INTERMEDIATE OR GREATER RISK

Transcatheter Aortic Valve Replacement

with the Edwards SAPIEN 3 Transcatheter Heart Valve

For Patients & Caregivers

Edwards

This patient booklet is for those who are suffering from severe aortic stenosis and are at intermediate or greater risk for surgical aortic valve replacement. This information will help you learn more about your heart, aortic stenosis and your treatment options, including a less invasive procedure called transcatheter aortic valve replacement (TAVR).

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

NewHeartValve.com

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This booklet is not intended to explain everything you need to know about your treatment options for aortic stenosis, or about the TAVR procedure. Please discuss any questions you have with your doctor. Only a specialized Heart Team can decide which treatment option is right for you.

YOUR HEART VALVES

The heart is a muscular organ in your chest that is about the size of your fist. The heart's main function is to pump blood to the rest of your body. Each valve usually has two or three leaflets (flaps of tissue) that open and close like gates to regulate the one-way flow of blood through the heart.

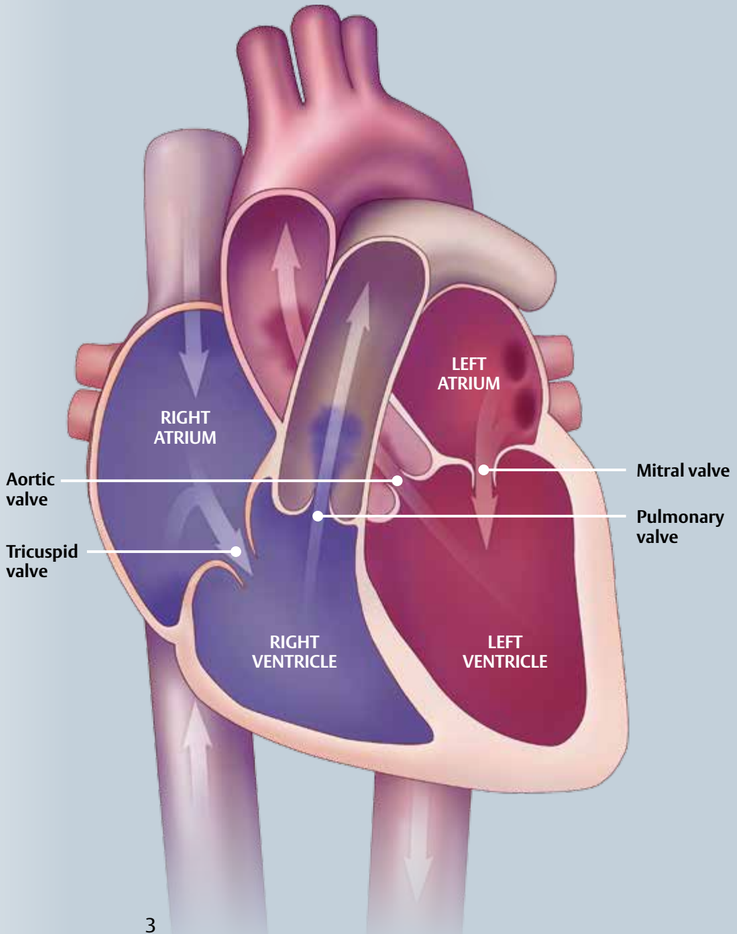
It is important that your valves are always working properly:

- Be properly formed and flexible
- Should open all the way so that the right amount of blood can pass through
- Close tightly so that no blood leaks back into the chamber

There are two problems that can occur in heart valves:

Stenosis: when your valve narrows and does not open completely

Regurgitation: when your valve does not close completely and blood can leak backwards



WHAT IS SEVERE AORTIC STENOSIS?

Aortic stenosis can be caused by a birth defect, rheumatic fever, radiation therapy or can be related to age. In elderly patients, severe aortic stenosis is sometimes caused by the build-up of calcium (mineral deposits) on the aortic valve's leaflets. Over time the leaflets become stiff. This reduces 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. As a result, less oxygen-rich blood flows from the lungs to the brain and rest of the body, which may cause symptoms. It's important to know that heart valve disease may occur with no outward symptoms.

