

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

Department of Cardiology

Information for Patients

Produced: April 2021

Updated: October 2023

Review: April 2024

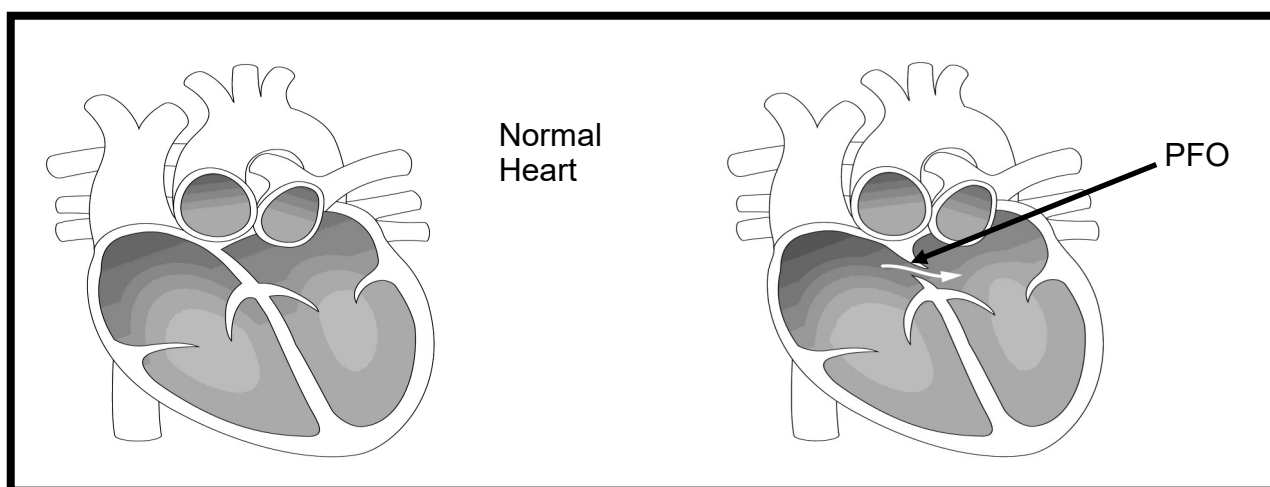
Leaflet number: 1173 Version: 1.1

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 often called a hole in the heart. This hole between the 2 top chambers of your heart is present in all babies when inside the womb, and closes in most people straight after birth. In around 1 in 4 people it may not close fully. In most patients, having a PFO does not cause any symptoms or problems. In some rare cases, it can allow blood clots to cross from the right side of the heart to the left, and then into the brain. This can cause a stroke.



Health information and support is available at www.nhs.uk
or call 111 for non-emergency medical advice

Visit www.leicestershospitals.nhs.uk for maps and information about visiting Leicester's Hospitals
To give feedback about this information sheet, contact InformationForPatients@uhl-tr.nhs.uk

How is a PFO closed?

A PFO occluder is a device which can be placed in your heart to stop blood flow through the PFO. In the past, the only way of closing these holes was by an open heart operation. Open heart surgery is very rarely done now for a PFO closure. Nowadays a PFO can be closed by a small operation using an artery in your groin.

Why should I have this procedure?

If you have a PFO and have had a stroke without a known cause (cryptogenic stroke), you may be at risk of having another stroke. In some patients, a second stroke can be prevented by closing the PFO.

Having this procedure will mean that the hole in your heart (PFO) will be closed. This will reduce the risk of complications linked to a PFO such as a stroke. The procedure has a success rate of 95%, where the closure device is implanted, with no major complications.

What are the risks of the procedure?

The risks of the procedure are given below and also detailed 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.

Additional procedures may need to be done during your operation. These may include:

- a blood transfusion (further information will be given to you in the pre-assessment clinic).
- giving you medications 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 proceed with the PFO closure you will be asked to come for a pre-assessment appointment with a nurse, a few days or a week before the procedure.
- We will talk to you about your past medical history and any medication you are taking. It is important that you bring a list of your all your medication with you. If you don't have a list, please bring all your medication with you.
- If you are taking any blood thinning medication please let us know, as 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 and 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

- You will be given a body wash (Stellisept) and nose cream to use for the 2 days before your procedure, which will be explained to you. This is important as it reduces 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, and all fluids must be stopped 2 hours before the procedure.
- Please bring your current medication or recent prescription with you.
- It is a day case procedure and 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?

