

Amplatzer™ Amulet™
Left Atrial Appendage Occluder

IMMEDIATE CLOSE IMMEDIATE FREEDOM



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


Abbott

YOUR DOCTOR HAS RECOMMENDED THAT YOU RECEIVE AN AMPLATZER™ AMULET™ DEVICE TO REDUCE YOUR RISK OF STROKE

NOW WHAT?

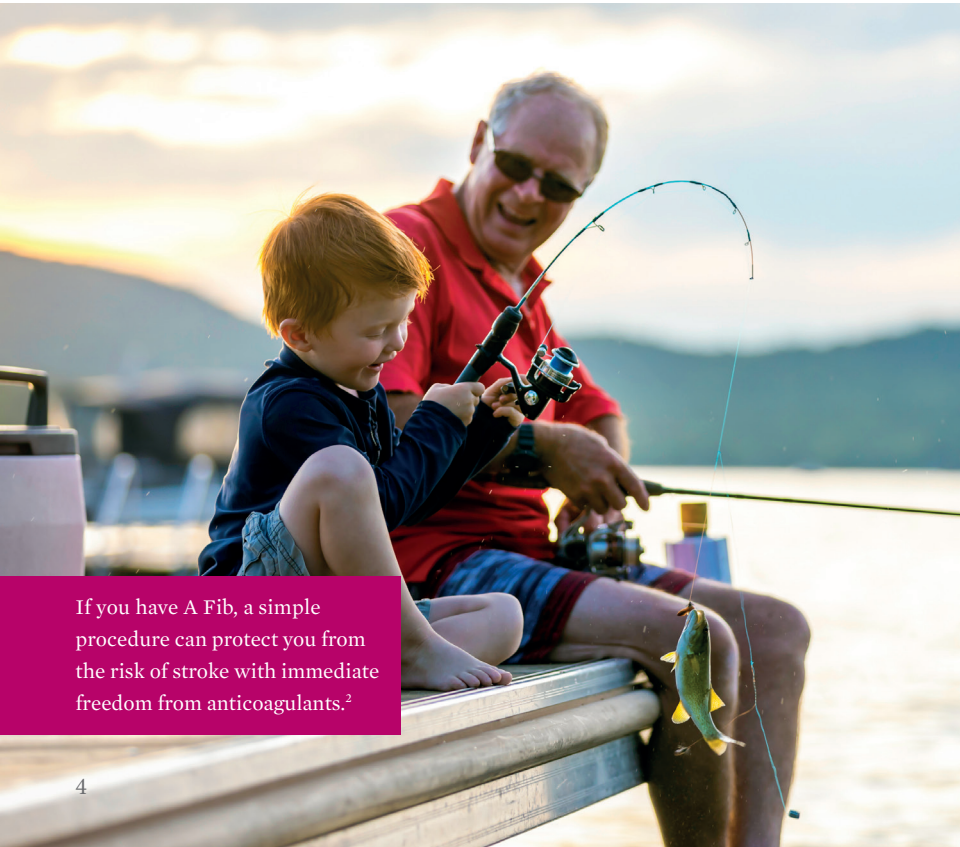
The more you learn and know about what your doctor is recommending, the more comfortable you'll feel in making the decision about *what is right for you*.

People who have Atrial Fibrillation, or “A Fib,” typically face a higher risk of stroke because their heart is not pumping as efficiently as it should be. This can cause blood to pool in certain areas of the heart, which can result in clots that can lead to a stroke. Medication, such as anticoagulants, or blood thinners, are traditionally used as the first line of treatment. They work by thinning the blood to reduce the risk of a clot forming that can lead to a stroke¹.

One of the primary challenges with being on anticoagulants is the risk of bleeding. In addition, many people find that they cannot tolerate this medication due to unpleasant side effects. Cost, compliance or the constant need for blood testing are other factors that may make anticoagulation difficult to manage long-term. In some cases, taking blood thinners is simply not possible due to other medical conditions.

