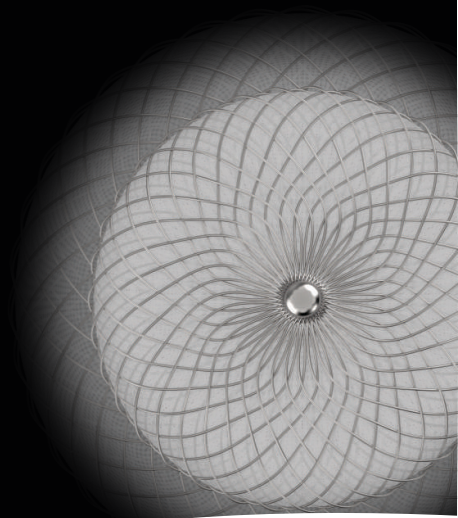




PFO Occluder

**No Compromise**





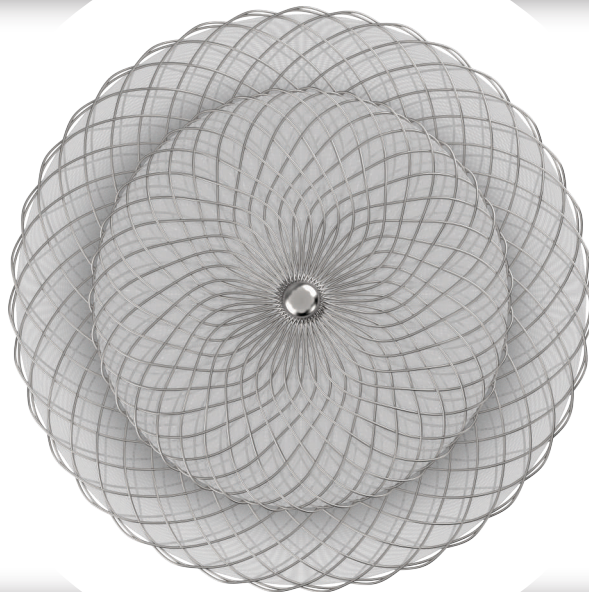
CE  
1434

PFO Occluder

# No **Compromise**

**Extensive size matrix so  
that there is no  
compromise**  
6 SKUs

**5 out of 6 occluders  
are  
8F sheath compatible**

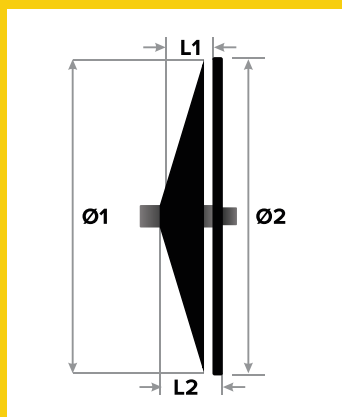


**Softness to protect**  
2+ times softer at the rims

**Designed to minimize  
nickel leaching**  
Platinum coating

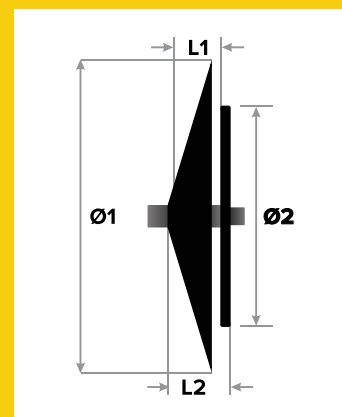
### Device Description

- 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<sup>#</sup>



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                               |

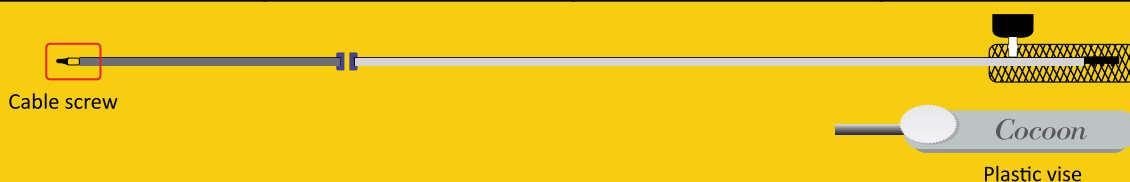
Consider shortest distance from defect to aortic root or distance from defect to superior vena cava orifice (mm)

