

AMPLATZER™ Duct Occluder

## A PATIENT'S GUIDE TO THE NON-SURGICAL CLOSURE OF A PATENT DUCTUS ARTERIOSUS



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MORE CONTROL. LESS RISK.

This brochure is intended to provide you with general information about the non-surgical 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. You should consult with a doctor regarding the diagnosis or treatment of your medical condition.

## Patent Ductus Arteriosus Overview

A patent ductus arteriosus (PDA) is a blood vessel connecting the aorta with the pulmonary artery. This channel is important prior to birth to allow oxygen-rich blood from the mother to circulate throughout the fetus's body. Normally, the vessel closes shortly after birth. If it does not close, oxygen-rich blood can mix with oxygen-poor blood, creating extra work for the heart.

- PDA is present in approximately 1 in 2,000 births<sup>1</sup>
- PDA accounts for approximately 5-10% of all congenital heart disease
- The female to male ratio of patients with PDA is 2:1<sup>2</sup>

## How does a PDA affect blood flow?

To best understand how a PDA 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 imbedded within the heart itself. Typically, oxygen-poor blood flows from the body into the heart through the right atrium and then fills the right ventricle. When the heart beats, this blood is pumped through the pulmonary artery out to the lungs to be filtered and receive oxygen. From the lungs, the now oxygen-rich blood enters the heart through the left atrium. It then fills the left ventricle and is pumped through the aorta out to the body to provide oxygen to all the organs and cells. After it circulates throughout the body, it becomes oxygen-poor and returns to the heart.

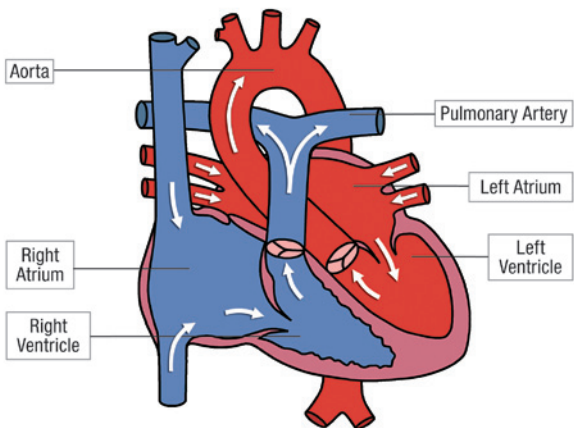


Figure 1  
Diagram of a healthy heart

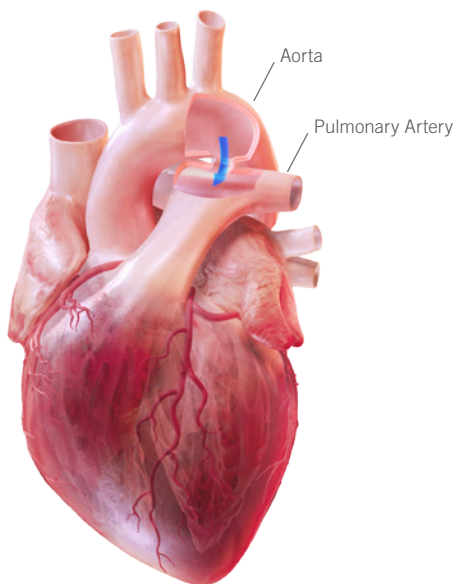


Figure 2  
Heart with patent ductus arteriosus

During fetal development, the heart has two openings that normally close shortly after birth. These openings allow the oxygen-rich blood from the mother to bypass the lungs and flow directly through the fetus's body. The first opening, called the foramen ovale, is between the left and right atrium. The second opening, called the ductus arteriosus, is a channel or pathway connecting the aorta with the pulmonary artery (Figure 2). If these do not close after birth, they are known as patent, or open.

If a patent ductus arteriosus is present, oxygen-rich blood can pass through the opening and mix with oxygen-poor blood. This causes the heart to overwork.

## What are the symptoms of a PDA?

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.<sup>2,3</sup> All sizes of PDAs may increase a patient's risk for a bacterial infection.

