Patent Foramen Ovale (PFO) Repair

Patient Information
Diagram of Heart with PFO

- Aorta
- Pulmonary Artery
- Patent Foramen Ovale
- Left Atrium
- Left Atrial Appendage
- Right Atrium
- Right Ventricle
- Left Ventricle
- Femoral Vein
Table of Contents

Overview ................................................................................................................................................. 4
Symptoms .................................................................................................................................................. 5
Causes .................................................................................................................................................... 5
Diagnosis ................................................................................................................................................ 6
Treatment .............................................................................................................................................. 6
Procedure ............................................................................................................................................... 7
Device / What is the Gore® Septal Occluder and what is it made of? .............................................. 8
How does the Gore® Septal Occluder work? ....................................................................................... 11
Frequently Asked Questions .................................................................................................................. 12
Complications ....................................................................................................................................... 16
Glossary .................................................................................................................................................. 17
Resources ............................................................................................................................................... 20
This brochure is intended to provide basic information about the GORE® Septal Occluder and the repair 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 you should talk to your doctor.
W. L. Gore & Associates has spent more than three decades making products for nearly every field of medicine, often using technology to advance the way procedures are performed. Today, more than 35 million Gore medical devices have been implanted worldwide.
Overview

What is a patent foramen ovale?

A patent foramen ovale (PFO) is a flap-like hole in the heart between the upper chambers. This hole is important during fetal development and normally closes at birth or within the first year or two. This congenital heart defect is fairly common and occurs in about 25% of the population.
**Symptoms**

Most people have no specific symptoms, however there is on-going clinical research to validate the relationship of the presence of a PFO and other medical conditions.

**Causes**

A PFO is a congenital abnormality that you are born with.
Diagnosis

How is a PFO diagnosed?

A PFO is diagnosed by a cardiologist using ultrasound, such as an echocardiogram or transesophageal echocardiogram. The ultrasound uses sound waves to evaluate the structure of the heart and direction of blood flow.

Treatment

Percutaneous catheter procedure

This catheter based procedure is performed in the cardiac catheterization lab. The procedure takes around an hour to complete. A local anesthetic is used at the puncture site, along with general anesthesia or IV sedation. Typically hospitalization is 6 to 24 hours. Most patients are back to their normal routine in about a week.

Surgical closure

Surgical repair involves directly suturing the flap down or suturing a patch over the defect. This open heart procedure leaves a scar, typically requires three to five days hospitalization and about four weeks at home to recover.
The Procedure

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

Physicians have been performing catheter-based procedures in the heart to make diagnoses and treat heart conditions for many years. Catheter-based closure of a PFO involves the placement of a permanent implant, such as the GORE® Septal Occluder, using a minimally invasive procedure (non-surgery, usually small incision or cut in skin).

A cardiac catheterization procedure for a PFO closure typically takes one to two hours to complete. General anesthesia is often used to keep the patient asleep during the procedure.

While the patient is asleep, 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 (the device that will close the hole in the heart).

A catheter (a long, narrow, hollow tube) will be inserted into a blood vessel through a small incision, usually located on the inner thigh. The catheter will then be advanced until it reaches the heart.

A PFO closure device will then be passed through the hollow catheter and into the heart where it will be positioned to close the heart defect.
Nonsurgical Closure of Patent Foramen Ovale

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

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 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® Septal Occluder and what is it made of?

The GORE® 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 wire frame covered with a thin ePTFE material. The ePTFE material, invented and manufactured by Gore, has been used in open-heart surgery for more than 35 years with a history of proven safety in medical implants. The wire frame is made of a nickel-titanium metal alloy called Nitinol with a platinum core.
GORE® Septal Occluder PFO Closure Device
How does a catheter-based procedure compare to surgery?

The surgical option requires that an incision is made in the chest to expose the heart. A heart-lung bypass machine pumps blood for the heart while the heart is stopped and opened so that the surgeon can close the defect in the heart with special patching material. Surgical patients usually require an overnight stay in the Intensive Care Unit (ICU) and a hospital stay of two days to one week.

Cardiac catheterization for a PFO closure may include a shorter hospital stay (usually just overnight), reduced scarring (typically on the leg instead of the chest), and an easier, more rapid recovery.

You should discuss these alternative PFO treatment options in detail with your physician to decide which option is best for you.

Your doctor may recommend that you avoid vigorous athletic activity for at least two weeks so that your implant has time to heal.
How does the GORE® Septal Occluder work?

Once inside the heart, the ePTFE material-covered wire frame of the GORE® Septal Occluder is deployed to form the device on either side of the defect between the left and right atria.

Your physician will choose a GORE® Septal Occluder size larger than the defect in order to cover the hole. The ePTFE material covering the wire frame acts as a framework for cells to attach. Over time, the device will become completely covered with the patient’s own tissue.
Frequently Asked Questions

How will my body respond to a permanent implant?

Both the ePTFE material and the wire used in the GORE® 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 the GORE® Septal Occluder to function as a permanent implant.

Will the GORE® 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 magnetic resonance imaging (MRI), may be slightly reduced because of the GORE® Septal Occluder wire frame. For this reason, you should inform the imaging technician that the GORE® Septal Occluder is in your heart.
More than 35 million Gore medical devices have been implanted worldwide.
Thousands of people around the globe have undergone catheter-based procedures for PFOs.

