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TRANSCATHETER  
HEART VALVE  
REPLACEMENT



# **T**ranscatheter Aortic Valve Replacement

## **INTRODUCTION**

The heart is a muscular organ located in your chest between your lungs which is designed to pump blood throughout the entire body. The right side of your heart pumps blood through the lungs, where the blood picks up oxygen. The left side of the heart receives this blood and pumps it to the rest of your body out through the AORTIC VALVE and into the circulation of the body.

## **HEART CHAMBERS AND VALVES**

The heart is divided into four main areas, or chambers – two upper chambers (the left and right atrium) and two lower chambers (the left and right ventricle). These are the 4 valves which regulate the flow of blood through the heart, lungs and subsequently into the body's circulation. They are called the aortic, mitral, pulmonary and tricuspid valves, whereas each is made of flaps of tissue called leaflets. See Figure 1

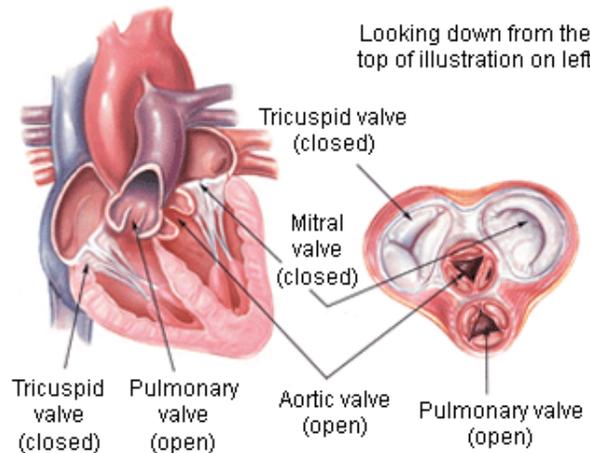


Figure 1

As the heart muscle contracts (squeezes), the valves open in one direction which allows the blood to circulate forward. When these valves close, the blood is prevented from flowing backward. There are 2 common problems that can develop in heart valves:

### **VALVE STENOSIS**

- This occurs when the valve is narrowed and does not completely open secondary to:
  - a build-up of calcium (mineral deposits)
  - high cholesterol (a waxy fat)
  - aging
  - genetics (such as a birth defect)

### **VALVE INSUFFICIENCY / REGURGITATION**

- This occurs when the valve does not fully close allowing blood to leak backward through the valve
  - Torn tendoniae (string-like architecture)
  - Ring dilation (degeneration like an automobile ring)

### **AORTIC STENOSIS-(AS)**

Severe *Aortic Valve Stenosis* occurs when the narrowing of your aortic valve leaflets do not allow normal blood flow outward. It can be caused by many different disorders such as a birth defect, rheumatic fever, radiation therapy; however most are related to the aging process.

The most common presenting symptoms of Severe *Aortic Valve Stenosis* are:

- chest discomfort
- exertional shortness of breath
- easy fatigue
- overall tiredness

Severe *Aortic Valve Stenosis* is often caused by the build-up of calcium (mineral deposits) on the aortic valve's leaflet tips. Over time the leaflets become stiff, reducing the ability to fully open and close. When the leaflets don't fully open, your heart must work harder to push blood through the aortic valve to your body. When Severe *Aortic Valve Stenosis* reaches a critical state it is possible for the heart to weaken thus the terminology of "Congestive heart failure."

## TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

This is a less invasive procedure which allows your aortic valve to be replaced with a new valve without open heart surgery. The valve is inserted with the use of your native artery circulation or less commonly through an incision between the ribs. The Transfemoral (groin artery) delivery of the **EDWARDS SAPIEN TRANSCATHETER HEART VALVE** was approved by the FDA in November of 2011. This technology consists of using a balloon expandable stent with an integrated Bovine (cow) pericardial valve. The TAVR technology consists of an integrated bovine pericardial valve crimped on a balloon-expandable stent for delivery. See below the **EDWARDS SAPIEN TRANSCATHETER HEART VALVE**. see Figure 2

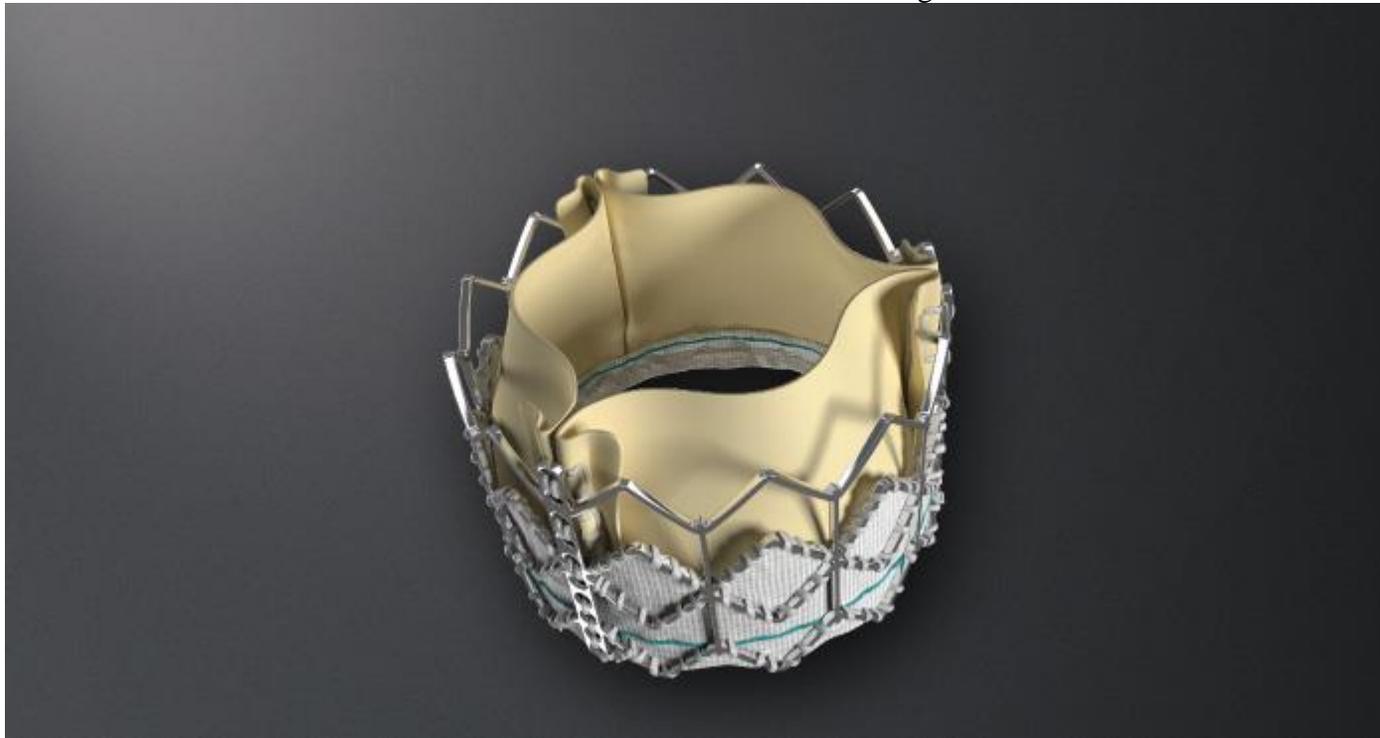


Figure 2

The *TAVR* procedure is not right for everyone. In certain cases, the risks of the procedure may outweigh the benefits. It is best to let us as your cardiologist or your cardiovascular surgeon make this determination with the use of various testing procedures.

These would include the use of:

- Physical examination (PE)-We will listen for evidence of a heart murmur, examine your vital signs and check for any other disorders
- Electrocardiogram-. An electrocardiogram (EKG) is used to record the heart's natural electrical currents. This can show the heart's rhythm, the heart's rate, and reviews the electrical currents.
- 2 Dimensional Echocardiography ( 2DE-Ultrasound of the heart)- from the top of the chest wall or Transesophageal Echocardiography (TEE) within the body- These tests use ultrasound waveforms to pick up sound waves that are moving through the heart which are then converted into moving pictures.
- Cardiac Catheterization- invasive procedure to determine whether the heart arteries besides the valve are involved in your particular case.
- CT Scanning of the Chest and Abdomen (CTA)- special x-rays to determine whether your body's arteries are large enough to allow passage of the **EDWARDS SAPIEN TRANSCATHETER HEART VALVE** system as well as the relationship of your coronary heart arteries to the native aortic valve.

