BRING LIVING BACK TO LIFE

An Educational Booklet for Recipients of the Abbott Portico™ Transcatheter Aortic Valve
Your role in the management of your health is very important. This information is not intended to replace the medical advice of your physician. All medical treatment decisions should be made in consultation with and under the direction of your physician. If the information you receive from your physician differs from this brochure, always follow your physician’s instructions.

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THE PORTICO TRANSCATHETER AORTIC VALVE

The Portico transcatheter aortic valve provides a minimally invasive treatment for patients diagnosed with severe aortic stenosis who are not candidates for open heart surgery.

The Portico transcatheter aortic valve is a tissue valve attached to a stent frame (Figure 1). The Portico valve leaflets are made from bovine (cow) tissue. This tissue is treated to preserve and prevent adverse reactions once the valve is implanted. A catheter delivers and positions the valve inside your diseased aortic heart valve (Figure 2).

HOW A HEALTHY HEART WORKS

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 3). Because of their pumping function, the ventricles are larger than the atria.

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 heartbeats 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 1. Portico transcatheter aortic valve

Figure 2. The Portico valve in place in the aortic heart valve

Figure 3. Chambers of the heart
Figure 4 shows the heart valves. On the right side of the heart, the blood flows through the tricuspid valve, which lies between the atrium and the 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 pulmonary 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.

**WHAT CAUSES SEVERE AORTIC VALVE STENOSIS?**

Heart valves may become defective for a variety of reasons. Some people are born with heart valve defects while others acquire valve damage from infection or other diseases. The results are the same: either a rigid valve that limits forward blood flow or a valve that does not close properly and permits backflow.

The end result of severe aortic valve stenosis 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.
TREATMENTS FOR SEVERE AORTIC VALVE STENOSIS

Symptom Evaluation

If you don’t need heart valve replacement right away, your cardiologist will do a consult and an echocardiogram every six to 12 months to evaluate for possible symptoms and for severity of aortic stenosis on the echocardiogram. If you do not have any symptoms and the valve is severely stenotic (< 1 cm²), your physician may order a “stress echo” to evaluate for possible symptoms and for heart function during exercise.

You should not get medications for symptoms related to severe aortic stenosis. The beginning of symptoms is a clear indication for valve replacement. When valve replacement is indicated, your cardiologist and a consulting surgeon will discuss with you the options of open heart surgery or percutaneous valve replacement.

Open-Heart Surgical Valve Replacement

Heart valve replacement surgery can offer several key benefits. The procedure is designed to help a heart pump blood more effectively, which means a patient may feel better immediately. Other patients may feel better gradually, regaining energy and strength over the first few weeks following the surgery. While there are many benefits to open-heart surgical valve replacement, it is estimated that over 250,000 people living with severe aortic valve stenosis are not candidates for surgical replacement due to age, frailty or other conditions that make surgery too risky.

Portico Transcatheter Aortic Valve Implantation

Portico transcatheter aortic valve implantation (TAVI) provides an alternative, minimally invasive treatment option for people living with severe aortic valve stenosis who are not candidates for open-heart surgery.

Through an incision in the groin, a catheter delivers the Portico valve to the diseased native aortic valve. The Portico valve is then positioned within the native aortic valve and partially opened. If the physician desires to change the position, the Portico valve
can be completely resheathed (the process of bringing the valve back into the delivery catheter), which allows the physician to reposition the valve at the implant site or retrieve the valve, before it is released from the delivery system.

**WHO IS ELIGIBLE FOR THE PORTICO VALVE**

Patients with severe aortic valve stenosis who are not candidates for surgical replacement are eligible for screening by their physician for a Portico valve.

**WHO SHOULD NOT HAVE THE PROCEDURE**

The valve is not recommended for patients with:

- any sepsis, including active endocarditis, and certain types of infections
- any evidence of left ventricular or atrial thrombus (blood clots in the heart)
- femoral, iliac or aortic vascular conditions (narrow veins or arteries with calcification such as stenosis, tortuosity or severe calcification) that make insertion and endovascular access to the aortic valve impossible
- stenotic aortic valve without calcium deposits
- an aortic valve with less than three leaflets
- the inability to take certain medications to prevent blood clotting

**VALVE IMPLANTATION RISKS**

There are risks with any heart valve replacement or implantation procedure. These may include, but are not limited to, blood cell damage; low red blood cell count; bleeding, infection, clotting in or on the valve; tissue on the valve; loose clots in the bloodstream that may block an artery in your arms, legs or brain; valve failure; leakage around the edge of the valve; abnormal heartbeat; stroke; angina; heart failure; heart attack; the need for operation or explantation; and death.
VALVE IMPLANTATION BENEFITS

Transcatheter aortic valve implantation (TAVI) 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 procedure. Be sure to talk to your physician about your progress and get advice on the exercises and activities you can do to regain your strength.

WHAT TO EXPECT IF YOU HAVE A PORTICO VALVE IMPLANT

Implantation of the Portico transcatheter valve differs from that of a surgical replacement valve. Following is a general overview of the procedure; however, your experience may be different. Please consult with your physician on what to expect during a Portico valve implant.

During the Procedure

The Portico implant will take place in a special cardiac suite with a team of physicians and nurses to perform the procedure and care for you. Normally, patients are sedated during the procedure and will not feel any pain. Your physician will decide how much sedation is required for you.

A small incision is made in your femoral artery in your groin and a sheath (access tube) is inserted within your artery. The physicians view the movement of the sheath using special imaging equipment, which guides them to know when the sheath is in the correct position.

Once the sheath is in position, a catheter with a balloon is delivered through the sheath and placed within your aortic valve. The balloon is inflated to open up your aortic valve as much as possible so that the Portico valve can be placed inside of it. The balloon catheter is then removed.
The Portico valve is delivered through the sheath and placed within your opened aortic valve (Figure 5). Your physician will continue to use special visualization equipment to see exactly where the Portico valve is positioned within your heart. The Portico valve will start to function as soon as your physician begins to release it from the catheter.

The sheath and Portico catheter are removed from your heart and groin, and the small incision in your groin is closed or sealed. The procedure is now complete.

**After the Procedure**

At the completion of your Portico transcatheter aortic valve implant, you will be moved to a hospital bed or occasionally to an intensive care unit (ICU) and monitored continuously.

Intravenous lines will give you fluid, blood and medications as needed. The nurse staff will assess your recovery status using a monitor to assess your heart rate, heart rhythm, blood pressure and other measurements. You will receive medications to ease your pain and anxiety as needed.

If you go to an ICU, 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. 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 health care team will continue to support and instruct you in recovery care, rehabilitation, medications, nutrition and other needs. You may stay at the hospital for two to five days until your physician feels that you are ready to be discharged.

Your physician will advise you whether you should take anticoagulation therapy, which is recommended for patients with tissue valves who have risk factors for clotting.
When to Call the Physician

Contact your physician if you experience 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
• bruising
• excessive bleeding
• blood in your urine
• bloody or tarry (blood will typically look like tar after it has been exposed to the body’s digestive juices) bowel movements
• unusual nosebleeds
• fever
• numbness or tingling in your arms or legs
• general weakness or loss of energy
• blurred or loss of vision
• unusual chest sensation

Returning Home

Remember to:

• take medication as prescribed
• follow-up with blood tests as directed by your physician
• enjoy a heart-healthy diet

Most patients have a significant improvement in quality of life after transcatheter valve implantation. Ask your physician what kinds of activities you should avoid. Report any falls, blows to the body or heart, or other injuries to your physician right away.

When you return home, you must take special care of yourself until you are fully recovered. The majority of patients feel meaningful improvement after the aortic valve replacement. Depending on your prior physical abilities, you may need help with rehabilitation to reach full physical capabilities. 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 to speed your recovery.

At your follow-up visit to your physician, around three weeks after discharge, you may need to undergo tests such as an electrocardiogram, echocardiogram or chest x-ray to evaluate how your new valve is working. Your physician 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 physician if you’re planning a trip.

Airport Metal Detectors
The amount of metal used in the Portico valve is very small. It is usually not enough to set off the metal detectors; however, if it does, simply show security personnel your patient identification card. Passing through a metal detector will not harm your heart valve.

MRI Testing
If you are told you need to have an MRI (magnetic resonance imaging), tell the physician that you have an artificial heart valve and show your ID card, which contains important information about how to perform an MRI safely with your valve.

Your physician or MRI technician may request the following information:

Non-clinical testing has demonstrated that Abbott heart valves are MR conditional.

They can be scanned safely under the following conditions:

• static magnetic field of 1.5 tesla (1.5T) or 3.0 tesla (3.0T)
• maximum spatial gradient field less than or equal to 3,000 Gauss/cm (30T/m)
• Normal Operating Mode: Maximum whole-body averaged specific absorption rate of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T

If you have questions or concerns about this and other diagnostic tests and your heart valve, please talk to your physician. It is wise to provide your physician with the information outlined above about MRI testing and your heart valve.

Life After a Portico Transcatheter Aortic Valve Implantation
Once the Portico valve has been implanted, you may experience immediate improvement in your quality of life or this may gradually evolve over time. Improvement may include:

• increased physical activity
• increased energy
• decreased or no chest pain
• decreased or no shortness of breath
Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

REFERENCES:

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 manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

St. Jude Medical is now Abbott.

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