

**ATS OPEN PIVOT® BILEAFLET HEART VALVE
PATIENT INFORMATION BOOKLET**

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The Structure and Function of Heart Valves

Your heart is a pump. It pumps blood that brings nourishment (food and oxygen) to the organs and tissues of your body.

Your heart has four chambers. The chambers on the right side of your heart pump blood only to your lungs; the left side chambers pump blood to the rest of your body. The left side chambers are thicker and stronger than those on the right.

There are four heart valves. Their job is to ensure that blood flows forward as your heart contracts and relaxes. The valves are made of thin but very strong flaps of tissue that open and close as your heart contracts and relaxes.

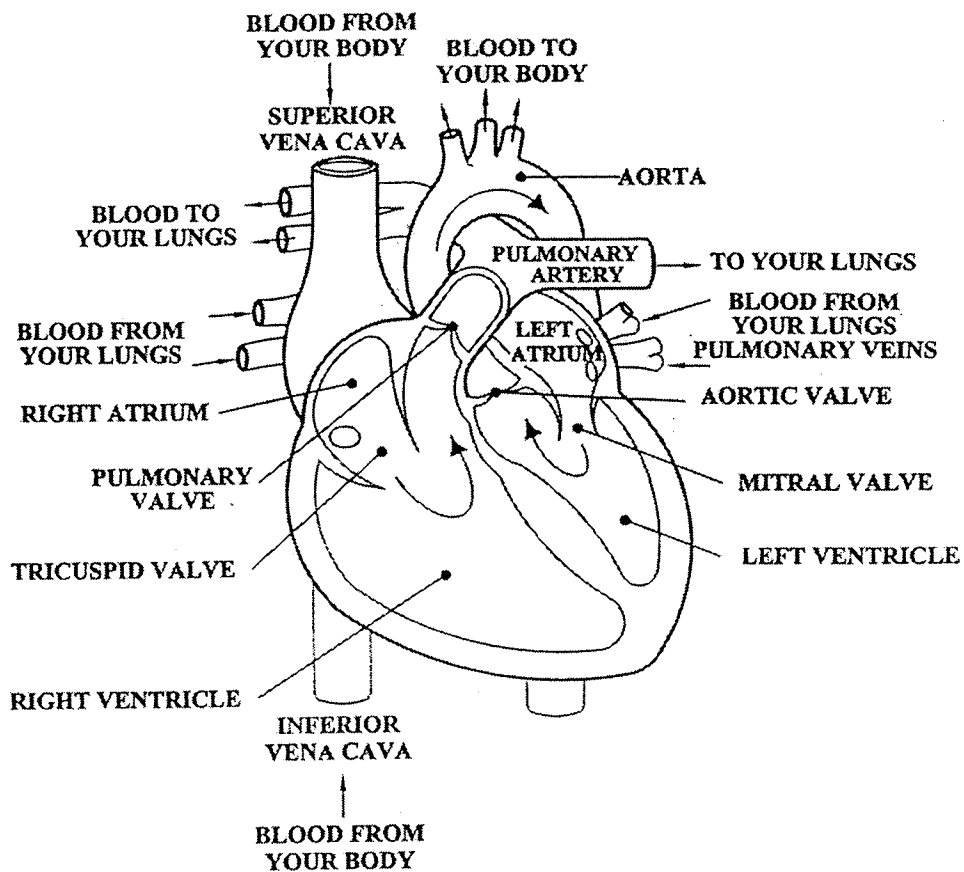
The diagram below shows the four chambers of the heart and location of the valves. It also shows, using arrows, how blood flows through the heart.

Heart Valve Disease

Heart valves may not always work as well as they should. Several things can cause problems with them. When disease causes the tissues to thicken and harden, the valve fails to open properly and blocks or interferes with blood flow. This blocking process is called stenosis. When a heart valve becomes weak or stretched, it may not close properly. If that happens, blood can leak back through the opening. This leakage is called regurgitation, incompetence, or insufficiency.

Any problem with a heart valve greatly increases your heart's work. That may cause the heart to enlarge or thicken to make up for its extra workload.

BLOOD FLOW THROUGH YOUR HEART'S CHAMBERS AND VALVES



Treatment Alternatives

Some people with diseased or damaged heart valves can lead normal lives as long as they get careful medical supervision. Medical treatment with drugs may prevent the need for further intervention. Others with more severe heart valve damage need surgery.

