Hospital Logo		Patient Identification Label

Informed Consent for Pacemaker Implantation

Name:	Age (in years):	Gender: ☐ M ☐ F ☐ Other
UHID No./Registration No.:		
Interpreter Service: ☐ Yes ☐ No	Consultant's Name:	

Medical Condition

The doctor has explained that I/my child/my ……..have the following medical condition:

……

and I/my child/my……have been explained and advised to undergo the following treatment/procedure:

……

I authorise Dr. …… and his/her associates to perform the above treatment/ procedure.

The doctor should document the site and/or side where relevant to the procedure:……..

……

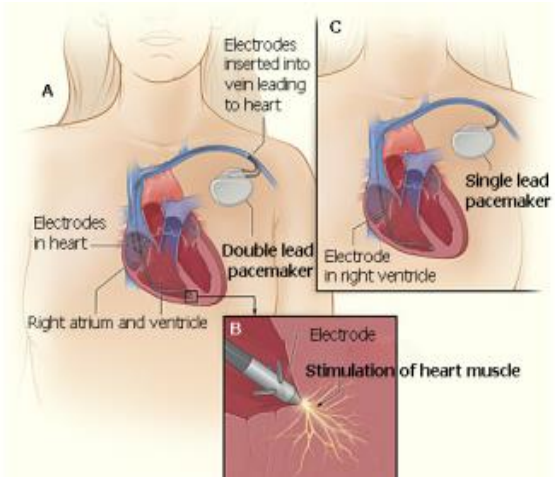
Introduction

A pacemaker is a device that is used to treat a slow heartbeat.

It is made of a pulse generator, which emits impulses and a lead(s), which sends impulses to and from the heart.

There are three types of pacemakers:

- Single chamber: It has a lead which will be connected to the lower chamber of the heart.
- Dual chamber: It has two leads. One lead will be connected to the upper chamber of the heart. And another lead will be connected to the lower chamber of the heart.
- Biventricular: It has three leads. One lead will be connected to the upper chamber of the heart. And two leads will be connected to the lower chambers of the heart.



The doctor will decide the type of defibrillator based on your condition.

The doctor will perform the procedure under local anaesthesia.

The doctor will cut the skin below your left or right collarbone. And place the lead(s) of the pacemaker into a cardiac vein. The lead(s) will be threaded down the vein, into the heart. The doctor will be able to see the placement of lead(s) using X-ray imaging.

Once positioned in the heart, the lead(s) will be tested to make sure they are working properly. The pulse generator of the pacemaker will be placed under the skin. And the lead(s) will be connected to the pulse generator. After placing the pacemaker, the doctor will sew the skin back together.

The doctor will check the battery of the pacemaker during check-ups. The battery cannot be recharged and it will last for about six to eight years. After which, the doctor will perform a similar procedure to change the battery of the pacemaker.

Consent for Blood Transfusion

Please see Blood Transfusion Consent Form. This will give you information about the type of the blood products, benefits and risks of blood transfusion. If you have any concern(s), please discuss with your doctor.

Consent for Anaesthesia

Please see Anaesthesia Consent Form. This will give you information about the type of the anaesthesia, its benefits and general risks. If you have any concern(s), please discuss with your anaesthetist(s).

Potential Benefits (To be documented by doctor)	**Alternatives** (To be documented by doctor)
▪ To reduce symptoms of a slow pulse, such as dizziness or breathlessness, fatigue or to reduce the risk of blackouts and injury. ▪ Others, if any specify:	

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Risks and Potential Complications (To be documented by doctor)

▪ Collapsed lung (pneumothorax) as a result of a needle perforating in the lung. This often requires no treatment but may require the insertion of a chest drain to help reinflate the lung ▪ The lead of the pacemaker can make a hole in the wall of the heart. This will lead to collection of blood around the heart (cardiac tamponade). ▪ Lead displacement within 30 days of the procedure. This would require a repeat operation to reposition the leads ▪ Pain, bleeding and bruising in or around the wound ▪ Large collection of blood (hematoma) over the pacemaker. This would usually get better, if not it may have to be treated with a further operation ▪ Arrhythmias (an irregular heartbeat) ▪ Infection of the pacemaker after implantation ▪ Death	▪ Others, if any specify:	**Patient Specific Risks** **(To be documented by doctor)** 1) 2) 3) 4) 5)

Specific Notes Related to Procedure (Strike out if not required)	**Precise Action Points Understood by the Patient/Substitute Decision Maker (To be documented by patient/substitute decision maker in his/her language)**

Patient's Authorisation

- The doctor has explained my/patient's medical condition and proposed treatment/procedure. I have been explained and have understood the intended benefits/risks known to be attached with the planned treatment/procedure including the risks that are specific to me/my patient and their likely outcomes.
- The doctor has explained other relevant/alternate treatment options and their associated benefits/risks. The doctor has also explained the risks of not having the procedure. I have been given the choice to take a second opinion.
- I was able to ask questions and raise concerns with the doctor about the procedure and its benefits/risks and my/patient's treatment options. My queries and concerns have been discussed and answered to my full satisfaction.
- I understand that the treatment/procedure may include blood/blood product transfusion (for which a separate consent shall be obtained).
- The doctor has explained the requirement for anaesthesia for this procedure and I understand the risks associated with anaesthesia, including the risks specific to me (for which a separate consent shall be taken).
- I understand that if organs or tissues are removed during the surgery that these may be retained for prescribed tests and shall be disposed of sensitively by the hospital as per the regulatory provisions.
- The doctor has explained to me, that during the course of or subsequent to the operation/procedure, unforeseen conditions may be revealed or encountered which may necessitate urgent surgical or other procedures in addition to or different from those contemplated. In such exigency, I further request and authorise the above-named physician/surgeon or his designee to perform such additional surgical or other procedures as he or they consider necessary or desirable in my interest. I understand and agree that in such condition there will be no requirement of any additional consent from me or my family members/attendants.
- I declare that no guarantee of whatsoever nature has been given by anyone as to the results that may be obtained.
- I understand that I have the right to refuse treatment before surgery/procedure. I agree that any such refusal shall be in writing and acknowledged by the hospital and I shall be solely responsible for the outcome of such refusal.

- I consent to if any photographing or television of operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes. However, suitable precautions shall be taken by the hospital that my identity is not revealed anywhere. □ **Yes** □ **No**
- For purposes of advancing medical education, I consent to the admittance of observers to the operating room. □ **Yes** □ **No**

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Patient /Substitute Decision Maker Name:	Relationship:		Signature:	Date and Time:
Witness 1 Name:	Relationship:	Reason (patient is unable to give consent because):	Signature:	Date and Time:
Witness 2 Name:	Relationship:		Signature:	Date and Time:
Interpreter Name:	Translation given in:		Signature:	Date and Time:

Declaration by the Doctor

I have explained to the patient / authorised representatives the medical condition, need for the procedure, its alternatives and benefits/risks, likely consequences if those risks occur and the significant risks and problems specific to this patient including the risks of not undergoing the procedure. I have given the patient/ authorised representatives an opportunity to ask questions about any of the above matters and raise any other concerns. I have answered all their queries to the best of my knowledge.

Name and Signature of the Doctor with Reg No:	Date and Time: