Queensland Government

Cardiac Device Removal 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:

Cardiac device removal: ☐ Yes

Venogram: ☐ Yes ☐ No

Trans-Oesophageal Echocardiogram (TOE): ☐ Yes ☐ No

Site/side of procedure /additional components:

D. Risks specific to the patient in having a cardiac device removal

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

E. Risks specific to the patient in *not* having a cardiac device removal

(Doctor to document specific risks in not having a cardiac device removal)

DO NOT WRITE IN THIS BINDING MARGIN

CARDIAC DEVICE REMOVAL CONSENT

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SW9028

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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 'Cardiac Device Removal' 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 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):

- ☐ 'Cardiac Device Removal'
- ☐ '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 cardiac device removal.

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

DO NOT WRITE IN THIS BINDING MARGIN

Queensland Government

Cardiac Device Removal

Adult (18 years and over)
Informed consent: patient information

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

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 cardiac device removal and how will it help me?

A pacemaker or Implantable Cardioverter Defibrillator (ICD) is a device you have had implanted under your skin to prevent the heart beating too slow or too fast. Most devices consist of two parts, a pulse generator and leads.

Your device may need to be removed if it is infected or if it is not working properly.

You will need to stay in hospital for a few days or until the infection has cleared and a new device can be inserted. Your cardiology doctor will discuss this with you.

The procedure may also involve the following:

- Venogram to show the anatomy of your veins, using iodinated contrast (x-ray dye) and x-rays.
- Trans-oesophageal Echocardiogram (TOE) to view the heart using an ultrasound probe that is inserted via a telescope into your oesophagus (feeding tube, from mouth to stomach).

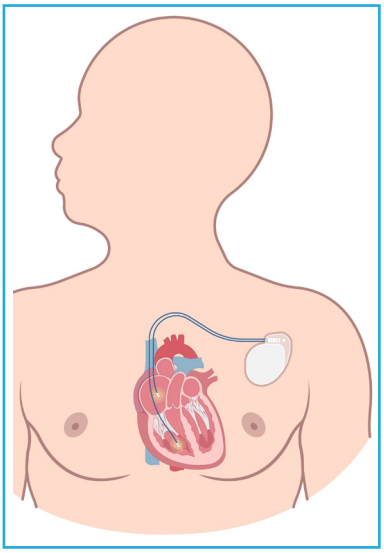

Image: Implantable cardiac device (adapted). ID: 2165111961. www.shutterstock.com

DO NOT WRITE IN THIS BINDING MARGIN

Preparing for the 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.

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Cardiac Device Removal

Adult (18 years and over)
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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.

This procedure will be done in the operating theatre and require the use of a local anaesthetic with general anaesthetic. Occasionally sedation will be used. 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 a cardiac device removal

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 fluid required during the procedure, including your anaesthetic. You will also have an arterial line inserted.

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This is a small plastic tube inserted in the artery usually in your wrist, and is used for monitoring your blood pressure.

You will be given a general anaesthetic to make you sleep. Once asleep, an endotracheal tube (breathing tube) will be placed through your mouth and into your throat. This will maintain your airway and help you breathe throughout the procedure. The tube is removed as you wake up.

Other observations will also be measured before and during the procedure, these may include cardiac rhythm, heart rate, respiratory (breathing) rate and oxygen levels. You will be connected to an electrocardiogram (ECG) to monitor the electrical activity of your heart.

The skin over your chest and groin will be cleaned, and a sterile drape will cover your body. The doctor will use local anaesthetic to numb the skin over the device for removal and over the blood vessels for the angiogram or the insertion of temporary pacing wires, if required (explained later in this section).

A venogram may be performed to assess the blood vessels around the heart. This requires a catheter (thin plastic tube) to be inserted into the vein in your groin.

The doctor will decide what parts of the device require removal (pulse generator and/or leads). This will depend on your circumstances and reason for removal. A small cut is made near the device to allow removal.

During the procedure you may be required to have a Trans-Oesophageal Echocardiogram (TOE). A TOE is an ultrasound of the heart, during which a flexible telescope is inserted into your mouth and down your oesophagus (feeding tube) to your stomach, to obtain images of your heart and surrounding structures.

A TOE can assist the doctor to monitor for any complications during the procedure.

When the cardiac device has been removed, the wound will be cleaned, closed with sutures and a dressing applied. Wound drains may need to be inserted at the end of the procedure. Drains are small, soft, flexible tubes, which can assist with the removal of any fluids that may lead to procedure complications.

Depending on your circumstances, a new device may be re-implanted at this time, your doctor will discuss this with you before the procedure. You will be required to sign an additional consent form if this is planned.

If a new device is not able to be implanted at this time, and to ensure you maintain your heart rate and have a good cardiac output, you may require the insertion of a temporary pacing wire. This is a wire inserted by the doctor through the jugular vein in your neck into the right ventricle of your heart. It will be connected to an external pacing device to monitor and control the speed of your heart.

After the procedure is complete, you will be transferred from the procedure room to a recovery area. You will be required to lie flat for 2–4 hours. Your observations and wound site will be checked regularly.

Once you are awake, you will be transferred to a ward or the Coronary Care Unit (CCU) for overnight stay.

Once they are no longer needed, your I.V. and arterial line will be removed.

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

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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

- minor bruising at the device 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.

Uncommon risks and complications

- abnormal heart rhythm that continues for a long time. This may need an electric shock to correct
- blood clot in the subclavian vein, below your collarbone (subclavian vein thrombosis). This may require blood thinners (Novel Oral Anticoagulants – NOACs or Warfarin) for a few months
- leads may not be able to be removed
- infection at the site of the device. This will need antibiotics
- damage to the tricuspid valve in your heart. This may require surgery to repair.

Rare risks and complications

- need for urgent heart surgery
- injury to blood vessels causing bleeding. This may require surgery to repair
- injury to heart. This will require surgery
- a punctured lung. This may require a tube to be inserted into the chest to reinflate the lung
- blood clot in the lung (pulmonary embolism)
- heart attack
- a stroke. This can cause long-term disability
- death is possible due to this 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

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, having severe renal impairment does not mean that iodinated contrast should not be given, if medically indicated[1].

Your treating doctor will discuss your specific circumstances with you.

(Affix identification label here)

URN:

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Given name(s):

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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[2].

What are the risks of not having a cardiac device removal?

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?

Depending on the reason for device and/or lead removal, a new device and/or leads may need to be inserted.

If your device was removed because of infection, you may need to recover from the infection in hospital, while you receive antibiotics. You may require ongoing antibiotics once discharged. Your cardiologist will discuss this with you before you leave the 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.
- Do NOT drink alcohol, smoke, vape or take recreational drugs. They may react with the anaesthetic medications.

The Cardiology department will give you instructions on how to care for your wound dressing.

There are driving restrictions for patients who experience life threatening, abnormal and fast heartbeats. Please discuss these with your doctor.

5. Who will be performing the procedure?

Doctors, cardiac physiologists/scientists, radiographers, sonographers, pharmacists, nurses, and patient support officers 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.

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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

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