

A new
approach
to Atrial
Septal Defect
(ASD) repair



Patient Information

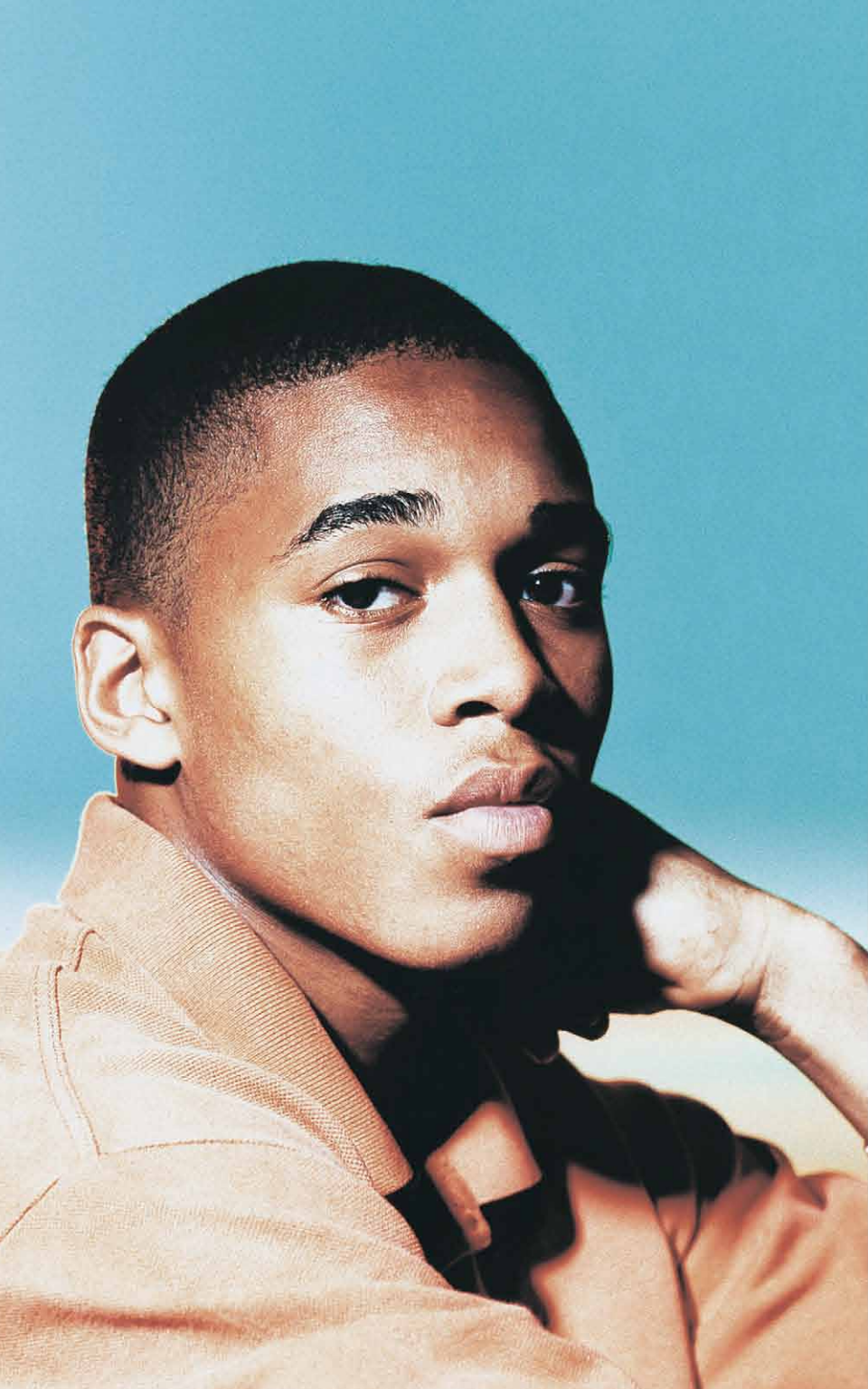


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*This brochure is intended to provide basic information about the GORE® HELEX Septal Occluder and the repair of **atrial septal defects (ASDs)** and to assist you in making an informed decision about your treatment options. If you have any questions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



Gore & Associates (Gore) 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.



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.

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 doctor may recommend treatment. The treatment choices for **ASDs** are open-heart surgery or the transcatheter delivery of a permanent implant.

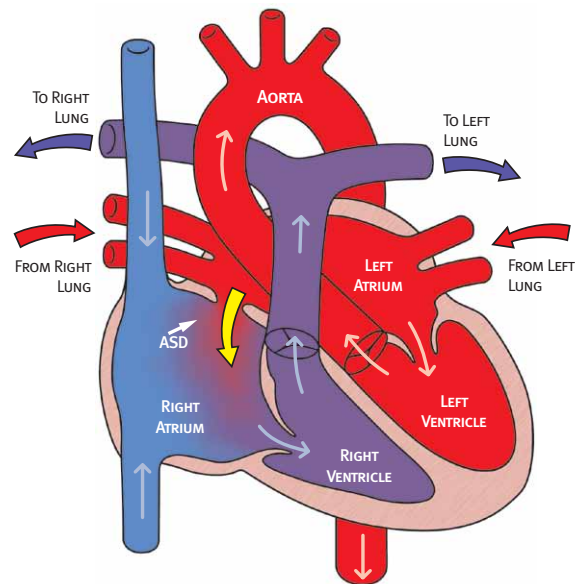


Diagram of Heart with ASD

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.

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. 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 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 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.

How do 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® HELEX 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** (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 **ASD** 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. 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**.

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

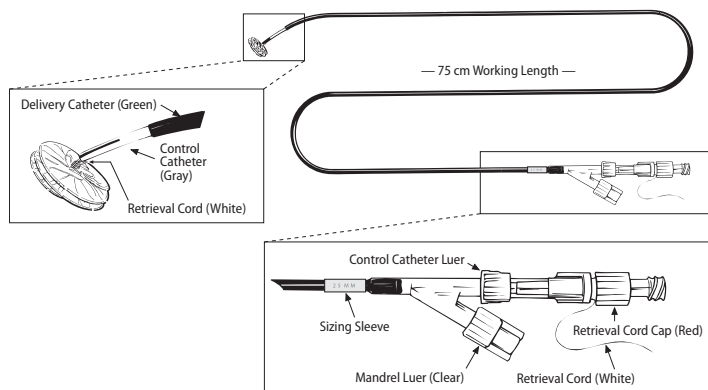
Your doctor will rely on two types of images to see the **ASD** closure device while it is being placed into the heart. A fluoroscopic image (X-ray) is used to see the metallic frame of the **ASD** closure device, and an ultrasound image allows the doctor to see the heart structures and blood flow.



What is

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

The GORE® HELEX 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 a thin ePTFE membrane. The membrane, invented and manufactured by Gore has been used in open-heart surgery for more than 20 years with a history of proven safety in medical implants. The wire frame is made of a nickel-titanium metal alloy called nitinol, also commonly used in cardiovascular implants.



GORE® HELEX Septal
Occluder ASD
Closure Device



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 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.

What are the

potential risks and benefits 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:

- Anesthetic reaction
- Bleeding at incision site
- Infection
- Bruising in groin or arm
- Injury to the **artery, vein** or nerves in the groin or neck
- Blood clots (**thrombus**)
- An air bubble or clot that blocks the flow of blood in a vessel (**embolus**)
- Wire frame fracture which could result in a device needing to be removed
- Perforation of the heart during the catheterization procedure or later, by the occluder, could produce fluid leakage into the chest that would need to be repaired or drained
- Perforation of a blood vessel
- Kidney failure
- Loss of regular heart rhythm (**arrhythmia**)
- Swelling or redness of the lining of the heart (**endocarditis**)
- Fever
- Headache, migraine, or seizure
- Repeat procedure for **ASD**
- Surgical intervention due to device failure or ineffectiveness
- Cardiac arrest
- **Stroke** or **transient ischemic attack**
- Death
- Blood pressure changes

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

Benefits:

- Shorter hospital stay and recovery time
- No chest scar
- No pain or scar associated with open heart surgery

Contraindications

Your doctor will discuss with you when the device should not be used to treat this condition.

