Now is your time. Now is your prime.



TAVR Info Kit

Talk to your doctor today about TAVR, the less invasive alternative to open heart surgery.

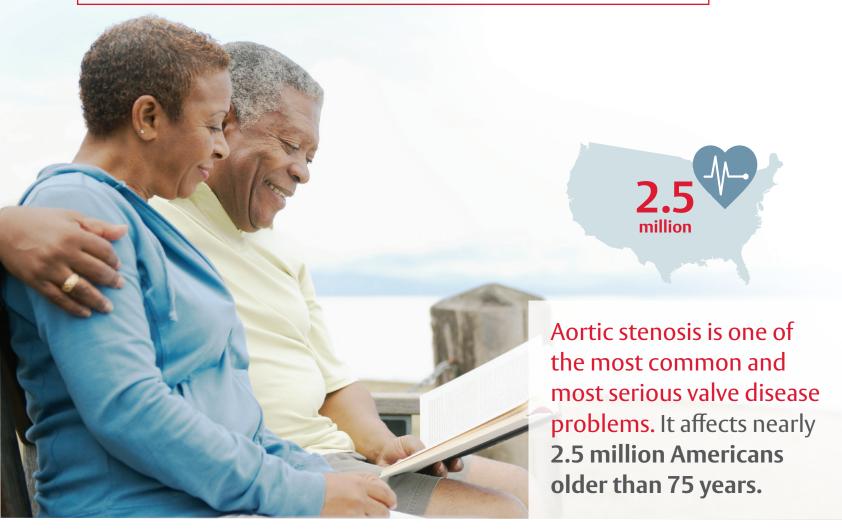


Table of Contents:

Know the Facts About Aortic Stenosis	4 - 8
TAVR as a Treatment Option	9 - 12
What to Expect with TAVR	13 - 16
Helpful Resources	17
Frequently Asked Questions	18-19

This document features interactive links, denoted by an icon like this. Click on them to access deeper information.





We all want to live life to its fullest. This information kit will help you take action and prompt you to ask your doctor proactive questions about all your available treatment options for your severe aortic stenosis, including TAVR.

Your Guide to Taking Control of Your Future With Transcatheter Aortic Valve Replacement



By taking an important step toward learning about aortic stenosis, also called aortic valve stenosis, you've shown you're ready to improve your heart health and live your second act!

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, your day-to-day life — and your future.

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 start by asking your doctor if you should treat your severe aortic stenosis soon. You'll want to learn about all your available options, including TAVR.

To get you started, this guide includes a symptom tracker for you to log any symptoms and changes in your health. Share this information with your doctor and be sure to ask him or her about your treatment options today. We have also included a list of TAVR Hospitals in your area, along with several helpful resources for you. For more information about severe aortic stenosis, TAVR, and to hear from people who have had the TAVR procedure, visit www.NewHeartValve.com.

It takes courage to address your severe aortic stenosis, a progressive disease that can impact your health. When you prioritize treatment, you are taking back your future. Ask your doctor where and when you can get treatment – because waiting shouldn't be an option.

Wishing you good health,

Dr. Martyn Thomas

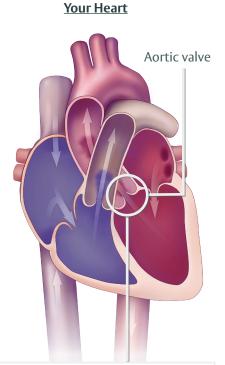
Vice President Medical Affairs, Transcatheter Heart Valves, Edwards Lifesciences

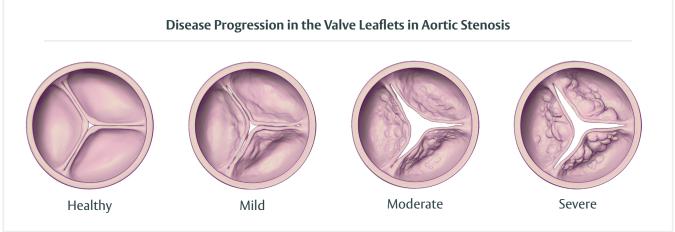
It's Important to Understand the Facts About Aortic Stenosis



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.**





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 a **birth defect**, **rheumatic fever**, and **radiation therapy**.



