

Contour™ and ThinProfile™

GOLD AND PLATINUM
EYELID WEIGHT IMPLANTS



Patient MRI Safety Information

MRI (magnetic resonance imaging)

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MRI PATIENT SAFETY INFORMATION

You may safely receive a Magnetic Resonance Imaging (MRI) scan only under certain specific conditions. Scanning using different conditions may cause an injury. If you need an MRI scan, inform your doctor and the staff at the MRI facility that you have an implant. Provide your implant card and the information below to the MRI facility staff before receiving an MRI scan.

If you have any questions concerning your MRI scan please discuss these with your doctor and MRI facility staff.

MRI Safety Information applies to the MedDev *Contour*[™] and *ThinProfile*[™] Eyelid Weight Implant product families in Gold and Platinum. Testing was completed using the largest Eyelid Weight Implants available, in Gold (LL3028) and Platinum (LL5028). Using these implants represents a worst-case analysis.



MR Conditional

MedDev Gold *Contour*[™] and *ThinProfile*[™] Eyelid Weight Implants are MR Conditional.

Non-clinical testing demonstrated that the *Gold Contour*[™] Eyelid Weight Implant (LL3028) is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)(extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system
- Under the scan conditions defined about the *Gold Contour*[™] Eyelid Weight Implant (LL3028) is expected to produce a maximum temperature rise of 3.4°C after 15-minutes of continuous scanning (i.e., per pulse sequence)

ARTIFACT INFORMATION

In non-clinical testing, the image artifact caused by the *Gold Contour*[™] Eyelid Weight Implant (LL3028) extends approximately 5-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.



MR Conditional

MedDev Platinum *Contour*[™] and *ThinProfile*[™] Eyelid Weight Implants are MR Conditional.

Non-clinical testing demonstrated that the *Platinum Contour*[™] Eyelid Weight Implant (LL5028) is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)(extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system
- Under the scan conditions defined about the *Platinum Contour*[™] Eyelid Weight Implant (LL5028) is expected to produce a maximum temperature rise of 3.2°C after 15-minutes of continuous scanning (i.e., per pulse sequence)

ARTIFACT INFORMATION

In non-clinical testing, the image artifact caused by the *Platinum Contour*[™] Eyelid Weight Implant (LL5028) extends approximately 10-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.