



## Tests and Procedures That Help Determine if TAVR is the Best Option for You

Some of the tests and procedures mentioned below are quick and painless. Others take more time and may require you to take medication.

Even if you've had one or several of these procedures before, the multidisciplinary Heart Team may request that they be done again in order to take special measurements and specific images that will determine the best TAVR approach. In some cases, you may have all of the necessary tests done in one day or you may need to take these tests over the course of several days. Speak with your Heart Team to arrange a schedule that works best for you and your caregiver.

### NON-INVASIVE



#### CHEST X-RAY

*Less than 30 minutes*

You will be placed between a metal plate and the X-ray machine. The X-Ray technician will take several images of your chest in a variety of positions.



#### TTE (Transthoracic echo)

*30-60 minutes*

Lying on a table, a probe is placed on the chest wall and uses sound waves to provide detailed pictures of your heart.



#### MRI (Magnetic resonance imaging)

*30-90 minutes*

You will be asked to lie down on a bed that moves into a large magnetic tube. You won't feel anything, but will hear a noise as the images are acquired. You will also be asked to lie very still throughout the duration of the test, but will be able to talk to the technician through the use of a microphone.

### MODERATELY INVASIVE



#### PFT (Pulmonary function test)

*60-120 minutes*

This is a group of tests that will measure how well the lungs are moving oxygen to the blood. These breathing tests use special equipment and are done by trained staff in a hospital or office setting.



#### CT SCAN (Computerized tomography scan)

*Up to 60 minutes*

You will be injected with contrast dye through an IV. You will be asked to lie down on a bed that passes through a "donut" shaped X-ray scanner to take clear images of your heart.

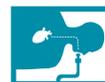
### MORE INVASIVE



#### ANGIOGRAM (Cardiac Cath)

*Approximately 60 minutes*

For the procedure, you will lie on your back on an X-ray table. You will be secured to the table because it may be tilted during the procedure. An IV will be inserted into your arm to give you medicine to relax. You will be awake during the procedure. A small incision is made and a thin tube, called a catheter, is placed into your vein either in the groin or just above the elbow. Dye is injected into the vein to make the area show clearly on the X-ray pictures. The doctor can then observe your blood flow.



#### TEE (Transesophageal echo)

*Approximately 90 minutes*

TEE is usually done in a hospital or a clinic. While lying on a table, a technician sprays your throat with medicine to numb and suppress your gag reflex. A nurse will insert an IV in your arm and give you medicine to make you relax. A thin flexible tube will be guided down your throat. The probe will send waves and collect sound, which become pictures on a video screen.





# What Should You Expect?

## BEFORE

### THE PROCEDURE



To determine what is the best TAVR approach for you, your Heart Team will review various tests or assessments, such as a chest X-ray, echo, angiogram, and others.



Be sure to talk to your Heart Team about any medication you may be taking. They might advise you to stop taking certain medication(s) for one week prior to the procedure.



Your doctor may tell you not to eat or drink anything after midnight. You should plan on making arrangements for a ride to and from the hospital, and arrange for help at home after the procedure.

## DURING

### THE PROCEDURE



1. At the hospital, you will be placed under anesthesia.

2. An incision will be made in one of the following locations:



- Your leg (or slightly higher up, known as the transfemoral approach).

- Between your ribs (transapical approach).

- In the chest (transaortic approach) where your doctor will insert a sheath (a short hollow tube).



3. Your doctor will take a catheter (a long tube with a balloon on the end) through the sheath to reach your aortic valve. The balloon will be inflated with fluid to open your narrowed valve, and then it will be deflated and removed.



4. Your new valve will be placed on a delivery system and compressed on the balloon to make it small enough to fit through the sheath. The valve is about the width of a pencil.



5. The balloon of the delivery system carrying the valve will be inflated with fluid, expanding this new valve within your diseased valve. During valve expansion, the heart is stabilized by temporarily speeding up the heartbeat. The new valve will push the leaflets of your diseased valve aside. The frame of the new valve is very strong and it will use the leaflets of your diseased valve to secure it in place. The balloon will then be deflated and removed.



