Patient Information to be retained by patient

Royal Cornwall Hospitals NHS
NHS Trust

affix patient label

Lead reposition/renewal/upgrade or revision/extraction of your implanted device

What is a pacemaker?

You will already have an artificial pacemaker implanted (fitted) because you have an abnormal heart rhythm. Pacemakers (both simple and complex devices) are implanted for a number of reasons, including:

- a heartbeat that is very slow or pauses intermittently, causing blackouts, falls or dizzy spells
- a heartbeat that is very fast, putting someone at risk of sudden cardiac death
- fast heart rhythms that require drugs to control – and these drugs may slow your heart rate too much at times
- a catheter ablation (see separate leaflet) that results in either deliberate or accidental damage to your heart's natural electrical system
- to improve the function of a damaged heart.

Why do I need this procedure?

You are having this procedure today to either:

- have a new lead for your pacemaker – this may be required due to an upgrade of your pacemaker, or due to failure of an existing lead
- have an existing lead repositioned – this is required when a lead displaces (moves) and is no longer pacing effectively
- have an upgrade to a different device – your needs may have changed and you now need a different type of device
- have revision of your wound – this may be necessary if the wound becomes infected or following a complication
- have your existing device extracted (removed) – this may be necessary if there is a known infection.

What does it involve?

You will usually come in to hospital on the day of your procedure. A nurse will complete a pre-procedure checklist and you will be given a hospital gown to change into. A specialist doctor will explain the proposed implantation to you and ask you to sign the consent form to confirm that you understand the procedure and agree to go ahead with it. Please ask any questions you want. A porter will take you to the Cardiac Catheter Lab where you will have the procedure.

1. You will lie on a table, which can be moved around. Mounted above it is an X-ray machine.
2. You will have an injection of local anaesthetic (which numbs the area) and you may also be given a sedative to make you feel relaxed and sleepy. Antibiotics will be given into a vein before we begin the procedure.
3. The pacemaker previously implanted just under the skin in a 'pocket' below your left collarbone is re-accessed or the wound attended to.
4. If you require lead reposition/a new lead, the electrodes(s) are inserted through a vein into your heart using X-ray screening for guidance. They are then attached to the pacemaker.
5. Stitches are usually inserted just under your skin to hold the pocket edges together and skin glue is often used. The scar is about 2 inches long.

How long does it take?

The procedure can last 1-3 hours depending on what you are having done.

Will I have any pain or discomfort?

The procedure shouldn't hurt, although you will feel pressure as the pacemaker is inserted. Your shoulder may feel uncomfortable for a week or so. You may have swelling and bruising but this should return to normal in 2-3 weeks.

You will be able to feel the pacemaker and sometimes the wires beneath your skin but don't worry, it won't pop out. It may feel rather strange at first.

What happens afterwards?

You may stay in hospital overnight and go home the next day or go home later that day. Once fully awake you should be able to eat and drink. Please ask for painkillers if you need them.

You may have a chest X-ray to check that the electrodes are in the correct position and that there has been no damage to the lung.

You may also be visited by a cardiac technician, who will check the pacemaker. A sensor is held over the pacemaker to programme it. This is painless, but you may be aware that your heart is beating slightly faster than normal. The device is then checked to make sure it is effective at managing your heart condition.

What happens when I go home?

- Please make sure that a friend of relative collects you and takes you home.
- You should be able to return to your normal activities in a week or so.
- Avoid vigorous arm movements for a few weeks, but otherwise move your arm normally.
- We will give you a pacemaker registration card (plus information from the manufacturer) following your implantation. Please carry it with you and show it to any dentist or doctor who may treat you.
- If you notice redness, swelling or a discharge at the site of your implant (signs of infection), please tell your GP immediately as infection can spread.

When can I resume driving?

If you have had a pacemaker implanted, you must inform the DVLA (Driver and Vehicle Licensing Agency). You should also inform your car insurance company. If you don't, your insurance may not be valid.

If you have an ordinary license, you can usually start driving after one week, provided you meet the DVLA criteria. If you have an HGV or PCV license, you will not be able to drive these vehicles for 6 weeks. Please follow DVLA guidance to get your HGV license back.

How long will my pacemaker last?

The pacemaker will last for years but the batteries will eventually run down (approximately 7-10 years) and then it will have to be replaced.

Will I need further appointments?

Yes, you should attend regular check-ups at the pacemaker clinic.

Do I need to take any precautions?

- **Mobile phones** – it is safe to use a mobile phone, but keep it as far as possible from your pacemaker, using the opposite ear or a headset.
- **Electronic surveillance** – security at airports or anti-theft devices in shops can interfere with pacemakers. They are safe provided you go through quickly, do not linger, and inform security staff.
- **MRI scans** – you must not have an MRI scan (body imaging scan) as it uses strong magnets, unless your pacemaker is specifically 'MRI compatible'. Other scans are safe.
- **Lithotripsy** – this is a type of treatment for kidney stones, which is unsuitable for patients with pacemakers.

