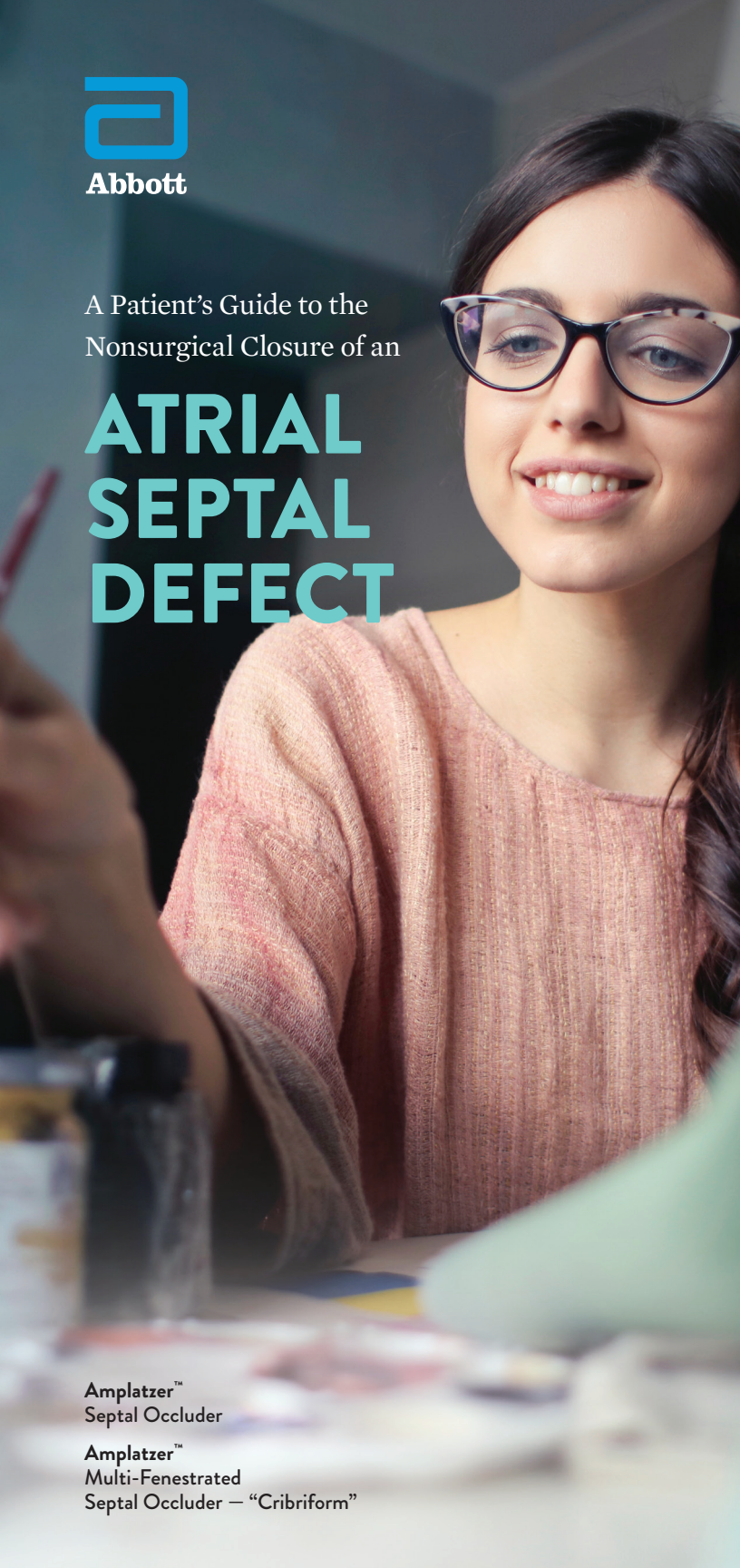

Abbott

A Patient's Guide to the Nonsurgical Closure of an

ATRIAL SEPTAL DEFECT

Amplatzer™
Septal Occluder

Amplatzer™
Multi-Fenestrated
Septal Occluder — "Cribriform"

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 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, 1.5:1 degree of left-to-right shunt or RV enlargement).

Indications for Use: The Amplatzer™ Cribriform Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the closure of multifenestrated (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 (such as, 1.5:1 degree of left-to-right shunt or right ventricular enlargement).

