Patient information and consent to permanent pacemaker implantation

Key messages for patients

- Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your operation.

- Please read this information carefully, you and your health professional will sign it to document your consent.

- It is important that you bring the consent form with you when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when you are admitted.

- Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.

- Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.

- We will confirm any medication changes required before your procedure.

- Please call ward K2 on telephone number 01223 256233 if you have any questions or concerns about this procedure or your appointment.

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so).

We will also only carry out the procedure on your consent form unless, in the opinion of the health professional responsible for your care, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.
About permanent pacemaker implantation

If your body’s natural pacemaker is not working properly, you may need to have a pacemaker fitted. This might be because you have:
- Intermittent or complete heart block
- An irregular heart rate or rhythm
- A slow natural pacemaker (“sinus node disease”)
- Heart failure

A pacemaker has a pulse generator (the actual pacemaker) and one, two or three electrode leads which are placed within the heart via a vein. Pacemakers with one lead are known as single chamber pacemakers, with two leads – dual chamber pacemakers, and three leads – bi-ventricular pacemakers.

The pacemaker has two parts: the power supply (battery) and the electronic circuit. It is sealed in metal to stop body fluids leaking in. The whole pacemaker weighs about twenty to fifty grams, and is smaller than a matchbox.

Small electrical impulses are conducted down the leads to the heart, which stimulate the heart to contract and produce a heartbeat.

Pacemakers usually last between six and ten years before they need to be replaced and will be checked regularly by a cardiac physiologist.

Intended benefits

A pacemaker is fitted to reduce symptoms of a slow pulse, such as dizziness or breathlessness, fatigue, or to reduce the risk of blackouts and injury.

Who will perform my procedure?

This procedure will be performed by a consultant cardiologist or cardiology specialist registrar.

Before your procedure

Most patients attend a pre-admission clinic, where you will meet a member of nursing staff. At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. The procedure will be explained to you. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have at any time.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring all your medications and any packaging (if available) with you. Please tell the ward staff about all of the medicines you use.

- If you take clopidogrel or anticoagulant (warfarin, dabigatran, rivaroxaban,
apixaban) to thin the blood, you will be advised whether these should be stopped before the procedure

- If you take water tablets (diuretics), these should be withheld on the morning of the procedure.

This procedure involves the use of local anaesthesia. We explain about the different types of local anaesthesia or sedation we may use at the end of this leaflet.

Most people will have this procedure as a day case, however, the procedure may take place whilst you are an inpatient if you are already in hospital.

You must stop eating four hours before the procedure and stop drinking clear fluids one hour before the procedure.

Medical and nursing staff will explain the procedure and ask you to sign the consent form to confirm that you understand and agree to go ahead with the procedure.

Please ask any questions. You should discuss any worries with the doctor or nursing staff before the procedure to be sure that you understand.

Please inform medical or nursing staff if there is any possibility that you might be pregnant. Females below the age of 55 will be asked.

Hair removal before an operation

If necessary, the healthcare team will use an electric hair clipper with a single-use disposable head, on the day of the procedure. Please do not shave the hair yourself or use a razor to remove hair, as this can increase the risk of infection. Your healthcare team will be happy to discuss this with you.

During the procedure

How is the pacemaker fitted?

You will change into a gown before your procedure and a nurse will prepare you by going through a check list. When it is your turn for the procedure you will be transferred to the Cath Lab where the staff will check your name, personal details and confirm the procedure you are expecting.

Once that is complete, the nursing staff will make you comfortable on the X-ray table. Monitoring devices may be attached to you, such as a heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter).

Pacemakers are fitted by “transvenous implantation” - which normally takes between thirty and ninety minutes. You will receive a local anaesthetic and remain awake throughout the procedure; a light sedative can be given if preferred, although this is not obligatory. A short (one to two inch) incision is made under the collar bone, and a small “pocket” is
created under the skin for the pacemaker to go in. The incision is then stitched up.

**After the procedure**

Once your procedure is completed you will usually be transferred to the recovery area where you will be looked after by specially trained nurses, under the direction of your cardiologist. They will monitor your heart rate, blood pressure, pulse and oxygen levels and check your pacemaker site. You will also require a chest x-ray and the cardiac technicians will complete a pacemaker check.

**Eating and drinking.** After this procedure, you should not have anything to eat or drink until advised.

**Getting about after the procedure.** We will help you to become mobile as soon as possible after the procedure. This helps improve your recovery and reduces the risk of certain complications. There will be some bruising around the pacemaker site and you may feel a little sore as the local anaesthetic wears off. These problems usually resolve within a few days.

**Leaving hospital.** Generally most people who have had this procedure will be able to leave hospital on the same day. However, the actual time that you stay in hospital will depend on your general health, how quickly you are recovering from the procedure and your doctor’s recommendations. Your pacemaker will be checked by a technician or doctor before you leave hospital. You will be given a pacemaker registration card detailing the model, and information about everyday life with a pacemaker.

**Resuming normal activities including work.** Your doctor will advise you on how quickly you can resume normal and more vigorous activity.

**Special measures after the procedure:** You will be given wound care advice, and will be told what types of stitches were used in your procedure. Often, these are soluble and do not need to be removed. You are advised not to elevate your arm above chest height for up to four weeks and to keep your dressing dry until you see your practise nurse (usually five to seven days post procedure). We will give you further information about any special measures you need to take after the procedure. We will also give you information about things to watch out for that might be early signs of problems (eg infection).

**Check-ups and results:** Regular follow-up appointments at the pacemaker clinic will be arranged before you are discharged from hospital. A discharge summary will be sent to your GP.
Significant, unavoidable or frequently occurring risks of this procedure

Serious complications are rare, but as with any invasive medical procedure, there are risks.

- **Bleeding** (1:100). Everyone gets a bruise. Some people may develop a blood clot under the skin, which can be sore for a few days.
- **Punctured lung** (1:100). Sometimes referred to as a “pneumothorax”, air can leak from the lungs into your chest during the procedure. Your x-ray will be checked for this before you leave the hospital. If this does occur, it occasionally (1:500) requires another procedure, namely a chest drain, and an extended hospital stay.
- **Heart Perforation** (a hole in the heart) (1:200). The pacing lead can make a hole in the wall of the heart. This does not always require action. It may, however, lead to pain or fluid accumulation around the heart. This may require an additional procedure to reposition the pacing lead or drain the fluid from around the heart.
- **Infection** (1:100). If you notice redness, swelling or discharge at the pacemaker site, contact your doctor or clinic immediately. The pacemaker may need to be replaced if the infection spreads.
- **Lead movement** (1:100). There is a small possibility that one of the pacemaker leads may move out of position. This risk increases to between 5-10% with biventricular pacemakers. The nurses involved in your care will advise you not to do any exercise for two to three weeks to reduce the chances of this happening. Lead fracture / failure needing replacement carries a risk of less than 4:1000 after discharge from hospital.
- **Skin erosion** occurs in less than 5:1000 post discharge.
- **Fluid collecting around the heart** (1:1000). Known as a “pericardial effusion”, fluid can leak in between the layers of tissue surrounding your heart, and this may require drainage.

Alternative procedures that are available

An alternative to this procedure is a decision not to have a pacemaker. We will discuss with you the implications of deciding not to have this.

Information and support

You will be given some additional patient information before and after the procedure, for example leaflets that explain what to do after the procedure and what problems to look out for. If you have any questions or anxieties, please feel free to ask a member of staff on 01223 256233.

Further information is also available on the British Heart Foundation website:

www.bhf.org.uk

Local anaesthesia

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted and some sensation of
pressure may be present, but there should be no pain. Local anaesthesia is used for minor operations such as stitching a cut, but may also be injected around the surgical site to help with pain relief. Usually a local anaesthetic will be given by the doctor doing the operation.

**Sedation**

Sedation is the use of small amounts of anaesthetic or similar drugs to produce a ‘sleepy-like’ state. Sedation may be used as well as a local or regional anaesthetic. The anaesthesia prevents you from feeling pain, the sedation makes you drowsy. Sedation also makes you physically and mentally relaxed during an investigation or procedure which may be unpleasant or painful (such as an endoscopy) but where your co-operation is needed. You may remember a little about what happened but often you will remember nothing. Sedation may be used by other professionals as well as anaesthetists.