If your aortic stenosis is severe and you have symptoms, then the time for treatment is now. Instead of waiting for your disease to get worse, you have the power to take control of your severe aortic stenosis with a less invasive option — you have the power to put yourself first. Ask your doctor at your next appointment if you are eligible for TAVR.

Aortic Stenosis Is a Deadly Disease That Will Worsen Over Time

To be proactive, work with your doctor to make sure 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.

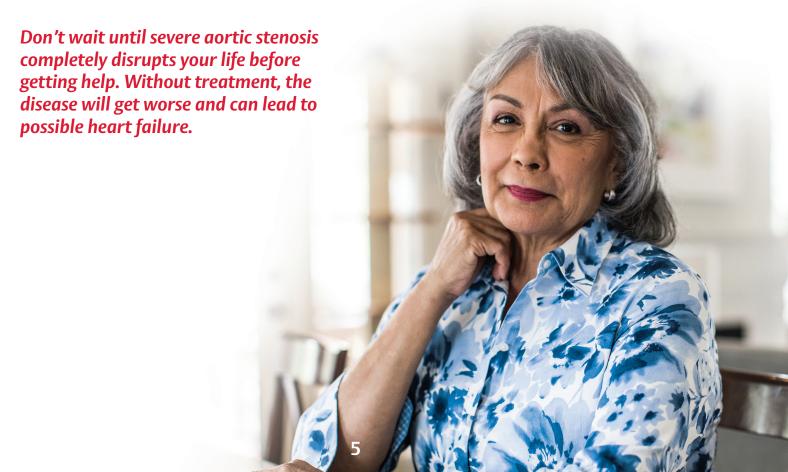


It's important to know that medicine alone cannot stop or cure aortic stenosis — it can only treat the symptoms.

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.

Take control of your treatment. Once your severe aortic stenosis has been diagnosed and you have symptoms, ask your doctor when you should get treatment. Getting a regular echocardiogram can help your doctor make that determination. Remember, waiting shouldn't be an option.



Monitoring Aortic Stenosis – Know When to Act

You will also 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.

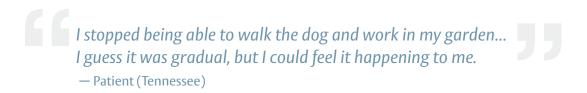
The test will show whether you have mild, moderate, or severe aortic stenosis. Follow-up echo tests will show whether the disease is progressing.*

Severity of Aortic Stenosis	How Often Should an Echocardiogram be Performed based upon the AHA/ ACC Guidelines?		
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 and make sure you understand when you will need treatment.



Now is the time to be proactive about your heart health. Ask your doctor about getting an echocardiogram.



^{*}The frequency of testing is based on guidelines from the American College of Cardiology Foundation and American Heart Association. Otto CM, Nishimura RA, Bonow RO, et al; ACC/AHA Task Force Members. 2020 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Practice Guidelines. Circulation. 2021;143(5):e72-e227. https://www.ahajournals.org/doi/epub/10.1161/CIR.000000000000923.

Is It a Symptom or a Sign of Getting Older?



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

Many people simply confuse the symptoms of aortic stenosis with the "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 activities with a doctor.



Use the doctor discussion guide on <u>page 21</u> and symptom tracker on <u>page 22</u> of this document to keep track of your symptoms and questions to ask your doctor.



Watch for 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 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



Tip for Family Members

You role is important in helping your loved one get back to living the life they love. 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 <u>symptom tracker</u> in the back of the book 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 for severe aortic stenosis may feel overwhelming, but you should not wait. After all, your future belongs to you, not your severe aortic stenosis. It's important that you ask your doctor proactive questions about all your treatment options. Early treatment for this progressive disease can make a significant difference in your long-term health. When you put your heart health first and ask questions and stay informed about your severe aortic stenosis, you can better advocate for the best treatment option for *you*.