Severe aortic stenosis is a very serious problem. Approximately 50% of the people who develop symptoms will die within an average of 2 years without aortic valve replacement.

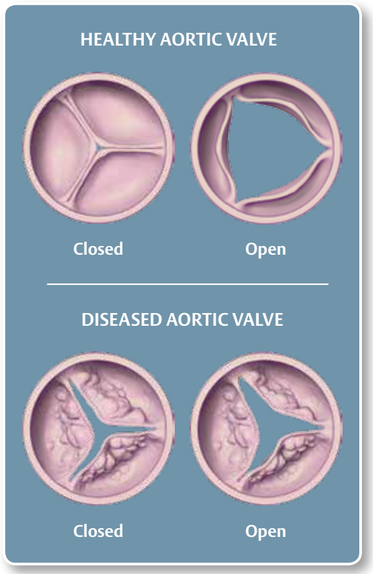
Factors Associated With Aortic Valve Disease

- Increasing age
- High blood pressure
- High cholesterol
- Smoking

What Are The Symptoms of Aortic Stenosis

- Chest pain
- Fatigue
- Shortness of breath
- Lightheadedness, feeling dizzy, and/or fainting
- Difficulty when exercising

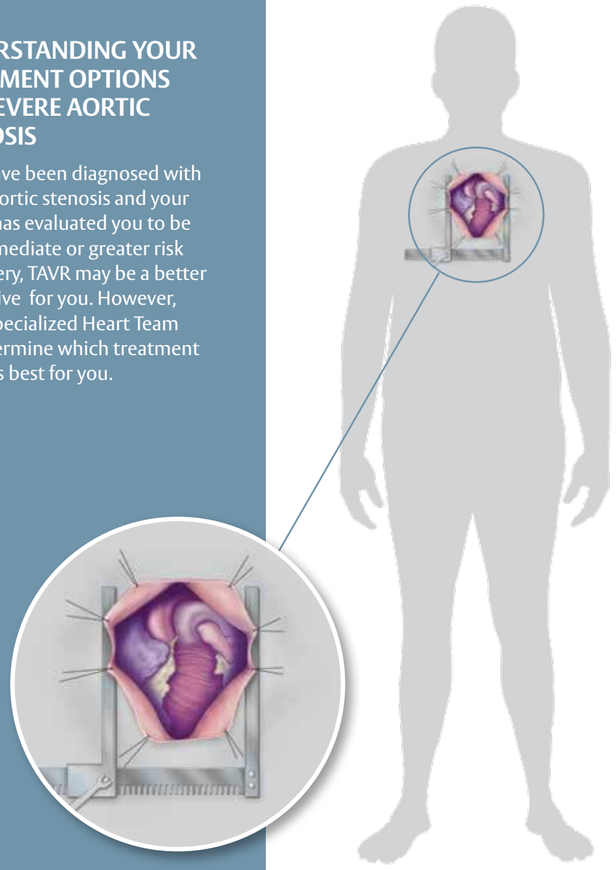
The symptoms of aortic stenosis are commonly misunderstood by patients as 'normal' signs of aging.



If you suspect any change in your ability to perform routine daily activities, consult your cardiologist right away.

UNDERSTANDING YOUR TREATMENT OPTIONS FOR SEVERE AORTIC STENOSIS

If you have been diagnosed with severe aortic stenosis and your doctor has evaluated you to be at intermediate or greater risk for surgery, TAVR may be a better alternative for you. However, only a specialized Heart Team can determine which treatment option is best for you.

