



## What You Need to Know About Aortic Stenosis

Millions of people in the United States have aortic stenosis, yet many people have never heard of it. As a caregiver, you may be asked to help navigate the road ahead with the person you care for. This may include scheduling and transporting the patient to and from medical appointments, discussing the treatment options, relaying the doctor's observations to family members, and ultimately helping the person you care for make the best treatment decision possible.

**Below is some basic information about aortic stenosis you will want to be familiar with.**

### WHAT CAUSES AORTIC STENOSIS?

Aortic stenosis is often caused by age-related calcium build-up on the valve, but can also be caused by rheumatic fever or radiation therapy.

### WHAT ARE THE SYMPTOMS?

**Because aortic stenosis prevents oxygen-rich blood flow, it may cause symptoms like severe shortness of breath and extreme fatigue. However, it's important to know that heart valve disease may occur with no outward symptoms.**

The symptoms of aortic disease are commonly misunderstood by patients as “normal” signs of aging. Many patients initially appear asymptomatic, but on closer examination, up to 32% exhibit symptoms.

What are some of the signs of aortic stenosis?

The person you care for may notice symptoms like:

- **Chest Pain**
- **Fatigue**
- **Shortness of Breath**
- **Lightheadedness, Feeling Dizzy, and/or Fainting**
- **Difficulty When Exercising**

If the person you care for experiences any of these signs or symptoms, consult a doctor right away.

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# What You Need to Know About Aortic Stenosis

## HOW IS IT DIAGNOSED?

The first thing the doctor will probably do is listen to their heart with a stethoscope. This is called auscultation. If the doctor suspects a heart murmur, they may refer them to a doctor who specializes in heart conditions, called a cardiologist. The cardiologist will more than likely require that an echocardiogram, also known as an "Echo," be performed. This test will confirm a diagnosis of aortic stenosis.



### AUSCULTATION

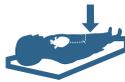
The doctor will use a stethoscope to listen for a murmur, click, or other abnormal sounds in the heart.



### ECHOCARDIOGRAPHY

A transthoracic echo, also known as a TTE, is another test performed to detect aortic stenosis. This is a noninvasive test where the patient lies down while a probe is placed on the chest wall. The probe uses sound waves to make detailed pictures of the heart.

Next, the cardiologist, as well as other members of the Heart Team, will ask for a number of specialized tests to assess if the TAVR procedure is the best option. In some cases, you may have already taken some of these tests. However, it is vitally important that you take these tests again at the request of the Heart Team. There are special angles and measurements used that the Heart Team will specifically request. These tests may include:



### CARDIAC CATHETERIZATION (ANGIOGRAPHY)

Under X-ray guidance, small hollow tubes (catheters) are advanced to the aortic valve and into the left ventricle. The rate of blood flow across the aortic valve and pressures can be measured.



### CHEST X-RAY

A chest X-ray usually shows a normal heart shadow. If heart failure is present, fluid in the lung tissue and larger blood vessels in the upper lung regions are often seen.



### ELECTROCARDIOGRAPHY (ALSO EKG)

An EKG is a recording of the heart's electrical activity using electrodes attached to the skin. An EKG can show the heart's rhythm, the heart's rate, and the strength and timing of the electrical currents.

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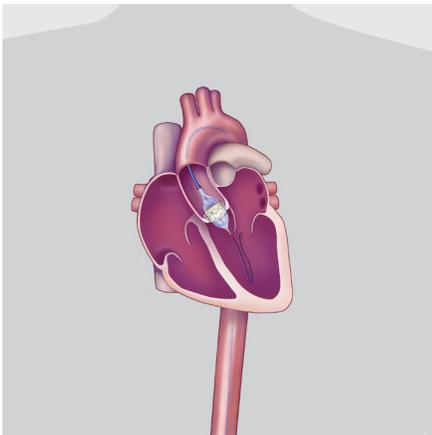


## WHAT ARE THE TREATMENT OPTIONS?

Treatment for aortic stenosis depends on how far the disease has progressed. If the stenosis is mild, medication may be prescribed to temporarily relieve symptoms, but is not effective long term. As the severity of the stenosis progresses, the doctor may recommend replacing the diseased aortic valve.

