Instructions for Use
LMGB0003-9 — 2020-11
EN

aerstent® TBS
Trachea Bronchus Stent

aerstent® TBJ
J Carina Stent

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a bess group company

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Table of Contents

1 About this Document

1.1 Symbols Glossary

Symbol	Description
	Caution: Consult Instructions for Use
	Do not use if package is damaged
	Keep away from direct sunlight
	Keep dry
	Use-by date
	Sterilized using ethylene oxide
	Do not re-use
	Do not resterilize
	Single sterile barrier system
	MR unsafe
	Medical device
	Catalog number
	Batch code
	Quantity per packaging unit
	Manufacturer
	Distributor
	Consult Instructions for Use. The Instructions for Use are provided in electronic form (e-labelling).
	Stent can be repositioned

Table 1: Symbols Glossary

1.2 Abbreviations

- OTW: Over the Wire; the delivery system is positioned using a guide wire.

1.3 Terminology

- Distal: From the surgeon's view further away
- Proximal: From the surgeon's view closer
- Target area: Site of the stenosis / leackage / fistula to be treated
- Repositioning: Pulling the partially released stent entirely back into the delivery system for intraoperative position correction

1.4 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of the general condition or the death of the patient, user, or a third party.

⚠ CAUTION

Non-compliance may result in light or moderate injuries or a light or moderate deterioration of the general condition of the patient, user, or a third party.

1.5 Additional Information

Download link for these Instructions for Use:	www.leufen-medical.eu/ifu/lmgb0003

2 Important Safety Information

⚠ WARNING

- Before using the product, read the Instructions for Use. Adhere to and save the Instructions for Use.
  Otherwise there are risks to the health of your patient.
- To be exclusively used by a physician with experience in interventional stent therapy, in cooperation with trained staff.
  Otherwise there are risks to the health of your patient.
- Do not disassemble or modify the product.
  Otherwise there are risks to the health of your patient.
- Use the product exclusively in the configuration specified in these Instructions for Use.
  Otherwise there are risks to the health of your patient.

3 Product Codes / REF

[Specifications, page 11]

4 Package Contents

- 1 x **aer**stent TBS / TBJ, preloaded in the delivery system OTW; in sterile packaging
- 1 x implant card

5 Intended Use

aerstent TBS: Stent for bridging malignant changes in the trachea and bronchus
aerstent TBJ: Same as **aer**stent TBS, but for status post pneumonectomy
The product is for long-term use (application duration > 29 days).

6 Indication

Changes of malignant origin:

- Stenoses of the central airways
- Tracheoesophageal fistulae, bronchial fistulae
- Leakages

7 Contraindication

- Tracheomalacia
- Compression of the target area by aneurysm

8 Special Patient Groups

Does not apply.

9 Product Description

- Self-expanding, woven metal stent
- Complete cover
- Atraumatic ends
- Superelastic properties of nitinol, high radial force at body temperature
- Preloaded in a delivery system OTW
- The stent can be repositioned into the delivery system

[Specifications, page 11]

10 Material

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

Not made with natural rubber (latex).
No products made with natural rubber (latex) are used in the production process.

11 Maximum Application Duration

Unless an earlier replacement is needed, it is recommended to replace the stent after 12 months as a precautionary measure.
The likelihood of complications and product damage increases with increasing application duration.
[Aftercare, page 9]

12 Shelf Life and Storage

For date of expiry, see the product label.
Store the product in unopened original packaging.

13 Possible Complications and Side Effects

The following product-related complications are known:

- 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

For patients with tracheostoma: Place the stent far enough from the tracheostoma to prevent reciprocal damage to the stent and the tracheal cannula.

14 Combining with Other Procedures

⚠ WARNING

- 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).
- 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.

Any method for reducing tissue, such as chemotherapy or radiation therapy, can lead to stent migration.

15 Reprocessing

⚠ WARNING

- Single use product: Do not reprocess (e.g., clean, disinfect, sterilize), resterilize or reuse the product.
  This is the only way to ensure the product is germ-free and functional. Due to the mechanical properties of the product, reprocessing or resterilization could lead to material degradation.

16 Application Instructions

⚠ WARNING

- Do not use the product if the packaging or the product is damaged or expired.
  This is the only way to ensure the product is germ-free and functional.

⚠ CAUTION

- Do not touch the product with pointed or sharp instruments.
  Otherwise, the product could be damaged.

16.1 Choose the Product

⚠ WARNING

- Choose stent size according to the anatomical situation.
  Otherwise, there may be necroses / stent migration.

IMPORTANT: The stent preloaded in the delivery system becomes shorter once it is released. The length of the released stent provided in the product specifications is decisive for the selection of the stent.
Stent length = Stenosis length + 10 mm
[Intended Use, page 5]
[Specifications, page 11]

16.2 Required Equipment/Material

- As usual for endoscopic intervention
  - Flexible bronchoscope
  - Rigid bronchoscope / rigid tracheoscope
- Guide wire (length at least double the total length of the delivery system, diameter according to the delivery system.) [Specifications, page 11]
- Fluoroscopic equipment
- Instruments for dilation, if necessary
- Rigid, atraumatic foreign body forceps

16.3 Preparing the Patient

As is usual for endoscopic intervention; fasting.

16.4 Implantation Technique with the Delivery System OTW

⚠ WARNING

- The product is intended for use with rigid bronchoscopy. Use the product without rigid bronchoscopy only if the benefit of this technique exceeds the risk associated with it.
  If using without rigid bronchoscopy, the risk for the patient in case of any complications is much higher.

Ensure the presence of hygienic / sterile conditions needed for the intervention.
The intervention is performed under endoscopic and fluoroscopic control (high resolution devices).
Dilation is needed only to the extent that passage of the delivery system is possible.
ATTENTION: The patient must be ventilated at all times.

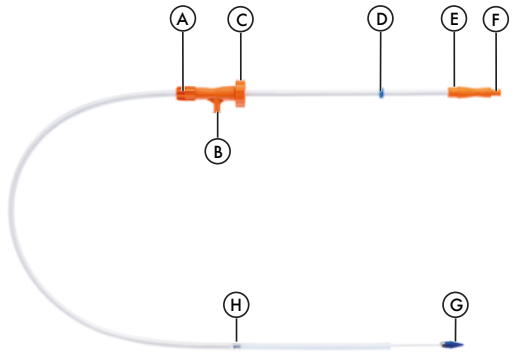


Illustration 1: Delivery system OTW

A	Distal handle; outer catheter
B	Injection port
C	Nut
D	Marking *Point of no return*
E	Proximal handle; inner catheter
F	Guide wire outlet
G	Distal x-ray marker, distal end of the delivery system, guide wire orifice
H	Repositioning gadget, radiopaque

16.4.1 Stent Positioning

1. Locate the target area endoscopically and radiologically and fix a radio-opaque marker distally and proximally.
2. Introduce the guide wire clearly beyond the target area via the working channel of the flexible bronchoscope which is inside the rigid bronchoscope.
3. Remove flexible bronchoscope.
4. Ensure that the guide wire continues to project so far beyond the target area that the stent can be positioned.
5. **aer stent TBJ:** Adjust the delivery system on the guidewire so that the stent curvature follows the respiratory tract path.
6. Advance the delivery system via the guide wire.
7. Align the delivery system so that the stent is centered in the target area.

16.4.2 Release the Stent

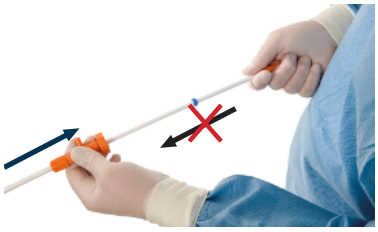
⚠ WARNING

- Never advance the inner catheter distally. For correct procedure see the following steps.
  Otherwise perforations may occur.

⚠ CAUTION

- Do not move the delivery system with a partially expanded stent.
  Otherwise lesions may occur.
- When removing the delivery system: Make sure that the tip of the delivery system does not get caught in the stent.
  Otherwise, the stent may migrate proximally. Lesions may occur. The stent must be extracted and a new stent inserted.

