

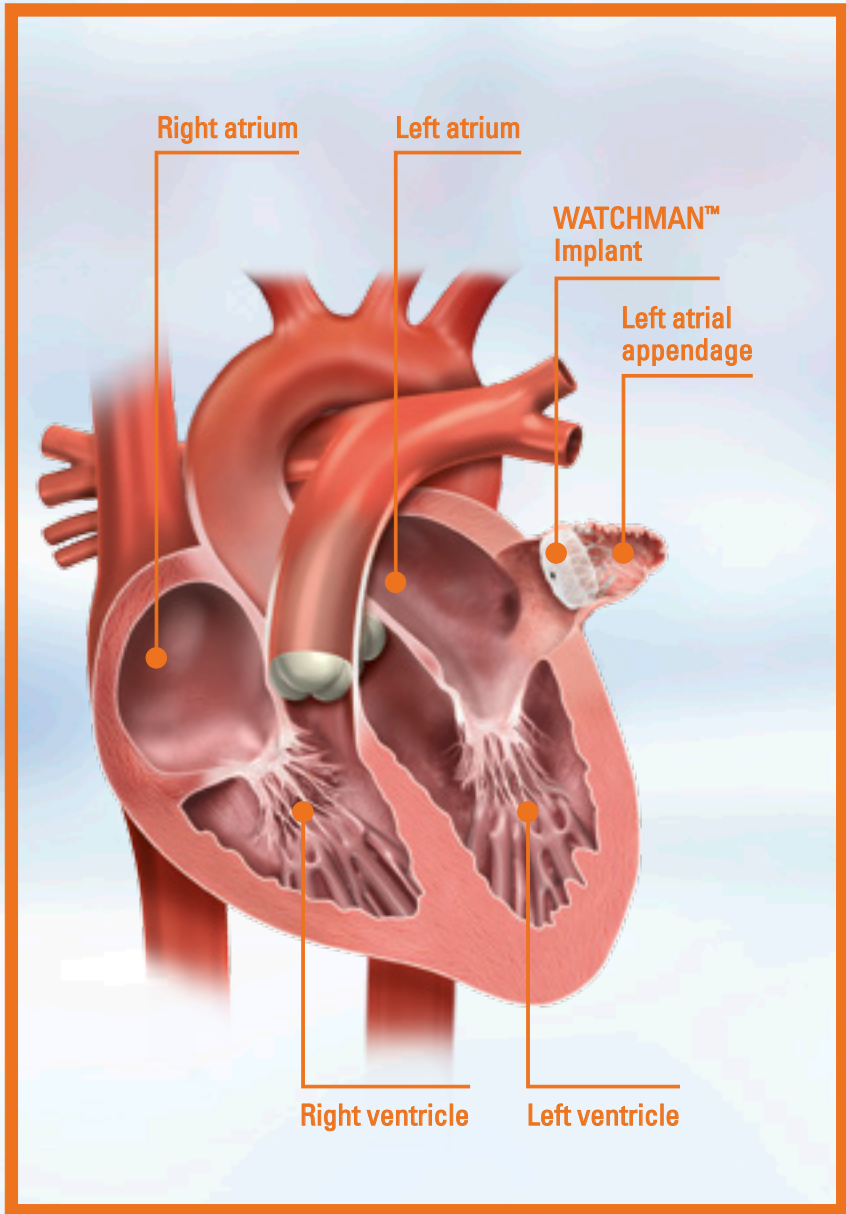
A PATIENT'S GUIDE TO THE LEFT ATRIAL APPENDAGE CLOSURE

Reducing the risk of stroke in atrial fibrillation

TABLE OF CONTENTS

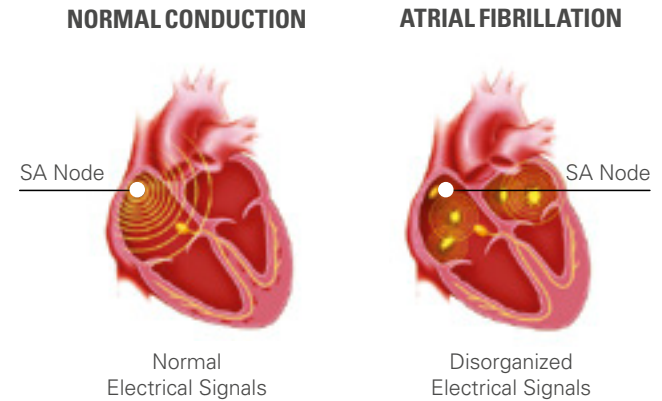
What is Atrial Fibrillation (AF)?	5
What causes Atrial Fibrillation?	6
What is a Stroke?	6
How Atrial Fibrillation is linked to Stroke?	7
What are the Treatment Options to reduce Stroke if you have AF?	8
What is the WATCHMAN™ LAA Closure Device?	9
How is the WATCHMAN™ implanted?	9
What happens after the Procedure?	10
What are the risks?	10
Who can benefit from a WATCHMAN™ Implant?	11

IMPORTANT – Please Note: Information provided by Boston Scientific Corporation (Boston Scientific) is gathered from internal and third-party sources and is presented for illustrative purposes only. This information does not constitute medical, reimbursement or legal advice, and Boston Scientific makes no representation or warranty regarding this information or its completeness, accuracy or timeliness. Boston Scientific strongly recommends that you consult with your physician, payers, reimbursement specialist and/or legal counsel regarding medical, coverage and reimbursement matters.



WHAT IS ATRIAL FIBRILLATION (AF)?

Atrial fibrillation is a heart condition, a type of irregular heartbeat. Atrial fibrillation itself is not life-threatening, but it can lead to stroke and heart failure and so it has potentially serious effects. Many patients often do not experience any symptoms, although a fast heartbeat may be felt. Other typical symptoms include tiredness, shortness of breath, chest pain, dizziness, which may not be attributed to atrial fibrillation correctly.



Normally, the electrical signal that tells your heart to beat comes from the sinoatrial node, or SA node, in the right atrium. But during AF, signals start irregularly from several areas in the atria.

Atrial fibrillation is the most common cardiac arrhythmia, affecting 1% – 2% of general population, and it is more common as the population gets older.

There are three main type of atrial fibrillation:

- **Paroxysmal**: AF episodes terminate spontaneously within seven days.
- **Persistent**: AF episodes last more than seven days and less than one year. In this setting, a regular rhythm should be reached through intervention.
- **Permanent**: AF episodes are continuous and last more than one year. The patient does not respond to interventional therapy to return to regular rhythm.

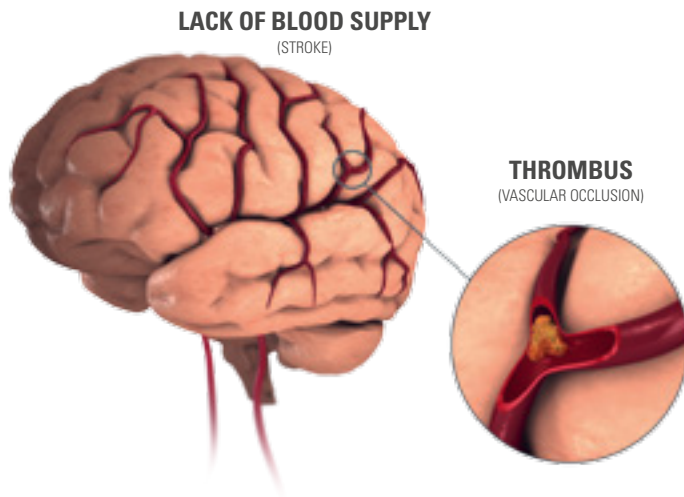
WHAT CAUSES ATRIAL FIBRILLATION?

The causes of AF are not completely understood, but the risk to develop it increases as you get older. However, it is more likely to occur in people with other heart conditions, such as:

- High blood pressure
- Cardiac insufficiency (heart failure)
- Coronary heart disease
- Some forms of heart valve diseases

WHAT IS A STROKE?

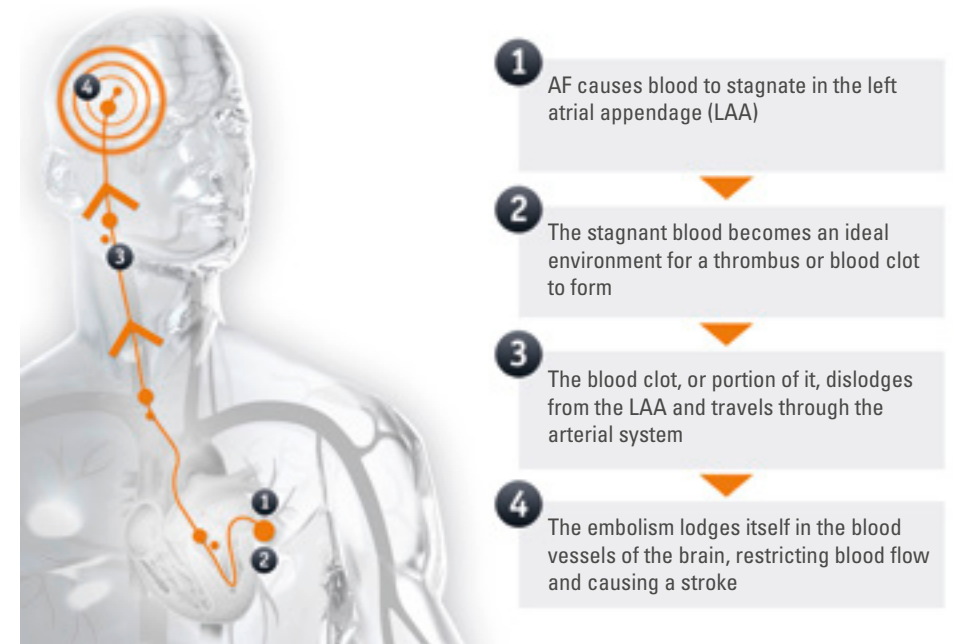
A stroke happens when the blood supply to part of the brain is cut off. This can be caused to a blockage in an artery by a blood clot (ischaemic stroke) or by bleeding in the brain caused by the sudden rupture of a blood vessel (haemorrhagic stroke). Stroke can happen suddenly and have immediate and lasting debilitating effect. Immediate medical treatment is required to minimize later complications.



