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Instructions for use

**EGIS Biliary Stent &
Introducer**

 **S&G BIOTECH INC.**

The logo features a stylized 'S' and 'G' intertwined within a circular border.

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EGIS Biliary Stent

(single bare/single covered/double bare/double covered)

PRODUCT INFORMATION

EGIS® Biliary Stent is a medical treatment device who can use only authorized physician trained in diagnostic and interventional technicians.

The physician should be following the technical instruction.

PRODUCT TYPE

EGIS® Biliary Stent consists of 4 type of style named Single Bare, Single Covered, Double Bare, Double Covered and Catheter which guides the Stent to the disease region.

The Stent has Radio-opaque markers at both ends and center of the Stent

EGIS® Biliary Stent has designed a self-expandable property made of Nitinol Wire which means constructed braded and biocompatible Nikel and Titanium alloy wire

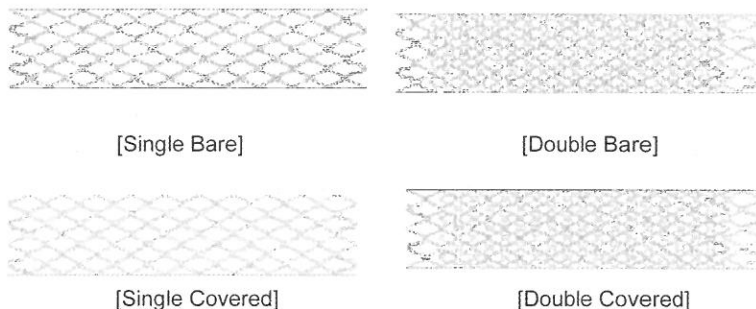


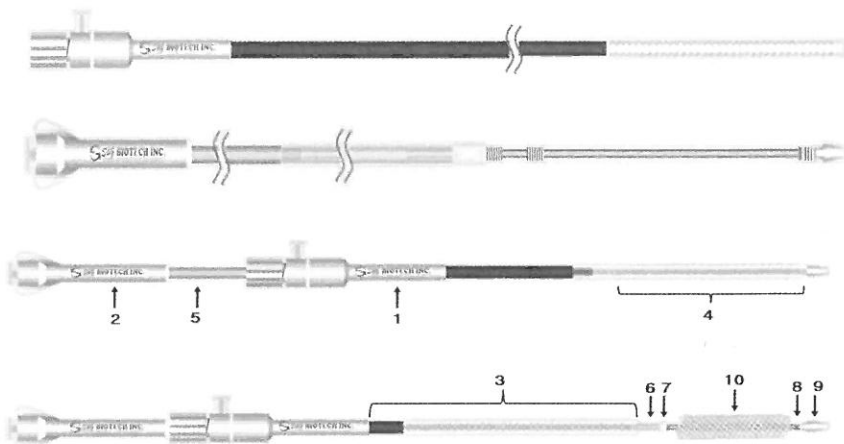
Fig.1 EGIS® Biliary Stent

PRODUCT DESCRIPTION

The Self-expandable EGIS® Biliary Stent is a flexible and excellent conformability which means maintaining the shape of the mesh tubular from the meandering stricture.

EGIS® Biliary Stent has three radio-opaque markers for each position of both ends and center of the Stent.

The stent is loaded in delivery system and upon deployment of the stent imparts an outward radial force on the luminal surface of the bile duct to establish patency.



[Fig. 2. Introducer system]

The Introducer consists of Sheath (Fig. 3 on 2) and Pusher (Fig. 5 on 6 of 2).

The Sheath (Fig.6 on 2), in its proximal part, is coupling with stainless steel pipe and shaft and then there is a tip (Fig. 9 on 2) on the other side (i.e. stent-Fig10 on 2) which is distal part.

The stent is loaded with compressed between Pusher and sheath, during Operation, by radio opaque marker (Fig. 7 on 2), the place of stent is measured accurately.

Indication for use

The Stent is used for the treatment of bile duct obstruction caused by malignant tumors.

Contraindication

The Stent is contraindicated for:

- Patients who exhibit allergic reactions to the metal
- Biliary stricture caused by benign tumors
- Patient with bleeding disorder
- Patient with ascites

Potential complications

Potential complications associated with the use of transhepatic biliary endoprotheses may Include, but are not limited to:

- Bile duct perforation

- Cholangitis
- Hemobilia
- Bile peritonitis
- Sepsis/infection
- Migration
- Tumor overgrowth or Ingrowth
- Sludge or occlusion

Warning and Precautions

- Use prior to the "Use by" date. Do not use the device if it is over.
- The safety and effectiveness of this device for use in the vascular system have not been established.
- Do not expose the introducer system to organic solvents (e.g., alcohol).
- Do not use with Lipiodol or Ethiodol contrast media.
- The stent is not designed for repositioning.

Once the stent is partially deployed, it cannot be "recaptured" or "resheathed" using the stent introducer system.

- Persons with allergic reactions to nickel may suffer an allergic response to this implant.
- Stenting across a major bile duct branch could lead to compromised future diagnostic or therapeutic procedures.

Instructions for use

- The Stent is compatible with Magnetic Resonance Imaging. (MRI)
- The Stent is intended for use by physicians who have got appropriate training.
- The Stent is supplied in sterile. Do not if the product package pouch is opened or damaged.
- The Stent is intended for single use only. Do not resterilize and/or reuse the device.
- The device could not be used except by intended purpose

RECOMMENDED STANDARD SIZE FOR EGIS

Single Bare / Single Covered	
Region length(cm)	Stent length(cm)
2cm ~ 3cm	5cm
3cm ~ 4cm	6cm
4cm ~ 5cm	7cm
5cm ~ 6cm	8cm
6cm ~ 7cm	9cm
7cm ~ 8cm	10cm

Double Bare/Double Covered	
Region length(cm)	Stent length(cm)
3cm	5cm
4cm	6cm
5cm	7cm
6cm	8cm
7cm	9cm
8cm	10cm

PROCEDURE FOR USE

1. Preparation

- Endoscope or/and fluoroscope
- Not bigger than 0.038 inch (0.9652mm)diameter guidewire.
- Balloon and balloon inflation set

2. Procedure

(1) Examine stricture endoscopically and fluoroscopically

- A. Examine both the proximal and distal segment of stricture endoscopically and/or fluouoscopically
- B. Internal luminal diameter should be measured exactly Endoscope or/and fluoroscope
- C. Pre and/or post stent, if necessary, you can try to balloon dilation.

(2) Stent Size Determination (Ref: RECOMMENDED STANDARD SIZE FOR EGIS)

- A. Measure the length of the target stricture.
- B. Select the stent longer than the measured length of the stricture enough to cover the both ends of lesion (about 10 to 20mm)
- C. Measure the diameter of the reference – it is necessary to select a stent which has an unconstrained diameter about 1 to 4mm larger than the largest reference diameter, to achieve secure placement.

(3) Stent Deployment Preparation

A. Fluoroscopy Procedure :

- a) Under the fluoroscope, insert a guide wire across the stricture to where the stent delivery system will be placed over the guide wire
- b) Ensure that the valve of connector connecting the inner shaft and outer sheath is locked by rotating the proximal valve end in a clockwise direction to prevent

premature stent stricture.

- c) Use fluoroscopic guidance to position the delivery System with the proximal radiopaque marker above the proximal tumor margin and the distal radiopaque marker below the distal tumor margin, centering the tumor between the markers.
- B. Endoscopy Procedure :
- a) Insert an endoscopic Cannula to the level of the obstruction.
 - b) Under the endoscopy, through the working channel of endoscope, insert a guide wire across the target stricture to where the stent delivery system will be placed over the guide wire.
 - c) Ensure that the valve of connector connecting the inner shaft and outer sheath is locked by rotating the proximal valve end in a clockwise direction to prevent premature stent deployment.
 - d) Advance the delivery system over the guidewire through the target stricture.
 - e) Use the endoscopic guidance to position the catheter with the proximal color marker above the proximal tumor margin and the distal tip below the distal tumor margin, centering the tumor between the markers.
- C. Stent Deployment Procedure :
- a) Under the fluoroscope and/or endoscope, position the delivery system to the target stricture exactly.
 - b) Unlock the valve of handle to counter clockwise direction.
 - c) After locating stent delivery system at the target stricture, initiate stent deployment by retracting the outer sheath while holding the hub & inner shaft in a fixed position.
 - d) Under the fluoroscope and/or endoscope, visualize the patient.
- D. After Stent Deployment
- a) View stent fluoroscopically and/or endoscopically to confirm expansion.
 - b) Carefully remove the delivery system and the guide wire from the patient. If excessive resistance is felt during removal, wait 3~5 minutes to allow further stent expansion.
 - c) In case of poor positioning, if it is necessary to remove the stent, it should be done prior to balloon dilatation using a forceps or snare.
- E. Post-Procedure
- a) Assess the size and structure of the stent lumen. A stent may require up to 1 to 3 days to expand fully.
 - b) Doctor's experience and discretion can be determined the appropriate drug regimen for each patient.

- c) Observe the patient for development of any complications

Storage

Store device in a cool and dark area.

Warranty

S&G Biotech Co. Inc warrants that reasonable care has been used in the design and manufacture of this instrument.

IFU01-EB (Rev.1 Date : 08.10.13)

Symbol



Authorized Representative in Europe



Catalog No.



Attention, consult instruction for use



Serial No.



Sterilized using ethylene oxide



Storage temperature



Do not reuse



Date of Manufacture



Use by(Expiration Date)



Manufacturer



Consult instruction for use



Do not use If package is damaged



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