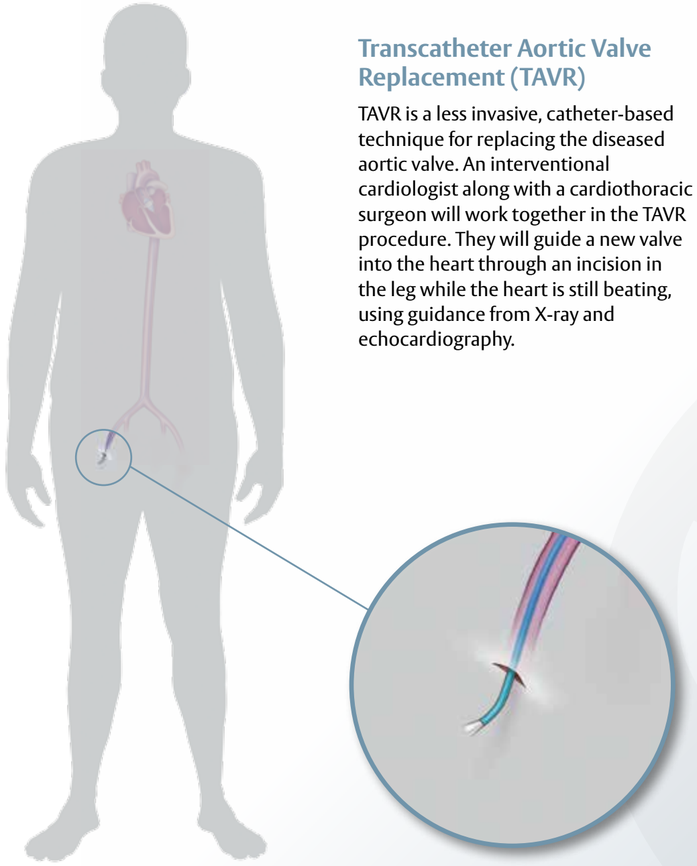


Surgery

Most open heart surgeries are performed through an incision across the full length of the breast bone, or sternum. This incision is called a median sternotomy. Occasionally open heart surgeries can be performed through smaller incisions.

Open heart surgeries, including those performed through smaller incisions, both require the use of a heart lung machine which temporarily takes over the function of the heart. During the procedure, the surgeon will completely remove the diseased aortic valve and insert a new valve. There are two different types of surgical valves:

- Mechanical (man-made material)
- Biological (animal or human tissue)



Transcatheter Aortic Valve Replacement (TAVR)

TAVR is a less invasive, catheter-based technique for replacing the diseased aortic valve. An interventional cardiologist along with a cardiothoracic surgeon will work together in the TAVR procedure. They will guide a new valve into the heart through an incision in the leg while the heart is still beating, using guidance from X-ray and echocardiography.

For more information on treatment options, please visit

NewHeartValve.com

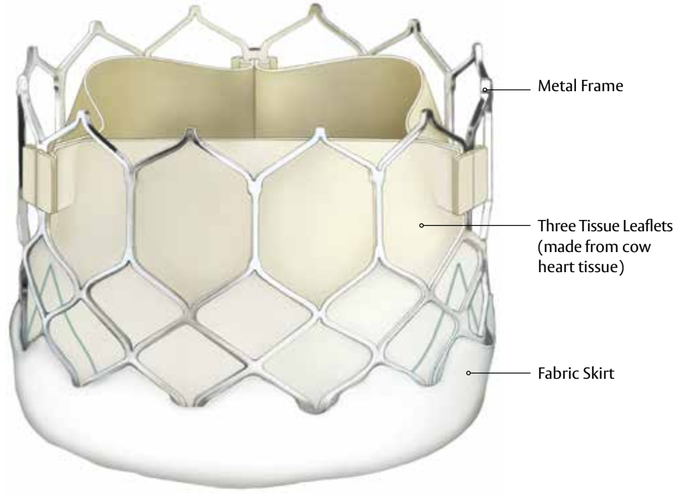
EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE

The Edwards SAPIEN 3 transcatheter heart valve is a biological tissue valve that will replace your diseased aortic valve. It is available in four sizes, 20, 23, 26 and 29 mm in diameter. Your specialized Heart Team will determine which size is right for you.

Edwards' first transcatheter heart valve was approved commercially in Europe in 2007 and in the United States in 2011. To date, Edwards' transcatheter heart valves have treated more than 150,000 patients in over 65 countries around the world.

An illustration of the SAPIEN 3 valve is pictured to the right.

Image is larger than actual valve size.



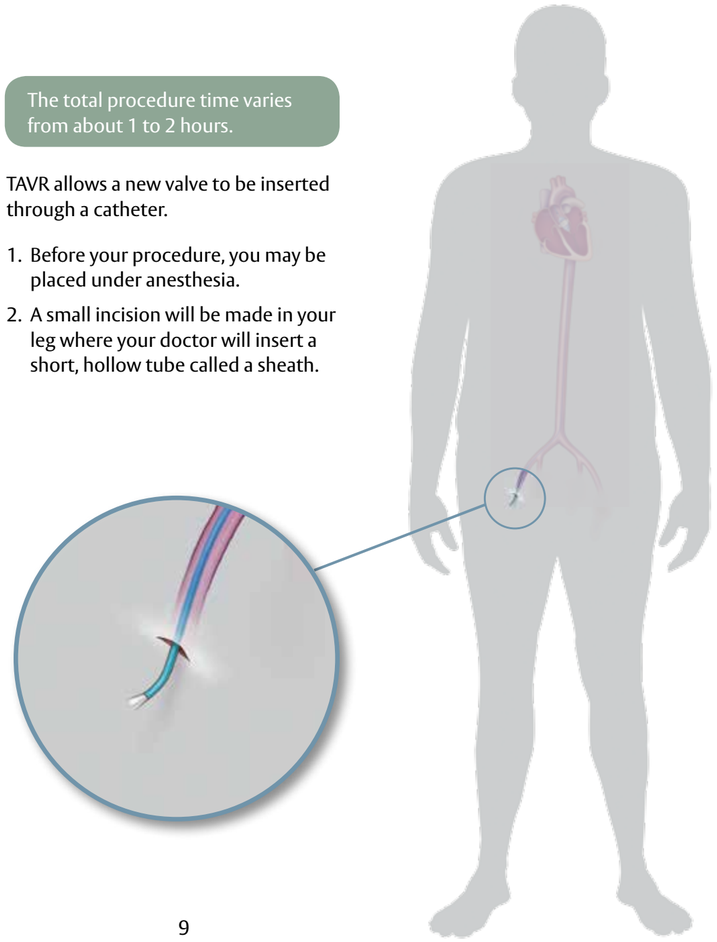
What Do You Need to Do Before the Procedure?

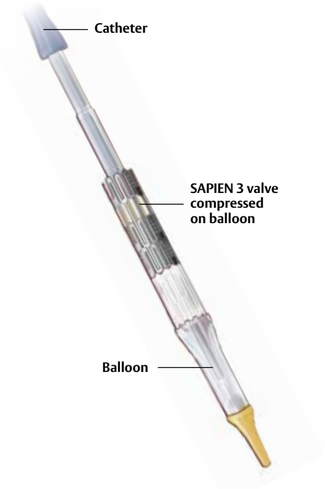
Be sure to talk with your specialized Heart Team about any medication you may be taking. They might advise you to stop taking certain medication up to one week prior to the procedure. Your doctor may tell you not to eat or drink anything after midnight. You should plan on making arrangements for a ride to and from the hospital, and arrange for help at home after the procedure.

The total procedure time varies from about 1 to 2 hours.

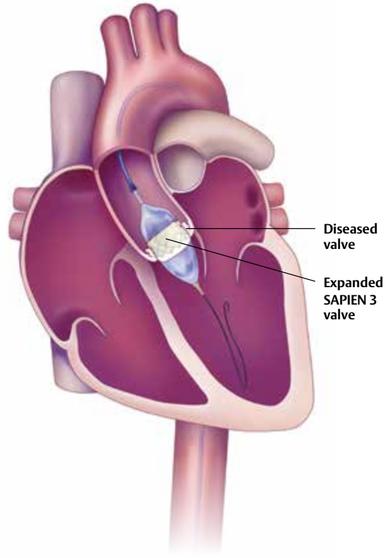
TAVR allows a new valve to be inserted through a catheter.

1. Before your procedure, you may be placed under anesthesia.
2. A small incision will be made in your leg where your doctor will insert a short, hollow tube called a sheath.

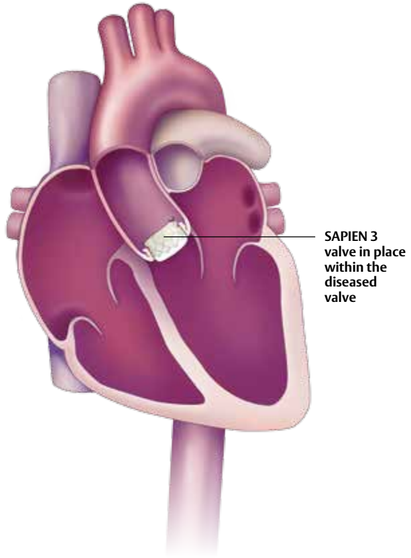




3. Your new valve will be placed on the delivery system tube and compressed on the balloon to make it small enough to fit through the sheath.



