



Queensland
Government

Transcatheter Heart Valve Implant 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:

- Transfemoral Transaortic Valve Implant (TAVI): Yes No
Transcarotid TAVI: Yes No
Axillary TAVI: Yes No
Transaortic/transapical TAVI: Yes No
Pulmonic transcatheter heart valve implant: Yes No
Transeptal mitral valve implant: Yes No
Tricuspid transcatheter heart valve implant: Yes No

Other:

D. Risks specific to the patient in having a transcatheter heart valve implant

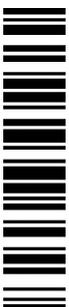
(Doctor to document additional risks not included in the patient information sheet)

E. Risks specific to the patient in *not* having a transcatheter heart valve implant

(Doctor to document specific risks in not having a transcatheter heart valve implant)

DO NOT WRITE IN THIS BINDING MARGIN

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TRANSCATHETER HEART VALVE IMPLANT 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 'Transcatheter Heart Valve Implant' 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 may lead to the need for a blood or blood products transfusion, an additional consent form will be required
- that tissues/blood may be removed and used for diagnosis/management of the 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):

- 'Transcatheter Heart Valve Implant'
- 'Transoesophageal 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 transcatheter heart valve implant.

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

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Adult (18 years and over)
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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 transcatheter heart valve implant and how will it help me?

The heart has four main valves and they control the flow of blood through the heart. These hardworking valves, or a previous valve replacement, can become diseased and cause symptoms, such as:

- shortness of breath
- poor exercise tolerance and fatigue
- chest pain
- dizziness and fainting
- fluid retention.

Your heart valve or your previous valve replacement can become:

- stenosed (the valve leaflets [flaps] become stiff and don't move easy or open fully)
- regurgitant (the valve leaflets don't join properly and cause a backflow of blood in the heart).

This procedure is done under sedation and may require the use of iodinated contrast (also known as x-ray dye) and x-rays. It involves passing a thin tube (catheter) via an artery to the heart, to implant a new valve, and can improve your symptoms from valvular heart disease.

The Heart Valve Team will decide on the safest method to deliver your new heart valve at the Heart Valve team meeting. The following access points can be utilized:

- an artery in your groin (femoral artery)
- a chest artery below your collar bone (subclavian artery)
- access via an incision between your ribs on your upper chest (direct aortic)
- access via an incision between your left lower ribs to access the valve through the base of your heart.

There are two types of transcatheter valve implants:

- balloon expandable valve implant (guided to your valve and expanded into place with the help of a balloon catheter)
- self-expanding valve implant (the valve implant is inside a catheter and springs into position when released).

The type and size of heart valve implant is decided by your cardiologist (specialist heart doctor) after a detailed review of all your investigations, or test results.

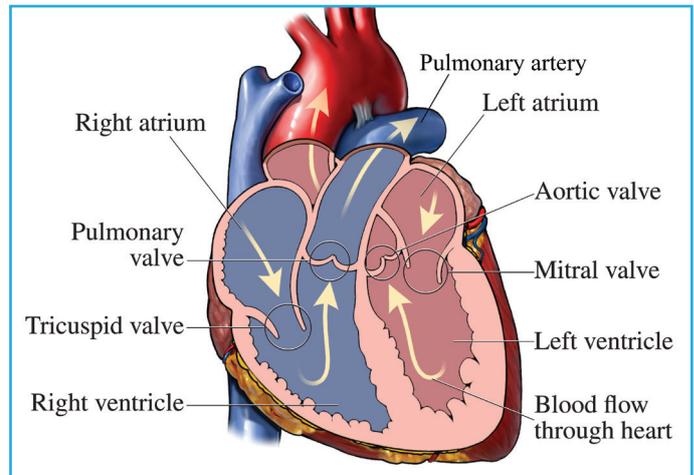


Image 1: Normal heart anatomy. Illustration Copyright © 2019 Nucleus Medical Media, All rights reserved. www.nucleusmedicalmedia.com

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Preparing for the procedure

Patients having this procedure are usually in hospital for at least 5 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.

