




Amplatzer™ Amulet™
Left Atrial Appendage Occluder

A PATIENT'S GUIDE TO THE NONSURGICAL CLOSURE OF **THE LEFT ATRIAL APPENDAGE**

STRUCTURAL INTERVENTIONS





THIS BROCHURE IS INTENDED TO PROVIDE YOU WITH GENERAL INFORMATION ABOUT THE NON-SURGICAL CLOSURE OF A LEFT ATRIAL APPENDAGE (LAA), WHICH SHOULD BE FURTHER DISCUSSED WITH A DOCTOR. IT IS NOT INTENDED TO PROVIDE MEDICAL CARE OR TREATMENT. YOU SHOULD CONSULT WITH A DOCTOR REGARDING THE DIAGNOSIS OR TREATMENT OF YOUR MEDICAL CONDITION.

OVERVIEW OF LEFT ATRIAL APPENDAGE AND ATRIAL FIBRILLATION

The left atrial appendage (LAA) is a muscular pouch connected to the left atrium of the heart. The LAA is a normal part of the heart anatomy and causes no problems in the general population. However, this pouch can be a major source of blood clots in patients with atrial fibrillation.¹

Atrial fibrillation (AF) is a significant risk factor for blood clots blocking blood flow to the brain and causing a stroke. Stroke can cause temporary or permanent brain or organ damage and is one of the top healthcare costs in many countries.²⁻⁵

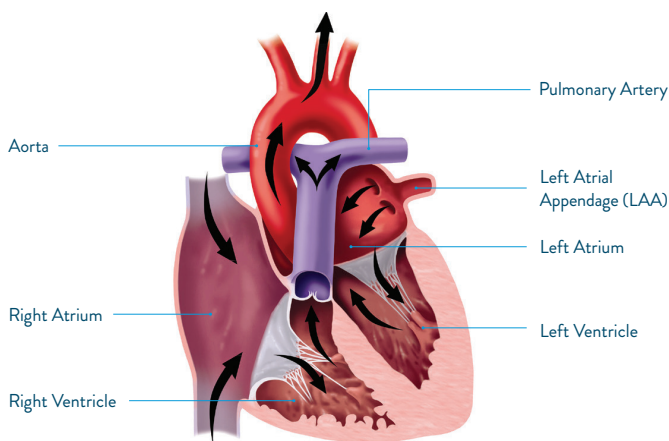
- The prevalence of AF increases with age.⁶
 - Approximately 4% of persons 60 years old and older have AF
 - Approximately 9% of persons 80 years old and older have AF
- More than 90% of blood clots are located in the left atrial appendage in patients with nonrheumatic, nonvalvular AF.⁷
- Current evidence suggests that catheter-based closure of the left atrial appendage can be effective in reducing the risk of blood clot-related complications associated with nonvalvular AF.⁸

HOW IS THE LEFT ATRIAL APPENDAGE RELATED TO STROKE IN PATIENTS WITH ATRIAL FIBRILLATION?

To best understand how the LAA is related to stroke in patients with AF, it is helpful to first understand how a normal heart works (Figure 1).

The heart is a pump with four chambers: two small upper chambers called the atria (you have a right and a left atrium) and two larger, more powerful pumping chambers called ventricles (just as in the atrium, you have a right and a left ventricle). A healthy heart pumps blood through the body and is controlled by a unique electrical system imbedded within the heart itself.

FIGURE 1
DIAGRAM OF A HEALTHY HEART



Typically, oxygen-poor blood flows from the body into the heart through the right atrium and then fills the right ventricle. When the heart beats, this blood is pumped through the pulmonary artery out to the lungs to be filtered and receive oxygen. From the lungs, the now oxygen-rich blood enters the heart through the left atrium. It then fills the left ventricle and is pumped through the aorta out to the body to provide oxygen to all the organs and cells. After it circulates throughout the body, it becomes oxygen-poor and returns to the heart.

In AF, irregular electrical impulses in the upper chambers of the heart cause those chambers to fibrillate, or quiver. This results in an irregular and frequently rapid heart rate. The irregular beating can cause poor blood flow, heart palpitations and shortness of breath. This irregular beating can also cause an increased risk for developing blood clots.

The LAA is a long, tubular pouch connected to the left atrium that can vary in size and shape.^{9,10} The function of the LAA is believed to be minimal.¹¹

During AF, blood clots have the potential to form in the LAA. When the heart rhythm normalizes, those blood clots can flow out of the LAA into the left atrium and enter the oxygen-rich blood stream. As mentioned above, oxygen-rich blood flows from the left atrium to the left ventricle and is then pumped out to the body. If blood clots are pumped out to the body, they may block flow of oxygen-rich blood to the brain and ultimately cause a stroke (Figure 2).

FIGURE 2

IN PATIENTS WITH ATRIAL FIBRILLATION, BLOOD CLOTS MAY FORM IN THE LAA AND CIRCULATE TO THE BRAIN

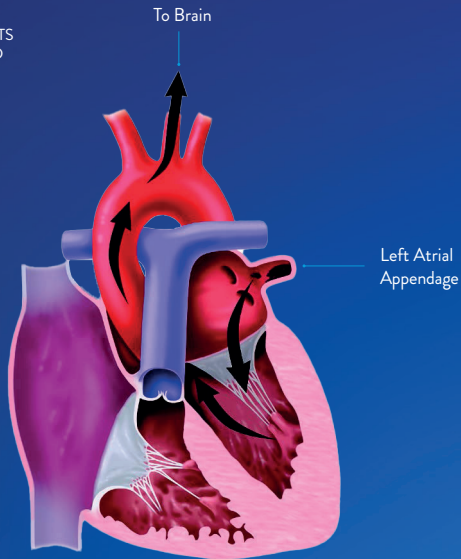
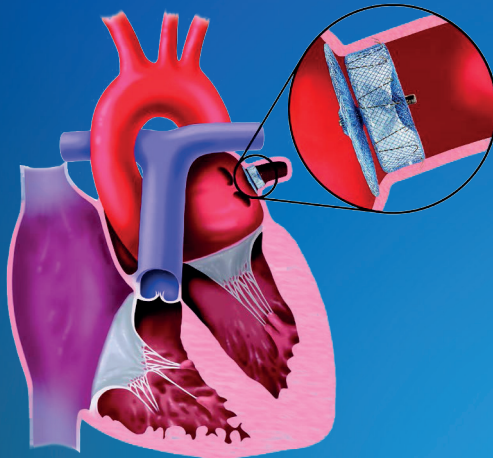


FIGURE 3

AN AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER IMPLANTED IN THE LEFT ATRIAL APPENDAGE DURING A CATHETER-BASED PROCEDURE



WHAT TREATMENT OPTIONS ARE AVAILABLE TO REDUCE THE RISK OF STROKE IN PATIENTS WITH ATRIAL FIBRILLATION?

There are a number of treatment options to reduce the risk of stroke in patients with atrial fibrillation, and there is no single option that is right for every patient. You should discuss with your doctor to learn about the best treatment option for you; however, there are a few standard approaches of which you should be aware. The first option is medication (i.e. blood thinners) which may be appropriate. Other treatment options include open-heart surgery to remove or close the LAA and catheter-based procedures to close the LAA (Figure 3).

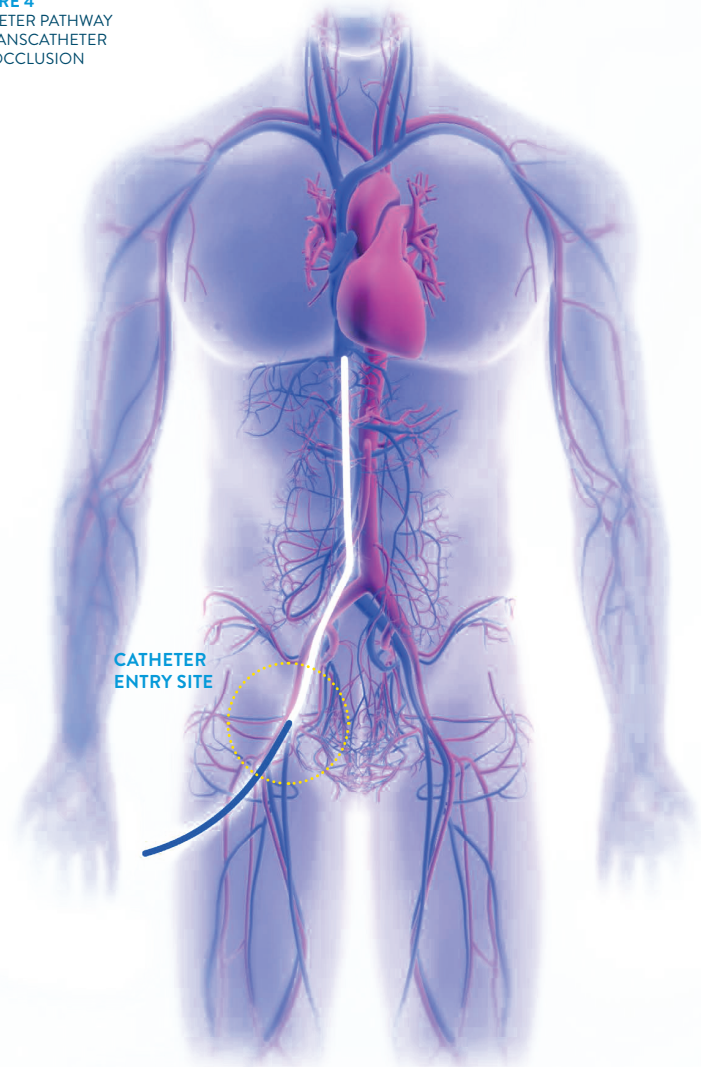
HOW DO I KNOW WHICH TREATMENT OPTION IS RIGHT FOR ME?

Every person is unique. Your doctor is your best resource for learning about the treatment options available to you and the best course for your condition. Talk to your doctor and follow his or her advice for your care.

What is involved with a catheter-based procedure?

A catheter-based procedure is a minimally invasive treatment option which involves inserting a small tube, called a catheter, through an incision typically in the groin. The catheter is navigated through the blood vessels to the procedure site within the heart (Figure 4). In a catheter-based LAA closure procedure, the doctor guides the closure device through the catheter to seal the entrance of the LAA. Once the device is placed in the LAA, the doctor will carefully study its position using cardiac imaging systems. Once satisfied with the position, the device is released to remain permanently in the LAA. The catheter is removed and the procedure is completed.

FIGURE 4
CATHETER PATHWAY
IN TRANSCATHETER
LAA OCCLUSION



THE PROCEDURE ITSELF SHOULD LAST ABOUT ONE TO TWO HOURS AND WILL TAKE PLACE IN A HEART CATHETERIZATION LABORATORY. YOUR DOCTOR MAY GIVE YOU AN ANESTHETIC, AND YOU SHOULD NOT FEEL ANY SIGNIFICANT DISCOMFORT.

WHAT EXACTLY IS AN AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER?

An Amulet Occluder is a device specifically designed to non-surgically close the LAA. The device is placed in the LAA during a catheter-based procedure and will remain permanently implanted.

All Amulet Occluders are made from braided nitinol wires (Figure 5). Nitinol is a metal with shape memory characteristics, meaning the device will return to its original ‘memorized’ shape even after it is stretched to pass through a catheter. The shape of the device was specifically designed to close the opening of the LAA.

Patients suitable to receive an Amulet Occluder should be deemed by their physician to have an appropriate rationale to seek an alternative to pharmacologic therapy such as the inability to tolerate long-term anticoagulants. The Amulet Occluder is intended to be an alternative when long term anticoagulation is unacceptable.

The image shows the Amplatzer Amulet Left Atrial Appendage Occluder, a medical device used to close the left atrial appendage. It consists of a blue, rectangular mesh cage with a central opening, attached to a long, thin, braided metal catheter. The device is shown against a solid blue background.

FIGURE 5
AMPLATZER™ AMULET™
LEFT ATRIAL APPENDAGE OCCLUDER

WHO SHOULD NOT RECEIVE THE DEVICE?

