

Nit-Occlud[®] PDA

A Patient's Guide to Non-Surgical Closure of
the Patent Ductus Arteriosus (PDA)

Using the Nit-Occlud[®] PDA

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English Version

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.

Warranty

pfm medical warrants that this medical device is free from defects in both materials and workmanship. The above warranties are in lieu of all other warranties, either expressed or implied, including any warranty of merchantability or fitness for a particular purpose.

Suitability for use of the medical device for any surgical procedure shall be determined by the user. pfm medical shall not be liable for incidental or consequential damages of any kind.

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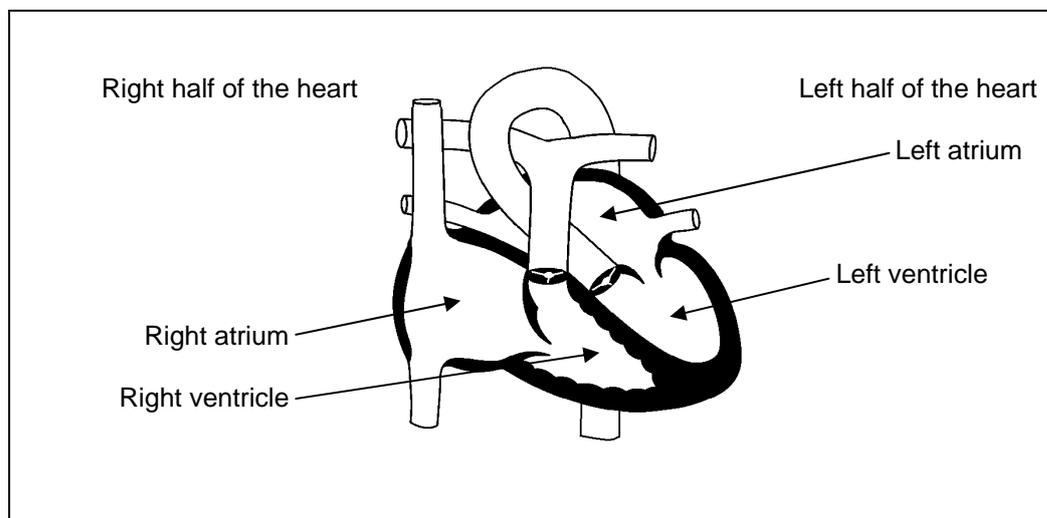
About "PDA" ("Patent Ductus Arteriosus")

Your heart has a small opening that allows blood to flow in a different way than a normal heart. It is called a "patent ductus arteriosus," or "PDA." This book will help you understand PDA, your procedure, and how to stay healthy afterward. **Always feel free to ask your doctor any questions!**

All About Your Heart

To better understand PDA, it is helpful to understand the way blood moves—or circulates—through and around your body. Your heart is a pump that pumps blood throughout your body. This allows your body—including all the organs, muscles, and tissues inside—to get the oxygen it needs to function.

There are two chambers on the right side and two on the left. The two chambers in the top of your heart are called the left atrium and the right atrium (**Picture 1**). The atriums receive and collect blood. The two chambers in the bottom are called "ventricles" (**Picture 1**).



Picture 1: A healthy heart.

The right ventricle pumps blood to your lungs to get fresh oxygen that your body needs to live. Inside your body, blood is carried by vessels. Vessels include veins and arteries. Some of the larger vessels that enter and leave your heart are the aorta, pulmonary

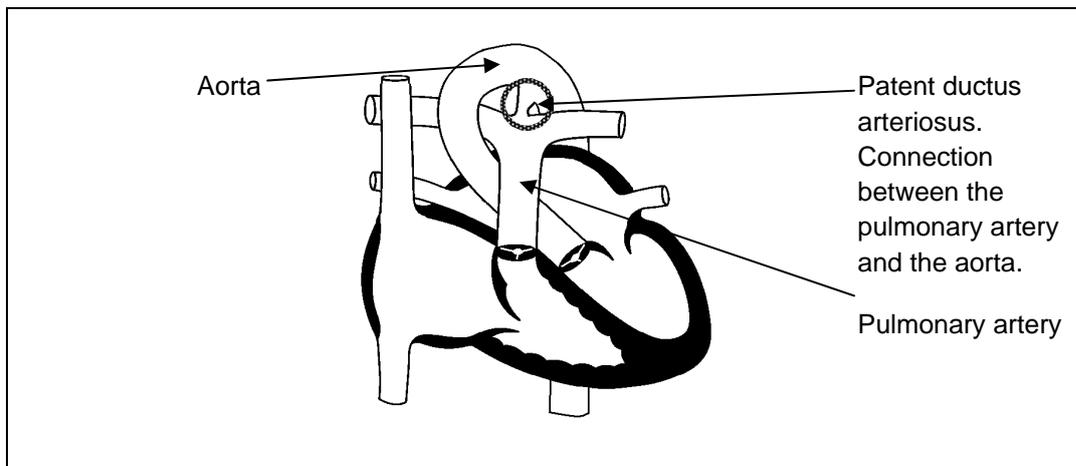
artery, and pulmonary vein. To get oxygen from the lungs, the right side of the heart pumps blood to the lungs by the pulmonary artery. It is the only artery in the body that carries blood without oxygen.

First blood is in the right side of the heart. Then it is pumped through the lungs, where it receives oxygen. After this, blood moves to the left side of your heart. There, it is pumped to your body by the left ventricle. The artery carrying blood to your body is called the aorta.

Questions? Ask your doctor!

Why We Have a PDA

During development in the womb, blood flows from your pulmonary artery to your aorta through the ductus arteriosus. (Picture 2)



Picture 2: Heart with a PDA ("Patent Ductus Arteriosus").

At birth the ductus arteriosus closes, allowing the pulmonary arteries to get oxygen from the lungs and the aorta to carry it to the rest of the body. If the ductus arteriosus remains open or "patent" after birth, it's called a "Patent Ductus Arteriosus," or "P-D-A."

No one knows why the ductus arteriosus doesn't close in some people. Being born before complete development (premature) may be one reason. PDA seems to be more

common in girls than boys. It also may be more common in kids with other heart problems called congenital heart defects.

The PDA can sometimes be detected (with a doctor's stethoscope) by the presence of a heart murmur. Other times doctors find out about a PDA after doing other tests on the heart.

Questions? Ask your doctor!

Why You Need to Visit the Hospital: Closing the PDA

Some people with PDAs that are not closed feel very tired. Others have trouble breathing or are at increased risk for infection. Still others don't grow and mature naturally. Some people have no signs of PDA at all.

If the PDA is not closed, blood can move in abnormal ways called "shunts." A shunt can carry blood from the left side of your heart to the right side through the PDA. This can overload the arteries supplying blood to your lungs, leading to "high blood pressure" in and around your lungs. In the body, high blood pressure in the main artery to the lungs—the pulmonary artery—can be very harmful. It can also lead to other problems such as inflammation or infection of the pulmonary artery or movement ("shunting") of blood from the right side of your heart to the left. Blood with too little oxygen from the right side of your heart can reach your aorta through the PDA and can cause your body to receive blood without enough oxygen.

Questions? Ask your doctor!

Purpose of the Nit-Occlud® PDA Device

To close (or occlude) your PDA, the doctor will place (or implant) a small coil in the duct connecting your pulmonary artery and aorta called the "Nit-Occlud® PDA." During the procedure, the Nit-Occlud® PDA will be passed into the PDA near your heart by a plastic tube

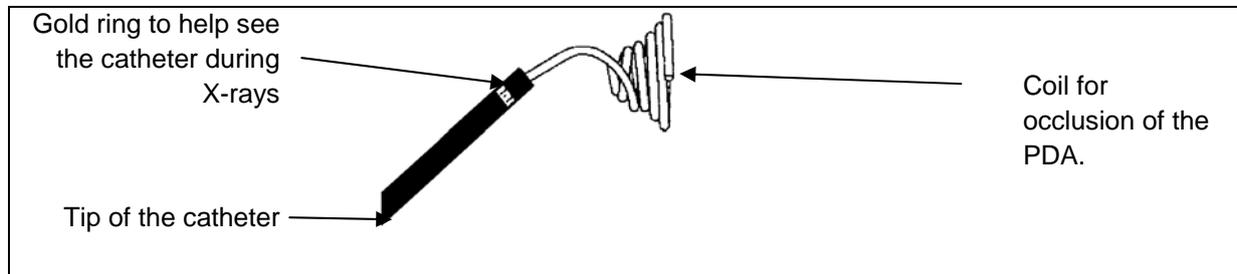
called a "catheter." To implant the device and close your PDA, the doctor will make a small opening in an artery and vein in your groin. Then the catheter can be passed toward your heart, and the coil moves within the catheter. Once the coil is released, it closes or occludes the PDA. The Nit-Occlud[®] PDA will stay there after your procedure and your body will grow around it. The coil will keep the PDA closed.

