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MRI Statement for Altomed Malhotra Platinum Segments ®

Non-clinical testing has demonstrated the Malhotra Platinum Segment® configurations up to a total weight of 2.0g are MR Conditional. Non-clinical testing demonstrated that the entire family of the Malhotra Platinum Segment® 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 or 3-Tesla
- Maximum spatial field gradient of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg in the Normal Operating Mode

Under the scan conditions defined, the Malhotra Platinum Segment® is expected to produce a maximum temperature rise of 2°C after 15-minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the Malhotra Platinum Segment® extends approximately 10-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

The Malhotra Platinum Eyelid Weight and may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury.