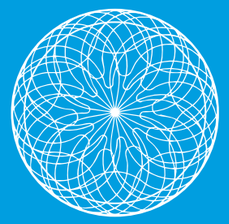
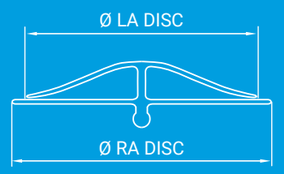
Occlutech PFO Occluder

Product specifications

PFO





Article No.	Defect Size [mm]	Ø LA Disc [mm]	Ø RA Disc [mm]	Sheath Size* [F]	Pusher Article No. (color)** Pistol Pusher	Flex Pusher II
LA Single Layer						
18PFO25S	8<D≤13	23	25	9	55PP165	51FP120
LA Double Layer						
19PFO18D	D≤8	16	18	7	55PP125	51FP100
19PFO25D	8<D≤13	23	25	9	55PP165	51FP120
19PFO30D	13<D≤15	27	30	9	55PP165	51FP120
19PFO35D	15<D≤18	31	35	11	55PP210	51FP160

Availability subject to regulatory approval. Product data may be subject to change. Contact your Occlutech representative for information.

* Occlutech Delivery Set (ODS).

** Color defines Pusher color.

Quality made in Europe

Occlutech adheres to the highest quality standards. We never compromise on quality. Our dedication to patients and the medical community is the main driver of our vision. We want to be at the forefront of developing technologies and products that matter, that make a difference and that help our customers be at the leading edge of better treatment for structural heart disease.

Content references:

1. *Occlutech Percutaneous Patent Foramen Ovale Closure: Safety and Efficacy Registry (OPPOSE), Multicentric Registry, UK.*
2. *Castleman LS et. al. Biocompatibility of Nitinol Alloy as an Implant Material. Journal of Biomedical Materials Research | 97 6;10:695.*
3. *Electrochemical Characterization of Nitinol Occluder, Natural and Medical Sciences Institute at the University of Tübingen, mNI<0,014 µg/(cm*d).*
4. *EuroIntervention – Amplatzer versus Figulla occluder for transcatheter patent foramen ovale closure.*