This kind of procedure is called "percutaneous," which means "beneath the skin" (through an artery and vein).

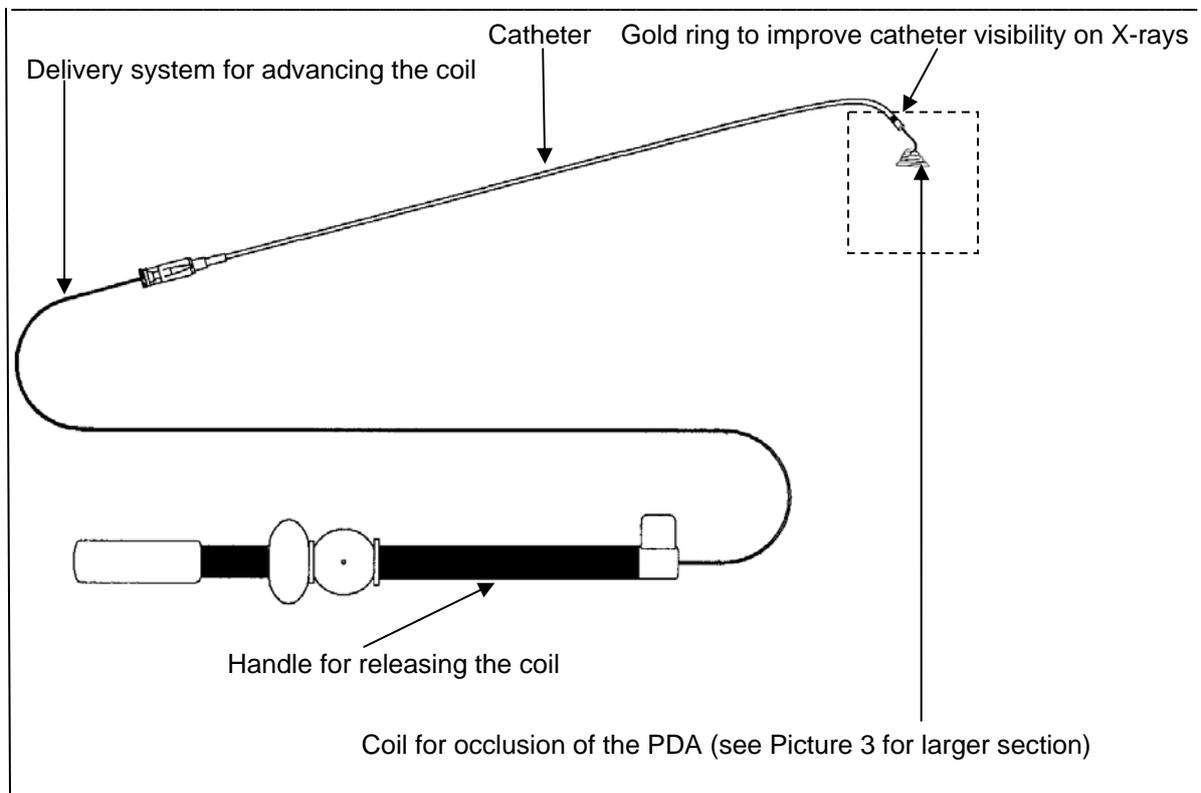
Questions? Ask your doctor!

Description of the Nit-Occlud® PDA Device

The Nit-Occlud PDA device is a small spring-like "coil" (**Picture 3**) shaped like a cone. The coil is made of nickel and titanium ("Nitinol").



Picture 3: Nit-Occlud® PDA catheter tip and coil system for closing ("occluding") the PDA.



Picture 4: Nit-Occlud® PDA system: coil, catheter, delivery system, and handle.

The coil can be pulled out of shape to pass through the catheter into your PDA. In this way, the metal has "memory." When it is pushed out of the catheter, it remembers its original coil shape and returns to that shape. The coil is designed to fit snugly inside the PDA. The Nit-Occlud® PDA coil is used to close small or medium PDAs—openings of

about 4 millimeters across ("in diameter") or less.

The Nit-Occlud[®] PDA includes the catheter and coil. A gold ring is fitted to the tip of the catheter so that the doctor can see it on X-rays. The coil is attached to a delivery system. The coil is pushed through the catheter using the delivery system. Once the coil has been placed in the PDA, it can be released from the delivery system using the handle (**Picture 4**).

Questions? Ask your doctor!



When the Device Should Not Be Used (Contraindications)

The Nit-Occlud[®] PDA should **NOT** be implanted if you have:

- An infection.

- A blood clot near where the Nit-Occlud[®] PDA coil will be placed. A clot is a clumping of blood cells called a "thrombus." A blood clot can block or "occlude" one of your veins or arteries and make the procedure difficult to perform (among other problems).

- A body weight of less than 11 pounds.

- High blood pressure in the pulmonary artery and smaller arteries in the lung.

- A very large PDA. Your doctor should not use the device to close PDAs that are more than 4 millimeters across (in "diameter").

- A blood clot in an artery that the Nit-Occlud[®] PDA coil needs to pass through.

- **Questions? Ask your doctor!**

Risks and Benefits of the Procedure

What Are the Risks?

All medical procedures involve risks. In the closing of PDAs using the Nit-Occlud[®] PDA, some risks are due to the procedure, and others are due to the device.

In a clinical study, a total of 357 patients at 15 hospitals in the United States received the Nit-Occlud[®] PDA to close their PDAs. These patients were ages 6 months to 21 years. The patients had PDAs with diameters of 4 millimeters or less, and the patients also weighed at least 11 pounds.

In the study, the following side effects ("adverse events") were seen. Most of these had no lasting effects.

In 3 patients out of 357 receiving the Nit-Occlud[®] PDA:

- The coil moved away from the PDA and entered a vein or artery. Patients experienced nausea and vomiting.

In 2 patients out of 357 receiving the Nit-Occlud[®] PDA:

- A blood clot formed in an artery.

In 1 patient each out of 357 receiving the Nit-Occlud[®] PDA:

- The device got trapped in a blood vessel.
- The aorta became more narrow than usual.
- A blood clot formed on the coil.
- A rash formed after tape was placed on a patient.
- The patient had trouble breathing.
- The patient got a fever (high body temperature).
- The patient had a seizure.

Other Possible Risks

Some harmful effects of the procedure not seen in the study mentioned above that can happen with this type of procedure include the following. (They may occur in less than 1 to 9 patients out of every 1,000):

- Abnormal connection between blood vessels
- Air bubbles in the blood, leading to blood vessels closing.
- Allergic drug reaction
- Allergic dye reaction
- Bruises in the region where the catheter was inserted.
- Changes in how the heart beats— arrhythmia.
- Chest pain
- Collection of blood outside the vessel (hematoma)
- Death
- Harming one of the valves in the heart.
- Harming "red blood cells," which carry oxygen. This is called "hemolysis."
- Harming the heart or vessels where the catheter was placed
- Headache/migraine
- Heart attack
- Heavy bleeding
- High or low blood pressure.
- Infection or inflammation of blood vessels or lining of the heart and valves.
- Piercing of a vessel or heart (perforation)
- Temporary absence of breathing (apnea)
- Temporary lack of oxygen to the brain (Stroke/ Transient Ischemic Attack)
- Weakening heart ("cardiac insufficiency").

What Are the Benefits

The main benefit of having the Nit-Occlud[®] PDA is that you most likely won't need open-heart surgery. Your "percutaneous" procedure is less "invasive" than surgery. This usually means:

- A shorter procedure: usually 1 to 2 hours instead of 2 or more hours for surgery.
- A shorter stay in the hospital: usually 1 to 3 days instead of 4 to 10 days for surgery.
- No scar on your chest. Very little scarring or no scarring at all (in your groin).

Other Ways to Handle a PDA (Alternatives to the Procedure)

- Surgical Closure of PDA. The chest is opened surgically. This allows the surgeon to see the whole heart and large vessels. The surgeon sews up the PDA using stitches to keep the PDA closed permanently. Sometimes this kind of surgery is needed when the PDA is large.
- Medication to help close the PDA or treat symptoms of the PDA
- No treatment: a small PDA may close on its own.

What to Expect Before, During, and After the Procedure

Before the Procedure

Before the procedure, the doctor will look at your heart with a test called an "echo" (echocardiogram), where pictures of your heart and vessels will be taken. The doctor will also perform an "ECG" ("electrocardiogram"). For this test, small pads (circles) made of plastic with metal endings ("leads") are placed on or around your chest and other parts of your body. The ECG helps your doctor make sure that your heart is beating in the right way.