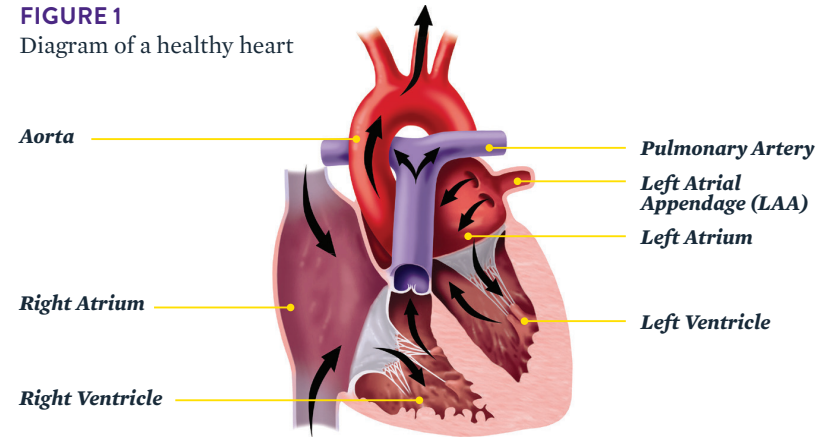


If you are considering an alternative to long-term or life-long anticoagulants (blood thinners), your doctor may recommend “Left Atrial Appendage Occlusion.” This is a minimally invasive procedure to close off a small area of the heart where clots are known to form. The procedure prevents clots that may have formed in the appendage from escaping into the body where they can pose a risk of stroke. In fact, current evidence suggests that this procedure can be effective in reducing the risk of blood clot-related complications associated with nonvalvular A Fib.²



If you have A Fib, a simple procedure can protect you from the risk of stroke with immediate freedom from anticoagulants.²

FIGURE 1
Diagram of a healthy heart



HEART LESSON 101: HOW DOES THE HEART WORK?

To best understand how the left atrial appendage (LAA) is related to stroke in patients with A Fib, let's review 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 (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.

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.

WHAT IS ATRIAL FIBRILLATION (A-FIB)?

If you have A Fib, 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, which can lead to a stroke. To reduce this risk, anticoagulants are often prescribed. However, many people find they cannot take this medication long-term.

WHAT IS A LEFT ATRIAL APPENDAGE?

The left atrial appendage (LAA) is a muscular pouch connected to the left atrium of the heart. Every patient's LAA is unique, in a wide range of shapes and sizes. The LAA is a normal part of the heart anatomy and causes no problems in the general population.³ As a matter of fact, the function of the LAA is believed to be minimal and your heart works just as well with the appendage closed.⁴

WHY IS MY DOCTOR SUGGESTING CLOSING OFF MY LEFT ATRIAL APPENDAGE?

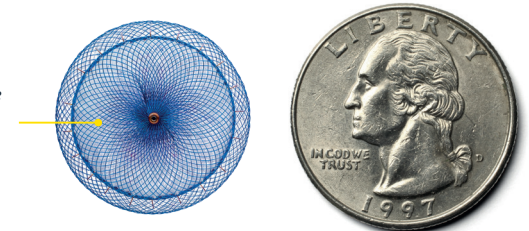
The LAA is known to be where the majority of clots form in people with A Fib. Your doctor may suggest the Amplatzer™ Amulet™ occluder, a small device about an inch long, that effectively seals off your LAA to prevent clots from escaping into the rest of your body.

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

The Amplatzer™ Amulet™ is a small device specifically designed to non-surgically close the LAA. Amulet has successfully been used in over 40,000 patients in Europe since 2015 and is now available for patients in the United States as well. (Read a patient experience with Amulet on page 12.)

The Amplatzer™ Amulet™ was specifically developed to seal off the LAA and is comprised of two connected parts designed to fit the anatomy. The thicker lobe section is inserted into the LAA, and the thinner “disc” closes off the entrance to the LAA and creates a highly effective seal. The Amulet is made from braided nitinol wires. Nitinol is a metal often used in medical devices because it has “shape memory,” allowing the device to return to its original “memorized” shape even after it is compressed to pass through a catheter during the procedure. Once the Amulet is inserted, it stays there permanently to protect you from blood clots that may form in the LAA.

