Patient information

Patent foramen ovale (PFO) repair

GORE CARDIOFORM SEPTAL OCCLUDER

This brochure is intended to provide basic information about the GORE® CARDIOFORM Septal Occluder and the closure of **patent foramen ovale (PFO)** and to assist you in making an informed decision about your treatment options. If you have any questions or concerns about the diagnosis or treatment of your medical condition, please talk to your doctor.

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Overview

What is a patent foramen ovale (PFO)?

Before birth, a baby's heart will have a hole with flap-like covering between the upper two chambers of the heart. This opening (the foramen ovale) allows blood rich in oxygen from the mother to bypass the baby's **lungs** which do not function until the baby is born. After birth, the flap-like covering will typically close the hole permanently. However, in about one out of every four individuals, the hole will remain open. This is called a **patent foramen ovale** or **PFO**. From time to time, a **PFO** may permit blood to pass from the right side of the heart to the left side of the heart bypassing the normal route of going through the **lungs** first.

Symptoms

In most people, a **PFO** creates no symptoms and requires no treatment. However, in a small minority, a **PFO** may permit blood clots to pass from the right side of the heart to the left side possibly leading to a **stroke**.

What is a stroke?

A **stroke** occurs when ~~either~~ the cells in the brain do not receive the oxygen needed to survive. When this happens, brain cells begin to die. The parts of the body controlled by the area of the brain damaged by the **stroke** may not function correctly. For instance, **stroke** can lead to problems speaking or moving.

What causes a stroke?

There are two main types of **stroke**. One type, called **hemorrhagic stroke**, occurs when injured blood vessels bleed into the brain tissue. This type of **stroke** happens most often in patients with high blood pressure.

A second type of stroke is called **ischemic stroke**. This occurs when a **blood vessel** carrying blood to the brain is blocked. Many times, these **strokes** have an identifiable cause. One common cause is the buildup of plaque (cholesterol and scar tissue) that blocks **blood vessels** within the neck or the brain, particularly in patients with high blood pressure, smoking, high cholesterol, and diabetes. Another common cause is a blood clot formed in the heart travels to the brain and blocks a brain **blood vessel**. Clot formation in the heart that can cause **ischemic stroke** usually occurs in patients with an irregular heartbeat condition called atrial fibrillation. Less common causes of **ischemic stroke** include brain **blood vessel** tears, and blood clots from artificial heart valves. Treatment of these conditions can help prevent another **stroke**.

In some patients, however, the cause for the **ischemic stroke** cannot be found after looking for the usual causes. These **strokes** are called **cryptogenic strokes** because they have an unknown cause. In some **cryptogenic stroke** patients, the presence of a **PFO** may provide a pathway for a blood clot to pass through the heart's upper chambers, travel to the brain, and block a brain **blood vessel** resulting in an **ischemic stroke**. An evaluation for the presence of a **PFO** is a standard test in young to middle-aged patients with a **cryptogenic stroke**.

A team of doctors (typically including a neurologist and cardiologist) should be consulted to help identify the cause of the **stroke** and identify what treatment or preventative measures may be required.

Diagnosis

How can a doctor tell if I had a cryptogenic stroke?

A medical team, including a neurologist and a cardiologist, will conduct tests to look for the cause of your **stroke**. These tests include collecting images of your brain, heart, and **blood vessels** (using ultrasound, CT and / or magnetic resonance imaging [MRI] scans), monitoring your heart rhythm, and blood tests. If your doctors do not find any likely cause of your **stroke** from this testing, they may conclude that you had a **cryptogenic stroke**.

How is a PFO found?

A **PFO** is found by a cardiologist using ultrasound pictures of the heart (**echocardiogram** or echo). The ultrasound uses sound waves to evaluate the structure of the heart and the direction of blood flow to see if blood can pass from the right side of the heart to the left side.

Could a PFO be the cause of my cryptogenic stroke?

If no other identifiable cause of the **stroke** can be found, your doctors may conclude that the **PFO** played an important role by permitting a blood clot to pass from the right side of your heart to the left side and blocking a **blood vessel** that supplies the brain.

Treatment options

Your doctor will inform you of the available options to help minimize your risk of a second **stroke**. For patients with a **cryptogenic stroke** and a **PFO**, several options are available for prevention of another **stroke**:

Catheter-based procedure to close the PFO

This procedure is performed in the **cardiac catheterization** lab. The procedure takes approximately one to two hours to complete. A local anesthetic is used at the site where the closure device is introduced to the body (usually a **vein** in the right groin area), along with general anesthesia or conscious sedation. After the **PFO** closure procedure, a typical hospitalization is six to 24 hours. Most patients are back to their normal routine in about a week. In addition to device implantation, your doctor will prescribe **antiplatelet** medications that you should take daily indefinitely.

