Aortic Valve Surgery

With the EDWARDS INTUITY Elite valve system

What you and your loved ones should know

Edwards

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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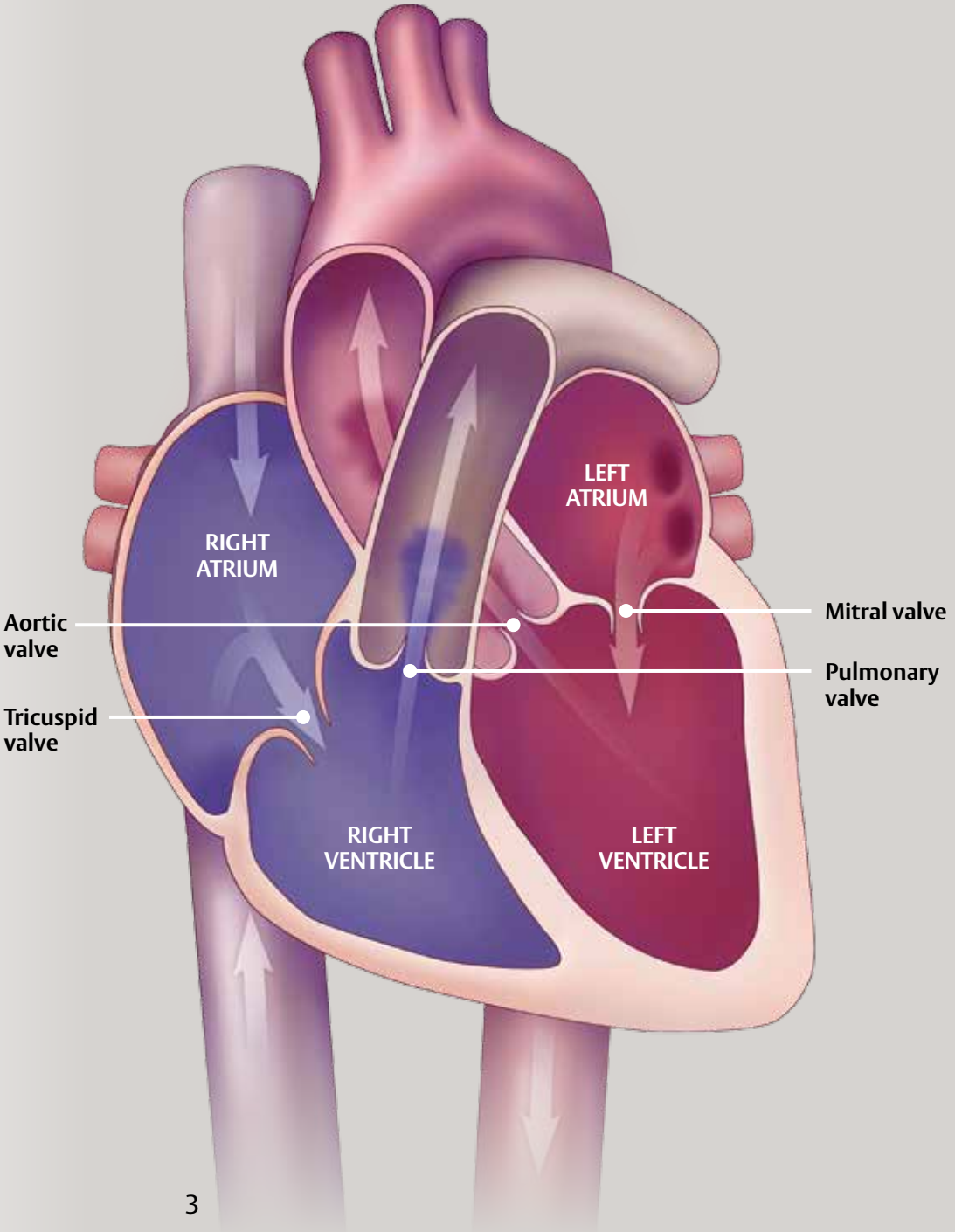
This booklet does not include everything you need to know about heart valves, heart valve replacement surgery, or about related medical care. Regular check-ups by your heart doctor are important. Call or see your doctor whenever you have questions or concerns about your health, especially if you have 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.



