

Understanding Tissue and Mechanical Aortic Valves:

A Patient Engagement Resource

How to use this interactive counseling tool

- Press **Get Started** to go to the **Patients** section
- For matching discussion guidelines for healthcare professionals, select the **HCPs** tab
- For a printable take-home resource for patients, select **Summary for Patients**
- **Important Safety Information** and **References** may be found at the end of the guide or by clicking on their respective tabs on the pages that follow



Edwards

Overview of Aortic Valve Disease

What is the aorta?

Your heart is a strong muscle that sits in your chest between your lungs. It works to keep blood moving through your body. **The aorta** is a large blood vessel that carries the blood to the rest of the body.

What is the aortic valve?

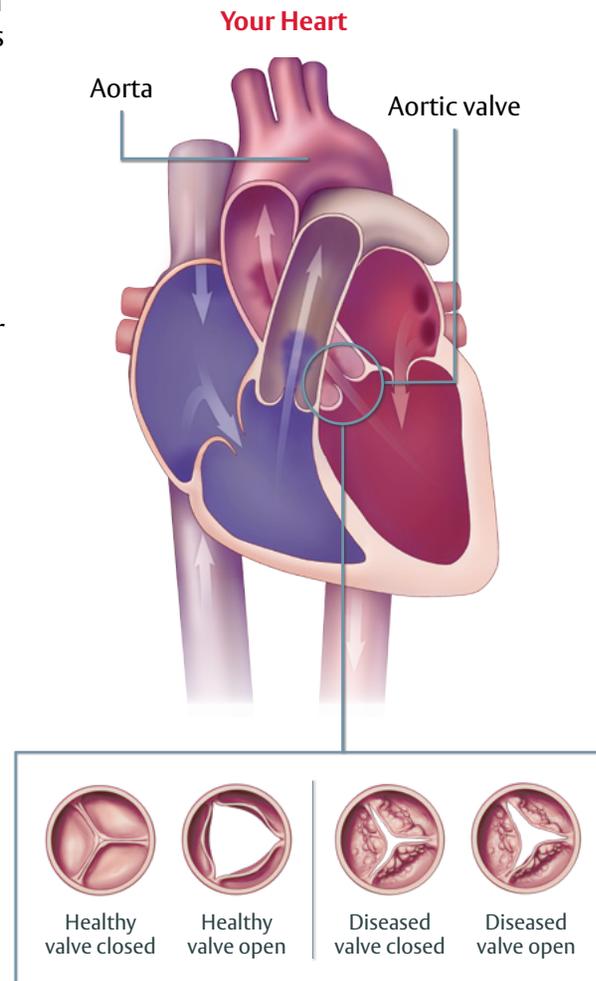
The **aortic valve** serves as the “door” between your heart and the rest of your body. It has three leaflets (or flaps) to make sure blood moves correctly from the lower left chamber of the heart to the aorta.

What is aortic valve disease?

There are two types of problems that can occur with aortic valves:

Aortic stenosis: The valve is narrowed and does not completely open, blocking the normal flow of blood.

Aortic regurgitation: The valve does not fully close and blood leaks backward (in the wrong direction) in the heart.



What are the symptoms of severe AVD?

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

Physical signs of heart valve disease include

-  shortness of breath
-  tiredness
-  lightheadedness or fainting
-  chest pain

Pay attention to new or worsening symptoms.

Treatment of Aortic Valve Disease With Surgical Aortic Valve Replacement

After your aortic valve disease has been diagnosed and you have jointly decided with your healthcare professional to receive treatment with surgical aortic valve replacement, you still have treatment decisions to make.



Aortic valve replacement

Valve replacement is the only treatment shown to improve survival and provide durable improvements in related symptoms.

Surgical aortic valve replacement (SAVR)

The most common treatment for severe aortic valve disease is to replace the valve through open heart surgery.

Tissue valve

Mechanical valve

The choice between a tissue valve and a mechanical valve should be based on a **shared decision-making process**.

What is shared decision making?

Shared decision making is a process in which healthcare providers and the patient **jointly decide on his or her best treatment path** after considering the clinical evidence and the patient's preferences.

Use this time with your healthcare professional to discuss which valve choice is best for you.

What are my valve options?



Mechanical Valve

- Mechanical valves are made from man-made materials
- Mechanical valves include leaflets that are made of a special type of carbon



Tissue Valve

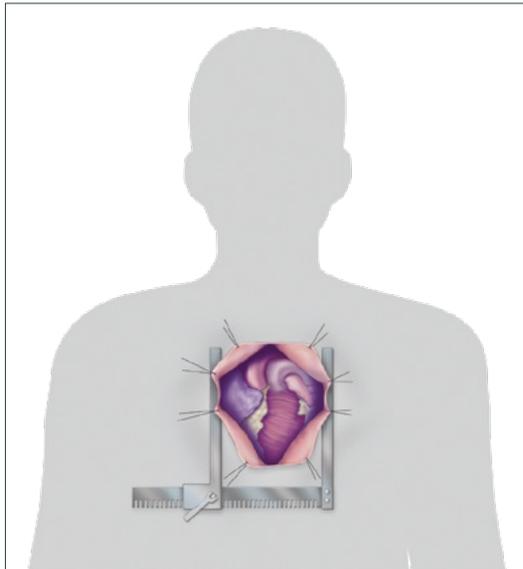
- Tissue valves are made with
 - bovine (cow) heart tissue (the tough sac around the heart)
 - porcine (pig) tissue
 - human valves from cadavers

Options for Surgical Aortic Valve Replacement

What surgical approach options are available?

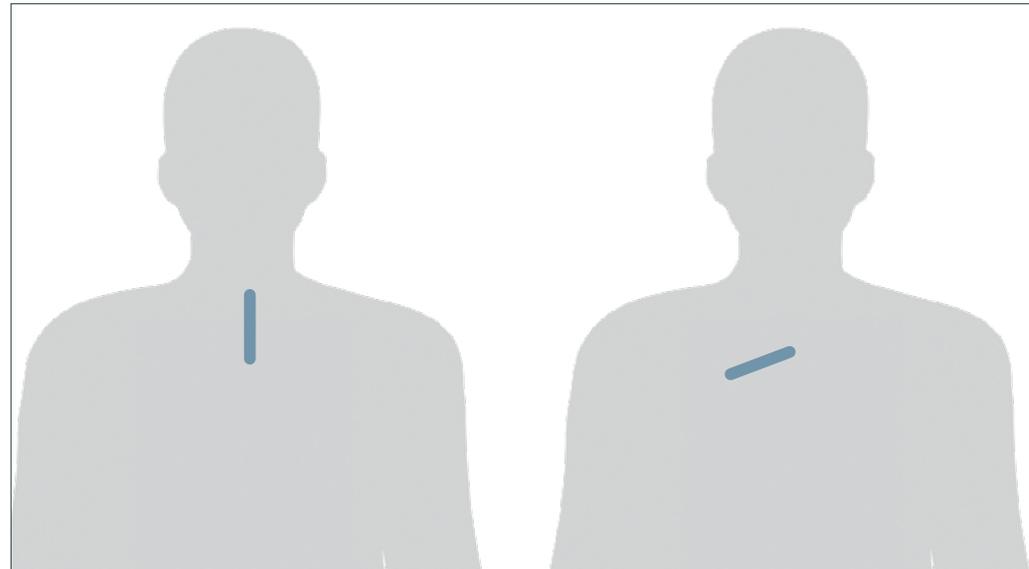
Standard surgical approach

- The surgeon makes an opening in the middle of the chest and breastbone to access the heart
- To keep the heart still enough for the surgeon to operate, a heart-lung machine takes over the job of pumping blood through the body
- The surgeon removes the diseased valve and puts a new heart valve in its place



Small-incision surgical approach

- The surgeon makes a small incision between the ribs or in the upper part of the chest
- Many of the steps that a surgeon follows for standard open-heart surgery are the same in small-incision surgery. However, because the incision is smaller, this surgery may be associated with faster healing times, less blood loss and tissue trauma, and a smaller scar on your chest
- Although patients often desire a simpler approach to surgery, you and your surgeon should discuss these options now, making sure that there is never a compromise of safety and results



Making a Decision: Tissue or Mechanical Valve?

Which valve you choose should be based on a shared decision-making process between you and your surgeon that takes into account your values and preferences.

