




Segmented Esophageal Stent System

These instructions will explain how to use the Segmented Esophageal Stent System correctly. Please follow these instructions carefully.

Warnings

	The Segmented Esophageal Stent System 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.

Caution

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 esophageal 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 patients.

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Brief Introduction

I Device Name

Segmented Esophageal Stent System

II Description

The Segmented Esophageal Stent System consists of a flexible delivery system preloaded with a self-expanding implantable metallic stent. The segmented stent is made of Nitinol wire by weaving in a tubular mesh shape, in several segments connected by a flexible suture (Figure1). This structure design can make the stent more flexible, compliant and self-expanding. The stent is entirely covered with a soft silicone sleeve to restrict tumor in-growth through the wire mesh and to occlude concurrent esophageal fistulas. The stent has a soft edge at both extremities to minimize tissue irritation. 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. The stent has flanges at both extremities to aid in minimizing migration after the stent has been placed in the esophagus. The delivery system is a coaxial sheath design. It consists of three coaxial sheaths. The outer sheath serves to constrain the stent before deployment and to recapture the stent, if desired, after partial deployment. The outer sheath has a transparent section so that the constrained stent is visible. There are three radiopaque markers and one visual marker to aid in the deployment of the stent (Figure 2). There are radiopaque markers on the inner sheath identifying the proximal and distal ends of the constrained stent (Figure 2, #1 and #2). There is an additional visual marker band between the front handle and the back handle to indicate at what point reposition is no longer possible (Figure 3, #4). The third radiopaque marker band at the distal end of the outer sheath indicates up to what point the stent has been deployed (Figure 2, #3). The olive tip is also radiopaque. The inner sheath contains a central lumen that accommodates a 0.038" (0.97mm) guidewire.

Notice: Figure 2, #2 has two functions, one is a radiopaque marker, and the other is a positioning hook which can help retrieve the stent back into the outer sheath, after partial deployment.

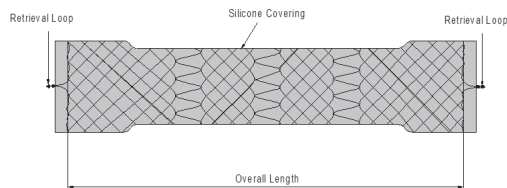


Fig.1 Segmented Esophageal Stent



Fig.2 Delivery System and Radiopaque Markers

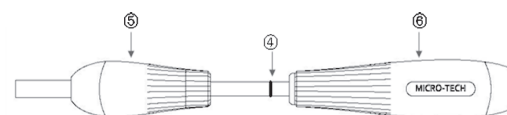


Fig.3 Delivery System, Visual Marker and Handles

Stent Characteristics

The stent is made from Nitinol due to the materials physical characteristics: excellent biocompatibility, prominent corrosion tolerance, shape memory effect, and superelasticity. Initially, the stent is intenerated under the condition of 0~10 °C so the stent can be loaded onto the delivery system. Under the conditions inside the human body, where the temperature is more than 33 °C, the stent will resume its original shape gradually after being deployed from the delivery system. The stent will engender a gentle radial force which acts on the inner wall of the esophageal tract to expand the stricture, gradually restoring patency. Superelasticity at body temperature helps the stent accommodates the esophageal peristalsis.

Caution: Read the entire Instructions for Use thoroughly before using the Segmented Esophageal Stent System. The Segmented Esophageal Stent System 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.

III Indications for Use

The Segmented Esophageal Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic, or extrinsic malignant tumors only, and occlusion of concurrent esophageal fistula.

IV Contraindications

Contraindications include, but not limited to:

- Patients with an aortic aneurysm and cardiac or pulmonary function failure;
- Stricture caused by benign tumors;
- Esophageal stricture and abnormality or Varicose veins caused by mediastinal tumors;
- Dysfunction of autonomic deglutition;
- Severe coagulopathy;
- Placement in strictures that can't be dilated enough to pass the endoscope or the delivery system;
- Those patients for whom endoscopic techniques are contraindicated;
- 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

- Stent misplacement
- Perforation
- Infection
- Bleeding
- Pain
- Foreign body sensation

POST PROCEDURAL COMPLICATIONS

- Stent occlusion due to food accumulation
- Restenosis due to granulomatous tissue formation at stent ends

- Stent occlusion due to granulomatous tissue ingrowth
- Esophageal wall ulceration and/or perforation and/or hemorrhage
- Stent fracture
- Stent migration
- Recurrent obstructive dysphagia related to stent occlusion or migration
- Death

VI Warnings

- Do not use if the pouch is opened or damaged.
- Do not use if labeling is incomplete or illegible.
- Do not use if the Esophageal Stent System has any visible signs of damage.
- Inspect the distal end of the delivery system before use, to ensure that the stent is entirely within the outer tube. Do not use if the stent is partially deployed.
- Do not expose the delivery system to organic solvents (e.g., alcohol).
- Upon completion of the procedure, dispose of the device per institutional guidelines for biohazardous medical waste.

