

Transcatheter Heart Valve Replacement

with the
LOTUS *Edge*™
Aortic Valve System



**A Guide for Patients
and their Families**



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

This guide is to help you understand more about the TAVR procedure and the LOTUS *Edge*™ Aortic Valve System that may be used to replace your diseased valve.

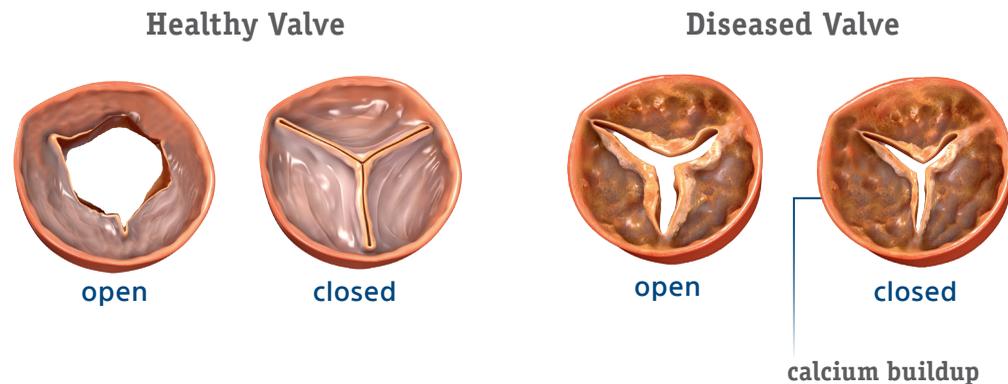
After reviewing this information, be sure to discuss any questions you have with your heart team.

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What Is Severe Aortic Stenosis?

Severe aortic stenosis is 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 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 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.

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, flexible, hollow tube.

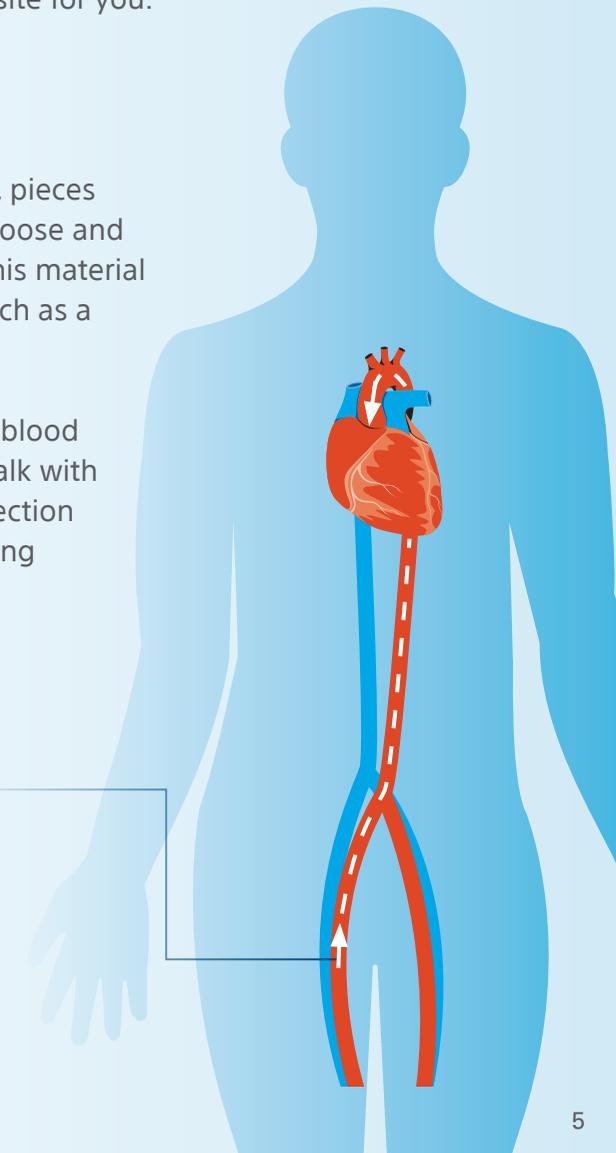
Although the femoral artery in your groin is often chosen, there are arteries in the chest and neck that lead to the heart as well. Because each patient's anatomy is unique, your doctor will select the best access site for you.

