UNDERSTANDING YOUR HEART VALVE
Hancock® II Valve
Hancock® Valved Conduit
A Message to You from the Employees at Medtronic, Inc.

We understand that having heart valve replacement surgery is an important change in your life. First, we want to assure you that we have been helping patients for more than 50 years. Each year, millions of patients are treated with Medtronic products and therapies.

Our company’s mission is to help restore people to full life and full health. Our products are of the highest quality because we, as employees, are passionate about this mission. We are proud of Medtronic’s reputation for quality, integrity, and innovation and are always looking for ways to enhance our product line to improve therapy for you—and all the patients we serve.

At Medtronic, we see our work as making a difference in your life. You are what motivates us to do our very best.

We wish you well in the days and months ahead, and welcome you to the Medtronic family.
Prosthetic (artificial) heart valves such as the Hancock® valves are used by physicians to replace the heart’s natural valves when they have been damaged, diseased, or weakened by age and no longer adequately control the flow of blood within the heart. Prosthetic valves are also used to replace other prosthetic valves that are no longer functioning properly.

This booklet is provided to help you and your family learn about Hancock valves and the Hancock® Valved Conduit and to answer questions you may have.
What is a heart valve?

Your heart is a powerful, muscular pump. Its continuous pumping action keeps your body supplied with oxygen-rich blood. Valves are essential to your heart’s pumping action. Your heart has four valves, or tissue flaps, that open and close, allowing blood to move between your heart’s four chambers. Each valve controls the flow of blood, causing it to flow forward into the next chamber. When your heart’s valve or valves become diseased, damaged or weakened by age, the pumping ability decreases.
What are the options in heart valve replacement?

When a patient requires a heart valve replacement, two types of prosthetic (artificial) heart valves are available: a **mechanical heart valve**, or a **tissue valve** that is made of animal or human tissue.

In simple terms, a mechanical valve is a ring through which blood flows in the heart. Mechanical valves are made from biocompatible materials such as titanium or carbon. In the device is a single movable disc or two “leaflets,” which open and close like a natural heart valve to control the flow of blood.

Tissue valves are rings or cylinders of material through which blood flows in the heart. Two types of tissue valves are available to patients: stented tissue valves and stentless tissue valves. A stented tissue valve is made from animal tissue and mounted on a plastic or metal frame called a “stent.”

A stentless tissue valve is most often an actual heart valve obtained from a human donor (homograft) or a pig (porcine bioprosthesis), whose anatomy closely matches that of humans. A stentless valve can also include some of the aorta, the large vessel that delivers blood to the body.

What is a Hancock® heart valve?

A Hancock® valve is a stented tissue valve obtained from a pig’s heart, which is very similar to a human heart. The valve leaflets, which control the flow of blood, are fitted and secured to a flexible frame (“stent”) that supports the valve. Utmost care is
taken in the handling, fitting, and sewing of the tissue to the stent to maintain the natural shape of the valve. The stent is covered with a cloth that is used to sew the valve into the heart. Each heart valve is quality control tested to assure optimal performance.

What is a Hancock® Valved Conduit?

A Hancock® Valved Conduit consists of a Hancock valve sutured into the center of a woven polyester fabric cylinder. The conduit is used for reconstructive procedures for the repair of congenital or acquired cardiac and blood vessel malformations.
What makes the Hancock® valve a good choice for my heart valve replacement?

Around the world, surgeons have implanted Hancock® valves for more than 20 years with good results. Clinical reports on Hancock valves have been published in numerous medical journals. Many patients who have a Hancock valve implanted can expect to experience less of the pre-operative symptoms of fatigue and shortness of breath.

The following illustration shows how a Hancock valve is placed within the heart to help it pump efficiently.
How long will a Hancock® heart valve last?

Prosthetic tissue valves wear slowly, in much the same way natural valves do. They typically last from 7 to 15 years, depending on the age of the patient. Fortunately, because tissue valves degenerate slowly, the patient and physician have time to plan for a reoperation, if one is required.

Is anticoagulation or other medication necessary?

Anticoagulation medication is a treatment prescribed by physicians and given to mechanical valve replacement patients and sometimes to tissue valve patients. It is used to prevent blood clots, which can be a serious health risk.

While anticoagulation medication will help prevent clots, it does so by delaying the blood coagulation process. Therefore, cuts and scrapes will bleed a little longer than normal. If anticoagulation medication is prescribed, it should be taken exactly as instructed.

The need for anticoagulation medication is usually minimal with tissue valves such as a Hancock® valve. Therefore, a Hancock® valve may be especially useful for: women in their childbearing years; elderly patients; and patients for whom anticoagulation medication is not recommended.

It is important to tell your dentist or physician that you have a heart valve before any dental work or surgical procedure is performed, as antibiotics may need to be prescribed. Consult with your doctor if you
have questions relating to your medical regimen or any significant symptoms or changes in your health or lifestyle.

What can I do to help maintain a healthy lifestyle with my newly replaced heart valve?

- Take all medications exactly as prescribed. It is normal for some heart valve patients to take anticoagulation medication.
- Tell your dentist or other doctors caring for you that you have had valve surgery. You may need to take antibiotics before your appointment.
- Inform your doctor of dramatic, unexpected weight gain, fever, pain, and other symptoms.
- Eat a low-salt diet if your doctor prescribes it for you.
- Follow your doctor’s recommendations to incorporate exercise and other physical activity into your life.
- Notify your doctor if you have any lifestyle changes.
Is it safe to have an X-ray when I have an artificial heart valve?

All prosthetic heart valves, including Hancock® valves, are completely safe with X-ray examinations.

Is it safe to have an MRI when I have a prosthetic heart valve?

Hancock Valves have been tested for MRI safety at 3.0 tesla. Your MRI center may request the information below.

- Static field ≤ 3.0 T
- Spatial gradient field ≤ 3.9 T/m
- Maximum whole body SAR of 1.1 W/kg for ≤ 20 minutes as read from equipment monitor

Is it safe to go through airport security when I have an artificial valve?

Airport security systems have no adverse effects on prosthetic heart valves, and normally the valves will not activate any alarms.

Resources for Patients

Please contact your physician or nurse for more information.

Help on the Internet:
- Medtronic Heart Valves: www.heartvalves.com
- American Heart Association: www.americanheart.org
- Heart Information Network: www.heartinfo.org
- Med Help International: www.medhelp.org
The Hancock® II valve is used to replace your heart’s natural valve when it has become diseased or weakened by age. It can also be used to replace your prosthetic valve when it is no longer working properly. (A prosthetic valve is a replacement valve made of human, animal, or artificial materials.) Valve replacement can include the following risks:

- Angina.
- Abnormal heart beat (cardiac arrhythmia and dysrhythmia).
- 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).
- Damage to red blood cells (hemolysis) that can result in anemia.
- Death.
- Inflammation of the lining of the heart (endocarditis).
- Heart failure.
- Any problem with the prosthetic valve that causes narrowing of the valve opening (stenosis).
- 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).

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

The Hancock® Porcine Valved Conduits is used to replace your heart’s natural aortic valve and the ascending aorta when it has become diseased or weakened by age. It can also be used to replace your prosthetic valve when it is no longer functioning properly. (A prosthetic valve is a replacement valve made of human, animal, or artificial materials.) Hancock® Valved Conduits are particularly intended for those patients where anticoagulants may be contraindicated. These valves should not be used in patients who are undergoing chronic hemodialysis. These patients have an increased tendency towards calcification of tissue valved conduits.

Valve replacement procedures may include, but are not limited to the following risks:

- Death.
- Failure of the valve to open and close properly.
- Infection.
- Damage to red blood cells (hemolysis) that can result in anemia.
- Blood clot formation on or around the valve. These blood clots may break loose and travel in the bloodstream (thromboembolism/thrombosis).
- Blood leaking across the valve or between the valve and the patient’s tissue (transvalvular leak/paravalvular leak).
- Hemorrhage.

This list is not inclusive of all risks. Talk to your physician regarding more information about valve replacement surgery.

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