Transcatheter Aortic Valve Replacement for Patients Who Cannot Have Open-Heart Surgery

What You and Your Loved Ones Should Know



This pamphlet was created for patients who feel sick from severe aortic stenosis (a narrowing of the aortic valve opening that does not allow normal blood flow) and who cannot have open-heart surgery. This information will help you and your loved ones learn more about your heart, how it works, and aortic stenosis. In addition, you will learn about a new procedure called transcatheter aortic valve replacement (TAVR).

Be sure to ask your doctor to explain your treatment options, and their risks, to help you decide which option is best for you.

See pages 13-14 to review the risks of the TAVR procedure.



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Please remember, this information is not meant to tell you everything you need to know about your treatment options for aortic stenosis, or about the TAVR procedure. Regular check-ups with your doctor are essential. Call or see your doctor whenever you have questions or concerns about your health, especially if you experience unusual symptoms or changes in your overall health.

HOW DOES YOUR HEART WORK?

The heart is a muscular organ located in your chest between your lungs. The heart is designed to pump blood through your 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.

Your heart beats between 60 and 100 times per minute. At 60 beats per minute, that's approximately 31.5 million beats per year.

Chambers and Valves

The heart is divided into four main areas, or chambers—two upper chambers (called the left and right atrium) and two lower chambers (called the left and right ventricle). There are four valves that control the flow of blood through your heart. They are called the aortic, mitral, pulmonary, and tricuspid valves, and each is made of flaps of tissue called leaflets. (See Figure on page 4)



NOTE: The left and the right side of the heart is pictured as the heart sits in your body.

Each time your heart beats, it pumps blood through these valves by contracting (squeezing) its chambers. These valves open in one direction, like one-way gates, allowing blood to flow forward. In between beats, the heart's chambers quickly relax, and its valves close, preventing blood from flowing backward.

There are two common problems that can develop in heart valves:

- When your valve is narrowed and does not completely open because of things like a build-up of calcium (mineral deposits), high cholesterol (a waxy fat), age, or genetics (such as a birth defect), this is called stenosis.
- When your valve does not fully close and allows blood to leak backwards through the valve, this is called regurgitation.

With either problem, your heart needs to work harder and may not pump enough oxygen-rich blood to your body.

The pulmonary valve

has three leaflets. It controls blood flow from the right ventricle to the pulmonary artery, sending blood to the lungs to pick up oxygen.

The tricuspid valve has three leaflets. It controls blood flow from the right atrium to the right ventricle. The aortic valve has three

leaflets. It controls blood flow from the left ventricle to the aorta, sending blood to the rest of the body.

The mitral valve has two

leaflets. It controls blood flow between the left atrium and left ventricle.



WHAT IS SEVERE AORTIC STENOSIS?

Severe aortic stenosis is a narrowing of your aortic valve opening that does not allow normal blood flow. It can be caused by a birth defect, rheumatic fever, or radiation therapy, or can be related to age.

In elderly patients, severe aortic stenosis is often caused by the build-up of calcium (mineral deposits) on the aortic valve's leaflets. Over time the leaflets become stiff, reducing their 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.

Eventually, your heart gets weaker, increasing the risk of heart failure (your heart cannot supply enough blood to your body). Severe aortic stenosis is a very serious problem. Without treatment, half of the people who feel sick from this problem die within an average of 2 years.



TRANSCATHETER AORTIC VALVE REPLACEMENT

If a cardiac surgeon determines that you are too sick for open-heart surgery and if medicine is not helping you feel better, transcatheter aortic valve replacement (TAVR) may be an alternative. This less invasive procedure allows your aortic valve to be replaced with a new valve while your heart is still beating.

	TAVR
Anesthesia	General
Cardiopulmonary bypass	Usually not required
Entry site	Cut in leg
Average total procedure duration*	4-5 hours
Average hospital stay	8 days

* The time required to perform the procedures necessary for the entire procedure

The TAVR procedure is not right for everyone. In certain cases, the risks of the procedure may outweigh the benefits. See pages 13-14 to review the risks of the TAVR procedure.

Who Should Not Have the Transcatheter Aortic Valve Replacement Procedure?

