

1. DEVICE DESCRIPTION

EGIS Biliary stent is a single use medical device self-expanding, flexible, nitinol (nikel-titanium alloy) stent that expands to its present diameter upon exposure to body temperature.

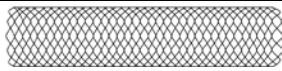
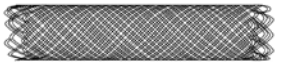



Model Name	Description	Number of Markers (EA)			
		Diameter	Left End	Middle	Right End
Single Bare Stent		8mm	2	2	2
		10,12mm	3	2	3
Double Bare Stent		All	2	2	2
Single Covered Stent (Silicone Type)		8mm	2	2	2
		10,12mm	3	2	3
Double Covered Stent (Silicone Type)		All	4	2	4
M-Valve Stent (e-PTFE Type)		All	2	2 (Left end of cover)	2

Figure 1. Stent Configurations

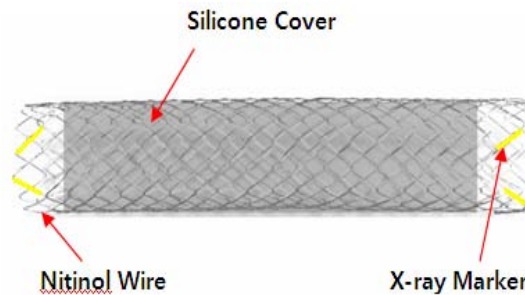


Figure 2. Stent

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

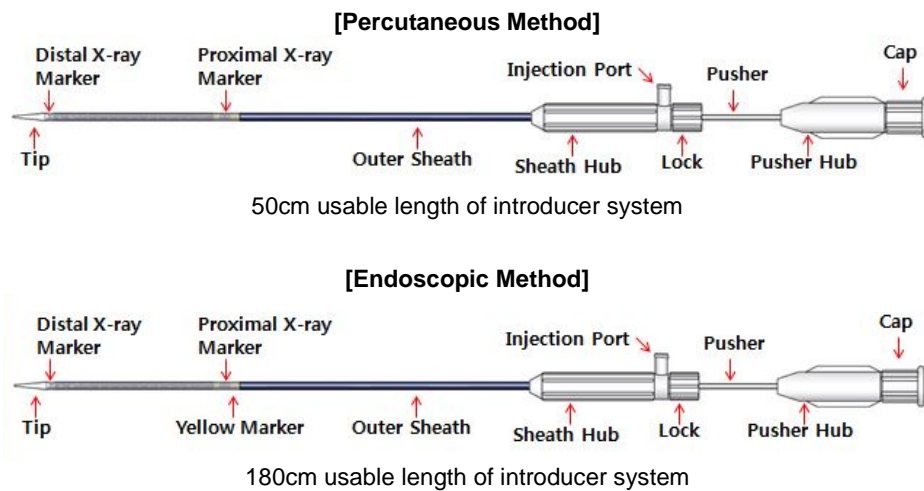


Figure 3. Introducer System

2. SUPPLIED CONDITION

Sterile: EGIS Biliary Stent is sterilized by using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged.

Storage: Store in a dry, dark, cool place.

3. INDICATIONS

The EGIS Biliary Stent is intended for maintaining biliary luminal patency in biliary strictures caused by intrinsic and/or extrinsic malignant strictures.

4. CONTRAINDICATIONS

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

- Uncorrected Bleeding disorders
- Strictures that do not allow passage of a guidewire.
- Any use other than those specifically outlined under indications for use.
- Patient with ascites.
- Biliary obstruction preventing either endoscopic or percutaneous cholangiography.
- Patients with coagulopathy.
- Cannot be suited for neonatal and pediatric use.

5. WARNINGS

General Warnings:

- Patient who is known to have 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.

Device Warnings:

- Visually inspect the packaging to verify that the sterile barrier is intact. DO NOT use if the sterile barrier is opened or damaged.
- Single use only. Re-processing 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.
- Stents cannot be repositioned after complete deployment, whereas there may be a chance to try for repositioning only when it is not fully deployed yet.
- Chemotherapy or radiation 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 Ethiodol or Lipiodol contrast media.
- After the use, the introducer system may become a potential biohazard. Dispose it in accordance with accepted medical practice.
- M-Valve stent should be used only under an endoscopic method.

6. PRECAUTIONS

The device is intended to 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
- Need careful attention when the physician is removing the introducer system and the guidewire immediately after stent deployment since this may result in stent dislodgement if the stent has not been adequately deployed.
- Use of fluoroscopy is recommended. Without fluoroscopy, it may result in misplacement of the stent.
- Use the EGIS Biliary Stent prior to the Expiration (Use-by) date specified on the package. Do not use if it is past the expiration date.
- MRI Compatible: EGIS Stent will not present an additional risk or hazard to a patient in a 3.0 tesla MRI environment or more.
- Partially deployed stents cannot be recaptured into the introducer system. (ONLY Single Bare Stent can be recaptured within 30% of stent deployment – There is a green marker on pusher's steel pipe, which indicates 30% of stent deployment)
- To maximize the accuracy of the stent placement, slowly and deliberately deploy the distal portion of the stent until you have visual confirmation of wall apposition before steadily deploying the remaining length of the stent.

