Operating Instructions – self expandable biliary Stents SU

Warnings

	The biliary 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 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 biliary 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

selfexpandable biliary Stent SU

Description

The Biliary Stent Delivery System comprises of two components: the implantable metallic stent and the delivery system (Refer to Fig. 1a and 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 tubes and stents aid in imaging during the deployment. The interior tube contains a central lumen that accommodates a 0.035in./0.89mm guide wire.

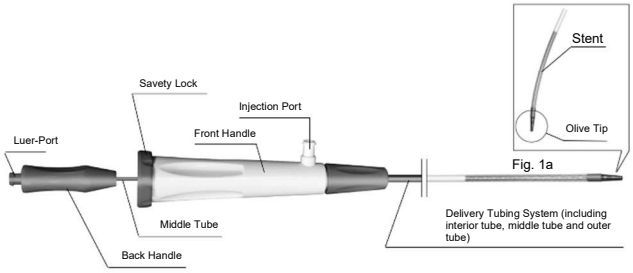

Fig.1b TTS Biliary Stent Delivery System for ERCP

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 biliary duct to expand the stricture gradually and rebuild the unobstructed lumen. Because of the special designs of the stent, the patient will feel more comfortable by keeping the biliary duct patent after the implant. Both ends of the stent are pliable and smooth without any sharp corners or burrs. This design can reduce risks of injury to the biliary duct (Refer to Fig. 2a).

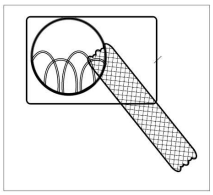

Fig. 2a

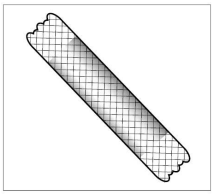

Fig. 2b

The stent can be covered by silcone on request. The silicone covering has characteristics of excellent biocompatibility and prominent corrosion tolerance to gastric acid. And it can inhibit the tumor ingrowth through the stent mesh as well as occlude the biliary duct fistula (Refer to Fig. 2b).

Indications for Use

The Biliary Stent is indicated for use in the treatment of biliary strictures caused by malignant neoplasms.

Contraindications

Contraindications include, but not limited to:

- Patients with obvious tendency of haemorrhage
- Patients allergic to contrast media;
- Patients with hydroperitoneum;
- Patients with space occupying lesion in puncturing path.

Potential Complications

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

PROCEDURAL COMPLICATIONS

- Stent misplacement
- incomplete removal of the covering membrane (covered stents)
- failure of the stent and/or the delivery system during stent deployment as well as failure of stent expansion and inability to remove the inner catheter after stent release (all stents)
- Perforation
- Infection
- Bleeding
- Pain

POST PROCEDURALCOMPLICATIONS

- Stent occlusion due to sludge
- Ulceration
- Perforation
- Hemorrhage
- Stent Break
- Stent migration
- Stent occlusion due to tumor ingrowth
- Stent occlusion due to granulomatous tissue ingrowth
- Recurrent obstructive dysphagia caused by stent occlusion or migration

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.

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

Operating Instructions – self expandable biliary Stents SU

- **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.

Pre-procedure
Equipment Required
- Endoscope, flexible
- A 0.035" (0.89mm) Guide Wire
- Biliary Stent Delivery System
- Syringe for irrigation
- Dilatation Balloon (as necessary)

Stent Preparation

Select the length of the stent:
Generally speaking, the stent should be 20mm longer than the stricture in length. The distal end of the stent should be 10 mm 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 diameter of the stent:
Generally speaking, the diameter of the stent is around 8~10mm depending on the conditions of the strictures. 6-8mm is advisable if two biliary stents need to be implanted.
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 cannot resume


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


Fig. 3c: Visually confirm that the stent can 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 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.

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 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 the saline flows out of the distal catheter tip (Refer to Fig. 4d).

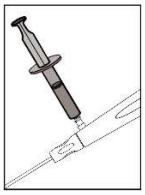
Fig. 4a

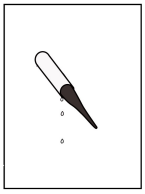
Fig. 4b

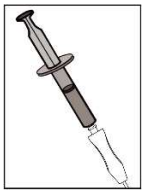
Fig. 4c

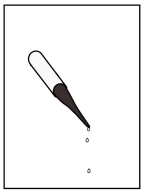
Fig. 4d

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

Procedure
Precaution
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. Harmful substances and intraluminal pressure can lead to material fatigue and fracture of the stent. Sphincterotomy is not always essential for stent delivery but may be performed based on the physicians' judgments.