This brochure is intended to provide you with general information about the nonsurgical 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 is located in the center of the atrial septum. About 80% of ASDs are in the ostium secundum.[1]
  - Nonsurgical 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]

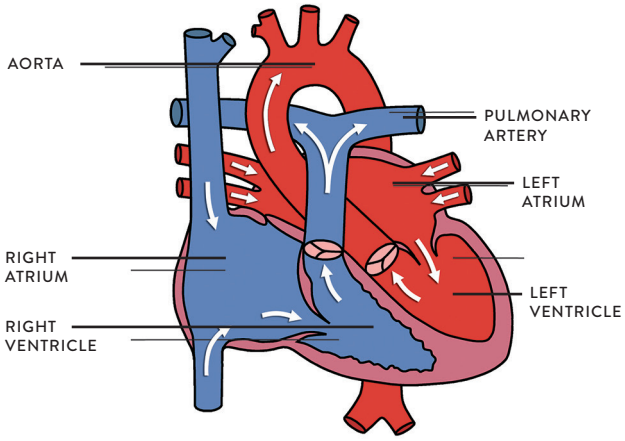

Figure 1: Diagram of a healthy heart

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

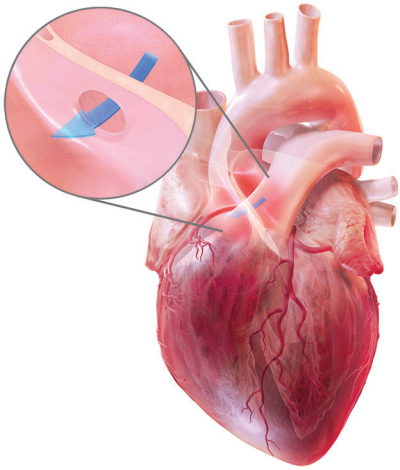

Figure 2: Heart with atrial septal defect

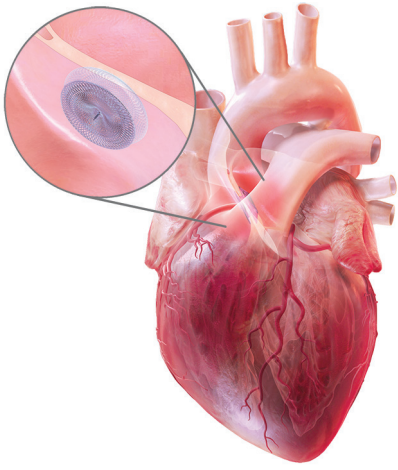

Figure 3: Amplatzer™ Septal Occluder implanted during a catheter-based procedure

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. Remember, an ASD can result in unpleasant symptoms and increased health risk. With proper care, however, it can generally be managed with medication or closure. There are different advantages and complications for each approach, and you should discuss these with your doctors.

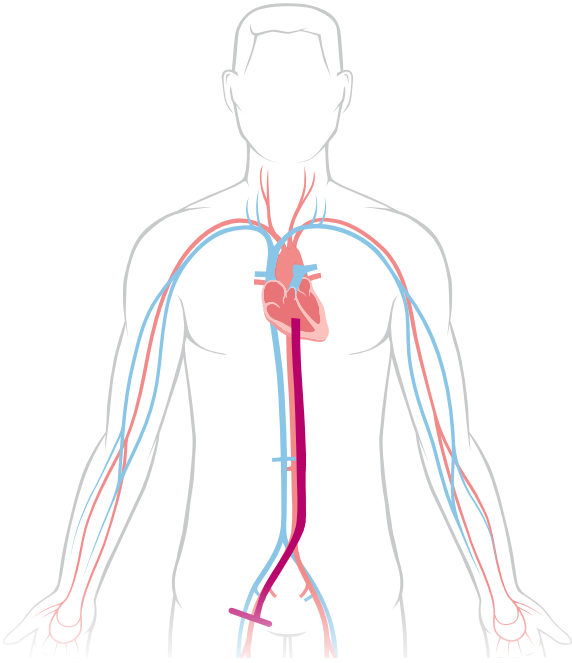

Figure 4: Catheter pathway in a transcatheter ASD closure procedure

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 an ASD, the doctor guides the device through the catheter or sheath and deploys it in the ASD to seal the hole. The device is successfully placed in the defect, and 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.

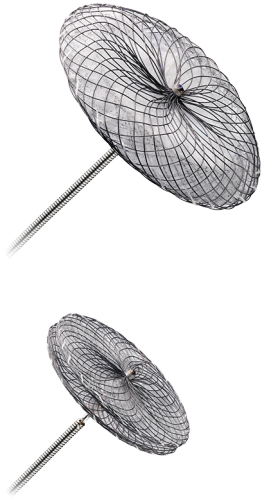

Figure 5: Amplatzer™ Septal Occluder (top) and Amplatzer™ Multi-Fenestrated Septal Occluder — "Cribriform" (bottom)

The procedure itself lasts about one to two hours and takes place in a heart catheterization laboratory, where many minimally invasive, nonsurgical procedures are performed. Your doctor may give you an anesthetic, and you should not feel any significant discomfort.

