



Tricuspid Valve Replacement Surgery

With the TRIFORMIS RESILIA
Tricuspid Valve

What you and your loved ones should know





Introduction

This guide is for patients who have tricuspid 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 tricuspid valve replacement surgery.

This booklet does not include everything you need to know about tricuspid heart valves, tricuspid 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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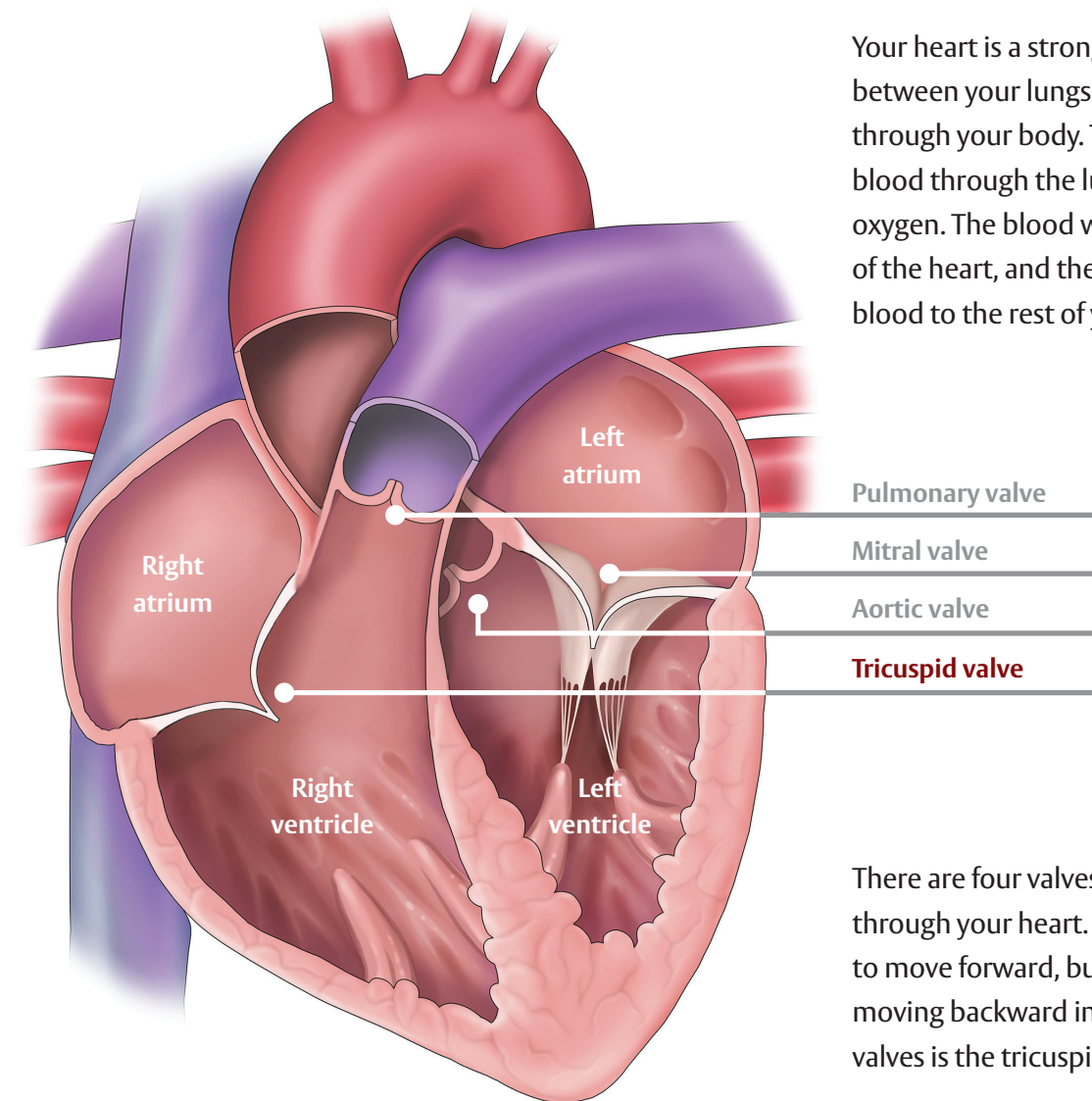
Part One

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- What is tricuspid valve disease?
- How is tricuspid valve disease treated?
- How is the operation performed?
- What are your surgical tricuspid valve options?
- How do surgical replacement valves compare?
- Why might the TRIFORMIS RESILIA valve be an option for you?