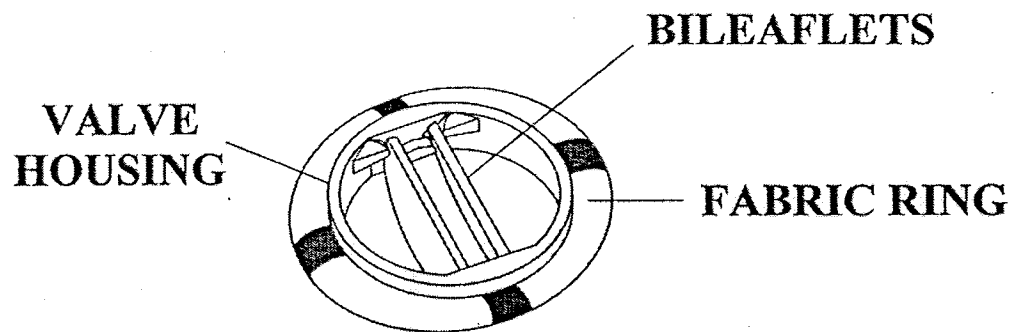
In some cases, operating to repair a patient's own valve may relieve the stenosis or leakage. In other cases, the valve is so badly damaged that it must be replaced.

The best solution depends on the patient's clinical condition as well as the patient's needs. Your doctor will discuss the options and recommend the best way to treat your condition.

Heart Valve Replacement

Sometimes heart valves are seriously deformed, degenerated, or destroyed. When that's the case, repairing the valve isn't reasonable. The old damaged native valve is removed and replaced with a new non-native prosthetic valve, which can be mechanical or made of tissue.

Mechanical valves are made of hard and durable metals, carbon ceramics, and plastic fabrics. These materials have been used for many years in mechanical heart valves. A fabric ring made from polyester is used to attach the mechanical valve to tissues in the patient's heart. The cuff in larger mitral valve sizes contains a polytetrafluoroethylene (PTFE) surgical felt. The ATS mechanical heart valve uses two half discs (bileaflets) that tilt to open and close. The leaflets are hinged to the valve housing.



The advantage of mechanical valves is that they are durable due to the strong materials used in their construction. These materials, however, are not natural to the body so they may need medications (anticoagulants) to prevent blood clots from forming on the mechanical valve. Most patients with mechanical valves must take anticoagulant medications every day for the rest of their lives. The effect of the drug on blood clotting must be regularly checked by a blood test called the prothrombin time or measurement of the International Normalized Ratio (INR).

A tissue valve has the advantage of being similar to the natural heart valve it replaces. That's why these valves are well tolerated in the body without special medication. The disadvantage of a tissue valve is that it is usually less durable than natural valves or mechanical valves.

A surgeon will use his or her experience and knowledge to recommend the valve best suited for a patient's condition. Factors include the patient's age, the extent of valve disease, the size of the valve being replaced, the patient's ability and willingness to take anticoagulation medications, and the need for the patient to take anticoagulation medications because of other cardiac conditions.

Surgical Procedure

Heart valve replacement surgeries have been performed effectively and safely for many years. Recent advances in surgical techniques have resulted in less invasive cardiac surgery. You should discuss with your surgeon the best approach for your surgery.

The replacement of your valve begins while your heart function is taken over by a heart-lung machine, which is also known as cardiopulmonary bypass. As blood enters the bypass system, carbon dioxide is exchanged for oxygen in a manner similar to your lungs. During the procedure your blood is filtered and maintained at the proper temperature.

Preparing for Heart Valve Surgery

If your doctor has told you that you need an operation to replace your valve, it is natural to feel anxious. It is important for you to understand why you need an operation and discuss this with the health care professionals involved in your case. Asking questions and discussing the procedure with your health care team should help you address your concerns.

After hospital admission, you'll have an opportunity to meet the surgeons, cardiologists, anesthesiologists, nurses, and therapists involved in your treatment. Feel free to include family members so that they'll understand the course of your treatment and care.

During Surgery

Heart valve operations take about 3-5 hours. While you're in the operating room, anesthesia will bring deep sleep, freedom from pain, and an absence of memory during the operation. During your operation, your family and friends should stay in the waiting room so the surgeon knows where to find them and keep them informed.

