

TAVR Procedure Guide

Your comprehensive guide to transcatheter aortic valve replacement (TAVR) – from treatment through recovery.



The TAVR Procedure: a Guide to Help You Take Charge of your Severe Aortic Stenosis



Did you know that more than 870,000 people worldwide have received the TAVR procedure?

If your aortic stenosis is severe, and you are experiencing symptoms, the time for treatment is *now*.

Your doctor may have evaluated you for severe aortic stenosis and told you that you will benefit from having transcatheter aortic valve replacement (TAVR; pronounced "TA-ver"), or you may have just started to look for information about the procedure. Either way, it's important to understand that your choice of valve matters.

This guide is designed to help you and your family understand this serious heart condition, which affects millions of older adults. You will learn how aortic stenosis can get worse over time and affect your health, your day-to-day life — and your future.

It will provide you with a clear understanding of what to expect from the procedure and why your choice in the valve you receive matters for your best possible outcomes and your overall management of aortic stenosis.

Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves are a part of the latest technology of heart valves from Edwards Lifesciences. Your doctor can help you decide on which Edwards TAVR valve is right for you.



SAPIEN 3 valve



SAPIEN 3 Ultra valve



SAPIEN 3 Ultra RESILIA valve

You have the power to put yourself first and treat your disease with a less invasive option, TAVR. Ask your doctor when you can get treatment and how, together, you can select the right valve.

How to use this guide

The booklet is divided into 4 sections that take you through what to expect before, during, and after your procedure. You'll also find frequently asked questions in the patient resources section.

Preparing for TAVR	Page 3
Life After TAVR	Page 6
For Caregivers	Page 17
Patient Resources	Page 18

Refer to this guide at each step along your TAVR journey, including your recovery.

Your future starts now with TAVR!

Preparing for Your Future With the TAVR Procedure

Your team of doctors and nurses has evaluated you and considered all aspects of your health and medical background to determine that TAVR is the best treatment option for you.

In this section, you'll learn about TAVR's benefits and risks, how it's performed, and how to prepare for your procedure.

What is TAVR?

If you have severe aortic stenosis, TAVR is a less invasive treatment option that doesn't require open heart surgery.

TAVR should be considered for all patients suffering from severe aortic stenosis, who are experiencing symptoms. If you have been told you are not a candidate for the procedure, please see a doctor to discuss your options. The sooner you treat severe aortic stenosis with TAVR, the sooner you get back to the life you want to live.

The TAVR procedure may provide the following benefits:



For more information, scan this code or visit newheartvalve.com



Improved heart function



Most patients go home the next day and recover quicker*



Relief of symptoms



Less pain, and anxiety*



Improved quality of life following the procedure



Minimal scarring*

Risks of the TAVR procedure

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

It is important to discuss your particular situation with your doctor to understand the possible risks, benefits, and complications associated with TAVR.

^{*}when compared to open heart surgery

How Is TAVR Performed?

Compared with open heart surgery, TAVR is a less invasive procedure. TAVR can be performed multiple ways, but the most common approach involves a small incision in the groin. This is called the transfemoral approach. Your doctor will determine the best place to make an incision based on your individual anatomy.

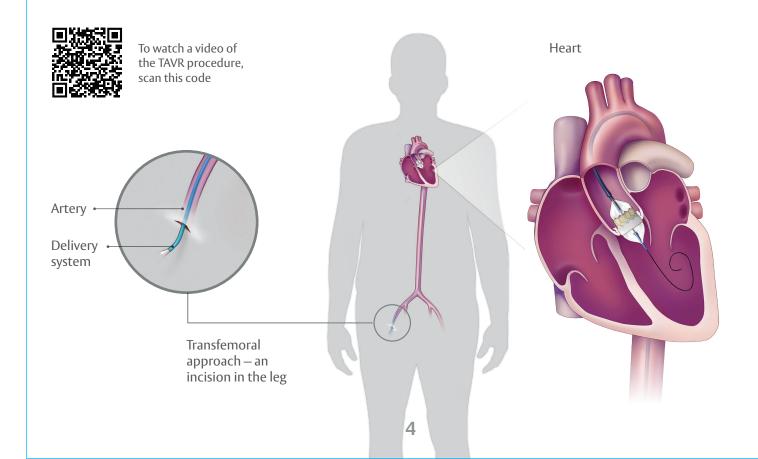
- The procedure starts with a small incision made in your groin. This is where your doctor will insert a short, hollow tube called a sheath into your femoral artery.
- The new valve is then placed on the delivery system tube with a balloon on the end. The new valve is compressed on the balloon to make it small enough to fit through the sheath.
- The delivery system carrying the valve is pushed up to your aortic valve where the balloon is inflated, expanding 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. Your doctor will make sure your new valve is working properly before closing the incision in your groin.

Sedation

During TAVR, you may be fully asleep during your procedure or you may be awake but given medication to help you relax and block pain. Your doctor will determine what type of anesthesia is best for you.



The average TAVR procedure is about 1 hour, compared to open heart surgery which lasts about 4 hours.



How Should You Plan for TAVR?

Your doctor will likely have specific instructions for you to follow before your TAVR procedure. Talk with your doctor about what you need to do to prepare for it.

Here are some things to consider in the weeks and days leading up to your procedure:



Ask How Much You Can Exercise

Ask your doctor what level of activity is appropriate. It is important to make note of new symptoms that might arise when exercising, such as shortness of breath, chest pain, or feeling faint.



Talk to Your Doctor About Your Medications

Consult your doctor to figure out which medications you should or should not take leading up to and on the day of your procedure.



Eat a Healthy Diet

Talk to your doctor about which foods are recommended. Also, discuss when you should stop eating or drinking prior to your procedure.



Get a Dental Check-up

Because oral bacteria can cause infection of the valve, it is important to visit your dentist prior to TAVR to make sure you are in good dental health.



Make a Recovery Plan

Your doctor will be able to tell you when it's safe to return home. It's important to work out details such as who will take you home, who will stay with you, or help you prepare meals.

What to Expect the Day of Your TAVR Procedure

On the day of your TAVR procedure, you and your caregiver should feel prepared and have a good understanding of what to expect.

Every hospital has different instructions for patients to follow. The recovery time and length of hospital stay may be different for each person, too. Most patients go home the next day and have a shorter recovery time when compared to open heart surgery, getting you back to everyday activities. Your doctor can tell you how long you can expect to stay in the hospital after the TAVR procedure. The goal is for you to go home as soon as it is safe for you to leave.



Refer to the Patient Resources section on page 18 for a packing checklist and frequently asked questions about preparing for TAVR.



To learn more about what to expect before the procedure, scan this code or visit newheartvalve.com

Life After TAVR: You're Just Getting Started

During your recovery, there are important steps that you — and your caregiver — can take to help you recover and return to your daily routine more smoothly. This section will help you through many of those steps, and it will address some of the concerns and questions you may have about life after TAVR, including the following:

- What to expect after your TAVR procedure while you're still at the hospital
- What to expect after you are discharged and leave the hospital
- Caring for your health
- · Important things to keep in mind
- What to know about imaging scans
- What to discuss with your doctor

Now is my time, now is my prime!



What Can You Expect After the TAVR Procedure?

While you're still in the hospital

After your TAVR procedure, the doctor will update your caregiver or loved ones on how you are doing. Talk with your team about what to expect and how long it may be before your visitors can see you.



To learn more about what you can expect after the procedure, scan this code or visit newheartvalve.com

As you recover in the hospital, your nurses and doctor will help you with the following:

Pain control	Pay attention to your pain, and tell your nurses how you are feeling. They can give you pain medicine to help keep your pain under control.
Sitting up and walking	After your procedure, you will be asked to sit up and be encouraged to move. Try to move as often as you are asked to. This will help with your recovery.
Breathing	You will be given breathing exercises to help keep your lungs clear and to help prevent complications.
Incision care	Your nurses will change and remove your incision dressing as needed. This can help prevent infection.
Medicines	Your doctor may prescribe more medicines for you, including blood thinners. Talk with your team if you have any questions about the medicines they prescribe.
Using the restroom	Ask your nursing team to help you if you need assistance with your usual bowel and bladder routine.
ર્ર્િ} Your new ર્ર્ડ્ેરે valve	Before you leave the hospital, you may be given an echocardiogram that shows moving images of your heart to make sure your valve is working correctly.

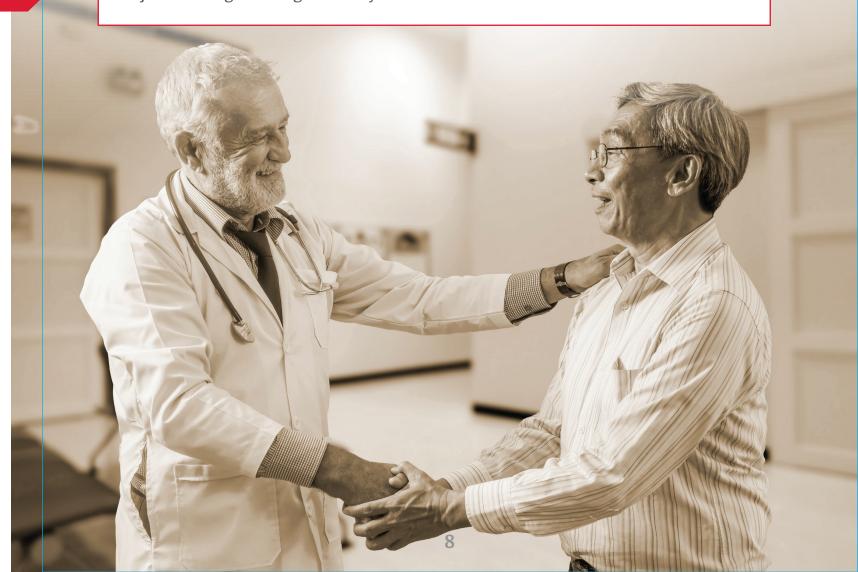
What to expect when you leave the hospital

As you leave the hospital after TAVR and begin your recovery, there are some important things to keep in mind. The information that follows is not meant to replace what your doctor tells you. Be sure to follow the instructions your team gives you at discharge — and contact them at any point during your recovery if you have questions or do not feel well.

Partnering with your caregiver

When you are ready to be discharged from the hospital, you will need someone to pick you up and drive you home. You also will need help for at least the first few days after your procedure and possibly longer. It is okay to ask for help as you get back to your daily life. Talk with your caregiver about what you need and how he or she can best help you. It may be useful to review the caregiver section on page 15 of this booklet together.

Discuss your activity with your doctor. While some people may notice improvement in their energy level and quality of life right away, for others it can take days or weeks. As you begin to increase your activities, remember your body may need time to adjust to being active again. Give yourself time to rest when needed.



Caring for Your Health

Here are some things to keep in mind as you start your recovery and care for your health.



Incision care

Follow the instructions you were given at the hospital to help the incision site heal and to reduce the risk of infection. Call your doctor right away if you notice any signs of infection, such as the following:

- Increased pain, redness, or swelling at the incision site
- Liquid oozing from the incision site
- Fever (check your temperature as often as your doctor tells you to)



Managing pain

You may have some aches and pains after TAVR, which are part of the normal healing process. You may have pain in your back, shoulders, neck, and chest. If you are sore or uncomfortable, take the pain medicine your doctor prescribed exactly as you were told to take it. It can help you be active. Let your doctor know right away if your pain medicine is not working well.



Lung care

Continue to perform the breathing and coughing exercises you learned at the hospital. They will help keep your lungs clear and prevent complications.



Daily activities

Be patient and follow the advice of your doctor. You may need help when you first go home. It is best to plan ahead so you have the help you need.



