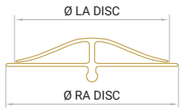
Product specifications & ordering information

PFO



Ø LA DISC: LEFT ATRIAL DISC DIAMETER
Ø RA DISC: RIGHT ATRIAL DISC DIAMETER

Occlutech PFO Occluder Ref. No.	Defect Size (D) [mm]	Ø LA Disc [mm]	Ø RA Disc [mm]	ODSv1* 45°, 800 mm (Size)	ODS III* 45°, 790 mm (Size)	Occlutech Procedure Pack Flex Pusher II Ref. No.	Occlutech Procedure Pack Pistol Pusher Ref. No.
LA SINGLE LAYER							
18PFO25S	8<D≤13	23	25	51DS009 (9F)	98DS009 (9F)	18PFO25SF	18PFO25SP
LA DOUBLE LAYER							
19PFO18D	D≤8	16	18	51DS007 (7F)	98DS007 (7F)	19PFO18DF	19PFO18DP
19PFO25D	8<D≤13	23	25	51DS009 (9F)	98DS009 (9F)	19PFO25DF	19PFO25DP
19PFO30D	13<D≤15	27	30	51DS009 (9F)	98DS009 (9F)	19PFO30DF	19PFO30DP
19PFO35D	15<D≤18	31	35	51DS011 (11F)	98DS011 (11F)	19PFO35DF	19PFO35DP

* Occlutech PFO Occluder is compatible with Occlutech Delivery Set, ODSv1 (Article no.: 51DSXXX, 45°) and Occlutech Delivery Set III, ODS III (Article no.: 98DSXXX, 45°).

Occlutech is a leading specialist provider of minimally invasive cardiac devices

Our mission is to improve the quality of life for people with heart conditions. The vision is to become a leading global specialist in cardiac devices, addressing congenital heart defects, stroke prevention and heart failure – because every beat counts for people living with heart conditions.

References:

1. *Trabattoni, D et al (2017). Eurointervention. 12: 2092-2099*
2. *Toggweiler, S et al (2024). J Invasive Cardiol 2024.*
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5. *Data on File*
6. *Krisnic, F et al (2010). The Journal of Invasive Cardiology 22, 26*
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8. *Leong, M, et al (2022). Cardiol Young. Oct;32(10):1621-1627*
9. *Tanabe, Y et al (2021). J Am Heart Assoc 10, e019282*
10. *Kenny, D et al (2019). Catheter Cardiovasc Interv. Feb 1;93(2):316-321*
11. *Haas, N et al (2016). Catheter Cardiovasc Interv. Oct;88(4):571-581*
12. *Van Den Branden, B et al (2010). Journal of Interventional Cardiology*
13. *Scalise, F et al (2016). Journal of Interventional Cardiology. Vol 29, No.4*
14. *Ates, A et al (2021). Turk Kardoyol Dern Ars. 2021;49(1):29-39*
15. *Oto, A et al (2011). Wiley Periodicals. 1074-1080*
16. *Aytemir, K et al , (2012). Journal of Interventional Cardiology. Vol.25, No. 4*
17. *Aparisi, A et al (2020). Cardiol J. 2020;27(5):524-532*
18. *Nakayame , R et al (2021). Heart Vessels. May: 36(5):704-709*
19. *PFO_CER_ver14 + LSR_PFO_ver01*

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Occlutech
Every beat counts

PFO

Occlutech PFO Occluder

Long-term proven **stroke protection**

Safe, effective and simply delivered

Occlutech
Every beat counts

An extensive and global footprint

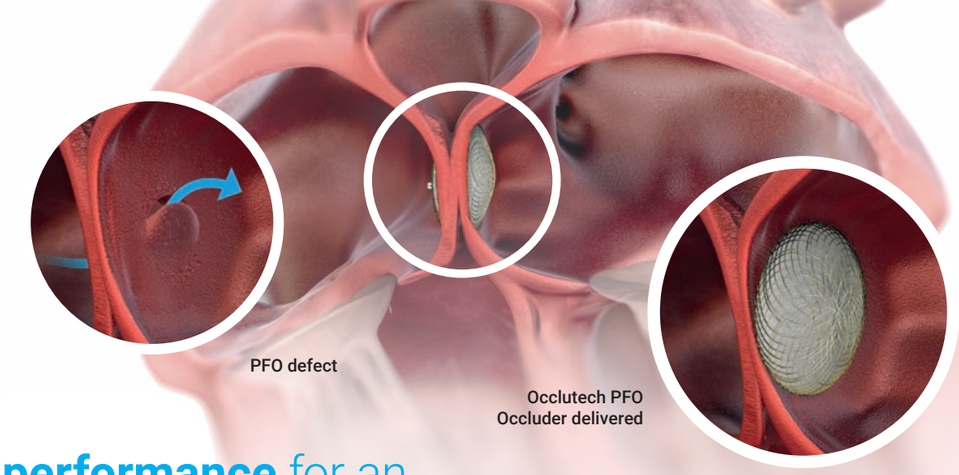
>60,000
Units delivered[5]

>50
Published papers[19]

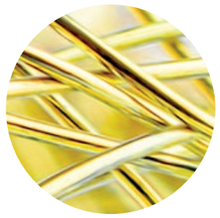
Up to 10-yr
follow-up data showing 99.5% freedom from stroke[3]

Long-term proven **stroke protection**

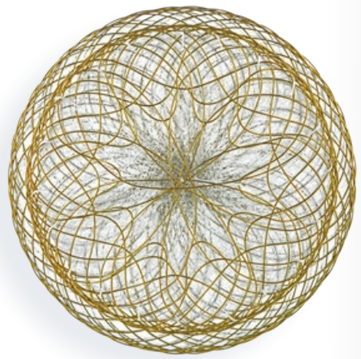
The unique design of the Occlutech PFO Occluder, including material reduction and higher flexibility, provides optimal septal alignment during the implantation procedure.[6-11]



Flexibility & conformability for a reliable PFO closure [3,4]



Unique and optimized braiding provides flexibility and conformability, respecting the surrounding structures, even in challenging PFO anatomies, for a reliable PFO closure.[1-4, 7-8, 12]



Optimized LA disc design, with no protruding hub, potentially enhancing endothelisation in areas where thrombus formation may occur.[9]

Facilitated delivery

Uniquely designed with a ball shaped connector and force free angulation up to 50 degrees, facilitating implantation and allowing the device to conform to the septum reaching the final implant-ation position for a safe and accurate positioning.[1-4, 6, 10, 11, 17-18]

Proven performance for an effective PFO closure [1-4]

Clinical evidence: The Occlutech PFO Occluder has been employed in >50 published studies and has the longest follow up time (up to 10 years) of all competitive PFO devices.*[3]

* As of January 2025

99.5%
Freedom from stroke/TIA at long-term follow-up (up to 10-years).[3]

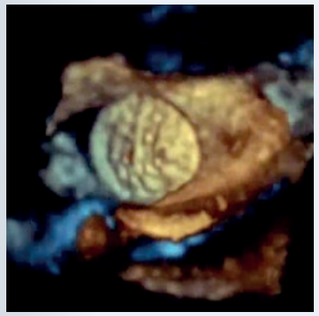
Safe
high protection against recurrent stroke[1-3, 13-14] with a low rate of arrhythmias (0.4% vs 2.2% of another competitive PFO device.[1])

>95%
Effective closure (no or Trivial residual shunt).[1-3, 12]

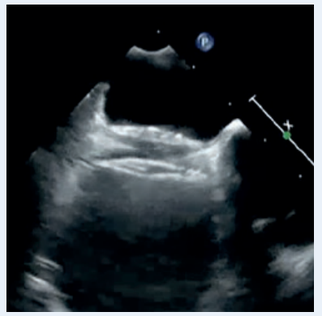
Effective
high implantation success rate at first attempt (>99%[1-3, 13]) and closure without complications to treat with confidence.[1-2,13-15]

≤26min
Mean Procedure duration.[3, 13, 15,16]

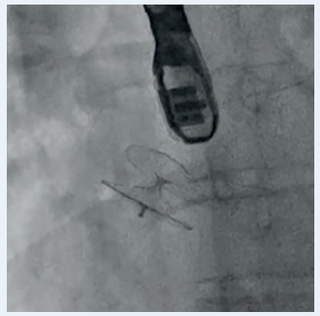
Simply delivered
easy to use, with short procedure and low Fluoroscopy times, which could lead to Cath-lab efficiencies and reduced radiation exposure.[1, 13, 15-16]



TEE cross-section of an optimally implanted Occlutech PFO Occluder.



The hubless distal disc in 3-D TEE projection.



The Occlutech PFO Occluder in X-Ray view

Occlutech