After the Surgery

Following the operation, you will be taken to an intensive care unit or recovery room. This room has special equipment to monitor your blood pressure, temperature, heart rate, and other body functions. The nursing staff will assist you while you awaken and become conscious after the operation. Family members may briefly visit shortly after your operation. The nursing staff will provide information regarding visits.

When intensive care monitoring is no longer needed, most hospitals move patients to a regular hospital floor. Once transferred, patients are encouraged to resume normal daily activities.

Returning Home

- Most heart valve patients often feel better after the operation because the symptoms of their valve disease have been relieved. Your doctor will prescribe specific information regarding your routine at home, exercise, driving a car, and returning to work.
- It is important to get back into a normal sleeping and waking routine as soon as you can.
- Follow your doctor's recommendations for exercise and increasing physical activity. Fatigue and emotional ups and downs are common during recovery. These are normal reactions.
- Some patients have reported that they have been able to hear their valve "click" as it closes. This is a normal part of valve operation. Most patients adjust to the sounds. Your health care team can suggest ways to minimize valve sounds such as using background music.

It is important that you follow your health care team's instructions during your recovery.

- All prescription medicines must be taken according to the instructions provided. If you have any questions, be sure to contact your physician and/or pharmacist.
- Be sure to tell all of the people that you go to for health care that you have had a replacement heart valve. Be especially sure to tell your dentist and anyone you go to for surgery. **During dental work, as in other surgical procedures, bacteria can be released into the blood stream and cause an infection in the replacement valve. Antibiotics before and after surgical or dental procedures will prevent possible infections.**
- Eating nutritious meals is important to the healing process.
- **Limiting how much salt you eat is often advised after heart valve replacement operations.** Salt may increase your blood pressure. Ask your health care team about how salt affects your overall medical condition. Some medical conditions may require special diets. Your health care team will provide dietary information.
- Anticoagulant medicine to prevent blood clots from forming on your replacement heart valves may be prescribed by your doctor. These medicines slightly prolong blood clotting time. Your doctor will prescribe a dose of medicine to keep your blood clotting within strict limits. It is important to very carefully follow your doctor's instructions about using this medicine and take it exactly as prescribed.

Patient I.D. Card

The U.S. Food and Drug Administration requires manufacturers to track replacement heart valves and maintain patient records. Before you leave the hospital, the staff will provide you with a patient identification card. You should keep this card with you for information about your valve that may be requested by your health care providers. The card provides information about your

replacement valve.

You should notify ATS Medical if you move so that we can update our records for the tracking regulations.

Example of ATS Medical Patient I.D. Card:

Front of I.D. Card:

Name/Address: (If you move, notify ATS Medical)

Smith, Mary

456 First St.

Anytown, MN 55447

Serial No: 12345

Size: 23 mm

Position: aortic

Implant date: 11 Mar 2000

Physician:

John Doe, M.D. Phone:

Back of I.D. Card

Heart Valve Patient Identification Card

ATS Medical, Inc. Heart Valve

Toll Free 800 399 1381

**Other Important Information on the ATS Open Pivot®
Bileaflet Heart Valve**

Indications for Use

The ATS Open Pivot® Bileaflet Heart Valve is intended for the replacement of diseased, damaged, or malfunctioning heart valves.

Risks of Heart Valve Surgery

The risks of heart valve surgery depend on your overall medical condition. Your physician will discuss the risks and complications based on your medical history. Your physician will answer questions about the surgery.

Benefits of Heart Valve Surgery

People who have heart valve disease may feel handicapped. Heart valve surgery may be an effective option to improve your quality of life. Many patients can do things after an operation that were no longer possible before surgery. Improvement can be expected in 3-6 months. Your recovery depends upon how well you follow your health care team's instructions, exercise, and follow a healthy life style.

Contraindications

There are no known contraindications to heart valve replacement surgery if the patient has been determined to be a candidate for mechanical heart valve replacement.

Magnetic Resonance Imaging (MRI)

The ATS Open Pivot® Bileaflet Heart Valve has been shown to be MRI safe when tested using MR systems operating with shielded static magnetic field strengths of 1.5 Tesla or less. However, the testing may cause significant MRI image artifacts or distortion. This phenomenon should not produce any harmful effects.

For additional information please contact:

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