AMPLATZER PICCOLO™ OCCLUDER

CLOSES EARLY PDAs FILLS LOVING HEARTS

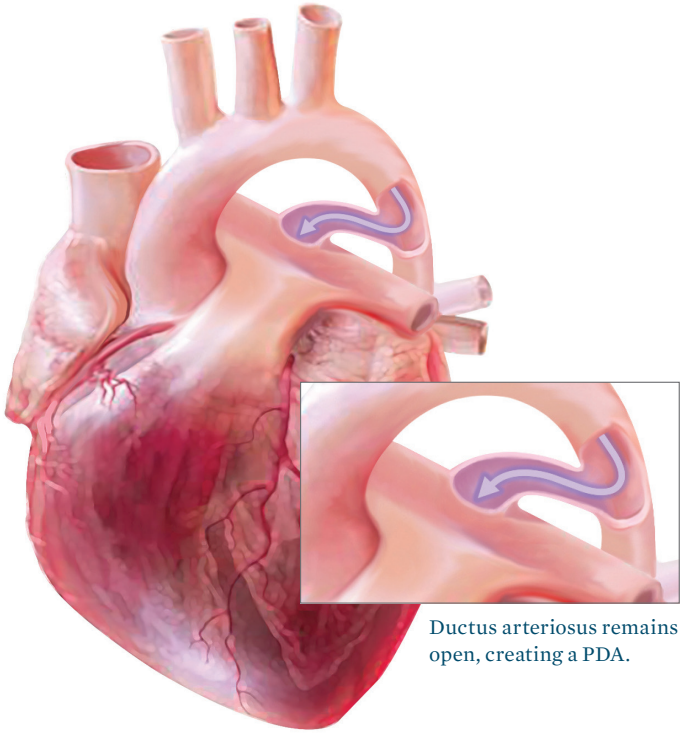
This brochure is intended to provide general information about the nonsurgical closure of a patent ductus arteriosus (PDA), which should be further discussed with a doctor. It is not intended to provide medical care or treatment. A doctor should be consulted regarding the diagnosis or treatment of the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

Abbott

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.



Ductus arteriosus remains open, creating a PDA.

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]

20-60%
OF PRETERM BABIES HAVE A PDA[3]

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

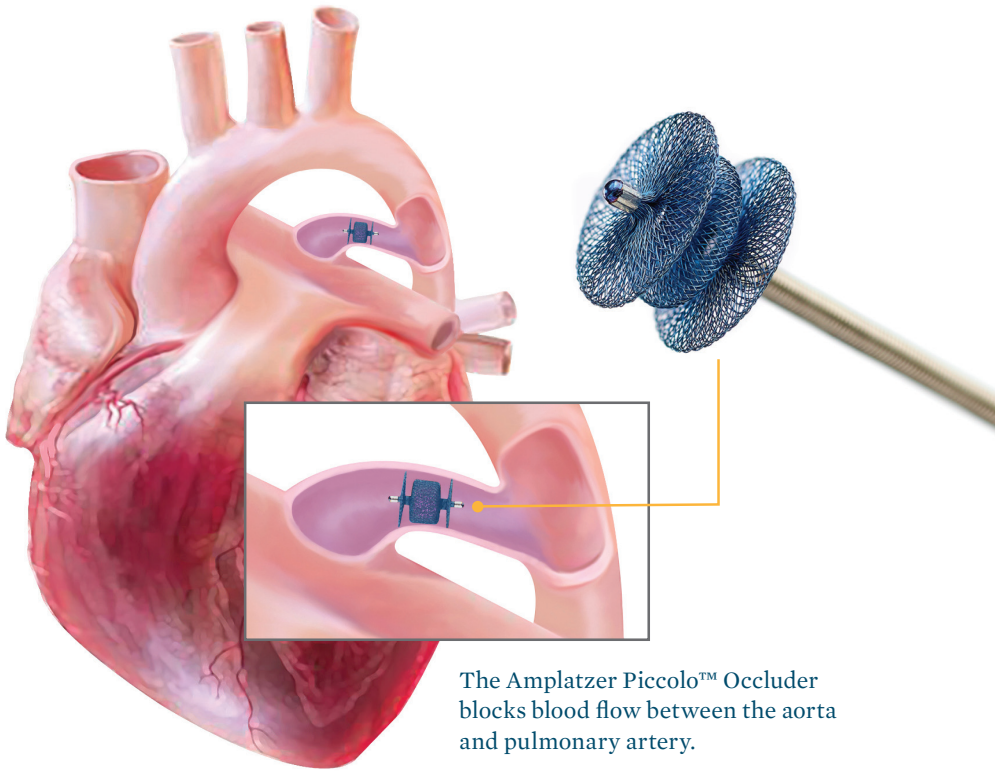
The Amplatzer Piccolo™ Occluder is proven to be safe and effective and can be placed in the ductus through a minimally invasive, catheter-based technique.