**Information about important questions on the consent form**

1. **Creutzfeldt Jakob Disease (‘CJD’)**

   We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2. **Photography, Audio or Visual Recordings**

   As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment, they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3. **Students in training**

   Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

**Privacy & dignity**

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one
Permanent pacemaker implantation, CF472, V3, August 2018

We are a smoke-free site: smoking will not be allowed anywhere on the hospital site. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language or audio, please contact interpreting services on telephone: 01223 348043, or email: interpreting@addenbrookes.nhs.uk For Large Print information please contact the patient information team: patient.information@addenbrookes.nhs.uk.
Consent Form

Permanent pacemaker implantation

A Patient’s side  left / right or N/A

Consultant or other responsible health professional

Name and job title:

☐ Any special needs of the patient (e.g. help with communication)?

Please use ‘Procedure completed’ stamp here on completion:

B Statement of health professional (details of treatment, risks and benefits)

1 I confirm I am a health professional with an appropriate knowledge of the proposed procedure, as specified in the hospital’s consent policy. I have explained the procedure to the patient. In particular, I have explained:

a) the intended benefits of the procedure (please state)

To stop the heart going too slow and prevent or reduce symptoms such as dizziness, fatigue, breathlessness or fainting.

b) the possible significant, unavoidable or frequently occurring risks involved including those specific to the patient:

• Infection (1:100)
• Punctured lung (1:100)
• Bleeding (1:100)
• Lead movement and requiring a further procedure (1:100)
• Fluid collecting around the heart needing a drain (1:1000)
• Heart perforation ( a hole in the heart) (1:200)

c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:
d) any extra procedures that might become necessary during the procedure such as:

- Blood transfusion
- Other procedure (please state)

2 The following information leaflet has been provided:

Permanent pacemaker implantation – BHF booklet – Trust pamphlet

Version, reference and date: CF472, version 3, August 2018

or I have offered the patient information about the procedure but this has been declined.

3 This procedure will involve:

- General and/or regional anaesthesia
- Local anaesthesia
- Sedation
- None

Signed (Health professional): Date: D.D.D / M.M.M / Y.Y.Y.

Name (PRINT): Time (24hr): H.H.; M.M.

Designation: Contact/bleep no:

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure and then put a tick in the relevant boxes for the following questions:

1 Creutzfeldt Jakob disease (CJD)
Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional.

- Yes
- No

2 Photography, Audio or Visual Recording
a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment.

- Yes
- No

b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting.

- Yes
- No

3 Students in training
I agree to the involvement of medical and other students as part of their formal training.

- Yes
- No
I have listed below any procedures that I do not wish to be carried out without further discussion.

I have read and understood the Patient Information about this procedure and the above additional information. I agree to the procedure or treatment.

Signed (Patient):  
Name of patient (PRINT):  
Date: D.D./M.M./Y.Y.Y.Y.

If signing for a child or young person; delete if not applicable.
I confirm I am a person with parental responsibility for the patient named on this form.
Signed:  
Relationship to patient:  
Date: D.D./M.M./Y.Y.Y.Y.

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.
Signed (Witness):  
Name of witness (PRINT):  
Address:  
Date: D.D./M.M./Y.Y.Y.Y.
D  Confirmation of consent

**Confirmation of consent** (where the treatment/procedure has been discussed in advance)

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

**Signed** (Health professional): ........................................... Date: ...D.D./M.M./Y.Y.Y.Y...

**Name (PRINT):** ................................................................. Job title: .................................................................

Please initial to confirm all sections have been completed:

E  Interpreter’s statement (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

**Signed** (Interpreter): ........................................................ Date: ...D.D./M.M./Y.Y.Y.Y...

**Name (PRINT):** .................................................................

Or, please note the language line reference ID number:

F  Withdrawal of patient consent

☐ The patient has withdrawn consent (ask patient to sign and date here)

**Signed** (Patient): ................................................................. Date: ...D.D./M.M./Y.Y.Y.Y...

**Signed** (Health professional): ........................................... Date: ...D.D./M.M./Y.Y.Y.Y...

**Name (PRINT):** ................................................................. Job title: .................................................................