Patient guide:

Catheter occlusion of

Patent Ductus Arteriosus

with the

*pfm Nit-Occlud® PDA coil occlusion system*
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**What is Patent Ductus Arteriosus (PDA)?**

Before birth, a baby’s heart and lungs function differently than they do after birth. Before birth, the lungs do not put oxygen into the baby’s blood. Instead, the baby receives oxygenated blood from the mother through the umbilical cord. The Ductus Arteriosus, a blood vessel which connects the pulmonary artery and the aorta, provides a “short-cut” for oxygen-rich blood to by-pass the lungs.

After birth, the baby is separated from the mother and the baby begins to breath. The lungs begin to supply the infant with oxygen. Blood now passes through the lungs and, for most infants, the Ductus Arteriosus closes. The Ductus normally closes on the first day after birth. However, sometimes it remains open (or patent). If the Ductus Arteriosus remains open beyond a few days after birth, it is referred to as a Patent Ductus Arteriosus (PDA).

After only a few days, blood flow through the PDA reverses direction and starts to flow into the lungs from the aorta. When this happens, the chamber of the heart known as the left ventricle not only has to pump blood to the body’s organs, but also has to pump blood through the PDA into the lungs. The lungs receive additional blood which may cause them to become congested. Lung congestion increases the effort required for breathing and also predisposes the infant or young child to lung infections. If the PDA is moderate or large in size, these problems may lead to poor growth, dilation and poor function of the heart, and heart failure.

In addition, the presence of a PDA, whether small, moderate, or large, increases the risk of a rare serious infection inside the PDA and pulmonary artery called endarteritis.

If a PDA is large and remains open for many years, the blood pressure in the pulmonary artery remains high and may damage the small branches of the pulmonary artery. Because of the high pressure, the walls of the pulmonary artery branches may become narrow and less flexible. Once the structure of the pulmonary vessel changes, the blood pressure in the pulmonary artery rises, and it is harder for blood to flow through the lungs. Eventually, the pulmonary artery pressure may become higher than the blood
pressure in the aorta causing the blood to reverse its flow a second time, flowing from
the pulmonary artery into the aorta. If this occurs, the patient becomes cyanotic, i.e. the
skin takes on a blue color because it is supplied with blood low in oxygen. This condition
is known as Eisenmenger Syndrome.

Figure 1: Illustration of a normal heart (left) and illustration of a heart with PDA (right). The
PDA is located between the aorta (AO) and the pulmonary artery (PA).

RA → right atrium
RV → right ventricle
PA → pulmonary artery
LA → left atrium
LV → left ventricle
AO → aorta
blue → blood low in oxygen
red → blood rich in oxygen
**Treatment of PDA**

Small PDA may close without treatment, usually by the time an infant is one year old. During the newborn period, especially in premature babies, medication may be given to help a PDA close. If the PDA does not close by itself or if it is very large, it may be treated with heart surgery. Surgery involves opening the chest, suturing the PDA so that it is permanently closed. Patients typically must be hospitalized for three to five days.

Heart catheterization technology provides a treatment option which is much less invasive than surgery and requires hospitalization for less than one day. A device may be placed using a heart catheter to occlude or plug the PDA. The Nit-Occlud® PDA occlusion system is inserted into the PDA through the groin (femoral) vein. The femoral artery must also be used to assist in positioning the device. This system implants a coil device that is carefully positioned in the PDA so that it blocks the flow of blood through the PDA. The pfm Nit-Occlud® PDA coil occlusion system is described below.

**Description of the Nit-Occlud® coil occlusion system**

The pfm Nit-Occlud® PDA coil occlusion system is a metal coil (figure 2) made of nickel and titanium (Nitinol). This metal has “shape-memory,” which means it remembers its coil shape after it has been pulled apart. Thus, it is possible to pull the coil straight and insert it through a small catheter. When the catheter is placed in position to implant the device in the PDA, the coil may be pushed out of the catheter and it rewinds into its original shape in the PDA.
Figure 2: Coil with implantation catheter (incl. gold marker in order to make the catheter visible by x-ray).

The coil is placed in a special transport system (figure 3), with which the cardiologist directs the coil to the heart, configures it and places it in the PDA. With this system, the coil can also be detached in the PDA.

Figure 3: The complete system (starting from the left)

a  →  handle ("remote control" to detach the coil)
b  →  transport system (to push the coil through the catheter)
c  →  valve which prevents blood from flowing from the patient through the catheter
d  →  implantation catheter
e  →  extended coil
When the coil occlusion system is appropriate (indicated) for closing a PDA

In most infants, children, and adults with small to moderate PDA, the Nit-Occlud® System implanted by heart catheterization is appropriate treatment.

Contact your doctor for further information!

When the coil occlusion system is inappropriate (contraindicated)

The following is a list of conditions that are contra-indications for using the coil occlusion method:

- Illnesses which cause a bleeding tendency
- Active infection at the time of the heart catheterization
- Allergy to angiographic contrast medium or to Nitinol metal
- Pulmonary hypertension (Eisenmenger’s Syndrome)
- Very large or dilated PDA
- Blood Clot (Thrombus) near the implantation location
- Thrombus in a blood vessel through which the Nit-Occlud® implantation system must pass
- Patient weight less than 5 kg (11 pounds).

