

Aortic Valve Replacement with Protected TAVR:

A guide for patients and their families





If you've been diagnosed with severe aortic stenosis, you probably have a lot of questions and concerns. The information in this booklet will help you learn more about your heart, severe aortic stenosis, and treatment options.

This guide will help you ask your heart team about the best treatment options for you. Please talk with them about any questions you have.

In This Guide

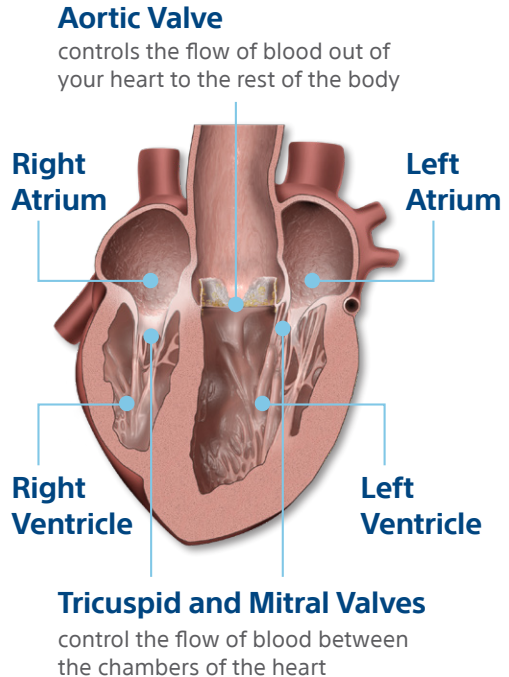
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About Your Heart

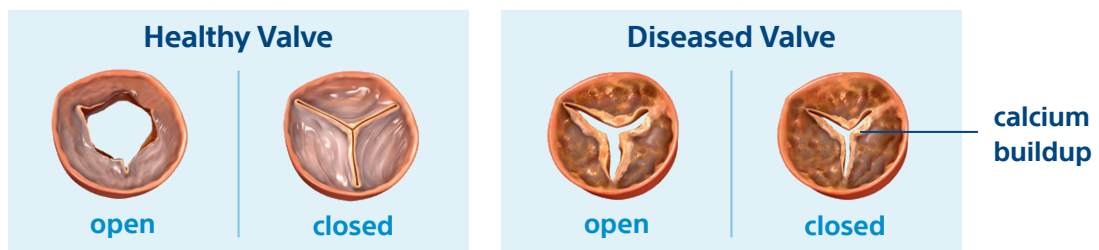
The heart is a muscle about the size of your fist. It is a pump that works nonstop to send oxygen-rich blood throughout your entire body.

The heart is made up of four chambers and four valves. The contractions (heartbeats) of the four chambers push the blood through the valves and out to your body.

The aortic valve is made up of two or three tissue flaps, called leaflets. Healthy valves open at every heart contraction, allowing blood to flow forward to the next chamber, and then close tightly to prevent blood from backing up. Blood flows in one direction only. This is important for a healthy heart.



What Is Severe Aortic Stenosis?

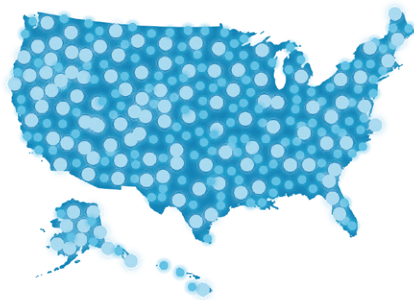


Severe aortic stenosis occurs when the valve leaflets become stiff, reducing their flexibility and ability to fully open and close properly. This results in a narrowing (stenosis) of the valve opening. This narrowing reduces and restricts blood flow, requiring your heart to work harder. As a result, less oxygen-rich blood flows from your lungs to the brain and the rest of your body.

Who Is Affected By Aortic Stenosis?

Severe aortic stenosis is an age-related, progressive disease. It can be caused by a congenital heart defect, rheumatic fever, or radiation therapy. The most common cause is the gradual buildup of calcium (mineral deposits) on the leaflets of the aortic valve.

Affecting about 7% of all people over the age of 65, aortic stenosis is the most common valvular heart disease in the world.¹



**An estimated
1.5 MILLION people in the U.S.
suffer from aortic stenosis.²**

**500,000 of those people
have a severe condition.²**

What Are The Symptoms?