If you have any of the following conditions, you may not be a good candidate to receive an Amulet Occluder.

- If you have blood clots in your heart
- If you have an infection
- If placement of the device would interfere with any structures in your heart or its vessels

WHAT HAPPENS AFTER THE PROCEDURE?

Because the procedure is minimally invasive, your recovery will likely be quick and easy. Many patients are discharged from the hospital within 24 hours. Your doctor can provide guidelines for activities and medications. He or she will prescribe drugs that you should take at home to continue your treatment and recovery. Many doctors require follow-up appointments over the next year to ensure your recovery is going well. What to expect during and after the procedure will vary. Discuss all questions or concerns you have with your doctor.

WHAT PRESCRIPTION DRUGS ARE REQUIRED AFTER THE PROCEDURE?

Use of an anticoagulation/antiplatelet medication may be recommended by your physician to reduce risks of adverse events after implant.

The following drugs are recommended post-procedure:

- Aspirin (or alternative antiplatelet medication) is recommended for patients for six months post implant procedure. The decision to continue this regimen after six months is at the discretion of your physician.
- Clopidogrel (or an alternate antiplatelet medication) is recommended for patients and prescription should follow routine standard of care.
- Appropriate endocarditis prophylaxis is recommended.

HOW LONG WILL IT TAKE ME TO RECOVER?

WHAT ACTIVITIES SHOULD BE AVOIDED AFTER MY PROCEDURE?

Every person recovers differently, and your doctor can help determine when activities can be resumed.

WILL I BE ABLE TO FEEL THE DEVICE?

No, you will not be able to feel the device once it's implanted.

CAN I TRAVEL WITH AN IMPLANTED DEVICE?

Your physician is your best resource for the answer to this question. Many patients find that with some extra planning and care, they can enjoy traveling even with an implanted device.

Though some patients worry about airport security systems, there is really no need for concern. The metal parts in the Amulet Occluder are very small and usually do not trigger metal detector alarms. However, the sensitivity setting of the metal detector and other factors may affect how the metal detector responds to your device. Simply show your patient identification card to security personnel.

WILL MEDICAL EQUIPMENT INTERFERE WITH MY DEVICE?

Although most medical equipment will have no effect on your device, it is best to tell hospital personnel that you have an implanted device before you undergo any medical procedure. Magnetic resonance imaging (MRI) scans are generally acceptable, and your Amulet Occluder has no known hazards when using a 3-tesla MRI, an MRI system more powerful and faster than standard MRI machines. If an MRI is needed, simply inform the MRI staff about your implant.

CAN I HAVE THIS PROCEDURE IF I AM PREGNANT? WHAT IF I AM A NURSING MOTHER?

The risk of increased x-ray exposure must be weighed against the potential benefits of this device. Your physician will ensure that care will be taken to minimize the radiation exposure to the fetus and the mother.

It is unknown if the device affects breast milk. You should discuss this issue with your doctor.

WHAT IF I EXPERIENCE ONE OR MORE OF THE FOLLOWING SYMPTOMS AFTER THE PROCEDURE: PAIN, NUMBNESS, SUDDEN WEAKNESS, DIZZINESS, OR RAPID HEARTBEAT?

If you experience any of the symptoms listed above, seek medical help immediately. An echocardiogram (ultrasound of the heart) should be performed.

WHAT RISKS ARE ASSOCIATED WITH THE AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER?

There are certain potential risks associated with catheter-based procedures as well as additional risks that may be associated with the device.

Your doctor is the best source of information about the risks of having an implanted device. Be sure to talk about all your questions and concerns.