Medical Management

Your doctor may prescribe blood-thinning medication alone to reduce the chance that clots form in your blood.

Surgical closure of the PFO

Surgical repair involves directly suturing a patch over the **PFO**. This open-heart procedure leaves an external scar, typically requires three to five days hospitalization, and about four weeks at home to recover. Surgical **PFO** closure is rarely performed today following a **cryptogenic stroke**.

Your physician can provide more details on each of these options.

Your doctor may recommend that you avoid strenuous athletic activity for at least two weeks so that your implant has time to heal.

Procedure

How do the catheter-based procedures for PFO closure work?

Catheter-based closure of a **PFO** involves the placement of a permanent implant, such as the GORE® CARDIOFORM Septal Occluder, using a minimally invasive procedure (non-surgery, usually involving a small incision or cut in the skin).

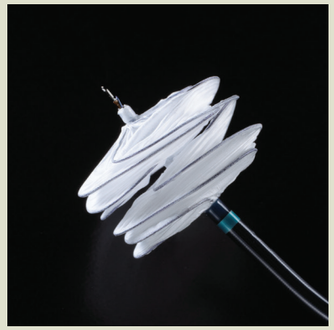
A **cardiac catheterization** procedure for a **PFO** closure typically takes one to two hours to complete. General anesthesia or conscious sedation is often used to keep the patient asleep or calm during the procedure. To begin the procedure, an ultrasound probe will be placed into the **esophagus** (tube running from the mouth to the stomach) or a **vein** to allow the physician to view the heart throughout the procedure. This will help ensure accurate positioning of the **PFO** closure device.

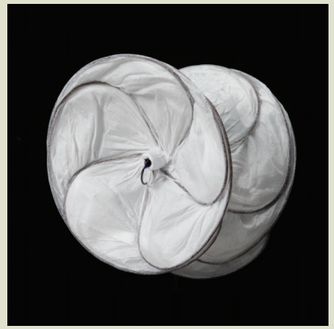
A **catheter** or hollow tube will be inserted into a **blood vessel** through a small incision, usually located in the right groin area. The **catheter** will then be advanced until it reaches the heart. A **PFO** closure device will then be passed through the **catheter** and into the heart where it will be positioned to close the **PFO**.

Nonsurgical closure of a PFO

The **PFO** closure device is released from the **catheter** and left in the heart, preventing the abnormal flow of blood between the right and left side of the heart.

Your doctor will rely on two types of images to see the **PFO** closure device while it is being placed into the heart. A fluoroscopic (X-ray) image is used to see the metallic frame of the **PFO** closure device, and an ultrasound image allows the doctor to see the heart structures and blood flow.





