CE 2797

MemoPart™ VSD Occluder
Instruction for Use

Shanghai Shape Memory Alloy Co., Ltd.
Address: 1F and 5F, Tower 41, No. 258 XinZhuan Road, Songjiang High-Tech Park,
CaoHeJing Development District, 201612 Shanghai, P.R. China
Code: 201612
Tel : +86-21-37013390
Fax : +86-21-37013391
Web: ***https://en.scientechmed.com/***

EC REP **Lepu Medical (Europe) Cooperatief U.A.**
Address: Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, the Netherlands
Tel: +31-515-573399
Fax: +31-515-760020

SHSMA
Shanghai Shape Memory Alloy Co., Ltd.

TABIE OF CONTENT

Read "Instruction for Use" carefully before use, Users should have the interventional treating practice or be guided by professionals.

- Use on or before the last day of the expiration month noted on the product packaging.
- This device is sterilized using ethylene oxide and is for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization, or patient harm.
- Do not use the device if the packaging sterile barrier is open or damaged.

1. Product Description

MemoPart™ VSD Occluder is a self-expanding double-disc nitinol mesh occlusion device. The 2 discs are connected by a short waist which corresponds to the defect size. Polyester fabric is securely sewn to each disc to secure the occlusion. The device is visible under X-ray.

2. Intended purpose

MemoPart™ VSD Occluder is specially designed for transcatheter closure of congenital ventricular septal defect.

2.1 Indications for Use

- *Membranous VSD Occluder*
  The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.
- *Muscular VSD Occluder*
  1) Patient with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) ;
  2) Patients who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition. High-risk anatomical factors for transatrial or transarterial surgical closure include patients:
     - Requiring left ventriculotomy or an extensive right ventriculotomy;
     - With a failed previous VSD closure;
     - With multiple apical and/or anterior muscular VSDs ("Swiss cheese septum");
     - With posterior apical VSDs covered by trabeculae.

2.2 Contraindications

- *For membranous ventricular septal defect*:
  - Presence of thrombi in the chambers of the heart and hemorrhagic diseases such as active ulcer;
  - Recent infection is found;

- Patients with very small vessels which are inadequate to accommodate the appropriate sheath size;
- The patient with a distance from the edge of the defect to the aorta or to the tricuspid valve less than 3mm;
- Anatomy in which the Membranous VSD Occluder would interfere which the aortic or atrioventricular valves;
- Patients with coagulation disorder who are unable to take antiplatelet or anticoagulant therapy;
- Patients with an intra-cardiac mass or vegetation.

- *For muscular ventricular septal defect*:
  - Patients who do not have a Muscular VSD or if the Muscular VSD is from a heart attack;
  - Patients with an infection anywhere in the body recently. They may receive the device only after the infection is gone;
  - Patients unable to take aspirin (unless they can take other anti-platelet agents for 6 months);
  - Patient whose heart or veins are very small, or if he cannot take undergo the procedure;
  - Patients with defects less than 4 mm distance from the semilunar (aortic and pulmonary) and atrioventricular valves (mitral and tricuspid);
  - Patients with severely increased pulmonary vascular resistance above 7 Wood units and a right-to-left shunt and documented irreversible pulmonary vascular disease.

3. Intended Patient Populations

1) This device is suitable for any patients with the above disease or medical condition except for whom with contraindications. The safety and efficacy of MemoPart™ VSD Occluder in pregnant women or men intending to father children, nursing mothers and the immunocompromised patients have not been established.
2) As for weight of intended patients:
   - MemoPart™ VSD Occcluder is recommended in the transcatheter closure of VSD in patients weighting ≥10kg;
   - For patients weighting <10kg, MemoPart™ VSD Occluder should be used under the suggestion of clinical professional.

4. Intended Users

The MemoPart™ VSD Occluder should only be used by a physician who are trained in transcatheter defect closure techniques. The physician should determine which patients are candidates for procedures that use this device.

Before use, the operator should have a full understanding of the using instruction, warnings and precautions.

5. Warning

6.1 Patients who are allergic to nickel may have an allergic reaction to this device.

6.2 This device should only be used by physicians who have been trained in transcatheter techniques and who should determine which patients are suitable candidates for procedures using this device.