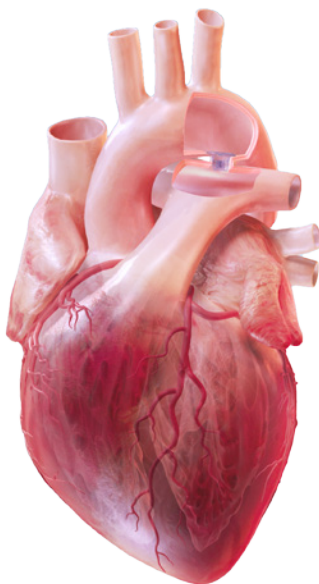


Figure 3  
AMPLATZER Duct Occluder implanted during catheter-based procedure

## How is a PDA treated?

There are a number of treatment options for a PDA, and there is no single option that is right for every patient. You should discuss with your 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. The first option is medication which may be appropriate to help close the PDA or in treating symptoms associated with the PDA. Other treatment options include open-heart surgery and catheter-based procedures (Figure 3).

## How do I know which treatment option is right for me or my child?

Every person is unique. Your doctor is your best resource for learning about the treatment options available and the best course for your or your child's condition. Talk to your doctor and follow his or her advice for care. Remember a PDA can result in unpleasant symptoms and increased health risk. With proper care, however, it can generally be managed with medication or closure.

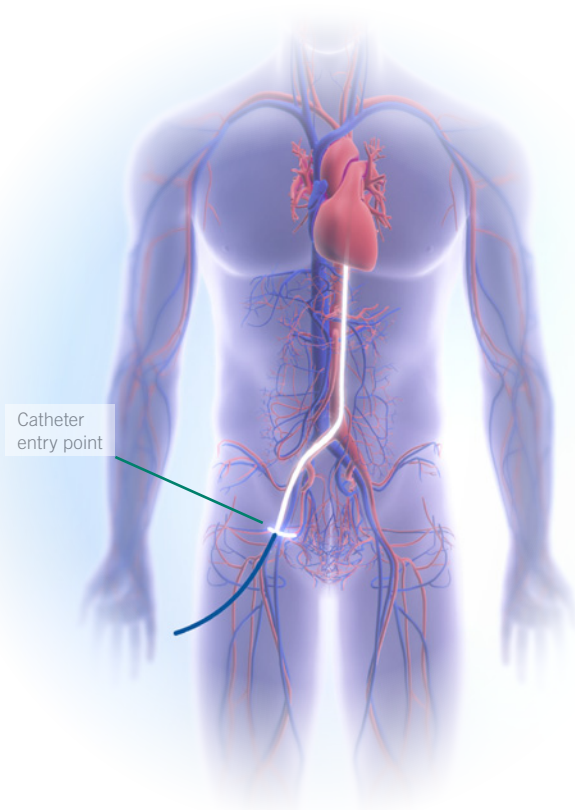


Figure 4  
Catheter pathway in transcatheter PDA closure procedure

## 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, to navigate through the blood vessels to the procedure site within the heart (Figure 4).

In patients with a PDA, 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 channel. The catheter is removed and the procedure is completed.

The procedure itself should last about one to two hours and will take place in a heart catheterization laboratory, where many minimally-invasive, non-surgical procedures are performed. The doctor may give the patient an anesthetic, and no significant discomfort should be felt.

## What exactly is an AMPLATZER Duct Occluder?

The AMPLATZER Duct Occluder is a device designed for the non-surgical closure of a PDA (Figure 5). The device is placed in the PDA during a catheter-based procedure and will remain permanently implanted.

The AMPLATZER Duct Occluder is 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 out to pass through a catheter. The shape of the device was specifically designed to stop blood flow through a PDA.



Figure 5  
AMPLATZER Duct Occluder

## 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 Duct Occluder.

- If they weigh less than 6 kg
- If they are less than 6 months of age
- If they have blood clots in their heart or vessels
- If they have an infection
- If they, their heart or veins are too small or if they cannot undergo the procedure
- If they have high blood pressure in the pulmonary arteries

## What happens after the procedure?

Because the procedure is minimally invasive, the recovery will likely be quick and easy. Many patients are discharged from the hospital within 24 hours. The doctor can provide guidelines for activities and medications. He or she will prescribe drugs that should be taken at home to continue treatment and recovery. The decision to prescribe these is at the discretion of each 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 or concerns you have with your doctor.

## How long will it take to recover? What activities should be avoided after the 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.



## **What is a patient identification card? Will the patient need to carry it with them?**

As a device patient, it is important to carry a patient identification card to identify as having an implanted device. The patient ID card includes the patient's name, implant date, doctor's contact information, and information about the device. The patient will be provided with this card after the procedure.

## **Can patients travel with an implanted device? Will the device trigger airport security systems?**

Your physician is your best resource for the answer to this question. Many patients find that with some extra planning and care, they can enjoy traveling even with an implanted device. It is always wise to carry the patient ID card, just in case there are 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 the device. The patient needs to simply show the patient identification card to security personnel.

