

AMPLATZER™ Septal Occluder

AMPLATZER™ Multi-Fenestrated Septal Occluder - “Cribiform”

A PATIENT'S GUIDE TO THE NON-SURGICAL CLOSURE OF AN ATRIAL SEPTAL DEFECT



ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

This brochure is intended to provide you with general information about the non-surgical closure of an atrial septal defect (ASD), which should be further discussed with a doctor. It is not intended to provide medical care or treatment. You should consult with a doctor regarding the diagnosis or treatment of your medical condition.

Atrial Septal Defect Overview

An atrial septal defect (ASD) is an opening in the tissue wall between the two upper chambers of the heart. This opening allows oxygen-rich blood to mix with oxygen-poor blood, creating extra work for the heart to supply the body with oxygen.

ASDs are one of the most common congenital heart defects seen in pediatric cardiology and often occur in conjunction with other cardiac defects.¹

- Congenital heart defects occur in about 7.5% of live births.² Of these, 7-10% are ASDs, making them one of the most common congenital cardiac malformations.^{3,4}

There are four types of ASDs and their location in the heart determines their type.¹

- Ostium secundum is the most common type of ASD and represents approximately 80% of ASDs.²
- Transcatheter device closure for ASD only benefits patients with ostium secundum ASDs.^{1,5}

If left untreated, the ASD may lead to significant morbidity and mortality.⁴

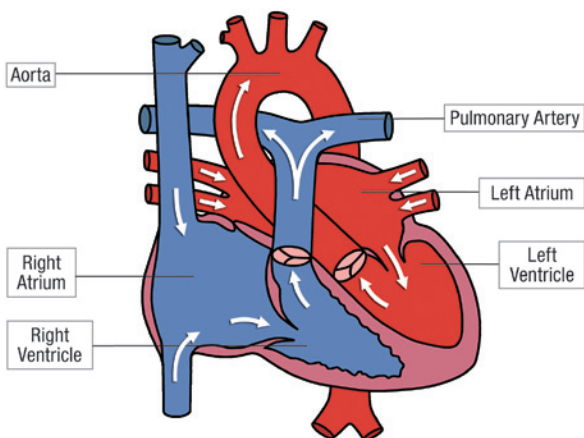


Figure 1
Diagram of a healthy heart

How does an ASD affect blood flow?

To best understand how an ASD affects blood flow, it is helpful to first understand how a normal heart works (Figure 1).

The heart is a pump with four chambers: two small upper chambers called the atria (you have a right and a left atrium) and two larger, more powerful pumping chambers called ventricles (again you have a right and a left ventricle). A healthy heart pumps blood through the body and is controlled by a unique electrical system imbedded within the heart itself. Typically, oxygen-poor blood flows from the body into the heart through the right atrium and flows into the right ventricle. When the heart pumps, this blood is pumped through the pulmonary artery out to the lungs to be filtered and receive oxygen. From the lungs, the now oxygen-rich blood enters the heart through the left atrium. It then flows to the left ventricle and is pumped through the aorta out to the body to provide oxygen to all of the organs and cells. After it circulates the body, it becomes oxygen-poor and returns to the heart.

An ASD is an abnormal opening in the tissue wall between the atria. Typically there is more pressure in the left atrium, causing the oxygen-rich blood to flow through the opening and mix with oxygen-poor blood (Figure 2).

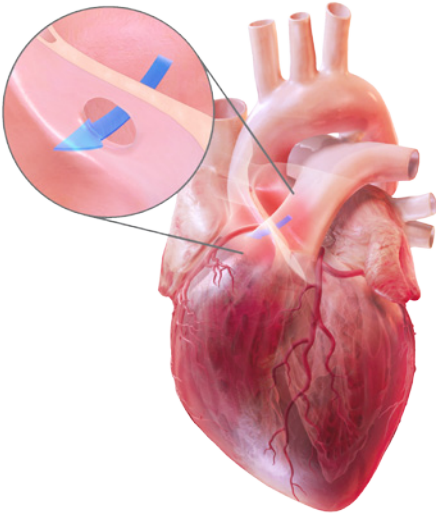


Figure 2
Heart with atrial septal defect

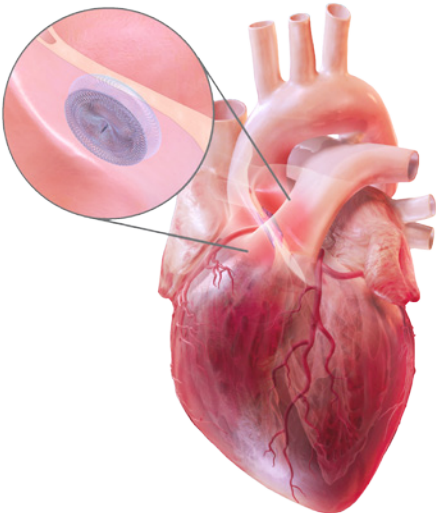


Figure 3
AMPLATZER Septal Occluder implanted during a catheter-based procedure

What are the symptoms of an ASD?