VII Precautions

The delivery system is not designed for use with contrast power injection systems.

Store in a cool and dry place.

Directions for use

Precaution

- Generally speaking, an esophageal stent should be implanted no higher than the superior border of the C7 vertebra, or the distance between the inserted stent and the incisor be at least 20 cm. For upper esophageal strictures it is possible to implant the stent, but careful patient selection by the physician is of utmost importance.
- There may be a small gap between the proximal end of the stent and the delivery system because of movement during transportation, which may result in difficulty in stent deployment. Some steps should be followed to eliminate the gap before being used in patients. First, insert a suitable guidewire into the stent delivery system through the luer port and loosen the safe lock. Then immobilize the front handle and push the back handle gently until the gap is eliminated. Finally, lock the safe lock and remove the guidewire.
- Some imaging equipment is required to aid in the procedure.
- If the endoscope will be used to check the stricture, and the stricture is so severe that the endoscope cannot pass through, forcing the endoscope to pass without the radiographic guidance may cause perforation. It is better to use a stiff guidewire under X-ray to reduce the risk of perforation.
- If one stent needs to be implanted into the esophagus where the aortic arch may be compromised, particular attention should be paid to the size of the stent. To minimize potential complications, the stent should be longer than the aortic arch.
- If one stent needs to be implanted into the esophagus near the trachea, it is better to perform a CT examination first. If the CT examination shows that the tumor locates between the esophagus and the trachea, it is better to implant a tracheal stent first before the esophageal stent implantation. Otherwise, the esophageal stent implantation alone may compress the trachea nearby and cause asphyxiation.
- Intraluminal circulating pressure and multiple corrosion by gastrointestinal secretion may lead to the metal fatigue and subsequent stent fracture.
- Before the procedure, the patient should undergo a barium esophagram to define the location, diameter, and length of the stricture so as to select a suitable stent.
- Whether pre-dilation is necessary or not depends on the situation and physician's judgment. If the stent delivery system can pass the stricture with minimal difficulty, pre-dilation is not necessary. If the patient was not pre-dilated, it might take several days for the inserted stent to expand completely. Perform pre-dilation only when the stricture is so tight that the stent delivery system can't traverse, because pre-dilation may increase the risks of perforation and migration.
- The patient should be fasting for six hours before the procedure. At ten minutes before the operation, the patient should be given a local anesthesia with 2% lidocaine spraying to the pharynx and the intramuscular injection of 15~20 mg anisodamine 654-2 to relax the

smooth muscle of esophagus and reduce the secretion of digestive tract. The condition of local anesthesia can be adjusted depends on the patients situation and physician's judgment.

- Do not release stent entirely, or it cannot be reloaded. Please change another one in this situation, reloading without proper training could lead to operation failure and result in harm or danger to the patients.

Flush the Delivery System

- It is advisable to flush luer port (guidewire port) of the stent delivery system with a 10cc syringe of saline to expel air. (Refer to Fig. 4a) Continue to flush until saline flows out of the distal catheter tip. (Refer to Fig. 4b)

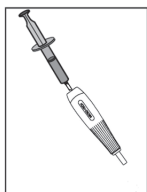


Fig. 4a

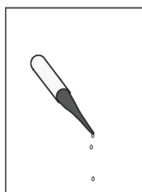


Fig. 4b

I Pre-procedure

Required Equipment

- Endoscope, flexible or rigid (if desired)
- A 0.038 in (0.97mm), 260cm guidewire with floppy olive tip
- Segmented Esophageal Stent System containing a stent of the appropriate length and diameter
- Syringe for irrigation
- Dilation balloon (if desired)

II Procedure

1. Locate the stricture

If using an endoscope, intubate the patient using a standard endoscope per standard technique. Access the stricture location upon direct visualization. Fluoroscopy can also be used to locate the stricture with the aid of a contrast medium.

2. Examine the Stricture (Endoscopically and/or Fluoroscopically)

A. Examine stricture Endoscopically

Endoscopically examine both the proximal and distal segments of the stricture. Using the external ruler on the endoscope, measure the distance between the distal margin of the stricture to the patient's incisors. Withdraw the endoscope to the proximal margin of the stricture and measure the distance to the patient's incisors. The stricture length is calculated as the difference between those two distances.

Caution: In some patients, tumor encroachment will make dilation of the stricture challenging. Physicians should use judgment based on experience in dilating esophageal strictures. Perforation or bleeding of an esophageal tumor is a risk during a tumor dilation procedure.

B. Examine stricture Fluoroscopically

The stricture may also be examined fluoroscopically. Leaving the endoscope in place, observe both the proximal and distal margins of the tumor fluoroscopically. Mark the locations with either radiopaque markers or use anatomical landmarks such as ribs or vertebrae. It is recommended to re-measure

the stricture length by measuring the distance between the radiopaque markers.

3. Choose the Stent Size

The size of the stricture must be accurately calculated to ensure the ideal stent size is used. Generally speaking, the stent should be 30~40mm longer than the stricture in length. The distal end of the stent should be 10 mm~20mm below the lower margin of the stricture and/or fistula while the proximal end should be about 20mm above the upper margin of the stricture and/or fistula. For stent use with a fistula, it is critical to ensure that the stent completely covers the fistula to avoid leakage and facilitate healing

Warning:

Passing the scope through a recently deployed stent is not recommended and could cause the stent to dislodge.

Caution:

Open the outer package to inspect the pouch to make sure that it is free from the damage. Carefully open the pouch and take the stent delivery system from the tray. Make sure that the device is free from any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.

4. Insert Guidewire and Place Through Stricture (Refer to Fig.5 to Fig.11)

Pass a guide wire through the working channel of the endoscope and then through the stricture and into the stomach. A floppy olive tip guidewire is recommended to reduce potential trauma from the tip of the wire.

A. Endoscopic Procedure

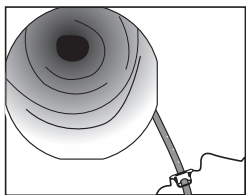


Fig. 5 Pass an endoscope into the esophagus

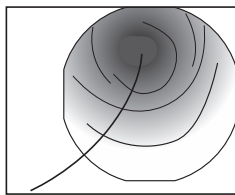


Fig. 6 Place a guidewire through the endoscope.

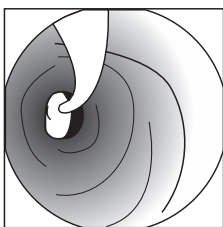


Fig. 7 Perform pre-dilation if necessary.

B. Interventional Procedure

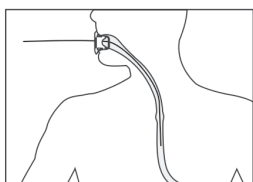


Fig. 8 Place a floppy tip guidewire through the stricture.

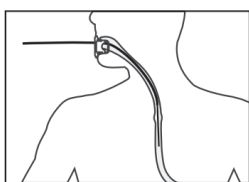


Fig. 9 Place an exchange catheter through the guidewire.

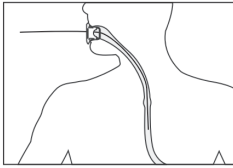


Fig. 10 Exchange a floppy tip guidewire with a stiff wire (if necessary).

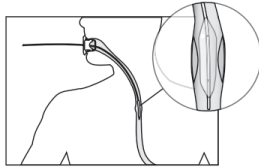


Fig. 11 Perform pre-dilate if necessary.

5. Advance the Delivery System over the Guidewire and Position Stent (Refer to Fig.12 to Fig.13)

There are three radiopaque markers and one visual marker to aid in the deployment of the stent. Radiopaque markers attached to the inner tube indicate the length of the constrained stent on the delivery system (Figure2, #1 and #2). A visual marker between the front handle and the back handle indicates at what point repositioning is no longer possible (Figure3, 4#). Prior to reaching this point, the stent may be recaptured and repositioned up to a maximum of two times. The third radiopaque marker at the distal end of the exterior tube indicates up to what point the stent has been deployed (Figure2, 3#).

A. Endoscopic Procedure

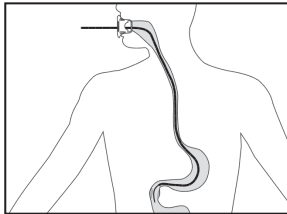
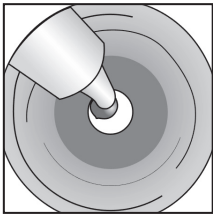


Fig. 12 Advance the OTW Esophageal Stent System over the guidewire towards the stricture.

B. Interventional Procedure

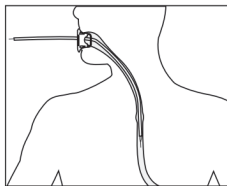


Fig. 13 Advance the Esophageal Stent System over the guidewire into the stricture.

6. Deploy Stent (Refer to Fig.14)

Loosen the safe lock first, begin stent deployment by holding the front handle (farthest from the operator, Figure3, 5#) of the delivery system with one hand, and using the other hand, grasp the back handle (closest to the operator, Figure3, 6#) and hold this handle stationary. Between the handles is a black segment with visual markers to aid in stent deployment (Figure3, 4#). To deploy the stent, slowly pull the front handle toward the back handle while holding the back handle stationary (Figure 14). Monitor the stent deployment, keeping the radiopaque markers on the delivery system between the identified stricture margins. If necessary, it is possible to stop deployment and adjust the stent position proximally prior to passing the re-constrained marker (Figure3, 4#).

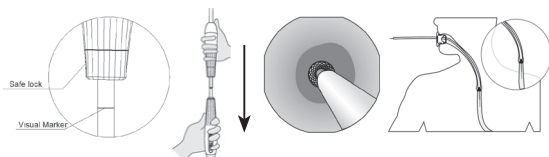


Fig. 14 Loosen the safe lock first, then withdraw the front handle to the visual marker to deploy the stent while immobilizing the back handle.

Reposition Technique

- The stent can be recaptured at any point up to the reposition marker (visual Figure 3, #4).

Note: Once crossing over the reposition marker, the stent can't be repositioned.

- Repositioning is done by reversing the direction of deployment, by holding the back handle stationary while pushing the front handle.
- The stent has been designed to be repositioned up to two times.

7. Assess the Deployed Stent and remove the Delivery

System(Refer to Fig.15 to Fig.17)

Following stent deployment, view the stent endoscopically to confirm stent expansion as tumor impingement may prevent the stent from achieving its maximum diameter immediately. Carefully remove the delivery system and the guidewire.

Warning: Before removing the stent delivery system, push the whole delivery system forward approximately 1cm to ensure that the proximal retrieval loop is detached from the positioning hook. Push the front handle forward until the outer sheath meets the olive tip.

Caution: An attempt to remove the delivery system and guidewire prior to stent expansion or when a stent is partially deployed may dislodge the stent. If excessive resistance is felt during delivery system removal, wait 3-5minutes to allow further stent expansion and then proceed with the following steps:

- Slowly withdraw the delivery system and guidewire.
- 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. Inflate the balloon to its recommended pressure.
- Deflate the balloon catheter and withdraw into the endoscope. Slowly withdraw the delivery system and guidewire.

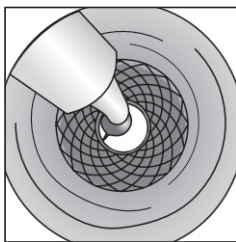


Fig. 15 Remove the delivery system.

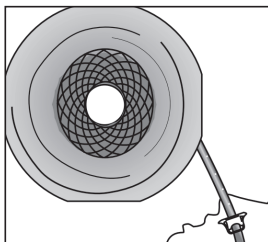


Fig. 16 Confirm endoscopically that the stent has been completely deployed.

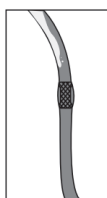
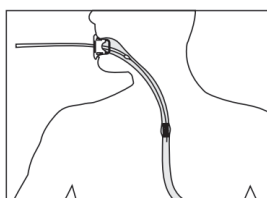


Fig. 17 Confirm radiographically that the stent is completely expanded.

This completes the initial stent placement procedure. Stent placement is considered permanent upon completion of initial stent placement procedure.

III Post Procedure

After the procedure, carry out radiography to ascertain the position of the stent. Cold drinks, viscous and hard foods are prohibited in case of stent occlusion. Nibble and swallow slowly when taking foods. Follow-up examinations by radiography and endoscopy should be performed to check any signs of complications.

Compatibility



MR Conditional.

Non-clinical testing and in-vivo electromagnetic simulations have demonstrated the Micro-Tech Segmented Esophageal Stent System is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5T and 3T
- Maximum spatial gradient field of 3000 gauss/cm (30.0 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of <2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Micro-Tech Segmented Esophageal Stent System is expected to produce a maximum temperature rise of 2 °C after 15 minutes of continuous scanning.





















In non-clinical testing, the image artifact caused by the device extends approximately 40 mm from the Micro-Tech Segmented Esophageal Stent System when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system.

Additional Information: The safety of performing an MRI procedure in a patient with overlapping Esophageal 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 Segmented Esophageal Stent System is supplied sterile (by ethylene oxide gas) and is intended for SINGLE USE ONLY.

Indications

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

Contacts



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