Warnings：

- **Carefully read all instructions. Failure to follow these guidelines, warnings, and precautionary measures may result in device damage, user injury, or patient injury.**
- **ValveClamp® can only be used by doctors who have been subject to trainings on transcatheter mitral valve repair procedures and knowledge of ValveClamp®.**
- **ValveClamp® is for single use only. Before use, check the sterile packaging of the product. If there is any damage, please do not use it.**
- **Do not turn the Pusher anticlockwise before releasing the Clamp.**
- **After use, destroy the medical wastes in accordance with the applicable local regulations and the hospital rules.**

Transapical Mitral ValveClamp System

Instructions for Use

Document No.: IFU-01-002

Version: V2.0

Shanghai Hanyu Medical Technology Co., Ltd.

Contents

Instructions for Use

1. Descriptions of the Medical Device

1.1 Product Name

Generic name: Transapical Mitral ValveClamp System
Trade name: ValveClamp® Mitral System

1.2 Brief Introduction

The Transapical Mitral ValveClamp System (hereinafter referred to as 'ValveClamp®') consists of the Mitral Valve Clamp (hereinafter referred to as 'Clamp'), the Delivery System and the Transvalvular Device. Based on the technique of Transcatheter Edge-to-Edge Repair (TEER), the transapical interventional procedure using ValveClamp® is performed with a minimally invasive incision. During the procedure, the Clamp is delivered to the mitral valve leaflets, positioned accurately to clamp the anterior and posterior leaflets of the mitral valve, and then released to make the leaflets closely coaptated, thereby achieving reduction of mitral regurgitation (MR).

1.3 Models

The models of ValveClamp® and the components are shown in Table 1.

Table 1 Models of ValveClamp® and the components

Abbreviation	Model	Clamp	Delivery System	Transvalvular Device
MVC-s	MVC-Is	MVC-Is	DS-16F-200	KBQ-12
	MVC-IIs	MVC-IIs		KBQ-12
	MVC-IIIs	MVC-IIIs		KBQ-14
MVC-f	MVC-If	MVC-If	DS-16F-165	KBQ-12f
	MVC-IIf	MVC-IIf		KBQ-12f
	MVC-IIIf	MVC-IIIf		KBQ-14f

1.4 Product Structure

ValveClamp® consists of the Mitral Valve Clamp, the Delivery System and the Transvalvular Device.
The Clamp is composed of an Upper Clamp, a Lower Clamp, a Closure Ring, PET Film and PET Suture. The Upper Clamp, the Lower Clamp and the Closure Ring are coated with PET Film as shown in Figure 1. The Upper Clamp and Lower Clamp, mainly made of nickel-titanium alloy, are featured with good shape memory and super elasticity. The Closure Ring made of the PEEK material is used to close the Upper Clamp and Lower Clamp.

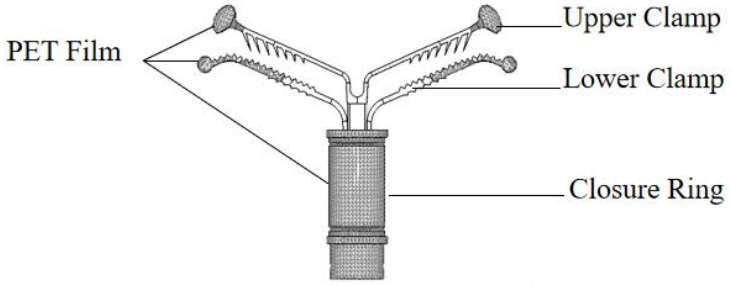

Figure 1 Mitral Valve Clamp

The Delivery System consists of a Transporter, a Pusher, a Loader, a Sheath Introducer, and a Dilator as shown in Figures 2 ~ 4.

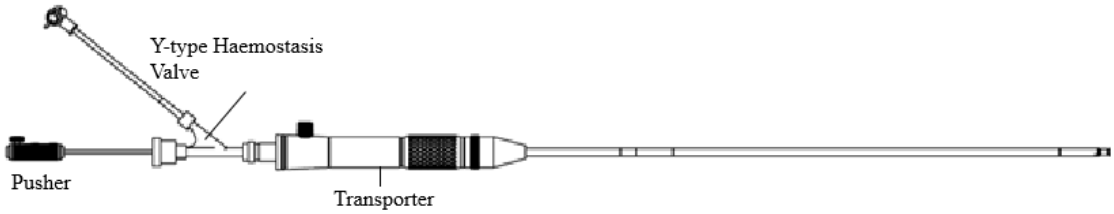

Figure 2 Transporter & Pusher (for DS-16F-200）

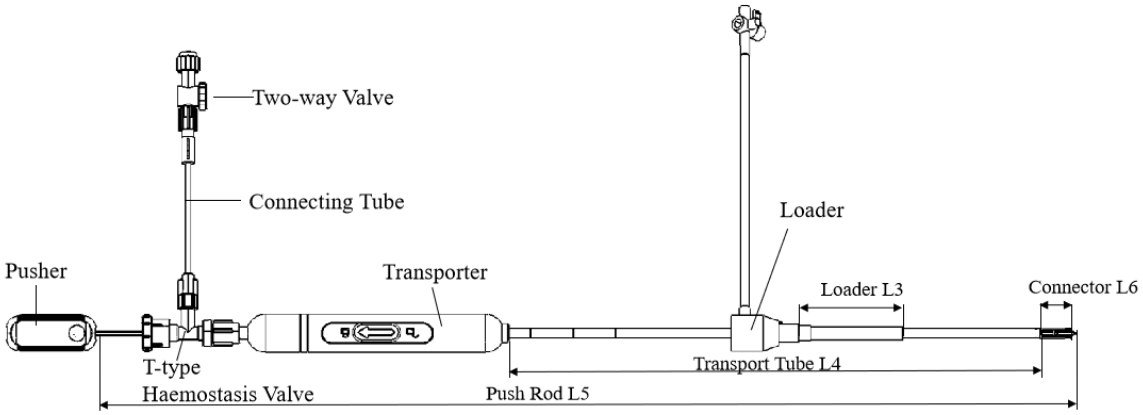

Figure 3 Transporter, Pusher and Loader (for DS-16F-165, the Loader is pre-loaded on the Transporter）

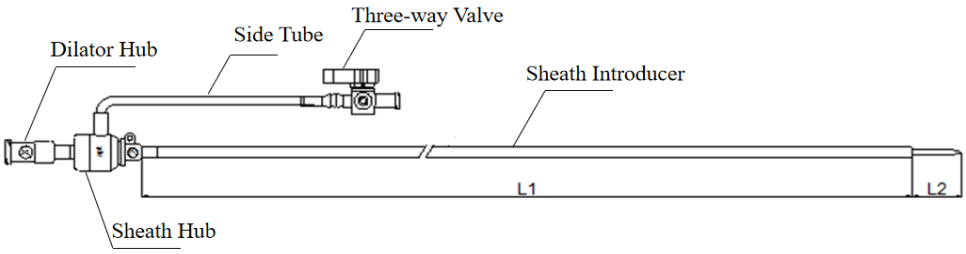

Figure 4 Sheath Introducer and Dilator

The Transvalvular Device is composed of a Transvalve Ball, a Shaft and an Annulus, and is made of nickel-titanium alloy and stainless steel materials, as shown in Figure 5.

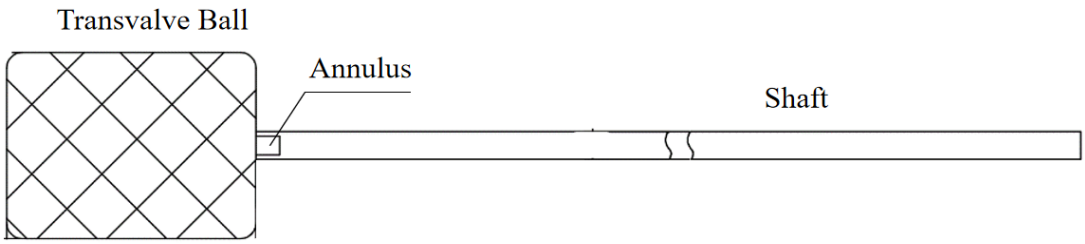

Figure 5 Transvalvular Device

1.5 Key Product Parameters

The dimension for the Clamp and the Delivery System are listed in Tables 2 and 3.

Table 2 List of Dimension for the Clamp (mm)

Parameter / Model	Upper Clamp Arm Length	Lower Clamp Arm Length
MVC-Is, MVC-If	7.5	8.5
MVC-IIs, MVC-IIf	8.5	9.5
MVC-IIIs, MVC-IIIf	9.5	10.5

Table 3 List of Dimension for the Delivery System (mm)

Model / Parameter	DS-16F-200	DS-16F-165
Inner diameter of the Sheath Introducer	5.51	
Outer diameter of the Sheath Introducer	6.11	
Working length of the Sheath Introducer /L1	200	165
Outer diameter of the Dilator	5.44	
Outer diameter of the Loader	6.39	
Working length of the Transport Tube /L4	400	290
Working length of the Push Rod /L5	700	580

2. Intended Use

The Transapical Mitral ValveClamp System is indicated for the transapical reduction of significant, symptomatic mitral regurgitation (MR≥ 3+) due to degenerative disease of the mitral apparatus in patients who have been determined to be at prohibitive or high risk for mitral valve surgery by a heart team, which

includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the MR.

3. Indications

3.1 Indications for use

The Transapical Mitral ValveClamp System is indicated for the transapical reduction of significant, symptomatic mitral regurgitation (MR≥ 3+) due to degenerative disease of the mitral apparatus in patients who have been determined to be at prohibitive or high risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the MR.
The product shall be used by doctors who have been subject to trainings on mitral valve repair procedures and knowledge of the Transapical Mitral ValveClamp System. In addition, a specialist in echocardiography is also required.

3.2 Intended Surgical Environment

The product is intended to be used in a sterile cardiovascular catheterization room, cardiac surgery room or hybrid operating room.

4. Contraindications

The Transapical Mitral ValveClamp System is contraindicated in patients with the following conditions:

1) Conditions unfavorable to surgeries, such as infections, uncorrected cardiogenic shock, acute pulmonary edema, and endocarditis.
2) Mitral stenosis, severe mitral calcification, cracks or perforations in the valve leaflets to be clamped, cardiac neoplasia or other masses, and other abnormalities.
3) Patients who have hemorrhagic diseases or abnormal coagulation functions and cannot tolerate procedural anticoagulation or post procedural antiplatelet regimen.
4) Rheumatic mitral valve diseases.
5) Evidence of heart apex or intracardiac thrombus.

5. Potential Complications and Adverse Events

Potential complications and adverse events from the product or mitral valve repair procedures include, but are not limited to the following (Table 4):

Table 4 Undesirable Side-Effects

Allergic reactions (anesthetics, heparin, nickel alloy, latex)	Hypotension/hypertension
Arrhythmias (atrial fibrillation, etc.)	Infection (Wound infection, pneumonia, etc.)
Bleeding (apex wound bleeding, chest bleeding) or hemorrhage requiring transfusion	Injury to mitral valves or impossibility to perform later surgical repair Thrombosis after implantation of ValveClamp®
Cardiac arrest	Embolization caused by the ValveClamp® component(s)
Cardiac perforation	

Cardiac tamponade/Pericardial effusion/ Pericardial adhesions	Mitral stenosis
Chordal entanglement/rupture	Mitral valve injury
Coagulopathy	Multiple organ failure
Conversion to standard valve surgery	Myocardial infarction
Death	Nausea/vomiting
Dislodgement of previously implanted devices	Pain
Partial or complete detachment of the Clamp	Prolonged mechanical ventilation
Dizziness	Pulmonary congestion
Drug reaction to anti-platelet/anticoagulation agents	Pulmonary thrombo-embolism
Dyskinesia	Renal insufficiency or failure
Dyspnea	Respiratory failure/atelectasis/pneumonia
Emboli (air, thrombus, ValveClamp® implant)	Septicemia
Emergency cardiac surgery	Anaphylactic or cardiogenic shock
Endocarditis	Single leaflet device attachment (SLDA)
Esophageal irritation	Stroke or transient ischemic attack (TIA)
Esophageal perforation or stricture	Urinary tract infection
Failure to deliver ValveClamp® to the intended site	Worsening heart failure
Failure to withdraw ValveClamp® components	Worsening mitral regurgitation
Fever or hyperthermia	Wound dehiscence
Gastrointestinal bleeding or infarct	Pneumothorax and subcutaneous edema
Hematoma	
Hemolysis	

For a patient/user/third party in the European Economic area; if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer (or its representative) and your national competent authority by the contact information in the basic information of this IFU.

