

MRI Safety Information for MedDev Eyelid Weight Products

This MRI Safety Information was developed using non-clinical testing and received marketing clearance by the FDA in August 2015. This information is being provided as guidance for physicians, radiologists and MRI technologists with patients using only MedDev Eyelid Weight Products in the MR environment. The information is not intended for the patient. This information is applicable only to **MedDev** Eyelid Weight Products.

MRI Safety Information for Eyelid Weight Implants

MRI Safety Information applies to the product family MedDev *Contour*[™] and *ThinProfile*[™] Eyelid Weight Implants ranges listed below. Testing was completed using the largest weight, the 2.8 gram *Contour*[™] Eyelid Weight Implant, for a worst-case analysis.

Reference Number	Brand Name	Material
LL3006 – LL3028	Contour [™]	Gold
LL5006 – LL5028	Contour [™]	Platinum
LL4006 – LL4016	ThinProfile [™]	Gold
LL6006 – LL6018	ThinProfile [™]	Platinum



MR Conditional

MedDev's 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's 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.

MRI Safety Information for External Eyelid Weight Products (non-implantable)

MRI Safety Information applies to the product family External Eyelid Weights listed below.

Reference Number	Description
TEW6006 – TEW6028	Blinkeze™ External Lid Weights
TEW7000 – TEW7004	Standard and Special Sizing Sets



MR Unsafe

MedDev's External Eyelid Weights are MR Unsafe. A patient cannot safely receive an MRI scan while using the External Lid Weight. Using an External Lid Weight during an MRI scan may result in patient injury. Please remove the External Lid Weight prior to

entering the MR environment. During the MRI scanning process, protect the eye from drying with suitable eye drops or other means recommended by patient's physician.

Removal of External Lid Weight:

To avoid pulling the eyelid skin when removing the External Lid Weight, hold the ends of the weight with both fingertips and gently lift the weight off the eyelid starting from one end of the weight. Reapply the External Lid Weight after the MRI procedure is completed and the patient has left the MR environment.



730 North Pastoria Avenue
Sunnyvale, CA 94085
Tel: 800.543.2789 / 408.730.9702
Fax: 408.730.9732
Email: info@meddev-corp.com
Web: www.meddev-corp.com

Warranty and Limitation of Liability

MedDev Corporation represents that reasonable care was used in the development of the MRI Safety Information for MedDev Eyelid Weight Products. MedDev Corporation shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this MRI Safety Information.

MedDev Corporation neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this information.

MedDev Corporation assumes no responsibility for the management of the patient relative to the use of MRI. It is the sole responsibility of the radiologist and referring physician to manage the patient relative to the use of MRI.

MedDev Corporation provides this information on an "AS IS" basis. All warranties of any kind, expressed or implied, including but not limited to the IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, freedom from contamination by computer viruses and non-infringement of proprietary rights ARE DISCLAIMED.