Information to be retained by the patient

Name:

Date of Birth:

Affix Patient Label

CHI:

NHS Golden Jubilee

Catheter Ablation for Atrial Fibrillation

What is Atrial Fibrillation? (AF)

Atrial Fibrillation is the most common heart rhythm disorder in the world. It is estimated that over 1 million people in the UK have this condition. It can affect adults of any age but gets more common as we get older. Approximately 0.5% of people aged 50-59 have AF and 10% above the age of 80 have AF. It results from abnormal electrical activity in the atria, the top chambers of the heart, causing the heart to beat irregularly and occasionally fast. This may lead to symptoms such as palpitations, feeling of a racing heart, breathlessness, light-headedness, lethargy and fatigue. Some people with AF sometimes do not know they a have the condition, as they have no symptoms.

Why treat AF?

The two main reasons to treat AF are to improve those who have symptoms and to reduce the chance of a clot forming in the heart which may lead to stroke. The risk of stroke is reduced by taking medication that make the blood less sticky. Examples of common blood thinners are warfarin, Apixaban, Rivaroxaban, Edoxaban and Dabigatran.

How are the symptoms of AF treated?

Successfully managing AF can be difficult. There are a number of treatment options and they involve either doing nothing, mediation (pills), cardioversion (electric shock under anaesthetic to normalize the heart rhythm), weight loss, pacemakers, catheter ablation or a combination. These therapies aim to either improve the symptoms of AF or restore normal rhythm. The choice of treatment will depend on you as an individual, the type of AF, how long you have had AF, your symptoms, the likelihood of that particular therapy working for you and the risks of the treatment. It is important that you are aware of these options and have discussed them with your doctor and health professionals looking after you.

Am I suitable for Catheter Ablation procedure for AF?

Catheter Ablation is not suitable for everybody and is currently indicated for those who have symptoms that significantly affect the quality of their life and either failed to feel better on medication (pills) or have had side effects from medication. It is very important to understand that the procedure has not been shown to make most people live longer or reduce their chance of stroke; it is only used to treat symptoms. However, a recent study has shown that catheter ablation may help people with a certain type of heart failure live longer, although this is only a single study and other research is needed to confirm the findings.

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 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 does Catheter affect AF and the success rate?

The aim of the procedure is to stop the abnormal electrical signals in the heart from causing AF. This is achieved by either freezing (cryoablation) or burning (Radiofrequency ablation) the heart tissue. In almost all patients this currently involves treating the four veins (Pulmonary vein isolation) in the top chamber on the left side of the heart (left atrium). The success rate depends on a number of factors including the type of AF, how long you have had AF and other health conditions you have. Generally, the success rate is 70-80% for those who go in and out of AF (Paroxysmal) and 50-70% for those in AF all the time (persistent). It is very important to realize that to achieve this level of success this may involve two, three or (very rarely) more procedures. This does not mean that it has been a failure.

What does it involve?

You will usually come in to hospital 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 implantation to you and ask you to sign the consent form to confirm that you understand the procedure, proposed 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. Catheter ablation is carried out in a cardiac catheterisation laboratory (Cath Lab). Staff from the room the procedure will be performed will come and introduce themselves to you and take you into the room. 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.

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. You will have a local anaesthetic at the top of the leg and given sedation to make you comfortable. Rarely a general anaesthetic will be given for your procedure. The top of your leg will be cleaned and a clean (sterile) blanket or drape will be used to cover you.

3. The procedure is performed with long tubes (sheaths) and wires (catheters) placed in the vein at the top of your leg and positioned in your heart using x-ray guidance.

4. The catheters are placed in the left atrium (top chamber) 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.

5. Once in position, the doctor will treat the top chambers to stop AF from occurring by freezing or burning round the pulmonary veins in the top left heart chamber (left atrium).

6. At the end of the procedure your doctor may wish to cardiovert you back into the normal rhythm (sinus rhythm) by delivering an electric shock to the heart. If this is performed you will be given more sedation so that you are asleep.

How long does it take?

The procedure takes about one to three hours. The length of the procedure depends on a number of factors including how many procedures you have had in the past and if you have other heart conditions. Generally, for a first time procedure we use the freezing technique and this takes approximately 1½ to two hours.

Will I have any pain or discomfort?

You may briefly feel a sharp pain with the local anaesthetic. Most patients tolerate the procedure very well but some can find it uncomfortable. Throughout the procedure a nurse will be monitoring you very closely and will be able to give you more sedation or painkillers if needed.

What happens after the procedure?

The tubes at the top of your leg are usually removed in the Cath Lab with a stitch and you will go back to the cardiology ward. You will lie flat for two to three 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 may be discharged home on day of procedure provided you have had a straightforward recovery and have been back in ward for a minimum of four hours. You should have somebody to take you home and stay overnight with you. Occasionally it might be preferable for you to stay overnight and go home the following day so please be prepared for an overnight stay should it be required.
The doctor and ward team 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 you had done and the plan for further follow-up and medication.

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. Most patients recover very quickly, however it may take a day or two to feel back to normal. 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 one 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. Prolonged bouts of palpitations in the first three months after a procedure do 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.

When can I resume driving?

You should not drive for the first two days after the procedure. If you feel well you can then resume driving. There is no formal rule about flying but this should ideally be avoided for the first two days.

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 advised to stop these pills they are usually continued for two to three months then stopped if you have had no recurrence of AF.

Blood Thinners (anticoagulants): Every patient will generally continue anticoagulants for the first 2 to 3 months after the procedure. You must understand that this procedure does not reduce your risk of stroke and your specialist will advise you whether you can stop taking these pills long-term. The decision will depend on other factors such as your age, gender (male or female) and other health problems.

Are there any risks?

The procedure is usually very successful, but as with all procedures there are some risks. It is important that you understand what these risks are so that you can make a decision whether you want to have the procedure performed. You will have the opportunity to ask any questions before the procedure is undertaken. Overall the risk of any complication is between three and 5%.

Common Complications (1% or greater):

- **Blood leak round the heart (Tamponade)** – there is a 1-3% (one to 3 in 100) chance of puncturing the heart and blood leaking round the heart. This can heal on its own without any treatment. Occasionally the escaped blood may need to be removed by placing a small drain (tube) under the ribs into the sac which encloses the heart. Very rarely (less than 1 in 500) you may require surgery to stop the bleeding.
- **Phrenic Nerve Damage** – there is a 1-5% (one to five in 100) chance of damaging one of the breathing nerves on the right side. In almost every case this recovers its function within a few minutes to weeks. We pace this muscle when we freeze round the veins on the right side.
- **Damage to Blood Vessels (Pseudoaneurysm or fistula)** – there is a 1% (one in 100) risk of damaging the artery, which is a blood vessel that runs beside the vein at the top of the leg. If there is damage then this usually heals up without any treatment. Less than one in 500 times you may need surgery or an injection to treat it.
- **Unable to Place Catheters or Perform Ablation** – There is a 5% (five in100) chance we may be unable to place one of the tubes or catheters into the blood vessels or heart. If this is the case we will stop the procedure and discuss the options with you after the procedure.

Uncommon complications (less than 1%):

- **Stroke or Heart Attack**– there is a one in 500 risk of a blood clot or air bubble causing a stroke or heart attack.
- **Atrio-Oesophageal Fistula**– There is a 0.1% (one in1000) chance of causing a hole between the back wall of the heart (left atrium) and swallowing tube (Oesophagus). It is a very rare but serious complication that can occur a few days to weeks after the procedure. Symptoms include fever, chills, vomiting or trouble swallowing – you must report immediately to hospital or your GP.
- **Pulmonary Vein Stenosis** – There is a 0.2% (one in 500) chance of narrowing of one of the veins on the left side of the upper heart chamber (pulmonary vein). Most patients have no symptoms but occasionally this can cause breathlessness.
- **Death** – fortunately this is extremely rare. Reported figures round the world suggest this is one in 1000 chance.

Will I need further appointments?

Yes, you will be sent an appointment to be seen in the Arrhythmia Clinic at Glasgow Royal Infirmary a few months after your procedure.

Are there Alternative Treatments?

There are alternative treatments for AF that you should talk to your doctor about. These include:

- **Medication:** Drugs can be used to treat AF if it causes your heart rate to be too fast (above 110 beats per minute). Strong drugs can also be used to keep you in the normal rhythm.
- **Pacemakers:** If AF or medication causes your heart rate to be too slow a pacemaker can be inserted to speed the rate up.
- **Pacemaker then Ablation of AV node:** This approach disrupts the electrical signals from the top to the bottom chambers of the heart. It involved two procedures with the pacemaker being implanted at least one month before AV node ablation.
- **Heart Surgery for AF:** This is reserved for patients undergoing heart surgery for other reasons.

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

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

Consent Form
Procedure Specific Patient Agreement

Name:

Date of Birth:

CHI:

NHS Golden Jubilee

Catheter Ablation for Atrial Fibrillation (AF)

A procedure to disrupt the electrical signals in the heart by freezing or burning round the Pulmonary Veins

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 top heart chambers, and in doing so improve symptoms of AF such as palpitations, breathlessness, fatigue and dizzyness.

Commonly occurring risks (1% or greater):

- The overall serious complication rate is 3-5%
- Mild bruising is common requiring no intervention.
- Major bleeding or haematoma requiring operation (0.5%).
- Risk of bleeding around the heart requiring (Tamponade) insertion of a drain is between 1-3%.

Uncommon but more serious risks:

- Stroke and Heart Attack (one in 500).
- Damage to Blood Vessel (Pseudoaneuryms, fistula) 1 in 100 (1 in 500 requiring an operation).
- The risk of death is less than in **one in 1000** procedures.

Uncommon possible later issues:

- Atrio-oesophageal Fistula (one in 1000) Communication between heart and swallowing tube (oesophagus).

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:

Catheter Ablation for Atrial Fibrillation (AF)

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: Catheter Ablation for Atrial Fibrillation 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:

File copy

Consent Form
Procedure Specific Patient Agreement

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