



Queensland
Government

Percutaneous Mitral Valve Balloon Valvuloplasty Consent

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?

Complete for ADULT patient only

- 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:

Complete for CHILD/YOUNG PERSON patient only

- Yes Although the patient is a child/young person, the patient may be capable of giving informed consent and having sufficient maturity, understanding and intelligence to enable them to fully understand the nature, consequences and risks of the proposed procedure and the consequences of non-treatment – 'Gillick competence' (*Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112). See the 'Guide to Informed Decision-making in Health Care' www.health.qld.gov.au/consent/clinician-resources/guide-to-informed-decision-making-in-healthcare for further information.

→ **GO TO** section B

- No Parent/legal guardian/other person* with parental rights and responsibilities to provide consent and complete this form.

→ **COMPLETE** section A

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health 'Guide to Informed Decision-making in Health Care' and local policy and procedures. Complete the source of decision-making authority as applicable below.

Name of parent/legal guardian/other person:

Relationship to child/young person:

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:

Percutaneous mitral valve balloon valvuloplasty: Yes

Additional component:

D. Risks specific to the patient in having a percutaneous mitral valve balloon valvuloplasty

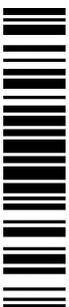
(Doctor to document additional risks not included in the patient information sheet)

E. Risks specific to the patient in *not* having a Percutaneous mitral valve balloon valvuloplasty

(Doctor to document specific risks in not having a percutaneous mitral valve balloon valvuloplasty)

DO NOT WRITE IN THIS BINDING MARGIN

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SW9027

PERCUTANEOUS MITRAL VALVE BALLOON VALVULOPLASTY CONSENT



Percutaneous Mitral Valve Balloon Valvuloplasty 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 'Percutaneous Mitral Valve Balloon Valvuloplasty' 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 the procedure leads to the need for a blood or blood products transfusion, an additional consent form will be required
- that if an immediate life-threatening event happens during the procedure:
 - for an adult patient, health care will be provided based on their 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)*
 - for a child/young person, health care will be provided in accordance with good clinical practice and in the best interests of the patient
- 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):

- 'Percutaneous Mitral Valve Balloon Valvuloplasty'
- 'About Your Anaesthetic' (*Adult patient only*)
- 'About Your Child's Anaesthetic' (*Child/young person patient only*)
- 'Blood and/or Manufactured Blood Products Transfusion (Full/Limited Consent)' (*Adult patient only*)
- 'Transfusion Consent: Fresh and/or Manufactured Blood Products (Full/Limited Consent)' (*Child/young person patient only*)
- Other (*specify*):

On the basis of the above statements,

I consent to having a percutaneous Mitral Valve Balloon Valvuloplasty.

Name of patient/substitute decision-maker/parent/legal guardian/other person:

Signature:

Date:

If the patient is a child/young person:

- I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person for this procedure (*not applicable if the child/young person is Gillick competent and signs this form*).

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

Percutaneous Mitral Valve Balloon Valvuloplasty

Adult and Child/Young Person
 Informed consent: patient information

(Affix identification label here)

URN:

Family name:

Given name(s):

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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.



1. What is a percutaneous mitral valve balloon valvuloplasty and how will it help me?

The mitral valve is an important valve in your heart. It controls the blood flow from the upper left chamber of the heart (atrium) to the lower left chamber (ventricle). Sometimes this valve becomes narrow, stiff or thickened because of disease. This is called mitral valve stenosis.

When this happens the flaps of the valve stick together, and this reduces the blood flow, causing a back-up of fluid in your lungs. If you have this problem, you may feel short of breath (puffed).

Valvuloplasty is a procedure used to treat mitral valve stenosis. The diseased valve is widened using a balloon. The balloon is attached to a catheter that enters a vein in your groin or wrist, and is passed through the vessels until it reaches your heart and the mitral valve. The balloon is inflated to open the valve. This will improve your blood flow, reducing pressure in the heart and lungs, and improve heart function.

The procedure may also involve the following:

- **Angiogram:** to show any narrowing or blockage in your coronary arteries.
- **Right heart catheter:** to measure pressures in the your heart.
- **Echocardiogram:** an ultrasound of your heart, to view the heart and its valves while the heart is beating. This can be either intracardiac (from within the heart) or oesophageal (via your feeding tube, from mouth to stomach, also referred to as Trans-Oesophageal Echocardiogram [TOE]).

Relief of symptoms is dependent on the severity of your valve disease. In some patients, valvuloplasty can provide relief of symptoms for up to 20 years, however, most patients have relief for 5 to 10 years. The procedure may need to be repeated, if symptoms return.

Iodinated contrast (also known as x-ray dye) is required for this procedure.

