

LIVING WITH YOUR NEW HEART VALVE

An Educational Booklet
for Recipients of the
Abbott Mechanical
Heart Valve



Abbott

YOUR ROLE IN THE
MANAGEMENT OF YOUR
HEALTH IS VERY IMPORTANT.
**THIS INFORMATION IS NOT
INTENDED TO REPLACE THE
MEDICAL ADVICE OF YOUR
DOCTOR. ALL MEDICAL
TREATMENT DECISIONS
SHOULD BE MADE IN
CONSULTATION WITH, AND
UNDER THE DIRECTION
OF, YOUR DOCTOR. IF
THE INFORMATION YOU
RECEIVE FROM YOUR
DOCTOR DIFFERS FROM
THIS BROCHURE, ALWAYS
FOLLOW YOUR DOCTOR'S
INSTRUCTIONS.**

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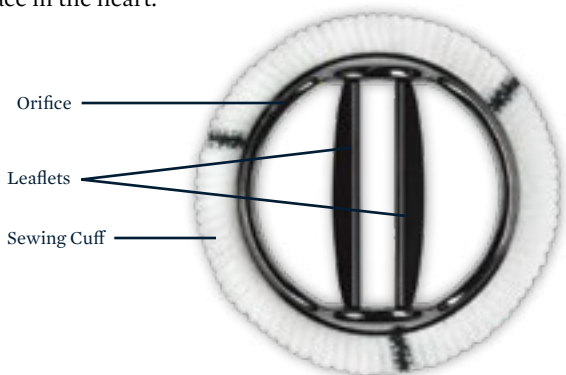
GLOSSARY

Angina	Chest pain
Anticoagulation Medicine	Medication prescribed to prevent blood clot formation
Aorta	Primary artery that carries oxygenated blood to the body
Aortic Valve	Valve located between the left ventricle and the aorta
Arrhythmia	Abnormal heart rhythm
Atria	Atria is the plural for atrium. The atrium refers to a chamber in which blood enters the heart, as opposed to the ventricle, where the blood is pushed out
Atrial Fibrillation	Atrial fibrillation is an irregular and often rapid heart rate that commonly causes poor blood flow to the body. During atrial fibrillation, the heart's two upper chambers (the atria) beat chaotically and irregularly – out of coordination with the two lower chambers (the ventricles) of the heart. Atrial fibrillation symptoms include heart palpitations, shortness of breath and weakness
Atrial Flutter	A regular heart rhythm in which many impulses begin and spread through the atria. The resulting rhythm is organized, but so rapid that the atria are not able to fully empty their contents into the ventricles
Bioprosthetic Valve	Replacement heart valve that is made from animal tissue
Bovine	Of cow origin
Dilated	Enlarged
Dysrhythmia	Abnormal heart rhythm
Endocarditis	Infection of the heart's inner lining or valves
Explantation	Surgical removal of medical device
Hemolysis	Change or destruction of red blood cells

Hemolytic Anemia	Anemia caused by excessive destruction of red blood cells
Hemorrhage	Excessive bleeding
Incompetent Valve	Valve unable to close completely, thus allowing blood to flow backward through the valve
Left Ventricle	The left ventricle is one of four chambers (two atria and two ventricles) in the human heart. The ventricle pushes the blood out of the heart
Native Valve	Original valve
Pericardial	Made of tissue from the pericardium — the protective sack that surrounds the heart
Perivalvular Leak	Leak near the valve
Polyester Cloth	Manmade material used to create the sewing cuff that is used to secure the implanted valve to the tissue
Porcine	Of pig origin
Prosthetic	Device used to replace some part of the body
Pumping Efficiency	Ability of the heart to force blood into the body
Regurgitant Valve	Valve unable to close completely, thus allowing blood to flow backward through the valve
Stenotic Valve	Narrowed or hardened valve that no longer opens completely
Stent	Mounting frame to provide structural support
Thromboembolism	Blood clot that travels through the bloodstream, eventually blocking a vessel
Thrombosis	Formation of a blood clot in the body
Valve	Structure that regulates flow
Valvular Pannus	Abnormally thick tissue around the valve

PRODUCT DESCRIPTION – ABBOTT MECHANICAL HEART VALVE

The Abbott mechanical heart valve has been implanted in more than 2.7 million patients worldwide.¹ The valve is manufactured with two pyrolytic carbon leaflets contained within a pyrolytic carbon orifice ring. The two leaflets open and close to regulate the flow of blood in one direction. Pyrolytic carbon is ideal for use in mechanical heart valves because of its hardness, strength, durability and resistance to the adherence of blood components. A sewing cuff, made of medical grade fabric, is attached to the valve and allows the surgeon to sew the valve into place in the heart.