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 or 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

- 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)*
- 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

ADVERSE EVENTS ASSOCIATED WITH THE AMPLATZER™ SEPTAL OCCLUDER — CONTINUED

- 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
- 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 – "CRIBRIFORM"

- 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)*
- 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 to work properly. Symptoms of this may be shortness of breath and/or chest pain, fainting and irregular heartbeat. If you have any of these symptoms, immediately call your doctor or go to the emergency room for an echocardiogram (ultrasound of the heart). Your doctor will be able to tell if you have this complication by doing this examination.

As of May 2012, it is estimated that worldwide, erosion may occur in one to three of every 1,000 patients.[5] This means that the risk of you experiencing an erosion is estimated to be somewhere between 0.1% and 0.3%.[5] The majority, almost 90%, of erosions occur within one year of being implanted, but some erosions have happened several years after implant.[5]

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2. McMahon, C. J., Feltes, T. F., Fraley, J. K., Bricker, J. T., Grifka, R. G., Tortoriello, T. A.,...Bezold, L. I. (2002). Natural history of growth of secundum atrial septal defects and implications for transcatheter closure. *Heart, 87*(3), 256-259.
3. Omeish, A., & Hijazi, A. M. (2001). Transcatheter Closure of Atrial Septal Defects in Children & Adults Using the Amplatzer Septal Occluder. *Journal of Interventional Cardiology, 14*(1), 37-44.
4. Balzer, D. T. (2004). Transcatheter closure of intracardiac shunts. *Cardiac Science, 6*, 717-722.
5. Crawford, G. B., Brindis, R. G., Krucoff, M. W., Mansalis, B. P., & Carroll, J. D. (2012). Percutaneous atrial septal occluder devices and cardiac erosion: A review of the literature. *Catheter Cardiovascular Intervention, 80*(2), 157-167.

IMPORTANT SAFETY INFORMATION
AMPLATZER™ SEPTAL OCCLUDER

℞ ONLY

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 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, 1.5:1 degree of left-to-right shunt or RV enlargement).

CONTRAINDICATIONS

The Amplatzer™ Septal Occluder is contraindicated for the following:

- Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery.
- Any patient known to have sepsis within 1 month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement.
- Any patient known to have a bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy, unless another antiplatelet agent can be administered for 6 months.
- Any patient known to have a demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi).
- Any patient whose size (such as, too small for transesophageal echocardiography probe, catheter size) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization.
- Any patient where the margins of the defect are less than 5 mm to the coronary sinus, inferior vena cava rim, AV valves, or right upper lobe pulmonary vein.

WARNINGS

- 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 as they may disrupt critical cardiac functions. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within the sheath.
- Use on or before the expiration date noted on the product packaging.
- This 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™ Septal Occluder from the delivery cable if the device does not conform to its original configuration, or if the device position

is unstable or if the device interferes with any adjacent cardiac structure (such as Superior Vena Cava (SVC), Pulmonary Vein (PV), Mitral Valve (MV), Coronary Sinus (CS), aorta (AO)). Recapture the device and redeploy. If still unsatisfactory, recapture the device and either replace with a new device or refer the patient for alternative treatment.

- Implantation of this device may not supplant the need for Coumadin™ in patients with ASD and paradoxical emboli.
- The use of echocardiographic imaging (TTE, TEE, or ICE) is required.
- Balloon sizing should be used to size the atrial septal defect using a stop-flow technique. Do not inflate the balloon beyond the cessation ofthe shunt (such as, stop-flow). DO NOT OVERINFLATE.
- Patients with a retro-aortic rim of less than 5 mm in any echocardiographic plane, or patients in whom the device physically impinges on (i.e. indents or distorts) the aortic root, may be at increased risk of erosion.
- Do not select a device size greater than 1.5 times the echocardiographic-derived ASD diameter prior to balloon sizing.

PRECAUTIONS

- The use of this device has not been studied in patients with patent foramen ovale.
- Use standard interventional cardiac catheterization techniques to place this device.
- Placement of the Amplatzer™ Septal Occluder may impact future cardiac interventions, for example transeptal puncture and mitral valve repair.
- 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.
- **MR Conditional to 3.0 Tesla**
  Caution should be used if an MRI is performed with a magnetic field of >3.0 tesla.

  Through non-clinical testing, the Amplatzer™ device has been known to be MR Conditional at field strengths of 3.0 tesla or less with a maximum whole-body-averaged specific absorption rate (SAR) of 3.83 W/kg at 1.5 tesla and 5.57 W/kg at 5.0 tesla for a 20-minute exposure to a B1 of 118 μT. The Amplatzer™device should not migrate in this MR environment. Non-clinical testing has not been performed to rule out the possibility of migration at field strengths higher than 3.0 tesla.

  In this testing, the device produced a temperature rise of 1.1°C at 1.5 tesla and 1.6°C at 5.0 tesla.

  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.

POTENTIAL ADVERSE EVENTS

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

Air embolus; Allergic dye reaction; Anesthesia reactions; Apnea; Arrhythmia; Cardiac tamponade; Death; Embolization; Fever Hypertension/ hypotension; Infection including endocarditis; Need for surgery; Pericardial effusion; Perforation of vessel or myocardium; Pseudoaneurysm including blood loss requiring transfusion; Stroke; Tissue erosion; Thrombus formation on discs; Valvular regurgitation

IMPORTANT SAFETY INFORMATION
AMPLATZER™ SEPTAL OCCLUDER

℞ ONLY

INDICATIONS FOR USE

The AMPLATZER™ Cribriform Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the closure of multifenestrated (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 (such as, 1.5:1 degree of left-to-right shunt or right ventricular enlargement).

CONTRAINDICATIONS

The AMPLATZER™ Cribriform Occluder is contraindicated for the following:

- Treatment of patients with patent foramen ovale (PFO) defects. This device has not been studied in patients with PFO defects.
- Patients known to have extensive congenital cardiac anomaly, which can only be, adequately repaired by way of cardiac surgery.
- Patients known to have sepsis within 1 month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement.
- Patients known to have a bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy unless another anti-platelet agent can be administered for 61 months.
- Patients known to have demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi).
- Patients whose size, (such as, too small for transesophageal echocardiography (TEE) probe, catheter size, vasculature size) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac cathet1e11ization.
- Any patient where the radius of the device is greater than the distance from the central defect to the aortic root or superior vena cava.

WARNINGS

- 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 as they may disrupt critical cardiac functions. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within the sheath.
- Use on or before the last day of the expiration month noted on the product packaging.
- This 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™ Cribriform 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.
- Implantation of this device may not supplant the need for Coumadin in patients with ASD and paradoxical emboli.
- The use of transthoracic, transesophageal, or intracardiac echocardiographic imaging (TTE, TEE, or ICE) is required

PRECAUTIONS

- The use of this device has not been studied in patients with patent foramen ovale.
- Use standard interventional cardiac catheterization techniques to place this device.
- 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.

Handling

- Store in a dry place.

Patient Selection

- Certain patients may be at higher risk for complications such as tissue erosion and device embolization. If higher risk patients have devices implanted, closer follow-up is warranted (see "Post-procedure Instructions" on page 9). Higher risk patients include the following:
  - Patients with deformation of the device at the aortic root
  - Patients with high defects (minimal aortic and superior rims)
  - Patients with less than a 9-mm distance from the central defect to the aortic root or superior vena cava orifice

Procedural

- 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.
- 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.
- Aspirin (for example, 81 mg or 325 mg) or an alternative antiplatelet/anticoagulant is recommended to be started at least 24 hours prior to the procedure.
- 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 esophageal anatomy must be adequate for placement and manipulation of the TEE probe.

Post-implant

- Patients should take appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at the discretion of the physician.
- 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.

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

Through nonclinical testing, the AMPLATZER™ Septal Occluder has been shown to be MR Conditional at field strengths of 3.0 tesla or less with a maximum whole-body-averaged specific absorption rate (SAR) of 3.83 W/kg at 1.5 tesla and 5.57 W/kg at 5.O tesla for a 20-minute exposure to a Bl of 118 μT. The AMPLATZER™ Septal Occluder should not migrate in this MR environment. The nonclinical testing has not been performed to rule out the possibility of migration at field strengths higher than 3.0 tesla.

In this testing, the device produced a temperature rise of 1.1°C at 1.5 tesla and 1.6°C at 5.0 tesla.

MR image may be compromised if the area of interest is in the exact same area or relatively close to the position of the device.

ADVERSE EVENTS

Observed Adverse Events - Tissue Erosion/Perforation

The reported incidence of tissue erosion/perforation is approximately 1 in 1,000 patients treated with the AMPLATZER™ Septal Occluder. Tissue erosion, while rare, has led to cardiac tamponade and death. Tissue erosion/perforation refers to the erosion or abrasion of the tissue of the atrium primarily in the area of the roof of the atrium near the aorta.

Potential Adverse Events

Potential adverse events may occur during or after a procedure placing this device may include, but are not limited to:
Air embolus; Allergic dye reaction; Anesthesia reactions; Apnea; Arrhythmia; Brachial plexus injury; Cardiac perforation; Death; Device collapse due to structural failure; Device embolization; Device removal (due to embolization or misplacement); Erosion; Fever; Headache/migraines; Hematoma/pseudoaneurysm including blood loss requiring transfusion; Hypertension; Hypotension; Infection including endocarditis; Infectious endocarditis; Pericardial effusion; Perforation of vessel or myocardium; Phrenic nerve injury; Stroke/transient ischemic attack; Thrombus formation on the device surface with the risk of subsequent embolization; Valvular regurgitation; Vascular access site complications

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.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

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