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 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

It takes courage for your loved one to seek treatment for severe aortic stenosis. You can help by seeking out a TAVR Heart Team early who will evaluate your loved one for the right treatment option. Then you can both get back to life and all the things you like to do together.

Help your loved one understand his or her treatment options so you can create a future without aortic stenosis that you can enjoy together.



How TAVR Improves the Lives of Patients Who Have Severe Aortic Stenosis



More than 450,000 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



Less pain and anxiety



Less invasive with minimal scarring



Relief of symptoms



Shorter recovery time to getting back to everyday activities



Helping your heart work better so that you feel better sooner



Shorter hospital stay



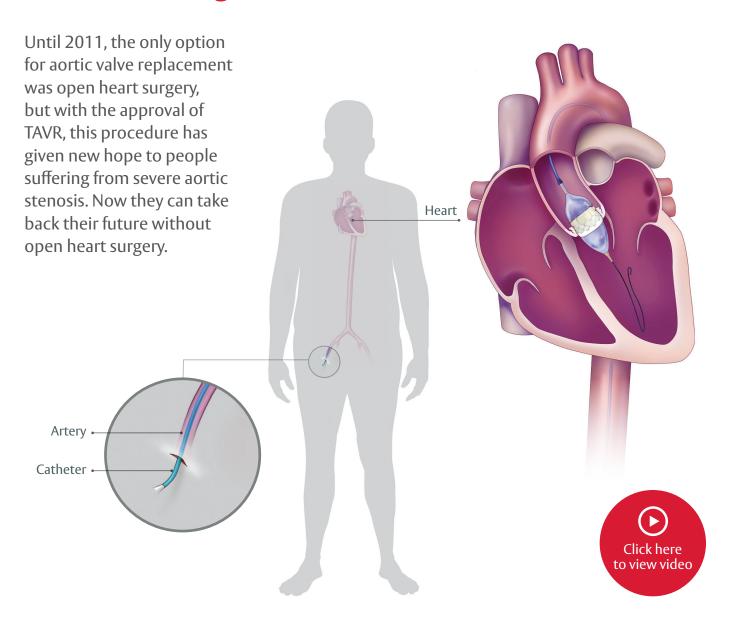
Better clinical outcomes

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)



Understanding the TAVR Difference



- 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 may be shorter than that with open heart surgery. On average, the TAVR procedure lasts approximately 1 hour



Your treatment journey starts with *you*. You can learn more about the benefits and risks of TAVR and view a video of the TAVR procedure by clicking here.

Is TAVR Right for You?

In the past, people living with severe aortic stenosis had very few effective treatment options. They could undergo open heart surgery or do nothing. Today, patients who have severe aortic stenosis have more treatment options than before — open heart surgery is not their only option.

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.

Your doctor will consider these factors:



Your medical history



Your age



Your current health status



Your ability to undergo the procedure and recover from it



The condition of your heart

Your doctor should review with you all the options available. If he or she doesn't, find a doctor trained in the TAVR procedure who will provide this information.



Did you know that in 2019 more patients with severe aortic stenosis received TAVR than open heart surgery?



Start by Getting a TAVR Evaluation

You can define your own future. Don't let severe aortic stenosis get in the way. Start by asking your doctor if you should treat your severe aortic stenosis soon. Learn about all available options and seek an evaluation for TAVR today.

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 Heart Team, 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 Heart 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 Heart Team. It is important for you to know that TAVR can be performed only by a trained TAVR Heart Team at certain hospitals across the country.





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 Heart Team**.

What Happens During a 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 Heart Team create a treatment plan based on your current images and measurements. They're important because your TAVR Heart Team wants to make sure he or she is recommending the best treatment for you.



Talk with the Valve Clinic Coordinator today at your TAVR Hospital about getting evaluated for your severe aortic stenosis.

What to Expect With the TAVR Procedure

Before the procedure

You will 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 Heart Team 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.

The major risks of TAVR are similar to open heart surgery and 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.

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 Heart Team 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.



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 Heart Team 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/patientstories



Caregiver resources

Family Caregiver Alliance. Learn more at caregiver.org



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 (870) 337-2050.

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

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.

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

As low as 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.

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.

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. This can be done through transcatheter aortic valve replacement (TAVR) or open heart surgery.



What if my doctor doesn't refer me to a TAVR Heart Team?

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.

How can I get an evaluation for TAVR?

Tesee whether the TAVR procedure is right for you, you will need to see a specialized R Heart Team 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

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

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

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 Heart Team through follow up from the TAVR procedure. They will help you navigate through the process of evaluation, possible treatment, insurance coverage, and financial needs.

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 short hospital stay, relief of symptoms, improved heart function, and reduced pain and anxiety.



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, and more than 450,000 people worldwide have received it. In 2019, the TAVR procedure was performed more often than open heart surgery for the treatment of severe aortic stenosis in the United States.



What can I expect after the TAVR procedure?

Quality of life studies with the TAVR procedure have shown patient health improvements within 30 days, including the ability to take care of themselves and participate in everyday activities.



What are the risks of the TAVR procedure?

Serious complications associated with the TAVR procedure may be death, major stroke, major vascular complications, or life threatening bleeding. It is important to discuss your particular situation with your doctor to understand all the possible risks, benefits, and complications.



How long does a TAVR valve last?

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. 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



Doctor Discussion Guide

This guide and symptom tracker can be used as an aid in talking with your doctor at appointments. It can also help you and your doctor determine the severity of your aortic stenosis, consider your treatment needs, and discuss your expectations and concerns.



Talk to your doctor about the following:

- Any changes in your ability to complete daily activities in the last 6 months
- Your overall health and well-being
- Your health history and the medicines you are currently taking
- If you have been sleeping more than usual or need to sleep sitting up
- The status of your last echocardiogram



Here are some suggested questions to ask your doctor:

- How can I tell if what I'm feeling is due to normal aging or to symptoms from aortic stenosis?
- How often should I get an echocardiogram?
- I'm not feeling any symptoms. How long until I will need treatment?
- Is my aortic stenosis severe?
- How soon will I need valve replacement?
- Do you think TAVR is an option for me?
- Would you recommend I be evaluated for TAVR? Why or why not?



Additional questions to ask your doctor? Write them down here:



Take this guide with you to your next doctor's appointment. Starting the conversation is an important step in taking control of your health and your future.

Aortic Stenosis Symptom Tracker



Aortic stenosis is a disease that gets worse over time. With this disease it's important to be aware of and track possible symptoms. The symptom tracker is designed to help you and your doctor monitor the potential symptoms of aortic stenosis. Share any changes in your symptoms with your doctor.

How to use the tracker

• Make copies of the tracker and complete it monthly

Date symptoms checked / Day Year									
	F	atigue or Extrei	ne Tiredne	ess		20	Shortness	of Breath	
	Never	Occasionally	Often	Always		Never	Occasionally	Often	O Always
(E)		Chest P	Pain			Dif	ficulty Walking	Short Dist	ances
	Never	Occasionally	Often	Always		Never	Occasionally	Often	O Always
(\bigcirc)		Rapid Fluttering	g Heart Be	at	([[Swollen Anl	des or Feet	
	Never	Occasionally	Often	O Always		Never	Occasionally	Often	O Always
	Not En	gaging in Activ	ities You O	nce Did		L	ight Headedne	ss or Dizzir	ness
	Never	Occasionally	Often	O Always		Never	Occasionally	Often	Always
(ZZZ	Difficu	ılty Sleeping or	Sleeping S	itting Up	(Faint	ting	
	Never	Occasionally	Often	Always		Never	Occasionally	Often	O Always
on a	ny of the	red "occasionall above, how fre ce the sympton	quently do		E	very week	Every mont	th Every fo	ew months
	v does a s when it o	ymptom disrup occurs?	t your	I barely notice	e it	l pause	onentarily		d to stop dress it



Although symptoms are not the only important clue for valve disease treatment decisions, a change in symptoms is important to discuss with your doctor.

Thank You

Thank you for taking the time to review this information kit.

Your healthcare provider

Name:	 	 	
Phone: _	 	 	
Address:	 	 	



References

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

