A new approach to Atrial Septal Defect (ASD) repair

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.

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 (roughly 20 out of 100) 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 surgical repair or passing of a catheter (a tube passed through the heart).

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 the HELEX Septal Occluder and what is it made of?

The 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 membrane made of GORE-TEX® expanded polytetrafluoroethylene (ePTFE). The ePTFE membrane, invented and manufactured by W. L. Gore & Associates, Inc., has been used in open-heart surgery for over 20 years with a history of proven safety in medical use. The wire frame is made of a nickel-titanium metal alloy called nitinol, also commonly used in cardiovascular implants.
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.

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 closure of an ASD involves the placement of a permanent implant, such as the HELEX Septal Occluder, using a minimally invasive procedure (non-surgery, usually small incision or cut in skin).

A cardiac catheterization procedure (placing a tube in the heart) for an ASD closure typically takes 1 to 2 hours to complete. General anesthesia is often used to keep the patient asleep during the procedure because some of the activities may be uncomfortable. While the patient is asleep, an ultrasound probe will be placed into the esophagus (tube from mouth to stomach) or a vein to get a good view of the heart and to ensure accurate positioning of the ASD closure device.

A flexible catheter (a long, narrow, hollow tube) is inserted into a blood vessel through a small incision, usually in the inner thigh. The catheter is then advanced until it reaches the heart. An ASD closure device (the device to block the hole in the heart) is passed through the hollow catheter and into the heart where it is positioned to close the defect.
The ASD closure device is released from the catheter, and left in the heart, stopping 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.

How does a catheter-based procedure compare to surgery?

The standard treatment for an ASD in the United States is open-heart surgery. 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 2 days to 1 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.

Most people resume normal activity within 2 days after a cardiac catheterization.

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 in the heart (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
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
- Patient heart 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 HELEX Septal Occluder contains nickel and you may be allergic to this metal. You should discuss this with your doctor.

How does the HELEX Septal Occluder work?

Once inside the heart, the membrane-covered wire frame of the HELEX Septal Occluder forms two opposing disks connected in the middle. One disk is placed on either side (left and right) of the defect across the septum. Your physician will choose a HELEX Septal Occluder with disks 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 disks 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 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 HELEX Septal Occluder to function as a permanent implant.

Over 13 million Gore ePTFE medical devices have been implanted worldwide.
Will the HELEX Septal Occluder be affected by the external environment?

No. Your HELEX implant will not be affected in any way 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 HELEX Septal Occluder wire frame. For this reason, you should inform the imaging technician that the HELEX Septal Occluder is in your heart.

What will happen after my procedure?

Following the procedure you may experience 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 4 to 6 hours. Most people are able to return to a normal (mild to moderate) activity level within 1 to 2 days. Your doctor may recommend that you avoid vigorous athletic activity for at least 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.

Your Doctor will also prescribe medications such as aspirin or clopidogrel to be taken for 6 months or longer after your procedure.

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.acaheart.org**
The purpose of our organization is to educate the public, adults with CHD, 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**
Our 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**
800 / 437-8181

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**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 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 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 to pass devices through.

Echocardiography/Echocardiogram/Echocardiographic (Echo) - The use of ultrasound to look at the heart, valves and great vessels.

Endocarditis - Redness, and swelling of the lining of the heart and its valves.

Endocarditis Prophylaxis - Medicine taken to prevent endocarditis.

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.

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.

Occlusion - to occlude or block an opening.

Patent - Open.

Patent Foramen Ovale (PFO) - A term used to describe a small hole 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.

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

Thrombus - Blood clot.
Transcatheter - Through a catheter.

Transesophageal Echocardiography (TEE) - An ultrasound test to visualize the heart and defect, where an imaging probe with a camera is placed in the esophagus.

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