CE 2797

MemoCarna™ ASD Occluder
Instruction for Use

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Shanghai Shape Memory Alloy Co.,Ltd.

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Read the "Instruction for Use" carefully before use.

1. Product Description and Performance Characteristics

MemoCarna™ ASD Occluder is a self-expanding double-disc device made from nitinol mesh, stainless steel bushing, suture line and polyester fabric membrane. The device has a left atrial (LA) disc, a right atrial (RA) disc, and a short waist corresponding to the size of the atrial septal defect (ASD). Polyester fabric membrane is securely sewn within each disc and the waist by suture line to ensure optimal occlusion. The device is visible under X-ray.
The nitinol mesh is braided with nitinol wire, which allows the device to be pulled into a delivery sheath and reshaped once it is released. When the device is correct positioned and firmly attached on both sides of the septum, it conforms to the septal wall and closes a present ASD. The nitinol mesh is filled with polyester fabric membranes which are securely sewn within each disc and the waist by suture line to stop the blood flow through the ASD as well as optimize tissue growth. There is one stainless steel bushing with female thread on the right atrial disc to connect the device to the pusher of an appropriate delivery system.

2. Intended purpose

The MemoCarna™ ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position.

3. Indications for use

Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (i.e.,1.5:1 degree of left-to-right shunt or RV enlargement).

4. Contraindications

4.1.Atrial septal defect complicated with severe pulmonary resistance hypertension.
4.2.Presence of thrombi in heart chambers or hemorrhagic diseases.
4.3.Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery.
4.4.Any patient known to have sepsis within 1 month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement.
4.5.Any patient whose size (e.g., too small for catheter size) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization.
4.6.Any patient where the margins of the defect are less than 5mm to the pulmonary vein, coronary sinus, superior and inferior vena cava, or mitral and tricuspid valves.

4.7.Any patient known to have a bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy unless another antiplatelet agent can be administered for a duration of 6 months.
4.8.Patients with ostium primum atrial septal defect.

5. Intended Patient Populations

This device is suitable for patients with the target diseases or medical indications, except for those with contraindications. The safety and efficacy of MemoCarna™ ASD Occluder in pregnant women or men intending to father children, nursing mothers and the immunocompromised patients has not been established.

6. Intended Users

The MemoCarna™ ASD Occluder should only be used by physicians who are 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 instruction for use, warnings, and precautions.

7. Warnings

7.1.Use on or before the expiration date noted on the product packaging.
7.2.This device is 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, inadequate sterilization, or patient harm.
7.3.Do not use the device if the sterile packaging barrier is open or damaged.
7.4.Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies.
7.5.This device should only be used by physicians who have been trained professionally in transcatheter defect closure techniques. The physicians should determine which patients are suitable candidates for procedures using this device.
7.6.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.
7.7.Embolized devices must be removed as they may disrupt critical cardiac functions. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within the sheath.
7.8.Do not release the occluder from the pusher of the delivery system if the device does not conform to its original configuration; if the device position is unstable, or if the device interferes with any adjacent cardiac structure (such as Superior Vena Cava (SVC), Pulmonary

Vein (PV), Mitral Valve (MV), Coronary Sinus (CS), aorta (AO)). Recapture the device and redeploy. If still unsatisfactory, recapture the device and replace with a new device, or refer the patient for alternative treatment.

7.9.Implantation of this device may not eliminate the requirement for Coumadin in patients with ASD and paradoxical emboli.

7.10.It is important to choose the appropriate delivery system to the atrial septal defect occluder (see Table1); if the delivery sheath of the delivery system does not match the occluder, it would be difficult to push or retrieve the occluder which may even cause damages to the blood vessels.

7.11.The use of echocardiographic imaging (TTE, TEE or ICE) is required.

8. Precautions

8.1.It is necessary for the medical facility where the procedure is conducted to have the appropriate infrastructure for cardiothoracic surgery. The procedure should be performed in a cardiac catheterization laboratory.

8.2.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. If cardiac tamponade occurs due to cardiac wall perforation, immediate pericardiocentesis drainage should be carried out. If bleeding persists, emergency surgery must be performed. Similarly, if the occluder is accidentally dropped after being released, emergency surgery must be promptly performed to remove the occluder.

