



Patent Foramen Ovale Repair

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

A. Interpreter / cultural needs

- An Interpreter Service is required? Yes No
- If Yes, is a qualified Interpreter present? Yes No
- A Cultural Support Person is required? Yes No
- If Yes, is a Cultural Support Person present? Yes No

B. Condition and treatment

The doctor has explained that you have the following condition: *(Doctor to document in patient's own words)*

.....

This condition requires the following procedure. *(Doctor to document - include site and/or side where relevant to the procedure)*

.....

The procedure may include the following:

Echocardiogram – an ultrasound which uses soundwaves to form a picture of the heart. This can be on your chest, via your oesophagus (food pipe) or via the catheter in your artery.

Right Heart Catheter – after an injection of local anaesthetic, a soft balloon ‘pressure catheter’ is put into the vein in your groin. The tube is passed along until it reaches the heart and then goes up into the blood vessels of the lungs. The pressures in the lungs and heart are recorded.

Angiogram – after an injection of local anaesthetic, a fine tube (catheter) is put into the artery in the groin/arm. This tube is passed into each coronary artery. A series of videos pictures are taken using x-rays and a contrast medium (x-ray dye). The contrast medium may be injected into the main pumping chamber of the heart (left ventricle). This is to measure the size of the heart and how well it is pumping.

A Septal Occluder is passed into the fine tube and advanced through your heart and put into the defect to close the hole.

C. Risks of a patent foramen ovale repair

There are risks and complications with this procedure. They include but are not limited to the following.

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment.

The risks/complications of this procedure are;

Common risks (more than 5%) include;

- Minor bruising at the puncture site.
- A higher lifetime risk from exposure to radiation.

- Abnormal heart rhythm that continues for a long time. This may need an electric shock to correct.
- Major bruising and swelling (Haematoma).
- Bleeding around catheter site.
- High or low blood pressure.
- Sore throat from the anaesthetic tube or echo probe.

Rare risks (less than 1%) include;

- Stroke or TIA (Transient Ischaemic Attack). This may cause long term disability.
- Incomplete closure of the defect. This may require surgery.
- An allergic reaction to the x-ray dye.
- Embolism. A blood clot may form and break off from the catheter. This is treated with blood thinning medication.
- Fever, headache or migraine.
- Injury to the artery, veins or nerves in the groin or neck. This may require surgery.
- Tear of oesophagus, vein or heart (from the camera). This may be life threatening. This may require surgery.
- Clots in the leg (deep vein thrombosis or DVT) with pain and swelling. Rarely part of this clot may break off and go into the lungs.
- Device Infection. This will need open heart surgery and antibiotics.
- Dislodgement of the Septal Occluder which may require open heart surgery to repair.
- Puncture of the heart with a collection of blood around the heart. This will require surgery to repair.
- Death as a result of this procedure is rare.

D. Significant risks and procedure options

(Doctor to document in space provided. Continue in Medical Record if necessary.)

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E. Risks of not having this procedure

(Doctor to document in space provided. Continue in Medical Record if necessary.)

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F. Anaesthetic

This procedure may require an anaesthetic. *(Doctor to document type of anaesthetic discussed)*

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G. Patient consent

I acknowledge that the doctor has explained;

- my medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- the anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- other relevant procedure/treatment options and their associated risks.
- my prognosis and the risks of not having the procedure.
- that no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- the procedure may include a blood transfusion.
- tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- if immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- a doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following Patient Information Sheet/s:

- Local Anaesthetic & Sedation for your Procedure**
- Patent Foramen Ovale Repair**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

On the basis of the above statements,

I request to have the procedure

Name of Patient:.....

Signature:.....

Date:.....

Patients who lack capacity to provide consent

Consent must be obtained from a substitute decision maker/s in the order below.

Does the patient have an Advance Health Directive (AHD)?

Yes ▶ Location of the original or certified copy of the AHD:.....