No medical treatments have been proven to delay the progression of severe aortic stenosis or to improve survival. Eventually, most people will need to have their heart valve replaced.

Today, there are 2 ways to replace diseased aortic valves:

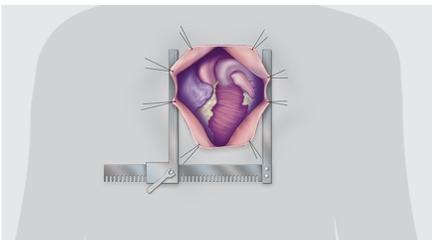


### 1. Transcatheter Aortic Valve Replacement (TAVR)

For people who have been diagnosed with severe aortic stenosis and are at intermediate or greater risk for open heart surgery, TAVR (sometimes called transcatheter aortic valve implantation, or TAVI), may be an alternative. This less invasive procedure allows a new valve to be inserted within the native, diseased aortic valve.

The TAVR procedure can be performed through multiple approaches, however the most common approach is the transfemoral approach (through an incision in the leg). Only a Heart Team can decide which approach is best, based on a person's medical condition and other factors.

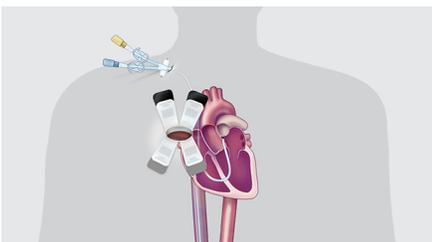
Please consult a Heart Team for more information on TAVR and its associated risks.



### 2. Open Heart Surgery

Open heart surgery is the most common treatment for severe aortic stenosis, and has been performed for many years.

During open heart surgery, the surgeon removes the diseased aortic valve and replaces it with either a mechanical valve (made from man-made materials) or a biological valve (made from animal or human tissue).



Aortic valve replacement can also be performed through minimal incision valve surgery (MIVS). In MIVS, the surgeon can replace the diseased valve through a smaller incision while looking directly at the heart or through a small, tube-shaped camera. MIVS may be an option for some patients.

Please consult a Heart Team surgeon for more information on surgical aortic valve replacement and its associated risks.

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## HOW IS THE TREATMENT PLAN DECIDED?

If you go to a Heart Team, you will make an appointment to visit their valve clinic, where they can run a number of tests and evaluations to help determine the best treatment plan. The Heart Team will ask for a number of specialized tests and assessments to help them make the best decision for the person you care for.

In some cases, they may have already taken some of these tests. However, it may be important that the tests be taken again at the request of the Heart Team. There are special angles and measurements used that the Heart Team will specifically request.

The Heart Team will make the best decision for the person you care for based on their medical condition and other factors, which means that after being screened for TAVR, open heart surgery may still be the best option.

## IS THERE SOMEONE MY LOVED ONE CAN TALK TO ABOUT THE TAVR PROCEDURE?

If someone you care for has been diagnosed with severe aortic stenosis, we're available with practical information and answers to their non-medical questions. With Edwards PatientConnect, your loved one will have a dedicated team member who can help them better understand treatment options for aortic valve disease, prepare for visits with their healthcare team, and provide personalized support along the way.

They may also be able to connect with one of our Patient Ambassadors—someone who has gone through their own TAVR journey and now volunteers to help others by listening, sharing, and caring.

For more information, go to [EdwardsPatientConnect.com](https://www.edwardspatientconnect.com).

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## ADVOCATE FOR YOUR LOVED ONE

Many people think symptoms of aortic stenosis are just normal signs of aging. If you're worried about someone's symptoms, encourage them to see a doctor to confirm if there is an underlying serious medical issue/condition.

When it's time for the next step, you can be there to look at all the options and how it can affect you with after care.