Device

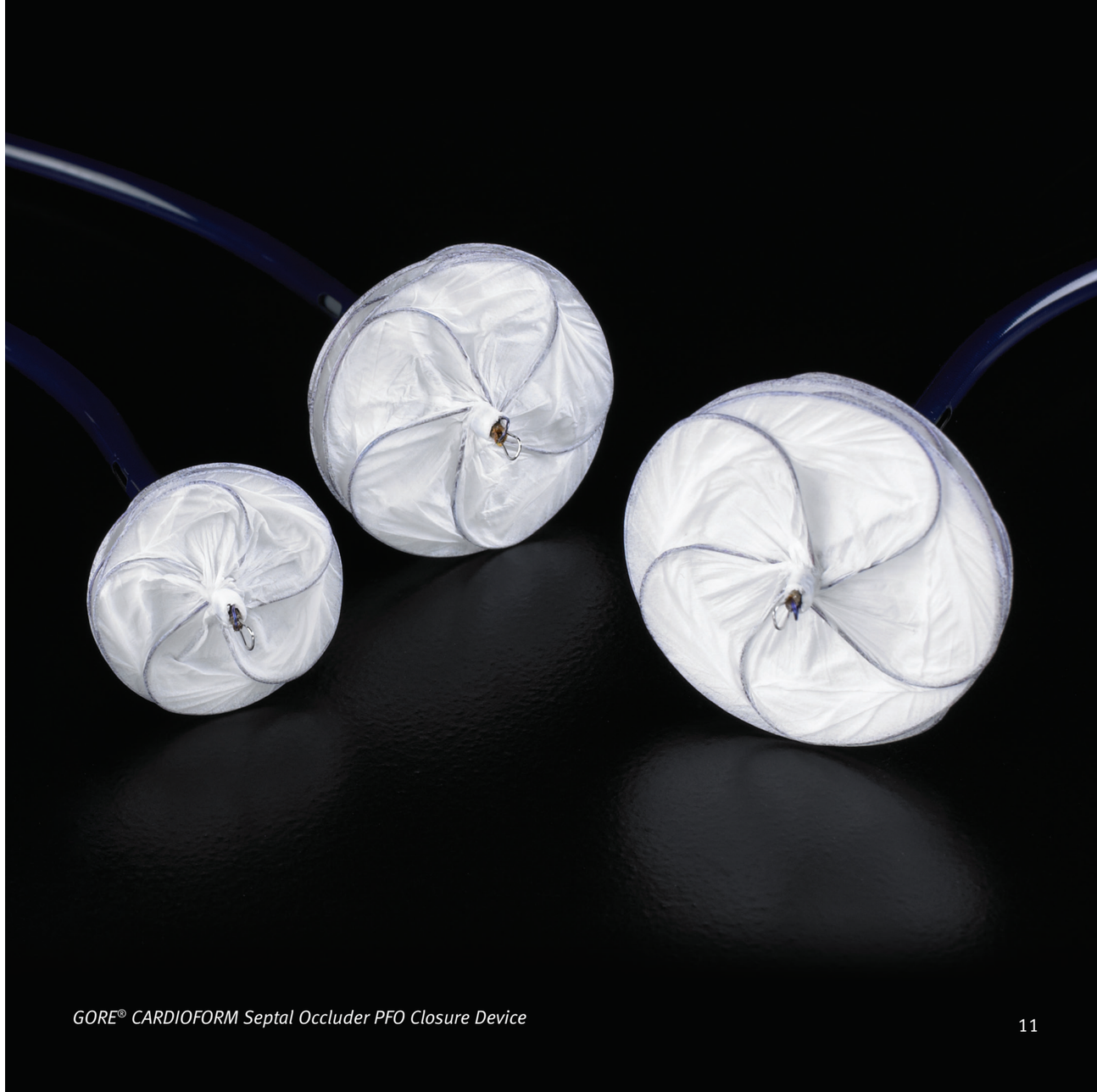
What is the GORE® CARDIOFORM Septal Occluder and what is it made of?

The GORE® CARDIOFORM Septal Occluder is a minimally invasive device intended for the closure of a **PFO** using **cardiac catheterization**. It is a permanent implant consisting of a near circular wire frame covered with thin **ePTFE** material. The soft, conformable **ePTFE** material, invented and manufactured by Gore, has been used in open-heart surgery for more than 40 years and has been shown to be safe in implanted medical devices. The wire frame is made of a nickel-titanium metal alloy called nitinol with a platinum core (so that it may be seen on X-ray images).

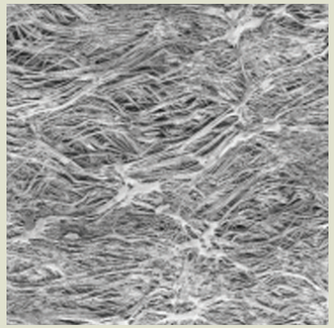
How does a catheter-based procedure compare to medical management?

The GORE® CARDIOFORM Septal Occluder was studied for **PFO** closure and the prevention of **stroke** in the Gore REDUCE Clinical Study, a study to evaluate the Gore device. This study enrolled 664 patients who had a **cryptogenic stroke** and a **PFO**. The study randomly assigned patients to either medical management (**antiplatelet** medications) alone or **PFO** closure plus medical management. The REDUCE Study was designed to determine if **PFO** closure plus medical management or medical management alone were better at preventing a second stroke from occurring.

In the REDUCE Study, patients treated with **PFO** closure had a 77% relative reduction in the stroke rate at an average follow-up of 3.4 years compared to individuals in the medical management alone group. It is important to note that a new **stroke** was relatively rare in both REDUCE study treatment groups. The study results



GORE® CARDIOFORM Septal Occluder PFO Closure Device



Gore's **ePTFE** is specially made to enhance **PFO** closure and facilitate tissue coverage.

suggested that if 1000 patients were treated with **PFO** closure, about four of these patients would have a stroke after one year compared with about 17 out of 1000 patients treated with medications alone. Overall, the REDUCE Study showed that **PFO** closure plus medical management was a better option to prevent another **ischemic stroke** than medical management alone.

Over the course of the REDUCE Study, 6.6% of patients treated with **PFO** closure developed an irregular heartbeat condition called atrial fibrillation compared to less than 1% of patients treated with medical management alone. About two-thirds of the atrial fibrillation episodes were considered non-serious, and most cases were resolved with medical treatment within two weeks.

