

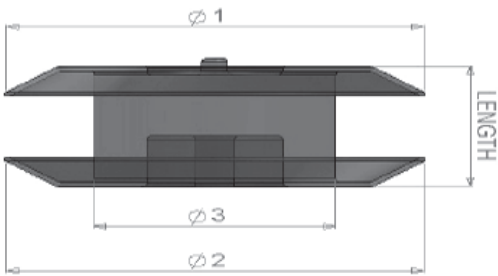


The Cocoon VSD Occluder is a percutaneous, transcatheter ventricular septal defect (VSD) closure device intended for the occlusion of hemodynamically significant ventricular septal defects. The Cocoon VSD Occluder is a self expandable double disk device made from Nitinol wire mesh coated with Platinum. The two discs are linked together by a connecting waist corresponding to the defect. In order to increase the closing ability the discs and the waist are filled with poly propylene fabric. The Cocoon VSD Occluder is available in waist lengths of 4mm, 7mm and 10mm.

Technical Specifications and Ordering Information

Cocoon VSD Occluder

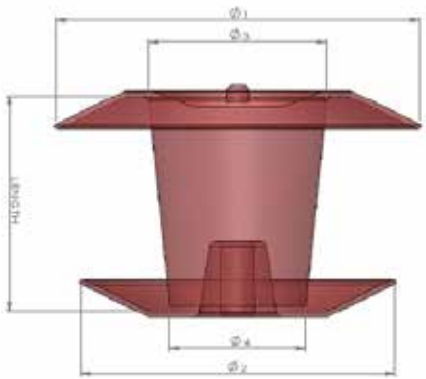
Device Dimensions					Recommendations
Catalog Number	LV Disc Diameter (Ø1)	RV Disc Diameter (Ø2)	Waist Diameter (Ø3)	Device Length (L)	Accessory Catalog Number
COV0404	10 mm	10 mm	3.25 mm	4 mm	COV6F/COVII6F
COV0604	12 mm	12 mm	5.25 mm	4 mm	COV6F/COVII6F
COV0804	14 mm	14 mm	7.25 mm	4 mm	COV6F/COVII6F
COV1004	16 mm	16 mm	9.25 mm	4 mm	COV7F/COVII7F
COV1204	18 mm	18 mm	11.25 mm	4 mm	COV7F/COVII7F
COV0407	10 mm	10 mm	4 mm	7 mm	COV6F/COVII6F
COV0607	12 mm	12 mm	6 mm	7 mm	COV6F/COVII6F
COV0807	14 mm	14 mm	8 mm	7 mm	COV6F/COVII6F
COV1007	16 mm	16 mm	10 mm	7 mm	COV7F/COVII7F
COV1207	18 mm	18 mm	12 mm	7 mm	COV7F/COVII7F
COV0410	10 mm	10 mm	4 mm	10 mm	COV6F/COVII6F
COV0610	12 mm	12 mm	6 mm	10 mm	COV6F/COVII6F
COV0810	14 mm	14 mm	8 mm	10 mm	COV6F/COVII6F
COV1010	16 mm	16 mm	10 mm	10 mm	COV7F/COVII7F
COV1210	18 mm	18 mm	12 mm	10 mm	COV7F/COVII7F



A delivery cable (catalog no. CDCV) is available to facilitate delivery of the Cocoon VSD Occluder to the ventricular septal defect. The delivery cable is packaged with a delivery cable sheath to support the delivery cable.

Cocoon VSD Occluder

Device Dimensions						Recommendations
Catalog Number	LV Disc Diameter (Ø1)	RV Disc Diameter (Ø2)	Waist Diameter (Ø3)	Waist Diameter (Ø4)	Device Length (L)	Accessory Catalog Number
COVA0604*	12 mm	10 mm	6 mm	4 mm	10 mm	COV6F/COVII6F
COVA0806*	14 mm	12 mm	8 mm	6 mm	10 mm	COV6F/COVII6F
COVA1006*	16 mm	12 mm	10 mm	8 mm	10 mm	COV6F/COVII6F
COVA1208*	18 mm	14 mm	12 mm	8 mm	10 mm	COV7F/COVII7F
COVA1408*	20 mm	14 mm	14 mm	8 mm	10 mm	COV7F/COVII7F
COVA0604-07*	12 mm	10 mm	6 mm	4 mm	7 mm	COV6F/COVII6F
COVA0806-07*	14 mm	12 mm	8 mm	6 mm	7 mm	COV6F/COVII6F
COVA1006-07*	16 mm	12 mm	10 mm	8 mm	7 mm	COV6F/COVII6F
COVA1208-07*	18 mm	14 mm	12 mm	8 mm	7 mm	COV7F/COVII7F
COVA1408-07*	20 mm	14 mm	14 mm	8 mm	7 mm	COV7F/COVII7F



* Not available for use in CE mark required countries.

Manufactured by:
Vascular Innovations Co. Ltd.
88/38 Moo 1, 345 Road, Bangtanai
Pakkret, Nonthaburi - 11120
Thailand
Tel: (66) 02-598-2361
Fax: (66) 02-598-2360
info@vascularinnovations.com
www.vascularinnovations.com

Distributed by:



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Cocoon

VSD Occluder

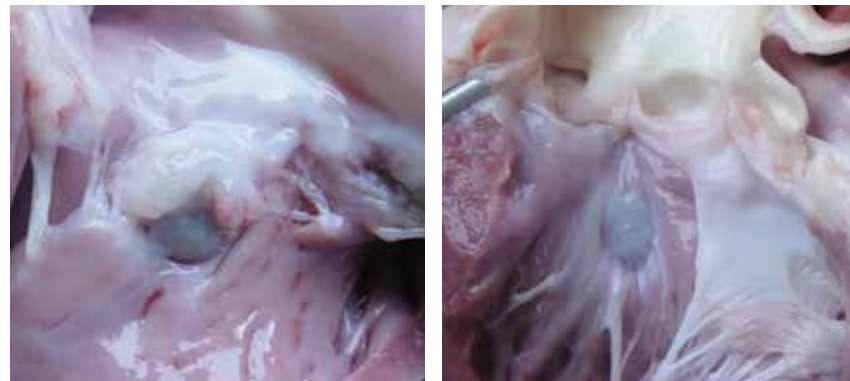
*Self-expandable device made from
nanoplatinum covered Nitinol wire mesh*

FEATURES

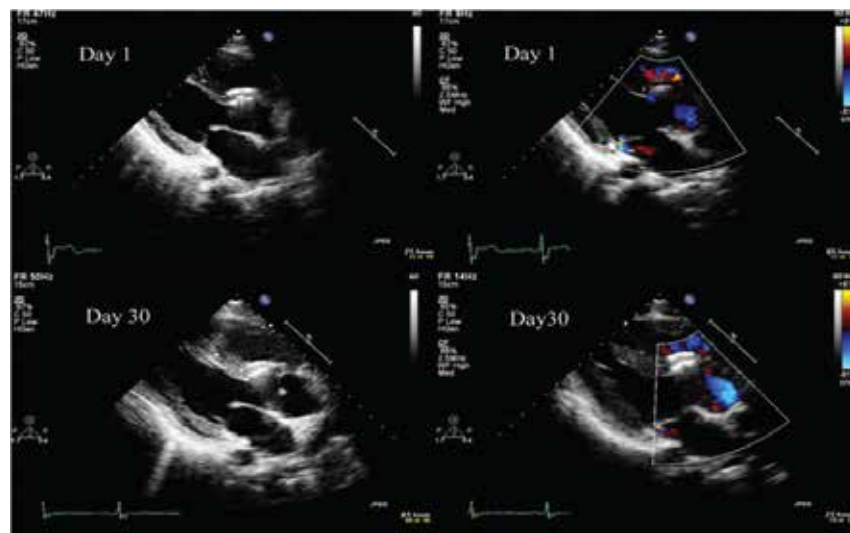
- The design of the occluder is a soft central waist and two strong discs
- Compressing the soft central waist elongates the device longitudinally instead of radially and avoids stenting of the defect
- The discs are designed to withstand high left ventricular pressure
- Platinum coating provides superior bio-compatible properties compared to bare nitinol
- Minimizes nickel leaching into the blood stream and into the heart

PRE-CLINICAL STUDIES

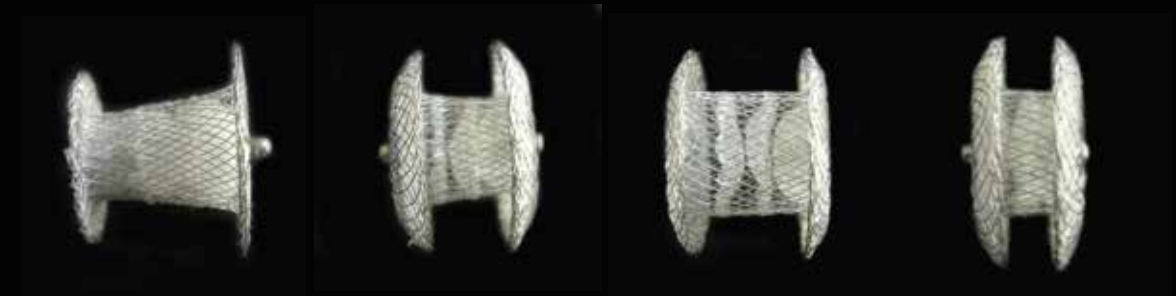
Ventricular Septal defect was created in swine models and subsequently implanted with a Cocoon VSD Occluder.



Explants at 30 days shows the device incorporated with tissues.



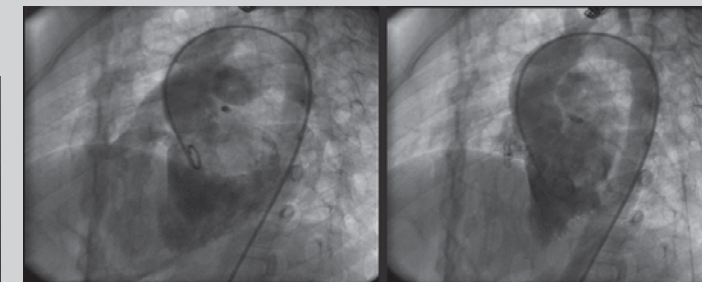
Echo images of the swine at day 1 and day 30 showing a complete closure of the defect.



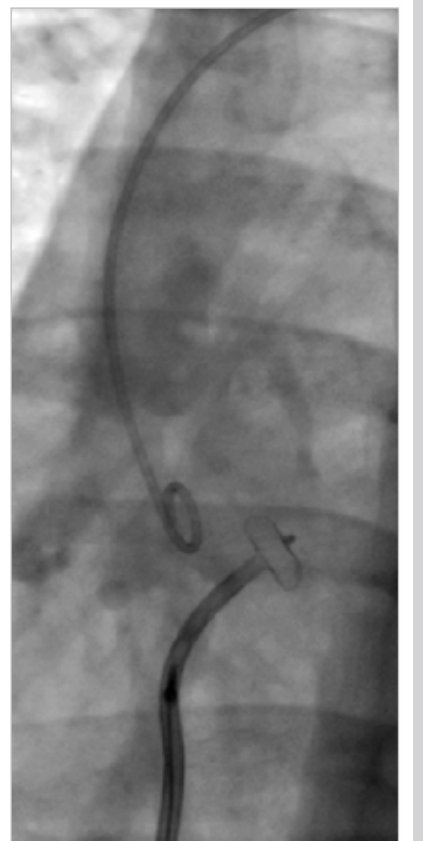
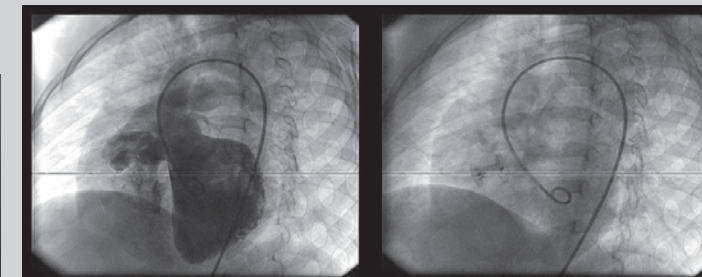
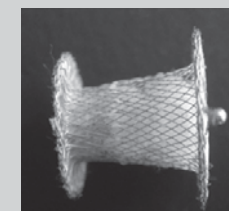
The platinum coated discs are filled with multiple polypropylene woven fabric which aids in total occlusion of the defect

CLINICAL STUDIES

6 year old boy
Perimembranous VSD
LV orifice 6.7 mm
RV opening 5.4 mm
Length 5.6 mm
Device COV0807



5 year old girl
Aneurysmal perimembranous VSD
LV orifice 10.9 mm
RV opening 4.6, 2 mm
Length 10 mm
Device COVA1006



The curve of the Cocoon VSD delivery system facilitates easy deployment of the device.