Taking medicines

- Take all of your medicines exactly as prescribed. Do not stop taking any medicine without first talking with your doctor
- Make sure to bring a list of all of your medicines to every healthcare appointment



Dental precautions

Let your dentist know that you have had a heart valve replacement. You will likely need to take an antibiotic before having any procedure, including a cleaning. This can reduce the risk for getting an infection in your new heart valve.



Talk with your doctor if you notice any change in the way you feel or if something does not feel right.

Follow-up After TAVR

Another part of your recovery is attending scheduled follow-up visits with your doctor. During these visits, the doctor will check your progress and ensure that your heart is working as it should. In addition:

- Blood tests may be performed to monitor how your medicines are working
- You might have your blood drawn to make sure the amount of blood thinner is steady to prevent blood clots

To check how you're healing, the doctor may order some tests, including the following:

- Echocardiogram to check valve function
- Electrocardiogram to detect any abnormal heart rhythms

Your doctor will discuss other factors affecting your health. Follow their advice regarding diet, exercise, and medicines.

Your follow-up appointments

Be sure to go to all of your scheduled appointments. Be an advocate for your own health. Monitor how you are feeling, and keep track of questions you have as you recover. Share this information with your doctor at your follow-up visits as you partner with them for a successful recovery.



See the next page for a typical follow-up schedule.

A Typical Follow-up Schedule

Your doctor will recommend a schedule that's best for you. Contact your doctor at any time during your recovery if you have questions or concerns.

Refer to this check list to know what to expect for your follow-up schedule.

Timeframe after TAVR	What to expect and do	
	In the first 24 hours up to the first few days after discharge, you may receive a follow-up phone call from your doctor who will be checking in on your symptoms, medicines, and well-being	
In the first 30 days after TAVR	You will likely be scheduled for an in-office follow-up visit. At this visit, you will likely have an echocardiogram recorded to check your new valve. You may also have other tests and be asked to share some information about your symptoms and quality of life. Some doctors may recommend that you see your primary care provider 5 to 7 days after discharge	
In the months after TAVR	Your doctor should transfer your care back to either your general cardiologist or your primary doctor. Please schedule your visit with your doctor within the first week of discharge. Talk with your doctor to see how you can check on your progress	
Every year after TAVR	You should schedule a follow-up appointment with your cardiologist specifically to check your heart. At this visit, you will likely have an echocardiogram recorded and may complete some additional tests	



Be sure to turn to the Resources tab for more helpful tools.





Life After TAVR

Incision care

	How do I keep the incision site clean?	
	How do I protect the incision site to help it heal?	
	Is there specific clothing I can wear to help keep the incision site comfortable?	
	How can I reduce my risk for infection?	
M	anaging pain	
	What kind of pain medicine will I take after my procedure? How often do I take it?	
	Are there other ways I can manage my pain in addition to my pain medication?	



Life After TAVR

Lung care

	How many times each day should I do my lung exercises?
•	When can I stop doing my lung exercises?
D	aily activities
•	Are there any showering instructions I need to follow?
	Can I take a bath or go swimming?
•	Are there any activities that I should avoid after my TAVR procedure?
	How soon can I get back to my day-to-day activities around the house?
	When and how can I increase my physical activity?
	When can I return to sexual activity?
_	
•	Will I be able to drive?

Taking Care of Your Loved One: Getting Back to Living!

Preparing for TAVR: tips and support for caregivers

The doctor will provide the person you are caring for with specific instructions for you to follow before the TAVR procedure. Talk with the doctor about how you can help him or her get ready. Here are some actions to consider in the weeks and days leading up to the procedure.