The doctor will also do a "physical examination" and blood test to make sure you don't have an infection.

Just before your procedure, you will be given anesthesia through an "IV" ("intravenous") line. You may also have a "local" anesthetic rubbed on your thigh or groin area where the doctor will insert the catheters for your procedure. This is to make the area numb so you don't feel discomfort during the procedure. Some patients feel temporary stinging or burning from the anesthetic.

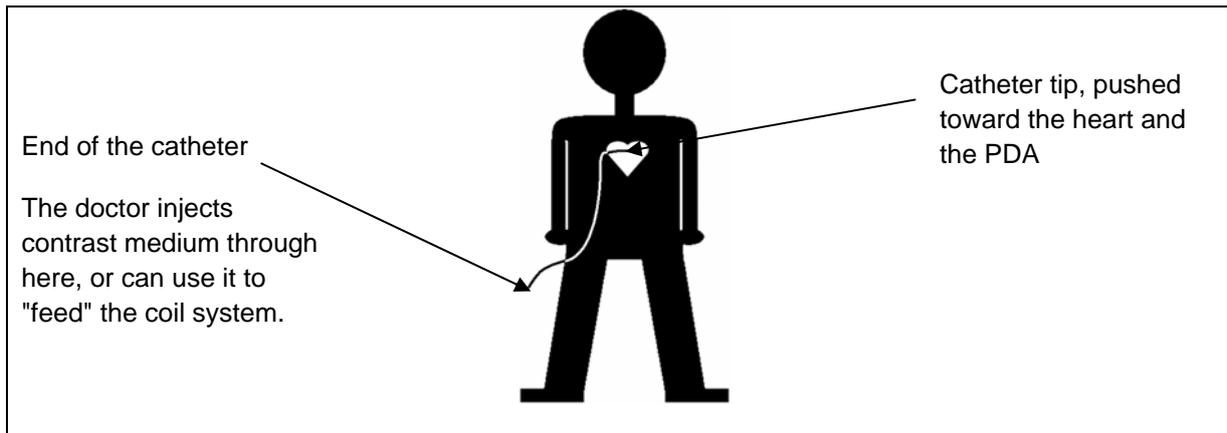
The procedure will take place in the "cath lab" ("catheterization laboratory") where hundreds or even thousands of procedures like yours are performed every year. The doctor will perform an "angiogram", which is a special X-ray that allows doctors to see inside your blood vessels. Doing this special test allows your doctor to get a clear picture of your PDA.

During the Procedure

The procedure itself takes 1 or 2 hours. During the procedure, cameras will move above your chest area to help guide the doctors. They will also use an ECG to monitor your heart. You may feel some discomfort in your groin area when the catheters go in. Some people feel extra heart beats from the catheter when it is inserted.

Step 1.

The doctor puts the two small plastic tubes (catheters) into a vein and artery in your groin. Then the doctor moves one of the catheters up your body toward your heart and vessels (pulmonary artery and aorta; **Picture 5**). In the other catheter, the doctor gives contrast medium. This liquid helps the doctor to see your PDA on an angiogram.

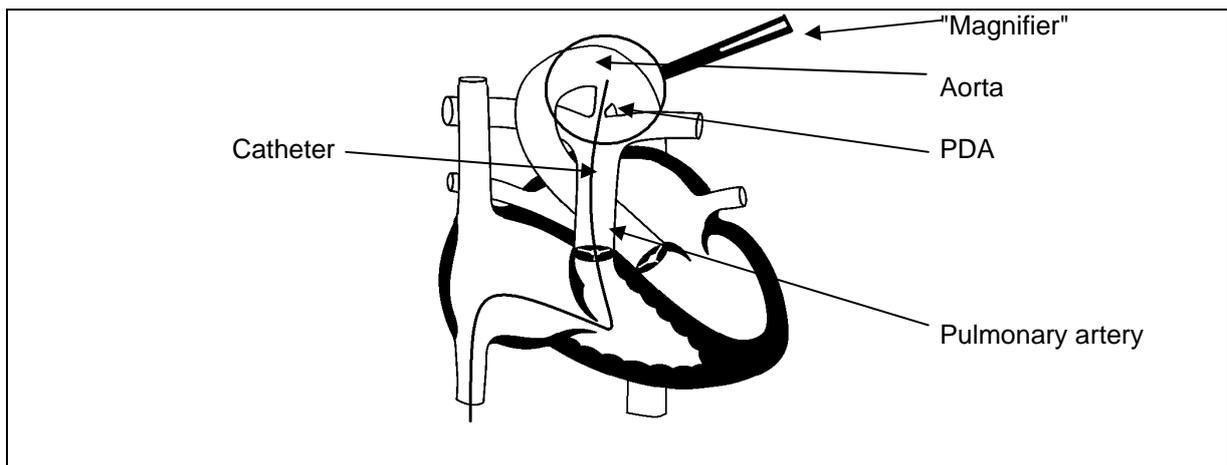


Picture 5: How the catheter moves through the body.

