



Queensland
Government

Atrial Fibrillation (AF) Ablation Consent

Adult (18 years and over)

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

This consent form and 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.

A. Does the patient have capacity to provide consent?

- Yes → **GO TO section B**
 No → **COMPLETE section A**

You must adhere to the Advance Health Directive (AHD), or if there is no AHD, the consent obtained from a substitute decision-maker in the following order: Category 1. Tribunal-appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.

Name of substitute decision-maker:

Category of substitute decision-maker:

B. Is an interpreter required?

- Yes No

If yes, the interpreter has translated:

- in person over the telephone

A verbal translation is a summary of the form.

Name of interpreter:

National Accreditation Authority for Translators and Interpreters (NAATI) code:

Language:

C. Procedure details

I confirm that the doctor has informed me about the following procedure(s) and I consent to:

Atrial Fibrillation (AF) ablation: Yes

Additional component:

D. Risks specific to the patient in having an Atrial Fibrillation (AF) ablation

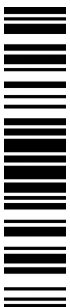
(Doctor to document additional risks not included in the patient information sheet)

E. Risks specific to the patient in *not* having an Atrial Fibrillation (AF) ablation

(Doctor to document specific risks in not having an Atrial Fibrillation (AF) ablation)

DO NOT WRITE IN THIS BINDING MARGIN

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SW9011

ATRIAL FIBRILLATION (AF) ABLATION CONSENT



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F. Alternative procedure options

(Doctor to document alternative procedure not included in the patient information sheet)

I have received the following consent and patient information sheet(s):

- 'Atrial Fibrillation (AF) Ablation'
 'Transoesophageal Echocardiogram (TOE)'
 'About Your Anaesthetic'
 Other (specify):

On the basis of the above statements,

I consent to having an Atrial Fibrillation (AF) ablation.

Name of patient/substitute decision-maker:

Signature:

Date:

H. Doctor confirms

I have explained to you the contents of this form and am of the opinion that the information has been understood.

Name of doctor:

Designation:

Signature:

Date:

I. Clinical student involvement

For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to my consent, assist with/conduct an examination or procedure on me/the patient while under sedation or anaesthetic.

I consent to a clinical student(s) undergoing training to:

- observe examination(s)/procedure(s): Yes No
- assist with examination(s)/procedure(s): Yes No
- conduct examination(s)/procedure(s): Yes No

Note: you will also have the opportunity to say yes or no to student involvement, on the day of your procedure.

For further information please see www.health.qld.gov.au/consent/students

G. Acknowledgment and consent

I acknowledge that the doctor has explained and I understand:

- the 'Atrial Fibrillation (AF) Ablation' patient information sheet
- the medical condition and proposed procedure, including the possibility of additional treatment
- this procedure requires sedation or general anaesthetic
- the specific risks and benefits of the procedure
- the prognosis and risks of not having the procedure
- alternative procedure options
- that there is no guarantee the procedure will improve the medical condition
- that if an immediate life-threatening event happens during the procedure, health care will be provided based on my AHD (Advance Health Directive) or ARP (Acute Resuscitation Plan). If no AHD or ARP is in place, health care will be provided in accordance with good clinical practice and the *Guardianship and Administration Act 2000 (Qld)*
- that a doctor other than the consultant/specialist may assist with/conduct the clinically appropriate procedure; this may include a doctor undergoing further training under supervision
- that if the doctor wishes to record video, audio or images during the procedure where the recording is not required as part of the treatment (e.g. for training or research purposes), I will be asked to sign a separate consent form. If I choose not to consent, it will not adversely affect my access, outcome or rights to medical treatment in any way.
- I was able to ask questions and raise concerns with the doctor.
- I understand I have the right to change my mind regarding consent at any time, including after signing this form.

Atrial Fibrillation (AF) Ablation

Adult (18 years and over)

Informed consent: patient information

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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.



1. What is an Atrial Fibrillation (AF) ablation and how will it help me?

Atrial Fibrillation (AF) is the most common type of recurring abnormal heart rhythm (arrhythmia). It sometimes causes the heart to beat faster and the beat can be irregular. AF causes the heart to work ineffectively due to the development of electrical short circuits inside the top chambers of the heart. These circuits are usually caused by abnormal electrical activity located within the pulmonary veins that drain blood from the lungs back to the left atrium of the heart. If AF is not treated, or well controlled, it may lead to heart failure or blood clots, caused by the abnormal flow inside the heart. Untreated, AF carries an increased risk of stroke.

There are **two parts** to an AF ablation:

- **Part 1: Electrophysiology Study (EPS)**, also referred to as Pulmonary vein isolation (PVI), is a test performed to help the doctor to work out what abnormal heart rhythms you have, and where they originate. To do this a special mapping catheter (fine tube) is passed through a vein in your groin or neck, into your heart. Most often, x-ray and/or specialised 3D mapping systems (magnetic and/or impedance [resistance] based) are used to guide the catheters to their positions in the heart.
- **Part 2: Ablation** is the delivery of extreme heat or cold to the inside of the heart, to scar the problematic tissue that may be the source of your abnormal heart rhythm. This is also referred to as Pulse Field Ablation (PFA). There are two types of ablation, Radiofrequency Ablation (RFA) and cryoablation. Radiofrequency ablation uses high frequency energy to increase the temperature (heat), thus ablating (scarring) a small area of problematic tissue. Cryoablation uses extreme cold to ablate a small area of problematic tissue. The type of ablation will be decided by your treating team. The most common target area is at the pulmonary veins at the back of the left atrium. Access to the left atrium requires crossing the tissue inside the heart that separates the right from the left atrium (called the interatrial septum). This is done using x-ray and/or ultrasound guidance.

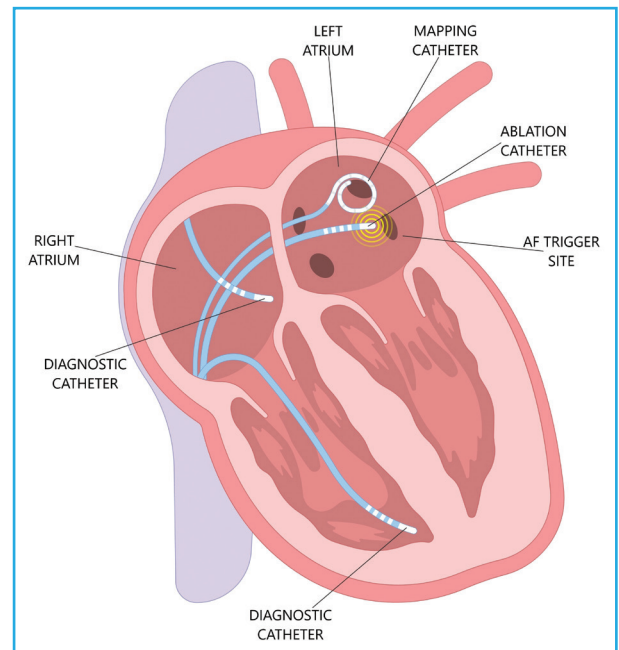


Image: Cardiac catheter ablation.
ID: 2144204399 (adapted). www.shutterstock.com

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Preparing for the procedure

Patients having this procedure are usually in hospital for 1–2 days. Your doctor will be able to confirm that this estimate is likely to be true for your 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 local anaesthetic and possibly a mild sedation.

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 sedation anaesthetic.

If you are having sedation and are being discharged on the same day, you cannot drive and you must have someone available to escort you home.

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.
- 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.

Sedation

Sedation is the use of medicines that help make you feel relaxed and drowsy for your procedure. You may remember some or little about what has happened. You may still be aware of your surroundings and should be able to follow simple instructions, such as holding your breath, when instructed by the doctor.

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If you are booked for an anaesthetic or sedation, please read the information sheet *About Your Anaesthetic*. If you do not have one of these information sheets, please ask for one.

For a substitute decision-maker of an adult without capacity to consent to having an AF ablation

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:

- a parent/adult (unless pregnant) may be invited into the procedure room to support the patient
- 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.

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

During the procedure

You will be transferred to the procedure room from your ward. The procedure room has a patient table, imaging equipment, monitoring equipment and other equipment used to do the ablation.

Before you enter the procedure room your details will be checked several times by different nurses and doctors. This is routine and part of the safety check prior to a procedure.

