A new approach to Atrial Septal Defect (ASD) and Patent Foramen Ovale (PFO) repair

GORE HELEX SEPTAL OCCLUDER

You or your child are being considered for a **transcatheter** therapy to repair an **atrial septal defect (ASD)** or **patent foramen ovale (PFO)**. The therapy may include the use of the GORE HELEX Septal Occluder, which is placed in the heart using a minimally invasive technique known as **cardiac catheterization**. This brochure is intended to provide basic information about the GORE HELEX Septal Occluder and the repair of ASDs and PFOs.

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What is a *patent foramen ovale?*

The foramen ovale is a flap-like opening between the heart's upper chambers (atria). This opening is present at birth and normally closes on its own soon after birth. When it does not close, the condition is known as a **patent** (which means open) foramen ovale. Your physician may recommend treatment for the PFO.

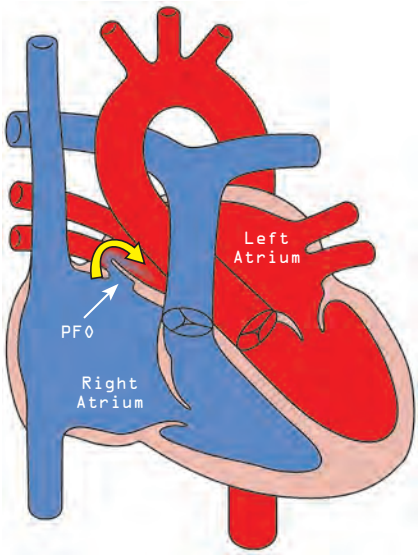
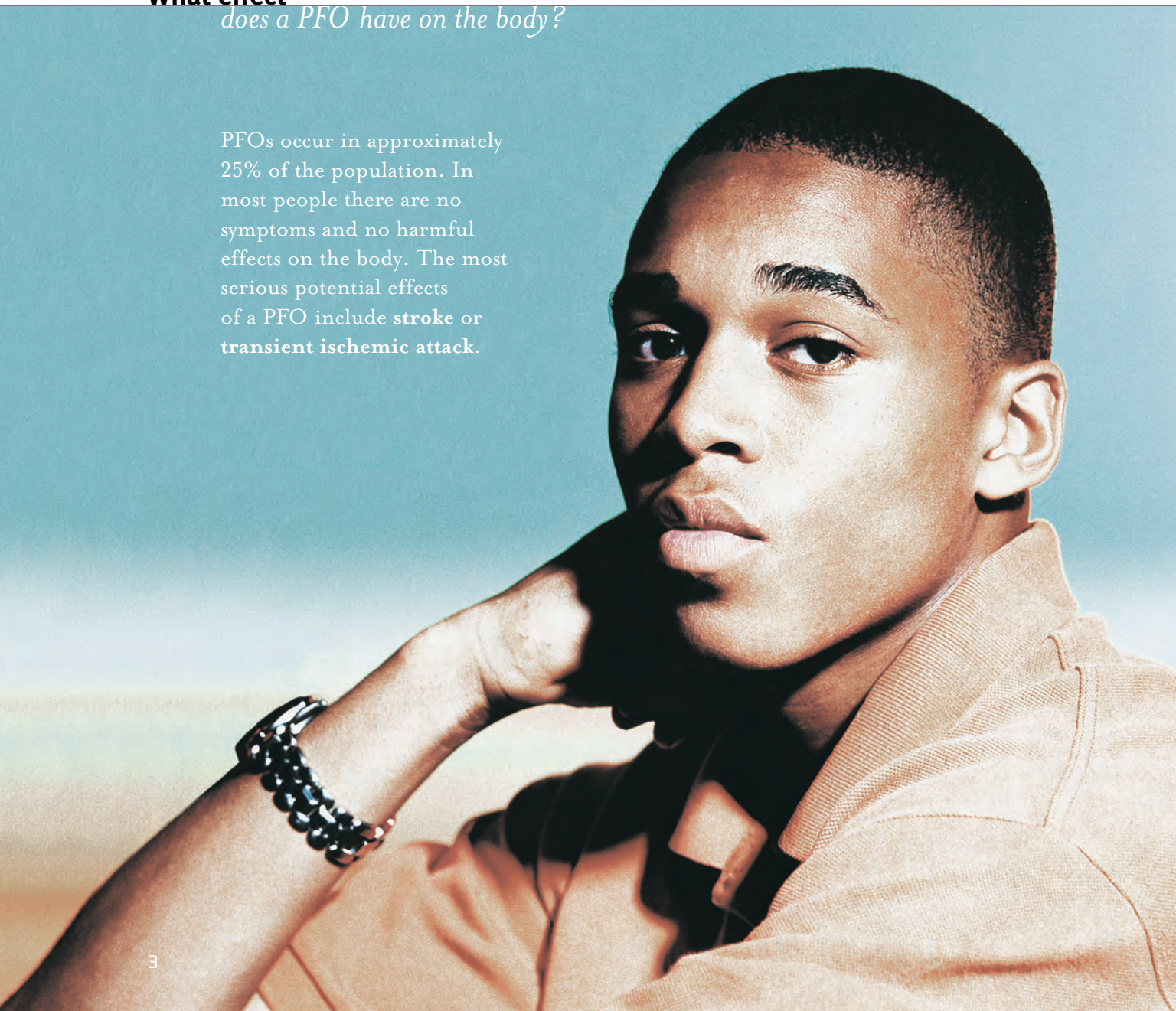


Diagram of heart with PFO

A PFO occasionally allows abnormal blood flow from the right atrium into the left atrium. In most cases this is not a problem, but the risk is that this flow could allow blood clots to travel through the heart to the brain which may lead to a stroke or transient ischemic attack.

What effect *does a PFO have on the body?*

PFOs occur in approximately 25% of the population. In most people there are no symptoms and no harmful effects on the body. The most serious potential effects of a PFO include **stroke** or **transient ischemic attack**.



How does medical therapy compare *to catheter-based closure for treatment of a PFO?*

If you have experienced a **stroke** or **transient ischemic attack**, your physician may recommend medical management through the **antiplatelet and / or anticoagulation therapy**. Drug therapy works by preventing clot formation but it does not close the **heart defect**. Medical therapy may avoid a closure procedure but may also necessitate modifying some lifestyle activities that may increase the chance of bleeding. Some medical therapies should not be used during pregnancy. You should discuss medical therapy with your physician to decide if this option is best for you.

What is an *atrial septal defect?*

An **atrial septal defect (ASD)** is an abnormal hole (defect) in the wall (septum) between the heart's upper chambers (atria). The hole might be as small as a pencil point or as large as the entire septum. The exact causes of an ASD are not known. Many ASDs close spontaneously in the first years of life.

If the defect does not close on its own, your physician may recommend treatment. The treatment choices for ASDs are open-heart surgery or the **transcatheter** delivery of a permanent implant.

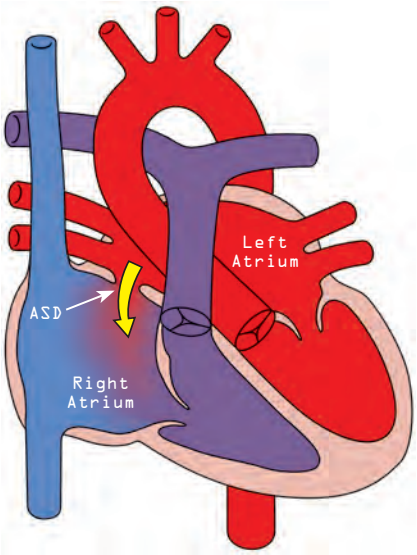


Diagram of heart with ASD

An ASD allows abnormal blood flow from the left atrium into the right atrium. This creates a surplus of blood in the right side of the heart and a surplus of blood flow to the lungs. The more blood that is diverted, the harder the heart and lungs need to work. This additional stress can lead to a weakening or enlargement of the right side of the heart.

What effect *does an ASD have on the body?*

Complications from an ASD tend to develop over time. Therefore, most physicians believe closing the defect in childhood will prevent serious medical problems in the future.

It is important to remember that many patients with an ASD may not suffer any symptoms; however, some may experience shortness of breath, fatigue, and labored breathing when exercising. Over time, enlargement of the right side of the heart and irregular heartbeats can develop. An ASD can lead to pulmonary hypertension (high blood pressure in the **arteries** of the **lungs**) which may contribute to lung congestion. Left untreated, pulmonary hypertension can lead to heart failure. In some people, an ASD may allow blood clots to travel through the heart to the brain which may lead to a **stroke** or **transient ischemic attack**.

