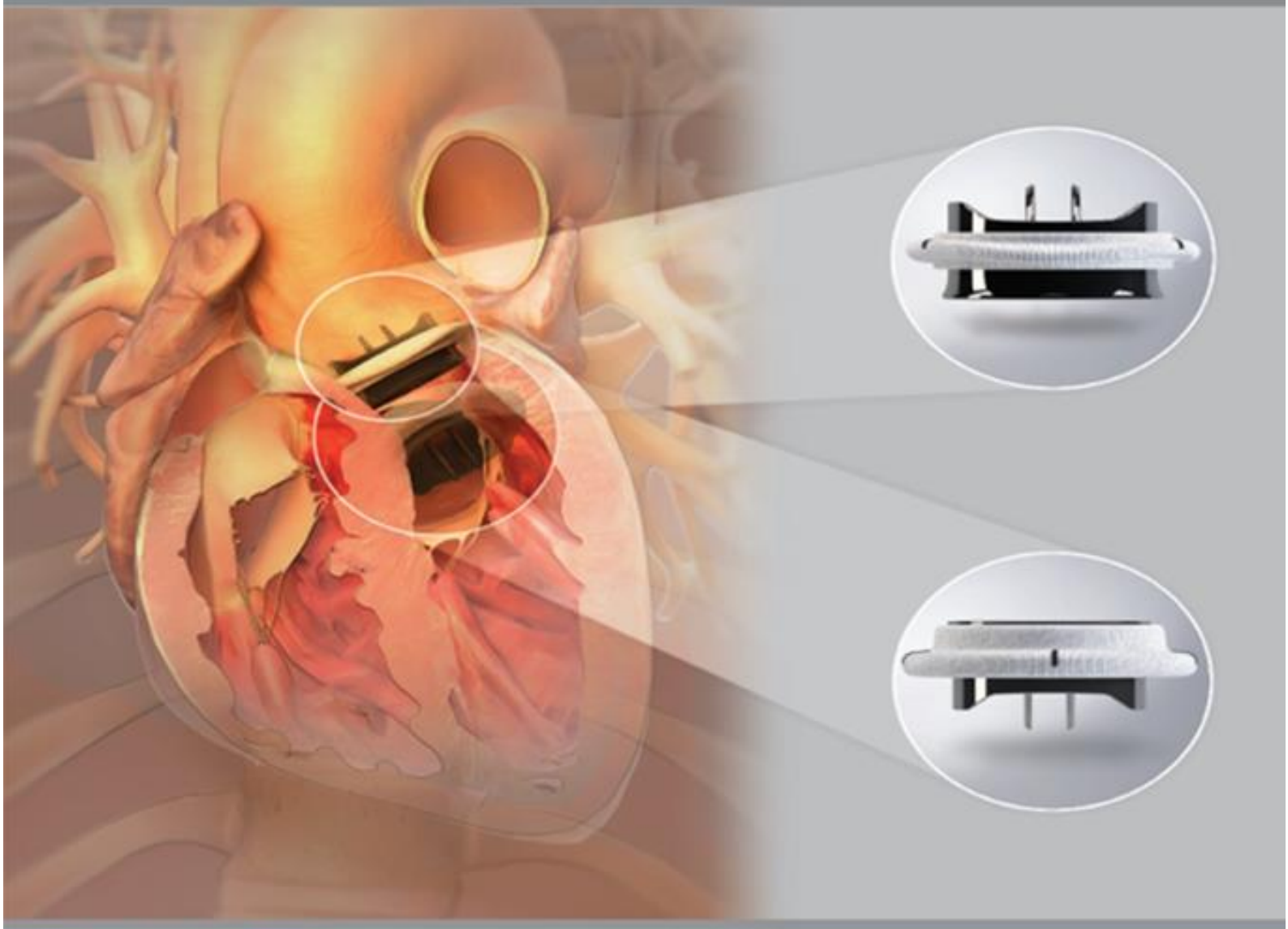
On-X® | Prosthetic Heart Valves
STEP AHEAD

On-X Prosthetic Aortic Valve with Anatomic Sewing Ring (ONXANE)
On-X Prosthetic Aortic Valve with Conform-X Sewing Ring (ONXACE)
On-X Prosthetic Aortic Valve with Standard Sewing Ring (ONXAE)
On-X Prosthetic Mitral Valve with Conform-X Sewing Ring (ONXMC)
On-X Prosthetic Mitral Valve with Standard Sewing Ring (ONXM)

On-X® Prosthetic Heart Valve
Patient Information Leaflet



CryoLife®
Life Restoring Technologies®

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1. Introduction to On-X Prosthetic Heart Valves

Millions of people suffer from a condition known as heart valve disease that causes a valve (or valves) within the heart to not open or close properly. Your doctor has proposed the use of the On-X® Prosthetic Heart Valve (artificial heart valve) for you to treat this condition.

The purpose of this information guide is to give you a better understanding of your heart valve replacement therapy and provide a fundamental understanding of your surgery. Clinical terms that are used throughout this guide will appear in **bold lettering** when first used and are defined in the glossary at the end of this guide.

Because this guide will not answer every question, it is vital that you have good communication with your physicians prior to surgery. Prepare written questions for your physician to answer before you go to your appointments.

2. Intended Use

The On-X Prosthetic Heart Valve is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic heart valves in the aortic and mitral positions.

3. Contraindications

The On-X Prosthetic Heart Valve is contraindicated for patients unable to tolerate anticoagulation therapy.

4. The Heart[1]

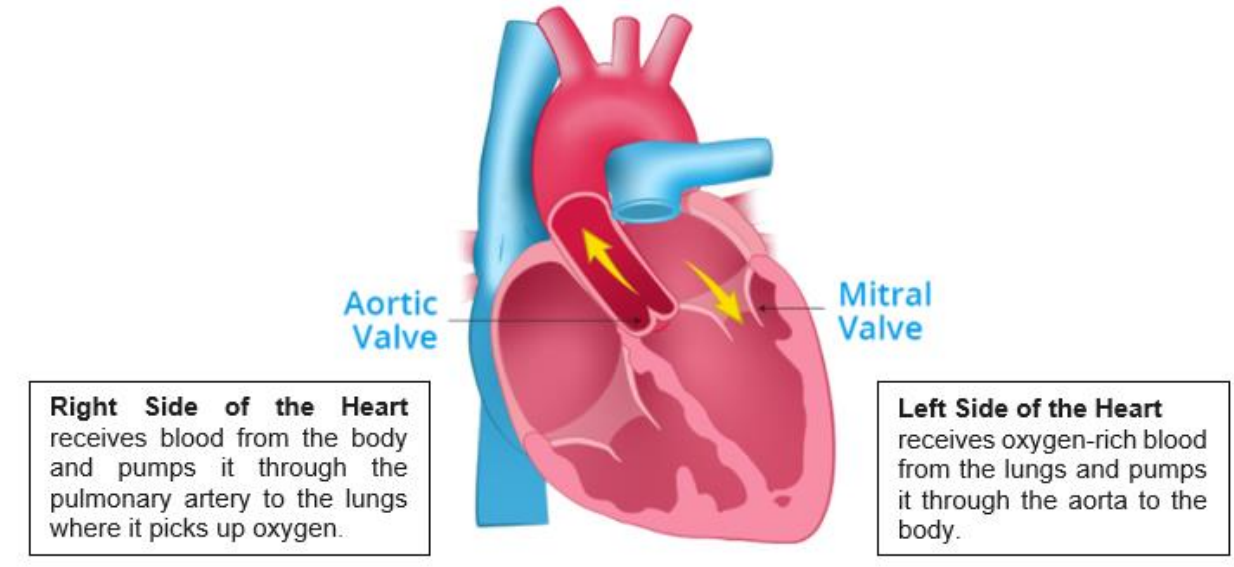
The heart is a pump that delivers blood together with life-maintaining nutrients to all parts of our bodies. It consists of four **chambers** (two **atria** and two **ventricles)** that beat regularly to push blood through the body and lungs. The flow of blood into and out of these chambers is regulated by four **heart valves.** These valves open to allow forward blood flow and close to prevent backward blood flow.

The four heart valves are:

1. **Aortic Valve** - Located between the left ventricle and the aorta (the main artery of the body). It prevents backflow of blood into the left ventricle.
2. **Mitral Valve** - Located between the left atrium and the left ventricle. It prevents backflow of blood into the left atrium.
3. **Pulmonary Valve** - Located between the right ventricle and the pulmonary artery (the artery leading to the lungs). It prevents backflow of blood into the right ventricle.
4. **Tricuspid Valve** - Located between the right atrium and the right ventricle. It prevents backflow of blood into the right atrium.

Blood is brought to the **right atrium** of the heart from all parts of the body through the veins. Contraction of this atrium pushes the blood through the **tricuspid valve** into the **right ventricle.** From there, contraction of the right ventricle pushes the blood through the **pulmonary valve** into the **pulmonary artery** and the lungs, where carbon dioxide is exchanged for oxygen. The blood then flows back to the **left atrium** of the heart from the **pulmonary veins.** Contraction of the **left atrium** occurs at the same time as the right atrium and causes the blood to enter the **left ventricle** through the **mitral valve.** The blood is then pushed out of the left ventricle through the **aortic valve** into the **aorta** and the whole body. Left ventricle contraction occurs at the same time as right ventricle contraction.

[1] Cardiac Surgery: Heart Valve Disease. Illinois: Northwestern Medicine Bluhm Cardiovascular Institute, 2019. Print.



5. Heart Valve Disease[1,2]

The normal heart valve opens and closes with each beat of the heart, about 50 million times per year for an entire lifetime. In a lifetime, that is up to 4 billion times, generally without failure. Heart valve disease causes the valve(s) to not open or close properly.

There are several possible causes of heart valve disease. Congenital defects at birth can result in valve malfunction later in life. Certain diseases, such as rheumatic fever, can damage the valves enough that they will eventually need to be repaired or replaced. Age can also result in stiffening or deposition of calcium on the valve, which may also require repair or replacement.

When a valve malfunctions, three (3) things may happen:

1. The valve does not open all the way, restricting the forward flow of blood (called **stenosis).**
2. The valve does not close properly, allowing blood to flow backwards (called **regurgitation).**
3. The valve neither opens nor closes properly, causing a combination of numbers 1 and 2 above.

5.1. Treatment of Valve Disease[1]

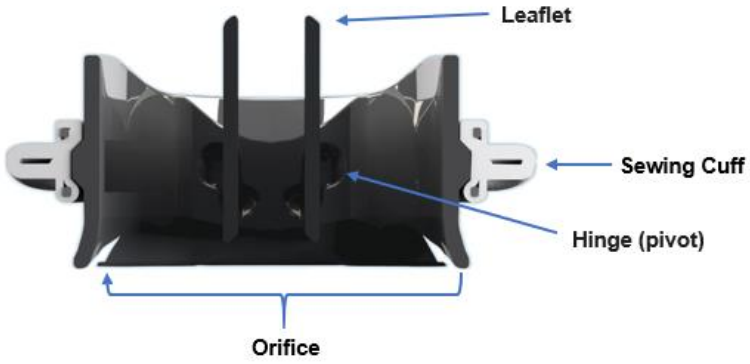
Often patients with early or mild forms of valve disease live a fairly normal life without treatment. In some cases, treatment with various types of drugs may be all that is required. When symptoms such as dizziness, fatigue, shortness of breath or chest pain become significant enough to affect daily life, surgical treatment must be considered.

For some patients, surgical repair of the natural valve can be successfully performed. In your case, the existing natural valve will need to be replaced by a prosthetic valve (artificial heart valve).

[2] Mayo Clinic. Common Causes for Aortic Valve Replacement. https://www.mayoclinic.org/tests-procedures/aortic-valve-repair-aortic-valve-replacement/about/pac-20385093.

6. On-X Prosthetic Heart Valves

On-X Prosthetic Heart Valves are mechanical heart valves that consist of a hollow tube called the **orifice** and two **leaflets** that open and close to regulate blood flow. The two (2) leaflets are held inside the orifice by the **hinge (pivot)** areas of the valve. A **sewing cuff** around the outside of the valve provides a means of attachment to the patient's heart tissue.



Mechanical valves are simple devices that do not wear out and rarely require reoperation due to failure. Mechanical valves can perform just as well years after surgery as they do when they are new.

All mechanical valve recipients are required to take **anticoagulant medication** (blood thinner) to reduce the risk of stroke and blood clotting on the valve. For some patients, the ticking of mechanical valves can be heard (like a wristwatch) in quiet settings.

6.1. Biological Compatibility

All components of the On-X Prosthetic Heart Valve, including the presence of any manufacturing residuals, have been shown to be biologically compatible. On-X Heart Valves are not made with Nickel-containing components. The table below provides a list of component materials.

Table 1: On-X Heart Valve Component Materials

Component	Material
Heart Valve Housing	Graphite substrate coated in On-X Pyrolytic Carbon
Heart Valve Leaflets	Graphite substrate with tungsten (10 weight%) coated in On-X Pyrolytic Carbon
Sewing Cuff	Polytetrafluoroethylene (PTFE) fabric
Suture	Polyester Fiber coated with PTFE
Retaining Rings	Titanium

7. Anticoagulant Information

Anticoagulant medication is commonly known as "blood thinner" even though it does not actually thin the blood. This medication interrupts the blood clotting mechanism and is required when the possibility of blood clot formation exists (See Section 9.4. for possible risks associated with the use of these medications). Blood clots can be stationary

(thrombosis) or they can travel in the bloodstream **(embolism)** and lodge in an important organ or artery and block blood flow.

The anticoagulant medication used for heart valve patients is warfarin sodium, commonly called warfarin or by the brand name **Coumadin.** All patients with mechanical heart valves need to take warfarin.

8. **International Normalized Ratio (INR)** is a measurement of the level of anticoagulant medication activity in the blood. An INR of 1.0 is normal for people not taking anticoagulant medication. For patients with mechanical aortic heart valves, an INR of 2.0-3.0 is recommended. For patients with mechanical mitral heart valves, an INR of 2.5-3.5 is recommended.

Patients taking warfarin have blood tests (finger prick) to make sure their INR level is in the safe range. Your doctor will tell you how often these tests should be performed (typically once or twice a month). **Home INR monitoring** is highly recommended because it improves patient safety by making frequent testing more convenient. This results in more stable INR levels.

9. Mechanical Heart Valve Complications

Despite the care given to heart valve design and patient welfare, problems may arise. Some complications of valve surgery are described here. These problems do not occur in most patients, but awareness of them can increase the likelihood of success with your new valve. As with all mechanical heart valves, it is possible that these complications could lead to: reoperation, explantation, permanent disability, or death.

Follow-up visits to your physicians should be scheduled during the first year after surgery. It is important to attend these visits and to take advantage of your time with your physician by asking questions and becoming more familiar with your valve.

9.1. Mechanical Valve Failure - Mechanical valves fail very rarely, but when they fail, they generally fail rapidly without early warning. Such issues include perivalvular leak (leakage around the outside of the device), regurgitation (blood flow backwards into device), structural dysfunction (mechanical failure of device). Any sudden change in your health is a cause for concern, and medical attention is required immediately.

Although mechanical valve failure is rare, it is extremely important to identify and correct it immediately. Untreated, these problems can be a threat to your life. Do not hesitate to contact your physician and receive treatment as fast as possible if anything unusual happens. WITH YOUR AWARENESS AND YOUR PHYSICIAN'S CARE, THE HAZARDS OF THESE PROBLEMS CAN BE MINIMIZED.

9.2. Pannus (scar tissue) overgrowth - The body will produce fibrous scar tissue or **pannus** where the native valve has been removed and a prosthesis is implanted. If it grows too far, this can lead to obstruction of the valve requiring reoperation.

9.3. Stuck leaflets (impingement) - Leaflets in mechanical valves can become trapped by pressure on the valve orifice. Tissue from underneath the valve in the mitral position or overgrown pannus tissue can cause leaflets to stick.

9.4. **Anticoagulant-related bleeding (hemorrhage)** - With all mechanical valves, your physician will prescribe anticoagulant medication and possibly platelet inhibiting drugs for you to take continually after surgery. In some instances, patients may suffer from bleeding due to these medications. Some signs to watch for are:

- bloody urine,
- black or bloody bowel movements,
- severe bruising,
- general weakness, and
- unusual pains in the abdomen.

It is extremely important when taking an anticoagulant that you have your blood monitored closely, that you work closely with your physician to be sure that you are taking the drug in the right amount and that you take this drug at the same time every day without fail. If you think you have the symptoms described above, contact your physician immediately. It is highly recommended that you carry identification noting that you are taking an anticoagulant.

9.5. **Thrombotic complications** - it is possible that blood could clot on the valve. Such a blood clot **(thrombus)** could grow large enough to affect the proper function of the valve **(valve thrombosis)** or could break loose **(embolize)** and travel with the blood to another part of the body and then block blood flow to that area **(thromboembolism)** causing a **stroke.**

The occurrence of bleeding and thrombotic complications reflect the balance required in taking your anticoagulants. Close cooperation with your physician in controlling your medicine can minimize the occurrence of both these complications.

9.6. **Other Potential Adverse Events:**

Other adverse events potentially associated with the use of prosthetic heart valves (in alphabetical order) include, but are not limited to: angina (chest pain), cardiac arrhythmia (irregular heartbeat), endocarditis (infection within the heart), heart failure, hemolysis (red blood cell damage), hemolytic anemia (disorder in which red blood cells are destroyed faster than they are made), myocardial infarction (heart attack), nonstructural dysfunction (device leakage, blockage, inappropriate sizing, etc.).

After surgery, if you notice a return of some of the same problems you had before surgery (shortness of breath), or if you experience any unusual dizziness, blurred vision, loss of hearing, numbness or weakness, contact your physician immediately.

10. After Your Heart Valve Surgery

When you leave the hospital, your physician will likely give you a routine to follow at home for your complete recovery. Your physical activities will likely be restricted at first, and then gradually you will likely return to normal activities. It is important to follow your physician's advice regarding your postoperative activities.

Be sure to ask questions about subjects that are important to you, for example, resumption of work, diet and recreation. Do not be shy or embarrassed about asking for answers to your concerns regarding your future activities.

Depending upon your situation, you may be placed on therapy with one or more drugs. Be sure that their use is fully explained to you by your physician. Learn why you need the drugs, how to take them and what side effects you may encounter. Particularly, with a mechanical heart valve you will be placed on anticoagulant (blood thinner) therapy. Anticoagulants are very useful and effective drugs; however, they also can have serious side effects. It is important that you are fully aware of the proper use of this class of drug.

You should also be aware that other medicines and diets can interfere with the action of your anticoagulant. Do not take any other medications without first clearing them with your physician. Make certain that your physician and other physicians who you see consider the effect of new medications on your anticoagulant before they prescribe them.

Follow-up visits to your physicians will be scheduled during the first year after surgery. It is important to attend these visits and to take advantage of your time with your physician by asking questions and becoming more familiar with your valve.

10.1. Magnetic Resonance Imaging (MRI) Compatibility

***Before* having any MRI performed —Call your doctor, so your On-X Prosthetic Heart Valve can be discussed with the MRI personnel.** The On-X Prosthetic Heart Valve was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials International, Designation: F2503-08.

MRI personnel can go to
http://www.onxlti.com/onxlti-hvm-mri-memo-3-0-tesla-march-2010.html
for more information.

11. Frequently Asked Questions

Question	Answer
Is there a patient identification card or implant card for my On-X Valve?	Yes, you should have received your On-X Patient Record Card from the hospital after your implant surgery, but in case you did not, please email info@heartvalvechoice.com for this request. You can also submit a request for a replacement Patient Record Card or updates to your contact information to info@heartvalvechoice.com.
Will my On-X Valve be detected by the airport full body scanner?	It is not likely that your On-X Valve will register a response by the airport full body scanner. In the event your On-X Valve is detected by this system, it is suggested that you present your On-X Patient Record Card to airport personnel. The full body scanner will not affect the performance of your On-X Valve.
Can I undergo hyperbaric oxygen therapy as an On-X Valve recipient?	There is no restriction on hyperbaric oxygen therapy with your On-X Valve since the valve exists in a closed, pressurized system that is not affected by external atmospheric pressure changes. A search of relevant literature indicated no reports of restrictions or contraindications.

Question	Answer
What are the bridging guidelines for a mechanical heart valve (aortic or mitral) patient undergoing a minor procedure or surgery while on anticoagulants?	It is recommended that anticoagulation therapy is continued at therapeutic range for mechanical heart valve patients undergoing minor procedures, such as dental extractions/cleaning, surgery on the skin, or eye surgery.[3]
Is it safe to have an MRI with a prosthetic heart valve.	On-X heart valves, like most other prosthetic heart valves, are listed as MRI conditional, which means it is safe under most conditions. Before having any MRI performed —Call your doctor, so your On-X Prosthetic Heart Valve can be discussed with the MRI personnel.
Will I hear my heart valve?	Patients who receive mechanical valves may hear a "click" related to valve closure. All mechanical valves cause this sound, some more than others. It also depends on patient size/shape and hearing ability.

12. Definitions

Term	Description
Anticoagulant medication	A substance that inhibits the blood clotting mechanism. Anticoagulant drugs are given to maintain the blood in a fluid state, thereby preventing abnormal or pathological clotting. Sometimes called blood-thinner.
Aorta	The main artery that conducts oxygenated blood from the left ventricle of the heart and circulates it to the rest of the body.
Aortic valve	A semilunar valve located between the left ventricle and the aorta that prevents backflow of blood into the left ventricle.
Arrhythmia	An irregular heartbeat caused by a disturbance in the neural conduction system of the heart.
Arteries	Blood vessels that carry blood away from the heart.
Atrium (atria)	One of two chambers upper chambers of the heart that receives blood from the body or lungs.
Coronary arteries	The blood vessels that provide nourishment to the heart muscle. There are two coronary arteries, the right and the left, and they originate behind two of the three leaflets of the aortic valve.
Coumadin®	Brand name of the most widely used anticoagulant. The generic name is warfarin sodium.
Embolism	A particle, such as a thrombus, debris or an air bubble, circulating in the bloodstream.
Heart failure	Inability of the heart to effectively and efficiently move the blood throughout the body. The most common causes are blocked coronary arteries, diseased native heart valves and deformities at birth but there are many other causes.
Heart valve	An anatomical structure in the heart that regulates blood movement.
Hemolysis	Red blood cell damage, which can lead to hemolytic anemia.

[3] After 3 months standard therapy. 1. Nishimura RA et al., 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. 2017;135:e1159-95.

