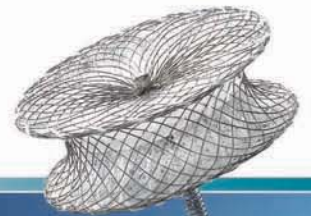


# AMPLATZER® Muscular VSD Occluder

A Patient's Guide to Transcatheter Closure of a  
Muscular Ventricular Septal Defect (VSD) Using the  
AMPLATZER® Muscular VSD Occluder System



leadership through innovation



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## 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.



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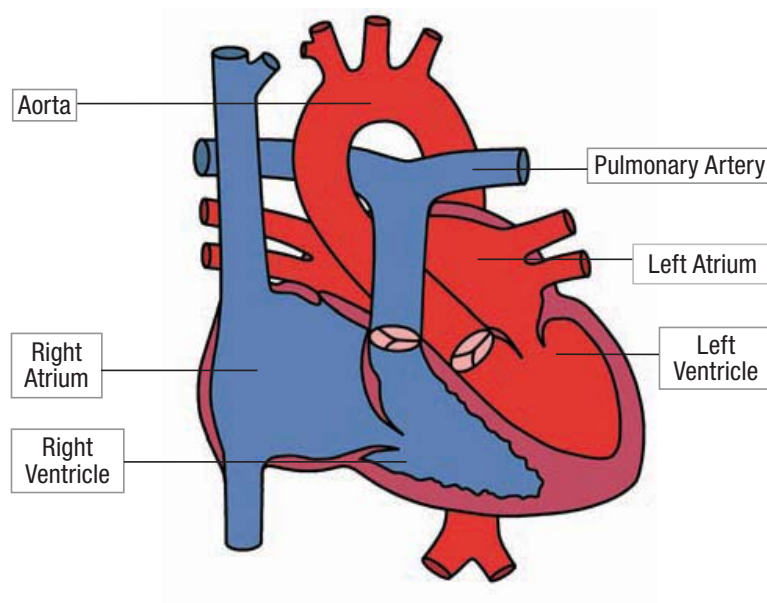
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# Introduction

You have been diagnosed with a **Muscular Ventricular Septal Defect (VSD)** which must be closed. The purpose of this brochure is to provide a better understanding of your medical condition and explain how non-surgical closure can be performed using the AMPLATZER® Muscular VSD Occluder.

## Normal Heart

Normally, the right side of the heart pumps blood low in oxygen to the lungs. The left side of the heart pumps oxygen-rich blood to the body. Refer to Figure 1.



**Figure 1**  
**Diagram of a Normal Heart**

**Blue** = Blood is pumped from the body to the **lungs**

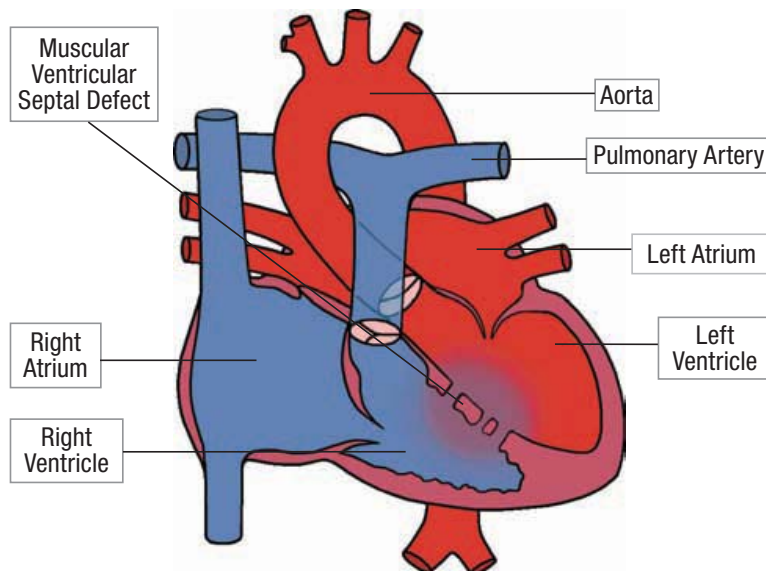
**Red** = Blood is pumped from the **lungs** to the body (oxygenated)

# Muscular Ventricular Septal Defect

A VSD is a **heart defect** that occurs when there is an opening (hole) between the heart's two lower chambers (the **ventricles**). Refer to Figure 2. If there is a hole in the wall of the heart between the ventricles, blood from the left side of the heart can pass through the unwanted hole into the right side of the heart. This causes the heart to work less efficiently because blood is going from the left ventricle to the right ventricle instead of going into the aorta as it should.

The position of the VSD in the partition between the ventricles varies from one patient to another. Sometimes there are multiple defects.

This condition can cause symptoms such as **cyanosis**, an enlarged heart and/or high blood pressure, leading to possible permanent damage to the blood vessel walls. Children born with these defects may suffer from poor growth, poor exercise tolerance, frequent respiratory infections such as colds and pneumonia, or **endocarditis**, strokes, fainting spells, heart failure or sudden death.



**Figure 2**  
**Heart with Muscular Ventricular Septal Defects (VSD)**

Your doctor has recommended that the VSD be closed using an implantable AMPLATZER Muscular VSD Occluder device.

## Purpose of the Device (Indications for Use)

The AMPLATZER Muscular VSD Occluder is for use in patients who have large Muscular Ventricular Septal Defects (VSD) that must be closed and who would experience high risks during a surgical procedure.

## Description of the Device

The AMPLATZER Muscular VSD 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 sewn into the device with polyester thread.



**Figure 3**  
**AMPLATZER® Muscular VSD Occluder**

The AMPLATZER Muscular VSD Occluder has a specially designed delivery system that your doctor will use to attach, deliver and release the AMPLATZER Muscular VSD Occluder in your heart.

## When the Device Should Not be Used (Contraindications)

Your doctor will have more information, but here are some circumstances when the AMPLATZER Muscular VSD Occluder should not be used:

- If you do not have a Muscular VSD or if your VSD is from a heart attack.
- If you weigh less than 5.2 kgs.
- If you have an infection anywhere in your body. You may receive the device only after the infection is gone.
- If you are unable to take aspirin (unless you can take other **anti-platelet agents** for 6 months).
- 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.

## Potential Risks and Benefits (What are the Risks?)

There are risks with **cardiac catheterization** procedures as well as additional risks that may be associated with the device.

Potential risks that could occur with the device and procedure include:

- An air bubble or clot that blocks blood flow in a vessel  
**(Air Embolus)**
- Allergic reaction to dye, drug or anesthesia
- Temporary absence of breathing **(Apnea)**
- Inflammation of the lining of the heart from infection  
**(Bacterial endocarditis)**
- Injury to the nerves in the arm and lower neck  
**(Brachial plexus injury)**
- Chest pain

- Headache/migraine
- Incorrect placement of the device  
**(Device malalignment)**
- Abnormally high blood pressure **(Hypertension)**
- Heart Attack **(Myocardial infarction)**
- Piercing of a vessel or the lining of the heart  
**(Perforation)**
- **Peripheral Embolism**
- Fluid around the lungs **(Pleural effusion)**
- Increased fluid inside the lung **(Pulmonary edema)**
- **Thrombus**
- Uncontrolled body spasms **(Seizure activity)**
- Invasive procedure **(Surgery)**
- Backwards flow of blood through a valve  
**(Valvular regurgitation)**
- An abnormal amount of blood in the veins  
**(Venous congestion)**
- Loss of vocal cord movement (Vocal cord paralysis)

### You should also be aware that:

- Patients allergic to nickel may suffer an allergic reaction to this device.
- If you are pregnant, you and your baby are at risk for increased x-ray exposure. Notify your doctor if you are (or believe you might be) pregnant.
- If the device were to be dislodged, you may need surgery for its removal. Your VSD would be repaired at the same time. Surgery following device placement may be more difficult.

- You will be exposed to radiation during the procedure. Patients in the clinical study were exposed to an average of 101 minutes of radiation. If you need to have additional procedures your radiation exposure may be longer. The long-term risks of prolonged radiation exposure are not known at this time.

Because the AMPLATZER Muscular VSD Occluder device is new, the long-term consequences of the implantation of the device are not known. There also may be other risks that are not known at this time.

