

<b>Starway Medical Technology, Inc.</b>	<b>Doc.No.: HYSJ-001</b>	<b>Section: 6.3</b>
	<b>Date: 01/April/2008</b>	<b>Version: E.0</b>

## **Starway Occluder System**

# **Instructions for Use**

*Read “Instructions for Use” carefully before use.*

*Users should have the interventional treating practice*

*Or be guided by professionals*

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**EO Sterilized. Single Use only. Do not Resterilize.**

**Do not Use Open or Damaged Packages.**

**Store in a Cool, Dry Place.**

### 6.3.1. Introduction

The Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD), Patent Ductus Arteriosus (PDA), Patent Foramen Oval (PFO) and Abnormality of Blood Vessels (Vascular Plug) are sorts of congenital heart diseases which causes growth and development abnormalities of the patients. Before the interventional method was applied, the cardiac surgery is the only way to cure the patients suffering the diseases. Now people are getting used to accept the interventional curing method because of its significant characters, such as: shorter in hospital-stay, less tracheal intubation or general anesthesia, less pain and hurt, quick recovery, and no operation scar left etc. The Occluder Systems we made are just the right interventional devices to meet the needs.

### 6.3.2. ASD Occluder System

#### 6.3.2.1 Cardi-O-Fix ASD Occluder:

The Starway Cardi-O-Fix ASD Occluder is a self-expandable, double disc implant device made from a Nitinol wire mesh. The two discs are linked together by a short connecting waist corresponding to the size of the ASD. In order to increase its closing ability, the discs and the waist are filled with polyester fabric. The polyester fabric is securely sewn to each disc by surgical sutures.

Starway ASD Occluders have been designed with two types, the traditional type and the improved type. The traditional type has double ends, and the improved type only has single end. Both types can be used for the intended patients.

Type one ( $A^1$ ) has double ends (Fig.1) and type two ( $A^2$ ) has single end only (Fig.2).

- a. Distal end
- b. Wire mesh
- c. Polyester
- d. Proximal end
- D. Device waist in diameter

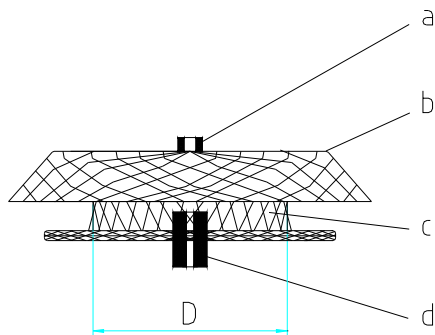


Fig. 1 ASD Occluder  
( $A^1$ Type)

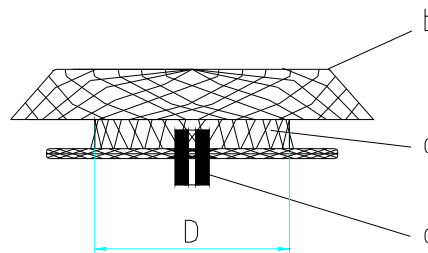


Fig. 2 ASD Occluder  
( $A^2$ Type)

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#### **6.3.2.2 Intended Use:**

The Starway Cardi-O-Fix ASD Occluder is a percutaneous, transcatheter, permanent implant device intended for the occlusion of atrial septal defects (ASD) in secundum position.

The Starway Cardi-O-Fix ASD Occluder is a single-use device, which is sterilized via ethylene oxide (EO).

#### **6.3.2.3 Indications:**

- 1) Patients have echocardiographic evidence of ostium Secundum atrial septal defect (ASD) with diameter  $\leq 36$  mm.
- 2) A distance of  $\geq 5$ mm from the margins of the defect to the coronary sinus, AV valves and right upper lobe pulmonary vein.

#### **6.3.2.4 Contraindications:**

- 1) Patients associated with other congenital cardiac anomalies which require cardiac surgery.
- 2) Ostium primum atrial septal defect.
- 3) Severe pulmonary hypertension, 'Eisenmenger's Syndrome'.
- 4) Total occlusion of inferior vena cava due to thrombosis.

#### **6.3.2.5 General Exclusion Criteria:**

- 1) Sepsis (local/generalized) .
- 2) History of repeated pulmonary infection.
- 3) Any type of serious infection < 1 month prior to procedure.
- 4) Malignancy where life expectancy is < 3 years.
- 5) Demonstrated intracardiac thrombi on echocardiography.
- 6) Inability to obtain informed consent.

#### **6.3.2.6 Cardi-O-Fix Delivery System:**

The Cardi-O-Fix Delivery System is comprised of a delivery sheath, dilator, loader, hemostasis valve, delivery cable with plastic vise.

Starway 45° Cardi-O-Fix Delivery System was designed specifically to facilitate attachment, loading, delivery and deployment of Cardi-O-Fix ASD and PFO Occluders.

The Cardi-O-Fix Delivery System is a single-use device which is sterilized via ethylene oxide (EO).

**Sizes of the Delivery System for ASD Occluder are:**

7F, 8F, 9F, 10, 12F and 14F (in French size)

**The Tip of Delivery Sheath is: 45° .**

**Delivery Sheath with Hemostasis Valve** - used to deliver the occluder device.

**Dilator** – used to prevent from penetration of tissue.

**Loader** – used to introduce the occluder into the delivery sheath.

**Delivery Cable** – the device is screwed onto the distal tip of the delivery cable, which allows for placement (and if necessary, retrieval) of the device.

**Plastic Vise** – facilitates directional control and serves as the “handle” for disconnecting (unscrewing) the delivery cable from the device.

(Fig. 1 Assembled Delivery System & Fig. 2 Parts of Delivery System)

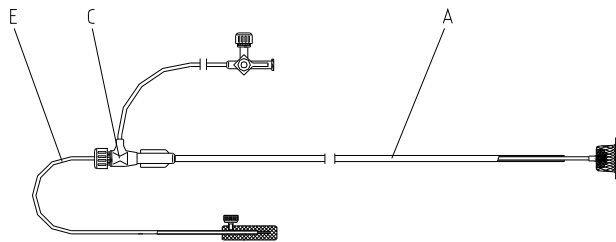
**A.** Delivery Sheath

**B.** Dilator

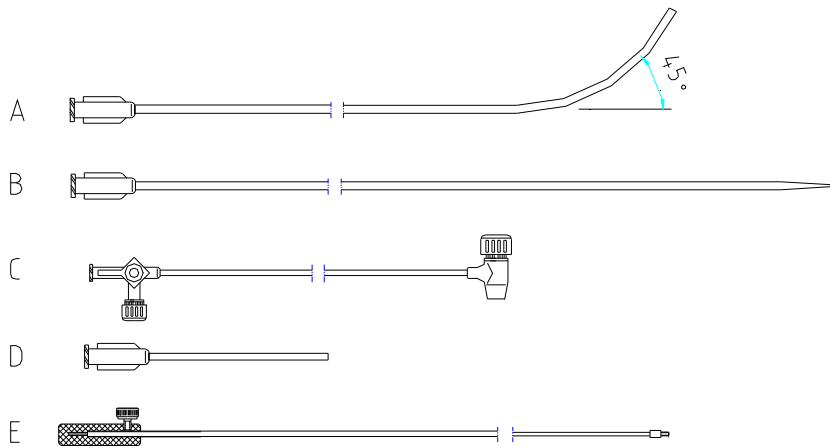
**C.** Hemostasis Valve

**D.** Loader

**E.** Delivery Cable with Plastic Vise



**Fig. 1 Assembled Delivery System for ASD & PFO Occluders**



**Fig. 2 Delivery System for ASD & PFO Occluders**

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### **6.3.2.7 Procedure:**

- 1) A standard right heart catheterization is performed following puncture of femoral vein.
- 2) The right heart catheter is introduced to left atrium, and to left upper pulmonary vein.
- 3) The stiff J tip guidewire is introduced to the left pulmonary vein through the right heart catheter, then the right heart catheter is removed together with vessel sheath. Meanwhile heparin is administered routinely via IV infusion route.
- 4) Before being advanced into the heart, the measure balloon is inflated with contrast medium to drive the air out, then deflated and kept in negative pressure by drawing the medium out. Balloon catheter is exchanged over the wire and positioned in the left atrium, inflated with contrast and pulled back across the defect under fluoroscopic and echocardiographic guidance. The size of the balloon just prior to its popping through the defect is the stretched diameter of the defect, where a slight deformity of the sizing balloon can be seen. The balloon catheter is removed, reinflated with the same amount of contrast, and pushed through holes on a sizing plate to determine the stretched diameter of the defect. Compare readings of the three different methods, and choose a proper device.
- 5) The delivery sheath is exchanged to left atrium over the wire. At this moment, pay more attention not to bring air into the body, otherwise air embolism in coronary arteries would happen.
- 6) The delivery cable is passed through the loader, and the occluder is screwed clockwise into the tip of the delivery cable. Screwed and unscrewed for 3-4 times, but not over-tightened when screwed on.
- 7) The device and the loader are immersed in saline solution as the device is pulled into the loader to remove the air. Flush via the side arm of the loader.
- 8) The loader is introduced into the delivery sheath, and without rotation the device is advanced into the left atrium.
- 9) With fluoroscopic and echocardiographic guidance, the sheath is retracted until the left atrial disc is opened in the middle of the left atrium. The sheath with the delivery cable in it is pulled back as one unit till the left atrial disc against the interatrial septum (it can be felt and also detected by echocardiography). The sheath is retracted further with constant tension on the delivery sheath and cable, and the right atrial disc is deployed in the right atrium.

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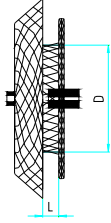
- 10) With echocardiographic observation, the delivery cable is pushed forward and pulled backward repeatedly with a proper tension, to confirm a stable position of the device. If misplacement occurs, the device can be retrieved into the delivery sheath and redeployed, or replaced by another device.
- 11) The device is released by turning the delivery cable counterclockwise using the plastic vise, as indicated by the arrow on the delivery cable.
- 12) Heparin is given during 3 days following the procedure, and an antiplatelet medicine (eg. Aspirin) for half a year.

#### **6.3.2.8 Complications & Solutions:**

There would be several complications during or after the procedure:

- 1) Air embolism in coronary arteries: It may happen if air is brought into the body due to improper manipulation, in that it can get reach to coronary arteries via left atrium-left ventricle-aorta route when patient kept in supine position. Symptoms and signs of acute myocardial infarction will be shown, which need immediate treatment such as sublingual nitroglycerin, oxygen, and intravenous vasodilators. If symptoms are relieved and electrocardiogram is returned to normal in a short time, the procedure can be continued. Otherwise stop the operation.
- 2) Thrombosis: Usually, it is caused by improper use of anticoagulants during or after the procedure, and should be treated symptomatically in most cases. However, thromboembolism must be differentiated from intracranial hemorrhage, especially in senior or hypertensive patients.
- 3) Arrhythmia: If severe arrhythmia occurs before the device released, the procedure should be stopped immediately. Retrieve the device and remove it out of the body. Then refer the patient to cardiac surgeon. If it happens after the procedure, drugs to diminish edema, protect myocardium or treat arrhythmia should be given. When necessary, temporary pacing lead should be advanced during the observation period within a few days. If arrhythmia persists and cannot be controlled by the drugs, it must be attempted to take the device out by surgery or/and implant a permanent pacemaker.
- 4) Device dislodgement: If it happens, the device must be taken out by interventional method or surgery at once.
- 5) Cardiac tamponade: Usually caused by improper operation. It is a severe adverse event and may be life-threatening if in delayed awareness and treatment. The clinical symptoms and signs include: sudden cardiac pain (at the moment of rupture), dropping blood pressure, increased heart rate, disappeared pulsing of cardiac edge and enlarged heart shadow on x-ray. Blood volume in pericardial cavity can be assessed by echocardiography. If it happens, pericardial puncture must be performed immediately. However, it can be prevented if it is assured to introduce over the guidewire and manipulate tenderly. When it is misplaced, the device should be retracted, removed and redeployed.

**6.3.2.9 Specifications of Cardi-O-Fix ASD Occluder:**

Occluder Drawing	Model Number		D (mm) Waist Dia.	L (mm) Waist Length	Recommended Sheath Size Fr. (mm)
	Type A <sup>1</sup> (Double-End)	Type A <sup>2</sup> (Single-End)			
	A <sup>1</sup> -04	A <sup>2</sup> -04	4	3	7 (2.7)
	A <sup>1</sup> -05	A <sup>2</sup> -05	5	3	7 (2.7)
	A <sup>1</sup> -06	A <sup>2</sup> -06	6	3	7 (2.7)
	A <sup>1</sup> -07	A <sup>2</sup> -07	7	3	7 (2.7)
	A <sup>1</sup> -08	A <sup>2</sup> -08	8	3	7 (2.7)
	A <sup>1</sup> -09	A <sup>2</sup> -09	9	3	7 (2.7)
	A <sup>1</sup> -10	A <sup>2</sup> -10	10	3	7 (2.7)
	A <sup>1</sup> -11	A <sup>2</sup> -11	11	4	7 (2.7)
	A <sup>1</sup> -12	A <sup>2</sup> -12	12	4	8 (3.0)
	A <sup>1</sup> -13	A <sup>2</sup> -13	13	4	8 (3.0)
	A <sup>1</sup> -14	A <sup>2</sup> -14	14	4	8 (3.0)
	A <sup>1</sup> -15	A <sup>2</sup> -15	15	4	9 (3.3)
	A <sup>1</sup> -16	A <sup>2</sup> -16	16	4	9 (3.3)
	A <sup>1</sup> -17	A <sup>2</sup> -17	17	4	9 (3.3)
	A <sup>1</sup> -18	A <sup>2</sup> -18	18	4	9 (3.3)
	A <sup>1</sup> -19	A <sup>2</sup> -19	19	4	10 (3.3)
	A <sup>1</sup> -20	A <sup>2</sup> -20	20	4	10 (3.3)
	A <sup>1</sup> -22	A <sup>2</sup> -22	22	4	12 (4.0)
	A <sup>1</sup> -24	A <sup>2</sup> -24	24	4	12 (4.0)
	A <sup>1</sup> -26	A <sup>2</sup> -26	26	4	12 (4.0)
A <sup>1</sup> -28	A <sup>2</sup> -28	28	4	12 (4.0)	
A <sup>1</sup> -30	A <sup>2</sup> -30	30	4	12 (4.0)	
A <sup>1</sup> -32	-	32	4	12 -14 (4-4.7)	
A <sup>1</sup> -34	-	34	4	12-14 (4-4.7)	
A <sup>1</sup> -36	-	36	4	12-14 (4-4.7)	
A <sup>1</sup> -38	-	38	4	12-14 (4-4.7)	
A <sup>1</sup> -40	-	40	4	12-14 (4-4.7)	

### 6.3.3. VSD Occluder System

#### 6.3.3.1 Cardi-O-Fix VSD Occluder:

The Starway Cardi-O-Fix VSD Occluder is a self-expandable, double disc implant device made from a Nitinol wire mesh. The two discs are linked together by a short connecting waist corresponding to the size of the VSD. In order to increase its closing ability, the discs and the waist are filled with polyester fabric. The polyester fabric is securely sewn to each disc by surgical sutures.

Starway VSD Occluders have been designed with two types, the traditional type and the improved type. The traditional type has double ends, and the improved type only has single end. Both types can be used for the intended patients.

Type one ( $V^1$ ) has double ends (Fig.1) and type two ( $V^2$ ) has single end only (Fig.2).

- a. Distal end
- b. Wire mesh
- c. Polyester
- d. Proximal end
- D. Device waist in diameter

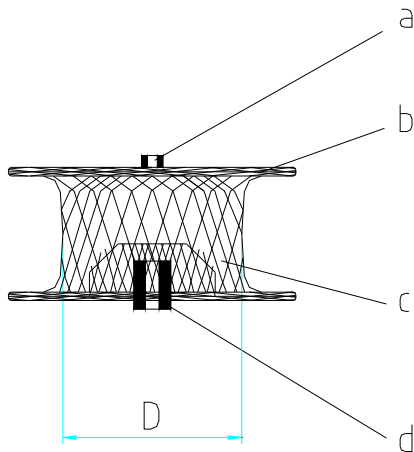


Fig. 1 VSD Occluder  
( $V^1$  Type)

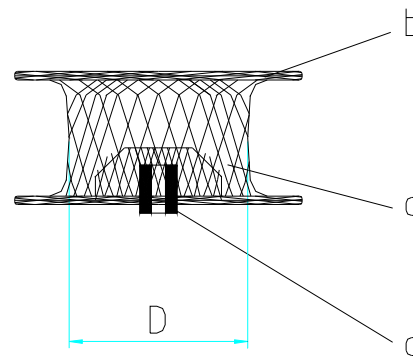


Fig. 2 VSD Occluder  
( $V^2$  Type)

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### **6.3.3.2 Intended Use:**

The Starway Cardi-O-Fix VSD Occluder is a percutaneous, transcatheter, permanent implant device intended for the occlusion of ventricular septal defects (VSD).

The Starway Cardi-O-Fix VSD Occluder is single-use device which is sterilized via ethylene oxide (EO).

### **6.3.3.3 Indications:**

The Starway Cardi-O-Fix VSD Occluder is indicated for use in patients with complex ventricular septal defects of significant size to warrant closure who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical conditions.

- 1) Patients with demonstrated muscular or membranous ventricular septal defects (VSD) .
- 2) Size of VSD: It should be 3-15mm from left ventricle. If it is multi-hole from right ventricle, the largest hole should be  $\geq$  2mm. In children, it should be < 10mm.
- 3) Margin of VSD from aortic valve > 2mm, no significant aortic valvular prolapse or regurgitation.
- 4) Margin of VSD from tricuspid valve  $\geq$ 1.5mm, no significant congenital anomaly or more than moderate regurgitation of tricuspid valve.
- 5) Patients who underwent surgical closure of ventricular septal defects and have a residual left-to-right shunt.
- 6) Patients with LV dilatation.
- 7) Patients with no other anomalies that require surgical correction.
- 8) Patients with age > 3 years old.

### **6.3.3.4 Contraindications:**

- 1) Patients associated with other congenital cardiac anomalies which require cardiac surgery.
- 2) Patients with aortic valve prolapse or regurgitation.
- 3) Patients with severe pulmonary hypertension, 'Eisenmanger's Syndrome'.
- 4) Patients with total occlusion of inferior vena cava due to thrombosis.

### **6.3.3.5 General Exclusion Criteria:**

- 1) Sepsis (local/ generalized).
- 2) History of repeated pulmonary infection.
- 3) Any type of serious infection within 1 month prior to procedure.
- 4) Malignancy where life expectancy is < 3 years.
- 5) Demonstrated intracardiac thrombi on echocardiography.
- 6) Inability to obtain informed consent.

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### 6.3.3.6 Cardi-O-Fix Delivery System:

Starway 180° Cardi-O-Fix Delivery System was designed specifically to facilitate attachment, loading, delivery and deployment of the Cardi-O-Fix VSD, PDA and Plug Occluder and it is comprised of a delivery sheath, loader, dilator, hemostasis valve, delivery cable with plastic vise.

Starway Cardi-O-Fix Delivery System is a single-use device which is sterilized via ethylene oxide (EO).

**The size of the delivery system for VSD Occluder: 7F, 8F and 9F.**

**The tip of delivery sheath: 180° .**

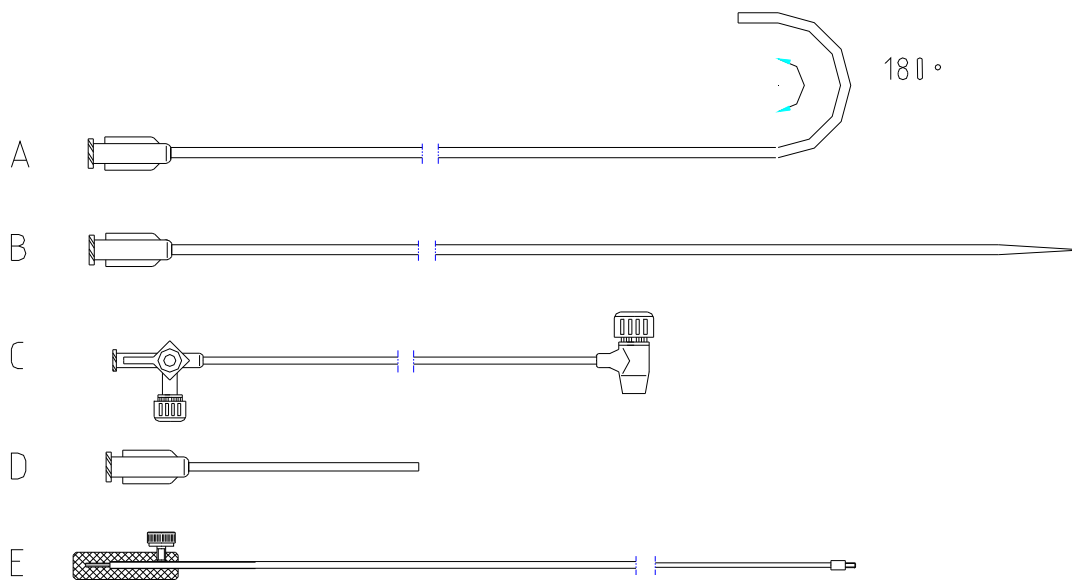


Fig. 3 Delivery System for VSD, PDA & Plug Occluders

### 6.3.3.7 Procedure:

- 1) A standard left and right heart catheterization are performed following puncture of femoral artery and vein.
- 2) Left ventricular angiography is performed in long axis view using pigtail catheter to assess the size, location and shape of VSD, and its relation to aortic valve.
- 3) A right coronary curve catheter or other specific catheter is used to cross the VSD from left ventricle (Note: tender manipulation to avoid ventricular arrhythmia). A 260mm long floppy exchange wire (hydrophilic or noodle) is easily introduced into right ventricle and to right atrium.
- 4) A right heart catheter is introduced to right atrium. The noodle guidewire is snared

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out to femoral vein with the snare-shaped foreign body forceps, so a continuous arteriovenous loop of aorta-left ventricle-VSD-right ventricle-right atrium-inferior vena cava is established.

5) The right heart catheter is removed with the vessel sheath. A delivery sheath is passed over the wire via the pathway of inferior vena cava-right atrium-right ventricle-VSD-left ventricle. Note: tip of the sheath should reach the apex of left ventricle.

6) The delivery cable is passed through the loader, and the occluder is screwed clockwise into the tip of the delivery cable. Screwed and unscrewed for 3-4 times, but not over-tightened when screwed on.

7) The device and the loader are immersed in saline solution as the device is pulled into the loader to remove the air. Flush via the side arm of the loader.

8) The loader is introduced into the delivery sheath, and without rotation the device is advanced into the apex of left ventricle.

9) With fluoroscopic and echocardiographic guidance, the sheath is withdrawn to the left ventricular outflow tract far from the mitral valve apparatus. Then the left disk is deployed and pulled back gently against the septum. Under gentle tension on the sheath the right disk is deployed by advancing the delivery catheter.

10) A left ventriculography is repeated to assess if there is any residual shunt or encroachment of aortic valve.

11) Careful observation using echocardiography if there is impingement of tricuspid valve.

12) Monitor if any cardiac arrhythmia exists on electrocardiography.

13) The device is released only when its position is optimal and interference with the aortic valve and tricuspid valve structures has been excluded.

14) When it is misplaced, the device should be retracted, removed and redeployed.

15) The device is released by turning the delivery cable counterclockwise using the plastic vise, as indicated by the arrow on the delivery cable.

#### **6.3.3.8 Complications & Solutions:**

There would be several complications during or after the procedure: thrombosis, occluder dislodgement, cardiac tamponade, hemolysis, cardiac arrhythmia, residual shunt, etc.


1) Thrombosis: Usually, it is caused by improper use of anticoagulants during or after the procedure, and should be treated symptomatically in most cases. However,

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thromboembolism must be differentiated from intracranial hemorrhage, especially in senior or hypertensive patients.

- 2) Device dislodgement: If it happens, the device must be taken out by interventional method or surgery at once.
- 3) Cardiac tamponade: Usually caused by improper operation. It is a severe adverse event and may be life-threatening if in delayed awareness and treatment. The clinical symptoms and signs include: sudden cardiac pain (at the moment of rupture), dropping blood pressure, increased heart rate, disappeared pulsing of cardiac edge and enlarged heart shadow on X-ray. Blood volume in pericardial cavity can be assessed by echocardiography. If it happens, pericardial puncture must be performed immediately. However, it can be prevented if it is assured to introduce over the guidewire and manipulate tenderly. When it is misplaced, the device should be retracted, removed and redeployed.
- 4) Hemolysis: Mechanic damage of red blood cell when insufficient occlusion occurs, that is attributed to improper device size or position, large residual shunt before occluder release and patent coagulation deficiency. If hemolysis happens, give some medicines to promote thrombogenicity, while monitoring hemoglobin or red cell count, renal function, and urine color. Some patients can get better with the treatment when delayed thrombosis gradually stops the abnormal shunt. However, if no signs of improvement show after medical therapy or renal function damage occurs, a surgical operation or another intervention should be attempted at once.
- 5) Arrhythmia: There are many conduction fibers passing through interventricular septum, so severe arrhythmia may be evoked during or after the procedure due to surrounding tissue edema, eg. third-degree AVB. If severe arrhythmia occurs before the device released, the procedure should be stopped immediately. Retrieve the device and remove it out of the body. Then refer the patient to cardiac surgeon. If it happens after the procedure, drugs to diminish edema, protect myocardium or treat arrhythmia should be given. When necessary, temporary pacing lead should be advanced during the observation period of a few days. If it persists and cannot be controlled by the drugs, it must be attempted to take the device out by surgery or/and implant a permanent pacemaker.
- 6) Residual shunt: It is considered normal if mild left to right shunt seen in a few patients just after the procedure, but it disappears as time goes by, usually in 2-3 months. While if the shunt persists half a year later, another interventional procedure should be considered one year after the first.

**6.3.3.9 Specifications of Cardi-O-Fix VSD Occluder:**

Occluder Drawing	Type		D (mm) Waist Dia.	L (mm) Waist Length	Recommended Sheath Size Fr. (mm)	
	Double-End	Single-End				
	V <sup>1</sup> -04	V <sup>2</sup> -04	4	2	6 (2.3)	
	V <sup>1</sup> -05	V <sup>2</sup> -05	5	2	6 (2.3)	
	V <sup>1</sup> -06	V <sup>2</sup> -06	6	2	6 (2.3)	
	V <sup>1</sup> -07	V <sup>2</sup> -07	7	2	7 (2.7)	
	V <sup>1</sup> -08	V <sup>2</sup> -08	8	2	7 (2.7)	
	V <sup>1</sup> -09	V <sup>2</sup> -09	9	2	8 (3.0)	
	V <sup>1</sup> -10	V <sup>2</sup> -10	10	2	8 (3.0)	
	V <sup>1</sup> -11	V <sup>2</sup> -11	11	2	9 (3.3)	
	V <sup>1</sup> -12	V <sup>2</sup> -12	12	2	9 (3.3)	
	V <sup>1</sup> -14	V <sup>2</sup> -14	14	2	12 (4.0)	
	V <sup>1</sup> -16	V <sup>2</sup> -16	16	2	12 (4.0)	

### 6.3.4 PDA Occluder System

#### 6.3.4.1 Cardi-O-Fix PDA Occluder:

Starway Cardi-O-Fix PDA Occluder is a self-expandable, mushroom shaped implant device made from a Nitinol wire mesh. A 2-millimeter retention skirt assures secure positioning in the mouth of the patent ductus arteriosus (PDA). The communication is closed by the induction of thrombosis which is accomplished by polyester patches sewn securely into the device.

Starway PDA Occluders have been designed with two types, the traditional type and the improved type. The traditional type has double ends, and the improved type only has single end. Both types can be used for the intended patients.

Type one ( $P^1$ ) has double ends (Fig.1) and type two ( $P^2$ ) has single end only (Fig.2).

- a. Distal end
- b. Wire mesh
- c. Polyester
- d. Proximal end
- D. Device size in diameter
- D1. Device size in diameter

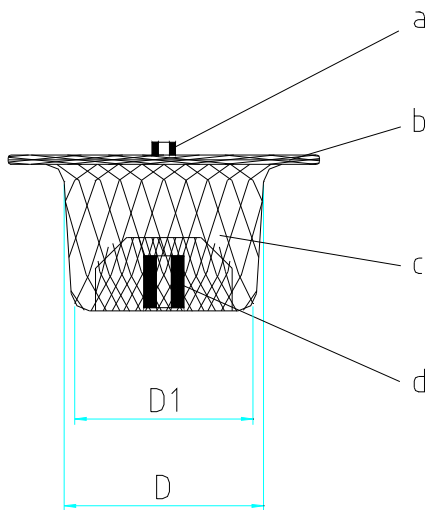


Fig. 1 PDA Occluder  
( $P^1$  Type)

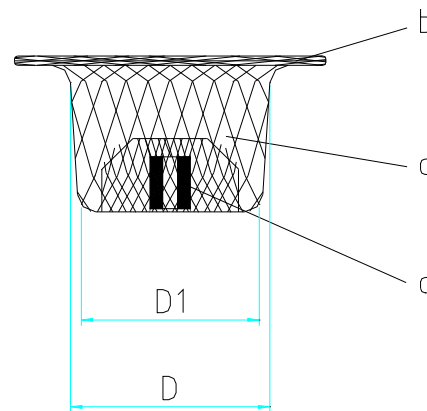


Fig. 2 PDA Occluder  
( $P^2$  Type)

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**6.3.4.2 Intended Use:**

Starway Cardi-O-Fix PDA Occluder is a percutaneous, transcatheter, permanent implant device intended for the occlusion of patent ductus arteriosus (PDA).

The Cardi-O-Fix PDA Occluder is a single-use device which is sterilized via ethylene oxide (EO).

**6.3.4.3 Indications:**

Patients who are diagnosed to suffer from the patent ductus arteriosus (PDA).

**6.3.4.4 Contraindications:**

- 1) Patients with ‘Silent’ PDA only diagnosed by echocardiography, but without any significant hemodynamic alteration or clinical symptom.
- 2) Associated with other congenital cardiac anomalies, which require cardiac surgery.

**6.3.4.5 General Exclusion Criteria:**

- 1) Sepsis (local/ generalized).
- 2) Any type of serious infection within 1 month prior to procedure.
- 3) Malignancy where life expectancy is less than 5 years.
- 4) Demonstrated venous thrombosis in lower limbs.
- 5) Severe pulmonary hypertension, ‘Eisenmenger’s Syndrome’.
- 6) Inability to obtain informed consent.

**6.3.4.6 Cardi-O-Fix Delivery System:**

Starway 180degree Cardi-O-Fix Delivery System was designed specifically to facilitate attachment, loading, delivery and deployment of Cardi-O-Fix PDA, VSD and Plug Occluder and it is comprised of a delivery sheath, dilator, loader, hemostasis valve, delivery cable with plastic vise.

The Cardi-O-Fix Delivery System is a single-use device which is sterilized via ethylene oxide (EO).

**The size of delivery system for PDA Occluder:** 6F, 7F, 8F, 9F and 10F.

**The tip of the delivery sheath is:** 180° .

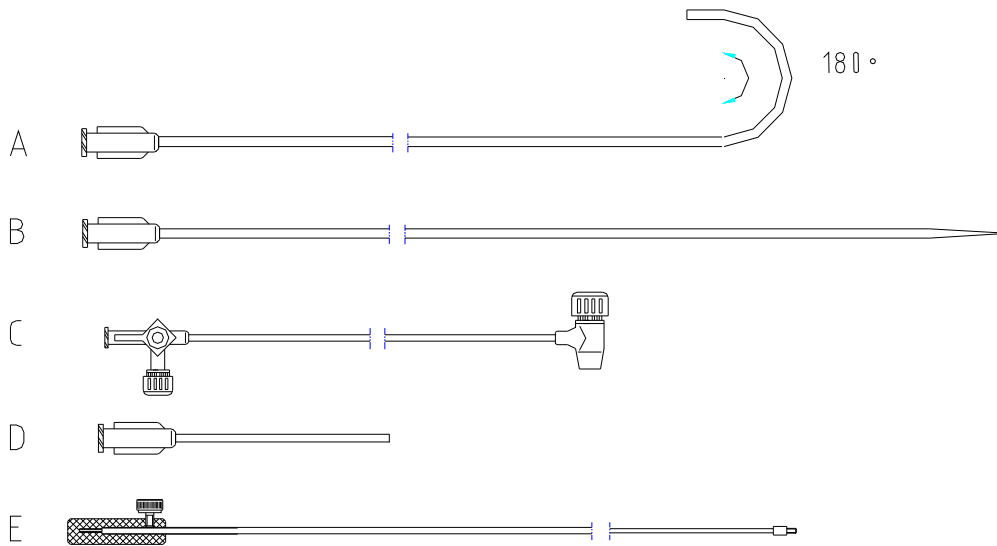


Fig. 3 Delivery System for VSD, PDA & Plug Occluders

#### 6.3.4.7 Procedure:

- 1) A standard right heart catheterization is performed following puncture of femoral artery and femoral vein.
- 2) A aortography is performed to demonstrate PDA by passing a pigtail catheter into descending aorta near the arch. Its anatomy, size and length are assessed.
- 3) A right heart catheter is introduced with the exchange wire retrogradely through the PDA to descending aorta, then the right heart catheter is removed together with vessel sheath. The delivery sheath is introduced over the wire and positioned in descending aorta.
- 4) According to the angiogram of PDA, a device of 2-4mm bigger than its narrowest diameter is chosen for loading.
- 5) The delivery cable is passed through the loader, and the occluder is screwed clockwise into the tip of the delivery cable. Screwed and unscrewed for 3-4 times, but not over-tightened when screwed on.

