

Informed Consent for Heart Valve Surgery

Name:	Age (in years):	Gender: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Other
UHID No./Registration No.:		
Interpreter Service: <input type="checkbox"/> Yes <input type="checkbox"/> No	Consultant's Name:	

Medical Condition

The doctor has explained that I/my child/myhave the following medical condition:

.....

and I/my child/my.....have been explained and advised to undergo the following treatment/procedure:

.....

I authorise Dr. and his/her associates to perform the above treatment/ procedure.

The doctor should document the site and/or side where relevant to the procedure:.....

.....

Introduction

Heart valve disease is when one or more valves of the heart are not working fully and blood does not flow through the heart as it should. This can put an extra strain on the heart and can cause symptoms such as breathlessness and swollen ankles. A severe heart valve disease can cause the heart to pump less efficiently. There are several causes of heart valve disease. These include:

- Rheumatic fever: A bacterial infection acquired during childhood.
- A "congenital deformity: A person may be born with an abnormal valve.
- Coronary artery disease: A blockage occurs in the arteries that supply blood to the heart. This condition can damage the valve of the heart.
- Cardiomyopathy: The disease in which the heart muscle becomes thickened or dilated which can cause the valves to malfunction.
- Age: With age the valves become less flexible, stretched or torn.

A surgery will be performed to treat the heart valve disease. During surgery, the diseased or abnormal valve will be replaced or repaired. Your doctor will advise you regarding the best treatment option (to repair or replace the valve) based on what is wrong with the valve and the seriousness of the problem. A heart valve surgery can eliminate or improve your symptoms and may prevent permanent damage to your heart.

The operation will be performed under general anaesthesia, so you will be asked to follow fasting instructions. The surgeon will make an incision (cut) down the middle of your breastbone (sternum) and will open your ribcage to reach your heart. You will be administered medication to temporarily stop your heart. Your blood will be re-routed to a heart-lung (bypass) machine. This will take over work from your heart and lungs and will add oxygen to your blood and maintain your circulation. The diseased valve will then be replaced or repaired. The length of your operation will depend on whether your valve is to be repaired or replaced and how many valves are going to be treated.

After a heart valve surgery, you will usually be required to stay for five to seven days in the hospital.

Valve replacement

Your surgeon will remove the diseased valve and sew in a replacement prosthetic (artificial) valve.

There are two types of prosthetic valves:

Mechanical valves: They are artificial manufactured valves. They are made of pyrolyte carbon. Often, they make a clicking sound, but most people get used to it. They last for a long time - usually a lifetime. However, there is a risk of a blood clot on the valve. You will have to take blood thinning drugs (anticoagulants) for the rest of your life to avoid this. Your doctor will prescribe these drugs (if required).

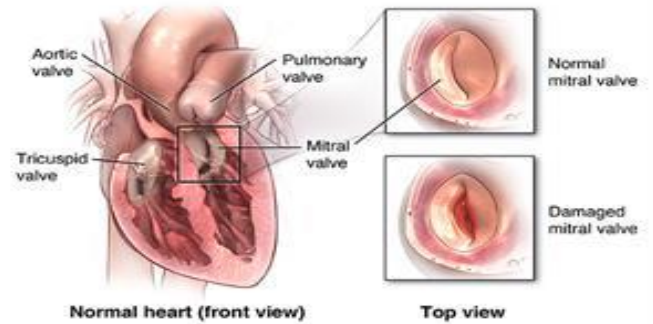
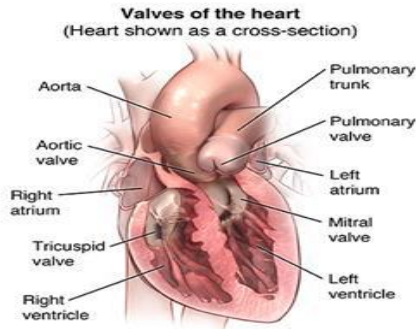
Biological valves: They are made from human or animal tissue (usually pig). You will probably not need to take anticoagulants for the rest of your life, but your surgeon may recommend them for the few weeks after the operation while the valve settles in. You may need a further surgery every 10-15 years, because these valves can wear out faster than the mechanical valves. They are not suitable for everybody - Your doctor will advise you whether they are the best choice for you.

Valve repair surgery

Valve repair is performed to repair mitral valves that are not seriously damaged. The mitral valve is on the left side of the heart. It separates the atrium from the ventricle. There are several techniques for repairing the valve depending on what is wrong with the valve.

After the valve(s) have been replaced or repaired, the surgeon will restart your heart and blood will flow back through your heart again. Your sternum will be re-joined using wires and the skin on your chest will be closed with dissolvable stitches. Tubes will be put into small holes in your chest to drain blood and fluid that will collect as part of the normal healing process.

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Consent for Blood Transfusion

Please see Blood Transfusion Consent Form. This will give you information about the type of the blood products, benefits and risks of blood transfusion. If you have any concern(s), please discuss with your doctor.

Consent for Anaesthesia

Please see Anaesthesia Consent Form. This will give you information about the type of the anaesthesia, its benefits and general risks. If you have any concern(s), please discuss with your anaesthetist(s).