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Occlutech

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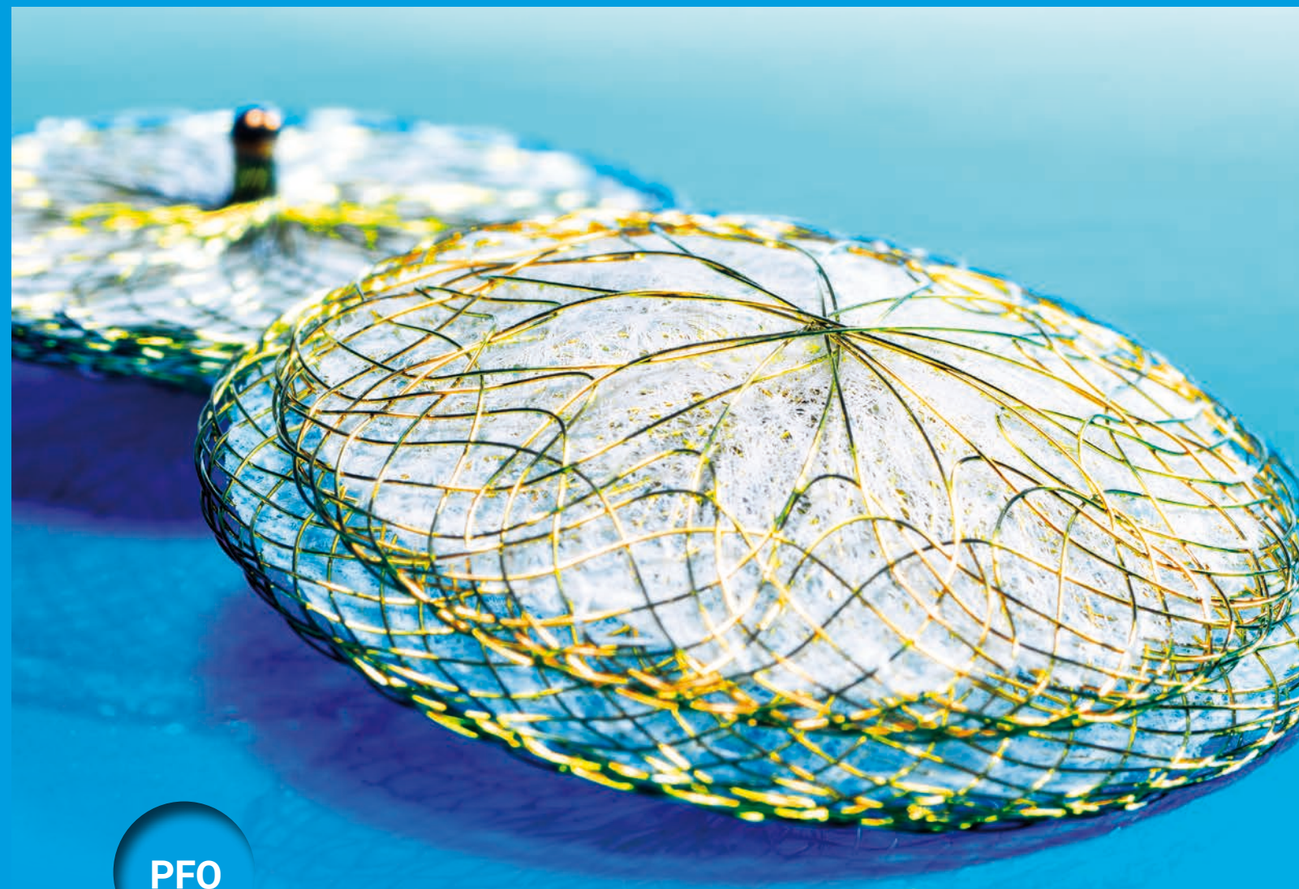
Perfecting Performance

