

(Front of Brochure):

**AMPLATZER™ PFO Occluder
Patient Information Guide**

(Left inside cover):

This brochure is intended to provide you with general information about non-surgical closure of a patent foramen ovale (PFO), which should be further discussed with a doctor. It is not intended to substitute for medical care or treatment. You should consult with a doctor regarding the diagnosis or treatment of your medical condition.

(Right inside cover):

Table of Contents:

- Section 1: About Stroke
- Section 2: About Patent Foramen Ovale
- Section 3: Transcatheter Patent Foramen Ovale Closure
- Section 4: Frequently Asked Questions

(Content)

Section 1: About Stroke

What is a stroke?

A stroke occurs when the blood supply to the brain is blocked or severely reduced by a blood clot or by a rupture in a blood vessel. Without the normal supply of nourishing oxygen contained in blood, brain cells quickly begin to die. The resulting damage can cause disability or death.

Are all strokes the same?

There are two major categories of stroke: hemorrhagic and ischemic. A hemorrhagic stroke occurs when there is abnormal bleeding in the brain, normally the result of a ruptured artery or blood vessel. An ischemic stroke occurs when there is a blockage within a vessel that keeps oxygen from getting to a portion of the brain.

What are the warning signs of a stroke?

The following are some warning signs of a stroke. These may occur suddenly:

- Weakness or numbness of the face, arm or leg, especially on one side of the body
- Confusion, difficulty speaking or understanding others
- Change in vision in one or both eyes
- Difficulty walking
- Dizziness, loss of balance or coordination
- Sudden severe headache with no known cause

What are the risk factors for stroke?

Not all strokes can be prevented, but being aware of risk factors and working with your physician to manage your medical conditions may reduce your risk of stroke. Risk factors for stroke include:

- High blood pressure
- Heart disease
- Diabetes
- Tobacco use
- Atrial fibrillation
- Previous heart attack

What is a cryptogenic stroke?

Nearly 40% of people who suffer an ischemic stroke have no known risk factors. These strokes are often considered “cryptogenic”, meaning stroke of an unknown origin or cause. Studies have shown that nearly half of people who suffer a cryptogenic stroke also have a patent foramen ovale (PFO).¹

Section 2: About Patent Foramen Ovale (PFO)

What is a Patent Foramen Ovale (PFO)?

A foramen ovale is a flap-like opening between the upper two chambers of the heart. It allows blood to flow from the right side of the heart to the left side. This opening is important prior to birth to allow oxygen-rich blood from the mother to circulate throughout the fetus.

After birth the foramen ovale fuses to form a solid wall (septum) because the right-to-left blood flow is no longer needed. However, in about 25% of people, the foramen ovale remains open, or patent, leaving a flap or tunnel which may open and close as pressures change in the right side of the heart.

¹ Sacco, R. et al: Infarcts of Undetermined Cause: The NINCDS Stroke Data Bank. *Annals of Neurology* 25 (4), 1989

How does a PFO affect blood flow? How might a PFO cause stroke?

To best understand how a PFO affects blood flow and potentially lead to a stroke, it is helpful to first understand how a normal heart works (Figure 1).

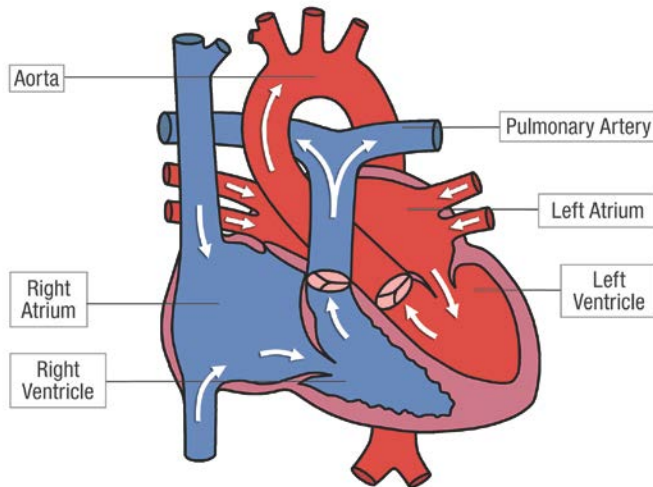
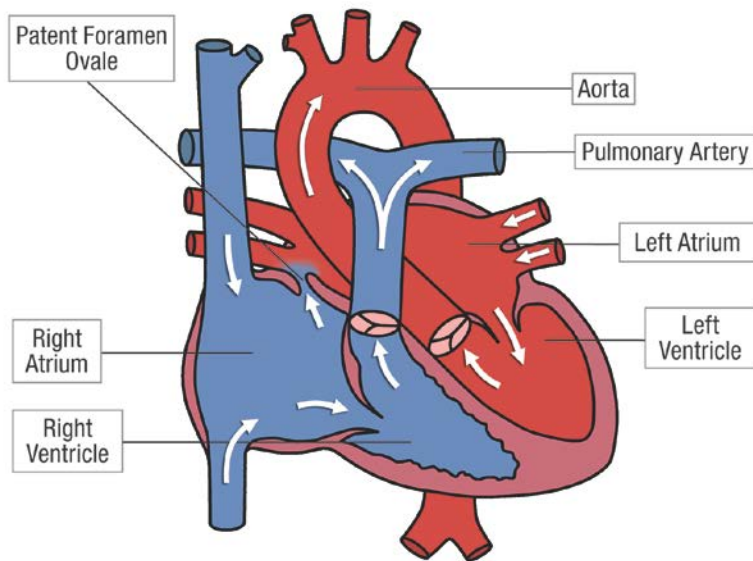


Figure 1

The heart is a pump with four chambers: two small upper chambers called the atria (you have a right atrium and a left atrium) and two larger, more powerful pumping chambers called ventricles (again you have a right ventricle and a left ventricle). In the normal adult heart, the right and left sides are completely separated by tissue wall.

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 left atrium. It then fills the left ventricle and is pumped through the aorta out to the body and the brain to provide oxygen to all the organs and cells. After it circulates throughout the body, it becomes oxygen-poor and returns to the heart.

When a patent foramen ovale is present, oxygen-poor blood can go directly from the right atrium to the left atrium – bypassing the lungs and mixing with oxygen-rich blood (Figure 2). The lungs not only provide oxygen to the blood, but they also act as a filter. In the normal heart (without a PFO), a blood clot from the body would be filtered and stopped in the lungs. However, in a heart with a PFO, the clot could cross from the right to the left side of the heart and enter directly into the blood stream, potentially reaching the brain and causing a stroke.



How can the risk of stroke be reduced in patients with a PFO who have experienced a cryptogenic stroke?

There are a number of treatment options to reduce the risk of another stroke in patients with a PFO, 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.

One option is medication therapy. Another option is closing the PFO. The PFO may be closed using one of the following approaches:

- Surgical closure involving open-heart surgery
- Device closure involving a catheter-based procedure (transcatheter PFO closure)

How do I know which treatment option is right for me?

Every person is unique. Talk to your doctor about the treatment options available to you and the best course for your condition.

Section 3: Transcatheter Patent Foramen Ovale Closure

What is involved with a catheter-based procedure?

A catheter-based procedure is a minimally invasive treatment option that may be appropriate for you. The procedure involves making a small incision, typically in the groin, and inserting a small tube, called a catheter or sheath, to navigate through the blood vessels to the procedure site within the heart.

In patients with a PFO, the doctor guides the closure device through the catheter or sheath to seal the PFO. Once the device is placed in the PFO, 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 heart. The catheter or sheath is removed and the procedure is completed.

The procedure itself should last about one to two hours and will take place in a heart catheterization laboratory, where many minimally invasive, non-surgical procedures are performed. Your doctor may give you an anesthetic, and you should not feel any significant discomfort.

The AMPLATZER PFO Occluder

An AMPLATZER PFO Occluder is a device specifically designed to stop blood flow through all types of PFO (Figure 3). The device is placed in the PFO during a catheter-based procedure and will remain permanently implanted.

The AMPLATZER PFO Occluder is made from a Nitinol wire mesh with shape memory characteristics. This means the device will return to its original shape even after it is stretched to pass through a catheter.

The device has two discs that are linked together by a short connecting waist. In order to increase its closing ability, the discs contain thin polyester fabric. The polyester fabric is securely sewn to each disc by a polyester thread.



Figure 3

Are all patients candidates for the device?

Not all patients are good candidates to receive the AMPLATZER PFO Occluder. If you have any of the following conditions, you may not be a good candidate to receive the AMPLATZER PFO Occluder.:

- If you have blood clots in your heart or blood vessels
- If you have other sources of right to left shunts, including atrial septal defect
- If you have an infection
- If your heart or veins are too small for the appropriate sheath size
- If the AMPLATZER PFO Occluder would interfere with other heart structures, such as valves or veins
- If you are unable to take antiplatelet or anticoagulant therapy
- If your blood clots easily
- If you have an intra-cardiac mass or vegetation or tumor

What happens after the procedure?

Because the procedure is minimally invasive, your recovery is expected to 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. The decision to prescribe drugs is at the discretion of your doctor. Many doctors require multiple follow-up appointments to ensure your recovery is going well. Discuss any questions or concerns you have with your doctor.

Will I be able to feel the device?

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

How long will it take me to recover? What activities should be avoided after my procedure? When can they resume?

Every person recovers differently, and your doctor can help determine when activities can be resumed. In general all strenuous activity should be avoided for one month after the procedure.

Section 4: Frequently Asked Questions**What is a patient identification card? Will I need to carry it with me?**

As a patient implanted with the AMPLATZER PFO Occluder, it is important to carry a patient identification card with you at all times. The patient ID card includes your name, implant date, your doctor's contact information, and information about your device. You will be provided this card after the procedure.

Can I travel with an implanted device? Will my device trigger airport security systems?

Your physician is your best resource for the answer to this question. Many patients find they can enjoy traveling even with an implanted device. It is always wise to carry your patient ID card, just in case you encounter difficulties while traveling.

Though some patients worry about airport security systems, there is really no need for concern. The metal parts in the AMPLAZTER PFO 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 AMPLAZTER PFO Occluder is compatible with imaging when using a 3-tesla MRI. 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 AMPLAZTER PFO Occluder is placed in the PFO using X-ray guidance during a catheter-based procedure and will remain permanently implanted. The risk of x-ray exposure must be weighed against the potential benefits of this device. Your physician will take care to minimize the radiation exposure to the fetus and 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: chest pain, numbness, sudden weakness, dizziness, shortness of breath or rapid heartbeat?

If you experience any of the symptoms listed above, seek medical help immediately.

What are the risks associated with the AMPLAZTER PFO Occluder?

There are certain potential risks associated with catheter-based procedures as well as additional risks that may be associated with the device. The RESPECT Clinical Trial demonstrated a low risk of device placement. 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
- Apnea (temporary absence of breathing)
- Arrhythmia (loss of regular heart rhythm)
- Bacterial endocarditis (infection that causes redness and swelling of the lining of the heart and its valves)
- Bleeding
- Brachial plexus injury (injury to the nerves in the arm or lower neck)
- Cardiac tamponade (blood or fluid build-up between the heart muscle and the sac that covers the heart)
- Cardiac thrombus

- Chest pain
- Death
- Deep vein thrombosis
- Device embolization (dislodging of the device)
- Device erosion
- Endocarditis
- Esophagus injury
- Fever
- Headache/migraine
- Hyper/Hypotension (abnormally high/low blood pressure)
- Myocardial infarction (heart attack)
- Pacemaker placement secondary to PFO device
- Palpitations (abnormal heart beat)
- Pericardial effusion (abnormal fluid build-up around the heart)
- Pericardial tamponade
- Pericarditis
- Peripheral embolism (when a small clot or piece of debris passes through the peripheral system causing decreased or blocked blood flow in an artery or vein)
- Pleural effusion (abnormal fluid build-up around the lungs)
- Pulmonary embolism
- Re-intervention for residual shunt/device removal
- Sepsis
- Stroke
- TIA (temporary lack of oxygen to the brain)
- Thrombus (blood clot)
- Valvular regurgitation (abnormal backward flow of blood through a valve)
- Vascular access site injury
- Vessel perforation

The device consists of a nickel-titanium alloy, which is generally considered safe. However, patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; inform your doctor immediately if you are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat.