Term	Description
Impingement	The inability of a moving part (valve leaflet) to move due to contact with another object.
International Normalized Ratio (INR)	This is a measurement of the level of anticoagulant medication activity in the blood determined by blood test. An INR of 1.0 (one) is normal for people not taking anticoagulant medication. For patients with mechanical aortic heart valves, an INR of 2.0-3.0 is recommended where an INR of 2.5-3.5 is recommended for patients with a mechanical mitral heart valves. Be sure to monitor and discuss these levels with your physician.
Leaflet (valve leaflet)	Leaflets are the moving parts of natural or prosthetic valves that open and close to control blood flow.
Left atrium	The left upper chamber of the heart, which receives oxygenated blood from the lungs via the four pulmonary veins.
Left ventricle	The left lower chamber of the heart, which receives oxygenated blood from the left atrium and pumps it to the systemic circulation via the aorta.
Mechanical prosthetic valve	A prosthetic device implanted to replace diseased heart valves. Current devices are made from various materials including pyrolytic carbon, graphite carbon, tungsten, titanium, and synthetic fabric.
Mitral valve	A large "parachute" type atria-ventricular valve located between the left atrium and the left ventricle that prevents backflow of blood into the left atrium.
Orifice (valve orifice)	A term used to refer to the short cylindrical tube that houses the leaflets of a manufactured mechanical heart valve.
Pannus ingrowth	Tissue growth in and around an implanted valve that can interfere with valve function.
Pivot (valve pivot)	A pivot is a recessed or protruding area in the orifice of a mechanical heart valve where the leaflets of the valve are secured. Pivot geometry dictates valve leaflet opening and closing angles.
Prosthetic heart valve	A prosthesis that is implanted to replace a natural heart valve or failed prosthesis. Prosthetic valves can be mechanical or tissue (biological).
Pulmonary artery	The large artery that conducts deoxygenated blood from the right ventricle to the lungs.
Pulmonary circulation	The circulation of deoxygenated blood through the lungs, where the blood becomes oxygenated. It is also known as the lesser circulation because the flow path is short and lower pressure is required for it to operate efficiently.
Pulmonary valve	A semilunar valve located between the right ventricle and the pulmonary artery that prevents backflow of blood into the right ventricle.
Pulmonary vein	A large blood vessel that returns blood to the heart from the lungs.
Pyrolytic carbon	Carbon from a carbon gas that is deposited on the surface of valve parts after the gas is split at very high temperature. Pyrolytic carbon has a smooth porcelain-like surface when polished. Some pyrolytic carbon contains silicon carbide.
Regurgitation	A heart valve disease (valve regurgitation) that allows backward flow of blood through a closed valve OR blood that flows backward during the closed phase of a mechanical or tissue heart valve.
Right atrium	The right upper chamber of the heart, which receives deoxygenated blood from the systemic venous system.
Right ventricle	The right lower chamber of the heart, which receives deoxygenated blood from the right atrium and pumps it to the lungs via the pulmonary artery.

Term	Description
Sewing cuff	A synthetic cloth structure attached to the outer circumference of a manufactured heart valve to allow attachment of the valve inside the heart.
Stenosis	A narrowing of the heart valve orifice (opening), which prevents the valve from opening completely and decreases the blood flow through the valve.
Stroke	Where the supply of blood to the brain becomes blocked.
Structural failure	Failure of prosthetic valve parts to function correctly.
Thromboembolism	The formation of a blood clot that circulates in the bloodstream and can block a vessel downstream from where it originated.
Thrombosis	The formation of a blood clot in a blood vessel, a chamber of the heart, or a natural or prosthetic heart valve.
Thrombus	A stationery blood clot.
Tricuspid valve	An atria-ventricular valve located between the right atrium and the right ventricle that prevents backflow of blood into the right atrium.
Ventricle	One of two lower chambers of the heart that acts as a pump to move the blood to the body or the lungs.
Warfarin Sodium	The generic name for the anticoagulant medication given to artificial heart valve recipients

13. Contact Information

Manufacturer

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Report all serious adverse events related to your device to your doctor, the manufacturer and to your local regulatory authority:

Australia (Therapeutic Goods Administration) https://www.tga.gov.au/