Safety and Performance Information

The MemoPart™ ASD Occluder should only be used by physicians who are trained in transcatheter defect closure techniques. Before use, the operator should have a complete understanding of the indications for use, warnings, and precautions.

Product Description and Performance Characteristics

The MemoPart™ ASD Occluder is a self-expanding double-disc device made of nitinol mesh, stainless steel bushing(s), 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. Stainless steel bushing is to anchor nitinol mesh, and the steel bushing on the right atrial disc is designed with female thread by which the device can be connected to the pusher of an appropriate delivery system.

Models & Specifications

Catalogue No	Device Size	A Connecting waist diameter (mm)	H Height (mm)	B LA Disc Diameter (mm)	C RA Disc Diameter (mm)	Recommended Size of Delivery System*
FQFDQ-I 06	06	6.0±0.5	5.5±0.5	16.0±1.0	14.0±1.0	8-9F
FQFDQ-I 07	07	7.0±0.5	5.5±0.5	21.0±1.0	17.0±1.0	8-9F
FQFDQ-I 08	08	8.0±0.5	5.5±0.5	18.0±1.0	16.0±1.0	8-9F
FQFDQ-I 09	09	9.0±0.5	5.5±0.5	23.0±1.0	19.0±1.0	8-9F
FQFDQ-I 10	10	10.0±0.5	5.5±0.5	20.0±1.0	18.0±1.0	9-10F
FQFDQ-I 11	11	11.0±0.6	5.5±0.75	25.0±1.25	21.0±1.25	9-10F
FQFDQ-I 12	12	12.0±0.6	5.5±0.75	22.0±1.25	20.0±1.25	9-10F
FQFDQ-I 13	13	13.0±0.6	5.5±0.75	27.0±1.25	23.0±1.25	9-10F
FQFDQ-I 14	14	14.0±0.6	5.5±0.75	24.0±1.25	22.0±1.25	9-10F
FQFDQ-I 15	15	15.0±0.6	5.5±0.75	29.0±1.25	25.0±1.25	9-10F
FQFDQ-I 16	16	16.0±0.6	5.5±0.75	30.0±1.5	26.0±1.25	10-12F
FQFDQ-I 17	17	17.0±0.75	5.5±0.75	31.0±1.5	27.0±1.25	10-12F
FQFDQ-I 18	18	18.0±0.75	5.5±0.75	32.0±1.5	28.0±1.5	10-12F
FQFDQ-I 19	19	19.0±0.75	5.5±0.75	33.0±1.5	29.0±1.5	10-12F
FQFDQ-I 20	20	20.0±0.75	5.5±0.75	34.0±1.5	30.0±1.5	10-12F
FQFDQ-I 22	22	22.0±1.0	5.5±1.0	36.0±1.75	32.0±1.75	10-12F
FQFDQ-I 24	24	24.0±1.0	5.5±1.0	38.0±1.75	34.0±1.75	12-14F

