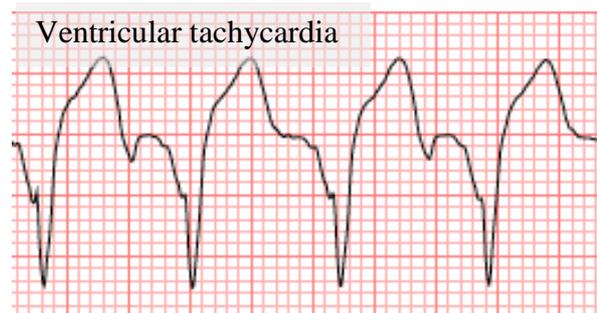


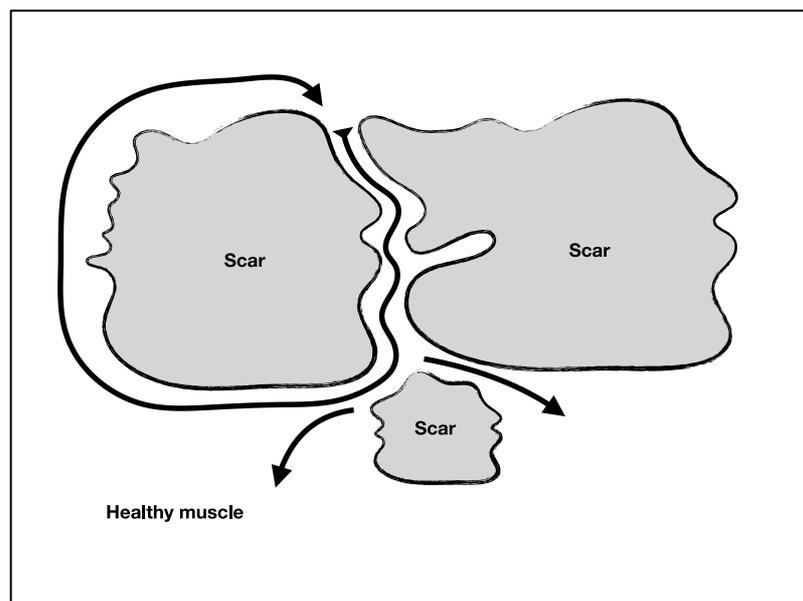
# Patient information leaflet and consent form for catheter ablation of ventricular tachycardia in structural heart disease.

## What is Ventricular Tachycardia (VT)?

The heart is made up of top chambers (atria) and lower chambers (ventricles). Normally, the atria and ventricles beat in sequence, with the atria beating slightly before the ventricles. Ventricular tachycardia is a heart rhythm disorder where the lower chambers pump abnormally fast, unrelated to what the atria are doing.



VT most frequently occurs because of a 'short circuit' within the heart muscle due to damage in the past. Commonly this is caused by a heart attack, but a variety of other heart conditions can also lead to scar formation and the development of VT. During VT electrical activity spreads through channels of surviving tissue in and around scars in a circuit, causing the heart to beat rapidly. Sometimes, rather than a sustained rapid beat, single extra beats can occur (ventricular ectopics). These can be unpleasant and if very frequent can cause problems with how well the heart is contracting. Ventricular tachycardia can also occur in the absence of a 'short circuit', as a result of a rapidly firing focus somewhere in the heart muscle.



During VT electrical activity travels round and round through the scar in a circuit. Every 'lap' causes an abnormal heart beat.

## Why treat VT?

Ventricular tachycardia impairs the ability of the heart to pump the blood, which means that the various organs, most importantly the brain and the heart itself, don't receive the essential nutrients and oxygen that they require to work properly. This causes unpleasant symptoms such as chest pain, breathlessness, and an awareness of a rapid heart-beat and loss of consciousness. For people with an implantable cardiac defibrillator (ICD), VT can also lead to distressing ICD therapies, including painful shocks. For some people, VT can cause life threatening events with sudden death or a deterioration in heart function.

Your doctor has recommended that you may benefit from this procedure to treat your arrhythmia

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 test, 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?

## How are the symptoms of VT treated?

There are several treatment options available for the treatment of VT. These include a variety of medications (anti-arrhythmic drugs), an implantable cardiac defibrillator, and catheter ablation.

Anti-arrhythmic drugs alter the electrical properties of the heart muscle and can prevent VT from occurring. The common medications used for VT are beta-blockers including a special type of beta-blocker called sotalol, and a drug called amiodarone. Anti-arrhythmic drugs are generally the first line therapy and can often be very effective.

The ICD is a life-saving device for people with VT and badly damaged hearts and people who have had life-threatening episodes of VT. Although very effective at stopping VT once it starts, ICDs do not prevent VT from occurring, and generally speaking act as a 'back-up'.

A VT ablation is a procedure involving the passage of flexible wires called catheters to the heart through a vein or artery in the top of the leg, or sometimes directly through a small incision in the lower chest. The abnormal circuits that allow VT to occur normally use channels of surviving muscle in and around scarred regions of the heart. These channels can be identified and then treated by heating them with radiofrequency energy (ablation).

## **Am I suitable for a catheter ablation procedure for VT?**

Catheter Ablation for VT is not appropriate for everybody and is normally only offered to people who have symptoms that significantly affect the quality of their life, and have either failed to respond to medication, or have had side effects from medication. In some cases, people may want to avoid taking pills and potential side effects in the future. The type of treatment you receive will depend on the type of VT you have, and the likelihood that a particular therapy will work for you. This must be weighed against the risks of the treatment, taking into account your preferences as an individual. It is important that you are aware of these options and have discussed them with your doctor and other health professionals looking after you.

The decision most frequently comes down to, how bad the symptoms are, and how bad the overall damage to the heart is. Other health problems you may have, for instance kidney and lung disease, weigh heavily on the decision.

## **What is the success rate of a VT ablation?**

Although the aim of the procedure is to eliminate VT completely, acceptable results may also include a reduction in the amount of VT that occurs, or may making previously difficult to control VT controllable by drugs. The success rate is quite variable depending on a number of factors. Generally speaking we hope to see complete elimination of VT, though a significant proportion of patients will experience recurrence over time, with recurrence rates in clinical trials ranging between approximately 10% to as much as 50% over a couple of years. However, even in those patients with recurrence this may still represent a good outcome as the frequency of shocks may be reduced significantly. For example, in a recent trial looking at catheter ablation for VT, the occurrence of VT requiring therapy from the ICD was reduced by some 65% compared to drugs alone. Patients who have VT because of heart disease unrelated to heart attacks, referred to as 'non-ischaemic VT', tend to have worse outcomes following a VT ablation. This is in part due to progression of the underlying condition, but also the scars may be technically harder to ablate.

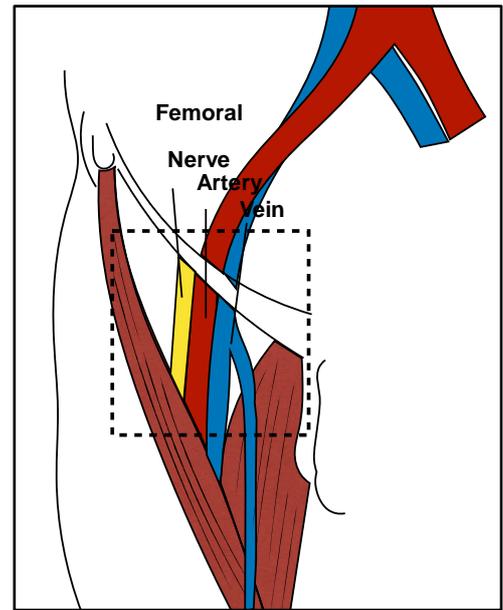
## **What does it involve?**

You will usually come in to hospital on the day before your procedure. You may already be admitted to hospital and require transfer by ambulance. 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 procedure to you, and ask you to sign the consent form to confirm that you understand what is happening and that you agree to go ahead with it. It is important to ask any questions that are important to you about the procedure.