POTENTIAL RISKS INCLUDE, BUT ARE NOT LIMITED TO:

- Air embolus (an air bubble that blocks blood flow in a vessel)
- Allergic drug reaction
- Allergic dye reaction
- Anesthesia reaction
- Arrhythmia (loss of regular heart rhythm)
- Bleeding
- Brachial plexus injury (injury to the nerves in the arm or lower neck)
- Cardiac arrest (unexpected loss of heart function)
- Cardiac tamponade (compression of the heart that occurs when blood or fluid builds up in the space between the heart muscle and the outer covering sac of the heart)
- Death
- Device embolization/migration (dislodging of the device)
- Embolic event (when a mass, such as an air bubble or blood clot, gets stuck in a blood vessel and blocks or decreases blood flow)
- Fever
- Foreign body embolization (blockage of blood flow in a vessel)
- Hyper/Hypotension (abnormally high/low blood pressure)
- Infection
- Multi-organ failure
- Myocardial infarction (heart attack)
- Perforation (piercing of a vessel or the heart)
- Pericardial effusion (excess fluid that may cause pressure on the heart)
- Renal failure/dysfunction
- Seizure
- Stroke/transient ischemic attack (temporary lack of oxygen to the brain)
- Thrombus formation (blood clot)
- Valvular regurgitation or insufficiency (abnormal backward flow of blood through a valve)
- Vascular access site complications
- Vessel trauma/injury

REFERENCES

1. Onalan, O., & Crystal, E. (2007). Left atrial appendage exclusion for stroke prevention in patients with nonrheumatic atrial fibrillation. *Stroke*, 38(2), 624-630.
2. Levi, M., Hobbs, F. R., Jacobson, A. K., Pisters, R., Prisco, D., Bernardo, A., ... & Willemin, W. A. (2009, September). Improving antithrombotic management in patients with atrial fibrillation: current status and perspectives. In *Seminars in thrombosis and hemostasis* (Vol. 35, No. 6, p. 527).
3. Stewart, S., Murphy, N., Walker, A., McGuire, A., & McMurray, J. J. V. (2004). Cost of an emerging epidemic: an economic analysis of atrial fibrillation in the UK. *Heart*, 90(3), 286-292.
4. Saka, Ö., McGuire, A., & Wolfe, C. (2009). Cost of stroke in the United Kingdom. *Age and ageing*, 38(1), 27-32.
5. Ringborg, A., Nieuwlaat, R., Lindgren, P., Jönsson, B., Fidan, D., Maggioni, A. P., ... & Crijns, H. J. (2008). Costs of atrial fibrillation in five European countries: results from the Euro Heart Survey on atrial fibrillation. *Europace*, 10(4), 403-411.
6. Go, A. S., Hylek, E. M., Phillips, K. A., Chang, Y., Henault, L. E., Selby, J. V., & Singer, D. E. (2001). Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the Anticoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. *Jama*, 285(18), 2370-2375.
7. Stollberger, C., Schneider, B., & Finsterer, J. (2003). Elimination of the left atrial appendage to prevent stroke or embolism?: anatomic, physiologic, and pathophysiologic considerations. *CHEST Journal*, 124(6), 2356-2362.
8. National Institute for Health and Care Excellence. (2014). Atrial fibrillation: The management of atrial fibrillation - NICE clinical guideline 180. August, 2014.
9. Veinot, J. P., Harrity, P. J., Gentile, F., Khandheria, B. K., Bailey, K. R., Eickholt, J. T., ... & Edwards, W. D. (1997). Anatomy of the Normal Left Atrial Appendage A Quantitative Study of Age-Related Changes in 500 Autopsy Hearts: Implications for Echocardiographic Examination. *Circulation*, 96(9), 3112-3115.
10. SYAO, S. S., Meisner, J. S., Factor, S. M., Frank, C. W., Strom, J. A., & Shirani, J. (1998). Assessment of left atrial appendage structure and function by transesophageal echocardiography. *Echocardiography*, 15(3), 243-256.
11. Johnson, W. D., Ganjoo, A. K., Stone, C. D., Srivyas, R. C., & Howard, M. (2000). The left atrial appendage: our most lethal human attachment! Surgical implications. *European Journal of Cardio-Thoracic Surgery*, 17(6), 718-722.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions, and Adverse Events.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY.
Always check the regulatory status of the device in your region.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

Abbott

3200 Lakeside Dr. Santa Clara, CA 95054

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

www.structuralheart.abbott

©2023 Abbott. All rights reserved. MAT-2308075 v1.0 | Item approved for OUS use only

