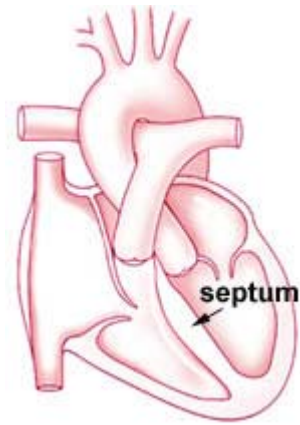


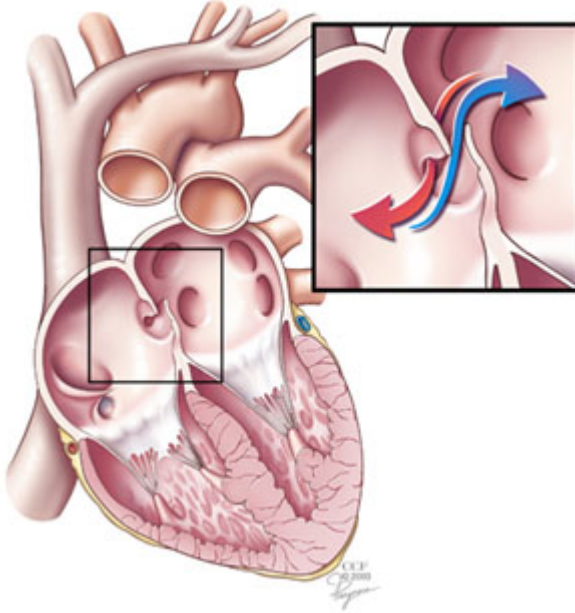
## PATENT FORAMEN OVALE

### Your septum

- The septum is the muscular wall separating the heart into the left and right sides.
- The atrial septum is the wall separating the atria (the two upper chambers).
- The ventricular septum is the wall separating the ventricles (the two lower chambers).



## Patent Foramen Ovale (PFO)



The foramen ovale is a small hole located in atrial septum that is used during fetal circulation to speed up the travel of blood through the heart. When in the womb, a baby does not use its own lungs for oxygen-rich blood; it relies on the mother to provide oxygen rich blood from the placenta through the umbilical cord to the fetus. Therefore, blood can travel from the veins to the right side of the baby's heart and cross to the left side of the heart through the foramen ovale and skip the trip to the baby's lungs.

Normally the foramen ovale closes at birth when increased blood pressure on the left side of the heart forces the opening to close. If the atrial septum does not close

properly, it is called a patent foramen ovale. This type of defect generally works like a flap valve, only opening during certain conditions when there is more pressure inside the chest. This increased pressure occurs when people strain while having a bowel movement, cough, or sneeze. If the pressure is great enough, blood may travel from the right atrium to the left atrium. If there is a clot or particles in the blood traveling in the right side of the heart, it can cross the PFO, enter the left atrium, and travel out of the heart and to the brain (causing a stroke) or into a coronary artery (causing a heart attack).

### How Common is Patent Foramen Ovale?

The prevalence of PFO is about 25 percent in the general population. In patients who have stroke of unknown cause (cryptogenic stroke), the prevalence of PFO increases to about 40 percent. This is especially true in patients who have had a stroke at age less than 55 years. (<http://stroke.ahajournals.org/cgi/content/full/37/2/577>)

A PFO can be associated with atrial septal aneurysm, which is characterized by excessive mobility of the atrial septum.

### Symptoms of PFO

Most patients do not have any symptoms with PFO.

Stroke and PFO: About 40 percent of patients who have an ischemic stroke have no known cause (called cryptogenic stroke). PFO is present and associated with an increase in stroke in about 40 percent of cases. The most common symptoms of stroke are:

- weakness or numbness of the face, arm or leg on one side of the body
- loss of vision or dimming (like a curtain falling) in one or both eyes
- loss of speech, difficulty talking or understanding what others are saying
- sudden, severe headache with no known cause
- loss of balance, unstable walking, usually combined with another symptom

Migraine headache and PFO: Migraine headaches are more common in patients with PFO. While it seems as though closure of PFO results in improvement of migraine symptoms, larger studies are needed to confirm this finding.

### **Diagnosis of PFO**

Patent Foramen Ovale can be detected by echocardiogram. In some cases the patient is asked to cough or perform the Valsalva maneuver to increase pressure in the right atrium. This can increase the flow of blood from the right to left atrium. Transesophageal echo can provide a closer and more detailed view of the PFO.

### **Treatment for Patent Foramen Ovale (PFO)**

#### **Medical management**

People with PFO do not need any treatment if there are no associated problems, such as a stroke. Patients who have had a stroke or transient ischemic attack (TIA) may be placed on some type of blood thinner medication, such as aspirin, plavix (clopidogrel), or coumadin (warfarin) to prevent recurrent stroke.

