Instructions for Use
0006629_3 — 2026-08
EN

Upper Eyelid Implant

Upper eyelid implant and accessories

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36028798120144779 —20.08.2026 16:10

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1 About this Document

1.1 Symbols Glossary

Symbol	Description
	Caution: Consult Instructions for Use
	Fragile; handle with care
	Do not use if package is damaged
	Keep away from direct sunlight
	Keep dry
	Use-by date
	Sterilized using irradiation
	Do not reuse
	Do not resterilize
	Single sterile barrier system
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system with protective packaging outside
	MR conditional
	Medical device
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Quantity per packaging unit
	Manufacturer
	Date of manufacture
	(USA) Caution: Federal Law restricts this device to sale by or on the order of a physician.
	Consult Instructions for Use. The Instructions for Use are provided in electronic form (e-labelling).
	Patient name
	Date of implantation
	Name of the implanting healthcare institution / provider
	Patient information website

Table 1: Symbols Glossary

1.2 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of the general condition or the death of the patient, user, or a third party.

1.3 Additional Information

This document is available in electronic form on the manufacturer's website. If required, a printed copy of this document can be requested from the manufacturer.

Download link for these Instructions for Use:[1)]	www.kurzmed.com/en/ifu/eye.html
Download link for the processing instructions: [1)]	www.kurzmed.com/en/ifu/reprocessing.html
 Download link for the Patient Information Document:[1)]	www.kurzmed.com/en/pi/eye.html
Disclaimer for the availability of the SSCP	As a general rule: The SSCP will only be made available after the product has been authorised in accordance with REGULATION (EU) 2017/745 (MDR). The implementation described here does not apply until the corresponding module of the Eudamed database comes into force. Until then, the SSCP is available at the following download link: www.kurzmed.com/en/sscp/eye.html
Summary of Safety and Clinical Performance (SSCP): [1)]	https://ec.europa.eu/tools/eudamed To search for the product-specific SSCP, enter the basic UDI-DI of the product.
Basic UDI-DI (device identifier):	++EHKM0047K
International addresses:	https://www.kurzmed.com/en/contact.html

[1)] Updated on an ongoing basis. Other language versions are also available there.

For the complete UDI (UDI-PI) please refer to the product label.

1.4 Safety-related Changes

Document number	Edition date	Safety-related Changes
0006629_ 1	2025-12	Initial edition
0006629_ 2	2026-02	None
0006629_ 3	2026-08	Added: WARNING: Apart from the specific provisions on MRI safety, the following applies: Do not expose the product to diagnostic or therapeutic electromagnetic radiation.

2 Important Safety Information

⚠ WARNING

- Before using the product, read the Instructions for Use. Adhere to and save the Instructions for Use.
  Otherwise there are risks to the health of your patient.
- Do not disassemble or modify the product.
  Otherwise there are risks to the health of your patient.

ATTENTION: In case that any serious incident has occurred in relation to the device the incident should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

3 Product Codes / REF

[▸Specifications, page 10]

4 Scope of Delivery

Upper Eyelid Implant	1 x upper eyelid implant 1 x implant card 4 x product label
Test Weight Set (accessory)	5 x test weights 1 x storage box with POM insert

5 Packaging and Sterility

Upper Eyelid Implant	Sterile, sterilized using irradiation. Packaging: Single sterile packaging with protective packaging on the inside (prosthesis in a plastic box in hard blister) + outer packaging (folding box)
Test Weight Set (accessory)	The product is not sterile. Packaging: Storage box + bag with press-fit closure

6 Product Description

6.1 General Information

Illustration 1: Upper Eyelid Implant: Upper eyelid implant with suture holes

Illustration 2: Test Weight Set: Test weights in the storage box

6.2 Structure and Operation

Upper Eyelid Implant	The implant uses gravity to help restore lid closure and blinking of the upper eyelid. The implant is inserted into the pocket formed on the tarsal plate in the middle of the upper eyelid. The implant is attached to the plate with a suture.
Test Weight Set (accessory)	Test weights are supplied as a set of reusable devices of different weights (corresponding to the actual implants). During preoperative implant selection, test weights are removably attached to the upper eyelid to assess eye opening/closure.

6.3 Materials with Potential Patient Contact

The following table lists all materials of the implant with which the user or the patient has contact during use, either for every application ("standard") or in case of a damage to the product ("potentially").

Product (part)	Material	Contact person	Type of contact
Upper Eyelid Implant	100 % Platinum-iridium	Patient	Standard

Test Weight Set: [Specifications, page 10]

Not made with natural rubber (latex).

No products made with natural rubber (latex) are used in the production process.

ATTENTION: Do not use the product if the patient has known intolerances / allergies to the materials used.

6.4 Accessories

	Test Weight Set [Selecting the Implant, page 8] [Specifications, page 10]

6.5 Other Devices to be Used in Combination with the Device

With the exception of equipment and materials required for implantation, the product is not intended for use in conjunction with any other products.

7 Intended Use

7.1 Intended Purpose

Upper Eyelid Implant	Ophthalmology Implant: The upper eyelid implants are intended for the gravity-assisted treatment of insufficient upper eyelid closure.
Test Weight Set (accessory)	The Test Weights are designed to select the appropriate KURZ Upper Eyelid Implant preoperatively.

7.2 Indications

Absence or loss of innervation and function of the orbicularis oculi muscle (lagophthalmos) due to facial palsy (congenital or acquired).

7.3 Contraindications

- Known sensitivity or allergy to platinum/iridium
- Lid closure unsuccessful with test weight
- Impaired wound healing
- Acute and chronic infections

7.4 Patient Target Group

- Children and youth
- Adults
- Patients of any gender

7.5 Intended User

The intended user is a physician with experience in treating similar cases with this product or with comparable products or a physician with the following specialty:

- ENT (otorhinolaryngology)
- Ophthalmologist

7.6 Expected Lifetime

Upper Eyelid Implant	No product-specific restrictions. Regular check-ups are needed.
Test Weight Set (accessory)	Frequent processing has little impact on these instruments. The end of the product lifetime is usually based on wear and tear as well as damage from use. Please refer to the processing instructions.

7.7 Intended Place of Use

Upper Eyelid Implant	Operating theatre

Test Weight Set (accessory)	Examination room (doctor's practice / outpatient area)

It is the responsibility of the user to decide on a case-by-case basis which precautions must be taken for any complications that may arise.

8 Expected Clinical Benefit

According to the clinical evaluation, the product can be used safely and effectively for treatment according to the indications mentioned.

9 Possible Complications and Side Effects

- Inflammation (irritation of tissue)
- Implant extrusion
- Migration
- Contouring
- Ptosis
- Astigmatism

10 Combining with Other Procedures

⚠ WARNING

- Laser therapy, high-frequency surgery, and other procedures, the effect of which is due to heat: Do not use those methods directly on the product.
  Otherwise, injury to the tissue and product damage are possible.
- Apart from the specific provisions on MRI safety, the following applies: Do not expose the product to diagnostic or therapeutic electromagnetic radiation.
  Otherwise there are risks to the health of your patient.
- The product is MRI conditional. Use the product in MRI fields only as per specification.
  Possible consequences of using the product in MRI fields outside the specifications include: Heating of the product, electrostatic discharges, consequential damages caused by the application of force to the product, errors in the imaging (also in the surrounding tissue)

For important information about MRI see:
http://www.kurzmed.com/de/mr-information.html

11 Shelf Life and Storage

For date of expiry, see the product label.
Store the product in original packaging.
Store the product in a dry place and protect it from sunlight.

12 Processing

Upper Eyelid Implant:

⚠ WARNING

- Single use product: Do not process (e.g., clean, disinfect, sterilize), resterilize or reuse the product.
  This is the only way to ensure the product is germ-free and functional. Due to the mechanical properties of the product, processing or resterilization could lead to material degradation.

Test Weight Set:

⚠ WARNING

- The product is not sterile. Process the product before first and any further application.
  This is the only way to ensure the product is germ-free and functional. Process in accordance with the processing instructions document. [Additional Information, page 4]

13 Application Instructions

⚠ WARNING

- Do not use the product if the packaging or the product is damaged or expired.
  This is the only way to ensure the product is germ-free and functional.

- Only remove the product from storage packaging immediately before use. When the product is removed from the packaging, observe the relevant hygienic regulations.
  Otherwise there are risks to the health of your patient.

Ensure the presence of hygienic / sterile conditions needed for the intervention.

13.1 Required Equipment and Materials

- As is customary for eyelid surgery.
- Monofilament, non-absorbable thread 8-0
- Test Weight Set
- Double-sided medical adhesive tape

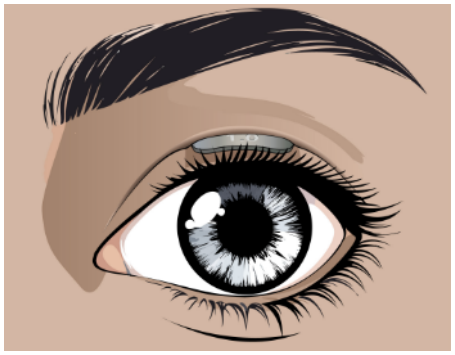
13.2 Preparation of the Patient

As is customary for eyelid surgery.

13.3 Selecting the Implant

Determine the appropriate weight of the implant using test weights during a preoperative functional examination..
ATTENTION: Perform the functional test before local anaesthesia.

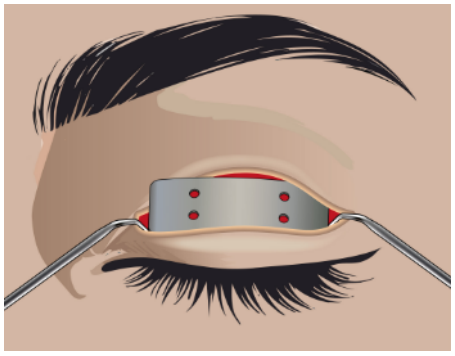
1. Place different test weights one after the other in the centre of the upper eyelid, above the pupil line. To do this, fix the test weight in place using double-sided medical adhesive tape so that it can be removed without leaving any residue.
2. A suitable weight is achieved when the eyelid closes completely and the palpebral fissure can be opened fully.
   Weight too low: A complete eyelid closure is not achieved.
   Weight too high: The palpebral fissure becomes smaller.



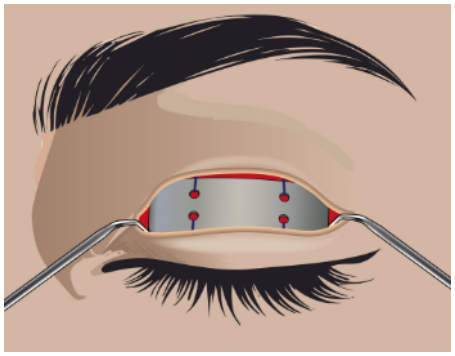
ATTENTION: The test weights are used solely to determine the required implant weight and are not intended for implantation.

13.4 Placing the Implant

1. Make an skin incision in the crease of the upper eyelid.
   Length: Length of the implant + approx. 3 mm



2. Prepare a pocket, expose the tarsus and insert the implant.



3. Fix the implant to the tarsus using non-absorbable suture material through all 4 suture holes. Ideally, use all 4 suture holes.

4. Close the wound.

13.5 Removing the Prosthesis

The prosthesis is intended to remain in the body. However, should it nevertheless be necessary to remove the prosthesis:
Before removing the prosthesis: Loosen any adhesions.
Follow-up treatment at the discretion of the treating physician.

14 Aftercare

- Follow-ups as indicated by the treating physician.

15 Instructing the Patient

ATTENTION: Also inform the patient about the consequences of combining with other procedures.
Implant card: [Implant Card, page 9]

16 Implant Card

1. Stick one of the product labels provided into the designated box on the implant card. Complete all other sections.

The implant card must be presented at every radiological examination.

17 Follow-up measures after removal of the product

The product is basically intended to remain in the body, but can be removed if necessary. In this case the follow-up treatment is at the discretion of the treating physician.

18 Disposal

⚠ WARNING

- The product was in contact with potentially infectious substances of human origin. Clean/pack the product for disposal according to the specific contamination risk. Dispose of the product in accordance with procedures for hazardous waste in hospitals.
  Otherwise there is a risk of infection for the user and for third parties.

Disposal must be in accordance with national disposal regulations and pursuant to the corresponding risk class.

19 Warranty

The reliability of the product's material and design at the time of shipment is guaranteed. The manufacturer does not know either the diagnosis of the patient or the nature of the application and has no influence on the conditions under which the product is used. The storage conditions after delivery of the product are also beyond the manufacturer's area of responsibility.
Due to biological and individual differences, no product is 100% effective under all circumstances.

Therefore, the manufacturer cannot guarantee a positive effect or the absence of negative effects for product application. The medical staff must use the product on the basis of their medical training and experience, and they are responsible for correct application.

The warranty (repair or replacement) applies only if the product is used in accordance with these Instructions for Use (for instruments, particularly with regard to handling, cleaning, sterilization and maintenance); the warranty period starts on the delivery date.

If you have reason to believe that a new product is faulty, please contact the Customer Service in writing immediately and provide as detailed a description as possible of the fault, the REF (product code), and the LOT (batch code) and/or series number. All allegedly defective products must be returned to us for inspection. Instruments have to be completely cleaned and sterilized, appropriate documentation must be enclosed with the return.

If the manufacturer finds that despite all due care the product was defective at the time of delivery, he will repair the product or replace it promptly. If repair or replacement of the product is not possible, the buyer has the right to cancel the purchase or to reduce the payment, but by a maximum of the purchase price amount.

Additional claims or those not mentioned here due to defect, and other claims regardless of the legal reason, including those based on illegal acts and for compensation of immaterial damages against the manufacturer, his agents, dealers and suppliers, are excluded unless existing law is contrary to the liability exclusion, e.g. in cases of intent or gross negligence or in the event of physical injury.

All claims based on the consequences of non-compliance with the Instructions for Use, including specified indications, contraindications, warnings, instructions, application, storage and off-label use, as well as the consequences of a combination with third-party products are excluded.

Furthermore, all claims that result from the use of products that have expired, or were used despite the obvious damage to the packaging, or resterilized and/or recycled contrary to the Instructions for Use, are excluded.

No one is allowed to change the above conditions, make further warranty or liability declarations, or guarantee any properties that surpass those specified in the Instructions.

20 Specifications

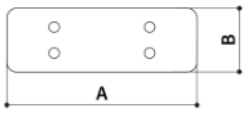
	REF	Weight [g]	A [mm]	B [mm]
	4007 002	0.6	15	5.2
	4007 003	0.8	15	5.2
	4007 004	1.0	15	5.2
	4007 005	1.2	18	5.2
	4007 006	1.4	20	5.2
	4007 007	1.6	20	5.2
	4007 008	1.8	23.7	5.2
	4007 009	2.0	23.7	5.2
	4007 010	2.2	25.7	5.2
Material: Platinum-iridium				

Table 2: Upper Eyelid Implant

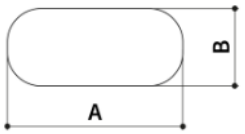
		Weight [g]	A [mm]	B [mm]
	8000 111	0.8	11.3	6.0
		1.0	14.0	6.0
		1.2	16.4	6.0
		1.4	18.0	6.0
		1.6	20.7	6.0
Material: Stainless steel				

Table 3: Test Weight Set (accessory)