

Name:

Date of Birth:

Affix Patient Label

CHI:

Implantation of a Cardiac Resynchronisation Therapy-Pacemaker (CRT-P)

What is a Cardiac Resynchronisation Therapy-Pacemaker (CRT-P)?

Your doctor has recommended that you have a Cardiac Resynchronisation Therapy-Pacemaker (CRT-P). This is a small metal battery-powered device. CRT devices are used to help treat heart failure (when the heart does not pump as well as it should) by acting as a pacemaker and stimulating both sides of your damaged heart simultaneously to improve pumping function.

Your doctor has recommended that you may benefit from this procedure.

We hope that reading this information pack will give you the information you need to decide whether to proceed. It is important that you understand and share in decision making about your treatment options.

Important questions to consider are:

- Is this test, treatment or procedure really needed?
- What are the potential benefits and risks?
- What are the possible side effects?
- Are there simpler, safer or alternative treatment options?
- What would happen if I did nothing?

Why do I need this procedure?

To treat your heart failure. The CRT-Pacemaker aims to make both sides of your damaged heart pump synchronously (at the same time), meaning you may feel less breathless, have more energy and your damaged heart may improve its function.

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:

- You will have a local anaesthetic and sedation or rarely, general anaesthetic for your procedure. Your doctor will discuss this with you.
- An incision (cut) is made under your collarbone.
- The electrodes (leads) are inserted into a large vein (blood vessel) that lies just under your collar bone, and positioned in your heart using X-ray screening for guidance.
- Once in position, the three (or two) electrodes are connected to the generator, which is placed in a pocket under your skin, below your collar bone.
- The leads and device are then checked and you will then go to a recovery room just outside the Theatre. After this you will go back to the ward.

How long does it take?

The procedure takes about one to three hours as sometimes the lead for the left side of the heart can be very difficult to implant. Very rarely (5%) 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 but the procedure shouldn't hurt. If it does, then you can be given more pain relief. Your shoulder 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.

You will be able to feel the device beneath your skin and it may feel rather strange at first, but this sensation resolves.

What happens afterwards?

You will either go home later that day or stay in hospital overnight and go home the next day. Your doctor will discuss this with you. Once fully awake you will be able to eat and drink. Please ask for painkillers if you need them.

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

A cardiac technician will check the device, either the same day, next day or the following week, we will let you know that day. A sensor is held over the CRT-P 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 CRT-P 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 arm movements and avoid lifting your arm (on the side of your device) above your shoulder for four to six weeks, but otherwise move your arm normally.
- We will give you a CRT-P 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.
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When can I resume driving?

The Driving and Vehicle Licensing Agency (DVLA) have strict driving restrictions related to having a CRT-P and these will be discussed with you following your implantation. As a guide:

You cannot drive for one week after CRT-P implantation or six weeks if you hold a PVC or HGV licence.

You should inform the DVLA that you have had a CRT-P implanted by filling out an H1 form, available from the Post Office or DVLA website (www.gov.uk/government/publications/h1-online-confidential-medical-information).

You will need to inform your car insurance company that you have had a CRT-P fitted.

You cannot drive for one week after your CRT-P box/battery change.

How long will my CRT-P last?

The CRT-P will last around six to 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.

Are there any risks?

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

- **Lung puncture** (pneumothorax) – there is a 1% (1 in 100) chance of puncturing the lung as the vein used for the wire runs close to it. This can heal on its own or the escaped air may need removing using a needle or a small drain (tube).
- **Lead replacement** – there is a 5-10% (5 to 10 in 100) chance of one or more of the electrodes slipping out of place or needing to be replaced because it stops working. This can occur on the same day or a few months or years after the procedure. If this happens it must be repositioned under X-ray guidance with a further operation.
- **Infection** – there is a 1-2% (1 to 2 in 100) risk of infection, which is minimised using antibiotics given before the procedure starts. If infection occurs the pacemaker system may need removing with another operation.
- **Bruise/haematoma** – there is a 4% (4 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 a few weeks.
- **Damage to vein** – there is a 1-2% (1 to 2 in 100) risk of damage to a vein round your heart which may stop us from placing a lead at that time. This can heal to allow a lead to be placed at another time (usually after a few weeks).

- **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 lead** – there is a 4% (4 in 100) chance we may be unable to place one of your leads. 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 keep it as far as possible from your CRT-P, using the opposite ear or a headset.
- **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.
- **Lithotripsy** – this is a type of treatment for kidney stones, which is unsuitable for patients with CRT-Ps.
- **Magnets** – Do not carry or place a magnet over your device as it can interfere with 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 four to six weeks.
- **Exercise** – Try to avoid contact sports and trauma to the site of the device as this can damage the CRT-P or leads.
- **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 CRT-P. It may be necessary to have your device checked or altered before or after the operation.

What happens at the weekend?

If you have your device procedure on a Friday and are discharged home the same day after a satisfactory x-ray and device check, you will receive a phone call from nursing staff either on the Saturday or Sunday to see how you are.

Useful Contacts

Arrhythmia Nurse Specialist: 07970187324 (M-F 8-4)
Ward 2E: 0141 951 5203
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

Arrhythmia Alliance

Helpline - 01789 450 787
PO Box 3697
Stratford-Upon-Avon Warwickshire
CV37 8YL
e-mail: info@heartrhythmcharity.org.uk
www.heartrhythmcharity.org.uk

Implantation of CRT-P

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 Cardiac Resynchronisation Therapy-Pacemaker (CRT-P) 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: Name (PRINT):
Job title: Date:

Important notes (tick if applicable):

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

I (the patient) understand that my information held by the NHS may be used to audit the quality and outcome of clinical treatment including the external validation of hospital notes.

Agree Disagree (tick as appropriate)

Patient signature: Name (PRINT): Date: