# Instructions for Use

LMGB0009-8 — 2020-11

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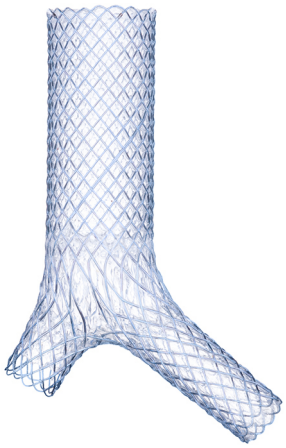
# aerstent® TBY

## 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



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a bess group company

## Table of Contents

## 1 About these Instructions for Use

### 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). |

*Table 1: Symbols Glossary*



### 1.2 Abbreviations

- Over the Wire; delivery system placed with the help of two guide wires.

### 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

### 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.

## 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.
- Use the product exclusively in the configuration specified in these Instructions for Use.
  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.

## 3 Product Codes / REF

[ Specifications, page 10 ]

## 4 Package Contents

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

## 5 Intended Use

Stent for bridging malignant changes in the area of the carina with involvement of at least one main bronchus and the trachea.
The product is intended for palliative use only in cases of known limited life expectancy, as it cannot be removed because of potential in-growing of tissue.
The product is for long-term use (application duration > 29 days).

## 6 Indication

Changes of malignant origin:
- Tracheal stenoses in the area of the carina with involvement of at least one main bronchus and the trachea.
- Tracheoesophageal fistulae, bronchial fistulae
- Leakage in the area of the carina

## 7 Contraindication

- Compression of the target area by aneurysm

## 8 Special Patient Groups

Does not apply.

## 9 Product Description

- Self-expanding, woven metal stent
- Partial cover
- Atraumatic ends
- Tantalum X-ray markers
- Superelastic properties of nitinol, high radial force at body temperature
- Preloaded in a delivery system OTW

[ Specifications, page 10 ]

## 10 Material

- Stent: Nickel titanium alloy (nitinol)
- Cover: Polyurethane
- 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

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

- 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

## 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.
[ Specifications, page 10 ]

### 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. See specifications at the end of this document.)
  - 1 x single color (e.g., black)
  - 1 x two colors (e.g., black and yellow)
- Fluoroscopic equipment
- Instruments for dilation, if necessary
- Rigid, atraumatic foreign body forceps

### 16.3 Preparing the Patient

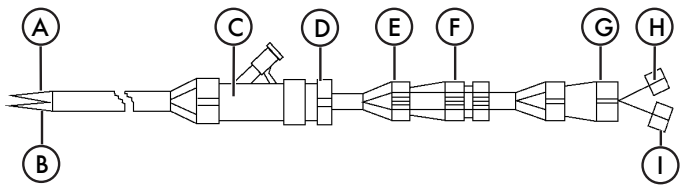
As is usual for endoscopic intervention; fasting.

### 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.




| | |
|---|---|
| A | Guide tip right |
| B | Guide tip left |
| C | Distal handle (outer catheter) with injection port |
| D | Nut |
| E | Intermediate lock |
| F | Locking mechanism |
| G | Proximal handle (inner catheter) |
| H | Holding thread, right |
| I | Holding thread, left |

*Illustration 1: Delivery system*

Follow the assignment in all steps:

| Bronchus | Guide wire | Thread guide lug | Guide tip |
|---|---|---|---|
| **Left** | Single color | Blue | Long, blue |
| **Right** | Two colors | White | Short, green |

*Table 2: Assignment of bronchus, guide wires, thread guide lug, guide tip*

#### 16.4.1 Stent Positioning

1. Locate the target area endoscopically and radiologically. Mark the carina with a radiopaque marker.

2. Introduce the guide wires clearly beyond the target area via the working channel of a flexible bronchoscope which is inside a rigid bronchoscope.
   ATTENTION: Introduce guide wires one after the other. Take note of guide wire assignment to the bronchi.
3. Remove flexible bronchoscope.
4. Ensure that the guide wires continue to project so far beyond the target area that the stent can be positioned.
5. Thread the guide wires into the guide tips of the delivery system. To do this, if needed, pull the outer catheter maximally so far proximally, that the tips of the guide wires protrude from the catheter.
   ATTENTION: Take note of guide wire assignment to the bronchi.
6. Advance the delivery system over the guide wires up to approx. 1 cm to the carina.
7. Ensure that the guide wires do not cross each other. If needed, rotate the delivery system to correct positioning.

