

# VenusP-Valve System

# **Patient Brochure**





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## **INFORMATION FOR YOU AND YOUR FAMILY**

VenusP-Valve System for Transcatheter Pulmonary Valve Replacement (TPVR). A non-surgical option to restore pulmonary valve function for adults and children.

This Booklet is provided to help you and your loved ones learn more about VenusP-Valve System. Please discuss any questions with your heart doctor. Only your doctor can help you decide if VenusP-Valve System TPVR is the right therapy for you.

With Venus Medtech TPVR, children and adults with pulmonary valve failure to deliver an option designed to restore pulmonary valve function and delay the need for surgery.



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This therapy is not for everyone. Please consult your physician. A prescription is required. For further information, please contact Venus Medtech at +86-571- 87772180, please see page 8 for important risk information.

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## **ABOUT THE HEART**

### **Congenital Heart Disease**

Congenital (from birth) heart disease (CHD) is the most common birth defect, affecting eight in one thousand infants born each year. There are many different types of CHD. Most have to do with a heart that doesn't develop like it should or with problems with the large blood vessels (the pulmonary artery, and/or aorta) connected to the heart.

### How the Heart Works

Your heart is a pump that keeps blood moving around your body. It works 24 hours a day to keep you alive. Each day, your heart beats about 100,000 times.

A normal heart has four chambers. The upper two chambers are the right and left atria. The lower two chambers are the right and left ventricles. Blood is pumped through the four heart chambers with the help of four heart valves - the tricuspid, pulmonary, mitral and aortic valves. The heart's job is to supply the body with oxygen-rich blood. First it sends blood without any oxygen to the lungs to get oxygen. It then returns it to the heart where the blood containing oxygen will be pumped to other parts of the body.

### **What Heart Valves Do**

There are four values in your heart. They act like gates that open and close, making sure that your blood travels in one direction through your heart - a bit like a one-way traffic system. They are called the tricuspid value and the pulmonary value on the right side of the heart, and the mitral value and the aortic value on the left.



## PULMONARY VALVE CONDITIONS AND VALVE FAILURE

The pulmonary valve directs blood flow from the right lower chamber (right ventricle) into the main pulmonary artery, which splits into two arteries so that the blood from the body can get to both lungs. Pulmonary valve disease is a condition in which the pulmonary valve doesn't function properly.

### **PULMONARY VALVE CONDITIONS**

The following congenital heart conditions most commonly affect the pulmonary valve.

Pulmonary Atresia

A condition where the pulmonary valve is abnormal and does not open like it should. This means that blood cannot go to the lungs to pick up oxygen.

### Tetralogy of Fallot

A condition which refers to four heart defects that usually occur together; a hole between the right and left pumping chambers of the heart (ventricles), a narrowed path between the heart and the lungs, an artery (aorta) that is connected to the heart closer to the right side of the heart than normal, and a thicker than normal pumping chamber (ventricle) on the right side of the heart.

- Double Outlet Right Ventricle

A condition in which both main arteries, one that carries blood to the lungs (main pulmonary artery) and one that carries blood to the rest of the body (aorta), are connected to the right lower chamber of the heart (ventricle). Usually, the aorta is connected to the left lower chamber of the heart.

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### **Pulmonary Valve Failure**

- Over time, mineral deposits may build up on the conduit (calcification), and it may become narrowed and/or leaky. This may happen as you outgrow your conduit, or as it wears out from the pressures of pumping blood or from calcium build up.
- Narrowing(Stenosis) | Stenosis may be caused by a build up of minerals on the conduit walls (calcification).
  Stenosis can limit blood flow from the heart to the lungs and forces the heart to work harder than normal, which makes the heart muscle thick and prevent it from working well.
- Leaking(Regurgitation) | Conduit does not have a working valve which causes blood to leak backward into the right lower chamber of the heart (ventricle). This causes the heart to pump harder than it should to bring blood to the lungs and the rest of your body.

### **Pulmonary Valve Failure Symptoms**

- Becoming tired or short of breath with activity
- Feeling tired, dizzy or too weak to do your normal activities
- Irregular heart beats or the feeling that your heart is racing or pounding in your chest
- Fainting or near fainting

Symptoms can range from mild to severe. If you are experiencing any of these symptoms, talk with your doctor. Regular check ups and testing can help determine how your pulmonary conduit is working.



## **PULMONARY VALVE FAILURE TREATMENT OPTIONS**

### **Surgical Valve Replacement**

The standard treatment for narrowed or leaking pulmonary valve conduits has been another heart surgery to place a new valve. During the surgery, your doctor removes your narrowed or leaking conduit and places a new pulmonary conduit containing an artificial pulmonary valve in its place.

### **Balloon Angioplasty/Valvuloplasty**

During this procedure, a thin, hollow tube (catheter) is inserted into a vein (typically in your leg) and guided to your heart. A deflated balloon is placed through the opening of the narrowed conduit. Your doctor then inflates the balloon, which pushes the narrowed conduit open so that blood may flow better.

### **Transcatheter Pulmonary Valve Replacement**

During this minimally invasive procedure, a catheter holding a artificial heart value is inserted through a small tube and guided to the intended location in your heart. Once the value has reached the correct location, the value will be released from the catheter and self-expanded, which should immediately begin to work and help control blood flow.





## **VENUSP-VALVE SYSTEM**

The intended purpose of VenusP-Valve is to replace the pulmonary heart valve with an artificial valve using a minimally invasive percutaneous approach, to treat right ventricular outflow tract (RVOT) dysfunction and specifically for the dilated outflow tracts to restore pulmonary valve function.



### Is VenusP-Valve System Right For You?

VenusP-Valve System may be an option for treating your falling pulmonary valve.

# When VenusP-Valve System Is Not An Option?

Your heart doctor can help you decide if VenusP-Valve System maybe right for you.

See additional Warnings and Precautions section in Instructions for Use, contact Venus Medtech (Hangzhou) Inc. at +86-571- 87772180.

\* Note: In Europe



## THE VENUSP-VALVE TPVR PROCEDURE

The following section describes what happens during the VenusP-Valve TPVR procedure. It is intended as a general overview; your experience may be different. Please talk to your doctor for more information about what to expect.

## **During The Procedure**

Typically, patients are asleep under anesthesia for the procedure and usually don't feel any pain.

- 1. Your doctor will insert the delivery system into your vein (typically in your leg) through a small access site.
- 2. A thin, hollow tube (catheter) holding the VenusP-Valve will be placed into the vein and guided into your heart.
- 3. Once the VenusP-Valve is in the right position, deploy the valve.
- 4. The VenusP-Valve will self-expand into place and begin to direct blood flow between the right lower chamber (ventricle) and your lungs.
- 5. The catheter will then be removed and the doctor will conduct a test to make sure the valve is working properly via angiograpy.
- 6. The access site will be closed. And the procedure will be complete.







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### **After The Procedure**

After the VenusP-Valve TPVR procedure, you will go to a recovery room. Once you are awake, you will be moved to a regular hospital room where you'll be able to eat and drink.

Your doctor will provide you with more specific care instructions as well as any limitations you may have. Usually, you can return to normal activities in one to two days. If you have any questions, please ask your heart doctor or nurse.

### **Follow-up Care**

After your VenusP-Valve TPVR procedure, it is important to follow your heart care team's instructions to ensure the best possible results.

- Continue to take medications as prescribed
- Follow your daily care plan
- Keep appointments to have your heart and VenusP-Valve checked
- Talk with your doctor if you have pain or other symptoms
- Inform your other doctors about your heart valve before any medical procedure
- If you have an unexplained, prolonged fever, contact your doctor to ensure you do not have an infection related to your heart valve
- Tell your dentist that you have an artificial tissue valve. During dental work, bacteria may be released into the bloodstream and cause infection in any tissue valve. This means that you may need to be on medicine (antibiotics) before any dental procedure, even routine cleaning

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Talk with your heart care team or nurse if you have more questions about living with your VenusP-Valve System.



## **RISKS AND BENEFITS**

### Possible Risks associated with VenusP-Valve TPVR

As with any medical procedure, there is a risk of side effects or complications during or after the VenusP-Valve TPVR procedure, which may be serious, including death. Potential complications and related incidents include, but are not limited to the following:

- Fever
- Bleeding
- Hematoma
- Endocarditis
- Arrhythmias
- Thrombosis
- Sepsis/infection
- Stent fracture
- Valve dysfunction
- Paravalvular leak
- Pain at the catheterization site
- Device embolization or migration

- Loss of structural integrity due to stent fracture
- Allergic reaction to contrast agents
- Perforation of cardiac chambers
- Rupture of the prosthetic RVOT conduit
- Laceration or rupture of blood vessels
- Device misorientation or misplacement

- Compression of the coronary arteries
- Distal thromboembolism
- Cerebrovascular incident
- Pseudoaneurysm
- Heart failure
- Death



### **VenusP–Valve System Clinical Benefits**

- Most patients receiving a VenusP-Valve can expect symptom relief:
  - **Relief of leaking (regurgitation):** Improvement in pulmonary regurgitation compared to pre-procedure as demonstrated by transthoracic echocardiography.
  - Increased cardiac function: Significant improvement in New York Heart Association (NYHA) Functional Classification compared with pre-procedure.
- Restored right ventricular function: Improvement in right ventricular remodeling and right ventricular function at 6 months after implantation.



NYHA Class	Baseline (N=79)	6MFU (N=76)	12M FU (N=69)	
I	16 (20.3%)	45 (59.2%)	61 (88.4%)	
Ш	39 (49.4%)	26 (34.2%)	8 (11.6%)	
III	5 (6.3%)	1 (1.3%)	0 (0%)	
IV	0 (0%)	1(1.3%)	0 (0%)	
Not Evaluated	19 (24.1%)	3 (3.9%)	0 (0%)	
*Clinical data from VenusP-Valve System CE Study 1year follow-up				9

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### **Important Information About Stent Fracture**

In some patients, the wire frame (stent) of the VenusP-Valve System may fracture because of the forces it is exposed to in your body.

In some cases, the fractured stent may not require any additional treatment.

However, you should realize a fractured stent has the potential to become serious and could result in the need for another procedure. Your doctor will decide your best treatment option.

In the VenusP-Valve System CE Clinical Interim Report data, eleven (11) stent fractures (14.5%) have been identified, which did not affect the Valve functionality and no need for additional treatment.



## **CONTRAINDICATIONS**

- Known hypersensitivity or contraindication to aspirin, heparin, ticlopidine, clopidogrel, nitinol, or sensitivity to contrast media which cannot be adequately pre-medicated
- Septicemia, including active endocarditis
- Recent myocardial infarction (< 30 days)
- Echocardiographic evidence of intracardiac mass, thrombus, or vegetation
- Any Contraindication of extracorporeal assist
- Evolutive or recent cerebral vascular accident (CVA)
- Obstruction of the central veins
- Bleeding diathesis, coagulopathy, patient refusal of blood transfusion
- Creatinine Clearance Calculator (CCR) <20mL/min
- Pregnancy
- Patients with known allergies to porcine materials
- Patients who are breastfeeding



## **FREQUENTLY ASKED QUESTIONS**

### 1. Are physical activities safe?

Physical activities are safe for most patients but you should talk with your heart doctor to decide what is best for you.

# 2. Is it safe to have an X-Ray with a VenusP- valve?

It is completely safe to have an x-ray with a VenusP-valve.

# 3. Is it safe to have a magnetic heart scan (MRI) with a VenusP-valve?

You may safely undergo MRI scanning under specific conditions. If you need a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a VenusP- valve or show your doctor your VenusP-Valve implant card.

# 4. Is it safe to go through airport security with a VenusP-valve?

Yes. Airport security systems do not affect VenusPvalve, and the valve will not set off airport alarms.

# 5. How long will my VenusP- valve last?

The length of time that your VenusP-valve will last depends on several factors including your unique anatomy and health condition. Some patients may require another procedure to restore function of the valve. Procedures to restore function of the VenusPvalve may include non-surgical procedures such as balloon angioplasty (inflating a balloon to push the valve open so that blood may flow better) or openheart surgery.

In vitro tests have shown that the valve has a life of at least five years.



## For more information about VenusP-Valve System:



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