CE 2797

MemoCarna™ VSD Occluder
Instruction for Use

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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 fill the implant card after reading the leaflet and provide the card 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, size and location of ventricular septal defect, 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, 22mm;
· RV disc diameter: 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20mm;
· Connecting waist diameter: 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16mm;
· Height of connecting waist: 4, 5mm.

The corresponding relationship with the catalogue number is listed in the table 1 in section 16, and to allow a user/patient to determine quantities of materials to which patient is exposed, can refer to the follow table.

Catalogue No	Device Weight (g)	Material Quantity (g)			
		Nickel-titanium alloy	00Cr18Ni14Mo3 Stainless steel	Polyethylene erephthalate (PET)	Polyamide 6 (PA6)
DMSQFDQ-II 04	0.06~0.08	0.02~0.03	0.024~0.039	0.008~0.018	Balance
DMSQFDQ-II 05	0.06~0.08	0.02~0.03	0.024~0.039	0.009~0.020	Balance
DMSQFDQ-II 06	0.08~0.10	0.04~0.05	0.024~0.039	0.011~0.025	Balance
DMSQFDQ-II 07	0.09~0.11	0.04~0.05	0.024~0.039	0.013~0.030	Balance
DMSQFDQ-II 08	0.11~0.13	0.05~0.07	0.027~0.044	0.014~0.033	Balance
DMSQFDQ-II 09	0.14~0.18	0.06~0.09	0.039~0.065	0.018~0.042	Balance
DMSQFDQ-II 10	0.15~0.19	0.07~0.10	0.039~0.065	0.020~0.047	Balance
DMSQFDQ-II 11	0.16~0.20	0.07~0.11	0.039~0.065	0.023~0.053	Balance
DMSQFDQ-II 12	0.16~0.20	0.07~0.10	0.039~0.065	0.026~0.060	Balance

Catalogue No	Device Weight (g)	Material Quantity (g)			
		Nickel-titanium alloy	00Cr18Ni14Mo3 Stainless steel	Polyethylene erephthalate (PET)	Polyamide 6 (PA6)
DMSQFDQ-II 13	0.22~0.26	0.10~0.15	0.049~0.081	0.029~0.068	Balance
DMSQFDQ-II 14	0.24~0.30	0.12~0.18	0.049~0.081	0.033~0.076	Balance
DMSQFDQ-II 15	0.24~0.29	0.11~0.17	0.049~0.081	0.036~0.084	Balance
DMSQFDQ-II 16	0.26~0.32	0.13~0.19	0.046~0.077	0.042~0.097	Balance

All materials used were subjected to biological safety assessment, don't contain other CMR (class 1A or 1B) and/or endocrine-disrupting substances more than 0.1%(w/w) but possible 2,2'-Methylenebis(6-tert-butyl-4-methylphenol).
The Occluder Delivery System is intended to facilitate the attachment, loading, delivery and deployment of VSD Occluder.

2.Performance

This device has the following performance characteristics ensuring clinical use:
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 shunt upon implantation to make the complications related to the defect disappeared;
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

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

3.1.Indications for Use

The MemoCarna™ VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

3.2.Contraindications

· Ventricular septal defect complicated with severe pulmonary resistance hypertension.
· Presence of thrombi in the heart chambers or hemorrhagic diseases such as active ulcer.
· Other abnormalities are present in need of surgical treatment.
· Patients with very small vessels that are insufficient to accommodate the appropriate sheath size.

· Recent infection.
· 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.

4.Intended Patient Populations

This device is suitable for patients, whose:
- Weight ≥ 10kg, male or non-pregnant woman; For patients weighing < 10 kg, MemoCarna ™ VSD Occluder should only be used after confirmation by a clinical professional that patients' vessels are sufficient to accommodate the appropriate sheath size.
- Membranous ventricular septal defect with abnormal hemodynamics or enlarged left heart diameter;
- The narrowest part of ventricular septal defect (VSD) is ≥3mm, ≤14mm;
- Distance of superior margin of the ventricular septal defect to right cusp of aortic valve ≥ 2mm, posterior margin of VSD to tricuspid septum ≥2mm, no right cusp of aortic valve prolapse into the defect and no aortic valve regurgitation.

