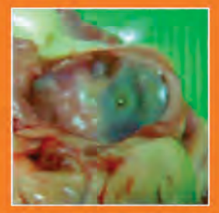
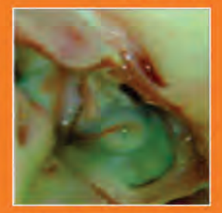
Cocoon

Septal Occluder
No Compromise

Preclinical studies**



Neoendothelialization on the left atrial surface of the device at 36 days after implantation

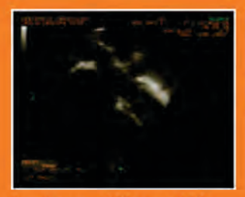


Neoendothelialization on the left atrial surface of the device at 42 days after implantation

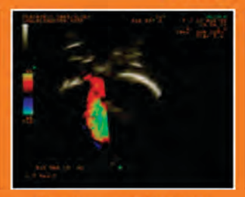
Neoendothelialization on the right atrial surface of the device at 36 days after implantation

Neoendothelialization on the right atrial surface of the device at 42 days after implantation

Clinical case**



Pre-closure - ASD size of 26 mm



Pre-closure - left to right shunt by colour doppler

Four chamber view showing complete ASD closure - 180 days after Cocoon device implantation

Parasternal short axis view showing complete ASD closure - 180 days after Cocoon device implantation

Ordering information

Product code	Sheath (F)	Cocoon accessory set catalog number	Cocoon delivery cable catalog number
COA08	6-7	COA6F / COA7F	CDC6F
COA10	6-7	COA6F / COA7F	CDC6F
COA12	8-9	COA8F / COA9F	CDC6F
COA14	8-9	COA8F / COA9F	CDC6F
COA16	8-9	COA8F / COA9F	CDC6F
COA18	10-12	COA10F / COA12F	CDC6F
COA20	10-12	COA10F / COA12F	CDC6F
COA22	10-12	COA10F / COA12F	CDC6F
COA24	10-12	COA10F / COA12F	CDC6F
COA26	10-12	COA10F / COA12F	CDC6F
COA28	10-12	COA10F / COA12F	CDC6F
COA30	12-14	COA12F / COA14F	CDC6F
COA32	12-14	COA12F / COA14F	CDC6F
COA34	12-14	COA12F / COA14F	CDC6F
COA36	12-14	COA12F / COA14F	CDC6F
COA38	12-14	COA12F / COA14F	CDC6F
COA40	12-14	COA12F / COA14F	CDC6F
COA42**	14	COA14F	CDC6F

ASD : Atrial Septal Defect
1. Hellenic J Cardiol. 2021 May-Jun;62(3):206-211.
2. Medicina. 2019 Mar;98(10).
3. Int J Cardiol. 2014 Dec 15;177(2):418-22.
4. Catheter Cardiovasc Interv. 2015 Sep 1;86(3).

*Data on SMT file. R & D tests performed using 26 mm Septal Occluders for both devices. The test results are an average of the test performed three times. **Not available for use in CE mark required countries. †Recapture and redeployment is possible only if delivery cable is securely connected to the disc.

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

Cocoon range of occluders are currently not approved by USFDA and are not available for sale in USA.

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'Sahajanand Estate', Wakharia Wadi, Near Dabholi Char Rasta, Ved Road, Surat 395004, Gujarat, INDIA Tel.: +91 261 6112800 Fax: +91 261 6112801
• CIN: U33119GJ2001PLC040121 • www.smtpl.com

COA/BRO/EN01 Rev.02

Cocoon CE 1434

Septal Occluder

No Compromise

SMT | VASCULAR INNOVATIONS

Cocoon

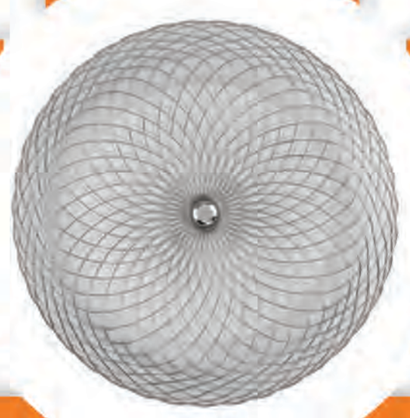
CE 1434

Septal Occluder

No Compromise

Optimal sealing of defects

Flexibility (disc level)



Designed to minimize nickel leaching Platinum coating

Softness to protect

Conformability (disc level)

