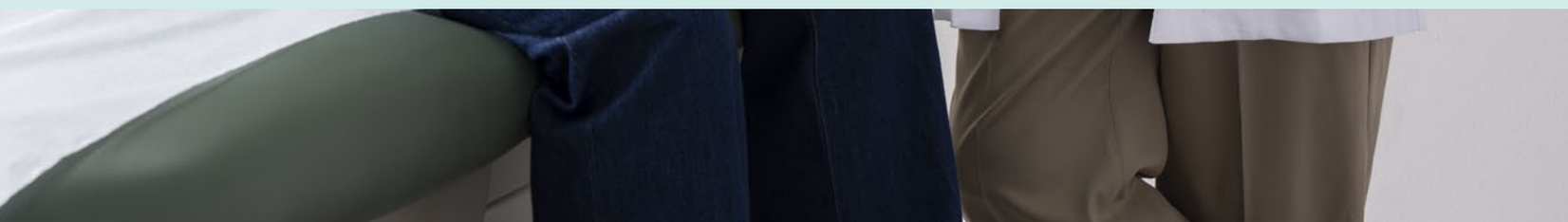
TAVR Info Kit

Ask your doctor about TAVR (transcatheter aortic valve replacement), a minimally invasive way to treat severe aortic stenosis (heart valve failure).

Edwards Lifesciences

Your doctor may call it **severe aortic stenosis**, but it's also called **heart valve failure.** Without treatment, it can be deadly.



Every week counts. By delaying treatment, you're putting your life at risk

Heart valve failure is a serious condition that can progress rapidly and unpredictably – which can lead to stroke or even death.

Don't let fixable become fatal, especially when there's TAVR.

Table of contents

Click on any section in the table of contents to quickly skip to it.
Print this brochure to bring to your next appointment as a reference.

What you should know about heart valve failure

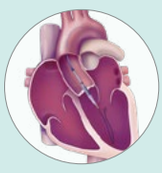
Aortic stenosis is a deadly type of heart valve disease and most common in people over 65.

For some, calcium buildup on the aortic valve is a normal part of aging. Aortic stenosis occurs when the flaps (or leaflets) of the aortic valve become stiff due to calcium buildup over time, preventing them from properly opening and closing.

Stages of aortic stenosis progression

Healthy | **Mild** | **Moderate** | **Severe aortic stenosis (heart valve failure)**

Watch **"What is heart valve failure?"** here to better understand this dangerous condition.



Heart valve disease only gets worse over time.
Untreated, it can become severe.

This is known as "heart valve failure," which can progress rapidly and unpredictably, putting your life at risk.
And you might not know until it's too late.

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

Medication can’t stop heart valve failure

If you have symptoms, medication can sometimes help control them, but it’s not a cure. Heart valve failure will continue to get worse until you have your valve replaced.

If it's heart valve failure, you have options

Two ways to fix your aortic valve

TAVR (transcatheter aortic valve replacement) and SAVR (surgical aortic valve replacement) – also called open heart surgery – are both ways to replace your heart valve. They reduce your risk of death from heart valve failure and treat any symptoms that could occur. There are key differences between them.

	TAVR **Minimally invasive procedure**	**SAVR** **Open heart surgery**
Short procedure time	☑	✕
Short recovery time	☑	✕
Short hospital stay	☑	✕
Less painful procedure	☑	✕
Relief of symptoms	☑	☑
Improved life expectancy	☑	☑
Improved heart function	☑	☑

TAVR by Edwards has better outcomes than open heart surgery in low-risk patients at 1 year – and was proven equally effective at 5 years.*