Catalogue No	Device Size	A Connecting waist diameter (mm)	H Height (mm)	B LA Disc Diameter (mm)	C RA Disc Diameter (mm)	Recommended Size of Delivery System*
FQFDQ-I 26	26	26.0±1.0	5.5±1.0	40.0±1.75	36.0±1.75	12-14F
FQFDQ-I 28	28	28.0±1.0	5.5±1.0	42.0±1.75	38.0±1.75	12-14F
FQFDQ-I 30	30	30.0±1.0	5.5±1.0	44.0±1.75	40.0±1.75	14F
FQFDQ-I 32	32	32.0±1.0	5.5±1.0	47.0±1.75	42.0±1.75	14F
FQFDQ-I 34	34	34.0±1.0	5.5±1.0	49.0±1.75	44.0±1.75	14F
FQFDQ-I 36	36	36.0±1.0	5.5±1.0	51.0±1.75	46.0±1.75	14F
FQFDQ-I 38	38	38.0±1.0	5.5±1.0	54.0±1.75	50.0±1.75	14F
FQFDQ-I 40	40	40.0±1.0	5.5±1.0	56.0±1.75	52.0±1.75	14F
FQFDQ-I 42	42	42.0±1.0	5.5±1.0	58.0±1.75	54.0±1.75	14F
FQFDQ-I 44	44	44.0±1.0	5.5±1.0	60.0±1.75	56.0±1.75	14F
FQFDQ-I 46	46	46.0±1.0	5.5±1.0	62.0±1.75	58.0±1.75	14F
FQFDQ-I 48	48	48.0±1.0	5.5±1.0	64.0±1.75	60.0±1.75	14F
FQFDQ-I 50	50	50.0±1.0	5.5±1.0	66.0±1.75	62.0±1.75	14F
WTFQFDQ-I 06	06	6.0±0.5	5.5±0.5	16.0±1.0	14.0±1.0	8-9F
WTFQFDQ-I 07	07	7.0±0.5	5.5±0.5	21.0±1.0	17.0±1.0	8-9F
WTFQFDQ-I 08	08	8.0±0.5	5.5±0.5	18.0±1.0	16.0±1.0	8-9F
WTFQFDQ-I 09	09	9.0±0.5	5.5±0.5	23.0±1.0	19.0±1.0	8-9F
WTFQFDQ-I 10	10	10.0±0.5	5.5±0.5	20.0±1.0	18.0±1.0	9-10F
WTFQFDQ-I 11	11	11.0±0.6	5.5±0.75	25.0±1.5	21.0±1.25	9-10F
WTFQFDQ-I 12	12	12.0±0.6	5.5±0.75	22.0±1.25	20.0±1.25	9-10F
WTFQFDQ-I 13	13	13.0±0.6	5.5±0.75	27.0±1.25	23.0±1.25	9-10F
WTFQFDQ-I 14	14	14.0±0.6	5.5±0.75	24.0±1.25	22.0±1.25	9-10F
WTFQFDQ-I 15	15	15.0±0.6	5.5±0.75	29.0±1.25	25.0±1.25	9-10F
WTFQFDQ-I 16	16	16.0±0.6	5.5±0.75	30.0±1.5	26.0±1.25	10-12F
WTFQFDQ-I 17	17	17.0±0.75	5.5±0.75	31.0±1.5	27.0±1.25	10-12F
WTFQFDQ-I 18	18	18.0±0.75	5.5±0.75	32.0±1.5	28.0±1.5	10-12F
WTFQFDQ-I 19	19	19.0±0.75	5.5±0.75	33.0±1.5	29.0±1.5	10-12F
WTFQFDQ-I 20	20	20.0±0.75	5.5±0.75	34.0±1.5	30.0±1.5	10-12F
WTFQFDQ-I 22	22	22.0±1.0	5.5±1.0	36.0±1.75	32.0±1.75	10-12F
WTFQFDQ-I 24	24	24.0±1.0	5.5±1.0	38.0±1.75	34.0±1.75	12-14F
WTFQFDQ-I 26	26	26.0±1.0	5.5±1.0	40.0±1.75	36.0±1.75	12-14F
WTFQFDQ-I 28	28	28.0±1.0	5.5±1.0	42.0±1.75	38.0±1.75	12-14F
WTFQFDQ-I 30	30	30.0±1.0	5.5±1.0	44.0±1.75	40.0±1.75	14F
WTFQFDQ-I 32	32	32.0±1.0	5.5±1.0	48.0±1.75	42.0±1.75	14F
WTFQFDQ-I 34	34	34.0±1.0	5.5±1.0	50.0±1.75	44.0±1.75	14F
WTFQFDQ-I 36	36	36.0±1.0	5.5±1.0	52.0±1.75	46.0±1.75	14F
WTFQFDQ-I 38	38	38.0±1.0	5.5±1.0	54.0±1.75	50.0±1.75	14F
WTFQFDQ-I 40	40	40.0±1.0	5.5±1.0	56.0±1.75	52.0±1.75	14F
WTFQFDQ-I 42	42	42.0±1.0	5.5±1.0	58.0±1.75	54.0±1.75	14F