## **Will medical equipment interfere with the device?**

Although most medical equipment will have no effect on the device, it is best the patient tells hospital personnel they have an implanted device before undergoing any medical procedure. Magnetic resonance imaging (MRI) scans are generally acceptable, and the AMPLATZER occlusion device has no known hazards when using a 3-tesla MRI, an MRI system more powerful and faster than standard MRI machines. If an MRI is needed, the patient should simply inform the MRI staff about the implant.

## **Will the patient be able to feel the device?**

No, the patient will not be able to feel the device once it's implanted.

## **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 physician will ensure that care will be taken to minimize the radiation exposure to the fetus and the mother.

It is unknown if the device affects breast milk. You should discuss this issue with your doctor.

## **What if the patient experiences one or more of the following symptoms after the procedure after the procedure: pain, numbness, sudden weakness, dizziness, or rapid heartbeat?**

If you or your child experiences any of the symptoms listed above, seek medical help immediately. An echocardiogram (ultrasound of the heart) should be performed.

## **What risks are associated with the AMPLATZER Duct Occluder?**

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:

- 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) (0.5%)<sup>4,a</sup>
- Arterial pulse loss (decreased amount of blood flow through an artery)
- Bacterial endocarditis (infection that causes redness and swelling of the lining of the heart and its valves)
- Bleeding
- Brachial plexus injury (injury to the nerves in the arm or lower neck)
- Chest pain
- Death (0.3%)<sup>a</sup>
- Delivery system failure
- Device embolization (dislodging of the device) (0.3%)<sup>a</sup>
- Fever
- Headache/Migraine
- Hematoma (collection of blood outside of a vessel)
- Hyper/Hypotension (abnormally high/low blood pressure)
- Loss of peripheral pulse (loss of pulse in extremities) (1.0%)<sup>a</sup>
- Myocardial infarction (heart attack)
- Partial obstruction of pulmonary artery (0.3%)<sup>a</sup>
- Perforation of vessel or myocardium (piercing of a vessel or 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)
- Pseudoaneurysm (false aneurysm of the femoral hematoma) (0.3%)<sup>a</sup>
- Stroke/TIA (temporary lack of oxygen to the brain)
- Thrombus (blood clot) (0.3%)<sup>a</sup>
- Valvular regurgitation or insufficiency (abnormal backward flow of blood through a valve)
- Vascular access site complications (1.7%)<sup>a</sup>

a. Adverse event observed with the AMPLATZER Duct Occluder during the clinical trial.

You should also be aware that:

- These devices consist of a nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from a similar AMPLATZER occluder device, made of the same Nitinol material as the AMPLATZER Duct Occluder 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 notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted. Some forms of nickel have also been associated with carcinogenicity (ability to cause cancer) in animal models. In humans, carcinogenicity has been demonstrated only through an inhalation route (breathing nickel in) which will not occur with this procedure.
- Patients allergic to nickel may suffer an allergic reaction to this device.
- There is limited clinical data for patients over 40 years of age.
- If you are pregnant, you and your baby are at risk for increased X-ray exposure. Notify your doctor if you are (or believe you might be) pregnant.
- If the device were to be dislodged, you may need surgery for its removal. Your PDA will be repaired at the same time. Surgery following device placement may be more difficult.

### My follow-up questions:



**For additional information, please contact your doctor.**

References:

1. Krasuki RA. Patent Ductus Arteriosus Closure. *Journal of Interventional Cardiology*. 2006;19:(5 Suppl):S60-S66.
2. Schneider DJ, Moore JW. Patent Ductus Arteriosus. Congenital Heart Disease for the Adult Cardiologist. *Circulation*. 2006;114:1873-1882.
3. Cincinnati Children's. Patent Ductus Arteriosus. Cincinnati Children's. <http://www.cincinnatichildrens.org/health/heart-encyclopedia/anomalies/pda.htm>. Accessed March 15, 2011.
4. AMPLATZER Duct Occluder Instructions for Use.

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**Rx Only**

Federal (USA) law restricts this device to sale to or on the order of a physician.

**Indications:** The AMPLATZER Duct Occluder is a percutaneous, transcatheter occlusion device intended for the non-surgical closure of patent ductus arteriosus (PDA).

**Brief Summary:** Please review the Instructions for Use prior to using this device for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Product referenced is approved for CE Mark.

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