6. Precautions

1) Before using the product, please read all the instructions carefully. Pay attention to all the warnings and precautions in the instructions.
2) ValveClamp® is intended for patients with mitral valve regurgitation who need surgical treatment. Before operation, risk assessment shall be carried out by a heart team with clinical experience. The suitability for ValveClamp® implantation shall be determined according to one or more high-risk surgical factors, mental state, activity intensity and other conditions of the patients.
3) The product is not indicated for the following population: the target population with unclear expected clinical risk/benefit, such as those not at high risk for surgical procedures.
4) Surgical high-risk candidates with degenerative mitral regurgitation (MR≥3+) refer to patients with organic heart diseases that cannot be reversed by conventional

medical treatment, whose surgical high-risk condition needs to be evaluated by doctors.

5) Selection of patients

- The surgical high-risk shall be determined according to the clinical judgment of a heart team (including cardiac surgeons experienced in mitral valve procedures and cardiologists experienced in treatment of mitral valve diseases) due to the presence of one or more of the following surgical risk factors:
  - Patients with the 30-day STS-predicted risk score of operative mortality of
    - ≥ 8% for patients deemed likely to undergo mitral valve replacement or
    - ≥ 6% for patients deemed likely to undergo mitral valve repair
  - Aortic calcification or extensive calcification of the ascending aorta
  - Frailty (assessed by in-person consultation of cardiologist)
  - Hostile chest
  - Severe liver disease/cirrhosis (MELD score >12)
  - Severe pulmonary hypertension (systolic pulmonary artery pressure > 2/3 systemic BP)
  - Unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, bridging internal mammary artery (IMA) at high risk of injury, etc.
  - Evaluable data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF < 20% or an LVESD > 60 mm. ValveClamp® should be used only when criteria for clamp suitability for DMR have been met.

6) The doctor shall make the patient fully informed of the risks and limitations of the product and the operation, and the importance of following the doctor's advice before operation.
7) ValveClamp® is sterilized by ethylene oxide and for single use. Before use, check the integrity of the packaging and the expiry date of the product. Do not use the product if the inner package is damaged or the sterilization indicator label is red. Do not use if the “Use-by” date has passed.
8) Do not bring non-sterile packaging into sterile area.
9) Do not use the product whose inner packaging label is not consistent with the color box label.
10) Please choose the model of the Clamp carefully. An improper size may lead to bad clamping effect.
11) Do not use the Clamp that is deformed, damaged or broken. Products damaged during operation shall not be used.
12) Do not attempt to reposition or withdraw the Clamp once the Clamp is released.
13) Do not process or change the product in any way (for example, modifying, bending or scratching the shape of the product) to prevent the product from failing.
14) Patients shall carry out postoperative restricted activities under the guidance of doctors to prevent complications that may result from product failure due to

excessive activity or weight-bearing after operation.

15) When an accident occurs during the use of products, take the following protective measures and emergency and corrective measures for the operators and users:
    - Allergies: If the patient is allergic to the nickel-titanium alloy material (rare), perform treatment according to the degree of allergy;
    - Embolism: Intraoperative anticoagulation shall be adequate to avoid embolization; intraoperative de-air shall be sufficient to avoid gas embolism;
    - Infection: Long operation time, or lax disinfection may cause infections. Strictly follow aseptic operation procedures, and use antibiotics prophylactically after operation;
    - Valve injury or chordal entanglement/rupture: Surgical repair of the damaged site may be required depending on the severity;
    - Clamp detachment: Unilateral detachment of the Clamp may result in surgical failure. Depending on the consequence of the Clamp detachment, conservative treatment, re-implantation of the Clamp, or surgical valve surgery may be required. If the detachment occurs on the both sides and cause embolism, interventional or surgical removal is required.
16) After using the product, destroy the medical wastes in accordance with the applicable local regulations and the hospital rules.

