Patient Information Document

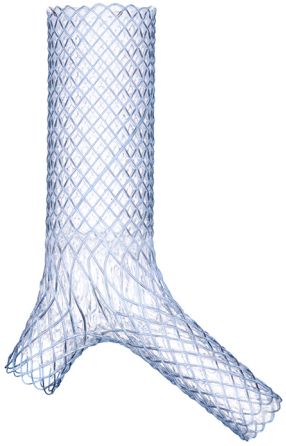
CMLMPI0009-2 — 2022-01

EN

Custom-made device

aerstent® TBY

Y Carina Stent



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

a bess group company

81064793763506571 —24.01.2022 16:35

1 Dear Patient,

You have been given an implant of the type aerstent TBY (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
	Manufacturer
	Distributor
	Patient name
	Implantation date
	Name of facility through which the implantation was performed
	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.

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
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 TBY 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 TBY 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)
- 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	With every use
Coating	100% Polyurethane	Patient	With every use

Product (part)	Material	Contact person	Type of contact
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 the patency of the target organ 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: 12 months

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

6 Expected Clinical Benefit

According to the clinical evaluation of the underlying standard product aerstent TBY the underlying standard product aerstent TBY an be easily and safely applied to close defects of the trachea and the bronchi and to keep the trachea and the main bronchi open.

7 Possible Complications and Side Effects

- Stent breakage
- Bleeding
- Perforations
- Stent migration
- Tracheal obstruction
- Formation of granulation tissue
- Ingrowth of / overgrowth with tissue
- Secretion obstruction
- Infection
- Foreign body sensation
- Persistent pain
- Restenosis due to progressive tumor growth
- Halitosis
- Decay of the cover due to microbial colonisation

Other known complications such as in endoscopic interventions.

Special caution recommended in the following cases:

- Severe cardiopulmonary dysfunction
- Ulcer in the target area or in the access to the target area
- Massive bleeding or blood clotting disorders

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.

- 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.

9 Other Residual Risks

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

10 Additional Information

Download link for the Patient Information Document:[1)]	www.leufen-medical.eu/pi/cmlmpi0009

[1)] Updated on an ongoing basis.

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

For Australia:

ATTENTION: 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/