

**A Patient's Guide to  
Transcatheter Closure of a Patent Ductus Arteriosus Using the  
AMPLATZER® Duct Occluder System**

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*This brochure is intended to provide you with general information to discuss with your doctor. It is not intended to provide medical care or treatment. You should consult with your doctor regarding the diagnosis or treatment of your medical condition.*

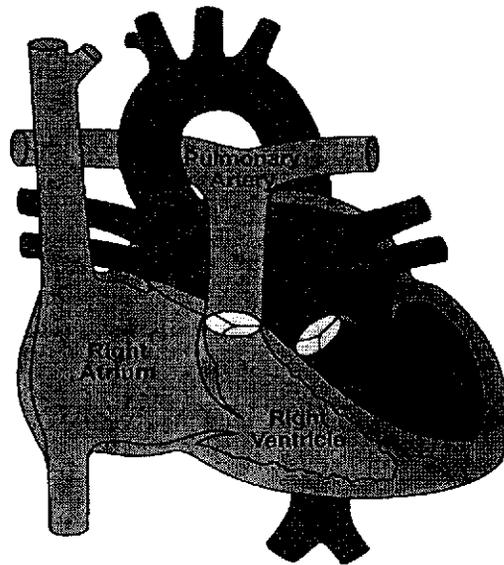
**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

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*Figure 1*  
*Diagram of a Normal Heart*

**Blue** = Blood is pumped from the body to the *lungs*

**Red** = Blood is pumped from the *lungs* to the body (oxygenated)

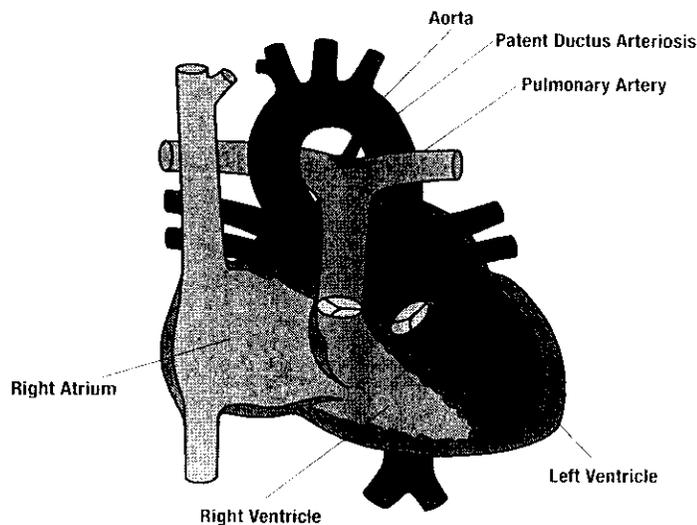
## INTRODUCTION

You have been diagnosed with a *patent ductus arteriosus (PDA)* which must be closed. The purpose of this brochure is to provide a better understanding of your medical condition and explain how non-surgical closure can be performed using the AMPLATZER Duct Occluder.

### *Patent Ductus Arteriosus*

A PDA is a *heart defect* that occurs when a *blood vessel* called the *ductus arteriosus* fails to close after birth, as it normally should. The *ductus arteriosus* is an open channel in every fetus that allows blood to bypass the *lungs*, which are not used until the baby takes its first breath after birth. Shortly after the baby's first breath, the *ductus arteriosus* should close permanently. If it does not close, it is known as a *patent ductus arteriosus*. Refer to Figure 2.

This condition can cause symptoms such as fatigue, difficult or rapid breathing, failure to grow normally, or chronic respiratory infections such as colds and pneumonia, or *endocarditis*. A patient with a PDA can also be asymptomatic (without symptoms). Large openings can lead to heart failure and death.



*Figure 2*  
*Heart with a Patent Ductus Arteriosus (PDA)*

Your doctor has recommended that the PDA be closed using an implantable AMPLATZER Duct Occluder device.

## PURPOSE OF THE DEVICE (INDICATIONS FOR USE)

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

## DESCRIPTION OF THE DEVICE

The AMPLATZER Duct Occluder is wire mesh made out of nickel and titanium (Nitinol). The wire mesh is filled with polyester fabric to help close the defect. The polyester fabric is sewn into the device with a polyester thread.