Key Tradeoffs Between Tissue and Mechanical Valves

	 Mechanical Valve	 Tissue Valve
Blood-thinning medicine requirement	<p>Lifetime requirement for a blood thinner</p> <ul style="list-style-type: none"> • Taking a blood thinner requires consistent daily management, including <ul style="list-style-type: none"> - routine blood tests - more frequent physician visits - dietary restrictions - lifestyle and activity limitations • Blood-thinning medicine that isn't managed correctly is associated with a higher risk of major bleeding or stroke 	<p>No lifetime requirement for a blood thinner</p> <ul style="list-style-type: none"> • Short-term treatment with a blood-thinning medicine is sometimes recommended for some patients
Likelihood of needing replacement	<p>Less likely than a tissue valve to require replacement in the future</p> <ul style="list-style-type: none"> • Replacement requires open heart surgery 	<p>More likely than a mechanical valve to require replacement in the future</p> <ul style="list-style-type: none"> • Replacement requires another procedure. This could be open heart surgery, or some patients may be eligible for a less invasive option called valve-in-valve transcatheter aortic valve replacement

Summary of Decision Points

This choice between a mechanical valve and a tissue valve should be made jointly between you and your healthcare professional.

	Recommendation Based on Age Only	Blood Thinning Considerations	Medical Concerns	Other Considerations
<p> A mechanical valve may be a better choice if you...</p>	<ul style="list-style-type: none"> are younger than 50 years 	<ul style="list-style-type: none"> are already taking a blood thinner for another reason 	<ul style="list-style-type: none"> have certain features of your heart that may limit your eligibility to have a future valve-in-valve procedure if your new valve ever needs to be replaced 	<ul style="list-style-type: none"> prefer to decrease the risk of needing another procedure have a medical history that increases the risk associated with a potential reintervention
	<p>If you are between the ages of 50 and 70 years, either valve may be appropriate for you.</p>			
<p> A tissue valve may be a better choice if you...</p>	<ul style="list-style-type: none"> are older than 70 years 	<ul style="list-style-type: none"> do not want to take blood thinners, regardless of your age are unwilling or unable to take blood thinners as prescribed have a high risk of complications from taking blood thinners 	<ul style="list-style-type: none"> are a woman who wants to become pregnant have other health conditions as discussed with your doctor 	<ul style="list-style-type: none"> think that a clicking sound a mechanical valve makes will bother you have an active lifestyle with a high risk of injury have limited access to routine medical care to help manage blood thinners

Considerations for Surgery

Before you decide to have surgery, it's important to fully understand the potential risks and benefits.

There are also many things to keep in mind and instructions that you will need to follow before and after surgery.

Benefits and Risks of Surgery



Benefits

- Greater ability to do the things you want and need to do
- Ease your symptoms
- Greater chance of longer life



Risks

- Bleeding during or after surgery
- Stroke
- Infection
- Low red blood cell count, resulting in weakness

Considerations Before and After Surgery



Before Surgery

- You will undergo medical tests and exams to check your heart and overall health
- Make sure you are prepared for surgery by following all of your surgeon's instructions
- Get all of your questions answered by your surgeon
- Talk to your surgeon about all of your concerns



After Surgery (Recovery)

- Standard recovery time is 8 to 12 weeks
- Follow all discharge instructions for medications, exercise, diet, and self-care
- Attend all follow-up appointments and checkups
- Discuss with your doctor any problems you are having with appetite, mood, sleep, constipation, and site healing

An estimated **80,000 to 85,000** aortic valve replacement procedures are performed every year in the United States.

Overview of Aortic Valve Disease

Define for your patients

- Heart valve disease
- Aortic valve disease (AVD)
- Aortic stenosis (AS)
- Aortic regurgitation
- Asymptomatic
- Heart failure
- Bicuspid aortic valve versus tricuspid aortic valve (if applicable)

Review with your patients

- **Symptoms** your patients may not have previously noticed or told you about
- **Tests** your patients may undergo to assess the **severity of their AVD**
- **Risk of disease progression** associated with your patient's current diagnosis

Key statistics

- Aortic stenosis affects 2% to 3% of the adult population in the United States
- As many as 32% of patients who initially present as asymptomatic actually show symptoms after further examination
- At least 40% of patients who need valve replacement do not get treatment



Lead the discussion by

- **defining** medical terms
- **reviewing** health information for informed decision making
- **reinforcing** key takeaway points

Engage your patients by

- **asking** them for their thoughts, concerns, and questions
- **confirming** they understand throughout the discussion

Treatment of Aortic Valve Disease With Surgical Aortic Valve Replacement

Define for your patients

- Mechanical valves
- Tissue valves
 - Porcine valves
 - Bovine valves
- Surgical aortic valve replacement (SAVR)
- Shared decision making

Review with your patients

- Factors that may determine the **timing** of treatment
 - Rate of disease progression
 - Disease severity and staging
 - Surgical risk
 - Concomitant heart disease
- Differences between **tissue valves** and **mechanical valves** in terms of their
 - performance
 - outcomes
 - quality
 - reliability
 - innovation



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Explain that there is a shared decision-making opportunity regarding **tissue versus mechanical valves** for SAVR procedures.

Options for Surgical Aortic Valve Replacement

Define for your patients

- Standard surgical approach
- Small-incision surgical approach

Review with your patient

- Risks and benefits of **surgical approach options**
 - Safety
 - Outcomes
 - Recovery

Ask your patients about their **preferences or concerns** regarding surgical approach options.



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Making a Decision: Tissue or Mechanical Valve?

Define for your patients

- Durability
- Warfarin/blood thinners
- INR (international normalized ratio)
- Transcatheter valve-in-valve
- Bleed risk
- Stroke risk

Review with your patients

- **Durability**
 1. Patient-specific risk of reoperation
 2. Potential for a future **valve-in-valve** procedure
- **Anticoagulation**
 1. Patient-specific risk of **bleeding and thromboembolic events**
 2. **Monitoring** requirements
 3. Modifications to **diet**
 4. **Lifestyle** considerations
- Important **discussion points** that may influence a patient's decision:

Physical factors	Psychosocial factors	Lifestyle factors
Age	Mental health	Quality of life
Surgical risk	Family dynamics	Hobbies
Comorbid conditions	Career demands	Day-to-day activities
	Access to healthcare	



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Summary of Decision Points

Define for your patients

- Valve size (if applicable)
- Complications
- Comorbid conditions

Review with your patients

- Reassure your patients that you want them to ask you as many **questions** as they want so that they feel comfortable with their decision
- Show your patients the decision summary found on the **Download Summary for Patients** tab above to help them **express their preferences and feelings** concerning the key decision points, including durability and anticoagulation
- Remind your patients to talk to their family about their decision and to **seek additional support** from patient organizations and other online resources (included on the attached decision summary)



Lead the discussion by

- **defining** medical terms
- **reviewing** health information for informed decision making
- **reinforcing** key takeaway points

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Considerations for Surgery

Define for your patients

- Stroke
- Infection
- Anemia

Review with your patients

- **Expectations** associated with presurgery and postsurgery
 - **Tests** that may be part of the presurgery assessment
 - Standard **recovery time**
 - **Potential concerns or problems** (eg, appetite, swelling, sleeping, constipation, mood swings, site healing) associated with recovery and explain how these problems may go away over time or be addressed
- **Postsurgery instructions** relating to diet, exercise, and rehabilitation
- Answers to **common questions about surgery**
 - How often do you perform the procedure that you've recommended, and what is your success rate?
 - Can you walk me through the entire process of surgery?
 - What are the potential side effects of this treatment?
 - Is minimally invasive surgery an option for me?
 - How long will I be in the hospital?
 - How long will I be out of work?
 - Will I have to take any long-term medications?
 - What will my follow-up care be like?



Lead the discussion by

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- **reviewing** health information for informed decision making
- **reinforcing** key takeaway points

Engage your patients by

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- **confirming** they understand throughout the discussion



It is very important to make sure that your patients have asked all of their **questions** by this time in the discussion.

Important Safety Information

Brief Summary: Aortic Bioprostheses

Indications: For use in patients whose aortic valvular disease warrants replacement of their natural or previously placed prosthetic valve.

Contraindications: Do not use if surgeon believes it would be contrary to the patient's best interests. **Complications and Side Effects:** Stenosis, regurgitation, endocarditis, hemolysis, thromboembolism, valve thrombosis, nonstructural dysfunction, structural valve deterioration, anemia, arrhythmia, hemorrhage, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, angina, any of which could lead to reoperation, explantation, permanent disability, and death. **Warnings:** Alternative therapies should be considered in the presence of conditions affecting calcium metabolism or when calcium containing chronic drug therapies are used, including children, adolescents, young adults, and patients on a high calcium diet or maintenance hemodialysis. Should be used with caution in the presence of severe systemic hypertension or when anticipated patient longevity is longer than the known longevity of the prosthesis. **CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.**

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