



# Implantation of a Leadless Pacemaker

Name	
Date of Birth	AFFIXPATIENTLABEL
CHI	

## Pacemaker

### What is a Leadless

Your doctor has recommended that you have a Leadless Pacemaker. This is a small metal battery-powered device and is used to treat slow heart rhythms (bradycardia). The Leadless Pacemaker is implanted inside the heart via a vein in your leg and unlike normal pacemakers, does not require any pacing leads.

### Why do I need this procedure?

To treat a slow heart rhythm that you either have or are risk of. A traditional pacemaker would require a lead to be placed into your heart from a vein under your collarbone. Your doctor's opinion is that you would benefit from a leadless pacemaker because of the difficulty of placing leads via the traditional route.

### What does it involve?

You will usually come in to hospital on the day of your procedure. A nurse will complete a check list 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, proposed risks and benefits and that you agree to go ahead with it. It is important to ask any questions that are important to you about the procedure. Antibiotics will be given into a vein on the ward and a porter will take you to the Theatre. Once in Theatre, the following will happen:

1. You will have either general anaesthetic or local anaesthetic and sedation for your procedure. Your doctor will discuss this with you.
2. A plastic tube is placed in a vein at the top of your right leg (femoral vein).
3. The pacemaker (half the size of a small finger) is placed into your right ventricle (pumping chamber on the right side of your heart).
4. The position is then checked with X-ray images in the procedure room and then the catheter is removed and a small suture (stitch) is placed in your leg. This stitch is removed on the ward after 3 hours
5. The device is then checked and you will return to the ward you were admitted to.

### How long does it take?

The procedure takes approximately 1 hour. Very rarely (less than 1%) we may not be able to implant the lead this way, but your doctor will discuss alternative options if needed.

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### **Will I have any pain or discomfort?**

You may briefly feel a sharp pain with the local anaesthetic. You will still be able to feel some pushing sensations if it is performed under local anaesthetic but the procedure shouldn't hurt. If it does, then you can be given more pain relief. Your thigh may feel uncomfortable for a week or so afterwards. You may have swelling and bruising, but this should return to normal in two to six weeks.

### **What happens afterwards?**

You will need to lie flat and keep the leg straight for two to six hours after the procedure. This prevents bleeding from the access site. Do not try to sit or stand. A sterile dressing will be placed on your groin area to protect it from infection. Once fully awake you will be able to eat and drink. Please ask for painkillers if you need them.

You may need to spend the night in the hospital and will be able to go home after your device check and a chest X-ray.

A sensor is held over the chest to programme it. This is painless, but you may be aware that your heart is beating slightly faster than normal. You will be given a Pacemaker identity card, emergency information and instructions at this check.

### **What happens when I go home?**

- Please make sure that a friend or relative collects you and takes you home and that someone is with you overnight
- You should be able to return to your normal activities in a week or so.
- Avoid vigorous exercise or movements for 1 weeks but otherwise move around normally.
- We will give you a Pacemaker registration card (plus information from the manufacturer) – 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.**

### **When can I resume driving?**

- The Driving and Vehicle Licensing Agency (DVLA) have strict driving restrictions related to having a Pacemaker and these will be discussed with you following your implantation. As a guide:
  - For a Group 1 License  
You must not drive for 1 week and must inform the DVLA
  - For a Group 2 License  
You must not drive for 6 weeks and must inform the DVLA

### **How long will my Pacemaker Last?**

The Pacemaker will last around 5-10 years but the batteries will eventually run down and then it will have to be replaced. This will be identified during your follow up.

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### Are there any risks?

The implantation is usually very successful, but as with all procedures there are some risks.

- **Problem at Groin Puncture Site**– there is a 1% (1 in 100) risk of a major bruise/haematoma which may rarely require a separate operation. A small amount of bruising is usual and settles within a few weeks.
- **Pacing Problem**– there is a <0.5% (<1 in 200) chance of problem with the pacemaker functioning requiring another procedure
- **Device Dislodgement** – there is a <0.2% (<1 in 500) chance of problems with the Pacemaker moving and having to be retrieved and repositioned by another procedure
- **Infection** – there is a 0.1% (1 in 1000) risk of infection, which is minimised using antibiotics given before the procedure starts. If infection occurs the pacemaker may need removing with another operation.
- **Damage to Blood Vessels (Pseudoaneurysm or fistula)**– there is a 1% (1 in 100) risk of damaging the artery, which is a blood vessel that runs beside the vein at the top of the leg. If there is damage then this usually heals up without any treatment. Less than 1 in 500 times you may need surgery or an injection to treat it.
- **Pericardial effusion** (blood leak round heart) – there is a 0.5% (1 in 200) risk of bleeding into the sack surrounding the heart, this can heal itself or you may need a small tube to be put in to remove the blood.
- **Unable to place pacemaker** – There is a <0.2% (<1 in 500) chance we may be unable to place the Leadless Pacemaker. If this is the case we will discuss the options with you after the procedure.

### Will I need further appointments?

Yes, you should attend regular check-ups at a Pacemaker clinic. You will receive a date for your first appointment before you go home. Some of the monitoring can be done with equipment supplied by the hospital but used at home with the phone and/or the internet.

### Do I need to take any precautions?

- **Mobile phones** – it is safe to use a mobile phone but try not to have your phone close to your heart chest area for a prolonged period of time. Keep it in a trouser pocket or bag.
- **Electronic surveillance** – security at airports or anti-theft devices in shops usually don't interfere with these devices. You are advised to walk through them at a normal pace and not to linger beside them.
- **MRI scans** – there may be restrictions on MRI scanning but increasingly devices are used that are safe with some MRI scans. Please inform the person performing the MRI.
- **Magnets** – Do not carry or place a magnet over your device as this may temporarily disable the device.
- **Exercise** – You can resume exercise after your leg has healed – usually after 1 week
- **Travel** – You can safely travel abroad with your device. You are advised to show the security staff your devices identification card and walk at a normal pace through the scanner. Insurance companies may try to increase your premiums to very high levels. It is suggested you shop around if this happens.
- **Operations** – If you require an operation you must tell your surgeon/doctor or anaesthetist that you have a Leadless Pacemaker.

## Useful Contacts

If you need any more information or have any queries please contact

Arrhythmia Nurse Specialist: 07970187324 (Week days/not in an emergency)

Golden Jubilee Switchboard: 0141 951 5000 and ask for Cardiac Day Unit (Monday-Friday 8-8)

Coronary Care Unit (CCU): 0141 951 5202

Golden Jubilee Hospital: 0141 951 5000

Further support and information is available from the:

### **British Heart Foundation**

Lyndon Place

2096 Coventry Road

Sheldon

Birmingham, B26 3YU

0300 330 3322

[www.bhf.org](http://www.bhf.org)

### **Arrhythmia Alliance**

Helpline - 01789 450 787

PO Box 3697

Stratford-Upon-Avon

Warwickshire

CV37 8YL

e-mail: [info@heartrhythmcharity.org.uk](mailto:info@heartrhythmcharity.org.uk)

[www.heartrhythmcharity.org.uk](http://www.heartrhythmcharity.org.uk)

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**CONSENT FORM**  
**PROCEDURE SPECIFIC PATIENT AGREEMENT**

# Leadless Pacemaker Implant

*Insertion of Leadless Pacemaker into the Heart.*

**STATEMENT OF HEALTH PROFESSIONAL** (to be filled in by health professional with appropriate knowledge of proposed procedure)

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

- *To prevent the heart from slowing or stopping*

**Significant, unavoidable or frequently occurring risks:**

- *Bleeding, bruising, and pain (<5%)*

**Commonly occurring risks (>1%):**

- *Mild bruising is common requiring no intervention. Major bleeding or haematoma requiring operation 1% (increased if taking blood thinners or dual anti-platelet therapy)*
- *Discomfort and pain at the top of the leg. This usually settles after 1 week*
- *The overall acute complication rate is <5%*

**Uncommon but more serious risks:**

- *The risk of death is less than 1 in 1000 procedures)*

**Uncommon possible later issues:**

- *Late displacement of pacemaker, major bleeds needing re-exploration, 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.

**The patient has had the information leaflet for this procedure and/or discussed it with a health professional and has had sufficient time to make an informed decision.**

**I am satisfied that this patient has the capacity to provide his/her 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: \_\_\_\_\_

Name

Date of Birth

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## Implantation of Leadless Pacemaker

### 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: Implantation of a Leadless Pacemaker 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.

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)

Patient signature:

Name (PRINT):

Date:

# CONSENT FORM

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