CE 2797

MemoCarna™ VSD Occluder
Instruction for Use

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SHSMA
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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.
- An implant card and an implant card information leaflet are supplied with each device, please complete the implant card after reading the leaflet, and then to the patient.

1. Product Description

MemoCarna™ VSD Occluder is a self-expanding, double-disc braided with nickel-titanium alloy wire into a mesh frame, in which filled with polyester fabric membrane that is benefit to the closure. The 2 discs are connected by a short waist corresponding to the size of the ventricular septal defect (VSD). The device is detectable under X-ray.

In order to suit the different type of ventricular septal defect and its size and location and reach the desired safety and efficacy, there are multiple sizes of occluder available, have the follow variants:

- LV disc diameter: 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 22, 24, 26, 28, 30mm;
- RV disc diameter: 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 22, 24, 26, 28mm;
- Connecting waist diameter: 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20, 22, 24mm;
- Height of connecting waist: 4, 5mm.

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

The device is mainly made of nitinol (40.24% ~ 66.52%), stainless steel (23.51% ~ 43.68%) and polyester (9.97% ~ 16.08%), all materials used were subjected to biological safety assessment, don't contain CMR and/or endocrine-disrupting substances.

The Occluder Delivery System is intended to facilitate the attachment, loading, delivery and deployment of VSD Occluder.

2. Intended purpose

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

2.1 Indications for Use

The MemoCarna™ VSD Occluder is used for minimally invasive transcatheter

closure of perimembranous ventricular septal defects.

2.2 Contraindications

- Ventricular septal defect complicated with severe pulmonary resistance hypertension.
- Presence of thrombi in the chambers of the heart and hemorrhagic diseases such as active ulcer.
- Other abnormalities are present in need of surgical treatment.
- Patients with very small vessels which are inadequate to accommodate the appropriate sheath size.
- Recent infection is found.
- 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.

3. Intended Patient Populations

This device is suitable for patients, whose:

- Age ≥6 months, ≤60 years old, weight greater than 5kg, male or non-pregnant woman;
- Membranous ventricular septal defect with abnormal hemodynamics or enlarged left heart diameter;
- The narrowest part of ventricular septal defect (VSD) is ≥3mm, ≤20mm;
- Distance of upper margin of the ventricular septal defect to right aortic coronary valve ≥2mm, to tricuspid septum ≥2mm, no right aortic coronary valve falling into the defect and no aortic valve regurgitation.
- Ultrasound at the 9-12 o'clock position of the short-axis five-chamber section of the great vessel.

4. Intended Users

The MemoCarna™ VSD Occluder should only be used by a physician who are trained in transcatheter defect closure techniques.

5. Warning

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

5.2 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.

5.3 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.

5.4 This product is fit for magnetic resonance imaging.

5.5 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.

5.6 The device should not be used with delivery systems other than those produced by the manufacturer, for the device may be incompatible with the screw thread on the distal end of the pusher and may result in technical failures and/or adverse events.

5.7 It is important to choose the appropriate delivery system 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

6.1 Pay attention to cardiac tamponade which may cause by cardiac wall perforation and dropping of occluder in the operation procedure. 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.

6.2 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

- Close the target defect;
- Restore or improve the morphology and function of heart.

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
- Delivery system (for matching size see table in section 16)
- 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 or precava 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.

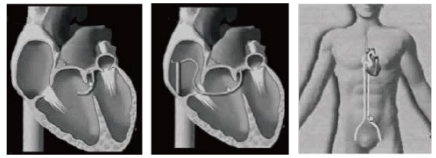

Fig. 2 Operation chart for artery-vein track

12.9 Insert the guiding wire into the delivery sheath and deliver it into the left ventricle. Choose the occluder with appropriate diameter according to the results of angiography; mostly the 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 Connect the loader to tail of the outer sheath, push forward under DSA and guided by echocardiography to left ventricle, 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.

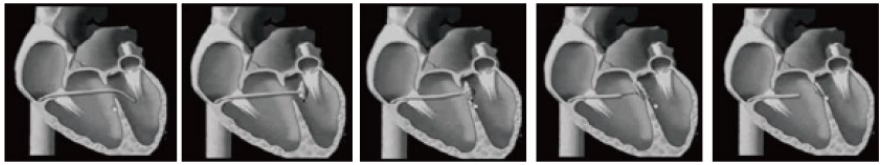

Fig. 3 Operation chart for VSD

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
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	DATE OF MANUFACTURE
	USE-BY DATE
	BATCH CODE
	CATALOGUE NUMBER
	SERIAL NUMBER
	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
	MEDICAL DEVICE
	UNIQUE DEVICE IDENTIFIER
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	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	B RV Disc Diameter /mm	H Height of connecting waist /mm	C Connecting Waist diameter /mm	Smallest Recommended Delivery system Size
DMSQFDQ-II 04	04	9.0±1.2	8.0±0.8	4±1.0	4±0.3	6F
DMSQFDQ-II 05	05	10.0±1.2	9.0±0.8	4±1.0	5±0.3	6F
DMSQFDQ-II 06	06	11.0±1.2	10.0±0.8	4±1.0	6±0.3	6F

DMSQFDQ-II 07	07	12.0±1.2	11.0±0.8	4±1.0	7±0.3	6F
DMSQFDQ-II 08	08	13.0±1.2	12.0±1.0	4±1.0	8±0.3	6F
DMSQFDQ-II 09	09	14.0±1.2	13.0±1.0	5±1.0	9±0.3	7F
DMSQFDQ-II 10	10	15.0±1.2	14.0±1.0	5±1.0	10±0.3	8F
DMSQFDQ-II 11	11	16.0±1.5	15.0±1.0	5±1.0	11±0.5	8F
DMSQFDQ-II 12	12	17.0±1.5	16.0±1.5	5±1.0	12±0.5	8F
DMSQFDQ-II 13	13	18.0±1.5	17.0±1.5	5±1.0	13±0.5	8F
DMSQFDQ-II 14	14	19.0±1.5	18.0±1.5	5±1.0	14±0.5	9F
DMSQFDQ-II 15	15	20.0±1.5	19.0±1.5	5±1.0	15±0.5	9F
DMSQFDQ-II 16	16	22.0±1.5	20.0±1.5	5±1.0	16±0.5	10F
DMSQFDQ-II 18	18	24.0±1.5	22.0±1.5	5±1.0	18±0.5	10F
DMSQFDQ-II 20	20	26.0±1.5	24.0±1.5	5±1.0	20±0.5	12F
DMSQFDQ-II 22	22	28.0±1.5	26.0±1.5	5±1.0	22±0.5	12F
DMSQFDQ-II 24	24	30.0±1.5	28.0±1.5	5±1.0	24±0.5	12F

17. E-IFU

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

Note:

When the manufacturer's instruction for use is updated, it will be uploaded timely. For it is difficult to trace to every end user to inform the change, so we advise the customer to browse and check it regularly.