MICRO-TECH™
ENDOSCOPY

Tracheal Stent System(Y-Shaped)

These instructions will explain how to use the Tracheal Stent System(Y-Shaped) correctly. Please follow these instructions carefully.

User Manual

Micro-Tech (Nanjing) Co., Ltd.

Warnings

$\mathbb{R}_{\text{X only}}$	Federal Law (USA) restricts this device to sale by or on the order of a physician.
	The Tracheal Stent System(Y-Shaped) is intended for single use only! DO NOT reuse, reprocess or re-sterilize the device. Reuse, reprocessing or re-sterilization 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 or reprocessing or re-sterilization 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 infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
	Use the stent system prior to the "Use By" date specified on the package.
	The complete Instructions for Use should be reviewed before using this system.

Cautions

Patients sensitive to Nickel Titanium (Nitinol) may suffer an allergic reaction to this implant. The stent should be used with caution and only after careful consideration in patients with significant preexisting pulmonary or cardiac disease. The device is intended for use by qualified endoscopy or radiology physicians who have received appropriate training. Radiographic equipment that provides high-quality images is needed.

Informed consent should be obtained from all patients who undergo Tracheal stent implantation. The doctors must inform the patients of all the possible benefits and risks as well as the short-term and long-term complications related to the procedure. Because of the complexity of the diseases, there may be other complications which are unpredictable or not listed that may lead to injury, illness or death of the patient.

Read the entire Instructions for Use thoroughly before using the Tracheal Stent System(Y-Shaped). The Tracheal Stent System(Y-Shaped) should be used by or under the supervision of physicians thoroughly trained. A thorough understanding of the technical principles, clinical applications, and surgical risks are necessary before using the device.

Patient can only be implanted only one Y-shaped stent.

This device is suitable for adults $>$ 21 years of age.

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Contents

Brief Introduction

I Device Name

Tracheal Stent System(Y-Shaped)

II Device Description

The Tracheal Stent System(Y-Shaped) consists of a flexible delivery system preloaded with a self-expanding implantable metallic stent.

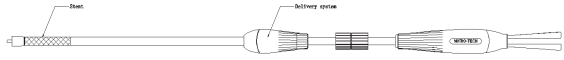


Fig.1 Tracheal Stent System(Y-Shaped)

Stent description

The stent is made of nitinol wire woven in a tubular mesh shape. This structure makes the stent flexible, compliant, and self-expanding. The stent is partially covered with silicone to restrict tumor in-growth through the wire mesh. A retrieval loop is threaded through the proximal and distal ends of the stent and is intended to aid in removal during the stent placement procedure. To aid in visibility under fluoroscopy there are radiopaque markers at key landmarks on the stent (proximal end, bifurcation, distal ends). The stent branches have flanges to help minimize migration after the stent has been placed in the trachea.

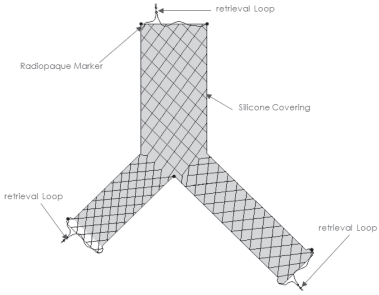


Fig.2 Tracheal Stent

Delivery system description

The delivery system consisting of four sheaths (Figure 3, #1,2,3). The outer sheath (Figure 3, #1) constrains the stent before deployment. The middle sheath assembly (Figure 3, #3) supports the delivery system. The outer sheath (Figure 3, #1) has a transparent section so that the constrained stent is visible. There are two radiopaque markers (Figure 3, #4,10) to aid in the deployment of the stent. The proximal radiopaque marker on the middle sheath (Figure 3, #10) identifies the proximal end of the constrained stent. The distal radiopaque marker (Figure 3, #4) at the distal end of the outer sheath aids in confirming the stent position relative to the tracheal carina during the operation. The olive tips are soft and oriented and they are also radiopaque(Figure 3, #12). The two inner sheaths (Figure 3, #2) each contain a central lumen that accommodates a 0.035 inches guide wire.

