A Patient's Guide to the

NON-SURGICAL CLOSURE OF A MUSCULAR VENTRICULAR SEPTAL DEFECT

Amplatzer™
Muscular VSD Occluder

See Important Safety Information referenced within.

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.

MUSCULAR VSD OVERVIEW

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

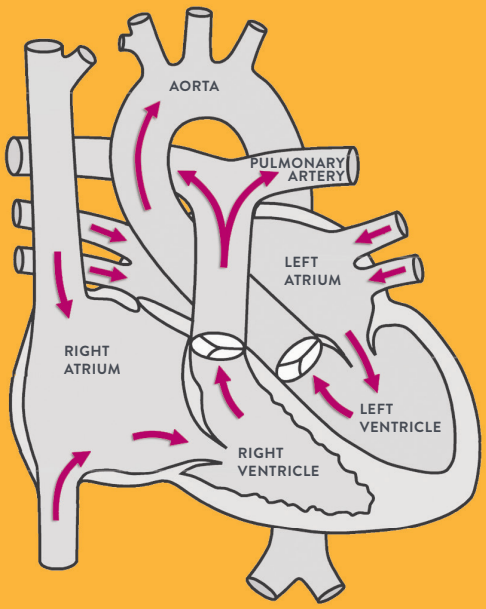

Figure 1
Diagram of a healthy heart

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

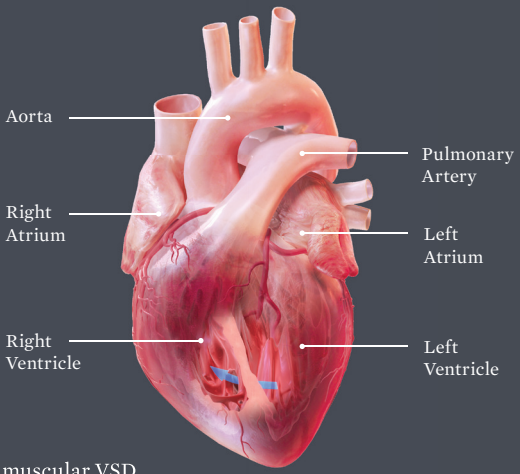

Figure 2
Heart with a muscular VSD

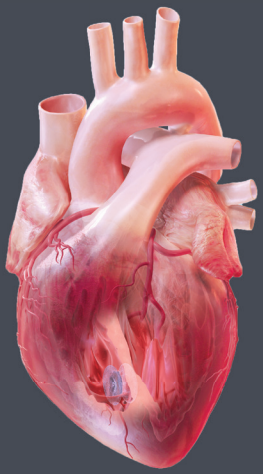

Figure 3
Amplatzer™ Muscular VSD Occluder implanted during a catheter-based procedure

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.

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. Keep in mind that a muscular VSD 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 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.

See Important Safety Information referenced within.

