



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent: Intracardiac Echocardiogram and Placement of Septal Occluder Device

This information is given to you so that you can make an informed decision about having an **Intracardiac Echocardiogram and Placement of Septal Occluder Device**. This procedure is most often done with moderate sedation or anesthesia.

Reason and Purpose of this Procedure:

A patent foramen ovale (PFO) or atrial septal defect (ASD) is a hole between the top two chambers of the heart. These chambers are known as the right and left atria. The purpose of this procedure is to seal a patent foramen ovale (PFO) or atrial septal defect (ASD). The device used to close the hole is a septal occluder device. This procedure will lower your stroke risk and stop the flow of blood between the top chambers of your heart. You will not need to take blood thinner medicine. Before the procedure an Intravenous (IV) line will be placed. This will allow medicines to be given during the procedure. The anesthesiologist will talk to you before the procedure.

- The procedure will be done in an x-ray room in the cath lab. You will be lying on an x-ray procedure table.
- Your groin will be cleaned with antiseptic. The area will be covered with sterile towels. This is done to prevent infection.
- A **right heart catheterization** is done to place the septal occluder device in the hole you have in your heart between the two chambers.
- The doctor will give you a local anesthetic in this area. The doctor will insert a small hollow tube in the blood vessel. This hollow tube will allow the doctor to place longer hollow tubes called catheters into the blood vessel.
- The catheter will be moved into the heart. The doctor uses x-ray and ultrasound to guide the placement of the device to close the ASD or PFO. It is passed up to the inside of the heart and placed across the hole. A series of pictures are taken using x-rays and x-ray dye.
- An **intracardiac echocardiogram** is an ultrasound picture of your heart. A tube (catheter) is passed up into your heart. At the end of this tube is a transducer that allows your doctor to perform the ultrasound from inside your heart.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Stroke risk reduction without need for long-term blood thinners.
- Stop abnormal blood flow between the top two chambers of your heart.

Risks of the Procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- Bruising and/or swelling at the puncture site. This may need surgery.
- Blood loss. Fluids or a blood transfusion may be needed.
- Heart rhythm problems. Fluids and medicine may be needed.
- Infection. Medicine or other treatment may be needed.
- Stroke. Rehabilitation may be needed.
- Allergic reaction to the contrast or dye. Fluids and /or medicines may be needed.
- Loss of kidney functions due to use of dye. This may require fluids and medicines or other treatments.
- Embolism. This is a clot that forms and breaks off from the catheter. This may require blood thinners.

- Fever, headache or migraine. This may require medicines.
- Reaction to the anesthetic may occur. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- Migration or movement of the device. This may need surgery to remove.
- Tear in the esophagus, vein or heart. This may need surgery.
- Other tests or treatment may be needed.
- Air bubble (embolism) – this may cause a stroke and you may need medicine and rehabilitation
- Death may occur.

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to You:

Alternative Treatments:

Other choices:

- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- You will need to take blood thinners to reduce your stroke risk.
- Bleeding risk related to taking blood thinners will remain high.

Information on Moderate Sedation:

You will be given medicine in an IV to relax you. This medicine will also make you more comfortable. This is called “moderate sedation”. You will feel sleepy. You may even sleep through parts of your procedure. We will monitor your heart rate and your blood pressure. We will also monitor your oxygen level.

If your heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may be unable to reverse the sedation. We may need to support your breathing.

Even if you have a NO CODE status:

- You may need intubation to support your breathing.
- You may need medications to support your blood pressure.

We will re-evaluate your medical treatment plan and your NO CODE status when sedation has cleared your body.

Benefits of Moderate Sedation:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Less pain during the procedure.
- Less anxiety or worry.
- Decreasing your memory of the procedure.

Risks of Moderate Sedation:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect. The list includes:

- Decreased breathing during the procedure and dropping oxygen levels. To help you breathe, a tube may be placed into the mouth or nose and into the trachea to help you breathe.
- Allergic reactions: nausea & vomiting, swelling, rash.
- Vomit material getting into the lungs.
- A drop in blood pressure. This needs fluids or medicine to increase blood pressure.
- Heart rhythm changes that may require medicines to treat.
- Not enough sedation or analgesia resulting in pain or discomfort.

Your physical and mental ability may not be back to normal right away. You should not drive, or make important decisions for at least 24 hours after the procedure.

General Information:

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be taken during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

Medical Implants/Explants

I agree to release my social security number, my name and address, and my date of birth to the company that makes the medical device that is put in or removed during this procedure. Federal laws and rules require this. The company will use this information to locate me.

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By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
 - I understand its contents.
 - I have had time to speak with the doctor. My questions have been answered.
 - I want to have this procedure: **Intracardiac Echocardiogram and Placement of Septal Occluder Device** _____
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- I understand that my doctor may ask a partner to do the procedure.
 - I understand that other doctors, including medical residents or other staff may help with the procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to procedure. If so, please obtain consent for blood/products.

Patient Signature: _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian/POA Healthcare

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: _____ ID #: _____ Date: _____ Time: _____

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back:

Patient shows understanding by stating in his or her own words:

_____ Reason(s) for the treatment/procedure: _____

_____ Area(s) of the body that will be affected: _____

_____ Benefit(s) of the procedure: _____

_____ Risk(s) of the procedure: _____

_____ Alternative(s) to the procedure: _____

OR

_____ Patient elects not to proceed: _____ Date: _____ Time: _____

(Patient signature)

Validated/Witness: _____ Date: _____ Time: _____