6.3 Physicians must be prepared to deal with urgent situations, such as device embolization, which require removal of the device. This includes the availability of an on-site surgeon.

6.4 This product is fit for magnetic resonance imaging.

6.5 There is a variety of pocket-type (aneurysm of membranous septum) ventricular septal defect and incomplete occlusion may take septal defects with big entrances and multiple exits, so appropriate occluder should be chosen with care. Angiography in left ventricle should be performed before releasing the occluder to determine if the shunt is present or not.

6.6 It is important to choose the appropriate sheath to the ventricular septal defect occluder (see Table 1); if the sheath cannot match the occluder, it would be difficult to push or retrieve the occluder which may even cause damages to the blood vessels.

6. Precautions

Before foreign like product happened the unexpected situations during the using were the cardiac tamponade caused by cardiac wall perforation, the dropping of occluder, auriculo-ventricular block, aortic insufficiency, tricuspid incompetence and hemolysis. Therefore, it should be pay an attention to prevention in the operation. And it's required that the institute which has the conditions for cardiothoracic surgery could use this occluder. In case the cardiac tamponade caused by cardiac wall perforation was occurred, the pericardiocentesis drainage should be immediately implemented, if the occluder was dropped after released, the emergency surgery should be implemented to remove the occluder.

MR Conditional: Non-clinical testing has demonstrated that the VSD occluder is MR Conditional.

Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5T and 3.0T;
- Maximum allowable spatial gradient of the magnetic field is 20T/m in 3.0T and 40T/m in 1.5T MR system;
- Maximum whole-body specific absorption rate (SAR) of 2W/kg for 15 minutes of scanning in normal operating mode.

- The presence of this implant might produce an image artifact.

7. Adverse Events

Potential adverse events may occur during or after a procedure placing this device may include, but are not limited to:

Death, Residual shunt, Cardiac arrhythmia, Heart block/Conductive block, Thrombosis, Dislocation/malposition/device migration, Device embolization, Infection including endocarditis, Fever, Cardiac perforation/tamponade, Cardiac erosion, Pericardial effusion, Pleural effusion, Valvular insufficiency/regurgitation, Valve damage, Vessel trauma/damage, Hematoma, Bleeding/Blood transfusion, Hemolysis, Arterio-venous fistula, Hypertension/hypotension, CVA/Stroke/TIA, Subaortic Stenosis, Ventricular outflow tract stenosis, Chest pain, Anesthesia reactions, Headache/migraine, Pulmonary hypertension, Cyanosis, Vomiting, Pulmonary edema, Arterial pulse loss, Brachial plexus injury, Device fracture, Syncope, Atelectasis, Cardiomyopathy, Abdominal gassiness, Stridor, Allergic reaction.

Any serious incident that has occurred in relation to the device should be repor ted to the manufacturer and the competent authority of the Member State in wh ich the user and/or patient is established.

8. Clinical Benefits to be expected

- High procedural success;
- High complete closure rate;
- Low rate of clinical adverse event.

9. Summary of Safety and Clinical Performance (SSCP)

The summary of safety and performance for the device is available on the website of EUDAMED: https://ec.europa.eu/tools/eudamed.

10. Materials recommended for use with this device

- 0.035-inch guidewire of sufficient stiffness
- 20 ml luer-lock syringe

11. Directions for Use

12.1 Perform preoperative disinfection and spread out the operating towel and drape.

12.2 Local anesthesia or general anesthesia.

12.3 Seldinger puncture at right femoral vein and artery is performed.

12.4 Place the leakage-proof sheath.

12.5 Inject 100μ/kg of heparin into the vein which would be increased by 1000-2000μ every hour.

12.6 Perform routine cardiac catheter examination and determine pressure inside each cardiac chamber as well as the blood oxygen content.

12.7 Deliver the angiography catheter of right coronary into the left ventricle and then into right ventricle via the ventricular septal defect; deliver the guiding wire through the catheter into precava or pulmonary artery (see Fig 2).

12.8 Deliver the right cardiac catheter into the pulmonary artery via the vein and into the snare through the catheter; hitch the guiding wire and pull it out of the body after which the artery-ventricular septal defect-vein track has been established.

