PATENT FORAMEN OVALE CLOSURE

with the Amplatzer™ Talisman™ PFO Occluder

INFORMATION GUIDE FOR PATIENTS AND CAREGIVERS

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THE FORAMEN OVALE

Before birth, there is an opening in the form of a tissue flap in the wall between the left and right upper chambers of the baby's heart (Figure 1). This opening ("foramen ovale") allows blood containing oxygen from the mother to bypass the baby's lungs, which do not function until the baby is born. When the baby is born, the flap opening usually closes, and within a few months it is sealed completely (Figure 2).

FIGURE 1: Prior to birth

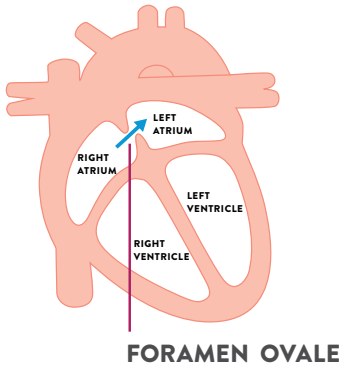
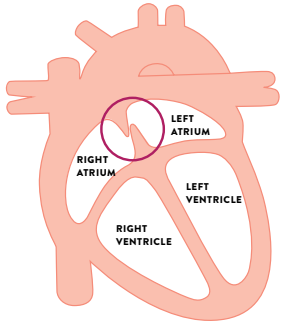


FIGURE 2: Post-birth; natural sealing of the PFO

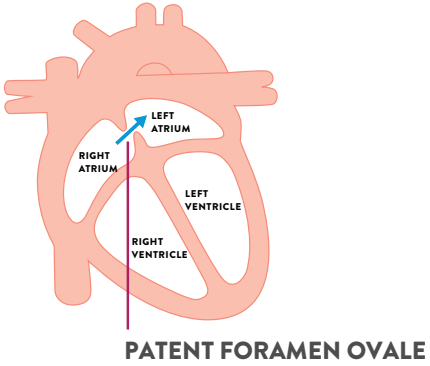


WHAT IS A PATENT FORAMEN OVALE (PFO)?

In about 25% of people, the foramen ovale tissue flap does not close completely at birth. When the foramen ovale remains open, it is called a “patent foramen ovale”, or PFO (Figure 3). A PFO can allow a small amount of blood to pass from the right side of the heart to the left side of the heart.

In the vast majority of individuals, a PFO causes no medical problems and, if found incidentally, requires no treatment or follow-up.

FIGURE 3: PFO remains open



WHAT IS A PFO-ASSOCIATED STROKE?

Although PFOs are very common in the general population, in rare cases, this small opening within the heart can allow a blood clot to pass from the right side of your heart to the left side of your heart, and then travel to the brain where it can block a blood vessel, resulting in a stroke.

If you have had an ischemic stroke, it may be considered a PFO-associated stroke if: 1) you also have a PFO, and 2) other causes of stroke unrelated to the PFO have been ruled out through a comprehensive evaluation. During this evaluation, a medical team consisting of a **neurologist** (a doctor that evaluates and treats strokes) and a **cardiologist** (a heart doctor) will perform several important tests to look for common and uncommon causes of ischemic stroke to guide your treatment.

UNDERSTANDING YOUR TREATMENT OPTIONS

If you have been diagnosed with a PFO-associated stroke, PFO closure with the Amplatzer™ Talisman™ PFO Occluder may be one treatment option for you.

Various treatment options include:

BLOOD-THINNING MEDICATION

Your doctor may prescribe blood-thinning medication, like Aspirin, to reduce your chance of having blood clots. Some physicians recommend stronger blood-thinning medications called anticoagulants.

OPEN HEART SURGERY TO CLOSE THE PFO

Most open heart surgeries are performed through an incision across the full length of the breast bone, or sternum. Surgery is rarely performed nowadays to close a PFO.

PFO CLOSURE VIA A CATHETER-BASED PROCEDURE TO IMPLANT THE AMPLATZER™ TALISMAN™ PFO OCCLUDER

The Amplatzer™ Talisman™ PFO Occluder is a device that can be placed in your heart to close the PFO through a minimally invasive, catheter-based technique.

In major studies that evaluated the safety and effectiveness of PFO occluders, most patients who were treated with the device also took blood-thinning medications.

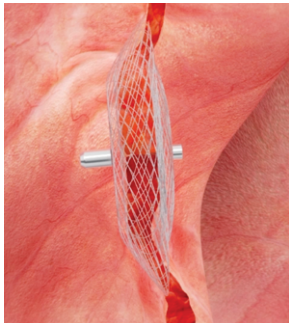
SPEAK WITH YOUR DOCTOR ABOUT THE POTENTIAL BENEFITS AND RISKS OF PFO CLOSURE TO DETERMINE THE RIGHT TREATMENT OPTION FOR YOU.

This patient guide is not intended to explain everything you need to know about your treatment options for PFO-associated stroke. Please discuss any questions you have with your doctor to determine which treatment option is right for you.

AMPLATZER™ TALISMAN™ PFO OCCLUDER

DEVICE DESCRIPTION

The Amplatzer™ Talisman™ PFO Occluder is an updated version of the Amplatzer™ PFO Occluder and is specifically designed to stop blood flow through a PFO. The device consists of two circular wire-mesh discs covered in a medical fabric that sandwich together to close the PFO between the two upper chambers in your heart. The wire mesh material can be collapsed down to fit in a small tube (catheter) that is used to position the device during the procedure. Once the device is placed in the PFO, it will remain permanently implanted in your heart. Over time, the body's natural healing process will cover the device with tissue.



A diagram of the Amplatzer™ Talisman™ PFO Occluder as it would sit in your heart.

The Amplatzer™ Talisman™ PFO Occluder is available in four sizes. The most commonly used device size, when expanded, is similar in diameter to a dime and quarter stacked on top of each other and half the thickness.

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.

You will receive a patient identification card before you are discharged from the hospital. Always carry your Amplatzer™ Talisman™ PFO Occluder implant card and tell other doctors that you have a PFO closure device before any medical, dental or MRI (magnetic resonance imaging) procedures. Failure to do so may result in health problems or damage to the device.

WHAT PRESCRIPTION DRUGS ARE REQUIRED AFTER THE PROCEDURE?

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

Clopidogrel may be prescribed for one month post-implant procedure, or longer in some cases. Aspirin may be prescribed for six months post-implant procedure, or longer in some cases. Your doctor may prescribe additional medication beyond six months.

CLINICAL EVIDENCE

The RESPECT Trial was designed to evaluate whether PFO closure with the Amplatzer™ PFO Occluder plus blood-thinning medication was more effective in reducing the risk of another ischemic stroke compared with blood-thinning medication alone.

The RESPECT Trial enrolled patients who, like you, were diagnosed with a PFO-associated stroke. This was the largest trial with the most extensive patient follow-up of any trial conducted on PFO closure and its impact on the prevention of recurrent ischemic stroke.

Patients were randomly assigned (like a flip of a coin) to receive the PFO closure device plus blood-thinning medication or blood-thinning medication alone.

PFO closure with the Amplatzer™ PFO Occluder was associated with a lower rate of recurrent ischemic stroke than blood-thinning medication alone.

POTENTIAL RISKS INCLUDE, BUT ARE NOT LIMITED TO:

- Air embolus
- Allergic reaction/toxic effect due to:
  - anesthesia, contrast media, medication, or metal
- Arrhythmia
- Arteriovenous fistulae
- Bleeding
- Cardiac perforation
- Cardiac tamponade
- Chest pain
- Death
- Deep vein thrombosis
- Device embolization
- Device erosion
- Endocarditis
- Esophagus injury
- Fever
- Headache/migraine
- Hematoma
- Hypertension/hypotension
- Infection
- Myocardial infarction
- Pacemaker placement secondary to PFO device closure
- Pain
- Pericardial effusion
- Pericarditis
- Peripheral embolism
- Pseudoaneurysm
- Pulmonary embolism
- Reintervention for residual shunt/device removal
- Stroke
- Transient ischemic attack
- Thrombus formation
- Valvular regurgitation
- Vascular access site injury
- Vessel perforation

WHO SHOULD NOT HAVE THE PROCEDURE?

The Amplatzer™ Talisman™ PFO Occluder should not be implanted in patients who:

- Have a tumor or history of blood clots at the implantation site of the device or in the vessels through which the device is advanced to reach the heart
- Have small blood vessels
- Have a body organ (all or in part) such as the heart, or blood vessels, or heart valves that would interfere with the required device size
- Have other types of heart defect
- Have inflammation or infection of the heart

ADDITIONAL INFORMATION

Please visit our website for more information:
www.PFOstroke.com

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Available by prescription only
Important Safety Information

AMPLATZER™ TALISMAN™ PFO OCCLUDER

WHAT IS THE AMPLATZER™ TALISMAN™ PFO OCCLUDER APPROVED FOR?

The Amplatzer™ Talisman™ PFO Occluder is a device that is placed in the heart during a minimally invasive, catheter-based procedure to close a patent foramen ovale (PFO) to reduce the risk of another stroke in patients who have already had a stroke that was found to be related to the PFO.

WHO SHOULD NOT RECEIVE THE AMPLATZER™ TALISMAN™ PFO OCCLUDER?

Patients who have any of the following conditions should not receive the Amplatzer™ Talisman™ PFO Occluder: blood clots in the heart or blood vessels; mass, vegetation, or tumor inside the heart; heart or veins that are too small for the appropriate sheath size; anatomy in which the Amplatzer™ Talisman™ PFO Occluder would interfere with other heart structures, such as valves or veins; other sources of right to left shunts, including atrial septal defect; active heart infection or other untreated infections; or inability to take anticoagulant or antiplatelet therapy.

WHAT ARE THE POSSIBLE COMPLICATIONS ASSOCIATED WITH THE AMPLATZER™ TALISMAN™ PFO 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 to anesthesia, contrast dye, medication, or metal; loss of regular heart rhythm; abnormal connection between an artery and a vein; bleeding; perforation of the heart muscle or vessels; blood or fluid build-up around the heart; blood clot formation over the device or in the heart, leg, or lung; chest pain; death; obstruction of a blood vessel by all or part of an implanted device that entered the blood stream; device erosion; infection or inflammation in the heart; injury to the esophagus; fever; headache or migraine; high or low blood pressure; heart attack; pacemaker implant; pain; blood leakage outside a vessel; intervention to remove the device; stroke; temporary lack of oxygen to the brain; abnormal backward flow of blood through a valve; injury to the incision site.

WHAT ARE THE WARNINGS ASSOCIATED WITH THE AMPLATZER™ TALISMAN™ PFO OCCLUDER?

Patients at increased risk for blood clots may be prescribed a blood thinning medication following the procedure. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Talk to your doctor to learn more about the risks associated with the Amplatzer™ Talisman™ PFO Occluder.

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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