

Transcatheter Aortic Valve Implantation with the Portico™ with FlexNav System

A GUIDE FOR PATIENTS WITH SEVERE AORTIC STENOSIS





Your role in the management of your health is very important. This guide provides you and your family with information about your heart and severe aortic stenosis, a condition where the aortic valve does not work properly.

Patients with severe aortic stenosis who cannot have open-heart surgery can learn about a less-invasive treatment option called transcatheter aortic valve implantation (TAVI) with the Portico™ valve. In this brochure, you can read an overview of the steps involved in TAVI and expectations for patients before, during, and after the procedure.

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. It is important that you discuss all available treatment options with your doctor, to determine which treatment is right for you.

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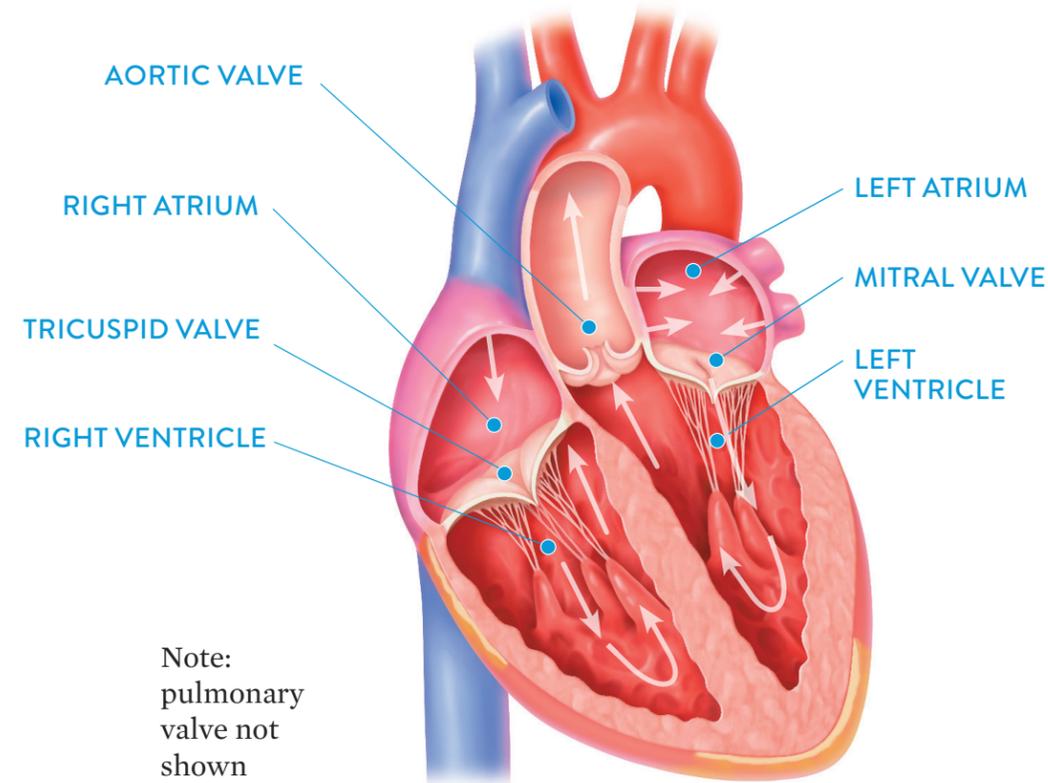
How a Healthy Heart Works

Your heart beats thousands of times per day, pumping dozens of gallons of blood each hour. It pumps blood through your lungs to replenish it with oxygen and then pumps the oxygen-rich blood back out to the rest of your body.

The heart has four chambers. The upper two chambers receive blood and are called atria (each one is an atrium), and the lower two chambers pump blood and are called ventricles (*Figure 1*).

There are four heart valves—one for each chamber—that keep blood moving through the heart in the right direction (*Figure 1*). These valves act like one-way doors, allowing blood to flow forward to exit each chamber of the heart. Each valve has flaps (leaflets) that quickly open and close once during each heartbeat so blood does not flow backward.

The mitral valve and tricuspid valve are located between the atria (upper heart chambers) and the ventricles (lower heart chambers). The aortic valve and pulmonary valve are located between the ventricles and the major blood vessels leaving the heart.



