



Patient identification label

ATRIAL SEPTAL DEFECT (ASD) / PATENT FORAMEN OVALE (PFO) CLOSURE CONSENT

PLEASE READ THE FOLLOWING INFORMATION

You have been referred to Eastern Heart Clinic for the closure of an Atrial Septal Defect (ASD) or a Patent Foramen Ovale (PFO). An ASD and a PFO are an abnormal communication (hole) between the two top chambers of the heart. These are known as the right and left atria.

Your procedure may be undertaken using either sedation or an anaesthetic, you will be advised of this by your Doctor. To close an ASD or PFO you are given some local anaesthetic in your groin. Once the area is anaesthetised a small tube is placed in the femoral vein. Through this tube the device to close the ASD or PFO is passed up to the atrial chambers and the device is placed across the hole. There are some risks involved in this procedure that you need to be aware of. There is a chance (1 in 200) of the device dislodging, a chance (1 in 100) of an irregular but temporary heartbeat and a rare risk of infection. There is also a very small risk of bruising around the puncture site and / or bleeding from the hole in the vein.

The successful closure of an ASD or PFO requires you also to undergo a Transoesophageal Echo (T.O.E.). A T.O.E. is a test that allows your doctor to look closely at the inside of your heart using ultrasound. The purpose of the T.O.E. is to ensure the correct position of the device. You will be given some sedation to help you relax prior to the T.O.E. and you will receive some local anaesthetic spray to the back of your throat. An ultrasound probe (tube) is passed into the food pipe (oesophagus) so that your doctor can visualise the chambers of your heart. A T.O.E. is a relatively simple procedure with a rare risk (1 in 5000) of oesophageal perforation.

These procedural risks will vary between individuals and depend on pre-existing risk factors and medical conditions so please discuss these issues with your Doctor if you are concerned. Your Cardiologist believes that the benefit of the procedure outweighs the risks outlined.

For this procedure we may have supplier representatives present to assist during the procedure.

CONSENT

Procedure 1: Transoesophageal Echo

I have read the above information and had the opportunity to ask questions and I am happy with the response. I hereby give my consent to undergo a Transoesophageal Echo (T.O.E.).

Patient / Guardian: _____ / _____ / _____
Signature Print Name Date

Doctor: _____
Signature Print Name

Interpreter: _____
Signature Print Name

Procedure 2: ASD / PFO Closure

I have read the above information and had the opportunity to ask questions and I am happy with the response. I hereby give my consent to undergo an ASD or PFO closure.

Patient / Guardian: _____ / _____ / _____
Signature Print Name Date

Doctor: _____
Signature Print Name

Interpreter: _____
Signature Print Name

FURTHER PATIENT DECLARATION

I have received a copy of the "Outcome Data Information Sheet" and I have read and understood my Rights and Responsibilities.

Patient / Guardian: _____
Signature Print Name