A Patient’s Guide to the Non-surgical Closure of a Patent Foramen Ovale
This brochure is intended to provide you with general information about the non-surgical closure of your patent foramen ovale (PFO), 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.

Patent Foramen Ovale Overview

Patent foramen ovale (PFO) 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’s body.

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

Although it is prevalent, a PFO is typically not large enough to create symptoms or require any immediate treatment during childhood. It is typically during adulthood that a person will begin to suffer from mild symptoms like shortness of breath or possibly more serious conditions including migraine or stroke.

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).

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 (again you have a right 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 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.

Figure 1
Diagram of a healthy 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.

What are the symptoms of a PFO?

Severity of symptoms often depends on the size of the PFO. Many PFOs cause no symptoms and go unnoticed. Sometimes there is so much blood passing through the PFO that it creates extra work for the heart to supply oxygen-rich blood to the body – causing the patient to feel fatigued.

How can the risk of stroke be reduced in patients with a PFO?

There are a number of treatment options to reduce the risk of 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 includes medication therapy which may be appropriate. Another option includes 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 (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. Remember a PFO can result in unpleasant symptoms and increased health risk. With proper care, however, it can generally be managed with medication or closure.
What exactly is an AMPLATZER™ PFO Occluder?

An AMPLATZER PFO Occluder is a device specifically designed to stop blood flow through all types of PFO (Figure 5). 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.

What is involved with a catheter-based procedure?

A catheter-based procedure is a minimally invasive treatment option available to some patients. 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 a 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 (Figure 4). 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.
Who should not receive the device?

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 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 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. The decision to prescribe these is at the discretion of your doctor. Many doctors require follow-up appointments over the next year to ensure the patient’s 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 is a patient identification card? Will I need to carry it with me?

As a device patient, it is important to carry a patient identification card with you to identify yourself as having an implanted device. The patient ID card includes your name, implant date, your doctor’s contact information, and information about your device. You will be provided with 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 that with some extra planning and care, 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 AMPLATZER occlusion devices 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 I be able to feel the device?

No, you will not be able to feel the device once it’s 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.
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 AMPLATZER occlusion device 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: 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) of your heart should be performed.

What risks are associated with the AMPLATZER PFO 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
- 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)
- Chest pain
- Death
- Device embolization (dislodging of the device)
- Device erosion
- Fever
- Hyper/Hypotension (abnormally high/low blood pressure)
- Myocardial infarction (heart attack)
- PFO placement secondary to PFO device
- Palpitations (abnormal heart beat)
- Perforation of myocardium (piercing of the heart)
- Pericardial effusion (abnormal fluid build-up around the heart)
- 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)
- Re-intervention for device removal
- Stroke/TIA (temporary lack of oxygen to the brain)
- Thrombus (blood clot)
- Vascular regurgitation or insufficiency (abnormal backward flow of blood through a valve)
- Vascular access site injury

You should also be aware that patients allergic to nickel may have an allergic reaction to this device.
My follow-up questions:
For additional information, please contact your doctor.
Indications: The AMPLATZER PFO Occluder is a percutaneous, transcatheter occlusion device intended to close all types of PFOs (i.e. classical as well as those with aneurysm of the septum) in patients with a history of stroke or transient ischemic attacks (TIAs) diagnosed by echocardiography with right-to-left shunting during the Valsalva maneuver.

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Product referenced is approved for CE Mark.

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