



Aortic Root Surgery

With the Edwards KONECT
RESILIA Aortic Valved Conduit

What You and Your Loved Ones Should Know



Edwards



Introduction

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

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

This booklet does not include everything you need to know about heart valves, the aorta, heart valve and aortic 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 Your Heart Works
- Types of Aortic Diseases
- How to Treat Aortic Diseases
- Treatment Options
- Aortic Valved Conduit Options
- KONECT RESILIA Aortic Valved Conduit



How Your Heart Works

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 then goes to the left side of the heart and the left side of the heart pumps the blood to the rest of your body.

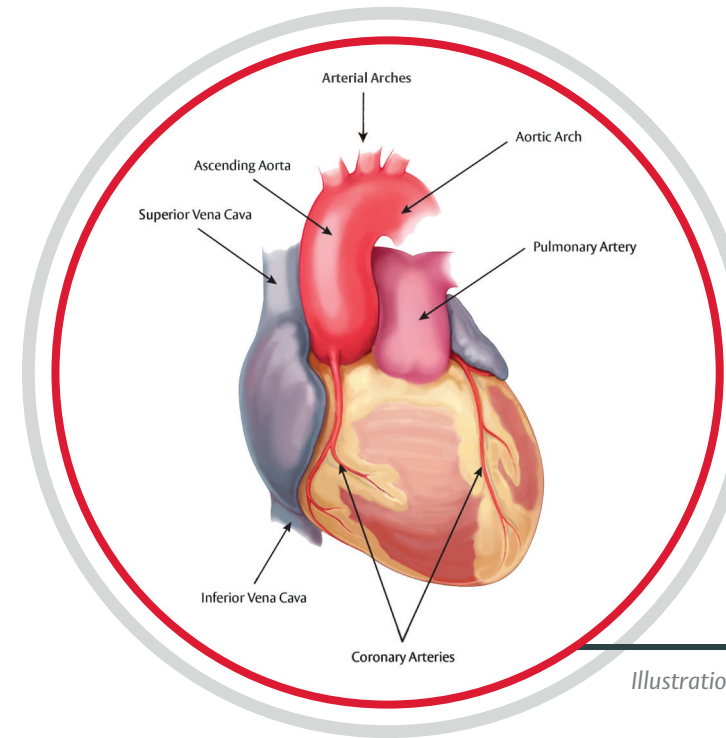


Illustration of the Thoracic Aorta

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 aortic valve.

The **aortic valve** serves as the “door” between your heart and the rest of your body. It has two or three leaflets (or flaps) to make sure blood moves correctly from the lower left chamber of the heart to the aorta. A small percentage of the population has a bicuspid aortic valve which means the valve has only two leaflets.

The **aorta, connected to the aortic valve**, is a large blood vessel that carries blood to the rest of the body. The aorta starts at the heart (aortic valve) and is shaped like a hook. Arteries branch off from the aorta to deliver oxygen throughout the body. The aorta is defined in different sections, depending on its shape, location, and what parts of the body the arterial branches serve.

Types of Aortic Diseases

Aortic diseases are typically divided into two categories – chronic (persistent over time) and acute (sudden or emergency onset). In some cases, chronic diseases can trigger acute events.

Both chronic and acute aortic disease can also affect the aortic valve. Sometimes, chronic diseases of the aortic valve can have long-term impact on the aorta, such as abnormal dilatation (enlargement of a portion of the aorta). This dilatation can occur as a result of having a bicuspid aortic valve.

Chronic Aortic Diseases

- **Aneurysm**
Dilation or enlargement of a portion of the aorta
- **Chronic Dissection**
Repeated separation of the inner lining or wall of the aorta

Acute Aortic Diseases

- **Aortic Rupture**
Rupture or breakage of the aorta
- **Aortic Ulcer**
Plaque in the aorta (from atherosclerosis) forms ulcers that penetrate the aortic wall
- **Aortic Dissection**
Rupture or tear in the inner lining of the aorta

Possible Causes

- **Atherosclerosis**
Hardening and narrowing of the aortic valve and/or aorta due to calcium build-up
- **Congenital (Genetic) Connective Tissue Diseases**
e.g. Bicuspid Aortic Valve, Marfan's Syndrome
- **Chronic Dissections**
A serious condition in which the inner layer of the aorta tears
- **Infection of Aortic Valve**
An infection involving the aorta or inflammation of the aorta



How to Treat Aortic Diseases

Treatment for aortic disease depends on the extent of the disease and the location of the aneurysm or dissection. Development of symptoms like shortness of breath, chest pain, and fatigue can be signs of a diseased valve. Since these symptoms can sometimes be confused with the normal signs of aging, cardiac surgery professionals will conduct specific tests to provide informed treatment recommendations. For instance, surgery is usually recommended if your thoracic aortic aneurysm is about 4.5 to 5.5 centimeters or larger. Your doctor may recommend a replacement of your aortic valve when aortic disease (leaking or narrowed valve) worsens. Your doctor will carefully assess your situation and advise you of the best option for you.

