Safety and Performance Information

The MemoPart™ PFO 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

The MemoPart™ PFO Occluder is a self-expanding double-disc occlusion device made of a nitinol mesh, stainless steel bushing(s), suture line (polyamide thread) and polyester fabric membrane. The two discs are connected by a short waist allowing free motion of each disc. Polyester fabric (PET) membrane is sewn into the occluder with polyamide (PA) thread to increase occlusion. The device is visible under X-ray.

Models & Specifications

Catalogue No	Device Size	A Connecting waist diameter (mm)	H Height (mm)	B LA Disc Diameter (mm)	C RA Disc Diameter (mm)	Smallest Recommended Size of Delivery System
LYKFDQ-I 1818	1818	3.5±1.0	6.0±2.0	18.0±2.0	18.0±2.0	10-12F
LYKFDQ-I 1824	1824	4.0±1.0	7.0±2.0	18.0±2.0	24.0±2.0	10-12F
LYKFDQ-I 2424	2424	4.0±1.0	7.0±2.0	24.0±2.0	24.0±2.0	10-12F
LYKFDQ-I 2228	2228	4.5±1.0	7.0±2.0	22.0±2.0	28.0±2.0	12-14F
LYKFDQ-I 2828	2828	4.5±1.0	7.0±2.0	28.0±2.0	28.0±2.0	12-14F
LYKFDQ-I 2534	2534	5.0±1.0	7.0±2.0	25.0±2.0	34.0±2.0	12-14F
LYKFDQ-I 3434	3434	5.0±1.0	7.0±2.0	34.0±2.0	34.0±2.0	12-14F
WTLYKFDQ-I 1818	1818	3.5±1.0	6.0±2.0	18.0±2.0	18.0±2.0	10-12F
WTLYKFDQ-I 1824	1824	4.0±1.0	7.0±2.0	18.0±2.0	24.0±2.0	10-12F
WTLYKFDQ-I 2424	2424	4.0±1.0	7.0±2.0	24.0±2.0	24.0±2.0	10-12F
WTLYKFDQ-I 2228	2228	4.5±1.0	7.0±2.0	22.0±2.0	28.0±2.0	12-14F
WTLYKFDQ-I 2828	2828	4.5±1.0	7.0±2.0	28.0±2.0	28.0±2.0	12-14F
WTLYKFDQ-I 2534	2534	5.0±1.0	7.0±2.0	25.0±2.0	34.0±2.0	12-14F
WTLYKFDQ-I 3434	3434	5.0±1.0	7.0±2.0	34.0±2.0	34.0±2.0	12-14F

Intended purpose

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

Indications

The MemoPart™ PFO Occluder is indicated for close all types PFOs (i.e., classical as well as those with aneurysm of the septum) in patients with a history of stroke or transient ischemic attacks (TIAs) diagnosed by echocardiography with right-to-left shunting during the Valsalva maneuver.

Contraindications

Presence of thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the defect is gained.
Active endocarditis or other infections producing bacteremia.
Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate sheath size.
Anatomy in which the PFO device size required would interfere with other intra-cardiac or intravascular structures, such as valves or pulmonary veins.
Patients who are unable to take antiplatelet or anticoagulant therapy.
Patients with known hypercoagulable states.
Patients with intra-cardiac mass or vegetation, thrombus, or tumor.
Patients aged < 18 years old.

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™ PFO Occluder in pregnant women or men intending to father children, nursing mothers and the immunocompromised patients has not been established.
MemoPart™ PFO Occluder is recommended in the transcatheter closure of PFO in patients aged ≥ 18 years old.

Clinical Benefits to be Expected

- High success rate of technical operation.
- High complete closure rate to treat patients with patent foramen ovale (PFO).

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
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 device 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. 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.
10. The use of echocardiography (TTE, TEE or ICE) is required.

Precautions

1. Handling
- 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.
- It is recommended to use the device with delivery systems produced by the manufacturer (SHSMA), for the occluder may be incompatible with other delivery system and may result in technical failures and/or adverse events.
- It is recommended to check whether the device reverts to its original shape prior to introducing in the patient. If the device does not revert to its intended shape, it is not suitable for implantation and shall be discarded.
2. Device size selection
Size the device based on the PFO morphology while taking into consideration the distances from the PFO to the aortic root and SVC. Ensure that the device does not impinge on the free atrial wall or aortic root.
3. Procedural
- Aspirin (3-5mg/kg/day) (or alternative antiplatelet/anticoagulant, if patient has aspirin intolerance) is recommended to be started at least 24 hours prior to the procedure.
- Antibiotics should be administered peri-procedurally.
- Patients should be fully heparinized throughout the procedure using adequate dosing so as to keep the ACT greater than 200 seconds.
- TEE or ICE is recommended as an aid in evaluating the PFO and placing the occluder. If TEE is used, the patient's esophageal anatomy must be adequate for placement and manipulation of the TEE probe.
- Be cautious when fluoroscopic x-ray guidance is used during placement of the device. The risk of increased x-ray exposure for patients who are pregnant must be weighed against the potential benefits of this technique.
- Care should be taken not to entrap right atrial Chiari networks or large Eustachian valves under the right atrial side of the device.
4. 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.
- If a left-sided thrombus is identified following device implantation, the patient should be evaluated for a hypercoagulable state and initiation of aggressive anticoagulant therapy should be given. Thrombolysis or surgical removal of the device should be considered if the patient does not respond to anticoagulant therapy.
- A patient Implant Card is located in each device box. Complete this card and give it to the patient.
- It is recommended to have clinical follow-ups with a cardiologist and undergo echocardiograms at specific intervals: immediately after implantation, one day post-implant, pre-discharge, and again at 1 week, 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.

5. 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 3.0T and 1.5T.
  - Maximum spatial gradient 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

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Further information can be found in the European database on medical devices (Eudamed) by searching the Basic UDI-DI “69330523XZ0004K7” at: https://ec.europa.eu/tools/eudamed (When Eudamed is available)