6. Your doctor will make sure that your new valve is working properly before removing the sheath and closing the incision.

▼ CONTINUE



## What Should You Expect?

### AFTER

#### THE PROCEDURE



**Your Heart Team will determine your immediate after-care plan.**

After the TAVR procedure, you may be taken to the ICU, or you may be taken directly to the hospital floor. You need to ask your Heart Team what to expect after your procedure.



**You will get specific discharge instructions.**

Your Heart Team will give you specific instructions to help you with your recovery, which may include a special diet, exercise, and medicine. It is important to carefully follow your doctor's directions, especially if blood-thinning drugs are prescribed. Your doctor will monitor your medicine and advise you when you can stop taking it. The Heart Team will schedule follow-up visits with you.



**You will be expected to attend regular check-ups.**

Regular check-ups with your doctor are very important. Call or see your doctor whenever you have questions or concerns about your health, especially if you experience any unusual problems such as bleeding, pain, other discomfort, or changes in your overall health.

▼ CONTINUE



## Is there someone I can talk to about the TAVR procedure?

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

You 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, please visit [EdwardsPatientConnect.com](https://www.EdwardsPatientConnect.com)



## What if my doctor doesn't know about TAVR or perform TAVR?

We recommend asking your doctor to refer you to a Heart Team. The Heart Team doctors at a TAVR Center are experts in valvular disease and valve replacement and are best able to determine the treatment option for you.

Find a Heart Team at [NewHeartValve.com/find-tavr](https://www.NewHeartValve.com/find-tavr)



## What if my doctor thinks I am not a candidate for TAVR?

If your doctor thinks you are not a good candidate, you may still contact a TAVR Center to receive a second opinion.

Find a Heart Team at [NewHeartValve.com/find-tavr](https://www.NewHeartValve.com/find-tavr)



## Are there different types of TAVR valves?

TAVR valves are manufactured by different manufacturers. You may want to check which valves are used and available at your medical center.

To learn more about Edwards transcatheter heart valves, visit [TAVRbyEdwards.com](https://www.TAVRbyEdwards.com)



## Can I ask for a specific TAVR valve?

Yes, you can ask for a specific TAVR valve. However, the particular valve clinic your Heart Team is associated with may not use the TAVR valve you request. Please speak with your Heart Team about which valve is right for you.



## What factors determine which approach of TAVR I will get?

A number of factors can determine which TAVR approach will be best for you, and that will be decided through consultations of the Heart Team members.



## How long have TAVR procedures been performed?

TAVR has been commercially available in Europe since 2007 and in the U.S. since 2011. More than 150,000 patients have been treated with Edwards SAPIEN transcatheter heart valves worldwide.

---



## Does Medicare cover TAVR?

Centers for Medicare & Medicaid Services (CMS) cover TAVR when certain conditions are met. For more information on these coverage conditions, please visit the CMS website at [www.cms.gov](http://www.cms.gov).

---



## Does my insurance cover TAVR and do I need a referral?

You should contact your insurance carrier directly prior to your first appointment with your Heart Team to see if they cover TAVR evaluations and the procedure and whether a referral is needed.

---



## How long does a TAVR valve last?

How long your tissue valve will last depends on many patient factors and medical conditions. The long-term durability of the SAPIEN 3 valve has not been established. However, regular follow-ups will help your doctor know how your valve is working.



## 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 co-morbidities 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



NewHeartValve.com  
Brought to You by Edwards Lifesciences

## 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.

**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 XT, NewHeartValve.com and the design logo, SAPIEN, SAPIEN 3, SAPIEN XT, and TAVRbyEdwards.com are trademarks of Edwards Lifesciences Corporation.