The safety and effectiveness of the AMPLATZER Muscular VSD Occluder was evaluated in a clinical study of 41 patients. The adverse events in Table 1 were reported in the 38 patients enrolled in the clinical trial who received a device (some patients had more than one adverse event). A total of 43.6% (17/39) of patients experienced a major adverse event by 6 months following the procedure, and 46.2% (18/39) of patients experienced a major adverse event by 12 months following the procedure.

**Table 1**

Adverse Event	Number of Patients Experiencing Adverse Event
Death	2
Damage to the brain due to lack of blood flow ( <b>stroke</b> )	2
The heart stops pumping blood ( <b>cardiac arrest</b> )	1
The heart muscle is perforated ( <b>cardiac perforation</b> )	1
Any disturbance in the electrical activity of the heart i.e. bradycardia, tachycardia, heart block or atrial flutter ( <b>arrhythmia</b> )	10
Heart muscle disease that affects the heart's ability to pump blood ( <b>cardiomyopathy</b> )	1
Decreased amount of blood flow through an artery ( <b>arterial pulse loss</b> )	2
Decrease in red blood cells as a result of blood loss or blood cell destruction ( <b>anemia</b> ) which may be treated with a <b>blood transfusion</b> .	7
The device dislodges from the defect it was placed in ( <b>device embolization</b> )	1
A narrowing of the area below the aortic valve ( <b>subaortic stenosis</b> )	1
Device or Delivery System Failure	3
Problems with blood clotting ( <b>coagulation disorder</b> )	1
A bluish tint to the skin, lips, fingernails and other parts of the body due to lack of oxygen to the tissues ( <b>cyanosis</b> )	1
Partial collapse of the lung ( <b>atelectasis</b> )	1
Blood clot in a vein ( <b>venous thrombosis</b> )	1
Abnormally low blood pressure ( <b>hypotension</b> )	7
High pitched breathing sound ( <b>stridor</b> )	1
Swelling or mass of blood ( <b>hematoma</b> )	2
Abnormally high body temperature ( <b>fever</b> )	1
Vomiting or nausea ( <b>emesis</b> )	1
Extremity Swelling ( <b>edema</b> )	1

## What are the benefits of this procedure?

The primary benefit of having a device is that the defect can be closed without surgery. There was no surgery group in the clinical trial for comparison, but use of the device may result in:

- Shorter hospital stay and recovery time
- No chest scar

In the clinical study, at 6 months after the procedure, 95.2% (20/21) of patients evaluated by their physician had a successfully closed defect (meaning very little or no blood could pass through the defect with the device in place). At 12 months after the procedure, 100% (25/25) of patients evaluated by their physician had a successfully closed defect.

## Alternatives to the Device

### ■ **Surgical Closure of Muscular VSD**

A cloth patch is sewn over the VSD to close it completely through an incision in the chest (open heart surgery). Later this patch is covered by the normal heart lining tissue and becomes a permanent part of the heart. Some defects can be sewn closed without a patch. Surgical closure is considered “standard of care” and has been done for many years.

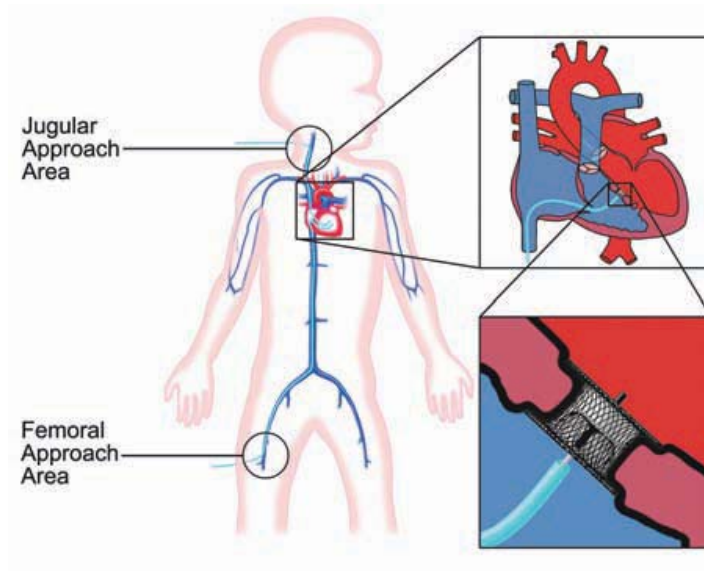
- Treatment with a different FDA Approved Device.
- No Treatment

