

# Patient information and consent to axillo-femoral/axillo-profunda bypass (to improve the blood flow in the leg)

## Key messages for patients

- **Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your operation.**
- Please bring with you any medications you use (including patches, creams and herbal remedies) and any information that you have been given relevant to your care in hospital, such as x rays or test results.
- Take your medications as normal on the day of the procedure **unless** you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. **Do not** take any medications used to treat diabetes.
- Please call the vascular surgery nurse practitioner on **01223 245151 extension 6382** if you have any questions or concerns about this procedure.

**Please read this information carefully**, you and your health professional will sign it to document your consent.

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

## Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the responsible health professional, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.

## About axillo-femoral / axillo-profunda bypass

An axillo-femoral / axillo profunda bypass is an operation to improve blood flow to the arteries in the leg.

The two main arteries in the leg are the femoral and profunda arteries. If there is a blockage in the iliac arteries that get blood flowing into these two leg arteries an alternative method of getting blood to the leg has to be found.

The most common bypass operations performed are either an axillo-femoral bypass or an axillo-profunda graft bypass. The precise name of your procedure depends on where the bypass starts and finishes. When one of the iliac arteries is blocked, usually due to atherosclerosis (hardening of the arteries), blood flow to the end of the leg is reduced. An X-ray or scan will usually show exactly where the blockage is, enabling treatment to be planned. If the leg is adjusting well to the reduced blood flow, it can be safe to leave the blockage alone, monitor any progress and prescribe some simple medicines to prevent further deterioration. However, the lack of blood flow can cause pain, ulceration and even gangrene in the foot, which will require surgical treatment to improve the blood flow.

A balloon or stent can sometimes be used to open up blocked arteries. If this is not possible a bypass operation is usually required.

## Before your procedure

Most patients attend a pre-admission clinic, when you will see the pre-assessment nurse. At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have at any time.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring any packaging with you.

This procedure involves the use of anaesthesia. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. You will see an anaesthetist before your procedure.

You will normally stay in hospital for seven to ten days.

## Hair removal before an operation

For most operations, you do not need to have the hair around the site of the operation removed. However, sometimes the healthcare team need to see or reach your skin and if this is necessary they will use an electric hair clipper with a single-use disposable head, on the day of the surgery. Please do not shave the hair yourself or use a razor to remove hair, as this can increase the risk of infection. Your healthcare team will be happy to discuss this with you.

## During the procedure

During the operation a new route for the blood to flow is made to bypass the blockage. The new 'artery' is a Y-shaped artificial graft, with one end being sewn onto a blood vessel near the shoulder (axillary artery) and the other two ends sewn onto the blood vessel in each groin. The operation itself involves a cut over each artery and the graft is then pushed under the skin between the cuts on the shoulder and in the groin. This allows the blood to flow around the blockage and into the leg. Typically, this operation takes two to three hours to perform.

## After the procedure

Once your surgery is completed you will usually be transferred to the recovery ward where you will be looked after by specially trained nurses, under the direction of your anaesthetist. The nurses will monitor you closely until the effects of any general anaesthetic have adequately worn off and you are conscious. They will monitor your heart rate, blood pressure and oxygen levels too. You may be given oxygen via a facemask, fluids via your drip and appropriate pain relief until you are comfortable enough to return to your ward. You will also have a small plastic tube in the bladder to help you pass urine after the operation.

Sometimes, people feel sick after an operation and might vomit. If you feel sick, please tell a nurse and you will be given medicine to stop the sickness/vomiting.

Most of the wound drains and drips are removed in the first 48 hours.

After certain major operations you may be transferred to the intensive care unit (ICU/ITU), high dependency unit (HDU), intermediate dependency area (IDA) or fast track/overnight intensive recovery (OIR). These are areas where you will be monitored much more closely because of the nature of your operation or because of certain pre-existing health problems that you may have. If your surgeon or anaesthetist believes you should go to one of these areas after your operation, they will tell you and explain to you what you should expect.

**If there is not a bed in the necessary unit on the day of your operation, your operation may be postponed as it is important that you have the correct level of care after major surgery.**



**Eating and drinking.** You will be able to eat and drink normally from the day after your operation.



**Getting about after the procedure.** We aim to gradually increase your mobility after the operation, when the pain and stiffness from the surgery settles down.

It is normal to feel some discomfort over the cuts and we will give you pain-killing tablets to make you more comfortable.



**Leaving hospital.** Most patients find they need seven to ten days to recover enough mobility to go home. However, the actual time that you stay in hospital will depend on how quickly you recover from your operation, the type of operation, and your doctor's opinion.



**Resuming normal activities including work.** You can usually begin gentle work/study within 28 days, but you might need to wait a little longer before resuming more vigorous activity.



**Special measures after the procedure:** Your leg might swell up because of fluid collecting in the leg. To help prevent this, you should keep your leg elevated when you are not moving around.



**Check-ups and results:** Before you leave hospital, we will give you a date to return to clinic for the results of your surgery. At this time, we can check your progress and discuss any further treatment, if recommended.

## Intended benefits

The purpose of the procedure is to improve blood flow to your leg/foot. This should reduce any pain, help any ulcers heal (and to stop gangrene spreading). If successful, the operation reduces the chances of needing to have an amputation.

Those patients who experienced pain in the calves on walking (claudication) will usually find they can walk further before the pain begins.

## Who will perform my procedure?

This procedure will be performed by the consultant vascular surgeon and the vascular surgical registrar.

## Alternative procedures that are available

Surgery is usually only undertaken when other non-surgical and X-ray based treatments have not succeeded or are not possible. The decision is then taken to either undertake surgery now or monitor the leg to see if it gradually improves on its own. Some limited improvement usually occurs on its own in about a third of cases.

If the leg deteriorates further, then amputation might be necessary.

## Significant, unavoidable or frequently occurring risks of this procedure

The bypass graft can block and stop working. This occurs early after the operation in one in ten patients. This blockage can be cleared successfully in some cases, but if this is not possible then there is a risk of losing the leg as a result of the operation.

Later on, in the months after the bypass, the graft can also block. Overall about six out of ten of the grafts keep working for three to five years.

Other complications that are specific to this surgery are:

- bleeding from the graft
- infection of the wounds and/or graft
- deep vein thrombosis (DVT) in the leg.

These occur in one out of 20 patients. Infection of the graft is difficult to treat and often ends with the graft being removed and if this happens there is a risk of amputation.

More general complications related to the anaesthetic and the stress of surgery include:

- pneumonia (chest infection)
- myocardial infarction (heart attack)
- major organ failure (for example, heart, kidney, lung): these affect approximately one in 20 patients.

The operation does carry some serious risks and there is approximately a one in twenty-five chance of dying from the operation. This figure will vary depending on the patient's health prior to the operation.

## Anaesthesia

Anaesthesia means 'loss of sensation'. There are three types of anaesthesia: general, regional and local. **The type of anaesthesia chosen by your anaesthetist depends on the nature of your surgery as well as your health and fitness.** Sometimes different types of anaesthesia are used together.

### Before your operation

Before your operation you will meet an anaesthetist who will discuss with you the most appropriate type of anaesthetic for your operation, and pain relief after your surgery. To inform this decision, he/she will need to know about:

- your general health, including previous and current health problems
- whether you or anyone in your family has had problems with anaesthetics
- any medicines or drugs you use
- whether you smoke
- whether you have had any abnormal reactions to any drugs or have any other allergies
- your teeth, whether you wear dentures, or have caps or crowns.

Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck and may review your test results.

### **Pre-medication**

You may be prescribed a 'premed' prior to your operation. This a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief, reduce the risk of you being sick, or have effects specific for the procedure that you are going to have or for any medical conditions that you may have. Not all patients will be given a premed or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.

### **Moving to the operating room or theatre**

You will usually change into a gown before your operation and we will take you to the operating suite. When you arrive in the theatre or anaesthetic room, monitoring devices may be attached to you, such as a blood pressure cuff, heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted and you may be asked to breathe oxygen through a face mask.

It is common practice nowadays to allow a parent into the anaesthetic room with children; as the child goes unconscious, the parent will be asked to leave.

**Before starting your anaesthesia the medical team will perform a check of your name, personal details and confirm the operation you are expecting.**

### **General anaesthesia**

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you at the correct level of unconsciousness for the period of the surgery. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement.