© 2016 Edwards Lifesciences Corporation. All rights reserved. PP--US-1284 v1.0

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



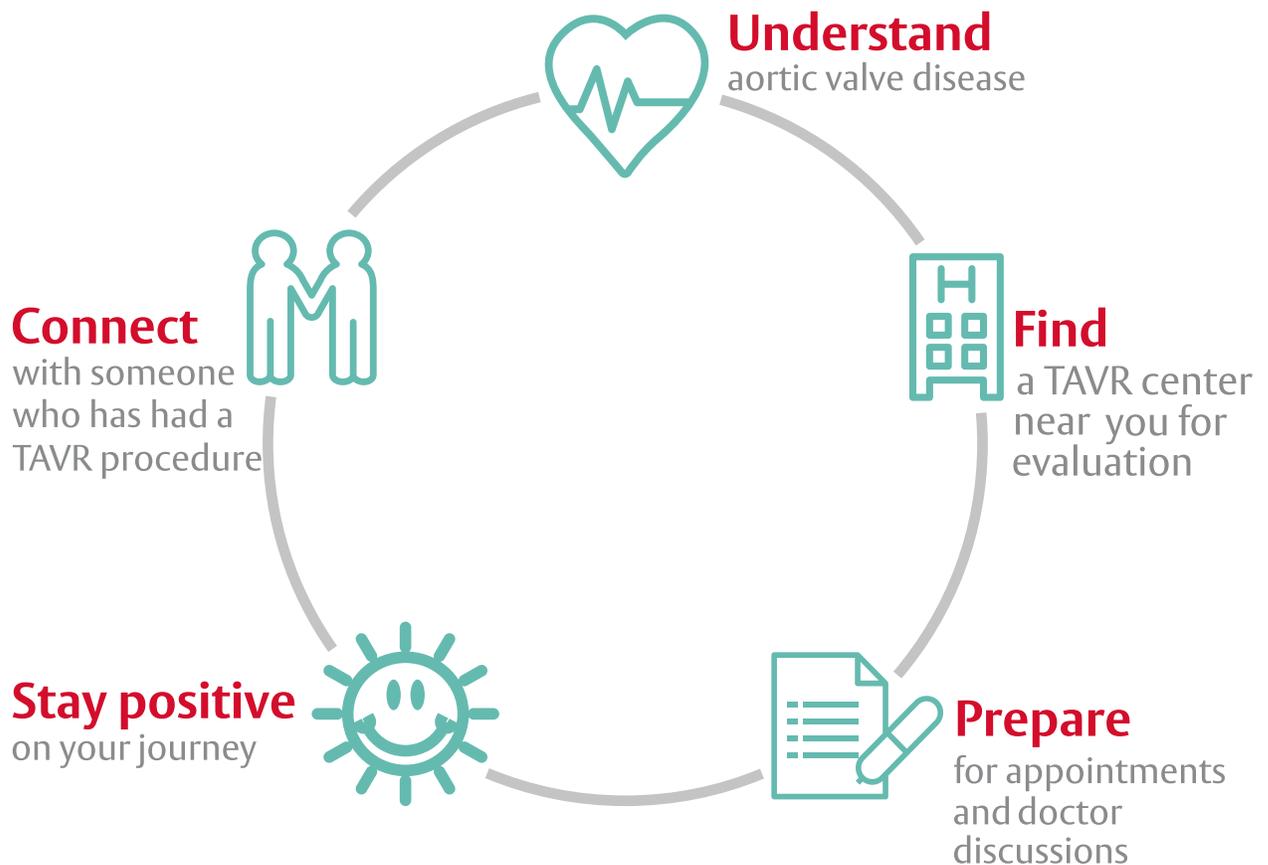
Edwards

# 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**



**VISIT [www.EdwardsPatientConnect.com](http://www.EdwardsPatientConnect.com)**

Edwards, Edwards Lifesciences, Edwards PatientConnect and the stylized E logo, are trademarks of Edwards Lifesciences Corporation.

All other trademarks are the property of their respective owners.

© 2016 Edwards Lifesciences Corporation. All rights reserved.

Edwards Lifesciences • One Edwards Way, Irvine, CA 92614 USA • [edwards.com](http://edwards.com)



**Edwards**