

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

*affix patient label*

## 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).

## Why do I need this procedure?

To treat your heart failure. The CRT-Defibrillator may also help to protect you from the risk of sudden cardiac death due to life-threatening heart rhythms (VT or VF). It makes 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 pre-procedure 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 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 electrodes 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 3 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-D 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-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** as infection can spread.

### When can I resume driving?

There are 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 6 months after your CRT-D implant and must inform the DVLA that you have had a CRT-D implanted. Before you are allowed to resume driving the DVLA will contact your cardiologist to check you are fit to resume 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 must not drive for one month and must inform the DVLA that you have had a CRT-D implanted.
- If you are having a replacement CRT-D, you cannot drive for one week.

### How long will my CRT-D last?

The CRT-D will last for years but the batteries will eventually run down (on average after 5-7 years) and then it will have to be replaced. The battery will be monitored when you have your regular device checks.

You may not require a CRT-D to be fully active for your whole life, especially if your health changes significantly (such as developing strokes, end-stage heart/kidney/lung failure, cancer etc). When a defibrillator is inactivated, the rapid pacing and shock functions are turned off but the defibrillator can still function as a basic pacemaker when needed.

### 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** – there is a 1-2% 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 small 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 days.
- **Inappropriate shocks** – about 5% of patients implanted with an ICD will receive an ICD shock when one was not required because there has either been a malfunction with the electrode or the defibrillator thinks it has seen a dangerous heart rhythm.
- **Electrode failure** – defibrillator electrodes are associated with up to 10% long-term failure rate that may require electrode removal and/or replacement. Defibrillator electrode removal may in itself be a high risk procedure when the electrode has been in place for many years.

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 an ICD clinic. 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 single shock from your device and you feel well, phone your local ICD clinic within 24 hours. It is not urgent but it needs to be recorded. However, if you get a single shock from your device and you feel unwell or if you get several shocks from your device, phone 999 and ask for urgent medical help.
- **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 can interfere with CRT-Ds. 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-Ds.

### 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](http://www.bhf.org)

**Arrhythmia Alliance**

Helpline - +44 (0)1789 867501

PO Box 3697

Stratford-Upon-Avon

Warwickshire

CV37 8YL

[www.heartrhythmcharity.org.uk](http://www.heartrhythmcharity.org.uk)

Patient copy

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-D (Biventricular Implantable Cardioverter Defibrillator)

NHS number: .....

Name of patient: .....

Address: .....

Date of birth: .....

CR number: .....

*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, 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 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 (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%); Unable to site LV lead (up to 5%); Discomfort and pain; 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%; Defibrillator electrode failure (lifetime risk up to 10%); Inappropriate shocks (5%)*

**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 (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.

**I have given and discussed the Trust's approved patient information leaflet for this procedure: Implantation of a Cardiac Resynchronisation Therapy-Defibrillator (CRT-D) (CHA3640) 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: .....

affix patient label

**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) (CHA3640) 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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