Severity of symptoms often depends on the size of the hole. Large ASDs may cause fatigue, pulmonary hypertension, arrhythmia, and/or an enlarged heart.

How is an ASD treated?

There are a number of treatment options for an ASD, and there is no single option that is right for every patient. You should discuss with your doctor to learn about the best treatment option for you; however, there are a few standard approaches of which you should be aware. The first option is medication which may be appropriate in treating symptoms associated with the ASD. Other treatment options include open-heart surgery and catheter-based procedures (Figure 3).

How do I know which treatment option is right for me?

Every person is unique. Your doctor is your best resource for learning about the treatment options available to you and the best course for your condition. Talk to your doctor and follow his or her advice for your care. Keep in mind an ASD can result in unpleasant symptoms and increased health risk. With proper care, however, it can generally be managed with medication or closure.

What is involved with a catheter-based procedure?

A catheter-based procedure is a minimally invasive treatment option available to some patients. The procedure involves making a small incision, typically in the groin, and inserting a small tube, called a catheter or sheath, to navigate through the blood vessels to the procedure site within the heart (Figure 4).

In patients with an ASD, the doctor guides the device through the catheter or sheath and deploys it in the ASD to seal the hole. Once the device is placed in the defect, the doctor will carefully study its position using cardiac imaging systems. Once satisfied with the position, the device is released to remain permanently in the defect (Figure 3). The catheter or sheath is removed and the procedure is completed.

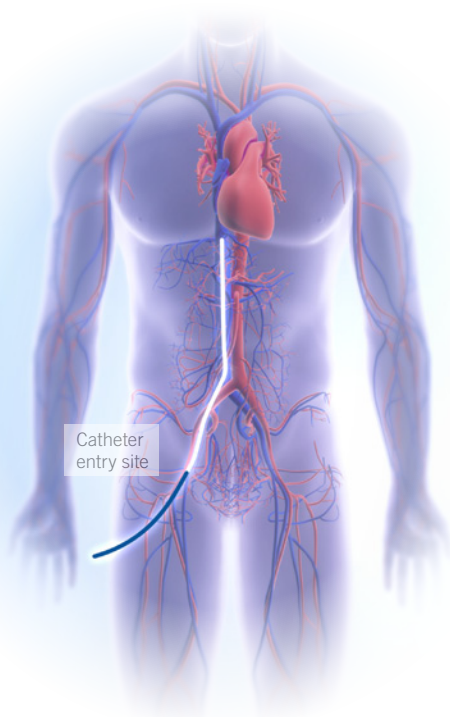


Figure 4
Catheter pathway in a transcatheter ASD closure procedure

The procedure itself should last about one to two hours and will take place in a heart catheterization laboratory, where many minimally invasive, non-surgical procedures are performed. Your doctor may give you an anesthetic, and you should not feel any significant discomfort.

What happens after the procedure?

Because the procedure is minimally invasive, your recovery will likely be quick and easy. Many patients are discharged from the hospital within 24 hours. Your doctor can provide guidelines for activities and medications. He or she will prescribe drugs that you should take at home to continue your treatment and recovery. The decision to prescribe these is at the discretion of your doctor. Many doctors require follow-up appointments over the next year to ensure the patient's recovery is going well. What to expect during and after the procedure will vary. Discuss all questions or concerns you have with your doctor.



Figure 5
AMPLATZER Septal Occluder (top) and AMPLATZER Multi-Fenestrated Septal Occluder - “Cribriform” (bottom)

What exactly is an AMPLATZER Septal Occluder and an AMPLATZER Multi-Fenestrated Septal Occluder - “Cribriform”?

The AMPLATZER Septal Occluder is a device specifically designed to close an ASD (Figure 5). The AMPLATZER Multi-Fenestrated Septal Occluder - “Cribriform” is specifically designed to close a multi-fenestrated ASD, a type of ASD consisting of many small holes rather than just one (Figure 5). Your doctor will choose the appropriate device for your specific ASD. The selected device is implanted during a catheter-based procedure and will remain permanently implanted.

Both devices are made from a braided Nitinol, a metal with shape memory characteristics. This means the device will go back to its original shape even after it is stretched to pass through a catheter. The shapes of the AMPLATZER Septal Occluder and AMPLATZER Multi-Fenestrated Septal Occluder - “Cribriform” were specifically designed to seal ASDs and multi-fenestrated ASDs respectively.

Who should not receive the device?