Amulet comes in **a wider range of sizes** than other occluders, to fit more anatomies.



FACT: After a successful procedure, patients treated with the Amplatzer Amulet may discontinue use of oral anticoagulants.

SO, I'M GETTING AN AMULET DEVICE WHAT IS THE PROCEDURE LIKE?



1 It is a minimally invasive treatment, and is NOT open heart surgery. The procedure typically takes 1-2 hours and it takes place in a heart catheterization lab.



2 Your doctor will provide anesthesia or sedation as needed to ensure you don't feel pain or discomfort.



3 The procedure 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 implant site within the heart.

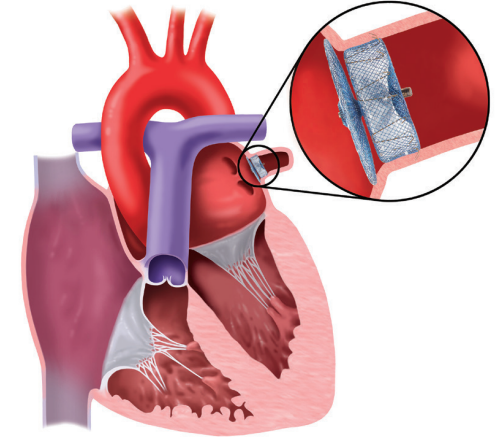


4 Your doctor will guide the Amulet closure device through the catheter to seal the entrance of the LAA. Once the device is placed in the LAA, the doctor confirms its position using cardiac imaging systems and then releases it to remain permanently in the LAA.



5 The catheter is removed and the procedure is completed.

An Amplatzer™ Amulet™ Left Atrial Appendage Occluder is implanted in the left atrial appendage during a short, minimally invasive procedure.



WHAT HAPPENS AFTER THE PROCEDURE TO PLACE MY AMULET?

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 will give you guidelines for activities and medications, and may want to schedule follow-up appointments over the next year to ensure your recovery is going well. Discuss all questions or concerns you have with your doctor.

WILL I NEED TO TAKE ANTICOAGULANTS AFTER THE PROCEDURE?

Unlike with other devices, patients do not typically need to take anticoagulants after getting an Amulet device. Your doctor may prescribe other medications based on your specific situation.

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 THE AMULET DEVICE?

Yes! Metal detectors in airport security should not be an issue as the metal parts in your Amulet device are so small that they typically do not trigger metal detector alarms. If needed, you can show your Amulet patient identification card to security personnel. Talk to your doctor for more specific guidance about travel.

WILL MEDICAL EQUIPMENT INTERFERE WITH MY AMULET DEVICE?

Most medical equipment will have no effect on your device, but it's best to tell hospital personnel that you have an implanted device before you undergo any medical procedure. Magnetic resonance imaging (MRI) scans are fine with your Amulet but be sure to let your technologist know in advance.



A PATIENT STORY

DEREK, AGED 84



One day in 2017, when Derek was 80, he suddenly started slurring his words and his wife, Barbara, noticed that his mouth was drooping on the left side. When the medics arrived, they told Derek that he had an irregular heartbeat, or **Atrial Fibrillation** (commonly called “A Fib”), something that he hadn’t been aware of before his episode.

FIGURING OUT THE BEST WAY FORWARD

Because patients with A Fib are at higher risk of stroke, they are commonly prescribed anticoagulants, or blood thinners. “These are very effective, but some people can’t tolerate them, or they don’t like the side effects. And some can experience serious bleeding” explains Dr. David Hildick Smith a Cardiologist from the Royal Sussex County Hospital in Brighton, England.

