LET'S TALK ABOUT THE DEFECT IN YOUR HEART

Because you or your child has been diagnosed with an atrial septal defect (ASD), you may now be thinking about treatment with the Amplatzer™ Septal Occluder. It's a device that is made to close the defect in your heart.[1]

ABOUT ASD

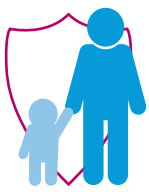
ASD is a defect in the wall (known as the septum) that separates the left from the right **atrium**. The defect increases the amount of blood that flows to the lungs. This increased blood flow can damage the vessels and, over time, may lead to symptoms such as shortness of breath.[2]

- ASD is one of the most common heart defects that people are born with[2,3]

Terms **bolded in blue** are defined in the Glossary on the back.

REASONS FOR CHOOSING THE AMPLATZER™ SEPTAL OCCLUDER

Amplatzer™ is the standard of care in the treatment of ASD—and is the most trusted, studied, and most commonly used device worldwide[1,4]



Amplatzer™ is safe in children and adults, with low major and minor complications[1]

Amplatzer™ is highly effective over the long term[1]

See Important Safety Information referenced within.

ABOUT THE DEVICE

The Amplatzer™ Septal Occluder is a device specifically designed to close an ASD, and it is available in many different sizes so that your doctor can choose the device that's right for you.[1]

Once the device is implanted, tissue will grow around it so you will not need another device in the future.

ABOUT THE PROCEDURE

Closing the defect with the Amplatzer™ device is a minimally invasive procedure.[1]

- The procedure takes about 1 to 2 hours and can usually be done without general anesthesia—you or your child may be able to go home the same day[1,5]
- During the procedure, a **catheter** is inserted into a blood vessel in your groin through a small incision and is used to guide the device into your heart. Once in position, the device remains in place, and the catheter is removed[1,5]
- In most cases, recovery is quick and easy, and you should be able to return to your normal activities shortly after the procedure. Your doctor will provide specific guidelines on activities[5]

GLOSSARY[2]

Atrium: an upper chamber of the heart, you have a right and a left atrium.

Catheter: a long, very thin and hollow tube.

NOTES:

See Important Safety Information referenced within.

MAT-2102074 v2.0 | Item approved for U.S. use only.

AMPLATZER™ SEPTAL OCCLUDER AND DELIVERY SYSTEM

Rx ONLY

IMPORTANT SAFETY INFORMATION

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 of the 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×T. 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.

References: 1. Amplatzer Septal Occluder IFU. 2018. **2.** Atrial septal defect (ASD). Mayo Clinic website. Accessed February 25, 2020. https://www.mayoclinic.org/diseases-conditions/atrial-septal-defect/symptoms-causes/syc-20369715. **3.** McMahon CJ, Feltes TF, Fraley JK, et al. Natural history of growth of secundum atrial septal defects and implications for transcatheter closure. *Heart*. 2002:87;256-259. **4.** Masura J, Gavora P, Formanek A, Hijazi ZM. Transcatheter closure of secundum atrial septal defects using the new self-centering Amplatzer septal occluder: initial human experience. *Cathet Cardiovasc Diagn*. 1997;42:388-393. **5.** Atrial septal defect transcatheter repair for children. Johns Hopkins Medicine website. Accessed February 25, 2020. https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/atrial-septal-defect-transcatheter-repair-for-children.

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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