Regent™ Aortic Mechanical Heart Valve

INDICATIONS FOR USE

The Abbott mechanical heart valve is intended for use as a replacement valve in patients with a diseased, damaged or malfunctioning aortic or mitral valve. This device may also be used to replace a previously implanted aortic or mitral prosthetic heart valve.

A HEARTY REMINDER

Remember you are an important member of your healthcare team. The information below will help you maintain a healthy heart.

Precaution: It is very important you follow the following advice.

- Report any signs of fluid retention to your doctor.
- It is very important to tell your dentist or physician you have an artificial heart valve because you will need to take antibiotics prior to any dental work or surgery to prevent infection of your heart valve.
- Take medication as prescribed.
- Follow up with blood tests as directed by your physician.
- Follow an exercise program as outlined by your physician.
- Enjoy a heart-healthy diet.
- If you are told you need to have an MRI (magnetic resonance image) tell your doctor you have an artificial heart valve and show him/her your patient identification card. It contains important information about how to perform an MRI safely with your valve.

VALVULAR HEART DISEASE

Heart valves may be impaired for a variety of reasons. Some people are born with heart valve defects while others acquire valve damage from infection, the aging process or other diseases. The results are the same: either a rigid valve limiting forward blood flow (called a stenotic valve) or a valve that does not close properly permitting backflow (called an incompetent, insufficient or regurgitant valve).

The end result of valvular heart disease is the reduction in the heart's pumping ability. The heart tries to compensate for ineffective valve function by working harder to deliver oxygen-rich blood to other organs and tissues. The overworked heart may begin to fail, causing shortness of breath, dizziness, chest pains, fatigue and fluid retention. After physical examination and further tests, physicians may recommend valve replacement.

VALVE REPLACEMENT RISKS

Adverse events potentially associated with the use of mechanical heart valves (in alphabetical order) include:

- Angina
- Cardiac arrhythmias
- Endocarditis
- Heart failure
- Hemolysis
- Hemolytic anemia
- Hemorrhage
- Leak, transvalvular or perivalvular
- Myocardial infarction
- Nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other)
- Prosthesis regurgitation
- Stroke
- Structural damage (calcification, leaflet tear, perforation or other)
- Thromboembolism
- Valve thrombosis

It is possible that these complications could lead to:

- Reoperation
- Explantation
- Permanent disability
- Death

VALVE REPLACEMENT BENEFITS

Heart valve repair surgery can offer several key benefits. The procedure is designed to help your heart pump blood more effectively, which means you may begin to feel better immediately. Others may feel better gradually, regaining energy and strength over the first few weeks following the surgery. Be sure to talk to your doctor about your progress and get advice on the exercises and activities you can do to regain your strength.

The first clinical replacement heart valve surgery took place in 1952. Today, several replacement valve options are available within two broad categories of valve types: mechanical heart valves and bioprosthetic or tissue heart valves.

Mechanical heart valves are constructed with strong, manmade materials and designs. The most important benefit of mechanical valves is that they are the most durable of the valve types and are designed to last the lifetime of the patient. Patients with mechanical replacement heart valves must take daily blood anticoagulation medication to minimize the risk of complications from blood clots.

Bioprosthetic heart valves are made with tissue from porcine (pig) heart valves or bovine (cow) heart tissue (or a combination of the two). These tissue replacement heart valves are designed to function similar to human heart valves. The most important benefit of this valve type is that the valve is very compatible with the bloodstream. Patients with tissue valves are not always dependent on daily medication to minimize complications from blood clots.

HOW LONG VALVES LAST

Mechanical heart valves are made of graphite and coated with pyrolytic carbon. Studies have shown that the Abbott valve is very durable and may last beyond 50 years.² However, complications unrelated to valve deterioration may impair valve function, necessitating valve replacement.

