VASCULAR
INNOVATIONS

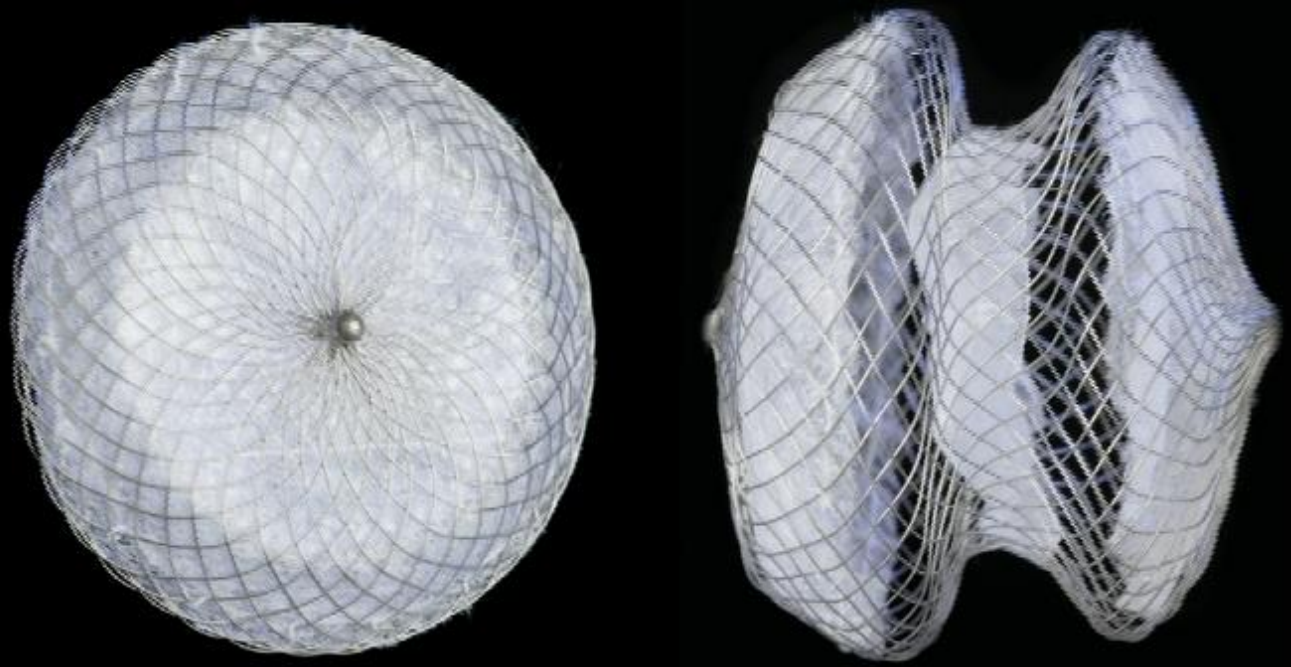
Cocoon

- Manufactured in United States
- Coated in Germany
- Packed and Steriled in Thailand

- Launched 2007
- CE approval 2010

Cocoon

Next Generation Devices



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Catheter closure of atrial septal defects using the Cocoon septal occluder: Preliminary results of a European multicenter study☆

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ABSTRACT

Despite its simplicity, device closure of atrial septal defects is still associated with rare but potentially lethal complications. In this prospective non-randomized multicenter study we investigated the safety and efficacy of the Cocoon septal occluder (CSO) for closure of atrial septal defects (ASDs) in 92 patients. Median age of the patients was 10.5 years (range 3–61 years) and median weight was 25 kg (range 13–65 kg). The device is an improved new generation double disc design made of Nitinol wire mesh that is coated with platinum using NanoFusion technology. The discs are connected by a waist with diameter ranging from 6 mm to 40 mm with 2 mm increments. All patients completed a 3-month follow-up. Mean ASD diameter was 21 ± 7 mm (range 10–35 mm), while the mean device diameter was 24 ± 8 mm (range 14–40 mm). The CSO was permanently implanted in all 92 patients. Complete echocardiographic closure of the defect immediately after the procedure or at the one month follow-up, was observed in all 92 patients (100%). No device-related complications were observed during the procedure or at short-term follow-up (range 3–12 months). Our preliminary results indicate that CSO is a promising device for transcatheter closure of ASDs. Further studies are required to document its efficacy, safety and long-term results in a larger patient population.