1. Define the stricture and biliary duct diameter.
Pass an duodenoscope until the duodenal papilla. Then advance the cannulating catheter through the working channel of the endoscope. Perform the catheter to pass through the papilla and inject contrast agent. Observe the contrast agent by radiograph to define the stricture and biliary duct diameter.

2. Insert the guide wire and perform pre-dilation if necessary.
Place a 0.035 inch (0.89mm) guide wire through the catheter until the biliary duct, then remove the catheter. If necessary, perform a sphincterotomy. If the stricture is so tight, perform pre-dilation by dilation balloon to accommodate the stent delivery system.

3. Advance the Biliary Stent Delivery System over the guide wire
Pull protective stylus out first. Advance The Biliary Stent Delivery System over the guide wire into the biliary duct until the proximal end of the preloaded stent is above the upper margin of the stricture and the distal end of the stent is below the lower margin of the stricture. Confirm the position by the radiopaque markers on the stent with the aid of radiography.

4. Deploy the stent.
General procedure: Loosen the safety lock first. Then retract the front handle by one hand to deploy the stent while immobilizing the back handle by the other hand.

5. Assess the deployed stent and remove the delivery system.
Confirm radiographically that the stent has been completely deployed from the system and in the right position. Carefully remove the delivery system and the guide wire while watching not to dislodge the stent with the olive tip.

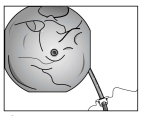
Fig. 5:
Pass an endoscope until the duodenal papilla.


Fig. 6:
Cannulate through the papilla.

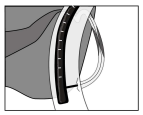
Fig. 7:
Inject contrast agent to define the stricture and biliary duct diameter.

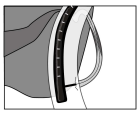
Fig. 8:
place a 0.035 inch (0.89mm) guide wire through Endoscope with the visualization of radiography.


Fig. 9:
Perform sphincterotomy if necessary.

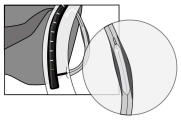
Fig. 10:
Perform pre-dilation if necessary.

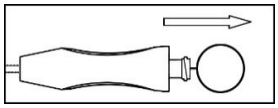
Fig. 11:
Pull the stylus out completely.

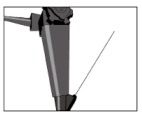
Fig. 12:
estimate the stricture length by measuring the length of the guide wire inserted when withdraw it.

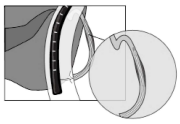
Fig. 13:
Advance the Biliary Stent Delivery System over the guide wire.

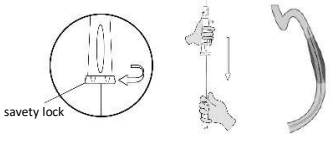

Fig. 14a:
Loosen the safety lock first. Then retract the front handle by one hand to deploy the stent while immobilizing the back handle by the other hand.

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

Operating Instructions – self expandable biliary Stents SU

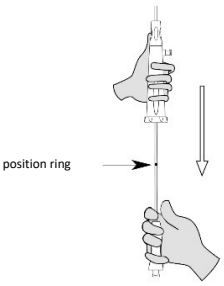

Fig. 14b:
If the delivery system is a resheathable one: only if the front handle doesn't pass the position ring can the stent be retracted entirely into the delivery system and deploy again.

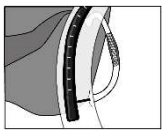

Fig. 15:
Remove the delivery system.

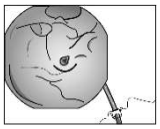

Fig. 16:
Confirm radiographically that the stent has been completely deployed.

Post Procedure
If the stricture reoccurs after stent implantation, it is unfavorable to dilate the stricture by balloon.

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 Biliary Stent or within approximately 5 mm of the position of the Biliary 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 Biliary 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		Protect from sunlight
LOT	Batch code		Attention
	Manufacturer	BILIARY	Usage biliary
	Date of manufacture	B	Stent dimensions
	Observe instructions for use	TTS: E G	Application Set TTS
STERILE EO	Sterilized with ethylene oxide	.035" Guide Wire Max. Guide Wire	Max. guide wire diameter
2	Single use	Rx Only	For the attending physician only
2 STERILIZE	Do not re-sterilize	MD	Medical Device
	Do not use if packaging is damaged		Simple sterile barrier system
	Expiry Date		Simple sterile barrier system with outer protective packaging
	Keep dry		

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