If a both a cardiovascular surgeon and cardiologist determine that you are too high risk for standard Aortic Valve Replacement (AVR), then transcatheter aortic valve replacement (TAVR) may be an alternative. The following are general statistics from the Texas Heart Institute (THI) at St Lukes Episcopal Hospital (SLEH) with the use of the **EDWARDS SAPIEN TRANSCATHETER HEART VALVE**.

- Anesthesia- General
- Cardiopulmonary bypass- Usually not required
- Entry Site-Through the Femoral Artery (Groin), externally placed artery graft of heart via a rib incision
- Average total procedure duration- 3-4 hours
- Average hospital stay-3-4 days

### **The Edwards Sapien Transcatheter Heart Valve should not be used in the following people:**

- Patients whose native aortic valve does not contain calcification.
- Patients whose native aortic valve only has one or two leaflets (usually due to a birth defect), normally there are 3
- Patients who have a blood clot or an abnormal growth on their native valve
- Patients who have an infection in the heart or infections elsewhere
- Patients who already have a prosthetic (man-made) valve or repair device implanted in any of their four heart valves
- Patients who have aortic stenosis along with aortic regurgitation (when your valve does not fully close and allows blood to leak backwards through the valve)
- Patients who have severe disease with their native mitral valve
- Patients whose aortic valve is either too small or too big for the new prosthesis to fit correctly
- Patients who have severe disease in their vessels leading to the heart, small vessels, or vessels that have a lot of bends that would not allow passage of the products necessary to perform the procedure although alternative do exist for this problem
- Patients who have thick aortic leaflets which are very close to the arteries that supply the heart with blood (coronaries)
- Patients who have severe problems with bleeding or blood clotting
- Patients who have a condition in which the heart muscle becomes too thick
- Patients who cannot take aspirin, heparin, ticlopidine (Ticlid) or clopidogrel (Plavix) or have sensitivity to contrast medium (fluid used to see your internal structures during the procedure)

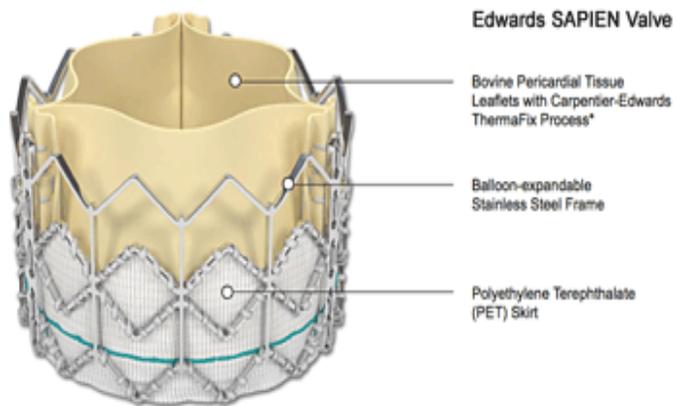


Figure 3

The **EDWARDS SAPIEN TRANSCATHETER HEART VALVE** is a biological (made from animal tissue) valve that replaces your aortic valve. See Figure 3

At the present time, it is provided in two sizes, 23 mm and 26 mm in diameter which fit most individuals who need an AVR.

We will determine the right size for you by carefully reviewing all of the tests previously performed.

## How is TAVR performed?

This is done in our cardiac catheterization suite which has both the availability for cardiologists and surgeons to work together with state of the art equipment. **General anesthesia** will be given to put you into a deep sleep. After you are asleep, a tube will be placed inside the trachea (breathing vessel) and promptly connected to a mechanical ventilator (a machine that will help you breathe during the procedure). See Figure 4 implantation of the valve

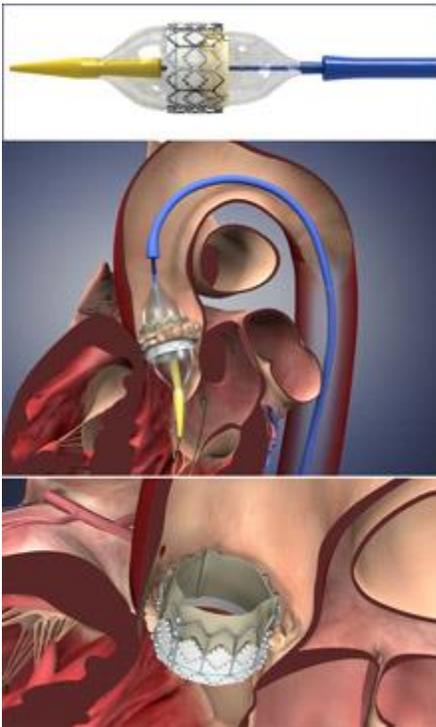


Figure 4

We use fluoroscopy (a type of x-ray) during the procedure as well as contrast medium (dye) in order to see your aortic valve. Some patients may have kidney problems or an allergic reaction as a result of the contrast medium thus please inform us before the procedure if this has been a problem in the past.

We will also use Trans esophageal echocardiography-TEE- (a type of ultrasound) to see your aortic valve inserted while you are asleep and then removed before you are awakened.

We will place a temporary pacing wire in the heart so we can control the heart rhythm at various times during the TAVR procedure. This will be turned on and off at various times to allow us to implant the new valve in the perfect exact location without the beating of the native heart getting in the way. After the procedure is done, the temporary pacing wire is removed.

After you are put to sleep we will make a small incision in the femoral artery (groin) just like in the previous heart catheterization procedure to allow insertion of the **Retroflex 3 delivery system** in a sheath. see Figure 5

First a balloon catheter will be used to open the diseased native aortic valve in preparation for the introduction of the new valve. The Edwards SAPIEN transcatheter heart valve will be placed on the delivery system (long tube with a small balloon on the end), and compressed on the balloon (using a crimper) to make it small enough to fit through the sheath. It will be about the width of a pencil.

Using our temporary pacemaker, we speed up the heart to in order to decrease the chance of the new valve from moving during its placement. We inflate the balloon holding the new valve in the exact position desired and observe its function using angiography and echocardiography. The pacemaker rate is then decreased, the balloon removed and various pictures are taken to confirm positioning of the **EDWARDS SAPIEN TRANSCATHETER HEART VALVE**.



Figure 5

We will make sure that your new valve is working properly before removing the delivery system and closing the incision in your groin area. In the rare instance that your new valve is not working properly, we may need to do something else which may include open-heart surgery, insertion of a second new valve or other additional surgery as we determine to be necessary.

## **W**hat Are the Possible Risks and Benefits 1 Year After the TAVR?

In the United States, The PARTNER Trial studied the safety and effectiveness of the **EDWARDS SAPIEN TRANSCATHETER HEART VALVE** in 358 patients whose doctors had determined them to be unable to undergo open-heart surgery. Half of the patients were treated with the Edwards SAPIEN transcatheter heart valve and half were treated with standard medical therapy.

Patients were examined at 30 days, 6 months, and 1 year after the procedure, and will continue to be examined each year for 5 years. Standard medical therapy may have included medicine or other procedures that treat aortic stenosis such as balloon aortic valvuloplasty (procedure to stretch the aortic valve opening).

The study revealed that patients who received the Edwards SAPIEN transcatheter heart valve lived longer and felt better, but had a higher stroke rate than those patients who did not receive a new valve (most of whom had balloon aortic valvuloplasty).

Additionally, the study showed that patients who received this new valve had improved heart function and felt much better at 1 year compared to patient who did not receive a new valve.

The major risks of the **TAVR** procedure with the Edwards SAPIEN transcatheter heart valve include:

- Death from any cause
- Stroke – a condition when blood stops flowing to the brain, which may cause partial or severe disability
- Major vascular complications – a tear or hole in blood vessels or the heart or the groin insertion site

**T**he following risks have been reported to occur in 1 or fewer out of 100 patients:

- Acute kidney injury (renal failure; when the kidneys cannot work properly), which can require hemodialysis
- Allergic reaction to anesthesia contrast medium (fluid used to see your internal structures during the procedure), or medicine
- Anemia (low red blood cell count)
- Damage to the nerves
- Device embolization (movement of the valve after placement)
- Narrowing of the valve
- Syncope (fainting)
- Bleeding into or around the heart sac (pericardium)
- Coronary artery obstruction (blockage in the coronary vessels around the heart).
- Device breakdown or degeneration
- Failure or poor function of the implanted valve
- Mechanical malfunction of the valve delivery system
- Need for valve explant (removal)
- Shortness of breath
- Arrhythmia
- Infection
- Pain at the insertion site

In addition, there is a possibility that you may experience other problems that are not listed above that have not been previously observed with this procedure.

