

# Contour™ and ThinProfile™

GOLD AND PLATINUM  
EYELID WEIGHT IMPLANTS



## Instructions for Use

### PHYSICIAN INFORMATION

MedDev  
CORPORATION

**Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.**

### INSTRUCTIONS FOR USE

Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

### DESCRIPTION

MedDev Contour™ and ThinProfile™ Eyelid Weight Implants are designed for the treatment of lagophthalmos, i.e. the inability of the eyelid to fully close. Lagophthalmos usually results from facial paralysis, specifically, paralysis of the orbicularis oculi muscle.

Once surgically implanted, the MedDev Contour™ or ThinProfile™ Eyelid Weight Implant utilizes gravity to restore a passive blink function upon relaxation of the levator muscle. This restored blink function serves to lubricate and protect the cornea from ocular exposure. Functional deficits that may be corrected or minimized include: ocular irritation, conjunctival desiccation, conjunctivitis, keratitis, corneal ulceration, discomfort and epiphora.

MedDev Eyelid Weight Implants are manufactured from either pure gold or platinum (>99.99% purity) and are available in 0.2 gram increments from 0.6 grams to 2.8 grams. A description of the materials and sizes available in the Contour™ and ThinProfile™ Eyelid Weight Implants is listed in the section of this 'Instructions for Use (IFU)' titled, PRODUCT INFORMATION.

### INDICATIONS FOR USE

MedDev Contour™ and ThinProfile™ Eyelid Weight Implants are designed for the gravity-assisted treatment of protracted or permanent lagophthalmos, usually resulting from facial paralysis.

### CONTRAINDICATIONS

- MedDev Eyelid Weight Implants are not indicated for patients with a known allergic reaction or sensitivity to pure gold or platinum (>99.99%).
- Patients with an active infection affecting the eye or ocular adnexa.

### PRECAUTIONS/WARNINGS

MedDev Eyelid Weight Implants are to be implanted in a surgical asepsis state. Proper surgical procedure is to be followed to avoid site infection.

- MedDev Contour™ and ThinProfile™ Eyelid Weight Implants are intended as single use medical devices. Clinical reprocessing (cleaning, disinfection and re-sterilization) is not recommended. Reprocessing may compromise the implant and cause patient injury, even though the implant may appear undamaged.
- Reuse of MedDev Contour™ and ThinProfile™ Eyelid Weight Implants can create a risk of contamination due to the potential transmission of infectious material.
- Any MedDev implant that has become soiled by blood, tissue, or bodily fluids should not be used and should be handled according to hospital protocol.
- Responsibility for the diagnosis, treatment method, implant selection, and surgical technique rests solely with the physician. MedDev assumes no liability for decisions made by the physician when using MedDev Contour™ and ThinProfile™ Eyelid Weight Implants.
- Non-clinical testing has demonstrated that MedDev Gold (Contour™ and ThinProfile™) and Platinum (Contour™ and ThinProfile™) Eyelid Weight Implants are MR Conditional. A patient with this device can be scanned safely in a MR system immediately after placement using the specific testing parameters listed in the section of this 'Instructions for Use (IFU)' titled, MRI SAFETY INFORMATION.

### ADVERSE REACTIONS

There is always a possibility of adverse reaction to any surgically implanted material. Complications that may occur include:

- Excessive edema and erythema of the eyelid as a result of sensitivity to gold or platinum.
- Infection requiring revision, possible removal of the implant, or further procedures.
- Displacement or erosion of the implant through the skin, especially in patients with thin or atrophic tissues.
- Induced astigmatism from the implantation of excessive weight.

- Ocular irritation due to placement of insufficient weight.
- Induced ptosis resulting from a partial or complete postoperative return of the facial nerve function.

**Report any adverse incidents directly to MedDev Corporation at 800-543-2789**

### DIRECTIONS FOR USE

Weight Selection: The weight required for adequate eyelid closure is determined preoperatively by testing different weights on the upper eyelid using MedDev Tantalum Sizing Eyelid Weights (Cat.# TEW 7000/TEW 7004). The weight range and increment of MedDev Tantalum Sizing Eyelid Weights correspond to the range of weights available for eyelid implants. A correct weight selection will cause a slight degree of immediate postoperative ptosis, (~ 1 mm), during primary gaze which should resolve 1-2 months after surgical implantation.

Surgical Placement: MedDev Contour™ and ThinProfile™ Eyelid Weight Implants are designed to conform to the ocular globe. The eyelid weight implants may be placed in a septal, pretarsal or mid-pretarsal position; appropriate placement is a matter of individual physician preference to be determined in consultation with the patient.

Proper surgical technique is the responsibility of the physician. Each physician must evaluate the procedure based on previous medical training and experience.

### HOW SUPPLIED

Sterility: This device is steam sterilized. It is intended for single use only. Do not resterilize. Do not use if the package is open or damaged.

