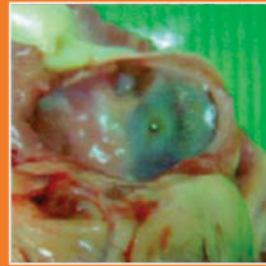




Septal Occluder No COMPROMISE

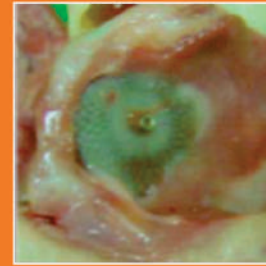
Preclinical studies**



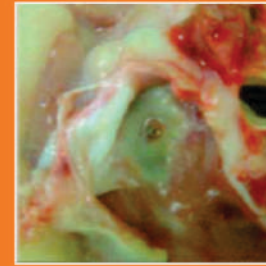
Neoendothelialization on the left atrial surface of the device at 36 days after implantation



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

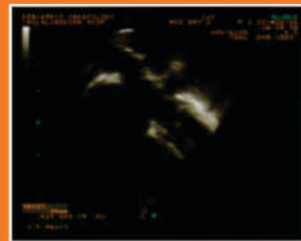


Neoendothelialization on the right atrial surface of the device at 36 days after implantation

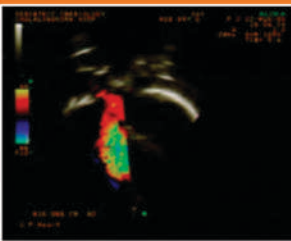


Neoendothelialization on the right atrial surface of the device at 42 days after implantation

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

COA/BRO/EN01 REV.01

ASD - Atrial Septal Defect

1. Hellenic J. Cardiol. 2021 May-Jun;62(3):206-211.
2. Medicine. 2019 Mar;98(6):10.
3. Int. J. Cardiol. 2014 Dec 15;177(2):418-22.
4. Catheter Cardiovasc Interv. 2015 Sep;106(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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Septal Occluder

No COMPROMISE





CE
1434

Septal Occluder No COMPROMISE

Optimal sealing
of defects

Flexibility
(disc level)



Designed to
minimize
nickel leaching
25 µ of Platinum
coating

Softness to
protect

Conformability
(disc level)



Septal Occluder No COMPROMISE

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

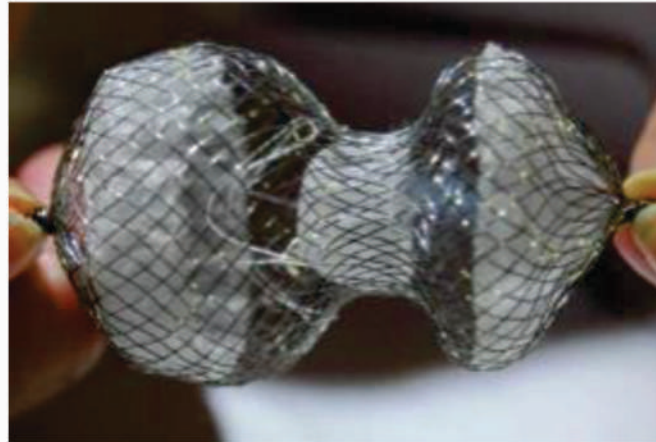
Catalog number	Profile	Length	Size
CDC6F	0.077"	117 cm	6F





Septal Occluder No COMPROMISE

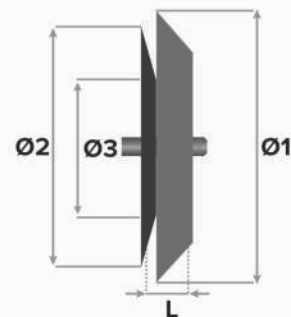
Optimal sealing of defects



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 patients¹
- 95% to 100% device success rate from early European experience^{3,4}



Design:

Left atrial disc diameter (Ø1)

Device size (Ø3)