8.3.Some patients may face elevated risks of complications such as tissue erosion and device embolization. If these higher-risk patients undergo device implantation, more frequent follow-up is necessary. Higher risk patients include the following:

· Patients with deformation of the device at the aortic root.

· Patients with high defects (minimal aortic and superior rims).

· Patients with IVC rim deficiency (risk of device embolization).

8.4.It is recommended to check the device prior to its use in patient. If the device appears damaged or does not revert to its original shape, it is not suitable for implantation and should be discarded.

8.5.It is recommended to use MemoCarna™ ASD Occluder in combination with the supporting delivery system produced by the manufacturer, for the device may be incompatible with other delivery system and may result in technical failures and/or adverse events.

8.6.Procedural

· Aspirin (e.g., 81mg or 325mg) or an alternative antiplatelet/anticoagulant is recommended to be started at least 24 hours prior to the procedure. Cephalosporin therapy is optional.

· Throughout the entire process, patients should be systemically heparinized, maintaining a minimum recommended active clotting time (ACT) of 200 seconds both prior to device insertion and throughout the procedure.

· It is recommended to employ the TTE to assist the placement of atrial septal defect occluder. If TEE is utilized, the patient's esophageal anatomy must be suitable to accommodate the placement and manipulation of the TEE probe.

8.7.Post-Implant

· Patients are advised to undergo appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to extend endocarditis prophylaxis beyond 6 months is left to the discretion of the physician.

· Patients should be treated with antiplatelet/anticoagulation therapy (such as aspirin) for 6 months post-implant. The decision to continue antiplatelet/anticoagulation therapy beyond 6 months is left to the discretion of the physician.

· It is recommended to have clinical follow-ups with a cardiologist and undergo echocardiograms at specific intervals: immediately after implantation, 1day post-implant, pre-discharge, and again at 1 week, 1 month, 6 months, and 12 months post-implant. Immediate consultation with a cardiologist is essential upon the emergence of any new symptoms suggestive of erosion or impending erosion. Routine clinical follow-ups with a cardiologist annually thereafter are also advised.

· A patient Implant Card is included in each device box. Complete this card and give it to the patient.

8.8.MR Conditional

· Non-clinical testing has demonstrated that the device 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 spatial gradient field is 20T/m in 3.0T and 40T/m in 1.5T MR system.

• Maximum whole-body specific absorption rate (SAR) of 2.0 W/Kg for 15 minutes of scanning in Normal Operating Mode.

· The presence of this implant might produce an image artifact

9. 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
- Arrhythmia (including mostly Atrial fibrillation, Supraventricular tachycardia, Atrial flutter, Tachybrady syndrom, Heart blocks and etc.)
- Heart blocks
- Cerebrovascular events (Stroke/TIA)
- Thrombosis
- Pericardial effusion
- Occluder migration/ malposition/dislocation

- Occlder embolization
- Cardiac Tamponade
- AV fistula
- Fever
- Cardiac perforation
- Air embolism
- False aneurysm
- Hemolysis
- Dissection
- Neurologic complication
- Pulmonary edema
- Valve damage
- Cardiac arrest
- Vessel damage
- Pulmonary hypertension
- Valvular insufficiency/ regurgitation
- Hematoma
- Device erosion
- Infective complications
- Shortness of breath
- Myocardial infarction / transient myocardial ischemia
- Pleural Effusion
- Device fracture
- Heart failure / Cardiac dysfunction
- Allergic reaction
- Hypertension/Hypotension
- Chest pain
- Headache/Migraine/ Dizziness
- Bleeding

Any serious incident related to the device must be promptly reported to reported to the manufacturer and the relevant competent authority in the Member State where the user and/or patient is based.

10. Clinical Benefits to be Expected

By successfully implanting the occluder and achieving complete closure of the ASD, it can provide relief from symptoms of atrial fibrillation, palpitation, heart failure and stroke to improve body functions of patients with congenital heart disease.

11. Summary of Safety and Clinical Performance (SSCP)

The summary of safety and performance for the device in the European database on medical devices (Eudamed) by searching the Basic UDI-DI "69330523XZ0008KF" at: *https://ec.europa.eu/tools/eudamed*

12. Joint use medical device

· Delivery system (mainly consisting of delivery sheath, dilator, loader and pusher; for matching size see table 1)

13. Directions for Use

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

13.2.Local anesthesia or general anesthesia.

13.3.Perform a Seldinger puncture at the right femoral vein.

13.4.Place the leakage-proof sheath.

13.5.Inject 100U/kg of heparin into the vein which should be increased by 1000-2000U every hour.

13.6.Perform routine right cardiac catheter examination and determine pressure inside pulmonary artery, right ventricle and right atrium as well as the blood oxygen content.

13.7.Deliver the right cardiac catheter through the ASD into the left superior pulmonary vein and deliver in a 0.035" hardened exchange guidewire through the catheter. Remove the catheter leaving the exchange guidewire in place.

13.8.The size of the ASD is measured using TTE (balloon catheter measurement should be used if necessary). For adults, choose a device size that is 4~6mm larger than the maximum defect diameter of the ASD measured using TTE. For pediatric cases, choose a device size that is 2~4mm larger than the maximum defect diameter. Measure the total length of atrial septal to determine whether the occluder has fully opened. For large ASD, choose a device size that is 8~10mm larger than the maximum defect diameter of ASD measured using TTE. Rinse the selected occluder with physiological saline, then pass it through the delivery sheath. In cases where the ASD is measured using a balloon catheter, the diameter of the selected occluder should be 1~2 mm larger than the stretched defect diameter measured using the balloon catheter.

13.9.Choose the suitable delivery system (mainly consisting of delivery sheath, dilator, loader and pusher) for the occluder, following the guidelines provided in Table 1. Prepare the delivery system according to the instructions outlined in its IFU.

13.10.Place the occluder into 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. Inject heparin saline through the side port of the hemostatic valve to remove any bubbles.

13.11.Plush 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 atrium, following echo or X-ray guidance. Carefully withdraw the dilator and guidewire, leaving the delivery sheath in place within the left atrium.

13.12.Insert the loader into the delivery sheath and guide the device into left atrium under echo or X-ray guidance. Open the disc within the left atrium and gently pull it against the atrial septum, which can be sensed and observed through echocardiography. Secure the pusher and withdraw the sheath to deploy the right disc of the occluder in the right atrium. Ensure a secure positioning across the defect by gently moving the occluder back and forth. If echocardiography confirms that the occlusion will not affect the function of the mitral valve, tricuspid valve, or other nearby structures, rotate the pusher counterclockwise to release the occluder.

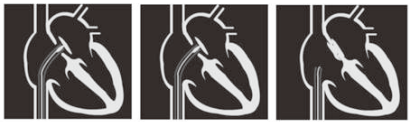

Fig.1 Operation chart for ASD

13.13.During the operation, TTE is performed using the four-chamber view at the cardiac apex, the xiphoid view of two atriums as well as the short-axis view. The occluder should only be released when all three views confirm that the occluder is closely adjacent to the residual edge of the atrial septum.

13.14.Slowly retract the distal end of the pusher into the delivery sheath and withdraw the sheath. Complete the operation.

14. Disposal

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

15. Storage and Expiry Date

15.1.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.

15.2.This product has an expiry date of five years from the date of manufacture of this product if it stored under specified condition.

16. 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	Double stertile barrier system
	STERILE EO Sterilized using ethylene oxide
STERILE EO	Double sterile barrier system with protective packaging outside
	STERILE EO Sterilized using ethylene oxide
	Do not resterilize
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight

Symbol	Explanation of Symbol
	Consult instructions for use
	Caution
MD	Medical Device
UDI	Unique Device Identifier
CE 2797	CE Marking and identification Number of Notified Body
MR	MR conditional
	Packing unit

The color of EO Sterilization indicator on the package bag turns yellow after EO sterilization.

17. 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.