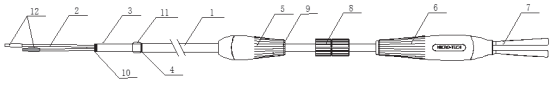


Fig.3 Delivery system

①Outer sheath	⑤Front handle	⑨Safe lock
②Inner sheath	⑥Back handle	⑩Radiopaque marker on the middle sheath
③Middle sheath assembly	⑦Thumb ring	⑪Outer Casing
④Radiopaque marker on the outer sheath	⑧Stopper	⑫Olive tip

Stent Characteristics

The stent design improves patient comfort by keeping the tracheal tract patent after implant.

The stent is made from nitinol, Under the conditions inside the human body, where the temperature is more than 33 ℃,The stent will resume its original shape gradually after being deployed from the delivery system generating a gentle radial force which acts on the inner wall of the Tracheal tract to expand the stricture gradually and create an unobstructed lumen.

III Indications for Use

The Tracheal Stent System(Y-Shaped) is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.

IV Contraindications

Contraindications include, but not limited to:
1. Patients with cardiopulmonary function inadequacy.
2. Stricture caused by benign tumors.
3. Severe coagulopathy.
4. Necrosis in tracheal wall and subsequent tracheal collapse.
5. Patients for whom bronchoscopic procedures are contraindicated.
6. Placement in strictures that cannot be dilated enough to pass the flexible bronchoscope or the delivery system.
7. Any use other than those outlined explicitly under indications for use.

V Potential Complications

Complications related to the procedure include, but not limited to:

PROCEDURAL COMPLICATIONS
1. Stent misplacement
2. Perforation
3. Infection
4. Bleeding
5. Pain
6. Foreign body sensation

POST PROCEDURAL COMPLICATIONS
1. Tracheal wall ulceration and/or perforation and/or hemorrhage
2. Perforation
3. Restenosis due to granulomatous tissue formation at stent ends
4. Stent occlusion due to granulomatous tissue ingrowth
5. Stent fracture
6. Stent migration
7. Recurrent obstructive dyspnea related to stent occlusion or migration
8. Edema
9. Ulceration
10. Death

VI Warnings

1. Do not use if the inner package is opened or damaged.
2. Do not use if labeling is incomplete or illegible.
3. Do not use if the Tracheal Stent System(Y-Shaped) has any visible signs of damage.
4. Inspect the distal end of the delivery system before use, to ensure that the stent is entirely within the outer sheath. Do not use if the stent is partially deployed.
5. Do not immerse the delivery system into organic solvents (e.g., alcohol).
6. This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

VII Precautions

Store in a cool and dry place.

Directions for use

Precaution
1. High resolution imaging equipment (e.g., flexible bronchoscope or X-ray machine) is required to aid in the procedure. Insert the delivery system slowly and carefully along the guide wire under effective visualization.

2. If the stricture is so severe that the flexible bronchoscope or delivery system cannot pass through, forcing the flexible bronchoscope or delivery system to pass may cause perforation. It is suggested that balloon should be used to pre-dilation the stricture.
3. Long term persistent coughing may lead to material fatigue and subsequent falling off of the silicone covering and stent break.

I Pre-procedure

Required Equipment

1. Flexible bronchoscope or X-ray machine.
2. Two 0.035 inches guide wires. The working length of guide wire should be ≥2600mm.
3. Dilation balloon (if desired)
4. CT machine (if desired)

II Procedure

1. Locate the stricture

If using a flexible bronchoscope, intubate the patient using a standard flexible bronchoscope per standard technique. Access the stricture location upon direct visualization or use radiography to define the location.

2. Examine the stricture

Use endoscope or CT to measure the Branch/ Carina stricture diameter and length of trachea or bronchus.

3. Choose the Stent Size

The size of the stricture must be accurately calculated to ensure the ideal stent size is used. Generally, It is suggested that the branch length of stent is 5-10 mm longer than the stricture length, and the main branch length of stent is 10-20 mm longer than the stricture length The recommended diameter of the stent is around 1.3 times than that of the stricture.

4. Open the package

Open the outer package to inspect the inner package to make sure that it is free from the damage. Carefully open the inner package and take the device from the tray.

5. Stent Deployment

5.1 Instructions for use under X-ray (Refer to Fig.4 to Fig.11):

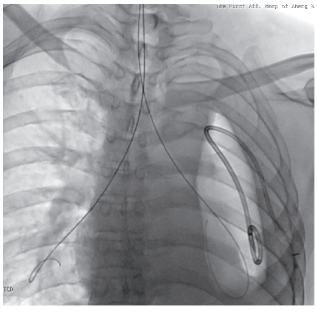


Fig.4 Insert the two guide wires through the mouth to right and left bronchi under the X-ray, Mark which guide wire enters the left bronchus and which guide wire enters the right bronchus.

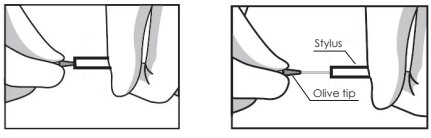


Fig.5 Remove the stylus from each of the olive tips by holding the olive tip with one hand and pulling the stylus out completely with the other.

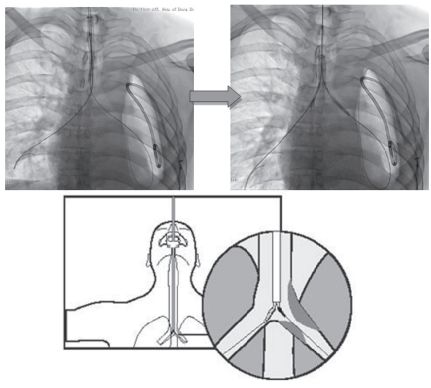


Fig.6 There are two different color olive tips in delivery system. The white olive tip is corresponds to the left branch of the stent. The blue olive tip is corresponds to the right branch of the stent. Please match the left and right sides. Insert the Delivery System following the two guide wires. When the delivery system reaches the carina, observe whether the two guide wires are crossed. If the wires are crossed, rotate the delivery system in the opposite direction of the crossing until the two guide wires are not crossed.

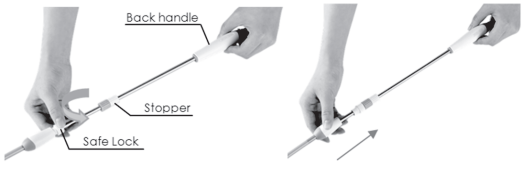


Fig.7 Loosen the safe lock. While holding the back handle stationary, withdraw the front handle to expose the two branch parts of the Y-shaped stent. Stop when the front handle reaches the stopper. Then lock the safe lock again.

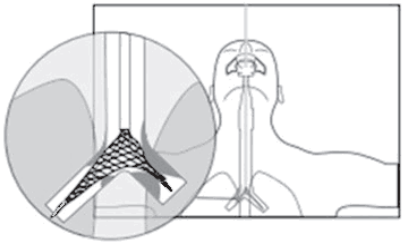


Fig.8 Insert the two branches of the delivery system over the guide wire into the bronchi. If the stent is not align well with the tracheal carina, push delivery system towards the tracheal carina to make the stent fully fitted to the tracheal carina.

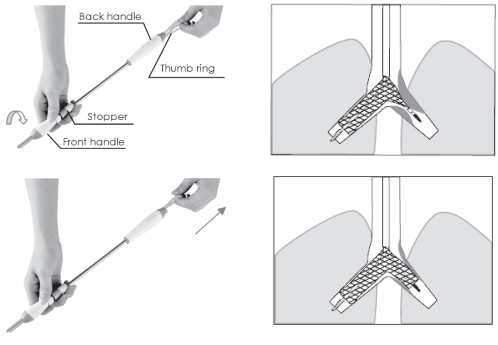


Fig.9 Pull the thumb rings to deploy each of the branch parts separately.

NOTE: While the branch parts are deployed and the main branch is not fully released, the patient airway is occluded. Release the main branch must as quickly as possible in next step.

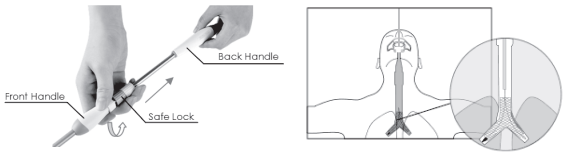


Fig.10 Loosen the safe lock and the stopper. While holding the back handle stationary, withdraw the front handle fully to complete deployment of the stent from of the delivery system.

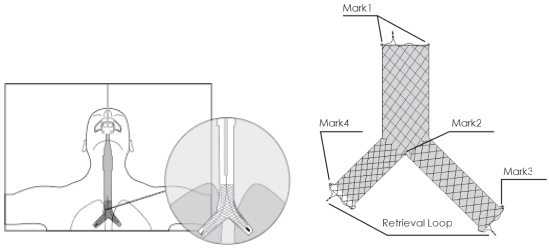


Fig.11 After the stent is deployed completely, remove the delivery system, and retain the guide wire. Observe the position of stent after deployment under X-ray. The four positions of the proximal end of the main branch, the carina of stent, the distal end of the left branch and the distal end of the right branch of the stent can be determined by the marker1/2/3/4 on the stent respectively, and the position of the stent in the patient's trachea can be determined.
If the position of the stent is found to be incorrect, insert grasping instruments such as the forceps into the trachea through the patient's mouth, and clamp distal nitinol wires of the left or right branch under the X-ray. The stent can be repositioned to the correct position by advancing the instruments. The reposition distance is no more than 20mm. Remove the guide wires and grasping instrument. The procedure is completed.

Warning:

Caution and stating: Passing the scope through a recently deployed stent could cause the stent to dislodge. Observe the position of the stent and correct as necessary.

Caution: An attempt to remove the delivery system and guide wires prior to stent expansion or when a stent is partially deployed may cause the stent to dislodge. If excessive resistance is felt during delivery system removal, wait 3-5minutes to allow further stent expansion and then proceed with the following steps:
A. Slowly withdraw the delivery system and guide wires.
B. If removal is still not possible, use a balloon dilation catheter to dilate the stent. It should not be necessary for the balloon diameter/size to be equal to the stent diameter. Judgment should be used when selecting the balloon size. Carefully position the balloon catheter within the stent and inflate the balloon to its recommended pressure.
C. Deflate the balloon catheter and withdraw into the flexible bronchoscope. Slowly withdraw the delivery system and guide wire.

5.2 Instructions for use under endoscopy (Refer to Fig.12 to Fig.20):

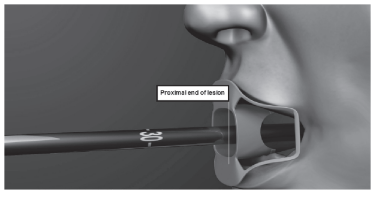
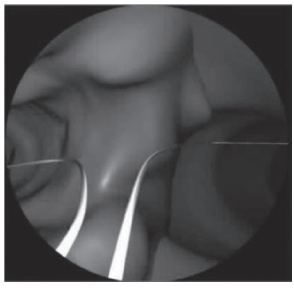


Fig.12 Insert the flexible bronchoscope through mouth. Correctly measure the carina to incisors.



