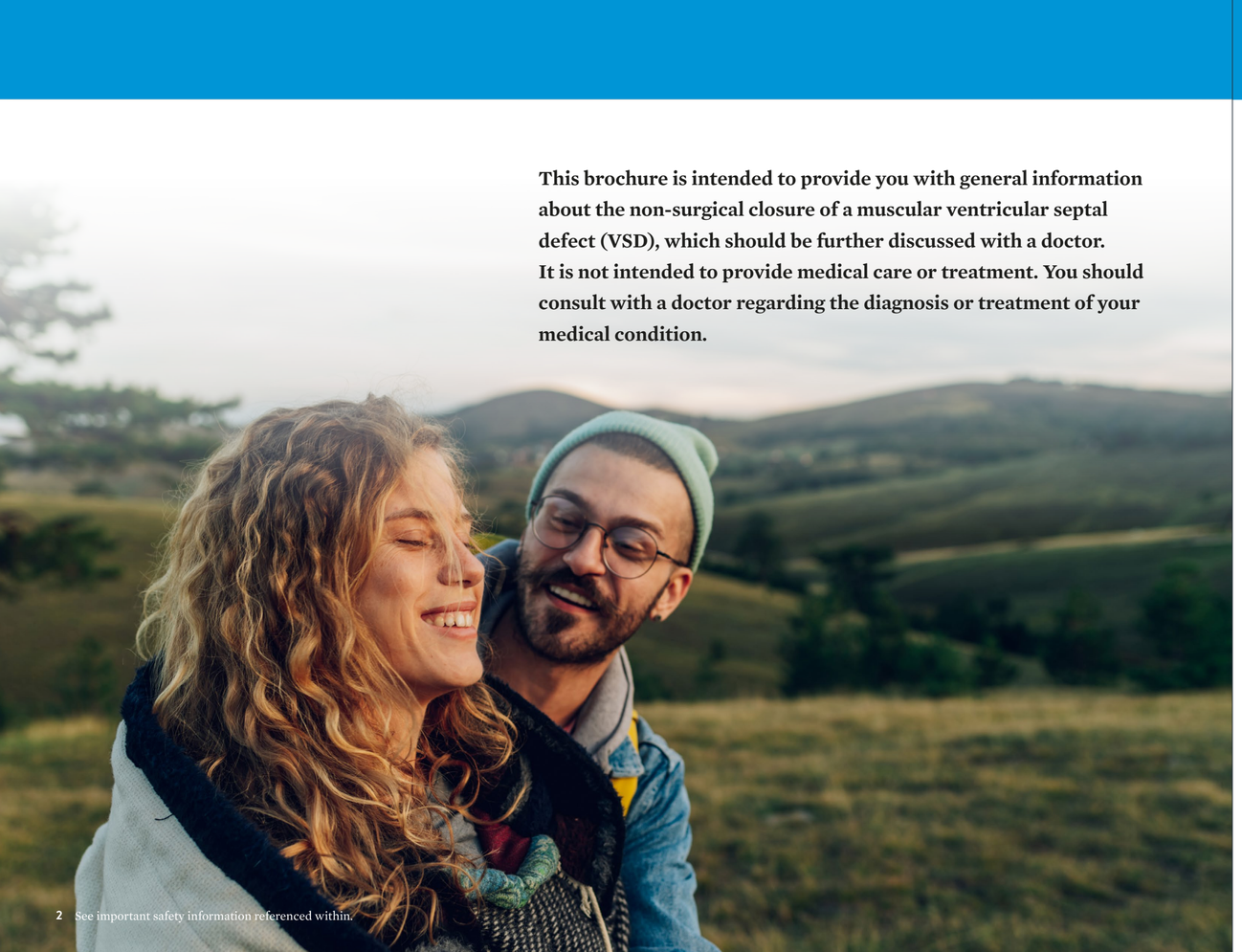
A PATIENT'S GUIDE TO THE

Non-surgical Closure of a Muscular Ventricular Septal Defect

Amplatzer™ Muscular VSD Occluder

Abbott

This brochure is intended to provide you with general information about the non-surgical closure of a muscular ventricular septal defect (VSD), 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.



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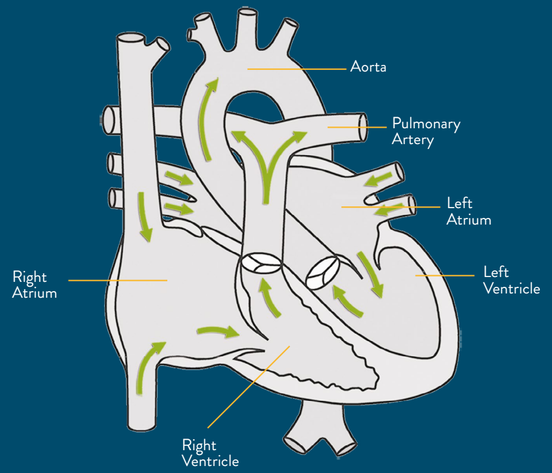
MUSCULAR VSD OVERVIEW

FIGURE 1
DIAGRAM OF A HEALTHY HEART



A ventricular septal defect (VSD) is an opening between the two lower chambers of the heart. This opening allows oxygen-rich blood to mix with oxygen-poor blood, creating extra work for the heart. A muscular VSD is one type of VSD and is located in the lower section of the ventricular septum.