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Self-Expanding Platinum-Coated Nitinol Devices for Transcatheter Closure of Atrial Septal Defect: Prevention of Nickel Release

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ABSTRACT: Background. A variety of nitinol-containing devices for transcatheter closure of atrial septal defects (ASD) has been widely used. However, there is concern about the release of nickel after nitinol device implantation. In this study, a platinum-coated nitinol device was braided from nanoplatinum-coated nitinol wires in order to prevent nickel release. The serum nickel levels before and after device implantation and the 1-year results were evaluated. **Methods.** Thirty-one patients, aged 4–59 years, and weighing 13.7–90.0 kg, underwent transcatheter closure. Blood samples for serum nickel levels were taken before, 1 day, 1 week, 1 month and 3 months after implantation. **Results.** Twenty-nine (93.6%) patients had a successful implantation. The mean ASD diameter was 19.7 ± 4.8 mm (range 10–30 mm). Procedure-related complications included transient brachial plexus injury in 1 patient, and transient dysrhythmia in 4 patients. All 29 patients had complete closure within 1 month after implantation. The mean serum nickel levels at baseline and at 1 day, 1 week, 1 month and 3 months after implantation were 0.65 ± 0.28, 0.63 ± 0.18, 0.67 ± 0.34, 0.55 ± 0.16, 0.52 ± 0.14 ng/ml, respectively. There was no significant difference in serum nickel levels before and after implantation. There were no device-related complications at 1-year follow up. **Conclusions.** Transcatheter ASD closure using a platinum-coated nitinol device can be performed safely and successfully with good outcomes. Nano-coating of platinum on nitinol wires can prevent nickel release following device implantation.

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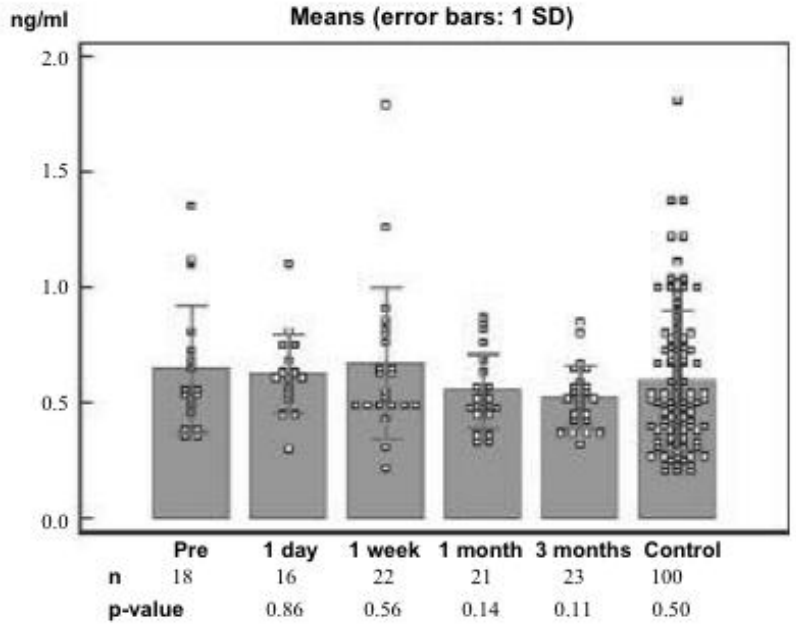

Figure 4. *Serum nickel levels at pre-and post-implantation. (n = number of cases in each group; p-value = the p-value as compared to the mean level at baseline).*

Features

- Nanofusion Platinum-coated Nitinol

- Platinum is superior bio-compatible, non-corrosive, non-allergic
- Platinum coating prevents nickel release into the blood
- Plantinum enhance the radio opacity of device
- Very smooth surface minimize the risk of adjacent cardiac structures
- Safe & Flexible
- MRI compatible

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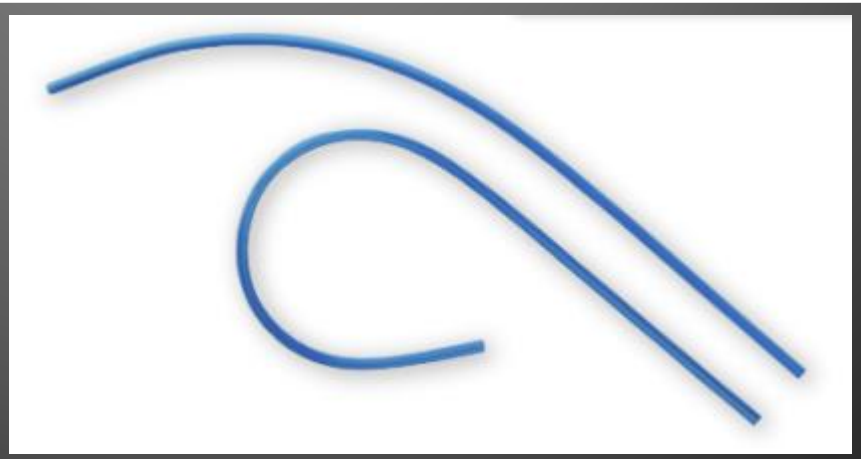
Features

