Amplatzer Piccolo™ Occluder

CLOSING EARLY PDAs FILLS LOVING HEARTS

This brochure is intended to provide general information about the nonsurgical closure of a patent ductus arteriosus (PDA), which should be further discussed with a doctor. It is not intended to provide medical care or treatment. A doctor should be consulted regarding the diagnosis or treatment of the medical condition.

INDICATION: The Amplatzer Piccolo™ Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA).

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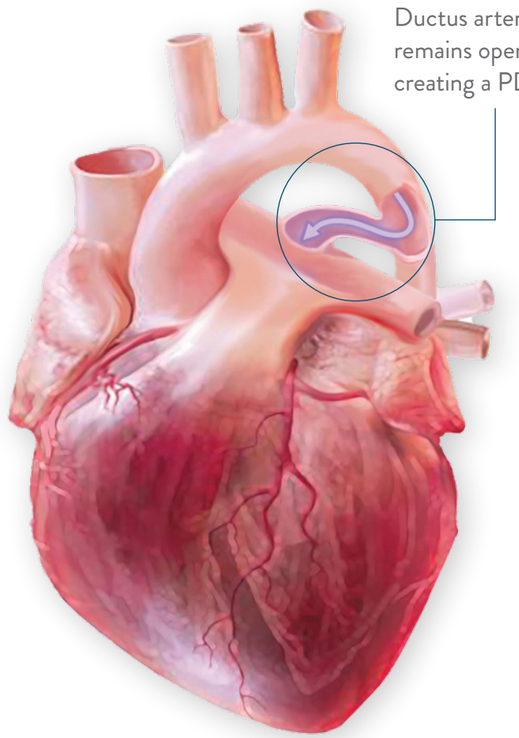
WHAT IS **PDA?**

Before birth, there is a blood vessel in the heart connecting the aorta with the pulmonary artery. This blood vessel, ductus arteriosus, allows oxygen-rich blood from the mother to circulate through the baby's body. Normally, the vessel closes shortly after birth.

When the ductus arteriosus remains open, it is called a patent ductus arteriosus, or PDA. When a PDA is present, oxygen-rich blood can pass through the opening and mix with oxygen-poor blood, which causes the heart to overwork.



WHAT ARE SOME SYMPTOMS OF A PDA?

The severity of symptoms often depends on the size of the PDA. Small PDAs may cause no symptoms and are sometimes only detected by the doctor hearing a heart murmur through a stethoscope. Medium to large PDAs may cause fatigue, poor growth, and eventually lead to heart failure.[2,3]

See Important Safety Information referenced within.

PDA FACTS

A PDA IS PRESENT IN APPROXIMATELY **1 IN 2,000 BIRTHS** AND IS SIGNIFICANTLY HIGHER IN PRETERM BABIES.[1]

PDAs ACCOUNT FOR APPROXIMATELY **5-10%** OF ALL CONGENITAL HEART DISEASES.[2]

THE FEMALE-TO-MALE RATIO OF PATIENTS WITH PDA IS **2:1**.[2]

UNDERSTANDING OPTIONS
FOR PDA TREATMENT

There are many treatment options for a PDA, and there is no single option that is right for every patient. You should talk with your child's 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.

WATCHFUL OBSERVATION

The doctor will monitor your baby's heart to evaluate whether the open blood vessel is closing properly.

MEDICATION

In premature infants, an intravenous (IV) medication called indomethacin may help close a PDA. Indomethacin works by stimulating the muscles inside the PDA to constrict, thereby closing the connection. Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen may also be recommended for older patients.

OPEN HEART SURGERY

Most open-heart surgeries for PDAs are performed through an incision made in the chest wall between two ribs. The surgeon binds the ductus with a simple ligature or with sutures to close the duct.

TRANSCATHETER CLOSURE

The Amplatzer Piccolo™ Occluder is proven to be safe and effective and can be placed in the ductus through a minimally invasive, catheter-based technique.

