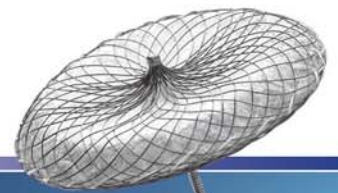


AMPLATZER® Septal Occluder

A Patient's Guide to the Non-Surgical Closure of
the Atrial Septal Defect Using the AMPLATZER
Septal Occluder System



AGA Medical Corporation
5050 Nathan Lane North
Plymouth, MN 55442 U.S.A.

(888) 546-4407 **Toll Free**
(763) 513-9227 **Phone**
(763) 647-5923 **Fax**
www.aboutheartdefects.com **Patient Website**
www.amplatzer.com **Corporate Website**

Not in any way connected with medical gas or
equipment sold under the "AGA" brand by AGA
AB or its successors.

MM00310 (02) Global 04/08



English Version

This brochure is intended to provide you with general information to discuss with your doctor. It is not intended to provide medical care or treatment. You should consult with your doctor regarding the diagnosis or treatment of your medical condition.

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



Table of Contents

Introduction (Atrial Septal Defect, Fenestrated Fontan) . . .	3
Purpose of the Device (Indications for Use)	5
Description of the Device	5
When the Device Should Not Be Used (Contraindications)	6
Alternatives to the Device and Treatment	7
Potential Risks and Benefits	7
What Should Be Expected During and After the Procedure	9
Frequently Asked Questions	12
Glossary of Terms	14
Questions for your Doctor	16

List of Figures

Figure 1: Diagram of a Normal Heart	3
Figure 2: Heart with an Atrial Septal Defect	4
Figure 3: Fenestrated Fontan	5
Figure 4: AMPLATZER® Septal Occluder	6
Figure 5: Vein Access Sites	10
Figure 6: Diagram of a Heart with the Device in Place . . .	11

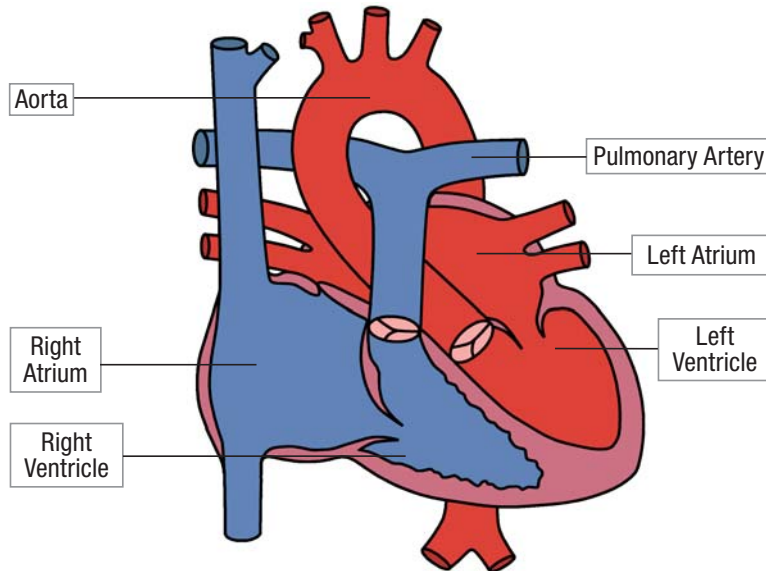


Figure 1
Diagram of a Normal Heart

Introduction

You have been diagnosed with an Atrial Septal Defect (**ASD**) or a Fenestrated Fontan (FF) which must be closed. The purpose of this brochure is to give you and your family a better understanding of your medical condition. Our main focus will be on what you can expect from this procedure, and what will be expected from you.

Atrial Septal Defect

Normally blood does not flow directly between the left and right chambers of the heart. An **ASD** is a hole between the upper left chamber (called the left **atrium**) and the upper right chamber (called the right **atrium**) of the heart. An ASD causes an abnormal increase in blood flow in the right side of the heart.

Because it is receiving so much extra blood, the right side of the heart does more than its normal share of work. This may cause you to feel tired, have a difficult time breathing, fail to grow normally, or be sick more often with respiratory infections such as colds or pneumonia. Larger ASDs can lead to heart failure and death.

Sometimes symptoms appear in newborns. Sometimes they do not appear until much later in life. Each case is different.

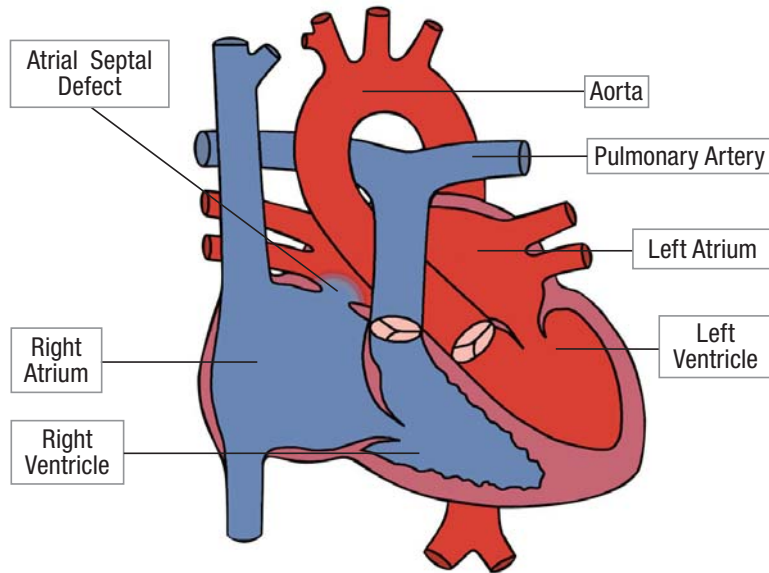


Figure 2
Heart with an Atrial Septal Defect

Fenestrated Fontan

Your blood must be cleaned by your lungs by getting oxygen. Some heart defects do not let enough blood to be pumped into your lungs to get the needed oxygen. If you have this type of defect, you may have a small patch of fabric with a hole in it placed in your heart. This patch is called a **Fenestrated Fontan**. Having this patch in your heart will allow blood flow into the lungs to get the needed oxygen - without being pumped by the right **ventricle**.

A **Fenestrated Fontan procedure** is an operation where this fabric patch with a small hole is placed in the heart to let blood flow easily to the lungs. This hole will need to be closed in most patients as they get older.

Your doctor has recommended that your ASD or FF be closed using an implantable AMPLATZER Septal Occluder device.

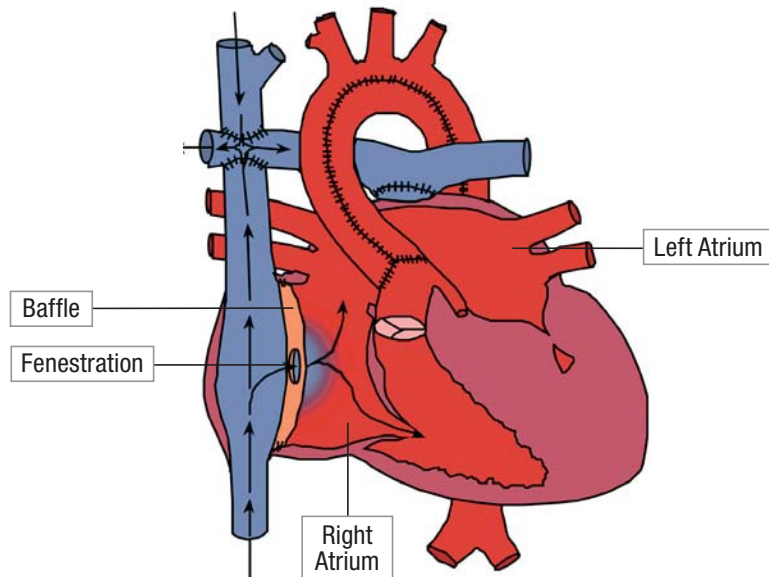


Figure 3
Fenestrated Fontan

Purpose of the Device (Indications for Use)

The AMPLATZER Septal Occluder is a **percutaneous, transcatheter, Atrial Septal Defect** closure device intended for the **occlusion** of Atrial Septal Defects (ASD) in the middle of the wall between the upper chambers of the heart. Patients indicated for ASD closure have **echocardiographic** evidence of an ASD and clinical evidence of an excess amount of blood being pumped into the **right ventricle (right ventricular (RV) volume overload)**. The device is also indicated in those patients who have undergone a **Fenestrated Fontan procedure** and who now require closure of the fenestration.

Description of the Device

The AMPLATZER Septal Occluder is wire mesh made out of nickel and titanium (Nitinol). The wire mesh is filled with polyester fabric to help close the defect. The polyester fabric is securely sewn into the device with a polyester thread. The AMPLATZER Septal Occluder has a specially designed delivery system that your doctor will use to attach, deliver and release the AMPLATZER Septal Occluder in your heart.