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.

Electrocardiogram (ECG) monitoring electrodes will be placed on your chest to monitor your heart. Electrical patches might be placed on your back and front to enable the use of the 3D mapping systems. This will not be painful, but may feel cold initially while going on to your skin.

An intravenous (I.V.) cannula will be inserted into a vein, usually in your hand or arm. This is for any medication or fluid required during the procedure, including sedation or general anaesthetic.

The skin over your groin area and/or neck will be cleaned and a sterile drape cover your body. The doctor will use local anaesthetic to numb the skin, and then make a small cut where the needle enters.

When you are under sedation, the vein in your groin (or neck) will be accessed with a needle. Special wires and catheters will be inserted into the vein and guided to the heart through the vessels using ultrasound and x-ray images. Occasionally, iodinated contrast (x-ray dye) may be used to visualise the vessels.

Blood-thinning medication will be administered during the procedure.

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Your heart may require monitoring with a special ultrasound probe that is inserted into your oesophagus (swallowing tube). This is called a Trans-Oesophageal Echocardiogram (TOE). A TOE provides clear images of the heart before, during and after the procedure. It will be removed before you wake up.

Sometimes the TOE will be done prior to your procedure day. Otherwise, it is done during the procedure.

The catheter will first enter the right atrium, (top chamber). As atrial fibrillation starts in the left atrium, ultrasound and x-ray imaging may be used to guide a long needle through the thin membrane separating the two top chambers of the heart to allow the catheter to enter the left atrium. This part of the procedure might be performed under x-ray, Intra-Cardiac Echocardiography (ICE) catheter, TOE or a combination of these.

Electrophysiology Study (EPS) is performed using a special mapping catheter. The doctor can map the heart muscle, and the origins of the electrical activity, throughout the heart. The map tells the doctor which areas of the heart are creating problematic signals, and interfering with the proper rhythm.

The doctor carefully destroys (ablates) the problematic tissue using a special catheter that delivers energy to the problematic area, causing it to scar and stop sending abnormal signals.

Once the procedure is complete, the catheter will be removed. Firm pressure will be placed over the area where the catheter went into your skin (puncture site). This allows the vein to seal over, so you will not continue to bleed. Once 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.

Your observations will be monitored regularly and your puncture site will be checked for swelling, oozing of blood and bruising.

When you are completely recovered, you may be transferred to a hospital bed, depending on the type of anaesthesia you had during the procedure.

It is not uncommon to have a mild sore throat and some mild chest discomfort after the procedure. This should improve in a couple of days.

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

Once 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

- mild bruising or discomfort may occur around the puncture site.

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Uncommon risks and complications

- develop another arrhythmia
- a hole is accidentally made in the heart or heart valve. This will need surgery to repair
- chest pain
- major bruising or swelling at the puncture site. This (rarely) may need surgery
- a stroke. This may cause long-term disability
- blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs
- skin injury from radiation (x-ray). This may cause reddening of the skin
- pericarditis. This is an inflammation of the heart sac that can cause chest pain for some weeks after the procedure
- 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
- narrowing of the veins from the lungs to the heart. This can be serious, causing breathlessness and may require further procedures
- heart attack
- damage to the phrenic nerve that controls the diaphragm (breathing muscle)
- atrial oesophageal fistula. A hole forms between the oesophagus and heart. This can cause vomiting of blood and a stroke. This may be life-threatening
- death as a result of this procedure is rare.

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

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. The risk of kidney injury from the contrast used in the ablation procedure is very low.

In patients with severe renal impairment or acute kidney injury, careful weighing of the risk versus the benefit of giving iodinated contrast needs to be undertaken. However, having severe renal impairment does not mean that iodinated contrast should not be given if medically indicated¹. Your treating doctor will discuss your specific circumstances with you.

Risks of radiation (x-ray)

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 procedure².

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What are the risks of not having an AF ablation?

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 ablation is life-long medication. Your doctor should discuss any alternative procedure options and their risks and benefits with you.

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.



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 and what level of activity is suitable after your procedure.

It is common to have 1 or 2 nights in hospital, but you might be discharged on the same day depending on circumstances.

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.



5. Who will be performing the procedure?

Doctors, cardiac scientists, radiographers, 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.

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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



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