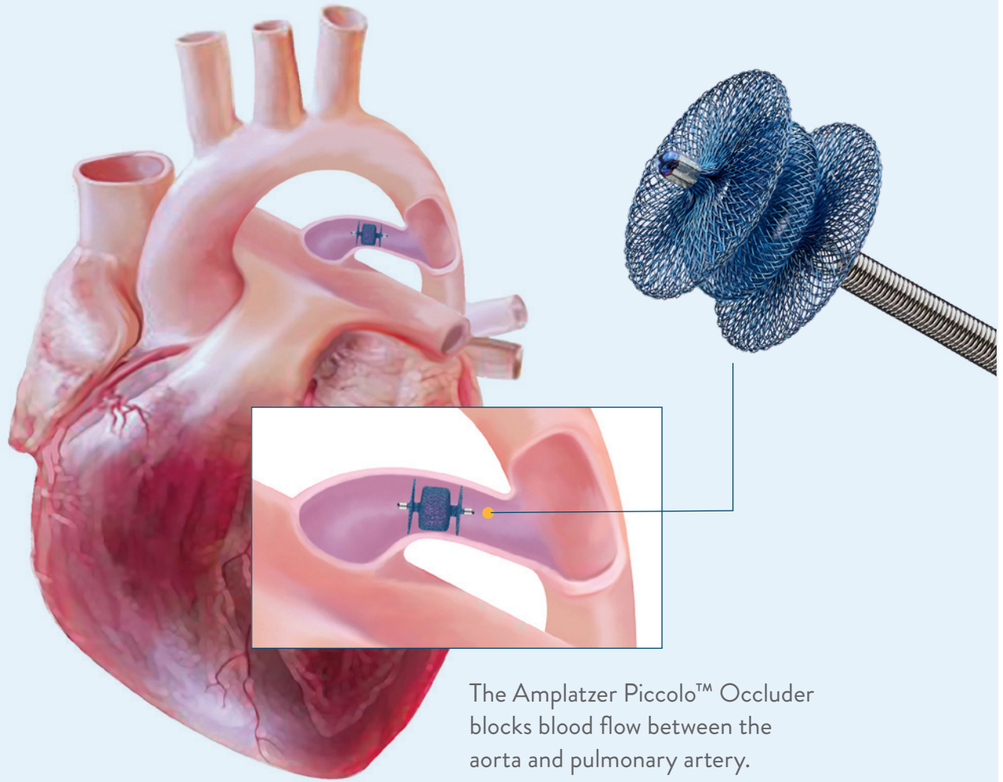
See Important Safety Information referenced within.

Amplatzer Piccolo™ Occluder

CLINICALLY PROVEN TO BE
SAFE AND EFFECTIVE

The Amplatzer Piccolo™ Occluder is a transcatheter closure device specifically designed to stop blood flow through a PDA. The device is made from braided nitinol wires. Nitinol is a metal with shape memory characteristics, meaning the device will return to its original shape after it is stretched to pass through a catheter.

Once the device is placed in the PDA, it will remain permanently implanted in the heart. Over time, the body's natural healing process will cover the device with tissue, and the heart will continue to grow with the device.



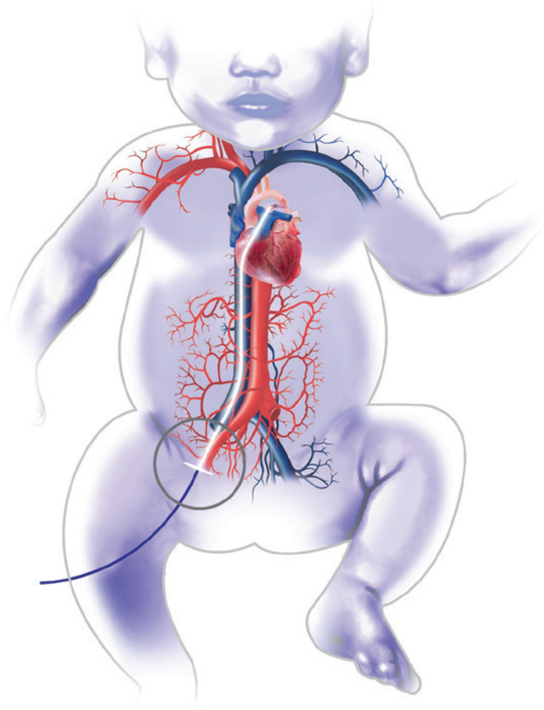
The Amplatzer Piccolo™ Occluder blocks blood flow between the aorta and pulmonary artery.

THE AMPLATZER PICCOLO™ OCCLUDER **PROCEDURE**

The Amplatzer Piccolo™ procedure is minimally invasive. It involves making a small incision, typically in the groin, and inserting a small tube, called a catheter, to navigate through the blood vessels to the procedure site within the heart.

The doctor guides the device through the catheter to seal the PDA. Once the device is placed in the PDA, the doctor will carefully study its position using cardiac imaging systems. Once satisfied with the position, the device is released to remain permanently in the PDA. The catheter is removed, and the procedure is completed.

The procedure itself will take place in a heart catheterization laboratory, where many minimally invasive, nonsurgical procedures are performed. The doctor may give an anesthetic so that no significant discomfort is felt.



See Important Safety Information referenced within.

WHAT HAPPENS **AFTER THE PROCEDURE?**

Your child's doctor can provide guidelines for activities and medications. He or she will prescribe drugs that should be taken at home to continue treatment of your child. The decision to prescribe these is at the discretion of your doctor. Many doctors require follow-up appointments over the next year to ensure your child's recovery is going well. What to expect during and after the procedure will vary, so it's important to discuss all questions and concerns you have with your doctor.

For more information about Patent Ductus Arteriosusu and the Amplatzer Piccolo Occlude, scan the QR code.