5.Intended Users

The MemoCarna™ VSD Occluder should only be used by a physician who is 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 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 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 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.

7.Precautions

7.1.It is essential to be vigilant to the possibility of cardiac tamponade, which can result from cardiac wall perforation and the accidental displacement of the occluder during the operation procedure. Additionally, it is necessary for the medical facility conducting the procedure to have the appropriate infrastructure for cardiothoracic surgery in order to utilize this occluder safely. If 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.Before using the product on children, pregnant and breastfeeding women, the benefit/risk ratio need to be considered, for there presents 2,2'-Methylenebis(6-tert-butyl-4-methylphenol) that could be above 0.10%(w/w) in the device.
7.3.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:
• Device configuration: GE 1.5T Signa HDx Echospeed Scanner, GE Signa HD 3.0T Scanner, Philips Achieva TX 3.0T Scanner;
• Static magnetic field of 1.5T or 3.0T;
• Maximum allowable spatial gradient of the magnetic field is 20.00T/m (2000 Gauss/cm) in 3.0T and 40.00T/m (4000 Gauss/cm) in 1.5T MR system;
• Maximum whole-body averaged specific absorption rate (SAR) shall be limited to 2.0 W/kg (normal operating mode only) for 15 minutes of continuous application of RF energy during a scan;
• There are no transmit coil restrictions.
Image Artifact Information: In non-clinical testing, the image artifact caused by the device extends less than 18mm from this VSD Occluder when imaged with a spin echo pulse sequence and a 3.0 Tesla MRI system, and that caused by the device extends less than

22mm from this VSD Occluder when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system. MR image quality may be compromised if the area of interest is relatively close to this VSD Occluder, and optimization of MR imaging parameter is recommended.

8.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 reported to the manufacturer and the regulatory authority in the member state where the user and/or patient is based.

9.Clinical Benefits to be expected

•It can improve body functions of patients with congenital heart disease and provide relief from symptoms, such as heart failure, shunt, arrhythmias, endocarditis, etc.;
•It can reduce probability of adverse events, such as death, residual shunt, arrhythmias, etc.

10.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.*
Basic UDI-DI: 69330523XZ0009KH

11.Materials recommended for use with this device

- 0.035-inch guidewire of sufficient stiffness
- Cardiac catheter
- Delivery system (for matching size see table 1 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 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.

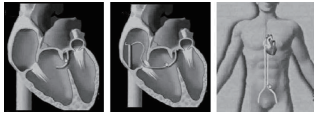

Fig. 2 Operation chart for artery-vein track

12.9.Choose the suitable delivery system (mainly consisting of delivery sheath, dilator, loader, pusher 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 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.
12.11.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.

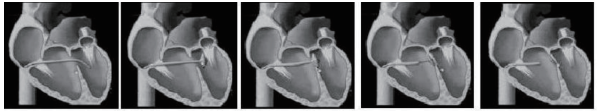

Fig. 3 Operation chart for VSD

12.14.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.
12.15.Slowly retract the distal end of the pusher into the delivery sheath and withdraw the sheath. Complete the operation.
12.16.Take orally 3-5 mg/kg aspirin after operation 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
EC REP	Authorized representative in the European Community

SYMBOL	EXPLANATION OF SYMBOL
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
SN	Serial number
STERILE EO	Sterilized using ethylene oxide
STERILE EO	Double sterile barrier system and sterilized using ethylene oxide
STERILE EO	Double sterile barrier system with protective packaging outside
	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.

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

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Table1 Device Specifications and Recommended Delivery System

Catalogue Number	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

18.E-IFU

The exact same pdf version e-IFU can also be found on the website: https://en.scientechmed.com/product/142.html.

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.