Royal Papworth Hospital
NHS Foundation Trust

Device procedures

A patient's guide and consent form

Compassion
Excellence
Collaboration

Instructions for clinicians

- Apply addressograph label above and on both consent pages
- Strike through pages that do not apply to this patient
- Complete consent form indicating page numbers that refer to risks and benefits of intended procedure
- Remove copy page of consent form for filing in patient notes
- Advise patient to keep this booklet and consent form throughout their treatment pathway and to bring it to all appointments

Contents

Normal heart function

The heart is a muscular pump that delivers blood containing oxygen to the body. It is divided into two upper chambers, or atria, which collect blood returning via the veins, and two lower chambers, the ventricles, which pump blood to the body and lungs.

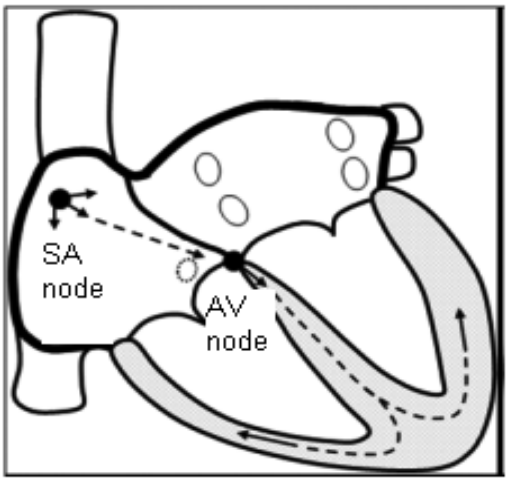
Some conditions cause damage to the pumping action of the heart that leads to the accumulation of fluid in the lungs or lower legs. This is described as 'heart failure' and may lead to symptoms of breathlessness and lethargy.

Normally, the heart beats in a regular, organised way at a rate of 60 to100 beats per minute. This is because it is driven by a specialised area of muscle in the right atrium called the sino-atrial (SA) node that emits electrical impulses. This is the natural pacemaker of the heart.

These impulses spread through the atria and are then channelled through another area of special cells called the atrio-ventricular (AV) node into the ventricles. The purpose of the AV node is to introduce a delay to prevent the atria from pumping blood into the ventricles when the ventricles are themselves pumping out. (This is what gives the characteristic double heart beat).

The impulses then spread rapidly throughout the ventricles making them contract and pump blood to the body and lungs. The normal pathway that the electrical impulses follow is called the **conduction system**.

The SA node controls the overall timing of the heart, according to the needs of the body. An example of this is during exercise, when the heart rate speeds up. When the heart is beating normally like this, we refer to it as **sinus rhythm** or **normal sinus rhythm**.



Heart rhythm disturbances and device procedures

Sometimes the special conducting system does not work as well as it should. Some heart rhythm disturbances can be identified by a simple heart tracing known as an ECG tracing, while others require more detailed investigation. The Implantable Loop Recorder (ILR) is a device which can capture the heart rhythm during a symptomatic episode. This is described in detail on page six of this booklet. The heart may beat too slowly, too quickly or erratically, causing dizziness, fainting or breathlessness.

There are several types of implantable devices that control the heart rhythm and improve symptoms. The implant procedure for each of the devices is similar, although the function of the device and the number of leads will vary depending on thecondition. The doctor or specialist nurse will explain your specific condition to you.

A pacemaker can help to control the heart rhythm, particularly if the heart is beating too slowly or irregularly.

If the abnormal heart rhythm is too fast, and arises from the lower chambers, the ventricles, it is known as ventricular tachycardia, or VT. This can be dangerous, particularly if it is associated with fainting.

An implantable cardioverter defibrillator (ICD) may be used to treat these fast rhythms. There

are other reasons why an ICD may be recommended; the doctor or specialist nurse will discuss the specific reason with you.

If the pumping action of the heart is affected, a special type of pacemaker may help your symptoms. This is known as a biventricular pacemaker or cardiac resynchronisation therapy (CRT). This can be combined with an ICD if appropriate.

