TAVR Info Kit

This guide is designed to help you and your caregiver better understand heart valve failure, your treatment options, the TAVR (transcatheter aortic valve replacement) procedure, and how you can get back to the life you want.

Edwards Lifesciences

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

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This brochure is broken into sections to ensure the info you need is easy to find. Use the Table of Contents to navigate it quickly.

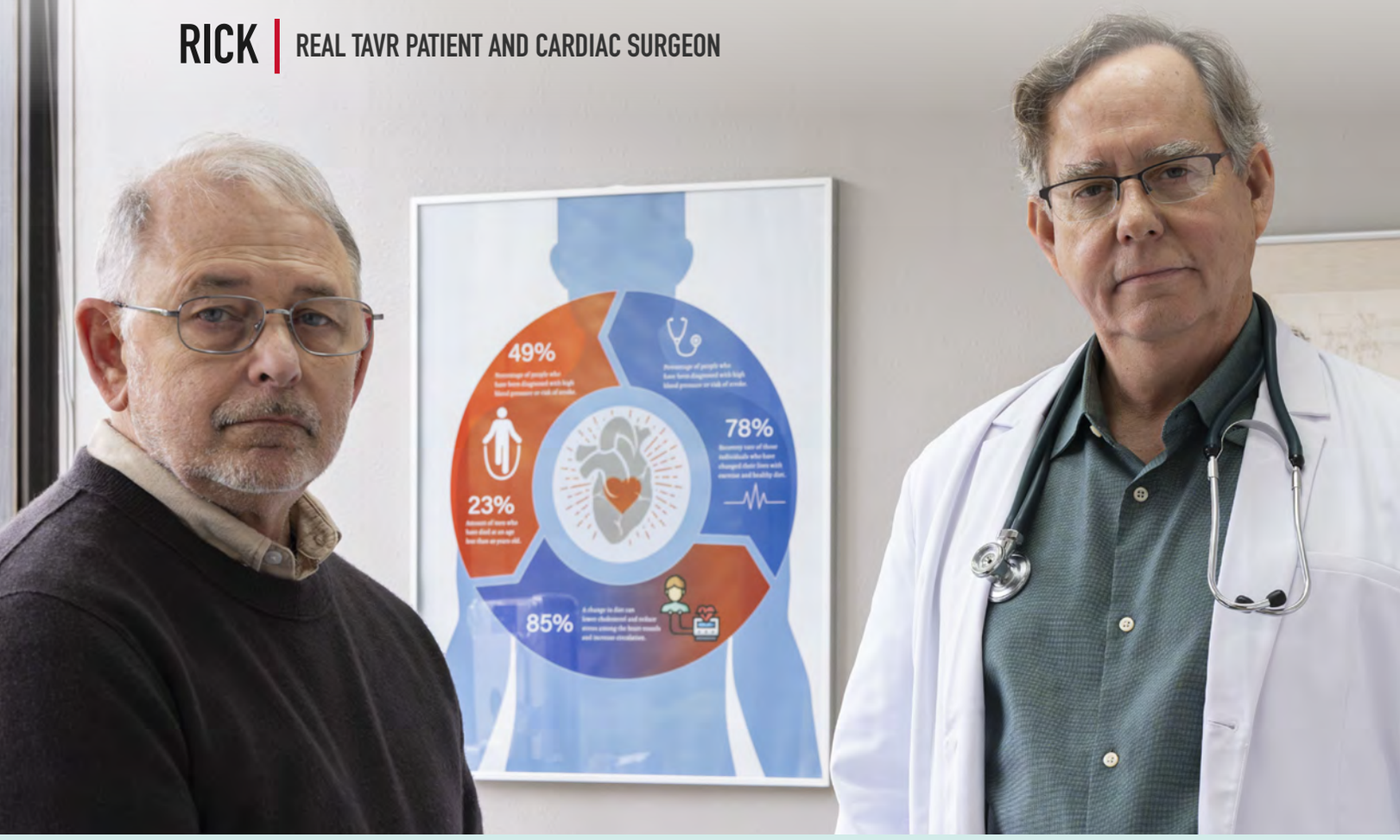
Look for helpful links to videos, tools, and resources throughout each section.