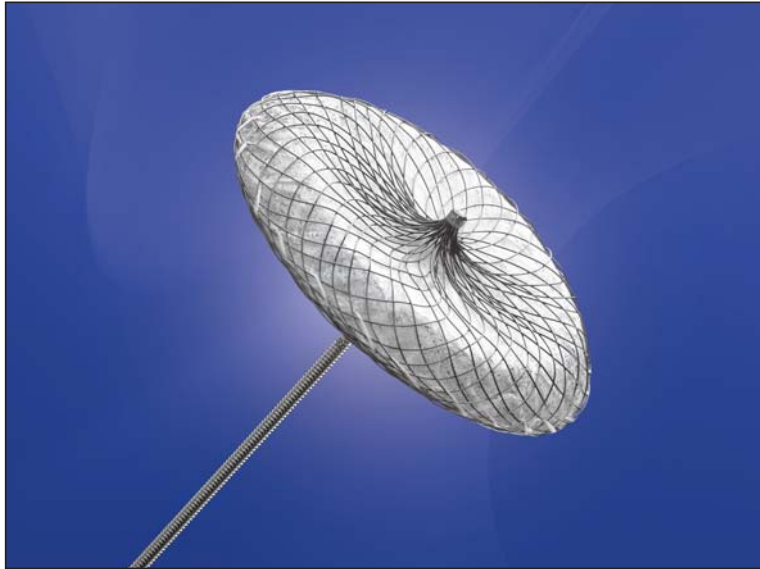


Figure 4
AMPLATZER® Septal Occluder

When the Device Should Not be Used (Contraindications)

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

- If you have blood clots in your heart.
- If you have a bleeding disorder, untreated ulcer or if you are unable to take aspirin. Your doctor may be able to prescribe another blood thinner, however sometimes that is not possible.
- If you, your heart or your veins are very small or if you cannot undergo the procedure, you may not be able 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 your heart does not have enough tissue to secure the device.

Alternatives to the Device and Treatment

- You may have open-heart surgery to close your ASD. During this surgery, the doctor will sew a patch (if the ASD is large) or use stitches (if the ASD is small) to close the defect.
- No treatment

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

What are the Potential Risks of the Device and Procedure?

There are risks with cardiac catheterization procedures as well as additional risks that may be associated with the device. Potential risks include, but are not limited to:

- Allergic dye reaction
- Anesthesia reactions
- Temporary absence of breathing (**Apnea**)
- Loss of regular heart rhythm (**Arrhythmia**)
- Bleeding around the area where the tube (**catheter**) is placed into your body through which the device will be inserted into your heart
- Injury to the nerves in the arm and lower neck (**Brachial plexus injury**)
- Bruising at the groin or arm
- Changes in blood pressure
- Death (related to device or procedure)
- Dislodgment of the device
- An air bubble or clot that blocks blood flow in a vessel (**Embolus**)

- Redness and swelling of the lining of the heart
(**Endocarditis**)
- Fever
- Headache/migraine
- A mass of blood from a broken blood vessel
(**Hematoma**)
- Too high or too low blood pressure
(**Hypertension; Hypotension**)
- Incomplete sealing of the defect
- Infection
- Injury to the artery, vein or nerves in the groin or neck
- Perforation of **esophagus** (from the **TEE** camera), vein or heart
- Stroke or **TIA**
- Blood clots (**Thrombus**)
- Abnormal backward flow of blood through a valve
(**Valvular Regurgitation**)
- X-ray exposure is increased

If the device were to be dislodged, you may need surgery for its removal. Your ASD would be repaired at the same time.

Some patients may be at a higher risk of complications. These include patients where the position of the ASD is near the top of the heart and there is minimal tissue surrounding the defect. In these circumstances, your physician should be careful to select the proper size device to prevent any damage to the top wall of the heart. If you have a higher risk of complications, you should be followed more closely by your physician after the procedure. See the section “What to Expect After the Procedure” for more information regarding post-procedure care for higher risk patients.

What are the Benefits of This Procedure?

The primary benefit of having a device is that surgery is avoided. This results in:

- Shorter hospital stay and recovery time
- No chest scar

What Should I Expect During and After the Procedure?

What to expect during and after the procedure will vary. Read this information carefully and discuss any questions or concerns you have with your doctor.

1. Your procedure will be performed in the heart catheterization laboratory, or “cath lab.” You will lie on an x-ray table, and an x-ray camera will move over your chest during the procedure. The staff will monitor your heart by attaching several small sticky patches to your chest.
2. Your doctor will give you an anesthetic. It may be general or local. This will depend on the technique the doctor uses to place the device. There should not be significant discomfort.
3. In order to see your heart, your doctor will use some form of imaging equipment (**echocardiography**). Ask your doctor which form he/she will use.
4. Your doctor will insert a **catheter** through a vein, and then navigate it through some of your body’s largest veins until it reaches your heart. The doctor will perform a procedure (**angiogram**) to visualize your heart and the ASD. Refer to Figure 5.
5. Your doctor will then measure the pressure and oxygen content in different chambers of your heart and measure the size of your ASD.

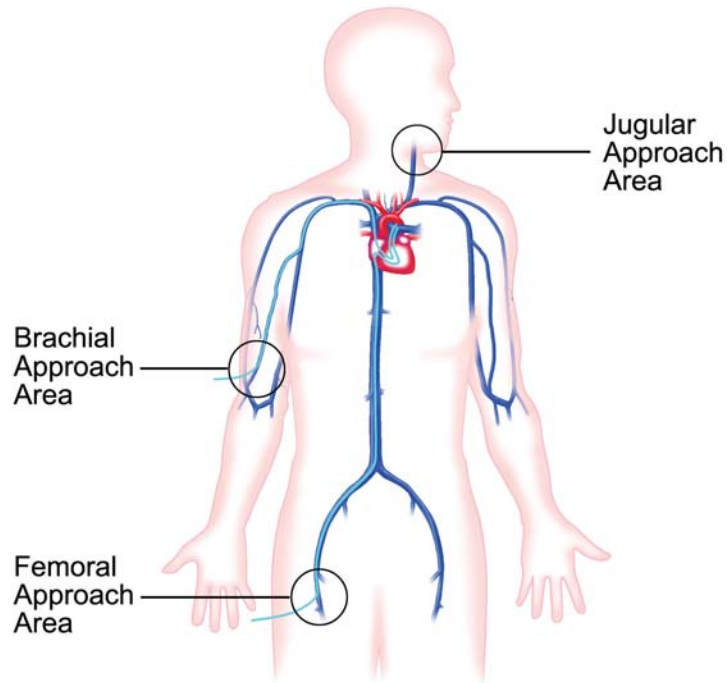


Figure 5
Vein Access Sites

6. The appropriate size device is screwed onto a cable, put into a special **catheter** and advanced through your ASD. Your doctor will then push the device out of the **catheter** until one of the device discs is on the left side of the hole and the other device disc is on the right side of the hole.
7. Your doctor carefully studies the device's position in your heart. When your doctor is satisfied with the device position, the device is released by unscrewing the cable that was used to slide it through the catheter. The AMPLATZER Septal Occluder is now implanted in your heart. Refer to Figure 6.
8. The **catheter** and **imaging probe** (if used) are removed and the procedure is completed. The procedure should take about one to two hours. The procedure is less invasive than open-heart surgery. Many patients have the procedure done in the morning and go home the following morning.

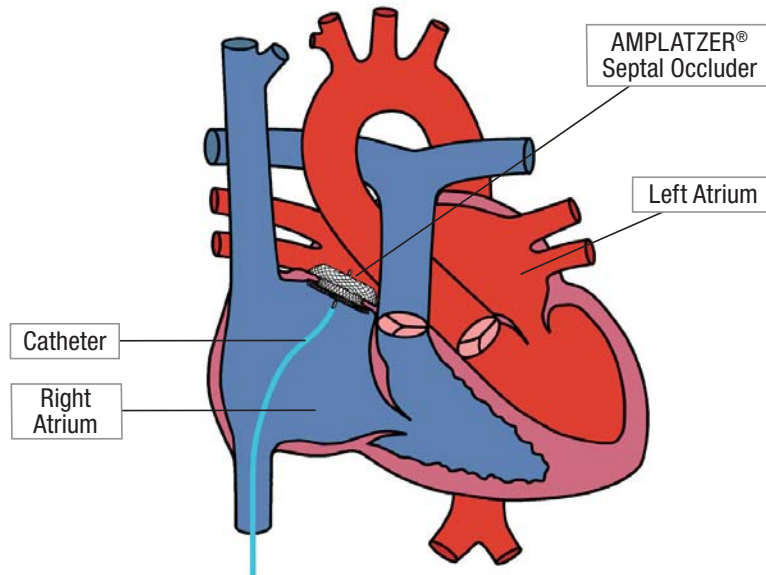


Figure 6
Diagram of a Heart with the Device in Place

What to Expect After the Procedure

After recovery from anesthesia and with adequate bed rest you should be able to sit up and walk about. If there are no complications, you can go home after staying overnight in the hospital. Before you leave the hospital, an **echocardiogram** will be performed to make sure the device is still positioned properly.