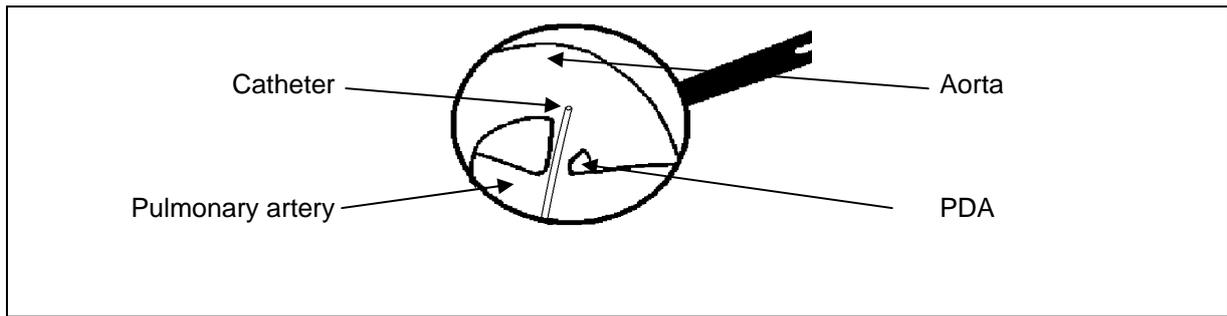
Step 2:

The Nit-Occlud[®] PDA device stays inside the catheter. The doctor passes the catheter (with the device inside) through an artery and vein. As he or she does, the coil gets closer and closer to your PDA.

First the coil pushes into the chambers on the right side of the heart until it reaches the pulmonary artery. The doctor uses the special X-ray (angiogram) to make sure that everything is in the correct place. When sure, the doctor feeds the catheter through the PDA and into the aorta (**Pictures 6 and 7**).



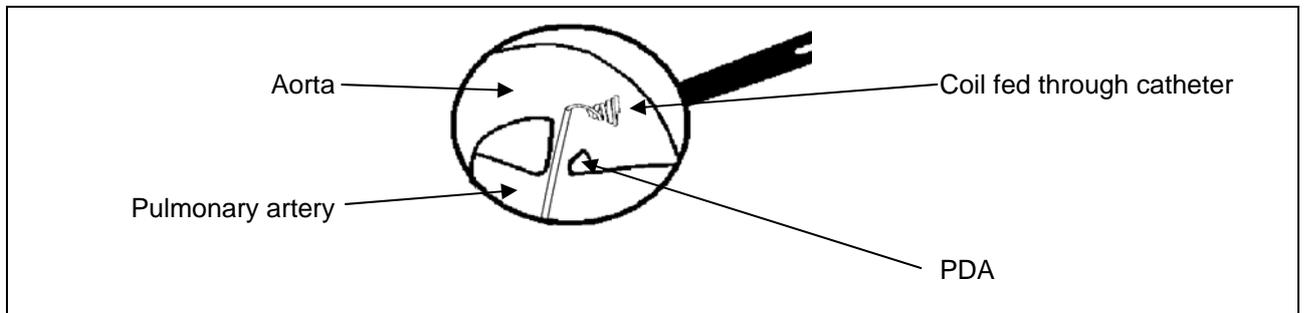
Picture 6: The catheter feeds through the heart and PDA into the aorta.



Picture 7: Bigger picture of Picture 6. The catheter feeds through the heart and PDA into the aorta.