### **Regional anaesthesia**

Regional anaesthesia includes epidurals, spinals or local anaesthetic blocks of the nerves to the limbs or other areas of the body. Local anaesthetic is injected near to nerves, numbing the relevant area and possibly making the affected part of the body difficult or impossible to move for a period of time. Regional anaesthesia may be performed as the sole anaesthetic for your operation, with or without sedation, or with a general anaesthetic. Regional anaesthesia may also be used to provide pain relief after your surgery for hours or even days. Your anaesthetist will discuss the procedure, benefits and risks with you.

### **Local anaesthesia**

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted and some sensation of pressure may be present, but there should be no pain.

Local anaesthesia is used for minor operations such as stitching a cut, but may also be injected around the surgical site to help with pain relief. Usually a local anaesthetic will be given by the doctor doing the operation.

## Sedation

Sedation is the use of small amounts of anaesthetic or similar drugs to produce a 'sleepy-like' state. Sedation may be used as well as an anaesthetic. The anaesthesia prevents you from feeling pain, the sedation makes you drowsy. Sedation also makes you physically and mentally relaxed during an investigation or procedure which may be unpleasant or painful (such as an endoscopy) but where your co-operation is needed. You may remember a little about what happened but often you will remember nothing. This is known as 'conscious sedation', and may be used by other professionals as well as anaesthetists.

## What will I feel like afterwards?

How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health. Most people will feel fine after their operation. Some people may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties.

You may have fewer of these effects after local or regional anaesthesia. When the effects of the anaesthesia wear off you may need pain relieving medicines.

## What are the risks of general or regional anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or performed in an emergency.

### **Very common (1 in 10 people) and common side effects (1 in 100 people)**

Feeling sick and vomiting after surgery  
Sore throat  
Dizziness, blurred vision  
Headache  
Bladder problems  
Damage to lips or tongue (usually minor)  
Itching  
Aches, pains and backache  
Pain during injection of drugs  
Bruising and soreness  
Confusion or memory loss

## **Uncommon side effects and complications (1 in 1000 people)**

Chest infection

Muscle pains

Slow breathing (depressed respiration)

Damage to teeth

An existing medical condition getting worse

Awareness (becoming conscious during your operation)

## **Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications**

Damage to the eyes

Heart attack or stroke

Serious allergy to drugs

Nerve damage

Death

Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK.

## Information about important questions on the consent form

### 1 Creutzfeldt Jakob Disease ('CJD')

We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

### 2 Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment, they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

### 3 Students in training

Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

### 4 Use of Tissue

As a leading bio-medical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet '*Donating tissue or cells for research*' gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on **01223 216756**.

## Information and support



We will give you additional information in the form of patient information leaflets. Please contact the vascular surgery nurse practitioner on **01223 245151** ext **6382** if you have any questions or anxieties.

Further information is available from The Vascular Society Website: [www.vssgbi.org/](http://www.vssgbi.org/)



### Privacy & Dignity

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.



We are currently working towards a smoke free site. Smoking is only permitted in the designated smoking areas. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169



### Help with this leaflet



If you would like this information in **large print**, another language or in audio format, please ask the department to contact Patient Information on 01223 216032 or [patient.information@addenbrookes.nhs.uk](mailto:patient.information@addenbrookes.nhs.uk)

### Document history

Authors	Mr Kevin Varty
Department	Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ <a href="http://www.cuh.org.uk">www.cuh.org.uk</a>
Contact number	01223 245151
Publish/Review date	April 2012/April 2015
File name	Axbifem_bypass.doc
Version number/Ref	5/CF207

# Consent Form

## Axillo-femoral / axillo-profunda bypass

For staff use only:

Hospital number:

Surname:

First names:

Date of birth:

NHS no: \_ \_ \_ / \_ \_ \_ / \_ \_ \_ \_

Use hospital identification label

**A** Patient's side left / right or N/A

### Consultant or other responsible health professional

Name and job title: .....

Any special needs of the patient (e.g. help with communication)? .....

Please use 'Procedure completed' stamp here on completion:

### B Statement of health professional (details of treatment, risks and benefits)

**1** I confirm I am a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the hospital's consent policy. I have explained the procedure to the patient. In particular, I have explained:

a) the intended benefits of the procedure (please state)

**Please complete for this procedure:**

**Axillary side: left/right .....**

**Groin incision: left/right/bilateral .....**

The purpose of the procedure is to improve blood flow to your leg/foot. This should reduce any pain, help any ulcers heal.

b) the possible risks involved. Addenbrooke's always ensures any risks are minimised. However all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient

- the bypass graft can block and stop working
- bleeding from the graft
- infection of the wounds and/or graft
- deep vein thrombosis (DVT) in the leg.

The operation does carry some serious risks and there is approximately a one in twenty-five chance of dying from the operation. This figure will vary depending on the patient's health prior to the operation.

c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:

# Consent Form

## Axillo-femoral / axillo-profunda bypass

For staff use only:

Hospital number:

Surname:

First names:

Date of birth:

NHS no: \_ \_ \_ / \_ \_ \_ / \_ \_ \_ \_

Use hospital identification label

**d)** any extra procedures that might become necessary during the procedure such as:

Blood transfusion

Other procedure (please state)

.....  
.....

The following information leaflet has been provided:

Axillo-femoral / axillo-profunda bypass

Version, reference and date: V5, CF207, April 2012

or  I have offered the patient information about the procedure but this has been declined.

**3** This procedure will involve:

General and/or regional anaesthesia

Local anaesthesia

Sedation

None

**Signed** (Health professional): ..... Date:   /  /  

**Name** (PRINT): ..... Time (24hr):   :  :  

**Designation:** ..... Contact/bleep no: .....

### **C** Consent of patient / person with parental responsibility

**I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.**

**Important:** please read the patient information about this procedure and then put a tick in the relevant boxes for the following questions:

#### **1** Creutzfeldt Jakob disease (CJD)

Have you ever been notified that you are at risk of CJD or variant CJD

for public health purposes? If yes, please inform your health professional.

Yes

No

#### **2** Photography, Audio or Visual Recording

**a) I agree** to the use of any of the above type of recordings for the purpose of diagnosis and treatment.

Yes

No

**b) I agree** to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting.

Yes

No

#### **3** Students in training

**I agree** to the involvement of medical and other students as part of their formal training.

Yes

No

# Consent Form

## Axillo-femoral / axillo-profunda bypass

For staff use only:

Hospital number:

Surname:

First names:

Date of birth:

NHS no: \_ \_ \_ / \_ \_ \_ / \_ \_ \_ \_

Use hospital identification label

### 4 Use of Tissue

a) **I agree** that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research.

Yes  No

b) *Where additional clinical information is needed for the purposes of ethically approved research, I agree* that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records.

Yes  No

I have listed below any procedures that **I do not wish to be carried out without further discussion.**

**I have read and understood** the Patient Information about this procedure and the above additional information. **I agree** to the procedure or treatment.

**Signed** (Patient): ..... Date: *DD/MM/YYYY*

**Name of patient** (PRINT): .....

*If signing for a child or young person; delete if not applicable.*

**I confirm** I am a person with **parental responsibility** for the patient named on this form.

**Signed:** ..... Date: *DD/MM/YYYY*

**Relationship to patient:** .....

*If the patient is unable to sign but has indicated his/her consent, a witness should sign below.*

**Signed** (Witness): ..... Date: *DD/MM/YYYY*

**Name of witness** (PRINT): .....

**Address:** .....

# Consent Form

## Axillo-femoral / axillo-profunda bypass

**For staff use only:**

Hospital number:

Surname:

First names:

Date of birth:

NHS no: \_ \_ \_ / \_ \_ \_ / \_ \_ \_ \_

Use hospital identification label

### D Confirmation of consent

**Confirmation of consent** (where the treatment/procedure has been discussed in advance)

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

**Signed** (Health professional): ..... Date:   D  D  /  M  M  /  Y  Y  Y  Y  .....

**Name** (PRINT): ..... Job title: .....

**Please initial to confirm all sections have been completed:** .....

### E Interpreter's statement (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

**Signed** (Interpreter): ..... Date:   D  D  /  M  M  /  Y  Y  Y  Y  .....

**Name** (PRINT): .....

Or, please note the language line reference ID number: .....

### F Withdrawal of patient consent

The patient has withdrawn consent (ask patient to sign and date here)

**Signed** (Patient): ..... Date:   D  D  /  M  M  /  Y  Y  Y  Y  .....

**Signed** (Health professional): ..... Date:   D  D  /  M  M  /  Y  Y  Y  Y  .....

**Name** (PRINT): ..... Job title: .....