

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

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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 also known as a biventricular pacemaker. A CRT-P is a type of permanent pacemaker placed in your chest. The heart has four compartments, or chambers. The upper chambers are called atria, and the lower chambers are called ventricles. For biventricular pacing (CRT-P), one electrode goes from the pacemaker to the right ventricle. Another electrode goes from the pacemaker to the left ventricle. CRT-P is different from pacemakers that treat slow heart rates. Pacemakers that treat slow heart rates have an electrode that leads only to the lower right side of the heart (right ventricle). A CRT-P also usually has a third electrode that leads to the right atrium (upper chamber on the right side of the heart) as well.

Why do I need this procedure?

A Cardiac Resynchronisation Therapy-Pacemaker is used to treat people with heart failure. It can help if you still have shortness of breath even though you are taking medicine for the problem. The main benefit of having a CRT-P is that it improves the pumping function of your heart. CRT-P helps your heart work more efficiently by helping the two pumping chambers of the heart work together properly and by helping the main pumping chamber of the heart (left ventricle) pump in a more co-ordinated way. By making the heart chambers pump synchronously (at the same time) you may feel less breathless and have more energy. It may help keep you out of hospital and may prolong your life.

What does it involve?

You will usually come in to hospital on the day of your procedure. A nurse will complete a pre-procedure checklist 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 and agree to go ahead with it. Please ask any questions you want. A porter will take you to the Cardiac Catheter Lab where you will have the procedure.

1. You will have a local anaesthetic, heavy sedation or general anaesthetic for your procedure. Antibiotics will be given into a vein before we begin.
2. An incision (cut) is made under your collarbone.
3. The electrode/s (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.
4. Once in position, the three electrodes are connected to the generator, which is placed in a pocket under your skin, in front of your shoulder.
5. Once in place, the skin is closed using dissolvable stitches and/or skin glue. Very rarely non-dissolvable stitches are used. If this is the case we will inform you after your procedure and advise when they need to be removed.

How long does it take?

The procedure takes about 1-3 hours as sometimes the lead for the left ventricle can be very difficult to implant. Very rarely (3-5%) we may not be able to implant this lead this way, but your doctor will discuss alternative options if needed.

Will I have any pain or discomfort?

As you will be given an anaesthetic, the procedure shouldn't hurt. 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 three weeks.

You will be able to feel the device beneath your skin but don't worry, it won't pop out. It may feel rather strange at first.

What happens afterwards?

You will stay in hospital overnight and go home the next day. Once fully awake you will be able to eat and drink. Please ask for painkillers if you need them.

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

The following day, a cardiac technician will check the device. 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. The device is then checked to make sure it is effective at stopping your fast heart rhythm.

What happens when I go home?

- Please make sure that a friend or relative collects you and takes you home.
- You should be able to return to your normal activities in a week or so.
- Avoid vigorous arm movements for a few weeks, but otherwise move your arm normally.
- We will give you a CRT-P registration card (plus information from the manufacturer) following your implantation – 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** as infection can spread.

When can I resume driving?

There are driving restrictions related to having a CRT-P and these will be discussed with you following your implantation. As a guide:

- You must let the Driver and Vehicle Licensing Agency (DVLA) know that you have had a CRT-P implanted. You can do this by filling out an H1 form, available on the DVLA website (gov.uk) or from the Post Office.
- You will not be allowed to drive for at least one week.
- If your CRT-P box is changed or revised, you must not drive for one week.

How long will my CRT-P last?

The CRT-P will last for years but the batteries will eventually run down (on average after 7-9 years) and then it will have to be replaced. The battery will be monitored when you have your regular device checks.

Are there any risks?

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

- **Lung puncture** – depending on whether we use a needle to access your vein, there is up to 1% chance of puncturing the lung. This is because the vein used for the electrode/s runs close to the lung. If we have used a needle to access your vein we will carry out a chest X-ray before you go home to check whether there is any escaped air. Often no corrective treatment is needed but sometimes the escaped air has to be removed using a small drain (tube).

- **Electrode slipping** – there is a 1-2% chance of each of the electrodes slipping out of place. If this happens it must be repositioned under X-ray guidance with a further operation.
- **Infection** – the 1-2% risk of infection is minimised using antibiotics given before the procedure commences. If infection occurs the pacemaker system may need removing with another operation.
- **Major bruise/haematoma** – there is a small risk of a major bruise/haematoma, which may rarely require a separate operation to remove. A small amount of bruising is usual and settles within a few days.

For some patients the risks may be higher; please speak to your specialist doctor before your operation if you have any worries.

Will I need further appointments?

Yes, you should attend regular check-ups at a pacing clinic.

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 can interfere with CRT-Ps. They are safe provided you go through quickly, do not linger, and inform security staff.
- **MRI scans** – there may be restrictions on MRI scanning but increasingly devices are used that are compatible with MRI scanning. Other scans are safe.
- **Lithotripsy** – this is a type of treatment for kidney stones, which is unsuitable for patients with CRT-Ps.

Any questions?

If you need any more information or have any queries please contact the Cardiac Investigation Unit on 01872 252726.

Further support and information is available from the:

British Heart Foundation

08450 708070

www.bhf.org

Arrhythmia Alliance

Helpline - +44 (0)1789 867501

PO Box 3697

Stratford-Upon-Avon

Warwickshire

CV37 8YL

www.heartrhythmcharity.org.uk

If you would like this leaflet in large print, Braille, audio version or in another language, please contact the General Office on 01872 252690

CONSENT FORM 1
PROCEDURE SPECIFIC PATIENT AGREEMENT

CRT-P (Biventricular pacemaker)

Insertion of wires to heart chambers and attaching to electronic pulse generator

NHS number:

Name of patient:

Address:

Date of birth:

CR number:

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by 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:

- *To restore and improve ventricular contraction by stimulating both the right and left ventricles (heart chambers), and in doing so improve symptoms of heart failure, improve effort capacity, reduce chances of hospital admission and prolong life*

Significant, unavoidable or frequently occurring risks:

- *Bleeding, bruising, infection (2-3%), and pain*

Commonly occurring risks:

- *Mild bruising is common. Major bleeding or haematoma requiring operation 1% (increased if taking anticoagulants or dual anti-platelet therapy; Infection (1-2%); Discomfort and pain; Unable to site LV lead (up to 5%); Pneumothorax (damage to lung covering leading to air leak and lung collapse) 1%; Acute lead displacement – RV lead 1%, RA lead 1-2%, LV lead 2-3%; The overall acute complication rate is 7-9%.*

Uncommon but more serious risks:

- *Haemothorax (bleeding into the chest cavity), pericardial effusion (bleeding around the heart), damage to blood vessels (including those supplying the heart), dangerous heart rhythms or cardiac perforation.*
- *The risk of death is less than 1 in 3000 procedures).*

Uncommon possible later issues:

- *Late displacement of pacemaker leads, major bleeds needing re-exploration, scarring, wound discomfort.*

Any extra procedures which may become necessary during the procedure:

- *Blood transfusion (required very infrequently)*
- *Pleural or pericardial drain (up to 1%)*
- *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.

I have given and discussed the Trust's approved patient information leaflet for this procedure: Implantation of a Cardiac Resynchronisation Therapy-Pacemaker (CRT-P) (CHA3641) which forms part of this document.

I am satisfied that this patient has the capacity to 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:

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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) (CHA3641) 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 (see guidance notes).

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)

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