



Pacemaker Insertion 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 doctor has informed me about the following procedure(s) and I consent to:

Pacemaker insertion: Yes

Type: Single chamber Dual chamber
 Biventricular Leadless

Site/side of procedure/additional component:

D. Risks specific to the patient in having a pacemaker insertion

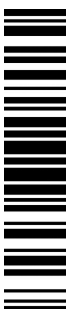
(Doctor to document additional risks not included in the patient information sheet)

E. Risks specific to the patient in *not* having a pacemaker insertion

(Doctor to document specific risks in not having a pacemaker insertion)

DO NOT WRITE IN THIS BINDING MARGIN

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SW9025

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F. Alternative procedure options

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

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

- 'Pacemaker Insertion'
- 'About Your Anaesthetic' (*Adult patient only*)
- 'About Your Child's Anaesthetic' (*Child/young person patient only*)
- Other (*specify*):

On the basis of the above statements,

I consent to having a pacemaker insertion.

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

G. Acknowledgment and consent

I acknowledge that the doctor has explained and I understand:

- the 'Pacemaker Insertion' patient information sheet
- the medical condition and proposed procedure, including the possibility of additional treatment
- this procedure requires sedation or general anaesthetic
- the specific risks and benefits of the procedure
- the prognosis and risks of not having the procedure
- alternative procedure options
- that there is no guarantee the procedure will improve the medical condition
- that if an immediate life-threatening event happens during the procedure:
 - 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.

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Pacemaker Insertion

Adult and Child/Young Person

Informed consent: patient information

This patient information sheet has been given to you to read carefully and allow time to ask your doctor any questions about this procedure. Your doctor will include the consent form and a copy of this patient information sheet in your medical record.

This patient information sheet uses the words 'I/you/your/me/my' to mean the patient or another person who is providing consent on behalf of the patient.



1. What is a pacemaker insertion and how will it help me?

A pacemaker is a device that is inserted in your chest to prevent your heart rate from going too slow. A slow heart rate can cause serious symptoms, such as shortness of breath, dizziness, blackouts and even death in some cases. The pacemaker is placed under your skin below your collarbone.

The pacemaker settings are tailored to each person depending on their need, and will only “step in” (pace) when required. The pacemaker will be ‘programmed’ to your needs by the doctor who puts the device in. An external machine is used to check and set the rate of the pacemaker. When your pacemaker’s function is checked, the pacing speed of your pacemaker may be temporarily increased and decreased. Then it will be reset to its normal setting. It is unlikely that you will feel anything when the pacemaker paces.

A standard pacemaker generally has two parts:

- **Pulse generator:** senses the heart beat and delivers impulses to the heart.
- **Lead(s):** sends impulses to and from the heart.

There are four types of pacemakers. The doctor will decide which pacemaker suits your condition.

1. **Single chamber:** Pacemaker is connected by one lead to a lower chamber of your heart.
2. **Leadless:** Pacemaker is inserted into the lower right chamber (right ventricle) of your heart. This pacemaker has only one part, a pulse generator.
3. **Dual chamber:** Pacemaker is connected by two leads. One to an upper and one to a lower chamber of your heart.
4. **Biventricular:** Pacemaker is connected by three leads. One to an upper and two to the lower chambers of your heart.

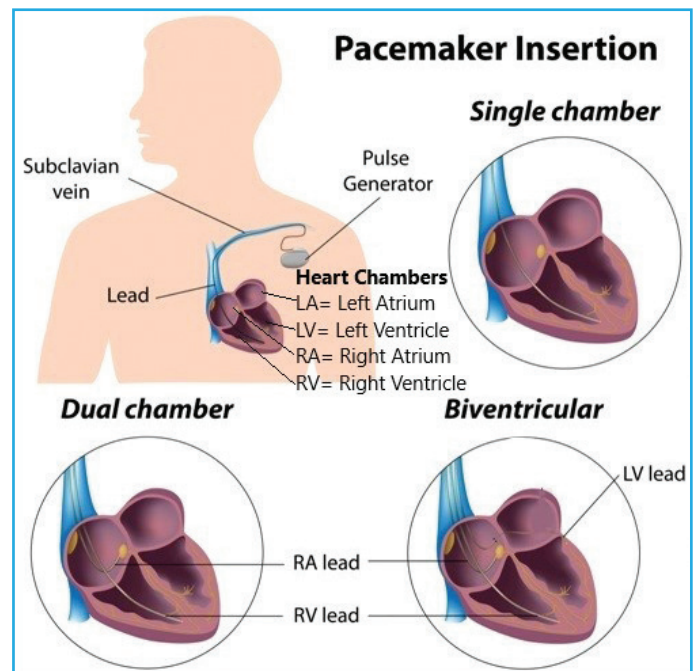


Image: Pacemaker insertion surgery.
ID: 90181147 (adapted). www.shutterstock.com

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Pacemaker Insertion

Adult and Child/Young Person

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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.

This procedure will require sedation, and possibly a general anaesthetic for a child or young person. If you received sedation and are being discharged on the same day, you must have someone available to escort you home. You are not permitted to drive for two weeks after your pacemaker insertion.

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 (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.

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For a substitute decision-maker/parent/legal guardian/other person of a child/young person/adult without capacity to consent to having a pacemaker insertion

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.

Other 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 sedation or general 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.

Before the procedure, you may be given antibiotics. These are given to prevent an infection from occurring.

Standard pacemaker

The skin of your chest will be cleaned, and a sterile drape will be applied to cover you. The doctor will use local anaesthetic to numb the skin where the pacemaker will be positioned, then a small cut is made near your collarbone. This cut creates a pocket under the skin for the pacemaker to be inserted.

A small cut is then made to put the lead(s) into a vein which leads to the heart. The lead(s) is threaded down the vein, into the heart.

The doctor can see the lead via x-ray images. Once positioned in the heart, the leads are tested to make sure they are working properly. They are then connected to the 'pulse generator'. The pulse generator is placed under the skin and the skin is stitched closed. A dressing is applied over the wound.

Leadless pacemaker

The skin of your chest and both groins will be cleaned and a sterile drape will be applied to cover you. The doctor will use local anaesthetic to numb the skin in your groin where the femoral vein, which is a large blood vessel in your thigh, will be punctured, to allow access of a catheter (tube) containing the pacemaker. X-rays are used to guide the catheter and pacemaker through the femoral vein and blood vessels to the heart.

Once the pacemaker is in the heart, it is tested to make sure it is working properly and is stable. The catheter is then removed and firm pressure is placed over the area where the catheter went into the skin (puncture site).

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This allows the vein to seal over so you will not bleed, a stitch may also be required. Once the bleeding has stopped, a small dressing will be applied to the puncture site.

All pacemakers

After the procedure is complete, you will be transferred from the procedure room to a recovery area. Your observations and the insertion site will be monitored regularly.

You may eat and drink after your procedure unless otherwise advised

If the I.V. cannula is no longer required, it will be removed after you have recovered.



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 pain, bleeding or bruising at the 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.

Uncommon risks and complications

- (*standard pacemakers only*) the pacemaker lead can move. The lead will need to be put back into place by repeating this procedure
- infection of the pacemaker site. This will need treatment with antibiotics and/or removal of the pacemaker
- failure to implant the leadless pacemaker inside the heart
- unexpected pacemaker failure. There is a risk of battery (generator) or lead failure. This is uncommon but means the battery or lead will need to be removed and a new one put in
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- a punctured lung. This may require a tube to be inserted into the chest to reinflate the lung
- blood clot in the subclavian (upper chest) vein used to insert pacemaker leads
- blood clot in the femoral (leg) vein used to insert leadless pacemaker
- a hole is accidentally made in the heart or heart valve. This will require surgery to repair
- blood clot in the lung
- heart attack
- a stroke. This can cause long-term disability
- dislodgement of the leadless pacemaker inside the circulation
- death is possible due to the procedure or other heart problems.

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

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- weakness
- heart and lung problems, such as a heart attack or pneumonia
- stroke resulting in brain damage.

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 procedure¹.

What are the risks of not having a pacemaker insertion?

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?

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

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

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

You cannot drive for 2 weeks after the insertion of your pacemaker.

Once you have a pacemaker, you will need it to be checked regularly for the rest of your life, to ensure it functions appropriately, and the data it records can be actioned when required. The pacemaker can only be tested, information reviewed, and settings changed by specialty staff using specialised equipment.

The battery is checked each time you attend your clinic appointment. The battery generally lasts between 6 and 8 years and cannot be recharged. When the battery needs changing, it will require another procedure like this one.

Go to your nearest Emergency department or GP (your local doctor) if you become unwell or have:

- pain unrelieved by simple pain relievers or those prescribed for you
- bleeding, swelling, redness or inflammation at the insertion site
- a fever
- other warning signs the doctor may have asked you to be aware of.

If you received sedation or anaesthetic and are going home on the same day as your procedure, a responsible person must escort you home and stay with you for 24 hours.

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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 physiologists/scientists, radiographers, sonographers, pharmacists, nurses, patient support officers and administration staff make up the cardiology team. All or some of these professionals may be involved in your journey.

A doctor other than the consultant/specialist may assist with/conduct your procedure. This could include a registered doctor who is undergoing further training. All trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/clinician will be performing your procedure, please discuss this with the doctor/clinician.

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

Information about driving restrictions are detailed in the Austroads' "Assessing Fitness to Drive" publications, which can be found at www.austroads.com.au

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.

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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. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au