BEFORE THE PROCEDURE

A nurse, patient advocate or your doctor will discuss the procedure with you on the day you are scheduled to receive your new valve. The length of the procedure varies for each patient.

DURING THE PROCEDURE

During the procedure, a general anesthetic will be administered that will put you to sleep so you do not feel any pain during the surgery.

Your surgeon will make an incision in your chest to reach your heart. Your heart will be stopped temporarily so the valve can be implanted and you will be placed on a heart-lung machine. First, the surgeon will remove the diseased valve and determine the correct replacement valve size. Next, the new valve will be positioned in the original valve location and firmly sewn into place. The surgeon then closes the incision, restarts your heart and closes all the other incisions. The heart-lung machine is then removed and your natural heart rhythm is returned.

AFTER THE PROCEDURE

After your heart valve surgery, you will be placed in the intensive care unit (ICU) where you can be monitored continuously. You will have help breathing during surgery and for a while afterward from a tube that has been placed down your throat and positioned in your lungs. You will probably wake up with this tube still in position. It will be removed as soon as you are stable and awake enough to breathe on your own. You will not be able to talk while this tube is in. Other tubes will come from your chest near the heart to drain extra blood and fluid from the surgical area.

Intravenous lines will give you fluid, blood and medications as needed, and you will have a bladder catheter to drain urine. You will be hooked up to a monitor that shows your heart rate, heart rhythm, blood pressure and other measurements that the nursing staff will use to assess your recovery status. You will receive medications to ease your pain and anxiety as needed.

The typical length of stay in the ICU is one or two days. It is important to remember that every patient recovers at a different rate. The nursing staff will monitor your recovery and remove the tubes as appropriate. From the ICU you will be moved to a cardiac medical-surgical floor where your heart will continue to be monitored, but there

you may be more independent and active. The healthcare team will continue to support and instruct you in recovery care, rehabilitation, medications, nutrition and other needs.

Keep in mind that every patient recovers at a different rate. Once you leave the hospital, it will typically be six to eight weeks before you are able to return to your normal routine.

Anticoagulation therapy is recommended for patients with mechanical heart valves. The American College of Cardiology/American Heart Association and the American College of Chest Physicians (ACCP) have established guidelines for the management of patients with prosthetic heart valves. Abbott recommends that you consult with your physician about these guidelines and what anticoagulation regimen is right for you.

WHEN TO CALL THE DOCTOR

Contact your physician(s) if you develop any of these symptoms:

- Redness or drainage of your incision
- Shortness of breath
- Swelling of your feet or ankles
- Chest, jaw, shoulder or arm pain
- Excessive bleeding or bruising
- Blood in your urine
- Unusual nose bleeds
- Fever
- Numbness or tingling in your arms or legs
- General weakness or loss of energy
- Blurred or loss of vision
- Unusual chest sensation
- Any signs of infection after you have recovered from your surgery
- Bloody or black tarry (blood will typically look like tar after it has been exposed to the body's digestive juices) bowel movements

RETURNING HOME

Remember to:

- Take medication as prescribed.
- Follow up with blood tests as directed by your physician.
- Enjoy a heart-healthy diet.

Valve replacement does not mean a sedentary lifestyle. Many people who receive valves are able to lead a more active and fulfilling life than before surgery. Ask your doctor what kinds of activities and sports you should avoid. Report any falls, blows to the body or head, or other injuries to your doctor right away.

Your involvement in caring for the health of your heart begins now. By understanding the recovery process and lifelong management necessary for your valve, you can make better heart-healthy decisions. Long-term management of your health requires your active participation. With your physician, you can work toward a healthy recovery.

When you return home, you must take special care of yourself until you are fully recovered. It may be about six to eight weeks before you are able to return to your normal routine. You will feel better each day; however, it is normal to experience some ups and downs. You will need to allow time to rest regularly; this will help speed your recovery.

At your follow-up visit to your doctor around three weeks, you may need to undergo tests such as an electrocardiogram, echocardiogram or chest X-ray to evaluate how your new valve is working. Your doctor may also perform blood work to assess your medication levels.