Step 3:

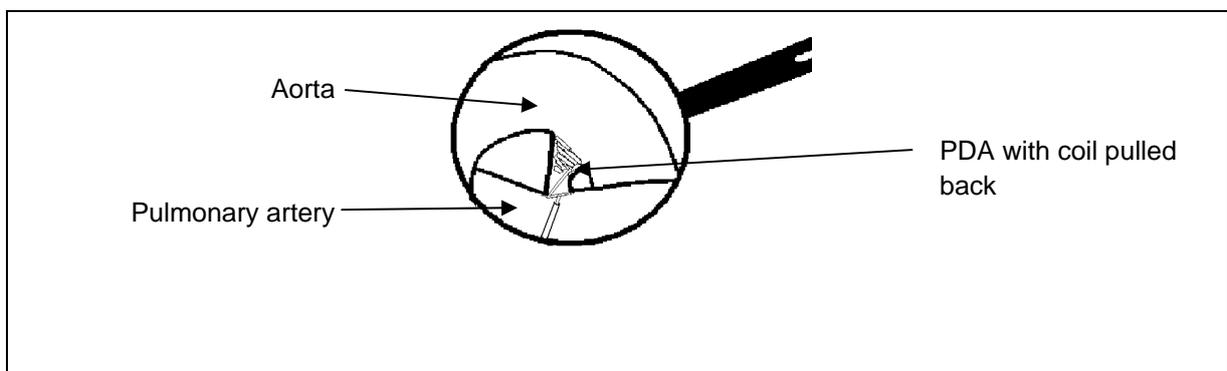
Next the doctor pushes the Nit-Occlud® PDA coil out through the catheter. Once out of the catheter, the coil returns to its spiral shape (**Picture 8**).



Picture 8: Coil fed through catheter.

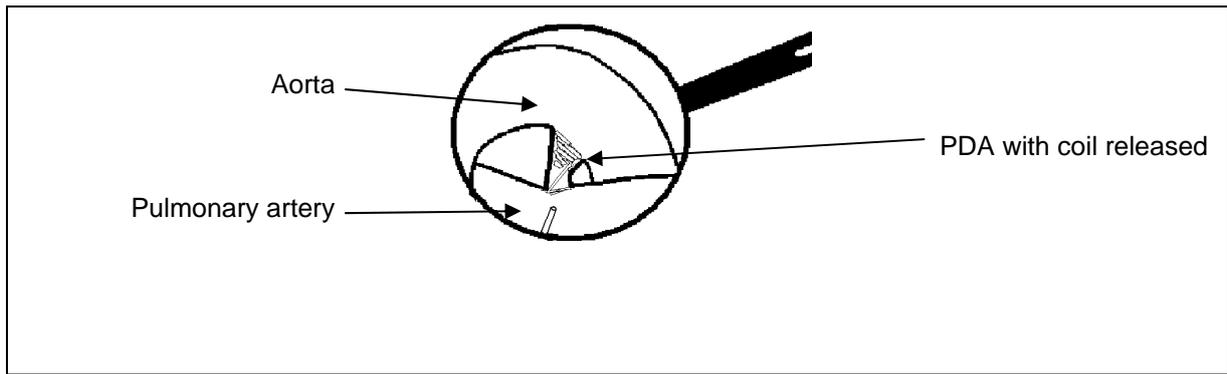
Step 4:

The coil is still attached to the catheter. Next, the doctor places the coil into the PDA (**Picture 9**). The coil is designed to fit snugly inside the PDA.



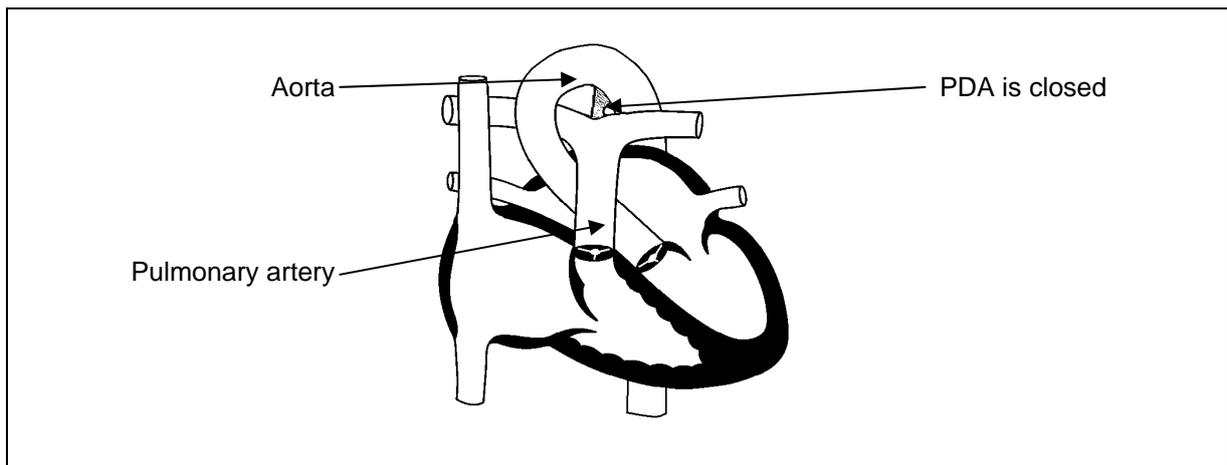
Picture 9: The coil is pulled back and fitted to the PDA.

