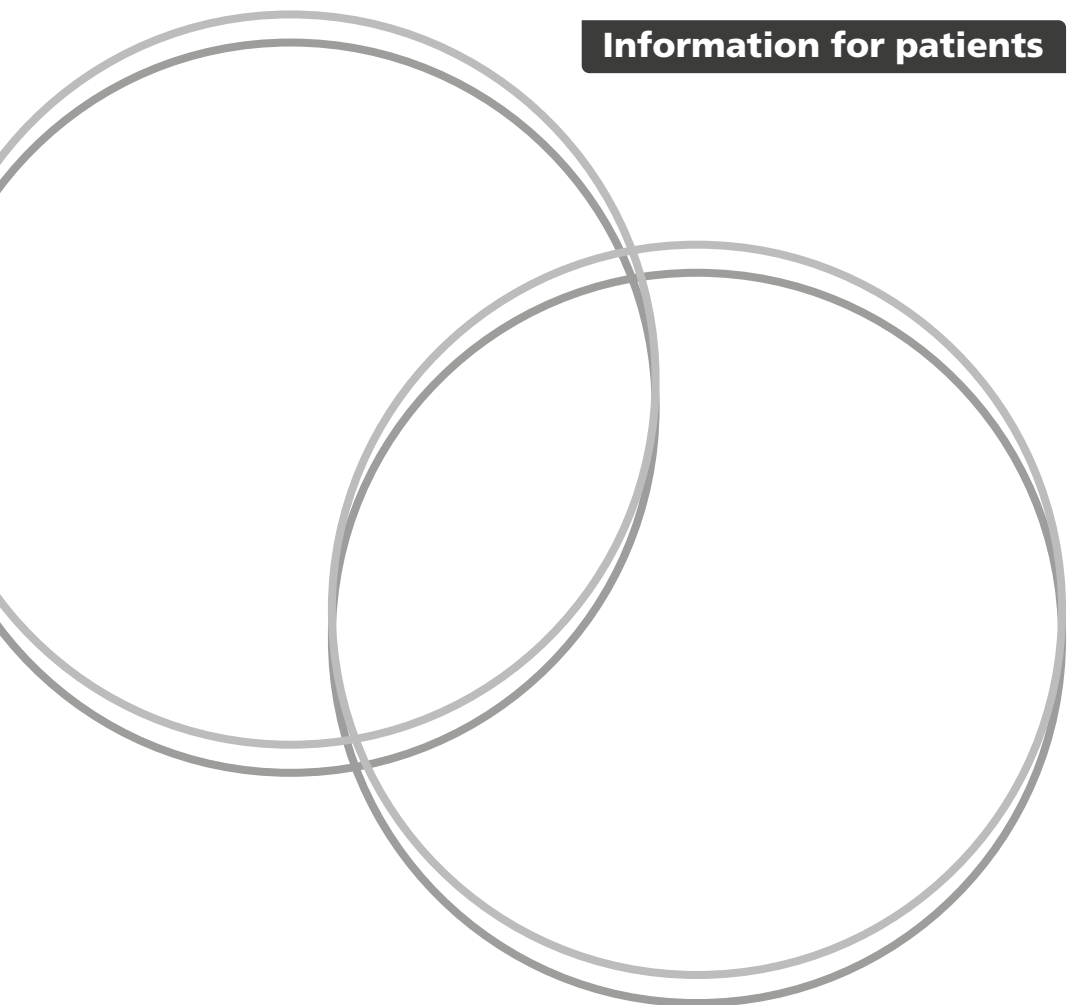


Pacemaker, Cardiac Resynchronisation Therapy (CRT) or Defibrillator Generator Change

Information for patients



Why would I have this procedure?

The team who monitor your pacemaker or defibrillator have identified that the battery in your device is running low. To ensure that your device continues to work you need to have a procedure to change the entire device (generator/battery) as it is not possible to change solely the battery. The device leads stay in place, unless otherwise discussed with you.

What does it involve?

You will usually come into hospital on the day of your procedure. A nurse will complete a checklist, and you will be given a hospital gown to change into. If it has not been done already, a member of the team will explain the proposed procedure 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 and to ensure that you understand fully what having the procedure will mean for you.

Antibiotics will be given into a vein.

