BONASTENT® Tracheal/Broncial Instructions For Use

Caution :

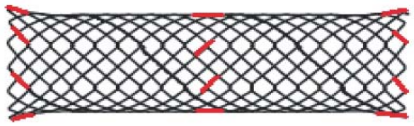
- US Federal Law restricts this device to sale by or on the order of a physician
- Warning : The safety and effectiveness of this device for use in the vascular system have not been established
- Read instructions thoroughly prior to use
- For single use only
- MRI safety has not been established for this device

Indications for Use

The BONASTENT® Tracheal/Bronchial is indicated for the treatment of tracheobronchial strictures caused by malignant neoplasms or benign strictures that are inoperable or no therapies available.

Stent Profiling *(see image below)*

This stent is a self-expanding polygon mesh surface structured prosthesis designed to maintain patency of tracheobronchial strictures caused by malignant neoplasms and benign strictures. This covered stent, with a silicone membrane, is to prevent in-growth, and the body structure is made with nitinol wire. There is a group of four radiopaque markers made of platinum wire positioned on both ends and the center of stent, and both ends shaped in flare structure to control the migration. The fully expanded diameter is 10, 12, 14, 16, 18 and 20mm, and there are various standard lengths available.



BONASTENT® Tracheal/Bronchial

The table below details the available stent sizes:

Cat. Number	Stent		Delivery Device	
	Diameter	Length	Diameter	Usable Length
BTB-100309	10	30	2.66 (8Fr)	900
BTB-100409	10	40	2.66 (8Fr)	900
BTB-100509	10	50	2.66 (8Fr)	900
BTB-100609	10	60	2.66 (8Fr)	900
BTB-100709	10	70	2.66 (8Fr)	900
BTB-100809	10	80	2.66 (8Fr)	900
BTB-120309	12	30	3.00 (9Fr)	900
BTB-120409	12	40	3.00 (9Fr)	900
BTB-120509	12	50	3.00 (9Fr)	900
BTB-120609	12	60	3.00 (9Fr)	900
BTB-120709	12	70	3.00 (9Fr)	900
BTB-120809	12	80	3.00 (9Fr)	900
BTB-140309	14	30	3.35 (10Fr)	900
BTB-140409	14	40	3.35 (10Fr)	900
BTB-140509	14	50	3.35 (10Fr)	900
BTB-140609	14	60	3.35 (10Fr)	900
BTB-140709	14	70	3.35 (10Fr)	900
BTB-140809	14	80	3.35 (10Fr)	900

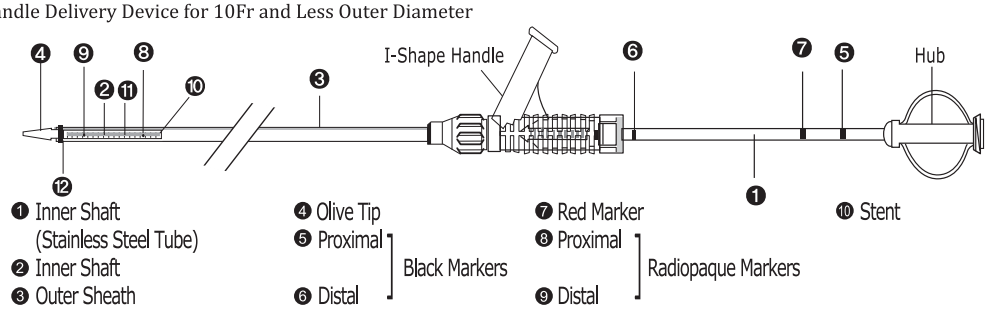
Cat. Number	Stent		Delivery Device	
	Diameter	Length	Diameter	Usable Length
BTB-160309	16	30	4.00 (12Fr)	900
BTB-160409	16	40	4.00 (12Fr)	900
BTB-160509	16	50	4.00 (12Fr)	900
BTB-160609	16	60	4.00 (12Fr)	900
BTB-160709	16	70	4.00 (12Fr)	900
BTB-160809	16	80	4.00 (12Fr)	900
BTB-180309	18	30	4.00 (12Fr)	900
BTB-180409	18	40	4.00 (12Fr)	900
BTB-180509	18	50	4.00 (12Fr)	900
BTB-180609	18	60	4.00 (12Fr)	900
BTB-180709	18	70	4.00 (12Fr)	900
BTB-180809	18	80	4.00 (12Fr)	900
BTB-200309	20	30	4.00 (12Fr)	900
BTB-200409	20	40	4.00 (12Fr)	900
BTB-200509	20	50	4.00 (12Fr)	900
BTB-200609	20	60	4.00 (12Fr)	900
BTB-200709	20	70	4.00 (12Fr)	900
BTB-200809	20	80	4.00 (12Fr)	900