7. Warnings

- **Do not use ValveClamp® outside of the labeled indication.**
- **ValveClamp® is intended to reduce mitral regurgitation. The ValveClamp® procedure is recommended to be performed when an experienced heart team has determined that reduction of MR to ≤2+ is reasonably expected following the ValveClamp®. If MR reduction to ≤2+ cannot be achieved, the benefits of reduced symptoms and hospitalizations, improved quality of life, and reverse LV remodeling expected from the ValveClamp® procedure may not occur.**
- **The ValveClamp® procedure can only be performed by doctors who have been subject to trainings on transcatheter mitral valve repair procedures and knowledge of ValveClamp®. It also requires involvement of echocardiographer who are proficient in mitral valve disease.**
- **Read all the instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps while handling ValveClamp® to avoid user injury.**
- **ValveClamp® is provided sterile and designed for single use only. Before use, check the sterile packaging of the product. If there is any damage, please do not use it. Cleaning, re-sterilization, and/or reuse may result in infections, malfunction of the device, or other serious injuries or death.**
- **Implant ValveClamp® with sterile techniques under the guidance of echocardiography (e.g., transesophageal echocardiography [TEE] and transthoracic echocardiography [TTE]) in a facility with a cardiac surgery team on site and immediate access to a cardiac operating room.**
- **The entire process of the ValveClamp® procedure needs to be guided by echocardiography. To ensure the effectiveness of the device, it is necessary to conduct preoperative evaluations of the mitral valve and potential pathology**

and anatomy as well as intraoperative assessment by echocardiography, and the procedure shall be performed by doctors who have received professional trainings on ValveClamp®. Inappropriate echocardiographic guidance or clamping operation may lead to unilateral or complete detachment of the Clamp, leaflet tear, postoperative moderate to severe mitral regurgitation, and other adverse events.

- **Anatomic considerations:**
  To obtain optimal outcomes, the following anatomical characteristics of patients should be considered. The safety and effectiveness of ValveClamp® outside of these conditions have not been established yet. Use outside of these conditions may be challenging or inadequate, and should be evaluated by a professional heart team.
  - **Mitral valve area ≥ 3.0 cm^2**
  - **None or minimal calcification in the clamping area**
  - **No leaflet cleft in the clamping area**
  - **The length of motional leaflet segment ≥ 7 mm**
- **The operation is performed under general anesthesia. Anesthesia evaluation should be conducted before operation. The pre-anesthetic drug usage and dosage should be determined based on the patient's heart function and other complicated diseases.**
- **Patients who are allergic to nickel, titanium, and/or polymer materials may have allergic reactions to ValveClamp®.**
- **ValveClamp® should be used in conjunction with the accompanied Delivery System and Transvalvular Device of Hanyu Medical. Do not turn the Pusher anticlockwise before releasing the Clamp.**
- **Postoperative medication recommendations: For patients without anticoagulant indications, there is no evidence from large-scale clinical studies to guide the selection of antiplatelet medications. According to previous studies, it is recommended to use aspirin 100 mg (once a day) and clopidogrel 75 mg (once a day) for antithrombotic therapy for 3 months, and then continue to use the above antithrombotic drugs alone for 3 months. For patients with anticoagulant indications, antithrombotic therapy is prescribed for at least 6 months. Follow the doctor's advice for specific medications.**

8. Instructions for Use

8.1 MVC-s

8.1.1 Check before use

(1) Check the use-by date of the product, and do not use the product if it expires.
(2) Check the sterile packaging of the product, and do not use the product if it has been opened or damaged.
(3) Unpack the inner packaging in the sterile area, remove the device from packaging, and check the patency of the Push Rod and the clamping and deploying performance of the Clamp.
(4) Check the integrity of the product, and do not use the product if it's damaged. Do not use the product if it falls from a height of 40 cm or more onto a hard surface because the product may be damaged and cannot be operated properly.
(5) Check whether the Pusher and the Upper Clamp are released or separated, do not use the device if so.

Note: The inner packaging of this product is a double-layer paper-plastic bag. The contents in the outer paper-plastic bag are provided aseptically and should be taken and placed under aseptic conditions to avoid contamination.
Do not rotate the Small Handle of the Pusher counterclockwise before use. The user must be fully trained.