HOW ATRIAL FIBRILLATION IS LINKED TO STROKE?

The average person with AF is 5 times more likely to suffer a stroke than someone with a regular heartbeat.

In people with AF not caused by a heart valve problem, more than 90% of stroke-causing clots that come from the heart are formed in a small appendage of the left atrium, the so-called left atrial appendage.



WHAT ARE THE TREATMENT OPTIONS TO REDUCE STROKE IF YOU HAVE AF?

There are different treatment options to reduce your stroke risk if you have AF not caused by a heart valve problem.

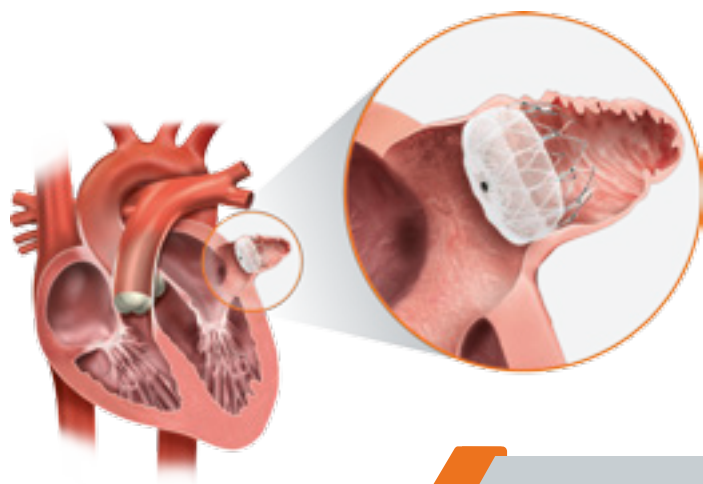
BLOOD THINNER THERAPY

Blood thinner medications, also called anticoagulant drugs, are an effective way to lower the risk of stroke in people with AF. The blood thinner warfarin has been available for more than 60 years and there are also several newer blood thinners available now, Novel Oral Anticoagulants (NOAC), including ELIQUIS® (Apixaban), PRADAXA® (Dabigatran), XARELTO® (Rivaroxaban), LIXIANA® (Edoxaban). These medications effectively reduce the risk of cardioembolic stroke, however they are not well tolerated by some patients and carry a risk for bleeding complications.



LEFT ATRIAL APPENDAGE CLOSURE

Some people with AF at high risk of stroke who should take oral anticoagulants are either unable or unwilling to take them because of associated risks, side effects or medical reasons that could also result in a high risk for bleedings. A minimally-invasive procedure called Left Atrial Appendage Closure provides an effective solution to reduce stroke risk in these people, permanently closing off the left atrial appendage.



The left atrial appendage is a small pouch of the left atrium. More than 90% of stroke-causing clots coming from the heart are formed here.

WHAT IS THE WATCHMAN™ LAA CLOSURE DEVICE?

The WATCHMAN™ device is a permanent implant designed to keep harmful blood clots from entering your blood stream, potentially causing a stroke. It is made from very light and compact materials commonly used in many other medical devices.

The device measures between 21 mm and 33 mm and is implanted at the entrance of the left atrial appendage.



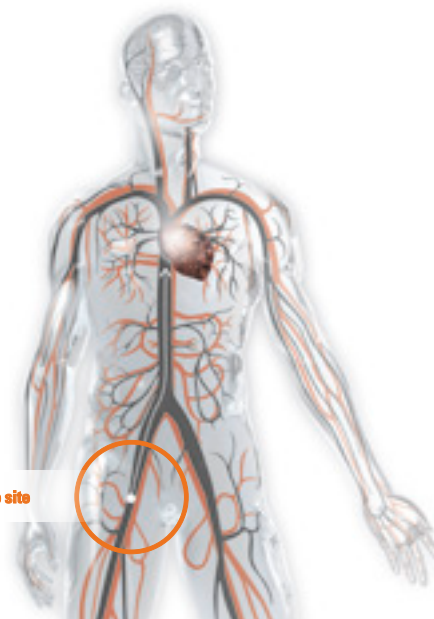
HOW IS THE WATCHMAN™ IMPLANTED?

