Transcatheter Heart Valve Replacement

With the Edwards SAPIEN 3 Transcatheter Heart Valve

for Patients & Caregivers
This patient booklet is for those who are suffering from a failing surgical bioprosthetic heart valve in the aortic or mitral position and are at high or greater risk for surgical valve replacement. This information will help you learn more about your heart and your treatment options, including a less invasive procedure called transcatheter valve replacement.

Be sure to ask your specialized Heart Team to explain all of your treatment options and the possible risks and benefits of each.
This booklet is not intended to explain everything you need to know about your treatment options or about the transcatheter procedure. Please discuss any questions you have with your doctor. Only a specialized Heart Team can decide which treatment option is right for you.

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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
- 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 leaks backwards
Why Could Your Surgical Bioprosthetic Heart Valve be Failing?

Your original heart valve may have been replaced with a surgical bioprosthetic heart valve. Over time, there are two common problems that can develop with a surgical bioprosthetic heart valve:

- **Stenosis**: when your valve narrows and does not open completely
- **Regurgitation**: when your valve does not close completely and blood leaks backwards

With either problem, your heart needs to work harder and may not pump enough blood to your body. In elderly patients, failing surgical bioprosthetic heart valves are sometimes caused by the build up of calcium (mineral deposits) on the valve’s leaflets. Over time, the leaflets become stiff, reducing their ability to fully open and close. When the leaflets don’t fully open and close, your heart must work harder to push blood through the valve to your body.

Eventually, your heart gets weaker. This increases the risk of heart failure (when your heart cannot keep up with its workload). Stenosis or regurgitation of your surgical bioprosthetic heart valve can be a very serious problem.

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

If you have a failing aortic or mitral surgical bioprosthetic heart valve, and your doctor has evaluated you to be at high or greater risk for surgery, transcatheter valve replacement may be an option for you.

However, only a specialized Heart Team can determine which treatment option is best for you.

Transcatheter Valve Replacement

Transcatheter valve replacement is a less invasive, catheter-based technique for replacing the failing valve. An interventional cardiologist, along with a cardiothoracic surgeon, will work together during the procedure. They will guide a new valve into the heart while the heart is still beating, using guidance from X-ray and echocardiography.

They may use one of the following delivery approaches: transfemoral (through an incision in your leg), transapical (through an incision in the bottom of your heart), transaortic (through an incision in the top of your heart), or transseptal (through an incision in your leg). Your doctor will determine the best delivery approach for you.
Surgical Valve Replacement

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, 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 or mitral valve and insert a new valve. There are two different types of surgical valves:

• Mechanical (man-made material)
• Biological (animal or human tissue)
Edwards SAPIEN 3 Transcatheter Heart Valve

The Edwards SAPIEN 3 transcatheter heart valve is a biological tissue valve that will replace your failing 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 Lifesciences’ first transcatheter heart valve was approved commercially in Europe in 2007 and in the United States in 2011.
**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.

Transcatheter valve replacement allows a new valve to be inserted through a minimal incision.

1. Before your procedure, you may be placed under anesthesia.
2. A small incision will be made 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 failing valve. The new valve will push the leaflets of your failing valve aside. The frame of the new valve is strong, and it will use the leaflets and frame of your failing 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.

Images above show the transfemoral approach to replace a failing aortic valve.
Examples of Delivery Approaches: Transcatheter Aortic Valve Replacement

Transaortic (TAo) Approach
An incision will be made in your upper chest to access your aorta.

Transapical (TA) Approach
A small incision will be made in your chest between your ribs to access the lowest part of your heart.

Transfemoral (TF) Approach
A small incision will be made in your leg.
Transapical (TA) Approach
A small incision will be made in your chest between your ribs to access the lowest part of your heart.

Transseptal (TS) Approach
A small incision will be made in your leg. The delivery system and valve will be guided from the right side of your heart to the mitral valve on the left side of your heart.
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.
What Are the Benefits?

Benefits of the Procedure: If you have a failing surgical bioprosthetic heart valve, transcatheter valve replacement will help your heart 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.
Clinical data for transcatheter valve patients with a failing surgical bioprosthetic aortic valve

The following table summarizes the discharge and 30-day results of patients at high or greater risk with a failing surgical bioprosthetic aortic valve who were treated with transcatheter valve replacement using the SAPIEN 3 valve.

