

Information to be retained by the patient

Implantation of a Subcutaneous Implantable Cardioverter Defibrillator (SICD)

Name:

Date of Birth:

CHI:



Why do I need this procedure?

Your doctor has decided you would benefit from this device. The subcutaneous implantable cardioverter defibrillator (SICD) will help to protect you from the risk of sudden death due to life-threatening fast heart rhythms. You will have been advised that you may benefit from an SICD if you have either suffered from an abnormal fast heart rhythm (Secondary Prevention) or are at high risk of developing an abnormal fast heart rhythm (Primary Prevention). These abnormal fast heart rhythms may occur in people with a heart muscle condition (cardiomyopathy) or abnormal heart electrics, which puts them at risk of developing dangerous fast heart rhythms.

What is a subcutaneous implantable cardioverter defibrillator?

This is a metal battery-powered device a bit like a pacemaker and sits underneath the skin. The SICD battery is a little larger than a pacemaker battery (approximately 8 x 7 x 1 cm). The SICD constantly monitors your heart rhythm and can treat life-threatening fast heart rhythms by delivering a shock therapy within the chest. Although this may be uncomfortable, it can be life-saving. These life-threatening heart rhythms are called ventricular tachycardia (VT) or ventricular fibrillation (VF). After a shock therapy, the device can also act like a pacemaker and treat a slow heart rhythm for a few seconds.

Your doctor has recommended that you may benefit from this procedure. We hope that reading this information sheet 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:

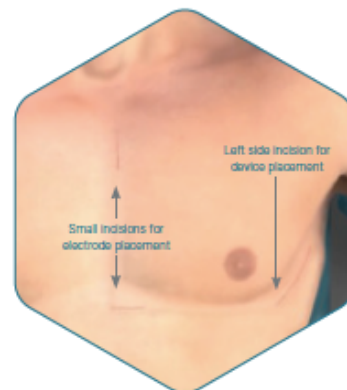
- Is this treatment or procedure really needed?
- What are the potential benefits and risks?
- What are the possible side effects?
- Are there simpler, safer or alternative treatment options?
- What would happen if I did nothing?



What does it involve?

You will usually come in to hospital the day before or 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 SICD implantation to you and ask you to sign the consent form to confirm that you understand the procedure, the proposed risks and benefits, and that you agree to go ahead with it. It is important to ask any questions that are concerning to you about the procedure. Antibiotics will be given into a vein on the ward or in the theatre, and a porter will take you to the theatre. Once in theatre, the following will happen:

1. You will have a general anaesthetic for your procedure. Your doctor will discuss this with you and the general anaesthetic will be given to you by an anaesthetist.
2. A small cut (incision) is made on the left side of the chest wall, next to the rib cage.
3. A pocket (pouch) is formed under the skin, where the battery will be inserted between two layers of muscle at the left side of the chest under the armpit.
4. A small cut is then made below the breastbone (sternum) to allow the electrode (lead) to be placed under the skin. A second small cut may also be made at the top of the breastbone to help with securing the lead in place. X-rays may be used to ensure the lead and battery are in the correct position.
5. The electrode (lead) is then attached to the battery.
6. Once the SCD has been implanted, we will test the device. You will be asleep during this part of the procedure. We will induce an arrhythmia (abnormal fast heartbeat) and the SCD will detect and stop your abnormal fast heart rhythm automatically. Some SCD settings may then be adjusted to work best for your heart.
7. The small cuts (incisions) will be closed with dissolving (absorbable) stitches.
8. The lead and device are then checked whilst you are still asleep. This involves us putting your heart into a fast rhythm and ensuring it detects the abnormal rhythm and treats it appropriately with a shock.
9. You will wake up in the theatre recovery area and then be returned to the ward.



How long does it take?

The procedure takes about one to two hours to complete.

Will I have any pain or discomfort?

You will be asleep during the procedure. When you wake up, you may have some pain and discomfort on the left chest wall and over the breastbone, and you may have some swelling and bruising, but this should return to normal in two to six weeks. You may be able to feel the battery and lead beneath your skin and it may feel rather strange at first, but this sensation will settle.

What happens afterwards?

You will either go home later the same 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.

There may be various checks required before you go home, which include an X Ray and a check of your device functions. One of our Cardiac Physiology team will hold a sensor over your SCD to programme it. This is painless. You will be given an SCD identity card, emergency information and discharge 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.
- We will give you an S-ICD 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 an S-ICD 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 S-ICD implant and must contact the DVLA. Please check with your doctor before driving.
 - If your S-ICD 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 must inform the DVLA.
 - If you are having an S-ICD battery change, you cannot drive for one week. There is no need to notify DVLA.
 - If you are having an S-ICD lead (electrode) revision, you cannot drive for one month. There is no need to notify DVLA.
 - S-ICD implantation is a permanent bar to **Group 2** licensing. In patients with a Group 2 license (including prophylactic/primary prevention) driving must stop permanently and the DVLA must be informed.

