LIVING WITH YOUR NEW HEART VALVE
A PATIENT INFORMATION GUIDE

MEDICAL CARBON RESEARCH INSTITUTE, LLC
MAKERS OF THE
ON-X™ PROSTHETIC HEART VALVE

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Heart valve surgery has proven to be very successful over the past 30 or more years. Still, the thought of heart surgery very often causes real apprehension. Medical Carbon Research Institute has prepared this information booklet for you and your loved ones to give you a better understanding of what heart valve replacement involves.

Surgical treatment of heart valve disease has proven to greatly improve the quality of the daily life and health of most patients who undergo valve surgery. Information in this booklet provides a basic understanding of your surgery. Clinical terms which are used throughout this booklet are defined within the glossary at the end of this booklet; these terms which are defined in the glossary are highlighted in bold lettering at the first use of the term.

This booklet cannot answer every question you may have. Your doctors can provide answers to questions which you might have that are not addressed within this booklet. It is suggested that you prepare written questions that you want your doctor to answer before your appointment; then, write down the doctor's answers in the office so that you can refer to them later.

THE HEART

The heart, as we all know, is critical to our lives. It acts as a pump to keep the blood delivering the life-maintaining nutrients that all parts of our bodies require.

The heart's minute to minute, continual function as a pump, however, is something that sometimes needs repair. Just as any other pump we encounter in our daily lives may break down, the heart can also break down.

How does the heart work? The heart consists of four chambers (two atria and two ventricles) that beat regularly in an orderly fashion to push blood through the body and lungs. The flow of blood into and out of these chambers is regulated by four heart valves: two of the valves are located between the atrial and ventricular chambers, and two are located between the ventricles and arteries. These valves open and close to regulate blood flow, opening to allow forward blood flow and closing to prevent backward blood flow. Without these valves, working as they are supposed to, the heart could not work effectively as a pump. Blood is brought to the **right atrium** of the heart from all parts of the body through the veins. Contraction of this atrium then 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. 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 the right ventricle contraction.

The four heart valves (Figure 1) 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.

VALVE DISEASE

The normal heart valve performs an amazing mechanical function, opening and closing with each beat of the heart, about 40 million times per year for an entire lifetime. That is over 2.5 billion times, generally without failure.

Unfortunately, there are times when heart valves may not work properly. Sometimes in children there will be congenital defects at birth, which sooner or later will result in valve malfunction. 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 deposits of calcium on the valve, which will also require repair or replacement. When a valve malfunctions, three 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** or **insufficiency**).

3. The valve neither opens nor closes properly, a combination of numbers 1 and 2 above.

Fortunately, today valve surgery can be performed to correct these problems and restore the function of the valves, thus restoring general health in many patients.

TREATMENT OF VALVE DISEASE

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

For some patients, the existing natural valve will need to be replaced by a prosthetic valve. In other cases, surgical repair of the natural valve can be done. Your doctor will explain your case, and the options you have in your upcoming surgery.

If your doctor recommends a prosthetic heart valve, there are two types of prostheses likely to be considered: a mechanical **prosthesis** or a tissue prosthesis. Mechanical heart valves are made of

synthetic materials and are designed to mimic as closely as possible the function of the natural valve. Early designs (Figure 2) were floating ball-in-cage types, and more recently tilting disc (also called monoleaflet and/or bileaflet) designs have been made.

Tissue valves (Figure 2) have been made from chemically-treated porcine (i.e., from a pig) aortic heart valves or bovine (i.e., from a cow) pericardium (the pericardium is a sac of tissue that surrounds the heart). Human heart valves that have been preserved by freezing are also available, but in very limited numbers. Each type of valve has its advantages and disadvantages. Your doctor will explain the choices of valves to you and go over all the various pluses and minuses of each valve type.

YOUR SURGERY

BEFORE:

As you prepare for surgery, take the time to think of any questions you have, and ask them. Find out what to expect in the hospital, what complications are possible in your case and how often they can occur. Ask about your preoperative, operative, and postoperative care, and ask about the procedure and valve that will be used in you. You will also want to ask about your recovery and resumption of normal activities. Express your concerns to your doctor, and if it's available get support from a local patient support group. In the United States, one such group is The Mended Hearts, 7272 Greenville Avenue, Dallas, Texas 75231, 1(800) 242-8721, www.mendedhearts.org.

