Your Guide to TAVR:

Transcatheter Aortic Valve Replacement

A guide for people with severe aortic stenosis who need treatment.

Edwards

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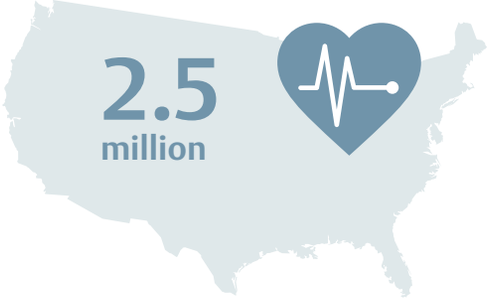
Aortic stenosis is one of the most common and most serious valve disease problems. It affects nearly **2.5 million Americans older than 75 years.**



Your Guide to Transcatheter Aortic Valve Replacement

You've taken an important step toward learning about aortic stenosis, also called aortic valve stenosis, and how you can improve your heart health. This educational guide can help you and your family learn more about this serious heart condition, which affects millions of older adults, and about the available treatment options.

This guide will explain how aortic stenosis can get worse over time and affect your health and day-to-day life. After reviewing the information, you'll have a better understanding of the symptoms of severe aortic stenosis and why they are not just normal signs of aging. You will also learn about treatment options for severe aortic stenosis, including a procedure called transcatheter aortic valve replacement (TAVR; pronounced "TA-ver"). It's important that you work with a TAVR Doctor so that together you can decide the best treatment option for you.

This guide includes a symptom tracker for you to log any symptoms and changes in your health. Share this information with your doctor. We have also included a list of TAVR Hospitals in your area. For more information about severe aortic stenosis, TAVR, and to hear from people who have had the TAVR procedure, visit www.NewHeartValve.com.

TAVR has helped many people get back to living their life. I hope you find this information helpful in your treatment journey.

Wishing you good health,

Dr. Martyn Thomas
Vice President Medical Affairs, Transcatheter Heart Valves,
Edwards Lifesciences

Click here to view video

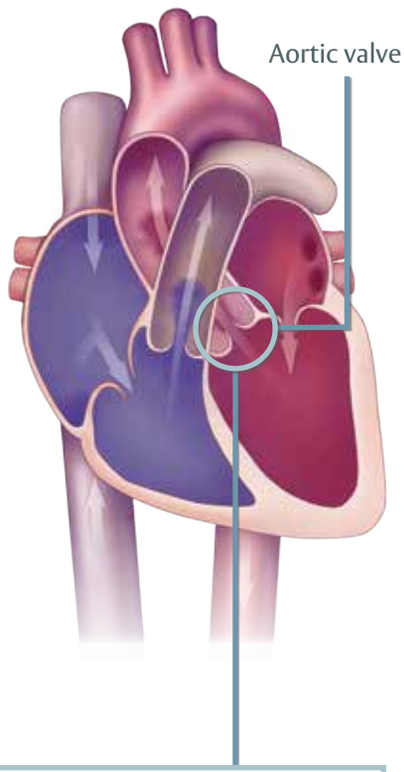
Know the Facts About Aortic Stenosis

Click here to view video

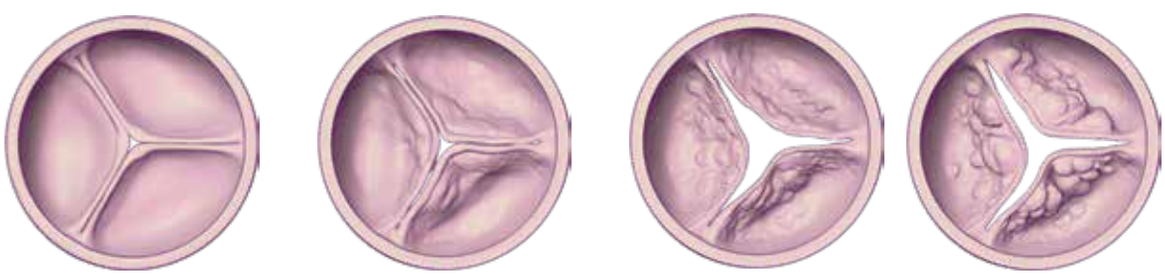
Your heart works hard every second of the day, pumping blood throughout the body. Your aortic valve is located inside your heart. The valve has thin leaflets that open and close like gates and control blood flow to the rest of your body. **Aortic stenosis** is a disease of the aortic valve. The disease makes the valve leaflets stiff, which means that the valve cannot fully open and close as it should. As the opening becomes smaller, it makes it harder for the heart to pump blood to the rest of your body, which can cause you to feel tired and out of breath.

Aortic stenosis is a serious condition that weakens the heart, damages your health, and makes it hard to do the things you want and need to do. **Aortic stenosis can be mild, moderate, or severe and may worsen over time.**

Your Heart



Disease Progression in the Valve Leaflets in Aortic Stenosis



Most often, aortic stenosis affects older adults and is caused by a build-up of calcium, a substance normally found in the blood. The disease can also be caused by:

- **birth defect**
- **rheumatic fever**
- **radiation therapy**

Aortic Stenosis Gets Worse Over Time

To protect your health, your heart will be monitored on a regular basis. If the aortic stenosis is "mild," your doctor may recommend “watching and waiting” and not prescribe treatment. For people who have "moderate aortic stenosis," medicine may be prescribed.

It’s important to know that medicine cannot stop or cure aortic stenosis – it can only treat the symptoms.

As the disease progresses and becomes "severe," you may need to have your aortic valve replaced.

With this disease it is important to be aware of possible symptoms. Your doctor will listen to your heart and ask about your activity level. People who have severe aortic stenosis may find it hard to take part in regular activities such as walking to get the mail or going up the stairs. They may also have an increased risk for heart failure.

“All was fine. I was active. I didn’t know anything was wrong. I have a cardiologist, and one day he said, ‘You have a heart murmur.’ And here I am now.”

— Patient (New York)

Not every heart murmur is heart valve disease.

Monitoring Aortic Stenosis

You will have an echocardiogram, or "echo" test, which is a noninvasive test that takes a picture of your heart. This test shows the size of the aortic valve and measures the speed of the blood that flows through the valve and the pressure on either side of it.

The test will show whether you have mild, moderate, or severe aortic stenosis. Follow-up echo tests will show whether the disease is progressing.*

Severity of Aortic Stenosis	How Often Should an Echocardiogram Be Performed?
Mild Aortic Stenosis	Every 3 to 5 years
Moderate Aortic Stenosis	Every 1 to 2 years
Severe Aortic Stenosis	**Seek treatment options**

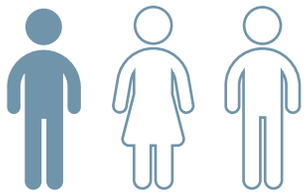
It's important to stay in touch with your doctor between tests. Report any new symptoms or any changes in current symptoms you may have even if they do not seem significant. Ask how often you should have an echocardiogram to monitor the progression of aortic stenosis.

If you are 70 years or older and have not had an echocardiogram, ask your doctor whether you should have one.

> *I stopped being able to walk the dog and work in my garden.... I guess it was gradual, but I could feel it happening to me.*
>
> — Patient (Tennessee)

*The frequency of testing is based on guidelines from the American College of Cardiology Foundation and American Heart Association. Nishimura RA, Otto CM, Bonow RO, et al; ACC/AHA Task Force Members. 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014;129(23):2440-2492. http://circ.ahajournals.org/content/circulationaha/early/2014/02/27/CIR.0000000000000029.full.pdf.

Symptoms of Aortic Stenosis or Signs of Getting Older?



About 1 out of every 3 people with aortic stenosis realize they have symptoms only when further evaluated.

Many people simply confuse the symptoms of aortic stenosis with "normal" signs of aging. People who have aortic stenosis may report no symptoms, but after closer examination, they realize in fact they have symptoms. This is why it's so important to talk with your doctor about your symptoms and changes in your daily activity. **Many times people do not know they have symptoms until they discuss their daily activity with a doctor.**

Use the doctor discussion guide and symptom tracker in the email to keep track of your symptoms and questions to ask your doctor.

