

## Informed Consent for Repair of Atrial Septal Defect

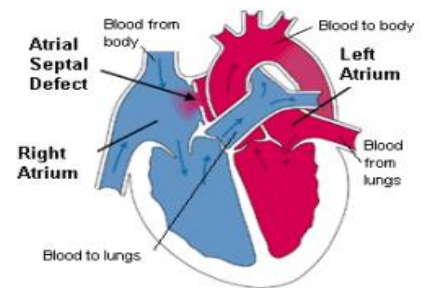
Name:	Age (in years):	Gender: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Other
UHID No./Registration No.:		
Interpreter Service: <input type="checkbox"/> Yes <input type="checkbox"/> No	Consultant's Name:	

**Medical Condition**  
 The doctor has explained that I/my child/my .....have 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**

Normally blood does not flow directly between the left and right chambers of the heart. An atrial septal defect (ASD) is a hole between the upper left chamber (called the left atrium) and the upper right chamber (called the right atrium) of the heart. It causes an abnormal increase in the blood flow in the right side of the heart. As it is receiving so much extra blood, the right side of the heart does more than its normal share of the work. This may cause you to feel tired, have a difficulty in breathing and can shorten your lifespan.

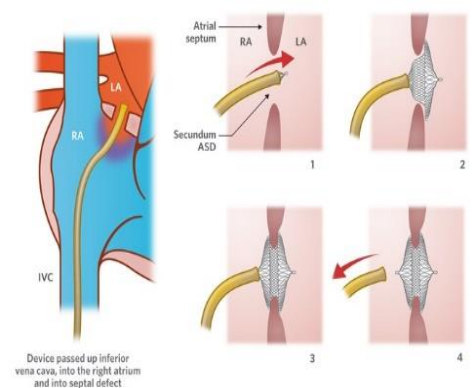
Here is a picture showing the defect



**Procedure**

- **Echocardiogram:** The doctor will take an ultrasound by placing the device on your chest or through your oesophagus (food pipe) or through the catheter in the artery. This will help the doctor to visualise a picture of your heart.
- **Right heart catheter:** The doctor will inject local anaesthesia. And insert a soft balloon pressure catheter into the vein in the groin. The catheter will be passed along until it reaches the heart and then goes up into the blood vessels of the lungs. The pressures in the lungs and heart will be recorded.
- **Angiogram:** After injecting local anaesthesia, the doctor will insert a fine tube (catheter) into the artery in the groin/arm. This tube will be passed into each coronary artery. A series of videos and pictures will be taken using X rays and a contrast medium. The contrast medium may be injected through the catheter into the main pumping chamber of the heart (left ventricle). This is to measure the size of the heart and how well it is pumping.
- **Septal occluder:** It is an artificial device that will be passed into the fine tube and advanced through your heart and put into the defect to close the hole.

Atrial septal defect closure using an expanding device



**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 Pediatric Anaesthesia Consent Form which will give you information of the general risks of the procedure. If you have any concerns, talk these over with your anaesthetist.

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**Risks of Procedure:** While majority of patients have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that one must be aware of the complications/risks that may arise out of this procedure which are as below:

### Risks (To be documented by doctor)

- Bruising at the puncture site
- A higher lifetime risk from exposure to radiation
- Abnormal heart rhythm
- Haematoma
- Bleeding
- High or low blood pressure
- Sore throat from the anaesthetic tube or echo probe
- Stroke or transient ischaemic attack (TIA)
- Incomplete closure of the defect
- An allergic reaction to the contrast medium

- A blood clot may form and break off from the catheter. This is treated with blood thinning medication
- Fever
- Headache or migraine
- Injury to the artery, veins or nerves in the groin or neck
- Tear of oesophagus, vein or heart (from the camera)
- Deep vein thrombosis with pain and swelling. Rarely part of this clot may break off and go into the lungs
- Device Infection. This will need open heart surgery and antibiotics
- Dislodgement of the septal occluder which may require open heart surgery to repair
- Puncture of the heart with a collection of blood around the heart
- Death
- Others, (if any specify):

### Patient Specific Risks (To be documented by doctor)

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

### Potential Benefits (To be documented by doctor)

- Increased lifespan.
- Decreased risk of abnormal heartbeat later in life.
- Best possible heart muscle function and blood supply.
- Decreased risk of blood clots passing into the blood circulation.
- Others, (if any specify):

### Alternatives (To be documented by doctor)

### Possible Results of Non-Treatment (To be documented by doctor)

### Specific Notes Related to Procedure (Strike out if not required)

### Precise Action Points Understood by the Patient/Substitute Decision Maker (To be documented by patient/substitute decision maker in his/her language)

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### Parent/Local Guardian Consent

- The doctor has explained my child's/ward's medical condition and the proposed surgery/procedure. I understand the benefits and risks of the surgery/procedure, including the risks that are specific to my child/ward and the likely outcomes.
  - The doctor has explained other relevant treatment options and their associated benefits and risks. The doctor has explained my child's/ward's prognosis and the risks of not having the procedure. I have been given the choice to take a second opinion.
  - The doctor has explained any significant risks and problems specific to my child and the likely outcomes if complications occur.
  - I was able to ask questions and raise concerns with the doctor about my child's/ward's condition, the surgery/procedure and its benefits/risks and my child's/ward's treatment options. My questions and concerns have been discussed and answered to my satisfaction.
  - I understand that the treatment/procedure may include blood/blood product transfusion (for which a separate consent shall be obtained).
  - I have been informed to refer pediatric anesthesia consent form. This gives the information about the type of the anaesthesia, its benefits and general risks.
  - I understand that if organs or tissues are removed during the surgery, that these may be retained for prescribed tests for a period of time and then disposed of sensitively by the hospital.
  - The doctor has explained to me that if immediate life-threatening events happen during the procedure to my child, they will be treated accordingly.
  - I understand that no guarantee has been made that the procedure done on my child will improve the condition and that the procedure may make my child's condition worse.
  - I understand that I have the right to refuse treatment before the procedure. I agree that any such refusal shall be in writing and acknowledged by the hospital and I shall be solely responsible for the outcome of such refusal.
  - I certify that I have received complete information and fully understood the above consent statement, that all of my questions have been answered to my satisfaction, in the language I understand. This consent is given with stable mind, freely, voluntarily and without reservation.
- I understand that photographs or video footage maybe taken during my child's/ward's operation. These may then be used for teaching health professionals. (The child/ward will not be identified in any photo or video).  **Yes**     **No**
- For purposes of advancing medical education, I consent to the admittance of observers to the operating room.  **Yes**     **No**

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: