



Queensland
Government

Alcohol Septal 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 referring doctor has informed me about the following procedure(s) and I consent to:

Alcohol septal ablation: Yes

Additional component:

D. Risks specific to the patient in having an alcohol septal ablation

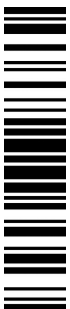
(Doctor to document additional risks not included in the patient information sheet)

E. Risks specific to the patient in *not* having an alcohol septal ablation

(Doctor to document specific risks in not having an alcohol septal ablation)

DO NOT WRITE IN THIS BINDING MARGIN

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SW9009

ALCOHOL SEPTAL ABLATION CONSENT



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F. Alternative procedure options

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

G. Acknowledgment and consent

I acknowledge that the doctor has explained and I understand:

- the 'Alcohol Septal 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.

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

- 'Alcohol Septal Ablation'
- 'About Your Anaesthetic'
- Other (specify):

On the basis of the above statements,

I consent to having an alcohol septal 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

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Alcohol Septal Ablation

Adult (18 years and over)

Informed consent: patient information

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 alcohol septal ablation and how will it help me?

Alcohol septal ablation is a procedure that is used to treat the symptoms of a condition called hypertrophic cardiomyopathy. This condition causes abnormal thickening of the ventricular septum, the muscle between the bottom chambers of the heart (ventricles).

Thickening of this area can obstruct the blood flow out of your heart, and can increase the pressure within the heart. These changes in your heart can lead to shortness of breath and feeling tired, and this procedure should relieve your symptoms.

During the procedure, alcohol is injected into the artery that is supplying the thickened muscle. The alcohol instantly makes the blood clot in the artery, and causes a controlled heart attack in the area of thickened muscle. The alcohol will also cause some of your heart muscle cells to shrink and die (the ablation). The scar tissue will be thinner than the thickened muscle was before, and the decrease in thickness allows more blood to flow out of your heart, relieving your symptoms.

The procedure is a less invasive option than open-heart surgery, and requires less recovery time.

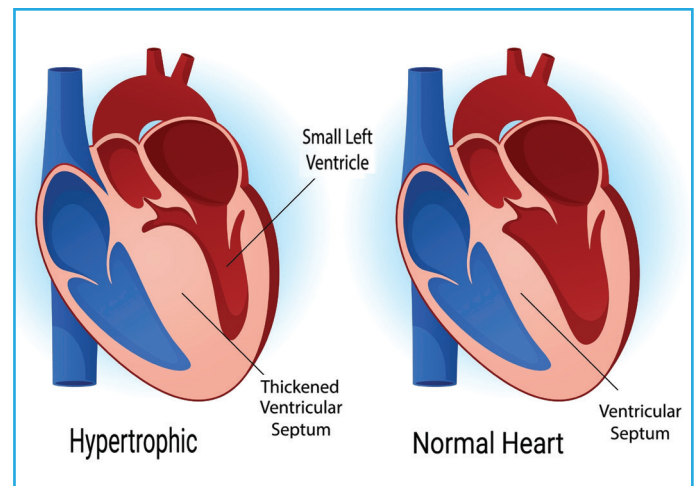


Image: Hypertrophic cardiomyopathy.
ID: 2266655813 (adapted). www.shutterstock.com

DO NOT WRITE IN THIS BINDING MARGIN

Preparing for the procedure

Patients having this procedure are usually in hospital for 2–3 days after your procedure. 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.

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Alcohol Septal Ablation

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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.
- 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.

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 alcohol septal 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.

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

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 anaesthetic.

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Alcohol Septal Ablation

Adult (18 years and over)

Informed consent: patient information

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.

The skin over your groin or wrist 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 then make a small cut in your groin or wrist, placing a special needle into the artery. Using iodinated contrast (x-ray dye) and x-ray guidance, the doctor will guide a catheter up through the blood vessels to your heart.

Images are taken as iodinated contrast is injected through the catheter. This will require the imaging equipment to move externally around your body. It is normal for the contrast to give you a warm flushed feeling while it is being injected.

Once the catheter tip is in the artery that supplies the thickened area of heart muscle, a small amount of alcohol will be injected. This destroys some of the heart muscle cells in this area, causing it to scar. This may cause discomfort; the cardiology team will monitor your discomfort to ensure it improves. If you do not already have a pacemaker, a temporary pacemaker may be inserted. If you have a heart rhythm problem, you may require insertion of a permanent pacemaker.

Once your 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 pressure allows the artery 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 dressing is applied, you will be transferred from the procedure room to a recovery area.

Your observations and puncture site will be checked regularly for swelling, oozing of blood and bruising. You may be required to have an electrocardiogram (ECG), to allow your doctor to confirm how successful the ablation procedure was.

You may be required to rest in bed for up to 6 hours. Moving too soon after this procedure may cause bleeding at the puncture site.

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

- mild pain or discomfort may occur around the puncture site
- chest pain
- abnormal heart rhythms (fast or slow). A permanent pacemaker or defibrillator device may be required
- heart block, a disruption to the electrical signals through your heart
- infection
- blood clots
- abnormal fluid build up around your heart
- coronary artery complications

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- shock
- failure of the procedure to work effectively.

Uncommon risks and complications

- bleeding at the puncture site
- bleeding 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
- abnormally slow heart rate that persists. This may require a permanent pacemaker
- a hole is accidentally made in the heart or heart valve. This will require surgical 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
- heart attack could occur, due to the strain on the heart
- embolism. A blood clot may break off from the catheter, causing a stroke
- ventricular septal defect (hole in the wall of the septum). This will require urgent surgical repair
- 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.

You may be asked to have a blood test to find out how well your kidneys are functioning.

In patients with severe renal function impairment or actively deteriorating renal function (acute kidney injury) careful weighing of the risk versus the benefit of giving iodinated contrast, needs to be undertaken. However, severe renal function 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

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.

What are the risks of not having a alcohol septal 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.

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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 alcohol septal ablation is a septal myectomy. In a septal myectomy, a surgeon removes excess muscle from the thickened septum. Because a septal myectomy is a type of open-heart surgery, it takes longer to recover. Both procedures decrease the thickness of the septum.

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.

After the procedure, the cardiologist (doctor) will review the final images and test results and then discuss them with you, including any follow-up that is required. They will also send the report to your treating/referring team.

You will receive the results of your report at your next follow-up appointment. Please make an appointment if you do not already have one.

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/clinician will be performing your procedure, please discuss this with the doctor/clinician.

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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