

Name:

Date of Birth:

Affix Patient Label

CHI:

Implantation of a Cardiac Resynchronisation Therapy-Defibrillator (CRT-D)

What is an Implantable Cardioverter Defibrillator (CRT-D)?

Your doctor has recommended that you have a Cardiac Resynchronisation Therapy-Defibrillator (CRT-D). 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. The defibrillator function can send impulses to the heart muscle when the heart beats too quickly, and can deliver a shock therapy within the chest to treat life-threatening heart rhythms. These life-threatening heart rhythms are called ventricular tachycardia (VT) or ventricular fibrillation (VF).

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 procedure really needed?
- What are the potential benefits and risks?
- 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-Defibrillator will help to protect you from the risk of sudden cardiac death due to life-threatening heart rhythms (VT or VF). It 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 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. A specialist doctor will explain the proposed procedure to you and ask you to sign the consent form to confirm that you understand the procedure, potential 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 you will then be taken to the procedure room. Once in the room, the following will happen:

- You will have a local anaesthetic injected into the area the device will be implanted – usually under the collar bone. You will also be given intravenous sedation and pain relief. Rarely, general anaesthetic may be used for your procedure.
- An incision (cut) is made under your collarbone.
- The electrodes (leads) are inserted into a 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 electrodes (1 to 3) 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 back to your room for monitoring. 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 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.

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-D 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-D 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-D 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.

When can I resume driving?

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

As a guide:

- If you have already had a fast heart rhythm in the past or if you have collapsed, you must not drive for six months after your CRT-D implant and must contact the DVLA. Please check with your doctor before driving.
- If your CRT-D is being implanted because you are at risk of having a fast heart rhythm in the future, but have not had one before (or collapsed before), you cannot drive for one month. You need to inform the DVLA.
- If you are having a replacement CRT-D, you cannot drive for one week. No need to notify DVLA.
- You will need to inform your car insurance company that you have had a CRT-D fitted.
- CRT-Defibrillator implantation is a permanent bar to Group 2 licensing. You must notify DVLA.

How long will my CRT-D last?

The CRT-D 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 an ICD 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?

- **Shocks** – if you get a shock from your CRT-D, phone your local pacing clinic within 24 hours. It is not urgent but it needs to be recorded. However, if you get several shocks from your CRT-D, contact your pacing clinic or cardiac department urgently as your CRT-D may need checking. Out of hours dial 999.
- **Mobile phones** – it is safe to use a mobile phone, but keep it as far as possible from your CRT-D, 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-Ds.
- **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 four to six weeks. The device will not cause any harm to your partner, even if a shock is delivered during intercourse.
- **Exercise** – Try to avoid contact sports and trauma to the device as this can damage the CRT-D 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-D. It may be necessary to temporarily switch off (deactivate) the shock function for the operation. This can be switched back on 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

Name:

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Consent Form

Procedure Specific Patient Agreement

CRT-D (Cardiac Resynchronisation Therapy Defibrillator)

Insertion of wires to heart chambers and attaching to electronic pulse generator +/- induction and termination of arrhythmia.

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure)

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 and to protect from recurrent or potential life threatening arrhythmias by delivering pacing or shock treatment from the device

Significant, unavoidable or frequently occurring risks:

- Bleeding, bruising, infection and pain (5-10%)

Commonly occurring risks (5-10%):

- Mild bruising is common requiring no intervention. Major bleeding or haematoma requiring operation 1% (increased if taking blood thinners or dual anti-platelet therapy)
- Infection (1-2%)
- Discomfort and pain
- Pneumothorax (1%) damage to lung covering leading to air leak and lung collapse
- Lead displacement (1-4%) – Right lower lead 1%, Right upper lead 2-3%, Left lower lead 2-3%
- The overall acute complication rate is 5-15%

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 in 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)
- 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.

The patient has had the information leaflet for this procedure and/or discussed it with a health professional and has had sufficient time to make an informed decision.

I am satisfied that this patient has the capacity to provide his/her consent to the procedure.

This procedure will involve:

General and/or regional anaesthesia

Local anaesthesia

Sedation

Health Professional signature:

Name (PRINT):

Job title:

Date:

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:

Implantation of CRT-D

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-Defibrillator (CRT-D) 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: _____

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Commonly occurring risks (5-15%):

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