CE 2797

MemoPart™ VSD Occluder
Instruction for Use

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CE-FDQ-VSD-001 Rev.08 Issued on:2025-05-26

SHSMA
Shanghai Shape Memory Alloy Co., Ltd.

TABIE OF CONTENT

Read the "Instruction for Use" carefully before use. Users should possess interventional treatment experience or be guided by professionals.

• Use on or before the last day of the expiration month noted on the product packaging.
• This device has been sterilized using ethylene oxide and is intended for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, insufficient sterilization, or patient harm.
• Do not use the device if the sterile packaging barrier is open or damaged.
• An implant card and an implant card information leaflet are supplied with each device. Please fill the implant card after reading the leaflet and provide the card to the patient.

1.Product Description

MemoPart™ VSD Occluder is a self-expanding, double-disc device made from a nickel-titanium alloy wire mesh. The two discs are connected by a short waist corresponding to the size of the ventricular septal defect (VSD). Polyester fabric is securely sewn onto the device to increase the defect closure ability. The device is visible under X-ray.

The company has developed multiple types of occluders to cater to different types of ventricular septal defects, their size, and location, and to reach the desired safety and efficacy levels. The following occluder variants are available:

◆ LV disc diameter: 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24,26, 28, 30, and 32 mm.
◆ RV disc diameter: 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 22, and 24 mm.
◆ Height of connecting waist: 1.8, 3.5, 4, 4.5, 5, 6, 6.5, 7, 7.5, 8, 8.5, 9.5, 10, 10.5, and 12 mm.
◆ Connecting waist diameter: 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, and 20 mm.

The corresponding relationship with the catalog number is listed in the table in section 16.

The primary materials used in the device are nitinol (23.8%~68.1%), stainless steel (23.8%~64.2%), and polyester (8.1%~12.0%); all materials used were subjected to biological safety assessment and do not contain CMR and/or endocrine-disrupting substances.

The Occluder Delivery System facilitates the attachment, loading, delivery and deployment of the VSD Occluder.

2.Performance characteristics

This device has the following performance characteristics ensuring its intended clinical performance:

(1) Nickel-titanium alloy wire constructed the device mesh frame which to facilitate the device deployment;

(2) Polyester fabric film filled in the device is engineered for the rapid cessation of left-to-right shunts in the ventricular septum upon implantation to prevent ventricular septal defect complications.

(3) Having multiple sizes of LV and RV disc diameter, height of connecting waist and connecting waist diameter, i.e. multiple size of the devices are available for the different defects;
(4) Visible under X-ray is conducive to operation.

3.Intended purpose

MemoPart™ VSD Occluder is specially designed for transcatheter closure of congenital ventricular septal defect.
3.1 Indications for Use
- For membranous ventricular septal defect:
The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.
- For muscular ventricular septal defect:
The Memopart™ Muscular VSD occluder is indicated for the following medical indications:
(1) Patient with a complex ventricular septal defect (VSD) of a significant size that warrants closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure).
(2) Patients 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.
3.2 Contraindications
- For membranous ventricular septal defect:
• Presence of thrombi in the heart chambers or hemorrhagic diseases such as active ulcer.
• Recent infection.
• Patients with very small vessels that are insufficient to accommodate the appropriate sheath size.
• Patients with a distance from the edge of the defect to the aorta or to the tricuspid valve of less than 3 mm.
• Patients with an anatomy wherein the membranous VSD occluder would interfere with 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 a recent infection anywhere in the body; they may receive the device only after the infection has completely cleared.
• 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 they cannot 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, a right-to-left shunt, and documented irreversible pulmonary vascular disease.

4.Intended Patient Populations

(1) This device is suitable for any patient with a congenital ventricular septal defect except for those in whom it is contraindicated. 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) Weight-based restrictions of use:
- MemoPart™ VSD Occcluder is recommended in the transcatheter closure of VSD in patients weighing ≥ 10 kg.
- For patients weighing < 10 kg, MemoPart™ VSD Occluder should only be used after confirmation by a clinical professional.

5.Intended Users

The MemoPart™ VSD Occluder should only be used by a physician who is trained in transcatheter defect closure techniques. The physician should determine the patients who can be candidates for procedures that use this device. Before use, the physician should have a complete understanding of the directions for use, warnings and precautions.

6.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. The physicians should determine which patients are suitable candidates for procedures using this device.

6.3 Physicians must be prepared to deal with emergency 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 suitable for magnetic resonance imaging.
6.5 The morphology of pocket-type ventricular septal defects, including those that involve a membranous septal aneurysm, exhibit considerable diversity. In situations with cases featuring a large defect entrance and multiple outlets, achieving complete occlusion may not always be feasible pose challenges. Therefore, it is essential to exercise prudence when selecting an appropriate occluder during surgical intervention. Prior to releasing the occluder, a left ventricular angiography should be conducted to confirm the absence of any residual shunt, and only then should the occluder be deployed.
6.6 The device should not be used with delivery systems other than those produced by the manufacturer as the device may be incompatible with the screw thread on the distal end of the pusher of a non-specified delivery system, which may result in technical failures and/or adverse events.
6.7 It is important to choose the appropriate delivery system for the ventricular septal defect occluder (see Table in section 16). If the sheath cannot match the occluder, it would be difficult to push or retrieve the occluder which may cause injury to the blood vessels.

7.Precautions

7.1 Unexpected situations during the use of the device includes cardiac tamponade caused by cardiac wall perforation, dropping of the occluder, auriculoventricular block, aortic insufficiency, tricuspid insufficiency, and hemolysis. Therefore, attention should be paid to prevention during the operation. And it is required that the device should be used under institute which has the conditions for cardiothoracic surgery. When cardiac tamponade occurs due to cardiac wall perforation, immediate pericardiocentesis drainage should be carried out. In the event that the occluder is accidentally dropped after being released, emergency surgery must be promptly performed to remove the occluder.
7.2 MR Conditional:
Non-clinical testing has demonstrated that the VSD occluder is MR Conditional.
Patients can be safely scanned 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 may produce an image artifact.

8.Adverse Events

Potential adverse events that may occur during or after a procedure for implanting 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 related to the device must be promptly reported to both the manufacturer and the relevant regulatory authority in the member state where the user and/or patient is based.

9.Expected Clinical Benefits

• High success rate of device implantation.
• High complete closure rate of ventricular septal defects.
• Low incidence of related clinical adverse events during and after the operation.

10.Summary of Safety and Clinical Performance (SSCP)

The summary of safety and performance of the device is available on the EUDAMED website: https://ec.europa.eu/tools/eudamed.
Basic UDI-DI: 69330523XZ0002K3

11.Materials recommended for use with this device

• 0.035-inch guidewire of sufficient stiffness
• Cardiac catheter
• Delivery system (for matching size, see table in section 16)
• 20 ml luer-lock syringe

12.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 Perform a Seldinger puncture at right femoral vein and artery.
12.4 Place the leakage-proof sheath.
12.5 Inject 100 μ/kg of heparin into the vein, which should be increased by 1000–2000 μ every hour.
12.6 Perform routine cardiac catheter examination and determine pressure within 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 guide wire through the catheter into precava or pulmonary artery (see Fig 2).
12.8 Introduce the right cardiac catheter into the pulmonary artery through the vein and into the snare using the catheter. Capture the guide wire with the snare and carefully withdraw it from the body, establishing the artery-ventricular septal defect-vein track.

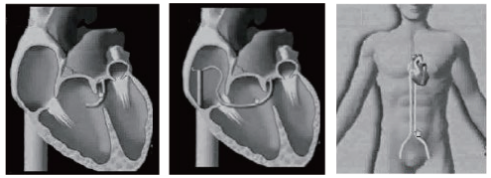

Fig. 2 Operation schematic for establishing the artery-vein track

12.9 Choose the suitable delivery system (mainly consisting of delivery sheath, dilator, loader, pusher and etc.) for the occluder, following the guidelines provided in Table 1. Prepare the delivery system according to the instructions outlined in its IFU.
12.10 Insert the guide wire into the delivery sheath and guide it into the left ventricle. Select an appropriate-sized occluder based on the results of angiography; typically, the occluder's disc diameter should be 2 mm larger than the determined diameter.
12.11 Place the occluder in heparinized saline. Pass the pusher through the loader and screw the device to the tip of the pusher by rotating it clockwise for four turns. After it is firmly attached, immerse the device and loader in the sterile heparinized normal saline (HepNS) and slowly pull the device into the loader. Use a syringe to inject heparin saline through the side arm of the delivery sheath to remove any bubbles.
12.12 Flush the delivery sheath and dilator with heparin saline. Insert the dilator into the delivery sheath and secure it with the locking mechanism. Guide the dilator/delivery sheath assembly over the guidewire into the left ventricle, following echo or X-ray guidance. Carefully withdraw the dilator and guidewire, leaving the delivery sheath in place within the left atrium.
12.13 Insert the loader into the longer sheath and advance it under X-ray guidance.

Open the disc near the left ventricle and pull it back toward the ventricular septum. If resistance is encountered around the ventricular septum as confirmed by echocardiography, secure the pusher, withdraw the sheath, and release the occluder disc near the right ventricle. Gently push and pull the occluder to ensure it is securely fixed. Verify with echocardiography that it does not interfere with the functioning of the aortic valve and tricuspid valve. Additionally, confirm through angiography that it does not affect the aortic valve's function. If both criteria are met, rotate the pushing pole counterclockwise to release the occluder.

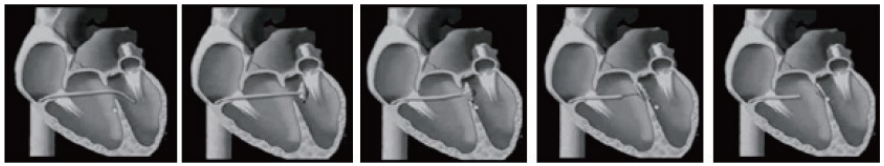

Fig. 3 Operation schematic for VSD

12.14 During the operation, TTE is conducted using the five-chamber view at the cardiac apex and the short-axis view. The occluder should only be released when both views confirm that it is positioned closely adjacent to the residual edge of the ventricular septum.
12.15 Slowly retract the distal end of the pusher into the delivery sheath and withdraw the sheath. Complete the operation.
12.16 After the operation, the patient should be administered 3–5 mg/kg aspirin orally for 6 months.

13.Disposal

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

14. Storage and Expiry Date

14.1 Store in a dry place, in a well-ventilated room with a relative humidity of no more than 80%, and with no corrosive gases or ultraviolet radiation.
14.2 This product has an expiry date of five years from the date of manufacture of this product if it stored under specified condition.

15. Symbol Definitions

SYMBOL	EXPLANATION OF SYMBOL
	MANUFACTURER
EU 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 AND STERILIZED USING ETHYLENE OXIDE
	DOUBLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE
	DO NOT RESTERILIZE
	DO NOT RE-USE
	DO NOT USE IF PACKAGE IS DAMAGED
	REFER TO INSTRUCTIONS FOR USE
MD	MEDICAL DEVICE
UDI	UNIQUE DEVICE IDENTIFIER
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	MR CONDITIONAL
CE 2797	CE MARKING AND IDENTIFICATION NUMBER OF NOTIFIED BODY
The color of the EO Sterilization indicator on the package bag turns yellow after EO sterilization.	

16.DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

Descriptions or specifications in any content provided by Shanghai Shape Memory Alloy Co., Ltd., 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 is not responsible for any direct, incidental, or consequential damages resulting from the abnormal use of the product.

17.Specification and Recommend sheath size

Table1 Device Specifications and Recommended Delivery System

Catalog 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 Delivery System 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	
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	

Catalog 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 Delivery System Size	Applicable defect
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	
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	

Catalog 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 Delivery System Size	Applicable defect
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
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	

Catalog 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 Delivery System Size	Applicable defect
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	
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	

Catalog 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 Delivery System Size	Applicable defect
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	
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	
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	Membranous defect
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	

Catalog 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 Delivery System Size	Applicable defect
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	
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	

Catalog 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 Delivery System Size	Applicable defect
WTSQFDQ-Ⅱa20	20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F	Membranous defect
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	
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	Membranous defect
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	
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	

Catalog 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 Delivery System Size	Applicable defect
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	Membranous defect
WTSQFDQ-Ⅲ05	05	13.0±1.0	4.0±1.5	5.0±1.0	9.0±1.0	8-9F	
WTSQFDQ-Ⅲ06	06	14.0±1.0	4.0±1.5	6.0±1.0	10.0±1.0	8-9F	
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	Membranous defect
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	

Catalog 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 Delivery System Size	Applicable defect
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	
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	
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: Device applicable for muscular ventricular septal defect cannot be used for membranous ventricular septal defect and vice versa.

18.E-IFU

The exact same e-IFU (pdf version) can also be found on the website: https:// en.scientechmed.com/product/.

Note:Whenever the manufacturer's instructions for use are updated, the revised version will be promptly uploaded. Due to the challenge of individually notifying every end user about these changes, we recommend that customers regularly browse and check the website for updates.

In addition, a computer installed windows system, one currently common browser and pdf file reader is required.