MicroPort CardioFlow

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Summary of Safety and Clinical Performance

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Patient version

Summary of Safety and Clinical Performance (SSCP) for Patient

Content

1 Scope

This document, known as the Summary of Safety and Clinical Performance (SSCP), is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

This SSCP is not intended to:

- give general advice on the diagnosis or treatment of particular medical conditions, nor
- replace the instructions for use (IFU) as the main document that will be provided to ensure the safe use of the device, nor
- replace the mandatory information on implant cards or in any other mandatory documents

Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

2 Device identification and general information

Device trade name:	VitaFlow Liberty™ Transcatheter Aortic Valve System
Manufacturer's name:	Shanghai MicroPort CardioFlow Medtech Co., Ltd
Manufacturer's address:	1601 Zhangdong Road, Shanghai Free Trade Pilot Area, 201203 Shanghai, China
Manufacturer's single registration name (SRN):	CN-MF-000002327
Basic UDI-DI:	69714935Z0213CEEU

3 Disease condition and Intended use of the device

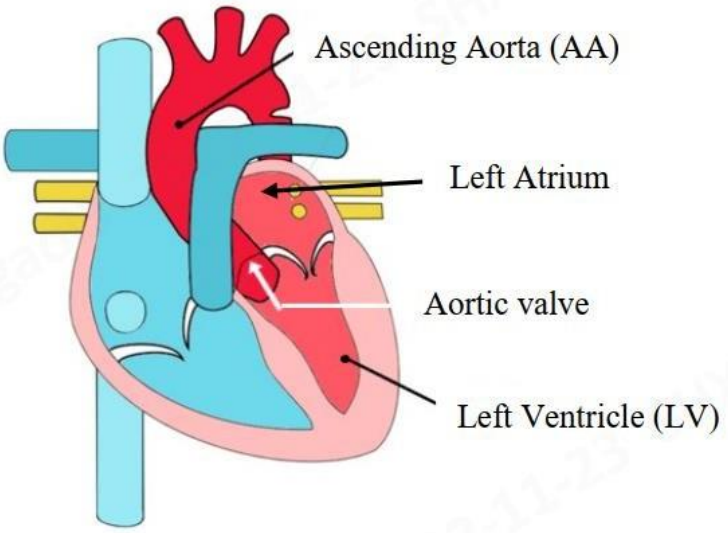
3.1 Disease condition

Many people over 65 years of age are suffering from a damaged heart valve valve, which is often related to the narrowing of the valve opening (stenosis) and leaking of the heart valve (regurgitation) [1].

Natural aortic valve: In normal conditions an aortic valve allows the blood to flow from the heart to the body and as such maintaining blood flow throughout the body stable. The aortic valve is located between the left ventricle (LV) which is the part of the heart that pumps your blood into the body and the aorta which is a large blood vessel that vehicles the blood to smaller vessels in

your body (see **Figure 1**) The natural heart valve may suffer from narrowing caused by calcium that attaches itself to the heart valve causing the heart valve tissue to harden and stiffen[1].

Figure 1 General heart anatomy (left side) and location of aortic valve



Narrowing of the aortic valve: Narrowing of the aortic valve restricts the blood to be pumped out of the heart into the body (See **Figure 1**). [2].

Traditionally, aortic narrowing (**aortic stenosis**) was treated by replacing the heart valve using open heart surgery. However, particularly elderly patients are so sick that open heart surgery involves too high risk. It has been shown that treatment not using open heart surgery for example, using medication or procedures like dilatation of the valve opening with a balloon are not highly efficient. Hence, a method such as the VitaFlow Liberty™ Transcatheter Aortic Valve System by which the aorta valve can be replaced using a valve fixed on a tube which is inserted through the groin avoids the risks of open-heart surgery. Over the years, this procedure has been optimized and is now widely used by cardiologists.

3.2 Intended purpose

The VitaFlow Liberty™ Transcatheter Aortic Valve System is intended to be used by professional physicians to replace the native aortic valve of patients with severe symptomatic, calcific aortic stenosis.