An estimated 250,000 patients with severe aortic stenosis experience symptoms. Severe aortic stenosis is a life-threatening condition. Your doctor may prescribe medications to ease the symptoms of your severe aortic stenosis. However, if the diseased valve is not replaced, your symptoms will probably worsen to heart failure and possibly even death.²⁻⁴

In the earlier stages of aortic stenosis, many people don't experience symptoms. As the severity increases, the most frequent symptoms include:



**Shortness
of
breath**



**Chest pain,
pressure,
or tightness**



**Feeling
lightheaded
or dizzy**



**Fatigue while exercising
or completing
day-to-day activities**

Treatment Options For Severe Aortic Stenosis

The only effective treatment for severe aortic stenosis is replacement of the aortic valve. There are two possible treatment options.

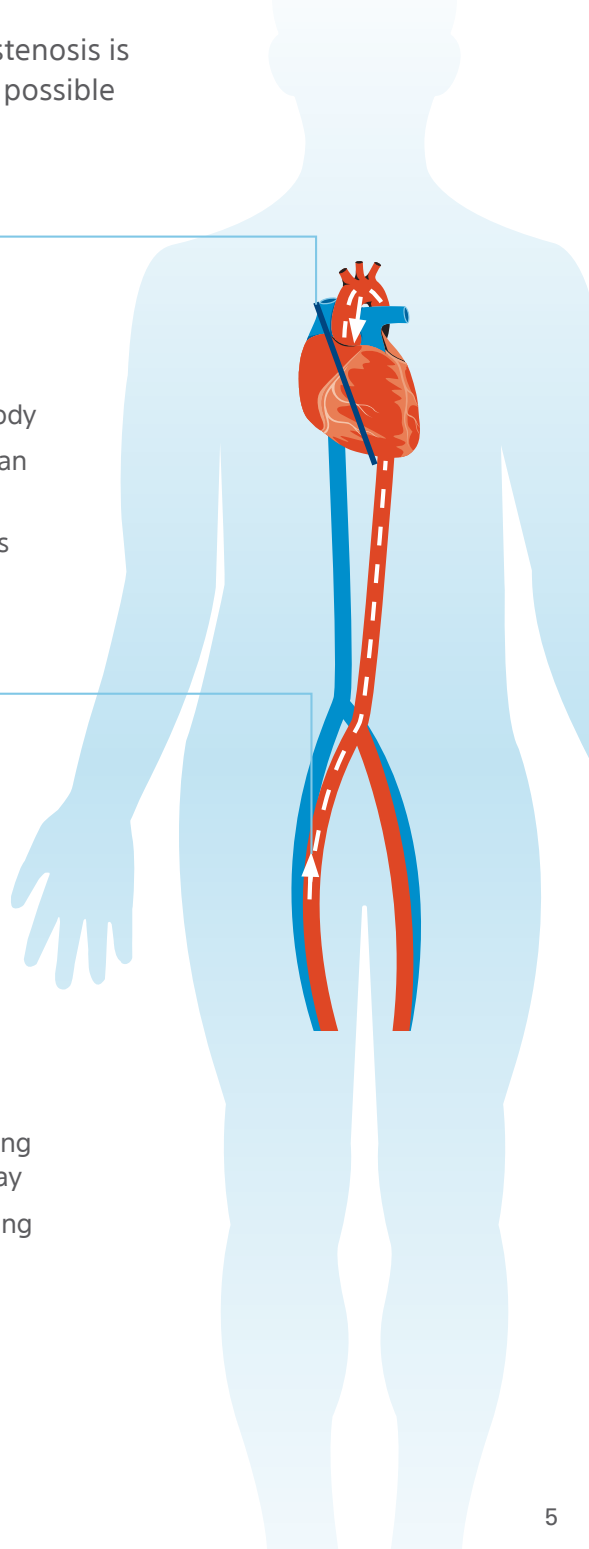
Surgical Aortic Valve Replacement (SAVR)

- Surgical aortic valve replacement is done through open-heart surgery
- During the operation, your heart is stopped and a heart-lung machine pumps blood through your body
- A surgeon replaces the diseased aortic valve with an artificial valve
- Recovery from open heart surgery frequently takes weeks to months

Transcatheter Aortic Valve Replacement (TAVR)

Transcatheter aortic valve replacement is a **less-invasive** procedure that replaces the aortic valve **without** opening your chest to reach your heart.