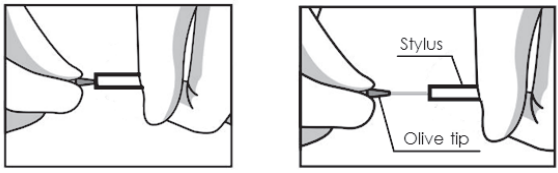


Fig.14 Remove the stylus from each of the olive tips by holding the olive tip with one hand and pulling the stylus out completely with the other.

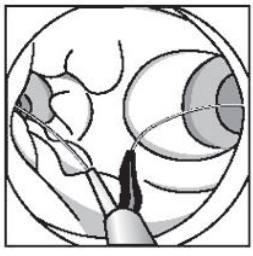


Fig.15 There are two different color olive tips in delivery system. The white olive tip is corresponds to the left branch of the stent. The blue o-live tip is corresponds to the right branch of the stent. Please match the left and right sides. Insert the Delivery System following the guide wires. The marker on the Delivery System should be aligned with the incisors. Insert the flexible bronchoscope again and arrange for side by side with the delivery system. Check whether the guide wires are crossed or not. If the guide wires are crossed, rotate the delivery system in the opposite direction of the crossing until the guide wires are not crossed.

Fig.16 Loosen the safe lock. While holding the back handle stationary, withdraw the front handle to expose the two branch parts of the Y-shaped stent. Stop when the front handle reaches the stopper. Then lock the safe lock.

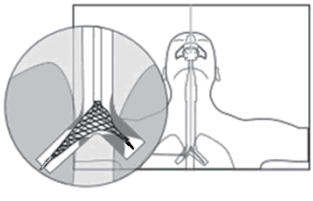


Fig.17 Insert the two branches of the delivery system over the guide wire into the bronchi, then adjust the system gently over the wires until the junction of the branch parts meet the tracheal carina very well.

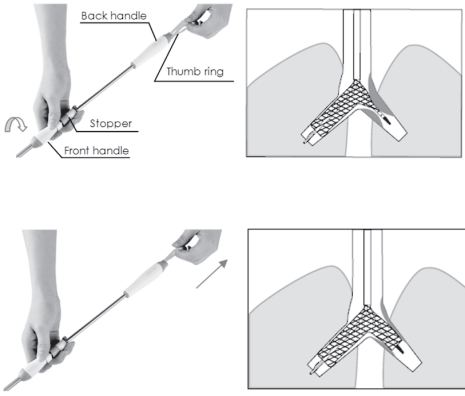


Fig.18 Pull the thumb rings to deploy each of the branch parts separately. If the stent is not align well with the tracheal carina, push delivery system towards the tracheal carina to make the stent fully fitted to the tracheal carina.
NOTE: While the branch parts are deployed and the main branch is not fully released, the patient airway is occluded. Release the main branch must as quickly as possible in next step.

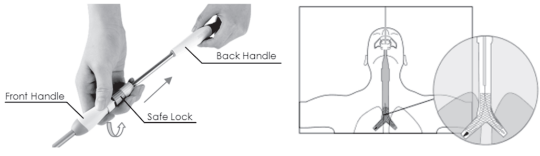


Fig.19 Loosen the safe lock and the stopper. While holding the back handle stationary, withdraw the front handle fully to complete deployment of the stent from of the delivery system.

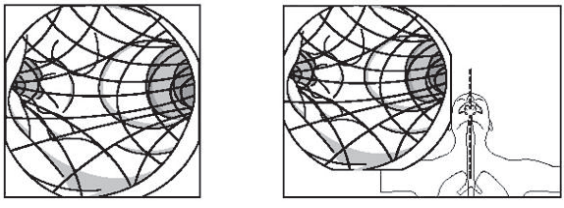


Fig.20 After the stent is deployed completely, remove the delivery system and retain the guide wire and flexible bronchoscope. Observe the position of stent after deployment under flexible bronchoscope. If the position of the stent is found to be incorrect, insert grasping instruments such as the forceps through the channel, clamp the retrieval loop of the left or right branch under the direct vision of the flexible bronchoscope. The stent can be repositioned to the correct position by advancing the flexible bronchoscope and forceps. The reposition distance is no more than 20mm. Remove the grasping instrument, flexible bronchoscope and guide wires. The procedure is completed.