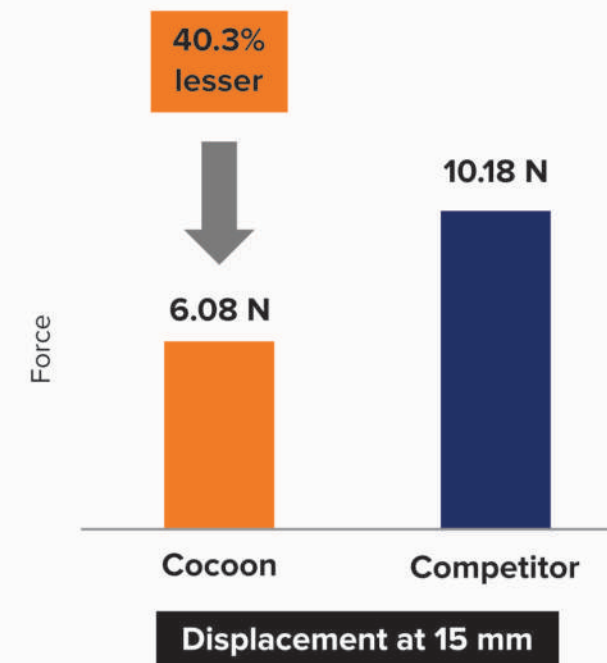
Right atrial disc diameter (Ø2)

Waist length (L)



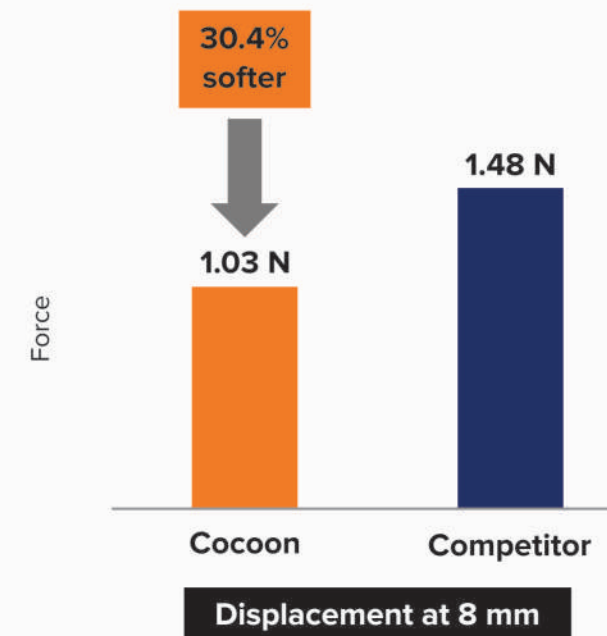
Septal Occluder No COMPROMISE

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**



Septal Occluder No COMPROMISE



Septal Occluder No COMPROMISE

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

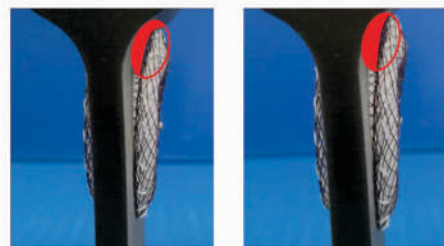
Left disc

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

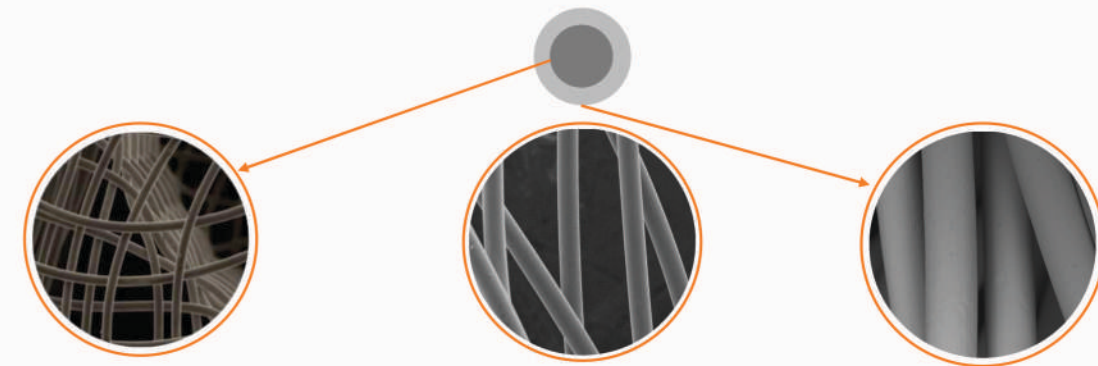


Competitor

Cocoon Septal Occluder is highly conformable

Designed to minimize nickel leaching 25 μ of Platinum coating

- 25 μ 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

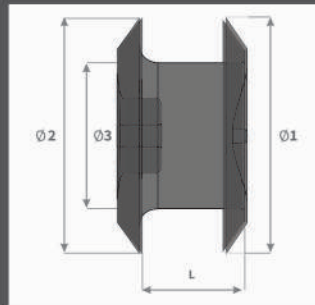
Non-allergic

More radiopaque



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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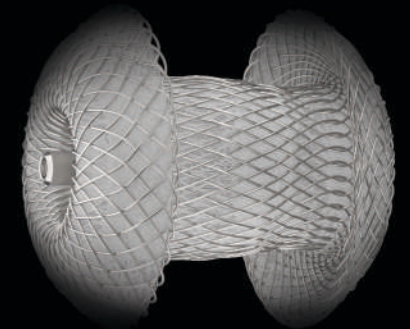
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VSD Occluder

No COMPROMISE



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VSD Occluder No COMPROMISE

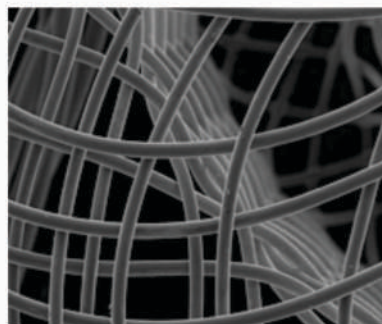
60,000+ implants globally



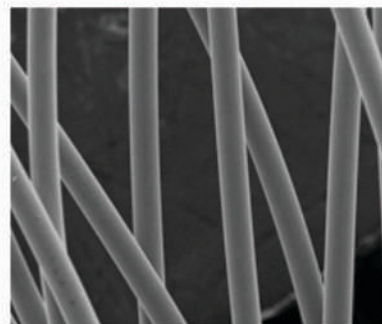
Platinum coating technology

Nitinol wire used in Cocoon occluders is coated with **Platinum** atoms (up to 25 microns) using nano fusion technology by plasma deposition.

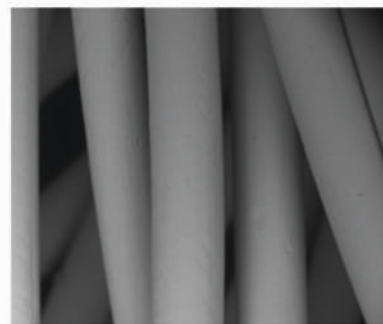
Raw Nitinol



Electropolished



Platinum coating



Platinum coating makes Cocoon occluders:

Biocompatible

Non-corrosive

Non-allergic

More radiopaque



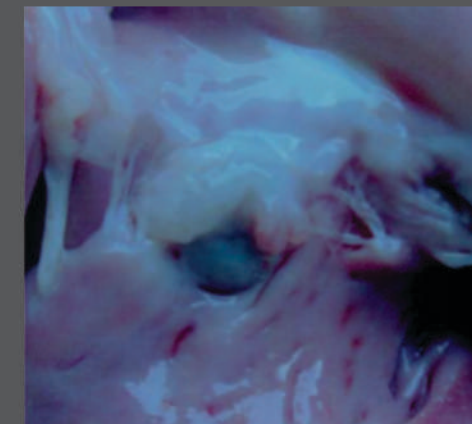
VSD Occluder No COMPROMISE

Key highlights

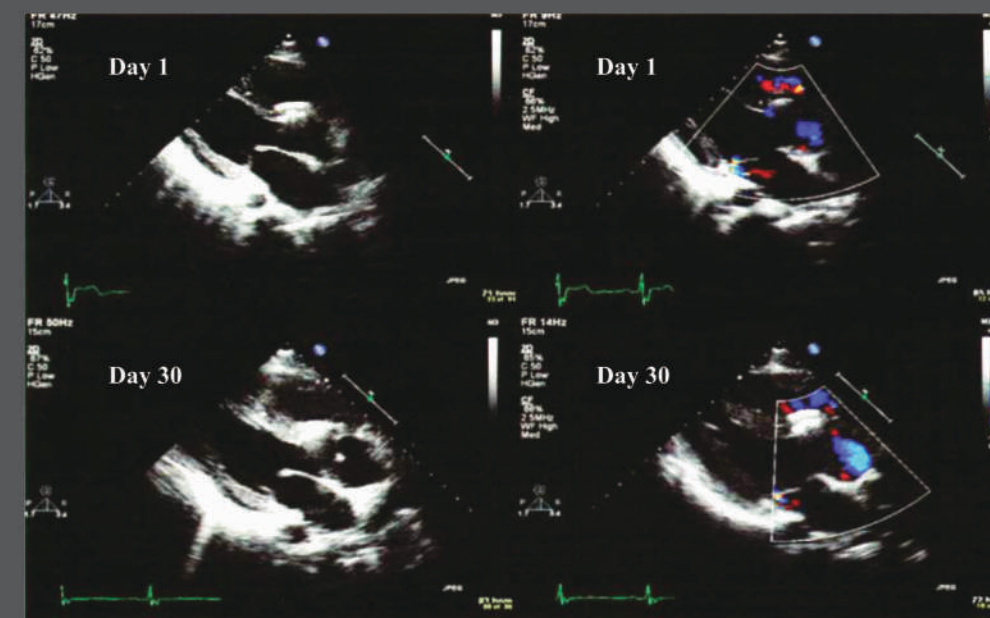
- Self-expanding, double disc device with unique Platinum coating
- 4, 7, & 10 mm waist lengths available
- Available in multiple lengths to match the types and locations of the ventricular septal defects to close membranous and muscular defects
- Discs are filled with polypropylene fabric which assists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

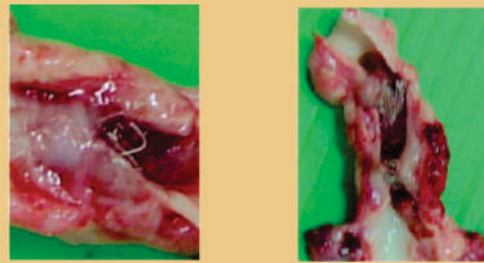


Echo images of the swine at day 1 and day 30 showing the complete closure of the defect



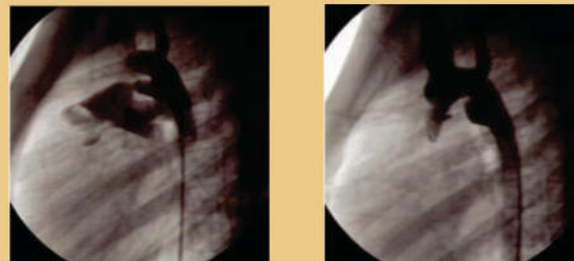
Duct Occluder No COMPROMISE

Preclinical studies*



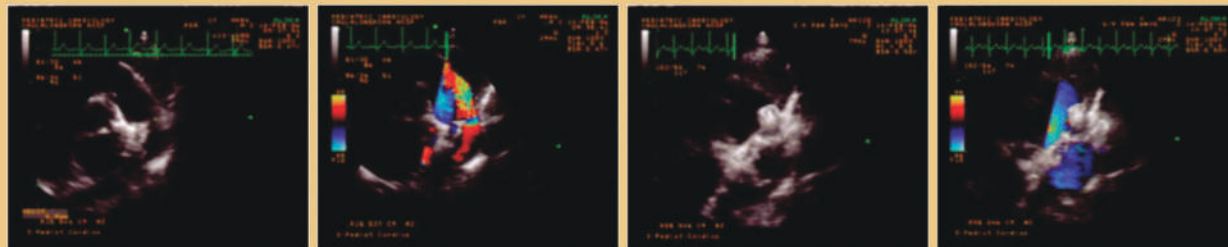
Seven days after implantation in a pig PDA shows a well-encapsulated device

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

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

#Recapture and redeployment is possible only if delivery cable is securely connected to the disc.

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Duct Occluder

No COMPROMISE





Duct Occluder No COMPROMISE

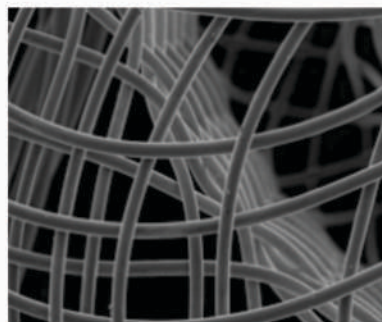
60,000+ implants globally



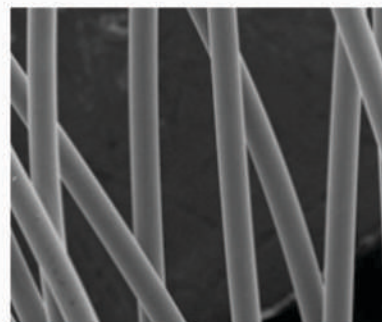
Platinum coating technology

Nitinol wire used in Cocoon occluders is coated with **Platinum** atoms (up to 25 microns) using nano fusion technology by plasma deposition.

Raw Nitinol



Electropolished



Platinum coating



Platinum coating makes Cocoon occluders:

Biocompatible

Non-corrosive

Non-allergic

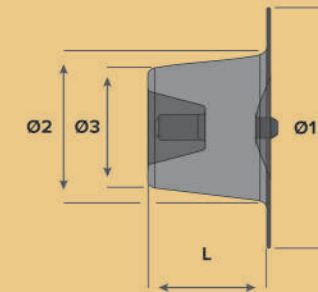
More radiopaque



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-up¹
- 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

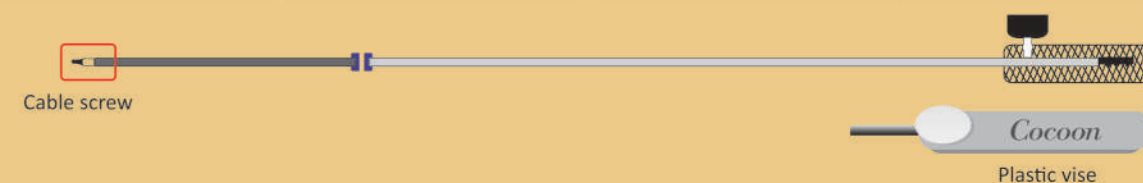
Product code	Retention skirt diameter (mm) Ø1	Device diameter at descending aorta (mm) Ø2	Device diameter at pulmonary artery (mm) Ø3	Device length (mm) L	Compatible sheath size (F)
COP0406	10	6	4	7	6-7
COP0608	12	8	6	7	6-7
COP0810	16	10	8	8	7-8
COP1012	18	12	10	8	7-8
COP1214	20	14	12	8	8-9
COP1416	22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





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.