You will be followed up in clinic to monitor the function of your device and its battery life. When the battery requires replacement, you will need a brief stay in hospital for a 'box change' or 'elective unit replacement' (EUR). Occasionally, the device may need to be removed; for example, if it becomes infected. This is described in detail within this booklet.

Your doctor or arrhythmia specialist nurse will indicate which pages of this book apply to your procedure.

Preparation for a device procedure

The procedure may be undertaken as a day case, although some people will be required to stay in hospital for one or two nights.

Prior to the procedure you will continue with most of your medication as usual. However, if you are taking warfarin you may need to stop it for three days or other blood-thinning drugs such as Dabigatran, Rivaroxaban, Edoxaban or Apixaban you will need to stop it for two days. If you have a mechanical heart valve, your warfarin should not be stopped and you should discuss this with the arrhythmia nurses before your admission on **01223 638947**.

It is very important to follow these instructions carefully as failing to do so may delay your procedure.

You will also be asked to go without food for a short period. Further advice will be sent with the admission letter.

Please shower the night before your procedure. You will be asked to shower again using antiseptic shower gel on the morning of the procedure, after having the operation site clipped (if necessary).

There is a restriction on driving associated with each of these procedures; you will be advised of this prior to the procedure.

The procedures described in this booklet are carried out in the catheter laboratory (cath lab) which is a room similar to an operating theatre. Occasionally they may be performed in the operating theatre. There will be a team of people present, some of whom you may have met before.

The doctor who specialises in heart rhythm management, an electrophysiologist, will carry out the procedure with the help of a cardiac physiologist, who provides technical support. The consultant electrophysiologist may have a trainee registrar assisting them. The nurses will look after you and assist the doctor, and the radiographer will assist with the X-ray equipment.

During the procedure you will be lying on your back on an operating table and several sticky pads will be applied to your chest to monitor your heart rhythm. You will be covered over with sterile paper sheets but will not have your face covered.

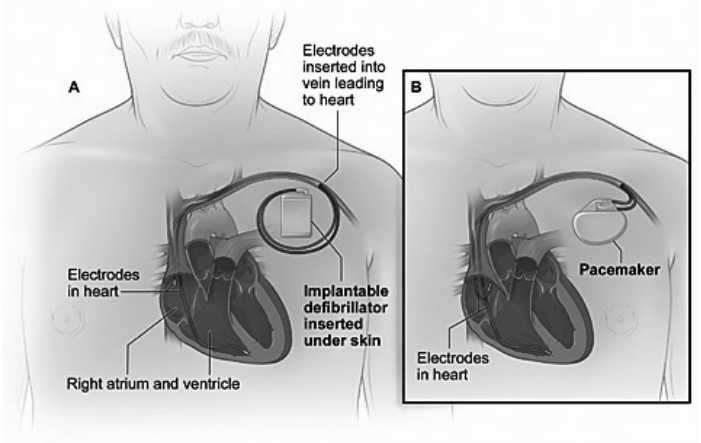
The implant procedure

You will have a small cannula inserted in the back of your hand or in your arm which is used to give antibiotics to minimise the risk of infection. The device is usually implanted on the left side just below your collar bone, using local anaesthetic to numb the area, and the use of sedation and painkiller as necessary. Some patients will have a general anaesthetic, but you will be advised of this in advance.

A cold antiseptic solution is applied to the skin to clean the surrounding area. A small incision is made to allow access to the vein and placement of the device in a small 'pocket' just beneath the skin. Lead(s) will then be inserted into a vein and threaded down into the heart. X-rays will help to guide the position of the lead(s). The leads are then connected to the device which is placed in the pocket.

The cardiac physiologist will confirm that it is functioning correctly while the wound is being sutured. The stitches, which are dissolvable, will be under the skin, and a dressing will be applied.

You will then be transferred back to the ward to recuperate, where you will remain in bed for a short time and you will be able to eat and drink as normal.



Following the procedure

You will return to the ward area following the procedure, where you will be attached to a heart monitor and remain on bed rest for a short time. You will have a dressing over the wound(s) which should be removed after four days.

Regular painkillers such as paracetamol may be taken as required. Later that day, or the morning after the procedure you will be seen by a cardiac physiologist to check the settings of the device and to ensure it is working correctly. You may also have a chest X-ray to confirm the position of the leads and to check for a pneumothorax (collapsed lung).

Often you can go home on the same day as the procedure - in which case you will need to have someone to stay with you for the first night.

Please note: Implanted medical devices such as pacemakers and defibrillators are occasionally subject to advisories relating to issues with software or hardware. Although these are rare, they are usually identified after many devices have been implanted, often years later. It is our responsibility to keep accurate records of all implanted devices and to inform you immediately we are informed of an advisory affecting your system. No action may be required but occasionally your device may need to be reprogrammed or rarely revised or replaced.

The implantable loop recorder (ILR) procedure

An Implantable Loop Recorder (ILR) is a small leadless device which is implanted beneath the skin on the left side of the chest. This is used to record your heart rhythm when you are experiencing symptoms such as palpitations, dizziness or fainting. Usually the procedure takes about 30 minutes.

Benefits of having an ILR

The ILR will help to determine whether or not your symptoms are related to a heart rhythm abnormality. This will help us to offer the most appropriate treatment and to plan any further procedures if this is recommended.

Risks associated with ILR

ILR implantation is considered to be a very safe procedure; however, all medical procedures carry some risks. For an ILR implant the risk of complications during or immediately after the procedure are as follows:

- Local bleeding/bruising/vascular damage 1% (1 in 100)
- Infection 1% (1 in 100)

Preparation before the ILR

This procedure is undertaken as a day case. Prior to the procedure you will continue taking your medication as usual. However, if you are taking warfarin or other blood-thinning medication you will be advised if or when to stop taking it.

You will be able to drink water up to the time of your procedure; however we ask that you go without food for two hours, and caffeinated drinks for four hours, prior to the procedure.

The ILR procedure

Your ILR will be implanted by a qualified doctor, cardiac physiologist or nurse. It will normally take place in one of the procedure rooms in the cardiac day ward or in the catheter laboratory.

The device will be implanted under the skin on the left side of your chest. A cold antiseptic solution is applied to clean the surrounding skin and a local anaesthetic will be used to numb the area.

A small incision is made to allow the placement of the device in a small 'pocket' just beneath the skin. Once the device has been inserted, steri-strips or sutures will be used to close the wound and a dressing placed over the top. This dressing can be left on for four days after the procedure.

A cardiac physiologist will confirm that the device is sensing the rate and rhythm of the heart correctly. You will then return to the day ward/ward to recuperate where you will remain for a short time before a physiologist explains how the home monitor works.

Following an ILR

Once you have had your ILR implanted you will have a teaching session on how to use your Carelink home monitor and symptom activator device. In order to set up your home monitor, one manual transmission is required, after which you do not need to do another unless we ask you to.

The symptom activator should be kept on your person at all times. When used, it triggers your device to highlight the ECG recorded before and after as a 'symptom'.

It is important to only press your symptom activator when you experience symptoms related to your heart such as palpitations, chest tightness, dizziness etc.

Remember to call or email the department with the details of your symptoms (contact details can be found in the booklet provided at implant).

If you have questions about the home monitoring please call 01223 639657 or 01223 638681.

Chest pain

The device you have had implanted will monitor the rate and rhythm of your heart and it may not detect the slightly different changes that occur with angina and a heart attack. Therefore, if you experience chest pain, it is always best to see your GP or go to A&E.

Driving

You will be allowed to drive three hours following your procedure, unless your driving has been restricted by the DVLA as a result of your symptoms or other health conditions.

Looking after your wound

Removal of an ILR

The ILR battery lasts about three years so after this it can be removed. This is done in a similar way to how it was implanted and will be removed by a doctor in the catheter laboratory.

A cold antiseptic solution is applied to clean the surrounding skin and a local anaesthetic will be used to numb the area.

A small incision is made to allow the removal of the device. Once it has been removed, steri-strips will be used to close the wound and a dressing placed over the top. The dressing can be removed three to four days after the procedure.