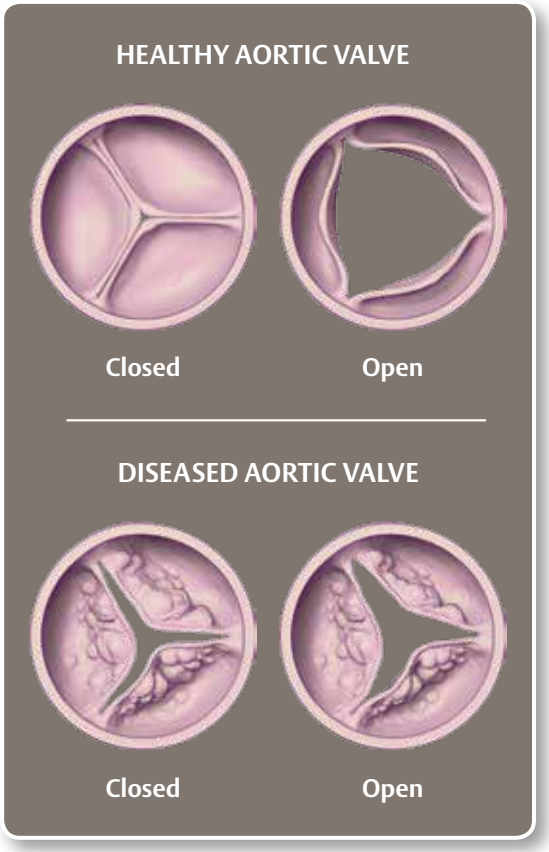
What is aortic valve disease?

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

- The valve is narrowed and does not completely open, blocking the normal flow of blood.
- 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 on the leaflets due to aging, birth defect, illness or certain therapies. The build-up of calcium (mineral deposits) on the valve's leaflet 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. When this happens, it increases the risk for calcium build-up on the valve.



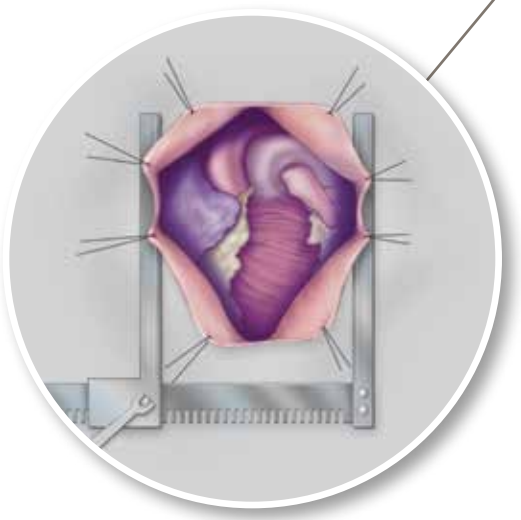
How is valve disease treated?

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?

