Safety and Performance Information

The MemoPart™ PDA 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™ PDA Occluder is a self-expanding device made of a nitinol wire mesh, stainless steel bushing(s), suture line (polyamide thread) and polyester fabric membrane. The design properties allow the device to be pulled into a delivery sheath and reshaped once it is released. As the occluder is implanted, it expands outward and the wires push against the wall of the ductus. A retention disc on the aortic side provides secure positioning in the ampulla of the ductus. Polyester fabric (PET) membrane is sewn into the occluder with polyamide (PA) thread to assure an effective closure of the duct. The device is visible under X-ray.

Models & Specifications

Catalogue No	Device Size	A Aortic disc Diameter (mm)	B Height (mm)	C Aortic waist diameter (mm)	D Pulmonic waist diameter (mm)	Smallest Recommended Size of Delivery System
WBFDQ-I 04	04	8.0±1.0	4.0±1.5	4.0±1.0	--	6-7F
WBFDQ-I 05	05	9.0±1.0	5.0±1.5	5.0±1.0	--	6-7F
WBFDQ-I 06	06	10.0±1.0	6.0±1.5	6.0±1.0	--	6-7F
WBFDQ-I 07	07	11.0±1.0	6.5±1.5	7.0±1.0	--	7-8F
WBFDQ-I 08	08	12.0±1.0	6.5±1.5	8.0±1.0	--	7-8F
WBFDQ-I 09	09	13.0±1.0	7.0±1.5	9.0±1.0	--	8-9F
WBFDQ-I 10	10	14.0±1.5	7.5±2.0	10.0±1.5	--	8-9F
WBFDQ-I 11	11	15.0±1.5	8.0±2.0	11.0±1.5	--	8-9F
WBFDQ-I 12	12	16.0±1.5	8.5±2.0	12.0±1.5	--	8-9F
WBFDQ-I 13	13	17.0±1.5	8.5±2.0	13.0±1.5	--	8-9F
WBFDQ-I 14	14	18.0±1.5	9.5±2.0	14.0±1.5	--	9-10F
WBFDQ-I 16	16	21.0±2.0	10.5±2.5	16.0±2.0	--	9-10F
WBFDQ-I 18	18	23.0±2.0	10.5±2.5	18.0±2.0	--	10-12F
WBFDQ-I 20	20	25.0±2.0	12±2.5	20.0±2.0	--	12-14F
WBFDQ-I 22	22	27.0±2.0	12±2.5	22.0±2.0	--	12-14F
WBFDQ-II 06	0406	10.0±1.0	6.0±1.5	6.0±1.0	4.0±1.0	6-7F
WBFDQ-II 08	0608	12.0±1.0	6.5±1.5	8.0±1.0	6.0±1.0	7-8F
WBFDQ-II 10	0810	14.0±1.5	7.5±2.0	10.0±1.5	8.0±1.5	7-8F
WBFDQ-II 12	1012	16.0±1.5	8.5±2.0	12.0±1.5	10.0±1.5	8-9F
WBFDQ-II 14	1214	18.0±1.5	9.5±2.0	14.0±1.5	12.0±1.5	8-9F
WBFDQ-II 16	1416	20.0±1.5	10.5+2.5	16.0±2.0	14.0±2.0	9-10F

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WBFDQ-II 18	1618	23.0±2.0	10.5±2.5	18.0±2.0	16.0±2.0	10-12F
WBFDQ-II 20	1820	25.0±2.0	12.0±2.5	20.0±2.0	18.0±2.0	12-14F
WBFDQ-II 22	2022	27.0±2.0	12.0±2.5	22.0±2.0	20.0±2.0	12-14F
WTWBFDQ-I 04	04	8.0±1.0	4.0±1.5	4.0±1.0	--	6-7F
WTWBFDQ-I 05	05	9.0±1.0	5.0±1.5	5.0±1.0	--	6-7F
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WTWBFDQ-I 09	09	13.0±1.0	7.0±1.5	9.0±1.0	--	8-9F
WTWBFDQ-I 10	10	14.0±1.5	7.5±2.0	10.0±1.5	--	8-9F
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WTWBFDQ-II 18	1618	23.0±2.0	10.5±2.5	18.0±2.0	16.0±2.0	10-12F
WTWBFDQ-II 20	1820	25.0±2.0	12.0±2.5	20.0±2.0	18.0±2.0	12-14F
WTWBFDQ-II 22	2022	27.0±2.0	12.0±2.5	22.0±2.0	20.0±2.0	12-14F

Intended purpose

The MemoPart^{TM} PDA Occluder is specially designed for transcatheter, percutaneous closure of congenital patent ductus arteriosus.

Indications

The MemoPart^{TM} PDA Occluder is indicated for close patent ductus arteriosus with clinical symptoms and left to right shunt and cardiac overload.

Contraindications

Patients with severe pulmonary hypertension and of right-to-left shunt.
Hemorrhagic diseases such as active ulcer.
Other abnormalities are present in need of surgical treatment.
Recent infection is found.
Patients weighing less than 6kg or patients less than 7 months of age.
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.
Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate sheath size.

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 MemoPart™ PDA Occluder in pregnant women or men intending to father children, nursing mothers and the immunocompromised patients has not been established.
MemoPart™ PDA Occluder is recommended in the transcatheter closure of PDA in patients with a weight of ≥ 6kg.
MemoPart™ PDA Occluder is recommended in the transcatheter closure of PDA in patients aged ≥ 7 months.

Clinical Benefits to be Expected

High success rate of device implantation.
High complete closure rate to treat patient with Patent ductus arteriosus (PDA).

Warnings

1. Use 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 resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization, or patient harm.
3. Do not use the device if the sterile packaging is open or damaged.
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 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. Do not remove an embolized occluder through intracardiac structures unless the occluder is fully recaptured inside a sheath.
8. It is important to choose the appropriate delivery system for the occluder; 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 injury to the blood vessels.
9. The heparinization should be fully used in the surgery to avoid the complications of thromboembolism.
10. Do not release the 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. Recapture the device and redeploy. If still unsatisfactory, recapture the device and replace with a new device.
11. If the selected occluder is larger than 12mm, the delivery sheath above 7F should be used, and it's better to use the anti-bending sheath to prevent the break and damage to veins.

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. Pay attention to avoid the occluder dropping during the operation procedure. If the occluder dropped after released, use a snare to remove the occluder. If the removing failed, an emergency surgery should be implemented to remove the occluder.
3. It is recommended to use MemoPart™ PDA Occluder with delivery systems produced by the manufacturer, for the occluder may be incompatible with other delivery systems and may result in technical failures and/or adverse events.
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.
- Any patient who has a residual shunt will undergo an echocardiographic evaluation of the residual shunt until complete closure of the defect has been confirmed.
- Lung perfusion scan should be completed if flow through is greater than 3 m/s, or if the or the Z-value for the lung artery diameter is -2.
- A patient Implant Card is included in each device box. Complete this card and give it to the patient.
5. MR Conditional
- Non-clinical testing has demonstrated that the occluder is MR Conditional. Patients can be safely scanned immediately after implantation under the following conditions:
    - Static magnetic field of 3.0 T 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 “69330523XZ0003K5” at: https://ec.europa.eu/tools/eudamed (When Eudamed is available)