If you have any of the following conditions, you may not be a good candidate to receive the device.

- If you need to have surgery to fix other defects in your heart.
- If you have an infection anywhere in your body. You may receive the device only after the infection is gone.
- If you have a bleeding disorder, untreated ulcer, or if you are unable to take aspirin.
- If you are unable to take antiplatelet or anticoagulant therapy.
- If you have blood clots in your heart.
- If you have a patent foramen ovale.
- If you, your heart, or your veins are very small or if you cannot undergo the procedure.
- If the device would interfere with other structures in your heart.

How long will it take me to recover? What activities should be avoided after my procedure? When can they resume?

Every person recovers differently, and your doctor can help determine when activities can be resumed. In general, all strenuous activity should be avoided for one month after the procedure.

Will I be able to feel the device?

No, you will not be able to feel the device once it's implanted.

What is a patient identification card? Will I need to carry it with me?

As a device patient, it is important to carry a patient identification card with you to identify yourself as having an implanted device. The patient ID card includes your name, implant date, your doctor's contact information, and information about your device. You will be provided with this card after the procedure.



Can I travel with an implanted device? Will my device trigger airport security systems?

Your doctor is your best resource for the answer to this question. Many patients find that with some extra planning and care, they can enjoy traveling. It is always wise to carry your patient ID card, just in case you encounter difficulties while traveling.

Though some patients worry about airport security systems, there is really no need for concern. The metal parts in AMPLATZER occlusion devices are very small and usually do not trigger metal detector alarms. However, the sensitivity setting of the metal detector and other factors may affect how the metal detector responds to your device. Simply show your patient identification card to security personnel.

Will medical equipment interfere with my device?

Although most medical equipment will have no effect on your device, it is best to tell hospital personnel that you have an implanted device before you undergo any medical procedure. Magnetic resonance imaging (MRI) scans are generally acceptable, and your AMPLATZER occlusion device has no known hazards when using a 3-tesla MRI, an MRI system more powerful and faster than standard MRI machines. If an MRI is needed, simply inform the MRI staff about your implant.

Can I have this procedure if I am pregnant? What if I am a nursing mother?

The risk of increased x-ray exposure must be weighed against the potential benefits of this device. Your physician will ensure that care will be taken to minimize the radiation exposure to the fetus and mother.

It is unknown if the device affects breast milk. You should discuss this issue with your doctor.

What if I experience one or more of the following symptoms after the procedure: pain, numbness, sudden weakness, dizziness, or rapid heartbeat?

If you experience any of the symptoms listed above, seek medical help immediately. An echocardiogram (ultrasound of the heart) should be performed.

What risks are associated with the AMPLATZER Septal Occluder and AMPLATZER Multi-Fenestrated Septal Occluder - “Cribiform”?

There are certain potential risks associated with catheter-based procedures as well as additional risks that may be associated with the device. Your doctor is the best source of information about the risks of having an implanted device. Be sure to talk about all your questions and concerns.

Potential risks include but are not limited to the events outlined in the following tables.

Adverse Events associated with the AMPLATZER Septal Occluder	
<ul style="list-style-type: none">■ Air embolus (an air bubble that blocks blood flow in a vessel)■ Allergic dye reaction■ Anesthesia reaction■ Apnea (temporary absence of breathing)	<ul style="list-style-type: none">■ Arrhythmia (loss of regular heart rhythm)■ Arteriovenous fistulae (abnormal connection between an artery and a vein)■ Bleeding
Continued	

Continued

- Brachial plexus injury (injury to the nerves in the arm or lower neck)
- Cardiac perforation (piercing of the heart)
- Cardiac tamponade (compression of the heart that occurs when blood or fluid builds up in the space between the heart muscle and the outer covering sac of the heart)
- Death
- Device embolization/migration (dislodging of the device)
- Dissection (separation of the layers of the heart tissue)
- Erosion
- Fever
- Foreign material embolic event (when a mass, such as an air bubble or blood clot, gets stuck in a small blood vessel and blocks or decreased blood flow)
- Headache/Migraines
- Heart block (an interruption in the normal rhythm of the heart beat)
- Hematoma/Pseudoaneurysm (collection of blood outside of a vessel) including blood loss requiring transfusion
- Hemolysis (breakdown of red blood cells)
- Hyper/Hypotension (abnormally high/low blood pressure)
- Infection including endocarditis (redness and swelling of the lining of the heart and its valves)
- Myocardial infarction (heart attack)
- Perforation (piercing of a vessel or the heart)
- Pericardial effusion (excess fluid that may cause pressure on the heart)
- Peripheral embolism (when a small clot or piece of debris passes through the peripheral system causing decreased or blocked blood flow in an artery or vein)
- Peripheral pulse loss (loss of pulse in extremities)
- Phrenic nerve injury
- Pleural effusion (excess fluid between the layers of tissue that line the lungs and chest cavity)
- Residual shunt (blood flow through the defect due to incomplete closure)
- Stroke/Transient ischemic attack (temporary lack of oxygen to the brain)
- Thromboembolic event (when a blood clot breaks loose and plugs a vessel)
- Thrombus formation/embolization (blood clot formation and breaking loose)
- Tissue trauma or damage
- Valve damage
- Valvular insufficiency
- Vascular access site complications
- Vessel trauma or damage
- Valvular regurgitation (abnormal backward flow of blood through a valve)

Adverse Events associated with the AMPLATZER Multi-Fenestrated Septal Occluder - “Cribiform”

- Air embolus (an air bubble that blocks blood flow in a vessel)
- Allergic dye reaction
- Anesthesia reaction
- Apnea (temporary absence of breathing)
- Arrhythmia (loss of regular heart rhythm)
- Brachial plexus injury (injury to the nerves in the arm or lower neck)
- Cardiac perforation (piercing of the heart)
- Death
- Device collapse due to structural failure
- Device embolization/migration (dislodging of the device)
- Device removal (due to embolization or misplacement)
- Erosion
- Fever
- Headache/Migraines
- Hematoma/Pseudoaneurysm (collection of blood outside of a vessel) including blood loss requiring transfusion
- Hyper/Hypotension (abnormally high/low blood pressure)
- Infection including endocarditis (redness and swelling of the lining of the heart and its valves)
- Infectious endocarditis
- Perforation (piercing of a vessel or the heart)
- Pericardial effusion (excess fluid that may cause pressure on the heart)
- Phrenic nerve injury
- Stroke/Transient ischemic attack (temporary lack of oxygen to the brain)
- Thrombus (blood clot) formation on the device surface with the risk of breaking loose
- Valvular regurgitation (abnormal backward flow of blood through a valve)
- Vascular access site complications



You should also be aware that:

- Patients allergic to nickel may have an allergic reaction to this device.
- Tissue erosion, while rare, has led to cardiac tamponade and death. Tissue erosion/perforation refers to the erosion or abrasion of the tissue of the atrium primarily in the area of the roof of the atrium near the aorta.
- Some patients have developed a very serious or life-threatening condition caused by the device rubbing against the wall of the heart and creating a hole. This may cause blood to build up in the sac that surrounds the heart. If too much blood builds up in this sac the heart will not be able to work properly. Symptoms of this may be shortness of breath and/or chest pain. If you have any of these symptoms, immediately call your doctor or go to the emergency room for an echocardiogram (ultrasound of the heart). Your doctor will be able to tell if you have this complication by doing this examination.

My follow-up questions:

For additional information, please contact your doctor.

References:

1. Moake L, Ramaciotti C. Atrial Septal Defect Treatment Options. *AACN Clin Issues*. 2005;16(2):252-266.
2. Hoffman JJ, Kaplan S, Liberthson RR. Prevalence of congenital heart disease. *Am Heart J*. 2004;147:425-439.
3. Balzer D. Transcatheter closure of intracardiac shunts. *Cardiac Science*. 2004;6:717-722.
4. McMahon CJ, Feltes TF, Fraley JK, et al. Natural history of growth of secundum atrial septal defects and implications for transcatheter closure. *Heart*. 2002;87:256-259.
5. Omeish A, Hijazi AM. Transcatheter Closure of Atrial Septal Defects in Children & Adults Using the Amplatzer Septal Occluder. *J Interv Cardiol*. 2001;14(1):37-44.

Global Headquarters

One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

Cardiovascular Division

177 East County Road B
St. Paul, Minnesota 55117
USA
+1 651 756 4470
+1 651 756 4466 Fax

Amplatzer Products

5050 Nathan Lane North
Plymouth, Minnesota 55442
USA
+1 763 513 9227
+1 763 513 9226 Fax

SJMhealth.com



ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

Rx Only

Federal (USA) law restricts this device to sale and use by or on the order of a physician.

Indications: The AMPLATZER Septal Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who now require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (ie, 1.5: degree of left-to-right shunt or RV enlargement). The AMPLATZER Multi-Fenestrated Septal Occluder - "Cribiform" is a percutaneous, transcatheter, atrial septal defect closure device intended for the closure of multi-fenestrated (cribriform) atrial septal defects (ASD). Patients indicated for ASD closure have echocardiographic evidence of fenestrated ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (ie, 1.5: degree of left-to-right shunt or RV enlargement).

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Products referenced are approved for CE Mark.

AMPLATZER, ST. JUDE MEDICAL, and the nine-squares symbol are trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical. All rights reserved.

MM00310 (03.3) EN Global 11/11