BRONSON

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** with moderate sedation or anesthesia.

Reason and Purpose of the 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 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.

Risks of this procedure:

- 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.

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.

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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:

- 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.

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 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: **Implantable Loop Recorder with Moderate Sedation or Anesthesia** _____

  _____
- 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 surgery. 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 surgery. 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: _____