Warning:
Caution and stating: Passing the scope through a recently deployed stent could cause the stent to dislodge. Observe the position of the stent and correct as necessary.

Caution: An attempt to remove the delivery system and guide wires prior to stent expansion or when a stent is partially deployed may cause the stent to dislodge. If excessive resistance is felt during delivery system removal, wait 3-5minutes to allow further stent expansion and then proceed with the following steps:
A. Slowly withdraw the delivery system and guide wires.
B. If removal is still not possible, use a balloon dilation catheter to dilate the stent. It should not be necessary for the balloon diameter/size to be equal to the stent diameter. Judgment should be used when selecting the balloon size. Carefully position the balloon catheter within the stent and inflate the balloon to its recommended pressure.

C. Deflate the balloon catheter and withdraw into the flexible bronchoscope. Slowly withdraw the delivery system and guide wire.

6. Stent removal:
The stent can be removed using grasping instruments.

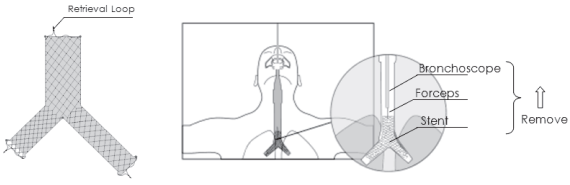


Fig.21 Insert the flexible bronchoscope into the trachea through the patient's mouth. Use grasping instruments such as the forceps inserted through the channel to clamp the retrieval loop of the main branch under the direct vision of the flexible bronchoscope. Then slowly retract flexible bronchoscope and forceps simultaneously until the stent is removed.

III Post Procedure

- Carefully observe the patient post procedure and report any breathing difficulties such as choking or aggressive coughing. If choking occurs, call emergency services immediately. Pain, cough and discomfort will be reduced after a few days. Any worsening of symptoms should be considered as an emergency.
- Upon completion of the procedure, dispose of the device per institutional guidelines for biohazardous medical waste.

MRI Safety Information

MR Conditional

The Tracheal Stent System (Y-Shaped) was determined to be MR-conditional.
Non-clinical testing demonstrated that the Micro-Tech Tracheal Stent System (Y-Shaped) is MR Conditional. The person is implanted with a Tracheal Stent System (Y-Shaped) can be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction. A patient with Tracheal Stent System (Y-Shaped) can be scanned safely in an MR system immediately after placement. Full MRI safety information is as follows:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only.
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg in the Normal Operating Mode of operation for the MR system.
- Under the scan conditions defined, the Micro-Tech Tracheal Stent is expected to produce a maximum temperature rise of 4.5 ˚C after 15-minutes of continuous scanning.
- Artifact Information: In non-clinical testing, the image artifact caused by the Micro-Tech Tracheal Stent extends approximately 11.2 mm from this implant when imaged using a T1-weighed spin echo pulse sequence and a 3-Tesla MR system.

Additional Information: The safety of performing an MRI procedure in a patient with overlapping Tracheal Stents or other MRI-conditional device(s) in direct contact with this device has not been determined. Performing MRI in such situations is not recommended.

How Supplied

The Tracheal Stent System(Y-Shaped) is supplied in sterile (by ethylene oxide gas) and is intended for SINGLE USE ONLY.

Indications

	Manufacturer		Prescription use
	Do not re-use		Do not resterilize
	Keep away from sunlight		Keep dry
	Use-by date		Date of manufacture
	Catalogue number		Batch code
	Consult instructions for use		Do not use if package is damaged
	Sterilized using ethylene oxide		Caution
	Diameter		Working length
	Recommended guide wire		Order number
	MR conditional		Not made with natural rubber latex

Contacts

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