Action	How You Can Help
Monitoring physical activity	Be watchful of the person you're caring for while he or she is exercising. Instruct him or her slow down or stop if there is any sign of shortness of breath, chest pain, or feeling faint. Report any worsening symptoms you notice back to the doctor.
Maintaining a balanced diet	It's important that the person you're caring for eats a well-balanced diet and that you offer encouragement. The doctor may have put restrictions on how much liquid and salt your loved one can have.
Taking medicines	It can be helpful to keep track of all the medicines the person you are caring for takes and when he or she should take them. You can use a pill organizer or a small notebook to stay organized.
Driving carefully	Typically, people with severe aortic stenosis are winded and may not be able to drive. Each person is different. Talk with the doctor about whether the person you are caring for should be driving.
Preparing legal documents	Consider helping to ensure the necessary legal paperwork is organized and completed.
Packing for the hospital stay	Help the person you're caring for pack for the hospital — a pair of pajamas and a comfortable outfit to go home in is enough. Do not bring valuables. A patient may be moved to another room at least twice during the hospital stay. It's possible for things to be misplaced during these moves. It may be best if you keep his or her clothes until the day of discharge.
Planning ahead for discharge	If the person you are caring for is discharged home, you can help with tasks related to his or her recovery. This includes helping with bathing, medicine reminders, and follow-up visits. You can also help with making meals, cleaning, and running errands. If you think additional help is needed, talk with your social worker or nurse about local people who may be available to help. Remember, while the patient may leave the hospital feeling better, he or she must listen to the doctor's orders and take it easy.



As a Caregiver: Questions to Ask the Doctor About Preparing for TAVR

	What kind of anesthesia will be used? Will it make the patient feel sick?
	If so, what should I do?
•	How long will the person I'm caring for be in the hospital?
•	Will I need to spend the night in the hospital to make sure he or she is properly cared for?
•	For how long will he or she have symptoms after the procedure, and what might they be?
•	How do I need to be prepared to provide care at home? What kind of additional support should I arrange for in advance?
	Will the person I'm caring for need physical therapy or rehab?
	Will this procedure affect any of his or her other health conditions?
	Are there any new medicines that he or she will need to take? What instructions do I need to know about them?
	What legal or other documents should I help my loved one prepare?
	What is the average length of time for recovery?
	What kind of quality of life will he or she have after TAVR?
•	What kind of resources are available to help us know how to plan for TAVR?

TAVR Patient Resources

You're just getting started, and we're here to support you. In the next few pages, you'll find helpful tips and tools to support you before, during, and after TAVR.

- Visit www.NewHeartValve.com to learn more about the TAVR procedure. You will also find all kinds of useful information, including patient testimonials, videos, brochures, and additional information on TAVR as a treatment option
- Visit www.TAVRbyEdwards.com to learn more about Edwards transcatheter heart valves, the Edwards valve difference, and clinical data. You'll find in-depth information to help guide you in making a decision with your doctor about choosing the right heart valve for your lifetime management of aortic stenosis.



Preparing for TAVR Packing for Your Hospital Stay

Most people who have TAVR go to the hospital the morning of the procedure. Sometimes people may be asked to go to the hospital the night before. Follow the instructions from your doctor.

Packing checklist:
Toothbrush and toothpaste
Comb or brush
Slippers (with nonslip soles)
Glasses
Denture case
Hearing aids
Reading materials
Pajamas
Comfortable clothes to go home in
It is recommended that you do not bring cash or valuables to the hospital.

Frequently Asked Questions

How many people have had the TAVR procedure?

More than 870,000 people in 75 countries have had a TAVR procedure.

How long is the TAVR procedure?

The average TAVR procedure is 1 hour compared to open-heart surgery, which lasts about 4 hours.

Are there different types of transcatheter heart valves and can I ask for a specific valve?

Transcatheter heart valves are made by different manufacturers. You can check which valves are used and available at your hospital. Although you can ask for a specific valve, your TAVR Doctor will recommend the best valve for you.

Learn more about Edwards transcatheter heart valves at TAVRbyEdwards.com.

What is TAVI, and is it different from TAVR?

TAVI stands for transcatheter aortic valve implantation. The procedure and its approaches are the same as TAVR. Your doctor may use the terms interchangeably when discussing your treatment options.

Does my heart have to be stopped for TAVR?

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

What does life after TAVR look like?

Research has shown patient health improvements within 30 days, including the ability to take care of themselves and participate in everyday activities.¹

How long does a transcatheter heart valve last?

How long your tissue valve will last depends on many patient factors and medical conditions. Follow all care instructions to ensure the best possible results. The Edwards transcatheter valve has been tested in a laboratory to mimic 5 years of use without failure. Regular follow-ups will help your doctor know how your valve is working.

What happens if my transcatheter heart valve fails?

Every year after TAVR you should have a follow-up appointment with your cardiologist, who will be checking your heart. During these visits, your cardiologist will likely perform an echocardiogram and complete other tests to make sure your valve and heart are still working properly. If your cardiologist discovers that your valve is no longer working the way it should, your doctor will determine next steps and decide if you need an evaluation for reintervention. If it is determined that another procedure is needed to fix your failing heart valve, and you have previously had a transcatheter heart valve to fix your severe aortic stenosis, you could be eligible to get another transcatheter heart valve placed into your failed artificial valve. This procedure is known as valve-in-valve and is currently approved for patients who are deemed high risk for open heart surgery.



For additional FAQs, scan this code or visit newheartvalve.com

What to Know About Imaging Scans

Is it safe to undergo an x-ray or computed tomography (CT) exam after TAVR?

Your valve is completely safe for both x-ray and CT examinations.

Will my valve cause a metal detector at the airport to go off?

Going through an airport metal detector will not affect your valve. The amount of metal used in valves is very small. It is usually not enough to set off metal detectors. If it does, simply show the security personnel your transcatheter valve identification card.

Is it safe to undergo a magnetic resonance imaging (MRI) scan after TAVR?

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



Be sure to inform all healthcare professionals that you have a transcatheter replacement valve, and share your transcatheter valve ID card with them.

Finding Support

As you recover from TAVR, it is normal to feel a wide range of emotions. It can help to share with others your experiences and how you are feeling. Find a friend or loved one whom you feel comfortable talking with, and share how you are feeling. Visit friends or go out socially when you feel ready. You might also look for local support groups where you can meet and share with people who know what you are going through. They can help you to talk about your emotions as you recover. You may find the following resources helpful:

Alliance for Aging Research: www.agingresearch.org

American Heart Association: www.heart.org/heartvalves

Family Caregiver Alliance: www.caregiver.org

Heart Valve Financial Aid Fund and CareLine: http://heartvalve.pafcareline.org/

Heart Valve Voice: www.heartvalvevoice.org

Mended Hearts: www.mendedhearts.org

WomenHeart: www.womenheart.org

Welcome to the TAVR Community!

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

Please call 888-892-0099 if you need a replacement card. You should keep this card with you at all times and show it to all your healthcare providers.

Included in the letter with your ID card will be an invitation to join the Edwards community to receive helpful information, updates by mail and email, and support during your first year after TAVR. It's up to you if you'd like to participate in and connect with Edwards and the heart patient community during your journey to heart health.

Making the right valve choice with your doctor is key to living your best life and managing severe aortic stenosis. Your doctor, healthcare professionals, and caregivers are there to help you during your journey. Wishing you a successful recovery and good health.

Learn More About the Edwards Lifesciences Difference and Your Transcatheter Heart Valve

With more than 60 years of experience, Edwards Lifesciences has developed innovative tools to help patients like you.



Phone (within the United States)

For TAVR inquiries: 1-888-713-1564



Mail

Edwards Lifesciences LLC One Edwards Way Irvine, California 92614



E-mail

TAVR@edwards.com



Online

www.edwards.com www.NewHeartValve.com www.TAVRbyEdwards.com

For additional information, ask your doctor for the Edwards Patient Brochure.

Reference:

1. PARTNER 3 trial, low-risk cohort unadjusted clinical event rates, AT population.

 $See\ accompanying\ Important\ Risk\ Information.$

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Edwards, Edwards Lifesciences, the stylized E logo, Edwards SAPIEN, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, NewHeartValve.com, PARTNER, PARTNER 3, RESILIA, SAPIEN, SAPIEN 3, SAPIEN 3 Ultra and TAVRbyEdwards.com are trademarks or service marks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

 $\hbox{@ 2023 Edwards Lifesciences Corporation.\,All rights reserved.\,PP--US-4344\,v4.0}$

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