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

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

Many heart valve failure patients may be eligible for TAVR (transcatheter aortic valve replacement) even before symptoms occur. If you don't have symptoms, TAVR by Edwards is a way to prevent a rapid drop in your quality of life. Once symptoms occur, TAVR can improve your quality of life.

RICK | REAL TAVR PATIENT AND CARDIAC SURGEON



Tip: Print this brochure to bring to your next appointment as a reference.

Heart valve failure

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

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.

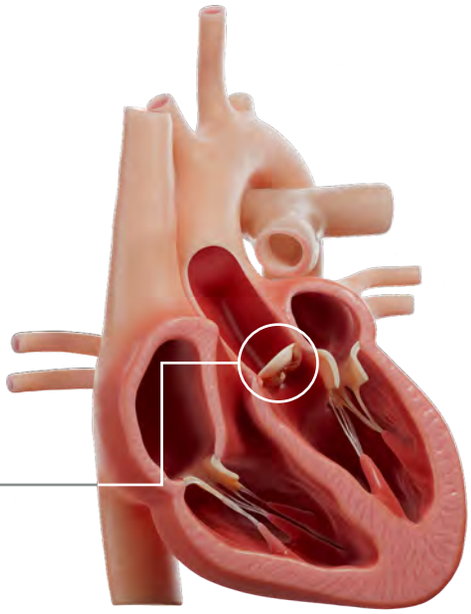
Stages of aortic stenosis progression

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

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

"Heart valve failure" can progress rapidly and unpredictably, putting your life at risk. And you might not know until it's too late.

Your aortic valve is located here



Left untreated, heart valve failure is deadly

Never wait on heart valve failure. 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

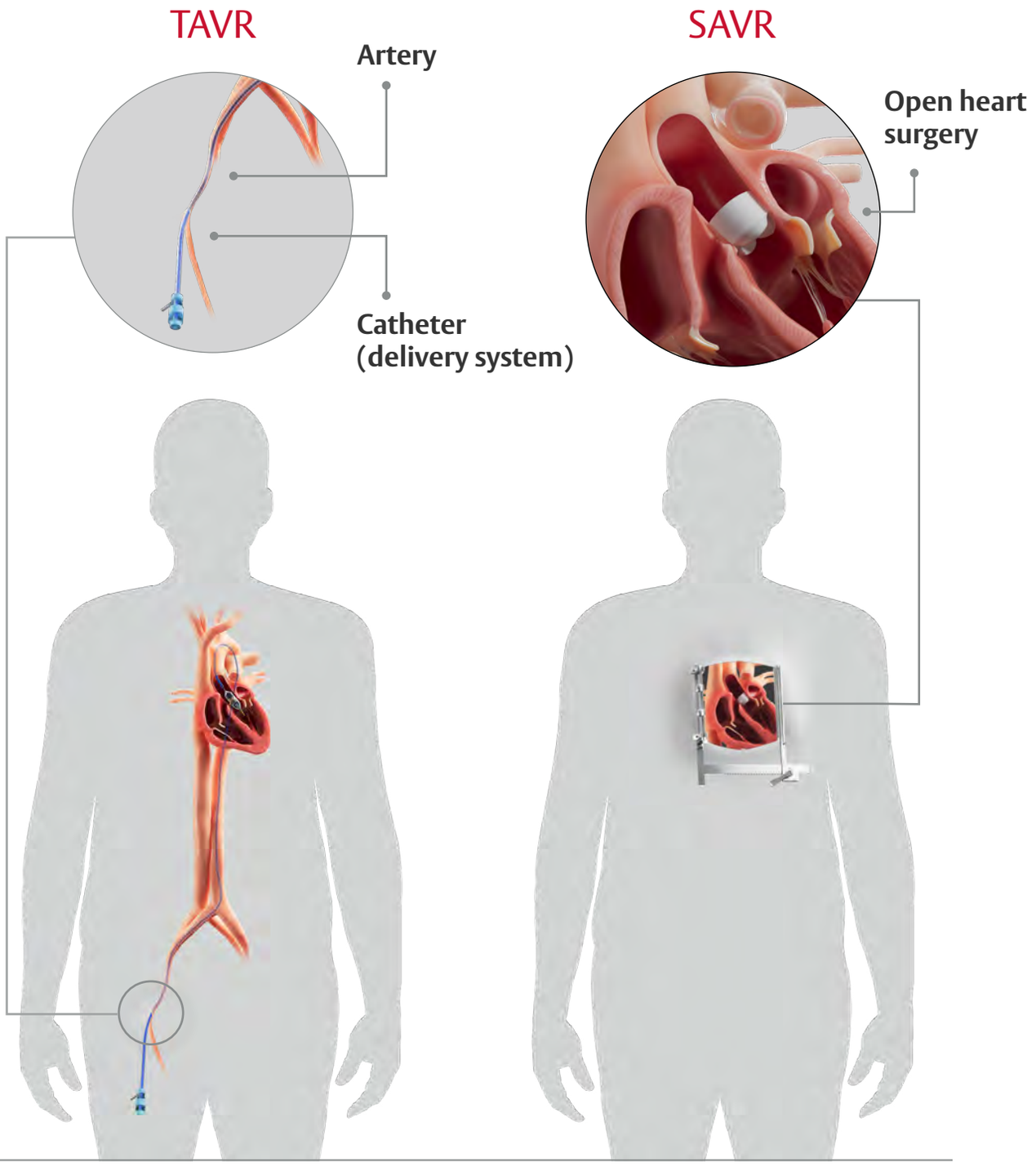
Not all patients experience symptoms, but for those who do, your doctor may prescribe medication to control them. However, heart valve failure will continue to get worse until you have your valve replaced.

Visit **TreatHeartValveFailure.com/Sign-Up** to sign up for the Heart Valve Strong community to receive emails on heart valve failure, TAVR, and tips for talking with your doctor.

Treatment

There are only 2 ways to replace your aortic valve

TAVR and SAVR (surgical aortic valve replacement – also called open heart surgery) are both ways to replace your heart valve. TAVR may prevent heart valve failure symptoms from starting. If symptoms do occur, both treatments can provide relief and reduce your risk of death from heart valve failure. There are key differences between them.



TAVR vs SAVR*

	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 7 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.

7-year data based on results from the PARTNER 3 study comparing TAVR to valve replacement by open-heart surgery.

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

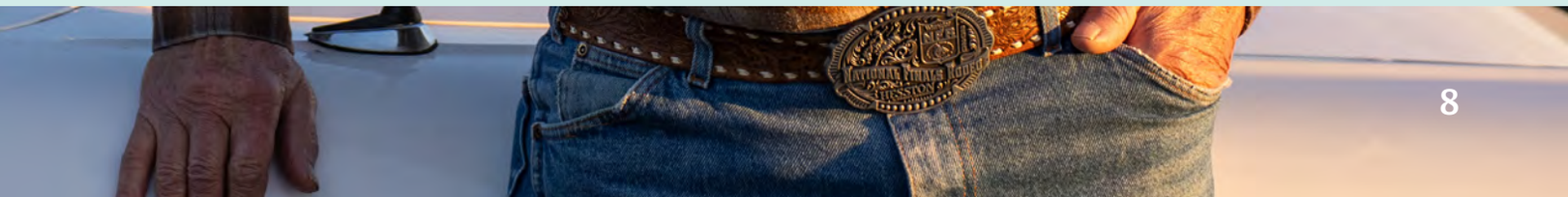
What you should know about TAVR

- TAVR is a minimally invasive way to replace a failing aortic heart valve compared to open heart surgery, also known as SAVR
- TAVR doesn't involve opening up the chest and, on average, takes 1 hour vs 4 hours with open heart surgery
- TAVR has become the preferred treatment for people with heart valve failure
- TAVR is covered by Medicare for all eligible patients
- Over 98% of TAVR recipients did not require a valve reintervention up to 10 years after receiving their valve*

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

HARRY | REAL TAVR PATIENT

People who experienced heart valve failure symptoms say they're still feeling better and living better, even several years after the TAVR procedure.



