

Aortic Valve Surgery with the
INSPIRIS RESILIA
Aortic Valve

What You and Your Loved Ones Should Know



Introduction

This guide is for patients who have aortic heart valve disease and whose doctors have proposed surgery to replace the valve. It will help you and your loved ones learn more about your heart and how it works. You will also learn about valve disease and surgery options.

Be sure to ask your doctor to explain the treatment choices and the heart valves used for surgery.



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This booklet does not include everything you need to know about heart valves, heart valve replacement surgery, or about related medical care. Regular check-ups by your heart doctor are important.

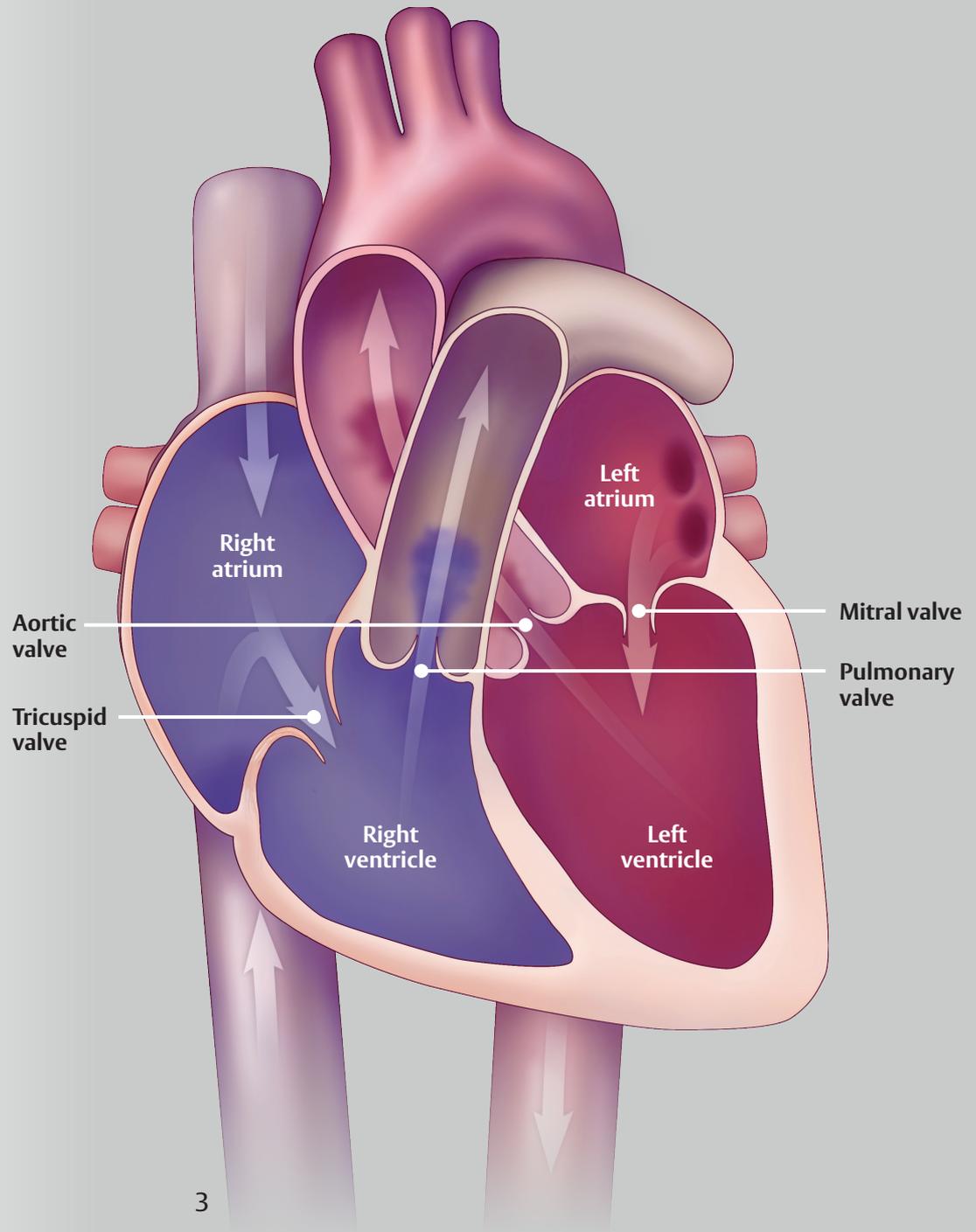
Call or see your doctor whenever you have questions or concerns about your health, especially if you have any unusual symptoms or changes in your overall health.