## **W**hat Happens After the Transcatheter Aortic Valve Replacement Procedure?

After the procedure, you will be moved to the cardiovascular recovery unit for careful monitoring. You may be given blood-thinning medicine.). These typically include Plavix (Clopidigrel) or a similar agent.

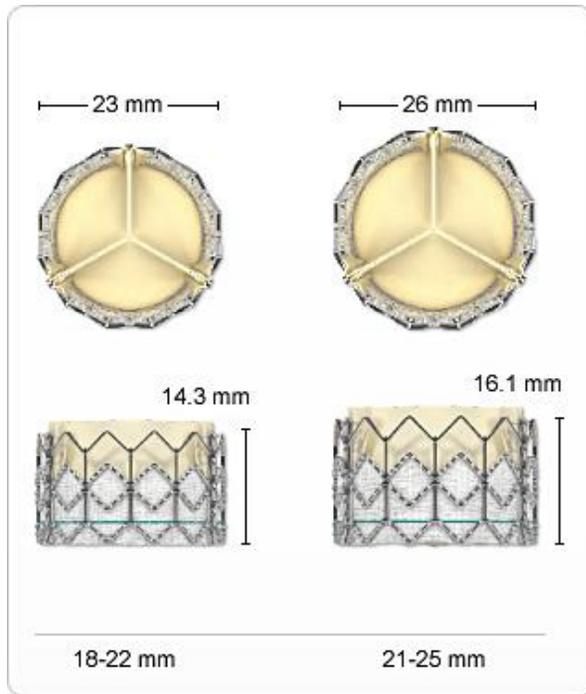
While in the hospital after the TAVR procedure, the following examinations are performed for further assessment of the new valve:

- Physical exam
- Chest X-ray
- Blood tests
- Electrocardiogram (EKG)
- Echocardiogram

You will remain in the ICU until we feel that you can be transferred to a regular hospital room, where you will continue to be monitored until you leave the hospital. The average ICU time is 1-2 days and the average hospital stay for this TAVR procedure is 3-4 days. You may feel better soon after your procedure.

You will receive specific instructions to help you with your recovery, which may include a special diet, exercise and medicine. Regular check-ups are very important. It is easier for patients with a replacement heart valve to get infections, which could lead to future heart damage. You will need to take any medicine as prescribed and have your heart checked from time to time with the ultrasound echocardiogram.

Always inform other doctors about your heart valve replacement before any medical or dental procedure. Before undergoing an MRI (magnetic resonance imaging) procedure, always notify the doctor (or medical technician) that you have an implanted heart valve. Failure to do so may result in damage to the valve that could result in death.



## Safety Warnings and Precautions

The safety of the valve implantation has only been established in patients who have senile degenerative aortic stenosis. Antibiotic medicine is recommended after the procedure in patients at risk for infection. Patients who do not take antibiotics may be at increased risk of infection.

Patients who receive a transcatheter heart valve should stay on blood-thinning medicine for 6 months after the procedure and aspirin for the rest of their lives, unless otherwise specified by their doctor. Patients who do not take blood-thinning medicine may be at increased risk of developing a dangerous blood clot after the procedure which may result in a stroke. Blood-thinning medicine may increase the risk of bleeding in the brain (stroke).

## **H**ow may TAVR procedures have been performed worldwide?

As of November 2011, > 15,000 patients have been implanted with this valve procedure by multi-disciplinary heart teams worldwide.

## **H**ow Long Will This New Valve Last?

How long your new valve will last is unknown at this time. Edwards Lifesciences has tested the valve in the laboratory to replicate 5 year durability. All valves tested for 5 year durability passed the test. The first Edwards transcatheter heart valve was implanted in 2002.

The most common reason that a biological valve may fail is a gradual build-up of calcium (mineral deposits). In this situation, the valve may not work properly, which may cause your aortic stenosis to return, and possibly chest pain, shortness of breath, irregular heart beat and fatigue. Talk to your doctor if you experience any of these symptoms. Regular medical follow-up is essential to evaluate how your valve is performing.