Cocoon

Technical specifications

Product code	Device size Ø3 (mm)	Left atrial disc diameter Ø1 (mm)	Waist length L (mm)	Right atrial disc diameter Ø2 (mm)	Sheath (F)
COA08	8	20	3	18	6-7
COA10	10	22	3	20	6-7
COA12	12	26	4	22	8-9
COA14	14	28	4	24	8-9
COA16	16	30	4	26	8-9
COA18	18	32	4	28	10-12
COA20	20	34	4	30	10-12
COA22	22	36	4	32	10-12
COA24	24	38	4	34	10-12
COA26	26	40	4	36	10-12
COA28	28	42	4	38	10-12
COA30	30	44	4	40	12-14
COA32	32	46	4	42	12-14
COA34	34	50	4	44	12-14
COA36	36	52	4	46	12-14
COA38	38	54	4	48	12-14
COA40	40	56	4	50	12-14
COA42**	42	58	4	52	14

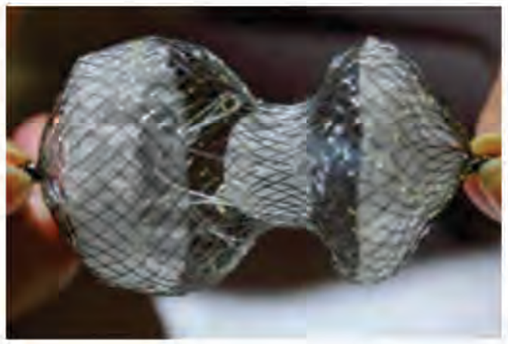
Usable length of compatible accessories (cm)

	6F	7F	8F	9F	10F	12F	14F
Sheath	60	60	78	78	78	78	78
Dilator	66	66	84	84	84	84	84
Loader	9	9	9	11	11	13	13

Delivery cable

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

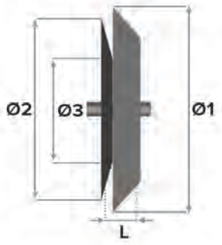
Optimal sealing of defects



The waist of Cocoon Septal Occluder has **adequate sealing strength** at the disc level: Up to **100% immediate closure** rates[1,2]

Device Description

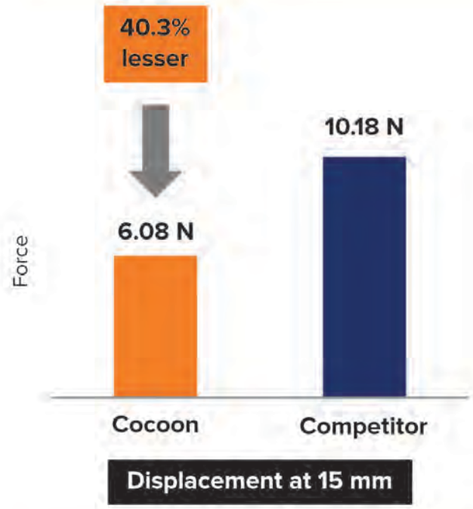
- **Self-expanding, self-centering double disc device with unique platinum coating**
- **Discs are filled with polypropylene fabric which assists thrombogenicity**
- **Ability to recapture and redeploy#**
- **0% erosion up to 43 months of follow-up in more than 4000 patients[1]**
- **95% to 100% device success rate from early European experience[3,4]**



Design:
Left atrial disc diameter (Ø1)
Device size (Ø3)
Right atrial disc diameter (Ø2)
Waist length (L)

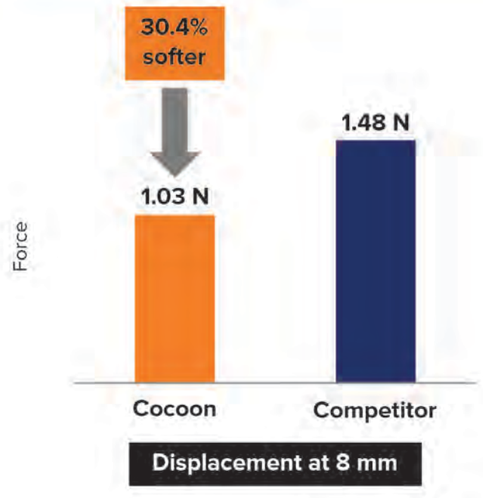
Cocoon
Septal Occluder
No Compromise

Flexibility at the disc level*



Cocoon Septal Occluder requires **40.3% less force** compared to competitor for displacement at 15 mm indicating **higher flexibility of the discs**

Softness to protect*



Cocoon Septal Occluder requires **30.4% less force** compared to competitor for displacement at 8 mm indicating **higher softness of the discs**