Stroke Risk Reduction

During the aortic valve replacement procedure, pieces of the calcified heart valve or tissue can break loose and travel in the bloodstream toward the brain. If this material reaches a vital organ serious consequences, such as a stroke, may occur.

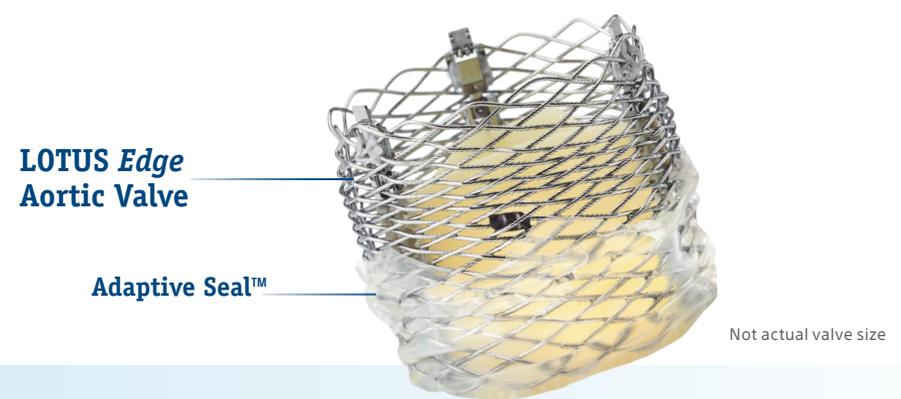
This material could cause a stroke, by blocking blood flow to the brain causing long-term damage. Talk with your heart team about a cerebral embolic protection system that may reduce your risk of stroke during your TAVR procedure.

Transfemoral TAVR procedure
through the femoral artery in the groin



The LOTUS *Edge*™ Aortic Valve System

The LOTUS *Edge* valve is made up of a wire valve frame and bovine (cow) animal tissue leaflets. It is placed within the diseased aortic valve to restore proper valve function.



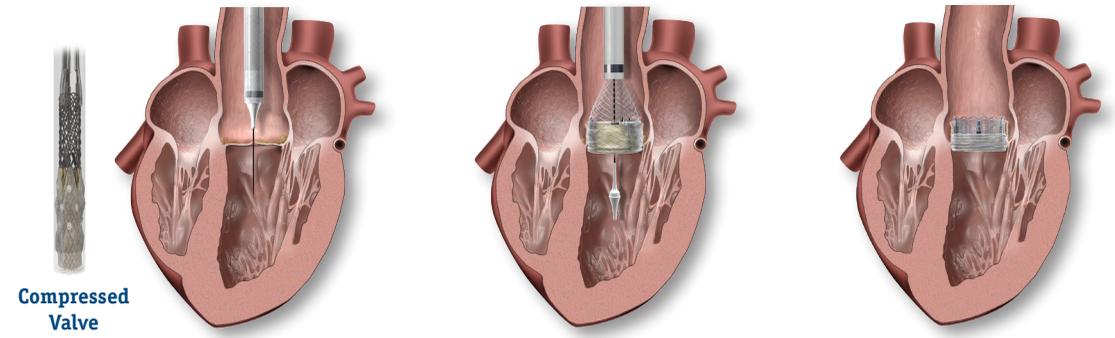
What makes the LOTUS *Edge* valve unique?

It is the only aortic replacement valve on the market that is **100% repositionable**. This enables your doctor to precisely place the new valve into an optimal position within your heart.

The LOTUS *Edge* valve has a **special Adaptive Seal** around the outside of the valve frame to help reduce any leakage of blood around the outside of the valve. This leakage, if it occurs, is called paravalvular leak, or PVL. PVL can lead to future complications.

The TAVR Procedure with LOTUS *Edge*

During the TAVR procedure, your doctor will use special X-ray equipment to guide the positioning and placement of your valve.



Step 1
The artificial valve is compressed onto a hollow catheter that travels through a large blood vessel to your diseased aortic valve.

Step 2
Your doctor will expand the artificial valve, pushing the diseased aortic valve leaflets out of the way.

Step 3
Your new valve will begin to function immediately and restore healthy blood flow. Once the valve is in place, your doctor will remove the catheter, close the incision, and transfer you to the recovery area.

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.

