Patient Information Document
CMLMPI0008-1 — 2021-07
EN

Custom-made device

aixstent® BDS
Bile Duct Stent

aixstent® BDP
Bile Duct Stent, percutaneous

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LEUFEN creating stability
a bess group company

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1 Dear Patient,

You have been given an implant of the type aixstent BDS / BDP (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 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. If you experience any discomfort, contact your treating physician.
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 / 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.

3 Important information for your treating physician

⚠ WARNING

- Laser therapy, argon plasma therapy, 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.

4 About Your Implant

4.1 Product Description

4.1.1 General information

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

4.1.2 Material

- Stent: Nickel titanium alloy (nitinol)
- Cover: Silicone
- X-ray markers: Tantalum

4.2 Intended Application Duration

Maximum application duration: 12 months

The actual application duration depends on your underlying disease as well as your general health and is at the discretion of your treating physician.

4.3 Follow-up measures after removal of the product

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.

5 About this Document

5.1 Symbols Glossary

Symbol	Description
	MR unsafe
	Catalog number

Symbol	Description
	Batch code
	Manufacturer
	Distributor
	Patient name
	Implantation date
	Name of facility through which the implantation was performed
	Patient Information Website

Table 1: Symbols Glossary

5.2 Safety Information Marking

⚠ WARNING

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

5.3 Additional Information

You can always find the latest version of this document here:

Download link for the Patient Information Document:	www.leufen-medical.eu/pi/cmlmpi0008

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