Other major complications related to the **PFO** closure procedure seen in the REDUCE Study include heart or major blood vessel injury, major bleeding, low blood pressure, blood clot on the **PFO** closure device, surgery to remove the **PFO** closure device, and atrial fibrillation. Each of these complications occurred in less than 1% of patients.

REDUCE Study patients will continue to be followed for up to five years.

As you consider which treatment option may be best for you, discuss with your doctor the risks and benefits of **PFO** closure versus other options.

How does the GORE® CARDIOFORM Septal Occluder work?

Inside the heart, a GORE® CARDIOFORM Septal Occluder is placed to form the device on either side of the **PFO** between the left and right upper chambers of the heart (see *Figure 1*). The **ePTFE** material acts as a framework for cells to attach. Over time, the device will typically become completely covered with heart tissue.

Your physician will choose the appropriate GORE® CARDIOFORM Septal Occluder device size best suited for your heart.

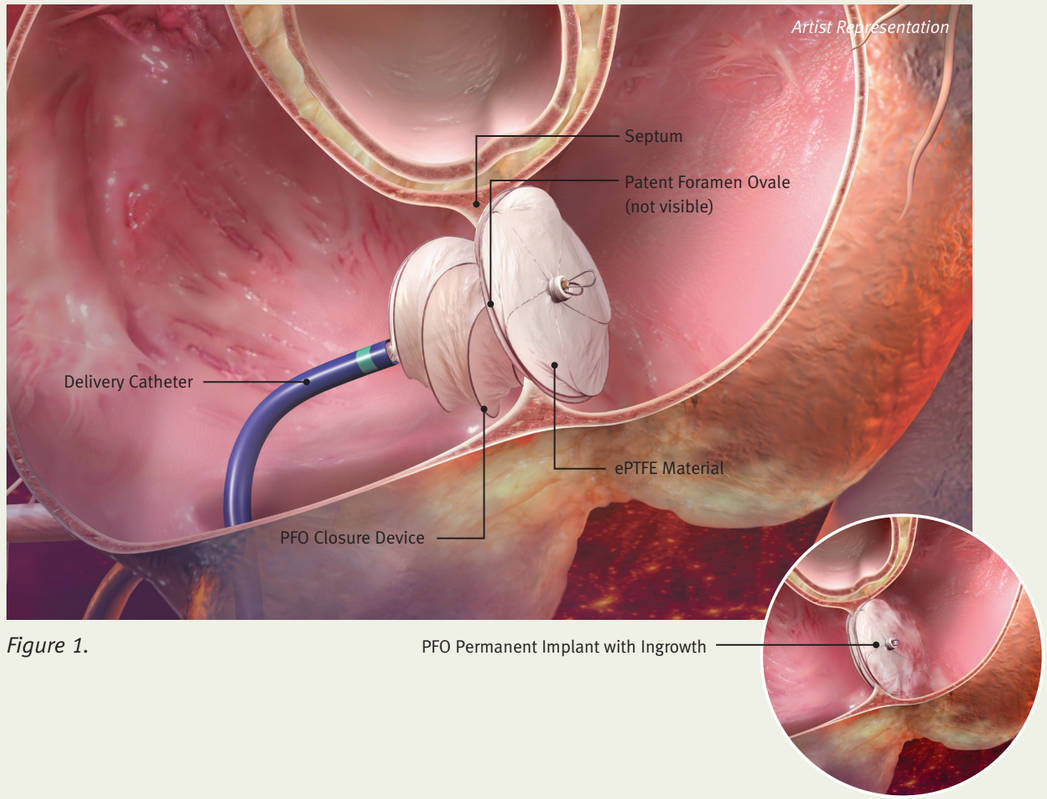


Figure 1.

Frequently asked questions

How will my body respond to a permanent implant?

Both the **ePTFE** material and the wire used in the GORE® CARDIOFORM Septal Occluder have a proven long-term history of safety within the body. Both materials are accepted by the body and are not likely to cause a negative biological response. Within a few days after the device is placed, your body's own tissue will begin to grow into the **ePTFE** material, allowing GORE® CARDIOFORM Septal Occluder to function as a permanent implant.

Will the GORE® CARDIOFORM Septal Occluder be affected by the external environment?

No. Your Gore implant will not be affected by medical imaging methods, household appliances, or security sensors. The clarity of medical images, such as MRI, may be slightly reduced because of the GORE® CARDIOFORM Septal Occluder wire frame. For this reason, you should inform the imaging technician that a GORE® CARDIOFORM Septal Occluder is in your heart.

What will happen after the procedure?