- To access your heart, your doctor makes a small incision in your artery or blood vessel, most often in the groin
- The artificial valve is compressed onto a catheter that travels through a blood vessel all the way to your heart
- Your doctor expands the replacement valve, pushing the diseased parts of the aortic valve out of the way
- Special X-ray equipment is used to guide positioning and placement of the new valve
- TAVR patients typically have an **easier time recovering** and **experience less discomfort**.
How quickly you recover and return to your daily routine will depend on your overall state of health



Risk of Stroke with TAVR

During the TAVR procedure, pieces of the calcified heart valve, or other debris, can break loose and travel through the arteries toward the brain. This material is called embolic debris and may block blood flow to the brain which can cause a stroke and long-term damage. Unfortunately, the damage is difficult to predict.

Reduce Your Risk of Stroke with SENTINEL™

The SENTINEL™ Cerebral Protection System (CPS) is the first and only device in the U.S. to offer you protection from the risk of stroke during TAVR. It works by capturing embolic debris dislodged during TAVR before it can reach the brain.

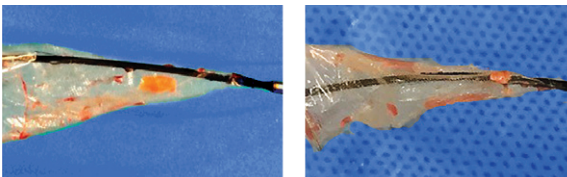
Clinical trials involving more than 3,500 patients have demonstrated that the SENTINEL device is safe and effective. The SENTINEL cerebral protection technology has been used to protect thousands of patients worldwide and is the most-studied embolic protection device in its field.

SENTINEL CPS captured visible embolic debris headed toward the brain in

99%
of TAVR cases.¹

Studies show more than a

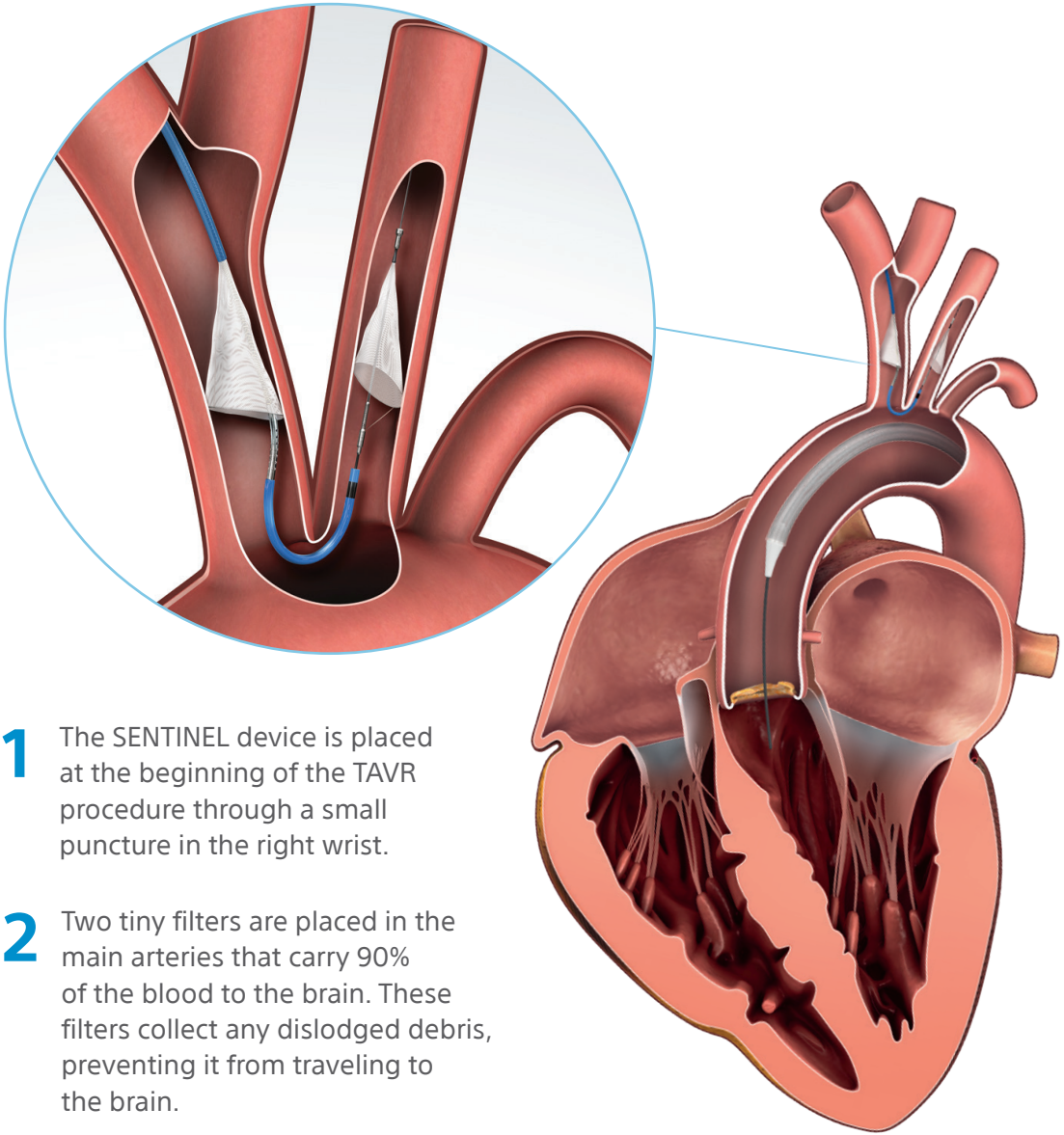
60-80%
reduction in TAVR-related
strokes when SENTINEL
Cerebral Protection was used.¹