The Edwards SAPIEN transcatheter heart valve should not be used in the following people:

- Patients whose aortic valve is not calcified
- Patients whose aortic valve only has one or two leaflets (usually due to a birth defect)
- Patients who have a blood clot or an abnormal growth
- 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 mitral valve
- Patients whose aortic valve is either too small or too big

- Patients who have severe disease in their vessels leading to the heart, small vessels, or vessels that have a lot bends that would not allow passage of the products necessary to perform the procedure
- Patients who have thick aortic leaflets which are very close to the arteries that supply the heart with blood
- Patients who have severe problems with bleeding or blood clotting
- Patients who have a condition in which the heart muscle becomes 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)
- Patients who can have open-heart surgery

If the Edwards SAPIEN transcatheter heart valve is used in the patients mentioned above, it may not work properly. This could make you feel very sick, or even cause death.

Which Products Will Be Used During the Transcatheter Aortic Valve Replacement Procedure?

The Edwards SAPIEN transcatheter heart valve and other accessories are used to perform the TAVR procedure. The Edwards SAPIEN transcatheter heart valve is a biological (made from animal tissue) valve that replaces your aortic valve. It is provided in two sizes, 23 mm and 26 mm in diameter. Your doctor will determine the right size for you.

What Do You Need to Do Before the Transcatheter Aortic Valve Replacement Procedure?

Be sure to tell your doctor what medicine you are taking and whether you have any allergies. Your doctor may ask you to change the medicine you are on before the procedure. Your doctor will also explain the procedure and answer any questions you may have.



What Will Happen During the Transcatheter Aortic Valve Replacement Procedure?

The procedure will be performed in the hospital. General anesthesia will be given to put you into a deep sleep. After you are asleep, a tube will be placed down your throat and connected to a mechanical ventilator (a machine that will help you breathe during the procedure).

Your heart's pumping function will be briefly suspended twice during the procedure. To do this your doctor will place a temporary pacing wire in your heart which causes the heart to race. This makes it hard for your heart to pump blood through your body well, which may result in low blood flow to your brain, kidneys, and other organs for a few seconds. After the procedure is done, the temporary pacing wire is removed.

The doctor will use fluoroscopy (a type of X-ray) during the procedure. The doctor will also use contrast medium (fluid used to see your internal structures during the procedure) in order to see your aortic valve. Some patients may have kidney problems or an allergic reaction as a result of the contrast medium. The doctor will also use echocardiography (a type of ultrasound) to see your aortic valve.

The average time required to perform the procedure is 4 to 5 hours.

- 1. You will be placed under general anesthesia (you will be in a deep sleep).
- A cut will be made in your leg, where your doctor will put in a sheath (a short hollow tube) that is slightly larger than the width of a pencil.

3. Your doctor will take a small balloon and put it through the sheath into your blood vessel to reach your aortic valve. The balloon will be inflated with fluid to open your narrowed valve, deflated, and then removed.

Balloon



- 4. 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.
- 5. The delivery system carrying the valve will be placed through the sheath and pushed up to your aortic valve, guided by a type of X-ray.
- 6. The balloon of the delivery system carrying the valve will be inflated with fluid, expanding this new valve within your diseased valve. 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 anchor securely in place. Next, the balloon will be deflated.
- 7. Your doctor will make sure that your new valve is working properly before removing the delivery system and closing the cut in your leg. If your new valve is not working properly, your doctor may need to do something else which may include open-heart surgery or other additional surgery.



What Are the Possible Benefits and Risks 1 Year After the Transcatheter Aortic Valve Replacement Procedure?

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 every year for 5 years.¹

Standard medical therapy may have included medicine or other procedures that treat aortic stenosis such as balloon aortic vavulopasty (procedure to stretch the aortic valve opening). The study results showed 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).¹

- 69 out of every 100 patients with severe aortic stenosis were alive at 1 year after receiving a new valve.
- In comparison, only 50 out of every 100 patients who did not receive a new valve were alive at 1 year.
- Additionally, the study showed that patients who received a new valve had improved heart function and felt much better at 1 year compared to patients who did not receive a new valve.