7. 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
- Stent obstruction secondary to tumor ingrowth through the stent, tumor overgrowth at the stent ends, or sludge occlusion

8. DIRECTIONS FOR USE

8.1 Visualization of stricture

- Examine the both proximal and distal segment of stricture endoscopically and / or fluoroscopically.
- Internal luminal diameter should be measured exactly by endoscopy and / or fluoroscopy.

8.2 Stent Size Determinations

- Measure the length of the targeted stricture.
- Select a stent longer than the measured length of the stricture enough to cover both ends of the lesion by about 20 to 40mm.
- Measure the diameter of the reference stricture – It is necessary to select a Stent which has an unconstrained diameter about 1 to 4mm larger than the largest reference target diameter, to achieve secure placement.

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

Table 1. Stent Information

8.3 Stent Deployment Preparations

The EGIS Biliary Stent can be placed with the aid of fluoroscopy, or under direct visualization alongside an endoscopy or the combination of both. Pass a 0.035" (0.89mm) guidewire to the level of the stricture. Carefully maneuver the guidewire until the wire traverses the obstructed area.

A. Fluoroscopic Procedure

- Under the fluoroscopy, insert a guidewire across the stricture to where the stent introducer system will be placed over it.
- Advance the introducer system over the guidewire through the stricture of biliary duct.
- Use fluoroscopic guidance to position the introducer system with the proximal radiopaque marker above the proximal tumor margin, centering the tumor between the markers.

B. Endoscopic Procedure

- Insert an endoscopy to the level of the obstruction.
- Under the endoscopy and through the working channel, insert a guidewire across the target stricture to where the stent introducer system will be placed over the guidewire.
- Advance the introducer system over the guidewire through the target stricture.
- Use the endoscopic guidance to position the introducer system 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.

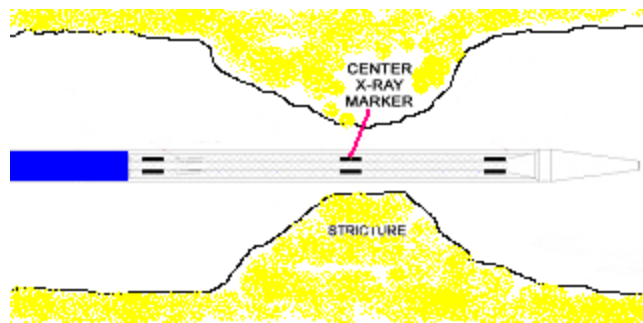


Figure 4. Stent Deployment Procedure

8.4 Stent Deployment Procedures

- Under the fluoroscopy and / or endoscopy, position the introducer system exactly to the center of the targeted stricture.
- To begin stent deployment, immobilize the Pusher hub in one hand and grasp the Sheath hub with the other hand. Gently slide the Sheath hub back along the pusher towards the Pusher hub. At the same time and the same rate, the endoscopist should gently withdraw the outer sheath to prevent inadvertent stent advancement.
- When the center X-ray marker reaches the center of targeted stricture, the stent can be deployed at any time. (See figure 4,5)

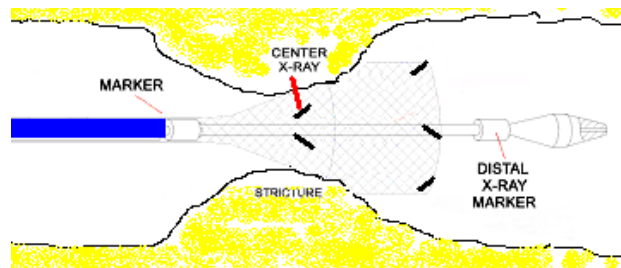


Figure 5. Stent during Deployment

8.5 After Stent Deployment

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










9. POST PROCEDURE

- Assess the size and structure of the stent lumen. A stent may require up to 1 to 3 days to fully expand.
- Physician's experience and discretion can determine the appropriate drug regimen for each patient.
- After implantation, patient should have soft diet.
- Observe the patient for development of any complications

10. WARRANTY

S&G Biotech Inc. warrants that reasonable care has been taken into 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 for a particular purpose. Handling, storage, cleaning and sterilization of this instrument is liable to S&G Biotech, whereas any other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond the S&G Biotech's control which directly affect the instrument is not. S&G Biotech's obligation under this warranty is limited to the repair or replacement of this instrument 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 instrument. 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 instrument. S&G Biotech assumes no liability with respect to instruments 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 instruments.

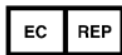
Graphical Symbols for Medical Device

	Authorized representative in the Europe
	Temperature Limitation
	Consult instructions for use
	Manufacturer
REF	Catalog No.
	Sterilized using ethylene oxide
	Attention, consult instructions for use
	Use by(Expiration Date)
SN	Serial No.
	Do not reuse
	Date of Manufacture



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