



Queensland  
Government

# Mitral Transcatheter Edge-to-Edge Repair 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:

Mitral transcatheter edge-to-edge repair:  Yes

Additional component:

## D. Risks specific to the patient in having a mitral transcatheter edge-to-edge repair

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

## E. Risks specific to the patient in *not* having a mitral transcatheter edge-to-edge repair

*(Doctor to document specific risks in not having a mitral transcatheter edge-to-edge repair)*

DO NOT WRITE IN THIS BINDING MARGIN

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MITRAL TRANSCATHETER EDGE-TO-EDGE REPAIR 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 'Mitral Transcatheter Edge-to-Edge Repair' 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, 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):

- 'Mitral Transcatheter Edge-to-Edge Repair'
- 'Trans-Oesophageal Echocardiogram (TOE)'
- 'About Your Anaesthetic'
- 'Blood and/or Manufactured Blood Products Transfusion (Full/Limited Consent)'
- Other (*specify*):

On the basis of the above statements,

## I consent to having a mitral transcatheter edge-to-edge repair.

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](http://www.health.qld.gov.au/consent/students)

# Mitral Transcatheter Edge-to-Edge Repair

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 a mitral transcatheter edge-to-edge repair and how will it help me?

The mitral valve is an important valve in our heart. It controls the blood flow from the upper left chamber of the heart (atrium) to the lower left chamber (ventricle). The valve consists of two leaflets (flaps), when the heart contracts, these leaflets stop the blood from leaking back into the top left chamber of the heart (atrium). When the leaflets do not close properly, leaking of blood occurs, and this is called mitral regurgitation. When mitral regurgitation is severe, it can lead to an irregular heart rhythm, heart failure, a reduction in heart function, chronic shortness of breath, and death.

The leaking can be reduced or stopped by inserting a clip to hold the leaflets together.

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.

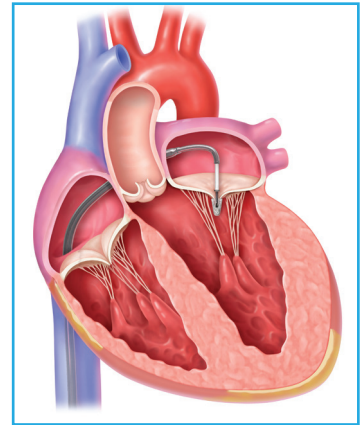
This is a minimally invasive alternative to open heart surgery. The clip will remain on the mitral valve permanently.

The procedure may also involve the following:

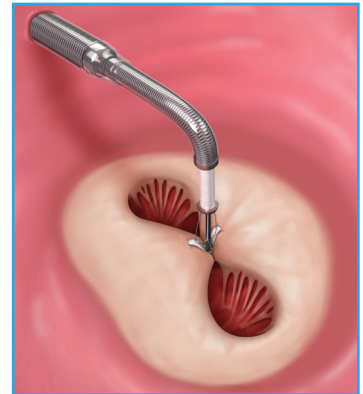
- **Echocardiogram:** To view the heart with ultrasound. This can be either intracardiac (from within the heart) or oesophageal (via your feeding tube, from mouth to stomach, also referred to as Trans-Oesophageal Echocardiogram [TOE]).
- **Transeptal puncture:** Access to the left atrium requires crossing the tissue inside the heart separating the right from the left atrium (called the interatrial septum). A small hole is made between the top two chambers of the heart (atria). This is performed using x-ray and/or ultrasound guidance.
- **Right heart catheter:** This is a procedure used to measure the pressures within your heart and assist doctors to determine cardiac output (the amount of blood the heart pumps every minute).

You will require antibiotics before this procedure.

You will be required to remain on blood-thinners after the procedure and be required to take antibiotics before any invasive medical or dental procedure in the future.



*Image 1: Clip closed to 20 degrees. MitraClip™ is a trademark of Abbott or its related companies. Reproduced with permission of Abbott, © 2024. All rights reserved.*



*Image 2: Mitral valve closed with an Abbott MitraClip™. MitraClip™ is a trademark of Abbott or its related companies. Reproduced with permission of Abbott, © 2024. All rights reserved.*

DO NOT WRITE IN THIS BINDING MARGIN

# Mitral Transcatheter Edge-to-Edge Repair

Adult (18 years and over)

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## Preparing for the procedure

Patients having this procedure are usually in hospital for at least 1 night. 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.