No ▶ Name of Substitute Decision Maker/s:.....

Signature:.....

Relationship to patient:.....

Date:..... PH No:.....

Source of decision making authority (tick one):

- Tribunal-appointed Guardian
- Attorney/s for health matters under Enduring Power of Attorney or AHD
- Statutory Health Attorney
- If none of these, the Adult Guardian has provided consent.

H. Doctor/delegate Statement

I have explained to the patient all the above points under the Patient Consent section (G) and I am of the opinion that the patient/substitute decision-maker has understood the information.

Name of Doctor/delegate:.....

Designation:.....

Signature:.....

Date:.....

I. Interpreter's statement

I have given a sight translation in

.....
(state the patient's language here) of the consent form and assisted in the provision of any verbal and written information given to the patient/parent or guardian/substitute decision-maker by the doctor.

Name of Interpreter:.....

Signature:.....

Date:.....

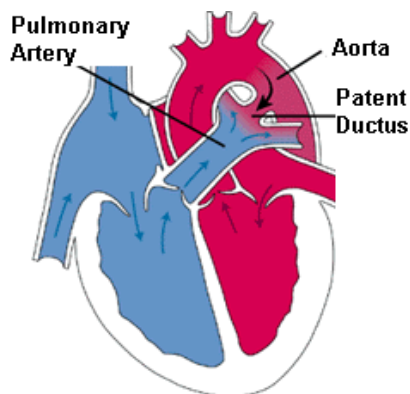
Consent Information - Patient Copy

Patent Foramen Ovale Repair

1. What is a patent foramen ovale repair?

The Foramen Ovale is an opening in the atrial septum that allows blood to flow between the atria in the foetus prior to birth. If the atrial septum doesn't close properly at birth, it is called a PFO. A PFO may allow blood or emboli to cross from the right atrium to the left atrium which is called a left to right shunt.

A Septal Occluder will be used to close the hole. This is a permanent artificial device put into the defect.



The procedure may include the following:

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Angiogram – after an injection of local anaesthetic, a fine tube (catheter) is put into the artery in the groin/arm. This tube is passed into each coronary artery. A series of videos pictures are taken using x-rays and a contrast medium (x-ray dye). The contrast medium may be injected into the main pumping chamber of the heart (left ventricle). This is to measure the size of the heart and how well it is pumping.

A Septal Occluder is passed into the fine tube and advanced through your heart and put into the defect.



One type of Septal Occluder

2. My anaesthetic

This procedure will require an anaesthetic.

See **Local Anaesthetic & Sedation for your procedure information sheet** for information about the anaesthetic and the risks involved. If you have any concerns, discuss these with your doctor.

If you have not been given an information sheet, please ask for one.

3. What are the risks of this specific procedure?

There are risks and complications with this procedure. They include but are not limited to the following.

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment.

The risks/complications of this procedure are;

Common risks (more than 5%) include;

- Minor bruising at the puncture site.
- A higher lifetime risk from exposure to radiation.
- Abnormal heart rhythm that continues for a long time. This may need an electric shock to correct.
- Major bruising and swelling (Haematoma).
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- High or low blood pressure.
- Sore throat from the anaesthetic tube or echo probe.

Rare risks (less than 1%) include;

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- Incomplete closure of the defect. This may require surgery.
- An allergic reaction to the x-ray dye.
- Embolism. A blood clot may form and break off from the catheter. This is treated with blood thinning medication.
- Fever, headache or migraine.
- Injury to the artery, veins or nerves in the groin or neck. This may require surgery.
- Tear of oesophagus, vein or heart (from the camera). This may be life threatening. This may require surgery.
- Clots in the leg (deep vein thrombosis or DVT) with pain and swelling. Rarely part of this clot may break off and go into the lungs.
- Device Infection. This will need open heart surgery and antibiotics.
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- Puncture of the heart with a collection of blood around the heart. This will require surgery to repair.
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Notes to talk to my doctor about:

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