Esophageal Stent System

INSTRUCTIONS FOR USE

STERILE EO

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CE 0123

Anrei Medical (Hangzhou) Co., Ltd.

WARNING:

1. Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your ANREI MEDICAL representative.
2. For single use only. DO NOT REUSE, REPROCESS OR RESTERILIZE. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and /or cause patient infection or cross-infection, including, but not limited to , the transmission of infections disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
3. After use, dispose of device and packaging in accordance with hospital, administrative and/or local government policy.

【Device Name】

Esophageal Stent System

【Intended Use】

This device is used for the expansion treatment for the esophagus, cardia, anastomotic and plugging fistula treatment of esophageal fistula.

【Structure】

The Esophageal Stent consists of the implantable metallic stent and Delivery system. The stent is made of Nitinol wire. It is a flexible, fine mesh tubular prosthesis which has radiopaque markers on each end and at the center.

The stent is loaded in Delivery system and upon deployment the stent imparts an outward radial force on the luminal surface of the esophagus to establish patency.

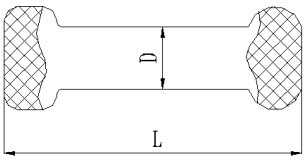
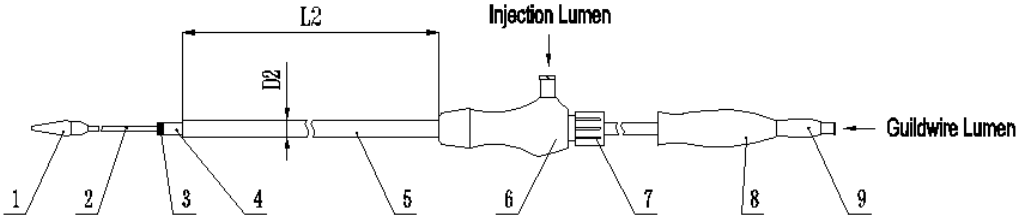


Fig 1. Stent Diagram



1. Soft Tip; 2. Inner Tube; 3. Radiopaque marker; 4. Middle Tube; 5. Outer Sheath;
6. Handle; 7.Locking Nut; 8. Rear Handle; 9. Nut.

Fig 2. Delivery System Diagram

1. the delivery system accepts a .038" guidewire . the stent delivery system is passed over the guidewire into the esophagus.

2. the stent is positioned appropriately using the Radiopaque markers for guidance under fluoroscopy.

3. the locking nut prevents an accidental deployment of the stent while the delivery system is being introduced over the guidewire.

4. the size of delivery system is described in its label on the package.

【Specifications】

AMH-ST1-□-□□-□□□-□-□□-□□□

- Delivery System Size：Catheter Diameter D2（Fr）×Length L2（cm）
- Delivery System Model：T-Push, K-Binding
- Stent Size：Diameter D（mm）×Length L（mm）
- Stent Coating：M-Coated；N- Uncoated
- Product Code：Esophageal Stent System
- Company Code

Stent*			Delivery System	
D (mm)	L (mm)	Coating	D2（Fr）	L2（cm）
14,16,	30～160	Coated	18、24	60/70
18,20,22,24, 26,28,30			24	
14,16,18,20,22, 24,26,28,30	30～160	Uncoated	18	

* There are some shapes of ends of the stent, such as ball, horn mouth, etc. Doctors can choose different shapes according to actual use.

【Precautions】

Read the Instructions for use thoroughly before using this device. It should only be used by or under the supervision of physicians thoroughly trained in the placement of stents.

A thorough understanding of the techniques, principles, clinical applications and risks associated with this procedure is necessary before using this device.

- Care should be taken when removing the delivery system and guidewire immediately after stent deployment since this may result in stent dislodgment if the stent has not been adequately deployed.

- Care should be taken when performing dilation after the stent has been deployed as this may result in perforation, bleeding, stent dislodgement or stent migration.
- Use of fluoroscopy is recommended to ensure correct placement of the device.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspected to be damaged, it should not be used.
- Do not use if labeling is incomplete or illegible.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

【Direction for Use】

WARNING: Visually inspect the system for any sign of damage, DO NOT USE if the system has any visible signs of damage. Failure to observe this precaution may result in patient injury.

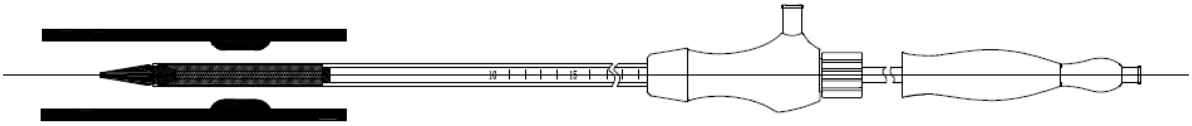
【Preparation】

1. **Examine stricture fluoroscopically and/or endoscopically.**
   a) Carefully examine both the proximal and distal segment of stricture fluoroscopically.
   b) The internal luminal diameter should be measured exactly with fluoroscope.
2. **Stent size determination**
   a) Measure the length of the target stricture
   b) Select a stent size that is 20 to 40mm longer than the measured length of the stricture in order to cover fully both ends of lesion
   c) Measure the diameter of the reference stricture- it is necessary to select a stent which has an unconstrained diameter about 1-4mm large than the largest reference target diameter, to achieve secure placement.
3. Make sure that the locking nut is firmly locked.
4. Maintain the delivery system as straight as possible outside the body.
5. Prepare 0.035” or 0.038” guidewire.
6. 【Operation procedure】

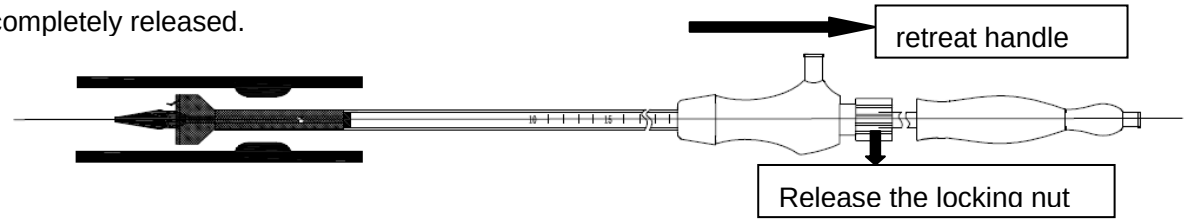
1） In the X - ray monitoring or endoscopy, Insert a guidewire across the stricture.

2） For the severely stricture, the operation should be carried out by the X-ray. The procedure is as follows: firstly, insert the super smooth guidewire into the stomach； then insert the catheter along with the super smooth guidewire； Finally, insert the super stiff guidewire to exchange the super smooth guidewire.

3） Insert the delivery system along with the super stiff guidewire until the distal of the stent system exceeds the distal of the stricture about 20mm.



4) Release the locking nut. Hold the rear handle and keep it still, retreat handle until the stent completely released.



5) after stent deployment

- Examine the stent fluoroscopically to confirm expansion before exiting the guidewire and delivery system. Carefully remove the delivery system and the guidewire from the patient. If excessive resistance is felt during removal, wait 3-5minutes to allow further stent expansion. (place the inner tube back into the outer sheath as the original state prior to removal.)
- Watch the position of the stent by endoscopy or X-ray, if the position of the stent is lower slightly, the Balloon dilation catheter can be used to adjust the position. On the contrary, if the position of the stent is higher than the stricture, the stent need to be removed and placed again, the procedure are as follows: cool the stricture(the patient can drink some cold water) to minimize the stent size, the biopsy forceps or other instruments can be used to remove the stent observed by the endoscopy.

【Caution】

- If the dilator is used to dilate the stricture, the size of the dilator should be smaller than the stent size for 2～3mm.
- Keep the Locking Nut locked in the process of inserting the delivery into body, to make sure that the relative position of the outer tube and middle tube cannot be changed.
- After releasing the stent, if balloon dilatation catheter is necessary, the expansion site must be located in the tumor's narrow segment. Expansion degree basis on the patient condition, but the maximum expansion size shall not be more than the stent's size.
- The delivery system is designed to accept a 0.038″ (0.96mm) guidewire.
- If the stent is placed in wrong place, the stent can be adjusted or removed in the endoscopy or X-ray.

【Precaution】

- The patient should be prostration after the stent has been placed; the top of the bed should raise 10° to avoid the stent displacement.
- Fasting and no drink for 2 hours after the stent has been placed, the patient can drink much warm

water to make the stent expand well.

- The patient can major eat liquid diet firstly. the diet temperature is 40～50℃. The food should be avoided if the temperature is lower than 5℃. And then can transition to semi-fluid food or semi-solid food. One month later, the patient can eat normal food and drink much water after the meal, can eat less each time but more times, eat slowly is recommended.
- The patient may feel discomfort in the first week, such as pain, nausea and vomit, etc. The doctor can take some measures to make the discomfort slightly.
- Cold, sticky and solid food are prohibited.

【Contraindications】

The esophageal stent is contraindicated for, but is not limited to:

- Stent placement in esophageal strictures caused by benign tumors.
- Placement in strictures that cannot be dilated enough to pass the delivery system.
- Intra-abdominal abscess/perforation.
- Placement in necrotic chronically bleeding tumors, if bleeding is active at the time of placement.
- Removal or repositioning of fully deployed uncovered/ bare stents is contraindicated.
- Any use other than those specifically outlines under indications for use.

【Potential Complications】

Complications associated with the use of the esophageal Stent may include:

Procedural Complications

- Bleeding
- Pain
- Stent misplacement or inadequate expansion
- Esophageal perforation
- Death

Post Stent Placement Complications

- Bleeding
- Pain
- Stent misplacement or migration
- Stent occlusion
- Persistent swallowing problems
- Foreign body sensation
- Stent occlusion due to tumor in-growth through stent
- Stent occlusion due to tumor over-growth around ends of stent
- Ulceration
- Infection
- Fever
- Death (other than that due to normal disease progression)

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is

indicated.

【WARNINGS】

- The device should be used with caution and only after careful consideration in patients with elevated bleeding times, coagulopathies, or in patients with radiation colitis or proctitis.
- Chemoradiation therapy or radiotherapy alone may lead to tumor shrinkage and subsequent stent migration.
- The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- Do not expose the delivery system to organic solvent (e.g. alcohol)
- Do not use with Ethiodol or Lipiodol contrast media.
- Full Covered Stent cannot be removed when there is tumor in-growth/over-growth/occlusion of the Stent lumen.
- Uncovered/ bare stents should not be remove once fully deployed; see contraindications.
- Do not attempt to recapture/reload a stent once its deployment is advanced.
- The intended lifetime of stent after placed is recommended not more than one year. Fully covered stent may be removed within 2 months.
- Fully covered stents may be removed within 8 weeks, stent removal shall be performed by a doctor according to the etiology of the stricture and the patient's conditions.
- Exercise care when removing a stent that has significant overgrowth around the stent ends.
- Magnetic Resonance Conditional: Non-clinical testing has demonstrated that the stent can be applied in MR Condition.
- Exercise care when removing a stent that has significant overgrowth around the stent ends.

【Packaging】

Pouch：1 set per pouch

Box：1 pouches per box

Carton：10 boxes per carton

【Date of Manufacture】

Please refer to the label on pouch

【Symbol Instruction】

	Catalogue number		Batch code
	Date of manufacture		Use-by date
	Sterilized using ethylene oxide		Do not re-use

	Do not resterilize		Do not use if the package is damaged
	Consult instruction for use		Caution
	Keep dry		Protect from heat and radioactive sources
	Manufacturer		Authorized representative in the European Community

【Storage】Store the device in a dry, cool (room temperature), clean place and protect it from direct sunlight, heat and/or aggressive chemical substances. Relative Humidity applicable range is less than 80%, temperature applicable range is 10°C - 40°C.

【Sterilization】 Sterilized using ethylene oxide

【Shelf Life】 2 years after sterilization.

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