Pictures show embolic debris captured by the **SENTINEL device**.



How the SENTINEL™ Cerebral Protection System Works



- 1** The SENTINEL device is placed at the beginning of the TAVR procedure through a small puncture in the right wrist.
- 2** Two tiny filters are placed in the main arteries that carry 90% of the blood to the brain. These filters collect any dislodged debris, preventing it from traveling to the brain.
- 3** At the completion of the TAVR procedure, the filters and collected debris are removed from the body.



See how SENTINEL works.
Watch the video now.

**Protected TAVR™
with the SENTINEL
Cerebral Protection
System provides
peace of mind for you
and your loved ones.**

“

Any occurrence of stroke is one too many. By both capturing and removing embolic debris, the SENTINEL CPS device may offer a unique neurologic-protective benefit.”

– Dr. Samir Kapadia, Cleveland Clinic

“

We are now able to universally remove debris that otherwise had the potential to travel to patients’ brains. This is a meaningful step in enhancing the safety of TAVR.”

– Dr. Raj Makkar,
Cedars-Sinai Medical Center

“

My only concern about having the TAVR procedure was ...a stroke. The fact the SENTINEL device would catch any debris prior to it going to my brain was like a dream come true.”

– Peter Poulos, TAVR and SENTINEL
Cerebral Protection System Patient

**Find a hospital with Protected
TAVR™ with SENTINEL near you.**



Take Action to Minimize the Risk of Stroke During Your TAVR Procedure

It’s important to have a conversation with your heart team before your TAVR procedure to ensure you’re getting the protection you need. Here are some helpful questions to get the conversation going.

- Are you familiar with the SENTINEL Cerebral Protection System?
- Do you use this device for your TAVR patients?
- Am I a candidate for **Protected TAVR** with SENTINEL CPS? Why or why not?

See the next page for a detailed doctor discussion guide.

Come prepared for a better conversation with your doctor.



Doctor Discussion Guide

Talking with your doctor about Severe Aortic Stenosis and your treatment options is an important part of getting the help you need. Bring these questions to your appointment to help guide a discussion with your heart team.

It's a good idea to bring along a family member or close friend to help you take notes.



Important Questions to Ask

1. What are my treatment options for Severe Aortic Stenosis?
2. Am I a candidate for Transcatheter Aortic Valve Replacement (TAVR)? [Yes](#) [No](#)
3. What more can you tell me about the TAVR procedure?
4. How long have you been performing TAVR procedures?
5. What risks are associated with TAVR?
6. What is cerebral embolic protection, and how does it reduce the risk of stroke during TAVR?
7. Do you use cerebral embolic protection for your TAVR patients? [Yes](#) [No](#)
8. What tests will I undergo before the procedure?
9. How long does the procedure take?
10. How many days will I spend in the hospital?
11. Should I plan to have someone with me when I leave the hospital?
12. Will I be given information on how to take care of myself when I return home?
13. Will I have any restrictions after the procedure?

Transcatheter Aortic Valve Replacement

PRE-PROCEDURAL CHECKLIST

Before your hospital admission and TAVR procedure, your doctor may conduct some of the following tests. Be sure to talk with your doctor about any medication you may be taking. They will advise you to stop taking certain medications up to one week before your procedure.

Your tests	Name of test	Description of procedure	Purpose of test
<input type="checkbox"/> Date: / / _____	History and physical exam	Physical examination by your doctor.	Evaluate your general health, well-being, strength and stamina.
<input type="checkbox"/> Date: / / _____	Electrocardiogram (EKG)	Your doctor places small electrodes (pads with wires) on different parts of the body.	Check if there has been any heart failure, possibly caused by aortic valve stenosis.
<input type="checkbox"/> Date: / / _____	Echocardiogram	This test uses a small handheld device to produce video images of your heart in motion.	Help evaluate your heart chambers, the aortic valve and the blood flow through your heart.
<input type="checkbox"/> Date: / / _____	Cardiac Computerized Tomography (CT) scan	This X-ray test takes detailed cross-sectional images of your heart and heart valves. You lie on a table that moves through the "hole" in the center of a large machine, called a CT scanner.	Measure the shape and size of your heart and the size of your artery system.

Checklist continued on the next page

Your tests	Name of test	Description of procedure	Purpose of test
<input type="checkbox"/> Date: <div> <div></div> <div>/</div> <div>/</div> </div>	Laboratory tests	These can include: <ul style="list-style-type: none"> • Blood and urine tests • Pulmonary test 	Check for abnormal values in your blood and urine; measure your lung capacity.
<input type="checkbox"/> Date: <div> <div></div> <div>/</div> <div>/</div> </div>	Cardiac Catheterization	A thin tube called a catheter is inserted into your groin or arm and threaded through the blood vessel to your heart. Your doctor may inject a contrast agent into the arteries of the heart to get a better view of the blood flow.	Detect potential blockages in your coronary arteries and measure the blood pressure on both sides of the aortic valve and the blood flowing through the valve.
<input type="checkbox"/> Date: <div> <div></div> <div>/</div> <div>/</div> </div>	Additional testing	Additional tests may be ordered by your doctor based on findings of the above tests. <div> <div></div> <div></div> <div></div> </div>	<div> <div></div> <div></div> <div></div> <div></div> </div>

Notes and Appointments:

What Are the Risks of TAVR?

A valve replacement is a major heart procedure. There are risks with all medical procedures. Speak with your heart team to understand the risks and benefits for you.

Risks of TAVR 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 valve injury
- Permanent disability
- Fluid in the space that surrounds the lungs or heart
- Kidney failure or damage
- Difficulty breathing
- Problems with the artificial valve such as leakage (regurgitation) or restriction (stenosis).

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

Illustrations for informational purposes – not indicative of actual size or clinical outcomes.

1. SENTINEL IDE Trial. Data presented at SENTINEL FDA Advisory Panel, Feb 23, 2017.; 2. Van Mieghem N., TVT 2018 (includes TIA); 3. Stripe, B. PCR LV 2019; 4. Rinaldi, TCT 2018. 5. Chakravarty T., TCT 2018; 6. Seeger J., et al., *JACC Cardiovasc Interv.* 2017.
2. Bach D, Radeva J, Birnbaum H, et al. Prevalence, Referral Patterns, Testing, and Surgery in Aortic Valve Disease: Leaving Women and Elderly Patients Behind. *J Heart Valve Disease.* 2007;362-9.
3. Iivanainen A, Lindroos M, Tilvis R, et al. Natural History of Aortic Valve Stenosis of Varying Severity in the Elderly. *Am J Cardiol.* 1996;97-101.
4. Aronow W, Ahn C, Kronzon I. Comparison of Echocardiographic Abnormalities in African-American, Hispanic, and White Men and Women Aged >60 Years. *Am J Cardiol.* 2001;1131-3.

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