

Mitral Valve Replacement Surgery

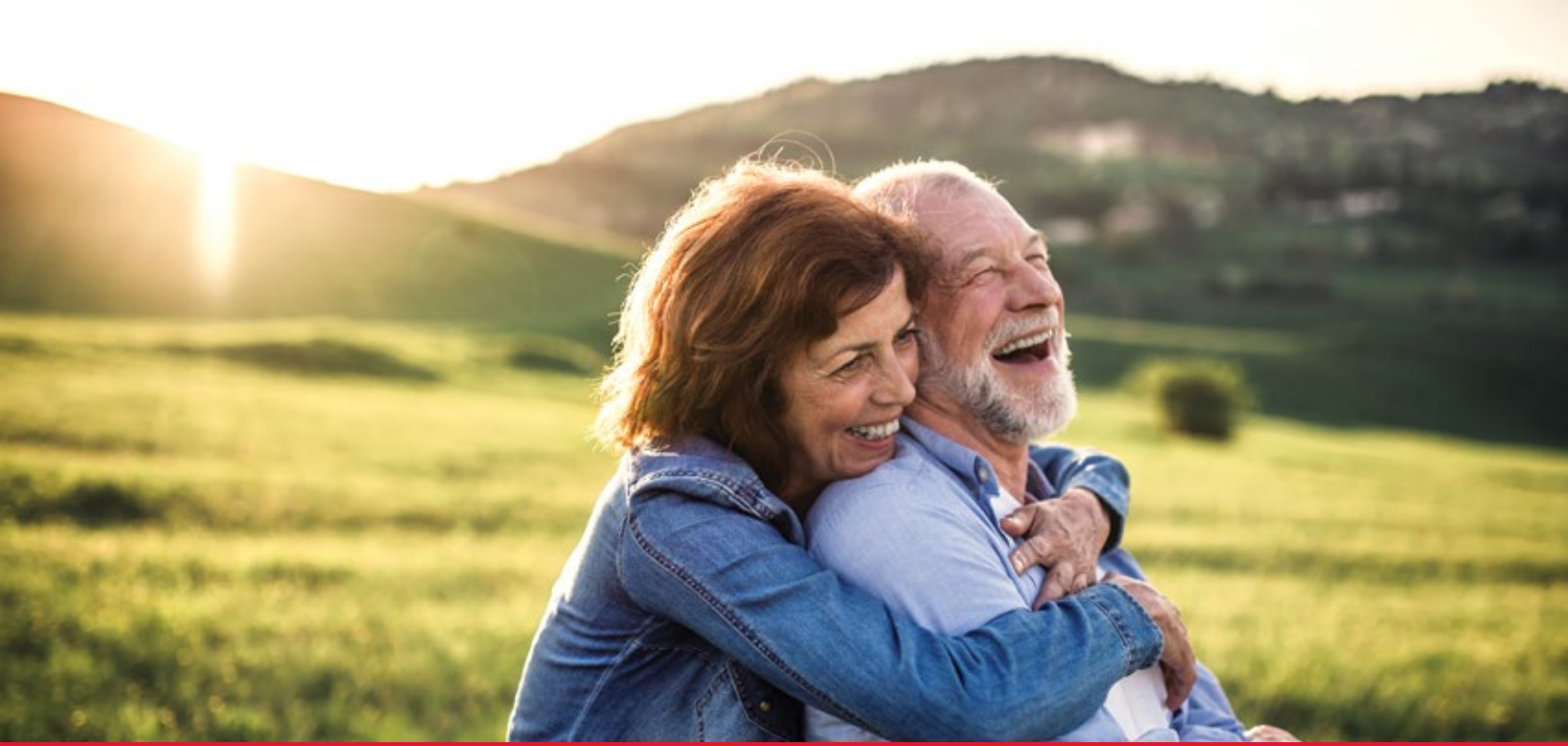
With the MITRIS RESILIA Mitral Valve



What You and Your Loved Ones Should Know



Edwards



Introduction

This guide is for patients who have mitral heart valve disease and whose doctors have proposed surgery to replace the valve.

Be sure to ask your doctor to explain the different treatment choices and the available heart valves used today for mitral valve replacement surgery.

This booklet does not include everything you need to know about mitral heart valves, mitral 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.

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Part One

- How does your heart work?
- What is mitral valve disease?
- How is mitral valve disease treated?
- How is the operation performed?
- What are your surgical mitral valve options?
- Why might the MITRIS RESILIA valve be an option?



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.

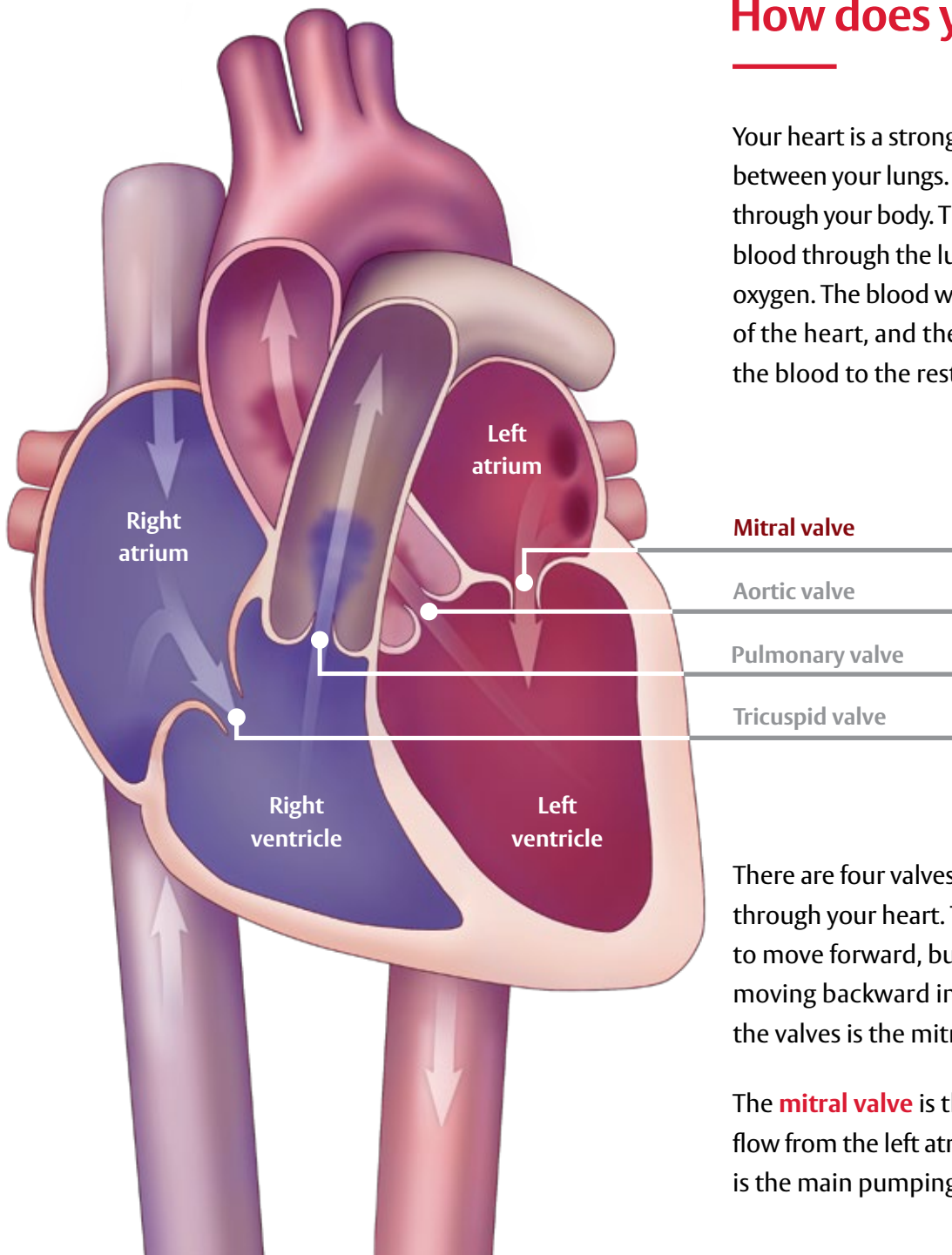


Illustration of the Thoracic Aorta

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 mitral valve.