*Figure 3*  
*AMPLATZER Duct Occluder*

The AMPLATZER Duct Occluder has a specially designed delivery system that your doctor will use to attach, deliver and release the AMPLATZER Duct Occluder in your heart.

## WHEN THE DEVICE SHOULD NOT BE USED (CONTRAINDICATIONS)

If you have any of the following conditions, the AMPLATZER Duct Occluder should not be used:

- If you weigh less than 6 kgs.
- If you are younger than 6 months of age.
- If you have blood clots in your heart or vessels through which access to the heart is gained.
- If you, your heart or your veins are very small or if you cannot undergo the procedure, you may not be able to receive the device.
- If you have an infection anywhere in your body. You may receive the device only after the infection is gone.
- If you have high blood pressure in the *pulmonary arteries*.

## POTENTIAL RISKS AND BENEFITS

### *What are the risks?*

There are risks with *cardiac catheterization* procedures as well as additional risks that may be associated with the device.

The following adverse events were seen during the clinical trial:

- Death (0.3%) – death during or after the procedure due to complications of the procedure.
- Dislodgment of the device (0.3%)
- Blood Clot (*Thrombus*) (0.3%)
- Partial Obstruction of Pulmonary Artery (0.3%) – device disrupting flow in the pulmonary artery
- False aneurysm (0.3%)
- Vascular access site complication (*Hematoma*) (1.7%)
- Loss of pulse in the leg (1.0%)
- Loss of regular heart rhythm (*Arrhythmia*) (0.5%)

There are additional potential risks that were not observed in the clinical trial, but could occur:

- An air bubble or clot that blocks blood flow in a vessel (*Embolus*)
- Allergic reaction to dye, drug or anesthesia
- Temporary absence of breathing (*Apnea*)
- Inflammation of the lining of the heart from infection (*Bacterial endocarditis*)
- Bleeding
- Injury to the nerves in the arm and lower neck (*Brachial plexus injury*)
- Chest pain
- Delivery System failure
- Fever
- Headache/migraine
- Too high or too low blood pressure (*Hypertension; hypotension*)
- Heart Attack (*Myocardial infarction*)
- Perforation (piercing) of the vein or heart
- Stroke, *TIA*, or peripheral embolism
- Valvular Regurgitation (backward flow of blood through the valve)

You should also be aware that:

- 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 would be repaired at the same time. Surgery following device placement may be more difficult.

Because the AMPLATZER Duct Occluder device is new, there may be other risks that are not known at this time.

***What are the benefits of this procedure?***

The primary benefit of having a device is that surgery is avoided. This results in:

- Shorter hospital stay and recovery time
- No chest scar

## **ALTERNATIVES TO THE DEVICE**

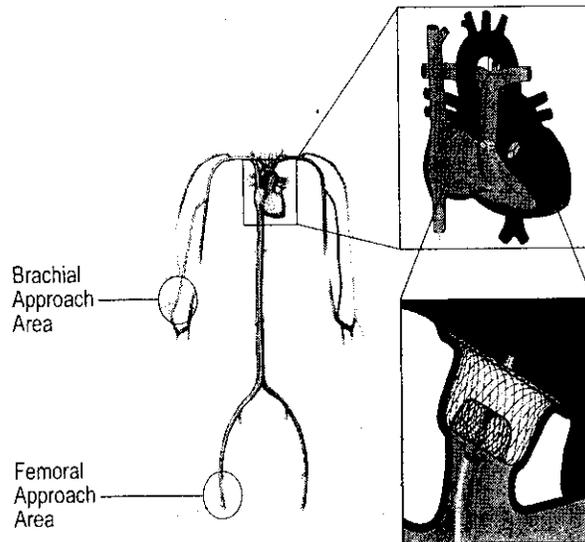
- **Surgical Closure of PDA**  
Surgery involves the Patent Ductus Arteriosus to be tied off surgically through an incision in the chest.
- **Medical therapy**  
Medical therapy may be appropriate depending on the size of the duct, presence of calcification, age of the patient, and overall medical condition. If medical therapy is used, it causes the ductus/opening to narrow, causing decreased blood flow through it. With repeated medical therapy the opening will close.
- **No Treatment**

## • WHAT SHOULD BE EXPECTED DURING AND AFTER THE PROCEDURE?

*What to expect during and after the procedure will vary. Read this information carefully and discuss any questions or concerns you have with your doctor.*

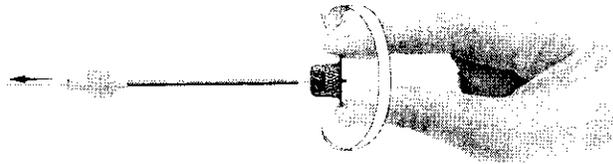
### *What to Expect During the Procedure*

1. Your procedure will be performed in the heart catheterization laboratory, or “cath lab.” You will lie on a x-ray table, and a x-ray camera will move over your chest during the procedure. The staff will monitor your heart using an Electrocardiogram (ECG). During an ECG, electrical sensing devices, called electrodes or leads, are placed on the skin over the heart and at other sites on the chest and limbs. The Electrocardiogram is painless and there is no danger of electrical shock. The ECG helps to evaluate both the heart rates – the number of beats per minute – and the flow of electrical impulses through the heart muscle.
2. Your doctor will give you an anesthetic. It may be general or local. This will depend on the technique the doctor uses to place the device. There should not be significant discomfort.
3. **Catheter** introduction into the groin is most common and requires a small incision to be made on the inside of your upper thigh. This incision will allow an introducer sheath to be inserted into your femoral vein or artery. Your doctor will then insert a guiding **catheter** into the introducer sheath and advance it until it reaches your heart. Another option for **catheter** introduction is the arm (or brachial) approach. A small incision is made on the inside of your elbow. *Refer to Figure 4.* The doctor will perform a procedure (**angiogram**) to visualize your heart and the PDA.



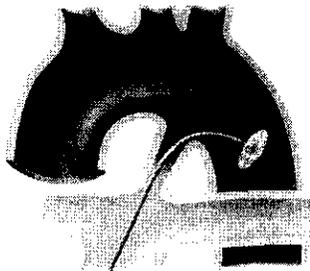
*Figure 4*  
*Access Sites*

4. Your doctor will then measure the pressure and oxygen content in different chambers of your heart and measure the size of the PDA.
5. The appropriate size AMPLATZER Duct Occluder is screwed onto an AMPLATZER Delivery Cable (Figure 5).



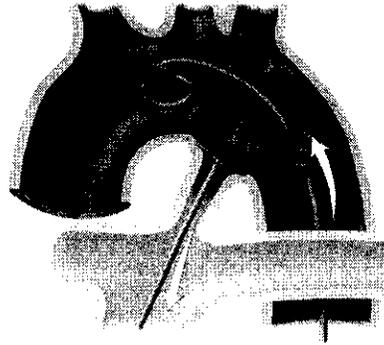
*Figure 5*

6. The Duct Occluder and the cable is put into a special *catheter* and advanced through the PDA. (Figure 6).



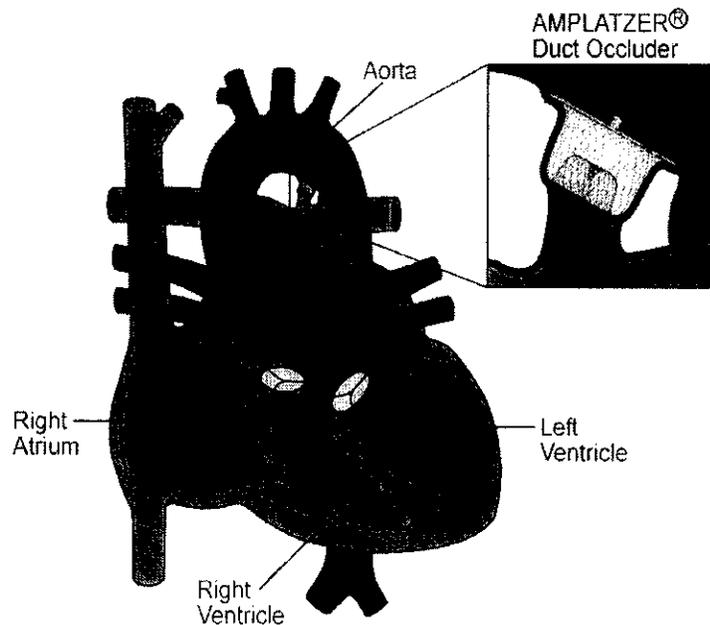
*Figure 6*

7. Your doctor will then push the device out of the *catheter* and implant the AMPLATZER Duct Occluder in the PDA. (Figure 7).