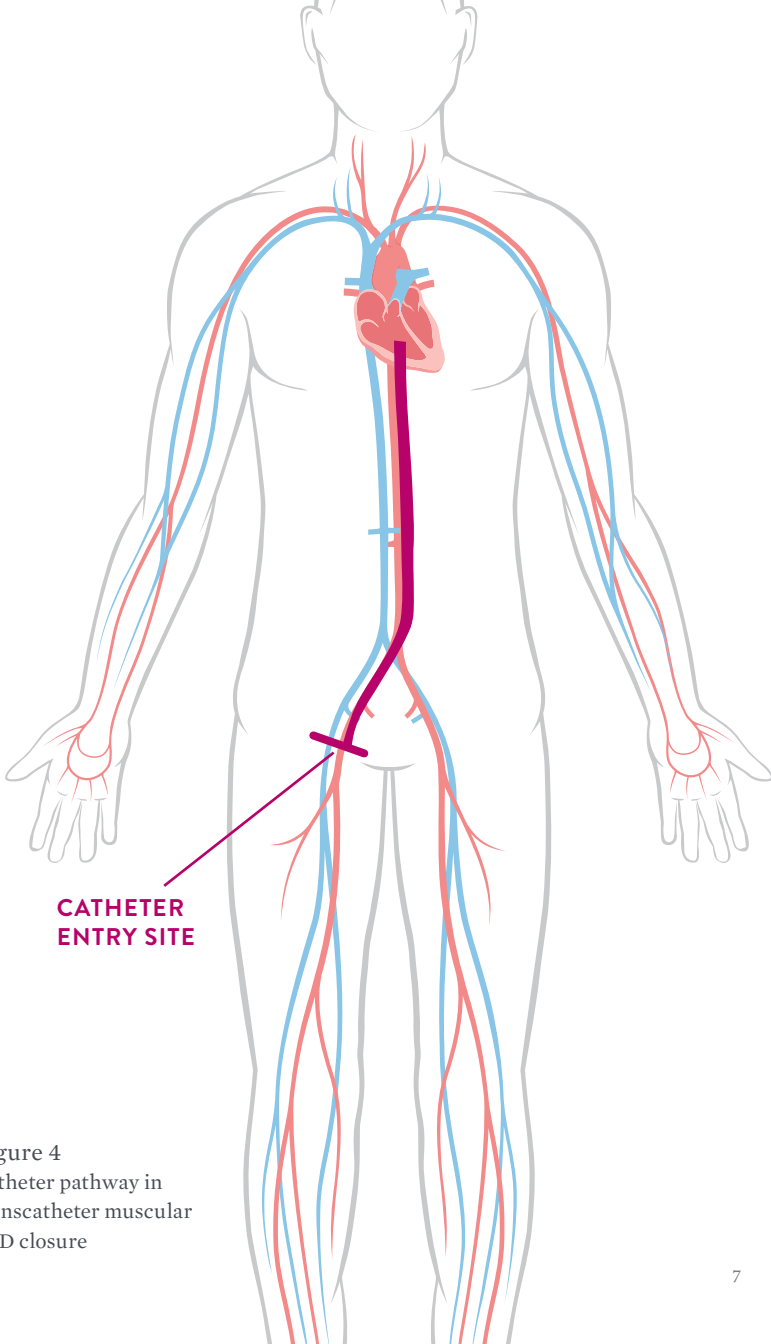

Figure 4
Catheter pathway in transcatheter muscular VSD closure

WHAT EXACTLY IS AN 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.

Figure 5
Amplatzer™
Muscular VSD Occluder

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

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.

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.**

ADDITIONAL NOTES AND QUESTIONS:

AMPLATZER™ Muscular VSD Occluder

Important Safety Information

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Indications and Usage

The AMPLATZER™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

High-risk anatomical factors for transatrial or transarterial surgical closure include patients:

- Requiring left ventriculotomy or an extensive right ventriculotomy.
- With a failed previous VSD closure.
- With multiple apical and/or anterior muscular VSDs (“Swiss cheese septum”).
- With posterior apical VSDs covered by trabeculae.

Contraindications

The AMPLATZER™ Muscular VSD Occluder is contraindicated for the following:

- Patients with defects less than 4 mm distance from the semilunar (aortic and pulmonary) and atrioventricular valves (mitral and tricuspid)
- Patients with severely increased pulmonary vascular resistance above 7 Wood units and a right-to-left shunt and documented irreversible pulmonary vascular disease
- Patients with perimembranous (close to the aortic valve) VSD
- Patients with post-infarction VSD
- Patients who weigh less than 5.2 kg. (Patients smaller than 5.2 kg were studied in the clinical trial, but due to poor outcome, these patients have been contraindicated for device placement. Data from these patients has not been included in the overall analysis.)
- Patients with sepsis (local/generalized)
- Patients with active bacterial infections
- Patients with contraindications to antiplatelet therapy or agents

Warnings

- The AMPLATZER™ Muscular VSD Occluder and delivery system should only be used by those physicians trained in transcatheter defect closure techniques.
- Physicians must be prepared to deal with urgent situations, such as device embolization, which require removal of the device. This includes the availability of an on-site surgeon.

- Embolized devices must be removed. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within a sheath.
- Use on or before the last day of the expiration month noted on the product packaging.
- The device is sterilized using ethylene oxide and is for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization, or patient harm.
- Do not use the device if the packaging sterile barrier is open or damaged.
- Do not release the AMPLATZER™ Muscular VSD Occluder from the delivery cable if the device does not conform to its original configuration or if the device position is unstable. Recapture the device and redeploy. If still unsatisfactory, recapture the device and replace with a new device.
- Device closure in patients who have suffered a previous thromboembolic stroke should be discussed with the patient or family. In addition, consultation with a neurologist and hematologist is suggested to determine if the benefit of device closure outweighs the risk.

