University Hospitals of Leicester
NHS Trust

Having a closure device placed to treat a hole (patent foramen ovale) in your heart

Department of Cardiology

Information for Patients

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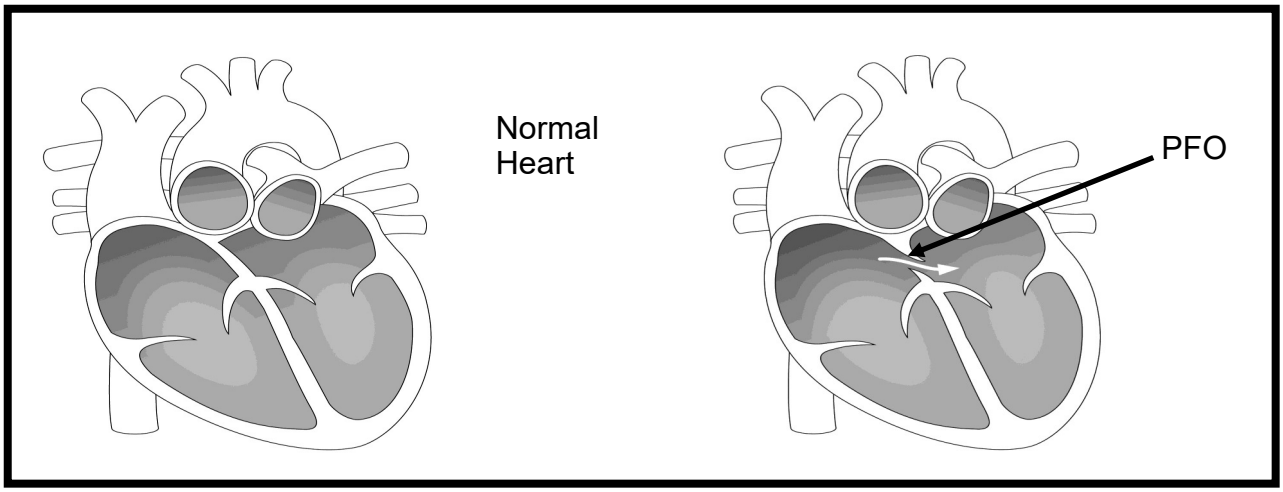
Introduction

You have a hole in your heart which is also known as a patent foramen ovale (PFO). This leaflet explains the procedure to close this hole in your heart, including why you need the procedure, the possible risks and what to expect when coming into hospital.

What is a patent foramen ovale (PFO)?

A PFO is a hole in the heart. This hole is between the 2 top chambers of your heart. All babies have it. It closes in most people straight after birth. In about 1 in 4 people, it may not close fully. Most people with a PFO do not have any symptoms or problems. In some rare cases, it can let blood clots cross from the right side of the heart to the left, and then into the brain. This can cause a stroke.



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How is a PFO closed?

A device called a PFO occluder can be placed in your heart. It stops blood flow through the PFO. In the past, the only way to close these holes was through an open-heart surgery. Nowadays, a PFO can be closed by a small operation using a vein in your groin.

Why should I have this procedure?

Closing the PFO lowers the risk of problems like stroke. The procedure is successful in 95% of cases, with no major complications. If you have had a stroke with no known cause (cryptogenic stroke), closing the PFO may help prevent another stroke.

What are the risks of the procedure?

The risks of the procedure are given below. They are also on the consent form:

There is a less than 1 in 100 overall risk of major complications in hospital, including:

- 1 in 1000 risk of death, heart attack (myocardial infarction), or major bleeding.
- 1 in 1000 risk of unintended position of the device causing an obstruction (device embolization), needing more surgery.
- 3 in 1000 risk of the device moving out of place (dislodgment).
- 3 in 1000 risk of stroke.

There is a 2 to 3 in 100 overall risk of minor complications, including:

- 1 in 100 risk of new or worsening irregular fast heart rate (atrial fibrillation).
- 1 in 200 risk of minor bleeding which may need surgery.
- 1 in 250 risk of the device positioned in an unintended location (device malposition).
- 3 in 1000 risk of new or worsening migraine.
- 1 in 1000 risk of minor cardiac structural complication.