Contact your doctor for further information!
Risks of the implant procedure and the Nit-Occlud® coil occlusion system

Complications related to the Nit-Occlud implant procedure or the Nit-Occlud® device are very unlikely but may include:

- Air embolism
- Arrhythmia requiring medical treatment or pacemaker insertion
- Blood loss requiring transfusion
- Death
- Embolization of the occluder, requiring percutaneous or surgical intervention
- Endarteritis
- Heart failure
- Hemolysis after implantation of the occluder
- Hypotension or shock
- Myocardial infarct
- Occluder fracture or damage
- Perforation of the heart or of blood vessels
- Residual PDA shunting
- Stenosis of the left pulmonary artery or descending thoracic aorta
- Thromboembolism
- Vessel damage at the place of the puncture (loss of pulse, hematoma etc.).

Note: Patients with a nickel allergy may have an allergic reaction to the device.

Also, if you are pregnant (or think that you might be pregnant), please inform your doctor. The X-rays may harm your baby.
Description of the implant procedure

The procedure is performed in the cardiac catheterization laboratory under x-ray guidance (fluoroscopy). The patient is attached to an ECG so that the heartbeat can be monitored during the entire intervention. The patient is given local anesthesia in the groin. The patient also receives intravenous medication or general anesthesia.

Catheters are inserted into the vein and artery in the groin (femoral vein and artery). Only two small needle punctures are needed for this.

A catheter is passed through the arteries up to the aorta and placed near the PDA. Contrast medium is injected through this catheter. With the help of the contrast medium, the PDA becomes visible and the cardiologist measures it and chooses the proper sized Nit-Occlud® coil to be implanted. An implantation catheter is advanced through the femoral vein to the heart. The catheter is passed through heart chambers (right atrium and right ventricle), the pulmonary artery, and across the PDA into the aorta. The occlusion system is passed through this catheter into the aorta and “shape memory” returns to the device to its predetermined coil shape (figure 4).

![Figure 4: Nit-Occlud® coil in the aorta](image)

At this point, the whole system is pulled into the PDA (Figure 5). Another contrast injection (angiogram) is performed to check the position of the coil. If the coil is in good position, it is detached from the delivery system (using the handle) (Figure 6).
After another angiogram, all catheters are removed from the patient's body and the patient has a pressure bandage placed on the groin area. The procedure usually takes less than two hours.

**What happens after PDA occlusion with the coil occlusion system?**

After the procedure the patient lies quietly in the recovery room for several hours. The leg on the side where the catheters were inserted, must stay straight. This is necessary
in order to prevent bleeding in the groin. The nursing staff checks the bandage frequently. In order to monitor the circulation in the patient’s leg, the pulse in the foot is also checked.

The patient usually leaves the hospital less than one day after the procedure. Before the patient is released from the hospital, an X-ray or echocardiogram is performed, in order to double check the position of the coil occlusion system.

The cardiologist informs the patient about further check-ups and activity guidelines. If dental procedures or certain other surgical procedures become necessary, the patient will be given antibiotics before the procedure.

**The patient should immediately contact the doctor for?**

- Pain, sensation of numbness, sensation of cold or weakness in the legs or feet
- Pain in the back, chest, stomach or groin
- Palpitations or strong rapid heart beats
- Shortness of breath
- Fainting or dizziness

**Patient Card**

After the coil implant, the patient receives a patient card. It is important that the patient or parent carry the card at all times. The card should be shown at medical examinations and treatments, so that physicians may be informed that you have a pfm Nit-Occlud® PDA coil occlusion system. Furthermore, the patient card provides information MRI safety.
Frequently asked questions

Is the procedure painful?

Temporary discomfort may occur where the catheters are inserted.

Will I feel the coil?

No.

What happens with the implanted coil?

The coil is a permanent implant and is completely covered by the body’s own cells within a few months. This means it becomes surrounded by the body’s own tissues.

For how long will I be limited in my activities after the implantation?

All heavy physical activities should be avoided for one month after the implantation.

What happens if an MRI (magnetic resonance imaging) has to be carried out?

Before MR procedures, consultation with a qualified radiologist is recommended. Inform the MRI doctor about the coil and present the patient card.

Can I go through the security checks at the airport without problems?

The implant should not activate security alarms.

Can I undergo this procedure during pregnancy?

The X-ray exposure may harm your baby. You and your doctor should consider the risks and benefits carefully.

What if I am breastfeeding?

There is no information available about this, and it has not been studied. However, there are no known harmful effects of the coil on mother’s milk.
Explanation of the terms used

**Air embolism**: air entering into the blood stream, possibly causing blockage of blood vessels.

**Arrhythmia**: irregularity of the heart rhythm, including very rapid or very slow heart rates.

**Coagulation**: clotting of blood.

**Descending Aorta**: a part of the aorta.

**Embolisation**: migration or moving to an unplanned location.

**Endarteritis**: inflammation of an artery caused by infection.

**Hematoma**: a collection of blood usually at the site of catheter insertion into the groin.

**Hemolysis**: destruction of the red blood cells causing low blood count.

**Heart attack**: heart: death or injury to part of the heart muscle.

**Hypotension**: low blood pressure.

**Myocardial infarct**: death or injury to part of the heart muscle.

**Percutaneous**: through the skin.

**Perforation**: rupture or puncture of tissue or an organ.

**Pulmonary artery**: lung artery.

**Rupture**: disruption of a blood vessel.

**Shunt**: blood flow directly between arterial and venous systems.

**Stenosis**: narrowing or partial blockage of blood vessels.

**Thrombo-embolism**: blockage of a blood vessel caused by a blood clot.

**Thrombus**: blood clot.

**Transfusion**: infusion of blood or blood components.
Further information

We are happy to answer any further questions you have.

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