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.

Sometimes the procedure may not be possible due to medical and/or equipment failure. This may result in a delay or re-booking of your procedure.

This procedure will require the use of a local anaesthetic and general anaesthetic. Please read the information sheet *About Your Anaesthetic*. If you do not have one of these information sheets, please ask for one.



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Adult (18 years and over)

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## For a substitute decision-maker of an adult without capacity to consent to having a mitral transcatheter edge-to-edge 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.

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.

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 fluids required during the procedure, including the 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.

When you are asleep, the skin of your groin area will be cleaned and a sterile drape will cover your body. The doctor will use local anaesthetic to numb your skin and make a small cut where the needle and catheter (thin tube) enter your vein.

Trans-Oesophageal Echocardiography (TOE) and x-rays are used to guide the specialised catheters and guidewires through the vessels from the vein in the groin (femoral vein) to the heart. The catheter is guided to the right upper side of your heart (atrium) and passed through the heart wall (septum) to the top chamber of the left side of the heart (atrium). Once in the left atrium, the wire is removed. The clips are inserted via this catheter system and placed on the the mitral valve leaflets.

When the procedure is complete, the catheters 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 and puncture site will be checked regularly for swelling, oozing of blood and bruising.

When you are completely recovered, you will 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 in 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.

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## 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

- swelling, bruising or haematoma (collection of blood outside the vessel) at the puncture site
- hypertension/hypotension (high or low blood pressure)
- abnormal heart rhythms
- bleeding could occur and may require a blood transfusion
- 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
- damage to the vein in the leg. This may need surgical repair
- femoral artery aneurysm (weak area in the artery resulting in a bulge) or pseudoaneurysm (false aneurysm) which may require surgical repair or stent placement
- increased risk of wound infection, chest infection, heart and lung complications, and blood clot in the leg or lungs for people who are obese.

### Uncommon risks and complications

- stroke or TIA (Transient Ischaemic Attack). This may cause long-term disability
- incomplete repair or damage to the mitral valve. This may require surgery
- embolism. A blood clot may form and break off from the catheter, causing a stroke
- air (air embolism) may enter the heart and cause cardiac arrest
- injury to the artery, veins or nerves in the groin or neck. This may require surgery
- tear of oesophagus, vein or heart. This may be life-threatening. It may require surgery
- clots in the leg (deep vein thrombosis or DVT) with pain and swelling. A part of this clot may break off and go into the lungs
- device infection. This could require open heart surgery and will need antibiotics.

### 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
- perforation or damage of vessels, myocardium or valve structures which may require emergency major surgery
- a punctured lung. This may require a tube to be inserted into the chest to reinflate the lung
- pericardial effusion (fluid collection around heart)
- dislodgement of the clip, which may require open heart surgery to retrieve
- blood clot formation on the mitral valve clip
- clip causing destruction of red blood cells
- infection of implanted clip
- 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

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. The risk of kidney injury from the contrast used in transcatheter mitral valve repair is very low.

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, having severe renal impairment does not mean that iodinated contrast should not be given if medically indicated<sup>1</sup>. 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<sup>2</sup>.

## What are the risks of not having a mitral transcatheter edge-to-edge 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?

An alternative may be available. 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.



## 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 will be given a Patient Implant Card (PIC) for your records with the specific details of any implanted devices used. This information may be helpful for future safety for any Magnetic Resonance Imaging (MRI) scans.

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**Bacterial endocarditis awareness:** After your mitral valve transcatheter edge-to-edge repair. If you require any invasive procedures (including dental treatment) it is important you let your treating doctor/dentist know about your valve 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.

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.

After the transcatheter mitral valve edge-to-edge repair, patients should remain on lifelong antiplatelet or anticoagulants medication. If stopped, there is an increased risk of thrombosis (clotting) of the mitral edge-to-edge repair.

The treating cardiologist should be notified for a plan if these medications need to be stopped or withheld.



## 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](http://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](http://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](http://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](http://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](http://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](http://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](http://www.arpansa.gov.au)