How does your heart work?

Your heart is a strong muscle that sits in your chest between your lungs. It works to keep blood moving through your body. The right side of the heart pumps blood through the lungs, where the blood picks up oxygen. The blood with oxygen goes to the left side of the heart, and the left side of the heart pumps the blood to the rest of your body.

There are four valves that control the flow of blood through your heart. The valves open to allow blood to move forward, but close to prevent blood from moving backward in the wrong direction. One of the valves 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. The aorta is a large blood vessel that carries the blood to the rest of the body.



What is aortic valve disease?

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

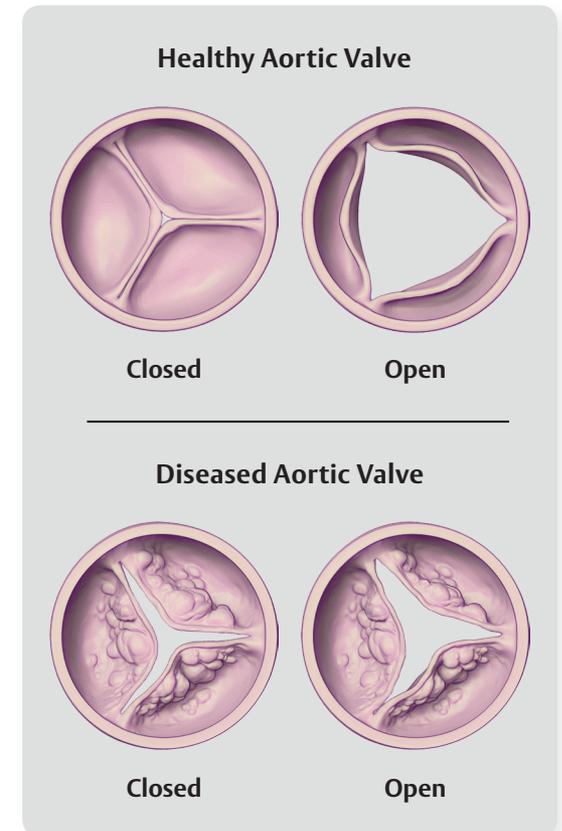
- **Aortic stenosis:** the valve is narrowed and does not completely open, blocking the normal flow of blood
- **Aortic regurgitation:** the valve does not fully close and blood leaks backward (in the wrong direction) in the heart

These problems can be caused by a build-up of calcium (mineral deposits) on the leaflets due to aging, birth defect, illness, or certain therapies. The build-up of calcium on the valve's leaflets over time hardens and thickens the valve. As a result, the valve does not open all the way, and blood flow is slowed. This forces the heart to work harder and can cause chest pain, difficulty exercising, shortness of breath, and fainting spells. Over time, your heart gets weaker. This raises your risk of heart failure (when your heart cannot pump enough blood for what your body needs).

Some people are born with two leaflets, instead of three. This is called a bicuspid valve. When this happens, it increases the risk for calcium build-up on the valve.

How is aortic valve disease treated?

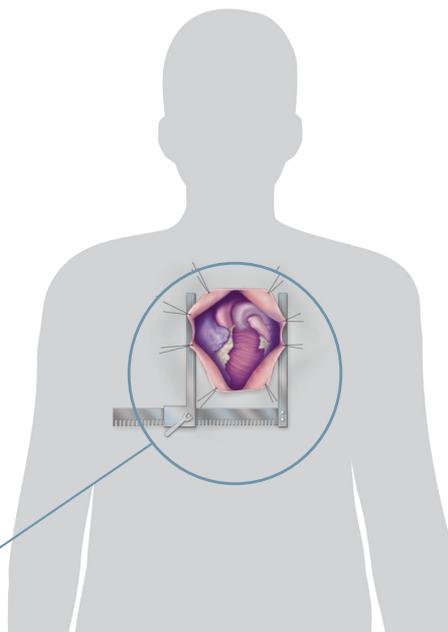
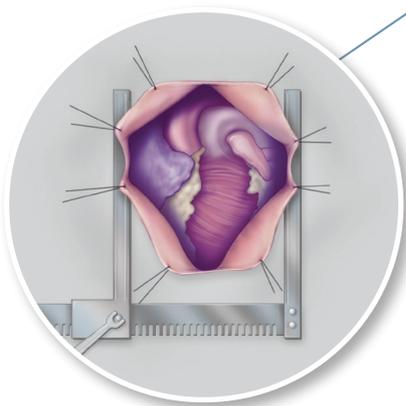
Treatment for valve disease depends on how much disease is in the valve. Medicine can relieve symptoms in many cases, but it will not fix the failing valve. As aortic valve disease worsens, your doctor may suggest replacing your valve. There are different ways to replace a valve. Your doctor will carefully assess your case and advise you of the best option for you



What are your treatment options?

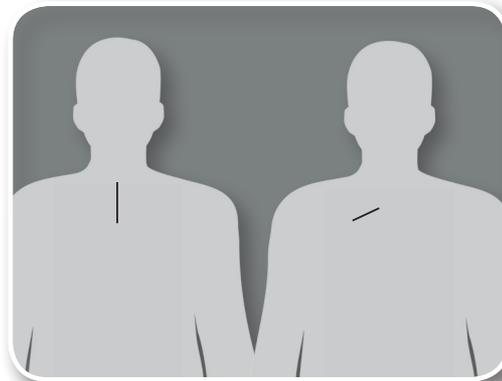
Standard surgical approach

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

In another type of open-heart surgical treatment used to replace a diseased valve, the surgeon puts a small incision between the ribs or in the upper part of the chest. Many of the same steps are used in small incision surgery as with standard open-heart 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. While patients often desire a simpler approach to surgery, you and your surgeon should discuss the options, making sure that there is never a compromise of safety and results.



Transcatheter approach

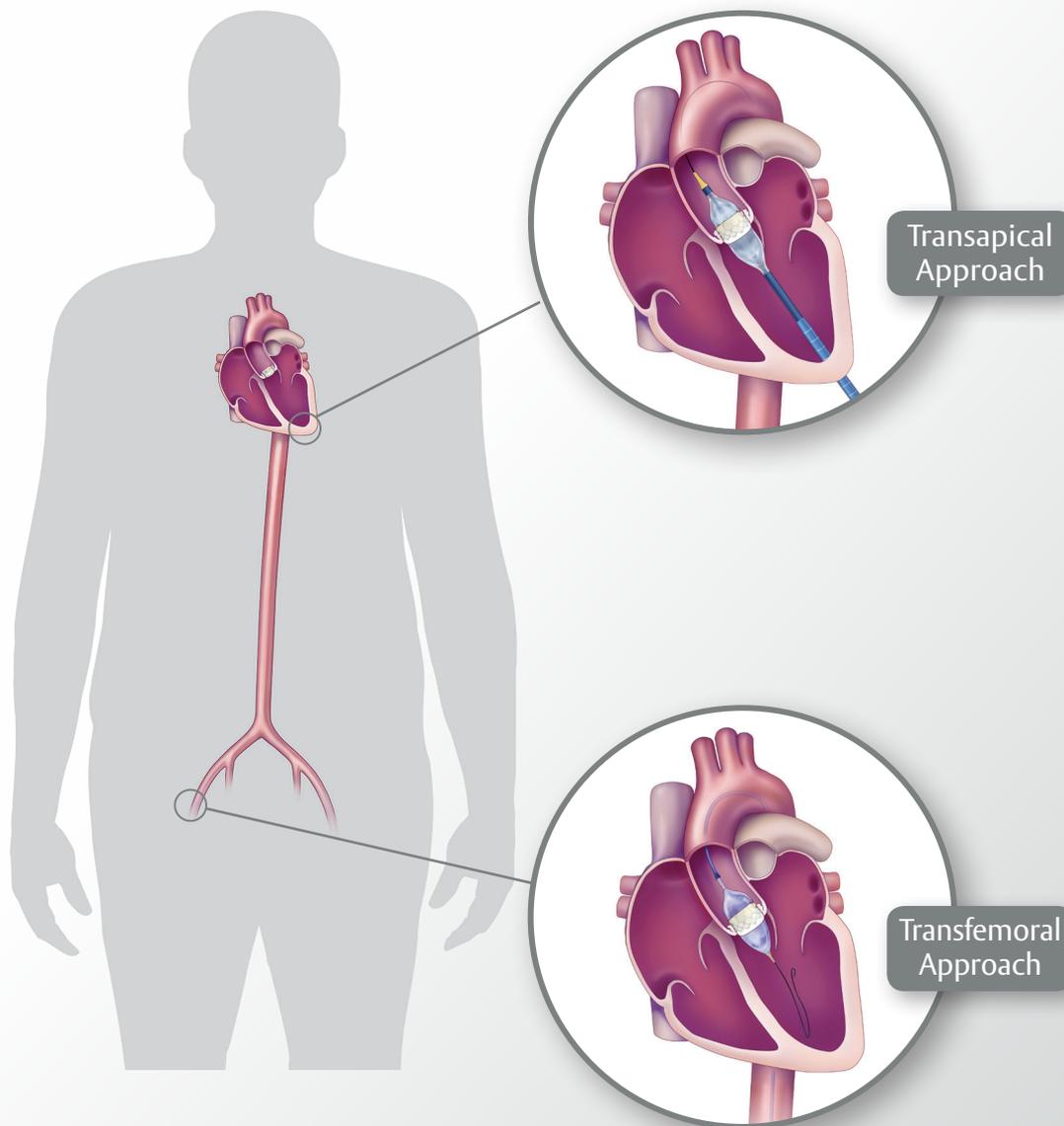
It is possible to replace the aortic valve using a catheter. This approach is called transcatheter aortic valve replacement (TAVR). With TAVR, a doctor guides a new valve into the beating heart through a small tube inserted into either a small opening in the leg, between the ribs, or in the front of the chest. The doctor uses a type of X-ray to see the valve, as it is guided into place. TAVR is available for only some patients.

What are your surgical aortic valve options?

There are two types of heart valves used to replace diseased valves:

- **Mechanical valves** made from man-made material
- **Tissue valves** made mostly from animal tissue, such as bovine (cow) heart tissue (the tough sac around the heart), porcine (pig) tissue, or human valves from cadavers

Discuss with your doctor the different types of valve options and which might be best for you.





Selecting the right valve for you

The choice between mechanical and tissue valves depends upon an individual assessment of the benefits and risks of each valve and the lifestyle, age, and medical condition of each patient.

Mechanical valves usually last over 20 years but require daily treatment with blood thinners, which may increase the risk of bleeding. This is an important consideration for those who have a history of bleeding issues, or an increased risk of injury related to active lifestyle activities. There are also dietary restrictions with eating foods high in vitamin K (like leafy greens). Patients taking blood thinners must be monitored regularly, so the doctor can make changes to medicine doses, if needed. There are also considerations for women and pregnancy, as blood thinners increase complications during pregnancy and delivery. Aside from considerations with blood thinners, there are also considerations for clicking sounds the mechanical valve may make as it opens and closes; this may bother some patients.