## What Should be Expected 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.

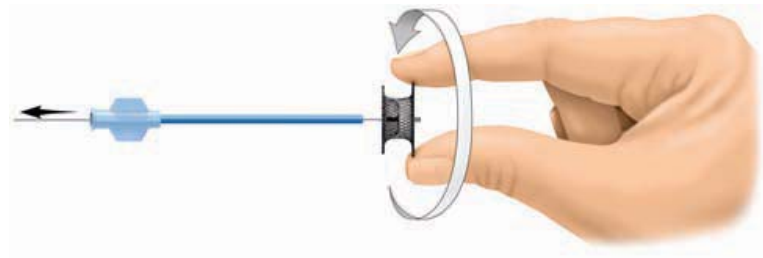
## What to Expect During the Procedure (Percutaneous Catheter Technique)

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 using an Electrocardiogram (ECG). During an ECG, electrical sensing devices, called electrodes or leads, are placed on the skin over the heart and at other sites on the chest and limbs. The Electrocardiogram is painless and there is no danger of electrical shock. The ECG helps to evaluate both the heart rates – the number of beats per minute – and the flow of electrical impulses through the heart muscle.
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. **Catheter** introduction into the groin is most common and requires a small incision to be made on the inside of your upper thigh. This incision will allow a guidewire to be inserted into your femoral vein or artery. Your doctor will then insert a **catheter** over the guidewire and advance it until it reaches your heart. Another option for **catheter** introduction is the neck (or jugular) approach. A small incision is made in your neck. Refer to Figure 4. The doctor will perform a procedure (**angiogram**) to visualize your heart and the VSD.



**Figure 4**  
**Access Sites**

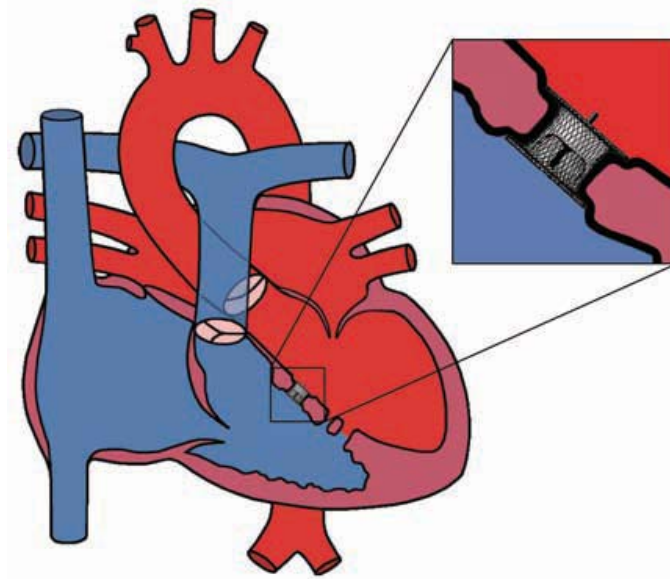
4. Your doctor will then measure the pressure and oxygen content in different chambers of your heart and measure the size of the Muscular VSD.
5. The appropriate size AMPLATZER Muscular VSD Occluder is screwed onto an AMPLATZER Delivery Cable (Figure 5).



**Figure 5**  
**AMPLATZER Delivery Cable**

6. The Muscular VSD Occluder and the cable is put into a special **delivery sheath** and advanced until it reaches the VSD.
7. Your doctor will then push the device out of the **delivery sheath** and implant the AMPLATZER Muscular VSD Occluder in the VSD.

8. Your doctor will carefully study 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 **delivery sheath**. The AMPLATZER Muscular VSD Occluder is now implanted in your heart (Figure 6).



**Figure 6**  
**Diagram Of The Heart With The Device In Place**

9. The **delivery sheath** is removed and the procedure is completed.

## What to Expect After the Procedure

After the procedure, you will be observed by the nursing staff. Your blood pressure will be checked frequently, and you may be attached to an ECG monitor so that your heart can be monitored continuously. While you are in bed, a nurse will check the site where the **catheter** was inserted as well as the pulses in your feet and arms.

If the femoral approach (groin area) was used for the procedure, you can expect to stay in bed for several hours. While the introducer sheath is in place, and for several hours after its removal, you will lie flat on your back in bed, keeping your leg with the sheath straight and still.