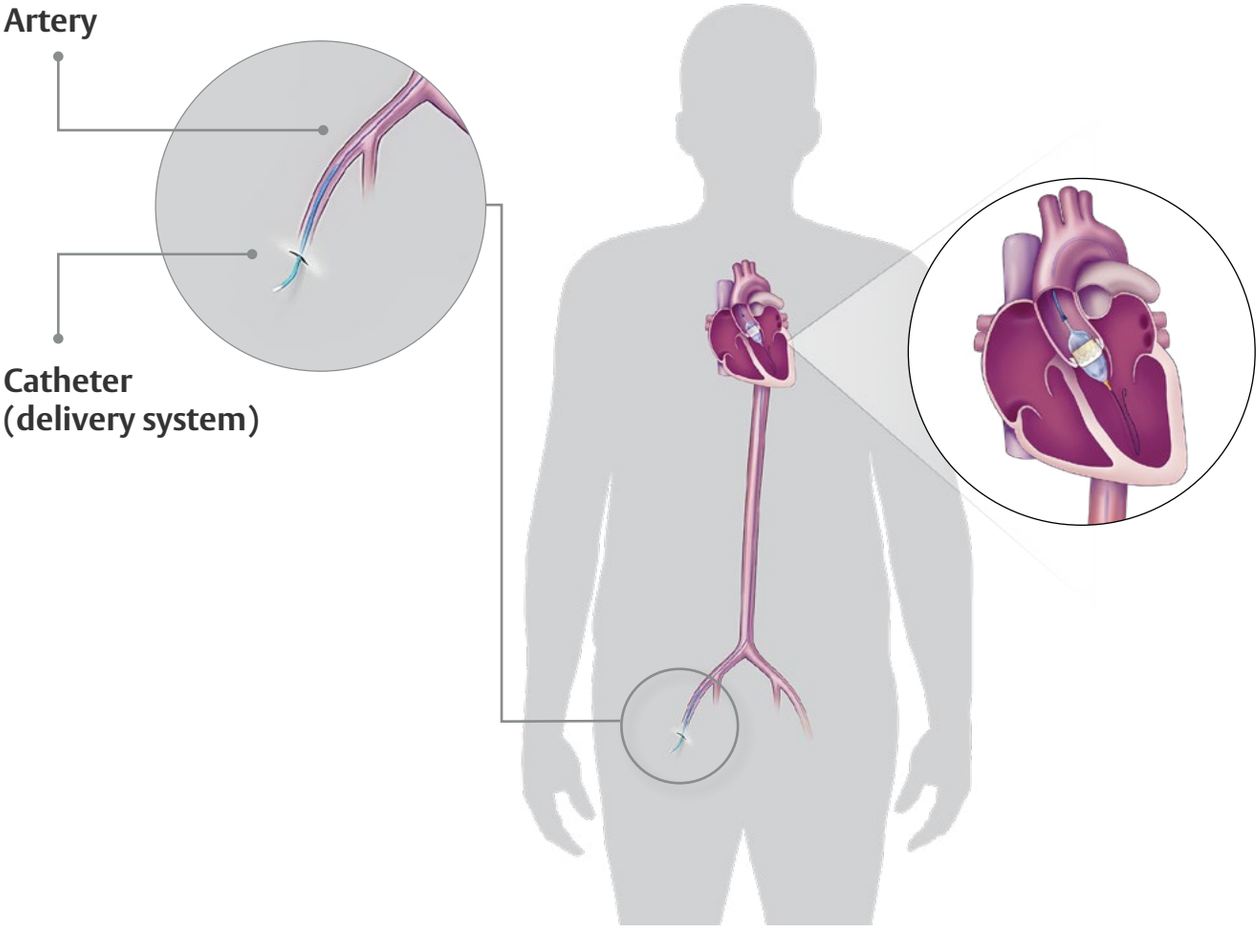
*The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint of all-cause death, all stroke, and rehospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low risk patients.

PARTNER 3 Trial 5-Year Results in low-risk patients – Low rates of cardiovascular mortality through five years (5.5% SAPIEN 3 TAVR to 5.1% SAVR). Low rates of all-cause mortality through five years (10.1% SAPIEN 3 TAVR vs. 8.2% with SAVR). Low rates of disabling stroke through five years (2.9% SAPIEN 3 TAVR to 2.7% SAVR). Low rates of stroke through five years (5.8% SAPIEN 3 TAVR vs. 6.4% SAVR). Lower rates of rehospitalization with SAPIEN 3 TAVR through five years (13.7% vs. 17.4%).