## TRACK SYMPTOMS

Keep an eye on the symptoms of aortic stenosis (chest pain, fatigue, shortness of breath, lightheadedness, difficulty with exercise). Are they worsening? Is it time to think about taking the next step in the treatment plan?

## ATTEND APPOINTMENTS

It can help to have someone at each appointment to get information first-hand and make sure all questions are answered. Keep a folder with appointment notes, medication lists, doctors' contact information, and calendar, and bring it with you to all appointments. Make a list of questions before the appointment and take notes during the discussion. If you are not nearby, ask if you can participate in appointments by phone.

## TALK ABOUT THE TREATMENT PLAN

Different treatment plans may need to be considered. The treatment plans will depend on how severe the disease is as well as other factors. Treatment options may include medications to relieve symptoms. You can help the person you care for by asking questions and discussing these options both during the doctor's appointment and at home.

## CONSIDER A SECOND OPINION

Part of being an advocate might mean getting a second opinion. The goal should always be for the patient to feel empowered about the treatment plan. If you're not sure about one doctor's recommendation, consult a Heart Team.

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## BEFORE

## THE PROCEDURE

**There are usually a number of tests that need to be done before the TAVR procedure.** They can be done in one day or over weeks, depending on the TAVR Heart Team. You may need to go with your loved one to some of these tests. You can also help organize the appointment schedule and ensure medications are taken as prescribed. If you have questions, ask the Valve Clinic Coordinator on the Heart Team.

### What should you do before the procedure?

Before the TAVR procedure, the Heart Team may want to do a number of different tests to check heart function and confirm the treatment plan. These tests are very important, and it may be helpful to the person you care for to have you there. You can help organize the appointment schedule and make sure medications are taken as prescribed.

Leading up to the TAVR procedure, if you notice any symptoms (e.g., tiredness, shortness of breath, etc.), call your Heart Team right away. As the caregiver, take note of any changes you see, make sure the Heart Team stays informed of changes, and keep in close touch with the Heart Team.

### Helping the person you care for prepare for TAVR



#### Activity level

Ask the Heart Team what level of activity is appropriate. Exercise, even for short periods of time, will be extremely difficult if the aortic stenosis is extremely severe. Be very watchful of the person you care for while he or she is exercising, and make sure they slow down if they get short of breath, have chest pain, or feel faint.



#### Monitor medication

Keep all medications organized and help make sure they're taken as prescribed by the Heart Team.



#### Driving

Typically, people with severe aortic stenosis will be extremely winded and will probably not be able to drive. Every person is different. Please talk to the Heart Team if the person you care for should be driving or if they need a driver.



#### Healthy eating

It's important for the person you care for to eat as well as possible and for you to be encouraging throughout this process. The Heart Team may have put restrictions on how much liquid and salt the person you care for can have. Help make sure the recommendations are followed.



#### Recovery plan

Have an open discussion about the care after TAVR. Some people can be released from the hospital within a few days of the procedure, but everyone is different. The main questions are: What will happen after they're released from the hospital? Where will they go? Who will take them? And who will stay with them?

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## Preparing for TAVR

### DAY OF THE PROCEDURE

**Talk to your TAVR Heart Team about whether the person you care for should stop eating before the procedure and for how long.** Make sure a bag is packed for the hospital stay. Your Valve Clinic Coordinator will provide specific instructions.

### What should you do the day of the procedure?

Most people who have TAVR come to the hospital the morning of the procedure. Sometimes, people may be asked to come to the hospital the night before. Follow the instructions from your Heart Team.

#### Things to consider for the hospital bag:

- Toothbrush and toothpaste
- Comb or brush
- Slippers (with non-slip soles)
- Glasses
- Hearing aid(s)
- Reading materials
- Pajamas
- Comfortable clothes to go home in

#### Do not pack a lot of cash or valuables.

Patients may be moved at least twice during their stay and it's possible for things to be misplaced during these moves. Also, it may be best if you keep their clothes until the day they leave the hospital, if possible.

### DURING THE PROCEDURE

#### The TAVR procedure will be performed in a hospital, under anesthesia.

The average total procedure time varies from about 1 to 2 hours, depending on the approach the doctor uses.

### What happens during the procedure?

- 1 Depending on the approach, the doctor will make a small incision, either in the leg, in the chest between the ribs, or in the upper chest.
- 2 At the incision area, the Heart Team will insert a short, hollow tube called a sheath.
- 3 Next, it is important to open the diseased valve and prepare it for the new valve. This may be done with a procedure called balloon aortic valvuloplasty, or BAV.
- 4 With BAV, a thin, flexible tube called a catheter is inserted through the sheath to gain access to the aortic valve. Once it reaches the valve, a balloon at the end of the tube is inflated. The balloon presses against the hardened tissue, which opens the valve leaflets. The balloon is then deflated and removed through the sheath.
- 5 Now that the diseased valve leaflets have been opened, the new valve is ready for placement. A new catheter carrying the artificial valve is inserted through the sheath and guided to the heart valve.



### DURING THE PROCEDURE (CONTINUED)

- 6 Once it reaches the heart valve, the balloon on the catheter is inflated, expanding the new valve within the diseased valve. The new valve pushes the leaflets of the diseased valve aside. The frame of the new valve will use the leaflets of the diseased valve to secure it into place.
- 7 The balloon is deflated and removed. Once the Heart Team has made sure the new valve is functioning properly, they will close the incision area.



Depending on the TAVR approach, the average total procedure time varies from 1 to 2 hours.

### AFTER THE PROCEDURE

**People who have the TAVR procedure will probably need help at home—though how much and for how long varies from person to person.** Before they leave the hospital, make sure you ask specific questions about eating, sleeping, activity level, medications, and follow-up appointments.

### What is your role after TAVR?

Every person's recovery with TAVR is different—from how long they stay in the hospital to how long it takes to feel normal again. Some people leave the hospital needing only minimal support at home. Some leave the hospital needing a month or more of active caregiving support. It's best to talk to the Heart Team about what to expect in regards to your particular situation.

#### Some things they may need to help with:

- Managing medication
- Preparing meals
- Keeping up the house—cleaning, laundry, getting the mail, watering plants, etc.
- Running errands
- Driving and attending follow-up appointments

**In cases of slow recovery, you may need extra caregiving help. The Heart Team and a social worker can assist you on where to get extra help.**

**If you need help finding caregivers to help the person you care for after their TAVR procedure, you can also visit the National Alliance for Caregiving website at [www.caregiving.org](http://www.caregiving.org).**



## IMPORTANT RISK INFORMATION FOR PATIENTS

### EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE

#### Indications:

The Edwards SAPIEN 3 transcatheter heart valve, model 9600TFX, and accessories are 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 at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality  $\geq 3\%$  at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

#### Contraindications (Who should not use):

The Edwards SAPIEN 3 transcatheter heart valve and delivery 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.

#### 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 allergic to chromium, nickel, molybdenum, manganese, copper, silicon, and/or polymeric materials.
- The SAPIEN 3 valve may not last as long in patients whose bodies do not process calcium normally.
- 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.
- Transcatheter aortic heart valve patients should take medications that thin the blood or prevent blood clots from forming, except when likely to have an adverse reaction, as determined by their physician. The Edwards SAPIEN 3 transcatheter heart valve has not been tested for use without medications that thin the blood or prevent blood clots from forming.

#### Precautions:

The long-term durability of the Edwards SAPIEN 3 transcatheter heart valve is not known, at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing. For patients who have previously had aortic valve replacement, the safety, effectiveness, and durability of putting a transcatheter valve in an already implanted artificial valve are not known at this time.

The safety and effectiveness of the transcatheter heart valve is also not known for patients who have:

- An aortic heart valve that is not calcified, contains only one or two leaflets, 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.
- Previous heart valve replacement or repair.
- 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 or irregularly shaped vessels leading to the heart. Vessels in the legs which are heavily diseased or too small for associated delivery devices, or a large amount of calcification at the point of entry to the heart.
- Allergies to blood-thinning medications or dye injected during the procedure.