8.1.2 Preinstallation

Rotate the Handle Screw to remove the Small Handle of the Pusher (Figure 6). After installing the Pusher into the Transporter, put the Small Handle of the Pusher back on the end of the Push Rod, and tighten the Handle Screw. Rotate the Pusher clockwise **(Note: Do not rotate the Pusher counterclockwise here)** until the Lower Clamp enters the unthreaded section of the Closure Ring.

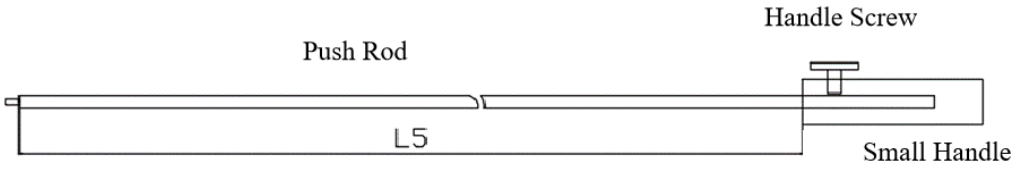

Figure 6 Pusher

8.1.3 De-air

Lock the Haemostasis Valve, push the Loader, retract the Clamp into the Loader in parallel, then open the Haemostasis Valve of the Delivery System, and flush the entire system with heparinized saline (12,000 units of heparin/1,000ml of saline) through a syringe to completely remove the air.

8.1.4 Puncture and transvalvular operations

Puncture the center of the purse-string of the apex with a puncture needle and advance the guide wire into the left ventricle (Figure 7-1, **Note: The puncture point should be located in the plane where the Delivery System perpendicular to the mitral annular**). Insert the Sheath Introducer and Dilator over the guide wire, and then remove the guide wire and Dilator (**Note: The Sheath Introducer shall not be inserted too deeply and shall be located below the level of the papillary muscle**). Advance the Transvalvular Device through the Sheath Introducer to the left ventricle (The Transvalvular Device is pre-installed in a sheath), push the Transvalve Ball out (Figure 7-2), and continue to advance the Transvalvular Device to the left atrium, advance the Sheath Introducer into the center of the left atrium through the Transvalvular Device (Figure 7-3), and then withdraw the Transvalvular Device (Figure 7-4).

Figure 7-1

Figure 7-2

Figure 7-3

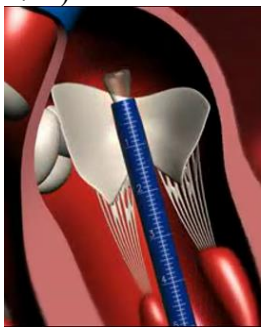

Figure 7-4

8.1.5 Implantation procedure

Perform real-time monitoring by transesophageal echocardiography (TEE) during the operation. Connect the Loader to the Sheath Introducer, push the Transporter into the Sheath Introducer to scale 1 (Figure 9), to expose and deploy the Upper Clamp in the left atrium (Figure 8-1); withdraw the Sheath Introducer and the Loader to scale 2, to expose and deploy the Lower Clamp in the left atrium (Figure 8-2); and continue to

withdraw the Sheath Introducer to scale 3, to fully expose the Closure Ring. Retract the Transporter and the Sheath Introducer until the Lower Clamp enters into the left ventricle, so that the Upper Clamp and Lower Clamp are positioned on the both sides of mitral valve leaflets (Figure 8-3); loosen the Haemostasis Valve, and rotate the Pusher clockwise **(Note: Do not rotate the Pusher counterclockwise here)** to make the Upper Clamp and Lower Clamp in place. Push the Transporter (i.e. push the Lower Clamp) to ensure that both the anterior and posterior mitral valve leaflets are captured, pull back the Pusher (i.e. pull back the Upper Clamp) to ensure that the mitral valve leaflets are firmly clamped, and tighten the Upper Clamp to make the Upper Clamp and Lower Clamp arms gathered together and retracted into the Closure Ring **(Note: Repeated clamping is allowed, but not for more than 3 times)**.
Rotate the Small Handle of the Pusher counterclockwise to release the Pusher (Figure 8-4); unscrew the front end cover of the Transporter, cut the Fixing Wire, and pull out the Fixing Wire along one end to release the Transporter and withdraw it **(Note: When pulling out the Fixing Wire, do not make the valve tethered)**. Then withdraw the Sheath Introducer.