Don’t wait for symptoms

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.

Most people who get TAVR:

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

Experience long-lasting durability of up to 7 years, similar to SAVR*

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) who are at high or greater risk for open heart surgery

*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.

7-year data based on results from the PARTNER 3 study comparing TAVR to valve replacement by open-heart surgery.

Only a Heart Valve Team can tell you if TAVR is right for you

- If you've been diagnosed with heart valve failure, you'll need to be evaluated for treatment
- Ask your doctor to refer you to a Heart Valve Team
- A Heart Valve Team will determine the best treatment option for you

What is a Heart Valve Team?

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 to determine what treatment is right for you.

Interventional Cardiologists | **Cardiac Surgeons** | **Imaging Specialists** | **Valve Clinic Coordinators**

Your 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

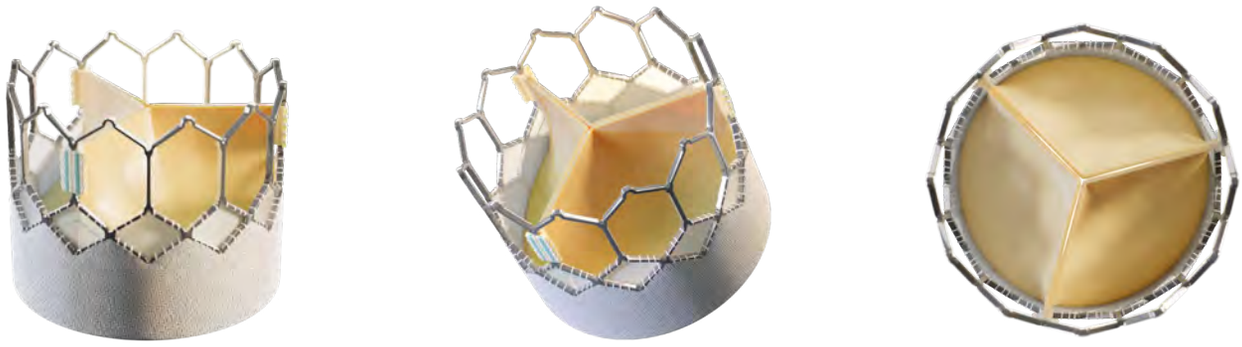
During your evaluation, your Heart Valve Team will consider these factors:

- 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

Diagnosed with heart valve failure?
Find a TAVR Hospital in your area. Visit **TreatHeartValveFailure.com/Find**

Your choice of heart valve matters

- TAVR by Edwards is shown to help reduce the rapid and unpredictable declines in your health caused by heart valve failure
- It's been clinically tested and shown that patients who received TAVR by Edwards 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



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

To date, more than 1 million people worldwide have received TAVR by Edwards.

TAVR by Edwards is the #1 choice in the US for transcatheter heart valve replacement

- The SAPIEN 3 Ultra RESILIA valve is the latest approved Edwards TAVR valve
- The SAPIEN 3 Ultra RESILIA valve is made of cow heart tissue that uses advanced technology to block the buildup of calcium. This RESILIA tissue treatment could potentially allow the valve to last longer*†

*Clinical data on surgical valves with RESILIA tissue up to the 7-year follow-up have been published, with additional follow-up to 10 years in progress. Beaver T, et al. *J Thorac Cardiovasc Surg*. 2024;168(3):781-791.

† RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards Lifesciences in a juvenile sheep model. Flameng W, et al. *J Thorac Cardiovasc Surg*. 2015;149(1):340-345.

Designed in different sizes to fit your anatomy

The Edwards SAPIEN 3 family of TAVR valves are not one-size-fits-all. They come in 4 sizes to meet the individual needs of each patient.

Edwards TAVR valves provide:

- Excellent durability and performance
- Low rates of needing valve replacement a second time
- Low rates of stroke and high rates of survival

Now is the time to talk to your doctor to see if an Edwards TAVR valve is right for you.

Discover the benefits of Edwards TAVR valves.

Watch a short, animated video about TAVR by Edwards valves.
Visit **TreatHeartValveFailure.com/Edwards**

Before

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.

Use this pre-procedure checklist

Please check the boxes as you prepare for your TAVR:

- ☐ **Get a dental clearance to ensure any infections present in your mouth or teeth don't spread to your heart valve**
- ☐ **Talk to your doctor about how much activity or exercise you should be doing (and let them know about any new or worsening symptoms)**
- ☐ **Go over any medicine you are taking with your doctor. Consult with your doctor to determine which medications you should or should not take leading up to and on the day of your procedure**
- ☐ **Talk to your doctor about which foods are recommended and when you should stop eating or drinking prior to your procedure**
- ☐ **Make sure you have someone to drive you to and from the hospital the day of your procedure**
- ☐ **Go over this information and any instructions you receive with your caregiver so you both know what to expect and can prepare**

Notes

Write down any questions you have for your doctor about your procedure or instructions you've received here.

During

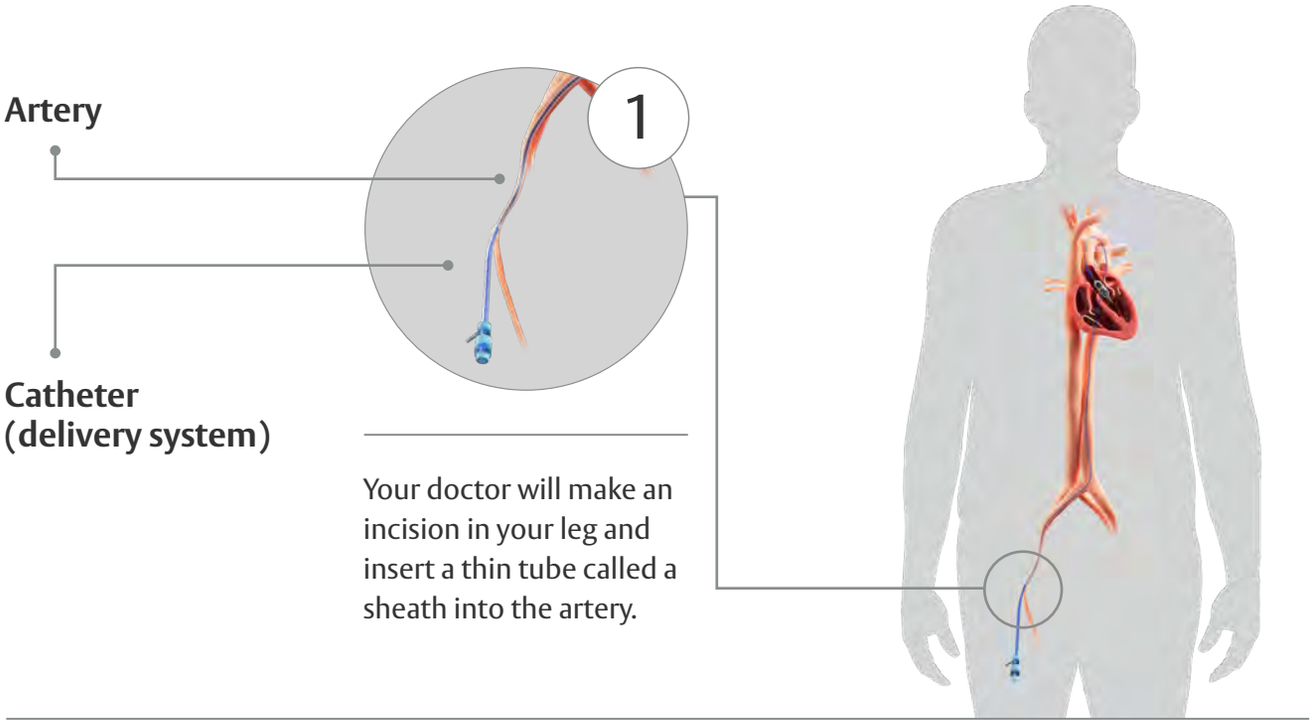
What to expect at the TAVR Hospital

Most people who have TAVR go to the hospital the morning of the procedure. Some people may be asked to go to the hospital the night before. Your doctor or care team will let you know when to arrive.

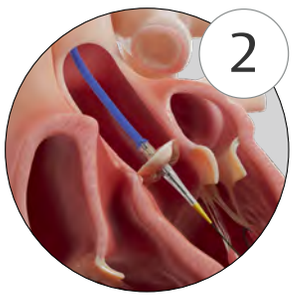
1 hour	The TAVR procedure usually takes about an hour
	Your TAVR doctor will decide what type of anesthesia is best for you. You may be asleep or awake and medicated while your valve is replaced
	Your loved one(s) will be told how the procedure went and how you're doing
	You'll be able to have visitors after the anesthesia wears off
	Nurses will encourage you to start sitting up and moving around soon after the procedure
	You'll learn how to care for yourself once you're home, including caring for your incision, doing breathing exercises, managing pain, and taking recommended medication

What to expect during the procedure

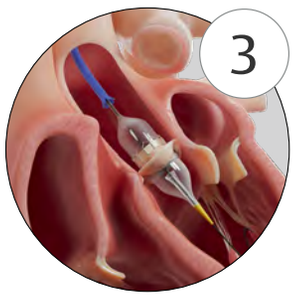
The TAVR procedure involves using a catheter, or narrow tube, to deliver your new valve to your heart. Most commonly, the catheter is inserted through a small incision (cut) in the leg near the groin. This is called the transfemoral approach.



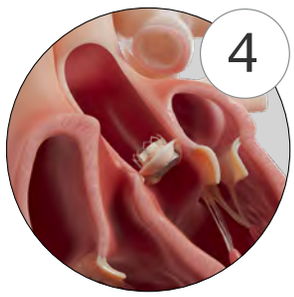
Your doctor will make an incision in your leg and insert a thin tube called a sheath into the artery.



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 and fix the new valve into place.



Your existing valve holds the new valve in place, and the balloon is deflated and removed. The new valve will open and close as a normal aortic valve should.

Watch this short video to get a closer look at the TAVR procedure.
Visit TreatHeartValveFailure.com/Treatment

After

Here's what your Heart Valve Team may cover with you before you leave the hospital:

- **Pain control** – you may experience some pain or discomfort and receive pain medicine if needed
- **Daily activities** – be patient and follow the advice of your doctor. You may need help when you first go home. It's best to plan ahead so you have the help you need
- **Breathing** – you may be given breathing exercises to help keep your lungs clear
- **Incision care** – your incision dressing will need to be changed to prevent infection
- **Medication** – your doctor may prescribe medication, including blood thinners
- **Your new valve** – you may be given an echocardiogram to see images of your new valve before you leave the hospital

What to expect after you leave the hospital:

- Recovery time and time in the hospital are different for everyone
- Most people get to go home the next day and recover faster compared to open heart surgery
- Most people experience symptom relief and can get back to everyday activities in as little as 30 days

Notes

List any additional questions you have for your doctor here.

After

Here are some steps that you – and your caregiver – can take to help you recover

- **Arrange to have help around the house** for the first few days after your procedure and possibly longer
- **Talk with your loved one or caregiver** about what you need and how they can best help you
- **Continue to care for your incision** as instructed in the hospital
- **Perform any breathing exercises** you learned at the hospital until your doctor says it's OK to stop
- **Keep your pain under control,** as directed by your doctor, to help you stay active while recovering
- **Take all medication as prescribed** and don't stop taking any without talking to your doctor
- **Attend all follow-up appointments** with your doctor

Notes

List any additional questions you have for your doctor here.

Getting back to life after TAVR

Joy wasn't about to wait around while her heart valve failure symptoms got in the way of doing what she loved. She decided to take back her life with TAVR.