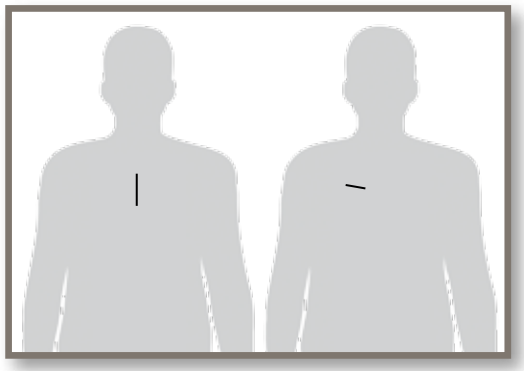
Standard Surgical Approach

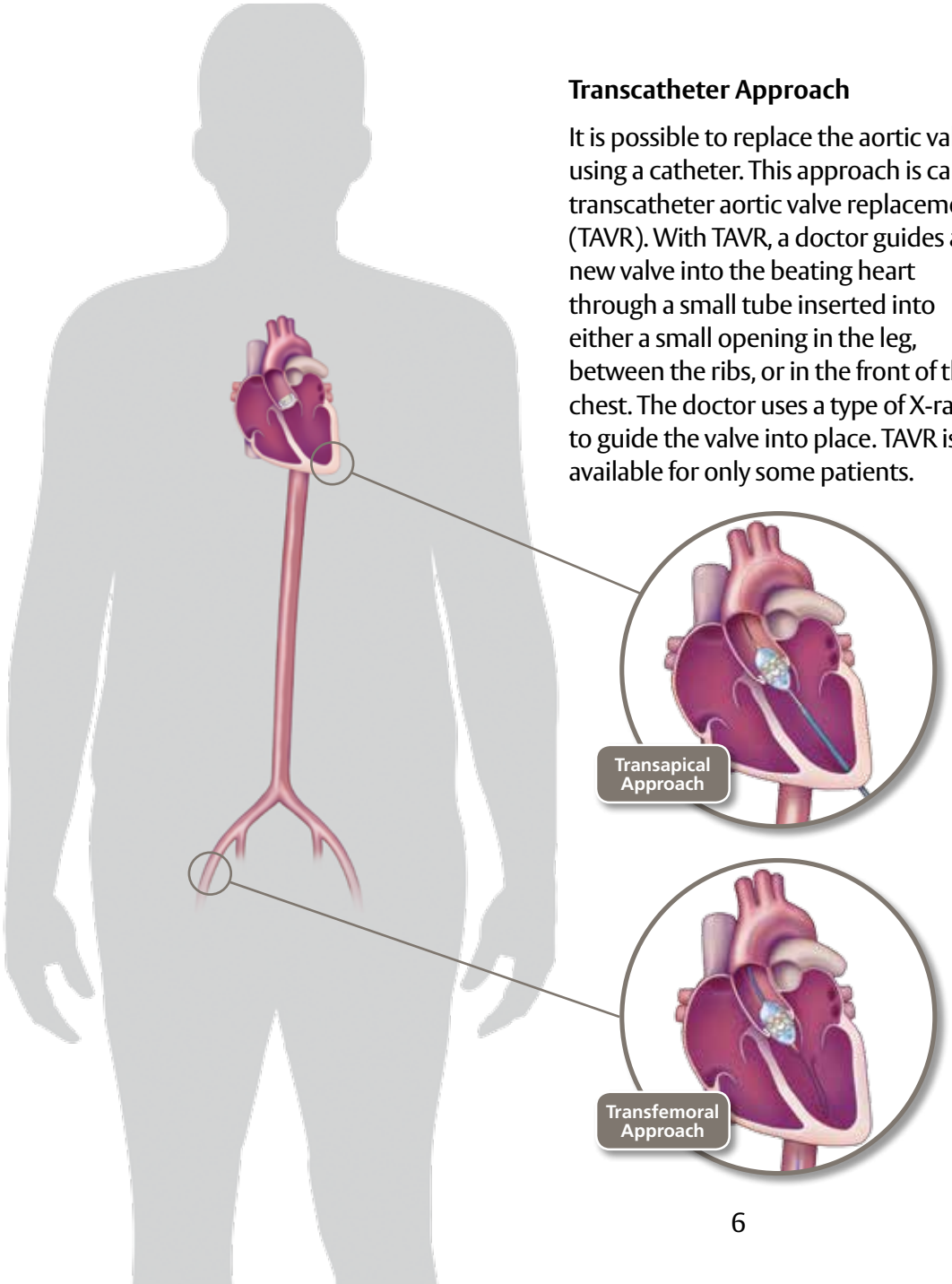
The most common treatment for severe aortic disease is to replace the valve through an open-surgery. The surgeon makes an opening in the middle of the chest and breastbone to access the heart. To keep the heart still enough for the surgeon to operate, a heart-lung machine takes over the job of pumping 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 surgical treatment used to replace a diseased valve, the surgeon uses 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 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 where safety or results are concerned.





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 guide the valve into place. TAVR is available for only some patients.

What are your aortic valve options?

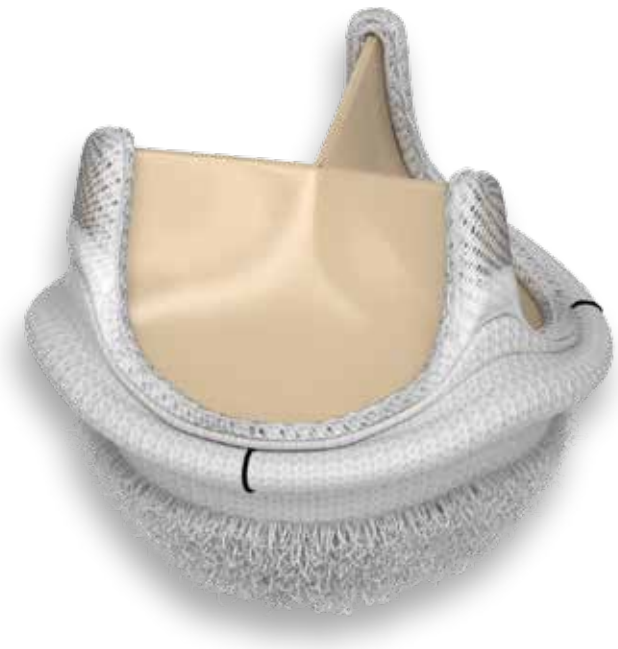
There are two types of heart valves used to replace diseased valves:

- **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 valve**s made from human-made material

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

Why might the EDWARDS INTUITY Elite tissue valve system be an option for you?

The EDWARDS INTUITY Elite valve is built upon the PERIMOUNT valve which has been widely used for 20+ years. The valve also uses technology from our transcatheter heart valves to simplify placement and shorten operation times. The EDWARDS INTUITY Elite valve differs from standard heart valves by only needing 3 guiding sutures for placement, instead of 12-15 sutures. Your doctors will decide if the EDWARDS INTUITY Elite valve is the right for you.



An illustration of the EDWARDS INTUITY Elite valve is pictured.
Image is larger than actual valve size.

Who will be on my 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.

- A doctor who specializes in heart disease. This doctor does not perform your surgery but 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.
- 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 is best for your valve disease.
- A doctor who provides medicine to help you relax or sleep during surgery.
- 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 surgery to replace my valve?

