S&G BIOTECH

Instructions for Use EGIS Biliary Stent

CE 0123

1. DEVICE DESCRIPTION

EGIS Biliary stents are single use medical devices for dealing with biliary obstruction.
They are a range of self-expanding, flexible, nitinol (nickel-titanium alloy) stents that expand to their nominal diameter upon exposure to body temperature.

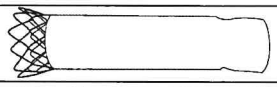
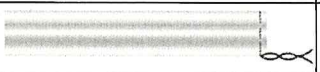
Model Name		Description	Number of Markers (EA)				EGIS Biliary RX System
			Diameter	Left End	Middle	Right End	
Single Bare Stent			8 mm	2	2	2	○
			10,12 mm	3	2	3	○
Double Bare Stent			8, 10 mm	2	2	2	○
Single Covered Stent (Silicone Type)			8 mm	2	2	2	○
			10 mm	3	2	3	○
Double Covered Stent (Silicone Type)			8, 10 mm	4	2	4	○
M-Valve Stent (e-PTFE Type)			8, 10 mm	2	2 (Left end of cover)	2	○
Flower Stent (e-PTFE Type)	Bare		8, 10 mm	2	0	2	○
	Partial Covered		8, 10 mm	2	0	2	○
	Full Cover		8,10 mm	2	0	2	○
Fully Covered stent			8, 10 mm	2	0	2	○
Kraken Stent			8, 10 mm	2	2	2	-

Table 1. Stent Configurations

1.1 Stent

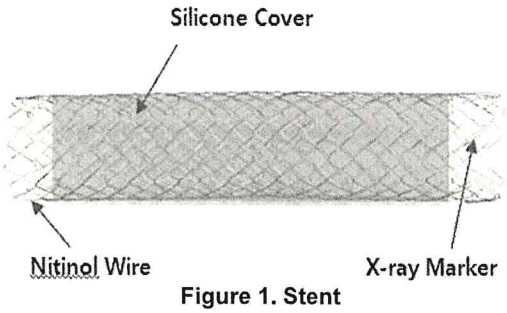
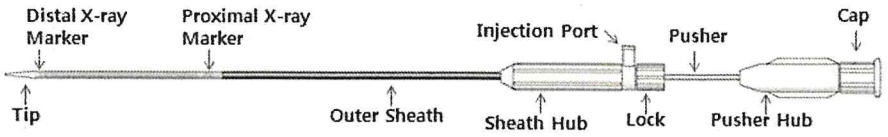


Figure 1. Stent

The Stent is pre-loaded into an introducer system and upon deployment it exerts outward pressure on the bile duct to establish patency.

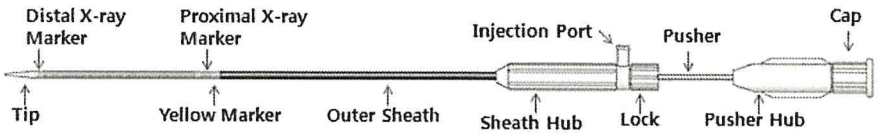
1.2 Delivery system

Percutaneous Delivery System



50cm usable length of introducer system

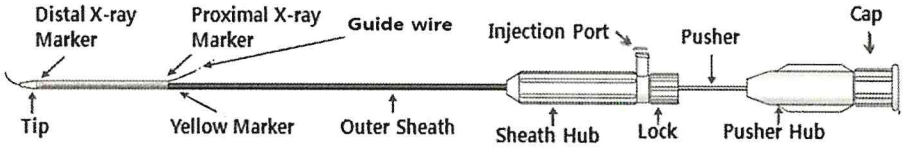
Endoscopic Delivery System



180cm usable length of introducer system

Figure 2. Introducer System

1.3 RX system



180cm usable length of introducer system

2. SUPPLIED PACKAGING

Sterile: EGIS biliary stents are sterilized with ethylene oxide (EO) and supplied in peel-open packaging. Product is sterile as long as packaging is intact. Do not use if sterile packaging is damaged.
Storage: Store in a dry, dark, cool place.

3. INDICATIONS

EGIS biliary stents are intended for re-establishing bile duct patency in intrinsic malignant strictures or malignant extrinsic compression, excluding lymphoma. In addition, the fully covered Flower and Kraken Stents may be used for temporary stenting in benign disease or lymphoma prior to treatment.

4. SUITABLE ACCESSORIES AND RELATED DEVICES

- Fluoroscope and/or Endoscope (with a channel size of 3.2mm ~ 4.2mm)
- 0.025 or 0.035inch (0.89mm) Guidewire (for RX system: 0.025inch Guidewire recommended)

5. CONTRAINDICATIONS

Contraindications for the EGIS Biliary Stents include, but may not be limited to:

- Patients with coagulopathy or uncorrected bleeding disorders
- Strictures that do not allow passage of a guidewire.
- Patients with large-volume ascites
- Extensive hepatic metastases precluding a percutaneous transhepatic approach
- Neonatal and pediatric use
- Benign strictures – except for fully covered, removable configurations
- Any use other than those specifically outlined under indications for use

6. WARNINGS

General Warnings:

- Patients with known hypersensitivity to nickel-titanium may suffer an allergic reaction to the device.
- Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.
- Placement of a straight covered stent across a patent cystic or pancreatic duct may cause occlusion. This is reduced with the *Flower* and *Kraken* stents.

Device Warnings:

- EGIS covered *Flower* stents and fully covered stents may be removed after clinical assessment of the stent and stricture conditions by a trained physician. Caution should be exercised in deciding if the stent should be removed.
- EGIS partially covered *Flower* Stent cannot be removed in case of tumor in-growth / over-growth / occlusion of the stent lumen.
- EGIS *Kraken* stents have lassos at both stent ends to prevent retrieval failures.
- Visually inspect the packaging to verify that the sterile barrier is intact. DO NOT use if the sterile packaging is open or damaged.

- For single patient use only. Do not reuse, reprocess or re-sterilized. 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.
- The introducer system is intended for stent deployment only and not for any other use.
- Chemoradiation therapy or radiotherapy alone may lead to tumor shrinkage and subsequent stent migration.
- Do not expose the introducer system to organic solvents. (e.g. Alcohol)
- Do not use with fat-soluble contrast media (Ethiodol or Lipiodol).
- After use, the stent introducer system is a potential biohazard. Handle and dispose it in accordance with accepted medical practice.

7. PRECAUTIONS

The device is intended for use only by physicians who are familiar with the principles, clinical applications, complications, side effects, and risks commonly associated with biliary stenting.

- Read the entire directions for use thoroughly before using this device. A thorough understanding of the techniques, principles, clinical applications and risk associated with this procedure is necessary before using the device.
- DO NOT kink the introducer system. Use of a stiff guidewire is recommended.
- Care should be taken when removing the introducer system immediately after stent deployment as this may result in stent dislodgement if the stent has not fully expanded.
- Use of fluoroscopy is recommended. Not using fluoroscopy may result in misplacement of the stent.
- EGIS Biliary Stents must be used prior to the Expiration ("Use-by") date specified on the package. Do not use if it is past the expiration date.
- Partially deployed stents CANNOT be recaptured into the introducer system.
- To ensure accurate placement, deploy the distal portion of the stent slowly and deliberately until you have visual confirmation of wall apposition before steadily deploying the remaining length of the stent.
- If the stent lumen is clear, carefully remove using a forcep. Grasp the lasso string and/or collapse the proximal end of the stent then carefully retrieve the stent. If the stent cannot be easily withdrawn, do not remove the stent.
- Testing of overlapping stents has not been conducted. Passing a second stent through a just deployed stent is not recommended.

8. POTENTIAL COMPLICATIONS

Potential adverse events associated with the use of EGIS Biliary Stent may include, but are not limited to:

- Bleeding
- Cholangitis
- Cholecystitis
- Duodenal perforation
- External biliary fistula
- Infection
- Liver abscess
- Pain
- Pancreatitis
- Stent fractures
- Stent malposition
- Stent migration
- Hemobilia
- Stent obstruction secondary to tumor in-growth through the stent, tumor overgrowth at the stent ends, or sludge occlusion

9. DIRECTIONS FOR USE

9.1. Stricture Assessment

a) Examine both the proximal and distal extent of the stricture.
b) Estimate the length and diameter of the stricture.

9.2. Determination of Stent Size

a) Select a stent long enough to cover each end of the stricture by at least 10mm.
b) Estimate the diameter of the stricture – It is necessary to select a Stent which has an unconstrained diameter 1 - 4mm larger than the largest target diameter in order to achieve secure placement.

Table 2. Stent Information

Single Bare Stent Single Covered Stent		Double Bare Stent Double Covered Stent	
Stricture length (cm)	**Stent length (cm)**	**Stricture length (cm)**	**Stent length (cm)**
1cm-2cm	4cm	2cm	4cm
2cm~3cm	5cm	3cm	5cm
3cm~4cm	6cm	4cm	6cm
4cm~5cm	7cm	5cm	7cm
5cm~6cm	8cm	6cm	8cm
6cm~7cm	9cm	7cm	9cm
7cm~8cm	10cm	8cm	10cm
8cm~10cm	12cm	10cm	12cm

9.3 Stent Insertion

Placement of EGIS Biliary Stents can be done percutaneously under fluoroscopy guidance or during endoscopic retrograde cholangiopancreatography (ERCP). Use of a 0.035inch (0.89mm) guidewire is recommended.

A. Percutaneous Procedure

a) Perform percutaneous puncture and demonstrate the stricture by injection of contrast medium.
b) Under fluoroscopy, insert a guidewire across the stricture.
c) Advance the introducer system over the guidewire through the stricture.
d) Use fluoroscopic guidance to position the catheter with the proximal radiopaque marker above the proximal tumor margin, centering the tumor between the markers.
e) For M-Valve stents ONLY: After deployment of the stent, advance the outer sheath back into the stent to the original position before stent deployment. Carefully withdraw introducer system and guidewire, so the stent valve maintains its position and is not withdrawn into the stents. Should the valve become inverted, careful injection of contrast medium or air can be used to straighten the valve.

B. Endoscopic Procedure

a) Perform ERCP and demonstrate the bile duct stricture.
b) Under endoscopy, insert a guidewire through the working channel of the endoscope across the target stricture.
c-1) Insert the end of guide wire through olive tip until the guide wire exit from pusher hub and advance the introducer system through the target stricture.
c-2)(When using Rapid exchange system) Insert the end of the guide wire through the olive tip of the delivery system and advance the introducer system until guide wire exit the tapered tube. Exit the guide wire approximately 30cm from the device and be careful to do not miss the guide wire.
d) Use fluoroscopic guidance to position the *distal* x-ray marker above the proximal tumor margin and the *proximal* x-ray marker in the duodenum centering the tumor between the markers.
e) Use endoscopic control to visualize the yellow marker and ensure position below the papilla in the duodenum.

9.4 Stent Deployment

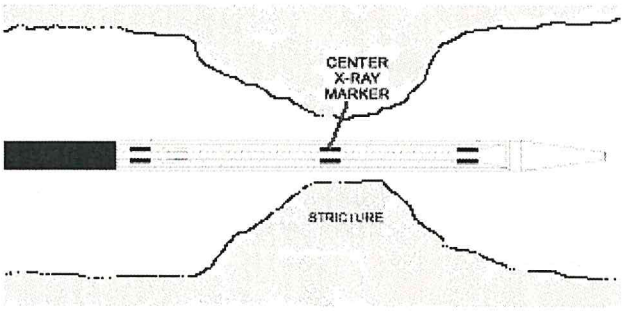


Figure 1. Stent Positioning

a) Under fluoroscopy and / or endoscopy, position the introducer system centered on the middle of the target stricture (Fig. 4).
b) Unlock the Sheath Hub by unscrewing the locking nut.
c) To begin stent deployment, immobilize the Pusher Hub with one hand and grasp the Sheath Hub firmly with the other hand. Gently withdraw the Sheath Hub along the Pusher towards the Pusher Hub. For ERCP this should be done by the endoscopy assistant.
d) Observe stent deployment fluoroscopically to maintain stent position and avoid inadvertent advancing of the stent.
For endoscopic placement the endoscopist should gently withdraw the outer sheath from the working channel at the same rate as release is performed by the assistant, to help prevent inadvertent stent advancement.
e) When the center X-ray markers have deployed in the center of the target stricture, the stent can be fully released. (Fig. 5)

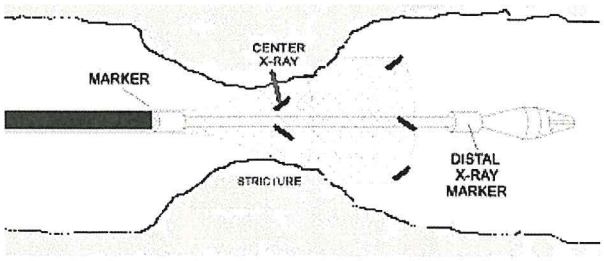


Figure 2. Stent during Deployment

9.5. After Stent Deployment

a) Examine stent fluoroscopically and / or endoscopically to confirm expansion.
b) Carefully remove the introducer system and the guidewire from the patient. If resistance is felt during removal, wait 3~5 minutes to allow further stent expansion.

10. POST PROCEDURE

a) Assess stent expansion. 40-50% initial expansion is usually sufficient for biliary drainage. Nitinol stents continue to expand and may require up to 7 days to reach full diameter.
b) Subsequent drug treatment depends on local protocol and individual physician's preference.
c) Observe the patient for development of any complications

NOTICE: If any serious incident has occurred in relation to the device, report to the manufacturer and the competent authority.

11. WARRANTY

S&G Biotech Inc. warrants that reasonable care has been taken into the design and manufacture of this device. 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 for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond S&G Biotech control directly affect the device and the results obtained from its use. S&G Biotech obligation under this warranty is limited to the repair or replacement of this device and S&G Biotech shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. S&G Biotech neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. S&G Biotech assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

12. Conditional safety in MRI environment

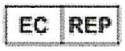
Basic description
Through non-clinical testing, EGIS Biliary stent is proven to be MR Conditional (Conditionally Safe in Magnetic Resonance Environment) under the below stated condition. The patients who have implanted this device may be scanned safely on a MRI Environment that satisfies as below:

- Static magnetic Field of 1.5-Tesla and 3.0-Tesla
- Maximum spatial gradient magnetic field of 3,000 gauss/cm
- Maximum MR system reported, whole body averaged specific absorption rate(SAR) of 2 w/kg

Additional description

. Under the above defined scanning conditions, the maximum temperature rise is expected to be less than 2.8℃ when the EGIS Biliary stent was MRI performed for 15 minutes of scanning.

From the non-clinical testing, the distorted image due to the medical device was extended up to 2.5 mm when it was scanned under T1 SE, GRE pulse sequence of 3.0-Tesla MRI.

	Manufacturer
	Authorized representative in the European Community
	Date of manufacture
	Use-by date
	Sterilized using ethylene oxide
	Catalogue number
	Serial number
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Temperature limit
	Do not re-use
	Consult instructions for use
	Caution
	MR Conditional

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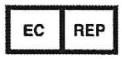

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