VitaFlow Liberty™ Aortic Valve is used in combination with VitaFlow Liberty™ Delivery System under the supervision of medical imaging equipment, and to be fixed at the aortic annulus* to replace the degenerated valve and improve the function.

*The base of a heart valve that supports the valve's leaflets is called the annulus.

3.3 Indications and intended patient groups

The VitaFlow Liberty™ Transcatheter Aortic Valve System is indicated for transcatheter delivery in patients with severe, symptomatic, calcific aortic stenosis who are considered at high risk for surgical aortic valve replacement (AVR). A high risk is defined by the Society of Thoracic Surgeons (STS)* operative riskscore of ⩾8% or as decided by the heart team agreement of risk for AVR due to frailty or

comorbidities.

*The STS score is a validated risk-prediction model for open surgery based on data from the STS National Adult Cardiac Surgery Database. In general, an STS predicted risk of surgical mortality of 4%-8% is considered intermediate risk and 8% or greater is considered high risk [3].

3.4 Contraindications

VitaFlow Liberty™ Transcatheter Aortic Valve System is contraindicated for patients presenting with any of the following conditions:

1) A known hypersensitivity or contraindication to all anticoagulation/antiplatelet regimens (or inability to be anticoagulated for the index procedure*), to nickel or titanium, to nitinol, to dairy products, to polyethylene terephthalate (PET) or contrast media;
2) Ongoing sepsis, including active endocarditis;
3) Pre-existing mechanical heart valve in aortic position.

* The Index procedure means the TAVI surgical procedure which is detailed in the section 4.2

4 Device description

4.1 Device description and material/substances in contact with patients tissues

The VitaFlow Liberty™ Aortic Valve is mounted on a tube (catheter) and then released through the opening of the natural valve. It has the ability to open like a spring (self-expandable). The valve is made of cow (bovine) heart-membrane tissue (pericardial tissue), sutured to the spring like metallic (Nitinol) frame.

Figure 2 Diagram of the VitaFlow Liberty™ Aortic Valve

Table 1 VitaFlow Liberty™ Aortic Valve specification

Model	Size (mm)	Available Aortic Annulus Diameter Range (mm)
TAV21	21	17-20
TAV24	24	20-23
TAV27	27	23-26
TAV30	30	26-29

*Bovine valve: this valve is derived from a cow with tissues taken directly from a cow's heart. Please note that the VitaFlow Liberty™ Aortic Valve is an animal tissue derived valve. Based on results of biocompatibility testing and clinical investigation, no substances causing sensitization or allergic reaction in patients or users are found.

4.1.1 VitaFlow Liberty™ Delivery System

The VitaFlow Liberty™ Delivery System, consists of a tube (catheter) which is attached to a handle. The front of the tube (catheter) is made to hold the valve while the system is inserted into the body up to the right location of the natural aortic valve. The handle stays outside the body and is operated by the cardiologist to release the valve once the tip of the catheter has reached the right place. This is done under X-ray visualization using the liquid (contrast medium).

Figure 3 Diagram of the VitaFlow Liberty™ Delivery System

Table 2 VitaFlow Liberty™ Delivery System specification

Model	Effective length L1 (cm)	Integrated sheath L2 (cm)	Capsule outer diameter D1(mm)
DSR21	112	30	6.8
DSR24			
DSR27			7.1
DSR30			

4.2 Description of how the device is used

VitaFlow Liberty™ Transcatheter Aortic Valve System, does not need open heart surgery but is placed by accessing the heart through the artery in your groin (femoral artery) and moving the catheter up to the heart at the level of your diseased natural aortic heart valve.

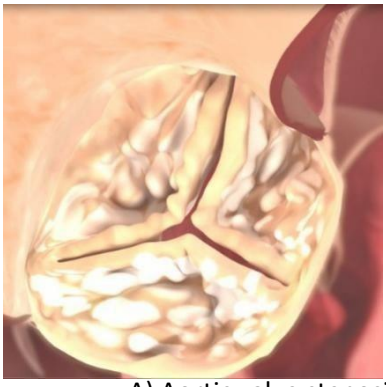
The surgeon starts by making a small hole in the femoral artery in the groin and places a thin wire (guidewire) via the arterial system through the aortic valve opening. The VitaFlow Liberty™ Delivery System is then advanced over the guidewire up to the target position of the natural aortic valve in the heart. (Figure 4-B).

The cardiologist uses the commands on VitaFlow Liberty™ Delivery System, to release the VitaFlow Liberty™ Aortic Valve in a motorized mode or a manual mode. The system also allows recapturing the valve when partially opened, if the cardiologists decides that the position needs to be improved. It can be recaptured on the tube and released after improving the positioning within the natural valve.

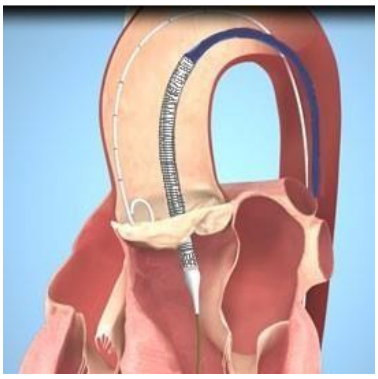
After the VitaFlow Liberty™ Aortic Valve is fully released, the physician starts to withdraw the Delivery System slowly out of the aorta space and then withdraws the entire Delivery System out of the body. The VitaFlow Liberty™ Aortic Valve remains in the heart and completely replaces the native valve to act as the new aortic valve. (Figure 4- D).

If you like to know more details about the device use, please refer to the Instruction for Use

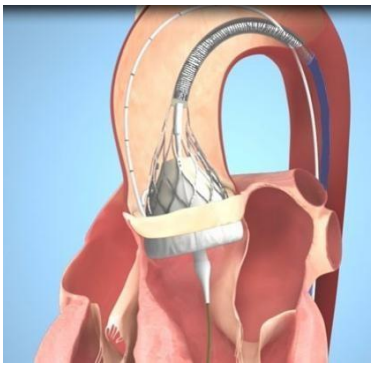
Figure 4 Basic working principle of VitaFlow Liberty™ Transcatheter Aortic Valve System



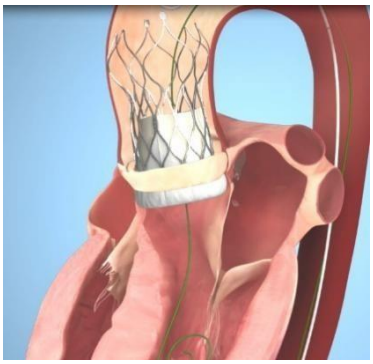
A) Aortic valve stenosis



B) The delivery system reaches the location



C) Bioprosthesis deployment



D) The bioprosthesis is left at the lesion site to replace the native valve, to improve valve function

5 Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

5.1 How potential risks have been controlled or managed

MicroPort CardioFlow carries out the risk management activities/benefit risk evaluations for VitaFlow Liberty™ Transcatheter Aortic Valve System on an ongoing basis according to standardized methods. Risks related to all aspects of the VitaFlow Liberty™ Transcatheter Aortic Valve System are analysed and carefully considered including risks related to the use of the system during placement and once in place over time. Measures are put in place to control or minimize risks so that they do not outweigh the benefits for the patients suffering from severe aortic narrowing and are treated with the VitaFlow Liberty™ Transcatheter Aortic Valve System.

