

# Having a leadless pacemaker to manage your heart rhythm

## Cardiac Rhythm Management

Information for Patients

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### Introduction

You may need a pacemaker fitted if you have a problem with the electrical pathways of your heart. This booklet has been designed to help you understand why you may need this device, what you will experience when you come in to have it implanted, and the after care when you go home.

### How does the heart beat normally?

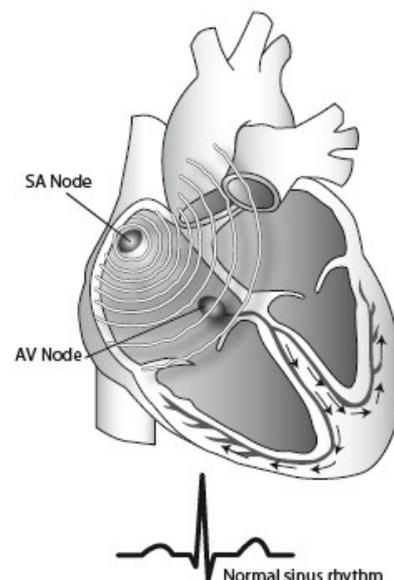
The heart is a pump that is responsible for circulating the blood around your body and to your brain. It pumps normally in a regular pattern between 60 to 100 times a minute.

The pumping action of the heart is driven by an electrical circuit which starts from your heart's natural pacemaker. This is called the "sinus node" and sits in the right upper chamber of the heart, also called the right atrium.

The electrical signals spread through the top chambers (atria) causing the muscle to contract and squeeze the blood into the bottom chambers of the heart (ventricles).

The electrical signals are then received by the middle junction box in the heart. This is called the Atrio Ventricular or AV node. The signals are slowed down and pass down to the bottom chambers of the heart (ventricles) through some 'conduction pathways' called bundle branches.

The bottom chambers then contract and squeeze the blood out around the body and brain from the left side, or to the lungs from the right side.



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## What is different in my heart?

If there is a problem with the normal electrical pathways in your heart, a pacemaker could help.

You may be experiencing dizziness, tiredness (lethargy), breathlessness or you may have collapsed. Some people don't have any symptoms, but a problem with the electrical pathway of your heart may be found during a routine check.

## What is a pacemaker?

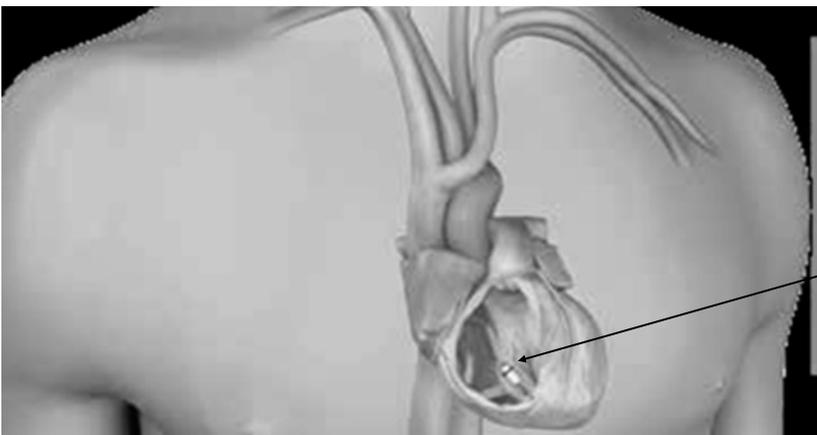
### Traditional pacemakers

Traditional pacemakers have a pulse generator (pacemaker box) placed under the skin below the collarbone that is connected to **1 lead** (single chamber pacemaker) or **2 leads** (dual chamber pacemaker). These are inserted through a vein to the heart to allow monitoring and stimulation of the heart (pacing).

### Leadless pacemakers

A smaller self-contained type of pacemaker (leadless) is now available which can be implanted into the heart through a vein in the leg. This type of pacemaker has no leads but has small flexible hooks which allow the device to be secured within the heart. Similar to a traditional pacemaker, the leadless pacemaker monitors the heart rate all the time but will only send out electrical impulses to pace the heart when it is needed.