- Congenital heart defects occur in about 7.5% of live births.[1] Of these, 20% are VSDs, making them one of the most common congenital cardiac malformations.[2]
- Muscular VSDs account for 10% of all VSDs.[3]

How does a muscular VSD affect blood flow?

To best understand how a muscular VSD 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 then fills the right ventricle. When the heart beats, 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 fills the left ventricle and is pumped through the aorta out to the body to provide oxygen to all the organs and cells.

HOW DOES A MUSCULAR VSD AFFECT BLOOD FLOW?

After it circulates throughout the body, it becomes oxygen-poor and returns to the heart.

A muscular VSD is an abnormal opening in the wall between the ventricles **(Figure 2)**. Because there is more pressure in the left ventricle, the oxygen-rich blood flows back into the right ventricle and mixes with oxygen-poor blood. This blood then re-circulates through the lungs and back to the heart causing the heart to overwork. Because some oxygen-rich blood flows through the VSD, less oxygen-rich blood is available to be pumped to the body.

What are the symptoms of a muscular VSD?

Severity of symptoms often depends on the size of the hole. While small muscular VSDs can sometimes cause no symptoms, medium to large muscular VSDs can allow more blood to pass through the hole, creating more work for the heart. The increased workload may cause fatigue, high blood pressure and/or an enlarged heart which can potentially cause permanent damage to the blood vessel walls. In babies, muscular VSDs can result in poor weight gain, poor exercise tolerance and possibly heart failure.[4]

How is a muscular VSD treated?

There are a number of treatment options for a muscular VSD, and there is no single option that is right for every patient. You should talk with your doctor to learn about the best treatment option for you or your child; however, there are a few standard approaches of which you should be aware.

One option is medication which may be appropriate to help in treating symptoms associated with the muscular VSD. Other treatment options include open-heart surgery and catheter-based procedures to close the hole in the heart **(Figure 3)**. Muscular VSDs have been known to close spontaneously or become insignificant in size during the first one or two years of life.[5] Therefore, your physician may recommend waiting a year or two to see if closure is necessary.

FIGURE 2
Heart with a muscular VSD

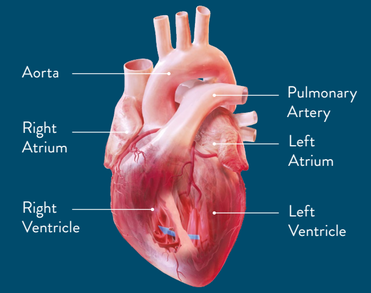


FIGURE 3
Amplatzer™ Muscular VSD Occluder implanted during a catheter-based procedure

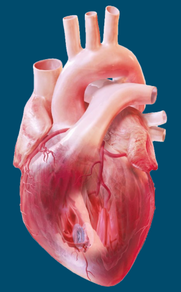
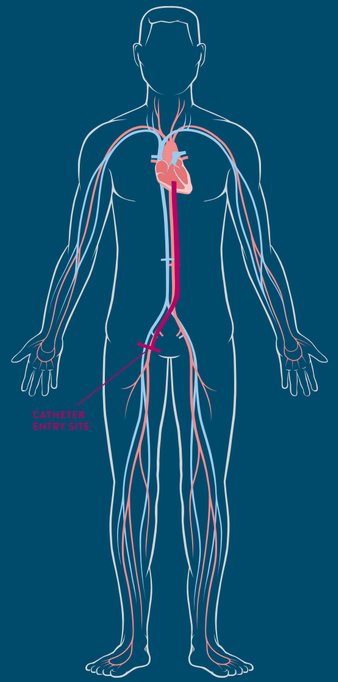


FIGURE 4

Catheter pathway in transcatheter muscular VSD 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 a muscular VSD, the doctor will then guide the device through the catheter or sheath to reach the muscular VSD. Once the device is placed in the hole, 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 hole. The catheter or sheath is removed and the procedure is completed.

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.

The Amplatzer™ Muscular VSD Occluder

An Amplatzer™ Muscular VSD Occluder is a device specifically designed to non-surgically close a muscular VSD **(Figure 5)**. The device is placed in the muscular VSD during a catheter-based procedure and will remain permanently implanted.

The Amplatzer Muscular VSD Occluder is made from braided nitinol wires. Nitinol is a metal with shape memory characteristics, meaning the device will return to its original "memorized" shape even after it is stretched to pass through a catheter. The shape of the device was specifically designed to stop blood flow through a muscular VSD.

Who should not receive the device?

If you have any of the following conditions you may not be a good candidate to receive the Amplatzer™ Muscular VSD Occluder.

