PHYSICIAN INFORMATION

HumanOptics AG is a manufacturer of ophthalmic implants. In the following we would like to inform you about the impact of an MRI scan on the products of HumanOptics AG.

For questions or further information, please contact our customer service at **+49 (0)9131 50 66 5-0** or **customerservice@humanoptics.com.**

INTRAOCULAR LENSES (IOL)

All intraocular lenses of HumanOptics AG with or without blue light filter (made from acrylic, silicone or PMMA) are MR compatible and show no temperature rise, image artifacts or movement during an MRI scan. All tests were performed at 7 Tesla.

Excluded are the occlusive intraocular lenses MS 612 black and MS 714 PB black with a black pigmented optic. MRI scans of these models can lead to movement of the IOL and irritation of the surrounding tissue as well as image artifacts in the area of the IOL. Therefore, it is recommended that the patient sees the treating ophthalmologist after an MRI scan. All tests were performed at 7 Tesla.

ARTIFICIAL*IRIS*

The ARTIFICIAL*IRIS* devices containing the maximal amount of magnetic pigments were tested according to ASTM Standards F2052-15:2015, F2119-07:2013, F2182-11a:2011 and F2213-17:2017.

Non-clinical testing of the worst-case scenario has demonstrated that the ARTIFICIAL*IRIS* devices are MR conditional.

In the USA the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is still classified as MR unsafe due to the FDA-PMA change process.

A patient with the ARTIFICIAL*IRIS* can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla, 3 Tesla and 7 Tesla, with
- Maximum spatial field gradient of 200 G/cm (2 T/m)
- Maximum force product of 8,000,000 G^2/cm (8 T^2/m)
- Theoretically estimated maximum head averaged (HA) and whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Care has to be taken when moving the patient inside and outside the imaging area, because spatial field gradients for almost all scanners are higher than the limits defined here. However, these higher spatial field gradients could affect the patient only for a very short period of time (a few seconds) and for a very short distance (within a few centimeters).

V3.0/2020-03

Under the scan conditions defined above, the ARTIFICIAL*IRIS* device is expected to produce a maximum temperature rise of less than

- 1.7°C (2 W/kg, 1.5 Tesla (WBA)) RF-related temperature increase with a background temperature increase of 1.8°C (2 W/kg, 1.5 Tesla)
- 1.3°C (2 W/kg, 3 Tesla (WBA)) RF-related temperature increase with a background temperature increase of 1.3°C (2 W/kg, 3 Tesla)
- 0.6°C (2 W/kg, 7 Tesla (HA)) RF-related temperature increase with a background temperature increase of 0.5°C (2 W/kg, 7 Tesla)

after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 24.2 mm from the ARTIFICIAL*IRIS* when imaged with a gradient echo pulse sequence and a 7 Tesla MR system.

MICRO*SIL* DIAPHRAGM

The implant is MR compatible and shows no temperature rise, image artifacts or movement during an MRI scan. All tests were performed at 7 Tesla.

CAPSULAR TENSION RING

All capsular tension rings of the HumanOptics AG are MR compatible and show no temperature rise, image artifacts or movement during an MRI scan. All tests were performed at 7 Tesla.

KRUMEICH CORNEA*RING*

The implant shows no significant temperature rise, image artifacts or movement during MRI scans up to 3 Tesla.