Risks and Potential Complications (To be documented by doctor)

Patient Specific Risks (To be documented by doctor)

Alternatives (To be documented by doctor)

- Bleeding from the wound or chest cavity. This may require re-opening of the surgical site.
- Heart rhythm changes, which are usually temporary and will need drug treatment.
- Short term memory loss, difficulty with concentration and reading and visual blurring may occur for a few weeks after the surgery.
- Pain in the chest wall.
- Breathlessness and feeling tired. This may be temporary or permanent.
- Delayed wound healing.
- Numbness of the left side of the chest due to harvesting the donor artery.
- Deep vein thrombosis (DVT): Blood clot in the leg that can cause pain and swelling. In rare cases, part of the clot may break off and go to the lungs.
- Lung collapse: Occasionally a tube will be placed between the ribs to remove air or fluid from the chest to improve breathing. This is more common in smokers or those with previous lung conditions.

- Kidney failure may occur in patients who have existing kidney problems. This may require dialysis.
- Wound infection in the chest, breastbone, blood, leg or arm. This will require antibiotics.
- Cardiac malfunction
- The graft may become blocked with a blood clot. This may require further treatment.
- Leaking of a valve or an ineffective valve. This will require further surgery.
- Respiratory failure. This may need drug treatment or a tracheostomy.
- Changes in the heart rhythm which may be required placement of a permanent pacemaker.
- Bacterial endocarditis: This is an infection of the inner lining of the heart including the valves. It is a serious condition and will require a long course of antibiotics.
- Stroke.
- Death.
- Others, if any specify:

- 1)
- 2)
- 3)
- 4)
- 5)

- Medical treatment: Various medicines can help to treat the symptoms of valve disease.
- Balloon aortic valvuloplasty (BAV): A very fine tube will be passed into the heart through an artery. A balloon on the end of the tube will be inflated to stretch the valve. This procedure can only be performed to correct narrowed valves.
- Cardiac transplant.
- Others, if any specify:

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<p>Potential Benefits (To be documented by doctor)</p> <p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p>	<p>Possible Results of Non-Treatment (To be documented by doctor)</p>
<p>Specific Notes Related to Procedure (Strike out if not required)</p>	<p>Precise Action Points Understood by the Patient/Substitute Decision Maker (To be documented by patient/substitute decision maker in his/her language)</p>
<p>Patient's Authorisation</p> <ul style="list-style-type: none"> • The doctor has explained my/patient's medical condition and proposed treatment/procedure. I have been explained and have understood the intended benefits/risks known to be attached with the planned treatment/procedure including the risks that are specific to me/my patient, and their likely outcomes. • The doctor has explained other relevant/alternate treatment options and their associated benefits/risks. The doctor has also explained the risks of not having the procedure. I have been given the choice to take a second opinion. • I was able to ask questions and raise concerns with the doctor about the procedure and its benefits/risks and my/patient's treatment options. My queries and concerns have been discussed and answered to my full satisfaction. • I understand that the treatment/procedure may include blood/blood product transfusion (for which a separate consent shall be obtained). • The doctor has explained the requirement for anaesthesia for this procedure and I understand the risks associated with anaesthesia, including the risks specific to me (for which a separate consent shall be taken). • I understand that if organs or tissues are removed during the surgery that these may be retained for prescribed tests and shall be disposed of sensitively by the hospital as per the regulatory provisions. • The doctor has explained to me, that during the course of or subsequent to the operation/procedure, unforeseen conditions may be revealed or encountered which may necessitate urgent surgical or other procedures in addition to or different from those contemplated. In such exigency, I further request and authorise the above-named physician/surgeon or his designee to perform such additional surgical or other procedures as he or they consider necessary or desirable in my interest. I understand and agree that in such condition there will be no requirement of any additional consent from me or my family members/attendants. • I declare that no guarantee of whatsoever nature has been given by anyone as to the results that may be obtained. • I understand that I have the right to refuse treatment before the procedure/surgery. I agree that any such refusal/withdrawal shall be in writing and acknowledged by the hospital and I shall be solely responsible for the outcome of such refusal. 	
<ul style="list-style-type: none"> • I consent to if any photographing or television of operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes. However, suitable precautions shall be taken by the hospital that my identity is not revealed anywhere. <input type="checkbox"/> Yes <input type="checkbox"/> No • For purposes of advancing medical education, I consent to the admittance of observers to the operating room. <input type="checkbox"/> Yes <input type="checkbox"/> No 	

Hospital Logo

Patient Identification Label

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Patient Name:		Signature:		Date and Time:
Substitute Decision Maker Name:	Relationship:	Reason (patient is unable to give consent because):	Signature:	Date and Time:
Witness Name:	Relationship:		Signature:	Date and Time:
Interpreter Name:	Translation given in:		Signature:	Date and Time:
Declaration by the Doctor I have explained to the patient / authorised representatives the medical condition, need for the procedure, its alternatives and benefits/risks, likely consequences if those risks occur and the significant risks and problems specific to this patient including the risks of not undergoing the procedure. I have given the patient/ authorised representatives an opportunity to ask questions about any of the above matters and raise any other concerns. I have answered all their queries to the best of my knowledge.				
Name and Signature of the Doctor with Reg No:			Date and Time:	