Conformability at the discs

Right disc

Better conformability of the right atrial disc with the Cocoon Septal Occluder

Cocoon Septal Occluder

Good conformability of the right atrial disc with the Competitor

Competitor

Cocoon Septal Occluder is **highly conformable**

Left disc

Left atrial disc shows no gap with Cocoon Septal Occluder

Cocoon Septal Occluder

Gap is evident, chances of edge penetration are higher with the Competitor

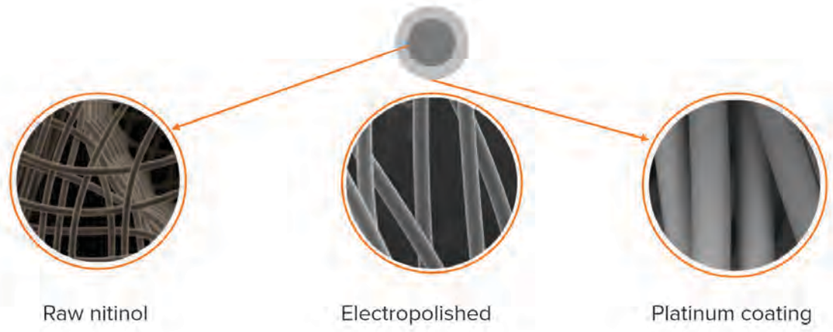
Competitor

Cocoon Septal Occluder is **highly conformable**

Cocoon
Septal Occluder
No Compromise

Designed to minimize nickel leaching
Platinum coating

- Ultrathin layer of **Platinum atoms** using **nanofusion technology** is coated on the Nitinol wire by a process called plasma deposition
- **Platinum** coating makes the Cocoon Occluders inert, biocompatible, non-corrosive and non-allergic and also enhances radiopacity



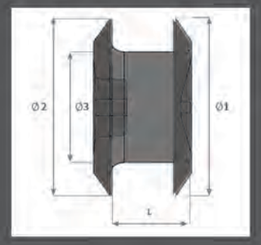
Platinum coating makes Cocoon Occluders:

- **Biocompatible**
- **Non-corrosive**
- **Non-allergic**
- **More radiopaque**

Cocoon

VSD Occluder
No Compromise

Technical specifications and ordering information



Design:
Ø1 - Left ventricular disc diameter
Ø2 - Right ventricular disc diameter
Ø3 - Waist diameter
L - Waist length

Thickness of the septum is considered for selecting the length of the device

Catalog number	Left ventricular disc diameter (Ø 1) (mm)	Right ventricular disc diameter (Ø 2) (mm)	Waist diameter (Ø 3) (mm)	Waist length (L) (mm)	Recommended for VSD size (mm)	Accessory catalog number
COV0404	10	10	3.25	4	3	COV6F / COVII6F
COV0604	12	12	5.25	4	3.1 to 5	COV6F / COVII6F
COV0804	14	14	7.25	4	5.1 to 7	COV6F / COVII6F
COV1004	16	16	9.25	4	7.1 to 9	COV7F / COVII7F
COV1204	18	18	11.25	4	9.1 to 11	COV7F / COVII7F
COV0407	10	10	4	7	2	COV6F / COVII6F
COV0607	12	12	6	7	2.1 to 4	COV6F / COVII6F
COV0807	14	14	8	7	4.1 to 6	COV6F / COVII6F
COV1007	16	16	10	7	6.1 to 8	COV7F / COVII7F
COV1207	18	18	12	7	8.1 to 10	COV7F / COVII7F
COV0410	10	10	4	10	2	COV6F / COVII6F
COV0610	12	12	6	10	2.1 to 4	COV6F / COVII6F
COV0810	14	14	8	10	4.1 to 6	COV6F / COVII6F
COV1010	16	16	10	10	6.1 to 8	COV7F / COVII7F
COV1210	18	18	12	10	8.1 to 10	COV7F / COVII7F

Usable lengths of accessories (cm)

	6F	7F
Sheath	83	83
Dilator	89	89
Loader	9	9

Delivery cable & sheath

Catalog number	Description	Diameter		Length
CDCV	Delivery cable	0.030"		140 cm
	Delivery cable sheath	ID	OD	125 cm
		0.055"	0.079"	

VSD : Ventricular Septal Defect
*Data on SMT file.
#Recapture and redeployment is possible only if delivery cable is securely connected to the disc.

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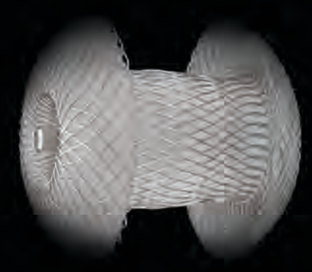
Cocoon CE 1434

VSD Occluder

No Compromise



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Cocoon

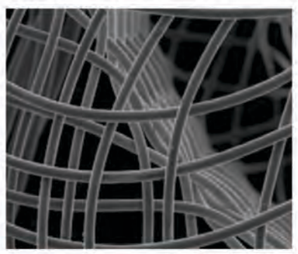
VSD Occluder
No Compromise

60,000+ implants globally

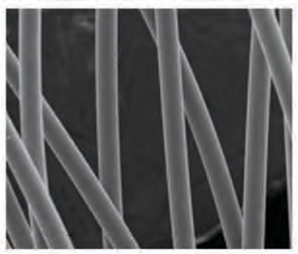
Platinum coating technology

Nitinol wire used in Cocoon occluders is coated with **Platinum** atoms using nano fusion technology by plasma deposition.

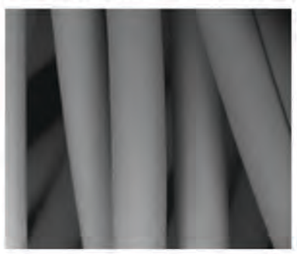
Raw Nitinol



Electropolished



Platinum coating



Platinum coating makes Cocoon occluders:

- **Biocompatible**
- **Non-corrosive**
- **Non-allergic**
- **More radiopaque**

Cocoon

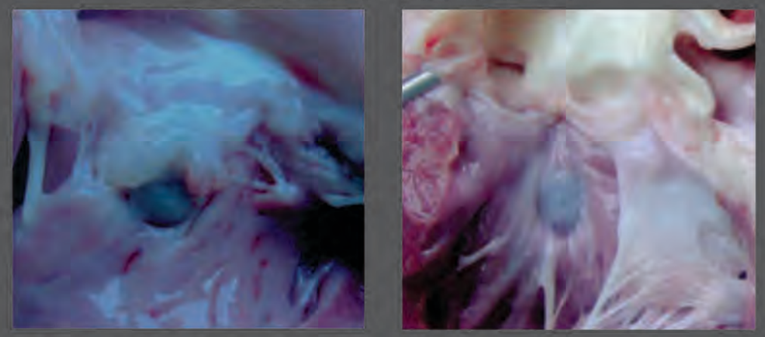
VSD Occluder
No Compromise

Key highlights

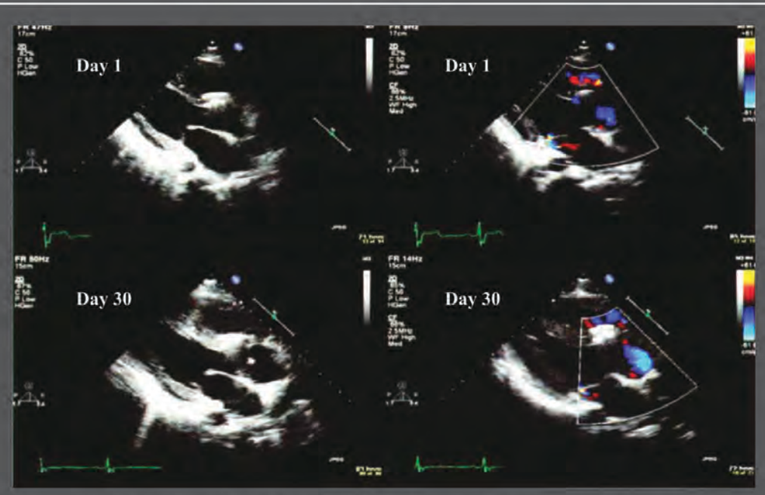
- Self-expanding, double disc device with unique Platinum coating
- 4, 7, & 10 mm waist lengths available
- Available in multiple lengths to match the types and locations of the ventricular septal defects to close membranous and muscular defects
- Discs are filled with polypropylene fabric which assists thrombogenicity
- Ability to recapture and redeploy#

Preclinical Studies*

Ventricular septal defect was created in swine models and subsequently implanted with a Cocoon VSD occluder.



Explants at 30 days show the device incorporated with tissues

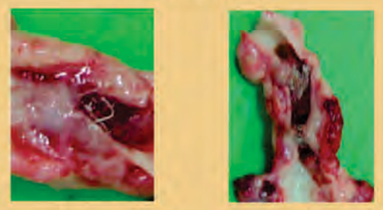


Echo images of the swine at day 1 and day 30 showing the complete closure of the defect

Cocoon

Duct Occluder
No Compromise

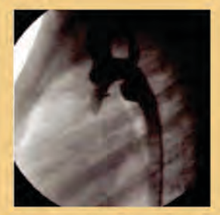
Preclinical studies*



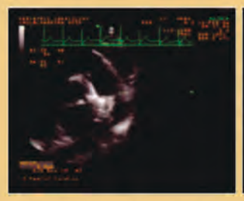
Seven days after implantation in
a pig PDA shows a well-encapsulated device

Clinical case*

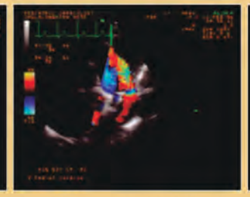
Aortogram in a 5-year-old girl
with PDA before
Cocoon device implantation