"I don't wait for anything. Especially heart valve failure."

JOY | REAL TAVR PATIENT

Hear Joy's story. Visit TreatHeartValveFailure.com

Follow-up appointments

It’s very important to attend all of your follow-up appointments so a doctor can check your progress. Ask questions or share any concerns with a doctor.

Your follow-up visits may include:

- Blood tests to see how your medication is working
- Tests to check how well your heart and new valve are working

Together, you can decide on a schedule that's best for you.

In the first 30 days after TAVR

In the first 24 hours up to the first few days after release from the hospital, you may receive a follow-up phone call from your doctor to check in on your symptoms, medication, and well-being.

You may be asked to see a primary care provider around 5 to 7 days after release from the hospital.

In the months after TAVR

Your TAVR doctor will eventually transfer your care back to either a general cardiologist or primary doctor.

Every year after TAVR

You should schedule a follow-up appointment with a cardiologist to check your heart valve, which may include getting an echocardiogram.

A few additional things to know

Tell your dentist that you have had a heart valve replacement. You will likely need to take an antibiotic before undergoing any new procedure, including a cleaning, to reduce the risk of getting an infection in your new heart valve.

An MRI scan will not affect your transcatheter heart valve. However, there's important information your doctor needs to know before you undergo an MRI scan. Refer your doctor or the MRI lab staff to **edwards.com/mri-safety** for more detailed information.

HARRY | REAL TAVR PATIENT

Be sure to **inform all healthcare professionals that you have a transcatheter replacement valve** and **share your TAVR Valve Implant Card** with them.

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.

How could I benefit from TAVR?

- The minimally invasive TAVR procedure is 1 hour vs 4 hours with open heart surgery
- Most people are up and walking in a few hours and able to go home the next day
- People experience improved heart function, often with less pain and anxiety
- Research has shown a person's health improves within 30 days, including the ability to take care of themselves and participate in everyday activities

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.

What are the risks of TAVR?

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

Does my heart have to be stopped for TAVR?

No, unlike open heart surgery, TAVR does not require stopping the heart.

How many people have had the TAVR procedure?

Over 1 million patients worldwide and counting.

Will my TAVR valve last?

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

TAVR by Edwards has better outcomes than open heart surgery in low-risk patients at 1 year – and was proven equally effective at 7 years.†

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

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7-year data based on results from the PARTNER 3 study comparing TAVR to valve replacement by open-heart surgery.

Patient stories: Hear from people who decided to do something about their heart valve failure

Millions of Americans have been diagnosed with heart valve failure. Watch patients describe their experiences from diagnosis and treatment through recovery.

"Now, years later, I'm feeling great and I've been doing things actively ever since."

THOM | REAL TAVR PATIENT

Hear Thom's story. Visit TreatHeartValveFailure.com

Additional support

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.

American Heart Association

For information and resources on heart health, visit **heart.org/heartvalves**

Heart Valve Voice

Find in-depth education, resources, and patient stories focused on heart valve disease at **heartvalvevoice.com**

Support for women's heart health

Join the movement to improve the lives of women with or at risk for heart disease – and to promote equity in care. Visit **womenheart.org**

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 **1-800-532-5274**

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 **1-888-713-1564**

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.

Edwards TAVR Community

There’s a community just for people who have received a TAVR. And once you’ve gotten a TAVR, you’ll be eligible to join.

After you've received your ID card, you'll be invited to join the Edwards community. Once you join, you’ll receive:

- Helpful information
- Updates by mail and email
- Support during your first year after TAVR

It’s up to you if you’d like to participate and connect with Edwards and the patient community during your journey to heart valve health.

Here's how to join the Edwards TAVR Community

You will receive a transcatheter valve temporary ID card when you leave the hospital. A TAVR Valve Implant Card will be mailed to your home within 6 to 8 weeks of your procedure.

Please call 1-888-713-1564 if you need a replacement card. Keep this card with you at all times and show it to all your healthcare providers.

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.

Edwards Lifesciences

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

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