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?

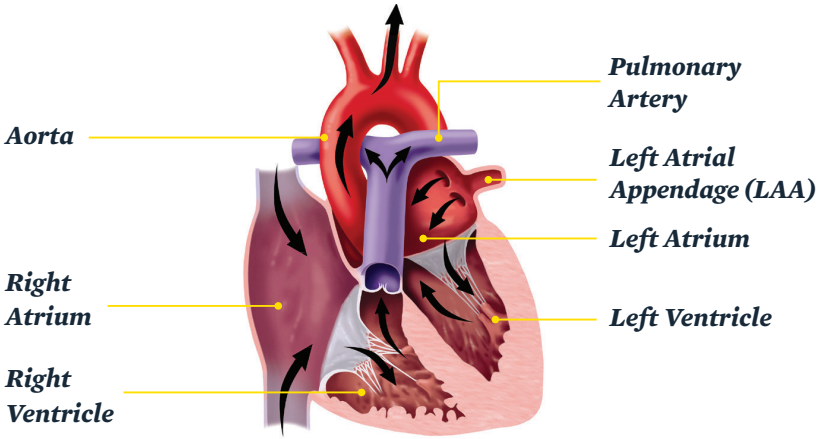
The more you learn and know about what your doctor is recommending, the more comfortable you'll feel in making the decision about ***what is right for you***.

People who have Atrial Fibrillation, or "AFib," 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 stroke[1].

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. This simple procedure can protect you from the risk of stroke, with immediate freedom from anticoagulants.[2] In fact, current evidence suggests that this procedure can be effective in reducing the risk of blood clot-related complications associated with nonvalvular AFib.[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 AFib, 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 (AFib)?

If you have AFib, 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?

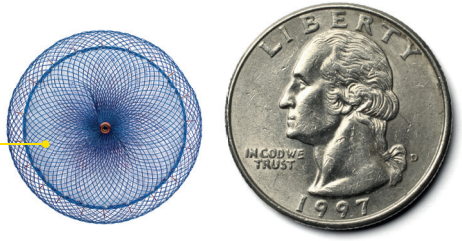
The LAA is known to be where the majority of clots form in people with AFib. Your doctor may suggest the Amplatzer™ Amulet™ occluder, a small device about an inch long, that effectively seals off your LAA to prevent clots from escaping into the rest of your body.

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[5]. (Read a patient experience with Amulet on page 10.)

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 Amplatzer™ Amulet™ device 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 device is inserted, it stays there permanently to protect you from blood clots that may form in the LAA.

The Amplatzer™ Amulet™ is about the size of a quarter, and comes in ***a wider range of sizes*** than other occluders, to fit more anatomies.



SO, I'M GETTING AN AMPLATZER™ 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 Amplatzer™ Amulet™ device 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.

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 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?

Patients do not typically need to take anticoagulants after getting an Amplatzer™ 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.

"IT WAS LIFE-CHANGING FOR ME"

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 "AFib"), something that he hadn't been aware of before his episode.

FIGURING OUT THE BEST WAY FORWARD

Because patients with AFib 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 AFib, he was now left unprotected from the risk of another stroke." So Derek's doctor recommended he receive an Amplatzer™ 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 reduces 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."

CAN I TRAVEL WITH THE AMPLATZER™ AMULET™ DEVICE 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 Amplatzer™ Amulet™ patient identification card to security personnel. Talk to your doctor for more specific guidance about travel.

WILL MEDICAL EQUIPMENT INTERFERE WITH MY AMPLATZER™ 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 Amplatzer™ Amulet™ but be sure to let your technologist know in advance.

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

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.

ABBOTT STRUCTURAL HEART AMPLATZER™ AMULET™ LAA OCCLUDER

PATIENT IMPORTANT SAFETY INFORMATION

℞ ONLY WHAT IS THE AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE (LAA) OCCLUDER APPROVED FOR?

The Amplatzer™ Amulet™ LAA Occluder is a device that is placed in the heart during a minimally invasive, catheter-based procedure to prevent blood clots from leaving the LAA in patients with atrial fibrillation who are at increased risk for stroke and unable to take blood thinning medication long-term.

WHO SHOULD NOT RECEIVE THE AMPLATZER™ AMULET™ LAA OCCLUDER?

Patients who have any of the following conditions should not receive the Amplatzer™ Amulet™ LAA Occluder: blood clots in the heart; active heart infection or other infections; anatomy in which the Amplatzer™ Amulet™ LAA Occluder would interfere with other heart structures, such as valves or veins.

WHAT ARE THE POSSIBLE COMPLICATIONS ASSOCIATED WITH THE AMPLATZER™ AMULET™ LAA OCCLUDER?

Potential adverse events that may occur during or after a procedure using this device include, but are not limited to: air bubble that blocks blood flow in a vessel; allergic reaction; anesthesia reactions; nausea; confusion; injury to the airway; difficulty breathing; fainting; loss of regular heart rhythm; a hole in the wall (septum) that separates the heart's upper chambers; bleeding; low blood count; heart suddenly stops beating; blood or fluid buildup around the heart or lung; chest pain and/ or discomfort; death; obstruction of a blood vessel by all or part of an implanted device that entered the bloodstream; device erosion; device failure; device in wrong position; movement of the device to other parts of the body; blood clot on the device; fever; high or low blood pressure; infection; multiple organ failure; heart attack; perforation of the heart muscle or vessels; heart failure; kidney failure; seizure; continued blood flow into the LAA; temporary or permanent stroke; blood clot, including in the heart, leg, or lung; abnormal backward flow of blood through a valve; injury to the incision site; groin pain; blood clot under the skin in the groin; injury to a blood vessel.

WHAT ARE THE WARNINGS ASSOCIATED WITH THE AMPLATZER™ AMULET™ LAA OCCLUDER?

Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Patients may develop a build-up of fluid or blood around the heart and should contact their physician if they experience chest pain or difficulty breathing after implant. Talk to your doctor to learn more about the risks associated with the Amplatzer™ Amulet™ LAA Occluder.

REFERENCES:

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. Amplatzer™ Amulet™ Left Atrial Appendage Occluder Instructions for Use.
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., Srivyas, 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.
5. Data on file at Abbott

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.

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