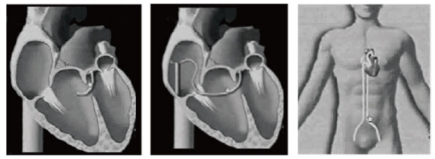

Fig. 2 Operation chart for artery-vein track

12.9 Insert the guiding wire into the delivery sheath and deliver it into the left ventricle. Choose the occluder with appropriate size according to the results of angiography; mostly the disc diameter of occluder would be 2mm larger than the determined diameter.

12.10 Put the occluder into heparinized saline, connect it with the pusher, rotate it clockwise for 4 rounds and pull it into the short sheath. Push in heparinized saline rapidly through the connecting tube of the haemostatic by-pass valve and drain all the bubbles out of the occlusion device.

12.11 Insert the dilator into the longer sheath and push forward under X-ray; open the disc at the side of the left ventricle and retrieve it back to ventricular septum; if the encountered resistance is tested to be around the ventricular septum by echocardiography, then fix the pusher and retrieve the sheath as well as release the disc of the occluder at the side of the right ventricle. Push and pull the occluder to see if it is fixed; if echocardiography shows that it would not impact the function of aortic valve and tricuspid valve and the angiography shows that it would not impact the function of aortic valve, and then the pushing pole could be rotated counterclockwise to release the occluder.

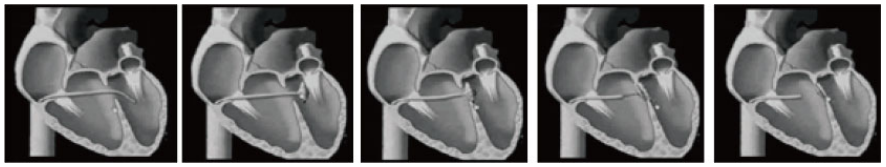

Fig. 3 Operation chart for VSD

12.12 During the operation, TTE is performed from the five-chamber view at the

cardiac apex and the short-axis view. The occluder could only be released when all results from these two views have shown that the occluder is closely next to the residual edge of the ventricular septum.

12.13 Push out the sheath and finish the operation.

12.14 Take orally 3-5 mg/kg aspirin after operation for 6 months.

12. Disposal

Treat all disposable devices appropriately according to the local requirements for medical device waste disposal.

13. Storage and Expiry Date

14.1 Store in a dry place without ultraviolet radiation and should be stored in a well-ventilated room with a relative humidity of no more than 80% and no corrosion gas.

14.2 The period of validity is five years when this product is stored under specified condition.

14. Symbol Definitions

SYMBOL	EXPLANATION OF SYMBOL
	MANUFACTURER
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	DATE OF MANUFACTURE
	USE-BY DATE
LOT	BATCH CODE
REF	CATALOGUE NUMBER
SN	SERIAL NUMBER
STERILE EO	STERILIZED USING ETHYLENE OXIDE
	DOUBLE STERILE BARRIER SYSTEM
	SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE
	SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE AND STERILIZED USING ETHYLENE OXIDE
	DO NOT RESTERILIZE
	DO NOT RE-USE
	DO NOT USE IF PACKAGE IS DAMAGED
	CONSULT INSTRUCTIONS FOR USE
MD	MEDICAL DEVICE
UDI	UNIQUE DEVICE IDENTIFIER
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
MR	MR CONDITIONAL
CE 2797	CE MARKING AND IDENTIFICATION NUMBER OF NOTIFIED BODY
The color of EO Sterilization indicator on the package bag turns yellow after EO sterilization.	

15. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

Descriptions or specifications in Shanghai Shape Memory Alloy Co., Ltd. printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. Shanghai Shape Memory Alloy Co., Ltd will not be responsible for any direct, incidental, or consequential damages resulting from the abnormal use of the product.

16. Specification and Recommend sheath size

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
SQFDQ-Ⅰa04	04	8.0±1.0	5.0±1.5	4.0±1.0	8.0±1.0	7-8F	Muscular defect
SQFDQ-Ⅰa05	05	9.0±1.0	5.0±1.5	5.0±1.0	9.0±1.0	7-8F	
SQFDQ-Ⅰa06	06	10.0±1.0	5.0±1.5	6.0±1.0	10.0±1.0	8-9F	

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
SQFDQ-Ⅰa07	07	11.0±1.0	5.0±1.5	7.0±1.0	11.0±1.0	8-9F	
SQFDQ-Ⅰa08	08	12.0±1.0	5.0±1.5	8.0±1.0	12.0±1.0	8-9F	
SQFDQ-Ⅰa09	09	13.0±1.0	5.0±1.8	9.0±1.0	13.0±1.0	8-9F	
SQFDQ-Ⅰa10	10	14.0±1.0	5.0±1.8	10.0±1.2	14.0±1.0	9-10F	
SQFDQ-Ⅰa12	12	16.0±1.0	5.0±1.8	12.0±1.2	16.0±1.0	9-10F	
SQFDQ-Ⅰa14	14	18.0±1.0	5.0±1.8	14.0±1.5	18.0±1.0	10-12F	
SQFDQ-Ⅰa16	16	20.0±1.0	5.0±1.8	16.0±1.5	20.0±1.0	10-12F	
SQFDQ-Ⅰa18	18	22.0±1.0	5.0±1.8	18.0±1.5	22.0±1.0	10-12F	
SQFDQ-Ⅰb04	04	10.0±1.0	7.0±1.5	4.0±1.0	8.0±1.0	7-8F	
SQFDQ-Ⅰb05	05	11.0±1.0	7.0±1.5	5.0±1.0	9.0±1.0	7-8F	
SQFDQ-Ⅰb06	06	12.0±1.0	7.0±1.5	6.0±1.0	10.0±1.0	8-9F	
SQFDQ-Ⅰb07	07	13.0±1.0	7.0±1.5	7.0±1.0	11.0±1.0	8-9F	
SQFDQ-Ⅰb08	08	14.0±1.0	7.0±1.5	8.0±1.0	12.0±1.0	8-9F	Muscular defect
SQFDQ-Ⅰb09	09	15.0±1.0	7.0±1.8	9.0±1.0	13.0±1.0	8-9F	
SQFDQ-Ⅰb10	10	16.0±1.0	7.0±1.8	10.0±1.2	14.0±1.0	9-10F	
SQFDQ-Ⅰb12	12	18.0±1.0	7.0±1.8	12.0±1.2	16.0±1.0	9-10F	
SQFDQ-Ⅰb14	14	20.0±1.0	7.0±1.8	14.0±1.5	18.0±1.0	10-12F	
SQFDQ-Ⅰb16	16	22.0±1.0	7.0±1.8	16.0±1.5	20.0±1.0	10-12F	
SQFDQ-Ⅰb18	18	24.0±1.0	7.0±1.8	18.0±1.5	22.0±1.0	10-12F	
SQFDQ-Ⅰc04	04	14.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F	
SQFDQ-Ⅰc05	05	15.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F	

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
SQFDQ-Ⅰc06	06	16.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F	
SQFDQ-Ⅰc07	07	17.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F	
SQFDQ-Ⅰc08	08	18.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F	
SQFDQ-Ⅰc09	09	19.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F	
SQFDQ-Ⅰc10	10	20.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F	
SQFDQ-Ⅰc12	12	22.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F	Muscular defect
SQFDQ-Ⅰc14	14	24.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F	
SQFDQ-Ⅰc16	16	26.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F	
SQFDQ-Ⅰc18	18	28.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F	
SQFDQ-Ⅰd04	04	18.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F	
SQFDQ-Ⅰd05	05	19.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F	
SQFDQ-Ⅰd06	06	20.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F	
SQFDQ-Ⅰd07	07	21.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F	
SQFDQ-Ⅰd08	08	22.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F	
SQFDQ-Ⅰd09	09	23.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F	
SQFDQ-Ⅰd10	10	24.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F	
SQFDQ-Ⅰd12	12	26.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F	
SQFDQ-Ⅰd14	14	28.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F	
SQFDQ-Ⅰd16	16	30.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F	
SQFDQ-Ⅰd18	18	32.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F	
WTSQFDQ-Ⅰa04	04	8.0±1.0	5.0±1.5	4.0±1.0	8.0±1.0	7-8F	Muscular defect

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
WTSQFDQ-Ⅰa05	05	9.0±1.0	5.0±1.5	5.0±1.0	9.0±1.0	7-8F	
WTSQFDQ-Ⅰa06	06	10.0±1.0	5.0±1.5	6.0±1.0	10.0±1.0	8-9F	
WTSQFDQ-Ⅰa07	07	11.0±1.0	5.0±1.5	7.0±1.0	11.0±1.0	8-9F	
WTSQFDQ-Ⅰa08	08	12.0±1.0	5.0±1.5	8.0±1.0	12.0±1.0	8-9F	
WTSQFDQ-Ⅰa09	09	13.0±1.0	5.0±1.8	9.0±1.0	13.0±1.0	8-9F	
WTSQFDQ-Ⅰa10	10	14.0±1.0	5.0±1.8	10.0±1.2	14.0±1.0	9-10F	
WTSQFDQ-Ⅰa12	12	16.0±1.0	5.0±1.8	12.0±1.2	16.0±1.0	9-10F	
WTSQFDQ-Ⅰa14	14	18.0±1.0	5.0±1.8	14.0±1.5	18.0±1.0	10-12F	
WTSQFDQ-Ⅰa16	16	20.0±1.0	5.0±1.8	16.0±1.5	20.0±1.0	10-12F	
WTSQFDQ-Ⅰa18	18	22.0±1.0	5.0±1.8	18.0±1.5	22.0±1.0	10-12F	
WTSQFDQ-Ⅰb04	04	10.0±1.0	7.0±1.5	4.0±1.0	8.0±1.0	7-8F	
WTSQFDQ-Ⅰb05	05	11.0±1.0	7.0±1.5	5.0±1.0	9.0±1.0	7-8F	
WTSQFDQ-Ⅰb06	06	12.0±1.0	7.0±1.5	6.0±1.0	10.0±1.0	8-9F	
WTSQFDQ-Ⅰb07	07	13.0±1.0	7.0±1.5	7.0±1.0	11.0±1.0	8-9F	Muscular defect
WTSQFDQ-Ⅰb08	08	14.0±1.0	7.0±1.5	8.0±1.0	12.0±1.0	8-9F	
WTSQFDQ-Ⅰb09	09	15.0±1.0	7.0±1.8	9.0±1.0	13.0±1.0	8-9F	
WTSQFDQ-Ⅰb10	10	16.0±1.0	7.0±1.8	10.0±1.2	14.0±1.0	9-10F	
WTSQFDQ-Ⅰb12	12	18.0±1.0	7.0±1.8	12.0±1.2	16.0±1.0	9-10F	
WTSQFDQ-Ⅰb14	14	20.0±1.0	7.0±1.8	14.0±1.5	18.0±1.0	10-12F	
WTSQFDQ-Ⅰb16	16	22.0±1.0	7.0±1.8	16.0±1.5	20.0±1.0	10-12F	
WTSQFDQ-Ⅰb18	18	24.0±1.0	7.0±1.8	18.0±1.5	22.0±1.0	10-12F	

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
WTSQFDQ-Ⅰc04	04	14.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F	
WTSQFDQ-Ⅰc05	05	15.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F	
WTSQFDQ-Ⅰc06	06	16.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F	
WTSQFDQ-Ⅰc07	07	17.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F	
WTSQFDQ-Ⅰc08	08	18.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F	
WTSQFDQ-Ⅰc09	09	19.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F	
WTSQFDQ-Ⅰc10	10	20.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F	
WTSQFDQ-Ⅰc12	12	22.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F	Muscular defect
WTSQFDQ-Ⅰc14	14	24.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F	
WTSQFDQ-Ⅰc16	16	26.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F	
WTSQFDQ-Ⅰc18	18	28.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F	
WTSQFDQ-Ⅰd04	04	18.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F	
WTSQFDQ-Ⅰd05	05	19.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F	
WTSQFDQ-Ⅰd06	06	20.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F	
WTSQFDQ-Ⅰd07	07	21.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F	
WTSQFDQ-Ⅰd08	08	22.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F	
WTSQFDQ-Ⅰd09	09	23.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F	
WTSQFDQ-Ⅰd10	10	24.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F	
WTSQFDQ-Ⅰd12	12	26.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F	
WTSQFDQ-Ⅰd14	14	28.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F	
WTSQFDQ-Ⅰd16	16	30.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F	

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
WTSQFDQ-Ⅰd18	18	32.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F	Muscular defect
SQFDQ-Ⅱa04	04	8.0±0.8	1.8±0.5	4.0±0.8	8.0±0.8	6-7F	Membranous defect
SQFDQ-Ⅱa05	05	9.0±0.8	1.8±0.5	5.0±0.8	9.0±0.8	6-7F	
SQFDQ-Ⅱa06	06	10.0±0.8	1.8±0.5	6.0±0.8	10.0±0.8	7-8F	
SQFDQ-Ⅱa07	07	11.0±0.8	1.8±0.5	7.0±0.8	11.0±0.8	7-8F	
SQFDQ-Ⅱa08	08	12.0±0.8	1.8±0.5	8.0±0.8	12.0±0.8	7-8F	
SQFDQ-Ⅱa09	09	13.0±0.8	1.8±0.5	9.0±0.8	13.0±0.8	8-9F	
SQFDQ-Ⅱa10	10	14.0±0.8	1.8±0.5	10.0±0.8	14.0±0.8	8-9F	
SQFDQ-Ⅱa12	12	16.0±0.8	1.8±0.5	12.0±0.8	16.0±0.8	9-10F	
SQFDQ-Ⅱa14	14	18.0±0.8	1.8±0.5	14.0±0.8	18.0±0.8	9-10F	
SQFDQ-Ⅱa16	16	20.0±0.8	1.8±0.5	16.0±0.8	20.0±0.8	10-12F	
SQFDQ-Ⅱa18	18	24.0±0.8	1.8±0.5	18.0±0.8	22.0±0.8	10-12F	
SQFDQ-Ⅱa20	20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F	
SQFDQ-Ⅱb04	04	8.0±0.8	3.5±1.0	4.0±0.8	8.0±0.8	6-7F	
SQFDQ-Ⅱb05	05	9.0±0.8	4.0±1.0	5.0±0.8	9.0±0.8	6-7F	
SQFDQ-Ⅱb06	06	10.0±0.8	4.0±1.0	6.0±1.0	10.0±0.8	7-8F	Membranous defect
SQFDQ-Ⅱb07	07	11.0±1.0	4.0±1.0	7.0±1.0	11.0±1.0	7-8F	
SQFDQ-Ⅱb08	08	12.0±1.0	4.0±1.0	8.0±1.0	12.0±1.0	7-8F	
SQFDQ-Ⅱb09	09	13.0±1.0	4.5±1.0	9.0±1.2	13.0±1.0	8-9F	
SQFDQ-Ⅱb10	10	14.0±1.5	4.5±1.0	10.0±1.2	14.0±1.5	8-9F	
SQFDQ-Ⅱb12	12	16.0±1.5	4.5±1.0	12.0±1.5	15.0±1.5	9-10F	

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
SQFDQ-Ⅱb14	14	18.0±1.5	4.5±1.0	14.0±1.5	17.0±1.5	9-10F	
SQFDQ-Ⅱb16	16	22.0±1.5	5.0±1.0	16.0±1.5	20.0±1.5	10-12F	
SQFDQ-Ⅱb18	18	24.0±1.5	5.0±1.0	18.0±1.8	22.0±1.5	10-12F	
SQFDQ-Ⅱb20	20	26.0±1.5	5.0±1.0	20.0±1.8	24.0±1.5	12-14F	
WTSQFDQ-Ⅱa04	04	8.0±0.8	1.8±0.5	4.0±0.8	8.0±0.8	6-7F	
WTSQFDQ-Ⅱa05	05	9.0±0.8	1.8±0.5	5.0±0.8	9.0±0.8	6-7F	
WTSQFDQ-Ⅱa06	06	10.0±0.8	1.8±0.5	6.0±0.8	10.0±0.8	7-8F	
WTSQFDQ-Ⅱa07	07	11.0±0.8	1.8±0.5	7.0±0.8	11.0±0.8	7-8F	
WTSQFDQ-Ⅱa08	08	12.0±0.8	1.8±0.5	8.0±0.8	12.0±0.8	7-8F	
WTSQFDQ-Ⅱa09	09	13.0±0.8	1.8±0.5	9.0±0.8	13.0±0.8	8-9F	Membranous defect
WTSQFDQ-Ⅱa10	10	14.0±0.8	1.8±0.5	10.0±0.8	14.0±0.8	8-9F	
WTSQFDQ-Ⅱa12	12	16.0±0.8	1.8±0.5	12.0±0.8	16.0±0.8	9-10F	
WTSQFDQ-Ⅱa14	14	18.0±0.8	1.8±0.5	14.0±0.8	18.0±0.8	9-10F	
WTSQFDQ-Ⅱa16	16	20.0±0.8	1.8±0.5	16.0±0.8	20.0±0.8	10-12F	
WTSQFDQ-Ⅱa18	18	24.0±0.8	1.8±0.5	18.0±0.8	22.0±0.8	10-12F	
WTSQFDQ-Ⅱa20	20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F	
WTSQFDQ-Ⅱb04	04	8.0±0.8	3.5±1.0	4.0±0.8	8.0±0.8	6-7F	
WTSQFDQ-Ⅱb05	05	9.0±0.8	4.0±1.0	5.0±0.8	9.0±0.8	6-7F	
WTSQFDQ-Ⅱb06	06	10.0±0.8	4.0±1.0	6.0±1.0	10.0±0.8	7-8F	
WTSQFDQ-Ⅱb07	07	11.0±1.0	4.0±1.0	7.0±1.0	11.0±1.0	7-8F	
WTSQFDQ-Ⅱb08	08	12.0±1.0	4.0±1.0	8.0±1.0	12.0±1.0	7-8F	

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
WTSQFDQ-Ⅱb09	09	13.0±1.0	4.5±1.0	9.0±1.2	13.0±1.0	8-9F	
WTSQFDQ-Ⅱb10	10	14.0±1.5	4.5±1.0	10.0±1.2	14.0±1.5	8-9F	
WTSQFDQ-Ⅱb12	12	16.0±1.5	4.5±1.0	12.0±1.5	15.0±1.5	9-10F	
WTSQFDQ-Ⅱb14	14	18.0±1.5	4.5±1.0	14.0±1.5	17.0±1.5	9-10F	
WTSQFDQ-Ⅱb16	16	22.0±1.5	5.0±1.0	16.0±1.5	20.0±1.5	10-12F	
WTSQFDQ-Ⅱb18	18	24.0±1.5	5.0±1.0	18.0±1.8	22.0±1.5	10-12F	
WTSQFDQ-Ⅱb20	20	26.0±1.5	5.0±1.0	20.0±1.8	24.0±1.5	12-14F	
SQFDQ-Ⅲ04	04	12.0±1.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F	
SQFDQ-Ⅲ05	05	13.0±1.0	4.0±1.5	5.0±1.0	9.0±1.0	8-9F	
SQFDQ-Ⅲ06	06	14.0±1.0	4.0±1.5	6.0±1.0	10.0±1.0	8-9F	
SQFDQ-Ⅲ07	07	15.0±1.0	4.0±1.5	7.0±1.2	11.0±1.0	8-9F	Membranous defect
SQFDQ-Ⅲ08	08	16.0±1.2	4.0±1.5	8.0±1.2	12.0±1.2	9-10F	
SQFDQ-Ⅲ09	09	17.0±1.2	4.5±1.5	9.0±1.2	13.0±1.2	9-10F	
SQFDQ-Ⅲ10	10	18.0±1.2	4.5±1.5	10.0±1.5	14.0±1.2	9-10F	
SQFDQ-Ⅲ12	12	20.0±1.5	4.5±1.5	12.0±1.5	16.0±1.2	10-12F	
SQFDQ-Ⅲ14	14	22.0±1.5	4.5±1.5	14.0±1.8	18.0±1.5	10-12F	
SQFDQ-Ⅲ16	16	24.0±1.5	5.0±1.5	16.0±1.8	20.0±1.5	10-12F	
SQFDQ-Ⅲ18	18	26.0±1.5	5.0±1.5	18.0±1.8	22.0±1.5	12-14F	
WTSQFDQ-Ⅲ04	04	12.0±1.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F	
WTSQFDQ-Ⅲ05	05	13.0±1.0	4.0±1.5	5.0±1.0	9.0±1.0	8-9F	Membranous defect
WTSQFDQ-Ⅲ06	06	14.0±1.0	4.0±1.5	6.0±1.0	10.0±1.0	8-9F	

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
WTSQFDQ-Ⅲ07	07	15.0±1.0	4.0±1.5	7.0±1.2	11.0±1.0	8-9F	
WTSQFDQ-Ⅲ08	08	16.0±1.2	4.0±1.5	8.0±1.2	12.0±1.2	9-10F	
WTSQFDQ-Ⅲ09	09	17.0±1.2	4.5±1.5	9.0±1.2	13.0±1.2	9-10F	
WTSQFDQ-Ⅲ10	10	18.0±1.2	4.5±1.5	10.0±1.5	14.0±1.2	9-10F	
WTSQFDQ-Ⅲ12	12	20.0±1.5	4.5±1.5	12.0±1.5	16.0±1.2	10-12F	
WTSQFDQ-Ⅲ14	14	22.0±1.5	4.5±1.5	14.0±1.8	18.0±1.5	10-12F	
WTSQFDQ-Ⅲ16	16	24.0±1.5	5.0±1.5	16.0±1.8	20.0±1.5	10-12F	
WTSQFDQ-Ⅲ18	18	26.0±1.5	5.0±1.5	18.0±1.8	22.0±1.5	12-14F	
SQFDQ-IV04	04	9.0±2.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F	
SQFDQ-IV05	05	10.0±2.0	3.5±1.5	5.0±0.8	9.0±1.0	7-8F	
SQFDQ-IV06	06	11.0±2.0	4.0±1.5	6.0±1.0	10.0±1.0	7-8F	
SQFDQ-IV07	07	12.0±2.5	4.0±1.5	7.0±1.0	11.0±1.0	8-9F	
SQFDQ-IV08	08	13.0±2.5	4.5±1.5	8.0±1.2	12.0±1.2	8-9F	
SQFDQ-IV09	09	14.0±2.5	5.0±1.5	9.0±1.2	13.0±1.2	9-10F	
SQFDQ-IV10	10	17.0±2.5	5.0±1.5	10.0±1.7	15.0±1.2	9-10F	
SQFDQ-IV12	12	20.0±3.5	5.0±1.5	12.0±1.7	18.0±1.2	10-12F	
SQFDQ-IV14	14	22.0±3.5	5.0±1.5	14.0±1.8	20.0±1.5	10-12F	Membranous defect
SQFDQ-IV16	16	24.0±3.5	5.0±1.5	16.0±1.8	22.0±1.5	10-12F	
WTSQFDQ-IV04	04	9.0±2.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F	
WTSQFDQ-IV05	05	10.0±2.0	3.5±1.5	5.0±0.8	9.0±1.0	7-8F	
WTSQFDQ-IV06	06	11.0±2.0	4.0±1.5	6.0±1.0	10.0±1.0	7-8F	

Catalogue No.	Device Size	A LV Disc Diameter /mm	H Height of connecting waist /mm	B Connecting Waist diameter /mm	C RV Disc Diameter /mm	Smallest Recommended Sheath Size	Applicable defect
WTSQFDQ-IV07	07	12.0±2.5	4.0±1.5	7.0±1.0	11.0±1.0	8-9F	
WTSQFDQ-IV08	08	13.0±2.5	4.5±1.5	8.0±1.2	12.0±1.2	8-9F	
WTSQFDQ-IV09	09	14.0±2.5	5.0±1.5	9.0±1.2	13.0±1.2	9-10F	
WTSQFDQ-IV10	10	17.0±2.5	5.0±1.5	10.0±1.7	15.0±1.2	9-10F	
WTSQFDQ-IV12	12	20.0±3.5	5.0±1.5	12.0±1.7	18.0±1.2	10-12F	
WTSQFDQ-IV14	14	22.0±3.5	5.0±1.5	14.0±1.8	20.0±1.5	10-12F	
WTSQFDQ-IV16	16	24.0±3.5	5.0±1.5	16.0±1.8	22.0±1.5	10-12F	Membranous defect

Note: The device that is suitable for muscular ventricular septal defect cannot be applied to membranous ventricular septal defect and vice versa.