The **mitral valve** is the valve which controls blood flow from the left atrium to the left ventricle which is the main pumping chamber of the heart.



What is mitral valve disease?

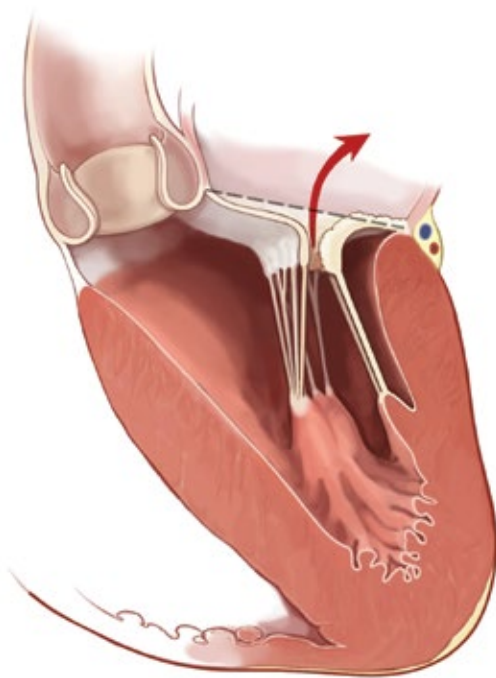
There are two main types of problems that can occur that could cause mitral valve dysfunction requiring mitral valve replacement.

Mitral valve regurgitation: the flaps, or leaflets, of the mitral valve don't close tightly, and causes blood to leak backward into the left atrium. This commonly occurs due to valve leaflets flopping back – a condition called mitral valve prolapse also known as “floppy valve”.

Mitral valve stenosis: the leaflets become thick or stiff. This results in a narrowed valve opening and reduced blood flow through the valve.



How is mitral valve disease treated?



Mitral regurgitation

Treatment for valve disease or dysfunction 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 mitral 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.

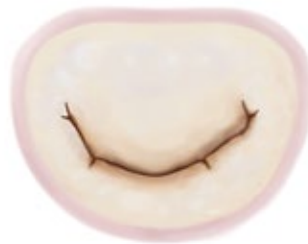


Illustration of normal mitral valve leaflets



Illustration of diseased mitral valve leaflets

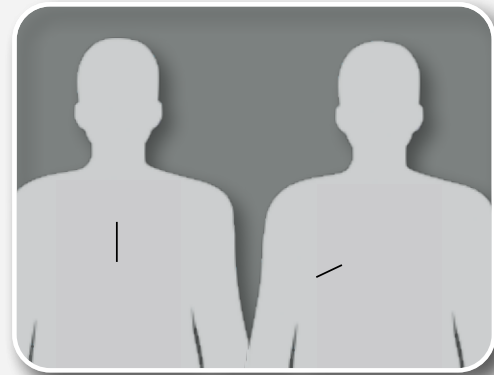
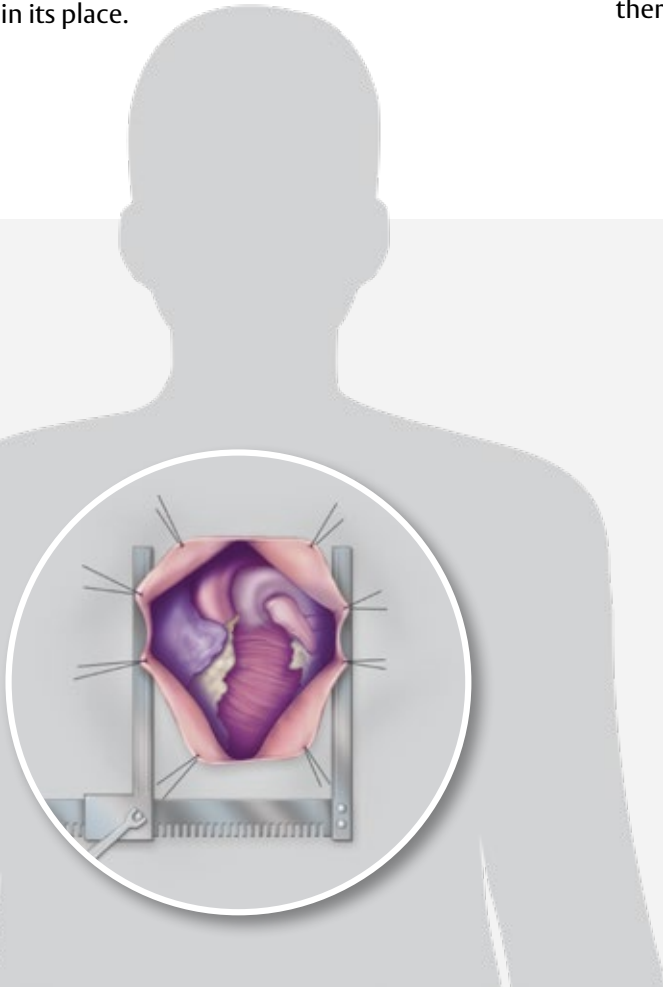
How is the operation performed?