Risks associated with ILR removal

ILR removal is considered to be a very safe procedure; however, all medical procedures carry some risks. For an ILR removal the risk of complications during or immediately after the procedure are as follows:

- Local bleeding/bruising/vascular damage 1% (1 in 100)
- Infection 1% (1 in 100)

Avoid any heavy lifting and strenuous exercise for 48 hours following your procedure, then slowly resume your normal activity levels.

The dressing over your wound is designed to stay in place for three to four days. You may bath or shower the day after your procedure and avoid putting on or around the wound site until the wound has healed.

If you experience any oozing, swelling, heat, or redness around the wound or if you notice any discharge through the dressing please contact your GP.

If you have any queries or questions after your discharge do not hesitate to contact the day ward on **01223 638150** Monday to Friday.

The pacemaker procedure

A pacemaker is a small electronic device with a battery, which is able to monitor and stimulate the heart when the heart rate is too slow. One or two leads are inserted into the heart and connected to the device. Small electrical impulses are transmitted from the device, through the leads to the heart which will trigger the heartbeat. You will not be able to feel these electrical impulses.

The heart rhythm may be slow for different reasons; the natural pacemaker of the heart (the sinus node) may not function normally and there may be episodes of a slow heart rate (bradycardia). This is called sick sinus syndrome. The heart rate may also be slow when the AV node is unable to transmit all the impulses through to the ventricles. This is called heart block and may be intermittent or 'complete' heart block and often occurs in older people.

A pacemaker may be used in these conditions in order to prevent the heart rate from going too slowly and relieve symptoms of dizziness, lethargy or fainting. Normally the procedure takes approximately 60 to 90 minutes and you may be required to stay overnight.

Benefits of having a pacemaker

The benefits of having a pacemaker are to prevent the heart from beating too slowly, and to improve your symptoms; you may not feel so dizzy, faint or breathless and your general quality of life may be improved.

Risks associated with the pacemaker procedure

The pacemaker procedure is considered relatively safe, but as with all medical procedures there are risks, the risks of complications during or following the procedure include:

- Risk of localised bleeding/bruising 1% (1 in 100)
- Infection 1% (1 in 100)
- Pneumothorax (collapsed lung) 1% (1 in 100)
- Lead displacement 1% (1 in 100)
- Lead perforation of cardiac wall < 0.5% (<1 in 200)

Driving

You will not be able to drive for a period after the pacemaker insertion. This is usually one week for a standard licence holder, but longer for a group two licence holder.

Please refer to the pacemaker follow up information guide for more detailed advice about what to do after you go home.

Leadless pacemaker procedure

Leadless pacemakers are smaller than traditional pacemakers (the size of a small battery), and contains a battery that lasts as long as those in traditional pacemakers.

Unlike a standard pacemaker, it is implanted into the heart through a vein in the leg and does not require a pacing lead. Due to the leadless pacemaker's miniature size and minimally invasive approach, it leaves no visible sign of a medical device under the skin. This can mean fewer post-implant activity restrictions. Leadless pacemakers are not appropriate for all patients so your doctor will advise you which device is best for you.

The doctor will insert a catheter system into a vein near the upper thigh area of the leg. The catheter system moves the device into the right ventricle of the heart and the device is placed against the heart wall and secured with flexible tines or retractable helix. An external programmer is used to test and program the device and the catheter system is then removed from the body.

Benefits of having a leadless pacemaker

The benefits of having a leadless pacemaker are the same as for a traditional pacemaker, but exclude the risks relating to pacing leads.

Risks associated with leadless pacemaker implantation

The pacemaker procedure is considered relatively safe, but as with all medical procedures there are risks, the risks of complications during or following the procedure include:

- Risk of localised bleeding/bruising 3% (3 in 100)
- Device dislodgement 0.1% (1 in 1000)
- Cardiac tamponade 0.1%(1 in 1000)
- Infection <0.1% (1 in 1000)

Driving

You will not be able to drive for a period after the pacemaker insertion. This is usually one week for a standard licence holder, but longer for a group two licence holder.