The procedure should take about 2-4 hours.

After recovery from anesthesia and bed rest, you should be able to sit up and walk about. You will be able to go home

that day or stay overnight in the hospital. Before you leave the hospital, a chest x-ray and/or **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 on the **catheter** insertion site (groin or neck).

Before you leave the hospital, your doctor will give you guidelines for activities and medications.

Antibiotics will be required for **endocarditis prophylaxis** for certain medical procedures. Ask your doctor which procedures require you to take antibiotics.

## Follow-up Visits with Your Doctor

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

## When Should a Doctor be Called?

If you experience any of the following symptoms, it is essential that you seek immediate medical attention:

- Pain, numbness, coldness or weakness in your legs or feet
- Any back, chest, abdominal, or groin pain
- Dizziness or fainting, rapid heartbeat, or sudden weakness

## Patient Identification Card

You will receive a wallet size Patient Identification Card. It is important to keep this card with you and show it to future health care practitioners to inform them that you have an AMPLATZER Muscular VSD Occluder. The Patient Identification Card also contains information to let health care practitioners know that it is safe for you to have an **MRI**.

# Frequently Asked Questions

## **Will I have pain from the procedure?**

You may experience some discomfort in the area where the **catheter** was inserted. 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 Muscular VSD 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 Muscular VSD 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 Muscular VSD 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.

## Glossary Of Terms

**Anemia** – A decrease in red blood cells as a result of blood loss or blood cell destruction.

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

**Anti-platelet agents** – Medication that helps prevent blood clots.

**Aortic Valve** – Heart valve between the left ventricle and the aorta. It has three flaps or cusps.

**Apnea** – Temporary absence of breathing.

**Arrhythmia** – Loss of regular heart rhythm.

**Arterial pulse loss** – Decreased amount of blood flow through an artery.

**Arteries** – Blood vessels that carry oxygen-rich blood away from the heart and to other tissues throughout the body.

**Atelectasis** – Partial collapse of the lung.

**Bacterial endocarditis** – Infection caused by bacteria that enters the bloodstream and settles in the heart lining (endocardium), a heart valve, or a blood vessel.

**Blood transfusion** – the process of transferring blood from one person to another

**Blood vessel** – The pathways through which blood travels in the body.

**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.

**Bradycardia** – A slow or unsteady heart beat.

**Cardiac arrest** – When the heart stops pumping blood.

**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 through a **catheter** from within the heart and its major **blood vessels**.

**Cardiomyopathy** – A disease of the heart muscle that affects the heart's ability to pump blood.

**Catheter** – A sterile, flexible, hollow tube designed for insertion into a vessel to permit injection or withdrawal of fluids or to pass devices through.

**Cyanosis** – A bluish tint to the skin, lips, fingernails and other parts of the body due to lack of oxygen to the tissues.

**Device embolization** – When the device dislodges from the defect that it was placed in.

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

**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.

**Emesis** – vomiting or nausea

**Endocarditis** – Redness, and swelling of the lining of the heart and its valves due to infection.

**Endocarditis Prophylaxis** – Medicine taken to prevent **endocarditis**.

**Fever** – abnormally high body temperature

**Heart block** – an interruption in the normal rhythm of the heart beat.

**Heart defect** – Imperfection or malformation of the heart.

**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.

**Lungs** – Pair of breathing organs located within the chest, which remove carbon dioxide from 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.

**Myocardial infarction** – Heart attack. Damage or death of myocardial (heart muscle) tissue caused by an interruption of blood flow to the area.

**Occlusion** – To occlude or block an opening.

**Percutaneous** – Passed through the skin.

**Perimembranous VSD** – Around, about or near the membranous septum

**Peripheral Embolism** – When a small clot or piece of debris passes through the peripheral system creating decreased or blocked blood flow in an artery or vein.

**Pulmonary Artery** – The artery connected to the heart's right ventricle that carries oxygen-depleted blood to the **lungs**.

**Stridor** – high-pitched breathing sounds.

**Stroke** – damage to the brain due to lack of blood flow.

**Subaortic stenosis** – A narrowing of the area below the aortic valve.

**Tachycardia** – A fast heart beat.

**Thrombus** – Blood clot.

**TIA (transient ischemic attack)** – A transient (or temporary) lack of oxygen to the brain.