Tissue valves usually do not require long-term treatment with blood thinners; however, they have a higher risk of re-operation to replace the valve, as tissue valves may not last as long as mechanical valves. Calcium can form on the tissue of the valve and cause it not to open and close properly. A new type of resilient tissue valve is now available. It is made of RESILIA tissue, a bovine (cow) heart tissue that has been preserved with a special Edwards technology to reduce calcium build-up on the valve tissue.¹

Comparison of tissue and mechanical valves

	Tissue Valves	Mechanical Valves
Long-term blood thinner required	No	Yes Daily blood thinner medication and regular blood tests for rest of life
Valve longevity	10 to over 20 years, depending on type of valve, patient characteristics, and other factors The new INSPIRIS RESILIA aortic valve has the added benefit of RESILIA tissue, (a new tissue that has been shown in animal studies to have less calcium buildup), potentially allowing the valve to last longer. ^{1*}	Over 20 years, in general
Lifestyle and dietary considerations	Yes May need to reduce calcium intake	Yes Limits active lifestyle and foods high in vitamin K (such as leafy greens) from diet
Noticeable sounds from valve	No	Yes Clicking sound as valve opens and closes
Pregnancy considerations	No No known pregnancy complication risk	Yes High pregnancy complication risks due to use of blood thinners

*RESILIA tissue has not been studied for long-term results in patients.

Why might the INSPIRIS RESILIA aortic valve be an option for you?

The INSPIRIS RESILIA aortic valve is built upon the Carpentier-Edwards PERIMOUNT valve which has been widely used in the US for over 25 years. The INSPIRIS valve is a resilient heart valve made of RESILIA tissue. It is a bovine (cow) heart tissue that has been preserved with a special Edwards technology to reduce calcium build-up on the valve tissue and allow the valve to be stored dry.¹ Traditional tissue valves are treated with, and many are stored in, *glutaraldehyde*, a chemical that attracts calcium. Calcium build-up on the valve tissue can cause the valve not to open and close properly, requiring re-operation to replace it. The special technology used in the RESILIA tissue on the INSPIRIS valve blocks the calcium from depositing on the tissue. It also prevents further exposure to *glutaraldehyde*, by allowing the valve to be stored dry. The RESILIA tissue has been shown in animal studies to significantly reduce calcium build-up over traditional valve tissues.^{1*} Less calcium build-up could potentially allow the valve to last longer.

Additionally, the INSPIRIS valve typically will not require you to take blood thinners for the long-term – unless you have other risk factors or medical conditions that would require it. Your doctors will decide if the INSPIRIS valve is right for you.

The questions on the next page may help guide your discussion with your doctor.



INSPIRIS RESILIA aortic valve
(with internal view of a section of the valve)



*RESILIA tissue has not been studied for long-term results in patients.

Questions to ask yourself and discuss with your doctor when selecting a valve

Be sure to talk to your doctor if you have any concerns related to any of these questions.

- Given my age and health, do I need to consider how long my new valve will last and how soon I will need to undergo a re-operation procedure?

- Does my job have a high chance for cuts and injuries? Will I be able to continue performing my job after surgery?

- Do I have high-activity hobbies, and will I be able to continue them after surgery?

- Do I have to take blood thinners? Will taking the medications daily and getting blood drawn on a regular basis be challenging for me?

- Do I want to get pregnant in the future?

- Will my daily activities be disrupted if I can hear the sounds from my valve opening and closing?

Who will be on your medical team?

If you plan to have a valve replaced, you will be cared for by a team of heart doctors and nurses committed to your safety and comfort before, during, and after surgery. Below you will find the different health-care professionals you may meet during your care.

- **Cardiologist:** A doctor who does tests to find out the cause of your heart problems and what treatment you should get to manage your heart disease. This heart doctor may prescribe medicine and/or refer you to a surgeon. He or she will provide long-term care for your heart disease after heart surgery.
- **Cardiac surgeon:** A doctor who does heart surgery. The surgeon helps to make decisions about timing and best course of action. This includes deciding which approach and which device are best for your valve disease.
- **Anesthesiologist:** A doctor who provides medicine to help you relax or sleep during surgery.
- **Intensivist:** Intensive-care doctors and nurses who work with your surgeon and heart doctor to closely care for you when you come out of heart surgery.