- Ceramic-coated Delivery

- Ceramic is bio-compatible, light, non-allergic, non-scratched



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Features

- Sizing balloon

- Measure markers are out of balloon
- Easy to calibrate

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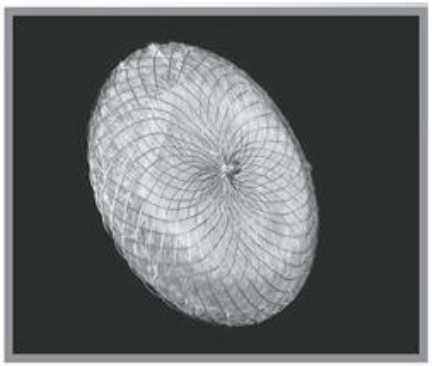
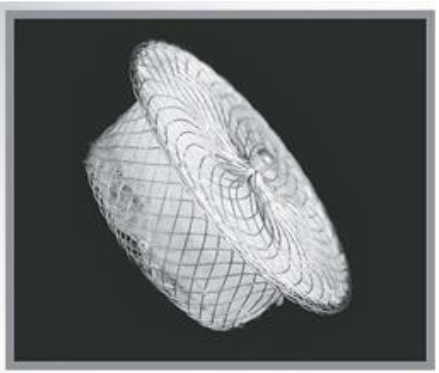
Portfolio



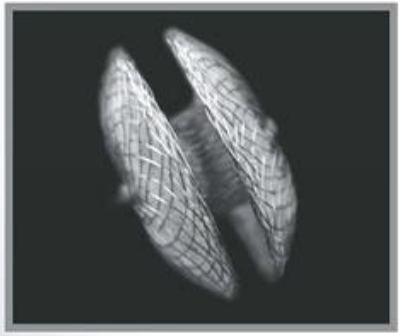
Septal Occluder

A self-expandable, double disk device used in transcatheter atrial septal defect closure



Duct Occluder

A percutaneous transcatheter occlusion device used in closure of patent ductus arteriosus



VSD Occluder

A percutaneous transcatheter ventricular septal defect closure device intended for the occlusion of hemodynamically signficant ventricular septal defects.

PFO Occluder

A percutaneous, transcatheter closure device intended for the occlusion of all types of PFOs in patients with a history of stroke or transient ischemic attacks.

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ASD

Catalog Number	Device size (=stretched ASD)	LA Disc Diameter	Width of connecting waist	RA Disc Diameter	Recommended Sheath size
C0A08	8 mm	20 mm	3 mm	18 mm	6-7 French
C0A10	10 mm	22 mm	3 mm	20 mm	6-7 French
C0A12	12 mm	26 mm	4 mm	22 mm	8-9 French
C0A14	14 mm	28 mm	4 mm	24 mm	8-9 French
C0A16	16 mm	30 mm	4 mm	26 mm	8-9 French
C0A18	18 mm	32 mm	4 mm	28 mm	10-12 French
C0A20	20 mm	34 mm	4 mm	30 mm	10-12 French
C0A22	22 mm	36 mm	4 mm	32 mm	10-12 French
C0A24	24 mm	38 mm	4 mm	34 mm	10-12 French
C0A26	26 mm	40 mm	4 mm	36 mm	10-12 French
C0A28	28 mm	42 mm	4 mm	38 mm	10-12 French
C0A30	30 mm	44 mm	4 mm	40 mm	12-14 French
C0A32	32 mm	46 mm	4 mm	42 mm	12-14 French
C0A34	34 mm	50 mm	4 mm	42 mm	12-14 French
C0A36	36 mm	52 mm	4 mm	46 mm	12-14 French
C0A38	38 mm	54 mm	4 mm	48 mm	12-14 French
C0A40	40 mm	56 mm	4 mm	50 mm	12-14 French

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PDA

Catalog Number	Device Diameter at Pulmonary Artery	Device Diameter at Desending Aorta	Retention Diameter	Device Length	Recommended Sheath size
COP0406	4 mm	6 mm	10 mm	7 mm	6-7 French
COP0608	6 mm	8 mm	12 mm	7 mm	6-7 French
COP0810	8 mm	10 mm	16 mm	8 mm	7-8 French
COP1012	10 mm	12 mm	18 mm	8 mm	7-8 French
COP1214	12 mm	14 mm	20 mm	8 mm	9-10 French
COP1216	14 mm	16 mm	22 mm	8 mm	9-10 French
COP1618	16 mm	18 mm	24 mm	8 mm	9-10 French
COP1820	18 mm	20 mm	26 mm	8 mm	9-10 French

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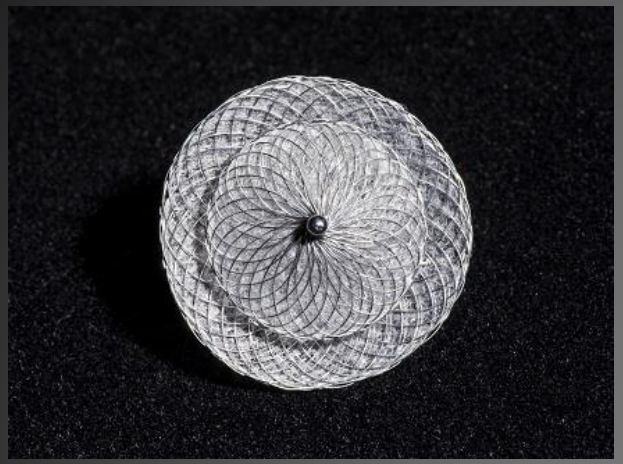
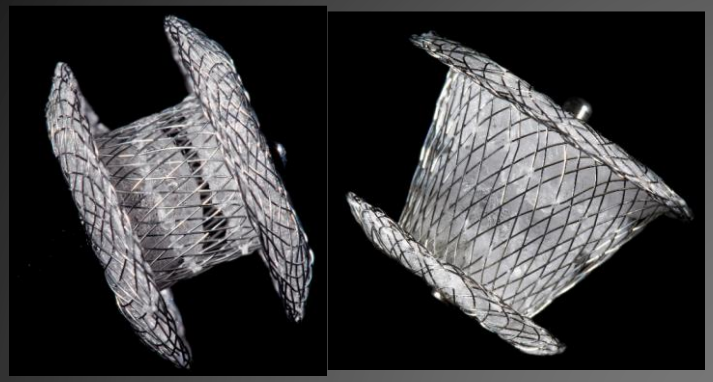
PFO



Catalogue Number	Right Atrial Disc Diameter	Left Atrial Disc Diameter	Recommended Accessory Set	Recommended Delivery Cable
CPF18	18 mm	18 mm	CPF8F	CDC6F
CPF25	25mm	18mm	CPF8F	CDC6F
CPF30	30mm	30mm	CPF8F	CDC6F
CPF35	35 mm	25 mm	CPF9F	CDC6F

VSD



Symmetric						
Device Dimensions					Recommendations	
Catalog Number	LV Disc Diameter (ø1)	RV Disc Diameter (ø2)	Waist Diameter (ø3)	Device Length (L)	For VSD size	Accessory Catalog Number
COV0404	12 mm	12 mm	3.5 mm	4 mm	3 mm	COV6F
COV0604	12 mm	12 mm	5.5 mm	4 mm	3.1 to 5 mm	COV6F
COV0804	14 mm	14 mm	7.5 mm	4 mm	5.1 to 7 mm	COV6F
COV1004	16 mm	16 mm	9.5 mm	4 mm	7.1 to 9 mm	COV7F
COV1204	18 mm	18 mm	11.5 mm	4 mm	9.1 to 11 mm	COV7F
COV0407	12 mm	12 mm	4 mm	7 mm	2 mm	COV6F
COV0607	12 mm	12 mm	6 mm	7 mm	2.1 to 4 mm	COV6F
COV0807	14 mm	14 mm	8 mm	7 mm	4.1 to 6 mm	COV6F
COV1007	16 mm	16 mm	10 mm	7 mm	6.1 to 8 mm	COV7F
COV1207	18 mm	18 mm	12 mm	7 mm	8.1 to 10 mm	COV7F
COV0410	12 mm	12 mm	4 mm	10 mm	2 mm	COV6F
COV0610	12 mm	12 mm	6 mm	10 mm	2.1 to 4 mm	COV6F
COV0810	14 mm	14 mm	8 mm	10 mm	4.1 to 6 mm	COV6F
COV1010	16 mm	16 mm	10 mm	10 mm	6.1 to 8 mm	COV7F
COV1210	18 mm	18 mm	12 mm	10 mm	8.1 to 10 mm	COV7F

