

MRI Safety Information

Figulla Flex II UNI occluders

| Art.- No. | Description | Disc diameter [mm] |
|-----------|----------------------|--------------------|
| 16UNI17 | Figulla® Flex II UNI | 17/17 |
| 16UNI24 | Figulla® Flex II UNI | 24/24 |
| 16UNI28 | Figulla® Flex II UNI | 28.5/28.5 |
| 16UNI33 | Figulla® Flex II UNI | 33/33 |
| 16UNI40 | Figulla® Flex II UNI | 40/40 |



Non-clinical testing and MRI simulations were performed to evaluate the entire family of the Figulla Flex II UNI 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 UNI 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 UNI Occluder extends approximately 10-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

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Occlutech*

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