Patient Information

Atrial Septal Defect (ASD) Repair

GORE CARDIOFORM SEPTAL OCCLUDER

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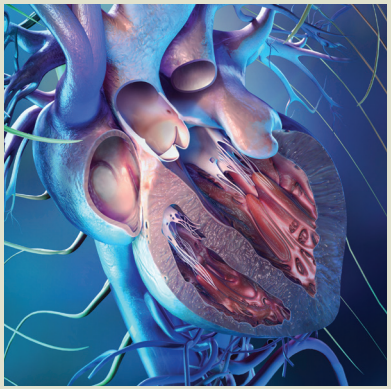
This brochure is intended to provide basic information about the GORE® CARDIOFORM Septal Occluder and the repair of **atrial septal defects (ASDs)** and to assist you in making an informed decision about your treatment options. You should ask your doctor if you have any questions or concerns about the diagnosis or treatment of your medical condition.

W. L. Gore & Associates has spent more than four decades making products for nearly every field of medicine, often using technology to advance the way procedures are performed. Today, more than 40 million Gore medical devices have been implanted worldwide.



A hole in the septum 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.

Overview

What is an atrial septal defect?

An **atrial septal defect (ASD)** is often a congenital (present at birth) heart defect that allows blood to flow between the left and right atria via a hole. This "hole in your heart" might be as small as a pencil point or as large as the entire **atrial septum**. If the defect does not close on its own, your doctor may recommend treatment.

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.

Symptoms

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

Although the majority of people with an **ASD** may not have any symptoms, **ASD** symptoms may include shortness of breath, fatigue, and labored breathing when exercising.

Causes

The exact causes of an **ASD** are not known. Many **ASDs** close spontaneously in the first years of life. An ASD is one of the most common congential heart defects seen in adults.

Diagnosis

How is an ASD 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 ultrasound imaging. The ultrasound uses sound waves to evaluate the structure of the heart and the direction of blood flow.

Treatment

Catheter-based procedure

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 puncture site, along with general anesthesia or conscious 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 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

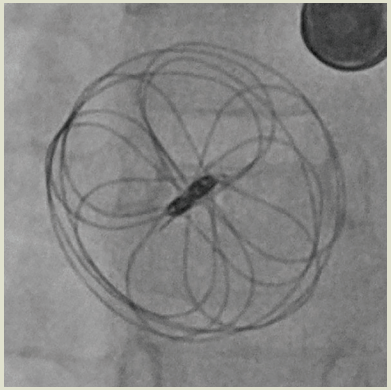
How do the catheter-based procedures for ASD closure work?

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

A **cardiac catheterization** procedure for an **ASD** 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** or a vein to allow the physician to view the heart throughout the procedure. This will help ensure accurate positioning of the **ASD** closure device.

A **catheter** 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. An **ASD** closure device will then be passed through the hollow **catheter** and into the heart where it will be positioned to close the heart defect.



Fluoroscopic image of GORE® CARDIOFORM Septal Occluder

Nonsurgical closure of atrial septal defects

The **ASD** 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 **ASD** closure device while it is being placed into the heart. A fluoroscopic (x-ray) image is used to see the metallic frame of the **ASD** 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 an **ASD** using **cardiac catheterization**. It is a permanent implant consisting of a circular wire frame covered with thin ePTFE material. The ePTFE material, invented and manufactured by Gore, has been used in open-heart surgery for more than 40 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 (for visibility on x-ray).

GORE® CARDIOFORM Septal Occluder ASD Closure Device

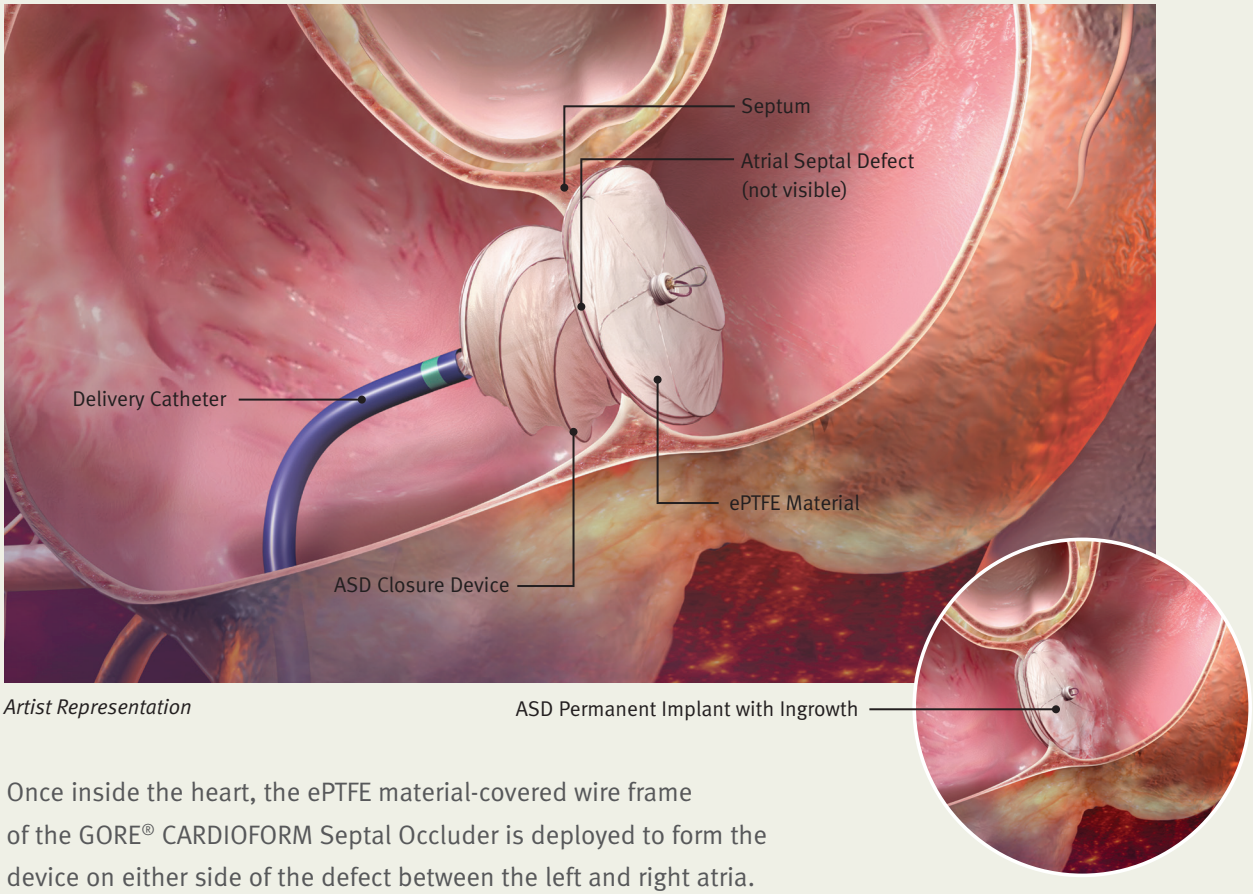
How does a catheter-based procedure compare to surgery?

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 an **ASD** 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 ASD treatment options in detail with your physician to decide which option is best for you or your child.

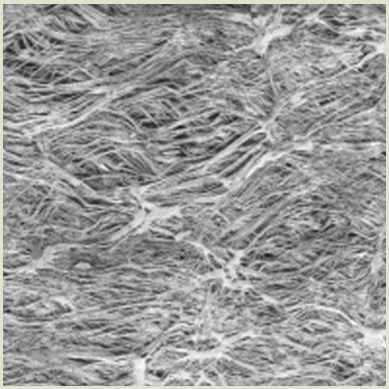
How does the GORE® CARDIOFORM Septal Occluder work?



Artist Representation

Once inside the heart, the ePTFE material-covered wire frame of the GORE® CARDIOFORM 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® CARDIOFORM Septal Occluder size larger than the defect in order to cover the hole. The ePTFE material acts as a framework for cells to attach. Over time, the device will become covered with the patient's own tissue.



Gore's ePTFE is specially made to enhance closure. At the microscopic level (shown above), the open ePTFE structure allows complete tissue coverage.

