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Transcatheter Heart Valve Replacement with the ACURATE™ Aortic Valve Platform

A Guide for Patients and Their Families

The ACURATE *neo2*™ and ACURATE *Prime*™ Valves are investigational devices and only available to you as part of the ACURATE IDE clinical trial. Please refer to the ACURATE IDE Informed Consent Form for all information related to the possible risks and side effects of taking part in this study.

Your cardiologist has recommended transcatheter aortic valve replacement (TAVR) to treat your severe aortic valve stenosis.

This guide is meant to help you understand more about the TAVR procedure and the investigational ACURATE™ Aortic Valve Platform that may be used to replace your diseased valve.

After reviewing this information, be sure to discuss any questions you have with your cardiologist or your study doctor.

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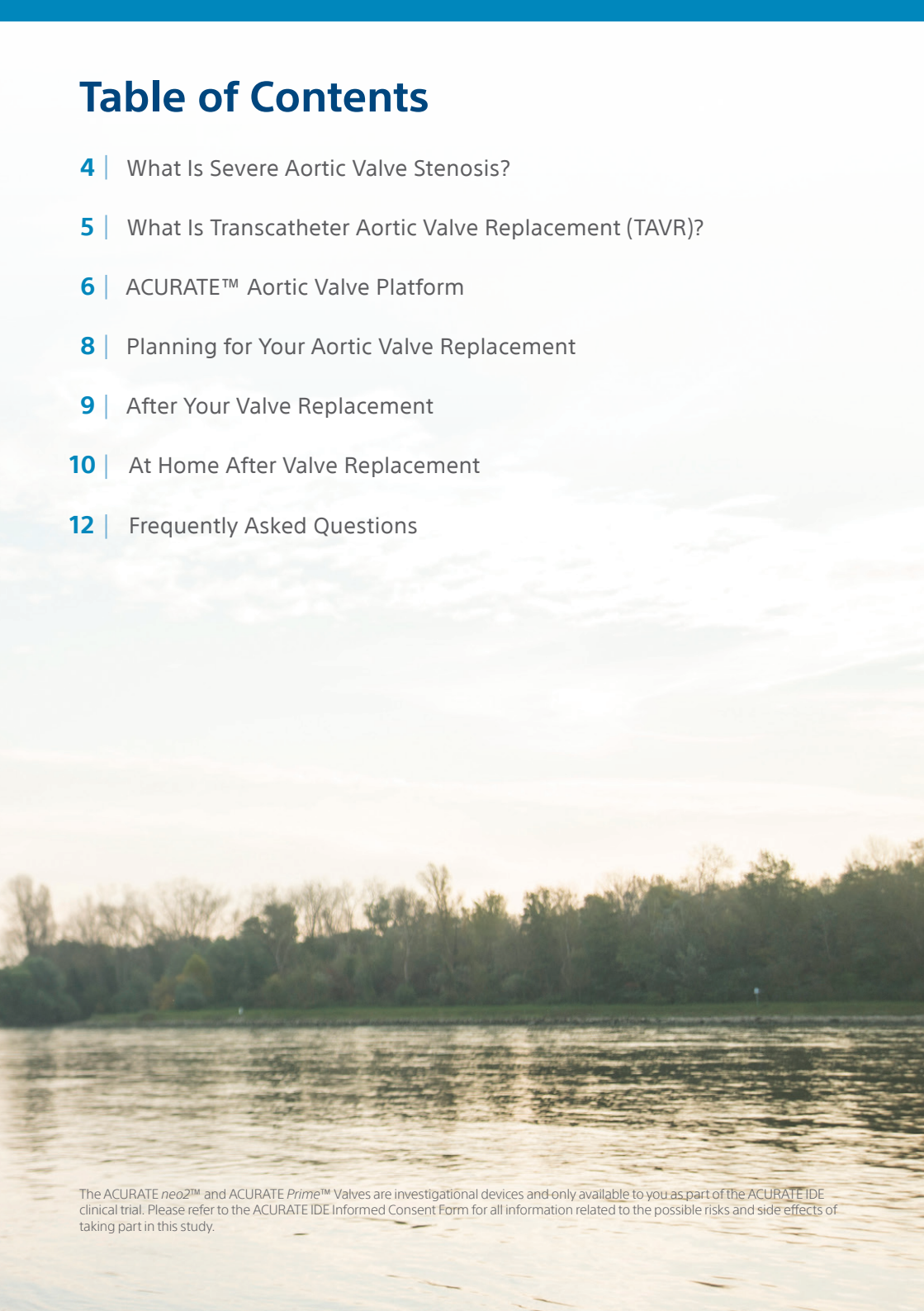

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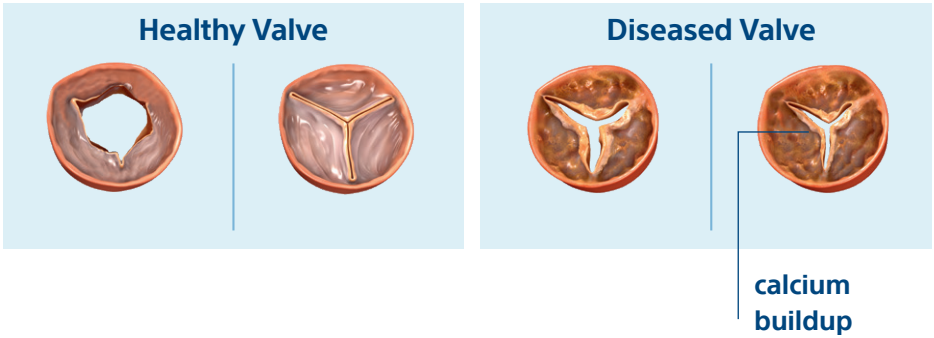
What Is Severe Aortic Valve Stenosis?

Severe aortic valve stenosis is the significant narrowing of the aortic valve opening. Over time, the valve leaflets can become stiff, reducing their ability to fully open and close, thus restricting blood flow out of the heart. When this happens, your heart must work harder to move blood throughout the body. This additional workload may eventually overwhelm the heart and cause it to fail.



The symptoms most frequently associated with **severe aortic valve stenosis** include:

- **Shortness of breath**
- **Chest pain, pressure, or tightness**
- **Fatigue**
- **Feeling lightheaded or dizzy**
- **Difficulty when exercising or completing day-to-day activities**

The only effective treatment for severe aortic valve stenosis is to replace the aortic valve. If the diseased valve is not replaced, your symptoms will probably worsen to heart failure and possibly even death.

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What Is Transcatheter Aortic Valve Replacement?

Transcatheter aortic valve replacement (TAVR) is a nonsurgical procedure to replace the aortic valve *without* open-heart surgery. To access your heart, your doctor will make a small incision in your artery and insert a small, hollow tube.

Although the femoral artery in your groin is often chosen, there are arteries in the chest and neck that lead to the heart as well.

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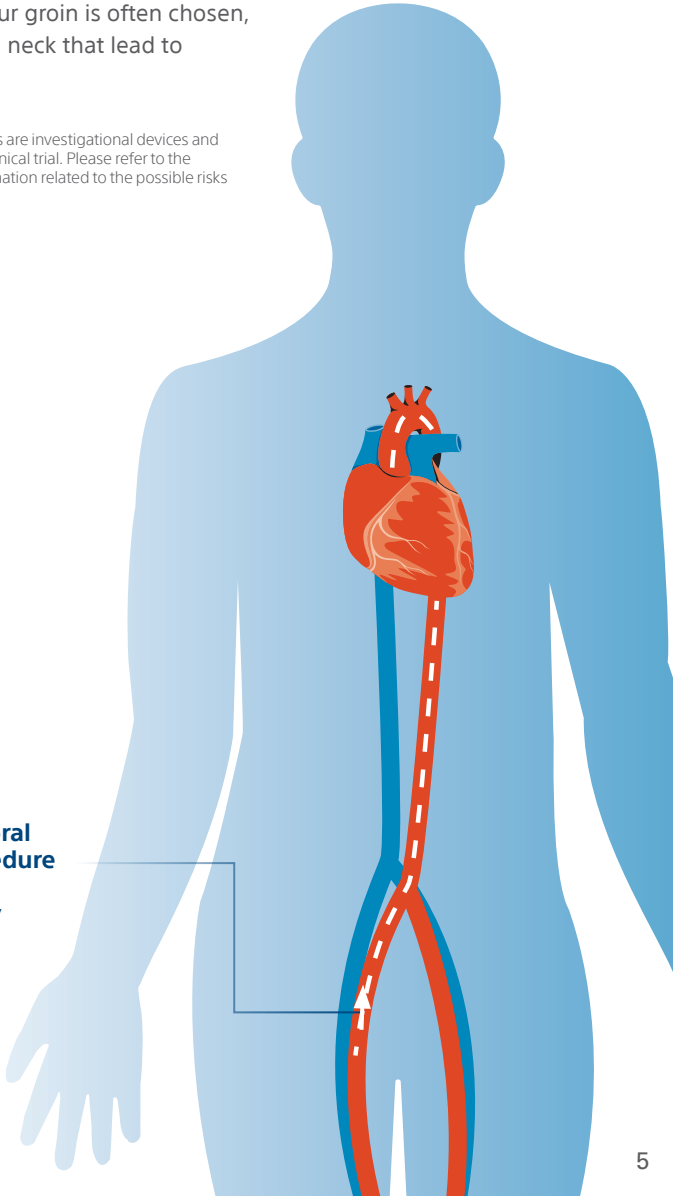

Transfemoral TAVI procedure
through the femoral artery in the groin

The ACURATE™ Aortic Valve Platform

The ACURATE™ Aortic Valve Platform is made up of a stent-like valve frame and animal tissue leaflets. It is placed within the diseased aortic valve to restore proper valve function. You could receive either the ACURATE *neo2*™ Aortic Valve or the ACURATE *Prime*™ Aortic Valve XL depending on the size of your diseased aortic valve. Sizing is determined using CT imaging during the screening process.

What makes the ACURATE™ Aortic Valve Platform unique?

