

What is TAVR?

Transcatheter Aortic Valve Replacement



Edwards

What Are Your Options for Treating Severe Aortic Stenosis?

Treatment for aortic stenosis depends on how far your disease has progressed. If your stenosis is mild, medication may be prescribed to help regulate your heartbeat and prevent blood clots.

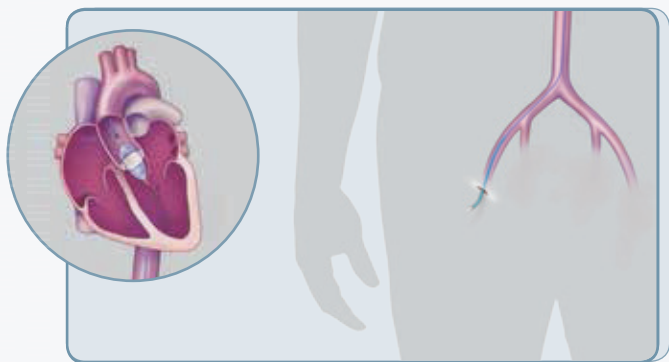
However, if the severity of your stenosis progresses, your doctor and a specialized Heart Team may recommend replacing your diseased aortic valve. Severe aortic stenosis cannot be treated with medication. The only effective treatment is to replace your aortic valve.

Today, there are two options to replace your diseased aortic valve: transcatheter aortic valve replacement (TAVR) or open heart surgery.

For more information on TAVR and open heart surgery, go to [NewHeartValve.com](https://www.newheartvalve.com).

Transcatheter Aortic Valve Replacement (TAVR)

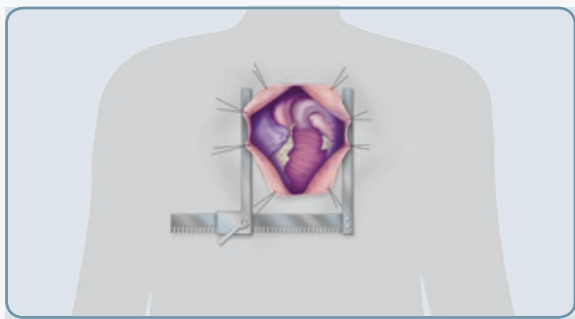
TAVR may be a preferred option for people who have been diagnosed with severe aortic stenosis and are at intermediate or greater risk for surgery. TAVR (sometimes called transcatheter aortic valve implantation, or TAVI) is a less-invasive procedure than open heart surgery. This procedure uses a catheter to implant a new valve within your diseased aortic valve. TAVR can be performed through multiple approaches; however, the most common approach is the transfemoral approach (through a small incision in the leg).



Only professionals who have received extensive training are qualified to perform the TAVR procedure. A properly trained and dedicated, multidisciplinary Heart Team at a TAVR Center will conduct a thorough evaluation to determine the most appropriate treatment option for you.

Open Heart Surgical Aortic Valve Replacement

Aortic valve replacement through open heart surgery is another option for treating severe aortic stenosis. Most open heart surgeries are performed through an incision across the full length of the breast bone, or sternum. Open heart surgeries require the use of a heart lung machine which temporarily takes over the function of the heart. During the procedure, the surgeon will completely remove the diseased aortic valve and insert a new valve. There are two different types of surgical valves, mechanical (man-made material) or biological (animal or human tissue). Please consult your doctor for more information on surgical aortic valve replacement and its associated risks.



Treatment for Failing Surgical Heart Valves

Your original heart valve may have been replaced with a surgical heart valve. Treatment for a failing surgical heart valve depends on how far the disease has progressed. Your specialized Heart Team may recommend that your failing surgical tissue valve be replaced through either TAVR with certain valves (sometimes called valve-in-valve) or open heart surgery.

Clinical Outcomes with TAVR

A recent clinical study of patients who underwent a TAVR procedure with the SAPIEN 3 valve was shown to have a 75% lower incidence of death and stroke compared to open heart surgery.* TAVR may shorten recovery time to allow patients to get back to everyday activities. Patients reported quality of life improvements within 30 days including the ability to take care of themselves.

For more information on the clinical benefits of TAVR with the SAPIEN 3 valve, go to [TAVRbyEdwards.com](https://www.tavrbyedwards.com).

*The PARTNER II trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=1,077).

Questions to Ask Your Doctor:

- Am I a candidate for transcatheter aortic valve replacement (TAVR)?
- What tests do I need?
- How soon will I need treatment?
- What are the risks associated with not having my aortic valve replaced?
- 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?

For a free doctor discussion guide, go to NewHeartValve.com.

See accompanying Important Risk Information

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Important Risk Information

Edwards SAPIEN 3 Transcatheter Heart Valve

Indications

The Edwards SAPIEN 3 transcatheter heart valve, model 9600TFX, and accessories 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 at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality \geq 3% at 30 days, based on The Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

The Edwards SAPIEN 3 transcatheter heart valve, model 9600TFX, and accessories are also 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 comorbidities unmeasured by the STS risk calculator).

Contraindications (who should not use)

The Edwards SAPIEN 3 transcatheter heart valve and delivery 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 allergic to chromium, nickel, molybdenum, manganese, copper, silicon, and/or polymeric materials.
- The Edwards SAPIEN 3 transcatheter heart valve may not last as long in patients whose bodies do not process calcium normally.
- 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.
- Transcatheter aortic heart valve patients should take medications that thin the blood or prevent blood clots from forming, except when likely to have an adverse reaction, as determined by their physician. The Edwards SAPIEN 3 transcatheter heart valve has not been tested for use without medications that thin the blood or prevent blood clots from forming.



Precautions

The long-term durability of the Edwards SAPIEN 3 transcatheter heart valve is 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 Edwards SAPIEN 3 transcatheter heart valve has not been established for placement inside a previously implanted transcatheter valve.

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

- An aortic heart valve that is not calcified, contains only one or two leaflets, 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 occluder.
- 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 that are heavily diseased or too small for associated delivery devices or that have large amounts 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, or 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 valve include:

- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery and possible removal of the Edwards SAPIEN 3 transcatheter heart 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 ingrowth, blood cell damage, etc.), or mechanical failure of the delivery system and/or accessories.

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