Following the **PFO** closure procedure, you may experience temporary, minor pain at the **catheter** incision site, and you may have a slight sore throat from the ultrasound probe. You will be admitted to the hospital before the procedure and usually discharged the next day. After the procedure, your doctor may perform a chest X-ray and an ultrasound evaluation to ensure that the device is positioned properly.

You may have a large bandage covering the catheterization site incision for four to six hours. Most people are able to return to a normal (mild to moderate) activity level within one to two days. Your doctor may recommend that you avoid vigorous athletic activity for at least two weeks so that your implant has time to heal.

You will need to return to the hospital for follow-up and heart monitoring tests a few times over the next year (e.g., **echocardiogram** evaluation at 1, 6, and 12 months).

Your doctor will also prescribe **antiplatelet** medications to be taken after your procedure to help prevent blood clotting and other potential sources of **stroke**. It is important that you do not interrupt these medications without first speaking with your doctor.

Are catheter-based PFO closures always successful?

Not all **PFOs** can be closed by a device implanted during a **cardiac catheterization** procedure. For example, your **PFO** may be too large to be adequately closed by a catheter-based closure device. In some cases, the heart's anatomy may not accommodate the **PFO** closure device, or the vessels may not accommodate the **catheter** delivery system.

In the event that your **PFO** cannot be closed by a catheter-based procedure, you and your doctor will need to discuss other treatment options. Your doctor will explain the details of **cardiac catheterization**, including the potential risks and complications.

Additionally, not all **strokes** can be prevented by **PFO** closure. **PFO** closure only prevents one type of stroke — those caused by clots moving from the right side of the heart to the left side. Other sources of **stroke** may be present, so your doctor may continue to prescribe medications to reduce your stroke risk.

Complications

What are the potential risks of the procedure?

As with any medical procedure, there is a possibility of complications due to the device and / or the procedure. Potential risks include, but are not limited to:

Most common

- A noticed or unnoticed rapid or irregular heartbeat
- Headache or migraine
- Dizziness or abnormal sensation
- Chest pain or discomfort
- Upper respiratory infection
- Back pain
- Nausea
- High or low blood pressure
- Pain at the incision site
- Difficulty breathing
- Bleeding
- Fatigue
- Anxiety

Most serious

- Death
- **Stroke** (major or minor)
- Heart attack
- Kidney failure
- Clot formation or **blood vessel** blockage due to clots or air
- Injury to the heart or **blood vessels**
- Perforation of the heart muscle or **blood vessels**
- Blood or fluid build-up between the heart and the sac covering the heart
- Infection

Other

- Movement of the device from its position in the **PFO** to other parts of the body
- A second surgical or interventional procedure

Warnings

- Patients allergic to nickel may suffer an allergic reaction to this device. Talk to your doctor if you have a nickel allergy.

Precautions

- Talk to your doctor about medications (blood-thinning drugs and / or antibiotics) you may need to take before or after the procedure
- It is recommended that patients avoid strenuous physical activity for a period of at least two weeks after **Occluder** placement
- Your physician may recommend you to return for follow-up visits to assess the placement and performance of the device

Who should not have the procedure?

The GORE® CARDIOFORM Septal Occluder should not be implanted in patients who:

- Are unable to take blood-thinning medications
- Have an anatomy not suitable for the required device size
- Have an active infection
- Have clots in their hearts

You may discuss any questions you may have with your physician to determine if **PFO** closure is the right treatment for you.

Glossary

Antiplatelet and / or Anticoagulation therapy
Medication (blood thinners) that helps prevent blood clots.

Blood vessel
The pathways through which blood travels in the body consisting of arteries and **veins**.

Cardiac catheterization
A procedure in which **catheters** are passed through the arteries and / or **veins** to the heart, such as closure of a **PFO**.

Catheter
A sterile, flexible, hollow tube designed for insertion into a vessel to permit injection or withdrawal of fluids or through which devices can be delivered.

Echocardiogram
A visual picture of the heart produced by sound waves through a device placed on the chest, down the throat, or in the heart itself.

ePTFE
A biocompatible polymer that has been frequently used in implanted medical devices.

Esophagus
The part of the body that connects the mouth to the stomach.

Lung / Lungs
Pair of breathing organs located within the chest, which remove carbon dioxide and bring oxygen to the blood. There is a right and left **lung**.

Occluder
A device used to occlude or block an opening.

Patent foramen ovale (PFO)
An opening between the upper two chambers of the heart.

Septum
The wall that divides the upper two chambers of the heart.

Stroke
The sudden loss of brain function caused by a blocked or broken **blood vessel** to the brain.

Vein / Veins
Blood vessels that carry blood towards the heart from the body.

Resource

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Notes

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Notes

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