

aerstent[®] TBS

Trachea Bronchus Stent



aerstent[®] TBJ

J Carina Stent



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a bess group company

1 Dear Patient,

You have been given an implant of the type aerstent TBS / TBJ. 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/lmpi0003
This patient information is based on the following instructions for use:	LMGB0003-14
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/sscp0003

¹⁾ Updated on an ongoing basis.

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

For Australia: In case that any serious incident has occurred in relation to the device the incident should be reported to the manufacturer and to the competent authority of the Member State in which you live. <https://www.tga.gov.au/>

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. To prevent any encrustation, perform regular damp inhalations with saline.
3. Contact your doctor if you experience one or more of the following symptoms: Foreign body sensation, halitosis (bad breath), bleeding, coughing, pain in the throat area, pain when speaking / articulation problems, shortness of breath, fever
4. 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 aerstent TBS / TBJ 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 aerstent TBS / TBJ has been reached ([▶Expected Lifetime, page 3]).

4 Product Description

4.1 General information

- Self-expanding, woven metal stent
- Complete cover
- Atraumatic ends
- Tantalum X-ray markers (aerstent TBJ only)

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
Struts	100% Nitinol ¹⁾	Patient	In the event of product damage
Coating	100% implant-grade silicone	Patient	With every use
X-ray markers (aerstent TBJ only)	100% Tantalum	Patient	In the event of product damage

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:

- Children and youth
- 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.

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

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

The following product-related complications are known:

- Stent breakage
- Bleeding
- Perforations

- Stenosis due to insufficient stent expansion
- Stent migration
- Formation of granulation tissue
- Ingrowth of / overgrowth with tissue
- Secretion obstruction
- Infection / fever
- Foreign body sensation
- Persistent pain
- Restenosis due to progressive tumor growth
- Halitosis
- Stent occlusion
- Decay of the cover due to microbial colonisation
- Mediastinitis
- Vocal chord edema
- Coughing

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 (e.g. tracheal closure). 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:

aerstent TBS: <http://www.leufen-medical.eu/tbs>

aerstent TBJ: <http://www.leufen-medical.eu/tbj>

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.