Rx Only
Important Safety Information

AMPLATZER PICCOLO™ OCCLUDER

INDICATION OF USE
The Amplatzer Piccolo™ Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA).

CONTRAINDICATIONS
- Weight < 700 grams at time of the procedure; Age < 3 days at time of procedure.
- Coarctation of the aorta.
- Left pulmonary artery stenosis.
- Cardiac output that is dependent on right to left shunt through the PDA due to pulmonary hypertension.
- Intracardiac thrombus that may interfere with the implant procedure.
- Active infection requiring treatment at the time of implant.
- Patients with a PDA length smaller than 3 mm.
- Patients with a PDA diameter that is greater than 4 mm at the narrowest portion.

WARNINGS
- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Do not use the device if the sterile package is open or damaged.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- Patients who are allergic to nickel can have an allergic reaction to this device.
- Prepare for situations that require the removal of this device. Preparation includes access to a transcatheter snare kit and an on-site surgeon.
- Accurate measurements of the ductus are crucial for correct occluder size selection.
- Do not release the occluder from the delivery wire if either a retention disc protrudes into the pulmonary artery or aorta; or if the position of the occluder is not stable.
- Remove embolized devices. Do not remove an embolized occluder through intracardiac structures unless the occluder is fully recaptured inside a catheter.

PRECAUTIONS
- This device should be used only by physicians who are trained in standard transcatheter techniques. Determine which patients are candidates for procedures that use this device.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants and antiplatelet drugs before, during, and/or after the use of this device.
- Patients should have an activated clotting time (ACT) of greater than 200 sec prior to device placement, unless the patient has a significant risk for bleeding and is unable to be anticoagulated.
- The device may be delivered via an anterograde (venous) or a retrograde (arterial) approach. However, in small infants (≤2 kg), the device should be delivered using the anterograde (venous) approach since small infants are at an increased risk for arterial injury.
- In small infants (≤2kg) the occluder size is chosen so that the entire device with both retention discs is placed within the duct (intraductal placement) to minimize the potential for protrusion into the aorta or left pulmonary artery.
- In larger infants (>2kg), the occluder size is chosen so that the central waist spans the entire length of the duct with the retention discs placed just outside the duct or within the ampulla (extraductal disc placement) to achieve improved positional stability and minimize the potential for device embolization.
- Prior to releasing the device from the delivery wire, it is important to rely on imaging to ensure there is no obstruction of the aorta or left pulmonary artery.
- The Amplatzer Piccolo™ Occluder 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 following implant. 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 seek immediate medical attention if there is suspicion of an allergic reaction. Symptoms may include difficulty in breathing or swelling of the face or throat. While data are currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.
- Use in specific populations
  - Pregnancy — Minimize radiation exposure to the fetus and the mother.
  - Nursing mothers — There has been no quantitative assessment for the presence of leachables in breast milk.
- Store in a dry place.
- Do not use contrast power injection with delivery catheter.

MR CONDITIONAL
Non-clinical testing has demonstrated that the Amplatzer Piccolo™ Occluder is MR Conditional. A patient with the Amplatzer Piccolo™ Occluder can be safely scanned in an MR system under the following conditions:
- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T)
- Maximum spatial gradient field of 19T/m (1900 G/cm)
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 2.0W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 9 mm from the Amplatzer Piccolo™ Occluder when imaged with a gradient echo pulse sequence and a 3.0T MRI System.

POTENTIAL ADVERSE EVENTS
Potential adverse events that may occur during or after a procedure using this device may include, but are not limited to:
- Air embolus
- Allergic reaction
- Anemia
- Anesthesia reactions
- Apnea
- Arrhythmia
- Bleeding
- Cardiac perforation
- Cardiac tamponade
- Chest pain
- Device embolization
- Device erosion
- Death
- Endocarditis
- Fever
- Headache/migraine
- Hemolysis
- Hematoma
- Hypertension
- Hypotension
- Infection
- Myocardial infarction
- Palpitations
- Partial obstruction of aorta
- Partial obstruction of pulmonary artery
- Pericardial effusion
- Pericarditis
- Peripheral embolism
- Pleural effusion
- Pulmonary embolism
- Re-intervention for device removal
- Respiratory distress
- Stroke
- Thrombus
- Transient ischemic attack
- Valvular regurgitation
- Vascular access site injury
- Vascular occlusion
- Vessel perforation

REFERENCES
1. Krasuki, R.A. Patent ductus arteriosus closure. Journal of Interventional Cardiology. 2006; 19 (5 Suppl), S60-66.
2. Schneider, D.J., & Moore, J.W. Patent ductus arteriosus. Circulation. 2006; 114(17), 1873-1882.
3. Cincinnati Children's. Congenital Patent Ductus Arteriusus. www.cincinnatichildrens.org/health/ heartencyclopedia/anomalies/pda.htm. Accessed February 2, 2016.

CAUTION: Product(s) 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 www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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