How does a catheter-based *procedure compare to surgery for closure of an ASD or PFO?*

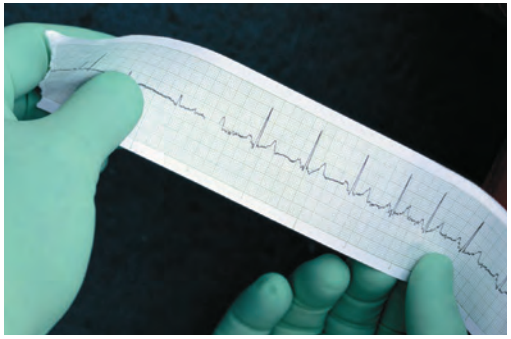
The surgical closure option involves an incision to the chest to expose the heart. A heart-lung bypass machine pumps blood for the heart while the heart is stopped and opened so that the surgeon can close the defect in the heart with special patching material. Surgical patients usually require an overnight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

Cardiac catheterization for an ASD or PFO closure would typically include a shorter hospital stay (usually overnight), reduced scarring, and an easier, more rapid recovery.

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

Most people resume a normal (moderate) level of activity within two days after a cardiac catheterization.

How are *ASDs and PFOs diagnosed?*



An ASD is most commonly noticed during a routine medical checkup when a physician hears an additional sound in the heart (a murmur). Because not all heart murmurs are ASDs, a physician will often listen to the heart over a period of time before deciding to conduct further evaluations that could lead to a diagnosis. The primary diagnostic tests for an ASD are non-invasive and include an electrocardiogram (ECG) and ultrasound imaging. The ECG measures the electrical changes during the heartbeat. The ultrasound uses sound waves to evaluate the structure of the heart and the direction of blood flow.

PFOs are also diagnosed by ultrasound imaging.

How do catheter-based *procedures for ASD and PFO closure work?*

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

Throughout the procedure, the physician will use ultrasound to get a good view of your child's or your own heart and ensure accurate position of the permanent implant. The ultrasound probe may be inserted into either the patient's **esophagus** or **blood vessel.**

General anesthesia may be used to keep the patient asleep during the procedure, depending on the type of ultrasound probe your physician selects.

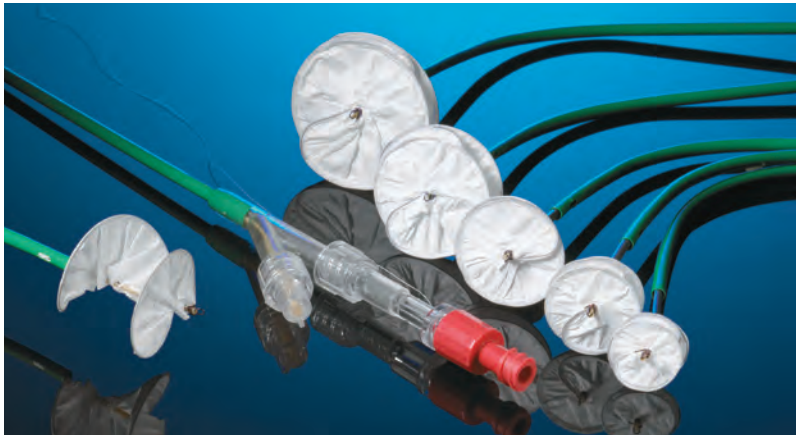
The permanent implant will be delivered through a **catheter** (a long, narrow, hollow tube) inserted into a blood **vessel** through a small incision, usually located at the inner thigh. The **catheter** is then advanced until it reaches the heart. The permanent implant is passed through the hollow **catheter** and into the heart where it is positioned to close the heart defect.

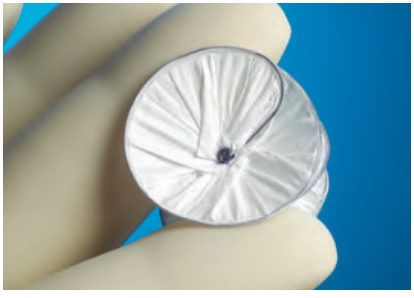
The closure device is released from the **catheter**, and left in the heart, preventing the abnormal flow of blood between the two chambers.

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

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

The GORE HELEX Septal Occluder is a minimally invasive device which is approved for the closure of ASDs and PFOs in many international markets including Europe. It is a permanent implant consisting of a circular wire frame covered with a thin membrane made of expanded polytetrafluoroethylene (ePTFE).