Figure 8-1


Figure 8-2


Figure 8-3


Figure 8-4

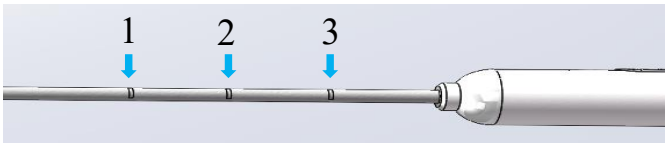

Figure 9

8.2MVC-f

8.2.1 Check before use

(1) Check the use-by date of the product, and do not use the product if it expires.
(2) Check the sterile packaging of the product, and do not use the product if it has been opened or damaged.
(3) Unpack the inner packaging in the sterile area, remove the device from packaging, and check the patency of the push rod and the clamping and deploying performance of the Clamp.
(4) Check the integrity of the product, and do not use the product if it's damaged. Do not use the product if it falls from a height of 40 cm or more onto a hard surface because the product may be damaged and cannot be operated properly.
(5) Check whether the Pusher and the Upper Clamp are released or separated, do not use the device if so.
(6) Check whether the anti-rotation knob (Figure 10) is locked "0".

Figure 10 Anti-rotation Knob

Note: The inner packaging of this product is a double-layer paper-plastic bag. The contents in the outer paper-plastic bag are provided aseptically and should be taken and placed under aseptic conditions to avoid contamination.

Do not rotate the Small Handle of the Pusher counterclockwise before use. The user must be fully trained.

8.2.2 De-air

After retracting the Clamp into the Loader in parallel, open the Haemostasis Valve of the Delivery System, and flush the entire system with heparinized saline (12,000U heparin/1,000ml saline) through a syringe to completely remove the air.

8.2.3 Puncture and transvalvular operations

Puncture the center of the purse-string of the apex with a puncture needle and advance the guide wire into the left ventricle (Figure 7-1, **Note: The puncture point should be located in the plane where the Delivery System perpendicular to the mitral annular**). Insert the Sheath Introducer and Dilator over the guide wire, and then remove the guide wire and Dilator (**Note: The Sheath Introducer shall not be inserted too deeply and shall be located below the level of the papillary muscle**). Advance the Transvalvular Device through the Sheath Introducer to the left ventricle (The Transvalvular Device is pre-installed in a sheath), push the Transvalve Ball out (Figure 7-2), and continue to advance the Transvalvular Device to the left atrium. advance the Sheath Introducer into the center of the left atrium through the Transvalvular Device (Figure 7-3), and then withdraw the Transvalvular Device (Figure 7-4).

8.2.4 Implantation Procedure

Perform real-time monitoring by transesophageal echocardiography (TEE) during the operation. Connect the Loader to the Sheath Introducer, push the Transporter into the Sheath Introducer to scale 1, to expose and deploy the Upper Clamp in the left atrium (Figure 8-1); withdraw the Sheath Introducer and the Loader to scale 2, to expose and deploy the Lower Clamp in the left atrium (Figure 8-2); continue to withdraw the Sheath Introducer to scale 3, to expose the connector. Retract the Transporter and the Sheath Introducer until the Lower Clamp enters into the left ventricle, so that the Upper Clamp and Lower Clamp are positioned on the mitral valve leaflets (Figure 8-3) **(Note: The Upper Clamp arm and the Lower Clamp arm should be kept as parallel as possible along the axial direction, and they cannot be retracted into the Closure Ring if the included angle is too large)**; loosen the Haemostasis Valve, and rotate the Pusher clockwise **(Note: Do not rotate the Pusher counterclockwise here)** to make the Upper Clamp and Lower Clamp in place. Push the Transporter (ie, push the Lower Clamp) to ensure that both the anterior and posterior mitral valve leaflets are captured, and then pull back the Pusher (ie, pull back the Upper Clamp) to ensure that the mitral valve leaflets are firmly clamped, and tighten the Upper Clamp to make the Upper Clamp and Lower Clamp arms gathered together and retracted into the Closure Ring **(Note: Repeated clamping is allowed, but not for more than 3 times)**.

Rotate the Anti-rotation Knob (Figure 10) to the unlocked state "🔓", rotate the Small Handle of the Pusher counterclockwise, unscrew the Push Rod, open the Connector to release the Clamp, and then withdraw the Sheath Introducer.

9. Magnetic Resonance (MR) Safety Information

According to non-clinical tests, the Clamp deflection angle is less than 45° under the static NMR condition of 3.0 T.
Under the static NMR condition of 3.0 T, the Clamp can generate a slight torque, which is less than the worst weight torque.
When MRI scanning is performed under the static NMR condition of 3.0 T at an average specific absorption rate (SAR) of 2.7 W/kg for 15 minutes, the maximum temperature rise of the Clamp will not exceed 1.0 ℃.
Under the static NMR condition of 3.0 T, the artifact width of the magnetic resonance image of the Clamp does not exceed 30.0 mm.

10.Packaging

10.1 Product packaging

The product is provided sterile, in a preformed tray with lid or on a liner, in a sealed double-layer paper-plastic pouch.

10.2 Packing list

ValveClamp®, 1 piece;
Instructions for use, 1 hardcopy;
Labels are accompanied.

11.Suggestive Content

11.1 Devices used in combination

ValveClamp® can be used in combination with the Mitral Valve Clamp System Fixator produced by Hanyu Medical, according to the needs of doctors.
Mitral Valve Clamp System Fixator, filing number: HMXB20210034

11.2 Additional equipment/materials used in combination

Equipment/devices to be provided by the healthcare facility include but are not limited to the following:
· Transthoracic echocardiography (TTE)
· Transesophageal echocardiography (TEE)
· Puncture needle
· Purse-string suture needle
· 0.038 inch guide wire
· 6~9 Fr sheath
· Heparinized saline
· Syringe

12.Sterilization

The product is sterilized by ethylene oxide, is disposable and has a shelf life of 3 years.

13.Storage and Transport

Store at room temperature. Keep dry, clean, well-ventilated, away from sunlight. Avoid corrosive gas.
Avoid direct sunlight, rain and snow immersion, moisture, high temperature, heavy pressure and impact during transportation.

14.Summary of Safety and Clinical Performance

14.1 Claimed Performance Characteristics

The ValveClamp® is designed to repair the mitral valve with an artificial clamp using a minimally invasive transapical approach.

14.2 Specified Clinical Benefits

➢ Most patients receiving a ValveClamp® can expect symptom relief:

- Improvement in mitral regurgitation compared to pre-procedure as demonstrated by transthoracic echocardiography.
- Significant improvement in New York Heart Association (NYHA) Functional Classification compared with pre-procedure.

14.3 Summary of Safety and Clinical Performance

Summary of Safety and Clinical Performance (SSCP) is available in the European database on medical devices (Eudamed), please use the Basic UDI-DI "697516329VC01M9" to search and find the intended SSCP.
URL to the Eudamed public website: https://ec.europa.eu/tools/eudamed.

15.Basic Information

Manufacturer: Shanghai Hanyu Medical Technology Co., Ltd.
Address: Room X4, 3rd Floor, Building 1, No. 18 Chunchang Road, Minhang District, Shanghai, 201108, P.R China
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Revision Date: April 23, 2024
Version: V2.0
Production Date: See label
Expiry Date: See label

16.Definitions of Symbols

No.	Symbol	Title	Description
1		Medical Device	Indicates the product is a medical device.
2		Manufacturer	Indicates the medical device manufacturer.

3		Authorized representative in the European Community	Indicates the authorized representative in the European Community.
4		Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
5		Date of Manufacture	Indicates the date when the medical device was manufactured.
6		Use-by date	Indicates the date after which the medical device is not to be used.
7		Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
8		Do not resterilize	Indicates a medical device that is not to be resterilized.
9		Keep dry	Indicates a medical device that needs to be protected from moisture.
10		Keep away from sunlight	Indicates a medical device that needs protection from light sources.
11		Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
12		Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.
13		MR Conditional	Indicates a medical device that is no danger under certain MR conditions.

14		Do not reuse	Indicates a medical device that is intended for one single use only.
15		Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
16		CE marking	Indicates a medical device that can meet the European Standards.