Queensland Government

Transcatheter Atrial Septal Defect (ASD) Repair

Adult and Child/Young Person
Informed consent: patient information

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

This patient information sheet has been given to you to read carefully and allow time to ask your doctor any questions about this procedure. Your doctor will include the consent form and a copy of this patient information sheet in your medical record.

This patient information sheet uses the words 'I/you/your/me/my' to mean the patient or another person who is providing consent on behalf of the patient.

DO NOT WRITE IN THIS BINDING MARGIN

1. What is a transcatheter Atrial Septal Defect (ASD) repair and how will it help me?

Transcatheter Atrial Septal Defect (ASD) repair is a procedure to repair an opening or hole between the upper left chamber (called the left atrium) and the upper right chamber (called the right atrium) of the heart.

In a normal heart, blood does not flow directly between the left and right chambers of the heart.

A hole between the top heart chambers is called an Atrial Septal Defect (ASD). An ASD causes an abnormal increase in blood flow in the right side of the heart. This may cause you to feel tired, have difficulty breathing, and it can shorten your lifespan.

This procedure is done under a general anaesthetic and requires the use of iodinated contrast (also known as x-ray dye) and x-rays. It involves passing a thin tube (catheter) via a vein in your groin (femoral vein) to the heart. A septal occluder implant (plug) will be used to close the hole. This is a permanent, artificial device.

Patients having this procedure are usually in hospital for 1–2 nights. Your doctor will be able to confirm that this estimate is likely to be true for your procedure.

This procedure may include the following additional procedures, an echocardiogram, a right heart catheter and/or an angiogram. These procedures are explained below *(overpage)*.

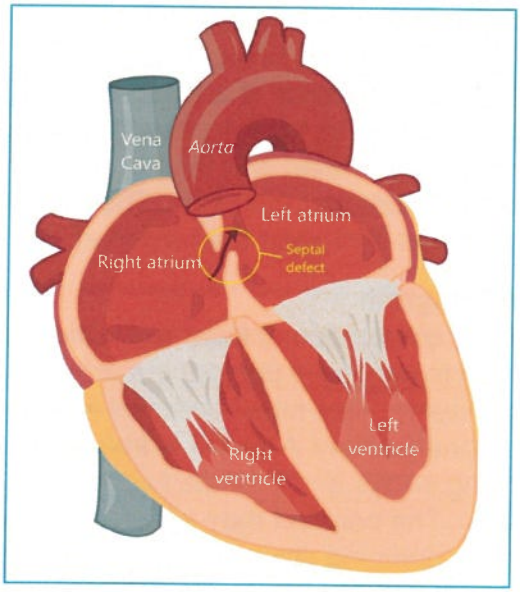

Image 1: Atrial Septal Defect (ASD).
ID: 2083531861. www.shutterstock.com

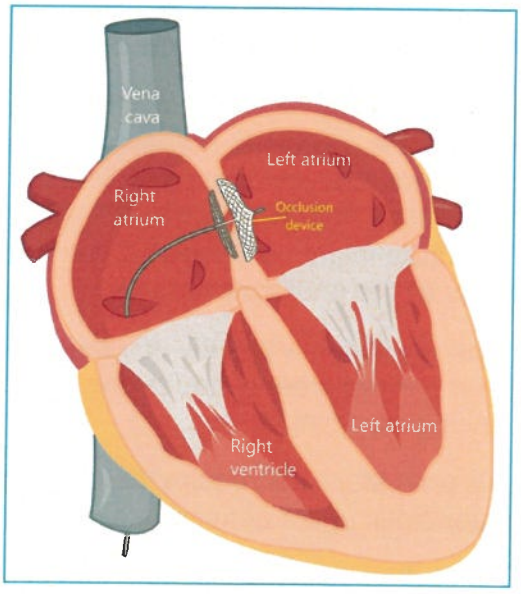

Image 2: ASD occluder implant (pug).
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Echocardiogram
An ultrasound uses soundwaves to form an image of the heart. This can be on your chest, via your oesophagus (food pipe) (Transoesophageal Echocardiogram [TOE]) or via the catheter in your artery or vein (Intracardiac Echocardiogram [ICE]).

Right heart catheter
After an injection of local anaesthetic, a '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 pressure 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 images are taken using x-rays and iodinated contrast (x-ray dye). The contrast 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.

Preparing for the procedure

The Cardiology department will give you instructions on how to prepare for the procedure. It is important to follow the instructions that are given to you. Your procedure might be delayed if you don't follow all the preparation steps.

Cardiology staff will notify you beforehand if you are required to stop taking any blood-thinning medication.

This procedure will require the use of a local anaesthetic and a general anaesthetic.

Do not drink alcohol, smoke, vape or take recreational drugs for at least 24 hours before the procedure as these may alter the effects of the anaesthetic.

Please tell the doctor if you:
- are breastfeeding or pregnant, or suspect that you may be pregnant
- have a drug or medication dependence.