Catheter ablation is carried out in a cardiac catheter laboratory (cath lab). Members of the cath-lab staff will come and introduce themselves to you before taking you to the lab. Patients will often walk unaided, though for a variety of reasons it may be more practical to travel to the cath-lab in a bed or trolley. There will be a team of people present, and the doctor (Electrophysiologist) will carry out the procedure with the help of physiologists, nurses and a radiographer who will help with the X-ray equipment. Sometimes non-NHS staff who work for the companies who manufacture the equipment we use will also be present to help with the procedure.

Once in the Cath Lab, the following will happen:

1. You will have adhesive pads attached to help monitor your heart rhythm and an oxygen mask will be fitted. You will have a blood pressure cuff attached and a clip on your ear (or finger) to monitor your oxygen levels during the procedure.
2. A tube may be placed in the bladder to collect urine.
3. The top of your leg will be cleaned and a clean (sterile) drape will be used to cover you, exposing the skin at the top of the leg. Feel free to shave this region the day before your procedure if you wish (within dotted line in figure). You will have a local anaesthetic at the top of the leg and given sedation to make you comfortable.
4. You may be given a general anaesthetic for your procedure. This decision will be made depending on a variety of factors.
5. Occasionally access to the heart will be achieved by a small incision under the breastbone. This is to gain access to the outer surface of the heart where abnormal circuits may be in some patients. Often there are clues that this might be the case before we start, and this approach will be discussed with you.
6. The procedure is performed with long tubes (sheaths) and wires (catheters) placed in the vein and artery at the top of your leg and positioned in your heart using x-ray guidance.
7. Often we will access the left side of the heart by making a small puncture hole in the wall between the left and right top chambers. This is called a transeptal puncture and is a very routine part of the procedures performed in the cath lab.
8. Once in position, the doctor will construct a map of the heart and will work out where the source of the VT is. This will often mean deliberately starting VT, or VT may start just moving the catheters around. Often VT is well tolerated and you can remain in VT for many minutes whilst we study where it's coming from. If you feel unwell with VT we will stop it, but this may require a shock. You will be sedated for this though there may be discomfort. Sometimes we may switch to a general anaesthetic if necessary.



## How long does it take?

The procedure normally takes about 3-5 hours, though can be longer. The length of the procedure depends on a number of factors, mainly relating to the location and extent of the scarring in the heart and if you have other heart conditions.

## Will I have any pain or discomfort?

Most patients tolerate the procedure very well but some can find parts of the procedure uncomfortable. It is important that you let us know if you do feel discomfort as we should be able to correct this.

You will briefly feel a sharp pain at the top of the leg when we inject the local anaesthetic. This will go numb quickly. When positioning catheters you may experience some brief discomfort in the chest and during the ablation it is common to experience discomfort in the chest whilst the treatment is applied. This may be in the chest, back and shoulders or into the neck, jaw or head. These sensations are not necessarily cause for concern, but you should feel able to let us know how you are feeling so we can make any necessary adjustments. Sometimes the pain killers may cause nausea, anti-sickness medication is normally given to counteract this. Throughout the procedure a nurse will be monitoring you very closely and they will be able to give you more sedation or painkillers if needed.

## **Are there any risks?**

As with all procedures there are some risks. It is important that you understand what these risks are so that you can decide whether you want to have the procedure performed. You will have the opportunity to ask any questions before the procedure is undertaken. The risk of significant complication is around 8% (8 in 100), although most do not lead to a permanent issue and can be treated. Serious complications often occur in in people who are unwell prior to their procedure. Fatal complication occurs in less than 1% of VT ablation. Some of the more common types of complications are listed on the next page.

### Procedural complications that may occur during a VT ablation

- **Minor bleeding** – Bruising at the top of the leg, or at other sites where blood vessels are punctured is very common but is not cause for concern.
- **Other bleeding** – Important bleeding may occur in around 1-2% (1 to 2 in 100) of patients. This can often be controlled with reversal of blood thinning medication though uncommonly an operation may be required to stop bleeding.
- **Damage to femoral artery** – there is a less than 2% (less than 1 in 50) risk of damaging the artery, at the top of the leg. Most commonly this causes something called a pseudoaneurysm or occasionally a communication between the artery and vein can form (fistula). Occasionally there can be a blood clot which blocks blood flow in the artery which can be serious and may require treatment. However, damage to the artery usually heals up without any treatment, though some patients may need surgery or stenting, or a special type of injection to fix the problem.
- **Bleed around the heart (Pericardial effusion)** – there is an approximate 1% (1 in 100) chance of puncturing the heart and blood leaking round the heart. This normally heals on its own without any treatment though often the pressure caused by the bleeding may need to be relieved by placing a small drain (tube) under the ribs into the sack round the heart. Uncommonly you may require surgery to stop the bleeding.
- **Heart failure** – If you have very poor heart function there is a chance that the stresses of the procedure will cause worsening of the heart function, increasing the need for diuretics and other heart failure therapies. This happens in about 0.5% (1 in 200) of patients, but the risk will depend heavily on how bad the heart function was prior to the procedure. This may prolong hospital stay following the procedure until we can stabilize the situation.
- **Heart attack or stroke** – There is a 0.5% (1 in 200) chance a stroke or heart attack occurs during the procedure. The seriousness of these events can be quite variable, from a very minor incident that passes without long term consequence to more serious, potentially life-threatening episodes. Often these are treatable.
- **Death** – Fortunately this is uncommon. Although most clinical trials report no death related directly to the procedure it can occur, and will generally relate to how unwell a patient is before undergoing the procedure. The risk of death is less than 1% (1 in 100). Most deaths relating to VT ablation occur due to failure to control the VT rather than a direct complication of the procedure itself.
- **Deep vein thrombosis** - The clot that forms in the vein because of placing the sheaths can cause obstruction to blood flow in less than 1% (1 in 100). This often requires no treatment but may need a course of blood thinning medication which can last up to 6 months.
- **Heart block** - Damage to the 'wiring' of the heart may occur during a VT ablation which may require a pacemaker. This is more common when the ablation needs to be performed in the middle of the heart. This may not matter as you may already have a ICD in place which will support the heart rate, however this may be significant for some people.
- **Other complications** – This is not a comprehensive list, and a variety of other rarer complications such as infection, damage to the heart valves or the leads of an existing defibrillator or pacemaker have been reported.

## What happens after the procedure?

If you've had a general anaesthetic you will normally be woken up while you are still in the cath lab, though it may take some time (sometimes hours) before you feel fully conscious. The tubes at the top of your leg are usually removed in the cath lab with a stitch put in the leg and often a special type of plug or stich is placed in the artery wall to seal the hole we have made. Sometimes one or more of the tubes will remain in your leg for a few hours. You may go back to the cardiology ward or sometimes a higher dependency unit for closer monitoring. You will lie flat for 2 to 3 hours and the nurses will monitor the top of your leg, blood pressure and heart rhythm. You will then gradually sit up, eat and drink and walk around. You will stay in overnight and it is usual to go home the following day. This will however depend on whether you were unwell prior to the ablation. If your heart function is very weak you may need several days following the procedure before you are fit to go home. The doctor will explain what to do with your medication before you go home and they will write to your GP and local referring doctor explaining what was done during the procedure and the plan for follow-up and medication.

## What happens when I go home?

Please make sure that there is someone to collect you and take you home, and there is someone who can stay with you overnight. Most patients recover very quickly, however it may take several weeks to feel back to normal. The recovery time may be longer if you have suffered a complication. You should be able to return to your normal activities as soon as you feel able, which will vary from individual to individual. It is best to avoid vigorous activity and heavy lifting for 1 week to allow the top of the leg to heal and reduce the risk of bleeding or a big bruise. It is common to feel extra or missed beats for a few weeks after the procedure and this is normal. Even prolonged bouts of palpitations in the first 3 months after a procedure does not necessarily mean that it has not worked. You will be sent an appointment to be seen back in the clinic a few months after your procedure.

If you have had an Angioseal plug in the artery, then we suggest you avoid bathing for 1 week.

## When can I resume driving?

It is best to clarify your specific restrictions with us as individual circumstances may be quite variable. Normally be a driving ban as a consequence of the VT and any ICD therapies you may have received. This will normally be at least 6 months even with an apparently successful ablation procedure. If for example your heart function is good, you may not have experienced any incapacity related to VT and you may not have had a defibrillator implanted. In these circumstances you may be able to drive sooner.

## Will I be able to stop my medication (pills)?

Heart Rhythm Tablets: It may be possible to stop these pills after the procedure; your specialist will advise you and your GP about this. If you are going to stop any pills they are usually continued for at least 3 months then stopped if you have had no recurrence of VT. Sometimes remaining on anti-arrhythmic drugs is still advisable but we may try to change to a less toxic medication.

Blood Thinners (anticoagulants): Ventricular tachycardia is not an indication for anticoagulants but you might be on them for other reasons. We may discontinue them just before the procedure and restart them the next day providing there are no bleeding issues. You may be started on a blood thinner following your ablation procedure.

## Will I need further appointments?

Yes, and you will be sent an appointment to be seen by an arrhythmia specialist a few months after your procedure. Sometimes you may be followed up by your local Cardiologist who will keep in contact with us so we know how you are doing.

## Useful Contacts

Arrhythmia Nurse Specialist: 07970187324 (M-F 8-4)  
Ward 2E: 0141 951 5000 and ask for Ward 2E  
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](http://www.bhf.org)

### Arrhythmia Alliance

Helpline - 01789 450  
787  
PO Box 3697  
Stratford-Upon-  
Avon  
Warwickshire  
CV37 8YL  
e-mail: [info@heartrhythmcharity.org.uk](mailto:info@heartrhythmcharity.org.uk)  
[www.heartrhythmcharity.org.uk](http://www.heartrhythmcharity.org.uk)

## CONSENT FORM PROCEDURE SPECIFIC PATIENT AGREEMENT

Name

Date of Birth

CHI

### Catheter Ablation for Ventricular Tachycardia (VT)

*A procedure to prevent abnormal electrical signals in the heart causing VT by heating the abnormal regions within the ventricular muscle.*

**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 normal electrical activity in the lower heart chambers, and in doing so improve symptoms of such as palpitations, breathlessness, fatigue and dizziness and stop or reduce shocks from an ICD or hospitalisation.*

The overall significant complication rate is up to 8%

**Commonly occurring risks (1% or greater):**

- *Mild bruising is common and requires no intervention.*
- *Major bleeding or haematoma requiring treatment (1-2%)*
- *Bleeding round the heart requiring insertion of a drain occurs in less than 1% of procedures.*
- *Damage to Blood Vessel (Pseudoaneurysms, fistula) occurs in 2% of procedures.*

**Uncommon risks (1% or less):**

- *Stroke or Heart Attack occurs in less than 1% of procedures.*
- *The risk of death is less than 1% of procedures*
- *Damage to the 'wiring' of the heart that may need a pacemaker or cause a problem.*
- *Infection*
- *Damage to the heart valves*

**Any extra procedures which may become necessary during the procedure:**

*Blood transfusion (required very infrequently)*

*Pericardial access*

*Cardiac surgery*

*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:

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:

Name

Date of Birth

CHI

## Catheter Ablation for Ventricular Tachycardia

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.

### STATEMENT OF PATIENT

**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: Catheter Ablation for Ventricular tachycardia 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:

Date:

Name (PRINT):

Job title:

**Important notes** (tick if applicable):

See advance decision to refuse treatment here)

Patient has withdrawn consent (ask patient to sign/date

Patient signature:

Name (PRINT):

Date:

**CONSENT FORM  
PROCEDURE SPECIFIC PATIENT AGREEMENT**

**Catheter Ablation for Ventricular Tachycardia (VT)**

*A procedure to prevent abnormal electrical signals in the heart causing VT by heating the abnormal regions within the ventricular muscle.*

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**I have explained the procedure to the patient.** In particular, I have explained the intended benefits:

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Patient signature:

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Date:

**Important notes** (tick if applicable):

See advance decision to refuse treatment

Patient has withdrawn consent (ask patient to sign/date here)