#### **Non-surgical treatment: Cardiac implant**

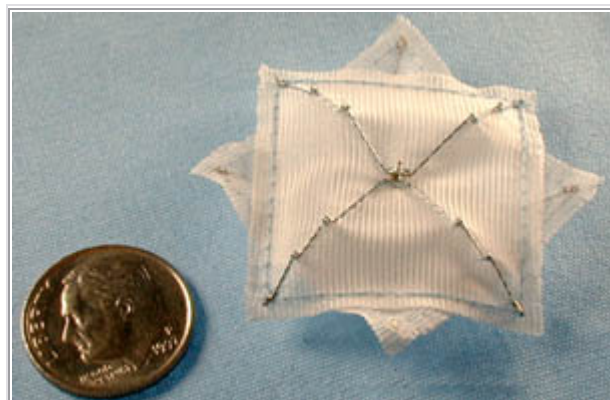
In some patients a cardiologist and a neurologist may recommend closure of PFO. Most frequently, percutaneous rather than surgical closure is preferred. As part of the procedure, you will first undergo a cardiac catheterization. During this test, catheters (hollow, flexible, tube) will be inserted into the veins in your groins and advanced to your heart. A balloon may be placed across the opening to determine the size and location of the hole in your heart. Measurements are taken of the pressure inside your heart chambers. A tiny catheter with an echo transducer is placed in the heart for imaging.

If the cardiac catheterization shows your PFO is an appropriate size and in an appropriate location for closure with this device, the cardiologist will position the device to close the hole.

#### **Closure devices**

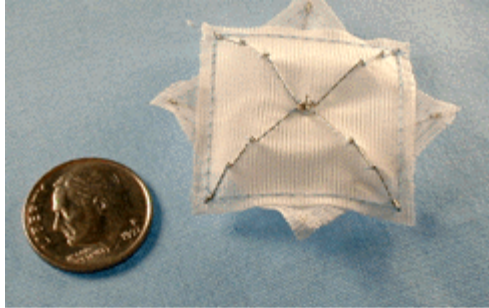
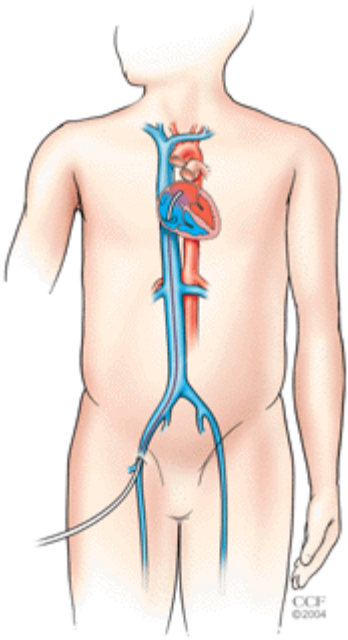
Currently there are no specially designed devices for PFO closure that is approved by the FDA. In patients that closure is indicated, devices that are approved for other heart defects are used.

The CardioSEAL® device is a small double umbrella arms attached to Dacron fabric. It is folded into a special catheter, similar to the catheter used during your catheterization. The special catheter is inserted into a vein in the leg and advanced into the heart and through the hole. The device is slowly pushed out of the special catheter allowing each umbrella to open up and cover each side of the hole (like a sandwich) and close it. When the device is in proper position, it is released from the special catheter.



**CardioSEAL® device**  
**Photo used with permission from NMT Medical**

Over time, heart tissue grows over the implant, becoming part of the heart



CardioSeal® for PFO closure. Image, With permission, from NMT Medical, Inc.

### How is a Patent Foramen Ovale (PFO) Closed Using a Catheter-based Procedure

#### How is a PFO closed using a catheter-

#### based procedure?

Catheter-based procedures are commonly used to diagnose and treat heart-related problems. For example, catheter-based procedures are used to diagnose and treat clogged arteries and heart attacks. A catheter can also be used to guide the placement of a patent foramen ovale closure device - which becomes a permanent implant - that will close the hole (prevent the flaps from opening) in the heart wall.

To further briefly explain what happens in a PFO catheter-based procedure, a cardiac catheterization involves slowly moving a catheter (a long, thin, flexible, hollow tube) into the heart. The catheter is initially inserted into a large vein through a small incision made usually in the inner thigh (groin area) and then is advanced into the heart. One or more tests will be done to measure the PFO and to be sure there are no other defects. An imaging test called angiography, (an injection of a certain type of dye followed by an x-ray motion picture) may be used to better visualize the heart. An ultrasound imaging technique called Intracardiac echo (ICE) is used to see the defect better and also to determine the size of the closure device needed, may be used. This involves passing an imaging device up to the heart through the vein in the patient's leg. In addition, a special balloon on a catheter is moved to the area of the hole and inflated across the hole in order to measure the size of the hole when it is gently stretched.

A PFO closure device is moved through the catheter to the heart and specifically to the location of the heart wall defect. Once in the correct location, the PFO closure device is allowed to expand its shape to straddle each side of the hole. The device will remain in the heart permanently to stop the abnormal flow of blood between the two atria chambers of the heart. The catheter is then removed and the procedure is complete.