Your admission time on the day of your procedure will be **7.30am** to a day case ward. On arrival to the ward you will be shown to our waiting room and then be seen by a nurse who:

- will discuss your current medications 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.

You will then be seen by one of the medical team 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 this may be given to you in theatre (please tell us if you have any allergies).

How is the PFO device implanted?

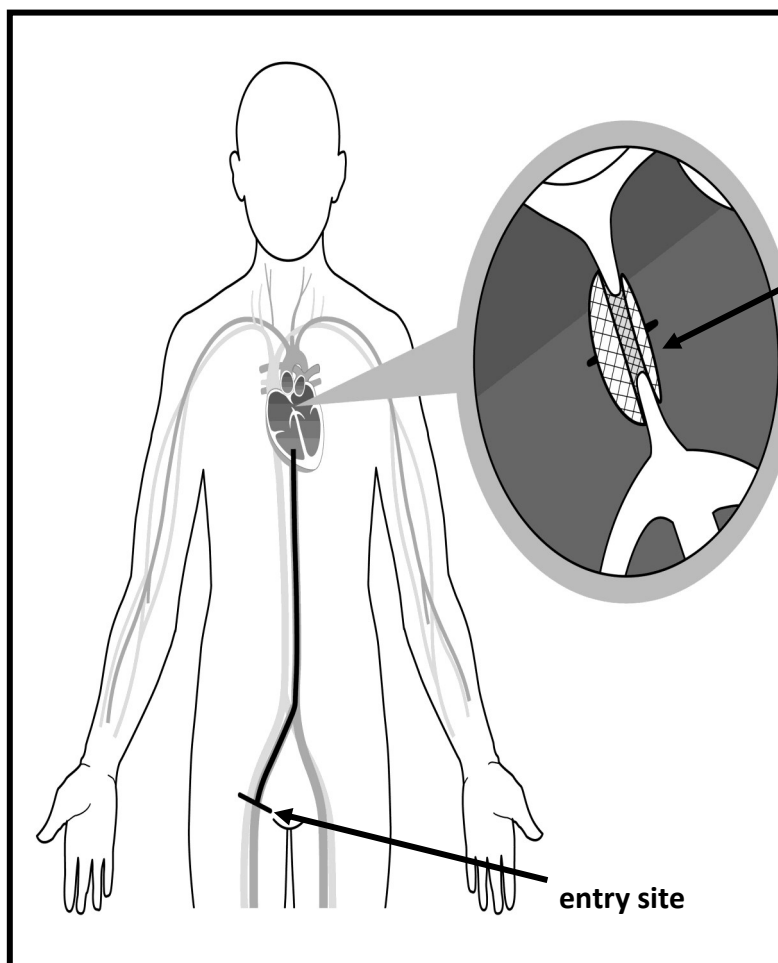
The PFO closure procedure is done under a general anaesthetic. This means you will be asleep during the procedure and won't feel any pain. A small cut is made in a vein at the top of your leg (groin). A small plastic tube called a sheath is passed through this vein.

A small ultrasound probe is placed in your food pipe (oesophagus) through your mouth. This is to look inside the heart and get some pictures of the hole to measure its size and make sure the closure device can be positioned correctly. This is called a transoesophageal echocardiogram (TOE).

The closure device (PFO occluder) is passed through the tube in your groin and placed into the hole in your heart. Once the device is in position, it is released to stay permanently. Your doctor may also use X-rays to help guide the positioning of the device during the procedure.

The procedure usually takes 1 or 2 hours.

The closure device consists of 2 metal discs 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 and stops blood travelling from one side to the other.

What happens after the procedure?

The sheath in the top of your leg (groin) will be taken out after the procedure and you will need to stay on bed rest for 2 to 4 hours. The nurse will continue to monitor you and check the small wound in your groin, as there is a small risk of bleeding or swelling.

You may be quite sleepy on your return to the ward as a result of the anaesthetic. As soon as you are awake enough, the nurse will get you something to eat and drink. You will usually be given sips of water first.

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. The small cut at the top of your leg may bleed slightly after the procedure. You will normally be discharged home the same day or the next day.

Your follow-up appointments

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

You will also be reviewed by your referring consultant 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.

Going home after the procedure

You will be given a discharge letter which will detail what has happened to you in hospital and which medication you are on. A copy of this letter will be sent to your GP.

If you were previously taking blood thinning tablets you will need to re-start this after the procedure to prevent large clots forming on the device. How long you need to continue taking these for will vary and will be confirmed to 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.

Advice to follow after your procedure

- The dressing over your wound/ cut can be removed after 24 hours and does not need to be replaced.
- Avoid any heavy lifting, pushing, or pulling for 5 days, as this may cause pressure on the wound site and cause bleeding.
- Every person recovers differently and generally all strenuous activity should be avoided for the first 4 weeks after the procedure. You should strictly **not** do any strenuous activity within the first 2 weeks. Moderate levels of exercise are allowed after 2 weeks if you feel comfortable.
- Although there are no specific DVLA driving restrictions after this procedure, we strongly recommend that you do not drive for at least 3 days. This will give the wound in your groin time to heal. Only start driving again if you feel well enough.
- You must not have a tub bath, go swimming, or go in a hot tub for 7 days.
- Most patients return to work within 1 week, although this will depend on the type of job you do. If you have a physical job please discuss with your consultant when you will be able to go back to work and how long you should avoid heavy lifting for.
- **After a PFO closure procedure, it is important that you must have antibiotics before having any dental work done, or before a surgical procedure, during the first 6 months. Please tell the medical team before having any procedure that you have had a hole in your heart closed.**

Common side effects after the procedure

- Tenderness or a small bump (size of a 2 pence coin) at the wound site.
- Bruising is common at the wound site.
- Feeling sensations in the chest (palpitations), chest discomfort, or pressure. This is very common for about 2 to 6 weeks and treatment is not usually needed.
- Slight bleeding at the wound/ insertion site.

It is rare to have severe bleeding from the wound site once you are home. If bleeding does happen you must:

- lie down.
- put pressure on the wound site and ask someone to call 999.

Get urgent medical advice if you feel unwell after the procedure with symptoms of:

- a painful leg, cold, red, swollen or has changed colour.
- a fever.
- white or yellow discharge coming out of the wound.

- suddenly feeling short of breath or have trouble breathing.
- severe pain or swelling at the wound site, or in your lower tummy area above the wound.
- severe chest pain.
- dizziness or fainting.

Will I able to feel the device?

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

Carrying a patient identification card after your procedure

It is important to carry a patient identification card with you to identify yourself as having an implanted device. The patient identification card includes your name, implant date and information about your device. You will receive this card shortly after your procedure.

The card will be useful to you when travelling abroad, to show medical staff if you are having another procedure, or in an emergency situation.

Will I have a problem when travelling abroad?

The metal parts of your device 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. Show your patient identification card to the security personnel if it trigger's the metal detector.

Will medical equipment interfere with my device?

Although most medical equipment will have no effect on your device, you should always tell hospital staff that you have an implanted device before you undergo any medical procedure. Magnetic resonance imaging (MRI) scans are generally not a problem, however, please inform the staff about your implant.

Contact details

Structural Heart Valve Clinical Nurse Specialist: 07950 870853 (Monday to Friday, 8am to 4pm)

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

Further 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** www.nhs.uk - provides online information and guidance on all aspects of health and healthcare, to help you make choices about your health.

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

اگر آپ کو یہ معلومات کسی اور زبان میں درکار ہیں، تو براہ کرم مندرجہ ذیل نمبر پر ٹیلی فون کریں۔
على هذه المعلومات بلغة أخرى، الرجاء الاتصال على رقم الهاتف الذي يظهر في الأسفل
જો તમને અન્ય ભાષામાં આ માહિતી જોઈતી હોય, તો નીચે આપેલ નંબર પર કૃપા કરી ટેલિફોન કરો

ਜੇ ਤੁਸੀਂ ਇਹ ਜਾਣਕਾਰੀ ਕਿਸੇ ਹੋਰ ਭਾਸ਼ਾ ਵਿੱਚ ਚਾਹੁੰਦੇ ਹੋ, ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਹੇਠਾਂ ਦਿੱਤੇ ਗਏ ਨੰਬਰ 'ਤੇ ਟੈਲੀਫੋਨ ਕਰੋ।
Aby uzyskać informacje w innym języku, proszę zadzwonić pod podany niżej numer telefonu

If you would like this information in another language or format such as EasyRead or Braille, please telephone 0116 250 2959 or email equality@uhl-tr.nhs.uk