Standard surgical approach

A common treatment for severe mitral 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. 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.



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

What are your surgical mitral valve options?

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

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.

Mechanical valves – made from man-made material.

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 may depend upon an individual assessment of the benefits and risks of each valve and your lifestyle, age, and medical condition. There are two types of valves:

Tissue Valves



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. Tissue mitral valves are predominately handmade from bovine (cow) tissue or actual porcine aortic (pig) valves that are constructed for implantation in humans.






Mechanical Valves



Mechanical valves usually last for the rest of the patient's life but require daily treatment with blood thinners. There are important considerations for those who take blood thinners such as an increased risk of bleeding, avoidance of high risk active lifestyle prone to injury causing bleeding, dietary restrictions, and pregnancy and delivery complications. Additionally, patients taking blood thinners must be monitored regularly, so the doctor can make changes to medicine doses, if needed. There are also considerations for clicking sounds the mechanical valve does make as it opens and closes; this may bother some patients.

What are your surgical mitral valve options?

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, in general, but could be shorter or longer depending on type of valve, patient characteristics, and other factors	Indefinitely, in general
 Lifestyle and dietary considerations	No – lifestyle limitations	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 risks	Yes – High pregnancy complication risks due to use of blood thinners

Why might the MITRIS RESILIA mitral valve be an option for you?

The MITRIS RESILIA valve is built upon the **Carpentier-Edwards PERIMOUNT valve which has been widely used for over 25 years.**

The MITRIS valve is a heart valve made of RESILIA tissue, a bovine (cow) heart tissue that has been preserved with a special Edwards technology designed to make the tissue more durable and resilient.*

The RESILIA tissue technology was developed to reduce calcium build-up on the valve tissue. However, clinical trials have not yet shown whether the RESILIA tissue technology lessens the amount of calcium build-up in humans.



MITRIS RESILIA Mitral Valve

Additionally, the **MITRIS 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 MITRIS valve is right for you.

The questions below may help guide your discussion with your doctor:

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

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

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

Do I plan to get pregnant in the future?

