

## MRI Safety Information

### Figulla Flex II PFO occluders

Art.- No.	Description	Disc diameter [mm]
18PFO25S	Figulla® Flex II PFO	23/25
19PFO18D	Figulla® Flex II PFO	16/18
19PFO25D	Figulla® Flex II PFO	23/25
19PFO30D	Figulla® Flex II PFO	27/30
19PFO35D	Figulla® Flex II PFO	31/35

**MR Conditional**

Non-clinical testing and MRI simulations were performed to evaluate the entire family of the Figulla Flex II PFO Occluder.

Non-clinical testing demonstrated that the entire family of this implant is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the Figulla Flex II PFO Occluder is expected to produce a maximum temperature rise of 2.3°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Figulla Flex II PFO Occluder extends approximately 10-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

**S. Klebon**

*Medical Device Safety Officer,  
Occlutech*

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