Chambers of the Heart and Heart Valves

Figure 1

The Aortic Valve and Severe Aortic Stenosis

On the left side of the heart, blood flows through the left ventricle into the aorta through the aortic valve. Severe aortic stenosis is a condition in which the aortic valve leaflets become thick or stiff, reducing their ability to fully open and close (*Figure 2*). This narrowing of the valve makes your heart muscle work harder to deliver oxygen-rich blood to the brain and the rest of the body.

The overworked heart may begin to weaken and fail, causing symptoms like shortness of breath, dizziness, chest pains, fatigue, and fluid retention. After physical examination and further tests, doctors may recommend valve replacement.

What Causes Aortic Stenosis?

Aortic stenosis is one of the most common valve diseases and usually develops later in life. Causes include:

- Buildup of calcium on the valve
- Infection of the heart
- Birth defects
- Rheumatic fever
- Radiation therapy



Aortic Stenosis

Figure 2

Symptoms of Aortic Stenosis

The symptoms of aortic stenosis are commonly misunderstood by patients as “normal” signs of aging. Symptoms of aortic stenosis include, but are not limited to:

- Chest pain
- Trouble breathing or feeling short of breath
- Feeling dizzy or light-headed, even fainting
- Difficulty walking short distances
- Rapid, fluttering heartbeat
- Not doing activities you used to enjoy
- Difficulty sleeping or the need to sleep sitting up
- Swollen ankles or feet

Occasionally, some patients don't experience any symptoms.



Symptom Evaluation

When you begin to have symptoms, your doctor will evaluate the severity of your aortic valve disease. If your symptoms are severe and your valve is severely narrowed, your doctor will recommend you for treatment. If your doctor determines that your valve needs to be replaced, your cardiologist and a consulting surgeon will discuss the available treatment options with you.

If you don't need heart valve replacement right away, your cardiologist will evaluate you for possible symptoms every six to 12 months and use an ultrasound (echocardiogram) to see if your aortic stenosis is getting worse.

If you do not have any symptoms and the valve is severely narrowed (measuring $< 1 \text{ cm}^2$ according to treatment guidelines), your doctor may order a "stress echo". A "stress echo" is often used to evaluate your heart function and determine if you have symptoms demonstrated during exercise or physical exertion. This diagnostic test will help determine which treatment you are eligible for.

Based on your level of risk, the outcomes from your diagnostic tests and lifestyle preference, your doctor will recommend the best treatment option for you. There are various treatment options for severe aortic stenosis including medication, balloon aortic valvuloplasty, surgical aortic valve replacement or transcatheter aortic valve implantation.



Surgical Aortic Valve Replacement

Aortic valve replacement can be performed using several surgical approaches to open-heart surgery, including traditional sternotomy (with an incision over the chest and sternum), minimally invasive surgery that does not involve opening the chest, and less invasive robotic procedures. Traditional open heart surgery requires the use of a heart-lung bypass machine, which temporarily takes over the function of the heart. During the surgery, the surgeon will completely remove the diseased aortic valve and replace it with an artificial tissue or mechanical valve. Your surgeon will then close the incision and restart your heart. Minimally invasive and robotic heart surgery involves smaller incisions than those used in traditional sternotomy open-heart surgery.

Transcatheter Aortic Valve Implantation (TAVI)

Transcatheter aortic valve implantation with the Portico™ valve provides an alternative, minimally invasive treatment option for people living with severe aortic stenosis who are not candidates for open-heart surgery due to age, frailty, or other conditions that make surgery too risky.

The Portico transcatheter aortic valve is a tissue valve attached to a stent frame (*Figure 3*). 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. The Portico valve is delivered via catheter to the diseased (native) aortic valve through various access sites on the body. The most common approach is through an incision in the groin, also referred to as the transfemoral approach.

Who is Eligible for the Portico™ Valve?

Patients with severe aortic valve stenosis who are not candidates for surgical replacement will be further screened by their doctor to see if they are eligible for a Portico valve.



**Portico™ Transcatheter
Aortic Valve**
Figure 3



The Portico TAVI procedure is not right for everyone. In some cases, the risks of the procedure may be higher than the benefits.

See page 18 to review the risks of the Portico TAVI procedure.

How Should You Prepare for Your Procedure?

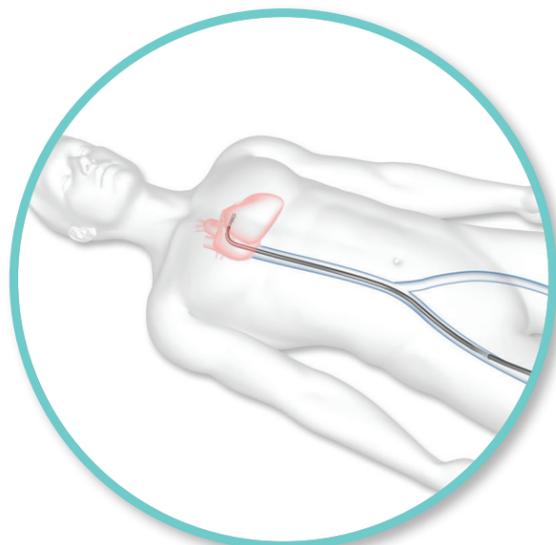
In the days before your procedure, it is important that you:

- Take all of your prescribed medications
- Tell your doctor if you are taking any other medications
- Make sure your doctor knows of any allergies you have
- Follow all instructions given to you by your doctor or nurse

What Will Happen During Your Procedure?

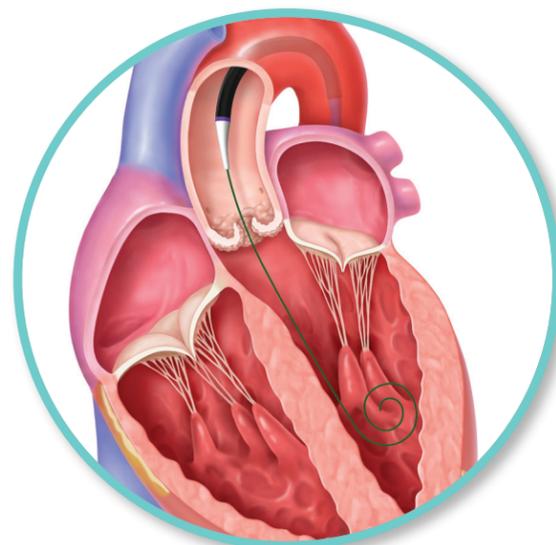
The Portico TAVI procedure will take place in a special cardiac suite with a team of doctors and nurses to perform the procedure and care for you. Normally, patients are sedated during the procedure and will not feel any pain. Your doctor will decide how much sedation is required for you.

The following steps provide a general overview of the Portico TAVI procedure. Experiences may vary. Your doctor will explain the procedure, provide you with specific details, and answer any questions you may have.



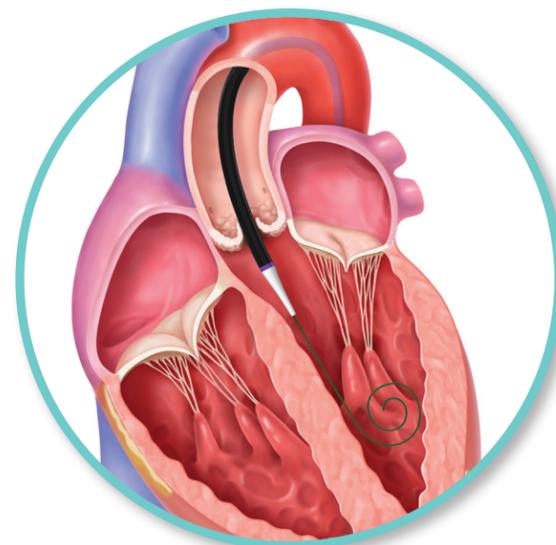
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Your doctor will determine the best approach for replacing your valve, but the most common approach is the transfemoral approach, described here. A small cut is made in a large artery in your groin and a sheath (access tube) is inserted within your artery. The doctors view the movement of the sheath using special imaging equipment, which guides them to know when the sheath is in the correct position.



