

# What is TAVR?

Transcatheter Aortic  
Valve Replacement



Edwards

# Know All the Options for Treating Severe Aortic Stenosis

There is hope for heart valve patients

Have you been told you have aortic stenosis? Aortic stenosis is one of the most common and serious heart valve disease problems. Treatment depends on how far the disease has progressed. If the aortic stenosis is mild, medication may be prescribed to help control symptoms and lower the chance of having certain complications.

However, aortic stenosis is a progressive disease. People simply confuse the symptoms of aortic stenosis with “normal” signs of aging.

**Many times people do not know they have symptoms until they discuss their daily activity with a doctor.**

## Symptoms Associated with Severe Aortic Stenosis:



Fatigue



Swollen ankles and feet



Shortness of breath



Not engaging in activities you used to enjoy



Chest pain



Feeling dizzy or lightheaded



Difficulty walking short distances



Difficulty sleeping



Rapid heartbeat



Fainting

# 2.5 MILLION



Americans over 75 years old  
suffer from aortic stenosis

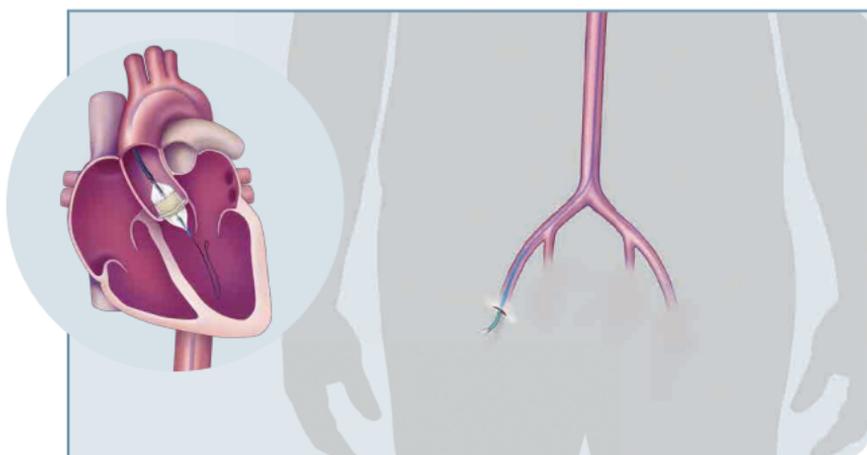
Although not everyone will have symptoms, the condition will get worse over time. The only effective way to treat severe aortic stenosis is to replace the aortic valve. This can be done through TAVR or open heart surgery.



Once a patient with severe aortic stenosis develops symptoms, they will have a survival rate as low as 50% at 2 years and 20% at 5 years without aortic valve replacement<sup>1</sup>

## Transcatheter Aortic Valve Replacement (TAVR)

TAVR is a less invasive treatment option for patients suffering from severe aortic stenosis and are experiencing symptoms. TAVR does not require open heart surgery. Now all severe aortic



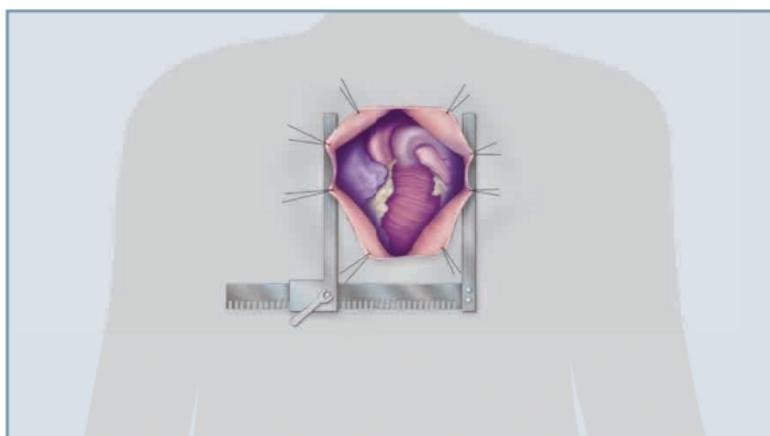
<sup>1</sup>Otto, C. VALVE DISEASE: Timing of aortic valve surgery. *Heart*. 2000;84(2):211-218.

stenosis patients should be evaluated for TAVR. Only a TAVR Doctor can evaluate which patients are right for this treatment.

- Compared with open heart surgery, TAVR is a less invasive procedure that involves making a small incision in the leg versus opening up the chest
- TAVR uses a small catheter, or tube, that is pushed through an artery to the heart to place a new valve within a diseased aortic valve

## Open Heart Surgical Aortic Valve Replacement

Open heart surgery for aortic valve replacement is where the doctor will open the chest and will completely remove the damaged valve and replace it with an artificial valve. Patients are connected to a heart-lung machine that takes over the work of the heart and keeps the blood flowing throughout the body. Patients usually need to stay in the hospital for a week or more, before beginning a long period of recovery.



On average, the TAVR procedure lasts about 1 hour, compared to 4 hours with open heart surgery.

More than 400,000 people worldwide have received the TAVR procedure.