What happens before, during, and after standard open-heart valve surgery?

Before surgery: Before surgery, you will have some medical tests and exams to take pictures of your heart. These tests will help your doctor assess your overall health, any allergies, your body structure, and the best surgery type for you.

For your surgery, you will check in at the pre-operating room at a time given to you by your surgeon. You will be asked to sign a consent form. You also may be asked to follow certain eating guidelines before your surgery. Your body may need to be shaved. You will then be given a medicine to help you relax or sleep.

During surgery: An incision is made in the middle of the chest through the breastbone. This incision generally heals quite well after surgery, with the bone requiring about six weeks for complete healing.

During surgery, your heart will be kept still enough for the surgeon to operate. A heart-lung machine will pump blood through your body while the surgeon removes and replaces your diseased valve. Once the diseased valve is replaced, your incision will be closed, and you will be moved to the intensive care unit (ICU) for continued care.

After surgery: After surgery, you will wake up in the ICU where you will be cared for and given medicine for pain. After a few days, depending on your recovery, you will be moved to a ward, where you will prepare to go home.

Your doctor will discuss your specific recovery plan with you. Each person is different, and recovery times can vary. Your doctor knows best what you can expect after surgery. You will see your doctor within a few weeks after surgery. After that, regular check-ups by a heart doctor are needed. You should call or see your doctor if you have questions or concerns about your health, especially if you have any unusual symptoms or changes in your overall health.

Diet and exercise – Two important parts of recovery and ongoing health are a good diet and regular exercise. If your doctor provides a certain diet, it is vital that you follow it. Even if a special diet has not been given to you, keeping a low-fat, low-cholesterol, high-fiber diet is best. Do not take extra calcium unless your doctor approves it. Combine a balanced diet with what your doctor recommends for exercise and weight control. Under your doctor's care, slowly build up your exercise and activity level. Before you begin a new sport or activity, check with your doctor.

Blood thinners – It is important to follow your doctor’s orders for taking medication, especially if you are taking blood thinners. You may be given blood thinners for a short time after your surgery or for a longer period of time, if your doctor decides it is needed. This type of medicine decreases the blood’s natural ability to clot.

Other health information – Before any dental work, cleaning or surgery, tell your dentist or doctor about your heart valve surgery. Patients with a valve implant are more prone to infections that could lead to future heart damage. You may need to take antibiotics before and after certain medical procedures to reduce the risk of infection.

Clinical studies

RESILIA tissue, the special Edwards tissue used in the INSPIRIS RESILIA aortic valve, has been evaluated in two large clinical studies that included a combined total of over 800 patients in the US and Europe. The studies showed that the tissue technology is safe, performs well, and improves blood flow.

