

ATRIAL SEPTAL DEFECT (ASD)

What is an atrial septal defect?

Atrial septal defect (ASD) is a hole in the wall (the septum) between the heart's two uppermost chambers, the right atrium and the left atrium. This hole allows blood to flow in either direction between the left and right atrium.

An ASD may cause several problems. First, it creates a condition in which the right side of the heart now contains extra blood, and extra blood also now flows to the lungs. This diversion of blood puts strain on the heart because it has to pump this extra blood to the lungs. This extra blood flow to the lungs may damage the arteries to the lungs over time, leading to high blood pressure in these vessels. In addition, the strain put on the right-sided pumping chamber can lead to a weakening or enlargement of the right side of the heart and eventually heart failure, if left untreated. This enlargement may also cause arrhythmias (irregular heart rhythms) to develop. Also, ASDs in some circumstances can allow blood clots from the body to enter the brain and cause a stroke.

What are the symptoms of an ASD?

Most patients do not have any symptoms in childhood. However, symptoms that might develop over time, depending on the severity of the ASD and other factors, include:

- shortness of breath, fatigue, and labored breathing while exercising
- irregular heart beats
- transient ischemic attacks (TIA), which result in stroke-like symptoms
- stroke
- pulmonary hypertension (high blood pressure in the arteries of the lung; can lead to heart failure if not treated)
- reduction in lifespan of about 20 years on average if the ASD is not closed

What causes ASD?

An ASD is congenital, meaning it is a defect that is inborn or exists at birth. Stated another way, the defect is an abnormality, not a disease. The septum between the two atria of the heart did not develop normally before birth. What *is* known is that about 20 percent of ASDs that occur in infants close on their own in the first years of life.

Heart defects in general

Sometimes a viral infection can cause heart defects to develop. Other causes include genetic factors, certain other medical conditions (Down's syndrome, for example), and some prescription and nonprescription drugs; however, in about 95% of the cases, no cause can be identified.

How is an ASD diagnosed?

During a routine examination, your doctor may hear a murmur when listening to your heart. A heart murmur is an additional swishing sound heard in the heart. If a murmur is identified, your doctor will order other tests that can include the following:

- **electrocardiogram** (ECG or EKG) - a test that records the electrical changes that occur during a heartbeat; reveals abnormal heart rhythms (arrhythmias) and detects heart muscle stress
- **chest X-ray** - a test to show the size and shape of the heart and lungs
- **echocardiogram** - a test that uses sound waves to create a moving picture of the heart's internal structures

- **Doppler ultrasound** - a test that uses sound waves to measure blood flow; often combined with echocardiogram to evaluate both the internal structure of the heart and blood flow across the heart's valves
- **cardiac magnetic resonance imaging (MRI)** - a test that uses three-dimensional imaging to reveal how blood flows through the heart and how the heart is working
- **cardiac catheterization** - a procedure that involves inserting a thin tube (a catheter) into a vein or artery and passing it into the heart to sample the level of oxygen, measure pressure changes, and make x-ray movies of the heart and its internal structures
- **angiography** - a dye-enhanced x-ray of the heart's internal structures

Additional tests may be ordered as necessary.

How is an ASD treated?

If you or your child is diagnosed with an ASD, your primary care doctor will recommend that you meet with a congenital heart specialist (a doctor who has the training and equipment to determine the heart problem), who will order the necessary special tests, medical care, heart surgery, and follow-up checkups. The best treatment approach will depend on the patient's symptoms as well as the size of the ASD. The ASD may need to be closed surgically through open-heart surgery or may be repaired through an outpatient catheter-based procedure.

How is an Atrial Septal Defect (ASD) Closed Using a Catheter-based Procedure

How is an ASD closed using a catheter-based procedure?