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- 6) The device and the loader are immersed in saline solution as the device is pulled into the loader to remove the air. Flush via the side arm of the loader.
- 7) The loader is introduced into the delivery sheath, and without rotation the occluder device is advanced into the descending aorta.
- 8) The delivery sheath is retracted until the retention disc is opened, then the sheath with the delivery cable in it is pulled back as one unit until the disc against the aortic side of the ductus (it can be felt and by flurosopic or echocardiographic observation). The sheath is further retracted with constant tension on the delivery cable, the round waist is deployed in the PDA.
- 9) Aortography is performed once more to confirm a correct placement or detect a residual shunt.
- 10) If it is misplaced, the device can be retrieved into the delivery sheath and redeployed, or replaced by another device.

The device is released by turning the delivery cable counterclockwise using the plastic vise, as indicated by the arrow on the delivery cable.

#### **6.3.4.8 Complications & Solutions:**

There would be three major kinds of complications: mild left to right shunt, hemolysis and device dislodgement.

- 1) Residual shunt: It is considered normal if mild left to right shunt seen in a few patients just after the procedure, but it disappears as time goes by, usually in 2-3 months. While if the shunt persists half a year later, another interventional procedure should be considered one year after the first.
- 2) Hemolysis: Mechanic damage of red blood cell when insufficient occlusion occurs, that is attributed to improper device size or position, large residual shunt before occluder release and patent coagulation deficiency. If hemolysis happens, give some medicines to promote thrombogenicity, while monitoring hemoglobin or red cell count, renal function, and urine color. Some patients can get better with the treatment when delayed thrombosis gradually stops the abnormal shunt. However, if no sign of improvement show after medical therapy or renal function damage occurs, a surgical operation or another intervention should be attempted at once.
- 3) Arrhythmia: If severe arrhythmia occurs before the device released, the procedure should be stopped immediately. Retrieve the device and remove it out of the body. Then refer the patient to cardiac surgeon. If it happens after the procedure, drugs to diminish edema, protect myocardium or treat arrhythmia should be given. When necessary, temporary pacing lead should be advanced during the observation

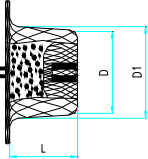
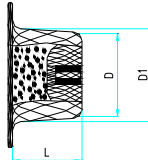
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period of a few days. If it persists and cannot be controlled by the drugs, it must be attempted to take the device out by surgery or/and implant a permanent pacemaker.

- 4) Device dislodgement: If it happens, the device must be taken out at once by either surgery or interventional method.

**6.3.4.9 Specifications of Cardi-O-Fix PDA Occluder:**

**Type and Specifications**

Occluder Drawing	Type		D (mm) Dia.	D1 (mm) Dia.	L (mm) Length	Recommended Sheath Size Fr. (mm)
	Double-End	Single-End				
	P <sup>1</sup> -0406	P <sup>2</sup> -0406	4	6	7	5 (2.0)
	P <sup>1</sup> -0608	P <sup>2</sup> -0608	6	8	7	6 (2.3)
	P <sup>1</sup> -0810	P <sup>2</sup> -0810	8	10	8	6 (2.3)
	P <sup>1</sup> -1012	P <sup>2</sup> -1012	10	12	8	7 (2.7)
	P <sup>1</sup> -1214	P <sup>2</sup> -1214	12	14	8	8 (3.0)
	P <sup>1</sup> -1416	P <sup>2</sup> -1416	14	16	8	8 (3.0)
	P <sup>1</sup> -1618	P <sup>2</sup> -1618	16	18	9	9-10 (3.3)
	P <sup>1</sup> -1820	P <sup>2</sup> -1820	18	20	9	9-10 (3.3)
	P <sup>1</sup> -2022	P <sup>2</sup> -2022	20	22	9	9-10 (3.3)
						

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### 6.3.5 Cardi-O-Fix PFO Occluder System

#### 6.3.5.1 Cardi-O-Fix PFO Occluder:

The Starway Cardi-O-Fix PFO Occluder is a self-expandable, mushroom shaped implant device made from a Nitinol wire mesh. The two discs are linked together by a short connecting waist with a diameter of 4mm. In order to increase its closing ability, the discs and the waist are filled with polyester fabric. The polyester fabric is securely sewn to each disc by a polyester thread. Starway Cardi-O-Fix PFO Occluder has two types. Type one (AF<sup>1</sup>) has double ends (Fig.1) and type two (AF<sup>2</sup>) has single end only (Fig.2). Both types can be used for the intended patients.

**LA.** Left Atrium side

**RA.** Right Atrium side

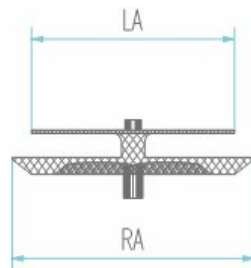


Fig. 1 PFO Occluder  
(AF<sup>1</sup> Type)

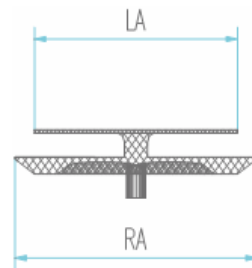


Fig. 2 PFO Occluder  
(AF<sup>2</sup> Type)

#### 6.3.5.2 Intended Use:

The Starway Cardi-O-Fix PFO Occluder is a percutaneous, transcatheter, permanent implant device intended for the occlusion of Patent Foramen Oval (PFO).

The Starway Cardi-O-Fix PFO Occluder and Cardi-O-Fix Delivery System are single use devices which are sterilized via ethylene oxide (EO).

#### 6.3.5.3 Indications:

Patients with clinical symptoms such as patent foramen ovale (PFO) with paradoxical cerebral embolism.

Patent Foramen Ovale is a defect in the atrial septum, the wall between the two upper chambers of the heart. The foramen ovale is a flap or tunnel shaped hole in the atrial septum during fetal development that allows blood to travel through the heart without going to the lungs. This small flap-like opening normally closes shortly after birth as the pressure from the baby's heart pushes the flap to the septal wall. If this opening does not close shortly after birth, a Patent Foramen Ovale (PFO) results.

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#### **6.3.5.4 Contraindications:**

- 1) Patients associated with other congenital cardiac anomalies which require cardiac surgery.
- 2) Patients with ostium primum atrial septal defect.

#### **6.3.5.5 General Exclusion Criteria:**

- 1) Sepsis ( local/generalized ).
- 2) History of repeated pulmonary infection.
- 3) Any type of serious infection < 1 month prior to procedure.
- 4) Malignancy where life expectancy is < 3 years.
- 5) Demonstrated intracardiac thrombi on echocardiography.
- 6) Inability to obtain informed consent.

#### **6.3.5.6 Cardi-O-Fix Delivery System:**

A 45 degree Cardi-O-Fix Delivery System is designed specifically to facilitate attachment, loading, delivery and deployment of the Cardi-O-Fix ASD and PFO Occluder and it is comprised of a delivery sheath, dilator, loader, hemostasis valve and delivery cable with plastic vise.

**The size of delivery system for PFO Occluder: 5F, 6F, 7F, 8F, 9F, 10F and 12F**

**The tip of the delivery sheath is: 45° .**

**Delivery Sheath with Hemostasis Valve:** used to deliver the occluder.

**Dilator:** used to prevent from penetration of tissue.

**Loader:** Used to introduce the occluder device into the delivery sheath.

**Delivery Cable:** The occluder device is screwed onto the distal tip of the delivery cable, which allows for placement (and if necessary, retrieval) of the device.

**Plastic Vise:** To facilitate directional control and serves as the “handle” for disconnecting (unscrewing) the delivery cable from the device.

(Fig. 1 Assembled Delivery System & Fig.2 Parts of the Delivery System)

**A. Delivery Sheath**

**B. Dilator**

**C. Hemostasis Valve**

**D. Loader**

**E. Delivery Cable with Plastic Vise**

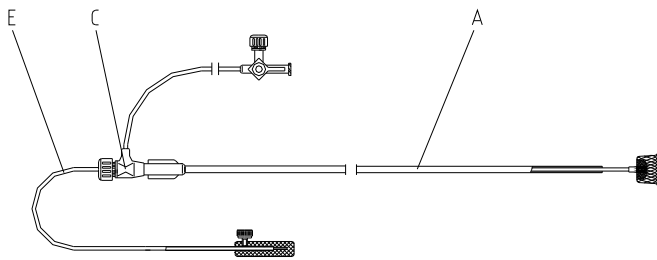


Fig. 1 Assembled Delivery System

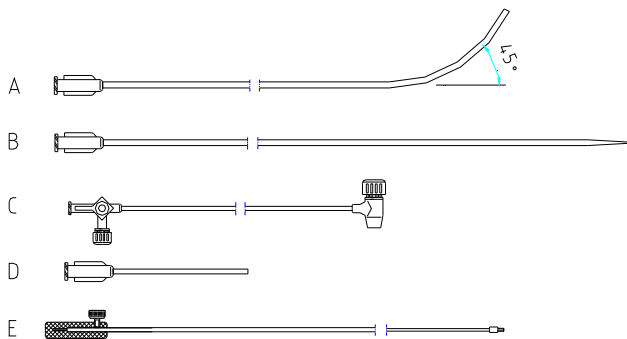


Fig. 2 Delivery System for ASD &amp; PFO Occluder

#### 6.3.5.7 Procedure:

- 1) A standard right heart catheterization is performed following puncture of femoral vein.
- 2) The right heart catheter is introduced to left atrium via the patent foramen oval, and to left upper pulmonary vein.
- 3) The stiff J tip guidewire is introduced to the left pulmonary vein through the right heart catheter, then the right heart catheter is removed together with vessel sheath. Meanwhile heparin is administered routinely via IV infusion route.
- 4) Before being advanced into the heart, the measure balloon is inflated with contrast medium to drive the air out, then deflated and kept in negative pressure by drawing the medium out. Balloon catheter is exchanged over the wire and positioned in the left atrium, inflated with contrast and pulled back across the defect under fluoroscopic and echocardiographic guidance. The size of the balloon just prior to its popping through the defect is the stretched diameter of the defect, where a slight deformity of the sizing balloon can be seen. The balloon catheter is removed, reinflated with the same amount of contrast, and pushed through holes

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on a sizing plate to determine the stretched diameter of the defect. Compare readings of the three different methods, and choose a proper device.

- 5) The delivery sheath is exchanged to left atrium over the wire. At this moment, pay more attention not to bring air into the body, otherwise air embolism in coronary arteries would happen.
- 6) The delivery cable is passed through the loader, and the occluder is screwed clockwise into the tip of the delivery cable. Screwed and unscrewed for 3-4 times, but not over-tightened when screwed on.
- 7) The device and the loader are immersed in saline solution as the device is pulled into the loader to remove the air. Flush via the side arm of the loader.
- 8) The loader is introduced into the delivery sheath, and without rotation the device is advanced into the left atrium.
- 9) With fluoroscopic and echocardiographic guidance, the sheath is retracted until the left atrial disc is opened in the middle of the left atrium. The sheath with the delivery cable in it is pulled back as one unit till the left atrial disc against the patent foramen oval (it can be felt and also detected by echocardiography). The sheath is retracted further with constant tension on the delivery sheath and cable, and the right atrial disc is deployed in the right atrium.
- 10) With echocardiographic observation, the delivery cable is pushed forward and pulled backward repeatedly with a proper tension, to confirm a stable position of the device. If misplacement occurs, the device can be retrieved into the delivery sheath and redeployed, or replaced by another device.
- 11) The device is released by turning the delivery cable counterclockwise using the plastic vise, as indicated by the arrow on the delivery cable.
- 12) Heparin is given during 3 days following the procedure, and an antiplatelet medicine (eg. Aspirin) for half a year.

#### **6.3.5.8 Complications & Solutions:**

There would be several complications during or after the procedure:

- 1) Air embolism in coronary arteries: It may happen if air is brought into the body due to improper manipulation, in that it can get reach to coronary arteries via left atrium-left ventricle-aorta route when patient kept in supine position. Symptoms and signs of acute myocardial infarction will be shown, which need immediate treatment such as sublingual nitroglycerin, oxygen, and intravenous vasodilators. If symptoms are relieved and electrocardiogram is returned to normal in a short time, the procedure can be continued. Otherwise stop the operation.
- 2) Thrombosis: Usually, it is caused by improper use of anticoagulants during or

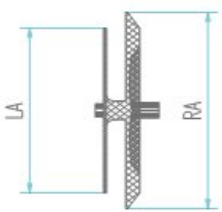
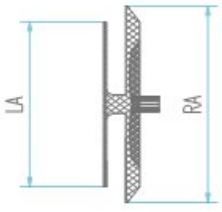
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after the procedure, and should be treated symptomatically in most cases. However, thromboembolism must be differentiated from intracranial hemorrhage, especially in senior or hypertensive patients.

- 3) Arrhythmia: If severe arrhythmia occurs before the device released, the procedure should be stopped immediately. Retrieve the device and remove it out of the body. Then refer the patient to cardiac surgeon. If it happens after the procedure, drugs to diminish edema, protect myocardium or treat arrhythmia should be given. When necessary, temporary pacing lead should be advanced during the observation period within a few days. If arrhythmia persists and cannot be controlled by the drugs, it must be attempted to take the device out by surgery or/and implant a permanent pacemaker.
- 4) Device dislodgement: If it happens, the device must be taken out by interventional method or surgery at once.

Cardiac tamponade: Usually caused by improper operation. It is a severe adverse event and may be life-threatening if in delayed awareness and treatment. The clinical symptoms and signs include: sudden cardiac pain (at the moment of rupture), dropping blood pressure, increased heart rate, disappeared pulsing of cardiac edge and enlarged heart shadow on x-ray. Blood volume in pericardial cavity can be assessed by echocardiography. If it happens, pericardial puncture must be performed immediately. However, it can be prevented if it is assured to introduce over the guidewire and manipulate tenderly. When it is misplaced, the device should be retracted, removed and redeployed.

**6.3.5.9 Specifications of Cardi-O-Fix PFO Occluder:**

<b>Type and Specifications</b>					
Occluder Drawing	Type		RA Disc Diameter (mm)	LA Disc Diameter (mm)	Minimum Recommended Sheath Size
	Double-End	Single-End			
 <p>Type AF<sup>1</sup></p>	AF <sup>1</sup> -1818	AF <sup>2</sup> -1818	18	18	8 French, 45 Curve.
	AF <sup>1</sup> -2518	AF <sup>2</sup> -2518	25	18	8 French, 45 Curve.
	AF <sup>1</sup> -3030	AF <sup>2</sup> -3030	30	30	8 French, 45 Curve.
	AF <sup>1</sup> -3525	AF <sup>2</sup> -3525	35	25	9 French, 45 Curve.
 <p>Type AF<sup>2</sup></p>					

### 6.3.6 Plug Occluder System

#### 6.3.6.1 Cardi-O-Fix Plug Occluder

The Starway Cardi-O-Fix Plug Occluder is a self-expandable, cylinder-shaped implant device made from a Nitinol wire mesh. In order to increase its closing ability, the discs and the waist are filled with polyester fabric. The polyester fabric is securely sewn to the cylinder-shaped part by a polyester thread. Starway Cardi-O-Fix Plug Occluder has two types. Type one (PL<sup>1</sup>) has double ends (Fig.1) and type two (PL<sup>2</sup>) has single end only (Fig.2). Both types can be used for the intended patients.

**D.** Diameter of the Device

**L.** Length of the Device

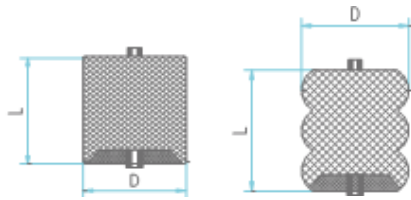


Fig. 1 Plug Occluder  
(PL<sup>1</sup> Type)

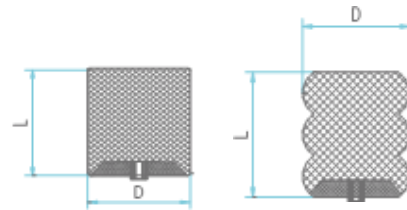


Fig. 2 Plug Occluder  
(PL<sup>2</sup> Type)

#### 6.3.6.2 Intended Use

The Starway Cardi-O-Fix Plug Occluder is a percutaneous, transcatheter, permanent implant device intended for the occlusion of abnormal blood vessels.

The Starway Cardi-O-Fix Plug Occluder and Cardi-O-Fix Delivery System are single use devices which are sterilized via ethylene oxide (EO).

#### 6.3.6.3 Indications:

The vascular plug may be used for a wide variety of occlusions of veins or arteries depending on the patient's diagnosis and treatment plan. Reducing or eliminating blood flow to an area of the body by blocking, or occluding, a blood vessel has become an accepted treatment option for a wide range of circulatory and internal organ diseases. Vascular plug can be used for a number of indications including patients with clinical symptoms of abnormal blood vessels, such as:

- Aortopulmonary collaterals
- Arteriovenous malformation

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- Surgical aortopulmonary shunts
- Anomalous venovenous connections
- Arteriovenous fistulas
- Peripheral vessels

**6.3.6.4 Contraindications:**

Patients abnormal blood vessels, but without any significant hemodynamic alteration.

**6.3.6.5 General Exclusion Criteria:**

- 1) Sepsis (local/generalized ).
- 2) History of repeated pulmonary infection.
- 3) Any type of serious infection < 1 month prior to procedure.
- 4) Malignancy where life expectancy is < 3 years.
- 5) Demonstrated intracardiac thrombi on echocardiography.
- 6) Inability to obtain informed consent.

**6.3.6.6 Cardi-O-Fix Delivery System**

Cardi-O-Fix Delivery System is designed specifically to facilitate attachment, loading, delivery and deployment of the Cardi-O-Fix ASD, VSD, PDA, PFO and Plug Occluders and it is comprised of a delivery sheath, dilator, loader, hemostasis valve and delivery cable with plastic vise. The Starway Cardi-O-Fix™ Plug Occluder and Cardi-O-Fix™ Delivery System are single use devices which are sterilized via ethylene oxide (EO).

The recommended sizes of Cardi-O-Fix Delivery System for Cardi-O-Fix Plug Occluder are 5F, 6F, 7F, 8F, 9F, 10 and 12F.

The tip of delivery sheath is 45° or 180° .

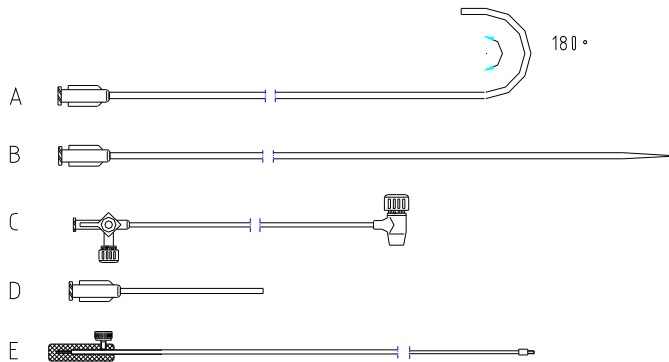


Fig. 1 Delivery System for VSD, PDA & Plug Occluder

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**6.3.6.7 Procedure:**

- 1) A standard right heart catheterization is performed following puncture of femoral artery and femoral vein.
- 2) A aortography is performed to demonstrate abnormal blood vessels by passing a pigtail catheter into the aorta. Their anatomy, sizes, amount, directions are assessed.
- 3) A right heart catheter is introduced with the exchange wire through the abnormal blood vessel to the part to be closure, then the right heart catheter is removed together with vessel sheath. The delivery sheath is introduced over the wire and positioned in part to be closure.
- 4) According to the angiogram of abnormal blood vessel, a device of 2-4mm bigger than its narrowest diameter is chosen for loading.
- 5) The delivery cable is passed through the loader, and the occluder is screwed clockwise into the tip of the delivery cable. Screwed and unscrewed for 3-4 times, but not over-tightened when screwed on.
- 6) The device and the loader are immersed in saline solution as the device is pulled into the loader to remove the air. Flush via the side arm of the loader.
- 7) The loader is introduced into the delivery sheath, and without rotation the occluder device is advanced into the blood vessel to be closed.
- 8) Aortography is performed once more to confirm a correct placement or detect a residual shunt.
- 9) If it is misplaced, the device can be retrieved into the delivery sheath and redeployed, or replaced by another device.
- 10) The device is released by turning the delivery cable counterclockwise using the plastic vise, as indicated by the arrow on the delivery cable.

**6.3.6.8 Complications & Solutions:**

There would be several complications during or after the procedure:

- 11) Air embolism in coronary arteries: It may happen if air is brought into the body due to improper manipulation, in that it can get reach to coronary arteries via left atrium-left ventricle-aorta route when patient kept in supine position. Symptoms

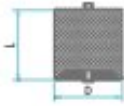

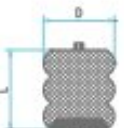
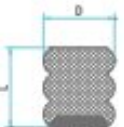
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and signs of acute myocardial infarction will be shown, which need immediate treatment such as sublingual nitroglycerin, oxygen, and intravenous vasodilators. If symptoms are relieved and electrocardiogram is returned to normal in a short time, the procedure can be continued. Otherwise stop the operation.

- 12) Thrombosis: Usually, it is caused by improper use of anticoagulants during or after the procedure, and should be treated symptomatically in most cases. However, thromboembolism must be differentiated from intracranial hemorrhage, especially in senior or hypertensive patients.
- 13) Arrhythmia: If severe arrhythmia occurs before the device released, the procedure should be stopped immediately. Retrieve the device and remove it out of the body. Then refer the patient to cardiac surgeon. If it happens after the procedure, drugs to diminish edema, protect myocardium or treat arrhythmia should be given. When necessary, temporary pacing lead should be advanced during the observation period within a few days. If arrhythmia persists and cannot be controlled by the drugs, it must be attempted to take the device out by surgery or/and implant a permanent pacemaker.
- 14) Device dislodgement: If it happens, the device must be taken out by interventional method or surgery at once.

Cardiac tamponade: Usually caused by improper operation. It is a severe adverse event and may be life-threatening if in delayed awareness and treatment. The clinical symptoms and signs include: sudden cardiac pain (at the moment of rupture), dropping blood pressure, increased heart rate, disappeared pulsing of cardiac edge and enlarged heart shadow on x-ray. Blood volume in pericardial cavity can be assessed by echocardiography. If it happens, pericardial puncture must be performed immediately. However, it can be prevented if it is assured to introduce over the guidewire and manipulate tenderly. When it is misplaced, the device should be retracted, removed and redeployed.

**6.3.6.9 Specifications of Cardi-O-Fix Plug Occluder:**

<b>Type and Specifications</b>					
<b>Occluder Drawing</b>	<b>Type</b>		<b>Diameter (mm)</b>	<b>Device Length (mm)</b>	<b>Minimum Sheath Requirements</b>
	<b>Double-End</b>	<b>Single-End</b>			
 Type PL <sup>1</sup>   Type PL <sup>2</sup>	PL <sup>1</sup> -0407	PL <sup>2</sup> -0407	4	7	5 French
	PL <sup>1</sup> -0607	PL <sup>2</sup> -0607	6	7	5 French
	PL <sup>1</sup> -0807	PL <sup>2</sup> -0807	8	7	5 French
	PL <sup>1</sup> -1007	PL <sup>2</sup> -1007	10	7	5 French
	PL <sup>1</sup> -1208	PL <sup>2</sup> -1208	12	8	5 French
	PL <sup>1</sup> -1408	PL <sup>2</sup> -1408	14	8	6 French
	PL <sup>1</sup> -1608	PL <sup>2</sup> -1608	16	8	6 French
 TYPE PLI <sup>1</sup>   Type PLI <sup>2</sup>	PLI <sup>1</sup> -0407	PLI <sup>2</sup> -0407	4	7	5 French
	PLI <sup>1</sup> -0607	PLI <sup>2</sup> -0607	6	7	5 French
	PLI <sup>1</sup> -0807	PLI <sup>2</sup> -0807	8	7	5 French
	PLI <sup>1</sup> -1007	PLI <sup>2</sup> -1007	10	7	5 French
	PLI <sup>1</sup> -1208	PLI <sup>2</sup> -1208	12	8	5 French
	PLI <sup>1</sup> -1408	PLI <sup>2</sup> -1408	14	8	6 French
	PLI <sup>1</sup> -1608	PLI <sup>2</sup> -1608	16	8	6 French

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### **6.3.5 Cardi-O-Fix Delivery System**

The Starway Cardi-O-Fix Delivery System consists of a delivery sheath, loader, dilator, hemostasis valve, delivery cable with plastic vise.

The delivery sheath, loader, dilator, hemostasis valve are made from polyethylene (HDPE), polytetrafluoroethylene (PTFE), polyamine and nylon. Delivery cable is made by 304/SS stainless steel.

The Cardi-O-Fix Delivery System was designed specifically to facilitate attachment, loading, delivery and deployment of the occluders to the defects, so there are separately Delivery Systems for ASD, PFO, VSD, PDA and Plug Occluders, the major difference of which are sizes of catheters and tip configuration of long sheath.

#### **6.3.5.1 Complication & Solution:**

The major complications of using the delivery system in transcatheter therapy of congenital heart diseases include: twisted or broken delivery sheath, premature detachment of the occluder from the delivery cable and unsuccessful release after correct placement.

##### **1) Twist and Rupture of Delivery Sheath:**

It is usually due to repeated use of the delivery sheath or non-guided introduction over the wire. So only one use of the delivery sheath and guided introduction over the wire during the procedure should be stressed. The procedure should be stopped immediately if twist of the delivery sheath happens. It must be removed and replaced with another new sheath. If the delivery sheath get broken, it should be removed using foreign body forceps.

##### **2) Premature Detachment or Unsuccessful Release:**

It is usually due to mismatch of screw and nut during manufacture of delivery sheath and occluder. Also, the occluder may be unstable or over-tightened when screwed into the tip of delivery cable. If premature detachment of occluder from delivery system happens, the dislodged occluder will become an intracardiac foreign body, so it must be removed at once by surgery or interventional method. If unsuccessful release of occluder occurs, it should be removed, unscrewed, rescrewed and reloaded.

##### **3) Mis-pacement:**

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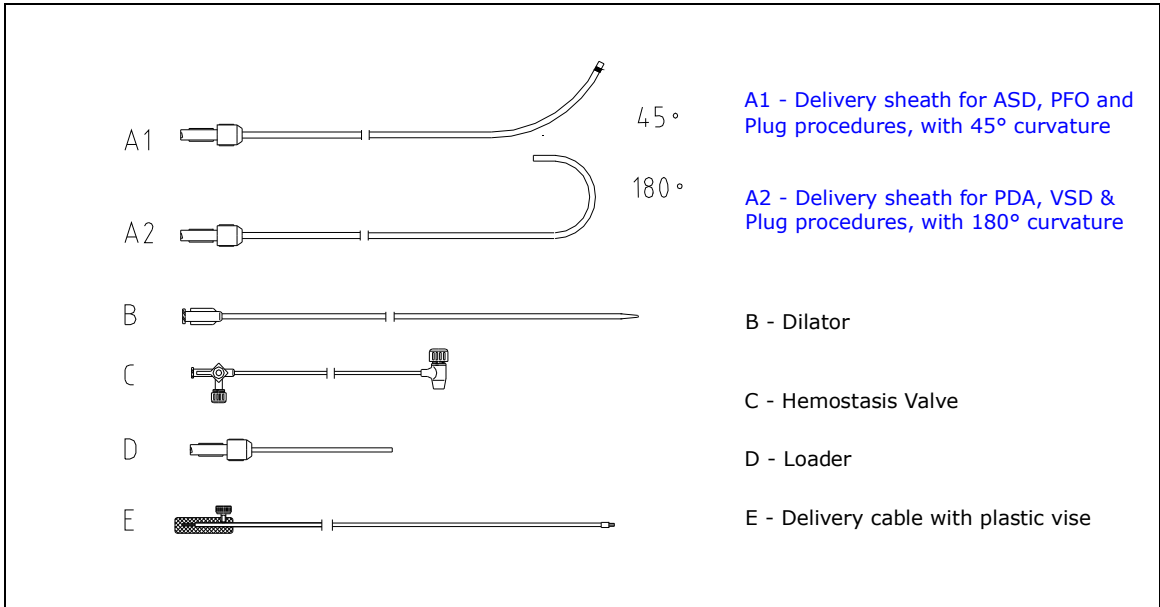
In case of mis-placement of the occluder, pull the device back into the sheath and repeat deployment. In the rare case of embolization, heparinize patient fully and transfer to operating theater for removal. The communication can be closed at the same time.

**6.3.5.2 Specifications of Cardi-O-Fix Delivery Systems:**

**Recommended Cardi-O-Fix Delivery Systems**

**Specifications and Application**

<b>Delivery System Component</b>	<b>Measurement</b>	<b>Application</b>		
		<b>ASD, PFO, Plug</b>	<b>PDA, Plug</b>	<b>VSD, Plug</b>
<b>Loader</b>	Effective Length, mm	100		
	OD, French	8F,9F,10F,12F,14F	6F,7F,8F,9F,10F	7F,8F,9F
	OD, mm	3.0,3.3,3.3,3.4,0.4,7	2.3,2.7,3.0,3.3,3.3	2.7,3.0,3.3
<b>Sheath with hemovalve (radiodetectable)</b>	Effective Length, mm	850		
	Angle, degree	45°		180°
	ID, French	8F,9F,10F,12F,14F	6F,7F,8F,9F,10F	7F,8F,9F,12F
	ID, mm	3.0,3.3,3.3,3.4,0.4,7	2.3,2.7,3.0,3.3,3.3	2.7,3.0,3.3,4.0
<b>Dilator (radiodetectable)</b>	Effective Length, mm			
	OD, French	8F,9F,10F,12F,14F	6F,7F,8F,9F,10F	7F,8F,9F,12F
	OD, mm	3.0,3.3,3.3,3.4,0.4,7	2.3,2.7,3.0,3.3,3.3	2.7,3.0,3.3,4.0
<b>Delivery Cable with vise</b>	Effective Length, mm	1000		
	Diameter, mm	2		



**6.3.6 Warnings**

- 1) Patients allergic to nickel may suffer from an allergic reaction to the device.
- 2) Starway Occluder System should only be used by those physicians trained in transcatheter defect closure techniques.
- 3) Physicians must be prepared to deal with urgent situations which require removal of embolized devices that result in critical hemodynamic compromise. This includes the availability of an on-site surgeon.
- 4) Embolized devices must be removed. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within a sheath.
- 5) Starway implants should only be performed at hospitals where cardiovascular surgery can be urgently performed.
- 6) During 2 years after the procedure, patients should avoid getting close to magnetic field or taking MRI examination.
- 7) During 2-3 months after the procedure, patients should avoid going in for competitive physical exercises or heavy labor work, as well as getting cold or fever. Severe cough or persistent hiccup also needs immediate control.
- 8) Half a year after the procedure, patients should have further consultation with a doctor.

**6.3.7 Precautions**

- 1) The Starway Occluder System are for single use only. Do not reuse or resterilize.

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- 2) The Starway Occluder System are MRI compatible. Do not use open or damaged packages.
- 3) Do not attempt to repair or reuse damaged product. If the package broken or products out of the EtO valid date, or mistake of labeling; please contact the manufacturer and get it replaced.
- 4) Accurate defect sizing is crucial and mandatory for the occluder device selection. The use of a compliant balloon catheter to determine defect size is recommended. Device selection should be equal to, or slightly larger than the balloon stretched diameter of the defect.
- 5) The patient was discharged on the day after the procedure on aspirin 3-5 mg/kg daily for 6 months.
- 6) Patients should be fully heparinized throughout the procedure with a minimum active clotting time (ACT) of 200 seconds prior to device insertion.
- 7) Transesophageal echocardiography (TEE) or similar imaging equipment (ie. intracardiac echocardiography) is recommended as an aid in placing the occluder device. If TEE is used, the patient's esophageal anatomy must be adequate for placement and manipulation of the TEE probe.
- 8) Patients should take appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at the discretion of the physician.
- 9) Patients should be treated with antiplatelet/anticoagulation therapy for 6 months post implant. The decision to continue antiplatelet/anticoagulation therapy beyond 6 months is at the discretion of the physician.

### **6.3.8 Transportation and Storage**

- 1) The packaged products should be kept in a well-ventilated environment with relative humidity less than 80% RH and without a corrosive gas. Do not open or damage packages.
- 2) We are not concerned with subjecting Nitinol to temperatures below -65 C. This is very common when utilizing air freight. The one thing to keep in mind is that properties will change as the temperature drops. A majority of the Nitinol materials will see cold temperatures but once they return to room temperature the properties will restore.
- 3) Transportation will comply with the sales contract. No heavy object on it.

### **6.3.9 Label Instruction**

The identification mark of Starway Occluder System is designed in accordance with principles in EN 1041:1998, EN980:2003 and Annex I of MDD 93/42/EEC.

#### **6.3.9.1 Identification in Minimum Package**

##### **a/ Product name and type:**

Cardi-O-Fix ASD Occluder

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Cardi-O-Fix VSD Occluder  
 Cardi-O-Fix PDA Occluder  
 Cardi-O-Fix PFO Occluder  
 Cardi-O-Fix Plug Occluder  
 Cardi-O-Fix Delivery System

**b/ Device size :** Occluder in diameter(mm), Delivery System in French (mm).

**c/ Executive standard:** CE

**d/ Sterilization method:** EO Sterilization

**e/ Disposable mark:** Single use only

**f/ Caution:** Read the Instructions for Use before use

**g/ Batch numbers:** Lot number

**h/ Expiry date:** 3 years

**i/ Manufactured date:**

**j/ Manufacturer:** Starway Medical Technology, Inc.

**k/EU Representative:** Yaotong S. L.

**l/ Quantity:** 1

**m/ Storage :** Store in a cool, dry place with humidity less than 80% RH.

**n/Transportation:** No heavy object on it.

### 6.3.9.2 Identification of Label Symbols:


a. Do not Reuse: 


b. Expiry Date: 

c. Batch Code: 

d. Date of Manufacture: 

e. Method of Sterilization Using Ethylene Oxide: 

f. Authorised Representative in the European Community: 

g. Manufacturer: 

h. Caution, Consult Accompanying Documents: 