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

Competitor information collected on 8th June 2022 from following sources

Abbott PFO Occluder: <https://www.cardiovascular.abbott/india/en/healthcare/products/structural-heart/structural-interventions/amplatzer-pfo.html>

Abbott Talisman Occluder: <https://www.cardiovascular.abbott/india/en/healthcare/products/structural-heart/structural-interventions/amplatzer-talisman.html>

Decoltech PFO Occluder: https://www.decotech.com/files/structure/Decoltech_PFO_Br.pdf

Cera PFO Occluder: <http://www.lifestechmed.com/en/product/p1/cera/385.aspx>

Ceraflex PFO Occluder: <http://www.lifestechmed.com/en/product/p1/ceraflex%20occluders/360.aspx>

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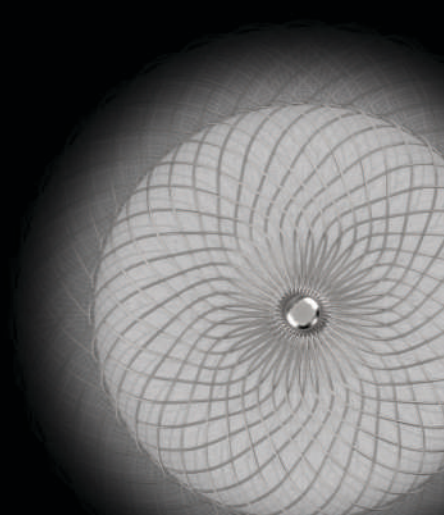