Surgeons may also look at the condition of the aortic root and the ascending aorta when determining a surgical therapy.

Based on the dilatation of the aortic root, your doctor may recommend you to have aortic root surgery using a Bentall procedure. A Bentall procedure is a replacement of the valve, the ascending aorta and the reattachment of the coronary arteries, the arteries which transport blood in and out of the cardiac muscle.



Treatment Options

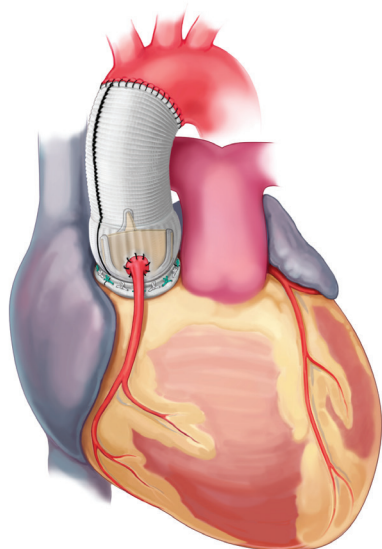


Illustration of Implanted Aortic Valved Conduit

A common treatment for severe aortic disease with involvement of ascending aorta and aortic root is to replace the valve and aortic root 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.

A common device used to replace a portion of the diseased aorta is called a **graft**, or **conduit**. The surgeon removes the diseased valve along with the dilated ascending aorta and the aortic root, and replaces them with an artificial tube graft or conduit with a new heart valve in its place. This is commonly known as an aortic root and ascending aorta replacement with aortic valved conduit.

If your aortic valve is healthy but the disease at the aortic root requires surgical therapy, your doctor may elect to replace the aortic root and leave the aortic valve intact. This is a highly specialized technique performed by expert surgeons.

Aortic Valved Conduit Options

When an aortic surgery requires the replacement of a segment of the aorta along with the valve, there are two types of aortic valved conduits:

Pre-assembled – tissue or mechanical valves pre-assembled with a graft made from man-made materials

Self-assembled – tissue or mechanical valves sewn together with a graft made from man-made materials by the surgeon

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

The choice between mechanical and tissue valves may depend upon an individual assessment of the benefits and risks of each valve and the lifestyle, age, and medical condition of each patient. There are two types of valves:



Mechanical Valves

Made from man-made material

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, risk of injury related to an active lifestyle, dietary restrictions, and pregnancy complications. Additionally, patients taking blood thinners must be monitored regularly, so the doctor can make changes to medicine doses, if needed.








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

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.

Aortic Valved Conduit Options

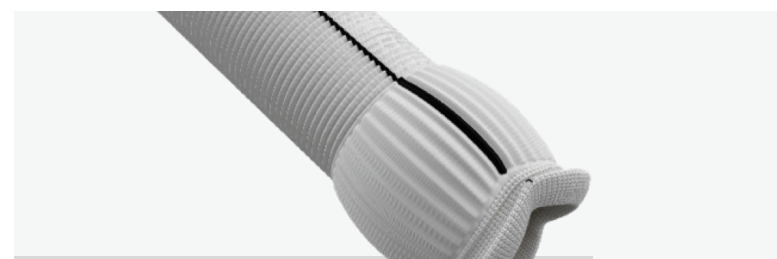
Comparison of Tissue and Mechanical Valves:

	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	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 risks	Yes – High pregnancy complication risks due to use of blood thinners

KONECT RESILIA Aortic Valved Conduit

A valved conduit usually consists of a graft or conduit sewn together with the tissue valve during the procedure, but the **KONECT RESILIA aortic valved conduit comes pre-assembled with a Gelweave Valsalva graft** to replace the aortic root and ascending aorta. The Valsalva graft is designed to closely match the shape of the native aortic root.

