

EXCHANGES

Blinkeze External Lid Weights can be exchanged for a weight of another size within the first 30 days of the original invoice date if it is determined the prescribed weight does not adequately close the patient's eyelid. For exchange instructions please call MedDev Customer Service. A Returned Goods Authorization (RGA) must be obtained from MedDev prior to returning the weight for exchange. Blinkenze External Lid Weights cannot be exchanged after 30 days from the original invoice date. Blinkenze External Lid Weights and EyeClose Adhesive Strips are not returnable.

PRODUCT INFORMATION

Blinkeze® External Lid Weights* (Non-Implantable)

CATALOG #	DESCRIPTION	NOMINAL LENGTH	WIDTH
<i>Standard Sizes</i>			
TEW 6006	0.6 grams	7.1 mm	5.0 mm
TEW 6008	0.8 grams	9.5 mm	5.0 mm
TEW 6010	1.0 grams	11.9 mm	5.0 mm
TEW 6012	1.2 grams	14.3 mm	5.0 mm
TEW 6014	1.4 grams	16.7 mm	5.0 mm**
TEW 6016	1.6 grams	19.0 mm	5.0 mm
TEW 6018	1.8 grams	21.4 mm	5.0 mm
<i>Special Sizes</i>			
TEW 6020	2.0 grams	23.8 mm	5.0 mm
TEW 6022	2.2 grams	26.2 mm	5.0 mm
TEW 6024	2.4 grams	28.6 mm	5.0 mm
TEW 6026	2.6 grams	30.9 mm	5.0 mm
TEW 6028	2.8 grams	33.3 mm	5.0 mm

* Weights are marked on the concave side with the weight in grams.

** Suggested order size

EyeClose® Double-Sided Adhesive Strips

CATALOG #	DESCRIPTION
LL 0505	Box of 100 strips (non-sterile)

PACKAGING

Blinkeze External Lid Weights are supplied NON-STERILE in a patient treatment kit. Each kit contains one hundred double-sided, hypoallergenic EyeClose® Adhesive Strips (non-sterile), an application mirror, and storage for an additional weight.

PROPER STORAGE

The Blinkenze External Lid Weight Treatment Kit should be stored at normal room temperatures between 50 – 80° F (10-27° C).

WARRANTY

MedDev Corporation warrants that reasonable care was used in the choice of materials and manufacture of this product. MedDev Corporation shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product other than its replacement should MedDev's investigation show that the product was defective at the time of shipment. The foregoing warranties as conditioned and limited are in lieu of and exclude all other warranties not expressly set forth herein whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for use.

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

CAUTION

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician. Blinkenze External Lid Weights are for external use only and not for implantation.

BIBLIOGRAPHY

1. Seiff SR, Boerner M, Carter SR. Treatment of Facial Palsies with External Eyelid Weights. American Journal of Ophthalmology, 120:pp 652-657, 1995.
2. Shepler, Seiff SR: Use of Isobutyl Cyanoacrylate Tissue Adhesive to Stabilize External Eyelid Weights in Temporary Treatment of Facial Palsies. Ophthalmic Plastic and Reconstructive Surgery, Vol. 17, No. 3: pp 169-173, 2001.

A more complete bibliography is available upon request.

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Blinkeze
EXTERNAL LID WEIGHTS

Three Decades
of Innovation

**PHYSICIAN
INFORMATION**

MedDev
CORPORATION

DESCRIPTION

Blinkeze® External Lid Weights are gravity-assisted eyelid weights designed to adhere to the pretarsal surface of the upper lid to provide passive closure of the eyelid when the levator muscle relaxes. By restoring a functional blink mechanism, the weight acts as “bandage” protection to help prevent decompensation of the corneal epithelium, and further ocular complications such as erosion, ulcers, perforations, reduction of visual acuity, and even blindness.

EyeClose® double-sided, hypoallergenic adhesive strips (MedDev catalog # LL 0505) provide a convenient and reliable method of securing Blinkeze External Lid Weights to the pretarsal surface of the upper eyelid. The external weight can be worn on a continuous basis by patients with temporary paralysis or as a permanent treatment for patients who are not suitable candidates for the surgical procedure. The external weight can also be worn as a trial before implantation to confirm adequate closure.

Blinkeze External Lid Weights are manufactured from pure tantalum, a dense, inert metal with high biocompatibility. The weight's exterior surface is painted in a selection of skin-tones to approximate a patient's complexion. Weights range from 0.6 g to 2.8 g in 0.2-g increments.

INDICATIONS AND USAGE

Blinkeze External Lid Weights are indicated for the non-surgical treatment of the functional deficits of lagophthalmos, usually resulting from facial paralysis, specifically the orbicularis oculi muscle. Paralysis may arise from facial nerve injury occurring from Bell's palsy, stroke, trauma, congenital defect, surgical nerve damage, tumor invasion, and resection of tumors (i.e. acoustic neuroma and parotidectomy).