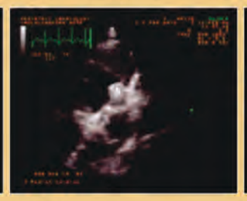
Aortogram in a 5-year-old girl
with PDA after
Cocoon device implantation



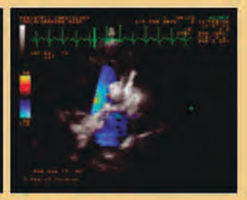
Echocardiographic study in
1-year-old boy
with PDA size 4.8 mm



Color Doppler showing flow from
descending aorta across
PDA to pulmonary artery



Echocardiographic study
2 hours after device
implantation showing
completely closed PDA



Color Doppler showing complete
closure, two hours after
device implantation

Ordering information

Product code	Sheath (F)	Cocoon accessory set catalog number	Cocoon delivery cable catalog number
COP0406	6-7	COP6F / COP7F	CDC5F / CDC6F
COP0608	6-7	COP6F / COP7F	CDC5F / CDC6F
COP0810	7-8	COP7F / COP8F	CDC6F
COP1012	7-8	COP7F / COP8F	CDC6F
COP1214	8-9	COP8F / COP9F	CDC6F
COP1416	8-9	COP8F / COP9F	CDC6F
COP1618	9	COP9F	CDC6F
COP1820	9	COP9F	CDC6F

COP/BRO/EN01 Rev.02

PDA: Patent Ductus Arteriosus
1. Medicine (Baltimore). 2019 Mar; 98(10): e14684.
*Data on SMT file.
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Cocoon CE 1434

Duct Occluder

No Compromise

VASCULAR INNOVATIONS

Cocoon

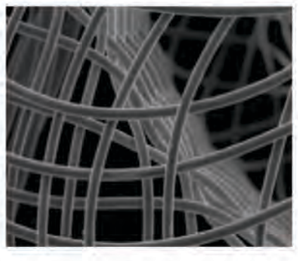
Duct Occluder
No Compromise

60,000+ implants globally

Platinum coating technology

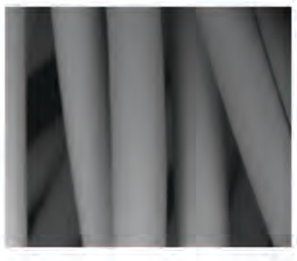
Nitinol wire used in Cocoon occluders is coated with **Platinum** atoms using nano fusion technology by plasma deposition.

Raw Nitinol



Electropolished

Platinum coating



Platinum coating makes Cocoon occluders:

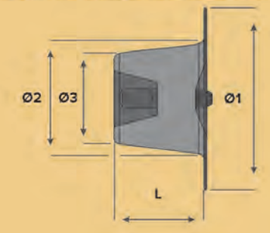
- **Biocompatible**
- **Non-corrosive**
- **Non-allergic**
- **More radiopaque**

Cocoon

Duct Occluder
No Compromise

Key highlights

- Hat-shaped design ensures secured implantation at aorta and minimizes risk of migration into pulmonary artery
- Unique Platinum coating
- Device is filled with polypropylene fabric to assist thrombogenicity
- Extended retention portion provides proper positioning of the device in the ductus arteriosus
- 100% occlusion rate at one month follow-up[1]
- Ability to recapture and redeploy[#]



Design:
Ø1 – Retention skirt diameter
Ø2 – Device diameter at descending aorta
Ø3 – Device diameter at pulmonary artery
L – Device length

Technical specifications

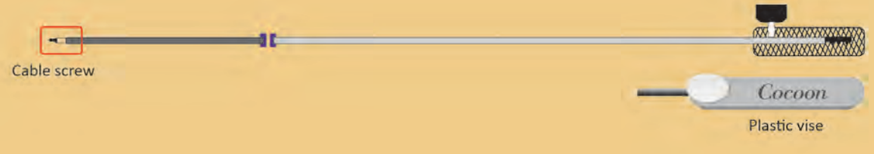
Product code	Retention skirt diameter (mm) Ø1	Device diameter at descending aorta (mm) Ø2	Device diameter at pulmonary artery (mm) Ø3	Device length (mm) L	Compatible sheath size (F)
COP0406	10	6	4	7	6-7
COP0608	12	8	6	7	6-7
COP0810	16	10	8	8	7-8
COP1012	18	12	10	8	7-8
COP1214	20	14	12	8	8-9
COP1416	22	16	14	8	8-9
COP1618	24	18	16	8	9
COP1820	26	20	18	8	9

Usable length (cm)