Are there any risks?

In general, the complication rates of any upgrade procedure/new lead implantation are higher than for new implants.

- There is a 1% chance of puncturing the lung as the vein used for the wire runs close to it. Sometimes, no corrective treatment is needed, and sometimes the escaped air has to be removed using a needle or a small drain (tube). For people with a serious lung disease, a pneumothorax can be a serious problem.
- There is a 1-2 % chance of the electrode slipping out of place. If this happens it must be repositioned under X-ray guidance with a further operation.
- The 1-2% risk of infection is minimised using antibiotics given before the procedure commences. If infection occurs the pacemaker system may need removing with another operation.
- There is a small risk of a major bruise/haematoma, which may rarely require removal with a separate operation. A small amount of bruising is usual and settles within a few days.

For some patients the risks may be higher. Please speak to your specialist doctor before your operation if you have any worries.

Any questions?

If you need any more information or have any queries please contact the Cardiac Investigation Unit on 01872 252726.

Further support and information is available from the:

British Heart Foundation
08450 708070
www.bhf.org

Arrhythmia Alliance
Helpline - +44 (0)1789 867501
PO Box 3697
Stratford-Upon-Avon
Warwickshire
CV37 8YL
www.heartrhythmcharity.org.uk

If you would like this leaflet in large print, Braille, audio version or in another language, please contact the General Office on 01872 252690

Patient copy

CONSENT FORM 1
PROCEDURE SPECIFIC PATIENT AGREEMENT

Royal Cornwall Hospitals NHS
NHS Trust

NHS number: .....
Name of patient: .....
Address: .....
Date of birth: .....
CR number: .....

AFFIX PATIENT LABEL

Lead reposition, renewal, revision or upgrade of your implanted device

+/- insertion of wires to heart chambers and attaching to electronic pulse generator, +/- reposition of original wires, +/- revision of wound, +/- upgrade of device

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained the intended benefits:

- *To improve the functioning of your implanted device +/- attending to an existing wound*

Significant, unavoidable or frequently occurring risks:

- *Mild bruising is common. Major bleeding or haematoma requiring operation 1% (increased if taking anticoagulants or dual anti-platelet therapy)*
- *Infection (2%)*
- *Pain*
- *Acute lead displacement – RV lead 1%, RA lead 1-2%, LV lead 2-3%*
- *Pneumothorax (damage to lung covering leading to air leak and lung collapse) 0.8%*
- *The complication rate from these procedures (especially upgrade procedures) is much higher than new implants and can be up to 15% in some cases*

Uncommon but more serious risks:

- *Haemothorax, pericardial effusion, damage to blood vessels (including those supplying the heart), dangerous heart rhythms or cardiac perforation. The risk of death is less than* **1 in 3000** *procedures*
- *Requirement for a pleural or pericardial drain (<1%)*

Uncommon possible later issues:

- *Late displacement of pacemaker leads, major bleeds needing re-exploration, scarring, wound discomfort*

Any extra procedures which may become necessary during the procedure:

- *Blood transfusion (required very infrequently)*
- *Other procedure (please specify):*

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I have given and discussed the Trust's approved patient information leaflet for this procedure: Lead reposition, renewal, revision or upgrade of your implanted device (CHA3644) which forms part of this document.

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve: ☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

Health Professional signature: ..... Date: .....

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

STATEMENT OF INTERPRETER (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: ..... Name (PRINT): ..... Date: .....

affix patient label

STATEMENT OF PATIENT

Please read this form carefully. If your treatment has been planned in advance, you should already have a copy of the patient information leaflet which describes the benefits and risks of the proposed treatment. If not, you will be given a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I understand that tissue samples will only be taken in relation to the procedure explained to me. No samples will be taken for quality control, clinical education or research purposes.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

.....

I have received a copy of the Consent Form and Patient Information leaflet: Lead reposition, renewal, revision or upgrade of your implanted device (CHA3644) which forms part of this document.

Patient signature: ..... Name (PRINT): ..... Date: .....

A **witness** should sign below if this patient is unable to sign but has indicated his or her consent.
Young people / children may also like a parent to sign here (see guidance notes).

Witness signature: ..... Name (PRINT): ..... Date: .....

CONFIRMATION OF CONSENT (to be completed by health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Health Professional signature: ..... Date: .....

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

Important notes (tick if applicable):

☐ See advance decision to refuse treatment ☐ Patient has withdrawn consent (ask patient to sign/date here)

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