

## MRI Safety Information

### Figulla Flex II ASD occluders

Art.- No.	Description	Waist diameter [mm]
29ASD04	Figulla® Flex II ASD	Size 4
29ASD05	Figulla® Flex II ASD	Size 5
29ASD06	Figulla® Flex II ASD	Size 6
29ASD07	Figulla® Flex II ASD	Size 7.5
29ASD09	Figulla® Flex II ASD	Size 9
29ASD10	Figulla® Flex II ASD	Size 10.5
29ASD12	Figulla® Flex II ASD	Size 12
29ASD13	Figulla® Flex II ASD	Size 13.5
29ASD15	Figulla® Flex II ASD	Size 15
29ASD16	Figulla® Flex II ASD	Size 16.5
29ASD18	Figulla® Flex II ASD	Size 18
29ASD19	Figulla® Flex II ASD	Size 19.5
29ASD21	Figulla® Flex II ASD	Size 21
29ASD24	Figulla® Flex II ASD	Size 24
29ASD27	Figulla® Flex II ASD	Size 27
29ASD30	Figulla® Flex II ASD	Size 30
29ASD33	Figulla® Flex II ASD	Size 33
29ASD36	Figulla® Flex II ASD	Size 36
29ASD39	Figulla® Flex II ASD	Size 39
29ASD40	Figulla® Flex II ASD	Size 40

**MR Conditional**

Non-clinical testing and MRI simulations were performed to evaluate the entire family of the Figulla Flex II ASD 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 ASD Occluder is expected to produce a maximum temperature rise of 3.1°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 ASD Occluder extends approximately 5-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*

**2017-12-14**

*Date, signature*