Know the Symptoms of Severe Aortic Stenosis

Listen to your body. Tell your doctor about changes in your health and any new or worsening symptoms. Once aortic stenosis becomes severe, people usually have symptoms but not always. The symptoms can appear suddenly, worsen quickly, and become life-threatening.

You may notice one or more of these symptoms:

Fatigue (extreme tiredness)

Swollen ankles and feet

Shortness of breath

Not engaging in activities you used to enjoy

Chest pain (tightness in the chest that often gets worse with exercise)

Feeling dizzy or lightheaded

Difficulty walking short distances

Difficulty sleeping (or need to sleep sitting up)

Rapid heartbeat (feels like your heart is fluttering in your chest)

Fainting

Other signs:

- Rapid weight gain
- Irregular heartbeat (heart murmur)
- Dry cough

Tip for Family Members

Your role is an important one. Keep an eye on any changes and new or worsening symptoms your loved one may experience. If you see changes, contact the doctor right away.

Use the symptom tracker in the email to make note of any changes in your loved one's health. Share this information with his or her doctor.

Know Your Treatment Options

Taking the next step to find out about treatment options for severe aortic stenosis may feel overwhelming, but you should not wait. It's important that you talk with your doctor about all available treatment options. Aortic stenosis can progress quickly, and you should understand what your options are before treatment becomes urgent. Early treatment for this progressive disease can make a significant difference in your long-term health.

The only effective way to treat severe aortic stenosis is by replacing your aortic valve. This can be done through transcatheter aortic valve replacement (TAVR) or open heart surgery. TAVR may be available for all aortic stenosis patients and is a less invasive option for replacing the aortic valve. Your risk for complications and your overall health will determine which treatment option is best for you.

Tip for Family Members

Seek treatment early so that you and your loved one can get back to life and all the things you like to do.

Click here for more information

Benefits of TAVR for Severe Aortic Stenosis

More than 400,000 people worldwide have received the TAVR procedure.

TAVR is a procedure that replaces the diseased aortic valve in people who have severe aortic stenosis. It is a less invasive procedure than open heart surgery that may help you get back on your feet faster.

Benefits of TAVR may include:

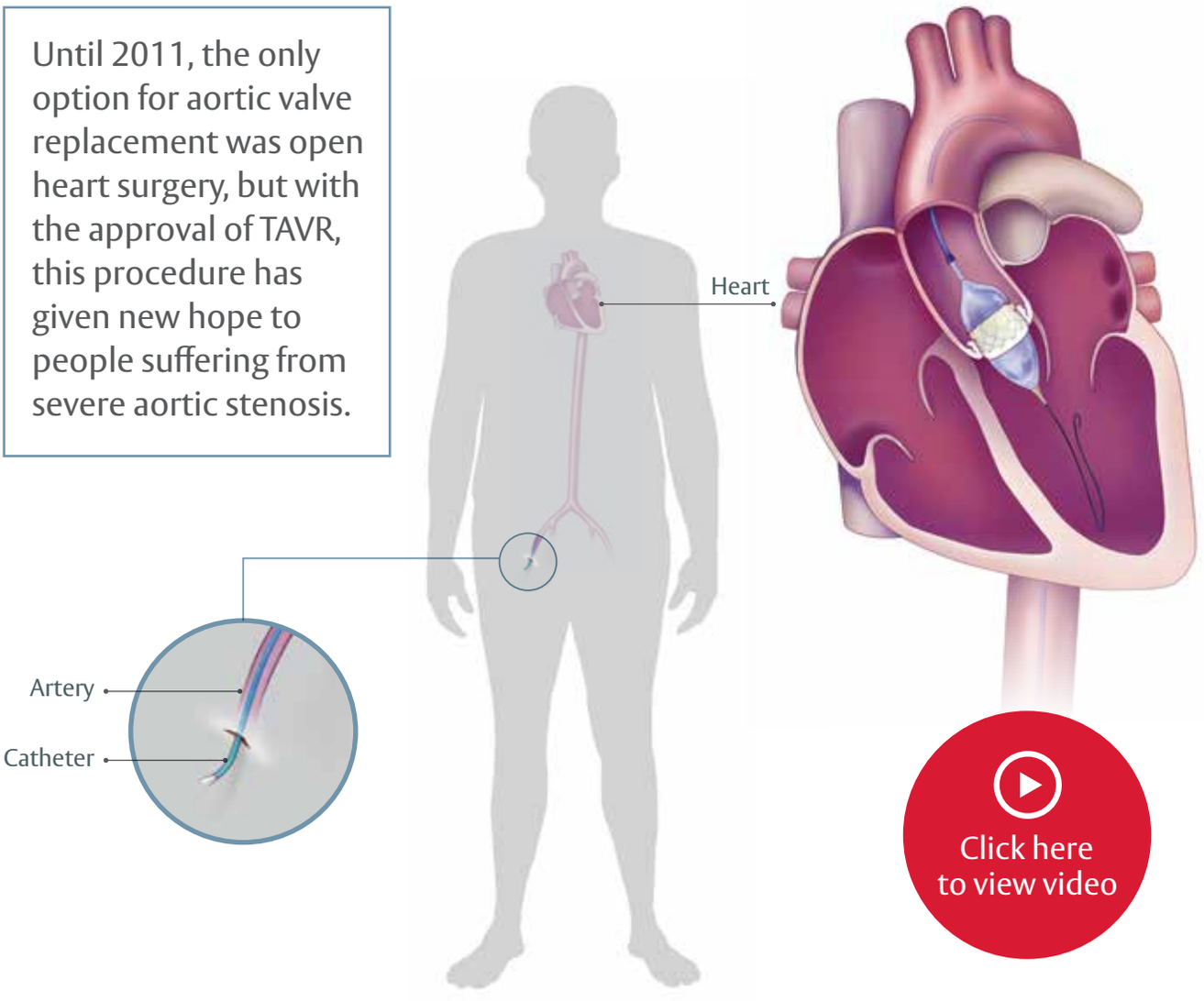
- Improved quality of life
- Relief of symptoms
- Shorter recovery time to getting back to everyday activities
- Less pain and anxiety
- Shorter hospital stay
- Better clinical outcomes
- Less invasive with minimal scarring

> *Having mom healthy again means that she can resume her life. I guess that also means that I can resume mine, now that she is back to her old self.*
>
> — Caregiver (Nashville)

Click here for more information

Learn How TAVR Is Different

Until 2011, the only option for aortic valve replacement was open heart surgery, but with the approval of TAVR, this procedure has given new hope to people suffering from severe aortic stenosis.



- Compared with open heart surgery, TAVR is a less invasive procedure that involves making a small incision in the leg versus opening up the chest
- TAVR uses a small catheter, or tube, that is pushed through an artery to the heart to place a new valve within a diseased aortic valve
- The recovery time after TAVR and the length of hospital stay is shorter than that with open heart surgery. On average, the TAVR procedure lasts approximately 1 hour

Click here to watch experiences of two patients who went through TAVR, as well as what to expect with the TAVR procedure.

Is TAVR Right for You?

TAVR may be recommended for people who have been diagnosed with severe aortic stenosis and need their valve replaced.

A specialized doctor at a TAVR Hospital will consider all factors about your health to decide whether TAVR is a treatment option for you.

Click here to view video

Your doctor will consider these factors:

Your medical history

Your age

Your current health status

The condition of your heart

Your doctor should review with you all the options available. If not, find a doctor trained in the TAVR procedure who will provide this information. TAVR may be the preferred option compared to open heart surgery for people who have severe aortic stenosis and have been told they are eligible for the procedure by a TAVR Team.

Remember, only a TAVR Doctor can determine whether TAVR is an option for you.

Where to Get a TAVR Evaluation

It's important to note that not every doctor is qualified to evaluate for or perform the TAVR procedure. Only certain doctors who have received extensive training can evaluate you or perform the TAVR procedure. TAVR is performed only at certain hospitals across the country.

The doctor who diagnosed you with severe aortic stenosis can refer you to a TAVR Doctor, or you can go directly to a TAVR Hospital. You will need to contact the Valve Clinic Coordinator (VCC) at a TAVR Hospital to make an appointment for an evaluation. The VCC is usually the first point of contact at a TAVR Hospital and can help you navigate through the process. He or she can contact your insurance provider to confirm your coverage for the evaluation and the TAVR procedure.

A TAVR Doctor and their team may need to perform a few tests and exams to

- Confirm the severity of your disease
- Determine the best treatment option for you

Ask to be referred to a TAVR Doctor. It is important for you to know that TAVR can be performed only by trained TAVR Doctors at certain hospitals across the country. Click here to find a hospital near you.

Tip for Family Members

You should feel empowered about your loved one's treatment plan. If you are unsure, seek a second opinion, see a TAVR Doctor.

The TAVR Evaluation

Once the patient is confirmed to have severe symptomatic aortic stenosis, he or she should be evaluated to determine whether TAVR is an option. A team trained in TAVR assesses aortic valve disease in patients who are referred for evaluation. The team includes cardiologists, cardiac surgeons, and imaging specialists. Together, this team looks at each patient and based on a number of factors, decides whether TAVR is an option for aortic valve replacement.

The evaluation may include these tests:

Echocardiography (echo test) – a noninvasive test that takes pictures of your heart

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

Chest x-ray scan – shows the size and shape of your lungs and heart

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

In some cases, you may have already had some of these tests. These assessments help the TAVR Doctor create a treatment plan based on your current images and measurements. They're important because your TAVR Doctor wants to make sure he or she is recommending the best treatment for you.

If you were previously told that you were not a candidate for TAVR because you are too young or healthy, now is the time to seek an evaluation with a TAVR Doctor. Call a Valve Clinic Coordinator (VCC) to get evaluated!

What to Expect With the TAVR Procedure

Before the procedure

You may need to get a dental clearance. Any infection that may be present in your mouth or teeth can spread and cause an infection in your heart valve. Therefore, it is important for your dentist to examine you and provide dental clearance before any valve procedure.

Your Valve Clinic Coordinator will give you information and instructions to get ready for the procedure. It is normal to be nervous. Your TAVR Doctor will be sure to review the risks and benefits of TAVR with you and answer any questions.

During the procedure

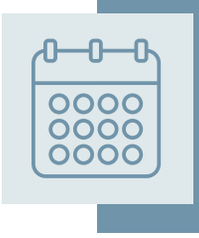
TAVR is performed in a hospital. Before the procedure, you will be given anesthesia. During a common TAVR procedure, the doctor will make a small incision in the leg and insert a thin tube called a catheter into the artery. The doctor will then guide the catheter, which is carrying the new valve on a 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. It begins working right away.

On average, the TAVR procedure lasts about 1 hour, versus 4 hours with open heart surgery.

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

After the procedure

The recovery time and length of hospital stay may be different for each person. However, patients who receive TAVR usually have a shorter hospital stay than those who receive open heart surgery. Your TAVR Doctor can tell you how long you can expect to stay in the hospital after the TAVR procedure.



Your quality of life may improve as early as 30 days after the TAVR procedure.

Click here for more information

Insurance Coverage and TAVR

Your Valve Clinic Coordinator will help you through the process from evaluation to procedure. They are available to help you with all TAVR-related questions, including concerns about insurance coverage and financial needs.

You should contact your insurance provider before your first appointment with a TAVR Doctor to determine whether the evaluation and TAVR procedure are covered and whether a referral is necessary.

TAVR is covered by Medicare and will cover most procedure-related expenses for those who meet certain risk criteria.

In need of assistance to help navigate insurance and reimbursement?

The Heart Valve CareLine may be the answer. For more information, please visit heartvalve.pafcareline.org or call (866) 318-7892.

Helpful Resources

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

Aortic Stenosis and TAVR website

For more information, visit **NewHeartValve.com**

TAVR patient stories

Visit the Patient Resources tab at **NewHeartValve.com/video**

Caregiver resources

Family Caregiver Alliance. Learn more at **caregiver.org**

TAVR by Edwards

See additional information about TAVR on **TAVRbyEdwards.com**

Patient support line

Figuring out the next steps in treating severe aortic stenosis may feel overwhelming. Edwards Patient Team is here to support you. For more information, please call (833) 387-6744.

