Operating Instructions – self expandable Duodenal and Colonic Stents SU

Warnings

	The Intestinal Stent Delivery System is intended for single use only! DO NOT reuse, reprocess or resterilize the device. 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 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.

Caution

Patients sensitive to Nickel Titanium (Nitinol) may suffer an allergic reaction to this implant.

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 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 will 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

Duodenal and Colonic Stent (Intestinal-Stent) SU

Description

The Intestinal Stent Delivery System comprises of two components: the implantable metallic stent and the delivery system (refer to Fig. 1a, 1b). 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 the deployment. The interior tube contains a central lumen that accommodates a 0.035 inch/0.89mm guide wire. TTS Intestinal Stent Delivery System is compatible with minimum 4.2mm working channel of the endoscope.

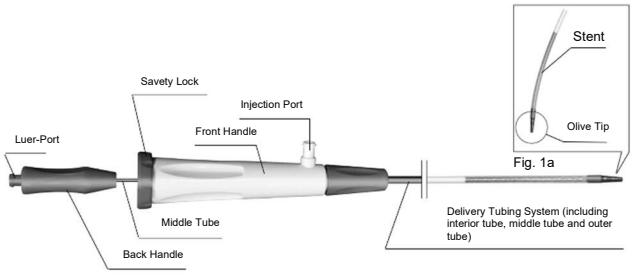

Fig. 1: Intestinal Stent system – TTS (TTS = Through the Scope)

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 ℃ 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 ℃, 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 intestinal tract to expand the stricture gradually and rebuild the unobstructed lumen. Super elasticity under body temperature helps the stent accomodate the intestinal peristalsis. Because of the special designs of the stent, the patient will feel more comfortable by keeping the intestinal tract patent after the implant.

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

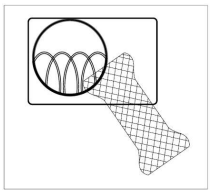

Fig. 2a

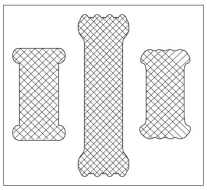

Fig. 2b

Different kinds of stents are available for different situations (Refer to Fig. 2b).

Indications

The Intestinal Stent is indicated for use in the treatment of intestinal strictures produced by malignant neoplasms, stricture in intestinal anastomotic stoma and the intestinal fistula occluding.

Contraindications

Contraindications Include, but not limited to:

- Severe coagulopathy
- Severe intestinal adhesion and subsequent intestinal obstruction
- Bleeding caused by severe hemorrhoid and Perianal varices (colonic stents)

Potential Complications

PROCEDURAL COMPLICATIONS

- Stent misplacement
- Intestinal perforation
- Infection
- Bleeding
- Pain

POST PROCEDURAL COMPLICATIONS

- Stent occlusion due to tumor overgrowth at stent ends
- Stent occlusion due to tumor ingrowth
- Stent occlusion due to granulomatous tissue ingrowth
- Restenosis due to granulomatous tissue formation at stent ends
- Intestinal ulceration and/or perforation and/or hemorrhage
- Stent break
- Stent migration
- Recurrence of defecation difficulties related to stent occlusion or
- food impaction
- tenesmus
- incontinence
- peritonitis
- pancreatitis and cholangitis

Warnings

Do not use if the pouch is opened or damaged before use. 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, 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:**
  The indication for the use of the product on women who are pregnant or breastfeeding must be narrowed down by the user based on the respective individual physiological and anatomical conditions of the patient.

ENDO-FLEX GmbH ° Alte Hünxer Str. 115 ° D-46562 Voerde ° Germany ° ☎ (0049) - (0)281 – 9 44 00 – 0 ° FAX: (0049) - (0)281 – 9 44 00 – 11
Email: sales@endo-flex.de ° www.endo-flex.de

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Pre-procedure
Equipment prepare
- Endoscope, flexible or rigid
- A 0.035 inch (0.89mm) guide wire
- Intestinal Stent Delivery System
- Syringe for Irrigation
- Dilation Balloon (as necessary)

Stent Preparation
- Select the right length of the stent:
  Generally speaking, the stent should be 20~30mm 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 10 mm above the upper margin of the stricture.
- Select the right diameter of the stent:
  Generally speaking, the diameter of the stent is around 18 ~30mm depending on the conditions of the strictures.
- 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.

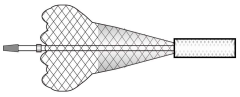
Fig. 3a: Partially release the stent to define it couldn't resume


Fig. 3b: Gently squeeze the stent to help it resume

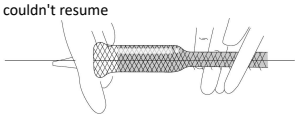
Fig. 3c: Visually confirm that the stent couldn't resume to its original shape

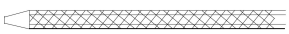
Fig. 3d: Put the stent back into the delivery system

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. Then 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.

Flush 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 the saline flows out of the distal catheter end (Refer to Fig. 4b).
It is advisalbe 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 the saline flows out of the distal catheter tip (Refer to Fig. 4d).

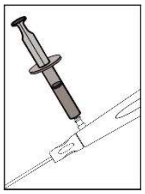
Fig. 4a

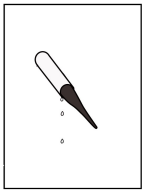
Fig. 4b

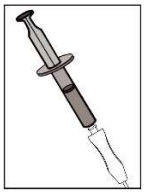
Fig. 4c

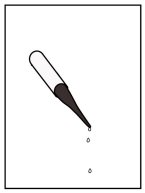
Fig. 4d

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

Notice: Before the procedure, carry radiography to define the location, diameter and length of the stricture so as to select a suitable stent. Patients should stop eating one day before the procedure. This device should be operated by qualified doctors in the procedure. 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. 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
Pre-caution
- 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 lure 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.
- Insert the delivery system slowly and carefully along the guide wire under some effectual monitoring.
- Patients treated by radiotherapy or chemotherapy may have 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.
- Intraluminal circulating pressure may lead to the metal fatigue and subsequent stent break.
- Patients should lie on their left side and the procedure should be monitored under endoscopic guidance with the aid of imaging equipments like X-RAY and CT.

Direction for General procedure

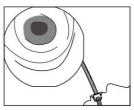
Fig. 5: Pass an endoscope into the duodenum

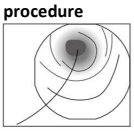
Fig. 6: Place a guide wire through the endoscope.


Fig. 7: Perform pre-dilation if necessary

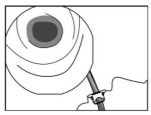
Fig. 8: Pass the endoscope through the stricture.

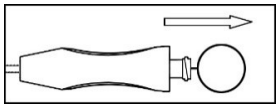
Fig. 9:
Pull the stylus out completely.

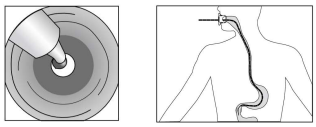
Fig.10:
remove the endoscope and advance the intestinal stent delivery system over the guide wire into the stricture.

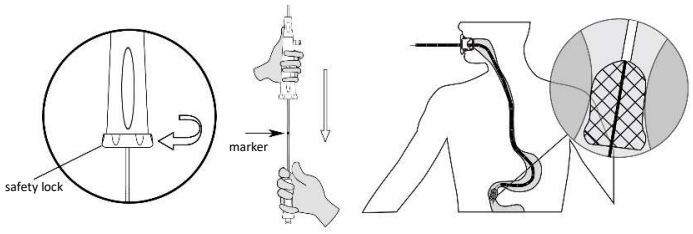

Fig. 11a:
For reshealthable type: loose the safety lock first, then withdraw the front handle to deploy part of the stent while immobilizing the back handle. **When pulling up to the marker, the stent can be pulled back into the delivery system.**

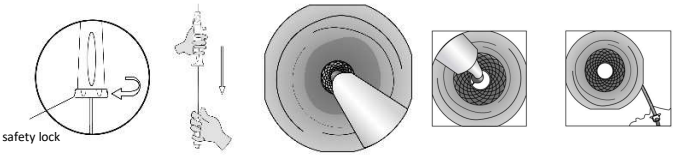

Fig. 11b:
For other types: Loose the safety lock first. Then withdraw the front handle by one hand to deploy the stent while immobilizing the back handle.

Fig. 12:
Remove the delivery system.

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

ENDO-FLEX GmbH ° Alte Hünxer Str. 115 ° D-46562 Voerde ° Germany ° ☎ (0049) - (0)281 – 9 44 00 – 0 ° FAX: (0049) - (0)281 – 9 44 00 – 11
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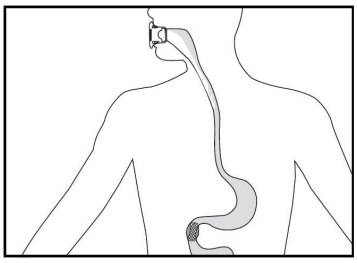

Fig. 14: Confirm radiografically that the stent has been completely deployed.

Post Procedure
After the procedure, carry out radiography to ascertain the position of the stent. Consult the doctors before takeing any food. Follow-up examinations by radiography and endoscopy should be performed to check any signs of complications.

Compatibility
MR 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) ≤ 2.0W/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 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

REF	Item Number		Attention
LOT	Batch code	DUODENUM	Usage duodenal
	Manufacturer	INTESTINAL	Usage intestinal
	Date of manufacture	P D	Stent diameter
	Observe instructions for use	C D	Stent length
STERILE EO	Sterilized with ethylene oxide	TTS: E G	Application Set TTS
	Single use	.035" Guide Wire Max. Guide Wire	Max. guide wire diameter
STERILIZE	Do not re-sterilize	Rx Only	For the attending physician only
	Do not use if packaging is damaged	MD	Medical Device
	Expiry Date		Simple sterile barrier system
	Keep dry		Simple sterile barrier system with outer protective packaging
	Protect from sunlight		

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