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 tricuspid valve.

The **tricuspid valve** is the valve which controls blood flow from the right atrium to the right ventricle, which is the pumping chamber that moves blood to the lungs.

Illustration of the Thoracic Aorta

What is tricuspid valve disease?

A normal, healthy heart valve:

- Minimizes obstruction, allowing blood to flow freely in only one direction
- Closes completely and quickly, not allowing any blood to flow back through the valve

When the valve cannot accomplish either or both of these, the heart must work harder to keep blood flowing through the valve as it should.

There are two main types of problems that could cause tricuspid valve dysfunction requiring tricuspid valve replacement.

Tricuspid valve stenosis: The leaflets become thick or stiff and cannot open fully. This results in a narrowed valve opening and reduced blood flow through the valve.

Tricuspid valve regurgitation: the annulus becomes dilated or the leaflets become prolapsed. This prevents full leaflet coaptation, allowing blood to leak backward.

It is possible for a valve to be both stenotic and regurgitant.

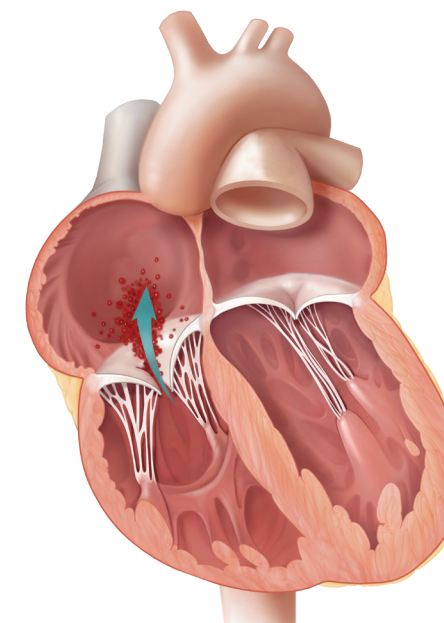


How is tricuspid valve disease treated?

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 tricuspid valve disease worsens, your doctor may suggest repairing or replacing your valve.

There are different ways to repair or replace a valve. Your doctor will carefully assess your case and advise you of the best option.

Only a specialized heart team can determine which treatment option is best for you.



Tricuspid regurgitation



Illustration of normal tricuspid valve leaflets



Illustration of tricuspid valve leaflets with endocarditis

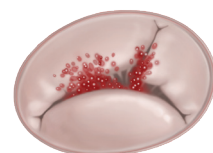


Illustration of tricuspid valve leaflets with functional tricuspid regurgitation

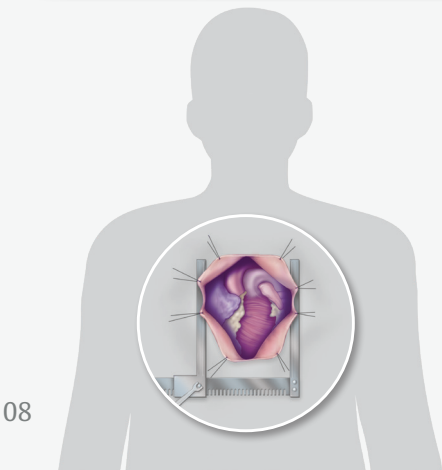
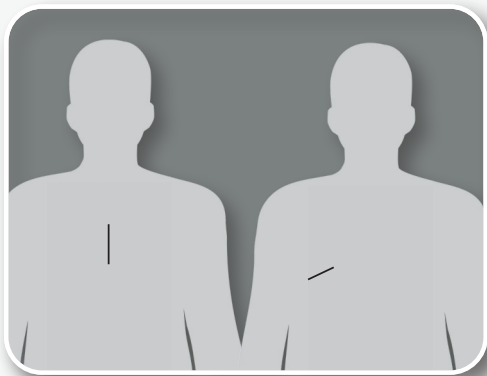
How is the operation performed?

Your doctor will determine if you are a candidate for repair or replacement in a transcatheter procedure or open heart surgery.

Transcatheter procedure

A transcatheter tricuspid valve repair (TTVr) is a catheter-based procedure to repair your tricuspid valve.

During a transcatheter tricuspid valve replacement (TTVR) procedure, the doctor replaces your old tricuspid valve using a delivery catheter (a tube-like device) with an artificial valve attached to its tip, inserted through an incision in the groin.