How is TAVR performed?
Watch a short animated video about the TAVR procedure at
TreatHeartValveFailure.com/Treatment

What happens during TAVR?

TAVR uses a small catheter, or tube with a balloon on the end, that is pushed through an artery to the heart to place a new valve within a diseased aortic valve. The balloon is inflated to expand the replacement valve. Once the new valve is anchored in place, it begins working right away.



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

TAVR may also be appropriate for patients with:

- Bicuspid aortic valves (abnormal heart valves that have 2 leaflets instead of the typical 3)
- Existing TAVR valves (valve-in-valve procedure)

1 hour

The average TAVR procedure takes around 1 hour.

TAVR is a minimally invasive way to get back to the life you want

Most patients:

Are done with the procedure in about an hour

Are up and walking in a few hours

Have a short recovery time and go home the next day

Are back to feeling like themselves in as little as 30 days

People who have had TAVR say they're still feeling and living better, even several years after the procedure.

HARRY | REAL TAVR PATIENT

Don’t “wait and see” with heart valve failure

Patients who get TAVR by Edwards before symptoms show up have better outcomes than those who take the “wait and see” approach. All patients diagnosed with heart valve failure should ask to be evaluated for TAVR right away.

Want to hear the story of a real TAVR patient?
Visit **TreatHeartValveFailure.com/PatientStories**

A Heart Valve Team can see you right away

A Heart Valve Team is made up of qualified healthcare professionals who specialize in the treatment of heart valve failure. They'll work closely with your cardiologist and primary care physician.

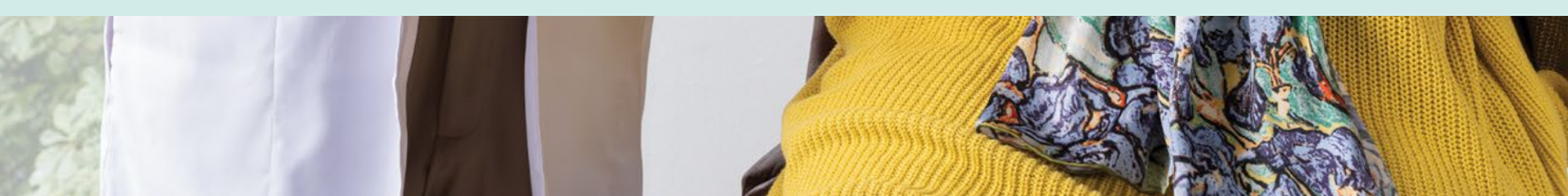
Once you're diagnosed with heart valve failure, you should be evaluated by a Heart Valve Team right away to determine whether TAVR is an option for you.

A Heart Valve Team includes:

- Interventional cardiologists
- Cardiac surgeons
- Imaging specialists
- Valve Clinic Coordinators

JOY | REAL TAVR PATIENT

Meet with a Heart Valve Team as soon as you're diagnosed.
To find yours, visit **TreatHeartValveFailure.com/Find**



The evaluation may include these tests:

Echocardiogram (echo) — noninvasive test that takes pictures of your heart

Stress test — involves walking on a treadmill or riding a stationary bike while your heart is monitored to show how your heart works during physical activity

Chest X-ray — shows the size and shape of your lungs and heart

Cardiac catheterization — shows the blood pressure and blood flow within your heart

These tests help the Heart Valve Team create a treatment plan for you.

After locating your Heart Valve Team, talk with the Valve Clinic Coordinator at your TAVR Hospital about getting evaluated for TAVR.

Is TAVR right for you?

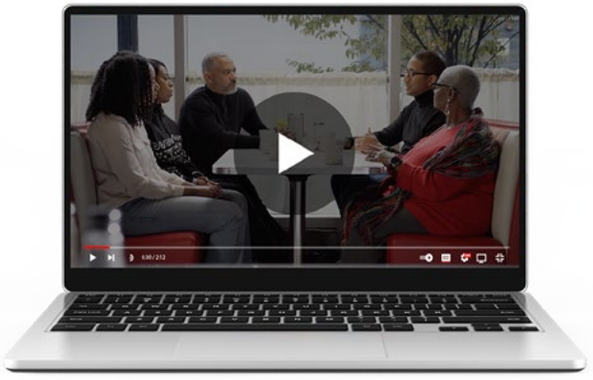
To find out, ask a Heart Valve Team

All patients with heart valve failure should ask for a TAVR evaluation with a Heart Valve Team at a TAVR Hospital, regardless of symptoms.