*Figure 7*

8. Your doctor carefully studies the device's position in your heart. When your doctor is satisfied with the device position, the device is released by unscrewing the cable that was used to slide it through the *catheter*. The AMPLATZER Duct Occluder is now implanted in your heart. Refer to Figure 8.



*Figure 8*

*Diagram of the heart with the device in place*

9. The *catheter* is removed and the procedure is completed.

### ***What to Expect after the Procedure***

After the procedure, you will be observed by the nursing staff. Your blood pressure will be checked frequently, and you may be attached to an ECG monitor so that your heart can be monitored continuously. While you are in bed, a nurse will check the site where the **catheter** was inserted as well as the pulses in your feet and arms.

If the femoral approach (groin area) was used for the procedure, you can expect to stay in bed for several hours. While the introducer sheath is in place, and for several hours after its removal, you will lie flat on your back in bed, keeping your leg with the sheath straight and still. If the brachial approach (your arm) was used for the procedure, you may be allowed to sit up afterwards, but you may be asked to stay in bed for several hours.

The procedure should take about 1-2 hours.

After recovery from anesthesia and bed rest, you should be able to sit up and walk about. You will be able to go home that day or stay overnight in the hospital. Before you leave the hospital, a chest x-ray and/or **echocardiogram** will be performed to make sure the device is still positioned properly.

Because the procedure is less invasive than open-heart surgery, your recovery should be easier. You may have an adhesive bandage on the **catheter** insertion site (groin or arm).

Before you leave the hospital, your doctor will give you guidelines for activities and medications.

Antibiotics will be required for **endocarditis prophylaxis** for certain medical procedures. Ask your doctor which procedures require you to take antibiotics.

### ***Follow-up visits with your Doctor***

It is important to keep all follow-up appointments that are scheduled for you. You will have to return to your doctor for periodic follow-up visits over the next year.

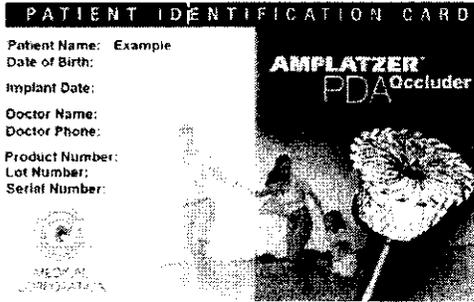
### ***When should a Doctor be called?***

If you experience any of the following symptoms, please contact your doctor immediately:

- Pain, numbness, coldness or weakness in your legs or feet
- Any back, chest, abdominal, or groin pain
- Dizziness or fainting, rapid heartbeat, or sudden weakness

***Patient Identification Card***

You will receive a wallet size Patient Identification Card. It is important to keep this card with you and show it to future health care practitioners to inform them that you have an AMPLATZER Duct Occluder. The Patient Identification Card also contains information to let health care practitioners know that it is safe for you to have a ***MRI***.



*Front of Card*

The carrier of this card has been treated with an implantable Patent Ductus Arteriosus closure device **3678**  
Device NON-FERROMAGNETIC / M.R.I. COMPATIBLE  
Notify your doctor if there is a change in your medical condition or address  
Manufactured by: **AGA Medical Corporation**  
Mendelssohn Avenue  
Golden Valley, MN 55427 (U.S.A.)  
Tel. +1-763-513-9227  
Toll Free +1-888-546-4407

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*Back of Card*

## FREQUENTLY ASKED QUESTIONS

***Will I have pain from the procedure?***

You may experience some discomfort in the area where the *catheter* was inserted. These symptoms should go away within a few days to a week.

***Will I be able to feel the device?***

No, you will not be able to feel the device.

***What happens with an AMPLATZER Duct Occlusion device once it gets implanted?***

The device is designed to remain permanently implanted in your body. It will take a matter of time (usually 3-6 months) before the device is completely covered by tissue.