18. Device specifications and recommend delivery system

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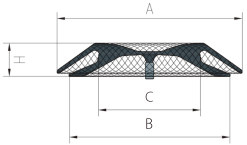

Fig 2.Representative structureof MemoCarna™ ASD Occluder

Table1 Device Specifications and Recommend sheath sizes

Catalogue Number	Device Size	C Connecting waist diameter (mm)	H Height (mm)	A LA disc diamete (mm)	B RA disc diameter (mm)	Smallest Recommended Size of Delivery System* (French)
DMFQFDQ-I06	06	6.0±0.5	5.5±1.0	20.0±1.0	16.0±1.0	7F
DMFQFDQ-I07	07	7.0±0.5	5.5±1.0	21.0±1.0	17.0±1.0	8F
DMFQFDQ-I08	08	8.0±0.5	5.5±1.0	22.0±1.0	18.0±1.0	8F
DMFQFDQ-I09	09	9.0±0.5	5.5±1.0	23.0±1.0	19.0±1.0	8F
DMFQFDQ-I10	10	10.0±0.5	5.5±1.0	24.0±1.0	20.0±1.0	8F
DMFQFDQ-I11	11	11.0±0.5	5.5±1.0	25.0±1.3	21.0±1.3	9F
DMFQFDQ-I12	12	12.0±0.5	5.5±1.0	26.0±1.3	22.0±1.3	9F
DMFQFDQ-I13	13	13.0±0.5	5.5±1.0	27.0±1.3	23.0±1.3	9F
DMFQFDQ-I14	14	14.0±0.5	5.5±1.0	28.0±1.3	24.0±1.3	9F
DMFQFDQ-I15	15	15.0±0.5	5.5±1.0	29.0±1.3	25.0±1.3	9F
DMFQFDQ-I16	16	16.0±0.5	5.5±1.0	30.0±1.5	26.0±1.5	10F
DMFQFDQ-I17	17	17.0±0.5	5.5±1.0	31.0±1.5	27.0±1.5	10F
DMFQFDQ-I18	18	18.0±0.5	5.5±1.0	32.0±1.5	28.0±1.5	10F
DMFQFDQ-I19	19	19.0±0.5	5.5±1.0	33.0±1.5	29.0±1.5	10F
DMFQFDQ-I20	20	20.0±1.0	5.5±1.0	34.0±1.5	30.0±1.5	10F
DMFQFDQ-I22	22	22.0±1.0	5.5±1.0	36.0±1.5	32.0±1.5	10F
DMFQFDQ-I24	24	24.0±1.0	6.0±1.0	38.0±1.5	34.0±1.5	12F
DMFQFDQ-I26	26	26.0±1.0	6.0±1.0	40.0±1.5	36.0±1.5	12F
DMFQFDQ-I28	28	28.0±1.0	6.0±1.0	42.0±1.5	38.0±1.5	12F
DMFQFDQ-I30	30	30.0±1.0	6.0±1.0	44.0±1.5	40.0±1.5	12F
DMFQFDQ-I32	32	32.0±1.0	6.0±1.0	46.0±1.5	42.0±1.5	12F
DMFQFDQ-I34	34	34.0±1.0	6.0±1.0	48.0±1.5	44.0±1.5	14F
DMFQFDQ-I36	36	36.0±1.0	6.0±1.0	52.0±1.5	46.0±1.5	14F
DMFQFDQ-I38	38	38.0±1.0	6.0±1.0	54.0±1.5	50.0±1.5	14F
DMFQFDQ-I40	40	40.0±1.0	6.0±1.0	56.0±1.5	52.0±1.5	14F
DMFQFDQ-I42	42	42.0±1.0	6.0±1.0	58.0±1.5	54.0±1.5	14F
DMFQFDQ-I44	44	44.0±1.0	6.0±1.0	60.0±1.5	56.0±1.5	14F
DMFQFDQ-I46	46	46.0±1.0	6.0±1.0	62.0±1.5	58.0±1.5	14F

LA Disc: Left atrial disc, RA Disc: Right atrial disc

Note: recommended delivery system

1. There are two types of recommended delivery systems with the following product name:
   · MemoPart™ Occluder Delivery System
   · MemoPart™ Occluder Delivery System Ⅱ
2. For more details of the delivery system, please refer to the related IFU of the delivery system.

19. Device Material Information

The MemoCarna™ ASD Occluder is made of Nitinol compliant with ASTM F2063 standard, 00Cr18Ni14Mo3 Stainless steel compliant with ISO 5832-1 standard, Polyethylene terephthalate (PET, CAS No.: 25038-59-9) and Polyamide 6 (commonly known as nylon 6 (PA6), CAS No.: 25038-54-4). The material used for each individual The MemoCarna™ ASD Occluder is made of Nitinol compliant with ASTM F2063 standard, 00Cr18Ni14Mo3 Stainless steel compliant with ISO 5832-1 standard, Polyethylene terephthalate (PET, CAS No.: 25038-59-9) and Polyamide 6 (commonly known as nylon 6 (PA6), CAS No.: 25038-54-4). The material used for each individual device is listed in the Table 2.