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

Click here to watch real doctors discuss the dangers of waiting on heart valve failure with a real patient.



Tip for Caregivers

You should feel confident in your loved one's treatment plan. **If their cardiologist is recommending open heart surgery – and you're feeling unsure – it's OK to ask for an evaluation from a Heart Valve Team.**

Get evaluated by a Heart Valve Team

Take an active role in your health. Find out if you qualify for TAVR today.

TAVR can only be performed by a trained Heart Valve Team at certain hospitals across the country.

Find a TAVR Hospital near you

A Heart Valve Team can help determine your treatment options.
Visit **TreatHeartValveFailure.com/Find**

How to ask your doctor to refer you to a Heart Valve Team:

- List all of your questions (try to prioritize for time)
- Be honest about how you're feeling – tell your doctor if you have any new or worsening symptoms. Keep in mind, some people with heart valve failure won't ever experience symptoms
- Ask about all treatment options, including TAVR
- Based on your discussion, ask if TAVR is right for you

Get the info you need to make an informed decision at
TreatHeartValveFailure.com/Informed

TAVR procedure: What to expect

Before the procedure:

- It's OK to be nervous. Your Valve Clinic Coordinator will tell you how to prepare for your procedure and your Heart Valve Team will review the risks and benefits
- You'll need to get a dental clearance because dental infections can spread to your heart valve

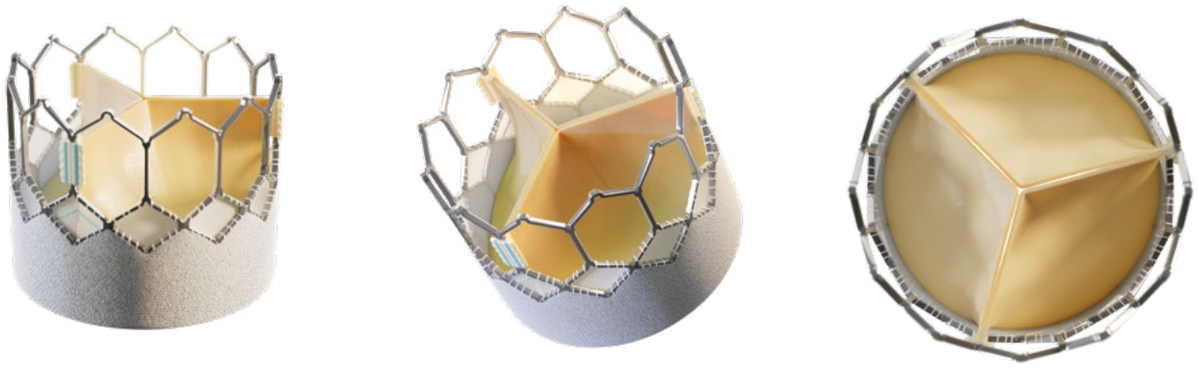
During the procedure:

- Your TAVR Specialist will decide what type of anesthesia is best for you. You may be asleep or awake and medicated while your valve is replaced
- Expect your doctor to make a small incision (cut), often in the leg, and insert a thin tube called a catheter into the artery. They will then guide the catheter, which is carrying the new valve on a balloon, up to the heart. The balloon is inflated to expand the new valve and push the leaflets aside. The new valve attaches to the calcification of the old diseased valve's leaflets and is anchored in place
- Your new heart valve will begin working immediately
- On average, the TAVR procedure takes about an hour

After the procedure:

- Recovery time and time in the hospital are different for each patient
- Most patients get to go home the next day and recover faster compared to open heart surgery
- Your TAVR Heart Valve Team can tell you how long your hospital stay will be after your procedure
- Most people experience symptom relief and can get back to everyday activities in as little as 30 days

TAVR by Edwards is the #1 choice for TAVR in the US



The benefits of getting TAVR before you have symptoms are clear

Edwards SAPIEN 3 is the only family of TAVR valves shown to help reduce the rapid and unpredictable declines in your health caused by heart valve failure.

In a clinical trial, patients who received TAVR before they felt any symptoms of heart valve failure maintained their current lifestyle and had fewer hospitalizations compared to patients who waited to have TAVR.

1M+

Over 1 million patients worldwide and counting:

Edwards TAVR valves have been used to replace more heart valves than any other valve.

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

Visit **TreatHeartValveFailure.com/Edwards**

Insurance coverage and TAVR

Your Valve Clinic Coordinator will help you with any questions you have about TAVR, including your insurance coverage and financial needs.

Contact your insurance provider before meeting with your Heart Valve Team to find out if the evaluation and TAVR procedure are covered. A referral is sometimes needed.

TAVR is covered by Medicare for all eligible patients.

Helpful resources

Taking control of your health can help you get the care you need. Free resources are available below for you and your loved ones to better understand heart valve failure and the TAVR procedure.

General resources

For information on heart valve failure and TAVR, along with patient stories, go to **TreatHeartValveFailure.com**

Caregiver resources

For caregiver support, visit the Family Caregiver Alliance at **caregiver.org**

Financial resources

If you need free professional assistance to help navigate insurance and reimbursement, visit **structuralheart.pafcareline.org** or call **(800) 532-5274**

Patient support line

Figuring out the next steps in treating heart valve failure may feel overwhelming. The Edwards Patient Team is here to support you. For more information, please call **(888) 713-1564**

Informed Decision Guide

This 7-minute questionnaire can help you and your doctor decide the best treatment path for you.
Find it at **TreatHeartValveFailure.com/Informed**

Need more resources?
Visit **TreatHeartValveFailure.com/Resources**

Frequently asked questions

How serious is heart valve failure?

With heart valve failure, every week counts. In fact, 1 in 10 people experiencing symptoms of heart valve failure may die within 5 weeks if they don't get their recommended aortic valve replacement.

Should I consider TAVR even if I'm not experiencing the symptoms of heart valve failure?

Only TAVR by Edwards is approved to treat severe aortic stenosis patients with or without symptoms.

Patients who were treated prior to getting symptoms were more likely to keep their current lifestyle and avoid hospitalizations.*

How long until I need my valve replaced?

Over 98% of TAVR recipients did not require a valve reintervention after 10 years of receiving their valve.†

What are the treatment options for heart valve failure?

Your doctor may prescribe medicine to help control your symptoms. However, it's important to know the only effective way to treat heart valve failure is by replacing your valve.

*In a clinical trial, researchers assessed whether early TAVR would lead to better outcomes than clinical surveillance in patients with asymptomatic severe aortic stenosis.

†Based on Medicare claims data which may underestimate the actual event rate.

Sign up here for the Heart Valve Strong community to receive emails on heart valve failure, TAVR, and tips for talking with your doctor.

What if my doctor doesn’t refer me to a Heart Valve Team?

If you do not agree with your doctor's recommendation that TAVR is not an option for you, you may still contact a Valve Clinic Coordinator at a TAVR Hospital to receive a second opinion. One of your most important rights is the ability to consult with another doctor to confirm a diagnosis and find possible treatment options available to you.

How can I find a Heart Valve Team?

Visit **TreatHeartValveFailure.com/Find** to locate a Heart Valve Team near you, or ask your doctor for a referral.

How could I benefit from TAVR?

With the minimally invasive TAVR procedure, people may return to daily activities sooner than with open heart surgery. People who undergo TAVR report improved quality of life following the procedure. Most people are up and walking in a few hours and able to go home the next day. Patients experience improved heart function, often with reduced pain and anxiety.

What are the risks of TAVR?

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

Don’t let fixable become fatal

Ask your doctor for a TAVR evaluation by a Heart Valve Team.

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

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