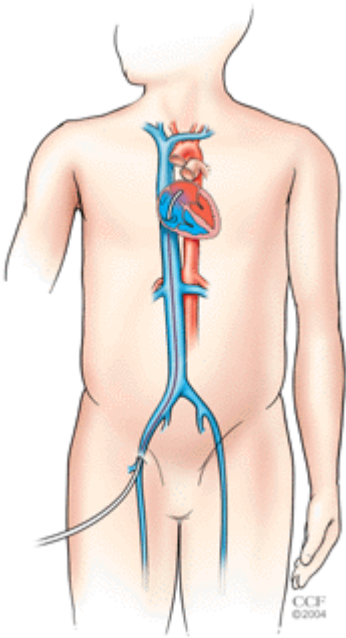
Catheter-based procedures are commonly used to diagnose and treat heart-related problems. For example, catheter-based procedures are used to diagnose and treat clogged arteries and heart attacks. A catheter can also be used to guide the placement of an ASD device - which becomes a permanent implant - that will close the hole in the heart wall.

To further briefly explain what happens in an ASD catheter-based procedure, a cardiac catheterization involves slowly moving a catheter (a long, thin, flexible, hollow tube) into the heart. The catheter is initially inserted into a large vein through a small incision made usually in the inner thigh (groin area) and then is advanced to and into the heart. One or more tests will be done to measure the ASD and to be sure there are no other defects. An imaging test called angiography, (an injection of a certain type of dye followed by an x-ray motion picture) may be used to better visualize the heart. An ultrasound imaging technique called Intracardiac Echo (ICE) is used to see the defect better and also to determine the size of the closure device needed. This involves passing an imaging device up to the heart through the vein in the patient's leg... In addition, a special balloon on a catheter is moved to the area of the hole and inflated across the hole in order to measure the size of the hole when it is gently stretched.

An ASD closure device is moved through the catheter to the heart and specifically to the location of the heart wall defect. Once in the correct location, the ASD closure device is allowed to expand its shape to straddle each side of the hole. The device will remain in the heart permanently to stop the abnormal flow of blood between the two atria chambers of the heart. The catheter is then removed and the procedure is complete.

How long does the procedure take?

The cardiac catheterization procedure for an ASD closure typically takes one hour to complete. A

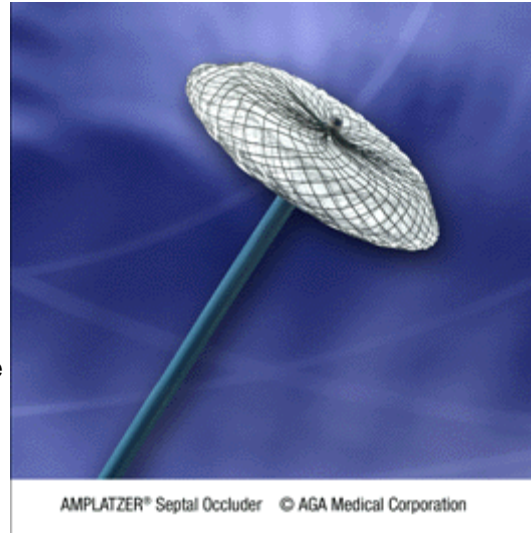


local anesthetic is used to numb the groin area where the catheter was inserted. Use of general anesthesia or sedation by IV is situation dependent -- depending on doctor preference and particular patient needs.

What types of ASD closure devices are there?

Two main types of ASD closure devices are currently being used - the Amplatzer® Septal Occluder System and the HELEX™ Septal Occluder.

The **Amplatzer® Septal Occluder** consists of a two attached circular discs - a larger disc, which will reside facing the left atrium, sandwiched on top of a smaller disc, which will face the right atrium. These discs are made of polyester fabric encased by a wire mesh made of a nickel-titanium metal alloy.



The **Helex Septal Occluder** consists of a circular wire frame made of a nickel-titanium metal alloy covered with a thin membrane made of Gore-Tex, a material that has been used in open-heart surgery for more than 20 years. Once the device is passed through the catheter it opens up to form one circular disk that covers the hole. The HELEX Septal Occluder is an investigational device only currently available to patients enrolled in a clinical trial. For more information, see the document "The HELEX Septal Occluder for Atrial Septal Defect: Continued Access Trial."

How does the body react to a permanent implant?

The materials used in the occluders have a proven long-term safety history and have been widely used in heart surgery procedures. It's not likely that the body will have a negative reaction to these devices. Within a few days, the body's own tissue will begin to grow over the device. By 3 to 6 months, the device is completely covered by heart tissue and at that point becomes a part of the wall of the patient's heart.

The patient will not be able to feel the device. The implant will not be affected by airport or other security sensors, or by any household appliances, or medical imaging methods. However, the clarity of medical images may be slightly reduced because of the wire frame on the occluder devices. For this reason, be sure to inform the imaging technician that you or your child has such a device in your heart. You will receive an identification card that should be carried with you/or by your child to show to medical personnel if necessary.

Can a catheter-based ASD closure procedure be used in all cases?

No. ASD closure devices cannot be used:

- If the ASD is too large to be adequately closed by a catheter-based closure device
- If the particular patient's heart structure will not allow an ASD closure device to be used (for example, if there is not enough atrial septal tissue left to secure the device)
- If the particular patient's blood vessels are too narrow to allow the catheter-based delivery system to be used
- If the patient has blood clots in his/her heart
- If the patient needs surgery to fix other heart defects
- If the patient has a bleeding disorder, untreated ulcer, or is unable to take aspirin
- If the patient has an active infection anywhere in the body (the device can be implanted after the infection is completely gone)

If your ASD cannot be closed with a catheter-based procedure, your doctor will discuss other treatment options including open-heart surgery.

How does an open-heart surgical procedure compare with a catheter-based procedure?

The catheter-based procedure for ASD closure usually results in a much shorter hospital stay (typically 6 to 24 hours), reduced scarring (limited to the leg area where the catheter is inserted) and an easier, more rapid recovery.

With open-heart surgery, an incision is made in the chest to expose the heart. A heart-lung bypass machine is used to pump blood for the heart while the heart is stopped and the wall defect is being repaired. The defect is closed by sewing a patch in place (if the defect is large) or by stitches (if the defect is small). Surgical patients usually stay overnight in the intensive care unit and then 3 to 5 days in the hospital and about 4 weeks of additional recovery time is necessary at home. Open-heart surgery results in a scar on the chest but may be the best or only option in some cases.

Your doctor will discuss these two treatment alternatives with you in order to make the best decision for you or your child.

What follow-up tests and home care instructions are typically given following a catheter-based procedure for ASD closure?

Within 24 hours after the procedure, a chest x-ray, electrocardiogram, and echocardiogram are conducted to make sure that the device is positioned correctly. Bed rest in the hospital for 6 hours after device placement is required. The patient may go home the evening of the procedure or possibly the following morning. The patient may experience minor pain at the catheter incision site and a slight sore throat for a few days if an ultrasound probe was used to check device placement. The patient will be instructed not to lift anything greater than 10 pounds for 1 week after the procedure. Your doctor will discuss when you or your child can return to regular activity (usually within a week).

Your doctor will prescribe medications that will need to be taken at home. Aspirin will need to be taken for six months and Plavix will need to be taken for three months after the procedure to prevent blood clots from forming. Antibiotics will also need to be taken 1 hour before certain medical procedures (for example, dental cleaning/dental surgical procedures as well as certain surgeries) for up to six months post device placement. Your doctor will provide information on which procedures will require antibiotic pre-treatment.

As with all medications, take them only as directed by your doctor, never stop taking the medication without talking with your doctor first, and call your doctor if you experience unpleasant reactions or have any concerns about the medication.

Finally, a few follow-up return trips to the hospital will be necessary over the next year to monitor the patient's heart and device placement. Each visit -- 6 months, and 1 year -- will include electrocardiogram and echocardiogram