How long will my subcutaneous implantable cardioverter defibrillator last for?

The S-ICD battery will last around six to eight years with normal use. The battery will eventually run down and then it will have to be replaced. This will be identified during your follow up visits.

Are there any risks?

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

- **Infection** – there is a 1-2% (one to two in 100) risk of infection, which is reduced by using antibiotics before the procedure starts. If infection occurs, the S-ICD system may need to be removed with another operation.
- **Bruise (haematoma)** – there is a 1% (one 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 six weeks.
- **Inappropriate shock** – there is a 1% (one in 100) risk that the S-ICD will deliver a shock wrongly when there is not an abnormal fast heart rhythm present, usually because of a different type of fast heart rhythm.
- **Lead replacement** – there is a rare risk (<1 in 100) of the lead (electrode) moving 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 with a further operation.
- **Failure of shock therapy** – during the S-ICD procedure, we will test the device by inducing an abnormal fast heartbeat. There is a rare risk (<1 in 100) that the S-ICD will not correctly detect

and stop the abnormal fast heart rhythm. In this situation, we will give an external shock (with a defibrillator) to put the heart back into the normal heart rhythm.

- **Allergy** – there is a very rare risk (<1 in 1000) of allergy to the medication we give you. This can be treated very quickly. Very rarely this can be serious and life-threatening.
- **Failure of ICD or lead:** there is a very rare risk (<1 in 1000) that you will hear an alarm on your ICD. This is a safety function to alert you that there may be a problem with the battery or lead. Please do not worry, but contact your local pacemaker/defibrillator clinic to have this checked. If the SICD manufacturer informs us about a potential problem with the device we will contact you and arrange appropriate safety checks.

Will I need further appointments?

Yes, you should attend regular check-ups at a pacemaker/defibrillator clinic, usually at your local hospital. 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 SICD, phone your local pacemaker/defibrillator clinic within 24 hours. It is not urgent but it needs to be recorded. However, if you get several shocks from your SICD or feel unwell, contact your pacemaker/defibrillator clinic or cardiac department urgently as your SICD 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 SICD, using the opposite ear or a headset.
- **Electronic surveillance** – security at airports or anti-theft devices in shops usually don't interfere with ICDs. 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 SICDs.
- **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 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 SICD battery or lead.
- **Travel** – You can safely travel abroad with your device. You are advised to show the security staff your SICD device 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 an SICD. It may be necessary to temporarily switch off (deactivate) the SICD shock function for the operation. This can be switched back on after the operation.

Useful Contacts

Golden Jubilee Hospital: 0141 951 5000 and ask for booking office or ward 3E

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

Patient copy

Name:

Date of Birth:

CHI:

Affix Patient Label



Consent Form

Procedure Specific Patient Agreement

S-ICD (Subcutaneous Implantable Cardioverter Defibrillator)

Insertion of a lead beneath the skin and attaching to electronic pulse generator, and 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 prolong life and to protect from potential life threatening heart rhythm problems 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 (1%):

- Mild bruising is common requiring no intervention. Major bleeding or bruising requiring operation 1% (increased if taking blood thinners)
- Discomfort and pain is common
- Infection (1%)
- Inappropriate shock (1%)
- Lead failure or need to reposition (1%)

Uncommon but more serious risks:

- The risk of death is less than in 1 in 3000 procedures
- Allergy to medication (<1 in 1000)

Uncommon possible later issues:

- Movement of lead requiring intervention, major bleeds needing reintervention, 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:

File copy

Name:

Date of Birth:

CHI:

Affix Patient Label



Implantation of S-ICD

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 Cardioverter Defibrillator (ICD) 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:

Patient copy

Name:

Date of Birth:

CHI:



Consent Form

Procedure Specific Patient Agreement

S-ICD (Subcutaneous Implantable Cardioverter 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 prolong life and to protect from potential life threatening heart rhythm problems 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 bruising requiring operation 1% (increased if taking blood thinners)
- Discomfort and pain is common
- Infection (1%)
- Inappropriate shock (1%)
- Lead failure or need to reposition (1%)

Uncommon but more serious risks:

- The risk of death is less than in 1 in 3000 procedures
- Allergy to medication (<1 in 1000)

Uncommon possible later issues:

- Movement of lead requiring intervention, major bleeds needing reintervention, 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:

File copy

Name:

Date of Birth:

CHI:

Affix Patient Label



Implantation of S-ICD

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 Cardioverter Defibrillator (ICD) 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:

