

Avalus™ Bioprosthesis | Indications: The Avalus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve replacement should use this device. Accelerated structural deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, or hyperparathyroidism). Adverse events can include: angina, cardiac dysrhythmias, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, infection other than endocarditis, transvalvular or paravalvular leak, myocardial infarction, nonstructural valve dysfunction (leaflet entrapment/impingement, obstructive pannus ingrowth, suture dehiscence, inappropriate sizing or positioning, or other), pericardial effusion or tamponade, prosthesis regurgitation, prosthesis stenosis, prosthesis thrombosis, stroke, structural valve deterioration (calcification, leaflet tear or perforation, or other), thromboembolism, tissue dehiscence, and transient ischemic attack. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability, or death.

Hancock™ II Bioprosthesis | Indications: For patients who require replacement of their native or prosthetic aortic and/or mitral valves. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Accelerated deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include: angina, cardiac arrhythmia, cardiac dysrhythmias, death, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

Mosaic™ Bioprosthesis | Indications: For the replacement of malfunctioning native or prosthetic aortic and/or mitral heart valves. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Accelerated deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include: angina, cardiac arrhythmia, cardiac dysrhythmias, death, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

Freestyle™ Aortic Root Bioprosthesis | Indications: For the replacement of malfunctioning native or prosthetic aortic valves with the option of aortic root replacement. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Accelerated deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include: cardiac dysrhythmias, death, endocarditis, hemolysis, hemorrhage, transvalvular or paravalvular leak, nonstructural dysfunction, structural deterioration, thromboembolism, valve thrombosis, or intracuspal hematoma.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For countries that use eIFUs, consult instructions for use at this website www.medtronic.com/manuals. Note: Manuals can be viewed using a current version of any major internet browser.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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PATIENT BOOKLET

MEDTRONIC SURGICAL VALVE REPLACEMENT

Tissue Valve for Aortic and Mitral Valve Replacement



Medtronic

ARE MEDTRONIC SURGICAL TISSUE HEART VALVES RIGHT FOR YOU?



Medtronic surgical heart valves are for people with aortic and mitral valve disease. Your doctor can help you decide if surgical valve replacement with a Medtronic valve is right for you. This booklet will help you learn more about the Medtronic surgical heart valve products.

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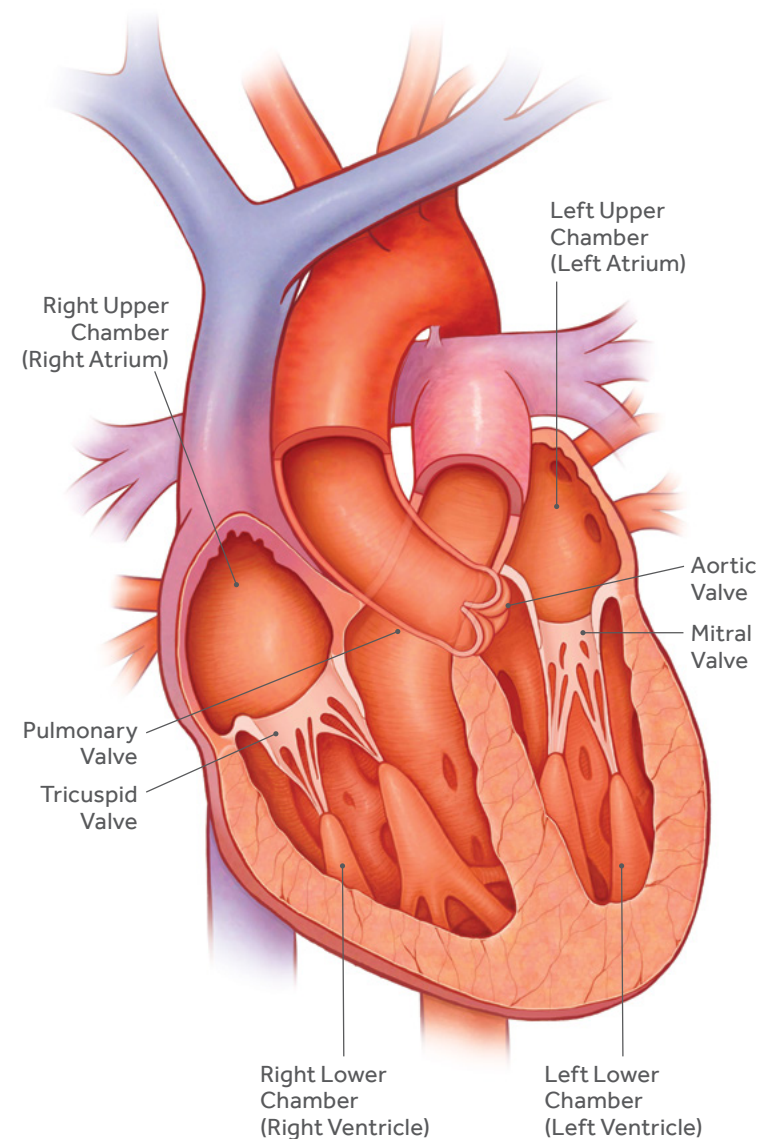
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ABOUT THE HEART

How the Heart Works

A healthy heart beats around 100,000 times a day. The heart's job is to supply the body with oxygen-rich blood.

The heart has four chambers. Blood is pumped through the four chambers with the help of four heart valves.



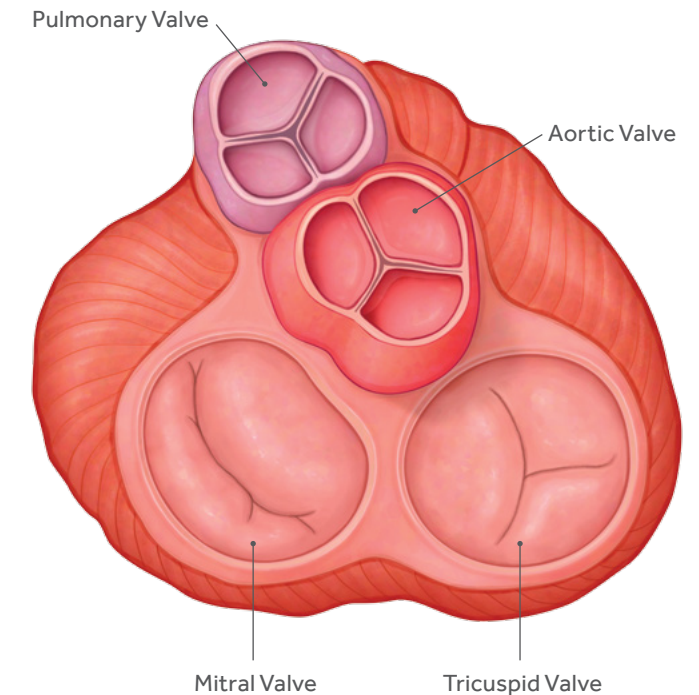
What Heart Valves Do

Heart valves open when the heart pumps to allow blood to flow. They close quickly between heartbeats to make sure blood does not flow backward. Any trouble in this normal flow will make it hard for the heart to pump the blood where it needs to go.

Pulmonic Valve | controls the flow of blood to the lungs to get oxygen.

Aortic Valve | controls the flow of blood as it exits the heart and is pumped to the rest of the body.

Mitral and Tricuspid Valves | control blood flow as it moves between the chambers of the heart.



AORTIC VALVE DISEASE

Severe Aortic Stenosis

Severe aortic stenosis (AS) occurs when the aortic valve doesn't open properly. This forces your heart to work harder to pump blood throughout your body. Over time, the heart muscle weakens. This affects your overall health and keeps you from participating in normal daily activities.

Left untreated, severe AS is a very serious, life-threatening condition, leading to heart failure and increased risk for sudden cardiac death.

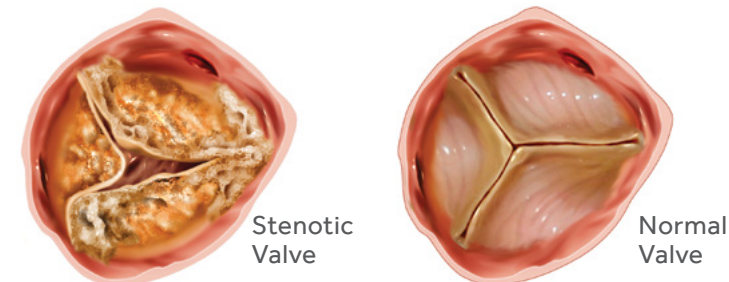
Severe AS is often not preventable, causes narrowing of the aortic valve, and may be related to the following:

- Age
- A buildup of mineral (calcium) deposits that narrows the aortic valve (stenosis)
- Radiation therapy
- A history of a bacterial infection of the heart (rheumatic fever)
- Increased fat in the blood vessels (high cholesterol)

Symptoms of Severe AS

Signs and symptoms of severe AS can include:

- Chest pain or tightness
- Feeling faint or fainting with activity
- Dizziness
- Fatigue
- Shortness of breath
- Irregular heart beat (palpitations)
- Unusual sound heard during a heartbeat (murmur)



Aortic Regurgitation

Aortic valve regurgitation, or aortic insufficiency, occurs when the aortic valve does not close tightly which allows some of the blood that was pumped out of the left ventricle to leak backwards.

This leakage may prevent your heart from efficiently pumping blood to the rest of the body and can cause patients to feel fatigued and/or shortness of breath. This affects your overall health and keeps you from participating in normal daily activities.

Aortic regurgitation may be related to the following conditions:

- Endocarditis
- Collagen disorders
- Marfan's Disease
- Systemic lupus – autoimmune disease
- Hypertension
- Aortic dissection

Symptoms of Aortic Regurgitation

- May not have any symptoms for years
- Fatigue
- Shortness of breath
- Swollen ankles and feet
- Rapid or irregular pulse

MITRAL VALVE DISEASE

In mitral valve disease, the mitral valve, which is located between your left heart chambers (left atrium and left ventricle), doesn't work properly.

Types of Mitral Valve Disease Include:

Mitral Valve Regurgitation | The flaps (leaflets) of the mitral valve don't close tightly, causing blood to leak backward into the left atrium of your heart. If not treated, it can result in heart muscle damage.

The most common cause of blood leakage is mitral valve prolapse, in which the leaflets bulge back into the left atrium as your heart beats.

Mitral Valve Stenosis | The flaps of the mitral valve become thick or stiff, and they may fuse together. This results in a narrowed valve opening and reduced blood flow in the heart.

Symptoms of Mitral Valve Regurgitation

Many people with severe mitral valve regurgitation may not have symptoms, yet may still benefit from early mitral valve repair. Signs and symptoms of mitral valve regurgitation can include:

- Blood flowing turbulently through your heart (heart murmur)
- Shortness of breath, especially with exertion or when you lie down
- Fatigue, especially during times of increased activity
- Heart palpitations — sensations of a rapid, fluttering heartbeat
- Swollen feet or ankles



Normal Closure



Prolapse Closure

TREATMENT OF YOUR HEART VALVE DISEASE WITH **A MEDTRONIC BIOPROSTHETIC VALVE**



Avalus™ Valve | The Avalus heart valve is an option for patients with aortic valve disease. The Avalus heart valve is made from cow heart (bovine pericardium) tissue. The tissue is cut into three matching leaflets which are mounted to a flexible frame with a firm base (stent). The valve is designed to simulate the structure and function consistent to a human valve with the leaflets regulating the flow of blood through the valve.

Hancock™ II Valve | The Hancock II heart valve is another option for patients with aortic or mitral valve disease. The Hancock II bioprosthesis is also made from a pig (porcine) heart valve since the anatomy of the pig heart is similar to a human heart valve. The valve is attached to a flexible frame that helps the surgeon implant the valve in the heart.



Mosaic™ Valve | The Mosaic heart valve is one option for patients with aortic or mitral valve disease. The Mosaic heart valve is made from the heart valve of a pig (porcine). A pig's heart valve anatomy is similar to that of a human heart. In order to implant the valve in the heart, the tissue is mounted on a flexible frame.

Freestyle™ Valve | The Freestyle heart valve is an option for patients with aortic valve disease. Like Mosaic and Hancock II, the Freestyle heart valve is made from a pig (porcine) heart valve; however, unlike the other products, there is no frame used. Instead, the Freestyle valve is designed and implanted with the full porcine root from the pig. This further aids in the valve functioning consistent to a human valve.



Please note that this information cannot replace discussions with your doctor.

UNDERSTANDING SURGICAL HEART VALVE REPLACEMENT

Open-heart Surgical Valve Replacement for Aortic and Mitral Valves

Valve replacement surgery is an effective, life-saving treatment option for people with aortic or mitral valve diseases. Depending on your risk factors, such as health, diagnosis, and age, your health care providers will be able to recommend the appropriate valve replacement for you.

Traditional heart valve replacement surgery (aortic and mitral valves) often requires an incision over the chest and sternum (some surgeries may be performed using a minimally invasive technique without opening the chest). The chest is then opened and spread apart using a surgical instrument. This provides the surgeon access to the heart and chest cavity, in order to replace your heart valve.

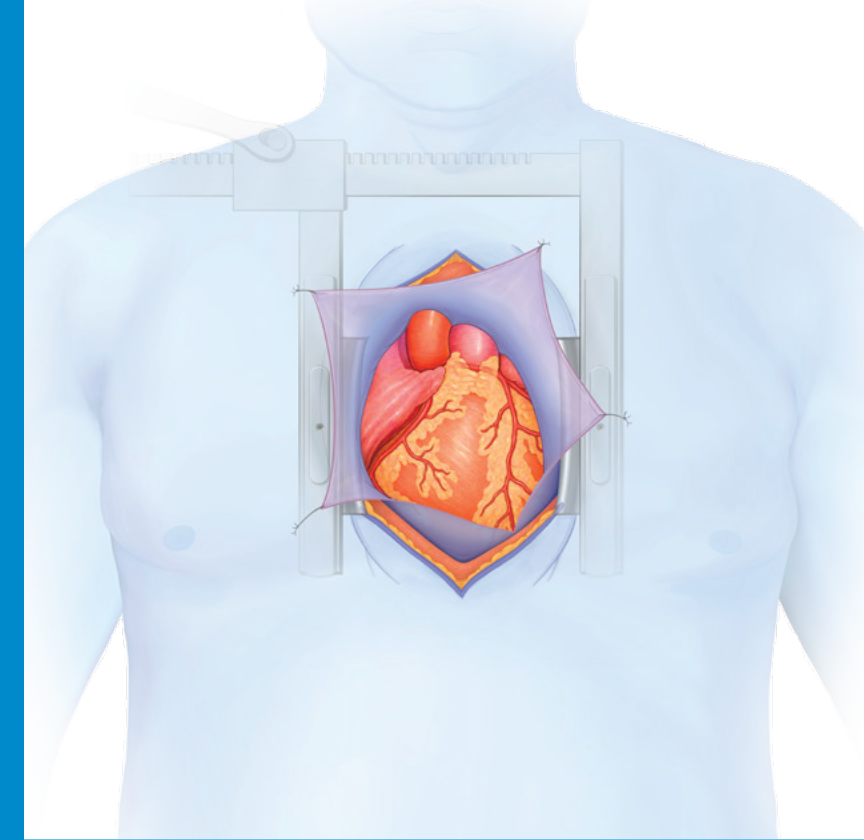
Since each patient has a unique medical history, this information cannot replace discussions with your doctor.

During the Procedure

The operation varies from patient to patient, lasting a minimum of two hours and often longer. During this time, you are asleep under general anesthesia. During the operation, the surgeon will remove any tissue and calcium deposits that are interfering with the normal function of the valve. Your damaged valve may be completely removed. Then, the new valve will be sewn into the space where your own valve used to be. After the surgeon makes sure your valve is working properly, blood flow will be restored to your heart and the incisions will be closed. Your surgery is performed while the function of your heart is taken over by a heart-lung machine (called cardiopulmonary bypass or CPB).

Procedural Overview of a Typical Open-heart Surgery

1. You will be administered general anesthesia to remain asleep and pain free during the procedure.
2. After preparation, an incision to access your heart is made.
3. You will be connected to a heart-lung machine to isolate the heart.
4. The old valve is removed.
5. A new valve is placed.
6. You are then weaned from cardiopulmonary bypass.
7. Your newly replaced heart valve will begin working. The doctor will conduct a test to confirm the valve is working properly.
8. All incisions are closed.
9. You are then transferred to ICU and kept on ventilator until deemed ready to remove.



POTENTIAL RISKS FOR **SURGICAL VALVE REPLACEMENT**

Clinical Studies

The Avelus bioprosthesis, Mosaic bioprosthesis, Hancock II bioprosthesis, and Freestyle bioprosthesis have been evaluated in multi-center studies with more than 800 patient-years of clinical evidence.

These studies looked at outcomes including death, blocking of the valve or blood vessel by blood clots, blood flowing in the wrong direction through or around the heart valve, infection, structural and nonstructural valve damage, whether the heart valve needed to be removed, and any problem with the heart valve that causes obstruction of blood circulation to the heart.

The data from these studies has demonstrated the safety and effectiveness of the Avelus bioprosthesis, Mosaic bioprosthesis, Hancock II bioprosthesis, and Freestyle bioprosthesis.

Valve replacement can include the following risks:

- Death
- Blood clots that develop in the heart or on the replacement valve. These clots may break loose and travel through the bloodstream (thromboembolism). This problem may cause a stroke or heart attack.
- Obstruction of blood circulation to the heart resulting in damage to the heart tissue (myocardial infarction)
- Angina
- Abnormal heart beat (cardiac arrhythmia and dysrhythmia)
- Heart failure
- Damage to red blood cells (hemolysis) that can result in anemia
- Blood leaking around the outside of the prosthetic valve (paravalvular leak) or any problem with the valve that causes leaking of blood after the valve has closed (transvalvular leak)
- Any problem with the prosthetic valve that causes narrowing of the valve opening (stenosis)
- Failure of the valve to open and close properly
- Inflammation of the lining of the heart (endocarditis)

The potential risks are shown in the order of severity, from most severe to least severe. This list is not inclusive of all risks. Talk to your physician regarding more information about valve replacement surgery.