Please refer to the pacemaker follow up information guide for more detailed advice about what to do after you go home.

Implantable Cardioverter Defibrillator procedure (ICD)

An ICD is a small electronic device similar to a pacemaker which monitors and regulates your heart rhythm if it is slow, but it can also treat fast heart rhythms. In some cases it can correct the fast rhythms by pacing (anti-tachycardia pacing). It also has the ability to deliver an electrical shock to the heart in order to restore normal sinus rhythm if a dangerous heart rhythm is detected.

An ICD is implanted if you have already experienced a fast abnormal heart rhythm (VT) which has required a shock (defibrillation), if your heart rhythm has become chaotic or 'stopped' (cardiac arrest) or if you are considered to be at high risk of developing a dangerous rhythm. You will have the opportunity to discuss the reason why you require the ICD and the implications of living with an ICD with the doctor or arrhythmia specialist nurse.

Benefits of an ICD

The benefit of an ICD is that it can treat dangerous heart rhythms by shocking the heart.

Risks associated with an ICD

- Risk of localised bleeding/bruising 1% (1 in 100)
- Infection 1% (1 in 100)
- Pneumothorax (collapsed lung) 1% (1 in 100)
- Lead displacement 1% (1 in 100)
- Lead perforation of cardiac wall <0.5% (<1 in 200)
- Death <0.1% (1 in 1000)

During the ICD implant

The doctor may want to test the device during the procedure to ensure it is working correctly. To do this, your heart is made to beat very quickly and the ICD will give a shock to correct the rhythm. You will be given sedation prior to this happening, so you should not feel the shock.

Following the ICD procedure

You will not be able to drive for a time after the ICD insertion. The period will depend on the reason for the implant. The doctor or arrhythmia specialist nurse will discuss this with you. Please refer to the ICD follow-up information guide for more detailed advice about what to do after you go home.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

PIC 136: patient agreement to PI 136 - Device procedures

Intended procedure/surgery

Statement of health professional

(To be filled in by a 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 and risks

- As detailed on page ..... of this booklet

Any extra procedures, which may become necessary during the procedure:

☐ Blood transfusion
☐ Other procedure - please specify below:

.....

.....

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.

This procedure will involve:

☐ General anaesthesia
☐ Local anaesthesia and sedation

Consultant/Performer/Registered Nurse

Signed: ……

Date: ……

Name (PRINT): ……

Job title: ……

Contact details
(If patient wishes to discuss options later)

……

Statement of patient

Please read the patient information and this form carefully.

If your treatment has been planned in advance, you should already have your own copy which describes the benefits and risks of the proposed treatment. If not, you will be offered 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 understand** what the procedure is and I know why it is being done, including the risks and benefits.
- **I agree** to the procedure or course of treatment described on this form and have read the information leaflet on Device Procedures (PI 136) and had the opportunity to ask questions.
- **I agree** to the use of photography for the purpose of diagnosis and treatment and I agree to photographs being used for medical teaching and education.
- **I understand** that any tissue removed as part of the procedure or treatment may be used for diagnosis, stored or disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.
- **I understand** that any procedure in addition to those described on this form will be carried out only if necessary to save my life or to prevent serious harm to my health.
- I have listed below any procedures **which I do not wish to be carried out** without further discussion:

.....

.....

Top copy to be filed in medical notes, carbon copy to be retained in booklet for patient.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

NHS
Royal Papworth Hospital
NHS Foundation Trust

- I have been told in the past by Public Health that I am at increased risk of CJD (Creutzfeldt-Jakob disease) or vCJD (variant Creutzfeldt-Jakob disease).

  ☐ Yes (Health professional to refer to Trust CJD procedure DN92.)

  ☐ No

Patient

Patient signature: ……

Date: ……

Name (PRINT): ……

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

Signed: ……

Date: ……

Name (PRINT): ……

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

Signed: ……

Date: ……

Name (PRINT): ……

Confirmation of consent

(To be completed by a 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.

Signed: ……

Date: ……

Name (PRINT): ……

Job title: ……

Important notes (tick if applicable).

☐ Patient has advance decision to refuse treatment (e.g. Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ……

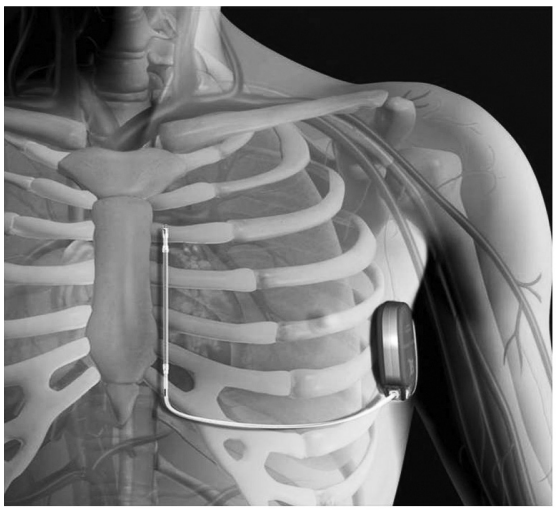
Date: ……

Name (PRINT): ……

Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) procedure

As with a traditional ICD (page 11), an S-ICD is an electronic device that monitors your heart rhythm and delivers an electric shock to the heart if a dangerous heart rhythm is detected, in order to restore normal sinus rhythm. It does not function as a pacemaker, but does provide a less invasive option as it has no leads going into the heart.

The S-ICD box is placed under the skin on the left side of the chest and an electrode is placed under the skin alongside the breastbone and connected to the box.



Benefits of an S-ICD

The benefit of an S-ICD is that it can treat dangerous heart rhythms by shocking the heart.

Risks associated with an S-ICD

- Risk of localised bleeding/bruising 1% (1 in 100)
- Infection 1% (1 in 100)

During the S-ICD implant

The procedure is performed under general anaesthetic and takes about an hour. There will be three wounds; a small wound at the top and bottom of the breastbone to secure

the lead, and another wound over the box on the left side of your chest. The doctor may want to test the device during the procedure to ensure it is working correctly.

You will not be able to drive for a time after the S-ICD insertion. The period will depend on the reason for the implant. The doctor or arrhythmia specialist nurse will discuss this with you. Please refer to the ICD follow up information guide for more detailed advice about what to do after you go home.

Cardiac resynchronisation pacemaker/defibrillator procedure

A Cardiac Resynchronisation Therapy (CRT) device is a special pacemaker that is designed to improve the pumping action (contraction) of the heart. Two of the leads are the same as a normal pacemaker, and an additional lead is passed into the heart around to the left side, so that both sides of the heart can be stimulated at the same time. This is why it may be termed a **biventricular** device.

Some patients with heart failure are also at risk of fast irregular heartbeats such as ventricular tachycardia or ventricular fibrillation. These may be treated with a defibrillator. Some CRT devices have the combined function of pacemaker and defibrillator.

Benefits of CRT

The benefit of a CRT pacemaker (CRT-P) is that it is able to improve the efficiency of your heart and reduce symptoms. When this is combined with a defibrillator (CRT-D) it will also be able to treat dangerous heart rhythms by shocking the heart.

Risks associated with a CRT device

The risks of complications during or immediately after the procedure are as follows:

- Risk of localised bleeding/bruising 2% (2 in 100)
- Infection 2% (2 in 100)
- Lead displacement 2% (2 in 100)
- Pneumothorax (collapsed lung) 1% (1 in 100)
- Pericardial effusion / tamponade 0.5% (1 in 200)

The procedure usually takes about two to three hours.

Driving

Following a CRT pacemaker (CRT-P) implant you may drive after one week. However, if you have a CRT combined with a defibrillator (CRT-D) the Driving and Vehicle Licensing Agency (DVLA) has strict rules. Different rules apply depending on the reason why you had the device, so please discuss this with your doctor, physiologist or nurse who will explain in more detail.

Please refer to the pacemaker/defibrillator follow up information guide for more detailed advice about what to do after you go home.

Battery change/device replacement

The device replacement procedure

The battery life of your implantable device will depend on the device and how much it is used. This procedure is sometimes known as an Elective Unit Replacement (EUR).