Once in theatre, the following will happen:

- 1.** You will have a local anaesthetic and sedation or rarely, general anaesthetic for your procedure. Your doctor will discuss this with you.
- 2.** We will clean your skin with an antiseptic solution and an incision (cut) is made over the existing device, usually along your existing scar, in some cases it may be necessary to make a cut in a different place to access the device. This will leave a scar.
- 3.** The existing device is removed, and the leads tested to ensure they are working correctly, they are connected to the new device.
- 4.** The new device is placed back in the pocket under your skin and the skin is closed with absorbable stitches.
- 5.** The leads and device are then checked, and you will then go to a recovery room just outside the theatre.

How long does it take?

The procedure takes about 1 hour to complete.

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, but the procedure shouldn't hurt. If it does, then you can be given more pain relief. The affected area may feel uncomfortable for a week or so afterwards. You may have swelling and bruising, but this should return to normal in 2 to 6 weeks. You may be able to feel the new device beneath your skin and it may feel different or strange at first, but this sensation resolves over time.

Are there any alternatives to having a generator change?

Sometimes it is appropriate to no longer have an active ICD or device if your health situation or wishes change. If you wish to deactivate the ICD aspect or would like to discuss no longer having an active device, please contact the device nurses to arrange a consultation:

Email: complexdevicenurses@ouh.nhs.uk

Telephone: 01865 220 981

What happens afterwards?

You will either go home later that day or stay in hospital overnight and go home the next day. The team will discuss this with you.

Once fully awake you will be able to eat and drink.

Please ask for painkillers if you need them.

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. If you have had sedation this can make you feel drowsy for up to 24 hours post procedure.

In the next 24 hours:

- do not go to work
- do not operate machinery
- do not make important decisions
- do not sign legally binding documents
- do not drink alcohol.

You should be able to return to your normal activities in a week or so.

Avoid vigorous arm movements or strenuous exercise and avoid lifting your arm (on the side of your device) above your shoulder for 4 to 6 weeks, but otherwise move your arm normally.

We will give you a new 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). **You must contact us immediately using the contact details on your ID card.**

Cardiac Physiology Team:

Telephone: 01865 220 981

How is my new device monitored?

You will be given an appointment between 6 to 12 weeks post procedure for device review – please contact the device team on 01865 220 981 if you do not receive an appointment in this time.

You may also receive a device to take home with you, or in some cases it may be sent through the post. This device allows the new device to communicate with the hospital.

The new device can report information to the hospital such as battery life and detect any problems with the heart rhythm, the leads, or the device itself.

The home monitor does not report any other data such as where you are located or what you are doing.

The home monitor uploads this data automatically as required, but some need you to do this manually. The team will advise if this is needed. The data is reviewed during working hours Monday to Friday.

Your device works without the home monitor, so if going on holiday you can just leave it at home.

When can I resume driving?

The Driving and Vehicle Licensing Agency (DVLA) have strict driving restrictions related to having a device change. There will be a driving restriction of 1 week after your generator change.

Are there any risks?

Having a generator change is usually a straightforward procedure, and most people will not have any problems. It is however important to highlight that, as with all procedures, there are some risks, and these are described below:

Commonly occurring risks

- Mild bruising requiring no intervention (common).
- Bleeding or bruising (increased if taking blood thinners) approximately 5% (5 in 100).
- Infection 1-2% (1-2 in 100), which can require extraction of the whole system.
- Discomfort and pain.
- Lead displacement or damage 1% (1 in 100).

Only if you have a defibrillator (ICD/CRTD)

- Inappropriate shock – 5% (5 in 100 people) may experience inappropriate shocks from the ICD/CRTD.
- We may test that the device can detect arrhythmia by inducing ventricular fibrillation, this is called a defibrillation threshold test (DFT). This will be discussed with you if it is required on the day.

Uncommon but more serious risks

- Dangerous heart rhythms.
- The risk of death is less than 1 in 3,000 procedures.

Uncommon possible later issues

- Major bleeds needing re-intervention.
- Wound discomfort.
- Blood clots in the vein supplying the arm or reduced blood drainage from the arm.
- Infection of the heart or heart valve.
- Premature battery depletion, lead failure or system failure.

Bleeding/bruise (haematoma)

There is a 5% (5 in 100) 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 6 weeks. The risk of bleeding and bruising is increased if you are taking blood thinners.

Infection

There is a 1 to 2% (1 to 2 in 100) risk of infection, which is minimised using antibiotics given before the procedure starts. If infection occurs the whole system including leads may need removing with another operation. Rarely, infection in a device can lead to infection of the heart valves or tissues and very rarely this can be life threatening.

Infection can also occur months or years after the original implant procedure, usually due to another infection in the body affecting the device.

