Patient Information Document

0006626_3 — 2026-08

EN

Upper Eyelid Implant

Upper eyelid implant

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GERMANY

18014399657549067 —31.08.2026 09:46

1 Dear Patient,

You have been given an implant of the type Upper Eyelid Implant. For your own safety, please read this Patient Information Document carefully and keep it somewhere safe. If you have any questions about your implant, please contact the physician who treats you.

2 About this Document

2.1 Symbols Glossary

Symbol	Description
	MR conditional
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Manufacturer
	Patient name
	Date of implantation
	Name of the implanting healthcare institution / provider
	Patient information website

Table 1: Symbols Glossary

2.2 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of your general condition or your death.

2.3 Additional Information

Download link for the Patient Information Document:[1)]	www.kurzmed.com/en/pi/eye.html
This patient information is based on the following instructions for use:	0006629_3 (2026-08)
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

[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.

The catalog number and batch code for your implant can be found on your implant card.

3 What you need to pay attention to

1. Always carry your implant card with you. Show your implant card and this Patient Information Document to your treating physician before undergoing diagnostic or therapeutic procedures.
2. Contact your doctor if you experience one or more of the following symptoms: Redness / itching / strong feeling of pressure / pain in the upper eyelid, drooping upper eyelid, blurred vision, contours of the implant visible through the eyelid
3. Stick to the appointments you make with your treating physician for follow-up examinations and observe their instructions for any necessary follow-up measures.

ATTENTION: Your implant must be monitored regularly by your attending physician. Be sure to keep your appointments for these follow-up examinations and follow your physician's advice on the necessary aftercare measures.

4 Product Description

4.1 General Information

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

4.2 Materials with Potential Patient Contact

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

5 Intended Use

5.1 Patient Target Group

- Children and youth
- Adults
- Patients of any gender

5.2 Expected Lifetime

No product-specific restrictions.
Regular check-ups are needed.

6 Expected Clinical Benefit

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

7 Possible Complications and Side Effects

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

8 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

9 Other Residual Risks

Beyond the listed safety instructions, possible complications and side effects, no further significant residual risks are known.

10 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.

11 Specifications

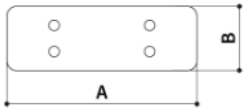
	REF	Weight [g]	A [mm]	B [mm]
	4007 002	0.6	15	5.2
	4007 003	0.8	15	5.2
	4007 004	1.0	15	5.2
	4007 005	1.2	18	5.2
	4007 006	1.4	20	5.2
	4007 007	1.6	20	5.2
	4007 008	1.8	23.7	5.2
	4007 009	2.0	23.7	5.2
	4007 010	2.2	25.7	5.2
Material: Platinum-iridium				

Table 2: Upper Eyelid Implant