The KONECT RESILIA aortic valved conduit is made with RESILIA tissue, a bovine (cow) heart tissue that has been preserved with a special Edwards technology designed to make the tissue more resilient. The RESILIA technology was developed to reduce calcium build-up on the valve tissue.¹ However, clinical trials have not yet shown whether the RESILIA tissue lessens the amount of calcium build-up in humans. **In addition to the RESILIA tissue technology, the KONECT RESILIA aortic valved conduit is built upon the Carpentier-Edwards PERIMOUNT valve platform, which has been widely used in the US for over 25 years.**



KONECT RESILIA Aortic Valved Conduit

Additionally, the KONECT RESILIA aortic valved conduit 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 KONECT RESILIA aortic valved conduit 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 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 sounds from my valve opening and closing?

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

Part Two

- Your Medical Team
- Surgery: What to Expect
- Clinical Trials
- Associated Risks

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 healthcare 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 the 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.



Surgery: What to Expect

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 twelve 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. During surgery, the diseased aortic valve, dilated root and a portion of ascending aorta, are removed. The KONECT RESILIA aortic valved conduit is sewn in place and your coronary arteries are reattached to the graft. Once the diseased aorta and valve are 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 Intensive Care Unit 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 will prepare to go home.

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. 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.

Surgery: What to Expect

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. 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 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 Trials

The clinical safety and effectiveness of the valve components of the KONECT RESILIA aortic valved conduit have been established based on the outcome of the COMMENCE trial.

Edwards valves with RESILIA tissue have been evaluated in a multi-center study with 771 patients (689 aortic and 82 mitral) implanted in the U.S. and Europe. This study looked at the safety and effectiveness of the valves. 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. These Edwards valves with RESILIA tissue have been proven safe and effective for the replacement of native or prosthetic heart valves.



Associated Risks

Valve Replacement Risk Information

As with any surgery, there are risks with the KONECT RESILIA aortic valved conduit. 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 added 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

Associated Risks

Aortic Root Graft Risk Information

- Arterial or venous thrombosis
- Fever or localized inflammation
- Allergic reaction to polyester / gelatin
- Arteriovenous fistula
- Stenosis
- Oedema
- Vascular spasm or vascular trauma
- Multi-organ failure
- Vessel damage
- Death
- Aneurysm infection
- Neointimal Hyperplasia
- Prosthesis occlusion
- Prosthesis dilatation
- Seroma
- Hepatic failure
- Infection of the prosthesis / wound site
- Lymphatic complications e.g. lymph fistula
- Aortic damage, including perforation, dissection, bleeding, rupture & death
- Renal complications e.g. renal dysfunction, artery occlusion, failure, infarction
- Bleeding, blood loss, haematoma, coagulopathy, re-opening
- Bowel complications e.g. ileus, perforation, transient ischaemia, infarction, necrosis
- Aneurysm enlargement, rupture, death
- Wound complications e.g. dehiscence, infection, haematoma, seroma, cellulitis, pain
- Genitourinary complications e.g. ischaemia, erosion, fistula, incontinence, haematuria, infection, impotence
- Cardiac complications e.g. arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension
- Respiratory complications e.g. pneumonia, respiratory failure, prolonged intubation, pulmonary oedema
- Neurological local or systematic complications e.g. confusion, stroke, transient ischaemia attack, paraplegia, paraparesis, paralysis
- Pseudoaneurysm

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.

Part Three

- Implant Patient Registry
- Contact Information



Notes

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: **1.800.822.9837**

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

Contact Information



Phone

Toll-free phone in the USA:

1.888.713.1564

Phone from outside the USA:

+1.949.250.2500



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Online

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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:

KONECT RESILIA Aortic Valved Conduit Indications: For use in replacement of native or prosthetic aortic heart valves and the associated repair and replacement of a damaged or diseased ascending aorta.

Contraindications (Who should not use): There are no known contraindications with the use of the KONECT RESILIA aortic valved conduit.

Complications and Side Effects: The risks with the KONECT RESILIA aortic valved conduit are similar to risks with other heart valves and vascular grafts, 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
- Graft infection
- Ballooning and weakening of an area in an artery
- Blood collecting between the layers of an artery
- Fluid buildup under the surface of the skin
- Fluid buildup around the graft
- Blockage of a blood vessel
- Immunological reaction to the materials in the valve or graft
- New tissue growth on the graft
- Enlargement of the graft

These could lead to the need for reoperation to replace the valve and/or graft, 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: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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