4. The balloon of the delivery system carrying the valve will be inflated, 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 strong and it will use the leaflets of your diseased valve to secure it in place. The balloon will then be deflated and removed.



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

What Happens After the Procedure?

Your specialized Heart Team will discuss your after-care plan with you. They will give you specific instructions to help you with your recovery. This may include a special diet, exercise and medicine. It is important to carefully follow your doctor's directions, especially if blood-thinning medication is prescribed.

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

Always tell other doctors about your heart valve replacement before any medical, dental or MRI (magnetic resonance imaging) procedures. Failure to do so may result in damage to the valve that could lead to death.

Average Length of Hospital Stay

5 DAYS

Make sure you speak to your specialized Heart Team regarding length of stay and how quickly you can expect to transition to home care.

What Are the Benefits of TAVR?

Benefits of the Procedure: If you have severe aortic stenosis, TAVR will help your heart to work better. It may also shorten your recovery time to getting back to everyday activities.

Quality of Life Improvement:
Quality of life studies with the SAPIEN 3 valve have shown patient health improvements within 30 days including: the ability to take care of themselves and to participate in everyday activities.

How Long Will My 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.

TAVR AND SURGERY CLINICAL DATA FOR INTERMEDIATE-RISK PATIENTS

The risks associated with surgery depend on how healthy or sick a patient is. Based on their health, some patients may be considered intermediate-risk for surgery. If you are at intermediate-risk for surgery, these clinical data may resemble what you can expect.

As part of the PARTNER II Trial, the SAPIEN 3 valve was studied in patients at intermediate-risk for surgery. The trial enrolled about 1,000 patients in the United States. Patients were examined at 30 days and 1 year after the procedure and will continue to be followed every year for 10 years.

The outcomes in this trial were compared to those of patients who participated in another trial and were treated with surgery. The following tables show results of these two groups of patients. Patients who received the SAPIEN 3 valve had clinically lower observed rates of death and stroke.

Clinical data for intermediate-risk patients with TAVR

The following table summarizes the 30-day and 1-year results of patients at intermediate-risk who were treated with TAVR with the SAPIEN 3 valve.

TAVR - Intermediate-Risk Clinical Outcomes

	Risk Within 30 Days	Risk Within 1 Year
Death From Any Cause	1 out of 100 patients	7 out of 100 patients
Cardiovascular Death*	1 out of 100 patients	4 out of 100 patients
Major Stroke	1 out of 100 patients	2 out of 100 patients
Aortic Insufficiency ≥ Moderate†	4 out of 100 patients	2 out of 100 patients
New Pacemaker Implantation‡	11 out of 100 patients	N/A
Major Vascular Complications	6 out of 100 patients	N/A
Myocardial Infarction (heart attack)	1 out of 100 patients	N/A
Endocarditis§	1 out of 100 patients	1 out of 100 patients

The frequency is shown as the number of patients out of every 100.