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.



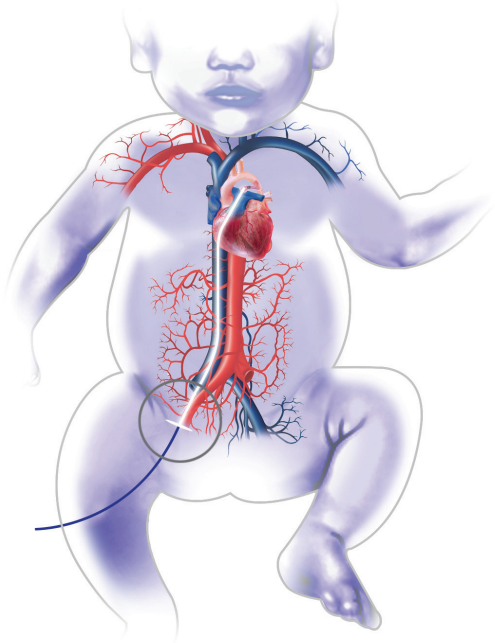
The Amplatzer Piccolo™ Occluder blocks blood flow between the aorta and pulmonary artery.

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.



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 the Amplatzer Piccolo™ Occluder, contact your Abbott sales representative or visit PICCOLODEVICE.COM or SCAN THE QR CODE.

WHAT RISKS ARE ASSOCIATED WITH THE AMPLATZER PICCOLO™ OCCLUDER?

There are certain potential risks associated with catheter-based procedures as well as additional risks that may be associated with the device. The 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
- Anesthesia reaction
- Apnea (temporary absence of breathing)
- Arrhythmia (loss of regular heart rhythm)
- Bacterial endocarditis (infection that causes swelling of the lining of the heart and its valves)
- Bleeding
- Cardiac perforation (a puncture in the tissue around the heart)
- Cardiac tamponade (fluid build-up in tissue around the heart, causes compression of the heart)
- Chest pain
- Death
- Device embolization (dislodging of the device)
- Device erosion (hole created by device rubbing against heart tissue)
- Fever
- Headache/Migraine
- Hematoma (collection of blood outside of a vessel)
- Hemolysis (breakdown in red blood cells)
- Hyper/Hypotension (abnormally high/low blood pressure)
- Infection
- Myocardial infarction (heart attack)
- Palpitations (irregular heartbeat)
- Partial obstruction of aorta or pulmonary artery
- Pericardial effusion (excess fluid around 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)
- Pleural effusion (excess fluid around the lungs)
- Pulmonary embolism (a clot or debris decreasing blood flow around the lungs)
- Reintervention for device removal
- Respiratory distress (severe shortness of breath due to fluid in the lungs)
- Stroke/Transient Ischemic Attack, or TIA (temporary lack of oxygen to the brain)
- Thrombus (blood clot)
- Valvular regurgitation or insufficiency (abnormal backward flow of blood through a valve)
- Vascular access site injury
- Vascular occlusion (a blocked blood vessel)
- Vessel perforation (piercing of a blood vessel)

WHO SHOULD NOT RECEIVE THE DEVICE?

- If the patient has any of the following conditions, they may not be a good candidate to receive the AMPLATZER Piccolo™ Occluder.
- If they weigh less than 700 grams at the time of the procedure
- If they are fewer than 3 days old at the time of the procedure
- If they have a narrowing in the aorta or in the left pulmonary artery
- If they have high blood pressure in the pulmonary arteries and the blood flow to the rest of the body must go through the PDA
- If the PDA length is shorter than 3mm
- If the PDA diameter at the narrowest portion is greater than 4mm
- If they have an active infection
- If they have a clot (thrombus) in their heart that may interfere with the implant procedure

AMPLATZER PICCOLO™ OCCLUDER
IMPORTANT SAFETY INFORMATION

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INDICATIONS AND USAGE

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.

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

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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