Functional deficits which may be corrected or avoided with the use of Blinkeze External Lid Weights include: inadequate eyelid closure, impaired corneal lubrication, serious keratopathy, ocular irritation, keratitis, corneal abrasion, corneal ulceration, and decreased vision due to ocular exposure.

CONTRAINDICATIONS

Blinkeze External Lid Weights are contraindicated for patients with:

- Excessively wrinkled or sagging eyelid skin (dermatochalasis).
- A known hypersensitivity to tantalum or adhesive.

PRECAUTIONS/WARNINGS

- Use of Blinkeze External Lid Weights should be discontinued if persistent eyelid irritation occurs.
- Blinkeze External Lid Weights are not suitable for patients with dermatochalasis as the weight may droop into the visual axis and obscure vision.
- Patients with prolonged paralysis may require reevaluation and possible replacement of a Blinkeze External Lid Weight with a surgically implanted gold or platinum weight.

ADVERSE REACTIONS

In rare cases, hypersensitivity to tantalum or adhesive may result in contact dermatitis. Other complications, while rare, may also occur and are typically alleviated by re-evaluation or discontinued use of the Blinkeze External Lid Weight:

- Excessive edema and erythema of the eyelid as a result of sensitivity to tantalum or adhesive
- Induced astigmatism from the placement of excessive weight
- Ocular irritation due to insufficient eyelid closure from the placement of a weight that is too light
- Blurred or obscured vision

WEIGHT SELECTION

MedDev Corporation conducted a survey of the most popular Blinkeze External Lid Weights ranging from 0.6 g to 2.8 g (in 0.2 g increments) prescribed over a 10-year period. The survey found weights in the range from 1.0 g to 1.4 g to be the most commonly ordered (see figure 1). Based on these findings, *MedDev suggests prescribing the 1.4 g weight at the upper end of the medium range to satisfy 81% of all non-surgical applications.*

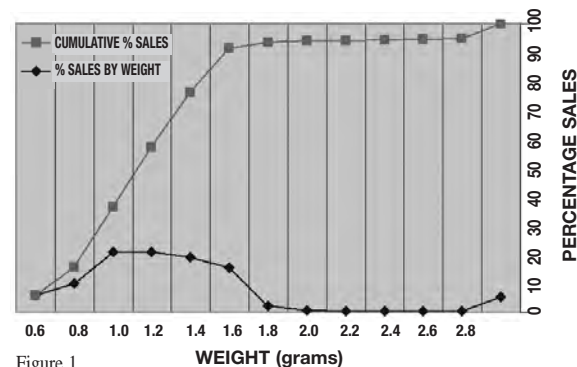


Figure 1

It is important to confirm that the weight adequately closes the patient's eyelid prior to the patient wearing the 1.4 g weight. This is determined by testing the patient with the 1.4g weight.

1. Place the EyeClose Adhesive Strip on the concave side of the 1.4 g Blinkeze External Lid Weight. (See *EyeClose® Adhesive Strip insert for instructions*).
2. With the patient sitting upright, secure the weight to the upper eyelid above the lash line, centered at the junction of the medial and central thirds of the eyelid (see Figure 2). At this point extension of the levator muscle is maximal.
3. Note the position of the eyelid as the patient looks up and down.
4. Because the levator strengthens after the weight is added, the correct weight closes the eyelid without difficulty while also inducing a slight ptosis of no more than 1.0 mm during primary gaze. The ptosis typically resolves as the weight is worn over a 1 to 2 month period.



Figure 2

If the 1.4 g weight does not adequately close the patient's eyelid, the weight can be exchanged for a weight of another size within the first 30 days from the original invoice date. A Tantalum Eyelid Weight Sizing Set (MedDev catalog #TEW7000/7004) can be requested at no cost for a 3-week loan period for use to determine the new weight.

SKIN TONE SELECTION

A Skin Tone Selector Card is used to determine the appropriate skin tone color for the exterior surface of the Blinkeze External Lid Weight. The selector card is included in the Tantalum Eyelid Weight Sizing Set or can be ordered separately from MedDev at no charge. The corresponding skin tone suffix is added to the end of the catalog number when ordering (i.e. TEW 6012-1):

-1 Pink/Neutral -2 Tan -3 Med Brown -4 Dk Brown

ORDERING

Blinkeze External Lid Weights are available only on order of a physician. Patients with a prescription may order directly from MedDev Corporation by calling MedDev Customer Service at 800.543.2789 (M-F 8:30 am to 5 pm PST). Payment can be made by credit card, or by mailing a check or money order in advance to MedDev Corporation.