You may need more procedures during your operation. These may include:

- a blood transfusion (we will give you more information in the pre-assessment clinic).
- giving you medicines to keep your blood pressure and heart rate within the normal range (urgent haemodynamic support).
- emergency cardiac surgery.

What happens before the procedure?

- You will meet with a heart doctor (cardiologist) to talk about your history and the procedure.

- If you agree to have the PFO closure you will be asked to come for a pre-assessment appointment with a nurse. This is a few days or a week before the procedure.
- We will talk to you about your past medical history and any medicines you are taking. It is important that you bring a list of your all your medicines with you. If you do not have a list, please bring all your medication with you.
- If you are taking any blood thinning medicines please let us know. You may need to stop these before your procedure.
- Please tell the nurse if you have any allergies.
- We will do a test to check your heart's rhythm and electrical activity (electrocardiogram (ECG)).
- We will also do blood tests, check your blood pressure and take a swab to test for MRSA bacteria. These will be explained to you. You will able to ask any questions you may have. These tests will all be done at your pre-assessment appointment.

Preparing for the procedure

- We will give you a body wash (Stellisept) and nose cream to use for the 2 days before your procedure. We will explain how to use them. They help to reduce your risk of getting an infection.
- You will need to fast before your procedure. Solid food will need to be stopped 6 hours before your procedure. All fluids must be stopped 2 hours before the procedure.
- Please bring your current medicines or recent prescription with you.
- It is a day case procedure. You will normally go home the same day, or next morning the following day. Please bring an overnight stay bag with you, should you need to stay overnight, or longer if there are any complications after your procedure.

What happens on the day?

You need to come to a day case ward at **7.30am**. We will show you to our waiting room. A nurse will see you who:

- will discuss your current medicines with you.
- may take a sample of your blood.
- will record your heart rate, temperature and blood pressure.
- will shave your groin area, and chest if needed.

One of the medical team will see you who will:

- explain the procedure to you.
- ask you to sign a consent form.
- give you 1 dose of antibiotics or other medication to prevent infection. Or we may give this to you in theatre (please tell us if you have any allergies).

How is the PFO device implanted?

You will have a general anaesthetic. This means you will be asleep during the procedure. You will not feel any pain.

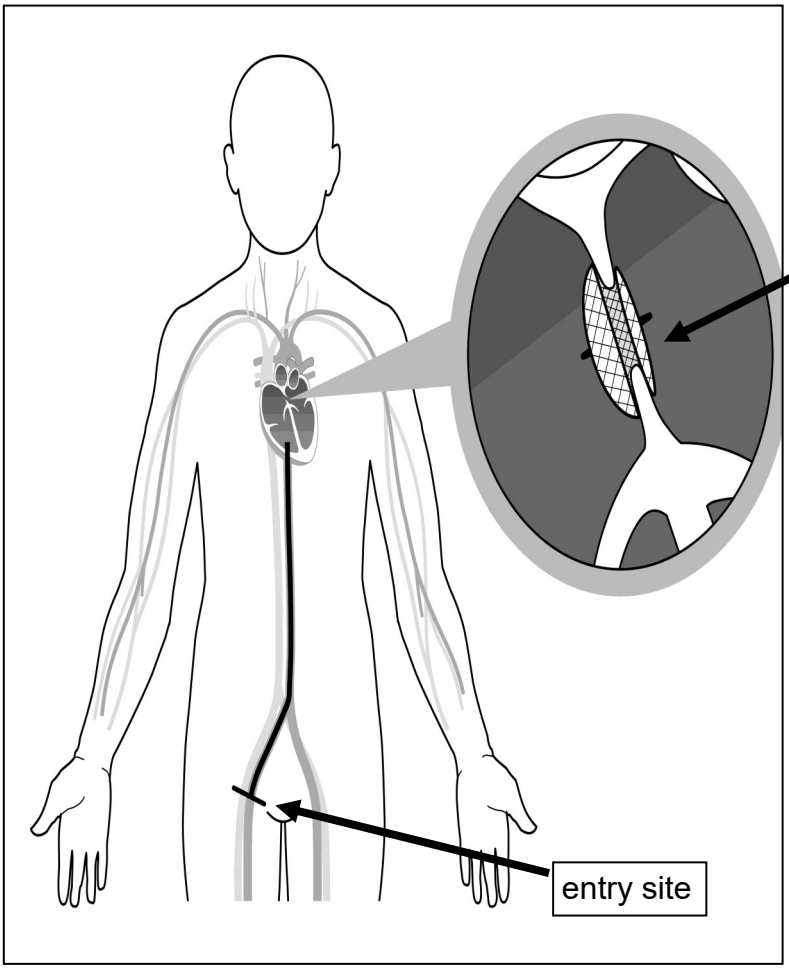
We will make a small cut in a vein at the top of your leg (groin). We will pass a small plastic tube called a sheath through this vein.