Discomfort/pain

There can be some discomfort as the local anaesthetic is inserted at the start. You will usually be given a dose of a painkiller and sedative at the start of the procedure. You will also likely feel sensation of pushing and pulling as the old device is removed and the new one inserted. This is usually mild, and most people tolerate this well. Rarely you may experience discomfort from the device after the procedure and if this occurs, you should discuss with the device clinic.

Lead displacement or damage

There is a 1% (1 in 100) chance of one or more of the electrodes slipping out of place or being damaged when the existing device is removed, or the new device is inserted. This can occur on the same day or a few months or years after the procedure. If this happens at the time it usually requires a new lead to be inserted. If this is detected after the initial procedure it will likely require a further operation.

Wound discomfort

Rarely some people may experience discomfort around the device long term. Some people may be more aware of their device after a generator change but this usually settles over time.

Blood clots in the vein supplying the arm

Rarely, if a new lead needs to be implanted in the vein, this can result in reduced blood flow from the arm causing swelling. This can also rarely result in a blood clot forming in the vein called a deep vein thrombosis. If this does occur, then it is usually managed by starting blood thinning medication.

Premature battery depletion

Very rarely, device batteries can deplete faster than expected. This is normally detected by the home monitoring service. Manufacturers advise us if this is noted more frequently than expected in the wider population. If the device manufacturer informs us about an advisory or potential problem with the device we will contact you and arrange appropriate safety checks.

Lead failure

Very rarely, lead conductors or connector can become brittle and fail. If this does occur, the data from your home monitor will usually highlight this to the hospital in advance and we will discuss this with you and arrange appropriate intervention.

Very rarely, lead failure can result in an appropriate shock or failure to deliver therapy if you have a defibrillator. If this occurs in a pacemaker it can result in episodes of light headedness or collapse.

System failure/device advisory

Very rarely, we may detect a problem with your new device. This will usually be identified by the home monitor or when you attend a device check.

If the device manufacturer informs us about an advisory or potential problem with the device, we will contact you and arrange appropriate safety checks.

Will I need further appointments/ review?

Yes, you will either receive a home monitor which needs to be plugged in and active or you will be seen via the pacing clinic. You will receive a date for your first appointment after your procedure. 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 do not directly place or hold a mobile phone over the device.

Electronic surveillance

Security at airports or anti-theft devices in shops usually doesn't interfere with 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 requesting the MRI.

Lithotripsy

This is a type of treatment for kidney stones, which is unsuitable for patients with cardiac devices.

Magnets

Do not carry or place a magnet over your device as this may temporarily disable the device.

Sexual activity

You can resume sexual activity after the procedure; however, you should avoid positions that place pressure on your arm or chest for the first 4 to 6 weeks.

Exercise

Try to avoid contact sports and trauma to the device as this can damage the device or leads.

Travel

You can safely travel abroad with your device. You are advised to show the security staff your device identification card.

Insurance companies may try to increase your premiums to very high levels. It is suggested you shop around if this happens – the BHF (details on the next page) have details of insurers that are known to be better at dealing with patients with Cardiology diagnoses.

Operations

If you require an operation, you must tell your surgeon/doctor or anaesthetist that you have a cardiac device. It may be necessary to temporarily switch off (deactivate) the shock function for the operation, either with a cardiac physiologist or a magnet. This can be switched back on after the operation.

Only if you have a defibrillator

Shocks

If you get a single shock from your defibrillator, phone your device clinic within working hours on 01856 220 981, or email complexdevicenurses@ouh.nhs.net. (8am to 6pm Monday to Friday). However, if you receive several shocks (more than two in 24 hours) from your defibrillator or are unwell please seek emergency attention.

Useful contacts

If you need any more information or have any queries, please contact the team looking after you.

John Radcliffe Pacing Team

Telephone: 01865 220 981
8am to 6pm, Monday to Friday

Complex Device Nurses

Email: complexdevicenurses@ouh.nhs.uk

Further support and information is available from the following organisations:

British Heart Foundation

Lyndon Place
2096 Coventry Road Sheldon
Birmingham
B26 3YU
Telephone: 0300 330 3322
Website: www.bhf.org.uk

Arrhythmia Alliance

PO Box 3697
Stratford-Upon-Avon
Warwickshire CV37 8YL
Telephone: 01789 450 787
Website: <https://heartrhythmalliance.org/aa/uk>

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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Oxford University Hospitals NHS Foundation Trust
www.ouh.nhs.uk/information



Making a difference across our hospitals

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