

# STARWAY MEDICAL TECHNOLOGY, INC.

## Cardi-O-Fix Occluder System



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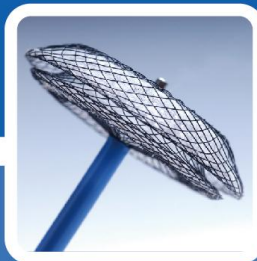
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## ASD Occluder System & PFO Occluder System

### ASD Occluder System

#### Intended Use:

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

#### ⦿ Indications:

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

#### ⦿ 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.

### PFO Occluder System

#### 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).

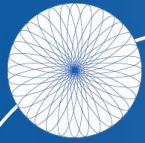
#### ⦿ Indications:

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.

#### ⦿ Contraindications:

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



Occluder Drawing	Model Number	Waist Diameter D (mm)	Waist Length L (mm)	Minimum Recommended Sheath Size (Fr.)
<p><b>ASD Occluder</b></p>	A-04	4	3	6~7
	A-06	6	3	6~7
	A-08	8	3	6~7
	A-09	9	3	7
	A-10	10	3	7
	A-11	11	4	7
	A-12	12	4	7
	A-13	13	4	7
	A-14	14	4	7
	A-15	15	4	7
	A-16	16	4	7
	A-17	17	4	7
	A-18	18	4	8
	A-19	19	4	8
	A-20	20	4	8
	A-21	21	4	8
	A-22	22	4	8
	A-23	23	4	9~10
	A-24	24	4	9~10
	A-25	25	4	9~10
	A-26	26	4	9~10
A-27	27	4	9~10	
A-28	28	4	9~10	
A-29	29	4	12	
A-30	30	4	12	
A-32	32	4	12	
A-34	34	4	12	
A-36	36	4	12	
A-38	38	4	14	
A-40	40	4	14	
<p><b>PFO Occluder</b></p>	Model Number	RA Disc Diameter (mm)	LA Disc Diameter (mm)	Minimum Recommended Sheath Size (Fr.)
	AF-1818	18	18	8
	AF-2518	25	18	8
	AF-3030	30	30	8
	AF-3525	35	25	9