	6F	7F	8F	9F
Sheath	83	83	83	83
Dilator	89	89	89	89
Loader	10	10	10	12

Delivery cable

Catalog number	Profile	Length	Size
CDC5F	0.043”	125 cm	5F
CDC6F	0.077”	117 cm	6F



Cocoon

PFO Occluder
No Compromise

Ordering information

Catalog number	Right atrial disc diameter Ø (mm)	Left atrial disc diameter Ø (mm)	Cocoon accessory set catalog number	Cocoon delivery cable catalog number
CPF18	18	18	CPF8F	CDC6F
CPF25	25	18	CPF8F	CDC6F
CPF2525	25	25	CPF8F	CDC6F
CPF3025	30	25	CPF8F	CDC6F
CPF30	30	30	CPF8F	CDC6F
CPF35	35	25	CPF9F	CDC6F

*Data on SMT file. R & D tests performed using 18/18 mm PFO Occluders for both devices. The test results are an average of the test performed three times.
**SVC : Superior Vena Cava
***PFO : Patent Foramen Ovale
#TTE : Trans Thoracic Echocardiogram
$Recapture and redeployment is possible only if delivery cable is securely connected to the disc

Caution: This product is intended for use by or under the direction of a physician. Prior to use, 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 specifications 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 marking is not the regulation in force. Tests performed by and data on file at Sahajanand Medical Technologies Limited (SMT). Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Sahajanand Medical Technologies Limited.

Cocoon PFO Occluder is manufactured by Vascular Innovations Co., Ltd. Thailand, a SMT group company. Cocoon is a trademark of Vascular Innovations Co., Ltd. Amplatzer PFO Occluder & Amplatzer Talisman PFO Occluder are trademarks of Abbott Group of companies. Occlutech PFO Occluder is a trademark of Occlutech International AB. Cera PFO Occluder & Ceraflex PFO Occluder are trademarks of Lifetech Scientific.

Cocoon range of occluders are currently not approved by USFDA and are not available for sale in USA.

Competitor information collected on 20th June 2023 from following sources
Abbott PFO Occluder & Abbott Amplatzer Talisman PFO Occluder: https://manuals.sjm.com/Search-Form?re=North-America&cc=US&lr=EN&ct=professional&fam=861f73cb-e36b-4f08-a58f-4b11fa263dcf&cat=71260c89-7cb8-475d-950b-0262191e7526&seg=dd28d64f-7d0b-4660-aa2c-da987bb7894e&qry=Amplatzer%20PFO%20occluder&pp=10
Occlutech PFO Occluder: https://occlutech.com/files/brochure/Occlutech_PFO_Br.pdf
Cera PFO Occluder: http://www.lifetechmed.com/en/product/p1/cera/385.aspx
CeraFlex PFO Occluder: http://www.lifetechmed.com/en/product/p1/ceraflex%E2%84%A2%20occluders/360.aspx

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• CIN: U33119GJ2001PLC040121 • www.smtpl.com

CPF/BRO/EN01 Rev.03

Cocoon CE 1434

PFO Occluder

No Compromise

SMT | VASCULAR INNOVATIONS

Cocoon

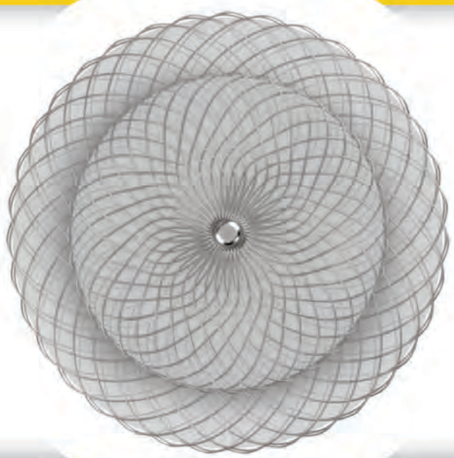
CE 1434

PFO Occluder

No Compromise

Extensive size matrix so that there is no compromise
6 SKUs
(vs 4 SKUs of the competitor)

5 out of 6 occluders
are
8F sheath compatible



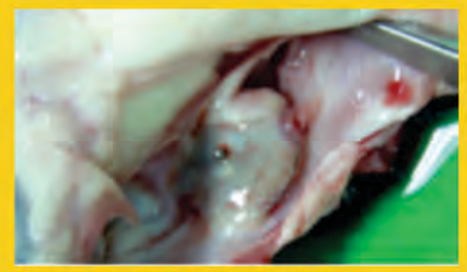
Softness to protect
2+ times softer at the rims