The WATCHMAN device is implanted in your heart in a one-time procedure. It's a permanent device that doesn't have to be replaced and can't be seen outside the body. The minimally-invasive procedure to implant a WATCHMAN device is performed by a cardiologist in a hospital. The procedure is generally performed under general anesthesia or conscious sedation and takes about an hour.

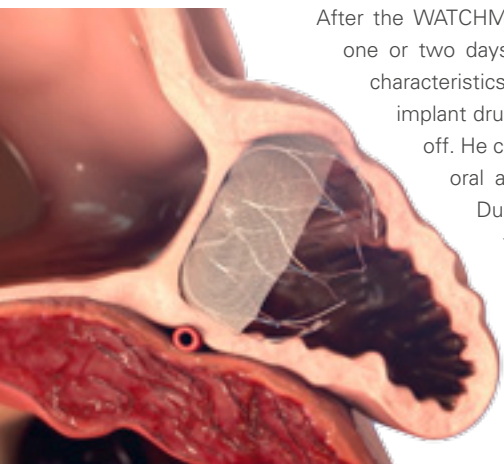
To implant WATCHMAN, your doctor makes a small cut in your upper leg and insert a narrow tube (catheter), as done in a standard stent procedure. Your doctor then guides WATCHMAN into the left atrial appendage of your heart. Once the catheter is in the correct position, the doctor will take pictures of your heart via x-ray and echocardiography to measure your left atrial appendage and determine the appropriate WATCHMAN size. Once the device is released, the catheter is removed and the puncture site is closed by a suture or pressure bandage.

A minimally-invasive procedure offers the advantage of faster healing, less pain after the procedure and faster recovery, allowing patients to leave the hospital earlier.

Puncture site



WHAT HAPPENS AFTER THE PROCEDURE?



After the WATCHMAN procedure, patients usually stay in the hospital for one or two days for follow-up. Your doctor will assess your individual characteristics and conditions and will decide which is the best post-implant drug regimen for you to have your LAA permanently closed off. He could prescribe you dual antiplatelet therapy (DAPT), novel oral anticoagulants (NOACs) or warfarin, along with aspirin.

During this time, heart tissue will grow over the implant to form a barrier against blood clots. Your doctor will monitor this process by taking pictures of your heart to see when you can stop taking medications.

Many doctors require follow-up appointments over the next year to ensure your recovery is going well. Clinical studies have shown that WATCHMAN safely and effectively reduce the risk of stroke and long-term risk of bleeding associated with anticoagulant use in patients with AF not caused by a heart valve problem.

WHAT ARE THE RISKS?

WATCHMAN can be successfully and safely implanted in most patients (98.5% implantation success rate in a large European study). The risk of complication during the procedure is less than 3% and is comparable to other cardiac procedures, e.g., ablation of cardiac arrhythmias. Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of the WATCHMAN Device.

Potential 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 WATCHMAN™ Closure 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.

WHO CAN BENEFIT FROM A WATCHMAN™ IMPLANT?

The WATCHMAN™ LAA closure therapy is intended to prevent thrombus to escape from the left atrial appendage and reduce the risk of life-threatening bleeding events in patients with AF not caused by heart valve problems. If you are at risk of stroke, should take oral anticoagulants but are either unable or unwilling to take them because of associated risks (high risk for bleedings included), you may benefit from the WATCHMAN Left Atrial Appendage Closure Implant. Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of the WATCHMAN Device.



MORE INFORMATION

Learn more about LAA closure
with WATCHMAN™

www.watchman.com/uk

All trademarks and copyrights are the property of their respective owners.
ATTENTION: These products may only be purchased by or on behalf of a physician. Indications, contraindications, warnings and instructions for use are to be found in the instructions for use attached to the product. Information only for use in countries with valid product registrations at the competent health authorities.
This information is not intended for use in France.

The patient's guide is for informational purposes only and is not intended for product advertising or medical diagnosis. This information does not constitute a medical or legal recommendation and Boston Scientific makes no representations or warranties, either express or implied, for the accuracy, completeness, accuracy or timeliness of this information. Accordingly, Boston Scientific strongly recommends that you consult your doctor regarding any matter of your health or any questions.

The content of this document relates to Boston Scientific and applies to the products of Boston Scientific, but does not apply to all left atrial appendage closure devices available in the EU market.

SH-541601-AA APR2018 Printed in Germany by medicalvision.

**Boston
Scientific**

Advancing science for life™

www.bostonscientific.eu

© 2018 Boston Scientific Corporation
or its affiliates. All rights reserved.
DINSH0131EA