



Affix Patient Label	
Patient Name:	Date of Birth:

**Informed Consent: Implantable Loop Recorder**

This information is given to you so that you can make an informed decision about having an **Implantable Loop Recorder**. This procedure is most often done with moderate sedation or anesthesia.

**Reason and Purpose of this Procedure:**

A small device is inserted under your skin below the collar bone usually on the left side of your chest. This device may help to find the cause(s) of your passing out or other heart rhythm issues. Certain heart abnormalities can cause passing out, such as abnormal heartbeats.

This device will record your heart activity for up to two years. If you were to pass out, the device will save the recording before, during, and after your episode. The recordings can then be read by your doctor to help find out why you are passing out.

**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.

- Benefits may include being able to find the problem and decide treatment.

**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.

- Bruising and/or swelling at the puncture site. This may need surgery.
- Blood loss. Fluids or a blood transfusion may be needed.
- Abnormal heart rhythms. Fluids, medicines or permanent pacing may be needed.
- Infection. Antibiotics or other treatment may be needed.
- Reactions to medicines or other substances used during the procedure.
- Additional tests or treatment may be needed.
- Emergency surgery may be needed.
- Your doctor may not be able to place the device in the chosen location.
- 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.

**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:**

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**Alternative Treatments:**

Other choices:

- Medicine and/or observation by your physician.
- Do nothing. You can decide not to have the procedure.

**If you Choose not to have this Treatment:**

- Your symptoms or heart rhythm may worsen.

**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.



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**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.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

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: **Implantable Loop Recorder** \_\_\_\_\_
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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: \_\_\_\_\_