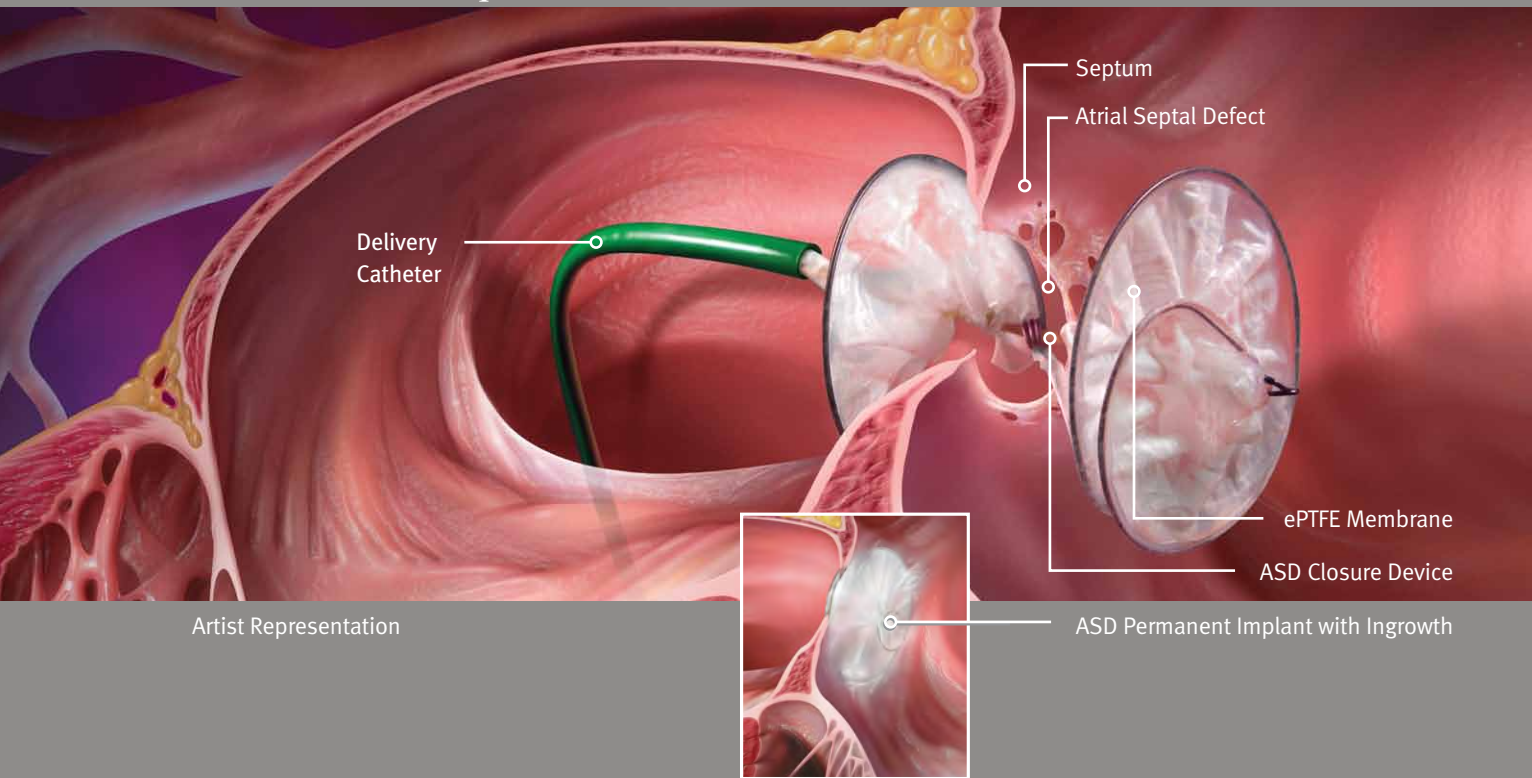
- Patient anatomy will not allow placement of an ASD closure device
- Patients with an infection or blood disorder
- Patients with small veins that would not allow a catheter to be inserted
- Patients unable to take aspirin, have a bleeding disorder or untreated ulcer
- Patients with blood clots in their heart