Planning for Your Aortic Valve Replacement

Before Your Procedure

Talk with your heart team about any medications you are taking. They will advise whether you need to stop taking any of these medications prior to your procedure.

Also discuss any planned medical or dental procedures you need in the coming weeks, as this may affect timing for your valve replacement.

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

Your heart team will give you specific instructions on eating and drinking prior to your valve replacement procedure.

Notes from my Heart Team



After Your Valve Replacement

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

You may be prescribed blood-thinning medications. Take these as prescribed by your doctor, even after you leave the hospital.

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



At Home After Valve Replacement

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

Medications

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

Post-procedure Doctor Visits

Successful recovery requires keeping scheduled visits with your doctor. Your doctor will check how well your heart is working, your healing and your overall health. You can expect to visit the heart team 30 days and one year after your procedure.

Identification Card

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

When to Seek Medical Attention

Seek immediate medical attention by going to an emergency room near you or by calling 911 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

Talk with your heart team about any questions you have regarding the treatment for severe aortic stenosis.

For more information about aortic stenosis and treatment options, visit

[TreatTheHeart.com](https://www.treattheheart.com)

Frequently Asked Questions

Will I feel the replacement valve?

Once the device is in place and the access site is healed, you will not feel the device. If you feel anything abnormal, please contact your heart team.

Will the replacement 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 heart team will tell you how often you need to be seen and explain any special symptoms you should look for.

Is the LOTUS Edge™ 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 LOTUS Edge device rust?

No, the device is made from a special medical-grade alloy that will not rust.

Can the LOTUS Edge valve crush, bend or move out of place?

Deformation or migration is possible but rare.





Precautions and Warnings

Patients typically stay on blood-thinning medication for six months after the procedure. Your doctor may recommend you take aspirin for the rest of your life to minimize risk of developing a dangerous blood clot. Blood-thinning medications increase the risk of bruising and may increase the risk of serious bleeding. For patients who are unable to tolerate blood-thinning medications, who have an active infection in the heart or elsewhere in the body, or who have allergies to dye that is injected during the procedure, the LOTUS Edge™ valve system should not be used. Not all risks or complications can be predicted.

Clinical research data on TAVR is continuing to accumulate, but there are still gaps; the safety of the LOTUS Edge valve is not known for patients who have:

- An existing artificial aortic heart valve or a previously implanted device in any heart valve
- A weak or enlarged heart
- An aortic valve that has been malformed since birth
- A diseased aortic valve where the main problem is leakage or calcium deposits on the leaflets that may block blood supply to the heart
- Patients with abnormalities in their heart, blood vessels or other valves
- Low white or red blood cell count or other blood abnormalities
- Aortic or arterial vessels that are heavily diseased or too small for device delivery

Important Contact Information

Valve Clinic Coordinator:

Name:

Phone:

Interventional Cardiologist OR Cardiac Surgeon:

Name:

Phone:

My Cardiologist:

Name:

Phone:

My Primary Care Physician:

Name:

Phone:

My Pharmacy:

Name:

Phone:

Other Phone Numbers:

Name:

Phone:

The LOTUS *Edge*™ Aortic Valve is a permanent implant designed to improve the aortic valve function for patients with severe calcific aortic stenosis who are at high risk for standard surgical valve replacement.

Risks are associated with all medical implantation procedures. The risks include but are not limited to:

- Access site complications, typically in the groin, including arteriovenous fistula, hematoma or lymphatic problems
- Allergic reaction to device or procedural materials
- Arrhythmia, abnormal heart beats, or new conduction system injury including need for permanent pacemaker
- Heart attack or heart failure
- Stroke, transient ischemic attack (TIA), cerebral infarction or neurologic deficits
- Death
- Clotting in the blood stream or thrombosis (including air, tissue, thrombus or device fragments)
- Heart tissue or valvular injury
- Permanent disability
- Fluid in the space that surrounds the lungs or heart
- Kidney failure or damage
- Difficulty breathing
- Damage to the artificial valve causing stenosis or regurgitation.

These complications may require additional medical, percutaneous or surgical intervention, including re-operation and replacement of the valve. These complications may be very serious and possibly fatal.

Be sure to talk with your doctor so that you thoroughly understand all the risks and benefits associated with the implantation of the LOTUS *Edge* Aortic Valve Device.

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