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. Your doctor will choose which type of medicine is best for you.

During Surgery

Most heart surgery is performed by making an incision in the middle of the chest. The incision goes through the breastbone. After surgery, this generally heals quite well, with the bone requiring about six weeks for complete healing.

In some patients, heart valve surgery can be performed using less invasive or small incision approaches. Small incision valve surgery does not require a large incision or cutting through the entire breastbone. The surgeon accesses the heart through one of three small, less visible incisions. The smaller incisions may be made between the ribs or at the breastbone. For small incision procedures, another small incision is often made in the groin for the machine that keeps your heart beating during surgery.

Your surgeon will select the location of the incisions and surgery approach that is best for you. Once your surgeon replaces or repairs the diseased valve, he/she will close your incision site(s), 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 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.

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 balanced diet of fruits, vegetables, whole grains, meats and dairy products may help speed healing and lessen fatigue. Most often, a low-fat, low-cholesterol, high-fiber diet is best. Do not take extra calcium unless your doctor approves it.

To improve overall heart health, it is helpful to combine a balanced diet with what your doctor recommends for exercise and weight control. Weight control is important. Excess weight increases the work of the heart and slows recovery. Following a regular exercise program is an important part of keeping a healthy lifestyle. Under your doctor's care, you should 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 this medicine for a short time after your surgery or for a longer period of time, if you 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 EDWARDS INTUITY Elite valve has been evaluated in a multi-center study with over 800 patients in the U.S. This study looked at the safety and effectiveness of the valve. It looked at outcomes including death, blocking of the valve or blood vessel by blood clots, blood flowing in the wrong direction outside the heart valve, infection, structural and nonstructural valve damage, whether the valve needed to be removed, and implant related new or worsening blood flow issues. The EDWARDS INTUITY Elite valve has been proven safe and effective.

Valve replacement risk information

As with any surgery, there are risks with the EDWARDS INTUITY Elite valve system. These include the following:

- Allergy to valve materials
- Damage to valve components
- Damage to the aorta
- Abnormal bleeding or bleeding problems from using blood thinners
- Damage to red blood cells that can result in low red blood cell count (hemolysis and anemia)
- Blood pressure changes (low or high)
- Cardiac arrest
- Heart failure
- Mitral valve damage
- Coronary artery blockage
- Death
- Heart infection (Endocarditis)
- Explant (removal) of device and added surgery
- The device does not open or work properly due to the narrowing of the valve
- Damage to the heart's main pumping chamber
- Heart attack
- Stroke or transient ischemic attack (TIA)
- Valve-heart mismatch due to sizing
- Fluid around the heart muscle
- Difficulty with exercise and shortness of breath
- Valve thrombosis (clot on the valve)
- Clots from around the valve or other areas of the heart enter the bloodstream and block blood flow
- Valve instability
- Leaking from the valve or areas around the valve
- Fracture or separation of the stent or valve components
- Problems with the electrical pathway of your heart that may require a pacemaker

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.

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 has 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

T o register with our Patient Registry or update your enrollment, please send us 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. Our registry can be reached at:

Toll free phone in the USA at:
800-424-3278

Phone from outside the USA at:
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 (FAQS)

How long will my new heart valve last?

How long a tissue valve lasts depends on your health and other factors. That is why it is hard to predict how long a valve will last in any one patient. Over time, you may begin to feel some of the symptoms you felt before your valve surgery. Sometimes you might not feel symptoms or you may feel different symptoms. Your doctor will be able to schedule a surgery to place a new valve, if the need arises. All patients with replaced heart valves should 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 dentist and doctor about taking antibiotics before dental or surgical procedures or endoscopy 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 these devices 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.

Can I have an MRI with my heart valve?

Most Edwards heart valves are safe for use with magnetic resonance imaging (MRI) procedures. Please have your doctor or imaging center visit www.edwardsmri.com or contact our Technical Services Department for details on specific product model numbers.

U.S. and Canada
800.822.9837

Outside the U.S.
1.949.250.2500 ext. 5030

Fax 1.949.250.2625
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 EDWARDS INTUITY Elite valve, do not require long-term therapy with 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 blood test measures the level of certain clotting factors. 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, there are foods you might need to avoid. Foods like leafy greens can affect clotting. Certain over-the-counter medicines also may affect your blood's clotting ability. Talk to your doctor, and make sure you report any unusual bleeding to your doctor right away.

Contact information

For more information on Edwards surgical valves, contact:

Toll free phone in the USA:
1.800.424.3278

Phone from outside the USA:
+1.949.250.2500

Email Address:
Tech_Support@edwards.com

Mail:
Edwards Lifesciences
One Edwards Way
Irvine, California 92614

Online:
www.edwards.com

CAUTION: Federal(United States) law restricts this device 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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