Because the procedure is less invasive than open-heart surgery, your recovery should be easier. You may have an adhesive bandage where the catheter was inserted. You also may have a minor sore throat if an **imaging probe** was used.

Before you leave the hospital, your doctor will give you guidelines for activities and medications. Your doctor should tell you when you can resume normal daily activities. Medications will be an important part of your treatment. Your doctor will prescribe drugs that you should take at home. The drugs should prevent blood clots from forming. Notify your doctor if your medications cause unpleasant reactions; but do not stop taking them unless instructed to do so. Your doctor may be able to prescribe new medications that better suit you.

You will be required to take aspirin every day for the next six months. Antibiotics will also be required for **endocarditis prophylaxis** for certain medical procedures. Ask your doctor which procedures require you to take **endocarditis prophylaxis**. The decision to continue taking aspirin and **endocarditis prophylaxis** beyond six months is at the discretion of your doctor.

You will have to return to your doctor for periodic follow-up visits over the next year. It is important to keep all appointments that are scheduled for you.

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 ultrasound of your heart (echocardiogram or “echo”). Your doctor will be able to tell if you have this complication by doing an echo examination of your heart.

Frequently Asked Questions

Will I have pain from the procedure?

You may experience some discomfort in the area where the **catheter** was inserted. You may also experience a sore throat from the **TEE imaging probe** (if used). These symptoms should go away within a few days to a week.

Will I be able to feel the device?

No, you will not be able to feel the device.

What happens with an AMPLATZER Septal Occlusion device once it gets implanted?

The device is designed to remain permanently implanted in your body. It will take a matter of time (usually 3-6 months) before the device will be completely covered by the normal heart lining tissue and becomes a permanent part of your heart.

What activities should be avoided after my procedure? When can they resume?

All strenuous activity should be avoided for one month after the procedure. Even though you may feel ready to resume your normal activity; you should take it easy for at least one month.

What happens if I need an MRI (Magnetic Resonance Imaging)?

Your AMPLATZER Septal Occluder device is MRI conditional in a 3 Tesla system. If an MRI is needed, the MRI staff should be informed about the presence of your implant. You will receive a patient identification card that you should always carry with you and show to medical personnel.

If I travel, can I go through metal detectors without setting off an alarm?

Your AMPLATZER Septal Occluder device should not set off metal detector alarms. Once again, your patient identification card should be shown to airport security if necessary.

Can I have this procedure if I am pregnant?

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

What if I am a nursing mother?

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

What if I have sudden shortness of breath or chest pain?

If you experience shortness of breath or chest pain, seek medical help immediately. An ultrasound (echo) of your heart should be done.

Glossary Of Terms

Angiogram – An x-ray of blood vessels or heart chambers filled with contrast media that allows your doctor to see moving pictures of your heart.

Apnea – Temporary absence of breathing.

Arrhythmia – Loss of regular heart rhythm.

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).

Brachial plexus injury – Injury to the nerves in the arm and lower neck that can result from positioning a patient on an x-ray table.

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.

Fenestrated Fontan procedure – An operation to treat complex difficult heart defects. A fabric patch with a small hole is placed in the heart to help increase blood flow as a part of the Fontan procedure.

Hematoma – A mass of blood which is a result of a break in a blood vessel.

Hypertension – High blood pressure.

Hypotension – Abnormally low blood pressure.

Imaging Probe – A flexible, tube-like medical instrument with a camera that shows a picture on a screen of what is inside the body.

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.

Percutaneous – Passed through the skin.

Right Ventricular (RV) Volume Overload – Excess amounts of blood being pumped into the right ventricle. This usually causes the right ventricle to enlarge.

Thrombus – Blood clot.

Transient Ischemic Attack (TIA) – A temporary lack of oxygen to the brain.

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

Transcatheter – Through a catheter.

Valvular Regurgitation – An abnormal backward flow of blood through a valve.

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