Valve replacement risk information

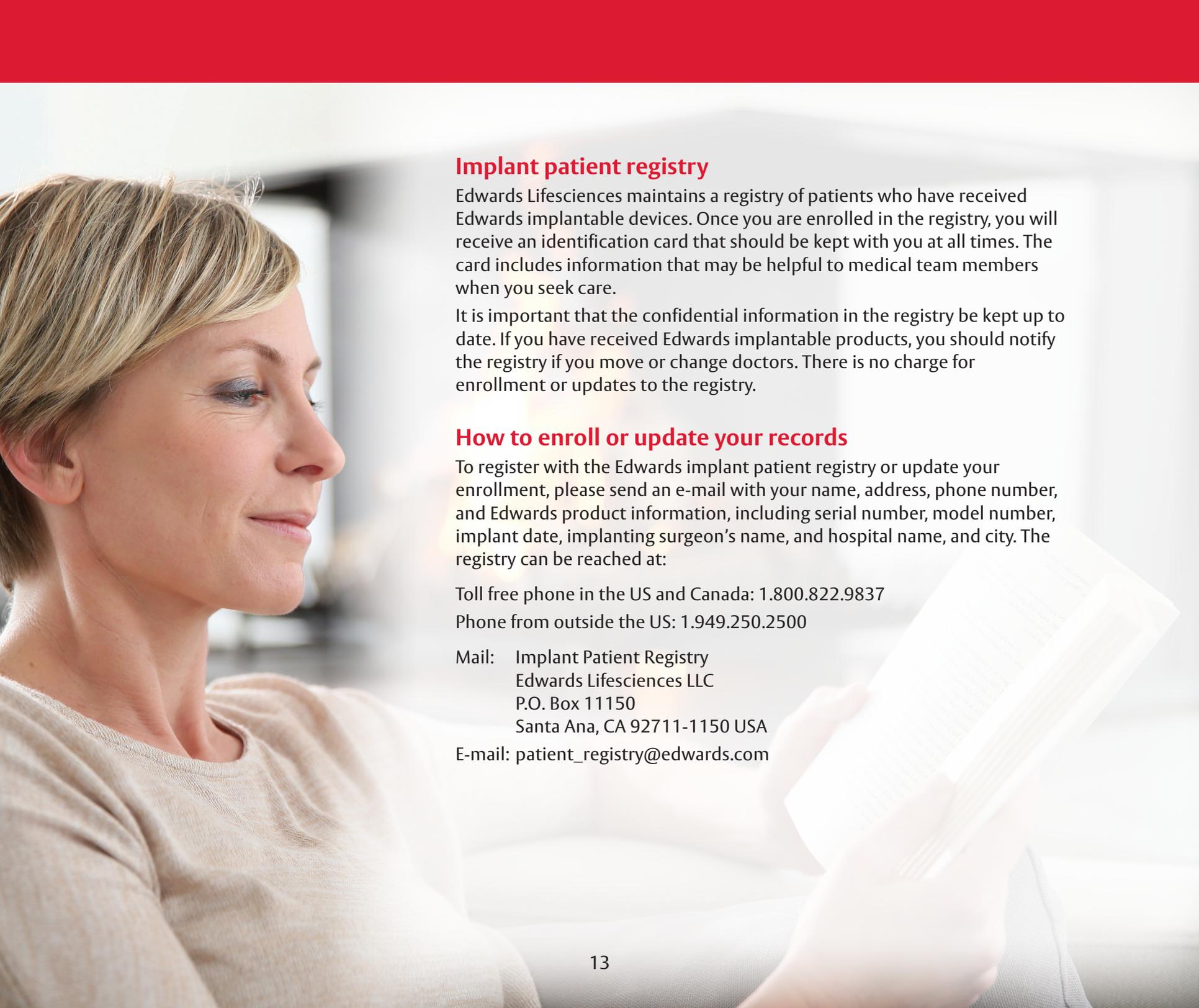
As with any surgery, there are risks with the INSPIRIS RESILIA aortic valve. These include the following:

- Heart failure
- Leaking from the valve or areas around the valve
- Improper opening and closing of the valve
- Damage to red blood cells that can result in low red blood cell count
- Heart lining inflammation
- Heart infection
- Abnormal bleeding or bleeding problems from using blood thinners
- Clots from around the valve or other areas of the heart entering the bloodstream and blocking blood flow
- Heart attack
- Heart rhythm problems that may lead to the need for implanting a permanent pacemaker, a device that helps your heart beat in regular rhythm

This is not a complete list of all the risks that can occur with heart valve surgery. Your doctor can give you more information about these and other risks.

This information is not a substitute for talking with your doctor.





Implant patient registry

Edwards Lifesciences maintains a registry of patients who have received Edwards implantable devices. Once you are enrolled in the registry, you will receive an identification card that should be kept with you at all times. The card includes information that may be helpful to medical team members when you seek care.

It is important that the confidential information in the registry be kept up to date. If you have received Edwards implantable products, you should notify the registry if you move or change doctors. There is no charge for enrollment or updates to the registry.