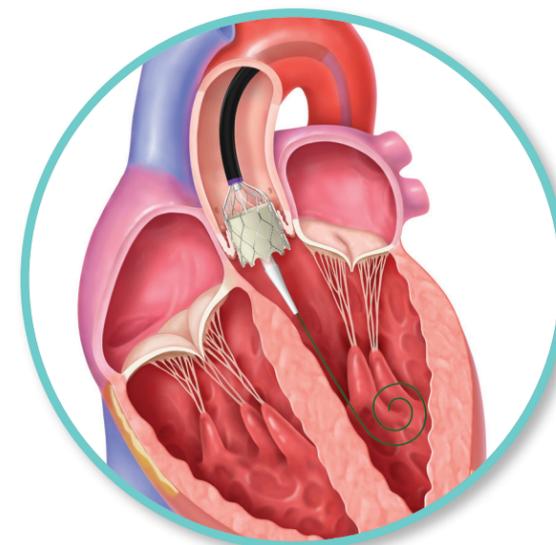
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Once the sheath is in position, a guiding wire and balloon catheter (thin, flexible tube) is delivered through the sheath and placed within your aortic valve. The balloon is inflated to open up your aortic valve as much as possible so that the Portico™ valve can be placed inside of it. The balloon catheter is then removed.



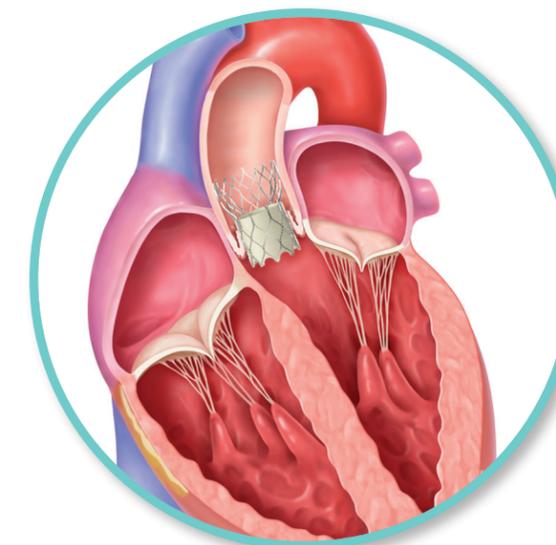
3

The Portico valve is delivered with a catheter through the sheath and placed within your opened aortic valve. Your doctor will deploy the valve into the correct positioning using special visualization equipment to ensure the valve is positioned accurately within your heart.



4

Once the valve is deployed and accurately in place, the Portico valve will start to function immediately.



5

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



What Will Happen After Your Procedure?

At the completion of your Portico transcatheter aortic valve implantation, you will be moved to a hospital bed or occasionally to an intensive care unit (ICU) and be closely monitored. Intravenous lines will give you fluid, blood, and medications as needed. Your heart rate, heart rhythm, blood pressure, and other measurements will be monitored to assess your recovery. 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. From the ICU you will be moved to a cardiac medical-surgical floor where your heart will continue to be monitored, but 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. Your doctor will determine how long you may need to stay at the hospital until you are ready to be discharged home.

You may be prescribed medication that thins the blood, which is recommended for patients with tissue valves who have risk factors for clotting. You will be released to the care of your cardiologist or family doctor. It is important that you attend all follow-up appointments and follow your doctor's instructions.



What Will Happen When You Return Home?

When you return home, you must take special care of yourself until you are fully recovered. The majority of patients feel meaningful improvement after TAVI. 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.

Follow-up Visits

You will likely be asked to return to see your doctor to have your heart valve checked at 30-days and 1 year after your procedure. At your follow-up visits 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.

AFTER BEING RELEASED FROM THE HOSPITAL, IT IS IMPORTANT THAT YOU:

- Carefully follow your doctor's instructions on your medications
- Follow-up with blood tests as directed by your doctor
- Call your doctor if you cannot continue your medications due to side effects
- Notify your doctor before any medical or dental procedure; you may need to be given medication to avoid possible infection
- Limit physical activities that are tiring for at least 30 days, or longer if your doctor thinks it is needed

Your Implant Identification Card

Following your procedure, you will receive an Implant Identification Card. The ID card is filled out by your doctor and shows that you have a Portico™ valve. You must carry it with you at all times. Show your ID card if you go to an emergency room, prior to an MRI (magnetic resonance imaging), or before any medical or dental procedure.