TRAVEL

After you've recovered, you should be able to enjoy traveling. Talk with your doctor if you're planning a trip to an exotic or tropical destination as certain destinations may harbor bacteria and other microbes that could be dangerous for your heart.

AIRPORT METAL DETECTORS

The amount of metal used in mechanical and tissue heart valves and heart valve rings is very small. It is usually not enough to set off the metal detectors; however, if it does, simply show security personnel your patient

See Important Safety Information referenced within.

identification card. Passing through a metal detector will not affect your heart valve.

If you do not receive your permanent, plastic ID card within 90 days of your surgery, or if you need a replacement card, contact Abbott to request a card:

Abbott Patient Device Tracking

Toll-free Phone: +1 800 344 5833

Email: catd_pdt@abbott.com

MRI TESTING

If you are told you need to have an MRI (magnetic resonance image), tell the doctor you have an artificial heart valve and provide the below link to your doctor:

<https://www.cardiovascular.abbott/us/en/hcp/resources/mri-ready-resources/structural-heart-mri-safety.html>

USER ASSISTANCE

If you have questions about your medical condition, please contact your doctor. Abbott, as a manufacturer of medical devices, does not provide medical advice.

Abbott Technical Services

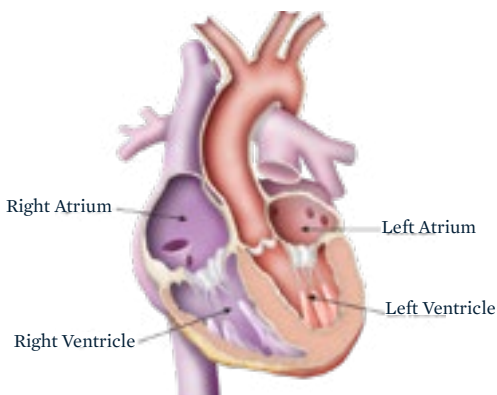
Phone: +1 855 478 5833

Email: USD_TechSupport@abbott.com

YOUR HEART

The heart consists of four chambers. The upper, receiving chambers are called the atria (each chamber is called an atrium) and the lower, pumping chambers are the ventricles (Figure 1). Because of their pumping function, the ventricles are larger than the atria.

FIGURE 1. CHAMBERS OF THE HEART



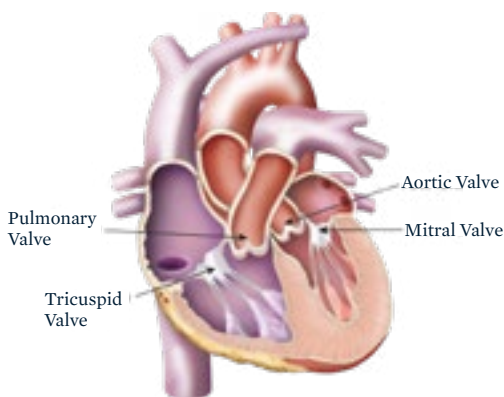
The main job of the heart is to pump oxygen-rich blood through your body. It does this by contracting an average of 70 times per minute for a total of more than 36 million heart beats per year.

Heart valves direct blood flow between the chambers of the heart. These valves act like one-way doors, allowing blood to flow forward into the next chamber. The valves close to prevent backflow.

Figure 2 shows the heart valves. On the right side of the heart, the blood flows through the tricuspid valve, which lies between the right atrium and the right ventricle. On the left side of the heart, blood flows between the left atrium and the left ventricle through the mitral valve.

Valves also separate the ventricles and the large blood vessels that carry blood away from the heart. Blood flows through the pulmonic valve between the right ventricle and pulmonary artery and lungs. On the left side of the heart, blood flows through the left ventricle into the aorta through the aortic valve.

FIGURE 2. HEART VALVES



CUSTOMER SERVICE

Abbott Customer Service

Toll-free Phone: +1 800 253 9073

Phone: +1 855 478 5833

Fax: +1 800 374 2505

Email: sjm-customerservice@abbott.com

FOR ADDITIONAL INFORMATION, PLEASE CONTACT YOUR DOCTOR.

See Important Safety Information referenced within.