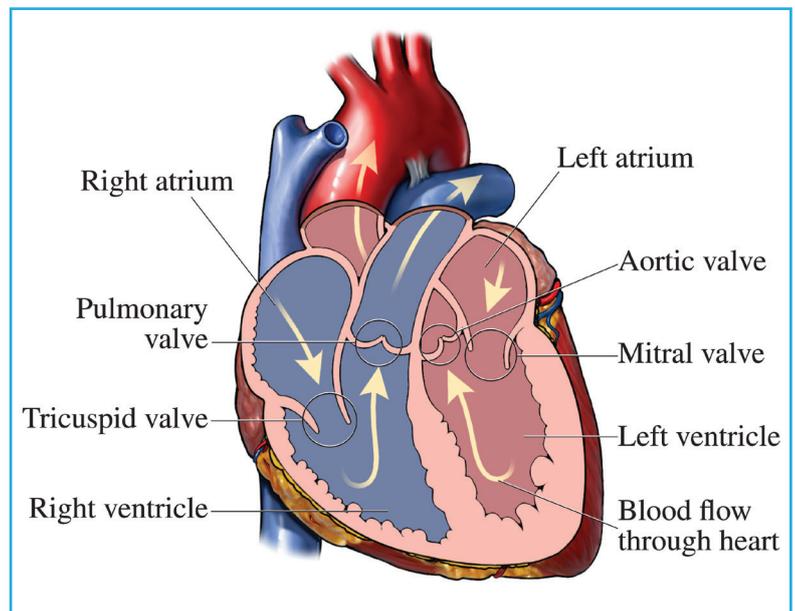


Image: Normal heart. Illustration Copyright © 2019 Nucleus Medical Media, All rights reserved. www.nucleusmedicalmedia.com

DO NOT WRITE IN THIS BINDING MARGIN

Percutaneous Mitral Valve Balloon Valvuloplasty

Adult and Child/Young Person

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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 a local anaesthetic and possibly a mild sedation. A child or young person patient may require a general anaesthetic. If you are having sedation or a general anaesthetic, and are being discharged on the same day, you cannot drive and you must have someone available to escort you home.

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.

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.

Percutaneous Mitral Valve Balloon Valvuloplasty

Adult and Child/Young Person
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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 percutaneous mitral valve balloon valvuloplasty

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.

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 sedation.

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.

The skin over your lower arm and/or groin 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 where the needle enters.

When you are under sedation, the vein in your groin (or arm) will be accessed with a needle, using ultrasound as a guide. A sheath (short plastic tube) is introduced into the vessel to allow special wires and catheters to be easily inserted into the vein and guided through the vessels to the heart.

If an angiogram is required, the artery in your lower arm or groin is also accessed by needle, sheath and catheter. An angiogram is done of each coronary (heart) artery using iodinated contrast (x-ray dye) and x-rays. This allows the doctor to assess and measure each artery. The doctor may also inject contrast directly into the heart chambers, to measure the size of the heart and assess how well it is pumping.

A right heart catheter is completed to assess pressures of the heart and lung vessels if required. A soft balloon pressure catheter is passed through the blood vessels, from the groin to the heart, and into the blood vessels of the lung. The blood pressures are recorded in these locations.

An echocardiogram may also be done at this time. This is an ultrasound of the heart done via the oesophagus (feeding tube, from mouth to stomach) or via the catheter already in the artery (intracardiac). This allows the doctor to get a close-up view of your heart and its valves while the heart is beating.

Percutaneous Mitral Valve Balloon Valvuloplasty

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When the measurements have been completed, a wire is passed along the blood vessel, up to the heart until it reaches the mitral valve. The doctor uses x-ray imaging to see the wire. When the wire is in place, a balloon is passed along the wire and into the damaged valve. The balloon is inflated where the valve is narrowed. You may notice some dizziness or brief discomfort. This should be relieved once the balloon is deflated.

The doctor may need to repeat this step several times to widen the valve, as far as possible.

At the end of the procedure the wire, catheters and sheath are removed. Firm pressure will be placed over the area where the catheters went into your skin (puncture site). You may have more than 1 puncture site. The pressure applied allows the vein (or artery) to seal over so you will not continue to bleed. The doctor may decide to use a special plug (closure device) to stop the bleeding. Your cardiologist will discuss this with you.

When the bleeding has stopped a small dressing will be applied to the puncture site. You will then be transferred from the procedure room to a recovery area.

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

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.

You will be transferred to the ward once you are awake and observations are stable.

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

- abnormal heartbeat lasting several seconds, which settles by itself
- bruising or swelling at the groin (or arm) 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
- loss of pulse in the arm after a radial artery (arm) procedure. This can be temporary or permanent
- a severe leak in the mitral valve can happen. This will need surgery to repair.

Uncommon risks and complications

- a stroke. This can cause long-term disability
- accidental puncture of the heart. This may need surgery to repair
- blood clot in a vein or artery. This may require blood thinning medication or surgery
- the valve may leak or can be damaged

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- temporary epilation (hairloss) or skin damage, due to x-ray radiation to the treated area
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- abnormal heart rhythm that continues for a long time. This may need a controlled electric shock to correct
- (*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
- damage to a puncture site or blood vessel, requiring surgical repair
- heart attack
- infection. This may need antibiotics and extended stay in hospital
- air embolism, oxygen may be given
- damage to the nerve in the leg
- permanent epilation (hairloss) or skin burns from exposure to x-rays
- Trans-Oesophageal Echocardiogram (TOE) – oral/dental/throat/oesophageal damage
- death is possible due to the procedure.

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.

Blood test results will be reviewed 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 percutaneous mitral valve balloon valvuloplasty?

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.

Percutaneous Mitral Valve Balloon Valvuloplasty

Adult and Child/Young Person

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3. Are there alternatives?

An alternative may be available. Your doctor will discuss the most appropriate procedure for your circumstances.

In some cases a possible alternative procedure is a mitral valve replacement. There are two main options:

- Surgical mitral valve repair/replacement, which requires open heart surgery.
- Trans-catheter Mitral Valve Replacement (TMVR), which requires access via a vessel in your groin.

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.

You may eat and drink your usual diet unless otherwise advised.

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

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.

Percutaneous Mitral Valve Balloon Valvuloplasty

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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