The major risks of the TAVR procedure with the Edwards SAPIEN transcatheter heart valve include:¹

- Death from any cause. Death occurred in 31 out of 100 patients within 1 year after receiving a new valve.
- Stroke a condition when blood stops flowing to the brain, which may cause partial or severe disability.

Stroke occurred in 11 out of every 100 patients within 1 year after receiving a new valve, which was approximately two and a half times as often as seen in patients who did not receive a new valve (most of whom had balloon aortic valvuloplasty).

- Major vascular complications a tear or hole in blood vessels or the heart, or a hematoma (a blood clot under the skin), which will require another procedure. Major vascular complications occurred in 17 out of every 100 patients within 1 year after receiving a new valve, which was approximately 8 times as often as seen in patients who did not receive a new valve (most of whom had balloon aortic valvuloplasty).
- Bleeding event a loss of blood that requires 2 or more units of a blood transfusion within the indexed procedure. A bleeding event occurred in 17 out of every 100 patients within 1 year after receiving a new valve, which was approximately 8 times as often as seen in patients who did not receive a new valve (most of whom had balloon aortic valvuloplasty).

The following table is a summary of the clinical risks observed at 1 year in The PARTNER Trial.¹ The frequency is shown as the number of patients out of every 100.

Risks Within 1 Year After the TAVR Procedure ¹		
	TAVR	Standard Medical Therapy
Death		
From any cause	31 out of 100 patients	50 out of 100 patients
From cardiovascular (heart-related) causes	20 out of 100 patients	42 out of 100 patients
Repeat hospitalizations	22 out of 100 patients	44 out of 100 patients
Major vascular complications	17 out of 100 patients	2 out of 100 patients
Bleeding event	17 out of 100 patients	2 out of 100 patients
Stroke	11 out of 100 patients	5 out of 100 patients
New pacemaker (device that can help regulate the heart) implantation	5 out of 100 patients	8 out of 100 patients
Need for additional procedures on the operated valve		
Balloon aortic valvuloplasty (procedure to stretch the aortic valve opening)	3 out of 100 patients	37 out of 100 patients
Repeat transcatheter aortic valve replacement	2 out of 100 patients	N/A
Surgical aortic valve replacement	1 out of 100 patients	6 out of 100 patients
Kidney failure	2 out of 100 patients	3 out of 100 patients
Myocardial infarction (heart attack)	1 out of 100 patients	1 out of 100 patients
Endocarditis (inflammation or infection of any internal heart structures, including the valves)	1 out of 100 patients	1 out of 100 patients
New atrial fibrillation (abnormal heartbeat)	1 out of 100 patients	2 out of 100 patients



What Are the Specific Procedural Risks 30 Days After the Transcatheter Aortic Valve Replacement Procedure?

As with any medical intervention, there is a possibility that complications may occur during or after receiving the Edwards SAPIEN transcatheter heart valve, even after leaving the hospital.

The major risks of the TAVR procedure with the Edwards SAPIEN transcatheter heart valve include:¹

- Death from any cause. Death occurred in 5 out of every 100 patients within 30 days after receiving a new valve.
- Stroke a condition when blood stops flowing to the brain, which may cause partial or severe disability. Stroke occurred in 7 out of every 100 patients within 30 days after receiving a new valve, which was approximately 4 times as often as seen in patients who did not receive a new valve (most of whom had balloon aortic valvuloplasty).

- Major vascular complications a tear or hole in blood vessels or the heart, or a hematoma (a blood clot under the skin), which will require another surgery. Major vascular complications occurred in 17 out of every 100 patients within 30 days after receiving a new valve, which was 15 times as often as seen in patients who did not receive a new valve (most of whom had balloon aortic valvuloplasty).
- Bleeding event a loss of blood that requires 2 or more units of a blood transfusion within the indexed procedure. A bleeding event occurred in 16 out of every 100 patients within 30 days after receiving a new valve, which was approximately 8 times as often as seen in patients who did not receive a new valve (most of whom had balloon aortic valvuloplasty).