Visit the patient support page at **NewHeartValve.com/patient-resources/patient-support**

Financial resources

Heart valve patients experiencing trouble getting care may receive free professional assistance and case management to help navigate insurance and reimbursement. For more information, visit **heartvalve.pafcareline.org** or call **(866) 318-7892.**

Frequently Asked Questions

Q If I am 70 years of age or older, how often should I get an echocardiogram or heart health evaluation?

Different factors contribute to heart disease, and age can be one of them. It's important to be aware of your risk and talk with your doctor about your heart health. Aortic stenosis is an age-related disease, so make sure to ask your doctor about whether you should get an echocardiogram.

Q How serious is severe aortic stenosis (also known as severe aortic valve stenosis)?

Up to 50% of people who develop symptoms from severe aortic stenosis will die within an average of two years if they do not have their aortic valve replaced.[1] If you have been diagnosed with severe aortic stenosis and have symptoms, talk to your doctor right away about your treatment options.

Q How long will it be before my aortic stenosis becomes so severe that I will need my valve replaced?

The progression of aortic stenosis is different for everyone, so it may take years or months before a valve replacement is necessary. Your doctor will be better able to assess the severity of aortic stenosis according to your physical symptoms and the results of your echo tests.

Q What are the treatment options for aortic valve stenosis?

Depending on how far your aortic stenosis has progressed, your doctor may prescribe medication to help control your symptoms. However, it's important to know the only effective way to treat aortic stenosis is by replacing your valve. TAVR is now the preferred treatment option for patients with severe aortic stenosis and may have symptoms.

Q What if my Doctor doesn't refer me to a TAVR Doctor?

If your current doctor does not think TAVR is an option for you, you may still contact a VCC 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/or find possible treatment options available to you.

Q How can I get an evaluation for TAVR?

To see whether the TAVR procedure is right for you, you will need to see a specialized TAVR Doctor at certain hospitals across the US. Only a TAVR Doctor can evaluate you for both TAVR and open heart surgery to determine the best treatment option for you. You can find three of your nearest TAVR Hospitals in the pocket of this guide.

Frequently Asked Questions

Q What if my doctor doesn't specialize in the TAVR procedure?

Ask your doctor to refer you to a TAVR Doctor. TAVR Doctors are experts in valve disease and valve replacement and can determine the appropriate treatment option for you. You can find a list of TAVR Doctors at certain hospitals in the US near you in the back pocket of this guide.

Q What is a Valve Clinic Coordinator (VCC)?

A VCC is usually your first point of contact at a TAVR Hospital. They are in charge of coordinating all activities regarding TAVR. The VCC provides support to patients from referral to a TAVR Doctor through follow up from the TAVR procedure. They will help you navigate through the process of evaluation, possible treatment, insurance coverage, and financial needs.

Q How could I benefit from transcatheter aortic valve replacement?

With the less 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. Other TAVR benefits include shorter hospital stay, relief of symptoms (sometimes immediately), improved heart function, and reduced pain and anxiety.

Q How long has the TAVR procedure been performed and for how many people?

TAVR has been commercially available in Europe since 2007 and in the United States since 2011, for more than 400,000 people worldwide.

Q What can I expect after the TAVR procedure?

Research has shown that patients who undergo the TAVR procedure have improved health within 30 days of their procedure.

Q What are the risks of the TAVR procedure?

Serious complications that could be associated with the TAVR procedure may be death, stroke, serious damage to the arteries, or serious bleeding. It is important to discuss your particular situation with your doctor to understand all the possible risks, benefits, and complications.

Q How long does a TAVR valve last?

The TAVR was approved in 2011 and long-term clinical data are still being reviewed. The Edwards TAVR valve is made from cow tissue, and it has been shown to last at least 5 years, according to US clinical data.

Our nurse was crucial to our overall comfort with the situation. She guided us through everything, translated the doctor speak, and helped us understand what decisions we had to make. She was special and important.

— Patient

Thank You

Thank you for taking the time to review this TAVR guide.

Your healthcare provider

Name: _____

Phone: _____

Address: _____

_____

NewHeartValve.com
by Edwards Lifesciences

References
1. Otto CM. Timing of aortic valve surgery. *Heart.* 2000;84:211-218.

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