The battery is a component of the pulse generator, the small metal box beneath the skin. To replace the battery, the pulse generator is changed by a small surgical procedure every seven to ten years.

Over the life of the battery, your cardiac condition and general health may change. Therefore at your routine check-up near the end of battery life you may see the consultant to discuss if any change in the type of device is required at the time of box change.

The other part of the system is the lead(s). Usually these leads last longer than the device battery, and a new lead will be placed if necessary.

Benefits of replacement

The benefit of device/battery replacement is to maintain the proper functioning of the device.

Risks associated with replacement

The risks of complications during or immediately after the procedure are as follows:

- Risk of localised bleeding/bruising 2% (2 in 100)
- Infection 2% (2 in 100)
- Pneumothorax (collapsed lung) 1% (1 in 100)
- Lead displacement 1% (1 in 100)
- Damage to lead <0.5% (<1 in 200)

The procedure usually takes about an hour.

Unless there has been a lead revision during the procedure you will not need any further device checks or X-rays before discharge and you may be able to go home the same day. Please refer to the pacemaker/defibrillator follow-up information guide for more detailed advice about what to do after you go home.

Driving

You will not be able to drive for a period of one week after a device box change but you do not need to notify DVLA.

Lead reposition/revision

After a device has been implanted, you will have a chest X-ray, and the cardiac physiologist will check that the device is working correctly. Occasionally, it will be seen that the lead (or wire) has become displaced and will require repositioning. This will usually take place during the same hospital stay, and may delay your discharge.

Alternatively, subsequent device checks may reveal a problem with the lead and require you to be admitted for a further procedure. This may be to reposition the existing lead, replace the existing lead (if it is a recent implant), or to place a new lead alongside the existing lead.

This procedure should take less than an hour and will be very similar to the initial procedure; please refer to page four for further information regarding preparation for the procedure and the implant procedure itself.

Benefits of the lead revision procedure

The benefits of the lead reposition or revision is to ensure the correct working of the device. It may also conserve battery life, if a lead issue is requiring the battery to work harder.

Risks associated with a lead revision

This procedure carries similar risks to your previous procedure. In general these are as follows:

- Risk of localised bleeding/bruising 1% (1 in 100)
- Infection 1% (1 in 100)
- Pneumothorax (collapsed lung) 1% (1 in 100)
- Pericardial effusion/cardiac tamponade 1% (1 in 100)
- Further lead displacement 1% (1 in 100)

Following the lead revision procedure

Recovery following a lead revision will be very similar to the previous procedure. Please see page five for information on the immediate recovery period, and page 18 for further advice.

Pacemaker and defibrillator lead extraction

The extraction procedure

Occasionally, a pacemaker or defibrillator system may need to be removed. The box, or pulse generator is easily removed from the small pocket beneath the skin.

However, the leads are designed to remain in the body, so the removal of the complete system is potentially a high-risk procedure.

Usually this procedure is performed under general anaesthetic with a team of highly-skilled medical professionals including a cardiologist, cardiac physiologist, anaesthetist and nurses, and a surgical team available if required. Specialist equipment will also be available.

Different types of extraction

The most common reason for lead extraction is infection. If any part of the system becomes infected it will usually require all the hardware to be removed from the body. Each lead passes through a vein into the heart and often scar tissue will form along the path of that vein. The lead needs to be freed from the scar tissue in order to remove it. There are several tools available that can be used to achieve this.

Another reason for extracting the leads is when there is a problem with the lead and a new lead is required. Sometimes, the broken lead can be secured under the skin and the new lead placed alongside it. However, if the vein is too small to accommodate another lead, the existing lead will need to be removed first.

Occasionally, leads that have been abandoned and secured under the skin may subsequently come to the surface and erode through the skin. These also require extraction in order to prevent any development of widespread infection. Usually the procedure takes two to three hours.

Benefits of a lead extraction

The benefits of pacemaker or defibrillator lead extraction are to remove hardware in order to treat infection, to prevent infection occurring in an eroded device or lead, and to allow room for additional lead(s) to be implanted and alleviate symptoms of a blocked vein. This is usually successful in about 90% of people.