Additional possible risks listed below are organized by how often they occurred in patients within 30 days of the TAVR procedure.¹

Risks Within 30 Days After the TAVR Procedure¹

Abnormal blood test results	20 out of 100 patients
Infection (including bacteremia, which is usually a temporary inflammation or infection of the entry site, or infection in the blood)	19 out of 100 patients
Arrhythmia (irregular heartbeat)	15 out of 100 patients
Blood leakage around the valve	15 out of 100 patients
Difficulty exercising	10 out of 100 patients
Pain or change at the entry site (where the doctor inserted the catheter with the valve)	10 out of 100 patients
Respiratory insufficiency or failure (any problems with breathing)	10 out of 100 patients
High blood pressure or low blood pressure	9 out of 100 patients
Heart failure (poor heart function, reduced ability of the heart to supply enough blood to the body)	5 out of 100 patients
Hematoma (small collection of blood under the skin) or changes at the entry site	5 out of 100 patients
Fever	4 out of 100 patients
Blood vessel blockage	3 out of 100 patients
Angina (cardiac chest pain or tightness)	2 out of 100 patients
Aortic valve reintervention (need for another procedure or surgery on your aortic valve)	2 out of 100 patients

In addition, the following risks occurred 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
- Decreased kidney function
- Device embolization (movement of the valve after placement)
- Narrowing of the valve
- Syncope (fainting)
- Bleeding into the heart sac
- Coronary 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

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.



What Happens After the Transcatheter Aortic Valve Replacement Procedure?

After the procedure, you will be moved to the intensive care unit (ICU) for careful monitoring. You may be given blood-thinning medicine. Patients who receive a transcatheter heart valve may be given 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). While in the hospital after the TAVR procedure, the following examinations will be completed:

- Physical exam
- Chest X-ray
- Blood tests
- Electrocardiography [ECG or EKG] (a test that records your heart's electrical activity)
- Ultrasound of your heart

You will remain in the ICU until your doctor feels 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 4 days and the average hospital stay for the TAVR procedure is 8 days. You should feel better soon after your procedure. Your doctor 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 bloodthinning drugs are prescribed. Your doctor will monitor your medicine and advise you when or if you can stop taking it.

Regular check-ups by your doctor are very important. It is easier for patients with a replacement heart valve to get infections, which could lead to future heart damage. 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 or other discomfort, or changes in your overall health. Even after you have fully recovered from the procedure, your doctor may want to check your progress occasionally. You will need to take any medicine as prescribed and have your heart checked from time to time. Be sure to discuss all your medicine (including over-the-counter medicine) with your doctor, and don't change any dosage unless instructed to, even if you feel better.

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.



WARNINGS

- The safety of the valve implantation has not been established in patients who have:
 - A prosthetic heart valve already implanted in the aortic position.
- Severe dysfunction of their left ventricle with an ejection fraction (fraction of blood pumped out of the left ventricle with each heart beat) < 20% (normal ejection fraction ranges between 50 and 65%).
- A condition in which the heart muscle becomes thick. The thickening makes it harder for blood to leave the heart, forcing the heart to work harder to pump blood.
- The safety of the valve implantation has only been established in patients who have:
 - Senile degenerative aortic stenosis

PRECAUTIONS

- 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 bloodthinning 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).
- Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance.

HOW LONG WILL YOUR 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 heartbeat, 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.

ADDITIONAL INFORMATION

For More Information on the Edwards TAVR Procedure

To contact Edwards Lifesciences for any inquiries:

Toll free phone in the USA: 1.800.424.3278

Phone from outside the USA: +1.949.250.2500

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Mail:

Edwards Lifesciences LLC 1 Edwards Way Irvine, CA 92614 USA

Online:

www.yourheartvalve.com (Under Resources) www.edwards.com (Click on "FOR PATIENTS")

PATIENT IMPLANT CARD

Edwards SAPIEN Transcatheter Heart Valve

Instructions: Please carry this card at all times after your procedure and show it to any medical personnel who may be treating you. If you do not receive one of these cards after your procedure, please contact your doctor.

References

1. Data on file at Edwards Lifesciences.

CAUTION: Federal (United States) law restricts the Edwards SAPIEN transcatheter heart valve to sale by or on the order of a physician. This device has been approved by the FDA for specific indications for use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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