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.

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.

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For a substitute decision-maker of an adult without capacity to consent to having a transcatheter heart valve implant

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

An intravenous (I.V.) cannula is a small plastic tube that will be inserted into a vein, usually in your hand or arm. This is for any medication or fluids required during the procedure, including sedation and anaesthetic medications.

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 around the access site, will be cleaned and a sterile drape will be applied to cover you. The doctor will use local anaesthetic to numb your skin and a short plastic tube (introducer) is inserted into your access artery. The cardiologist may use iodinated contrast and x-ray imaging to guide special wires and catheters through the vessels to the heart. They may also choose to 'balloon' your own valve prior to implanting your new valve.

Another catheter with your loaded valve implant is inserted and directed towards your valve or valve replacement.

The valve is implanted with either a balloon catheter or self-expands from inside the catheter.

The new valve implant starts functioning straight away and no tissue is cut or removed. The leaflets of your old valve are pushed out against the valve wall.

In addition to x-ray, a Transoesophageal Echocardiogram (TOE) may be performed during the procedure. A TOE involves the use of ultrasound to create images of the heart, and is done via your oesophagus (food pipe). Imaging assists the cardiologist with the correct positioning of your new valve.

A pacing wire is utilised to increase your heart rate when the valve is expanding into position.

The pacing wire may remain in place if your heart rate or rhythm changes during the procedure.

At the end of the procedure the wire and balloon are removed. A closure device (artery closing suture) will be used to close the artery where the catheters went in (puncture site). This allows the artery to seal over so you will not continue bleed.

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

You may be required to rest in bed for up to 4 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.



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 at the insertion site
- bleeding from insertion 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

- hypertension/hypotension (high or low blood pressure)
- abnormal heart rhythms
- a permanent pacemaker implant may be required for a slow heart rate
- pain at wound or insertion site.

Uncommon risks and complications

- bleeding from insertion site requiring blood transfusion
- artery aneurysm or pseudoneurysm (false aneurysm) which may require drug treatment or a stent (small mesh tube)
- infection requiring antibiotics
- worsening or failure of kidney function
- heart attack caused by the new valve blocking the coronary arteries
- blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to your lungs (pulmonary embolus)
- stroke (blood clot or bleeding in the brain) potentially causing permanent disability.

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, heart muscle, heart valves or chambers. This may require surgery to repair
- valve implant moving from where it is initially placed. The valve may need to be removed with a special catheter or open heart surgery
- opening or tear in the lining of the aorta
- infection settling on the new valve which requires long term antibiotics
- leakage around the new valve
- respiratory failure

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- (axillary [armpit] only) temporary or permanent nerve damage to arm
- 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 the risk to kidney function

Iodinated contrast is removed from the blood by the kidneys through the urine.

In patients with severe renal function impairment or actively deteriorating renal function (acute kidney injury) careful weighing of the risk versus the benefit of, iodinated contrast media administration needs to be undertaken. However, severe renal function impairment does not mean that iodinated contrast should not be given, if medically 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 transcatheter heart valve implant?

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?

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?

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

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

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.

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- Do NOT drink alcohol, smoke, vape or take recreational drugs. They may react with the anaesthetic medications.

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

Bacterial endocarditis awareness

After your aortic valve implant is inserted, 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 need 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 treating or local 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
- other warning signs the doctor may have asked you to be aware of.

After the transcatheter heart valve implant, you will stay on lifelong antiplatelet or anticoagulation medications. If these are stopped the risk of thrombosis (clot) within the heart valve implant increases.

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

You will not be able to drive for 4 weeks. For more information see Ausroads website <https://austroads.com.au/publications/assessing-fitness-to-drive/ap-g56/cardiovascular-conditions>.



5. Who will be performing the procedure?

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.

Clinical students

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

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

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

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6. Where can I find support or more information?

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

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

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

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

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

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



7. Questions

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

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



8. Contact us

In an emergency, call Triple Zero (000).

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

References:

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