

Operating Instruction – self expandable Esophageal Stents SU

Warnings

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|--|--|
| | The Esophageal Stent System is intended for single use only! DO NOT reuse, reprocess or resterilize 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 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 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. |
| | Pay attention to the instructions for use. Make sure to read the instructions before using. |

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 endoscopists 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 implant. 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.

Warranty

ENDO-FLEX warrants that reasonable care and prudence has been exercised in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning, and sterilization of this instrument as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond ENDO-FLEX' control directly affect the instrument and the results obtained from its use. ENDO-FLEX' obligation under this warranty is limited to the repair or replacement of this instrument and ENDO-FLEX shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. ENDO-FLEX neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. ENDO-FLEX assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such instrument.

Brief Introduction

Device Name

Esophageal Stent SU

Description

components: the implantable metallic stent and the delivery system (Refer to Fig. 1). The stent is made of Nitinol wire by weaving in a tubular mesh shape. This shape design can make the stent more flexible, compliant and self-expanding. The delivery system consists of three coaxial tubes. The outer tube serves to constrain the stent until being retracted during the stent deployment. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. The interior tube contains a central lumen that accommodates a 0.038 inch guide wire.

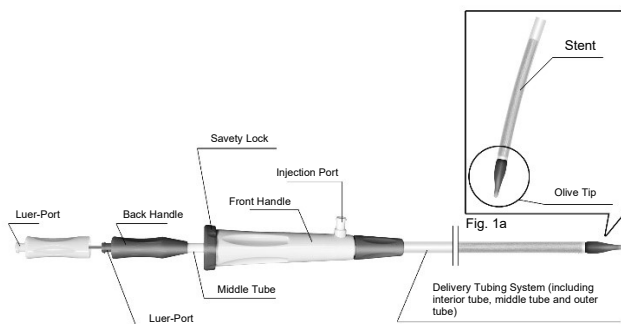


Fig. 1: OTW Esophageal Stent Delivery System (OTW = Over the Wire)

Stent Characteristics

The reason why the Nitinol is used as the material lies in its physical characteristics: excellent biocompatibility, prominent corrosion tolerance, shape memory effect and

super elasticity. Initially, the stent is intenerated under the condition of 0~10 °C or in ice water where its shape can be changed, so the stent can be easily loaded to 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 esophageal tract to expand the stricture gradually and rebuild the unobstructed lumen. Super elasticity under body temperature helps the stent accommodate the esophageal peristalsis. Because of the special designs of the stent, the patient will feel more comfortable by keeping the esophageal tract patent after the implant.

Both ends of the stent are pliable and smooth without any sharp corners or burrs that can reduce risks of injury to the esophageal tract (Refer to Fig. 2a).

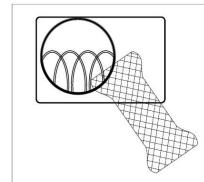


Fig. 2a

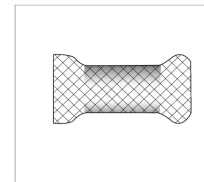


Fig. 2b

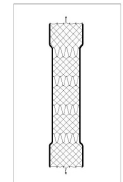


Fig. 2c

The stent can be covered by silicone on request. The silicone covering has characteristics of excellent biocompatibility and prominent corrosion tolerance to gastric acid. And it can inhibit the tumor in growth through the stent mesh as well as occlude the esophageal fistula (Refer to Fig. 2b). Different kinds of stents are available for different situations (Refer to Fig. 2c).

Indications

The Esophageal Stent implant is indicated for use in the treatment of esophageal stricture caused by neoplasms, cardia stricture, anastomotic stoma stricture, and the esophageal fistula occluding.

Contraindications

Contraindications include, but not limited to:

- Patients with abdominal aortic aneurysm
- Stricture caused by tumors
- Esophageal stricture
- Dysfunction of autonomic

Potential Complications

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

PROCEDURAL COMPLICATIONS

- Stent misplacement
- Perforation
- Infection
- Bleeding
- Pain

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
- esophageal leaks
- gastro-esophageal reflux
- aspiration pneumonia
- tracheal compression
- Stent break
- Stent migration
- Obstructive dysphagia related to stent occlusion or migration

Warnings

Do not use if the pouch is opened or damaged. Do not expose the delivery system to organic solvents (e.g. alcohol). Upon completion of procedure, dispose of device per institutional guidelines for biohazardous medical waste.

Precautions

The delivery system is not designed for use with power injection systems. Store in a cool and dry place.

Patient Population

The patient population or target patient group is derived from the indication determined by the responsible doctor who diagnostically or therapeutically treats the patient as part of an endoscopic procedure (the leading procedure per se) according to the intended use of the medical device.

There are no known restrictions to the patient population or the target patient group.

• Use of the product on minors:

The user can use the product on minors in the case that the physiological and anatomical conditions of the patient permit the use of the product.

Use of the product on women who are pregnant or breastfeeding:

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The indication for the use of the product on women who are pregnant or breast-feeding must be narrowed down by the user based on the respective individual physiological and anatomical conditions of the patient.

Pre-procedure

Equipment Required

- Endoscope, flexible or rigid
- A maximum .038 inch guide wire
- OTW Esophageal Stent Delivery System
- Syringe for irrigation
- Dilatation balloon (as necessary)

Stent Preparation

- Select the length of the stent:
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 while the proximal end should be about 20 mm above the upper margin of the stricture.
- Select the diameter of the stent:
Generally speaking, the diameter of the stent is around 18 -22mm depending on the conditions of the strictures. For the stricture caused by the radiation therapy, it is advisable to select the stent with diameter 16-18 mm and cup-mouthed or spherical design for both ends.
- If the stent is covered with silicone, it may not expand smoothly after being deposited in the delivery system for a long time, because the silicone coating is relatively sticky. So we strongly recommend you to check the manufacturing date before using.

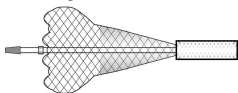


Fig.3a partially release stent to define it couldn't resume.



Fig.3b gently squeeze the stent to help it resume.

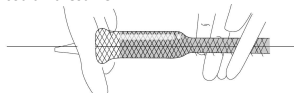


Fig.3c Visually confirm the stent resume to its original shape.

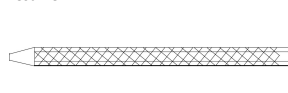


Fig.3d put the stent back into the delivery system.

If the covered stent has been stored for more than 12 months, please follow the following steps to help it resume manually. First of all, partially release the stent but make sure that at least 2cm of its length remaining in the delivery system. If the stent couldn't resume independently, gently squeeze it to help it resume by hands. Hold the delivery system with one hand and push gently outer flange of the stent to squeeze it with another hand. (Refer to Fig. 3a and 3b). Finally, when the stent can resume its original shape, put it back into the delivery system again. (Refer to Fig.3c and 3d)

Notice: Do not release stent entirely, or it can not 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.

Visual Inspection

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.

Flushing the Delivery System

- Flush the stent delivery system with a 10cc syringe of saline through the injection port to expel air (Refer to Fig. 4a). Continue to flush until saline flows out of the distal catheter end (Refer to Fig. 4b).
- It is advisable to flush luer port (guide wire port) of the stent delivery system with a 10cc syringe of saline to expel air (Refer to Fig. 4c). Continue to flush until saline flows out of the distal catheter tip (Refer to Fig. 4d).

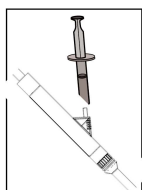


Fig. 4a

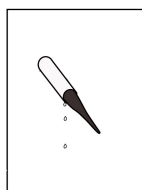


Fig. 4b

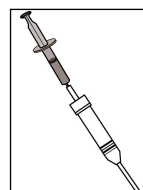


Fig. 4c

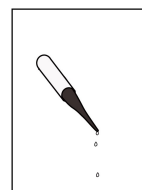


Fig. 4d

Reconfirmation

Observe the distal end of the catheter to ensure that the stent is totally placed inside the outer sheath. Do not use if the stent is partially deployed.

Notice:

Before the operation, the patient should take the barium esophagogram to define the location, diameter and length of the stricture so as to select a suitable stent.

- 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.
- 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, predilation is not necessary. If the patient was not being predilated, it may cost several days for the inserted stent to expand completely. Perform pre-dilation only when the stricture is so tight enough that the stent delivery system can't traverse, because pre-dilation may increase the risks of perforation and migration.

Procedure

Precaution

- Generally speaking, the stent should be inserted not higher than the superior border of C7 vertebra or the distance between the inserted stent and the incisor is at least 20 cm. However, for some special higher esophageal strictures, it is still possible to implant the stent but careful patient selection by the doctor is of utmost importance.
- There may be one gap between the proximal end of the stent and the delivery system because of transportation, which may result in difficulty in stent deployment. Some steps should be followed to eliminate the gap before being used in patients. First of all, insert one guide wire into the stent delivery system through the luer port and release the safety lock. Then immobilize the front handle and push the back handle gently until the gap eliminates. Finally, lock the safety lock.
- Some imaging equipments are required to aid in the procedure.
- One stent deployed across the cardia may lead to gastroesophageal reflux, so stents with an anti-reflux valve should be used in this condition. Patients treated by radiotherapy or chemotherapy may result in tumor shrinkage and subsequent stent migration. Radiotherapy or chemotherapy can be carried out 30 days later in order to greatly decrease the risk of stent migration.
- If the endoscope will be used to check the stricture, and the stricture is so serious that the endoscope cannot pass through, forcing the endoscope to pass without the radiographic guiding may cause perforation. It is better to use a stiff guide wire under X-ray, thus the possibility of perforation will be reduced greatly.
- If one stent needs to be implanted into the esophagus where the aortic arch may be compromised, special attention should be paid to the size of the stent. In order to prevent the hemorrhage caused by perforation, the stent should be longer than the aortic arch in length in general.
- 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 may lead to the metal fatigue and subsequent stent break.