5.2 Remaining risks and undesirable effects

Potential risks associated with the implantation of the VitaFlow Liberty™ Transcatheter Aortic Valve System (and Transcatheter aortic valve procedure) may include, but are not limited to, the following:

- death;
- Complications to the heart (cardiac complications);
  - Sudden heart beat stop (cardiac arrest)
  - Failure of the heart to pump (heart failure)
  - Low volume off blood pumping from the heart (low cardiac output)
- Partial or complete blocking (as by blood clot or spasm) of an artery of the heart (including severe and sudden) (coronary occlusion, obstruction, or vessel spasm (including acute coronary closure));
- emergency heart surgery or emergent need for other interventions to the heart.;
- Heart attack (myocardial ischemia/infarction);

- Pain in the chest due to reduced blood flow to the heart muscle (angina pectoris);
- heart suddenly stops pumping blood (cardiogenic shock);
- Malfunction of the heart's electrical system (conduction disturbances and arrhythmias);
- complications or damage to an artery during the procedure (vascular complications);
- extra fluid builds up between the heart and sac around the heart (pericardium) potentially preventing the heart from pumping blood (cardiac tamponade);
- valve-related complications;
  - damages to the heart valve structure
  - valve moves out of its position or blocking of the valve (valve migration/valve embolization)
- Leakage or injury of the mitral valve – heart valve that permits the blood to flow in the right direction between upper and lower part of the heart (mitral valve regurgitation or injury);
- major or minor bleeding that may or may not require blood transfusion or intervention to stop the bleeding;
- Low red blood cells (anemia);
- Destruction of red blood cells (hemolysis);
- allergic reaction to blood thinning medication or other substances used during the procedure (antiplatelet agents, contrast medium, or anesthesia);
- infection;
- inflammation;
- fever;
- Condition whereby multiple vital organs in the body stop working properly (multi-organ failure);
- Stroke which can be asymptomatic or with symptoms and can also lead to brain damage in severe occasions causing permanent disabilities;
- Abnormal functioning of the kidneys (renal insufficiency or renal failure (including acute kidney injury));
- Damage of cells in your body (tissue erosion);
- Lung complications such as short of breath (dyspnea) , impossible to breath (respiratory failure), fluid in your lungs (pulmonary edema), damage to the sac around your lungs causing leakage (pleural effusion);
- ;
- impaired blood supply to the tissues in your body (peripheral ischemia);
- Whooshing sound of heart beats caused by rough blood flow through the heart valve (heart murmur);
- non-urgent reoperation;
- Too low or too high blood pressure (hypotension or hypertension);
- Loss of consciousness (syncope);
- Abnormalities in blood results (abnormal lab values (including electrolyte imbalance));

5.3 Warning and precautions

The manufacturer does not state any warnings and precautions specifically addressed to the

patient. Additionally, warnings and precautions to the attending physician should be observed.

6 Summary of clinical evaluation and Post market clinical follow up (PMCF)

6.1 Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

According to the guidelines of the European Society of Cardiology for the management of valvular heart disease, the treatment options of the severe, symptomatic narrowing of the heart valve includes replacement of the heart valve via open heart surgery, dilating the heart valve using a balloon not requiring surgery, medication, and replacing the aortic valve using a catheter that brings the replacement valve to the heart without open heart surgery(transcatheter aortic valve implantation - TAVI).

6.2 The clinical evidence for the CE-marking

MicroPort CardioFlow has initiated three main clinical investigations for the VitaFlow Liberty™ Transcatheter Aortic Valve system: Two of these are conducted in China (TAVI 1 and TAVI 2 studies) and 1 in Europe (Vitale study). A total of 176 patients received the VitaFlow Liberty™ aortic valve implanted in the heart.

The follow up in all studies is still ongoing until 5 years after each patient has received the aortic valve in the heart. The information currently analysed and published is on the data of 166 patients in whom the valve was at least in their body for 12 months but for some up to 3 years.

The data confirmed that in 87% of all patients the VitaFlow Liberty™ valve was successfully implanted and functioning well. A successful procedure without major complications was achieved in 81% of the patients.

Over the course of the first 12 months follow up, death occurred in 6% of the patients of which 3% were due to a heart problem. The death cases increase over time in this very sick population and amounts to 7% at 2 years, 14% at 3 years and 15% and 4 years follow up.