Your pacemaker will be set specifically for you.



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## Pre-admission

Usually patients having a pacemaker fitted will be seen in the Cardiac Rhythm Pre-Admission Clinic so that you will know what to expect on the day of your procedure. At your preadmission appointment we will talk to you about the risks and benefits of the procedure, your medication and when to stop eating and drinking. Please ask any questions that you may have.

### Please bring to your pre-admission appointment:

- your current medication or recent prescription.
- your record of INR blood tests if you take warfarin.
- list of allergies (especially antibiotics, other drugs and metals).

Please also phone the Cardiac Rhythm Team if you have a procedure date and have not received a pre-admission appointment or it is **less than 7 days** before your procedure on **0116 258 3848** for advice on your medication.

## How do I prepare myself?

At your pre-admission appointment, you will be given antimicrobial nose ointment and body wash. Please use these as instructed for the **2 days before** your implant, and also on the day that you are coming into hospital

## Eating and drinking (fasting)

Your admission time on the day of your implant will be either 8am or 1pm. If your admission time is:

**8am:** Nothing to eat from midnight the night before.  
You can have clear fluids only, up to the time of your procedure.

**1pm:** A light breakfast until 9am then nothing to eat.  
You can have clear fluids only, up to the time of your procedure

**(Clear fluids includes black tea and coffee but no milk, no alcohol)**

You will be admitted to ward 32. Please bring:

- all of your medication.
- if you are on warfarin, your record of INR blood tests.
- This is often a day case procedure however please bring a small overnight bag in case you need to stay overnight.

## What does the procedure involve?

The procedure usually happens under a local anesthetic, so you will be awake. You may also be given some sedation to help you feel relaxed.

### On Ward 32

When you arrive on ward 32 you will meet the nurse who will be caring for you.

The nurse will ask you some questions and take your blood pressure, pulse, temperature and a small plastic tube (cannula) will be placed into a vein in your arm.

You will be given an antibiotic through the cannula. This is to reduce your risk of developing an infection.

You will be asked to put on a hospital gown and paper pants and the nurse may need to remove hair from the groin area before the procedure to keep infection risk low.

The pacemaker implant takes place in the procedure room (Catheter Lab) away from the ward and contains special X-ray and monitoring equipment.

### In the procedure room (Catheter Lab)

The staff in the procedure room will be wearing theatre gowns, masks and hats as this is a clean (sterile) procedure. You will be transferred onto the X-ray table which is narrow and firm. Heart monitoring and other monitoring equipment will be attached to your arms, legs and chest as needed.

Your groin area will be cleaned with an antiseptic solution and a sterile drape will be used to cover the surrounding area. The doctor will inject local anaesthetic into the skin in your groin (usually on the right side). This allows the area to become numb before passing a tube into the vein in the groin. The doctor will use an ultrasound scanner to see the tube as it passes under the skin, along one of the veins and into your heart.

The leadless pacemaker then travels through the tube and into the heart. It is carefully positioned against the middle wall of the heart (in the right ventricle) and secured in place. The leadless pacemaker is then checked to make sure it is detecting the electrical signals coming from the heart and is pacing correctly. The settings are adjusted to suit your needs. The entry site in your groin will be closed with a stitch. The stitch will be removed a few hours later. Your pacemaker will be checked again by a member of the pacing team at the end of the procedure.

The procedure may take up to 2 hours. During this time you will be given sedation if needed and pain relief to ensure you are kept comfortable throughout.

## What happens afterwards?

After the procedure you will go back to the ward on your bed/trolley and will stay on bed rest for 2 hours. You can eat and drink as normal.

Your groin area may be slightly bruised and swollen after the procedure. It is normal to feel some discomfort around that area - please tell the nursing staff and they will offer you pain relief.

The nursing staff will encourage you to get up and start moving around. Before you go home you will have a chest X-ray and be given an appointment card for your first check up in pacing clinic in 4 to 6 weeks. You may also be seen by one of the Cardiac Rhythm nurses.

## Risks and benefits of leadless pacemakers

The leadless pacemaker is a step forward in heart pacing, with good results so far. They are reliable and pace the heart as needed. They have reduced some of the complications found with traditional pacemakers especially those associated with the leads and pocket made under the skin.

The risks and benefits of having a leadless pacemaker instead of a traditional pacemaker will have been discussed with you in detail.

### Traditional pacemakers

Approximately 35,000 traditional pacemakers are implanted in the UK each year and have been used for many years for slow heart rhythms. Having a traditional pacemaker is a routine procedure however there are risks which include:

- bleeding into the pacemaker pocket - this may settle in time but you may need another procedure to stop the bleeding.
- collapse of the lung - this may settle on its own but sometimes needs a small drain put into the lining of the lung to help it re-expand.
- infection of the pocket - this may mean the implant has to be taken out.
- problems with the leads moving out of place or failing to work.

These risks are low but can be serious.

### Leadless pacemakers

Leadless pacemakers are relatively new, they were first used in people in 2012. They have developed from traditional pacemakers. We are still collecting information about how they perform in the longer term and how they perform towards the end of their battery life compared to traditional pacemakers. Unlike traditional pacemakers, they can only pace a single chamber in the heart (right ventricle). This means you can only have one fitted if you need single chamber pacing.

Leadless pacemakers have been developed to prevent some of the complications linked with traditional pacemakers. They are put in through a vein in the groin, this means there is no risk of lung collapse. As the pacemaker is not implanted under the skin in a pocket there is no risk of bleeding from the pocket or pocket infection. There are no leads, so there is no risk of leads moving out of place or lead failure in the longer-term. However, leadless pacemakers do carry some risk as discussed over the page.

## What are the specific risks with leadless pacemakers?

### Infection

There is always a small risk (approximately 1 in 700) of getting an infection and needing to have the pacemaker taken out and replaced. You will be given antibiotics before and sometimes after the implant to help minimise the risk. You will be given advice about the signs of infection and what to look for when you go home.

### Groin complications

Bruising in the groin where the tube is passed into the vein is very common. In about 1 in 200 patients there may be damage to the vein and a small operation may be needed to repair it. This is more common if you are taking 'blood thinning medication' (e.g. Rivaroxaban, Apixaban, Dabigatran, Edoxaban or Warfarin). If there is any extra bleeding (sometimes called a haematoma), pressure will be applied to control it and this may result in more bruising to the groin. This could last some weeks. Some people may feel some discomfort for a few days after the procedure.

### Device displacement

There is a 1 in 700 risk that the pacemaker may move out of position. You may not know that this has happened until you come for pacemaker checks in clinic. If this happens the leadless pacemaker will need to be repositioned which will need another procedure.

### Puncture of the heart (pericardial effusion/tamponade)

There is a 1 in 300 risk of a bleed around the heart during the procedure. If this were to happen, a small drain may need to be inserted into the lining of the heart to drain away the collection of blood. Very rarely, it can lead to the need for heart surgery.

### Radiation risk

The procedure has an approximate risk of 1 in 15,000 of causing a fatal cancer. This will vary depending on the complexity of the procedure. The amount of radiation that you will be exposed to is the equivalent of the background radiation you are exposed to through living in Leicester in 180 days (assuming background radiation of 2.6mSv per year).

Depending on the complexity of the examination there is a small chance of skin reddening (radiation induced erythema). We will talk to you about this after the procedure if it is a risk for you.

These risks will be discussed again with you at pre assessment and before signing the consent form. Please ask any questions that you may have.

## Going home

### Pain relief

You may experience some pain and discomfort after the procedure, we advise you take some regular pain killers for a few days as needed. Seek advice from your GP or pharmacist if your pain lasts for more than a few days.

### Groin care

For the 2 days after the procedure you should avoid any hot baths or showers to allow time for your groin to heal.

For the first 2 days you should limit your exercise. You will then need to avoid any strenuous exercise for at least 1 week to allow your groin to heal.

### Signs of infection

If you have a higher than normal temperature or feel unwell, the wound may look very red and feel hot or have fluid leaking from it. If you notice any of these signs or symptoms you must contact the your GP, or call 111 as soon as possible, as the infection may spread into the device and you may need to have the pacemaker replaced.

## Everyday life with your pacemaker

### What will it feel like to have a pacemaker?

You won't feel the leadless pacemaker working or be aware of it.

When you return home you may get relief from symptoms such as light-headedness, dizziness and fainting. Some people feel they have more energy.

### Battery

The battery life of your device will be checked on every visit to the pacemaker clinic. It is unusual for pacemakers to have technical failures however, if you go for regular follow up checks at your pacemaker clinic, staff can detect any problems as they happen.

The battery usually lasts approximately 10 years and battery life is affected by how much pacing the device needs to do. You will need a new device once the battery runs low. Your doctor will discuss the type of pacemaker you need with you.

## General advice

### Driving and insurance

If you have a Group 1 Car/motorcyclist the DVLA guidelines state that you should not drive for **1 week** after your pacemaker has been implanted, although you may wish to allow more time for your groin to heal if it is still sore. If you have a Group 2 Lorry/Bus license DVLA states you must not drive for **6 weeks** after having your pacemaker implanted.

You must inform the DVLA and your insurance company that you have had a pacemaker implanted. Please fill in a medical questionnaire. You can download this from the website: [www.direct.gov.uk/driverhealth](http://www.direct.gov.uk/driverhealth) or call DVLA on 0300 790 6806 for **Group 1 Car / Motorcyclist** or 0300 790 68067 for **Group 2 Lorry / Bus**. (Information as per DVLA Guidelines October 2017).

### Travel

Pacemaker devices do not usually cause problems with airport security systems however, when travelling please carry your 'Pacemaker Identification Card' (this will be given to you before you go home).

Move quickly through the security arch if asked to do so. If you need to have a hand search, make sure that the metal detector is not placed directly over your pacemaker.

### Mobile phones

You can safely use your mobile phone but keep it at least 15cm / 6 inches from your pacemaker. Always use the ear on the opposite side to the pacemaker and do not place the phone in a shirt pocket over the pacemaker site.

### Electrical equipment

Electrical equipment that you use in the home such as well maintained microwave ovens, DVD players and electric drills will not cause any problems to your pacemaker as long as you use them 15cm / 6 inches away from your device. See advice below for Induction hobs.

### Magnets

Some magnets may interfere with how the leadless pacemaker works. Equipment like large stereo speakers, hand held massagers and induction hobs should be kept a minimum of 60cm away from the heating zone. We advise you not to sleep on beds with a magnetic mattress or pillow as this may affect the pacemaker. For further advice contact Pacemaker Clinic.

### Medical and dental tests and treatments

Some hospital equipment may interfere with pacemakers. It is usually safe to have an MRI scan with a leadless pacemaker however you should always check with the pacemaker clinic or your doctor.

If you have any questions please write them down to remind you what to ask when you speak to your consultant or specialist nurse.

## Questions

If you have any questions please write them down to remind you what to ask when you speak to your consultant or specialist nurse.

## Contact details

Your doctor or Community Heart Failure services may be able to give you more information.

<b>Pacing Clinic:</b>	0116 258 3837	<b>Evenings &amp; Weekends:</b>	
<b>Cardiac Rhythm Nurses:</b>	0116 258 3848	Ward 33	0116 256 3733
		Ward 28	0116 256 3848

### Heart Rhythm Charity

Email: [info@heartrhythmcharity.org.uk](mailto:info@heartrhythmcharity.org.uk) Tel: 01789 450787

### British Heart Foundation

Website: [bhf.org.uk](http://bhf.org.uk) Tel: 0300 330 3311

**Health information and support is available at [www.nhs.uk](http://www.nhs.uk)  
or call 111 for non-emergency medical advice**

Leicester's Hospitals is a research active trust so you may find research is happening on your ward or in your clinic.

To find out more about the benefits of research and become involved yourself, speak to your clinician or nurse, call 0116 258 8351 or visit [www.leicestersresearch.nhs.uk/patient-and-public-involvement](http://www.leicestersresearch.nhs.uk/patient-and-public-involvement)