



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent: Placement of Left Atrial Appendage Occluder Device with Trans-esophageal Echocardiogram (TEE)

This information is given to you so that you can make an informed decision about having: **Placement of Left Atrial Appendage Occluder Device with Trans-esophageal Echocardiogram (TEE)**. This procedure is done using **general anesthesia**.

Reason and Purpose of this Procedure:

The purpose of this procedure is to seal the left atrial appendage in your heart. This will lower your risk of stroke without the need to take blood thinning medicine. Before the procedure an intravenous (IV) line will be placed. This allows medicines to be given during the procedure. The anesthesiologist will talk to you before the procedure.

- **A right heart catheterization with a transeptal puncture** is performed to place the Left Atrial Appendage Occluder device in your heart.
- The procedure is done in an x-ray room in the cath lab. You will be lying on a procedure table.
- Your groin area will be cleaned with antiseptic and covered with sterile towels. This is done to prevent infection.
- The doctor will give you a local anesthetic in this area. A small hollow tube is inserted in the blood vessel.

This hollow tube allows the doctor to place longer hollow tubes called catheters into the blood vessel. The catheter will be moved toward the heart. Using x-ray and ultrasound as guides, a needle is placed through the hollow tube in order to cross from the right side of the heart to the left side. X-ray dye is then injected into the area of the heart where the device will be placed. Using x-ray and ultrasound, the device will then be placed into the left atrial appendage and opened. Once a proper seal is confirmed, the device will be left in place.

This procedure also uses Trans-esophageal echocardiography (TEE) to take a picture of your heart using an ultrasound test. A camera-like tube, about the thickness of a finger, is placed into your mouth and into your esophagus (the tube that connects the mouth to the stomach). Placing the camera-like tube into the esophagus provides pictures that are more detailed. The camera-like tube is able to get a better picture because it is closer to the heart. The view is not blocked by other parts of the body such as ribs and lungs.

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.

- Less risk of stroke without need for taking blood thinning medicine.

Risks of this 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.

The risks may include:

- Bruising and/or swelling at the puncture site. This may need surgery.
- Blood loss. Fluids or possibly 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.

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- Loss of kidney functions due to use of dye. This may require fluids and medicines or other treatments.
- Emergency surgery.
- Heart perforation may occur, which could require a drainage catheter or surgical intervention.
- Death may occur.
- 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 require surgery to remove.
- Damage to teeth and gums or esophagus.

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:

- Your stroke and or bleeding risk will remain elevated.

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 done 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: **Placement of Left Atrial Appendage Occluder Device with a Trans-esophageal Echocardiogram (TEE)**_____
- 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 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: _____