



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent: Open Heart Surgery with Heart-Lung Machine and Transesophageal Echocardiography

This information is given to you so that you can make an informed decision about having **Open Heart Surgery with Heart-Lung Machine and Transesophageal Echocardiography** and one or more of the following special procedures:

- Coronary Artery Bypass Grafting
- (Left/Right)Radial Artery Harvest
- Aortic Valve Replacement
- Mitral Valve Repair or Possible Replacement
- Ligation/Excision Left Atrial Appendage
- Pulmonary Vein Isolation (Epicardial Maze)
- MAZE IV (includes Left Atrial Appendage Ligation)
- Tricuspid Valve Repair

Reason and Purpose of this Procedure:

Your cardiologist and heart surgeon have determined that the best way to treat your heart condition is to have open heart surgery with heart-lung machine and transesophageal echocardiography.

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.

- Lower risk of death related to your heart condition.
- Reduce or eliminate symptoms of heart pain (angina), fatigue, shortness of breath.
- Reduce or eliminate heart related fluid retention (congestive heart failure).

General Risks of Procedures:

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.

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- 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.
- Bleeding may occur. If bleeding is excessive, you may need a transfusion. Uncontrollable bleeding may lead to another procedure to find the source of bleeding and control it at the site.
- 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 of this Procedure:

- **Wound infection.** You may need antibiotics, wound care, or other procedures.
- **Major heart attack or heart failure.** You may need additional support from medications or mechanical heart pumping assist devices.
- **Abnormal heart rhythm.** You may need treatment with medications, temporary pacemaker, or permanent pacemaker.
- **Stroke.** This could lead to minor or major disability.
- **Risk of pneumonia.** You may need antibiotics and breathing treatments. In rare cases, you may need longer-term ventilator support.
- Other lung complications. A weak diaphragm, collapsed lung, or fluid buildup in the lungs may require drainage or inhaled oxygen. Severe lung complications could lead to additional ventilator support or temporary tracheostomy.

- **Temporary brain dysfunction** such as confusion.
- **Kidney complications.** You may need temporary or permanent dialysis.
- **Liver dysfunction** such as elevated blood markers. These usually return to normal as you heal.
- **Gastrointestinal complications.** In rare cases, bleeding of the stomach can occur. You may also experience muscle weakness and need an alternate route of feeding.
- **Nerve damage.** Peripheral nerve injury could occur causing hand numbness or pain.
- **Body mal-alignment.** Back, shoulder, or joint pain or injuries caused by the way you are positioned for surgery.
- **Medication reaction.** Reactions to many medications including heparin blood thinner may occur. This may lead to abnormal clotting.
- **Death.**

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:

- High-risk/non-standard percutaneous coronary intervention (PCI).
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- Symptom progression.
- Death or sudden cardiac arrest.

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 salespeople 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: **Open Heart Surgery with Heart-Lung Machine and Transesophageal Echocardiography** and one or more of the following special procedures:
 - Coronary Artery Bypass Grafting
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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

Reason patient is unable to sign: _____ Telephone Consent Obtained

First Witness Signature: _____ Second Witness Signature: _____ Date: _____ Time: _____
 (One witness signature MUST be from a registered nurse (RN) or provider)

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: _____