Patient Information Document
CMLMPI0002-2 — 2024-04
EN

Custom-made device

aixstent® OES

Esophageal Stent

aixstent® OEL

Esophageal Leakage Stent

aixstent® OEC

Cardia Umbrella Stent

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1 Dear Patient,

You have been given an implant of the type aixstent OES / OEL / OEC (custom-made device). 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 unsafe
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Manufacturer
	Distributor
	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.leufen-medical.eu/pi/cmlmpi0002
This patient information is based on the following instructions for use:	CMLMGB0002-3

[1)] Updated on an ongoing basis.

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

3 What you need to pay attention to

3.1 General

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. Stick to the appointments you make with your treating physician for follow-up examinations and observe their instructions for any necessary follow-up measures.
3. Contact your doctor if you experience one or more of the following symptoms: Foreign body sensation, pain (also in the chest area), bleeding, difficulties swallowing, breathing difficulties, fever

ATTENTION: Your aixstent OES / OEL / OEC 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. This is especially true when the intended lifetime of your aixstent OES / OEL / OEC has been reached ([▸Expected Lifetime, page 3]).

3.2 Diet

1. Do not eat liquid food until at least 4 hours after implantation.
2. Discuss with your physician when you can start eating solid food. As a general rule, you can eat solid food when the stent is securely and stably in place.
3. Do not consume cold drinks until at least 3 days after implantation. Otherwise the expansion force of the stent will be impaired and the stent will not achieve a stable and secure fit.

4 Product Description

4.1 General information

- Self-expanding, woven metal stent
- Without cover / with partial / with complete silicone cover (depending on specifications)
- Atraumatic ends
- Extraction threads at both ends (depending on specifications)
- Tantalum X-ray markers (depending on specifications)

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
Struts	100% Nitinol[1)]	Patient	Stents with complete cover: In the event of product damage Stents without complete cover: With every use
Coating	100% implant-grade silicone	Patient	With every use
X-ray markers	100% Tantalum	Patient	Potentially (stents with complete cover) / standard (stents without complete cover)
Extraction threads	100% stainless steel, surgical quality	Patient	With every use

[1)] Potentially sensitizing / allergenic material

5 Intended Use

5.1 Intended Purpose

The stent is intended to maintain or enable the patency of natural and artificial lumen in the body and/or to cover pathological changes.

5.2 Patient Target Group

The product is suitable for the following patient groups:

- Children and youth
- Adults
- Patients of all genders

Custom-made device. The suitability of the product for the patient must be checked and confirmed by the prescribing physician/facility.

5.3 Expected Lifetime

Expected lifetime of the product: 12 months

The likelihood of complications and product damage increases with increasing application duration.

Stents without complete cover:

The product is intended to remain in the body.

Stents with complete cover:

Unless an earlier replacement is needed, it is recommended to replace the product after 12 months as a precautionary measure.

6 Possible Complications and Side Effects

- Stent breakage
- Bleeding
- Perforations
- Stenosis due to insufficient stent expansion
- Stent migration
- Formation of granulation tissue
- Ingrowth of / overgrowth with tissue
- Infection / fever
- Foreign body sensation
- Persistent pain, also in the chest area
- Stent obstruction due to food
- Stent occlusion
- Regurgitation
- Recurring dysphagia
- Pneumonia
- Mediastinitis
- Esophagitis
- For **aix**stent OEC: Reflux, long-term drug therapy is needed

Other known complications such as in endoscopic interventions.
Inter-individual differences in comorbidities and complications may result in some complications becoming more difficult to manage. In rare and extreme cases, this may result in death.

7 Combining with Other Procedures

⚠ WARNING

- Laser therapy, argon plasma coagulation, high-frequency surgery, cryotherapy and other procedures, the effect of which is due to heat or cold: Do not use those methods directly on the product.
  Otherwise, injury to the tissue and product damage are possible.
- MRI safety of the product has not been proven. Therefore, the product must be considered MRI unsafe and must not be used in MR fields.
  The possible consequences of the application of non-MRI safe products in MR-fields include: Heating of the product, electromagnetic discharges, consequential damages caused by the application of force to the product, interferences in the imaging (also in the surrounding tissue).

Any method for reducing tissue, such as chemotherapy or radiation therapy, can lead to stent migration.

8 Other Residual Risks

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

9 Follow-up measures after removal of the product

Stents with complete cover:
The follow-up measures after removal of the product will depend on your underlying disease as well as your general health and shall be at the discretion of your treating physician.
Stents without complete cover:
The product is intended to remain in the body.