LivaNova

Health innovation that matters

AORTIC VALVE REPLACEMENT WITH PERCEVAL SUTURELESS VALVE

Patient's guide

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Scope

This booklet is for patients who have had, or who will have, heart valve surgery. This guide will teach you about your heart, how it works, and aortic stenosis. The guide also talks about a new treatment for valve replacement called the Perceval sutureless heart valve. If you are a family member or friend, you may also find this information helpful.

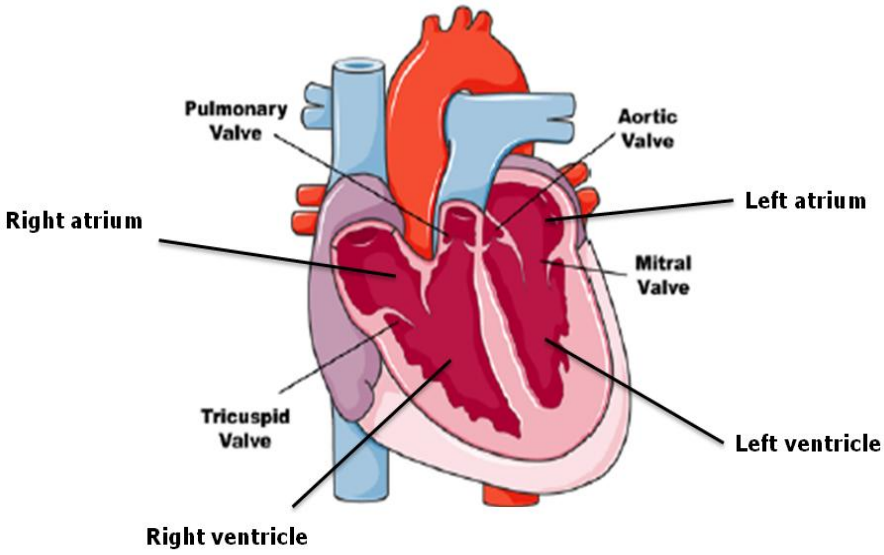
Each patient has his or her unique medical history, this information cannot replace discussions with your healthcare professional. You should see your healthcare professional whenever you have symptoms or changes in your health and especially if you have questions about your heart valve surgery.

The Human Heart

The heart is a muscular organ in your chest which pumps blood through the blood vessels of the body. Blood provides the body with oxygen and nutrients, and also removes wastes.

The left side of the heart pumps blood throughout the body, while the right side of the heart pumps blood through the lungs.

Blood is pumped with the help of four valves. The valves are made up of tissue and this tissue forms the leaflets which open and close to help move blood through the heart. The valves work with the heart to continuously pump blood during rest and during exercise.



How Does The Heart Work?

The heart is designed to pump blood through your body. A cardiac cycle (heart beat) includes two steps that occur at the same time:

- The right side of the heart receives deoxygenated blood from all parts of the body and pumps it through the lungs, where the blood picks up oxygen.
- The left side of the heart receives oxygenated blood from the lungs and pumps it to the rest of the body.

Valves keep the blood flowing through the heart in the correct direction. The valves open and then close in order to prevent the blood from going backwards.

Heart Valve Diseases

When heart valves are damaged, blood cannot flow through the heart normally. The following two problems can occur in heart valves:

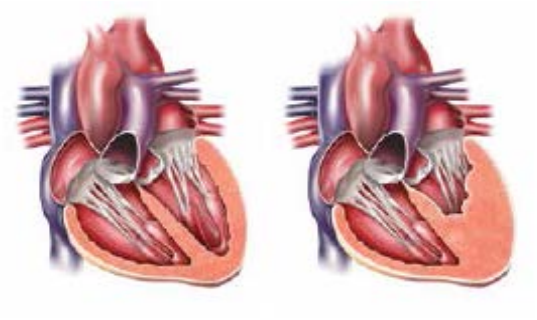
- **Valve stenosis:** The valve opening becomes narrow and cannot completely open due to a build-up of calcium (mineral deposits), high cholesterol (a waxy fat), age, or genetics (such as a birth defect).
- **Aortic regurgitation or insufficiency**: the valve does not fully close and allows blood to leak backwards through the valve.

With either problem, your heart needs to work harder and may not pump enough oxygen-rich blood to your body.

Valve Stenosis

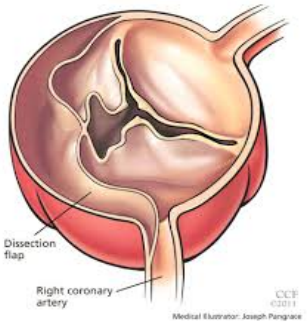
Aortic stenosis is a narrowing of your aortic valve opening that does not allow normal blood flow. It can be caused by a birth defect, rheumatic fever, radiation therapy, or can be related to age.

