A Patient's Guide to the
Nonsurgical Closure of a

Patent Ductus Arteriosus

Amplatzer™ Duct Occluder and

Amplatzer™ Duct Occluder II

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

This brochure is intended to provide you with 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. You should consult with a doctor regarding the diagnosis or treatment of your medical condition.

What is a PDA?

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.

- A PDA is present in approximately 1 in 2,000 births[1]
- PDAs account for approximately 5–10% of all congenital heart disease[2]
- The female-to-male ratio of patients with PDA is 2:1[2]

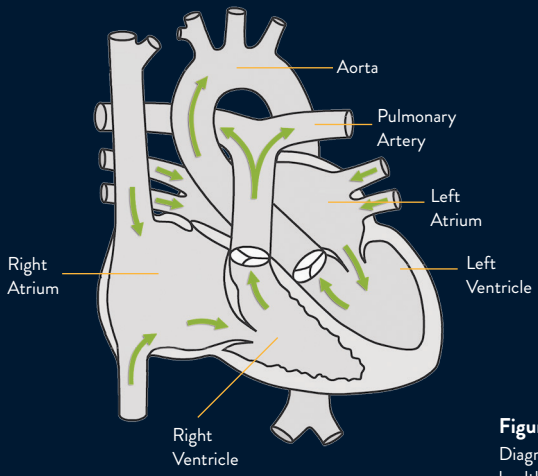


Figure 1
Diagram of a healthy heart

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 embedded 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.

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 atria. 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.[2,3] All sizes of PDAs may increase a patient's risk for a bacterial infection.

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 talk 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)**.

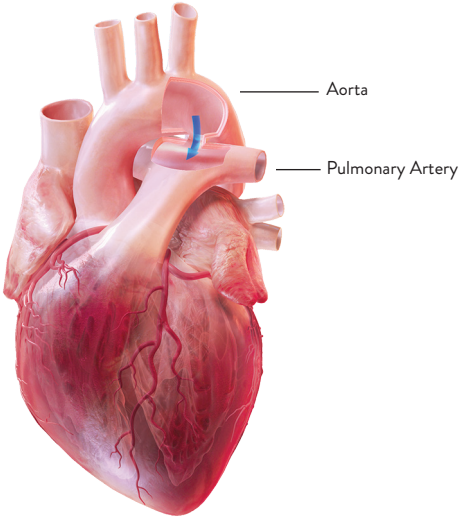


Figure 2
Heart with patent ductus arteriosus

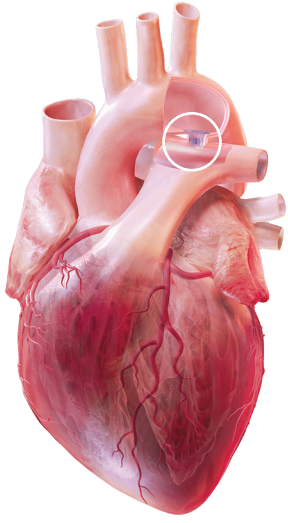


Figure 3
Amplatzer™ Duct Occluder implanted during a catheter-based procedure

HOW DO I KNOW WHICH TREATMENT OPTION IS RIGHT FOR ME?

Every person is unique. Your doctor is your best resource for learning about the treatment options available to you and the best course for your condition. Talk to your doctor and follow his or her advice for your 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.

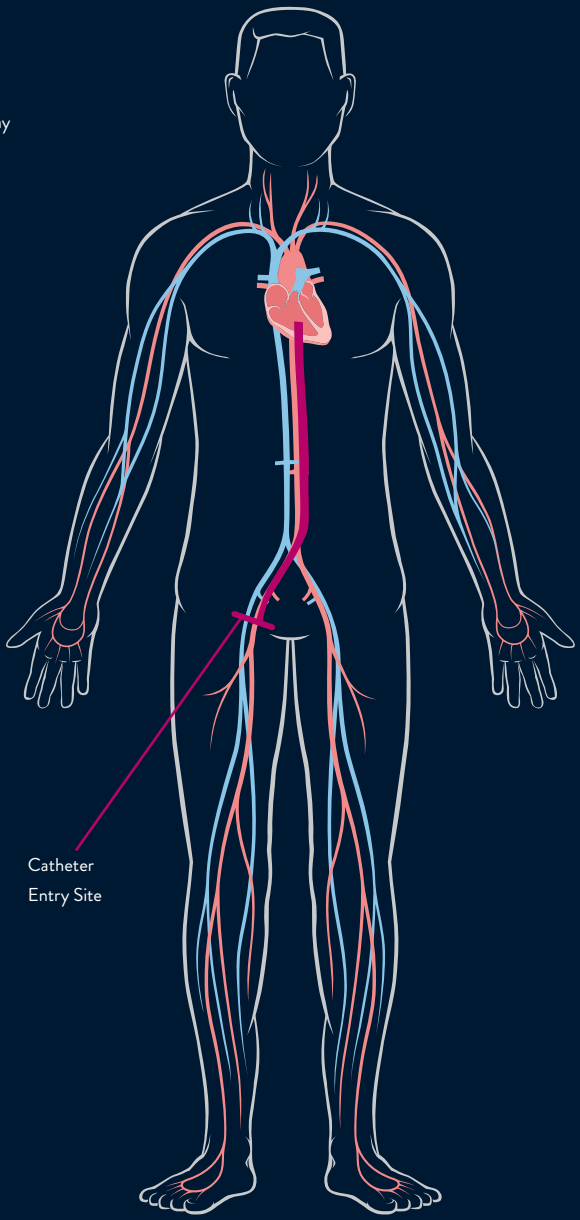
WHAT IS INVOLVED WITH A CATHETER-BASED PROCEDURE?

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, nonsurgical procedures are performed. Your doctor may give you an anesthetic, and you should not feel any significant discomfort.

Figure 4
Catheter pathway
in transcatheter
PDA closure



What is an Amplatzer™ Duct Occluder and Amplatzer™ Duct Occluder II?

The Amplatzer™ Duct Occluder and Amplatzer™ Duct Occluder II are devices designed for nonsurgical PDA closure **(Figure 5)**. The devices have different design features, and your doctor will select the most appropriate device for your PDA. The device is placed in the PDA during a catheter-based procedure and will remain permanently implanted.

Both devices are made from braided nitinol wires. Nitinol is a metal with shape memory characteristics, meaning the device will return to its original shape even after it is stretched to pass through a catheter. The shape of each device was specifically designed to stop blood flow through a PDA.

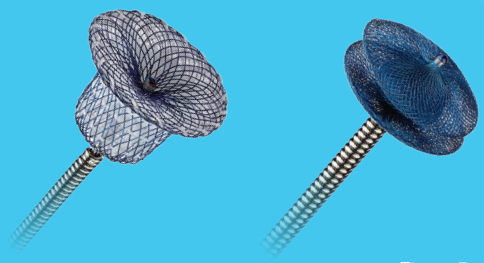


Figure 5
Amplatzer™ Duct Occluder (left) and Amplatzer™ Duct Occluder II (right)

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 their veins are too small or if they cannot undergo the procedure
- If they have high blood pressure in the pulmonary arteries

If the patient has any of the above conditions or any of the following conditions, they may not be a good candidate to receive the Amplatzer™ Duct Occluder II.

- If they have a window-type PDA
- If the blood flows from right to left through the PDA
- If they have other heart defects that require surgery
- If they have had more than two lower respiratory infections within the past year
- If they are unable to take blood thinner medication
- If the size of their ductus (channel) is too large for the device

WHAT HAPPENS AFTER THE PROCEDURE?

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

HOW LONG WILL IT TAKE ME TO RECOVER? WHAT ACTIVITIES SHOULD BE AVOIDED AFTER MY 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.

WILL I BE ABLE TO FEEL THE DEVICE?

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

WHAT IS A PATIENT IDENTIFICATION CARD? WILL I NEED TO CARRY IT WITH ME?

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

CAN I TRAVEL WITH AN IMPLANTED DEVICE? WILL MY 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 your patient ID card just in case you encounter 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 your device. Simply show your patient identification card to security personnel.

WILL MEDICAL EQUIPMENT INTERFERE WITH MY DEVICE?

Although most medical equipment will have no effect on your device, it is best to tell hospital personnel that you have an implanted device before you undergo any medical procedure. Magnetic resonance imaging (MRI) scans are generally acceptable, and your 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, simply inform the MRI staff about your implant.

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 I EXPERIENCE ONE OR MORE OF THE FOLLOWING SYMPTOMS AFTER THE PROCEDURE: PAIN, NUMBNESS, SUDDEN WEAKNESS, DIZZINESS OR RAPID HEARTBEAT?

If you experience 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 AND AMPLATZER™ DUCT OCCLUDER II?

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%)[a]
- Arterial pulse loss (decreased amount of blood flow through an artery)
- Bacterial endocarditis (infection that causes swelling of the lining of the heart and its valves)
- Bleeding
- Brachial plexus injury (injury to the nerves in the arm or lower neck)
- Cardiac arrest (unexpected loss of heart function)
- Cardiac perforation and tamponade
- Chest pain
- Compromised hemodynamics (compromised blood circulation)
- Critical limb ischemia (severe blockage in the arteries of the legs)
- Critical limb loss
- Death (0.3%)[a]
- Delivery system failure
- Device embolization (dislodging of the device) (0.3%)[a]
- Device erosion

- Device migration
- Embolic event (when a mass, such as an air bubble or blood clot, gets stuck in a blood vessel and blocks or decreases blood flow)
- Fever
- Foreign material embolic event (blockage of blood flow in a vessel)
- Headache/Migraine
- Hematoma (collection of blood outside of a vessel)
- Hemolysis (breakdown of red blood cells)
- Hyper/Hypotension (abnormally high/low blood pressure)
- Infection
- Loss of peripheral pulse (loss of pulse in extremities) (1.0%)[a]
- Myocardial infarction (heart attack)
- Partial obstruction of aorta or pulmonary artery (0.3%)[a]
- 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)
- Pressure gradient
- Pseudoaneurysm (false aneurysm of the femoral hematoma) (0.3%)[a]
- Pulmonary hypertension
- Residual shunt (blood flow through the defect due to incomplete closure)
- Seizure
- Stroke/TIA (temporary lack of oxygen to the brain)
- Thrombus (blood clot) (0.3%)[a]
- Tissue trauma or damage
- Valvular regurgitation or insufficiency (abnormal backward flow of blood through a valve)
- Vascular access site complications (1.7%)[a]
- Vascular damage
- Vascular irritation

[a]Adverse event observed with the Amplatzer™ Duct Occluder during the clinical trial.

You should also be aware that:

- The Amplatzer™ Duct 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. 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 are currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.
- 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.

For additional information, please contact your doctor.

1. Krasuki, R. A. (2006). Patent ductus arteriosus closure. *Journal of Interventional Cardiology, 19* (5 Suppl), S60-S66.
2. Schneider, D. J., & Moore, J. W. (2006). Patent ductus arteriosus. *Circulation, 114*(17), 1873-1882.
3. Cincinnati Children's. Congenital Patent Ductus Arteriosus. www.cincinnatichildrens.org/health/heart-encyclopedia/anomalies/pda.htm. Accessed February 2, 2016.

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