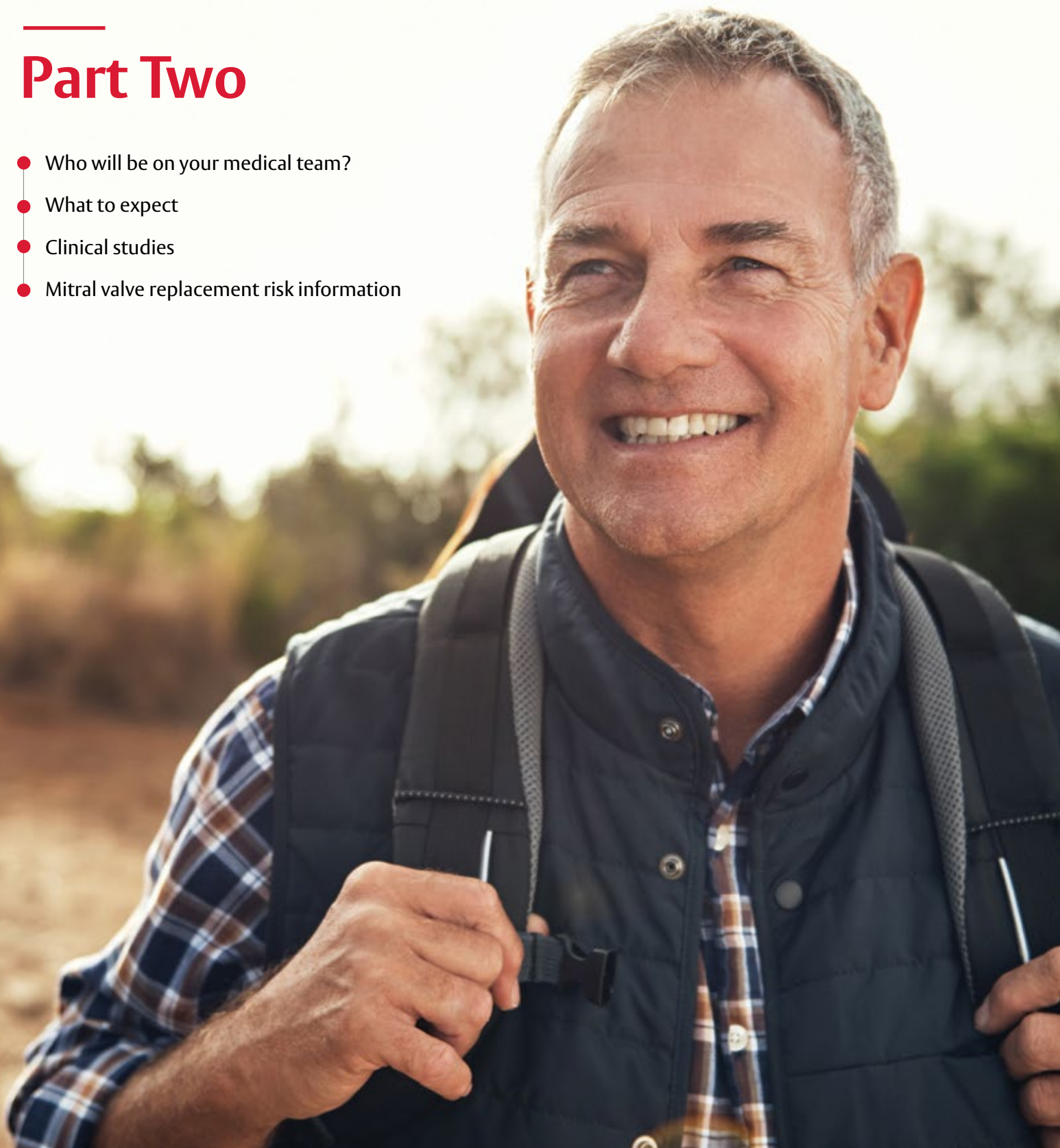
Will my normal activities be disrupted if I can hear sounds from my valve opening and closing if I were to be implanted with a mechanical valve?

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

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

Part Two

- Who will be on your medical team?
- What to expect
- Clinical studies
- Mitral valve replacement risk information



Who will be on your medical team?

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



Cardiologist

A doctor who performs 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 after heart surgery.



Cardiac Surgeon

A doctor who performs heart surgery. The surgeon helps to make decisions about timing, and best course of action. This includes deciding which approach and which type of valve is best for you.



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 and recover postoperatively in the hospital Intensive Care Unit (ICU).

What happens before, during, and after standard mitral valve surgery?