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 the 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 **magnetic resonance imaging (MRI)**, may be slightly reduced because of the GORE® CARDIOFORM Septal Occluder wire frame. For this reason, you should inform the imaging technician that the GORE® CARDIOFORM Septal Occluder is in your or your child's heart.

More than 40 million Gore medical devices have been implanted worldwide.

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 **antiplatelet** and / or **anticoagulation** therapy to be taken for six months or longer after your procedure to help prevent blood clotting.

Are catheter-based ASD closures always successful?

Not all **ASDs** 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 **ASD** closure device, or the **blood vessels** may not accommodate the **catheter** delivery system.

In the event that your **ASD** 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 other treatment options, including the potential risks and complications.

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

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
- Occluder disc expansion resulting in clinical sequelae or 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. Surgery following device placement may be more difficult and present more risk. Discuss any questions you may have with your physician.

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**).

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
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 **ASD**.

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 40 million medical devices.

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

Heart Defect
Congential 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 caries 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
(available in other languages)

American College of Cardiology • www.acc.org

American Heart Association • www.americanheart.org
(available in other languages)

Congenital Heart Information Network • www.tchin.org

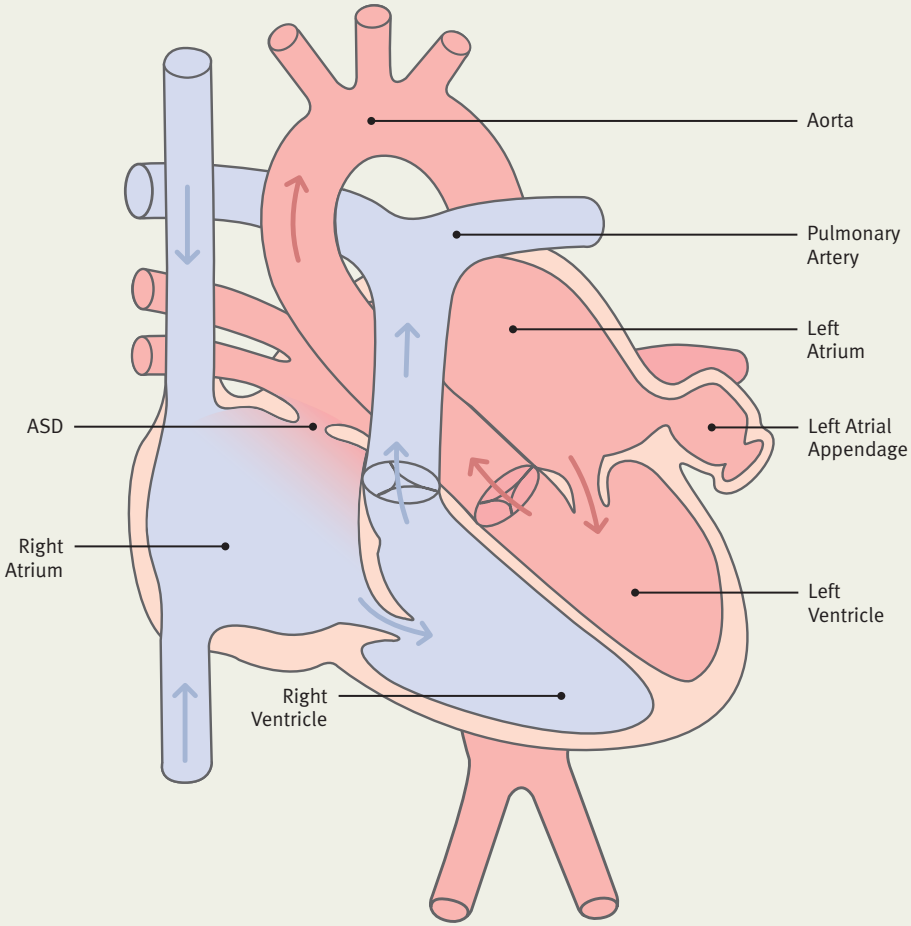
The Heart Center Online • www.theheartcenteronline.com

Mayo Clinic • www.mayo.edu

US National Library of Medicine • www.medlineplus.gov
(available in other languages)

W. L. Gore & Associates • www.goremedical.com/products/cardioform

Diagram of Heart with ASD



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