Open-heart surgery

This surgery is often done in conjunction with another heart valve procedure. This type of surgical procedure is typically done in one of two ways:

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 may repair the diseased valve by implanting a ring or may remove the diseased valve and implant 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 neither safety nor results are compromised.

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

Why might the TRIFORMIS RESILIA tricuspid valve be an option for you?

The TRIFORMIS RESILIA tricuspid valve is a heart valve 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 and make the tissue more durable and resilient.*

Tissue valves usually do not require long-term treatment with blood thinners. Calcium can form on the tissue of the valve and cause it not to open and close properly; however, this valve is made with advanced tissue treatment technology designed to reduce this.

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



TRIFORMIS RESILIA tricuspid valve

Additionally, the **TRIFORMIS RESILIA tricuspid 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 TRIFORMIS RESILIA tricuspid 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 tricuspid valve will last and if or how soon I will need to undergo a re-operation?

Will my job have a high chance for cuts and injuries? 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?

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

*Clinical data on valves with RESILIA tissue up to 7-year follow-up have been published, with additional follow-up of up to 10 years in process.

Part Two

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



Who will be on your medical team?

If you plan to have your tricuspid valve replaced, you will be cared for by a team of heart doctors and nurses committed to your safety and wellbeing before, during, and after surgery. You may meet a number of different healthcare professionals 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 tricuspid valve surgery?

Before tricuspid 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 tricuspid 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 tricuspid 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

The clinical safety and effectiveness of the TRIFORMIS RESILIA tricuspid valve have been established based on the outcomes of a real-world tricuspid valve replacement study evaluating eligible mitral valves used in the tricuspid position.

The study included existing data from health records and medical claims of 204 patients in the US who had their tricuspid valve replaced from January 2016 to August 2024. It looked at outcomes including death due to any cause, whether any procedure or treatment was needed to correct a problem with the valve such as by replacing the valve that was not working properly with a new one, blood clot forming in the valve (valve thrombosis), leaking around the valve (paravalvular leak), infection of a heart valve (endocarditis), and whether hospitalization was needed for heart failure. The results provided reasonable assurance of safety and effectiveness in a diverse tricuspid valve disease population.

If you undergo tricuspid valve replacement with the TRIFORMIS RESILIA tricuspid valve, the data shown in the table below displays possible complications that may occur based on the real-world evidence study.

Major Complications	Risk within 30 days	Risk within 1 year
Death due to any cause	7 out of 100	27 out of 100
Valve failure requiring re-intervention (transcatheter)	--	0 out of 100
Valve failure requiring medical intervention or treatment	--	0 out of 100
Valve failure requiring surgical reoperation	--	0 out of 100
Blood clot forming on the valve (valve thrombosis)	--	0 out of 100
Major leak around the valve (paravalvular leak)	--	2 out of 100
Infection of a heart valve (endocarditis)	--	44 out of 100
Heart failure hospitalization	--	18 out of 100
Pulmonary embolism	--	11 out of 100
Major bleeding	--	5 out of 100
Dialysis	--	8 out of 100
Ventricular assist device implant or heart transplant	--	1 out of 100

Tricuspid valve replacement risk information

Associated risks

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

- Death
 - Allergic reaction
 - 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

The TRIFORMIS RESILIA valve cannot be used in people who have an untreatable allergy to nickel or titanium.

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

Notes

Frequently asked questions (FAQ)

How long will my new tricuspid heart valve last?

How long a bovine 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 tissue 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 tricuspid 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 tricuspid heart valve make airport metal detectors go off?

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

The TRIFORMIS RESILIA tricuspid 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, including the TRIFORMIS 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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Email

patient_support@edwards.com



Online

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Important Risk Information: TRIFORMIS RESILIA Tricuspid Valve

Indications: For use in replacement of native or prosthetic tricuspid heart valves. **Contraindications (Who should not receive):** The TRIFORMIS RESILIA valve cannot be used in people who have an untreatable allergy to nickel or titanium. **Complications and Side Effects:** The risks with the TRIFORMIS RESILIA tricuspid valve are similar to risks with other heart valves, and 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, injury could occur to the heart tissue or blood flow could be blocked, allergic reaction to the materials in the valve.

These could lead to the need for reoperation to replace the valve, permanent disability, or death. 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.

CAUTION: US law restricts this device to sale by or on the order of a physician.

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