
## What is Heart Valve Failure?

Without treatment, heart valve failure can be deadly. In fact, 1 in 10 people with heart valve failure who are experiencing symptoms may die within 5 weeks while waiting for their aortic valve replacement. **Don't let fixable become fatal.** Learn what you can do to treat heart valve failure.

Edwards Lifesciences

# What is aortic stenosis?

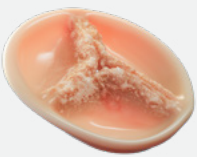
Aortic stenosis is a type of heart valve disease that's common in people over 65.

This disease occurs when the leaflets (or flaps) of the aortic valve become stiff due to calcium buildup over time, preventing them from properly opening and closing.

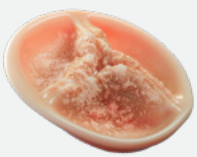
**Aortic stenosis is progressive, meaning it gets worse over time.**

Healthy

Mild



Moderate



Severe aortic stenosis (heart valve failure)

**When aortic stenosis becomes severe, it is also known as heart valve failure.**

Heart valve failure can progress rapidly and unpredictably. By delaying treatment, you're risking hospitalization, stroke, or even death.

## Heart valve failure is deadly

People who are experiencing symptoms and wait to replace their aortic valve are at risk:

**1 in 10**
may die within 5 weeks

**5 in 10**
may die within 2 years

## With heart valve failure, you may not experience symptoms. But if you do, they may include:

- Shortness of breath
- Chest pain
- Fatigue (low energy)
- Lightheadedness, feeling dizzy, and/or fainting
- Difficulty walking short distances
- Swollen ankles and feet
- Rapid, fluttering heartbeat

## If you have heart valve failure, you will need to have your aortic valve replaced eventually.

**What is heart valve failure?**
Watch this video to take a look at this deadly disease.

**Visit TreatHeartValveFailure.com**

# See a Heart Valve Team

**Once you're diagnosed, don't wait.** Ask your doctor to refer you to a Heart Valve Team right away.

During your evaluation, your Heart Valve Team will consider these factors:

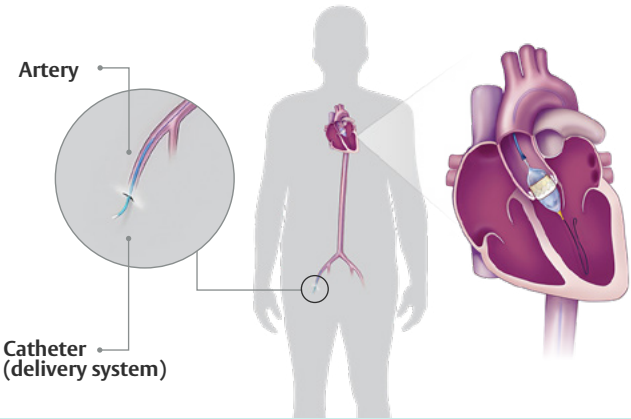
- Your medical history
- Your age
- Your current health status
- Your ability to undergo the procedure and recover from it
- The overall condition of your heart

**Your Heart Valve Team can decide whether a procedure like TAVR (transcatheter aortic valve replacement) is right for you.**

| *With TAVR,* **YOU CAN EXPERIENCE:** | |
|---|---|
| Relief of symptoms | ✓ |
| Improved life expectancy | ✓ |
| Improved heart function | ✓ |

# Ask for TAVR

TAVR is a way to replace a failing aortic heart valve without opening the chest. It's usually done by making an incision (cut) in the leg near the groin and guiding the valve into your heart through a catheter.




**1 hour** The average TAVR procedure takes around 1 hour.

## Spend less time recovering and more time living. Most people who get TAVR:

- Are up and walking within hours
- Have a short recovery time and go home the next day
- Are back to feeling like themselves in ~30 days

The most serious risks of TAVR include death, stroke, serious damage to the arteries, or serious bleeding.


“Thanks to TAVR, there’s still more road to travel.”
HARRY | REAL TAVR PATIENT

# Time to take action

If you're waiting for just the right time to treat your heart valve failure, the time is now. **Delaying treatment could be deadly.**

**Here is your checklist:**

- ☑ **Ask your doctor to see a Heart Valve Team**
- ☑ **Get evaluated by a Heart Valve Team**
- ☑ **Get a TAVR Info Kit to learn more**

For even more details about treating heart valve failure, order your **free TAVR Info Kit**.

Visit TreatHeartValveFailure.com

**See Important Risk Information on the next page.**

# Important Risk Information

## Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

**Indications:**
The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated to reduce the risks associated with progression from asymptomatic to symptomatic severe native calcific aortic stenosis in patients who are judged by a heart team to be appropriate for transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is 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, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to a failing (stenosed, insufficient, or combined) surgical or transcatheter bioprosthetic aortic valve, or a native mitral valve with an annuloplasty ring 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 ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to a failing (stenosed, insufficient, or combined) surgical bioprosthetic mitral valve 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 ≥ 4% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

**Contraindications (Who should not use):**
The Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA 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.
- Have a mitral ring that is damaged and can no longer support the valve.

**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 anesthesia, contrast media, cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or plastics.
- The Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA 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. Patients who do not may be at increased risk of a stroke. Blood-thinning medication may increase the risk of bleeding in the brain (stroke).
- Transcatheter valve replacement is not recommended in previous mitral valve rings that are damaged or have become too rigid.

**Precautions:**

The long-term durability of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA 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. Limited clinical data are available for transcatheter aortic valve replacement in patients who are born with an aortic heart valve that has only two leaflets and who are determined to be at low risk for open heart surgery. A patient's anatomical characteristics should be considered by their physicians when using the valve in this patient population. In addition, patient age should be considered as long-term durability of the valve has not been established. Data on TAVR in patients with asymptomatic severe aortic stenosis are based on study of predominantly low surgical risk patients. Limited clinical data to inform benefit-risk considerations are available for TAVR in patients with asymptomatic severe aortic stenosis who are deemed to be at intermediate or greater surgical risk. Patients who need a dental procedure should talk to their doctor about risk of infection and needing antibiotics. Patients should be treated post-procedure for heart infection as a precaution.

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, 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.
- Who have a prosthetic ring in the tricuspid position.
- 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 the delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- Whose previously implanted artificial valve or ring is not securely in place or is damaged that could cause it to leak.
- Whose previously implanted valve or ring could block a blood vessel caused from the leaflet partially detaching.

**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, sudden loss of heart function, 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, dizziness, 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, serious damage to the arteries, severe bleeding in the heart or in the body that could require a transfusion or surgery.
- 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 or emergency heart surgery and possible removal of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), valve issues not related to structure (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage) or mechanical failure of the delivery system and/or accessories.

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

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