CPF/BRO/EN01 REV.01



PFO Occluder

No COMPROMISE

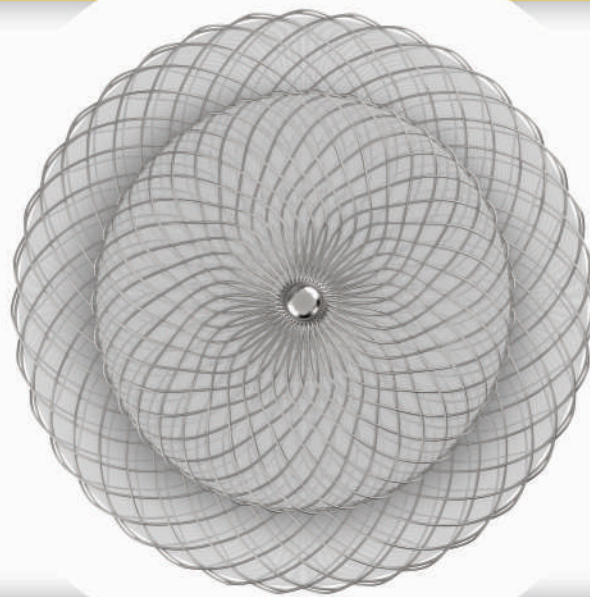




PFO Occluder
No COMPROMISE

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
 25 μ of Platinum coating



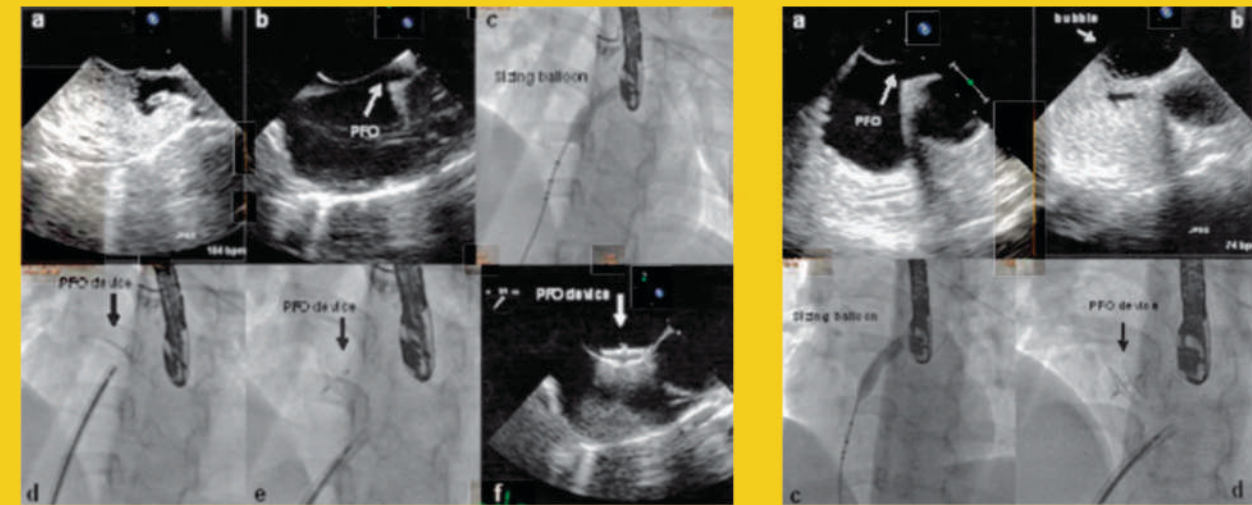
PFO Occluder
No COMPROMISE

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**

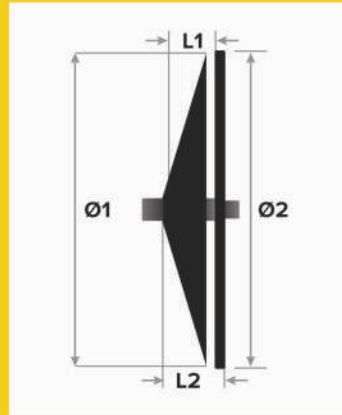
a. Demonstrating PFO by transesophageal echo-cardiography (arrow) b. Agitated saline injection filled in right atrium and left atrium (arrow) c. Sizing balloon used to evaluate PFO tunnel d. PFO device after detachment from cable



PFO Occluder No COMPROMISE

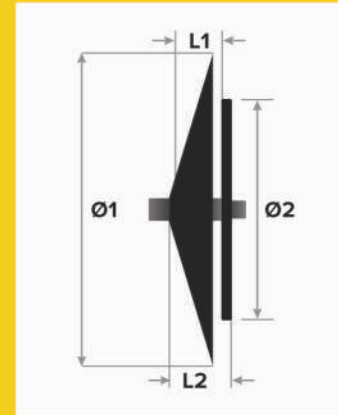
Device Description

- 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

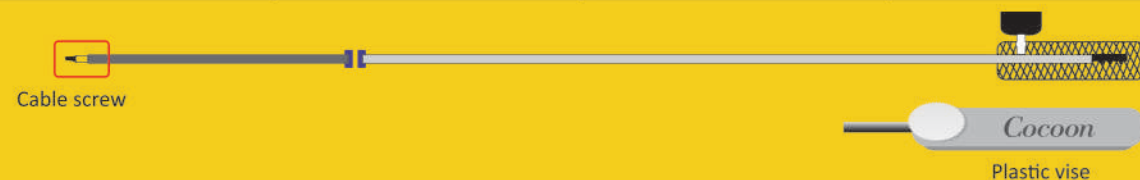
Consider shortest distance from defect to aortic root or distance from defect to superior vena cava orifice (mm)