All sizes are in mm

Delivery Device Profiling *(see image below)*

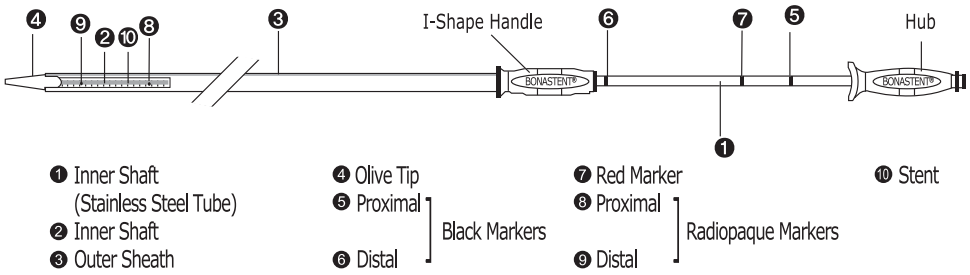
The delivery device is composed of an outer sheath③ with Y-Shape or I-Shape Handle and an inner shaft①, which fits the olive tip④ in the distal end. The proximal part of inner shaft① is made with a stainless steel tube, and there are two black markers⑤⑥ and a red marker⑦ between the black markers. The two black markers ⑤⑥ represent the margins of both ends of the pre-loaded stent, and the red marker⑦ indicates the maximum marginal length for repositioning. It is possible to re-constrain the stent if the outer sheath③ of the delivery device was not pulled beyond the red marker⑦. The inner tube② has two radiopaque markers⑧⑨ to indicate the exact position of both ends of the stent for the beginning of deployment procedure. The delivery device allows a 0.035" guide wire, and its usable length of the delivery device is 50cm and 90cm. The delivery device has two types of Handle as below.

1) Y-Shape Handle Delivery Device for 10Fr and Less Outer Diameter



SWML-BST-IFU33

2) I-Shape Handle Delivery Device for Larger than 10Fr Outer Diameter



Precautions

1. This device should only be used by a physician with a proper training in stent implantation and post-stent implantation patient care.
2. This device has been sterilized. Do not use if the package has been opened or damaged.
3. Inspect the device carefully prior to its use to verify that the device has not been tampered with during shipment or storage, and that its size and condition are suitable for the selected procedure.
4. Keep the device at normal room temperature and avoid direct sunlight.
5. Do not use expired products.
6. Implantation of the stent should be performed under fluoroscopic or endoscopic guidance.
7. The stent can be reloaded into the delivery device for a repositioning procedure. Repositioning is possible only when the Y-shape or I-shape handle of the outer sheath is positioned between the red marker ⑦ and the distal black marker ⑥ on the inner shaft.
8. Do not advance a partially deployed stent. (Make sure to reconstrain the partially deployed stent completely before the deployment procedure.)

Potential Complications

- Bleeding
- Fever
- Foreign Body Sensation
- Death (other causes than due to a normal disease progression)
- Pain
- Tumor Over-Growth
- Ulceration
- Stent Migration
- Perforation
- Edema
- Stent Rupture

Selection and Preparation

1. Choose a stent with optimum diameter and length after measuring and monitoring the length of the stricture using a bronchoscope.
2. Choose a stent, which is long enough to cover both ends of the actual stricture. This will prevent the risk of tumor over-growth, which may occur later.
3. Maintain the delivery device as straight as possible outside the body.

Procedures

1. Insert a 0.035" guide wire fully across the stricture.
2. In the case of a tight stricture it may be necessary to use a balloon catheter prior to stenting to expand the strictured area.
3. Advance the delivery device carefully over the guide wire until the distal end of the stent ⑨ passes through the stricture.
4. Deploy the stent by pulling the outer sheath ③ slowly while maintaining the position of inner shaft ① by the handle.
5. Verify the location of the stricture before deployment. If the stent was not positioned correctly, reload the stent back into the outer sheath③ by pushing until it reaches the distal black marker ⑥, and resume the deployment procedure from the beginning. (Refer to Repositioning Technique below)
6. Remove the delivery device carefully when the stent expansion has been confirmed.

Caution

If the tight stricture does not allow the olive tip ④ to be pulled back after the deployment, wait a few minutes to allow the stent to fully open and then, remove the delivery device;, or reload the inner tube ② into the outer sheath ③ and remove the delivery device

Deployment

1. Advance the delivery device over the guide wire across the stricture.
2. Immobilize the inner shaft ① by holding the hub firmly with one hand, and then, gently start pulling the Y-shape or I-Shape handle of outer sheath ③ backwards.

Caution

1) When the withdrawal of outer sheath ③ is interrupted, stop the pulling immediately. Reload the stent back into the outer sheath and remove the whole delivery device gently to perform the procedure from the beginning.
2) Do not apply excessive force or twist the stainless steel inner shaft ①. If twisting of the delivery device is necessary, hold the Y-shape or I-Shape handle of the outer sheath ③ and the inner shaft ① together to turn the delivery device together.

3. Withdraw the delivery device carefully after the stent placement has been completed.

Repositioning Technique

1. Immobilize inner shaft ① by holding it firmly by the hub.
2. Push the Y-shape or I-Shape handle of outer sheath ③ gently until the distal black marker ⑥ appears on the stainless steel tube of inner shaft to reload the stent. It is recommended to verify this process using a fluoroscope.

Caution:Repositioning is possible only when the I-shape handle of the outer sheath ③ is positioned between the red marker ⑦ and the distal black marker ⑥ on the inner shaft ①.

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Warranty

SEWOON Medical Co., Ltd. warrants that this product has been manufactured under appropriate procedures. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, which are beyond SEWOON Medical Co., Ltd.'s control as such as warranties implied to the application of law, sales or specially purposed suitability after handling, storage, cleaning and sterilization of this product as well as matters related to the patient, diagnosis, treatment, surgical procedures, and any other details. SEWOON Medical Co., Ltd. shall not be liable for any incidental, or consequential loss, damage or expense directly or indirectly arising from the use of this product other than the replacement of it. SEWOON Medical Co., Ltd. shall neither take any additional responsibility nor authorize such responsibility or duty to other person related to this product.

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