

AMPLATZER™ Septal Occluder

AMPLATZER™ Multi-Fenestrated Septal Occluder - “Cribriform”

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). It is not intended to provide medical care or treatment recommendations. You should talk with a doctor about the diagnosis or treatment of your medical condition.

Atrial Septal Defect Overview

An atrial septal defect (ASD) is an abnormal opening (hole) in the wall between the two upper chambers (atria) of the heart. This opening allows abnormal flow of blood between the atria chambers and usually results in too much blood flow to the lungs.

- ASDs are one of the most common congenital heart defects seen in pediatric cardiology and often occur in conjunction with other cardiac defects.¹⁻³
- In older patients with ASDs, stroke is also more common.
- 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 are located in the center of the atrial septum. About 80% of ASDs are in the ostium secundum.¹
 - Non-surgical closure (using a transcatheter device) of ASDs only benefits patients with centrally located ostium secundum ASDs.^{1,4}
- If left untreated, the ASD may be debilitating and could be fatal.^{1,3}

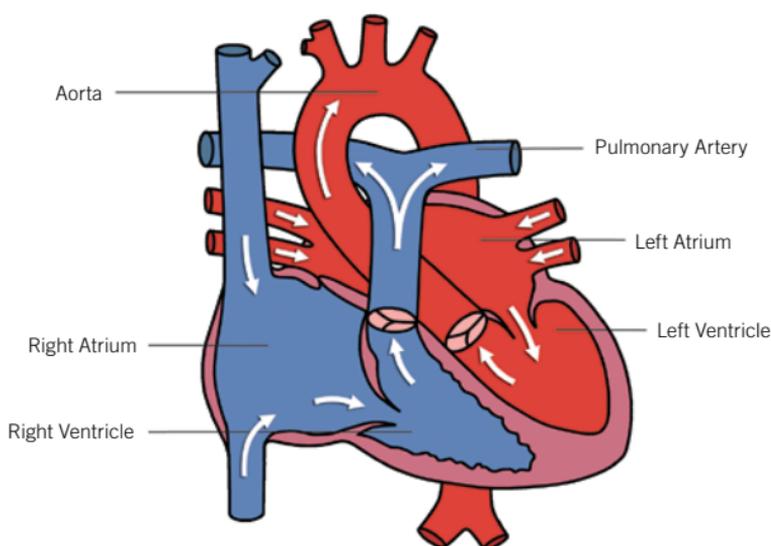


Figure 1
Diagram of a healthy heart

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” within the heart itself. Typically, oxygen-poor blood flows from the body into the heart through the right atrium and then flows into the right ventricle. When the heart pumps, the blood in the right ventricle is pumped out through the pulmonary artery to the lungs where it is filtered and receives 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 out through the aorta into the body to provide oxygen to all of the organs and cells. As it circulates through the body, it becomes oxygen-poor and returns to the heart and the cycle begins again.

An ASD is an abnormal opening (a hole) in the tissue wall between the atria. Typically, there is lower resistance to flow on the right side of the heart, which causes the oxygen-rich blood from the left atrium to flow through the opening and into the

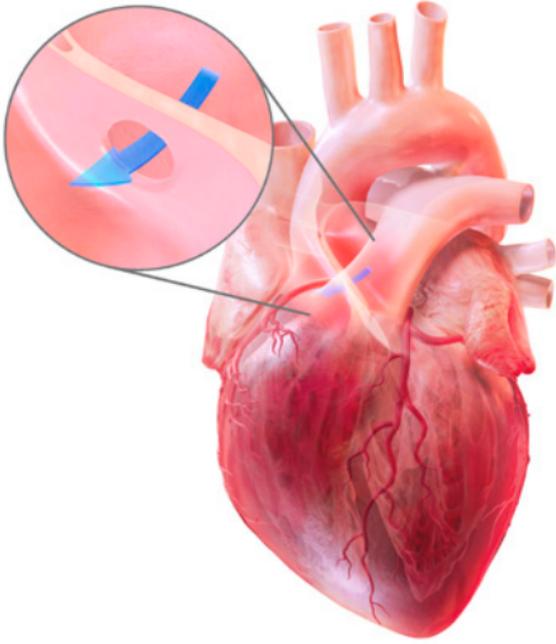


Figure 2
Heart with atrial septal defect

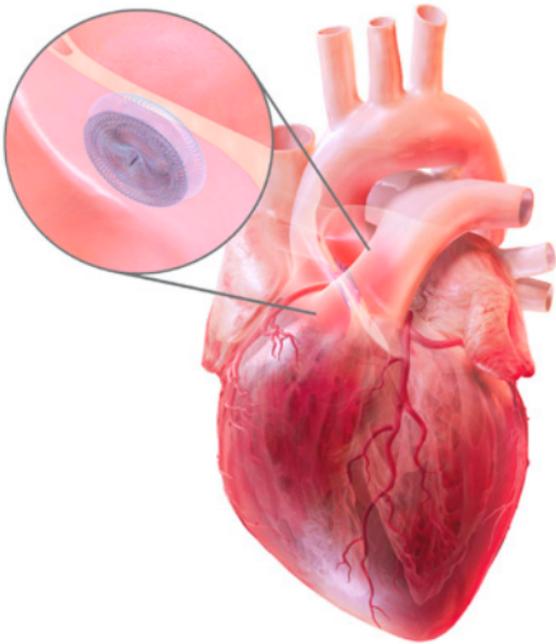


Figure 3
AMPLATZER Septal Occluder implanted during a catheter-based procedure

right atrium. This results in too much blood flow to the lungs and can cause heart failure (Figure 2).

