

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 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 at birth.^{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 complications¹



Amplatzer[™] is highly effective over the long term¹

See Important Safety Information referenced within.

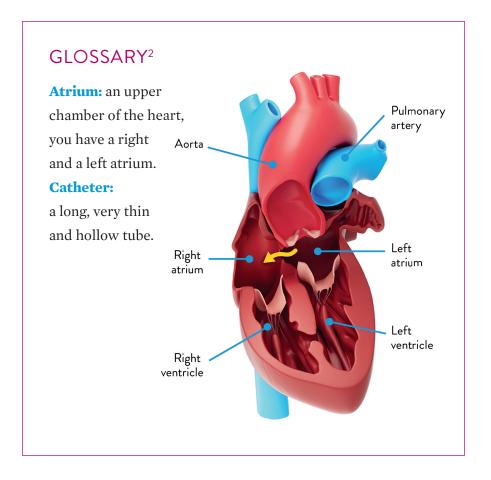
ABOUT THE DEVICE

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.



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 activities⁵





Scan the QR code to watch how the Amplatzer[™] Septal Occluder allowed Christy to have minimal downtime to continue training to run the Boston Marathon.



NOTES:



See Important Safety Information referenced within.

AMPLATZER™ SEPTAL OCCLUDER AND DELIVERY SYSTEM

R Important Safety Information

WHAT IS THE AMPLATZER™ SEPTAL OCCLUDER APPROVED FOR?

The Amplatzer™ Septal Occluder is a device that is placed in the heart during a minimally invasive, catheter-based procedure to close an atrial septal defect (ASD) in patients with an ostium secundum ASD.

WHO SHOULD NOT RECEIVE THE AMPLATZER™ SEPTAL OCCLUDER?

Patients who have any of the following conditions should not receive the Amplatzer[™] Septal Occluder: other defects in the heart that require surgery to repair; infection anywhere in the body that cannot be successfully treated prior to receiving the device; bleeding disorder, untreated ulcer, or unable to take aspirin or other blood-thinning medication; blood clots in the heart; small size or any condition such as an active infection that makes the patient a poor candidate for the procedure; anatomy in which the device would interfere with or come in contact with other heart structures, such as valves or veins.

WHAT ARE THE POSSIBLE COMPLICATIONS ASSOCIATED WITH THE AMPLATZER[™] SEPTAL OCCLUDER?

The Septal Occluder procedure carries risks which may include, but are not limited to: air bubble that blocks blood flow in a vessel; allergic reaction to contrast dye or anesthesia; temporary pause in breathing; loss of regular heart rhythm; blood or fluid buildup around the heart; death; obstruction of a blood vessel; fever; high or low blood pressure; infection, including infection or inflammation in the heart; need for surgery; fluid buildup around the heart; perforation of a vessel or the heart; blood leakage outside a vessel, including blood loss requiring a transfusion; erosion or abrasion of the tissue of the atrium; stroke; blood clot formation over the device; abnormal backward flow of blood through a valve.

WHAT ARE THE PRECAUTIONS ASSOCIATED WITH THE AMPLATZERTM SEPTAL OCCLUDER?

Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies.

Talk to your doctor to learn more about the risks associated with the Amplatzer™ Septal Occluder.

Reference: 1. Amplatzer Septal Occluder IFU. 2018. 2. Atrial septal defect (ASD). Mayo Clinic website. December 12, 2023. 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 December 12, 2023. 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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