It is sometimes caused by the build-up of calcium (mineral deposits) on the aortic valve leaflets. Over time the leaflets can become stiff and no longer fully open and close. When the leaflets don't fully open, the heart must work harder to push blood through the aortic valve to the body. Because of this extra work, the ventricle walls become thicker over time.



Aortic Regurgitation

Sometimes the valve leaflets become damaged and fail to close completely. When this happens, some of the blood can leak backwards, in the wrong direction, instead of going forward. This valve problem makes it hard for the heart to pump enough blood to the rest of the body. This problem can be caused by infection, rheumatic fever, coronary artery disease, or can be related to age.



What Are the Symptoms Of Aortic Valve Disease?

There are many symptoms which may result from heart valve problems (either heart valve stenosis or regurgitation) including, but not limited to:

- Shortness of breath, especially with exertion or when you lie down
- Fatigue, especially during times of increased activity
- Cough, especially at night or when lying down
- Heart palpitations — sensations of a rapid, fluttering heartbeat
- Swollen feet or ankles
- Heart murmur
- Excessive urination
- Chest pain (angina) or tightness
- Feeling faint or fainting with exertion
- Dizziness

What Are the Options in Heart Valve Replacement?

Your healthcare professional considers many factors in selecting the right approach to treat your valve problem. Typically, your healthcare professional will consider:

- Your age
- Whether you have other diseases
- Your lifestyle and level of physical activity
- Whether you can tolerate daily anticoagulant medication
- Whether you are a woman of childbearing age
- Whether you are able to have an open heart surgery and the related risks

You are encouraged to discuss specific treatment recommendations with your healthcare professional. If the disease is mild, valves can be treated through medication. However, when medical treatment is not sufficient, your healthcare professional may recommend replacing the diseased valve.

When a patient needs a heart valve replacement, two types of prosthetic (artificial) heart valves are available: Mechanical heart valves and tissue heart valves.

Mechanical Valves

Mechanical heart valves are made from materials such as titanium or synthetic carbon. In the device, there are two “leaflets,” which open and close like a natural heart valve to control the flow of blood.

One advantage of mechanical valves is that they may last a patient’s lifetime.

One disadvantage of mechanical valves is that they require life-long anticoagulation therapy (medicine)**.**

Tissue Valves

Tissue valves are made of animal tissue. There are three types of tissue valves available to patients:

- **Stented tissue valve:** made from animal tissue and mounted on a plastic or metal frame called a “stent”.
- **Stentless tissue valve:** made entirely from tissue that is similar in size and shape to that of humans. The valve may be an actual heart valve obtained from a human donor (homograft) or a valve derived from animal tissue (pig or cow).
- **Sutureless valve:** made from a stented tissue valvethat can be compressed to become smaller. The valve does not require sutures to stay in place.

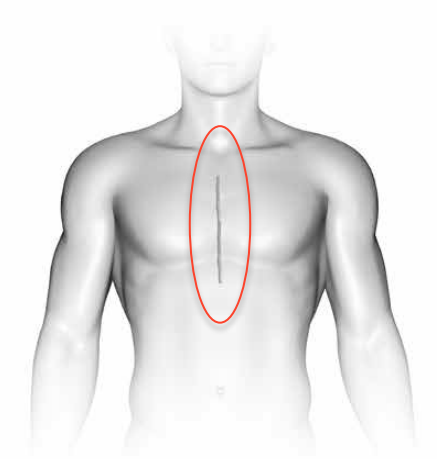
One advantage of tissue valves is that they don’t require patients to use anticoagulants (blood thinner medicine).

One disadvantage of tissue valves is that they wear out over time and may need replacement.

How can aortic valve disease be treated?

Standard Surgical Approach

Aortic valve replacement (AVR) through open-heart surgery is the most common treatment for patients with aortic stenosis. In this operation your diseased heart valve is removed and a new heart valve is put in its place.

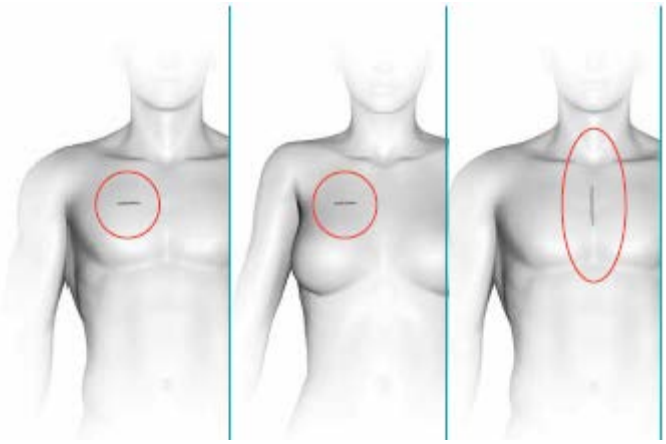


Surgical AVR is an open-heart procedure. After the chest is opened, you are put on cardiopulmonary bypass – which temporarily takes over providing blood flow and oxygen to your body during surgery.

Surgical AVR has been performed for many years and commonly produces excellent results to lengthen patients' lives and improve their quality of life.

Minimally Invasive Surgery

A minimally invasive procedure, referred to as minimal incision valve surgery, can also be performed to replace a malfunctioning valve.



The surgical incisions are smaller than in open heart surgery and made either between the ribs or in the chest.

Patients sometimes experience less pain, shorter hospital stay and faster recovery with minimally invasive surgery compared to open heart surgery.

The main types of minimally invasive heart valve replacement procedures are called mini-sternotomy and mini-thoracotomy.

What are the possible benefits and risks of Heart Valve Replacement?

The most common benefit from heart valve replacement is improvement in the patient's aortic valve function, condition, and quality of life.

The possible risks for patients that have their aortic valve replaced with a tissue valve include, but are not only limited to:

- Chest pain (angina)
- Heart failure (acute cardiac failure)
- Abnormal heart rhythm (arrhythmias)
- Valve dysfunction leading to aortic regurgitation (blood leaking around the outside of the prosthetic valve or intra-valvular)
- Failure of the valve to open and close properly
- Damage to red blood cells leading to anemia
- Inflammation of the lining of the heart (endocarditis) or other infections
- Clinically significant hemorrhage (bleeding);
- Blood clots that develop in the heart or on the replaced valve (prosthesis thrombosis) that may cause a thomboembolism, stroke or heart attack
- Obstruction of blood circulation to the heart resulting in damage to the heart tissue (myocardial infarction)
- Conduction system disturbances (e.g., atrioventricular node block, left-bundle branch block, asystole), which may require a permanent pacemaker implant

Other potential adverse events related to the Perceval valve may include dislodgment of the prosthesis if malpositioned or placed in an unfavorable anatomy.

It is possible that these adverse events may lead to death, permanent disability, reoperation, explantation or other forms or re-interventions.

This list is not inclusive of all risks. Talk to your physician regarding more information about valve replacement surgery.

What is a Perceval valve and why is it a good option for my heart valve replacement?

The Perceval valve is the result of over 30 years of research and development in heart valve replacement. It is a tissue heart valve with a sutureless and collapsible stent. The collapsible stent makes the valve smaller during surgery.

The Perceval valve is intended for patients that need their heart valves replaced and may reduce or eliminate their symptoms of fatigue and shortness of breath.

The Perceval valve is different from stented and stentless valves that require 20 to 30 sutures, because it can be implanted without any suturing. The valve allows quick placement with a reduced operation time. Shorter operation times can sometimes lower complication risks and sometimes result in faster recovery time. The collapsible design of the Perceval valve also allows easier implantation through smaller incisions (minimally invasive procedure).

The Perceval valve may not work well for everyone and this option has to be evaluated by your surgeon.

Who should not receive the Perceval valve?

A patient who should not or cannot undergo heart surgery should not receive this valve. Other patients who should not receive the Perceval valve include:

- Patients with aneurysmal dilation or dissection of the ascending aortic wall
- Patients with known sensitivity to nickel or cobalt alloys

Your doctor will consider other factors to determine if you should receive this valve such as the size and shape of your heart, as well as your medical history and other clinical conditions (e.g. renal function). The Perceval valve has not been evaluated in children and adolescents.

What will happen before and during the surgery?

Before your surgery your doctor will perform a thorough assessment to determine if you are eligible for the Perceval valve. He/she will perform a physical examination and take pictures of your heart using a technique called echocardiography. Your doctor will provide information to you about the care you should expect after the surgery including possible medications or follow up doctor visits. Be sure to ask any questions you have to your doctor at this time.

The medical staff will prepare you for the surgery and will give you anesthetic medications that will put you to sleep. The operation time may vary from patient to patient, depending also from possible additional procedures you may require besides aortic valve replacement, typically lasting a minimum of two hours and often longer.

During the procedure to implant the Perceval valve the surgeon will make an incision into your chest. This incision may be smaller than what is typically performed for other surgical heart valves because the Perceval valve is collapsible and does not need to be sutured into place in your heart, allowing easier implantation and shortening the duration of the surgery. During the procedure a machine will be used to pump your blood throughout your body while the surgeon works on your heart. After the new heart valve is in place, the pump will be stopped and your heart will begin pumping. The surgeon will check that your valve is working properly and then will close the incision in your chest to complete the surgery.

What will happen after the Surgery?

After the surgery you will spend a few days in the Intensive Care Unit, where you will be closely monitored by the medical staff.
When this intensive monitoring will be no longer needed, you will be moved to ward for a few more days. Most patients are often surprised at how soon their conditions improve and how quickly they can come back to normal daily activities such as walking, eating and bathing.

After you'll leave the hospital, you will need to see periodically your healthcare professional for follow-up visits. During these follow-up visits, you may need echocardiography to identify possible valve malfunction or leaking.
Your healthcare professional may prescribe you an anticoagulation treatment. These medications decrease the body's ability to form blood clots and prevent a clot that has already started forming from getting larger; they also reduce the chance that pieces of a clot will break off and cause a heart attack or stroke. If anticoagulation medication is prescribed, it should be taken exactly as instructed.

According to the medications you will be prescribed, you may need to pay attention to your diet, since some food and beverages (e.g. alcohol) may interfere with them. Moreover if you are taking

any other medications you will need to consult with your healthcare professional about possible interactions.

Patients under anticoagulants may need to undergo regular blood tests to regularly monitor the effects of their medication dosage. These tests usually require going to the hospital, healthcare professional's office or laboratory on a monthly, bimonthly or weekly basis.

To help you recover as soon as possible, your healthcare professional will prescribe an exercise program and may recommend a special diet.
Be sure to refer to your healthcare professional if you're experiencing any change in your condition like chest pain, breath shortening or other symptoms.

Clinical Studies

The benefits of the Perceval valve were evaluated in the CAVALIER clinical trial which lasted 4 years and included 658 patients who were able to undergo surgical heart valve replacement. Patients were examined while still in the hospital, after 3-6 months, and on a yearly basis up to 4 years after receiving the Perceval valve. The benefits and risks of the Perceval valve were compared to the typical performance observed for other valve available in the US including stroke, bleeding, thromboembolism, paravalvular leak (flow moving in the wrong direction outside of the valve), endocarditis (infection), and other criteria. The Perceval valve was observed to perform similarly for the above criteria and improved the patient's aortic valve function and clinical conditions.

FAQs

- **How long will my valve last?**

  Tissue valve durability has improved greatly over the past decade. Patient's age and health factors play a large role in the life span of the valve, and although patient conditions vary, tissue valves typically last from 7 to 15 years. Fortunately, because tissue valves degenerate slowly, the patient and physician have time to plan for a reoperation, if one is required.

- **Is anticoagulation therapy or other medication needed?**

  Anticoagulation medication is a treatment prescribed by physicians and given to mechanical valve replacement patients and sometimes to tissue valve patients.

  The Perceval valve (similar to other tissue valves) typically do not require long-term anticoagulation therapy. However, your doctor may recommend that you take anticoagulation therapy for the first three months after implant and thereafter only if required by other medical conditions.

  Anticoagulant medications decrease the body's ability to form blood clots. These medications prevent a clot that has already started forming from getting larger and they also reduce the chance that pieces of a clot will break off and cause a heart attack or stroke.

  The anticoagulation medication slows down the blood clotting process. Therefore, cuts and scrapes will bleed a little longer than normal. If anticoagulation medication is prescribed, it should be taken exactly as instructed.

- **How will I know if my prosthetic valve isn't working well?**

  Prosthetic (artificial) valves can wear out in much the same way a natural valves does. If your prosthetic valve isn't working well, you may feel the same symptoms you experienced when your natural valve wasn't working well. You also may feel different symptoms than before, or no symptoms at all. This is one of the many reasons why it is important that you follow your healthcare professional's recommendations, have routine follow-up care, and maintain a healthy lifestyle. As with all heart disease and natural valves, prevention and early detection of any problem with your prosthetic valve is important.

- **Is it safe to have an X-ray after Perceval valve replacement?**

  The Perceval valve is completely safe with X-ray examinations.

- **Is it safe to have an MRI after Perceval valve replacement?**

  The Perceval valve is classified as "MR Conditional". This means that you will be able to safely undergo a magnetic imaging examination immediately after the intervention, under certain conditions that will be indicated in a card that you will receive before leaving the hospital. You should keep this card with you and provide it to your doctor if you need and MRI scan.

Contact Information

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