

Implantable Cardioverter Defibrillator (ICD) Insertion

Adult and Child/Young Person
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 an Implantable Cardioverter Defibrillator (ICD) insertion and how will it help me?

An Implantable Cardioverter Defibrillator (ICD) is only offered to people who are either at risk of, or have experiences of, a prolonged, life-threatening, abnormal fast heart rate. The heart does not pump blood around the body properly during these fast heartbeat episodes, and if left untreated, it can cause serious symptoms, such as shortness of breath, dizziness, blackouts or death. The ICD is inserted subcutaneously (under the skin) below your collarbone.

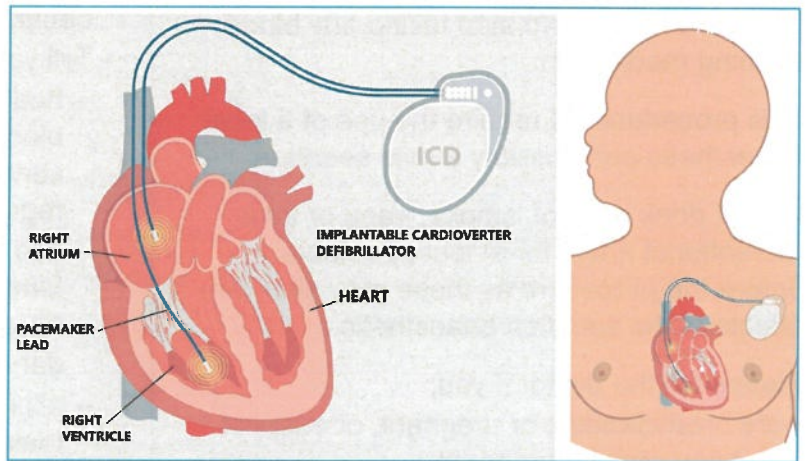


Image: Implantable Cardioverter Defibrillator (ICD).
ID: 2165111961 (adapted). www.shutterstock.com

The ICD stops the abnormal fast heartbeat. The treatment is done by either briefly "pacing" (stimulating) the heart rapidly, or by giving it an electrical shock. In addition, almost all ICDs also function as a pacemaker if required, to ensure the heart does not beat too slow.

The ICD is 'programmed' to your needs by the doctor who inserted it. An external machine is used to check and to program the ICD. The ICD is battery powered. The ICD 'stands by' and monitors your heart rate. If the heart rate is too fast, it will deliver an impulse.

The ICD 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 ICDs. Your doctor will decide which ICD suits your condition.

1. **Single chamber:** one lead to a lower chamber (ventricle) of the heart.
2. **Dual chamber:** two leads. One to the upper (atrium) and one to a lower chamber of the heart.
3. **Biventricular:** three leads. One to the upper and one to each of the lower chambers of the heart.
4. **Subcutaneous ICD (S-ICD):** this is a less invasive alternative. Pulse generator is placed under the skin at the side of the chest, below the armpit, and is connected to an electrode that runs along the breastbone, but does not enter the heart.

DO NOT WRITE IN THIS BINDING MARGIN

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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 the use of a local anaesthetic and possibly a mild sedation.

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 an ICD 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.

The skin over your chest will be cleaned, and a sterile drape will be applied to cover your body. The doctor will use local anaesthetic to numb the skin where the ICD will be positioned, then a small cut is made near your collarbone (or side of chest, under armpit, for S-ICDs). This cut creates a pocket under the skin for the ICD to go into.

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

(S-ICDs only) A small cut is then made near the breastbone to insert the electrode.

The doctors can see the leads (or electrode) using 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.

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

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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 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

- the ICD lead can move. The lead will need to be put back into place by repeating this procedure
- infection of the ICD site. This will need treatment with antibiotics and/or removal of ICD and leads
- unexpected ICD failure. This 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.

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 your lung or subclavian vein (upper chest), requiring further treatment
- a hole is accidentally made in the heart or heart valve. This will require surgery to repair
- heart attack
- a stroke. This can cause long-term disability
- 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
- 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 an ICD 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.

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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 may be helpful for safety in any future Magnetic Resonance Imaging (MRI) scans.

When you have an ICD, you will need to have it checked regularly for the rest of your life. This is to ensure that it is functioning appropriately, and the data it records can be actioned, when required. The ICD can only be tested, information reviewed, and settings changed by specialty staff, using specialised equipment.

There are driving restrictions for patients who experience life threatening, abnormal, and fast heartbeats, which ICDs are designed to treat, and for patients who receive an ICD. Please discuss these with your doctor.

The battery is assessed each time your ICD is checked. The battery lasts about 5 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.

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 physiologist/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.



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