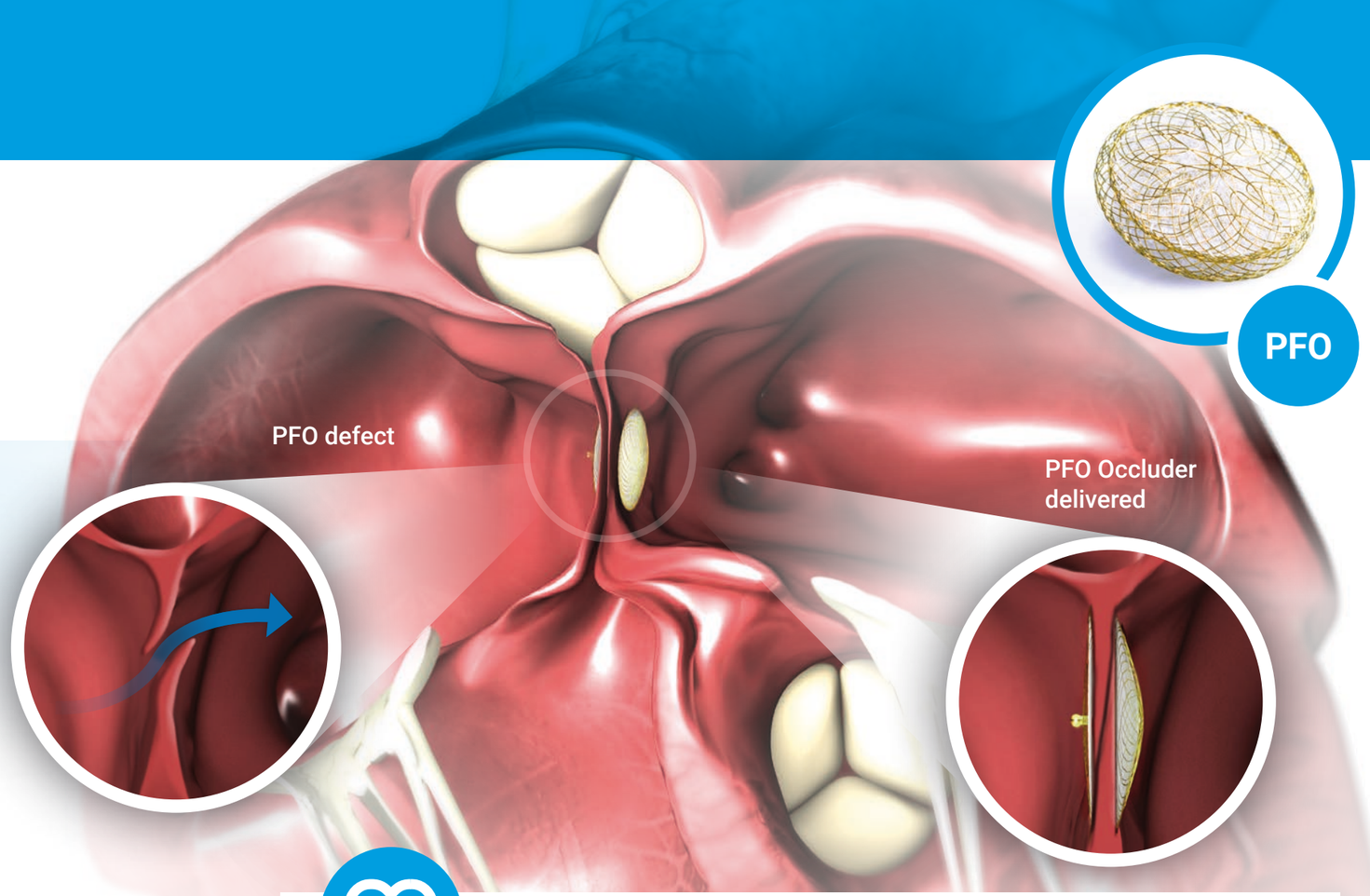
Occlutech

Occlutech PFO Occluder



PFO

Designed for safety and excellence

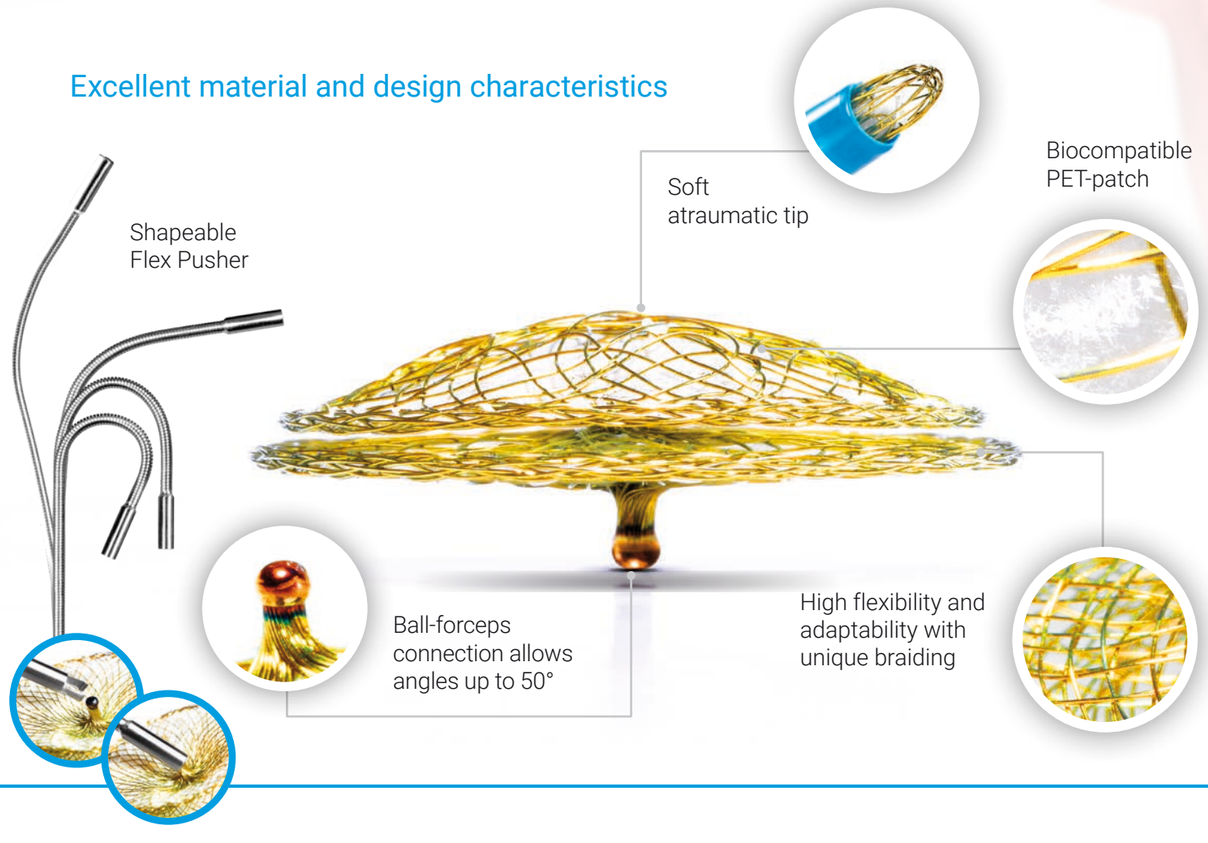


PRODUCT FEATURES

The Flex II PFO occluder enables physicians to simplify implantations and achieve state-of-the-art results[1] with a steep learning curve.

- The unique ball-connection between pusher and Occluder safely locks it, while it freely follows the anatomy. Once in place it is easy and fast to deliver.
- Handknitted biocompatible PET-patch allows immediate verification of occlusion effect by Ultrasound and X-Ray.
- Titanium oxide covered Nitinol shows the best values of biocompatibility[2] and minimized Nickel release.[3]
- Optimized braiding: No hub and reduced material on left arterial disc guarantees better ingrowth.

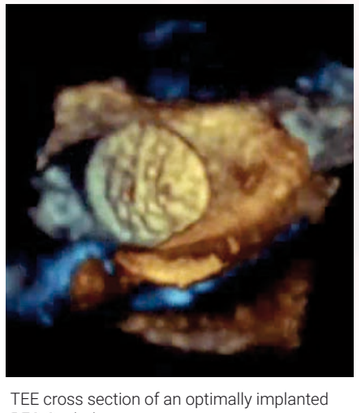
Excellent material and design characteristics



CLINICAL BENEFITS

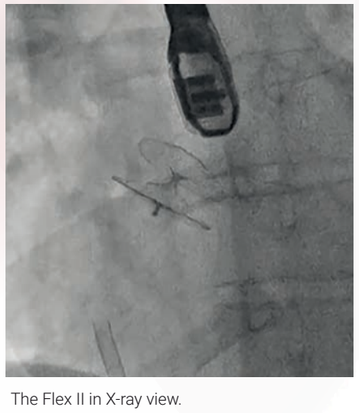
Over 50,000 PFO occluders have been delivered to over 80 countries around the world, with excellent track records for performance and safety.

- Excellent periprocedural outcome and excellent 3 months TEE-follow up results for PFO reshunting.[4]
- Mean procedure time: less than 30 minutes with decreased fluoroscopic time.[4]



TEE cross section of an optimally implanted PFO Occluder.

The hubless distal disc in 3-D TEE projection.



The Flex II in X-ray view.