We will put a small ultrasound probe in your food pipe (oesophagus) through your mouth. This is to look inside the heart. We will be able to get some pictures of the hole. This is called a transoesophageal echocardiogram (TOE).

The closure device (PFO occluder) is passed through the tube in your groin. It is put into the hole in your heart. Once the device is in place, it is released to stay permanently. Your doctor may also use X-rays to help guide the placing of the device.

The procedure usually takes 1 or 2 hours.

The closure device is made of 2 metal discs. They are made of a special mesh. When put into position, it looks a bit like 2 umbrellas joined at the centre. Over time a layer of skin-like tissue will grow over the device. This should cover any small holes or leaks that may remain. Please tell your doctor if you have an allergy to metals such as nickel.



The image shows a PFO occluder device.

It sits between the two top chambers of the heart . It stops blood travelling from one side to the other.

What happens after the procedure?

We will remove the sheath from the top of your leg (groin).

You will need to stay in bed rest for 2 hours. During this time, the nurse will monitor you and check the small wound in your groin. There is a slight risk of bleeding or swelling.

You may feel quite drowsy when you return to the ward due to the anaesthetic. Once you are awake enough, the nurse will give you something to eat and drink. They will start with sips of water.

After a few hours of bed rest, you will be able to get up and move around the ward. You may have some bruising and discomfort in your groin area. The small cut at the top of your leg may bleed slightly after the procedure. You can usually go home the same day or the next day.

Going home after the procedure

We will give you a discharge letter. It will explain what has happened. It will also explain what medicines you are on. A copy of this letter will be sent to your GP.

If you were taking blood thinning tablets before you will need to re-start this after the procedure to stop large clots forming on the device. How long you need to carry on taking these will vary. We will confirm this with you before discharge, or later by your referring consultant.

For 24 hours after your procedure, while the general anaesthetic wears off:

- do not drive a car or ride a bicycle.
- do not operate any machinery or do anything which needs skill or judgement (including cooking).
- do not drink alcohol.
- do not take sleeping tablets.
- do not sign any legal documents or contracts, or make any important decisions.

For the first 3 days, you should limit your activities as much as possible. This means:

- **No heavy lifting**
- **No heavy cleaning**
- **No heavy shopping**
- **No heavy gardening**

- It is common for a painful bruise to develop around a puncture wound in the groin due to bleeding beneath the skin. If a painful lump forms, especially if you feel discomfort in the groin while walking, you must get medical help.
- After the procedure, you may notice bruising and discoloration above and below the groin. This may go as far as the knee. This discoloration can be blue as blue-purple at the start and then slowly change to yellow over the course of a week. It may look quite unpleasant.

It is important to note that this often does not cause pain. It is not serious. If you have minor pain, you can take paracetamol.

- Avoid baths, hot tubs, or swimming pools for the first 5 days or until the wound is closed. Showers are okay after 24 hours (1 day). Do not let the spray hit the site.
- Avoid bending or squatting or any intense activity such as running, or lifting anything over 20 pounds for 1 week.
- Take short walks (5 to 10 minutes) 4 or 5 times a day and build up slowly.

Taking care of the wound site

You will have a small wound. You may have some bruising at the site where the catheters were inserted, which is most often in the groin area. You can remove the dressing after 48 hours (2 days). It does not need to be replaced.

Check your wound site every day. Contact your GP as soon as possible if you have:

- Redness and warmth that does not go away
- Yellow or green discharge from the wound
- Fever and chills
- Numbness in your leg which gets worse
- Pain at the site which gets worse

Your follow-up appointments

You will have had a bubble echocardiogram (echo) scan to diagnose the PFO before. We will arrange for you to have the same test again in 6 months. We will inject very small salt water bubbles through a fine tube (cannula) in your arm. These flow into your heart. They can be seen on screen. From this we can check if there is still any leakage into the left chamber of your heart.