What will happen after the procedure?

Following the 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 will perform a chest X-ray and an ultrasound evaluation to ensure that the device is positioned properly.

You will 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.

Your doctor will also prescribe medications such as aspirin or clopidrogel to be taken for six months or longer after your procedure to prevent blood clotting.
Are catheter-based PFO closures always successful?

Typically, your doctor can close your PFO closure device depending on the size of the hole. Not all PFOs can be closed by catheterization. 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, which may include open-heart surgery. Your doctor will explain the details of cardiac catheterization, including the potential risks and complications.
Complications

What are the potential risks of the procedure?

**Risks:** There are risks associated with cardiac catheterization procedures as well as additional risks that may be associated with the implant device. Potential risks include, but are not limited to:

- Repeat procedure to the septal defect
- Device embolization
- New arrhythmia requiring treatment
- Intervention for device failure or ineffectiveness
- Access site complications requiring surgery, interventional procedure, transfusion, or prescription medication
- Thrombosis or thromboembolic event resulting in clinical sequelae
- Perforation of a cardiovascular structure by the device
- Device fracture resulting in clinical sequelae or surgical intervention
- Air embolism
- Myocardial infarction
- Pericardial tamponade
- Cardiac arrest
- Renal failure
- Sepsis
- Significant pleural or pericardial effusion requiring drainage
- Significant bleeding
- Endocarditis
- Headache or migraine
- TIA or stroke
- Death

If the device were to dislodge, you may need to return to the catheterization laboratory or to surgery for removal at which time your PFO would be repaired. Surgery following device placement may be more difficult and present more risk.
Glossary

**Antiplatelet and / or Anticoagulation Therapy**
Medication that helps prevent blood clots.

**Aorta**
The largest *blood vessel* in the body. The *aorta* is connected to the heart’s left *ventricle*. The *aorta* carries oxygen-enriched blood to the body.

**Arrhythmia**
Loss of regular heart rhythm.

**Artery / Arteries**
*Blood vessels* that carry oxygen-rich blood away from the heart and to other tissues throughout the body (except for the *pulmonary artery*, which carries oxygen-poor blood to the *lungs*).

**Patent Foramen Ovale (PFO)**
An abnormal opening between the upper two chambers of the heart.

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

**Atrium**
*pl. atria* One of the upper two chambers of the heart (right and left atrium).

**Blood Vessel**
The pathways through which blood travels in the body.
**Cardiac Catheterization**
A procedure in which catheters are passed through the arteries and/or veins of 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.

**Endocarditis**
Redness and swelling of the lining of the heart and its valves.

**Embolus**
A mass, such as an air bubble or blood clot, that travels in the bloodstream and gets stuck in a small blood vessel and blocks or decreases blood flow.

**ePTFE**
A biocompatible polymer that has been used in more than 30 million implants.

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

**Heart Defect**
Congenital malformation of the heart.

**Hematoma**
A mass of blood which is a result of a break in a blood vessel.

**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.
Magnetic Resonance Imaging (MRI)
A type of test used to visualize body tissue that uses a magnetic field.

Occluder
A device used to occlude or block an opening.

Pulmonary Artery
The artery connected to the heart’s right ventricle that carries oxygen-depleted blood to the lungs.

Pulmonary Vein
The vein that receives oxygen-rich blood from the lungs and delivers it to the heart's left ventricle.

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

Thrombus
Blood clot.

Transient Ischemic Attack
A 'warning stroke' and 'mini-stroke' that produces stroke-like symptoms but no lasting damage.

Vein / Veins
Blood vessels that carry oxygen-poor blood towards the heart from tissues throughout the body (except for the pulmonary vein, which carries oxygen-rich blood to the heart from the lungs).

Ventricles (right and left)
One of the two lower chambers of the heart.
Resources

**Adult Congenital Heart Association • www.achaheart.org**
The Adult Congenital Heart Association’s purpose is to educate the public,
• Adults with congenital heart disease,
• The medical community about adult congenital heart issues through the
development of forums,
• Newsletters, support groups and other methods of public information.

**American College of Cardiology • www.acc.org**

**American Heart Association • www.americanheart.org**

**Congenital Heart Information Network • www.tchin.org**
The Congenital Heart Information Network’s goal is to provide information and
resources to families of children with congenital and acquired heart disease, adults
with congenital heart defects, and the professionals who work with them.

**The Heart Center Online • www.theheartcenteronline.com**
The mission of The Heart Center Online is to be the premier cardiovascular
specialized health care site on the Internet, to provide cardiovascular patients, their
families and other site visitors with the tools they need to better understand the
complex nature of heart-related conditions, treatments and preventive care, and to
provide services and applications that deliver value to cardiology practices.

**Mayo Clinic • www.mayo.edu**
Mayo Foundation is a charitable, not-for-profit organization based in Rochester,
Minnesota. Mayo’s mission is to provide the best care to every patient every day
through integrated clinical practice, education and research.

**PFO Research Foundation • pforesearch.org**
The PFO Research Foundation seeks to educate the public about patent foramen
ovale (PFO) and support research into the condition’s related disorder. The PFO
Research Foundation (PRF) was formed by patients for patients and is supported by
leading experts in the field of PFO medicine.

**US National Library of Medicine • www.medlineplus.gov**

**W. L. Gore & Associates • www.goremedical.com/goreseptaloccludereu**
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