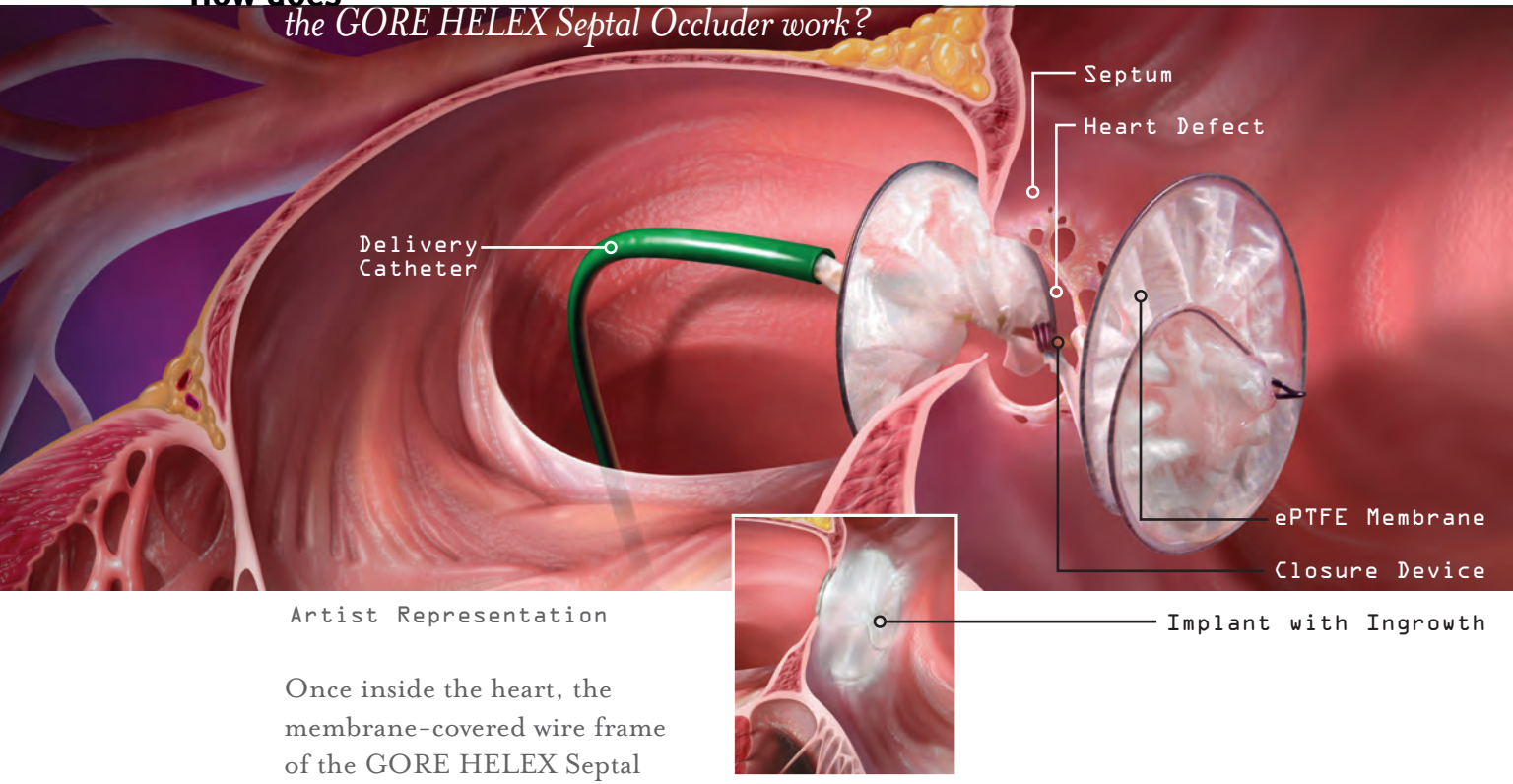




GORE HELEX Septal Occluder

The ePTFE membrane, invented and manufactured by Gore & Associates has been used safely in open-heart surgery for more than 20 years. The wire frame is made of a nickel-titanium metal alloy called nitinol, also commonly used in cardiovascular implants.

How does *the GORE HELEX Septal Occluder work?*



Artist Representation

Once inside the heart, the membrane-covered wire frame of the GORE HELEX Septal Occluder forms two opposing discs connected in the middle. A disc is placed on each side (left and right) of the defect across the septum. Your physician will choose a GORE HELEX Septal Occluder with discs larger than the defect in order to cover the hole. The membrane covering the wire frame acts as a framework for cells to attach. Over time, the discs will become completely covered with the patient's own tissue.