How to enroll or update your records

To register with the Edwards implant patient registry or update your enrollment, please send an e-mail with your name, address, phone number, and Edwards product information, including serial number, model number, implant date, implanting surgeon's name, and hospital name, and city. The registry can be reached at:

Toll free phone in the US and Canada: 1.800.822.9837

Phone from outside the US: 1.949.250.2500

Mail: Implant Patient Registry
Edwards Lifesciences LLC
P.O. Box 11150
Santa Ana, CA 92711-1150 USA

E-mail: patient_registry@edwards.com

Frequently asked questions

How long will my new heart valve last?

How long a tissue valve lasts depends on the valve you received, your health, and other factors. That is why it is hard to predict how long a valve will last in any one patient. The INSPIRIS RESILIA aortic valve has the added benefit of the RESILIA tissue, which has been shown to significantly reduce calcium build-up in animal studies, and may make the valve last longer.^{1*} It is important, however, that all patients with replaced heart valves have periodic tests and check-ups to assess heart valve function.

Should I expect to feel better right after heart valve surgery?

The results of valve surgery vary for each individual. Most people feel relief from symptoms right away. Other patients begin to notice an improvement in their symptoms in the weeks following surgery. Your doctor can help you assess your progress and health after your surgery.

How do I take care of my valve?

Be sure your dentist and doctors know that you have had heart valve surgery. Ask your healthcare professional about taking antibiotics before dental, surgical or endoscopic procedures to help

prevent valve infection. Always follow your doctor's instructions carefully. Keeping a balanced diet and healthy lifestyle, and making sure you go to all your check ups will also help you care for your valve.

Will my new heart valve make airport metal detectors go off?

The amount of metal in your heart valve is very small, but airport metal detectors can be very sensitive. It is possible your valve could cause airport systems to go off, but it is very unlikely. Be sure to carry your patient identification card with you at all times to show airport personnel if a need arises.

Can I have an MRI with my heart valve?

The INSPIRIS RESILIA aortic valve is safe for use with magnetic resonance imaging (MRI) procedures under certain imaging settings. Please have your doctor or imaging center visit www.edwardsmri.com or contact the Edwards Technical Services Department for details, before undergoing the MRI procedure.

US and Canada: 1.800.822.9837

Outside the US: 1.949.250.2500
ext. 5030

tech_support@edwards.com

What do I need to know if I am required to take blood thinners after my surgery?

Typically, tissue heart valves, like the INSPIRIS RESILIA aortic valve, do not require long-term blood thinners. Blood thinners decrease the blood's natural ability to clot. If you must take blood thinners, you will need to have regular blood tests. The test result helps your doctor give you the right dose of medicine. The test should be done at the same lab every time, because results may vary from one lab to another. It may take a while to find the right dosage of this drug for you, so working with your doctor is important. While taking blood thinners, avoid foods like leafy greens and certain over-the-counter medicines that can affect clotting. Talk to your doctor, and make sure you report any unusual bleeding right away.

*RESILIA tissue has not been studied for long-term results in patients.

Contact information

For more information on Edwards surgical heart valves, talk to your doctor, or contact Edwards at:

Toll free phone in the US:
1.800.424.3278

Phone from outside the US:
+1.949.250.2500

Email: tech_support@edwards.com

Mail: Edwards Lifesciences LLC
1 Edwards Way
Irvine, CA 92614 USA

Online: www.edwards.com

Reference:

1. Flameng et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg.* 2015;149:340–5.

Important Risk Information: INSPIRIS RESILIA Aortic Valve

Indications: For use in replacement of native or prosthetic aortic heart valves. **Contraindications:** There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve. **Complications and Side Effects:** Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death. **Warnings:** DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO/ OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19 – 25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-Valve procedures in an INSPIRIS valve should be performed according to the combinations in the SAPIEN XT IFU. Other combinations have not been evaluated and may result in the embolization of transcatheter devices anchored within or result in annular rupture.

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.

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