Endoscope Procedure

Direction for general procedure

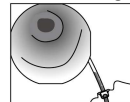


Fig. 5 Pass an endoscope into the esophagus

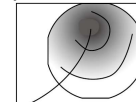


Fig. 6 Place a guide wire through the endoscope.

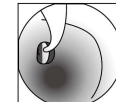


Fig. 7 Perform pre-dilation if necessary.

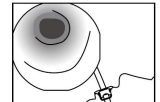


Fig. 8 Pass the endoscope in.

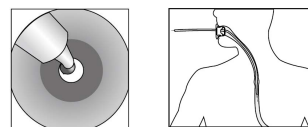


Fig. 9 Advance the OTW Esophageal Stent System over the guide wire towards the stricture.

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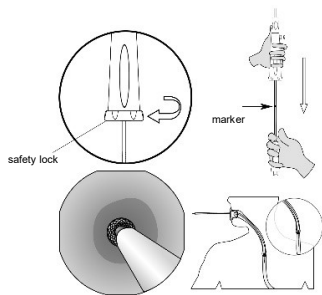


Fig. 10
 For resheathable type: loose the safety lock first, then withdraw the front handle to deploy part of the stent while immobilizing the back handle. **When pulling up to the marker, the stent can be pulled back into the delivery system.**

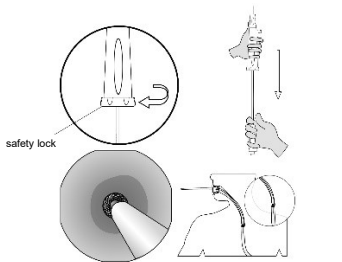


Fig. 11
 For other types: Unlock the safety lock, hold the back handle stationary with one hand, and withdraw the front handle with the other hand to deploy the stent.

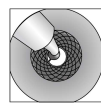


Fig. 12
 Remove the delivery system.

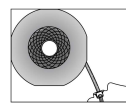


Fig. 13
 Confirm endoscopically that the stent has been completely deployed.

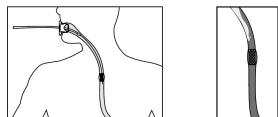


Fig. 14 Confirm radiographically that the stent is completely deployed.

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

This symbol indicates that this device is suitable for magnetic resonance imaging.

Non-clinical testing has demonstrated that this stent is MR Conditional according to ASTM F2503. A patient with this stent can be scanned safely immediately after placement under the following conditions.

Static Magnetic Field

- Static magnetic field of 3 Tesla or less
- Maximum spatial magnetic gradient of 720 Gauss/cm or less outside of scanner covering, accessible (to a patient or individual).

MRI-Related Heating

- 1.5 and 3.0 Tesla Systems: It is recommended to scan in normal operation mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg). ("Normal Operating Mode" is defined as the mode of operation of the MR system in which none of the outputs have a value that cause physiological stress to the patient) for 15 minutes of scanning (i.e., per scanning sequence).
- Non-clinical testing was conducted on the stent under the following conditions, and produced a maximum temperature rise of 2.8 °C
 - a maximum whole body average specific absorption rate (SAR) of 2.9 W/kg (corresponding to a calorimetry measured value of 2.1 W/kg) for 15 minutes of MR scanning in a 1.5 Tesla Magnetom (Siemens Medical Solutions, Malvern, PA, Software Numaris/4) MR scanner.
 - a maximum whole body average specific absorption rate (SAR) of 2.9 W/kg (corresponding to a calorimetry measured value of 2.7 W/kg) for 15 minutes of MR scanning in a 3.0 Tesla Excite (GE Electric Healthcare, Milwaukee, WI, Software 14X.M5) MR scanner.

Image Artifacts

MR image quality may be compromised if the area of interest is within the lumen of the Esophageal Stent or within approximately 5 mm of the position of the Stent as found during non-clinical testing using the sequences:

T1-weighted, spin echo pulse sequence and Gradient echo pulse sequence in a 3.0 Tesla Excite (GE Electric Healthcare, Milwaukee, WI, Software 14X.M5) MR system

with body radiofrequency coil. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

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

Transport and Storage Conditions

- Products may only be transported and stored in the packaging provided for this purpose.
- Products must be stored dry and protected from sunlight at room temperature.
- Do not place any objects on the storage packaging and the sterile barrier system!
- Ensure the instruments are not kept near to chemicals, disinfectants or radioactive radiation!

Symbols used

| | | | |
|--|------------------------------------|--|---|
| | Item Number | | Protect from sunlight |
| | Batch code | | Attention |
| | Manufacturer | | Usage esophageal |
| | Date of manufacture | | Stent diameter |
| | Observe instructions for use | | Stent length |
| | Sterilized with ethylene oxide | | Application Set OTW |
| | Single use | | Max. guide wire diameter |
| | Do not re-sterilize | | For the attending physician only |
| | Do not use if packaging is damaged | | Medical Device |
| | Expiry Date | | Simple sterile barrier system |
| | Keep dry | | Simple sterile barrier system with outer protective packaging |