Catalogue No	Device Size	A Connecting waist diameter (mm)	H Height (mm)	B LA Disc Diameter (mm)	C RA Disc Diameter (mm)	Recommended Size of Delivery System*
WTFQFDQ-I 44	44	44.0±1.0	5.5±1.0	60.0±1.75	56.0±1.75	14F
WTFQFDQ-I 46	46	46.0±1.0	5.5±1.0	62.0±1.75	58.0±1.75	14F
WTFQFDQ-I 48	48	48.0±1.0	5.5±1.0	64.0±1.75	60.0±1.75	14F
WTFQFDQ-I 50	50	50.0±1.0	5.5±1.0	66.0±1.75	62.0±1.75	14F
FQFDQ-II 06	06	6±0.75	5.5±0.5	30±1.5	22±1.5	9-10F
FQFDQ-II 08	08	8±0.75	5.5±0.5	32±1.5	24±1.5	9-10F
FQFDQ-II 10	10	10±0.75	5.5±0.5	34±1.5	26±1.5	10-12F
FQFDQ-II 12	12	12±0.75	5.5±0.5	36±1.5	28±1.5	10-12F
FQFDQ-II 14	14	14±0.75	5.5±0.5	38±1.5	30±1.5	10-12F
FQFDQ-II 16	16	16±0.75	5.5±0.75	40±1.5	32±1.5	12-14F
FQFDQ-II 18	18	18±0.75	5.5±0.75	42±1.5	34±1.5	12-14F
FQFDQ-II 20	20	20±0.75	5.5±0.75	44±1.5	36±1.5	12-14F
FQFDQ-II 22	22	22±0.75	5.5±0.75	46±1.5	38±1.5	12-14F
FQFDQ-II 24	24	24±0.75	5.5±0.75	48±1.5	40±1.5	14F
WTFQFDQ-II 06	06	6±0.75	5.5±0.5	30±1.5	22±1.5	9-10F
WTFQFDQ-II 08	08	8±0.75	5.5±0.5	32±1.5	24±1.5	9-10F
WTFQFDQ-II 10	10	10±0.75	5.5±0.5	34±1.5	26±1.5	10-12F
WTFQFDQ-II 12	12	12±0.75	5.5±0.5	36±1.5	28±1.5	10-12F
WTFQFDQ-II 14	14	14±0.75	5.5±0.5	38±1.5	30±1.5	10-12F
WTFQFDQ-II 16	16	16±0.75	5.5±0.75	40±1.5	32±1.5	12-14F
WTFQFDQ-II 18	18	18±0.75	5.5±0.75	42±1.5	34±1.5	12-14F
WTFQFDQ-II 20	20	20±0.75	5.5±0.75	44±1.5	36±1.5	12-14F
WTFQFDQ-II 22	22	22±0.75	5.5±0.75	46±1.5	38±1.5	12-14F
WTFQFDQ-II 24	24	24±0.75	5.5±0.75	48±1.5	40±1.5	14F

*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.

Intended purpose

The MemoPart™ ASD Occluder is specially designed for transcatheter, percutaneous closure of congenital patent foramen ovale.

Indications

Patients eligible for ASD closure display 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).

Contraindications

1) Patient suffers from atrial septal defect complicated by severe pulmonary resistance hypertension.
2) Any patient known to have a demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi).
3) Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery.
4) Patients afflicted by infectious diseases within the preceding month or those whose infectious status remain unchanged (such as influenza, pneumonia, etc.).
5) Any patient known to have sepsis within one month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement.
6) Any patient whose size (i.e., too small for catheter size, etc.) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization.
7) 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.
8) 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 6 months.
9) Patients with ostium primum atrial septal defect.

Intended Patient Populations

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

Clinical Benefits to be Expected

Memopart^{TM} ASD occluder is used for safe and efficient closure of the left-to-right shunts in the atrial level to achieve the positive management of potential complications of Atrial septal defects.

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, heart blocks, cerebrovascular events (Stroke/TIA), thrombosis, pericardial effusion, occluder migration/malposition/dislocation, occluder 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.

Warnings

1. Use on or before the last day of the expiration date noted on the product packaging.
2. This device is sterilized using ethylene oxide and is for single use only. Do not reuse or re-sterilize. Attempts to re-sterilize the device may result in device malfunction, inadequate sterilization, or patient harm.

3. Do not use the device if the packaging sterile barrier is open or damaged. Do not use a damaged device.
4. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies.
5. This device should only be used by physicians who have been trained professionally in transcatheter defect closure techniques to determine which patients are suitable candidates for procedures using this device.
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. 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.
8. Do not release the MemoPart™ ASD occluder from the pusher of the delivery system if the device does not conform to its original configuration, or 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.
9. Implantation of this device may not eliminate the requirement for Coumadin in patients with ASD and paradoxical emboli.
10. 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.
11. It is important to choose an appropriate delivery system for the occluder; if the delivery sheath of the delivery system cannot match the occluder, it would be difficult to push or retrieve the occluder, which may even cause injury to the blood vessels.
12. The use of echocardiography (TTE, TEE or ICE) is required.

Precautions

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.
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.
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).

4) Placement of the MemoPart™ ASD Occluder may impact future cardiac interventions, for example transeptal puncture and mitral valve repair.
5) 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 TTE to assist in the placement of the atrial septal defect occluder. In the event TEE is utilized, the patient's esophageal anatomy must be suitable to accommodate the placement and manipulation of the TEE probe.

6) 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, 1 day 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.

7) MR Conditional

Non-clinical testing has demonstrated that the ASD 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 3T 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 may produce an image artifact.

Manufacturer

Shanghai Shape Memory Alloy Co., Ltd.
1F and 5F, Tower 41, No. 258 XinZhuan Road, Songjiang High-Tech Park, CaoHeJing Development District, Shanghai 201612, China
Tel: +86-21-37013390
Fax: +86-21-37013391

Further information can be found in the European database on medical devices (Eudamed) by searching the Basic UDI-DI “69330523XZ0001JZ” at: https://ec.europa.eu/tools/eudamed (When Eudamed is available)