The doctor releases the coil (**Picture 10**). X-rays (angiograms) guide the doctor. The coil is now inside the PDA.



Picture 10: The coil leaves the catheter toward the PDA.

Now, or soon after, the doctor takes out all catheters from your heart and body. The Nit-Occlud[®] PDA coil stays near your heart. The PDA is now closed (**Picture 11**). Over time, your body will grow around and over it.



Picture 11: The PDA is closed.



After the Procedure: REST!!

The doctor will take out the catheters. There may be two small marks in your groin where the catheters were inserted, and you may have some soreness or tenderness in your groin area. These will go away and you should have no scars or very small ones.

A special large adhesive bandage will be placed on your groin called a "pressure bandage." This helps to prevent bleeding at the place where the catheters were inserted. You should be able to go home (or be discharged) after 1 to 3 days in the hospital. Before discharge, a chest X-ray and an echocardiogram may be done to confirm that your device is in the correct place and your heart is OK. If the device is working, it will stay in your body for the rest of your life.

The doctor will go over your medicines and activities with you and your family or caregivers. You may need to take medication so you do not get an infection that can be serious. Your doctor will let you know if you need to take them and, if so, for how long.

During the first 4 to 6 weeks after returning home, strenuous activity such as heavy lifting should be avoided, Activities such as jumping, running, lifting, biking, or gymnastics should also be avoided. After 4 to 6 weeks, most patients can return to normal activity.

Questions? Ask your doctor!

Patient ID ("Identification") Card

As a patient with a Nit-Occlud[®] PDA device, it is important to carry a Patient ID Card to identify you as having an implanted device. Show it whenever you see a doctor or dentist for treatment. The Patient ID Card has information about safety including safe ways to do MRIs in patients with a Nit-Occlud[®] PDA. You or your mother, father, guardian, or caregiver should register the MRI information in your Patient ID Card with MedicAlert. MedicAlert provides important information to healthcare workers. This helps emergency responders, hospital staff, and others make informed decisions about your care.

Contact:

Mail: MedicAlert Foundation International

2323 Colorado Avenue

Turlock, CA 95382

Phone: (800) 432 5378 (toll-free)

Emergency: (800) 625 3780 (toll-free)

Fax: (800) 863 3429 (toll-free) or (209) 669 2495

Web: www.medicalert.org

Follow-up Visits With Your Doctor

You will probably go back and see your doctor a few times in the first year after getting your Nit-Occlud[®] PDA. It is important for you and your family or caregivers to make and keep appointments with your doctor. The doctor may wish to do an echocardiogram to make sure everything is OK.

When to Call the Doctor

If you feel any of the feelings below, you, your family, or caregiver should contact your family doctor right away:

- Pain, numbness, or a feeling of coldness or weakness in your legs or feet.
- Any pain in your back, chest (or rib cage), stomach, or groin region.
- A stronger and faster heartbeat than usual ("palpitations").
- Trouble breathing ("breathlessness").
- Fainting ("passing out"/"syncope") or dizziness.

Additional Information and Help

You, your family, or caregiver can find useful information on the Internet. Feel free to visit the following websites.

- The Adult Congenital Heart Association provides information and support for adults and older kids ("adolescents"). They provide information about heart problems that people are born with ("congenital heart disease") to patients, their families, and healthcare professionals. Click on: <http://www.achaheart.org/>
- The Congenital Heart Information Network is a non-profit group that provides support and information on congenital heart disease. They work to make people more aware of these problems. Click on: <http://tchin.org/>
- Little Hearts Inc. is a non-profit group that provides support services for families affected by heart disease. Click on: <http://www.littlehearts.org/>
- The Children's Heart Society is a non-profit group including parents and extended families of children with heart disease. Click on: <http://www.childrensheart.org/>

(The respective operators are solely responsible for the contents of the websites listed above.)

For More Information, Contact pfm medical:



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