On the day of your procedure

- Nothing to eat or drink ('nil by mouth'): you will be told when to have your last meal and drink. Do NOT eat (including lollies), drink or chew gum after this time otherwise your procedure may be delayed or cancelled. This is to make sure your stomach is empty so that if you vomit, there will be nothing to go into your lungs.
- If you take medicines, most should be continued before a procedure and taken at the usual time, even on the day of the procedure, with a sip of water. There are some important exceptions:
  - your doctor will provide specific instructions about your medicines
  - take to the hospital all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements. This may include and is not limited to blood-thinning medicines, the contraceptive pill, antidepressants and/or medicines for treating diabetes (e.g. insulin).
- If you feel unwell, telephone the Cardiology department for advice.
- Tell your doctor if you have:
  - health problems (e.g. diabetes, high blood pressure, infectious diseases, serious illnesses), including if undergoing regular treatment
  - had previous problems and/or known family problems with anaesthesia
  - false teeth, caps, loose teeth or other dental problems
  - allergies/intolerances of any type and their side effects.

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- You will be required to change into a hospital gown and remove some of your jewellery. Your belongings will be kept in a safe location during the procedure.

If you are booked for an anaesthetic or sedation, please read the information sheet *About Your Anaesthetic (for adults)* or *About Your Child's Anaesthetic (for child/young person)*. If you do not have one of these information sheets, please ask for one.

For a substitute decision-maker/parent/ legal guardian/other person of a child/ young person/adult without capacity to consent to having a transcatheter ASD repair

To prepare the patient for this procedure and to ease their concerns, tell them what they can expect to happen during the procedure. This information sheet will assist you with this.

We welcome your help and support in preparing the patient for the procedure and in explaining why it's so important to lie still.

At the discretion of the procedure staff, if the patient is having a general anaesthetic, you may be able to see them off to sleep. Once they are asleep, you will be asked to leave the procedure room and wait in the waiting area.

Other children are not allowed into the procedure room, and they must be supervised at all times by another parent/ adult.

During the procedure

Before the procedure begins, an intravenous (I.V.) cannula (a small plastic tube) will be inserted into a vein, usually in your hand or arm.

This is for medication or fluid required during the procedure, including your anaesthetic.

Routine observations will be measured before and during the procedure, these may include cardiac rhythm, blood pressure, heart rate, respiratory (breathing) rate and oxygen levels. You will also be connected to an Electrocardiogram (ECG) to monitor the electrical activity of your heart.

Once you are asleep, the skin over your groin area will be cleaned and a sterile drape will be applied to cover your body. The doctor will use local anaesthetic to numb your skin and make a small cut where the catheter enters.

Imaging and iodinated contrast are used to guide the specialised catheters and guidewires through the vessels from the puncture site to the heart. When the catheter is in the correct position in your heart, a septal occluder implant (plug) is passed into the catheter and moved through the catheter to your heart. The implant, or plug, is released from the catheter and closes the hole in your heart.

Once the procedure is complete, the catheters and guidewires will be removed. Firm pressure will be placed over the area where the catheters went into your skin (puncture site). This allows the vein to seal over, so you will not continue to bleed. When the bleeding has stopped, a small dressing will be applied to the puncture site.

After the procedure is complete, you will be transferred from the procedure room to a recovery area.

You will be required to rest in bed for 2–4 hours. Your observations will be monitored, and your puncture site will be checked regularly for swelling, oozing of blood and bruising.

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When you are completely recovered you might be transferred to a ward bed for an overnight stay and observation.

It is common to have a mild sore throat and some mild chest discomfort after the procedure. This should improve within a couple of days after the procedure.

You may eat and drink after your procedure, unless otherwise advised.

If the I.V. cannula is no longer required, it will be removed.

2. What are the risks?

In recommending the procedure, the doctor believes that the benefits to you from having the procedure exceed the risks involved. There are risks and possible complications associated with the procedure which can occur with all patients – these are set out below.

Your doctor will discuss any additional risks, specific to your individual condition and circumstances, with you. These should be written on the consent form before you sign it.

Common risks and complications

- minor bruising, bleeding, pain or discomfort may occur around the puncture site
- bleeding or bruising is more common if you have been taking blood-thinning medicines, such as warfarin, aspirin, clopidogrel (Plavix, Iscover), prasugrel, dipyridamole (Persantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- abnormal heart rhythm that continues for a long time. This may need the doctor to give a controlled electric shock to correct
- high or low blood pressure
- sore throat from the anaesthetic tube or echo probe, which is a small probe that was used for your ultrasound (TOE).

Uncommon risks and complications

- major bruising and swelling (haematoma)
- stroke or Transient Ischaemic Attack (TIA). This may cause long-term disability
- incomplete closure of the defect. This may require surgery
- 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 equipment). This may be life-threatening. This may require surgery
- heart block requiring a pacemaker
- 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
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- *(iodinated contrast only)* allergic reactions rarely occur, but when they do, they occur within the first hour, with most happening in the first five minutes. Late reactions have been known to occur up to 1 week after the injection, but these delayed reactions are mild
- death as a result of this procedure is rare.

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If a general anaesthetic or sedation is given, extra risks include:

- faintness or dizziness, especially when you start to move
- fall in blood pressure
- nausea and vomiting
- weakness
- heart and lung problems, such as a heart attack or pneumonia
- stroke resulting in brain damage.

Iodinated contrast and risk to kidney function

Iodinated contrast is removed from the blood by the kidneys through the urine. It is easily removed from the body if you have normal kidney function.

You may be asked to have a blood test to find out how well your kidneys are functioning. In patients with severe renal impairment or acute kidney injury careful weighing of the risk versus the benefit of iodinated contrast media administration needs to be undertaken. However, severe renal function impairment does not mean that iodinated contrast should not be given, if medically indicated[1]. Your treating doctor will discuss your specific circumstances with you.

Risks of radiation

The risks of radiation exposure from this procedure need to be compared to the risks of your condition not being treated. Exposure to radiation may cause a slight increase in the risk of cancer to you over your lifetime. However, the potential risk is small compared to the expected benefit of this procedure[2].

What are the risks of not having a transcatheter ASD repair?

There may be adverse consequences for your health if you choose not to have the proposed procedure. You and your doctor should discuss these.

If you choose not to have the procedure, you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the procedure.

3. Are there alternatives?

A possible alternative to transcatheter ASD repair is surgery. Surgical repair takes place in an operating theatre and will require:

- a general anaesthetic
- an incision in your chest to access your heart
- a connection to heart-lung bypass machine which will control your heart beat and oxygenate your blood for the duration of the procedure
- a patch will be used to cover the hole
- a longer recovery.

Your doctor will discuss the most appropriate procedure for your circumstances.

Making the decision to have a procedure requires you to understand the options available. Your doctor will discuss any alternative procedure options and their risks or benefits with you, before signing the consent form.

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4. What should I expect after the procedure?

Your healthcare team will talk to you about what to expect after your procedure and upon discharge from hospital.

Go to your nearest Emergency department or GP (your local doctor) if you become unwell or have:

- pain unrelieved by simple pain relievers or those prescribed for you
- bleeding, swelling, redness or inflammation at the puncture site
- a fever
- other warning signs the doctor may have asked you to be aware of.

If you had sedation or an anaesthetic, this will affect your judgement for about 24 hours. For your own safety:

- Do NOT drive any type of car, bike or other vehicle.
- Do NOT operate machinery including cooking equipment.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, smoke, vape or take recreational drugs. They may react with the anaesthetic medications.

You will be given a Patient Implant Card (PIC) for your records with the specific details of any implanted device used. This information is important for future safety for any Magnetic Resonance Imaging (MRI) scans.

Bacterial endocarditis awareness: (after your implant is inserted) if you require any invasive procedures (including dental treatment) it is important you let your treating doctor/dentist know about your implant, as you may require antibiotics prior to the procedure, to reduce the risk of your new valve becoming infected.

It is very important to report **any** fevers and infections to your doctor, as soon as possible.

5. Who will be performing the procedure?

Doctors, cardiac scientists, radiographers, cardiac sonographers, pharmacists, nurses, patient support officers and administration staff make up the cardiology team. All or some of these professionals may be involved in your journey.

A doctor other than the consultant/specialist may assist with/conduct your procedure. This could include a registered doctor who is undergoing further training. All trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor will be performing your procedure, please discuss this with the doctor.

Clinical students

For the purpose of undertaking professional training in this teaching hospital, subject to your consent, a clinical student(s) may observe medical examination(s) or procedure(s). A clinical student may also, subject to your consent, assist with/conduct a clinically necessary examination or procedure on you while you are under the influence of anaesthetic.

You are under no obligation to agree to an examination(s) or a procedure(s) being observed or undertaken by a clinical student(s) for training purposes.
If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way.

For more information on student care, please visit www.health.qld.gov.au/consent/students

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6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website www.qld.gov.au/health/services/hospital-care/before-after where you can read about your healthcare rights.

Queensland Health respects the privacy of patients and their families. To learn more about health records and personal information visit our website www.health.qld.gov.au/system-governance/records-privacy/health-personal

You can also see a list of blood-thinning medications at www.health.qld.gov.au/consent/bloodthinner

Further information about informed consent can be found on the Informed Consent website www.health.qld.gov.au/consent. Additional statewide consent forms and patient information sheets are also available here.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss this with your doctor.

Queensland Health recognises that First Nations Peoples' culture must be considered in the patient's clinical care to ensure their holistic health and individual needs are met.

7. Questions

Please ask the doctor if you do not understand any aspect of this patient information sheet or if you have any questions about your proposed procedure.

If you have further questions prior to your appointment, please contact the Cardiology department via the main switchboard of the facility where your procedure is booked.

8. Contact us

In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.

References:
1. Iodinated Contrast Media Guideline, V2.3 The Royal Australian and New Zealand College of Radiologists, March 2018. Available from www.ranzcr.com/college/document-library/iodinated-contrast-guidelines-2016
2. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au