Patient Information Document

LMPI0008-3 — 2023-11

EN

aixstent® BDS

Bile Duct Stent

aixstent® BDP

Bile Duct Stent, percutaneous

bess pro gmbh
Gustav-Krone-Str. 7
D—14167 Berlin
Germany

Leufen Medical GmbH
Gustav-Krone-Str. 7
D—14167 Berlin
Germany
Tel.: +49 30 816 90 93 00
Fax: +49 30 816 90 93 93
www.leufen-medical.eu
contact@leufen-medical.eu

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a bess group company

1 Dear Patient,

You have been given an implant of the type aixstent BDS / aixstent BDP. 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/lmpi0008
This patient information is based on the following instructions for use:	LMGB0008-8
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):	4063106AST8Z
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/sscp0008

[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 must look out for

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: Bleeding, pain, fever
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 aixstent BDS / aixstent BDP 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 BDS / aixstent BDP has been reached ([Expected Lifetime, page 3]).

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
- Tantalum X-ray markers

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 (stents with coating only)	100% implant-grade silicone	Patient	With every use
X-ray markers	100% Tantalum	Patient	Potentially (stents with complete cover) / standard (stents without complete cover)

[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 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.

Duration of treatment at the discretion of the treating physician.

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

- Bleeding
- Perforations
- Stenosis due to insufficient stent expansion
- Stent migration
- Ingrowth of / overgrowth with tissue
- Infection / fever
- Persistent pain
- Stent occlusion, especially with aixstent BDS, with the possible consequence of cholangitis, cholecystitis, pancreatitis
- Cholangitis
- Cholecystitis
- Pancreatitis
- Biliary peritonitis
- Haemobilia
- Liver abscess
- Subcapsular liver hematoma
- Ulcerations

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.

8 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, electromagnetic 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:
aixstent BDS: https://www.leufen-medical.eu/bds
aixstent BDP: https://www.leufen-medical.eu/bdp
Any method for reducing tissue, such as chemotherapy or radiation therapy, can lead to stent migration.

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

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.