SJM REGENT™ MECHANICAL HEART VALVE

IMPORTANT SAFETY INFORMATION

**R
ONLY**

INDICATIONS

The SJM Regent™ Mechanical Heart Valve is intended for use as a replacement valve in patients with a diseased, damaged, or malfunctioning aortic valve. This device may also be used to replace a previously implanted aortic prosthetic heart valve.

CONTRAINDICATIONS

The SJM Regent™ Mechanical Heart Valve is contraindicated for individuals unable to tolerate anticoagulation therapy.

WARNINGS

- For single use only. Attempts to reuse the valve may result in valve malfunction, inadequate sterilization, or patient harm.
- Do not use if:
 - The valve has been dropped, damaged, or mishandled in any way.
 - The expiration date has elapsed.
 - The tamper-evident container seal or inner/outer tray seals are damaged, broken or missing.
- Remove any residual tissue that may impair valve size selection, correct seating of the valve, rotation of the valve, or leaflet motion.
- Proper valve size selection is crucial. Do not oversize the valve. If the native annulus measurement falls between two SJM Regent™ Mechanical Heart Valve sizes, use the smaller size SJM Regent™ Mechanical Heart Valve.
- Use only St. Jude Medical™ mechanical heart valve sizers.
- The outer tray is not sterile, and should not be placed in the sterile field.
- To minimize direct handling of the valve during implantation, do not remove the holder/rotator until the valve has been seated in the annulus.
- Do not use hard or rigid instruments to test leaflet mobility, as this may result in structural damage to the valve or thromboembolic complications. Use a St. Jude Medical™ leaflet tester to gently test valve leaflet mobility.
- Do not use cutting edge needles in the sewing cuff. If use of these needles is necessary, placement of sutures in the outer half of the sewing cuff is imperative.
- Never apply force to the valve leaflets. Force may cause structural damage to the valve.
- Use only the valve holder/rotator packaged with the SJM Regent™ Mechanical Heart Valve to perform valve rotation. Use of other instruments could result in structural damage. The valve holder/rotator is intended for single use only and should be discarded after surgery.
- The two retention sutures on the valve holder/rotator must be cut and removed before the SJM Regent™ Mechanical Heart Valve can be rotated.
- Do not pass catheters or other instruments through St. Jude Medical™ mechanical heart valves. This could result in scratched or damaged valve components, or leaflet fracture or dislodgment.
- Cut suture ends short, especially in the vicinity of the pivot guards, to prevent leaflet impingement.

PRECAUTIONS

- Do not touch the prosthetic valve unnecessarily, even with gloved hands. This may cause scratches or surface imperfections that may lead to thrombus formation.
- Be careful not to cut or tear the valve sewing cuff when removing the identification tag and the holder/rotator from the SJM Regent™ Mechanical Heart Valve.
- Before placing sutures in the valve cuff, verify that the valve is mounted correctly on the valve holder/rotator.
- To avoid structural damage, the valve must be rotated in the fully closed position.
- To minimize rotational torque, verify that the valve holder/rotator is properly seated in the valve, and that the valve holder handle is perpendicular to the valve.
- Remove any loose suture or thread, which may be a source of thrombus or thromboembolism.

POTENTIAL ADVERSE EVENTS

Complications associated with replacement mechanical heart valves include, but are not limited to:

- Hemolysis
- Infections
- Thrombus or thromboembolism
- Valve dehiscence
- Unacceptable hemodynamic performance
- Hemorrhagic complications secondary to anticoagulation therapy
- Prosthetic failure
- Heart failure or death

Any of these complications may require reoperation or explantation of the device.

1. Abbott. Data on File.
2. Elizondo, D. R., Boland, E. D., Ambrus, J. R., & Kurk, J. L. (1996). Mechanical cardiac valve prostheses: wear characteristics and magnitudes in three bileaflet valves. *The Journal of Heart Valve Disease*, 5(Suppl. 1), S115-123.

The information provided is not intended for medical diagnosis or treatment or as a substitute for professional medical advice. Consult with a physician or qualified healthcare provider for appropriate medical advice.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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3200 Lakeside Dr., Santa Clara, CA 95054 USA
Tel: 1 800 227 9902
www.cardiovascular.abbott

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