



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent: Device Lead Revision

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

Reason and Purpose of this Procedure:

A lead attached to your device needs to be replaced. A small cut is made in the chest after it is numbed. Your doctor inserts pacer lead(s) through a vein in your chest that is connected to your heart. These leads are reconnected to a pacemaker. It is then inserted into a pocket made under the skin.

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.

- Your heart may beat normally.
- Symptoms may get better. These may include:
 - Tiredness.
 - Shortness of breath.
 - Dizziness.
 - The feeling of your heart beating hard in your chest.

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.
- Heart attack.
- Heart rhythm disturbances. You may need fluids and medicine.
- Infection. Antibiotics or other treatment may be needed.
- The device or equipment used to do the procedure may fail.
- Stroke.
- The procedure may not cure or relieve your condition.
- Additional tests or treatment may be needed.
- Your doctor may not be able to place the device in the desired location.
- Pneumothorax, also known as a lung puncture. Emergency surgery may be needed.
- Emergency surgery.
- 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:

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.

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: **Device Lead Revision** _____
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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: _____