Risks associated with lead extraction

Lead extraction is a complex procedure with some unavoidable risks. As the lead is separated from the tissue, there is a small chance of tearing the surrounding blood vessel, or perforating the heart. In general the risks are as follows:

- Damage to surrounding structures 2% (2 in 100)
- Risk of bleeding requiring urgent surgery 2% (2 in 100)
- Risk of localised bleeding/bruising 1% (1 in 100)
- Pneumothorax (collapsed lung) 1% (1 in 100)
- Risk of death less than 1% (<1 in 100)

Preparation before a lead extraction procedure

The procedure will require at least an overnight stay, and some people will need to stay longer depending on their condition.

During the procedure

Lead extraction procedures are usually carried out under general anaesthetic. A temporary pacemaker may be inserted at the same time, to provide pacemaker support until a new device is implanted.

Following the extraction procedure

After the procedure, you will spend a short time in recovery, and then return to the ward where you will continue to be monitored.

You may need to stay in hospital for a few nights to monitor the wound and to observe for any evidence of infection. If the device was removed for infection, you may require a longer stay while you receive intravenous antibiotics. This allows time for the infection to clear, before implanting a new device.

Further investigations may be required as sometimes it is not necessary to implant another device. This will all be explained to you and you will be kept informed at each stage of the treatment plan.

If you require an extended period of antibiotics, it may be possible for you to be transferred back to your local hospital for completion of the course.

After an implantable device procedure

Recovery

Most people recover quickly from having a device implanted and feel well enough to carry on with normal activities after a few days. However you should avoid heavy lifting or stretching the arm nearer to the pacemaker for one month, to allow the device and leads to settle in.

It is important however to keep the shoulder joint moving to reduce the risk of a frozen shoulder.

You may develop some swelling over the device which should reduce gradually over the next few days. If the site becomes very swollen or painful please contact us or, in an urgent situation, contact your GP or out of hours service or attend A&E.

There may be some bruising around the device area, which is normal and should resolve over the next few weeks. If you have any discomfort around the wound, simple painkillers such as paracetamol should be sufficient to resolve this or stronger painkillers are available from chemists.

The dressing over your wound is designed to stay in place for three to four days. You may bath or shower the day after your procedure, but avoid putting talcum powder on or around the wound site until the wound has healed. The stitches in your wound are dissolvable.

Please refer to the pacemaker/defibrillator follow up information guide for more detailed advice about what to do after you go home.

On-going management

The team of people involved in your care will include the doctors, cardiac physiologists, and arrhythmia specialist nurses. Arrangements will be made for you to be followed up by the most appropriate members of this team either in person or by telephone. You will need to have your device checked regularly the physiologist either at Royal Papworth your local hospital.

Within one to two weeks, your doctor will write to your GP about your procedure and on-going management arrangements and you will receive a copy of that letter.

Further help and advice

If you have questions, concerns, or are having on-going symptoms, please contact:

Arrhythmia specialist nurse (ASN)

Helpline: **01223 638947 Monday to Friday 09:00 – 17:00**

Other useful resources:

Arrhythmia Alliance - the heart rhythm charity

PO Box 3697
Stratford-Upon-Avon
Warwickshire
CV37 8YL
24hr Helpline: **+44 (0)1789 450787**
Email: **info@heartrhythmcharity.org.uk**
Website: **heartrhythmcharity.org.uk**

The British Heart Foundation

BHF
Greater London House
180 Hampstead Road
London NW1 7AW
Heart Helpline: **0300 330 3311**
Email: **supportservices@bhf.org.uk**
Website: **bhf.org.uk**

DVLA

Drivers Medical Group
DVLA
Swansea
SA99 1TY
Tel: **0300 790 6806**
Email: **eftd@dvla.gsi.gov.uk**
Website: **dft.gov.uk/dvla**

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Large print copies and alternative language versions of this leaflet can be made available on request.

View a digital version of this leaflet by scanning the QR code.

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