#### 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, 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.
- Risks to your lungs or breathing, including difficulty breathing, fainting, 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.
- 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 valve include:

- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery and possible removal of the SAPIEN 3 valve, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), nonstructural valve dysfunction (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage, etc.) or mechanical failure of the delivery system and/or accessories

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

# IMPORTANT RISK INFORMATION FOR PATIENTS



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## EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE

### Indications:

The Edwards SAPIEN XT transcatheter heart valve, model 9300TFX, and accessories are 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 at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality  $\geq 3\%$  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 XT transcatheter heart valve and accessories are also indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., STS operative risk score  $\geq 8\%$  or at a  $\geq 15\%$  risk of mortality at 30 days).

### Contraindications (Who should not use):

The Edwards SAPIEN XT transcatheter heart valve and delivery 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.

### Warnings:

- There is a higher risk of stroke in transcatheter aortic valve replacement procedures, compared to balloon aortic valvuloplasty and other standard treatments for aortic stenosis in the high or greater risk population.
- Implanting a valve that is too small may cause blood leakage and valve movement. Implanting a valve that is too large can cause a buildup of pressure in the valve or a rupture of blood vessels in or around your heart. Your Heart Team will do tests to determine the best valve size for you.
- The SAPIEN XT valve may not last as long in patients whose bodies do not process calcium normally.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are allergic to chromium, nickel, molybdenum, manganese, copper, silicon, and/or polymeric materials.
- 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.
- Transcatheter aortic heart valve patients should take medications that thin the blood or prevent blood clots from forming, except when likely to have an adverse reaction, as determined by their physician. The Edwards SAPIEN XT transcatheter heart valve has not been tested for use without medications that thin the blood or prevent blood clots from forming.

### Precautions:

The long-term durability of the Edwards SAPIEN XT transcatheter heart valve is not known, at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing. The safety, effectiveness, and durability of implanting a new valve inside a previously implanted surgical tissue valve has not been established.

The safety and effectiveness of implanting:

- A transcatheter valve inside a transcatheter valve is not known
- A transcatheter valve inside a surgical tissue valve is not known in the intermediate-risk population

The safety and effectiveness of the transcatheter heart valve is also not known for patients who have:

- An aortic heart valve that is not calcified, contains only one or two leaflets, 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
- Previous heart valve replacement or repair
- 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 or irregularly shaped vessels leading to the heart. Vessels in the legs which are heavily diseased or too small for associated delivery devices, or a large amount of calcification at the point of entry to the heart, depending on delivery method
- Allergies to blood-thinning medications or dye injected during the procedure

### 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, a heart that does not pump well, irregular heartbeat that may result in a need for a permanent pace maker, chest pain, heart murmur, false aneurysm, recurring aortic stenosis (narrowing), too much fluid around the heart.
- Risks to your lungs or breathing, including difficulty breathing, fainting, 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.
- 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.
- For a valve in valve procedure, there is a risk of leakage if the previously implanted tissue valve is not securely in place or if it is damaged. There is also the possibility that a partially detached valve leaflet from the previously implanted valve could block a blood vessel. The safety and effectiveness of the transcatheter heart valve has not been determined when the valve is implanted:
  - Inside a stented previously implanted valve smaller than 21 mm.
  - Inside an unstented previously implanted aortic tissue valve.

Your Heart Team will do tests to determine the exact size of the new valve you should receive and communicate what to expect.

### Additional potential risks specifically associated with the use of the heart valve include:

- Valve movement after deployment, blockage or disruption of blood flow through the heart, sudden loss of heart function, heart failure, need for additional heart surgery and possible removal of the SAPIEN XT valve, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), nonstructural valve dysfunction (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue ingrowth, blood cell damage, etc.) or mechanical failure of the delivery system and/or accessories.

Be sure to ask your Heart Team to explain your treatment options and the possible benefits and risks of the procedure.