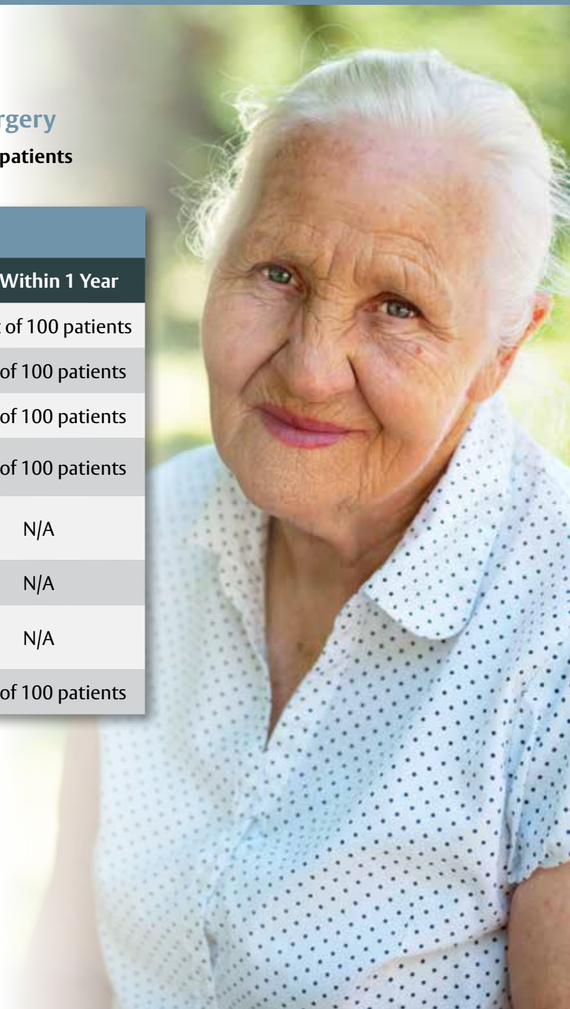
Clinical data for intermediate-risk patients with surgery

The following table summarizes the 30-day and 1-year results of patients at intermediate-risk who were treated with surgery.

Surgery - Intermediate-Risk Clinical Outcomes

	Risk Within 30 Days	Risk Within 1 Year
Death	4 out of 100 patients	13 out of 100 patients
Cardiovascular Death*	3 out of 100 patients	8 out of 100 patients
Major Stroke	4 out of 100 patients	6 out of 100 patients
Aortic Insufficiency ≥ Moderate†	1 out of 100 patients	1 out of 100 patients
New Pacemaker Implantation‡	7 out of 100 patients	N/A
Major Vascular Complications	5 out of 100 patients	N/A
Myocardial Infarction (heart attack)	2 out of 100 patients	N/A
Endocarditis§	0 out of 100 patients	1 out of 100 patients

The frequency is shown as the number of patients out of every 100.



** From heart-related causes*
† When the aortic valve does not close tightly and causes a backward flow of blood
‡ Device that can help regulate the heart
§ Inflammation or infection of any internal heart structures, including the valves

TAVR CLINICAL DATA FOR HIGH-RISK AND INOPERABLE PATIENTS

The risks associated with surgery depend on how healthy or sick a patient is. Based on their health, some patients may be considered high-risk or too sick for surgery. If you are at high-risk or too sick for surgery, these clinical data reflect what you can expect.

The PARTNER II Trial studied the SAPIEN 3 valve in patients who are at high-risk or too sick for surgery. The trial was conducted in the United States in approximately 600 patients. They were examined at 30 days and 1 year and will continue to be examined every year for 10 years.

Clinical data for high-risk and inoperable patients with TAVR

The following table summarizes the 30-day and 1-year results of patients at high-risk or too sick for surgery who were treated with TAVR with the SAPIEN 3 valve.

TAVR - High-Risk and Inoperable Clinical Outcomes

	Risk Within 30 Days	Risk Within 1 Year
Death From Any Cause	2 out of 100 patients	13 out of 100 patients
Cardiovascular Death*	1 out of 100 patients	8 out of 100 patients
Major Stroke	2 out of 100 patients	2 out of 100 patients
Aortic Insufficiency ≥ Moderate†	3 out of 100 patients	3 out of 100 patients
New Pacemaker Implantation‡	14 out of 100 patients	17 out of 100 patients
Major Vascular Complications	6 out of 100 patients	N/A
Myocardial Infarction (heart attack)	1 out of 100 patients	2 out of 100 patients
Endocarditis§	1 out of 100 patients	2 out of 100 patients

The frequency is shown as the number of patients out of every 100.

** From heart-related causes*
† When the aortic valve does not close tightly and causes a backward flow of blood
‡ Device that can help regulate the heart
§ Inflammation or infection of any internal heart structures, including the valves

WHAT ARE THE RISKS OF TAVR?