How will my body respond *to a permanent implant?*

Both the membrane and the wire used in the GORE HELEX 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 membrane allowing the GORE HELEX Septal Occluder to function as a permanent implant.

More than 25 million Gore medical devices have been implanted worldwide.

Will the GORE HELEX Septal Occluder *be affected by the external environment?*

No. Your GORE HELEX Septal Occluder 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 HELEX Septal Occluder wire frame. For this reason, you should inform the imaging technician that the GORE HELEX Septal Occluder is in your heart.

What will happen
after my 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 physician will perform a chest x-ray and an ultrasound evaluation to ensure that the device is positioned properly.

You will have a bandage covering the catheterization site incision for four to six hours.

Most people are able to return to a normal (moderate) activity level within one to two days. Your physician may recommend

that you avoid vigorous athletic activity for the first two weeks so that your implant has time to firmly adhere to your heart. You will need to return to the hospital for follow-up and heart monitoring tests a few times over the next year.

Thousands of people around the globe have undergone catheter-based procedures for ASDs and PFOs.

Are catheter-based *ASD and PFO closures always successful?*

No. Not all ASDs and PFOs can be closed by **catheterization**. For example, your ASD 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 closure device, or the vessels may not accommodate the **catheter** delivery system.

In the event that your ASD or PFO cannot be closed by a **catheter**-based procedure, you and your physician will need to discuss other treatment options, which may include medical therapy or open-heart surgery. Your physician will explain the details of **cardiac catheterization**, including the potential risks and complications.

Gore & Associates has spent more than 30 years making products for nearly every field of surgery, often using technology to advance the way procedures are performed. Today, more than 25 million Gore medical devices have been implanted worldwide.

Where can I *get more information?*

Adult Congenital Heart Association **www.achaheart.org**

The Adult Congenital Heart Association's purpose is to educate the public, adults with congenital heart disease, and 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**

The Association for European Paediatric Cardiology **www.aepc.org**

European Society of Cardiology **www.escardio.org**

Children's Health Information Network **www.tchin.org**

The Children's Health 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.

Heart Center Online **www.heartcenteronline.com**

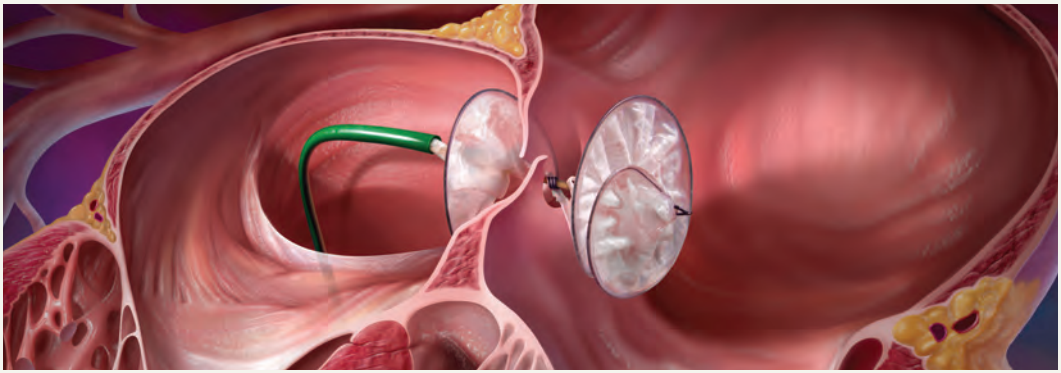
The mission of the HeartCenterOnline is to be the premier cardiovascular specialized health care site on the Internet, to provide cardiovascular patients, their families and other site visitors with the tools they need to better understand the complex nature of heart-related conditions, treatments and 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.

U. S. National Library of Medicine **www.medlineplus.gov**

W. L. Gore & Associates **www.goremedical.com**



Glossary

A - B

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

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**).

Atrial Septal Defect (ASD)
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
Plural 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. Pressures are measured, and blood samples are taken from within the heart and its major **blood vessels**.

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.

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

H - P

Heart Defect
Imperfection or malformation of the heart, existing at birth.

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.

Patent
Open.

Patent Foramen Ovale (PFO)
A term used to describe a tunnel / flap in the section of the **arterial septum** that is called the Foramen Ovale.

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.

Transcatheter
Through a **catheter**.

Transient Ischemic Attack
A 'warning **stroke**' or '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.

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