Heart Valve
Fact Sheet

Transcatheter Aortic Valve Implantation (TAVI), also referred to as Transcatheter Aortic Valve Replacement (TAVR), is an innovative and life-saving treatment option for patients suffering from severe aortic stenosis (or narrowing of the aortic heart valve), who are considered to be high risk or inoperable for conventional open-heart valve replacement therapy.

The Portico™ Transcatheter Aortic Heart Valve from St. Jude Medical is the only approved transcatheter valve that can be completely resheathed (the process of bringing the valve back into the delivery catheter), repositioned at the implant site or retrieved before it is released from the delivery system.

The Portico heart valve is implanted through a small incision in the femoral artery (main artery of the leg). The procedure uses a catheter placed percutaneously (through the skin) to deliver and position the valve in the heart and occurs while the heart continues to beat. This avoids the need to place patients on cardiopulmonary bypass, a process in which a machine takes over heart and lung function during surgery.

The valve was designed in collaboration with leading physicians to address limitations of current-generation devices by improving control and accuracy in positioning and placement of the valve, minimizing paravalvular leak (a common complication with first-generation transcatheter valves) and potentially reducing the need for implantation of a permanent pacemaker after the procedure.

Featuring leaflets made of bovine pericardial tissue attached to a self-expanding stent, the Portico valve was designed to help increase physician control and placement accuracy during deployment of the valve. This emerging technology was granted European CE Mark in November 2012.

HEART VALVE BACKGROUND

The heart has four heart valves that function like one-way doors to keep blood flowing in the proper direction. There is a valve between each atrium (heart chamber where blood enters the heart) and ventricle (chamber where blood is pushed out of the heart). There is also a valve between each ventricle and vessel (artery) to carry blood away from the heart and out to the lungs or the body.

In the right side of the heart:
- the tricuspid valve is between the right atrium and the right ventricle
- the pulmonary valve separates the right ventricle from the pulmonary artery

In the heart’s left side:
- the mitral valve is between the left atrium and left ventricle
- the aortic valve separates the left ventricle from the aorta
The valves open to allow blood to flow through, and they close to prevent the backflow of blood. Opening and closing of the valves is controlled by blood pressure changes within each heart chamber.

WHAT HAPPENS WHEN HEART VALVES BECOME DIASEASED?
Heart valve disease has many causes and comes in many different forms. When a heart valve becomes diseased, one or a few things may happen:

- Incompetence: the valve doesn’t close tightly enough to keep blood from backing up into the chamber from which it flowed.
- Stenosis: the valve doesn’t open widely enough to allow adequate amounts of blood to flow through it.

When blood flow is compromised, mild to severe symptoms can result, including shortness of breath, chest palpitations and fainting.

WHAT CAUSES HEART VALVE DISEASE?
Rheumatic fever, endocarditis, coronary artery disease, heart attack, cardiomyopathy (heart muscle disease), syphilis, hypertension, aortic aneurysms and connective tissue diseases are common causes of valve disease. Less common causes of valve disease include tumors, some types of drugs and radiation.

In many cases, there is no way to prevent heart valve disease as it may be caused by a congenital heart disorder or advancing age.

HOW IS HEART VALVE DISEASE TREATED?
Outside of transcatheter valve replacement, additional options to treat a diseased valve is surgical repair or replace the valve, in order to help the heart function more efficiently.

Heart Valve Repair
Heart valve repair can offer advantages to certain patients because it preserves the native heart valve and potentially helps the patient avoid long-term anticoagulation therapy (medication that slows the blood’s clotting process, sometimes referred to as “blood thinners”), which is often required for an artificial (prosthetic) mechanical heart valve. However, heart valve repair is not an option for every patient.

Surgical Heart Valve Replacement
If a surgeon cannot repair a heart valve, it will be removed and the physician will implant a prosthetic valve in its place. Throughout the world, 95 percent of all valve replacements surgeries performed are for mitral or aortic valves.

Additional kinds of heart valves:
- **Mechanical Valves** – are constructed from manufactured materials that are highly durable and biocompatible. Carefully designed to last a lifetime, mechanical heart valves mimic the function of a native heart valve. Patients who receive a mechanical heart valve require long-term anticoagulation therapy.
- **Tissue Valves** – are made from animal or, less frequently, human donors. Once the tissue is explanted (removed), it is chemically treated and prepared for human use. Some tissue valves have a frame or a stent to support the valve, others feature a stentless design. While tissue valves do not require anticoagulation therapy, they also do not last as long as mechanical valves.