- **MRI testing:** If you are told you need to have an MRI, tell the doctor 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
- **Airport metal detectors:** The amount of metal used in the Portico valve is very small and is usually not enough to set off metal detectors. However, if it does, simply show security personnel your ID card. Passing through a metal detector will not harm your heart valve.



When to Call Your Doctor

After being released from the hospital, it is important that you: contact your doctor 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 bowel movements (blood will typically look like tar after it has been exposed to the body’s digestive juices)
- 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



Benefits

Transcatheter aortic valve implantation with the Portico™ valve can offer several key benefits. It is less invasive than open-heart surgery, with minimal scarring and a shorter hospital stay and recovery time.

Once the Portico valve has been implanted, you may experience immediate improvement in your quality of life or you may feel better gradually. Improvement may include:

- Increased physical activity
- Increased energy
- Decreased or no chest pain
- Decreased or no shortness of breath
- Decrease severity of all or most previous symptoms

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.

Risks

There are risks with any heart valve implantation procedure. The most serious risks are: death, stroke, serious damage to the arteries and serious bleeding. Additional risks include, but are not limited to:

- Access site complications (e.g., pain, bleeding, infection, blood vessel damage)
- Buildup of deposits (plaque) in and on the walls of coronary arteries
- Heart attack - blockage of blood flow to the heart muscle
- Allergic reaction to medication or products/devices used during the procedure (medication to prevent blood clotting, x-ray dye, components of the valve delivery process)
- Tear or burst of the aorta
- Irregular heart rate
- Disruption or injury of electrical system in your heart leading to the need for a permanent pacemaker implant
- Tear or separation of the layers of the wall of an artery
- Obstruction of an artery, typically by a clot of blood or an air bubble
- Inflammation of the lining of your heart
- Failure of your heart to pump enough blood to the body's organs
- Unstable blood flow
- Rupture or destruction of blood cells
- Blood cell damage
- Low red blood cell count
- Bleeding, infection, clotting in or on the valve or tissue of the valve
- Loose clots in the bloodstream that may block an artery in your arms, legs, or brain
- Spasm vessel or escape of blood from a ruptured blood vessel
- Blood pressure changes above or below the normal levels
- Infection
- Reduced blood flow to your heart, preventing the heart muscle from receiving enough oxygen
- Changes to the Mitral valve where it doesn't close tightly
- Multi-organ failure - inflammation from a severe infection or injury causes dysfunction in two or more organ systems
- Wrong sizing or positioning of the implanted valve
- Collection of fluid or blood around your heart
- Perforation or tear of the heart muscle, ventricle or blood vessel
- Formation of scar tissue that may cover or block the valve from functioning normally
- Leakage of blood around the edge of the valve
- Valves in your heart don't close tightly, allowing blood to flow backward in your heart
- Kidneys lose the ability to remove waste and balance fluids
- Blood doesn't have enough oxygen or has too much carbon dioxide
- Sepsis
- Structural deterioration of the implanted valve (i.e., calcification, leaflet tear)
- Having an abnormal particle (air or blood clots) floating in the bloodstream or attached to an object, including the valve
- When extra fluid builds up in the space around the heart
- When the transcatheter valve moves or is dislodged from the deployment position/location
- Permanent disability
- The need for additional medical procedures to include blood transfusions, operation to remove the valve, use of a balloon to adjust the valve (valvuloplasty), and catheter insertion in to coronary arteries to treat blockages.

TAVI Clinical Trial Data

The Portico valve was studied in patients at high-risk or those who cannot have surgical valve replacement also known as open heart surgery. Abbott initiated the study with the Portico valve and original delivery system in 2014. As a part of this initial trial, the Portico valve and original delivery system was studied in comparison to the other transcatheter valves available in the market at the time. More than 700 patients were enrolled in the original trial. 375 received the Portico valve with the original delivery system, while 362 patients received the other available transcatheter valves. With continuous product enhancements designed to improve patient outcomes, the Portico™ with FlexNav™ TAVI system was added to the trial in 2018 and 193 patients received the