The results of these studies shot that the VitaFlow Liberty™ Transcatheter Aortic Valve System has an acceptable safety profile comparable with the results from studies of similar devices and in line with what the European Society of Cardiology is considering acceptable .

In summary, results show that the implantation of the VitaFlow Liberty™ valve relieved the symptoms of the narrowed aortic valve and improved the overall blood flow, heart function and quality of life of the patients who received the device. Current data at 12 months follow up show this improvement was maintained still at 12 months and longer. The analysis showed same results for Chinese and European patients.

6.3 Safety

The results presented in this document show that there is a clear benefit for patients getting better by receiving the VitaFlow Liberty™ , the heart problems are reduced and the patients can regain a better quality of life. No procedure is without risks, but the complications that were found in the study were not more frequent than with other established similar devices on the market.

The studies also concluded that no other problems that had not been anticipated by the manufacturer occurred. It can therefore be concluded that the risks of the VitaFlow Liberty™ implantation procedure are lower than the benefits a patient who is too sick to undergo an open heart surgery can expect.

In order to gather longer-term safety and performance data for the VitaFlow Liberty™ Transcatheter Aortic Valve System, more clinical investigations will be conducted to continue to observe how well the VitaFlow Liberty™ works in more patients after the system will be placed on the market.

Table 3 *PMCF plan*

Description of activity	Timelines of the activity
Literature search for published data from patients exposed to VitaFlow Liberty™ Transcatheter Aortic Valve System, VitaFlow® TAV, and similar devices, including the relevant EU and other national vigilance databases	Updated annually
Long-term follow-up of TAVI I/TAVI II/VITALE studies	annually report after the completion of the primary endpoint
New PMCF study (Europe)	

7 Suggested training for physicians

All the physicians who want to use the VitaFlow Liberty™ system must have comprehensive knowledge of heart disease and working experience with interventions on the heart.

Physicians will also be trained by Microport CardioFlow's professional trainers.

In general, beginner physicians of VitaFlow Liberty™ will perform several procedures with an experienced cardiologist.

If some features of the VitaFlow Liberty™ Transcatheter Aortic Valve System are changed or updated, physicians will be trained before being allowed to use the new devices.

8 References

[1] Z. Shao *et al.*, "Recent progress in biomaterials for heart valve replacement: Structure, function, and biomimetic design," *View*, vol. 2, no. 6, p. 20200142, Dec.2021, doi: 10.1002/VIW.20200142.

[2] "Aortic Stenosis Overview | American Heart Association." https://www.heart.org/en/health-topics/heart-valve-problems-and-disease/heart-valve-problems-and-causes/problem-aortic-valve-stenosis#:~:text=Aortic stenosis is one of,pressure in the left atrium. (accessedJun. 07, 2022).

[3] "The Society of Thoracic Surgery Risk Score as a Predictor of 30-Day Mortality in Transcatheter vs Surgical Aortic Valve Replacement: A Single-Center Experienceand its Implications for the Development of a TAVR Risk-Prediction Model." https://www.hmpgloballearningnetwork.com/site/jic/articles/society-thoracic- surgery-risk-score-predictor-30-day-mortality-transcatheter-vs-surgical-aortic- valve-replacement-single-center-experience-and-its-implications-development-tavr-risk-prediction-model#:~:text=The STS score is a,National Adult Cardiac Surgery Database.&text=In general%2C an STS predicted,greater is considered high risk. (accessed Jun. 07, 2022).

9 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the NB
A	2021/12/27	New document	□Yes Validation language: ☑ No
B	2022/7/29	Revised content to improve readability	□Yes Validation language: ☑ No
C	2022/11/16	Update Section 3.3 Indications and intended patient groups	□Yes Validation language: ☑ No
D	2023/01/05	1. Change Manufacturer's address in Section 2 2. Delete the	☑Yes Validation language:English □No

		information of eIFU in Section 4.2	