Precautions

Handling

Store in a dry place.

Sizing

Accurate defect sizing is crucial and mandatory for AMPLATZER™ Muscular VSD Occluder device selection. The VSD should be assessed and sized at end diastole by transesophogeal echocardiography (TEE) or angiography to determine the appropriate device size. Device selection should be 2 mm larger than the defect size.

Procedural

- This device contains nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should be instructed to seek medical assistance immediately if they suspect they are experiencing an allergic reaction. Symptoms may include difficulty in breathing or swelling of the face or throat. While data is currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this device.

- This device should only be used by physicians who have been trained in transcatheter techniques and who should determine which patients are suitable candidates for procedures using this device.
- Aspirin (eg, 81 mg or 325 mg) or an alternative antiplatelet/ anticoagulant is recommended to be started at least 24 hours prior to the procedure. Cephalosporin therapy is optional.
- Maintain a recommended minimum active clotting time (ACT) of 200 seconds prior to device insertion and throughout the procedure.
- If TEE is used, the patient's esophogeal anatomy must be adequate for placement and manipulation of the TEE probe.
- Patients requiring multiple devices and/or concomitant catheterization procedures might require prolonged fluoroscopy times and multiple cineangiograms. The risks of radiation exposure (eg, increased cancer risk) should be discussed in detail with the patient or family and alternatives which do not involve radiation exposure should be reviewed.

Post-implant

- Patients should be treated with antiplatelet/anticoagulation therapy (such as aspirin) for 6 months post-implant. The decision to continue antiplatelet/ anticoagulation therapy beyond 6 months is at the discretion of the physician.
- Endocarditis prophylaxis should be followed according to the American Heart Association recommendations.
- Any patient who has a residual shunt should undergo an echocardiographic evaluation of the residual shunt every 6 months until complete closure of the defect has been confirmed.
- Patients should be instructed to avoid strenuous activity for 1 month. Strenuous activities such as contact sports prior to 1 month after implant may cause the device to dislodge and embolize.

Use in Specific Populations

- Pregnancy - Care should be taken to minimize the radiation exposure to the fetus and the mother.
- Nursing mothers - There has been no quantitative assessment of the presence of leachables from the device/ procedure in breast milk, and the risk to nursing mothers is unknown.

MR Conditional[1]

Through non-clinical testing, AMPLATZER™ devices have been shown to be MR Conditional. A patient with an implanted AMPLATZER™ device can be scanned safely immediately after placement of the device under the following conditions:

- Static magnetic field of 3 tesla or less
- Spatial gradient magnetic field of 720 G/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

During testing, the device produced a clinically non-significant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning in a 3-tesla MR system using a transmit/receive body coil.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Potential Adverse Events

Potential adverse events may occur during or after a procedure using this device may include, but are not limited to:

Air embolus; Allergic drug reaction; Allergic dye reaction; Anemia; Anesthesia reactions; Apnea; Arrhythmia; Arterial pulse loss; Atelectasis; Bacterial endocarditis; Blood loss requiring transfusion; Brachial plexus injury; Cardiac arrest; Cardiomyopathy; Chest pain; Cyanosis; Death; Device embolization; Device fracture; Fever; Headache/migraine; Heart block; Hypotension; Myocardial infarction; Perforation of the vessel or myocardium; Peripheral embolism; Stridor; Stroke; Subaortic stenosis; Thrombus formation on device; Vascular access site injury; Venous thrombosis; Vomiting

1. MR Conditional as defined in ASTM F 2503-05.

1. Hoffman JI, Kaplan S, Liberthson RR. Prevalence of congenital heart disease. *Am Heart J. 2004*;147:425-39.

2. Pedra CAD, Pedra SRF, et al. Transcatheter closure of perimembranous ventricular septal defects. *Expert Rev Cardiovasc Ther. 2004*;2(2):253-64.

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.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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