What are the symptoms of an ASD?

Severity of symptoms often depends on the size of the hole. Large ASDs may cause fatigue, shortness of breath, 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 your options with your doctor; however, there are a few standard approaches that you may want to consider. The first option is medication that may be used in treating symptoms associated with the ASD. Other treatment options include open-heart surgery and catheter-based procedures to close the opening (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 and sometimes debilitating symptoms and early death if left untreated. With proper care, however, it can generally be managed with either surgery or catheter-based closure. There are different advantages and complications for each approach, and you should discuss these with your doctors.

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).

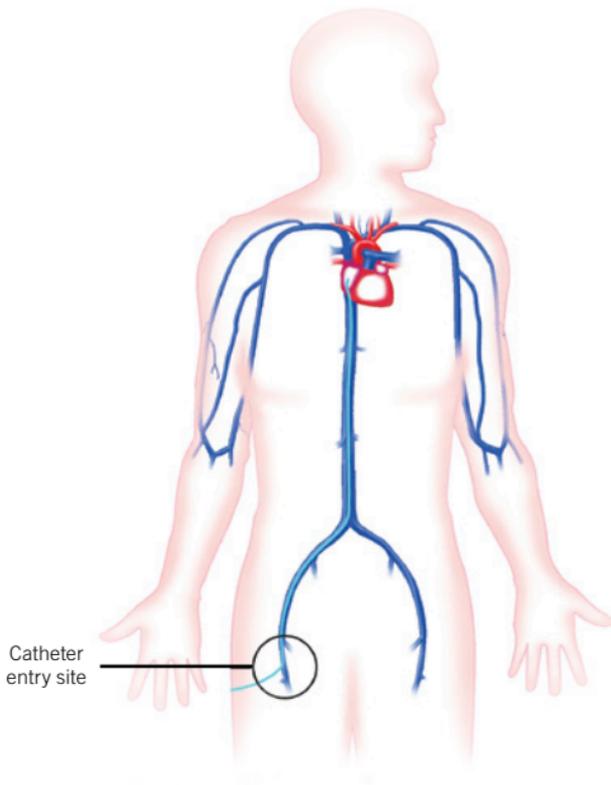


Figure 4
Catheter pathway in a transcatheter ASD closure procedure

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 successfully placed in the defect, the doctor will carefully study its position using cardiac imaging systems. Once the physician is 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.

The procedure itself lasts about one to two hours and takes 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.



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

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 may prescribe drugs that you should take at home to continue your treatment and recovery. The decision to prescribe these is up to 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 and concerns you have with your doctor.

What exactly are 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 a device 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 remains 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 (i.e., blood thinning medications).
- 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 there is any reason you cannot undergo the procedure.
- If the device would interfere with or come in contact 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 patient with an implanted medical device 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. If an MRI is needed, simply tell the MRI staff about your implant and show them your patient ID card.

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 doctor 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: chest pain, numbness, sudden weakness, dizziness, fainting, shortness of breath or rapid heartbeat?

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

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

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 those listed 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)▪ Arrhythmia (loss of regular heart rhythm)▪ Arteriovenous fistulae (abnormal connection between an artery and a vein)▪ Bleeding▪ Brachial plexus injury (injury to the nerves in the arm or lower neck)▪ Cardiac perforation (piercing of the heart)	<ul style="list-style-type: none">▪ 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)▪ 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 decreases blood flow)▪ Headache/Migraines

Continued

Continued

- 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 erosion (abrasion of the device through the heart tissue)
- 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)

Continued



Continued

- Device removal (due to embolization or misplacement)
- 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 (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
- Tissue erosion (abrasion of the device through the heart tissue)
- Valvular regurgitation (abnormal backward flow of blood through a valve)
- Vascular access site complications

You should also be aware that:

- People who are allergic to nickel may have an allergic reaction to this device.
- Some patients have experienced tissue erosion, 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

References

1. Moake L, Ramaciotti C. Atrial Septal Defect Treatment Options. *AACN Clin Issues*. 2005;16(2):252-66.
2. McMahon CJ, Feltes TF, Fraley JK, et al. Natural history of growth of secundum atrial septal defects and implications for transcatheter closure. *Heart*. 2002;87:256-9.
3. 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.
4. Balzer D. Transcatheter closure of intracardiac shunts. *Cardiac Science*. 2004;6:717-22.
5. Crawford GB, Brindis RG, Krucoff MW, et al. Percutaneous atrial Septal Occluder devices and cardiac erosion: A review of the literature. *Cathet Cardiovasc Intervent*. 2012(80)2:157-67.

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

US Division

6300 Bee Cave Road
Building Two, Suite 100
Austin, Texas 78746
USA
+1 512 286 4000
+1 512 732 2418 Fax

SJM Coordination Center BVBA

The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium
+32 2 774 68 11
+32 2 772 83 84 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 (such as, 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. ©2012 St. Jude Medical. All rights reserved.

MM00310 (05.2) EN Global 01/13 IPN 1924-12

