

Pacemaker

Facility:

Family Name:

Given Names:

Address:

Date of Birth:

Sex: M F

A. INTERPRETER / CULTURAL NEEDS

An Interpreter Service is required? Yes No

B. CONDITION AND TREATMENT

The doctor has explained that you have the following condition:

.....
This condition requires the following procedure.

.....
You will have the following procedure:

You will have an injection of Local Anaesthetic. The pacemaker is put in below the left or right collarbone, just under the skin. The skin is cut to put the pacing wires (leads) into a vein which leads to the heart. The leads are threaded down the vein, into the heart.

The doctors can see the lead by using x-rays. 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 sewn back together.

C. RISKS OF A PACEMAKER

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment.

The risks/complications of this procedure are;

Common risks (more than 5%) include;

- Bruising at the pacemaker site.

Uncommon risks (1- 5%) include;

- The pacemaker lead can move. The lead will need to be put back into place by repeating this procedure.
- Bad bruising if you are taking blood thinning drugs such as Warfarin, Aspirin, Clopidogrel (Plavix or Iscover) or Dipyridamole (Persantin or Asasantin).

- 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.
- Infection of the pacemaker site. This will need treatment with antibiotics and/or removal of the pacemaker.

Rare risks (less than 1%) include;

- A punctured lung. This may require a tube to be inserted into the chest to reinflate the lung.
- Blood clot in the subclavian vein.
- A hole is accidentally made in the heart or heart valve. This will need surgery to repair.
- Blood clot in the lung.
- Heart attack.
- A stroke. This can cause long term disability.
- Death is possible due to the procedure or other heart problems.

D. SIGNIFICANT RISKS AND TREATMENT OPTIONS

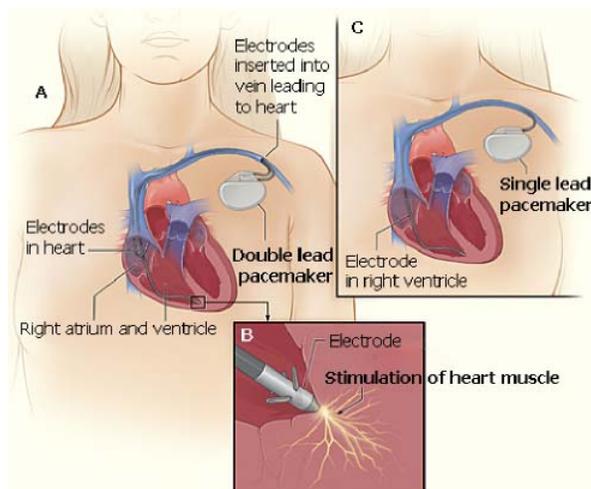


Fig 1. National Heart, Lung and Blood Institute

Pacemaker

Facility:.....

URN:

Family Name:

Given Names:

Address:

Date of Birth:

Sex: M F

E. RISKS OF NOT HAVING A PACEMAKER

options. My questions and concerns have been discussed and answered to my satisfaction.

- I understand I have the right to change my mind at any time before the procedure, including after I have signed this form but, preferably following a discussion with my doctor.

On the basis of the above statements,

I REQUEST TO HAVE THE PACEMAKER

Name of Patient/
Substitute decision
maker and relationship :

Signature :

Date:

F. ANAESTHETIC

This procedure may require an anaesthetic.

Substitute Decision-Maker: Under the Powers of Attorney Act 1998 and/or the Guardianship and Administration Act 2000. If the patient is an adult and unable to give consent, an authorised decision-maker must give consent on the patient's behalf.

G. PATIENT CONSENT

I acknowledge that the doctor has explained;

- my medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- the anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- other relevant procedure options and their associated risks.
- my prognosis and the risks of not having the procedure.
- that no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- the procedure may include a blood transfusion.
- tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- if immediate life-threatening events happen during the procedure, they will be treated accordingly.
- if I am a doctor other than my Cardiologist may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following Patient Information Sheets;

**Local Anaesthetic and Sedation for your procedure
Pacemaker**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment

H. DOCTOR'S STATEMENT

I acknowledge that I have explained to the patient all the above points under the Patient Consent section (G) and I am of the opinion that the patient/substitute decision-maker has understood the information.

Name of
Doctor :

Designation : Cardiologist

Signature :

Date :

I. INTERPRETER'S STATEMENT

I have given a sight translation in

.....
of the consent form and assisted in the provision of any verbal and written information given to the patient/parent or guardian/substitute decision-maker by the doctor.

Name of
Interpreter :

Signature :

Date :

Consent Information - Patient Copy Pacemaker

1. WHAT IS A PACEMAKER?

A pacemaker will treat a slow heart beat.

There are three types of Pacemakers. The doctor will decide which Pacemaker suits your condition.

Single Chamber – one lead to the upper or lower chamber of the heart

Dual Chamber – two leads. One to the upper chamber and one to the lower chamber of the heart

Biventricular – three leads. One to the upper chamber and two to the lower chambers of the heart

A Pacemaker is made of two parts, a pulse generator, which gives off impulses and a lead(s), which sends impulses to and from the heart.

The pacemaker is 'programmed' to your needs by the doctor who puts the device in. An external machine is used to check the pacemaker. The rate of the pacemaker can be set using this machine. As part of the clinic test, the pacing speed of your pacemaker may be temporarily increased and decreased. Then it will be reset to its normal setting.

Pacemakers 'stand by' until the heart rate falls below the set rate of the pacemaker. It will then step in and 'pace' your heart rate.

You will have the following procedure:

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

A needle with a tube connected to it will be put in your arm. This is called an intravenous line or IV.

You will have an injection of local anaesthetic. The pacemaker is put in below the left or right collarbone, just under the skin. The skin is cut to put the pacing wires (leads) into a vein which leads to the heart. The leads are threaded down the vein, into the heart. The doctors can see the lead using x-ray imaging. Once positioned in the heart, the leads are tested to make sure they are working properly.

Then they are connected to the 'pulse generator'. The pulse generator is placed under the skin and then the skin is sewn back together.

Pacemaker Device

The battery is checked each time you come to your clinic appointment. The battery lasts between 6 and 8 years and cannot be recharged. When the battery needs changing, it will require a procedure similar to this.

You cannot drive for 2 weeks after a Pacemaker.

2. MY ANAESTHETIC

This procedure will require an anaesthetic.

See **Local Anaesthetic and Sedation for your procedure information sheet** for information about the anaesthetic and the risks involved. If you have any concerns, talk these over with your doctor. If you have not been given an information sheet, please ask for one.

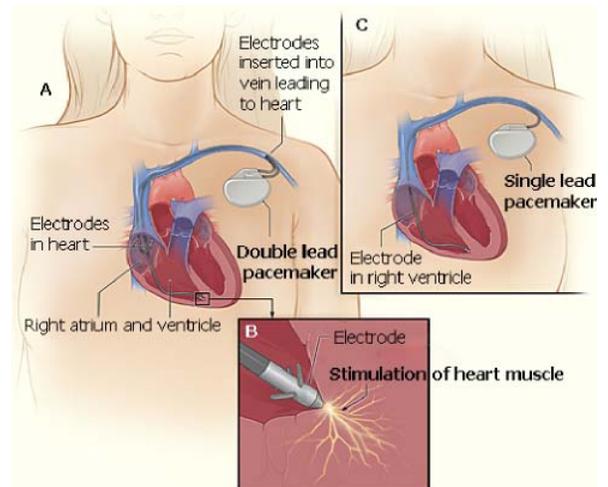


Fig 1. National Heart, Lung and Blood Institute

3. WHAT ARE THE RISKS OF THIS SPECIFIC PROCEDURE?

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment.

The risks/complications of this procedure are;

Common risks (more than 5%) include;

- Bruising at the pacemaker site.

Uncommon risks (1- 5%) include;

- The pacemaker lead can move. The lead will need to be put back into place by repeating this procedure.
- Bad bruising if you are taking blood thinning drugs such as Warfarin, Aspirin, Clopidogrel (Plavix or Iscover) or Dipyridamole (Persantin or Asasantin).
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- Infection of the pacemaker site. This will need treatment with antibiotics and/or removal of the pacemaker.

Rare risks (less than 1%) include;

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