#### How long does the procedure take?

The cardiac catheterization procedure for a PFO closure typically takes one hour to complete. A local anesthetic is used to numb the groin area where the catheter was inserted. Use of general anesthesia or sedation by IV is situation dependent—depending on doctor preference and particular patient needs.

#### What types of PFO closure devices are there?

Two major types of PFO closure devices are currently being used at our hospital - the CardioSEAL® Occluder and the Helix Septal Occluder.

The **CardioSEAL® Occluder** is available for use under humanitarian device regulations. The CardioSEAL® Occluder consists of a two wire frameworks to which two small pieces of polyester fabric are attached. The metal in the framework and the fabric are the same that is used in implants in other open-heart and other surgeries. The implant looks like two opened square umbrellas, with the two opened sides directly against each other. Special spring coils in the framework help hold the device in place, with one "umbrella" positioned on each side of the defect. Pressure from the blood in the heart also helps to keep the device in place. Your doctor will choose an occluder device that is slightly larger than the size of the defect. Over time, the patient's own tissue grows into and around the fabric and metal framework.

#### How does the body react to a permanent implant?

The materials used in the closure device products have a proven long-term safety history and have been widely used in heart surgery procedures. It's not likely that the body will have a negative reaction to these devices. Within a few days, the body's own tissue will begin to grow over the device. By 3 to 6 months, the device is completely covered by heart tissue and at that point becomes a part of the wall of the patient's heart.

The patient will not be able to feel the device. The implant will not be affected by airport or other security sensors, or by any household appliances, or medical imaging methods. However, the clarity of medical images may be slightly reduced because of the wire frame on the occluder devices. For this reason, be sure to inform the imaging technician that you or your child has such a device in your heart. You will receive an identification card that should be carried with you/or by your child to show to medical personnel if necessary.

**Can a catheter-based PFO closure procedure be used in all cases?**

No. At the present time, the FDA has approved the use of the CardioSEAL® Occluder for a very specific indication. The StarFlex® Occluder is available in the United States only to patients enrolled in the CLOSURE I trial, a trial being conducted at the Cleveland Clinic.

The desire to close PFOs through a nonsurgical, catheter-based procedure (such as with the CardioSEAL® Occluder) is gaining doctors' interest. These methods may avoid the long-term need for powerful blood-thinning medications (the most often used current method of treatment) and still reduce the risk of recurrent stroke or TIA.

**How does the catheter-based PFO closure procedure compare with the use of medication?**

The catheter-based procedure has not been compared with medical therapy (the blood-thinning drugs aspirin, warfarin) for PFO closure in the "gold standard" format for comparison, a clinical trial. One of the goals of a trial, the CLOSURE I trial, will be to determine how these two approaches to PFO closure compare in this scientific format.

Doctors who are using or studying the CardioSEAL® or the StarFlex® Occluders believe the primary advantage of these catheter-based approaches is that they permanently seal the defect, making the long-term use of blood-thinning medications unnecessary in some patients. They also believe this approach may reduce the risk of a recurrent stroke or transient ischemic attack as much as medications have been shown to do. Although this has not been proven yet in a scientific clinical trial, such a trial is currently underway.

Your doctor will discuss these two treatment alternatives with you in order to make the best decision for you.

**What follow-up tests and home care instructions are typically given following a catheter-based procedure for PFO closure?**

Within 24 hours after the procedure, a chest x-ray, electrocardiogram, and echocardiogram are conducted to make sure that the device is positioned correctly. Bed rest in the hospital for 6 hours after device placement is required. The patient may go home the evening of the procedure or possibly the following morning. The patient may experience minor pain at the catheter incision site and a slight sore throat for a few days if an ultrasound probe was used to check device placement. The patient will be instructed not to lift anything greater than 10 pounds for 1 week after the procedure. Your doctor will discuss when you can return to regular activity (usually within a week).

Your doctor will prescribe medications that will need to be taken at home. Aspirin will need to be taken for six months and Plavix will need to be taken for three months after the procedure to prevent blood clots from forming. Antibiotics will also need to be taken 1 hour before certain medical procedures (for example, dental cleaning/dental surgical procedures as well as certain surgeries) for up to six months post device placement. Your doctor will provide information on which procedures will require antibiotic pre-treatment.

As with all medications, take them only as directed by your doctor, never stop taking the medication without talking with your doctor first, and call your doctor if you experience unpleasant reactions or have any concerns about the medication.

Finally, a few follow-up return trips to the clinic will be necessary over the next year to monitor the patient's heart and device placement. Each visit -- 6 months, and 1 year—will include electrocardiogram and echocardiogram.

**Echocardiogram Showing PFO Closure** – initial bubble study shows bubbles going across the septum. The PFO closure device is successfully deployed under echo and fluoroscopic guidance.

<http://www.kcheart.com/video/EchoshowingPFOclosure.mpg>

**Video showing illustration of PFO Closure Procedure -**

<http://www.kcheart.com/video/PFOClosureSchematicvideo.wmv>