Precautions

The GORE® HELEX Septal Occluder contains nickel and you may be allergic to this metal. You should discuss this with your doctor.

How does

the GORE® HELEX Septal Occluder work?



Artist Representation

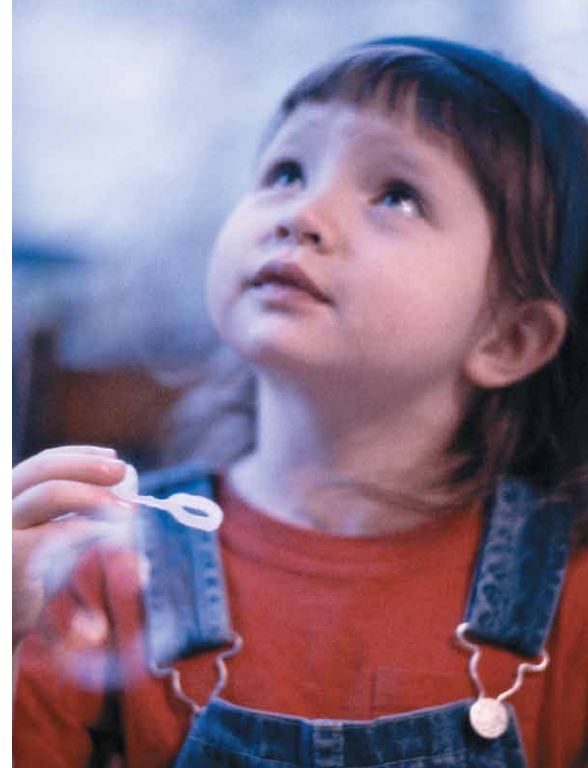
Once inside the heart, the membrane-covered wire frame of the GORE® HELEX Septal Occluder forms two opposing discs connected in the middle. A disc is placed on each side (left and right) of the defect across the septum.

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 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® HELEX Septal Occluder wire frame. For this reason, you should inform the imaging technician that the GORE® HELEX Septal Occluder is in your or your child's heart.

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 clopidogrel to be taken for six months or longer after your procedure to prevent blood clotting.



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



Are catheter-based

ASD closures always successful?

No. 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 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 **cardiac catheterization**, including the potential risks and complications.

Alternatives:

Surgery to close your ASD

This may require an incision through your breastbone so the surgeon can see your heart and sew in a patch (if the **ASD** is large) or stitches (if the **ASD** is small).

No treatment

Studies have shown that if a large **ASD** is not closed, people have problems as they get older. These problems include irregular heartbeats, high blood pressure, and heart failure.

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

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.

US National Library of Medicine, www.medlineplus.gov

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

800.437.8181

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. 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.

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.

Esophagus

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

Heart Defect

Imperfection or malformation of the heart, existing at birth.

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.



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Indications for Use in the US: The GORE HELEX Septal Occluder is a permanently implanted prosthesis indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs). Refer to *Instructions for Use* at goremedical.com for a complete description of all contraindications, warnings, precautions and adverse events.

Products listed may not be available in all markets.

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