### 16.4.2 Release the Stent

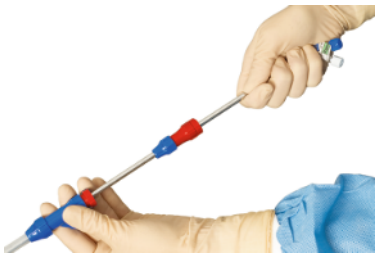
**⚠ WARNING**

- Never advance the inner catheter distally. For correct procedure see the following steps.
  Otherwise perforations may occur.
- Ensure that the stent bifurcation sits on the carina.
  Otherwise, there is a risk of tracheal obstruction.
- Pull out the outer catheter beyond the intermediate lock only after the bronchus branches of the stent have expanded.
  Otherwise, there is a risk of tracheal obstruction. For correct procedure see the following steps.
- Open the tracheal section of the stent right after expanding the two bronchial branches.
  Otherwise, there is no ventilation and the patient cannot be ventilated.
- Do not move the released expanded stent.
  Otherwise, there is a risk of tracheal obstruction.

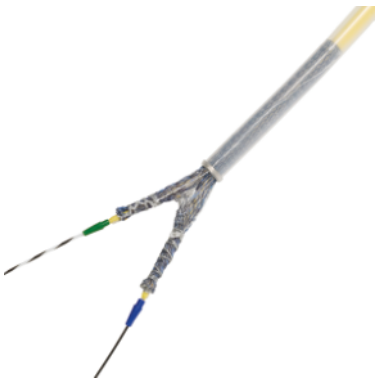
**⚠ CAUTION**

- 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 at the distal handle to release the locking of the handle. 2 to 3 rotations are enough.

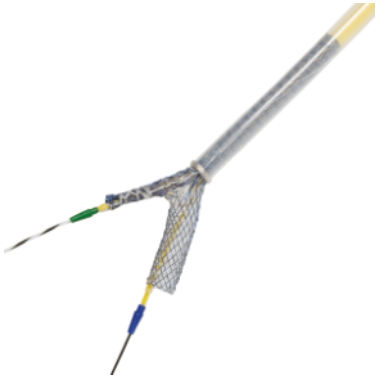


2. Keep the inner catheter in place on the proximal handle. Pull the outer catheter at the distal handle proximally up to the intermediate lock.



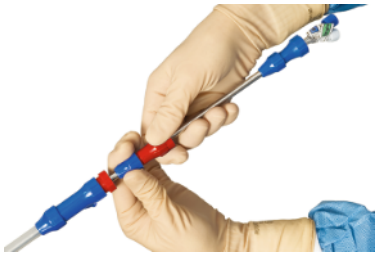
3. The bronchial branches of the stent are released and the stent takes its y-shape, but the bronchial branches do not expand yet.
4. Carefully advance the entire delivery system under fluoroscopic control, until the stent bifurcation sits on the carina. The x-ray marker on the stent bifurcation must be in direct proximity to the carina. Apply light pressure on the carina through the delivery system in order to prevent stent migration.

5. Pull the left holding thread.

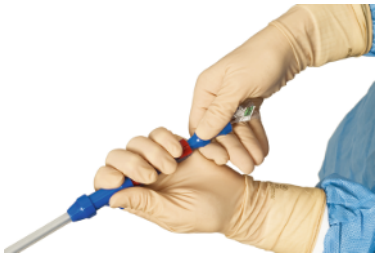


6. The left bronchus branch of the stent will expand.

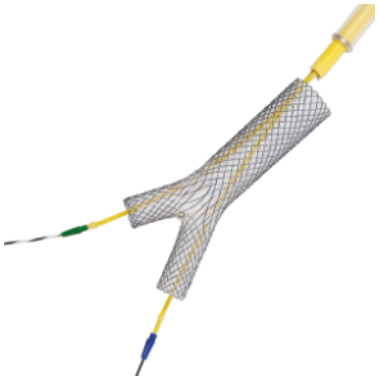
7. Repeat on the right.
   ATTENTION: Once both bronchus branches are opened, there is no ventilation and the patient cannot be ventilated. Therefore, the following step must be taken immediately.



8. Loosen the nut at the intermediate position to loosen the locking mechanism. To do this, keep the intermediate position fixed and rotate the adjoining nut counterclockwise.



9. Carefully pull the distal handle proximally until the end. The tracheal part of the stent will be released and expands. ATTENTION: Do not change the stent position in the process.



10. Only after the stent has expanded so far that removing the delivery system does no longer produce an effect on the stent's position: Remove the delivery system and the guide wires carefully under fluoroscopic control.

11. Check the position and integrity of the stent endoscopically and radiologically. Replace a damaged / incorrectly positioned stent with a new one.[ In case of incorrect stent placement, page 8 ]

### 16.5 In case of incorrect stent placement

1. Move the bronchoscope / tracheoscope as close to the stent as possible.
2. Advance rigid atraumatic foreign body forceps through the bronchoscope / tracheoscope until the target area. Open the foreign body forceps.
3. 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.
4. Carefully turn the foreign body forceps until the stent collapses.
5. Pull the proximal part of the stent into the bronchoscope / tracheoscope and remove the stent together with the bronchoscope / tracheoscope.

6. Place a new stent.

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. Therefore, appropriate medical measures must be taken in case of product damage.

## 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.

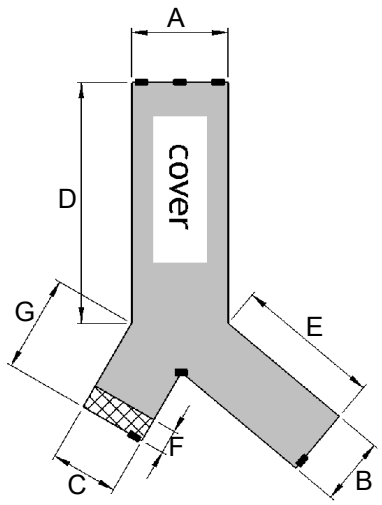
Additional claims or those not mentioned here due to defect, and other claims regardless of the legal reason, including those based on illegal acts and for compensation of immaterial damages against the manufacturer, his agents, dealers and suppliers, are excluded unless existing law is contrary to the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

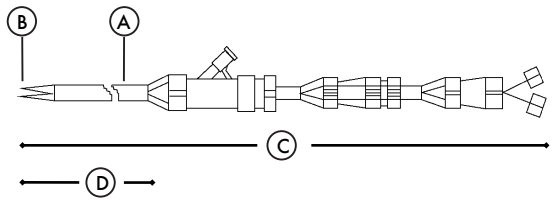
All claims based on the consequences of non-compliance with the Instructions for Use, including specified indications, contraindications, warnings, instructions, application, storage and off-label use, as well as the consequences of a combination with third-party products are excluded.

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

| aerstent TBY | | | | | | | |
|---|---|---|---|---|---|---|---|
| REF | A Ø [mm] | B Ø [mm] | C Ø [mm] | D [mm] | E [mm] | F [mm] | G [mm] |
| |  | | | | | | |
| 512-16-040 | 16 | 12 | 10 | 40 | 30 | 5 | 20 |
| 512-18-040 | 18 | 12 | 10 | 40 | 30 | 5 | 20 |
| 512-18-050 | 18 | 14 | 12 | 50 | 30 | 5 | 20 |
| 512-20-050 | 20 | 14 | 12 | 50 | 30 | 5 | 20 |
| 522-16-040 | 16 | 12 | 10 | 40 | 30 | 5 | 15 |
| 522-18-040 | 18 | 12 | 10 | 40 | 30 | 5 | 15 |
| 522-18-050 | 18 | 14 | 12 | 50 | 30 | 5 | 15 |
| 522-20-050 | 20 | 14 | 12 | 50 | 30 | 5 | 15 |

| OTW | | | |
|---|---|---|---|
| A Ø [F] | B Ø [inch] | C [mm] | D [mm] |
|  | | | |
| 24 | 0,035 | 970 | 600 |