THE HOSPITAL STAY:

On the day of surgery you will be prepared to go to the operating room by the nursing staff. Then you will be taken to the operating room, where one of your doctors will give you the anesthesia, which will cause you to sleep. The operation will generally take about 3 to 5 hours and will use the latest heart surgery techniques and equipment.

After the surgery, you will be taken to the intensive care unit, where you will wake up a few hours later. Under normal circumstances, you will remain there for about 48 hours, until you can be transferred to a regular hospital room.

In the next few days, you will progress steadily from sitting to standing to walking and from liquid food to solid food. In general, you are more likely to feel sensations of pressure in the chest and stiffening in the back and neck, rather than pain. You will be given physical therapy with breathing exercises, which are important to your recovery.

AFTER:

When you leave the hospital, your doctor will give you a routine to follow at home for your complete recovery. Your physical activities will be restricted at first, and then gradually you will return to normal activities. In many cases, you may find you are able to do more after your surgery than you were able to do before the surgery. Follow your doctor'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 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 doctor. 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, which are discussed later. It is important that you are fully aware of the proper use of this class of drugs. You should also be aware that other medicines can interfere with the action of your anticoagulant. Do not take any other medications without first clearing them with your doctor. Make certain that your doctor and other doctors who you see consider the effect of new medications on your anticoagulant before they prescribe them.

Follow-up visits to your doctors will be scheduled over the first 6 – 12 months. Take advantage of these visits to ask questions and become more familiar with your valve.

PROBLEMS WITH PROSTHETIC HEART VALVES

As well as heart valves are designed, and as good as medical care can be, problems can still arise as a result of your heart valve surgery. Some of the complications of valve surgery are described here, including how to recognize the problems, what to do about them and how to help prevent them. These problems do not occur in most patients, but awareness of them can increase the likelihood of success with your new valve.

Anticoagulant-related bleeding - With all mechanical valves and many tissue valves, your doctor will prescribe an anticoagulant medication for you to take continually after the surgery. In some instances, patients may suffer from unexpected bleeding due to these medications. Some signs to watch for are: cloudy urine, black bowel movements, general weakness and unusual pains in the abdomen. If you think you may have this problem contact your doctor immediately. It is extremely important when taking an anticoagulant that you have your blood monitored closely, that you work closely with your doctor to be sure you are taking the drug in the right amount and that you take this drug at the same time every day without fail. It is highly recommended that you carry identification noting that you are taking an anticoagulant. Identification cards and bracelets are available from several sources, including the MedicAlert Foundation, 2323 Colorado Avenue, Turlock, California 95382, 1(888) 633-4298, www.medicalert.org.

Thrombotic complication - With any valve, 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 and travel with the blood to another part of the body and then block blood flow to that area (**thromboembolism**). If you notice a return of some of the same problems you had before surgery, or if you experience any unusual dizziness, blurred vision, loss of hearing, numbness or weakness, contact your doctor immediately. The occurrence of bleeding and thrombotic complications reflect the delicate balance required in taking your anticoagulants. Close cooperation with your doctor in controlling your medicine can minimize the occurrence of both these complications. Regular, routine blood tests will be required to assure that your

anticoagulant prescription is correct.

Prosthetic valve infection – Any foreign body placed inside your body is subject to the possibility of becoming infected. While this does not occur often with prosthetic heart valves, it is something about which you should be aware. Any fever which you experience should be reported to your doctor. Your doctor will have tests run to rule out prosthetic valve infection. You can minimize the chance of this occurring by keeping all your doctors informed that you have a heart valve prosthesis. Especially inform your dentist, because any dental procedure carries the risk of infecting your prosthesis. Your dentist will prescribe an important antibiotic treatment prior to your dental appointments to help avoid infection. Be careful with anything that could lead to an infection, such as cuts and blisters, and keep your doctor informed of any suspicious events.

Hemolytic anemia – In rare circumstances, cases of anemia have been reported with heart valve replacement. This occurs when too many red blood cells are damaged and broken down by contact with, or flow through, an artificial valve. Red blood cell breakdown leads to a reduction in oxygen-carrying hemoglobin, which can cause listlessness, weakness, or fatigue. Your doctor is aware of this possibility and can provide treatment when necessary.

Prosthetic valve failure - Failures of prosthetic heart valves have been reported. For tissue valves, failure generally is a slow, progressive deterioration of valve function ending in the need to replace the prosthesis. This can occur anytime from 1 to 15 years or more after implant. Mechanical valves fail much less frequently, but when they fail, they generally fail rapidly without early warning. Any sudden change in your health is cause for serious concern, and medical attention is required immediately. Although mechanical valve failure is rare, it is extremely urgent to correct it immediately when it occurs.

While the occurrence of the above-mentioned problems may be low, it is critically important to recognize that they can be very serious problems when they happen. Untreated, these problems can be a real threat to your life. Therefore, you should not hesitate to contact your doctor immediately and receive treatment as fast as possible if anything unusual happens. **WITH YOUR AWARENESS AND YOUR DOCTOR'S CARE, THE HAZARDS OF THESE PROBLEMS CAN BE MINIMIZED.**

YOU AND YOUR DOCTORS

Clearly, you can have a major effect on the success of your new heart valve. Being diligent and careful with your medications and communicating with your doctors are extremely important things you can do. Because of the impact that both you and your doctors have on your health, it is highly recommended that you develop a continuing, open, honest and trusting relationship with your doctors. If you experience any unusual sensations, any of the problems described earlier or any of the symptoms you had prior to surgery, contact your doctor immediately.

Because continuing medical care is now important in your life, it is important that you carry an emergency identification card at all times, and that you consider membership in an emergency identification plan such as MedicAlert.

An identification card is provided with your valve and should be given to you by the hospital staff. Please fill out and carry this card with you at all times. If you do not receive the card, please contact Medical Carbon Research Institute, Patient Records Department, at (888) 339-8000, and one will be sent to you.

GLOSSARY OF MEDICAL TERMS

Anticoagulant	A substance which inhibits the blood clotting mechanism. Anticoagulant drugs are given to maintain the blood in a fluid state, thereby preventing abnormal or pathological clotting.
Anticoagulant Therapy	A management program of long-term anticoagulation for patients with chronic propensities for blood clot formation.
Aorta	The main artery that conducts oxygenated blood from the left ventricle 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.
Biological (or Tissue) Graft	A general term which can be used to refer to a non-living glutaraldehyde-preserved graft or to a living cryopreserved graft. May be further subdivided into: Allograft: Donor and recipient of the graft are the same species (i.e., human) Homograft: Donor and recipient of the graft are the same species (i.e., human) Heterograft: Donor and recipient of the graft are different species (e.g., pig) Xenograft: Donor and recipient of the graft are different species (e.g., pig) Autograft: Transplant from one part to another part of a patient's own body
Bovine Graft	A biological graft derived from a cow (a variety of heterograft or xenograft).
Chordae Tendineae	The "parachute" strings that bind the free edges of the atrio-ventricular valves (the mitral valve and the tricuspid valve) to the papillary muscles.
Cryopreservation	The preserving of living cells, tissues, or organs by subjecting them to very low temperature processes. Cells and tissues preserved by this method continue to maintain

	viability even after thawing and transplantation.
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.
Coumarins	A family of anticoagulant drugs that inhibit the formation of certain blood clotting factors made by the liver.
Embolism	A particle, such as a thrombus, debris or an air bubble, circulating in the bloodstream.
Glutaraldehyde	A chemical substance used to fix, sterilize and store non-living tissue or biological grafts.
Heart-Lung Machine	A mechanical device, also called a pump oxygenator, that temporarily takes over the functions of the heart and lungs and is used during cardiac surgery.
Hemodynamics	The study of the movements of blood.
Hemolysis	Red blood cell damage, which can lead to hemolytic anemia.
Incompetence	With heart valves, the inability to close completely and prevent backflow. Also known as insufficiency or regurgitation.
Inferior Vena Cava	The large vein that collects deoxygenated blood from the veins of the legs and lower body and delivers it to the right atrium.
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.

Mitral Valve	A large "parachute"type atrio-ventricular valve located between the left atrium and the left ventriclethat prevents backflow of blood into the left atrium.
Porcine Graft	A biological graft derived from a pig (a variety of heterograft or xenograft)
Pressure Gradient	A differential pressure between two areas, which for a heart valve signifies the pressure difference across the valve.
Prosthesis	An artificial body part.
Pulmonary	Pertaining to the lungs.
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. Its 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.
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.
Semilunar	Literally, half-moon shaped, pertaining to the characteristic shape of the leaflets of the aortic and pulmonary valves.
Stenosis	A narrowing of the heart valve orifice (opening), which prevents the valve from

	opening completely and decreases the blood flow through the valve. *Aortic Stenosis*: a narrowing of the aortic valve orifice. *Mitral Stenosis*: a narrowing of the mitral valve orifice. *Pulmonary Stenosis*: a narrowing of the pulmonary valve orifice. *Tricuspid Stenosis*: a narrowing of the tricuspid valve orifice.
Superior Vena Cava	The large vein that collects deoxygenated blood from the veins of the head and upper body and delivers it to the right atrium.
Systemic Circulation	The circulation of oxygenated blood from the left ventricle of the heart to all systems and organs of the body. It is also known as the *greater* circulation because the flow path is long and higher pressures are required for it to operate efficiently.
Thromboembolism	The formation of a blood clot which circulates in the bloodstream and blocks a vessel.
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 blood clot.
Tricuspid Valve	An atrio-ventricular valve located between the right atrium and the right ventricle that prevents backflow of blood into the right atrium.

IMPORTANT CONTACTS

SURGEON

NAME _____
ADDRESS _____
_____
TELEPHONE _____

CARDIOLOGIST

NAME _____
ADDRESS _____
_____
TELEPHONE _____

NEAREST RELATIVE

NAME _____
ADDRESS _____
_____
TELEPHONE _____

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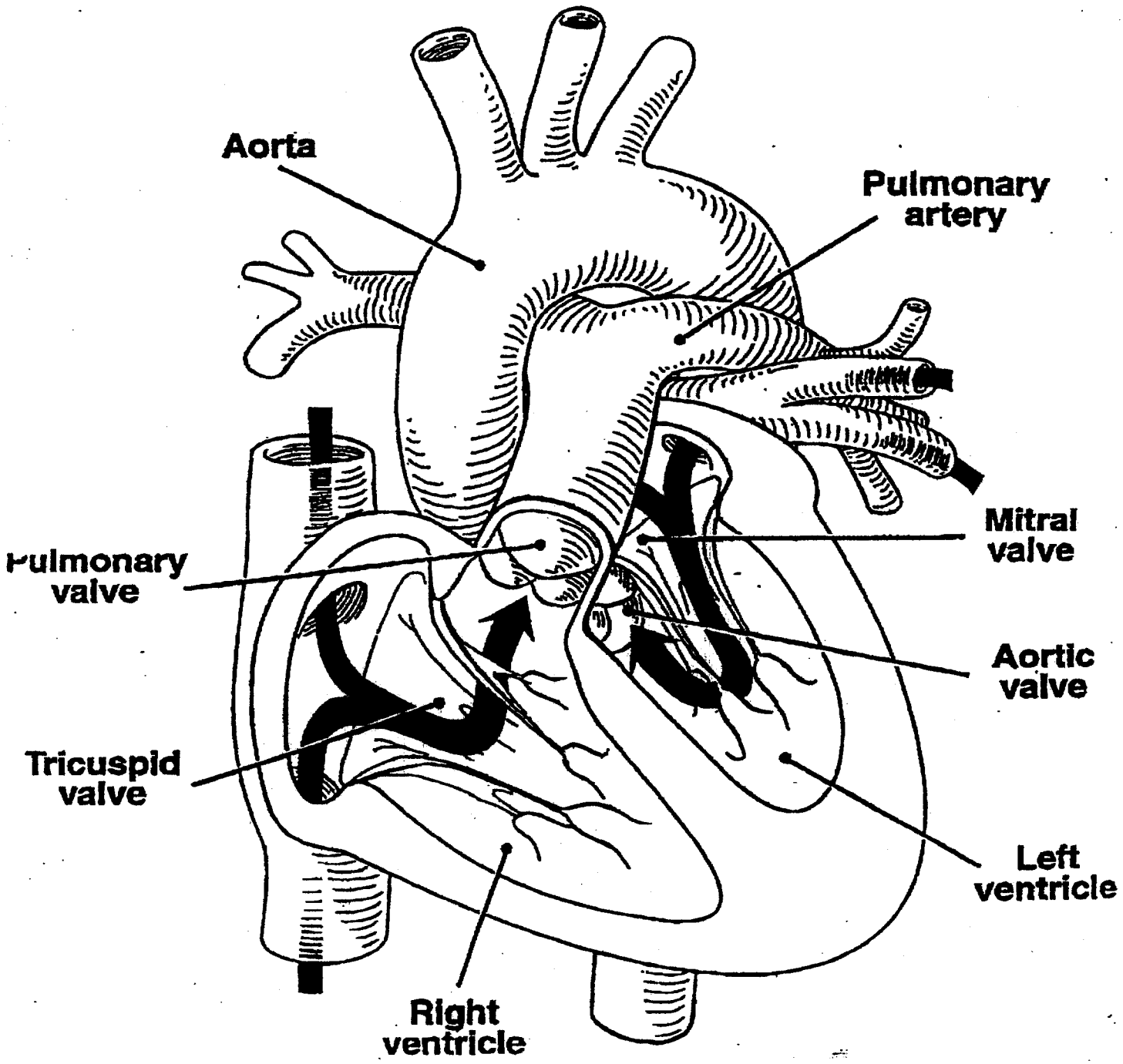
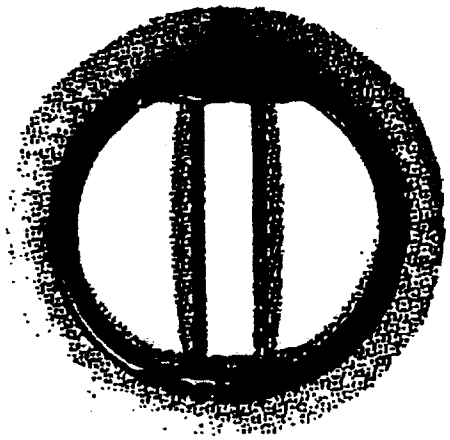
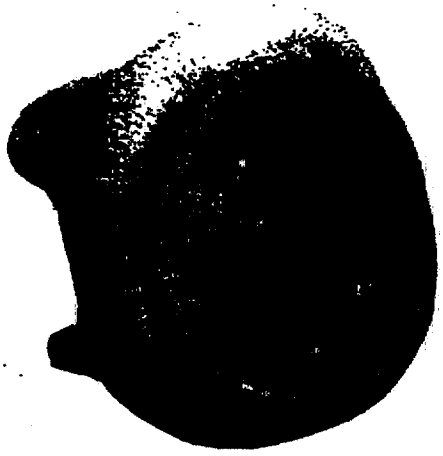

