investigational use only. Not available for sale.

Please talk to your physician about any additional risks related to the CHAMPION AF trial.

Important Safety Information

The WATCHMAN and WATCHMAN FLX 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, pneumothorax, pulmonary edema, pulmonary vein obstruction, 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.

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

2 WatchUsNow.com. *The Harris Poll online survey.* Boston Scientific. SH-574213-AA. https://www.watchusnow.com/?page=d75be9d4-ba36-456c-a72d-dc3df07892da. Accessed March 28, 2019.

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