Designed to minimize nickel leaching
Platinum coating

Cocoon

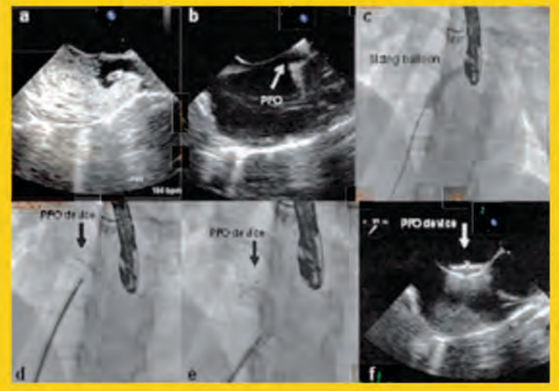
PFO Occluder
No Compromise

Preclinical studies*

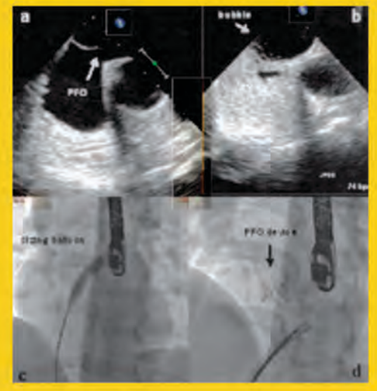


Images from preclinical studies of closure device depicting neoendothelialization.
Pigs were sacrificed at 36 and 42 days

Clinical case*



a. Small PFO detected during agitated saline injection b. Catheter crossing the PFO and demonstrating the tunnel c. Sizing balloon showing the PFO tunnel d. and e. PFO device (arrow) position f. PFO device after implantation as demonstrated by TTE[22]



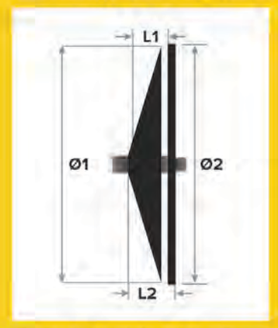
a. Demonstrating PFO by transesophageal echo-cardiography (arrow) b. Agitated saline injection filled in right atrium and left atrium (arrow) c. Sizing balloon used to evaluate PFO tunnel d. PFO device after detachment from cable

Cocoon

PFO Occluder
No Compromise

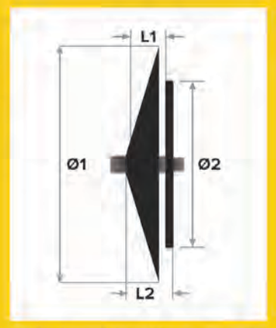
Device Description

- Self-expanding, self-centering double disc device with unique platinum coating
- Device is filled with polypropylene fabric to assist thrombogenicity
- Ability to recapture and redeploy#



CPF18, CPF2525, CPF30

Design:
Right atrial disc diameter (Ø1)
Left atrial disc diameter (Ø2)
Waist length (L1)
Total length (L2)



CPF25, CPF3025, CPF35

Technical specifications

Catalog number	Right atrial disc diameter (Ø1) (mm)	Left atrial disc diameter (Ø2) (mm)	Waist length (L1) (mm)	Total length (L2) (mm)	Sheath size (F)	Cable size (F)
CPF18	18	18	3	5	8	6
CPF25	25	18	3	5	8	6
CPF2525	25	25	3	5	8	6
CPF3025	30	25	3	5	8	6
CPF30	30	30	3	5	8	6
CPF35	35	25	3	5	9	6

Sizing recommendations

Distance from defect to aortic root or SVC** (consider shortest distance)	Suggested Cocoon PFO*** 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

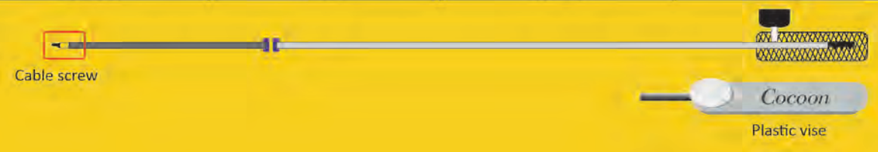
Consider shortest distance from defect to aortic root or distance from defect to superior vena cava orifice (mm)

Usable length (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



Cocoon

PFO Occluder
No Compromise

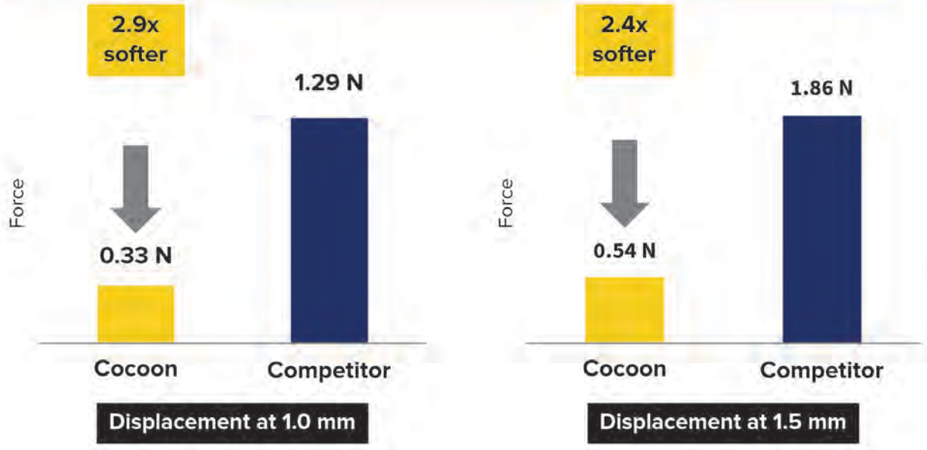
Extensive size matrix so that there is no compromise