1. Loosen the nut. 2 to 3 rotations are enough.



2. Keep the inner catheter in place on the proximal handle. Carefully pull the distal handle proximally. The stent will be distally released and will expand.
3. As soon as the distal handle reaches the *Point of no Return marking:* Check whether the stent is placed correctly.
   If the stent is placed correctly: Pull the distal handle further proximally. The *Point of no Return marking will be passe*d/shifted. The stent can no longer be repositioned in the delivery system.
   If the stent is not placed correctly:
   [▸Repositioning the Stent into the Delivery System, page 8]
4. For **aer**stent TBJ, ensure by means of the x-ray markers that the stent is optimally positioned lengthwise.
5. Only after the stent has expanded so far that removing the delivery system no longer produces an effect on the stent's position: Remove the delivery system and guide wire carefully under fluoroscopic control.
   ATTENTION: Make sure that the tip of the delivery system does not get caught on the stent.

16.5 Intraoperative Adjustments

16.5.1 Repositioning the Stent into the Delivery System

- Only possible if the distal handle does not exceed the *Point of no Return* marking
- Only when needed as a correction

1. Keep the inner catheter in place on the proximal handle. Carefully advance the distal handle distally.
   IMPORTANT: Move the distal handle only until you feel resistance. The resistance indicates that the stent has been repositioned.
2. Tighten the nut. The stent can now be released again.

16.5.2 Adjust the Released Stent's Position

⚠ WARNING

- Do not move the released stent distally.
  Otherwise perforations may occur. In addition, the cover may be damaged; a stent replacement would be required.

1. Advance rigid atraumatic foreign body forceps through the bronchoscope / tracheoscope until the target area. Open the foreign body forceps.
2. Grip the stent. In order to do that, position one jaw between the tracheal wall and the stent and the second jaw inside the stent.
3. Carefully pull the stent proximally until the desired position is reached.
4. If the position adjustment is not successful: Extract the stent and insert a new one.

Reuse of the product is not possible.

16.6 Extract the Stent

⚠ WARNING

- Before removing the stent free it completely from adherent and ingrown tissue.
  Otherwise perforations may occur.

1. Proceed similarly to position adjustment. [Adjust the Released Stent's Position, page 9]
2. Carefully turn the foreign body forceps until the stent collapses.
3. Pull the proximal part of the stent into the bronchoscope / tracheoscope and remove the stent together with the bronchoscope / tracheoscope.

Reuse of the product is not possible.

17 Instructing the Patient

The instruction to the patient must include:

- If symptoms persist, see the treating doctor.

ATTENTION: Fill out the implant card and give it to the patient.

18 Aftercare

- Immediately after implantation: Perform regular damp inhalations with saline solutions to prevent incrustation from secretion.
- Monitor the patient's blood pressure, pulse and pain
- Follow-up examination (e.g., endoscopy) every 4 weeks

If products are damaged, there is an increasing likelihood of a malfunction; at the same time, removing the product is increasingly difficult and risky.

19 Maintenance

Does not apply.

20 Disposal

⚠ WARNING

- The product was in contact with potentially infectious substances of human origin. Clean/pack the product for disposal according to the specific contamination risk.
  Otherwise there is a risk of infection for the user and for third parties.

Disposal must be in accordance with national disposal regulations and pursuant to the corresponding risk class.

21 Warranty

The reliability of the product's material and design at the time of shipment is guaranteed. The manufacturer does not know either the diagnosis of the patient or the nature of the application and has no influence on the conditions under which the product is used. The storage conditions after delivery of the product are also beyond the manufacturer's area of responsibility.

Due to biological and individual differences, no product is 100% effective under all circumstances.

Therefore, the manufacturer cannot guarantee a positive effect or the absence of negative effects for product application. The medical staff must use the product on the basis of their medical training and experience, and they are responsible for correct application.

The warranty (repair or replacement) applies only if the product is used in accordance with these Instructions for Use (for instruments, particularly with regard to handling, cleaning, sterilization and maintenance); the warranty period starts on the delivery date.

If you have reason to believe that a new product is faulty, please contact the Customer Service in writing immediately and provide as detailed a description as possible of the fault, the REF (product code), and the LOT (batch code) and/or series number. All allegedly defective products must be returned to us for inspection. Instruments have to be completely cleaned and sterilized, appropriate documentation must be enclosed with the return.

If the manufacturer finds that despite all due care the product was defective at the time of delivery, he will repair the product or replace it promptly. If repair or replacement of the product is not possible, the buyer has the right to cancel the purchase or to reduce the payment, but by a maximum of the purchase price amount.

Additional claims or those not mentioned here due to defect, and other claims regardless of the legal reason, including those based on illegal acts and for compensation of immaterial damages against the manufacturer, his agents, dealers and suppliers, are excluded unless existing law is contrary to the liability exclusion, e.g. in cases of intent or gross negligence or in the event of physical injury.

All claims based on the consequences of non-compliance with the Instructions for Use, including specified indications, contraindications, warnings, instructions, application, storage and off-label use, as well as the consequences of a combination with third-party products are excluded.

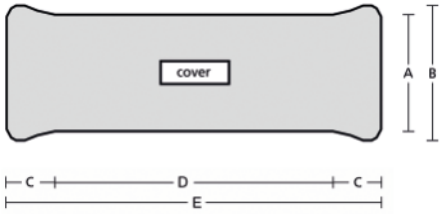
Furthermore, all claims that result from the use of products that have expired, or were used despite the obvious damage to the packaging, or resterilized and/or recycled contrary to the Instructions for Use, are excluded.

No one is allowed to change the above conditions, make further warranty or liability declarations, or guarantee any properties that surpass those specified in the Instructions.

The General Terms and Conditions of the manufacturer, which can be accessed at http://www.leufen-medical.eu/agb apply in all remaining instances.

22 Specifications

22.1 aerstent TBS

REF	A Ø [mm]	B Ø [mm]	C [mm]	D [mm]	E [mm]	OTW Ø [F]
						
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503-10-030	10	12	3	24	30	18
503-10-040	10	12	3	34	40	18
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503-12-030	12	14	5	20	30	18
503-12-040	12	14	5	30	40	18
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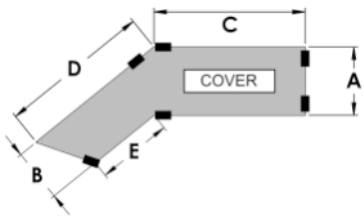
503-16-060	16	18	5	50	60	24
503-16-080	16	18	5	70	80	24
503-18-030	18	20	5,5	19	30	24
503-18-040	18	20	5,5	29	40	24
503-18-050	18	20	5,5	39	50	24
503-18-060	18	20	5,5	49	60	24
503-18-080	18	20	5,5	69	80	24
503-20-040	20	22	5,5	29	40	24
503-20-050	20	22	5,5	39	50	24
503-20-060	20	22	5,5	49	60	24
503-20-080	20	22	5,5	69	80	24
503-22-060	20	24	6	48	60	24

22.2 aerstent TBJ

REF	A Ø [mm]	B Ø [mm]	C [mm]	D [mm]	E [mm]	OTW Ø [F]
						
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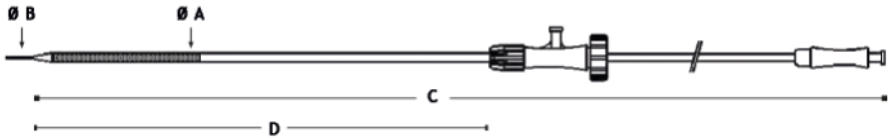
533-18-040	18	14	40	40	20	24
533-20-050	20	14	50	40	20	24

22.3 Delivery System OTW

REPO?	A Ø [F]	B Ø [inch]	C [mm]	D [mm]
				
	18	0,035	970	600
	24	0,035	970	600