### Usable length (cm)

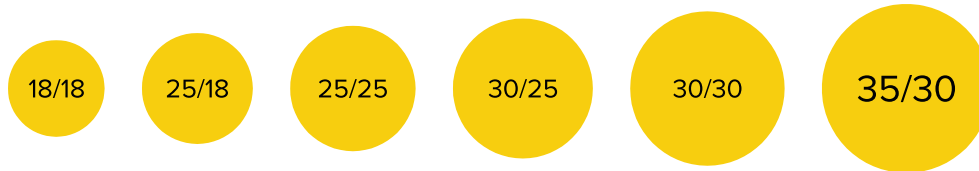
|         | 8F | 9F |
|---------|----|----|
| Sheath  | 78 | 78 |
| Dilator | 83 | 83 |
| Loader  | 10 | 12 |

### Delivery Cable

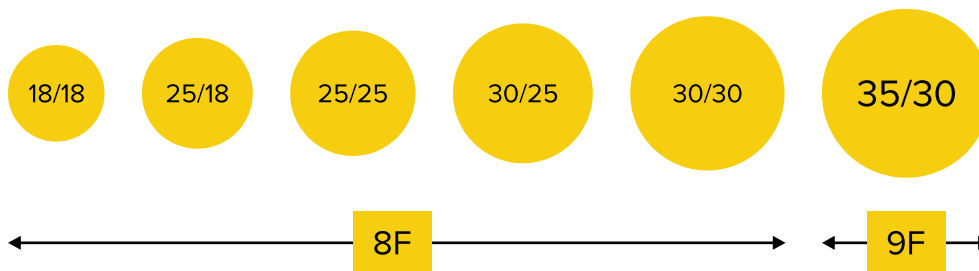
| Catalog number | Profile | Length | Size |
|----------------|---------|--------|------|
| CDC6F          | 0.077"  | 117 cm | 6F   |



### Extensive size matrix

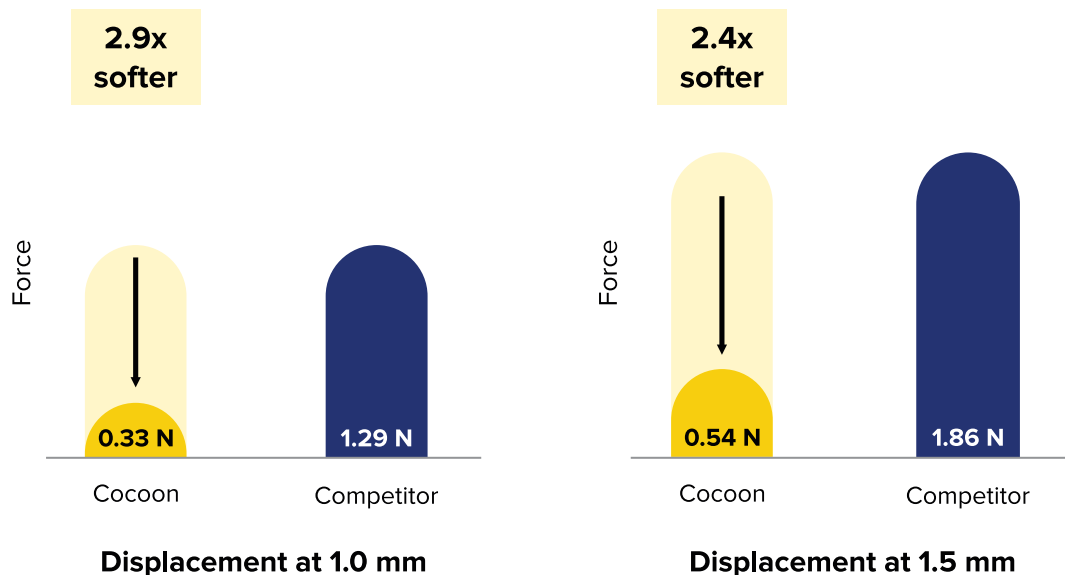


### 5 out of 6 occluders are 8F compatible



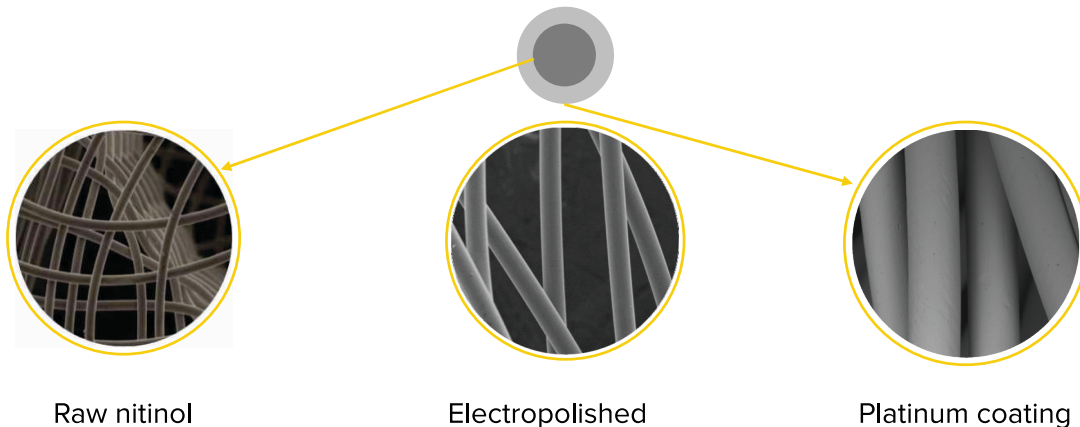
### Softness to protect\*

2+ times softer at the rims



### Designed to minimize nickel leaching

- 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**

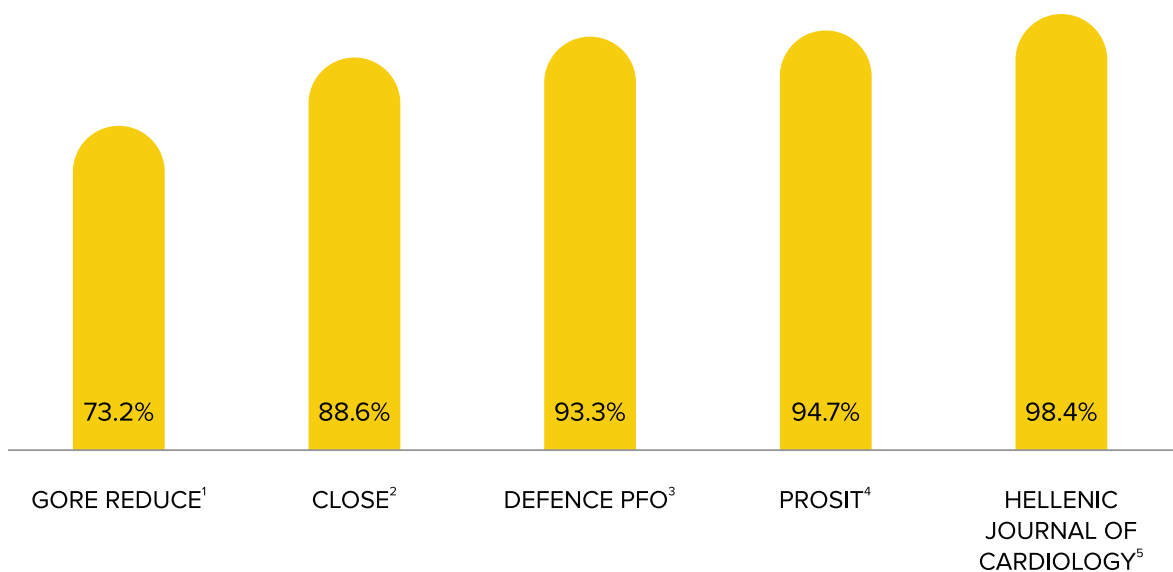
**Non-allergic**

**More radiopaque**

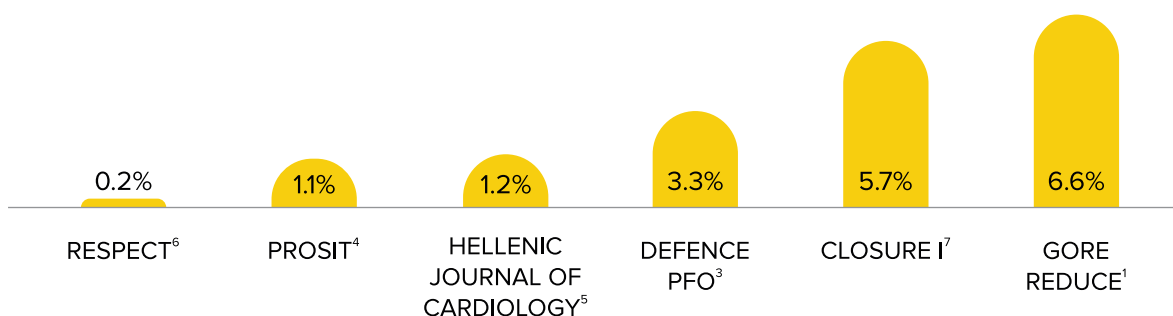
### Clinical Data

#### Higher acute closure rates

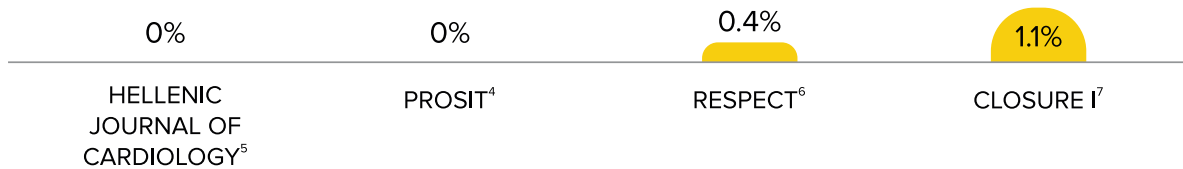
| Trial                                       | Definition of no/residual shunt |
|---|---------------------------------|
| GORE REDUCE <sup>1</sup>                    | 0 microbubbles                  |
| CLOSE <sup>2</sup>                          | <10 microbubbles                |
| DEFENCE PFO <sup>3</sup>                    | <10 microbubbles                |
| PROSIT <sup>4</sup>                         | 0 bubbles                       |
| HELLENIC JOURNAL OF CARDIOLOGY <sup>5</sup> | 0 microbubbles                  |



#### Low new onset atrial fibrillation



### Cardiac or device-related thrombus

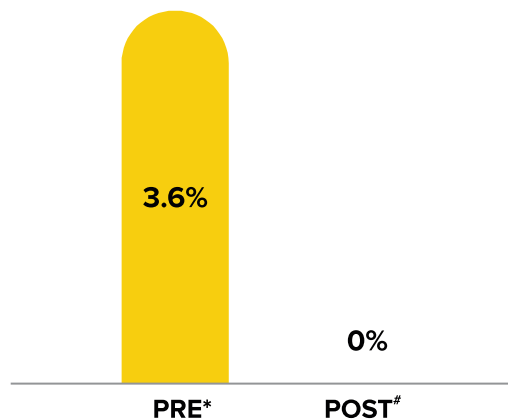


### Real-world clinical experience<sup>5</sup>

Hellenic Journal of Cardiology

Impact Factor: 4.1 (2023)

DOI: 10.1016/j.hjc.2023.04.011



\*Patients that had nickel allergy documented with the use of a TRUE skin patch test.

# Nickel allergic reactions post procedure and at follow-up

**“It should be noted that no patient in our study developed nickel allergy including those with positive nickel allergy skin test”**

\*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

<sup>†</sup>Recapture and redeployment is possible only if delivery cable is securely connected to the disc.

1. N Engl J Med. 2017 Sep 14;377(11):1033-42. 2. N Engl J Med. 2017 Sep 14;377(11):1011-21. 3. J Am Coll Cardiol. 2018 May 14;71(20):2335-42.

4. Front Cardiovasc Med. 2023 Jan 11;9:1064026. 5. Hellenic J Cardiol. 2024 Jan-Feb;75:21-25. 6. N Engl J Med. 2013 Mar 21;368(12):1092-100.

7. N Engl J Med. 2012 Mar 15;366(11):991-9.

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.

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

**Disclaimer:** © 2024 Sahajanand Medical Technologies Limited – All rights reserved. Specifications are subject to modification, revision and improvement.

Registered Office: Sahajanand Medical Technologies Limited

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

• CIN: U33119G12001PLC040121 • www.smtpl.com