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<th>Clinical Data for Transcatheter Valve Replacement</th>
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<td>Discharge</td>
<td>Risk Within 30 Days</td>
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<tr>
<td>Death From Any Cause</td>
<td>3 out of 100 patients</td>
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<tr>
<td>Cardiovascular Death*</td>
<td>1 out of 100 patients</td>
</tr>
<tr>
<td>Ischemic Stroke†</td>
<td>1 out of 100 patients</td>
</tr>
<tr>
<td>Aortic Insufficiency ≥ Moderate‡</td>
<td>2 out of 100 patients</td>
</tr>
<tr>
<td>New Pacemaker Implantation§</td>
<td>3 out of 100 patients</td>
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<tr>
<td>Major Vascular Complications</td>
<td>1 out of 100 patients</td>
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<tr>
<td>Myocardial Infarction (heart attack)</td>
<td>0 out of 100 patients</td>
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The frequency is shown as the number of patients out of every 100.

* From heart-related causes
† Events evaluated by an independent committee
‡ When the aortic valve does not close tightly and causes a backward flow of blood
§ Device that can help regulate the heart

Transcatheter Valve Replacement
Clinical Data

The TVT Registry collects safety and efficacy data from hospitals treating patients with THV’s. The registry included patients with failing aortic or mitral surgical bioprosthetic valves who received a SAPIEN 3 or SAPIEN XT valve.

The following tables show TVT Registry results. The first table shows results of 314 patients with a failing surgical bioprosthetic aortic valve who received a SAPIEN 3 valve. The second table shows 311 patients with a failing surgical bioprosthetic mitral valve treated with either a SAPIEN 3 or a SAPIEN XT valve.
Clinical data for transcatheter valve patients with a failing surgical bioprosthetic mitral valve

The following table summarizes the discharge and 30-day results of patients at high or greater risk with a failing surgical bioprosthetic mitral valve who were treated with transcatheter valve replacement using the SAPIEN 3 valve or the SAPIEN XT valve.

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<th>Transcatheter Mitral Valve Replacement - Clinical Outcomes</th>
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<tr>
<td>Death From Any Cause</td>
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<tr>
<td>Cardiovascular Death*</td>
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<tr>
<td>Readmission for Heart Failure†</td>
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<tr>
<td>Ischemic Stroke†</td>
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<tr>
<td>Hemorrhagic Stroke†</td>
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<tr>
<td>Cardiac Arrest</td>
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<tr>
<td>Mitral Regurgitation &gt; Moderate‡</td>
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<tr>
<td>Major Vascular Complications</td>
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<tr>
<td>Myocardial Infarction (heart attack)</td>
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<td>Endocarditis</td>
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* From heart-related causes
† Events evaluated by an independent committee
‡ When the aortic valve does not close tightly and causes a backward flow of blood
|| Inflammation or infection of any internal heart structures, including the valves

The frequency is shown as the number of patients out of every 100.
What Are the Risks?
As with any medical procedure, there is a possibility of complications.

The most serious risks of the 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 or blood clots) floating in the blood stream or attached to an object, including the valve
- Infection in your heart, blood, or other areas
- Injury to your blood vessels or heart that requires 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, or 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, including removal of the THV
- Fainting or dizziness
- Weakness or trouble exercising
- Allergic reaction
- Inability to move (paralysis)
- Permanent disability
- Kidney failure
- Chest pain
- Damage to blood cells
- Repeat hospitalization
- Sudden or unexpected loss of heart function
- Injury to nerve
- Partial or complete blockage of coronary artery (artery supplying blood to the heart)
- Extra or unusual sound during heartbeat (heart murmur)
Precautions

• The safety, performance, and durability of the SAPIEN 3 valve has not been established for placement inside a previously implanted transcatheter valve.

• 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).

• Patients who are going to have dental procedures performed 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:
  - 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 previously implanted prosthetic ring in any heart valve
  - 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 transcatheter procedures.

• Major blood vessel complications may occur in transcatheter procedures.

• 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 procedure:

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