“Unfortunately, a side effect of Derek’s anticoagulant treatment was a cerebral hemorrhage. We immediately stopped the anticoagulants, but because of his A Fib, he was now left unprotected from the risk of another stroke.” So Derek’s doctor recommended he receive an Amulet Left Atrial Appendage occluder. “It physically deals with the problem by sealing the appendage. It is extremely effective in reducing the risk of stroke,” said Dr. Hildick Smith.

When asked about how getting this procedure affected him, Derek responded, “It gave me back my confidence. I didn’t have to thin down my blood, and it reduce my chance of getting a blood clot from the LAA by more than 90%. I felt like I’d won the lottery in some ways. It was such a good result. **It was life-changing for me**, mainly because I’ve got no worries about my condition now. You can’t measure how wonderful that feels.”

WHO SHOULD NOT RECEIVE THE DEVICE?

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

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

WHAT RISKS ARE ASSOCIATED WITH THE AMPLATZER™ AMULET™ DEVICE?

There are certain potential risks associated with catheter-based procedures as well as additional risks that may be associated with the device or the implant procedure. The potential (but rare) adverse events include but are not limited to: air embolism, airway trauma, allergic reaction, anemia, anesthesia reactions (nausea, vasovagal reaction, confusion/altered mental status or other), arrhythmia, atrial

septal defect, bleeding, cardiac arrest, cardiac tamponade, chest pain/discomfort, congestive heart failure, death, device related thrombus, device embolization, device erosion, device malfunction, device malposition, device migration, fever, hematuria, hypertension/ hypotension, infection, multi-organ failure, myocardial infarction, perforation, pericardial effusion, pleural effusion, renal failure/dysfunction, respiratory failure, seizure, significant residual flow, stroke, thrombocytopenia, thromboembolism: peripheral and pulmonary, thrombus formation, transient ischemic attack, valvular regurgitation/insufficiency, valvular access site injury (hematoma, pseudoaneurysm, arteriovenous fistula, groin pain or other), or vessel trauma/injury.

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.

CLINICAL DATA FOR PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

The Amulet IDE trial was designed to assess the safety and effectiveness of the Amplatzer™ Amulet™ occluder in 1878 patients with non-valvular atrial fibrillation. Half of them were randomly (like flipping a coin) assigned to receive the Amulet device and the other half to an approved device. Doctors successfully placed the Amulet device in 900 out of 915 patients (98.4%). About 4 in every 5 patients stopped anticoagulation medication after a successful procedure, and 97% of subjects were off the anticoagulation treatment at one year. The study showed that patients in the Amulet group achieved a very high rate of success in closing off the left atrial appendage. Compared to the approved device group, patients treated with the Amulet device had a similar rate of strokes or other significant blocked artery caused by a blood clot after 18 months. Both groups also had similar rates of the combination of procedure-related complications, death (from any cause), and major bleeding.

RISKS WITHIN 1 YEAR	
	1 Year
Death Related to the Procedure	1 out of 100
Stroke	2 out of 100
Bleeding Related to the Procedure	3 out of 100
Complications related to the procedure and requiring invasive treatment	
Pericardial Effusion 0-2 days post procedure (buildup of fluid or blood around the heart)	1 out of 100
Pericardial Effusion >2 days post procedure	1 out of 100
Device Embolization (movement of the device to another part of the body)	1 out of 100
Vascular Access Site Complications (bleeding or injury of blood vessel in groin)	<1 out of 100

1. Levi, M., Hobbs, F. R., Jacobson, A. K., Pisters, R., Prisco, D., Bernardo, A., ... & Wuillemin, 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).
2. Onalan, O., & Crystal, E. (2007). Left atrial appendage exclusion for stroke prevention in patients with nonrheumatic atrial fibrillation. *Stroke*, 38(2), 624-630.
3. 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.
4. Johnson, W. D., Ganjoo, A. K., Stone, C. D., Srivivas, R. C., & Howard, M. (2000). The left atrial appendage: our most lethal human attachment! Surgical implications. *European Journal of CardioThoracic Surgery*, 17(6), 718-722.

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