Table 2 Device material information

Catalogue No	Device Weight (g)	Material Quantity (g)			
		Nitinol	00Cr18Ni14Mo3 Stainless steel	Polyethylene erephthalate (PET)	Polyamide 6 (PA6)
DMFQFDQ-I 06	0.22~0.27	0.13~0.20	0.048~0.080	0.007~0.017	Balance
DMFQFDQ-I 07	0.25~0.31	0.16~0.24	0.045~0.076	0.008~0.019	Balance
DMFQFDQ-I 08	0.27~0.33	0.18~0.26	0.045~0.076	0.010~0.024	Balance
DMFQFDQ-I 09	0.28~0.34	0.18~0.28	0.045~0.076	0.012~0.028	Balance
DMFQFDQ-I 10	0.28~0.34	0.18~0.28	0.045~0.076	0.012~0.028	Balance
DMFQFDQ-I 11	0.35~0.43	0.25~0.37	0.045~0.075	0.014~0.033	Balance
DMFQFDQ-I 12	0.36~0.45	0.26~0.38	0.045~0.075	0.015~0.036	Balance
DMFQFDQ-I 13	0.36~0.44	0.25~0.37	0.045~0.075	0.016~0.036	Balance
DMFQFDQ-I 14	0.34~0.42	0.23~0.34	0.045 ~0.075	0.021~0.049	Balance
DMFQFDQ-I 15	0.48~0.58	0.34~0.51	0.055~0.092	0.020~0.046	Balance
DMFQFDQ-I 16	0.42~0.51	0.28~0.42	0.055~0.092	0.022~0.051	Balance
DMFQFDQ-I 17	0.50~0.61	0.35~0.52	0.055~0.092	0.025~0.059	Balance
DMFQFDQ-I 18	0.57~0.70	0.40~0.61	0.068~0.113	0.026~0.060	Balance
DMFQFDQ-I 19	0.61~0.74	0.43~0.65	0.068~0.113	0.029~0.067	Balance
DMFQFDQ-I 20	0.63~0.77	0.45~0.67	0.068~0.113	0.030~0.070	Balance
DMFQFDQ-I 22	0.65~0.79	0.45~0.68	0.068~0.113	0.036~0.084	Balance
DMFQFDQ-I 24	0.75~0.92	0.54~0.81	0.065~0.108	0.044~0.103	Balance
DMFQFDQ-I 26	0.78~0.95	0.56~0.84	0.065~0.108	0.047~0.109	Balance

Catalogue No	Device Weight (g)	Material Quantity (g)			
		Nitinol	00Cr18Ni14Mo3 Stainless steel	Polyethylene erephthalate (PET)	Polyamide 6 (PA6)
DMFQFDQ-I 28	0.89~1.09	0.66~0.99	0.064~0.107	0.047~0.110	Balance
DMFQFDQ-I 30	0.91~1.11	0.66~1.00	0.064~0.107	0.056~0.130	Balance
DMFQFDQ-I 32	1.00~1.22	0.74~1.11	0.064~0.107	0.063~0.146	Balance
DMFQFDQ-I 34	1.20~1.46	0.90~1.35	0.093~0.154	0.049~0.115	Balance
DMFQFDQ-I 36	1.32~1.61	0.98~1.47	0.088~0.147	0.071~0.166	Balance
DMFQFDQ-I 38	1.57~1.92	1.22~1.82	0.083~0.138	0.069~0.162	Balance
DMFQFDQ-I 40	1.80~2.20	1.40~2.10	0.083~0.138	0.085~0.198	Balance
DMFQFDQ-I 42	1.86~2.27	1.42~2.13	0.106~0.177	0.090~0.209	Balance
DMFQFDQ-I 44	1.97~2.41	1.51~2.27	0.106~0.177	0.095~0.221	Balance
DMFQFDQ-I 46	2.18~2.67	1.69~2.54	0.106~0.177	0.099~0.230	Balance

20. Device lifetime

The expected lifetime of the MemoCarnaTM ASD Occluder is 10 years, which has been demonstrated by in-vitro bench testing.