6 SKUs (vs 4 SKUs of the competitor)

Cocoon PFO Occluder Total SKUs = 6		18/18	25/18		25/25	30/25		30/30	35/25	
Amplatzer PFO Occluder (Abbott) Total SKUs = 3		18/18	25/18						35/25	
Amplatzer Talisman PFO Occluder Total SKUs = 4		18/18	25/18			30/25			35/25	
Occlutech PFO Occluder Total SKUs = 4	18/16			25/23			30/27			35/31
Cera PFO Occluder (Lifetech) Total SKUs = 6		18/18	25/18		25/25	30/25		30/30	35/25	
CeraFlex PFO Occluder (Lifetech) Total SKUs = 6		18/18	25/18		25/25	30/25		30/30	35/25	

Softness to protect*

2+ times softer at the rims



5 out of 6 occluders are 8F sheath compatible

Occluder Brand	Sheath Compatibility (No. of SKUs)						
	7F	8F	9F	10F	11F	12F	14F
Cocoon PFO Occluder Total SKUs = 6		5	1				
Amplatzer PFO Occluder Total SKUs = 3		2	1				
Amplatzer Talisman PFO Occluder Total SKUs = 4		2	2				
Occlutech PFO Occluder Total SKUs = 4	1		2		1		
Cera PFO Occluder Total SKUs = 6		1	2	2			1
CeraFlex PFO Occluder Total SKUs = 6			1	2		2	1

5 out of 6 occluders are 8F sheath compatible

Cocoon PFO Occluder Total SKUs = 6		18/18 8F	25/18 8F		25/25 8F	30/25 8F		30/30 8F	35/25 9F	
Amplatzer PFO Occluder (Abbott) Total SKUs = 3		18/18 8F	25/18 8F						35/25 9F	
Amplatzer Talisman PFO Occluder Total SKUs = 4		18/18 8F	25/18 8F			30/25 9F			35/25 9F	
Occlutech PFO Occluder Total SKUs = 4	18/16 7F			25/23 9F			30/27 9F			35/31 11F
Cera PFO Occluder (Lifetech) Total SKUs = 6		18/18 8F	25/18 9F		25/25 9F	30/25 10F		30/30 10F	35/25 14F	
CeraFlex PFO Occluder (Lifetech) Total SKUs = 6		18/18 9F	25/18 10F		25/25 10F	30/25 12F		30/30 12F	35/25 14F	

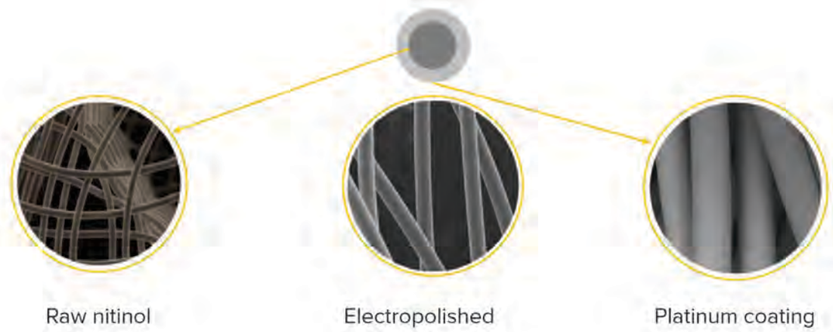
7F 8F 9F 10F 11F 12F 14F

Colours used to highlight sheath size are only for aesthetic purpose and do not represent actual sheath colour coding.

Cocoon
PFO Occluder
No Compromise

Designed to minimize nickel leaching Platinum coating

- Ultrathin layer of **Platinum atoms** using **nanofusion technology** is coated on the Nitinol wire by a process called plasma deposition
- **Platinum** coating makes the Cocoon Occluders inert, biocompatible, non-corrosive and non-allergic and also enhances radiopacity



Raw nitinol | Electropolished | Platinum coating

Platinum coating makes Cocoon Occluders:

- **Biocompatible**
- **Non-corrosive**
- **Non-allergic**
- **More radiopaque**