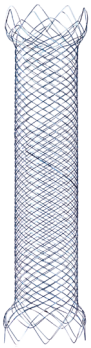
Patient Information Document

LMPI0005-4 — 2025-07

EN

aixstent® DUS

Duodenum Stent



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1 Dear Patient,

You have been given an implant of the type aixstent DUS. 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
	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/lmpi0005
This patient information is based on the following instructions for use:	LMGB0005-12
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.leufen-medical.eu/sscp/sscp0005
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):	4063106ASTAIXMP

[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, bleeding, nausea, vomiting, fever

ATTENTION: Your aixstent DUS 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 DUS has been reached ([▸Expected Lifetime, page 3]).

3.2 Diet

1. Eat a low-fibre diet.

4 Product Description

4.1 General information

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

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
Struts	100% Nitinol[1)]	Patient	With every use
Coating (stents with coating only)	100% implant-grade silicone	Patient	With every use
X-ray markers	100% Tantalum	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 use in the following patient groups:

- Adults
- Patients of all genders

5.3 Expected Lifetime

Expected lifetime of the product: 12 months
The product is intended to remain in the body.

6 Possible Complications and Side Effects

The following product-related complications are known:

- Stent breakage
- Bleeding
- Perforations
- Stenosis due to insufficient stent expansion / kinking of the stent
- Stent migration
- Ingrowth of / overgrowth with tissue
- Infection / fever
- Foreign body sensation

- Persistent pain
- Stent occlusion
- Cholangitis
- Cholecystitis
- Pancreatitis
- Liver abscess
- Subcapsular liver hematoma
- Sepsis
- Nausea
- Vomiting

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.
- 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:
https://www.leufen-medical.eu/dus
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.