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



PFO Occluder No COMPROMISE

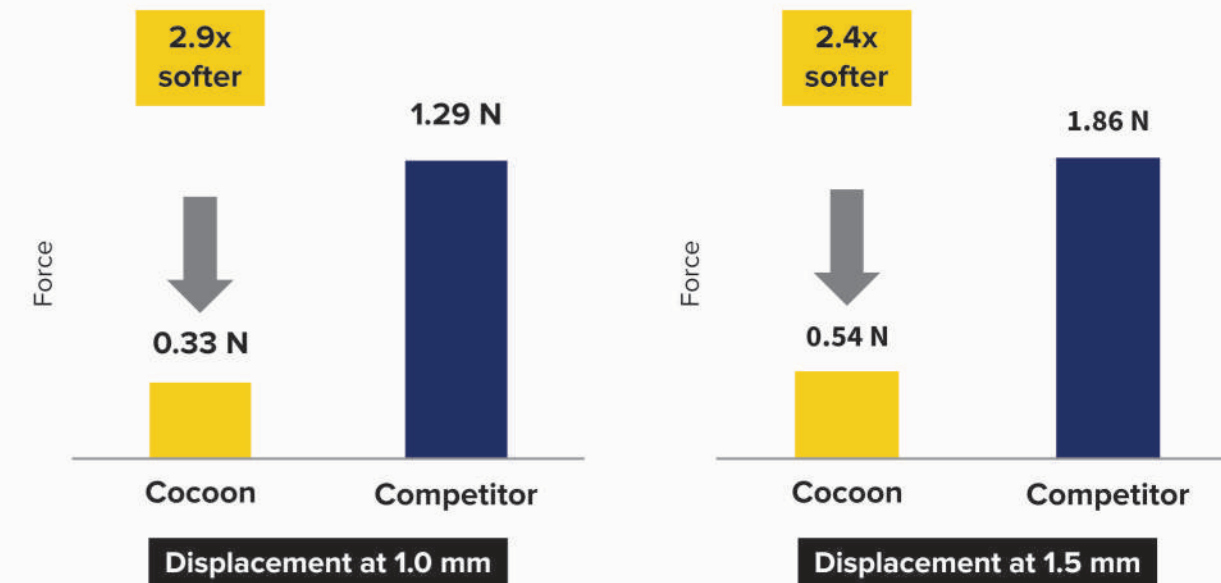
Extensive size matrix so that there is no compromise

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 = 4		18/18	25/18					30/30	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





PFO Occluder No COMPROMISE



PFO Occluder No COMPROMISE

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 = 4		2	2				
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

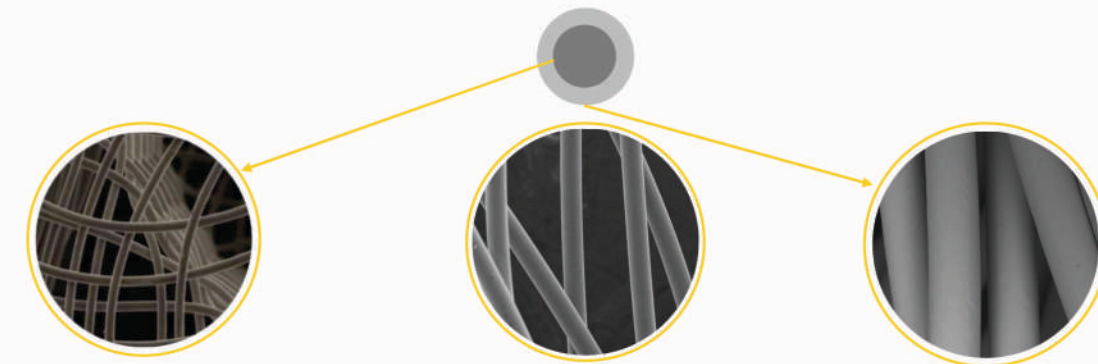
Cocoon PFO Occluder Total SKUs = 6		18/18 8F	25/18 8F		25/25 8F	30/25 8F		30/30 8F	35/25 9F	
Amplatzer PFO Occluder (Abbott) Total SKUs = 4		18/18 8F	25/18 8F					30/30 9F	35/25 9F	
Amplatzer Talisman PFO Occluder Total SKUs = 4		18/18 8F	25/18 8F			30/25 9F			35/25 9F	
Occlutech PFO Occluder Total SKUs = 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 11F	
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.

Designed to minimize nickel leaching
25 μ of Platinum coating

- 25 μ 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