



Affix Patient Label

Patient Name:

Date of Birth:

## **Informed Consent: Transaortic Transcatheter Aortic Valve Replacement (TAVR) Procedure**

This information is given to you so that you can make an informed decision about having **Surgical Access and Repair, Balloon Aortic Valvuloplasty, and Transcatheter Aortic Valve Replacement.**

### **Reason and Purpose of this Procedure:**

This is done to treat severe aortic stenosis which is a disease of the heart valves where the opening of the aortic valve is narrowed. This is for non-open heart surgical candidates.

A surgical cut is made in your chest wall. A catheter (long thin tube) is inserted into your aorta and passed into your aortic valve. Once the catheter is in the valve, x-ray dye is added through the catheter and x-rays are taken.

Then, a valvuloplasty (which makes your own valve bigger) will be performed. A balloon is placed in the narrowing of the valve. It will then inflate to open up the narrow valve. Once the aortic valve is bigger, the stented valve will be opened within your own valve. Several attempts may be needed.

Heparin (blood thinning medication) will be given to prevent blood clots from forming.

The aortic valve (a valve in the heart that stops blood from flowing from the aorta back into the heart) may be replaced.

### **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.

- Improved quality of life.
- Relief of symptoms associated with severe aortic stenosis.

### **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.
- A strain on the heart or a stroke may occur.
- Bleeding may occur. If there is a lot of bleeding, you may need a transfusion.
- 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. General anesthesia will be used.

### **Risks of this Procedure:**

- Respiratory failure. This happens to 10 out of 100 patients. You may need to be on a ventilator.
- High blood pressure or low blood pressure. This happens to 9 out of 100 patients. You may require medications.
- Stroke. This happens to 7 out of 100 patients. You may need rehabilitation.
- Heart failure. This happens to 5 out of 100 patients. You may need medications.
- Death. This happens to 5 out of 100 patients. You are not a candidate for open chest valve replacement. If complications occur during this procedure that do not allow us to place the valve or if the valve tears the aorta, you will not be offered emergency open chest aortic valve replacement. As a result, it is possible you will not survive the procedure.

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- Hematoma (collection of blood) or changes at your entry site. This happens to 5 out of 100 patients. You may need treatment.
- Blood vessel blockage. This happens to 3 out of 100 patients. You may need treatment.
- Chest pain. This happens to 2 out of 100 patients. You may need further treatment.
- Aortic valve reintervention. This happens to 2 out of 100 patients.

**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:

- Do nothing. You can decide not to have the procedure.
- Continue treatment with medications.

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

- Your symptoms will continue and get worse.
- You may die sooner than someone without severe aortic stenosis.

**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.



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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: **Surgical access and repairs, balloon aortic valvuloplasty, transcatheter aortic valve replacement (TAVR)** \_\_\_\_\_
- 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: \_\_\_\_\_