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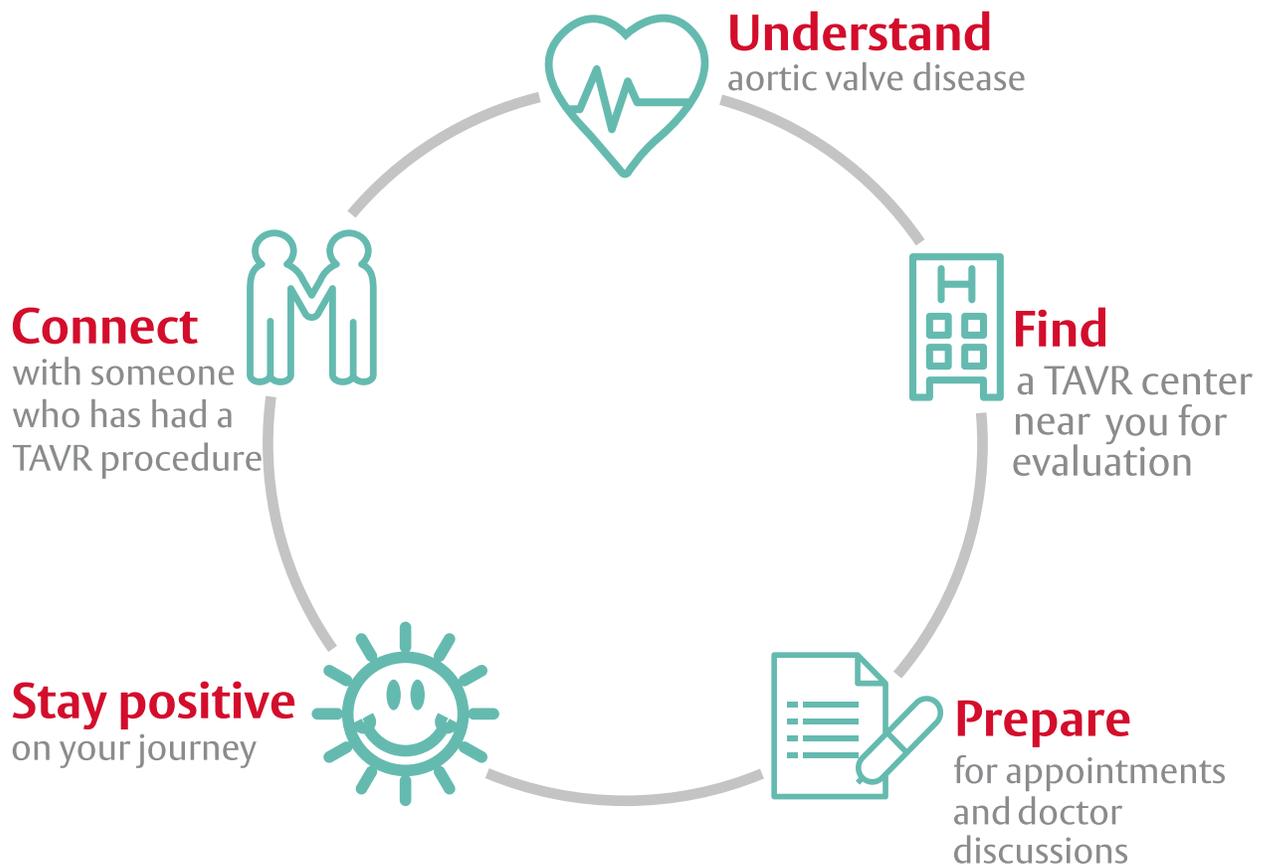
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# Edwards PatientConnect Support Program

*Helping You Navigate Your Aortic Valve Treatment Journey*

Have you or your loved one seen a cardiologist or other heart specialist about severe aortic valve stenosis? Do you need more information, or have questions about next steps and valve replacement treatment options? **Edwards PatientConnect**, sponsored by Edwards Lifesciences, is here to provide support to patients considering transcatheter aortic valve replacement (TAVR) along each step of the treatment journey from diagnosis through recovery.

A dedicated team member is ready to help you:



 **CALL 1-855-213-4133**



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