- If your VSD is too close to your heart's valves
- If your VSD is a perimembranous VSD
- If your VSD resulted from a heart attack
- If you weigh less than 5.2 kg (11.4 lbs)
- 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 antiplatelet medication

FIGURE 5

Amplatzer™ Muscular VSD Occluder

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. Many doctors require follow-up appointments over the next year to ensure your recovery is going well. What to expect during and after the procedure will vary. Discuss all questions or concerns you have with your doctor.

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.

See important safety information referenced within.

CAN I TRAVEL WITH AN IMPLANTED DEVICE?

Will my device trigger airport security systems?

Your physician is your best resource for the answer to this question. Many patients find that with some extra planning and care they can enjoy traveling even with an implanted device. 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 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 the 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: 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™ Muscular VSD Occluder?

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:

- Air embolus (an air bubble that blocks blood flow in a vessel)
- Allergic drug reaction
- Allergic dye reaction
- Anemia (a decrease in or lesser than normal quantity of healthy red blood cells)
- Anesthesia reaction
- Apnea (temporary absence of breathing)
- Arrhythmia (loss of regular heart rhythm)
- Arterial pulse loss (decreased amount of blood flow through an artery)
- Atelectasis (collapse of part or all of the lung causing lack of gas exchange within alveoli)
- Bacterial endocarditis (infection that causes swelling of the lining of the heart and its valves)
- Blood loss requiring transfusion
- Brachial plexus injury (injury to the nerves in the arm or lower neck)
- Cardiac arrest (unexpected loss of heart function)
- Cardiomyopathy (deterioration of the function of the heart muscle)
- Chest pain
- Cyanosis (bluish discoloration of the skin due to lack of oxygen)
- Death
- Device embolization (dislodging of the device)
- Device fracture
- Fever
- Headache/Migraine
- Heart block (an interruption in the normal rhythm of the heart beat)
- Hypotension (abnormally low blood pressure)
- Myocardial infarction (heart attack)
- Perforation of vessel or myocardium (piercing of a vessel or 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)
- Stridor (high pitched wheezing)
- Stroke
- Subaortic stenosis (abnormal narrowing of the left ventricle below the aorta)
- Thrombus formation on device (blood clot)
- Vascular access site injury
- Venous thrombosis (condition resulting in blood clots forming in a vein)
- Vomiting

You should also be aware that

Patients allergic to nickel may suffer an allergic reaction to this device.
For additional information, please contact your doctor.

Available by prescription only

AMPLATZER™ MUSCULAR VSD OCCLUDER

What is the Amplatzer™ Muscular VSD Occluder approved for?

The Amplatzer™ Muscular VSD Occluder is a device that is placed in the heart during a minimally invasive, catheter-based procedure to close a muscular ventricular septal defect (VSD) in patients who are considered to be at high risk for traditional open-heart surgery.

Who should not receive the Amplatzer™ Muscular VSD Occluder?

Patients who weigh less than 5.2 kg or who have any of the following conditions should not receive the Amplatzer™ Muscular VSD Occluder: VSD that is too close to any of the heart valves; disease affecting the blood vessels within the lungs; VSD that occurs after a heart attack; blood infection; active bacterial infection; unable to take blood-thinning medication.

What are the possible complications associated with the Amplatzer™ Muscular VSD Occluder?

The Muscular VSD Occluder procedure carries risks which include, but are not limited to: air bubble that blocks blood flow in a vessel; allergic reaction to contrast dye, medication, or anesthesia; low number of red blood cells; temporary pause in breathing; loss of regular heart rhythm; absence of a pulse; partial or complete collapse of the lung; infection or inflammation in the heart; blood loss requiring transfusion; weakness, loss of sensation, or loss of movement in the upper arm; heart suddenly stops beating; disease of the heart muscle; chest pain; bluish color to the skin due to a lack of oxygen in the blood; death; obstruction of a blood vessel by all or part of an implanted device that entered the bloodstream; fracture of the device; fever; headache or migraine; disruption of the electrical signal that controls the heartbeat; low blood pressure; heart attack; perforation of a vessel or the heart; blood clot formation over the device or in the heart, leg, or lung; noisy or high-pitched sound with breathing; stroke; narrowing of the area just below the aorta; injury to the incision site; vomiting.

What are the precautions associated with the Amplatzer™ Muscular VSD Occluder?

Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Aspirin or an alternative blood-thinning medication is recommended to be started at least 24 hours before the procedure and to continue for at least 6 months after the procedure. Talk to your doctor to learn more about the risks associated with the Amplatzer™ Muscular VSD Occluder.

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3. Thanopoulos BD, Karanassios E, Tsaousis G, et al. Catheter Closure of Congenital/Acquired Muscular VSDs and Perimembranous VSDs Using the Amplatzer Devices. *J Interven Cardiol. 2003*;16:399-407.

4. Taylor MD. Ventricular Septal Defect, Muscular Clinical Presentation. *Medscape Reference*. http://emedicine.medscape.com/article/899873-clinical. Accessed May 2011.

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