Your referring consultant in will review you in the outpatient clinic 6 to 12 months after the procedure.

If you were originally referred from another hospital for the procedure, the bubble echo test and follow-up appointments will be arranged by your local hospital.

Will medical equipment interfere with my device?

Most medical equipment will have no effect on your device. You must tell hospital staff that you have an implanted device before you have any medical procedure.

Magnetic resonance imaging (MRI) scans are generally not a problem, but please tell the staff about your implant.

In the unlikely event that your groin site starts to bleed, whilst you wait for help:

- Do not panic but lie down on the floor (not the bed), where you are less likely to faint
- Ask a relative or friend to apply pressure with the flat of the fingers of both hands or a clenched fist over the groin wound for 30 minutes
- Ask someone to call 999
- Keep your leg as straight as possible and head down
- Do not drive yourself to the emergency department

You should get urgent medical advice if you feel unwell with after the procedure with symptoms of:

- Chest pain
- Dizziness
- Fainting
- Shortness of breath

Driving

There are no specific DVLA driving instructions following a PFO closure procedure. However, you should discuss this with your consultant to receive individualised advice. We also recommend informing your insurance company to avoid any potential issues with future claims.

Return to work

Most patients are able to return to work within 1 week. This will depend on various factors such as the overall state of your health and type of work you do. Please discuss this in more detail with your consultant

Will I able to feel the device?

No, you will not able to feel the device once it is implanted.

Will I have a problem when travelling abroad?

The metal parts of your device are very small. They so not usually trigger metal detector alarms.

Contact details

Structural Heart Valve Clinical Nurse Specialist: **0795 087 0853** (Monday to Friday, 8am to 4pm)

Structural Heart Valve Co-ordinator: **0116 258 3361** (Monday to Friday, 8am to 4pm)

More information

- **NHS PFO device YouTube video**: https://www.youtube.com/watch?v=b7FeAxXINxA
- **NHS helpline 111:** offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day.
- **NHS website** provides online information and guidance on all aspects of health and healthcare, to help you make choices about your health: www.nhs.uk

Glossary of terms

Cardiac catheterisation: examines how well your heart is working. It also finds out if you have

- disease of the heart muscle,
- valves or
- heart (coronary) arteries.

During this test, doctor's put a long, narrow tube called a catheter into a blood vessel in your arm or leg. They guide it to your heart with the aid of a special X-ray machine. Doctors inject a contrast dye into your blood vessel through the catheter. This creates X-ray videos of your valves, arteries, and heart chambers.

Catheter laboratory (cath lab): an examination room in a hospital or clinic. It has diagnostic imaging equipment to look at the arteries and chambers of the heart, and treat any stenosis or abnormality found.

Contrast dye: a solution that radiologists use to see your organs and tissues more clearly in medical images such as X-rays, MRI and CT scan.

Coronary angioplasty: your doctor inserts a catheter with a tiny balloon at the tip into your arteries supplying blood to your heart. When this balloon is inflated, it pushes plaque out and widens your artery. A tiny mesh tube called a stent is placed into your artery to help keep it open.

Haemodynamic support: medications used to keep your blood pressure and heart rate within the normal range.

Intensive care unit (ICU): a specialist ward in a hospital that offers close monitoring and treatment for patients who are very ill.

Multidisciplinary team (MDT): a group of professionals from one or more clinical areas. Together they make decisions about the best form of treatment for you.

Percutaneous: this is a method to access the inner organs via a needle puncture of the skin.

Radiologist: a doctor who is specially trained to interpret diagnostic images such as X-rays, MRI and CT scans.

Transcatheter aortic valve implantation (TAVI): a procedure using catheters to replace a narrowed aortic valve in the heart.

Transoesophageal echocardiogram (TOE): a test is sometimes done to take clearer pictures of the heart. We put a probe down your throat. You will lie down and swallow the tube. You may be given some drugs to help you relax before this is done.

If you have any questions, write them down here to remind you what to ask when you speak to your nurse/ consultant/ doctor:

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