## Benefits of TAVR may include:



Better clinical outcomes



Less invasive with minimal scarring



Shorter hospital stay



Shorter recovery time to get back to everyday activities



Less pain and anxiety



Improved quality of life



Relief of symptoms

The **Major Risks** of TAVR are similar to open heart surgery and include death, stroke, bleeding and vascular complications.



For more information on the benefits and risks of TAVR and to get a free TAVR information kit visit [NewHeartValve.com](http://NewHeartValve.com)



## Questions to Ask Your Doctor:

- Is my aortic stenosis severe?
- What tests do I need?
- How soon will I need treatment?
- What are the risks associated with not having my aortic valve replaced?
- How do I get a TAVR evaluation?
- Do all doctors perform TAVR?
- How long is the TAVR procedure vs. open heart surgery?
- How long will I be in the hospital for TAVR vs. open heart surgery?
- What will the recovery be like for TAVR vs. open heart surgery?
- What restrictions and/or medications (if any), would I be on after the procedure for TAVR vs. open heart surgery?
- How frequently will I need to have follow-up visits for TAVR vs. open heart surgery?



**Order a free TAVR information kit including a doctor discussion guide at [NewHeartValve.com](http://NewHeartValve.com)**

**See accompanying Important Risk Information.**

**CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.**

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# Important Risk Information

## Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

### Indications:

The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality  $\geq$  8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

### Contraindications (Who should not use):

The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System should not be used in patients who:

- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.

### Warnings:

- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, compared to other standard treatments for aortic stenosis in the high or greater risk population.
- If an incorrect valve size for your anatomy is used, it may lead to heart injury, valve leakage, movement, or dislodgement.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are sensitive to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials.
- The SAPIEN 3 Ultra and SAPIEN 3 valves may not last as long in younger patients, or patients with a disease that results in more calcium in their blood.
- During the procedure, your doctors should monitor the dye used in the body; if used in excess it could lead to kidney damage. X-ray guidance used during the procedure may cause injury to the skin, which may be painful, damaging, and long-lasting.
- Patient's creatinine level should be measured prior to the procedure.
- Patients who have already had a valve replaced should be carefully assessed by their physician prior to receiving a new valve to ensure proper placement of the new valve.
- Injury can occur if the delivery system is not used properly.
- Transcatheter heart valve patients should talk to their physicians about the potential need for medications that thin the blood or prevent blood clots from forming.

### Precautions:

The long-term durability of the Edwards SAPIEN 3 Ultra and SAPIEN 3 transcatheter heart valves are not known at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing. Safety, performance, and durability of the SAPIEN 3 Ultra and SAPIEN 3 valves have not been established for placement inside a previously implanted transcatheter valve.

The safety and effectiveness of the transcatheter heart valves are also not known for patients who have:

- An aortic heart valve that is not calcified, contains only one leaflet, two leaflets in low surgical risk patients, has leaflets with large pieces of calcium that may block the vessels that supply blood to the heart or in which the main problem is that the valve leaks.
- Previous prosthetic ring in any position.
- Previous atrial septal occlude.
- A heart that does not pump well, has thickening of the heart muscle, with or without blockage, unusual ultrasound images of the heart that could represent irregularities such as a blood clot, a diseased mitral valve that is calcified or leaking, or Gorlin syndrome, a condition that affects many areas of the body and increases the risk of developing various cancers and tumors.
- Low white, red or platelet blood cell counts, or history of bleeding because the blood does not clot properly.
- Diseased, abnormal or irregularly shaped vessels leading to the heart. Vessels which are heavily diseased or too small for associated delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- For a valve in valve procedure, there is a risk of leakage if the previously implanted tissue valve is not securely in place or if it is damaged. There is also the possibility that a partially detached valve leaflet from the previously implanted valve could block a blood vessel.
- Additional pre-procedure imaging will be completed to evaluate proper sizing.

### Potential risks associated with the procedure include:

- Death, stroke, paralysis (loss of muscle function), permanent disability, or severe bleeding.
- Risks to the heart, including heart attack or heart failure, a heart that does not pump well, irregular heartbeat that may result in a need for a permanent pacemaker, chest pain, heart murmur, false aneurysm, recurring aortic stenosis (narrowing), too much fluid around the heart, injury to the structure of the heart.
- Risks to your lungs or breathing, including difficulty breathing, fainting, buildup of fluid in or around the lungs, weakness or inability to exercise.
- Risks involving bleeding or your blood supply, including formation of a blood clot, high or low blood pressure, limited blood supply, a decrease in red blood cells, or abnormal lab values, bleeding in the abdominal cavity, collection of blood under the skin.
- Additional risks, including life-threatening infection, dislodgement of calcified material, air embolism (air bubbles in the blood vessels), poor kidney function or failure, nerve injury, fever, allergic reaction to anesthesia or dye, reoperation, pain, infection or bleeding at incision sites, or swelling.

### Additional potential risks specifically associated with the use of the heart valves include:

- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery and possible removal of the SAPIEN 3 Ultra and SAPIEN 3 valve, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), nonstructural valve dysfunction (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage, etc.) or mechanical failure of the delivery system and/or accessories.

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