

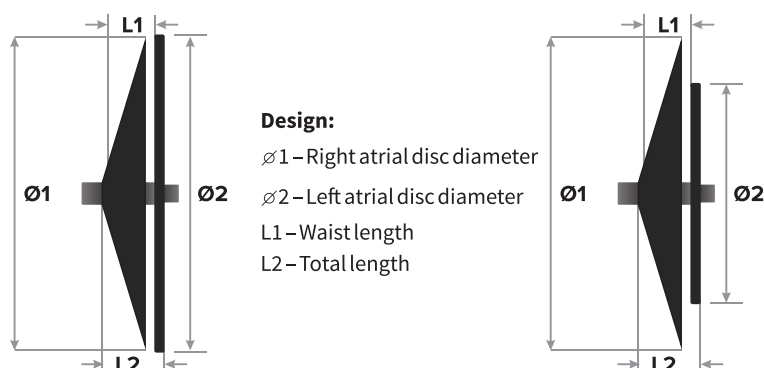


PFO Occluder

TECHNICAL SPECIFICATIONS

Product Description

- The Cocoon PFO Occluder is a self-expandable, double disc device made from a Nitinol wire mesh. It is coated with a thin layer of Platinum.
- The two discs are linked together by a short connecting waist allowing free motion of each disc.
- The discs and the waist are filled with polypropylene fabric to increase its closing ability. The polypropylene fabric is securely sewn to each disc by a polyester thread.



Indication

- The Cocoon PFO Occluder is intended for the occlusion of normal and aneurysm type patent foramen ovales, in patients with a history of stroke or transient ischemic attack, as diagnosed by echocardiography with right-to-left shunting during Valsalva maneuver.

Technical Specifications

Wire mesh material	Nitinol
Coating	Platinum
Fabric material	Polypropylene
Size matrix	18/18 mm, 25/18 mm, 25/25 mm, 30/25 mm, 30/30 mm, 35/25 mm
MRI compatible	Yes

Sizing Recommendations

Distance from defect to aortic root or superior vena cava (consider shortest distance)	Suggested Cocoon patent foramen ovale device size
Less than 9 mm	Do not implant
Between 9 and 12.4 mm	CPF18
Between 12.5 and 14.9 mm	CPF25
	CPF2525
Between 15 and 17.4 mm	CPF3025
	CPF30
More or equal to 17.5 mm	CPF35

Consider shortest distance from defect to aortic root or distance from defect to superior vena cava orifice (mm)

Catalog number	Right atrial disc diameter (mm) (Ø1)	Left atrial disc diameter (mm) (Ø2)	Waist length (mm) (L1)	Total length (mm) (L2)	Sheath size (F)
CPF18	18	18	3	5	8
CPF25	25	18	3	5	8
CPF2525	25	25	3	5	8
CPF3025	30	25	3	5	8
CPF30	30	30	3	5	8
CPF35	35	25	3	5	9



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Usable length of compatible accessories (cm)

	8F	9F
Sheath	78	78
Dilator	83	83
Loader	10	12

Delivery cable

Catalog number	Profile	Length	Size
CDC6F	0.077"	117 cm	6F

Ordering Information

Catalog number	Sheath size (F)	Cocoon accessory set catalog number	Cocoon delivery cable catalog number
CPF18	8	CPF8F	CDC6F
CPF25	8	CPF8F	CDC6F
CPF2525	8	CPF8F	CDC6F
CPF3025	8	CPF8F	CDC6F
CPF30	8	CPF8F	CDC6F
CPF35	9	CPF9F	CDC6F

Usage Conditions

Single use product

Storage Conditions

Store in cool and dry place

Sterilization method

Ethylene oxide

CE certification

N.B.: 1434

EU representative

Obelis S.A.

Shelf life

36 Months

Disclaimer: Cocoon PFO Occluder is manufactured by Vascular Innovations Co. Ltd., Thailand, an SMT Group Company. Cocoon is a trademark of Vascular Innovations Co. Ltd. Specifications are subject to modification, revision, and improvement.

Caution: This product is intended for use by or under the direction of a physician. Please refer to the "Instructions for use" supplied with these devices for indications, contraindications, side effects, suggested procedure warnings and precautions. As part of our continuous product development policy, we reserve the right to change product specification without prior notification. Information contained herein is for distribution outside the USA & Japan. Check the regulatory status of the device before distribution in areas where CE is not the regulation in force.

Cocoon PFO Occluder is manufactured by Vascular Innovations Co., Ltd. Thailand, an SMT group company. Cocoon is a trademark of Vascular Innovations Co., Ltd. Thailand.

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