Asymmetric						
Device Dimensions						Recommendations
Catalog Number	LV Disc Diameter (ø1)	RV Disc Diameter (ø2)	LV Waist Diameter (ø3)	RV Waist Diameter (ø4)	Device Length (L)	Accessory Catalog Number
COVA0604	12 mm	10 mm	6 mm	4 mm	10 mm	COV6F
COVA0806	14 mm	12 mm	8 mm	6 mm	10 mm	COV6F
COVA1006	16 mm	12 mm	10 mm	6 mm	10 mm	COV6F
COVA1208	18 mm	14 mm	12 mm	8 mm	10 mm	COV7F
COVA1408	20 mm	14 mm	14 mm	8 mm	10 mm	COV7F
COVA0604-07	12 mm	10 mm	6 mm	4 mm	7 mm	COV6F
COVA0806-07	14 mm	12 mm	8 mm	6 mm	7 mm	COV6F
COVA1006-07	16 mm	12 mm	10 mm	6 mm	7 mm	COV6F
COVA1208-07	18 mm	14 mm	12 mm	8 mm	7 mm	COV7F
COVA1408-07	20 mm	14 mm	14 mm	8 mm	7 mm	COV7F

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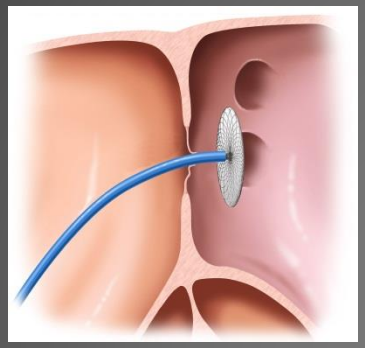

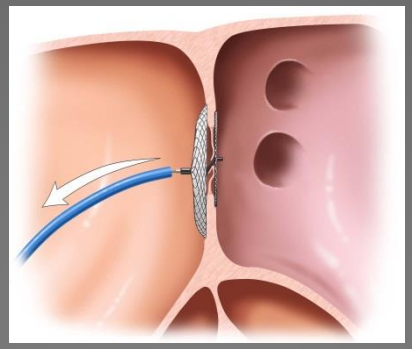

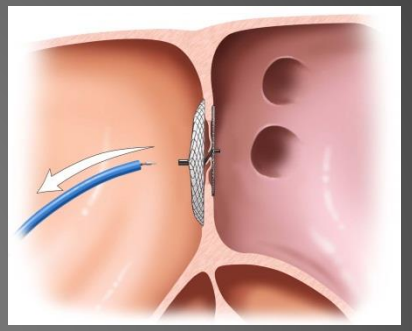

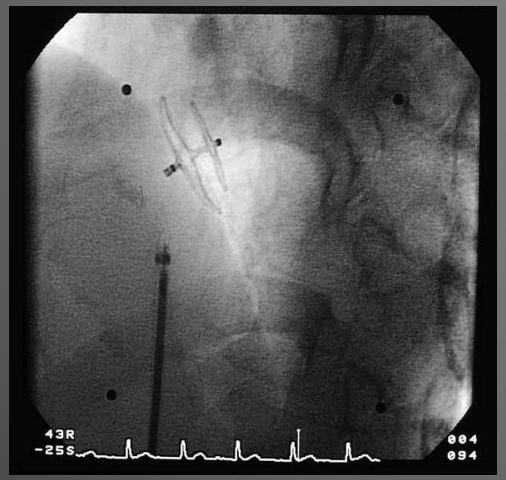

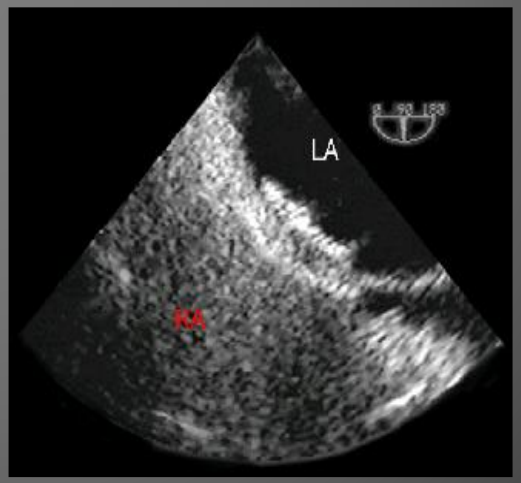

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