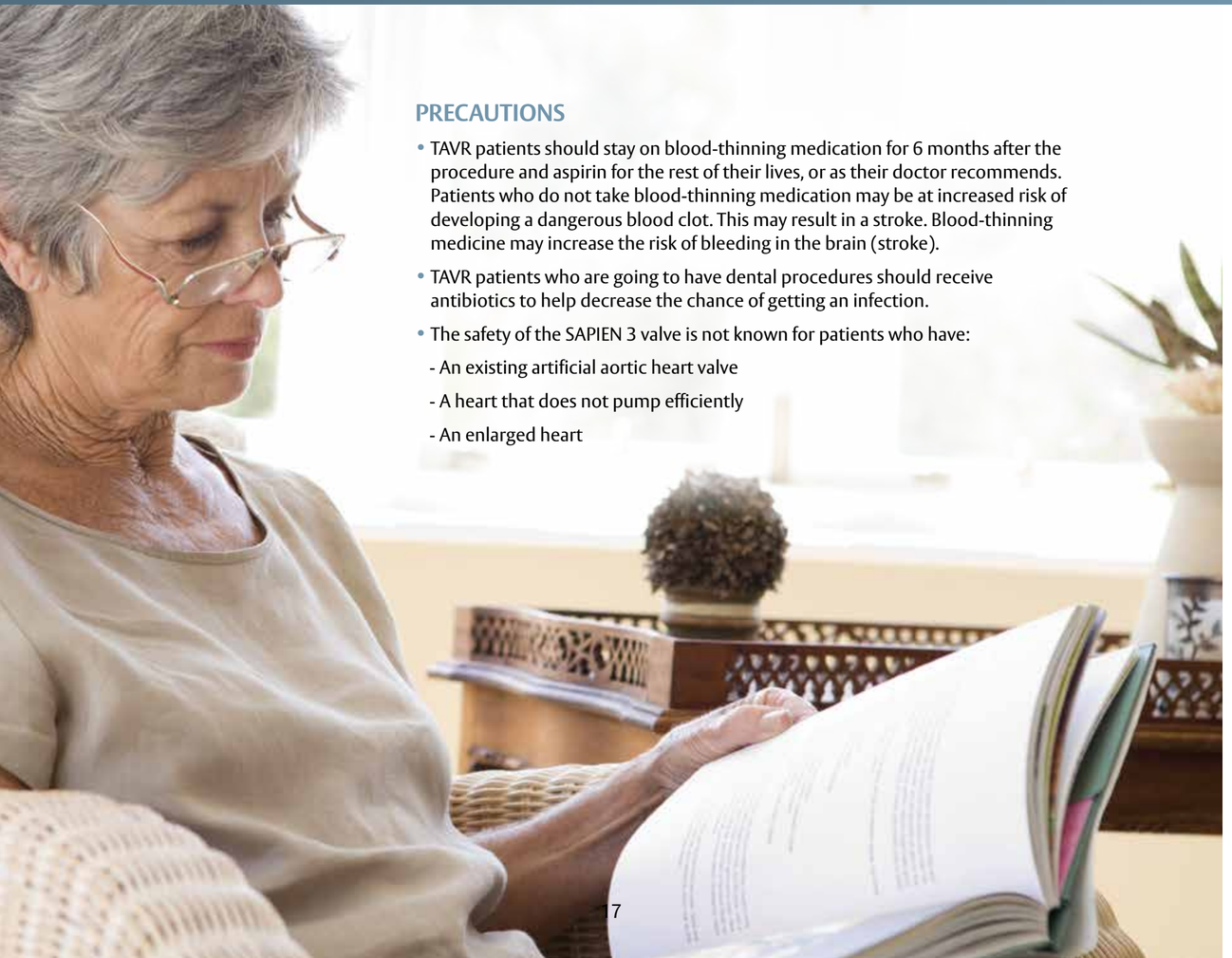
As with any medical procedure, there is a possibility of complications.

The most serious risks of the TAVR procedure with the SAPIEN 3 valve include:

- Death
- Major stroke; a condition when blood stops flowing in the brain, which may cause severe disability
- Major vascular complications; a large blood clot under the skin, which will require another surgery
- Life threatening bleeding event; a bleeding event that requires a blood transfusion

Additional potential risks associated with the procedure include:

- Heart attack
- Failure of your heart to pump enough blood to the body organs
- Irregular heart rate
- Problems with the electrical pathway of your heart that requires a pacemaker
- Collection of fluid or blood around your heart
- Having an abnormal particle (air, blood clots) floating in the blood stream or attached to an object, including the valve
- Infection to your heart, blood or other areas
- Injury to your blood vessels or heart that require treatment
- Blocking, narrowing or bulging of a blood vessel
- Blood clot, including a blood clot on the valve
- Trouble or inability to breathe
- Fluid build-up in your lungs
- Anemia
- Lab values that are not normal
- Abnormally high or low blood pressure
- Pain, inflammation and fever
- Pain or changes at the incision site
- Problems with the valve or accessories that do not allow it to work well, including but not limited to: wear, tear or movement forward (prolapse) or backward (retraction) from the normal position of the valve leaflets, calcium build up on the leaflets, or a break in the frame
- Incorrect position of valve or valve movement
- Blood leak around the valve
- Additional cardiac surgery, vascular surgery or intervention



PRECAUTIONS

- TAVR patients should stay on blood-thinning medication for 6 months after the procedure and aspirin for the rest of their lives, or as their doctor recommends. Patients who do not take blood-thinning medication may be at increased risk of developing a dangerous blood clot. This may result in a stroke. Blood-thinning medicine may increase the risk of bleeding in the brain (stroke).
- TAVR patients who are going to have dental procedures should receive antibiotics to help decrease the chance of getting an infection.
- The safety of the SAPIEN 3 valve is not known for patients who have:
  - An existing artificial aortic heart valve
  - A heart that does not pump efficiently
  - An enlarged heart

- The safety and performance of the SAPIEN 3 valve has not been established for patients who have:
  - An aortic heart valve that is not calcified
  - An aortic heart valve that only has one or two leaflets
  - A diseased aortic valve in which the main problem is valve leakage
  - A previously implanted medical device in any heart valve
  - A diseased mitral valve that is calcified or leaking
  - Low white blood cell count, low red blood cell count, or other abnormalities in the blood
  - Unusual ultrasound images of the heart that could represent abnormalities such as a blood clot
  - Allergies to blood-thinning medications or dye that is injected during the procedure
  - An aortic valve that is too small or too big to fit the transcatheter heart valve
  - Diseased or abnormally shaped vessels leading to the heart
  - Femoral vessels that are heavily diseased or too small for the delivery device
  - Aortic valve leaflets with large pieces of calcium that may block the vessels that supply blood to the heart

WARNINGS

- **Stroke may happen in patients who get TAVR procedures. This happens less if aortic stenosis is treated with medicine and by inflating a balloon inside the heart.**
- **Major blood vessel complications may occur in TAVR procedures. This occurs less if aortic stenosis is instead treated with medicine and by inflating a balloon inside the heart**
- **The valve implant may not last as long in patients who do not process calcium normally**
- **Talk to your doctor if you are allergic to the implant materials. These include anesthesia, contrast media, chromium, nickel, molybdenum, manganese, copper, silicon, and plastics**
- **X-ray may cause radiation injury to the skin**

WHO SHOULD NOT HAVE THE PROCEDURE?

The SAPIEN 3 valve and delivery systems 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

CONTACT INFORMATION

For more information on the SAPIEN 3 valve or the TAVR procedure:

Toll free phone in the USA:
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Phone from outside the USA:
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One Edwards Way
Irvine, California 92614

Online:
www.NewHeartValve.com
www.TAVRbyEdwards.com
www.Edwards.com

Data on file at Edwards Lifesciences.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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

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SAPIEN 3 Transcatheter Heart Valve Important Risk Information

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 ≥ 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 3 transcatheter heart valve, model 9600TFX, and accessories are indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral 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., predicted risk of surgical mortality ≥ 8% at 30 days, based on the 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. Safety, performance, and durability of the SAPIEN 3 valve has not been established for placement inside a previously implanted transcatheter valve.

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 prosthetic ring in any position.
- Previous atrial septal occlude.
- 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, abnormal or irregularly shaped vessels leading to the heart. Vessels which are heavily diseased or too small for associated delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- 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.
- Additional pre-procedure imaging will be completed to evaluate proper sizing.

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, injury to the structure of 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 (United States) law restricts these devices to sale by or on the order of a physician.