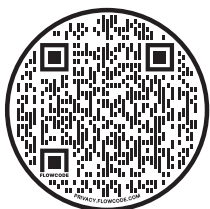




My heart.  
My voice.  
My future.

Your heart valve should support  
the life you love.



This guide provides an overview of aortic stenosis and how it's managed, to assist you in making the treatment choice that's right for you. Speak to your cardiologist about the options available.

Visit our patient website [Edwards.com](https://www.edwards.com)  
to learn more about aortic stenosis

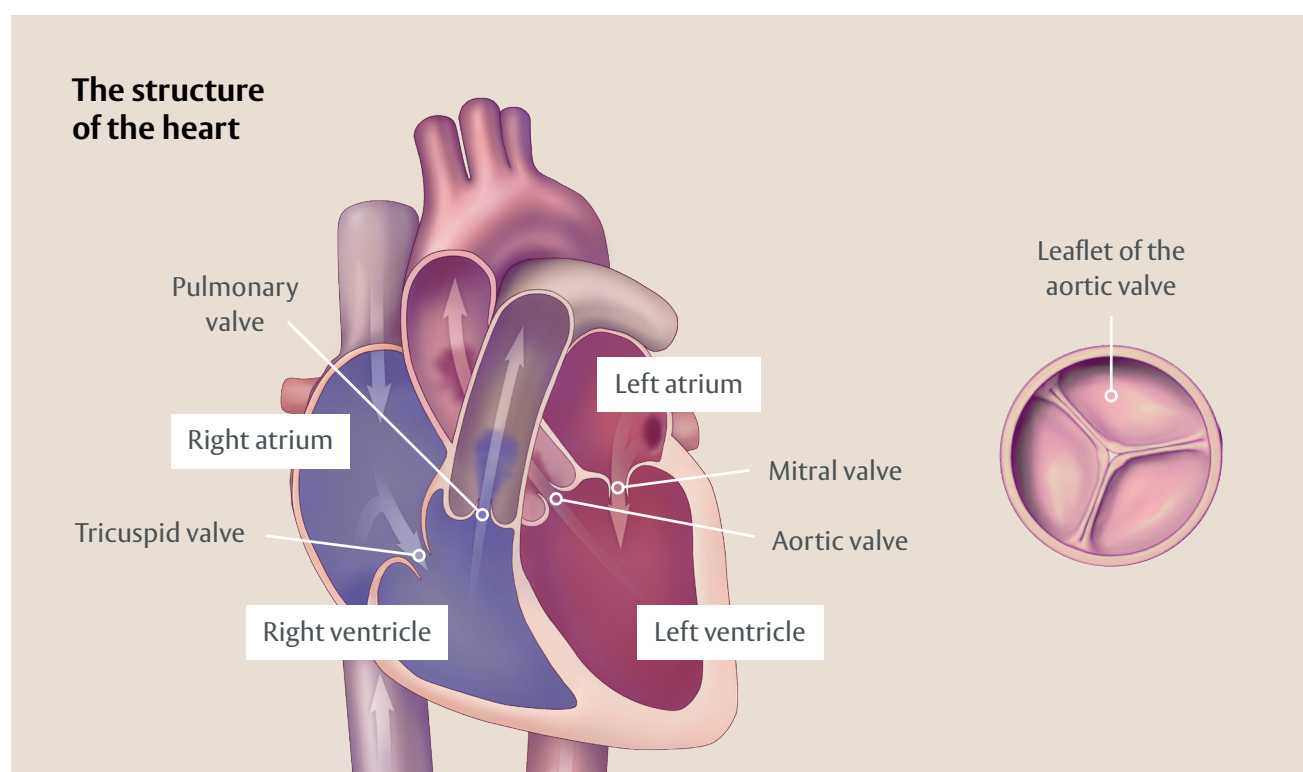


Edwards

# Your heart.



Your heart is a muscle that keeps you alive by pumping blood with essential oxygen and nutrients around your body. It is made up of two upper (atria) and two lower (ventricles) chambers.<sup>1</sup> The four heart valves, with their leaflets (flaps of tissue), act like doors between the chambers, opening and closing with every heartbeat.<sup>2</sup> This makes sure the blood flows in the right direction.<sup>2</sup>



## What is aortic stenosis?

Your condition, aortic stenosis, is associated with the aortic valve. Aortic stenosis is the most common heart valve disease and involves the narrowing of the aortic valve.<sup>3,4</sup> As we age, calcium can build up on the valve making it harder for blood to flow from the heart to the body.<sup>4,5</sup> Defects of the valve leaflets acquired at birth and, less commonly, infections like rheumatic fever can also cause aortic stenosis.<sup>5</sup>

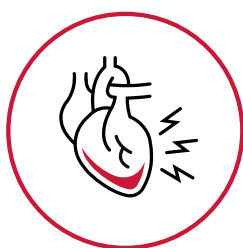
# What are the symptoms of aortic stenosis?



Aortic stenosis ranges from mild to moderate to severe.<sup>5</sup> Initially you may not have any symptoms, but as the condition progresses, you may experience:<sup>5,6</sup>



**An irregular heartbeat**



**Chest pain**  
(also called angina)



**Dizziness or lightheadedness**



**Feeling faint or fainting**



**Feeling tired, especially after being active**

Mild aortic stenosis does not require immediate treatment<sup>7</sup> but if it becomes severe and is left untreated, serious complications like heart failure can occur, and, in some cases it can be fatal.<sup>5</sup>

# Your choice.



## What are my treatment options?

The treatment options available to you will depend on how severe your aortic stenosis and symptoms are. If you have:

### Mild to moderate aortic stenosis

You should have regular check-ups every 2–3 years (or every year for moderate aortic stenosis). This will help make sure that your condition is not getting any worse.<sup>7</sup> Your doctor might also recommend some simple changes like eating well, cutting down on alcohol and quitting smoking to reduce the strain on your heart.<sup>4,8</sup>

### Severe aortic stenosis

Your heart valve may need to be replaced with an artificial valve, using one of the two procedures below.<sup>7</sup> The choice of the procedure depends on things like your age and whether you have other medical conditions.<sup>7</sup>

#### Surgical aortic valve replacement (SAVR)

Your surgeon will replace your existing heart valve with one made from metal or animal tissue through open heart surgery.<sup>4</sup>

This procedure is recommended for patients younger than 75 years of age at low surgical risk.<sup>7</sup>

#### Transcatheter aortic valve implantation (TAVI)

This involves inserting a narrow flexible tube (catheter) into a blood vessel in your upper leg or chest and passing it towards your aortic valve to insert a tissue valve.<sup>4</sup>

This procedure is recommended for patients 75 years of age or older at high surgical risk.<sup>7</sup>

# Your choice.



## Mechanical or tissue valve?

When choosing a heart valve for your aortic valve replacement, your healthcare team will discuss your options and help you decide what the best valve replacement choice is for you.

You will be fitted with either a tissue or mechanical valve. Below are some important considerations that may help you with your choice:

	<b>Tissue valve</b>	<b>Mechanical valve</b>
<b>What is the valve made out of?</b>	Animal tissue, usually from pigs or cows <sup>9</sup>	Materials such as titanium and carbon <sup>9</sup>
<b>How is it implanted?</b>	SAVR or TAVI, depending on the type of tissue valve <sup>9</sup>	SAVR <sup>4</sup>
<b>How long will the valve last?</b>	Approximately 10–20 years, depending on the type of valve and your health and lifestyle <sup>10</sup>	Usually lasts a lifetime <sup>10</sup>
<b>Will I need to be on long-term anticoagulation medication?</b>	No <sup>7</sup>	Yes, mechanical valves need lifelong use of an anticoagulant, which prevents blood clotting <sup>7</sup>
<b>Do I need to make any lifestyle changes?</b>	No	Yes, taking an anticoagulant means regular monitoring, avoiding contact sports, and taking extra care with sharp objects such as knives and scissors <sup>11</sup>
<b>Do I need to consider my diet?</b>	You might need to reduce your calcium intake <sup>12</sup>	Keep the amount of food high in vitamin K (leafy greens like kale, brussels sprouts, or broccoli) consistent in your diet <sup>11,13</sup>
<b>Will I be able to hear my replacement valve?</b>	No	Yes, you'll be able to hear some clicking sounds as your valve opens and closes <sup>14</sup>
<b>What are the risks if I am planning on becoming pregnant in the future?</b>	No known pregnancy complication risk <sup>7</sup>	High pregnancy complication risk <sup>7</sup>

SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Unlike mechanical valves, tissue valves can wear out faster, especially in patients younger than 60 years old.<sup>15,16</sup> This has led researchers to develop tissue valves that can potentially last longer in the body called 'advanced tissue valves'.


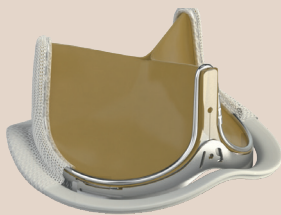
# Your future.



## What is an advanced tissue valve?

Build-up of calcium on the leaflets is the main reason a tissue valve may break down<sup>15</sup> and means you could need a second operation to replace the tissue valve. Advanced tissue valves contain specially-treated tissue designed to limit calcium build-up, which is expected to make the tissue valve more durable.<sup>17</sup>

For over 40 years, Edwards Lifesciences has been pioneering the development of advanced tissue valves.<sup>18</sup> Edwards Lifesciences has developed RESILIA tissue, which has been treated with a special preservation technology shown to reduce calcium build-up compared to previous generation tissue valves.<sup>17,19</sup> All products shown below are manufactured by Edwards Lifesciences and are an example of how tissue valves have evolved.

	 <b>Previous generation: Carpentier-Edwards PERIMOUNT Magna Ease valve<sup>20</sup></b>	 <b>Latest generation: INSPIRIS RESILIA valve<sup>19</sup></b>
<b>Long-term anticoagulant not required</b>	✓	✓
<b>Includes RESILIA tissue* technology to reduce calcium build-up</b>	✗	✓
<b>Designed to assist with potential future valve replacements</b>	✗	✓

## Who might benefit from an advanced tissue valve?<sup>7,11</sup>

- Frequent travellers
- Sports enthusiasts
- Physically-demanding career professionals (e.g. construction, military)
- Women hoping to start a family

\*No clinical data are available to evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

# Your voice.



It's a good idea to think ahead when choosing your first aortic valve, as it may impact your future treatment options. Your medical team will be on hand to talk you through the options and help you make the best decision for you. **Remember, this is a collaborative process, and your thoughts and preferences are important.**

*"[People] are much better informed nowadays, there's much more information available in the literature and on the web. And I think that is a good thing, patients need to be able to decide what type of valve they're going to choose."* **Mr Ahmed**

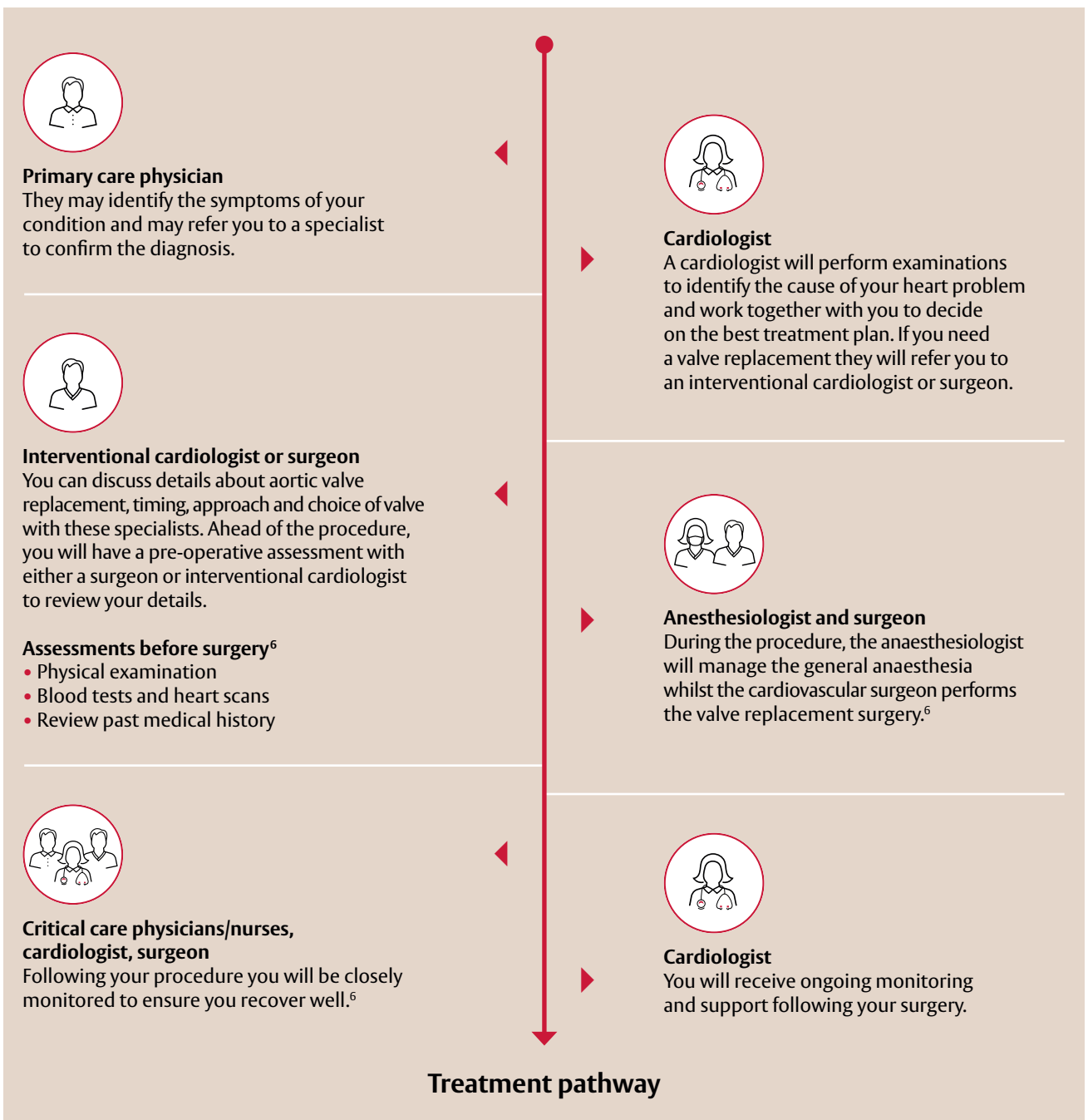
The below chart outlines key recommendations that can help to guide your decision

<b>A mechanical valve</b> may be a better choice if you...	Are younger than 60 years <sup>7</sup>	Are already on long-term anticoagulant for another reason <sup>7</sup>	Are at high risk of complications if you need another valve operation <sup>7,10</sup>	Prefer to decrease the risk of needing another procedure <sup>10</sup>
	Are between the ages of 60–65 years; either valve may be appropriate <sup>7</sup>			
<b>A tissue valve</b> may be a better choice if you...	Are older than 65 years <sup>7</sup>	Do not want to take an anticoagulant <sup>7</sup>	Wish to become pregnant in the future <sup>7</sup>	Have an active lifestyle with a high risk of injury <sup>7</sup>
		Are unable to take an anticoagulant as prescribed or are at high risk of complications from taking an anticoagulant <sup>7</sup>		Have limited access to routine medical care to help manage anticoagulants <sup>11</sup>
				Think the clicking sound of mechanical valves would bother you <sup>14</sup>

# Your team.



If you're going to have heart valve replacement surgery, you will be cared for by a team of cardiac medical specialists.<sup>7</sup> Your healthcare team is committed to ensuring your safety and comfort before, during, and after your procedure.<sup>7</sup> Below you will find a typical patient journey and the different healthcare professionals you may meet during your care:



Your healthcare team is here to help, but when it comes to your heart and your future, your voice is crucial. Visit [Edwards.com](https://www.edwards.com) to help you make the right choice.



# Glossary.



**Angina:** Chest pain caused by reduced blood flow to the heart  
**Anticoagulant:** A drug which prevents the clotting of blood  
**Aortic stenosis:** A type of heart valve disease which involves narrowing of the aortic valve so that blood cannot flow normally  
**Aortic valve:** The valve between the left ventricle and the aorta  
**Artery:** Blood vessels which carry blood away from the heart  
**Atrium:** Upper chamber of the heart that receives blood from the veins  
**Calcification:** Calcium present in the blood may collect and deposit calcium in body tissues, such as the leaflets of heart valves, which reduce the flexibility of the leaflets  
**Endocarditis:** Inflammation or infection of the lining of the heart and valve leaflets  
**Heart failure:** A condition that develops when your heart doesn't pump enough blood for your body's needs  
**Rheumatic fever:** A very rare condition that can develop after a bacterial throat infection and can cause painful joint and heart problems  
**Stenosis:** Narrowing of an opening  
**Surgical aortic valve replacement:** Open heart surgery to treat aortic stenosis by replacing the human valve with a mechanical or tissue valve  
**Transcatheter aortic valve implantation:** A minimally-invasive procedure to treat aortic stenosis involving the insertion of a narrow flexible tube (catheter) inserted into a blood vessel in your upper leg or chest to implant a tissue valve  
**Ventricle:** the large lower pumping chambers of the heart

## Abbreviations

SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

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No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

**Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult [eifu.edwards.com](https://eifu.edwards.com) where applicable).**

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