Contents: One (1) STERILE Eyelid Weight Implant individually sealed in a double pouch system. The package labeling indicates the catalog number, device size, implant material and manufacturer's lot number.

Storage: Store in original sealed box at normal room temperature (50° - 80° F, 10° - 27° C and relative humidity between 10 – 65%). Do not store in areas where condensation may occur. Do not store where the box may become crushed or damaged. Storage of the box outside of the recommended parameters may compromise the package integrity.

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1. Bair RL, Harris GJ, Lyon DB, Komorowski RA: Noninfectious inflammatory response to gold weight eyelid implants. Ophthalmic Plastic and Reconstructive Surgery, 11(3): pp 209-214, 1995.

2. Jobe RP: A technique for lid loading in the management of lagophthalmos of facial palsy. Plastic and Reconstructive Surgery, 53: pp 29-32, 1974.

3. Seiff SR, Sullivan JH, Freeman LN, Ahn J: Pretarsal fixation of gold weights in facial nerve palsy. Ophthalmic Plastic and Reconstructive Surgery, 5(2): pp 104-109, 1989.

4. Silver AL, Lindsay RW, Cheney ML, Hadlock TA: Thin-Profile platinum eyelid weighting: A superior option in the paralyzed eye. Plastic and Reconstructive Surgery, 123(6): pp 1697-1703, 2009.

5. Rofagha S, Seiff SR: Long-term results for the use of gold eyelid load weights in the management of facial paralysis. Plastic and Reconstructive Surgery, 125(1): pp 142-149, 2010.



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MRI Safety Information applies to MedDev Contour™ and ThinProfile™ Eyelid Weight Implant product families in Gold and Platinum. Testing was completed using the largest eyelid weight implant available, in Gold (LL3028) and Platinum (LL5028). Using these implants represents a worst-case analysis. The table below lists all products covered by this safety information.

Reference #	Brand Name	Material
LL3006 to LL3028	Contour™	Gold
LL5006 to LL5028	Contour™	Platinum
LL4006 to LL4016	ThinProfile™	Gold
LL6006 to LL6018	ThinProfile™	Platinum



**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 a 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 Implant (LL5028) is MR Conditional. A patient with this device can be scanned safely in a 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.

### LEGEND OF SYMBOLS USED



Sterilized using steam heat



Do not reuse, single-use device



Catalog number



Manufacturer's lot number



CAUTION, consult the instructions for use



Do not use if packaging is damaged



Authorized representative in the EU



Manufacturer, name, address, contact information



Use-by date



MR Conditional. Patient with this device can be safely scanned under specific conditions only. This symbol may have a yellow background

### MEDDEV EYELID WEIGHT IMPLANTS

#### ThinProfile™ Eyelid Weight Implants

GOLD		PLATINUM	
Catalog #	Description	Catalog #	Description
<i>(Standard sizes)</i>		<i>(Standard sizes)</i>	
LL 4006	0.6 g	LL 6006	0.6 g
LL 4008	0.8 g	LL 6008	0.8 g
LL 4010	1.0 g	LL 6010	1.0 g
LL 4012	1.2 g	LL 6012	1.2 g
LL 4014	1.4 g	LL 6014	1.4 g
LL 4016	1.6 g	LL 6016	1.6 g
		LL 6018	1.8 g

#### Contour™ Eyelid Weight Implants

GOLD		PLATINUM	
Catalog #	Description	Catalog #	Description
<i>(Standard sizes)</i>		<i>(Standard sizes)</i>	
LL 3006	0.6 g	LL 5006	0.6 g
LL 3008	0.8 g	LL 5008	0.8 g
LL 3010	1.0 g	LL 5010	1.0 g
LL 3012	1.2 g	LL 5012	1.2 g
LL 3014	1.4 g	LL 5014	1.4 g
LL 3016	1.6 g	LL 5016	1.6 g
LL 3018	1.8 g	LL 5018	1.8 g

<i>(Special sizes)</i>		<i>(Special sizes)</i>	
LL 3020	2.0 g	LL 5020	2.0 g
LL 3022	2.2 g	LL 5022	2.2 g
LL 3024	2.4 g	LL 5024	2.4 g
LL 3026	2.6 g	LL 5026	2.6 g
LL 3028	2.8 g	LL 5028	2.8 g

#### Tantalum Eyelid Weight Sizing Set \*

Catalog #	Description
TEW 7000	Standard Sizing Set - includes 7 weights from 0.6 grams to 1.8 grams, storage box, 100 adhesive strips and a skin tone selector card.
TEW 7004	Special Sizing Set - includes 5 weights from 2.0 grams to 2.8 grams, storage box, 100 adhesive strips and a skin tone selector card.

\* Tantalum eyelid weights are not for implantation.

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