

Implantation of an implantable loop recorder (ILR)

affix patient label

What is an Implantable Loop Recorder (ILR)?

This is a small, metal, battery powered device for monitoring and recording (if required) your heart rate and rhythm. The device is very small (3cm x 0.5cm) and has no wires attached. You will be given an external remote control to make a recording. The device has a battery life of up to 2-3 years. Information stored in the ILR is retrieved through a remote device that is placed on the skin over the implant and communicates with the ILR.

When the ILR has successfully recorded the heart rhythm and a diagnosis has been made, or if the battery runs out, it can be left in place to prevent the need for a further procedure or removed if preferred.

Why do I need this procedure?

You may have been experiencing blackouts or palpitations that may indicate you have an abnormal heart rhythm. The loop recorder is commonly used to study the heart rhythm in patients with blackouts / syncope / falls. If you have symptoms and press the activator button, it will store your heart rhythm so that the doctor can review it later.

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 or technician 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 procedure room, which may be a Cardiac Cath Lab or a room specially designated for the procedure.

1. You will lie on a table that can be moved around. Mounted above it there may be an X-ray machine, although you won't need X-ray guidance for this procedure.
2. You will have injections of local anaesthetic and you may be given a sedative to make you feel relaxed.
3. The loop recorder is injected just under the skin in the front of your chest.
4. The wound is closed with either a suture (stitch) or steristrips. The scar is 0.5cm long.

How long does it take?

The procedure takes less than an hour.

Will I have any pain or discomfort?

The procedure shouldn't hurt, although you will feel pressure as the loop recorder is inserted. You may have some mild swelling or bruising around the scar but this should return to normal within two weeks.

What happens afterwards?

You will return to the ward to recover where you will be able to eat and drink. The cardiac technician will come back to programme the device. You will be given a small remote control to 'activate' the recorder. You will also receive information about the recorder and how to contact the Pacemaker Clinic if required. Routine face-to-face follow up is not usually needed as your device will be monitored remotely.

When can I go home?

You can go home 1-2 hours later the same day.

Are there any risks or complications?

The implantation is a very low risk procedure. However, there is a low risk of bleeding, bruising or infection (1%).

When can I drive?

The DVLA states that you cannot drive if you have been suffering from blackouts. There may be some special instructions and/or regulations regarding driving and this information will be given to you by the doctor, nurse or cardiac physiologists before you go home.

Any questions?

More detailed information is available at: www.heartrhythmcharity.org.uk

Contact us

Pacemaker Clinic

Royal Cornwall Hospital
01872 252431

Cardiac Investigations Unit

Royal Cornwall Hospital
01872 252726

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**Implantation of an implantable
loop recorder (ILR)**

NHS number:

Name of patient:

Address:

Date of birth:

CR number:

Insertion of device to monitor heart rhythm

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 and summarised the risks, as below:

- *To diagnose heart rhythm abnormalities (causing dizzy spells, black outs, slow or fast irregular heart beating etc)*

Significant, unavoidable or frequently occurring risks:

- *Bleeding, bruising, infection and pain*

Uncommon but more serious risks:

- *None*

Uncommon possible later issues:

- *Infection, scarring*

Any extra procedures which may become necessary during the procedure:

- *None*

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 an implantable loop recorder (ILR) (CHA3089) 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 an implantable loop recorder (ILR) (CHA3089) 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)

Patient signature: _____ Name (PRINT): _____ Date: _____

CONSENT FORM 1
PROCEDURE SPECIFIC PATIENT AGREEMENT**Implantation of an implantable
loop recorder (ILR)**

NHS number:

Name of patient:

Address:

Date of birth:

CR number:

AFFIX PATIENT LABEL

Insertion of device to monitor heart rhythm

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 and summarised the risks, as below:

- *To diagnose heart rhythm abnormalities (causing dizzy spells, black outs, slow or fast irregular heart beating etc)*

Significant, unavoidable or frequently occurring risks:

- *Bleeding, bruising, infection and pain*

Uncommon but more serious risks:

- *None*

Uncommon possible later issues:

- *Infection, scarring*

Any extra procedures which may become necessary during the procedure:

- *None*

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 an implantable loop recorder (ILR) (CHA3089) 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 an implantable loop recorder (ILR) (CHA3089) 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)

Patient signature: _____ Name (PRINT): _____ Date: _____