***What activities should be avoided after my procedure? When can they resume?***

All strenuous activity should be avoided for one month after the procedure. Even though you may feel ready to resume your normal activity, you should take it easy for at least one month.

***What happens if I need an MRI (Magnetic Resonance Imaging)?***

Your AMPLATZER Duct Occluder device is *MRI* compatible up to 1.5 Tesla. If a *MRI* is needed, the *MRI* staff should be informed about the presence of your implant. You will receive a patient identification card that you should always carry with you and show to medical personnel.

***If I travel, can I go through metal detectors without setting off an alarm?***

Your AMPLATZER Duct Occluder device should not set off metal detector alarms. Once again, your patient identification card should be shown to airport security if necessary.

***Can I have this procedure if I am pregnant?***

The risk of increased x-ray exposure must be weighed against the potential benefits of this technique. Your doctor will ensure that care will be taken to minimize the radiation exposure to the fetus and the mother.

***What if I am a nursing mother?***

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

## GLOSSARY OF TERMS

**Angiogram** – An x-ray image of *blood vessels* or heart chambers filled with contrast media that allows your doctor to see moving pictures of your heart.

**Aorta** – The largest *blood vessel* in the body. The aorta is connected to the heart's left ventricle. The aorta carries oxygen-enriched blood to the body.

**Apnea** – Temporary absence of breathing.

**Arrhythmia** – Loss of regular heart rhythm.

**Arteries** – *Blood vessels* that carry oxygen-rich blood away from the heart and to other tissues throughout the body (except for the *pulmonary artery*, which carries oxygen-poor blood to the *lungs*).

**Blood vessel** – The pathways through which blood travels in the body.

**Brachial plexus injury** – Injury to the nerves in the arm and lower neck that can result from positioning a patient on an x-ray table.

**Cardiac catheterization** – A procedure in which *catheters* are passed through the *arteries* and veins of the heart. Pressures are measured and blood samples are taken through a *catheter* from within the heart and its major *blood vessels*.

**Catheter** – A sterile, flexible, hollow tube designed for insertion into a vessel to permit injection or withdrawal of fluids or to pass devices through.

**Cyanosis** – A bluish tint to the skin, lips, fingernails and other parts of the body due to lack of oxygen to the tissues.

**Ductus Arteriosus** – Small *blood vessel* connecting the *pulmonary artery* to the *aorta*.

**Echocardiography/Echocardiogram/Echocardiographic (Echo)** – The use of ultrasound to look at the heart, valves and great vessels.

**Endocarditis** – Redness, and swelling of the lining of the heart and its valves due to infection.

**Endocarditis Prophylaxis** – Medicine taken to prevent *endocarditis*.

**Embolus** – A mass, such as an air bubble or blood clot, that travels in the bloodstream and gets stuck in a small *blood vessel* and blocks or decreases blood flow.

**Heart defect** – Imperfection or malformation of the heart, existing at birth.

**Hematoma** – A mass of blood which is a result of a break in a *blood vessel*.

**Hemolysis** – The destruction of red blood cells.

**Hypertension** – High blood pressure.

**Hypotension** – Abnormally low blood pressure.

**Imaging Probe** – A flexible, tube-like medical instrument with a camera that shows a picture on a screen of what is inside the body.

**Lungs** – Pair of breathing organs located within the chest, which remove carbon dioxide from and bring oxygen to the blood. There is a right and left lung.

**Magnetic Resonance Imaging (MRI)** – A type of test used to visualize body tissue that uses a magnetic field.

**Myocardial infarction** – Heart attack. Damage or death of myocardial (heart muscle) tissue caused by an interruption of blood flow to the area.

**Occlusion** – To occlude or block an opening.

**Patent** - Open

**Patent Ductus Arteriosus (PDA)** – A term used to describe an open arterial duct connecting the *pulmonary artery* to the aorta.

**Percutaneous** – Passed through the skin.

**Pulmonary Artery** – The artery connected to the heart's right ventricle that carries oxygen-depleted blood to the *lungs*.

**Thrombus** – Blood clot.

**Transcatheter** – Through a *catheter*.

**Valvular Regurgitation** – An abnormal backward flow of blood through a valve.