Aorta
Pulmonary artery
Pulmonary valve
Mitral valve
Aortic valve
Tricuspid valve
Left ventricle
Right ventricle

Figure 1

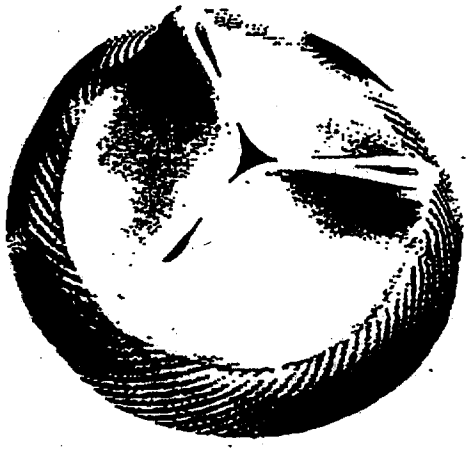
Tilting Disc Mechanical Valve



Bileaflet Mechanical Valve



Porcine Tissue Valve



Pericardial Tissue Valve

Figure 2

Patient: _____

Address: _____

_____

_____

Telephone: _____

In case of Emergency Notify:

Name: _____

Address: _____

_____

_____

Telephone: _____

This person has a mechanical prosthetic heart valve implant. Any medical care should consider this fact. Generally, this person is maintained on permanent anticoagulation drug therapy.

The On-X® Prosthetic Heart Valve has been shown to be magnetic reasonance imaging (MRI) safe when tested using systems operating with shielded static magnetic field strengths of 1.5 Tesla or less. Note, however, that the effects of a time-varying magnetic field were not examined. The testing should not cause significant MRI image artifacts or distortion. Should this occur, this phenomenon produces no harmful effects to the patient.

Patient Record Card

On-X® Prosthetic Heart Valve

SZmm:

SN-

MCRI™
8200 Cameron Road,
Suite A-196
Austin, Texas 78754 USA

Medications:

Type	Dose

Next Doctor's Appointment

Position: _____

Implant Date: ___ /___ /_____

Surgeon: _____ Telephone: _____

Address: _____

Following Physician: _____ Telephone: _____

Address: _____

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