



Cardiac Biopsy (Femoral Vein Approach)

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

A. Interpreter / cultural needs

- An Interpreter Service is required? Yes No
- If Yes, is a qualified Interpreter present? Yes No
- A Cultural Support Person is required? Yes No
- If Yes, is a Cultural Support Person present? Yes No

B. Condition and treatment

The doctor has explained that you have the following condition: *(Doctor to document in patient's own words)*

.....

This condition requires the following procedure. *(Doctor to document - include site and/or side where relevant to the procedure)*

.....

The following will be performed:

You will have an injection of local anaesthetic into your right groin. A fine tube (catheter) is put into the vein in the groin. You may feel pressure in your leg while the tube is placed in the vein. The tube is passed up until it reaches the right heart chamber. The doctor will use X-ray images to see the catheter. 'Biopsy forceps' or pincers at the end of the catheter are used to take the tissue samples. This is repeated at least 4 times to get enough samples. The biopsy pieces are very small (one to two millimetres). You will feel a few extra heartbeats otherwise this part of the procedure is painless.

At the end of the procedure the forceps and catheter are removed.

C. Risks of a cardiac biopsy (femoral vein approach)

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment.

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications (more than 5%) include:

- Minor bleeding and bruising at the puncture site.
- Abnormal heartbeat lasting several seconds and then settles by itself.

Uncommon risks and complications (1- 5%)

- include:
- Unable to get the catheter into the leg vein. The procedure may be changed to the opposite leg or to a different approach eg. the neck or an arm vein.
 - Abnormal heart rhythm that continues for a long time. This may need an electric shock to correct.
 - The femoral artery (in the groin) is accidentally punctured. This usually just requires pressure on the artery. In rare cases this may require surgery to repair.
 - Unable to get any heart samples. This may be due to scarring of the heart.

Rare risks and complications (less than 1%)

- include:
- Infection can occur, requiring antibiotics and further treatment.
 - Allergic reaction to the local anaesthetic. This may require some medication to treat.
 - Embolism. A blood clot may form and break off from the catheter. This is treated with blood thinning medication.
 - A hole is accidentally made in the heart or the heart valve. This will need surgery to repair.
 - Damage to the vein in the leg. This may need surgery to repair.
 - Damage to the nerve in the leg.
 - Air embolism. Oxygen may be given.
 - A stroke. This may cause long term disability.
 - Death as a result of this procedure is extremely rare.

D. Significant risks and procedure options

(Doctor to document in space provided. Continue in Medical Record if necessary.)

.....

E. Risks of not having this procedure

(Doctor to document in space provided. Continue in Medical Record if necessary.)

.....

F. Anaesthetic

This procedure may require an anaesthetic. *(Doctor to document type of anaesthetic discussed)*

.....

PROCEDURAL CONSENT FORM



Cardiac Biopsy (Femoral Vein Approach)

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

G. Patient consent

I acknowledge that the doctor has explained;

- my medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- the anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- other relevant procedure options and their associated risks.
- my prognosis and the risks of not having the procedure.
- that no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- the procedure may include a blood transfusion.
- tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- if immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- a doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following Patient Information Sheet/s:

- Local Anaesthetic and Sedation for Your Procedure**
- Cardiac Biopsy (Femoral Vein Approach)**
- Blood & Blood Products Transfusion**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

On the basis of the above statements,

I request to have the procedure

Name of Patient:

Signature:

Date:

Patients who lack capacity to provide consent

Consent must be obtained from a substitute decision maker/s in the order below.

Does the patient have an Advance Health Directive (AHD)?

Yes ▶ Location of the original or certified copy of the AHD:

No ▶ Name of Substitute Decision Maker/s:

Signature:

Relationship to patient:

Date: PH No:

Source of decision making authority (tick one):

- Tribunal-appointed Guardian
- Attorney/s for health matters under Enduring Power of Attorney or AHD
- Statutory Health Attorney
- If none of these, the Adult Guardian has provided consent.

H. Doctor/delegate statement

I have explained to the patient all the above points under the Patient Consent section (G) and I am of the opinion that the patient/substitute decision-maker has understood the information.

Name of Doctor/delegate:

Designation:

Signature:

Date:

I. Interpreter's statement

I have given a sight translation in

.....
(state the patient's language here) of the consent form and assisted in the provision of any verbal and written information given to the patient/parent or guardian/substitute decision-maker by the doctor.

Name of Interpreter:

Signature:

Date:

1. What is a cardiac biopsy (femoral vein approach)?

The doctor takes samples of heart tissue to help diagnose a number of cardiac conditions.

A needle with a tube connected to it will be put in your arm. This is called an intravenous line or IV.

You will have an injection of local anaesthetic into your right groin. A fine tube (catheter) is put into the vein in the groin. You may feel pressure in your leg while the tube is placed in the vein. The tube is passed up until it reaches the right heart chamber. This is usually painless. The doctor will use X-ray images to see the catheter.

‘Biopsy forceps’ or pincers at the end of the catheter are used to take the tissue samples. This is repeated at least 4 times to get enough samples. The biopsy pieces are very small (one to two millimetres). You will feel a few extra heart beats otherwise this part of the procedure is painless.

At the end of the procedure the forceps and catheter are removed.

2. My anaesthetic

This procedure will require an anaesthetic.

See **Local Anaesthetic and Sedation for your Procedure information sheet** for information about the anaesthetic and the risks involved. If you have any concerns, discuss these with your doctor.

If you have not been given an information sheet, please ask for one.

3. What are the risks of this specific procedure?

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment.

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications (more than 5%) include:

- Minor bleeding and bruising at the puncture site
- Abnormal heartbeat lasting several seconds and then settles by itself.

Uncommon risks and complications (1- 5%) include:

- Unable to get the catheter into the leg vein. The procedure may be changed to the opposite leg or to a different approach eg. the neck or an arm vein.
- Abnormal heart rhythm that continues for a long time. This may need an electric shock to correct.
- The femoral artery (in the groin) is accidentally punctured. This usually just requires pressure on

the artery. In rare cases this may require surgery to repair.

- Unable to get any heart samples. This may be due to scarring of the heart.

Rare risks and complications (less than 1%) include;

- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction to the local anaesthetic. This may require some medication to treat.
- Embolism. A blood clot may form and break off from the catheter. This is treated with blood thinning medication.
- A hole is accidentally made in the heart or the heart valve. This will need surgery to repair.
- Damage to the vein in the leg. This may need surgery to repair.
- Damage to the nerve in the leg.
- Air embolism. Oxygen may be given.
- A stroke. This may cause long term disability.
- Death as a result of this procedure is extremely rare.

Notes to talk to my doctor about:

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....