30 DAY – HIGH AND EXTREME RISK CLINICAL DATA			
Risks	Portico™ Valve with Original Delivery System	Other Available Transcatheter Valves	Portico™ Valve with FlexNav™ TAVI System
Death (From Any Cause)	5 out of 100 patients	1 out of 100 patients	1 out of 100 patients
Disabling Stroke	2 out of 100 patients	1 out of 100 patients	2 out of 100 patients
Life-threatening Bleeding	5 out of 100 patients	4 out of 100 patients	4 out of 100 patients
Acute Kidney Injury with Dialysis	1 out of 100 patients	1 out of 100 patients	0 out of 100 patients
Major Vascular Complications	10 out of 100 patients	7 out of 100 patients	6 out of 100 patients
New Permanent Pacemaker	28 out of 100 patients	12 out of 100 patients	15 out of 100 patients
Moderate to Severe Leak Around the Valve	6 out of 100 patients	2 out of 100 patients	3 out of 100 patients

1 YEAR – HIGH AND EXTREME RISK CLINICAL DATA			
Risks	Portico™ Valve with Original Delivery System	Other Available Transcatheter Valves	Portico™ Valve with FlexNav™ TAVI System
Death (From Any Cause)	15 out of 100 patients	12 out of 100 patients	5 out of 100 patients
Disabling Stroke	2 out of 100 patients	3 out of 100 patients	2 out of 100 patients
Life-threatening Bleeding	Not Reported	Not Reported	Not Reported
Acute Kidney Injury with Dialysis	Not Reported	Not Reported	Not Reported
Major Vascular Complications	Not Reported	Not Reported	Not Reported
New Permanent Pacemaker	31 out of 100 patients	14 out of 100 patients	18 out of 100 patients
Moderate to Severe Leak Around the Valve	8 out of 100 patients	2 out of 100 patients	1 out of 100 patients

Not reported: certain events are not reported after 30 days based on trial research criteria

Portico valve with the updated and improved delivery system.

The following charts include a summary of risks observed in the original product, the other available transcatheter valves, as well as the device that you will receive – the Portico with FlexNav TAVI system. The Portico valve with FlexNav TAVI system clinical data demonstrated improved outcomes from the Portico valve with original delivery system data set.

All the patients were examined at 30 days and 1 year after the procedure.

The risks with the TAVI procedure may depend on the overall health of the patient. If you are at high risk or cannot have open heart surgery, the clinical data shown in the following charts could be what you would expect.

Who Should Not Have the Procedure?

You should not receive the Portico™ valve if you have any of the following conditions:

- Have any kind of infection, including an active infection in the heart
- Cannot tolerate medication that thins the blood or prevents blood clots from forming
- Have a reaction or allergy to nitinol, an alloy of nickel and titanium

The Portico™ valve system has not been studied in the following patient populations and therefore should not be used in patients who:

- Have any evidence of a blood clot (thrombus), intracardiac mass or vegetation in, on or around the heart
- Have narrow veins or arteries with calcification that make insertion of the delivery sheath and access to the aortic valve impossible
- Have stenotic (narrowed) aortic valve without calcium deposits
- Have a heart valve defect from birth with either one or two leaflets vs. the normal three leaflets
- Are pregnant or breastfeeding
- Are age 21 or younger at the time of diagnosis or treatment
- Have an ejection fraction, or volume of blood fluid, less than 20%

- Have unstable heart function requiring mechanical assistance or drug therapy to support the normal function of the heart
- Are low or intermediate surgical risk
- Have had a previous heart valve or ring in any position in the heart
- Have mixed aortic valve disease (stenosis and regurgitation)
- Have severe mitral valve disease (calcification, stenosis or inefficiency)
- Have a medical condition that affects the cellular or plasma components of the blood
- Have significant coronary artery disease that requires treatment
- Have abnormally thick heart muscle (hypertrophic cardiomyopathy)
- Are on dialysis, have kidney failure or inefficiency
- Have known allergy or sensitivity to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media/dye
- Have bulky calcium build up on the valve leaflets close to the coronary ostia which are the main arteries delivering blood from the heart to the rest of the body
- Have significant aortic disease, including abdominal aorta, thoracic aneurysm or any other folding, bending or narrowing which would make access to the aortic valve impossible



Contact Information

For more information on the Transcatheter Aortic Valve Implantation with Portico™ Valve, please contact Abbott:

Toll-free phone in the USA:
1-800-227-9902

Email Address:
av.customercare@av.abbott.com

Mail:
Abbott
3200 Lakeside Dr.
Santa Clara, CA 95054



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3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1.800.227.9902

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