Before mitral valve replacement surgery

- 1.** Before surgery you will have the opportunity to discuss with your surgeon the type of valve you prefer (patient preferences), recovery, and medications. The surgeon will discuss with you the best option, risks and what recovery will be like.
- 2.** 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 mitral valve replacement surgery

- 3.** 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 twelve weeks for complete healing.
- 4.** 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.
- 5.** 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

6. 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 the ward where you prepare to go home.
7. Your doctor will discuss with you your specific recovery plan. 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.
8. After that, regular check-ups by a cardiologist 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.



After standard mitral valve surgery

After-Surgery Care



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. Please consult your doctor if you wish to take calcium or any other supplements. 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 medicine, 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 has been evaluated in a multi-center study with 771 patients (689 aortic and 82 mitral) implanted in the U.S., Canada, and Europe.

This study looked at the safety and effectiveness of the tissue. It looked at outcomes including death, infection, structural and nonstructural valve damage, whether the valve needed to be removed, and implant related new or worsening blood flow issues.

The RESILIA valves* have been proven safe and effective for the replacement of native or prosthetic mitral heart valves.



**The RESILIA valves studied were models 11000A and 11000M, predecessors of the INSPIRIS RESILIA aortic (11500A) and MITRIS RESILIA mitral valves (11400M).*

Mitral valve replacement risk information

Associated risks

As with any surgery, there are risks with the MITRIS valve. These include the following:

- Allergy to valve materials
- Damage to valve components
- Blood pressure changes (low or high)
- Cardiac arrest
- Angina (chest pain)
- Explant (removal) of the device and additional surgery
- The device does not open or work properly due to the narrowing of the valve
- Valve-heart mismatch due to sizing
- Fluid around the heart muscle
- Difficulty with exercise or shortness of breath
- Fracture or separation of the stent or valve components
- Damage to the heart's main pumping chamber
- Infection of heart valve
- Heart failure
- Heart rhythm problems
- Leaking from the valve or areas around the valve
- Improper opening and closing of the valve
- Heart lining inflammation
- Damage to red blood cells that can result in low red blood cell count
- Heart infection
- Abnormal bleeding or bleeding problems from using blood thinners
- Valve thrombosis (clot on the valve)
- 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
- Pneumonia
- Lung failure / low oxygen level in the blood
- Kidney failure
- Stroke
- Valve dislodgement / instability
- Valve deterioration and/or failure
- Infection
- Death

This is not a complete list of all the risks that can occur with mitral 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.

Part Three

- [Implant Patient Registry](#)
- [Frequently asked questions \(FAQ\)](#)
- [Contact Information](#)



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 email with your name, address, phone number, and Edwards product information, including serial number, model number, implant date, implanting surgeon's name, hospital name, and city.

The registry can be reached by:



Phone

Toll-free phone in the USA and Canada: **800.424.3278**

Phone from outside the USA: **1.949.250.2500**



Mail

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



Email

patient_registry@edwards.com

Frequently asked questions (FAQ)

How long will my new mitral heart valve last?

How long a bovine mitral 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 mitral valve will last in any one patient. It is important 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 mitral valve?

Be sure your dentist and doctors know that you have had heart valve surgery. Ask your dentist and doctor about taking antibiotics before dental or surgical 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 checkups will also help you care for your valve.

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

The amount of metal in your mitral heart valve is very small, but airport metal detectors can be very sensitive. It is possible your mitral 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 mitral heart valve?

The MITRIS RESILIA 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.

U.S. and Canada: 800-424-3278
Outside the US: 1.949.250.2222 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 MITRIS RESILIA 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.

Contact Information



Phone

Toll-free phone in the USA:

800.424.3278

Phone from outside the USA:

+1.949.250.2500



Mail

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1 Edwards Way
Irvine, CA 92614 USA



Email

patient_support@edwards.com



Online

www.edwards.com

Important Risk Information: MITRIS RESILIA Mitral Valve

Indications: For use in replacement of native or prosthetic mitral heart valves.

Contraindications: There are no known contraindications with the use of the MITRIS RESILIA mitral 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, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability, and death.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

See Instructions for Use for full prescribing information.

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