ACURATE *neo2*
(Available in S, M, L*)

ACURATE *Prime*
(Available in XL*)

*Pictures are for illustrative purposes and not indicative of actual valve size.

It is designed to softly expand and **adapt to your valve anatomy**, fitting right into your native valve.

A special seal outside of the valve is designed to **minimize the risk of blood leakage** outside the valve frame.[1]

[1] Limited clinical data have shown a numerical decrease in frequency and severity of blood leakage (paravalvular leak) for newer iterations of the ACURATE™ Aortic Valve Platform.

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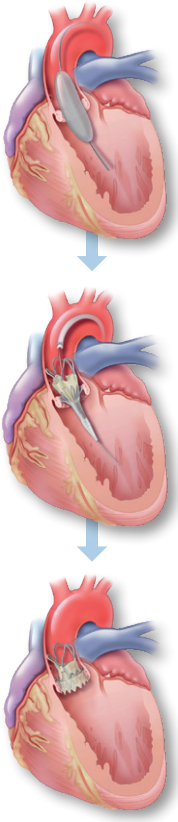
The TAVR Procedure with ACURATE™ Aortic Valve Platform

During the TAVR procedure, your doctor will use special X-ray equipment to guide the positioning and placement of the new valve. For the most common transfemoral valve replacement, your doctor will make a small incision in your artery at the groin and insert a small, hollow tube catheter.



Step 1

A special balloon is placed within the aortic valve and then inflated to stretch open your narrowed aortic valve. The balloon is then removed.

Step 2

The artificial valve is compressed onto a catheter that travels through your body to your heart, inside a large artery that leads to your diseased aortic valve.

Step 3

Your doctor will expand the valve, pushing the impaired parts of the aortic valve out of the way.

Step 4

The new valve will begin to function immediately and restore blood flow. Once the valve is in place, your doctor will remove the catheter.

Most people begin feeling better and can resume normal everyday activities soon after a TAVR procedure. How quickly you recover and return to your daily routine depends upon your overall state of health.

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Planning for Your Aortic Valve Replacement

Before Your Procedure

You will be asked to sign an Informed Consent Form prior to your procedure. This document will provide you with all of the necessary information on the procedures and risks involved with receiving an ACURATE™ Aortic Valve Platform (which is only available for you as part of the ACURATE IDE clinical trial).

Talk with your cardiologist and study doctor about any medications you are taking. They will advise whether you need to stop taking any of these medications prior to your procedure.

Also talk with your cardiologist, study doctor, and care team about any planned medical or dental procedures you need in the coming weeks, as this may affect timing for your procedure.

It is helpful to arrange for a family member or caregiver to help at home for the first few days after the procedure.

Your care team will give you specific instructions on eating and drinking prior to the procedure.

Notes:

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After Your Valve Replacement

The time spent in the hospital will depend upon how quickly you recover.

You will be prescribed blood-thinning medications as required by the clinical trial protocol. Take these as prescribed, even after you leave the hospital.

Before leaving the hospital, you will be given instructions regarding follow-up study appointments. Ask questions if you have any concerns about your new heart valve, medications you'll be taking, or the clinical trial follow up requirements.

If you have any medical events that occur in between your follow up appointments, it is important to inform your study doctor.

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At Home After Valve Replacement

After your TAVR procedure, there are some important things to keep in mind.

Medications: Call your study doctor if you encounter any problem with medications. Do not stop taking any of the prescriptions without talking to your study doctor.

Post-procedure study doctor visits: Successful recovery requires keeping scheduled visits with your study doctor. Your study doctor will check how well your heart is working, your healing, and your overall health.

Identification card: You will receive an identification card with information about your implanted heart valve. Always carry this card with you. Be sure to share this information with all of your healthcare providers.

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When to seek medical attention:
Seek immediate medical attention by going to an emergency room near you or by calling the emergency number if you experience:

- Chest pain or trouble breathing
- Sudden numbness or weakness in your face, arms, or legs
- A bowel movement that is dark black or bright red
- Dizziness or fainting
- Swelling in your hands, feet, or ankles
- Shortness of breath that doesn't get better by resting

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Talk with your cardiologist or study doctor about any questions you have regarding the treatment for severe aortic valve stenosis.

Frequently Asked Questions

Will I feel the valve?
Once the device is placed and the access site is healed, you will not feel the device. If you feel anything abnormal, please contact your study doctor.

Will the valve cause problems with metal detectors or interfere with future X-ray procedures?
No, the device will not set off a metal detector. The device is visible on X-ray but will not hamper the ability to perform future medical imaging procedures. However, you should notify your doctor that you have an artificial valve, especially before you have X-rays, CT scans, or MRI scans.

How often should I see my doctor?
Your study doctor will tell you how often you need to be seen and explain any special symptoms you should look for.

Is the ACURATE™ Aortic Valve Platform device sterile?
Yes, the artificial valve is not a live tissue implant. The valve has been processed and sterilized prior to being placed into the body.

Will the ACURATE™ Aortic Valve Platform device rust?
No, the device is made from a special medical-grade alloy that will not rust.

Can the ACURATE™ Aortic Valve Platform valve crush, bend, or move out of place?
Deformation or migration is possible but rare.

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